Spinal Technology®

Orthotic Management of Adolescent Idiopathic Scoliosis

Spinal Technology

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Introduction

At Spinal Technology®, we believe that sharing our knowledge, absorbing that of others, and working together as a team, is the most effective way to advance the treatment and care for all patients.

Adolescent idiopathic scoliosis is recognized as the most common type of spinal deformity and estimated to affect anywhere from 2% to 5% of all children. The course of treatment can vary depending on the severity and can include observation, physical therapy, orthotic bracing, surgery, or various combinations thereof. For most patients with scoliosis, this means that they will likely have interactions with multiple practitioners of varying expertise throughout their youth. Communication, continuity, and collaboration among all disciplines involved, including support of the patient's family, are paramount to successful outcomes and quality of life for each patient.

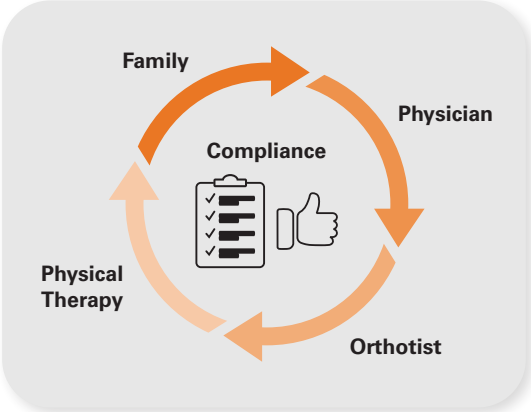
As part of the clinical team, we are driven to go beyond the physical products that we provide, and offer our expertise and support with all the resources we have. With a passion for treating scoliosis, we make it our priority to share our knowledge, teach what we know best, and create the tools and materials for improving patient care.

The introduction of varying brace designs can often present conflicting perspectives on the appropriateness of any particular method of treatment. As extensive research is presented on a broad scope of new concepts, the basic principles and understandings of effective bracing tend to become less clear. We believe a concise foundation of knowledge is critical to successful scoliosis management.

At Spinal Technology® we recognize the importance of continuous education and are pleased to provide informational material and support to those who share our commitment to advancing the care of patients challenged with scoliosis.

The Clinical Development & Education Team at Spinal Technology®

Scoliosis Bracing and The Challenge of Patient Compliance



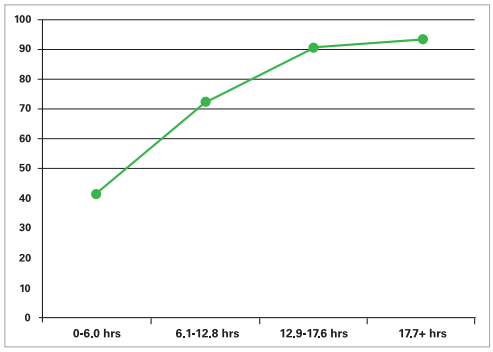
Initial correction in-brace has long been the benchmark for determining the effectiveness of any particular brace design, as well as the accuracy and fit of an orthosis. Other factors are highly important, such as balance, stability, comfort, and compliance, but they are often considered as secondary criteria for design considerations. The one variable that stands out above all others is that of least control, patient compliance.

For any care plan to be effective, a patient must adhere to the dosing and scheduling of the prescribed treatment. This is by far the biggest challenge to bracing for adolescent idiopathic scoliosis.

For many adolescents, brace wear can present a significant disruption in daily life. Considering that the majority of adolescent idiopathic scoliosis patients are in their early teenage years, it is important to recognize the entirety of their development. These children are navigating through new physical, emotional, and social challenges, all of which can be further complicated by the introduction of an orthosis into their daily lives, particularly in school. Not surprisingly, as was found in the BrAIST Clinical Trial, where *"On average, subjects wore the brace 12 hours per day (range 0 to 23)"*, obtaining sound compliance is a difficult task. It is well understood that most successful compliance is achieved by the presence of a strong support system that includes family, physician, orthotist, and physical therapist working together. While it is not always possible to create or control an ideal environment, it is greatly important to maintain a strong emphasis on good compliance with every encounter.

Additionally, brace design options should be carefully assessed for patient acceptance. There are a multitude of bracing options throughout the world, some of which have competent research to support their effectiveness; yet most lack a substantive component of actual wear time, leaving the reliance only to subjective feedback, which is most often overstated. As research continues to progress, the SRS (Scoliosis Research Society) has instituted guidelines that incorporate compliance measures as a standard, which logic suggests should also reduce the dilution of positive outcomes by the inclusion of non-compliant patient data. This will also provide empirical data on the efficacy of various bracing systems, as it relates to patient acceptance and successful outcomes.

