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Idiopathic Scoliosis

[Clinical Policy Bulletins](#) | [Medical Clinical Policy Bulletins](#)

Number: 0398

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Policy

Scope of Policy

This Clinical Policy Bulletin addresses idiopathic scoliosis.

Policy History

[Last Review](#)  02/15/2024
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[Review History](#) 

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Additional Information

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I. Medical Necessity

- A. Aetna considers surface electrical muscle stimulators (direct or alternating current, not high-voltage galvanic current) experimental and investigational for the management of idiopathic scoliosis because there is inadequate evidence of its effectiveness and safety in the peer-reviewed published medical literature.
- B. Aetna considers surgery (e.g., spinal fusion with instrumentation and bone grafting) for the treatment of idiopathic scoliosis medically necessary for *any* of the following conditions:
1. Idiopathic scoliosis with curve greater than or equal to 40 degrees in an adolescent younger than age 18; *or*
 2. Idiopathic scoliosis with curve greater than or equal to 50 degrees in a young adult age 18 to 25.
- C. Aetna considers growing rods technique medically necessary in the treatment of idiopathic scoliosis for persons who meet criteria for surgery above. Please note this includes the MAGEC System; but does not apply to other expandable magnetic growing rods (e.g., Phenix Growing Rod device) which are considered investigational and experimental.

Scoliosis braces and casts

1. Aetna considers an orthosis (orthopedic brace) and/or prosthesis medically necessary when:
 - a. Care is prescribed by a physician, nurse practitioner, podiatrist or other health professional who is qualified to prescribe orthotics and/or prosthetics according to state law; *and*
 - b. The orthosis or prosthesis will significantly improve or restore physical functions required for mobility related activities of daily living (MRADL's); *and*

- c. The member's participating physician or licensed health care practitioner has determined that the orthosis or prosthesis will allow the member to perform ADLs based on physical examination of the member; *and*
- d. The orthosis or prosthesis is provided within six months of the date of prescription; *and*
- e. The orthotic or prosthetic services are performed by a duly licensed and/or certified, if applicable, orthotic and/or prosthetic provider. (All services provided must be within the applicable scope of practice for the provider in their licensed jurisdiction where the services are provided); *and*
- f. The services provided are of the complexity and nature to require being provided by a licensed or certified professional orthotist and/or prosthetist or provided under their direct supervision by a licensed ancillary person as permitted under state laws. (Services may be provided personally by physicians and performed by personnel under their direct supervision as permitted under state laws, as physicians are not licensed as orthotists and/or prosthetists); *and*
- g. The certified professional orthotist or prosthetist must be in good standing with *one or more* of the following:

- i. American Board for Certification (orthotics, prosthetics, pedorthics) (ABC); *or*
- ii. Board of Certification/Accreditation (prosthetics, orthotics) (BOC); *or*
- iii. Licensed by the state in which services are provided (where legally required).

2. Aetna considers the following types of braces and casts medically necessary durable medical equipment (DME) for the treatment of scoliosis:

- a. Boston scoliosis brace
- b. Charleston scoliosis brace
- c. Milwaukee scoliosis brace
- d. Providence brace
- e. Rigo-Cheneau brace
- f. Risser jacket
- g. Standard thoracolumbosacral orthosis (TLSO).

D. Pre-operative inpatient cranial skeletal traction (e.g., halo-gravity traction) as an adjunct to surgery for the treatment of idiopathic scoliosis when criteria for spinal fusion are met. **Note:** A total of 7 inpatient days are considered medically necessary initially for pre-operative inpatient cranial skeletal traction, and additional days of pre-operative inpatient cranial skeletal traction may be considered medically necessary on a case-by-case basis with documented response to traction with improved alignment on serial imaging.

II. Experimental and Investigational

The following procedures are considered experimental and investigational because the effectiveness of these approaches has not been established:

- A. Copes scoliosis brace
- B. Expandable magnetic growing rods (e.g., Phenix Growing Rod device) except for the MAGEC System (see above)
- C. Idiopathic scoliosis surgery when criteria (see above) are not met.
- D. Manual therapy
- E. Myofascial release
- F. Posterior dynamic deformity correction devices (e.g., ApiFix) for the treatment of adolescent idiopathic scoliosis
- G. Resistive exercises (including the Schroth method)
- H. Rosenberger brace
 - I. Sacroiliac fusion
 - J. ScoliBrace
- K. Scoliosis Flexibility Trainer
- L. ScoliScore and other genetic testing (e.g., the CHD7 gene, estrogen receptor beta (ESR2) rs1256120 single nucleotide polymorphism (SNP) testing, insulin-like growth factor 1 (IGF1) gene rs5742612 SNP testing, the matrilin-1 gene (MATN1), melatonin receptor 1B gene (MTNR1B) rs4753426 and rs10830963 polymorphism testing, and the transforming growth factor beta 1 (TGFB1) gene; not an all-inclusive list)
- M. Screening for adolescent idiopathic scoliosis

N. Silicon Valley Scoliosis Method

O. Spinal manipulation. See also [CPB 0107 - Chiropractic Services \(../100_199/0107.html\)](#).

P. Spinal unloading devices (e.g., LTX 3000, Orthotrac). See also [CPB 0569 - Lumbar Traction Devices \(../500_599/0569.html\)](#).

Q. SpineCor Dynamic Corrective Brace

R. The CLEAR protocol

S. The inversion table

T. The ScoliSmart activity suit

U. Ultrasound shear wave elastography for identification of children at risk for idiopathic scoliosis

V. UNYQ customized brace

W. Vertebral body stapling and vertebral body tethering

X. Whole body vibration.

III. Policy Limitations and Exclusions

Reimbursement and Coding Notes

Some plans exclude coverage of durable medical equipment (DME). Please check benefit plan descriptions for details.

There is no separate payment if CAD-CAM or 3-D printing technology is used to fabricate an orthosis. Reimbursement is included in the allowance of the codes for custom fabricated orthoses. Fabrication of an orthosis using CAD/CAM or similar technology without the creation of a positive model with minimal self-adjustment at delivery is considered as off-the-shelf (OTS). See also [CPB 0009 - Orthopedic Casts, Braces and Splints \(../1_99/0009.html\)](#).

There is no separate allowance for the following (included in orthosis):

- Additional fabrication time of an orthosis
- Consult and evaluation

- Digital scanning and casting
- Fabricating an orthosis
- Fitting of orthosis
- Follow up appointments
- Model modification
- Use of CAD-CAM technology
- X-Ray evaluation.

The use of HCPCS code L0999 (addition to spinal orthosis, not otherwise specified) or L1499 (spinal orthosis, not otherwise specified) must not be used to bill for any features or functions included in the base code nor should it be used when a specific L-code exists. Use of these two codes in these circumstances is considered incorrect coding (unbundling).

HCPCS codes L1499 and L0999 should not be used as base codes for a scoliosis orthosis.

There is no additional allowance for the features of the Rigo Cheneau (WCR) (NYRC) scoliosis brace. Additional features of the Rigo Cheneau type brace are not considered durable medical equipment as it is not an orthopedic product, but a corrective concept. According to Wood and Rigo (2017), "The Cheneau type brace is not an orthopedic product, but a corrective concept."

There are 5 base Healthcare Common Procedure Codes (HCPCS) available to fully describe scoliosis braces. The Rigo Cheneau (WCR) (NYRC) brace, the custom Boston scoliosis brace, the Charleston brace, and the Providence brace are properly described by Healthcare Common Procedure Code System (HCPCS) code L1300.

Three HCPCS codes: L1005, L1300, and L1310 are all inclusive and are not billed with addition codes. The use of addition codes with these three codes will be considered incorrect coding (unbundling).

Two HCPCS codes: L1000 (Cervical-Thoracic-Lumbar-Sacral Orthosis (CTL SO) (Milwaukee), inclusive of furnishing initial orthosis, including model) and L1200 (thoracic-lumbar-sacral-orthosis (TLSO), inclusive of furnishing initial orthosis only) (Risser Jacket) (standard thoracolumbosacral orthosis) (pre-fabricated Boston brace) have specific addition codes which can be used to describe components utilized to support or resist the progression of the user's specific spinal curve pattern.

Add-ons to HCPCS codes L1000

The following table lists addition codes which describe components or features that can be physically incorporated into the L1000 custom fabricated base orthosis, but are not considered to be included in the allowance for the L1000 orthosis. These addition codes will be denied as not separately payable if billed without the related base code, L1000.

Table: L1000 Addition Codes Not Considered Included in the Allowance for L1000 Orthosis

Code	Narrative
L1010	Addition to cervical-thoracic-lumbar-sacral orthosis (CTL SO) or scoliosis orthosis, axilla sling
L1020	Addition to CTL SO or scoliosis orthosis, kyphosis pad
L1025	Addition to CTL SO or scoliosis orthosis, kyphosis pad, floating
L1030	Addition to CTL SO or scoliosis orthosis, lumbar bolster pad
L1040	Addition to CTL SO or scoliosis orthosis, lumbar or lumbar rib pad
L1050	Addition to CTL SO or scoliosis orthosis, sternal pad
L1060	Addition to CTL SO or scoliosis orthosis, thoracic pad
L1070	Addition to CTL SO or scoliosis orthosis, trapezius sling
L1080	Addition to CTL SO or scoliosis orthosis, outrigger
L1085	Addition to CTL SO or scoliosis orthosis, outrigger, bilateral with vertical extensions
L1090	Addition to CTL SO or scoliosis orthosis, lumbar sling

L1100	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather
L1110	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather, molded to patient model
L1120	Addition to CTLSO, scoliosis orthosis, cover for upright, each

Add-ons to HCPCS code L1200

The following table lists addition codes which describe components or features that can be physically incorporated into the L1200 orthosis, but are not considered to be included in the allowance for the L1200 orthosis. These addition codes will be denied as not separately payable if billed without the related base code, L1200.

Table: L1200 Addition Codes Not Considered Included in the Allowance for L1200 Orthosis

Code	Narrative
L1210	Addition to TLSO, (low profile), lateral thoracic extension
L1220	Addition to TLSO, (low profile), anterior thoracic extension
L1230	Addition to TLSO, (low profile), milwaukee type superstructure
L1240	Addition to TLSO, (low profile), lumbar derotation pad
L1250	Addition to TLSO, (low profile), anterior asis pad
L1260	Addition to TLSO, (low profile), anterior thoracic derotation pad
L1270	Addition to TLSO, (low profile), abdominal pad
L1280	Addition to TLSO, (low profile), rib gusset (elastic), each
L1290	Addition to TLSO, (low profile), lateral trochanteric pad

IV. Related Policies

- [CPB 0009 - Orthopedic Casts, Braces and Splints \(../1_99/0009.html\)](#)
- [CPB 0107 - Chiropractic Services \(../100_199/0107.html\)](#)

- [CPB 0569 - Lumbar Traction Devices \(../500_599/0569.html\)](#)

CPT Codes / HCPCS Codes / ICD-10 Codes

CPT codes covered if selection criteria are met:

Code	Code Description
20661	Application of halo, including removal; cranial
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)
+20930	Allograft, morselized, or replacement of osteopromotive material, for spine surgery only
+20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
+20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
+20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision)
+20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic
22214	Osteotomy of spine, posterior or posterolateral approach, one vertebral segment; lumbar

Code	Code Description
+22216	each additional vertebral segment
22548 - 22819	Arthrodesis
+22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)
+22842	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments
+22843	7 to 12 vertebral segments
+22844	13 or more vertebral segments
+22845	Anterior instrumentation; 2 to 3 vertebral segments
+22846	4 to 7 vertebral segments
+22847	8 or more vertebral segments
+22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic Bony structures) other than sacrum
22849	Reinsertion of spinal fixation device
22852	Removal of posterior segmental instrumentation
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
29010	Application of Risser jacket, localizer; body only
97014	Application of a modality to one or more areas; electrical stimulation (unattended)

Code	Code Description
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
CPT codes not covered for indications listed in the CPB:	
<i>Melatonin receptor 1B gene (MTNR1B) rs4753426 and rs10830963 polymorphism testing, estrogen receptor beta (ESR2) rs1256120 and insulin-like growth factor 1 (IGF1) gene rs5742612 single nucleotide polymorphism testing, CAD-CAM technology, 3-D printing, myofascial release, ultrasound shear wave elastography, Silicon Valley scoliosis method—no specific code</i>	
22505	Manipulation of spine requiring anesthesia, any region [not covered for adult scoliosis]
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
22837	8 or more vertebral segments
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed
98925 - 98929	Osteopathic manipulation (OMT)
98940 - 98943	Chiropractic manipulative treatment (CMT) [not covered for adult scoliosis]
Other CPT codes related to the CPB:	
77072	Bone age studies
HCPCS codes covered if selection criteria are met:	
<i>MAGEC System - no specific code:</i>	
L1200	Thoracic-lumbar-sacral-orthosis (tlso), inclusive of furnishing initial orthosis only
L1210	Addition to tlso, (low profile), lateral thoracic extension
L1220	Addition to tlso, (low profile), anterior thoracic extension
L1240	Addition to tlso, (low profile), lumbar derotation pad
L1250	Addition to tlso, (low profile), anterior asis pad

Code	Code Description
L1260	Addition to tlso, (low profile), anterior thoracic derotation pad
L1290	Addition to tlso, (low profile), lateral trochanteric pad
L1300	Other scoliosis procedure, body jacket molded to patient model
HCPCS codes not covered for indications listed in the CPB:	
<i>UNYQ customized brace, ScolioBrace, Scoliosis Flexibility Trainer, Posterior dynamic correction devices (Apifix)</i> – no specific code:	
E0744	Neuromuscular stimulator for scoliosis
ICD-10 codes covered if selection criteria are met:	
M41.00 - M41.08	Infantile idiopathic scoliosis
M41.112 - M41.27	Juvenile, adolescent and other idiopathic scoliosis
ICD-10 codes not covered for indications listed in the CPB:	
Z13.828	Arthrodesis status
<i>Vertebral body tethering:</i>	
CPT codes not covered for indications listed in the CPB:	
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed

Background

Scoliosis may be classified as functional or structural. Functional scoliosis may be transient or fairly persistent, but is not associated with any structural alterations. Structural scoliosis involves a fixed lateral curve with rotation, and is associated with many conditions including neuropathic

diseases/disorders such as cerebral palsy, poliomyelitis, and muscular dystrophy; congenital causes such as failure of formation or segmentation, and myelomeningocele; traumatic causes such as fracture or dislocation (non-paralytic) and post-radiation; soft tissue contractures such as post-empyema and burns; osteochondrodystrophies such as achondroplasia and spondyloepiphyseal dysplasia; tumor; and rheumatoid disease. However, the most common type of structural scoliosis is idiopathic scoliosis. Although idiopathic scoliosis is thought to have a genetic predisposition, its exact cause is still unknown.

Idiopathic scoliosis can be further divided into 3 categories: (i) infantile (0 to 3 years of age), (ii) juvenile (3 to 9 years of age), and (iii) adolescent (10 years of age up to and including 25 years of age, because between ages 18-25 scoliosis may be presumed to have been present since adolescence). Idiopathic scoliosis most frequently affects young girls. The spinal curvature that persists after skeletal maturity is termed adult scoliosis.

The traditional treatment for adolescent idiopathic scoliosis is the use of a supportive brace, (e.g., the Milwaukee brace, the Boston brace). Torso exercises to increase muscle strength have been used in conjunction with braces, but there is inadequate evidence to support this. Since bracing is restrictive and must be worn 23 hours a day for up to several years, non-compliance has been estimated to be 20 to 50 % (Moe and Kettelson, 1970). Additionally, this method is associated with side effects such as anxiety, depression, and sleep disturbance.

Another non-invasive method to straighten abnormal lateral curvature is surface electrical muscle stimulation. This has been shown not to be effective and is no longer considered standard of care (O'Donnell, et al, 1988). In this approach, muscles on one side of the spine are stimulated electrically (direct or alternating current, not high-voltage galvanic current) to contract and pull the vertebrae into a more normal position. Surface electrical muscle stimulation is usually applied for 8 to 10 hours during sleep. Treatment is terminated when patients reach skeletal maturity and structural stability. It is postulated that electro-muscular stimulation in the scoliotics may produce changes in muscle structure resulting in more fatigue-resistant muscles which increase the ability for postural stabilizing muscle activity in the spine (Grimby et al, 1985). Advantages of surface

electrical muscle stimulation include freedom from bracing, the need for only part-time therapy, and an improvement of self-image in the affected adolescents. In severe cases, spinal fusion with instrumentation is effective in halting progression of the curve(s).

Surface electrical muscle stimulation has not been shown by well controlled studies to be effective in reversing or arresting progression of spinal curvatures in adolescents with idiopathic scoliosis. Brown et al (1984) reported the findings of a multi-center study on the use of night-time lateral electrical surface stimulation (LESS) for the treatment of juvenile or adolescent idiopathic scoliotics (484 girls and 64 boys, mean ages of 12.8 and 13.9 years, respectively). Only individuals with rapidly progressing scoliosis and at least 1 year of growth remaining were selected for this trial. The mean treatment time was 12 months, and the longest follow-up was 51 months. During the initial 6 months of therapy, a pre-treatment curvature progression rate of 1 degree/month was reversed to a reduction rate of 0.5 degree/month. Overall, 395 (72 %) patients had either reduced or stabilized their scoliosis. Seventy-one (13 %) patients had experienced temporary progression with subsequent stabilization and treatment continuation, while 82 (15 %) patients dropped out because of progression of their conditions. The major problem with LESS was skin irritation. The authors concluded that LESS treatment is a viable alternative to bracing for patients with idiopathic scoliosis.

Dutro and Keene (1985) performed a literature review on surface electrical muscle stimulation in the treatment of progressive adolescent idiopathic scoliosis. Patient selection criteria for studies reviewed were as follows: (i) Cobb angle of 25 to 45 degrees as indicated by radiographic studies, (ii) documented history of progression, (iii) minimum of 50 % correction on forced lateral bending, and (iv) minimum of 1 year of bone growth remaining. The authors concluded that electro-muscular stimulation is equally effective as bracing in treating progressive adolescent idiopathic scoliosis -- progression was arrested in 60 to 84 % of treated curves. The authors stated that, for juvenile scoliosis, if treatment begins early enough and progression is not too severe, a curve cannot only be arrested, but reversed. Surface electro-muscular stimulation can also be employed to halt progression while patients await surgery.

A prospective study by the Scoliosis Research Society (Nachemson & Peterson, 1995) found electrical stimulation to be less effective than bracing and no more effective than observation in idiopathic scoliosis. In this study, 286 girls who had adolescent idiopathic scoliosis, a thoracic or thoracolumbar curve of 25 to 35 degrees, and a mean age of 12 years and seven months (range, 10 to 15 years) were followed to determine the effect of treatment with observation only (129 patients), an underarm plastic brace (111 patients), and nighttime surface electrical stimulation (46 patients). Thirty-nine patients were lost to follow-up, leaving 247 (86 percent) who were followed until maturity or who were dropped from the study because of failure of the assigned treatment. The endpoint of failure of treatment was defined as an increase in the curve of at least 6 degrees, from the time of the first x-ray, on two consecutive x-rays. As determined with use of this endpoint, treatment with a brace failed in seventeen of the 111 patients; observation only, in 58 of the 129 patients; and electrical stimulation, in 22 of the 46 patients. According to survivorship analysis, treatment with a brace was associated with a success rate of 74 percent (95 percent confidence interval, 52 to 84) at four years; observation only, with a success rate of 34 percent (95 percent confidence interval, 16 to 49); and electrical stimulation, with a success rate of 33 percent (95 percent confidence interval, 12 to 60). The 39 patients who were lost to follow-up were included in the survivorship analysis for the time period that they were in the study. Treatment with a brace was successful ($p < 0.0001$) in preventing six degrees of increase or more until the patients were 16 years old. The investigators noted that, even a worst-case analysis, in which the 23 patients who were dropped from the study after management with a brace were considered to have failed treatment, showed that the brace prevented progression and that this effect was significant ($p = 0.0005$). The investigators reported that there was no difference in the degree of increase in the curve between the patients who were managed with observation only and those who were managed with electrical stimulation.

The peer-reviewed medical literature suggest that surgery is indicated for growing children whose curve has exceeded 40 degrees; for individuals of any age whose curve is greater than 50 degrees; individuals with scoliosis-related pain that is refractory to conservative treatments; and patients with thoracic lordosis that can't be treated conservatively.

Braces are a primary treatment for idiopathic scoliosis. Standard scoliosis braces include the Milwaukee brace and the Boston brace.

Unlike other commonly used scoliosis braces, such as the Boston brace and the Milwaukee brace, the Charleston brace is worn only at night. Clinical studies have been published that have shown that the Charleston brace compares favorably to the traditional Boston and Milwaukee TLSO braces (Trivedi et al, 2001; Gepstein et al, 2002; Howard et al, 1998). The Charleston brace is especially useful for children with scoliosis who are not compliant with a traditional Boston or Milwaukee TLSO brace or who do not respond well to TLSO braces (Roach, 2002).

Unlike other commonly used scoliosis braces, such as the Boston brace, Wilmington brace (custom fit TLSO) and the Milwaukee brace (CTLTO), the Charleston and the Providence braces are worn only at night. Clinical studies have shown that for curves under 35 degrees the Charleston brace compares favorably to the traditional Boston, custom fit TLSOs, and Milwaukee (CTLTO) braces. (Trivedi et al, 2001; Gepstein et al, 2002; Howard et al, 1998). The Charleston brace may be useful for children with scoliosis who are not compliant with a traditional Boston or Milwaukee TLSO brace or who do not respond well to TLSO braces (Roach, 2002).

The Providence Scoliosis System is similar to the Charleston brace but has the added advantage of derotation forces and likewise is designed to be worn only at night (d'Amato, et al., 2001). The Providence Scoliosis System includes pressure sensors to ascertain if sufficient pressure is being administered. Recent work by Janiski et al showed the Providence brace to be more effective for curves less than 35 degrees as compared to standard TLSO which may be because of better compliance. A report by d'Amato et al (2001) of their experience with the first consecutive 102 patients with adolescent idiopathic scoliosis treated with the Providence brace who were followed for 2 years after completing treatment. Yrjonen et al (2006) evaluated the results of treatment of adolescent idiopathic scoliosis (AIS) with the Providence night-time brace at 1.8 years after discontinuation of bracing. A total of 36 female patients with an average Cobb angle of 28.4 degrees and an apex below T-10 were studied prospectively. For comparisons, 36 matched patients treated with the Boston full-time brace were studied retrospectively. With the Providence night brace an average of 92 % for brace correction of the primary curve was achieved and during follow-up progression of the curve greater than 5 degrees occurred in 27 % of the patients. In the control group of the Boston full-time brace patients, brace correction was 50 % and the

progression of the major curve occurred in 22 % of the patients. The authors concluded that the Providence night brace may be recommended for the treatment of AIS with curves less than 35 degrees in lumbar and thoracolumbar cases.

The Copes Scoliosis Brace is a custom-fitted polypropene support structure that utilizes air to attain spinal curvature correction. This is achieved through the use of strategically placed pneumatic force vector pads that are adjusted every 4 to 6 weeks during treatment. The brace is generally used for 12 to 36 months in conjunction with hydrotherapy, regular muscle strengthening exercises, as well as chiropractic treatments such as osseous manipulation and muscle stimulation therapy. There is no scientific evidence that the Copes Scoliosis Brace is effective in treating scoliosis. Additionally, there are no published data concerning the long-term effectiveness of this device, the rate of recurrence of scoliosis after patients stop wearing the brace or the number of patients who eventually have to undergo surgical intervention. Furthermore, the Copes Scoliosis Brace is used in conjunction with hydrotherapy, regular muscle strengthening exercises and chiropractic treatments. Thus, it is unclear what role the brace actually plays in the improvement, if any, of the condition. Similar to the Copes system is the "Clear method" of treating scoliosis. Likewise there is no data to support the Clear method .

There is a lack of scientific evidence in the peer-reviewed published medical literature to support the effectiveness of the SpineCor Scoliosis System in treating idiopathic scoliosis, including insufficient data on its long-term effectiveness and a lack of studies directly comparing the dynamic corrective brace with rigid bracing systems.

In a prospective, observational study, Couillard and colleagues (2007) assessed the effectiveness of the Dynamic SpineCor brace for adolescent idiopathic scoliosis in accordance with the standardized criteria proposed by the Scoliosis Research Society Committee on bracing and non-operative management. From 1993 to 2006, 493 patients were treated using the SpineCor brace. A total of 249 patients met the criteria for inclusion, and 79 patients were still actively being treated. Overall, 170 patients have a definitive outcome. All girls were pre-menarchal or less than 1 year post-menarchal. Assessment of brace effectiveness included (i) % of patients who have 5 degrees or less curve progression, and % of patients who have 6 degrees or more progression; (ii) % of patients who have been recommended/undergone surgery before

skeletal maturity; (iii) % of patients with curves exceeding 45 degrees at maturity (end of treatment); and (iv) 2-year follow-up beyond maturity to determine the % of patients who subsequently underwent surgery. Successful treatment (correction, greater than 5 degrees, or stabilization, \pm 5 degrees) was achieved in 101 (59.4 %) of the 170 patients from the time of the fitting of the SpineCor brace to the point in which it was discontinued. Thirty-nine immature patients (22.9 %) required surgical fusion while receiving treatment. Two (1.2 %) of 170 patients had curves exceeding 45 degrees at maturity. One mature patient (2.1 %) needed surgery within 2 years of follow-up beyond skeletal maturity. The authors concluded that the SpineCor brace is effective for the treatment of adolescent idiopathic scoliosis. Moreover, positive outcomes are maintained after 2 years because 45 (95.7 %) of 47 patients stabilized or corrected their end of bracing Cobb angle up to 2 years after bracing. The results of this observational study are promising; however the findings need to be validated by future well-designed studies.

Wong and colleagues (2007) stated that the conventional rigid spinal orthosis and the flexible spinal orthosis, SpineCor, have different treatment principles in the management of AIS. These may influence the patients' gait pattern and clinical outcome. In this study, gait analysis on patients with AIS undergoing these 2 orthotic interventions were conducted. The patients' lower limb kinematic and kinetic data during level walking were collected using a motion analysis system and 2 force platforms in 4-test conditions: pre-intervention, having used the orthosis for 1 month and 1 year (in and out of the orthosis). A total of 21 subjects were randomly assigned to the rigid spinal orthosis group (10 subjects) and the SpineCor group (11 subjects). Neither group showed gait asymmetry when comparing the convex and concave sides in the 4-test conditions. However, significant reduction in the range of motion of the pelvis and hip joints in the coronal plane were found. Although patients with AIS undergoing these 2 orthotic interventions showed significant changes in walking pattern within the study period, their long-term effect on gait and function requires further investigation through long-term prospective studies.

The Rosenberger brace is a low-profile, custom-molded thoracolumbosacral orthosis (TLSO) that includes design changes from other TLSOs that are intended to improve compliance and, therefore, outcomes. The Rosenberger low profile orthoses is intended to offer better appearance than the Milwaukee orthosis with its neck ring (Gavin et al, 1986). While the Rosenberger brace was developed in the 1980's, the effectiveness of the brace had never been evaluated in the

literature prior to 2004 (Gavin et al, 1986; Grabowski and Gelb, 2005). At that time, Spoonamore et al (2004) assessed the effectiveness of the Rosenberger brace in preventing curve progression in adolescent idiopathic scoliosis (n = 71). The investigators found the brace to have an overall failure rate similar to that of untreated cases from published natural history studies, although subgroups of patients had lower failure rates. These findings suggested the need for further refinement of the indications for the Rosenberger brace.

The Cheneau brace is a thermo-plastic scoliosis brace modeled on a hyper-corrected positive plaster cast of the patient. This is a 3-dimensional (3-D) correctional brace that has significant pressure and expansion areas built into the brace, which provides correction in all 3 anatomical planes. It follows the general correction principle as was written by Dubousset -- detorsion and sagittal plane normalization, which would effect correction of the coronal and transversal planes, resulting in some elongation of the spine, without any significant distraction force. The Rigo System Cheneau (RSC) brace is a scoliosis brace that is based on the original theories of Dr. Cheneau, however Dr. Rigo furthered the designs by combining his new scoliosis classification types, to design the RSC brace also known as El corse de RSC. The brace is manufactured with an Ortholutions CAD CAM technique.

Rigo et al (2002) reported a retrospective series that included 105 idiopathic scoliotic patients treated with a Chêneau brace. With an average age of 12.5 years old and a mean Risser sign of 0.9, the initial major Cobb angle was 36.8 degrees corrected to 25.9 degrees in the brace (31.1 % of the primary correction), and the major torsion angle was 16.8 degrees corrected to 12.9 degrees in the brace (22.2 % of the primary correction). A total of 37 patients have finished the treatment with a mean follow-up of 16.8 months. For this group, the initial Cobb and torsion angles were not significantly changed (36.4 degrees Cobb to 34.1 degrees Cobb at follow-up, and 16.9 degrees Perdriolle to 15.7 degrees Perdriolle at follow-up). The proportion of patients without progression greater than 5 degrees Cobb (n = 20) and with an improved final Cobb angle (n = 10) was greater than failures (n = 7). However, due to the catastrophic nature of some progressions, which generally coincide with a high Cobb angle right from the start, with low primary correction, and with non-compliance, the final Cobb angle showed a slight tendency to

decrease but without reaching high significance. These results demonstrate that the Chêneau brace can effectively prevent the progression of Cobb and torsion angles, even in cases of bad prognosis.

