ABSTRACT

Interventions for Scoliotic Curves and Associated Spinal Deformities: A Context and Analysis of Novel Scoliosis Surgeries Over the Past 20 Years

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Scoliosis, curvature of the spine in the coronal plane, is a condition that leads to nearly 30,000 surgeries a year in the United States alone. The surgeries for this condition have seen significant changes and advances over the past two decades. The two surgeries performed around 2000 were non-expandable rod placement with full-fusion or fusion only at the rod anchor points (2-3 vertebrae each, rostral and caudal to affected spine). In 2005, anchor-fusion Growing-Rods that could be expanded were introduced, allowing for continued growth but requiring multiple subsequent surgeries and definitive fusion upon achieving full growth. Growing-Rods have a complication rate from 17% to 40%. Additionally, motion is limited due to the either real or de facto fusion of the spinal apparatus. After 2010, laparoscopic tether-based surgery (VBT) was introduced to allow growth with no fusion. In VBT, screws are placed horizontally through the vertebrae indicated in the curve, and a tether is run through the screws' heads and tightened to correct the curve. Correction further improves with growth. Later in 2015, surgeons performing tether-based surgeries began using an anterior semi-open approach (ASC) which allowed for secondary techniques to improve correction. Those techniques and the surgical approach made multi-staged and revision surgeries easier to perform while simultaneously reducing their necessity. Additionally, the possible candidate populations for ASC range from 7 years-old to over 50 versus 10 to 15 for VBT. Given the overall benefits of ASC relative to the other surgeries, it should be the first-line surgery for childhood and adolescent scoliosis.

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INTERVENTIONS FOR SCOLIOTIC CURVES AND ASSOCIATED SPINAL DEFORMITIES: A CONTEXT AND ANALYSIS OF NOVEL SCOLIOSIS SURGERIES OVER THE PAST 20 YEARS

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By

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CHAPTER ONE

Introduction

Scoliosis surgery impacts tens of thousands of patients every year. In the past, the surgeries available have come with outsized costs only justified by the even greater costs of not performing them. Although significant improvements have been made over the past few decades, scoliosis surgeries still primarily consist of the older treatments. This minimal degree of progress to date is unfortunate. Fusion and Growing-Rod operations are irreversible, with life-long consequences including reduced mobility, reduced capacity for weight-bearing exercise, and increased risk for disk degeneration. Other first-line surgical treatments such as Vertebral Body Tethering (VBT) and Anterior Scoliosis Correction (ASC) are available that eliminate all of those consequences; these new approaches succeed in a supermajority of cases, and maintain all therapy options post-operation. It is unfortunate that Fusion and Growing-Rod surgeries are still the first recommendations when conservative treatment fails.

Before the introduction of ASC, there was still justification for performing Fusion on curves over 60 degrees, since VBT is unlikely to correct a curve of that severity. With the development of ASC, that justification is no longer valid. In a limited sense, the current state of affairs is not without reason. There is a high entry cost to the tether-based procedures and the novelty of the mechanism of the treatment does justify some level of reticence. Beyond those small factors, the balance of evidence weighs toward at least attempting a tether-based surgery before moving toward fusion operations, as fusion remains a subsequent option if tether-based surgery fails. As will be argued in later chapters, there is a good argument to be made that ASC, since it allows for multiple operations, could supersede the need for fusion in all cases but those with disk degeneration.

While there are other novel surgical options, including the Apifix self-adjusting Growing-Rod system, semi-constrained Growing-Rods, and vertebral staples, this thesis does not cover them. Those options are either not studied in humans, are precursors to current operations and have fallen out of general practice, or solve a surgical problem that is manifestly better solved by other operations.

This thesis will argue that when both ASC and another surgical procedure are indicated, ASC is the superior treatment. In showing why ASC is the superior option, it will be necessary to refer to many aspects of the etiology and anatomy of scoliosis. These aspects will be the subject of the following chapter.

CHAPTER TWO

Defining Scoliosis, its Manifestations, and the General Implications Thereof

Definition

Scoliosis is defined as one or more curves in the coronal plane of the spine with multiple curve types as pictured in figure 2.2.[1] Scoliosis can be either idiopathic or non-idiopathic. The former is called idiopathic because there is no definitively known cause for its occurrence. Idiopathic scoliosis is divided into pediatric, which presents between 3 and 9 years of age, and adolescent, which presents between 10 and 18 years of age.[2] Idiopathic scoliosis is the most common kind of scoliosis. Non-idiopathic scoliosis is divided into congenital and neuromuscular. Congenital scoliosis appears as a result of asymmetrical spinal formation in utero and neuromuscular scoliosis is the result of a disorder in the nerve or muscular systems supporting the spine.[3] While congenital and idiopathic scoliosis must be treated mechanically, it is possible to treat some forms of neuromuscular scoliosis through the neuromuscular cause. The lack of an immediately evident cause of idiopathic scoliosis has led to competing theories including, but not limited to, anterior longitudinal ligament shortening, vestibular asymmetry, inflammation, and hypokyphosis.[4] However, it is widely recognized that each of those factors may be either independent or interdependent factors in the progression of scoliosis. In other words, it is theoretically possible that any one of those factors alone

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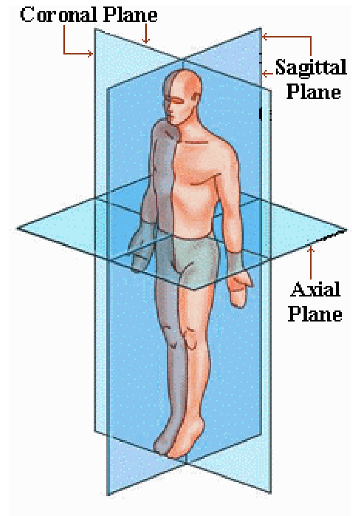
[1] Figure 2.2

[2] Mo et al.

[3] Boston

[4] Glossary

could be the first cause for a case of scoliosis or could be part of a feed-forward cycle of accelerating curve progression. The latter model provides an explanation for why curve progression tends to accelerate with increased severity independent of its primary cause. That also indicates that neuromuscular and congenital scoliosis can see idiopathic-like progression if not treated.[5]



While there is no consensus as to the cause of idiopathic scoliosis, there are some forms of spinal deformation correlated with and reinforcing of scoliotic curves. One common association with cases of scoliosis is rotation in the axial plane, with the anterior portion of the disks facing toward the apex of the coronal curve.[6] That can lead to a shortening of the stabilizing spinal ligaments increasing the stiffness of the curve. Another association is thoracic hypokyphosis, (insufficient curvature in the sagittal plane of the spine with the vertex on the dorsal side) caused by the expansion of the anterior portion of the disks. That pathological spinal arrangement can lead to reduced axial stability directly increasing the rotational aspect of the curve and indirectly increasing the coronal curve. The stacking effect associated with normal levels of kyphosis in the spine produces rotational stability; hypokyphosis removes that and the scoliotic spine cannot compensate. Those two associations notably combine to make a curve more difficult to treat because the isolated correction of the curve to one of those parameters will necessarily lead to increasing the severity in another. There are other deformities that,

[5] Orthoinfo

[6] Figure 2.4

while not reinforcing scoliosis, can cause health ramifications through contributing to Thoracic Insufficiency Syndrome (TIS).[7]

Measurement-Based Classifications

The primary measurement used to determine the severity of a scoliosis curve is the Cobb angle. This is measured using a (usually standing) spinal x-ray taken in the coronal plane. The physician marks the two vertebrae above and below the apex of any curves that are most deviated from the normal vertical orientation and measures their relative angular deviation. Because of the geometric equivalencies between angles, there are multiple ways to measure that relative angular deviation.

The primary classification system in use today was developed by Lawrence Lenke and relies on several factors beyond the Cobb angle. The location and number of the curves help inform the classification. A curve is either major (the largest curve and always considered structural) or minor (not fulfilling the requirements to be considered major). There are two sufficient conditions for a structural curve. It must be the largest curve for a given patient and/or greater than 25 degrees in an X-Ray where the patient bends their trunk in the opposite direction of the curve to be measured.[8] If the curve does not fit either of those criteria it is designated as non-structural. Another factor is the amount of lumbar deviation (how far the lumbar spine laterally deviates from the line normal to the alignment of the pelvis). The severity is categorized increasingly from A-C.[9] The amount of kyphosis (curvature in the sagittal plane of the spine with the vertex

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[7] Reduced space for the heart and lungs caused by shrinking of the thoracic cavity

[8] Figure 2.2

[9] Figure 2.2, Figure 2.3

on the dorsal side) is also considered. That is also categorized by the number and severity of the curve(s).[10]

Another factor that varies between individuals is how resistant the curve is to mechanical intervention, or how "stiff" it is. Some curves are reduced more in response to mechanical force than others. This is a factor that is touched on by the Lenke system by classifying structural or non-structural curves, but not sufficiently to decide between the modern options of surgical procedures. A curve with more axial rotation will tend to be stiffer.[11] A greater Cobb angle is also associated with more axial rotation.[12]

Sequelae of Scoliosis

The ultimate purpose of medical interventions in severe cases of idiopathic scoliosis is to prevent the negative downstream effects of the curve. Consequently, to evaluate any interventions properly it is necessary to understand exactly what those effects are. Resulting deformities in the thoracic cavity can lead to reduced space for both the heart and the lungs consistent with TIS. Patients with reduced rotational flexibility, thoracic hypokyphosis, and rib vertebral angle asymmetry have reduced pulmonary function consistent with thoracic insufficiency syndrome.[13] The resulting deformities can also lead to social consequences.[14] An increased rate of catabolic and inflammatory

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[10] Slattery et al.

[11] Lee et al. Figure 1.4

[12] Harris et al.

[13] Upadhyay et al.

[14] These will be more prevalent in pediatric populations where the difference in physical appearance and ability compared with peers causes isolation and/or bullying behavior.

activity in disks due to both the coronal and axial rotation may contribute to subsequent degradation.[15] That degradation could increase the prevalence of bulging and herniated disks leading to significant neurological problems later in life.

Scoliosis and its resulting deformities tend to become more severe with continued growth, particularly in the absence of treatment. A greater Cobb angle is associated with a greater risk for curve progression. All else being equal, a patient with more somatic growth potential will typically be treated more aggressively than one with less. Also important is that as scoliosis progresses, a curve that was once non-structural according to the definition provided by Lenke may become structural due to an increased initial degree of deformity prior to bending and increased stiffness due to axial rotation along with other factors. The location of the curve may also lead to difficulty in its correction. For example, a structural thoracic curve with its apex nearer to the top of the spine will be more difficult to pressure at its apex using conservative treatments, leading to decreased correction and a more rapid progression.

If left untreated, scoliosis will lead to the sequelae described above. That is not considered an acceptable medical outcome, so physicians have developed both surgical and conservative treatments. The treatment used varies based on the characteristics of the scoliotic curve. Although this thesis is primarily comparative, it will be useful to give an overview of the different treatments to aid in that comparison. This is the subject of the next chapter.