Average Full-Time Brace Wear, BrAIST Clinical Trial



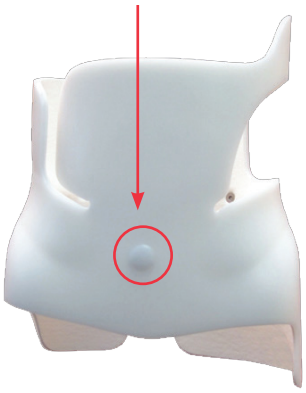
*preliminary data

On average, subjects wore the brace 12 hours per day (range 0 to 23)

As the average hours per day increased, so did the success rate ($p<0.0001$)

Regardless of brace type being used, it is important to have insight into each patients "actual" wear time, and consider their adherence to the protocol as a factor in the treatment outcomes. Bracing monitors are easily accessible and are a cost effective way to measure compliance. It has also been shown that just the presence of a monitor can improve compliance. The stWear™ Compliance System allows practitioners to customize patient brace wearing data into comprehensive reports and three types of linear graphs to chart wearing compliance. Users have the ability to set up multiple patients, establish individual schedules by date and time, and view and print reports. Most monitors are very low profile in design and easily fabricated into the orthosis.

stWear™ Brace Monitor



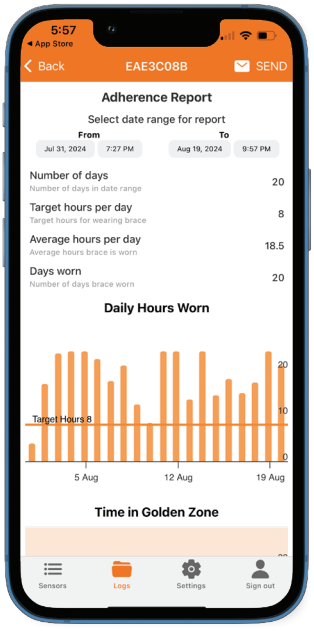
The **stWear™** Compliance Monitoring System has a web based clinician interface which allows data to be shared between physicians, parents and orthotists.

The Providence Nocturnal Scoliosis® Orthosis

"As with other medical treatments, success depends upon treatment actually being performed. In the case of bracing for adolescent idiopathic scoliosis, it is often incorrectly assumed that brace patients are compliant with their treatment."

ADVANCES IN SCOLIOSIS BRACE TREATMENT,
William J. Shaughnessy, MD

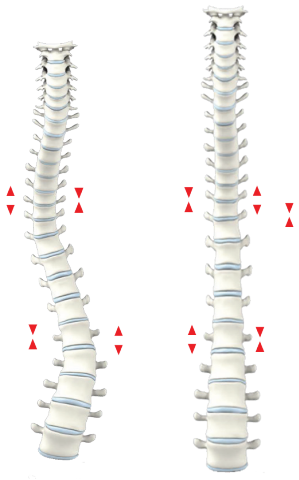
Strong consideration should be made to adopting nighttime bracing as a primary method of treatment. Research has shown that the hyper-corrective Providence® Brace, worn only at night, provides outcomes equal to or greater than those of its full-time counterparts. The option of limiting brace wear to nighttime use at home, significantly increases compliance rates and improves "Quality of Life" measures in brace-wearing scoliosis patients.



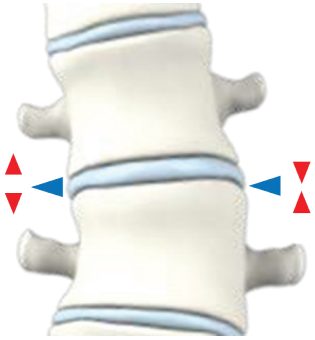
A new smartphone app allows parents to monitor their child's success in real-time with bluetooth technology.

Scoliosis Bracing – Growth Plate Physiology

Heuter - Volkman Law showing longitudinal deformation of vertebral bone growth with imbalance of loading across the growth plates.



Understanding the mechanics of scoliosis and the impact of asymmetrical loading on the spine, Hueter-Volkmann law illustrates a few things about the nature of curve progression and the requirements for halting or reversing that course. The longitudinal deformation of vertebral bone growth can most likely be attributed to the imbalance of loading across the growth plates prior to reaching skeletal maturity. Compressive forces on the concave side of the curve will effectively decrease the rate of growth, while distractive unloading on the convex side will accelerate growth. The magnitude of this discrepancy has been estimated to reach as high as 40% or greater (Stokes et al.).



By understanding these dynamics in asymmetrical growth, one can relate to principles of inhibiting curve progression. Leveling out the forces across the growth plates can alter the course of development, allowing for a more normal growth pattern.

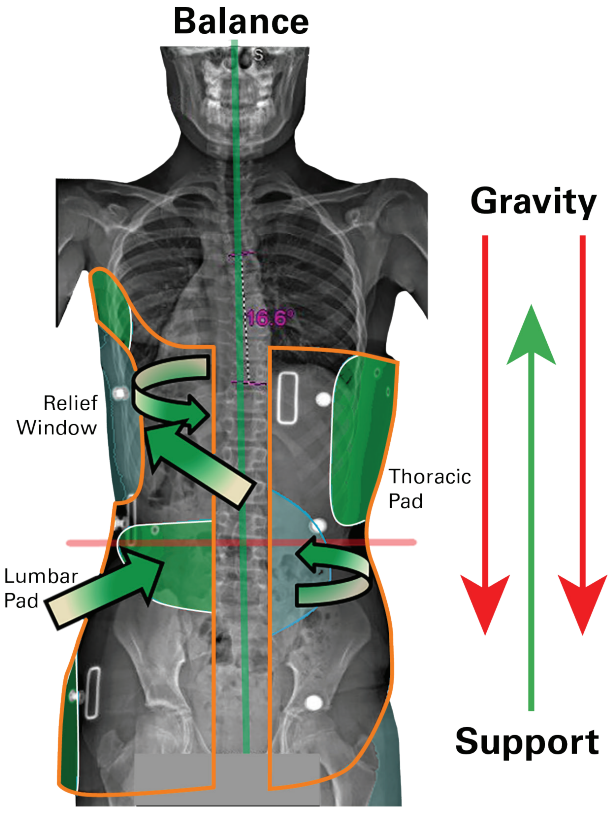
It has long been established that effective bracing requires a minimum of 50% in-brace correction in a full-time orthosis. This has been the determination based on the goal of limiting progression to no greater than 5 degrees post bracing, as well as the prevention of surgery.