Weiss et al (2006) stated that in patients with idiopathic scoliosis (IS), reduced thoracic kyphosis and reduced lumbar lordosis frequently occur in correlation with the lateral spinal curvature. Normalization of the sagittal profile and hyper-correction of the deviation in frontal and coronal plane are the main issues of the latest concept of bracing. The purpose of this study was to investigate the influence of sagittal counter forces (SCF) on the scoliotic deformity. A case series of 4 patients with IS treated with 2 braces designed to improve the sagittal profile (Rigo-System-Chêneau-brace and with a sagittal counter force brace, SCF-brace). The short-term effect (30 mins) of both braces was evaluated using surface topography (Formetric surface topography system, Diers International, Wiesbaden). One patient (Cobb angle 92 degrees) showed no short-term correction in the frontal and coronal planes; others (Cobb angles between 39 and 48 degrees) exhibited valuable correction in frontal and coronal planes. There was no short-term correction in the sagittal plane for either brace. The authors concluded that the application of SCF seems to have similar short-term effects as 3-D correction and should be addressed more in future concepts of scoliosis bracing.

Grivas and Kaspiris (2010) stated that there is a lack of a systematic examination of the braces commonly used in Europe. Thus, the objective of this report was the description of the European braces widely used. The history, design rationale, indications, biomechanics, outcomes and comparison between some braces were reported. Chêneau Brace is used in France and other European Countries. There are 2 Cheneau derivatives, namely the RSC brace used in Spain and the ScoliOlogiC "Chêneau light" used in Germany. The Lyonnaise brace is used in France and Italy. The Dynamic Derotating brace is used in Greece. The TriaC brace is used in the Netherlands. The Sforzesco brace based on the SPoRT concept and the Progressive Action Short brace are used in Italy. Correction of spinal deformities is achieved in conservative treatment with passive and active brace mechanisms. The mode of operation of modern braces is in accordance with various principles of correction, namely active or passive extension with the

aid of a neck ring and correction by lateral pads, lateral pressure according to 3-point principle, compression, bending the trunk towards the opposite side, active bracing and correction by means of pressure exerted by bands during movement and by means of metallic blades.

The Risser jacket has been used to correct scoliosis for many years. The Research Committee of the American Orthopaedic Association's report on end-result study of the treatment of idiopathic scoliosis (Shands et al, 1941) discussed the use of the Risser jacket to correct the curve prior to fusion in 149 patients. Clinical improvement of the rotation deformity was observed following correction with the Risser jacket in 48 % of the 126 patients on whom these data were available.

In addition, the best clinical appearances of the back were obtained in the group treated by correction in the Risser jacket and spine fusion. James (1952) noted that correction of the primary curvature in scoliotic patients is achieved by the use of the Risser turnbuckle jacket, the most effective method yet devised. Furthermore, a review on infantile scoliosis by Lakshmanan and colleagues (2009) stated that management with orthosis is necessary when the curve is considered to be progressive or if a compensatory curve has developed. Various types of orthosis are available for children younger than 3 years. The most commonly used orthoses include the hinged Risser jacket, the Milwaukee brace, and the Boston brace. The brace should be used for 23.5 hours a day and should be removed only for exercises and swimming. It needs to be used until skeletal maturity is attained, because curves usually do not progress after skeletal maturity; however, curves may progress in spite of using a brace.

Negrini and associates (2003) performed a systematic review of the literature to verify the effectiveness of physical exercises in the treatment of AIS. These investigators carried out a search of different databases, and a hand-search of the non-indexed pertinent literature, and found 11 papers: none of the studies was randomized, 6 were prospective, 7 were controlled, and 2 compared their results to historical controls; 1 paper had both a prospective design and a concurrent control group. The methodological quality of the retrieved studies was reviewed and found to be very poor. With one exception, the published studies demonstrated the effectiveness of physical exercises in reducing both the rate of progression and the magnitude of the Cobb angle at the end of treatment. However, being of poor quality, the literature failed to provide solid evidence for or against the efficacy of physical exercises in the treatment of AIS.

Negrini et al (2008) examined if the indication for treatment with specific exercises for AIS has changed in recent years. A bibliographic search with strict inclusion criteria (patients treated exclusively with exercises, outcome Cobb degrees, all study designs) was performed on the main electronic databases and through extensive manual searching. These researchers retrieved 19 studies, including 1 randomized controlled trial (RCT) and 8 controlled studies; 12 studies were prospective. A methodological and clinical evaluation was performed. The 19 papers considered included 1,654 treated patients and 688 controls. The RCT (highest-quality study) compared 2 groups of 40 patients, showing an improvement of curvature in all treated patients after 6 months. These investigators found 3 papers on Scoliosis Intensive Rehabilitation (Schroth), 5 on extrinsic autocorrection-based methods (Schroth, side-shift), 4 on intrinsic autocorrection-based approaches (Lyon and SEAS) and 5 with no autocorrection (3 asymmetric, 2 symmetric exercises). Apart from 1 (no autocorrection, symmetric exercises, very low methodological quality), all studies confirmed the efficacy of exercises in reducing the progression rate (mainly in early puberty) and/or improving the Cobb angles (around the end of growth). Exercises were also shown to be effective in reducing brace prescription. The authors concluded that in 5 years, 8 more papers have been published to the indexed literature coming from throughout the world (Asia, the United States, Eastern Europe) and proving that interest in exercises is not exclusive to Western Europe.

The review by Negrini and colleagues (2008) emphasized a RCT by Wan et al (2005) of exercise in idiopathic scoliosis. The article by Wan et al is in Chinese, but the description of the study by Negrini et al indicated that the study duration was 6 months, raising questions about the durability of results. Subjects in both the exercise group and control group improved from baseline (15 degrees in the exercise group and 7 degrees in the control group), and there is no report whether the differences between the 2 groups at the end of treatment were statistically significant. Furthermore, the Cobb angles at initiation of therapy (25 degrees in the exercise group and 24 degrees in the control group) were within a range for which children are often managed with observation.

Furthermore, the American Academy of Orthopedic Surgeons (2007) stated that exercise programs have not been found to be effective treatments for scoliosis. The National Institute of Arthritis and Musculoskeletal Diseases of the National Institutes of Health (2008) stated that

exercise has not been shown to prevent curve progression. Additionally, Schiller and co-workers (2010) stated that although numerous non-operative methods have been attempted, including exercise, only bracing is effective in preventing curve progression and the subsequent need for surgery.

Spinal Unloading Devices

In a pilot study, Chromy and colleagues (2006) evaluated potential benefits of axial spinal unloading (LTX 3000 Lumbar Rehabilitation System) over a 3-month period. A total of 5 adolescent girls with scoliosis were enrolled in the study. Three laboratory sessions: (i) initial baseline, (ii) immediately after 3-month treatment period (axial unloading by using LTX 3000 for 2 10-min treatments daily), and (iii) 1-month post-treatment. Initial baseline postural data were obtained from 2 sets of radiographs (standing antero-posterior [AP] and lateral, sitting AP and lateral), back range of motion (ROM) measurements, and numeric pain scales. The following were assessed: static postural changes; potential functional benefits; and therapeutic compliance. All subjects elicited reductions in lumbar Cobb angles immediately after 3 months of treatment; initial average scoliotic curves of 13.7 degrees were reduced 42 % to 8 degrees ($\alpha = 0.05$, $p = 0.004$). Additionally, such reductions were evident 1 month post-treatment; average original curves were reduced by 27 %. Subjects' ROM and lumbar lengthening were not significantly altered by this therapeutic protocol. Reported subject compliance was high (95 %). The authors concluded that the LTX 3000 is a potential adjunct therapy for the treatment of adolescent scoliosis. The findings of the present study need to be validated by randomized controlled trials with large sample size and long-term follow-up.

Vertebral Body Stapling

Vertebral body stapling (VBS) is an alternative to bracing or spinal fusion for the treatment of progressive scoliosis. It is believed that for patients with progressive moderate scoliosis who are still growing, intervertebral body stapling of the outer (convex) side of the anterior spine (the side of the spine facing the chest) may keep the curve from progressing. With the convex growth plates held in check, continued development of the inner (concave) growth plates should stabilize the progression and may allow correction of deformity as the subject grows. This approach

employs a special metal device that is clamp-shaped at body temperature, but can be straightened when subjected to cold temperatures and inserted into the spine. When warmed up, the staple returns to its clamp shape and supports the spine.

Betz and colleagues (2003) reported the feasibility, safety, and utility of VBS without fusion as an alternative treatment for adolescent idiopathic scoliosis. These researchers retrospectively reviewed 21 patients (27 curves) with adolescent idiopathic scoliosis treated with VBS. Patients were immature as defined by Risser sign less than or equal to 2. The procedure was safe, with no major complications and three minor complications. One patient had an intra-operative segmental vein bleed resulting in an increased estimated blood loss of 1,500 ml as compared to the average estimated blood loss of 247 ml for all patients. One patient had a chylothorax and one pancreatitis. No patient has had a staple dislodge or move during the follow-up period (mean 11 months, range of 3 to 36 months), and no adverse effects specifically from the staples have been identified. Utility (defined as curve stability) was evaluated in 10 patients with stapling with greater than 1-year follow-up (mean of 22.6 months) and pre-operative curve less than 50 degrees. Progression of greater than or equal to 6 degrees or beyond 50 degrees was considered a failure of treatment. Of these 10 patients, 6 (60 %) remained stable or improved and 4 (40 %) progressed. One of 10 (10 %) in the stapling group had progressed beyond 50 degrees and went on to fusion. Six patients required stapling of a second curve, 3 as part of the primary surgery, and 3 as a second stage, because a second untreated curve progressed. The results need to be considered with caution, as the follow-up was short. The authors concluded that the data showed that VBS for the treatment of scoliosis in the adolescent was feasible and safe in this group of 21 patients. In the short-term, stapling appears to have utility in stabilizing curves of progressive adolescent idiopathic scoliosis.

Betz et al (2005) reported the findings of 39 consecutive patients who have had VBS of 52 curves (26 patients with one curve stapled and 13 patients with two curves). For patients who were 8 years or older with less than 50 degrees pre-operative curve and a minimum 1-year follow-up, coronal curve stability was 87 % when defined by progression less than or equal to 10 degrees. Fusion was necessary in 2 patients. No curves less than 30 degrees at the time of stapling progressed greater than or equal to 10 degrees. Major complications occurred in 1 patient (2.6

%, diaphragmatic hernia) and minor complications occurred in 5 patients (13 %). The authors concluded that further follow-up of treated patients and more research into effectiveness and indications are needed.

Cunningham et al (2005) noted that standard interventions for adolescents and adults, including spinal deformity correction and fusion, may not be appropriate for young patients with considerable growth remaining. Alternative surgical options that provide deformity correction and protect the growth remaining in the spine are needed to treat this population of patients. Several groups have reported advances in the field of deformity spine surgery. Updated findings concerning the successful implementation of growing rods have revived this technique as a viable option for preserving near normal growth of the spine. New techniques have also been recently described, including vertebral stapling that produces asymmetric and corrective growth of the concavity of a deformity, and vertical expandable prosthetic titanium rib instrumentation that indirectly corrects spine deformity and protects spine growth remaining to treat an associated thoracic insufficiency syndrome. The authors concluded that new techniques and instrumentation allow the treatment of this challenging patient population to approach the goals of deformity correction and maintenance with preservation of potential growth. Preliminary outcomes from the different techniques are promising, but further investigation, including long-term follow-up, is needed.

In an assessment of VBS for the treatment of idiopathic scoliosis, the Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (2005) concluded that limited evidence exists on the safety and effectiveness of VBS. Current evidence of this procedure is limited to small patient numbers and short-term follow-up. Furthermore, long-term safety and effectiveness data from prospective, RCTs will be needed before VBS can be widely accepted.

Guille et al (2007) stated that the recent investigations of convex anterior VBS have offered promising early results with use of improved implants and techniques. The use of a shape memory alloy staple tailored to the size of the vertebral body, the application of several staples per level, the instrumentation of the Cobb levels of all curves, and the employment of minimally invasive thoracoscopic approaches all offer substantial improvements over previous fusionless techniques. Patient selection may also play a role in the current success of these fusionless

treatments, with perhaps the ideal candidates for this intervention possessing smaller and more flexible curves. However, the authors stated that long-term results of the effects on the instrumented motion segments and adjacent spine are not yet available.

Betz et al (2010), in a retrospective review, reported the results of vertebral body stapling (VBS) with a minimum 2-year follow-up in 28 patients with idiopathic scoliosis. Inclusion criteria included Risser 0 or 1 and coronal curve measuring between 20 and 45 degrees. There were 26 thoracic and 15 lumbar curves, and average follow-up was 3.2 years. The procedure was considered a success if curves corrected to within 10 degrees of preoperative measurement or decreased greater than 10 degrees. Thoracic curves measuring less than 35 degrees had a success rate of 77.7%. Curves which reached less than or equal to 20 degrees on first erect radiograph had a success rate of 85.7%. Flexible curves with greater than 50% correction on bending films had a success rate of 71.4%. Of the 26 thoracic curves, 4 (15%) showed correction greater than 10 degrees. Kyphosis improved in 7 patients with preoperative hypokyphosis (less than 10 degrees of kyphosis from T5 – T12). 83.% of patients had remaining normal thoracic kyphosis of 10 to 50 degrees. Lumbar curves demonstrated a success rate of 86.7%. Four of the 15 lumbar curves (27%) showed correction greater than 10 degrees. Major complications included rupture of an unrecognized congenital diaphragmatic hernia (one patient) and curve overcorrection (one patient). Two minor complications included superior mesenteric artery syndrome (one patient) and atelectasis due to a mucous plug (one patient). There were no instances of staple dislodgment or neurovascular injury. In conclusion, analysis of patients with idiopathic scoliosis with high-risk progression treated with VBS and a minimum 2-year follow-up showed a success rate of 87% in all lumbar curves and in 79% of thoracic curves less than 35 degrees. Thoracic curves greater than 35 degrees were not successful and require alternative treatments. Of the 63 patients with IS age at surgery 7-15 , 57 had x-rays at most recent follow-up that allowed for visualization of iliac crest. Skeletal maturity was defined as having a Risser score ≥ 4 . Among the thoracic curves, 12 of the successful outcomes were \geq Risser 4 while 5 of the failures were \geq Risser 4. Thus, the success rate for mature thoracic curves was 71% (12/17). Among the lumbar curves, 17 of the successful outcomes were \geq Risser 4 while 2 of the failures were \geq Risser 4. Thus, the success rate for mature lumbar curves was 89% (17/19).

In a single-surgeon, retrospective case-series study, Bumpass et al (2015) described clinical and radiographic outcomes of patients undergoing VBS, with the goal of learning if VBS is a safe and effective alternative to bracing for treating moderate IS in the growing pediatric patient. Existing studies stated successful curve control rates equivalent to bracing, but the majority of reports had come from a single institution. All IS patients who underwent VBS by 1 surgeon were included.

Indications were brace intolerance and a structural coronal curve of 25° to 40°. Proportional nitinol staples were used in all cases. Pre- and post-operative radiographs, pulmonary function testing, and physical exam measurements were serially recorded. Vertebral body stapling was performed on 35 patients (28 females, 7 males) with mean age 10.5 years (range of 7.0 to 14.6). A total of 31 patients (33 stapled curves) completed follow-up. Pre-operative Risser grade was 0 in 31 patients, 1 in 1 patient, and 2 in 3 patients. Stapled curves were controlled with less than 10° of progression in 61 % of cases. Curves less than 35° had a control rate of 75 %, and patients less than 10 years had a 62 % curve control rate; 11 patients (31 %) required subsequent fusions; 2 curves (6 %) over-corrected. Pre-operative supine flexibility greater than 30 % was predictive of ultimate curve control. No neurologic complications were encountered; 5 patients (14 %) developed small pneumothoraxes. The authors concluded that this series contained the most patients and longest follow-up reported for VBS. They noted that successful curve control was achieved less frequently than in previous reports, particularly in patients less than 10 years. This study provided Level IV evidence.

Chiropractic Manipulation and Exercise

In a systematic literature review of non-surgical treatment in adult scoliosis, Everett and Patel (2007) stated that the evidence on the use of chiropractic manipulation for adult scoliosis is very weak.

Hrysomallis and Goodman (2001) noted that exercise has been promoted in an attempt to correct postural deviations, such as excessive lumbar lordosis, scoliosis, kyphosis, and abducted scapulae. One of the assumed causes of these conditions is a weak and lengthened agonist muscle group combined with a strong and tight antagonist muscle group. Strengthening and stretching exercises have been prescribed accordingly. It is implied that strengthening exercises will encourage adaptive shortening of the muscle-tendon length, reposition skeletal segments,

and produce static posture realignment. A review of the literature has found a lack of reliable, valid data collected in controlled settings to support the contention that exercise will correct existing postural deviations. Likewise, objective data to indicate that exercise will lead to postural deviations are lacking. It is likely that exercise programs are of insufficient duration and frequency to induce adaptive changes in muscle-tendon length. Additionally, any adaptations from restricted range-of-movement exercise would likely be offset by daily living activities that frequently require the body segments to go through full ranges of motion.

Mooney and Brigham (2003) reported on the use of progressive resistive exercise in adolescents with scoliosis. A total of 20 adolescent patients (18 girls and 2 boys) with scoliosis ranging from 15 degrees to 41 degrees in their major curve were treated with a progressive resistive training program for torso rotation. All patients demonstrated an asymmetry of rotation strength measured on specialized equipment, and surface electrode electromyograms showed inhibition of lumbar paraspinal muscles. Sixteen of 20 patients demonstrated curve reduction, and no patient showed an increase in curve. These results would need to be replicated in a larger trial. The durability and effectiveness compared with bracing would also need to be evaluated.

In a pilot study, McIntire and colleagues (2008) examined treatment of adolescent idiopathic scoliosis with quantified trunk rotational strength training. Patients received a 4-month supervised followed by a 4-month home trunk rotational strength training program. Trunk rotational strength was measured in both directions at 5 positions at baseline, 4 months, and 8 months. Patients were followed clinically. A total of 15 patients (12 females and 3 males), with an average age of 13.9 years and an average main Cobb of 33 degrees were enrolled. At baseline, there was no significant asymmetry. After 4 months of supervised strength training, involving an average of 32 training sessions, each lasting about 25 mins, their strength had significantly increased by 28 % to 50 % ($p < 0.005$ to $p < 0.001$). After 4 months of unsupervised home strength training their strengths were unchanged. The 3 patients with baseline curves of 50 to 60 degrees all had main or compensatory curve progression and 2 had surgery. For patients with 20 to 40-degree curves, survivorship from main curve progression of greater than or equal to 6 degrees was 100 % at 8 months, but decreased to 64 % at 24 months. The authors concluded that quantified trunk rotational strength training significantly increased strength. It was not effective for curves measuring 50 to 60 degrees. It appeared to help stabilize curves in the 20 to 40-degree ranges

for 8 months, but not for 24 months. Periodic additional supervised strength training may help the technique to remain effective, although additional experimentation will be necessary to determine this.

Whole Body Vibration

Li and colleagues (2011) stated that numerical techniques were used to study the vibration response of idiopathic scoliosis patients with single thoracic curve. These researchers analyzed the dynamic characteristics of the idiopathic scoliotic spine under the whole body vibration (WBV) condition. The influence of the upper body mass was also studied. The relationship between the WBV and the spinal disorders has been investigated using finite element method. However, the dynamic response features of the scoliotic spine to the vibration were poorly understood. The resonant frequencies of the scoliotic spine and the effects of the body weight were studied using a finite element model described previously. Modal and harmonic analysis was conducted. The amplitudes of 6 fundamental vertebral movements around the long, coronal and sagittal axis were quantified in the frequency range of 1 to 35 Hz. The vibration-induced rotation amplitudes of the apex of the thoracic deformity were higher than that of the lumbar segments. The apical vertebrae had the greatest rotation amplitudes at 2 and 8 Hz, and the largest lateral translation amplitudes at 16 Hz. Vibration could cause large lateral flexion amplitudes in the apex of the thoracic deformity. The apical vertebrae had the largest side flexion amplitudes at 6 Hz.

Increasing upper body mass could not change resonant frequency of vibration-induced lateral translation and rotation around the long axis of the apical vertebrae. The authors concluded that the scoliotic spine is more sensitive to vibration than the normal spine. For a patient with single thoracic curve, long-term WBV may do more harm to the thoracic deformity than to the lower lumbar segments. Axial cyclic loads applied to an already deformed spine may cause further rotational and scoliotic deformity. Patients with idiopathic scoliosis are more likely to suffer from vibration-induced spinal disorders than those by normal persons.

Genetic Tests

Adolescent idiopathic scoliosis is a lateral spinal curvature observed in children 10 years of age or older, and approximately 100,000 new cases of AIS are diagnosed annually. Of these most are small curvatures of less than 15 to 20 degrees requiring only routine observation for progression.

If a curve reaches 20 to 40 degrees, orthotic bracing is used to prevent further progression. If the bracing is unsuccessful and the curve progresses beyond 40 degrees surgical correction may be required. Only about 7 to 10 % of patients require braces and only 1 to 4% require surgery. Patients identified with AIS are periodically monitored for progression of the curve using various methods based on the angular relationships of the vertebrae and assessment of skeletal maturity. Recently a genetically-based test has been developed that is supposed to identify those individuals with the highest risk for curve progression. Those with a low-risk would require less frequent monitoring and x-ray exposure, while those at higher risk would be checked more frequently. The ScolioScore™ AIS Prognostic Test is being offered by Axial Biotech, Inc., and is intended for children between 9 and 13 years of age with a primary diagnosis of AIS and a mild spinal curvature (defined as less than 25 degrees) and who are of Caucasian ethnicity. The test examines a total of 53 genetic markers and converts the result into a risk score using a proprietary software algorithm. A score of 1 to 50 constitutes low-risk for curve progression, 51 to 180 intermediate-risk, and 181 to 200 high-risk.

No articles were found in the peer-reviewed medical literature to independently assess the ScolioScore™ test for analytic validity, clinical validity or clinical utility. A review article by Ogilvie (2010) described how studies of families have been used to determine the inherited nature of AIS. The article declared the test has been validated in Caucasian girls and boys but is not validated in Asians or African-Americans. No details of any clinical trials were discussed. Without clinical trials information in the scientific literature it is not possible to reach conclusions on health outcomes. There is a substantial body of literature addressing evaluation of curve progression by standard methods but none of these studies or reviews mentioned genetic testing. As no articles are currently available in the literature, it is not possible to determine if ScolioScore™ improves net health outcomes. Nor have there been any comparison studies to address whether the use of the genetic test is at least as effective as standard monitoring.

Ward et al (2010) developed and tested the negative predictive value of a prognostic DNA test for AIS and established clinically meaningful endpoints for the test. Logistic regression was used to develop an algorithm to predict spinal curve progression incorporating genotypes for 53 single nucleotide polymorphisms (SNPs) and the patient's presenting spinal curve (Cobb angle). Three cohorts with known AIS outcomes were selected to reflect intended-use populations with various

rates of AIS progression: 277 low-risk females representing a screening cohort, 257 females representing higher risk patients followed at referral centers, and 163 high-risk males. DNA was extracted from saliva, and genotypes were determined using TaqMan assays; AIS Prognostic Test scores ranging from 1 to 200 were calculated. Low-risk scores (less than 41) had negative predictive values of 100 %, 99 %, and 97 %, respectively, in the tested populations. In the risk model, these researchers used cut-off scores of 50 and 180 to identify 75% of patients as low-risk (less than 1 % risk of progressing to a surgical curve), 24 % as intermediate-risk, and 1 % as high-risk. The authors concluded that prognostic testing for AIS has the potential to reduce psychological trauma, serial exposure to diagnostic radiation, unnecessary treatments, and direct and indirect costs-of-care related to scoliosis monitoring in low-risk patients. They stated that further improvements in test performance are expected as the optimal markers for each locus are identified and the underlying biologic pathways are better understood. The validity of the test applies only to white AIS patients; versions of the test optimized for AIS patients of other races have yet to be developed.

Liu et al (2010) examined the association between the promoter polymorphisms of matrix metalloproteinase (MMP)-3 (-1171 5A/6A rs3025058) and interleukin (IL)-6 genes (-174G/C rs1800795) and AIS in a Chinese Han population. A total of 487 Chinese girls with AIS and 494 healthy age-matched adolescent girls were recruited consecutively during a 3-year period. Statistical analysis of genotype frequencies between AIS patients and normal controls were performed by Chi-test. In this association study of the MMP-3 polymorphism and the risk of scoliosis, no significant difference was found between cases and controls, both in term of allelic association (6A: 81.2 % in cases versus 81.8 % in controls, 5A: 18.8 % in cases versus 18.2 % in controls, $p = 0.745$) or genotype association (6A/6A: 65.9 % in cases versus 66.2 % in controls, 5A/6A: 30.6 % in cases versus 31.2 % in controls, and 5A/5A: 3.5 % in cases versus 2.6 % in controls; $p = 0.733$). Among AIS patients, the maximal Cobb angles were also not different among MMP-3 genotypes (6A/6A: 31.1 degrees +/- 9.7 degrees, 5A/6A: 29.1 degrees +/- 10.5 degrees, and 5A/5A: 29.4 degrees +/- 11.2 degrees; $p = 0.392$). As for IL-6 polymorphism, -174G/C polymorphism was not found in the Chinese AIS patients, and all 100 AIS patients and 100 normal controls were found to carry the G/G wild type. The authors concluded that these findings did not find any significant association of promoter polymorphisms of the MMP-3 (-1171 5A/6A rs3025058) and IL-6 gene (-174G/C rs1800795) with AIS. The results indicated that the

MMP-3 promoter polymorphism is not associated with AIS in the Chinese population. They noted that further studies, however, are needed to rule out the potential association with other promoter polymorphisms in IL-6.

Sharma et al (2011) noted that AIS is an unexplained and common spinal deformity seen in otherwise healthy children. Its pathophysiology is poorly understood despite intensive investigation. Although genetic underpinnings are clear, replicated susceptibility loci that could provide insight into etiology have not been forthcoming. To address these issues, these investigators performed genome-wide association studies (GWAS) of approximately 327,000 SNPs in 419 AIS families. They found strongest evidence of association with chromosome 3p26.3 SNPs in the proximity of the CHL1 gene ($p < 8 \times 10^{-8}$ for rs1400180). They genotyped additional chromosome 3p26.3 SNPs and tested replication in 2 follow-up case-control cohorts, obtaining strongest results when all 3 cohorts were combined (rs10510181 odds ratio (OR) = 1.49, 95 % confidence intervals (CI): 1.29 to 1.73, $p = 2.58 \times 10^{-8}$), but these were not confirmed in a separate GWAS. CHL1 is of interest, as it encodes an axon guidance protein related to Robo3. Mutations in the Robo3 protein cause horizontal gaze palsy with progressive scoliosis (HGPPS), a rare disease marked by severe scoliosis. Other top associations in the authors' GWAS were with SNPs in the DSCAM gene encoding an axon guidance protein in the same structural class with Chl1 and Robo3. These researchers additionally found AIS associations with loci in CNTNAP2, supporting a previous study linking this gene with AIS. Cntnap2 is also of functional interest, as it interacts directly with L1 and Robo class proteins and participates in axon pathfinding. The authors concluded that these findings suggested the relevance of axon guidance pathways in AIS susceptibility, although these results require further study, particularly given the apparent genetic heterogeneity in this disease.

Huang and colleagues (2011) examined if the matrix metalloproteinase 9 gene (MMP9) polymorphism is associated with the onset or progression of AIS in Chinese Han female. Three SNPs (rs17576, rs2250889, rs1805088) were genotyped through TaqMan-based real-time polymerase chain reaction (PCR) assay in 190 AIS patients and 190 controls, all of whom were females from Chinese Han population with matched age. Analyses performed included Hardy Weinberg equilibrium test, Pearson chi-square test, Logistic regression analysis, linkage disequilibrium analysis and haplotype analysis. The mean maximum Cobb angles with different

genotypes in case-only dataset were also compared. All 3 SNPs have reached Hardy-Weinberg equilibrium in the controls. Genotype and allele frequencies of all SNPs were found similar between cases and controls by Pearson chi-square test and Logistic regression. Genotype-phenotype analysis showed that patients with CC genotype in rs2250889 featured larger maximum Cobb angles. The authors concluded that MMP9 may not be a predisposition gene of AIS in Han female. However, homozygous mutation in rs2250889 can render scoliosis more severe, implying that MMP9 defect may result in deterioration of AIS.

