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Editor

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A Clinical Guide to Diagnosis and Management

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Preface

This is the first edition of *Adult Lumbar Scoliosis: A Clinical Guide to Diagnosis and Management*. The goal is to provide the spinal surgeon and practitioner with the most current concepts in the treatment of this complex problem. With our aging population, spinal pathology is ever increasing. The cascade of spinal degeneration leading to adult lumbar scoliosis is disabling, and the impact on a patient's quality of life is significant. Additionally, the adult patient is different today than they were even a decade ago as they are more active and demand more from their body.

Surgical intervention for every patient is clearly not possible, nor is it responsible. Health-care providers must be aware of the medical economics and outcomes of spinal treatments in order to choose the best patients and best procedures. Individualized health care and delivery are on the horizon, and we all play a role in its management. This book will allow practitioners to determine both care and the surgical or nonsurgical goals for each patient.

For this book, we gathered leaders from around the country to discuss their specific area of expertise. In each chapter, their passion for best practices and their dedication to their craft are evident. The topics range from the nonoperative care to the economics of spinal deformity and future directions. Each of these authors used their clinical acumen, as well as the body of literature and personal research, to provide us with the most current concepts. I am inspired by their work and appreciative of their commitment.

Over the past few decades, we have seen the acceptance of radiographic parameters and in particular spinopelvic parameters to determine the goals of spinal reconstruction for best outcomes. We now face the challenge to merge patient expectations with individualized alignment goals while minimizing complications. We are all deformity surgeons, who are either correcting deformity or creating it; the key is to know the difference.

I hope that you enjoy the book. It is an exciting time to be a spinal surgeon.

Sacramento, CA, USA — Eric O. Klineberg

Acknowledgements

I would like to express my appreciation to my patients who have given me their utmost trust and allowed me to care for them. You have inspired me to grow as a surgeon and share that passion with my fellows and residents. Thank you.

To my children Maren, Walsh and Holt who continue to support me with their love and patience. And finally, to my wife Joy, who despite my long hours, travel, fatigue and complaining, has loved and supported me throughout this journey. I could not do any of this without you.

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Defining Adult Lumbar Scoliosis

1

Durga R. Sure, Michael LaBagnara, Justin S. Smith, and Christopher I. Shaffrey

Introduction

Adult lumbar scoliosis is defined as coronal spinal curvature with Cobb angle >10° in skeletally mature patients [1]. Often this is associated with an abnormal sagittal (lordotic or kyphotic) curve and a rotational component resulting in a three-dimensional deformity [2]. Lumbar scoliosis may be associated with adjacent (nonstructural) compensatory curves involving the thoracolumbar spine [3]. Thus it is typically described in the literature in the broader context of thoracolumbar adult spinal deformity (ASD).

Etiology and Pathogenesis

The two main types of adult lumbar scoliosis are degenerative and idiopathic scoliosis. The main distinction between these is the age of onset and presentation. Adult idiopathic scoliosis results from untreated or residual adolescent idiopathic scoliosis (AIS), which progresses into adulthood, and thus often presents in younger adults. Adult degenerative scoliosis typically presents in older adults, usually above age 50. Degenerative scoliosis is thought to develop from asymmetric disc and facet degeneration, but secondary drivers may include leg length discrepancy, hip pathology, and metabolic bone disease such as osteoporosis [1]. Distinguishing between adult idiopathic scoliosis and degenerative scoliosis can be difficult in some patients, especially if the patient does not recall the timeline of onset of symptoms or has not previously been diagnosed with scoliosis earlier in life (Fig. 1.1).

Adult Degenerative Scoliosis

Degenerative scoliosis is the most commonly encountered form of adult lumbar scoliosis in clinical practice. It is synonymous with de novo scoliosis or primary degenerative scoliosis (Fig. 1.2).

The true incidence of adult scoliosis is not known. The reported prevalence of adult scoliosis ranges from 8.3 to 68% [4–9], with the majority of patients at least 60 years of age [3, 8]. The prevalence is gradually increasing due to a combination of increasing life expectancy and increased clinical awareness [10]. The mean age at presentation has been reported to be approximately 70 years [9], with most literature suggesting a higher proportion of women [5, 11, 12]. Among degenerative deformities, lumbar scoliosis curves are more common than thoracic or thoracolumbar curves [8].

The pathogenesis is likely multifactorial in origin. It is thought to be a result of age-related asymmetric disc degeneration in combination

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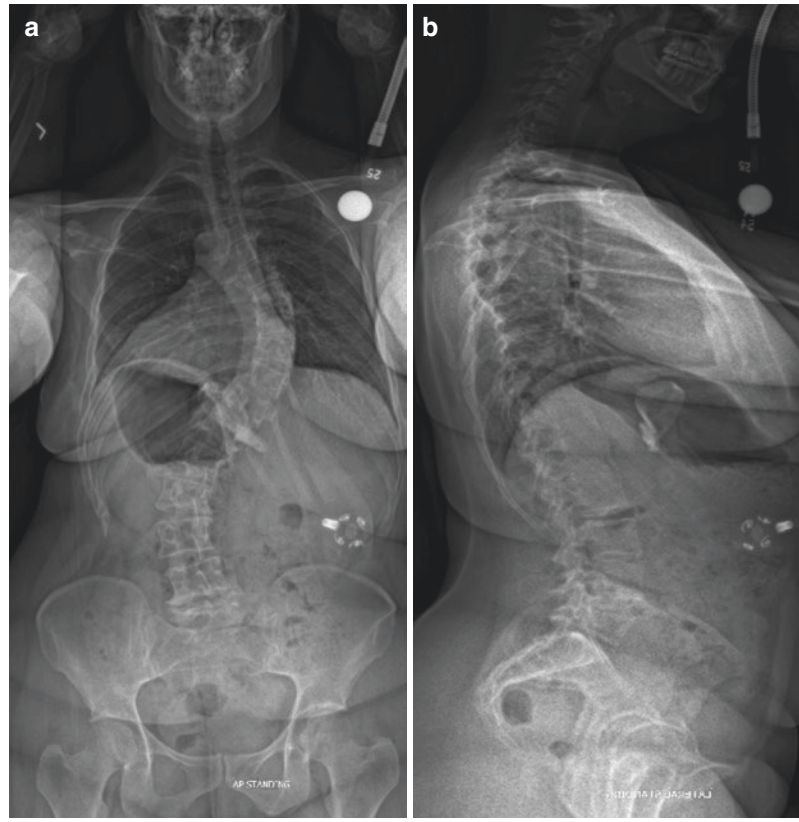

Fig. 1.1 Posteroanterior (**a**) and lateral (**b**) full-length X-rays of a 36-year-old woman with known history of adolescent idiopathic scoliosis with superimposed degenerative changes who presented with low back pain and left leg radicular pain

with facet arthropathy and ligament laxity that results in regional malalignment [1, 9, 13, 14]. This can be exacerbated by osteoporosis-related vertebral compression fractures and concurrent sagittal and rotational components [3, 15]. Other less common but increasingly prevalent causes include previous lumbar fusion resulting in iatrogenic flat back deformity or a history of trauma.

Adult degenerative lumbar curves typically have an apex at L3 and are associated with a distal fractional curve and may include a nonstructural compensatory curve [9]. There is typically a rotational component and often lateral listhesis, involving the apical region of the curve [1, 9]. Curve magnitude is inversely proportional to prevalence, with only 24 % of the curves greater than 20° in magnitude [16]. Curve progression is more commonly seen in curves with Cobb angle greater than 30°, apical vertebral rotation greater than a grade II (Nash-Moe classification), lateral listless greater than 6 mm, and/or cases in which the intercrest line passes through L5 [17].

Progression of degenerative scoliosis typically occurs slowly. Current literature reports the natural rate of progression for adult degenerative scoliosis is 1–6° per year, with an average of 3°. One caveat to this are compression fractures due to poor bone density which can result in accelerated progression [17].

Adult Idiopathic Scoliosis

Adult idiopathic scoliosis is the continuation of adolescent idiopathic scoliosis into adulthood after skeletal maturity (Fig. 1.3). Thus the typical age of presentation is younger than those patients with adult degenerative scoliosis. The prevalence of adolescent idiopathic scoliosis (AIS) ranges from 0.4–3.9 % in North America [18]. These patients usually have major thoracic/thoracolumbar and/or lumbar curves with compensatory curves that have become structural. The major curves tend to have greater Cobb angles compared to adult degenerative scoliosis. Curve progression

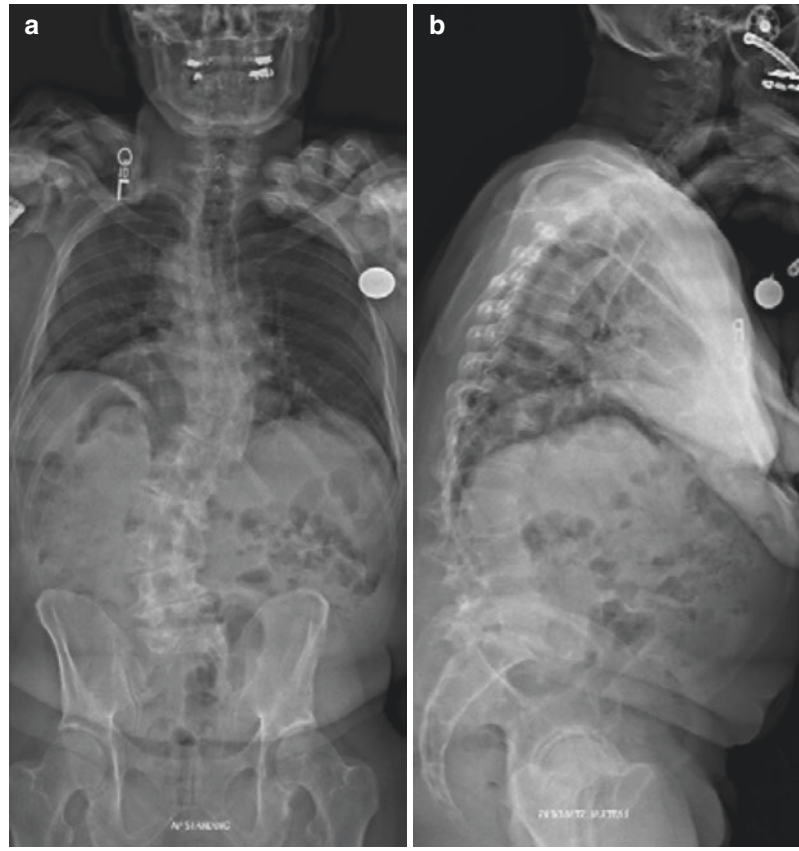

Fig. 1.2 Posteroanterior (**a**) and lateral (**b**) full-length X-rays of a 69-year-old man with adult degenerative lumbar scoliosis and sagittal imbalance

is seen most commonly with Cobb angles greater than 50 degrees [19, 20].

Unlike adolescent scoliosis, curve progression in skeletally mature patients typically occurs slowly. Years or even decades may pass without significant radiographic progression. Most reported progression rates in the literature for lumbar curves greater than 30° in skeletally mature patients are similar [20–23]. Weinstein et al. reported an average progression of 16.2° over 29 years in their small cohort [20], and Ascani et al. in their 29 patients reported a progression rate of 16° over the same time frame [23]. Thus, the typical rate of progression is roughly 0.5° per annum.

Adult idiopathic curves typically have a multilevel rotational component and a multilevel lateral listhesis component. In isolated lumbar curves, lateral listhesis is most commonly seen at L3–4 [20]. Concurrent sagittal malalignment may be seen in AIS patients who underwent fusion with distraction rods and among older patients with superimposed degenerative scoliosis.

The main differences between adult degenerative scoliosis and adult idiopathic scoliosis are summarized in Table 1.1.

Clinical Presentation

Adult scoliosis patients typically present with pain and disability. This is in contrast to adolescent scoliosis patients who typically present with deformity progression resulting in cosmetic concerns and pain.

Back Pain

Back pain is the most common symptom of adult degenerative scoliosis [1, 2, 14, 24–27]. The prevalence of low back pain in adult degenerative scoliosis patients ranges from 60 to 93 % [14, 16,

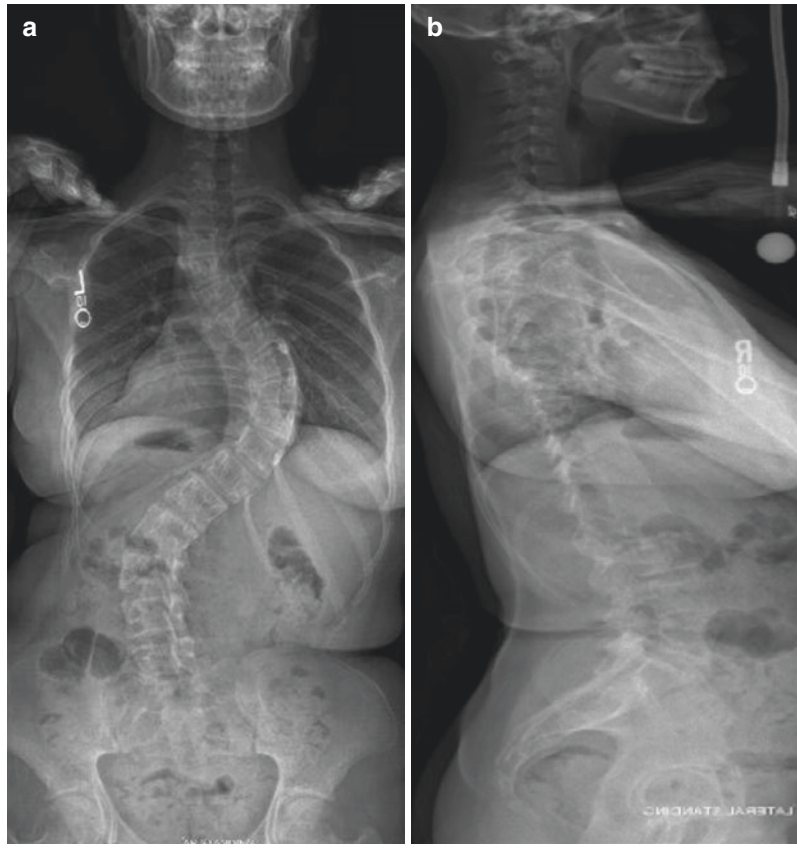

Fig. 1.3 Posteroanterior (**a**) and lateral (**b**) full length X-rays of 18YF with adolescent idiopathic scoliosis

Table 1.1 Primary differences between adult idiopathic scoliosis and adult degenerative scoliosis

	Adult idiopathic scoliosis	Adult degenerative scoliosis
Age at presentation	Younger	Older
Presenting complaints	Deformity, cosmetic concerns, psychosocial issues, back pain	Back pain, leg pain, disability
Spinal stenosis	Less common	Common
Compensatory curves	Common, usually structural	Less common, usually nonstructural
Sagittal malalignment	Not common unless previously fused	Common
Coronal Cobb	Large Cobb angles	Small-to-moderate Cobb angles
Rotatory component	Involves large segment of the curve	Generally at the apex
Lateral listhesis	Involves multiple segments	Generally at the apex

26]. There is usually a combination of axial back pain and radicular leg pain [14, 24].

The etiology of back pain is not always clear, and in all likelihood is multifactorial. Potential causes include muscle fatigue due to spinal imbalance, from facet joint arthropathy, or disc degeneration and micro-instability resulting in central or foraminal stenosis [1, 14, 21]. Age-related asymmetric disc degeneration and facet joint arthropathy causes segmental instability and results in lateral listhesis, antero-/posterolisthesis, rotatory subluxation, or a combination

thereof. This abnormal motion results in more pain and progression of degenerative changes. Ligamentous hypertrophy, disc herniation, and osteophyte formation with resultant spinal canal and foraminal stenosis can cause radiculopathy. In severe coronal curves, the rib cage on the concave side may impinge on the pelvis and produce severe pain. Low back pain from chronic muscle fatigue is most commonly seen in patients with sagittal imbalance [28].

Back pain is a less common chief complaint in patients with adult idiopathic scoliosis. Pain in this group of patients is associated with more significant thoracolumbar/lumbar curves and with curve progression [19, 22]. In a 50-year study of AIS patients, Weinstein et al. reported a higher prevalence of back pain in scoliosis patients compared with age-matched controls [11]. Patients with AIS in early life are not immune to developing degenerative disease in the spine as they age. As these age-related degenerative changes progress throughout their lives, AIS patients can thus present with axial back pain and radiculopathy similar to the non-scoliosis population. It can occasionally be challenging to properly diagnose a 60-year-old who presents with back pain and newly discovered scoliosis and age-appropriate spinal degeneration.

Radicular Symptoms

Ligamentous hypertrophy, osteophyte formation, and disc degeneration can result in central canal and foraminal stenosis [12]. Disc herniation, lateral end plate osteophyte formation, and facet joint hypertrophy along with abovementioned degenerative changes can cause direct lateral recess or foraminal stenosis and resultant radiculopathy. Disc height loss can cause foraminal stenosis indirectly. Radicular symptoms tend to occur on the concave side of the curve. However, stretching of a nerve on the convex side may also produce radiculopathy. In their retrospective study, Smith et al. reported the prevalence of severe radicular leg pain among adult degenerative scoliosis patients seeking operative treatment to be 64 % [24].

Neurogenic Claudication and Weakness

Neurogenic claudication is an important symptom at presentation in adult degenerative scoliosis [1]. It is mainly due to central canal stenosis, although severe lateral recess and foraminal stenosis can result in similar symptoms. Spinal stenosis is seen more frequently with adult degenerative scoliosis (90 %) when compared to adult idiopathic scoliosis (31 %) [16]. Again, age-related changes and symptoms will be seen more frequently in an older population. With neurogenic claudication, patients typically describe bilateral leg weakness and pain with walking or standing, which improve with sitting or bending forward [29]. The classic description is that patients are in less pain and can walk further while leaning on a grocery cart. In severe cases of stenosis, neurogenic bladder [30] or cauda equina symptoms can develop.

It is prudent to distinguish neurogenic claudication from vascular claudication, which also affects patients in this age group. By history, patients with vascular claudication describe alleviation of their leg symptoms with rest alone, regardless of body position. They will usually have a history of vascular disease, although not always. On physical examination they commonly have weak or absent distal pulses with poor capillary refill. They also tend to have exacerbation of their leg symptoms while riding a stationary bicycle, whereas patients with neurogenic claudication typically do not.

Deformity and Disability

Deformity is the result of abnormal curvature in the coronal, axial, and sagittal planes. Sagittal balance has been strongly correlated to disability and quality of life in spine surgery [14, 28]. Patients with degenerative scoliosis may report that they are unable to stand up as straight as they could when they were younger. They often compensate by retroverting their pelvis, bending their knees, hypokyphosing their thoracic spine, and hyperlordosing the cervical spine in order to stand upright

and maintain horizontal gaze. This causes excessive muscular strain and results in fatigue after walking or standing for short periods.

Multiplanar deformity resulting in cosmetic deformity is usually the primary presenting complaint in patients with adult idiopathic scoliosis [21]. In this younger population, cardiopulmonary compromise may result from severe deformity. Perception of their appearance can also have psychosocial effects such as depression and poor self-image.

Cardiopulmonary manifestations due to severe deformity as reported in the AIS literature are associated with curvatures greater than 60° [21]. However, because of the heterogeneous study groups, clear prevalence in pure AIS is uncertain [21]. Weinstein et al. in their 50-year natural history study of AIS patients noticed no significant differences with respect to shortness of breath with daily activities or walking for one block in both adult idiopathic scoliosis patients and their controls. But they did notice that shortness of breath is more common in patients with major thoracic curves greater than 80°, compared to those with major lumbar curves greater than 50° [11]. This study found that Cobb angle greater than 50° at skeletal maturity is a predictor of decreased pulmonary function [11].

Previous literature regarding psychosocial issues is conflicting [21]. Weinstein et al., in their natural history study, showed that there is no significant difference in the self-reported depression rate compared to controls [11]. However AIS patients' perception of body image was slightly dissatisfied compared to their controls [11].

Bess et al., in their retrospective analysis of a prospective, multicenter database, evaluated the health impact/disability of symptomatic adult spinal deformity (SASD) patients [31]. SF-36 physical (PCS) and mental (MCS) components of 497 SASD patients without a history of spine surgery were compared with the US general population and by patients with chronic disease. In contrast to the prior studies, this study also analyzed the impact of sagittal plane deformity in combination of coronal plane deformity [31].

This study found that SASD patients have substantial disability and worsening physical functional limitations with age in comparison with the US population. Overall, the mean SASD PCS score was greater than 3 NBS (norm-based scores) points worse than chronic back pain and hypertension but was similar to diabetes, cancer, and heart disease.

Deformity subtype analysis showed that thoracic scoliosis patients have similar disability to those with chronic back pain. Patients with primarily lumbar scoliosis reported similar disability scores as osteoarthritis and chronic heart disease. Patients with primarily severe sagittal deformity SVA (sagittal vertical axis) greater than 10 cm had similar functional capacity as the lower 25th percentile of chronic lung disease patients. Lumbar scoliosis in combination with severe sagittal deformities (SVA >10 cm) had severe disability scores similar to patients with limited vision and limited function of arms and legs [31].

Clinical Evaluation

History

Obtaining a thorough history during the initial visit is of the utmost importance. Most patients will not remember specific details and present their history in an organized manner. Physicians should develop their own standard approach to obtain the history in a chronological and precise manner.

All aspects of the pain should be investigated, including onset, location, character, intensity, radiation, and alleviating/exacerbating factors.

A detailed neurological history should also be obtained, including but not limited to any weakness, balance problems, decreased or altered memory, bowel or bladder dysfunction, gait incoordination, recent falls, and any difficulty with fine motor skills. It is important to elucidate any history of upper motor neuron dysfunction or myelopathy, which could be secondary to cervical or thoracic stenosis. The reported incidence of tandem spinal stenosis is as high as 28 % [32].

Information pertaining to previous spine surgeries should be also obtained, if applicable.

Specific details should be discussed regarding symptoms pre- and postoperatively, success or failure of nonoperative therapies, previous diagnostic and/or therapeutic interventions, and if there were any complications during the preoperative period. This information may be helpful in both understanding the patient's current symptoms and in formulating a successful management plan.

The patient's overall health and physical condition must be carefully assessed. Can this patient physically tolerate the surgery required to address his/her problem? Cardiopulmonary function and the presence or absence of major systemic illness, such as peripheral vascular disease, nicotine or other substance abuse, endocrine function, history of malignancy, and symptoms of osteopenia or osteoporosis, should be identified.

When suspicious of adult idiopathic scoliosis, history should be obtained focusing on age of onset, nonoperative therapies tried, and any past or current psychosocial issues.

Exam

Thorough physical examination should be performed to assess the overall condition of the patient, including but not limited to their deformity and neurological exam.

Examination should start in the most comfortable position for the patient. General physical examination may include measurement of vital signs and cardiopulmonary exam. Detailed neurological examination should include assessment of mental status, memory, cranial nerves, muscle tone and bulk, motor strength, sensory examination, deep tendon reflexes, clonus, coordination, and gait.

Examination of Standing Posture

This involves evaluation of the patient's ability to move from sitting to standing or from supine to standing position, with careful attention to facial expressions and any balance issues.

The general shape of the patient's trunk should be noted. While doing so, observe how the lower extremities are positioned while sharing the load in standing position: hip adduction/abduction, knees flexed/extended, and feet arched/parallel/everted/inverted.

Lumbar lordosis and thoracic kyphosis should be inspected for sagittal imbalance and shoulder level should be evaluated for coronal imbalance. Location of the anterior iliac spine in the vertical plane and iliac crests in the horizontal plane helps to identify pelvic obliquity and leg length discrepancy [33]. Leg length discrepancy can be measured from the anterior iliac spine to the medial malleolus and compared with the contralateral side. Also, measuring the distance between the ribcage and iliac crests can give an idea of magnitude of a thoracolumbar/lumbar coronal curve. Rib hump prominence may be accentuated by having the patient bend forward.

Testing truncal range of motion is important to assess the magnitude and flexibility of the curve. Compensatory mechanisms such as pelvic retroversion, knee and hip flexion while trying to stand straight should be observed. Shoe lifts can help to alleviate the impact on coronal balance if any pelvic obliquity is identified, and thus examination should be performed with shoes removed.

Palpation along the bony spine and paraspinal areas should be performed routinely and may help to identify muscle spasm or tenderness. This can be accomplished at the time of inspection. The presence of cutaneous stigmata should be noted carefully, as it may help identify underlying congenital spinal anomalies.

Standing on the tiptoes and on the heels should be tested, first with both feet simultaneously and then each foot individually, to help delineate any subtle weakness in foot dorsiflexion and plantar flexion. Sometimes, it may require a few repetitions to elicit subtle weakness.

Testing for gait should also be performed. Appropriate support should be provided for the patient while examining in the standing position to avoid any falls. A "pitched forward" position while standing or walking is commonly seen in patients with sagittal deformity and/or with neurogenic claudication.

Examination in Supine Position

Observation of the patient while changing positions is crucial. Careful attention should be paid to the ability to lay flat supine with legs extended, as this may help to elucidate a hip flexion contracture. Failing to recognize a contracture at this stage can have ramifications, as spine surgery does not directly improve this. If identified, an appropriate physical therapy regimen should be instituted prior to any spinal intervention.

Examination of the sacroiliac joints and hip joints should be performed. The sacroiliac joint distraction test helps to identify any SI joint-related pain [34]. This is performed with the patient in supine position and by exerting downward and outward pressure on both anterior superior iliac spines simultaneously, in an effort to elicit unilateral pain [35]. The sacral thrust test and the drop test are other tests to assess SI joint pathology. Reliability of any single test in diagnostic accuracy has not been proven [36], and the results should always be interpreted in combination with other clinical and radiological findings.

Evaluating for hip joint pathology is important if there are complaints of unilateral buttock and or anterior thigh pain. Eliciting unilateral pain with passive hip flexion, or with internal or external rotation, aids in establishing this diagnosis. The straight leg raise in conjunction with the above tests can help in the diagnosis of hip joint pathology but is not confirmatory. The reliability of this is not proven in diagnostic accuracy [37], and the results should always be interpreted in combination with other clinical and radiological findings.

Motor and sensory examination in all dermatomes and myotomes should be performed in a meticulous manner.

A peripheral vascular exam should be performed on all extremities. Edema and venous congestion should be noted, as they may be signs of underlying systemic conditions.

Examination in Prone Position

This helps mainly in accessing general condition of the patient and ability to tolerate the surgery for long hours. Also some muscle groups are better assessed in this position, such as hip extensors and knee flexors.

Examination in sitting position helps in assessing the deformity in the absence of leg length discrepancy or hip flexion contractures.

Conclusion

Adult lumbar scoliosis comprises a broad range of conditions. Degenerative (de novo) and adult idiopathic are common. Typically this is a complex deformity with sagittal and rotational plane components. With increasing life expectancy and an aging population, its prevalence is increasing. Clinical evaluation should include obtaining a thorough history, performing a thorough physical examination, and accessing concomitant comorbidities.

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Imaging Adult Lumbar Scoliosis

2

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Introduction

Radiographic assessment is an integral component of the evaluation and management of lumbar scoliosis. Fortunately for patients and clinicians, modern imaging modalities permit the evaluation of the bony, neuromuscular, and soft tissue components of the spine with exquisite detail. The anatomic relationships and, occasionally, physiologic parameters provided by these studies are used to diagnose and quantify deformity, monitor progression, and inform decision-making by physicians and patients alike. Though plain radiographs are frequently adequate in the initial assessment of spinal deformity, the spine surgeon is equipped with several tools used to evaluate a patient radiographically with guidance based on history, physical exam, and specific clinical questions. The tools most commonly used in the radiographic evaluation of lumbar deformity include conventional radiography and advanced imaging modalities such as computed tomography (CT) and magnetic resonance imaging (MRI), each of which may be adapted or occasionally substituted as necessary to glean specific information. The primary goal of this chapter is to introduce the imaging modalities used to assess patients within each phase of evaluation and their applications to particular clinical scenarios.

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Conventional Radiography

The earliest musculoskeletal imaging dates back to the first radiograph of the hand of Wilhelm Conrad Roentgen's wife in 1895 after he observed a new ray that could pass through soft tissues but not bones or metal objects. Despite significant technological advances in cross-sectional imaging, more than 100 years after that Nobel Prize winning discovery, radiography remains the primary imaging study used to evaluate the spine. In its modern application, plain film radiography is the foremost used imaging modality largely due to its widespread availability, low cost, and capacity to produce expedient, high-resolution images of the spinal column. Despite minimal utility in the imaging of soft tissues, plain radiographs remain indispensable in the evaluation of bony morphology and implants. In many instances this modality may be the only imaging required in the radiographic assessment of lumbar scoliosis, especially for patients without a previous history of spine surgery and those with deformity limited to the lumbar spine.

Plain film radiography is the principal tool used in the diagnosis of spinal deformity, particu-

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larly in adults with lumbar scoliosis. Initial evaluation includes global and regional assessment with AP and lateral views ensuring visualization of C2 to the pelvis including the femoral heads, which are used in the measurement of several spinopelvic parameters. Ideally, full-body imaging is obtained in the upright, unsupported, weight-bearing position. This evaluation illustrates the true degree of deformity with axial loading [1–3], the recruitment of compensatory mechanisms, and other pathology which may contribute to pain and disability [4]. For purposes of standardization and to optimally visualize critical landmarks used in the measurement of spinopelvic parameters, the "clavicle position" should be used. In this position, the patient is asked to stand comfortably without support, with elbows fully flexed and fingers placed at the supraclavicular fossa [5].

Since its introduction to commercial practice in 2007, the innovative, whole-body stereotactic radiographic imaging system (EOS imaging, Paris, France) has revolutionized radiographic evaluation of the spine. Using Nobel Prize winning particle detection technology, stereotactic radiography offers significant advantages compared to the traditional 36-inch cassette. Firstly, with the application of slot-scanning technology, stereotactic radiography produces a high-quality image with significantly less radiation compared to standard techniques [6, 7]. Previously, evaluation and long-term monitoring of deformity resulted in significant radiation exposure to patients. Extrapolated over a lifetime of monitoring, the relatively low-dose stereotactic radiographic technique substantially reduces radiation exposure and consequently the risk of radiation-related cancer and mortality [8]. Additionally, stereotactic radiography permits the simultaneous full-body posterior-anterior (PA) and lateral (LAT) image acquisitions in an upright weight-bearing position. This unique imaging technique not only allows for full-body evaluation including compensatory mechanisms such as pelvic retroversion and knee flexion but also permits the reconstruction of a three-dimensional (3D) image from the two-dimensional (2D) biplanar digital output [9].

Conventional radiography is an especially useful imaging modality in the longitudinal surveillance of spinal deformity. On initial evaluation, plain full-body films provide an illustration of coronal and sagittal alignment and often highlight osseous abnormalities related to the deformity's etiology. While the origins of scoliosis in the aging spine are remarkably diverse, adult lumbar scoliosis is most frequently the result of asymmetric degenerative changes occurring within the intervertebral discs and facet joints. Imaging of these patients frequently reveals late findings in the natural history of the degenerative pathophysiology including disc space narrowing, endplate osteophyte formation, and facet arthrosis while providing a method of exclusion for other uncommon causes of deformity. Furthermore, patient position during imaging can be adapted to improve visualization of structures. For example, oblique, Ferguson, or Stagnara views may be used to better examine the pars interarticularis, sacrum, and pedicles, respectively. Finally, thanks to its ease of acquisition, low cost, and informative capacity, conventional radiography is ideally suited for the serial evaluation of deformity, occasionally identifying progression [10, 11], or the origins of new neurologic complaints and informing treatment.

In addition to the utility of conventional radiography in the diagnosis and longitudinal monitoring of spinal deformity, digital radiography provides a wealth of information in the postoperative evaluation as well. With the now routine use of implants for immediate stabilization of the postoperative spine, plain radiographs are an especially important tool in the radiographic assessment of patients after instrumentation [12, 13]. Unlike the metal-induced artifacts generated by cross-sectional imaging techniques, indwelling implants produce minimal artifact on conventional radiography, permitting routine monitoring of patients in the perioperative period, staged during recovery, and pending clinical symptoms such as pain, new neurological deficit, or infection.

Routine postoperative evaluation, similar to the preoperative assessment, begins with PA and lateral full-body radiography. These images are used in the assessment of coronal and sagittal alignment, implant location, and integrity as well as fusion status. All of these outcomes are impor-

tantly monitored following the alteration of spinal biomechanics, given their long-term consequences and influence on the success of operative treatment. In the nonroutine evaluation, plain radiographs serve as a practical screening tool for the identification of generators of postoperative symptomology and complications such as implant failure, pseudarthrosis, and infection. For example, though plain radiography lacks the specificity of advanced imaging modalities, osteomyelitis may be visualized without the delay associated with advanced imaging and prompt immediate intervention.

In addition to the global and regional assessment provided by PA and lateral films, supplementary studies including oblique, supine, and dynamic radiographs may be used to address specific clinical questions and for preoperative planning as well. As discussed elsewhere, the restoration of sagittal and coronal alignment requires the anticipation of reciprocal changes in the unfused segments following surgery. The interpretation of standard PA and lateral whole-body films and dynamic radiographs provides unmatched insight into the overall alignment, the mechanisms of compensation, the stability of adjacent segments, and the degree of correction expected with a given procedure. Ultimately, each of these factors will guide the formulation of treatment strategy and the anticipation of outcomes.

Secondary to the degree of the deformity itself, flexibility and stability are among the most important preoperative considerations in the primary correction of lumbar scoliosis. Whether a deformity is fixed, rigid, or flexible will have radical implications on the prognosis and management of deformity [14–16]. Curve flexibility and the ability to compensate in adjacent regions will ultimately influence surgical approach, fusion levels, and the selection of implants. Unfortunately, there are few studies evaluating the effectiveness of radiographic methods used to determine curve flexibility among adult patients with deformity, and those evaluating adolescent idiopathic scoliosis (AIS) and neuromuscular scoliosis are instead extrapolated. To achieve this evaluation, supine, prone, standing, bending, flexion, and extension images offer a distinct advantage in allowing for a dynamic assessment of instability and flexibility which can be occulted using static imaging modalities alone. Furthermore, the severity and type of curve may instruct the use of additional studies such as push-prone, traction, or bolster radiographs which can be helpful in assessing flexibility of large, rigid scoliotic or kyphotic curves [5, 17–21].

The flexibility of a curve is often measured in the coronal plane using supine, PA, left and right lateral bending films, preferably obtained on a 36-inch cassette. While lateral bending films may be limited by strength and effort, fulcrum bending films, which involve the patient in the lateral decubitus position bent over a radiolucent fulcrum, may be more predictive of flexibility and correctability [15, 16], as they passively hinge the deformity. Additionally, because curve rigidity and adjacent compensation can vastly differ between weight-bearing and non-weight-bearing images [22], upright lateral bending films may provide additional information and influence correction. Similar to the evaluation in the coronal plane, active and passive correction of deformity is evaluated in the sagittal plane with lateral views demonstrating maximal extension and bolstered. Additionally, sitting and standing views are obtained to assess the involvement of the pelvis and distal compensatory mechanisms [23, 24]. With the combination of these views, clinicians are able to thoroughly investigate the flexibility of the deformity and optimally plan for operative correction (Fig.2.1) [22, 25]. For example, a patient demonstrating minimal flexibility on both hyperextension laterals may require anterior release and fusion or a three column osteotomy.

Despite the numerous advantages of plain radiography, advanced imaging modalities are occasionally indicated for the comprehensive evaluation and management of lumbar scoliosis. As the incidence of spinal fusion procedures is increasing nationally, it is not uncommon for patients to present with iatrogenic scoliosis, particularly affecting the lumbar spine. These patients with a history of previous surgery will often require cross-sectional imaging due to the alterations in anatomy and presence of indwelling

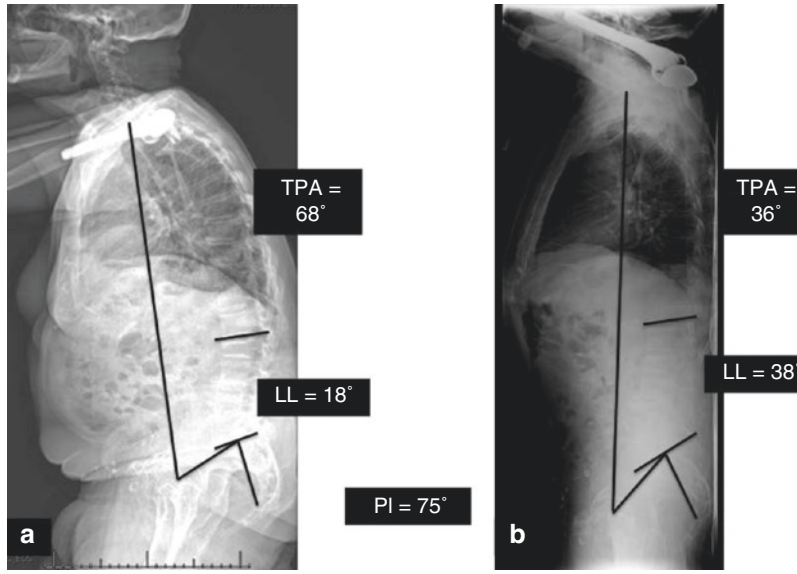

Fig. 2.1 (**a**) Standing lateral radiograph of a 73-year-old male with adult spinal deformity. T1 pelvic angle (TPA) is 68°, lumbar lordosis (LL) is 18°, and pelvic incidence (PI) is 75° with a PI-LL mismatch of 57°. (**b**) Supine lateral radiograph demonstrating considerable flexibility of the regional lumbar and global sagittal spinal deformity. TPA improves to 36° and LL to 38°; PI-LL mismatch improves to 37°

implants. In general, these patients are evaluated with a CT scan which provides axial views with superior bony characterization and soft tissue contrast when compared to plain films.

As discussed previously, plain radiographs are of little utility in the evaluation of the soft tissue components of the spine including the discs, neural elements, articular cartilage, and paravertebral musculature. Nevertheless, evaluation of these neurovascular and muscular components may be indicated as a significant proportion of patients suffer pain secondary to the compressive effects of deformity, causing stenosis, radiculopathy, or a combination of both [26]. Evaluation of these soft tissue structures, in the absence of contraindications, is generally achieved using MRI.

Computed Tomography

Computed tomography (CT) is an imaging modality which utilizes ionizing radiation, similar to conventional radiography, to generate cross-sectional images. CT offers superior characterization of bony and soft tissue abnormalities when compared to conventional radiography although the improved image quality comes at a cost of significantly increased radiation exposure [8] and image degradation in those patients with indwelling implants. The principal advantage of CT imaging over plain radiography is the assessment of bony and soft tissue structures in three planes with faster acquisition speed, lower cost, and fewer contraindications when compared to MRI.

Though CT has been largely replaced as the primary method of advanced spine imaging, there remain a number of circumstances for which CT is the preferred radiographic study. Because CT provides improved visualization of bony anatomy compared to conventional radiography and permits assessment in three planes, it is the modality of choice for nearly any indication requiring detailed evaluation of the spines bony elements.

Though not routinely indicated for the evaluation of isolated lumbar deformity, CT may be useful in the planning of operative correction. The most notable use of CT for this purpose includes the assessment of rotational deformity.

Despite high doses of radiation and limited interpretation secondary to supine positioning [2, 27], CT offers the advantage of axial imaging which most accurately illustrates rotational deformity [28]. As the degree of apical rotation is predictive for progression [10, 11] and influences curve rigidity [29], its detailed assessment may provide valuable information used to guide operative decision-making. Nevertheless, with the ability to generate accurate 3D images using EOS, the use of CT solely for this purpose is predicted to decline [30].

Prior to the widespread use of MRI, CT myelography was the study of choice in the radiographic evaluation of the neural elements. This invasive procedure involves standard CT imaging after the introduction of contrast material intrathecally. Using this study, examiners provide an indirect evaluation of the soft tissue abnormalities within the spinal canal and adjacent structures including spinal cord, nerve root bundles, vertebral discs, and thecal sac with simultaneous characterization of bony anatomy and the benefit of multiplanar reconstruction. Together, this information provides a helpful means for direct and indirect evaluation of the intrathecal contents and extradural soft tissues as well as the identification of compressive pathologies such as foraminal and central canal stenosis. Though largely replaced as an imaging modality due to its invasiveness, radiation exposure, and mediocre soft tissue contrast, CT myelography remains an important tool in the evaluation of those patients with contraindications to MRI.

Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) is a modern imaging modality that utilizes a strong magnetic field rather than ionizing radiation in order to characterize properties of a tissue. With the application of numerous sequences, MRI provides superior characterization of soft tissues and neural elements compared to all other imaging modalities with high tissue contrast and spatial resolution. In contrast with CT, MRI provides the direct visualization of many structures of interest including the spinal cord, nerve roots, and intervertebral discs with poor characterization of bony anatomy. Because of this superior soft tissue visualization, MRI can be an important modality for delineating the presence, extent, and complications of degenerative spinal disease.

Despite MRI's significant advantages, however, there are several limitations to its use. MRI is an expensive imaging modality with limited availability and long acquisition times, making it a poor choice as a first-line modality and for urgent applications where other studies may provide sufficient evaluation (i.e. trauma). Additionally, though modern advances in implant composition have reduced this obstacle, the presence of indwelling implants may produce important artifacts which preclude adequate image interpretation [31]. Furthermore, appropriate technique and interpretation are required in the postoperative setting, as normal postoperative imaging may include small epidural collections, granulation tissue, and osteoclastic bone resorption which can be misinterpreted as abnormal. Finally, and perhaps most significantly, there are several contraindications to MRI, imposed by its use of a strong magnetic field. The most common contraindication encountered within the aging population with lumbar scoliosis is the presence of electrically conductive devices including some permanent cardiac pacemakers, implantable cardioverter defibrillators (ICD), and implantable neurostimulators. Other relevant contraindications include metallic implants such as certain vascular stents, prosthetic heart valves, cochlear implants, and all other ferromagnetic foreign bodies.

While MRI is not indicated in the routine evaluation of isolated lumbar scoliosis, patients with neurologic complaints or physical exam findings consistent with neuropathy should receive evaluation of the implicated neural components as these findings will instruct the extent of decompression in corrective management [32, 33]. Despite the effect of axial unloading in supine imaging, conventional MRI is the most frequently used modality in the evaluation of a deformity's compressive effects, frequently illustrating varying degrees of spinal stenosis, radiculopathy, or a combination of both [26].

MRI demonstrates exceptional sensitivity in characterizing lumbar disc pathology, foraminal stenosis, epidural fibrosis, and spinal stenosis. As an example, MRI is uniquely suited for illustrating the integrity of the annulus fibrosis and hydration of the nucleus pulposus using T2-weighted or STIR sequences. Radiculopathy, resulting from nerve root impingement within the lateral recess, neural foramen, or extraforaminally, can also be visualized readily using MRI. Axial images are best used in the evaluation of lateral recess stenosis and may reveal facet osteophytes, posterior ligamentous thickening, or disc herniation. In contrast, sagittal images of neural foraminal stenosis may reveal a characteristic "keyhole" deformity, while imaging with gadolinium may illustrate inflammatory changes in and around the involved nerve root. The most common cause of spinal stenosis, degenerative change, may be characterized with equivalent accuracy to CT myelography; however, MRI offers the additional advantage of visualizing the neural structures and potential spinal cord pathology in a noninvasive procedure. Signal abnormalities associated with myelopathy, for example, are readily observed on T2-weighted images including increased intramedullary signal, potentially reflecting inflammatory edema, chronic ischemia, myelomalacia, or cystic cavitation [34].

Clinical Scenarios

In addition to the most common applications of spine imaging, there are a number of specific clinical scenarios which will occasionally require the use of special tests in combination with routine methods of evaluation. The vast majority of these scenarios include concerns for early and late complications following operative correction such as instrument malposition, CSF leak, pseudarthrosis, and infection. Despite the presence of artifacts attributed to indwelling implants, the development of metal artifact reduction techniques and advances in implant composition have significantly improved image quality and the ability to evaluate most postoperative complications. Given the challenges in evaluating these clinical entities, the modalities used in the assessment of these complications are presented separately.

Instrument Malposition/Failure

The evaluation of indwelling implant is an important undertaking in the postoperative period as instrument malposition and failure are not uncommon complications. With the increased use of bone graft, interbody cages, and plates and pedicle screws, the potential for postoperative neurologic injury secondary to malposition is not trivial. Acute L5 radiculopathy, for example, may result following anterior malpositioning of sacral pedicle screws, irritating the L5 nerve roots along the anterior sacral surface. In a retrospective study by Lonstein et al., authors identified an overall complication rate of 2.4 % *per* pedicle screw, most of which resulted from medial angulation and violation of medial cortex [35], highlighting the potential for impingement on exiting nerve roots in the lateral recess and neural foramina. Furthermore, implant failure such as fusion cage subsidence and pedicle screw fractures are encountered not infrequently [35]. In a recent series of interbody fusions using recombinant bone morphogenetic protein (rhBMP), for example, authors observed subsidence of fusion cage through the osseous endplate (>3 mm) at a rate of approximately 14 % [36].

Accurate radiographic assessment of instrumentation in the postoperative period can be achieved using multiple modalities including plain films, CT, and MRI. While plain films are often sufficient in the routine assessment of metal, the axial views generated with CT confer increased accuracy, particularly in determining pedicle screw position or loosening [37]. The selection of imaging modality, however, is greatly influenced by the implant type, size, and material composition being assessed. Interbody cages composed of carbon and titanium, for example, can be imaged using both CT and MRI, while satisfactory imaging of tantalum cages requires MRI. With the rapid advancements

observed in implant composition and imaging technology, the radiographic evaluation of these implants is undoubtedly expected to improve in quality and ease.

Epidural Hematoma

Epidural hematoma is potentially devastating complication which may present with the acute onset of neurologic deficit in the immediate postoperative period. Given the potential for permanent injury, early identification of this complication is essential as is prompt surgical decompression.

The radiographic diagnosis of postoperative epidural hematoma can be complicated by the presence of instrumentation and its effect on image quality. The two most commonly used modalities for diagnosis of hematoma include CT myelography and MRI. Plain CT imaging is of little utility in the assessment of intraspinal hematoma due to the similar densities of muscle and hematoma; however, CT myelography in this setting may demonstrate the location of the compressive lesion. Nevertheless, similar to plain CT, CT myelography fails to differentiate hematoma from other forms of fluid and is therefore reserved for patients whom cannot undergo MRI evaluation. Given the limitations of other imaging modalities, MRI is the study of choice for the evaluation of this complication, despite implant-associated degradation [38–40]. If significantly sized, MR imaging may demonstrate an extradural convex, lens-shaped mass with increased signal intensity compressing adjacent thecal sac and transversing nerve roots.

Pseudomeningocele

Pseudomeningocele is the result of CSF extravasation through a dura-arachnoid tear that becomes encysted within the wound, adjacent to the spinal canal. Incidental durotomy is an underestimated event in spinal surgery with serious risks if left undiagnosed [41–45]. In a retrospective review including more than 2000 patients by Cammisa et al., authors estimated a 3.1 % incidence of dural tears among patients undergoing primary decompression for lumbar stenosis, of which 9 % were detected postoperatively requiring open surgical repair [44]. When unrecognized or repaired inadequately, persistent cerebrospinal fluid leak can result in symptoms including postural headache, vertigo, nausea, diplopia, photophobia, tinnitus, and blurred vision [46, 47] and may result in complications as significant as remote intracranial hemorrhage [48, 49].

Although myelography, CT, and MRI have been described as effective means for diagnosing postoperative pseudomeningocele, this complication can be difficult to diagnose. Due to superior soft tissue characterization mentioned previously, MRI is the neurodiagnostic study of choice in diagnosing CSF leak. CSF leak is often revealed on MRI with an evidence of epidural or paraspinal fluid collections, dilation of the epidural venous plexus, and diffuse dural thickening and enhancement. Dynamic CT myelography can also be a useful adjunct in identifying both fast and slow leaks. Studies have demonstrated an off-label use of MRI with intrathecal gadolinium to identify leaks occult to CT myelography [50].

Pseudarthrosis

Pseudarthrosis is a well-known complication of lumbar arthrodesis representing fibrous rather than osseous union of the fusion complex with rates ranging from 5 to 35 % [51–54]. Though there are numerous imaging studies used in the assessment of fusion, diagnosis remains challenging. Historically, fusion assessment was performed with surgical exploration however technological advancements in noninvasive imaging have made this practice nearly obsolete in the modern era. Currently, plain radiography and CT are the most commonly used modalities for fusion assessment [55].

Radiographs are the best suited modality for the postoperative surveillance of fusion. While signs of bridging bone are typically evident on radiographs 6–9 months postoperatively, as an

early tool, plain films may be evaluated to assess for resorption versus incorporation of the graft material. In addition to the use of static imaging, dynamic lateral flexion and extension films may be used to assess the progress of interbody arthrodesis and intervertebral motion. Although pseudarthrosis may have a subtle appearance in its early development, mature pseudarthrosis characteristically demonstrates a well-defined corticate linear lucency around graft material. Several studies evaluating the utility of radiographs in diagnosing fusion have demonstrated sensitivities and specificities ranging from 42 to 89 % and 60 to 89 %, respectively, reflecting the subjective nature of this evaluation [56–58]. Nevertheless, criteria for fusion assessment with conventional radiography have been suggested (Table 2.1).

Despite adequate evaluation using plain radiography, CT is now the preferred method of fusion assessment to confirm findings or when radiographs are equivocal. Depending on the approach, distinct stages of fusion are identifiable with CT evaluation. Progress of an anterior fusion, for example, is evident by trabecular bridging without lucencies or cystic changes adjacent to hardware, while a posterolateral fusion mass begins as a conglomerate of morselized bone fragments and progresses to discrete fragments and finally solid bony bridge. In contrast to these findings, CT imaging of pseudarthrosis often illustrates cystic changes and lucencies adjacent to implants, suggestive of residual intervertebral movement [59]. Prior to numerous advances in high spatial frequency algorithms and multiplanar thin section CT, studies evaluating CT for detection of lumbar fusion estimated sensitivities and specificities ranging from 53 to 97 % and 28 to 86 %, respectively [56, 58, 60].

Table 2.1 Radiographic criteria for the assessment of fusion utilizing conventional radiography

1. Less than 3° of intersegmental position change on lateral flexion and extension views
2. No lucent area around the implant
3. Minimal loss of disc height
4. No fracture of the device, graft, or vertebra
5. No sclerotic changes in the graft or adjacent vertebra
6. Visible bone formation in or about the graft material

Source: Ray [62]

Infection

Despite substantial advancements in the operative treatment of spinal deformity, surgical site infections remain a significant source of morbidity and mortality. Postoperative infection can occur in the form of meningitis, arachnoiditis, discitis, osteomyelitis, and superficial or deep wound infection and may manifest well into the late postoperative period [61]. Identifying infection in the postoperative spine is an especially challenging task and will often require the use of several modalities combined with clinical judgment given the wide range of both normal and abnormal postoperative findings.

Evaluation and diagnosis of infections limited to the soft tissue structures of the spine are relatively straightforward. The modality of choice for evaluating this complication is most commonly CT.

In contrast to the more superficial wound infections which are readily observed on CT images, deep infections adjacent to the spinal cord pose additional diagnostic challenges: meningitis, arachnoiditis, and discitis.

Osteomyelitis is an especially difficult complication to identify radiographically and may require the use of several imaging modalities for diagnosis.

Assessment of Bone Mineral Density

The preoperative radiographic evaluation of patients with lumbar scoliosis is not complete without an assessment of bone mineral density. Degenerative scoliosis is more prevalent among elderly patients. Schwab et al. demonstrated that 68 % of volunteer subjects over the age of 60 had scoliotic deformities [63]. With the aging of our population, the prevalence of adult spinal defor-

mity and that of osteoporosis will continue to increase [63, 64]. Osteoporosis is defined by the World Health Organization as having a T-score less than −2.5, which is a bone mineral density that is 2.5 standard deviation below that of an average 25 years old [64].

Dual-energy x-ray absorptiometry (DEXA) is the standard for assessing bone mineral density, and low DEXA scores have been correlated with increased fracture risk and diminished treatment efficacy [65]. The American College of Radiology recommends osteoporosis screening for all women older than 65 and men older than 70 years of age [66]. However, a DEXA assessment may be indicated in younger patients if there is reasonable clinical suspicion of low bone mineral density especially in the setting of planned surgical correction of lumbar scoliosis [64]. Schreiber et al. proposed an alternative to DEXA using Hounsfield units measured from CT scans which allows for a more direct regional assessment of bone mineral density of the spine [67]. They correlated Hounsfield units with DEXA T-scores, age, and compressive strength of the vertebra. Pickhardt et al. described using CT scans obtained for other clinical reasons as "opportunistic" screening tools for osteoporosis [68]. Meredith et al. demonstrated that patients with fractures adjacent to spine fusions had lower bone mineral density measured by Hounsfield units at the fracture level and globally in the spine when compared to nonfracture controls. Moreover, low bone mineral density has been found to be an important risk factor in the development of proximal junctional kyphosis and proximal junctional failure following adult spinal deformity correction [69, 70]. These findings demonstrate the clinical importance of bone mineral density assessment prior to correction of lumbar scoliosis.

Conclusion

A complete radiographic assessment of lumbar scoliosis includes the use of standing 36-inch cassette x-rays or full-body stereotactic radiography for the assessment of global spinal deformity and compensatory mechanisms, advanced axial imaging to define spinal canal stenosis and neurologic compression, supine imaging for the assessment of deformity flexibility, and DEXA or CT imaging for the assessment of bone mineral density. Only with a complete radiographic understanding of the spinal deformity can the surgeon undertake the appropriate preoperative planning and intraoperative execution of the surgical goals for an optimal postoperative outcome.

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Radiographic Parameters of Adult Lumbar Scoliosis

3

Patrick Reid, Jeffrey Varghese, and Virginie Lafage

Introduction

Radiographic evaluation is essential in the management of scoliosis. X-rays provide objective insight into a patient's structural deformity, often validating a proper yet subjective history and physical. Radiographic measurements from posteroanterior and lateral standing films provide the language we use to communicate about patients and compare results. Since the advent of the Risser sign and the Cobb angle, through the evaluation of spinopelvic alignment and the sagittal plane, radiographic measurements have provided reliable, objective measurements for the diagnosis and treatment of scoliosis.

The radiographic analysis of scoliosis in the twentieth century concentrated primarily on coronal deformities; coronal alignment continues to occupy a position of primacy in the evaluation and treatment of childhood scoliosis. In the management of adult deformity, however, emphasis has shifted toward the correction of sagittal malalignment. Analyzing the sagittal plane is more complex than analyzing the coronal or axial planes, owing to the natural kyphosis and lordosis of the spine. This complexity has driven the development of parameters to simplify and guide the management of adult deformity. The work of Roussouly and others have characterized the normal curvatures of the spine and, importantly, its relationship to the pelvis [1, 2, 10, 12, 15, 16, 18, 25, 38]. Building upon this, parameters defining pathological alignment in the sagittal plane were evaluated using patient-reported outcome studies, leading to the development of the SRS-Schwab classification system for adult scoliosis [7, 28–30, 32].

History of Radiographic Parameters in Scoliosis

X-ray measurements have been a keystone in the evaluation of scoliosis since the advent of the Risser and Cobb measurements in the 1950s. The Risser sign, a measurement of iliac ossification, has been used to evaluate skeletal maturity and has persisted in the study of adolescent idiopathic scoliosis. Likewise, John Cobb's end plate-to-end plate angular measurement still serves as the primary radiographic finding in coronal deformity and is used to diagnose, discuss, classify, and treat these curves. The Cobb measurement, in particular, has been used in multiple classification systems designed to predict the natural history and surgical outcome from the angle and location of coronal curves. Ponseti and Friedman; James, Collis, and Ponseti; and Harrington combined Cobb angles with other factors, e.g., curve location, rotation, progression, and length, as

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well as patient maturity, to form distinct classification systems intended to guide management [9, 21].

In 1983, King published a classification system based entirely on posteroanterior upright and bending x-rays of the thoracolumbar spine, combining Cobb angle measurements with curve patterns, locations, relative flexibilities, and vertebral axial rotations [13]. It also required more than just the Cobb angle, codifying many of the terms used in deformity evaluation today, e.g., the center sacral line, stable and neutral vertebrae, and a "flexibility index" derived from comparing lateral bending in thoracic and lumbar curves. This system was designed to guide selection of fusion levels in adolescent idiopathic scoliosis and was the first classification system to be widely adopted.

The widespread adoption of the King classification offered an excellent opportunity to study a large population of deformity patients. Systematic examination ultimately exposed the weaknesses in the classification; more significant than its reliability pitfall was its lack of consideration for the sagittal plane [36]. Several subsequent AIS classification schemes improved on the King system, adopting its attention to the coronal curve but adding parameters to characterize pathologic sagittal alignment. The Lenke classification accounted for the chief shortcomings of the King system, improving reproducibility and adding a modifier for lordosis as measured on lateral films [17]. The Lenke Classification for AIS served as a starting point for the radiographic examination and classification of adult deformity, although the disease processes and important measures for each would prove very different.

Adult Deformity and the Cone of Economy

The study of adult deformity, separate from its juvenile counterpart, has grown rapidly over the past few decades. The application of key radiographic parameters and classification systems used in AIS and other juvenile scoliotic diseases has proved largely ineffective [7]. Emphasis has shifted away from coronal realignment—frequently the primary goal of juvenile scoliosis surgery—toward alignment correction in the sagittal plane.

Spinal alignment is more complicated in the sagittal plane than it is in the coronal or axial planes. Whereas the goal of coronal and axial correction is to straighten and de-rotate, correction in the sagittal plane must account for the natural spinal lordosis and kyphosis. Appropriate alignment in the sagittal plane has been shown to improve outcomes in the adult scoliotic population [14, 32]. As such, the parameters that constitute pathologic sagittal malalignment, including compensatory measures outside the thoracolumbar spine, have been the subject of increasing study [19, 20, 22, 24, 26, 33, 34].

The "cone of economy" as published by Dubousset in 1994 describes the range of standing postures in which the body can remain balanced without support and with minimum energy expenditure [3]. Those unable to maintain a standing posture in the center of the cone demand the muscles and joints of the spine and legs to compensate, which can result in fatigue, pain, and disability. Many of these patients require external aids such as walkers or canes to stand. Studies on flatback syndrome have noted the clinical sequela of iatrogenic sagittal malalignment since the 1970s. That, with the quantification of normal and pathologic spinal curvatures, has driven the development of many radiographic parameters [5].

Multiple studies have attempted to characterize radiographic alignment in the sagittal plane. Stagnara, in 1982, proposed normal reference values for thoracolumbar lordosis and kyphosis, as well as for sacral slope [35]. His findings—that there were wide and irregular variations between healthy subjects for both values, belying the idea of a "normal" lumbar lordosis or thoracic kyphosis—have been born out in subsequent studies. The study did note the intra-patient relationships between lordosis, kyphosis, and sacral slope, which would also be a theme of sagittal analysis going forward.

Quantitative Radiographic Evaluation for Sagittal Plane

A landmark study by Jackson et al. in 1994 compared healthy adult volunteers with patients reporting low back pain, noting a wide but largely similar range of values for lordosis ad kyphosis in healthy patients, as well as similar C7 plumbline values, between the two groups [11]. However, they noted a critical proximal shift in segmental lordosis and a decrease in sacral inclination in back pain patients, representing possible compensatory mechanisms for any loss of lordosis at the lower lumbar levels in these patients.

An emphasis on sagittal alignment led to widespread use of the sagittal vertical axis (SVA), determined by measuring the AP translation relative to S1 of a cephalad vertebrae. Gelb et al. examined the horizontal distance between a plumbline dropped from the middle of the C7 vertebral body to the anterior superior corner of the sacrum on a standing lateral x-ray, noting the tendency for SVA to move anteriorly in older subjects, while sagittal alignment remained neutral in asymptomatic patients [6]. Van Royen et al. examined the horizontal distance between a plumbline dropped from the tip of the C7 spinous process to the anterior superior S1 vertebral body in a single patient with an ankylosed spine to isolate the relationship between posture and SVA (Fig. 3.1) [37]. They pointed out that small angular adjustments in the lower extremities resulted in significant changes to SVA measurements, implying that SVA ought to be considered in the context of compensatory postural mechanisms. Further studies pointed out inadequacies in SVA measurements: a dependence on arm position, a lack of correlation to "functional" standing position, and a poor correlation between a cervical plumbline and the true center of gravity. Still, poor clinical outcomes have been shown to correlate linearly with increasing sagittal malalignment as measured with a C7 plumbline, indicating SVA as an important parameter for health-related quality of life.

The incorporation of pelvic parameters led to a fuller understanding of sagittal alignment and its contribution to quality of life outcomes. In 1998, Legaye and Duval-Beaupere et al. proposed pelvic incidence (PI), a measure quantifying the interface between the spine and the pelvis [4, 16]. Defined as the angle between the line from the femoral head axis to the midpoint of the superior S1 end plate and the line perpendicular to the S1 end plate, PI is morphologically unique to each individual and is independent of postural changes. PI, a fixed value, correlated well with LL; patients with a high PI were also likely to have a high LL. They postulated that a chain of interdependence existed between the pelvic and spinal parameters. Other parameters proposed by

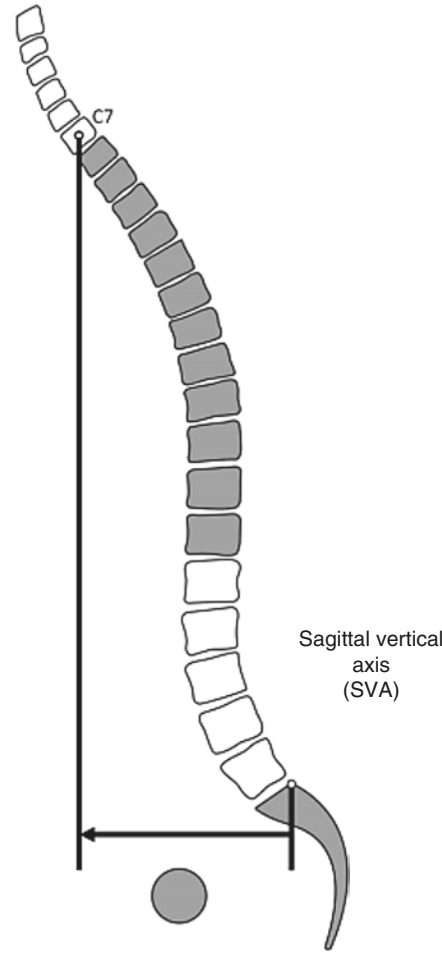

Fig. 3.1 Schematic diagram for sagittal vertical axis (SVA)

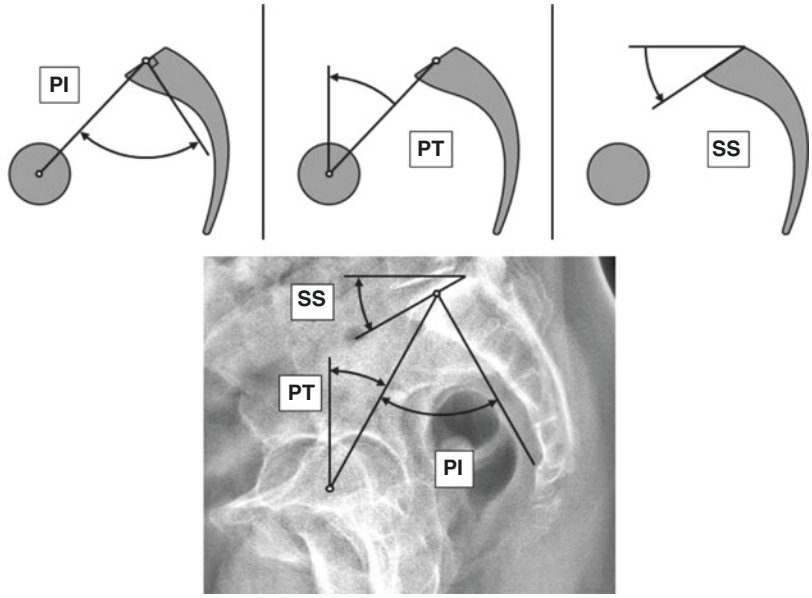

Fig. 3.2 Schematic diagrams for pelvic parameters

Legaye include sacral slope (SS), defined as the angle between the S1 end plate and the horizontal on a lateral standing x-ray, and pelvic tilt (PT), defined as the angle between the line from the mid-axis of the femoral heads to the midpoint of the superior S1 end plate and the vertical on a lateral standing x-ray (Fig. 3.2).

Attention to the pelvic parameters revealed the importance of pelvic compensation for sagittal malalignment. Earlier papers had characterized the effect of small, angular changes in posture around the hip axis on the SVA, but in the late 1990s and early 2000s, efforts were made to quantify this compensation [1, 12].

Pelvic Parameters and the Sagittal Plane

The high degree of patient-to-patient variability in spinal sagittal alignment complicates the study of pathologic malalignment. Roussouly et al., in 2005, published a classification system describing categories of lumbar lordosis in relation to curve apices and spinopelvic relationships in 160 normal subjects [25]. In addition to describing an association between PI and LL, they found a reciprocal relationship between the sacral slope and pelvic tilt and established the equation: SS + PT = PI. Relating spinal sagittal curves to pelvic parameters lends meaning to these measurements that otherwise vary so wildly as to make radiographic identification of pathology, in many cases, difficult if not impossible.

Spinopelvic alignment criteria have been shown to correlate with patient-reported outcomes. Previous studies sought to delineate, without success, a relationship between coronal deformity and clinical outcomes. However in the sagittal plane, Glassman et al. demonstrated that positive sagittal malalignment is predictive of poor clinical health status; their two studies revealed that symptom severity increased linearly with worsening positive sagittal malalignment and that restoring normal sagittal alignment improved clinical symptoms [7, 8].

The identification of sagittal alignment as a primary driver in adult scoliosis patient satisfaction, both pre- and post-op, set the stage for the establishment of the SRS-Schwab classification system, which has undergone several iterations since the early 2000s. Based originally on a prospective analysis of 95 patients, the initial study in 2002 identified L3 and L4 end plate obliquity in the frontal

plane, lateral olisthesis, lumbar lordosis, and thoracolumbar kyphosis as radiographic parameters that correlated with increased pain [29]. This led to the first SRS-Schwab classification system, which grouped patients into three categories based on lumbar lordosis and L3 coronal obliquity. The system was then expanded; the curves were further characterized by their coronal deformity apex, degree of lordosis, and intervertebral subluxation. Coronal curve categories were prescriptive—different curve types demanded tailored surgical approaches—while the lordosis and subluxation modifiers stratified patients into clinical groups, with higher grades indicating worsening HRQOL.

The work of Glassman et al. led to the inclusion of a global sagittal balance modifier in later iterations [8]. Ultimately, outcome-driven criteria led to refining the SRS-Schwab classification system to include a coronal curve modifier and three sagittal alignment modifiers: PI-LL, SVA, and pelvic tilt (Fig. 3.3). The coronal modifier describes the coronal curve type: T for thoracic only, L for thoracolumbar or lumbar only curves, D for double curves (T and TL/L curves both >30°), and N for no coronal curves>30°. The three sagittal modifiers, stratifying patients by clinical symptomatology, were established based on HRQOL studies:

PI-LL, calculated by subtracting the lumbar lordosis from pelvic incidence: 0 (non-pathologic) for PI-LL < 10°, + (moderate deformity) for PI-LL between 10° and 20°, and ++ (marked deformity) for PI-LL>20°

Global alignment, assessed by measuring the translational distance from the posterior superior S1 body to a plumbline dropped from the middle of the C7 vertebral body: 0 (non-pathologic) for SVA< 4 cm, + (moderate deformity) for SVA between 4 and 9.5 cm, and ++ (marked deformity) for SVA<9.5 cm

Pelvic tilt, measured as the angle between the line from the mid-axis of the femoral heads to the midpoint of the S1 plate and a vertical line: 0 (non-pathologic) < 20°, + (mild deformity) between 20° and 30°, and ++ (marked deformity) > 30°

The SRS-Schwab classification provides a framework for interpreting radiographic parameters by incorporating the current base of knowledge regarding sagittal alignment, spinopelvic parameters, and compensatory measures [27]. The classification has been validated using patient-reported outcomes for both operative and nonoperative patients [30, 31]. When combined with clinical judgment, the SRS-Schwab classification can guide treatment in adult scoliosis patients. Prospective studies have validated the

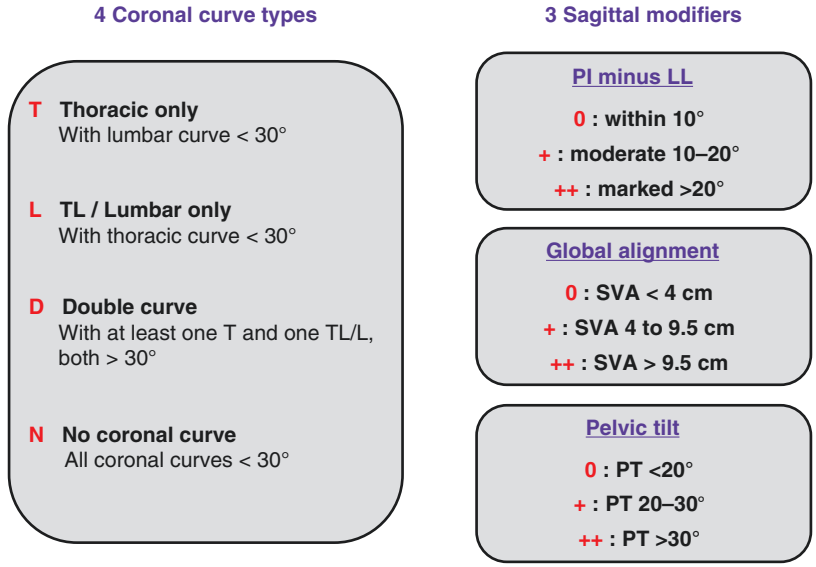

Fig. 3.3 SRS-Schwab classification for adult spinal deformity

classification in follow-up studies, relating improvement in SRS-Schwab classification with higher HRQOL scores [32].

Future Directions

Sagittal alignment and spinopelvic parameters have allowed surgeons to pursue evidence-based radiographic goals anchored in patient-reported outcomes. Still, complications persist, and outcomes are not perfect. Several parameters show promise with regard to predicting complications and patient dissatisfaction beyond those described by the SRS-Schwab classification. Patients with severe sagittal malalignment, unsurprisingly, have poorer outcomes than those with mild or moderate deformities. High preoperative PT and SVA have been specifically shown to increase the risk of poor surgical outcomes. Poor postoperative alignment is a common cause of patient dissatisfaction and low HRQOLs; careful and adequate planning is critical in providing the proper degree of sagittal correction tailored to each individual patient. Postsurgical reciprocal changes, e.g., alterations in TK after lumber realignment surgery, have been observed. Surgical planning will need to account for these changes, although they are currently still difficult to predict.

Staying true to the global nature of malalignment, concomitant cervical deformity is also not uncommon in adult thoracolumbar disease. 53% of thoracolumbar deformity patients have cervical deformity, either as a compensatory mechanism or as a primary disease process [33]. New cervical deformity has also been found in 48% of post-op patients, as has improvements in preoperative cervical deformity following thoracolumbar realignment [19, 20, 22, 34]. This is a logical extension of the chain of interdependence connecting the pelvis and thoracolumbar spine. Radiographic parameters to quantify and predict cervical deformity are currently being studied, including T1 angle, T1 spinopelvic inclination, C2-T1 SVA, and cervical lordosis. T1 spinopelvic inclination also correlates with HRQOL outcome scores in adult scoliosis patients [23, 26]. Caudal to the spinopelvic axis, studies are being directed at knee flexion, another compensatory mechanism with similar biomechanics to pelvic tilt.

Predicting outcomes from adult scoliosis surgery has proven difficult. Patients on either end of the disease spectrum tend to improve after surgery; it is those who fall between the extremes—the majority of patients—that have mixed results. Poor outcomes occur even after a successful sagittal realignment. This emphasizes the need for further studies to determine if there are radiographic parameters that can be further optimized to increase chances of obtaining good clinical results.

Conclusion

Radiographic parameters, clinically backed with patient-reported outcomes, are both useful in the baseline evaluation of and the treatment selection for adult spinal deformity patients. With the spinopelvic parameters and the SRS-Schwab classification in mind, a framework has been established to deliver a more personalized surgical approach, resulting in better clinical outcomes and greater patient satisfaction.

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4 Patient-Reported Outcome Measures Available for Adult Lumbar Scoliosis

Vadim Goz, Joseph F. Baker, and Darrel S. Brodke

Introduction

Patient-reported outcome measures (PROMs) or patient-reported outcomes (PROs) are a set of tools that quantify health states by patient self-report. Traditionally these tools have focused on quantification of pain and function, as the improvement in these two qualities represents key goals consistent across musculoskeletal care. Over the past two decades, PROs have played an increasingly important role in healthcare and particularly in adult spine surgery. The tools available for assessment of pain, function and mental health have undergone a rapid evolution.

Early outcome tools were developed using classical test theory (CTT); these tools will be referred to as legacy measures throughout this chapter. Legacy measures include general assessments of pain and function, such as the Short Form 36 (SF-36) and the Sickness Impact Profile (SIP), and disease-specific measures, such as the Oswestry Disability Index (ODI), which is specific to lumbar spine pathology, and the Scoliosis Research Society (SRS) questionnaire for assessing several domains in patients with spinal deformity. Outcome tools took a major step forward with the development of Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS is a novel tool that has been demonstrated to outperform many legacy measures in spine patients.

PROs play an integral part in research by facilitating comparison of outcomes between interventions, as well as in the pursuit of value in healthcare, and in helping physicians communicate to patients and discuss expectations and outcomes of treatment. This chapter will cover a broad range of topics with regard to PROMs including available tools, methodology used for developing outcome tools, the evolution of PROs and the current and future roles of PROs in orthopaedics.

Legacy Outcome Measures

Legacy outcome measures are a group of tools that have served as the foundation of PROs. There are two general types: general outcome measures and disease-specific measures. General measures allow comparisons of patients' health across different medical conditions, for example, comparison of spinal surgery to cardiac surgery. General considerations for assessing these measurement tools include their validity, reliability and responsiveness. A summary of key terms used for assessing the usefulness of a PROM is shown in Table 4.1.

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Table 4.1 Key terms and definitions

Concurrent validity	A measure is compared to an already established, validated measure
Criterion validity	A measure is compared with a similar variable
Discriminative validity	Refers to a measure's ability to differentiate between the various stages and severities of a disease process
Domain	A single trait or characteristic such as pain, function, social health and mental health. Can be subdivided into related groups of traits (e.g. types of pain) called subdomains
External responsiveness	Ability to detect change as a result of some external modifier, e.g. a change in mental health impacting on physical domain
Internal consistency	This measures whether questions in a particular domain actually represent that domain and is reported using a statistical measure: Cronbach's α
Internal responsiveness	Ability to detect expected change, e.g. improvement or otherwise after surgical intervention
Psychometrics	The science of using quantitative tools to measure skills, knowledge and traits, as well as the science of developing and evaluating those tools
Reliability	A reliable measure is one free from random error
Reproducibility	Also known as test-retest reliability and reported using the intra-class coefficient (ICC). Score approaching one confers greater reliability
Responsiveness	Ability of a measure to detect change over time, i.e. detect treatment effects or the changes according to natural history of the disease
Validity	To validate a measure, it needs to be compared with a known standard or process – there are three types of validity
Trait	A characteristic or skill such as pain, function or mental health
Computer adaptive testing (CAT)	A technique by which the response to a given item determines the next item to be administered to a test taker. This produces a customized test, based on the trait level of the examinee that minimizes the number of questions required for a test to estimate a testee's ability
Unidimensionality	The ability of a test/question to assess a single trait without influence by confounders

Understanding measurement tools is essential to interpret results and outcomes from clinical studies and treatments. As an example, Fairbank highlighted previously a potential flaw in reporting outcome data when a non-validated version of the Oswestry Disability Index was used that, when tested, actually resulted in a much higher baseline score than the contemporary validated version [1]. A general understanding of these measures is key to assessing their utility and limitations in spine patients.

General Measures

Short Form 36

Short Form 36 (SF-36) is one of the most widely used tools to assess a patient's general condition and has been translated into over 40 languages. The Medical Outcomes Study Short Form (SF) questionnaires include 6, 12 and 36 question versions. The shortened forms were developed for ease of use and rapid completion [2, 3]. They are most useful for determining the general health of an individual and are used across a variety of surgical and non-surgical fields.

The SF-36 takes between 5 and 10 min to answer all of the questions, and it assesses eight different domains: physical function, bodily pain, social functioning, general mental health,

vitality, role limitations due to physical health, and role limitations due to emotional problems and general health perceptions [4]. It can be used to assess and report outcomes from a single domain (i.e. bodily pain or physical function), or the answers can be rolled up into two combined scores, Physical Component Score (PCS) and Mental Component Score (MCS). It has been shown to be acceptable to patients with moderate disabilities although changes have been suggested to accommodate patients who are wheelchair bound, for example, after spinal cord injury [5, 6]. A strength of the SF-36 is the existence of normative data to allow comparison to the population mean [7]. More details on the SF-36 including a comprehensive review of the literature pertaining to the analysis of the scoring, details of development and application for use of the scoring tools and licencing are available online (http://www.sf-36.org/). A disadvantage is that the SF-36 is copyrighted and a licencing fee is required for its use in commercial applications, though generally for non-commercial applications, a licence can be obtained without a fee.

The SF-12 was developed in 1996 as an abbreviated form of the full survey. It can be recorded in the same mode as the SF-36 but has the advantage of taking less than 5 min to complete. The SF-12 is not as sensitive in detecting change at the level of the individual but is fine as a population tool. It also generally requires a licence to use.

The SF-6D is a preference score or quality metric that utilizes six dimensions from the SF-36 – the general health perceptions were omitted, and the limitations as a result of physical and emotional problems were combined. Brazier et al. also developed it as a utility measure for cost-effectiveness research (CER) [8]. In total it describes 18,000 different health states, and anyone completing the SF-36 and SF-12 can be classified according to the SF-6D. Importantly the SF-6D allows one to obtain quality of life-adjusted years for cost-utility analysis (CUA) (like the EQ-5D, discussed below). The SF-6D is also copyrighted and a licence is required.

A concern with any specific PROM is its ability to represent and detect change in clinical status according to treatment. Condition-specific PROs have been tested against the SF-36. Haro et al. jointly assessed the utility of the Japanese Orthopaedic Association (JOA) score, Oswestry Disability Index, Visual Analogue Scale (VAS) and SF-36 (version 2) in a cohort of patients undergoing surgery for lumbar spine stenosis and found good correlation between the four assessments over 24 months of follow-up [9]. The authors determined that the combination of measures was complimentary and the specific strengths of the SF-36 were its assessment of both physical and psychological well-being. Grevitt et al., in a UK cohort of patients undergoing lumbar discectomy, found high reliability for each component of the SF-36. Additionally, all components of the SF-36 correlated well with more specific measures, including the Oswestry Disability Index, except for the mental health domain [10].

Similarly, in a study assessing patient-reported measures in both neck and back disease, Guilfoyle et al. found that SF-36 physical function and bodily pain domains correlated well with the Roland-Morris Disability Index [11]. They also revealed that VAS pain scores for leg pain were strongly correlated with bodily pain scores. They reported that the relevant domains of the SF-36 were free of floor or ceiling effects; however, recent data reveals a significant floor effect for the physical function domain of the SF-36 in the spine patient population, limiting its usefulness [12]. Ware et al. reported on the SF-12 noting acceptable validity and reliability [13]. The SF-6D has good reliability and validity with a significant floor effect, suggesting that it overpredicts poor health states [8, 14, 15].

Veteran RAND Health Surveys

The Veteran RAND (VR) Health Surveys were developed with the support of the Department of Veteran Affairs. These consist of 36- and 12-item questionnaires to assess health-related quality of life across eight domains, much like the SF-36 and SF-12, but however do not require a fee to use. Licencing is still required. Further details about the V-RAND surveys and information about usage can be found online at http://www.rand.org.

The VR-6D is a utility measure composed of six. It was developed in part because of a concern about floor effects of the SF-6D and also the difficulty converting SF-12 scores into SF-6D [16]. The six domains include physical functioning, physical and mental role limitations, social functioning, pain, mental health and vitality. Similar to the SF-6D health state, the scale ranges from 0 to 1 with 0 equivalent to death and 1 being optimum health. It has been shown that as a utility measure, the VR-6D is comparable to the SF-6D [16]. The questionnaires can be completed face to face or over the telephone. Interestingly it has been noted that recording of scores over the telephone results in higher scores (better health quality) than when done face to face [17].

EQ-5D

The EuroQol Group created a non-disease-specific general health measure in 1987 [18]. Initially members included predominantly European nationalities (Dutch, Finnish, Norwegian, Swedish and British); however, the assessment tool has since become increasingly used globally with development centres located in New Zealand, Zimbabwe and the USA among others [19]. It is frequently used as an outcome tool in national registries [20–22].

The principal aims of the EuroQol Group were to create a standardized instrument that would complement rather than replace existing tools for describing health-related quality of life independent of the medical condition of the individual [19, 23]. Details in the measure are available at http://www.euroqol.org. Use of the instrument requires registration and payment of a fee determined by the EuroQol group.

The EQ-5D comprises 245 health states. These are divided into five dimensions and were originally further divided into three levels of severity (3L): no problem, moderate problem and severe problem. After detection of ceiling effects in some general population cohorts, the questionnaire was revised in 2005 to include five levels (5L): no problems, slight problems, moderate problems, severe problems and extreme problems [24]. The dimensions considered include mobility, self-care, usual activities, pain and anxiety/depression.

The EQ-5D can be completed without face-to-face interaction, making completion at home via postal delivery an option. Data gleaned from the EQ-5D can be delivered in three different fashions: it may be reported as a descriptive profile detailing impairment in each dimension, as a population-based score and as a self-rated perceived health status (based on the visual analogue scale component of the questionnaire) [25]. There is a large reference range available for data comparison from the normal population as well as for different diseases making it a useful tool for comparative analyses [26].

The EQ-5D has been tested for its validity in measuring change in health state after lumbar spine surgery for degenerative conditions. Solberg et al. compared it to the ODI in a cohort of over 300 patients undergoing such surgery with 12 months follow-up [27]. They determined cross-sectional construct validity of the EQ-5D in assessing pain, employment, function and health state when compared to the ODI. Only small differences in responsiveness were noted. In a study of patients with adolescent idiopathic scoliosis, the Scoliosis Research Society-22 score was compared with the EQ-5D for repeatability, reliability, consistency and concurrent validity [28]. The authors concluded that the disease-specific and non-specific questionnaires measure different constructs, as the concurrent validity of the EQ-5D was poor to moderate. One drawback for the EQ-5D is the possibility for a ceiling effect and clustering.

Within the field of spine surgery, the EQ-5D has been commonly used in cost-utility analyses (CUAs) [29]. CUA uses ‘health-state utilities’ as an assessment of health outcomes. A utility score provides a preference-based value for a health state ranging from 0 (death) to 1 (perfect health). In CUA, a common approach to representing health-state utilities has been the quality-adjusted life year (QALY). QALYs are defined as the area under the curve of a graph of health-state utility versus time. The EQ-5D has proven to be a useful tool for defining health-state utility scores from which QALYs can then be calculated.

CUA is particularly useful for evaluating outcomes of care where the intended outcome is improvement in the quality of life. The great majority of spine surgery falls under this category. An example of the use of CUA in spine surgery is the work by Tosteson et al. [30] that evaluated the cost-effectiveness of operative versus nonoperative treatment for patients with lumbar disc herniation using data from the Spine Patient Outcomes Research Trial (SPORT). For each cohort QALYs were calculated by using EQ-5D-derived health-state utility scores at 6 weeks, 3, 12 and 14 months. Direct and indirect costs were calculated. The data showed that the cost per QALY gained with surgery compared to nonoperative treatment ranged from $34,355 to $69,403.

While cost-utility analysis is a powerful tool that has been used to evaluate a number of spine procedures, it has its limitations. CUA is not a useful tool for evaluation of procedures that are meant to prevent the deleterious outcomes of disease progression. For example, spine surgery for adolescent idiopathic scoliosis would likely not show significant improvement in quality of life after surgery comparing to before, since the primary goal of the procedure is to prevent future complications of untreated scoliosis. The same applies to resection of asymptomatic tumours that will not lead to immediate improvement in quality of life but will lead to improved overall survival.

Sickness Impact Profile

The Sickness Impact Profile was developed by Gilson et al. in 1975 and subsequently revised by Bergner et al. in 1981 [31, 32]. The assessment is more time consuming or burdensome, requiring 20–30 min to complete. It assesses patient performance over 14 different domains of function encountered on a daily basis and is available in a number of different languages [8]. The patient completes the SIP by selecting statement that best applies to them on the day of completing the questionnaire. Such statements include 'I sit much of the day'. An overall score is calculated with a higher score indicating a greater level of dysfunction. It can thus be reported as a total score is by using a single domain.

It has been well tested for validity and reliability [7, 33]. Deyo et al. tested the SIP for validity and reliability in a back pain population and found to have substantial test-retest reliability with change in the appropriate direction according to clinical status [34]. It may be useful in populations that are seriously ill in which other measures may be limited by floor effects [33].

At present it is a less frequently used general outcome measure having been supplanted by the aforementioned measures. Frequently cited reasons for its lack of use are its length and the time required for completion. This has prompted efforts to create an abbreviated version that may be more user-friendly [35]. Internal consistency of the abbreviated form (SIP-68) has shown to be excellent; however, there is an additional concern for a large ceiling effect of the SIP in healthy populations [36].

McGill Pain Questionnaire

Melzack and Torgerson developed the McGill Pain Questionnaire in 1971 at McGill University [37]. This is a patient-completed questionnaire that is used to describe the quality and intensity of a patient's pain. There are three components to the questionnaire. The first section comprises a list of descriptors for the type of pain the patient is experiencing across 20 groups. Only those descriptors that match the patients pain are selected with each term assigned a numeric rating (higher score more severe). The second section asks how the pain changes with time, and the third uncovers relieving factors. The final section asks questions to determine the severity of the pain. The score is provided 0 (not seen in a patient with pain) to a maximum pain score of 78.

A short form (SF-MPQ) was reported by Melzack in 1987 consisting of 15 descriptors of pain rated from 0 to 3 with the higher score indicating greater severity [38]. This abbreviated version also included a Visual Analogue Scale and

Present Pain Intensity (PPI) index from the standard MPQ. A further revision with expansion of the rating scales to a wider format allowing rating from 0 to 10 was reported in 2009 [39]. Acceptable validity and reliability were confirmed in a non-spine cohort.

Visual Analogue and Numeric Pain Rating Scales

Visual Analogue Scales (VAS) or Numeric Pain Rating Scales (NPRS) are used to measure a variety of symptoms, with pain being the most frequent application. Often these are subdivided into back and leg pain separately when dealing with lumbar spine pathology.

The VAS is typically represented by a line, often 100 mm in length with one end representing no pain and the other end most severe possible pain and scored 0–100. No localizing marks other than at each end are allowed, as they may influence the answer. The patient is asked to mark the line between ends (no pain and the severest possible pain) that represents their pain level. The score is reported in centimetres or millimetres along the line from 0 to 10 or 0 to 100. The NPRS on the other hand is typically an 11-point scale from 0 through to 10, similarly representing no pain through the worst possible pain and scored as whole numbers from 0 to 10.

Ostelo et al. previously reviewed the literature with the aim of providing guidelines regarding the Mean Clinically Important Difference (MCID) on commonly used measures including both VAS and NPRS [40]. They determined that a change of 15 mm and 2 for the VAS and NPRS, respectively, represented the MCIDs and a change of 30 % from baseline was a useful threshold. Parker et al. determined a broader range of MCID when analysing a cohort of patients undergoing transforaminal interbody fusion with the mean MCID for VAS 2.8 cm or 28 mm and 2.1 cm or 21 mm for the back and leg pain, respectively [41]. A change of two points on the NPRS has also been deemed to signify a clinically important change by Childs et al., who followed patients with low back pain treated with physical therapy for a 4-week period [42].

A common criticism of the VAS and NPRS is that it is not necessarily clear whether pain is being measured on a particular day or whether it is being measured in general. It also seems as sensitive to anxiety as it is to pain itself. The impact of other painful conditions cannot be negated such as neuropathy or arthroses affecting the appendicular skeleton. Depression and somatization can also influence these measures.

Lumbar Spine-Specific Scores

Oswestry Disability Index

The Oswestry Disability Index (ODI) was developed in the 1970s, first reported in 1980, and is one of the most widely used tools in assessment of lumbar spine pathology [43, 44]. Its widespread use more than 30 years on since its development is a tribute to its developer. It is now licenced to the Mapi Research Trust.

The latest version of the ODI is 2.1a, the previous versions being modified in response to feedback from medical specialists [45]. The ODI contains ten questions pertaining to daily activities performed over the preceding 4 weeks, each of which had six ordinal responses. All the questions relate to activities that may be affected by lower back pain. Each question is scored from 0 to 5; no interference with said activity to maximal interference. The score is then doubled to provide a percentage score from 0 to 100. Scores from 0 to 10 are considered normal, 11–20 minimally disability, 21–60 significantly and increasingly disabled and 61–80 bedridden, while scores over 80 may be spurious [44]. The MCID has been reported previously as 12.8 in a systematic review of patients with an established surgical pathology [46].

The ODI requires no training to use, is self-administered and can be completed in less than 5 min. It has excellent test-retest reliability and has proven validity. Among subjects considered to be ‘unchanged’, Davidson and Keating

reported an ICC of 0.74 [47]. It has been well correlated with the Quebec Back Pain Disability Index [48]. Grevitt et al., as mentioned earlier, have shown excellent correlation of the ODI with the SF-36, particularly the physical component of the general score [10].

Criticisms of the ODI include some difficulty with the phrasing of certain questions particularly when considering North American responders [49]. Some modifications have been made to the original version, but one must be careful to ensure that the modified version used is actually a properly validated version to avoid drawing inaccurate or misleading conclusions about treatment effect. The current correct version is 2.1a, and a side-by-side comparison of this with an unvalidated version can be seen in the *Journal of Neurosurgery: Spine* [45].

In a recent study examining the ODI (v2.0) in comparison to PROMIS, Brodke et al. showed that the ODI physical function domain (PFD) in fact has significantly greater ceiling and floor effects, more so floor [50]. When comparing ODI to both SF-36 and PROMIS, the ODI was also shown to have poorer reliability. When assessing the psychometrics and performance of the ODI (v2.0) in a cohort of over 1600 patients with back pain while reaching the conclusion that the ODI performed relatively well, floor and ceiling effects were again detected limiting interpretation of patients at the ends of the spectrum, and suboptimal unidimensionality was demonstrated (inability to accurately measure a single construct without influence from other variables, e.g. depression or anxiety) [12]. Further discussion on the use of PROMIS and conversion from the ODI to PROMIS is discussed below.

Roland-Morris Disability Questionnaire

In 1983, Roland and Morris, both from a general practice background, published this measure of low back pain to assess disability encompassing a wide range of functional domains [51]. It was tried and tested initially in a general practice cohort with testing on almost 200 subjects at weeks 0, 1 and 4. The original version was developed from the Sickness Impact Profile with modification of the questions to include the phrase 'because of my back' [52]. It contained 24 items, but was later revised to include only 18 [53].

Little training in its used is required and is considered easy to complete taking approximately 5 min [49]. It is widely available, and the original 24-statement version can be obtained free from http://www.srisd.com/Roland-Morris.pdf. Translations are available in several languages. Unlike others there is no determining degree or severity of disability in each of the activities – the patient either has or has no difficulty on the given day. The number of items checked off over time can track improvement. The MCID has been determined to be only 2–3 points or a 30 % reduction in baseline score [54].

It has shown excellent internal consistency. Over 200 patients completed the questionnaire twice within 2–4 days with an ICC of 0.91 [48]. However, Davidson and Keating reported an ICC of 0.53 in almost 50 patients, unchanged in symptomatology, retested after 4 weeks [47]. It has been able to distinguish patients who are working from those who are not and those who require medication for their back condition [48].

While its ease of use and widespread use are positives, its dichotomous response categories are seen as a weakness compared to other measures that offer either multiple responses or a scale to determine degree of severity. Another potential drawback is the lack of psychosocial or psychological disability analysis, and hence there is less correlation with other measures that include these domains.

North American Spine Society (NASS) Lumbar Spine Outcome Assessment Instrument

NASS created a taskforce in 1991 for the purpose of developing an outcome measure for the impact of lumbar spine pathology. Daltroy was the lead author in the creation of this instrument, and they

reported their development of this tool in 1996 [55].

It contains 34 items and these are broken down into summative scales. In addition there are a series of single-item questions. The scales include pain and disability, neurogenic symptoms, job difficulty, job exertion, expectations and satisfaction. Each subscale is cored from 1 to 6, best to worst. The mean of all items in each subscale is used as the scale score.

No training is required to use the tool and is a self-administered written questionnaire. It is easily accessed from the American Academy of Orthopaedic Surgeons (AAOS) website (www.aaos.org). Interclass coefficients testing reproducibility of the various subscales were all 0.85 or above [49]. The NASS Pain and Disability Scale has been strongly correlated with Visual Analogue Pain Scale, the SF-36 Pain Scale and the SF-36 Physical Limitation Scale [49].

On the flipside a reading level of eighth grade is required which is higher than the significant portion of the US population [56]. Consideration needs to be given for testing the NASS instrument in non-surgical populations and in longitudinal cohort studies [49].

Lumbar Stiffness Disability Index

This is a more recent addition to the armoury of PROMs for the lumbar spine, created and reported by Hart et al. in 2013 [57]. It was born out of a desire to determine what functional impairment resulted from the loss of movement as a consequence of arthrodesis as opposed to loss from pain and other symptoms.

A ten-item questionnaire was tested for validity, reliability and consistency in a cohort of 32 patients undergoing lumbar spine arthrodesis procedures and followed for a year. The ten items each assess the impact of stiffness on daily activities and result in a score from 0 to 100 with higher scores indicative of greater impairment. The scores were correlated also with the degree of resulting stiffness as determined by the range of movement from T12 to S1 on flexion-extension radiographs of the lumbar spine.