These goals, however, were established primarily as a result of the many scientific studies of full-time brace wear, in which the magnitude of correction in-brace can be somewhat limited. Alternatively, other bracing methodologies (specifically nighttime bracing) allow for considerably more correction in-brace. The tolerance for brace wear in the recumbent position provides the ability to apply hyper-corrective forces, effectively leveling out the forces across the growth plates entirely, or even providing for over-correction as high as 115%. Under these conditions, the vertebra are free to develop unrestricted and may progress towards a more corrective state. By creating such a scenario while the patient is sleeping and growth rates are at their highest, it is possible to achieve greater outcomes to that of more traditional daytime bracing, in a shorter amount of time and with greater tolerance for the patient.

In addition to nighttime bracing, recent developments in surgical approaches are taking advantage of growth plate development. Anterior vertebral body tethering (AVBT) has shown great promise in modulating vertebral growth. By altering the forces across the growth plates with targeted asymmetrical elastic compression, while at the same time maintaining flexibility and allowing for movement throughout the spine, the resulting growth pattern can be redirected towards more normal development.

Corrective Forces of Full-Time Bracing

In order to effectively treat and correct the multi-planar deformities of scoliosis, it is necessary to employ some basic principles. Full-time bracing presents unique challenges which must be addressed in the design of an orthosis. Due to the fact that the patient is upright and continuously in motion throughout the day, trying to maintain balance and fighting the effects of gravity, the form, fit, and function of a full-time brace must be accurate and consistent for 18 to 22 hours, every day.



- In order to gain control of the torso and apply manipulative forces, a solid foundation is needed. The pelvis is the base of support, providing the necessary stability and leverage.

- The waist rolls must be tight and deep between the iliac crest and the lower ribs, comfortably capturing the ASIS. This helps to capture and control the pelvis, as well as properly locate the brace to prevent migration. In combination with abdominal compression, this applies hydraulic forces that will help to offload weight from the lumbar spine, assisting in elongation and correction of a lumbar curve.

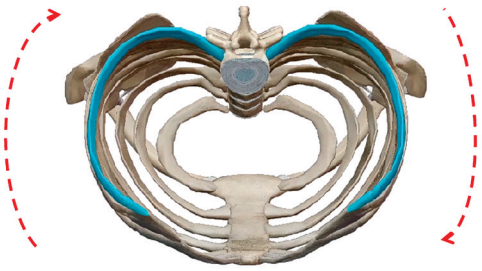
- Both the lumbar and thoracic pads are positioned posterior laterally to apply anterior de-rotational and medially directedforces. The pads are placed at and below the apex of each curve, with few exceptions.

- Substantial relief is necessary opposite any pad or force, in order to provide room for migration. It may argued that reliefs are more important than pads, as a symmetrical brace will inher-ently add some degree of correctional forces to an asymmetrical patient, as long as there is space for the deformity to migrate.

Positioning the pads below the apex of the curve and shaping them to create an upwards force vector provides the support needed to effectively lift the apex up and towards midline. This is necessary to counteract the effects of gravity and relieve some of the loads carried by the intervertebral discs. With daytime wear, the brace acts as a support structure, helping to reduce the axial load on the spine, alleviating some of the compressive forces of gravity across the discs and endplates. In order to correct the curvature and vertically elongate the spine, it is necessary to lift and support the weight carried above each vertebral level.

Greater force is required for correction in an upright/standing position, compared to that in a recumbent state. Daytime brace wear requires the consideration of gravity, ground reaction forces, and balance in brace design.

Principles of 3D Bracing – Design and Methodologies



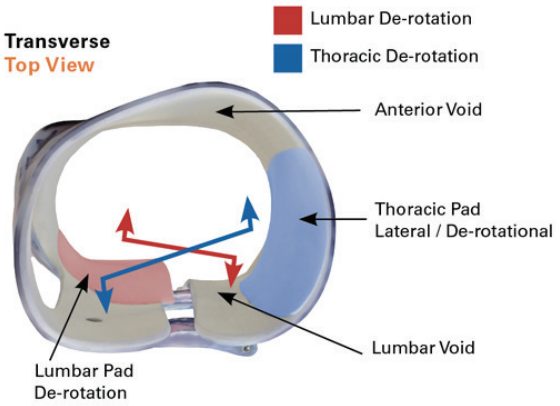
3D Bracing incorporates the de-rotational and translation forces applied through the ribs

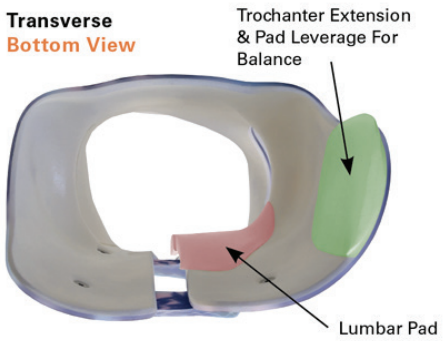
Three dimensional bracing is not a new concept by any means. Dating as far back as the late 5th century, when Hippocrates identified Scoliosis (root "skol": meaning twists and turns), it has been well understood that the nature of the deformity presents in multiple planes. Orthotic approaches to managing these characteristics have long taken into account the dynamics of de-rotation, medial translation, and balance. Much of what you will find in 3D bracing is achievable in a well-adjusted, modified, and custom fit orthosis that began as a symmetrical module, albeit quite a bit of time and effort to get there.