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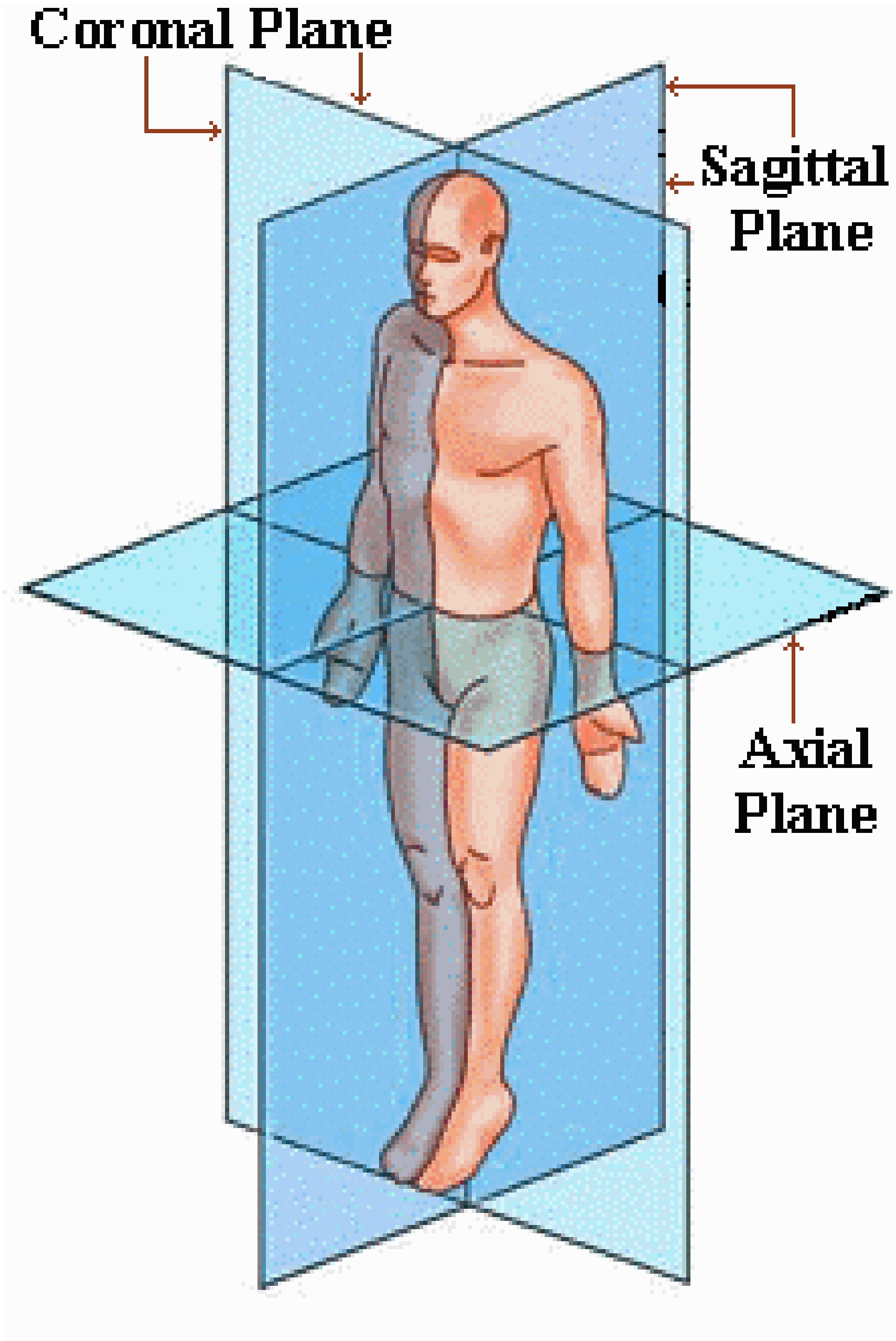
[15] Bertram et al.

Figure 2.1: Bodily Planes



[16]

16 Bridwell

Figure 2.2: Lenke Classification System

A

CURVE TYPE				
Type	**Proximal Thoracic**	**Main Thoracic**	**Thoracolumbar/Lumbar**	**Description**
1	Non-Structural	Structural (Major)*	Non-Structural	Main Thoracic (MT)
2	Structural	Structural (Major)*	Non-Structural	Double Thoracic (DT)
3	Non-Structural	Structural (Major)*	Structural	Double Major (DM)
4	Structural	Structural (Major)*	Structural	Triple Major (TM)§
5	Non-Structural	Non-Structural	Structural (Major)*	Thoracolumbar/Lumbar (TL/L)
6	Non-Structural	Structural	Structural (Major)*	Thoracolumbar/Lumbar-Main Thoracic (TL/L-MT)

STRUCTURAL CRITERIA
(Minor Curves)

Proximal Thoracic - Side Bending Cobb ≥25°
- T2-T5 Kyphosis ≥+20°

Main Thoracic - Side Bending Cobb ≥25°
- T10-L2 Kyphosis ≥+20°

Thoracolumbar/Lumbar - Side Bending Cobb ≥25°
- T10-L2 Kyphosis ≥+20°

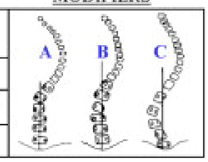
*Major = Largest Cobb measurement, always structural
Minor = All other curves with structural criteria applied
§Type 4 - MT or TL/L can be major curve

LOCATION OF APEX
(SRS Definition)

CURVE	APEX
Thoracic	T2-T11/12 Disc
Thoracolumbar	T12-L1
Thoracolumbar/Lumbar	L1/2 Disc-L4

MODIFIERS

Lumbar Spine Modifier	**Center Sacral Vertical Line to Lumbar Apex**
A	CSVL between pedicles
B	CSVL touches apical body(ies)
C	CSVL completely medial



Thoracic Sagittal Profile T5-T12	
– (Hypo)	<10°
N (Normal)	10° - 40°
+ (Hyper)	>40°

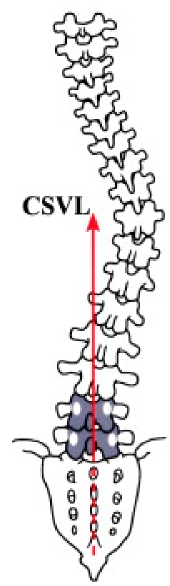
Curve Type (1-6) + Lumbar Spine Modifier (A, B, C) + Thoracic Sagittal Modifier (-, N, +) = Classification (e.g. 1B+): ____

B

LUMBAR SPINE MODIFIER RULES
A, B, C

1. Examine upright coronal radiograph.
2. Accept pelvic obliquity <2 cm. If >2 cm, then must block out leg length inequality to level pelvis.
3. Draw CSVL = Center Sacral Vertical Line with a fine tipped pencil/marker. Bisects proximal sacrum and drawn vertical to parallel lateral edge of radiograph.
4. Stable Vertebra – Most proximal lower thoracic or lumbar vertebra most closely bisected by CSVL. If a disc is most closely bisected, then choose next caudad vertebra as stable.
5. Apex of curve is the most horizontal and laterally placed vertebral body or disc.
6. SRS Definitions

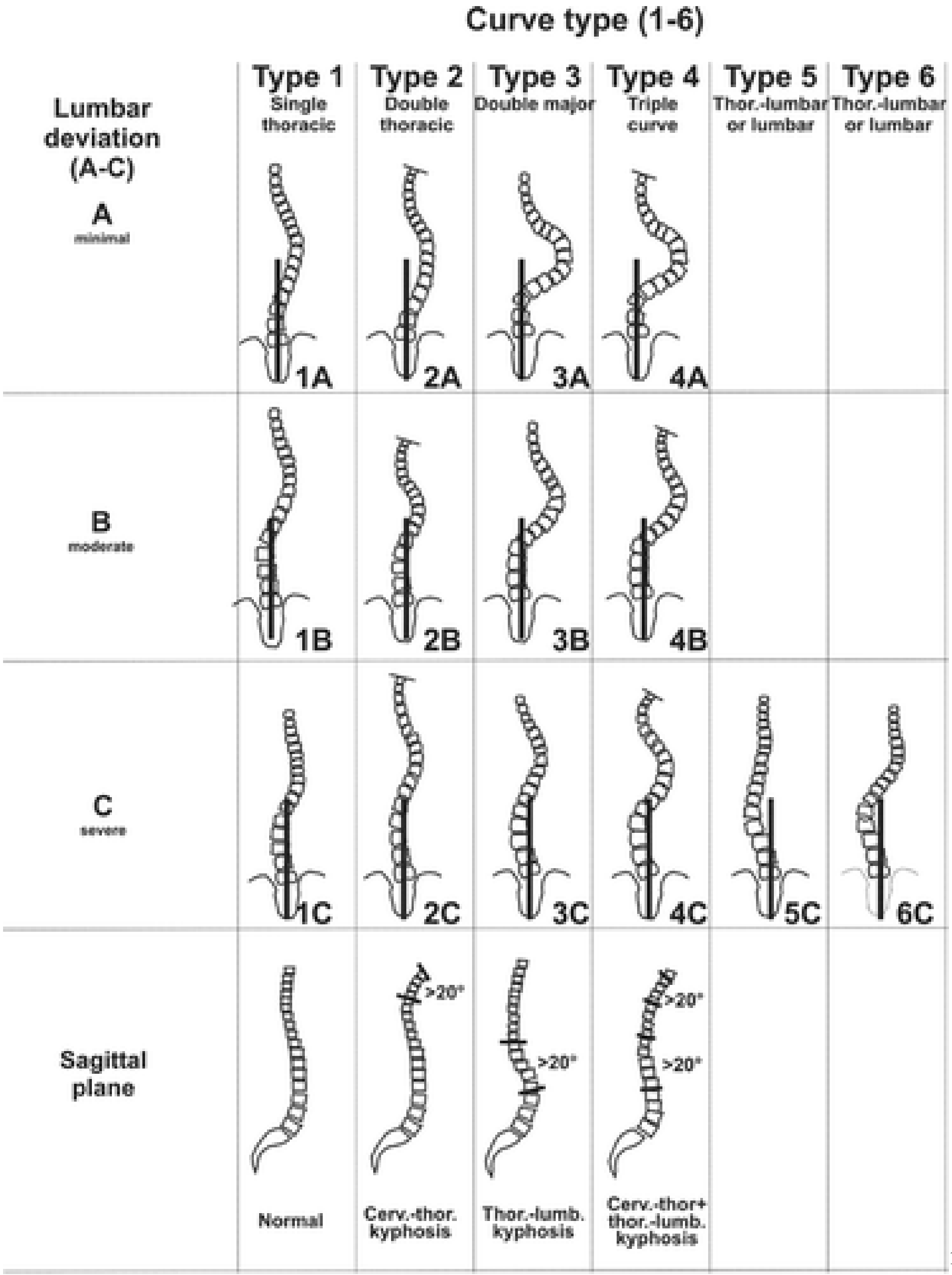
SRS Definitions	Apex
Thoracic Curves	T2-T11-12 disc
Thoracolumbar Curves	T12-L1
Lumbar Curves	L1-2 disc to L4



[17]