Xu and associates (2011) examined if the predisposition genes previously reported to be associated with the occurrence or curve severity of AIS may play a role in the effectiveness of brace treatment. A total of 312 AIS patients treated with bracing were enrolled in this study. The Cobb angle of the main curve was recorded at the beginning of brace treatment as well as at each follow-up. The patients were divided into 2 groups according to the outcome of brace treatment (success/failure). The failure of brace treatment was defined as a curve progression of more than 5 degrees compared to the initial Cobb angle or surgical intervention because of curve progression. Single nucleotide polymorphism sites in the genes for estrogen receptor α (ER α), estrogen receptor β (ER β), tryptophan hydroxylase 1 (TPH-1), melatonin receptor 1B (MTNR1B) and matrillin-1 (MATN1), which were previously identified to be predisposition genes for AIS, were selected for genotyping by the PCR-RFLP method. Differences of genotype and allele distribution between the 2 groups were compared by the χ^2 test. A logistic regression analysis was used to figure out the independent predictors of the outcome of brace treatment. There were 90 cases (28.8 %) in the failure group and 222 cases (71.2 %) in the success group. Patients in the failure group were associated with the genotype GA (50.9 versus 17.9 % $p < 0.001$) and the G allele (27.1 versus 12.0 %, $p < 0.001$) at SNP rs9340799 of the ER α gene. Similarly, they were also associated with the genotype AT (33.3 versus 13.0 %, $p = 0.002$) and the A allele (16.7 versus 9.6 %, $p = 0.033$) at SNP rs10488682 of the TPH-1 gene. For MTNR1B, the difference of genotype distribution between the 2 groups was found to be statistically significant, while the difference of allele distribution between the 2 groups was found to be marginally statistically significant; for the MATN1 and ER β genes, these investigators found no significant differences of the genotype or allele distribution between the 2 groups. In the logistic regression analysis, ER α and TPH-1 were demonstrated to be independent factors predictive of bracing effectiveness. The authors

concluded that ER α and TPH-1 might be potential genetic markers that could predict the outcome of brace treatment. Patients with the G allele at the rs9340799 site of the ER α gene and the A allele at the rs10488682 site of the TPH-1 gene are prone to be resistant to brace treatment.

Miller (2011) stated that idiopathic scoliosis is one of the most common complex genetic disorders of the musculo-skeletal system. The clinical parameters relating to onset, curve progression, and severity in relation to clinical prognosis and current treatment modalities have been defined, but do not address the cause of this disorder. In an effort to define causative genetic elements, multiple studies have delineated potential genetic loci that are statistically related to idiopathic scoliosis in a variety of populations. The question remains how future genetic testing and genomic profiling may be of aid in the therapeutic algorithms related to this disorder.

Thus, it seems that AIS is a complex disorder that result from the interaction of multiple genetic loci and the environment, however, the details of these interactions are unclear. Furthermore, an UpToDate review on "Treatment and prognosis of adolescent idiopathic scoliosis" (Scherl, 2012) does not mention the use of genetic testing.

In a review of management of idiopathic scoliosis published in the New England Journal of Medicine, Hresko (2013) commented on genetic testing for idiopathic scoliosis: "A genetic-screening test based on identification of single-nucleotide polymorphisms to predict the risk of progression of mild idiopathic scoliosis to scoliosis that requires surgical treatment is commercially available, but it has not been independently validated. Data are currently lacking to indicate that genetic testing adds meaningfully to predictions made on the basis of skeletal maturity and curve magnitude".

Ogura et al (2013) examined if the association of 53 SNPs with curve progression reported in white patients with AIS are replicated in Japanese patients with AIS. These researchers recruited 2,117 patients with AIS with 10° or more (Cobb angle) of scoliosis curves. They were divided into progression and non-progression groups according to their Cobb angle. These investigators defined the progression of the curve as Cobb angle more than 50° for skeletally mature subjects and more than 40° for immature patients, subjects. They defined the non-progression of the curve as Cobb angle 50° or less only for skeletally mature subjects. Of the 2,117 patients, 1,714

patients with AIS were allocated to either the progression or non-progression group. These researchers evaluated the association of 53 SNPs with curve progression by comparing risk allele frequencies between the 2 groups. They evaluated the progression (n = 600) and non-progression (n = 1,114) subjects. Their risk allele frequencies were not different significantly.

They found no replication of the association on AIS curve progression in any of the SNPs. The authors concluded that the associations of the 53 SNPs with progression of AIS curve are not definite. Moreover, they stated that large-scale association studies based on appropriate criteria for progression would be necessary to identify SNPs associated with the curve progression.

Tilley et al (2013) performed model-independent linkage analysis and tests of association for 22 SNPs in the CHD7 gene in 244 families of European descent with familial idiopathic scoliosis (FIS). This study was carried out to replicate an association between FIS and the CHD7 gene on 8q12.2 in an independent sample of families of European descent. Model-independent linkage analysis and intra-familial tests of association were performed on the degree of lateral curvature considered as a qualitative trait (with thresholds of greater than or equal to 10°, greater than or equal to 15°, greater than or equal to 20°, and greater than or equal to 30°) and as a quantitative trait (degree of lateral curvature). Results from the tests of associations from this study and the previous study were combined in a weighted meta-analysis. No significant results ($p < 0.01$) were found for linkage analysis or tests of association between genetic variants of the CHD7 and FIS in this study, failing to replicate the findings from the previous study. Furthermore, no significant results ($p < 0.01$) were found from meta-analysis of the results from the tests of association from this sample and from the previous sample. The authors concluded that no association between the 22 genotyped SNPs in the CHD7 gene and FIS within this study sample was found, failing to replicate the earlier findings. They stated that further investigation of the CHD7 gene and its potential association to FIS may be required.

Ryzhkov and associates (2013) performed a genetic association study of the transforming growth factor beta 1 (TGFB1) gene with AIS in Russian population. These researchers examined if common genetic polymorphisms C-509T (rs1800469) and Arg25Pro (rs1800471) of the TGFB1 gene are associated with susceptibility to AIS. A total of 600 unrelated adolescents from central Russia (Moscow) were recruited in this study, including 300 patients with AIS and 300 age- and sex-matched healthy adolescents. The polymorphisms were genotyped by PCR-restriction

fragment length polymorphism. The allele -509T and genotype -509TT of the TGFB1 gene were significantly associated with the increased risk of AIS in both females and males ($p < 0.01$). Logistic regression analysis has revealed a recessive model of the genetic association between polymorphism C-509T of the TGFB1 gene and AIS. Moreover, these investigators found sexual dimorphisms in the relationships of SNP C-509T of the TGFB1 gene with both the age of disease onset and curve severity: the polymorphism was found to determine both an early onset of scoliosis and the severity of curvature in females but not in males ($p < 0.05$). The authors concluded that the present study, for the first time, highlighted the importance of TGFB1 gene for the development and progress of AIS. These researchers hypothesized several mechanisms by which the TGFB1 gene may contribute to spinal deformity in patients with AIS.

In a meta-analysis, Liang et al (2014) investigated whether or not the rs11190870 polymorphism is associated with susceptibility to AIS in East Asian population. A systematic search of all relevant studies published through August 2013 was conducted using the MEDLINE, EMBASE, OVID, and ScienceDirect. Single nucleotide polymorphism of rs11190870 was evaluated. The included studies were assessed in the analysis of the following allele model: (a) T-allele versus C-allele for the allele level comparison; (b) TC+TT versus CC for dominant model of T-allele; (c) TT versus TC+CC for recessive model of T-allele, and (d) TT versus CC for extreme genotype. A total of 4 studies with 8,415 total participants (2,889 AIS patients and 5,526 controls), which were all East Asian population were eligible for inclusion. These investigators searched for genotypes T allele versus C allele, TT versus TC+ CC, TC + TT versus CC and TT versus CC in a fixed/random-effects model. The effect summary ORs) and 95 % CIs were obtained, which shows significant association between rs11190870 and AIS in East Asian populations (all genetic models $p < 0.001$). Subgroup group analyses were conducted according to the gender. The results showed that a significant association between rs11190870 and AIS in female (all genetic models $p < 0.001$), but not in male (all genetic models $p > 0.05$). The authors concluded that the present meta-analysis demonstrated that the T allele of SNP rs11190870 may be a major susceptibility locus in the East Asian population with AIS, especially in female.

Zhang et al (2014) noted that several previous studies have evaluated the association between rs1149048 polymorphism in the matrilin-1 gene (MATN1) and the risk of AIS. However the results of those studies were inconsistent. These investigators conducted a meta-analysis to examine if

rs1149048 polymorphism was involved in the risk of AIS and evaluated the associations in different ethnicities. Electronic databases, such as: PubMed, EMBASE, WANFANG databases in any languages up to December 2012 were searched to assess the association between rs1149048 polymorphism and AIS. Meta-analysis was performed by STATA 12.0 software to estimate the pooled OR and the 95 % CI. Finally 4 papers including 5 studies which involved 1,436 AIS patients and 1,879 controls were identified for this meta-analysis. The results showed that G allele of the rs1149048 was significantly associated with increased AIS risk [OR = 1.13, 95 % CI: 1.02 to 1.25], $p = 0.023$]. As for genotype (GG versus GA + AA), homozygous GG genotype was also found to be a risk factor of developing AIS. The subgroup meta-analysis results showed G allele and GG genotype were significantly associated with AIS in Asian group but not in Caucasian group. Neither Egger's test nor Begg's test found evidence of publication bias in current study ($p > 0.05$). The authors concluded that this meta-analysis found an overall significant association of rs1149048 polymorphism with risk of AIS, especially in Asian population. Moreover, they stated that the relationship between rs1149048 polymorphism and AIS in other ethnic population needed to be investigated.

Also, an UpToDate review on “Adolescent idiopathic scoliosis: Clinical features, evaluation, and diagnosis” (Scherl, 2014) states that “Genetic testing -- Adolescent idiopathic scoliosis (AIS) is a complex disorder that appears to result from the interaction of multiple genetic loci and the environment, but the details of these interactions are not fully understood”.

ScoliScore Test

In a replication association study that used genomic data generated from French-Canadian case and control cohorts, Tang et al (2015) examined if the 53 SNPs that were previously associated with spinal deformity progression in an American Caucasian cohort are similarly associated in French-Canadian population. Genomic data were collected from the French-Canadian population, using the Illumina HumanOmni 2.5M BeadChip. Fifty-two SNPs, tested in ScoliScore or in high linkage disequilibrium with SNPs in the test, were selected to evaluate their association with scoliosis generally, and with spinal curve progression. One SNP in ScoliScore, rs16909285, could not be evaluated in the Genome-Wide association study. None of the SNPs used in ScoliScore was associated with AIS curve progression or curve occurrence in French-Canadian

population. These researchers evaluated 52 SNPs in severe patients by comparing risk allele frequencies with those in non-severe patients and with those in control individuals. There was no significant difference between the severe group and the non-severe group or between the severe group and the control group. The authors concluded that although the 52 SNPs studied here were previously associated with curve progression in an American population of European descent, they found no association in French-Canadian patients with AIS. They stated that this second replication cohort suggested that the lack of association of these SNPs in a Japanese cohort is not due to ethnicity.

Melatonin Receptor 1B Gene (MTNR1B) (rs4753426 and rs10830963) Polymorphism Testing

In a meta-analysis, Yang and colleagues (2015) examined if melatonin receptor 1B (MTNR1B) rs4753426 and rs10830963 polymorphisms are correlated with AIS. An systematic online search was performed using PubMed, EMBASE, Web of Science and the Cochrane Library to identify case-control studies investigating the relationship between MTNR1B rs4753426 and rs10830963 polymorphisms and the susceptibility of AIS. The pooled OR with 95 % CI was calculated to assess the associations, and subgroup meta-analyses were performed according to the ethnicity of the study populations. A total of 5 studies involving 2,395 cases and 3,645 controls met the inclusion criteria after assessment by 2 reviewers. Overall, no significant associations were found between MTNR1B rs4753426 polymorphism and AIS risk (C versus T: OR = 1.11, 95 % CI: 0.94 to 1.30, $p = 0.21$; CC versus TT: OR = 1.15, 95 % CI: 0.97 to 1.36, $p = 0.12$; CT versus TT: OR = 1.14, 95 % CI: 0.97 to 1.35, $p = 0.10$; CC/CT versus TT: OR = 1.14, 95 % CI: 0.98 to 1.33, $p = 0.09$; CC versus CT/TT: OR = 1.10, 95 % CI: 0.84 to 1.45, $p = 0.48$), as well as the MTNR1B rs10830963 polymorphism (G versus C: OR = 0.99, 95 % CI: 0.88 to 1.12, $p = 0.91$; GG versus CC: OR = 0.99, 95 % CI: 0.74 to 1.33, $p = 0.96$; CG versus CC: OR = 1.00, 95 % CI: 0.84 to 1.18, $p = 0.88$; GG/CG versus CC: OR = 0.99, 95 % CI: 0.84 to 1.17, $p = 0.93$; GG versus CG/CC: OR = 0.99, 95 % CI: 0.75 to 1.30, $p = 0.92$). When stratified by ethnicity, there were no significant associations between MTNR1B rs4753426 and MTNR1B rs10830963 polymorphisms and AIS risk in either Asian or Caucasian populations. The authors concluded that MTNR1B rs4753426 and MTNR1B rs10830963 polymorphisms are not obviously associated with risk of AIS in either Asian populations or Caucasian populations.

The CLEAR Protocol

The CLEAR protocol for treating scoliosis consists of 3 components: (i) Mix, (ii) Fix, and (iii) Set. The objective of the first part of the protocol (Mix) is to warm up the spine, and prepare it for the rest of the treatment. In this portion of the protocol the patient performs several activities to warm up and loosen up the spine. These activities include the wobble chair, and different tractioning devices designed put motion into the spine. The second part of the treatment protocol (Fix) entails chiropractic adjustments. Chiropractors also perform other modalities that begin to cause correction of the spinal curvatures. During the last part of the program (Set), the patient receives several treatments that are designed to stabilize the spine in a more corrected position.

There is currently insufficient evidence that chiropractic or osteopathic manipulation is effective in treating scoliosis.

In a systematic review, Romano and Negrini (2008) verified the evidence on the effectiveness of manual therapy in the treatment of adolescent idiopathic scoliosis. These investigators included in the term manual therapy all the manipulative and generally passive techniques performed by an external operator. In a more specific meaning, osteopathic, chiropractic and massage techniques have been considered as manipulative therapeutic methods. They performed systematic researches in Medline, Embase, Cinhal, Cochrane Library, Pedro with the following terms: idiopathic scoliosis combined with chiropractic; manipulation; mobilization; manual therapy; massage; osteopathy; and therapeutic manipulation. The criteria for inclusion were as follows: Any kind of research; diagnosis of adolescent idiopathic scoliosis; patients treated exclusively by one of the procedures established as a standard for this review (chiropractic manipulation, osteopathic techniques, massage); and outcome in Cobb degrees. These researchers founded 145 texts, but only 3 papers were relevant to this study. However, none of the 3 satisfied all the required inclusion criteria because they were characterized by a combination of manual techniques and other therapeutic approaches. The authors concluded that the lack of any kind of serious scientific data prevented them from making any conclusion on the effectiveness of manual therapy for the treatment of adolescent idiopathic scoliosis.

Canavese and Kaelin (2011) noted that the strategy for the treatment of idiopathic scoliosis depends essentially upon the magnitude and pattern of the deformity, and its potential for progression. Treatment options include observation, bracing and/or surgery. During the past decade, several studies have demonstrated that the natural history of adolescent idiopathic scoliosis can be positively affected by non-operative treatment, especially bracing. Other forms of conservative treatment, such as chiropractic or osteopathic manipulation, acupuncture, exercise or other manual treatments, or diet and nutrition, have not yet been proven to be effective in controlling spinal deformity progression, and those with a natural history that is favorable at the completion of growth. Observation is appropriate treatment for small curves, curves that are at low-risk of progression, and those with a natural history that is favorable at the completion of growth. Indications for brace treatment are a growing child presenting with a curve of 25° to 40° or a curve less than 25° with documented progression. Curves of 20° to 25° in patients with pronounced skeletal immaturity should also be treated.

Gleberzon et al (2012) conducted a search of the literature between 2007 and 2011 investigating the use of spinal manipulative therapy (SMT) for pediatric health conditions and performed a systematic review of eligible retrieved clinical trials. The Index of Chiropractic Literature and PubMed were electronically searched using appropriate search words and MeSH terms, respectively, as well as reference tracking of previous reviews. Studies that met the inclusion criteria were evaluated using an instrument that assessed their methodological quality. A total of 16 clinical trials were found that met the inclusion criteria and were scored. Six clinical trials investigated the effectiveness of SMT on colic, 2 each on asthma and enuresis, and 1 each on hip extension, otitis media, suboptimal breastfeeding, autism, idiopathic scoliosis and jet lag. None investigated the effectiveness of SMT on spinal pain. The authors concluded that many studies reviewed suffered from several methodological limitations. They stated that further research is needed in this area of chiropractic health care, especially with respect to the clinical effectiveness of SMT on pediatric back pain.

Also, an UpToDate review on "Treatment and prognosis of adolescent idiopathic scoliosis" (Scherl, 2013) states that "Options for treatment include observation, bracing, and surgery, as discussed below [2-6]. Physical therapy, chiropractic treatment, electrical stimulation, and biofeedback have been shown to be ineffective".

Vertebral Body Tethering

Samdani et al (2014) reported the 2-year results of the initial cohort undergoing anterior vertebral body tethering (VBT). After obtaining institutional review board approval, these researchers retrospectively reviewed their first 11 consecutive patients who underwent anterior VBT with 2-year follow-up. They collected pertinent pre-operative, intra-operative, and most recent clinical and radiographical data. Student t-test and Fisher exact test were utilized to compare different time-points. Eleven patients with thoracic idiopathic scoliosis (8 females) were identified, with a mean age of 12.3 ± 1.6 years. Pre-operatively, all were skeletally immature (Sanders mean = 3.4 ± 1.1 ; Risser mean = 0.6 ± 1.1). All underwent tethering of an average of 7.8 ± 0.9 (range of 7 to 9) levels, with the most proximal being T5 and the most distal L2. Pre-operative thoracic Cobb angle averaged $44.2 \pm 9.0^\circ$ and corrected to $20.3 \pm 11.0^\circ$ on first erect, with progressive improvement at 2 years (Cobb angle = $13.5 \pm 11.6^\circ$, % correction = 70 %; $p < 0.00002$). Similarly, the pre-operative lumbar curve of $25.1 \pm 8.7^\circ$ demonstrated progressive correction (first erect = $14.9 \pm 4.9^\circ$, 2 year = $7.2 \pm 5.1^\circ$, % correction = 71 %; $p < 0.0002$). Thoracic axial rotation as measured by a scoliometer went from $12.4 \pm 3.3^\circ$ pre-operatively to $6.9 \pm 3.4^\circ$ at the most recent measurement ($p < 0.01$). No major complications were observed. As anticipated, 2 patients returned to the operating room at 2 years post-operatively for loosening of the tether to prevent over-correction. The authors concluded that anterior VBT is a promising technique for skeletally immature patients with idiopathic scoliosis. This technique can be performed safely and can result in progressive correction. They stated that further study with longer term follow-up will hopefully elucidate the potential risks and benefits of this innovative technology.

The same group of investigators (Samdani et al, 2015) also published 1-year results of anterior VBT for more patients ($n = 32$). Clinical and radiographic data were retrospectively analyzed. They reviewed 32 patients who underwent thoracic VBT with a minimum 1-year follow-up. Pertinent clinical and radiographic data were collected. ANOVA, Student's t-test and Fisher's exact test were utilized to compare different time-points. A total of 32 patients with thoracic idiopathic scoliosis (72 % female) with a minimum 1-year follow-up were identified; mean age at surgery was 12 years. All patients were considered skeletally immature pre-operatively; mean Risser score 0.42, mean Sanders score 3.2. Patients underwent tethering of an average of 7.7 levels (range of 7 to 11). Median blood loss was 100 cc. The mean pre-operative thoracic curve

magnitude was $42.8^{\circ} \pm 8.0^{\circ}$, which corrected to $21.0^{\circ} \pm 8.5^{\circ}$ on first erect and $17.9^{\circ} \pm 11.4^{\circ}$ at most recent. The pre-operative lumbar curve of $25.2^{\circ} \pm 7.3^{\circ}$ demonstrated progressive correction (first erect = $18.0^{\circ} \pm 7.1^{\circ}$, 1 year = $12.6^{\circ} \pm 9.4^{\circ}$, $p < 0.00001$). Thoracic axial rotation measured 13.4° pre-operatively and 7.4° at the most recent measurement ($p < 0.00001$); 1 patient experienced prolonged atelectasis, which required a bronchoscopy; otherwise, no major complications were observed. The authors concluded that these early results indicated that anterior VBT is a safe and potentially effective treatment option for skeletally immature patients with idiopathic scoliosis. These patients experienced an improvement of their scoliosis with minimal major complications. However, longer term follow-up of this cohort will reveal the true benefits of this promising technique. (Level of Evidence: IV).

Furthermore, an UpToDate review on “Adolescent idiopathic scoliosis: Management and prognosis” (Scherl, 2017) does not mention anterior vertebral body tethering as a therapeutic option.

The Tether - Vertebral Body Tethering System was approved by the Food and Drug Administration (FDA) in August 2019 via a humanitarian device exemption (HDE), which is an approval process provided by the FDA allowing a medical device for a rare disease or condition to be marketed without requiring evidence of effectiveness. The FDA calls a device approved in this manner a "Humanitarian Use Device" (HUD). In this case, the HDE requires that the manufacturer conduct post-marketing studies to determine safety and effectiveness.

Newton et al (2018) stated that anterior spinal growth tethering (ASGT) has been shown to alter spinal growth with the potential to correct scoliosis while maintaining spine flexibility. In a retrospective review, these investigators reported the 2 to 4-year outcomes of ASGT in skeletally immature patients with thoracic scoliosis. Patient demographics, peri-operative data, and radiographic outcomes were reported. A "successful" clinical outcome was defined as a residual curve of less than 35° and no posterior spinal fusion indicated or performed at latest follow-up. A total of 17 patients met the inclusion criteria. The etiology was idiopathic for 14 and syndromic for 3. The mean follow-up was 2.5 years (range of 2 to 4 years). Pre-operatively, all patients were at Risser stage 0, with a mean age at surgery of 11 ± 2 years (range of 9 to 14 years). There was an average of 6.8 ± 0.5 vertebrae tethered per patient. The average thoracic curve magnitude

was $52^{\circ} \pm 10^{\circ}$ (range of 40° to 67°) pre-operatively, $31^{\circ} \pm 10^{\circ}$ immediately post-operatively, $24^{\circ} \pm 17^{\circ}$ at 18 months post-operatively, and $27^{\circ} \pm 20^{\circ}$ at latest follow-up (51% correction; range of 5 % to 118 %). Revision surgery was performed in 7 patients: 4 tether removals due to complete correction or over-correction, 1 lumbar tether added, 1 tether replaced due to breakage, and 1 revised to a posterior spinal fusion. In 3 additional patients, posterior spinal fusion was indicated due to progression; 8 (47 %) of the patients had a suspected broken tether; 10 (59 %) of the 17 were considered clinically successful. The authors concluded that despite most patients having some remaining skeletal growth at the time of review, the results of the current study demonstrated that at mid-term follow-up, ASGT showed a powerful, but variable, ability to modulate spinal growth and did so with little peri-operative and early post-operative risk. Fusion was avoided for 13 of the 17 patients. The overall success rate was 59 %, with a 41 % revision rate. Understanding the parameters leading to success or failure will be critical in advancing a reliable definitive non-fusion treatment for progressive scoliosis in the future. Level of Evidence = IV.

In a commentary on the afore-mentioned study by Newton et al (2018), Herring (2018) stated that “A number of issues require further research. First, the indications for surgery must be better defined relative to both curve severity and patient skeletal maturity. If the patient is too immature, curves will overcorrect. With larger, stiff curves, there may be failure to correct or continued progression. Second, the nature of the tether must be studied. Unknowns include the exact force needed to alter the growth of the vertebrae and the ideal tensile strength of the tether along with the fatigue resistance at the interface of the tether and the vertebra. Prior studies show continued mobility between tethered segments, so it is likely that the tether will be continuously fatigued, perhaps for the lifetime of the patient. The third unknown is thus the fate of the spine with residual, untethered curvature: is progression likely to occur? It is very important for the spinal-deformity community to give these and others who are pioneering this research time to answer these important questions before “jumping on the band wagon” and performing many surgical procedures. The follow-up of these patients is quite limited; and many shortcomings are likely to surface in the near future. We should let these respected researchers continue their careful work before encouraging widespread clinical application”.

Wong et al (2019) stated that anterior vertebral body tethering to effect scoliosis correction in a growing spine has been shown to work with varying degrees of success. In a prospective, observational, single-center study, these researchers described the mid-term results of this technique using a new device composed of a braided ultra-high molecular weight polyethylene (UHMWPE) cord anchored to bone screws applied without segmental compression. This trial was of an investigational device. A total of 5 female patients aged 9 to 12 years with thoracic scoliosis underwent thoracoscopic insertion of the UHMWPE tether. Radiographs and magnetic resonance imaging (MRI) were performed, and the Scoliosis Research Society (SRS)-22 was administered, pre-operatively and at regular intervals after surgery, with a minimum of 4 years of follow-up. All tethering devices spanning the end vertebrae (range of 7 to 8 vertebrae) were implanted successfully. Mean blood loss was 136 ml, and the mean operative time was 205 mins. The mean pre-operative main thoracic Cobb angle was 40.1°. Curve correction of the tethered segment ranged from 0 % to 133.3 % at 4 years. These investigators observed greater correction in 2 patients with open triradiate cartilage (TRC), achieving full scoliosis correction at 2 years and 121.5 % at 4 years. MRI showed improvement in periapical disc wedging morphology and 55 % improvement of rotation at 3 years. There were 20 adverse events (AEs), of which 16 were mild and 4 were moderate in severity. The 4 moderate events of pneumonia, distal decompensation, curve progression, and over-correction occurred in 3 patients, 2 of whom required fusion. The authors concluded that anterior vertebral body tethering resulted in scoliosis deformity correction in the coronal and axial planes, with preservation of curve flexibility. Actual correction by growth modulation was noted only in patients with open TRC, whereas curve stabilization was noted in patients with closed TRC. Over-correction, curve progression, and distal decompensation were problems with this technique. These researchers stated that additional studies with more patients and longer follow-up will allow better evaluation of the indications and outcomes for this surgical procedure. Level of Evidence = IV.

Cheung et al (2019) noted that idiopathic scoliosis is the most common spinal disorder in the pediatric population. The goals of treatment for pediatric idiopathic scoliosis are to correct deformity, prevent curve progression, restore trunk symmetry and balance, and minimize pain and morbidity. Surgical treatment has advanced significantly, from the advent of segmental pedicle screw instrumentation several decades ago to the recent development of robotic-assisted surgery and growth-modulating fusionless surgery. These investigators reviewed the reported data on

emerging techniques in the surgical treatment of idiopathic scoliosis in children and adolescents. The PubMed and Google Scholar electronic databases were used to identify studies that had examined new emerging techniques in the surgical treatment of idiopathic scoliosis in children and adolescents. Major developments in the surgical techniques for pediatric idiopathic scoliosis have included robotic-assisted pedicle screw placement, vertebral body stapling, vertebral body tethering, magnetically controlled growing rods, ApiFix (not currently approved for use by the FDA), and sublaminar polyester bands. Such growth-modulating fusionless surgical techniques have received increasing attention in recent years, especially for the younger pediatric scoliosis population with significant growth potential remaining. The authors concluded that various emerging techniques in the surgical treatment of idiopathic scoliosis in children and adolescents have demonstrated promising results in the reported data thus far. However, these researchers stated that longer term, prospective studies with larger cohorts are needed to better evaluate their safety and efficacy.

Ergene (2019) examined the early-term post-operative thoracic complications in videothoroscopic anterior vertebral body tethering surgery. The study included 56 patients (3 males, 53 females; mean age of 12.6 years; range of 10 to 16 years) operated with a total of 65 videothoroscopic anterior vertebral body tethering surgeries between April 2014 and November 2018. Surgical indications were adolescents with different growth potentials, who had thoracic, thoraco-lumbar or double curves less than 70°. Surgical details and post-operative thoracic complications were recorded. A total of 42 patients were administered thoracic tether, whereas 5 and 9 patients were administered thoraco-lumbar tether and both approaches concomitantly, respectively; 2 patients developed ipsilateral total atelectasis, 1 patient contralateral lobar atelectasis, 1 patient chylothorax, 1 patient pleural effusion, and 1 patient pneumothorax after chest drain removal. Overall thoracic complication rate was 9.2 % and 30-day re-admission rate was 1.8 %. All patients achieved their rehabilitation goals. The authors concluded that videothoracoscopy-assisted anterior vertebral body tethering was a safe and efficient technique that yielded low complication rates; early post-operative functional results were promising with high patient satisfaction. Pre- and post-operative respiratory rehabilitation may decrease thoracic complication rates. Moreover, these researchers stated that longer-term follow-up with wider case series is needed on this subject.

Newton (2020) noted that the standard of care for progressive spinal deformity that is greater than 45 to 50 degrees in growing children is deformity correction with spinal fusion and instrumentation. This sacrifice both spinal motion and further spinal growth of the fused region. Idiopathic scoliosis in particular is associated with disproportionate anterior spinal column length compared to the posterior column (hypokyphosis) that is associated with the coronal (scoliosis) and axial plane (rib and lumbar prominence) deformities. In theory, application of compression to the convex and anterior aspects of vertebrae could decrease both anterior and lateral growth via the Hueter-Volkman principle, while allowing growth on the concave and posterior aspect resulting in spinal realignment created by altered growth. Animal models and preliminary clinical experience suggested spinal growth can be modulated in this way using a flexible tether applied to the convex side of scoliotic vertebral column. Experimental studies suggested disc health is preserved with a flexible tether as disc motion is maintained during the growth period. Anterolateral tethering been performed via a thoracoscopic spinal approach clinically for a number of years and the early clinical outcomes are beginning to appear in the literature. Initial results of antero-lateral tethering in growing patients with spinal deformities are encouraging, however the results 3 to 4 years after the procedure are somewhat mixed. The author stated that further research is ongoing and many remain optimistic that improvements in technology and understanding will continue to lead to better patient outcomes.