In a later study, it was seen that patients undergoing a single-level arthrodesis actually reported less stiffness according to their LSDI, whereas those who underwent three-, four- or five-level procedures were worse off secondary to the degree of stiffness [58].

Overall, this is a relatively new specific measure but offers assessment of an area that earlier measures have perhaps overlooked. As surgery for adult spinal deformity becomes increasingly utilized, it is likely this measure will have a greater role to play.

Scoliosis Research Society-22

Haher et al. published on the development of the Scoliosis Research Society, the SRS-24, score in 1999 [59]. This was prompted by the lack of patient-reported measures on clinical outcome with a large degree of assessment in the adolescent idiopathic scoliosis population based on radiographic measures.

The initial instrument took approximately 5 min to complete and contained 24 questions. These questions covered seven equally weighted domains: pain, general self-image, post-operative self-image, general function, overall activity level, post-operative function and satisfaction. Reliability was confirmed with a Cronbach's α of over 0.6 for each domain. Test-retest reliability was also confirmed with testing on normal controls.

After concerns regarding test-retest reliability, a modified version was later reported on by Asher et al. having been tested in a cohort of 30 patients who has previously undergone surgery for AIS [60]. The modified version was felt to improve the scope of the instrument but also improve internal consistency. It was comparative to the SF-36 in terms of validity. A single question was later removed due to low internal consistency resulting in the SRS-22, and this version has been well tested for concurrent and discriminatory validity, reliability and responsiveness [61–63].

The latest version SRS-r22 is the result of further minor changes in the function domain [64].

Its utility among adult spinal deformity patients was confirmed by Berven et al. who tested it on 146 patients with scoliosis and 34 without [65]. The SRS-22 had less floor and ceiling effects when compared to the SF-36, and test-retest analysis confirmed a high level of reproducibility – Cronbach's α was over 0.75 for each domain. Bridwell et al. further confirmed its use in the adult population analysing a consecutive series of ASD patients over a 12-month period and comparing the SRS-22 to the SF-12 and ODI [66]. They found the SRS-22 is better equipped to detect change in health status than both the generic measures. Except for pain, each domain retained excellent Cronbach's α scores, and test-retest reliability was excellent. Its responsiveness to change has also been confirmed, particularly in the self-image domain [67]. The reliability and validity of the revised SRS questionnaire have been determined in non-English versions also [68, 69].

Quebec Back Pain Disability Scale

Kopec et al. developed the Quebec Back Pain Disability Scale as a measure of disability secondary to low back pain. As a basis it used the World Health Organizations (WHO) definition of 'disability' as a restriction in performing an important activity. It contains 20 items and utilizes Likert scale responses for each without any breakdown into subscales. It was initially developed across a broad range of subspecialties including family practice and psychiatry as an assessment tool for those with low back pain. A strong positive correlation has been found with the Roland Scale, SF-36 physical function subscale and ODI [49]. It has proven to be a reliable, valid and responsive measure, and its conceptual design linking it with the WHO definition of disability is attractive [49].

No training is required for its use and it takes less than 5 min to complete. No equipment is needed, is considered easy to complete and is available free of charge from the authors.

Test-retest stability was initially thought to be good, with an ICC of 0.89 in subjects who had stable symptoms [47]. Reassessed in a separate study, the ICC dropped to 0.55 in patients who reported no improvement over a 4-week period [70]. Those who were unable to return to employment fared worse than those who were able to return [70]. Kopec et al. also tested the Quebec Back Pain Disability Scale in a cohort of almost 250 patients with back pain over a period of 6 months [48]. Retesting was performed after several days then again after 2–6 months. Test-retest reliability was again high (0.92) and Cronbach's-α was 0.96. Expected changed with time were seen confirming its suitability for detecting change with treatment and the natural evolution of a condition.

Zurich Claudication Questionnaire

This is a self-reported measure that is used most often in clinical trials or studies reporting outcomes for treatment of spinal stenosis. It was first reported as a measure in 1996 to complement existing general health measures [71]. It is also at times referred to as the Swiss Spinal Stenosis Questionnaire. Its validity and test-retest reliability have been confirmed in English and other languages [71–73].

The questionnaire consists of three subscales: symptom severity (seven questions), physical function (five questions) and treatment satisfaction (six questions). Symptom severity scale scores range from 1 to 5, while the remainder range 1–4 with higher scores indicating greater disability or loss of function. All questions relate to the patients perception over the preceding month. The maximum possible score is 79, and the result is typically reported as a percentage of maximum score.

The symptom severity subscale can be broken down into two further sections: a pain domain (questions 1–4) and a neuroischemic domain (5–7). While normally reported in its entirety, the physical function subscale is occasionally reported in isolation. This section asks specifically about walking and activities involving walking and is

considered an excellent tool to measure the outcome following treatments for spinal stenosis.

Recently the questionnaire has been used in a number of studies reporting the outcome for interventions for spinal stenosis [74].

Other Specific Scales

A number of other scoring systems exist both non-specific and specific to the spine. A full review is beyond the scope of this chapter. Other systems one may come across include the Waddell Disability index. This was a concise nine-item scoring system used to determine physical disability as a result of back pain [75]. The Million Visual Analogue Scale (VAS) was also developed and reported on in the early 1980s and contained 15 questions each with their own visual analogue scale [76]. The Low Back Outcome Score was designed for patients with back pain and sued weighted questions about a patient's activities (employment, domestic activity, sporting activity, sex life, daily activity, rest), current pain and use of medical services and medication [77].

Classical Test Theory, Item Response Theory and Computer Adaptive Testing: The Evolution of PRO Tools

Legacy measures in orthopaedics were developed using classical test theory (CTT). CTT was originally described in the early twentieth century by Spearman [78]. It involves two key parameters: validity and reliability. The fundamental principle of CTT is that a person's observed score is equal to the true score plus measurement error [79]. In this case both the observed score and the true score are functions of the total score for a given test. A test is then validated in a given population, and the reliability of the test score is specific to the population in which it was validated.

The major limitation is that CTT presumes that a single standard error applies to the entire spectrum of ability covered by the test. In practice the reliability is variable depending on the level of trait being measured. For example, when measuring function, a given test typically is more reliable to differentiate between mid-range function levels and is less reliable at the very high or very low ends of function. In practice, for a test designed using CTT to thoroughly cover the entire spectrum of a trait, it would have to be prohibitively lengthy. The other issue is that a given test is validated as a whole and cannot be modified without revalidation.

Item response theory (IRT) addresses many of the shortcomings of CTT. IRT was developed in the 1920s based on the works of Thurstone and Lord [80]. IRT employs a statistical approach that describes the probability of an individual to answer a single item correctly as being dependent on the difficulty of the item and the trait level of the individual. To simplify this further, if we apply this theory to a math test, it says that the probability of answering a math question correctly depends on how good the testee is at math as well as how difficult the question is. Each item, or question, is individually validated and can be thought of as a single measure or grouped into a set of items to increase precision and coverage. The psychometric properties of a test as a whole are then the sum of the individual properties of each testing item.

The key advantages of IRT modelling over CTT are closely related to IRT's two invariance properties: (1) The properties of a question, such as its ability to estimate a trait, are not dependant on the specific group of patients taking the test. (2) A patient's trait level, such as level of function or pain, is independent of the specific set of questions chosen out of a pool of validated questions [81, 82]. This leads to a number of advantages over CTT when applied to PROs in healthcare.

First, IRT-derived tests can be developed that evaluate domains of health (i.e. physical function or depression) across many disease states, rather than measures specific to one disease. Second, a given test item is an independent tool with predictable properties and measures the same trait with the same difficulty regardless of which other items accompany it. This allows for customized tests with varying items dependent on the level of

the trait that needs to be evaluated. In addition, items can be added to the upper end or lower end of the trait scale if needed, to improve coverage.

If a total item bank contains questions that vary from low-function-oriented questions such as "Can you ambulate within the house without an assistive device?" to high-function-oriented questions, such as "Can you run five miles?" this ensures that both the low- and high-functioning individuals are covered and can be accurately assessed by the exam. Patients of widely varying abilities still sit along the same trait scale, just at different locations. Furthermore, a test can be customized to the level of the individual, with higher-functioning individuals getting questions that require a higher trait level and allow for more accurate definition of the test taker's trait.

The process of selecting appropriate questions to accurately define a test taker's trait level with minimum number of questions is optimized with computer adaptive testing (CAT). CAT technology utilizes an algorithm to determine which question should follow in a given test based on the response to the prior question(s). For example, if a test taker answers that she can jog 1 mile without difficulty, little additional information will be gained by asking whether she can comfortably ambulate about the household without the use of assistive devices. The test taker's trait level will be better defined if the next question asks whether she can run 5 miles. This results in significantly less burden on the patient and clinic staff by limiting the total number of questions required to define the test taker's trait level. Studies show that IRT-derived PRO tools administered using CAT achieve higher levels of accuracy, better coverage of the population and lower burden with many fewer questions than legacy measures developed using CTT [83, 84].

One of the consequences of increased emphasis on value is the increasing importance, and increased support for, comparative effectiveness research (CER). Part of the 2010 Patient Protection and Affordable Care Act emphasizes that clinical care and clinical research must incorporate the patient perspective [85]. PRO tools allow for quantification of both health states by the patient and subsequent comparison of health states before and at different time points after various interventions.

Increased support of CER sets the stage for developing of PROs that measure domain-specific outcomes such as ability to engage in physical activity, depression and sleep quality. These domains have been demonstrated as important to patients and their perception of treatment success [86]. Domain-specific outcomes rely on the theory that health attributes are not disease specific and that each disease state has a unique profile in terms of impact on different health domains. In order for PROs to be successfully integrated into CER, and into clinical practice, these instruments must be carefully calibrated and critically evaluated whether they are able to successfully measure the domains of interest in a timely and efficient manner.

Patient-Reported Outcomes Measurement Information System (PROMIS)

PROMIS began in 2004 as a National Institutes of Health (NIH)-funded initiative to develop a novel outcome tool that has improved precision, reliability and validity as compared to legacy tools developed using CTT and has applicability across a wide range of disease states [87, 88]. This initiative is part of the 'Roadmap for Clinical Research in the Twenty-First Century' report presented by the director of the NIH in 2002. The project began as collaboration between six primary research sites, a central core of statisticians and several NIH institutes.

Initial work was focused on developing the PROMIS item library by applying IRT methodology and three key protocols: domain mapping, archival data analysis and qualitative data review. The domain mapping protocol involved domain-specific groups that collaborated to define the domain framework for the PROMIS item bank. The ultimate goal of this framework is to have a number of well organized, when appropriate hierarchical, unidimensional domains that together accurately describe a disease state.

Unidimensionality is the ability of a test or question to assess a single trait without influence by confounders, for example, testing physical function without interference from depression. Each domain group contained experts in the domain-related field as well as statisticians.

The domain framework underwent iterative revisions using literature review, data analysis and consensus opinion to move towards the goal of unidimensional categories that accurately define a disease state. The PROMIS Adult health framework contains four general categories: global health, physical health, mental health and social health [89]. Each of those categories has a number of domains and subdomains under it. For example, the physical health item bank is composed of questions from the following five 'profile' domains: physical function, pain intensity, pain interference, fatigue and sleep disturbance.

The archival data analysis and quality item review (QIR) protocols were used to incorporate questions from existing PRO tools into the PROMIS item banks. Questions from pre-existing questionnaires were evaluated and assigned to appropriate domains. Each question underwent extensive psychometric testing via IRT analysis. The QIR protocol carefully examined all questions in each domain and eliminated redundant questions [90]. Large field tests were carried out using IRT methods to calibrate the item bank to the general US population.

The domain-driven approach taken by PROMIS for its item banks is a departure from the disease-specific approach of legacy PRO tools. Domains are unidimensional health attributes, based on the World Health Organization (WHO) domains of health, and the domain-specific approach functions under the assumption that each domain is not unique to a disease. This approach allows for comparison of outcomes between disease states, in patients with various combinations of diseases. The domain-specific approach taken by PROMIS particularly lends itself to comparative effectiveness research [19, 91]. It also may be helpful at the level of individual patient care, for adding an objective measure to the discussion of how the patient is doing with treatment, and may lead to effective shared decision-making.

PROMIS has an ever-expanding number of item banks – currently there are 52 available item banks across the three general domains of mental health, physical health and social health. The physical health domain is perhaps the most helpful domain for spine patient assessment. Under this category, a number of item banks can be useful including physical function, pain interference, pain behaviour and sleep disturbance. Physical function with mobility aids item bank may be particularly useful for older patients that have a lower level of function and use assistive devices for ambulation.

Within the mental health domain, the depression and anxiety item banks offer relevant options. The social health domain offers interesting potential for better understanding spine patients, but has not been looked at yet in this specific population. The 'Ability to Participate in Social Roles and Activities' and 'Satisfaction with Social Roles and Activities' item banks may be particularly applicable to the spine patient population and are worthy of further investigation.

The psychometric properties of the physical function PROMIS item bank have been compared to legacy measures in a number of orthopaedic specialties. PROMIS has been shown to correlate highly with the QuickDASH score in upper extremity but take significantly less time to complete [92, 93]. Tyser et al. found that PROMIS outperformed the QuickDASH in terms of floor and ceiling effects [83]. In the upper extremity, PROMIS was also compared to Constant score, and the Short Musculoskeletal Functional Assessment (SMFA), and was found to correlate highly with all legacy measures while requiring less time to administer [94]. PROMIS outperforms the SMFA in terms of ceiling effect in the trauma population with SMFA ceiling effect of 14 % compared to no measurable ceiling effect for PROMIS [84].

The foot and ankle literature also contains comparisons between PROMIS physical function item bank and legacy measures. PROMIS has better reliability comparing to the Foot and Ankle Ability Measure – Activity of Daily Living (FAAM-ADL) subscale and the Foot Function Index five-point verbal rating scale (FFI-5 pt) and requires less time to administer [95]. PROMIS lower extremity item bank has a better floor and ceiling effect than both the FAAM_ADL and the FFI [96].

The majority of research on PROMIS in the spine literature has also been specific to the physical function (PF) item bank. PROMIS PF CAT has been demonstrated to have impressive ceiling (1.7 %) and floor (0.2 %) effects in a large population of spine patients with diverse range of conditions [97]. Analysis of the Oswestry Disability Index (ODI) in a similar population of spine patients reveals that while it has good reliability (person reliability 0.85, item reliability 1), it has a significant floor effect (29.9 %) and a modest ceiling effect (3.9 %) [98].

Similar findings are seen with analysis of the Neck Disability Index (NDI) with a large floor effect (35.5 %) and significant ceiling effect (4.6 %) [99]. The NDI has other psychometric flaws. It exhibits poor unidimensionality; the unexplained variance of the NDI was 9.4 %. It also has an extremely poor raw score to measure correlation, suggesting that while the scores are ordinal, they are not interval (the distance of between five points at one part of the scale is not the same as the distance between five points at another part of the scale), problematic when discussing MCID or using standard parametric statistics.

Lastly, when contemplating using a new measure, it is important to know if older data can still be used or compared. Score conversion is an important element of the PROMIS system with crosswalk or linking tables developed to convert common general outcome scores to PROMIS measures (http://www.prosettastone.org). Working on correlation of disease-specific measures in the spine, Brodke et al. found that SF-36 and ODI scores can be accurately predicted with the PROMIS PF CAT, allowing for development of linking tables [100].

The Road Ahead: Future Directions of Patient-Reported Outcomes

The next step in the development and utilization of outcomes scores, and PROMIS in particular, is application across the clinical and research settings. There has also been a shift in emphasis from tracking strictly biologic outcomes in clinical trials to tracking more subjective outcomes that patients have identified as important [86]. Patient-reported outcomes are ideally poised to measure the health domains important to patients themselves.

Now, in some settings, patients can fill out PRO measures at home, as well. This creates the possibility of capturing more frequent data points and long-term data points, as well as to collect information prior to the office visit in order to use the data provided by the patient to guide the visit. One of the significant hurdles to meaningful integration of PRO tools into patient care is that while PROs are currently being collected at an increasing rate, data is lacking to support a significant impact on patient care or outcomes [77].

The next step in evolution of PRO tools is to incorporate them into clinical practice. PRO data has the potential to facilitate patient-centred outcome-driven care by providing outcome data to guide informed decision-making both by the patient and the physician. As applications become available that ease the process of viewing aggregated data, physicians can show patients the expected outcomes after various surgical and nonoperative intervention and how a patient is doing compared to their expected

$$\text{Value} = \frac{\text{Health outcomes}}{\text{Costs of delivering the outcomes}}$$

Fig. 4.1 Definition of value

course. This technology will ideally improve patient-physician communication and provide ample evidence on which to base clinical decision-making (Fig. 4.1).

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5 Impact of Depression on the Treatment of Adult Lumbar Scoliosis

Joshua Bunch and Douglas Burton

Introduction

The lifetime prevalence of major depressive episodes is 14.6 % among adults from high-income countries according to a large cross-national study [1]. Women are nearly twice as likely to have major depressive episodes compared to men. Among developed countries, a significant undertreatment of mental disorders exists compared to physical disorders [2]. These findings are important to consider when evaluating patients in a surgical spine practice. In this chapter, we will review the prevalence of depression and depressive symptoms in a spinal deformity population. We will discuss the tools used to identify depression and present studies that evaluate the effect of depression on the results of surgical treatment of lumbar deformity patients.

Prevalence

The prevalence of depression among spine patients undergoing operative treatment has been reported between 4.5 and 34 % [3–6]. An analysis of the National Hospital Discharge Survey database found the rate of depression to be 4.5 % among patients undergoing primary spinal fusion or laminectomy with associated rates of anxiety (2.5 %,), schizophrenia (0.2 %), and dementia (2 %) [3]. A study of 232 patients undergoing lumbar spinal fusion found 34 % of the patients had depressive symptoms preoperatively as defined by a Depression Scale score of 12 or greater with a higher rate in females (37 %) compared to males (27 %) [6]. Miller et al. reported a 19.5 % prevalence of moderate or severe depression among 919 patients undergoing lumbar decompression or fusion [4]. Moderate or severe depression was defined as a Patient Health Questionnaire 9 (PHQ-9) score greater than 14.

Sinikallio et al. found a 20 % prevalence of depression in a population of 100 patients undergoing decompression surgery for lumbar spinal stenosis [5]. At 1-year follow-up, the prevalence of depression among the same population was unchanged at 18 %.

In a study recently submitted for publication, the prevalence of low SF-36 Mental Component Summary scores among surgically treated adult spinal deformity patients with low physical health was 39.4 % [7]. Conversely, only 15.2 % of the same adult spinal deformity patients with low physical health had Mental Component Summary scores greater than or equal to the 75th percentile for age- and sex-matched US population norms.

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Screening Tools/Questionnaires: Distress and Risk Assessment Method (DRAM), SRS Mental Health Score, SF-36, Zung, PHQ-9, BDI

The Distress and Risk Assessment Method (DRAM) was originally described by Main et al. and categorizes patients into four groups including normal, at-risk, distressed-depressive, and distressed-somatic groups [8]. The assessment tool is a combination of two other questionnaires, the modified Zung Depression Index and the Modified Somatic Perception Questionnaire (MSPQ). The DRAM was originally designed as a first stage screening assessment. The original article defined the cutoff points for each category as follows: normal, modified Zung score less than 17; at risk, modified Zung score 17–33 and MSPQ less than 12; distressed depressive, modified Zung score greater than 33; and distressed somatic, modified Zung score 17–33 and MSPQ greater than 12.

The SF-36 is a short-form health survey with 36 questions [9]. It is a generic measure and does not target a specific disease, age, or treatment group. The SF-36 provides an eight-scale profile of functional health and well-being in addition to physical and mental health summary measures as shown in Fig. 5.1. SF-36 may be administered to individuals 14 years of age and older in a number of manners including self-administration, computerized administration, or administration by a trained interviewer in person or by telephone.

The Zung Depression Scale is a 20-item questionnaire that rates four depression characteristics including the pervasive effect, physiological equivalents, psychomotor activities, and other disturbances [10, 11]. Scores range from 20 (no depression) to 80 (major depression) [10]. A score greater than 49 indicates significant depressive symptoms [10].

PHQ-9 is a self-administered assessment for depression [12]. It evaluates the nine DSM-IV criteria for major depressive disorder. The assessment includes nine questions, each of which is scored from 0 to 3 for a total score ranging from 0 to 27. The total score is commonly divided into five categories: minimal depression (score 0–4),

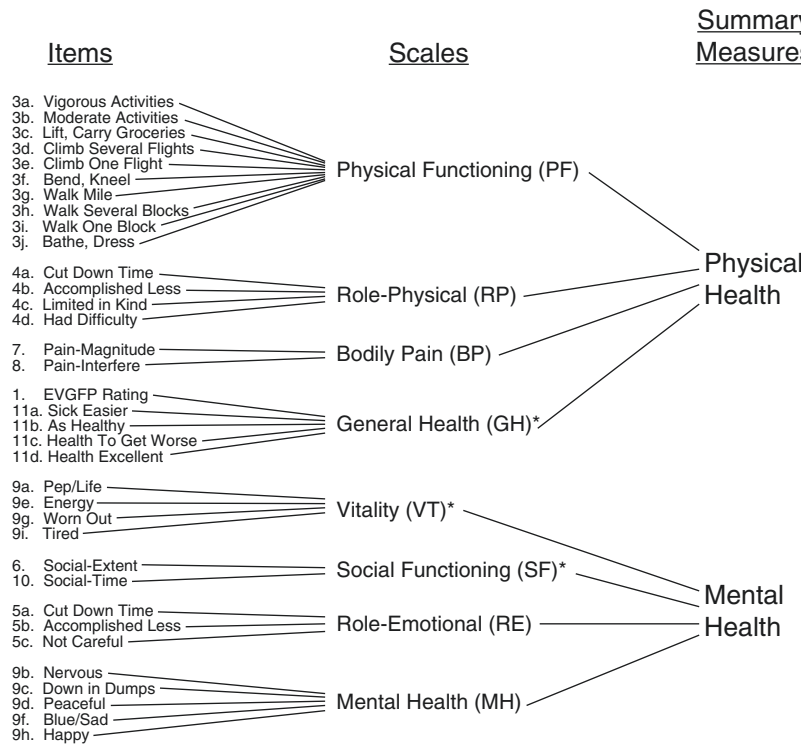

Fig. 5.1 Items, subscales, and summary measures of the SF-36 [9]

mild depression (score 5–9), moderate depression (score 10–14), moderate-severe depression (score 15–19), and severe depression (score 20–27).

The BDI was developed in 1961 by Beck et al. [13]. It is a 21-item questionnaire with each question scored from 0 to 3 with a total score of 0–63. The cutoff point for depression in recent spine literature has varied slightly among studies. Cutoff points have included 9/10 and 14/15 with values greater than or equal to 10 and 15, respectively, indicating depression [5, 14].

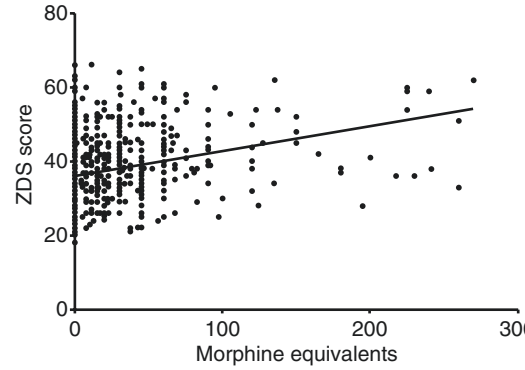

Fig. 5.2 Changing Zung Depression Scale score with increasing preoperative narcotic use [15]

Demographics and Associated Conditions

Depression and other mental health disorders in spinal surgery patients have been associated with other comorbidities and patient characteristics. Among those individuals undergoing primary spinal fusions or laminectomies, females comprised over two-thirds the individuals with depression [3]. In this same study, which included an estimated 5,382,343 discharges following these procedures, 60 % of those patients with depression, anxiety, schizophrenia, or dementia had additional comorbidities, including hypertensive disease (27 %), chronic pulmonary disease (8.7 %), and diabetes mellitus (8.2 %). In an analysis of 232 patients undergoing lumbar spinal fusions, those with depressive symptoms reported a significantly higher rate of back pain compared to those without depressive symptoms, but no significant difference was found with regard to leg pain among the two groups [6].

A study of 264 surgically treated adult spinal deformity patients found those with low mental health (SF-36 Mental Component Summary scores less than or equal to the 25th percentile) had significantly higher BMIs compared to patients with high mental health (SF-36 Mental Component Summary scores greater than or equal to the 75th percentile) [7]. Additionally, the patients in the low mental health group had significantly higher rates of leg weakness, hypertension, and neurologic diseases. There was also an increased rate of unemployed, disabled, or retired individuals due to back pain in the low mental health group.

Opioid use has been shown to be associated with both increasing depressive symptoms and diminished outcomes in spine surgery patients. Among 583 patients undergoing spine surgery, those categorized as depressed based on a Zung Depression Scale score of 33 or more were found to have a statistically significant increase in preoperative narcotic use compared to those patients who were not depressed [15]. Additionally, as preoperative morphine equivalents increased, so did the Zung Depression Scale score (Fig. 5.2). In a study based on the same prospective cohort, increased preoperative opioid use was found to be a significant predictor of decreased patient outcomes at 3 and 12 months postoperatively based on decreased 12-Item Short-Form Health Survey and EuroQol-5D scores and increased Oswestry Disability Index and Neck Disability Index scores [16].

Treatment of Depression in the Surgical Patient

Despite the high prevalence of depression and depressive symptoms in spine surgery patients, many patients go untreated. In the prospective cohort of surgically treated spinal stenosis patients followed by Sinikallio et al., 64.7 % of those patients depressed at 1-year follow-up were also depressed preoperatively [5]. Only 3 of 11

patients with depression were reported to have used antidepressant medication at 1-year follow-up [5]. In an additional study by Sinikallio et al., the authors divided the study population of surgically treated patients into a misery group and non-misery group [17]. The misery group was comprised of patients with elevated pain ratings (based on VAS values) and depression (based on BDI scores) at 3 months postoperatively. 24 of the 93 patients were assigned to the misery group. At 1-year follow-up, only three patients reported use of an antidepressant, none of which were in the misery group. At 2-year follow-up, seven patients reported use of an antidepressant, and only two of these patients were in the misery group.

Interestingly, in a prospective study of 96 patients undergoing surgery for lumbar spinal stenosis, patients who had depression at baseline, but recovered from depression by follow-up at 2 years, demonstrated similar improvements compared to the group of patients without depression throughout the study [14]. Similar findings were seen for the same study population when examined at 3 months postoperatively [18].

Effect of Poor Mental Health on Surgical Outcomes

There are numerous studies that link poor mental health with inferior outcomes in spinal surgery. Again, Sinikallio et al. followed a group of patients treated surgically for lumbar spinal stenosis [5, 14]. One-year follow-up data showed an independent association between higher preoperative BDI and depressive burden (sum of preoperative and 3-month BDI scores) scores and multiple outcomes at 1 year including worse functional ability, symptom severity, and walking capacity [5]. The high depressive burden was predictive of all outcome variables at 1-year follow-up including greater pain, symptom severity, disability, and poorer walking capacity. At 2-year follow-up, the authors found those patients with continuous depression to have worse improvement in symptom severity, disability score, and walking capacity compared to those patients without depression at any phase [14]. High preoperative BDI scores (increasing depressive symptoms) were independently associated with disability and symptom severity at 2-year follow-up. In another study utilizing the BDI, life satisfaction in patients surgically treated for lumbar spinal stenosis was reported out to a 2-year follow-up in a study of 100 patients [19]. The depression burden (sum of BDI scores preoperatively at 3 and 6 months) and a high depressive burden variable (depression burden greater than or equal to 20) were both independently associated with life dissatisfaction at 2 years postoperatively.

In a prospective study of 96 patients undergoing surgery for lumbar spinal stenosis, high preoperative BDI scores were associated with 2-year disability (as measured by ODI score) and symptom severity (based on the Stucki Questionnaire) [14]. Those patients with continuous depression showed less improvement in symptom severity, disability, and walking capacity compared to those with no depression throughout the study. Hasenbring et al. followed 111 patients with symptomatic lumbar disc prolapse or protrusion who were treated both operatively and nonoperatively [20]. Psychological variables including depression as measured by the BDI were found to be predictive of persistent pain as well as application for early retirement at 6 months following hospital discharge. A prospective observational study of patients undergoing surgical treatment for lumbar spinal stenosis demonstrated an association between high depressive burden and poorer functional ability as measured by ODI scores at 5 years postoperative [21]. Depressive burden was calculated by summing individual BDI scores across all observation points in this study. Although the above association exists, both low depressive burden and high depressive burden groups showed improvement in walking distance and ODI scores from preoperative values.

In a retrospective cohort study, Adogwa et al. found the Zung Depression Scale to be predictive of outcome in patients undergoing revision lumbar surgery for symptomatic adjacent segment disease, pseudarthrosis, and same-level recurrent disease

[10]. Those patients with preoperative Zung depression scores in the top quartile (most depressed) reported significantly less improvement in disability as measured by the Oswestry Disability Index (ODI) at 2 years postoperatively compared to those patients with preoperative Zung depression scores in the bottom quartile (least depressed). The same authors found the Zung Depression Scale was predictive of patient satisfaction at 2 years following revision lumbar decompression and fusion [22]. They reported a decrease in patient satisfaction with increasing Zung depression scores despite improvement in all other outcome measures at 2 years. For those patients scoring in the bottom quartile (least depressed), the overall satisfaction rate was 94 % compared with only a 6 % satisfaction rate at 2 years for patients scoring in the top quartile (Fig. 5.3).

Among patients undergoing a single-level lumbar discectomy, those with increasing preoperative depression (based on the Zung Depression Scale) were found at 12 months postoperatively to have less likelihood of achieving the minimum clinical important difference for disability and quality of life as measured by the ODI and SF-36 Physical Component Summary scores, respectively [23]. There was also less likelihood of achieving the minimum clinical important difference for disability and quality of life at 12 months postoperatively in those patients with increasing preoperative somatic anxiety as measured by the Modified Somatic Perception Questionnaire (MSPQ).

In an analysis of 14,939 patients who underwent instrumented spine surgery, Akins et al. determined depression to be an independent risk factor for readmission within 30 days [24]. After multivariate logistic regression analysis, the odds ratio for depression was found to be 1.48.

Baseline depression was found to be associated with more pain postoperatively at 6 months

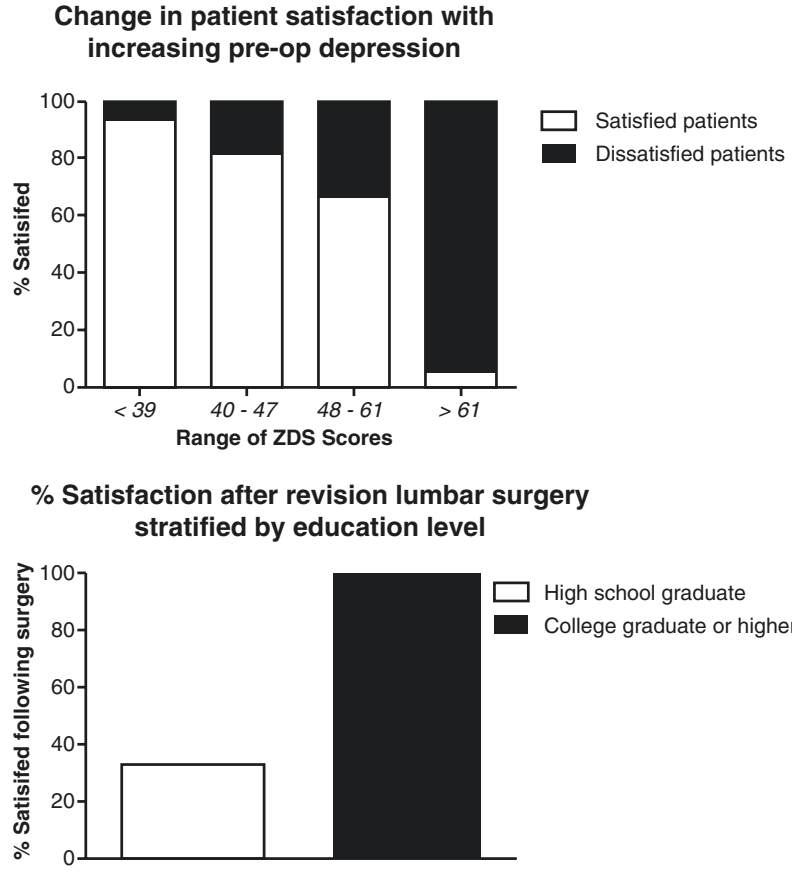

Fig. 5.3 Zung depression scores predictive of patient satisfaction in revision lumbar decompression and fusion [22]

according to a systematic review by Aalto et al. [25]. Additionally, depression was associated with poorer treatment satisfaction and more severe symptoms.

Menendez et al. conducted a large analysis of the National Hospital Discharge Survey database [3]. Perioperative outcomes among individuals undergoing primary spinal fusions or laminectomies were assessed in relation to the presence of certain psychiatric diagnoses (depression, anxiety, schizophrenia, and dementia). Higher rates of adverse events were seen in those individuals with schizophrenia and dementia compared to those patients without psychiatric comorbidity. The rate of adverse events was similar among those with depression, anxiety, and no psychiatric comorbidity. Dementia was the only psychiatric disorder associated with a higher in-hospital mortality rate (3.2 % in those with dementia versus 0.4 % in those without a mental disorder).

Smith et al. assessed two groups of adults (younger, 18–45; older, 46–85) who underwent surgery for adult scoliosis [26]. Each age group of adults was further stratified into groups with the best and worst outcomes at 2 years postoperatively based on ODI and SRS-22r values. Among both the younger and older adult groups, depression/anxiety was found to be a predictor of poor outcome. Additional predictors of poor outcome in both groups included narcotic medication use and greater BMI. In a similarly designed study, the International Spine Study Group examined 227 patients with adult spinal deformity who were treated operatively [27]. The authors in this study again created best and worst outcome groups based on SRS-22r and ODI values at 2-year follow-up. Compared to the groups with the best outcomes, the worst outcome groups had higher prevalence of baseline depression, more comorbidities, increased BMI, greater baseline disability, higher complication rate, and greater SVA at 2-year follow-up.

Silverplats et al. assessed factors associated with outcome after lumbar discectomy in 171 patients [28]. Follow-up time points were 2 years and a long-term time point (mean of 7.3 years). Baseline depression as measured by the Zung Depression Scale was not found to be predictive of patient satisfaction or objective outcome at either the 2-year or long-term follow-up. Baseline depression was found to be predictive of improved VAS back pain at 2-year follow-up.

DRAM and Zung Depression Scale both were found to be predictive in a prospective study of 102 patients undergoing lumbar surgery [29]. Patients were assessed at 6 months and 1 year postoperatively. Preoperative depression as measured by the Zung Depression Scale was found to be predictive of failure to return to work, less improvement in back and leg pain, and failure to report improved functional abilities. Preoperative DRAM was predictive of work status, change in back and leg pain, and functional disability.

Among 919 patients undergoing lumbar decompression or fusion, depression as measured by PHQ-9 scores was found to be significantly associated with worsening postoperative improvement in quality of life as measured by the EuroQol five-dimension (EQ-5D) assessment [4]. Additionally, preoperative PHQ-9 was found to be a significant predictor of decreased postoperative quality of life improvements exceeding the minimum clinically important difference for EQ-5D (reported to be 0.1).

Levy et al. assessed 6679 patients with lumbar spinal stenosis and lumbar disc herniations to determine the impact of a three-question depression screener [30]. Individuals with a positive depression screener reported longer duration of symptoms (>7 weeks) and failure to improve. Positive depression screeners had higher rates of obesity, workers' compensation involvement, and lower SF-36 scores on all subscales compared to those with a negative depression screener.An observational study of 3482 patients was conducted by Slover et al. [31]. The authors found decreasing improvements in bodily pain, physical function, Physical Component Summary scores of the SF-36, and ODI scores with increasing number of comorbidities following lumbar spine surgery. Additionally, depression was found to have a negative effect on the improvement of ODI and Physical Component Summary scores at 3 months postoperatively.

In an analysis of 507 patients with sciatica, less depression and anxiety as measured by the

SF-36 mental health subscale were found to be predictive of lower sciatica symptom frequency, less pain, and better physical function [32]. In a study of 264 surgically treated adult spinal deformity patients with low physical health as defined by SF-36 Physical Component scores, patients with low mental health (SF-36 Mental Component Summary scores less than or equal to the 25th percentile) had significantly greater improvements in SF-36 Mental Component Summary scores and SRS Mental scores at 2 years postoperatively than patients with high mental health (SF-36 Mental Component Summary scores greater than or equal to the 75th percentile) [7]. Interestingly, the patients in the high mental health group had significantly larger improvements in Physical Component Summary scores, SRS satisfaction scores, and back pain scores at 2 years postoperatively compared with the low mental health group. Additionally, having low mental health was an independent predictor for failure to reach the Physical Component Summary and SRS Activity MCID values.

Abtahi et al. assessed 103 patients presenting to a spine center for outpatient clinical encounters to determine the association between the presence of psychological distress and patient satisfaction scores [33]. The authors found a significant decrease in overall patient satisfaction and satisfaction with their provider (based on the Press Ganey Medical Practice Survey) among those patients who were psychologically distressed (distressed-depressive and distressed-somatic DRAM groups) compared to those patients in the normal or less distressed groups (normal and at-risk DRAM groups).

Not all studies, however, have shown uniformly decreased results in patients with depressive symptoms. Wahlman et al. found a 34 % rate of preoperative depressive symptoms in an analysis of 232 patients undergoing instrumented lumbar spinal fusion [6]. Rates of depressive symptoms improved to 13 and 15 % at 3 months and 1 year postoperatively. The authors found that both the patients with and without depressive symptoms showed improvements in back and leg pain postoperatively and there was no significant difference in the amount of improvement seen between these two groups. This may indicate that some of the depressive symptoms are linked to the spinal pathology and that by eliminating or decreasing the organic lesion, the depressive symptoms can by decreased as well.

Patients were grouped based on the presence or absence of depression (based on a BDI score of 10 or greater) preoperatively in a study of 58 patients undergoing surgical treatment for lumbar spinal stenosis [34]. Depression was alleviated in 14 of 29 patients at 12 months postoperatively. Compared to the 43 patients without depression postoperatively, the 15 patients with persistent depression showed poorer clinical outcomes at 12 months postoperatively including increased severe back pain, severe leg pain, and severe disability. Additionally, only 33 % of those with persistent depression symptoms postoperatively indicated "surgery helped a lot," whereas 76 % of patients without depression symptoms selected this choice.

Preoperative psychological disturbance as measured by the Zung Depression Scale and Modified Somatic Perception Questionnaire was not found to be predictive of outcome in a study of 148 individuals undergoing lumbar decompression surgery [35]. However, those individuals who had a good outcome 12 months postoperatively had a significant improvement in the psychological disturbance score compared to those individuals with a poor outcome (Fig. 5.4).

In a systematic review, McKillop et al. found preoperative depression to be a likely prognostic factor for postoperative lumbar spinal stenosis-related symptom severity and disability, but found the prognostic value of depression to be less clear regarding the outcomes of pain and walking capacity [36]. Another systematic review of the literature regarding patients undergoing lumbar surgery identified preoperative somatization, depression, anxiety, poor coping, and increased pain duration as factors associated with poor response to lumbar surgery [37].

The vast majority of the literature indicates that preoperative depression is a risk factor for a diminished outcome. However, many studies also show that improvement of these preoperative symptoms can lead to satisfactory outcomes

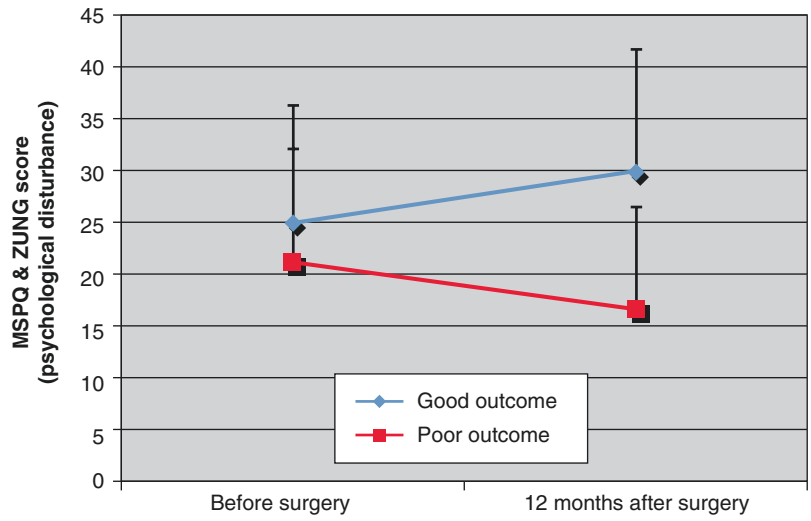

Fig. 5.4 Psychological disturbance in patients' rating outcome as good and poor following lumbar decompression surgery [35]

postoperatively. These studies do not make clear whether this improvement is due to diminution of the physical symptoms of pain from the surgery itself or due to concomitant treatment of the underlying mental health disorder.

Role for Screening and Diagnosis

Given the plethora of studies that suggest a link between depression and poor outcomes, it seems logical that presurgical screening is common. However in a study of 110 spine surgeons, Young et al. found only a 37 % rate of routine presurgical psychological screening [38]. The use of presurgical psychological screening was highest among those surgeons without university affiliation, more experience, and higher annual volume. One limitation to the study was the predominance of respondents who were affiliated with a university (76 of 110, 69.1 %).

Many surgeons believe they can identify these "at-risk" patients based on clinical intuition. This hypothesis was tested in a study of 400 patients presenting for initial clinical evaluation by spine specialists. This study found spine surgeons perform poorly in identifying patients who are highly distressed (as defined by the DRAM categories of distressed depressive and distressed somatic) based on clinical impression [39]. Results for spine surgeons included only a 19.6 % sensitivity in identifying patients correctly in the highly distressed categories (distressed depressive and distressed somatic).

There may be surrogates for identifying these patients based on commonly collected information (not using specific screening tools). Daubs et al. performed a retrospective study of 388 consecutive patients to determine the clinical factors predictive of psychological distress among patients presenting for evaluation of a spinal disorder [40]. Patients with high psychological distress (distressed depressive and distressed somatic) as measured by the Distress and Risk Assessment Method (DRAM) were found to have a visual analog scale (VAS) score greater than 7, be taking antidepressants or other psychotropic medications, have an Oswestry Disability Index (ODI) score greater than 58, and have a history of surgery. This model was 89.8 % sensitive and 99.4 % specific for predicting individuals classified as distressed depressive and distressed somatic by DRAM.

In a prospective cohort study, Choi et al. attempted to identify the best screening test for depression among patients with chronic spinal disorder [41]. The authors used the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV Axis I Disorders (SCID-I) as the gold standard for diagnosing major depressive disorder (MDD). The Beck Depression Inventory (BDI), Hamilton Rating Scale for Depression (HRSD), and Nine-

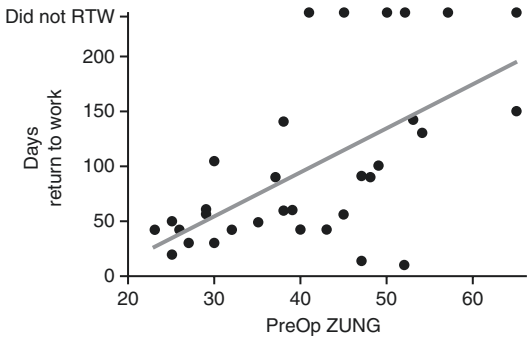

Fig. 5.5 Relation of time to return to work as a function of preoperative Zung Depression Scale scores [42]

Item Patient Health Questionnaire (PHQ-9) performed similarly in their ability to distinguish between depressed and nondepressed individuals. Each of these measures outperformed the Short Form 36 (SF-36) in this study.

Parker et al. examined the effect of preoperative Zung Depression Scale scores on time to return to work among 58 patients undergoing transforaminal interbody fusion (TLIF) for degenerative spondylolisthesis [42]. After controlling for patient age as well as preoperative and postoperative pain (VAS), disability (ODI), and quality of life (EQ-5D), the authors found increased preoperative Zung Depression Scale scores to be significantly associated with a prolonged time to return to work (Fig. 5.5).

Conclusion

The treatment of adult spinal deformity remains a challenge despite multiple advances in the past two decades. As our care of these patients continues to focus on improving outcomes and delivering safe and compassionate care, we must better evaluate the mental health of this population. In our effort to make these surgeries more effective, we should evaluate the patients' mental health just as we do their cardiac and pulmonary systems. We should seek to improve their mental readiness for surgery just as we counsel in nicotine cessation, weight loss, and treatment of bone density prior to performing these surgeries. This complete approach to the patient will be necessary to continue to improve our outcomes and add value to our surgeries.

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Preoperative Clinical Evaluation of Adult Lumbar Scoliosis

6

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Introduction

Complication rates for complex adult lumbar scoliosis surgery are high. Complication rates reported in the literature range from 25 to 80 % [1]. Intraoperative adverse event rates reported in the literature for general spine surgery reach 10 % [2–8]. Complex spine surgery to correct adult lumbar scoliosis is high risk and is often morbid in nature [9–12].

Complications can be divided into three categories: (1) intraoperative, (2) short term (within the first 90 days postoperative), and (3) long term (greater than 90 days postoperative). Preventable intraoperative complications include severe blood loss, surgeon error or misjudgment, coagulopathy, and hypotensive sequelae [13]. Short-term complications include local or systemic infection, thromboembolism, poor wound healing, implant-related problems with neurologic sequelae, continued postoperative pain requiring reoperation, and complications arising from comorbid conditions. Long-term complications include pseudarthrosis, latent infection, implant fatigue and failure, and proximal and distal junctional failures [14–18].

Standardized protocols encompassing a comprehensive set of perioperative processes have been shown to significantly reduce the likelihood of a spectrum of complications within each time period in complex adult lumbar scoliosis surgery [13]. These systematic protocols bring together risk management strategies that were designed to target specific complications individually [14, 19–21].

To increase patient safety and reduce risk, a trained and dedicated team should care for the adult lumbar scoliosis patient from their preoperative state through to their recovery. Many domains of expertise and differing care management processes are required to increase the likelihood of positive patient outcomes. The recently published full-spectrum, system-focused Seattle Spine Team Protocol (SSTP) approach to managing adult lumbar scoliosis patients centered on: (1) A live multidisciplinary preoperative complex spine conference to assess whether surgery was appropriate on a case-by-case basis and coordinate care from the preoperative state through discharge. (2) A collaborative intraoperative surgical team focused on increasing efficiency and reducing error through the use of two attending co-surgeons and a specialized complex spine surgery anesthesia team. (3) A rigorous intraoperative protocol to monitor and treat coagulopathy and blood loss [13]. This systemic three-pronged

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approach to risk management addresses all standard complication domains described. Effective preoperative evaluation and management forms a core component of these full-spectrum protocols and contributes greatly to assessing and managing risk, reducing complication rates, and improving patient safety and outcomes.

This chapter describes preoperative patient evaluation in adult lumbar scoliosis surgery. Areas of focus include (1) the appropriate management of medical conditions; (2) the role, composition, and activities of the multidisciplinary team; and (3) considerations for the management of osteoporosis. Patient evaluation approaches and processes are scientifically supported by the evidence-based Seattle Spine Team Protocol and the research literature.

Management of Medical Conditions

We propose that a range of medical specialties must be involved in the preoperative patient evaluation process. These clinical groups should include anesthesiologists, neurosurgeons, orthopedic surgeons, neurologists, intensivists, internists, and cardiologists. The attending complex spine anesthesiologist for each patient should be closely involved early in the process. The anesthesiologist provides an initial early overview of the patient's medical record and proposes any early medical evaluations that may be required prior to clearance for surgery. These evaluations typically include pulmonary and cardiac consultations. The results of these consultations form an integral part of subsequent decision-making processes and are often primary topics of discussion at the preoperative conference.

All patients referred to the Seattle surgical spine clinic with a diagnosis of adult lumbar scoliosis undergo a thorough history and comprehensive physical examination. This first step in the patient review process includes an assessment of the patient's functional status. The patient's mobility is assessed along with their ability to conduct daily living activities. Their pain status is assessed by visual analog score (VAS), and their current pain medication regimen is noted. Patients are required to complete an Oswestry Disability Index (ODI) and a European Quality of Life-5 Dimensions (EQ-5D) questionnaire at this stage. The patient's smoking history is elucidated, along with their current smoking status, which is recorded by volume and frequency. If a patient is found to be a smoker, surgery is delayed until they have stopped smoking. This is confirmed with a urine nicotine test 1 week prior to the proposed potential surgery date. Their current medication list is recorded as well as any significant comorbidities. The cardiac, pulmonary, and hemostatic systems are assessed for pertinent and potential comorbidities by direct questioning and review of the medical record.

A standard set of preoperative studies are obtained for all patients. These studies include 36-inch (91.4 cm) standing anteroposterior and lateral spine films and a dedicated lumbar spine X-ray including flexion-extension views. Magnetic resonance imaging of the lumbar spine is obtained for patients with symptoms of neurogenic claudication or radiculopathy. These X-rays and MRI scans are carefully assessed in conjunction with the information gathered in the thorough history-taking and physical examination process to determine whether a patient would be likely to benefit from surgical intervention.

Thorough preoperative radiographic evaluation includes measurements of sagittal and coronal balance, pelvic parameters, and Cobb angles of major and minor curves [22]. These measurements in conjunction with the patient's history suggest potential surgical procedures that are most likely to alleviate the patient's symptoms and improve their functional status. Refinement of the potential surgical procedure is based on a discussion held between multiple (at least two) senior surgeons, typically at least one neurosurgeon and at least one orthopedic surgeon. The semi-structured discussion and proposed surgical procedure include consideration of all data collected and are based on their combined expertise and experience. This discussion then results in the formulation of a feasible, effective, safe, and bespoke surgical strategy. A computed tomography scan of the spine and a dual-energy X-ray absorptiometry (DEXA) scan are also ordered for potential operative patients [19, 23, 24]. After presentation at the multidisciplinary conference, any further recommendations of the medical specialists that arose during the conference discussion are acted upon prior to scheduling of the surgical case. Figure 6.1 links the preoperative medical evaluation processes with the main risks it aims to reduce.

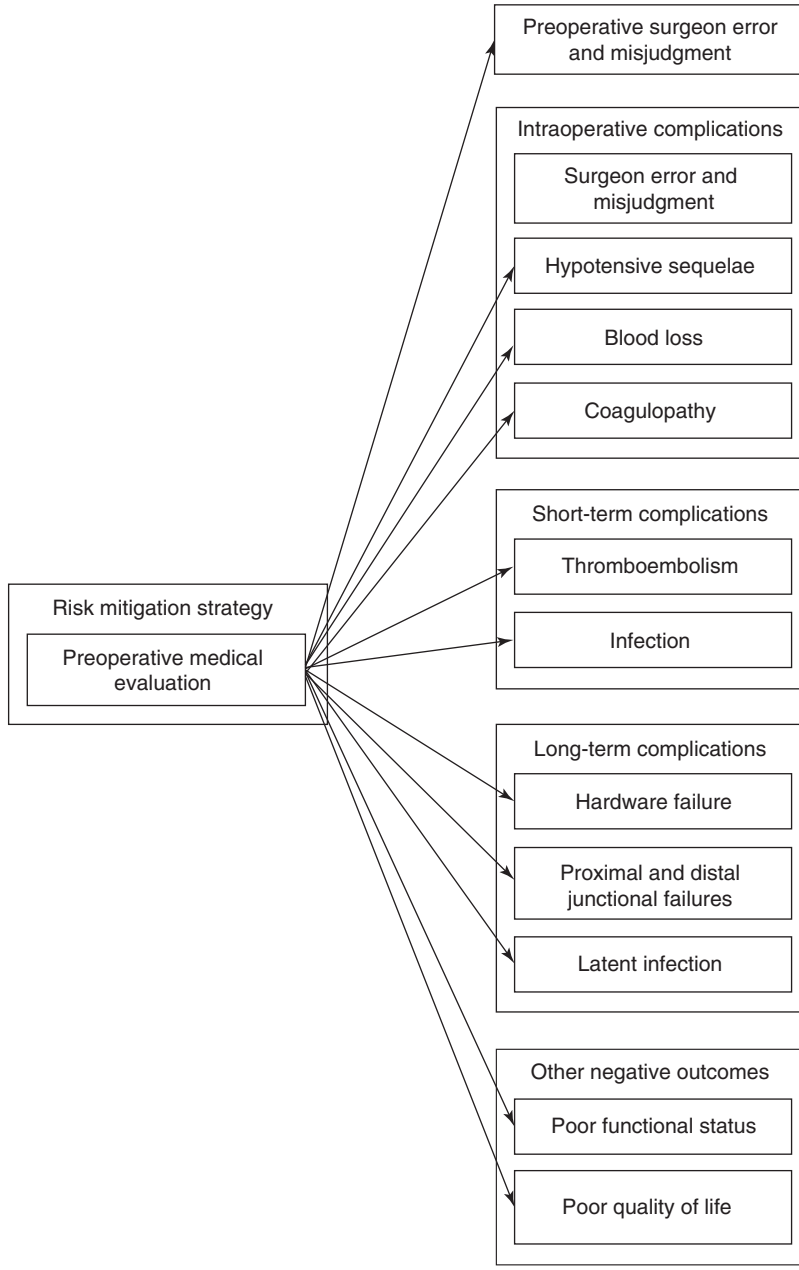

Fig. 6.1 Risks mitigated by the preoperative medical evaluation processes of the SSTP

The Multidisciplinary Spine Team Conference

The SSTP calls for a live, in-person preoperative multidisciplinary evaluation and discussion of all complex spine patients [13]. This comprehensive multidisciplinary medical review and consultation is aimed at ensuring that the patient receives optimal treatment, whether surgical or nonoperative. The discussion is focused on the potential risk of complications and the steps to mitigate these risks should spine surgery be deemed necessary.

Once a patient has been deemed as a potential operative candidate for the correction of a major lumbar kyphoscoliotic deformity based on the

surgical evaluation, their case progresses to the multidisciplinary review conference. These conferences are conducted on a monthly basis. These conferences involve representatives from many medical and allied health specialties, including cardiologists, physiatrists, specialized complex spine anesthesiologists, neurologists, intensivists, internists, neurosurgeons, and orthopedic surgeons. Allied health specialists involved in the conferences include physiotherapists, nurses, physician's assistants, and clinical researchers. At least two members of the dedicated complex spine anesthesiology team play an integral role in the review of each case. The spine clinic nurses who coordinate the preoperative complex spine patient education class are also in attendance.

The anesthesiologists and an internist review each patient's history and medical issues before the conference. A written summary of the patient's past medical history, their spine clinic evaluation summary note, relevant laboratory values, and screening tests (electrocardiogram, echocardiogram, etc.) is then generated and sent to the conference participants a week prior to the conference date for review.

For each patient, discussion focuses on both the proposed surgical correction, the correction process, and the preoperative and postoperative medical issues relevant to the patient. One hallmark of the conference discussion is that both non-surgeon members (e.g., internal medicine, anesthesia) and surgeon members of the committee have equal power to decide the suitability of a case for surgery. The views of all attendees are taken into account and seriously considered.

This "equal voice" setup differs from traditional approaches taken at other institutions. It has been our experience that in most academic institutions and spine surgery practices, the surgeons wield the primary decision-making power. They are the ones who, often without involvement of other clinicians, make the decision when it comes to determining whether or not to move ahead with surgery. In these situations, the non-surgeon members of the patient care team are often left to attempt to prepare patients as best as possible preoperatively and care for them postoperatively, all the while wondering why a particular patient was ever selected for surgery in the first place. Because of differences in training, patient exposure, and experience, these stakeholders may be more acutely aware of factors that may be critical in the preoperative decision-making process to maximize patient safety and decrease the risk of complications. With the increasing specialization of medical care, we believe that it is not realistic to expect that a complex spine surgeon can nowadays fully understand and effectively manage the various cardiac, pulmonary, hematologic, and renal risks and complications that may arise for every patient under time pressure.

The SSTP requires that each surgical patient has majority, although not unanimous, support from all interested parties mentioned above who are involved in the conference. This protocol requirement does mean that patients who might appear to be surgically viable based on radiographic imaging, physical examinations, and clinical history can be deemed unsafe for surgery due to factors or concerns raised by the non-surgeon members of the conference review team. The developers of the SSTP [13] firmly assert that this focus on removing the influence of potential biases driven by politics and economic incentives in the decision-making process is critical to ensuring that an appropriate and safe decision is made for every patient.

A significant proportion of potential complex spine surgery patients is rejected as a result of the multidisciplinary conference review process. Over the past 5 years, the multidisciplinary medical team involved in the SSTP conference review process came to the decision that approximately 25 % of patients initially presented at the conference had medical conditions that rendered them unsuitable for the extent of complex surgical treatment that was being proposed. When this outcome occurs, the case may be deferred until further workup is completed or a nonoperative plan is proposed and pursued for these patients [25]. In some instances, a patient may require medical optimization or further studies before a reliable final decision can be made. These delayed patients are exposed to further in-depth evaluation and pretreatment processes based on the

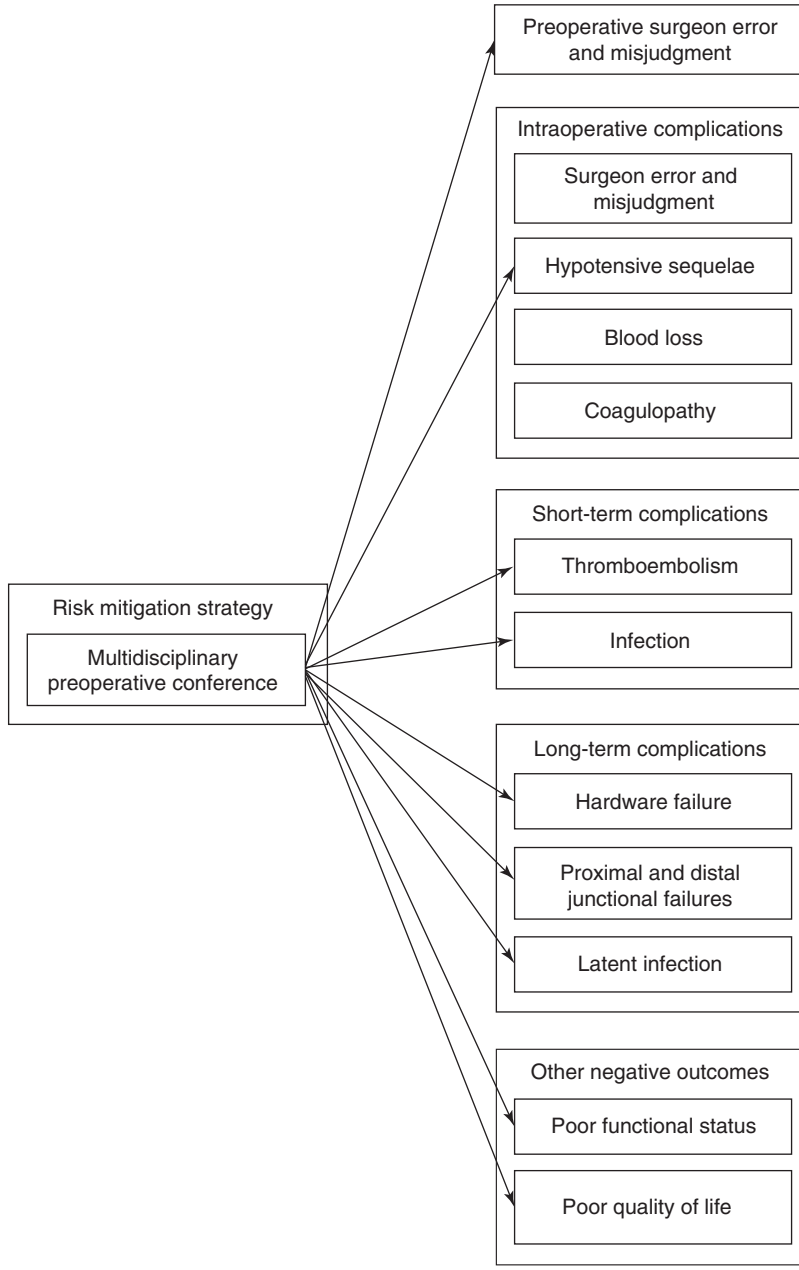

Fig. 6.2 Risks mitigated by the preoperative multidisciplinary review conference of the SSTP

conference discussion and are then brought back for re-review at a later date.

The result of each patient's conference discussion is summarized and placed into the medical record. The primary surgeon also discusses the results of the conference review directly with the patient. This discussion facilitates a shared decision-making process, which values and takes into account the concerns, views, and preferences of the patient.

The preoperative multidisciplinary conference is designed to reduce a multitude of potential

short- and long-term postoperative complications through appropriate patient selection and preoperative optimization. Figure 6.2 links the preoperative multidisciplinary conference process with each main risk it is designed to address.

Osteoporosis

Osteoporosis can substantially impact outcomes associated with complex spine surgery [26]. A patient's bone quality is therefore an important consideration in the preoperative evaluation and decision-making process. All patients receive a preoperative DEXA scan. The T-score at the femoral neck is the primary bone quality measure that is taken into account. Any patient classified as being osteopenic (T-score between −1 and −2.5) is considered for cement augmentation at two locations at the time of surgery: the upper instrumented vertebra (UIV) and the vertebra above the UIV. Low bone mineral density is significantly associated with proximal junctional kyphosis in patients with adult scoliosis [26]. For any patient with a T-score less than −2.5, the team is unlikely to recommend surgery as an appropriate course of treatment except in rare cases of severe neurologic compromise or decline. These osteoporotic patients are referred to endocrinology and are evaluated for appropriate treatment with teriparatide by the endocrinology team.

Patient Preparation and Preoperative Optimization

Once a patient has been cleared by the conference and has been deemed eligible for surgery, they enter the next phase of the SSTP. All surgical patients attend a 2-h education class run monthly by clinic nurses and one of the spine deformity surgeons. This class focuses on the postoperative recovery period and involves a question-and-answer session and the distribution of printed materials to foster understanding. All patients are then engaged in a lengthy informed consent process that includes a discussion of risks. Risks discussed include the likelihood of severe bleeding, infection, proximal junctional kyphosis, implant failure, postoperative neurologic injury, blindness during spine surgery, stroke, and death [3, 27–30].

At this point, an internist performs a more detailed preoperative evaluation. Depending on the patient's needs and the conference discussion, further cardiac evaluation for these patients is obtained based on the guidelines of the American College of Cardiology and American Heart Association for perioperative risk stratification [31]. Pulmonary function tests are obtained if needed [32]. If the patient has normal preoperative hematologic and coagulation panels, they have four units of packed red blood cells and four units of thawed plasma crossed and typed. If the evaluation team discovers abnormalities in hematocrit or coagulation, an additional workup is completed involving both internal medicine and hematology.

Members of the acute pain service team in the Department of Anesthesiology also evaluate all patients to further assess their baseline pain and current pain regimen. This analysis informs the development of a tailored individual perioperative pain regimen for each patient. The attending anesthesiologists who direct the pain service and supervise the resident and fellow team are closely involved with the complex spine surgery team. These pain anesthesiologists are therefore keenly aware of the unique issues and problems that may be faced by these patients. They understand the importance of early mobilization and frequent communication with members of the daily rounding primary spine care team.

Figure 6.3 presents an activity diagram that synthesizes the entire preoperative evaluation process. This diagram illustrates the process steps and key decision points for (1) the preoperative medical evaluation, (2) the multidisciplinary review conference, and (3) further post-conference preoperative evaluation activities. The preoperative evaluation process is multifaceted, systematic, comprehensive, and structured.

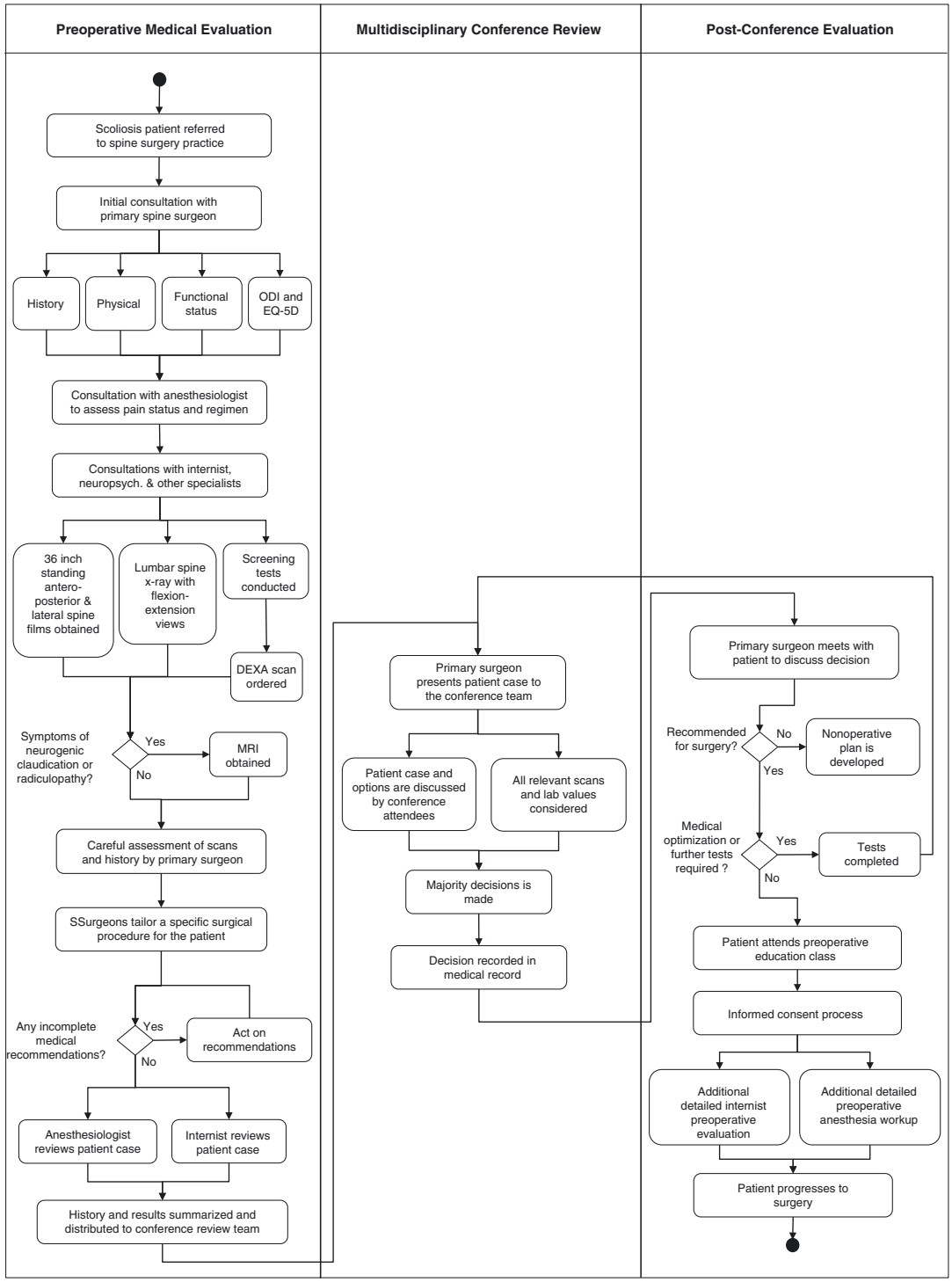

Fig. 6.3 Activity diagram illustrating the entire preoperative evaluation process and key decision points

Assessing Risk Reduction Efficacy

Recently published data suggested that the processes of the SSTP have significantly reduced complication rates even in an institution where baseline complication rates were lower than published practice benchmarks [13]. Outcomes of complex spine surgery patients who were exposed to the full SSTP process were compared to the outcomes of patients who underwent complex spine surgery prior to the implementation of the SSTP. The overall complex spine surgery complication rate of 16 % in the SSTP group was significantly lower than the total complication rate of the non-protocol group (52 %). The SSTP group was less likely to return to the operating room during the postoperative 30-day period (0.8 % vs. 12.5 %) and showed significantly lower rates of urinary tract infection requiring antibiotics (9.7 % vs. 32.5 %) [13].

Continuous Improvement

The SSTP is predicated upon the principles of continuous improvement [33–35]. High-quality outcomes and safe patient care are the SSTP's primary priorities. If care team members and researchers identify potential improvement opportunities, then these improvements are discussed, trialed, and implemented. To continue to improve the safety of patients undergoing complex spine surgery, input is elicited from all care members and considered thoughtfully by the team. It is important to continually eliminate inefficiencies in this detailed process and to arrange for the adequate provision of resources to ensure process timeliness and thoroughness. As one example, we found that in our early conferences, the nonsurgical team members would arrive at the conference without having had a chance to review the patient list before the conference and identify any red-flag items. We were therefore spending time during the conference combing the medical record for specific details to questions that arose during the discussion. This inefficiency was identified, and at this time the list for each conference is drawn up 1 week prior to the meeting, with the understanding that the surgeons will come prepared to discuss the proposed surgical plan and the anesthesiologists and internists will have already reviewed the medical record to discuss potential medical or perioperative concerns. At regular points in time, a member of the complex spine surgery team conducts a review process that involves purposefully gathering information from stakeholders across the care continuum to identify these types of process improvement opportunities. Perioperative data is constantly collected, tracked, and analyzed to generate insights into the efficiency and efficacy of the system. Results are compared to the most recent data published in the literature and other examples of best practice. Data and information are tracked and adjustments are made if needed. Continuous improvement of the SSTP occurs by leveraging the ideas and insights of the broader hospital care team. With the national move in the USA to delivering value-based healthcare, proactive strategies aimed at maximizing healthcare quality can attract patients and drive long-term practice success [36].

Conclusion

Preoperative evaluation is critical to providing appropriate and safe treatment to patients with adult lumbar scoliosis. Preoperative evaluation reduces the risk of a constellation of complications and involves comprehensive preoperative medical review and individual consultation with multiple medical specialists, presentation of the patient's case at a live multidisciplinary conference, additional subsequent specialist medical review, and continuous improvement. A systematic multidisciplinary approach to preoperative evaluation is essential to maximizing quality and safety in complex spine surgery designed to treat adult scoliosis.

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Non-operative Management of Adult Lumbar Scoliosis

7

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The incidence of adult lumbar scoliosis is expected to rise as the proportion of the population over the age of 65 increases. Surgeons generally begin with conservative management for symptoms of lumbar scoliosis due to the high complication rates associated with surgical care and poor bone quality in this age group. Additionally, patients are generally reluctant to consider major reconstructive surgery without efforts at non-operative treatment. Many health insurers also require that surgeons document failure of conservative treatment prior to proceeding with surgical intervention. There is a lack of consensus on the most successful conservative clinical treatment. Steroid injections, physical therapy, bracing, and nonsteroidal anti-inflammatory drugs (NSAIDs) are currently the mainstays of non-operative treatment. However, there is little literature to support the efficacy of nonsurgical modalities.

The utilization of epidural steroid injections has grown considerably. From 1999 to 2009, lumbar epidural steroid injections have increased by nearly 900,000 treatments per year [1]. Epidural steroid injections are commonly prescribed to help treat pain from the spinal stenosis and radiculopathy that may be associated with adult lumbar scoliosis. Degenerative changes leading to spinal stenosis can precede a spinal deformity resulting in de novo scoliosis [2]. Lumbar stenosis from degenerative changes can also occur within a preexisting deformity. Epidural steroid injections are widely used to treat leg pain caused by neurogenic claudication in lumbar spinal stenosis patients. However, rigorous data is lacking regarding the effectiveness and safety of these injections. A double-blinded multi-site trial failed to show any significant difference between Roland–Morris Disability Questionnaire (RMDQ) and leg pain intensity scores at 6 weeks in a group of 400 randomized spinal stenosis patients receiving epidural steroid injections with lidocaine versus lidocaine alone [3]. This study concluded that epidural injection of glucocorticoids plus lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine alone.

The use of epidural steroid injections for the treatment of radicular pain appears to be more promising. Lumbar radicular pain can be caused by foraminal stenosis and other conditions in the lumbar spine such as lumbar disk herniations or facet cysts. Cooper et al. explored the effectiveness of transforaminal epidural steroid injections in a retrospective study of 61 patients with degenerative scoliosis of greater than 10° with radicular complaints [4]. In this study, a successful outcome was defined as a patient who was both satisfied with his or her results and experienced at least a 2-point improvement in numeric rating

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scale, summary pain, and summary function scores. The results showed that 59.6 % of the patients had a successful outcome at 1 week postinjection, 55.8 % at 1 month postinjection, 37.2 % at 1 year postinjection, and 27.3 % at 2 years postinjection ($p < 0.01$). However, the conclusions are limited as this study used historical recall. Another prospective randomized study compared the outcomes of transforaminal injection of steroid and local anesthetic, local anesthetic alone, or normal saline, and an intramuscular injection of steroid or normal saline in patients with disk herniations and lumbar radicular pain [5]. Patients and outcome evaluators were blinded to the agent administered. The primary outcome measure was the proportion of patients who achieved at least 50 % pain relief 1 month after treatment. A greater proportion of patients treated with transforaminal injection of steroid (54 %) achieved relief of pain than did patients treated with transforaminal injection of local anesthetic (7 %) or transforaminal injection of saline (19 %), intramuscular steroids (21 %), or intramuscular saline (13 %). Relief of pain was corroborated by significant improvements in function and disability and reductions in the use of other health care. Outcomes were equivalent for patients with acute or chronic radicular pain. However, the number of patients who maintained relief diminished over time, and only 25 % reported pain relief at 12 months. Overall, there is Level III, weak evidence, for the use of transforaminal epidural steroid injections in the treatment of radiculopathy and/or spinal stenosis associated with adult lumbar scoliosis.

Spondylosis of the lumbar facet joints is also thought to be a common pain generator causing chronic back pain in patients with adult degenerative scoliosis. Non-operative management of symptomatic facet arthrosis includes intra-articular facet injections, facet joint nerve blocks, and radio-frequency neurotomy. Although these procedures are commonly utilized to treat facet joint pathology, there is little evidence to support their use. In a systematic review by Manchikanti et al., 21 randomized controlled trials and five observational studies were analyzed to access the efficacy of these treatment modalities. In the lumbar spine, for long-term effectiveness (>6 months of pain relief), there is Level II evidence for radio-frequency neurotomy and lumbar facet joint nerve blocks, whereas the evidence is Level III for lumbosacral intra-articular injections [6].

Physical therapy is also a commonly prescribed modality used in the conservative treatment of adult lumbar scoliosis. Physical therapy referrals for adult degenerative spine disorders have increased by 1.4 million visits per year between 1999 and 2009 [1]. In a clinical study performed by Barrios et al., 30 patients with adult degenerative scoliosis with Cobb angles ranging from 25 to 65° were evaluated for curve correction and pain control using physiotherapy [7]. The patients were initially treated with heat and lumbar traction, followed by the use of a traction device with pressure applied to the apex of the deformity. Patients were treated with 20–60 sessions of physical therapy with the use of NSAIDs as needed. The results were compared with a control group of patients with scoliosis, but their treatment is not described in detail. The authors found a statistically significant improvement in curve magnitude (38.75 %) compared with the control group (18.75 %). The results in this study also reported a significant reduction in pain as 77 % of the patients were stated to be symptomatic prior to treatment, compared to only 7 % after treatment. However, the method of pain assessment, therapy protocols, and independence of the radiographic reviewers were not well described, making the study conclusions difficult to extrapolate to specific patient populations. Another study looking at exercise-specific therapy was also reported in skeletally mature patients with scoliosis [8]. The patients in this study underwent the use of a side-shift exercise toward the concavity with a 4-year follow-up. The study failed to show any significant benefit as the patients within this study stayed essentially the same or improved slightly in relation to degree of curve.

The Schroth method, first described in the 1920s, is another exercise-specific program that has been used in the treatment of scoliosis. The Schroth method is a rehabilitation program that

focuses on the correction of posture and breathing patterns. Although recently repopularized and used in the treatment of adult scoliosis, there is little data to support its efficacy. In one case report, a 26-year-old woman with scoliosis (Cobb's angle of 20.5°) and back pain was treated with 8 weeks of Schroth exercises [9]. It was reported that her thoracic Cobb's angle decreased from 20.5 to 16.3° and pain decreased from a visual analogue scale (VAS) 5–1. However, follow-up was only 8 weeks for this single case. Overall, there is Level IV, weak evidence on the use of physical therapy for the treatment of adult lumbar scoliosis.

There is also a lack of research to support the use of chiropractic manipulation in the non-operative management of adult scoliosis. In a case series of two adult scoliosis patients with back pain and Cobb angles of 40 and 63, chiropractic manipulation was reported to help with pain reduction [10]. It was also suggested in this study that the routine chiropractic care in the patient with the larger curve led to reduced curve progression. However, the reports of pain reduction were subjective, and the suggestion of decreased curve progression was anecdotal. There is very limited and weak, Level IV, data to support the use of chiropractic care for non-operative management of adult scoliosis.

Bracing is a well-accepted modality to prevent curve progression in *skeletally immature* patients with adolescent idiopathic scoliosis with at-risk curves [11]. However, the use of bracing has failed to provide benefit in *skeletally mature* patients with adult lumbar scoliosis. In one case report, a custom lumbar-sacral orthosis (LSO) was used in a patient with neurogenic claudication and adult scoliosis. In the short term, her ambulation distance improved, but her pain was minimally changed [12]. In another study by the same authors, 29 women with an average Cobb angle of 37° and average age of 41 years were treated with a custom LSO (to restore "sagittal balance") and followed for an average of 7.5 months [13]. The patients noted an immediate but only short-term relief of pain with the brace, and 22 had stopped wearing the brace at the time of follow-up. In another observational study, 67 patients with chronic low back pain (>24 months) and the diagnosis of scoliosis or hyperkyphosis were treated with a sagittal realignment brace [14]. Short-term measurements showed that pain reduction is possible in chronic postural low back pain using this brace that aims to improve sagittal balance by increasing lumbar lordosis. However, no improvement was measured at 6 months. These results were also reaffirmed in a retrospective analysis of studies focused on all parameters concerning degenerative scoliosis associated with stenosis [15]. In their analysis, the use of a lumbosacral orthosis or thoraco-lumbosacral orthosis was thought to provide only temporary pain relief. But, long-term use was thought to be counterproductive as it may result in muscle wasting without any effect on curve progression. Based on limited studies and lack of support, there is Level IV, very weak evidence for bracing adult scoliosis.

The potential risk of muscle deconditioning and spine off-loading with bracing is particularly important to consider in the postmenopausal female population who are at risk for osteoporosis. Proper nutrition and weight-bearing activities that increase the loads on the spine, with pharmacologic treatment as an adjunct, are preferred over bracing in this at-risk population.

NSAIDs, muscle relaxants, and narcotics are commonly prescribed to help patients with the pain associated with adult lumbar scoliosis. Intermittent use of these oral medications is often used to treat acute symptomatic and chronic musculoskeletal pain syndromes. Prior studies have shown that NSAIDs may be more efficacious than placebo in the treatment of acute and chronic low back pain in patients with degenerative spondylosis [16]. However, the use of muscle relaxants and narcotics has not been shown to be as successful. In a recent randomized double-blinded study in patients with acute, nontraumatic, nonradicular low back pain, adding cyclobenzaprine or oxycodone/acetaminophen to naproxen did not improve functional outcomes or pain at 1-week follow-up [17]. In patients with lumbar stenosis with neurogenic claudication, a recent randomized, double-blinded placebo-controlled trial failed to demonstrate a significant

effect of oxymorphone hydrochloride or propoxyphene/acetaminophen compared with placebo [19]. Considering the limited data supporting the efficacy of narcotics and the significant risk potential associated with their chronic use, we do not recommend the use of narcotics for routine non-operative care.

Gabapentin has also shown promising effects in the treatment of low back pain with radiculopathy. A recent multicenter randomized study evaluated whether an epidural steroid injection or gabapentin is a better treatment for lumbosacral radiculopathy [20]. This study included 145 patients with lumbosacral radicular pain secondary to herniated disk or spinal stenosis. Results showed small differences in favor of the injections at 1 month, but no significant differences in primary outcome measures (average leg pain at 1 and 3 months). However, the efficacy of the two treatments is difficult to assess as there was no placebo group.

Unfortunately, current literature has shown that documented costs of non-operative modalities are substantial without a clear evidence of improvement in health status [21]. In a prospective cohort study, adult scoliosis patients treated non-operatively were followed for 2 years. During this time, data was collected on the type and quantity of non-operative treatment used including medication, physical therapy, exercise, injections/blocks, chiropractic care, pain management, bracing, and bed rest. It was shown that the cost of non-operative care was not insignificant with a mean treatment cost over the 2-year observation period of $10,815. Despite high costs, no improvement in health-related quality of life (HRQOL) was observed in adult scoliosis patients receiving nonsurgical treatment as compared to untreated patients. However, an important caveat of this study is that the treatment was not randomized and the treatment group may have deteriorated if not for the nonsurgical care they received.

Due to the high cost of non-operative care, current research is also being performed to help physicians better understand which patients with adult lumbar scoliosis would benefit most from these conservative modalities. The International Spine Study Group performed a retrospective review of 215 patients using a multicenter database that used health-related quality-of-life measures, including the Scoliosis Research Society (SRS)-22 questionnaire [22]. It was concluded that patients with lower SRS pain scores (3.0 vs. 3.6) and less coronal deformity in the thoracolumbar (TL) region (29.6° vs. 36.5°) would more likely benefit from non-operative care. Characteristics including greater baseline SRS pain scores and large coronal deformities in the TL region were associated with vertebral obliquity and less potential for improvement with non-operative care.

The treatment of adult degenerative scoliosis continues to be a challenging problem. Identifying the source of pain is crucial in formulating a plan of treatment. It can be difficult to differentiate pain from age-related degenerative changes from pain related to the curve. Non-operative treatment is preferred for those adults with mild or moderate pain or elderly patients for whom surgery is not prudent. Operative management can be associated with a high morbidity due to patient age, bone quality, and surgical procedures often needed for the correction of complex coronal and sagittal deformities. Despite the lack of Level I evidence on the efficacy of non-operative care, it may be prudent to refrain from performing complex surgical deformity procedures in high-risk patients with multiple medical comorbidities, advanced age, poor social and emotional state, and osteoporosis. There is a need for studies to show which patients have the most improvement from non-operative treatment and which patients have the most improvement and the fewest complications from surgical reconstruction to help determine the optimal cost-benefit ratio for individual patients.

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Surgical Alignment Goals for Adult Lumbar Scoliosis

8

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Abbreviations

ASD	Adult spinal deformity
BMP	Bone morphogenetic protein
C7PL	C7 plumb line
CSVL	Central sacral vertical line
HRQOL	Health-related quality of life
LL	Lumbar lordosis
ODI	Oswestry Disability Index
PCS	Physical component summary
PI	Pelvic incidence
PI-LL	Pelvic incidence–lumbar lordosis
PSO	Pedicle subtraction osteotomy
PT	Pelvic tilt
SF-36	Short-form health survey-36
SS	Sacral slope
SVA	Sagittal vertical axis
TPA	T1 pelvic angle
T1-SPI	T1-spinopelvic inclination

Introduction

The overall prevalence of adult spinal deformity (ASD) has been estimated to be as high as 32 % in the general population and 68 % in patients older than 60 years of age [1]. Considering the increasing life expectancy and aging population in industrialized countries, the prevalence of ASD and its social and economic impact is expected to continue increasing [2].

Although most patients with ASD are older and have significant comorbidities, evidence suggests that ASD independently and substantially burdens the health of the affected patients [3–5]. A study on two independent large-scale international databases reported that physical component summary (PCS) scores of short-form health survey (SF)-36 in ASD patients (managed either surgically or nonsurgically) were lower than patients with other well-recognized chronic morbid conditions such as osteoarthritis, congestive heart failure, chronic lung disease, and diabetes [3]. Of note, the domain of SF-36 most severely influenced by ASD was bodily pain. Other studies based on US population reported similar findings with worsening of PCS of SF-36 with lumbar scoliosis and increasing sagittal vertical axis (SVA) [4].

Surgical management of ASD has been shown to provide substantial improvement in health-related quality-of-life (HRQOL) scores, surpassing thresholds of minimal clinically important difference [6]. Others have questioned the efficacy of nonoperative strategies in ASD, in terms of back and leg pain [7, 8], and their cost-efficiency and value due to lack of improvement in HRQOL parameters [9]. However, recent data suggests that for patients with mild ASD, nonoperative care should still be considered as an

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option as it was associated with improved outcome scores at 1-year follow-up [10]. Considering advanced age, multiple comorbidities, and low physiologic reserve of most ASD patients and the high risk of corrective procedures, e.g. perioperative complications (up to 70 %) [6], judicious criteria should be applied for indicating surgery in this group of patients.

Indications for Surgery in Adult Spinal Deformity

Several studies have demonstrated that surgery in patients with ASD, if appropriately indicated, is associated with superior outcomes compared to nonoperative management [11]. Patients who fail to achieve adequate symptomatic relief and functional recovery with nonoperative measures are generally considered appropriate surgical candidates. The preoperative evaluation should include thorough scrutiny of the clinical scenario and the radiographic findings. More importantly, assessing the correlations between the clinical presentation and the radiographic findings is of utmost importance in determining the need for surgery. Loss of lumbar lordosis, increased thoracic kyphosis, rotatory subluxation, and the grade of obliquity of L3 and L4 endplates are highly correlated with severity of back pain [12]. Generally, symptomatic lumbar curves with coronal Cobb angles higher than 30–40° or significant curve progression (i.e., >10°) and curves with major (>6 mm) or progressive (increase >3 mm) olisthesis are considered as surgical candidates [13]. Provided the approximately 50% coexistence of back and leg pain in the ASD population, progressive neurological deficits can also indicate surgery. At times, further diagnostic modalities such as injections are required for precise elucidation of the pain generator(s), which must be addressed during the surgery to achieve the best outcomes.

Other than the location, type, and severity of malalignment, considerations in age, associated comorbidities, and physiologic reserves of the vital organs determine a patient's eligibility for undergoing general anesthesia and various types of deformity procedures with varying potentials for major complications.

Aside from the medical risks related to complications, the risk of alignment failure following surgery may be elevated in certain settings. Examples include patients with a lack of compensatory pelvic retroversion (low PT or even pelvic anteversion) in the context of highly positive SVA, which can be associated with an imbalance between flexor and extensor muscles of the pelvis, or those with preoperative flexion contracture of the hips [14].

Goals of Surgery

The goal of surgery in ASD is to alleviate patients' pain and disability and to allow them to have their desired level of physical function. To achieve these goals, proper alignment at both global and regional levels is necessary, aside from proper decompression. Precise assessments of patients as well as a comprehensive understanding of the biomechanics of the axial skeleton and the interactions between the head, spine, pelvis, and lower extremities in different postures are essential. Preoperative evaluation consists of a detailed history, physical examination, and imaging studies which include full-body imaging in the standing position (such as with EOS technology [15]) as well as dynamic imaging in both coronal and sagittal planes to assess the rigidity of the curves and the stability of the segments. The goals of surgery may need to be adjusted based on the age, health status, constitutional morphology of the spine, and patient expectations with regard to their desired level of physical function and/or appearance. Therefore, the goals of surgery as well as the definition of successful outcomes should be tailored based on each individual patient.

Surgical Planning

Preoperative planning for the management of ASD can be challenging. The complex nature of the pathology, the diversity of available treatment options, and the importance of an individualized

approach contribute to the complexity of surgical planning. More importantly, optimal realignment targets and the amount of correction that is required to achieve those alignment targets are not easy to define and at times remain unclear.

Following clinical evaluation, the radiographic parameters of the spine in both coronal and sagittal planes should be measured. An important part of radiographic analysis of the deformity is the determination of the driver and its compensatory mechanisms. The driver mechanism is responsible for initiating the chain of compensatory changes in various parts of the axial skeleton. However, both the driver and the compensation contribute to the emergence of a clinically significant deformity. For instance, in most cases of degenerative ASD and sagittal decompensation, the driver mechanism is the spinopelvic mismatch (i.e., pelvic incidence–lumbar lordosis mismatch or PI-LL mismatch). This usually occurs via a loss of lumbar lordosis secondary to the degeneration of lower lumbar disks, which contribute most to the lordosis of the lumbar spine. The loss of lordosis and the consequent PI-LL mismatch lead to several compensatory changes at different levels, resulting in thoracic hypokyphosis, pelvic retroversion, hip extension, and knee flexion [16, 17] (Fig. 8.1). These compensatory changes are reactive to the driver of malalignment and are expected to improve with adequate correction of the driver mechanism if the affected joints remain mobile. However, in patients with a late presentation, the joints in which the compensatory mechanisms occur will lose their mobility and therefore become part of the rigid deformity. They then also need to be addressed, to achieve optimal realignment.

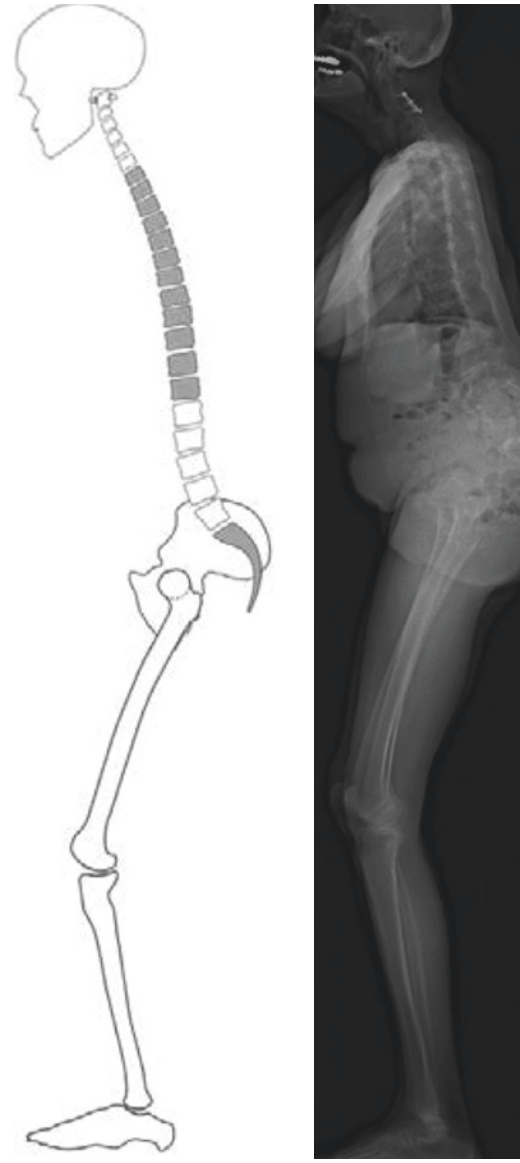

Fig. 8.1 Compensatory changes shown in the schematic figure and radiograph of an ASD patient: pelvic retroversion, hypokyphosis, and knee flexion

To precisely evaluate the radiographic deformity, software tools can be helpful for surgeons. Current picture archiving communication systems (PACS) provide universal tools, such as distance and angle tools, for surgeons to precisely measure the radiographic parameter mentioned in previous chapters. For spine surgeons with the desire to measure with spine-specific tools quickly, Surgimap software (Nemaris, New York, USA) is an alternative choice and serves as a dedicated and validated software solution for radiographic analysis of the spine. With ten clicks (Fig. 8.2), the complete sagittal profile with various sagittal parameters can be presented as quantified numbers. OrthoView and SpineView are other software solutions which are more complicated but may offer different advantages for research purposes.

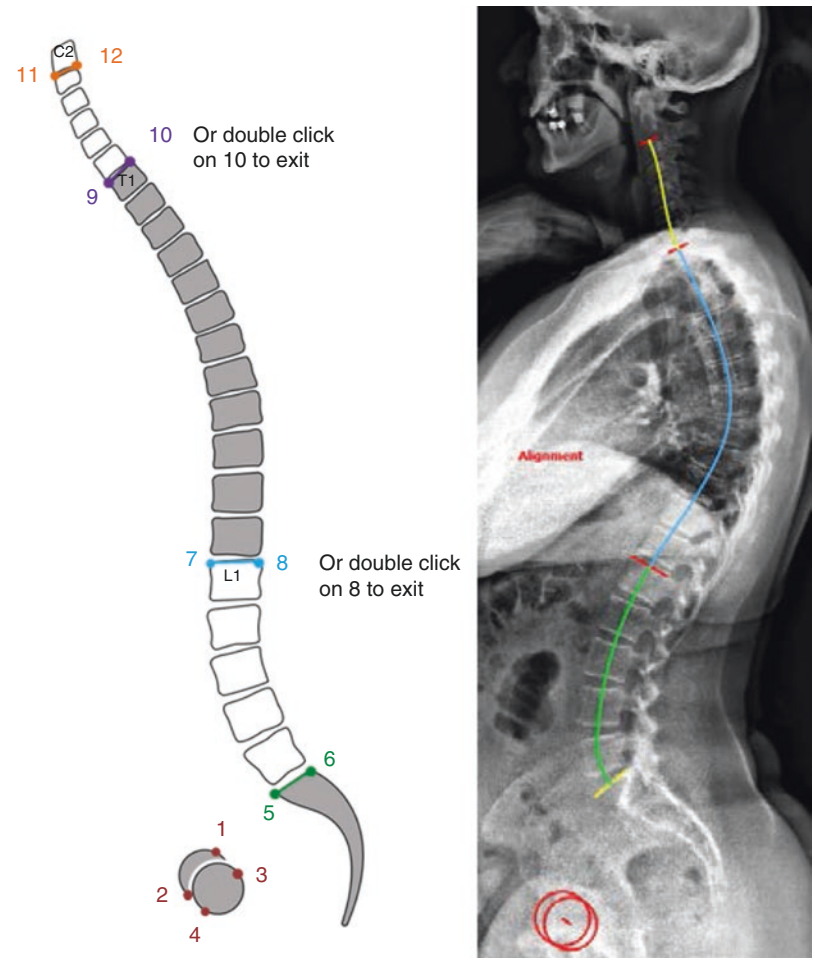

Fig. 8.2 Illustrations of how to measure sagittal alignment with Surgimap®

Alignment Targets

Although characteristics of the ideal posture have yet to be defined, normal ranges for various radiographic parameters of regional and global alignment in the standing posture have been described in the asymptomatic population [18–23].