[17] Moore

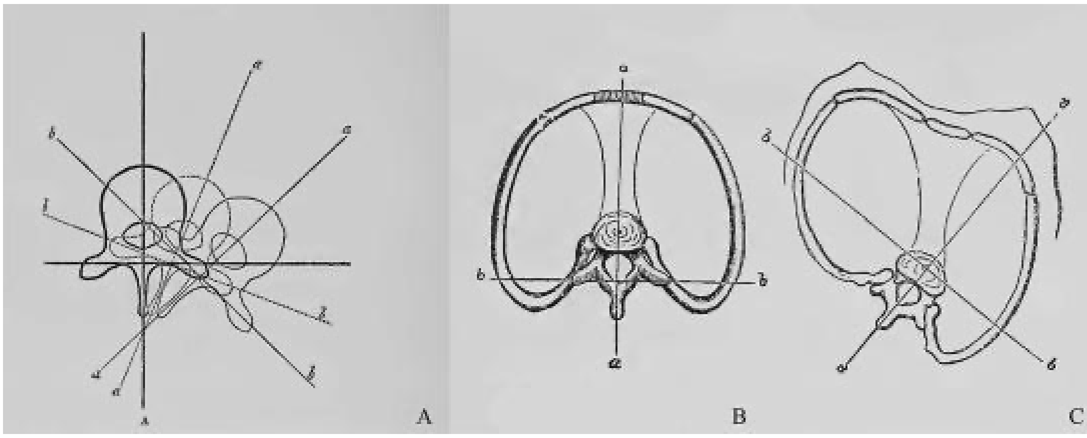
Figure 2.3: Lenke Classification System Images



[18]

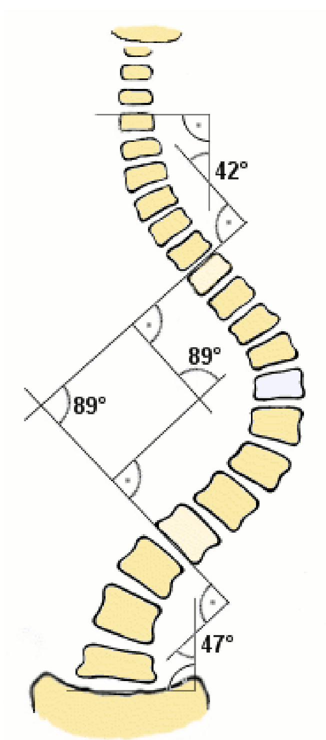
[18] Anitha

Figure 2.4: Axial Rotation



[19]

Figure 2.5: Cobb Angle



[20]

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[19] Illés et al.

[20] *Cobb*

CHAPTER THREE

Conservative and Surgical Treatments

Conservative Treatments

Physical Therapy

Corrective exercise-based therapy can play a significant role in reducing curve progression. Gamiz found that there is "moderate-quality evidence of a medium effect of corrective exercise-based therapy" on the Cobb Angle comparable with bracing.[1] In the studies in this particular meta-analysis, there is very little standardization of treatment regarding physical therapy alone. Given the fairly extensive searching protocol Gamiz et al. used, it follows that there are few replicated trials for each form of treatment. That would make it impossible to do a meta-analysis to find high-quality evidence of any given regimen of physical therapy treatment. Additionally, the variance in the control group used for each study further confounds the results.

Despite those problems, the overall results are meaningful. For instance, adding physical therapy as an adjunct treatment to bracing may increase the overall reduction of the Cobb angle. That could, in turn, reduce the amount of bracing needed. It could also correct for the core strength loss caused by aggressive bracing protocols.[2]

Since one of the major detracting factors of compliance is time spent in the brace, adjunct physical therapy could improve overall compliance in the treatment program.

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[1] Gamiz et al.

[2] The extracorporeal stabilization caused by bracing can reduce activation of the core muscles normally performing that stabilization. This will lead to weakening and may cause an inability to stabilize when outside the brace.

Another factor affecting compliance with conservative treatment is a healthcare provider's ability to monitor it. When it comes to physical therapy, it is possible for either some or all of the sessions to be directly monitored. There was also a medium to large improvement effect on pain, self-image, and mental health, although not on the overall quality of life in the SRS 22 questionnaire used by Gamiz. Given the questionnaire's cumulative nature, independently meaningful factors can be obscured by statistical noise.

A physician may prescribe physical therapy if increased brace time leads to a reduction in core strength. Some physicians will also prescribe physical therapy prophylactically. One reason for that is the theory that the resulting lack of core strength could be an independent factor for curve progression.

Bracing

The most commonly indicated conservative treatment for idiopathic scoliosis is bracing. Typically bracing is used on curves between 25 and 40 degrees to decrease the rate of curve progression according to its Cobb angle. Although the precise form of a brace may vary, they all operate by at least exerting lateral force on the apex of the scoliotic curve in order to reduce its severity. As the curve approaches the upper end of the treatment range, the amount of prescribed brace time will be increased up to a maximum of 23 hours a day. Braces vary in the way that they attempt to correct the scoliotic curve. While all correct the coronal aspect of the curve, there are some that also attempt to correct the axial rotation component. The latter is referred to as a three-dimensional brace. Those three-dimensional braces tend to produce more consistently positive results and minimize the negative effects of bracing[3], such as "pain, skin irritation, lung, and kidney dysfunction".[4]

Since the brace uses pressure on the thoracic cavity to produce the corrective force, it can result in a torso that conforms to the shape of the brace rather than following normal growth patterns. It is also possible for the wedge used to correct the curve to flatten the surrounding ribs. That is because force must be transferred first through the ribs, then to the spine. Those effects will be more pronounced with "two-dimensional" than "three-dimensional braces" because the former will require more force in the coronal plane to achieve the same amount of correction (see explanation of the feed-forward cycle of scoliosis progression in chapter 1). Insufficiently frequent brace remodeling/replacement will also increase those effects because patient growth will change the torso size and shape along with curve characteristics. That will in turn cause the brace to fit the patient's torso less well, causing more secondary – and undesired – growth modulation effects.[5]

Increased time in the brace will also increase the severity of those negative effects along with having the additional consequence of reducing core strength. As described in footnote 2, extracorporeal stabilization will weaken the anatomy normally performing that action. This means that the more time spent in the brace, the greater the degree of core atrophy will occur. The attending physician will often prescribe physical therapy for core strengthening, among other reasons.

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[3] Kwan et al.
[4] Zhang et al.
[5] Costa et al.

A lack of patient compliance in sufficient wearing of the brace is also a significant problem. Lack of compliance can be due to physical discomfort of the brace (as discussed earlier) along with social stigma. The physical discomfort may be made more severe by increasing the wearing time prescribed by the physician and leaving too long of a period between remodeling/replacement of the brace.

As mentioned previously, bracing is the indicated treatment for curves between 25 and 40 degrees. Curves with higher or lower Cobb angles usually have other indicated treatments; higher angles suffer from bracing's lack of invasiveness and lack of ability to reduce the rate of curve progression. The inconvenience of bracing is not justified for curves below 25 degrees. Scoliosis-specific PT may be sufficient to prevent curve progression below that point without requiring an outsized time investment. When above 40 degrees, the brace will typically not be able to sufficiently impact progression, even with aggressive protocols. Additionally, if the curve is above 40 degrees, bracing has already likely been tried, and failed to reduce progression. Some standards also include curves up to 45 degrees. In those cases, the brace is typically used to delay the ultimate surgical correction. That could allow for a single fusion surgery instead of Growing-Rod placement followed by fusion, reducing the overall risk of complications.

Surgical Treatments

Definitive Fusion

Definitive fusion is called such because it is a final and irreversible operation to fuse the spine, and does not directly indicate any subsequent surgical operations. Modern procedures use a pedicle screw technique that is able to achieve better correction across the 3-D deformities of scoliosis.[6] The procedure is known widely for its consistency and efficacy in correcting scoliotic curves with a low revision rate that ranges from 2% to 20% depending on the follow-up period length and the meta-analysis used.[7] That is due both to the simplicity of the construction and the strength of an ossified spinal fusion. The spinal column is fused along the length of the scoliotic curve with the placement of a spring-like Harrington rod along with pedicle screws that serve to both straighten and stabilize the spine during the healing process.[8] This rod works through a combination of the anchoring of the pedicle screws in the vertebrae and continuous distractive force on the concave portion of the curve.[9] Fusion is usually performed only after or near the cessation of growth because the Harrington rod is unable to extend; placement before the end of significant growth would lead to an abnormal shortening of the torso along with other complications. There is some evidence, however, that posterior fusion may be an indicated treatment option for patients between the ages of 9 and 11.[10] Although the sample size is fairly large and the statistical evidence strong, it is important to note that the patient demographics have an impact on the age range where definitive fusion is appropriate. Those factors along with an analysis of spinal maturity scores are important in determining in which patients definitive fusion may be indicated.

The fusion of the spine and stability of the instrumentation allows for, and in many cases requires, the operating physician to perform techniques that release or remove the natural stabilizing mechanisms of the spine that are corrupted by scoliosis.

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[6] Ma et al.
[7] Shin et al. Riouallon et al.
[8] Glossary, Figure 3.1
[9] Xu et al.
[10] Xu et al.

Those techniques, in turn, can increase the amount of correction achieved. Natural stabilizers that can be removed include the intervertebral disks, postural muscle, and connective tissue surrounding the spine.

The two main drawbacks of Harrington rod fusion are that it does not allow room for growth and it does not preserve motion. The former limits the age range for which fusion is an appropriate operation. The latter can lead to both limitations in the types of activities the patient may perform post-operatively, and degradation of the disk immediately rostral and caudal to the surgical site.[11] There is also an increased risk for injury in the event of an unexpected forceful trauma, such as that associated with a motor vehicle collision. Both of the above-delineated drawbacks become more severe with a fusion procedure involving more vertebrae.

During the healing period, the combination of complete disk removal, bone grafts, and spinal immobilization by the rod leads to spinal vertebral fusion. That eventual fusion of the spine is the main stabilizing mechanism of the operation and is much stronger than any rod alone could be. A definitive fusion operation will usually have a recovery period of at least six months to allow the fusion to set and the soft tissue disruption to heal.

Growing-Rod Procedures

Growing-Rod procedures were developed to account for definitive fusion's inability to account for the growth of the patient, and to allow earlier surgical correction. The solution was to develop a procedure that uses rods that can be lengthened; the rods themselves serve as the primary stabilizing mechanism to correct the scoliotic curve (as

[11] Sherman et. all

opposed to complete spinal fusion) with fusion of the vertebrae only at the anchor points of the rods.[12] The lengthening procedure of the rods will introduce progressively added distraction of the spine to correct the coronal curve. Upon the patient reaching full adult growth, definitive Harrington rod fusion is performed.

There are two variations of Growing-Rod available for use in this type of procedure, conventional Growing-Rods (CGR) and magnetic Growing-Rods (MGR). CGRs require additional surgeries to lengthen the rods during the therapeutic course, whereas MGRs can be lengthened with extracorporeal magnets. The advantage of CGRs is that they tend to have fewer mechanical failures, resulting in a reduced number of unplanned subsequent operations compared to the magnetic variety.[13] Because of these potential unplanned operations, MGRs overall do not necessarily succeed in their goal of reducing the number of times a patient must go into the operating theater. Moreover, the unplanned nature of any returns and the need to replace failed implanted hardware upon that return may lead to a greater burden on the patient and the family than a planned procedure would. Possible points of failure of the implanted hardware include the rod breaking, which would only require an operation to replace the rod; the anchor of the rod to the vertebrae can also break, which would require an operation to revise the anchor. Failed implanted hardware may simply lead to revision of Growing-Rods, or could result in unplanned early fusion (depending on the age at which the Growing-Rods fail). Either possibility entails a lengthy recovery period.

