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Effects of adherence to bracing treatment in children with adolescent idiopathic scoliosis: a preliminary study

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Thesis

EFFECTS OF ADHERENCE TO BRACING TREATMENT IN CHILDREN WITH ADOLESCENT IDIOPATHIC SCOLIOSIS:

A PRELIMINARY STUDY

by

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B.A., University of San Diego, 2011

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Master of Science

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EFFECTS OF ADHERENCE TO BRACING TREATMENT IN CHILDREN WITH ADOLESCENT IDIOPATHIC SCOLIOSIS: A PRELIMINARY STUDY

ABRAHAM ICHINOE

ABSTRACT

Objective: The objective of this study is to determine the different biological, psychological, and social factors that affect patient adherence in bracing treatment for adolescent idiopathic scoliosis. By comparing adherent and non-adherent bracing patients, we hope to gain insight into how to improve patient adherence in bracing as a means of primary treatment and to avoid secondary and tertiary treatments such as surgery.

Methods: Of the 19 patients (15 adherent, 4 non-adherent) who were examined for this study, the majority of them completed all psychosocial surveys at one time point in their bracing treatment. Patients answered surveys for multidimensional anxiety, generalized anxiety, pain-related fear and avoidance, pain catastrophizing, and quality of life. Quantitative sensory testing was performed on only 5 of the 19 patients at the time of writing. Sensory testing was conducted to gather information on thermal sensitivities and thresholds. Statistical t-test significance was determined for all surveys distributed to adherent and non-adherent bracing groups, and scaled T-scores were calculated for each survey measure to determine clinical significance.

Results: There were no statistically significant differences in any measures examined between adherent and non-adherent bracing patients. The only statistically significant difference was the number of hours of brace wearing, with the adherent group wearing their brace over 11 hours more than the non-adherent group (p < 0.0004).

Conclusions: Because of the underpowered nature of this study, measures for multidimensional anxiety, generalized anxiety, pain-related fear and avoidance, pain catastrophizing, and quality of life should be reexamined for potential differences between adherent and non-adherent bracing patients. Quantitative sensory testing should be included as a measure of possible sensory differences between the two groups. A future study with a larger sample size may provide greater understanding into the motivations for bracing adherence in an effort to help patients avoid more invasive means of intervention in treating adolescent idiopathic scoliosis.

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LIST OF ABBREVIATIONS

AIS	Adolescent Idiopathic Scoliosis
FOPQ	Fear of Pain Questionnaire
IBM	International Business Machine
IRB	Institutional Review Board
MASC	Multidimensional Anxiety Scale for Children
PCS	Pain Catastrophizing Scale
PedQL	Pediatric Quality of Life
РРР	Persistent Postoperative Pain
QST	Quantitative Sensory Testing
REDCap	Research Electronic Data Capture
SPSS	Statistical Package for the Social Sciences
TLSO	Thoraco-Lumbo-Sacral Orthosis
USPSTF	United States Preventive Service Task Force

INTRODUCTION

Adolescent Idiopathic Scoliosis

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal development disease of unknown pathology. Currently, there is ongoing research into identifying a potential genetic cause for AIS, but there is no definitive basis (Miller, 2011; Sharma et al., 2011; Wise et al., 2008). The lack of knowledge in the origin of the disease, however, does not leave children who have AIS without any means of accurately assessing risk or managing the rate of curve progression. The disease is diagnosed in 2%-4% of adolescent children between the ages of 10 and 18 years, making it the most common type of scoliosis diagnosis in the age range (Horne et al., 2014; Scoliosis Research Society, 2015).

Scoliosis itself is considered to be a lateral curve greater than 10 degrees with vertebral column rotation. Both males and females have the same probability of developing AIS when curve angles are about 10°, but the ratio increases to 5:1, female to male, when angles are greater than 20° (Roach, 1999). Aside from the cosmetic dissatisfaction of the child, there are usually no associated clinical symptoms with AIS other than spinal curvature. Some symptoms that have been associated with AIS are mild lower back pain and shortness of breath, which are symptoms typically found in other types of scoliosis. In addition, if curve progression persists to extreme angles (greater than 50°), some normal functionality of vital organs, such as the heart or the lungs, is affected, visible deformity is observed, and emotional distress can develop (Bunnell,

1984; Glassman et al., 2010; Horne et al., 2014; Reamy and Slakey, 2001; Roach, 1999; Weiss, 2008).

Screenings

In 2004 the United States Preventive Service Task Force (USPSTF) issued a recommendation on the efficacy of school-administered scoliosis screenings. The recommendation concluded that asymptomatic children with idiopathic scoliosis neither benefited nor suffered from scoliosis screenings specifically related to the detection of the disease. The study stated that the benefits seen in treated children with idiopathic scoliosis were of marginal value in regard to reducing back pain or disability. If a child's curve progressed to a point which required surgical intervention, the study concluded that an assessment could be made without prior screening. Finally, the USPSTF believed that children who were positively screened for idiopathic scoliosis were often subjected to unnecessary brace wearing and clinical visits. The conclusion was based on a three-year study that followed 30,000 students between the ages of 10 and 14 years for three years with annual scoliosis screenings and biennial health checkups and found that none of the students required surgical intervention for idiopathic scoliosis (Horne et al., 2014).

Scoliometer Readings

Children are screened mainly in their school but also in their primary care physician's clinic. The Adam's forward bend test is one means of determining whether a child has or is at risk for developing scoliosis. The test consists of the child taking off his or her shirt, bending forward only at the waist, and coming into the horizontal plane with arms dangling loosely. The examiner will primarily look for asymmetry in the spine, specifically for spinal rotation or a rib hump viewed from behind and the side of the child. If a rib hump is discovered, the examiner uses an inclinometer, also known as a scoliometer, to assess the degree to which the vertebral column is rotated. Generally, if a child has a scoliometer reading of greater than 5°, it identifies curvatures of 20° or more and indicates that further radiological workup is advisable (Bunnell, 1984). In order to make an official diagnosis of scoliosis, a Cobb angle must be subsequently measured by radiography.

Cobb Angles

Cobb angles are obtained by taking an X-ray in the anterior to posterior plane that consists of the entire spine while the child is standing. A study has suggested that taking the X-ray from the posterior side of the child will help minimize radiation exposure to the breasts (Greiner, 2002). It is also recommended that physicians view the radiograph in the same orientation as viewing their patient from the posterior, the opposite of how a traditional chest X-ray is viewed (Greiner, 2002). The standard error in Cobb angle measurements from the same end vertebrae is 3° to 5° for one observer and 5° to 7° from one observer to another (Morrissy et al., 1990; Pruijs et al., 1994). Therefore, it is important for physicians to be consistent in measuring from the same end vertebrae when determining Cobb angles for their patients, especially since error could be mistaken for curve progression (Greiner, 2002). In addition, because the Cobb angle is used as one criterion in determining whether a child qualifies for surgical treatment, a mistake in its measurement could lead to an incorrect recommendation of surgery after considering other qualifying criteria.

The naming of the curve starts with the location of the apex vertebrae, which can be classified into 5 regions: thoracic, lumbar, thoracolumbar, cervical, or double major (two curves in different areas of the spine) (see Figure 1). Thoracolumbar curves have an



Figure 1. Types of spinal curves in scoliosis. Figure taken from <u>www.rad.washington.edu</u> (University of Washington Radiology Department, Seattle, WA)

apex vertebrae affected at the level of T12 or L1. Double major curves can be further classified into a major and minor curve, along with a primary and secondary curve. All curves can be either structural or nonstructural as determined by having the child bend to correct the curve. If the curve of the spine corrects upon bending, then it is considered to be nonstructural. However, if the curve of the spine persists upon attempting to correct, then it is considered to be structural (see Figure 2). The classification of a structural or nonstructural curve requires additional radiographic imaging.



Figure 2. Effect of curve correction on nonstructural and structural curves. Figure taken from www.rad.washington.edu (University of Washington Radiology Department, Seattle, WA)

Finally, the Cobb angle is measured by drawing a horizontal line from the top of the apex vertebrae that extends up and out. A second horizontal line is drawn from the bottom vertebrae which extends down and out. Perpendicular lines are then drawn from the two previously drawn lines, and the degree of curvature can be measured from the angle of intersection of the two perpendicular lines (see Figure 3).

By obtaining a Cobb angle, a physician can reasonably track a child's curve progression with repeated checkups every 3 to 4 months. Curve progression can also be anticipated by taking into consideration other major factors such as sex, degree of curve on presentation, and potential growth (Lonstein and Carlson, 1984; Reamy and Slakey, 2001; Tan et al., 2009). A study performed by Tan et al. (2009) examined 186 patients with idiopathic scoliosis to determine the magnitude of different factors that influence curve progression. The study concluded that the initial Cobb angle was the single most important predictor of long-term curve progression and behavior past skeletal maturity. The study also concluded that initial age, gender, and pubertal status were less important prognostic factors.



Figure 3. Definition of Cobb angle for curve progression. Figure taken from <u>www.rad.washington.edu</u> (University of Washington Radiology Department, Seattle, WA)

Risser Staging System

While a Cobb angle is useful in determining curve progression in a child, a Risser grade is useful in assessing growth potential. Risser grades are divided into 6 stages, 0 to 5, with each stage signifying the degree to which ossification and fusion of the iliac apophysis have taken place. A higher Risser stage indicates that the child is reaching skeletal maturity, whereas a lower Risser stage signifies the potential for more growth and, in the case of a child with AIS, potentially more curve progression. Currently, there are some discrepancies between the United States and French Risser staging systems, particularly in the Risser stages of 2 to 4 (Hacquebord and Leopold, 2012). The major difference between the two systems comes from whether the apophysis is divided into quarters or thirds, the former used by the United States and the latter by the French (see Figure 4). The Risser staging system has been used since 1958 and is one of the few

radiographic signs validated through clinical investigation. Studies performed by Goldberg et al. (1988), Reem et al. (2009), Sanders et al. (2007), and others have confirmed the utility of the Risser staging system and showed that there is acceptable interobserver reliability and accuracy in determining skeletal maturity and anticipating growth potential (Hacquebord and Leopold, 2012). By considering both the Cobb angle and the Risser grade, physicians are able to anticipate the likelihood of curve progression and in turn make a decision in regard to referral and treatment.



Figure 4. Risser staging system for assessment of skeletal maturity. Figure taken from Hacquebord et al. (2012).

Treatments

There are three treatment options for a child diagnosed with AIS. If the child's initial curve at presentation is less than 10° to 15°, then there is no required active treatment, and simple observation by radiography is acceptable (Greiner, 2002). For

moderate curves between 25° and 45°, bracing has been the primary treatment; however, the effectiveness of bracing has come into question because of poor patient compliance with wearing a brace (Greiner, 2002). In a study to determine bracing efficacy, it was noted that 48% of untreated patients had stable Cobb angles without bracing, while 41% of treated patients had stable Cobb angles even though they admitted to spending minimal time in their braces (Carragee and Lehman, 2013). The length of time each child spends in a brace is determined by the type of brace which is prescribed as well as the severity of the curve, but wear time is generally between 8 and 24 hours (Weinstein et al., 2013).

