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# Biomechanical Characterization of Semi-Rigid Constructs and the Potential Effect on Proximal Junctional Kyphosis in the Thoracic Spine

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#### Abstract

Long spinal fusions are the mainstay of treatment in adult spinal deformity; however, proximal junctional kyphosis (PJK) is a common and potentially catastrophic complication that can occur following this procedure. It has been hypothesized that using semi-rigid constructs at the superior aspect of the instrumentation may decrease this complication. The objective of this thesis was to determine if there is a biomechanical advantage between various semi-rigid constructs utilized in long spinal fusions to help decrease the risk of PJK. Nine human cadaveric spines  $(T1 - T12)$  instrumented with the standard all-pedicle-screw construct (APS) were compared to various semi-rigid constructs including sublaminar bands (SB), supralaminar hooks (SLH), transverse process hooks (TPH), and short pedicle screws (SS). Results demonstrated that TPH reduced motion at the junction between the instrumented and non-instrumented spine segments and had the most linear change in motion. In comparison, SLH and SS were found to have a high degree of stiffness. No differences were seen between APS and SB. Overall, semi-rigid constructs alter the biomechanics at adjacent levels. TPH provides the most gradual change in motion, which may reduce mechanical stress and decrease the risk of PJK.

# Keywords

Proximal junctional kyphosis, proximal junctional failure, adjacent level disease, semi-rigid constructs, adult spinal deformity, spinal fusion, thoracic spine, biomechanics

#### Summary for Lay Audience

Adult spinal deformity (ASD) is a disorder where the spine is abnormally curved which can cause symptoms such as back pain, leg pain, and weakness or numbness in the legs. It is a common condition, affecting approximately 8-13% of the adult population. Treatment for ASD includes physiotherapy, medications, and injections; however, if these treatments fail, surgery can be performed. This involves straightening the spine and fusing the vertebrae (the bony building blocks of the spine) together. In order to do this, screws are placed into the vertebrae and a long rod is attached on either side of the spine. This surgery has been shown to help alleviate symptoms associated with ASD and has become the mainstay of treatment for this condition. However, complications can occur after surgery. One such complication is called proximal junctional kyphosis (PJK). This occurs when the spine above the part that is fused collapses forward. Unfortunately, this can cause people to experience significant pain, they can have damage to the spinal cord and nerves, the screws and rods can break, and a second surgery may be needed to correct this.

One of the reasons PJK occurs is due to the very sudden change in the amount of movement between the fused part of the spine and the not fused part, which creates a lot of stress at the junction where they meet. To help decrease the risk of PJK occurring, semi-rigid instruments were created to be placed at this junction to allow a more gradual change in movement. This project looked into different types of these semi-rigid instruments to help determine if one is better than the other.

To do this, we completed a biomechanical study to assess how four different semi-rigid instrumentations effect movement of the spine. We used spines from people that had donated their bodies to research, which were then tested by moving them through many directions of motion and recording their movement for comparison. Overall, we found that several of the semi-rigid instruments did lead to a more gradual change in motion at the junction between the fused and not-fused spine. This information will help surgeons decide which semi-rigid instruments to use during surgery for ASD to help reduce the risk of developing PJK.

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#### Contributions

This thesis was made possible due to a team of individuals with diverse expertise. Contributions are as follows:

**Chapter 1**: Chloe Cadieux – sole author

**Chapter 2**: Chloe Cadieux – study design, data collection, data analysis, wrote manuscript; Renan Fernandes – study design, reviewed data analysis, reviewed manuscript; Pawel Brzozwski – study design, data collection, data analysis; Radovan Zdero – reviewed data analysis; Chris Bailey – reviewed data analysis, reviewed manuscript; Parham Rasoulinejad – study design, reviewed data analysis, reviewed manuscript

**Chapter 3**: Chloe Cadieux – study design, data collection, data analysis, wrote manuscript; Renan Fernandes - study design, reviewed data analysis, reviewed manuscript; Pawel Brzozwski – study design, data collection, data analysis; Radovan Zdero – reviewed data analysis; Chris Bailey – reviewed data analysis, reviewed manuscript; Parham Rasoulinejad – study design, reviewed data analysis, reviewed manuscript

**Chapter 4**: Chloe Cadieux – sole author



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## Chapter 1

# 1 INTRODUCTION

*This chapter provides a basic overview of relevant spinal anatomy, spinal disorders and associated treatments, as well as a literature review of pertinent instrumentation techniques.*

## 1.1 ANATOMY OVERVIEW

The human spine is a complex structure that provides integral function and support to the human body. The osseous and ligamentous features allow for multi-directional movement, maintenance of an upright posture, and protection of the spinal cord and neural elements. The bony anatomy of the spine consists of 33 vertebrae which are split into five distinct segments: cervical, thoracic, lumbar, sacral, and coccygeal. The vertebrae share many common features, with the majority of vertebrae being comprised of an anterior vertebral body and a posterior arch, linked together by two horizontal pillars called pedicles.<sup>1,2</sup> Projecting posteriorly from the pedicles, the posterior arch has several processes: a spinous process, bilateral transverse processes, and superior and inferior articular processes that form joints with adjacent vertebrae, called facet joints (Figure 1). Multiple ligamentous and soft tissue structures throughout the spine resist specific movements and provide stability.<sup>3</sup> However, each segment of the spine has its own unique characteristics, and the remainder of this thesis will focus on the thoracic spine.

The thoracic spine has several distinguishing features. It is the longest segment, including 12 vertebrae, and it is characterized by its kyphotic curvature. One of the most notable features is the association of the ribcage. The ribcage, and the associated costovertebral joints and ligaments, provide a strong stabilizing effect that is not present in other spinal segments. Previous biomechanical studies have illustrated this by demonstrating significant differences in range of motion (ROM) between thoracic spines with the ribs intact compared to those that have been disarticulated. 4,5 From a clinical perspective, the thoracic spine is frequently affected in spinal deformities in both the paediatric and adult populations.



#### **Figure 1: Thoracic Vertebrae**

A lateral (top) and axial (bottom) image of the thoracic vertebrae and its associated anatomy. The vertebral body sits anteriorly and is connected to the posterior processes by pedicles bilaterally. This forms a protective arch around the spinal cord, which sits in the spinal canal. In addition to the superior and inferior processes, which form joints with adjacent vertebrae, the thoracic vertebrae have additional articulations for attachments of the ribcage.