In a retrospective study, Newton et al (2020) compared outcomes for patients with thoracic idiopathic scoliosis between a group of patients who underwent anterior vertebral body tethering (AVBT) and a matched cohort of patients treated with posterior spinal fusion and instrumentation (PSF). The inclusion criteria were determined on the basis of the AVBT cohort: primary thoracic idiopathic scoliosis with a curve magnitude between 40° and 67°, Risser stage of less than or equal to 1, age of 9 to 15 years, no prior spine surgery, index surgery between 2011 and 2016, and minimum follow-up of 2 years. Demographic, radiographic, clinical, and patient-reported outcomes and revisions were compared between groups. There were 23 patients in the AVBT cohort and 26 patients in the PSF cohort. The mean follow-up (and standard deviation [SD]) was similar between groups: 3.4 ± 1.1 years for the AVBT group and 3.6 ± 1.6 years for the PSF group ($p = 0.6$). Pre-operatively, the groups were similar in all measurements of radiographic and clinical deformity, with mean main thoracic curves of $53^\circ \pm 8^\circ$ for the AVBT group and $54^\circ \pm 7^\circ$ for the PSF group ($p = 0.4$). At the time of final follow-up, the AVBT cohort had significantly more

residual deformity, with a mean thoracic curve of $33^{\circ} \pm 18^{\circ}$ compared with $16^{\circ} \pm 6^{\circ}$ for the PSF group ($p < 0.001$). There were 9 revision procedures in the AVBT cohort (with 3 conversions to PSF and 3 more pending) and none in the PSF cohort. Revisions occurred at a mean post-operative time of 2.3 years (range of 1.2 to 3.7 years); 12 patients (52 %) had evidence of broken tethers; of these patients, 4 underwent revision. The post-intervention patient-reported outcomes were similar. The authors concluded that both AVBT and PSF resulted in post-operative correction; however, 2-year correction was better maintained in the PSF group. There were no differences in post-intervention patient-reported outcomes. These researchers also noted that AVBT resulted in less deformity correction and more revision procedures than PSF; but resulted in the delay or prevention of PSF in the majority of patients. Level of Evidence = III.

In a commentary on the afore-mentioned study by Newton et al (2020), Herring et al (2020) stated that “The data, which are honestly reported in detail, are not favorable to vertebral tethering. Indeed, some of the data contradict portions of the authors’ earlier reports. The discussion of the results presents a more favorable interpretation than is deserved, an opinion noted by each reviewer prior to publication. ... The frequency of breakage of the tethers, 52 %, is alarming. It is alarming because it represents failure of the construct and especially because we do not know what will happen to the spine in the future. Will the untethered segment(s) allow continued progression, and will the patient have pain? It is also concerning because, in this study, with longer follow-up, the incidence of breakage of tethers has increased. I noted in a prior commentary that we simply do not have enough follow-up of this surgical procedure to promote wider usage, and this article by Newton et al reinforces my conclusion². For certain, we need development of a more durable, fatigue-resistant cable prior to generalized use ... In their earlier work, Newton et al and others showed proof of the concept that anterior tethering of vertebrae can alter spinal growth to correct deformity with continued growth. This an important finding and will certainly be of use in the future. To get a real benefit from the technology, we must perform studies that identify the circumstances of deformity and maturity in which the advantages of gradual correction and lack of fusion can be appreciated. Can we achieve gradual correction without overcorrection? Should this technique replace brace management of smaller curves in younger patients? Surely, we can come up with more fatigue-resistant cable materials; and continuing to use current models with > 50 % failure is not wise”.

In an in-vivo study, Lalande et al (2020) examined the relationship between the tether tension and the pressures transmitted onto the vertebral end plates by a cyclic anterior vertebral body tethering (AVBT) prototype. AVBT is a recent surgical technique for the treatment of pediatric scoliosis that compresses the convex side of the spine with a sustained tension, to modulate the growth to progressively correct the deformity over time. Previous studies demonstrated that cyclic compression has similar growth modulation capacity but with less detrimental effects on the integrity of the discs and growth plates. A 3-month old healthy Duroc pig was anesthetized and a lateral thoracotomy was performed. The T7 to T10 segment was instrumented and compressed during 50 s with the load oscillating (0.2 Hz) from + 30 to – 30 % of the following mean tensions: 29, 35, 40, 44, and 49 N. The pressure exerted on T9 superior vertebral end plate was monitored during the cyclic loading; 3 repetitions of each test were performed. The resulting mean pressure exerted on the vertebral end plate was linearly correlated with the mean tether tension ($r^2 = 0.86$). Each cycle translated in a hysteresis profile of the measured pressure and tension, with amplitudes varying between ± 11.5 and ± 29.9 %. The authors concluded that this experimental study documented the relationship between the tether tension and the pressure. This study confirmed the feasibility of cyclic AVBT principle to transfer varying pressures on the vertebral end plates, which is intended to control vertebral growth, while keeping the spine flexibility and preserving the health of soft tissues such as the intervertebral discs and the growth plate but remained to be further verified. Level of Evidence = IV.

Pehlivanoglu et al (2020) presented the minimum 2-year results of AVBT applied to 21 skeletally immature patients with adolescent idiopathic scoliosis (AIS). A decision to proceed with surgery was established after the detection of curve progression despite the brace (greater than 40 degrees) with a minimum curve flexibility of 30 %. Patients had an average age of 11.1 and an average follow-up period of 27.4 months. All patients underwent thoracoscopic placement of thoracic screws, from the convex side of curves. An average of 7.1 levels of tethering was undertaken. Average pre-operative major thoracic curve magnitudes improved from 48.2 to 16 degrees on the 1st erect post-operative x-ray, and to 10 degrees at the last follow-up ($p < 0.001$). Immediate post-operatively, 1 case with chylothorax was detected and treated conservatively, and another case with tether breakage was detected at the 3rd post-operative year and replaced thoracoscopically. No other major complication was observed. The authors concluded that AVBT as a growth modulating therapeutic option by allowing the correction of the scoliotic deformity and

preserving coronal balance was detected to be a safe and effective option for the surgical treatment of AIS in skeletally immature patients, if applied under strict inclusion criteria. These investigators stated that AVBT by allowing preservation of spinal segmental motion is yielding promising radiographic results without causing any major complications. Level of Evidence = IV.

Parent and Shen (2020) stated that the management of idiopathic scoliosis in the skeletally immature patient can be challenging; PSF is indicated for severe scoliosis deformities. However, the skeletally immature patient undergoing PSF is at risk for developing crankshaft deformities. Moreover, bracing treatment remains an option for patients who are skeletally immature, and although it was found to be effective, it does not completely preclude deformity progression. Recently, fusionless therapeutic options, such as anterior vertebral body growth modulation, have been developed to treat these patients while avoiding the complications of posterior rigid fusion. Good results have been shown in recent literature with proper indications and planning in the skeletally immature patient. This was a review article; it did not provide any clinical data on the safety and effectiveness of AVBT.

In a retrospective study, Hoernschemeyer et al (2020) reported post-operative radiographic and clinical outcomes for patients treated with VBT. This clinical and radiographic review of 31 consecutive patients included an analysis of pre-operative, peri-operative, and post-operative details, including the Lenke classification; Cobb angle measurements of the proximal thoracic, main thoracic, and lumbar curves; the sagittal profile; and skeletal maturity. Successful outcomes were defined by a residual curve of less than or equal to 30° in skeletally mature patients who did not undergo a PSF. Of the 31 patients treated, 29 met the inclusion criteria, and 2 were lost to follow-up. The mean patient age (and SD) at the time of the surgical procedure was 12.7 ± 1.5 years (range of 10.2 to 16.7 years), with most patients classified as Risser grade 0 or 1 (52 %) and Sanders stage 3 (32 %). A mean of 7.2 ± 1.4 vertebral levels were instrumented, with a minimum pre-operative Cobb angle of 42°. At the latest follow-up, 27 patients had reached skeletal maturity (Sanders stage of greater than or equal to 7) and 20 patients exhibited a curve magnitude less than or equal to 30°, for a success rate of 74 %. A suspected broken tether occurred at greater than or equal to 1 level in 14 patients (48 %); 2 patients underwent PSF and 4 had tether revision. The overall revision rate was 21 % (6 of 29). The authors concluded that the findings of this study showed the success and revision rates as well as the impact of a suspected

broken tether on the procedural success of VBT. Despite this patient population being slightly more mature at the time of the surgical procedure compared with previous studies, these investigators had a higher success rate and a lower revision rate. A PSF was avoided in 93 % of patients, indicating that VBT may be a reliable therapeutic option for adolescent scoliosis in skeletally immature individuals. Level of Evidence = IV.

Meza et al (2022) critically analyzed the study by Hoernschemeyer et al (2020) that assessed the clinical and radiographic outcomes of VBT in the treatment of adolescent scoliosis. The authors demonstrated successful treatment in 74 % of patients, based on radiographic outcomes and avoidance of subsequent posterior spinal fusion. Nearly 25 % of patients required revision surgery. Almost 50 % suffered a broken tether, although the effects of such complications were not fully understood. The study provided valuable information for determining which patients are reasonable candidates for VBT and emphasized several questions surrounding this novel technology that remain unanswered. Meza et al discussed the study's strengths and weaknesses, suggested potential directions of future research, and examined the potential indications for VBT.

Miyanji et al (2020) noted that spinal fusion remains the gold standard in the treatment of idiopathic scoliosis; however, AVBT is gaining widespread interest, despite the limited data on its efficacy. These researchers examined the efficacy of AVBT in skeletally immature patients with idiopathic scoliosis. All consecutive skeletally immature patients with idiopathic scoliosis treated with AVBT enrolled in a longitudinal, multi-center, prospective database between 2013 and 2016 were analyzed. All patients were treated by 1 of 2 surgeons working at 2 independent centers. Data were collected prospectively in a multi-center database and supplemented retrospectively where necessary. Patients with a minimum follow-up of 2 years were included in the analysis. Clinical success was set a priori as a major coronal Cobb angle of less than 35° at the most recent follow-up. A total of 57 patients were included in the study. Their mean age was 12.7 years (SD 1.5; 8.2 to 16.7), with 95 % being female. The mean pre-operative Sanders score and Risser grade was 3.3 (SD 1.2), and 0.05 (0 to 3), respectively. The majority were thoracic tethers (96.5 %) and the mean follow-up was 40.4 months (SD 9.3). The mean pre-operative major curve of 51° (SD 10.9°; 31° to 81°) was significantly improved to a mean of 24.6° (SD 11.8°; 0° to 57°) at the 1st post-operative visit (45.6 % (SD 17.6 %; 7 % to 107 %); $p < 0.001$) with further significant

correction to a mean of 16.3° (SD 12.8°; -12 to 55; $p < 0.001$) at 1 year and a significant correction to a mean of 23° (SD 15.4°; -18° to 57°) at the final follow-up (42.9 % (-16 % to 147 %); $p < 0.001$). Clinical success was achieved in 44 patients (77 %). Most patients reached skeletal maturity, with a mean Risser score of 4.3 (SD 1.02), at final follow-up. The complication rate was 28.1 % with a 15.8 % rate of unplanned revision procedures. The authors concluded that AVBT was associated with satisfactory correction of deformity and an acceptable complication rate when used in skeletally immature patients with idiopathic scoliosis. Improved patient selection and better implant technology may improve the 15.8 % rate of revision surgery in these patients. Moreover, these researchers stated that further scrutiny of the true effectiveness and long-term risks of this technique remains critical.

The authors stated that this study had several drawbacks. These investigators analyzed lumbar and thoracic tethers together for clarity. As numbers grew, further work is needed to examine if their responses to AVBT differ. These researchers also analyzed radiological parameters and this study lacked any functional health-related quality of life (HR-QOL) assessments. The concern for the latter was that patient-reported outcome measures (PROMs) in these patients could be misleading as many presented with the desire to undergo AVBT; thus, introduces a significant bias when evaluating treatment effect using PROMs. The authors felt that the cognitive dissonance would greatly skew any meaningful interpretations of PROMs. Furthermore, a minimum 2-year follow-up was not an adequate benchmark for these patients and clearly longer follow-up is needed to make any definitive statements regarding the true value of this technique. Given the increased interest in AVBT from both patients and surgeons globally, these researchers felt strongly that these data, despite their drawbacks, need to be disseminated to the readership and added to the paucity of literature so that the efficacy and true impact of this technique can be rigorously evaluated prior to its widespread adoption.

Baker et al (2021) noted that AVBT is a non-fusion surgical procedure for correction of scoliosis in skeletally immature individuals. With the approval from the FDA in 2019, AVBT technology is spreading and early to mid-term reports are being published. Early clinical reports are promising while precise indications, outcomes, complication profiles, and best practices are being established. Patients who are skeletally immature and wish to avoid a fusion surgery may benefit

from this procedure. The authors highlighted the translational science foundation, early to mid-term clinical reports, and future directions for this growing technique in pediatric spinal deformity surgery.

Hedge et al (2021) noted that AVBT offers a dynamic fusionless correction option for children with AIS. Few existing clinical studies evaluating novel AVBT in skeletally immature children have questioned the mid-term efficacy with concerns of overcorrection and curve progression with remaining growth. These investigators examined the effect of AVBT in skeletally mature children (Risser greater than or equal to 4 and Sanders greater than or equal to 7) with AIS with limited remaining growth potential. They evaluated skeletally mature children with AIS who underwent the AVBT technique for a single structural major curve between 40° and 80° with greater than or equal to 50 % flexibility on dynamic radiographs and a minimum of 1 year of follow-up. Pertinent clinical and radiographic data collected include skeletal maturity, curve type, Cobb angle, sagittal parameters, and a patient-reported outcome measure Scoliosis Research Society-22 (SRS-22) questionnaire. All 10 children were female with a mean age of 14.9 ± 2.7 years at the time of surgery. The mean follow-up was 24.1 ± 3.6 months. The mean Risser and Sanders scores were 4.2 ± 0.6 and 7.2 ± 0.6 , respectively; 3 patients had major thoracic curves, and 7 patients had thoracolumbar/lumbar curves. Cranial and caudal instrumented levels were T5 and L4. Mean pre-operative Cobb's angle was $52.0^\circ \pm 11.6^\circ$ and was corrected to $15.9^\circ \pm 6.8^\circ$ on the first erect post-operative radiograph, with stabilization of corrected curve at the 1-year follow-up (mean Cobb's angle of $15.3^\circ \pm 8.7^\circ$). Mean pre-operative and post-operative SRS-22 scores were 78.0 ± 3.2 and 92.5 ± 3.1 , respectively ($p < 0.01$). No complications were noted until the last follow-up. The authors concluded that their preliminary experience with this novel AVBT as an alternative technique to fusion to stabilize progressive idiopathic scoliosis in skeletally mature children is promising. These researchers stated that long-term outcome of large series documenting the ideal candidate for surgery, ideal curve characteristics, ideal timing of surgery, and magnitude of intra-operative curve correction will be critical for this novel technique to reduce the re-operation rate or convert into fusion surgery. Level of Evidence = IV.

The authors stated that drawbacks of this preliminary study included small sample size ($n = 10$), heterogeneous curve patterns, and lack of a control group. Furthermore, these researchers did not objectively measure spinal range of motion (ROM) to support the claim of preservation of

motion by this novel technique. Prior sample size calculation and power analysis were not feasible as this novel surgical technique effect size is not well documented.

In a retrospective study, Baroncini et al (2021) examined the feasibility of correcting double-curve scoliosis using dynamic scoliosis correction (DSC, also known as vertebral body tethering), which requires a bilateral anterior approach with deflation of both lungs. Typically, this approach falls under the exclusionary criteria for the eligibility for anterior scoliosis surgery. No data exists on the feasibility of single-staged bilateral DSC. These researchers carried out an analysis using the data from 25 patients who underwent a bilateral anterior thoracic approach and instrumentation; 30-day postoperative complication rates were analyzed. A learning curve sub-analysis was also performed to compare the first 12 patients to the remainder of the 13 patients, with a T-test ($p \leq 0.05$). Of the 25 patients treated, there was 1 intra-operative event: After performing lumbar DSC, the contralateral DSC was abandoned due to unexpected pleural scarring and staged selective thoracic fusion was performed. These investigators observed 4 post-operative complications: 2 patients had recurrent pleural effusions, 1 patient was diagnosed with pneumonia, and 1 patient had a minor pulmonary embolism (PE) without cardiopulmonary consequences (after an international 24-hour flight). All patients recovered well. These researchers observed a significant influence of learning curve on surgical time (328 versus 280 mins, $p = 0.03$) and blood loss (480 versus 197 ml, $p = 0.03$). The authors concluded that these data suggested that bilateral, single-stage surgery for DSC was feasible albeit with an elevated complication rate that may partly be attributable to the learning curve. These researchers stated that future research should focus on the cause of pulmonary complications and include a matched comparative analysis with traditional posterior fusion.

The authors stated that this study had several drawbacks. These researchers did not provide statistically comparable radiographic data, nor was the aim of this study to promote DSC as a standard treatment for scoliosis. They were aware that additional data needs to be analyzed and continue to work toward that venture. These studies include the analysis of radiographic and clinical data and will be evaluated once their patients meet the minimal follow-up time of 24 months. However, given the demand from clinicians to report outcomes from DSC, we felt it was valid to report early outcomes from this select cohort.

Senkoylu et al (2020) stated that management of scoliosis in young children needs a comprehensive approach because of its complexity. There are many debatable points; however, these investigators discussed serial casting, growing rods (including traditional and magnetically controlled) and AVBT. The authors concluded that AVBT appeared to be a promising novel technique for the treatment of idiopathic scoliosis in immature cases. It provides substantial correction and continuous curve control while maintaining mobility between spinal segments; however, long-term results, adverse effects and their prevention should be clarified by future studies.

Trobisch and Baroncini (2021) analyzed the rate of tether breakages after lumbar VBT and examined the effects and possible benefits of the use of a 2-tether construct. Tether breakage is a known mechanical complication after VBT; however, the literature only referred to thoracic VBT, and no data on the breakage rate or 2-tether construct following lumbar VBT are available. Patients who underwent lumbar VBT with lowest instrumented vertebra at L3 or L4 and had a 1-year follow-up were included. Radiologic data were obtained pre-operatively, at the 1st standing X-ray and at the 1-year follow-up to study breakage rate, loss of correction and lumbar lordosis in 1- and 2-tether constructs. Data from 30 patients (mean age of 14.7 ± 1.8 years) were available, 12 with double tether. Double tether did not decrease lumbar lordosis. The breakage rate was 24 % in segments instrumented with a single tether and 16 % in segments instrumented with a double tether (odds ratio [OR] 1.6, $p = 0.4$). Lumbar loss of correction was $10^\circ \pm 6.8^\circ$ in the entire cohort and $12.1^\circ \pm 5.4^\circ$ in patients with a breakage ($p = 0.2$). Revision rate was 10 %, due to tether breakage and loss of correction. The authors concluded that breakage rate following lumbar VBT was high; but was improved with the use of a 2-tether construct. Despite tether breakage, loss of correction was limited and the revision rate low. The use of a double tether does not have a kyphotic effect on the lumbar spine. This was a relatively small ($n = 30$) study with short-term follow-up (1 year); and it examined the rate of tether breakages of a 2-tether construct.

Pehlivanoglu et al (2021a) noted that in skeletally immature patients with adolescent idiopathic scoliosis (AIS), VBT as a fusionless minimally invasive therapeutic option has been shown to correct the deformity by growth modulation. In a prospective, cohort study, these researchers presented the minimum 2 years' results of double-sided VBT applied to double curves of 13

skeletally immature patients with AIS. All patients were followed-up within a brace for at least 6 weeks. A decision to proceed with surgery was established after the detection of curve progression within the brace (greater than 40° thoracic, greater than 35° lumbar) with a minimum curve flexibility of 30 %. Patients had an average age of 11.8 years, average follow-up duration of 36.4 months (range of 24 to 46), average pre-operative main thoracic/thoracolumbar or lumbar curve magnitudes of 48.2°/45.3°. An average of 11.8 levels of tethering was undertaken. Thoracic screws were placed thoroscopically, while mini-thoracotomy/lumbotomy was added for thoraco-lumbar levels. Post-operatively, an average 1st erect thoracic/thoraco-lumbar major curve magnitudes of 17.3°/14.3° were acquired, while they improved to 9.7°/8.2° at the last follow-up. No neurologic or implant-related complications were acquired. The authors concluded that the present study for the first time in the literature successfully proposed a promising solution for double curves of skeletally immature patients as a result of the use of double-sided VBT. A gradual, growth-assisted correction of both curves together with the preservation of thoracic kyphosis, lumbar lordosis, coronal–sagittal balance was reported without any major complications.

The authors stated that the limitations of this study included the non-existing comparison group and the still existing controversy regarding the ideal amount of tethering to be applied to curves with different magnitudes in patients with different ages. It should also be emphasized that a longer-term follow-up is mandatory prior making any recommendations regarding the use of double-sided VBT procedure to skeletally immature patients with double curves, since this operation is still considered as experimental and potential complications regarding the implants might occur in the longer time follow-up. Lack of intra-operative radiation exposure data was considered as another limitation of this study and these investigators believed a study should be designed regarding this particular point, which is of high importance.

In a retrospective study, Pehlivanoglu et al (2021b) presented the preliminary findings of the comparison of clinical and functional outcomes of VBT and posterior spinal fusion (PSF) for the first time in the literature. A total of 21 thoracolumbar (T5-L3) VBT patients (VBT group); and 22 age-gender-fusion level and minimum follow-up duration matched thoracolumbar (T3 to L3) PSF patients (PSF group) were enrolled. Average FU duration of group 1 and 2 were 37.1/37.8 months ($p = 0.33$). Patients' clinical data together with SRS-22 scores and SF-36 scores were

compared. was undertaken. VBT group was detected to have superior lumbar range of motion (ROM); superior anterior-lateral lumbar bending flexibility; superior flexor and extensor endurance of trunk, and superior average motor strength of trunk muscles with high statistical significance. VBT group was also detected to have superior scores regarding life quality, including better average total SRS-22 and better average SF-36 MCS/PCS scores with also high statistical significance. The authors concluded that of this study for the 1st time in the literature concluded, that in skeletally immature patients with AIS, VBT as a result of the use of growth modulation was able to yield significantly superior lumbar ROM, lumbar anterior and lateral flexibility, trunk flexor-extensor endurance and trunk motor strength as compared to patients who underwent fusion. By yielding significantly superior SRS-22 and SF-36 scores, VBT was detected to provide better quality of life (QOL) and patient satisfaction than fusion. This study concluded hereby, that by applying VBT, spinal motion could be preserved; and complications of fusion could be avoided.

The authors stated that this study had several drawbacks. First, the follow-up durations of the VBT group and PSF (matched) group were only 3 years. It was simply because of the novelty of the VBT procedure, which was started to be applied to skeletally immature patients under strict inclusion criteria recently. Another drawback was the potential differences regarding the indications of VBT and PSF procedures, including the curve flexibility (higher in VBT group) and curve magnitudes (higher in PSF group), even if the patients were selected age-, gender-, follow-up duration- and instrumented level-matched. This might have affected the radiographic results more than the functional results, which the present study was based on. The matching process of the 2 surgical procedures (VBT and PSF) with overlapping, as well as distinct indication criteria was an important limitation which could be attributed to the retrospective and comparative design of the present study which might also be considered as a possible weakness. Another drawback was the retrospective nature of this trial, even though a comparative design was employed.

Rushton et al (2021) stated that the value of AVBT is currently unclear given the paucity of available data. In a prospective, case-series study, these researchers examined the effectiveness of AVBT in skeletally immature patients. Consecutive skeletally immature patients with AIS were treated with AVBT between 2012 and 2018 by 1 of 2 surgeons working at 2 independent centers and followed-up for more than 2 years. Data were collected prospectively and supplemented

retrospectively where necessary. Outcomes were measured pre-operatively, at first erect radiograph (FE), 1-year post-operatively and at most recent follow up (FU). A total of 112 patients underwent 116 primary tethering procedures (108 thoracic and 8 lumbar tethers); 4 patients had primary tethering of both lumbar and thoracic curves. At surgery mean age was 12.7 ± 1.4 years (8.2 to 16.7) and Risser 0.5 ± 0.9 (0 to 3). Follow-up was mean 37 ± 9 months (15 to 64). Pre-operative mean coronal Cobb angle of the 130 tethered curves was $50.8^\circ \pm 10.2$ (31 to 81) and corrected significantly to $26.6^\circ \pm 10.1$ (-3 to 61) at FE radiograph ($p < 0.001$). Further significant improvement was observed from FE to 1-year, to mean $23.1^\circ \pm 12.4$ (-37 to 57) ($p < 0.001$). There was a small but significant increase between 1-year and FU to $25.7^\circ \pm 16.3$ (-32 to 58) ($p < 0.001$), which appeared to reflect tether breakage. Untethered minor curves were corrected from $31.0^\circ \pm 9.5$ (3 to 57) to $20.3^\circ \pm 10.3$ (0 to 52) at FU ($p < 0.001$). Rib hump was corrected from 14.1 ± 4.8 (0 to 26) to $8.8^\circ \pm 5.4$ (0 to 22) at FU ($p < 0.01$); 25 patients (22 %) had 28 complications; and 15 patients (13 %) requiring 18 revision operations including 6 completed and 1 awaited fusions. The authors concluded that AVBT of immature cases was associated with satisfactory deformity correction in the majority of cases; however, complication and revision rates suggested the need for improved implants and patient selection. These researchers stated that long-term follow-up remains crucial to establish the effectiveness of this procedure. Level of Evidence = III.

The authors stated that this study had several drawbacks. Pre-operative Sanders score was only available for 33 patients. These investigators analyzed lumbar and thoracic tethers together. Further work is needed to determine if their responses to AVBT differ. No PROMS were reported. Their concern for the latter was that many patients presented with the desire to undergo AVBT; thus, cognitive dissonance may impede meaningful interpretations of PROMs. Furthermore, duration of follow-up was inadequate with longer term results needed to understand the true value of AVBT.

Polly et al (2021) noted that AVBT is a non-fusion, minimally invasive, growth-modulating procedure with some early positive clinical outcomes reported in pediatric patients with idiopathic scoliosis (IS). VBT offers potential health-related QOL (HR-QOL) benefits over spinal fusion in allowing patients to retain a greater ROM after surgery. These investigators carried out an early cost-utility analysis (CUA) to compare VBT with fusion as a 1st-choice surgical treatment for

skeletally immature patients (age greater than 10 years) with moderate-to-severe IS, who have failed non-operative management, from a U.S. integrated healthcare delivery system perspective. The CUA uses a Markov state transition model, capturing a 15-year period following index surgery. Transition probabilities, including revision risk and subsequent fusion, were based on published surgical outcomes and an ongoing VBT observational study. Patients were assigned utilities derived from published patient-reported outcomes (PROs; SRS-22r mapped to EQ-5D) following fusion and the above VBT study. Index and revision procedure costs were included. Probabilistic (PSA) and deterministic sensitivity analyses (DSA) were performed. VBT was associated with higher costs but also higher quality-adjusted life years (QALYs) than fusion (incremental costs: \$45,546; QALYs gained: 0.54). The subsequent incremental cost-effectiveness ratio for VBT versus fusion was \$84,391/QALY gained. Mean PSA results were similar to the base case, indicating that results were generally robust to uncertainty. The DSA indicated that results were most sensitive to variations in utility values. The authors concluded that this was the 1st CUA comparing VBT with fusion in pediatric patients with IS and suggested that VBT may be a cost-effective alternative to fusion in the U.S., given recommended willingness-to-pay thresholds (\$100,000 to \$150,000). The results relied on HR-QOL benefits for VBT compared with fusion. Moreover, these researchers stated that further analyses with larger VBT sample sizes, longer-term VBT data, and head-to-head studies are needed to help address remaining uncertainties and inform decision-making for the most appropriate treatment for pediatric patients.