The third treatment option is reserved for more severe curves, which are considered to be greater than 45°. For children with a Cobb angle of 45° or greater, surgical intervention is highly considered. The specific type of procedure that children with AIS undergo is either a posterior or anterior spinal fusion with instrumentation depending on the location of the curve. Posterior fusion with instrumentation is the more common of the two procedures since it allows for the surgeon to place more anchors into the spine, which results in less frequent implant failure (Maruyama and Takeshita, 2008). Anterior fusion with instrumentation is preferred in some cases when the curve is located in the thoracolumbar or lumbar regions of the spine because of the ability to obtain sufficient correction with fewer fused levels; however, this procedure has recently declined in usage (Maruyama and Takeshita, 2008).

Aside from the common complications associated with any type of surgery involving anesthesia, some factors that should be examined by patients considering spinal

fusion are the experience of the surgeon performing the procedure and the potential to develop chronic pain. Studies have shown that more experienced surgeons, particularly ones who perform spinal fusions frequently, produce more favorable outcomes in regard to postoperative pain and self-image (Cahill et al., 2014). Chronic pain that persists beyond the 6-month postoperative recovery period is often referred to as a condition called persistent postoperative pain (PPP), which can influence the quality of life for a child going through his or her developmental adolescent and teenage years. The aim of our study is to determine how children can avoid this third option by becoming more adherent to their bracing protocol. The following description provides a more in-depth view into the various aspects of a child undergoing bracing treatment.

Bracing in Particular

When a child is determined to be a good candidate for bracing treatment, there are a number of brace types that can be prescribed. The purpose of having the different types of braces is to allow for the physician to choose a style that will best target the specific curve of the child. For example, a child who is being treated for scoliosis in the thoracic region of the spine will have a different brace from a child with scoliosis in the lumbar region of the spine.

One of the first modern-era braces developed was in 1946 by Walter Blount, called the Milwaukee brace. His brace was designed to be a removable cervico-thoracolumbo-sacral brace, which would immobilize the entire length of a child's spine. Blount originally developed the brace for children who had undergone spinal surgery for neuromuscular scoliosis as a result of polio (Fayssoux et al., 2010). Currently, the Milwaukee brace is primarily used in the treatment of thoracic and double curves (Lonstein and Winter, 1994; Schiller et al., 2010). The brace consists of a molded pelvic girdle with three metal uprights connecting to a throat pad. The entire construct is fairly bulky, making it difficult for children to hide under their clothes and unacceptable in appearance to teenagers (Fayssoux et al., 2010). The brace is intended for full-time wear with an exception during physical activity like sports (Schiller et al., 2010). Although the original brace was commonly prescribed, the development of lighter weight, lower profile braces has resulted in the Milwaukee brace not being prescribed as often anymore (Fayssoux et al., 2010; Schiller et al., 2010).

The Wilmington brace was developed in 1969 after G. Dean MacEwen had an adolescent patient who refused to use the Milwaukee brace. The young girl would only adhere to a bracing treatment that utilized a brace that was both inconspicuous and removable (Fayssoux et al., 2010; Howard et al., 1998; Schiller et al., 2010). Unlike the Milwaukee brace, the Wilmington brace spans only the thoraco-lumbo-sacral regions of the spine. The brace is essentially a custom-molded cast with an opening in front that is semi-rigid because it is composed of a mixture of plastics (Schiller et al., 2010). The entire construct is held closed by an adjustable Velcro strap, which allows it to be removed during physical activity, and is often prescribed to be worn for near full time (Schiller et al., 2010). Currently, the Wilmington brace is one of the most popular types of braces that are being prescribed for AIS patients (Fayssoux et al., 2010).

In 1972, the Boston brace was developed at Boston Children's Hospital by John Hall and William Miller as a low-profile thoraco-lumbo-sacral orthosis (TLSO). The major difference between the Boston brace and the Wilmington brace is that the Boston brace is made from a prefabricated set of molds custom-fitted to the patient. The major advantage of the Boston brace is that it reduced the necessary time required to create a mold from the patient's body. The brace can be prescribed as a treatment for all types of scoliosis and is intended for full-time use (Schiller et al., 2010).

The Dynamic Spine-Cor brace was developed between 1992 and 1993 (Schiller et al., 2010). This brace relies on a program called Spine-Cor Assistant software which provides the guidelines for corrective movements (Schiller et al., 2010). The theory behind the brace is the idea that scoliosis is related to "postural disorganization, muscular dysfunction, and unsynchronized spinal growth that can lead to spinal deformation" (Coillard et al., 2003; Fayssoux et al., 2010). Unlike previous braces which utilized semi-rigid to rigid materials, the Spine-Cor consists of a pelvic base that has multiple corrective elastic bands going around the patient to create tension forces for correction. In addition, the brace is only recommended for use in treating curves that are smaller than 15° (Fayssoux et al., 2010). Similar to other braces, the Spine-Cor is intended for full-time wear (Fayssoux et al., 2010).

The Charleston brace was developed with the intention of placing the patient in an over-corrected position in order to treat scoliosis (Fayssoux et al., 2010; Howard et al., 1998; Schiller et al., 2010). The brace was created in 1979 by Frederick Reed and Ralph Hooper in Charleston, SC. Since the brace places the patient in an over-corrected

position, it produces greater reduction force and consequently results in reduced wearing time, which is preferentially done at nighttime (Fayssoux et al., 2010; Federico and Renshaw, 1990). The nighttime wearing regimen has seen improved adherence as well as lower psychological stress (Federico and Renshaw, 1990). Through a study conducted by Climent and Sanchez (1999) investigating the effects of different types of braces, it was discovered that nighttime bracing, particularly with the Charleston brace, had the least impact on the quality of life in adolescents with AIS.

Another nighttime brace was developed in 1992 by Charles d'Amato and Barry McCoy at the Children's Hospital of Rhode Island (Providence, RI). Unlike the Charleston brace which relies on the concept of over-correction, the Providence brace focuses on translational and rotational forces to bring the apices of the curve to midline (d'Amato et al., 2001; Fayssoux et al., 2010; Schiller et al., 2010). Initially, d'Amato et al. (2001) developed the brace to determine supine spinal flexibility for preoperative radiographic planning and coincidentally discovered its corrective applicability due to the direct forces applied to the patient's spine. The Providence brace can be prescribed for the treatment of single and double curves and is designed and manufactured by using a computer-assisted program (d'Amato et al., 2001; Fayssoux et al., 2010; Schiller et al., 2010).

Bracing Efficacy and Adherence

The success of bracing in treating scoliosis is variable among studies. A common criterion used in determining the success of bracing treatment is whether a brace is able

to keep curve progression under 5° before skeletal maturity (Shaughnessy, 2007). Less frequently, investigators have considered a failure in bracing treatment to be a curve that progresses beyond 10° or an overall curve that exceeds 45° (Richards et al., 2005).

There are a number of studies that have proven the efficacy of bracing treatment in terms of achieving the aforementioned parameters as well as avoiding surgical intervention. In all studies considered, the end goal of bracing treatment for scoliosis was to prevent the curve from progressing, stabilize the curve, and avoid surgery (Schiller et al., 2010). In a study conducted by Lonstein and Carlson (1984), 727 patients were retrospectively analyzed for curve progression without any form of intervention. They discovered that of the 727 patients, approximately 23% displayed curve progression with correlations to the magnitude and pattern of the curve, patient's age at presentation, Risser sign, and menarchal status if female (Lonstein and Carlson, 1984). In a later study conducted by Lonstein and Winter (1994), 1020 patients who received bracing treatment with the Milwaukee brace as their sole intervention were examined. Of the 1020 patients, 22% eventually required surgical intervention, and the rate of surgical intervention was greater in patients who had curves greater than 30° and a Risser sign of 0 or 1 at the time of bracing (Lonstein and Winter, 1994). The study concluded that in patients with curves greater than 25° and a Risser sign of 0, a bracing protocol should begin immediately even if curve progression is not documented (Lonstein and Winter, 1994).

Other studies have investigated the efficacy of specific types of braces as well as comparisons between them. Bassett et al. (1986) examined 79 patients with curves ranging from 20° to 39° and a Risser sign of 0 or 1 who were treated with the

Wilmington brace. In most cases, a curve reduction of approximately 50% was observed; however, some of the initial reduction was lost during and after the bracing treatment. Of the 79 patients, only 11% eventually required surgical intervention, and it was concluded that the Wilmington brace was appropriate in treating patients with curves between 20° and 39° (Bassett et al., 1986).

In a comparison study between the Boston brace and the Charleston brace conducted by Katz et al. (1997), the Boston brace was shown to be more effective in preventing curve progression and avoiding surgical intervention. The study investigated 319 patients with AIS, of which 153 patients were undergoing treatment in a Boston brace and 166 patients were in a Charleston brace. The Boston brace cohort had 24 patients needing surgical intervention compared with 46 patients in the Charleston brace cohort. The study recommended that the Boston brace was preferable in treating single thoracic curves between 36° and 45°. The Charleston brace was more suitable for smaller single thoracolumbar and single lumbar curves where the efficacy was comparable with the Boston brace (Katz et al., 1997).

The efficacy of Spine-Cor was investigated in a study conducted by Coillard et al. (2012) for small, moderate, and large curves defined as 15°-30°, 30°-40°, and 40°-50°, respectively. The study examined 657 patients, of which 378 had small curves, 207 had moderate curves, and 72 had large curves. Coillard et al. (2012) determined that Spine-Cor was successful in stabilizing or correcting a patient's curves in approximately 81% of small curves, 63% of moderate curves, and 46% of large curves. In an older study conducted by Coillard et al. (2007), 493 patients were treated with the Spine-Cor brace,

and outcomes were assessed according to standardized criteria set by the Scoliosis Research Society Committee on Bracing and Nonoperative Management. Of the 493 patients being treated, 249 patients met the study's inclusion criteria with 170 patients having a definitive outcome. The results showed that approximately 60% of the 170 patients had successful treatment, while 23% required surgical intervention. It was concluded from this study that the Spine-Cor brace was an effective form of bracing treatment (Coillard, 2007). However, the literature on the Spine-Cor brace is still lacking, and more studies are needed to confirm these findings. Although comparisons have been examined between full-time and nighttime braces as discussed by Katz et al. (1997), there have been no definitive studies indicating the superiority of full-time braces with regard to treatment success (Schiller et al., 2010).

Studies that were conducted to investigate the efficacy of full-time braces have also been performed with nighttime braces. Price et al. (1997) conducted a study that looked at the efficacy of the Charleston brace in 98 patients with AIS and a curve greater than 25°. The study showed that 66% of patients either improved or maintained their curve under 5° of progression, while 17% of patients eventually needed surgical intervention. In a study conducted by d'Amato et al. (2001) which investigated nighttime bracing efficacy in 102 adolescent females with the Providence brace, an initial in-brace correction of 96% was achieved for major curves and 98% for minor curves. The results showed that 74% of patients had curves that did not progress beyond 5°, and 26% of patients had curves that either progressed greater than 6° or required surgical

intervention. The conclusion of the study was that the Providence brace was suitable in the treatment of curves that were less than 35° (d'Amato et al., 2001).