## 1.2 ADULT SPINAL DEFORMITY

Adult spinal deformity (ASD) is a heterogeneous disorder characterized by deformity in the sagittal and/or coronal planes leading to an imbalance of the spinal column (Figure 2). This complex disorder frequently occurs in the thoracic and lumbar spine with deformity defined by a spinal curve greater than 10° in the coronal plane or a sagittal imbalance greater than 5cm.<sup>6,7,8</sup> A broad spectrum of conditions falls under the umbrella of ASD, including De novo scoliosis, idiopathic scoliosis, iatrogenic deformity, hyperkyphosis, and more. It is thought that progressive and asymmetric changes result in degeneration of the disc and/or facet joints leading to pain and possible compression of neural elements. Patients with ASD present numerous ways; often with complaints of back pain, radiculopathy, or symptoms of stenosis. These symptoms can range from mild to severe, potentially with an inability to participate in activities of daily living. Studies have shown that ASD has a significant impact on quality of life, with patients scoring lower in all eight domains of the 36-Item Short Form Health Survey (SF-36) compared to the general population.<sup>8</sup> Although the historical incidence of ASD was thought to be between  $8 -$ 13%, it has more recently been documented at a higher frequency and is likely to continue to increase as the population ages. $9,10$ 

Treatment for ASD consists of both nonoperative and operative strategies, with nonoperative management generally applied as first-line treatment. <sup>6</sup> However, a lack of consensus exists on optimal nonoperative management. Evidence has shown that physical therapy, core strengthening, non-narcotic pharmacotherapy, and injections may provide adequate symptom management for mild symptoms.<sup>11,12</sup> Surgical intervention is

generally recommended for patients who have failed nonoperative management, have documented curve progression, or develop neurologic compromise. Surgery must be tailored to the specific pathology but may include procedures such as decompression, instrumented fusion, or osteotomies to correct the deformity. Currently, long posterior instrumentation and fusion is the mainstay of treatment. 10,11 This involves placing screws through the pedicles of the vertebrae and attaching a metal rod to these screws along both sides of the spinal column (Figure 3). This allows for intervertebral segmental stability and substantial corrective ability to address the deformity. Studies have demonstrated satisfactory patient outcomes with this procedure, such as decreased pain, increased function, and improved health-related quality of life (HRQOL) scores postoperatively. 12,13 However, the surgery is not without complications.

Complications following long posterior spinal fusions can be divided into patient-specific versus surgery-specific factors. Surgery-specific complications can be further subdivided into non-mechanical (dural tear, infection, etc.) and mechanical complications (screw pull-out, proximal junctional kyphosis, etc.).<sup>12</sup> While there is a plethora of literature on all types of complications, there is an increased interest in mechanical complications to help better optimize surgical equipment and technique. One mechanical complication in particular continues to plague surgeons and pose ongoing challenges: proximal junctional kyphosis (PJK).



#### **Figure 2: Adult Spinal Deformity**

Adult spinal deformity may involve deformity in the sagittal and/or coronal planes. These x-rays demonstrate a large curvature seen in the coronal plane (left) with increased kyphosis in the sagittal plane (right). The sagittal vertical axis (SVA) is drawn from the C7 vertebral body to the posterosuperior aspect of S1 (right), with a normal SVA being  $<$ 5 cm.



**Figure 3: Posterior Instrumentation and Fusion**

Posterior instrumented fusion is the mainstay of treatment for spinal deformities. These x-rays demonstrate a long posterior instrumented spinal fusion from T5-L3. The deformity correction and fusion is performed by placing pedicle screws into the vertebrae and connecting these with a metal rod, as seen above.

#### 1.3 PROXIMAL JUNCTIONAL KYPHOSIS

PJK is a common complication of long posterior spinal instrumentation and fusion, with an incidence ranging from  $6\%$  up to  $69.4\%$ .<sup>14,15,16</sup> It occurs when the vertebrae immediately cephalad to the instrumented segment collapses into a kyphotic deformity. It was initially described by Glattes et al. as a kyphotic deformity with a sagittal Cobb angle of greater than or equal to  $10^{\circ}$  and at least  $10^{\circ}$  greater than the preoperative measurements.<sup>14</sup> This angle is measured from a line from the inferior endplate of the most proximal vertebrae instrumented with pedicle screws, called the uppermost instrumented vertebrae (UIV), and a line from the superior endplate of the vertebrae two levels above that (UIV+2) (Figures 4 and 5). Although it's definition is based on radiographic measures, PJK can have substantial clinical implications. Most notably, it may progress to proximal junctional failure, resulting in events such as vertebral body fracture, subluxation, pain, neurologic deficits, and need for revision surgery.<sup>18</sup> Thus, PJK is a critical complication due to both its frequency and sequelae.



#### **Figure 4: Proximal Junctional Kyphosis Angle Measurement**

Proximal junctional kyphosis (PJK) is defined by a sagittal Cobb angle of  $\geq$ 10° and at least 10° greater than the preoperative radiograph measurements. This angle is measured by a line drawn from the inferior endplate of the uppermost instrumented vertebrae (UIV) and a line drawn from the superior endplate of the vertebrae two levels above the UIV as shown above.



#### **Figure 5: Proximal Junctional Kyphosis**

Hypermobility at the junction between the instrumented and non-instrumented spine is thought to lead to proximal junctional kyphosis (PJK). This lateral x-ray demonstrates PJK with the segment immediately above the uppermost instrumented vertebrae falling into an abnormal kyphosis. The kyphotic angle measures approximately 49°.