Yucekul et al (2021) stated that VBT was claimed to prevent disc degeneration due to its less rigid nature compared to other growth-friendly techniques. Yet, the consequences of VBT surgery on discs and facet joints have not been precisely acknowledged. These investigators examined the changes in the intermediate and adjacent levels at least 2 years after surgery. Patients with AIS who underwent thoracoscopic VBT between 2014 and 2017 were included. Outcome measures included degeneration of the intervertebral discs using the Pfirrmann classification, and degeneration of facet joints using a scale of 0 to 3. Demographic, peri-operative, clinical, radiographic data were collected. Skeletal maturity and height gain were assessed in every follow-up. Over-correction, tether breakage, mechanical and pulmonary complications as well as re-admission and re-operations were recorded. MRIs taken before surgery and at a minimum of 2 years follow-up were evaluated for degeneration at the intermediate and adjacent segment

intervertebral discs and facet joints by a blinded senior radiologist and compared. A total of 25 patients with a mean of 38.6 ± 10.6 months (24 to 62) of follow-up were included. The mean age at surgery was 12.2 years (10 to 14), and the median Sanders stage was 3 (1 to 7). A mean of 7.7 ± 1.1 (6 to 11) levels were tethered. The mean pre-operative main thoracic curve magnitude of $46^\circ \pm 7.7^\circ$ was corrected to $23.3^\circ \pm 5.9^\circ$ post-operatively, which was subsequently modulated to $12^\circ \pm 11.5^\circ$ during the follow-up. At the time of the MRI (mean 29 ± 9.5 (24 to 62) months), the median Sanders stages was 7 (5 to 8). A total of 217 levels of discs and bilateral facet joints were evaluated in the pre-operative and follow-up MRI images. Analyses of disc and facet scores revealed no significant differences between patients. Deterioration of previously degenerated discs was noted in 1 patient (from grade 2 to 3), while previously healthy lower adjacent facet joints were degenerated (grade 2) in another patient. The authors concluded that intermediate discs and facet joints were preserved after growth modulation with VBT surgery at a mean of 29 months of follow-up. Moreover, these researchers stated that studies in larger cohorts with longer follow-up are needed to have more in-depth analyses of the effects of relative stabilization and altered biomechanical loads.

Hedge et al (2021) stated that AVBT offers a dynamic fusionless correction option for children with AIS. Few existing clinical studies evaluating novel AVBT in skeletally immature children have questioned the mid-term effectiveness with concerns of over-correction and curve progression with remaining growth. These investigators examined the effect of this technique in skeletally mature children (Risser 4 or greater and Sanders 7 or greater) with AIS with limited remaining growth potential. These researchers evaluated skeletally mature children with AIS who underwent the AVBT technique for a single structural major curve between 40° and 80° with 50 % or greater flexibility on dynamic radiographs and a minimum of 1 year of follow-up. Pertinent clinical and radiographic data collected included skeletal maturity, curve type, Cobb angle, sagittal parameters, and a patient-reported outcome measure (PROM) Scoliosis Research Society-22 (SRS-22) questionnaire. All 10 children were female with a mean age of 14.9 ± 2.7 years at the time of surgery. The mean follow-up was 24.1 ± 3.6 months. The mean Risser and Sanders scores were 4.2 ± 0.6 and 7.2 ± 0.6 , respectively. A total of 3 patients had major thoracic curves, and 7 patients had thoracolumbar/lumbar curves. Cranial and caudal instrumented levels were T5 and L4. Mean pre-operative Cobb's angle was $52.0^\circ \pm 11.6^\circ$ and was corrected to $15.9^\circ \pm 6.8^\circ$ on the 1st erect post-operative radiograph, with stabilization of corrected curve at the 1-year

follow-up (mean Cobb's angle of $15.3^{\circ} \pm 8.7^{\circ}$). Mean pre-operative and post-operative SRS-22 scores were 78.0 ± 3.2 and 92.5 ± 3.1 , respectively ($p < 0.01$). No complications were noted until the last follow-up. The authors concluded that their preliminary experience with this novel AVBT as an alternative technique to fusion to stabilize progressive idiopathic scoliosis in skeletally mature children is promising. Level of Evidence = IV.

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Qiu et al (2021) stated that AVBT, or spinal growth tethering, is an emerging technology that recently received FDA approval through a humanitarian device exemption (HDE) designation to treat idiopathic scoliosis patients with remaining growth. These researchers compared patients who underwent AVBT with those treated with standard-of-care (SOC) posterior spinal fusion

(PSF) to determine inherent differences in patients and families who seek cutting-edge treatments. The authors reviewed 62 PSF patients from a multi-center registry and 20 AVBT patients from an FDA-approved investigational clinical trial. The authors examined demographics, pre-operative clinical and radiographic variables, and health-related quality of life (HR-QOL). All included patients pre-operatively were classified as Lenke type 1 or 2 with a thoracic curve of 35° to 60°, a lumbar curve less than 35°, and a skeletal maturity score of Risser sign 0 or Sanders bone age of 4 or less. Idiopathic scoliosis patients treated with surgical intervention were primarily White females who were 12 years old. No differences in demographics, clinical variables, and radiographic measures were detected between the PSF and AVBT cohorts. The AVBT group showed more thoracic flexibility on bending radiographs, correcting on average 59 % compared with 43 % for PSF patients ($p = 0.005$). Patients had similar HR-QOL total scores and scores across each of the 5 domains of the Scoliosis Research Society Questionnaire Version 22. The percentage of patients scoring below 4.0 within each domain was comparable between cohorts. The authors concluded that scoliosis patients who underwent vertebral tethering at a level of deformity magnitude and maturity similar to those who underwent posterior fusion did not differ at baseline regarding demographics, clinical variables, and HR-QOL. These researchers stated that these findings established a baseline for future work analyzing the outcomes of tether patients and how they compare with the current SOC surgical treatment under a diversity of patient factors with the objective of optimizing care and minimizing risks.

The authors stated that the drawbacks of this study included a methodology that compared a multi-center database of fusion patients with a single-center perspective of tether patients. To address this concern, an analogous multi-center registry of tether patients is currently being planned. At the same time, it will be essential that as many data points for pre-defined variables be collected as possible. For example, the fusion cohort: in the current analysis had incomplete pulmonary function test results; thus, limiting the authors' ability to analyze patients' respiratory function. Also, this study did not report on outcomes between the therapeutic options due to lack of sufficient follow-up. Such efforts are ongoing; and in the future will aid in contributing to the preliminary body of work reported on growth modulation in patients.

Samdani et al (2021) provided interim results from an FDA IDE study. The authors concluded that anterior VBT is a promising technique that has emerged as a therapeutic option for patients with immature idiopathic scoliosis. These investigators presented the results from the 1st FDA-approved IDE study on AVBT, which formed the basis for the eventual HDE approval. The findings affirmed the safety and effectiveness of this technique and suggested opportunities for improvement, especially with respect to re-operation rates. Level of Evidence = IV.

These researchers stated that the findings of this study suggested that AVBT as a viable option for skeletally immature children with scoliosis; however, they must diligently ensure, via constant study, that they continue to improve the procedure. Remaining growth is important for growth modulation, but too much growth can result in over-correction. These investigators stated that they need to determine the degree of growth modulation that can occur with a low chance of over-correction in appropriately selected patients undergoing optimized surgical technique. Furthermore, the potential long-term consequences of AVBT remain unknown and may include continued curve progression, disc degeneration, and development of additional curves.

Shin et al (2021) noted that AVBT is a growth-modulation technique theorized to correct AIS without the post-operative stiffness imposed by PSF; however, data were limited to small series examining short-term outcomes. To evaluate AVBT's potential as a viable alternative to PSF, a comprehensive comparison is warranted. In a meta-analysis, these investigators compared post-operative outcomes between patients with AIS undergoing PSF and AVBT. The primary objective was to compare complication and re-operation rates at available follow-up times. Secondary objectives included comparing mid-term Scoliosis Research Society (SRS)-22 scores, and coronal and sagittal-plane Cobb angle corrections. They carried out a systematic review of outcome studies following AVBT and/or PSF procedures. The inclusion criteria included the following: AVBT and/or PSF procedures; Lenke 1 or 2 curves; an age of 10 to 18 years for greater than 90 % of the patient population; less than 10 % non-AIS scoliosis etiology; and follow-up of 1 year or longer. A single-arm, random-effects meta-analysis was carried out. Deformity corrections, complication and re-operation rates, and post-operative SRS-22 scores were recorded. A total of 10 AVBT studies (211 patients) and 14 PSF studies (1,069 patients) were included. The mean follow-up durations were similar for both groups. Pooled complication rates were 26 % for AVBT versus 2 % for PSF, and re-operation rates were 14.1 % for AVBT versus 0.6

% for PSF with non-overlapping CIs. The pooled re-operation rate among studies with follow-up times of 36 months or longer was 24.7 % in AVBT versus 1.8 % in PSF. Deformity correction, clinical outcomes, and mid-term SRS-22 scores were similar. The authors concluded that this study showed greater rates of complications and re-operations with AVBT compared with PSF. Re-operation rates were significantly greater in AVBT studies with longer follow-up (36 months or longer). Deformity correction, clinical outcomes, and mid-term SRS-22 scores were similar. While a potential fusionless treatment for AIS merits excitement, clinicians should consider AVBT with caution. Moreover, these researchers stated that future prospective, randomized, long-term, studies are needed. Level of Evidence = III.

The authors stated that this meta-analysis had several drawbacks. First, nearly all of the AVBT articles were case-series studies, limiting the study design to a single-arm meta-analysis. Therefore, the data in this study stemmed from heterogeneous patient populations, and the potential for confounding abounds. Second, the lack of Cobb-angle-correction SDs precluded accurate estimations of the variability of correction rates. Third, SDs for curve measurements were frequently unreported in the PSF group, which necessitated imputation. Fourth, these investigators only assumed 0 complications and re-operations for studies that explicitly reported so; thus, it was possible that some patients who underwent PSF had unreported complications. However, the complication rate was similar to that of a previous meta-analysis examining PSF outcomes of patients with AIS. The lack of patient-level data prevented the authors from comparing complication rates by surgical approach (open versus thoracoscopic). Fifth, the revised inclusion criteria, applied symmetrically to both AVBT and PSF studies, resulted in the inclusion of 2 patients with syndromic etiologies and 4 patients who were 9 years of age. However, these patients comprised less than 3 % of the total population; and excluding all other patients in these studies who otherwise met inclusion criteria would have led to a loss of 40 % of the AVBT population. As such, to increase the generalizability and not introduce bias by exclusion of these studies, these investigators accepted slightly more variance with regard to these criteria.

In a retrospective study, Takahashi et al (2021) examined associations between changes in segmental vertebral coronal angulation (screw angulation) and overall height after anterior spinal growth tethering for the treatment of idiopathic scoliosis and compared the rates of coronal angulation change using the pre-operative Sanders stage. The authors concluded that scoliosis

correction was associated with overall height changes and occurred primarily within 2 to 3 years after surgery in this cohort of largely Risser stage-0 patients. The correction rate was 2.8° per segment per year for the first 2 years in the Sanders stage-2 group, compared with 1.2° per segment per year for the Sanders stage-3 group. Surgical timing that considered the patient's skeletal maturity was an important factor in generating proper post-operative correction after anterior spinal growth tethering. Moreover, these researchers stated that further studies are needed to help determine the optimum timing of anterior spinal growth tethering and the amount of tension that should be placed on the cord to properly treat patients on the basis of their skeletal maturity level and curve severity; however, these segmental rates of correction for each year after anterior spinal growth tethering in patients at Sanders stages 2 and 3 should provide some data in planning such procedures in the future. Level of Evidence = III.

The authors stated that this study had several drawbacks, including those inherent to a retrospective review and the small sample size ($n = 23$). Furthermore, the initial tension in the tethers at each level was not known; thus, these researchers could not determine the effect that tension had on screw angulation or the rate of deformity correction. Further studies are needed to elucidate the association of tension in the cord with height velocity and correction rates. Although 83 % of patients reached skeletal maturity defined as Risser stages 4 and 5, at the time of the latest follow-up, longer term data are needed to ascertain the final outcome of anterior spinal growth tethering.

Antonacci et al (2021) noted that treatment for AIS is multi-factorial, including curve type and magnitude, curve progression, skeletal maturity, as well as clinical trunk deformity. While fusion is effective at achieving curve correction, it has disadvantages including prominent implants beneath the skin, back muscle scarring and atrophy, decreased spine ROM, as well as decreased functional spinal mobility. Additional concerns include the potential for longer term development of premature adjacent level disc and facet joint degeneration above and below the fusion. As a consequence of these issues with spinal fusion, surgeons have explored alternative surgical approaches to correct spinal deformity and halt curve progression using either growth modulation or re-modeling of the spine while preserving motion. This study provided an overview of a new non-fusion scoliosis correction technique called anterior scoliosis correction (ASC), which is a multi-year, multi-generational advancement of VBT, using the same screws and cords as VBT but

based on the principle of detethering the scoliotic spine, and is not dependent on growth modulation. ASC can be carried out on both immature and mature patients, allowing for more curve correction via significant de-rotation at surgery, and can restore normal kyphosis. These researchers stated that ASC can be used for patients with both idiopathic scoliosis and with other diagnoses with good predictable clinical success in greater than 90 % of patients.

Furthermore, an UpToDate review on “Adolescent idiopathic scoliosis: Management and prognosis” (Scherl, 2021) states that “Growth modulation techniques (e.g., vertebral body stapling or tethering) are intended to gradually correct scoliosis by slowing growth on the convex side of the curve. They are minimally invasive, preserve motion, and do not preclude spinal fusion if they are unsuccessful. A single tethering device has been approved by the US Food and Drug Administration for the correction of idiopathic scoliosis that has not responded to conservative treatment options (e.g., bracing)”. Moreover, growth modulation techniques are not mentioned in the “Summary and Recommendations” section of the review.

Bernard et al (2022) stated that VBT is a non-fusion technique to correct scoliosis. It allows correction of scoliosis through growth modulation (GM) by tethering the convex side to allow concave unrestricted growth similar to the hemi-epiphysiodesis concept. The other modality is anterior scoliosis correction (ASC) where the tether is able to perform most of the correction immediately where limited growth is expected. These researchers carried out a retrospective analysis of clinical and radiological data of 20 patients aged between 9 and 17 years old, (with a 19 female: 1 male ratio) between January 2014 to December 2016 with a mean 5-year follow-up (4 to 7). There were 10 patients in each group with a total of 23 curves operated on. VBT-GM mean age was 12.5 years (9 to 14) with a mean Risser classification of 0.63 (0 to 2) and VBT-ASC was 14.9 years (13 to 17) with a mean Risser classification of 3.66 (3 to 5). Mean pre-operative VBT-GM Cobb was 47.4° (40° to 58°) with a Fulcrum unbend of 17.4 (1° to 41°), compared to VBT-ASC 56.5° (40° to 79°) with 30.6 (2° to 69°) unbend. Post-operative VBT-GM was 20.3° and VBT-ASC Cobb angle was 11.2°. The early post-operative correction rate was 54.3 % versus 81 % whereas Fulcrum Bending Correction Index (FBCI) was 93.1 % versus 146.6 %. The last Cobb angle on radiograph at mean 5-year follow-up was 19.4° (VBT-GM) and 16.5° (VBT-ASC). Patients with open tri-radiate cartilage (TRC) had 3 over-corrections. Overall, 5 % of patients required fusion. This 1 patient alone had an over-correction, a 2nd-stage tether release,

and final conversion to fusion. The authors reported a high success rate (95 %) in helping children avoid fusion at 5 years post-surgery. VBT is a safe technique for correction of scoliosis in the skeletally immature patient. This was the 1st report at 5 years that showed 2 methods of VBT can be employed depending on the skeletal maturity of the patient: GM and ASC.

The authors stated that the findings of this study must be taken with caution. However, despite the numbers being small ($n = 10$ in each group), this follow-up reported one of the longest-term data in the literature. The group may appear heterogenous compared to Samdani et al (2015) but these researchers believed they adequately differentiate their 2 groups for comparison.

Furthermore, there was a learning curve as described by Baroncini et al (2021) that surgeons undertaking this procedure should be aware of; experience with anterior spinal surgery is fundamental. These results may also suffer from reporting the early cases during the learning curve. These researchers stated that understanding which technique is to be employed is key. Further analysis must be performed to identify the “sweet spot” for both skeletal maturity as well as the magnitude of correction to allow for predicted correction in skeletally immature patients. Experience in leaving some slack in the system without immediate over-correction is a nuance that is part of the learning curve. There is a caveat for the immature patient with open TRC, as GM is more unpredictable, and in 1 child constituted the authors' only unplanned 2nd stage and final fusion in the same patient. Aiming for the unbending fulcrum Cobb is a good surrogate marker. This differs in the Risser 3 to 5 late maturity ASC group, where a high fulcrum bending correction index (FBCI) is appropriate (correction beyond fulcrum and normal physiological flexibility). Excellent correction can be achieved with better predictability and fewer complications, but one must be aware of long-term stress relaxation with some increase in final Cobb angles.

In a retrospective review of prospective data from multi-center registry, Mackey et al (2022) compared outcomes of posterior spinal fusion (PSF) versus magnetically controlled growing rods (MCGR) versus VBT in 8- to 11-year-old idiopathic early onset scoliosis (EOS) patients. A total of 130 idiopathic EOS patients, 81 % female, aged 8 to 11 at index surgery (mean of 10.5 years), underwent PSF, MCGR, or VBT. Scoliosis curve, kyphosis, thoracic and spinal height, complications, and QOL were assessed pre-operatively and at most recent follow-up (prior to final fusion for VBT/MCGR). Of 130 patients, 37 (28.5 %) received VBT, 51 (39.2 %) MCGR, and 42 (32.3 %) PSF. The VBT cohort included more females ($p < 0.0005$), was older ($p < 0.0005$),

more skeletally mature ($p < 0.0005$), and had smaller major curves ($p < 0.0005$). At follow-up, scoliosis curve corrected 41.1 ± 22.4 % in VBT, 52.2 ± 19.9 % in PSF, and 27.4 ± 23.9 % in MCGR ($p < 0.0005$), however, not all VBT/MCGR patients finished treatment; 15 complications occurred in 10 VBTs, 6 requiring unplanned surgeries; 45 complications occurred in 31 MCGRs, 11 requiring unplanned surgeries, and 9 complications occurred in 6 PSFs, 3 requiring unplanned revisions. Cox proportional hazards regression adjusted for age, gender, and pre-operative scoliosis curve revealed that MCGR (hazard ratio [HR] = 21.0, 95 % CI: 4.8 to 92.5; $p < 0.001$) and VBT (hazard ratio [HR] = 7.1, 95 % CI: 1.4 to 36.4; $p = 0.019$) patients were at increased hazard of requiring revision, but only MCGR patients (HR = 5.6, 95 % CI: 1.1 to 28.4; $p = 0.038$) were at an increased hazard for unplanned revisions compared with PSF. Thoracic and spinal height increased in all groups; QOL improved in VBT and PSF patients, but not in MCGR patients. The authors concluded that in older idiopathic EOS patients, MCGR, PSF, and VBT controlled curves effectively and increased spinal height; however, VBT and PSF had a lower hazard for an unplanned revision and improved QOL. Level of Evidence = III.

Mishreky et al (2022) compared the outcomes of AVBT surgery between overweight and non-overweight patients. AIS/JIS patients with AVBT with 2-year follow-up from a multi-center pediatric spine database were evaluated pre-operatively, 1st post-operative erect, and 2 years post-operatively. ANOVA was used to compare 3 categories of BMI with significance as per Tukey-Kramer HSD post-hoc test. Risk of scoliosis progression was analyzed with Mid-P exact test. A total of 121 patients (51 underweight, 58 normal, 12 overweight; mean age of 12.5 ± 1.6 years; BMI 18.8 ± 4.6 kg/m²) were identified. Comparing underweight, normal, and overweight groups: mean pre-operative age (13 years, 13 years, 12 years), scoliosis (52° , 50° , 52°), pre-operative kyphosis (29° , 28° , 33°), peri-operative scoliosis correction (44 %, 42 %, 46 %), and complications by 2-year follow-up (23 %, 24 %, 17 %) were similar between groups. There was 1 broken tether in each of the underweight and normal weight groups. Change in percent scoliosis correction from 1st erect to 2-year post-operative (i.e., growth modulation phase) was not significantly different between groups; however, the risk ratio for scoliosis progression during this period was 4.74 (1.02 to 22.02; $p = 0.04$) for overweight patients. The authors concluded that the findings of this study demonstrated that, as compared to normal weight and underweight patients, overweight patients did not have a statistically significant difference in intra-operative scoliosis

correction or in risk of experiencing complication; however, overweight patients had a risk ratio of 4.74 for progression of scoliosis during the growth modulation phase of treatment from first erect radiographs to minimum 2-year follow-up. Level of Evidence = III.

Shankar et al (2022) stated that durability of outcomes following VBT is a concern and may be impacted by tether breakage (TB), which has been unstudied in a large cohort. These researchers examined TB rates and their impact on clinical outcomes in the largest single-surgeon series to-date. Inclusion criteria were VBT patients with AIS, major Cobb angle less than or equal to 75°, and minimum 2-year FU. TBs were identified on 1- and 2-year FU X-rays. TB rates between single-cord and double-cord tethers were evaluated using 2-proportion z test. Curve correction rates and SRS-22 scores between patients with and without TB at 2 years were evaluated using Mann-Whitney U test. A total of 69 patients were included. By 2-year FU, 18 (27 %) had experienced TB. TB primarily occurred in major (70 %) versus minor curves and thoraco-lumbar tethers (75 %) versus thoracic. TB rates between thoraco-lumbar single (32 %) and double-cord tethers (30%) were not significantly different ($p = 0.88$). Mean major curve correction at 2-year FU was lower ($p = 0.02$) in patients with major curve TB (48° to 24°, 50 %) versus those without (53° to 21°, 60 %); 2 patients (3 %) required re-operation, 1 due to foraminal encroachment from a screw tip and 1 for curve progression with TB. The authors concluded that TB rate was 27 % at 2 years following VBT. Broken major curve tethers were associated with minor loss of correction that may not be clinically significant. TB rates were higher for thoraco-lumbar curvatures and double cords may not be protective against TB. Moreover, these researchers stated that further study of long-term TB rates is imperative. Level of Evidence = IV.

Raitio et al (2022) stated that VBT represents a new surgical technique to correct idiopathic scoliosis using an anterior approach, spinal instrumentation with vertebral body screws, and a cable compressing the convexity of the curve. According to the Hueter-Volkman principle, compression reduces, and distraction increases growth on the growth plates. VBT was designed to modulate spinal growth of vertebral bodies and hence, the term “growth modulation” has also been used. These investigators described the indications and surgical technique of VBT. Furthermore, they carried out a systematic review of published studies to examine the results and complications of this technique. In a total of 23 included studies on 843 patients, the pre-operative main thoracic curve corrected from 49 to 23 degrees in a minimum 2-year follow-up.

The complication rate of VBT was 18 %. The results showed that 15 % of VBT patients required re-operations for pulmonary or tether-related issues (10 %) and less than 5 % required conversion to spinal fusion. The authors concluded that as a relatively novel technique, VBT allows correction of the scoliotic deformity while preserving motion especially in patients with moderate curvature. The majority of these patients appeared to avoid posterior spinal fusion with a major curve less than 35 degrees, when followed-up to skeletal maturity; however, some of these patients required replacement of a broken tether, and overall risk of revision surgery appeared to be around 15 %. Moreover, these researchers noted that there were no RCTs or even prospective follow-up studies comparing the outcomes of AVBT and segmental pedicle screw instrumentation; therefore, there is a lack of evidence-based recommendations on which to treat patients with instrumented spinal fusion and to use AVBT. They stated that while the reported median-term results of VBT appeared promising, long-term studies are required to clarify curve characteristics, rate of complications, and their prevention.

Bizzoca et al (2022) summarized available evidence regarding the safety and effectiveness of AVBT in the management of idiopathic scoliosis (IS) in skeletally immature patients. From January 2014 to January 2021, Ovid Medline, Embase, Cochrane Library, Scopus, Web of Science, Google Scholar and PubMed were searched to identify relevant studies. The methodological quality of the studies was examined, and relevant data were extracted. A total of 7 clinical trials recruiting 163 patients were included in the present review; 5 of the 7 studies were classified as high quality, while the remaining 2 studies were classified as moderate quality. A total of 151 of 163 AVBT procedures were performed in the thoracic spine, and the remaining 12 tethering in the lumbar spine. Only 117 of 163 (71.8 %) patients had a non-progressive curve at skeletal maturity; 23 of 163 (14.11 %) patients required unplanned revision surgery within the follow-up period. Conversion to posterior spinal fusion (PSF) was performed in 18 of 163 (11 %) patients. The authors concluded that AVBT is a promising growth-friendly technique for treatment of IS in growing patients; however, it has moderate success and peri-operative complications, revision and conversion to PSF. These researchers stated that future level-I studies, with long-term follow-up, are needed to define the limits and potentials of this emerging surgical technique.

The authors stated that the key drawback of the present study was the low level of evidence of the included studies, since no randomized clinical trials have been published on AVBT. Currently, 6 ongoing clinical trials are available on Clinicaltrials.gov: 4 prospective clinical trials focusing on AVBT and 1 prospective, comparative, non-randomized and 1 randomized clinical trial are aiming to compare AVBT to PSF. The ongoing and future studies should confirm the surgical criteria for AVBT, prove tethering's safety and long-term effectiveness, focus on PROMs, and propose strategies to avoid peri-operative complications and long-term implant failures. These researchers stated that a more durable, fatigue-resistant cable should be developed to prevent the high number of broken tethers observed in the published studies.

Zhang et al (2022) systemically reviewed the preliminary outcomes of VBT in the treatment of AIS. The electronic databases PubMed, Embase, and Web of Science were queried up to January 2022 for studies on VBT. Basic characteristics of patients, changes of radiographic parameters in coronal and sagittal planes, and clinical outcomes of surgical treatment of VBT including complication and revision rates were summarized. A total of 25 studies met the inclusion criteria. Most studies (23/25) included patients with only skeletal immaturity. The average % correction of the main/tethered curve at final follow-up, and % correction of thoracic kyphosis at final follow-up were reported to be 15.6 % to 106.5 % and - 31.8 % to 20.0 %, respectively. The most common complications for VBT were tether breakage (n = 145; 21.3 %), pulmonary complications (n = 49; 6.9 %), and over-correction (n = 30; 4.2 %). The revision rate was 13.1 %. The authors concluded that VBT could safely and effectively correct spinal deformity in skeletally immature patients with AIS and preserve the motion and growth of the spine. However, VBT has a relatively high complication and revision rates; thus, surgeons should cautiously consider VBT for the treatment of AIS. These researchers stated that further investigation is needed to lower the complication and revision rates. These investigators stated that VBT is still in its infancy and may have a promising future as a non-fusion solution for AIS.

Pahys et al (2022) noted that AVBT for AIS is postulated to preserve motion compared with traditional posterior spinal fusion (PSF); however, few studies exist to-date. In a retrospective, single-center study, these researchers employed a validated computerized 3D model to compare trunk motion between patients treated with PSF and AVBT; and analyzed trunk motion in relation to the lowest instrumented vertebra (LIV). They reviewed a consecutive series of skeletally

immature patients with AIS who underwent motion analysis before PSF (n = 47) or AVBT (n = 65) and 2 years post-operatively. Patients were divided into 4 groups on the basis of the LIV (\leq L1, L2, L3, L4). Computerized 3D kinematic evaluations included thoracic and lumbar flexion, extension, side-bending, and rotation. Patient outcomes were assessed using the Scoliosis Research Society (SRS)-22 questionnaire. The LIV was \leq L1 in 48 patients treated with AVBT and 23 treated with PSF, L2 in 4 AVBT and 8 PSF patients, L3 in 10 AVBT and 8 PSF patients, and L4 in 3 AVBT and 8 PSF patients. PSF patients had a significant loss of motion in all 4 directions at 2 years post-operatively (e.g., flexion loss was 11° for \leq L1 to 30° for L4; $p < 0.001$). This equated to a 7° loss of trunk flexion per additional LIV level included in the fusion. AVBT patients only demonstrated loss of flexion and side-bending at 2 years post-operatively (e.g., flexion loss of 11° for L1 to 17° for L4; $p < 0.001$). Pre-operative curve size and flexibility did not have any significant impact on differences in trunk motion between AVBT and PSF. SRS-22 scores were predominantly similar for AVBT versus PSF pre-operatively and at 2 years post-operatively. The authors concluded that patients treated with AVBT experienced predominantly less motion loss compared with PSF patients at 2 years post-operatively. Patients treated with PSF demonstrated loss of motion in all planes that increased with each additional LIV from \leq L1 to L4, with 7° loss of flexion per additional LIV. However, the differences in total trunk motions were relatively modest for PSF and AVBT with an LIV of \leq L1. Pre-operative curve magnitude and flexibility had no significant impact on trunk motion in either group. SRS-22 scores were similar for both groups at 2 years post-operatively. . The authors are currently creating a multi-center study to examine specific activities and sports to objectively evaluate the true impact that these procedures have on the lives of patients, to provide the qualitative analysis of function that was not performed as part of this study. Finally, longer-term follow-up evaluations are underway to assess the long-term repercussions of growth modulation surgery versus traditional spinal fusion with regard to patient function Level of Evidence = III.

The authors stated that this study had several drawbacks. First, the sophisticated motion analysis center that is required to perform the assessments in the study may not be available to many surgeons. The authors are therefore evaluating wearable sensors that do not require a motion laboratory, to make this technology more accessible. The alternative of radiographic assessment of trunk motion, while it allows for detailed measurement of each disc space, requires additional radiation exposure and could not assess rotation. Second, the measurement error of the motion

capture system was 4 degrees; however, the authors felt that that was reasonable and comparable with that in radiographic assessment of the angle of the coronal curve. Third, the UIV (upper instrumented vertebra) distribution, which ranged from T2 to T6, was not equal between the treatments, given the inherent anatomic challenges of accessing the upper thoracic spine in an anterior AVBT approach. Therefore, the differences in thoracic motion could be due to the lower UIVs in patients treated with AVBT rather than to that procedure itself. Fourth, the data in this study provided an objective quantitative assessment of trunk motion before and after PSF and AVBT; however, the study did not examine the true functional impact of the procedures with regard to return to activities and sports, which would be of greater interest to most patients. While the post-operative outcome scores were similar for both groups, these researchers were unable to examine if the observed trunk motion preservation or loss had any substantial impact on the normal daily activities and/or sports participation of the patients.