Based on HRQOL outcomes such as the Oswestry Disability Index (ODI), it seems that correlations exist between radiographic parameters of sagittal alignment and the level of disability in both surgical and nonsurgical patients [12, 24, 25]. Prospective multicenter studies have shown that the sagittal parameters most strongly correlated with HRQOL scores are PI-LL mismatch, sagittal vertical alignment (SVA), and pelvic tilt (PT) [26]. Thresholds for those radiographic parameters have been defined to identify patients with severe disability (i.e., ODI >40) [26]. Patients with one or more radiographic parameters beyond the thresholds are therefore at significantly higher likelihood of requiring surgery due to substantial disability [26]. Although similar thresholds are generally proposed as realignment targets for reconstructive spine procedures to achieve satisfactory clinical outcomes, the interaction between various components of the axial skeleton has driven the spine community to search for comprehensive formulas that would account for such interactions.

Coronal Alignment

Although the magnitude of the coronal curve (Cobb angle) is not strongly correlated with the HRQOL scores, evidence supports the clinical relevance of other coronal radiographic parameters such as obliquity of the endplate of L3 and L4 vertebrae, the level of apical vertebra, lateral rotatory subluxation, and the degree of coronal decompensation (i.e., the distance between C7 plumb line and central sacral vertical line or C7PL-CSVL offset) [12, 27]. The threshold for acceptable lateral subluxation and coronal decompensation has been suggested to be 7 mm and 4–5 cm, although these thresholds have not been validated by external studies [28]. Recently, Bao et al. proposed a coronal malalignment classification based on C7PL-CSVL offset with the direction (convex or concave) of offset and a threshold of 3 cm (Fig. 8.3) [29].

Sagittal Alignment (Fig. 8.4)

- Spinopelvic (PI-LL) mismatch

The PI-LL relationship represents the state of harmony between pelvic morphology and the lumbar spine and has strong correlations with HRQOL measures [26]. PI is a morphological parameter of the pelvis and directly influences the orientation of superior sacral endplate (sacral slope). The superior sacral endplate determines the lumbar lordosis via its orientation with regard to the superior endplate of L1 vertebra. Therefore, assuming non-pathological conditions without compensatory pelvic tilt, individuals with constitutionally higher PI are expected to have higher sacral slopes (SS) (i.e., more vertical orientation of the sacral endplate) and therefore an exaggerated lumbar curve. Normative data shows that in the majority of asymptomatic population, LL is within 10° of PI. As a general rule, based on HRQOL scores in ASD patients, the aim of corrective surgery for pathologic loss of LL should be to return the PI-LL<10° since evidence supports higher PI-LL mismatch is associated with significant disability [30]. However, in daily practice, in patients with extremely high PI, postoperative LL is aimed to be restored to PI - 10° to avoid exaggerated lumbar lordosis, and in patients with very low PI, the target LL is attempted to be PI + 10 to avoid hypolordosis. In addition, the determination of the target LL should not be only limited to the pelvic morphology but also be in

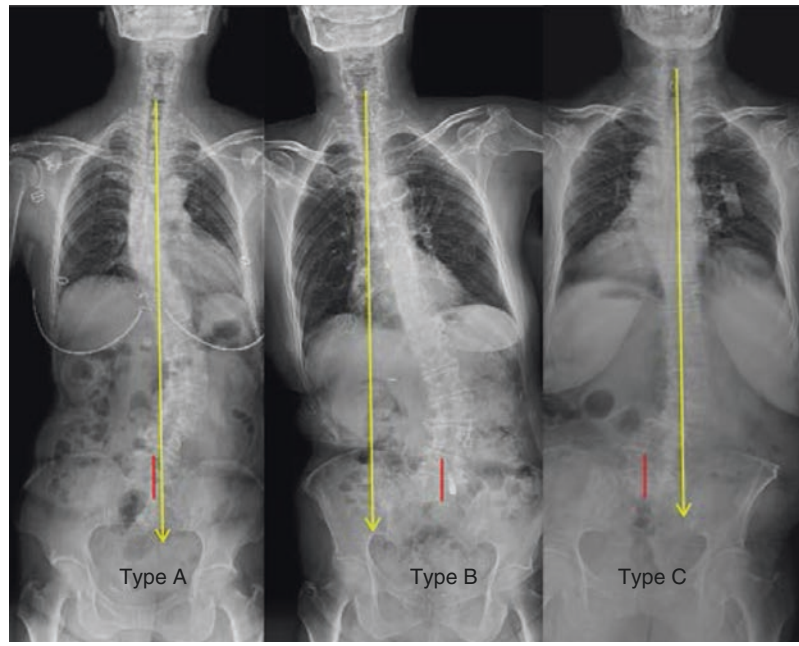

Fig. 8.3 Coronal malalignment patterns by Bao et al. *Type A*: C7PL-CSVL offset <3 cm. *Type B*: offset > 3 cm and shift to concave side. *Type C*: offset >3 cm and shift to convex side

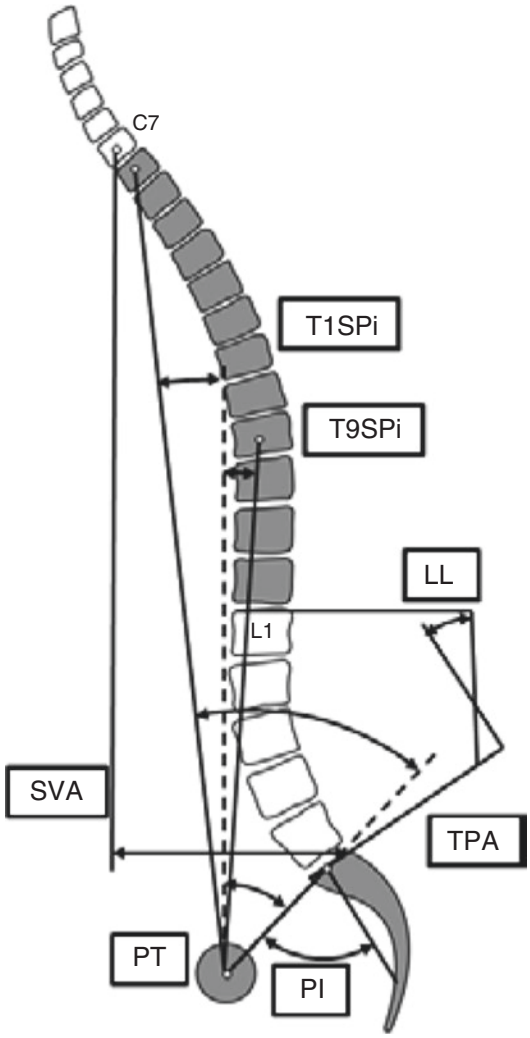

Fig. 8.4 Schematic illustration of the sagittal parameters

harmony with the morphology of the thoracic spine. In patients with an accentuated thoracic kyphosis, a higher LL is required to maintain a compensated sagittal posture. Therefore, if the pathologic malalignment extends beyond the lumbar spine and into the thoracic spine (i.e., thoracic hyper- or hypokyphosis), the reconstruction of LL should take into account both PI and thoracic kyphosis. A recent mathematical formula for the theoretical LL with respect to both PI and TK was proposed by the Schwab and Lafage team: $tLL = \frac{TK + PI}{2} + 10$. Further validation is required.

- Sagittal vertical axis (SVA)

SVA represents the overall sagittal relationship between the base of the cervical spine and the sacral endplate. SVA is a clinically practical parameter. It is strongly correlated with HRQOL measures and is particularly sensitive to changes in lumbar lordosis, the most common driving mechanism in sagittal malalignment pathologies. However, its shortcomings include the need for a calibrated X-ray and its disregard for cervical spinal alignment. More importantly, evidence suggests that the SVA can better represent the malalignment scenario, should it be considered in conjunction with pelvic parameters [31]. According to an analysis of normative data and HRQOL, the maximally tolerable SVA (and therefore the target of realignment surgery) is less than 4.6 cm [30].

- T1-spinopelvic inclination (T1-SPI) angle

T1-SPI can be considered as an alternative parameter for global sagittal alignment to SVA and has strong correlations with both SVA and HRQOL scores. Moreover, it has the advantage of not requiring a calibrated X-ray [25, 32]. Based on its correlation with HRQOL scores, the maximal tolerable value (i.e., the realignment target) for T1-SPI has been calculated to be less than 0° [33].

- Pelvic tilt (PT)

PT reflects the compensatory pelvic retroversion secondary to sagittal spinal malalignment. It is considered as one of the most critical compensatory parameters because of its substantial influence on global sagittal alignment. An increased pelvic tilt is unfavorable as it requires considerable energy expenditure by the hip extensors, ultimately affecting the functional ability of patients. Although PT is not directly addressed by the corrective surgery, its change after surgery can serve as a surrogate measure for the success. Normal PT is considered to be below 20°.

Age Considerations in Alignment [17]

Cross-sectional studies on asymptomatic patients suggest age-related remodeling of spinopelvic alignment occurs. These changes are distinct from pathologic degenerative changes. The linear progression of positive sagittal alignment occurs with age but at a much smaller magnitude than pathologic degenerative changes [17]. Although the exact mechanisms for these changes remain not fully understood, age-related changes in the spine affecting the disks, ligaments, paraspinal muscles, facet capsules, and vertebral bodies as well as suboptimal function of the control centers of posture and balance in the central nervous system may have roles.

A recent study showed that PT, PI-LL, SVA, and T1 pelvic angle (TPA) all increase with age suggesting that normal thresholds for sagittal alignment are affected by age [34]. What may seem as nearly pathologic in young patients can well be tolerated in the elderly population (Table 8.1). On the other hand, studies on non-ASD patients show that HRQOL measures decline with aging, and therefore age should be considered for adjustment of the normative values of HRQOL scores. In other words, patients of different age groups require age-specific radiographic alignment targets. Considering young and old patients together is inappropriate due to the substantial differences in the target functionality and quality of life. In younger patients, stricter targets for radiographic parameters (i.e., closer to those of normal population) should be applied, while the same targets in the older population may be unnecessary and may lead to overtreatment and overcorrection. Consequently, the alignment targets need to be adjusted by age. Overcorrection in the elderly increases the risks of future proximal junctional failure or increased regional kyphosis (PJK, Fig. 8.5) [35].

Mathematical Formulas

Several mathematical methods have been proposed to help the preoperative planning of surgery in ASD. Some methods use geometrical calculations to predict the optimal correction obtained by osteotomy techniques, while others aim to define an optimized sagittal alignment based on the correlation between the postoperative radiographic sagittal parameters (Table 8.2).

Ondra et al. developed the "trigonometric method" to calculate the correction magnitude based on the level and resection angle of the pedicle subtraction osteotomy (PSO) [36, 37]. This method is a geometrical calculation of the position of SVA following a PSO. Despite high correlations between the predicted and actual degrees of correction at the PSO site, validation analysis demonstrated that the trigonometric method was only useful for predicting poor SVA

Table 8.1 Alignment targets adjusted per age and disability level

	PI-LL (°)		SVA (mm)		PT (°)	
Age group (years)	Moderate disability	Severe disability	Moderate disability	Severe disability	Moderate disability	Severe disability
<35	-6.8	1.8	−17.4	5.0	11.3	13.2
35–44	−2.7	5.9	5.2	27.6	15.1	17.0
45–54	0.2	8.8	21.6	44.0	17.8	19.7
55–64	2.9	11.5	36.1	58.5	20.2	22.2
65–74	5.5	14.1	50.4	72.8	22.6	24.6
≥74	8.3	16.9	65.8	88.2	25.2	27.1

Moderate and severe disability were considered as Oswestry Disability Index (ODI) thresholds of >20 and >40, respectively (Adapted from Lafage, et al. [34])
LL lumbar lordosis, *PI* pelvic incidence, *PT* pelvic tilt, *SVA* sagittal vertical alignment

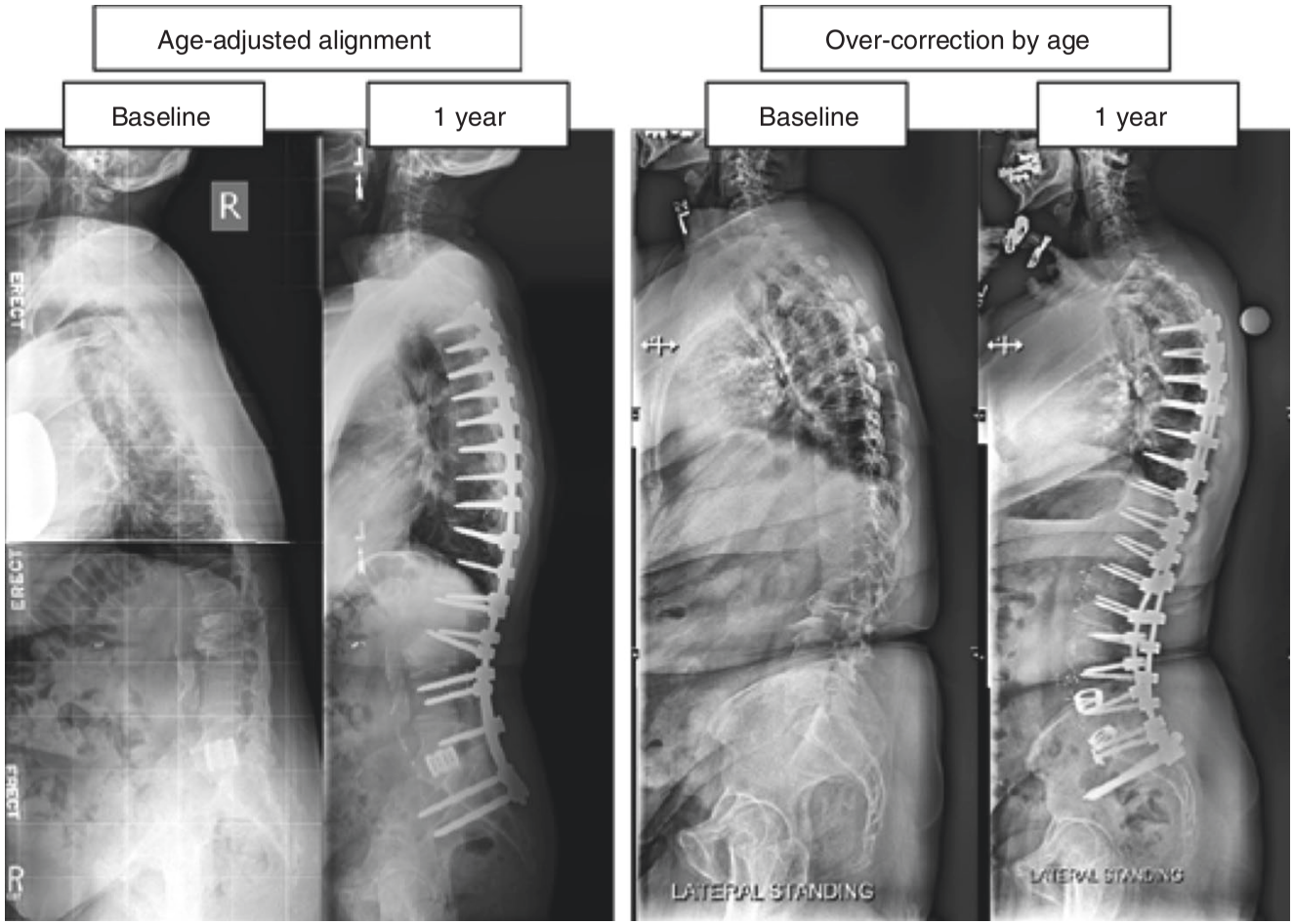

Fig. 8.5 Two patients (66 y/o and 65 y/o) with different post-op alignment. At post-op, PI-LL was 12.1° on the left patient, which was close to the age-adjusted target (10.5°), while PI-LL was relatively overcorrected (−3.9°) on the right patient. At 1-year follow-up, PJK occurred on the right patient who had a post-op relative overcorrection.

Table 8.2 Common mathematical methods used for surgical planning in realignment surgery for adult spine deformity

Author (year)	Method/formula description
Ondra et al. (2006) [36, 37]	Trigonometric method
Kim et al. (2006) [47]	LL ≥ TK + 20°
Yang et al. (2007) [48]	Spline method
Rose et al. (2009) [49]	LL + PI + TK ≤ 45°
Schwab et al. (2009) [40]	LL = PI – 10° (In patients with loss of lumbar lordosis: LL = PI + 9 ± 9°)
Lafage et al. (2011) [50, 51]	SVA = −52.87 + 5.90 (PI) – 5.13 (LL_{max}) – 4.45 (PT) – 2.09 (TK_{max}) + 0.57 (age)
Le Huec et al. (2011) [39]	Angle of correction = C7PL translation angle + hip flexion + pelvic tilt

outcomes. It was inaccurate for predicting a good postoperative alignment and had a wide margin of error [31, 38]. Le Huec et al. recognized the limitations of this method, and to overcome its ignorance of the compensatory mechanisms, he proposed a "full balance integration" formula, in which two major compensatory mechanisms, pelvic tilt and hip flexion angle on standing X-ray, are considered in addition to Ondra's calculation method [39]. They also suggested that the angle of hip flexion should be added to the angle of correction. Moreover, if pelvic tilt is below or above 25°, 5 or 10°, respectively, it should be added to the final angle of correction. This method has yet to be validated by external studies.

Other mathematical formulas have also been used to plan for osteotomies by estimating the LL required for adequate sagittal realignment (Table 8.2). Comparing the predictive accuracy of these formulas demonstrated that the Lafage formula, which incorporates major spinopelvic parameters, was more accurate in predicting both good and poor postoperative SVA corrections [31] Any modifications in spinal alignment will be associated with changes in the orientation of the pelvis, and therefore the modeling methods have to include parameters of the spine, pelvis, and ideally the hips and knees [40].

The applicability of these formulas is limited by the dynamic nature of the spine. After correction surgery, the unfused mobile segments, both above and below, react to the newly fixed segment. These postoperative changes, often termed reciprocal change, remain a challenge for predicting postoperative alignment [41].

Challenges of Surgical Planning

There are certain unique challenges in planning for corrective ASD surgery. For instance, pelvic morphology and compensatory pelvic retroversion can affect the magnitude of optimal correction. In patients with more pronounced preoperative compensatory pelvic retroversions (increased PT), the magnitude of correction should be greater than those with smaller pelvic retroversions [38]. Therefore, excluding PT from the surgical planning process would lead to undercorrecting patients with severe deformities and with compensatory increases in PT [42]. Another challenging aspect of surgical planning is the potential for postoperative reciprocal changes in the non-instrumented segments, which can negatively influence the postoperative alignment [41]. High PI, severe deformity, and advanced age have been described as risk factors for postoperative thoracic kyphosis in the unfused segments, especially if the instrumentation ends in the thoracolumbar junction proximally [31, 43]. Preoperative prediction of the optimal postoperative thoracic kyphosis is hindered by the obligatory kyphosis imposed by a positive sagittal malalignment and by the compensatory contracture of the thoracic musculature attempting to decrease kyphosis to achieve an acceptable horizontal gaze [38].

Surgical Management

The surgical procedure for ASD consists of three basic elements of (1) alignment correction in both the coronal and sagittal planes, (2) decompression of neural structures, and (3) stabilization of the realigned and/or decompressed segments.

Therefore, the final steps of surgical planning consists of detailing of the basic elements including approach, positioning of the patient, decompression levels (if needed, central, foraminal, or both), realignment techniques (i.e., release of ligamentous structures, distraction/compression, and osteotomies), fusion levels, instrumentation (interbody fusion, fixation technique, and supplemental instrumentation such as extra rods, hooks, wires, straps, etc.), and strategies for fusion augmentation such as decortication, bone graft, and bone morphogenetic protein (BMP)-2.

The level of expertise and experience of the surgeon and the availability of instrumentation should also be considered. The speed of the operative flow related to procedural execution, meticulous hemostasis, and safe performance of the procedure are essential in minimizing the risks of complications. The surgeon should always expect the potential need to change the plan intraoperatively and should contemplate alternative strategies prior to the surgery. The intraoperative assessment of adequacy of bone fixation, surgical complications (such as neuromonitoring signal change and hemodynamic instability) or complications related to general anesthesia, can substantially influence the final surgical plan. As mentioned earlier, the surgical plan should be tailored to the patients' severity of symptoms, radiographic characteristics of the malalignment, and expected function after surgery. Furthermore, the patients' optimized health should also be taken into account particularly when major procedures with high physiological demand are necessary.

In general, the surgical procedure selected for a patient is selected from a wide spectrum of possible strategies. The least invasive extreme of this spectrum consists of decompression procedures for release of neural elements without any need for realignment and/or fixation. The spectrum continues with procedures that include limited to extended instrumentation, and at its most invasive extreme lies the corrective techniques such as osteotomies and vertebral resection. Several algorithms for open and minimally invasive techniques in ASD surgery have defined this spectrum [13, 44, 45].

Silva and Lenke suggested the use of a matrix of clinical and radiographic parameters, which included neurogenic claudication, radiculopathy, back pain, anterior bridging osteophytes, olisthesis, coronal Cobb angle, loss of lumbar lordosis, and global imbalance for planning open surgery in a stepwise progression toward more invasive procedures [13]. In patients with focal degenerative disease, no instability, and minimal deformity, fusion and realignment procedures may not be necessary, and surgical decompression may suffice. Potential candidates are patients presenting with neurogenic claudication and/or radiculopathy, little or no low back pain, small coronal curves (<30°), minimal subluxation (<2 mm), maintained lumbar lordosis, and aligned in both coronal and sagittal planes. Nevertheless, decompression-only procedures, depending on the extent of bone and soft tissue resection, are associated with an increased risk of future instability. This should be considered and discussed with the patient prior to surgery. If neurogenic claudication and/or radiculopathy is associated with localized low back pain and segmental instability, limited segmental fusion can be considered in addition to decompression, provided the Cobb angle is small; lumbar lordosis is maintained; and no thoracic hyperkyphosis, thoracolumbar kyphosis, and global imbalance (coronal and/or sagittal) exist. In patients with symptoms of primary back pain associated with a major curve (>45°) and subluxation (>2 mm) yet a maintained lumbar lordosis and coronal and/or sagittal alignment, the whole lumbar curve may require stabilization with instrumentation. Of note, in patients with similar presentations who have hypolordotic lumbar curves, additional interbody releases and fusions either via an anterior, lateral, or posterior approach may be considered. The presence of thoracic hyperkyphosis and coronal or sagittal imbalance may dictate the need to extend of the fusion levels to the thoracic vertebrae and/or additional osteotomies [13]. Certain factors should be considered for the extent of the fusion. In patients with poor spinopelvic harmony (decreased LL, high PT, positive sagittal imbalance), the L5-S1 disk is unable to withstand the junctional stress of the lumbar/thoracolumbar constructs. In these patients, extension of the fusion to the sacrum and pelvis with interbody fusion at L5-S1 (to diminish the inherent high rate of nonunion at this level) is recommended (Fig. 8.6). Cranially, the fusion should not end at an unstable, rotated, or kyphotic level. With regard to realignment, patient

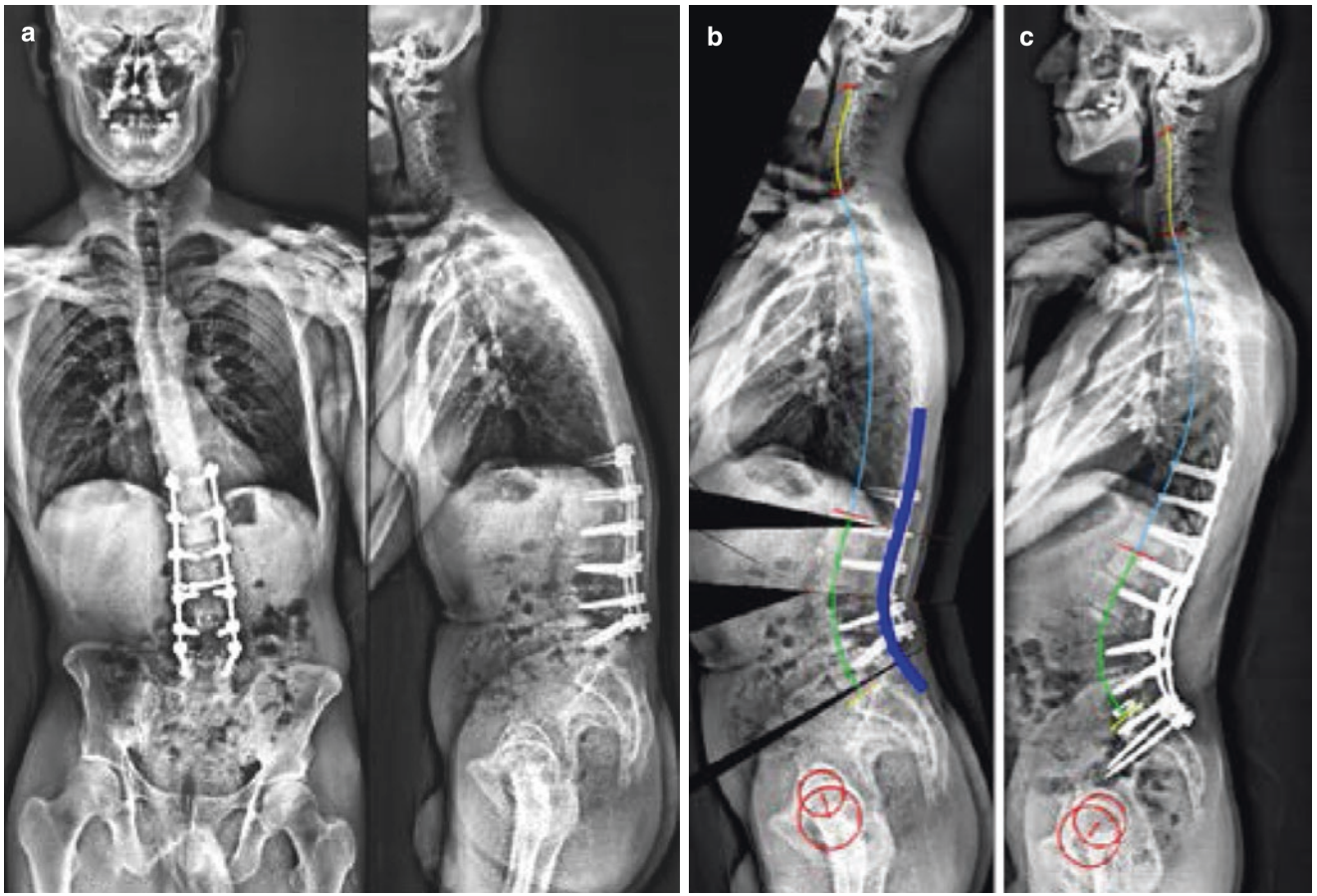

Fig. 8.6 A patient with iatrogenic sagittal malalignment and low back pain. (**a**) Baseline radiographs showing sagittal malalignment and the corresponding compensatory changes; (**b**) surgical planning showed L3 PSO and L5-S1 interbody fusion are needed to restore sagittal alignment; (**c**) the patient was well aligned after surgery

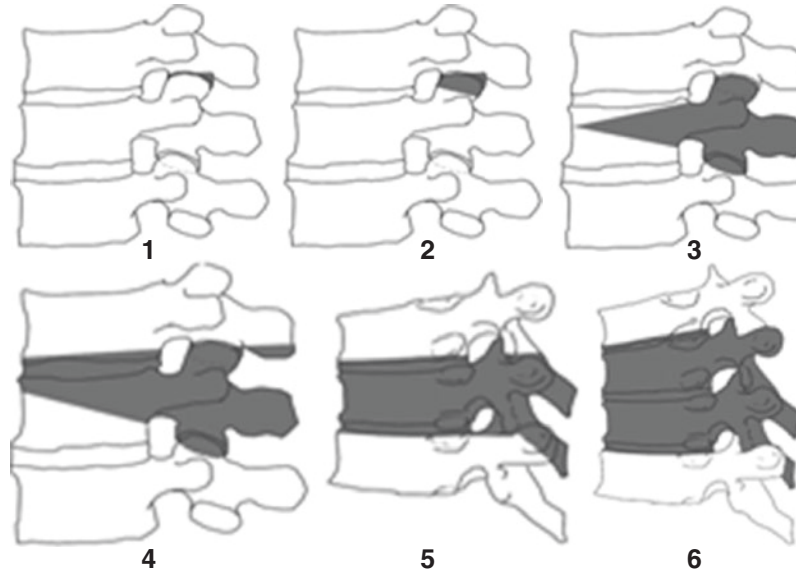

Fig. 8.7 Six grades of osteotomies by Schwab. *Grade 1*: partial facet joint. *Grade 2*: complete facet joint. *Grade 3*: pedicle and partial vertebral body. *Grade 4*: pedicle, partial vertebral body, and disk. *Grade 5*: complete vertebra and disks. Grade: multiple vertebrae and disks

positioning (especially with hips in extension to induce as much lumbar lordosis as possible) is of utmost importance and at times contributes substantially to the overall correction. The degree of rigidity of the curve, mobility of the disks, and the presence of local and/or global malalignment may determine the type of additional realignment techniques such as soft tissue release, distraction/compression manipulations, and osteotomies. Although not originally intended to be a guide for indication of osteotomies, the classification suggested by Schwab et al. provides a graded outline for corrective osteotomy techniques in terms of progressive anatomical bone resection (Fig. 8.7) [46]. In addition to sagittal management, postoperative coronal malalignment also calls for attention. The abovementioned coronal malalignment classification by Bao provides clinical guides for patients with baseline coronal global malalignment [29]. In the study, Type C patients were more predisposed to postoperative coronal global malalignment than Type A and B patients. Therefore, for Type C patients, it is necessary to restore the balance between the spine and pelvis with an SPO or PSO on the convex side of the fractional curve, before performing osteotomy on the apical region. A transforaminal lumbar interbody fusion (TLIF) is recommended at the convexity of fractional curve, restoring the horizontal level of L4 and L5. After the osteotomy at the apical segments, the optimal sequence of correction for Type C patients then starts from the concave side of the main curve. Translation, instead of compression, is recommended during trunk shift correction to avoid deterioration of the coronal imbalance in Type C patients. During manipulative reduction of the kyphosis and scoliosis, it is important to keep the spine centered over the pelvis with hand pressure on the convex deformity.

Mummaneni et al. have recently suggested an algorithm for the use of minimally invasive techniques in ASD [44]. Following the same concept as described by Silva and Lenke, they defined three classes of patients according to the severity of the deformity and proposed MIS techniques to be considered for the first two classes. Class I deformities have relatively mild and flexible spinal deformity without instability. These patients mainly present with symptoms of central, lateral recess or foraminal stenosis and have minimal or no back pain with regard to their deformity. Radiographically, the Cobb angle is usually below 20°, and minimal listhesis (i.e., lateral or sagittal subluxation < 6 mm) or instability (i.e., Meyerding class <2) exists. Sagittal alignment is maintained (PI-LL less than 10° and SVA <6 cm); PT is below 25° without thoracic hyperkyphosis. Patients with class I deformities can be consid-

ered for MIS decompression procedures with or without limited fusion depending on whether minimal instability exists. In patients with class II deformities, back pain and deformity-related symptoms are more prominent, and radiographically they present with worse parameters of deformity such as major Cobb angle above 20°, PI-LL mismatch of 10–30°, lateral listhesis of greater than 6 mm, and Meyerding class ≥2. These patients usually have SVA < 6 cm. However, if SVA is higher than 6 cm but the curves are partially corrected in the supine position, it can still be considered as class II deformity. MIS surgery in these patients consists of multilevel decompression, instrumentation, and fusion techniques. Patients with class III deformities usually complain of substantial back pain, and they present with rigid curves with coronal and/or sagittal malalignment (i.e., SVA>7 cm, PI-LL mismatch>30°, PT>25°, and thoracic kyphosis >60°). These patients most commonly require osteotomy corrections and should be approached via standard open techniques [44].

Conclusion

The Optimal approach to surgical managing adult spinal deformity goes beyond the severity of clinical symptoms and radiographic parameters. Patient demands and physiologic eligibility must be considered in a personalized approach to care. The surgical plan should take into account patient's concerns, expectations, and desired level of function. The risks and benefits of surgical procedures should be assessed. The surgeon should also consider and discuss with the patient alternative plans that might be necessary in case intraoperative incidents oblige a modification of the original surgical plan. Preoperative staging of the patients, based on clinical and radiographic assessments, allows for determination the details of the surgical acts during the procedure. The alignment targets are challenging to define, and recent research discerns different targets based on a better understanding of patients, what they need, and what they can handle. This emphasizes the continued push for individualizing surgical care for adult spinal deformity patients.

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Intraoperative Management of Adult Lumbar Scoliosis

9

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Introduction

While numerous studies demonstrate the benefits of operative correction of adult lumbar scoliosis, these surgeries are not without serious risks [1–4]. Recent studies estimate the rate of complications to be as high as 80 % in certain populations following decompression and fusion [1, 5–7] with significantly greater risk associated with increased age, construct length, number of osteotomies, and revision [1, 5, 8]. Major complications occurring in the perioperative period include, for example, vascular injury, excessive blood loss, deep vein thrombosis, nerve root injury, and deep wound infection as well as life-threatening complications such as sepsis, myocardial infarction, pulmonary embolism, and catastrophic neurologic injury.

The rate of complications associated with operative correction of lumbar scoliosis is not entirely attributable to the procedures alone. Due to the frequently degenerative nature of lumbar scoliosis, the afflicted population tends to be older, often with multiple medical comorbidities. Even in the absence of comorbid conditions, older patients demonstrate diminished physiologic reserve compared to their younger counterparts including cardiac, renal, pulmonary, and immunologic functions contributing to an increased vulnerability to external insults. In a 2007 study of outcomes following adult spinal deformity surgery, authors estimated that patients older than 69 years were nine times more likely to experience a major complication compared to those younger than 69 years [8]. Combined with comorbid disease states, these patients are increasingly susceptible to a cascade of peri- and postoperative complications. Despite the risks associated with advanced age and comorbidity, however, it is important to recognize that these patients with lumbar scoliosis exhibit staggering preoperative disability and have the greatest potential for improvement after surgery [2].

Notwithstanding medical optimization and consideration for patient risk factors, there are a number of perioperative interventions with the potential to significantly reduce the risks associated with these complex procedures. The primary goal of this chapter is to introduce several concepts of intraoperative management with the ultimate goal of reducing complications and improving overall patient safety.

Blood Conservation Techniques

Blood loss volumes ranging from 500 mL to >4 L are not uncommon in spinal deformity surgery, and though no single definition of excessive

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blood loss exists between studies, it is frequently cited as the most common complication [9, 10]. Moller et al., in a prospective study of patients undergoing lumbar spinal fusions, found that instrumented patients experienced an average blood loss of 1.5 L with one patient suffering as much as a 7 L loss [11]. In another study of 199 patients with degenerative lumbar deformity undergoing fusion, more than half of patients experienced blood loss greater than 500 mL, which corresponded with a significantly greater rate of perioperative complications and length of hospital stay [10]. Intraoperative blood loss is predictably correlated with the number of fusion levels and operative time as well as number and type of osteotomies. A posterior vertebral column resection, for example, can be associated with blood loss of 10 L [12]. Excessive blood loss in these settings contributes to greater fluid shifts, which can detrimentally impact cardiac, pulmonary, and renal function [13]. Efforts to reduce perioperative blood loss in major spine surgery are an important step to improve patient outcomes.

In general, the two types of strategies used to prevent the sequela of excessive blood loss are responsive and preventative. Responsive measures are those methods that treat the resulting hypotension and anemia with blood replacement, fluid administration, and medications such as vasopressors. Though these tools are employed with great success in trauma patients with major blood loss, recent investigations examining the ratios and volumes of crystalloids, colloids, and blood products administered to spine patients suggest potentially negative influences on postoperative recovery including, for example, extubation status [14, 15]. These authors suggest that further investigation be pursued to better describe shifts between fluid compartments and optimal resuscitative protocols in this patient population.

Blood transfusions are also not without risks. Even blood salvage procedures which collect and reinfuse autologous blood have been shown to cause minor transfusion reactions including fever, chills, and tachycardia [16] and are associated with significantly increased costs [17]. Furthermore, exposures to allogenic blood products are known to increase the risk for disease transmission, hypothermia, coagulopathy, hyperkalemia, hypocalcemia, and transfusion reactions while increasing data suggest those products impair immune response and potentially increase risk of postoperative infections [18–20]. Though exceedingly rare, transfusion-related acute lung injury, hemolytic transfusion reactions, and transfusion-associated sepsis are now known to be the leading causes of allogenic blood transfusion-related deaths [21, 22]. Until relatively recently, these responsive measures have served as the primary methods used to address excessive blood loss intraoperatively and demonstrate measured success.

In addition to the resuscitative measures used to limit the impact of severe blood loss, several blood conservation methods have been effectively employed for surgeries where blood loss is of significant concern. These preventative methods include controlled hypotensive anesthesia, autologous blood donation, and antifibrinolytic administration to name just a few. Even simple maneuvers such as patient positioning can influence blood loss during spinal surgery [23]. By allowing the abdominal contents to hang freely using a Jackson frame, intra-abdominal pressures are reduced and transmitted to the inferior vena cava and epidural venous system, thereby reducing bleeding at the operative site. Combined or used in isolation, these preventative measures have the potential to drastically reduce perioperative blood loss and improve patient outcomes.

Controlled Hypotensive Anesthesia

Since as early as the 1970s, spine surgeons have advocated for hypotensive anesthesia as a method to reduce blood loss and improve visualization of the surgical field [24]. Several medications have been used historically to achieve a mean arterial pressure (MAP) of 60 mmHg including ganglion blocking agents, calcium channel antagonists, nitroprusside, and nitroglycerin though little evidence which supports the superiority of any one particular agent [25–27]. Reduced intraoperative blood pressure leads to a direct reduction in

bleeding from injured arteries and arterioles while venous dilation decreases bleeding especially from cancellous bony sinuses that do not collapse when transected. Controlled hypotensive anesthesia is a blood conservation technique frequently used in AIS cases with good results; however, caution must be used in its application to older patients. While adolescents may well tolerate a MAP of 50–60 mmHg, patients with carotid artery stenosis or coronary artery disease, for example, are at increased risk of hypoperfusion and end-organ injury. The careful balance of hypotension and perfusion are particularly relevant in the context of deformity surgery given the sensitivity of neurophysiologic monitoring modalities to cord hypoperfusion. This is especially true in deformity surgery that may require a three-column osteotomy in the setting of an already sick or injured spinal cord. Despite the risks, previous studies have demonstrated a reduction in blood loss and transfusion requirements with the use of this technique alone or in combination with other techniques [28–31].

Autologous Blood Donation

Autologous blood donation is another technique frequently practiced in the United States used to decrease rates of allogenic transfusion during spine surgery [32]. The two most common applications of autologous blood donation include pre-donation and acute normovolemic hemodilution. Pre-donation of autologous blood occurs between 1 and 4 weeks prior to surgery and may be supplemented with the administration of recombinant erythropoietin [33]. Acute normovolemic hemodilution is a similar method used to obtain autologous blood for transfusion; however, it is typically performed on the day of surgery with replacement of blood volume using crystalloid fluids to achieve normovolemia [34].

Though pre-donation of autologous blood is proven to reduce rates of allogenic transfusion [35], recent publications have questioned its overall value [36]. Several disadvantages of receiving allogenic blood products are similarly shared with pre-donated blood. Of significant concern, pre-donation and storage of autologous blood is an expensive procedure which stores blood as pRBCs without coagulation factors. Additionally, the procedure of pre-donation does not eliminate the risk of receiving the "wrong" blood and may expire in the event of a rescheduled surgery. Lastly, critics of pre-donation blood programs point to the risk of preoperative anemia; however, the use of recombinant erythropoietin has the potential to reduce this risk [33].

Acute normovolemic hemodilution is a blood conservation method with the benefits of autologous blood donation yet fewer disadvantages compared to pre-donation. Because blood is collected for same-day transfusion, a superior blood replacement, whole blood, is made available for use intraoperatively. Additionally, the expensive procedure of collecting and storing pre-donated blood is avoided while the risk of receiving the "wrong" blood is substantially reduced. And lastly, though normovolemic hemodilution should only be used for patients with normal preoperative hematocrits and recombinant erythropoietin, and other supplements may be used for preoperative augmentation. Despite the demonstrated value of autologous blood donation, national trends illustrate increasing rates of allogenic blood transfusions over the last several years with declines in pre-donated autologous blood transfusions and stable perioperative autologous transfusions [32].

Antifibrinolytics

For generations, clinicians have sought pharmacologic methods to reduce perioperative bleeding and its associated morbidity and mortality. Following the elucidation of the hemostatic pathway, the fibrinolytic system became the logical target of those pharmacologic agents. Derived from bovine lung, aprotinin was the first antifibrinolytic agent introduced into clinical practice in 1950 for the treatment of pancreatitis and later prophylactically to reduce blood loss in complex cardiac surgery [37]. Aprotinin quickly became ubiquitous within several surgical specialties as studies demonstrated an impressive

reduction in postoperative blood loss and transfusion [37–40] by competitively inhibiting plasmin. Despite later safety concerns regarding the use of aprotinin in complex cardiothoracic surgery and its subsequent withdrawal from the US market [41, 42], the benefits of antifibrinolytics have been demonstrated across several surgical specialties leading to their pervasive use [43–48].

The two antifibrinolytics used most widely today are synthetic lysine analogues, tranexamic acid (TXA), and ε-aminocaproic acid (EACA). Both discovered and described by Okamoto in the 1950s [49, 50], these agents act by competitively inhibiting the lysine binding sites of plasminogen, plasmin, and tissue plasminogen activator, thereby inhibiting the lysis of polymerized fibrin. Tranexamic acid is seven to ten times more potent than EACA [51]. TXA and EACA are widely used prophylactically when large blood losses are anticipated including cardiac, trauma, liver, obstetric, neurosurgical, and orthopedic surgeries. Though recent studies employ various dosing regimens for TXA, there are current efforts to determine the superiority of high versus low dosing regimens in randomized controlled studies. Meanwhile, retrospective cardiothoracic studies suggest TXA reduces blood loss more effectively than EACA [52, 53], though no prospective studies involving surgery of the spine support this conclusion.

Numerous studies throughout the orthopedic and spine literature demonstrate the efficacy of TXA and EACA in reducing perioperative blood loss and transfusion requirements [44, 45, 54–59]. In a 2015 study by Xie et al., authors examined more than 50 patients undergoing complex spine deformity correction and found that those patients who received high-dose TXA demonstrated a statistically significant reduction in blood loss (2441 ± 1666 mL vs. 4789 ± 4719 mL) and decreased rate of transfusion compared to controls without an increase in complications [60]. Similarly, in a recent meta-analysis including 11 randomized controlled trials (644 total patients) investigating the use of TXA on surgical bleeding in spine surgery, authors found that TXA reduced intra-, post-, and total operative blood loss, leading to a reduction in the proportion of patients who received blood transfusions [56].

Despite the proven reduction in intraoperative blood loss, the potential complications of antifibrinolysis remain controversial. By the very nature of their mechanism, the antifibrinolytics have the theoretical potential to promote thromboembolic events such as deep vein thrombosis or pulmonary embolism. While recent evidence does suggest that aprotinin increases the risk of myocardial infarct, cerebrovascular accident and death in the context of complex cardiothoracic procedures, no studies to date demonstrate detrimental prothrombotic effects of the lysine analogues EACA or TXA despite their use for more than 50 years [56, 57, 61]. Of more significant concern, in recent years TXA has been linked to the occurrence of seizures, particularly at high doses. In a retrospective investigation of postoperative seizures among patients undergoing aortic valve replacement with cardiopulmonary bypass, authors found 6.4 % of patients who received TXA experienced seizure within 24 hours of surgery compared to 0.6 % of patients who received EACA [52]. Despite this association demonstrated in retrospective studies of cardiothoracic patients, no prospective trials to date support the association between TXA and increased seizure risk. Nevertheless, these authors acknowledge that many questions remain unanswered regarding the unintended effects of TXA and other lysine analogues that necessitate further study on their usage and safety in numerous clinical applications.

Intraoperative Neurophysiologic Monitoring

Risk of neurologic injury is inherent to all spine surgeries and as such many tools have been developed to prevent and identify this complication in the intraoperative setting. Prior to the widespread adoption of intraoperative neurophysiologic monitoring (IONM), studies estimated an incidence of postoperative neurological deficit between 0.5 and 17 % in patients undergoing corrective

surgery for scoliosis with more than half representing partial or complete paraplegia [62–64]. As early as the 1970s, recognizing the frequency and impact of these devastating complications, clinicians utilized advanced techniques of monitoring electrophysiologic potentials in order to predict and prevent serious neurologic insult in real time. Since their introduction, modern IONM has become the standard of care for complex reconstructive spine surgery [65–67], sharply reducing the incidence of postoperative neurologic deficits [66–68]. Following extensive research and broad uptake, in 2009 the Scoliosis Research Society concluded that neurophysiological monitoring is the "preferred method for early detection of an evolving or impending spinal cord deficit," with the Stagnara wake-up test as a useful adjunct [69].

Stagnara Wake-Up Test

Prior to the popularization of IONM during spine surgery, the Stagnara wake-up test was routinely used to assess neurologic function in the semiconscious patient after instrumentation prior to closure [64, 70]. In 1973, Vanzelle et al. published their principal work describing case reports of routine motor assessments in the awakened patient during surgical correction of severe spinal deformity [70]. During this gross assessment of motor function, patients are asked to move their hands and feet to predict postoperative paraplegia. Authors demonstrated in this study that in some circumstances, patients regained voluntary motor control after initial loss followed by removal of hardware.

Though the wake up test is easily performed and reliable in predicting postoperative motor deficit, clinicians note several practical limitations. In order to perform the wake-up test, the patient must be able to follow commands and is necessarily brought to a semiconscious state with weaning of anesthesia, a process that can take several minutes, prolonging intraoperative time and decreasing the potential for neurologic recovery following injury. Furthermore, strong proponents of IOMN note the delay in injury identification and the challenge in discerning the inciting event or instrumentation. Despite these limitations, given its reliability to predict neurologic deficit, the wake-up test is frequently the standard against which other methods of neurophysiologic monitoring are compared.

The earliest applications of modern neurophysiologic monitoring techniques date back to the 1940s whereby physicians examined changes in electrical potentials detected on the scalp in response to electrical stimulation of peripheral nerves [71]. Since that time, significant advancements in technology and neuroscience have propelled the field of neurophysiology, allowing examiners to closely monitor various pathways between the central and peripheral nervous systems. Application of this field in the surgical setting allows clinicians to monitor neurologic status while the patient is under anesthesia and unable to participate in the traditional neurologic exam. For nearly half a century, clinicians have utilized these advanced methods of neurophysiologic monitoring to improve safety during complex spine procedures.

Somatosensory Evoked Potentials

Somatosensory evoked potential (SSEP) monitoring was one of the earliest applications of IOMN and continues to be the most widely used modality today. These potentials are generated with stimulation of peripheral nerves distal to the spinal cord region being assessed and measured at the corresponding sensory cortex. SSEPs are evaluated with regard to amplitude, latency, and signal velocity and may be continuously monitored throughout surgery. Given our understanding of the somatosensory pathway, SSEPs illustrate the integrity of the dorsal column-medial lemniscus pathway including the peripheral nerve, dorsal column, medial lemniscus, thalamus, and primary sensory cortex. Generally, the median and ulnar nerves are utilized for SSEP monitoring in the upper extremity while the posterior tibial or peroneal nerves are used in the lower extremity. Intact, this pathway mediates tactile sensation, vibration, and proprioception.

When compared with other IONM modalities, SSEP monitoring has important advantages. The simple, low-amplitude characteristics of the SSEP waveform make it a highly specific indicator of neurologic injury. In a 1995 study of more than 50,000 scoliosis cases in which SSEPs were used, authors calculated a sensitivity and specificity for new postoperative motor defects of 92 % and 98 %, respectively [66]. Subsequent studies have reported sensitivities ranging from 25 to 52 % with specificities in the range of 95–100 % [68, 72–75].

Though SSEP monitoring is the most frequently used IONM modality, there are several limitations to its use as a standalone tool. As discussed previously, SSEPs provide information regarding the integrity of the dorsal column-medial lemniscus tract with excellent reliability [76–78] without providing information regarding corticospinal function. SSEP monitoring can be critically important, for example, while passing sublaminar wires, a notable opportunity for direct injury to the dorsal columns, though it is of little utility in the event of nerve root injury. Additionally, SSEP interpretation can be confounded by systemic conditions in the absence of neurologic injury. Hypotension, hypothermia, hypocarbia, hypoxemia, anemia, and even specific anesthetics all have the potential to attenuate the SSEP signal. Lastly and perhaps most critically, SSEP interpretation requires temporal summation and averaging which can delay detection of an acute injury. Dependent on ambient noise, detection of a significant signal change may lag by 5 min or more from the time of injury reducing the window of opportunity for successful intervention. In a 2004 comparison of SSEPs and motor evoked potentials (MEPs), authors found that SSEP signal alterations lagged behind those of the MEPs by 16 min on average, with one patient demonstrating a 33-min delay in detection [74].

Despite the various limitations of its use, studies demonstrate that SSEP monitoring reduces rates of postoperative neurologic deficit. In a retrospective review of 295 patients undergoing spinal stabilization following acute injury, authors identified new postoperative neurologic deficit in 0.7 % of patients monitored intraoperatively with SSEP compared to 6.9 % of patients who were unmonitored or tested by wake up alone [79]. In a similar comparison of patients undergoing cervical spine surgery, Epstein et al. identified eight (3.7 %) of 218 unmonitored patients with postoperative quadriplegia compared to 0 instance in 100 patients monitored by SSEP [80].

Motor Evoked Potentials

The direct monitoring of the corticospinal pathway via motor evoked potentials (MEPs) gained widespread use following improvements to Merton and Morton's 1980 landmark work describing transcranial stimulation of the motor cortex. MEPs are similar to SSEPs in that they are used to assess a specific pathway between the central and peripheral nervous systems and are evaluated with regard to amplitude, latency, and signal velocity. In contrast to SSEPs, however, MEPs are generated with transcranial stimulation of the motor cortex and measured distally at multiple upper and lower extremity muscle groups. In this way, MEPs illustrate the integrity of the entire motor axis including the motor cortex, corticospinal tract, nerve root, and peripheral nerve similar to the SSEP and the somatosensory pathway. Intact, the corticospinal pathway mediates voluntary muscle contraction.

There are several distinct advantages to MEP monitoring when compared to SSEP. Unlike SSEP monitoring which is highly specific in predicting postoperative somatosensory deficit, MEPs describe the integrity of the motor axis, a domain of significant functional importance. Furthermore MEP monitoring demonstrates excellent sensitivity in detecting postoperative motor deficits and even demonstrates good reliability in detecting spinal cord ischemia [81–83]. In a 2007 study involving more than 1100 cases of scoliosis, MEP monitoring demonstrated 100 % sensitivity in identifying postoperative motor loss, compared to SSEP which demonstrated a sensitivity of 43 % [68]. Several other studies report similar MEP sensitivities ranging from 75 to 100 % and specificities ranging from

84 to 100 % [68, 73–75, 84–87]. Lastly, MEP monitoring in contrast to SSEP monitoring, which requires averaging of potentials for interpretation, allows for immediate assessment of corticospinal integrity without delay.

Though the use of MEP monitoring confers important advantages compared to SSEPs, significant disadvantages exist as well. The ability to monitor the entire motor axis from the cortex to the peripheral nerve and muscle requires a complete and functional pathway. As such, the utility of MEP monitoring is significantly diminished with the use of inhalation anesthetics which decrease MEP amplitude and increase latency [88] and muscle relaxants [84] which interfere with transmission at the neuromuscular junction. For these reasons total intravenous anesthesia is the anesthetic of choice during MEP monitoring [82], though in practice low-dose halogenated agents such as isoflurane are frequently used. Similar to the effects on SSEP signal, systemic conditions such as hypotension, hypothermia, hypocarbia, hypoxemia, and anemia may attenuate MEPs, further complicating their interpretation. Unlike SSEP monitoring, which can be performed continuously throughout surgery, MEP monitoring is performed intermittently though permitting immediate assessment after high-risk maneuvers. Lastly, and of great importance, the characteristics of the MEP waveform make their interpretation challenging [89]. MEPs demonstrate high amplitude with much greater variability when compared to SSEPs. A change in signal amplitude following instrumentation therefore can be the result of neurologic insult or a characteristic of the waveform. For these reasons, several definitions of warning criteria are used in the interpretation of MEPs with varying sensitivities and specificities.

Electromyography

Electromyography (EMG) is another valuable tool used by clinicians to monitor neurophysiologic status in the intraoperative setting. Briefly, EMG is a procedure which monitors compound action potentials in specific muscle groups either with (triggered EMG, tEMG) or without stimulation (spontaneous EMG, sEMG) proximally. Because postoperative radiculopathy is a complication encountered more frequently than spinal cord injury, EMG monitoring is of particular utility in the setting of spinal instrumentation, providing the ability to monitor selective nerve roots at risk of injury.

Spontaneous EMG (sEMG) and triggered EMG (tEMG) are two common applications of EMG with distinct applications, advantages, and information conveyed. sEMG monitoring is performed without stimulation of the nerve root, producing a continuous recording of activity within select muscle groups. At baseline, a healthy nerve root does not produce activity, whereas irritation or injury during surgery results in distinctive patterns of neurotonic discharges. Phasic type discharges, for example, are most often associated with blunt mechanical trauma, whereas tonic waveforms are frequently the result of nerve ischemia due to traction, heat from electrocautery or irrigation [90]. tEMG, on the other hand, is a technique which makes use of nerve stimulation to record conduction velocity and amplitude at the muscle. Based on this principle, tEMG is a particularly useful modality in assessing pedicle screw placement [91]. A pedicle screw, well-positioned in cortical bone, should be electrically insulated. Any change observed in EMG following direct stimulation of that screw therefore is assumed to be in close contact with the nerve root, and further investigation of pedicle integrity should be promptly pursued.

Both sEMG and tEMG demonstrate excellent sensitivity in detecting neurologic compromise. In a retrospective analysis of more than 200 patients undergoing thoracolumbar spine surgery with sEMG monitoring, Gunnarsson et al. identified 6.6 % of patients with new postoperative neurologic symptoms, all of which demonstrated significant EMG activation intraoperatively. Despite a sensitivity of 100 %, authors also identified many instances of EMG activation without subsequent neurologic deficit resulting in a specificity of only 23.7 % [72]. This seemingly low specificity however must be interpreted with

caution given the ability to modify a procedure in response to EMG changes and therefore prevent neurologic impact. Similar to sEMG's ability to detect nerve root injury, tEMG shows excellent accuracy in assessing pedicle screw placement [91, 92]. In a prospective study confirming screw position by CT scan, authors evaluated more than 500 pedicle screws in 90 patients and determined that a stimulation threshold greater than 15 mA provides 98 % confidence in accurate screw placement [93]. Due to the high sensitivity and utility of sEMG and tEMG intraoperatively, both have emerged as common methods of preventing neurologic injury during spine surgery.

Multimodal Intraoperative Monitoring (MIOM)

Multimodal monitoring, as the name suggests, combines two or more of the IONM modalities discussed previously and as such is capable of enjoying the benefits of individual methods while compensating for their limitations. A combination of SSEP and MEP monitoring, for example, in scoliosis surgery confers the ability to monitor both ascending sensory and descending motor pathways with the benefit of SSEP continuous observation and prompt detection of injury with the use of MEPs. With the careful interpretation of a combination of these modalities, patients are benefitting from sensitivities and specificities approaching 100 % [74, 94–96].

Teamwork

An increasingly prominent feature among all surgical specialties is the role of teamwork and other nontechnical skills in delivering safe, high-quality healthcare. Efforts to reduce the incidence of preventable complications have spawned numerous studies which highlight the impact of experience and communication on patient safety. Several studies, for example, demonstrate that nearly 60 % of major perioperative complications are attributable to failures in nontechnical skills such as communication, teamwork, and leadership [97–100]. In response to these staggering statistics and their impact on patient outcomes, the spine community has begun to employ specialized spine teams and protocols with the shared purpose of reducing perioperative complications, morbidity, and mortality.

Specialized Surgical Teams

With the extraordinary increase in knowledge and technical skill necessary for complex surgical procedures to be performed successfully, specialized surgical teams are now commonplace. The perioperative team including surgeons, anesthetists, nurses, and technicians who routinely participate in these complex procedures is inherently more experienced with advanced knowledge and skills unique to the specialty and patient population. With the use of these highly specialized teams, efforts to improve team communication and trust result in reduced intraoperative time and enhanced patient safety [101, 102]. Furthermore, proponents of specialized surgical teams note the unique technical knowledge and skills required for complex surgical instrumentation, technological operation, and patient management in a high-volume surgical practice [102, 103]. For these reasons, specialized teams are already utilized in nearly all surgical specialties, with cardiovascular, orthopedic, and neurosurgery being the most common.

The successful performance of any team, be it in sport or surgery, demands trust and communication between all team members and leadership. The significance of these team dynamics has been repeatedly demonstrated by studies of wrong-site operations, surgical checklists, and timeouts [99, 102, 104–106]. Specifically in regard to surgery of the spine, the importance of communication and trust among team members can be illustrated in the use of intraoperative neurophysiologic monitoring (IONM). As discussed previously, each of the IONM modalities requires careful interpretation of signal changes with significant implications on postoperative neurological function. IONM activations therefore must be communicated and investigated

early to prevent permanent injury. Consequently, the effective use of this advanced technology necessitates an ongoing and composed conversation between an anesthetist, monitoring personnel, and surgeon. Finally, with improved communication, trust, and experience, the entire surgical team is poised to prevent and identify even the rarest complications including, for example, postoperative visual loss and myocutaneous and perfusion injuries.

Dual Surgeon Approach

Especially within the field of spine surgery, where elderly patients with increasingly complex spinal deformity make up a significant proportion of patient volume, efforts to reduce perioperative complications, intraoperative time, and blood loss are imperative. A single intervention with the goal of achieving each of these reductions is with the use of two attending surgeons. This strategy has long been employed within the field of spine surgery and utilizes two surgeons that act as equal members of the surgical team rather than acting in primary and secondary roles.

While logic and empiric evidence support the concept that two heads are better than one, many studies also demonstrate the benefits of this approach in spine and other surgical specialties [101, 107–110]. Several studies within the spine literature, for example, demonstrate a reduction in operative time, blood loss, and rates of major complications with the use of two attending surgeons compared to one [101, 109, 110]. The odds of developing a postoperative surgical site infection are even reduced with the use of two attending surgeons [111]. A recent study of complex deformity procedures requiring pedicle subtraction osteotomies demonstrated a 3 L reduction in blood loss and 2.5 hr reduction in operative time when using two attending surgeons compared to one [101]. In a similar study of operative treatment of adolescent idiopathic scoliosis (AIS), authors demonstrated that the use of two surgeons decreased operative time, blood loss, need for allogenic transfusion, postoperative narcotic usage, and even length of stay [110].

Surgeon experience has been investigated as a potential cause of improved outcomes observed between one versus two attending surgeon approaches. A recent study by Cahill et al. compared outcomes of AIS cases between surgeons with greater than 5 years of experience with those less than 5 years. Authors demonstrated significant operative and postoperative differences including greater blood loss and longer intraoperative times among the less experienced surgeons. Patients treated by more experienced surgeons also demonstrated significantly better patient-reported outcome measures with shorter hospital stays [112]. In another study assessing the accuracy of free-hand thoracic pedicle screw placement by Samdani et al., authors found that the rate of medial breach was significantly lower for more experienced surgeons [113]. Though surgeon experience certainly confounds the impact of the two-surgeon approach to spinal deformity correction, there is no doubt that having two attending surgeons operate together increases the amount of skill and experience available during a given procedure.

Spine Surgery Protocols

Due to the complexity of treatment and heterogeneity of the patient population, few randomized, controlled, level one studies exist within the field of complex spinal deformity, challenging the creation of evidence-based protocols. Though protocol-based approaches are proven to reduce complications and improve outcomes across several medical and surgical specialties [114–118], the treatment of spinal deformity remains largely individualized based on patient goals and surgeon experience. Despite this challenge in creating spine protocols, operative teams at several institutions have made significant strides in their development and institution. Few protocols of this kind exist currently; however, early studies indicate that these goal-directed and evidence-based protocols lead to fewer complications and improved outcomes [119–121].

The Northwestern High-Risk Spine Protocol is one example of a comprehensive management

protocol implemented within the pre-, peri-, and postoperative phases of surgery with the goal to reduce complications, morbidity, and mortality [119]. The protocol is initiated preoperatively, when high-risk patients are identified based on surgical complexity and comorbid conditions. At that time, with the combined efforts of the surgeon, patient, and necessary medical providers, patients receive a comprehensive medical evaluation with specific goals to determine patient risk, team expectations, and mechanisms to optimize medical conditions. The preoperative phase additionally ensures that providers are well-versed in the patients' health status with an established line of communication [120]. Intraoperatively, there is an emphasis on team communication with hourly updates on goals and risks (if not more frequently) to improve recognition and response to complications. Finally, in the postoperative period and throughout each phase of the protocol, there are prescribed, evidence-based laboratory assessments and methods of resuscitation.

Another recent example of a standardized, systems-based approach to deformity surgery comes from leaders at the Virginia Mason Medical Center. The Seattle spine team's Major Spine Protocol utilizes a dedicated spine team composed of two attending surgeons (one neurosurgeon and one orthopedic) as well as a two-member anesthesia team with a dedicated anesthesia technician [121]. In addition to several of the components shared with the High-Risk Spine Protocol discussed previously, this protocol involves the collaboration with several other specialists in a formal conference setting. In attendance are internists, rehabilitation physicians, at least 2 members of the dedicated spine anesthesia team, coordinating nurses, and the operative surgeons. At the conclusion of this conference, a written summary is generated (including relevant medical history, laboratory values, and screening tests) and provided to all conference participants. Initial studies evaluating the impact of this protocol are encouraging and estimate a reduction in complications by more than 50 % compared to historical controls [121]. Authors similarly demonstrated a reduction in perioperative return to the operating room and lower rates of wound infection, thromboembolic complications, and neurological complications.

Despite growing evidence supporting the benefits of surgical teams, the experience of these authors suggests that the components and practice of teamwork may differ substantially between institutions with great success and that there is no single best method used to achieve that end. We therefore do not specifically endorse the beforementioned approaches but rather point to their evolution which may benefit patients and practitioners elsewhere.

Conclusion

Given the vulnerability of the patient population and risks associated with spine surgery, it is important to recognize and capitalize on any procedures which may reduce risk of complications and improve patient outcomes. There are several perioperative interventions with the potential to significantly reduce the risks associated with complex spinal deformity surgery including, for example, the use of antifibrinolytics, IONM, and team-based approaches with continued advancement and research involving these perioperative interventions patients will certainly benefit.

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Biologics for Adult Lumbar Scoliosis

10

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Introduction

Adult scoliosis, arising either as a sequelae of untreated adolescent idiopathic scoliosis or as a de novo degenerative deformity, has been estimated in as much as 68 % of adults over the age of 60 [1]. Anwar et al. further reported that adult lumbar scoliosis in particular was significantly underreported, particularly in scoliotic curves <20° [2]. Many patients with adult lumbar scoliosis can be managed nonoperatively. However, in patients with subsequent neurological deficits related to stenosis, significant sagittal imbalance, or chronic pain as a result of the underlying deformity, surgical correction with or without neurologic decompression can offer relief and return to activities of daily living. While the clinical presentation of adult lumbar scoliosis is variable, the disease presents a significant structural and mechanical challenge. Depending on the patients' symptoms, the surgical goals are to provide neurologic decompression, correct scoliosis curve magnitude, reduce sagittal imbalance, and maintain long-term stability of the construct for those patients with neurological and structural deficits [3, 4]. Operative indications for degenerative lumbar scoliosis are equally as variable as the clinical presentation, though lumbar curves with >30–40° are commonly considered for operative treatment [3, 5]. The Lenke-Silva Treatment Levels I–VI matrix offers distinct procedural options for lumbar scoliosis indications, which range from decompression only to decompression with instrumentation utilizing varying surgical approaches, construct lengths, and need for osteotomy inclusion [3].

Ultimately, the achievement of solid mature fusion mass is of paramount importance within the field of adult spinal deformity to maintain correction and prevent progression. While various forms of spinal fixation and instrumentation can provide immediate rigidity and stability, ultimately the longevity of arthrodesis depends on bony union between motion segments. Consequently, increased efforts in assessing and treating deformity have provided insight into ideal methods of correction, fixation, and ensuring arthrodesis, particularly in the field of osteobiologics as a means of optimizing surgical management and preventing adverse outcomes [6]. Arthrodesis can be achieved through the adjunct use of autologous and alternative bone grafts to create fusion masses [7–9]. Osteobiologics retain particular value in this surgical context, given persistent debate regarding factors contributing to the etiology and progression of degenerative scoliosis. Vanderpool et al. reported a 36 % osteoporosis incidence and a 38 % osteomalacia prevalence in elderly

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(≥50 years) scoliotic patients, driving an initial hypothesis that the etiology of degenerative scoliosis is related to increased metabolic bone disease incidence [10]. This assertion has since been contested, though osteopenia and osteoporosis have been implicated in curve progressions, instrumentation failure, and proximal junctional kyphosis in adult spinal deformity [3, 11, 12].

Significant technological strides have been made in the field of alternative bone grafts as substitutes to autologous iliac crest bone graft (ICBG), which still remains the gold standard for spinal fusions. Other graft substitutes include bone marrow aspirate (BMA), mesenchymal stem cells, bone morphogenetic protein (rhBMP-2), demineralized bone matrix (DMB), ceramics, and gels. These substances differ from ICBG in their relative osteoconductive, osteoinductive, and osteogenic properties, thereby imparting varying levels of scaffolding and support for fusion promotion. The effectiveness of these biologic substitutes and the level of evidence supporting their use are particularly important for complex scoliosis corrective procedures and are summarized in Table 10.1. Indeed, complication rates are high in most reported series examining lumbar scoliosis, often ranging from 20 to 40 %. The most significant complications requiring revision procedures, including symptomatic pseudarthrosis, wound infection, proximal junctional kyphosis (PJK), and instrumentation failure, reported in 17–37 % of cases [21, 22]. In order to prevent pseudarthrosis and optimize fusion rates, it has been advocated that surgeons utilize supplemental biologic substances for longer constructs where insufficient autograft is available as well as for fusions crossing the lumbosacral junction [23–25]. Osteobiologic substitutes also offer an alternative to harvesting autograft, which is also not without complications.

Given steady surgical volume increases for adult lumbar spinal pathology, with arthrodesis representing the most common reason for autologous bone grafting, this chapter will explore the utility of various osteobiologic substances in the surgical setting of adult lumbar scoliosis [26, 27]. Specifically, this chapter will provide an overview of ICBG, rhBMP-2, BMA, DMB, and ceramics and gels, with a focus on long-term arthrodesis rates and complications associated with degenerative lumbar scoliosis correction, including adjacent level disease, proximal junctional kyphosis (PJK), pseudarthrosis, and instrumentation failure.

Table 10.1 Highest level of evidence and comparative pseudarthrosis rates of spinal arthrodesis biologics

Biologic substance	Highest level of evidence	Pseudarthrosis rates
ICBG	Gold standard	0–10 %
Local autograft	Level 1 [13]	5–10 %
Unconcentrated bone marrow aspirate + scaffold	Level 1 [14]	1.4–16 %
Bone marrow aspirate concentrate	Level 2 [15]	Unreported
Fresh-frozen/ freeze-dried allograft	Level 1 [16]	8.7–14 %
Demineralized bone matrix	Level 1 [17]	3.2–14 %
Ceramics	Level 1 [18]	7.5 %
Platelet gels	Level 2 [19]	4–10 %
Bone morphogenetic protein	Level 1 [20]	0–8 %

Autograft

Traditionally, autologous bone has been utilized as a foundation for arthrodesis [28]. Various forms of autologous bone available for use in spine procedures include: iliac crest bone graft; local bone harvested during a laminectomy, facetectomy, corpectomy, vertebrectomy, or osteotomy; and bone marrow aspirate. However, each method carries with it its own set of limitations in terms of ability to achieve fusion as well as complication profile.

Iliac Crest Bone Graft

The anterior and posterior iliac crests have long been utilized as a source for harvesting autogenous bone graft [29, 30]. In many cases, ICBG is readily available within the same surgical incision for procedures involving the lumbosacral

spine. For anterior spinal or posterior procedures not involving the lumbosacral region, the anterior or posterior iliac crest may be included within the surgical field and accessed through a separate incision to harvest cortical, cancellous, or corticocancellous graft. Cancellous graft provides an osteogenic, osteoinductive, and osteoconductive scaffold while cortical grafts can provide structural support [30].

ICBG is often considered the gold standard for obtaining solid arthrodesis in spinal surgery [31, 32]. In uninstrumented lumbar posterolateral fusion procedures, fusion rates of 40–65 % have been reported [33–36]. With the addition of rigid internal fixation, arthrodesis rates up to 95 % have been reported [35–40]. Much variability on fusion rates exists in the literature because investigations are performed on a multitude of surgical fixation techniques, as well as different radiographic methodologies (plain radiograph versus CT scan) used to determine whether fusion has occurred. ICBG used in isolation for adult spinal deformity has demonstrated 72 % fusion rate [7], suggesting that long lumbar fusions may require supplementary sacrum grafting.

Harvesting from the iliac crest is not without complications, however. Major complications such as arterial or neurological injury, iliac fractures, abdominal content injuries, and deep wound infection are rare. Minor complication rates of 10–50 % have been reported, including superficial infection, hematoma or seroma formation, donor site numbness, and persistent postoperative donor site pain [30, 41–43]. Typically, persistent donor site pain has been reported as the most common complication in 2–60 % of patients [7, 37, 38, 44–46]. Accessing the iliac crest through a separate incision and obtaining tricortical full thickness graft have the highest prevalence of complications [47]. Similarly, anterior harvest has been shown to have significantly higher complications compared to posterior harvesting, including magnitude and duration of postoperative donor site pain [29]. In addition, ICBG harvest complications can lead to worse patient-reported disability in terms of ability to perform activities of daily living (ADLs) and work activity [31]. It must be noted that confounding factors such as surgical technique, harvest of cancellous versus corticocancellous graft, volume of crest harvested, and performance of concomitant lumbosacral procedures all may affect the interpretation of postoperative donor site pain. In comparing low lumbosacral to thoracolumbar fusion procedures, patients with fusion above L3 reported significantly less donor site pain, suggesting that patients may not be able to differentiate between lumbosacral back pain and pain from the harvest site [48]. A subgroup analysis of the Spine Outcomes Research Trial (SPORT) found no difference in patient-reported outcomes or complication rates between patients that had fusions performed with ICBG and those who had no ICBG [49]. This discrepancy has been demonstrated in other studies as well [48, 50, 51]. Ultimately, the amount of pain directly attributable to the iliac crest harvest is a difficult variable to define.

Local Autograft

Given the complications, limited supply, and additional operative time associated with harvesting ICBG, autologous local bone obtained during the operative procedure can be used as an ICBG alternative that maintains many of the biological benefits of the autologous bone. Depending on the volume obtained, the laminectomy-derived bone may be applied in isolation or used as a bone graft extender with ICBG [52, 53]. A 90–95 % fusion rate has been demonstrated in the operative management of single level lumbar spondylolisthesis using the laminectomy-derived bone for posterolateral fusion [13, 54]. Lee et al. similarly observed bilateral fusion masses in 62 % and unilateral fusion masses in 31 % of patients receiving in situ local bone from spinous processes and laminae used in instrumented posterolateral lumbar fusion [55]. Single-level posterior lumbar interbody fusion has shown similar union rates between the local bone and iliac crest graft [56]. The study of the local bone in isolation for lumbar scoliosis deformity cases is however understudied. One report, Violas et al. considered the efficacy of local autograft bone utilization with Cotrel-Dubousset instrumentation for scoliosis correction [57]. Successful fusion was deter-

mined radiographically in all double-curve cases with an average of 10 levels fused.

Bone Marrow Aspirate

Autologous local bone alone may not provide sufficient volume of graft to obtain adequate union rates in posterolateral fusions of more than two levels [58]. Bone marrow aspirate (BMA), typically the iliac crest or vertebral body, contains osteoprogenitor cells and has shown promising results in spinal arthrodesis procedures and when combined with the autologous local bone has shown similar lumbar fusion rates with ICBG alone [14, 59, 60]. Though aspirate does not provide as high a concentration of stem cells as ICBG, there is some evidence supporting clinical use to induce bone formation [61]. However, typically BMA has been applied to allograft matrices or ceramics as an autograft alternative and has shown similar arthrodesis rates compared to ICBG in posterolateral fusion [62, 63].

In BMA harvested from a 35-year-old patient, there is roughly one mesenchymal stem cell (MSC) per every 250,000 cells and one hematopoietic stem cell (HSC) per every 10,000 cells, the two principal drivers of bone growth and formation. With such small concentrations of MSC's and HSC's even in ideal candidates, concentration of the aspirate has been recommended to improve efficacy. A recent study using bone marrow aspirate concentrate (BMAC) in conjunction with allograft has shown equivalent arthrodesis rates to autologous ICBG [15]. Also, several recent studies using BMAC to treat nonunions and osteonecrosis have shown equivalence with autografting techniques [64–66]. These studies conclude that BMA should be supplemented through either concentration or additional growth factors; however, studies on clinical efficacy are currently lacking [67, 68].

Allograft

In response to the aforementioned complications associated with iliac crest bone graft, a significant focus has been placed on the utility and effectiveness of allograft alternatives for successful lumbar fusion. Allograft products, bone harvested from cadaveric donor tissues, encompass extenders and/or substitutes to ICBC. These grafts serve primarily as an osteoconductive matrix with no self-supplied osteogenic or osteoinductive properties. The benefits of intraoperative allograft use include decreased operative time, reduced blood loss, alleviation of donor site morbidity, and elimination of the need to harvest autogenous bone. Allograft is available in three different forms: fresh-frozen, freeze-dried, and demineralized freeze-dried, each imparting differential structural strength [69].

Fresh-Frozen and Freeze-Dried Allograft

Allograft bone, rather than inducing de novo bone formation like autogenous bone graft, promotes osteoconduction due to its matrix: the porosity provides a scaffolding material for new bone growth to create a solid fusion. The three-dimensional scaffold matrix provides an appropriate environment for bone cells and bone morphogenetic proteins (BMPs): migration, adhesion, and proliferation. Fresh-frozen and freeze-dried allografts differ in their processing, and consequentially retain specific advantages and disadvantages. Fresh-frozen allografts have the simplest preparation protocol, carry a higher risk of disease transmission and generation of an immune reaction, and are typically implemented as a graft extender or scaffold adjunct rather than used in isolation. As such, the efficacy of isolated allograft for use in lumbar spine fusions is not very well supported. Allograft processing mitigates the osteoinductive potential, and consequently the graft is not as readily incorporated by the host. An et al. compared arthrodesis achievement among 144 posterolateral lumbar fusion patients using side-by-side grafts comparing: (1) iliac autograft, (2) demineralized cancellous chips, (3) demineralized cortical power, (4) demineralized cortical powder mixed with autograft, or (5) mineralized cancellous chips [70]. Radiographic analysis at 1-year postoperative follow-up revealed significantly lower fusion rates in allograft alone or in combination with

autograft. In a comparable study design, Jorgenson et al. found that ethylene oxide-treated allograft was inferior to autograft for achievement of posterior lumbar fusion at 1-year postoperatively [71]. Thalgott et al. have conversely observed success in using fresh-frozen allograft as a structural interbody graft for circumferential lumbar fusions [16]. The authors reported a greater fusion rate of 77 % in patients receiving fresh-frozen allograft versus 65 % in freeze-dried allograft cases, with the latter group displaying a significantly higher likelihood of pseudarthrosis at 24-month follow-up.

Beyond concerns surrounding efficacy, allograft use is correlated with a risk of disease transmission that is inherently absent from autograft. As such, the FDA has implemented strict regulations related to the procurement, testing, and distribution of allograft. Reported rates of disease transmission are 1 in 1.6 million with fresh-frozen allograft and 1 in 2.8 billion with freeze-dried allograft [72]. There has been only one documented case of HIV transmission in the setting of spine surgery in 1992 prior to FDA regulations [73].

Demineralized Bone Matrix

Demineralized bone matrix (DBM) is a family of allograft bone that is derived via demineralization of human corticocancellous bone by means of acid extraction. The remaining matrix is composed of non-collagenous proteins, and osteogenic growth factors, including BMPs, and collagen fibers. DBM possesses a moderate degree of osteoconductive ability based on these properties. Given that DBM is derived from human tissue, its quality is affected by donor-specific characteristics such as age and bone quality and has disease transmission rates similar to those of the allograft bone [74, 75].

The purported advantage of DBM over the allograft bone is the isolation of BMPs through the demineralization process, thereby imparting osteoinductive potential to the product. The wide variability in production of DBM products, however, had caused concern over the extent to which DBM actually contributes osteogenic potential. There have been few well-designed randomized clinical trials that document the efficacy of DBM in lumbar spine fusion. Animal models, such as that of Peterson et al. have compared spine fusion rates between DBM (Synthes) and various other products, such as Grafton putty (Osteotech) and AlloMatrix injectable putty (Wright Medical Technology) [76]. Analysis of single-level posterolateral arthrodesis in athymic male rates revealed varying amounts of residual demineralized bone matrix and new bone formation, with Grafton eliciting the greatest radiological and histological evidence of fusion [76].

Despite limited data, several clinical studies have supported the use of DMB as a bone graft extender in posterolateral lumbar fusion procedures. Cammisa et al. conducted a multicenter, prospective, controlled trail investigating the effectiveness of DBM as a graft extender for ICBG in the setting of posterolateral instrumented lumbar fusions [77]. Of 120 patients enrolled, a comparable fusion rate was observed in both treatment arms—52 % for patients receiving Grafton DBM and 54 % with autograft. These results signified the potential for DBM to act as an effective extender, decreasing the amount of ICBG required for solid arthrodesis. The pilot study of Schizas et al. supports this recommendation; in evaluating the radiographic and clinical outcomes of 59 consecutive patients undergoing 1- and 2-level posterolateral instrumented lumbar fusion, the authors failed to observe a significant difference in a 1-year fusion status between DBM mixed with autograft/BMA versus isolated autograft (69.7 % vs. 76.9 %, p=0.57) [78]. Similarly, in a prospective randomized study, Kang et al. compared fusion rates among single-level instrumented fusion patients receiving either local autogenous bone and Grafton DBM or ICBG [17]. Final fusion rates among 41 included patients at 2-years were 86 % (Grafton Matrix) versus 92 % (ICBG), though this difference in rates was not statistically significant. There was also a nonsignificant trend for improved clinical outcome scores in the Grafton group. In another study, Thalgott et al. evaluated clinical and radiographic outcomes for patients undergoing instrumented posterolateral fusion [79]. The authors found that patients receiving

coralline hydroxyapatite with an additional 10 cc Grafton DBM experienced lower fusion rates (89.3 %) compared to those that did not receive the DBM addition.

The significant variability of DBM's osteoinductive properties between donors renders its use in isolation rare. Application of DBM may be best in conjunction with autogenous bone or marrow to expand the graft volume with particular effectiveness when supplementing arthrodesis combined with stable internal fixation [6, 80].

Cellular Bone Matrix

Similar to mesenchymal stem cells obtained through autologous bone marrow aspirate, several commercial products are available consisting of prepared, cryopreserved mesenchymal stem cells harvested from cadaveric tissue (bone, adipose, or placental tissue) embedded within an allograft carrier [81]. Preliminary retrospective studies have reported fusion rates during interbody procedures of over 90 % [82–84]. However, there is currently a lack of randomized clinical trials evaluating the efficacy and safety profile of cellular bone matrices.

Ceramics

Ceramics are matrices of inorganic, nonmetallic atoms held together by ionic and covalent bonds [85]. Given that the capacity of each biologic is dependent upon its structural, cellular, and biochemical properties, ceramics are prepared to mimic the mineral phase of the bone [86]. Ceramic materials used in spine surgery include calcium sulfate and calcium phosphate, particularly used in the setting of implant coatings and defect fillers. Bone mineral and ceramic matrices display similar crystal structure and molecular compositions as the bone and yield an osteoconductive surface for arthrodesis [87]. For example, Pro-Osteon and Interpore are two frequently employed hydroxyapatite biologics made by application of extreme heat to the calcium phosphate body of a coral, *Porites astreoides*, which was chosen for its pore size—comparable to the bone. There are several preparations of calcium phosphate and calcium sulfate that display different characteristics as bone graft extenders, with optimal remodeling matching the degradation and remodeling profile of the bone. However, ceramics lack the organic phase of the bone and are therefore brittle with low tensile strength and significantly higher modulus of elasticity than the bone.

Hydroxyapatite and tricalcium phosphate (TCP), the ceramic forms most frequently employed in medicine, are purely osteoconductive and are replaced by the host bone through a process of creeping substitution. They exist in the forms of powders, pellets, putty, and injectable cements. Hydroxyapatite is the most studied calcium phosphate material since the 1970s [88]. Hydroxyapatite directly bonds to the bone, allowing for osteoblast proliferation into its scaffold [89]. TCP has similar biocompatibility of hydroxyapatite formations and comparable tensile and compressive strength to the bone but dissolves more rapidly in situ.

Ceramic-based bone grafts have been widely used in spinal surgical procedures to reduce the complications associated with autograft. However, recent studies in the lumbar spine do not present clear support for its use [90]. For example, Sathira-Angkura et al. in 2011 reported "doubtful fusion" in 22 of 23 patients at a 2-year follow-up when hydroxyapatite was mixed with autogenous bone marrow in posterolateral lumbar fusion [91]. Similarly, Acharya et al. prematurely ended a study after 95 % of the hydroxyapatite group had poor consolidation of the graft after 1 year [92]. However, the study and control groups in examination of hydroxyapatite have generally been of poor quality. According to a meta-analysis by Kaiser et al. in 2014, ceramic bone grafts are demonstrably feasible graft extenders or substitutes [90].

Platelet Gels

Platelets are activated at sites of injury where they physically limit blood loss and promote generation of thrombin to coagulate blood [93]. Additionally, platelets are also involved in wound

healing and aid repair of highly vascularized bone tissue by releasing growth factors that attract mesenchymal cells of the bone marrow [94]. Lowery et al. suggested in 1999 that the application of platelet-rich plasma results in higher bone density 6 months after lumbar spine fusion and that osteoblasts lining a cancellous bone surface survive transplantation and respond to platelet growth factors [95]. And, given usage of hemocomponents like hyper-concentrated platelets gels as a wound sealant, platelet gels have seen the use in combination with autologous bone during lumbar spine fusions [96]. Platelet gels, combinations of concentrated platelets with thrombin, have been used successfully as autologous fusion adjuncts in both animal and human models and are now being marketed to promote bony growth [93, 97–99].

Studies into the efficacy of platelet gels as bony fusion enhancers are limited. Carreon et al. reported a nonunion rate of 25 % in the platelet gel with ICBG group compared to 17 % in the control group with ICBG alone [97]. Castro et al. in 2004 detailed an increase in pre-anesthesia time of 18 min for obtaining the platelet gel and a 19 % lower arthrodesis rate in the platelet gel group [100]. These preliminary reports on platelet gel's decreased efficacy as a growth factor adjunct have limited further research. To date, there have been no level one evidence studies on the effect of platelet gels in lumbar fusion.

Bone Morphogenetic Protein

Bone morphogenetic proteins (BMPs) are a family of soluble signaling factors in the transforming growth factor-β (TGF-β) superfamily of growth factors discovered by Marshal Urist in 1965. Several BMP molecules have been identified, though only certain forms demonstrate significant osteogenic properties, including BMP-2 [101–103]. Currently, recombinant human BMP-2 (*rh*BMP-2) and osteogenic protein-1 (OP-1) are available for commercial use. BMP-2 has been previously reported to induce bone and cartilage formation through osteoblastic differentiation of mesenchymal stem cells [104]. The original US FDA approval of BMP in 2002 was in the setting of anterior lumbar interbody fusion, though BMP-2 has since been implemented with varying success in posterolateral fusion and posterior or transforaminal interbody fusion [20, 105–107]. Currently, it is estimated that the off-label use of these agents exceeds 85 % in primary spine procedures [108]. The reported benefits of BMP centralize on achieving higher fusion rates and decrease donor site morbidity in comparison to autograft [109]. In the operative management of lumbar scoliosis, the use of BMP has proven to be advantageous as a suitable bone graft alternative for multilevel fusion, though reported adverse events may cause a reevaluation of BMP's efficacy in these procedures. Substantial variation in the literature surrounding BMP's use, integrated with unclear cost-effectiveness, requires continued evaluation.

BMP use in the surgical treatment of adult lumbar pathologies varies by surgeon preferences and specific pathology. Currently, the only FDA-approved use of BMP in spine surgery is in single-level anterior lumbar interbody fusion (ALIF) with interbody cage [20]. In 2002, Burkus et al., in a multicenter, prospective, randomized study, compared *rh*BMP-2 on absorbable collagen sponges versus autogenous iliac crest bone graft for interbody fusion in patients with degenerative lumbar disc disease to evaluate fusion progression at 6, 12, and 24 months post-operative. Radiographic fusion assessment was highest (94.5 %) in patients receiving *rh*BMP-2 compared to ICBG (88.7 %), though new bone formation was identified in all investigational patients. Moreover, the authors reported a 5.9 % rate of adverse events related to the iliac crest graft harvest and a 32 % graft site discomfort rate at 1-year post-op [20]. The summation of these findings was used to highlight the use of BMP as a viable alternative to ICBG in the lumbar spine, given new bone formation in all investigated patients. Multiple studies in subsequent years also underscored the effectiveness of BMP-2 in lumbar spinal fusion. In 2004, Haid et al. evaluated the use of BMP-2 on a collagen sponge carrier in single-level posterior lumbar interbody fusions (PLIF) against an ICBG control in a multicenter, prospective, randomized trial [110]. Clinical and radiographic outcomes were

assessed in 6-month intervals through a 2-year follow-up. At 24 months, the authors observed a nonsignificant difference in fusion rates in favor of the investigational cohort (92.3 %) compared to the controls (77.8 %). The authors did not report any device-related adverse events compared to a 6.1 % rate in the control patients. Moreover, patients receiving *rh*BMP-2 reported superior improvement in Numeric Rating Scale Back Pain scores at 24-months postoperative, while 60 % of controls complained of donor site pain. Kim et al. reported on structural lumbar curve fusions with a posterior approach augmented with structural anterior interbody grafting. These authors used BMP as deemed necessary in concentrations ranging from 24 to 96 mg based on the number of levels fused. BMP was soaked on an absorbable collagen sponge and then wrapped around the cortical bone and placed onto the posterior elements [4]. In total, Kim et al. used *rh*BMP-2 in 12 cases in anterior column reconstructions and posterior spinal fusions with significantly more BMP use in patients with an anterior apical release.

The utilization of BMP in adult spinal deformity (ASD), where pseudarthrosis is a common postoperative major complication, is driven by different surgical and radiographic indications [24, 111, 112]. Interbody support though has shown consistent effectiveness in stabilizing long fusions for lumbar deformity. Surgeons are recently trending away from the standalone use of ICBG and using instead a combination of locally harvested autogenous bone graft and allograft to stimulate fusion. Crandall et al. evaluated the use of TLIF with *rh*BMP-2 among 509 patients, of which 123 were diagnosed with lumbar deformity (including adult idiopathic scoliosis and degenerative lumbar scoliosis) [113]. The arthrodesis rate was 98.4 %, and, of the eight patients that developed nonunions at TLIF levels, five were long fusions for deformity. These lumbar scoliosis patients had significantly lower preoperative visual analog scale (VAS) functional scores, though they also displayed significant improvements at a 2-year follow-up. Comparably, Maeda et al. reported on long fusions to the sacrum and found that of the 23 patients receiving *rh*BMP-2, only 1 (4.3 %) developed a pseudarthrosis in contrast to a rate of 28.1 % in the ICBG cohort. However, the BMP group was limited by a shorter follow-up interval—2.7 years versus. 4.9 years in the ICBG group [114]. As previous usage recommendations were established largely based on trials studying single- and double-level fusions, which represents 85 % of rhBMP-2 use, the role of BMP in the context of ASD and lumbar scoliosis surgery in particular is continually being refined [115–117]. For example, Bess et al. in 2014 found no increased risk of perioperative complications using BMP versus ICBG in long fusions for ASD [118]. Future research on BMP in ASD should focus on a dose effect and correlations with longer-term outcomes to provide meaningful recommendation for use.

Since its initial introduction, the use of BMP-2 in the lumbar spine has been associated with several adverse events and complications. Contraindications for BMP use include active malignancy, pregnancy, active infection at the operative site, and hypersensitivity, among others. At the forefront of discussion is the impact of BMP on the growth and invasiveness of malignancy, given BMP's properties as a growth factor. Despite preclinical safety, data regarding BMP-2 effects on cancer cell proliferation failed to unveil any mutagenic associations, and high expression of BMP surface receptors have been observed in certain tumors [115, 119, 120]. Carragee et al. evaluated the risk of new malignancy in patients receiving a high dose (40 mg) of *rh*BMP-2 in a compression-resistant matrix in single-level posterolateral arthrodesis for degenerative lumbar spine conditions compared to autogenous bone control [121]. At 2-year follow-up, the author identified 15 distinct cancer events in the *rh*BMP-2 group with an incidence rate of 3.37 (95 % confidence interval, 1.89–5.56) compared to two cancer events in the control arm. This observed risk was sustained in a retrospective cohort study of Malham et al. of lumbar fusion (anterior, lateral, posterior, and posterolateral) with rhBMP-2 [122]. Twenty-seven of 527 patients were diagnosed with invasive cancer following treatment. Despite support in the litera-

ture, there remains as of yet no definitive or causative link between BMP use and tumorigenesis. Importantly, the Yale University Open Data Access (YODA) Project meta-analyses displayed no clinical advantage of BMP over bone graft, further confounding direct indications for BMP use.

Reports of emerging complications linked to *rh*BMP-2 use in the lumbar spine began in 2006, citing adverse events in ranges of 20–70 % [116]. The most commonly reported complications, as reported by Cahill et al., are derived from overactivity of the pro-inflammatory and chemotactic pathways: vertebral osteolysis (44 %), graft subsidence (27 %), graft migration (31 %), antibody reaction (26 %), heterotopic bone formation (7 %), and hematoma formation (3 %) [123].

Vertebral osteolysis and bone resorption, though a normal part of the remodeling process resulting in fusion, may nevertheless result in significant mechanical failures including cage migration, endplate subsidence, or fracture. Elevated rates of resorption have been noted in BMP use, presumably due to enhanced osteoclastic activity [124]. These complications have been reported in TLIF procedures when BMP-2 was used as an adjunct. McClellan et al. evaluated a total of 26 patients and 32 lumbar vertebral levels to identify bone resorption defects in 69 % of levels inspection. Of note, 31 % (7 of 22) were characterized as severe defects [125]. Lewandrowski et al. similarly evaluated 68 TILF patients using BMP-2 and interbody cages for treatment of degenerative spondylolisthesis. Though osteolysis was only observed in five cases, these patients reported worsening back and leg pain as early as 4 weeks postoperative. In this series, all osteolytic defects filled in spontaneously with reported resolution of symptoms within an additional 3 months of nonoperative management [126]. Conversely, osteolysis with subsequent nonunion has been reported by Pradhan et al. In a consecutive series of 36 ALIF patients using femoral ring allografts and *rh*BMP-2, pseudarthrosis was identified in 56 % of patients, and radiographic evaluation revealed early and aggressive allograft resorption in this group [127]. In a systematic review, Mroz et al. also reported a 44 % incidence rate of bone resorption, 25 % rate of graft subsidence, and 27 % rate of cage migration in *rh*BMP-2 use in lumbar interbody fusion, though without a long-term detrimental impact [124].

The majority of extradiscal, ectopic, or heterotopic bone formation reports have been in the setting of *rh*BMP-2 use in PLIF or TLIF procedures, though these complications have been reported often anecdotally and in narrow ranges [75]. The formation of heterotopic bone has been attributed to the elution of BMP outside of the disk space, and certain supplemental theories implicate the role of surgical hematoma and the use of hemostatic agents as BMP carriers to promote growth. Importantly, the potential for resulting bone growth may contribute to fusion of additional vertebral levels and neurologic impairment and/or radiculopathy due to canal or foraminal stenosis [128]. In 2007, Joseph and Rampersaud identified heterotopic bone formation in the epidural and foraminal spaces of 20.8 % of patients undergoing 1- to 2-level PLIF or TLIF with *rh*BMP-2 and local autogenous bone graft in a prospective study [129]. This was in comparison to an 8.3 % rate in cases not receiving BMP; however, both treatment groups remained asymptomatic with no adverse clinical outcomes. Meisel et al. detected radiographic evidence for intracanalar bone formation in 6 % of patients that underwent a 1- or 2-level PLIF with *rh*BMP-2 in a prospective cohort analysis. Similarly, these patients did not display any associated clinical sequelae [130]. In evaluating ten single-level PLIF patients receiving *rh*BMP-2 mixed with a collagen carrier, Kanayama et al. noted bone growth surrounding cartilage in 29 % of cases [131]. The impact of heterotopic bone formation on long-term symptomatic patient outcomes remains, however, to be fully evaluated.

New onset of severe postoperative radiculitis is an additional reported adverse event associated with BMP use, particularly in the setting of PLIF and TLIF. However, the presence of radiculitis as a well-known complication following fusion without BMP use and obscures the role the biologic may play in this complication [132]. In a retrospective cohort study, Mindea et al. found

that 11 % of TLIF *rh*BMP-2 patients reported new postoperative radiculitis occurring between 2 and 4 days following surgery. Rihn et al. reported a higher radiculopathy rate of 17 %, with an onset of on average 12 weeks postoperative in patients undergoing single-level TLI with *rh*BMP-2 [133].

