## THE IMPACT OF TRUNK DEFORMITY ON SHOULDER MECHANICS AND IMPLICATIONS FOR UPPER EXTREMITY FUNCTION AFTER CORRECTIVE SPINAL SURGERY IN IDIOPATHIC SCOLIOSIS

by

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A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biomechanics and Movement Science

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#### ABSTRACT

Adolescent idiopathic scoliosis (AIS) is the most common orthopedic disorder affecting individuals between the ages of 11 and 18. The disease produces a structural deformity of the spine and patients often report difficulty performing some activities of daily living along with pain in the upper back or scapular region. Despite evidence that trunk deformity negatively affects shoulder complex mechanics in other populations, upper extremity function is still poorly understood in the AIS population.

Prior studies indicate diminished function and abnormal scapulothoracic (ST) mechanics in AIS, however these investigations have been limited to the motion of humerothoracic (HT) elevation. Scapular kinematics associated with activities of daily living have not yet been investigated. Additionally, it is unknown whether existing kinematic abnormalities are resolved once the scoliotic curvature is corrected. Posterior spinal fusion surgery results in a dramatic improvement of the deformity, but introduces instrumentation and substantial musculoskeletal trauma to the thoracic region. Postoperative evaluations of shoulder function have previously been limited to assessment of HT motion, and thus it is unknown whether the treatment has beneficial or detrimental effects on ST kinematics.

The purpose of this study was to expand current understanding of how the scoliotic deformity impacts shoulder complex mechanics. This study analyzed ST kinematics and patient-reported shoulder function in AIS and compared results to a typically developing cohort. We also analyzed how surgical correction of the spinal curvature impacts shoulder function, and how postoperative patients with AIS

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compare to their typically developing peers. Finally, we investigated how curve severity interacts with shoulder function and how the degree of curve correction influences postoperative changes in ST kinematics.

Our results confirmed previous findings of reduced patient-reported function and lower resting upward rotation and posterior tilt of the scapula on the convex side of the curvature. We also determined that these kinematic abnormalities persisted across a range of positions encompassing motion involved in activities of daily living. While the adolescents in our study did not exhibit any deficits in HT range of motion, reduced upward rotation and posterior tilt are associated with shoulder pathology, and patients with AIS may be at risk for future shoulder dysfunction.

The comparison of ST mechanics before and after posterior spinal fusion revealed that all patients experienced some significant change in kinematics. Following surgery, scapular resting orientations normalized, but patients with AIS still displayed abnormal ranges of motion when compared to their typically developing peers. The scapulae on the concave shoulders demonstrated excessive range of motion, while the convex scapulae demonstrated diminished range of motion, particularly in positions involving humeral elevation. These results indicate that, while posterior spinal fusion is associated with significant changes in shoulder mechanics, these changes do not necessarily result in normal shoulder function.

Finally, we determined that curve severity appeared to influence preoperative ST mechanics, however postoperative ST kinematics were much more associated with preoperative levels of function than with curve parameters. These findings have substantial clinical impact for understanding of upper extremity function in AIS. Curve progression may exacerbate existing shoulder complex abnormalities, and may

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warrant an evaluation of ST mechanics along with the normal course of treatment in AIS. For adolescents considering posterior spinal fusion surgery, a preoperative shoulder complex rehab protocol may contribute to improved postoperative upper extremity outcomes. Ultimately, the results of this study encourage consideration of upper extremity factors in the treatment of AIS.

#### Chapter 1

#### INTRODUCTION

#### 1.1 Background

Adolescent idiopathic scoliosis (AIS) affects up to 5.2% of children between the ages of 11 and 18. <sup>1</sup> While the cause is unknown, the symptoms are consistent: a lateral curvature of the spine, axial rotation of vertebrae and corresponding deformities in the thoracic cage. Patients with AIS do not typically demonstrate neurological symptoms; however, the structural changes alone can affect function and quality of life. There is evidence that even small-sized curves can cause difficulty performing daily activities. <sup>2</sup> Additionally, complaints of back and shoulder pain <sup>3–7</sup> as well as dissatisfaction with the appearance of the trunk <sup>4</sup> are common in AIS patients. There is a marked asymmetry in the trunk and upper extremity <sup>8</sup>, with scapular asymmetry in particular noted as one of the greatest contributors to the appearance of trunk deformity. <sup>9</sup>

In addition to observable scapular asymmetry, patients with AIS report localized pain in the scapular region <sup>5–7</sup>, suggesting shoulder dysfunction. Structurally, the scoliotic curvature has clear implications for scapulothoracic (ST) mechanics: severe curves are accompanied by a distorted ribcage, warping the surface upon which the scapula tracks. The resulting convex and concave regions of the trunk may require alterations in muscle length and scapular position, <sup>10</sup> impacting the orientation of the scapula at rest and in motion. <sup>11</sup> This may present concerns for the AIS population, as abnormal scapular motion can lead to glenohumeral (GH) dysfunction. <sup>12–17</sup> In particular, deficits in posterior tilting and upward rotation of the scapula can increase risk for subacromial impingement syndrome and subsequent rotator cuff pathology. <sup>18–</sup>

Without treatment, curve progression and worsening of the trunk deformity are common in AIS.<sup>21</sup> For growing adolescents, an increasing distortion of the thoracic region may require the scapula to remodel its shape and/or migrate to an abnormal resting orientation. <sup>9</sup> Since the ability of the shoulder to support loads is dependent upon joint orientation, this remodeling can have a direct effect on the load bearing capacity of the shoulder. An altered scapular orientation may redirect GH compression loads into less tolerated shear forces. Consequently, while a clinical exam may confirm that a patient can raise his arms above his head, a mal-aligned joint could make load-bearing activities (e.g. lifting an object, removing something from a shelf, throwing) difficult. This may be related to the observed shoulder pain, however at this point, the functional consequences of scapular kinematics in AIS are still inadequately understood.

A relationship between trunk shape and shoulder dysfunction has been reported in other populations. Thoracic spine position has been shown to influence scapular kinematics. Slouched posture results in less upward rotation and less posterior tilting of the scapula, <sup>11</sup> and clinical measures of thoracic kyphosis have been associated with subacromial impingement syndrome. <sup>22</sup> Despite these established links between trunk deformity and pathological shoulder motion, upper extremity mechanics have not been a focus of research for the AIS population. Clinical examinations in scoliosis involve measurements of humerothoracic (HT) range of motion, and in this context, most patients with AIS can achieve normal ranges. <sup>23–25</sup>

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Still, an assessment limited to HT motion neglects valuable information regarding the underlying ST and GH contributions to shoulder function.

Previous investigations of ST kinematics in AIS have identified some shoulder dysfunction and scapular kinematic abnormalities. <sup>26,27</sup> These studies, however, were constrained to humeral elevation and did not evaluate the complex multiplanar upper extremity motion involved in activities of daily living. Additionally, both studies utilized a measurement technique that has accuracy limitations outside of a confined range of motion <sup>28–30</sup> and has been shown to produce errors in both typically developing children and adolescents and those with pathological upper extremity motion. <sup>31–33</sup> At this stage, the extent of shoulder dysfunction in adolescents with idiopathic scoliosis is still unknown.

The implications of curve correction for shoulder mechanics are also not comprehensively understood. For adolescents with severe curves (typically greater than 50°), the most common treatment is posterior spinal fusion with instrumentation. <sup>34</sup> This procedure involves dissection of several ST muscles and often a reduction of over 50% of curvature. <sup>35</sup> The surgery results in a modified thoracic cage with potentially altered muscle lengths and joint congruity. These structural changes and musculoskeletal trauma suggest that surgical treatment for scoliosis has significant potential to influence the function of the ST and GH joints. However, it is unknown whether treatment returns the shoulder joints to normal, or exacerbates existing abnormalities. Evaluations of upper extremity function after scoliosis surgery have focused primarily on the return of gross HT motion to its pre-surgical range, and previous studies concluded that patients returned to baseline range of motion after six months. <sup>23,24,36</sup> Still, there is evidence that many of these patients experience upper

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back and shoulder pain long after the surgical correction, <sup>37,38</sup> which supports the need for improved understanding of surgical effects on GH and ST components of overall shoulder function.

A detailed analysis of the effect of surgery may also identify specific factors associated with consequences at the shoulder. In some cases, fusion surgery can dramatically change both the lateral curvature (Cobb angle) and the rib hump. <sup>39,40 35</sup> The interaction of these aspects of thoracic deformity is complex, but all are essential considerations for functional outcomes after surgery. <sup>41</sup> Reduction of the rib hump can theoretically have the most impact on the scapular path of motion. However, the rib hump is also the most resistant to treatment, and supplemental procedures to address the rib hump, such as thoracoplasty, must sometimes be performed. <sup>42</sup> Supplemental procedures to correct the rib hump may eventually be considered for improving shoulder function, if the rib hump correction is implicated as a primary factor in the restoration of shoulder motion.

Understanding the specific effects that common surgical interventions have on ST and GH function can add insight into the origins of post-surgical shoulder pain frequently reported by patients. The expected outcomes of this study included 1) a comparison of ST kinematics between patients with AIS and their typically developing peers, 2) evaluation of the effect of surgical treatment on ST and GH joint contributions and 3) improved understanding of the relationship between thoracic cage structure and corresponding alterations in shoulder kinematics.

#### **1.2** Specific Aims and Hypotheses

# **1.2.1** Aim 1: Determine the differences in scapular kinematics between adolescents with idiopathic scoliosis and typically developing adolescents and how these differences relate to patient-perceived function

We employed a three-dimensional motion capture system to record the scapular kinematics of adolescent with idiopathic scoliosis and typically developing adolescents performing motions involved in activities of daily living. We utilized the Disabilities of the Arm Shoulder and Hand (DASH) questionnaire to ascertain patientperceived function in both groups. The resulting data were used to test the following hypotheses:

**Hypothesis 1.1** ST angles in functional positions will differ between the idiopathic scoliosis group and the typically developing group

**Hypothesis 1.2** ST angles in functional positions will differ between the convex and concave sides of the idiopathic scoliosis group

**Hypothesis 1.3** The idiopathic scoliosis group will have worse average patientreported function than the typically developing group

# **1.2.2** Aim 2: Determine the effect of operative treatment for scoliosis on scapular kinematics

A subset of subjects with AIS performed the protocol in Aim 1 before and six months after posterior spinal fusion surgery. Kinematic and functional data were analyzed to test the following hypotheses:

**Hypothesis 2.1** Postoperative ST angles in functional positions will change compared to preoperative ST motion

**Hypothesis 2.2** Postoperative ST angles in functional positions will be significantly different from those of typically developing adolescents

# **1.2.3** Aim 3: Determine the effect of curve severity on shoulder motion and function and determine how curve correction changes ST contribution to motion

We measured multiplanar spine and trunk curvature (the Cobb angle and scoliometer measures of the rib hump) in patients before and after surgery. Measures of curvature were analyzed in conjunction with the kinematic and functional data to test the following hypotheses:

**Hypothesis 3.1** Preoperative curve severity (Cobb angles and scoliometer measures) will be associated with worse DASH scores

**Hypothesis 3.2** Preoperative curve severity (Cobb angles and scoliometer measures) will be related to scapular resting orientation and range of motion

**Hypothesis 3.3** Preoperative curve severity (Cobb angles and scoliometer measures) will be related to differences in scapular orientations between the convex and concave sides in the idiopathic scoliosis group

**Hypothesis 3.4** Magnitude of curve correction (as measured by degrees Cobb correction) will correlate with change in scapular resting orientation and range of motion

**Hypothesis 3.5** Magnitude of change in rib hump (as measured by degrees scoliometer change) will correlate with the change in scapular resting orientation and range of motion

#### 1.3 Innovation

This study brought innovative upper extremity analysis to the scoliosis population in two ways: 1) performing a comprehensive assessment of pre-surgical scapular kinematics and 2) improving the postoperative evaluation to include information about the entire shoulder complex.

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#### **1.3.1** Comprehensive Assessment of Scapular Kinematics

Previous analysis of scapular kinematics in AIS have established differences in both motion and function as compared to typically developing adolescents. <sup>26,27</sup> However, these investigations have been constrained to humeral elevation, and have not examined scapular kinematics in other functional positions. Additionally, motion has only been evaluated within a confined range, due to limitations in measurement technique. <sup>28</sup> The proposed study will analyze ST contribution to upper extremity function using a set of motions relevant to the performance of activities of daily living. Data acquired from the preoperative analysis will expand upon current knowledge of shoulder dysfunction in AIS.

#### **1.3.2** Improving Postoperative Evaluation

This study will also expand the current practice of assessing postoperative upper extremity function to include information regarding ST joint mechanics. This study will be the first to evaluate the effect of scoliotic curve correction on kinematics of the individual joints.

