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Biomechanical Evaluation of a Growth-Friendly Rod Construct

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Abstract

Background—Distraction type rods mechanically stabilize the thorax and improve lung growth and function by applying distraction forces at the rib, spine, pelvis, or a combination of locations. However, the amount of stability the rods provide and the amount the thorax needs is unknown.

Methods—Five freshly frozen and thawed cadaveric thoracic spine specimens were tested lateral bending, flexion/extension, and axial rotation in displacement control (1°/sec) to a load limit of ± 5 Nm for five cycles after which a growth-friendly unilateral rod was placed in a simulated rib-to-lumbar attachment along the right side. The specimens were tested again the same modes of

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bending. From the seven Optotrak Orthopedic Research Pin markers (Northern Digital Inc., Waterloo, ON, Canada) inserted into the top potting to denote T1, and the right pedicles at T2, T4, T5, T8, T9, and T11 and the Standard Needle Tip Pressure Transducers (Gaeltech, Isle of Skye, Scotland) inserted into the T4/T5 and T8/T9 discs, motion, stiffness, and pressure data were calculated. Parameters from the third cycle of the intact case and the construct case were compared using two-tailed paired t-tests with 0.05 as the level of significance.

Results—With the construct attached, the T1–T4 segment showed a 30% increase in NZS during extension (p = 0.001); the T8–T12 segment experienced a 63% reduction in the in-plane ROM during flexion (p = 0.04); and the T8/T9 spinal motion unit had a significant decrease of 24% in EZS during left axial rotation (p = 0.04).

Conclusions—It's clear the device as tested here does not produce large biomechanical changes, but the balance between providing desired changes while preventing complications remains difficult.

Clinical Relevance—Investigating the biomechanical effect growth-friendly rods have on the thoracic spine could lead to better understanding of treatment outcomes, both positive and negative.

Keywords

Scoliosis; biomechanics; autofusion; intradiscal pressure

1. BACKGROUND

Growth preserving spine implants are commonly used in the surgical treatment of early onset scoliosis (EOS).[1] Because these patients are still growing, EOS is often a challenge to treat.[2] Currently, distraction based spine implants are the most commonly used in EOS treatment.[2–4]

Distraction based implants mechanically stabilize the spine and/or thorax in the hope of preventing spinal deformity progression while allowing for pulmonary development in a growing child.[5] Traditional "growing rods" utilize anchors on the spine, both cephalad and caudal to the curve apex. More recently, the use of ribs as cephalad anchor sites has been described as a hybrid to the traditional system.[6] The first description of a rib based distraction system, however, was by Campbell.[7,8] The VEPTR®/VEPTR II™ Vertically Expandable Prosthetic Titanium Rib Vertical Expandable Prosthetic Titanium Rib (VEPTR) was designed to treat children with thoracic insufficiency syndrome, defined as the inability of the thorax to support normal respiration or lung growth.[9]

A well- known challenge to surgeons and engineers alike is finding the right balance between having enough stability to prevent deformity progression and implant failure, and an acceptable amount of motion to prevent autofusion of the thoracic spine.[10–13] Sankar described the law of diminishing returns with subsequent lengthening of growing rods, which was felt to likely be secondary to autofusion.[14] Cahill et al. reported an 89% incidence of autofusion in their series of 9 patients treated with growing rods.[15] Although rib based distraction is felt to maintain spinal growth,[16] the occurrence of unwanted ossification is still an issue with rib-based distraction systems. [7,8] This problem complicates the effort of obtaining additional improvements in spinal balance at the time of definitive fusion.

While very little is known about the exact cause of autofusion, most feel it is the direct result of the spine being somewhat immobilized by rigid implants. Currently, there is little biomechanical data regarding in-plane range of motion, out-of-plane range of motion, stiffness, motion symmetry, or disc pressure within the thoracic spine under the constraint of a pediatric unilateral distraction rod.[17–20] Motion, stiffness, and pressure experienced at an intervertebral joint are all clinically rooted biomechanical measures that can be used to monitor the integrity of the joint and the spine as a system.[21–24] By evaluating the implant biomechanics more closely, it may be possible to improve clinical success and reduce complications and the need for multiple procedures.