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[12] Figure 3.2

[13] Teoh et al.

The more widely accepted CGR placement will typically require at least three additional surgical operations: two for lengthening and one for definitive fusion. The initial placement of the rods and eventual definitive fusion will both generally require a 6-month recovery for the respective fusions to set through ossification.[14] The lengthening procedures will generally have a shorter recovery. Lengthening procedures are absolutely required for CGR, else the rods will increase the severity of the curve by transitioning from spinal distraction to spinal traction as the patient grows. Therefore, the Growing-Rod procedure should not be thought of as one surgery, but rather the beginning of a treatment plan involving multiple subsequent operations. With the ideal implementation of MGR, two operations will be required. The first is the placement of the rod with a recovery of at least 6 months, and the second is the definitive fusion also with a recovery of at least 6 months.

Growing-Rods, while only involving the surgical fusion of the anchor points, also introduce a functional fusion of the spine between those anchor points. That fusion will, in most cases, lead to the ossification of at least some disks in the involved span of vertebrae; this ossification reduces the potential for both correction of the curvature over time and growth modulation. One study found that of 9 patients with Growing-Rods, 8 had autofusion with an average of 7 resultant osteotomies that had to be performed at the time of definitive fusion.[15]While the sample size is fairly small, the effect is sufficiently extreme to indicate significance.[16] This resulting autofusion is another reason that

[14] Anagnost et al, Columbia

[15] Cahill et al.

[16] The .99 1-prop z interval for 8 out of 9 is (.62, 1.16). Even with expanding the confidence interval from the usual .95 to .99 to account for the inherent non-normality of such a small sample, the minimum effect rate is still a sizable .62.

definitive fusion must be performed at the end of Growing-Rods treatment, in order to harness and control the fusion that has already taken place. In the event that the spine is not surgically fused post-autofusion, the stabilizing effect of auto-fusion would not be as robust as in a controlled fusion.

Flexible Tether-Based Surgeries

Tether-based scoliosis surgeries operate on the general principle of using a flexible tether to pull the spinal curve into alignment, much like a series of cantilevers. These procedures involve the horizontal placement of screws through the spinal vertebrae along the convexity of the curve. A flexible tether is then threaded through the heads of the screws on the convexity of the curve and subsequently pulled tight.[17] The tether is then locked in at each screw. The tightening across each vertebral pair is calibrated to achieve curve correction. In the event that the tether breaks between two screws of a vertebral pair, the correction would still be effective across all of the vertebral pairs between which the tether did not break.

The tightened tether introduces correction through a combination of traction along the convex side of the curve and distraction along the concave. The increased force on the convex side of the curve is what allows for the distraction along the concave through a cantilever effect, using the vertebral disk as a fulcrum. That will in turn theoretically increase osteoclast activity along the convexity (where there is too much bone) and osteoblast activity on the concavity (where there is too little bone). Some surgeons also believe that there is a significant amount of growth modulation in the disk to reduce the

[17]Figure 3.3

curve as well. This growth modulation would be significant given that one of the primary drivers of scoliotic hypokyphosis is a ventrally expanded disk.

One area of significance for this procedure is that rather than producing a general stabilizing force across the spine as in rod constructions, it primarily provides force counteracting and stabilizing against the pathological aspects of the curve. For example, rather than preventing bending (and spinal flexing) that both makes the scoliotic curve more or less severe, the tether only prevents bending that makes the curve more severe. The same holds for twisting and kyphotic bending. This means that most of the spine's normal stabilizing mechanisms must continue to operate, but it also allows for nearly complete spinal mobility following the procedure and no restrictions after full recovery. There are no required subsequent fusion operations. A subsequent operation is only required for revision in the event of overcorrection or if the tether breaks in enough places for the correction to no longer be sufficient.

While the maintenance of spinal mobility comes with several advantages, it also limits the scope of what the surgeon may do. This limitation and the surgical method of approach largely define the two types of tether-based surgeries. Vertebral Body Tethering (VBT) is performed thoracoscopically without lung collapse and focuses primarily on the coronal curve. Anterior Scoliosis Correction (ASC) uses a semi-open thoracotomy approach that involves collapsing the lung on the side of the surgical approach; ASC tends to involve more secondary techniques within the same operation to facilitate a full curve correction.

VBT, depending on the severity, stiffness, and axial rotation of the scoliotic curve, is generally able to correct the curve down to 20-30 degrees and reduce the axial rotation to 2/3 of its original severity. This procedure tends to achieve less correction for curves with greater axial rotation. This is due to connective tissue and disk changes that tend to hold the curve in place, preventing the curve from being corrected; in cases with greater axial rotation, the connective tissue and disk deformity tend to be greater. For these cases with greater axial rotation, rather than relying only on the initial surgical correction, the hope is that the growth modulation effect of the forces produced by the tether will lead to more coronal curve and axial rotation correction over time. Essentially, the plan is for VBT surgical correction to be followed by the patient "correcting as they grow." This approach has some difficulties, as a stiffer curve achieving less correction is more likely to break a tether. With increasing curve severity, the forces on the tether increase because the normal biomechanical stacking effect of the spine is disrupted and transfers compressive force on the spine to tensile force on the tether. A broken tether will, in turn, further reduce the amount of correction achieved. If the failure reaches a point where revision surgery is required, the laparoscopic approach will be more difficult because of scar tissue buildup resulting from the original operation. All of those factors combined make it so that VBT is more indicated for flexible curves with limited axial rotation that are likely to achieve sufficient surgical correction for the resulting system to be stable. Given the difficulty of revision surgeries for VBT, it is also more appropriate for patients that will not require subsequent surgeries because of overcorrection. The more skeletally immature the patient is, the more likely overcorrection is to occur. The exact amount of growth left is impossible to determine in a given patient, but estimates are possible. In very young patients, overcorrection in a single-stage operation is almost inevitable.

The semi-open approach of ASC attempts to address some of the problems with VBT. The greater amount of space in which to work (chest cavity with collapsed lung) allows both the placement of screws in a way that will achieve more correction of any axial rotation of the spine, and allows for some limited modification of the connective tissue that may retain a stiffer curve than is optimal for a tether surgery. Examples of potential connective tissue modification include the removal of a portion of the disk that interferes with correction of the curve, or cutting a spinal ligament that is shortened as a result of the spinal curvature. These modifications require a light and delicate touch from the surgeon, because altering the connective tissue of a spine that still has to perform normal stabilizing functions could introduce instability if done overzealously. Depending on the situation, these stabilizing issues may be offset by both the age of the patient and the amount of additional correction that may be achieved. A younger patient is more likely to heal well from a more aggressive modification of the spinal connective tissue, and a greater degree of correction will result in less work needing to be done by the modified connective tissue. Since these changes offset existing additional stress on the tissues in correction, it is unlikely that, when done well, they introduce outsized risk for the patient.

Conclusion

While a description of the surgeries is useful for understanding each individually, the overall landscape of scoliosis surgery cannot be fully realized without a comparison of the operations. Particularly, the relative superiority of the tether-based surgeries in general and ASC in particular are not immediately obvious without direct comparison. The following comparisons will also flesh out why surgical procedures are necessary in many cases of scoliosis.