#### Chapter 2

#### SHOULDER COMPLEX MECHANICS IN ADOLESCENT IDIOPATHIC SCOLIOSIS AND THEIR RELATION TO PATIENT-PERCEIVED FUNCTION

#### 2.1 Introduction

Adolescent idiopathic scoliosis (AIS), a three-dimensional spinal deformity mostly associated with a lateral curvature of the spine, develops in up to 5.2% of children between the ages of 11 and 18. <sup>1</sup> Patients with AIS do not typically demonstrate neurological symptoms; however, the structural changes alone can affect function and quality of life. There is evidence that even small-sized curves can cause difficulty performing daily activities. <sup>2</sup> Additionally, complaints of back and shoulder pain, <sup>3–7</sup> as well as dissatisfaction with the appearance of the trunk <sup>4</sup> are common in AIS. There is a marked asymmetry of the trunk and upper extremity <sup>8</sup> and scapular asymmetry in particular has been established as one of the greatest contributors to the appearance of trunk deformity. <sup>9</sup>

The observation of scapular asymmetry, along with reports of pain in the scapular region <sup>5–7</sup> suggest a relationship between altered trunk structure and scapular mechanics. Scoliotic curvature has clear implications for scapulothoracic (ST) function: severe curves are accompanied by a distorted ribcage, warping the surface upon which the scapula tracks. The resulting convex and concave regions of the trunk may require alterations in muscle length and scapular position, <sup>10</sup> impacting the orientation of the scapula at rest and in motion. <sup>11</sup> This presents concerns for the AIS

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population, as abnormal scapular motion can lead to glenohumeral (GH) dysfunction. <sup>12–17,43</sup> In particular, deficits in posterior tilting and upward rotation of the scapula can increase risk for subacromial impingement syndrome and subsequent rotator cuff pathology. <sup>18,19</sup>

When the spinal curvature progresses (as is common in AIS before treatment), <sup>21</sup> the trunk deformity worsens. In growing adolescents, the scapula may respond to this deformity migrating to an abnormal resting orientation. <sup>9</sup> Since the ability of the shoulder to support loads is dependent upon joint orientation, this remodeling can have a direct effect on the load bearing capacity of the shoulder. An altered scapular orientation may redirect GH compression loads into less tolerated shear forces. Consequently, while a clinical exam may confirm that a patient can raise his arms above his head, a mal-aligned joint could make load-bearing activities (e.g. lifting an object, removing something from a shelf, throwing) difficult. This may be related to the shoulder pain observed in the scoliosis population.

An association between trunk shape and shoulder dysfunction has been reported in other populations. Thoracic spine position has been shown to influence scapular kinematics. Slouched posture results in less upward rotation and less posterior tilting of the scapula, <sup>11</sup> and clinical measures of thoracic kyphosis have been associated with subacromial impingement syndrome. <sup>22</sup> Despite these established links between trunk deformity and pathological shoulder motion, upper extremity mechanics in the AIS population are still poorly understood. Prior investigations of ST kinematics in AIS have identified some abnormal patterns of scapular motion, but have limited the analysis to humeral elevation, rather than scapular kinematics associated with moving the arm to positions involved in activities of daily living. <sup>26,27</sup>

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Additionally, the measurement technique utilized in these studies can be inaccurate in extremes of humeral elevation, in typically developing children and adolescents, and in children with musculoskeletal pathology. <sup>28–31,33,44</sup> Finally, previous research has been limited to patients with mild or moderate curvature, which may neglect the upper extremity implications that occur with the curve progression commonly seen in AIS. <sup>45</sup>

This study analyzed ST contribution to motion in a set of positions relevant to the performance of activities of daily living. These positions are widely used in clinical evaluation of shoulder function. <sup>46</sup> We hypothesized that patients with AIS would have alterations in scapular kinematics and functional scores compared to their typically developing peers. We also hypothesized that the AIS group would exhibit asymmetrical patterns of scapular motion on the convex and concave sides of the scoliotic curve. Finally, we hypothesized that any abnormalities in scapular orientation in the scoliosis group would be related to patient-reported functional scores.

#### 2.2 Methods

#### 2.2.1 Subjects

Fifty-nine subjects were recruited for this study: 33 typically developing adolescents, and 26 diagnosed with AIS (Table 2.1). The demographics of each group were compared with Student's t-tests (ratio/interval data) and Fisher's exact tests (categorical data).

	Typically developing $(n = 33)$	Scoliosis $(n = 26)$	<i>p</i> -value
Age	15.2 (1.6)	14.7 (1.7)	0.28
BMI	21.3 (4.4)	21.8 (8.3)	0.42
Gender (Females: Males)	24:9	18:8	0.77
Dominant Hand (Right: Left)	26:7	21:5	0.85
Cobb Angle Range (Degrees)		35-115	

Table 2.1: Subject characteristics and statistical comparisons across groups

Subjects were recruited in accordance with informed consent and assent procedures established by the institutional review boards at the University of Delaware (typically developing), Philadelphia Shriners Hospital for Children and Nemours/A.I. duPont Hospital for Children (AIS) (Appendix). All subjects with AIS presented with a primary right thoracic curvature and had not undergone any surgical treatment for scoliosis. Subjects from both groups were excluded if they had any history of previous shoulder surgery or injury, allergies to skin adhesives, or a body mass index greater than the 85<sup>th</sup> percentile for the subject's age and gender. <sup>47</sup>

#### 2.2.2 Motion Capture

Subjects sat on a stool in a comfortable position, wearing three-dimensional retro-reflective markers at the following locations:

*Thorax:* sternal notch, T1 spinous process, T8 spinous process, thoracic vertebral spinous process above apex of scoliotic curve\*, vertebral spinous process below apex of scoliotic curve\*, lower lumbar vertebral spinous process\*.

*Humerus:* medial epicondyle, lateral epicondyle, posterolateral humerus

Scapula: acromion process

\*indicates that these markers were only placed on scoliosis subjects.

Subjects held their arms in a series of 4 positions (Figure 2.1).



Figure 2.1: Static positions for capture

At each position, the trigonum spinae and inferior angle of the scapula were palpated. Palpation has proven to be a reliable and accurate way to capture scapular orientation in static positions. <sup>48</sup> As available methods for measuring dynamic scapular motion can be inaccurate in extreme humeral elevation, <sup>49</sup> along particular axes of scapular motion, and in populations with pathological motion, <sup>31,44</sup> this study was

limited to a static analysis to avoid spurious conclusions due to measurement inaccuracy.

Two additional retro-reflective markers were placed on the palpated locations (Figure 2.2) and removed once the position was captured.



Figure 2.2: Marker placement, including scapular landmarks.

Marker locations were captured with a 12 camera Motion Analysis (Santa Rosa, CA) system (Delaware and Nemours) or a 12 camera Vicon (Centennial, CO) system (Shriners) operating at 60 Hz. Although two different motion capture systems were used in this study, the accuracy of each system is identical, and data collected

from the systems are interchangeable. <sup>50</sup> Raw data files were processed with the same custom LabVIEW software (National Instruments, Austin, TX).

#### 2.2.3 Patient-Rated Outcome Measures

All subjects completed a Disabilities of the Arm Shoulder and Hand (DASH) questionnaire. The DASH is a 30-item scale used to assess patient-reported shoulder pain and physical function as well as social and emotional function. <sup>51</sup> The score ranges from 0 to 100 where 0 indicates no disability and 100 indicates the most severe disability. The DASH was chosen for this study because it has been shown to be valid and reliable in patients with shoulder pathologies, <sup>52–54</sup> and focuses on activities of daily living. Additionally, the use of the DASH to evaluate shoulder function in adolescents is well established. <sup>55–57</sup>

#### 2.2.4 Data Processing

Coordinate systems for the humerus and trunk were created using recommendations from the International Society of Biomechanics (ISB). <sup>58</sup> Pilot testing revealed no Euler sequence suitable (without gimbal lock) for all positions and thus a modified globe approach <sup>59,60</sup> was utilized to calculate HT orientation, described by elevation angle, internal rotation, and cross-body adduction. Cross-body adduction conventions were defined such that if the humerus was aligned with the trunk coronal plane, the cross-body adduction angle would be 0°, and the more anterior the humerus, the more positive the cross-body adduction angle.

The scapular coordinate system was constructed as a modification of ISB recommendations, substituting the acromion process for the acromion angle, for ease of palpation. Scapulothoracic orientations were calculated by the ISB-recommended

YXZ Euler sequence, in which rotation about the Y axis corresponded to internal and external rotation (protraction/retraction), rotation about the X axis corresponded to upward and downward rotation, and rotation about the Z axis corresponded to anterior and posterior tilt. <sup>58</sup> Scapulothoracic displacement from the neutral resting position to each terminal position was calculated in a similar manner.

#### 2.2.5 Statistical Analysis

Scapular kinematic differences between the AIS group and the typically developing group, as well as differences between the convex and concave sides of the AIS group, were analyzed with a mixed 3-way analysis of variance (ANOVA). There was one between-group factor (scoliosis or typically developing) and two within-group factors: side (left/concave and right/convex) and position (neutral, abduction, forward reach, and hand to spine). Dependent variables consisted of ST orientation values (angles). Separate ANOVAs (3) were performed for each axis of ST motion as is customary with statistical analyses of scapular kinematics, <sup>13,26,61–65</sup> and Bonferroni corrections were applied to adjust for multiple comparisons. Greenhouse-Geisser corrections were violated. The specifics of group differences were explored with Tukey HSD post-hoc tests, pending any significant interaction. Additionally, an identical statistical analysis was performed using HT angles as the dependent variable, to determine if the groups differed in global upper extremity expression of the positions.

A t-test was used to assess differences in DASH scores between the scoliotic and typically developing groups.

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When a significant ST angle difference was determined along a particular axis of motion or in a particular position, a Pearson product-moment correlation analysis was employed to examine the relationship between patient-perceived function (DASH scores) and ST angles.

#### 2.3 Results

#### 2.3.1 Humerothoracic Orientations

No significant differences between groups were found for any axis of HT orientation (Figure 2.3).



Figure 2.3: Humerothoracic angles in each terminal position.

#### 2.3.2 Scapulothoracic Upward/Downward Rotation

The ANOVA revealed a significant interaction between group and side for ST upward rotation ( $F_{3,57} = 10.212$ , p = 0.002). Post-hoc testing indicated that the convex

side of the AIS group had significantly less upward rotation than the right side of the typically developing group (p = 0.001) (Table 2.2). The convex side also had significantly less upward rotation than the concave side of the scoliosis group (p < 0.001). In contrast, there were no significant differences between right and left sides within the typically developing group. No significant differences between groups were found for ST upward rotation displacement (Table 2.3). Side by side comparisons of ST upward rotation displacements from neutral to each of the terminal positions are displayed in Figure 2.4.



Figure 2.4: ST upward rotation for right (convex) and left (concave) sides of the typically developing (TD) and scoliosis groups. Solid shapes (star, diamond, square and circle) indicate neutral (resting) position, while the arrows indicate displacement to the terminal position.

#### 2.3.3 Scapulothoracic Internal/External Rotation

No significant differences were found for terminal orientations along the ST internal/external rotation axis (Table 2.2). However, there was a significant interaction between group, side, and position for ST internal/external rotation displacement (F<sub>2,56</sub>

= 3.950, p = 0.025). Post-hoc testing revealed differences both within the AIS group and between the AIS and typically developing groups (Table 2.3). The convex side of the AIS group presented with significantly less ST internal rotation displacement (protraction) than the concave side (p < 0.001) and the typically developing right side (p < 0.001) side in the forward reach position. Additionally, the concave side of the AIS group demonstrated significantly less external rotation (retraction) in abduction than the convex side (p < 0.001) and the typically developing left side (p = 0.014). Side by side comparisons of ST protraction and retraction from neutral to each of the terminal positions are displayed in Figure 2.5.



Figure 2.5: ST internal rotation for right (convex) and left (concave) sides of the typically developing (TD) and scoliosis groups. Solid shapes (star, diamond, square and circle) indicate neutral (resting) position, while the arrows indicate displacement to the terminal position.

#### 2.3.4 Scapulothoracic Posterior/Anterior Tilt

A significant interaction between group and side was revealed for ST posterior tilt (F<sub>3,57</sub> = 21.438, p < 0.001). Post-hoc testing revealed that the convex side of the AIS group was significantly more anteriorly tilted than the right side of the typically developing group (p < 0.001) (Table 2.2). Within the AIS group, the convex side was more anteriorly tilted than the concave side (p < 0.001), whereas there were no significant differences between sides within the typically developing group. A significant interaction between group and side was also found for ST anterior/posterior tilt displacement ( $F_{1,57} = 4.917$ , p = 0.039). Post-hoc testing determined that the concave side of the AIS group had significantly less posterior tilt/more anterior tilt displacement than the left side (p = 0.002) of the typically developing group (Table 2.3). Side by side comparisons of ST anterior and posterior tilt displacements from neutral to each of the terminal positions are displayed in Figure 2.6.


Figure 2.6: ST posterior tilt for right (convex) and left (concave) sides of the typically developing (TD) and scoliosis groups. Solid shapes (star, diamond, square and circle) indicate neutral (resting) position, while the arrows indicate displacement to the terminal position.