In order to help describe the severity of PJK, two classifications have been established (see Appendix A). The first was described by Yagi et al., which breaks down the mode of failure and the degree of kyphosis present.<sup>20</sup> While this classification system provides language to describe PJK, it does not guide management or assist with prognostication. Thus, a new classification system was developed by the International Spine Study Group to help address these gaps and guide treatment decisions.<sup>21</sup> This system assigns points to six different categories: neurological deficit, focal pain, instrumentation problem, change in kyphosis/posterior ligament complex integrity, fracture location, and level of UIV. Although studies are still being conducted to evaluate the utility of this classification, a score of  $\geq$ 7 is thought to indicate need for revision surgery.<sup>15,17,21</sup>

The etiology of PJK is likely multifactorial. It is hypothesized that the abrupt transition in relative motion between the instrumented segment, which is rigid, and the noninstrumented segment, which is flexible, may contribute to the development of PJK.<sup>17</sup> Several risk factors have been identified in the development and progression of PJK. Patient factors such as increased age (>55), high body mass index (BMI), osteoporosis, and smoking have been linked with increased incidence of PJK. 15,17 Radiographic features such as the degree of preoperative sagittal imbalance has also been identified as a risk factor. 15,17,18,22 Numerous surgical factors likely play a role as well. First, there appears to be several approach-related considerations in the development of PJK. For example, damage to the posterior soft tissues appear to increase the incidence of PJK. Although meticulous intraoperative dissection may help prevent this concern, structures may still be disrupted when placing pedicle screws for fixation. In addition to soft tissue

management, a combined anterior and posterior approach increases the risk three times compared with a posterior-only approach, possibly due to increased rigidity of concurrent anterior and posterior fixation.<sup>15,17,18</sup> Thus, a posterior-only approach is typically recommended when possible. Next, the level of the UIV may also affect the likelihood of PJK. While some argue that starting instrumentation in the upper thoracic versus lower thoracic simply changes the mode of failure, others have shown an increased incidence with the UIV placed lower in the thoracic spine.<sup>17,23</sup> Lastly, construct stiffness is thought to contribute to the development of  $PIK<sup>24</sup>$  All-pedicle-screw (APS) constructs are classically used in long posterior fusions; however, this creates a stiff lever arm that places significant biomechanical stress at the junction between the instrumented fusion and adjacent non-instrumented spine.<sup>18,25</sup> It has been hypothesized that using semi-rigid constructs to "top-off" the fusion construct may decrease the stress at this transition. In doing so, the goal is to create a more gradual change in motion from the rigid construct to the mobile spine and ultimately decrease the risk of PJK.

## 1.4 SEMI-RIGID CONSTRUCTS

Various semi-rigid constructs have been proposed to help decrease the risk of PJK, including tethers, sublaminar bands, laminar hooks, and transverse process hooks. Within the spine literature, there are promising results on the effectiveness of these constructs. For example, Helgeson et al. performed a multicentre retrospective study including 283 patients who underwent posterior instrumentation with either APS constructs versus a construct with proximal hooks and found significantly higher rates of PJK with the APS construct.<sup>26</sup> These results were further supported by Kim et al.<sup>27</sup> Additionally, sublaminar tapes were investigated by Viswanathan et al. in 40 patients and found reduced incidence of PJK (0%) compared to APS constructs (8%). This study also assessed patient outcomes and reported significantly improved scores in the group with sublaminar tape.<sup>28</sup> Another construct that has been utilized is the transverse process hook. Both Hassanzadeh et al. and Yagi et al. demonstrated significantly lower rates of PJK in patients with this construct compared to patients with the APS construct.<sup>20,29</sup> However in contrast, two other studies found no difference in PJK incidence between APS and transverse process hook constructs.<sup>30,31</sup> Finally, numerous studies looked into tethers. The tethers were typically made of Mersilene tape and placed in various configurations and degrees of tension. Although multiple studies demonstrated significant differences in PJK rates between APS and tethered constructs, these results were not universal.<sup>32,33,34</sup> Furthermore, the ideal tension and configuration of these constructs remain unclear.

While there are encouraging results in many of the above studies, it is important to consider potential disadvantages to these constructs. First, increased exposure may be required for application of semi-rigid constructs as they are placed one level above the standard instrumentation. Furthermore, it is possible that the level instrumented with a semi-rigid construct could eventually fuse. As semi-rigid constructs are designed to allow for motion, a fusion would decrease the benefit of the construct. However, PJK typically occurs early in the post-operative period, whereas a fusion occurs much later; thus, these constructs would provide benefit during the most crucial period. 18,20

Overall, while there are encouraging results in many of the above studies, the clinical research remains inconsistent. Small sample sizes and short-term follow-up may also affect the quality of the evidence on semi-rigid constructs, necessitating further research into the area. In addition to clinical studies, biomechanical studies can provide important insight into the effects of these constructs as their utility is not yet fully understood.

## 1.5 BIOMECHANICAL RESEARCH

Although it has been postulated that semi-rigid constructs may help prevent PJK in long instrumented spinal fusions, it remains unknown if there is a biomechanical superiority to any one of the constructs that have been utilized. Although the literature is not robust, various biomechanical studies have explored the use of semi-rigid constructs placed at the proximal aspect of an instrumentation fusion compared to the standard APS construct.

Prior to further discussion of the literature, it is important to understand the nomenclature used to describe the levels of instrumentation in the majority of biomechanical studies.<sup>35-</sup>  $40$  In general, the most crucial levels to consider are the UIV, UIV+1, and UIV+2. The UIV is defined by the uppermost vertebrae that is instrumented with standard pedicle screws, UIV+1 is the level immediately cephalad where semi-rigid constructs are placed, and UIV+2 has no instrumentation. The rationale for this terminology is best explained by considering the vertebral levels that are involved in the fusion, with the UIV as the last vertebrae included. As semi-rigid constructs are designed to allow for movement, they are not a part of the fusion; instead, they are used to "top-off" the fusion construct. Thus,

semi-rigid constructs are applied at the UIV+1 to help create a smooth transition from the rigid fusion (UIV) to the mobile spine (UIV+2).