Varying incidences of complications have been reported for anterior lumbar interbody fusion due to potential intraoperative injury to abdominal viscera, nerve roots, ureter, and great vessels. An additional surgical complication associated with BMP-2 use during ALIF is retrograde ejaculation (RE), which has garnered more attention in recent years. During the ALIF procedure, retrograde ejaculation results from damage to the superior hypogastric nervous plexus in the retroperitoneal space that innervates the internal vesicle sphincter of the bladder and has been reported from 0.5–8 % [134–137]. This is considered to be due to either mechanical trauma or a pro-inflammatory response resulting from the presence of BMP-2.

Conclusion

Remarkable advances in the field of bone graft alternatives for lumbar spinal fusion have occurred in recent years with regard to the variability, safety, efficacy, and comparative advantages and disadvantages of numerous osteobiologic products. Central to successful fusion treatment in the lumbar spine is the restoration of proper alignment and maintenance of mechanical stability. The proliferation of literature in recent years has sustained the efficacy of autograft as the gold standard in lumbar spine fusion procedures, though alternative products may be valuable in adjunct use dependent on the surgical approach. Both allograft and ceramics offer effective osteoconductive scaffolding, though they retain little further potential. The development of BMP as a powerful osteoinductive agent represents a stride forward in achieving arthrodesis, though continued and definitive research into long-term complications and appropriate dosing remain to be undertaken. Despite the wide array of osteobiologics available for use in lumbar scoliosis correction, to some extent effective treatment should be customized to the specific surgical procedure selected and patient-specific risk factors for fusion failure.

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11 Assessing the Need for Decompression for Adult Lumbar Scoliosis

Thomas Kosztowski, C. Rory Goodwin, Rory Petteys, and Daniel Sciubba

Introduction

As the number of elderly continues to increase in the USA, the number of people affected by adult deformity is expected to rise. In the USA, as many as 60 % of the elderly demonstrate some degree of adult spinal deformity (ASD) [1]. Adult spinal deformity, including scoliosis and sagittal plane deformities, is a relatively common finding [1–3] and is broadly classified into two subgroups, adult idiopathic and adult degenerative, defined by the primary etiology of the deformity [1, 4, 5]. One of the characteristic features of adult deformity in comparison to adolescent deformity is the increased prevalence of axial pain and radicular pain in adult deformity [6–8]. Adolescent deformity typically presents with cosmetic concerns or deformity progression, while adult deformity presents with pain and disability [9–11]. A combination of degenerative disc disease, facet arthropathy, trunk imbalance, and muscle fatigue is involved in the pathogenesis of pain in adult deformity [12]. Trunk imbalance and muscle fatigue are primarily influenced by sagittal and to a lesser degree coronal imbalance, and degenerative disc disease, facet arthropathy, and central and foraminal stenosis are more likely to directly cause signs and symptoms of nerve root and thecal sac compression such as radicular pain or neurogenic claudication.

Adult deformity is oftentimes a result of cumulative degenerative changes over a person's lifetime. As people age, intervertebral discs undergo dehydration, asymmetrical degeneration, and collapse. The summative contributions of the lumbar intervertebral discs to lumbar lordosis are thus lost. This loss in lumbar lordosis may cause sagittal imbalance. Disc herniation with nuclear material protruding or extruding into the perineural space can occur through radial tears of the annulus [13]. This often occurs in tandem with facet degeneration and ligamentous laxity. These degenerative processes may have synergistic effects on one another. Loss in disc height leads to increased loading on the facet joints accelerating the degeneration of the facet joints with resultant joint arthrosis and osteophytosis, a condition termed facet joint arthropathy [13]. Moreover, disc degeneration and facet arthropathy contribute to narrowing of the spinal canal and neural foramina resulting in spinal stenosis and neural foraminal stenosis, respectively. Especially in older osteoporotic patients, compression fractures are another concern and may result in sagittal plane deformity. Asymmetric degenerative collapse, on the other hand, may contribute to the development of coronal imbalance and resultant scoliosis [14]. All these combined changes contribute to the development and progression of adult degenerative deformity with resultant kyphosis, spondylolisthesis, lateral

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listhesis, and rotation [14]. In addition to degenerative processes, iatrogenic surgery may also contribute to the development of adult deformity, such as flat back syndrome in patients who have had prior lumbar fusion. Lumbar laminectomies and/or fusions may result in loss of lumbar lordosis contributing to sagittal plane deformity [15].

Clinical Assessment

It is important to understand that adult deformity differs from adolescent deformity in multiple aspects from presentation to treatment. While adolescent deformity most commonly presents with concerns about cosmesis or curve progression, adult deformity patients present with pain, disability, and neurologic deficits [9–11]. In the evaluation of the presenting signs and symptoms, it is important to understand the etiology of the deformity as this may alter the decompression strategies during surgery. The majority of adult deformity is from either adult idiopathic or degenerative (de novo) scoliosis, and thus we will focus on these two etiologies of adult deformity [16]. Adult idiopathic scoliosis may present at any point in life. Younger adults are more likely to present with back pain and issues of cosmesis, while older adults are more likely to experience back pain in addition to leg pain from curve progression or from superimposed degenerative changes [17]. In contrast, adult degenerative scoliosis typically occurs in older adults and characteristically presents with pain and disability with both back and leg symptoms (Fig. 11.1). In both etiologies, canal stenosis and foraminal narrowing are common but especially prevalent in the older adult degenerative scoliosis patients (Fig. 11.2). In a study of patients with adult idiopathic scoliosis, Simmons and Jackson found canal compression and foraminal narrowing in 3 % and 13 %, respectively [18]. Another study found spinal stenosis (in the form of foraminal or central stenosis) in 31 % of adult idiopathic scoliosis patients, whereas spinal stenosis was found in 90 % of the adult degenerative patients [19]. Fu et al. assessed 36 symptomatic adult degenerative scoliosis patients age 51–85 years old and identified severe foraminal stenosis in 97 % of patients [17]. In 83 % of those patients, the maximum foraminal stenosis was found in the curve concavity [17]. This study found that 97 % of the patients had at least one level of severe foraminal stenosis, and 83% had maximal stenosis at the levels of the curve concavity. Almost all the patients (35 of 36 patients) in the study reported significant radicular pain, including 78 % with discrete and 19 % with multiple-level radiculopathies. Of those with discrete radiculopathies, 76 % had pain corresponding to areas of the most severe foraminal stenosis, and 24 % had pain corresponding to areas of moderate stenosis. Understanding the etiology of ASD allows the clinician to focus on pertinent clinical history. Given that ASD commonly manifests with neurologic symptoms, the physical exam is vital in the assessment of this patient.

It is important to investigate whether the patient has any neurologic deficits (i.e., weakness, decreased or altered sensation, bladder or bowel dysfunction, gait disturbance, or decreased coordination). A detailed neurologic exam assessing motor strength, sensation, reflexes, tone, coordination, and gait needs to be documented preoperatively. In the examination, the physician must look for signs of myelopathy including hyperreflexia, pathological reflexes, and clonus. It is important to consider the entire spine when evaluating myelopathic patients with lumbar deformity, as up to 28 % of these patients have coinciding cervical stenosis [20]. Gait should also be carefully assessed as antalgic gait may suggest nerve impingement. The time frame that the patient has developed these symptoms, as well as the impact on normal function, is also important to understand. If any neurologic deficits have developed acutely, MRI of the cervical, thoracic, and/or lumbar spine needs to be performed, and the acuity of these symptoms may change the urgency of intervention [15].

Identification and characterization of pain generators are another critical component of the examination of a patient presenting with adult deformity. A history of neurogenic claudication that is exacerbated with standing or walking and alleviated with bending forward or

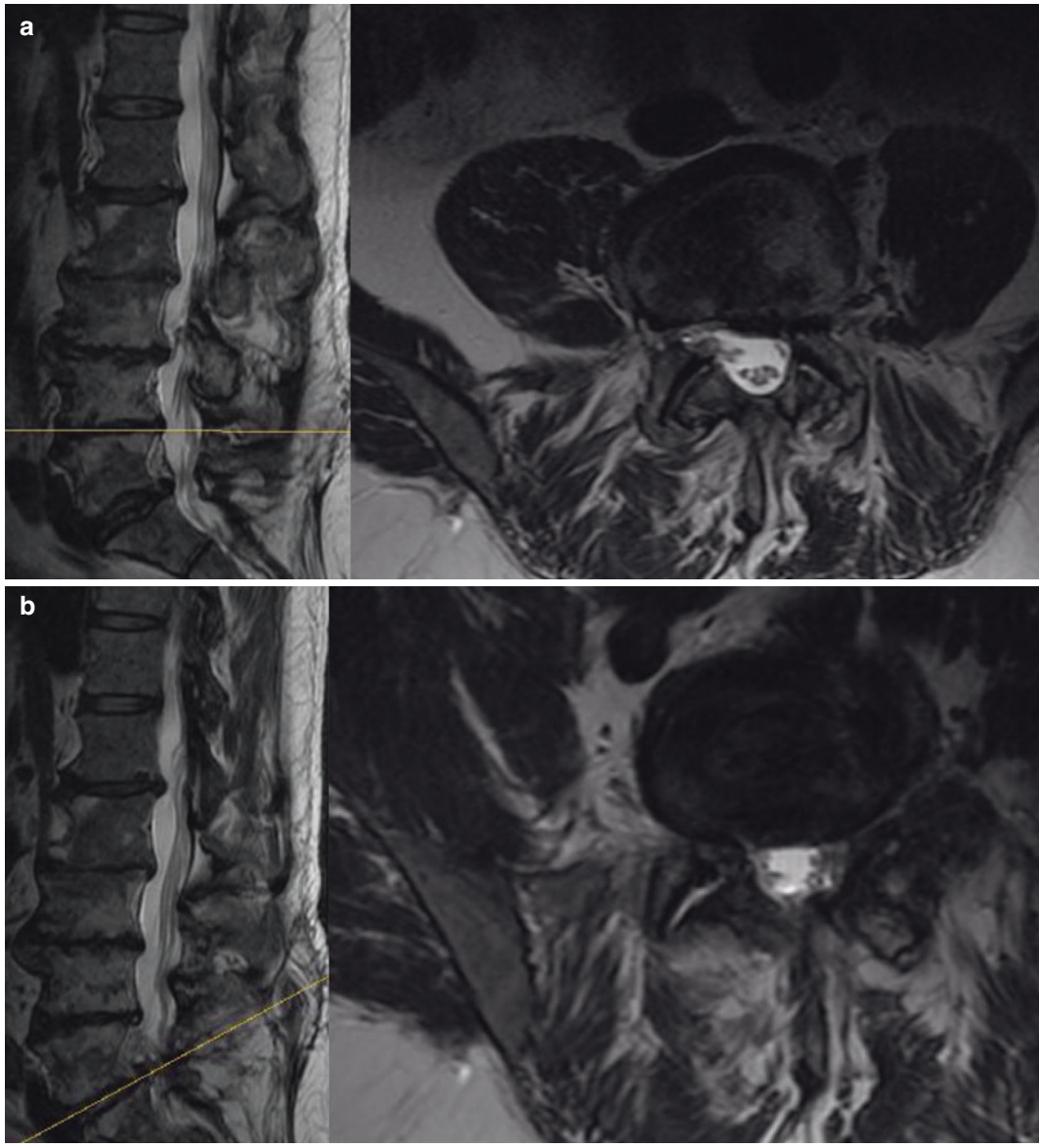
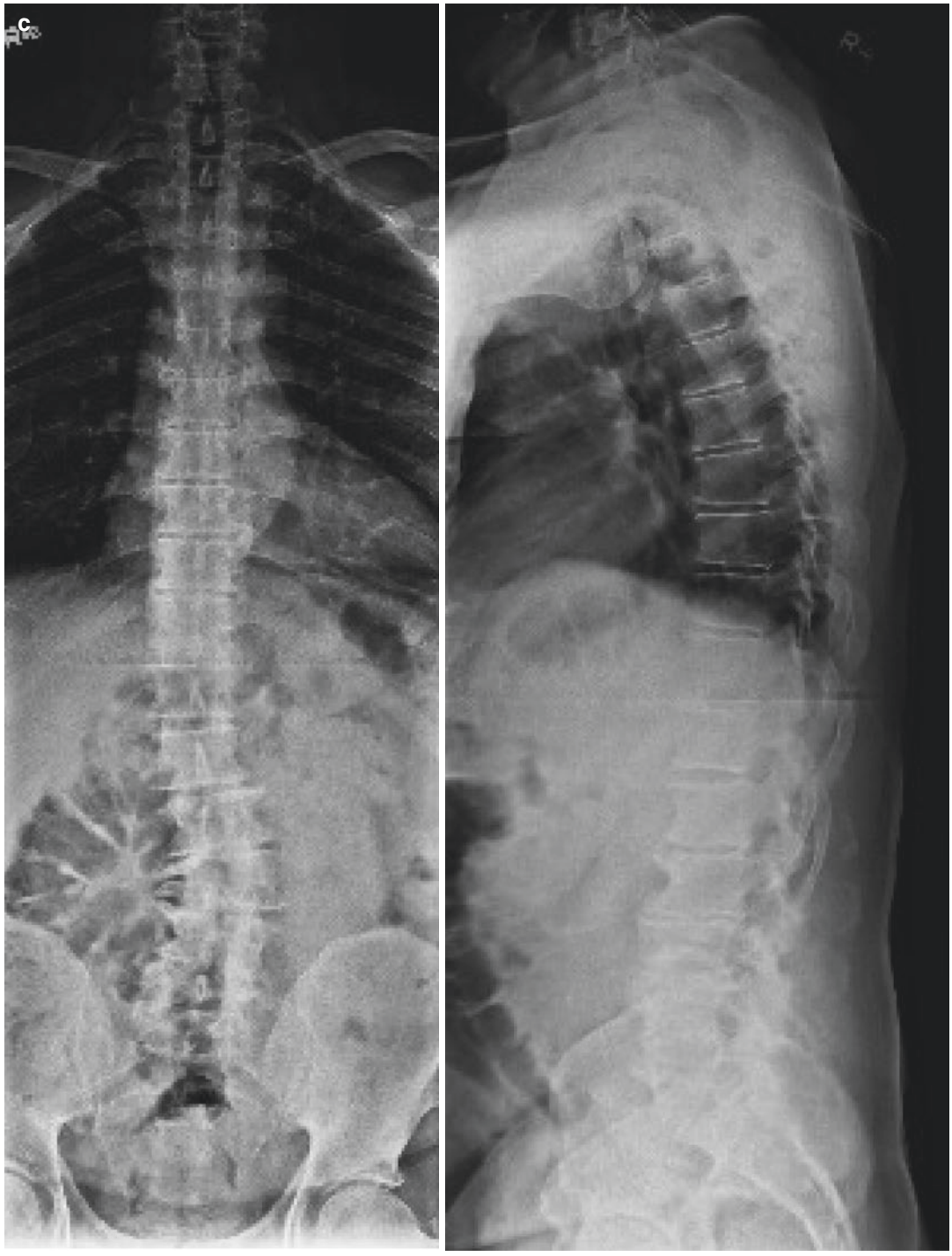


Fig. 11.1 This is a 60-year-old man with a history of adult degenerative scoliosis who presented with back and leg pain, left greater than right. On his preoperative imaging, he was found to have spondylolysis at L5/S1 on the left with corresponding back and leg pain. (**a**) Upon initial evaluation for back and leg pain, an MRI of the lumbar spine was performed and demonstrated significant degenerative changes throughout the lumbar spine. At L4-5, there were severe bilateral facet hypertrophy and loss of disc height resulting in bilateral foraminal narrowing. (**b**) The same was true at the L5/S1 level with the foraminal narrowing more severe on the left. There was also 6 mm of anterolisthesis of L5 on S1. (**c**) 36-inch scoliosis films showed flattening of lumbar lordosis with positive sagittal imbalance. The patient demonstrated about 30° of lumbar lordosis-pelvic incidence (LL-PI) mismatch and about 6 cm of positive sagittal imbalance. The patient was found to have mild levoscoliosis centered around L3 on films. (**d**) Flexion/extension films showed marked stiffness of the lumbar spine (left panel, neutral; middle panel, flexion; right panel, extension). (**e**) The patient was operatively treated with a L1-pelvic instrumented fusion utilizing S2-alar-iliac (S2AI) screws bilaterally. To create more lumbar lordosis, Ponte osteotomies were performed at L2-3, L3-4, L4-5, and L5/S1. During the Ponte osteotomies, particular attention was paid at the L4-5 and L5/S1 levels where neural foraminal compression had been worst with significant facet hypertrophy on the preoperative MRI. After the Ponte osteotomies were performed at these levels, the nerve roots were inspected to ascertain that they had been adequately decompressed. Instrumentation was placed, and the deformity was corrected in the sagittal and coronal planes with rod placement and reduction. The patient did well postoperatively with significant reduction in both back and leg pain



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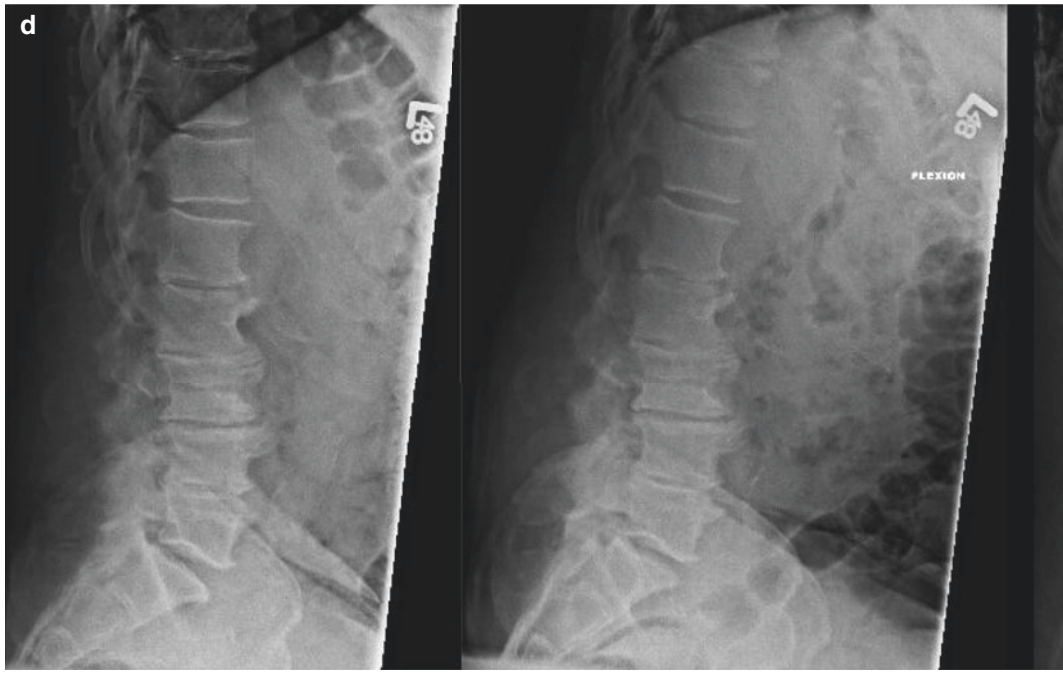

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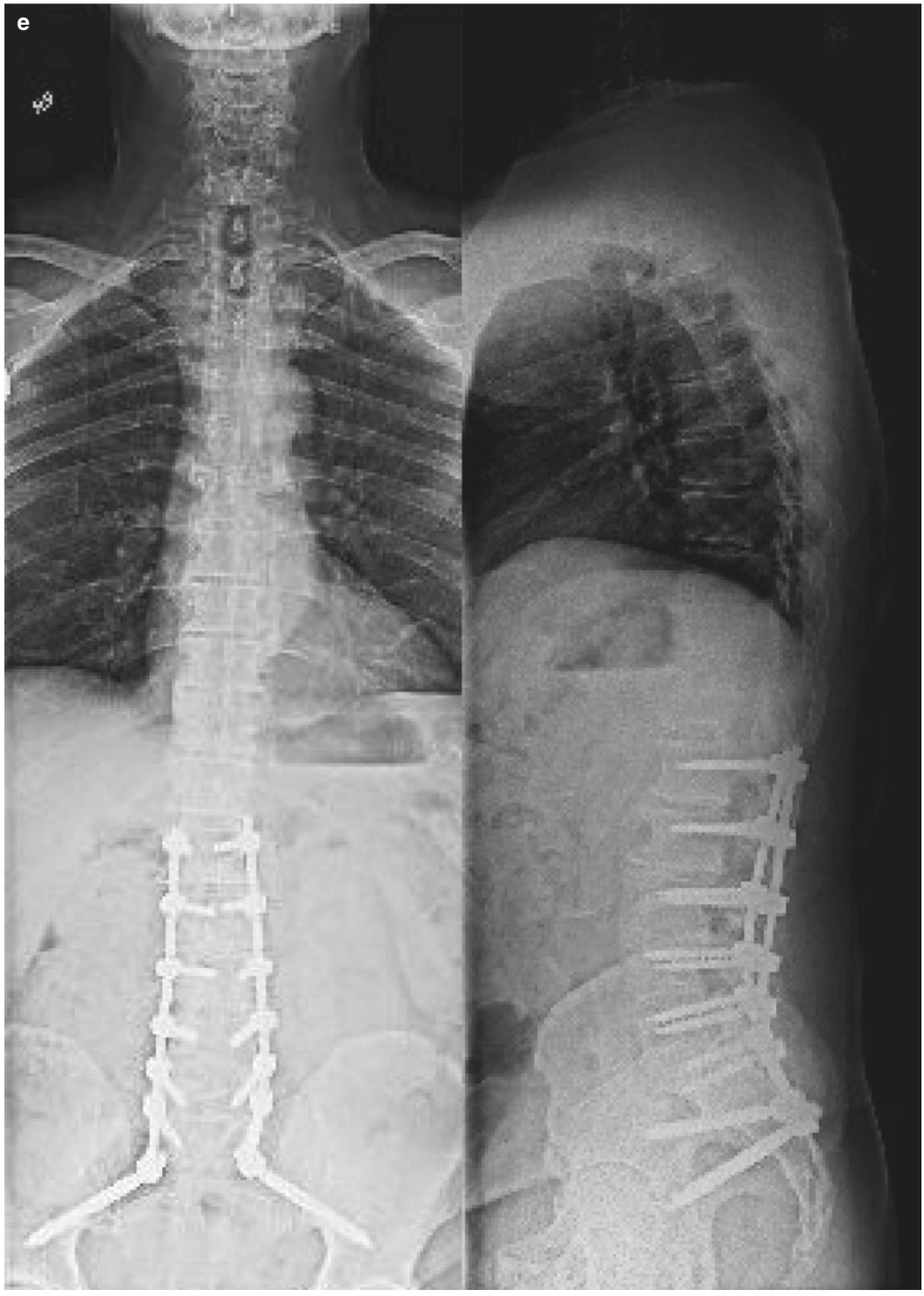

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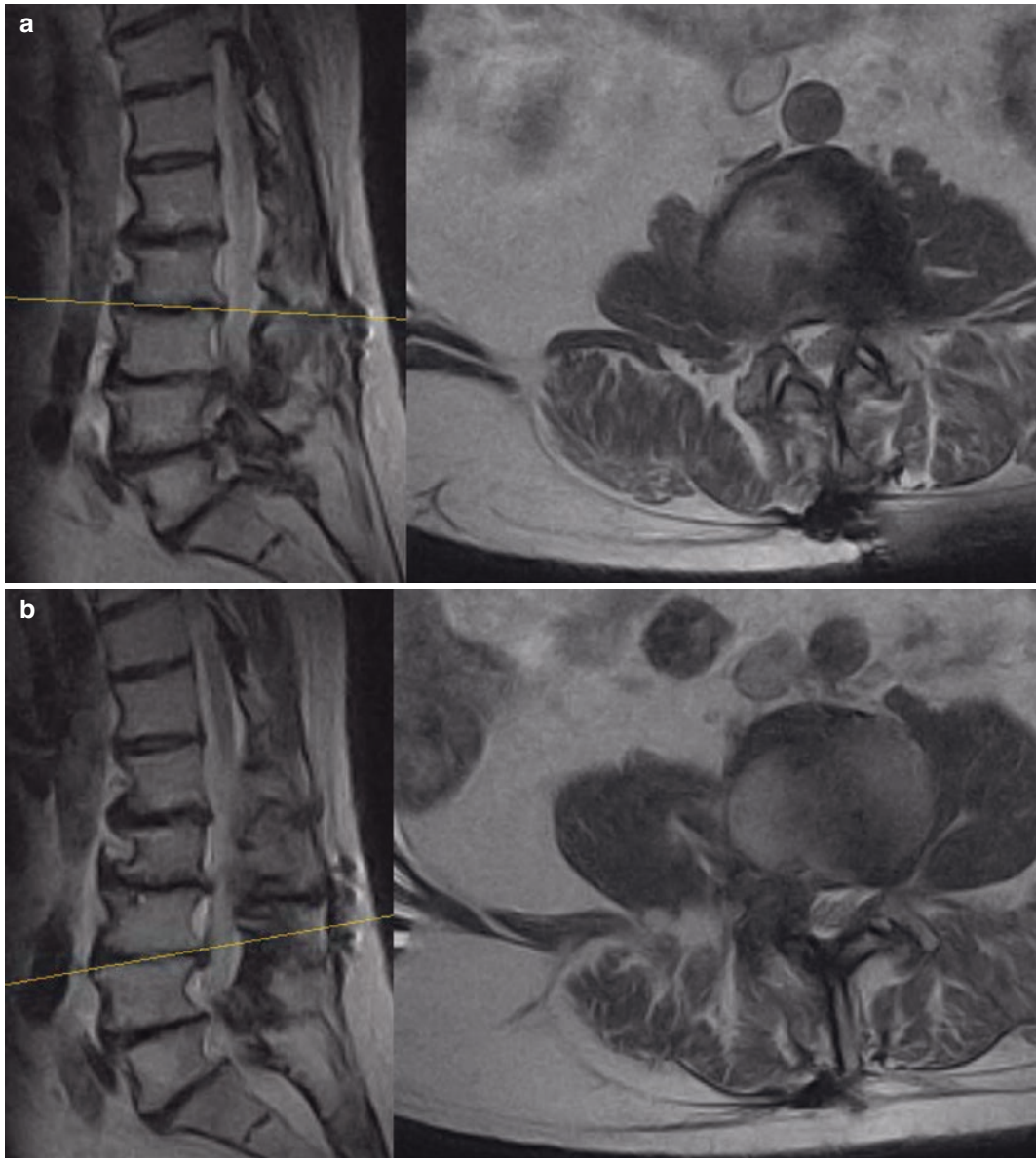
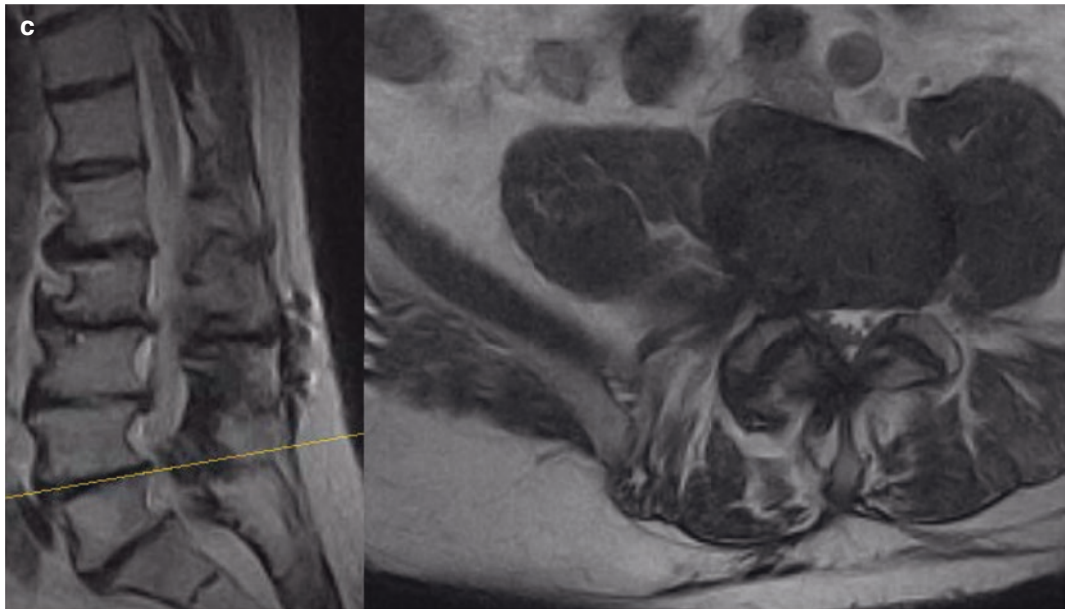


Fig. 11.2 This is a 72-year-old man who presented with a long-standing history of back pain and had more recently developed neurogenic claudication as well. The back pain was triggered by any sort of ambulation and by prolonged standing. It was relieved by leaning forward, sitting down, or lying down. Although not as severe as the back pain, the patient complained of pain radiating down the right leg as well. (**a**–**d**) An MRI showed extensive degenerative changes throughout the lumbar spine with foraminal narrowing (worse on the right) and spinal stenosis at multiple levels. There was also mild anterolisthesis of L4 relative to S1. Of note, the patient had four lumbar vertebrae. (**e**) Based on preoperative standing films, the PI-LL mismatch was calculated to be about 23° with a pelvic incidence of 59 and lumbar lordosis of 36°. (**f**) The patient opted for surgical management. The spine was instrumented from T10 to the pelvis including S2-alar-iliac screws. Bilateral Ponte osteotomies were performed at T12-L1, L1-2, L2-3, L3-4, and L4-S1. In order to mobilize the spine a bit further, because of its stiffness, bilateral discectomies were performed at L2-3 and L3-4. The rods were locked down from T10 to the pelvis, and reduction devices were able to correct the sagittal alignment as well as the coronal deformity. After surgery, the PI-LL mismatch was less than 10°. In the postoperative period, the patient's back pain and leg pain improved significantly



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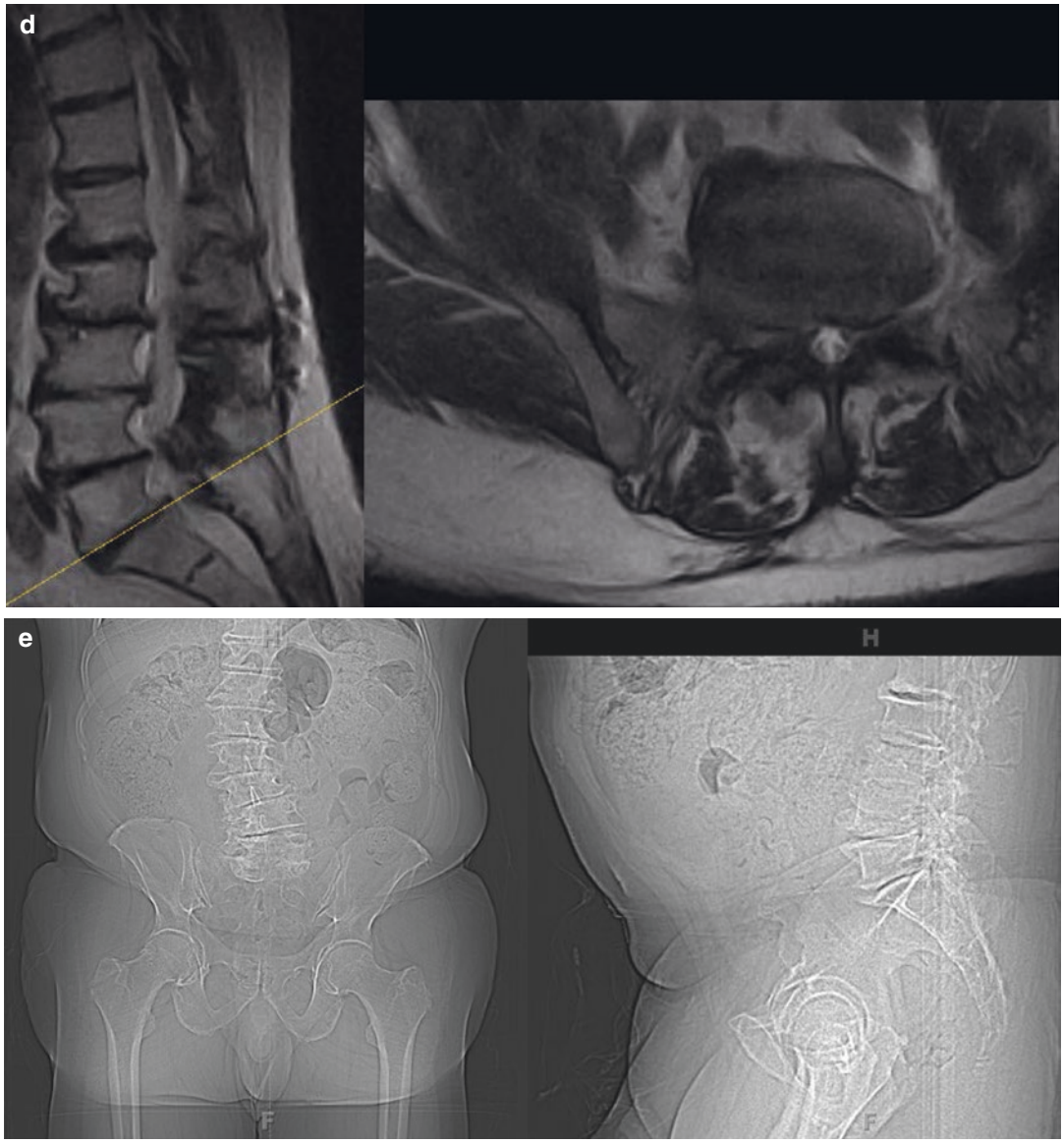

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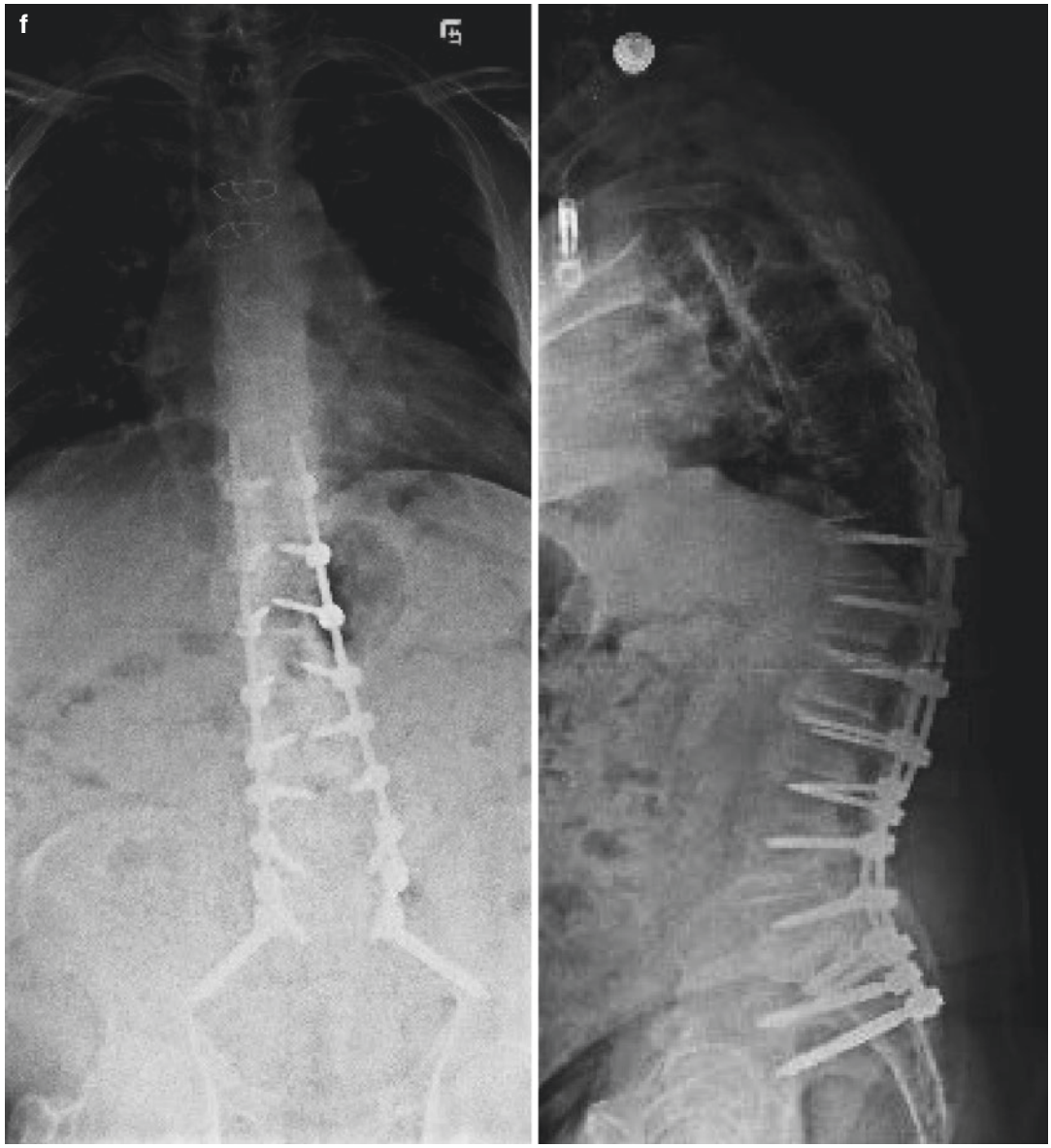

Fig. 11.2 (continued)

sitting suggests central stenosis. This must be differentiated from the back pain from sagittal imbalance. It is important to also understand and localize the source of radiating pain and correlate it to radiographic studies (e.g., MRI) where there may be lumbar stenosis or foraminal stenosis compressing individual nerve roots. These symptoms and radiographic findings can then be taken into account for the surgical plan to decompress these structures [21–23]. Lastly, it is important to rule out on physical exam any hip pathology that may be confused as radiating leg pain.

In the evaluation, the clinician must also inquire what surgeries have already been done. Many ASD patients have already had some sort of spine surgery performed whether it be a simple decompression and/or multiple-segment fusion [24]. The indications for these procedures and whether they were successful at ameliorating symptoms and the duration of their efficacy should be recorded. The associated complications that occurred with these procedures should also be noted (e.g., CSF leak, implant failure, neurologic worsening, or infection).

Role of Leg Pain in Disability

ASD patients commonly present with complaints of pain and disability [21, 25, 26]. The pain they experience can affect the back and/or legs and is often multifactorial [10, 25]. Most of the ASD research over the past decade has focused on patient-reported outcomes and general measures of function and health status (e.g., Short-Form Health Survey (SF-36), Oswestry Disability Index (ODI)). However, such measures such as the ODI focus on disability due only to back pain and neglect leg pain [21, 27]. The few studies in the ASD population that specifically look at leg pain estimate its prevalence to be between 40 and 85 % [25, 26]. It is important to understand that pain is the primary concern of ASD patients and the reason why these patients most commonly present for surgical evaluation [25, 26]. For this reason, much of the literature has recently begun to shift its attention toward the effect of operative care on back [10] and leg pain [6] in ASD patient. Most have found that both types of pain improve with operative care compared to nonoperative management. Studies investigating large cohorts of ASD patients treated with operative care found significant improvements in the numerical rating scale (NRS) pain scores for back [10] and leg pain [6].

In one of the first large studies to compare operative versus nonoperative treatment for leg pain in ASD patients, Smith et al. retrospectively reviewed a prospective database of 326 patients of which 208 (64 %) had leg pain at presentation (mean numerical rating scale (NRS) score of 4.7) [6]. In this study, 46 % ($N = 96$) of the patients were managed operatively, while 54 % ($N = 112$) were managed nonoperatively. Before treatment, the operative cohort had a higher mean NRS score for leg pain (5.4 vs. 4.1) and a higher mean ODI (41 vs. 24). At 2-year follow-up, patients in the nonoperative cohort experienced no significant improvement in either NRS score for leg pain or ODI, whereas the surgical cohort had significant improvement in NRS score for leg pain (5.4 vs. 2.2) and ODI (41 vs. 24) compared to preoperative baseline. At 2-year follow-up, the operative cohort had better mean NRS leg pain scores (2.2 vs. 3.8) and mean ODI (24 vs. 31) [6]. In regard to the operative treatments provided in the study, 96 % of the patients underwent a posterior procedure either in isolation ($N = 42$) or in combination with an anterior procedure ($N = 47$). Regarding direct or indirect decompressive procedures, laminectomy was performed in 40 % of patients, whereas transforaminal or posterior lumbar interbody fusion was performed in 11 %. Of the patients treated with posterior only or combined approach, all but three patients had placement of at least one interbody cage/graft [6]. There was no mention or inclusion of patients treated with lateral approach interbody grafts in this particular study.

To further evaluate pain responsiveness to operative treatment, Scheer et al. went one step further and evaluated the pain outcomes of ASD patients based on their initial NRS severity, curve type, and utilization of osteotomies in treatment [21]. The retrospective study sought to characterize changes in back and leg pain after operative

versus nonoperative management of ASD in a prospective multicenter database of 421 ASD patients with 2-year follow-up [21]. ASD patients managed operatively were three times more likely to have an improvement in leg pain and 6.2 times more likely to have an improvement in back pain compared to nonoperative ASD patients. In fact, nonoperative ASD patients were more likely to have their back or leg pain remain unchanged or worsen with time. In the operative cohort of patients who presented with any preoperative back or leg pain, 37.8 % were free of leg pain and 24.3 % were free of back pain at the 2-year follow-up. Although the operative cohort experienced significantly improved leg pain, there still was a 37 % incidence of postoperative leg pain at 6 weeks and 33.3 % at 2-year follow-up. Patients treated with decompression had a greater rate of improvement in leg pain and increased rate of reaching minimum clinically important difference (MCID) (decrease in the NRS score of 1.2–1.6 points [28]). Although decompression was effective in relieving leg pain, it did not have a significant effect on back pain. Interestingly, although osteotomies (Smith-Petersen osteotomy, three-column osteotomy, or both) were associated with an improvement in back pain, there was a higher incidence of leg pain postoperatively. Lastly, the study found that reductions in back pain contributed greater to improvements in ODI, PCS scores, and patient satisfaction than reductions in leg pain did.

Soon after this study was published, the International Spine Study Group (ISSG) published a paper by Smith et al. comparing outcomes of operative and nonoperative cohorts with ASD [29]. The study was a multicenter propensity-matched cohort (N = 97 in each cohort) assessment of ASD patients with at least 2-year follow-up. The study corroborated the findings of other studies that leg pain improved to a greater extent with operative treatment compared to nonoperative management. The average baseline NRS leg pain scores before treatment were 3.2 and 3.1 for nonoperative and operative cohorts, respectively, with no significant difference between the two groups. At 2-year follow-up, the average NRS leg pain scores were 3.7 and 1.8, respectively, reaching a statistically significant difference. NRS back pain scores at baseline were actually higher in the operative cohort (6.4) compared to the nonoperative cohort (5.1), but at 2-year follow-up, the NRS back pain scores in the operative cohort (2.7) were significantly improved compared to the nonoperative cohort (5.5). It is evident from multiple studies in the literature that in appropriately selected ASD patients, operative treatment can have positive effects on back and leg pain.

Radiographic Assessment

In order to effectively treat the pain generators in ASD patients, radiographic studies are essential and add important information to the history and physical examination of the patient. Evaluation of ASD patients involves multiple imaging modalities including magnetic resonance imaging (MRI), computed tomography (CT), dual-energy X-ray absorptiometry (DEXA) scan, 36-inch standing scoliosis films, and dynamic films.

Thirty-six-inch standing scoliosis films of the entire spinopelvic axis are necessary in the evaluation of coronal and sagittal imbalance including spinopelvic parameters. This topic will be discussed in other chapters, and thus we will focus our attention toward imaging modalities to evaluate the need for decompression of neural structures in ASD patients.

While adolescent deformity does not rely much on MRI, ASD frequently utilizes MRI because neural impingement is much more common in the adult population. MRI provides detailed images of soft-tissue structures and thus is excellent in the assessment of the spinal cord and nerve impingement, disc disease, and other spinal abnormalities. The clinician must carefully evaluate the patient's imaging studies to identify areas of neural compression that correlate to the patient's symptoms. Spinal stenosis, in the form of foraminal or central stenosis, is found in 31 % of adult idiopathic scoliosis and in 90 % of adult degenerative scoliosis (Fig. 11.2) [19]. Spinal stenosis more commonly occurs on the concavity of the scoliosis than on the convexity [30]. MRI should be carefully assessed for

kinking of the nerve root between the pedicle and disc especially on the concavity of the scoliotic curve. Neurological symptoms may also develop on the convex side of the scoliosis curve by overstretching of the nerve roots [30]. Lastly, careful attention should be paid to lateral vertebral subluxation and severe facet hypertrophy as these are often associated with foraminal stenosis [18].

CT also plays an important role in the assessment of ASD patients as it provides exceptional bony detail that is essential for surgical planning regarding placement of instrumentation. CT myelography allows for visualization of neural compression and intraspinal disease while also providing the high-resolution bony detail of the typical CT scan. These scans are particularly useful for patients who already have extensive instrumentation that creates artifact on MRI.

Standing dynamic studies may be also helpful in determining the presence and degree of instability associated with a spondylolisthesis as well as assessing the rigidity of the spine and the ability to reduce the sagittal and coronal deformities. These films may also influence whether an interbody graft is needed at the level of the spondylolisthesis if there is significant instability.

Determining Levels of Decompression

Determining the levels necessary for central and foraminal decompression is decided by a combination of clinical and radiographic findings. For example, if the patient demonstrates signs of neurogenic claudication and has corresponding significant lumbar central stenosis, then laminectomies and decompression should be incorporated into the surgical plan in addition to correction of the deformity. Similarly, if the patient has signs of a particular radiculopathy and corresponding foraminal stenosis on imaging, then the surgeon should be conscientious about decompressing those nerve roots in the surgical plan either through direct or indirect decompression methods. The surgeon must also be careful during the reduction of the deformity across osteotomy levels as nerve compression may result from iatrogenic narrowing of the neural foramen or of the spinal canal [21, 31]. If there is neurologic worsening assessed via decreased signals on neuromonitoring after the deformity has been reduced, the surgeon should release the reduction on the rod and assess and recheck neuromonitoring. If the patient awakens postoperatively with neurologic worsening, the surgeon should not hesitate to obtain imaging with either CT myelogram or MRI to assess for any iatrogenic central canal stenosis or foraminal narrowing from the procedure.

Direct Versus Indirect Decompression

The clinical presentation of the patient, the characteristics of the deformity, and the medical comorbidities of the patient dictate the role for decompression in ASD [12, 32]. Decompression of the neural elements may be achieved by direct laminectomy and/or facetectomy or indirectly via interbody grafts or other devices that increase foraminal height and/or canal diameter [6]. In some cases, direct decompression alone, i.e., lumbar laminectomy, may be the best option, especially in patients with predominantly leg symptoms and advanced age or other comorbid conditions that preclude more extensive procedures. In others, decompression may be performed in concert with posterolateral fixation, osteotomy and deformity correction, and fusion, or some combination thereof. The clinician must consider the patient's presenting symptoms, degree of deformity, and comorbid conditions when determining the role of decompression in lumbar scoliosis surgery [32, 33]. Furthermore, many of the methods and maneuvers utilized in deformity surgery can work counter to the goals of decompression, and thus surgeons must be very careful when performing osteotomies and correcting the deformity [21, 31].

Direct Decompression

Direct decompression with foraminotomy and laminectomy can be highly effective in relieving localized nerve compression and thecal sac compression. Direct decompression of the lumbar nerve roots can be achieved by laminectomy

and/or facetectomy, with or without instrumented fixation. Although not a specific goal of the study, Smith et al. found that ASD patients who underwent laminectomy had significantly greater improvement of leg pain compared with those who did not [6].

The major advantage of direct decompression is that it affords the ability to address all modes of stenosis via a single procedure. Lumbar laminectomy with medial facetectomy and foraminotomy can successfully alleviate compression from central, lateral recess, and foraminal stenosis. This procedure is often considered the gold standard treatment for lumbar stenosis and is familiar to all spine surgeons. Direct decompression alone may be considered for patients with a predominance of leg symptoms and little to no back pain or for those who cannot tolerate more extensive surgery with instrumented fixation and fusion. Direct decompression alone may be considered in select cases of elderly patients in poor medical condition who are at high likelihood of a perioperative complication.

Direct decompression does have several drawbacks. First, the extent of laminectomy and facetectomy required to adequately decompress the neural elements leads to extensive exposure of the lumbar dura, which could increase the risk of dural injury and cerebrospinal fluid leak, especially if synovial cysts or calcified ligamentum flavum is present. This more extensive exposure of the dura may also increase epidural scar formation leading to persistent or recurrent symptoms and making reoperation challenging. Second, one must be mindful that wide laminectomy and facet joint resection may significantly destabilize the spine and result in further deformity or recurrence of spinal stenosis if the spine is not adequately stabilized after decompression [34]. The tissue trauma and disruption required to directly decompress the lumbar spine can lead to postoperative instability and progression of deformity when instrumented fixation is not performed [34–36]. This may lead to recurrence of symptoms and progression of sagittal plane deformity, which is highly associated with disability.[15] There are also greater tissue trauma and blood loss from direct decompression compared to less invasive methods of indirect decompression (i.e., anterior or lateral interbody graft placement) [37]. Lastly, by removing the entirety of the lamina for direct decompression, the effective surface area for bony fusion is reduced.

Indirect Decompression

Decompression of neural elements can also be achieved indirectly in the lumbar spine. This is accomplished by either distracting the posterior elements or increasing disc space height to increase foraminal height and canal diameter, thereby indirectly relieving compression of the nerve roots. Interspinous, interlaminar, or dynamic fixation devices can achieve distraction of the posterior elements; however, the role for these devices in ASD is limited as they effectively reduce lumbar lordosis and can exacerbate sagittal plane imbalance, which may lead to increased deformity, back pain, and disability [34, 38]. Restoration of disc space height and indirect decompression can also be achieved via anterior column reconstruction, including interbody device placement. These methods include anterior (anterior lumbar interbody fusion [ALIF]), anterolateral (oblique lumbar interbody fusion [OLIF] and lateral lumbar interbody fusion [LLIF]), and posterolateral (transforaminal lumbar interbody fusion [TLIF] and posterolateral lumbar interbody fusion [PLIF]) techniques.

Anterior and anterolateral interbody fusions (ALIF and LLIF/OLIF) are powerful techniques for the restoration of disc space height and indirect decompression [39, 40]. Both approaches permit excellent exposure for thorough disc removal and end plate preparation and allow the surgeon to place a large interbody device across the apophyseal ring of the disc space. This increases the surface area for potential fusion and can help prevent graft subsidence, maintaining indirect decompression. Placement of a large interbody device can significantly increase the foraminal height and improve the canal diameter, thereby relieving compression of the lumbar nerve roots [37, 40, 41]. The maintenance of

sagittal and coronal plane correction is also aided by the anterior column support provided by interbody placement [42]. Both approaches offer the ability to achieve significant segmental sagittal correction through placement of lordotic interbody devices, especially when combined with resection of the anterior longitudinal ligament (ALL) as has been studied with LLIF approaches in the form of anterior column reconstruction/release (ACR) [43, 44].

The anterior and anterolateral approaches are associated with less blood loss than posterolateral approaches to interbody placement and, when combined with percutaneous instrumentation and/or minimal access posterior decompression, further limit tissue disruption and blood loss [37, 45]. This can be particularly advantageous in elderly patients with multiple comorbidities in whom complication rates after posterior decompression and fusion are very high. Several authors have reported favorable results incorporating multilevel ALIF/LLIF procedures with posterior fixation in elderly patients with degenerative deformity [41, 46–50]. The relief of back and leg symptoms via fixation and indirect decompression was also favorable in these studies. The major disadvantage to ALIF and OLIF/LLIF approaches is that repositioning of the patient is required to accomplish posterior fixation, osteotomy, and decompression, if indicated. Furthermore, ALIF is not infrequently associated with major vascular injury and retrograde ejaculation [39], while ipsilateral psoas muscle weakness and thigh paresthesias can occur after OLIF/LLIF [41].

Posterolateral interbody device placement via TLIF or PLIF can be attractive options in adult lumbar scoliosis surgery. These procedures can be performed in conjunction with direct decompression, instrumented fixation, and osteotomy for deformity correction through a single incision or approach. Indeed, some degree of direct decompression is necessary to perform both TLIF and PLIF. Both approaches permit some restoration of disc space height and indirect decompression, though perhaps not as robust as anterior and anterolateral methods, as the ALL cannot be easily resected [39, 40]. The major disadvantage of these approaches is the tissue disruption and increased blood loss when compared to less invasive lateral or anterolateral approaches [37].

Conclusion

Adult spinal deformity commonly involves malalignment in both the coronal and sagittal planes. More frequently than other forms of deformity, back and leg pain along with disability play a prominent role in the presentation of these ASD patients. Evaluation of these patients requires a thorough history, physical exam, and radiographic evaluation paying attention not only to spinal balance but also to pain generators. Careful attention to correction of the spinal balance along with decompression of compressed nerves gives the best chance of achieving a favorable result with improved back and leg pain along with decreased disability. Although much of the adult deformity literature emphasizes disability and back pain, there is now ample evidence that leg pain also plays an important role in these patients and that leg pain can be improved with appropriate operative attention. Decompression of central and foraminal areas can be accomplished through a variety of methods of both direct and indirect decompression. Understanding the variety of options available allows the surgeon to decide upon the most appropriate patient-specific surgical plan.

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Minimally Invasive Techniques for Adult Lumbar Scoliosis

12

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Introduction

Minimally invasive spinal (MIS) surgery has increased in popularity over the last two decades as an alternative to open techniques. MIS lumbar fusion techniques have shown the potential to reduce blood loss, decrease postoperative back pain, and decrease the length of hospital stay [1]. Foley was one of the first to describe the minimally invasive surgery for transforaminal lumbar interbody fusion (MIS-TLIF) in 2003 using a tubular retractor [2]. Subsequent modifications included a mini-open approach using an expandable tubular retractor that allows for direct visualization of screw placement [3]. In this chapter, patient selection, technique, comparison to open surgery, and complications of the MIS-TLIF are reviewed.

Patient Selection

Indications for MIS-TLIF

MIS-TLIF is an excellent surgical option to achieve circumferential fusion from a single approach. Bone graft and an interbody spacer are placed through a posterolateral transforaminal route into the disk space to supplement a pedicle screw construct. Indications include low-grade (Meyerding grade I or II) spondylolisthesis, degenerative disk disease causing discogenic low back pain, recurrent lumbar disk herniation with significant mechanical back pain, post-diskectomy interbody space collapse with neuroforaminal stenosis and radiculopathy, recurrent disk herniation, treatment of pseudarthrosis, post-laminectomy kyphosis, and deformity with coronal and/or sagittal plane imbalance [3, 4]. Relative contraindications include single-level disk disease causing radiculopathy without symptoms of mechanical low back pain or instability, osteomyelitis/diskitis, severe central canal stenosis, more than three levels of arthrodesis, Cobb angle more than 20° over fused segments, and severe osteoporosis [3] (see Table 12.1). Patients with radiculopathy without low back pain or instability are candidates for decompression without fusion. Those with osteomyelitis/diskitis may need open debridement. Patients with severe multilevel stenosis may benefit from open posterior decompression. Multilevel arthrodesis (more than two levels) for back pain in the absence of instability or deformity may not be efficacious. Scoliosis may be treated with multilevel MIS-TLIF, but that is technically challenging and typically undertaken by those who are very experienced. Patients with osteoporosis are at risk for pseudarthrosis and may need to have their bone density corrected medically before a MIS fusion is undertaken.

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Table 12.1 Indications and relative contraindications for the use of MIS-TLIF

Indications	Low-grade spondylolisthesis Degenerative disk disease causing discogenic low back pain Recurrent disk herniation with significant mechanical back pain Post-diskectomy interbody space collapse with neuroforaminal stenosis and radiculopathy Recurrent disk herniation (third or more), lumbar disk herniation with radiculopathy (with or without back pain) Treatment of pseudarthrosis Treatment of post-laminectomy kyphosis Treatment of lumbar deformity with coronal/sagittal plan imbalance
Relative contraindications	Single-level disk disease causing radiculopathy without symptoms of mechanical low back pain or instability Osteomyelitis/diskitis Severe central canal stenosis Greater than three levels of surgery Cobb angle >20° over fused segments[a] Severe osteoporosis

[a]Except as guided by the MISDEF algorithm

The advantages of the transforaminal approach (MIS and open) for interbody placement are numerous. There is direct decompression of the nerve root on the ipsilateral side of the interbody graft placement. The graft is placed through Kambin's triangle and typically does not require any retraction on the thecal sac or the exiting nerve root. The posterior lumbar interbody fusion (PLIF) technique, on the other hand, often requires retraction of the thecal sac placing the traversing nerve root at risk during interbody graft placement. The anterior lumbar interbody fusion (ALIF) and lateral lumbar interbody fusion (LLIF) are an additional way to achieve interbody fusion and indirect decompression of the nerve roots. However, additional fixation may be required with percutaneous screws and/or additional decompression, which may require changing the patient's position or staging the procedure adding to the overall operative time. Disadvantages of MIS-TLIF include the limited size of the interbody graft that can be placed through Kambin's triangle. Pedicle screw distraction while placing an interbody graft could allow a surgeon to place a larger interbody spacer. Newer interbody technology including expandable cages and rotated cages may allow for a taller interspace device than what must fit through the annulotomy in Kambin's triangle. While multiple levels may be addressed through a MIS-TLIF, an open TLIF may be a better option for multilevel fusions with severe central canal stenosis to decrease operative time. Additionally, it may be difficult to adequately decompress a severely stenotic contralateral foramen without significant risk of durotomy or nerve root entry though a MIS approach.

Adult Spinal Deformity

With the increasing age of the overall population, adult spinal deformity (ASD) is increasing in incidence and has a significant impact on health and disability. Traditional open spinal deformity correction surgery is associated with significant intraoperative blood loss, relatively high perioperative morbidity, increased length of hospital stay, and pain. To reduce these surgical comorbidities, MIS approaches for spinal deformity correction have been utilized. There are limitations on the amount of sagittal correction and curve correction that can be accomplished through MIS techniques. The minimally invasive spinal deformity (MISDEF) algorithm [5] can be a guide for patient selection with MIS techniques in ASD (Fig. 12.1). This algorithm underwent multiple revisions prior to its current state. It was revised from six arms of treatment to three arms to decrease the complexity and increase the inter- and intraobserver reliability. The algorithm was developed with a Delphi approach by 11 fellowship-trained spinal surgeons. A Class I approach is accomplished through a minimally invasive or mini-open muscle-sparing decom-

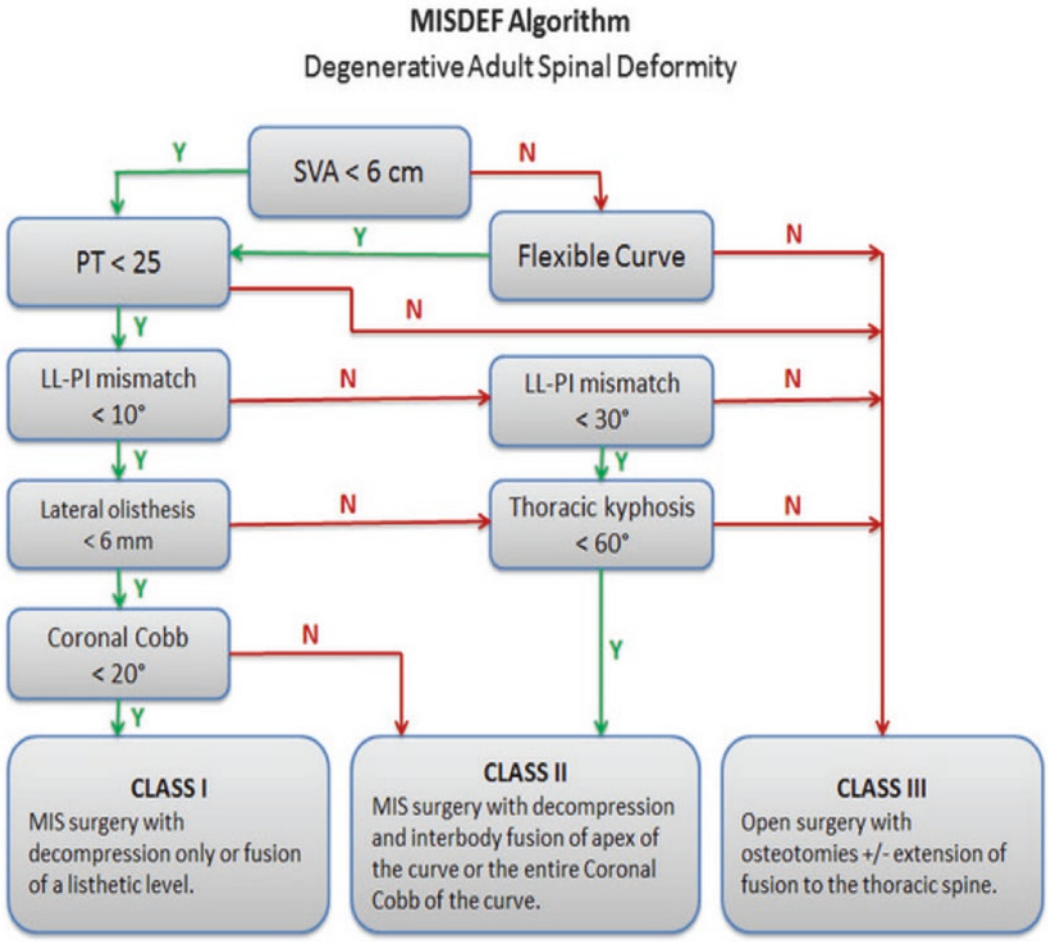

Fig. 12.1 Minimally invasive spinal deformity (*MISDEF*) algorithm for decision-making when considering less invasive surgery. *Y* yes, *N* no

pression alone or MIS fusion of a single listhetic level regardless of the curve apex. Instrumentation may be placed via a percutaneous technique or through an expandable port tube. A Class II approach entails MIS or mini-open decompression and interbody fusion of the curve apex or the entire coronal Cobb angle of the major curve. A Class III approach entails a traditional open surgical approach involving osteotomies and/or extension of the fusion into the thoracic spine. Class I patients have a sagittal vertical axis (SVA) less than 6 cm, pelvic tilt (PT) less than 25°, lumbar lordosis-pelvic incidence (LL-PI) mismatch of less than 10°, lateral listhesis less than 6 mm, and coronal Cobb angle less than 20°. These patients are candidates for MIS-TLIF with a single-level fusion. Class II patients have a SVA less than 6 cm, PT less than 25°, LL-PI mismatch of 10°–30°, a lateral listhesis greater than 6 mm, thoracic kyphosis less than 60°, and/or a coronal Cobb angle larger than 20°. Additionally, flexible curves with SVA >6 cm that correct to less than 6 cm when supine are included in this group. These Class II patients may be candidates for a multilevel decompression and fusion at the apex or along the entire coronal Cobb of the curve. Interbody fusion may be accomplished with multiple MIS-TLIF. Class III patients have SVA greater than 6 cm that do not correct on supine films, PT >25°, LL-PI mismatch greater than 30°,

and/or thoracic hyperkyphosis greater than 60°. Class III patients cannot typically be corrected with MIS techniques because these patients have deformities that often require extensive open posterior osteotomies.

Technique

Patient Positioning

Optimal preoperative positioning of the patient is required to achieve success with the MIS-TLIF. We prefer a prone position on a Wilson frame attached to a radiolucent Jackson table. The use of the Wilson frame allows us to maximize access during the interbody work by flexing the spine in the "cranked-up" position. Following interbody placement the Wilson frame is "cranked down" to maximize lumbar lordosis prior to securing rods. Prior to draping patients, we routinely obtain anterior-posterior (AP) and lateral fluoroscopic images to identify the bony spinal anatomy including the pedicles and verify that the surgery can be accomplished safely (Fig. 12.2). For L4-5 level fusions, we keep the operative table parallel to the floor. However, for L5-S1 cases, we usually position the operative table in 20°–30° of reverse Trendelenburg to allow the surgeon to have a more convenient view of the inferiorly angled L5-S1 disk space by orienting it perpendicular to the floor.

Pedicle Screw Placement

Pedicle screws may be placed either through a percutaneous technique or via a mini-open technique. The percutaneous technique utilizes AP and lateral fluoroscopy to visualize the pedicles. The skin is incised just lateral and slightly superior to the pedicle. A Jamshidi needle is placed on the upper and lateral border of the pedicle while contacting the bone. It is then driven to the medial border of the pedicle wall under AP fluoroscopy. Lateral views then confirm the depth of the Jamshidi needle. If the Jamshidi needle has been driven to the depth of the posterior edge of the vertebral body without violating the medial border on AP images, it is advanced approximately 2 cm further into the vertebral body. A K-wire is placed through the Jamshidi needle, and the Jamshidi needle is removed. The pedicle is subsequently tapped, and a pedicle screw is placed over the K-wire using fluoroscopy to ensure the K-wire is not being driven deeper into the vertebral body.

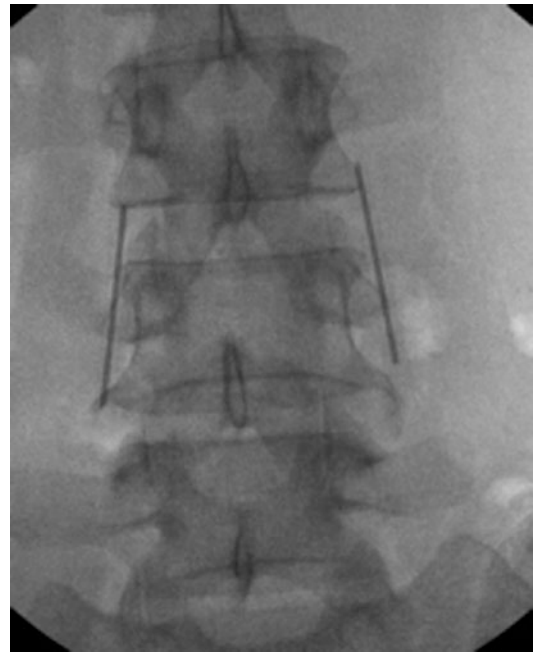

Fig. 12.2 AP x-ray marking the lateral borders of the pedicles at L4 and L5 prior to draping the position. The skin is marked and the needle removed prior to prepping the patient

An alternative is the mini-open technique. A tubular retractor is docked on the facet joint to be fused after splitting the paraspinal muscles with sequential dilator tubes. The tubular retractor may then be expanded in a cranial and caudal direction to expose the transverse processes. The entry point of the pedicle is identified (junction of the midpoint of the transverse process and lateral facet joint) and decorticated with a high-speed drill or an awl (Fig. 12.3). The pedicles are probed and tapped under direct visualization and with the assistance of lateral fluoroscopy to achieve a trajectory parallel with the superior end plate (Fig. 12.4). We typically place our contra-

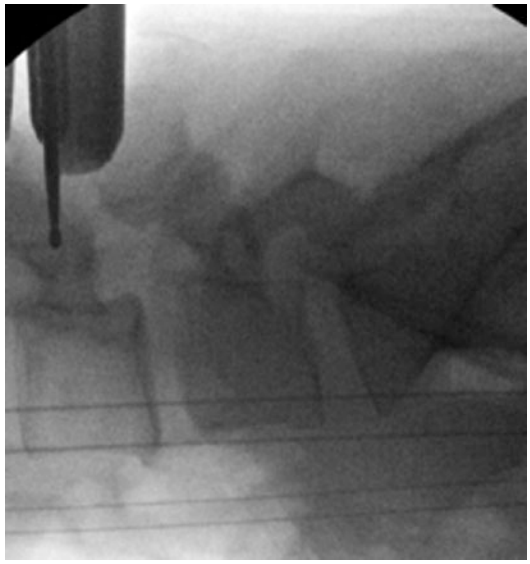

Fig. 12.3 Lateral x-ray marking the starting point with a high-speed drill prior to creating the entry point

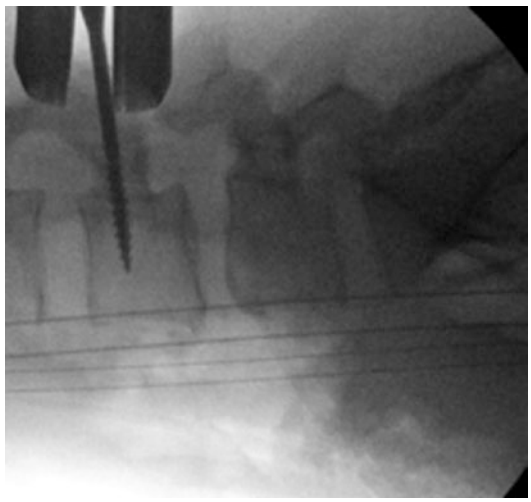

Fig. 12.4 First a gear shift is used to create a pilot hole. A lateral x-ray shot assesses whether a subsequent tap remains parallel to the end plate

lateral screws first, followed by tapping of the ipsilateral pedicles. Pedicle markers are placed through the tubular retractor prior to completing the facetectomy, diskectomy, and interbody graft placement. The pedicle markers are removed, and the ipsilateral pedicle screws are placed after the interbody work is completed and the cage placed (Fig. 12.5).

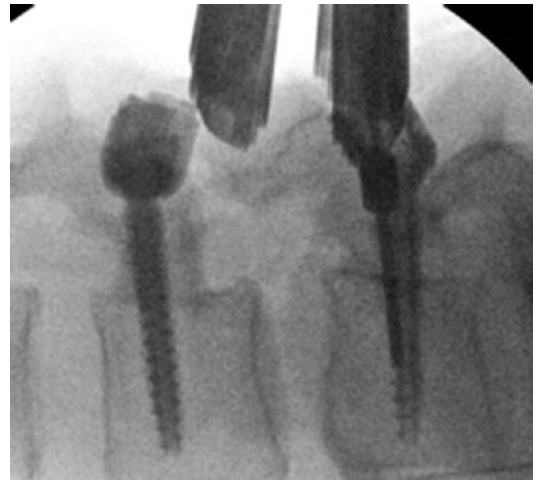

Fig. 12.5 Lateral x-ray demonstrating the contralateral pedicle screws are in place along with the superior ipsilateral pedicle screws. The inferior ipsilateral pedicle is probed, palpated, tapped, and palpated again prior to placing a pedicle marker in place before starting the decompression with removal of the ipsilateral facet joint

Interbody Fusion and Bone Fusion Material

Through a tubular retractor, the decompression and interbody fusion are performed. An ipsilateral total facetectomy is completed using a combination of a quarter-inch osteotome and mallet or high-speed drill and Kerrison rongeurs. Bone from the facet complex is saved for fusion material. The bone is then morselized on the back table in preparation for use as autograft in the interbody space. The exiting nerve root, the lateral edge of thecal sac, and the superior border of the inferior pedicle are directly visualized to identify Kambin's triangle. The intervertebral disk is identified within the borders of Kambin's triangle. Epidural veins overlying the disk are cauterized with bipolar coagulation. The disk is opened sharply with a 15-blade, taking care not to cut the exiting nerve root or the thecal sac. The disk is removed in a piecemeal fashion using serial end plate shavers and pituitary rongeurs. Rasps and currettes are used to remove the annulus exposing the cortical end plates. Local autograft is then packed in the interbody space using a funnel. This may be supplemented with iliac

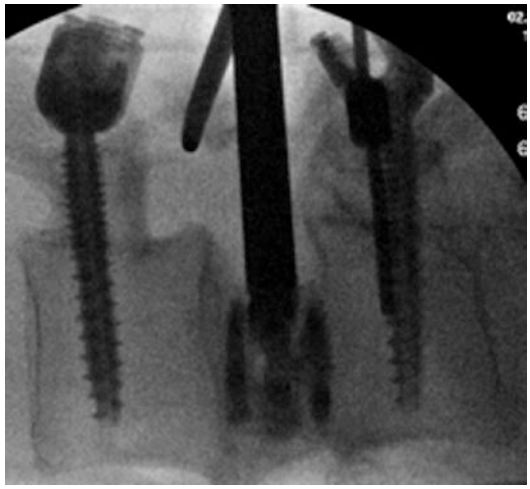

Fig. 12.6 The interbody cage is placed with the use of fluoroscopy to aid final placement. An anteriorly positioned cage is favored. Note that the cage is not released until final placement is confirmed

crest autograft or aspirate mixed with allograft and bone graft extenders. An appropriately sized interbody graft is determined with lateral fluoroscopy and placed in the intervertebral space. Its position is confirmed with AP and lateral fluoroscopy prior to releasing the inserter (Fig. 12.6).

If performing a MIS laminectomy for decompression, we typically perform it after the interbody work is completed. Ipsilateral pedicle screws are placed and their position confirmed with fluoroscopy. The Wilson frame is cranked down to maximize lumbar lordosis. Rods are placed and secured to the pedicle screws with locking cap screws.

In correcting deformities using a MIS-TLIF technique, we typically will perform the facetectomy on the concave side of the deformity. This is typically the side of unilateral recess stenosis and foraminal stenosis. The facetectomy then releases concave side of the curve allowing for straightening of the spine in a coronal plane. Sagittal plane correction is accomplished by reestablishing height in the anterior column of the spine. Placement of the interbody spacer is usually central, though we will occasionally place the graft to the concave side of the interbody to increase our correction. Screwhead distraction on the concave side may help with placing a larger graft and correcting the coronal Cobb angle. Whether or not screwhead distraction and compression at the time of final tightening of the locking cap screws are as advantageous as a Smith-Petersen osteotomy has not been compared using a MIS-TLIF technique.

MIS-TLIF Versus Open TLIF

Operative Time, Estimated Blood Loss, Length of Stay, and Radiation Exposure

Dhall et al. reported that mini-open TLIF may reduce operative time compared to traditional open TLIF for single-level surgeries [1]. A meta-analysis by Khan et al. demonstrated no significant decrease in operative time when compared to open techniques [6]. Several studies showed MIS-TLIF resulted in significantly less blood loss and decreased length of hospital stay when compared to open techniques [6–8]. However, there was increased radiation exposure to the patient and surgeon with the use of MIS techniques [9]. No differences were found in fusion rate in a meta-analysis performed by Khan et al. [6].

Complication Avoidance and Management

Cerebrospinal Fluid Leaks

One surgical pearl to avoid dural tears is to delay dural exposure until the placement of the interbody graft is complete. We protect the lateral thecal sac and avoid the exiting nerve root during the diskectomy. The pars may initially be left in place as a bony protection of the exiting nerve root. The exposed dural elements are then covered with a small cottonoid when attaching the pedicle screws to the rods with set screws.

CSF leaks that occur in MIS-TLIF cases can be difficult to repair because of the limited exposure

and reduced working space. If a dural tear occurs, we attempt to sew the leak closed with a piece of muscle and inject fibrin glue over the area of the leak. If we cannot achieve an appropriate seal with repair suture, placing a lumbar subarachnoid drain in a patient with CSF leak is considered. We believe that the smaller potential postoperative dead space with the MIS-TLIF has the advantage of preventing a larger pseudomeningocele. Therefore, conversion of a MIS technique into a large, open exposure procedure has not typically been necessary at our institution.

Nerve Root Injury

Excessive nerve retraction is to be avoided as it may result in radiculitis or nerve injury. Although rare, a small number of patients may have a large exiting nerve root or conjoined nerve roots occupying the entire neural foramen. Limited mobilization permitted by these anatomical variations may make it hard to acquire access to the disk space. We prefer a posterolateral fusion and subsequent anterior lumbar interbody fusion for these patients, or we perform the TLIF from the contralateral side.

Malpositioned Hardware

Placement of hardware including pedicle screws and interbody spacers through minimally invasive tubular retractor limits the surgeon's operative field of view and orientation. Thus, an excellent understanding of the fluoroscopic anatomy is required given the limited number of visual landmarks. We prefer to use fluoroscopy to identify the entry point and direction of pedicle screws. Fluoroscopy is used in the placement of interbody grafts to determine size and depth of final placement. The combination of AP and lateral fluoroscopy is an excellent method to check the position of hardware. Sometimes, we confirm screw and graft positioning with an intraoperative portable CT scan (especially in cases with rotational deformity) prior to closure.

Conclusion

MIS-TLIF is an effective tool in the surgeon's armamentarium. Advantages include decreased blood loss and hospital stay in appropriately selected cases. Typically, MIS-TLIF is used for one- or two-level surgery in patients with spondylolisthesis (most common application). It may be used for spinal deformity correction for some patients, and patient selection in deformity cases is guided by the MISDEF algorithm.

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Anterior Column Release for Adult Lumbar Scoliosis

13

Gregory M. Mundis Jr and Pooria Hosseini

Introduction

Reestablishment of spinopelvic harmony and restoration of sagittal balance have been directly linked to satisfactory postsurgical outcomes as demonstrated by health-related quality of life (HRQOL) data in adult spinal deformity surgery. Glassman et al. [1] showed that even those with a mild positive sagittal balance in adult spinal deformity surgery can have altered HRQOL measures. In addition, they showed that severity of symptoms increases in a linear fashion with progressive sagittal balance and kyphosis is not tolerated in the lumbar spine. Lafage et al. showed that self-reported disability deteriorates with increased anterior sagittal balance and increased pelvic retroversion [3]. Realignment objectives for sagittal plane correction independent of surgical technique have been defined and include PT <20°, SVA <50 mm, T1SPI <0, and LL= PI ± 10° [2, 4]. However, more recently the International Spine Study Group (ISSG) in a study by Lafage et al. [5] found that sagittal spinopelvic alignment varies with age. Thus, operative alignment targets should account for age especially with younger patients requiring more rigorous alignment objectives.

Focal kyphotic deformities are traditionally corrected by posterior-based osteotomies ranging from posterior column osteotomies (PCO) to three-column osteotomies (3CO) such as pedicle subtraction osteotomy (PSO) and vertebral column resection (VCR). Though effective in correcting the focal kyphosis, these techniques are associated with significant morbidity including prolonged operative times, neurological complications, and a high volume of blood loss [6–8]. It has been shown that the extent of the osteotomy is the defining factor for the relatively high rate of complications in these conventional techniques (28 % with PCO and 61 % with VCR) [9].

To address the high rate of complications in the conventional techniques, the lateral lumbar interbody fusion (LLIF) surgery was developed.

Conflict of Interests
Gregory Mundis – Nuvasive (a, d, g, h), K2 M (a, d), ISSGF (g), Society of Lateral Access Surgery (h), San Diego Spine Foundation (h), Global Spine Outreach (h)
The rest of coauthors' declared none.
(a) Royalties (b) Speakers bureau/paid presentations (c) Paid employee (d) Paid consultant (e) Unpaid consultant (f) Stock or stock options (g) Research support from a company or supplier as a PI (h) Board member/committee appointments for a society (i) Other financial or material support

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LIF techniques have been shown to be effective in treating a wide variety of spinal pathologies, including spinal deformities, with decreased morbidity and operative time [10, 11]. Rodgers et al. [12] reported that with the use of minimally invasive surgical (MIS) techniques, surgical treatment of spinal pathologies need not be withheld on the basis of age. Elderly patients can successfully be treated using MIS techniques and enjoy significant improvement in pain, mobility, and quality of life.

Current approaches to the anterior and middle columns utilizing LIF techniques rely on the competence of the anterior longitudinal ligament (ALL) for graft tensioning and a barrier to prevent anterior dislodgement of the interbody graft. However, when considering a sagittal plane deformity correction with ACR and application of a hyperlordotic cage, the ALL and anterior annulus are the primary barrier to anterior column lengthening, sagittal realignment, and deformity correction. In such a situation, ALL release and anterior/lateral release of the annulus are required [6].

Indications

Junctional kyphosis after a previous fusion is the most common indication for the ACR procedure. However, current literature has also considered progressive sagittal plane deformity, instability, motion at the level of focal deformity, and declining quality of life as less common indications for ACR surgery [6].

Contraindications and Limitations

On the basis of the authors' experience, this technique may only be considered in carefully selected patients with favorable anatomy with sagittal deformity. Patients with abnormal vascular anatomy, previous retroperitoneal infection, fibrosis, or previous anterior spinal or retroperitoneal surgery are not good candidates for ACR. In addition, fixed deformities at the level of disk space, which require more extensive surgery, are a relative contraindication to ACR. The same is true with a solid posterior spinal fusion, which may require posterior osteotomies prior to ACR.

In addition, it is highly recommended that only surgeons with adequate experience in the management of the adult spinal deformity as well as lateral approach surgery of the spine attempt this approach.

Surgical Technique

Since the first ACR surgery in 2005, the technique has evolved significantly. The newer instruments and retractors have made this approach safer and more reproducible. In this section we elaborate on the preferred technique of the authors.

To begin, ACR technique with or without ALL release requires evaluation of flexibility of the spine at the desired intervertebral disk. This evaluation can be carried out by using full-length 36″ standing radiographs and supine hyperextension cross-table lateral radiographs using a large bolster at the apex of the deformity. Evaluation of surgical anatomy by MRI and/or CT myelogram to understand the location of the anterior vascular structures and the psoas and lumbar plexus anatomy is of paramount importance.

The operation begins with standard positioning and preoperative fluoroscopic targeting for lateral retroperitoneal approach. In order to minimize the tension on the psoas muscle and associated neurological structures, excessive flexion of the operating table should be avoided. In order to prevent anterior migration of the retractor, the retractor should be secured with the posterior shim into the annulus. The preferred docking point for the lateral retractor is on the posterior quarter of the disk space. In order to separate the plane between ALL and anterior structures, gentle anterior dissection with the help of custom instrumentation including specialized curve retractors, which accommodate the curvature of the anterior vertebral body, should be performed (Fig. 13.1). Next, a thorough diskectomy with a wide ipsilateral and contralateral annulus release is performed. For appropriate implant selection,

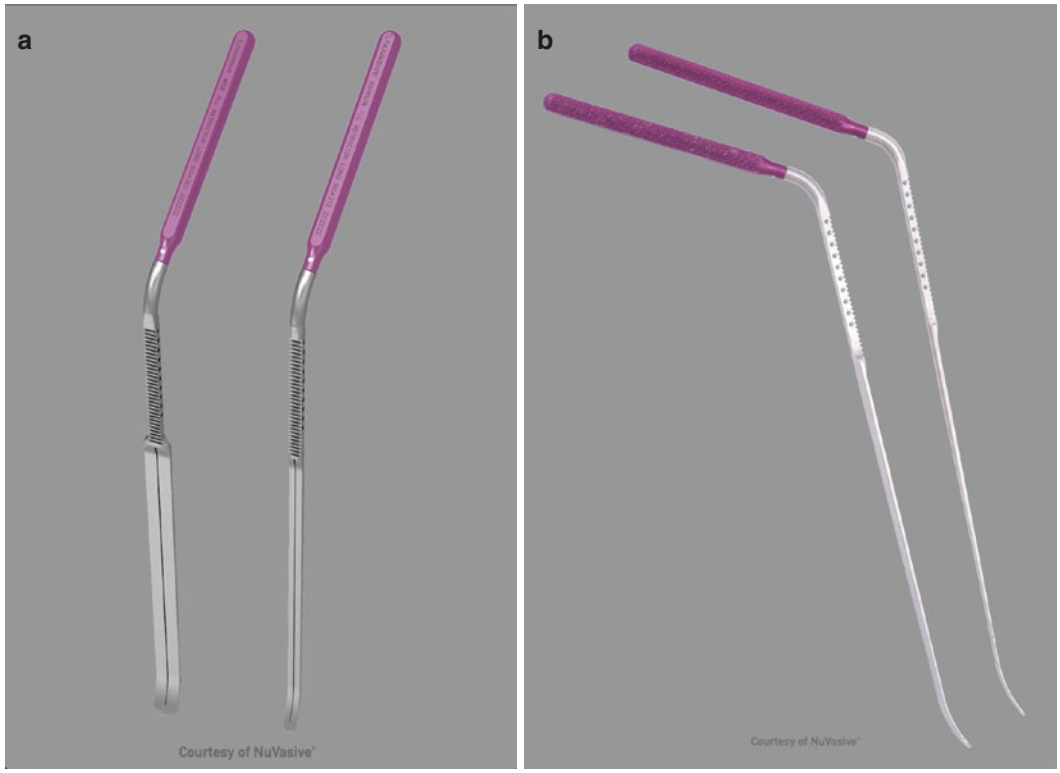

Fig. 13.1 (**a**, **b**) Front and lateral view of anterior longitudinal ligament retractor (courtesy of NuVasive, Inc.)

the anterior-posterior length of the exposure needs to be broad. The authors have found that in order to accommodate a 22 mm wide implant, a minimum anterior-posterior exposure length of 24 mm is required. Prior to releasing the ALL, broad anterior retractors are placed between the great vessels and the spine to avoid the retractor falling into the disk space after the release. The ALL and the remaining annulus are released sharply with a knife along the trajectory of the anterior retractor. Paddle distractors inside the disk space will confirm adequate release of the ALL. Incomplete ALL release and incomplete contralateral or posterior annulus removal can contribute to persistent tension during distraction testing. If the disk space does not freely move, then the release is incomplete, and proceeding with trialing is not indicated, but rather the diskectomy needs to be reevaluated and repeated. Sequential trialing is then performed working up in size until the desired (preoperatively planned) implant size is achieved. The implant is then filled with graft material and inserted into the disk space using an integrated implant/posterior blade slide, which ensures that the implant will rest in the position of the posterior blade and not migrate anteriorly. This slide design is also useful to use during trialing. AP and lateral fluoroscopic images are performed with the trial in place to ensure appropriate positioning. Care must be taken to have accurate X-ray images as the release may cause a substantial shift in patient alignment. To secure the cage and prevent migration fixation to the vertebral body are achieved by placing one or two screws through the flanged design of the cage.

It is highly recommended to limit the expansion of the retractors docked within the psoas muscle throughout the procedure. The ACR portion of the lateral interbody fusion can add 10–20 min to the surgical time; therefore, careful attention must be paid to the amount of time and the degree of retraction of the psoas. The authors recommend a surgical pause of

1–2 min after 20 min of retractor time. During this break, the retractors should be collapsed to allow a release of tension of the neural elements. Furthermore, the retractor aperture should be limited only to what must be visualized for the given stage of the ACR. During the interbody prep, the cephalocaudal retraction should be minimal and just sufficient to visualize the disk space and should only be expanded further temporarily during trialing and implant placement.

Finally, at our institution an approach-specific neuromonitoring system, Neurovision (Nuvasive, San Diego), is used to decrease the risk of neurological complications. This neuromonitoring system provides direction-specific feedback and free-running EMG to help guide the placement of the dilators and retractors and to allow direct identification of neurological structures in vicinity of the approach [6]. Furthermore, we recommend both MEP and SSEP monitoring to allow for detection of any intraoperative monitoring changes. (Figure 13.2 and 13.3)

Advantages

Mean estimated intraoperative blood loss in ACR surgery is significantly less than conventional posterior-based techniques. Akbarnia et al. [6] reported 111 mL of blood loss during ACR surgery and 1484 mL for posterior procedure versus 2–3 l with PSO [8, 13].

Segmental correction of focal kyphosis after PSO has been reported between 24° and 34° [14, 15]. Akbarnia et al. [6] reported an average of 28° in their single motion segment angle (MSA) correction, which compares favorably with PSO, and the overall correction with additional posterior approach with or without PSO was 37°.

Complications

Although minimally invasive ACR is developed to minimize the complications of deformity correction procedures while maintaining the surgical

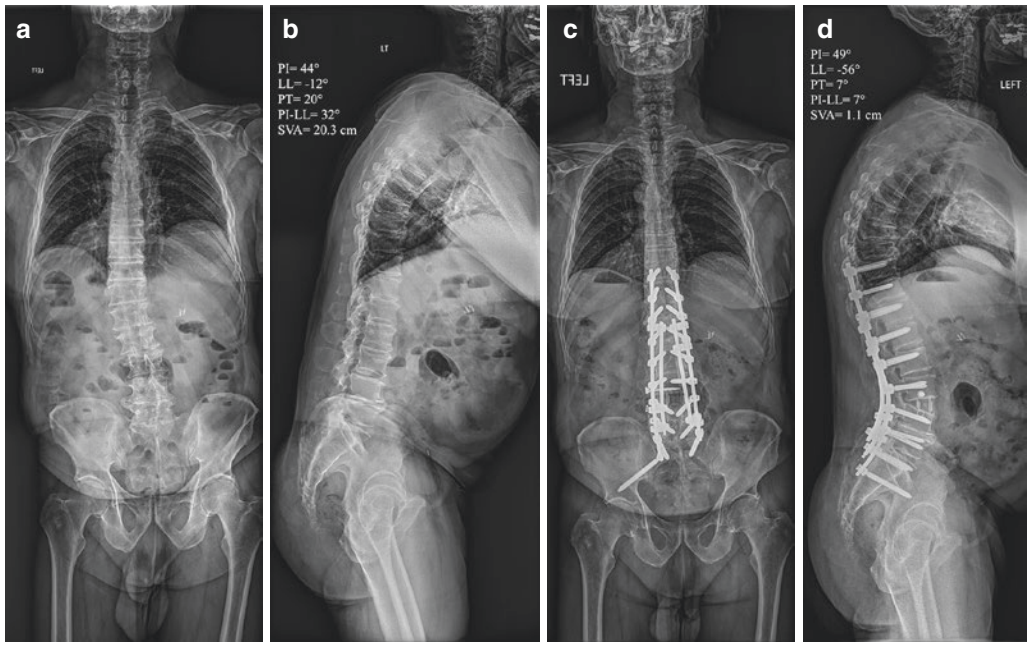

Fig. 13.2 (**a**, **b**) Anteroposterior and lateral radiographs of a 58-year-old male with degenerative flat back deformity. Has previous L4-S1 uninstrumented fusion 20 years ago. PI = 44°, LL = −12°, PT = 20°, SVA = 20.3 cm. (**c**, **d**) Postoperative anteroposterior and lateral 36" radiographs with L3-4 ACR and posterior instrumented fusion with L3-4 posterior column osteotomy. PI = 49°, LL = −56°, PT = 7°, SVA = 1.1 cm

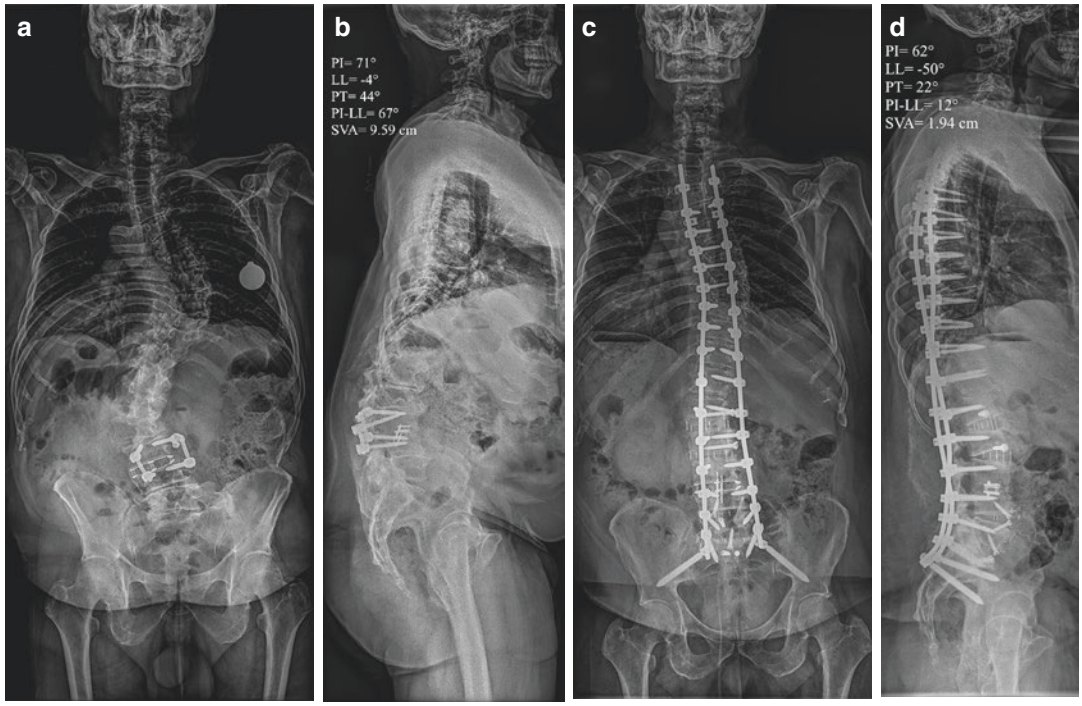

Fig. 13.3 (**a**, **b**) Anteroposterior and lateral radiographs of a 64-year-old male with adult idiopathic scoliosis and lumbar kyphosis with previous L3-4 fusion now with nonunion. PI = 71°, LL = −4°, PT = 44°, SVA = 9.59 cm. (**c**, **d**) Postoperative AP and lateral 36" radiographs with L4-5, L5-S1 ALIF ACR; L1-2 and 2-3 LLIF ACR; and T4-ileum posterior spinal fusion with instrumentation. PI = 62°, LL = −50°, PT = 22°, SVA = 1.94 cm

goals, they have their own subset of unique complications. Akbarnia et al. [6] reported up to 47 % complication rate in their series, which were all neurological complications in nature with 3 months as the cutoff point for categorization into minor or major subgroups. In another study by Murray et al. [16], it was shown that 9/47 (19 %) of cases experienced ACR-related complications of which eight of them were iliopsoas weakness and one retrograde ejaculation. In that study, there were no reported vascular, visceral, or surgical site infection complications associated with ACR procedure. In addition, Murray et al. have classified MIS ACR complications into major medical, major surgical, minor medical, and minor surgical (Table 13.1), modified from Auerbach et al. [17]. Berjano et al. [18] reported two major complications including bowel perforation and postoperative early infection of the posterior wound that required surgical debridement, among a series of 11 enrolled cases.

Below are some of the ACR-related complications that the authors have experienced in their own practice.