The goal of this study was to determine how VEPTR, a unilateral growth-friendly distraction rod construct, implanted in a simulated rib-to-lumbar attachment affects the kinematics, stiffness, and loading of the thoracic spine. With this information, inferences regarding clinical performance can be made. It was hypothesized that the implantation of VEPTR leads to (i) an increase in in-plane elastic zone stiffness (EZS), in-plane neutral zone stiffness (NZS), out-of-plane range of motion, and in-plane motion asymmetry, and (ii) a decrease in in-plane range of motion (ROM), in-plane elastic zone range of motion (EZ), and in-plane neutral zone range of motion (NZ) within the construct region compared to the intact cadaver specimen. As disc pressure increases have been found adjacent to long constructs, increased disc pressure was expected adjacent to the construct region.[25] However, no significant pressure differences were expected within the construct region, based on the findings of Mahar et al.[26] Increased out-of-plane range of motion was expected above the construct region, but no other biomechanical changes were expected.

2. MATERIALS AND METHODS

2.1 Specimen

Five freshly frozen and thawed cadaveric thoracic spine specimens, three male, were prepared to include vertebrae, intact rib cage, intervertebral discs, sternum, and stabilizing ligaments from T1–T12. Mean age was 68 ± 3.6 years. Exclusion criteria included vertebral fractures, severe scoliosis or kyphosis, and a history of spine surgery.

2.2 Setup

Potting parallel to the vertebral endplates at the superior (T1) and inferior (T12) ends of the specimen allowed for secure attachment to the test machine. Seven Optotrak Orthopedic Research Pin markers (Northern Digital Inc., Waterloo, ON, Canada) were inserted into the top potting to denote T1, and the right pedicles at T2, T4, T5, T8, T9, and T11. Standard Needle Tip Pressure Transducers (Gaeltech, Isle of Skye, Scotland) were inserted into the T4/T5 and T8/T9 discs, as described by Anderson et al. [27] Implementation of the pressure transducers was based on Cripton et al.[28] Disc pressure data was recorded using LabVIEW (National Instruments, Austin, TX, United States). A follower load of 400 N was applied by threading a cable from the T1 potting through ball joint rod ends connected to threaded rods inserted at T3–T11 vertebral body centers and hung off the T12 base from pulleys, as first described by Anderson et al.[27] A six degree component AMTI MC5-6-5000 (AMTI, Inc., Watertown, MA) was mounted at the T12 specimen base to verify that the resultant force acting on the spine was in the direction of the cable.

2.3 Testing

The FS20 Biomechanical Spine Test System (Applied Test Systems, Butler, PA) was used to test specimens in lateral bending, flexion/extension, and axial rotation in displacement control (1°/sec) to a load limit of ± 5 Nm for five cycles. The intact spines (T1–T12) were tested first in all modes of bending. A unilateral VEPTR system was then proximally attached to the right T5 rib, approximately 2.5 cm right lateral to the costotransverse joint. The distal attachment was secured to the inferior potting, creating a mechanical equivalent to a rigid attachment at the lumbar spine. The specimen with VEPTR system attached was then tested in all modes of bending again. A schematic of the setup is shown in Figure 1.

2.4 Analysis

Customized MATLAB (MathWorks, Natick, MA, USA) programs were used to calculate stiffness and motion parameters using Euler decomposition techniques for both the intact and construct case. In-plane ROM and stiffness parameters and out-of-plane ROM were computed for all modes of bending in the T1–T4, T4–T8, and T8–T12 spinal segments and for the T1/T2, T4/T5, and T8/T9 spinal motion units.[29] Parameters from the third cycle of the intact case and the construct case were compared using two-tailed Wilcoxon Signed Ranks tests with 0.05 as the level of significance.

Results

The objective of this study was to determine the biomechanical differences caused by a growth-friendly construct implanted in the thorax. Although significant differences between the intact case and the construct case were expected in many parameters, very few significant differences were found. The in-plane and out-of-plane ROM values are shown for spinal segments and spinal motion units in Tables 1–3 for axial rotation, lateral bending, and flexion/extension, respectively. In-plane stiffness values for both spinal segments and motion units are found in Table 4. Where motion sensors were blocked by the construct or the sensor resolution was too low to accurately capture the motion, biomechanical parameters could not be calculated.