#### 1.5.1 TRANSVERSE PROCESS HOOKS

Throughout biomechanical studies, transverse process hooks are widely used. Although one study did not find significant differences between these hooks and APS constructs, many others found positive results.<sup>41</sup> For example, Thawrani et al. and Facchinello et al. both utilized porcine spines to demonstrate significant differences in ROM between the hook and APS constructs.<sup>42,43</sup> They concluded that transverse process hooks provide a more gradual motion transition, which was later supported by a recent human cadaveric study.<sup>36</sup> A finite element analysis by Brummond et al. added to the evidence and found transverse process hooks resulted in decreased pressure within the intravertebral disc at adjacent levels, suggesting that using hooks may reduce mechanical stress.<sup>45</sup>

#### 1.5.2 LAMINAR HOOKS

Mixed results have been found with laminar hooks, with one study demonstrating a beneficial effect toward gradual motion and the other showing no difference from APS.<sup>35,46</sup> In the latter, the authors hypothesized that laminar hooks likely came in contact with the superior lamina to create a blocking effect, leading to stiff motion segments.<sup>37,46</sup>

#### 1.5.3 SUBLAMINAR BANDS

Another popular choice of instrumentation are sublaminar bands, which appeared to provide a protective effect against PJK. Lange et al. tested six different constructs in eight calf lumbar spines and concluded that sublaminar bands reduced ROM to approximately 40% compared to other implants. From this, they hypothesized that these implants were likely the best option for obtaining a smooth transition of motion.<sup>46</sup> Additionally, Viswanathan et al. found that using sublaminar bands decreased ROM at the adjacent vertebral level while also reducing intervertebral disc pressure, suggesting a gradual transition of motion and decreased mechanical stress. <sup>38</sup> Doodkorte et al. supported these results in their study of seven human thoracolumbar spines. This group compared 1- and 2-level sublaminar tapes that were secured to the rod by either a clamp or knot. They found that all the variations extended transitional zone over multiple segments, except for the 2-level clamped band, which acted similar to the APS construct.<sup>36</sup>

#### 1.5.4 TETHERS

Different configurations of tethers have been trialled across studies with variable success. In several studies, significant differences in ROM were reported in flexion and extension but not in lateral bending or axial rotation; likely due to the fact that they are applied in the sagittal plane.<sup>46</sup> Furthermore, studies by Mar et al. suggest the effect of tethers were directly correlated with the degree of pretension, while other studies noted no significant differences between hand-tied and tensioned tethers. 46,47,48 Thus, as the literature remains inconclusive, further research is required.

## 1.6 THESIS RATIONALE

Long spinal instrumented fusion is the mainstay of treatment for ASD; however, complications such as PJK may lead to poor outcomes, neurologic deficits, and revision surgery. As an abrupt change in motion at the junction between the instrumented and non-instrumented spine segments is thought to contribute to the risk of developing PJK, it is hypothesized that creating a "smooth transition" in motion across the junction may decrease the risk. Thus, semi-rigid constructs have been developed for this purpose.

As highlighted above, several clinical and biomechanical studies have investigated these constructs; however, to our knowledge, no study compares these commonly cited constructs directly in human thoracic spines. Some studies have compared laminar hooks to bands; however, they did not include transverse process hooks. <sup>45</sup> Similarly, one study compared variations of sublaminar bands to transverse process hooks but did not include supralaminar hooks.<sup>36</sup> Furthermore, vastly different protocols utilized between studies make inter-study comparison difficult. Thus, this thesis aims to perform a head-to-head comparison between multiple types of semi-rigid constructs to assess the biomechanical differences and how this relates to PJK and adjacent level disease. It is hypothesized that all semi-rigid constructs will lead to decreased ROM at the junctional level. However, based on previous clinical and biomechanical data, it is expected that transverse process hooks and sublaminar bands will provide the most gradual transition in motion.

# Chapter 2

# 2 METHODS

*This chapter provides an overview of the materials and methodology utilized for this thesis.* 

# 2.1 CONSTRUCT SELECTION

A systematic review was previously completed to determine commonly used semi-rigid constructs.49 Using this information, four constructs were chosen for this thesis (Figure 6). Most of the constructs selected (transverse process hooks, supralaminar hooks, and sublaminar bands) have been shown to be associated with decreased rates of PJK in clinical studies, as well as provide a more gradual change in motion in biomechanical studies. In addition, short pedicle screws (SS) were selected as they had previously been used clinically at the London Health Sciences Centre (LHSC); however, there were no studies identified that included this construct. All constructs were available at the study institution.

## 2.2 CADAVER PREPARATION

Prior to the onset of the study, approval was granted from the Institutional Research Ethics Board (ID 118078). Twelve full spine cadaveric samples were purchased through Science Care, a donor organization that provides cadavers for medical education and research. All specimens included non-identifiable information regarding their medical history, cause of death, sex, and age. All specimens were stored in a -20° freezer before use.



## **Figure 6: Semi-Rigid Constructs**

The following semi-rigid constructs were selected for use: sublaminar bands (A), short pedicle screws (B), supralaminar hooks (C), and transverse process hooks (D).

Full cadaveric specimens were then subject to a Computed Tomography (CT) scan to rule out bone tumours, fractures, or any internal bony abnormalities. The spines were scanned using a GE Lightspeed VCT 64 slice CT Scanner with a slice thickness of 0.625mm. The protocol used for clinical complete spine imaging at LHSC was followed. All soft tissues were kept intact during the scanning process. Once complete, the specimens were sectioned into cervical, thoracic, and lumbosacral segments. Sectioning was carefully completed through the intervertebral disc space in order to preserve bony structures. For this study, the isolated thoracic spine (T1-T12) was selected for use.

Once specimens were evaluated by CT scan, medical history, and visual inspection, three specimens were excluded from use in the current study. One specimen was excluded due to a history of a primary bone disorder (Paget's disease), one was excluded due to irregular vertebral body anatomy, and one was excluded due to a significant spinal deformity. Thus, a total of nine specimens were included in the study. The average age of the donors was 63.8 years. The demographics of these specimens can be found in Table 1.

### **Table 1:**

# *Cadaveric Specimen Demographics*



Next, the specimen were cleaned and prepared for testing. All specimen were thawed for at least 24 hours prior to preparation and testing. The majority of the musculature was dissected off of the specimen and care was taken to leave the facet capsules, posterior ligamentous complex, and costovertebral joints intact. The most cranial (T1) and caudal (T12) vertebrae were then potted in cement with the endplates parallel to the ground, which was accomplished using a laser level (Figure 7). Several drywall screws had been drilled into the vertebrae prior to potting to increase fixation. The native spine was then tested prior to any instrumentation according to the testing protocol described in Section 2.4.



**Figure 7: Preparation of Cadaveric Specimen**

Complete cadaveric thoracic spines  $(T1 - T12)$  were cleaned by dissecting off musculature and potted into cement at both the cranial (T1) and caudal (T12) ends of the spine.