However, the methods, tools, and accuracy have changed with the incorporation of scanning and CAD design. This is where we begin to see the value of what has been termed "3D Bracing". The advantages arise from direct manipulation of the patient model in a digital format. Rather than adding localized pads to generate our forces, and heating or cutting out spaces for reliefs, the same can be done effectively by de-rotating and shifting segments of the patient's model as a whole. Any segmental changes made will inherently create forces and reliefs, as the section is moved as a complete unit. This becomes most beneficial when addressing the Thoracic region. Rather than having a singular pad contributing to the de-rotation and translation forces transferred through the ribs on one side, capturing the entirety of that segment and manipulating it as a whole greatly improves accuracy, increases leverage, and adds more comfort for the patient by maintaining a greater surface area for contact.

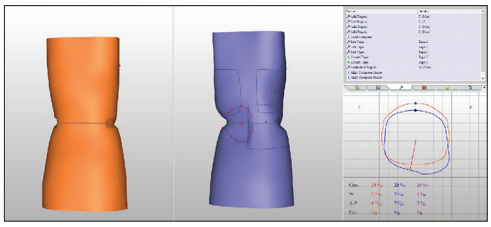
By working directly with the patient model, form-fitting contact can be maintained in most areas, while providing for ample relief where necessary for corrective movement. In addition, modification of the model prior to brace fabrication offers the ability to incorporate some features not easily created after the fact, when the brace is being fit. The best examples of that can be seen in the anterior de-rotational void in front of the posterior-lateral thoracic force, as well as the anterior thoracic de-rotation force on the contralateral side and the accompanied posterior relief.

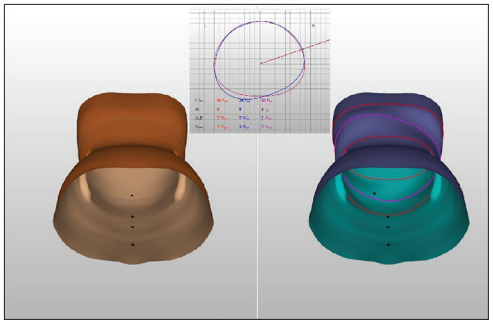
Transverse views showing de-rotational forces and void areas





Principles of 3D Bracing – Modifications and Approach to Curve Analysis and Brace Design

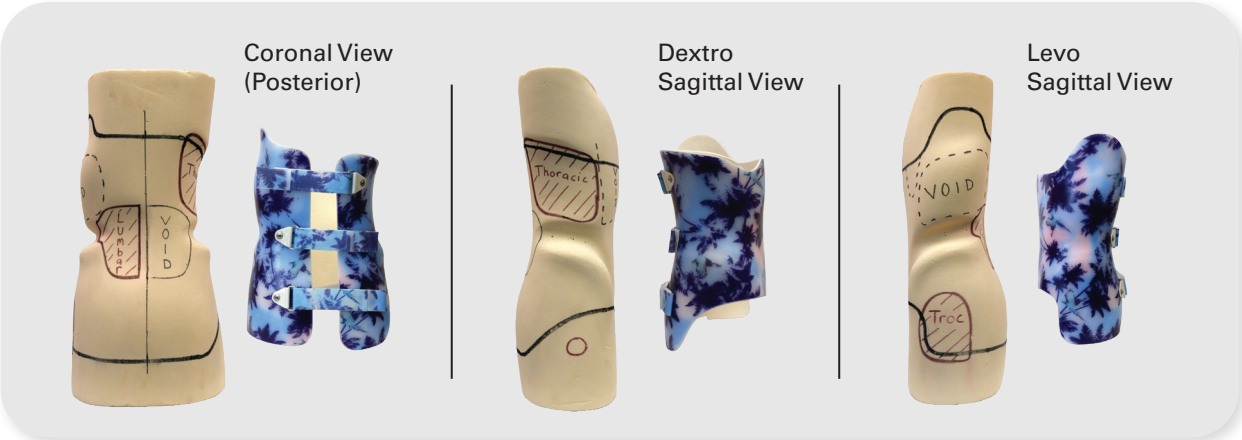




Torso CAD scans modified for patient curve(s), segmental de-rotation & brace design

In 3D bracing, it is important to evaluate all aspects of each patient's radiograph and determine the best design and modifications accordingly. Taking into consideration the patient's complete profile and the nature of the curve(s) allows the creation of a comprehensive blueprint of the most effective design. Some of the criteria for evaluation include the magnitude of each curve, apex, vertebral tilt at each level, vertebral rotation, patient balance and alignment, symmetry and balance of the pelvis, skeletal maturity (Risser), as well as identification of any vertebral anomalies or deformations, among others.