		С	oncave/Le	eft	Concave/Right		
		AIS	TD	p-value	AIS	TD	p-value
	Neutral	2.0† (9.7)	1.0 (7.4)	0.684	-3.8*† (8.8)	1.1* (7.6)	0.004
Upward	Abduction	44.4† (8.3)	45.4 (9.8)	0.674	40.2*† (9.2)	47.1* (8.4)	0.021
Rotation	Forward Reach	26.3 (11.8)	26.1 (11.4)	0.951	22.3* (12.9)	26.5* (9.1)	0.043
	Hand to Spine	-0.6† (9.5)	-0.6 (7.5)	0.989	-8.2*† (8.1)	-1.7* (6.8)	0.002
	Neutral	42.1 (9.3)	40.9 (8.9)	0.544	41.5 (6.4)	39.8 (5.8)	0.552
Internal	Abduction	39.7 (12.7)	35.5 (12.2)	0.617	35.2 (10.1)	34.1 (9.4)	0.280
Rotation	Forward Reach	58.2 (12.9)	58.9 (8.2)	0.637	52.8 (7.8)	57.3 (5.9)	0.339
	Hand to Spine	37.2 (10.2)	36.2 (8.2)	0.675	36.4 (8.5)	34.7 (4.7)	0.337
	Neutral	4.5† (6.6)	1.4 (6.4)	0.818	-7.3*† (6.0)	-1.0* (6.4)	< 0.001
Posterior	Abduction	3.8*† (9.0)	4.5* (9.3)	0.038	-9.2*† (7.9)	1.4* (8.2)	< 0.001
Tilt	Forward Reach	-5.2† (10.2)	-5.4 (7.8)	0.995	-11.0*† (7.7)	-5.5* (8.3)	0.012
	Hand to Spine	-4.8† (5.8)	-3.2 (8.8)	0.722	-11.4*† (6.0)	-3.6* (9.0)	< 0.001

Table 2.2: Mean (SD) ST angles in the terminal orientation of all positions

p-values listed are for the pairwise comparisons between the AIS and typically developing groups. \* indicates significant differences between the groups, whereas  $\dagger$  indicates significant differences between the contralateral sides within the group. Significance was determined by Bonferroni-adjusted *p*-values < 0.05.

		Concave/Left			Convex/Right			
		AIS	TD	p-value	AIS	TD	p-value	
Upward Rotation	Abduction	42.6 (8.1)	44.3 (9.3)	0.919	43.7 (12.0)	45.8 (10.4)	0.622	
	Forward Reach	25.1 (11.0)	24.6 (10.8)	0.772	27.0 (15.5)	25.1 (7.3)	0.384	
	Hand to Spine	-2.5 (8.3)	-2.2 (7.9)	0.890	-5.3 (7.8)	-3.6 (6.5)	0.371	
Internal Rotation	Abduction	-1.9*† (7.5)	35.5* (12.2)	0.014	-6.9† (7.6)	-6.4 (8.2)	0.816	
	Forward Reach	15.0† (9.5)	58.9 (8.2)	0.566	9.8*† (6.2)	16.5* (5.8)	< 0.001	
	Hand to Spine	-4.4 (8.8)	36.2 (8.2)	0.859	-6.0 (8.1)	-4.9 (6.1)	0.467	
Posterior Tilt	Abduction	-1.1* (7.0)	4.5* (9.3)	0.005	-1.6 (4.6)	2.3 (5.1)	0.123	
	Forward Reach	-7.7* (9.5)	-5.4* (7.8)	0.019	-3.5 (7.1)	-4.7 (5.4)	0.650	
	Hand to Spine	-7.5* (5.3)	-3.2* (8.8)	0.045	-3.6 (3.7)	-2.5 (5.3)	0.381	

Table 2.3: Mean (SD) ST displacement from neutral to all positions

p-values listed are for the pairwise comparisons between the AIS and typically developing groups. \* indicates significant differences between the groups, whereas  $\dagger$  indicates significant differences between the contralateral sides within the group. Significance was determined by Bonferroni-adjusted *p*-values < 0.05.

## 2.3.5 Patient-Reported Function

Adolescents with idiopathic scoliosis had significantly higher (worse) DASH scores on average than the typically developing group:  $4.3 \pm 3.9$  for the AIS group compared to  $2.6 \pm 3.7$  for the typically developing group (p = 0.027).

## 2.3.6 Relationship of Functional Scores to Kinematics

Correlational analyses were performed between the DASH scores and scoliosis

ST angles for axes and positions that differed significantly from the typically

developing group: convex side upward rotation in all positions, convex side internal rotation displacement in the forward reach position, convex side posterior tilt in the neutral, abduction and hand to spine positions, concave side external rotation displacement in the abduction position, and concave side posterior tilt displacement in the abduction, forward reach and hand to spine positions. No relationship was determined to be more than weakly correlated (Table 2.4). <sup>66</sup>

Correlations	between DAS	H scores and	l ST kinemati	cs in the scoliosis	3
group that	significantly of	liffered from	the typically	developing group	p.

	ST angles	Correlation with DASH Scores
	External rotation displacement – Abduction	0.09
Left	Posterior tilt displacement - Abduction	-0.07
(Concave)	Posterior tilt displacement – Forward Reach	-0.19
	Posterior tilt displacement – Hand to Spine	0.11
	Upward rotation - Rest (neutral)	-0.06
	Upward rotation – Abduction	0.13
	Upward rotation – Forward Reach	0.17
	Upward rotation – Hand to Spine	-0.18
Right (Convex)	Internal rotation displacement – Forward Reach	-0.36
(Convex)	Posterior tilt - Rest (neutral)	-0.02
	Posterior tilt – Abduction	-0.12
	Posterior tilt – Forward Reach	-0.19
	Posterior tilt – Hand to Spine	-0.08

Correlation strengths were evaluated according to the recommendations of Dancey and Reidy. <sup>66</sup> Greater than 0.7 was considered strongly correlated, between 0.4 and 0.69 was considered moderately correlated, between 0.1 and 0.39 was considered weakly correlated, and less than 0.1 was considered to have no relationship.

### 2.4 Discussion

This study is the first to perform a comprehensive analysis of scapular kinematics in adolescents with idiopathic scoliosis and how these mechanics compare to those of a typically developing cohort. Statistical testing revealed several significant kinematic abnormalities, supporting both our first and second hypotheses. The significant differences between convex and concave sides in the neutral position provide quantitative evidence of the observed scapular asymmetry. <sup>9</sup> The resting scapular orientation on the concave side was significantly more posteriorly tilted than the typically developing group, while the convex side scapula was significantly more downwardly rotated and anteriorly tilted at rest. These alterations in resting position appear to be a direct result of the trunk deformity, aligning with the rib hump commonly occurring on the convex side of the spinal curvature.

Subjects in the scoliosis group were able to achieve all terminal positions with no apparent functional deficits as measured by a traditional HT assessment. However, the pattern of scapular motion was significantly different between groups. Kinematic evaluation of the ST joint revealed that the upward rotation and posterior tilt range of scapular motion (displacement) was similar between the scoliosis convex side and the typically developing group; however, the altered scapular resting position shifted this range of motion in the scoliosis group. As a result, shoulders on the convex side of the scoliosis group presented with significantly less upward rotation and posterior tilt in all terminal positions. This pattern of motion may result in a reduced subacromial space and has been associated with impingement syndrome <sup>19</sup> and GH joint instability. <sup>15–17,43</sup> The biomechanics observed in this study suggest that, while HT range of motion may appear normal during a clinical exam, adolescents with idiopathic scoliosis may still be at risk for shoulder pathology.

The convex shoulders of the AIS group also demonstrated less ST protraction in a forward reach motion than the typically developing group. Again, a right thoracic curvature (present in all participants of this study) can be accompanied by a rib hump on the convex side. Shoulder movements requiring protraction would require gliding of the scapula across this hump. The evidence of protraction deficits on the convex side in the scoliosis group suggests that the rib hump may hinder the pattern of scapular motion during reaching. As HT orientations were similar across groups, the

ST protraction deficits of the convex shoulders imply that a greater contribution from the GH joint is required achieve the terminal position.

Other kinematic observations include asymmetrical ST behavior between the convex and concave sides. Scapular kinematic differences between dominant and nondominant sides have been reported in healthy individuals. <sup>61</sup> However, the AIS and typically developing groups in this study had similar distributions of hand dominance, and no statistically significant differences were found between right and left sides of the typically developing group. This suggests that the asymmetry observed in the AIS group is more likely related to the geometry of the trunk deformity than to limb dominance. Furthermore, while the convex and concave shoulders differed significantly in scapular upward rotation and posterior tilt, ST angles on the concave side were similar to the typically developing group in all terminal positions, implying adequate functional scapular motion on this side. This, along with the findings of significant differences between the convex side and the typically developing group, implies that the convex side may be the isolated shoulder with increased risk for pathology.

DASH scores indicated significantly more patient-reported dysfunction in the scoliosis group. While this finding is consistent with previous analyses of patient-reported shoulder function in scoliosis, <sup>26</sup> scores in both groups were better than normative data from the general population, <sup>67</sup> and the difference between groups was less than the minimal clinically important difference for the questionnaire. <sup>54</sup> This could be due to an age or ceiling effect, <sup>68</sup> however the lack of substantial patient-reported shoulder dysfunction may also be related to differences between global and joint-specific upper extremity kinematics. Humerothoracic kinematics were normal in

the scoliosis group, implying an unimpaired ability to place the hand in space. This may contribute to positive patient perception of function, as the DASH is primarily composed of questions regarding the ability to perform specific upper extremity tasks. Nevertheless, reports of scapular pain in previous studies <sup>5,6</sup> and the ST kinematic abnormalities observed in this study suggest that the AIS population may still be risk for shoulder pathology.

Results of the correlation analysis suggested that functional scores were not notably related to ST kinematics. The strongest correlations were between DASH scores and ST displacement, not terminal orientation, suggesting that impairment in range of motion—not necessarily end position—was more associated with how patients assessed their shoulder function. Still, this relationship was weak at best, and the data did not support our third hypothesis. While adolescents with idiopathic scoliosis reported lower shoulder functional scores than the typically developing group, this study could not associate the degree of dysfunction with any pattern of scapular motion. The lack of association could also imply that patient-reported shoulder function is more closely related to global shoulder motion than to any specific movement pattern of the underlying joints.

#### 2.5 Conclusions

Adolescents with idiopathic scoliosis displayed altered scapular kinematics along all three axes of scapular motion. The most notable abnormalities—deficits in upward rotation and posterior tilt—are patterns associated with shoulder pathology. While the ability to place the hand in space appears to be unaffected in scoliosis, the contributions from individual joints may lead to further dysfunction. Ultimately, the

ST orientation abnormalities revealed in this study suggest that consideration of upper extremity factors is warranted in the AIS population.

### Chapter 3

## ANALYSIS OF SHOULDER COMPLEX FUNCTION AFTER POSTERIOR SPINAL FUSION IN ADOLESCENTS WITH IDIOPATHIC SCOLIOSIS

#### 3.1 Introduction

Adolescent idiopathic scoliosis (AIS) is one of the most common orthopedic disorders affecting children between the ages of 11 and 18. <sup>4</sup> Curve progression is common without treatment and can be accompanied by symptoms of cosmetic deformity, functional difficulty, pain, and cardiopulmonary complications. <sup>21,45,69,70</sup> Small curves in younger children are first treated non-surgically <sup>71,72</sup> or with growth modulation techniques. <sup>73</sup> In skeletally mature patients—especially those with curves greater than 50°—the most common treatment approach is posterior spinal fusion with instrumentation (PSF). <sup>34</sup>

It is generally accepted that PSF produces satisfactory clinical and radiological correction of the scoliotic deformity and improved quality of life with minimal morbidity. <sup>74–77</sup> Most patients recover sufficiently for return to physical activity, including non-contact sports by six months after surgery. <sup>78–80</sup> Still, a subset of patients present with postoperative back pain at this point, frequently in the thoracic region. <sup>37,38</sup> Postoperative back pain has been linked to a variety of factors including age, curve severity, psychosocial factors and level of preoperative pain. <sup>38,81</sup> However, to our knowledge there have been no investigations into the function of the underlying musculature in the region of reported pain. Given the prevalence of pain in the thoracic back, specifically the scapular region, an investigation into postoperative

shoulder mechanics and function of the scapulothoracic joint may provide insight into pain that is otherwise unexplained at follow-up.

Prior to surgery, patients with AIS exhibit altered shoulder kinematics and lower patient-reported function compared to typically developing adolescents. <sup>26,27</sup> The trunk distortion creates an altered scapular resting position and is associated with decreased upward rotation and posterior tilt in positions representing activities of daily living. This pattern of scapular motion is associated with a variety of shoulder pathologies, including subacromial impingement syndrome, rotator cuff injury and glenohumeral (GH) instability. <sup>13,14,18,20</sup> Accordingly, patients with AIS may be at risk for shoulder dysfunction, however, it is unknown if the typical course of treatment for severe scoliosis (i.e. PSF) returns the shoulder joints to normal, or exacerbates existing abnormalities.

While PSF does not directly target the shoulder musculature, scapulothoracic (ST) mechanics may be affected as a consequence of the structural changes and muscular trauma occurring during surgery. Alterations in scapular kinematics have been observed following other surgeries in the thoracic region such as mastectomies and breast reconstructions. <sup>82,83</sup> During PSF, exposure of the spine necessitates dissection of several ST muscles. These muscles are sutured before closing; however, the structural modification of the thoracic cage has potential implications for resting muscle length and joint congruity. <sup>10</sup> The proximity of the scapula to the region of surgical impact suggests that the treatment has significant potential to influence the function of the ST joint.

After PSF, the spinal curvature and the associated ribcage deformity are substantially altered. <sup>35,84</sup> Still, the effect of the surgery on ST kinematics remains

unknown. Prior evaluations of upper extremity function after scoliosis surgery have focused primarily on the return of gross humerothoracic (HT) motion to its presurgical range, and these studies concluded that patients return to baseline range of motion after six months. <sup>23,24,36</sup> Nevertheless, the extensive evidence of reported scapular region pain long after the surgical correction supports the need for improved understanding of surgical effects on the contribution of the ST joint to overall shoulder function.