Mathew et al (2022) stated that VBT is growing in popularity for skeletally immature patients with scoliosis because of presumed preservation of spinal motion. Although results have shown preserved thoracic motion, there is minimal data to support motion over the lumbar instrumented segments following VBT. In a retrospective study, these researchers analyzed the range of motion (ROM) of the thoracolumbar and lumbar spine following lumbar VBT. This trial included patients who were treated with lumbar VBT; they underwent low-dose biplanar flexion-extension and lateral bending radiographs at 1 year after surgery to assess motion. Coronal motion at 1 year was compared with pre-operative side-bending radiographs. The angle subtended by the screws at the upper instrumented vertebra and lower instrumented vertebra was measured on left-bending and right-bending radiographs to examine the coronal arc of motion and was compared with pre-operative values over the same levels measured from the endplates. At 1 year post-operatively, the sagittal angle was measured over the instrumented levels on flexion and extension radiographs. Of the 71 scoliosis patients who underwent VBT at the authors' center eligible for 1-year follow-up, 20 had lumbar instrumentation, all of whom had lumbar bending films available at 1 year after surgery; 7 patients had both thoracic and lumbar VBT on the same day and 13 had lumbar or thoracolumbar tether only. Mean age was 13.5 ± 1.9 years. Mean pre-operative major coronal curve measured 52 ± 8 degrees (range of 42 to 70) and mean 27 degrees (range of 13 to 40) at latest follow-up. Mean levels instrumented was 8 (range of 5 to 12), with the lowest instrumented level typically L3 ($n = 14$). The mean pre-operative coronal arc

of motion over the instrumented segments was 38 ± 13 degrees (range of 19 to 73 degrees) and decreased after surgery to a mean arc of 17 ± 7 degrees (range of 7 to 31 degrees). However, 19 of the 20 (95 %) had at least a 10-degree coronal arc of motion. Patients maintained on average 46 % (range of 22 % to 100 %) of their pre-operative coronal arc of lumbar motion over the instrumented lumbar segments. On flexion-extension lateral radiographs taken at 1 year post-operatively, there was a mean post-operative arc of motion of 30 ± 13 degrees. The authors concluded that lumbar VBT resulted in preserved flexion and extension motion at 1 year post-operatively. These investigators also noted some preserved coronal plane motion,; however, this was decreased compared with pre-operative values by approximately 50 %. These findings provided proof-of-concept that some spinal motion is preserved after lumbar VBT in contrast to lumbar fusion where no motion is retained over the instrumented segments.

The authors stated that this study had several drawbacks. First, this study lacked a control group such as healthy adolescent patients or AIS patients without PSF who had bending radiographs that could be used for comparison. Such radiographs may be challenging to obtain, because bending radiographs are typically only obtained as standard of care in pre-operative patients, and many Institutional Review Boards (IRBs) will not approve radiographs obtained solely for research purposes in the pediatric population. Second, standing post-operative bending imaging in the biplanar slot scanner may restrict the maximum achievable motion; therefore, the amount of motion recorded on radiograph in this study may be under-estimated. This study, however, did include coronal range of motion measurements in the same patients obtained at 2 time-points using the same standardized technique according to an institutional protocol. Third, these researchers also lacked pre-operative baseline sagittal flexion-extension bending radiographs to compare the post-operative sagittal arc of motion. Therefore, there was no baseline measure of pre-operative sagittal plane lumbar spine mobility in their cohort. It is challenging to obtain X-rays for research purposes in adolescents because of radiation concerns. This trial did, however, demonstrate a notable sagittal arc of motion over the instrumented segments at 1 year post-operatively. In addition, surgeons could agree that, in contrast to VBT, fusion surgery allows for no movement over the instrumented segments. Fourth, radiographic measurements were subject to 3 to 5-degree measurement error. Fifth, this study lacked long-term follow-up of 2 to 5 years. Although these researchers noted preservation of sagittal plane motion at 1 year post-operatively, it was unclear whether motion of the lumbar spine was preserved over time. Only 9 of the 20

patients had 2-year follow-up of which 1 patient demonstrated tether cord breakage at L2 to L3 between 1- and 2-year follow-up. Therefore, further long-term follow-up is needed to determine complications and potential cord breakage following VBT. If spontaneous fusion were to occur after VBT, one would think that this would occur by the 1-year post-operative time-point. It would be interesting to know whether motion will persist over 5 to 10 years or even increase because of tether breakage. The authors published their results because they believed that early reporting of VBT data is needed to inform patients and surgeons regarding the limitations and possible advantages of the technique. These researchers plan to report on the 2-year outcomes of this cohort including PROMs once minimum 2-year follow-up is obtained.

Zhang et al (2022) noted that VBT is a novel alternative to spinal fusion surgery for the treatment of skeletally immature AIS and was approved to correct idiopathic scoliosis in August 2019 by FDA. In a systemic review, these investigators examined the preliminary outcomes of VBT in the treatment of patients with AIS. The electronic databases PubMed, Embase, and Web of Science were queried up to January 2022 for studies regarding VBT. Basic characteristics of patients, changes of radiographic parameters in coronal and sagittal planes, and clinical outcomes of surgical treatment of VBT including complication and revision rates were summarized. A total of 25 studies met the inclusion criteria. Most studies (23/25) included patients with only skeletal immaturity. The average % correction of the main/tethered curve at final follow-up, and % correction of thoracic kyphosis at final follow-up were reported to be 15.6 % to 106.5 % and - 31.8 % to 20.0 %, respectively. The most common complications for VBT were tether breakage (n = 145; 21.3 %), pulmonary complications (n = 49; 6.9 %), and over-correction (n = 30; 4.2 %). The revision rate was 13.1 %. The authors concluded that VBT could safely and effectively correct spinal deformity in skeletally immature patients with AIS and preserve the motion and growth of the spine. However, VBT has a relatively high complication and revision rates; thus, surgeons should cautiously consider VBT for treating AIS. Moreover, these researchers stated that further investigation is needed to reduce the complication and revision rates. They stated that VBT is still in its infancy and may have a promising future as a non-fusion solution for AIS.

In this meta-analysis, Mariscal et al (2023) examined the safety and effectiveness of AVBT in patients with AIS. These investigators carried out a literature search and analyzed the following data: baseline characteristics, efficacy measures (corrections of the main thoracic curve, proximal

thoracic curve, and thoracolumbar curve, thoracic kyphosis, lumbosacral lordosis, rib hump, lumbar prominence and SRS-22 scores, and complications. Analyses were performed with Cochrane's Review Manager version 5.4. A total of 12 studies met the inclusion criteria. Significant corrections of the main thoracic (mean difference [MD] 22.51, 95 % CI: 12.93 to 32.09) proximal thoracic (MD 10.14°, 95 % CI: 7.25° to 13.02°), and thoracolumbar curve (MD 12.16, 95 % CI: 9.14 to 15.18) were found. No statistically significant corrections were observed on the sagittal plane assessed by thoracic kyphosis (MD - 0.60°, 95 % CI: - 2.45 to 1.26; participants = 622; studies = 4; I² = 36 %) and lumbosacral lordosis (MD 0.19°, 95 % CI: - 2.16° to 2.54°). Significant corrections were identified for rib hump (MD 5.26°, 95 % CI: 4.19° to 6.32°) and lumbar prominence (MD 1.20°, 95 % CI: 0.27° to 2.13°) at final follow-up. Significant improvements of total SRS-22 score (MD - 0.96, 95 % CI: - 1.10 to - 0.83) were achieved at final follow-up. The most common complication was over-correction (8.0 %) and tether breakage (5.9 %), with a re-operation rate of 10.1 %. The authors concluded that AVBT is effective to reduce the curve in the coronal plane and clinical deformity; maximum correction was achieved at 1 year. Moreover, these researchers stated that AVBT is a new procedure and further studies including more skeletally mature patients, curve types, and higher curves would allow a more complete assessment of its safety and effectiveness.

The authors stated that his review had several drawbacks. First, follow-up of less than 36 months. Second, low number of studies included in the clinical variables and some of the complications. Third, the impossibility of creating subgroups for some variables between curve type, skeletal maturity, and age. Fourth, absence of a control group and range of motion analysis.

Siu et al (2023) stated that correcting AIS without fusion can be achieved with AVBT; however, little is known regarding the peri-operative outcomes, pain control, and clinical outcomes in patients undergoing AVBT compared with instrumented PSF (IPSF). In a retrospective, cohort study, these investigators compared pediatric patients with AIS who underwent either AVBT or IPSF. Inclusion criteria were based on the AVBT group, which included primary thoracic idiopathic scoliosis, Risser 1 or less, curve magnitude 40 to 70 degrees, age of 9 to 15 years, no prior spine surgery, index surgery between 2014 and 2019, and minimum 2-year follow-up. Patient demographics, peri-operative metrics, pain visual analog scale (VAS) scores, opiate morphine equivalent usage (MEU), cost data, and radiographic outcomes were compared. These

researchers identified 23 patients who underwent AVBT and 24 matched patients in the IPSF group based on inclusion criteria. Patients undergoing AVBT and PSF were similar in age (12 ± 1 years versus 13 ± 1 years, $p = 0.132$) and average follow-up time (3.8 ± 1.6 years versus 3.3 ± 1.4 years, $p = 0.210$). There were 23 female patients (87 %) in the AVBT group and 24 female (92 %) patients in the IPSF group. Intra-operatively, estimated blood loss (EBL; 498 ± 290 versus 120 ± 47 ml, $p < 0.001$) and procedure duration (419 ± 95 versus 331 ± 83 mins, $p = 0.001$) was significantly greater in the IPSF group compared with AVBT. Length of stay (LOS) was lower in the AVBT group compared with PSF (4 ± 1 versus 5 ± 2 days, $p = 0.04$). PSF patients had significantly greater total post-operative opiate MEU compared with AVBT (2.2 ± 1.9 versus 5.6 ± 3.4 mg/kg, $p < 0.001$). Overall direct costs following PSF and AVBT were similar ($\$47,655 \pm \$12,028$ versus $\$50,891 \pm \$24,531$, $p = 0.58$). Pre-operative radiographic parameters were similar between both 2 groups, with a major thoracic curve at 51 ± 10 degrees for AVBT and 54 ± 9 degrees for IPSF ($p = 0.214$). At the most recent follow-up, IPSF patients had greater curve reduction to a mean major thoracic curve of 11 ± 7 degrees (79 %) compared with 19 ± 10 degrees (63 %) in AVBT patients ($p = 0.002$). A total of 9 patients (39 %) required revision surgery following AVBT compared with 4 patients (17 %) following IPSF ($p = 0.09$). The authors concluded that in a select cohort of patients, AVBT offers decreased surgical time, blood loss, LOS, and post-operative opiate usage compared with IPSF. Although IPSF resulted in greater deformity correction at 2-year follow-up, the majority of patients who underwent AVBT had 35 or less major curves and avoided fusion. There is optimism for AVBT as a therapeutic option for select AIS patients; however, long-term complications are still being understood, and the risk for revision surgeries remains high. Level of Evidence = III.

Wong et al (2023) stated that AVBT was introduced as a fusionless alternative to the treatment of AIS while preserving ROM. This is the 1st systematic review to compare the ROM outcomes between AVBT and PSF in treating AIS. These researchers carried out a comprehensive search on PubMed, Embase, Medline, and Cochrane Library. Inclusion criteria were patients with AIS treated with AVBT or PSF or both, and clearly defined ROM outcomes; exclusion criteria were scoliosis other than AIS, biomechanical or cadaveric studies, non-English publications, case reports, conference summaries, unpublished literature, commentaries, and reviews. Primary outcome was ROM. Secondary outcomes included Cobb angle correction, QOL, complications, and muscle strength and endurance. A total of 12 studies were included in this review. These

investigators found moderate evidence to support that AVBT resulted in superior ROM outcomes than PSF while achieving comparable Cobb angle correction with low evidence. The comparison of QOL outcomes between AVBT and PSF remained inconclusive. In addition to the complications noted conventionally in PSF, AVBT could result in over-correction and distal adding-on. These researchers also found very low evidence to support that AIS patients treated with AVBT had superior muscle strength and endurance when compared to those treated with PSF. The authors concluded that this was the 1st systematic review examining the ROM outcomes for AVBT compared with PSF in treating AIS. These researchers found adequate evidence to show that AVBT provided better preservation of ROM and muscle strength post-operatively when compared with PSF, while achieving comparable curve correction. Nonetheless, over-correction remains one of the biggest challenges in treating AIS patients with AVBT. They stated that future studies can focus on examining the growth trajectory of the spine to determine the window of opportunity to perform AVBT in AIS to achieve maximal curve correction with minimal risk of over-correction. For fair comparisons, clinical studies should also consider LIV and upper instrumented vertebra (UIV) when comparing the mobility, curve correction, complications, functional outcomes, and long-term outcomes for AVBT and PSF. Patients opting for AVBT may have a higher demand for athletic activities; thus, return-to-sport activities and high athletic functional performance should also be assessed in future studies.

The authors stated that this systematic review had several drawbacks. First, this review only examined the generalized ROM outcomes instead of any specific direction of ROM. Second, it was difficult to make fair comparisons between the included studies as there were no standardized measurement methods for ROM. However, despite different modalities of measurement for ROM, all confirmed superior ROM outcomes in AIS patients treated with AVBT compared to PSF. Third, the variability in the operated segments, including the LIV and UIV, made fair comparisons between studies rather challenging. Fourth, the long-term complication of add-on or de-compensation in the PSF group may be more and not reported in studies directly comparing AVBT versus PSF due to the limited duration of follow-up.

Furthermore, an UpToDate review on “Adolescent idiopathic scoliosis: Management and prognosis” (Scherl and Hasley, 2023) provides the following information:

- Vertebral body tethering - Vertebral body tethering devices are intended to gradually correct scoliosis by slowing growth on the convex side of the curve. A single tethering device has been approved by the US Food and Drug Administration (FDA) for the correction of idiopathic scoliosis that has not responded to conservative treatment options (e.g., bracing).
- Additional studies are necessary to determine which patients are likely to benefit from growth modulation techniques, to better understand and refine the modulation technique (e.g., force necessary to slow growth, tensile strength), and to see whether and how the concave side of the curve progresses over time.

Magnetically Controlled Growing Rods

In a prospective case-series study, Cheung et al (2012) evaluated the safety and effectiveness of a new magnetically controlled growing rod (MCGR) for non-invasive outpatient distractions in skeletally immature children with scoliosis. These investigators implanted the MCGR in 5 patients, 2 of whom have now reached 24 months' follow-up. Each patient underwent monthly outpatient distractions. These researchers used radiography to measure the magnitude of the spinal curvature, rod distraction length, and spinal length. They assessed clinical outcome by measuring the degree of pain, function, mental health, satisfaction with treatment, and procedure-related complications. In the 2 patients with 24 months' follow-up, the mean degree of scoliosis, measured by Cobb angle, was 67° (SD 10°) before implantation and 29° (4°) at 24 months. Length of the instrumented segment of the spine increased by a mean of 1.9 mm (0.4 mm) with each distraction. Mean predicted versus actual rod distraction lengths were 2.3 mm (1.2 mm) versus 1.4 mm (0.7 mm) for patient 1, and 2.0 mm (0.2 mm) and 2.1 mm (0.7 mm) versus 1.9 mm (0.6 mm) and 1.7 mm (0.8 mm) for patient 2's right and left rods, respectively. Throughout follow-up, both patients had no pain, had good functional outcome, and were satisfied with the procedure. No MCGR-related complications were noted. The authors concluded that the MCGR procedure can be safely and effectively used in outpatient settings, and minimizes surgical scarring and psychological distress, improves quality of life, and is more cost-effective than is the traditional growing rod procedure. The technique could be used for non-invasive correction of abnormalities in other disorders. The main drawbacks of this study were its small sample size and incomplete follow-up. Furthermore, the MCGR procedure was associated with increased radiation exposure

from frequent radiographs. The authors noted that a prospective, large-scale, multi-center trial is underway to further validate these preliminary findings and evaluate other aspects of this technology.

In a prospective, non-randomized study, Akbarnia et al (2013) reported the preliminary results of MCGR technique in children with progressive early onset scoliosis (EOS). Distractions were performed in clinic without anesthesia/analgesics. T1-T12 and T1-S1 heights and the distraction distance inside the actuator were measured after lengthening. A total of 14 patients (7 females) with a mean age of 8 yrs + 10 mos (3 yrs + 6 mos to 12 yrs + 7 mos) had 14 index surgeries, single rod (SR) in 5 and dual rod (DR) in 9, with overall 68 distractions. Diagnoses were idiopathic (n = 5), neuromuscular (n = 4), congenital (n = 2), syndromic (n = 2) and NF (n = 1). Mean follow-up was 10 mos (5.8 to 18.2). Cobb angle changed from 60° to 34° after initial surgery and 31° at latest follow-up. During distraction period, T1-T12 height increased by 7.6 mm for SR (1.09 mm/mo) and 12.12 mm for DR (1.97 mm/mo). T1-S1 height gain was 9.1 mm for SR (1.27 mm/mo) and 20.3 mm for DR (3.09 mm/mo). Complications included superficial infection in 1 SR, prominent implant in 1 DR and minimal loss of initial distraction in 3 SR after index. Partial distraction loss observed following 14 of the 68 distractions (1 DR and 13 SR) but regained in subsequent distractions. There was no neurologic deficit or implant failure. The authors concluded that these preliminary results indicated MCGR was safe and provided adequate distraction similar to standard growing rod. Dual rod achieved better initial curve correction and greater spinal height during distraction compared to single rod.

The MAGEC System is composed of an implantable rod, an external remote controller (ERC), and accessories. The implanted spinal rod is used to brace the spine during growth to minimize the progression of scoliosis. Magnetic components in both the MAGEC rod and MAGEC ERC allow for distraction of the rod to be performed non-invasively and without the need for repeated surgeries as found in traditional growing rod systems.

Dannawi et al (2013) stated that conventional growing rods are the most commonly used distraction-based devices in the treatment of progressive early-onset scoliosis. This technique requires repeated lengthening with the patient anesthetized in the operating theatre. These investigators described the outcomes and complications of using a non-invasive magnetically

controlled growing rod (MCGR) in children with early-onset scoliosis. Lengthening was performed on an out-patient basis using an external remote control with the patient awake. Between November 2009 and March 2011, a total of 34 children with a mean age of 8 years (5 to 12) underwent treatment. The mean length of follow-up was 15 months (12 to 18). In total, 22 children were treated with dual rod constructs and 12 with a single rod. The mean number of distractions per patient was 4.8 (3 to 6). The mean pre-operative Cobb angle was 69° (46° to 108°); this was corrected to a mean 47° (28° to 91°) post-operatively. The mean Cobb angle at final review was 41° (27° to 86°). The mean pre-operative distance from T1 to S1 was 304 mm (243 to 380) and increased to 335 mm (253 to 400) in the immediate post-operative period. At final review the mean distance from T1 to S1 had increased to 348 mm (260 to 420). Two patients developed a superficial wound infection and a further 2 patients in the single rod group developed a loss of distraction. In the dual rod group, 1 patient had pull-out of a hook and 1 developed prominent metal-work. Two patients had a rod breakage -- 1 patient in the single rod group and 1 patient in the dual rod group. The authors concluded that these results showed that the MCGR is safe and effective in the treatment of progressive early-onset scoliosis with the avoidance of repeated surgical lengthening.

Hickey et al (2014) reported the early experience of a magnetically controlled growing rod system (MAGEC, Ellipse). These investigators performed a review of pre-operative, post-operative and follow-up Cobb angles and spinal growth in case series of 8 patients with a minimum 23 months' follow-up (23 to 36 months). A total of 6 patients had dual rod constructs implanted and 2 patients received single-rod constructs. Four patients had MAGEC rods as a primary procedure; 4 were revisions from other systems. Mean age at surgery in the primary group was 4.5 years (range of 3.9 to 6.9). In patients who had MAGEC as a primary procedure, mean pre-operative Cobb angle was 74° (63 to 94), with post-operative Cobb angle of 42° (32 to 56) $p \leq 0.001$ (43 % correction). Mean Cobb angle at follow-up was 42° (35 to 50). Spinal growth rate was 6 mm/year. One sustained proximal screw pull out. A final patient sustained a rod fracture. Mean age at surgery in the revision group was 10.9 years (range of 9 to 12.6). Mean pre-operative Cobb angle was 45° (34 to 69). Post-operative Cobb angle was 42° (33 to 63) (2 % correction). Mean Cobb angle at follow-up was 44° (28 to 67). Mean spinal growth rate was 12 mm/year. Two patients developed loss of distraction. The authors concluded that the MAGEC growing rod system effectively controlled early onset scoliosis when used as either a primary or revision procedure.

They stated that although implant-related complications are not uncommon, the avoidance of multiple surgeries following implantation is beneficial compared with traditional growing rod systems.

Jenks et al (2014) noted that the MAGEC system comprises a magnetically distractible spinal rod implant and an external remote controller, which lengthens the rod; this system avoids repeated surgical lengthening. Rod implants brace the spine internally and are lengthened as the child grows, preventing worsening of scoliosis and delaying the need for spinal fusion. The Medical Technologies Advisory Committee at the National Institute for Health and Care Excellence (NICE) selected the MAGEC system for evaluation in a NICE medical technologies guidance. A total of 6 studies were identified by the sponsor (Ellipse Technologies Inc.) as being relevant to the decision problem. Meta-analysis was used to compare the clinical evidence results with those of one conventional growth rod study, and equal efficacy of the 2 devices was concluded. The key weakness was selection of a single comparator study. The External Assessment Centre (EAC) identified 16 conventional growth rod studies and undertook meta-analyses of relevant outcomes. Its critique highlighted limitations around study heterogeneity and variations in baseline characteristics and follow-up duration, precluding the ability to draw firm conclusions. The sponsor constructed a de-novo costing model showing that MAGEC rods generated cost savings of £9,946 per patient after 6 years, compared with conventional rods. The EAC critiqued and updated the model structure and inputs, calculating robust cost savings of £12,077 per patient with MAGEC rods compared with conventional rods over 6 years. The year of valuation was 2012. NICE issued a positive recommendation as supported by the evidence (Medical Technologies Guidance 18).

The British National Health Service's draft policy on "Non-Invasively Lengthened Spinal Rods for Scoliosis" (NHS, 2014) provided the following selection criteria for the use of the MAGEC System:

- Spinal surgeon feels that an instrumented spinal fusion will result in an unacceptable reduction in final height and respiratory function, and
- Member is between the ages of 2 and 11 for girls and 2 and 13 for boys. Some children are not as skeletally mature as their chronological age so a radiograph confirming bone age within the acceptable age limits is satisfactory. Use outside the specified

chronological and skeletal age range may be appropriate if the patient is particularly small for age, has late development or has an increase in respiratory risk.

The NHS also noted the following exclusion criteria regarding the use of the MAGEC system:

- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device
- Metal allergies and sensitivities
- Person with pacemaker
- Person requiring MRI imaging during the expected period device will be implanted
- Person younger than 2 years old
- Person weighting less than 25 lb (11.4 kg).

Figueiredo et al (2016) examined the safety and effectiveness of MCGR for the treatment of pediatric scoliosis. This is an evidence-based systematic review of literature for the surgical management of patients with pediatric scoliosis using MCGR technique. A total of 6 clinical studies regarding the use of MCGR were included in this review, with a total of 68 patients, and mean age of 8.38 years. The dual-rod (DR) technique of rod construct with MCGR was used in 33.85 % and the single-rod (SR) in 66.15 % of the patients. The mean pre-operative main coronal curve for the DR was 65.9°, and for the SR was 69.6° ($p > 0.05$). At the latest follow-up, it was 36.8° for DR and 43.0 degrees for SR ($p < 0.05$). The mean pre-operative T1 - S1 spinal length was 298.7 mm for the DR and 303.5 mm for the SR group ($p < 0.05$). According to the latest follow-up, using the DR construct, the spinal length increased to 347 mm with 13.92 % of total lengthening; and using the SR construct, the average lengthening was 339 mm, with 10.48 % of total lengthening ($p < 0.05$). Post-operative complications were similar, 25 % in DR and 31.57 % in the SR group ($p > 0.05$). The authors concluded that level IV of medical evidence supports the use of MCGR as a safe and effective alternative for the treatment of severe pediatric scoliosis. They stated that recommendation Grade C supports the role of MCGR with DR construct as an option to achieve a better correction of the scoliotic curve and to maximize the post-operative T1 - S1 spinal length.

In a prospective, non-randomized, radiological study, Thompson et al (2016) evaluated the preliminary results of using the MAGEC System to treat children with EOS. Between January 2011 and January 2015, a total of 19 children were treated with MCGRs and underwent distraction at 3-monthly intervals. The mean age of this study cohort was 9.1 years (4 to 14) and the mean follow-up 22.4 months (5.1 to 35.2). Of the 19 children, 8 underwent conversion from traditional growing rods. Whole spine radiographs were carried out pre- and post-operatively: image intensification was used during each lengthening in the out-patient department. The measurements evaluated were Cobb angle, thoracic kyphosis, proximal junctional kyphosis and spinal growth from T1 to S1. The mean pre-, post-operative and latest follow-up Cobb angles were 62° (37.4 to 95.8), 45.1° (16.6 to 96.2) and 43.2° (11.9 to 90.5), respectively ($p < 0.05$). The mean pre-, post-operative and latest follow-up T1-S1 lengths were 288.1 mm (223.2 to 351.7), 298.8 mm (251 to 355.7) and 331.1 mm (275 to 391.9), respectively ($p < 0.05$). In all, 3 patients developed proximal pull-out of their fixation and required revision surgery: there were no subsequent complications. There were no complications of out-patient distraction. The authors concluded that the findings of this study showed that MCGRs provided stable correction of the deformity in EOS in both primary and revision procedures. They have the potential to reduce the need for multiple operations and thereby minimize the potential complications associated with traditional growing rod systems.

In a prospective, non-randomized study, Heydar et al (2016) evaluated the safety, effectivity profile of MCGR in patients with EOS. A total of 18 patients with progressive EOS were treated by MCGR, 2 of them had undergone final fusion operation. Patients were followed-up for a minimum time of 9 months from the time of initial surgery. Radiological data were analyzed in terms of Cobb angle, kyphosis angle, T1-T12 and T1-S1 distances in pre-operative, post-operative and last follow up. The mean pre-operative Cobb and kyphosis angle were 68° (44 to 116°), 43° (98 to 24°), it was corrected to 35° (67 to 12°), 29° (47 to 21°) immediately after initial operation and maintained at 34.5° (52 to 10°), 33° (52 to 20°) at last follow up, respectively. The mean pre-operative T1-T12 and T1-S1 distance were 171 mm (202 to 130), 289 mm (229 to 370), it was increased to 197 mm (158 to 245), 330 mm (258 to 406) immediately after initial operation and further increased to 215 mm (170 to 260), 357 mm (277 to 430) at last follow-up, respectively; 2 patients had undergone final fusion, they had overall mean Cobb angle correction of 66° (62 to 70), kyphosis angle change of 53° (26 to 80). Total height gain in T1-T12 and T1-S1 of 80.5 mm

(67 to 94) and 119 mm (105 to 133), respectively. The authors concluded that MCGR is safe and effective technique in correction of EOS deformity and in maintaining the correction during non-surgical distraction procedures. A further correction of the deformity and more spinal height gain can be achieved in the final fusion operation.

Ridderbusch et al (2017) stated that growth-sparing techniques for the treatment of EOS have developed significantly over the last years. Traditional growing rods (GRs) require repeated surgical lengthening under anesthesia. Since June 2011 these researchers have been using the MCGR to treat patients with progressive EOS. A total of 35 patients with EOS of different etiologies underwent treatment with MCGR. These researchers recorded about the preliminary results of 24 patients who fulfilled the inclusion criteria of a minimum follow-up (FU) of 12 month and greater than 3 lengthening. The mean age at surgery was 8.9 ± 2.5 years. Correction of the primary curve after the index surgery and after lengthening was measured on standing radiographs using the Cobb technique; T1-T12 and T1-S1 spinal length were also measured. Intra-operative and post-operative complications were recorded. The mean FU was 21.1 ± 7.3 months. All patients had a minimum of 3 out-patient lengthening [mean of 4.6 ± 1.5 (range of 3 to 8)]. The mean primary curve was 63 ± 15 degrees (range of 40 to 96) and improved to 29 ± 11 degrees (range of 11 to 53; $p < 0.001$) after MCGR. The mean major curve after most recent lengthening was 26 degrees (range of 8 to 60; $p < 0.07$). The T1-T12 as well as the T1-S1 length increased significantly ($p < 0.001$). The mean pre-operative thoracic kyphosis decreased from 43 ± 24 degrees (range of -32 to 86) to 27 ± 12 degrees (range of 9 to 50 degrees; $p < 0.001$) after surgery, respectively, and measured 32 ± 12 degrees (range of 12 to 64; $p < 0.05$) at last FU. In 1 patient a loss of distraction occurred making rod exchange necessary; 3 patients developed a proximal junctional kyphosis and in another patient a screw pull out occurred that required revision surgery. The authors concluded that these findings demonstrated that MCGR is a safe and effective non-fusion technique in the treatment of progressive EOS avoiding repeated surgical lengthening procedures. It provided adequate distraction similar to standard GR. The magnetically induced transcutaneous lengthening allows non-invasive distraction achieving spinal growth comparable to conventional GR techniques.