The hypotheses proposed for the areas above and within the construct region were not supported by the data. Of all the parameter comparisons between the intact and construct case, only four were statistically significant. With the construct attached, the T4–T8 segment had an 11% decrease in ROM and the T8–T12 segment had a 44% ROM decrease during extension ($p = 0.04$); the T8–T12 segment experienced a 63% ROM reduction during flexion ($p = 0.04$); the T4–T8 segment had a significant decrease of 12% in EZ ROM during axial rotation ($p = 0.04$); and the out-of-plane motion in the sagittal plane during lateral bending significantly increased by 293% ($p=0.04$). No significant differences were found in the other in-plane motion, in-plane stiffness, out-of-plane motion, disc pressure, or symmetry between the intact and construct case for either segments or motion units.

DISCUSSION

The purpose of the growth-friendly rod construct is to provide stability to the thorax during development while preventing negative biomechanical changes; however, the ideal amount of stability for the construct to provide has not been determined. The challenge is to balance the distractive forces of the implant with the forces progressing the deformity. Too little rigidity and force could mean too little correction or retracting correction, perpetuating a poor quality of life; too much rigidity and force can lead to ossifications, rib dislocations, rib fracture, and subsidence.[6, 12, 30–35]

Understanding the biomechanical effect corrective constructs have on the thoracic system provides a better understanding of the clinical effect as well. Because the spine is a linked system, the rod attachment and simulated lumbar attachment altered biomechanical parameters outside and within the construct region. Because of the comparably flexible nature of rib-attached constructs, fewer changes occurred near and between attachment sites than initially expected. It is well known that the type of construct affects the resulting biomechanical parameters, with more rigid constructs causing greater biomechanical differences. Rod material, number of rods, addition of cross connectors, and rod attachment types have all been shown to increase the stiffness and/or decrease the mobility of the spine.[17–20, 36, 37] Other studies have shown that a less rigid construct produces fewer adjacent level changes.[20] This study utilized a rod construct with a simulated rib-to-lumbar attachment, producing a comparably flexible system, which had not been tested previously.

Very few studies have been conducted to determine the biomechanical effect of VEPTR system. The two major innovations of this study, inclusion of the rib cage and the unconstrained superior motion, were implemented to create testing conditions more similar to clinical conditions. The inclusion of the rib cage has significant effect on the thoracic biomechanics.[38, 39] With rib attached constructs, including or at least simulating the rib cage is vital in biomechanical tests. While trends with previous research may be similar, it is difficult to draw direct comparisons due to the inclusion of the rib cage in the present study. For example, a study by Rodriguez- Martinez et al. implemented four variations of long rod constructs in the thoracic spine and found the greatest motion variation in the sagittal plane.[40] Similarly, the present study also found the greatest motion changes occurred in the sagittal plane. However, the 75%–76% loss of sagittal motion in that study is not similar to the 24%–58% loss of sagittal motion that was found in the present study.[40] While implementing this innovation inhibits direct comparisons to other research in the field, it provides a more clinically relevant mechanism for studying biomechanical changes in deformities and treatments of the thoracic spine.

Intradiscal pressure has not previously been investigated in a growth-friendly distraction rod model, but has been shown to be an important indicator for disc degeneration and therefore is important to investigate.[24] Some studies found significant intradiscal pressure changes in single level fusions and others found significant trends that suggest these pressure changes increase with increasing construct length.[25, 41, 42] However, this is not the case for all studies. One study investigated the disc pressure at two levels between attachment points in long rod constructs meant for definitive fusions, one level directly adjacent to the superior attachment and one level in the midpoint between the two attachment sites. At both disc locations, no significant pressure changes were noted, which agrees with the findings of the current study.[26] Another study showed that at the level adjacent to the superior attachment, intradiscal pressure was reduced when a less rigid construct was implemented.[43] Despite the length of the construct, more flexible systems are able to avoid pressure changes at the adjacent level. The construct used in the current study allowed for more similar loading above the construct and between construct attachment points, resulting in no significant intradiscal pressure changes at the level adjacent to the superior attachment site or within the construct region.