This study examined ST mechanics in positions representing activities of daily living before and six months following PSF. Patient-reported shoulder function scores were also collected at those time points. We hypothesized that subjects with AIS would experience significant changes in mechanics and patient-reported function from preoperative to postoperative evaluations. We also hypothesized that as a group, AIS subjects would continue to exhibit significant ST kinematic differences from their typically developing peers at the six-month follow-up evaluation.

## 3.2 Methods

### 3.2.1 Subjects

Eighteen subjects with AIS were recruited for this study. A previouslyrecruited group of 33 typically developing adolescents were analyzed for the comparison with post-operative AIS subjects. The demographics of each group were compared with Student's t-tests (ratio/interval data) and Fisher's exact tests (categorical data) (Table 3.1).

	Typically-developing $(n = 33)$	Scoliosis $(n = 18)$	p-value
Age	15.2 (1.6)	15.0 (1.7)	0.220
BMI	21.3 (4.4)	20.1 (2.7)	0.297
Gender	24 Females, 9 Males	15 Females, 3 Males	0.461
Dominant Hand	26 Right, 7 Left	15 Right, 3 Left	0.771
Cobb Angle (degrees)		Range: 35-78	

Table 3.1: Subject characteristics and statistical comparison across groups

Subjects were recruited in accordance with informed consent and assent procedures established by the institutional review boards at the University of Delaware (typically-developing), Philadelphia Shriners Hospital for Children and Nemours/A.I. duPont Hospital for Children (AIS) (Appendix). All subjects with AIS presented with a primary right thoracic curvature and had no prior surgical treatment for scoliosis. Subjects from both groups were excluded if they had any history of previous shoulder surgery or injury, allergies to skin adhesives, or a body mass index greater than the 85<sup>th</sup> percentile for the subject's age and gender. <sup>47</sup>

### 3.2.2 Patient-Rated Outcome Measures

At the sessions before and six months following surgery, all subjects completed a Disabilities of the Arm Shoulder and Hand (DASH) questionnaire. The DASH is a 30-item scale used to assess patient-reported shoulder pain and physical function as well as social and emotional function. <sup>51</sup> The score ranges from 0 to 100 where 0 indicates no disability and 100 indicates the most severe disability. The DASH was chosen for this study because it has been shown to be valid and reliable in

patients with shoulder pathologies <sup>52–54</sup> and focuses on activities of daily living. Additionally, the use of the DASH to evaluate shoulder function in adolescents is well established. <sup>55–57</sup>

## **3.2.3** Motion Capture

Subjects sat on a stool in a comfortable position, wearing three-dimensional retro-reflective markers at the following locations:

*Thorax:* sternal notch, T1 spinous process, T8 spinous process, thoracic vertebral spinous process above apex of scoliotic curve\*, vertebral spinous process below apex of scoliotic curve\*, lower lumbar vertebral spinous process\*.

Humerus: medial epicondyle, lateral epicondyle, posterolateral humerus

Scapula: acromion process

\*indicates that these markers were only placed on scoliosis subjects.

Subjects held each arm in a series of 4 positions (Figure 3.1), first the right side, then the left. At the preoperative data collection, subjects performed three trials of each position.



Figure 3.1: Static positions for capture

At each position, the: trigonum spinae and inferior angle of the scapula were palpated by a trained investigator. Two additional retro-reflective markers were placed on the palpated locations (Figure 3.2) and removed once the position was captured. The palpation approach was selected for two reasons. First, palpation has proven to be a reliable and accurate way to capture scapular orientation in static positions. <sup>48</sup> Second, as available methods for measuring dynamic scapular motion can be inaccurate in extreme humeral elevation, <sup>49</sup> along secondary axes of scapular motion, <sup>33</sup> and in populations with pathological motion, <sup>31,44</sup> this study was limited to a static analysis to avoid spurious conclusions due to measurement inaccuracy.



Figure 3.2: Marker placement including scapular markers in the hand to spine position

An additional feature was implemented during the postoperative data collection for scoliosis subjects. Real-time feedback on motion capture was provided to ensure that the subject sufficiently replicated the positions to within 10° of preoperative HT orientations. Prior to the follow-up data collection, preoperative HT elevation angles were calculated for all trials in each position. During the

postoperative data collection, subjects were instructed to match the preoperative HT elevation angles, guided by a block figure representation of the subject (Figure 3.3).



Figure 3.3: Representation of target positions for real-time motion capture matching at postoperative appointment

The subject moved his or her arm (represented in red) to match the target position (in blue). When the subject replicated the position to within the 10° threshold, the arm turned green. The subject held that position as scapular landmarks were palpated, and the position was captured. This approach helped reduce differences

between preoperative and postoperative ST angles that could have been attributed to inter-session variability in expression of these positions. In addition to the matched trials, the subjects performed one additional unconstrained trial to evaluate whether differences existed in HT expression of each position before and after surgery.

Marker locations were captured with a 12 camera Motion Analysis (Santa Rosa, CA) system (Delaware and Nemours) or a 12 camera Vicon (Centennial, CO) system (Shriners) operating at 60 Hz. The data collected from the systems are interchangeable, <sup>50</sup> and raw data files were processed with the same custom LabVIEW software (National Instruments, Austin, TX).

### **3.2.4 Data Processing**

Humerothoracic coordinate systems were created using recommendations from the International Society of Biomechanics (ISB). <sup>58</sup> Pilot testing revealed that no single Euler sequence could provide clinically interpretable HT orientations across all positions. Thus, a modified globe approach <sup>59,60</sup> was utilized to calculate HT orientation, described by elevation angle, internal rotation, and cross-body adduction.

The scapular coordinate system was created from the acromion process, trigonum spinae and inferior angle. Scapulothoracic orientations and displacements from the neutral resting position to each terminal position were calculated by the ISBrecommended YXZ (internal/external rotation (or protraction/retraction), upward/downward rotation, posterior/anterior tilt) Euler sequence. <sup>58</sup>

### 3.2.5 Statistical Analysis

A paired t-test was employed to evaluate changes in DASH scores. A 3-way repeated-measures analysis of variance (ANOVA) was employed to determine changes in resting scapular resting position after PSF. Within-subject factors included preoperative/postoperative, side, and axis of motion. The specifics of postoperative differences were explored with Tukey HSD post-hoc tests, pending any significant interaction. The minimal important difference (MID) <sup>85</sup> was calculated for both sides along each axis of scapular orientation.

To determine whether significant changes in ST range of motion for an individual subject occurred as a result of surgical intervention, simulation modeling analysis (SMA) <sup>86</sup> was performed on ST displacements calculated from the three preoperative trials and three postoperative trials for each of the three positions (abduction, forward reach, hand to spine). Data from the three preoperative trials were compared to data from three postoperative trials to determine whether there was a significant change in joint orientations for each individual subject.

The SMA approach provides an individualized statistical analysis of short time-series data. First, the autocorrelation of the series is calculated and adjusted for small-n bias. <sup>87</sup> Next, the correlation between phase vector (e.g. preoperative vs. postoperative) and dependent variable (e.g. ST upward rotation at each time point) is calculated. The model then randomly generates 5000 simulated data sets with the same autocorrelation and phase size parameters. Correlations between each of these simulated data sets and the phase vector are calculated. The resulting p-value represents the proportion of correlations (out of 5000 simulated data sets) that are more correlated with the phase vector than the input data. A low p value would thus imply that the observed correlation between dependent variable and phase was unlikely to have occurred by chance. Figure 3.4 displays an example of a two-phase

experiment with three data points in each phase, similar to the preoperative/postoperative comparison in this study.



Figure 3.4: Example of SMA with three observations in each phase

The SMA approach was applied in place of the more traditional ANOVA design in order to facilitate the understanding of individual differences that resulted from surgery. While the ANOVA design can be used to evaluate changes in group performance, we are also interested in identifying individuals who either exhibit or fail to exhibit kinematic changes in ST contribution to joint function as a result of surgical correction. SMA enables us to differentiate subjects who demonstrate significant changes in ST function from those who do not. In order to explore the relationship between surgical impact and preoperative levels of ST function, Pearson correlations were calculated between the changes after surgery and the preoperative values for each measure of ST displacement.

Postoperative AIS patients were also evaluated alongside their typically developing peers. Scapular kinematics of the two groups were compared with a mixed ANOVA. There was one between-group factor: group (scoliosis or typically developing) and two within-group factors: side (left/concave and right/convex) and position (neutral, abduction, forward reach, and hand to spine). Dependent variables consisted of ST terminal orientations and displacements (angles). Separate ANOVAs (a total of three) were performed for each axis of ST motion as is customary with statistical analyses of scapular kinematics. <sup>13,26,61–65</sup>

A two factor repeated measures ANOVA (trial type by position) was also performed for each axis of motion to compare HT angles across the matched and unconstrained trials for each position. This analysis was employed to determine if the subjects differed in unrestricted upper extremity expression of the positions before and after surgery.

Group statistical analyses were performed in SPSS (IBM Corp, Armonk, NY) with a significance level of 0.05. Greenhouse-Geisser corrections were implemented for within-subjects analyses when sphericity assumptions were violated. The specifics of group differences were explored with Tukey HSD post-hoc tests, pending any significant interactions, and Bonferroni corrections were applied to adjust for multiple comparisons The SMA was performed using open-source software <sup>86</sup> with a significance level of 0.05.

## 3.3 Results

# 3.3.1 Individual Postoperative Changes

# 3.3.1.1 Humerothoracic Orientations

No significant differences in HT angles were revealed between the matched and unconstrained trials ( $F = 0.044 \ p = 0.837$ ) (Figure 3.5).



Figure 3.5: HT angles for the matched and unconstrained trials

# 3.3.1.2 Changes in Scapular Resting Orientation

The ANOVA revealed a significant interaction between

preoperative/postoperative, side and axis (F = 4.889, p = 0.013). A large proportion of

subjects experienced changes in resting scapular orientation greater than the MIDs, becoming more upwardly rotated and posteriorly tilted on the convex side and more downwardly rotated, externally rotated and anteriorly tilted on the concave side (Table 3.2).

		Concave (Left)				Convex (Right)			
		% subjs > MID	MID (°)	Avg. change (all subjs) (°)	Corr. with preop values	% subjs > MID	MID (°)	Avg. change (all subjs) (°)	Corr. with preop values
	UR	65%	1.8	-6.9*	-0.60	82%	1.2	5.9*	-0.80
Neutral	IR	65%	1.3	-2.8	-0.53	35%	1.7	-0.2	-0.05
	PT	71%	1.2	-3.1*	-0.66	71%	1.2	4.2*	-0.53

Table 3.2: Change (postoperative – preoperative) in scapular resting orientations

UR = upward rotation, IR = internal rotation, PT = posterior tilt. Blue shading represents consistent changes (large average changes from preop to postop and a large proportion of subjects who experienced a change greater than the MID). Yellow shading indicates minimal changes (a small average change and small proportion of subjects who experienced a change greater than the MID). An \* indicates a change was significant at the  $\alpha = 0.05$  level.

### **3.3.1.3** Changes in Scapular Range of Motion

The SMA demonstrated that every subject experienced a significant postoperative change in ST displacement along at least one axis of motion, with many subjects experiencing changes along all three axes. Changes in displacement could be grouped into three categories: minimal changes (kinematic variables which were not affected after PSF), consistent changes (kinematic variables for which subjects many experienced a significant change in the same direction) and inconsistent changes (kinematic variables for which subjects experienced significant changes in both directions). The largest and most consistent changes occurred for the scapulae on the convex side of the curvature, where subjects lost upward rotation displacement and shifted toward internal rotation and anterior tilt displacement (Table 3.3).

		Concave (Left)			Convex (Right)				
		% subjs with sig. change	% with incr. disp.	% with decr. disp.	Corr. with preop values	% subjs with sig. change	% with incr. disp.	% with decr. disp.	Corr. with preop values
	UR	59%	70%	30%	-0.08	47%	12%	88%	-0.21
Abduction	ER	18%	100%	0%	-0.26	65%	27%	73%	-0.29
	PT	59%	70%	30%	-0.56	59%	20%	80%	-0.28
Forward Reach	UR	41%	43%	57%	-0.61	47%	12%	88%	-0.53
	IR	18%	0%	100%	-0.85	47%	25%	75%	-0.48
	AT	41%	43%	57%	-0.78	53%	11%	89%	-0.47
	UR	35%	83%	17%	-0.56	41%	14%	86%	-0.47
Hand to Spine	ER	65%	46%	54%	-0.78	59%	20%	80%	-0.44
Spile	AT	41%	57%	43%	-0.64	47%	12%	88%	-0.45

Table 3.3: Proportion of subjects who experienced significant changes in ST displacement and the relationship of changes to preoperative values.

UR = upward rotation, DR = downward rotation, ER = external rotation, IR = internal rotation, AT = anterior tilt, and PT = posterior tilt. Yellow shading indicates minimal changes, blue shading indicates consistent changes, and red shading represents inconsistent changes in ST displacements.

## 3.3.1.4 Patient-Rated Outcomes

Postoperative DASH scores demonstrated a trend toward lower (better)

postoperative scores, however the change was not statistically significant (mean

difference =  $-1.4 \pm 5.1$ , *p* = 0.26).

