## Providence TLSO Effectiveness

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Clinical Question: For patients with adolescent idiopathic scoliosis, how effective are Providence TLSOs in reducing treatment failure compared to full time orthotic intervention with a Boston scoliosis TLSO?

**Background:** Patients with adolescent idiopathic scoliosis (AIS) present with spinal curvature and rotation (3D deformity) which can progress in severity as the patient grows. The efficacy of bracing patients with AIS has been debated for years but has recently been validated as a successful intervention.<sup>1</sup> The BRAIST study in 2013 indicated the significant orthotic treatment success compared to observation and has also set a gold standard in research regarding scoliosis interventions.<sup>1</sup> Success is defined as preventing progression of the curve magnitude (out of brace) of more than 5°, at preventing progression past 45°, or at reducing the frequency of recommendation or performance of surgical intervention.<sup>1-6</sup> The Providence TLSO is a nighttime orthosis that applies derotational and lateral forces that can fully correct, or overcorrect, the spinal curvature when the patient is wearing the orthosis.<sup>2</sup> The efficacy of the Providence TLSO is still being studied despite the growing prevalence of use in the orthotic field.<sup>3</sup>

## Search Strategy:

Databases Searched: PubMed, Science direct, CINAHL, Google Scholar

Search Terms: PubMed - "idiopathic scoliosis bracing effectiveness"; Science direct - "adolescent idiopathic scoliosis providence", in The Spine Journal; CINAHL -

"Effectiveness of Providence Scoliosis", Google Scholar -- "boston vs providence scoliosis"

Inclusion/Exclusion Criteria: Pubmed 2017-2021, free full text, English; Others 2015-2021; Also used references of articles found by primary search; Included suggested articles from review committee

**Synthesis of Results**: This review focused on the efficacy of Providence TLSO intervention for patients with AIS opposed to traditional, Boston TLSO intervention. Treatment success was defined as avoiding the following: curve magnitude (out of brace) progression of more than 5°, curve magnitude progression past 45°, or need of surgical intervention. Unfortunately, the quantity of literature comparing Providence and Boston TLSO treatment success was limited.<sup>4</sup> Two articles were identified directly comparing the Providence and Boston TLSOs.<sup>6,7</sup> Both Yrjonen and Ohrt-Nissen showed that there was no statistical difference in the success of the Providence when comparing to the Boston TLSO. When further reviewing the literature for any full time TLSO treatment versus nighttime Providence TLSO intervention or Providence TLSO intervention as more successful than the other in treating AIS.<sup>8</sup> Janicki stated that there was a statistically significant difference in the subgroup of individuals with curves between 25°-35°; Providence TLSO intervention.<sup>5</sup> When reviewing the literature for information simply determining success rates of the Providence TLSO, three articles were evaluated.<sup>2,3,9</sup> Bohl and Simony suggested that the Providence TLSO provided similar or better results than the natural history<sup>3</sup> or utilizing a full time TLSO<sup>9</sup>. Simony had significantly higher success rates in limiting progression more than 5° (88.7%) when compared to Bohl (50%) and Davis (51.78%).<sup>2,3,9</sup> Bohl suggested that 74% of the patients avoided progressing past 45° or being indicated for the need of surgery whereas Davis found 57.1% success in this measure and Simony reported only 6% of patients progressed to surgical intervention in their study.

Although the evidence is rudimentary considering the sample sizes along with the limited research available<sup>4</sup>, the effectiveness of a Providence TLSO in preventing progression past 45° (or indication for surgical intervention) for the average individual with AIS seems to range from 55%-74%. The evidence that directly compares the Providence with full time bracing was limited as well as dated.<sup>5,6</sup> There were conflicting results regarding the progression of more than 5° between a Providence TLSO and fulltime TLSOs, however, the Providence was overall more effective in preventing progression past 45°. It appears that a Providence TLSO is more effective at preventing progression past 45° than preventing more than 5° of progression.<sup>2,3,5</sup> It was also difficult to directly compare studies as the type of full time bracing was not specified.<sup>1,6</sup> The retrospective nature of several studies limited the researchers' control over the instructions presented, the compliance monitoring, and the details of the fabrication of the orthosis.

As the literature directly comparing Providence TLSO and Boston TLSO treatment success was limited, conclusions of this review focused on the Providence intervention success as defined consistently across these studies. The effectiveness of the Providence TLSO can be impacted by many factors (eg location of curve apex, initial curve magnitude, and initial stage of skeletal maturity (Risser sign)). It is suggested that the outcomes will improve with curve apices in the lower spine (T10/T12 and caudal).<sup>2,6</sup> Curve magnitudes that

were higher initially had a higher chance of progression.<sup>7,9</sup> When considering Weinstein's<sup>1</sup> conclusion that higher compliance indicates greater success in orthotic intervention, along with potential psychosocial impacts of using a full time TLSO, the Providence TLSO appears to be a satisfactory intervention in limiting the progression of AIS.<sup>2,3</sup>

**Clinical Message:** The level of effectiveness of a Providence TLSO in treatment of AIS compared to full time orthotic intervention (such as a Boston TLSO) is difficult to determine with certainty. The available evidence is limited in quantity and is mostly existent in retrospective studies which presents limitations in research quality. Providence TLSOs appear to be most effective for curves with initial Cobb angle out of brace under 30-35° and for patients with an initial Risser sign of 1 or 2. Compliance is important for any orthotic intervention and the Providence may allow for better compliance as the psychosocial impacts of utilizing orthoses during the day are eliminated. The Providence has largely been determined to be as effective or more effective than traditional, fulltime TLSO treatment.