Neurological Complications Injuries to the nervous system are among the main concerns in this technique. Neurological complications can be categorized as major and minor. Minor complications include transient dysesthesia or paresthesia in the ilioinguinal, iliohypogastric, genitofemoral, lateral femoral cutaneous (LFCN), or anterior cutaneous nerve distributions persistent beyond 1 month of surgery that resolve by 3 months from surgery. Approach-related side effects are defined as occurrence of any of these complications immediately after surgery and resolving within 1 month. Major neurological complications are defined as persistent radiculopathy, paresthesia, and dysesthesia, which continue beyond 3 months postoperatively, requiring surgical revision, not approach-related neurologic weakness isolated to a specific nerve

Table 13.1 Classification of complications of spinal deformity surgery

Perioperative complications	Follow-up complications
Major medical	
Deep venous thrombosis Pulmonary embolism Pulmonary effusion Respiratory failure Severe hypertension Optic deficit Cerebrovascular accident Cardiac arrest/ myocardial infarction Death Other cardiopulmonary	Cerebrovascular accident Myocardial infarction Deep venous thrombosis Pulmonary embolism Pneumonia
Major surgical	
Major motor deficit Other neurological major deficits Vascular injury Visceral injury Deep infection	Persistent motor deficit Other major neurological deficits Deep infection Instrumentation or junctional failure
Minor medical	
Minor cardiopulmonary Non-spinal infection	
Minor surgical	
CSF leak Anterior thigh numbness Other sensory deficits Other minor deficits Superficial infection Vertebral fracture	Instrumentation failure without change in alignment Persistent anterior thigh numbness Minor neurological deficit CSF leak Superficial infection Seroma

Modified from Auerbach et al. [17] classification

root or persistent iliopsoas weakness beyond 1 month postoperatively. Motor weakness has been reported in the quadriceps, iliopsoas, and tibialis anterior muscle groups. It is difficult to ascertain which portion of the surgery results in the neurological deficit, as many of these procedures are multilevel interbodies with only one level that included an ACR. Despite careful use of intraoperative neuromonitoring, neurological complications may still occur, which warrant a full patient workup including CT and MRI when indicated to rule out a stenotic or structural element secondary to sagittal realignment (foraminal stenosis). Most patients that suffer from a neurologic injury find improvement in function over the course of their treatment [6]. Most of the data published includes an experience of ACR surgery from several years ago. Our current practice includes several strict protocols that allow for a more predictable postoperative recovery. This includes retractor times no more than 20 min without a 2 min break, continuous EMG trigger testing of the posterior blade of the retractor, minimal to no "breaking" of the operating room table, postoperative drain usage, and intraoperative administration of IV steroid.

Vascular Complications Vascular injuries, which can be life-threatening if not acted upon immediately, can happen during any anterior dissection. Higher incidence of vascular injuries when removing anterior implants has been previously reported [19] using an anterior approach. An example of vascular injury during ACR surgery is iliac artery tear, which has been reported [6]. Intraoperatively, if there is any concern for the possibility of vascular injury, the suspicious site should be packed immediately. A determination should be made whether the bleeding is venous or arterial. If venous, then the wound should be packed with material that can remain in place and does not require future removal such as Fibrillar, Gelfoam with thrombin, and Surgicel. Once the bleeding is controlled, the surgical site should be carefully examined, and determination is made whether or not to abort the operation. If bleeding persists despite packing, then the vascular surgeon should be immediately consulted intraoperatively to determine if primary repair versus stenting is indicated. Various vascular structures can be involved including the segmental artery and vein (particularly if the retractor unknowingly shifts), the ascending iliolumbar vein (in the case of a left-sided approach), the common iliac vein (less likely artery), the vena cava, and the aorta. Surgical planning is critical to complication avoidance with careful evaluation of the MRI and any other available imaging. It is always prudent to perform this technique when the vascular surgeon is available in the hospital, and one should not hesitate to seek their help if required. Although exceedingly uncommon,

the authors recommend the following regarding vascular complications: inform the vascular surgeons about the procedure you are performing before the day of surgery, have intraoperative supplies open and available (SURGIFOAM with thrombin, Gelfoam soaked in thrombin, Surgicel, and Fibrillar) with additional supplies available that are unopened, and always prepare the surgical site to include the umbilicus anteriorly in case the incision needs to be extended for primary repair.

Sympathetic Dysfunction Any injury to the sympathetic plexus adjacent to the site of operation can present with changes of temperature and perspiration disturbances in the lower limb. Sympathetic lesions differ based on the level of instrumentation. There may be a significant increase in the skin temperature of the foot due to unopposed vasodilation by parasympathetic fibers [20]. On the basis of available literature, any temperature difference more than one standard deviation from others' foot temperature should be considered as pathologic [21]. Injuries to hypogastric sympathetic plexus can lead to retrograde ejaculation, impotence, and even neurogenic priapism [22–24]. Dysesthesia, discoloration, and swelling of the lower extremity are among other presentations of sympathetic disturbances [22, 24]. However, it is important to know that HRQOL results do not differ significantly between control groups and sympathetically disturbed patients [25]. According to literature, postoperative sympathetic chain lesions tend to recover over time in some patients; however, there are hardly any reliable data on the time needed for recovery, which varies between 3 weeks and 1 year [22–24].

Incomplete ALL Release and Endplate Fracture Forcing a hyperlordotic cage in an intervertebral disk space with an incomplete ALL and annulus release can lead to endplate fracture and cage subsidence. This needs to be recognized intraoperatively during trialing. The trials should not have any resistance during insertion. If there is resistance or the trial is forced anteriorly, then it is highly likely that an incomplete release has been performed. To avoid implant migration and endplate fracture, it is recommended that the anterior release be reexamined. Common areas for incomplete release include the contralateral anterior/lateral corner of the annulus and the posterior annulus. On occasion the dissection and release need to be carried forth more posteriorly to allow for symmetric disk space opening.

Conclusion

The authors believe that the ACR technique is a viable alternative as a less invasive surgical correction of sagittal deformity. Compared with posterior-based techniques, less invasive ACR surgery has similar correction capacity and similar rate of morbidity. We believe that ACR technique in the hands of a well-experienced surgeon in deformity surgery as well as minimally invasive surgery can provide satisfactory results for select cases of focal kyphosis and adjacent segment deformity. As the technique matures and the surgery is made reproducible, we believe that it will become more useful, and the integration of ACR into the practice of the deformity surgeon will increase. ACR surgery is a relatively new technique with limited published literature and will likely require multicenter collaboration to answer many questions surrounding this technique.

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Anterior Column Support Options for Adult Lumbar Scoliosis

14

Ashish Patel, Federico Girardi, and Han Jo Kim

Introduction

Anterior column support is frequently used at the base of medium to long thoracolumbar constructs during realignment surgery for adult spinal deformity [1]. Anterior column support can provide immediate mechanical stability against axial compression and flexion moments, improved fusion rates, and the ability to improve segmental sagittal and coronal alignment [2]. In addition, structural interbody support is a good strategy for minimizing longitudinal rod and screw-bone interface strain, thus increasing the chance for arthrodesis.

Historically, anterior column support has been used in single-level and multilevel disease for patients requiring spinal realignment and arthrodesis [3]. Data from prospective multicenter clinical data has resulted in a shift toward posterior-only surgery and increased use of three-column osteotomies for major spinal realignment surgery [4, 5]. The use of anterior column support in posterior-only approaches is typically reserved for the lower lumbar motion segments. With the increased utility of the minimally invasive lateral approach, there has been a resurgence of interest in multilevel interbody support throughout the lumbar spine for spinal realignment; however there is still limited data to support this approach [6, 7]. Conceptually, multilevel interbody devices may reduce the need for posterior osteotomies via segmental correction, reduce the mechanical stress on posterior fixation points, and increase segmental stability with placement of large interbody devices. The opportunity for increased fusion rates via discectomy and thorough endplate preparation is desirable in order to achieve the best clinical outcome. Although early reports on multilevel lateral interbody grafting suggest comparable coronal deformity correction to posterior-only approaches, there has been limited success in realignment of the sagittal plane without performing additional corrective maneuvers such as the transection of the anterior longitudinal ligament (ALL) [8].

Decision-making and methodology regarding anterior structural support during adult spinal deformity surgery are multifactorial in nature. Strategic placement of interbody devices may be accomplished via anterior, posterior, or combined approaches. The literature supports the ability for anterior interbody devices to restore intervertebral height, provide indirect decompression of foraminal stenosis, and improve segmental sagittal alignment [9–11]. Transitional zones in the spine, specifically at the thoracolumbar and sacropelvic junctions, are notable for higher rates of pseudoarthrosis. Anterior column support at the lumbosacral junction improves local mechanical stability, reducing micromotion and subsequently resulting in improved fusion rates.

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Anterior structural support in adult spinal deformity has historical implications and has undergone contemporary refinement. The purpose of this chapter is to outline current considerations when using anterior structural support during the treatment for adult spinal deformity. Our discussion for anterior structural support includes the indications for use, surgical approach considerations, and choice of graft material(s). The literature on outcomes and complications is also reviewed.

Indications

Operative goals for adult spinal deformity include restoration of sagittal and coronal plane alignment, stabilization via instrumentation, and decompression of neural elements. Certainly, fusing the smallest number of spinal segments possible while achieving these goals is desirable to maximize motion segments above and below the fused spinal segments and to reduce the morbidity associated with long thoracolumbar fusions. Anterior structural support for adult spinal deformity is most commonly utilized at the lumbosacral junction. Clear indications for arthrodesis to the sacrum include a spinal deformity involving the lumbosacral junction, advanced degeneration of the L5–S1 motion segment, and lumbosacral instability. Stopping short of the lumbosacral junction in these patients sets the stage for progressive global sagittal and/or coronal decompensation and possible neurological compression from progressive disc degeneration and instability at the L5–S1 segment. If the patient does not exhibit L5–S1 deformity and instability and the disc is considered to be "healthy," fusing short of the lumbosacral junction may be considered. However, it is important to consider the implications of this construct.

Edwards et al. [12] attempted to answer the question of whether to fuse across the lumbosacral junction in patients with healthy L5–S1 discs during adult spinal deformity surgery. They reported on the radiographic and functional outcomes in a matched cohort analysis. The 39 patients included in this analysis (L5: n = 28 patients, S1: n = 12 patients) were matched for age, smoking history, preoperative SVA, number of fused levels, and status of the L5–S1 disc. Of the 28 patients in the L5 fusion group, degeneration was graded as "no degeneration" in 25 % and "mild degeneration" in 75 %. Zero percent of the patients had advanced degeneration at L5–S1. At a mean 4.8 years postoperatively, 67 % of the patients (18/28) developed advanced degeneration at L5–S1 (52 % moderate, 15 % severe). In fact, four patients underwent extension of fusion to the sacrum during the follow-up. Patients with advanced degeneration developed a progressive and larger positive shift in SVA than the patients that maintained a healthy L5–S1 disc. However, patients fused to the sacrum experienced an increased rate of complications compared to patients fused to L5. These complications included an increased rate of pseudoarthrosis (42 % vs. 4 %) and medical morbidities such as DVT, pulmonary embolism, postoperative infection, and acute respiratory disease syndrome (ARDS) (33 % vs. 0 %). Final outcome scores (SRS-24) were similar for each cohort. From this data, it is evident that fusions across the lumbosacral junction are larger procedures which result in higher surgical and medical complication rates. For those patients with a healthy L5–S1 disc, fusing short of the sacrum is a valid option if sagittal realignment is achieved and no risk factors for failure such as deformity, disc degeneration, or instability are evident on preoperative evaluation. That being said, early data suggests that progressive degeneration of the L5–S1 disc occurs with subsequent positive shift in the sagittal vertical axis (SVA) which may necessitate revision surgery to the sacrum in symptomatic patients.

In a follow-up study by the same group [13], 31 patients with thoracolumbar fusions to L5 were evaluated after a mean 9.8 years of follow-up. Two groups of patients were identified, those patients with "healthy" L5–S1 discs at latest follow-up and those with subsequent advanced disc degeneration (SAD). The groups had similar preoperative and immediate postoperative parameters; however at latest follow-up, the patients with SAD had an increased rate of sagittal malalignment (postoperative development SVA>5 cm),

revision surgery to the sacrum, and lower outcome scores. Risk factors identified for SAD included patients with a more proximal upper instrumented vertebra (UIV) (72 %: T1–T7 UIV vs. 28 %: T8–T12) and patients who underwent circumferential lumbar fusion vs. posterior-only surgery (87 %: A/P vs. 45 %: P-only). This investigation provides useful information when considering saving a healthy L5–S1 motion segment during thoracolumbar fusions. If performing an extended fusion into the proximal thoracic spine or anterior-posterior (circumferential) arthrodesis at the base of the construct, fusion across the lumbosacral junction to the sacrum is preferred over stopping at L5 evidenced by the high incidence of subsequent disc degeneration, sagittal alignment decompensation, and rate of revision surgery.

Once the decision has been made regarding distal fusion level, thought can be placed into the instrumentation strategy at the base of the construct. General benefits of placing an anterior structural device within the base of the construct include an improved arthrodesis rate especially at junctional levels (L5–S1), indirect decompression of exiting nerve roots via restoration of foraminal height, and improvement of local coronal and sagittal alignment via intervertebral distraction and posterior compression of pedicle screws. Depending on the overall objective of the surgery and the objective at each given level, anterior structural support may be used at a single or in a multilevel manner during adult spinal deformity surgery. Placement of the intervertebral support may be accomplished in several ways depending on the surgical level of interest. These are discussed in the following section.

Approach Considerations

Decision-making regarding anteriorly or posteriorly placed structural interbody graft at the lumbosacral junction is based on specific patient factors such as the rigidity of the deformity, revision status, likelihood of successful arthrodesis, spinal realignment goals, and the general health of the patient [12]. With the pendulum shift toward posterior-only surgery [4] for adult spinal deformity, the comfort of the treating surgeon with the anterior approach is also a consideration.

Anterior Approach

The anterior approach to the lower lumbar spine may be accomplished via several methods. Generally a midline or paramedian approach is utilized with consideration of the vascular structures draped over the L4–L5 and L5–S1 discs on preoperative magnetic resonance imaging (MRI) or computed tomography (CT). A surgical corridor is identified, typically on the left side of the patient due to the mobility of the great vessels and location of the arterial vessels. Fluoroscopy may be used to image the level of interest and localize the area for incision. For the left paramedian approach, a 4–5 cm incision is used 3–4 cm off midline. Blunt dissection is carried down to the anterior rectus fascia which is then divided in line with the incision. The rectus is retracted medially, and the posterior rectus transversalis fascia is divided to gain access into the retroperitoneum. Blunt dissection is used to sweep retroperitoneal fat medially, and visualization of the psoas, ureters, and great vessels is made. The ureter is retracted medially, vessels are carefully mobilized, and the anterior sacral artery is ligated. At this time, access to the L5–S1 disc space may be accomplished.

Advantages of the anterior approach include improved access to the disc space for a more thorough discectomy and endplate preparation. Resection of the ALL and annulus may release the segment sufficiently to accommodate a large, wide intervertebral graft. Clinically, this is ideal for restoration of intervertebral and foraminal height and also provides a more stable configuration that can be obtained with a smaller posteriorly placed graft. An added benefit of the anterior lumbar interbody fusion (ALIF) approach is that an intact posterior annulus can serve as structural barrier between the disc space and neural elements when bone growth factors (BMPs) are used within the intervertebral implant. Additional benefits include less posterior bone removal

(facets) for fusion surface and the greater ability to influence sagittal alignment with various graft sizes and dimensions. Newer hyperlordotic cages, with up to 30° of angulation, may be placed to influence sagittal alignment requirements. Several reports have compared the effectiveness between approaches regarding alignment and fusion rates. ALIF is found to outperform transforaminal lumbar interbody fusion (TLIF) and lateral lumbar interbody fusion (LLIF) in generating lordosis. In a retrospective analysis comparing ALIF ($n = 32$) to TLIF ($n = 25$), ALIF was found to increase foraminal height by 18.5 % and increase local (mean 8.3°) and regional (mean 6.2°) lumbar lordosis. Additionally, the TLIF technique was found to decrease foraminal height by 0.4 % and reduce local (mean 0.1°) and regional (mean 2.1°) lumbar lordosis [14]. These findings have been substantiated by other researchers, concluding that the ALIF is technically easier for interbody implant placement and enhancement of lordosis [15].

The disadvantages of ALIF include the possible need for an access surgeon, potential for vascular injury, and retrograde ejaculation [16, 17]. In addition, in cases requiring posterior instrumentation and fusion, ALIF is associated with increased operating time and blood loss, as well as prolonged recovery time leading to longer inpatient hospital stay [16].

Posterior Approach

The posterior approach to the intervertebral space in the lumbar spine may be accomplished via either posterior lumbar interbody fusion (PLIF) or TLIF. Both approaches use the standard midline posterior approach. The TLIF approach utilizes a more lateral access to the disc space and thus reduces retraction of the thecal sac and nerve roots. The TLIF technique allows access to the posterior interbody below the level of the conus and unilateral access for circumferential fusion. This can avoid the need for extensive bilateral epidural dissection especially in revision cases. Initially, the technical demands of these procedures limited their use. However, interest in these posterior procedures was renewed with the development of improved instrumentation, interbody implants, and interbody graft sources [18]. These approaches gained popularity in adult spinal deformity as it allows the surgeon to decrease operative time and avoid the anterior approach and its potential complications (see Figs. 14.1 and 14.2). Nevertheless, the literature points toward improved maintenance/restoration of lordosis with the ALIF. In a meta-analysis of TLIF versus ALIF techniques, the TLIF was found to induce kyphosis. For ideal restoration of sagittal alignment and to improve lordosis, the interbody graft should be placed as anteriorly as possible. In this position, the graft can then be anterior to the instantaneous axis of rotation (IAR) of the spine and allow substantial introduction of lordosis. Without an interbody graft anterior to the IAR acting as a fulcrum for compression, restoration of local lordosis will not be achieved. A further limitation of TLIF is that the contralateral facet complex typically remains intact. The intact facet will limit compression and the capacity to restore lordosis. In cases of sagittal spinal malalignment, a Smith-Petersen osteotomy (SPO) to remove bilateral facets in conjunction with TLIF should be employed. Using compression applied across the disc space and closure of the osteotomy, 5–7° of lordosis may be achieved at each level. Therefore, to achieve lordosis correction with TLIF, one should place the graft as anteriorly as possible relative to the IAR and consider a contralateral facetectomy to increase the magnitude of compression posterior to the IAR [19].

Fusion of these interbody levels is of primary importance, and variations in preparation of the disc space via ALIF vs. TLIF/PLIF have been hypothesized as potential differences. In a prospective multicenter comparative study, Fritzell et al. [16] randomized and analyzed 201 patients in a 6-year span into three groups: group 1, posterior fusion without instrumentation; group 2, posterior fusion with instrumentation; and group 3, posterior fusion with interbody device *either* PLIF or ALIF. Fusion was assessed by an independent radiologist and found to be 72 %, 87 %, and 91 %, respectively. Pursuing a circumferential fusion by the addition of an interbody device

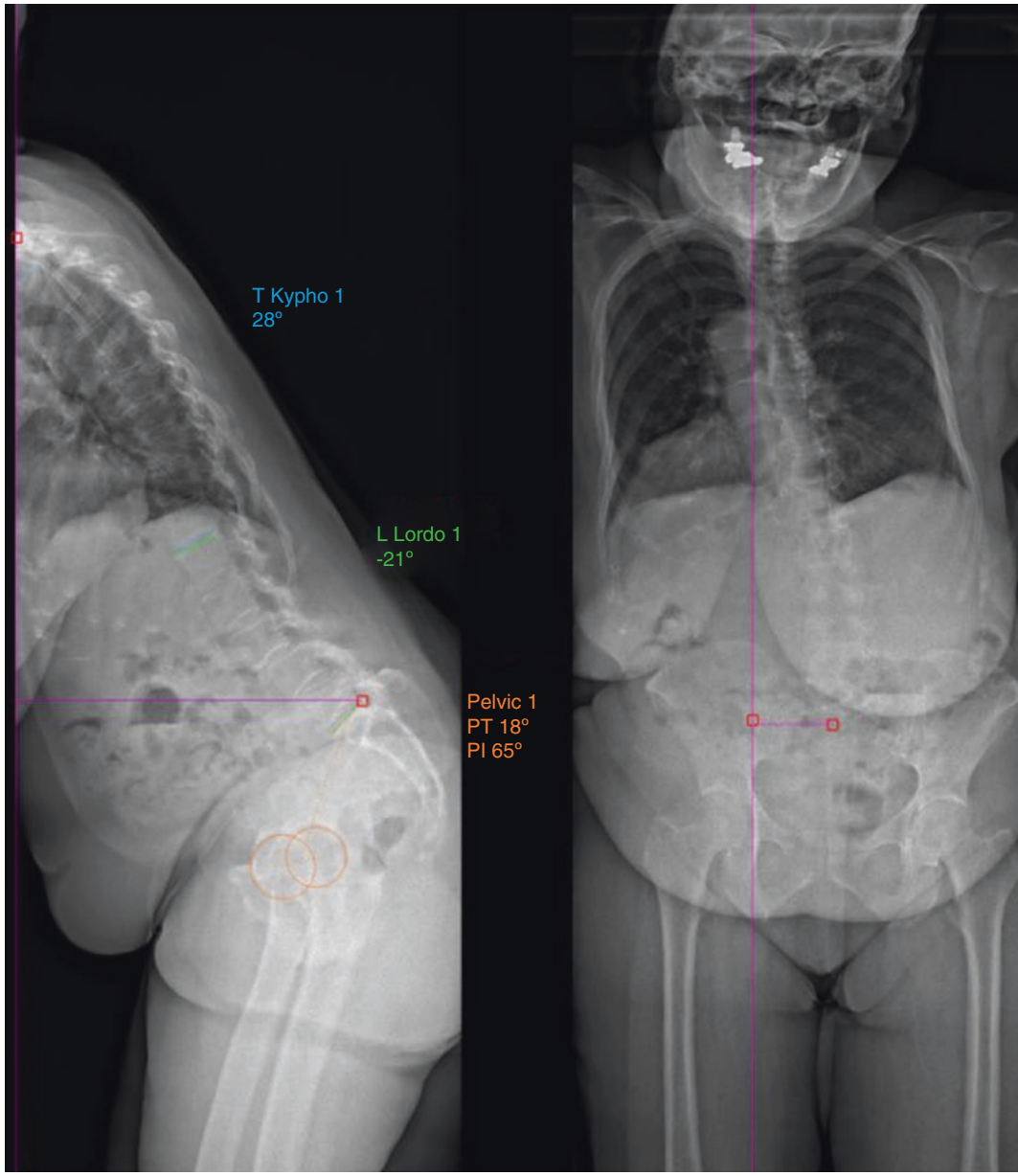

Fig. 14.1 Preoperative anteroposterior and lateral standing radiographs demonstrating substantial loss of lumbar lordosis and a forward leaning posture. Patient exhibits a large PI-LL mismatch

significantly increased the fusion rate in one- and two-level fusions via either the ALIF or PLIF approach. Discectomy and placement of an interbody device with graft material increases the number of potential fusion surfaces to obtain a solid arthrodesis. No differences in fusion rates and outcomes were found between ALIF and PLIF patients. Similar fusion rates between these two groups have been documented by several published reports [19]. Since placement of interbody devices has collectively improved segmental fusion rates, the focus of various grafting options has now shifted to the preservation and enhancement of lordosis.

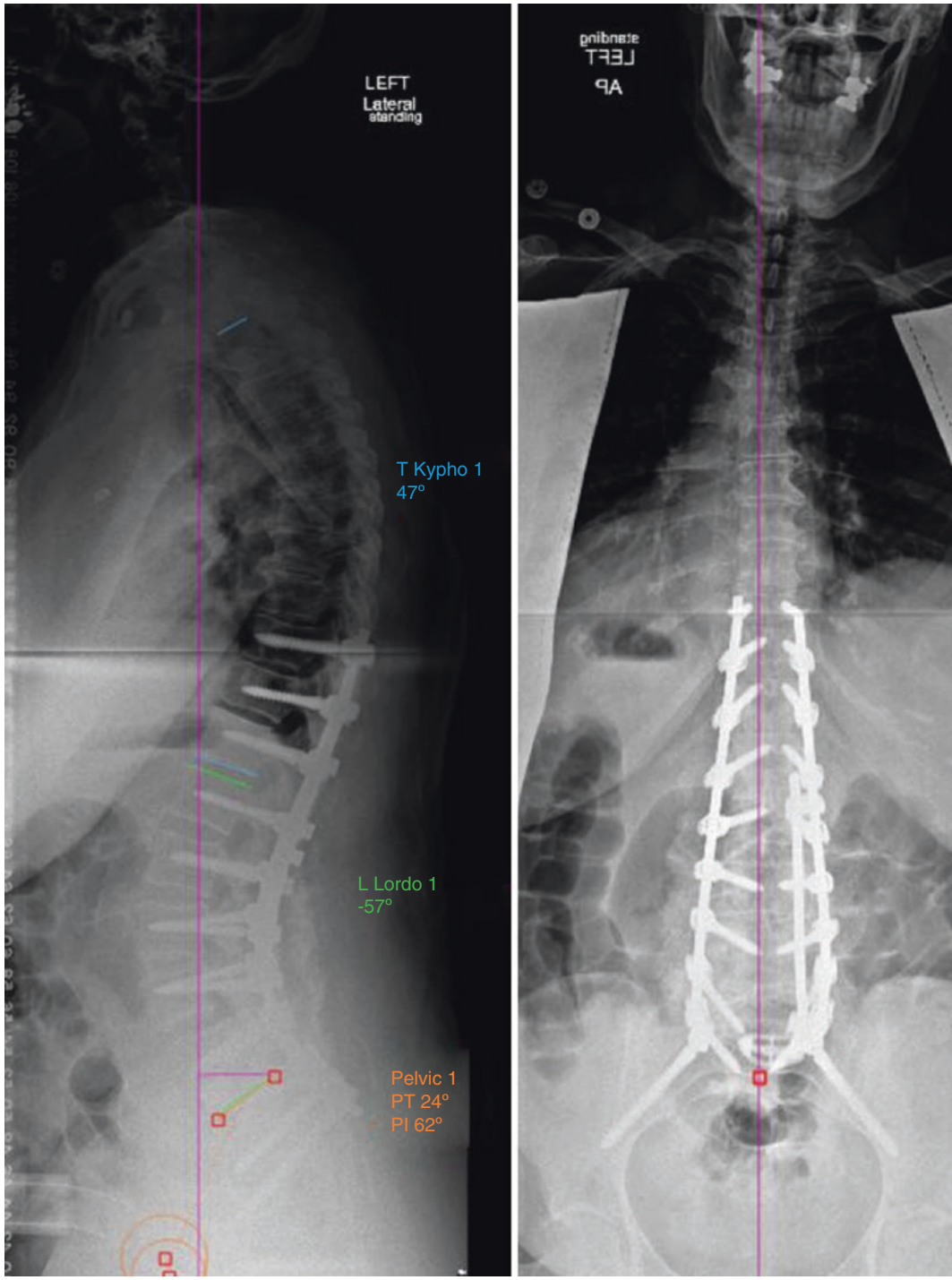

Fig. 14.2 Postoperative anteroposterior and lateral standing radiographs demonstrating restoration of sagittal curves and coronal alignment s/p T10-pelvis with TLIF L5–S1

General complications between PLIF/TLIF and ALIF techniques are directly linked to the surgical approach. Phan et al. [19] reported on complications between the ALIF and TLIF techniques using a meta-analysis. The rates of dural injury were found to be significantly lower in the ALIF group compared with those in the TLIF group (0.4 % vs. 3.8 %; $P = 0.05$). Neurological deficits were comparable between ALIF and TLIF groups (6.8 % vs. 7.9 %; $P = 1.00$) primarily related to the posterior decompression portion of the surgery. Blood vessel injury occurred significantly more frequently in the ALIF cohort compared with that in TLIF (2.6 % vs. 0 %; $P = 0.04$). However, there were no differences between the ALIF and TLIF groups regarding infection rates (4.9 % vs. 4.3 %; $P = 0.89$), allograft malposition (2.4 % vs. 1.8 %; $P = 0.80$), or pedicle screw malposition (7.7 % vs. 6.8 %; $P = 0.20$).

Lateral Approach

With recent advances in instrumentation and techniques, the lateral lumbar interbody fusion (LLIF) approach to the spine has replaced the traditional thoracoabdominal approach for multilevel lumbar interbody device placement (see Figs. 14.3, 14.4 and 14.5). It is generally categorized under minimally invasive surgery (MIS) due to the smaller incision, use of specialized retractors, and use of modified instrumentation to complete the procedure. The technique is reported to improve coronal Cobb angle and segmental lordosis and restore intervertebral/foraminal height [20, 21]. Several advantages of the LLIF approach have been recognized as an adjunct for spinal deformity correction. They include (1) an interbody cage construct with posterior instrumentation that provides a more evenly distributed biomechanical support in all three spinal columns, (2) the use of a wide interbody cage which takes advantage of the apophyseal ring (the strongest area of the endplate), and (3) the use of an interbody cage with greater surface area than traditional cages that allows for placement of additional fusion-promoting biologics. Several disadvantages of the LLIF approach have been recognized and include (1) risk of vascular injury <1 % [8, 22], (2) 19–40 % with immediate postoperative thigh numbness/pain, and (3) 10–55 % with immediate psoas/quad weakness. Most studies report the slow resolution of severe thigh dysesthesias and psoas weakness (<5 % at 1 year), but cases of permanent neurological deficit do occur [20, 21, 23].

Manwaring et al. [24] reported on the outcomes of LLIF with and without anterior column realignment (ACR – release of the anterior longitudinal ligament) in patients with degenerative scoliosis. Analysis consisted of radiographic analysis after the first stage of a multilevel LLIF (with and without ACR) and after the second stage consisting of posterior instrumentation. Thirty-six patients were analyzed. The non-ACR group underwent a mean 4.2 LLIF levels, while the ACR group underwent a mean 3.4 LLIF levels (mean 1.7 ACRs per patient). The non-ACR group gained significant improvements in coronal Cobb angle (28.9° to 16.9°) after the first stage. After posterior instrumentation, there was a mild significant improvement in central sacral vertical line offset (2.5° to 1.6°). However, no significant improvements in sagittal spinopelvic alignment were observed from pre- to stage 1 or from stage 1 to final follow-up: regional lordosis (43.7° to 45.5° to 45.9°), SVA (2.3 to 2.9 to 3.8 cm), and PT (24.9° to 27.2° to 28.6°). Patients in the ACR group gained significant improvements ($p<0.05$) from pre- to post-second stage in several parameters including coronal Cobb angle (24.8° to 9.7°), SVA (8.3° to 3.5°), and segmental (2.4° to 14.4°) and regional lumbar lordosis (36.5° to 53.4°). The authors concluded that the use of the multilevel LLIF approach may gain only modest improvements in segmental, regional, and global sagittal alignment. However, the addition of the ACR technique allows for much larger implant placement, with large lordotic geometries, and thus a

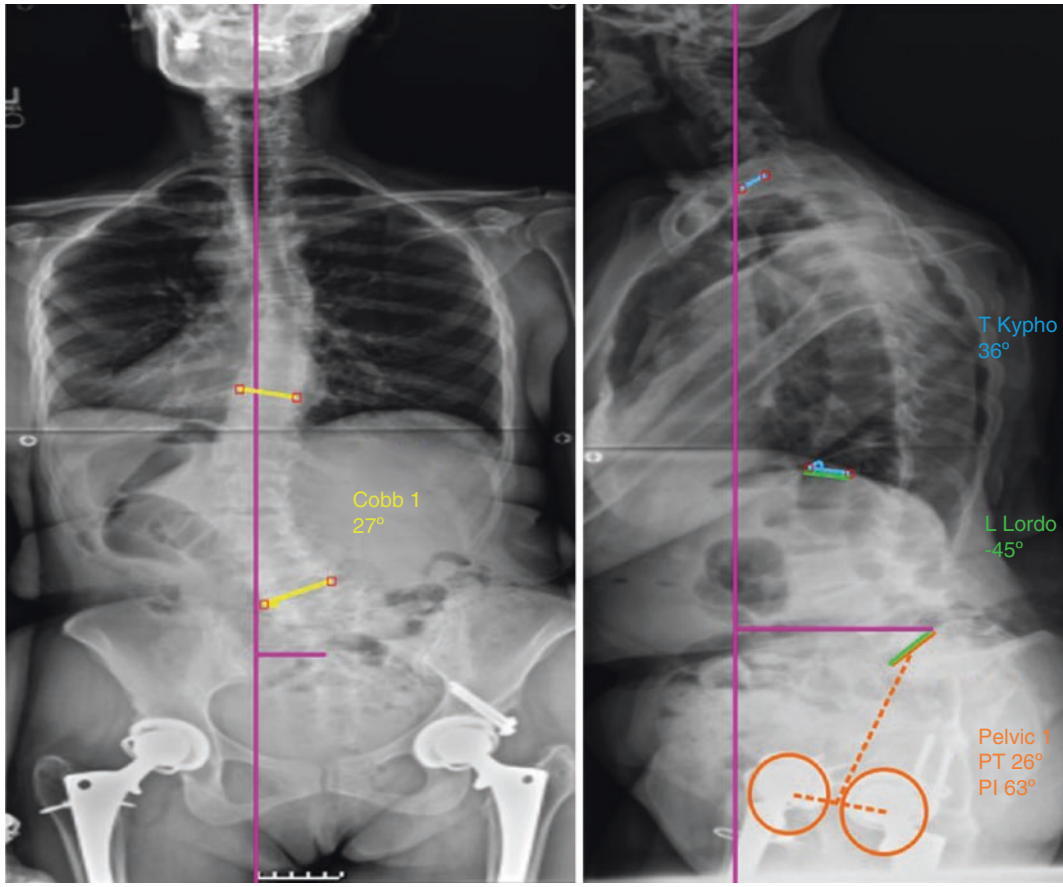

Fig. 14.3 Preoperative anteroposterior and lateral standing radiographs of adult patient with degenerative scoliosis and subsequent coronal and sagittal offset (case provided by Federico Girardi MD)

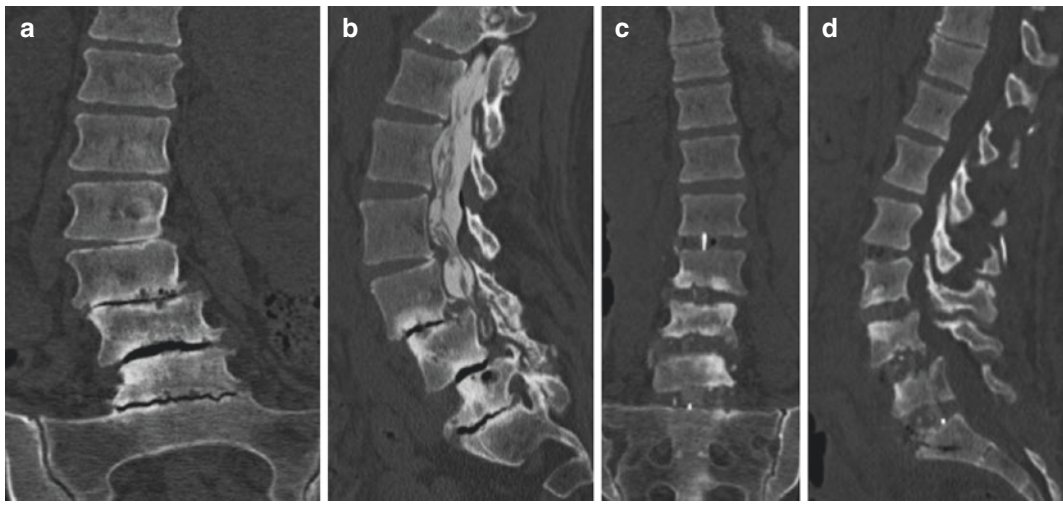

Fig. 14.4 (**a**, **b**) Preoperative CT reconstructions demonstrating multilevel spondylosis and central stenosis. (**c**, **d**) Post-multilevel L2–5 LLIF and L5–S1 ALIF. Restoration of disc height and correction of coronal curvature

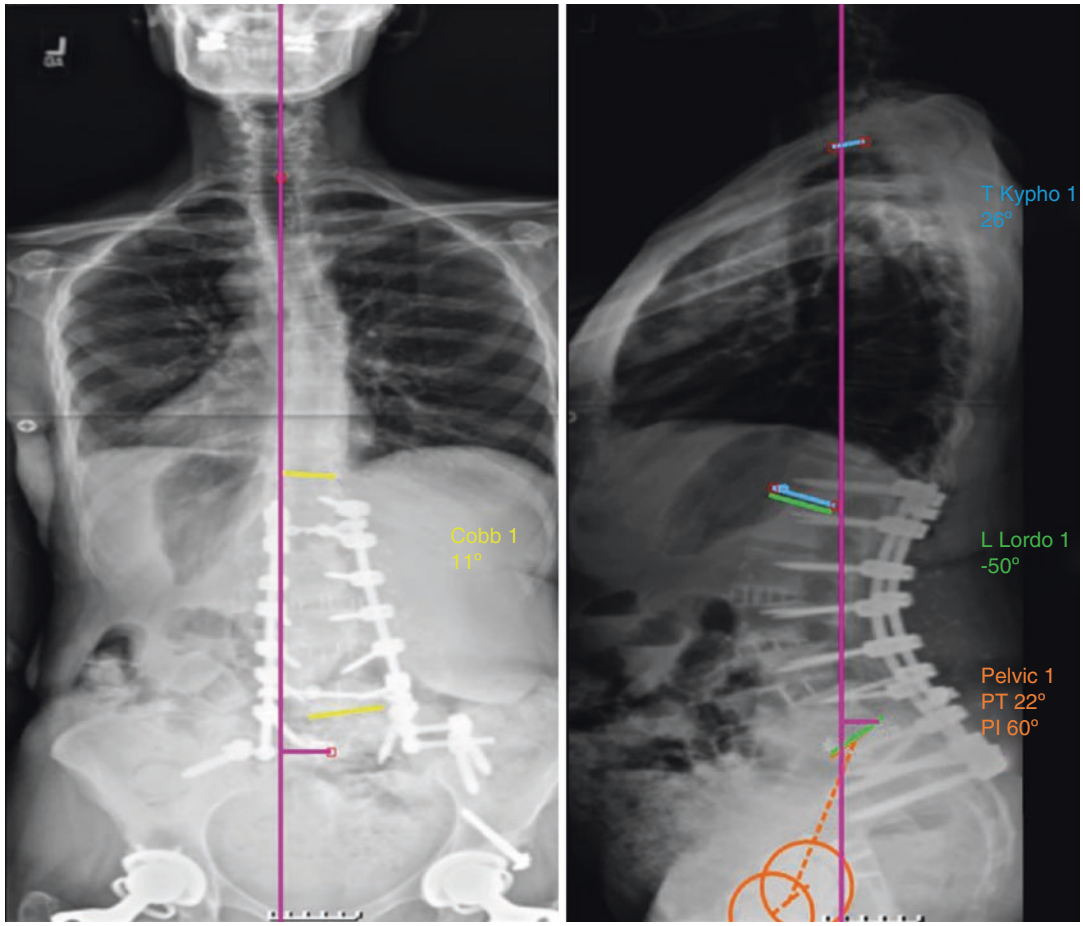

Fig. 14.5 Postoperative AP and lat. Substantial improvement in coronal alignment and Cobb angle with mild improvement in sagittal parameter over the instrumented area

greater impact on the sagittal plane. The authors suggest that the ACR technique may be regarded as obtaining sagittal plane correction similar to a Smith-Petersen osteotomy (SPO). Segmental lordotic improvement mean of 10° and an improvement of 3.1 cm in SVA per ACR level can be reliably obtained.

Initial reports demonstrate the LLIF technique with ACR to be promising as part of a multilevel deformity approach. Controversy still exists as to the impact of anterior column lengthening with multilevel anterior interbodies vs. posterior-only column shortening with an SPO or three-column osteotomies (PSO and VCR). Further investigation is required to fully define the indications, safety, and outcomes for the LLIF procedure.

Interbody Graft Considerations

Tricortical iliac crest, allograft bone, and morcellized bone chips were used as anterior column graft for many years [25]. Cages were developed, as they are able to provide customized distraction, immediate stability, and axial support. Currently, there are a wide variety of cage/interbody designs and material options available for anterior structural support [26]. These range from circular and tapered to rectangular with and without curvature among other variations. Cages with biconvex geometry have been hypothesized to maximally increase cage-endplate contact for greater load sharing, whereas narrow cages (vs. wider cages) may have the benefit of less facet

removal and neural retraction for placement from a posterior approach. Recently hyperlordotic cages have been introduced to aid in sagittal realignment, particularly following all release.

The material properties of the interbody devices may also be varied and can include structural autograft, allograft, or metal. Unfortunately three disadvantages emerged with the use of metal cages. These include the potential for subsidence of the cage in the adjacent vertebrae, difficulties in assessing fusion during radiological imaging, and the stiffness of the material. The stiffness of titanium alloys may reduce the amount of mechanical stimulation to the bone graft, which may delay fusion from stress shielding. More recently polyetheretherketone (PEEK) has been largely accepted as a suitable biocompatible structural interbody graft. PEEK is a polymer that has similar stiffness as cortical bone. In addition, it is radiolucent which is of benefit when assessing for fusion. The ideal anterior structural support would maximize contact area and provide adequate structural support until bony fusion occurs, limit subsidence and stress shielding, and maximize area for bony integration.

The initial stability of the implant is an important consideration during the immediate postoperative period. Each graft type has its own unique advantages and disadvantages though fusion still remains the primary objective.

Titanium

There are many advantages to using structural Harms cages to support the anterior column. There is no risk of disease transmission as with allograft. Multiple cages with varying diameters and heights are available, and compared to PEEK implants, they have a larger internal volume to pack bone graft before insertion. Compared with allograft, the cages have better interdigitation with the vertebral end plates, allowing for more secure implantation and greater stability of the segment. Cages made out of titanium have a Young's modulus of around 110 GPa, as compared to the Young's modulus of cortical bone at 12–20GPa. Because of the large discrepancy in stiffness, these rigid cages may cause stress shielding of the grafted bone placed within the cage [27]. The combination of a thin outer profile and high modulus may also increase the likelihood of cage subsidence. Eck et al. [28] conducted a retrospective study on patients treated with structural titanium mesh cages in the anterior column. There were no cases of cage migration, dislodgment, or fatigue. Cage settling (>2 mm) was observed in 33 % of cases of intradiscal cages and in 47 % of the cases in which cages were used after corpectomy. That said, only a small loss of sagittal correction occurred. The loss of correction was only 4° for patients who had cage settling compared with 2° for patients without cage settling. Care was taken to maintain the vertebral end plates, and therefore cage settling was thought to represent the interdigitation of the mesh implants into the superior and inferior end plates [28]. Carbon fiber, titanium fiber mesh, and threaded titanium cages continue to be popular graft choices. Fusion assessment, however, can be difficult using metallic cages because they obscure radiologic imaging. Plain radiography and computed tomography are used to assess fusion status in the postoperative period, although scatter from the metallic implants can limit the effectiveness of both radiographic techniques.

PEEK/Carbon Fiber

PEEK and carbon fiber cages have increased in utility over the years and anecdotally seem to be the structural implant of choice for most surgeons. These implants are available in a wide variety of shapes and sizes. The biomechanical advantage in support of using PEEK over titanium is that the Young's modulus of PEEK is 3.6 GPa. This is much closer to that of cortical bone (12–20 GPa), as compared to titanium (110 GPa). This allows for more even distribution of the load through both implant and packed bone graft within and surrounding the cage leading to a more favorable fusion environment. Using finite element analysis, Vadapalli et al. [27]

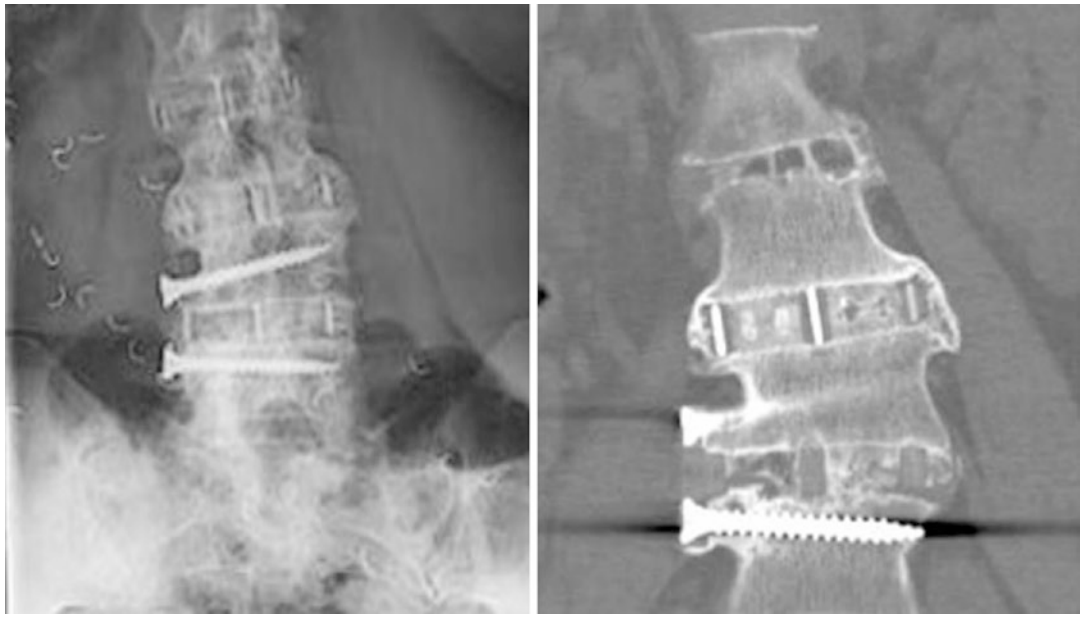

Fig. 14.6 CT scan demonstrating bony fusion across PEEK implant

demonstrated that spacers of lesser stiffness, like PEEK, still provide initial stability similar to titanium spacers while minimizing the risk of subsidence. An additional benefit of PEEK is assessment of fusion. While titanium spacers limit adequate radiographic assessment of fusion, PEEK, being a radiolucent polymer, allows a more clear assessment (see Fig. 14.6).

Although PEEK implants have several speculative advantages over titanium implants, there is limited data to suggest superiority of one material over another. Schimmel et al. [29] recently reported the unfavorable radiological outcome in patients treated with PEEK cages. Their radiological evaluation by CT scans revealed that 24 % of 95 patients after an anterior lumbar interbody fusion with a PEEK cage were re-operated for symptomatic pseudarthrosis [30]. A possible reason for decreasing fusion rates with PEEK is its biological inertness. PEEK has a low amount of surface hydrophilic groups and only provides limited cell adhesion. In an animal model with either titanium cage or PEEK cage, scanning electron microscopy demonstrated that the titanium plasma-treated cage had the greatest proportion of its surface in contact with bone (42 %), while only 12 % of the PEEK surface was in contact with bone surfaces [31]. This finding may have a direct impact on fusion success as evidenced by a few reports. In a retrospective analysis in patients undergoing a TLIF procedure with either a titanium cage or PEEK cage, the 1-year fusion rate (as assessed via fine cut CT) was 96 % and 64 %, respectively. At 24 months, fusion rate in titanium group was increased to 100 %, while fusion rate improved to 76 % in the PEEK group. Cage subsidence at 24 months was observed in eight patients (35 %) in the titanium group and seven patients (28 %) in PEEK group; the difference was not significant. Although fusion success has been questioned with PEEK devices, there are also a significant body of literature that documents favorable or even superior fusion rates with PEEK devices in various interbody applications [32].

Conclusion

Anterior structural support is a useful adjunct to the adult spinal deformity treatment strategy. Due to high historical pseudoarthrosis rates at the lumbosacral junction, contemporary deformity constructs frequently include

iliac fixation and one or two levels of interbody support at the base of the construct during a posterior-only approach. During a combined approach, anterior column support may be used in a single or multilevel manner. Benefits for anterior column support include immediate mechanical stability against axial compression and flexion moments, improved fusion rates, and the ability to improve segmental sagittal and coronal alignment. Fusion rates and clinical outcomes are similar between differing approaches. Enhancement of lordosis is more technically challenging using the TLIF/PLIF technique but has the benefit of a single-stage, single-approach intervention. Anterior and lateral approaches, especially those that resect the ALL, achieve the greatest change in sagittal alignment. Implants are available in various materials, shapes, and sizes for custom implant selection based on surgical strategy. Titanium and PEEK remain the most commonly used implant materials with each having inherent advantages and disadvantages. Both have performed well in the literature with segmental fusion being the ultimate goal.

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Releases and Osteotomies Used for the Correction of Adult Lumbar Scoliosis

15

Munish C. Gupta and Sachin Gupta

Introduction

Adult lumbar scoliosis is a frequent diagnosis in any adult deformity spine practice. Adult lumbar scoliosis is being treated surgically more and more. First, the population as it is aging and living longer is seeking treatment for disabling pain in the back and in the legs associated with lumbar scoliosis. Second, there are many more well-trained spine surgeons that are available to help this patient population.

These lumbar deformities are seen frequently in two diagnostic categories: adult idiopathic scoliosis and adult degenerative scoliosis. For adult idiopathic scoliosis, patients had scoliosis in their adolescence which was treated in a brace or observed. The scoliosis then progresses or remains the same but develops additional degenerative changes over time which may require a surgical intervention. These patients usually present in their 40s with mostly back pain. The lumbar curve has significant rotation and is usually in the 60° range. The other main category of lumbar scoliosis is adult degenerative scoliosis or de novo scoliosis. These patients usually have no curvature in adolescence but develop curvature as the lumbar soft spine degenerates. Originally, it was thought that degenerative scoliosis was caused by osteoporosis; however, currently it is thought to be caused by degenerative changes of the disc space and the facet joints causing instability with lateral and rotatory listhesis. This usually starts at L3–L4 or L4–L5 causing a domino effect on the adjacent segments creating a lumbar curvature. The patients with degenerative scoliosis usually present in their 60s. The lumbar curve is an average of 30° and does not have large vertebral rotation. Usually, these patients have lumbar stenosis at multiple levels but most often at L3–L4 and L4–L5 with associated symptoms of neurogenic claudication or lumbar radiculopathy. Treatment of both these lumbar deformities has to be planned carefully with appropriate preoperative testing.

The goals of adult lumbar scoliosis surgery have to be clear from the beginning. These patients need to have a correction that results in a well-aligned spine in the coronal and sagittal plane that leads to a balanced correction and not ultimate correction. The coronal plane deformity is corrected to align the head, chest, and pelvis and obtain correction of the curvature. The lumbar curvature in the coronal plane does not have to be corrected fully. An excellent cosmetic appearance is usually a secondary goal in this population. Recently, the sagittal plane has gained a lot of emphasis. The sagittal plane deformities appear to be more painful and poorer outcomes on health-related quality of life

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questionnaires [1, 2]. When the lumbar scoliosis is corrected, one has to pay special attention to obtain adequate lumbar lordosis. The lumbar lordosis is related to the amount of pelvic incidence of that specific patient. The pelvic incidence is specific to each patient. The higher the pelvic incidence, the higher the lumbar lordosis needs to be. There is nothing worse than a lumbar scoliosis that is diffuse without adequate lumbar lordosis leading to a very flat rigid lumbar spine resulting in a flat back posture. These patients usually end up requiring a pedicle subtraction osteotomy so they can stand up straight.

Challenges of Adult Deformity Surgery

There are significant challenges in treating adult spinal deformity. The greatest challenge being that the spine is more rigid than in an adolescent idiopathic scoliosis patient. This spine is more rigid anteriorly in the disc spaces as well as posteriorly at the facet joints. The disc spaces are narrow and stiff due to the advanced degenerative disc disease. There are osteophytes present at the degenerated levels that are frequently bridging across the disc space over time. At times, the facet joints are hypertrophied and almost ankylosed. Often, in order to correct the spinal deformity, one has to release the disc space by cutting the entire annulus, removing the disc, and distracting the disc space manually. The intradiscal release provides the ability to change the alignment coronally and sagittally. Resecting the facet joints posteriorly also provides the ability to mobilize the spine to gain segmental correction. The anterior intradiscal approach has gained some popularity in the recent past with not only a formal anterior approach but also the advent of minimal access lateral approaches. The ability to gain lumbar lordosis and achieve a fusion in the lower lumbar spine anteriorly with lordotic grafts is hard to beat even with the improved transforaminal lumbar interbody fusion techniques and expanding cage technology. The anterior approach release is dependent upon adequate bone stock to distract against. There is nothing more disheartening than the disc space spreader plowing through the vertebral body end plate. After this maneuver, one may not be able to distract the disc space or place an implant that will not subside into the end plate.

Osteopenia and osteoporosis seem to be ubiquitous in this population. The osteopenia prevents manipulation of the spine through the screws, with the weakest link being the bone-implant interface. If one does not gain adequate release of the spine, manipulating the spine with the implants may just lead to implant loosening or migration inside the bone of the vertebral body or pedicles. More and more patients with T scores that are less than 2.5 are being treated with recombinant parathyroid hormone to improve the bone density. The patients require at least 3 months of treatment with teriparatide which is continued for at least a year postoperatively. There are no controlled randomized trials to guide the preoperative and postoperative treatment with parathyroid hormone of surgically treated adult spinal deformity patients. Postoperatively, proximal and distal junctional kyphosis has plagued the adult spinal deformity patients. The osteoporosis and osteopenia play a key role in failures of the pedicles and vertebral bodies above an instrumentation and fusion.

Once the correction is performed, the next challenge is the ability to achieve a solid fusion. These patients have a higher nonunion or pseudarthrosis rates than the adolescent population, and the fusion takes a much longer time to occur. The instrumentation has to hold the correction for a much longer time and have a much greater fatigue life than in an adolescent. In one study the pseudarthrosis rate was reported to be as high as 17 % [3, 4]. The pseudarthrosis occurred in 58 % of patients at the thoracolumbar junction and 25 % of the patients in the lumbosacral junction. In addition, the large percentage of the pseudarthroses did not appear until more than 3 years after surgery. Only 58 % of the total pseudarthroses were seen at 3 years of less postoperatively. The rest of the

pseudarthroses were found much later, in the third and fourth year in 20 % and 5–10 years in the remaining 23 %. Anterior spinal fusion of the lumbar spine was performed more often in the past because of the high pseudarthrosis rate in the lumbar spine in the adult patient. Recently, posterior release and osteotomy techniques have obviated the need for an anterior release. The use of bone morphogenetic protein has also helped decrease the need for an anterior spinal fusion just for achieving fusion. In recent years, the use of bone morphogenetic protein has decreased the rate of pseudarthroses to approximately 6.4 % or less when compared to autograft bone [5, 6].

The Sagittal Plane in Lumbar Scoliosis

The Scoliosis Research Society and Schwab classification is frequently used to communicate the amount and location of adult spinal deformity. The SRS Schwab classification describes the major deformity as a first descriptor [7, 8]. The categories are major thoracic curves (T), lumbar curves (L), double curves (D), or no coronal deformity (N). The sagittal modifiers are the most important part of this classification. The first modifier is the difference between the pelvic incidence and the lumbar lordosis (PI-LL). The greater the difference between the pelvic incidence and lumbar lordosis, the greater the sagittal modifier, 0–10° being 0, 10–20° being moderate, and greater than 20° being marked. Global alignment is the sagittal modifier described by the sagittal vertical access or SVA. The greater the malalignment sagittally in terms of the global malalignment, the greater the modifier, less than 4 cm being 0, 4–9.5 cm being moderate, and more than 9.5 cm being marked. The next sagittal modifier is the pelvic tilt. The pelvic tilt describes the position of the sacrum in relation to the femoral head and refers to the amount of compensatory retroversion. The pelvic tilt is important because it is the junction of the spine and pelvis to the lower extremities. With a high pelvic tilt and a retroverted pelvis, the patient may not be able to compensate with hip extension and ultimately may have to bend his knees in a flat back posture for forward gaze. Figure 15.1 demonstrates a patient that has a retroverted pelvis and high pelvic tilt with a coronal deformity of the lumbar spine. This patient has sagittal modifiers that are all high: pelvic incidence and lumbar lordosis mismatch, global sagittal malalignment with a SVA that is very high, and a large pelvic tilt showing significant pelvic retroversion. Although the lumbar curve is moderate, the sagittal modifiers make the spinal deformity much harder to treat.

The goal of surgical correction of the lumbar scoliosis has to include consideration of the sagittal plane. The surgical plan may require intradiscal work, posterior releases, or Smith-Petersen osteotomies just to correct the sagittal plane. The aim of the sagittal plane realignment should be to get a gravity line that passes through or behind the femoral heads. Try to achieve a lumbar lordosis and pelvic incidence within 10° of each other. The pelvic tilt should be close to 20°. In older patients, the sagittal correction may not need to be as perfect because the older patients sometimes naturally have a SVA that is greater than the normal population. This area is currently being investigated by many researchers. The eventual goal may be to adjust the sagittal correction with the normal age parameters of that age group.

The author's personal preference is to determine if the anterior approach is needed from the sagittal profile of the lumbar spine. If there is a significant thoracolumbar kyphosis or lumbar kyphosis, an anterior approach is performed prior to the posterior procedure. Special emphasis is placed on obtaining adequate lumbar lordosis in line with the pelvic incidence for that specific patient. The lumbar and thoracolumbar kyphosis is harder to correct with posterior-only approach. Intradiscal approaches can be used via lateral, transforaminal lumbar interbody fusion or posterior lumbar interbody fusion to help correct the lumbar kyphosis as well.

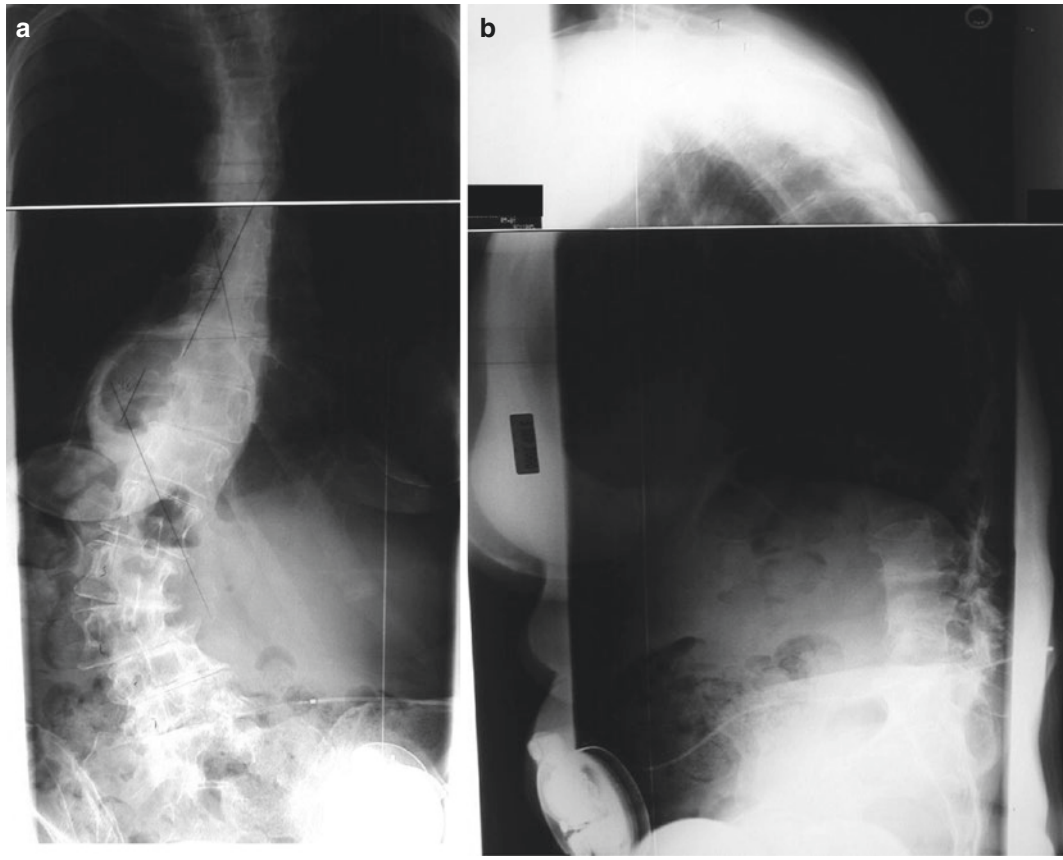

Fig. 15.1 (**a**) The coronal reformats in computed tomography of a lumbar scoliosis patient shows collapsed narrow disc spaces and osteophytes that are almost bridging over the disc space. (**b**) These are radiographs of a patient with degenerative scoliosis. In the Schwab classification, the patient would have a classification of L for the lumbar curve, +++ for the marked gap between the pelvic incidence and lumbar lordosis, +++ for a large positive sagittal balance with a high SVA, and +++ for the high pelvic tilt

Strategies for Correcting Lumbar Scoliosis

Adult lumbar scoliosis is a challenging deformity to correct in adults for all the reasons described already. There are various strategies involved in the assessment and correction of the lumbar spinal deformity.

Posterior Release

There is a spectrum of posterior-only releases and osteotomies. The posterior release also known as the wide posterior release was first described by Shufflebarger [9, 10]. He uses this approach with a three-stage approach done in a single day. He first performs a posterior release by removing the ligamentum flavum interspinous ligament and release through the facet joints with partial facetectomy. At the time of the posterior release, he places the pedicle screws in the lumbar spine. He performs an anterior approach and discectomies at multiple levels in the lumbar spine. The disc spaces are then prepared for fusion with disc height elevation with harms cages. The posterior procedure then involves placing the final rods and compression

to achieve lordosis and correction of the lumbar scoliosis. The multiple stages of posterior and anterior and then posterior approach are not used very often. Most deformities are done posterior-only or anterior or lateral approach followed by posterior approach.

Posterior Facetectomy

The posterior approach involves removing the interspinous ligament, part of the spinous process and lamina, the ligamentum flavum, and the entire facet joint. This was originally described in a fused spine where the osteotomy was performed through the facet joint that was already fused (Smith-Petersen osteotomy) (see Fig. 15.2a, b). In the mobile spine with supple disc spaces, the release is called a Ponte osteotomy. The osteotomy allows for aggressive posterior release, direct decompression of the neural elements, and shortening of the posterior column. Most surgeons are able to achieve 5–10° of lordosis through each level of osteotomy. This osteotomy can be very useful in correction of the lumbar curve as well as obtaining lumbar lordosis. If the disc space is rigid or fused, a posterior-only facetectomy is not as effective and may need to be combined with additional approaches and releases.

Posterior Interbody Release

Various posterior lumbar interbody fusion techniques have been utilized. Posterior lumbar interbody fusion (PLIF) was the first to mobilize lumbar segments at multiple levels. After mobilization of the discs, posterior lumbar interbody spacers are placed to achieve lordosis as well as provide stability. This can be accomplished utilizing a bilateral approach. More recently, transforaminal lumbar interbody fusions (TLIF) have been utilized more often. The transforaminal lumbar interbody cage is inserted from one side only compared to the posterior lumbar interbody fusion cages that are inserted bilaterally. Transforaminal interbody fusion cage is shaped like a crescent and placed as anterior as possible to create lordosis. The PLIF approach involves more retraction of the nerve roots and can cause nerve root damage. It is however very useful in mobilizing the disc space bilaterally. Difficulty with the transforaminal lumbar interbody fusion technique is the amount of distraction that can be obtained within the disc space without cutting the annulus. If the annulus is mobile, the TLIF approach is very successful. On the other hand, if the annulus is stiff and fibrotic, it is difficult to obtain release of the disc space and adequate distraction to gain lordosis. In addition, the end plate preparation and placement of the graft have

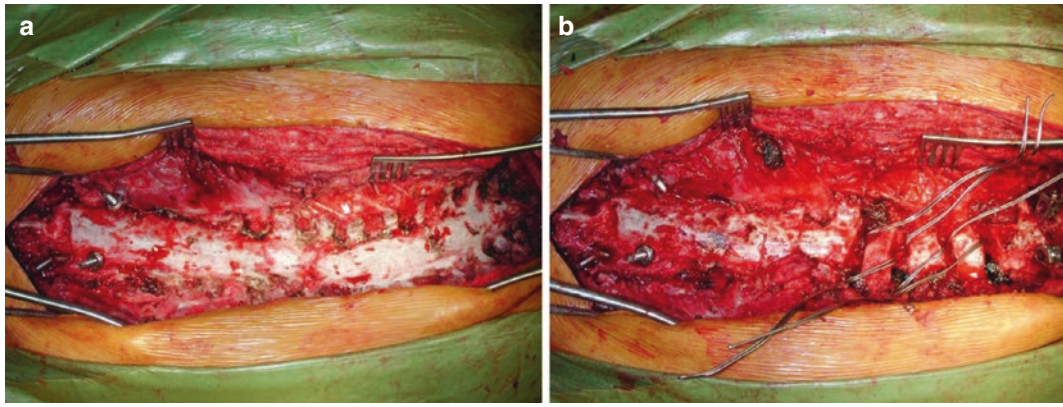

Fig. 15.2 (**a**) This intraoperative photograph illustrates a fused spine. (**b**) The Smith-Petersen osteotomies are performed to correct the spinal deformity. The osteotomies are performed between the two sets of transverse processes to the canal before correction. This intraoperative photograph illustrates a fused spine

to be meticulously done to avoid end plate violation and subsequent graft subsidence. A study reported by Cho et al. found that 42 % of the patients developed sagittal decompensation after TLIF combined with a posterior fusion [11]. The preoperative sagittal imbalance as well as a high pelvic incidence proved to be the most significant risk factors in developing sagittal decompensation postoperatively. This study also found additional complications at the more distal segments including pseudarthrosis and implant failure at the lumbosacral junction. The radiographs shown in the paper found that the S1 screws were not protected with iliac fixation [11]. Other authors have also shown that sagittal plane realignment is very important but harder to obtain with TLIF [12].

Lateral Release

Lateral minimally invasive approaches have been developed by multiple surgeons. There are two basic approaches. The first approach obtains disc access by dilating through the substance of the psoas muscle. There is a specific retractor that docks onto the disc space and then is used to dilate the muscle in a controlled fashion. Neural monitoring is used to place and dilate this retractor to avoid damaging the lumbar plexus [13–15]. The next approach achieves disc access by docking anterior to the psoas muscle [16]. This minimally invasive approach attempts to minimize the risk of injury to the lumbar plexus. The lateral minimally invasive approaches have had some adverse events. The grafts that are used can subside into the vertebral body if the end plate is not carefully prepared or the graft violates the end plate as it is inserted. The lumbar plexus is at risk as it is in the substance of the psoas muscle. There have been reports of pain from compression of the lumbar plexus and weakness in the proximal thigh. The recommendation is to minimize the distraction of the self-retaining retractor and minimize that time the retractor is pushing onto the lumbar plexus through the psoas muscle. Neural monitoring is mandatory for this technique especially when dilating through the psoas muscle in order to prevent nerve damage.

Anterior Release and Posterior Fusion

The anterior release through a thoracoabdominal or lumbar approach has been used for decades. Thoracoabdominal approach is performed for patients that need an approach to the thoracolumbar curve. Patients with thoracolumbar curves that are associated with kyphosis may benefit from the anterior release, discectomy, and fusion. Thoracoabdominal approach involves taking the diaphragm down. This approach is more extensive since it requires a chest tube and closure of the diaphragm, chest, and abdominal muscles. The lumbar anterior approach is tolerated better as this does not require a chest tube. The lumbar anterior approach can be done through a flank incision, paramedian, Pfannenstiel, or midline approach. The lumbar anterior approach is still a popular approach to obtain a release of the lower lumbar spine segments. After the annulotomy and discectomy are performed, the amount of distraction that can be obtained to gain lower lumbar lordosis appears to be more effective with large lordotic grafts. The anterior approach is frequently combined with a posterior release, instrumentation, and fusion. This method is extremely powerful in obtaining correction of the fractional lumbosacral curve and large lumbar curves that are stiff. In addition, the anterior discectomy and grafting are extremely helpful in obtaining a reliable fusion. The anterior disc space is an ideal fusion bed, there is heavy bleeding from the bony surface area of the end plate of the vertebral bodies, and the graft is under compression. The distance that the fusion has to occur from one end plate to the other is smaller compared to the intertransverse process distance in a posterolateral fusion. Figure 15.3 is an example of the patient with lumbar kyphosis that was treated with an anterior release, posterior release, and posterior instrumentation and fusion. The anterior release is very powerful in helping reverse the kyphosis into lordosis.

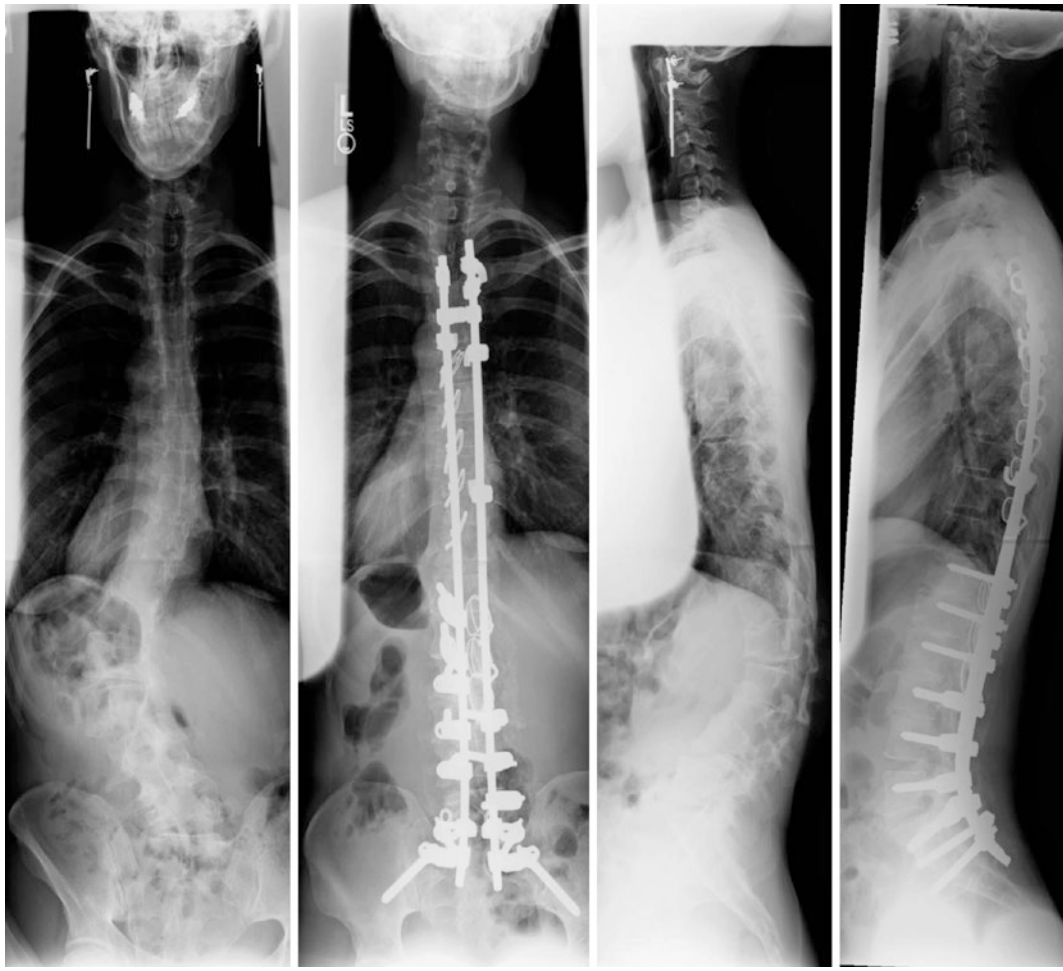

Fig. 15.3 This case demonstrates the use of anterior release and fusion combined with posterior lumbar release and fusion to reverse the kyphosis in the lumbar spine to lordosis

The anterior approach is not without its downsides. The approach adds to a longer operative time with combined approaches. There is significant morbidity of an additional approach. Sometimes, these approaches are staged, but the surgical delay leads to additional days for the hospital stay. The abdominal approach also may have some chronic pain associated with it in addition to the weakness of the abdominal wall giving rise to a pseudohernia at times. Vascular injury can occur at the time of the approach. The vascular injury can be repaired but can have some long-term complications. The venous thrombosis and pulmonary embolus are more common with an anterior approach especially when used in a combined procedure.

Pedicle Subtraction Osteotomy

Pedicle subtraction osteotomies were first utilized to shorten the middle and posterior column in the treatment of ankylosing spondylitis patients. The osteotomy was described in the lumbar spine to create lumbar lordosis. Usually, the posterior elements, facet joints, lamina, and pedicle are removed to shorten the posterior and middle column of the spine. The anterior column is not shortened to create a wedge configuration of the vertebral body to restore lordosis. Pedicle subtraction osteotomy can also be utilized to treat lumbar scoliosis by performing an asymmetrical osteotomy at the apex of the lumbar scoliosis. This approach can help avoid anterior

and posterior combined approaches. The pedicle subtraction osteotomy however also has its own risks. There is increased risk of bleeding, nerve damage as well as pseudarthrosis, and failure of instrumentation. Buchowski et al. reported an 11 % nerve deficit in these patients [17]. A majority of the neurologic deficits came from inadequate removal of the bony elements that could impinge on the dura and the nerves during the closure of the osteotomy. The other source of neurologic injury can be from the dural buckling as the spinal column is shortened in the middle and posterior column.

Rod breakage and pseudarthrosis are additional complications of pedicle subtraction osteotomies as reported by Smith et al. [18, 19]. The satellite rod technique used by the author seems to protect the rods from early failure [20, 21]. This is accomplished in three ways. First, the rod does not have to be bent in an acute angle at the level of the pedicle subtraction osteotomy. Second, the four rods share the area of most stress at the level of the pedicle subtraction osteotomy. Third, the longitudinal rods are bent less than the short rods at the apex reducing the stress on the long rods as well.

The author's preferred technique is to do a large laminectomy encompassing the entire lamina of the vertebral body at the level of the PSO, removal of the proximal level lamina, and creating a semilunar decompression of the distal lamina from the level of the osteotomy. This large decompression helps avoid impingement from bony elements and soft tissue at the time of the closure of the osteotomy. Six pedicles and four nerve roots are identified prior to starting the pedicle subtraction osteotomy. The nerve roots are followed out to the lateral part of the vertebral body (see Fig. 15.4a, b).

Although pedicle subtraction osteotomies are used in primary or revision spine surgery, the authors prefer to use the pedicle subtraction osteotomy technique in patients that have had a previous fusion of the lumbar scoliosis but have been fused with suboptimal flat lumbar lordosis [22]. The osteotomy is closed with the screws above and below the osteotomy. The operating room table is used to close the osteotomy once the posterior elements, the pedicle, the lateral portion of the vertebral body, and the posterior wall have been resected. The medial part of the pedicle is used to protect the nerves while performing the vertebral and pedicle resection. The pedicle is then resected followed by removal of the posterior wall of the vertebral body. Two small rods are used to control the closure of the osteotomies and the connections tightened.

Longitudinal rods are then placed independent of those two rods and are not attached to them. The small rods are called satellite rods.

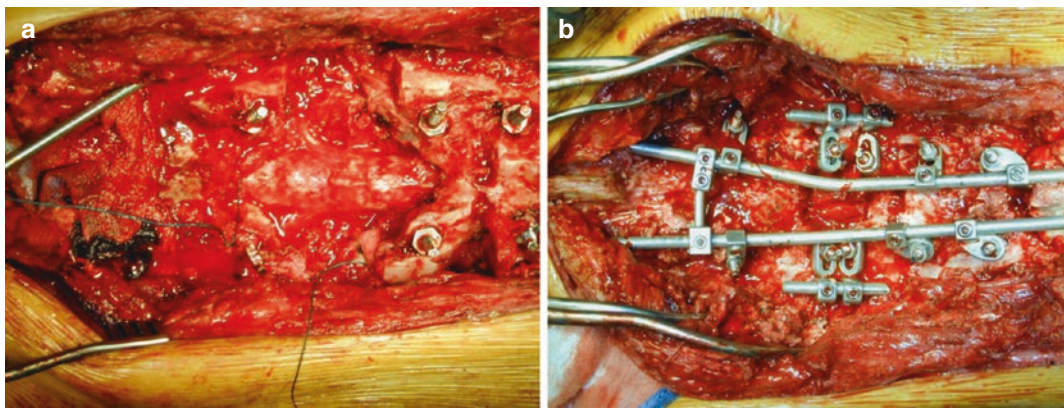

Fig. 15.4 (**a**) This intraoperative photograph illustrates the decompression needed before starting a PSO. One should see six pedicles and four nerve roots fully dissected out. (**b**) After resection the pedicle screws are approximated and stabilized with a short rod. The long rods are then placed independent of the short rod in a satellite configuration

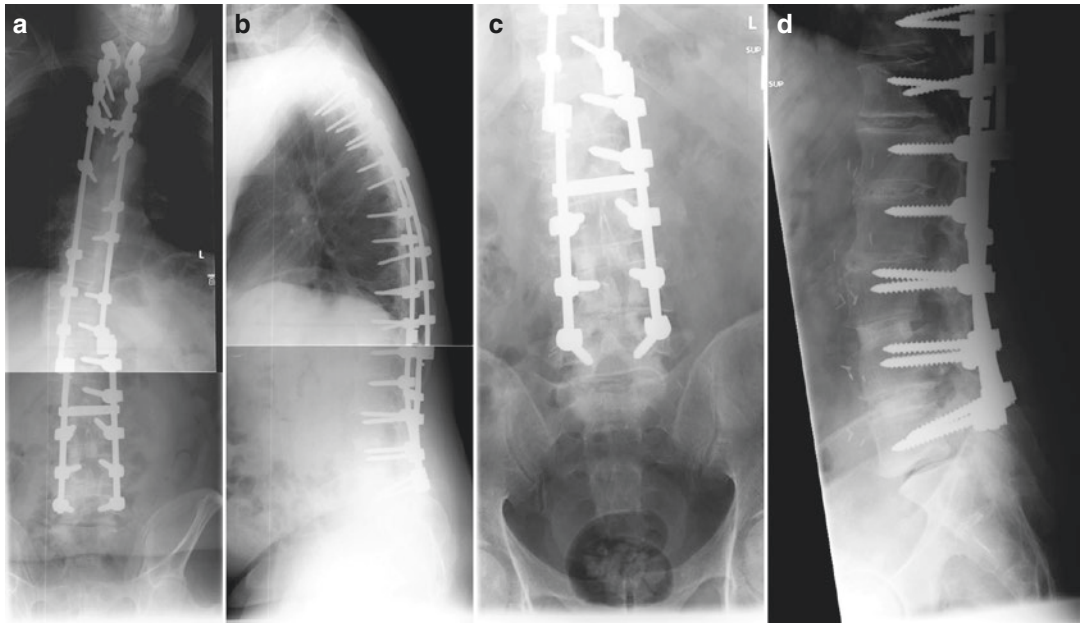

Fig. 15.5 (**a**) A 64-year-old male with severe back pain, hard to stand and walk, previous anterior and posterior T1 to L5 fusion. (**b**) The lumbar spine is fused in a flat position. Patient also had a discectomy at L5–S1 with disc degeneration L5–S1. (**c**) Anterior fusion was performed with a femoral ring allograft at L5–S1. (**d**) Pedicle subtraction osteotomy was performed at L3 to regain the lordosis with an extension of instrumentation to the pelvis. After anterior L5–S1 fusion and pedicle subtraction osteotomy, a marked improvement in the sagittal plane and clinical function was seen

The longitudinal rods do not have to be contoured deep into the apex of the lordosis that is needed to correct the lumbar deformity. The fact that they are not bent into that significant lordosis makes it less vulnerable to fracture. The small rods control the osteotomy after it has been performed and do not let the osteotomy site separate during the placement of the longitudinal rods [23]. Additional correction can also be obtained above and below the level of the osteotomy if posterior release and facetectomies are performed to obtain additional correction. If only two rods are used, often the major correction is at the osteotomy site, but additional correction is limited. The majority of the correction is at the osteotomy site which is the most mobile when placing the rods. Occasionally, correction is obtained at the osteotomy site, but correction is lost at the upper and lower segments adjacent to the pedicle subtraction osteotomy site, thus reversing the correction of the lumbar lordosis.

As one improves in the clinical skills of performing pedicle subtraction osteotomy, one can move from performing osteotomies on for mostly sagittal plane deformities to a combination of coronal and sagittal plane deformities. Figure 15.5 shows a case of a patient who underwent treatment for adult scoliosis. Pedicle subtraction osteotomy was utilized to restore the lumbar lordosis and achieve global balance.

Summary

Anterior lumbar interbody fusion is still a very useful tool in correction of lumbar scoliosis. The restoration of the lumbar lordosis and sagittal plane is important. It is easier to release the entire annulus, remove the disc, and distract the end plate rather than try to separate vertebral bodies via a posterior-only approach. Transforaminal lumbar interbody fusion and lateral interbody approaches are useful in treating less severe lumbar curves. Even though pedicle subtraction osteotomies can be used to treat primary lumbar curves, pedicle subtraction osteotomies are utilized primarily to

correct previously fused lumbar scoliosis curves with inadequate lordosis.

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Distal Fixation for Adult Lumbar Scoliosis: Indications and Techniques

16

Tina Raman and Khaled Kebaish

Introduction

Despite the myriad of advances and improvements in spinal instrumentation and techniques, fixation failure and pseudarthrosis at the lumbosacral junction continue to pose a challenge to spine surgeons [1–3]. Pseudarthrosis rates at the lumbosacral junction are reportedly 10 % for an L5–S1 fusion, up to 20 % for two-level fusions, and up to 72 % for a long construct for adult spinal deformity that extends to the sacrum [2, 3]. It is critical that surgeons have an understanding of the diagnosis and prevention of this complication, as studies demonstrate that self-reported clinical outcomes are worse in adult spinal deformity patients who develop a pseudarthrosis [4, 5]. Efforts to improve lumbosacral fusion rates after adult spinal deformity surgery have focused on spinal instrumentation, techniques, and understanding the local biology in this region. The poor bone quality of the sacrum, the complex anatomy, and the biochemical forces unique to this area constitute the essential difficulties of this portion of the operation.

The relationship of the pelvis to the femoral head is critical in appropriately balancing the spine over the pelvis. In this regard, pelvic incidence, pelvic tilt, and sacral slope are all parameters that must be carefully considered with fusing the spine to the pelvis. The importance of achieving adequate sagittal alignment is critical, as studies demonstrate that it correlates highly with patients' satisfaction and self-reported outcomes [6].

Options for distal fixation in the sacrum include S1 pedicular screw (unicortical, bicortical, or tricortical), S2 screws, and sacral alar screws. Fixation ending at the sacrum, including S1 pedicle screws and sacral alar screws, demonstrated high failure rates [7, 8]. It has been demonstrated that S1 screw strain and risk of sacral fracture is greatest when S1 pedicle screws alone are used at the distal end of a long construct and that the strain only appreciably decreases with the additional of fixation into the ilium [9]. Particularly, the flexion-extension moment on the S1 screw is decreased by the addition of pelvic fixation [10]. However, S1 and S2 screws, or S1 and sacral alar screws, at the distal end of a long construct, have not been shown alone to significantly improve biomechanical stability or reduce pseudarthrosis rates [9, 11].

McCord et al. demonstrated that the use of long anchors projecting into the ilium was the most mechanically effective form of sacropelvic fixation because the moment arm of the anchors extends well anterior and lateral to the spine [12]. Various spinopelvic fixation techniques for adult spinal deformity surgery have been described and utilized over time, with differing results. Currently, the most commonly used types of

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sacropelvic fixation are iliac screws and S2-alar-iliac screws. Distal fixation to the pelvis has been shown to provide greater biomechanical stability, decrease pseudarthrosis rates, and lead to decreased screw pullout [12–15]. Success can perhaps best be achieved by instrumentation at the lumbosacral junction that offers biomechanical advantages, reproducibility, low rate of complications, and improved outcomes. We will discuss the history of conventional and newer distal fixation techniques and the indications and outcomes for each.

Historical Perspective of Distal Fixation

Harrington followed by Luque et al. was the first to describe a separate fixation technique for the lumbosacral junction [16]. In the 1960s, Paul Harrington developed a spinal instrumentation system consisting of rod fixation utilizing limited transverse process or lamina fixation points for distraction of the spine [16]. The simple design of this system offered the advantage of ease of application, but there were many problems when it spanned the lumbosacral junction. Studies demonstrate a high incidence of flat back deformity, loss of lumbar lordosis, pseudarthrosis rates approaching 40 % in most series, and the rate of caudad sacral hook dislodgment to be as high as 26 % [17, 18].

In the 1970s, Edward Luque improved on the Harrington technique for pelvic fixation in utilizing multiple points of fixation with sublaminar wiring connected to L-shaped rods [18]. This type of "segmental instrumentation" construct reduced the distractive forces required for correction, thereby lessening the incidence of flat back deformity and improving correction of sagittal balance. However, biomechanically, the construct lacked torsional stability and the ability to resist motion at the lumbosacral junction [18–20].

Many of the complications of lumbosacral fixation that were associated with previous instrumentation systems were diminished with the advent of the Galveston technique in 1976, by Ben Allen and Ron Ferguson [21]. The Galveston technique involves inserting a long contoured rod through the posterior superior iliac spine into each ilium between the inner and outer tables and extended within the ilium to the region above the sciatic notch (Fig. 16.1). Placement of the rod between the inner and outer tables of the pelvis increased

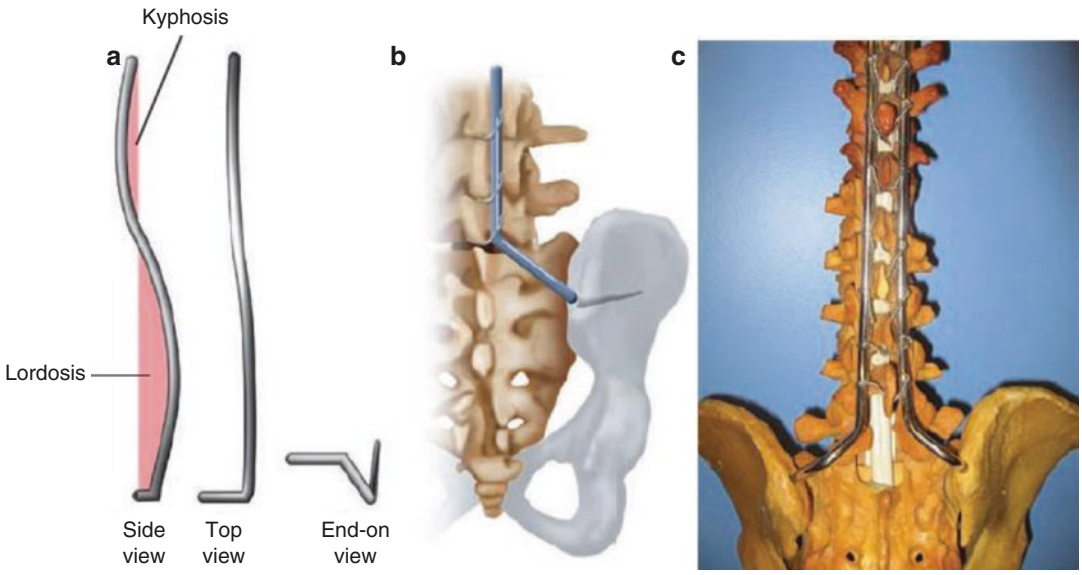

Fig. 16.1 (**a**) Contouring of the L-rod. (**b**, **c**) Diagram and model demonstrating placement of the Galveston rod into the table of the ilium

stiffness and stability at the lumbosacral junction, with a significantly improved pseudarthrosis rate, compared to prior techniques, of 7 % [22].

A major advancement in sacropelvic fixation was described in the 1980s, with the development of the Cotrel-Dubousset system which utilized a hybrid construct consisting of hooks and caudal pedicle screws [15, 23]. It was the first system to use hooks in combination with pedicle screws, resulting in more rigid fixation. The constructs with sacral pedicle and/or alar screws as the most distal fixation, offered poor flexion control at the lumbosacral junction in adult patients with a deformity extending to that level [24]. As a result, these constructs exhibited high rates of pseudarthrosis (33 %) and instrumentation-related complications (70 %) [8].

Some of the challenges associated with the Galveston technique have been addressed with iliac fixation using screws. Iliac fixation allows placement of fully or partially threaded iliac screws or posts to be connected with the longitudinal rod construct in the lumbar spine by means of monoaxial or polyaxial connectors and offsets (Fig. 16.2). The system has the advantage of modularity and easier placement of implants, placement of more than one iliac screw on each side, and placement of screws in sites of previously harvested grafts [18]. When subjected to load to failure, iliac screws were three times stronger than Galveston intrailiac rods [24].

The S2A alar iliac (S2AI) technique was developed at Johns Hopkins, and has been widely adopted elsewhere, for adult and pediatric patients requiring sacropelvic fixation. Fixation through the S2 ala into the ilium allows for a starting point in line with the S1 pedicle screw (Figs. 16.3, 16.4, and 16.5) and it is reproducible. Decreased implant prominence is another main advantage of this technique, as the starting point is 15 mm deeper than that for entry at the posterosuperior iliac spine [25, 26]. The technique also allows for a single rod to be utilized, without the complex use of connectors. A report from our institution documented the 2-year follow-up for this technique in adult and pediatric patients and demonstrated a complication rate lower than that of the traditional iliac screws technique – only 1 of 52 patients required implant removal at 2 years [27].

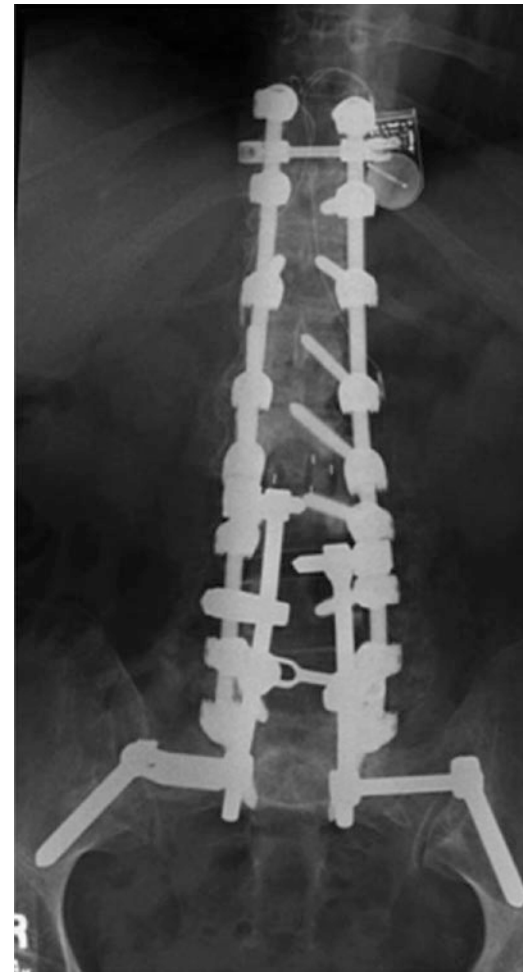

Fig. 16.2 A radiograph demonstrating iliac screws and the use of multiple connectors

Anatomy

The sacrum serves as the keystone that connects the two hemipelves and plays a critical role in pelvic ring stability. It is comprised of five fused vertebrae with transverse processes that merge laterally into the thick continuous sacral ala. Its anteroposterior diameter tapers from 47 mm at S1 to 28 mm at S2 in women and, similarly, from 50 to 31 mm in men [28]. The lumbosacral junction represents a transition from a highly mobile segment to a stiff segment with the sacrum and pelvis functioning as one unit. Forces that act on instrumentation and fusion mass in this region include axial loading, shear stresses, and torsion

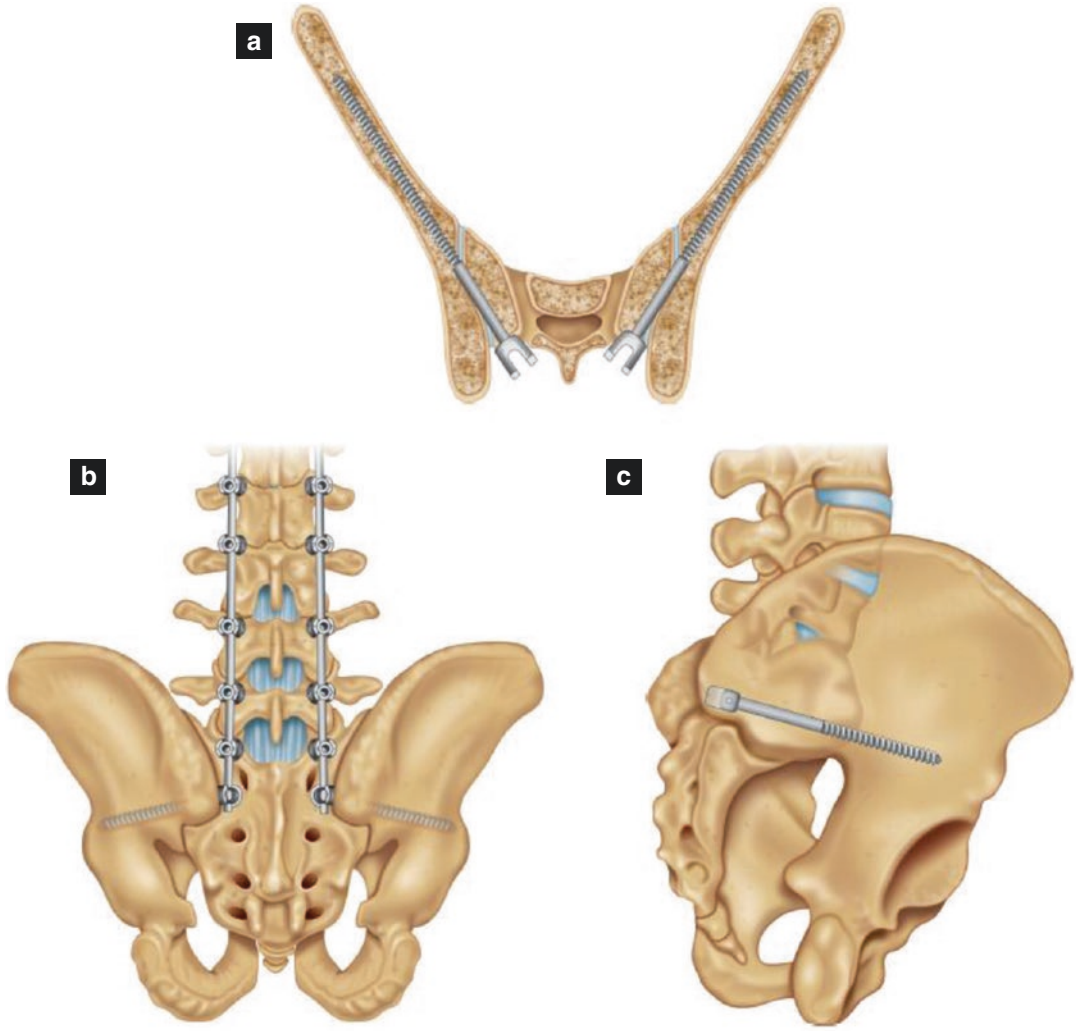

Fig. 16.3 Representation of the S2AI screw trajectory in the transverse (**a**), coronal (**b**), and sagittal (**c**) planes

[29]. An additional challenge for fixation in this region is the critical nature of the anatomical structures overlying the ventral aspect of the sacrum including the internal iliac artery and vein, middle sacral artery and vein, sympathetic chain, lumbosacral trunk, and colon [30].