## **3.3.2** Comparison to Typically Developing Individuals

### **3.3.2.1** Scapular Upward and Downward Rotation

Results of the ANOVA for ST upward rotation indicated a significant interaction between group, side, and position (F = 7.923, p < 0.001).

Scoliosis group convex (right) sides were not significantly different than the typically developing group in the neutral position, but were significantly less upwardly rotated in abduction (mean difference  $7.5^{\circ}$ , p = 0.007), forward reach (mean difference  $8.3^{\circ}$ , p = 0.008) and spine (mean difference  $7.3^{\circ}$ , p = 0.002) (Figure 3.6A). This change can be attributed to the scoliosis group achieving less range of motion along the upward rotation axis, as evidenced by a significant group by side interaction for upward rotation displacement (F = 17.702, p < 0.001). Post hoc testing revealed that the convex side of the scoliosis group had significantly less upward rotation displacement than the right sides of the typically developing group (mean difference  $4.2^{\circ}$ , p = 0.032).

Scoliosis group concave (left) sides were significantly less upwardly rotated than the typically developing group left sides in the neutral position (mean difference  $6.4^{\circ}$ , p = 0.006) and in the hand to spine position (mean difference  $4.9^{\circ}$ , p = 0.050) (Figure 3.6B).

There were no significant differences between right and left sides in the typically developing group, however within the scoliosis group, the concave (left) scapulae were significantly less upwardly rotated than the convex (right) scapulae in the neutral position (mean difference  $5.1^\circ$ , p = 0.001) and had significantly more upward rotation displacement (mean difference  $7.6^\circ$ , p < 0.001).



Figure 3.6: ST upward rotation displacement for (A) concave/left sides and (B) convex/right sides of preoperative AIS patients (red), typically developing subjects (blue) and postoperative AIS patients (green). Dots represent the resting (neutral) orientation, while arrows indicate displacement along the upward (+) and downward (-) rotation axis.

### 3.3.2.2 Scapular Internal and External Rotation

There were no significant differences in absolute ST internal rotation between the postoperative scoliosis group and the typically developing group (Figure 3.7A-B). However, there was a significant interaction between group, side, and position for internal/external rotation displacement (F = 3.777, p = 0.030). Post hoc testing revealed that, while there were no significant differences between sides within the typically developing group, the concave (left) side of the scoliosis group had significantly more internal rotation displacement (protraction) than the convex (right) side in the forward reach position (mean difference =  $4.9^\circ$ , p = 0.008).



Figure 3.7: ST internal/external rotation displacement for (A) concave/left sides and (B) convex/right sides of preoperative AIS patients (red), typically developing subjects (blue) and postoperative AIS patients (green). Dots represent the resting (neutral) orientation, while arrows indicate displacement along the internal (+) and external (-) rotation axis.

### 3.3.2.3 Scapular Posterior and Anterior Tilt

There was a significant interaction between group and side for ST posterior tilt across all positions (F = 4.277, p = 0.044). Post hoc testing revealed that the scoliosis convex (right) scapulae were more anteriorly tilted than the typically developing right scapulae (mean difference = 4.1°, p = 0.028) (Figure 3.8A-B). Additionally, within the scoliosis group, the convex scapulae were significantly more anteriorly tilted than the concave scapulae (mean difference = 4.4°, p = 0.001). There were no significant differences in anterior/posterior tilt displacement.



Figure 3.8: ST posterior/anterior tilt displacement for (A) concave/left sides and (B) convex/right sides of preoperative AIS patients (red), typically developing subjects (blue) and postoperative AIS patients (green). Dots represent the resting (neutral) orientation, while arrows indicate displacement along the posterior (+) and anterior (-) tilt axis.

## 3.4 Discussion

Posterior spinal fusion results in structural changes and musculoskeletal trauma that have the potential to influence function of the upper extremity. Prior analyses of postoperative shoulder function only considered the range of motion of the HT joint, which was determined to be normal after surgery. <sup>23,24,36</sup> The results of this study support previous findings that HT function is unchanged after PSF. Examination of the ST joint, however, revealed that the AIS patients in this study experienced significant changes in scapular kinematics following PSF. At the six-month postoperative follow up, the comparison with the typically developing group revealed that some features of scapular mechanics normalized, while others exhibited pathological patterns of motion. To fully understand the effect of surgery on shoulder function, an analysis of both individual changes and deviations from a normal cohort is warranted.

### 3.4.1 Individual Changes

A normalization of scapular resting position and alterations in range of motion were evident in the analysis of individual changes following surgery. The three categories of changes (minimal, consistent, and inconsistent) clarify which outcomes may be expected following PSF, as well as which outcomes may vary due to individual patient characteristics. For the inconsistent outcomes, correlations with preoperative levels provide insight into which patients experienced changes of a certain magnitude or in a specific direction.

## 3.4.1.1 Minimal Changes

Displacements of the concave scapula along the internal/external rotation axis in the abduction and reach positions and along the upward/downward rotation axis in the hand to spine position were mostly unchanged after PSF. Preoperatively, these displacements were small and similar to the typically developing group, and thus this motion seemed to be unaffected by the surgery and generally normal in AIS.

### **3.4.1.2** Consistent Outcomes

Changes in resting (neutral) scapular orientation were consistent within the AIS group. Concave scapulae became less upwardly rotated and less posterior tilted, while convex scapulae became more upwardly rotated and more posteriorly tilted. The opposing bilateral direction of these changes suggest that the alterations in neutral orientation may be directly related to the modification of the curvature. Straightening of the spine may re-orient muscle fibers, pulling the scapula into a resting position that corresponds to the new trunk structure. Additionally, the normalization of the scapular position on the convex side may correspond to reductions in the rib hump that occur in association with the correction of spinal curvature.

Before surgery, AIS subjects exhibited more variability in scapular resting orientation than their typically developing peers—most likely a feature of the range of trunk distortion in the AIS group. Correlations between significant changes in neutral orientation and preoperative levels were moderately or highly negative, indicating reduced variability of the group after surgery. These correlations and the corresponding changes support the theory that normalization of the trunk deformity also results in normalization of the scapular resting orientation.

Changes in range of motion displacement on the convex side were also consistent across subjects. In the abduction position, over half of all subjects lost significant amounts of ST displacement, and an additional 25% experienced losses that were not of statistically significant magnitude. Similar percentages of the group experienced losses in upward rotation displacement in the abduction and reach positions, and a shift toward greater internal rotation displacement and anterior tilt displacement, regardless of position.

Changes in concave (left) side scapular displacement were generally less consistent. However, when humeral elevation was required (the abduction position), 60% of patients experienced a significant increase in upward rotation displacement with an additional 15% experiencing increases that were not statistically significant. The increase in upward rotation displacement had no relationship to preoperative displacement and may have occurred in conjunction with the more downwardly rotated resting position on this side in order to achieve the terminal scapular orientation necessary for positions of elevation.

The reduction in convex scapulae displacement and increase in concave scapulae displacement may also be related to muscle length asymmetries that may persist following surgeries. Asymmetrical muscle fiber length and orientation have been observed in a cadaveric study of untreated scoliosis, <sup>88</sup> and reduced displacement would be consistent with shorter muscles on the convex side of the curvature. At this stage, however, it is unknown whether muscle length asymmetry normalizes with correction of the spinal curvature or if displacement abnormalities persist beyond a six-month follow-up.

#### 3.4.1.3 Inconsistent Outcomes

Alterations in other kinematic variables were less consistent across subjects and appeared to be related to preoperative ST kinematics. A substantial fraction of patients with AIS experienced significant changes in posterior tilt on the concave side. However, the average of all significant changes was less than 2° across all positions, indicating that significant changes occurred in both directions. Correlations between these changes in tilt displacement and preoperative posterior tilt in the corresponding position were strong. The negative correlations indicated that the subjects with less posterior tilt displacement before surgery gained displacement, whereas those with higher preoperative displacement lost some of this range of motion following surgery. As with the changes in resting orientations, these correlations may represent a reduction in range of motion (displacement) variability due to correction of the trunk deformity.

A substantial proportion of patients also experienced significant changes in external rotation displacement during the hand to spine position. The correlation of changes along this axis with preoperative external rotation displacement was strongly negative. Subjects who before surgery utilized excessive ST retraction to place the hand behind the back demonstrated considerably less motion after surgery. Similarly, subjects who demonstrated scapular winging (internal rotation) before surgery appeared to control this behavior postoperatively. This is another example of the more homogenized postoperative group of subjects: internal/external displacement variability in all positions was much lower following PSF. Examining the relationship of ST kinematics with curve severity and change in curve parameters may elucidate how these changes in range of motion are related to correction of spinal curvature.

## 3.4.1.4 Summary of Individual Changes

In general, normalization of scapular resting position and changes to the convex shoulder (loss of upward rotation displacement, gain of anterior displacement and shift toward greater internal displacement) were consistent across subjects, and changes were large in magnitude. These outcomes may reasonably be expected for an AIS patient undergoing PSF. In contrast, changes to displacement of the concave shoulder were variable. Correlations with preoperative values were moderate to high and thus a patient's preoperative function may provide insight into postoperative outcomes.

### 3.4.2 Comparison with Typically Developing Individuals

Patients with non-surgically treated AIS have demonstrated alterations in ST kinematics compared to their typically developing peers. <sup>26,27</sup> Previously, it was unknown whether these differences resolved following correction of the scoliotic curve with posterior spinal fusion surgery. The results of this study indicate that, while individuals do experience significant changes in ST kinematics following surgery, they still demonstrate patterns of ST motion that differ from a typically developed cohort.

Post fusion surgery, the convex side scapulae exhibited a more normalized resting orientation. However, when moving to each terminal position, the AIS group displayed deficits compared to their typically developing peers. The AIS group had less overall motion (scapular upward rotation, retraction, and posterior tilt) in
abduction, and in general demonstrated scapular motion biased towards internal rotation and anterior tilt.

In contrast, the concave (left) side scapulae were more downwardly rotated than the typically developing scapulae at rest, but compensated with more upward rotation displacement in positions that required humeral elevation. The excessive posterior tilt seen in many patients prior to surgery normalized after PSF, however the direction of motion along this axis remained primarily in the anterior tilt direction.

Compared to the typically developing group, the postoperative AIS group generally displayed a similar scapular resting orientation, but alterations in range of motion. Both excessive and deficient upward rotation displacement introduce risk for shoulder pathology. Limitations in upward rotation displacement are associated with rotator cuff disease and impingement syndrome, <sup>13,18–20</sup> and a hypermobile scapula can compromise shoulder joint stability. <sup>15,16</sup> The onset of injury or disease may be long-term and thus it may be valuable to examine whether these patterns of ST motion persist beyond the six-month postoperative mark.

## 3.4.3 Patient-Rated Outcomes

Scores from the DASH questionnaire improved postoperatively on average, however this improvement was not statistically significant. Ten of 17 subjects either improved or stayed the same from their preoperative scores, leaving 7 subjects who worsened. Changes in ST variables were examined for each of the groups (improved/unchanged vs. worsened) to identify ST kinematic trends that may be related to patient perceived function.

Changes in neutral orientations were similar between groups (Table 3.4). These results are consistent with the analysis of individual changes, which revealed

that a large proportion of subjects experienced significant changes in neutral orientation in a consistent direction.

		Concave (Left)	Convex (Right)
Unword Detation	Improved	-7.9 (7.2)	6.0 (6.7)
Opward Rotation	Worse	-5.4 (8.4)	5.8 (4.8)
Internal Detetion	Improved	-2.9 (6.2)	-0.7 (6.8)
Internal Rotation	Worse	-2.7 (5.7)	0.5 (6.7)
Destarian Tilt	Improved	-1.3 (7.0)	4.8 (4.3)
Posterior 111t	Worse	-4.4 (4.3)	3.5 (5.5)

Table 3.4: Average change in neutral orientation (SD) for patients with improved and worse postoperative DASH scores.

Displacement changes differed between groups most notably along the ST upward rotation axis (Figure 3.9). The group of patients with improved DASH scores gained more upward rotation displacement on the concave side and lost less on the convex side than the group with worse DASH scores following surgery. Change in displacement along the other axes of ST motion appeared to be unrelated to change in DASH scores. Further analysis with additional subjects may clarify this relationship between change in ST kinematics and patient-perceived function.



Figure 3.9: Average change in ST displacement (degrees) for concave and convex sides of subjects separated into groups based on whether DASH scores improved or worsened postoperatively

# 3.5 Conclusion

The results of this study demonstrate value in considering upper extremity implications of PSF in adolescents with idiopathic scoliosis. Patients with AIS experience significant changes in ST kinematics following surgery, and at six months following PSF exhibit alterations in range of motion when compared to their typically developing peers. Some of the postoperative outcomes, such as normalization of scapular resting position and reduction in convex shoulder range of motion, seem to be typical consequences of correcting the scoliotic curve. Other results only occur in some subjects, and preoperative analyses may be able to shed light on postoperative results. Change in patient-perceived shoulder function following surgery may be related to changes in ST kinematics and further analysis of this relationship along with the relationship to curve severity may help clarify clinical outcomes.