#### 2.3 INSTRUMENTATION

A multi-level pedicle screw fixation was performed from T6 – T9, making T6 the UIV. The start point for the pedicle screws was identified based on anatomical landmarks previously described and placed free hand as per standard surgical technique.<sup>50</sup> The screw track was examined for breaches using a pedicle probe, rotating the probe in a stepwise progression around 360°. The depth of the track was then measured, and an appropriate length of screw was chosen, ranging from 35mm to 45mm. The pedicle screws were inserted by hand with care taken to maintain a constant angle and speed until the screw was seated.

Further instrumentation occurred in a semi-random order using a ladder formation, with no specimen undergoing the same sequence (Table 2). All semi-rigid constructs were placed at T5 (UIV+1) (See Figures 8 and 9). Specimen were subjected to testing immediately following instrumentation of a construct prior to placement of the next construct. Instrumentation of each construct was completed as described in the steps below:

- All-pedicle-screw (APS): A titanium 5.5mm rod was attached to the pedicle screws, spanning  $T6 - T9$ .
- Transverse process hook (TPH): A scalpel was used to reveal the edge of the transverse process and create space between the transverse process and rib head. The hooks were then placed at the midpoint on the transverse process bilaterally. Once secured, the rod was attached to the TPH.
- Sublaminar band (SB): A 5mm Mersilene® tape (Ethicon, Sommerville, NJ) was utilized, as previously described in the literature.<sup>38,47,48</sup> A hemilaminectomy was performed on the superior lamina with a Kerrison bone punch. A suture needle attached to the band was then passed under the T5 lamina and retrieved at the cranial edge. The needle was cut off, and the band was looped around the rod. Two square knots were thrown, followed by three half-hitches with the final on an alternating post.
- Supralaminar hook (SLH): In order to facilitate placement of the supralaminar hook, a hemilaminectomy of the superior lamina was performed using a Kerrison bone punch. The ligamentum flavum was removed from the cranial edge of the T5 lamina. Hooks were then placed over the cranial edge of the lamina bilaterally and attached to the rod.
- Short pedicle screw (SS): Screws were placed using the same sequence of steps described for the multi-level fixation; however, screw length and size were standardized to a 5.5mm diameter, 25mm pedicle screw. A rod was then attached to the pedicle screws.
## **Table 2**

## *Semi-Random Testing*



*Note: A sequence for instrumentation was generated, with subsequent specimen undergoing a different sequence using a ladder formation as shown in the table below. A new sequence was generated once the ladder was complete.* 



#### **Figure 8: Instrumentation of Semi-Rigid Constructs**

Semi-rigid constructs were instrumented at the level of T5. Transverse process hooks (TPH) were placed on the transverse process (A), short pedicle screws (SS) were placed into the pedicle and vertebral body (B), sublaminar bands (SB) were placed around the lamina (C), and supralaminar hooks (SLH) were placed over the lamina (D).



**Figure 9: Cadaveric Instrumentation of Semi-Rigid Constructs**

Thoracic spine cadavers instrumented with semi-rigid constructs at the level of T5, connected to the multi-level fixation from T6 – T9. Constructs include: TPH (A), SS (B), SB (C), and SLH (D).

## 2.4 TESTING PROTOCOL

The potted spines were then mounted onto a testing machine with custom-design modifications (Instron® 5967, Norwood, MA, USA) (Figure 9). Loads were individually applied in axial rotation, flexion-extension, and lateral bending according to a pure moment protocol. Non-destructive controlled motion of 1°/second was applied until a load limit of 5Nm was reached, based on previous protocols.<sup>51</sup> Each test was repeated for three cycles, with the first two cycles used for preconditioning and data from the third cycle used for motion analysis. Testing was completed over approximately six hours per specimen.

ARAMIS Adjustable 12M system (GOM Metrology, Braunschweig, Germany) was used as a digital imaging camera (DIC) system to track intersegmental motion between vertebrae. Two cameras with a focal length of 24mm and resolution of 4096-by-3600 pixels (pixel size of 3.45 µm) were used. The cameras were set at a 25˚ angle, 3 Hz, and illuminated with two polarized LED light sources. Prior to each test, the DIC setup was calibrated using a standard calibration protocol and calibration plate provided by GOM Metrology for a measuring volume of 570-by-430-by-430 mm<sup>3</sup>. Images were then processed in ARAMIS Professional 2019 (GOM Metrology, Braunschweig, Germany).

## 2.5 STATISTICAL ANALYSIS

SPSS statistical software  $(v27)$  was used for analysis. Each specimen acted as its own control. Statistical significance was established at  $\leq 0.05$ . Data was normalized to account for inter-specimen variation and was calculated by dividing by the ROM of the native state. Normalized ROMs were analyzed using a one-way analysis of variance (ANOVA) to compare the ROM of the intersegments for each construct. Stiffness (K) was calculated using the formula K= $\Delta M/\Delta ROM$ , where  $\Delta M$  and  $\Delta ROM$  is the difference in the moments and ROM between points, respectively. A linear regression analysis was completed for levels T3 – T7. These levels were selected to highlight the transitional segments from T4 – T6. Linearity was expressed through the coefficient of determination  $(R^2)$ , with a value approaching 1.00 indicating a high linear correlation.



### **Figure 10: Biomechanical Testing Set-Up**

The complete thoracic spine was mounted onto the custom table-top testing machine (Instron) and secured to the top and baseplates. Loads were applied in all planes of motion and an optical tracking system monitored intersegmental motion.