La Rosa et al (2017) presented a series of 10 patients with early-onset scoliosis (EOS) managed with magnetically controlled growing rod (MCGR) (Ellipse TM MAGEC System, Irvine, CA). These investigators implanted MCGR in 10 patients affected by EOS. Scoliosis and kyphosis angles, T1-T12 and T1-S1 length were evaluated pre-operatively, post-operatively, and at the last follow-up. A visual analog scale (VAS) score was used to evaluate pain during out-patient rod distraction procedures. The mean follow-up was 27 months. All patients attended distractions of the magnetic rod through an external remote control every 3 months. The mean predicted distraction was 3 mm at each lengthening session. The mean Cobb angle value was 64.7 ± 17.4 degrees (range of 45 to 100) pre-operatively and 28.5 ± 13.9 degrees (range of 15 to 59) at the latest follow-up. The mean T1-S1 length value was 27.1 ± 5.4 cm (range of 16 to 34.8 cm) pre-operatively and 32.8 ± 4 cm (range of 26.5 to 39) at the latest follow-up. The mean T1-T12 length value was 16.2 ± 2.7 cm (range of 10 to 19 cm) pre-operatively and 20.6 ± 2.9 cm (range of 15.5 to 23.5 cm) at the latest follow-up. The average monthly T1-T12 height increase was 0.8 mm, whereas the average monthly T1-S1 increase was 0.9 mm; 2 patients experienced a rod breakage and 1 patient had a pull-out of the apical hooks. The authors concluded that although implant-related complications could occur, as in all EOS growing rods procedures, MCGR can be effectively used in patients with EOS. This spinal instrumentation can overcome many of the complications related with the traditional growing rods implants. This procedure can be effectively used in out-patient settings, minimizing surgical scarring, surgical site infection, and psychological distress due to multiple surgeries needed in the traditional growing rods system, improving quality of life, and saving health care costs.

Estrogen Receptor Beta (ESR2) Rs1256120 Single Nucleotide Polymorphism Testing

In a systematic review and meta-analysis, Zhao and colleagues (2017) evaluated the current evidence on the association between rs1256120 single nucleotide polymorphism (SNP) of the estrogen receptor beta gene (ESR2) and AIS. Using a sensitive search strategy, PubMed (Medline), Embase, and HuGE Literature Finder databases were searched to identify relevant studies for inclusion in the systematic review and meta-analysis. Risk of bias was assessed using a modified Newcastle-Ottawa Scale. The inverse variance model was used to calculate summary ORs and corresponding 95 % CIs for the allelic (C versus T) and genotypic comparisons.

Planned subgroup and sensitivity analyses were performed. A total of 3 studies were included for

systematic review and meta-analysis (n = 1,264 AIS cases and n = 1,020 controls). A null relationship was found between rs1256120 and AIS (allelic OR = 1.20, 95 % CI: 0.81 to 1.78, p = 0.36, I = 84.9 %), with the first reported association likely to be false-positive and contributing substantially to heterogeneity. The authors concluded that findings from the systematic review and meta-analysis suggested that rs1256120 of ESR2 is unlikely to be a predisposing or disease-modifying genetic risk factor for AIS.

IGF1 Gene Rs5742612 Single Nucleotide Polymorphism Testing

In a meta-analysis, Guan and colleagues (2017) evaluated the association between insulin-like growth factor 1 (IGF1) gene SNP (rs5742612) and AIS. These investigators searched PubMed, Embase, Web of Science and Cochrane Library up to January 19, 2016 to obtain relevant studies using our research strategy. A total of 4 articles all belonging to case-control studies were included in this meta-analysis. The 4 studies contained 763 cases and 559 controls who satisfied the inclusion criteria after judgment by 2 reviewers. No significant associations were detected between IGF1 gene SNP (rs5742612) and AIS (T versus C, OR = 1.10, 95 % CI: 0.91 to 1.34, p = 0.32; TT versus CC: OR = 1.28, 95 % CI: 0.82 to 2.02, p = 0.28; TC versus CC: OR = 1.29, 95 % CI: 0.82 to 2.06, p = 0.27; TT/TC versus CC: OR = 1.28, 95 % CI: 0.83 to 1.98, p = 0.27; TT versus TC/CC: OR = 1.06, 95 % CI: 0.82 to 1.36, p = 0.66). The authors concluded that IGF1 gene SNP (rs5742612) is not significant associated with susceptibility to AIS in either Asian or Caucasian populations. However, IGF1 gene rs5742612 may be associated with severity of AIS. They stated that further studies with larger sample size and different population groups involving the relationship are needed to confirm the potential association.

Manual Therapy

Czaprowski (2016) evaluated the effectiveness of non-specific manual therapy (NMT; including manual therapy, chiropractic, osteopathy) used in the treatment of children and adolescents with IS. The study analyzed systematic reviews (Analysis 1) and other recent scientific publications (Analysis 2). Analysis 1 encompassed papers on the use of NMT in patients with IS. Works concerning specific physiotherapy (SP) or bracing (B) and other types of scoliosis were excluded from the analysis. Inclusion criteria for Analysis 2 were: treatment with NMT; subjects aged 10 to 18 years with IS. The following types of papers were excluded: works analyzing NMT combined

with SP or B, reports concerning adult patients, analyses of single cases and publications included in Analysis 1. Analysis 1: a total of 6 systematic reviews contained 6 papers on the effectiveness of NMT in the treatment of IS. The results of these studies were contradictory, ranging from Cobb angle reduction to no treatment effects whatsoever. The papers analyzed are characterized by poor methodological quality: small group sizes, incomplete descriptions of the study groups, no follow-up and no control groups. Analysis 2: a total of 217 papers were found; none of them met the criteria set for the analysis. The authors concluded that (i) few papers verifying the effectiveness of manual therapy, chiropractic and osteopathy in the treatment of IS have been published to date, (ii) the majority were experimental studies with poor methodology or observational case studies, (iii) the effectiveness of NMT in the treatment of patients with IS cannot be reliably evaluated, and (iv) it is necessary to conduct further research based on appropriate methods (prospective RCTs) in order to reliably evaluate the usefulness of NMT in the treatment of IS.

Resistive Exercises (Including the Schroth Method)

Lee and colleagues (2016) examined the effect of the Schroth method (3D convergence exercise) of emphasis of active holding on pain and Cobb's angle in patients with scoliosis. These researchers applied the Schroth method program of emphasis of active holding individually to 3 subjects 3 times/week for 15 weeks. All subject were measured for Cobb's angle and pain. After 15 weeks, pain and Cobb's angle decreased compared to values before. The authors concluded that these findings showed the benefit of the Schroth exercise program of emphasis of active holding on decreasing pain and Cobb's angle in patients with idiopathic scoliosis. Moreover, they stated that this study included a small sample size ($n = 3$); further research with more subjects is needed to verify the effect of applying the Schroth method to treat patients with idiopathic scoliosis.

Kim and Hwangbo (2016) examined the effects of the Schroth exercise on the Cobb's angle and vital capacity of patients with growing idiopathic scoliosis, an operative indication. A total of 5 idiopathic scoliosis patients with a Cobb's angle of the thoracic vertebra of 40 degrees or higher and Risser sign stage 3 or higher were included in this study. The Schroth exercise was applied 3 times/week for 12 weeks. These researchers measured the thoracic trunk inclination, Cobb's

angle, and vital capacity before and after the exercise program. The thoracic trunk rotation angle decreased from 11.86 ± 3.32 to 4.90 ± 1.91 degrees on average, the thoracic Cobb's angle decreased from $42.40 \pm 7.86^\circ$ to 26.0 ± 3.65 degrees on average, and the vital capacity also increased from 2.83 ± 1.23 L to 4.04 ± 1.67 L on average. All these effects were significant. The authors concluded that the 12-week Schroth exercise caused significant effects in the thoracic trunk inclination, Cobb's angle, and vital capacity. The conservative treatment method was found to be effective even at a 40 degree or higher Cobb's angle. They noted that universal exercise approach methods and preventive training for the treatment of scoliosis should be developed further. The main drawback of this study was the limited number of patients with 40 degrees or greater scoliosis and the difficulty in finding time for the subjects to participate in this study because most were students who had to attend school. They stated that a study comparing the effects with a group among whom the Schroth exercise is combined with orthosis treatment will be necessary.

Schreiber and colleagues (2017) noted that recent RCTs support using physiotherapeutic scoliosis-specific exercises (PSSE) for AIS. All RCTs reported statistically significant results favoring PSSE; but none reported on clinical significance. The number needed to treat (NNT) helps determine if RCT results are clinically meaningful. The NNT is the number of patients that need to be treated to prevent 1 bad outcome in a given period. A low NNT suggested that a therapy has positive outcomes in most patients offered the therapy. The objective of this trial was to determine how many patients require Schroth PSSE added to standard care (observation or brace treatment) to prevent 1 progression (NNT) of the largest curve (LC) or sum of curves (SOC) beyond 5 and 10 degrees, respectively over a 6-month interval. This was a secondary analysis of a RCT. A total of 50 consecutive participants from a scoliosis clinic were randomized to the Schroth PSSE + standard of care group ($n = 25$) or the standard of care group ($n = 25$). These researchers included males and females with AIS, age 10 to 18 years, all curve types, with curves 10 to 45 degrees, with or without brace, and all maturity levels. They excluded patients awaiting surgery, having had surgery, having completed brace treatment and with other scoliosis diagnoses. The local ethics review board approved the study. The Schroth intervention consisted of weekly 1-hour supervised Schroth PSSE sessions and a daily home program delivered over 6 months in addition to the standard of care. A prescription algorithm was used to determine which exercises patients were to perform. Controls received only standard of care. Cobb angles were

measured using a semi-automatic system from posterior-anterior standing radiographs at baseline and 6 months. These investigators calculated absolute risk reduction (ARR) and relative risk reduction (RRR). The NTT was calculated as: $NNT = 1/ARR$. Patients with missing values (PSSE group; $n = 2$; and controls; $n = 4$) were assumed to have had curve progression (worst case scenario). The RRR was calculated as $RRR = ARR/CER$. For LC, $NNT = 3.6$ (95 % CI: 2.0 to 28.2), and for SOC, $NNT = 3.1$ (95 % CI: 1.9 to 14.2). The corresponding ARR was 28 % for LC and 32 % for the SOC. The RRR was 70 % for LC and 73 % for the SOC. Patients with complete follow-up attended 85 % of prescribed visits and completed 82.5 % of the home program. Assuming zero compliance after drop-out, 76 % of visits were attended and 73 % of the prescribed home exercises were completed. The authors concluded that the short-term of Schroth PSSE intervention added to standard care provided a large benefit as compared to standard care alone; 4 (LC and SOC) patients required treatment for the additional benefit of a 6-month long Schroth intervention to be observed beyond the standard of care in at least 1 patient.

The main drawback of this study was its short-term follow-up (6 months). Thus, these researchers could not draw conclusions regarding the effects of a longer period of treatment, and could not answer the question “how many patients need to be treated with Schroth PSSE added to standard of care to prevent one surgery or prevent the need for a brace?” However, this study showed that the Schroth PSSE intervention added to standard care consisting of bracing or observation can delay the time where a more aggressive scoliosis management is indicated. The small sample size ($n = 25$ for the Schroth PSSE + standard of care group) precluded these researchers from conducting subgroup analysis related to compliance, curve type, baseline severity or maturity. Interestingly, of 25 patients in the exercise group, 20 reported greater than 75 % compliance with home exercise program. In the control group, there were 17 patients who wore braces. Of those, only 7 were considered compliant as they wore their braces more than 16 hours/day. This might have resulted in a larger number of deteriorated patients in the control group as compared to the exercise group. The authors also stated that small sample size also affected CI of the NNTs.

The U.S. Preventive Services Task Force review of adolescent idiopathic scoliosis found that the evidence on the effects exercise on health or spinal curvature in childhood or adulthood is “insufficient.”

Furthermore, an UpToDate review on “Adolescent idiopathic scoliosis: Management and prognosis” (Scherl, 2018) states that “Physical therapy or exercise programs such as Schroth exercises have been increasing in popularity, but the evidence for their efficacy is limited”.

Dimitrijevic et al (2022) noted that idiopathic scoliosis can be defined as a complex 3D deformity of the spine and trunk, which occurs in basically healthy children. Schroth scoliosis-specific exercises have shown good results in reducing idiopathic scoliosis progression. In a systematic review and meta-analysis, these researchers examined the effect size of Schroth method. A total of 4 databases were included in the search: PubMed, Cochrane Library, Web of Science, and Google Scholar. The following keywords were used: "Schroth exercise", "idiopathic scoliosis", "Cobb angle", "angle of trunk rotation", and "quality of life". Only studies written in English that met the following criteria were included in this analysis: subjects who had idiopathic scoliosis, the Schroth method was used, and Cobb angle or angle of trunk rotation or QOL as outcomes. A total of 10 RCTs were included in this study. The effect size of the Schroth exercise ranged from almost moderate to large, for the outcomes used: Cobb angle (ES = -0.492, $p < 0.005$); ATR (ES = -0.471, $p = 0.013$); QOL (ES = 1.087, $p < 0.001$). The authors concluded that the findings of this meta-analysis indicated that the Schroth method has a positive effect on subjects with idiopathic scoliosis. These researchers believed that their study can be of benefit to all those dealing with IS problems, especially clinicians, physiotherapists, and physical activity specialists, and will encourage future scientific research.

The authors stated that this this systematic review and meta-analysis had several drawbacks. First, only studies written in English were included in the review. Second, the number of studies found was still small, despite a thorough search, with a small number of common outcomes being assessed. Third, the studies included in this analysis had a relatively small number of respondents ranging from 15 to 50. Fourth, the disadvantage of the studies included was that they did not yet have the common outcomes they measured.

Ceballos-Laita et al (2023) stated that the Schroth method is one of the most common physiotherapeutic scoliosis-specific exercises intervention used in the management of AIS. This approach consists of 3D correction of the specific curve pattern of the patient using a combination of sensorimotor, postural, and corrective breathing exercises. In a systematic review and meta-

analysis, these investigators examined the effects of the Schroth method in isolation on Cobb angle, QOL, and trunk rotation angle compared to no intervention or other conservative treatments in patients with AIS. PubMed, Physiotherapy Evidence Database, Scopus, Cochrane Library, and Web of Science databases were searched. Studies were included if they were RCTs that compared the effects of the Schroth method in isolation to conservative interventions or no intervention. The quality of the studies was assessed with the PEDro Scale, and the risk of bias with the Cochrane Collaboration tool. Two independent assessors extracted data via a standardized form. Meta-analyses were carried out using fixed or random effects models according to the heterogeneity assessed with I² coefficient. Data on outcomes of interest were extracted by a researcher using RevMan 5.4 software. A total of 317 studies were screened; and 6 were included in the meta-analysis involving 144 patients with AIS. The methodological quality of the included studies ranged from high to low. The Schroth method in isolation showed significant improvements in Cobb angle (MD = -3.18°; 95 % CI: -4.30 to -2.07; I²: 0 %), QOL (MD = 0.28; 95 % CI: 0.18 to 0.38; I²: 0 %) and trunk rotation angle (MD = -2.12°; 95 % CI: -3.44 to -0.80; I²: 71 %) in the short-term. The authors concluded that the Schroth method in isolation was effective for reducing the Cobb angle and the trunk rotation angle and for improving the QOL in the short-term compared to no intervention or other conservative therapies in AIS; however, the improvement in Cobb angle did not exceed the minimum clinically important difference. Moreover, these researchers stated that further investigation is needed to determine the medium- and long-term effects in patients with AIS and to determine the best multi-modal intervention.

The authors stated that this systematic review and meta-analysis had several drawbacks. First, the search strategy may have been limited by the omission of other databases, such as SportDiscus, and these researchers may have missed relevant articles. Second, the inclusion of patients aged between 10 to 18 years old with Cobb angle greater than 10° and Risser signs between 0 and 5 could increase the heterogeneity of the study population, which could mean that the patients presented different risks of progression. Third, the heterogeneity found in treatment duration complicated the interpretation of these findings. Fourth, the insufficient sample size that could have over-estimated the results. Fifth, the lack of follow-up measurements of the studies. Sixth, PSSE that have evolved from the Schroth method were not considered in this study; thus, other research on these methods may have been omitted. These investigators stated

that future studies should describe the total number of sessions and the duration of the intervention to allow replicability and comparison of the study. Finally, the combination of therapies that produce the best effects should be examined, as well as their doses.

Screening for Adolescent Idiopathic Scoliosis

Dunn and colleagues (2018) noted that AIS, a spinal curvature of 10° or more, is the most common form of scoliosis, with a prevalence of 1 % to 3 %. Curves progress in approximately 2/3 of patients with AIS before skeletal maturity, and large curves (greater than 50 degrees) may be associated with adverse health outcomes. These investigators systematically reviewed evidence on benefits and harms of AIS screening for the US Preventive Services Task Force (USPSTF). Cochrane Central Register of Controlled Trials, Medline, ERIC, PubMed, CINAHL, and relevant systematic reviews were searched for studies published from January 1966 to October 20, 2016; studies included in a previous USPSTF report were also reviewed. Surveillance was conducted through July 24, 2017. Fair- and good-quality studies that evaluated the accuracy of screening children and adolescents aged 10 to 18 years for AIS, the benefits of AIS treatment, the harms of AIS screening or treatment, or long-term health outcomes were included for analysis. Two investigators reviewed abstracts and full-text articles and extracted data into evidence tables.

Results were qualitatively summarized. Main outcome measures included health outcomes and spinal curvature in adolescence and adulthood, accuracy of screening for AIS, any harm of AIS screening or treatment. A total of 14 studies (n = 448,276) in 26 articles were included. Accuracy of AIS screening was highest (93.8 % sensitivity; 99.2 % specificity) in a cohort study of a clinic-based program using forward bend test, scoliometer, and Moiré topography screening (n = 306,082); accuracy was lower in cohort studies of 6 programs using fewer modalities (n = 141,161); 4 controlled studies (n = 587) found evidence for benefit of bracing on curve progression compared with controls. A randomized clinical trial and a non-randomized trial of exercise treatment (n = 184) found favorable reductions in Cobb angle of 0.67 to 4.9 degrees in the intervention group compared with increases of 1.38 to 2.8 degrees in the control group; 2 cohort studies (n = 339) on long-term outcomes found that braced participants reported more negative treatment experience and body appearance compared with surgically treated or untreated participants. A study that combined a randomized clinical trial and cohort design (n = 242) reported harms of bracing, which included skin problems on the trunk and non-back body

pains. There was no evidence on the effect of AIS screening on adult health outcomes. The authors concluded that screening can detect AIS. Bracing and possibly exercise treatment can interrupt or slow progression of curvature in adolescence. However, there is little or no evidence on long-term outcomes for AIS treated in adolescence, the association between curvature at skeletal maturity and adult health outcomes, the harms of AIS screening or treatment, or the effect of AIS screening on adult health outcomes.

Furthermore, the authors stated that limitations of the body of evidence include the lack of studies on screening approaches in targeted populations based on sex or other factors associated with likelihood of curve progression. In addition, several studies found few adolescents willing to be randomized to a treatment group and therefore did not sufficiently accrue participants. The lack of long-term outcomes data stratified by degree of curvature at skeletal maturity limits the ability to draw conclusions about the long-term clinical effect associated with the interruption of curve progression during adolescence. Studies that prospectively enroll cohorts at AIS diagnosis or treatment for the purpose of long-term follow-up into adulthood would strengthen the body of evidence on the long-term effects of screening. Also needed are controlled trials of scoliosis screening programs that allow comparison of screened and non-screened populations, different screening settings, personnel, and procedures. Ideally, screening results should be reported for all relevant populations, including female patients and children with a family history of scoliosis. Prospective, systematic collection of data on the potential harms of screening -- including psychosocial effects and radiation exposure estimates for screened (as opposed to treated) populations -- also is needed. Because the utility of screening ultimately is determined by whether treatment of people with AIS identified through screening is effective in improving long-term health outcomes, the body of evidence also would be strengthened by additional good-quality studies of treatment, such as more prospective studies of exercise and brace treatment and studies on surgical treatment for people whose AIS was identified through screening. High-quality studies assessing the procedural and quality-of-life (QOL) harms of screening and treatment also are needed.

The USPSTF (2018) stated that the current evidence is insufficient to assess the balance of benefits and harms of screening for AIS in children and adolescents aged 10 to 18 years.

Spinal Manipulative Therapy

Theroux and colleagues (2017) performed a systematic review of clinical trials of spinal manipulative therapy for AIS. Search strategies were developed for PubMed, CINAHL, and CENTRAL databases. Studies were included through June 2016 if they were prospective trials that evaluated spinal manipulative therapy (e.g., chiropractic, osteopathic, physical therapy) for AIS. Data were extracted and assessed by 2 independent reviewers. Cochrane risk of bias tools were used to assess the quality of the included studies. Data were reported qualitatively because heterogeneity prevented statistical pooling. A total of 4 studies satisfied the inclusion criteria and were critically appraised. The findings of the included studies indicated that spinal manipulative therapy might be effective for preventing curve progression or reducing Cobb angle. However, the lack of controls and small sample sizes precluded robust estimation of the interventions' effect sizes. The authors concluded that there is currently insufficient evidence to establish whether spinal manipulative therapy may be beneficial for AIS. The results of the included studies suggested that spinal manipulative therapy may be a promising treatment, but these studies were all at substantial risk of bias. They stated that further high-quality studies are needed to determine if spinal manipulative therapy may be effective in the management of AIS.

Furthermore, an UpToDate review on “Adolescent idiopathic scoliosis: Management and prognosis” (Scherl, 2018) does not mention manipulation/spinal manipulative therapy as a management tool.

In a meta-analysis, Sun et al (2023) examined the available evidence of the effectiveness of manual therapy (MT) on AIS. All RCTs of MT for the management of patients with AIS were included in the present study. The treatment difference between the experimental and control group was mainly MT. The outcomes consisted of the total effective rate, the Cobb angle, and Scoliosis Research Society-22 (SRS-22) questionnaire score. These investigators searched electronic database from database inception to July 2022, including the Cochrane Library, PubMed, Web of Science, Embase, Wanfang Data, CNKI, and VIP. The pooled data were analyzed using RevMan 5.4 software. A total of 4 RCTs with 213 patients in the experimental group were finally included. There were 2 studies of stand-alone MT in the experimental group and 3 studies of MT with identical conservative treatments in the control group. A total of 3 trials

reported total effective rate, and a statistically significant difference was found ($p = 0.004$); 3 trials reported Cobb angle, and a statistical difference was found ($p = 0.01$). Then, sensitivity analysis showed that there was a significant difference in the additional MT subgroup ($p < 0.00001$) while not in the standalone MT subgroup ($p = 0.41$); 3 trials reported SRS-22 scores ($p = 0.55$) without significant differences. The authors concluded that there is insufficient data to determine the effectiveness of spinal manipulation limited by the very low quality of included studies. These researchers stated that high-quality studies with appropriate design and follow-up periods are needed to determine if MT may be beneficial as an adjunct therapy for AIS. Currently, there is no evidence to support spinal manipulation.

UNYQ Customized Brace

UNYQ braces are customized braces (supposedly thinner and lighter) for the management of AIS. While their lighter and thinner features may help improve patient compliance in patients with AIS, there is a lack of evidence to support this notion. There is also a lack of evidence that customized UNYQ braces are superior to other convention braces.

Gallo (2014) stated that orthotic treatment of patients with degenerative deformations of the spine is a complex endeavor. It is a great orthopedic technical challenge to reduce the accompanying pain and to help patients regain and keep their mobility. Due to difficult therapies and poor compliance, a surgical intervention to brace the spine is usually the first therapeutic choice. The author presented 2 cases in which individualized torso orthoses were successfully used to treat adults with degenerative diseases and disorders of the sagittal line as well as 3-D deformities of the spine. The author noted that using torso orthoses allowed treatment of these patients with as few invasive measures as possible without losing maximal functionality.

In a systematic review, Veis Karami and colleagues (2020) examined the effect of brace treatment on balance in subjects with AIS. The search strategy was based on the Population Intervention Comparison Outcome (PICO). PubMed, Scopus, ISI web of knowledge, Ovid, the Cochrane library (CENTRAL) and Google scholar databases and also the reference lists of relevant articles were searched for articles of clinical trials with level of evidence of 3 or more of AIS that underwent spinal bracing treatment. A total of 10 studies, examining a total of 282 subjects with

AIS, met the inclusion criteria; AIS subjects were characterized by a significant increase in the excursion of their center of pressure position compared with healthy subjects; AIS subjects were able to control their quiet standing balance via muscle co-contraction and proprioceptive stimulation, but following a short period of brace wear, no further improvement in balance parameters had been observed. The authors concluded that there is a need to follow-up the use and wear of orthoses and also for studies with high quality in subjects with AIS.

ScoliBrace

ScoliBrace appears to be a custom-made 3D spinal braces for children and adolescents with scoliosis. It is indicated for juvenile, infantile, adolescent idiopathic scoliosis (AIS) and some neuromuscular curves (curves between 25 to 60 Cobb).

Gubbels et al (2019) stated that there is a paucity of high-quality data pertaining to the conservative management of adult spinal deformity, particularly Scheuermann's kyphosis. Long-term follow-up data for both treated and untreated Scheuermann's patients is also lacking. Given that changes in sagittal balance are associated with increased morbidity, and that these changes are increasingly prevalent in the spines of ageing populations, it is imperative that potential strategies aimed at reversing or minimizing this type of deformity are explored. As the number of elderly patients in developed countries increases, so does the need for a safe and effective non-surgical management option for patients with spinal deformity/sagittal imbalance. This case study detailed the influence of ScoliBrace rigid TLSO bracing in combination with a specific rehabilitation program in an adult patient with kypho-scoliosis. The authors described a case involving the treatment of a 26-year old man with Scheuermann's kyphosis and a lumbar scoliosis. The patient received 12 months of bracing with a supplemental exercise program. The patient was followed for a period of approximately 12 months. Patient progress was assessed using ODI, SRS-22r, NPRS, and radiographic Cobb angle measurements throughout treatment. The patient presented with an initial ODI score of 18/100, a SRS-22r score of 3.0, and an average NPRS score of 4/10. Initial Cobb angle measurements demonstrated a 79° thoracic kyphosis and a 30° (coronal plane) lumbar scoliosis. At the final assessment, the patient reported an ODI score of 6/100, an SRS-22r score of 3.91, and an average NPRS score of 0/10. The coronal plane Cobb angle measured 63°, and the thoracolumbar scoliosis had reduced to 25°. The authors

concluded that the findings from this case study highlighted that this type of brace in combination with exercise rehabilitation may be useful for reducing the magnitude of curves and reducing symptoms in patients presenting with adult kypho-scoliosis. Moreover, these researchers stated that further investigation of this style of treatment is needed in patients with sagittal plane imbalance.

Scoliosis Flexibility Trainer

The Scoliosis Flexibility Trainer is a unique FDA-registered device that helps to unbend and untwist a scoliosis curve non-surgically. The Scoliosis Flexibility Trainer avoids the destruction of these important spinal joints completely by providing an effective non-surgical way to release contractures. This increases range of motion (ROM) of the spine, reduces the scoliosis curve, and prepares the spine to be better straightened in brace. All of this works together to provide a drastically better treatment outcome while avoiding the pitfalls and limitations of surgery.