#### Chapter 4

# THE INFLUENCE OF CURVE SEVERITY ON SHOULDER COMPLEX MECHANICS IN ADOLESCENT IDIOPATHIC SCOLIOSIS

## 4.1 Introduction

Adolescent idiopathic scoliosis (AIS) is one of the most common orthopedic disorders affecting the teenage population. <sup>4</sup> The idiopathic classification is assigned when neuromuscular and congenital factors are excluded, <sup>1</sup> and the diagnosis is unique in that the condition presents with insufficient information regarding the cause or progression of the disease. This limited understanding despite the prevalence of AIS has motivated a number of studies investigating the pathoetiology of idiopathic scoliosis.

Clinical research has previously looked to the lower extremity for insight into the association of AIS with biomechanical pathology. Several abnormalities have been identified in gait with restricted range of motion of the hip and pelvis among the most consistent findings. The relationship between the gait pathology and degree of spinal curvature has garnered considerable interest in the hope of identifying some systemic biomechanical characteristic associated with the progression of the disorder. The two largest studies to date yielded conflicting results; Mahaudens, et al. <sup>89</sup> determined that gait parameters were unrelated to degree of trunk deformity, while Syczewska et al. <sup>90</sup> found significant correlations between the Cobb angle and multiple kinematic variables. Currently, the association of curve severity with gait pathology is still unclear.

Theoretically, the impact of AIS on lower extremity motion would derive from an unknown underlying neurological pathology or from an altered center of mass position that imposes kinematic compensations. In contrast, upper extremity motionparticularly motion of the scapula—is directly affected by the trunk deformity found in AIS. Scoliotic curvature can influence length and orientation of scapulothoracic (ST) muscle fibers. <sup>88</sup> Additionally, the rib hump, which commonly occurs with thoracic curves, distorts the kyphosis of the trunk, which has been shown to impact ST kinematics. <sup>10,11,91</sup> The direct anatomical relationship of the scapula and the thoracic cage suggests that shoulder mechanics should be linked to the degree of curvature in scoliosis. While alterations in ST kinematics have been established in AIS, <sup>26,27</sup> no study has analyzed whether the extent of shoulder dysfunction is related to curve severity. Furthermore, if scapular mechanics are indeed dependent on scoliotic curvature, correction of the structural deformity should lead to correction of the shoulder joint pathology. An analysis of surgical curve correction and corresponding changes in ST kinematics may clarify factors relating to postoperative outcomes at the shoulder.

The purpose of this study was to investigate the relationship between the degree of scoliotic curvature and shoulder complex mechanics. Two parameters of curvature, the Cobb angle and the scoliometer measure of the rib hump, were examined in conjunction with a three-dimensional analysis of ST joint motion and patient-reported function. These parameters were analyzed before and six months after posterior spinal fusion (PSF) to investigate the influence of curve correction on the ST kinematic changes introduced from surgery. We hypothesized that curve severity would be related to patient-perceived function, and that adolescents with larger curves

would have a greater degree of ST kinematic pathology and bilateral asymmetry. We also hypothesized that the postoperative changes in ST kinematics would be related to both the change in the frontal plane deformity (i.e. the Cobb angle) and the change in the rib hump.

## 4.2 Methods

### 4.2.1 Subjects

Twenty-six patients with AIS (average age:  $14.7 \pm 1.7$ ) were recruited for this study, in accordance with informed consent and assent procedures established by the institutional review boards at Philadelphia Shriners Hospital for Children and Nemours/A.I. duPont Hospital for Children (AIS) (Appendix). All subjects with AIS presented with a primary right thoracic curvature ranging from 35° to 115°. Subjects were excluded if they had any history of previous shoulder surgery or injury, allergies to skin adhesives, or a body mass index greater than the 85<sup>th</sup> percentile for the subject's age and gender. <sup>47</sup>

A subset of these patients (n = 18) returned following PSF surgery. The following protocol was performed on both the entire (pre-surgical) group and the smaller group of patients at their six-month follow-up appointments.

## 4.2.2 Motion Capture

Subjects sat on a stool in a comfortable position, wearing three-dimensional retro-reflective markers at the following locations:

*Thorax:* sternal notch, T1 spinous process, T8 spinous process, thoracic vertebral spinous process above apex of scoliotic curve\*, vertebral spinous process below apex of scoliotic curve\*, lower lumbar vertebral spinous process\*.

*Humerus:* medial epicondyle, lateral epicondyle, posterolateral humerus

Scapula: acromion process

\*indicates that these markers were only placed on scoliosis subjects.

Subjects held their arms in a series of 11 positions (Figure 4.1).



Figure 4.1: Static positions for capture

At each position, the trigonum spinae and inferior angle of the scapula were palpated. Retro-reflective markers were placed on the palpated locations (Figure 4.2) and removed once the position was captured. Note that palpation has proven to be a reliable and accurate way to capture scapular orientation in static positions. <sup>48</sup> Due to the fact that available methods for measuring dynamic scapular motion can be inaccurate in extreme humeral elevation, <sup>49</sup> along particular axes of scapular motion, <sup>33</sup> and in populations with pathological motion, <sup>31,44</sup> this study was limited to a static analysis to avoid spurious conclusions due to measurement inaccuracy.



Figure 4.2: Marker placement, including scapular landmarks.

An additional feature was implemented during the postoperative data collection for scoliosis subjects. Prior to the follow-up data collection, preoperative

HT elevation angles were calculated for three of the positions that encompassed a broad range of ST motion: abduction, forward reach, and hand to spine. Real-time feedback using motion capture was provided to ensure that the subject sufficiently replicated the HT positions to within  $10^{\circ}$  of preoperative orientations. During the postoperative data collection, subjects were instructed to match the preoperative HT elevation, guided by a block figure representation of the subject (Figure 4.3).



Figure 4.3: Representation of target positions for real-time motion capture matching at postoperative appointment

Marker locations were captured with a 12 camera Motion Analysis (Santa Rosa, CA) system (Nemours) or a 12 camera Vicon (Centennial, CO) system (Shriners) operating at 60 Hz. Although two different motion capture systems were used in this study, the accuracy of each system is identical, and data collected from the systems are interchangeable. <sup>50</sup> Raw data files were processed with the same custom LabVIEW software (National Instruments, Austin, TX).

#### 4.2.3 Patient-Rated Outcome Measures

All subjects completed a Disabilities of the Arm Shoulder and Hand (DASH) questionnaire. The DASH is a 30-item scale used to assess patient-reported shoulder pain and physical function as well as social and emotional function. <sup>51</sup> The score ranges from 0 to 100 where 0 indicates no disability and 100 indicates the most severe disability. The DASH was chosen for this study because it has been shown to be valid and reliable in patients with shoulder pathologies, <sup>52–54</sup> and focuses on activities of daily living. Additionally, the use of the DASH to evaluate shoulder function in adolescents is well established. <sup>55–57</sup>

#### 4.2.4 Measures of Curvature

Radiographs for each of the scoliosis subjects were obtained from the hospital's electronic medical records. The Cobb angle was calculated from the intersection of the lines drawn parallel to the endplate of the most superior vertebrae in the scoliotic curve and the endplate of the most inferior vertebrae in the curve. <sup>92</sup> Clinical measures of rib hump prominence were collected using an iPhone scoliometer app (Figure 4.3). <sup>93,94</sup> A trained investigator placed the device on the most severe angle

of the thoracic trunk, with the patient flexed forward at the waist. Measurements were repeated at the six-month follow-up point for the subset of postoperative patients.



Figure 4.4: Scoliometer iPhone app measuring rib hump prominence

# 4.2.5 Data Processing

The trunk coordinate system was created using recommendations from the International Society of Biomechanics (ISB). <sup>58</sup> The scapular coordinate system was constructed using a modification of ISB recommendations, substituting the acromion process for the acromion angle, for ease of palpation. Scapulothoracic orientations were calculated by the ISB-recommended YXZ Euler sequence, in which rotation about the Y axis corresponded to internal and external rotation (protraction/retraction), rotation about the X axis corresponded to upward and downward rotation, and rotation about the Z axis corresponded to anterior and posterior tilt. <sup>58</sup> Scapulothoracic range of motion was determined by the maximum and minimum values along each axis across all positions.

# 4.2.6 Data Analysis

The relationship between curvature and patient reported outcomes was evaluated through Pearson product-moment correlations between Cobb angles and DASH scores. The relationship between curvature and kinematics was evaluated through the correlations between curvature (Cobb angles and scoliometer measures) and ST kinematics (neutral orientations and ranges of motion for each axis). The convex and concave sides were analyzed separately.

The relationship between curvature and scapular orientation asymmetry within scoliosis subjects was assessed through correlation between curvature (Cobb angles and scoliometer measures) and absolute differences in scapular orientations between the convex and concave sides for neutral and the three representative positions (abduction, forward reach, and hand to spine). A global measure of symmetry was also calculated for each axis by averaging absolute bilateral differences across all 11 positions.

The relationship between each component of curve correction and kinematic changes was assessed with correlations between change in Cobb angle, change in scoliometer measure and changes in ST neutral orientations and range of motion along each axis.

Additionally, a multiple regression analysis was performed to analyze the relationship between postoperative measures of ST kinematics, preoperative levels of the corresponding kinematic variables, and preoperative Cobb angle and scoliometer

measures. A stepwise regression was performed with the criteria of F probability less than or equal to 0.05 to enter the model and greater than or equal to 0.10 to be removed from the model.

Statistical analyses were performed in SPSS (IBM Corp, Armonk, NY) with the criteria for statistical significance set at  $\alpha = 0.05$ . Interpretation of correlation coefficients adhered to the recommendations of Dancey and Reidy: a correlation coefficient greater than 0.70 was considered a strong correlation, a coefficient between 0.40 and 0.69 was considered moderately correlated, and a coefficient of less than 0.40 was considered weakly correlated. <sup>66</sup>

#### 4.3 Results

#### 4.3.1 Relationship of Curve Severity to Patient-Reported Function

The DASH scores were not related to the Cobb angles (r = 0.14) or the scoliometer measures (r = 0.24).

#### 4.3.2 Relationship of Curve Severity with Preoperative ST Kinematics

Scapular range of motion on the concave side of the curve was moderately correlated with the Cobb angle for two out of three axes. Coefficients indicated that upward and internal rotation range of motion decreased with increasing curve severity. On the convex side of the curve, ST upward rotation and posterior tilt were moderately to strongly related to curve parameters. Resting posterior tilt decreased with greater Cobb angles and scoliometer measures. Upward rotation and posterior tilt range of motion were also moderately to strongly related to curve severity, decreasing with greater Cobb angles and scoliometer measures (Table 4.1).

			Coefficient of	f Correlation
			Cobb Angle	Scoliometer
		Upward Rotation	-0.02	-0.09
Concave	Neutral	Internal Rotation	-0.28	-0.01
		Posterior Tilt	0.29	0.11
	ROM	Upward Rotation	-0.57	-0.28
		Internal Rotation	-0.42	-0.24
		Posterior Tilt	-0.18	-0.09
Convex		Upward Rotation	-0.16	-0.17
	Neutral	Internal Rotation	0.01	0.09
		Posterior Tilt	-0.53	-0.67
	ROM	Upward Rotation	-0.61	-0.40
		Internal Rotation	-0.28	-0.05
		Posterior Tilt	-0.40	-0.41

# Table 4.1: Correlations between Cobb angle or scoliometer measures and ST kinematics

Yellow shading indicates moderate correlations. Green shading indicates strong correlations.

## 4.3.3 Relationship of Curve Severity to ST Joint Asymmetry

Scapular orientation asymmetry was moderately related to curve severity at rest and in the four representative positions. (Table 4.2). Coefficients indicated that ST internal rotation and posterior tilt asymmetry increased with greater curve severity, while upward rotation asymmetry decreased with greater curve severity, particularly in positions involving humeral elevation. Global asymmetry (average absolute differences between sides across all positions) increased with more severe curves and was more related to the Cobb angle than to scoliometer measures (Figure 4.5).

		Coefficient of correlation	
		Cobb Angle	Scoliometer
	Upward Rotation	-0.30	-0.20
Neutral	Internal Rotation	0.48	0.04
	Posterior Tilt	0.58	0.52
	Upward Rotation	-0.33	-0.38
Abduction	Internal Rotation	0.38	0.04
	Posterior Tilt	0.60	0.53
	Upward Rotation	-0.42	-0.45
Reach	Internal Rotation	0.25	0.07
	Posterior Tilt	0.45	0.28
Spine	Upward Rotation	-0.25	-0.09
	Internal Rotation	0.57	0.15
	Posterior Tilt	0.53	0.57

Table 4.2: Relationship of absolute convex and concave side ST kinematic differences to curve parameters

Yellow shading indicates moderate correlations.



Figure 4.5: Relationship between global ST asymmetry (average absolute difference between convex and concave sides across all positions) and curve parameters (Cobb angle and scoliometer measure).

# **4.3.4** Relationship of Curve Correction to Postoperative Changes in ST Kinematics

Preoperative and postoperative levels of curvature and kinematics are displayed in Table 4.3. Changes in curve parameters following PSF were moderately correlated with changes in internal rotation range of motion on the concave shoulder. For the convex shoulder, changes in scoliometer measures were moderately correlated with changes in resting posterior tilt, and changes in the Cobb angle were moderately correlated with changes in upward rotation range of motion (Table 4.4).

The multiple regression analysis indicated that the most important factor influencing postoperative ST kinematics was the preoperative level of the corresponding kinematic variable. The preoperative scoliometer measure did not significantly influence any postoperative kinematic levels, and the preoperative Cobb angle only made a significant contribution to postoperative upward rotation range of motion for the convex shoulder (Table 4.5).