The magnitude of the rotational component can accurately be assessed based on the alignment of the pedicles (as seen in the radiograph), along with any asymmetry apparent in the patient's CAD model. The approach then is to segment and de-rotate at the appropriate levels within the patient's model. After de-rotating, the corrective forces are accentuated accordingly, and the reliefs expanded to accommodate for additional de-rotation and medial translation. All 3D braces include some degree of de-rotation within the model, as that modification efficiently creates relief for all associated components of correction. Applying de-rotational voids and reliefs via CAD provides significant advantages in the thoracic region, where it can be challenging to adjust post-fabrication in a typical symmetrical orthosis.



Additionally, experience has shown that each patient responds differently to bracing, therefore prompting the clinician to make adjustments as they see fit. For that purpose, the best approach is to apply moderate corrective forces directly into the mold and provide additional padding separately, allowing the clinician the ability to increase those forces should they find it advantageous and tolerable for the patient. In consideration of obtaining additional correction, it is always important to enhance the relief areas to accommodate for further migration.

Advantages of Nocturnal Bracing

Historically, full-time bracing has been the most prominent and widely accepted method for the conservative management of adolescent idiopathic scoliosis. Over the years, many variations of design have been introduced, with each one claiming to offer exceeding benefits over its predecessors. There's no shortage of research comparing various iterations of full-time orthoses, yet very little evidence exists to really demonstrate any significant and repeatable advantages of one over all others. Ultimately, the effectiveness of any orthosis relies on meeting just a few principles and requirements; in-brace correction (reduction of Cobb and rotation); alignment and balance; and, of course, patient compliance. The combination of those criteria for success can create some complicated scenarios when it comes to treating actual patients, especially those required to wear a brace for 18 to 22 hours per day. The challenges most often stem from the need for the patient to be upright and mobile. That alone contributes to the majority of the complications faced in traditional full-time brace design.

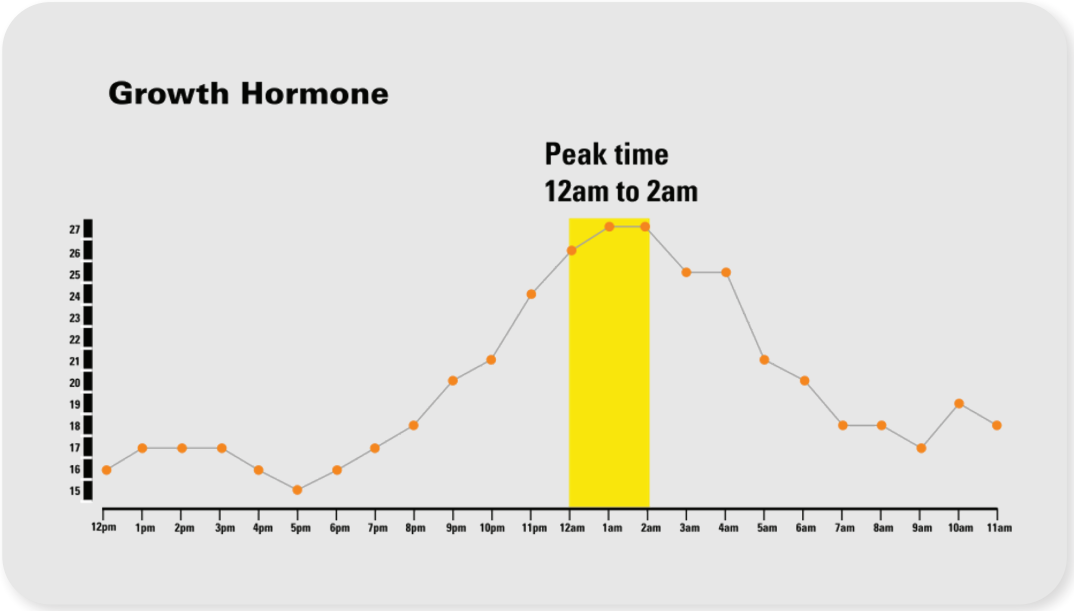
With nighttime bracing, most of those challenges do not exist. There are significant advantages to bracing at night that not only simplify brace design and allow for more targeted corrective forces, but greatly impact compliance, providing for better outcomes. When the patient is at rest in a recumbent position, the muscles are relaxed and no longer resisting the corrective forces. In this state, righting reflexes become inactive and body positioning, stance, and balance are of no concern. The patient experiences little to no irritation, as they are not sitting, standing, or walking. The recumbent position also eliminates the need for complex brace design to counteract gravity. Additionally, this makes it possible to take true advantage of growth rates and modulation of the vertebra.

As patient flexibility increases and muscle activity decreases, patients are able to tolerate much greater corrective forces. Effective manipulation of the spine, by the use of targeted hyper-corrective pads, is much more achievable at night. The results, in the case of the Providence® Brace, is significant correction of all curve types, averaging **98% in-brace** and exceeding upwards of 115% in some cases.