While these aforementioned retrospective studies examined specific types of braces and their respective efficacies, Weinstein et al. (2013) carried out a multicenter prospective study investigating the efficacy of bracing compared with observation. The study successfully recruited 242 patients, of which 116 patients were randomly assigned to bracing or observation and 126 patients chose between bracing and observation. The bracing cohort was asked to wear a brace for at least 18 hours a day. Bracing treatment was viewed as successful if it limited curve progression to less than 50° up until skeletal maturity. The overall results showed that 72% of patients who underwent bracing treatment, compared with 48% of patients in the observational cohort, were considered successful. Furthermore, 75% of patients who were randomly assigned to bracing treatment achieved successful outcomes, while only 42% of patients randomly assigned to observation were considered successful. The study concluded that bracing, in general, is a highly effective treatment modality that decreases the risks of curve progression in an effort to avoid surgical intervention (Weinstein et al., 2013). As further support of these results, Aulisa et al. (2014) performed a similar study in the correlation between compliance and brace treatment and also found that curve progression and surgical intervention were lower in patients with high adherence.

As evidence for the efficacy of bracing continues to grow, regardless of the type of brace used in treating AIS, adherence has continued to interfere with bracing treatment success rates. In a male patient-focused study, bracing efficacy was studied in 112

patients with idiopathic scoliosis (Karol, 2001). Of the 112 patients, 74% of the boys experienced a curve progression of 6° or greater, and 46% eventually required surgical intervention. The results showed that only 38% of patients were considered to be in good adherence, which was estimated by reviewing orthopedic clinical notes and orthotic department records (Karol, 2001). In a more limited study that examined bracing adherence among 10 female patients diagnosed with AIS, adherence ranged from 8% to 90% with an average of 65% (Nicholson et al., 2003). Nicholson and coworkers (2003) discovered that female patients who were adherent to their bracing treatment generally wore their brace consistently throughout the day with the exception of bathing and exercise. Those female patients who were considered to be non-adherent generally wore their brace sporadically throughout the day. Adherence measurements were discreetly measured by placing thermal sensors within the brace and recording temperature at the skin-brace interface every 16 minutes with a date/time stamp for up to 88 days. The study concluded that the use of discreet thermal measurement recordings throughout bracing treatment was an effective tool in determining bracing adherence (Nicholson et al., 2003).

While most bracing efficacy and adherence studies rely on a more subjective interpretation of the physician's progress notes in regard to a patient's brace wearing habits, Rahman et al. (2005) conducted one of the first studies that objectively correlated adherence with efficacy. The study utilized temperature sensors and loggers that were embedded in a Wilmington brace. Thirty-four patients with idiopathic scoliosis were followed for the duration of their bracing treatment. The study results showed that adherence among patients who had a curve progression of greater than 5° was 62%. In

contrast, an adherence of 85% was observed in patients who did not see a progression in their curve. It should be noted, however, that one out of nine patients who had an adherence of 90% or greater had a curve progression of 11%, while 14 out of 25 patients with low adherence had curve progression in general (Rahman et al., 2005). Although not all patients who are adherent with their bracing treatment will slow down the natural history of their curve progression, bracing was still considered to lend itself to a more favorable outcome. In more recent studies, the utility of thermal monitoring in brace wearing was confirmed, and the potential for improving this system was noted, especially if patient and family were informed of ongoing monitoring (Donzelli et al., 2012; Miller et al., 2012).

The motivations behind why a child does or does not adhere to a bracing treatment are complex at best. The literature indicates that bracing is an effective treatment which will help patients avoid curve progression and surgical intervention, yet adherence rates are inconsistent across multiple demographics. Schiller et al. (2010) cited a study investigating the reasons behind poor adherence in an adult female population undergoing bracing treatment. The common causes of non-adherence mentioned in the study were the following: negative appearance of the brace resulting in poor self-esteem, functional discomfort from pressure points, irritation in hot weather, and restriction of movement. The general theory behind bracing is to create a force that will slowly manipulate the patient's curve into a corrected position. Therefore, the forces that are generated by a brace can understandably be uncomfortable for the patient who is being braced. In addition, although more modern braces have become relatively discreet when

compared with their predecessors, it is difficult to completely hide all parts of a brace under a patient's clothes. While thermal monitoring in bracing seems promising, a psychological approach could prove to be more effective in treating the emotional and mental aspects of non-adherence rather than direct oversight as a subtle form of coercion. In essence, if the patient can develop a positive perception of brace wearing, it would undoubtedly have an increase in bracing adherence.

Currently, there has been limited research on the psychological motivators in bracing adherence, which could serve as another resource in helping patients become more adherent to their bracing treatment. The ultimate result of a failed brace treatment is the eventual surgical intervention, and aside from the surgery itself, there are potential consequences as a result of the surgery. Recent research by Dr. Christine Sieberg's lab (Boston Children's Hospital) found that patients reported moderate to severe pain at 1 and 2 years postsurgically, with an increase in the prevalence in pain at 5 years (Sieberg et al., 2013). This study also identified five groups from the examination of longitudinal pain trajectories: a no-pain group and a high-pain group at all times, a pain improvement group, a short-term pain group, and a delayed-pain group. From the identified groups, multiple factors such as age, perceived body image, and functional limitations prior to surgery were identified as playing significant roles in differentiating between groups (Sieberg et al., 2013).

Chronic Pain in Children

One-fifth of patients who experience chronic pain attribute the main cause to surgery (Crombie et al., 1998). Chronic pain can cause individuals to miss days of work or school and can pose socioeconomic burdens, which in turn can affect the quality of life (Fortier et al., 2011; Kehlet and Rathmell, 2010). Although studies have been performed in order to quantify the trends that exist among individuals, there is still a lack of information on the predictors that influence whether or not a patient will experience persistent postsurgical pain (PPP) (Kehlet and Rathmell, 2010). In addition, a majority of the studies have focused on PPP in adults with hardly any literature written on the effects in children (Fortier et al., 2011). Overall, there was generally a decrease in pain that was observed among children who underwent spinal surgery, but a small proportion still reported pain after 1 year and 2 years postsurgery (Landman et al., 2011; Sieberg et al., 2013). Furthermore, there was an increase in prevalence that was observed 5 years postsurgery with a steady use of pain medication throughout the 5 years despite the initial overall decrease in reported pain (Sieberg et al., 2013). In another study, PPP was reported in 52% of subjects after 5 years postsurgery, 20% of whom required medication to alleviate their symptoms (Wong et al., 2007). Moreover, it was noted that individuals who reported having mild to moderate pain prior to surgery were less likely to develop PPP compared with individuals who reported having severe pain prior to surgery (Wong et al., 2007).

The importance of bracing adherence is crucial for avoiding surgical intervention and for minimizing the chances of a child to develop PPP. Because of the still unpredictable nature of who is at high risk for developing PPP, a focus on adherence in bracing treatments could serve to strengthen bracing as the primary treatment for children with AIS. This will require examining biopsychosocial factors that impact adherence through the use of proven surveys and sensory tests in collecting relevant data. The biopsychosocial model of health examines the influences of biology, psychology, and society on an individual's life in relation to his or her health. The surveys that are employed in the current study have been proven to help researchers understand various psychosocial measures of the patients studied. In addition, to complement the psychosocial data obtained from the surveys, quantitative sensory testing allows for the collection of biological data in relation to patients with AIS.

Quantitative Sensory Testing

To objectively assess and quantify the sensory function of patients, quantitative sensory testing (QST) has been used as a means to measure thermal, sensory, and pain thresholds. These three thresholds are chosen because they can be attributed to discrete fibers throughout the neuroanatomy (Shy et al., 2003). The purpose of performing QST has been to screen for peripheral neuropathies, monitor neuropathic disease progression, and evaluate therapy efficacy (Meier et al., 2001; Shy et al., 2003). Although the type of stimuli produced by QST is objective, the response is dependent on the patient and is therefore subjective. The cooperation that is required between the tester and the patient is paramount in obtaining consistent and reliable results. In addition to assessing the various thresholds and sensitivities of patients who have neuropathic pathologies, QST is

currently being investigated in non-pathologic patients as well (Arendt-Nielsen et al., 2009).

The term QST encompasses a number of sensory tests in which various measurements of sensitivity and threshold can be obtained. For example, von Frey hairs can be used by an investigator to determine sensitivity to mechanical stimuli, and threshold sensitivity can be assessed by asking the patient to indicate when the von Frey hair begins to feel sharp. The diameter of the von Frey hair is incrementally increased as the patient denies any sensation. As soon as multiple positive responses are recorded for a certain diameter of von Frey hair, the investigator makes note and continues to use increasing diameters of von Frey hairs until multiple positive responses are recorded for a sharp sensation. In other sensory testing, a pressure algometer is utilized to evaluate a patient's sensitivity to pressure stimuli. The investigator increases the amount of force exerted on the patient's nail bed until the patient communicates an unpleasant sensation, signifying the patient's pressure pain sensation threshold. Finally, another device used in QST is a thermode block which changes temperature while strapped to the patient's skin. The patient is initially asked to click a responder when any change in temperature is felt, identifying the temperature sensitivity threshold. A second round of temperature changes takes place, but the patient is asked to only click the responder when the temperature becomes unpleasant. Each test is conducted first with cold stimuli and then with hot stimuli.

The QST results from these various measurements of thermal, sensory, and pain thresholds can be compared with larger studies to determine whether a patient would be considered more or less sensitive than normal (Blankenburg et al., 2010). QSTs performed in bracing patients could potentially reveal objective sensory differences that exist between bracing adherent and non-adherent patients, contributing to further psychological differences.

Specific Aims/Objectives

As shown in previous studies, both the development and the quality of life of a child are affected by chronic pain. The specific examination of the motivations and barriers to an effective bracing treatment will allow for the development of a better approach in attaining improved adherence by patients. Bracing has been proven to be an effective treatment in avoiding surgical intervention, which has risk factors including PPP. The benefits of this research will help to better equip the clinician and treatment team in assisting their patients to become successful in their bracing treatment. Two key questions from these studies are: What role does bracing treatment play in helping these children avoid surgical intervention? How can adherence in children undergoing bracing treatment be improved more effectively?

The goal of the present study is to identify the motivations for adherence to a prescribed bracing treatment and to determine the effects it has in regard to avoiding extensive spinal surgery. The primary aim is to explore biological, psychological, and social influences that contribute to the non-adherence, functional disability, and poor quality of life in pediatric bracing patients. The two hypotheses we are testing are:

- (1) Psychological factors of anxiety, high pain-related fear, low pain acceptance, pain catastrophizing, and poor body image will contribute to non-adherence as well as poor quality of life in patients with AIS who are undergoing bracing treatment.
- (2) Lower pain thresholds as measured with QST will predict greater chance of non-adherence in bracing treatment.