			Preop		Postop	
			Avg.	SD	Avg.	SD
Curvature (Degrees)		Cobb Angle	59.1	15.9	21.8	5.3
		Scoliometer	14	5	3.3	1.4
		Upward Rotation	1.8	9.6	-5.4	7.4
	Neutral	Internal Rotation	42.4	9.2	41.4	6.2
Concave ST		Posterior Tilt	1.6	6.6	2.2	5.3
(Degrees)	ROM	Upward Rotation	54.8	7.4	60.4	8.2
		Internal Rotation	41.7	10.4	42.8	7.8
		Posterior Tilt	20.3	8.4	16.7	3.6
Convex ST Kinematics (Degrees)	Neutral	Upward Rotation	-4.7	6.5	-0.3	3.9
		Internal Rotation	41.6	6.5	43.9	5.2
		Posterior Tilt	-6.9	5.9	-2.3	5.3
	es) ROM	Upward Rotation	60.7	8.3	60	8.2
		Internal Rotation	36	8.8	39.9	8.2
		Posterior Tilt	15	5.1	17.5	4.3

Table 4.3: Means and standard deviation of preoperative and postoperative levels of curvature and kinematics.

			Coefficient of Correlation	
			Cobb Angle	Scoliometer
		Upward Rotation	-0.03	-0.20
	Neutral	Internal Rotation	0.17	-0.24
Conceve		Posterior Tilt	0.14	-0.07
Concave	ROM	Upward Rotation	-0.21	-0.07
		Internal Rotation	-0.43	-0.41
		Posterior Tilt	-0.18	-0.32
Convex	Neutral	Upward Rotation	-0.22	-0.27
		Internal Rotation	0.20	0.24
		Posterior Tilt	-0.03	-0.40
	ROM	Upward Rotation	-0.56	-0.21
		Internal Rotation	-0.23	-0.07
		Posterior Tilt	0.05	-0.12

 Table 4.4: Correlations between postoperative changes in Cobb angle or scoliometer measure and postoperative changes in ST kinematics

Yellow shading indicates moderate correlations.

			Coefficient of Correlation		
			Preop. Level	Cobb Angle	Scoliometer
		Upward Rotation	0.59*	0.01	-0.16
Concave	Neutral	Internal Rotation	0.79*	0.40	0.44
		Posterior Tilt	0.52*	0.38	0.23
		Upward Rotation	0.45	0.36	0.19
	ROM	Internal Rotation	-0.13	0.25	0.32
		Posterior Tilt	-0.10	-0.11	0.01
Neutr Convex ROM		Upward Rotation	0.47	-0.16	-0.01
	Neutral	Internal Rotation	0.72*	0.11	0.06
		Posterior Tilt	0.65*	-0.33	-0.55
	ROM	Upward Rotation	0.49	-0.60*	0.08
		Internal Rotation	0.26	-0.08	0.06
		Posterior Tilt	0.48	-0.35	-0.48

Table 4.5: Correlations between postoperative measures of ST kinematics and preoperative levels of the same variable and curve parameters.

I.

Yellow shading indicates moderate correlations. Green shading indicates strong correlations. An \* indicates statistical significance of the regression at p < 0.05.

#### 4.4 Discussion

The aim of this study was to examine the relationship of curve severity and curve correction to upper extremity function in patients with AIS. The results indicate that several aspects of scapular motion are indeed influenced by the scoliotic deformity, particularly the lateral spinal curvature. Still the extent of correction of this curvature does not appear to dictate the magnitude of change in kinematics. Instead, postoperative kinematics appear to be more dependent upon preoperative levels of ST function.

#### 4.4.1 Relationship of Curve Severity to Patient-Reported Function

Correlations between DASH scores and curve parameters indicated little to no relationship. While the DASH enjoys widespread use as a patient-reported shoulder disability questionnaire, <sup>52–57,95–97</sup> this study represents the first use of the questionnaire in patients with AIS. Findings from the previous chapters indicate that DASH scores are lower in AIS than in typically developing adolescents, however the differences are less than the minimum clinically important difference associated with the questionnaire. <sup>54</sup> These findings, along with the lack of relationship to degree of deformity, suggest that this questionnaire may not be particularly useful in the AIS population. Limitations of the DASH have been identified in assessments of young athletes. <sup>68</sup> The study identified a substantial ceiling affect that dampened differences within the athlete population and differences compared to other cohorts. Many adolescents with AIS are also high-functioning and participate in sports and other physical activities. The reported ceiling effect may limit the capacity of the questionnaire to detect differences in patient-reported shoulder function between adolescents with varying degrees of spinal curvature.

#### 4.4.2 Relationship of Curve Severity with Preoperative ST Kinematics

The degree of scoliotic curvature affected the resting scapular orientation, but only on the convex side. Greater curves were associated with a more anteriorly tilted scapula at rest. A more severe rib hump, as measured by the scoliometer, was particularly influential. The rib hump creates a hyperkyphotic surface on the convex side and a hypokyphotic surface on the concave side. As the apex of thoracic curvature occurs close to the inferior border of the scapula, the bone rests along the kyphosis of the surface, resulting in a more downwardly rotated and anteriorly tilted orientation (Figure 4.6). The association of orientation with the curve parameters suggest that resting scapular position is a direct response to the thoracic deformity.



Figure 4.6: Rib cage and scapular resting position for a typically developing individual in the A) sagittal view and B) top view and an individual with AIS in the C) sagittal view and D) top view.

The scapular range of motion of both shoulders was also influenced by curve severity. Convex shoulder upward rotation and posterior tilt range of motion decreased with greater Cobb angle and rib hump measures. As with the resting orientation, the hyperkyphotic surface on the convex side of the curvature appears to directly impact scapular positioning. A more severely distorted surface over which the scapula tracks may impede end range motion, particularly along the upward rotation axis, where the scapula experiences the greatest amount of displacement. Motion on the concave side was also affected. Range of motion decreased along the upward rotation and internal rotation axes as Cobb angles increased. Correlations between range of motion and the scoliometer were weak, but consistently in the same direction as correlations with the Cobb angle.

The relationship of concave side scapular range of motion to lateral spinal curvature may be a function of muscle length and orientation. The lateral curvature of the spine shifts the origin of the ST musculature toward the convexity of the curvature. Without a corresponding increase in muscle fiber lengths, the scapula would be limited in motion around the thoracic surface, particularly during movements involving protraction. While research regarding muscle fiber length and orientation is limited in scoliosis, this theory could explain the detrimental effect of curvature on range of motion that was observed in this study.

# 4.4.3 Relationship of Curve Severity to ST Joint Asymmetry

Healthy individuals can exhibit asymmetrical ST motion between dominant and non-dominant limbs, but differences are generally small and not clinically significant. <sup>14,61,98</sup> Absolute differences between limbs in this study reached over 30°, much higher than those reported in studies examining a typically developing cohort.

Morphological properties been implicated in the origin of scapular asymmetry, <sup>99</sup> and thus it follows that the thoracic deformity in AIS could engender asymmetrical patterns of scapular motion. The moderately positive correlations in this study support that theory, indicating that more severe curvature is associated with greater asymmetry along the internal rotation and posterior tilt axes. In contrast, more severe curvature is associated with less upward rotation asymmetry. While this initially seems contradictory, the reversal of relationship may be due to the limitations of motion experienced by individuals with severe curves. As observed in this study, upward rotation range of motion decreases with greater spinal and rib curvature. Asymmetry is typically greatest in the end ranges of motion, <sup>61</sup> and it may be possible that individuals with more severe curvature cannot achieve the range of scapular upward rotation where asymmetry is apparent.

# 4.4.4 Relationship of Curve Correction to Postoperative Changes in ST Kinematics

In general, the degree of curve correction, did not correspond in an obvious way to changes in ST kinematics following PSF. Greater correction of the Cobb angle was moderately associated with a greater gain of internal rotation range of motion for the concave shoulder and a greater gain of upward rotation range of motion for the convex shoulder. Greater correction of the rib hump (change in scoliometer measure) was also moderately associated with a greater gain of internal rotation range of motion for the concave shoulder and a shift toward a more posteriorly tilted resting position of the scapula on the convex shoulder. Still, most correlations were weak or zero, and the moderate associations identified did not correspond to the scapular kinematic parameters that changed most significantly following PSF. It appears that curve correction is not particularly useful as a predictor of change in ST kinematics. Consequently, given the broad range of curve severity of the individuals who underwent surgery, we examined the influence of preoperative levels of curvature on ST kinematics following PSF.

The correlation analysis indicated some moderate associations between preoperative curvature and postoperative ST kinematics, but most correlations were weak or negligible. When examined alongside preoperative levels of ST kinematics using a multiple regression approach, the only variable for which curvature contributed significantly to the model was postoperative upward rotation range of motion. All other measures demonstrated stronger relationships to preoperative levels of ST kinematics, rather than spinal curvature or trunk deformity.

The relationship of postoperative kinematics to preoperative levels is consistent with the previous chapter's analysis of changes in scapular motion following PSF. However, the lack of relationship to levels or changes in curvature was surprising. Patients with AIS experience many significant changes in ST kinematics following PSF. While some of these changes are experienced consistently across patients, other measures significantly increase in some patients and significantly decrease in others. We theorized that an analysis of spinal curvature could help elucidate the variability in postoperative changes, however no clear relationship was apparent in this study. The single moderate association between Cobb angle and postoperative convex shoulder upward rotation range of motion fails to add substantial insight, as the reduction in range of motion after PSF was experienced almost uniformly across subjects.

This lack of association may be a consequence of the distribution characteristics of the postoperative AIS group. After surgery, the AIS group demonstrated much less variability—both in spinal curvature and in kinematics (Table 4.3). The reduced variability in spinal curvature is associated with a normalized trunk structure and represents the efficacy of PSF for a range of curve severity. However, the reduced variability in ST kinematics and lack of relationship with curvature may represent a systemic effect of the invasiveness of PSF. One potential explanation is that the abnormal scapular kinematics observed in postoperative AIS patients are related to the presence of instrumentation and associated musculoskeletal trauma in the thoracic region, rather than any residual deformity. After PSF, convex shoulder range of motion is reduced, suggesting a functional muscle lengthening, whereas concave shoulder range of motion increases, suggesting a functional muscle shortening. This theory has yet to be confirmed with imaging evidence, however it represents a plausible explanation of the observed results and potential direction for future studies.

## 4.5 Conclusion

The severity of the trunk deformity influences scapular resting orientation, range of motion and bilateral symmetry in patients with AIS. The extent of the rib hump dictates the position of the convex side scapula, while greater spinal curvature influences displacement of the concave side scapula. More severe curves are associated with more asymmetrical motion along the internal rotation and posterior tilt axes. The influence of curvature before any surgical treatment is apparent, however curve severity and curve correction do not substantially impact changes in ST motion following PSF. While analysis with more subjects may expound on this absence of

association, the preoperative level of ST motion currently appears to be the most relevant factor in predicting the kinematic response to surgery in AIS.

# Chapter 5

## CONCLUSION

# 5.1 Introduction

The aim of this study was to examine how the trunk deformity and surgical treatment of spinal curvature impact shoulder complex function in patients with adolescent idiopathic scoliosis (AIS). Compared to research regarding motion of the spine and lower limbs, there has been relatively little attention paid to understanding the effect of the scoliotic deformity on shoulder function, and even less attention paid to understanding the effects of corrective surgery on shoulder mechanics. This study provided a three-dimensional analysis of how scapulothoracic (ST) kinematics in AIS differ from a typically developing cohort and how these differences influence patient-perceived function. We then analyzed how surgical correction of the spinal curvature impacts shoulder function, and how postoperative patients with AIS compare to their typically developing peers. Finally, we investigated how curve severity interacts with shoulder function and how the degree of curve correction influences postoperative changes in ST kinematics.

#### 5.2 Summary of Results

#### 5.2.1 Comparison Between AIS and Typically Developing Adolescents

Adolescents with idiopathic scoliosis exhibited abnormal ST function compared to their typically developing peers. Patients with AIS reported significantly worse scores than healthy adolescents on the Disabilities of the Arm Shoulder and Hand (DASH) questionnaire. However, the difference between groups was small, and the scores were unrelated to deviations in kinematics. DASH scores may be subject to a ceiling effect in young, high-functioning populations <sup>68</sup> which may reduce the clinical relevance of the questionnaire for AIS.

Kinematic differences were more pronounced. Patients with AIS exhibited alterations in scapular resting position and range of motion. The concave scapula was more posteriorly tilted than the typical scapula, and the convex scapula was more downwardly rotated and anteriorly tilted. In motion, particularly to positions of humeral elevation, the convex scapula displayed reduced ST upward rotation and almost no posterior tilt. This type of motion is associated with a variety of shoulder pathologies. While patients with AIS do not display any deficits in humerothoracic motion, the ST joint demonstrates patterns of movement that may place individuals at risk for shoulder dysfunction.

#### 5.2.2 Impact of Surgical Treatment on Shoulder Function

Prior to this study, it was unknown whether the abnormal shoulder mechanics identified in AIS were improved with correction of the spinal curvature. For the group of patients who underwent posterior spinal fusion (PSF) it was determined that all patients experienced significant changes in ST kinematics following surgery, but at a six-month follow-up point still demonstrated alterations in range of motion compared to their typically developing peers.