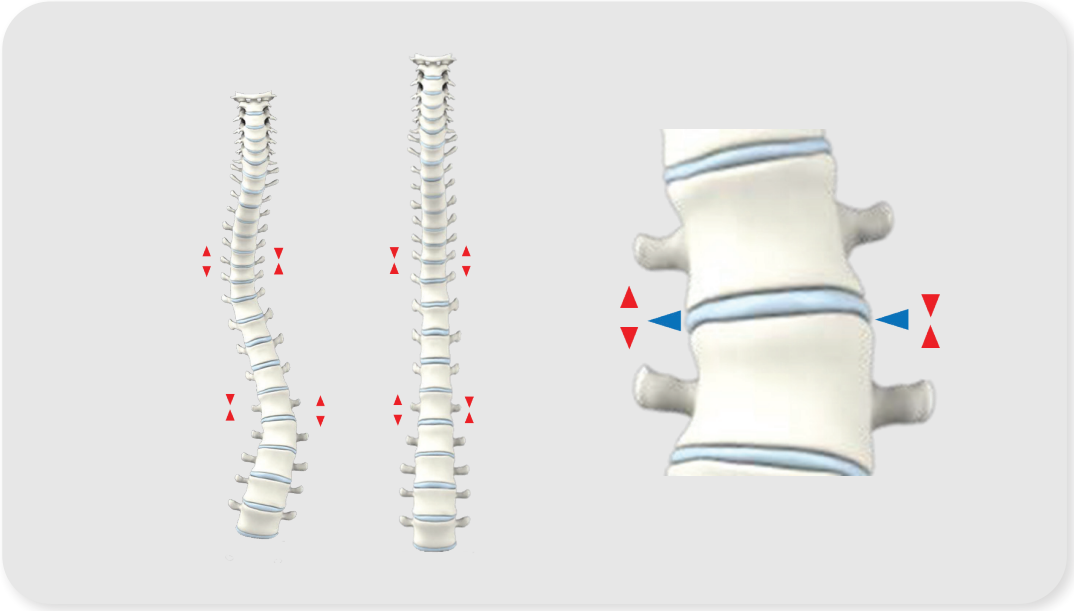
Initial Correction Results*		
Brace Type		
Milwaukee –	Carr et al.	55-60%
Boston –	Emans et al.	50%
Wilmington –	Basset et al.	50%
Miami –	McCollough et al.	50%
Charleston –	Price et al.	73%
Providence Brace –	d'Amato et al.	**98%**

* Spine Journal, September 15, 2001, Volume 26, Issue 18

This magnitude of correction creates a major advantage to obtaining highly successful results for bracing at night. The impact these rates have on the ultimate outcomes is due to the fact that the majority of growth occurs at night, during sleep. Studies have shown that the largest output of HGH (Human Growth Hormone) occurs shortly after entering deep sleep (Stage 3 sleep), typically peaking between 12am and 2am. Considering the rates of growth throughout the night, this is the most advantageous time to be leveling off the forces across the growth plates. According to Hueter-Volkmann, balancing these forces will allow for even growth. Additionally, when considering the starting asymmetry of the vertebra, hyper-correction of the curve may accelerate growth on the concave side beyond the rate of the convex side, reversing the course towards a more corrected state as opposed to just halting progression. Taking corrective action with nocturnal bracing may provide the best chance of having the greatest impact on patients with adolescent idiopathic scoliosis.

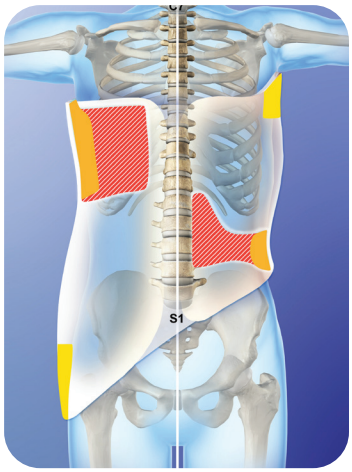


The output of HGH is greatest at night, presenting the most advantagious time for obtaining successful correction.

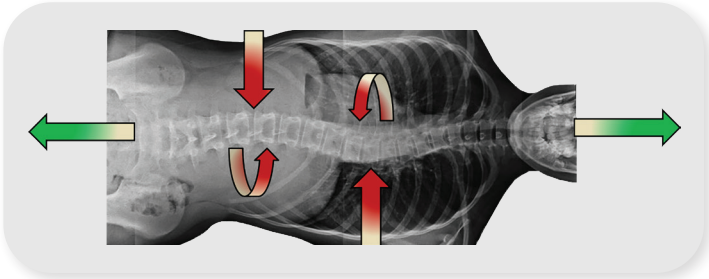


Heuter Volkman Law suggests that leveling the forces across the growth plates, will allow for symetrical growth.

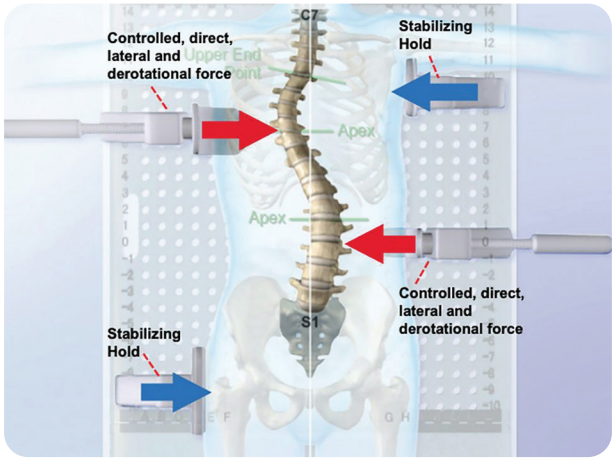
Hyper–Correction Forces and The Providence Nocturnal Scoliosis® Orthosis