We expect this study to provide preliminary data in the investigation of the psychological and sensory factors involved with bracing adherence. In an effort to better serve children who are faced with the emotional and mental burden of going through bracing treatment, it is our hope that supplemental psychological treatment plans can be formulated from future data. By helping children cope with issues such as poor self-image or performance anxiety, we will have the capability to increase bracing adherence, avoid the need for surgical intervention, and eliminate the potential of developing PPP.
METHODS

The following sections were taken and adapted from the approved Institutional Review Board (IRB) Protocol #P00000-428.

Study Design

The study that was performed was a prospective study carried out at Boston Children's Hospital (Boston, MA). Data were collected from patients as they were recruited to the study and asked to come in for QST once.

Patient Selection and Inclusion/Exclusion Criteria

Patients and parents qualified for the study if they were scheduled for an appointment in regard to a child's scoliosis. Eligible families were identified prior to their appointment with their physician and were mailed a study recruitment flyer in the mail. Human Subjects approval was granted by the IRB prior to recruitment.

Additional inclusion criteria used in the study were:

- The ability to speak and understand sufficient English in order to complete distributed questionnaires.
- (2) Patients aged 10 years or older considering that spinal fusions typically occurred in patients older than 10 years of age.

(3) Patients specifically diagnosed with adolescent idiopathic scoliosis who were seeking nonsurgical bracing treatment from the Spinal Program of the Department of Orthopedics (Boston Children's Hospital).

Additional exclusion criteria used in the study were:

- The inability to speak and understand sufficient English in order to complete distributed questionnaires.
- (2) Severe cognitive impairment according to the patient chart (e.g., mental retardation and severe head injury).
- (3) Co-morbid and/or pain conditions that potentially confounded the data (e.g., cancer, juvenile idiopathic arthritis, fibromyalgia, and epilepsy).

Recruitment Methods

Patients and families who satisfied the above criteria for inclusion and did not meet any of the exclusion criteria were contacted by phone call to participate in the study. For bracing patients, informed consent from the patient's parents and assent from the child were obtained either by mail or email before questionnaires were sent.

Definition of Primary and Secondary Outcomes/Endpoints

The primary outcome of the study focused on psychological functioning, quality of life, and adherence. The secondary outcome was sensory functioning.

Data Collection Methods, Assessments, and Schedule

Patients and parents who were deemed eligible to participate in the study were sent a recruitment flyer with an option to opt out of being approached at the preoperative appointment, future scoliosis checkup appointment, or any other time in regard to the study. In addition, approximately 1 to 2 weeks after the flyer had been sent out, a research assistant attempted to contact the family by phone to address any questions or concerns. Generally, verbal consent was obtained during the phone call if the parents were able to answer the phone. In the event a child answered the phone, the research assistant left a message and phone number for the parent to call back the research assistant. Once the research assistant was able to contact the family and receive verbal consent, arrangements were made to meet the family the same day as their bracing checkup appointment. The research assistant met with the family, explained the consent/assent paperwork, and answered any questions regarding the different steps of the study. Quantitative Sensory Testing (QST) was performed in a private room either on the day of a routine brace checkup or on an agreed-upon date that was convenient for the participants.

REDCap questionnaires were sent out in order to collect psychosocial data. The REDCap electronic data capture tools hosted by Children's Hospital of Boston were utilized. If a patient and his or her family did not have access to a computer or the Internet, a printed copy of the questionnaire was sent by mail along with an addressed return envelope.

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REDCap (Research Electronic Data Capture) is a secure, web-based data platform that specializes in the collection, storage, and dissemination of clinical and translational research data. The program enables (1) user authentication and role-specific security, (2) auditing procedures that allow for tracking of entered data, (3) data export functions that allow for transfer of data from REDCap to other common statistical packages, and (4) the ability to import bulk data from outside sources (Harris et al., 2009).

Email was not utilized in the study to obtain data. Instead, after verification of the authenticity of the participant's email address, a secure link was sent from the REDCap system to the verified address. At that point, participants were still allowed to request a paper copy of the questionnaire. Electronic blind carbon copies were utilized in instances in which multiple participants were contacted by email in order to prevent participants from identifying each other and inappropriately replying to all individuals addressed on an email.

Any sensitive information associated with the study, including the study title, was omitted from email communication. If a participant did not complete a REDCap questionnaire within three days of receipt, a research assistant attempted to contact the family by phone. The majority of the email correspondence was through parent participants; however, some emails regarding child REDCap questionnaires were directed to the child participant. Scheduling QSTs and in-person meetings was strictly coordinated through the parent participant. In compliance with the Clinical Research Program (CRP) protocol, password-protected links were used to authenticate the identity of participants

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responding to REDCap surveys. Finally, parent and child participants were supplied with their own personal links to surveys.

Only the child participant was compensated at various points during the study. The major compensation time points were after the REDCap questionnaire and QST session. The compensation provided to the child participant was a \$10 American Express Gift Cheque for the REDCap questionnaire completed (total = \$10) and a \$25 American Express Gift Card for each QST session (total = \$25).

General Measures

Demographic data were collected from patient charts or in-person interviews and included: (1) child's date of birth, (2) gender, (3) grade in school, (4) relation of caretaker completing clinical intake forms, (5) marital status, (6) ethnic background, (7) level of parent education, and (8) parent occupation.

Child Measures

(1) *Multidimensional Anxiety Scale for Children (MASC)* assessed four areas of anxiety in children: physical symptoms, harm avoidance, social anxiety, and separation anxiety. The questionnaire consisted of 10 items for each area of anxiety and was answered on a 4-point scale (0 to 3 points). A higher score indicated that the child had a higher level of anxiety in the respective area, while a lower score indicated a lower level of anxiety in the respective area. (2) Fear of Pain Questionnaire (FOPQ) – Child Version (Simons et al., 2011) assessed the child's pain-related fears. Examples of statements in the questionnaire were: "My pain controls my life." and "I begin shaking/trembling when doing an activity that increases pain." The questionnaire was comprised of a total of 24 items, and each had a 5-point rating scale (0 to 4 points). A 0 rating meant that the child strongly disagreed with the statement, while a 4 rating meant that the child strongly agreed with the statement. The items of the questionnaire were summed to produce a total score. A higher score indicated that the child had higher levels of pain-related fear.

(3) *Pain Catastrophizing Scale (PCS) – Child Version* (Crombez et al., 2003) is a 13-item, 5-point scale that assessed negative thinking associated with pain. All the items were summed to produce a total score. A higher score indicated that the child had higher levels of catastrophic thinking.

(4) *Pediatric Quality of Life (PedQL)* (Varni et al., 1999) assessed the child's perception of quality of life. The questionnaire contained 23 items that were divided into 4 subscales: physical, emotional, social, and school. The measure is rated on a 5-point Likert-type scale to determine how much of a problem each item has been in the past month (0-4 points). A 0 rating meant that the child never had a problem, while a 4 rating meant that it was almost always a problem. The items are reverse scored and transformed into a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0). A higher PedQL score indicates a higher quality of life in the respective subscale.

Testing Procedures

Quantitative Sensory Testing (QST)

Quantitative sensory testing (QST) was conducted at the preoperative and 6month time points of the study. The testing locations were at the proposed surgical incision site (3 cm to either the left or the right of the midline as identified by the spinous processes) on the thoracolumbar spine and at two randomly selected control sites on either the left or the right thenar eminence for thermal sensory testing and on the dorsum of the hand for mechanical sensory testing. The subjects were seated in a comfortable chair during the entirety of the testing. In order to familiarize the patient with the testing process, a standardized script was read, and a practice trial was performed on a nonpainful, nonsurgical site of the patient's body.

(1) *Light-Touch Detection and Pain Thresholds:* Light-touch detection and pain thresholds were tested by utilizing a kit of 20 nylon von Frey monofilaments (Semmes-Weinstein Monofilaments; Stoelting, Wood Dale, IL, USA). The monofilaments, which increased in diameter and firmness, were calibrated in a logarithmic scale from 0.008 to 300 grams (0.08 to 2943 mN) within a 5% standard deviation. Numbers on each monofilament ranged from 1.65 to 6.65, representing the common logarithm of 10 times the force in milligrams. The monofilaments were applied in increasing thickness, following the method of limits, on the lower lumbar region between pelvic crest and lowest rib and on the unaffected site successively, in a randomized sequence from patient to patient, until a pain threshold was detected. The patient gave a clear verbal signal when

the stimulus was perceived to be painful. Each monofilament was applied three times, with approximately 10 seconds between two successive stimuli in order to avoid summation. The monofilament was applied perpendicularly to the skin surface for approximately 2 seconds until a bending of 3-5 mm of the monofilament was produced. Patients were asked to keep their eyes closed during the testing to avoid visual feedback concerning the stimuli. The pain threshold was defined as the logarithmic number on the monofilament in which at least two out of three applications on the postsurgical site resulted in the perception and subsequent reporting of pain. Once a pain threshold was reached, the test was concluded. The duration of the procedure was approximately 10-15 minutes (Keizer et al., 2007).

(2) *Dynamic Mechanical Touch Sensation Test:* Stimulus-evoked touch and allodynia were assessed by a standardized testing protocol. Brush allodynia (dynamic mechanical allodynia) was evaluated by stroking the skin of the back area with a handheld soft brush at a rate of approximately 3-5 cm/second. The intensity of pain evoked was graded on a numerical rating scale (Meier et al., 2001; Sethna et al., 2007).

(3) *Sensation of Pressure and Pressure-Pain Sensation:* The sensation of pressure was transduced primarily by slowly adapting mechanoreceptors in the skin and muscles. Pressure algometry was used to deliver a firm and quantifiable pressure through a flat base applied to the skin. The electronic pressure algometer (Somedic, Hörby, Sweden) was a handheld, gun-shaped instrument with a stimulation tip localized at the end of the

barrel. The tip was a pressure-sensitive strain gauge covered by a 0.5 cm² circular probe and connected to a pressure transducer built into the handle. The probe was overlaid with a soft polypropylene disk to avoid injury to the skin. The pressure applied through the probe was converted and amplified to an electrical reading on a digital display. In an effort to avoid prolonged pressure application and trauma to the underlying tissues, pressure was applied perpendicularly to the examination point in increments of approximately 1 N/second. As soon as discomfort or pain was felt, the subject verbally indicated the condition to the research assistant, and the pressure algometer was immediately removed from the patient's skin. The digital display showed the pressure exerted immediately before removal of the algometer. The process was repeated a total of three times with 30 seconds between each measurement. The mean of the three measurements was taken as the patient's pain and pressure threshold. The disk on the probe was cleaned with 70% alcohol after it was used on the patient. The patient was blind to the pressure algometer measurements. The duration of each measurement with the pressure algometer lasted approximately 2 minutes for each site. The total duration of the algometry testing session, including instructions and practice, was approximately 6 minutes.