Biomechanical Principles

Certain principles are necessary to understand the biomechanical advantages conferred specifically by sacropelvic fixation. McCord et al. defined the concept of an anterior pivot point for the flexural lever arm, using a model of lumbosacral calf spines [12]. They described the pivot point near the middle osteoligamentous column at the L5–S1 disk space (Fig. 16.4). Stiffness of the construct increases as the instrumentation extends anterior to the pivot point.

O'Brien et al. described three distinct zones of the sacropelvic region: Zone 1 comprises the S1 vertebral body and the cephalad margins of the sacral alae; Zone 2 comprises the inferior margins of the sacral alae, S2, and the area extending

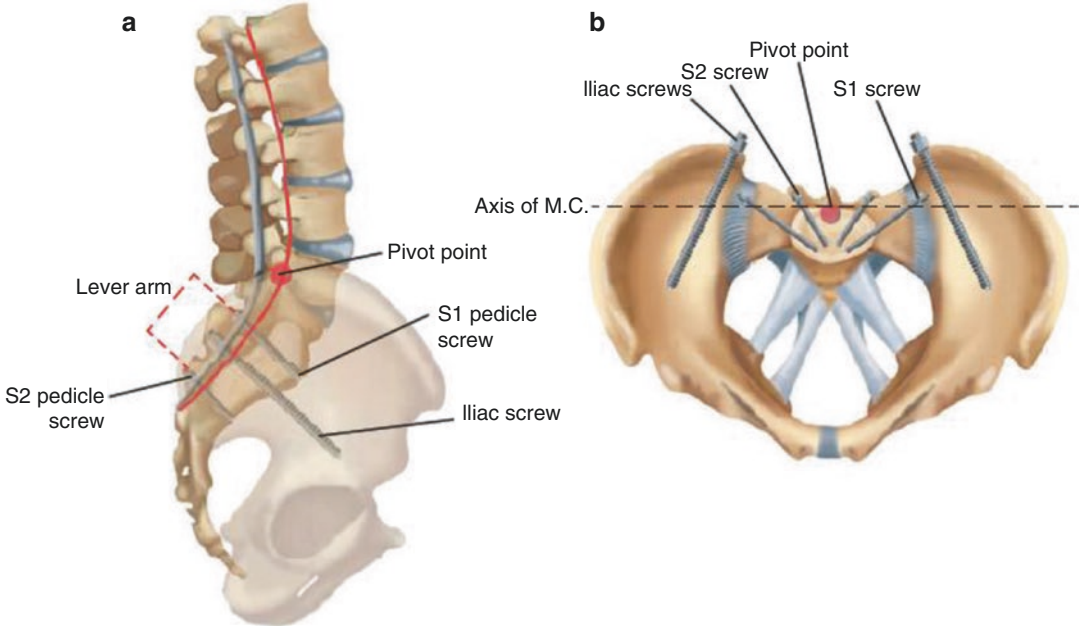

Fig. 16.4 Depiction of lumbosacral pivot. Sagittal (**a**) and axial (**b**) views

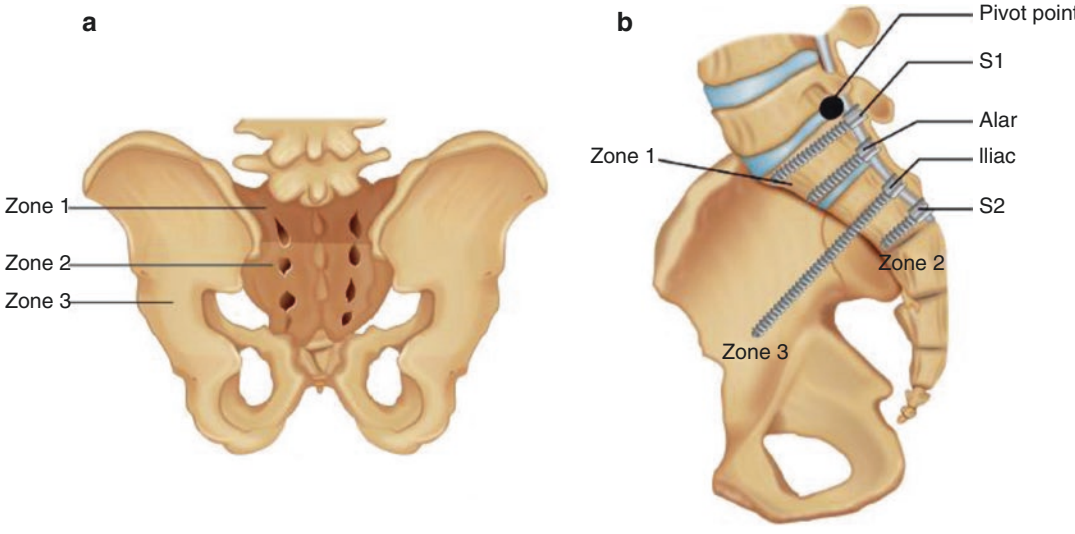

Fig. 16.5 Zones of sacropelvix fixation as defined by O'Brien et al. [27] in the (**a**) coronal plane. (**b**) Sagittal representation of sacropelvic fixation techniques in relation to the three zones described by O'Brien et al. and the flexural pivot point described by McCord et al. [12]

to the tip of the coccyx; Zone 3 comprises both ilia [31]. Fixation strength and construct stiffness are greatest in Zone 3, as there is potential in this region for instrumentation to extend far anterior to the pivot point (Fig. 16.5).

Indications for Pelvic Fixation

Pelvic fixation should be considered and utilized when there are greater biomechanical stresses expected than S1 screws can withstand. An

inability to achieve adequate fixation strength through sacral screws only can lead to an unacceptably high risk of implant loosening, pseudarthrosis, and failure. In this regard, the primary goal of pelvic fixation is to ensure a stable foundation for the construct and allow for maintenance of the deformity correction and solid arthrodesis. This is particularly critical for patients with greater preoperative and persistent postoperative sagittal malalignment and pelvic incidence (PI) minus lumbar lordosis (LL) mismatch and older patients and those with osteoporosis.

High-Grade Spondylolisthesis

Primary indications for pelvic fixation include high-grade lumbosacral spondylolisthesis (Meyerding Grade III or IV). For high-grade spondylolisthesis, the reduction of lumbosacral kyphosis to restore spinopelvic sagittal alignment can result in high mechanical complication rates due to the significant shear forces at the lumbosacral junction. Biomechanically, fixation extending to the pelvis helps offset the cantilever forces exerted for correction of high-grade spondylolisthesis [32].

Long Fusions to the Sacrum

A common indication for pelvic fixation is a long construct fusion for adult spinal deformity, particularly in the revision setting where distal fixation in the sacrum has previously failed and incorporation of the pelvis is required. Historically, what constitutes a long construct has been controversial. Some surgeons consider it to be one that extends to L2, while others contend that a long fusion is one that crosses the thoracolumbar junction [18, 33–35]. It is our experience that for most adult patients, fusion that extends proximally to L2 or higher creates sufficient biomechanical stresses at the lumbosacral junction that pelvic fixation is required.

Other conditions that may require pelvic fixation include paralytic kyphoscoliosis and neuromuscular kyphoscoliosis and congenital scoliosis. Lumbosacral deformities warrant pelvic fixation to offset the biomechanical stresses imposed on the construct to maintain deformity correction.

Rather than a specific level, more important is the concept that ending the distal construct in the lumbar spine could result in residual coronal imbalance or sagittal kyphosis that could progress over time. Multiple authors therefore advocate extending long spinal arthrodeses to the pelvis and augmenting it with anterior L5–S1 interbody fusion to prevent the development of flat back syndrome [36–38]. In the revision setting, the presence of pseudarthrosis at the L5–S1 junction with loose S1 screws is another indication for extension of fusion, with inclusion of pelvic fixation.

Degenerative spinal deformities involving the lumbosacral junction are common indications for sacropelvic fixation, including oblique take-off of L5, adult degenerative scoliosis, revision decompression surgery, and postlaminectomy flat back syndrome. Along with advanced degeneration of the L5–S1 motion segment, these conditions cause lumbosacral instability, exerting huge biomechanical stresses on the construct. In such deformities, extending the fusion to the pelvis is a prerequisite to achieving and maintaining the correction [39].

Corrective Osteotomies

In the setting of adult spinal deformity, sacropelvic fixation is indicated with the use of corrective osteotomies to correct coronal and sagittal malalignment. A three-column osteotomy or multiple posterior column osteotomies, when utilized to recreate lumbar lordosis, may require extension of fusion to the pelvis to maintain the correction. It is our recommendation that a minimum of six points of fixation are required distal to the osteotomy site; however, if pelvic anchors are used, four points of distal fixation in addition to two pelvic anchors may be adequate to prevent excessive motion and pseudarthrosis at the lumbosacral junction.

Other Conditions

Other indications include long segment fusions in the setting of osteoporotic or traumatic fractures.

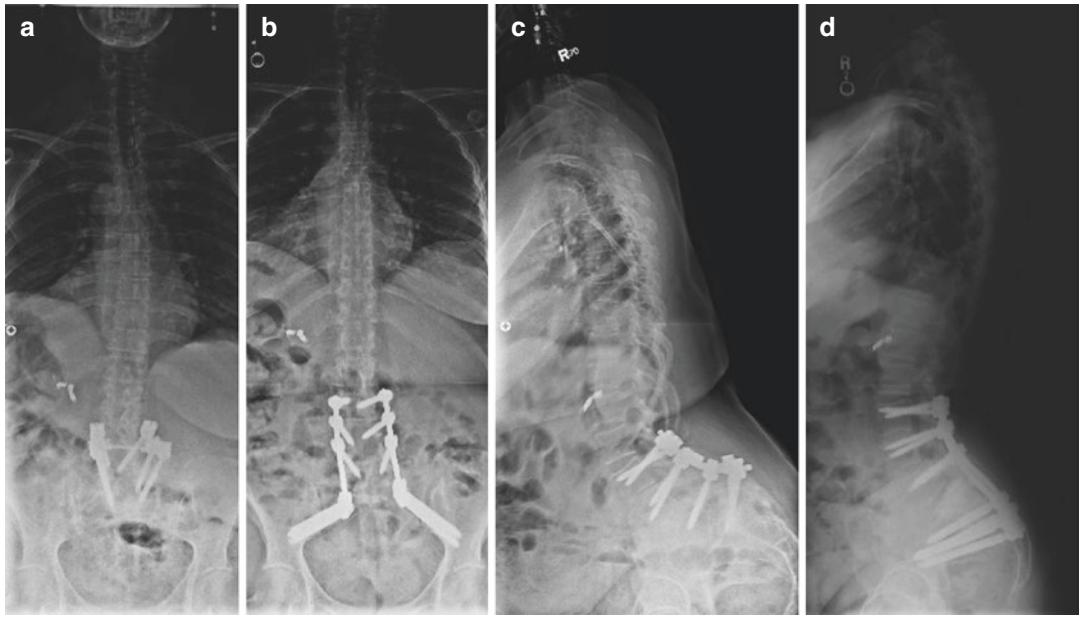

Fig. 16.6 Preoperative (**a**, **c**) radiographs of a 52-year-old female with previous L3–S1 fusion who developed an S1 fracture. Postoperative radiographs (**b**, **d**) after revision fusion, sacral osteotomy, and dual S2AI screws bilaterally

We had a case at our institution of a 52-year-old female, with severe osteoporosis, who developed a sacral fracture and sagittal malalignment 6 months after posterior spinal fusion L3–S1 for degenerative scoliosis at an outside institution. Our approach for this case was to remove all previous instrumentation and use larger size, bicortical, pedicle screws at L3–S1 for sufficient purchase. We then proceeded to place two S2AI screws bilaterally, referred to as a dual screw technique, and perform a sacral osteotomy to achieve correction in the sagittal plane, as well as translation (Fig. 16.6).

In all of these cases, the purpose of sacropelvic fixation is to provide structural support to partially unload S1 and/or S2 screws until fusion has occurred, thereby preventing fixation failure and progressive deformity. In particular, sacral insufficiency fractures complicating long fusions can pose a significant challenge. The authors believe that rigid spinopelvic fixation is the best prophylactic measure and serves at the same time as the treatment of choice for these fragility fractures [34]. Traumatic lower lumbar vertebra or sacral fractures with spinopelvic dissociation similarly demand spinopelvic fixation, a mechanically stable construct that allows weight bearing.

Pelvic fixation is also used in pathologies involving destruction of the sacrum, such as from neoplasm, infection, or sacral fractures leading to spinopelvic disassociation. The sacroiliac joint plays a critical role in load transmission from the axial skeleton to the lower limbs, and therefore lumbopelvic stabilization should be considered in the case of sacrectomies above the S1 foramina and total sacrectomies. If it is not possible to salvage the sacral pedicle for screw fixation, options include a bridging bone graft from the L5 transverse process to the sacrum or an anterior lumbar interbody fusion at L5–S1 for caudal support [40].

Options for Sacropelvic Fixation

Sacral (S1) Tricortical Pedicle Screws

To preface, failure with S1 pedicle screw fixation as the sole means of distal fixation of a long construct can be as high as 44 % [8, 15]. The key factors that play a role in distal sacral fixation alone

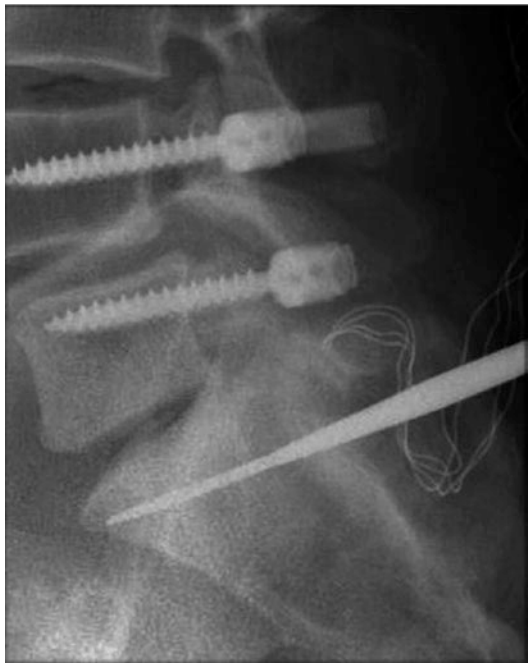

Fig. 16.7 Intraoperative lateral radiograph showing the pedicle finder in the direction of the tricortical S1 screw

include screw length and diameter, as well as bi- or tricortical screw placement. Studies have also confirmed the relationship between bone mineral density (BMD) and screw fixation strength [41]. Failure of the S1 pedicle screw largely occurs from insufficient sacral bone stock, whether by virtue of a small S1 sacral body or osteoporotic bone, or incorrect direction or depth of the screw.

Options for S1 pedicle screws include bicortical fixation with an entry point either in the anterior sacral cortex or the S1 superior endplate, or tricortical fixation incorporating the apex of the sacral promontory (posterior sacral cortex). Tricortical technique involves directing the screw toward the medial sacral promontory, allowing purchase of the dorsal cortex, the anterior cortex, and the superior endplate cortex (Fig. 16.7). This technique therefore provides three potential points of fixation. Studies have confirmed the biomechanical advantage of tricortical versus bicortical S1 screws, based upon the ability to insert longer screws with the tricortical purchase trajectory, and doubling the insertional torque of the bicortical screw inserted parallel to the S1 endplate [42]. This latter configuration is thought to improve pullout strength and to increase load to failure, both of which are particularly important concepts in osteoporotic bone.

S1 and S2 Pedicle Screws

Although the combination of S1 and S2 pedicle screws is stronger than S1 screws alone, the S2 pedicle screw remains dorsal to the lumbosacral pivot point limiting its effect on overall strength of the lumbosacral fixation construct [12]. Thus, S2 screws add little to the overall biomechanical strength of the construct in resisting flexion at the lumbosacral junction. Zindrick et al. noted that, compared with other sacral screws, medially directed S2 screws had the worst pullout strength and that screws inserted at a 45° lateral angle into the ala and medially into the first sacral pedicle were the strongest [11].

Sacral Alar Screws

Sacral alar screws are placed into the lateral anterior cortical bone of the sacrum and are aimed laterally 30° to 45° [30]. The safe zone is narrow, with potential for injury to the lumbosacral trunk, the internal iliac vein, and the sacroiliac joint. Screw lengths average 38 mm with 30° lateral angulation and 44 mm with 45° lateral angulation [30]. Poor clinical results and high pseudarthrosis rates have been noted when these screws were used for long fusions to the sacrum [8].

S2 Pedicle Screws and Sacral Alar Anchors

A potential adjunct to S1 pedicle screws are S2 pedicle or alar screws. Like S1 pedicle screws, S2 pedicle screws are dorsal to the flexural pivot point and from a biomechanical standpoint do not contribute to resistance of pullout or load to failure forces [12].

Sacral alar screws are inserted between the S1 and S2 dorsal foramina and directed laterally at a

45° angle for bicortical purchase. The medial to lateral "safe zone" trajectory has been demonstrated in cadaveric studies to be a narrow one. Specifically, this safe zone is 15 × 25 mm anterior to the lateral sacral ala [43]. Penetrating the anterior alar cortex carries the risk of injury to the L5 nerve root which runs in close proximity.

While the addition of sacral alar screws improves construct strength and resistance to pullout compared to S1 pedicle screws alone, long constructs utilizing S1 pedicle screws and S2 pedicle or alar screws as distal fixation still have unacceptably high rates of pseudarthrosis at the lumbosacral junction [8].

Iliac Screws

One of the driving principles for the development and implementation of the iliac screw technique was the search for a simple method of fixation to the pelvis, without the complications associated with the Galveston technique including rod migration and proximal screw pullout. A rod construct utilizing iliac screws allows for additional points of fixation in the lumbar spine and sacrum.

Coupled S1 iliac screws at the base of long constructs have been shown to improve fusion rates [14, 24]. The starting point for the iliac screws is identified by exposing the posterior superior iliac spine (PSIS). To reduce the prominence of screw heads, the start point is actually slightly deep to the PSIS, along the medial aspect of the inner table of the ilium. Iliac screw fixation in the stout posterior column of the pelvis allows for a rigid anchor for proximal instrumentation.

The iliac wings are exposed, and the outer table of the ilium can be exposed with a Cobb elevator to help identify the screw trajectory of approximately 20–45° caudal and 30–45° lateral. A pedicle finder is introduced along the planned trajectory, aiming anterior to the sciatic notch, and a ball-tipped probe is used to confirm integrity of the osseous path before screw placement (Fig. 16.8).

Biomechanical studies have demonstrated that iliac screws have a greater load to failure than do rods placed using the Galveston technique, with nearly three times the pullout strength [9, 44]. Further, iliac fixation provides anchors ending anterior to the lumbosacral pivot point, which has been shown to contribute to increased stability during the forward flexion moment. The modularity of iliac screws precludes the need for complex bending of rods necessary for the Galveston technique.

Iliac screw fixation allows placement of fully or partially threaded iliac screws or posts to be connected with the longitudinal rod construct in the lumbar spine by means of monoaxial or polyaxial connectors and offsets. Using a medial-lateral connector between the S1 and iliac screw does confer another potential interface for loosening and instrumentation failure.

Iliac screw placement requires additional dissection to expose the PSIS, which can increase blood loss. Complications related to this technique may include infection, which may be related to the soft tissue dissection. Studies demonstrate infection rates in patients treated with iliac fixation to be approximately 4 % [6]. There are no reports of injury to structures traversing the greater sciatic notch with placement of iliac screws, although care must be taken to prevent injury to primarily the superior gluteal artery and sciatic nerve. A more common concern is lucencies surrounding the iliac screws or area of rod bend, also referred to as "halos" [6, 45]. These lucencies are thought to be related to micromotion of the iliac screws, and no studies to date have demonstrated a correlation with lucencies or "halos" and rate of fusion at the lumbosacral junction. Prominence of iliac screws heads can also pose a problem, particularly in thinner patients and in neuromuscular deformities in the pediatric population.

Iliosacral Screws

Iliosacral screws are placed by exposure of the lateral surface of the ilium and the PSIS. A guidewire can be inserted cephalad and anterior to the PSIS, 1 cm below the iliac crest, crossing the inner table of the pelvis, and directed toward

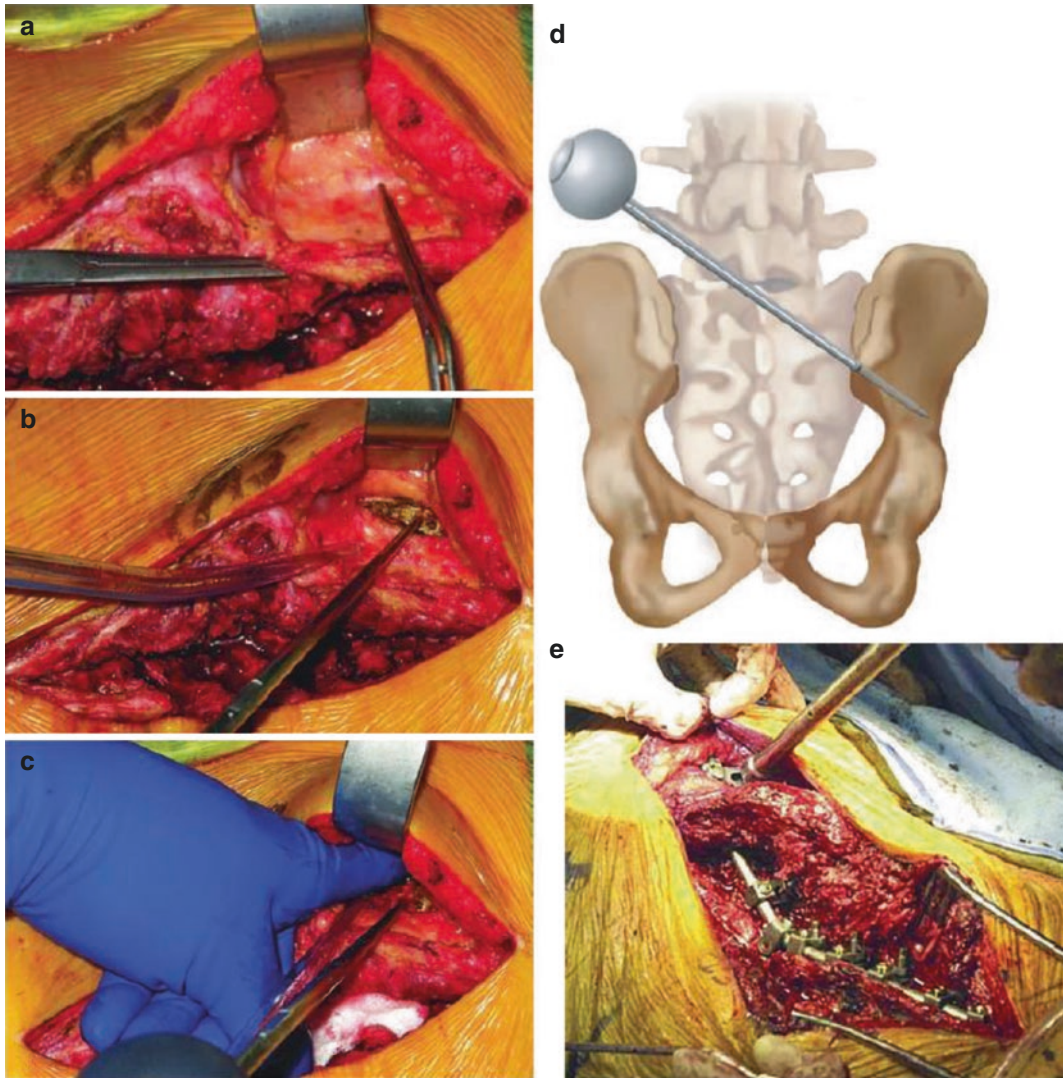

Fig. 16.8 (**a**) Extension of midline incision to PSIS for iliac screw placement; PSIS marked by forceps. (**b**) Pedicle seeker in table of ilium, angled toward ASIS. (**c**) Finger placed in greater sciatic notch to guide seeker. (**d**) Line diagram of iliac screw trajectory. (**e**) Iliac screws attached to main construct using connectors (**b**, **c**, **e**: From Moshirfar et al. [49])

the S1 pedicle and up to the S1 anterior cortex though not through it. The screws remain dorsal to the sacroiliac joint. The instrumentation, consisting of an iliosacral screw, a connector, and a longitudinal rod, offers the advantage of a screw trajectory that is perpendicular to the direction of the pullout forces. In addition, the engagement of three or four cortices increases the pullout strength [46].

A potential complication can be loosening or dislodging of the screw. Further, the procedure does require extensive dissection of the PSIS and ilium, and can entail resection of the dorsal sacroiliac ligament, which is a critical stabilizer of the sacroiliac (SI) joint. Studies indicate a 28 % failure rate of iliosacral screw fixation [15]. While fusion rates in most studies appear to be over 90 %, most authors describe a steep learning curve for mastery of this technique with potential for serious complications to pelvic structures such as the rectum and vascular trauma.

S2 Alar Iliac (S2AI) Screws

The S2AI is a technique developed at Johns Hopkins, our institution, and is our preferred technique. It uses screws inserted through the sacral ala into the ilium. S2AI screws are placed after all proximal points of fixation, including the S1 screws, are secured. The anatomic trajectory to insert screws begins with a sacral starting point midway along the line that connects the lateral edge of S1 and S2 dorsal foramina (Fig. 16.9). The angle of the trajectory is approximately 40° laterally and 20° caudally, running through the widest portion of the sacral ala and into the thickest portion of the ilium within 20–25 mm from the sciatic notch. It often traverses the fibrous portion of the sacroiliac joint. A 2.5-mm drill bit (3.2-mm drill bit in denser bone) is used to go across the sacral ala, the SI joint, and into the ilium; this distance is 40 mm on average in most patients (Fig. 16.10). The position of the drill can be confirmed with a C-arm using an AP view. Once the drill bit is about 10–15 mm past the SI joint, a teardrop view will confirm the position and the medial, lateral, and inferior cortices of the distal ilium (the teardrop). The teardrop view is a fluoroscopic view obtained by rolling the C-arm roughly 30° over the table and tilting it roughly 30° caudal, which creates an overlap of the AIIS and the PSIS and the image of a teardrop (Fig. 16.11). Because of the in-line placement of the S2AI and the remaining pedicle screws, no additional offset connectors are required, as is often the case with a traditional iliac screw.

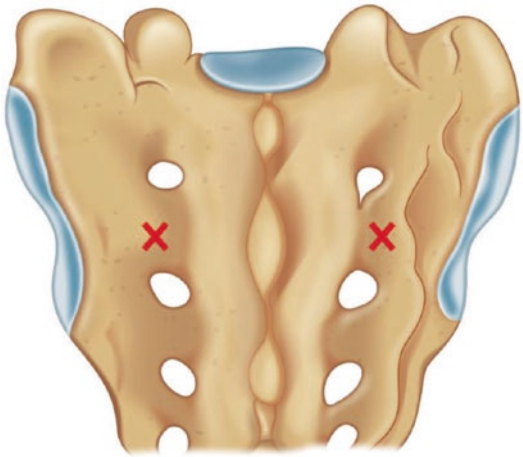

Fig. 16.9 The anatomic trajectory to insert screws begins with a sacral starting point midway of the line that connects the lateral edge of S1 and S2 dorsal foramina

The trajectory of this technique allows a length longer than that of traditional iliac screws, but the screws are >1.5 cm deeper beneath the skin [26]. In addition, the more oblique angle of this technique does not allow the screws to back out dorsally. The anchor is in line with all of the other spinal anchors so that no offset connector is needed. The length and width of the anchor allowed through this trajectory is longer than that of other iliac screws so that pelvic obliquity can be corrected even in the presence of osteopenic bone.

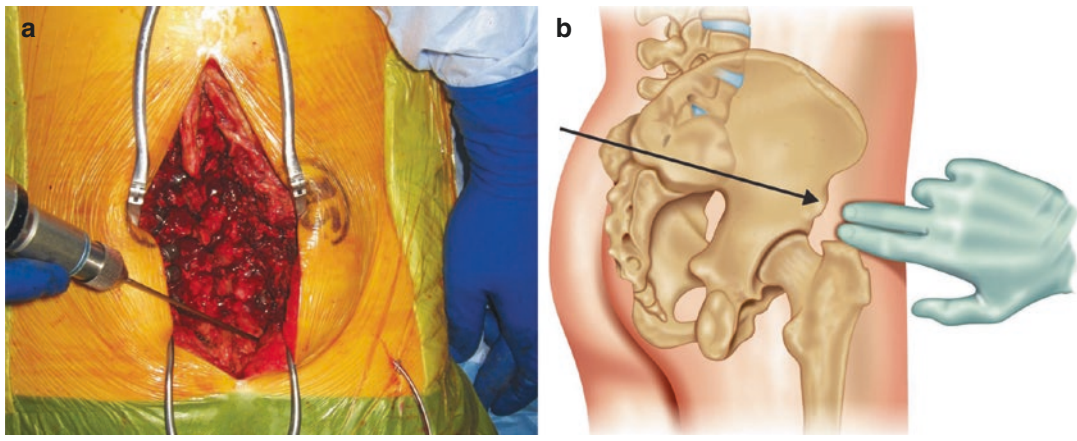

Fig. 16.10 Intraoperative photograph showing the direction of drilling of the S2AI screw toward the tip of the greater trochanter (**a**), as a proxy for the AIIS, which may be felt by the surgeon's opposite hand (**b**)

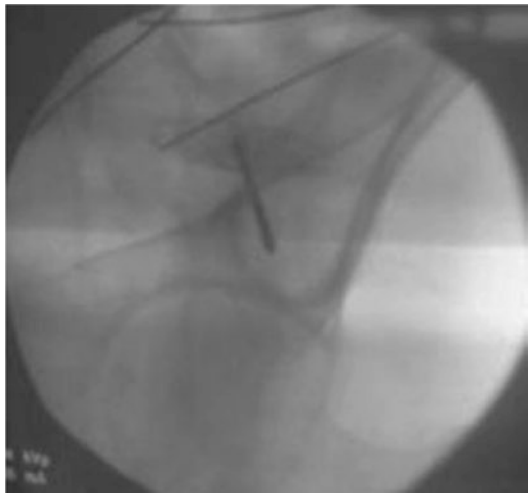

Fig. 16.11 The teardrop view is a fluoroscopic view obtained by rolling the C-arm roughly 30° over the table and tilting it roughly 30° cephalad

Placement of pelvic fixation into the ilium through a pathway from the sacral ala allows for insertion of long screws (up to 110 mm) anterior to the flexural pivot point. Further, the screw pathway just above the greater sciatic notch allows for the use of the largest screw diameter possible to capture the sciatic buttress, the strongest bone of the ilium, which provides very rigid pelvic anchorage. Decreased implant prominence is one of the primary advantages of this technique, as the starting point is approximately 15 mm deeper than that required for screws originating at the PSIS [26].

Studies at our institution demonstrate a low rate of infection in patients treated with S2AI fixation, ranging from 0 to 4 %, with fusion rates greater than 90 % [27]. These results are generalizable, as the S2AI technique is also associated with significantly lower rates of infection and need for revision surgery, and implant loosening, when compared with the iliac screw technique at other institutions [27, 47, 48]. There appears to be no significant effect on the SI joint at 2 years based on radiographs and clinical exam; however, the long-term effect of violating the SI joint is unknown, and longer follow-up is needed.

Conclusion

While fixation at the lumbosacral junction was initially a significant challenge within adult spinal deformity surgery, the advent of new techniques and developments in spinal instrumentation has helped lead to lower lumbosacral fixation failure rates. It is important to consider sacropelvic fixation for long fusions to the sacrum, high-grade spondylolisthesis, decompression caudad to a long fusion, lumbar osteotomy for correction of sagittal and/or coronal plane deformities, pelvic obliquity, and reconstruction following sacrectomy for resection of a tumor, sacral fracture, and osteoporosis in the setting of lumbosacral fusion.

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17 Diagnosis and Classification of Proximal Junctional Kyphosis and Proximal Junctional Failure

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Introduction

Pedicle screw instrumentation constructs have become a cornerstone in the treatment of adult spinal deformity and instability. They are known to provide greater rigidity and enhanced ability to correct and maintain spinal alignment. Biomechanical data, however, demonstrate that increased construct stiffness is associated with increased loading within adjacent segments [1–9]. Increasingly stiff constructs can create vulnerability at the proximal segments and, in some cases, lead to proximal junctional pathologies with various radiographic and clinical manifestations [10–12]. Adjacent segment degeneration (ASD) is a well-documented phenomenon that can occur after thoracolumbar or lumbar spinal fusion [5, 6, 13–24]. Proximal junctional kyphosis (PJK) is a relatively more benign form of junctional pathology, manifesting primarily as a minimally symptomatic radiographic diagnosis [16, 19, 25, 26]. On the other hand, proximal junctional failure (PJF) represents a more severe form of junctional pathology associated with mechanical failure and increased risk of neurologic injury, deformity, pain, and the need for revision surgery [27–30]. PJF has important clinical implications especially for elderly patients with issues of reduced bone density. In this population, increased loads in the setting of decreased bone strength can lead to adjacent segment failure [5, 15, 31, 32]. When proximal junctional failure manifests with clinical symptoms, treatment can be complex, typically requiring osteotomy and extension of instrumentation and fusion. Recently, an increased amount of information describing the incidence, classification, prevention, and treatment of this problem has been developed.

Definition, Epidemiology, and Clinical Significance

Proximal Junctional Kyphosis

Proximal junctional kyphosis (PJK) primarily is a spinal deformity that manifests as the development of minimally symptomatic kyphosis immediately above a spinal fusion construct [16, 19, 25, 26]. There is no consensus regarding a precise definition of PJK. Glattes et al. originally defined PJK as a sagittal Cobb angle between the

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uppermost instrumented vertebra (UIV) and the two levels above the UIV (UIV +2) of 10° or greater and at least 10° greater than the preoperative measurement [16]. Bridwell et al. [33] and O'Shaughnessey et al. [34] used 20° as the cutoff for defining PJK. More recently, Helgeson et al. [35] described PJK as a postoperative increase of 15° or more between the UIV and UIV+1 (instead of UIV+2) [35]. To date, Glattes' definition of PJK appears to be the most commonly utilized in the literature (Fig. 17.1).

Sacramento-Dominguez et al. [36] evaluated the reproducibility of using the UIV+1 and UIV+2 to measure PJK. Although they demonstrated moderate to very high intra- and inter-rater reliability, the authors could not conclude which of the two vertebrae is the better landmark to use for measuring PJK [36]. Further work has recently shown that radiographic measurement of kyphosis from UIV to UIV+2 is highly repeatable, with or without the presence of PJF and at either upper thoracic or thoracolumbar junction [62].

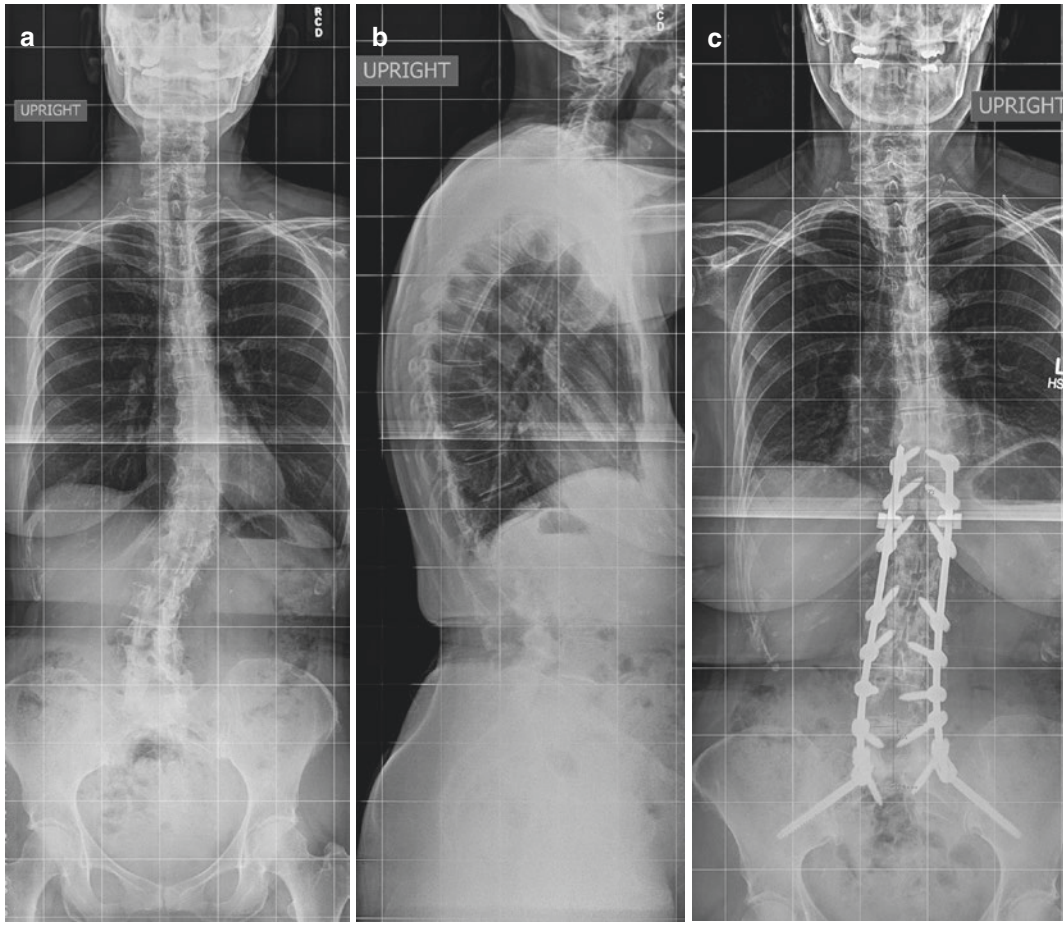
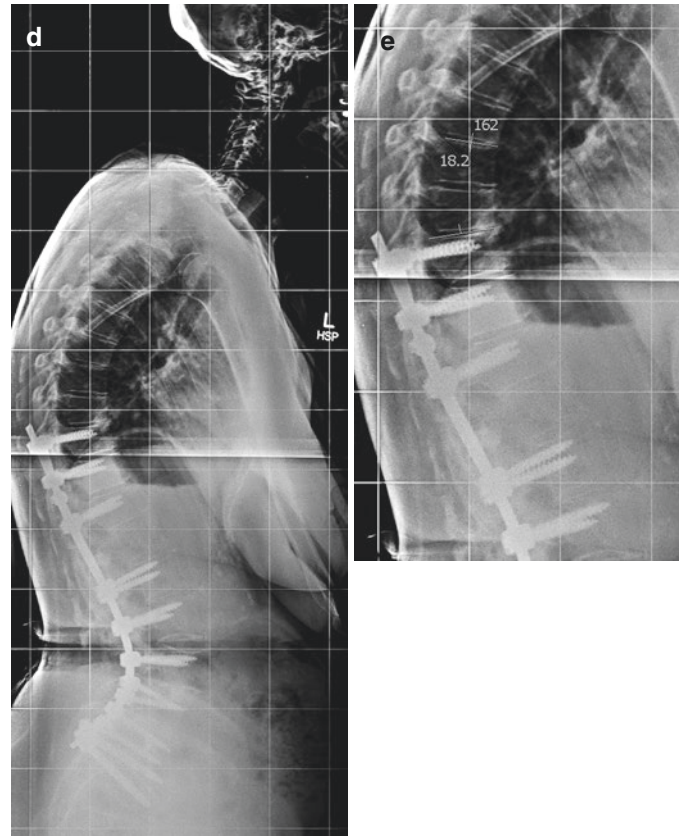


Fig. 17.1 PJK without mechanical failure. (**a**, **b**) Preoperative AP and lateral radiographs demonstrating lumbar degenerative scoliosis with coronal imbalance and L4–5 spondylolisthesis. Her pelvic incidence (PI) measured 55° and lumbar lordosis (LL) measured 66°. (**c**, **d**) Postoperative AP and lateral radiographs demonstrating T10 to pelvis fusion. Her PI–LL mismatch remained within acceptable range postoperatively (PI = 55° and LL = 64°). Radiographs also illustrate kyphosis at the proximal adjacent segment. (**e**) Close-up lateral radiograph demonstrating proximal junctional kyphosis (PJK) measurement of about 18° between the upper instrumented vertebra (UIV) and the upper instrumented vertebra +2 (UIV +2) without evidence of implant failure or vertebral body fracture. This patient remains asymptomatic from her PJK and is being serially monitored with radiographs and clinically assessment

Fig. 17.1 (continued)



Proximal Junctional Failure

PJF is more severe than PJK and is becoming increasingly recognized as one of the most frequent reasons for reoperation after adult spinal deformity surgery. It results, in some cases, in a higher need for revision surgery, a greater risk of neurologic injury, increased deformity, and pain [27–30]. Other terms used to describe this phenomenon have included "topping off syndrome," "proximal junctional fracture," and "proximal junctional acute collapse." These terms highlight the associated structural failure and mechanical instability that distinguish this more severe form of proximal junctional pathology from its more common and more benign PJK counterpart. The estimated cost of revision surgery after PJF is $77,432, indicating a greater clinical and economic burden of this condition [18].

The structural failure that occurs with PJF can present as vertebral body fracture, implant pullout or breakage, and/or disruption of the posterior osseo-ligamentous complex [27, 29]. The development of a single definition and classification system for PJF remains ongoing. Yagi and colleagues defined PJF as a symptomatic PJK requiring any type of revision surgery [37]. Hostin et al. [29] and Smith et al. [30] defined acute PJF as 15° or more of PJK along with fracture of the UIV or UIV +1, failure of UIV fixation, or need for extension of instrumentation within 6 months of the index surgery. Hart and colleagues [28] described PJF on the basis of 10° or greater postoperative increase in kyphosis between the UIV and UIV + 2, along with one or more of the following features: fracture of the vertebral body of the UIV or UIV + 1, posterior osseo-ligamentous disruption, or pullout of instrumentation at the UIV (Fig. 17.2).

Epidemiology and Clinical Significance

It is difficult to ascertain the exact prevalence of these conditions in the adult population due to the varied definition of PJK and PJF. Different authors report the prevalence of PJK ranging from 20 to 39 % after spinal deformity fusion surgeries [16, 19, 38–41]. The prevalence of PJF is lower and has been reported to range between 1.4 and 35 % [29, 30, 37].

Experts continue to debate whether PJK is simply a radiographic diagnosis or has potential clinical implications for patient outcomes. Most studies have failed to demonstrate that PJK diminishes clinical outcomes [16, 19, 38, 39, 41]. Only when using 20° as the threshold for defining PJK did Bridwell et al. report a significant difference in self-image subscale scores of the SRS-22 [33]. In a large retrospective study, Kim et al. also demonstrated higher rates of pain in patients with PJK (29.4 %) compared to those without PJK (0.9 %) and that the presence of upper back pain had an odds ratio of 12.5 for prediction of PJK [42]. There is also an evidence that PJK can be progressive and that increased absolute PJK angles (in some cases likely an indication of structural failure) are directly correlated with pain and inversely correlated with function [42, 43].

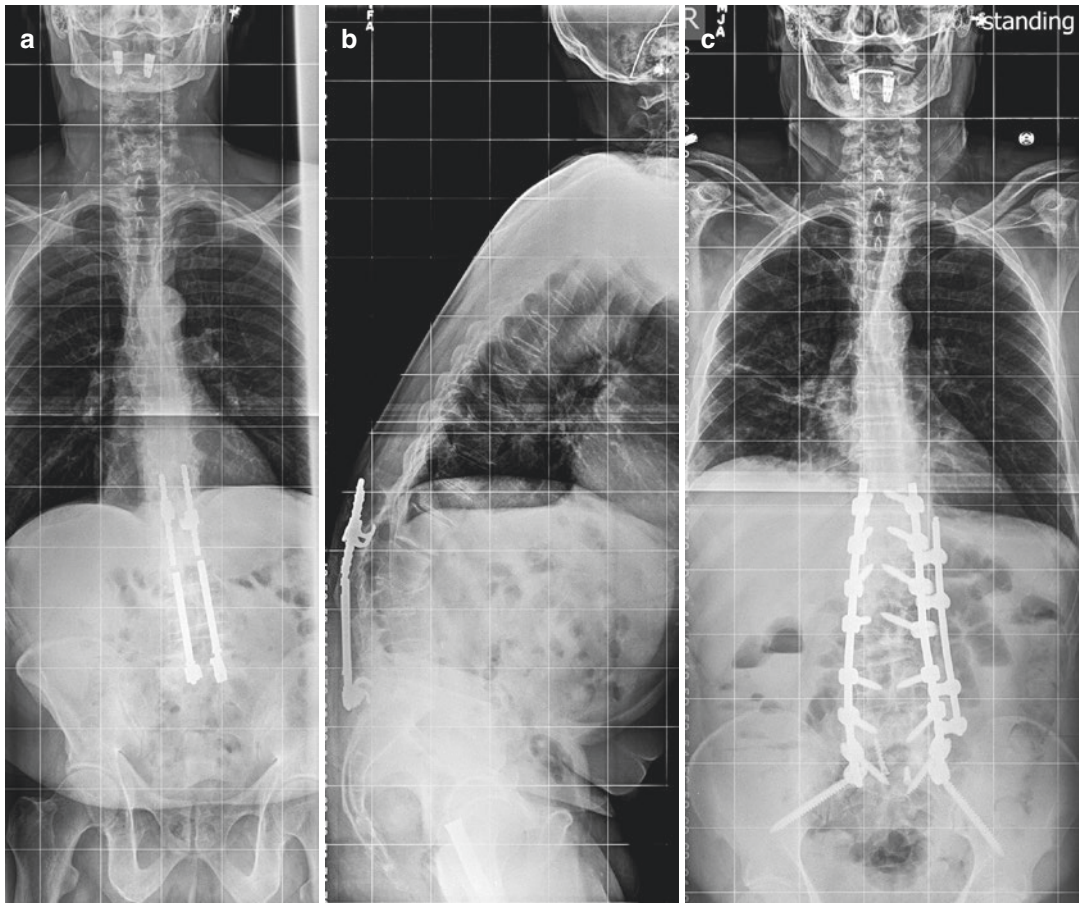


Fig. 17.2 Minimally symptomatic PJF. (**a**, **b**) Preoperative AP and lateral radiographs demonstrating flat back deformity and coronal and sagittal global imbalance. Preoperative PI–LL mismatch measured 56° (PI = 46°, LL = 10° kyphosis). (**c**, **d**) Immediate postoperative AP and lateral radiographs illustrating improved alignment after T11 to pelvis fusion and reconstruction. His PI–LL mismatch became normalized postoperatively (PI = 46° and LL = 55°). (**e**, **f**) Full-length and close-up lateral x-rays on their most recent follow-up illustrate classic features of proximal junctional failure (PJF), including compression deformity of the upper instrumented vertebra and proximal junctional kyphosis angle measuring 17°. This patient remains asymptomatic from his PJF and is being serially monitored with radiographs and clinical assessment

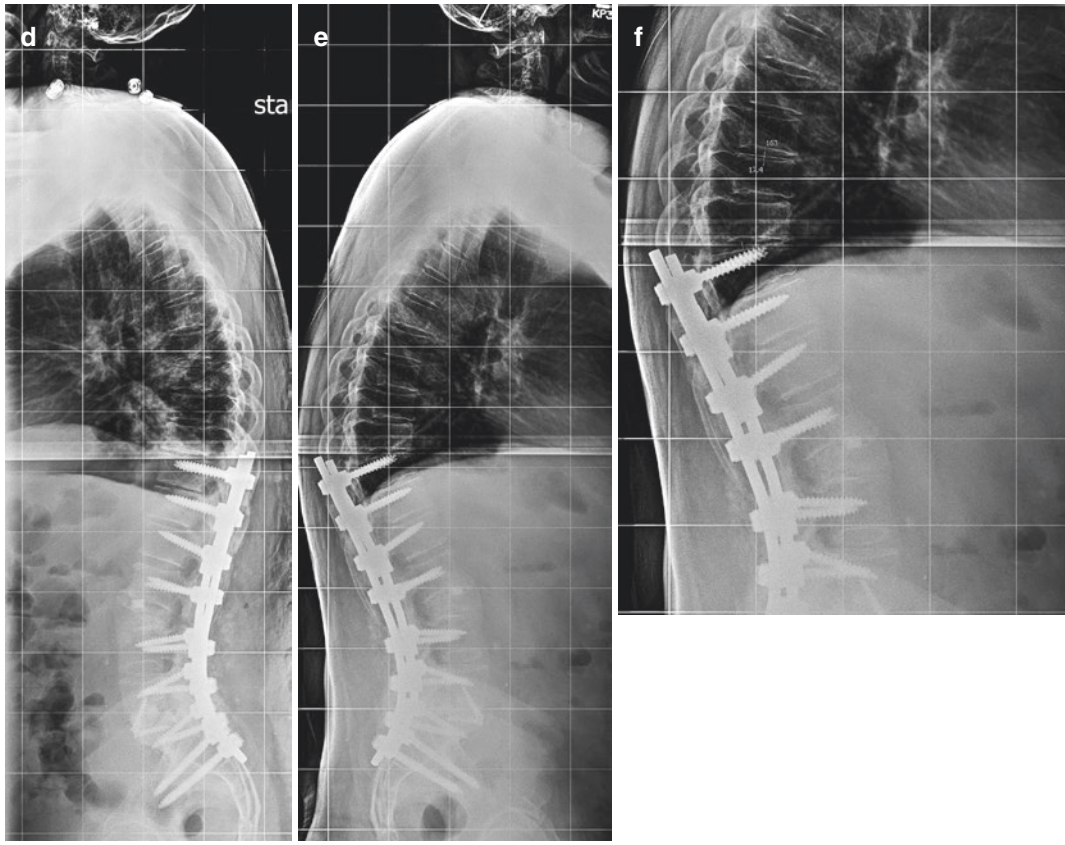


Fig. 17.2 (continued)

Current literature suggests that separating PJK and PJF as two unrelated conditions may be overly simplistic. Rather, a more supported model is to conceptualize PJK and PJF as different clinical entities residing on the proximal junctional pathology spectrum. With worsening degrees of PJK, patients can develop the structural failures that define PJF. This may be accompanied by subsequent pain, neurologic deficit, gait difficulties, sagittal imbalance, and social isolation. While patients with PJK may be initially asymptomatic, Hart et al. [27] report that nearly half (47.4 %) of patients who developed acute PJF required revision surgery within 6 months of their index procedure.

Risk Factors

The etiologies of PJK and PJF are likely multifactorial as no study has elucidated a single variable that strongly and consistently predicts their development. However, several major risk factors for PJK and PJF have been described. The potentially modifiable risk factors include greater curvature correction [30, 33, 45, 47–50], combined anterior–posterior spinal fusion [19, 33, 41, 43, 51, 52], fusion to the sacro-pelvis [30, 34, 39–41, 43, 46], and residual sagittal imbalance [53]. Non-modifiable factors with clear correlation to PJK development include older age (>55 years) [19, 22, 33, 47] and severe preoperative sagittal imbalance [30, 41, 43–46, 50, 54, 55]. Other less well-established but likely risk factors include low bone density [43], the presence of a comorbidity [33], and high body mass index [22, 33].

There remains conflicting evidence regarding whether the type of instrumentation used at the UIV, the number of levels fused, or the location of the UIV influence the risk of PJK development. The use of hooks, wires, or pedicle screws at the proximal level has not been consistently shown to significantly affect the risk of PJK across studies [35, 39, 44–46, 51]. There are

studies demonstrating that both a greater and lesser number of levels fused [33, 44] are risk factors for PJK. Similarly, both a UIV at the upper and lower thoracic level have been associated with the development of PJK [26, 33, 52].

Modes of Failure and Classification

Modes of Failure

Given that the prevalence of elevated thoracic kyphosis ranges between 20 and 40 % and is more common in geriatric patients, some authors posit that PJK represents a recurrence of deformity and/or natural history of aging rather than a postoperative complication. This assertion is supported by the fact that many of the radiographic features associated with the development of PJK correspond with those seen in the natural history of kyphosis observed with normal aging: osteopenia, facet joint degeneration, disc height loss and wedging, and compression deformities of vertebrae [16, 56]. The true etiology may be multifactorial, involving iatrogenic effects of altered mechanics and adjacent segment surgical injury, along with deformity progression and the processes of natural aging. Indeed, several authors have submitted evidence suggesting that surgical disruption of the posterior soft tissue tension band, construct stiffness, and correction forces may all play an important role in the pathogenesis of PJK [24, 26, 35, 41, 56–58].

Unlike PJK, the underlying pathology for PJF appears to be an acute structural event, most typically early in the postoperative period, although it can also include progressive deformity occurring over months to years [18, 22, 24, 28, 29]. Hostin and colleagues [29] reported that fracture was the most common mechanism of failure (47 %), followed by soft tissue disruption (44 %). They reported that 9 % of their patient cohort experienced PJF as a result of trauma and screw pullout accounted for approximately 9 % of failures. This variety in failure mechanisms accounts for the spectrum of severity in clinical presentations of PJF. Fracture subluxation and dislocation of the adjacent segment(s) has also been reported [22, 24, 29, 56, 59]. Hostin and colleagues [29] also reported that failure resulted more frequently from vertebral body fractures when the UIV ended in the thoracolumbar region, while when the UIV ended in the upper thoracic spine, soft tissue disruption and subluxation without fracture or instrumentation failure were the more common modes of failure [29].

Classification

Several studies have proposed a classification scheme for PJK and PJF [27, 37, 41, 60]. Yagi and colleagues initially presented their PJK classification scheme in 2011 and subsequently modified it in 2014 [37, 41]. While their modified classification system is simple and easy to use, it lacks prognostic information and does not guide management. The ideal classification scheme should both guide treatment and provide information regarding severity of the pathology. Recently, Hart et al. [60] and the International Spine Study Group (ISSG) proposed a Proximal Junctional Kyphosis Severity Scale (PJKSS) that assigns points to six different components thought to be important in the evaluation and management of PJK/PKF. Points are summed to give a total severity score. The PJKSS has been shown to strongly correlate with health-related quality of life (HRQOL) outcome scores and indication for revision surgery [61]. Demonstration of its reproducibility and reliability has also been completed [62] (Table 17.1).

Evaluation and Preoperative Planning

Evaluation

Failure to recognize and differentiate PJF from PJK and initiate the proper workup and treatment can put patients at risk of neurologic compromise. Unlike patients with PJK, patients with PJF can experience loss of neurologic

Table 17.1 Hart-ISSG PJK Severity Scale (PJKSS)

Hart-International Spine Study Group (ISSG) Proximal Junctional Kyphosis Severity Scale (PJKSS)		
Parameter	Qualifier	Severity score
Neurologic deficit	None	0
	Radicular pain	2
	Myelopathy/motor deficit	4
Focal pain	None	0
	VAS ≤4	1
	VAS ≥5	3
Instrumentation problem	None	0
	Partial fixation loss	1
	Prominence	1
	Complete fixation loss	2
Change in kyphosis/PLC integrity	0–10°	0
	10–20°	1
	>20°	2
	PLC failure	2
UIV/UIV + 1 fracture	None	0
	Compression fracture	1
	Burst/chance fracture	2
	Translation	3
Level of the UIV	Thoracolumbar junction	0
	Upper thoracic spine	1

VAS visual analogue scale, *PLC* posterior ligamentous complex, *UIV* upper instrumented vertebra

function. Although pain can be substantial, some patients may have limited new complaints [18, 22, 24, 27, 29]. On physical examination, the patient's gait and posture should be noted and compared to previous findings. Kyphotic deformity, tenderness to palpation at the proximal junction of instrumentation, and implant prominence and skin tenting should be assessed. If there are concerns, infection should be considered in the differential diagnosis, and the appropriate blood work should be ordered (CBC with differential, erythrocyte sedimentation rate, C-reactive protein). A thorough neurologic examination should be performed to evaluate for evidence of spasticity. Upright 36-inch-long cassette AP and lateral x-rays and, if indicated, advanced imaging such as computed tomography (CT) and magnetic resonance imaging (MRI) are essential in the complete assessment of symptomatic patients.

Preoperative Planning

When revision surgery is planned, performing a thorough history and physical exam and obtaining a complete imaging workup are mandatory. Full-length 36-in. standing anteroposterior and lateral radiographs allow for accurate assessment of segmental and global spinal alignment parameters. Inclusion of the femoral heads within the field of view is required for spinopelvic alignment parameter measurements. In addition, supine hyperextension lateral radiograph over a bolster can provide information regarding the flexibility of the kyphotic deformity. Preoperative CT with sagittal and coronal reconstructions is helpful in identifying anterior ankylosis, as well as delineating vertebral fractures and hardware fracture or pullout. CT can also be valuable in evaluating prior fusions and planning osteotomies. MRI or CT myelogram should be obtained if there is suspicion for neural element compression. Bone

mineral density should be measured if it has not been done within the previous 6 months. Osteoporosis or osteopenia should be treated with teriparatide if possible, prior to consideration for elective revision surgery in order to reduce the chance of a second recurrence. If the procedure is more urgent, then it can be started postoperatively.

Treatment Concepts

Currently, there is no standard consensus to guide the surgeon in determining which patients with PJK would benefit most from revision surgery. In general, patients who are asymptomatic are managed with reassurance, education, and close monitoring (Figs. 17.1 and 17.2). On the other hand, those with significant symptoms and higher severity of deformity or instability can be considered for revision surgery. Some authors suggest that treatment may be essential even in the absence of symptoms in patients with disruption of the posterior column, due to risk of deformity progression and neurologic injury [19, 43].

Hart et al. [27] reported that about 47 % of patients with PJF underwent revision surgery within 6 months of their index procedure. The authors also elucidated several factors that may influence the surgeon to recommend revision surgery for PJF: traumatic etiology of PJF, severity of kyphosis, combined anterior/posterior approaches at the index surgery, female sex, and higher SVA [27]. Interestingly, mode of failure (soft tissue vs. bony), age and BMI, number of levels fused, and location of UIV did not statistically correlate with the decision to revise [27]. Smith et al. [30] also identified other factors affecting the decision to perform revision surgery, including the presence of hardware failure, uncontrolled pain, neurologic deficits, and myelopathy (Fig. 17.3). Of note, they also reported that the revision rates differed by the location of the UIV. In their patient cohort, the revision rate was much higher when the UIV was located in the lumbar or lower thoracic spine [30].

In general, extension of the fusion up to the next stable level (with or without decompression) may be all that is required if the spine is flexible, and global balance can be achieved without the use of osteotomies. However, if the spine above the fusion construct is rigid and the kyphotic deformity is severe, the use of osteotomies may be indicated. Smith-Petersen or Ponte osteotomies are usually adequate to restore sagittal alignment if the intervertebral discs are supple and there is no anterior column ankylosis. Three-column osteotomies, such as pedicle subtraction osteotomy or vertebral column resection, are reserved for cases of severe, rigid deformity or when neurological compromise due to anterior spinal cord compression is present (Fig. 17.4). The use of anterior interbody support should be considered when significant anterior column defect (>50 % bone loss) exists or to aid in obtaining greater sagittal alignment correction and improving fusion rates (Fig. 17.5). Yagi et al. [37] recently reported a 48 % recurrence rate of PJK/PJF at the new UIV after revision surgery. Of those patients with a recurrence PJK/PJF, 82 % required repeat revision surgeries, highlighting the importance of prophylactic procedures at the time of revision to reduce the risk of recurrence.

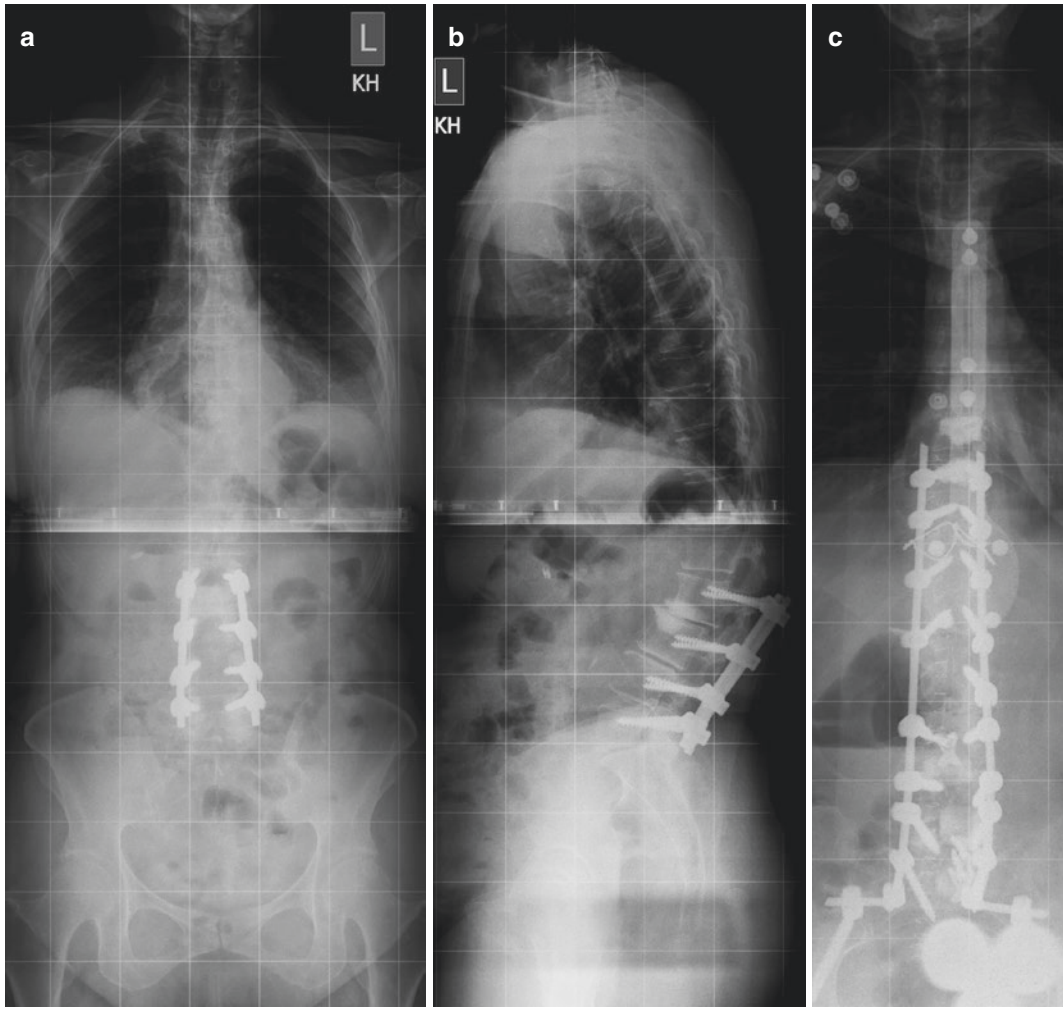
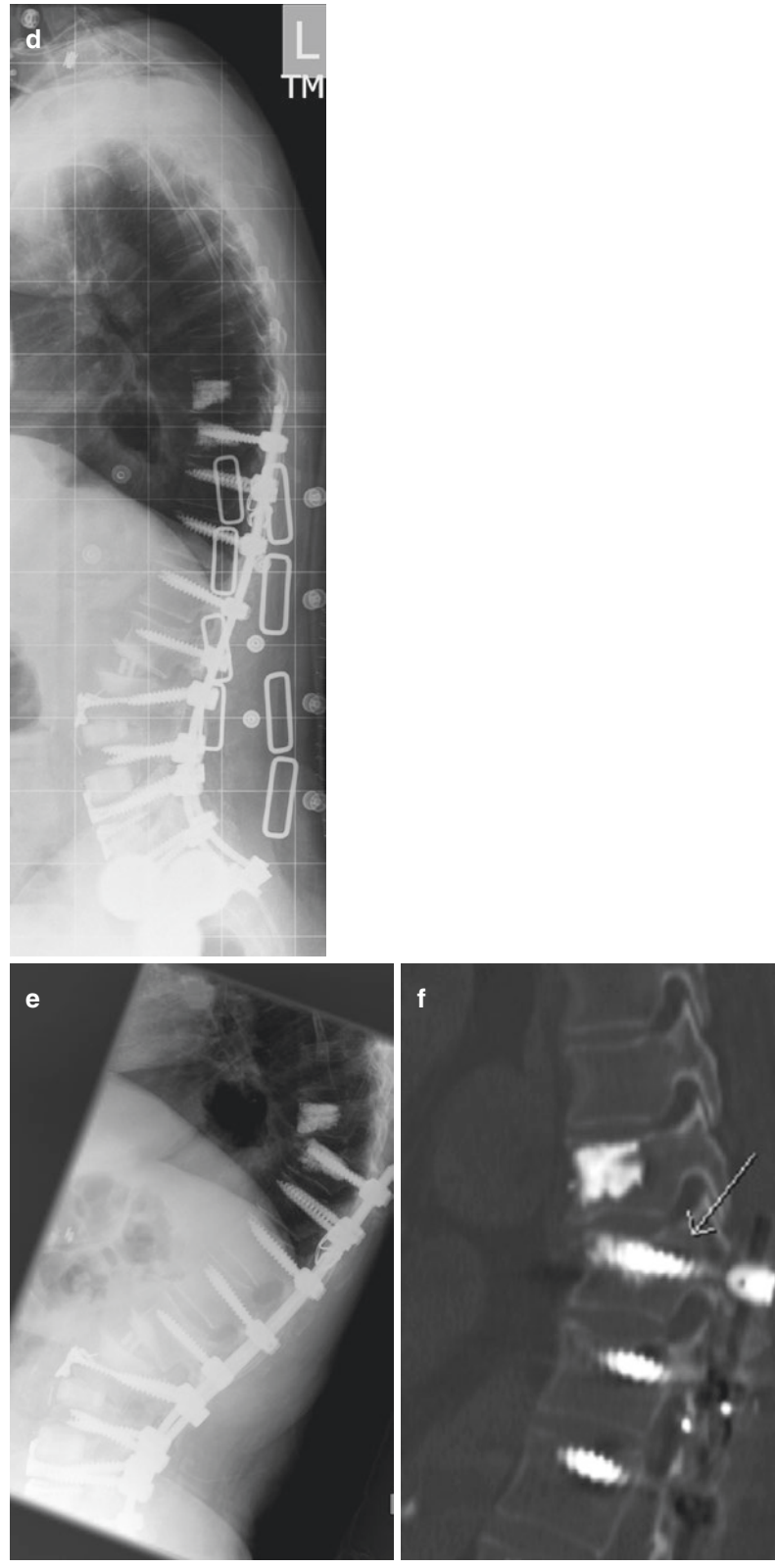


Fig. 17.3 PJF with neurological deficit. (**a**, **b**) Preoperative AP and lateral radiographs demonstrating iatrogenic flat back deformity and thoracolumbar kyphosis. Preoperative PI–LL mismatch measured 62° (PI = 42°, LL = 20° kyphosis). (**c**, **d**) Immediate postoperative AP and lateral radiographs status post extended lumbar spinal fusion and instrumentation with prophylactic vertebroplasty of the UIV and the UIV +1. Her PI–LL mismatch improved postoperatively (PI = 42° and LL = 65°). Because her PI is low, we corrected her LL to a greater degree than the PI = LL ± 9° relationship would recommend. (**e**) Lateral views 5 weeks postoperatively, demonstrating increased junctional kyphosis up to 35° and subtle anterior subluxation. (**f**) CT revealed a fracture of the T10 bilateral pedicles. The patient exhibited signs and symptoms of cord injury and myelopathy and underwent revision surgery with extension of instrumentation and fusion to the upper thoracic spine. (**g**, **h**) AP and lateral radiographs status post revision surgery for severe proximal junctional failure with associated fracture/subluxation and myelopathy

Fig. 17.3 (continued)



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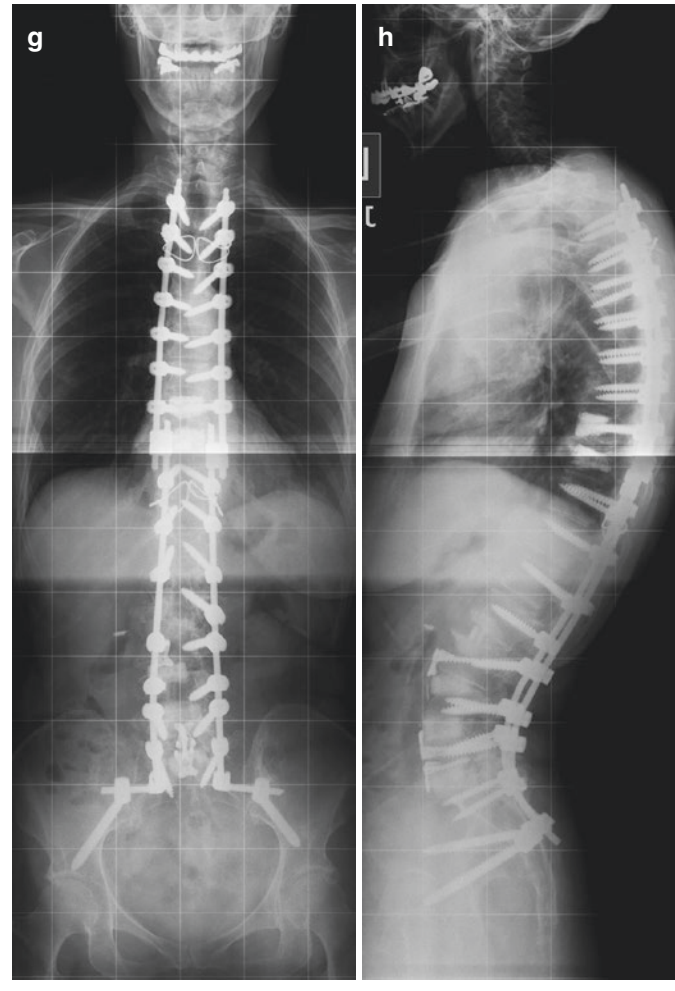


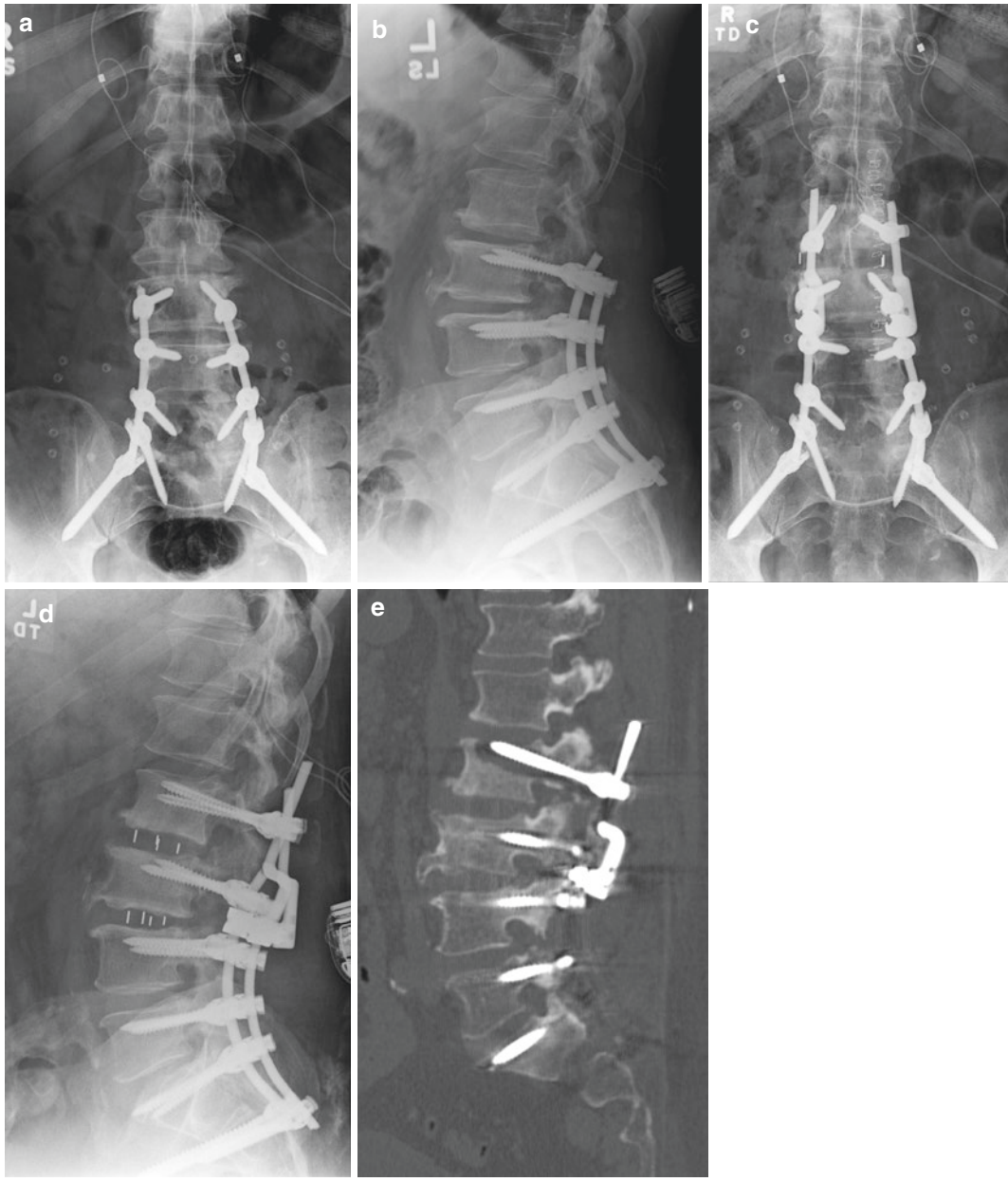
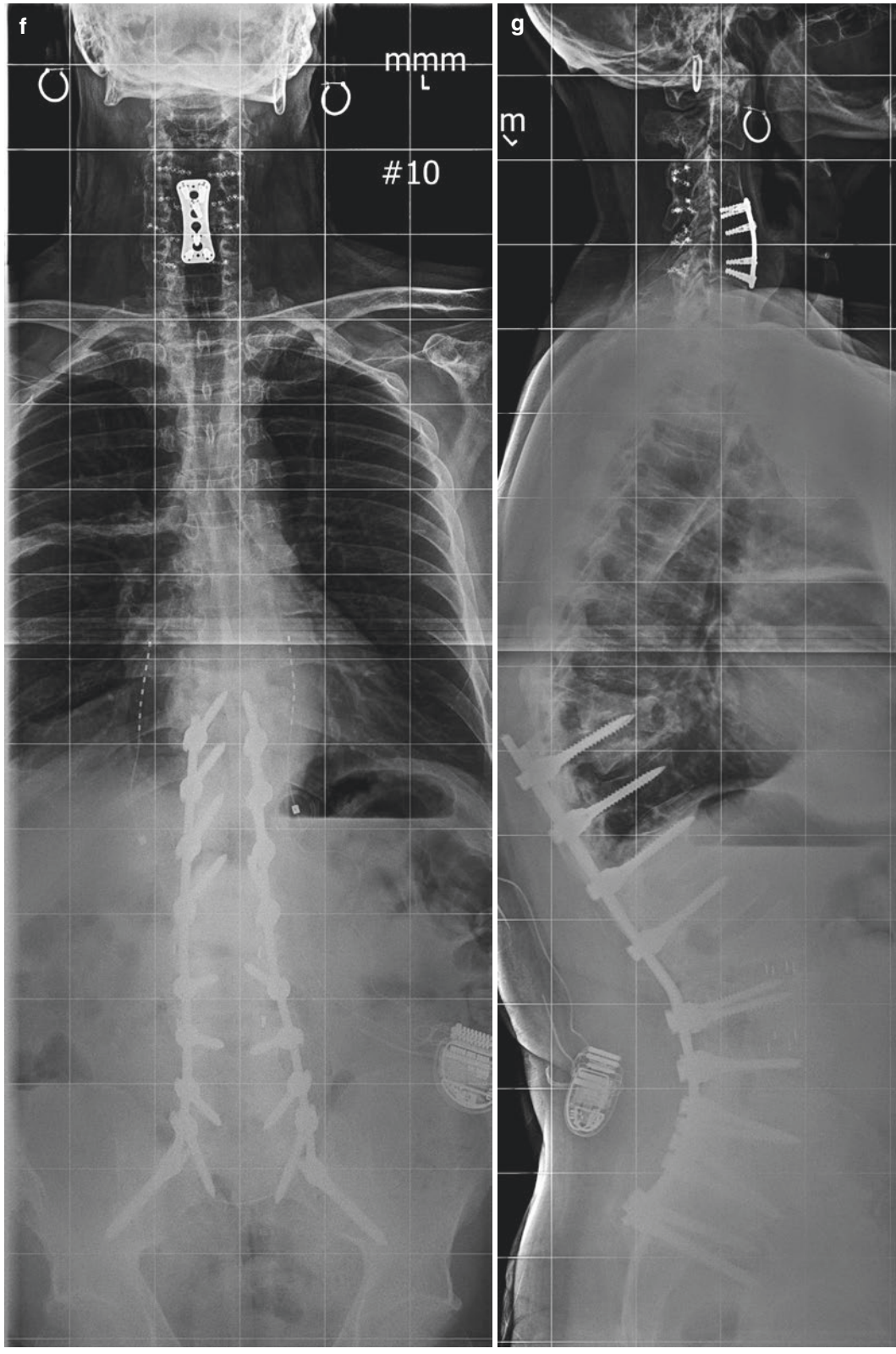


Fig. 17.4 Treatment of chronic PJF with associated wound infection. (**a**, **b**) AP and lateral radiographs demonstrating an L3 to pelvis fusion and instrumentation with evidence of screw loosening and nonunion at the top of the construct. (**c**, **d**) AP and lateral radiographs illustrating revision surgery with extension of the fusion to L2 with XLIF at L2–3 and L3–4. (**e**) Postoperative CT scan reveals cutout of the right L2 screw and associated bony resorption around the screw secondary to postoperative deep infection and osteomyelitis. (**f–i**) Radiographs and CT scan showing another revision surgery with an L2 PSO and extension of the fusion construct up to T10. Postoperative PI–LL mismatch after this third procedure measured 14° (PI = 68° and LL = 82°). The patient subsequently developed proximal junctional failure with fracture of T10 and associated bony resorption, screw cutout, and thoracic myelopathy. The postoperative LL is arguably too high for the already large PI and may have contributed to the development of PJF in this case. The same surgeon had performed the above three procedures prior to the patient seeking care at our institution. (**j**, **k**) AP and lateral postoperative radiographs status post T10 vertebral body resection, interbody cage placement and fusion T9–T11, and extension of posterior fusion and instrumentation to T3 (performed by the senior author). The patient remains on lifelong suppression antibiotics



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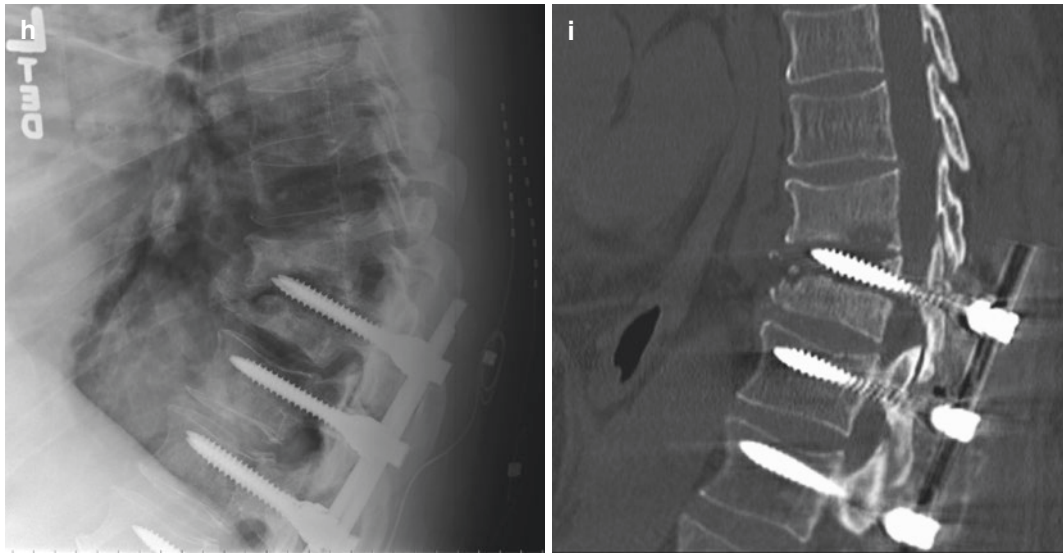

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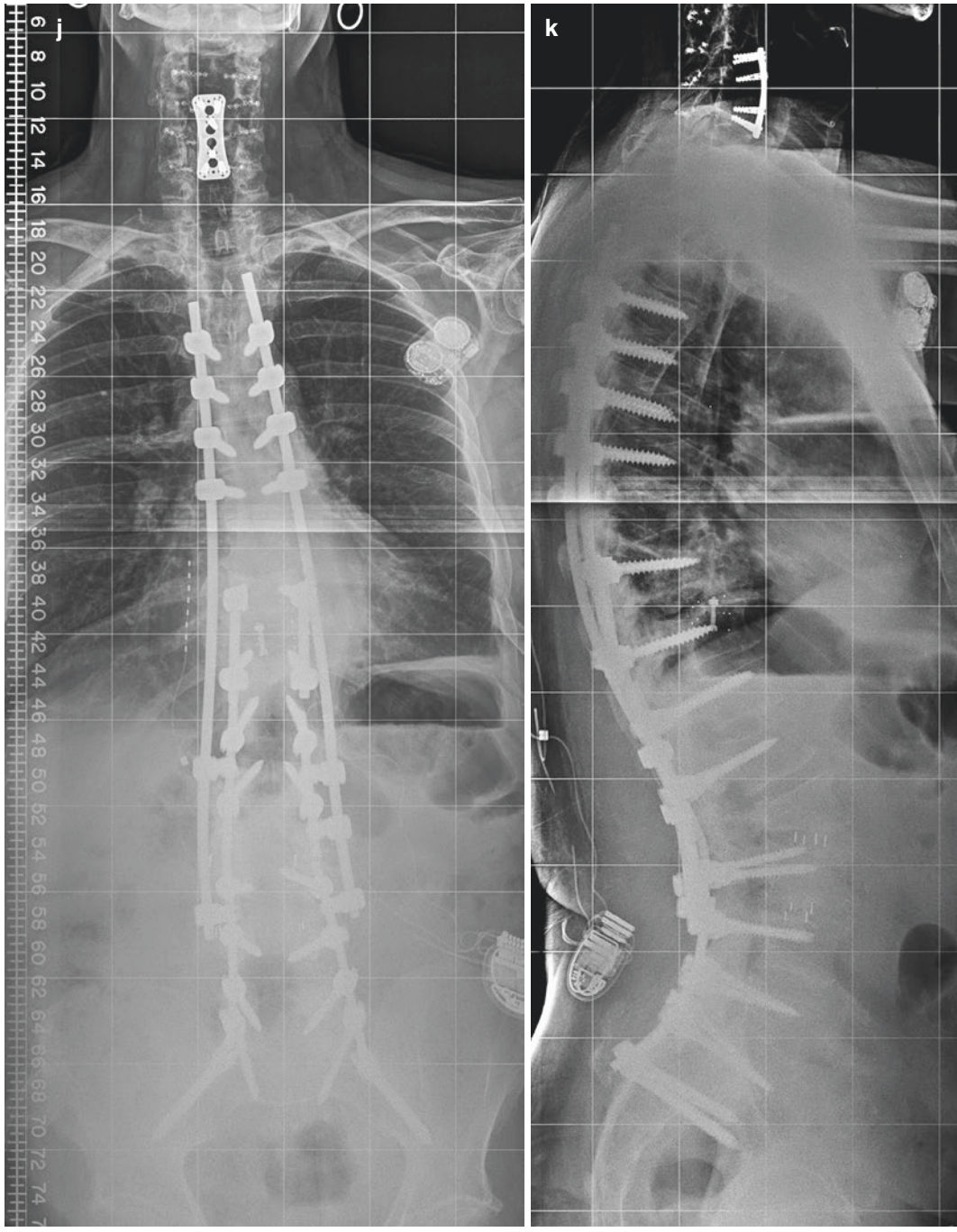

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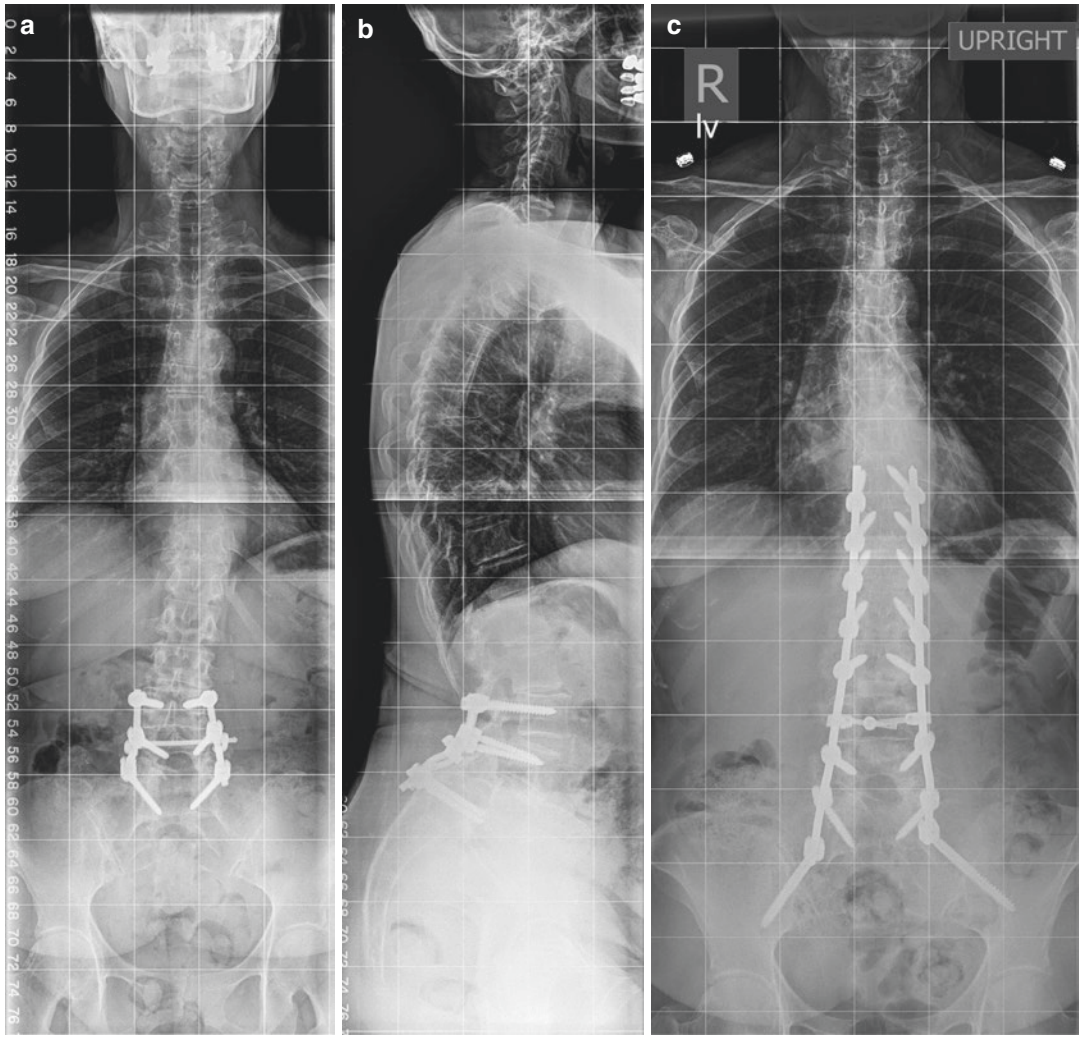
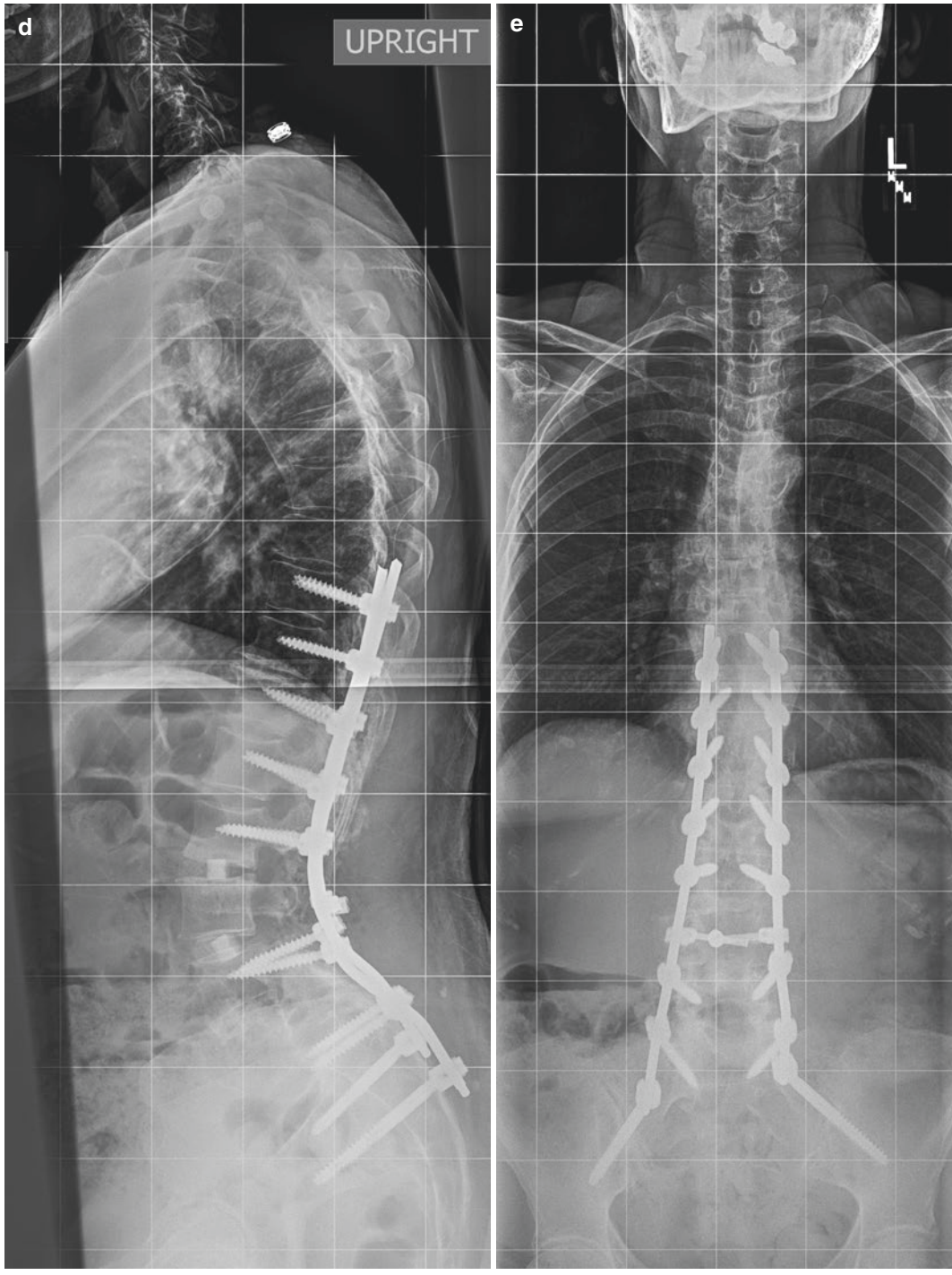


Fig. 17.5 Treatment of chronic PJF with associated adjacent segment degenerative disease and stenosis. (**a**, **b**) Preoperative AP and lateral radiographs demonstrating prior L3–S1 fusion for high-grade spondylolisthesis. Patient presents with symptoms and disability secondary to L3–4 nonunion and L2–3 stenosis secondary to adjacent segment degeneration. Preoperative PI–LL mismatch is within acceptable range (PI = 69°, LL = 60° kyphosis). (**c**, **d**) Immediate AP and lateral postoperative radiographs demonstrate revision surgery involving removal of hardware and T10 to pelvis fusion and instrumentation. Her PI–LL mismatch remains unchanged as intended (PI = 69° and LL = 62°). Because her PI is high, we took care to keep the LL less than the PI within the limits of the PI = LL ± 9° relationship. (**e**, **f**) Two-year follow-up imaging reveals proximal junctional failure with compression fracture of T9, kyphosis measuring about 30°. (**g**, **h**) MRI and CT imaging reveals stenosis at T8/9 and T9/10 and severe bony destruction of T9 vertebral body. The patient had severe back pain but no myelopathy. (**i**, **j**) Postoperative radiographs after revision surgery involving T9 vertebrectomy, partial T8 vertebrectomy, cage placement, and extension of fusion to T4 with quadruple rod construct



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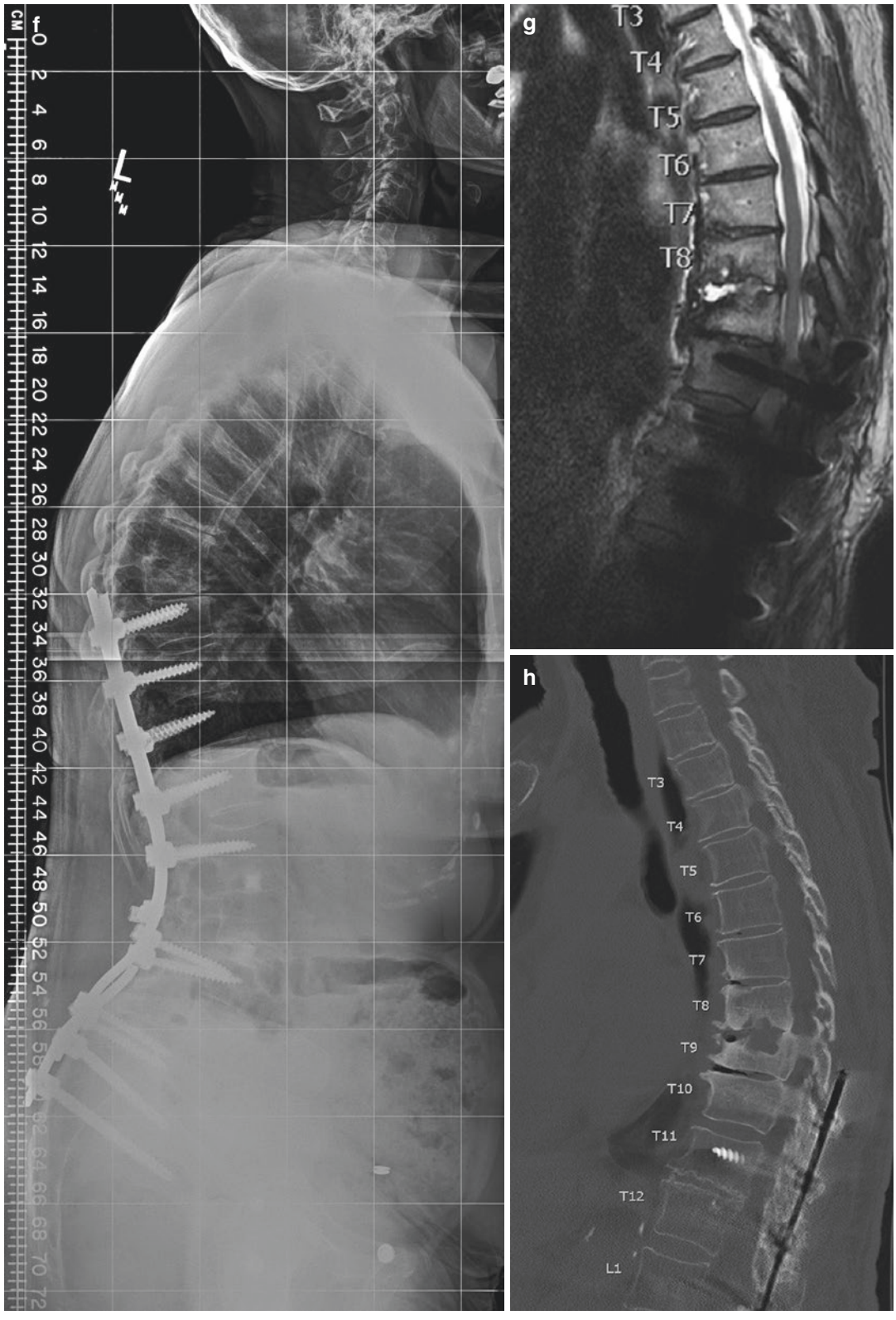

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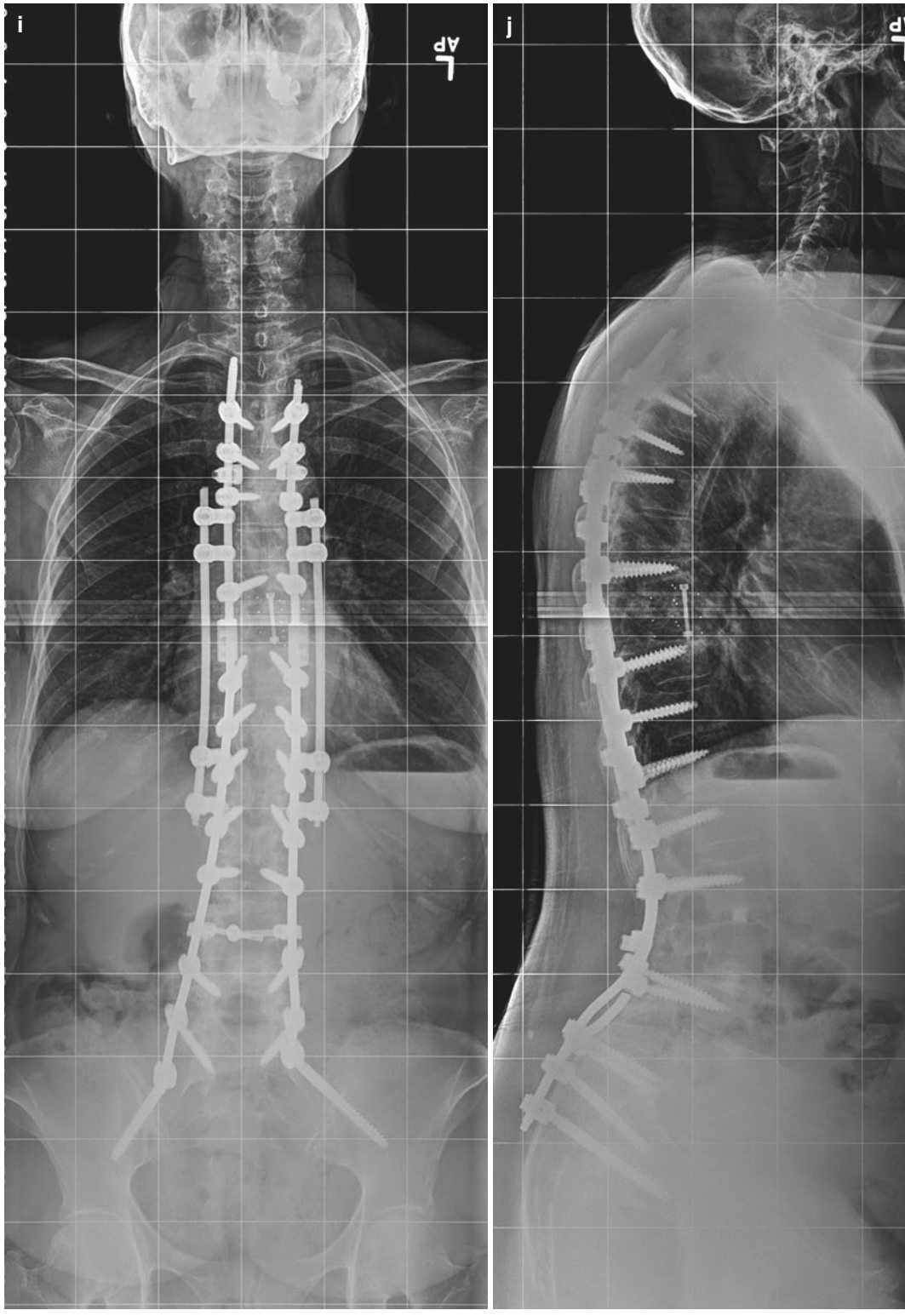

Fig. 17.5 (continued)

Conclusion

Advances in surgical techniques and technology have revolutionized the treatment of adult spinal deformity. The ability to perform aggressive global realignment of spinal deformities has also led to the discovery of new complications such as PJK and PJF. Spine surgeons are beginning to reach consensus on the definition, classification, and pathophysiology of these entities. The risk factors, means of prevention, and treatment strategies for this problem, however, remain incompletely described. While PJK is generally an asymptomatic radiographic diagnosis, PJF is a more serious condition on the adjacent segment pathology spectrum with significant clinical, psychosocial, and economic ramifications that often require revision surgery and proximal extension of the fusion construct. Continued research on PJK and PJF will be needed in order to reduce the incidence and impact of this challenging complication.