## **References:**

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- 4. Karavidas N. Bracing in the treatment of adolescent idiopathic scoliosis: evidence to date. Adolescent Health, Medicine and Therapeutics. 2019; 10:153-172
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Evidence Table										
	Weinstein, 2013 <sup>1</sup>	Bohl, 2014	Davis, 2018	Karavidas, 2019	Janicki, 2007	Yrjonen, 2006	Ohrt-Nissen, 2019	Ruffilli, 2020	Simony, 2019	
Population	242 patients, 116 randomized and 126 preferential High risk AIS, 10-15 years old, Risser 0-2, Cobb angle out of brace 20°-40°, no previous treatment	34 patients, Providence TLSO Initial age 10 or older, initial Risser between stage 0 and 2, initial Cobb angle out of brace between 25° and 40°, no prior treatment, no secondary diagnosis, and if female, initially premenarchal or less than 1 year post-menarche. With two year follow up post bracing	56 patients treated with Providence TLSO with AIS Age 10-18 years, curve btwn 25° and 40° out of brace, Risser btwn 0-2, if female, less than 1 yr post- menarche at brace initiation	Articles until Aug 2019 that were written in English and were indicated with the following search terms: "brace", "adolescent idiopathic scoliosis", "orthosis", "scoliosis", "non- operative treatment"	83 patients, initial age 10yrs or older, initial curve 25°- 40°, Risser 0-2, if female less than one year post menarche, no previous treatment	36 patients for Providence with no previous treatment, follow up with minimum 1 year after discontinuation Control group: Boston brace, 36 patients, matched to Providence Inclusion criteria: Apex T 10 or below	40 patients for Providence, 37 patients for Boston, with no previous bracing, Risser less than or equal to 2, major curve between 25° and 40° out of brace with apex between T7 and T11	7 studies comparing full time TLSO usage to nighttime TLSO (Charleston or Providence) usage	124 patients with AIS with Cobb angle greater than 20° out of brace, 80 finished treatment in this timeframe and were evaluated for follow up to brace treatment (Providence nighttime brace)	
Study Design	Prospective multi-site randomized and preference study	Retrospective cohort review	Retrospective review	Literature Review	Retrospective cohort review	Prospective for Providence group with retrospective comparison to control Boston group	Retrospective longitudinal dual center study, 2 parallel study groups 1. Full time Boson (18hr/day min) 2. Providence (8 hr/day min)	Literature Review	Prospective to classify Providence effectiveness	
Intervention	TLSO to be worn 18 hrs/day	Wear Providence orthosis minimum 8 hrs when sleeping at	Providence TLSO prescribed to weartime of 8- 10 hrs at night	N/A	Providence TLSO or regular TLSO	Providence TLSO	Providence TLSO or Boston TLSO	N/A	Providence TLSO	

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		night until skeletal maturity							
Comparison	No orthotic intervention vs TLSO for 18 hrs/day	N/A	Xrays/clinical info compared btwn success and failure groups	Evidence for bracing Predictive factors for success Brace weaning Brace and PT exercises Adult bracing Brace types	Providence vs regular TLSO	Providence TLSO vs Boston TLSO	Providence TLSO vs Boston TLSO	Effectiveness of nighttime TLSO (Either Charleston or Providence depending on paper) vs full time TLSO	Effectivenes s compared across groups of participant based on curve magnitude
Methodology	Wear time tracked with temperature logger but intent to treat (compliance did not disqualify pts from data analysis) X-rays every 6 months QOL and adverse events	Retrospective study based on Scoliosis Research Society (SRS) criteria for standardization of bracing studies; data analyzed using Pearson's chi- square test	Retrospective study based on SRS criteria Following X- rays reviewed: initial, in brace, final follow up (Cobb angle, type and Risser sign); data analyzed with descriptive statistics (Paired t-tests for curve deg and in brace correction), chi-square for categorical (gender, riser sign, location of curve)	Searched databases with inclusion terms listed in "population" Separated results based on "comparison" lists Analyzed and synthesized results based on categories	Identified patients who met inclusion criteria and evaluated success of treatment for all with "intent to treat" (regardless of compliance)	Providence group: Fit with orthosis, x-rays every 6 months to track progression, told to wear orthosis 8 hours a night Boston group matched according to age, skeletal age, Risser sign, apex of curve, and curve magnitude	Retrospective study comparing two groups of patients at two different facilities	Searched data bases, Reviewed abstracts/titles to identify relevant literature Assessed quality of literature Reported summary of findings	Patients diagnosed with AIS and the following criteria: older than 10 yrs old at diagnosis, less than 12 mo post- menarche, Cobb between 20°-42°, no previous scoli treatment, initial in brace curve correction greater than 60%, follow up xrays at least 12 mo