(4) *Temporal Summation (Wind-Up Pain Perception):* The test of summation, or wind-up to repeated punctate stimuli at the pain detection threshold, was measured by the von Frey monofilaments used in the previous touch detection threshold testing. For each patient, the particular threshold detection monofilament was applied consecutively at a

rate of 10 stimuli over 10 seconds. The patients were asked to rate their sensation of pain on a scale of 0 to 10. A rating of 0 indicated no pain, and a rating of 10 indicated the worst possible pain. The experiment was performed a total of three times with 10 seconds between each testing.

(5) Thermal Quantitative Sensory Testing: Quantitative thermal detection thresholds were determined by using a Medoc TSA-2001 device (Medoc Ltd. Advanced Medical Systems, Rama Yishai, Israel). The thermal sensory analyzer was operated by a microcomputer driving a $3.0 \times 3.0 \text{ cm}^2$ Peltier thermode. The entire thermode-stimulating surface was placed in contact with the skin of the testing site and secured by a Velcro band without stretch. The thermode baseline temperature was kept at 32 °C, and stimulation temperatures ranged from 0 °C to 50 °C. If patients were unable to feel thermal pain at the cutoff temperature values of 0 °C or 50 °C, the upper-temperature limit value of 50 °C was assigned to avoid potential tissue injury. The rate of temperature change was kept constant at 1 °C/second for assessment of thermal sensation and at 1.5 °C/second for assessment of thermal pain. The thermal stimulus intensity was increased or decreased linearly from the baseline thermode temperature of 32 °C, and patients were asked to press a button when a specified sensation was first perceived (detection threshold). Pressing the button caused the thermode to stop increasing or decreasing the temperature and to immediately return to baseline. The return rate of the stimulus was 1 °C/second for thermal sensation and 10 °C/second for thermal pain. Stimuli were presented as a train of 4 stimuli with an inter-stimulus interval of 6 seconds for

measurement of cold and warm detection thresholds, and as a train of 3 stimuli at 10second intervals for cold- and heat-pain detection thresholds. Mean values of a set of responses to a train of stimuli were calculated as the detection threshold. Patients were given standard instructions and briefly familiarized with all test modalities demonstrated on unaffected skin areas in a "dry run" before study testing. Patients were asked to report evoked sensations as undetected, detected, painful, or nonpainful. To determine pain evoked by mechanical allodynia, the skin was brushed with a handheld soft bristle brush at a rate of approximately 3-5 cm/second. The use of two different modalities (warm and mechanical) allowed detection of sensitization within the brain during the painful and nonpainful clinical states. The test duration was approximately 10-15 minutes (Meier et al., 2001; Sethna et al., 2007).

Adverse Event Criteria and Report Procedures

There were few risks associated with the sensory testing procedures in the study. Testing should have felt similar to what is experienced during a shower, a shave, or brief exposure to outdoor temperatures. However, some participants with low pain thresholds were particularly sensitive to temperature and touch. In the event that a participant became distressed at any point during the testing, they were given the option to stop the test and the interview. Additionally, Dr. Sieberg (PI) was available by page and voicemail for consultation regarding any interviewee who experienced distress. Caregivers were offered a referral to outpatient psychiatric services (Medical Coping Clinic, Children's Hospital of Boston), with contact facilitated upon request.

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Given that the study assessed psychological distress, a plan of action was also in place if any risk of suicidality was discovered during the review of questionnaire data. If there was indication of risk for harm to self or suicidality, a suicide risk assessment was conducted, and a mental health clinician determined the best course of action to ensure the safety of the child or the parent. In order to deal with the potential discovery of child abuse, the Child Protection Team at Children's Hospital was consulted, and a 51A Report with the Massachusetts Department of Children and Families was filed in accordance with that consultation.

Data Management and Statistical Analysis

Data Management Methods

All questionnaire data collected for the study were entered into SPSS (Statistical Package for the Social Sciences, version 20; IBM, Armonk, NY, USA) software. Data were maintained in password-protected files on computers at the Children's Hospital of Boston. The hospital system provided nightly backup of files stored on its server. All hard copies of questionnaires and testing were stored in a locked file cabinet. A second locked file cabinet contained consent and assent forms and other documentation with identifying information. Only approved research staff were able to access the files. Identifying information was not entered or stored on a computer that also had behavioral data; thus all relevant data were de-identified except for consent forms that were held in a separate location.

Quality Control Methods

Questionnaire data were entered and verified electronically using the SPSS DataBuilder (SPSS Data Entry Builder) program (version 20). Data were double-entered by trained research staff and reviewed by the PI for accuracy and completeness.

Data Analysis

All data analysis was conducted with SPSS software. Levene's test for equality of variances was used to assess the assumption that variances of the populations from which different samples were drawn were equal. The results showed that the adherent and non-adherent bracing groups had about the same amounts of variability between the various scores (significance > 0.05). An independent samples t-test was then performed to determine the significance in the differences of means pertaining to each measure. The following are definitions of parameters used in the results:

- Mean difference = (adherent mean) (non-adherent mean)
- Mean total score for subscale (MASC) = sum of category means
- Mean total score for Total Anxiety Index (MASC) = sum of mean total scores of subscales
- Mean total score for FOPQ or PCS = sum of subscale means
- Mean total score for PedQL = mean of 4 subscale means
- Mean total scale for Psychosocial = mean of 3 PedQL subscale means

A Z-score was calculated by the descriptive function in SPSS. The general equation used for calculating Z-scores is Z-score = (score – mean) divided by the

standard deviation. Finally, a T-score was calculated by the computing variable function in SPSS. The equation used for calculating T-scores is T-score = (Z-score)(10) + 50. The mean T-score was calculated by taking the mean of the T-scores in each group.

Not all patients who were examined for this study completed all surveys that were provided to them. Furthermore, if a patient failed to complete all questions within a scale or subscale, then a subscale or total score could not be calculated. All scores were compared between adherent versus non-adherent bracing patients. Once all scores were calculated for each survey and the respective subscales, a Z-score and subsequently a Tscore were calculated. Using the T-score, the two groups were identified as having a score that fell in the low, average, borderline significant (top 5%), or clinically significant (top 2%) range. T-scores for the PedQL questionnaire were used to compare adherent and non-adherent bracing patients and were not assigned a clinical significance.

RESULTS

A total of 20 eligible patients undergoing bracing treatment were examined for this study with 1 patient withdrawing from the study (N = 19). Because of the underpowered nature of the study, the following results should be considered as preliminary. The majority of patients were considered to be adherent to their prescribed bracing treatment (N = 15) as determined by the progress note dictated by their physician. Of the 15 that were adherent to their bracing treatment, the physician prescribed the number of hours per day a brace was worn for all patients. The average number of hours per day a brace was worn by the 15 patients was 16.87 hours (Table 1). The average number of hours per day a brace was worn by the 4 non-adherent patients was 5.25 hours. The mean difference for the hours per day a brace was worn between adherent and nonadherent patients was 11.62 (p < 0.0004) (Table 2).

Table 1. Group	Means for	Brace V	Wearing D	Adherence	and Hours	s per I)ay
							•

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean
	Adherent	15	16.87	4.24	1.10
Brace Hours Per Day	Non-adherent	4	5.25	6.40	3.20

Levene	s Test	t-test for Equality of Means							
F	Sig	t	df	*Sig	MD	SED	95% CI		
	-			_			Lower	Upper	
2.10	0.17	4.40	17	0.0004	11.62	2.64	6.04	17.19	

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Multidimensional Anxiety Scale for Children (MASC)

Physical Symptoms

Of the 19 patients who completed the multidimensional anxiety scale for children (MASC) survey, 17 completed the survey in its entirety. The physical symptoms subscale symptoms were categorized as either tense or somatic symptoms (Table 3). The mean score for adherent bracing patients was 4.00 with a standard deviation of 3.63 in tense symptoms (N = 13) and 4.53 with a standard deviation of 3.00 in somatic symptoms (N = 15). The mean for non-adherent bracing patients was 6.25 with a standard deviation of 3.30 in tense symptoms and 5.25 with a standard deviation of 3.40 in somatic symptoms (N = 4).

The mean total score for the physical symptoms subscale in adherent bracing patients was 8.46 with a standard deviation of 6.24 (N = 13). The mean total score for the physical symptoms subscale in non-adherent bracing patients was 11.50 with a standard deviation of 5.92 (N = 4).

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean
	Adherent	13	4.00	3.63	1.00
Tense Symptoms	Non-adherent	4	6.25	3.30	1.65
	Adherent		4.53	3.00	0.77
Somatic Symptoms	Non-adherent	4	5.25	3.40	1.70
	Adherent	13	8.46	6.24	1.73
Total Score	Non-adherent	4	11.50	5.92	2.96

 Table 3. Group Means for Physical Symptoms Subscale

An independent samples t-test indicated that there was a t-test significance of 0.29, 0.68, and 0.40 between means present when equal variances were assumed in the physical symptoms subscale: tense symptoms, somatic symptoms, and total score (Table 4). A mean difference of -2.25, -0.72, and -3.04 was calculated between adherent and non-adherent bracing patients for tense symptoms, somatic symptoms, and total score, respectively. In general, the non-adherent group had more anxiety in the physical symptoms subscale; however, the values reported in this study were not statistically significant (p < 0.05) as indicated by the t-test.

	Levene's Test		t-test for Equality of Means						
	F	Sig	t	df	*Sig	MD	SED	95%	6 CI
								Lower	Upper
Tense Symptoms	0.35	0.56	-1.10	15	0.29	-2.25	2.04	-6.60	2.10
Somatic Symptoms	0.02	0.89	-0.42	17	0.68	-0.72	1.73	-4.37	2.93
Total Score	0.21	0.65	-0.86	15	0.40	-3.04	3.53	-10.57	4.89

 Table 4. Difference in Means for Physical Symptoms Subscale Score

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Harm Avoidance

The harm avoidance subscale was divided into either perfectionism or anxiety coping (Table 5). The mean score for adherent bracing patients was 8.21 with a standard deviation of 2.52 in perfectionism and 9.64 with a standard deviation of 3.05 in anxiety coping (N = 14). The mean for non-adherent bracing patients was 9.00 with a standard

deviation of 2.00 in perfectionism and 10.00 with a standard deviation of 2.16 in anxiety coping (N = 4).

The mean total score for the harm avoidance subscale in adherent bracing patients was 18.38 with a standard deviation of 4.48 (N = 13). The mean total score for the physical symptoms subscale in non-adherent bracing patients was 19.00 with a standard deviation of 4.08 (N = 4).