Figure 3.1: Harrington Rod

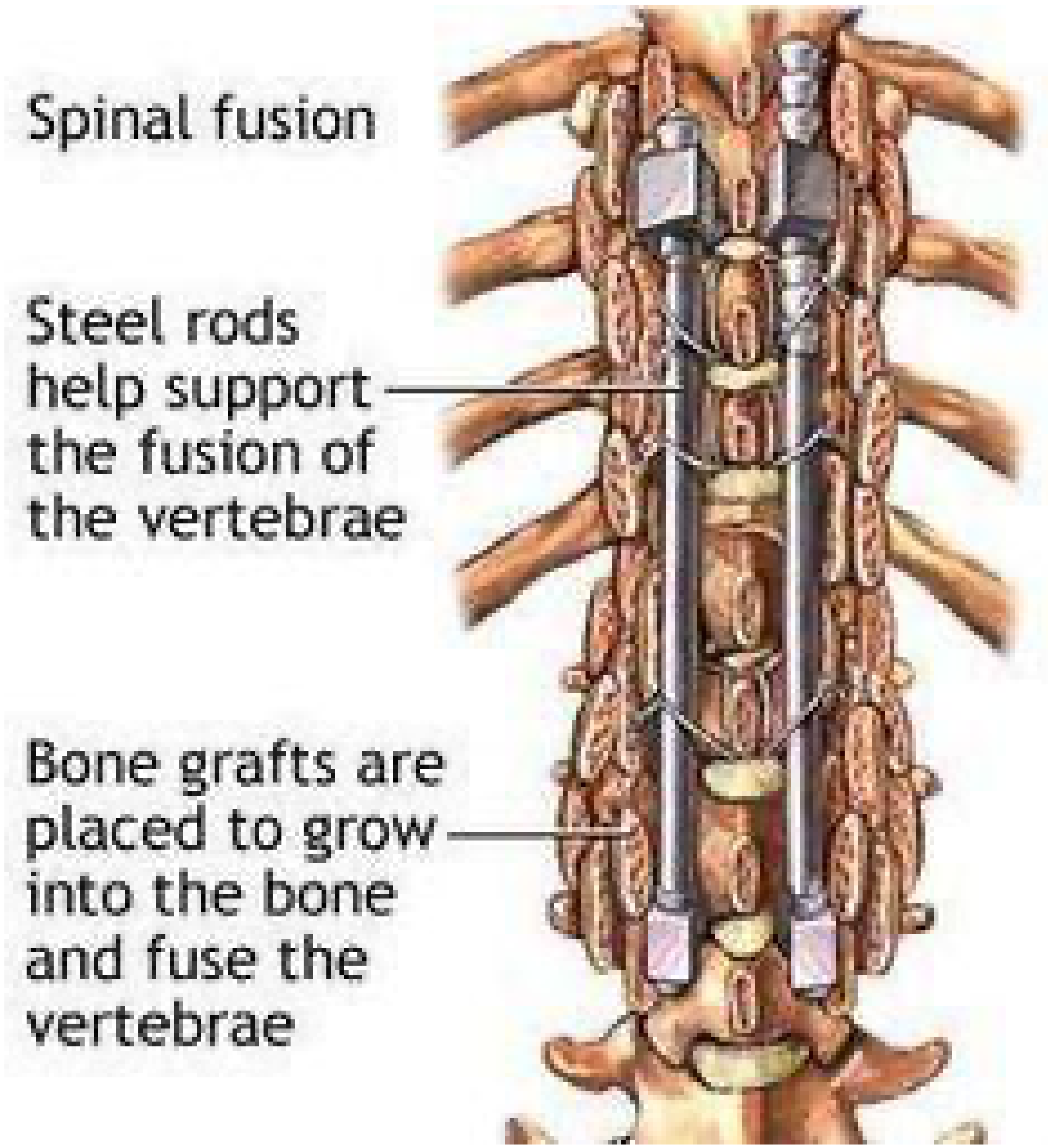
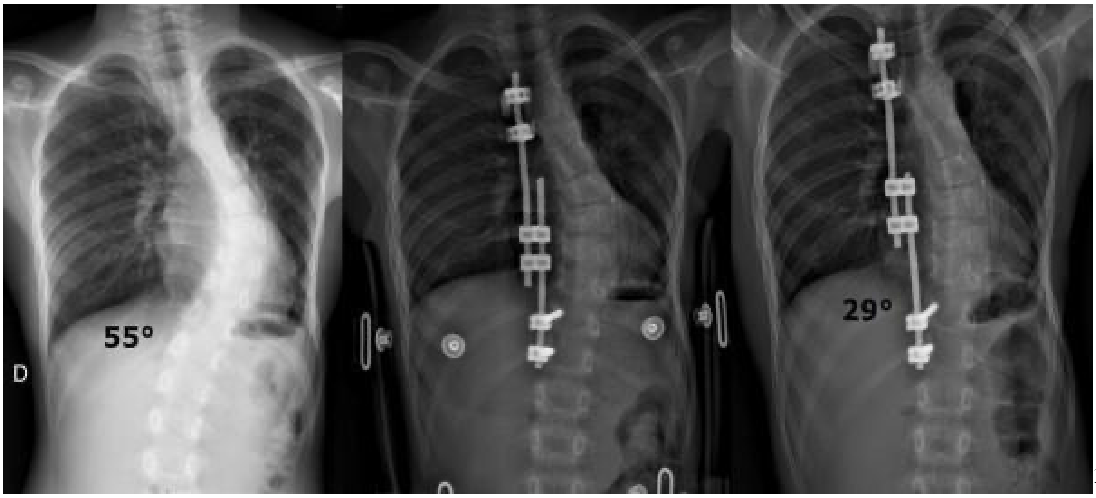
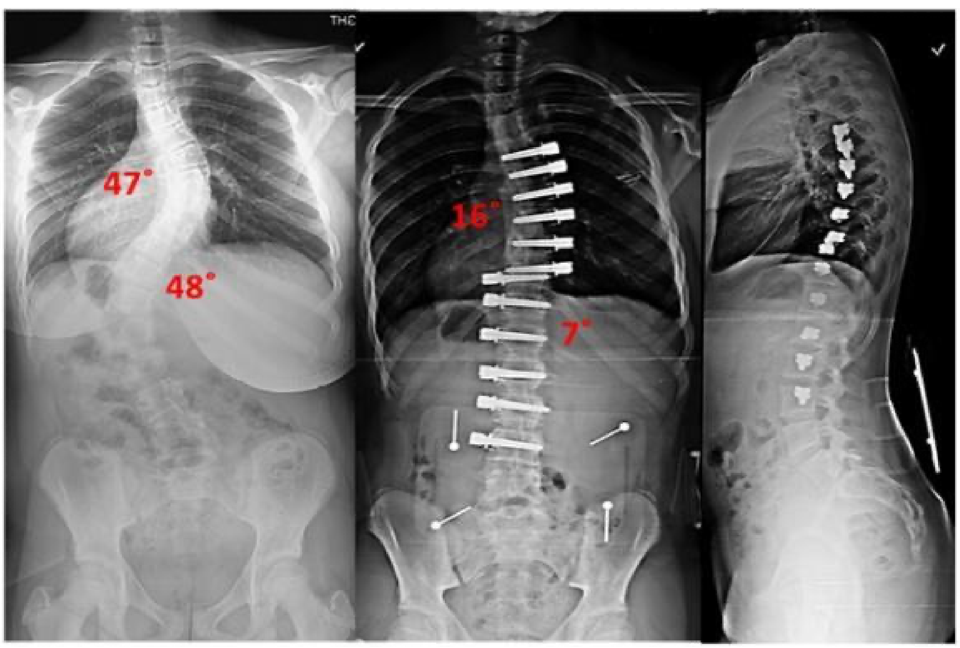


Figure 3.2: Growing-Rods



[18]

Figure 3.3 Tethering Surgery



[19]

[18] Pediatric
[19] Scoliosis

CHAPTER FOUR

Comparison of the Scoliosis Treatments

This chapter will be organized around comparisons of all previously described therapies with ASC since the argument of this thesis is that ASC is the best first-line surgical option.

Physical Therapy

Like bracing, there is little overlap between the populations where either physical therapy alone or ASC would be indicated. Physical therapy is not likely to be effective in curves above 45 degrees, the curve severity for which ASC is indicated.

The goals for either treatment option are different. Physical therapy is to reduce the progression of the Cobb Angle and improve core strength to avoid the need for surgical treatments. ASC, as described above, is for severe curves where surgery is either the only or best option given all the circumstances.

Physical therapy and ASC are treatments for two different populations, so any substantial comparison is difficult. It is sufficient to reiterate that as a conservative treatment, physical therapy's primary goal is to either delay or avoid the need for surgical intervention.

Bracing

Like physical therapy alone, there is little overlap between the groups of patients for whom either ASC or bracing would be indicated. Bracing is only considered to be effective on curves below 45 degrees, on the high-end, and surgical operations are largely only indicated for curves above that 45 degree cutoff; as such, there is little basis for comparison.

The goal for bracing is to avoid further curve progression, or reduce progression to avoid or delay surgery. Consistent with that goal, bracing is typically performed in patients whose curves do not indicate an immediate need for surgery.

The goal of ASC is to correct the curve significantly from a severe state where conservative treatment has not succeeded or is unlikely to succeed. Given its minimally invasive nature and maintenance of possibilities post-operation, ASC may be indicated even when bracing could succeed, but only at significant cost to the patient. These significant costs of bracing would include a requirement for all-day bracing protocols, severe discomfort when bracing, and irritation of the vital organs.

Although there is little overlap between the populations for bracing and ASC, there may be some based on the comparative costs and benefits of each for particular patients. In general, where ASC is indicated/appropriate, it is a superior option to bracing

Definitive Fusion

Due to the relatively destructive nature of the definitive fusion surgery requiring extensive recovery times in excess of 6 months and life-long limitations on activity, it is the more heroic option compared to either of the tether-based surgeries.[1] Its primary advantage is consistency and immediate, definitive curve correction. Since tether-based surgeries require the preservation of the existing (and often pathological) spinal anatomy, the tether-based surgeries can often be inconsistent in their results. When a surgeon does

[1] Appendix B

all of the work associated with fusing the spine, issues of asymmetric disks and deformed vertebrae are decreased significantly. The use of secondary techniques, such as removing the shortened spinal ligaments and surrounding musculature that can make correction difficult, means that the results of fusion will be more repeatable.

Definitive fusion allows for a much greater use of the secondary techniques than ASC. Despite that relative advantage for fusion, ASC allows for secondary techniques to the extent that consistency in correction is possible without impairing the stabilizing function of the spine. These techniques also allow surgeons to operate on curves where fusion would otherwise be the only reasonable course of treatment. The extent to which ASC may be preferable to fusion is not entirely clear, but given some assumptions, it may be possible to draw an approximate picture. Those assumptions are that motion preservation is a priority second only to the overall health of the patient and that the available qualitative comparison is generalizable to the population overall.

The factors affecting comparison of ASC with definitive fusion are significantly affected by the patient's age, so it is useful to divide the age groups into those having achieved spinal maturity (adults) and those who have not achieved spinal maturity (youth).

Comparison by Age Group

Adults

Adults are an age group that has generally been seen as requiring definitive fusion for severe cases of scoliosis in preference to all other surgical solutions. The population that is definitely best treated by fusion is adult scoliosis complicated by significant disk degeneration. Since ASC requires that the spine maintain its original role of stabilization, degeneration would interfere with the long-term success of this therapeutic approach.

Adults without significant spinal pathology beyond the existence of the spinal curve may be good candidates for ASC in preference to fusion, particularly those with flexible curves. It is notable that, as a whole, adult curves tend to be less flexible and would therefore require more of the secondary techniques in ASC like disc and ligament release, which would inherently increase the risk of the operation. Due to the lack of quantitative data available, it is difficult to develop hard qualifications defining the situations in which ASC may or may not be appropriate. Surgeons with expertise in both surgical procedures will be able to make those distinctions on an individual patient basis. Adult cases of scoliosis can be more complex, so all-encompassing guidelines would be impossible to outline, especially given the lack of data on ASC for that group.

Youth

Those who still have significant growth remaining are not considered good candidates for definitive fusion because of its effect on that growth.

Patients who are nearing the end of their growth have traditionally been candidates for definitive fusion, but given the advances in tether-based surgeries, there is overlap between the possible candidate populations. Those nearing the end of growth tend to have acceptable spinal flexibility profiles, some ability for long-term remolding of the originally deformed tissue, the ability to heal well from the secondary techniques, and would face a greater cost from a reduction in spinal mobility than adults. The latter is because the age group tends to have a greater and more intense baseline of physical activity. Moreover, they would face a greater period of time with a spinal fusion, placing an outsized lifetime risk of damage on the disk caudal to the fused section. That particular risk for disk health will vary with the location and length of the fusion, but the general principle holds for all fusions. ASC is superior to fusion in youth because of the above factors.

Considering the above, patients with significant growth remaining are obviously in a difficult position. The curve is sufficiently severe to indicate surgical treatment, but fusion would not be indicated because it would interfere with growth. ASC has proven to be a superb solution to this conflict. Historically, before the advent of tether-based surgeries, the solution to this quandary was Growing-Rods.

Growing-Rods

The mechanism of correction and stability for Growing-Rods is entirely different from the mechanism for ASC. While Growing-Rods rely on extension of the rod to produce a purely distractive force to produce correction, ASC relies on the cantilevering effect that provides simultaneous distraction and traction.

The two procedures produce different sources and types of stability. Growing-Rods provide rigid stability that immobilizes the spine. ASC provides stability only against progression of the curve. Those differing modes of correction and stability inform the rest of the comparison as defined by the age of the patient.

Comparison by Age Group

Adults

Growing-Rod Surgery is never indicated for adults because it was developed specifically for the purpose of treating youth with remaining growth for whom fusion is not indicated.

Youth

The only population for which Growing-Rods have been indicated is children with a severe case of scoliosis that is not treated effectively by bracing. Growing-Rod operations were developed specifically for that population because there were no other satisfactory treatment options available. At the time of development, Growing-Rods represented a significant improvement in therapy for that population. As discussed in Chapter 2, however, Growing-Rods come with significant downsides. The prevalence of autofusion (8/9), the requirement for subsequent lengthening and definitive fusion, and the long recovery times for the rod placement and definitive fusion are significant downsides to the operation. There is also the complication rate to consider. One group, for example, found a complication rate of 76% in a 37 patient cohort including 10 magnetically controlled Growing-Rod patients and 27 conventional Growing-Rod patients. That combined with pre vs. post-operational curve ratio of .67 (57.8°:38.8°) and the need for an average of approximately 9.7 lengthening operations, does not compare well with the recent data for either variation of the tether-based surgeries.[2]

The most recent meta-analysis for VBT, with a mean starting curve of 46 degrees, ended with a mean curve of 22.5 degrees at greater than 3 years after the operation.[3] That is a significantly greater amount of correction relative to the starting curve than achieved

[2] Teoh et al.
[3] Shin et al.

by Growing-Rods, and notably does not require multiple subsequent operations. The rate of unplanned revisions is also significantly lower for VBT. Although the basis for comparison is ASC for this Chapter, a VBT study was chosen because there was a meta-analysis available. It is notable that recent ASC studies available have significantly better outcomes than VBT had in this meta-analysis.[4]

While it is notable that the populations for these two studies are significantly different (7.5 years for the Growing-Rod study and 12.7 for the tether study), given the nature of both operations and case studies of younger patients, there is significant reason to believe that the pattern would hold. Some surgeons have seen initial success with ASC for patients as young as six years, although the only sources of information on those are interviews that do not delve into specific data. The main difference would be the need for anticipated revision surgeries with a frequency of less than one every 2 years for tethering surgery compared to an average of one every 9.5 months for the CGR group.