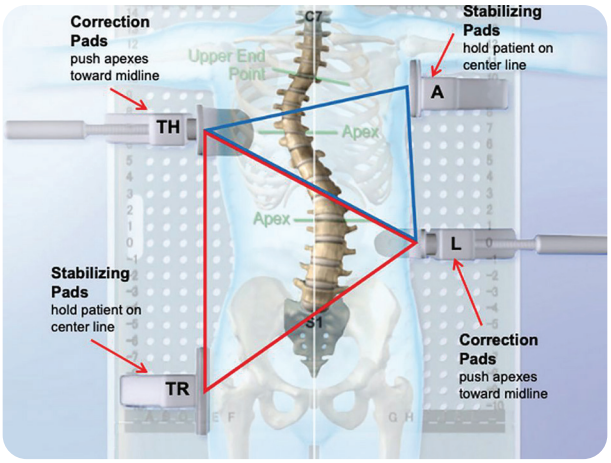


The Providence Nocturnal Scoliosis® System's objective is to move the apices of scoliotic curves to midline or beyond, through the application of controlled, direct, lateral and de-rotational forces to the spine. In contrast to daytime brace wear, bracing in the recumbent position eliminates the conflicting forces of gravity, allowing for natural elongation of the spine and horizontal rib alignment. This creates a wider space between the floating ribs and the iliac crest, providing greater access to the lumbar vertebrae, enabling effective lateral and de-rotational forces. When thoracic ribs are aligned horizontally, thoracic pads may be applied more precisely. Locating the correct apices to apply the appropriate push towards midline and appropriate de-rotational forces is vital to successful correction. The natural elongation of the spine helps provide access, control, and correction of higher thoracic curves.



Natural elongation of the spine in the recumbent position





The Providence® orthosis utilizes overlapping 3-point pressure systems with opposing voids and segmental de-rotation at selected points.

- The objective of the Providence® is to move the curve apices to mid-line, identified as a straight line between C7 and S1.
- Without the need to support under the forces of gravity, the most efficient application of force involves directly targeting the apex of the curve with a vector that is perpendicular to midline, while incorporating elements of de-rotation.
- Forces applied at the apex are countered by stabilizing pads, located at the upper and lower ends of the curve on the opposing side, allowing for effective and unobstructed migration.
- Single curves use a single 3 point system, while thoracic and double curves utilize an overlapping 3 point pressure system.

Patient Outcomes

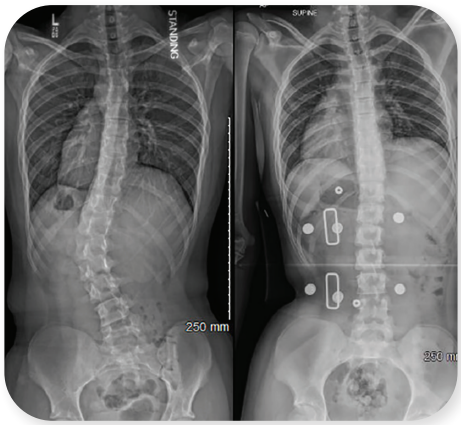
CLINICAL STUDY

Providence® nighttime bracing is effective in treatment for adolescent idiopathic scoliosis even in curves larger than 35°

124 patients

"Providence® nighttime braces are an effective treatment for adolescent idiopathic scoliosis patients. This study reports a success rate of 89%, and the results are comparable to full-time treatment with the Boston brace."

Ane Simony, et al., European Spine Journal, September 2019, Volume 28, Issue 9



Original In-Brace (Supine)

CLINICAL STUDY

Nighttime Bracing With the Providence Brace in Adolescent Girls With Idiopathic Scoliosis

102 patients

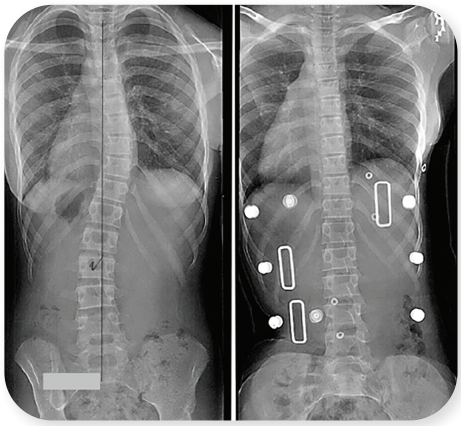
"Excellent initial in-brace correction of adolescent idiopathic scoliosis was observed with this computer-designed and manufactured recumbent brace."

"success rate of 79% (n 5 71) if the apex was at or below T9."

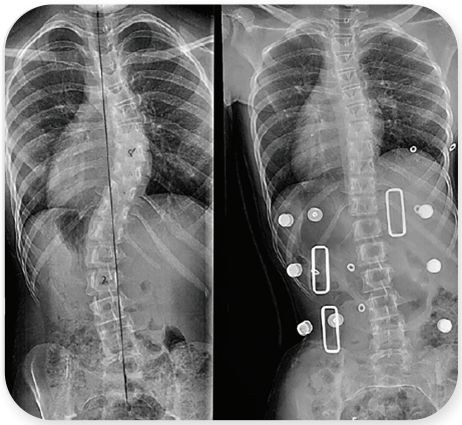
"The average initial correction with a supine in-brace radiograph of the all major and all compensatory was 96% and 98%, respectively."