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean
	Adherent	14	8.21	2.52	0.67
Perfectionism	Non-adherent	4	9.00	2.00	1.00
	Adherent	14	9.64	3.05	0.82
Anxiety Coping	Non-adherent	4	10.00	2.16	1.08
	Adherent	13	18.39	4.48	1.24
Total Score	Non-adherent	4	19.00	4.08	2.04

 Table 5. Group Means for Harm Avoidance Subscale

An independent samples t-test indicated that there was a t-test significance of 0.58, 0.83, and 0.81 between means present when equal variances were assumed in the harm avoidance subscale: perfectionism, anxiety coping, and total score (Table 6). A mean difference of -0.79, -0.36, and -0.62 was calculated between adherent and non-adherent bracing patients for perfectionism, anxiety coping, and total score, respectively. Again, the non-adherent group experienced a higher anxiety level for the harm avoidance subscale, but there was no statistical significance (p < 0.05) indicated by the t-test.

	Levene's Test			t-test for Equality of Means									
	F Sig		F Sig		F Sig		t	df	*Sig	MD	SED	95% CI	
		-						Lower	Upper				
Perfectionism	0.08	0.79	-0.57	16	0.58	-0.79	1.38	-3.70	2.13				
Anxiety Coping	1.57	0.23	-0.22	16	0.83	-0.36	1.65	-3.85	3.14				
Total Score	0.01	0.94	-0.24	15	0.81	-0.62	2.52	-5.98	4.75				

Table 6. Difference in Means for Harm Avoidance Subscale Score

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Social Anxiety

The social anxiety subscale was divided into either humiliation fear or performance fear (Table 7). The mean score for adherent bracing patients was 4.21 with a standard deviation of 3.89 in humiliation fear and 3.50 with a standard deviation of 2.74 in performance fear (N = 14). The mean for non-adherent bracing patients was 7.25 with a standard deviation of 4.03 in humiliation fear and 5.25 with a standard deviation of 2.99 in performance fear (N = 4).

The mean total score for the social anxiety subscale in adherent bracing patients was 7.71 with a standard deviation of 5.78 (N = 14). The mean total score for the social anxiety subscale in non-adherent bracing patients was 12.50 with a standard deviation of 6.35 (N = 4).

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean
Humiliation Fear	Adherent	14	4.21	3.89	1.04
	Non-adherent	4	7.25	4.03	2.02
	Adherent	14	3.50	2.74	0.73
Performance Fear	Non-adherent	4	5.25	2.99	1.49
	Adherent	14	7.71	5.78	1.54
Total Score	Non-adherent	4	12.50	6.35	3.18

Table 7. Group Means for Social Anxiety Subscale

An independent samples t-test indicated that there was a t-test significance of 0.19, 0.28, and 0.17 between means present when equal variances were assumed in the social anxiety subscale: humiliation fear, performance fear, and total score (Table 8). A mean difference of -3.04, -1.75, and -4.79 was calculated between adherent and non-adherent bracing patients for humiliation fear, performance fear, and total score, respectively. The non-adherent group experienced a higher anxiety level in the social anxiety subscale, but no statistical significance (p < 0.05) was indicated by the t-test.

	Levene's Test F Sig		t-test for Equality of Means							
			t	df	*Sig	MD	SED	95%	6 CI	
								Lower	Upper	
Humiliation Fear	0.04	0.84	-1.37	16	0.19	-3.04	2.22	-7.74	1.67	
Performance Fear	0.19	0.67	-1.11	16	0.28	-1.75	1.58	-5.10	1.60	
Total Score	0.05	0.83	-1.44	16	0.17	-4.79	3.33	-11.84	2.27	

 Table 8. Difference in Means for Social Anxiety Subscale Score

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Separation Anxiety

The separation anxiety subscale was not further divided into categories (Table 9). The mean score for adherent bracing patients was 7.20 with a standard deviation of 4.54 (N = 15). The mean for non-adherent bracing patients was 6.75 with a standard deviation of 3.86 (N = 4).

Adherence Ν Mean Std. Deviation Std. Error Mean 15 7.20 4.54 1.17 Adherent Separation/Panic Non-adherent 4 6.75 3.86 1.93

Table 9. Group Means for Separation Anxiety Subscale

An independent samples t-test indicated that there was a t-test significance of 0.859 between means present when equal variances were assumed in the separation anxiety subscale (Table 10). A mean difference of 0.45 was calculated between adherent and non-adherent bracing patients. Finally, the non-adherent group exhibited a lower separation anxiety with respect to the adherence group, but no statistical significance (p < 0.05) was indicated by t-test analysis.

Table 10. Difference in Means for Separation Anxiety Subscale Score

	Levene	t-test for Equality of Means							
	F Sig		Sig t		*Sig	MD	SED	95%	6 CI
		-			_			Lower	Upper
Separation/Panic	0.50	0.55	0.18	17	0.86	0.45	2.49	-4.81	5.71

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = Significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, Sig = significance; t-test: t = t-statistic, df = degrees of Sig = significance; t-test: t = t-statistic, df = degrees of Sig = significance; t-test: t = t-statistic, df = degrees of Sig = significance; t-test: t = t-statistic, df = degrees of Sig = significance; t-test: t = t-statistic, df = degrees of Sig = significance; t-test: t = t-statistic, df = degrees of Sig = significance; t-test: t = t-statistic, sig = significance; t-test: t = t-statistic, t = t-st significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Anxiety Disorder Index

The anxiety disorder index served as its own scale, separate from the other MASC subscales, but was calculated from the data obtained from MASC (Table 11). The mean score for adherent bracing patients was 11.86 with a standard deviation of 5.57 (N = 14). The mean for non-adherent bracing patients was 16.50 with a standard deviation of 2.89 (N = 4).

Table 11. Group Means for Anxiety Disorder Index

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean
	Adherent	14	11.86	5.57	1.49
Anxiety Disorder Index	Non-adherent	4	16.50	2.89	1.44

An independent samples t-test indicated that there was a calculated t-test significance of 0.133 between means present when equal variances were assumed in the anxiety disorder index (Table 12). However, because the significance was not below the accepted statistical significance threshold (p < 0.05), the results were not significant. A mean difference of -4.64 was calculated between adherent and non-adherent bracing patients.

	Levene	t-test for Equality of Means								
	F Sig		t	df	*Sig	MD SED		95%	95% CI	
					-			Lower	Upper	
Anxiety Disorder Index	3.47	0.08	-1.58	16	0.13	-4.64	2.94	-10.86	1.58	

Table 12. Difference in Means for Anxiety Disorder Index

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Total Anxiety Index

The total anxiety index was comprised of all subscale scores contained within the MASC. A total of 16 patients completed all parts of the MASC survey, which allowed for a total anxiety index to be calculated (Table 13). The mean score for adherent bracing patients was 41.33 with a standard deviation of 16.57 (N = 12). The mean for non-adherent bracing patients was 49.75 with a standard deviation of 12.53 (N = 4).

Table 13. Group Means for Total Anxiety Index

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean
	Adherent	12	41.33	16.57	4.78
Total Anxiety Index	Non-adherent	4	49.75	12.53	6.26

An independent samples t-test indicated that there was a t-test significance of 0.371 between means present when equal variances were assumed in the total anxiety index (Table 14). A mean difference -8.42 was calculated between adherent and non-adherent bracing patients. Overall, the non-adherent group displayed a higher total

anxiety, but there was no statistical significance (p < 0.05) according to the t-test significance value calculated.

	Levene		t-test for Equality of Means						
	F	Sig	t	df	*Sig	MD	SED	95%	6 CI
		-			_			Lower	Upper
Total Anxiety Index	2.94	0.11	-0.92	14	0.37	-8.42	9.12	-27.97	11.13

Tab	le 14.	. Difference	e in I	Means	for	Total	Anxiety	/ Index
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Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Fear of Pain Questionnaire (FOPQ)

The fear of pain questionnaire (FOPQ) was fully completed by 18 participants. Of the 18 participants, 15 were considered to be adherent bracing patients and 3 were nonadherent bracing patients. The questionnaire was divided into three subscales: fear of pain, avoidance of activities, and avoidance of school.

Fear of Pain

The mean fear of pain score for adherent bracing patients was 7.33 with a standard deviation of 5.49. The mean fear of pain score for non-adherent bracing patients was 6.33 with a standard deviation of 5.03. The differences in means between the two groups indicated that adherent bracing patients experienced a higher fear of pain than the non-adherent bracing patient group. An independent t-test was performed to determine the significance between the differences in means. A significance of 0.78 was calculated

from the t-test, indicating that there was no statistically significant difference (p < 0.05) between the two groups.

Avoidance of Activities

The mean avoidance of activities score for adherent bracing patients was 5.33 with a standard deviation of 5.90. The mean avoidance of activities score for non-adherent bracing patients was 1.67 with a standard deviation of 2.89. Overall, the adherent bracing group tended to avoid activities more than the non-adherent patient group. A significance of 0.32 was calculated from performing an independent t-test, indicating that there was no statistically significant difference (p < 0.05) in means between the two groups.

School Activity Avoidance

The mean school activities avoidance score for adherent bracing patients was 5.00 with a standard deviation of 2.89. The mean school activities avoidance score for non-adherent bracing patients was 3.33 with a standard deviation of 3.51. The differences in means in this subscale indicated that adherent bracing patients tended to avoid school-related activities more than their non-adherent counterparts. A significance of 0.47 was calculated from performing an independent t-test, which indicated that there was no statistically significant difference (p < 0.05) in means between the two groups.

Total Score

The mean total FOPQ score for adherent bracing patients was 17.67 with a standard deviation of 14.30. The mean total FOPQ score for non-adherent bracing patients was 11.33 with a standard deviation of 11.06. Overall, the adherent bracing group had a higher fear of pain when compared with the non-adherent patient group. A significance of 0.48 was calculated from performing an independent t-test, which indicated that there was no statistically significant difference (p < 0.05) between the two groups.

Pain Catastrophizing Scale (PCS)

The pain catastrophizing scale (PCS) consisted of three dimensions of catastrophizing: rumination, magnification, and helplessness. Of the 19 patients who were surveyed, one did not complete the necessary questions for a magnification score to be calculated. The mean scores and standard deviations for rumination, magnification, helplessness, and total score are presented in Table 15. An independent t-test was performed to determine the significance between the differences in means. A significance of 0.39, 0.95, 0.90, and 0.77 was calculated from the t-test for rumination, magnification, helplessness, and total score, respectively. According to the t-test significance values, there were no statistically significant differences (p < 0.05) between the two groups with respect to the PCS scores.

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean	
	Adherent	15	9.20	3.45	0.89	
Rumination	Non-adherent	4	11.00	4.24	2.12	
	Adherent	15	2.60	1.84	0.48	
Magnification	Non-adherent	3	2.67	1.53	0.88	
	Adherent	15	5.87	5.21	1.35	
Helplessness	Non-adherent	4	5.50	3.32	1.66	
	Adherent	15	17.67	9.88	2.55	
Total Score	Non-adherent	4	19.25	8.54	4.27	

Table 15. Group Means for Pain Catastrophizing Subscales and Total Scores

Pediatric Quality of Life (PedQL)

The pediatric quality of life (PedQL) survey was broken into four subscales: physical, emotional, social, and school. The mean of the three subscale scores for emotional, social, and school was calculated to determine a psychosocial score. The total pediatric quality of life score was calculated as the mean of the four subscale scores for physical, emotional, social, and school. Of the 19 patients who were examined for the study, 18 participants completely filled out the PedQL survey.