VBT

Compared to VBT, ASC is the better option in almost every respect. The recovery times are shorter because ASC does not require cutting through muscle. The repeatability of ASC in the event of complications is better because there would be no need to cut through already damaged muscle when going back in. ASC's correction is better because there are more options available to the surgeons including the angles at which the screws may be placed and the possibility of disk release. The main advantage of ASC, relative to

[4] Antonacci et al. Bernard et al.

VBT, is the entry method that allows for multiple operations in the event of the first procedure's failure.

ASC gives surgeons the option to achieve correction superior to VBT, depending on the circumstances. Bernard et al. found a post-operative correction rate of 54.3% with VBT, and 81% with ASC.[5] What is important to note in this particular study was the decision to either use or not to use secondary techniques that increase the correction beyond what the tether can do alone. Although this particular study does not indicate what the entry method for either operation was, it can be reasonably assumed that they used the same entry method for both operations due to the lack of specification. ASC is defined as a tethering surgery using the semi-open approach for the purposes of this thesis, that allows for, but does not require any secondary techniques. Consequently, both operation types described in that paper qualify as ASC as defined by this work. The difference is the decision to use or not use those secondary techniques like disk release and anterior longitudinal ligament release to increase correction. It is also important to note that the physicians opted for less correction in the VBT group because there was more growth remaining. Otherwise, they would have led to overcorrection. A similar trend can be seen in the study by Antonacci et al. They varied the level of residual curve based on how much growth is remaining to avoid overcorrection.[6]

Using ASC as the basis for comparison has shown that when conservative treatment fails, it is generally the superior operation. ASC is superior to fusion because it maintains motion, allows for low-impact revision surgery, and has a much shorter

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[5] Bernard et al.

[6] Antonacci et al.

recovery. ASC is superior to Growing-Rods because it requires many fewer operations, leads to better correction, has a much shorter recovery time, and does not require subsequent definitive fusion. ASC is superior to VBT because the improved entry mechanism allows for revisions when needed, and more consistent correction using secondary techniques.

Comparing the different scoliosis treatments available provides significant insight. However, it also highlights that there are several areas where the gaps in the available literature limits the efficacy of that comparison. The next chapter will address those gaps.

CHAPTER FIVE

Defining Scoliosis, its Manifestations, and the General Implications Thereof

There are some profound gaps in the available literature on Scoliosis Treatments. Those gaps are in several areas: the efficacy of different physical therapy and bracing protocols, long-term disk effects in fusion operations, risk factors for instrument breakage in Growing-Rods, and tether operations in older (patients older than 20 years) and younger (less than 8-year-old patients).

Physical Therapy

The literature contains an extensive variety of physical therapy regimens used to treat scoliosis. The main problem with the data available is that the protocols used in the studies all vary significantly. The types of protocols used vary based on whether the treatment tested is physical therapy alone or with bracing. They also vary according to the type of physical therapy and the amount of physical therapy. All of those factors could affect the results of a study. That variance also reduces the possible statistical strength for a meta-analysis. This lack of strength would only be fixed by a much larger proportion of the treatment providers collecting data on scoliosis treatment plans involving physical therapy.

Bracing

Bracing seems to have sufficient data to understand its overall effects. There are, however, limitations attributable to the variation in the kinds of braces available. A rigid brace that is designed as specifically for the patient as possible and changed out as often as is useful would have a very different effect than a soft brace that is never changed.

Between these two ends of the spectrum would be a brace that is adjusted to a middling degree to the patient and replaced with a reasonable, although not ideal, frequency. Studies investigating the varying efficacy of those different bracing regimens are sparse. Further complicating the issue is that physical therapy often accompanies bracing, which will further change the results. All of those factors combined complicate the literature. Despite that complexity, it is theoretically possible to develop studies with sufficient statistical strength to parse the differences in treatment.

Since the population of scoliosis patients that are in a brace is reasonably large in a statistical sense, and they are in a phase of treatment that lends itself well to study follow-up, the collection of data that takes all of the different bracing regimens into account would be possible although difficult. Determining how effective bracing is in the context of an overall conservative treatment plan would help to sharpen the lines between the ideal patients for that intervention and those that other treatments would better serve. In that vein, it would be negligent to ignore that there is a significant time and social cost to executing a comprehensive conservative treatment plan; an ideal treatment plan should consider these factors in addition to that of mere effectiveness. If a child, who needs time to develop properly into adolescence and adulthood in a healthy manner, spends 20 hours a week on active scoliosis treatment and has their ability to play spontaneously reduced by wearing a brace, the cost will be significant. Those considerations are more difficult to grasp with just data, but some data collection in that area further supported by quantitative research on childhood development would help draw the lines circumscribing ideal bracing therapy.

Growing-Rods

While there are some studies on the Growing-Rod surgeries, the number of studies performed and the size of the data sets are lacking. In particular, there has been little statistical analysis of the risk factors for implanted instrument breakage. Instrument failure can be either in the rod, which would only require a surgery to replace the failed portion; or the anchor, which would require surgery to revise that portion. Failure at the anchor would lead to a revision requiring a longer recovery period. Since the rate of breakage is so significant, it would be useful for both researchers and surgeons to be able to predict when that outcome is likely. Given the nature of Growing-Rods, it may be impossible to prevent implanted instrument breakage adequately. That difficulty lies in the fact that the overwhelming majority of the stabilization offered is by instrumentation that has to be able to extend, making the Growing-Rod inherently less stable than other instrumentation. Given the inherent instability of scoliotic curves, it is difficult to account for the forces caused by movement and physical activity. Reducing physical activity is a possibility, but it may be insufficient.

The intervention of reducing activity is clearly not ideal because it will significantly impact the post-operative child's development. Nevertheless, assuming it is possible to adequately handle the risk of instrumentation breakage without inhibiting development to an unreasonable degree, an increase in the amount of data concerning factors of physical activity would be useful. It may also indicate which types of physical activity are most likely to break implanted Growing-Rod instrumentation. Physicians could, in turn, give targeted recommendations that patients may be more likely to follow.

Empirical data may be able to bring out subtleties regarding the different risks involved in physical activity that expert rationale could not.

Fusion

Definitive fusion is so consistent an operation that the data available give a good accounting of its effects. However, the one area that seems to be underrepresented in the literature is the long-term morphological and pathological effects on the disk caudal to the fusion in scoliosis specifically. Those effects vary widely based on human variation, including the propensity for inflammation in the disks and the ability to heal. If a hypothetical surgical operation only varies in the length of recovery based on those factors, it is one thing. Long-term effects are another thing altogether, as they do not vary solely with length of recovery. Instead, there is likely significant variance in long-term effects of fusion throughout the population. The more variance in a population, the more data are needed to find the reality of the situation with an adequate degree of certainty. Finding the long-term results of fusion when one begins transitioning to old age would help clarify the extent of the long-term consequences. It may also help reveal the populations for which definitive fusion would be a superior alternative to a tether-based surgery. While that data would be useful, it would be challenging to obtain.

There are difficulties in obtaining data for fusion’s long-term results during transition to old age, primarily due to the length of follow-up that would be necessary. Most fusion operations are done on adolescents, so there would have to be follow-up that lasts over 50 years to understand the full effects of fusion specific to scoliosis surgery. That is a significant hurdle, as loss to follow-up would be difficult to prevent. It would also require a level of forethought and investment that is rare, although not unheard of.

The effort, however, would lead to significant rewards. One means of accomplishing this long follow-up would be to develop a database of those who have received scoliosis fusion surgeries, recruit them for a study, and do a retrospective cohort analysis of the data. That method would come with limitations, but the increase in the data pool size would help alleviate the problems, especially with a judicious stratification of the data set accompanied by genetic analysis.

Tether-Based Surgeries

As the newest surgical procedures for scoliosis, there is a paucity of data for tether-based surgeries. The practice is still in its infancy, and there are wide-ranging implications in its development that have not yet been realized. There is a significant possibility that tether-based surgeries will supersede even some of the conservative treatments. There is currently a robust argument that because of the short recovery and significant correction of anatomy with few sequelae, tethering surgery is, in effect, less heroic than bracing for 20 hours every day. In order to resolve this argument, it will be necessary to publish data and case reports on tethering surgery patients that could otherwise have been treated by more traditional measures. That includes cases of pediatric patients and older patients. It will need to include more data on patients that would have received definitive fusion or Growing-Rods, been braced, or prescribed physical therapy.

The advent and the development of tether-based surgeries will and already has redrawn the lines of appropriate scoliosis treatment. Right now, those lines are blurry, but data analysis will bring them into sharper focus, thereby allowing for better and more consistent treatment. Consistent standards, supported by data, will also bring in more surgeons to a sparsely populated field. The process to become a procedural expert is lengthy, so the sooner more comprehensive data is published in article format, the better.

There are some meta-analyses available for VBT, and recently there has been publication of high-quality studies on ASC. These new studies improve the situation significantly. Unfortunately, the quality of the meta-analyses is limited by the total amount of data available to review.[1] The amount of data available for ASC is much more limited than for VBT, so it does not approach the volume needed to perform a meaningful quantitative meta-analysis.

The FDA relies on those analyses to develop guidelines for surgical procedures. To put it bluntly, as long as there is not rigorous and varied statistical analysis of surgical procedures in areas with sparse or absent publication, it will be very difficult to get FDA approval for said procedures. That lack of approval will in turn make existing surgeons less willing to adopt the new techniques out of risk to themselves and a lack of surety toward their effectiveness. It is therefore essential that the surgeons who are operating on those age groups and finding success publish exactly what they are doing to find that success and what exactly the nature of that success is.

[1] Shin et al.

CHAPTER SIX

The Future of Scoliosis Treatment

Conclusion

Although this thesis concerns the development of scoliosis surgeries and treatments in general, it focuses on ASC, the most novel of the approaches. That is because the evidence available indicates that ASC will redraw the lines of scoliosis treatment. It may take the place of physical therapy and bracing because the six week recovery is of lower cost than aggressive conservative treatment. ASC will take the place of fusion operations as the less heroic but just-as-effective option. ASC will take the place of Growing-Rods because it does not require subsequent fusion or lengthening operations, has a lower complication rate, and retains motion. The question then is not whether ASC has a place in the future landscape of scoliosis surgery. Instead, the question is, where do the other options still have a place?

Physical Therapy

Physical therapy is of limited overall efficacy in the treatment of scoliosis. As a conservative treatment, its range of effectiveness ends at around 45 degrees. Before that point, it is an effective treatment to either delay progression of the curve or reverse it. Use of physical therapy alone is not considered to be standard of care in scoliosis treatment.