Clinically, many construct variations have provided the needed rigidity to stabilize the thorax during childhood development, but have resulted in complications caused by biomechanical changes to the adjacent levels and the region as a whole. Ossifications at the attachment sites, along the implant, between ribs, and between vertebrae have been found with differeing level of incidence.[10–12, 30, 31, 34] These ossifications are thought to contribute to curve stiffening.[11, 12, 30, 35] Anchor point migration is a common occurrence with these devices,[6, 12, 30–35] and in some cases rib fracture or dislocation has occurred.[30, 32–35] These issues are seen in rib-to-rib, rib-to-lumbar, and rib-to-pelvis variations of these constructs to varying degrees. Because the prevalence varies based on the type or configuration of the construct, there seems to be an underlying biomechanical cause for these complications. Ossifications most often occurred at attachments at the lumbar spine and were more prevalent when the construct had a high rate of load sharing and when the curve correctability was lower, indicating a stiffer thoracic curve.[10, 12] By design, repeated pressure is applied at attachment sites. This allows for flexibility of the construct, which mitigates rib fracture and dislocation, but leaves the periosteum suseptible to injury and subsequent ossification.[12]

To the authors' knowledge, this pilot study was the first of its kind to investigate the in-plane and out-of-plane motion biomechanics, as well as intradiscal pressure, of a growth-friendly construct in a thoracic spine and rib cage model. While this type of investigation helps to characterize the biomechanical changes brought on through this type of treatment, there are limitations of this study design. The spines used were not representative of an early onset scoliosis population, both in terms of age and deformity characteristics due to the extreme difficulty of acquiring specimen within the appropriate age range. Bone quality as well as anatomic geometry would have an effect on the biomechanical parameters, and these were not appropriately simulated in an older adult cadaveric model. This type of device is typically tensioned to apply a distraction force and no such force was applied in this study since the purpose was to investigate the influence of the VEPTR rather than distraction forces on spinal biomechanics, which has been previously studied (Mahar 2015). Applying clinically relevant tension could affect the biomechanics of the region. A more accurate model, including rod tensioning should be investigated in the future. With the sample size in this pilot study, true differences between the intact and construct case were difficult to discern.

From the interpretations of this data, several interesting areas of further investigation emerge. As rib migration and dislocation occurs clinically, tracking the movement of both the construct and rib head could provide insight as to what biomechanical changes cause these clinical complications. Further work could expand upon this study to investigate the motion and stiffness differences at the costovertebral joint and pressure changes at the rib fixation point. The motion and pressure at these sites are more directly tied to complications seen clinically. Additionally, distraction forces similar to those applied during surgery should be used for further biomechanical investigation.

In conclusion, understanding the biomechanical effect of implants within the body is paramount, as it helps to improve treatments and reduce complications. This study investigated the biomechanics of a unilateral growth-friendly construct in a simulated rib-to-lumbar attachment and found very few biomechanical changes above or within the construct region. The changes seen were reduced range of motion within the construct region, and increased out of plane motions during lateral bending. Research suggests the biomechanical changes seen here are primarily caused by the type of construct used, as more flexible constructs are less disruptive of native spinal biomechanics. It is clear the device as tested here does not produce large biomechanical changes, but the balance between providing desired changes while preventing complications remains difficult.