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Prevention Strategies for Proximal Junctional Kyphosis

18

Michael M. Safaee†, Taemin Oh†,
Ngoc-Lam M. Nguyen, Christopher Y. Kong,
Robert A. Hart, and Christopher P. Ames

Introduction

Proximal junctional kyphosis (PJK) is a well-recognized complication following posterior spinal instrumentation and fusion in patients undergoing surgery for adult spinal deformity (ASD). Broadly, PJK is defined as abnormal kyphosis within the vertebrae adjacent to the upper-instrumented vertebra (UIV) of the fusion. The degree of kyphosis is calculated as the sagittal Cobb angle between two lines: one subtended from the inferior end plate of the UIV and another subtended from the superior end plate of the vertebral body that is two levels above the UIV (UIV+2).

Within the literature, there is considerable debate regarding the specific parameters of this diagnosis. Studies range from diagnosing PJK purely based on radiographic findings, regardless of symptomatology, while others also include neurologic deficits, pain, and other quality-of-life impairments that warrant reoperation, a condition termed proximal junctional failure (PJF) [1, 2]. Nevertheless, literature consensus on radiographic diagnosis classifies PJK as an increase in kyphosis of 10–20° compared to the preoperative baseline [3, 4]. Importantly, radiographic diagnosis becomes particularly challenging when accounting for extensive operations (e.g., vertebral column resections), as reciprocal compensatory changes in non-instrumented segments are expected and can exaggerate the degree of thoracic kyphosis [5, 6].

Etiology

Overall PJK rates range between 17 and 39 % [3, 7–12], with most cases occurring relatively early in the postoperative period (two-thirds within the first 3 months, 80 % within first 18 months after surgery) [7, 13]. Causes of PJK are believed to be multifactorial: age-related degenerative disk disease, disruption of the posterior ligamentous complex (PLC), vertebral body fractures, instrumentation failure, and facet violation have all been cited as etiologies [1, 3, 14–16]. By extension, preoperative risk factors for developing PJK include patient age [10, 17–19] and worse preoperative sagittal malalignment [7, 8, 13, 20–23]. Operative risk factors include pedicle

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screw placement [4, 13, 21, 23], greater magnitude of curvature correction [13, 21, 23], disruption of posterior intervertebral elements [17, 18, 20, 21], and fusion instrumentation extending down to the lower lumbar vertebrae or the sacrum [7–9, 11, 13, 24]. The underlying pathology for PJF may be distinct from PJK, secondary to an acute event in the early postoperative period or chronic progressive deformity occurring over months to years. Hostin et al. found that fractures were the most common mechanism of failure (47 %) followed by soft tissue disruption (44 %); only 9 % of patients in the cohort experienced PJF secondary to trauma, with screw pullout accounting for an additional 9 % [25]. The authors also found that vertebral fractures were the more common mechanism of failure when the UIV terminated in the thoracolumbar region, while soft tissue disruption was more commonly responsible in the upper thoracic spine. Regardless of etiology, revision surgery for PJK and PJF causes significant hardship for patients and add tremendous cost to surgery, necessitating novel prevention strategies.

Prevention Strategies

Revision of ASD surgery is a costly endeavor, reported to add an estimated $100,000–170,000 per patient admission [26, 27]. Common causes include infection, persistent or worsening deformity, pseudarthrosis, and implant failure [28, 29]. PJK/PJF prevention can reduce costs associated with ASD and reduce the morbidity of the operation. Although there are few definitive strategies in the literature, both vertebroplasty [30, 31] and hook fixation [4, 21, 32] have been shown to reduce PJK rates. Other interventions that have been shown to reduce the risk of PJK include fusion of all segments with kyphosis greater than 5°, implementation of transition rods, soft tissue preservation at the UIV, application of composite metals that afford greater flexibility, and optimizing sagittal balance [3, 14, 20, 22, 33, 34]. Identifying patient-appropriate PJK prevention strategies will be an important area of research moving forward. Presently, soft tissue preservation near the UIV, appropriate selection of the UIV and spinopelvic parameter goals, terminal rod contouring, vertebroplasty, and ligament augmentation will play an important role in reducing rates of PJK/PJF.

Soft Tissue Preservation

Failure to respect the soft tissues around the UIV is considered a risk factor for PJK [34]. Preservation of the interspinous ligaments, supraspinous ligaments, and supra-adjacent facet and capsule are all believed to decrease the risk of PJK and PJF [14, 34]. Avoiding inadvertent exposure of adjacent levels is ideal; however, in the case of patients with multiple previous surgeries, even the most meticulous dissection and instrumentation techniques cannot always mitigate preexisting atrophic and degenerated soft tissues.

Terminal Rod Contouring

Persuading under-contoured rods into the top pedicle screws of a long fusion construct may predispose the patient to proximal junctional degeneration by introducing a pullout preload. We recommend careful and meticulous in situ contouring of the proximal rod such that they lay fully seated within the screw heads at the proximal two levels. This can be verified when locking caps are placed; ideally no additional force should be required to secure the rods into the screw heads.

Selection of the UIV and Hook Fixation

Proper selection of the UIV is important; however, no level is immune to PJK. Interestingly, the presence of thoracic hyperkyphosis has important implications for surgical planning as it is a well-known risk factor for the development of PJK and PJF [7, 8, 13, 20–23, 35–37]. Therefore, in patients with thoracic hyperkyphosis, extending

the fusion and instrumentation to the upper thoracic levels is considered desirable to minimize the risk of PJK/PJF and to achieve appropriate sagittal realignment. For constructs terminating in the upper thoracic spine, transverse process hook fixation has been used in an attempt to reduce rates of PJK, since failure at these levels is often caused by ligamentous fatigue. Spinal hooks reduce the amount of subperiosteal dissection required in surrounding muscle and facets, thereby resulting in less compromise of the facet joint, and also improve dynamic fixation at the top of the construct by reducing the stress transition to the UIV [4, 23, 38]. Several studies have reported less PJK in patients who receive hook fixation versus pedicle screws at the UIV, with rates of 0–30 % and 30–35 %, respectively [4, 23]. While there is more consistent data in the adolescent scoliosis literature demonstrating the beneficial effect of hook and hybrid instrumentation at the proximal construct in decreasing the risk of PJK [4, 21, 23], the evidence in the adult population is inconclusive at best. In their biomechanical investigation of six adult spine models, Cammarata and colleagues reported that the use of hooks and transition rods with reduced proximal diameter at the UIV was effective at reducing biomechanical effects thought to play important roles in the pathogenesis of PJK and PJF; however, there was limited clinical benefit [34]. The currently available clinical evidence is mixed; however, the reduced subperiosteal dissection and preservation of adjacent facet joints combined with compelling biomechanical rationale makes this a promising adjunct that will require additional investigation [3, 12, 18, 24, 32].

Spinopelvic Parameter Goals

Schwab and colleagues have demonstrated the importance of correcting underlying pelvic incidence (PI) and lumbar lordosis (LL) mismatch, with a goal of less than 10° difference (PI = LL ± 9) [39]. Restoring this PI–LL mismatch has since become a central tenet of adult deformity surgery. It should be noted that there are at least two circumstances in which the association between PI and LL deviates from this linear equation. Patients with extremely high PI (greater than 70°) require slightly less lumbar lordosis than the PI = LL ± 9° equation would suggest, while those with a low PI (less than 40°) require slightly more lumbar lordosis. The second situation where deviation from the typical PI–LL mismatch goals occurs, is in the elderly. The International Spine Study Group showed that spinopelvic parameters corresponding with HRQOL scores (e.g., PT, PI–LL mismatch, SVA) are substantially greater at baseline in the elderly; therefore, these authors advocate for incorporating consideration of the patient's age into the determination of optimal postoperative spinopelvic parameter alignment [40]. Adjusting for age-appropriate alignment goals and avoiding overly strict adherence to PI–LL relationship rules at the extremes of anatomic variability may reduce the risk of under- and overcorrection and subsequent development of PJK and PJF.

Vertebroplasty

The technical aspects of vertebroplasty involve decorticating the pedicles of the desired level and filling them with a thrombin-rich hemostatic matrix to occlude venous channels and minimize the risk of cement embolization. The vertebral body is then slowly injected with cement. This technique offers greatest benefit when applied to constructs terminating at the thoracolumbar junction, as fractures are often responsible for instrumentation failure at this level. When tested in biomechanical studies performed on cadaveric model, vertebroplasty has been shown to be successful. In a study by Kebaish et al., prophylactic vertebroplasty of the UIV/UIV+1 reduced rates of junctional fractures following long-segment instrumentation [30]. Kayanja et al. enhanced up to three vertebral bodies with cement, assessing their effects on the stiffness and strength of the final construct [41]. Their results showed that the integrity of the construct is contingent on bone mineral density, thus concluding that vertebroplasty should be performed on vertebral bodies with highest risk for fracture. In a clinical study,

Hart et al. reported that prophylactic vertebroplasty of the UIV and UIV +1 levels not only reduced the risk of PJF but was also cost-effective when compared to the cost of a revision procedure [31]. Nevertheless, there are certain limitations associated with vertebroplasty, as it not only can accelerate degenerative disk disease by restricting blood supply to the disks adjacent to the cemented vertebra [42] but also can increase the risk of fractures at adjacent levels by virtue of altering spinal load mechanics [43, 44].

Prophylactic Rib Fixation

Hart et al. introduced the concept of prophylactic rib fixation without fusion at the level of the UIV+1 [2, 45]. Early in the development of this technique, vertical expandable prosthetic titanium rib (VEPTR) hooks were inserted at the medial posterior portion of the UIV+1 ribs. Two separate longitudinal incisions (approximately 3 cm long) are made over the medial posterior portion of the UIV+1 ribs. The ribs are exposed in a subperiosteal manner circumferentially, with care taken to avoid inadvertent violation of the pleural cavity. The VEPTR hooks are then placed around the exposed ribs, which are then connected to titanium rods that are tunneled subcutaneously and connected to the midline rods bilaterally via connectors. The second iteration of this technique involved the use of sublaminar bands instead of VEPTR hooks. More recently, sublaminar hooks have been used in a manner similar to the VEPTR (Fig. 18.1). Preliminary analysis supports the efficacy of this technique in reducing the risk of PJF [46].

Ligament Augmentation

As disruption of the posterior ligamentous complex is thought to play an important role in the pathogenesis of PJK and PJF, technical measures aimed at reinforcing the posterior tension band may prove to be effective. The main objective of ligament augmentation is to provide additional support to the upper levels of theconstruct (i.e., UIV+1, UIV, and UIV-1), reduce junctional stress at those levels, and reinforce the ligamentous complex. An illustration of the technique is shown in Fig. 18.2, with clinical example in Fig. 18.3. Using a high speed bur, a hole is drilled through the center of the spinous processes at the UIV, UIV+1, and UIV-1. A sublaminar cable is passed through these holes in a mirrored fashion, pulled taut on each side, and then fixed to the rod to maintain the desired amount of tension. The facet joint is left intact without adding significantly to intraoperative blood loss or operative time. This technique effectively creates a tension band loop encompassing the involved levels and adds strength to the upper construct while also providing a smooth transition from rigid fused levels to the more mobile segments above.

Illustrative Cases

Case 1 A 67-year-old female with scoliosis presented at age 65 with severe low back and leg pain. She had a thoracic kyphosis of 97° and was taken to the operating room for C7 to pelvis instrumented fusion with T8 vertebral column resection. She tolerated the procedure well, but 6 months later developed neck pain, heaviness, and inability to lift her head. Imaging revealed proximal junctional kyphosis/failure at C7 with severe cervical sagittal deformity (Fig. 18.4a, b). She was taken back to the operating room for extension of fusion to C2 with a C7 pedicle subtraction osteotomy. She tolerated this procedure well with improvement in her deformity (Fig. 18.4c, d).

Case 2 A 58-year-old female presented after having undergone multiple prior spinal fusions including a T4–L4 posterior instrumented fusion. She was taken for T2-pelvis posterior instrumented fusion with L4–L5 and L5–S1 transforaminal interbody fusion. She presented 7 months later with severe back pain and inability to stand upright. Imaging revealed proximal junctional kyphosis (Fig. 18.5a, b). She was

taken back to the operating room for a T1-pelvis posterior instrumented fusion with T4 vertebral column resection and T1–T3 ligament augmentation. She tolerated this procedure well with most recent imaging showing intact spinal implants without failure or proximal junctional kyphosis.

Case 3 A 71-year-old female with scoliosis presented with debilitating back and leg pain. Preoperative imaging revealed a lumbar levoscoliosis, a pelvic incidence–lumbar lordosis mismatch of 30°, grade 1 spondylolisthesis at L5–S1, and 7.4 cm sagittal vertical axis (Fig. 18.6a, b). She was taken to the operating room for T10-pelvis posterior instrumented fusion with L1–S1 type one osteotomies along with T9–T10 vertebroplasty and T9–T11 ligament augmentation for proximal junctional kyphosis prevention. On last imaging at over 1 year after surgery, she was doing well with no evidence of proximal junctional kyphosis, fractures, or implant failure (Fig. 18.6c, d).

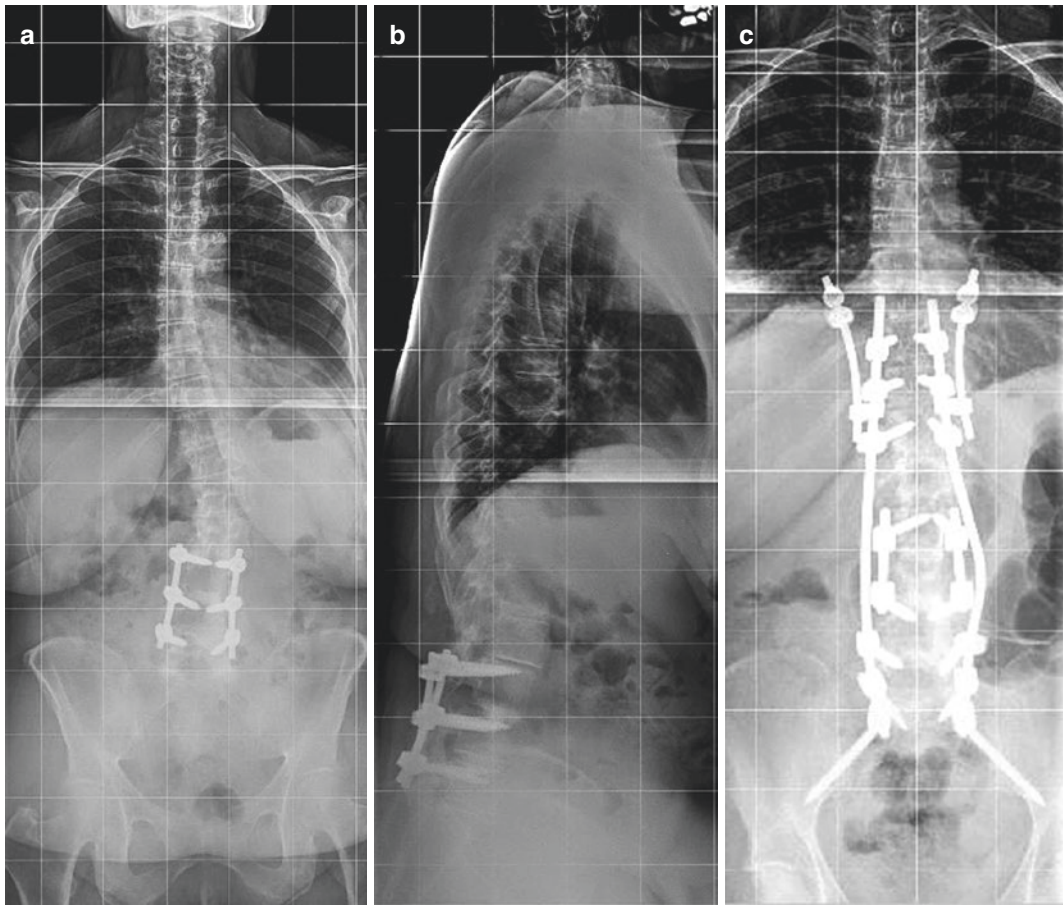
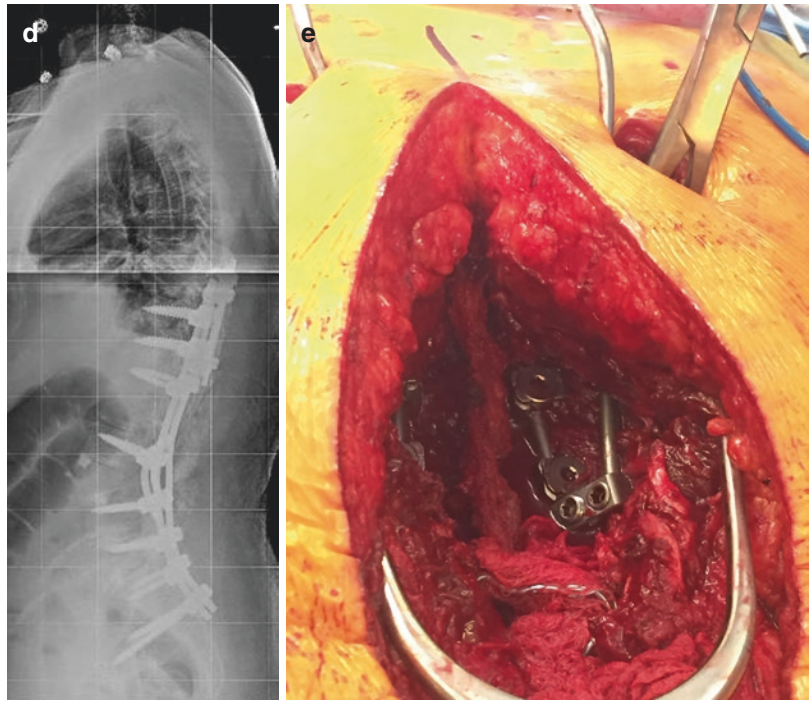


Fig. 18.1 PJK/PJF prophylaxis using rib fixation. (**a**, **b**) Preoperative AP and lateral radiographs demonstrating iatrogenic flat back deformity with global sagittal imbalance. Preoperative PI–LL mismatch measured 25° (PI = 50°, LL = 25°). (**c**, **d**) Postoperative AP and lateral views status post T10-pelvis fusion with L3 PSO and quadruple rod construct, illustrating the senior author's technique of using sublaminar hooks (DePuy Synthes Expedium 5.5 mm sublaminar hooks, J&J Inc.) encircled around the UIV +1 rib and connected to the midline rods via bilateral titanium rods and connectors. Her PI–LL mismatch became normalized postoperatively (PI = 50° and LL = 58°). (**e**) Intraoperative photograph illustrating the rib fixation construct

Fig. 18.1 (continued)



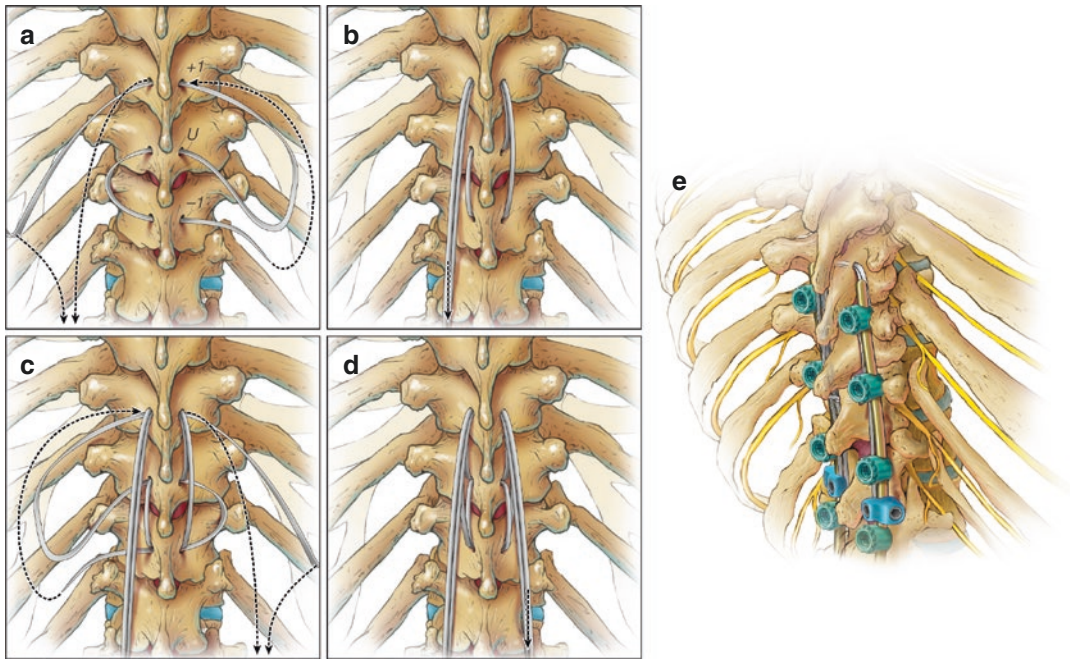


Fig. 18.2 Ligament augmentation. Using a matchstick burr, holes are drilled through the spinous processes of the UIV and the levels immediately above and below. A sublaminar cable is passed through each level in a stepwise fashion (**a**) then pulled to one side (**b**). The process is repeated with a second cable on the opposite side (**c**) then pulled down to obtain the desired amount of tension (**d**). The cables are then locked onto the rods on each side using supplied connectors (**e**)

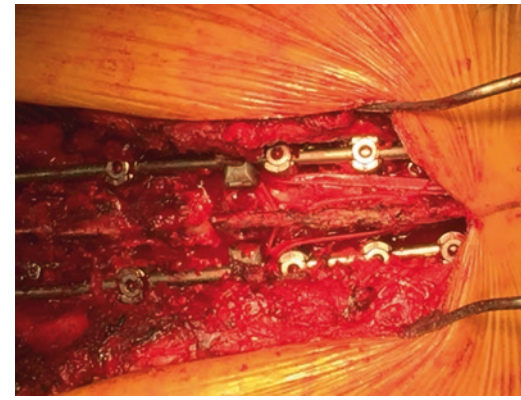


Fig. 18.3 PJK/PJF prophylaxis using spinous process augmentation. Intraoperative photography demonstrating the Zimmer Universal Clamps (Zimmer Biomet Holdings, Inc.) applied as spinous process fixation devices. Drilled holes are created at the spino-laminar junction of the UIV +1, UIV, and UIV −1 levels. The bands on the clamps are passed through the drilled holes in a weave fashion in opposite directions to create a tension band loop encompassing the involved vertebral levels. The bands are tensioned and the clamps are secured to each of the main rods, effectively creating a functional posterior tension band

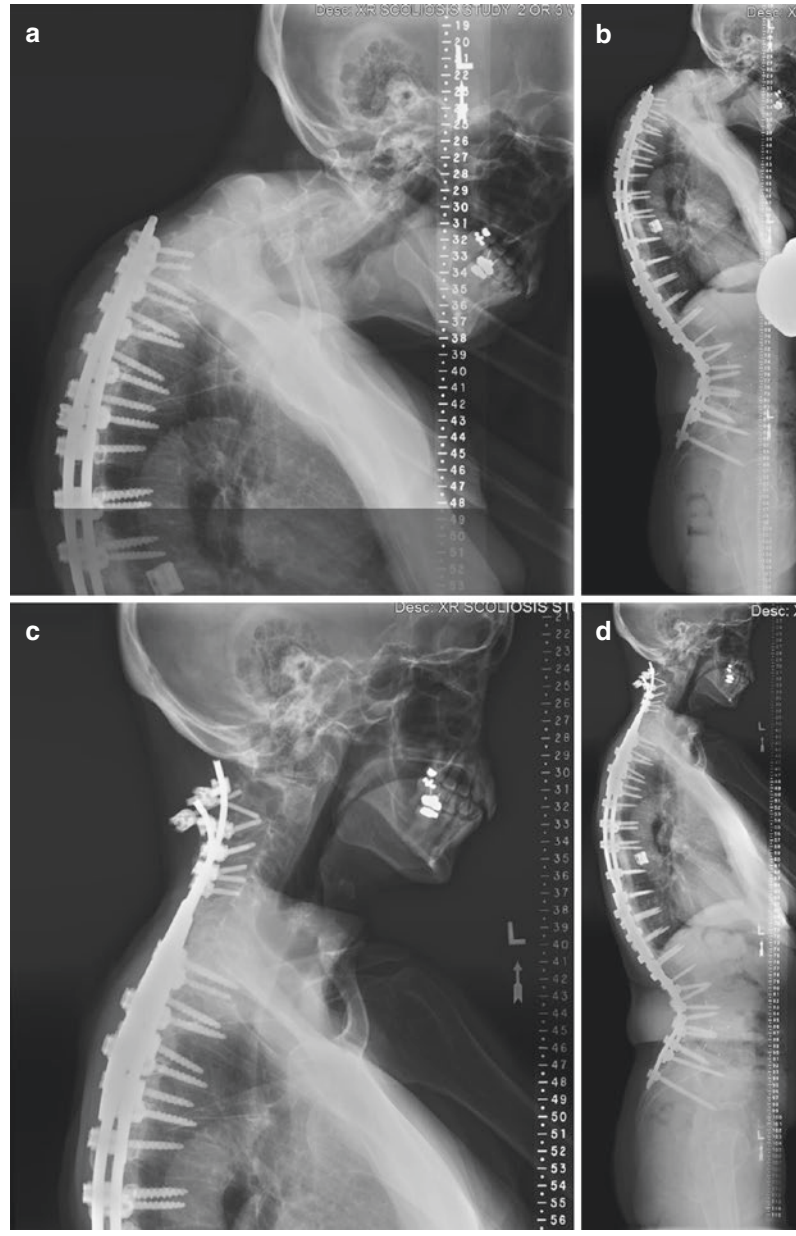


Fig. 18.4 Case 1 – proximal junctional kyphosis. Lateral cervical (**a**) and standing (**b**) X-rays showing proximal junctional kyphosis after prior C7-pelvis posterior instrumented fusion. The patient was taken to the operating room for extension of fusion to C2 with a C7 pedicle subtraction osteotomy resulting in resolution of her symptoms and improvement in her cervical deformity (**c**, **d**)

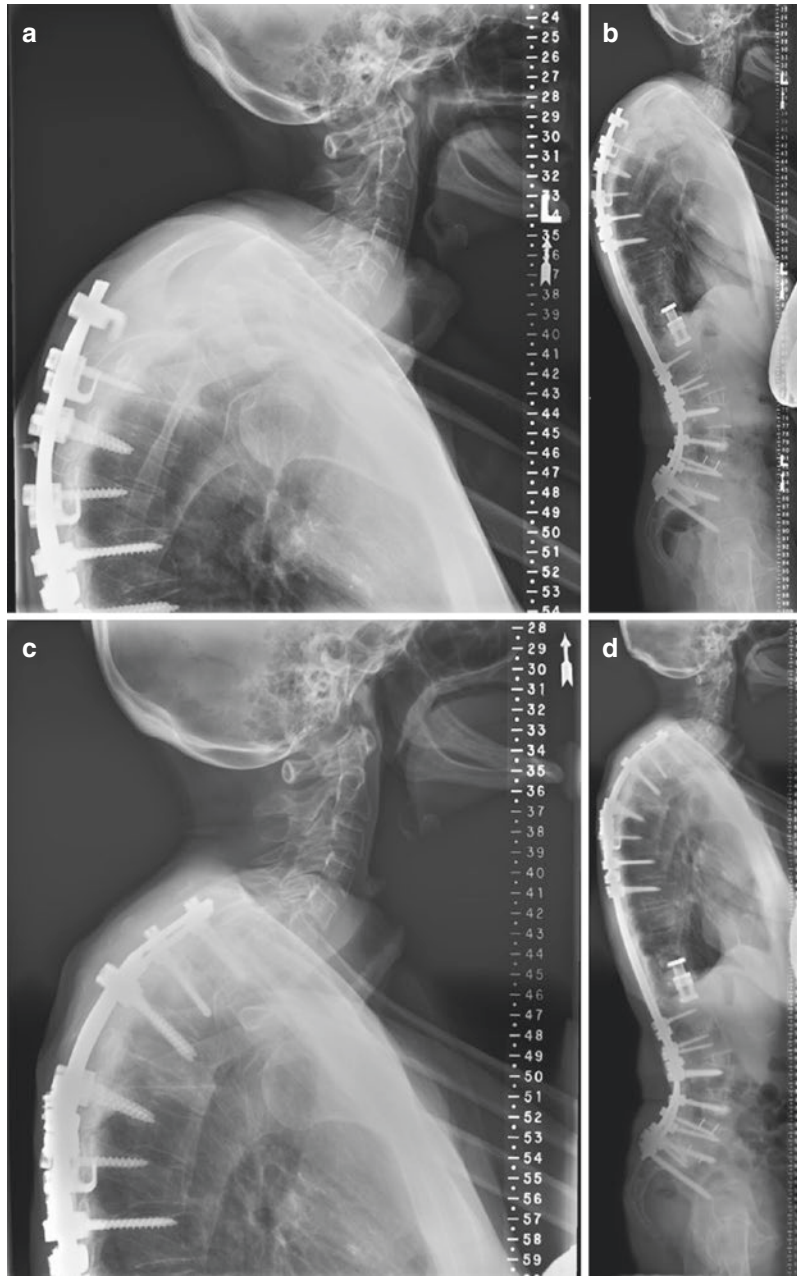


Fig. 18.5 Case 2 – proximal junctional kyphosis. Lateral cervical (**a**) and standing (**b**) X-rays showing proximal junctional kyphosis after a previous T2-pelvis posterior instrumented fusion. The patient developed proximal junctional kyphosis requiring extension of fusion to T1 with a T4 vertebral column resection and T1–T3 ligament augmentation. At last follow-up, her spinal implants were intact with improved cervical and sagittal alignment and resolution of her symptoms

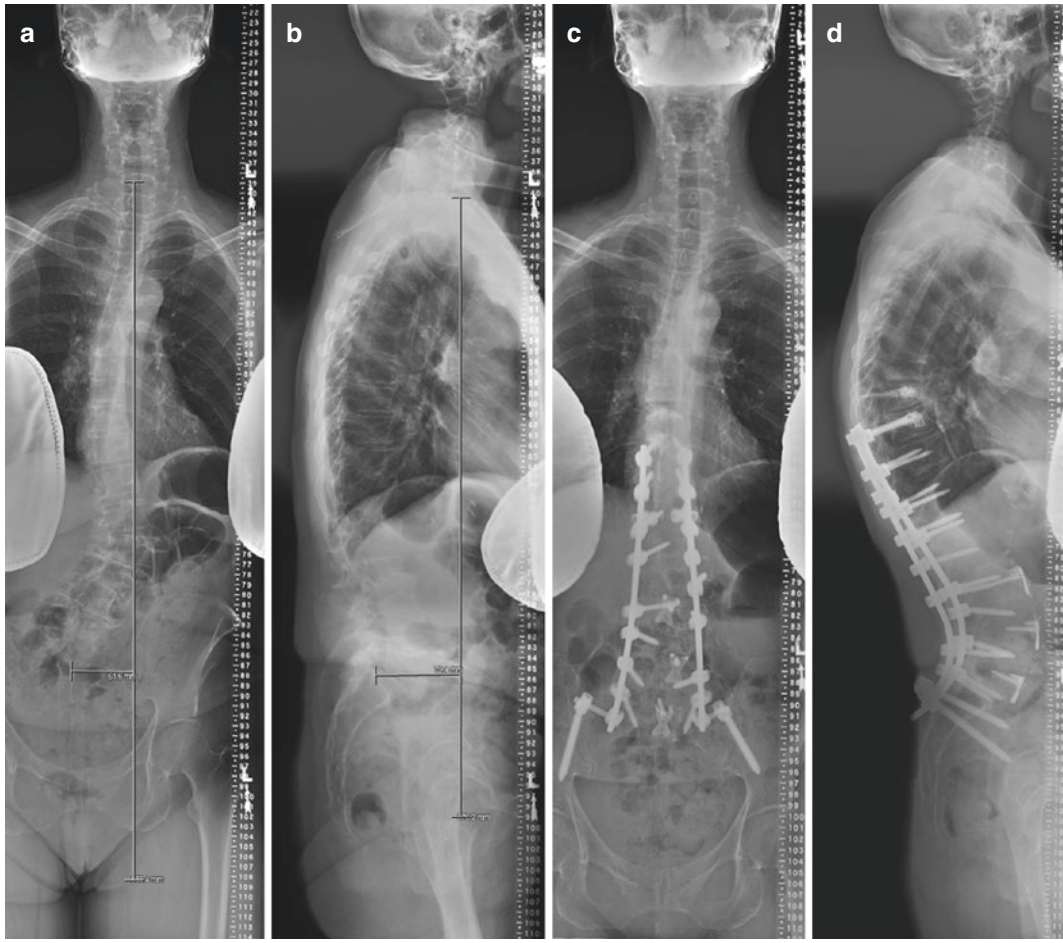


Fig. 18.6 Case 3 – proximal junctional kyphosis prevention strategies. A 71-year-old female with scoliosis presented with debilitating back and leg pain. Preoperative imaging revealed a 47° lumbar levoscoliosis, grade 1 spondylolisthesis at L5–S1, and 7.4 cm sagittal vertical axis (**a**, **b**). She was taken to the operating room for T10-pelvis posterior instrumented fusion with L1–S1 type one osteotomies and T9–T10 vertebroplasty and T9–T11 ligament augmentation for proximal junctional kyphosis prevention. On last imaging at over 1 year after surgery, she was doing well with no evidence of proximal junctional kyphosis, fractures, or implant failure (**c**, **d**)

Conclusion

PJK is a well-described complication following surgery for adult spinal deformity. Technical considerations in decreasing rates of PJK are critical to reducing the morbidity and cost associated with reoperations following initial deformity correction. Preservation of soft tissue above the fusion, terminal rod contouring, appropriate selection of the UIV, vertebroplasty, hook fixation, and ligament augmentation have the potential to reduce rates of PJK/PJF and should be considered in high-risk cases. Prospective studies are underway to further evaluate these strategies and their efficacy.

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19 Complications Following Surgical Intervention for Adult Lumbar Scoliosis

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Introduction

The surgical treatment of adult lumbar scoliosis is similar to any other surgery in that complications occur, and they can be challenging for both patient and surgeon. But what defines a complication? Is a dural tear that is primarily repaired and has no further consequence really a complication? Recent literature on this topic has divided surgical complications into categories and further subdivided these into major and minor complications. This chapter continues this organizational scheme and discusses both the types of complications and their potential impact.

Defining Complications

Rampersaud and colleagues [26] defined a complication as "a state, directly or indirectly resulting from a surgical operation that altered the anticipated recovery of the patient." Categorizing and grading complications is common in databases and outcome studies; however, standardized reporting has not been established. In the table below, complications are categorized and graded into major and minor derived from a consensus agreement of study group adult deformity surgeons (Table 19.1) [10, 40]. The grading reflects a combination of the impact on duration of stay and recovery, amount of additional treatment required, and whether there is prolonged or permanent morbidity. Any complications requiring reoperation were classified as major. Regardless of the category or grading, each complication may affect outcome measures in unique ways.

Incidence of Complications

Understanding the incidence of the various complications allows providers to make informed treatment decisions and provide appropriate counseling to patients. Numerous studies have reported the incidence of complications, but most are limited by retrospective data collection, limited cohorts, and limited focus on complications. Several groups have provided comprehensive meta-analyses to simplify the challenge of navigating the wide spectrum of data. However, retrospective studies have inherent bias.

The Scoliosis Research Society (SRS) has one of the largest databases of adult scoliosis patients. Importantly, the SRS database is a voluntary self-reporting database of complications by member surgeons and likely represents a lower-end estimate of the rates for most reported complications. In a review of 4,980 cases of surgically treated adult scoliosis submitted from 2004 to 2007, Sansur et al. found 10.5 % (521 of 4980) of adult patients undergoing scoliosis correction

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Table 19.1 Complications checklist for patients undergoing ASD surgery [10, 40]

Complications	Major	Minor
Infection	Deep	Superficial
	Pneumonia	Urinary tract infection
	Sepsis	*Clostridium difficile*
Implant	Hook dislodgement	Cross-link dislodgement
	Interbody fracture	Interbody subsidence
	Interbody migration	Painful implants
	Rod fracture	Prominence
	Rod dislodgement	Screw malposition
	Screw fracture	Screw-bone interface loosening
		Set screw dislodgement
Neurological	Bowel/bladder deficit	Delirium
	Brachial plexus injury	Neuropathy or sensory deficit
	Cerebrovascular accident/stroke	Pain (radiculopathy)
	Nerve root injury with weakness	Peripheral nerve palsy
	Retrograde ejaculation	
	Spinal cord injury with complete deficit	
	Spinal cord injury with incomplete deficit	
	Visual deficit/blindness	
Cardiopulmonary	Acute respiratory distress syndrome	Arrhythmia
	Cardiac arrest	Coagulopathy
	Congestive heart failure	Pleural effusion
	Deep vein thrombosis (DVT)	Pneumothorax
	Myocardial infarction	
	Pulmonary embolism	
	Reintubation	
	Respiratory arrest	
Gastrointestinal	Bleed requiring surgery	Bleed not requiring surgery
	Cholecystitis requiring surgery	Cholecystitis not requiring surgery
	Liver failure	Ileus
	Obstruction	Pancreatitis not requiring surgery
	Pancreatitis requiring surgery	
	Perforation	
	Superior mesenteric artery syndrome	
Radiographic	Distal/proximal junctional kyphosis requiring surgery	Distal/proximal junctional kyphosis not requiring surgery
	Pseudarthrosis	Sagittal imbalance
		Coronal imbalance
		Adjacent segment degeneration
		Curve decompensation
		Heterotopic ossification
		Adjacent segment degeneration
Renal	Acute renal failure requiring dialysis	Acute renal failure requiring medical intervention
Wound problems	Dehiscence requiring surgery	Hematoma/seroma not requiring surgery
	Hematoma/seroma with neurological deficit	Hemia
	Hematoma/seroma, no neurological deficit requiring surgery	Dehiscence not requiring surgery
	Incisional hernia	

Table 19.1 (continued)

Complications	Major	Minor
Operative	EBL>4 L	Dural tear
	Retained sponge/instrument	Fixation failure (hook/screw)
	Unintended extension of fusion	Implant failure
	Vascular injury	Pedicle fracture
	Visceral injury	Posterior element fracture
	Wrong surgical level	Vertebral body fracture
Vascular	Vascular injury	Coagulopathy
		Thrombophlebitis

surgery experienced at least one major perioperative complication and reported an overall mortality rate of 0.3 % [27]. The most common complications reported were durotomy (2.9 %), superficial or deep wound infection (2.4 %), implant complication (1.6 %), acute or delayed neurological deficits (1.5 %), epidural or wound hematoma (0.6 %), and deep vein thrombosis/pulmonary embolism (0.4 %) [27].

Sciubba et al. [30] conducted a comprehensive review of adult spinal deformity literature published since 2000 and extracted 11,692 patients from 93 publications (81 retrospective, 12 prospective). Not all patients in these studies were diagnosed with scoliosis as the deformities included adult degenerative, idiopathic, neuromuscular, congenital, traumatic, and infection-related (e.g., tuberculosis), ankylosing spondylitis, osteoporotic, and iatrogenic. The patient population averaged 53.3 years old with 2.1 L blood loss. Follow-up ranged from as low as 6 weeks with an average of 3.5 years. On average, 34.2 % of patients experienced a perioperative complication (18.5 % major and 15.7 % minor). Long-term complications occurred in 20.5 % of patients [30]. The overall complication rate depended on the type of osteotomy with the highest rate in three-column osteotomy (66 %), followed by "non-three-column osteotomy" (45 %), and with the highest subtype of three-column osteotomy being vertebral column resection (35 %). The most common perioperative complications included any infection (3.2 %), neurological deficit (3.1 %), need for further surgery (3.0 %), any respiratory complication (2.1 %), instrumentation/graft failure (1.3 %), and excessive bleeding (1.2 %). Dural tears occurred in 3 % of cases and transient neurological deficits in 1.5 % (Table 19.2). The most common long-term complications included pseudarthrosis (7.6 %), instrumentation/graft failure (3.3 %), proximal junction kyphosis (PJK) (2.9 %), adjacent segment degeneration (2.7 %), and symptomatic instrumentation (2.0 %) (Table 19.2). The aggregate instrumentation related and radiographic defined failure was 20.5% [30].

These rates of complications are likely underestimated due to the study variations, inconsistent length of follow-up, and not including complications from any subsequent reoperation. Smith and colleagues reported substantially higher complication rates as the result of a rigorous prospective study of 291 adult spinal deformity patients from 11 centers with a minimum of 2-year follow-up using standardized data collection with on-site coordinators [34]. Inclusion criteria included a minimum degree of deformity, and ultimately the group averaged 11.1 surgical levels, 7.1 h operative time, and 1.9 L of blood loss, and 64 % received an osteotomy. 82 (28.2 %) patients required one or more reoperations. 69.8 % of patients experienced at least one complication. 52.2 % of patients experienced at least one perioperative complication (125 major and 145 minor, mean 0.93 complications per patient). 42.6 % of patients experienced at least one complication after 6 weeks post-op (137 major, 62 minor, mean 0.68 complications per patient). 82 (28.2 %) patients required one or more reoperations, and resulting complications from that revision surgery were also included in the data [34].

Table 19.2 The incidence of major perioperative complications, minor perioperative complications and long-term complications following adult spinal deformity surgery

Major perioperative complication	*n* (%)
All major complications	1,379 (18.5)
Neurological deficit (not transient, not full recovery, resolved with reoperation, or classified as "major")	322 (3.1)
Unspecified requiring surgery	148 (3.0)
Wound infection requiring debridement and/or reoperation (especially deep)	232 (2.4)
Instrumentation/graft failure requiring revision (breakage, dislodgement, or resulting in inadequate correction)	62 (1.3)
Excessive bleeding	122 (1.2)
Unspecified pulmonary	43 (0.9)
Pulmonary embolism or thrombosis of major vessel	71 (0.7)
Respiratory distress syndrome/respiratory failure	28 (0.6)
Pneumonia/lung infection	27 (0.6)
Vascular injury (intraoperative)	22 (0.5)
Death	44 (0.4)
Epidural hematoma	39 (0.4)
Wound hematoma or seroma	38 (0.4)
Pleural effusion or pneumothorax (requiring intervention)	15 (0.3)
Reintubation	15 (0.3)
Stroke	15 (0.3)
Vertebral compression fracture	12 (0.2)
Sepsis	23 (0.2)
Myocardial infarction/cardiac arrest	22 (0.2)
Misplaced screw possibly causing nerve-related pain (requiring reoperation)	10 (0.2)
Congestive heart failure or unspecified cardiac	9 (0.2)
Compartment syndrome ± shock (abdominal or extremity)	7 (0.1)
Cardiorespiratory (non-pleural effusion)/systemic	6 (0.1)
Visual acuity change	12 (0.1)
Pedicle or laminar fracture (intraoperative)	4 (0.1)
Wound dehiscence requiring surgery	4 (0.1)
Fistula	3 (0.1)
Gastrointestinal complication (bleeding, ischemia, or other)	3 (0.1)
Line-related infection	3 (0.1)
Post-thoracotomy syndrome or other pain-related issues	3 (0.1)
Breakdown of L5–S1 disc (perioperative not long term)	2 (0.0)
Cerebral edema	2 (0.0)
Incision abdominal hernia (reoperation)	2 (0.0)
Painful rib remnant requiring excision	2 (0.0)
Renal failure	2 (0.0)
Ischemia in extremities	1 (0.0)
Massive fluid overload	1 (0.0)
Multiple-organ failure	1 (0.0)
Pancreatitis	1 (0.0)
Retroperitoneal hematoma	1 (0.0)

Minor perioperative complications [30]	*n* (%)
Minor complications	1,215 (15.7)
Unspecified or other	302 (3.1)
Dural tear	292 (3.0)
Ileus/gastrointestinal complication	101 (2.1)
Transient neurological deficit (foot drop, brachial plexopathy, peroneal nerve palsy, radiculopathy, cauda equina, partial spinal cord injury, etc.)	148 (1.5)
Wound infection (medical/interventional treatment) or superficial	99 (1.0)
Deep vein thrombosis	66 (0.7)
Urinary tract infection	32 (0.7)
Delirium	28 (0.6)
Cerebrospinal fluid leak	20 (0.4)
Arrhythmia or tachycardia	15 (0.3)
Unspecified or miscellaneous infection (e.g., yeast)	15 (0.3)
Pleural effusion	12 (0.3)
Pneumothorax	11 (0.2)
Pulmonary congestion	10 (0.2)
Hemothorax	7 (0.2)
Hypotension	7 (0.2)
Other intraoperations	7 (0.2)
Instrumentation failure (managed conservatively)	6 (0.1)
Unspecified pulmonary (resolved via simple measures)	6 (0.1)
Wound healing complications (nonsurgical)	6 (0.1)

Table 19.2 (continued)

Minor perioperative complications [30]	*n* (%)
Other iatrogenic damages	4 (0.1)
Pedicle infraction (intra)	4 (0.1)
Subluxation or translation at surgical site (intraoperative)	3 (0.1)
Fever of unknown origin	2 (0.0)
Hematoma, seroma, or bursa (no surgery)	2 (0.0)
Miscellaneous cutaneous complications	2 (0.0)
Retained drain	2 (0.0)
Reversible coagulopathy	2 (0.0)
Exacerbation of carpal tunnel requiring release	1 (0.0)
Revision (intraoperative)	1 (0.0)
Symptomatic gallstones	1 (0.0)
Thrombophlebitis	1 (0.0)
Long-term complications	***n* (%)**
All long-term complications	1,021 (20.5)
Pseudarthrosis	337 (7.6)
Instrumentation/graft failure (breakage, dislodgement, screw loosening, or resulting in sagittal/coronal decompensation)	295 (3.3)
Proximal junctional kyphosis, especially requiring extension	119 (2.9)
Adjacent segment degeneration	105 (2.7)
Symptomatic screws/skin impingement/prominent hardware/painful graft possibly requiring removal	80 (2.0)
Vertebral compression fracture	33 (0.8)
Late deep infection	18 (0.5)
Neurological deficit	8 (0.2)
Superficial wound infection or other wounds	7 (0.2)
Other fractures (e.g., sacral, pelvic)	5 (0.1)
Iliac stress fracture or sacroiliac joint degeneration	3 (0.1)
Unspecified revision	3 (0.1)
Disc herniation	3 (0.1)
Deep vein thrombosis	2 (0.1)
Death	1 (0.0)
Hearing loss	1 (0.0)
Pneumonia	1 (0.0)

Adapted from Sciubba et al. [30]

Analyzing Complications

Multiple methods of assessment for spine surgery complications result in highly inconsistent incidence data [9]. With the rapid development of outcome assessment standards in the management of spinal deformity, understanding the impact surgical complications have on outcomes will help to isolate risk factors and aid in risk management decisions. Reliable and consistent reporting of relevant complications is needed to maximize the knowledge ascertained from assessment standards [22]. Complications need to be assessed from both the patient's and the surgeon's perspective since even commonly reported complications can have little correlation with certain patient-reported outcomes [11]. Even patients who experience major perioperative complications still tend to have significant improvements in early clinical outcome measures, but when followed for 3–5 years, the complications correlated with significant impacts in ODI and SRS scores [36]. Multidimensional and longitudinal assessment methods are needed to understand how particular complications impact outcomes.

Surgical Complications

Early Complications

Neurological Injury

Spine surgery has the potential risk of neurological injury. Iatrogenic neurologic injury is among the most concerning complications of spine surgery. These injuries may lead to new radiculopathy, motor or sensory deficits, or paralysis and can occur intraoperatively or postoperatively. Mechanisms of injury include compression, traction, laceration, direct trauma, or vascular compromise.

In the ISSG multicenter prospective study [34], Smith and colleagues found 27.8 % of patients experienced a neurological complication, with 12.7 % of patients experiencing a

major complication. 7.2 % of all patients underwent a reoperation that was at least partially related to a neurological deficit. The most common were radiculopathy (8.9 %), motor deficit (4.8 %), sensory deficit (3.8 %), and nerve root deficit (2.7 %) [34].

In a retrospective review of 5,801 cases of surgically treated scoliosis from the SRS, 107 (1.84 %) developed new neurological deficits: 88 (1.52 %) nerve root deficits, 15 (0.26 %) spinal cord deficits, and 4 (0.07 %) cauda equina syndromes [12]. Complete recovery occurred in the majority of patients (data included pediatric scoliosis). 52.9 % of nerve root deficits recovered completely, with only 1.7 % without deficit recovery. 37.5 % of patients who developed cauda equina syndrome recovered completely, and 25 % showed no improvement. 57.3 % of patients with new spinal cord deficit had completely recovery, and 6.1 % failed to improve. Of the subgroups in this analysis, degenerative scoliosis was associated with the highest rate of new neurologic deficit (2.49 %), followed by idiopathic scoliosis (1.45 %) and neuromuscular scoliosis (1.03 %) [12]. Of all SRS cases reviewed, variables associated with increased frequency of new neurologic deficit included revision procedures, fusions, and use of implants.

The rotational components and superimposed degenerative disease can make instrumentation placement challenging for even experienced surgeons. Pedicles on the concave side tend to have significantly smaller diameters, as much as 25 % smaller [20]. With more extreme deformities, malpositioned screws and pedicle breaches occur more frequently [49]. Applying compression to realign the spine without aggressive foraminal decompression can also result in foraminal stenosis and potentially new symptoms. Rapid or overaggressive correction of curves may produce increased tension on neural elements. Insufficient arterial perfusion pressures (MAP < 60) may increase the risk of ischemic injury of already compressed or stretched neural elements, with potentially devastating results [23]. Special attention to evoked potentials during deformity correction is critical to identify and prevent neurologic injury. Slow, controlled corrective maneuvers with sufficient perfusion pressures allow tissue accommodation and may help to decrease the risks of new neurological deficits.

Durotomy

Unintended durotomy occurs in 1–4 % of patients treated for scoliosis in most studies, with an incidence of 2.2 % of degenerative scoliosis patients in the SRS registry [43]. In the ISSG multicenter prospective study [34], Smith and colleagues reported dural tears in 10.7 % of patients (31/291). Persistent cerebrospinal fluid (CSF) leaks, pseudomeningoceles, meningitis, headache, and intracranial/intraspinal hemorrhage can result from dural tears. Small CSF leaks can often be managed with a primary suture repair. Dural substitutes, fascial grafts, and a wide spectrum of glues and allografts are available to aid in the repair of more extensive injuries. The use of drains with a durotomy is highly dependent up on the individual case and surgeon preference. While some studies see no significant difference in incidences of dural tear between primary and revision procedures [8], the majority of studies suggest a significantly greater risk with revisions.

Surgical Site Infections

Infection is one of the leading causes of morbidity for many surgical procedures. It is responsible for up to 46 % of readmissions following de novo adult deformity operations [28] and 14.5 % of revision deformity cases [48]. Surgical site infections lengthen hospital stay by an average of 9.7 days and increase admission costs by $20,842 [4, 7]. The reported incidence of surgical site infections in instrumented spine operations is usually around 2–4 % [1, 4, 7]. Deep infections are those below the fascia, and superficial infections are supra-fascial, including the skin and subcutaneous tissue. In a review of 5,801 adult scoliosis operations from the SRS database, 1.1 % of patients developed superficial infections and 2.5 % developed deep infections (Table 19.3) [37]. A review of 108,419 spinal operations in the SRS database showed an increased risk of infection associated with implant use (28 % greater, 2.3 % vs. 1.8 %), spinal fusion (33 % greater,

Table 19.3 Rate of infection among patients with a primary diagnosis of scoliosis, stratified based on patient age and subtype of scoliosis [37]

Type of scoliosis	No. of cases	Superficial infection (%)	Deep infection (%)	Total infection (%)
Adult (>21 years) scoliosis	5801	66 (1.1)	146 (2.5)	212 (3.7)
Neuromuscular	292	8 (2.7)	18 (6.2)	26 (8.9)
Posttraumatic	30	0 (0.0)	2 (6.7)	2 (6.7)
Degenerative	2533	31 (1.2)	73 (2.9)	104 (4.1)
Congenital	137	1 (0.7)	4 (2.9)	5 (3.6)
Idiopathic	2488	23 (0.9)	46 (1.8)	69 (2.8)
Other	139	3 (2.2)	2 (1.4)	5 (3.6)
Not recorded	182	0 (0.0)	1 (0.5)	1 (0.5)

2.4 % vs. 1.8 %), and revision surgery (65 % greater, 3.3 % vs. 2.0 %) [37]. The surgeon-reported SRS database had a significantly lower infection rate when compared to the chart-abstracted American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database (1.21 % compared to 2.05 % in ACS-NSQIP, $p < 0.001$), and this significance remained when looking specifically at adult idiopathic scoliosis [42].

Gram-positive organisms are slightly more common than gram-negative (*S. aureus* 27 %, methicillin-resistant *S. aureus* 17 %, *S. epidermidis* 31 %, gram-negative 30 % [1]), although nearly half of spinal surgery site infections are polymicrobial [1, 25]. Surgical variables associated with surgical site infections include inadequate antibiotic dosing, longer operative time/number of levels, pelvic fixation, and blood transfusions [1, 25, 32, 48]. Potentially modifiable risk factors associated with increased rates of surgical site infectious include obesity (BMI > 30–35), smoking, diabetes/serum glucose, and MRSA colonization (Table 19.4) [4].

Vancomycin powder has been reported to be protective against superficial, deep, and staph infections [3, 5] with only rare case reports of anaphylaxis and sterile seromas [21, 47]. While there is some uncertainty about its utility, topical vancomycin powder is currently used by many surgeons in an attempt to reduce infectious complications.

The use of recombinant human bone morphogenetic protein-2 (rh-BMP2) has been associated with a higher rate of deep wound infections in combination with anterior/posterior thoracolumbar fusions (1.1 % vs. 0.2 %, $p < 0.001$); however, the same study showed no difference in the patients being treated for adult scoliosis (1.8 vs. 2.0 %, $p = 0.9$) [44]. The impact that rh-BMP2 has on infection is unclear.

Table 19.4 Modifiable risk factors associated with spinal SSI

Obesity BMI > 30	Smoking
Diabetes	Suboptimal antibiotic timing
Thoracolumbar surgical site	History of previous SSI
Greater operative blood loss	Razor shaving of hair
Longer surgical duration	Participation of >2 residents

Evidentiary table-modifiable risk factors [4]

Surgical site infections in scoliosis patients where stability is dependent upon instrumentation present unique challenges. If detected early and managed aggressively with debridement, infections can often be treated reliably (88.2–89.3 % [2, 33]) without the need for instrumentation removal.

Bleeding/Hematoma

In the ISSG multicenter prospective study [34], Smith and colleagues reported 8.9 % (26/29) of patients had an estimated blood loss of >4 L, which they defined as a major complication. The use of cell-saving devices and ensuring adequate preoperative blood availability help to minimize blood loss-related complications. Multiple groups have

investigated the effects of perioperative aspirin on blood loss and associated complications. Most studies do find a significant but small increase in perioperative blood loss with aspirin, but outcomes do not seem to be affected. Park et al. demonstrated that perioperative blood loss among two-level posterior lumbar fusions was significantly greater in patients currently taking aspirin (1297 ml, $p = 0.033$) or holding aspirin for 7 days (1298 ml, $p = 0.034$) compared to no aspirin (960 ml) [24]. However, there was no difference when the groups were not controlled for any other NSAID usage [24]. Given the irreversible mechanisms of aspirin, some effects may remain even after a week. Kang et al. compared patients not taking aspirin to those who stopped aspirin 7 days prior to surgery in a retrospective case study of 38 patients undergoing posterior lumbar instrumentation and fusion [14]. While there were no differences in patient outcomes or intraoperative blood loss, those patients holding aspirin for 7 days had significantly higher wound drain outputs (864 ml vs. 458 ml, $p < 0.001$) and transfusion requirements postoperatively (2.4 units vs. 1.6 units, $p = 0.030$) [14]. Looking specifically at patients with cardiac stents, Cuellar et al. found that perioperative aspirin resulted in no significant increase on perioperative blood loss, bleeding-related complications, length of stay, or readmission rate [6].

Late Complications

Implant-Related and Radiographic-Identified Complications

Implant-related complications (IRC) and radiographic-identified complications (RIC) are usually the most common cause of reoperation. In the ISSG multicenter prospective study [34], Smith and colleagues reported 24 % (71/291) of patients required reoperation, primarily due to RIC and/or IRC. With ever-expanding surgical techniques and implant designs, understanding potential complications is essential for both patient selection and safety. Implant-related complications include breakage, malposition, migration/dislodgement, and pain/prominence. Radiographic-defined complications included PJK, distal junctional kyphosis, pseudarthrosis, adjacent segment degeneration, sagittal malalignment, curve decompensation, heterotopic ossification, and vertebral fracture [41].

Table 19.5 Radiographic and implant-related complications from 246 patients [41]

Complication	*N*	%
Implant related		
Rod breakage	16	47
Prominence	5	14.70
Painful implant	4	11.70
Screw breakage	3	8.80
Screw loosening	2	5.90
Screw malposition	2	5.90
Implant dislodgement	2	5.90
Total	34	13.82
Radiographic		
Proximal junctional kyphosis	24	54.50
Pseudarthrosis	5	11.40
Adjacent segment disease	5	11.40
Distal junctional kyphosis	5	11.40
Sagittal malalignment	3	6.80
Implant fracture	2	4.60
Flat back	1	2.30
Total	45	18.29
Total (radiographic + implant-related)	79	31.7

In a review of adult spinal deformity patients with more than 20 degrees of scoliosis from the ISSG, Soroceanu et al. [41] reported that 32 % (78 of 246) of patients developed an implant or radiographic-identified complication, of which 53 % required reoperation (Table 19.5). Rod breakage and PJK accounted for more than half of the complications (40/79). When compared to patients without radiographic or implant-related complications, these patients had greater BMI, had more comorbidities, and were more likely to have had previous operations. Patients with radiographic-identified complications tended to have greater preoperative pelvic tilt (PT), greater mismatch between pelvic incidence and lumbar lordosis (PI-LL), and greater sagittal malalignment [41].

An ISSG prospective series of surgically treated deformity patients reported a 9.0 % (18/200) overall rate of rod fracture, with mean occurrence at 14.7 months postoperatively [38]. In the ISSG multicenter prospective study [34], Smith and colleagues reported 13.7 % (40/291)

Table 19.6 Rates of implant and radiographic complications in 291 adults surgically treated for spinal deformity with minimum 2-year follow-up [34]

Complication	Minor	Major	Required re-op
All implants n (%)	14 (4.8)	67 (23)	32 (11)
Rod breakage	0	40 (13.7)	15 (5.2)
Implant prominence	6 (2.1)	5 (1.7)	4 (1.4)
Painful implant	2 (0.7)	5 (1.7)	5 (1.7)
Screw breakage		6 (2.1)	1 (0.3)
Screw loosening	4 (1.4)	2 (0.7)	1 (0.3)
Interbody spacer dislodgement		3 (1)	1 (0.3)
Screw medial breach	1 (0.3)	1 (0.3)	1 (0.3)
Implant failure		1 (0.3)	1 (0.3)
Rod dislodgment		1 (0.3)	1 (0.3)
Screw dislodgement		1 (0.3)	1 (0.3)
Cross-link dislodgement	1 (0.3)		
Fixation failure		1 (0.3)	1 (0.3)
Hook dislodgement		1 (0.3)	
All radiographic n (%)	29 (10)	52 (17.9)	39 (13.4)
Proximal junctional kyphosis	18 (6.2)	21 (7.2)	18 (6.2)
Pseudarthrosis		15 (5.2)	10 (3.4)
Adjacent segment disease	6 (2.1)	4 (1.4)	2 (0.7)
Coronal imbalance	4 (1.4)	4 (1.4)	4 (1.4)
Sagittal imbalance	1 (0.3)	4 (1.4)	3 (1)
Distal junctional kyphosis		4 (1.4)	2 (0.7)

of patients developed a rod fracture by 2 years postoperative (Table 19.6). The highest rate of rod fracture was seen in patients undergoing pedicle subtraction osteotomy (PSO), with 22 % of patients exhibiting rod fracture versus 4.7 % in those without PSO (Fig. 19.1) [38]. Only 66 % (12 of 18) of the patients with rod fractures were symptomatic with new onset pain [38]. Significant risk factors included older age, greater BMI, history of previous spine surgery, PSO, greater baseline sagittal spinopelvic malalignment (SVA, PT, and PI-LL mismatch), and greater magnitude of sagittal spinopelvic malalignment correction with surgery (SVA and PI-LL mismatch) [38].

Increasing literature regarding implant-related complications and the desire to provide greater sagittal plan correction have led to renewed interest in methods of avoidance. The use of multiple-rod constructs across three-column osteotomy sites has been demonstrated to significantly reduce rates of implant failure and pseudoarthrosis [13]. Optimal deformity correction with advanced lumbosacral fixation and restoration of global sagittal alignment have been reported to significantly decrease revision rates and improve clinical outcomes [16]. The high incidence of reoperations for correction of radiographic and implant-related complications has led to the development of optimal radiographic alignment parameters and to aid with patient selection and counseling [15–18, 29, 39]. Numerous studies have reviewed risk factors associated with the development of PJK and pseudarthrosis. These risk factors include type of osteotomy, greater number of levels fused, fusion to the sacrum, thoracoplasty procedure, disruption of supporting ligaments, older age, higher BMI, and lower bone density. A comprehensive discussion of these topics can be found in Chaps. 3, 5, 9, 16, 17, 18, 19, and 22.

Medical Complications

Death

While rates of mortality are low, patient safety demands a careful understanding of factors associated with mortality. In the ISSG multicenter prospective study [34], Smith and colleagues reported two mortalities of 339 patients (5.9 per 1000) within 6 weeks of surgery. Mortality within 6 weeks of surgery occurred in 20 of 5801 adult scoliosis cases in the 2004–2007 SRS database,

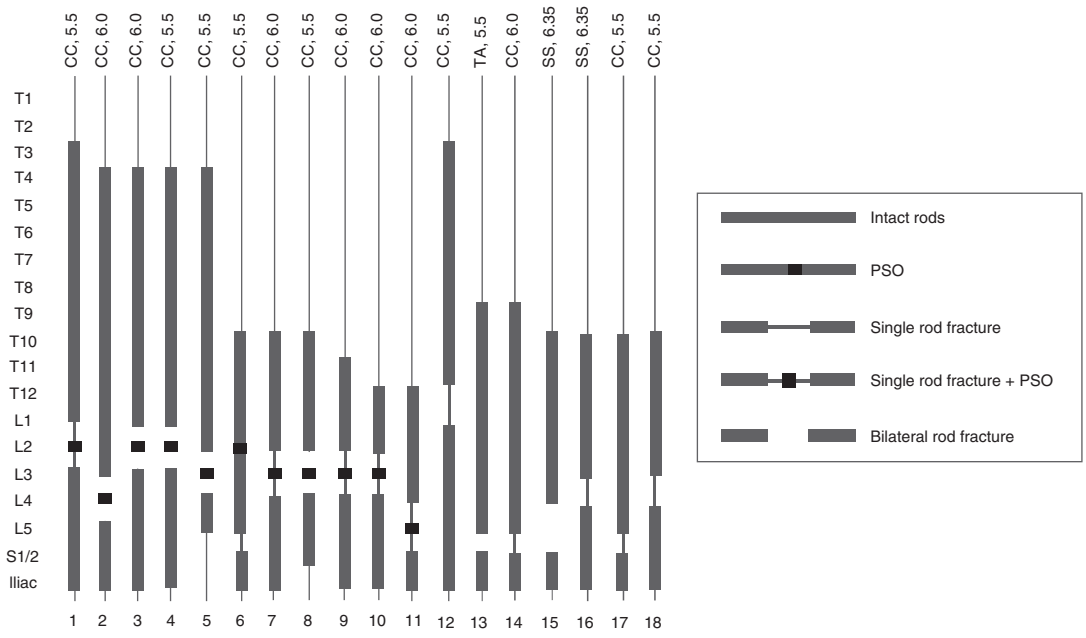

Fig. 19.1 Characteristics of instrumentation constructs developing rod fractures [38]

yielding an overall mortality rate of 3.5 per 1000 cases (2.0 per 1000 for all adult cases) (Table 19.7) [35]. Similar to rates in the data from 2009 to 2011, respiratory/pulmonary, cardiac, sepsis, stroke, and intraoperative blood loss represented the most common causes. Higher ASA scores and the use of implants or a fusion were also associated with higher mortality rates [31, 35].

Using the Nationwide Inpatient Sample (NIS) to review 11,982 adult scoliosis operations with greater than four levels fused, Worley et al. analyzed surgical factors and comorbidities associated with increased morbidity/mortality (Table 19.8) [46]. The overall mortality rate they reported was 28 per 1000 patients (0.28 %). A review of surgical factors found that revision status and greater number of levels fused were not associated with additional mortality risk, but age >65 had a significant increased risk (OR 3.49). Morbidity risk did increase in patients having greater than nine levels fused (OR 1.69) or revision surgery (OR 1.08) [46].

Cardiopulmonary

Cardiopulmonary complications are the source of the vast majority of mortalities related to adult scoliosis surgery. Cardiac complications are mainly due to myocardial infarction and heart failure. Appropriate preoperative assessment, identification of cardiac risk factors, and rapid identification and treatment of cardiac insults are essential. Myocardial infarction following noncardiac surgery is associated with a mortality rate as high as 70 % [45]. In a review by Sciubba et al. [30], 2.1 % of patients experienced a major pulmonary complication. Minimizing these risks begins at the first patient visit, working to control modifiable risk factors (smoking cessation, weight loss, rehabilitation programs, and appropriate pharmacologic and medical management). Continuing a low-dose perioperative aspirin may be warranted in some of these patients. A vigilant and experienced medical team will help to control these risks in the perioperative period.

GI

Ileus is not uncommon following surgery, but can become problematic when it lasts for an extended period. Standardized protocols will help minimize these complications and early mobilization is usually one of the most useful therapies.

Table 19.7 Reported causes of mortality stratified by primary diagnosis [31, 35]

	SRS 2004–2007		SRS 2009–20,011	
Reported causes of mortality	Scoliosis (26, 421)	All cases (107,996)	Scoliosis (50,553)	All cases (87,161)
Respiratory/pulmonary	18	83	24	48
Respiratory failure	6	23	6	13
PE		11	9	15
Presumed PE	2	9	3	8
Pneumonia	2	9	3	5
Aspiration	2	9	2	5
ARDS	2	3	1	2
Other/not specific	4	19		
Cardiac	8	41	19	32
Failure/not specific	4	8	9	12
Cardiac arrest	3	13	4	9
Myocardial infarction		16	6	11
Sepsis	7	35	7	12
Multisystem organ failure		3	4	9
Stroke	3	15	5	6
Blood loss	5	8	7	7
Other	4	6	5	13
Unknown	3	6	3	3
Total	48	197	74	130
Deaths per 1000 cases	1.82	1.82	1.46	1.5

Reported causes of mortality, stratified by primary diagnosis for cases collected on the basis of the new system (2009–2011) [31]

Table 19.8 Medical comorbidities as risk factors for mortality [46]

Comorbidity	Odds ratio	Lower – 95 % CI	Upper – 95 % CI	*p*-value
Liver disease	36.09	16.16	80.59	<0.0001
Pulmonary circulation disorders	8.94	4.43	18.03	<0.0001
Pathologic weight loss	7.28	4.36	12.14	<0.0001
CHF	5.67	3.3	9.73	<0.0001
Renal failure	5.51	2.57	11.82	<0.0001
Electrolyte imbalance	4.63	3.15	6.81	<0.0001
Coagulopathy	2.32	1.44	3.76	0.0006
Peripheral vascular disorders	1.76	0.68	4.53	0.24
Neurological disorders	1.24	0.63	2.46	0.539
Obesity	0.74	0.29	1.94	0.545
Chronic pulmonary disease	0.32	0.16	0.64	0.001
Diabetes, uncomplicated and complicated	0.25	0.09	0.67	0.006
Hypertension, uncomplicated and complicated	0.15	0.09	0.23	<0.0001
Anemia (deficiency)	0.11	0.04	0.28	<0.0001

Vascular

Deep vein thrombosis (DVT) and related pulmonary thromboembolism are unfortunately common and well-established risks of both morbidity and mortality. Low thresholds for assessing duplex ultrasounds can be beneficial as can standard preoperative screening in high-risk patients. The potential risks and benefits of perioperative TXA and amicar in relation to increased thromboembolism are discussed in Chap. 10.

Renal/Genitourinary

Urinary tract infections (UTIs) have been reported to be the most frequent postoperative medical complication of adult scoliosis surgery [27]. UTIs have potential to lead to bacteremia and sepsis. Early removal of Foley catheters can help to minimize the risk of developing UTIs, but must be carefully weighed against the benefits from accurate monitoring of urinary output to guide fluid replacement and mitigate hypovolemia and renal failure.

Acute renal failure can result from suboptimal management of prerenal failure secondary to hypoperfusion. Avoidance of perioperative administration of blood pressure medications which interfere with the renin-angiotensin pathway will significantly reduce these risks. Standardized nursing protocols to monitor urine output and watch for urinary retention are essential to minimize these complications.

Retrograde ejaculation can be found in up to 4 % of patients after spinal fusion and is mainly associated with anterior transperitoneal approaches to the lumbar spine, more so than with retroperitoneal approaches. Injury to the hypogastric plexus must be avoided during approaches to the lumbar spine. The plexus is located in front of the vessel bifurcation, close to the peritoneum. In transperitoneal approaches, the plexus is split directly under the peritoneum. Retroperitoneal approaches allow reflection of the peritoneum and therefore make injury less likely. The restrictive use of bipolar cauterization may also reduce this risk.

Impact of Complications

Correction of adult lumbar scoliosis and deformity utilizes a variety of complex and technically demanding procedures with high associated complication rates. With an aging population presenting with more challenging conditions, minimizing the complications is essential. Using the 2004–2007 Scoliosis Research Society database, Sansur et al. found only 10.5 % (521 of 4980) of adult patients undergoing scoliosis correction surgery experienced at least one complication [27]. However, complication rates as high as 95 % have been reported in patients over 70 years old [19]. Using the Adult Deformity Outcomes (ADO) multi-institutional database, Smith et al. demonstrated that despite a perioperative complication rate of 71 %, the elderly experienced a significantly greater benefit from spinal deformity surgery than the younger patients with only a 17 % perioperative complication rate (Figs. 19.2 and 19.3) [36].

Even patients who experience major perioperative complications still tend to have significant improvements in early clinical outcome measures.

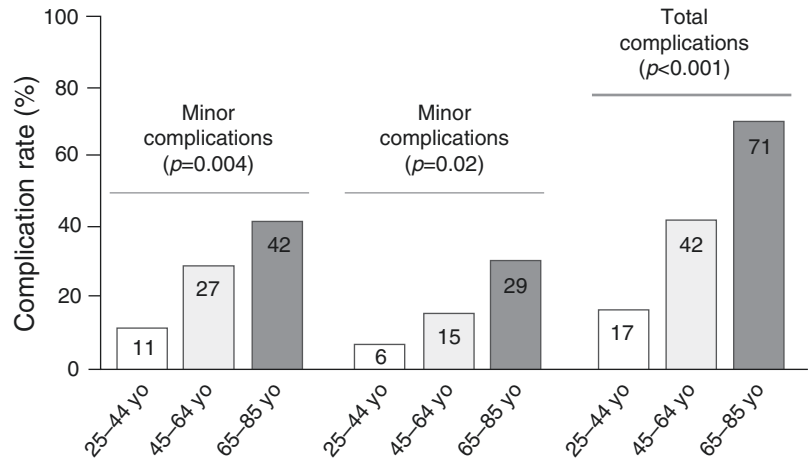

Fig. 19.2 Short-term complication rates with scoliosis undergoing surgery stratified by age from the Adult Deformity Outcomes (ADO) multi-institutional database [36]

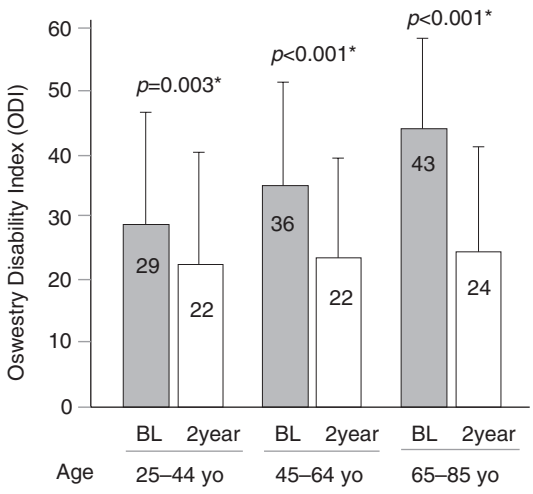

Fig. 19.3 "Relationship of patient age to improvement of disability in adults with scoliosis after surgical treatment. Bars indicate standard deviations. **p*-values are from paired t-tests. [36]"

Conclusion

With the rapid development of outcome assessment standards in the management of spinal deformity, understanding the impact surgical complications have on outcomes will help to isolate risk factors and aid in risk management decisions. Multidimensional and longitudinal assessment methods should be used to understand the true significance of these complications on surgical outcomes.

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20 Perioperative Patient Management of Adult Lumbar Scoliosis

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Introduction

Adult spinal deformity (ASD) surgery requires significant interventions as have been outlined in the previous chapters. With these larger surgeries, attention to detail and pre- and postsurgical planning are critical. The spinal surgeon must preemptively intervene to minimize the risks of commonly occurring complications. In this chapter we will try to delineate the interventions that are undertaken in the perioperative period that have been shown through literature or personal experience to minimize complications.

Medical Optimization

Healthier patient populations experience fewer medical complications in general and lower infection rates overall. There are individual medical risk factors that can be identified which are associated with higher infection rates. These include ASA grade $\geq$ 3, diabetes, smokers, COPD, renal insufficiency or failure, CHF, preoperative malnutrition with serum albumin <3, and preoperative history of wound infection. Once a risk factor is identified, corrective measures should be undertaken, including optimization of glucose control, smoking cessation, urinary tract sterilization and/or urologic consultation, optimization of nutritional status, and perioperative cardiology and pulmonology consultation when needed. Clearly, when the risk factors for medical complications exceed the risk of potential benefit from the intervention, surgery should not be offered, or postponed until the patient has been optimized. (Table 20.1 summarizes several postoperative complications and their prevalence among patients undergoing spine surgery who were registered in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database) [1].

In a study of approximately 3,500 patients undergoing spinal reconstructive surgery abstracted from the National Surgical Quality Improvement database, there was a nearly 8 % complication rate. This included an infection rate of 1 % (30 deep wound infections), a mortality rate of 0.3 % (10 deaths) and cardiac complications of 1 %. There were an additional 37 VTE with a 0.4 % rate of pulmonary embolism (PE). The rate of postoperative neurologic deficits reported is 0.1 % with 106 patients (3 %) requiring a return to the operating room. Clearly the rate of complications is significant, and both complication minimization and the informed consent process should be addressed with care [1]. Table 20.1 summarizes several risk factors and their influence mortality, one or more

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Table 20.1 Risk of postoperative complications [1]

Risk factor	# out of 3475 patients in the study (%)
Death	10 (0.3)
Deep wound infection	30 (1)
Cardiopulmonary complications	28 (1)
DVT	25 (0.7)
Pulmonary embolism	12 (0.4)
Cerebrovascular accident	3 (0.3)
Post-op neurologic deficit	5 (0.1)
Return to operating room	106 (3)

complications, and one or more major complications [1].

It is our protocol to obtain cardiac consultation in patients with significant prior cardiac history, including myocardial infarction or stent placement. If the suspicion is high enough for undiagnosed cardiac hypoperfusion, we will obtain a dobutamine stress echocardiography. Wall motion abnormalities and reversible ischemic defects can be identified, and when necessary cardiac revascularization via bypass grafting or stenting can be performed. Without a high index of suspicion, cardiac hypoperfusion may go undiagnosed until major spinal reconstruction surgery and demand ischemia may occur.

Surgical Site Infection Prevention

The surgical literature indicates that length of operation or operation requiring instrumentation of multiple vertebral levels is associated with an increased risk of postoperative infection [2]. Higher implant density is required with associated muscular dissection and longer retractor deployment with greater degree of tissue necrosis. However, even with less invasive surgical procedures, recolonization of the epidermis and wound occurs. Host flora begins to expand and multiply with locally occurring bacteria from a patient's dermal adnexa, e.g., oil glands, hair follicles, and sweat glands. These bacteria recolonize over time even in relatively simple operations. The skin preparation is able to eradicate bacteria for only a limited period of time. Some surgeons advocate for re-prepping the skin at different time points during the case. However, it is clear that recolonization should be assumed for any case that lasts greater than 4 h [3].

To minimize the risk for surgical site infection, we have instituted several treatment strategies at our institution. In our patient population, we determine if patients are carriers of methicillin-resistant *Staphylococcus aureus* (MRSA) by preoperative nasal culture surveillance. For patients who have MRSA-positive nasal cultures, we prescribe Bactroban (mupirocin) as literature has found a reduction in postoperative SSI in patients who are treated with appropriate topical nasal antimicrobial therapy [4].

In an effort to reduce bacterial skin colonization, we begin topical skin prep with chlorhexidine gluconate skin towelettes beginning 3 days prior to operation. Preoperative skin preparation is first alcohol, followed by either a chlorhexidine or Betadine skin prep. We then administer a broad-spectrum anti-staphylococcal intravenous antibiotic dose within 1 h of skin incision (cefazolin or clindamycin) and may combine this with vancomycin for high-risk patients or procedures. Our guidelines have been accomplished with the assistance of infectious diseases physicians based upon the high prevalence of MRSA present in our community. At the conclusion of the operation and prior to placement of bone graft, we irrigate our posterior spine wounds with 4 L of dilute Betadine containing solution (3 % weight/volume) and then irrigate until clear with normal saline. This diminishes the bacterial counts in wounds which have been open for longer periods of time. We subsequently add 1–2 g of vancomycin powder (depending on wound size) prior to closure. Using the aforementioned procedures, we have been able to reduce our SSI over 50 % [5].

Pain Management

Adequate pain control is paramount not only to patient experience and satisfaction but also to early post-op ambulation and rehabilitation. These factors are closely linked to reduction of

perioperative complications such as ileus, embolic events, and length of stay.

Efficacious pain protocols are variable among institutions; however, the need of standard protocols is paramount to delivering quality perioperative care to this patient population. Pain management is often complicated by long history of chronic pain and opiate dependence and necessitates individualized pain management regimes. The involvement of a proficient pain management team in the care of the most complicated patients is advised.

For chronic pain patients, an account of all analgesics being taken should be recorded and converted to IV morphine equivalents and noted in the preoperative assessment to facilitate intraoperative and postoperative pain requirements. Careful consideration should be given to patients with pain pumps. The type and dosage of the medication and the brand of the pump should be carefully noted. A pre-op CT scan should be considered to delineate the route of the catheter. Patients receiving opiates through their pumps need to be provided with equivalent preoperative medication dosing.

Surgeons must be particularly aware of the patients with intrathecal baclofen (ITB) pumps. Acute withdrawal of ITB may lead to a life-threatening syndrome of high fever, altered mental status, and profound muscular rigidity that may progress to fatal rhabdomyolysis. The definitive treatment for ITB withdrawal is the restoration of drug administration by the same route [6]. Surgeons must plan their surgical dissection by carefully studying the route of the catheter on pre-op CT scan to avoid severing the catheter and also plan of having catheter repair kits available in case it is damaged during the surgery. It is prudent to notify the device representative to be available if such issues arise.

Effective pain management protocols can be divided to the preoperative, intraoperative, and postoperative periods.

Preoperative

At our institution the following preoperative pain guidelines are used for patients undergoing large spinal deformity surgery. Preoperatively extended release opiates are used with attention to patient age: OxyContin 20 mg (<70yo), OxyContin 10 mg (70–80yo), and no OxyContin >80yo. Also gabapentin 900 mg oral liquid and IV tylenol 1000 mg are administered.

Gabapentin has been shown to be efficacious in reducing postoperative pain and narcotic requirements after spinal surgery, and in some studies there is evidence of up to 40 % reduction for additional postoperative pain treatment during the first 20 h [7, 8]. Also there is evidence for improved postoperative nausea and reduced incidence of vomiting/retching due to either the diminished need for postoperative opioids or due to the antiemetic effect of gabapentin itself. We continue gabapentin postoperatively at 300 mg QHS until the first postoperative visit.

Intraoperative

Ketamine

Acute pain management of patients with chronic pain who are opioid tolerant is often difficult.

In addition to traditional opioids such as fentanyl, remifentanil, sufentanil, Dilaudid, and morphine, ketamine should be considered as part of multimodal therapy for all patients with chronic pain who are undergoing spinal deformity surgery.

In a randomized controlled trial, intraoperative administration of ketamine reduced opioid consumption after spine surgery in patients with chronic pain who are opioid tolerant. The benefit of intraoperative ketamine did not have any apparent increase in side effects. Its mechanism of action is likely due to a combination of a reduction in central sensitization via NMDA receptor antagonism. Also ketamine has not been shown to have any deleterious effects on motor- or sensory-evoked potentials. Most protocols recommend ketamine 0.5 mg/kg as a bolus and then beginning a constant infusion at 0.1 mg/kg/h [8, 9].

Methadone

Recent studies have demonstrated efficacy in the perioperative administration of a single bolus of methadone before surgical incision. This resulted in a significant reduction of pain scores and

reduced requirement of opioids in patients presenting for multilevel complex spine surgery. These patients continue to experience pain postoperatively, and the addition of a long-acting opioid such as methadone has been suggested as a safe alternative to a continuous infusion of short-acting opiates. Gottschalk et al. suggest that methadone (working as a combined opiate receptor agonist/N-methyl-D-aspartate receptor antagonist) may be an optimal drug for these patients given the probable involvement of N-methyl-D-aspartate systems in the mechanism of opioid tolerance and hyperalgesia. The dose and timing for this protocol would include administration of IV methadone (up to 0.2 mg/kg) following induction in opioid-tolerant patients [10].

Local Anesthetic Catheter

An additional modality includes intraoperative placement of local anesthetic delivering catheter, such as On-Q® PainBuster® (I-Flow Corp., Lake Forest, CA). Long-acting anesthetics such as ropivacaine can be delivered at a controlled and adjustable rate and have been used with some success [11, 12].

Postoperative

Postoperative regimes include a combination of oral and parenteral opiates including PCA or nurse-controlled IV analgesia with conjunction of benzodiazepines to treat muscle spasms.

Postoperative pain medications are adjusted individually for opiate-tolerant patients and are usually done by calculating patients' average opiate usage and prescribing the baseline dose in addition to our pain protocol. For example, a patient known to take an average of 40 mg of oxycodone will receive that amount in and extended release tablet in addition to their post-op pain medications.

Immediately after surgery patients are considered for patient-controlled analgesic (PCA) pump administering hydromorphone. Patients unable to use the pump are prescribed nurse-administered IV injections of hydromorphone in Q2–3 h increments based on their weight, age, and opiate naivety (see Table 20.2).

Spasmolytic medications are prescribed regularly and are very effective in controlling for muscle spasms. Consideration to the risks of respiratory depression when any of these medications are given in combination with opioids. Several options include baclofen 5–10 mg po TID prn for patients tolerating oral medications and tizanidine 2–4 mg po q 8–12 h. An IV alternative may be diazepam 1–2 mg IV TID prn muscle spasm [13].

NSAID use following spinal fusion has been discouraged in the adult population due to concerns regarding postoperative bleeding and pseudarthrosis. A retrospective study by Glassman in 1998 for adult patients found that NSAIDs have an adverse effect on fusion, with increase in nonunions for those that received IV ketorolac [14].

It is worth mentioning that several studies have demonstrated the efficacy and low risk of complications associated with IV NSAIDS following pediatric spine fusion [15]. Due to inconclusive evidence in the adult population, the

Table 20.2 Postoperative pain, diet, and VTE prophylaxis that can be considered for ASD patients (many of which are part of the ASD postoperative care protocol at our institution)

Pain	Diet/bowel	VTE Prophylaxis
Oxycodone 5 mg–15 mg q3h	Sips and ice chips to start	Sequential compressive devices (calf/ calf+foot)
OxyContin 10 mg × 4 doses	Chewing gum	Lovenox 40 mg 48 h post-op
Acetaminophen 1000 mg q6h	Clear liquid after flatus	Asa 81 mg qday × 3 weeks after discharge
Gabapentin 300 mg QHS	Docusate 100 mg BID	For those going on flight within 2 months or going to SNF: Lovenox 40 mg 2 weeks post-op followed by asa 325 mg qday for 4 weeks
	As needed: Senokot, Dulcolax; milk of mag	

authors recommend that NSAIDs be avoided in the early postoperative period, especially high-dose NSAIDs [16].

Bracing

There is scant evidence and clinical trials regarding postoperative brace use. Although many deformity surgeons brace their patients postoperatively, there is variability regarding the most appropriate type, duration, and indications for immobilization. With adult deformity reconstruction, the high rates of proximal junctional kyphosis (PJK) and proximal junctional failure (PJF) are significant concerns, and many surgeons attempt to protect their patients with postoperative orthosis. However, no evidence exists to support bracing influencing the incidence of PJK or PJF. Further prospective, clinical studies may play role in evaluating the efficacy of postoperative bracing protocols.

Other hypothesized benefits of bracing and immobilization include protection of surgical construct and enhancement of arthrodesis rate, better pain control, and improved wound healing. Many surgeons also recognize the psychological effects of bracing and commonly warrant postoperative bracing as they may function to "slow down" patients and remind them to avoid certain activities which may compromise their clinical outcomes [17].

At our institution, adult deformity patients receive off-the-shelf TLSO brace. Several surgeons also have advocated the use of a cervical orthosis after thoracolumbar fusions in order to prevent kyphotic posturing at the cervicothoracic junction.

Disposition

Patients undergoing major spine surgery (defined as ≥6 levels of fusion, ≥6 h case duration, and/or >2 l EBL) are frequently observed in the ICU in the immediate post-op period, and few require longer than 24 h of ICU stays. Length of ICU stay is influenced by many factors such as patient age, medical comorbidities, operative time, surgical approach, and blood loss.

Major spine surgery requires prolonged prone positioning and large fluid shifts which can lead to postoperative airway edema. The first consideration for ICU care is the safe and timely evaluation of the patient for extubation by the anesthesia team. This is influenced by case duration, blood loss, fluid and blood requirements, and body habitus. The use of opioids also affects respiratory drive and can be a barrier to extubation. We rarely keep patients intubated in the postoperative period, but patients may be observed overnight in the intensive care unit with strict control of hematocrit and coagulation factors.