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Outcomes	Cobb Angle out of brace Progression to less than 50° out of brace (threshold for surgery)	Cobb Angle out of brace Primary: progression of more than 5° of Cobb angle at skeletal maturity out of brace Secondary: progression to more than 45° at	Cobb Angle out of brace Progression of more than 5° out of brace Progression to greater than 45° out of brace or surgery	N/A	Cobb Angle out of brace Progression of more than 5° out of brace Progression to more than 45° out of brace Progression to sx	Cobb Angle out of brace Treatment failed if progression more than 5° out of brace occurred or if sx was performed	Primary: main curve progression to more than 45° at follow up out of brace Secondary: progression of main thoracic or thoracolumbar or proximal thoracic curve more than	Varied outcomes reported in each paper All concerning preventing curve progression out of brace	after end of treatment Providence made if recommende d, curve correction in brace measured, compliance tracked subjectively Progression of 5° or more during or after treatment, out of brace Progression to surgery? In brace correction measured
Key Findings	Brace efficacy was so high that it was determined unethical to continue with just observation group, terminated study early Higher compliance	skeletal maturity out of brace, recommendation +/or performance of fusion 50% success in preventing progression of more than 5° out of brace 74% success to prevent progression to more than than 45 out of brace ° or surgery Noncompliance not associated	51.78% success in preventing progression of more than 5° out of brace 57.1% success prevent progression to more than 45° out of brace or surgery	Evidence for bracing: Rigid more effective than soft, BRAIST study indicated treatment success, not effective for curves over 40° out of brace Predictive factors for success: High in brace correction increased success,	Providence better for avoiding sx, statistically significant in curves 25°-35° out of brace For curves 25°-40° out of brace initially: 15% success in preventing progression of more than 5° out of	73% success in preventing curve progression more than 5° out of brace for Providence and 78% success in Boston One patient progressed to sx for Providence and no patients	Main curve did not progress to more than 45° out of brace in 65% of Boston and 57% of Providence 38% success in preventing curve progression more than 5° out of brace for Boston	Current research does not show definite evidence for recommending nighttime TLSOs or traditional TLSOs as the "gold standard" for orthotic scoliosis intervention	using Cobb Angle Mean in brace correction was 83%, better for lower magnitude curves 88.7% successful in preventing progression

	Weinstein, 2013 <sup>1</sup>	Bohl, 2014	Davis, 2018	Karavidas, 2019	Janicki, 2007	Yrjonen, 2006	Ohrt-Nissen, 2019	Ruffilli, 2020	Simony, 2019
	resulted in more successful outcomes Randomized bracing success was 72% and 48% with observation	with primary, was associated with secondary (56% vs 20%) "suggest a rate of progression similar to or lower than reported natural history" Should consider psychosocial effects	Increases compliance bc does not impact QOL due to psychosocial impacts Better prognosis if apex below T10 or Risser greater than or equal to 1	good compliance increases success, Risser unconclusive result, high BMI can lower success Brace types: Rigid is better than elastic, No conclusive evidence for nighttime vs daytime one piece was as follows "Providence more effective for curves below 35° out of brace but overall high failure rate, compared to other studies, could raise doubts about the quality of brace designs in this study" <sup>5</sup> Brace Weaning: should be based on not only Risser and should be done in combination with exercises to reduce progression Concluded that for high risk curves, rigid, daytime orthoses are needed	brace for TLSO and 31% for Providence 44% success in preventing progression to more than 45° out of brace for TLSO and 55% for Providence 21% success in preventing progression to sx for TLSO and 40% for Providence For curves 25°-35° initially, out of brace: 15% success in preventing progression of more than 5° out of brace for TLSO and 42% for Providence 48% success in preventing progression to more than 45° out of brace for TLSO and 71% for Providence 24% success in preventing progression to sx for TLSO and 54% for Providence	progressed to sx in Boston Providence can alter natural hx for curves under 35° out of brace and with apex T12 and under No statistical difference for this subset of patients	and 45% success in Providence Initial age not significant factor of risk of progression No statistically/clinic ally significant differences Main predictor was initial curve size (median initial curve size for Providence group was larger)		past 5° out of brace 5 patients progressed to surgery (1 for cosmetic reasons) Progression and need for surgery was higher in curves larger than 40° out of brace initially Outcomes similar to Boston TLSO/other full time TLSOs
Study Limitations	Did not control for brace design	Retrospective, no control/comparis on group, no randomizations Small sample	Retrospective, compliance not tracked	Literature Review, reviewed broad array but did not provide conclusive results, more overview of previous studies	What kind of normal TLSO? Boston?	No data tables Small sample	Compliance not tracked Initial curves not same in Boston vs Providence	Difficult to compare studies as there were different outcomes and different curve types as well as	Compliance tracked subjectively No control cohort

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			than clearly applicable results Did identify lack of high level of evidence in this area of field				different TLSO designs (Charleston vs Providence) Compliance not tracked	Risser grade not determined before treatment