## Chapter 3

# 3 RESULTS

*This chapter details the results of the biomechanical testing. All specimens (n = 9) underwent three cycles of testing. All tests were completed successfully. When reviewing the below results, it is important to recall that T6 is the UIV (i.e. last vertebrae instrumented with a standard pedicle screw), whereas the semi-rigid constructs (SB, SLH, SS, and TPH) are instrumented at T5 (UIV+1).*

# 3.1 RANGE OF MOTION

The distribution of data (median and interquartile range) can be seen in Figures  $10 - 12$ . Mean normalized ROMs are reported as a percentage of the native state ROM and are displayed in Figures  $13 - 15$ . In flexion-extension, there were no significant differences in ROM between APS and SB at any level. In contrast, SLH  $(M = 11.48, SD = 26.61, p <$ .001), SS ( $M = 18.03$ ,  $SD = 10.94$ ,  $p < .001$ ) and TPH ( $M = 50.06$ ,  $SD = 27.64$ ,  $p < .001$ ) were all found to have significantly reduced ROM compared to APS ( $M = 116.90$ ,  $SD =$ 26.61) at the level of T5 – T6. Additionally, SLH and SS were also significantly reduced compared to TPH ( $p = .006$ ,  $p = .03$ , respectively). At T4 – T5, SLH was found to have significantly reduced ROM ( $M = 30.69$ ,  $SD = 19.62$ ) compared to all other constructs. Flexion and extension were then separated as isolated movements, as seen in Figure 16. In both isolated flexion and extension, similar results were found. SLH, SS, and TPH were found to have significantly reduced ROM at T5 – T6 compared to APS and SB, while SLH was found to have significantly reduced ROM at  $T4 - T5$  compared to all other constructs.

In lateral bending, a similar pattern was found. Significantly reduced motion was seen with SLH ( $M = 23.19$ ,  $SD = 15.04$ ,  $p < .001$ ), SS ( $M = 22.39$ ,  $SD = 8.68$ ,  $p < .001$ ), and TPH ( $M = 45.03$ ,  $SD = 22.69$ ,  $p < .001$ ) compared to APS ( $M = 105.11$ ,  $SD = 18.59$ ) at T5 – T6. Furthermore, SLH ( $p = .04$ ) and SS ( $p = .03$ ) had significantly lower ROM compared to TPH at T5 – T6. At T4 – T5, SLH ( $M = 70.46$ ,  $SD = 13.63$ ) was significantly reduced compared to all other constructs. No significant differences were found between APS and SB.

In axial rotation, SLH (*M* = 38.42, *SD* = 17.24, *p* < .001), SS (*M* = 31.38, *SD* = 13.06, *p* < .001), and TPH ( $M = 47.81$ ,  $SD = 21.38$ ,  $p < .001$ ) had significantly reduced ROM compared to APS ( $M = 101.92$ ,  $SD = 9.01$ ) at T5 – T6. No significant difference was found between APS and SB. SLH  $(M = 48.78, SD = 18.73)$  was again found to have significantly lower ROM than all other constructs at T4 – T5.

There were no significant differences between constructs at the levels above T4. Similar ROM was found throughout the fused segments  $(T6 - T9)$  for all conditions with no significant differences seen. As all significant changes in motion occurred between levels T4 – T6, this was defined as the "transition zone". All absolute values (mean and standard deviation) for the transitional levels can be found in Appendix B**.**

#### **Flexion-Extension**



### **Figure 11: Distribution of Data in Flexion-Extension**

Boxplots indicate median and interquartile range from T4 – T7. Constructs include: allpedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH).



### **Figure 12: Distribution of Data in Lateral Bending**

Boxplots indicate median and interquartile range from T4 – T7. Constructs include: allpedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH).



### **Figure 13: Distribution of Data in Axial Rotation**

Boxplots indicate median and interquartile range from T4 – T7. Constructs include: allpedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH).



**Figure 14: Normalized Range of Motion in Flexion-Extension**

Line graphs indicate normalized mean ROM from T3 – T7. Constructs include: allpedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). \* = Significant difference from APS and SB, \*\* = Significant difference from APS, SB, and TPH, \*\*\* = Significant difference from all constructs.



**Figure 15: Normalized Range of Motion in Lateral Bending**

Line graphs indicate normalized mean ROM from T3 – T7. Constructs include: allpedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). \* = Significant difference from APS and SB, \*\* = Significant difference from APS, SB, and TPH, \*\*\* = Significant difference from all constructs.



**Figure 16: Normalized Range of Motion in Axial Rotation**

Line graphs indicate normalized mean ROM from T3 – T7. Constructs include: allpedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). \* = Significant difference from APS and SB, \*\* = Significant difference from APS, SB, and TPH, \*\*\* = Significant difference from all constructs.







Line graphs representing normalized mean ROM in flexion (A) and extension (B) as isolated directions of motion. Constructs include: all-pedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). \* = Significant difference from APS and SB, \*\* = Significant difference from APS, SB, and TPH, \*\*\* = Significant difference from all constructs.

## 3.2 STIFFNESS

The stiffness of each construct was calculated and compared using average normalized values from the entire thoracic spine  $(T1 - T12)$ . Normalized values were utilized to limit the inherent variation between specimens. Mean stiffness values are reported in Newtonmetres per degree (Nm/º). In all directions of motion, SLH was found to have maximal stiffness. In flexion-extension, SLH was found to have the highest degree of stiffness (*M*  $= 148.66$ , *SD* = 31.94) as compared to APS (*M* = 120.24, *SD* = 17.21), as seen in Figure 17. Significant differences were found between the overall stiffness of SLH compared to the native spine ( $p < .001$ ). Additionally, SS ( $M = 137.32$ ,  $SD = 27.19$ ) and the native spine were significantly different ( $p = 0.016$ ). In lateral bending, the greatest degree of stiffness was seen with SLH  $(M = 137.72, SD = 15.55)$ . This was significantly different than both APS ( $M = 116.8$ ,  $SD = 12.33$ ,  $p = .026$ ) and SB ( $M = 117.8$ ,  $SD = 13.18$ ,  $p =$ .037) (Figure 18). Finally, SLH was the stiffest in axial rotation (*M* = 156.25, *SD* = 12.62). It was significantly stiffer than APS (*M* = 126.01, *SD* = 5.27, *p* < .001) and SB (*M*  $= 127.52$ , *SD* = 6.51, *p* < .001) and TPH (*M* = 137.88, *SD* = 12.19, *p* < .001). Furthermore, SS ( $M = 141.80$ ,  $SD = 10.09$ ) was found to be significantly stiffer than APS

 $(p = .006)$ . All constructs had significantly increased stiffness as compared to the native spine in axial rotation (Figure 19).