The means and standard deviations for the physical, emotional, social, and school subscales are presented in Table 16. In addition, the means and standard deviations for the psychosocial and total score are also presented. In general, the adherent bracing group had higher PedQL scores, which indicated that they had a better quality of life in the respective areas when compared with the non-adherent bracing group.

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean	
	Adherent	15	83.33	20.75	5.36	
Physical	Non-adherent	3	68.75	3.13	1.80	
	Adherent	15	79.67	21.25	5.49	
Emotional	Non-adherent	3	75.00	8.66	5.00	
	Adherent	15	92.67	13.21	3.41	
Social	Non-adherent	3	88.33	10.41	6.01	
	Adherent	15	75.75	12.41	3.20	
School	Non-adherent	3	61.67	5.77	3.33	
	Adherent	15	82.69	12.95	3.34	
Psychosocial	Non-adherent	3	75.00	7.64	4.41	
	Adherent	15	82.85	14.56	3.76	
Iotal Score	Non-adherent	3	73.44	5.250	3.03	

Table 16. Group Means for Pediatric Quality of Life and Total Scores

The results of an independent samples t-test performed on all scores are presented in Table 17. The significance values indicated that there were no statistically significant differences (p < 0.05) between adherent and non-adherent bracing groups with respect to PedQL scores.

	Levene	e's Test	t-test for Equality of Means									
	F	Sig	t	df	*Sig	MD	SED	95%	6 CI			
								Lower	Upper			
Physical	2.75	0.12	1.19	16	0.25	14.58	12.30	-11.48	40.65			
Emotional	3.09	0.10	0.37	16	0.72	4.67	12.72	-22.30	31.64			
Social	0.15	0.70	0.53	16	0.60	4.33	8.16	-12.95	21.62			
School	1.23	0.28	1.89	16	0.08	14.08	7.45	-1.72	29.88			
Psychosocial	0.48	0.50	0.98	16	0.34	7.69	7.85	-8.94	24.33			
Total Score	0.92	0.35	1.08	16	0.30	9.42	8.69	-9.01	27.84			

Table 17. Difference in Means for Pediatric Quality of Life Survey

Levene's test: F = F-statistic, Sig = significance; t-test: t = t-statistic, df = degrees of freedom, *Sig = significance (2-tailed), MD = mean difference, SED = standard error difference, 95% CI = 95% confidence interval of the difference.

Quantitative Sensory Testing (QST)

Of the 19 patients who were examined, 7 underwent thermal quantitative sensory testing (QST). Means were calculated for cool detection, warmth detection, cold detection, and hot detection. All measures were taken from both the hand and the back as described in the methods. Because of the underpowered nature of this measure, a general descriptive statistical approach was taken. Table 18 provides the mean for each measure analyzed.

An independent t-test was performed on the QST data, but there were no statistically significant results (p < 0.05) considering that there was only one non-adherent bracing patient. Means were calculated for all patients undergoing bracing treatment (adherent and non-adherent) to present a descriptive representation. The non-adherent bracing patient's QST data did not differ from the other adherent bracing patients.

		Cool -	Cool -	Warm -	Warm -	Cold -	Cold -	Hot -	Hot -
		Hand	Back	Hand	Back	Hand	Back	Hand	Back
	Valid	6	7	7	7	7	7	7	7
Ν	Missing	1	0	0	0	0	0	0	0
M	ean (°C)	29.96	30.68	34.05	34.36	10.86	13.86	44.71	42.55
S	O (°C)	0.81	0.62	1.39	0.82	10.62	12.31	5.51	4.80

 Table 18. Frequencies of Thermal Quantitative Sensory Testing Measures

N = number of patients, Mean = mean temperature, SD = standard deviation of temperatures.

T-Scores for Various Measures

T-scores were calculated for each of the patients, and then a mean T-score was calculated for each measure. Interpretations were based on a T-score clinical interpretations rubric. The PedQL measure was used as a comparative measure between adherent and non-adherent bracing patients for their respective quality of life. The interpretations for PedQL were indicated as "better" or "worse" with respect to the other group examined. Table 19 presents all T-scores obtained from all surveys examined.

Table 19. Mean T-scores for MASC, FOPQ, PCS, and PedQL Measures and	
Interpretations	

	Adherence	Ν	Mean	Std. Deviation	Std. Error Mean	Interpretation
MASC	Adherent	12	49.58	10.26	2.96	Average
Physical	Non-adherent	3	56.24	10.19	5.89	Average
	Adherent	12	50.13	10.81	3.12	Average
Harm Avoidance	Non-adherent	3	53.44	10.20	5.89	Average
	Adherent	13	48.46	9.86	2.74	Average
Social Anxiety	Non-adherent	3	55.87	12.83	7.41	Average
	Adherent	13	51.01	11.16	3.10	Average
Separation/Panic	Non-adherent	3	53.63	1.34	0.77	Average
	Adherent	14	48.09	10.32	2.76	Average
Anxiety Disorder Index	Non-adherent	4	56.69	5.35	2.67	Average
	Adherent	12	48.66	10.55	3.04	Average
Total Anxiety	Non-adherent	4	54.02	7.97	3.99	Average
FOPQ	Adherent	15	50.32	10.38	2.68	Moderate
Fear of Pain	Non-adherent	3	48.42	9.53	5.50	Moderate
	Adherent	15	51.09	10.49	2.71	High
Avoidance of Activity	Non-adherent	3	44.57	5.13	2.96	Moderate
	Adherent	15	50.79	10.16	2.62	Moderate
School Avoidance	Non-adherent	3	46.06	9.95	5.75	Moderate
	Adherent	15	50.77	10.41	2.69	Moderate
Total Score	Non-adherent	3	46.16	8.05	4.65	Moderate

PCS	Adherent	15	48.94	9.63	2.49	Severe
Rumination	Non-adherent	4	53.97	11.85	5.93	Severe
Magnification	Adherent	15	49.94	10.52	2.72	Severe
Magnineation	Non-adherent	3	50.32	8.71	5.03	Severe
Helplessness	Adherent	15	50.16	10.87	2.81	Severe
	Non-adherent	4	49.40	6.92	3.46	Severe
Total Soora	Adherent	15	49.65	10.50	2.71	Severe
	Non-adherent	4	51.33	9.07	4.54	Severe
PedQL	Adherent	15	51.24	10.55	2.72	Better
Physical	Non-adherent	3	43.82	1.59	0.92	Worse
Emotional	Adherent	15	50.40	10.85	2.80	Better
Emotional	Non-adherent	3	48.02	4.42	2.55	Worse
Social	Adherent	15	50.60	10.47	2.70	Better
Social	Non-adherent	3	47.14	8.25	4.76	Worse
School	Adherent	15	51.86	9.81	2.53	Better
001001	Non-adherent	3	40.72	4.57	2.64	Worse
Psychosocial	Adherent	15	51.03	10.45	2.70	Better
	Non-adherent	3	44.83	6.16	3.56	Worse
Total Score	Adherent	15	51.14	10.54	2.72	Better
	Non-adherent	3	44.32	3.80	2.19	Worse

DISCUSSION

Although a small number of children undergo surgical intervention due to adolescent idiopathic scoliosis (AIS), there are some who could avoid this extremely invasive procedure by adhering to their bracing treatment. It has been proven that longterm brace treatment and strict adherence to the prescribed regimen could prevent children from such circumstances (Weinstein et al., 2013). The major issue that is expressed by children in bracing treatment is the length of hours a brace needs to be worn, resulting in discomfort and interference with other daily activities. For most mild AIS patients, a nightly regime is prescribed until curve progression is observed. At this point if progression is severe enough, the child is moved to a full-time schedule. Children who are prescribed a full-time schedule are recommended to wear a brace up to 20 hours a day. In addition, the types of braces that are available are limited, and the type of brace to use is determined by the type of curve a child has rather than which brace the child is most comfortable wearing. If we can understand how the child is affected by brace wearing, both physically and psychologically, we may be able to provide an additional support system serving as a treatment to the symptoms of the child's brace instead of their condition. By alleviating or mitigating the negative consequences of wearing a brace, a child may be more inclined to adhere to his or her prescribed regimen, therefore avoiding surgical intervention due to lack of adherence.

Aside from the obvious benefit of avoiding surgical intervention, a more longterm benefit is the avoidance of the potential to develop the condition of persistent

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postoperative pain after surgery. Sieberg and colleagues (2013) have shown that persistent postoperative pain can continue for years. Given that adolescents are going through a phase of development that involves interacting with their peers at school or in extracurricular activities, chronic pain may lead to a child withdrawing from such interactions. Ultimately, chronic pain could negatively alter the course of a child's future.

Through the administration of psychosocial questionnaires and sensory testing, we can begin to understand the complete picture of what a child is experiencing while going through bracing treatment. Questions that could be answered include: What are their fears? Why do they really not like wearing the brace? Is it because they are afraid of being made fun of by their peers or because it is truly uncomfortable to wear? Is it both reasons? Finally, by comparing adherent and non-adherent bracing patients, we can objectively determine the benefits of bracing treatment adherence to better educate the child and parent.

The objective of this study was to compare adherent and non-adherent bracing patients with respect to their psychosocial and physical parameters. Although this is a preliminary study, there has been little other research done to examine the psychological aspects of why a child may or may not follow a bracing program.

Bracing Adherence

One of the most significant differences observed in this study was the mean difference between the number of hours a brace was worn between adherent and nonadherent bracing patients. Most adherent patients were determined to wear their brace over 11 hours more than their non-adherent counterparts (p < 0.0004). In considering that normally a full-time schedule requires a child to wear his or her brace for 20 hours a day, one could assume that a child wearing a brace for half the prescribed time could eventually lead to surgical intervention according to Weinstein et al. (2013). Whereas the study performed by Weinstein and coworkers examined bracing patients compared with non-braced patients, a study comparing a larger number of adherent versus non-adherent bracing patients could be a future area of investigation.

MASC

Because of the low number of participants, the study was underpowered and did not yield many significant results in all measures examined. Although there were no significant differences between adherent and non-adherent bracing groups, social anxiety and the anxiety disorder index had the greatest calculated t-test significance. The lack of statistical significance between the two groups in this measure implies that there could be potential for significance if a larger sample is examined. With a larger sample size, a more reliable conclusion can be made about the utility of the MASC measure in regard to the differences that exist between adherent and non-adherent bracing patients.