"The average percentage of Cobb angle initial in-brace correction for each curve type while the patient was wearing the brace was 94% for thoracic curves, 111% for thoracolumbar curves, 103% for lumbar curves, and 90% and 91%, respectively, for both curves of a double curve pattern."

d'Amato et al., SPINE Volume 26, Number 18, pp 2006–2012 ©2001



Original In-Brace (Supine)



Original In-Brace (Supine)

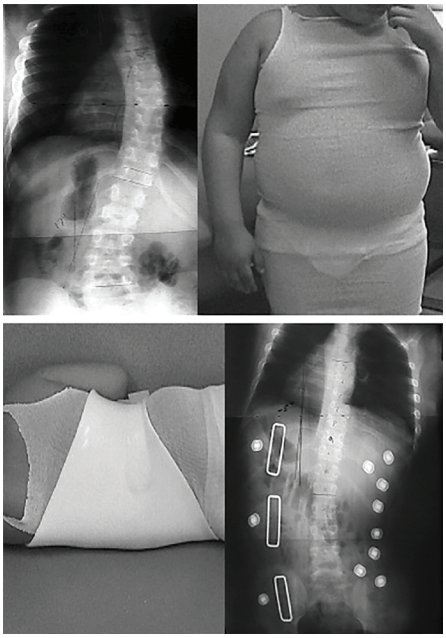
High BMI Body Types and Considerations for Brace Selection

One important consideration in determining which type of bracing is most suitable to maximizing positive outcomes is the patient's body type. The ability to achieve successful results becomes more challenging in children who may be overweight or maintain excess soft tissue. The difficulty is largely due to the reduced ability to transfer sufficient force to the spine to effectively shift and de-rotate the vertebrae appropriately *[See The Journal of Bone & Joint Surgery (May, 2005) - "Decreased Orthotic Effectiveness in Overweight Patients with Adolescent Idiopathic Scoliosis," O'Neill, Patrick J., MD1; Karol, Lori A., MD2, et al.]*. While patients with high BMI may experience some correction in a well-fitted symmetrical orthosis, it is important to consider various bracing methodologies when excess soft tissue is present.

Patients with high BMI present a challenge for obtaining acceptable correction in a full-time orthosis. The displacement of tissue drastically reduces the ability to achieve effective correction. The correction obtained is largely the result of hydraulic forces caused by the circumferential pressure of the orthosis. Circumferential forces will compress around the soft tissue and the abdominal cavity, creating a lifting effect, partially offloading the weight of the upper body. This helps to elongate the spine, aiding in correction. However, absent of sufficient applied forces, the results are often minimal. Additionally, excess tissue will have a tendency to fill into the voids and reliefs, limiting the amount of clearance for corrective shifts and de-rotations.

Excessive soft tissue inhibits our ability to locate and capture essential skeletal features. Any orthosis designed to be worn throughout the day must take into consideration active motion and positioning. An effective full-time brace will maintain a strong foundation around the pelvis, capturing the iliac crest, and locking the brace in the proper fitting location. This establishes control of the pelvis and limits brace migration.

Patients presenting with high BMI are strong candidates for nocturnal bracing. There are several advantages to treating these patients in the recumbent position with a hyper-corrective orthosis. See information on the Providence Nocturnal Scoliosis® Orthosis for more information.



Providence Nocturnal Scoliosis® Orthosis and Patients With High BMI

The Providence® orthosis is ideally suited for patients who present with bracing challenges due to excess soft tissue. In the recumbent position, the spine elongates and ribs align horizontally. This creates a wider space between the floating ribs and the iliac crest, facilitating greater access to the lumbar spine to apply effective forces. Moreover, these patients benefit significantly by avoiding the physical discomfort they typically endure with full-time brace wear, thus encouraging higher compliance rates.

Spinal Technology, LLC

Spinal Technology, LLC is the global leader in the design and fabrication of Spinal Orthoses, for the stabilization, immobilization, and the correction of various abnormalities of the spine. Specializing in the treatment of Aadolescent idiopathic scoliosis, we employ the latest technologies and methods for treating each and every patient. Medical experts around the world depend on our expertise for the assessment of patient curvature, the blueprinting of x-rays, the design of each orthosis, and the x-ray evaluation of patients in-brace. We continuously maintain expertise in a multitude of proven scoliosis bracing methodologies, and remain on the forefront of research and development. Our clinical team proudly supports the medical community with advanced educational courses and seminars, along with the dedicated teaching and resources we deliver to various colleges and universities.

As part of our commitment to world-class patient care, we deliver custom fabrication services and support to practitioners across the United States and around the world. With two facilities located in the United States – West Yarmouth, Massachusetts and Louisville, Kentucky – Spinal Technology® is positioned to provide practitioners with unparalleled service that includes delivery of our custom braces within 24 hours and, in some cases, the same day.

We provide 24-hour support, 365 days a year, for thousands of medical practitioners and their patients. Our team consists of American Board Certified Orthotists, highly skilled & experienced technicians, and dedicated Customer Service experts. Together we are focused on providing Physicians, Orthotists, and their patients with the most effective spinal orthoses, contributing to positive outcomes and enhancing quality of life.

Spinal Technology® is the exclusive manufacturer of the Providence Nocturnal Scoliosis® System, a nighttime s/b bracing system designed to prevent the progression of adolescent idiopathic scoliosis (AIS). In addition, Spinal Technology® fabricates a myriad of other custom-designed orthoses to meet each patient's specifications.

For more information visit Spinal.Tech/AIS

We're the Scoliosis Specialists™

Providence Nocturnal Scoliosis® Brace

Boston (Style) Scoliosis Brace

SCT 3D Boston (Style) Scoliosis Brace

SCT 3D Chêneau (Style) Scoliosis Brace

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