#### **Figure 18: Stiffness in Flexion-Extension**

Columns represent stiffness calculated using average normalized ROM values in flexionextension. Each error bar is constructed using a 95% confidence interval of the mean. Constructs include: all-pedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). Bars denoted by a



### **Figure 19: Stiffness in Lateral Bending**

Columns represent stiffness calculated using average normalized ROM values in lateral bending. Each error bar is constructed using a 95% confidence interval of the mean. Significance was set to p=0.05. Constructs include: all-pedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). Bars denoted by a common letter indicates no significant difference between constructs.



### **Figure 20: Stiffness in Axial Rotation**

Columns represent stiffness calculated using average normalized ROM values in axial rotation. Each error bar is constructed using a 95% confidence interval of the mean. Significance was set to p=0.05. Constructs include: all-pedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH). Bars denoted by a common letter indicates no significant difference between constructs.

# 3.3 LINEAR REGRESSION

A linear regression model was created from T3 – T7. Average absolute values were used. All  $\mathbb{R}^2$  values can be found in Table 2. The linear regression yielded higher  $\mathbb{R}^2$  values for TPH, SS, and SB constructs compared to APS in all directions of motion. More specifically, TPH was found to have the highest  $R^2$  values across all constructs (flexionextension, 0.999; lateral bending, 0.980; axial rotation, 0.986) compared to APS (flexionextension, 0.745; lateral bending, 0.945; axial rotation, 0.669).

### **Table 3**

#### *Linear Regression Coefficient of Determination (R2 )*



*Note: A linear regression analysis of ROM was performed from T3 – T7, with R2 values displayed below, for flexion-extension (A), lateral bending (B), and axial rotation (C). Constructs include: all-pedicle screw (APS), sublaminar band (SB), supralaminar hook (SLH), short pedicle screw (SS), and transverse process hook (TPH).*

## Chapter 4

# 4 DISCUSSION AND FUTURE DIRECTIONS

*This chapter includes a summary and discussion of the results presented, limitations of the study, and suggests directions for future biomechanical and clinical research.*

## 4.1 DISCUSSION AND SUMMARY

Long posterior instrumentation and fusion is the mainstay of treatment for ASD. The standard technique for this procedure involves using pedicle screws spanned by a long rod for fusion.<sup>52,53</sup> However, this creates a rigid lever arm that places mechanical stress on adjacent vertebrae. It is thought that the stress and hypermobility experienced at the levels cephalad to the fusion construct may increase the risk of developing PJK postoperatively.54 This is an important complication to consider as it can lead to poor patient outcomes, revision surgery, and increased healthcare costs.<sup>9,55</sup> Due to the gravity of this complication, strategies to reduce the risk of PJK have been explored, such as the use of semi-rigid constructs. It is hypothesized that using semi-rigid constructs at the proximal aspect of instrumentation may lead to a smoother transition between the long rigid fusion and the mobile spine.

This study demonstrated that several semi-rigid constructs reduced ROM over the transitional levels. In particular, SLH, SS, and TPH were found to decrease ROM at UIV+1, while SLH was found to significantly decrease ROM over both UIV+1 and UIV+2. Although at first glance it may appear beneficial that SLH decreased motion over two levels, these results should be assessed critically. Looking further into this, SLH resulted in a small amount of motion occurring at UIV+2; however, a substantial amount occurred at UIV+3. In other words, there was a large increase in motion between UIV+2 and UIV+3. This was even more pronounced when analyzing isolated flexion and extension. For example, in extension, SLH reduced motion to 24.50% at T4 – T5, but climbed to 105.23% at T3 – T4. This raises the question that SLH simply shifts the abrupt change seen with APS to a higher level, rather than gradually changing across levels.

To help better understand this transition, a linear regression was performed. These results showed a nonlinear change in motion with SLH; thus, it can be hypothesized that the transition in motion was not gradual. In comparison to the literature, Metzger et al. found that SLH did produce a gradual change; however, the authors reported ROM from just UIV to UIV+2, at which point only 40% of intact motion was achieved.<sup>37</sup> Consequently, it is possible that a large increase in ROM may have occurred at UIV+3, but was not captured in their results. In other studies, SLH was found to have comparable stiffness to APS.<sup>45</sup> To explain this, the authors suggested that the hooks likely came into contact with the superior lamina. This contact would subsequently block motion at adjacent levels, most notably in extension. This theory is of particular interest to the current study, as the most extreme reduction in ROM occurred with SLH in extension. Hence, it is possible that this phenomenon occurred. Unfortunately, this reduction in extension could have negative clinical consequences as it may lead to a greater degree of kyphosis at the adjacent level.

In comparison, TPH was found to reduce motion at adjacent levels, but was not as stiff as SLH. This mirrors the results of previous biomechanical studies, which have demonstrated a gradual change in motion with TPH as compared to APS.<sup>36,42,43</sup> In one of these studies, Doodkorte et al. compared TPH, APS, and various configurations of sublaminar tape and found TPH had the highest  $R^2$  value amongst all constructs.<sup>36</sup> The present study found similar results, indicating that motion increased progressively in a linear fashion. It should be noted that comparing the  $R^2$  values alone does not necessarily provide meaningful information, but in combination with ROM and stiffness analyses, further insight is gained on how the constructs affect motion. From a clinical perspective, several studies have shown decreased rates of PJK with TPH compared to APS constructs. It is suggested that the more limited dissection required for application of these hooks may contribute to their success and possibly increase stability at adjacent levels, as compared to pedicle screws. 29,54

Other semi-rigid constructs investigated included SS and SB. In this study, SS was found to have similar levels of stiffness compared to SLH in all directions of motion. Furthermore, with the exception of SLH, it significantly decreased ROM compared to all constructs. Although it was hypothesized that using a shorter length of pedicle screw may be more flexible, the current study did not support this. It is possible that the rigidity seen with SS may be secondary to the length of the pedicle screw chosen, as a 25 mm screw may result in 3-column fixation and act similar to a standard pedicle screw. To our knowledge, no other study has included SS; however, a study out of Turkey found that leaving two screw threads out of the cortex at the UIV led to a more gradual change in

motion as compared to fully seated screws.<sup>55</sup> While this thesis does not support the use of SS as a semi-rigid construct, future studies could be considered using modifications to pedicle screws and their length.