It is the view of this author that physical therapy should be used more often in cases of scoliosis that require bracing. That is because it has the possibility to both improve the outcome of treatment and improve long-term core strength. If ASC becomes the default scoliosis surgery, increased core strength may help improve results. It is also possible that in some instances, postoperative physical therapy may help improve the results of ASC. Since ASC maintains the spine's existing stabilizing mechanisms, that is a possibility.

Given the preceding, the conclusion that can be made of physical therapy relative to ASC is that they cover different severities of scoliosis curves. However, given the relatively low impact of the ASC operation, it may be appropriate for some patients that currently are prescribed physical therapy. Physical therapy may be an effective adjunct to ASC since there is reason to believe that the success of ASC depends partly on the patient's truncal stability.

Bracing

Bracing appears to have a continuing role in scoliosis treatment because there will continue to be minor cases of scoliosis that can avoid surgery altogether through its use. However, given the difficulties implicit in the treatment, bracing's place may shrink with the introduction of effective surgeries with shorter recovery times. It is possible that over time scoliosis treatment will reach an equilibrium that involves operating on more minor cases. Bracing is a years-long commitment that requires constant compliance to be effective. Those years can involve pain, skin irritation, and lung and kidney dysfunction.[2] These difficulties are in addition to core-muscle atrophy and undesirable growth modulation. There are a few possible situations where the curve severity threshold to perform surgery is lowered. The first is that the patient finds the brace intolerable. The second is that the physician wishes to avoid the growth modulating effects attendant with

[2] Zhang et al.

the amount of bracing required to prevent the progression of a specific curve. The third is that the patient shows a pattern of continued progression despite bracing.

In those cases, it may be preferable to operate in order to avoid the secondary deformation effects that would result from waiting for progression to the 40-45 degree threshold for ASC. If future surgery is deemed likely, it could be best to head off the negative effects of bracing and possibly lead to a greater level of correction by performing ASC at an earlier point. Curves tend to become stiffer as they progress, so earlier treatment on small curves may allow surgeons to achieve better long-term results. As tether-based surgeries become more common, physicians will have the tools to make those kinds of decisions in dialog with patients and their parents. Bracing is an effective treatment in many cases of scoliosis. That effectiveness is likely to continue, but with the addition of more and better tools for treatment, there is likely to be some curtailment of its overall role in deference to ASC, which gives superior results compared to bracing for a given degree of scoliotic curvature.

Consistent with bracing's previous role, surgical treatment is still the best option for patients whose curves are so severe that bracing is no longer effective. The preferred surgery in that situation is now ASC.

Surgical Treatments

While there is partial overlap between the treatment ranges for conservative treatment and ASC, the overlap between ASC and the other surgical treatments is more complete.

Fusion

There may be a continued place for fusion in the treatment of scoliosis. That would primarily be if the patient has a spinal condition such as degenerative disk disease that would require fusion even without scoliosis. In other cases, where the spine is healthy except for a scoliotic curve, performing a fusion operation would no longer make sense. That is regardless of the relative stiffness of the spine. With the modern implementation of ASC, surgeons can perform disk releases, place parallel tethers, and perform multistage operations. Given the ability to use all of those techniques to improve correction, there is unlikely to be a case of scoliosis so severe that it requires the complete removal of the disk and fusion of the spine to achieve correction.

There are two primary advantages of ASC over fusion. The first is that it is a motion-preserving surgery. That means that the normal functionality of the spine is preserved post-operation. It also means that the later effect of disk degradation caudal to the fused section is avoided.

The significance of the second advantage is impossible to overstate. No options are sacrificed by performing ASC. It is possible to revise with a new tether in the event of failure. It is also possible to perform a fusion operation in the event of failure. For fusion, the operation is definitive. It is impossible to go back to a normal spine post-fusion. That makes the choice of ASC over fusion obvious. ASC removes no options, has a minimal recovery time, preserves motion, and is likely to succeed; fusion closes off all other options, has an extensive recovery time, does not preserve motion, and has a success rate at best 15 percent higher. The benefit of reduced need for reoperation with fusion does not come close to making up for its losses in the other categories when compared with ASC. Ultimately, in patients where both ASC and fusion are indicated, ASC is the superior choice.

Growing-Rods

It is difficult to see a future for Growing-Rods in scoliosis treatment. They simply have too high of a cost to the patient. The complication rate of 76%, high rate of autofusion, low amount of correction, minimum of a 6-month recovery, need for subsequent operations averaging less than a year apart, and necessity of subsequent definitive fusion do not paint an encouraging picture for the operation. That is especially true when compared to ASC, which in most cases requires a single operation with a six-week recovery. The one caveat to that conclusion is that there is no quantitative data on the performance of ASC in a pediatric population. Given the rationale behind the surgery, and the fact that some surgeons are seeing initial success with that patient group, the positive results in adolescents are likely to translate well to pediatric patients.

Growing-Rods were a great innovation at the time of their development because they treated a population that would otherwise require premature definitive fusion or aggressive bracing protocols that do not fully stop curve progression. While the operation does not provide much curve correction, it is more than capable of halting progression and does lead to more successful fusion operations later in life. ASC is an option in every patient in which Growing-Rods is indicated, and is superior in approach and outcomes; as such, ASC will likely obviate the role of Growing-Rods in the near future, leading to a significant improvement in the quality of life for pediatric scoliosis patients.

ASC, because of its numerous advantages over other scoliosis treatments, is going to either reduce or entirely remove the role of the other treatments. ASC could take the place of bracing in patients that would otherwise require heroic nearly all-day bracing protocols. ASC could take the place of physical therapy because the low patient-burden of the operation could move the window for surgery to a lower range than 45 degrees in some cases. Most cases of scoliosis treated with fusion could be treated ASC. If ASC is chosen in those cases, the role of fusion in scoliosis will be reduced to the periphery. There is nothing that Growing-Rods do that ASC cannot do and ASC does them with a shorter recovery, fewer operations, and no activity limitations. With those possibilities there is a need for more surgeons to start performing the operations because there are nowhere near enough to handle the 30,000 patients requiring scoliosis surgery per year.

ASC still has the limitation of relying on the existing anatomy for stabilization. That makes it so that some cases of adult scoliosis with disk degeneration would indicate fusion as the better operation. The following section discusses a possibility to remove that problem.

Possibilities for a Future Modality

It is essential to state that this section is purely speculative and based on an overwhelming lack of personal expertise of the author. Despite that, it will try to speculate on a future possibility for a surgical procedure beyond and superior to ASC.

One problem with ASC is that it relies almost entirely on the body's built-in stability mechanisms. In the absence of a functional disk, for instance, the surgery cannot be performed. Instead, fusion would be the indicated operation. There is a novel approach to disk pathology, however: the replacement of the pathological disk with an artificial one, a procedure known as disc arthroplasty. That replacement allows for the maintenance of normal spinal function while getting around what would otherwise have been a need for surgery.

Arthroplasty would be an exciting idea in scoliosis treatment for a few reasons. The first is that one of the main drivers of the scoliotic curve is the deformation of the disks. The ability to replace them would help with that problem. It would help achieve a normal level of kyphosis in the spine and replace the wedge-shaped twisted disk with a disk with normal morphology. The second is that inflammatory markers in disks tend to be elevated by scoliosis, increasing the risk of degradation. If the patient is older with a severe curve, there is likely to be additional disk pathology from scoliosis that cannot be fixed by just correcting the curve.

Disk replacement would come with problems or limitations. For one thing, it would make the operation significantly more complex. Usually, arthroplasties are stand-alone operations and are usually limited to replacing 2-3 discs at once. The additional complexity introduced by scoliosis would require in-depth expertise that most spinal surgeons do not possess. So not only would the practitioner have to be an expert in ASC, they would also have to be an expert in arthroplasty. Additionally, just as the arthroplasty would make the ASC more complicated, the ASC would make the arthroplasty more complicated. The surgeon is not dealing with normal spinal anatomy where the design of the new disk will fit in perfectly as designed. The surgeon would then have to be excellent at two non-overlapping surgical disciplines. The use case would also be limited for the surgery. A surgeon can only replace so many disks. That means that the disk pathology would have to be limited to a few.

Additionally, the durability of the artificial disk is significantly affected by the alignment of the vertebrae directly rostral and caudal. The better the alignment, the more durable the arthroplasty is likely to be. Scoliosis would naturally lead to worse alignment because the spine is not vertically stacked. The insertion of the artificial disk would help alleviate the problem because asymmetry in the natural disk is a significant cause of that alignment problem. One possibility is a two-staged surgery where ASC is performed first with the expectation of inserting the artificial disk later. This would allow for more planning in the artificial disk operation and possible further tightening of the tether in the second operation leading to better alignment of the vertebrae immediately rostral and caudal to the curve.

The Path Forward

The current state of scoliosis surgery is not the best it could be. There are still patients receiving surgeries that have life-long negative consequences. Growing-Rod surgeries always require subsequent definitive fusion. Additionally, although incredibly effective at correcting curvature, definitive fusion comes with significant consequences. The place for fusion surgeries should be far smaller than it currently is, limited to cases where fusion likely would have been required otherwise.

There are multiple factors currently limiting the adoption of newer surgeries such as ASC. The first is that VBT has many more practitioners than ASC. VBT has limitations on the severity of the curve that can be corrected, the stiffness of the curve that can be corrected, the ability to revise a failed operation, and lasting spinal rotation that requires continued growth to correct. These factors limit the age range in which the operation may be performed.

There are several problems that prevent more wide-range adoption of ASC. It is a relatively new operation. Even with improved methods of communication provided by technology, the modern medical landscape still takes significant time to adapt to new methods. Moving to a new surgical procedure requires a significant upfront cost of developing experience. Those who perform traditional rod-based operations and VBT know the subtleties of those operations and, therefore, know what to expect. Primary care providers are also part of that paradigm and have knowledge of rod-based operations. Additionally, it is unreasonable to expect practitioners to jump into the unknown. It would be irresponsible to do so. The marginal cost of staying at the forefront of development in any field is high and, in many cases, does not produce a corresponding benefit. The current state of affairs is both a likely and reasonable one. Given time, however, those barriers will fall.

There is also the complexity of ASC operations. They require the knowledge of both an orthopedic surgeon intimately familiar with the spine and a thoracic surgeon skilled in thoracoscopy. Beyond the breadth of the surgeon's skill is the consideration of the behavior of the ASC-instrumented spine itself. A spine with continued mobility will behave differently than a spine that has been fused. This effect is compounded by the initial scoliotic state of the spine. The founders of the ASC surgery had a lengthy development period for their current iteration after having performed fusion most of their careers, so that problem is not unexpected. There is also the added complexity of the secondary techniques essential to applying ASC to a broader range of patients. It is impossible to operate successfully on most curves over 60 degrees or in older patients without those secondary techniques. The list of difficulties above only scratches the surface of the situation.

In time, the problems with the adoption of ASC will be resolved. It is more difficult to lay a path than to follow one. That principle applies to the medical world.