After PSF, most subjects displayed a normalization of scapular resting position, particularly on the convex shoulder. Range of motion was also significantly impacted, with the convex shoulder experiencing a loss of upward rotation displacement and a shift toward internal rotation and anterior tilt displacement. While these changes were large and consistent across the group, other postoperative changes varied across subjects. Patient-reported function improved for some subjects and worsened for others. Similarly, postoperative kinematics of the concave scapula varied across the group. Some subjects experienced significant increases in ST displacement, while others experienced significant decreases. Many of these changes were moderately to strongly correlated with preoperative levels with displacement, indicating the preoperative level of function may be a factor in postoperative outcomes.

When the group of postoperative AIS patients were compared to their typically developing peers, they displayed a similar scapular resting orientation, but altered range of motion. The convex shoulders demonstrated deficits in upward rotation displacement, while the concave shoulders were hypermobile along this axis. These scapular movement patterns are associated with rotator cuff disease, impingement syndrome, and shoulder instability. <sup>13,15,16,18–20</sup> These findings illustrate that patients with AIS still exhibit atypical ST motion and may still be at risk for shoulder pathology, even after curvature abnormalities are resolved.

#### **5.2.3** Influence of Curve Severity

The investigation of the relationship between the severity of scoliosis and shoulder function revealed that some parameters were associated with degree of curvature, while others appeared unrelated. Patient-reported function as measured by the DASH was not related to Cobb angles or scoliometer measures. However, curve severity did influence scapular resting orientation, range of motion and bilateral symmetry in patients who had not undergone surgical treatment. A more pronounced

rib hump was associated with a more upwardly rotated and anteriorly tilted scapula and less range of motion on the convex shoulder. More severe spinal curvature was associated with less range of motion of the concave shoulder. Greater curvature was also associated with more internal rotation and tilt asymmetry, but less upward rotation asymmetry, perhaps due to limits in upward rotation range of motion experienced by individuals with the most severe curves. The alterations in ST kinematics correspond to an anatomical response to the structural deformity. Analysis of ST muscle length and muscle fiber properties may elaborate upon these findings.

While preoperative ST kinematics were notably related to spinal curvature, postoperative ST kinematics and the changes resulting from surgery had little association with levels of curvature or the degree of correction. Preoperative values for ST kinematics appeared to be a much more important factor than spinal curvature in determining postoperative changes in ST function.

## **5.3** Future Work and Clinical Impact

The scope of this study is primarily confined to a quantitative analysis of kinematics and curvature. While the DASH was employed to interpret the kinematics results in the context of function, the results indicate minimal patient-reported disability, and a potential ceiling effect of the questionnaire. Scapular region pain is often reported as "back pain", and thus may not be accounted for in a survey regarding shoulder function. Furthermore, the DASH includes several questions regarding use of the wrist and elbow, which are unlikely to be affected by the scoliotic deformity. Future investigations may benefit from a functional analysis more suited to specific upper extremity issues in scoliosis. Additionally, incorporating strength measures in addition to kinematics may augment the understanding of shoulder function in AIS.

The interpretation of scapular kinematic changes after PSF would benefit from an analysis of the ST musculature. This study theorizes changes in muscle length and orientation that would result from the structural changes after PSF, however these have yet to be confirmed with imaging. Understanding the length-tension properties of these muscles after the surgical trauma may explain some of the range of motion abnormalities observed in postoperative patients.

Finally, the assessment of scapular mechanics in AIS would benefit from follow-up analyses. The alterations in scapular kinematics observed in the preoperative patients are typically associated with chronic injury. Accordingly, the onset of disease may be long-term, and it would be valuable to examine whether these patterns of ST motion impact shoulder function into adulthood. Similarly, ST kinematics after PSF may change as the adolescent adjusts to the presence of hardware in the thoracic region. Evaluation of mechanics past the six-month postoperative point may elucidate whether the response to surgery is short-term or a permanent structural adaptation.

# 5.4 Conclusions

This study delivered objective information describing shoulder function in patients with AIS. We identified three-dimensional abnormalities in scapular motion and noted those which were exacerbated with increased curve severity. Patients with AIS demonstrate kinematic patterns that may place them at risk for future shoulder pathology, and monitoring shoulder complex mechanics may become an important component of long-term treatment for AIS.

This was the first study to examine whether common surgical treatment h as beneficial or detrimental effects on shoulder dysfunction. While correction of the

scoliotic curvature with surgical treatment normalizes the resting orientation of the scapula, deficits in range of motion persist even after surgery. The postoperative analysis revealed kinematic changes that occurred for most if not all subjects and thus may be considered expected outcomes following surgery. Additionally, we identified components of ST motion that may significantly increase or decrease based on patient characteristics. Preoperative curve severity appears to have little bearing on postoperative shoulder outcomes. Instead, levels of ST motion before surgery may provide a better indicator of postoperative motion.

Idiopathic scoliosis remains the most common orthopedic disorder affecting the adolescent population. Continued research into the pathoetiology of the disease and development of less invasive treatment options will greatly benefit patients. In the meantime, this work highlights the importance of considering upper extremity factors in the evaluation and treatment of AIS.

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Appendix

**IRB APPROVAL DOCUMENTATION** 



RESEARCH OFFICE

210 Hullihen Hall University of Delaware Newark, Delaware 19716-1551 Ph: 302/831-2136 Fax: 302/831-2828

DATE:

May 16, 2017

TO:	Elizabeth Rapp, BS
FROM:	University of Delaware IRB
STUDY TITLE: : SUBMISSION TYPE:	[767133-7] Scapular Kinematics in Adolescents with Idiopathic Scoliosis Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	May 16, 2017
EXPIRATION DATE:	June 16, 2018
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # (9)

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that <u>informed consent</u> is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

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If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

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Nemours Office of Human Subjects Protection Nemours/Alfred I. duPont Hospital for Children 1600 Rockland Road Wilmington, DE 19803 Fax: 302-651-4883 Office: 302-298-7613 MEMORANDUM

DATE:	January 30, 2017
TO:	Suken Shah, MD
FROM:	Nemours IRB 2
STUDY TITLE:	[833806-6] Scapular Kinematics in Adolescents with Idiopathic Scoliosis - Nemours
IRB#:	833806
SUBMISSION TYPE:	Response/Follow-Up
ACTION:	APPROVED
APPROVAL DATE:	January 30, 2017
EXPIRATION DATE:	January 29, 2018

Thank you for your submission of Response/Follow-Up materials for this research study. Your initial submission received Expedited Review and met all DHHS criteria for approval. The approval was contingent on the response to minor stipulations. Your response has received Expedited Review and is accepted. The renewal of the above-referenced research study is approved.

The IRB has determined that:

- This is research not involving greater than minimal risk per 45CFR46.404 and 21CFR50.51. [Informed Consent or Parental Permission is required prior to initiation of any research procedures using only the most current IRB approved form(s) posted as a Board Document in IRBNet. All approved study documents can be accessed through "Designer" by clicking "Review Details" in IRBNet.
- The permission of one parent is sufficient. A person who is not a parent may not give permission
  without prior IRB review and approval.
- Assent of minors is required prior to initiation of any research procedures, using only the most current assent form(s) posted as a Board Document in IRBNet.
- A signed copy of the Parental Permission/Informed Consent form must be included in the Nemours' medical record. Research data may also be included into the Nemours medical record.
- The IRB requires that a copy of the participant brochure: "Becoming A Research Volunteer" will be given to every individual enrolled in a research study. The PDF file for this document has been attached to this study as a Board Document.
- To continue, the research requires IRB review and approval on an annual basis. January 29, 2018 is
  the last day that research may be conducted. To avoid closure of your study, you need to take one
  of the following actions: Submit an application for continuing review on a timely basis (see HSP-031
  and HSP-007) OR Submit a closure report at an earlier date.
- You, as the Principal Investigator, are responsible for the timely submission of the continuing review application. Please post this date on your research calendar. Please be reminded that applications for continuing review need to be submitted at least 4 weeks ahead of the expiration date to give sufficient time for IRB review.

Reviewed/approved documents in this submission:

Child Assent - Adolescent Assent - AIS - Rapp July 2016.docx (UPDATED: 01/19/2017)

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- Other Response Memo AIS Rapp.docx (UPDATED: 01/19/2017)
- Parental Permission Form Parental Permission AIS Rapp July 2016.docx (UPDATED: 01/19/2017)

**Investigator Agreement:** As the PI, you have agreed to assure that this research is conducted in compliance with Nemours policy and all applicable federal regulations and ICH standards, which also includes the following:

- All research must be conducted in accordance with this approved submission. Any revision to approved materials must be approved by the IRB prior to initiation.
- Remember that informed consent/parental permission is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.
- All serious and unexpected adverse events and unanticipated problems affecting participants must be reported promptly to the IRB according to NOHSP policy.
- All non-compliance issues or complaints regarding this study must be reported to the Director, NOHSP.
- · All research records must be retained for a minimum of three years.
- A Closure Report must be submitted to the IRB when this protocol is completed.

If you have any questions, please contact Caroline Schierle at Nemours Children's Specialty Care, 807 Children's Way, Jacksonville, FL 32207 at (904) 697-3415 or <u>Caroline.Schierle@nemours.org</u>. Please include your study title and reference number in all correspondence with this office.

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Western Institutional Review Board⊛ 1019 39<sup>th</sup> Avenue SE Suite 120 | Puyallup, WA 88374-2115 Office: (360) 252-2500 | **Toll Free**: (800) 562-4789 www.wirb.com Certificate of Approval

# THE FOLLOWING WERE APPROVED

INVESTIGATOR: Amer Samdani, MD 3551 N Broad Street Philadelphia, PA 19140, United States BOARD ACTION DATE: 05/12/2017 PANEL: 4 STUDY APPROVAL EXPIRES: 06/06/2018 STUDY NUM: 1165433 WIRB PRO NUM: 20161188 ONLINE TRACKING: INVEST NUM: 199002 WO NUM: 6-1001999-1 CONTINUING REVIEW: Annually SITE STATUS REPORTING: Annually INST, NUM: PHL1507

SPONSOR: Shriners Hospitals for Children PROTOCOL NUM: PHL1507 AMD. PRO.NUM: TITLE: Scapular Kinematics in Adolescents with Idiopathic Scoliosis

## APPROVAL INCLUDES:

Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

# WIRB APPROVAL IS GRANTED SUBJECT TO:

#### WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH: Shriners Hospitals for Children, Philadelphia, 3551 N. Broad St, Philadelphia, Pennsylvania 19140

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

## ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

- Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.
- Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.
- 3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada, when there is a local IRB and WIRB approved materials are reviewed by the local IRB and translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)
  - a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
  - b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB unless other arrangements have been made and approved by WIRB.
  - c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

## IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



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- 4. Enrollment of limited readers and non-readers: unless consent has been waived or the protocol excludes enrollment of limited readers or non-readers, involve an impartial witness in the consent process when enrolling limited or non-readers and document the participation of the impartial witness using the designated signature lines on the WIRB-approved consent form In the absence of designated signature lines, download the WIRB standard impartial witness form from www.wirb.com
- 5. Enrollment of pregnant partners that do not have the capacity to consent for themselves and require consent be provided by a legally authorized representative: unless the protocol excludes the enrollment of pregnant partners that do not have capacity to consent for themselves, obtain consent from the pregnant partners legally authorized representative and document consent using the pregnant partner legally authorized representative signature lines on the WIRB-approved consent form. In the absence of designated signature lines, download the WIRB standard legally authorized pregnant partner form from www.wirb.com
- 6. Obtain pre-approval from WIRB for changes in research.
- 7. Obtain pre-approval from WIRB for planned deviations and changes in research activity as follows:
  - If the research is federally funded, conducted under an FWA, or is a clinical investigation of a drug or biologic, then all planned protocol deviations must be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].
  - However, if the research is a clinical investigation of a device and the research is not federally funded and not conducted under an FWA, then only planned protocol deviations that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects [(DHHS 45 CFR § 46.103(b)(4); (FDA 21 CFR § 56.108(a)(4); ICH 3.3.7].

The reason for these different requirements regarding planned protocol deviations is that the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) drug and biologic divisions have adopted the regulatory interpretation that every planned protocol deviation is a change in research that needs prior IRB review and approval before implementation; however, the FDA device division operates under a distinct regulation (See 21 CFR 812.150(a)(4).

Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.

- 8. Report the following information items to the IRB within 5 days:
  - New or increased risk
  - Protocol deviation that harmed a subject or placed subject at risk of harm b.
  - Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject C.
  - d. Audit, inspection, or inquiry by a federal agency
  - Written reports of federal agencies (e.g., FDA Form 483) e.
  - f. Allegation of Noncompliance or Finding of Noncompliance
  - Breach of confidentiality
  - g. h. Unresolved subject complaint
  - Suspension or premature termination by the sponsor, investigator, or institution i.
  - Incarceration of a subject in a research study not approved to involve prisoners 1.
  - k. Adverse events or IND safety reports that require a change to the protocol or consent
  - State medical board actions
  - Unanticipated adverse device effect m.
  - Information where the sponsor requires prompt reporting to the IRB n.

Information not listed above does not require prompt reporting to WIRB.

Please go to www.wirb.com for complete definitions and forms for reporting.

- 9. Provide reports to WIRB concerning the progress of the research, when requested.
- 10. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

Board Action: 05/12/2017; Study: 1165433

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