SB was not significantly different than APS in stiffness or ROM. This could be explained by the tension on the bands when applied. Although previous studies utilized hand-tied bands, others used industrial products (ex. Universal Clamp®, Zimmer Biomet, Indiana, USA) or custom-made tensioning devices to secure them.<sup>36,39,45</sup> The use of these tools likely results in a higher degree of tension compared to hand-tying, which may lead to a greater ability to reduce ROM. This theory is supported by a biomechanical study by Mar et al. that used cadaveric functional spine units (FSU) to study spinous process tether pretension, and found that the degree of tension applied significantly affected ROM.<sup>47</sup> Although their protocol differed from the current study, as they utilized spinous process tethers on a FSU, the principles may still be applicable. Ultimately, while the present study did not find that SB resulted in a gradual change in motion, it is possible that this was due to the method in which they were applied. Future studies could consider the use of a custom-tensioning device to ensure fair comparison.

While there are many variations of constructs that have been included in the literature, this thesis focused on commonly cited constructs. However, it should be noted that posterior tethers were not selected as a construct, despite their popularity elsewhere. As placement of these tethers requires disruption to the posterior ligamentous complex, it is possible that their application could affect the integrity of the specimen for the remainder of testing.56-58 Therefore, they were not selected to ensure appropriate testing conditions for other constructs.

### 4.2 LIMITATIONS AND FUTURE DIRECTIONS

This thesis provides further insight into semi-rigid constructs and their application to decrease the risk of developing PJK postoperatively. However, it was not without limitations. First, there was a small sample size due to the use of cadavers, which could affect statistical analysis. However, the sample size used was deemed appropriate for the goal of this thesis as it followed recommendations for biomechanical spine research.<sup>51,59</sup> Furthermore, the size was in keeping with previously published biomechanical studies that investigated semi-rigid constructs. With that being said, larger studies could be performed in the future.

Next, the quality of the cadaveric soft tissues must be considered. For example, paraspinal musculature is thought to play a role in the development of PJK; however, in this protocol, paraspinal muscles were dissected off of the cadaveric specimens in order to facilitate instrumentation and testing, which ultimately may not reflect in-vivo conditions.60 Additionally, the posterior ligamentous complex could be disrupted with repetitive testing over time. Since this complex is thought to be crucial in protecting against PJK, it is possible that results could be affected if damage occurred.<sup>56,57</sup> In order to mitigate this potential concern, instrumentation was completed in a semi-random order.

Finally, T3 or T4 is typically selected for semi-rigid instrumentation in a clinical setting, whereas this protocol selected T5. This was done to ensure that ROM could be measured at least two levels above, while leaving sufficient room for the most proximal vertebrae to be potted. Although this was a pragmatic decision based on available resources, it is still supported by biomechanical studies that have suggested upper thoracic spine segments  $(T1 - T6)$  have similar kinematics, which differs from the lower thoracic spine.<sup>61</sup> Furthermore, there is limited research on semi-rigid instrumentation in the upper thoracic spine, despite PJK commonly occurring in this region.<sup>62</sup> To our knowledge, only one other biomechanical study has selected the UIV/UIV+1 between  $T1 - T6$ .<sup>41</sup> Therefore, this protocol provides valuable insight into the use of semi-rigid constructs in the upper thoracic spine, despite the difference in the level of the UIV/UIV+1 from clinical practice. Additionally, no other study was identified that included the entire thoracic spine, with the costovertebral joints intact, which may better reflect physiologic conditions.63

This study adds novel information to the current body of literature on semi-rigid constructs and PJK. Future biomechanical studies should be considered to compare the failure mechanism of various semi-rigid constructs, as this could not be addressed in the current study. In addition, clinical studies should be completed to help better understand the effects of semi-rigid constructs on adjacent level disease and PJK.

## 4.3 CONCLUSIONS

Semi-rigid constructs have been proposed as a method to decrease the risk of PJK following long spinal fusions. This biomechanical study supports previous research that demonstrates semi-rigid constructs can decrease ROM at adjacent levels and possibly provide a more gradual change in motion. In particular, consistent results have been seen with TPH across numerous studies.<sup>36,42,43</sup> As it is currently believed that hypermobility at the transition between the instrumented and non-instrumented spine is a risk factor for PJK, it can be hypothesized that TPH may help decrease the risk of PJK by reducing motion and mechanical stress at this junction. In contrast, although SLH substantially decreases ROM, it may lead to increased stress at superior levels. Overall, this study provides spine surgeons with a direct biomechanical comparison of commonly used semi-rigid constructs and suggests that TPH is best able to provide a smooth transition in motion. Therefore, TPH should be considered over other constructs to top-off long rigid spinal fusions to help decrease the risk of PJK. By reducing this risk, patients may have improved outcomes with fewer revision surgeries required; subsequently reducing the morbidity and economic burden associated with PJK.

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# Appendices

## *Appendix A: Classification Systems*

### **Table 4**

*Classification of Proximal Junctional Kyphosis Described by Yagi et al.* 



#### **Table 5**

Parameter	Qualifier	<b>Severity Scale</b>
Neurologic deficit	None	$\boldsymbol{0}$
	Radicular pain	$\overline{2}$
	Myelopathy	4
Focal pain	None	$\overline{0}$
	VAS $<4$	1
	VAS $\geq$ 5	3
Instrumentation problem	None	$\overline{0}$
	Partial fixation loss	
	Prominence	
	Complete fixation loss	$\overline{2}$
Change in kyphosis	$0-10^{\circ}$	$\overline{0}$
	$10 - 20^{\circ}$	1
	$>20^\circ$	2
	Posterior ligamentous complex failure	$\overline{2}$
Vertebral fracture	None	$\boldsymbol{0}$
	Compression fracture	1
	Burst/chance fracture	2
	Translation	3
Level of uppermost instrumented vertebrae	Thoracolumbar junction	$\overline{0}$
	Upper thoracic spine	1

*Hart – International Spine Study Group Proximal Junctional Kyphosis Severity Scale*

*Note: This scoring system was designed to help guide treatment decisions, with a score* 

³*7 indicating a need for revision surgery.*

#### **Table 6**

#### *Mean Absolute Range of Motion and Standard Deviation (SD)*



*Note: ROM for each vertebral level was recorded and intersegmental motion (i.e. T3 –*

*T4) was subsequently calculated from absolute values. All values are reported in degrees.*