Takaso et al (2010) stated that congenital muscular dystrophy (CMD), among the myopathic disorders is one form of flaccid neuromuscular disorder (NMD). Patients with NMD frequently develop progressive spinal deformity. For NMD patients who have a severe spinal deformity, sitting is often difficult and is accompanied by pain and breakdown of the skin. Spinal deformity surgery in these patients has been highly effective in stabilizing the spine, maintaining upright, comfortable sitting balance, and improving patients' quality of life (QOL). However, many studies have reported significant rates of peri-/post-operative complications in these patients. To the authors' knowledge, there has been no study on the results of spinal deformity surgery in patients with CMD. These investigators reviewed the clinical and radiological results of spinal deformity surgery in this group of patients with CMD. Between 2004 and 2007, a total of 10 CMD patients underwent scoliosis surgery. There were 3 patients with Fukuyama CMD, 3 with Ullrich CMD, and 4 with non-syndromic CMD (merosin-negative). They were non-ambulatory. All the patients had standard posterior spinal fusion and pedicle-screw-alone fixation from T3 or T4 to L5 for spinal deformity. The inclusion criteria required that each patient (i) had considerable difficulty with sitting balance and pain or breakdown of the skin due to scoliosis; (ii) was able to ventilate his or her lung autonomously; (iii) was not ventilator-dependent; and (iv) did not have cardiac failure. Sufficient informed consent was important, and the decision to perform surgery was

made by the patient/family with sufficient pre-operative informed consent. Patients were trained with inspiratory muscle training (IMT) using an inspiratory muscle trainer (Threshold IMT) for 6 weeks prior to surgery. Cardiac function was assessed pre-operatively; whereas pulmonary function tests were performed pre-operatively and post-operatively. Radiographic assessments were performed on sitting antero-posterior (AP) and lateral radiographs. These assessments were made periodically. The Cobb angles of the curves and spinal pelvic obliquity (SPO) on the coronal plane, thoracic kyphosis, and lumbar lordosis were measured. The pre-operative AP radiograph and side-bending films were examined to determine flexibility. Patients' and parents' satisfaction were surveyed by a self-completed questionnaire at the last follow-up. Percent forced vital capacity (%FVC) increased from a mean of 30 % before IMT to a mean of 34 % the day before surgery. The pre-operative scoliosis was 75 degrees (range of 61 degrees to 95 degrees). The scoliotic curvature on pre-operative side-bending films was 19 degrees (range of 11 degrees to 28 degrees). All patients were extubated on the day of surgery. No patients developed cardiac or respiratory complications. The scoliotic curvature was 18 degrees (range of 10 degrees to 25 degrees) immediately after surgery, and 19 degrees (range of 12 degrees to 27 degrees) at the last follow-up. The pelvic obliquity improved from a mean of 17 degrees (range of 14 degrees to 20 degrees) pre-operatively to a mean of 6 degrees (range of 4 degrees to 9 degrees) post-operatively and to 7 degrees (range of 4 degrees to 10 degrees) at the last follow-up. Balanced sitting posture was achieved and maintained. On the sagittal plane, good reconstruction of sagittal plane alignment was recreated and maintained. There were no major complications or deaths. All patients/parents completed the outcome satisfaction questionnaire; 8 patients/parents were very satisfied and 2 were satisfied. The authors concluded that pedicle-screw-alone fixation and fusion to L5 was safe and effective in CMD patients with scoliosis of less than 95 degrees and pelvic obliquity of less than 20 degrees. Scoliosis curves were flexible (75 % correction) on side-bending films pre-operatively. Curve correction and maintenance of correction in the coronal and sagittal plane was excellent. The pelvic obliquity significantly improved. Balanced sitting posture was achieved and maintained in all patients. The patients with CMD spinal deformity and a moderately and severely decreased FVC could be operated on safely and successfully with general anesthesia. All patients were extubated in the operating room. There were no major complications or deaths. The authors believed a FVC of less than 30 % alone is not a predisposition to pulmonary complications. However, cardiomyopathy might be a determining risk

of mortality, and they believed surgery for these patients should be avoided. Patients' and parents' satisfaction was high.

Furthermore, UpToDate reviews on “Scoliosis in the adult” (Hey, 2020) and “Adolescent idiopathic scoliosis: Management and prognosis” (Sherl, 2020) do not mention Scoliosis Flexibility Trainer as a management option

The Use of Para-Spinous Muscle Flap Reconstruction for Scoliosis Surgery

Manstein et al (1998) stated that coverage of mid-line posterior wounds presents a challenge to the reconstructive surgeon, especially when spinal stabilization hardware has been present and exposed in the wound. Most commonly those wounds that involve the mid to upper thoracic spine have been covered by latissimus dorsi muscle or musculocutaneous flaps. Lower mid-line wounds, especially in the thoraco-lumbar region, have needed more complex means of coverage. These have included reversed latissimus dorsi flaps, free flaps, extended intercostal flaps, or fascio-cutaneous rotation flaps. These researchers have utilized a far simpler and effective muscle flap: the para-spinous muscle flap. They have raised para-spinous muscle flaps bilaterally and have been able to cover a number of difficult wounds. The wounds were presented by 8 patients with exposed Harrington rods, 3 patients with cerebrospinal fluid (CSF) leaks, and 1 patient with exposed spinous processes. The wounds in 5 of these 12 patients were in the upper thoracic region, where a latissimus flap was utilized as an additional layer of muscle coverage. The other 7 patients had wounds in the lower mid-line region below the potential reach of the latissimus dorsi. In the latter patients the only flaps employed were para-spinous muscle flaps. These investigators had only 1 failure in all patients, which involved a recurrent CSF leak in which there was no decompression of the CSF pressure utilized in the immediate post-operative period to protect the dural repair. In that instance, a leak recurred.

Hultman et al (2006) noted that infected spinal stabilization devices represent a significant reconstructive challenge by threatening spinal stability and increasing the risk of neurologic complications. These researchers provided an anatomic and clinical investigation of posterior mid-line trunk reconstruction using para-spinous muscle flaps as the primary method of repair. They retrospectively analyzed a series of 25 consecutive patients (mean age of 57.2 years; range

of 32 to 78 years) with complex spinal wounds, reconstructed with para-spinous muscle flaps, at a single university healthcare system. To help define the versatility of these muscle flaps, these investigators also performed cadaveric dissections with lead oxide injections in 10 specimens, with an emphasis on regional blood supply, flap width, and arc of rotation. From 1994 to 2000, these researchers successfully reconstructed 25 patients with complex spinal wounds, using 49 para-spinous muscle flaps as the primary method of reconstruction. Hardware present in 22 patients was replaced or retained in 17 cases. Long-term spinal fusion with preservation of neurologic status was observed in all patients, with no cases of dehiscence or re-infection. Wound complications included CSF leak (n = 1), skin necrosis (n = 1), sinus tracts (n = 3), and seroma (n = 2). Mean length of stay (LOS) was 24 days (range of 8 to 57 days); 1 post-operative death occurred. Para-spinous dissections and injections confirmed a segmental type IV blood supply with medial and lateral perforators, arising from intercostal vessels superiorly and lumbar and sacral vessels inferiorly. Flap width was 8 cm at the sacral base, 5 cm at the level of the inferior scapular angle, and 2.5 cm at the 1st thoracic vertebra. The authors concluded that para-spinous muscle flaps could be used as the primary reconstructive option to cover and preserve spinal hardware, control local infection, and enable long-term spinal stabilization. Cadaveric dissections confirmed the usefulness of para-spinous flaps, which can be based upon lateral or medial perforators and can be safely mobilized to reliably reconstruct complex spinal wounds. The main drawback of this study were its retrospective design and small (n = 22 patients with spinal hardware present) sample size.

Merikli et al (2010) stated that with increasingly complex spine surgeries now being performed on a more co-morbid patient population, the reconstruction of mid-line back wounds from these procedures is becoming a frequent dilemma encountered by plastic surgery. These researchers examined the effect of various pre-operative risk factors on post-operative wound healing complications after para-spinous muscle flap reconstruction of mid-line back defects. An Institutional Review Board (IRB)-approved, 11-year, retrospective, office and hospital chart review was conducted. All adult patients who underwent para-spinous muscle flap reconstruction during the study period were included. There were 92 patients in the study, representing the largest reported series to-date for the para-spinous muscle flap procedure. Mean follow-up was 120 days. Several wound-healing risk factors were present in this patient population: 72 % were mal-nourished, 41 % had hypertension, 37 % were obese, 34 % had a history of smoking, 32 % had

diabetes, 16 % were on chronic steroids, 14 % had a history of more than 2 previous spine surgeries, and 9 % had a history of radiation to the wound area. Factors significantly ($p < 0.05$) associated with post-reconstruction wound complications included history of traumatic spine injury, pre-reconstruction hardware removal, a history of more than 2 spine surgeries, hypertension, and lumbar wound location. This patient population possessed multiple co-morbidities making complex wound healing difficult. Several specific risk factors were associated with an increased rate of post-reconstruction wound complications after para-spinous muscle flaps. The authors stated that paraspinous muscle flap remains an important tool for spinal wound reconstruction in the reconstructive surgeon's armamentarium. This study primarily addressed the pre-operative risk factors on post-operative wound healing complications after para-spinous muscle flap reconstruction.

Ward et al (2017) noted that post-operative wound complications after posterior spinal fusion are difficult to manage. The incidence in the non-idiopathic patient population is significantly higher than the adolescent idiopathic population. A comparison of wound complications after posterior spinal fusion for non-idiopathic scoliosis between the utilization of the orthopedic surgical team at the time of closure performing a non-standardized wound closure versus a plastic surgeon with a plastic multi-layered closure technique and rotational flap coverage when needed had not previously been evaluated. These researchers compared the complication rate between non-standardized and plastic multi-layered closure of the surgical incision in patients undergoing posterior spinal fusion for non-idiopathic scoliosis. The charts of 76 patients with a primary diagnosis of scoliosis associated with a syndrome or neuromuscular disease and who underwent a posterior spinal fusion were reviewed; 42 patients had their incisions closed using the non-standardized technique and 34 using the plastic multi-layered technique. These 2 groups were compared for age, sex, primary diagnosis, number of levels fused, estimated blood loss (EBL), number of blood units transfused, operating room time, wound complication, and return to operating room. The wound complication rate in the non-standardized closure group was 19 % (8/42) compared with 0 % (0/34) in the plastic multi-layered closure group ($p = 0.007$). The unanticipated return to the operating room rate was 11.9% (5/42) for the non-standardized closure patients versus 0 % (0/34) for the plastic multi-layered closure patients ($p = 0.061$). The authors concluded that the use of the plastic multi-layered closure technique in this patient population was important in an effort to decrease post-operative wound complications. The ability

of the surgical team to decrease the infection rate of non-idiopathic scoliosis cannot be overstated. The method of wound closure plays a major role in lowering this incidence. Level of Evidence = III.

Adapa et al (2018) noted that wound complications can occur in up to 20 % of patients following multi-level posterior spinal fusion. Currently, the use of local flaps has been reported in high-risk patients with a history of spinal neoplasm, radiation therapy, exposed hardware, multiple spine surgeries, or wound infections. However, there are no reports of prophylactic muscle flap wound closure in patients undergoing multi-level spinal fusion for degenerative pathology. Given the extensive soft tissue dissection for exposure compounded by patient co-morbidities, there is potential to minimize the risk of wound complications with prophylactic trapezius and/or para-spinal flap coverage. These investigators described the utility and outcomes of prophylactic muscle flaps for wound coverage after instrumented posterior spinal fusion for multi-level degenerative spine disease and spinal deformity. An IRB-approved retrospective review of 26 consecutive patients who underwent a multi-level posterior spinal fusion for degenerative pathology with concurrent muscle flap coverage at a single institution (August 2016 to February 2017) was carried out. Patient demographics, clinical profile, procedures, and outcomes at a minimum 6-month post-operatively have been described. Patients had a mean age of 59.7 ± 13.0 years with a mean body mass index (BMI) of 31.0 ± 8.6 kg/m². Para-spinous muscle flap (61.5 %), trapezius (3.8 %), and combination flaps (34.6 %) were used for coverage of an average wound defect of 325 cm² extending over average 10.2 vertebral levels. All wounds healed completely with no complications at an average of 9.1 months follow-up. Only 1 patient (3.8 %) developed a seroma for which interventional radiology (IR)-drainage was sufficient. The authors concluded that prophylactic trapezius and/or para-spinous muscle flap coverage using a team approach could reduce the risk of wound complications after extensive spinal fusion for multi-level degenerative disease or adult spinal deformity (ASD). These researchers stated that preliminary results from their institution suggested that routine use of such a protocol has the potential to improve quality of care and reduce healthcare expenditure associated with this relatively morbid procedure. They stated that further experience with this approach from their institution and development of individual protocols nationwide will help substantiate these preliminary results.

The authors stated that this study was primarily limited by its retrospective nature and small sample size (n = 26). Furthermore, findings from a single institution may not always be uniformly generalized. There may be variability in the support and availability of plastic surgeons across institutions nationwide for such a team approach. Given the muscle flap closure protocol in place, these investigators were unable to report results from a comparative group undergoing standard wound closure techniques. A lower incidence of wound complications can be taken as indirect evidence for overall cost savings associated with complex spine surgery; however, analysis of cost-effectiveness was beyond the scope of this study.

Merikli et al (2019) stated that patients undergoing surgeries involving extensive posterior spine instrumentation and fusion often have multiple risk factors for wound healing complications. These investigators performed a systematic review and meta-analysis of the available evidence on immediate (proactive/prophylactic) and delayed (reactive) spinal wound reconstruction. They hypothesized that immediate soft-tissue reconstruction of extensive spinal wounds would be associated with fewer post-operative surgical site complications than delayed reconstruction. In accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, a PubMed database search was performed to identify English-language, human-subject literature published between 2003 and 2018. Data were summarized, and the pooled prevalence of various wound complications was calculated, weighted by study size, using the generic inverse variance method. A subgroup analysis of all studies with a comparison group (Oxford Centre for Evidence-based Medicine level 3 or better) was performed, and Forest plots were created. The database search yielded 16 articles including 828 patients; 428 (51.7 %) received an immediate spinal wound reconstruction and 400 (48.3 %) had a delayed reconstruction. Spinal neoplasm was the most common index diagnosis. Para-spinous muscle flap reconstruction was performed in the majority of cases. Pooled analysis of all studies revealed immediate reconstruction to be associated with decreased rates of overall wound complications (28.5 % versus 18.8 %), hardware loss (10.7 % versus 1.8 %), and wound infections (10.7 % versus 7.6 %) compared with delayed reconstruction. The authors concluded that these findings suggested immediate soft-tissue reconstruction of high-risk spinal wounds was associated with fewer wound healing complications and increased hardware retention. Moreover, they stated that additional studies are needed, in which simple primary closure is compared with immediate prophylactic para-spinous muscle flap reconstruction. Such a study would allow

researchers to definitively risk stratify this patient population and accurately predict who would derive the greatest clinical benefit from an immediate soft-tissue reconstruction at the time of an index spine surgery.

The authors stated that a limitation of this meta-analysis was that the articles available for systematic review on the topic of spinal reconstruction were Oxford Centre for Evidence-based Medicine (OCEBM) level of evidence III and IV; thus, the risk of selection bias confounding these data was considerable. These investigators chose to only include studies published in the past 15 years, in an effort to limit technical and instrument-related heterogeneity. However, as indicated by the I² values, there was still interstudy heterogeneity when some variables were compared. This can be attributed to the fact that, owing to the small number of studies available, the authors chose to include all articles detailing immediate or delayed spinal wound reconstruction, regardless of the specific technique used, disease process, or patient population. These researchers acknowledged that this decision introduced the potential for bias, but their intent was to maximize power for the statistical analyses. The authors believed that including only studies with high-level evidence on this focused topic would have generated under-powered, inconclusive, and irrelevant data analyses. Despite these limitations, the data provided important information that support the concept of immediate wound reconstruction in high-risk patients.

Furthermore, an UpToDate review on “Adolescent idiopathic scoliosis: Management and prognosis” (Scherl, 2020) does not mention para-spinous muscle flap reconstruction as a management option.

Posterior Dynamic Deformity Correction Devices (e.g., ApiFix)

Floman and associates (2015) stated that surgery in AIS is a major operative intervention where 10 to 12 vertebrae are instrumented and fused. A smaller motion-preserving surgery would be more desirable for these otherwise healthy adolescents. The ApiFix system is a novel less invasive short segment pedicle screw-based instrumentation inserted around the apex of the main curve. The system has a ratchet mechanism that enables gradual post-operative device elongation and curve correction. The ratchet is activated by performing specific spinal exercises. The unique features of the device allow curve correction without fusion. The system that has a

CE approval was employed in adolescents with main thoracic curves. More than 12 ApiFix surgeries have been performed so far. The pre-operative Cobb angle was $45^{\circ} \pm 8$, and $25^{\circ} \pm 8$ at final follow up. The following was a report on 3 adolescent girls aged 13 to 16 years with curves between 43° to 53° and Risser sign of 1 to 4 who underwent surgery with ApiFix. Two pedicle screws were inserted around the curve apex and the ratchet-based device with poly-axial ring connectors was attached to the screws. No fusion attempt was performed. Operative time was approximately 1 hour. Two weeks after surgery the patients were instructed to perform Schroth like daily exercises with the aim of rod elongation and gradual curve correction. Patients were followed for 6 months to 2 years. Curves were reduced and maintained between 22° to 33° .

Patients were pain-free and were able to perform their spinal exercises. Post-operative gradual elongation of the device was observed. No screw loosening or rod breakage were observed. No adding on or curve progression was seen. The authors stated that 3 factors may contribute to the success of ApiFix: poly-axial connections that prevented mechanical failure, gradual curve correction by spinal motion, and spinal growth modulation. The ApiFix system allowed managing moderate AIS with a simple and minor surgical intervention; recovery was rapid with negligible motion loss. It allowed gradual and safe curve correction with high patient satisfaction. It may also serve as an internal brace for AIS. Moreover, these researchers stated that longer term clinical trials with a larger patient cohort are needed.

Holewijn and co-workers (2017) stated that recently, a posterior concave peri-apical distraction device for fusionless scoliosis correction was introduced. In a biomechanical study, these researchers quantified the effect of the peri-apical distraction device on spinal ROM in comparison with traditional rigid pedicle screw-rod instrumentation. Using a spinal motion simulator, 6 human spines were loaded with 4 N m and 6 porcine spines with 2 N m to induce flexion-extension (FE), lateral bending (LB), and axial rotation (AR). ROM was measured in 3 conditions: untreated, peri-apical distraction device, and rigid pedicle screw-rod instrumentation.

The periapical distraction device caused a significant ($p < 0.05$) decrease in ROM of FE (human, -40.0 %; and porcine, -55.9 %) and LB (human, -18.2 %; and porcine, -17.9 %) as compared to the untreated spine, while ROM of AR remained unaffected. In comparison, rigid instrumentation caused a significantly ($p < 0.05$) larger decrease in ROM of FE (human, -80.9 %; and porcine, -94.0 %), LB (human, -75.0 %; and porcine, -92.2 %), and AR (human, -71.3 %; and porcine, -86.9 %). The authors concluded that although no destructive forces were applied, no device

failures were observed. Spinal ROM was significantly less constrained by the peri-apical distraction device compared to rigid pedicle screw-rod instrumentation; thus, provided that scoliosis correction is achieved, a more physiological spinal motion is expected after scoliosis correction with the posterior concave peri-apical distraction device.

Floman and colleagues (2020) reported that a posterior dynamic deformity correction (PDDC) system was used to correct AIS without fusion. The preliminary outcomes of bridging only 3 to 4 discs in patients with variable curve severity have previously been reported. These researchers examined a subgroup of patients with the authors' proposed current indications for this device who were also treated with a longer construct. Inclusion criteria were a single AIS structural curve between 40° and 60°, curve flexibility of less than or equal to 30°, PDDC spanning 5 to 6 levels, and minimum 2-year follow-up. They carried out a retrospective review and demographic and radiographic data were recorded. A successful outcome was defined as a curve magnitude of less than or equal to 30° at final follow-up. Any serious AEs and re-operations were recorded. A total of 22 patients who met the inclusion criteria were operated on with the PDDC in 5 medical centers. There were 19 girls and 3 boys, aged 13 to 17 years, with Risser grades of greater than or equal to 2; 13 had Lenke type 1 curves and 9 had type 5 curves. The mean pre-operative curve was 47° (range of 40° to 55°). At a minimum of 2 years' follow-up, the mean major curve measured 25° (46 % correction, $p < 0.05$). In 18 (82 %) of 22 patients, the mean final Cobb angle measured less than or equal to 30° (range of 15° to 30°). Trunk shift was corrected by 1.5 cm (range of 0.4 to 4.3 cm). The mean minor curve was reduced from 27° to 17° at final follow-up (35 % correction, $p < 0.05$). For Lenke type 1 patterns, the mean 2D thoracic kyphosis was 24° pre-operatively versus 27° at final follow-up ($p < 0.05$), and for Lenke type 5 curves, mean lumbar lordosis was 47° pre-operatively versus 42° at final follow-up ($p < 0.05$). The mean pre-operative Scoliosis Research Society-22 questionnaire score improved from 2.74 ± 0.3 at baseline to 4.31 ± 0.4 at 2 years after surgery ($p < 0.0001$). The mean pre-operative self-image score and satisfaction scores improved from pre-operative values, while other domain scores did not change significantly; 4 patients (18 %) underwent revision surgery because of nut loosening ($n = 2$), pedicle screw backup ($n = 1$), and ratchet malfunction ($n = 1$). The authors concluded that in AIS patients with a single flexible major curve up to 60°, the fusionless PDDC device achieved a satisfactory result as 82 % had residual curves of less than or equal to 30°. These researchers stated that the findings of this study suggested that the PDDC device may serve as an alternative

to spinal fusion in select patients. Moreover, these investigators stated that the main drawbacks of this study were the small sample size ($n = 22$) and the retrospective outcomes evaluation; however, the radiographic and patient outcomes were encouraging.

Floman and associates (2020) stated that growth modulating spinal implants are used in the management of scoliosis such as anterior vertebral body tethering. A motion-sparing PDDC was recently approved for the treatment of moderate AIS. In a retrospective, comparative, multi-center study, these researchers examined if the PDDC could modulate growth in skeletally immature patients with AIS. From a database of patients treated with the PDDC over 4 years, these investigators identified those who had a minimum of 2 years follow-up. Pre-operative and post-operative Cobb angles and coronal plane wedging of the apical vertebra were evaluated on standing full-length radiographs. Independent sample t-test and 1-way ANOVA with post-hoc Tukey HSD analysis was employed to compare 3 groups in varying skeletal maturity: Risser 0 to 1, Risser 2 to 3, and Risser 4 to 5. A total of 45 patients (14.2-years old, 11 to 17) were examined with a mean pre-op curve of 46° (35° to 66°). The average pre-operative major curve magnitude, of either Lenke 1 or 5 curve type, was similar among the 3 groups -- 47.6° , 46° and 41.5° .

Deformity correction was similar in the 3 groups, with reduction to 26.4° , 20.4° and 26.2° , respectively, at final follow-up [$p < 0.05$]. Pre-op wedging 7.4° (3.8° to 15°) was reduced after surgery to 5.7° (1° to 15°) ($p < 0.05$). Of those patients, Risser 0 to 1 ($n = 16$) had pre-operative wedging of 9.5° (6° to 14.5°) that was reduced to 5.4° (1° to 8°) post-operatively ($p < 0.05$); Risser 2 to 3 ($n = 15$) had pre-operative 7.7° (4° to 15°) versus post-operative 7.0° (3° to 15°); Risser 4 to 5 ($n = 14$) had pre-operative 4.8° (3.8° to 6.5°) versus post-operative 4.7° (3.7° to 6.5°). Delta Wedging in Risser 0 to 1 stage was significantly different than for Risser 2 to 3 and for Risser 4 to 5. The authors concluded that the posterior dynamic deformity correction device was able to modulate vertebral body wedging in skeletally immature patients with AIS. This was most evident in patients who were Risser 0 to 1. In contrast, curve correction was similar among the 3 groups.

The authors stated that the main drawbacks of the study were the small cohort, retrospective analysis, and the lumping together of Risser 0 and Risser 1 cases. Another drawback was related to the measurement of the wedged apical vertebra. While the deformation of the apical wedge in scoliosis is 3 dimensional, these researchers measured only the coronal wedge deformation; however, their measurements of apical vertebral wedging were similar to the measurements

described in a finite element model of AIS. Another aspect of curve morphology that was not examined in this study was the shape of the intervertebral disc, which was also affected by the altered mechanics in a spinal curvature.

Stadhouder et al (2021) noted that conventional surgical treatment for adolescent idiopathic scoliosis (AIS) consists of correction of the spinal deformity with rigid spinal instrumentation and fusion. Less invasive and fusionless surgery could potentially improve patient outcomes. In a prospective, cohort study, these researchers examined the effectiveness of a recently FDA-approved posterior peri-apical self-distracting device (ApiFix) that is designed to gradually correct the deformity without spinal fusion. This trial included 20 patients with AIS (Risser stage 1 to 4; Lenke 1 or 5; major curve Cobb angle, 40° to 55°; and Bunnell scoliometer rotation, less than 15°) were managed with the ApiFix device. Clinical and radiographic performance was evaluated. A total of 20 patients with a mean age (and standard deviation) of 14.8 ± 1.4 years were followed for a mean of 3.4 ± 1.0 years. The average major curve was reduced from 45.4° preoperatively to 31.4° at 2 weeks post-operatively and 31.0° at the time of the latest follow-up. The average minor curve measured 31.3° pre-operatively, 26.1° at 2 weeks post-operatively, and 24.2° at the time of the latest follow-up; 10 patients had serious complications that required revision surgery, including osteolysis (n = 6), screw and/or rod breakage (n = 2), failure of the ratchet mechanism (n = 1), and pain without explainable cause (n = 1). During revision surgery, metallosis was observed in all patients and cultures showed growth of *Cutibacterium acnes* in 6 patients. Because of the high failure rate, the study was terminated early. The authors concluded that this study on the use of the ApiFix device for fusionless scoliosis surgery highlighted an unacceptably high rate of implant-related complications, and no curve correction or distraction of the ratchet was observed post-operatively. The design of the implant resulted in metal wear and probably induced high screw and screw-bone interface loads. These failure mechanisms could potentially be mitigated with more and stronger anchors (screws) and higher-quality mobile bearings that are less prone to wear. However, the fundamental design problem and lack of post-operative correction remain. All patients in the current cohort will be monitored closely. The local medical ethics committee and all included patients and their guardians have received written information about the complications and the decision to terminate further inclusions. Level of Evidence = IV.

Myofascial Release for the Treatment of Lower Back Pain in Idiopathic Scoliosis

Lopez-Torres and colleagues (2021) stated that idiopathic scoliosis is associated, among others, to muscular imbalance, functional limitations, and the most prevalent, lower back pain (LBP).

Treatments usually entail exercise, bracing or surgery. The objective of corrective exercise is to reduce symptoms and improve functional capacity and QOL. Myofascial release (MFR) or self-myofascial release (SMFR) are manual techniques, intended to restore optimal muscle and fascia length, decrease pain, and improve function. In a systematic review, these researchers analyzed the effects of MFR and postural control programs in LBP and scoliosis curves. They carried out a literature review in high quality databases to identify the existing evidence of the effects of MFR and postural control on reducing LBP and scoliosis curves. A total of 17 studies met inclusion criteria; 533 subjects and 94 MFR/SMFR applied interventions lasting 1 to 24 weeks/sessions were identified. A total of 10 studies used MFR, 6 SMFR and 1 mixed technique. A total of 7 MFR and 5 SMFR studies shown positive result; 1 study using MFR and 1 using SMFR applied also postural control exercises. MFR was useful to reduce LBP in all studies included that aimed in that matter. Furthermore, 12 studies reported improvements in flexibility and/or stiffness reduction, and 2 studies observed improvements in postural control and balance. The authors concluded that the combination of MFR and postural control programs might be suitable for reducing scoliosis and LBP; however, due to the reduced number of studies and the relatively small sample sizes used, results may be carefully interpreted, and more studies are needed.

Ultrasound Shear Wave Elastography for Identification of Children at Risk for Idiopathic Scoliosis

de Reuver and colleagues (2022) stated that ultrasound (US) shear wave elastography (SWE) is a radiation-free and low-cost technique for evaluating the mechanical properties of different tissues. In a systematic review, these researchers examined available evidence on SWE of the intervertebral disc (IVD). The objective was 2-fold. First, to determine the validity of the elastography method (i.e., the correlation between elastographically measured shear wave speed (SWS) and disc mechanical properties, and inter-/intra-operator reliability. Second, to examine if disc elastography is potentially useful in identifying children at risk for AIS. This systematic review was carried out according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines. A comprehensive search was carried out in PubMed and Embase,

and study quality was assessed using the AXIS (Appraisal Tool for Cross-sectional Studies) critical appraisal instrument; a total of 7 articles were included – 3 animal ex-vivo studies reported moderate-to-good correlations between SWS and disc mechanical properties ($r = 0.45$ to 0.81); 3 studies reported high intra-operator repeatability (intra-class correlation coefficient [ICC] 0.94 to 0.99) and inter-operator reproducibility (ICC 0.97 to 0.98); 4 clinical studies measured SWS in asymptomatic children; 2 studies reported significantly higher SWS in scoliosis patients compared with healthy controls, measured in discs both inside and outside the scoliotic curve. The authors concluded that this study systematically reviewed all relevant literature on SWE of the IVD, with the purpose of determining its validity, reliability and potential usefulness in identifying children at risk for AIS. Excellent repeatability and reproducibility were reported with moderate-to-strong levels of evidence. Multiple studies determined a correlation between elastographically measured SWS and the apparent stiffness/elasticity of IVDs under axial loading, however with a large variation and in different circumstances. These researchers stated that although it is promising that in clinical studies ultrasound elastography could make a distinction between IVDs in patients with and without AIS, the correlation between SWS measurements and disc stiffness and possible confounding factors is not yet fully understood.

The authors stated that the main drawbacks of this systematic review were not methodological but related to the outcome, as 6 of 7 included studies were performed at the same institute. In addition, only 2 included studies tested SWE in a clinical setting on patients with AIS. There were a limited number of studies on the subject, with large variability in both study design and study population characteristics. Of the 7 included studies, data were only analyzed descriptively, as no meta-analysis could be carried out. Finally, relatively small sample sizes and heterogeneity in reported data made thorough comparison and interpretation of the results difficult. Thus, this systematic review provided only an overview of current literature on US-based SWE of the IVD in relation to scoliosis, with a few tentative conclusions.

Silicon Valley Scoliosis Method

Silicon Valley Scoliosis Method is a new way for preventing surgery in curves of 30 degrees and under (a moderate curve is between 25 degrees and 40 degrees). Supposedly, this method not only eliminates the need for surgery, it can make the spine grow straighter. However, there is a

lack of evidence to support the use of Silicon Valley Scoliosis Method for the management of scoliosis.

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The above policy is based on the following references:

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