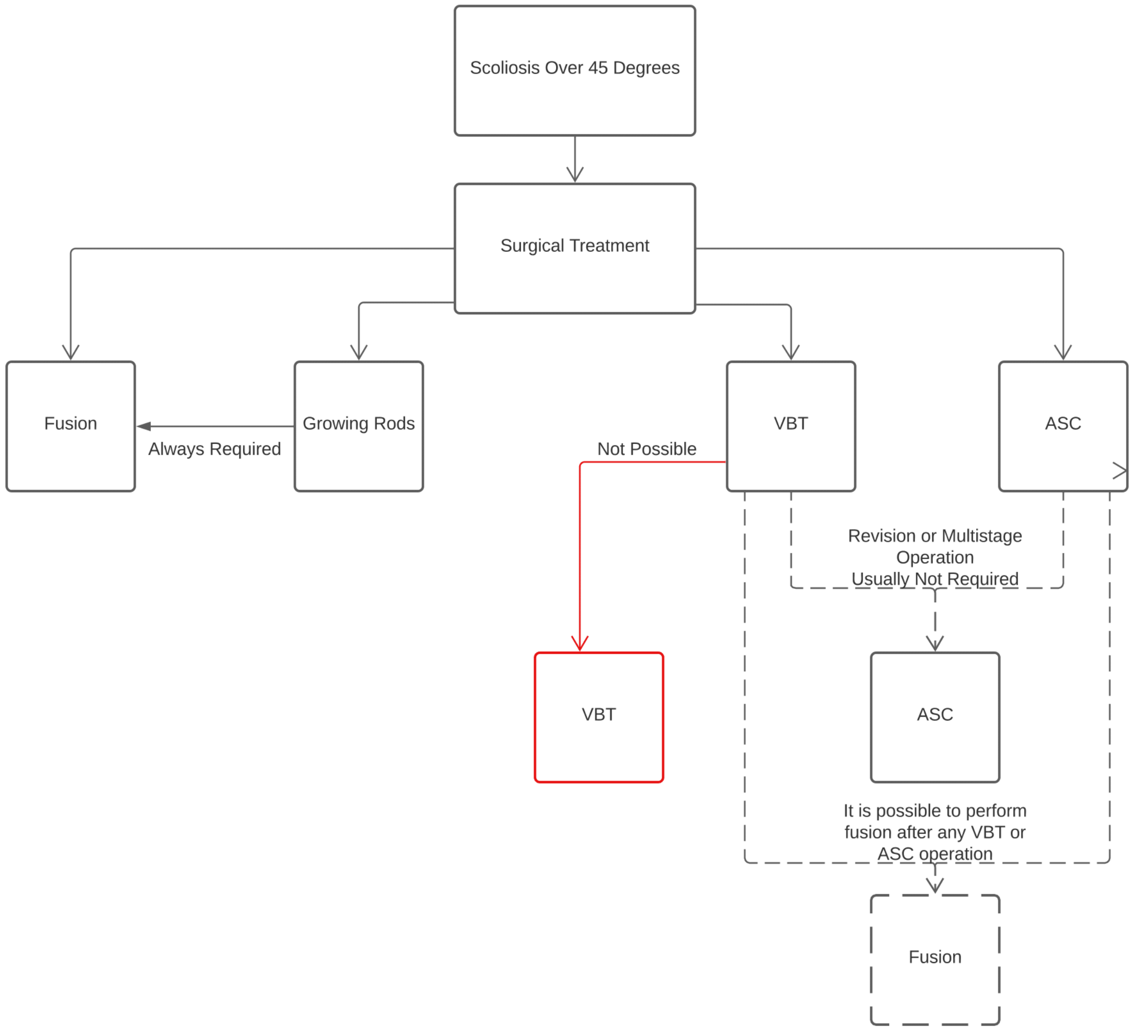
Surgeons have thought about the operations for nearly a decade now. Most of the technique perfection for ASC and VBT has been done. The amount of information available on the surgery increases every single year. Moreover, there are workshops to learn the basics of VBT now that it is an on-label use of the equipment. Just recently, there have been two major studies on ASC indicating similar correction to fusion and a low rate of complications. One possibility for the future of ASC is its inclusion in the training that a spine surgeon receives as part of residency. A fellowship may also be appropriate given the complexity of the ASC operation. That will allow surgeons to acquire the expertise necessary to perform the surgery just a few years after leaving residency.

What is needed now is for more surgeons to start performing tether-based operations. There is evidence that the benefits outweigh the upfront cost of learning. Conversations with those who already perform the operations will be at least as important moving forward as the published data. While published data can give a general view of the situation, it cannot have the same impact of personally addressing the questions that another expert on orthopedic spinal surgery has. Beyond that, primary care providers should become acquainted with the available literature regarding VBT and ASC, focusing on the more recent studies. Primary care providers have a significant effect on the course of treatment. Beyond that, however, they have the advantage of a generalist viewpoint from which they can more clearly perceive the various concerns a patient may have.

While tether-based surgeries have seen a relatively long adoption period, it is vital to note that the overall movement of scoliosis surgery has been positive. The outlook for the future is even more positive. Just a decade ago, the only good option for a patient with scoliosis requiring surgery was fusion, with all of its associated costs. Developments in ASC have continued to expand the populations for whom fusion is no longer necessary. Additionally, ASC is on its way to obviating Growing-Rod surgeries. It is reasonable to expect that trend of improvement to continue, whether it is from an increase in the number of surgeons performing ASC or developments in the operation. There have been challenges in the adoption of motion-preserving scoliosis operations. Nevertheless, the direction is positive, and the progress can be reasonably expected to continue.

APPENDICES

APPENDIX A



Scoliosis Over 45 Degrees
Surgical Treatment
Fusion
Growing Rods
Always Required
VBT
ASC
Not Possible
VBT
Revision or Multistage Operation Usually Not Required
ASC
It is possible to perform fusion after any VBT or ASC operation
Fusion

APPENDIX B

<table>
<tr><th>Operation</th><th>Description</th><th>Advantages</th><th>Limitations</th><th>Comparison with ASC</th></tr>
<tr><td>Fusion</td><td>The spinal column is fused along the length of the scoliotic curve with the placement of a spring-like Harrington rod along with pedicle screws that serve to both straighten and stabilize the spine during the healing process.
The disks, spinal musculature, and supporting ligaments are removed along the fused section.
The fused section becomes like a single bone during the 6 month to 1 year recovery period</td><td>• The most consistent surgery
• Has been performed the longest
• Can be performed on almost any fully-grown spine</td><td>• The mobility of the spine is reduced along the fused section.
• Activity is limited depending on the location of the fused section
○ No barbell squatting
○ Limited thoracic hyperextension
○ Limited movement in the axial plane
○ Limited ability to lift objects from the ground
• Degradation of the disk caudal to the fused section
• 6 month to 1 year recovery period</td><td>• ASC maintains full motion and ability
• ASC has a shorter recovery period
• ASC has easier revisions
• ASC achieves similar curve correction</td></tr>
<tr><td>Growing Rods</td><td>The surgeon implants rods that can be extended through subsequent operations.
These rods are anchored at fused sections of the spine rostral and caudal to the section of the spine with the scoliotic curve.
The rods are lengthened as the patient grows using subsequent operations
The rods are the primary stabilizing mechanism of the spine post-operation.</td><td>• Can be performed on spines with significant growth remaining
• Allows patients to avoid extensive bracing in childhood</td><td>• Always requires several lengthening operations.
○ The frequency of lengthening is every 6 months to 1 year
• Always requires fusion after full growth is achieved
• Has a relatively high revision rate
• Activity is even more limited than with fusion
○ This is to avoid the need for revision
• 6 month to 1 year recovery period</td><td>• ASC maintains full motion and ability
• ASC has a shorter recovery period
• ASC has easier revisions
• ASC has a lower complication and revision rate
• ASC requires only 1 surgery in most cases, rather than several</td></tr>
</table>

Vertebral Body Tethering	The surgeon performs a horizontal placement of screws through the spinal vertebrae along the convexity of the curve using a closed thoracoscopic surgical approach. A flexible tether is then threaded through the heads of the screws on the convexity of the curve and subsequently pulled tight. The tether is then locked in at each screw. The tightening across each vertebral pair is calibrated to achieve maximal curve correction.	• Maintains full range of motion • Recovery period of only 6 weeks • Can correct most surgical cases of scoliosis	• Limited to curves below 60 degrees • Limited ability to correct "stiffer curves" • Difficult to revise using the same entry mechanism • Provides limited correction of the axial rotation component of scoliosis • Limited to patients with a few years of growth remaining (generally 2-3 years)	• ASC can correct more curves • ASC can achieve more correction • ASC is easier to revise • ASC has a lower rate of revision • ASC corrects the axial rotation and hypokyphosis aspects of scoliosis more effectively

Anterior Scoliosis Correction	The surgeon performs a horizontal placement of screws through the spinal vertebrae along the convexity of the curve using a semi-open thoracoscopic surgical approach.
	A flexible tether is then threaded through the heads of the screws on the convexity of the curve and subsequently pulled tight.
	The tether is then locked in at each screw.
	The tightening across each vertebral pair is calibrated to achieve maximal curve correction. If the patient has
		• Can correct almost any curve
		• Is relatively easy to revise with the semi-open thoracoscopic surgical approach
		• Can correct the axial rotation component
		• Maintains full range of motion post-operation.
		• Maintains full ability post-operation
		• Recovery period of only 6-weeks
			• Is less consistent than fusion
			• The amount of initial correction achieved has to be reduced if the patient has growth remaining
			  ○ This is to avoid over-correction
			• Some surgeons have indicated concern over the microdiscectomies causing long-term disc problems
			  ○ There have been 1 year post-op MRIs performed that indicate that this is not likely	

Anterior Scoliosis Correction Cont.	significant growth remaining the surgeon may leave a larger curve to prevent over-correction. The semi-open thoracoscopic approach allows secondary techniques to be employed that can improve correction. • Microdiscectomy (disk release) • Anterior longitudinal ligament release Adjustment of the axial position of the screws to improve the axial rotation component of scoliosis	• Typically only requires 1 operation		

GLOSSARY

- Anterior Scoliosis Correction
    - The tether-based surgery with an anterior thoracoscopic approach, including lung collapse allowing for secondary techniques, additional 3D correction, and multi-staged operations/revisions
- Idiopathic
    - A disorder that cannot be tied to a root cause
- Thoracic Insufficiency Syndrome
    - Insufficient space in the thoracic cavity leading to breathing and cardiovascular deficiencies
- Vertebral Body Tethering
    - The tether-based surgery with a thoracoscopic approach without lung collapse that only allows for tether placement and difficult to impossible multi-staged operations/revisions
- Pedicle Screws
    - Screws that allow rods to interact with the spine at multiple points in definitive fusion, this allows for improved 3D correction and a better rate of fusion.
- Vestibular Asymmetry
    - When the body’s system that orients the body in space and relative to itself is not accurate, this can exacerbate scoliosis by affecting self-perceived posture and muscular activation.

TABLE OF ABBREVIATIONS

1. TIS
    a. Thoracic Insufficiency Syndrome
2. CGRs
    a. Conventional Growing-Rods
3. MGRs
    a. Magnetic Growing-Rods
4. VBT
    a. Vertebral Body Tethering
5. ASC
    a. Anterior Scoliosis Correction

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