The social anxiety subscale was further divided into two subsets of humiliation fear and performance fear. The humiliation subset reflects the extent to which a child may be anxious about being humiliated, embarrassed, or rejected by peers in a social setting. The fear of humiliation may be attributed to the fact that some of these children are going through a period of growth which, in addition to increasing size and height, is

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amplifying any physical deformities they may have. Aside from their own physical appearance, children wearing a brace during school hours may be self-conscious that none of their peers are wearing a brace. Not all braces are the most discreet, and protrusion from under a child's shirt may cause other children to take notice. In this study, the mean for humiliation fear score was lower for adherent bracing patients than for non-adherent bracing patients by approximately 3. The lowered humiliation fear score may be attributed to the psychological aspect that children who are bracing and bracing well are confident that they are fixing their condition. In addition, children who wear their brace at school may be more confident in wearing their brace at school or may not worry so much about the appearance of their brace but more about their physical performance in a brace. Conversely, children who refuse to wear their brace at school may have lower self-confidence and may be more aware of their concerns about what their peers may think about being seen in a brace.

Although not statistically significant, another difference between groups noticed in the MASC questionnaire was the anxiety disorder index. Although it is not a subscale of the MASC, it is an additional measure that was calculated from the survey data. The anxiety disorder index reflects the extent to which a child may be experiencing the same symptoms as a child diagnosed with anxiety disorder. Common symptoms of anxiety disorder are an elevated concern about future events and their associated physical actions, such as performing physical exercises during gym class or having to walk down a set of stairs. For those children with a very elevated anxiety disorder index score, they exhibited tendencies to excessively check things out first, feel tense, have trouble breathing, feel

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sick to their stomach, or keep the light on at night (March et al., 1999). Similar to the mean differences seen in the social anxiety subscale, adherent bracing patients had a lower anxiety disorder index score than non-adherent bracing patients by 4.6. Although it was mentioned that the adherent bracing patients may be concerned about their physical performance in a brace, they may not be as anxious to participate in physical activities when compared with non-adherent bracing patients. Since non-adherent bracing patients are not wearing their brace and consequently not addressing their condition, they may have overall increased anxiety as well. The combination of fearing humiliation in social situations and increased anxiety could essentially compound the symptoms associated with each measure.

FOPQ

The FOPQ was divided into three subscales of fear of pain, avoidance of activities, and school activity avoidance. A total score was also calculated by combining the three subscale scores. No significance was indicated by an independent t-test performed between adherent and non-adherent patients. However, when a T-score was produced for each measure, both groups were determined to have moderate fear of pain in most subscales examined. Although the FOPQ scores of both groups fell within the moderate designation, the majority of the T-scores for the subscales were toward the upper limit bordering a high fear of pain. The range for a child to be considered to have a moderate fear of pain is a T-score between 35 and 50. In comparison, a T-score between 51 and 96 indicates a high fear of pain. The subscale T-scores for adherent bracing
patients were between 50 and 51, with a total FOPQ score of 50.77. The subscale Tscores for non-adherent bracing patients were between 44 and 48, with a total FOPQ score of 46.16. In considering the mean FOPQ scores and standard deviations, any participant could have been in the moderate to high fear of pain range. Because of the nature of each child's physical condition, it is understandable that all participants exhibit an elevated fear of pain. Although some children will report that on most days they do not experience any pain, once they participate in physical activity and experience pain, an association between the two can develop. In general, adherent bracing patients exhibited a higher fear of pain than non-adherent bracing patients. An explanation for the difference in scores may be due to the child's initial fear of pain. Although both groups may have a fear of pain, the adherent bracing cohort may be motivated to wear a brace more because of a heightened fear of pain. The non-adherent bracing patients may not be wearing their brace because they have a lower fear of pain compared with the adherent bracing patients. As a future direction with the FOPQ questionnaire, it would be of interest to investigate another measure that would elucidate the correlation between a child's fear of pain and how it affects his or her motivation to wear a brace.

PCS

The PCS questionnaire was divided into the subscales of rumination, magnification, and helplessness. A total score was calculated by combining the three subscale scores. Similar to the FOPQ questionnaire, an independent t-test did not produce any significance between the means of adherent and non-adherent bracing patients. However, also like the FOPQ questionnaire, when T-scores were calculated for each measure of the PCS, significance in all measures was observed. A T-score between 26 and 52 indicated severe catastrophizing of pain by the child. The range of T-scores for adherent bracing patients was between 48 and 50, with a total PCS score of 49.65. The range of T-scores for non-adherent bracing patients was between 49 and 53, with a total PCS score of 51.33. As indicated by the range and total PCS score, both groups of patients severely catastrophized their pain. There is an understanding that catastrophic thinking in relation to pain could be a potential risk factor for chronicity (Sullivan et al., 1995). In regard to this study, the severe catastrophizing of pain by a child could potentially lead to a chronic pain condition even without insult of surgery. The implications from this are that chronic pain, and even the condition of persistent postoperative pain, may begin before surgery. The psychological and emotional distress of children compulsively focusing on their pain, magnifying that pain in their minds, and ultimately feeling like they cannot remedy the pain, could have severely negative effects on their development. The combination of the results from the PCS questionnaire and connections between pain catastrophizing and chronic pain could indicate that although pain is most often treated with medication, it is only cured once it is eradicated from the mind. In general, non-adherent bracing patients tended to have a higher T-score than adherent bracing patients for the subscales (except helplessness) contained within the PCS. The difference in T-scores may be attributed to the mental fortitude of each group, in that adherent bracing patients are motivated by the fact that bracing will help them correct their scoliosis. As discussed earlier with the previous measures, self-confidence

may play a role in how children perceive themselves and how they feel about what their peers think. Since non-adherent bracing patients are not bracing and therefore not correcting their scoliosis, they may feel as if there is nothing that can be done for them. A future direction for the PCS questionnaire would be to further examine how catastrophizing pain contributes to the development of chronic pain in adolescents, as most research has been conducted in an adult population.

PedQL

The PedQL questionnaire was divided into four subscales of physical, emotional, social, and school. A summary psychosocial score was obtained by combining the emotional, social, and school subscales. Finally, a total score was calculated by combining all four of the subscale scores. The PedQL is reverse scored so that higher scores indicate a better health-related quality of life. Of all the subscales that were examined, the school subscale had the most difference between the two groups. The school subscale mean T-score difference between adherent and non-adherent bracing patients was more than 11 points. In all categories of the PedQL, adherent bracing patients exhibited a higher quality of life than the non-adherent bracing patients. In addition, the greatest difference in quality of life was seen in the school setting. This difference reinforces the ideas presented with the previously mentioned measures that adherent bracing patients may have relatively more self-confidence, particularly in what could be the most important of settings, the school. Since adolescents are formulating their own identities among their peers, especially in the school setting, having the

confidence to wear a brace in public may positively reinforce their outlook on their own lives. Once again, in the case of adherent bracing patients, it may not be so much that they are concerned about what others think of them, but more about what they are able to achieve while wearing their brace. In contrast, non-adherent bracing patients are concerned with what their peers think of them, leading them to not wear their brace and consequently increasing their anxiety about their scoliosis as well as the associated symptoms. Ultimately, we may see a type of divergence between adherent and nonadherent bracing patients. Adherent bracing patients are knowingly correcting their scoliosis, gaining self-confidence, and in essence creating a positive-feedback loop. In contrast, non-adherent bracing patients create a negative-feedback loop by knowingly not correcting their scoliosis, worrying more and more about what will happen in the future as their condition worsens, and losing their motivation to do anything about the situation.

QST

As a result of the underpowered nature of the QST data, no meaningful analysis was performed. It is hoped that more participant data can be collected in the future so that a comparison can be made between adherent and non-adherent bracing patients.

Conclusions

Since this study compared adherent bracing and non-adherent bracing patients in regard to their psychological and physical parameters, the preliminary data collected should be used to investigate the differences that exist between successful versus unsuccessful bracing patients. With the knowledge that bracing treatment has a high success rate in preventing children from undergoing surgical intervention, increasing the number of adherent bracing patients will be a priority in the shift to preventative medicine within the medical community. In addition, by further investigating and addressing the psychological factors that contribute to chronic pain, it may help in reducing the amount of resources spent in treating chronic pain by actually curing the condition. By using the measures in this study, chronic pain can ultimately be addressed in a two-pronged approach: first, preventing children from being put at risk for developing persistent postoperative pain due to surgery; and second, reducing the risk factors that are involved with a child developing chronic pain due to non-surgically related reasons.

For a future study, it would be of clinical value to investigate the following hypotheses:

- Adherent bracing patients who avoid surgical intervention experience better psychological and physical outcomes with respect to their non-adherent counterparts.
- (2) Non-adherent bracing patients are more likely to develop chronic pain regardless of surgical intervention for their scoliosis.

Limitations

This study presented some limitations which were often difficult to address. The number of participants in the study was underpowered; therefore, all results should only

be considered as preliminary. The overall recruitment strategy was successful, but it was difficult to get patients to come in for their QST after initial contact. In addition, many of the participants needed to be reminded multiple times by e-mail and phone call to complete their surveys. In this regard, increasing the dollar amount for each completed portion of the study might have provided more incentive. Finally, with more time, we would have had more participants in the study who completed their surveys and QST sessions.

Future Directions

The primary limitation of being an underpowered study will most likely be remedied by the passing of time and the recruitment of additional participants. Furthermore, the response rate by patients will increase dramatically by increasing the dollar amount for completing each portion of the study. Once meaningful data and trends have been identified from a larger participant group, the actual development and implementation of treatment strategies for factors identified should begin. The implications from successfully improving the adherence of children in bracing treatments are potentially an increase in the child's personal outlook as well as, on a larger scale, an increase in the socioeconomic benefits for the child's family and the associated healthcare system.

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Boston University - Division of Graduate Medical Sciences Boston, MA **M.S. Medical Sciences** Expected May 2015

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Experience

Boston Children's Hospital Boston, MA **Anesthesia Clinical Research Unit Intern Research Assistant to Christine Siebergy, PhD.** July 2014 – Present

- Examined the biopsychosocial parameters of persistent postsurgical pain in children undergoing spinal fusion or bracing protocol for treatment of adolescent idiopathic scoliosis.
- Performed quantitative sensory testing in pediatric patients to determine thresholds of sensitivity to mechanical, pressure, and thermal stimuli.
- Independently coordinated meeting times, survey distribution, and communications with patient and patient's family.

Salem Brain & Spine LLC

Student Shadow

- Performed a history and physical for new patients and presented patient to • physician.
- Interpreted MRIs of brain and spine.
- Observed and assisted in minor tasks during operations.
- Assisted with preparing patient charts to be signed off by physician.
- Took part in post-operational rounding and assessing progress of recovery. •

Salem, OR

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Scribes STAT

EMR EPIC Tutor

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- Individually worked with physicians to customize administrative documents used • for patient charts.
- Optimized workflows in EPIC specific to medical specialties.
- Provided on-call support to high volume departments.
- Assisted in training new hires on a one-on-one basis in specific departments. ٠

University of San Diego – Chemistry Department **Undergraduate Researcher** November 2009 – May 2011

- Synthesized small molecule and polymeric synthetic targets related to • antimicrobial materials.
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- Created presentations of updates on progress which was presented to the lab. •