Close hemodynamic monitoring after large fluid shifts requires cardiac monitoring and urine output. Additional laboratory values including lactate, base deficit, and hematocrit allow the surgeon to access post-op resuscitation. This is best achieved on a hospital unit that has experience and is well equipped to care for these complex patients. The majority of patients can be transferred to a general floor on postoperative day one. They are mobilized with physical therapy as soon as possible, usually by day one or two.

When the patient is discharged to the ICU, a handoff between both the surgical team and anesthesia team to the ICU team is critical. On the first post-op day, patients should be accessed for complications inherent to high-risk spine surgery including [18]:

- Stroke (mental status exam and gross neurologic exam)
- Ophthalmic complications (ocular exam including relative afferent pupillary defect "Marcus–Gunn pupil" and visual acuity for monitoring for optic neuritis) [19]
- Skin complications (skin exam of the chin, forehead, chest, knees, and feet (checked for pressure ulcers due to prolonged prone positioning))
- Compartment syndrome (abdominal and extremity exam for tension and pain out of proportion)
- Epidural hematoma (elevated pain and neurologic decline)

Follow-Up

The relationship between spine surgeons and their complex deformity patients is an enduring one, and close early follow-up and regular long-term follow-up are essential. Clinical and radiographic assessment and tracking of patient-reported outcome scores are critical in caring for the individual patient's needs and to improve care of adult deformity patient population in general.

At our institution full-length standing radiographs are obtained and reviewed prior to patient discharge. Patients are scheduled for clinical follow-up at 4–6 weeks, 3 months, 6 months, and then 1, 2, 3, and 5 years postoperative. The surgical incision is cleaned and inspected at first postoperative visit, and the brace is removed by the 3-month visit. Having a high suspicion for late complications is prudent, and close attention to new onset of pain and/or constitutional symptoms should alert the physician. Pseudarthrosis with rod breakage is a common late complication, especially after complex osteotomies [20]. Early and late complications including infection, PJK, PJF and pseudarthrosis are discussed in detail in subsequent chapters.

Late Complications

Venous thromboembolism (VTE) is a complication that repeatedly presents in patients after major surgery. VTE is a collective term that includes two conditions: deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT is an embolism that forms in deep veins and generally localizes to legs. PE is a migrating embolism that can obstruct blood vessels in the lungs to cause cardiorespiratory problems and even death.

Historically the triad of venous stasis, activation of coagulation, and endothelial damage have been cited as the actuating factors. Current research has identified many various risk factors such as age, sex, race, type of operative procedure, obesity, and tobacco consumption as risk factors of developing VTE. It is important to identify these factors to better risk stratify our patients and implement proper treatment algorithms [21, 22].

Table 20.3 Risk of VTE after individual or combined primary methods of prophylaxis [23]

Intervention	Incidence of VTE (%)
Compression stockings (CS)	2.7
Pneumatic sequential compression device (PSCD)	4.6
Combined CS and PSCD	1.3
Chemical anticoagulants	0.6
Chemical anticoagulants	0.6
Inferior vena cava filters	22

In patients undergoing spinal surgery, a systematic review of the literature and analysis of pooled data by Glotzbecker et al. concluded the incidence of DVT after spinal surgery was 2.1 %. The rate was affected further by different prophylaxis as demonstrated in the table below:

The incidence of symptomatic thromboembolism after various spinal surgeries was reported in a large study by Platzer et al. demonstrating a 2.2 % incidence of symptomatic thromboembolic events with a mean period of diagnosis of 17 days. Thromboembolic complications were more common in surgical procedures of the lumbar spine and those that used an anterior spinal approach [22].

At our institution all patients undergoing spine surgery receive pneumatic sequential compression device (PSCD) postoperatively, considering the low risk and some evidence in effectively reducing the incidence of DVT and PE in patients undergoing orthopedic procedures including spinal surgery [24] (Table 20.3 summarizes the risk of VTE after several methods of prophylaxis).

Chemoprophylaxis

Routine chemoprophylaxis for thromboembolic events is not used at many institutions for elective spinal surgery; however, it is more widely recommended in high-risk patients after major spine surgery and particularly in patients with combined anterior/posterior approach.

There is variability in surgeons' practices regarding chemoprophylaxis in high-risk spine surgery patients. The lack of clear scientific evidence concerning the risk for symptomatic epidural hematoma, PE, and DVT and the efficacy and safety of specific chemoprophylactic protocols after spine surgery is a major driving factor.

A survey of close to 100 spine surgeons by Glotzbecker et al. regarding chemoprophylaxis revealed most responders reported that a safe time point to start chemoprophylaxis was 48 h after surgery. However, there was great variability with some indicated they would start chemoprophylaxis before surgery, whereas others responded they would never use it. Also 63 % stated that they based this decision on personal experience over evidence-based review of the literature. A majority of surgeons (58 %) selected low-molecular-weight heparin (LMWH) as their agent of choice. Respondents most commonly felt that the risk of clinically relevant postoperative epidural hematoma was between 1 and 5 %; and 29 % felt the risk was less than 1 % [25].

At our institution chemoprophylaxis for adult spine deformity patients is used routinely after risk stratification of their individual risk factors. Patients undergoing anterior/posterior approach and patients with a history of VTE are at elevated risk and are started on chemical proprophylaxis at 24 h postoperative. The type of agent and timing is left to the discretion of the individual surgeon and ranges from American College of Chest Physician Guidelines (325 mg aspirin daily) to a health system guideline (once daily, subcutaneous low-molecular-weight heparin) for all patients regardless of approach beginning 24–48 h post-op.

Strong consideration is given to initiation of LMWH for all adult spine deformity patients in the 24–48 h window [26]. Variables such as patient mobility and drain output also influence this decision postoperatively. While the overall risk of hemorrhage or epidural hematoma is difficult to assess, we only rarely experience clinically significant epidural hematomas. This risk does not seem to be dependent upon the administration of prophylaxis dosage, but has been seen in therapeutic dosage range. Obviously, those patients must be monitored closely in an acute care setting.

Ileus

Postoperative ileus (POI) is a prevalent problem after major spinal surgery and may lead to significant postoperative morbidity, prolonged hospitalization, and increased health-care costs. Several mechanisms are thought to play a role in POI, including sympathetic neural reflexes, local and systemic inflammatory mediators, and generalized sympathetic hyperactivity, and other exacerbating influences such as opiates use and electrolyte abnormalities.

Several potential treatment options exist for POI, but data regarding the efficacy are generally limited. Strategies such as preoperative probiotics, preoperative carbohydrate loading, preoperative COX-2 inhibitors, gum chewing, and use of stool softeners/laxative have been used in various combinations and have some probable beneficial effects but have not proven to be independently beneficial [27].

Prokinetic agents such as metoclopramide and erythromycin have not been conclusively shown to decrease the duration of POI. Early enteral feeding and early ambulation have also not been definitively shown to shorten the duration of POI, but each appears to have some beneficial effects and may decrease postoperative morbidity and thus should be encouraged.

Opioid-receptor antagonists have shown some promise in reducing postoperative ileus in the general surgery literature but still require further studies in setting of orthopedic and spine patients, especially those whom are already opioid tolerant.

At our institution chewing gum is encouraged for the prophylactic prevention of ileus. Studies in the general surgery literature have shown that the act of masticating stimulates the cephalic-vagal circuits leading to increased GI motility and reduced rates of ileus [28] (see Table 20.2).

Studies have suggested that postoperative spinal patients with ileus secondary to acute colonic pseudo-obstruction that is unresponsive to conservative therapy may benefit from treatment with neostigmine, resulting in safe, rapid decompression of the colon. All the patients in this study had evidence of the Ogilvie syndrome that was unresponsive to 24 h of conservative therapy [29].

Multimodality treatment approaches combining several therapies may represent a logical approach but require further evaluation in larger, randomized trials, as do novel emerging therapies.

Conclusion

Preventing postoperative complications in spine surgery patients requires careful preoperative patient selection and optimization. Once this has been completed, a team approach is needed to determine the surgical and anesthetic plan and preparation for postoperative and rehabilitative care. Successful ASD surgery requires individualized care, and there are many considerations in perioperative surgical period. In this chapter we outlined interventions that may be undertaken in that have been shown through literature and personal experience to minimize complications and improve outcomes.

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21 Patient-Reported Outcomes Following the Treatment of Adult Lumbar Scoliosis

Stuart H. Hershman, Megan E. Gornet, and Michael P. Kelly

Introduction

Adult spinal deformity (ASD) is a heterogenous disease that encompasses a vast array of pathology and symptoms. Patients may present with primary or iatrogenic deformities, degenerative changes, neglected idiopathic curves, neuromuscular diseases, or any combination of the above (Figs. 21.1, 21.2, and 21.3). As varied as the etiology of ASD may be, so is the multitude of interventions available to treat these patients; therefore, it is perhaps easiest to divide treatment options into nonoperative and operative modalities. Nonoperative management runs the gamut from benign neglect to more invasive interventions such as epidural steroid injections. Similarly, operative management can range from minimally invasive surgery (MIS) (Fig. 21.4) and smaller open procedures to much larger operations addressing multiple levels of the spine. Anterior, lateral, and posterior approaches, as well as posterior column, and three-column osteotomies (3CO) are all routinely used to treat ASD.

Shared decision-making in ASD requires a consensus between the surgeon, patient, and family members with an understanding of the expected benefits of surgery. Patient factors associated with the decision to choose surgery have been examined. Glassman et al., using Spinal Deformity Study Group (SDSG) patients, found that the magnitude of the deformity and pain complaints were greater in those patients who chose to pursue operative intervention [1]. Patients choosing surgery also complained of progressive deformity, with changing body shape, and greater decline in social function directly attributed to ASD. Similar results were seen when subjects were enrolled in a prospective, dual-arm (observational and randomized), National Institutes of Health funded trial (ASLS) [2]. Patients who chose operative treatment complained of more baseline back and leg pain, as well as greater self-image dissatisfaction. As part of the ASLS study, participants also performed a functional measure of disability, the treadmill test; patients who ultimately chose surgery complained of more back and leg pain after walking. An important conclusion from the ASLS study is exemplified by the difficulty encountered enrolling patients in the randomized arm. Enrollment in the observational cohort was completed more than 1 year earlier than the randomized cohort. This suggests that patients were more determined

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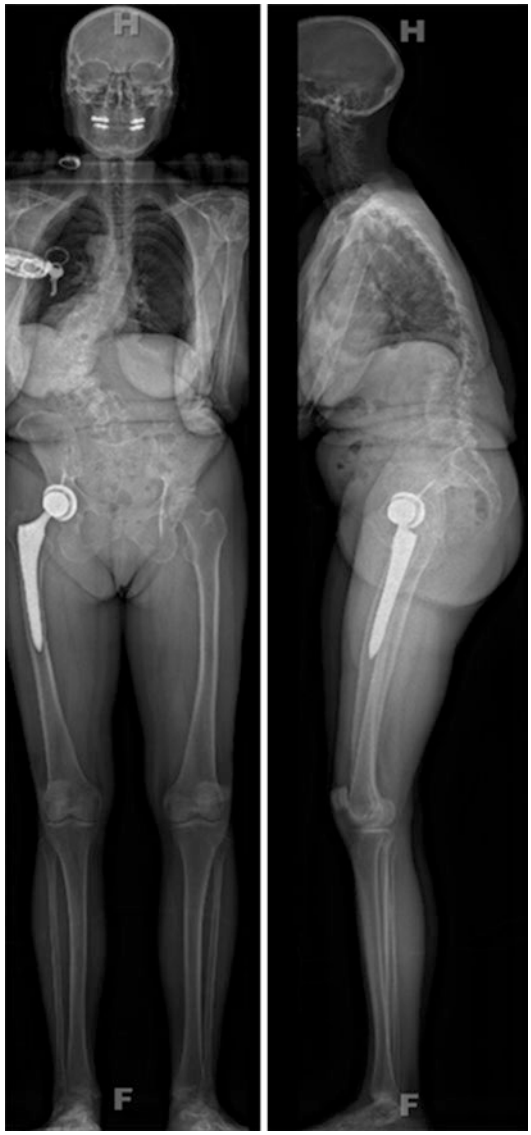

Fig. 21.1 Adult, idiopathic scoliosis in a 71-year-old woman complaining of progressive deformity, back pain, and neurogenic claudication

to direct their care than the term "shared decision-making" implied.

Patient-reported outcomes form the basis of comparative effectiveness research. Assessment of these outcomes is necessary as we move forward in a value-driven healthcare economy. Commonly used HRQOL tools include general measures of health, such as the Short Form-36 (SF-36), and disease-specific measures such as the Oswestry Disability Index (ODI), for degenerative lumbar disease, and the Scoliosis Research Society (SRS), for spinal deformity, questionnaires. These instruments are discussed elsewhere, though for the purpose of understanding HRQOL results and goals in ASD surgery, it is important to understand normative values for the SRS outcomes instruments. A study of 1,346 adults without scoliosis found that SRS domain scores ranged from 4.1 to 4.6, on average, where the maximum score is 5.0 [3]. The mean values for each domain score fell with increasing age. This has important implications for the management of ASD patients. It is important to communicate, before surgery, that perfection after surgery is unlikely, and patients will worsen over time from aging alone. Also critical to understanding HRQOL and related research is the concept of the minimum clinically important difference (MCID) [4]. This is the smallest change in HRQOL that could be deemed clinically relevant to the patient, an important threshold for nonprogressive disease.

Nonoperative Management

There has been little written regarding the nonoperative management of adult spinal deformity. The majority of studies are retrospective cohorts, though several prospective observational cohort studies offer more robust information. A prospective, randomized trial comparing nonoperative and operative management of adult spinal deformity is currently underway and will hopefully provide the highest quality evidence for both modalities in the management of ASD [5]. A shortcoming of many of these studies is the lack of a directed protocol for nonoperative treatments, making the benefits associated with any particular treatment difficult to ascertain.

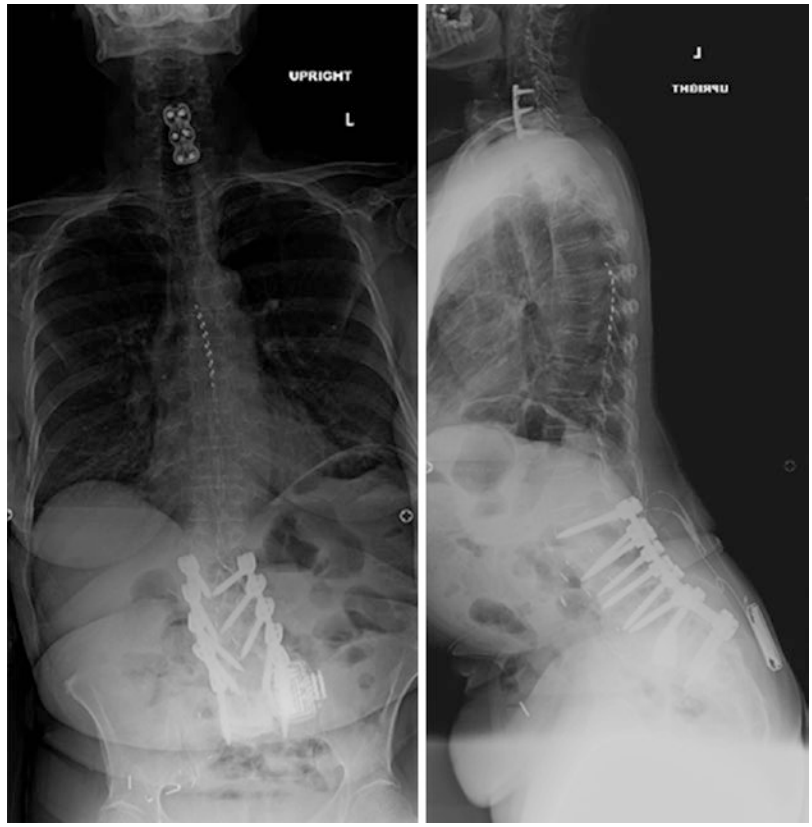

Fig. 21.2 Iatrogenic deformity in a 52-year-old woman with flat back and a kyphotic sacral fracture leading to extreme sagittal plane deformity. The primary complaint was back pain and deformity, without neurological symptoms

Nonoperative management options for adult spinal deformity are numerous. They range from truly "noninvasive" techniques such as cognitive behavioral therapy, oral medications, and physical therapy to epidural steroid injections and radio-frequency ablations (Fig. 21.5). Bracing, while commonly used in adolescent idiopathic scoliosis, is not commonly used in the skeletally mature adult. The goal of nonoperative management is pain and functional improvement by reduction of pain due to instability, deformity, and neural compression. Thus, in many cases the indication for any nonoperative intervention is borrowed from lumbar degenerative disease, where degenerative flat back and stenosis with radiculopathy and claudication are common. Whether the effectiveness in treating lumbar degenerative disease translates to adult spinal deformity remains to be proven. This suspicion is confirmed by Cooper et al., who reviewed 52 patients with lumbar scoliosis treated with epidural steroid injections for management of deformity-associated radiculopathy [6]. The authors conclude that epidural steroid injections are effective; however, a successful result was obtained in only 60 % of patients at 1 week and only 37 % of patients at 1 year.

A 2007 systematic review of the literature investigating nonoperative treatment options for adult spinal deformity confirmed the paucity of evidence for these interventions [7]. There were two articles investigating bracing, three articles investigating physical therapy, two articles investigating manipulation, and one article investigating injections. Given the high prevalence of adult spinal deformity, the lack of evidence to support

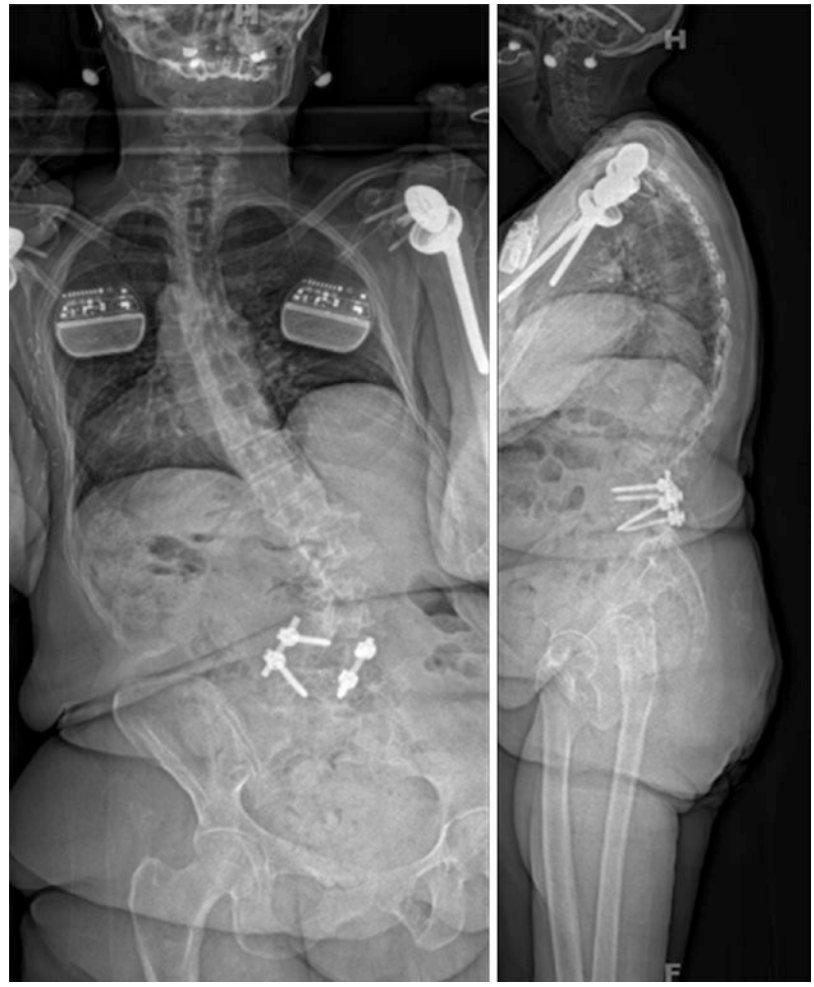

Fig. 21.3 Progressive neuromuscular deformity in a 65-year-old woman with Parkinson's disease

these seemingly common interventions is concerning. The authors conclude that activity modification and anti-inflammatory medications may be the most appropriate options and that shared decision-making and individual preferences and goals will determine which treatments are appropriate for different patients. Opioid use, not detailed in this systematic review, is becoming increasingly common [8].

The Spinal Deformity Study Group (SDSG) collected a large volume of observational data regarding the care of adult spinal deformity patients, including nonoperative treatments [9, 10]. Commonly employed nonoperative modalities included exercise/physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDS), and pain management including opioids and injections. Over 70 % of the patients examined reported using some type of nonoperative technique [9]. Less symptomatic patients were not uncommonly treated with observation alone, while patients with greater symptomatic complaints were more likely to receive formal pain management referral, which included epidural steroid injections. The effectiveness of nonoperative treatments was questioned, however. The change in health-related quality of life (HRQOL) scores was compared between patients treated with observation alone versus various nonoperative treatments [10]. Over a 2-year time frame, there were no observed improvements in HRQOL for those patients utilizing nonoperative modalities. Those patients

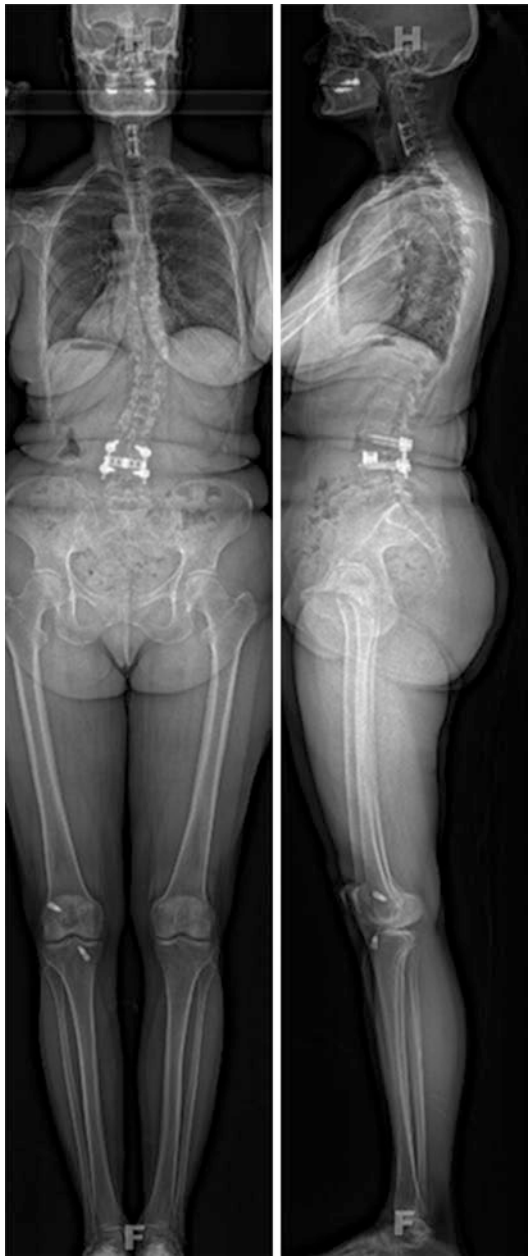

Fig. 21.4 Minimally invasive transpsoas interbody fusion at the degenerated apex of a small scoliosis. Percutaneous screws were placed

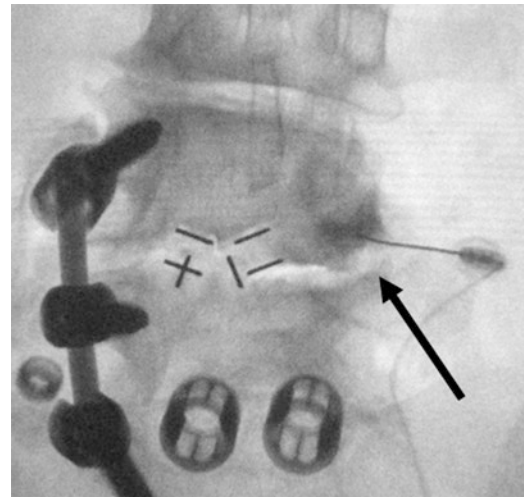

Fig. 21.5 Transforaminal epidural steroid injection at the concave apex of an iatrogenic spinal deformity

treated with observation alone improved in satisfaction alone, without improvements in pain or function. Not surprisingly, the charges associated with the nonoperative care were large, with an average of almost $10,000. The authors concluded by questioning the cost-effectiveness of nonoperative treatments, given the lack of improvement and relatively large resource utilization. This lack of improvement in HRQOL was echoed by the European Spine Study Group, who nevertheless concluded that nonoperative care may be appropriate for less symptomatic patients, thus preserving a relatively high quality of life [11]. Conversely, more symptomatic patients are less likely to improve with nonoperative care and should consider surgery more strongly.

Operative Management

The decision to operate in adult spinal deformity requires an informed decision-making process between the patient and surgeon, with an understanding of the expected risks and benefits of surgery. As previously noted, ASD is a heterogeneous diagnosis, with countless combinations of underlying pathologies. Perhaps the simplest division of ASD diagnoses comes with the distinction of primary and revision surgery. Within each of these subcategories, patients may present with or without evidence of neural compression (radiculopathy, myelopathy, or both), with fixed or flexible deformities, with iatrogenic, neurological, or degenerative causes of the deformity. All of these factors must be considered when assessing the

possibility of success in ASD surgery. Furthermore, understanding potential results of surgery, in terms of HRQOL improvement, will allow for appropriate patient expectations and subsequent satisfaction with their surgery. There is voluminous information regarding ASD surgery in the peer-reviewed literature. We offer here a review of the outcomes of ASD surgery, with some division by the various diagnoses associated with the ASD. We would recommend that the information offered here be a "starting point" rather than a summation of the available evidence in ASD surgery.

Operative Treatment of Adult Spinal Deformity

Primary, symptomatic adult scoliosis is frequently characterized by smaller deformities in terms of coronal and sagittal plane malalignment, with subluxations and stenosis contributing to symptoms of radiculopathy and claudication. Nonoperative management has been shown useful to maintain current HRQOL measures, without reliable improvement [10, 12]. Many patients present to the surgeon having tried nonoperative management and desiring surgical intervention. Those patients choosing surgical management have been shown to have larger thoracic and lumbar Cobb measurements, more frequent leg pain, and more severe back pain [1]. These findings were consistent when participants in a dual-arm study with a randomized cohort were examined [2]. Patients electing to undergo surgery, and forgoing possible randomization into a nonoperative arm, had larger spinal deformity and greater complaints of leg and back pain. Cosmesis is also likely an important driver of the decision to have surgery, as more surgical patients report unhappiness with body image as well as concerns about progressive changes to their appearance [1]. Recognition of these drivers of surgical decision-making has important implications for the success of surgery.

Bridwell et al. studied the results of surgery for ASD and found improvements in ODI, SRS, and numerical rating scores for back and leg pain [13, 14]. Most ASD reconstructions are large surgeries and there may be a recovery period where patients do not appreciate any benefit from the surgery. It seems that true recovery takes 6–12 months, as ODI and SRS scores will continue to improve after surgery over this time frame. Beyond 1 year, however, HRQOL scores seem to plateau, and patients should not reasonably expect more improvement. As adjacent segment degeneration and pseudarthrosis are potential long-term complications of any spine fusion surgery, the durability of ASLS surgery needs to be examined as well. Bridwell et al. found that, in the absence of a complication requiring reoperation, the radiographic and clinical outcomes of adult symptomatic lumbar scoliosis surgery are durable at up to 5 years [13]. However, 10 % of patients in this cohort encountered some complication including pseudarthrosis with broken implants or junctional degeneration. In these cases, the HRQOL results were negatively affected. The negative effect of proximal junctional kyphosis (PJK) is due primarily to increasing complaints of pain, while the remainder of the SRS-22 domains may be similar to patients without this complication [15]. These findings emphasize attention to detail to minimize surgeon modifiable risk factors for complications.

The results from the SDSG have been echoed by the International Spine Study Group (ISSG) experience. Scheer et al. reported on over 400 patients with ASD and found that surgery was more effective, in general, in relieving complaints of both back and leg pain [16]. At a 2-year follow-up, nearly 70 % of operative patients reported improvements in back pain, while 25 % reported no change. Just under 50 % of operative patients reported improvements in leg pain complaints. Important to note is that nearly one third of patients complained of unchanged or worsening leg pain, and one third complained of new onset leg pain. Fortunately, improvement in back pain was associated with patient satisfaction and may be a prime driver of postoperative satisfaction. This group looked further into the deformity type, noting that patients with a pure sagittal plane deformity (Schwab type N) were the least likely to report improvements in back pain, while

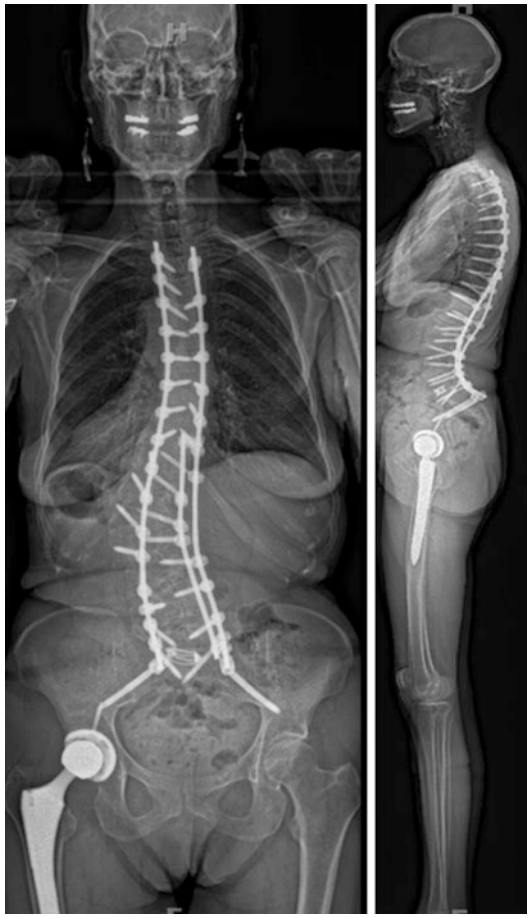

Fig. 21.6 Postoperative radiographs of the patient from Fig. 21.1. Treatment consisted of T3 – sacrum and ilium posterior spinal fusion and posterior column osteotomies

patients with degenerative scoliosis and coronal plane deformities were more likely to report improvements in both back and leg pain, as well as achieve clinically relevant improvements in ODI and SRS scores [17]. The importance of the deformity type, as adult deformity is a widely heterogeneous diagnosis, was emphasized by Smith et al. [18] Patients whose SVA increased over time had a concomitant decline in HRQOL scores. Similarly, those patients whose pelvic incidence-lumbar lordosis mismatch increased experienced a decline in HRQOL scores. Improvement in these radiographic parameters are associated with improvements in ODI, SF-36 Physical Component Summary score, SRS-Activity, and SRS-Pain scores (Fig. 21.6). These findings are consistent in the literature, with increasing disability (poor HRQOL) with increasing sagittal plane deformity [19]. Residual sagittal plane deformity is associated with lower HRQOL and again underscores the importance of preoperative planning in ASD.

The ISSG has also investigated the relationship between age and outcomes in patients undergoing complex ASD surgeries [20]. Patients greater than 75 years of age improved more following ASD reconstructions, including 3CO, than with nonoperative care. It is important to note, however, that not all patients achieved a minimum clinically important difference, with fewer than 50 % improving to MCID or better for ODI and 67 % of patients achieving a MCID or better change for SF-36 Physical Component Summary. O'Neill et al. did not find age to be associated with HRQOL outcomes following 3CO [21]. The only preoperative factor associated with a poor result was a history of prior spine surgeries. Complications requiring repeat reoperation were also found to negatively affect HRQOL scores, consistent with other reports. At 5 years postsurgery, SRS-22 domain scores were improved with the exception of SRS-Function, which had not improved beyond a minimum clinically important difference [22]. This fact is important for preoperative counseling, as patient expectations need to be set appropriately and a post-VCR spine may not allow many recreational activities for the sake of maintenance of correction, stability, and durability.

The ISSG cohort has reported a 17 % reoperation rate [23]. Similar to the SDSG, two common reasons for reoperation were pseudarthrosis and junctional degeneration. Not surprisingly, those patients that required revision surgery reported lower ODI and SRS-22 scores in 1 year postoperatively. The indication for reoperation may have been due to technical factors leading to worse HRQOL scores and led the authors to conclude that meticulous attention to preoperative planning, and intraoperative performance is required to optimize results (Fig. 21.7). These findings are consistent across the peer-reviewed literature. These results were echoed by Koller et al. who found a negative effect on HRQOL

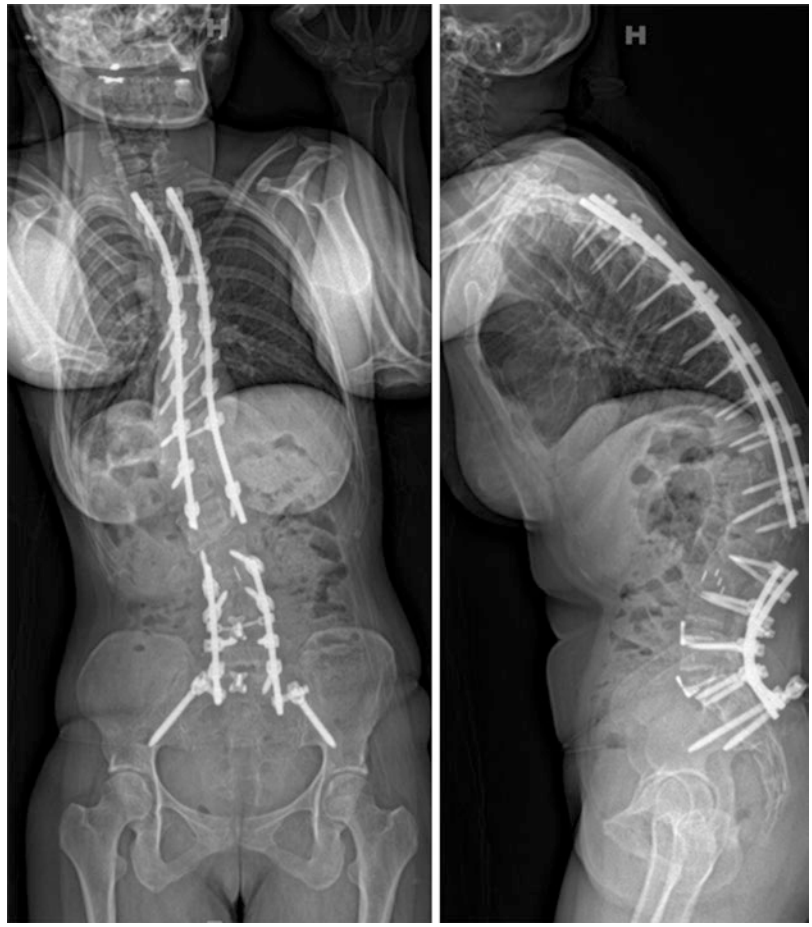

Fig. 21.7 Coronal and sagittal plane deformity as a result of pseudarthrosis and implant failure. Note the poorly positioned pedicle screws in the thoracic and lumbar spine, possibly weakening the construct

scores with persistent malalignment after ASD surgery [24]. Also, pseudarthrosis led to lower HRQOL scores leading the authors to emphasize the importance of preoperative planning in ASD and to identify appropriate proximal and distal fusion levels, with appropriate instrumentation. These results are in contrast to the results of Hassanzadeh et al. who found no difference between outcomes of primary versus revision ASD surgery [25]. These contrasting results emphasize the importance of patient selection in ASD, which warrants additional investigation.

Perioperative complications are common in ASD surgery, with rates approaching 75 % [26]. As previously noted, perioperative complications requiring reoperation may negatively affect HRQOL scores. Medical complications, such as myocardial infarction, delirium, and venothromboembolic event, are common [27]. However, occurrence of these complications does not appear to affect ultimate HRQOL scores. These results are consistent with an analysis of patients undergoing 3CO for severe ASD [28]. One quarter of patients sustained a major medical or surgical complication. The analysis did not find that these major complications had a negative effect on outcomes after a resolution of the complication. This cohort included a small number of permanent deficits due to complication, limiting a definitive conclusion regarding their effect on final outcomes scores. It is reasonable, however, that a permanent deficit will most likely negatively affect HRQOL following ASD surgery.

As in degenerative lumbar disease, there may be a component of mental health that may portend a poor prognosis, and patients must have reached some threshold of disability to appreciate the benefits offered by surgery [29]. The

response to the SF-36 question "have you felt downhearted or depressed" may be the most readily available screening tool in the HRQOLs commonly obtained to predict postoperative outcomes in degenerative disease [30]. The mental health component of preoperative optimization goes beyond depression alone, however. A prior diagnosis of depression may not negatively affect outcomes in ASD surgeries [31]. This cohort did, however, show that the Distress and Risk Assessment Method (DRAM) and Modified Somatic Perceptions Questionnaire (MSPQ) were helpful in identifying those patients at risk for poor outcomes. The MSPQ may be more sensitive to anxiety-like traits, and this may be more beneficial to identify and optimize preoperatively. As with the many other components that comprise the decision to proceed to surgery, surgeons should be aware of patient expectations and social supports available to recover from and appreciate ASD surgery.

There is an increasing prevalence of opioid use for chronic pain conditions, such as ASD [8, 32]. Preoperative opioid use may negatively affect the outcomes of surgery, however little investigation into adult spinal deformity has been performed [33, 34]. Mesfin et al. found that preoperative opioid exposure did not negatively affect the results of ASD surgery with respect to HRQOL [35]. Those patients using opioids for pain control preoperatively experienced greater improvements in the SRS-Pain subscore. Furthermore, more than half of the preoperative opioid users were able to stop opioid consumption postoperatively. It seems that it is reasonable to minimize opioid intake preoperatively, though preoperative exposure to opioids may not be associated with a poor result or more difficult postoperative pain control.

Minimally Invasive Surgery and Adult Spinal Deformity

Minimally invasive spine surgery (MIS) covers a variety of techniques, including anterior lumbar interbody fusions, lateral/transpsoas interbody fusions, and transforaminal lumbar interbody fusions in combination with open and percutaneous pedicle screw fixation. Advances in techniques, instrumentation, and experience have expanded the use of MIS in the setting of ASD. Proponents of MIS believe that it has the potential to lower costs by reducing blood loss and length of stay [36–38]. They also report shorter operative times, reduced blood loss, shortened length of hospital stays, and more rapid time to mobilization, all while producing comparable results to traditional open surgery. However, not all patients with ASD are candidates for MIS techniques, and an algorithm (MISDEF) has been offered to help surgeons identify those patients that may be amenable to MIS ASD surgeries [39]. The MISDEF has been shown to have good intraobserver and interobserver reliabilities. It should be noted that the deformities deemed amenable to MIS by the MISDEF are smaller/modest deformities which are not comparable to many of the larger deformities previously discussed, particularly those that require a 3CO. Unfortunately, as these more advanced MIS techniques are relatively new, adequate long-term data are lacking, and there is a paucity of HRQOL data available. These facts emphasize the need for standardized data collection, particularly HRQOL, in the study of ASD [40, 41].

A comparison of open versus hybrid open MIS and MIS techniques confirmed that the magnitude of deformity treated with the three techniques varied, with generally larger deformities treated with traditional open surgery [42]. Similar VAS pain and ODI outcomes were obtained with the three techniques at 1 year postoperatively, with similar magnitudes of improvement noted as well. The MIS surgeries fused fewer levels, reinforcing the difference in deformities treated with the three techniques. Unfortunately, follow-up was limited to 1 year, which is inadequate for multilevel spinal fusions, and the SRS questionnaire was not administered as a scoliosis disease-specific outcomes measure. A subsequent comparison of MIS and hybrid techniques found similar HRQOL improvements in ODI and VAS back and leg pain scores [43]. It is important to note that the average sagittal vertical axis measurements in both groups were less than

5 cm, indicating little to no sagittal plane deformity, which is important to consider when comparing these less invasive results to traditional open surgery.

A comparison of the "best" outcomes, as judged by ODI improvement, and "worst" outcomes found that sagittal plane alignment was a prime driver of HRQOL improvement [42]. The baseline ODI scores in the two cohorts were different, which makes comparison of the groups difficult. The ODI scores in the "worst" cohort declined, though VAS back and leg pain outcomes improved similar to the "best" results. The effect of obesity on outcomes in MIS surgery was also studied in this cohort, with no apparent detrimental effect observed in obese patients, as both the obese and nonobese improved in terms of ODI and VAS back and leg pain scores [44].

Transpsoas and transforaminal interbody fusions have been described for MIS in the setting of adult scoliosis [45–47]. Phillips et al. collected SF-36 scores, in addition to ODI and VAS measurements, one of the few MIS ASD studies to do so. The average SF-36 PCS improvement was nearly 18 points, showing a good improvement in overall general health. Oswestry Disability Index score improvement was approximately 20 points, and final VAS back and leg pain ratings were near 2.5. These improvements are consistent with other transpsoas techniques, as well as with TLIF and hybrid approaches to MIS ASD surgery. Thus, it is important to discuss with the patient that complete back and leg pain relief is likely an unrealistic expectation and that symptom improvement, rather than symptom resolution, is the goal of surgery. Surgeons must consider that these improvements in back and leg pain are similar to traditional open surgery, and the long-term potential benefits of MIS ASD surgery remain to be seen.

Conclusion

Adult spinal deformity is a complex, heterogeneous disease, affecting patients in a variety of ways. As such, measuring and comparing patient-reported outcomes is difficult, but a necessary part of the preoperative and postoperative data gathering for all surgeons treating ASD. Nonoperative care of ASD is varied and does not seem to result in sustained improvement in health-related quality of life, though it may help the patient remain at their current level [14]. Operative techniques in ASD are as varied as the disease itself. Traditional open surgery and minimally invasive surgery appear to benefit the patient, so long as the appropriate procedure is chosen. Emphasis on alignment goals and achieving a balanced spine are critical for patient improvement. Surgeons must understand the spinal deformity and the needs and goals of the patient in order to achieve a good outcome [16, 29, 45, 46, 48].

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Health Economic Issues Related to Adult Lumbar Scoliosis

22

Corneliu Bolbocean, Chessie Robinson, Neil Fleming, and Richard Hostin

Introduction

This chapter discusses key concepts for understanding how to assess the value of health care interventions. Value has been defined as a comparison of the outcomes achieved to the costs incurred related to an intervention [1]. Evidence-based medicine has emerged as a field designed to satisfy increasing needs to balance benefits of treatment with health care interventions to rising health care costs. A gradual shift toward a value-driven rather than resource utilization-based health care system has occurred. There have been increased demands to contain costs with greater focus on outcomes (rather than process), which require the application of appropriate methods of economic evaluation. Cost-effectiveness analysis is increasingly used by health care decision makers to allocate scarce resources in an increasingly value-maximizing, patient-centered health care system that considers outcomes (effectiveness) in relation to resources (cost). This chapter introduces several basic concepts regarding the economic measurement of health benefits, costs, and cost-effectiveness methods applicable to spine care.

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Measuring and Valuing Health Outcomes

Clinical or biomedical measures and outcomes such as survival, mortality, remission, and complications are routinely collected and readily available. However, these measures are unable to quantify a patient's quality of life, which includes aspects such as physical, mental, and social well-being. A large and growing literature exists on the theory and practice of quantifying health outcomes and the burden of illness. Health-related quality of life (HRQOL) tools reliably measure changes in the overall health status of a patient.

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There are four types of commonly used HRQOL measures: generic or general, disease specific, pain scales, and health utilities.

Generic measures are attractive because they can be applied to broad ranges of diseases and allow comparisons among patients with different types of health conditions. A standard health index includes two components: a health state classification instrument and a formula to assign a utility/score to any unique set of responses to that instrument [2]. The score measure may either be based on people's preferences or on arbitrary scoring algorithms. The most widely used generic measures are the EuroQol (EQ-5D), the Medical Outcomes Short Form-36 (SF-36), and the Health Utility Index (in versions HUI-I, HUI-II, HUI-III). Studies have shown that these measures are reliable and valid in large patient populations [3–11]. One downside of generic measures is they might misrepresent important changes in health outcomes related to specific diseases or treatments.

Disease-specific measures are tailored to the symptoms associated with a given medical condition. The spine-specific instruments are designed to capture disease pain, disability, spine-related function, and other relevant attributes to spine health; however, these instruments provide a limited ability to compare outcomes across unrelated diseases. The most commonly used spine-specific outcome measures are the Oswestry Disability Index (ODI), the Roland Morris Disability Questionnaire (RMDQ), and the Scoliosis Research Society Questionnaire (SRS-22).

Health-Related Quality of Life (HRQOL)

HRQOL are measures designed to quantify health status across different health states. The majority of HRQOL are commonly assessed through self-reported questionnaires, capturing responses in domains such as physical function, social function, mental health, and general health.

Generic Measures

EuroQol (EQ-5D)

EQ-5D is a five-dimension measure of health status developed by a consortium of European researchers using a mailed survey to collect information about health and functional states being experienced by individuals [12–20]. EuroQol is a brief, easy-to-use questionnaire that allows self-completion or interviews in a matter of minutes [18]. Preference weights have been developed for the various health states described by the EQ-5D, making the measure suitable for use as quality adjustments to compute quality-adjusted life years (QALYs). The five dimensions of the EQ-5D are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of the five dimensions has three levels resulting in a combined total of 243 possible health states. The instrument contains a visual analog scale calibrated from 0 (the worst possible state) to 100 (the best possible state).

Health Utilities Index

The Health Utilities Index questionnaire has three versions (HIU-I, HUI-II, HUI-III). The latest, HUI-III, classifies health status along eight dimensions: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain [21, 22]. HUI-III defines 972,000 possible health states, and a utility value is obtained by inputting weights for each dimension into a multiplicative formula. The dimension weights have been estimated from valuation data obtained from a sample of patients from Hamilton, Ontario, Canada.

Medical Outcomes Short Form-36

The SF-36 is a questionnaire composed of 36 questions to be answered by the patient. It assesses health status across seven different health domains: physical function, social function, limitations in role because of physical

health, limitation in role because of mental health, vitality, bodily pain, and general health [23]. Responses in each domain are combined in order to compute a score between 0 – "worst health" and 100 "best health." Two composite measures can also be computed: a mental composite summary score and a physical composite summary score. Using a norm-based scoring algorithm, all domain scales have a mean of 50 and a standard deviation of 10 based on the general 1998 US population. Thus, scores >50 are above the general population mean. Many validation studies have confirmed the SF-36's use in measuring general health across a variety of diseases populations, including spine deformity [23–29].

Spine Disease-Specific Measures

Oswestry Disability Index

The ODI was developed to measure lower back pain [30]. The questionnaire includes questions regarding functional abilities, daily living activities, and social life in relation to spine deformity. The questionnaire includes topics regarding personal care, lifting, walking, sex life, sitting, standing, and sleeping. In the USA, a modified version of ODI was endorsed by the American Academy of Orthopaedic Surgeons as a part of the Musculoskeletal Outcomes Data Evaluation and Management System Initiative [31].

The ODI has been validated in numerous studies [31–34]. The ODI instrument has also been modified to create the Neck Disability Index (NDI) [35]. See Fig. 22.1, which illustrates the scoring chart created as an aid to show all possible ODI scores.

Roland-Morris Disability Questionnaire

The RMDQ consists of 24 statements related to daily physical activities such as dressing, walking, and using of stairs [36, 37]. The patient is asked to put a check mark that corresponds to his or her current situation. The check marks are added up with a total score of 24, with a higher score representing greater disability. Studies document that RMDQ and ODI have a high level of correlation to each other [38–40].

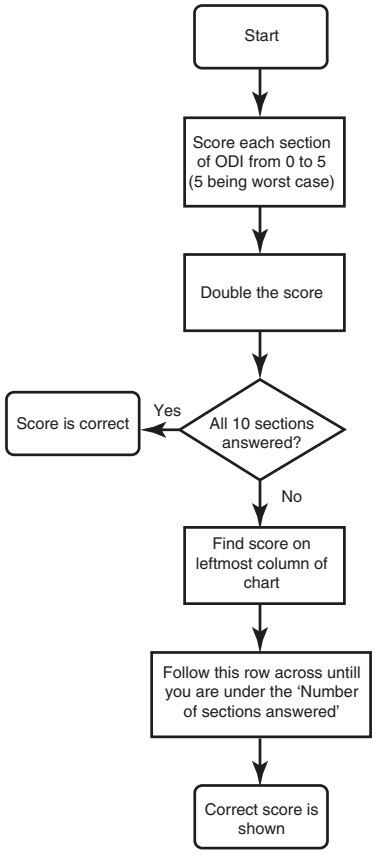
Scoliosis Research Society Questionnaire

The SRS-22 is a scoliosis-specific HRQOL questionnaire. The questionnaire comprises 22 items with five domains – pain (5 items), appearance or self-image (5 items), activity or function (5 items), mental health (5 items), and satisfaction and management (2 items) [41]. Each domain score ranges from 1 to 5, with higher scores indicating better outcomes. For example: question 8 asks the respondent: "Do you experience back pain when at rest?"; question 17 asks: "In the past three months, have you taken any sick days from work/school due to back pain and, if so, how many?"

The SRS-22 is the most widely used tool to measure changes in health-related quality of life in patients with scoliosis [8, 42–47]. The SRS-22R instrument is a refinement of the SRS-22 and was created to assess quality of life following surgery in patients with adolescent idiopathic scoliosis [48]. Additionally, the SRS-22R assesses patient's self-image; however, studies suggest that the questionnaire might not accurately assess the health status of younger patients or those with milder forms of scoliosis [49, 50].

Quality-Adjusted Life Years

QALYs remain the most popular measure of health benefits used in economic evaluation of health care interventions [51]. QALY measures were introduced to create a standard unit of health utility measure in order to value the length and quality of life on a single scale [52–54]. The advantage of the QALY as a measure of health outcome is that it can simultaneously



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34	38	42	49	57	68	85			
36	40	45	51	60	72	90			
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Fig. 22.1 ODI scoring system. *Note*: Scoring chart was created as scoring aid to show all possible ODI scores (Mehra et al. [95])

capture gains from reduced morbidity (quality gains) and reduced mortality (quantity gains) and combine both into a single measure [55]. The QALY measure assumes that an additional year of life has the same value regardless of the age or other characteristics of the person who receives it, assuming that the different life years are of comparable quality [56]. A year of life extension for an infant or a 35-year-old all have the same value in QALYs and, in turn, in a cost-effectiveness analysis using QALYs, which assumes no difference in the quality of the year of life extension.

QALYs are a measure of health outcome that assigns to each period of time a weight, ranging from 0 to 1, corresponding to the health-related quality of life during that period, where a weight of 1 corresponds to optimal health and a weight of 0 corresponds to a health state judged equivalent to death; these are then aggregated across time periods [57]. QALYs are computed using Health Utilities Indexes such as the EQ-5D, or

SF-6D, and estimates of the length of time a treatment benefit will last. For example, consider a patient with spinal deformity who has a health state of 0.6. Without the surgery, the patient lives for 10 years. With the surgery, the patient's health state improves to 0.9, and his life expectancy is increased by 5 years. Thus, QALY gained with surgery = quality of life years with the surgery – quality of life years without the surgery = 0.9 * 15 – 0.6 * 10 = 7.5QALYs. See Fig. 22.2, which exemplifies QALYs gained from an intervention.

QALYs are primarily used as an outcome of interest in cost-effectiveness analysis and are typically expressed as costs divided by the QALYs gained from a treatment or intervention (cost/QALY). However, other quality-adjusted measures available in the literature are Disability-Distress Index (DDI) [58], the Quality of Well-Being (QWB) Scale [59], and disability-adjusted life years (DALYs) [60].

Costs and Resource Use

It is important to consider not only the clinical outcomes of care but also the costs required to achieve the outcomes associated with treatment. Over the last decade, total charges for spine deformity surgery have increased dramatically with over 20,000 discharges associated with ICD-9 diagnosis codes 737.0–737.9, which is defined as "curvature of the spine," in 2013 [61]. See Fig. 22.3, which shows discharges and costs per year for spine deformity surgeries related to curvature of the spine.

There are multitudes of spine deformity treatments available; some treatments may be very expensive but very beneficial, while others may be inexpensive but do little to improve clinical or quality of life outcomes. Standardized methods of calculating the costs of operative and non-operative treatments for spine disorders are necessary for value-driven decision making. Therefore,

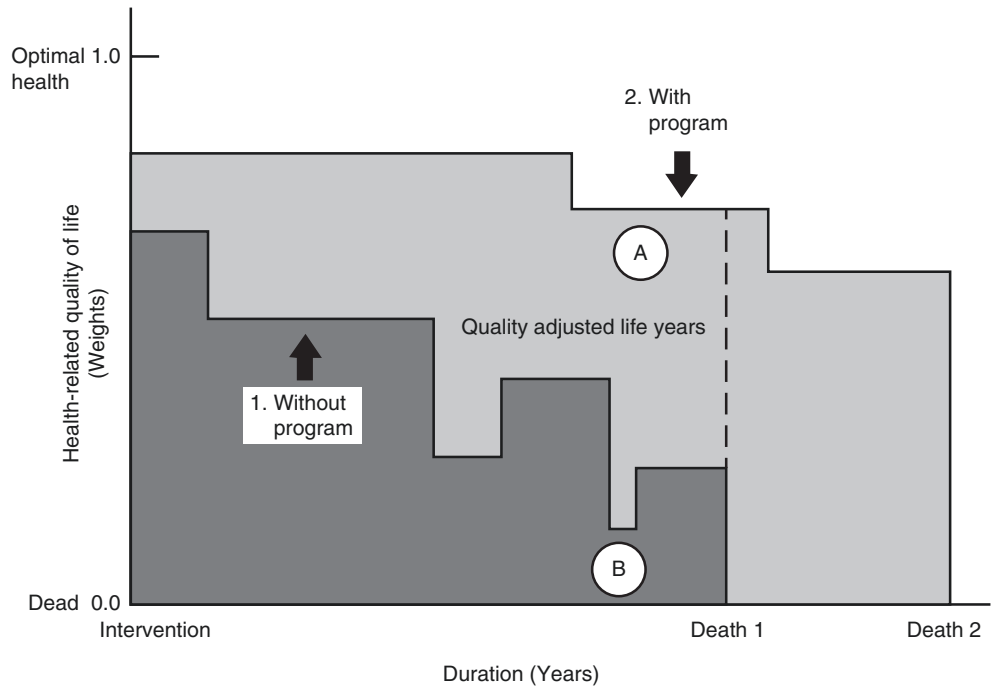
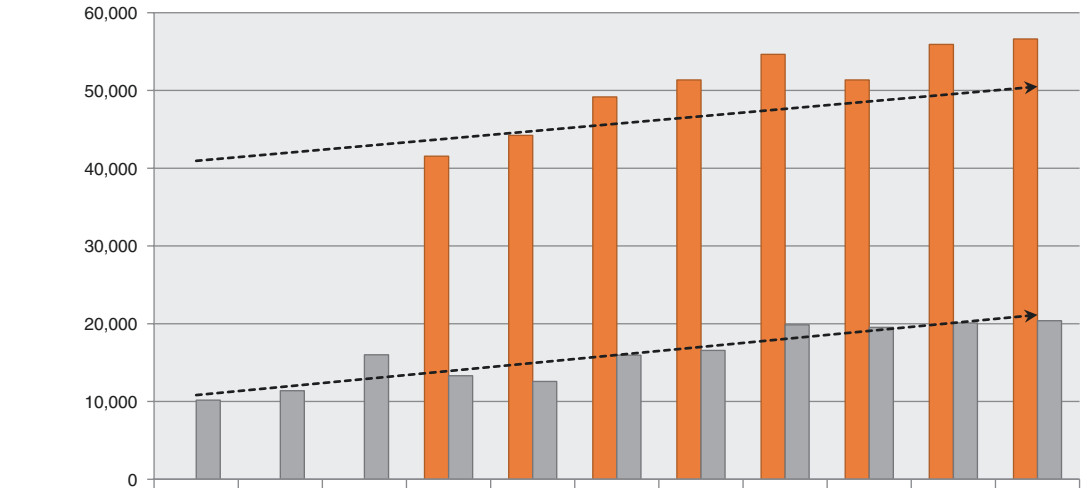


Fig. 22.2 Health-related quality of life with and without treatment. *Note*: The figure illustrates QALYs gained from an intervention. *Circle B* indicates the quality of life without the intervention, while *Circle A* indicates the additional QALY gained from the intervention (Reproduced from Gold et al. [57], Figure 4.2, p. 92, Copyright © 1996, with permission of Oxford University Press, USA)



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Costs (mean)	$-	$-	$-	$41,542	$44,235	$49,165	$51,347	$54,644	$51,347	$55,931	$56,623
Discharges	10,177	11,390	16,005	13,307	12,571	15,951	16,565	19,863	19,537	20,090	20,380

Fig. 22.3 Discharges and costs per year for spine deformity surgeries ICD-9 diagnosis codes related to curvature of the spine (ICD-9 codes 737.0–737.9). *Note*: Spine deformity defined as ICD-9 primary diagnosis codes 737.0–737.9 (Data from Healthcare Cost and Utilization Project, National Inpatient Same, Available at www.hcupnet.ahrq.gov)

determining the value of surgical treatment requires both the clinical, patient-specific, or societal outcomes and the associated costs to provide those outcomes. In addition to determining which costs to include, appropriate methods to measure and analyze costs are all equally important considerations in health economic evaluation.

Identifying all relevant costs associated with treatment is vital in the economic evaluation of a health care intervention. Accurate measurement of costs requires estimation of the amount of resources used in natural and comparable units of measurement. Costs related to health care interventions can be categorized into several types, including direct and indirect costs, operative and non-operative costs, and formal and informal costs. Direct costs are costs that are directly associated with the illness, procedure, or treatment or in addressing the side effects of treatment. These include costs of implants, operating room staff, tests, medications, and supplies. Indirect costs are not directly associated with the illness or treatment and may not be incurred by the individual who is receiving treatment. These often include overhead costs, such as administrative costs, as well as productivity losses associated with illness or death. It is important to note that some of these resources are challenging, if not impossible, to accurately quantify and capture. For example, how can we quantify a reestablished family routine due to reductions in pain?

The appropriate estimation of costs is varied in the literature, due to scope and specific research question being answered, not to mention the cost data that are available to the researcher. Costs have been analyzed using charges, reimbursements, payments, direct cost, total costs, allowable rates, relative value units, etc. Each of these provides some interesting information, but alone, each often fails to provide the complete cost of care.

Defining Costs

Total hospital costs: Direct and indirect costs.

Direct costs: Direct resources used for the intervention.

Indirect costs: Opportunity costs, patient and family burden due to disease or intervention.

Charges: Seldom represents true costs due to markup and contracting.

Payments: Expense incurred for the treatment, amount paid by insurer, not easy-to-access managed care claims data.

Allowable rates: Public data is easily accessible but differs dramatically from managed care payments.

Cost data and measurement are also constrained by the confidentiality among competing health care providers and insurers as well as by differences within the US health care system [62]. From whose perspective costs are considered is an important concept in cost evaluation. The perspective of the one performing the cost evaluation influences the methodologies incorporated and ultimately can lead to very different conclusions. For example, a health care consumer deciding whether to pay for a generic or more costly prescription may be willing to pay more or less for the medication than a hospital, insurance company, or another patient would do [63].

There are two broad categories of cost perspective, the health service perspective and the societal perspective. These can be broken down into more specific categories such as providers, payers (e.g., insurance companies and employers), patients, and policy makers. The health service perspective usually considers costs incurred by the provider or payer, while a societal perspective considers broader costs to society at large and is usually indifferent to who incurs the expense. For example, a societal perspective may consider patient expenses, including productivity loss and family disease burden. Alternatively, an individual hospital may be interested in its internal costs to treat a disease-specific population [64].

Another important concept in cost assessment is the time horizon considered. Assessment of the cost of spine deformity surgery should consider not only the cost of the surgery itself but future costs and outcomes that are realized or avoided as a result of the surgery [63].This is also related to the durability of treatment, i.e., how long an intervention will continue to provide benefits. This often manifests itself in repeat revision surgeries for spinal deformity patients. Future costs may be very substantial, and analyses may underestimate the cost if it is not incorporated in the assessment. For example, the cost of surgery includes not only the inpatient stay but preoperative visits, pain medication, postoperative follow-up, time off from work, etc. In this same vein, it is not only the costs incurred but the avoided costs of forgoing treatment (i.e., the continued disease burden on family and work life, comorbidities that were exacerbated due to spinal deformity). Non-operative costs include pain management, physical therapy, and post-acute care. Although surgery involves expensive inpatient costs, the reduction of expensive non-operative treatment may outweigh the costs of the surgery, when considered over an extended period of time. Therefore, what appears to be the more expensive initial treatment may reduce total costs over the long run.

After determining appropriate costs to include and how best to accurately capture the costs of care, analyzing cost data comes with its own pitfalls [62].The distribution of costs for surgical treatment tends to be skewed instead of normally distributed.

Due to the skewed nature of the distribution, careful consideration of the statistical approach is necessary. Frequently used methodologies include log transformation of the costs variables and generalized linear models that consider the statistical distribution. A multitude of literature has been written for those interested in learning more about these models and their assumptions [65–71].

In this section we have covered the importance of defining, accurately capturing, and modeling costs for the surgical care of spinal deformity. Ultimately the continual pursuit of the true cost of care will allow for accurate comparisons and help define value and best practices in spine deformity.

Discounting

As a rule, all costs and benefits of health care programs are observed over different points in time. For example, the benefits to the individual and

society of adult lumbar scoliosis surgery are incurred over the patient's lifetime after the procedure. However, individuals value the benefits sooner rather than later in life and prefer to incur costs later in life.

Discounting accounts for the differential timing of health care costs and benefits. All future costs and benefits associated with an intervention should be discounted by computing the present value of these [72]. To calculate the present value of future costs and benefits (both monetary and nonmonetary), the following formula is applied:

$$\mathrm{PV} = \sum_{t=0}^{N} \frac{\$a_t}{(1+r)^t}$$

where PV is the present value, $\$a_t$ is the dollar amount of cost or benefit in period t, r is the discount rate, and N is the maximum time periods. A discount rate of 5 % is prevalent in the existing literature. The US Public Health Service Panel on Cost-Effectiveness in Health and Medicine recommended that a 3 % rate be applied for health interventions [55]. Moreover an inflation-adjusted discount rate should be used if it is expected that inflation might impact health care costs and benefits.

Types of Economic Evaluation of Health Care Programs

Economic evaluation is used to describe a range of methods that investigate the costs and consequences of different treatments or interventions [73]. These methods are designed to identify and appropriately quantify all costs and benefits of health care interventions. There are three main types of economic evaluations: cost-utility analysis, cost-effectiveness analysis, and cost-benefit analysis.

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is a type of economic evaluation in which both costs and consequences of health treatments are examined. The health outcomes of interest are measured and presented in the most appropriate natural, physical, or clinical units, such as symptom-free days, lives saved, complications avoided, or cases of illness avoided [55]. While monetary valuation of outcomes is not always performed, the total net costs of an intervention are calculated and then divided by the number of health outcomes averted to yield the total net cost per unit of health outcome.

Another form of this type of analysis considers the cost of the intervention in relation to the change (effectiveness) from a pre- to post-intervention state of health as from a value perspective. For instance, McCarthy et al. (2013) estimated that the marginal cost of a 1-point improvement in the SRS-22 self-image domain was approximately $5,700 for adult spinal deformity surgery patients, while the average estimate on a similar 1-point improvement in the SF-36 Physical Component Score incurred a cost of approximately $26,000 [74].

Cost-Utility Analysis

Cost-utility analysis (CUA) is a special form of CEA, in which the health outcomes in the denominator are valued in terms of utility units [55]. The consequences are measured in quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs). The result of a CUA is usually expressed as the total net cost per unit of utility or measure of quality (net $ cost or savings per QALY gained). The results of a cost-utility analysis are expressed in terms of cost per QALYs. CUA has become the standardized method to allow comparisons across different health care interventions and medical conditions.

Meaningful comparisons based on relative cost-effectiveness may be made between competing health care interventions using QALY league tables [75, 76] and construction of cost-effectiveness league tables.

Cost-Benefit Analysis

Cost-benefit analysis lists all the costs and benefits that might arise as a result of a health care treatment over a specified time horizon [55].

These costs and benefits are converted to present value terms by discounting. If the total discounted benefits are greater than the total discounted costs, the intervention is said to have a positive net present value. The implication is that any intervention deemed to have a positive net present value should be pursued.

Incremental Cost-Effectiveness Ratio (ICER)

ICERs are used to compare two or more competing health care interventions and represent the incremental cost of one unit of outcome gained by a health care intervention when compared to an alternative. An ICER is estimated using [2]:

$$\text{ICER} = \frac{C_1 - C_0}{E_1 - E_0} = \frac{\Delta C}{\Delta E}$$

where C_1 and C_0 are the mean values of the costs using Interventions 1 and Intervention 0; E_1 and E_0 are effectiveness values yielded by Intervention 1 and 0, respectively; and ΔC and ΔE are incremental costs and incremental effectiveness gained/lost. For CUA, ΔE is computed in terms of QALYs. ICER is increasingly used in many countries to determine which interventions to fund. An ICER of $50,000 per QALY is the conventional threshold for cost-effectiveness [77]. In the literature, health care interventions valued below this threshold are considered "cost-effective" and those above are not [78, 79]. However, the World Health Organization suggests a threshold of three times a nation's gross domestic product per QALY, which in the USA in 2014 would be closer to $140,000 per QALY [80]. Either of these thresholds may be higher or lower than what a decision maker may deem as their true willingness to pay. Therefore, there is no clear consensus on a universal cost-effectiveness threshold [63, 81]. Instead of the threshold, a cost-effectiveness acceptability curve (CEAC) may be created to allow for different willingness to pay thresholds. For example, for the treatment under consideration in Fig. 22.4 below, if the decision maker's willingness to pay threshold is under $100,000 per QALY, there is almost a 100 % probability the intervention is cost-effective at that threshold. If the willingness to pay threshold is $80,000, there is about a 40 % probability that the intervention is cost-effective at that threshold. See Fig. 22.4, which shows the incremental cost-effectiveness acceptability curve.

ICERs reported for spine interventions are becoming increasingly available. For example, evaluation of cost-effectiveness of surgical vs. nonsurgical treatment of lumbar disk herniation revealed that cost/QALY gained for the surgical cohort in the Medicare population was $34,355, and for general populations, it was $69,403 [82]. A cost-utility analysis comparing surgical with nonsurgical care for a lumbar disk herniation reported an ICER of $4,648 [83]. Periacetabular osteotomy performed with the goal of preventing or delaying the need for total hip arthroplasty reported an ICER of $7,856 [84].

However, this measure has its limitations mainly because value assessments are inherently subjective, and there are oversimplifications of complex processes [85]. The National Institute for Health and Clinical Excellence in England was criticized for refusing to cover four kidney cancer medications in 2008 based largely on assessments of ICERs that exceeded the $50,000 (£30,000) threshold [86]. However, despite its limitations, QALY remains the main tool for cost-effectiveness research methodology.

Simulation Modeling

Decision models or trees are used formally to model a decision problem. A model reflects the question to be answered and a graphical representation of the main elements (variables and their relationships) of a clinical decision. Figure 22.5 illustrates a basic decision model related to spine surgery.

Sensitivity Analysis

Sensitivity analysis is an essential part of economic evaluation that allows the assessment of how sensitive a study's results are to variations in

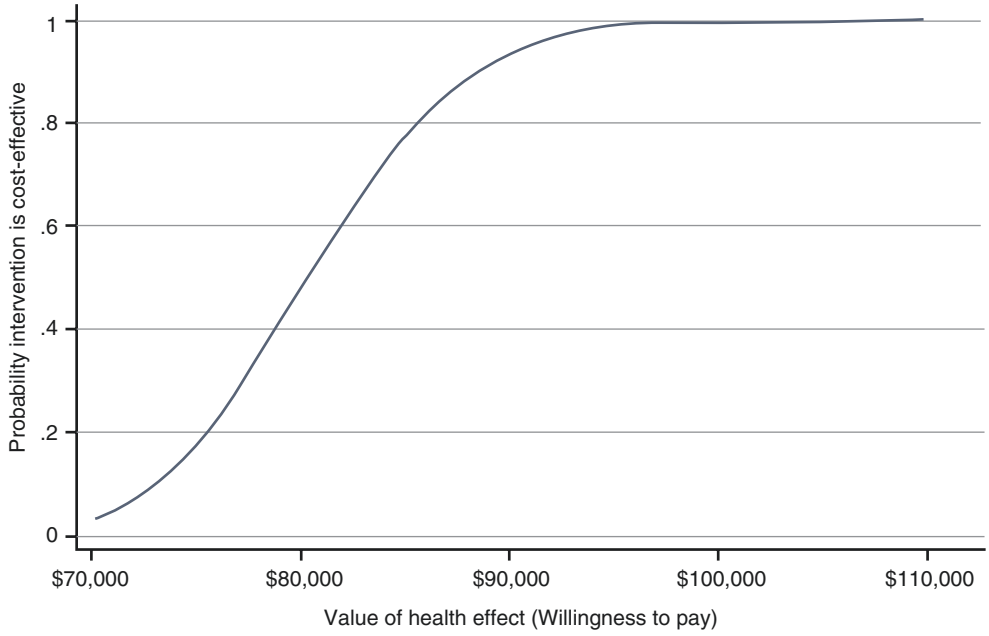


Fig. 22.4 Incremental cost-effectiveness acceptability curve. *Note*: Cost-effectiveness acceptability curves illustrate the probability that the dollar per QALY improvement falls below a given threshold value, i.e., the "willingness to pay" for surgical treatment for spine deformity (McCarthy et al. [92])

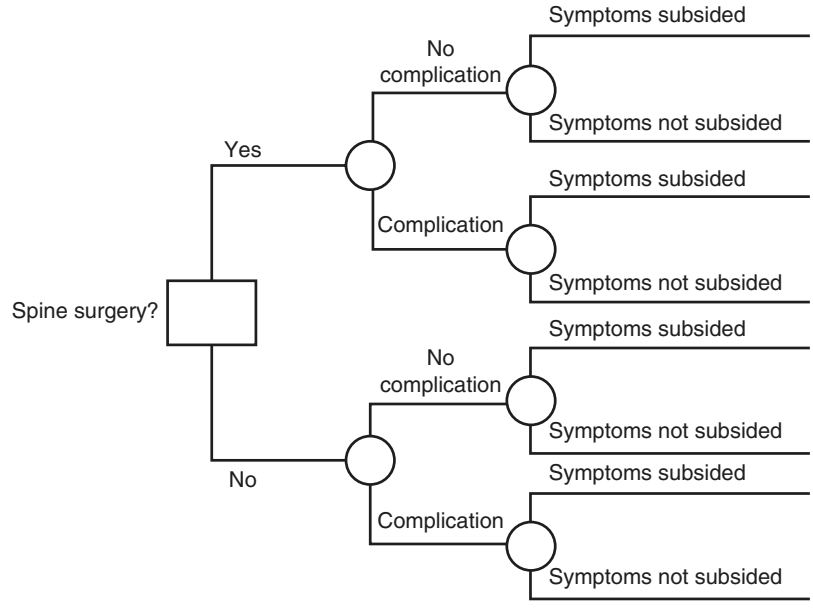


Fig. 22.5 Decision analysis model. *Note*: The "decision node" *square symbolizes* the decision between surgical and nonsurgical management. The "chance node" *circles symbolize* potential outcomes resulting from the decision (Angevine and Berven [88])

key parameters (transition probabilities, costs, utility values) that were used in the primary analysis. The goal of sensitivity analysis is to find out which variables in the model most impact the results and whether changes in parameters will result in savings or costs. Several methods to deal with uncertainty are employed: simple sensitivity analysis, threshold analysis, probabilistic sensitivity analysis, and value of information analysis. In a simple sensitivity analysis, one or more

parameters are varied across a range of possible values. The purpose of threshold analysis is to identify the critical value of a parameter above or below which will change the conclusions of the study. The probabilistic sensitivity analysis (PSA) treats all input parameters as random variables with known probability distributions. PSA measures the uncertainty around a prediction of cost-effectiveness. Value of information analysis uses PSA to examine the effect of reducing the uncertainty around the model's parameters [87].

Issues in Cost-Effectiveness Research Related to Spine

Spine disorders are extremely expensive to treat surgically. In particular, the disorders of the lumbar spine such as lumbar stenosis, lumbar degenerative spondylolisthesis, and lumbar disk herniation are expensive to treat and cause significant disability. The evidence around cost-effectiveness of operative vs. non-operative treatment of the lumbar spine disorders is inconclusive, and the studies that suggest that surgery is advantageous over nonsurgical treatment fail to report that surgery is actually cost-effective.

Short follow-up periods are one of the main reasons the cost-effectiveness of operative vs. non-operative treatment has been difficult to quantify. For example, the cost-effectiveness data from the Spine Patient Outcomes Research Trial used a 2-year follow-up period. For lumbar disk herniation, the study reported several ICERs both under $100,000 depending on two different ways direct surgical costs were estimated [82]. Considerations over a longer time horizons might improve calculated cost-effectiveness estimates [88–94]. The choice of time horizon and costing methodology greatly affects the results and must be determined thoughtfully when undertaking cost-effectiveness research or reviewing published work. For example, the short follow-up cost-effectiveness studies are more likely to underestimate the improvements in utility which would reduce ICERs. However, studies with longer time horizon might not necessarily yield more favorable ICERS as these are more likely to account for reoperations following surgery for spinal deformity and thus increase the costs.

Summary

It is becoming increasingly important for clinicians to weigh costs and benefits of competing health care interventions. Formal methods of economic analysis are required to assess the cost-effectiveness of health care interventions. This chapter introduced several basic concepts regarding the economic measurement of health benefits, costs, and cost-effectiveness methods necessary to define the value of spine care. We expect that spine care providers will increasingly use cost-effectiveness analysis methods in their own practice given the overall shift toward a patient-centered and value-driven health care environment.

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Future Directions for Adult Lumbar Scoliosis

23

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Adult degenerative lumbar scoliosis is an emerging epidemic that requires substantial attention from a medical and health-care policy standpoint. The reported prevalence of adult lumbar scoliosis ranges from 6 to 68 %, and as the life expectancy continues to rise within the United States, solutions for the medical and economic resources associated with providing care and maintaining quality of life for the aging population must be addressed [1, 2]. Recent findings have provided insight to the substantial pain and disability reported by adults that have lumbar scoliosis [3–5]. Consequently, cost-effective diagnostic and treatment modalities must be identified that help improve quality of life and allow for patient care that is both suitable for the patient and sustainable for the health-care system. These emerging health-care needs provide opportunity for research efforts that will develop treatment solutions for patients with adult lumbar scoliosis. This chapter will address future directions needed for the diagnosis and treatment for adult lumbar scoliosis including (1) improved methodologies to evaluate patient-reported disability and patient-reported treatment outcomes, (2) risk stratification to optimize patient safety and resource utilization, and (3) creation of predictive modeling formulas based upon patient-specific data that will help assess individualized risk/benefit ratios for treatment modalities for patients with adult lumbar scoliosis.

The assessment of patient-reported outcomes (PROs) is critically important to evaluate patient function, disability, and pain levels. PROs also allow for comparisons of treatment efficacy between different treatment modalities and the associated impact on health-related quality of life (HRQOL). As a consequence, the quality of the instruments used to assess patient-reported outcomes, termed patient-reported outcome measures (PROMs), is fundamental to the accurate assessment of patient-reported outcomes, because the accuracy of the patient-reported data hinges on the tool used to collect that data. Previous chapters in this text described the use of PROMs for adult patients with lumbar scoliosis; however, the importance of PROMs as it pertains to future directions for the topic of adult lumbar scoliosis lies in developing PROMs and generating research that provides HRQOL comparisons of patients

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with adult lumbar scoliosis to other disease conditions. The ultimate basis for this comparative research is that resource allocation for medical care is becoming increasingly dependent upon demonstration of the health impact of the disease state. Then, based upon the reported impact of the specific disease on HRQOL, analyses can be performed on the cost-effectiveness of different treatment modalities between disease states. To this end, Bess et al. utilized data from the International Spine Study Group multicenter database to compare baseline, pretreatment 36-Item Short Form Health Survey (SF-36) scores for 497 patients with adult spinal deformity (ASD) that had no prior history of spine surgery to SF-36 scores for the US general population and values for patients with chronic medical conditions [5]. The health-related impact of ASD, as measured by the SF-36 Physical Component Score (PCS), was similar to that reported by patients with diabetes and cancer. Importantly, the authors found that different types of spinal deformity had varying impact on SF-36 scores. Adult lumbar scoliosis was found to have a devastating effect on HRQOL, as PCS values for the adult lumbar scoliosis cohort were similar to values reported by patients with chronic heart disease. These data demonstrate that ASD can have a tremendous impact upon HRQOL, and this negative impact upon HRQOL is often similar to or greater than the impact of more recognized chronic diseases, including diabetes and heart disease. More data is needed to help understand the disability associated with ASD in comparison to other more familiar medical conditions. This will generate an increased awareness in the greater medical community of the pain and disability associated with ASD and assist in the allocation of appropriate care for patients with ASD.

There is little data that compares the cost-effectiveness of spine care to other musculoskeletal and non-musculoskeletal chronic health conditions. Hansson et al. compared the heath impact of and surgical treatment outcomes for chronic low back pain, lumbar spinal stenosis, lumbar disc herniation, and lumbar spondylolisthesis to other orthopedic conditions including hip, knee, and ankle osteoarthritis and knee meniscus tear [6]. Patients with chronic low back pain and lumbar spinal stenosis reported the worst pretreatment quality of life, as measured by the EuroQol (EQ-5D). Following treatment, patients receiving decompression and instrumented spinal fusion for lumbar spinal stenosis (with or without spondylolisthesis) demonstrated the greatest improvement in EQ-5D, followed by primary total hip replacement (THR). Anderson et al. performed a meta-analysis of treatment outcomes for patients receiving anterior cervical decompression and cervical disc arthroplasty, anterior cervical decompression and fusion (ACDF), total knee arthroplasty (TKR), and THR [7]. The reported improvement in the SF-36 PCS was greater for cervical decompression and arthroplasty patients compared to TKR and THR. ACDF demonstrated greater PCS improvement than TKR and similar PCS improvement as THR. Jansson and Granath compared outcomes for 14 different orthopedic procedures performed at a large tertiary care hospital and compared these outcomes to reported values from the Swedish EQ-5D population survey [8]. At 12-month follow-up, the majority of patients receiving orthopedic procedures demonstrated improvement in EQ-5D scores. Importantly, patients receiving THR demonstrated postoperative improvements in EQ-5D that brought the mean THR EQ-5D values to EQ-5D scores similar to that of age- and gender-matched populations. This improvement demonstrates essentially an elimination of disease burden of hip osteoarthritis via THR. Patients receiving other orthopedic procedures, including TKR, trauma-related operations, rheumatoid arthritis surgery, and spine surgery, showed postoperative improvement in EQ-5D; however, they did not reach EQ-5D values of the normative matched population. These data demonstrate that surgery for spine pathologies can have a similar beneficial effect as other orthopedic procedures. More data is needed that compares the impact of spine care to medical care provided for other chronic medical conditions, such as diabetes, cardiac disease, and pulmonary disease.

The ability to compare the health impact of different diseases and the ability to measure treatment

Table 23.1 Patient-reported outcome measures used for spine and conditions for use

General health	Disease specific
36-Item Short Form Health Survey (SF-36)	Oswestry Disability Index (ODI; lumbar degenerative disorders)
12-Item Short Form Health Survey (SF-12)	Roland-Morris Disability Questionnaire (lumbar degenerative disorders)
EuroQol (EQ-5D)	Odom's Scale (typically cervical and lumbar degenerative disorders)
Quality of Well-Being Scale	Neck Disability Index (NDI; cervical degenerative conditions)
	Scoliosis Research Society questionnaire (SRS versions 22, 22r, and 30; adult and adolescent spinal deformity)
	Nurick Scale (myelopathy)
	Modified Japanese Orthopaedic Association scale (mJOA; myelopathy)

efficacy depend upon standardization of the PROMs that are administered to study patients. Unfortunately, multiple PROMs exist, including general health PROMs (used to measure the global health condition of the patient) and disease-specific PROMs (used to measure the health impact that a specific disease has upon the patient; Table 23.1). As a consequence, the literature is filled with multiple studies that use multiple different PROMs, and therefore, much of the PRO data that exists for each study is compartmentalized to results that pertain only to that study. In an attempt to unify clinical outcomes-based research, the National Institutes of Health (NIH) developed the Patient-Reported Outcomes Measurement Information System (PROMIS) [9, 10]. PROMIS is comprised of a large question bank that is organized by three specific health categories (physical, mental, and social health) as well as a global health category. Within the physical, mental, and social health categories, there are specific domains that pertain to each health category (Table 23.2). It is these specific domains that are the health items tested by the PROMIS tool; for example, physical function and pain intensity are testable domains within the physical health category. Consequently, there is no single PROMIS score. Instead there are scores reported for each of the domains that the investigator chooses to administer to the patient. So then investigators looking to evaluate physical function and pain intensity associated with a specific disease will administer the physical function and pain intensity questionnaires to the patient. The rationale for this domain-driven approach is to not only eliminate the use of different PROMs for patients with the same disease state but to also reduce or eliminate the use of disease-specific PROMs and unify clinical research by utilizing specific testable domains that theoretically could be applicable to all disease states. The PROMIS domains can be administered in two general formats: a static questionnaire or, for some domains, using computer adaptive testing (CAT). The static questionnaires come in long form or short forms, in which all questions are administered in a standard, sequential manner with no variability in questions administered or the order by which the questions are administered. Conversely, the CAT format uses an algorithm-based approach to administer the item bank questions. In this manner, the questions administered for PROMIS CAT are based upon the responders' answers to each question, so that each subsequent question administered is based upon the response to the prior question. Notably, the available CAT versions of the PROMIS domains have been found to have the same precision as the long-form questionnaire with greater brevity than the short form [11–14].

Little data exists for use of PROMIS in spine surgery, however data that is emerging for the use of PROMIS, and more specifically PROMIS CAT, in orthopedic populations that has demonstrated favorable results compared to traditional PROMs. Hung et al. evaluated the psychometric properties of the entire PROMIS physical function (PF) item bank for patients with spine-related conditions presenting to a university-based orthopedic outpatient clinic [15]. The authors found low ceiling (1.7 %) and floor (0.2 %) effects for the PROMIS PF item bank. Item reliability was 1.00 and person reliability was 0.99. The authors concluded that the PROMIS PF item bank adequately addressed outcomes of patients with spinal disorders and that the results of this validity study supported further evaluation of the PROMIS PF short form and CAT

Table 23.2 Patient Reported Outcomes Measurement Information System (PROMIS) architecture

Global health	Physical health	Mental health	Social health
	Physical function	Depression	Ability to participate in social roles and activities
	Pain intensity	Anxiety	Satisfaction with social roles and activities
	Pain interference	Anger	Social support
	Fatigue	Cognitive function	Social isolation
	Sleep disturbance	Self-efficacy	Companionship
	Pain behavior		
	Pain quality		

Four health categories and associated domains

for patients with spine disorders. Hung et al. also performed a validation study on the use of two PROMIS mental health domains (anxiety and depression, short-form questionnaires) compared to the distress and risk assessment method modified Zung Depression Index (mZDI) for patients receiving treatment for spinal disorders [16]. All three instruments were highly correlated with each other, and the PROMIS anxiety and the PROMIS depression short forms (SF-4) were able to explain variance demonstrated in the mZDI. The actual mZDI scores and predicted mZDI scores using either the PROMIS anxiety SF-4 or the PROMIS depression SF-4 were similar for age and gender. The authors concluded that the PROMIS anxiety and depression SF-4 are a viable alternative to the mZDI for patients with spinal disorder with similar results and reduced question burden. Papuga et al. evaluated the use of PROMIS CAT, including PF and pain interference (PI) domains, compared to the Oswestry Disability Index (ODI) and Neck Disability Index (NDI) [17]. The PROMIS CAT instruments each required 4.5 ± 1.8 questions and took 35 ± 16 s to complete, compared to ODI/NDI questionnaires, each of which requires ten questions and took approximately 188 ± 85 s to complete. Linear regression analysis between ODI and PROMIS PF CAT demonstrated *r*-values ranging from 0.5846 to 0.8907, indicating moderate to strong correlations. The authors concluded that the PROMIS CAT instruments are a viable alternative to legacy PROMs, requiring less time for completion and good correlation. Beckmann et al. evaluated the performance of PROMIS PF CAT for patients with rotator cuff disease compared to legacy PROMs for shoulder and elbow disease (American Shoulder and Elbow Surgeons [ASES] score and Simple Shoulder Test [SST]) [18]. The PF CAT had improved reliability compared with the ASES score and fewer floor effects compared with the SST score despite requiring fewer questions to complete. Hung et al. compared the PROMIS PF CAT to the short Musculoskeletal Function Assessment (sMFA) for orthopedic trauma patients in a university outpatient setting [14]. Test completion time was lower for PROMIS PF CAT vs. sMFA (44 vs. 599 s; $p < 0.05$). Both instruments showed high item reliability (Cronbach alpha = 0.98). Analysis of instrument coverage demonstrated neither instrument had a floor effect; however, the sMFA demonstrated a 14.4 % ceiling effect, whereas the PROMIS PF CAT had no ceiling effect. These early data indicate that PROMIS may provide a good solution to unifying outcomes research that utilizes PROM. The next steps for PROMIS, as pertains to adult lumbar scoliosis, are to validate the use of the PROMIS instruments for patients with adult spinal deformity (ASD) and to choose the appropriate domains that accurately evaluate the health-related impact as well as treatment outcomes. As research on PROMIS evolves, economic data also needs to be integrated into the evaluation of PROMIS measured outcomes, to develop cost/quality of life measures using PROMIS. This will allow for further standardization of patient-reported outcomes analysis and allow researchers to evaluate cost and efficacy of different treatment types for adult lumbar scoliosis compared to other chronic diseases.

Predictive analytics and, more specifically, predictive modeling will potentially play a large role in the manner by which health care is

allocated and delivered. The definition of predictive analytics is the field of data mining that focuses upon creation of forecasting probabilities and trends. Predictive modeling is the methodology used in predictive analytics to actually create the statistical model of future behavior. Predictive modeling is used widely in information technology including customer relationship management, financial management, disaster recovery, security management, meteorology, and city planning. As pertains to medicine, the hypothesis for predictive mathematics is that if companies are currently using predictive analytics to create predictive models that are used to screen employee applicants for risk factors for dissatisfaction, theft, and poor performance, as well as to identify factors that lead to employee success, it stands to reason that similar methodologies can be applied to patients to predict good vs. poor outcomes and create risk models for postoperative complications and resource utilization. Kimmel et al. used the American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP) database to identify risk factors for complications in spine surgery and then develop a model that could predict postoperative complications [19]. Multivariate regression analysis identified 20 factors associated with complications. Assigning 1 point for the presence of each factor, a risk model was developed. The range of risk scores for the study cohort was 0–13 with a median score of 4. Three risk groups were created according to risk score (low, 0–4; intermediate, 5–7; and high, 8–13). The authors reported the risk model robustly predicted complication rates, with a reported complication rate of 3.7 % for the low-risk group, 14.4 % for the intermediate group, and 38.5 % for the high-risk group. The risk score also correlated strongly with length of hospital stay. The study did not evaluate the ability of the model to predict a specific complication, likely due in part to the lack of granularity of the NSQIP database. Lee et al. used prospective data from a large university registry to model the risk for medical complications following spine surgery [20]. Variables that were used to create the predictive model included patient demographics, medical comorbidities, body mass index, diagnosis, and extent of surgery including a surgical invasiveness index. The authors found that the ability of their model to predict any medical complication had a receiver operator characteristic curve of 0.76 (fair predictive model ability), and the model ability to predict any major medical complication had a receiver operator characteristic curve of 0.81 (good predictive model ability). The authors concluded that the predictive formulas, subsequently made available online via www.spinesage.com, can be used for patient counseling and health policy structuring to identify high-risk patients. Scheer et al. used data from the International Spine Study Group multicenter database to develop two different predictive models for postoperative complications in patients undergoing ASD surgery, including evaluation of modeling techniques to predict postoperative major complications and a separate modeling study to specifically predict postoperative proximal junctional kyphosis (PJK)/proximal junctional failure (PJF) following ASD surgery [21, 22]. Methodology for the major complications modeling study involved analysis of 45 variables from 557 ASD patients undergoing multilevel ASD surgery [22]. The variables analyzed included patient demographics, comorbidities, surgical procedure, baseline HRQOL scores, and radiographic parameters. Twenty variables were identified as the most important predictors of a major complication (importance $\geq$0.90 as determined by the model), including patient age, total number of spine levels decompressed, total number of interbody fusions performed, osteoporosis, magnitude of spinal deformity, and several HRQOL indices. The authors reported the overall model accuracy was 87.6 % with an AUC of 0.89, indicating a very good model fit. The postoperative PJK/PJF modeling study investigated risk factors for the occurrence of clinically significant PJK (defined as an increase in postoperative proximal junctional angle $\geq 20^\circ$ with concomitant deterioration of at least one SRS-Schwab sagittal modifier grade) or PJF (defined as any form of PJK requiring surgical treatment) following multilevel surgery for ASD [21]. The overall accuracy of the model was 86.3 % with an AUC of 0.89 indicating a good model fit. The strongest

predictors for clinically significant PJK and/or PJF (importance ≥0.95) were patient age, upper and lower instrumented vertebra, implant type, and preoperative sagittal spinopelvic deformity. The authors concluded that the findings from these studies demonstrate the feasibility of predictive modeling as pertains to spine surgery and, more specifically, ASD. More work is needed to accurately risk stratify patients for specific complications. Ultimately these predictive modeling techniques will help physicians identify patients that are at risk as well as patient-specific risk factors that are modifiable to allow for effective patient optimization, counseling, and surgical planning prior to surgery in order to minimize perioperative complications and reduce length of hospital stay.

Predictive modeling for patient-reported HRQOL values is equally as important as predictive modeling for postoperative complications. However, modeling HRQOL is more difficult than modeling complications because there is a large subjective component to patient-reported HRQOL. Consequently, the outcome variables are in part dependent upon measures that are difficult to quantify including patient expectations, individual goals, and satisfaction, as well as more objective measures such as physical function. McGirt et al. developed a clinical outcome and complications prediction model using demographic, operative, and HRQOL data from over 1800 patients undergoing lumbar spine surgery for degenerative disorders. Correlation values (r^2) for 12-month ODI prediction was ranged from 0.47 to 0.51 [23]. AUC values for complications, hospital readmission, inpatient rehabilitation, and return to work ranged from 0.72 to 0.84, demonstrating good predictability of the model. Scheer and the International Spine Study Group evaluated the ability to create a predictive model for attainment of minimal clinically important difference (MCID) for ODI scores following ASD surgery [24]. The predictive model used 43 pretreatment demographic, radiographic, surgical, and HRQOL variables from 198 ASD patients. The model accuracy was 86.0 % correct with an AUC of 0.94 indicating a good model fit. The top predictors of MCID outcome included gender, the American Society of Anesthesiologists (ASA) grade, primary vs. revision surgery, preoperative sagittal spinopelvic malalignment, and preoperative HRQOL scores including SRS pain and SRS total scores. Tetreault et al. created and then subsequently validated a clinical prediction model to predict surgical outcome for patients with cervical spondylotic myelopathy (CSM) [25, 26]. The model consisted of six covariates including patient age, duration of symptoms, severity of presurgical modified Japanese Orthopaedic Association (mJOA) scale, psychiatric comorbidities, gait impairment, and smoking status. The AUC for the model was 0.77, indicating good discrimination and internal validity. The authors concluded that the most significant global predictors of surgical outcome for CSM were baseline myelopathy severity, age, smoking status, and impaired gait. Lubelski et al. evaluated the ability to create prediction models for patients treated with membrane-stabilizing agents (MSAs) for neuropathic pain associated with lumbar spinal stenosis (LSS) [27]. The authors evaluated the ability to predict need for surgery within 1 year after initiating MSA treatment, time to surgery after initiating MSA treatment, and EQ-5D score following the treatment period. The prediction model was not robust for need for surgery within 1 year of MSA treatment, and age was the only predictor for time to surgery (the authors reported that for each patient 10-year increase in age, there was a 20 % increase in the hazard of eventually having surgery). However, prediction models for EQ-5D score and for reaching MCID for EQ-5D were good with C-statistics 0.73 and 0.85, respectively. Predictive factors for superior outcomes included lower baseline EQ-5D, less baseline depression, greater median income, and being married. Further work is needed in this area. The relevance of these predictive models currently lies not in the specific data that is created by the models, but rather the importance lies in demonstration that the prediction models can actually be created. As predictive modeling techniques become more refined and the data integrated into the models become more advanced, the predictive models will continue to improve. The models will then assist physicians identify patient-specific

treatments that minimize cost and complications and optimize treatment outcomes.

In conclusion, the field of adult lumbar scoliosis is prime for innovations that will improve patient outcomes and help find solutions for the growing need and cost of treatment. Many of these efforts are already underway including the use of advanced methodologies to assess and capture patient-reported outcomes and the development of predictive models for patient complications and treatment outcomes. PROMIS and other efforts that look to reduce patient question burden and improve questionnaire accuracy have the potential to unite clinical outcomes research. This will allow for standardization of PROMs used in clinical research and allow for comparisons of the HRQOL impact of different diseases. These research efforts will help promote a greater understanding of the disability associated with ASD and, more specifically, adult lumbar scoliosis. Integration of these data into predictive modeling efforts will help standardize treatment by identifying patient-specific treatment modalities that will identify opportunities for patient optimization and improve treatment outcomes. Subsequent comparative analysis of the cost-effectiveness of different treatment modalities for different diseases will be facilitated by these unified research efforts and will allow for appropriate allocation of health-care dollars to help curb the increasing cost of medical care. These and other efforts should strive to create a safe, effective, and sustainable treatment environment for patients with adult lumbar scoliosis.

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Index

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