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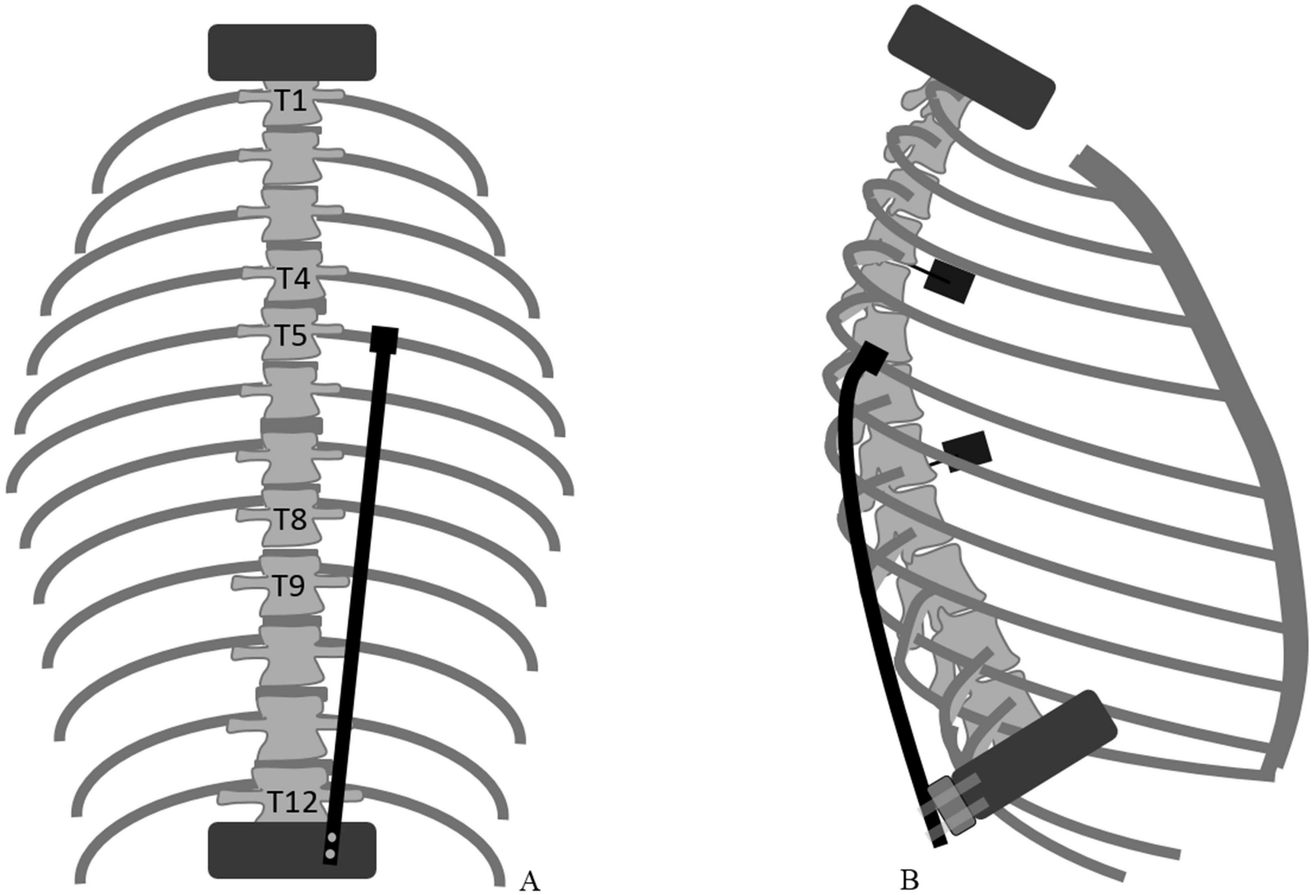

Figure 1.

a: Posterior View of Cadaver Specimen Setup

The specimen was potted at T1 and T12 with rib cage intact. Rod construct was proximally placed approximately 2.5cm right laterally to the costotransverse joint at the T5 level. The distal attached was rigidly affixed to the inferior potting, simulating a lumbar attachment.

b: Lateral View of Cadaver Specimen Setup

Specimen were positioned such that the potting was parallel to the vertebral endplates. Needle tip pressure transducers we inserted into the intervertebral space at the T4/T5 level and T8/T9 level, as shown.

Table 1

Intact and Construct In-plane and Out-of-plane Range of Motion Averages for Spinal Segments during Axial Rotation

In-plane and out-of-plane range of motion for the upper, mid, and lower thoracic regions of axial rotation are presented here. During axial rotation, the primary plane is the axial plane; the secondary plane is the coronal plane; and the tertiary plane is the sagittal plane. The averages are of the intact and construct cases as groups; however, the statistical analysis was a paired difference test between individual specimens within the group.

Region/ Level	State	RIGHT ROTATION			LEFT ROTATION		
		Axial	Coronal	Sagittal	Axial)	Coronal	Sagittal
T1–T4	Intact	7.02 ± 4.22	1.18 ± 0.78	5.76 ± 1.45	1.91 ± 1.40	1.31 ± 0.88	5.97 ± 1.42
	Construct	7.35 ± 5.45	1.43 ± 0.32	4.63 ± 1.95	7.27 ± 5.41	1.47 ± 0.33	4.71 ± 1.91
T4–T8	Intact	7.09 ± 2.30	2.48 ± 1.68	3.02 ± 0.89	7.17 ± 2.28	2.43 ± 1.76	2.99 ± 0.85
	Construct	6.37 ± 2.45	2.37 ± 1.49	2.78 ± 1.00	6.39 ± 2.45	2.38 ± 1.54	2.82 ± 0.97
T8–T12	Intact	11.39 ± 3.22	4.96 ± 2.12	3.91 ± 3.16	11.47 ± 4.18	4.81 ± 1.94	3.85 ± 2.85
	Construct	11.20 ± 4.12	5.83 ± 2.75	4.86 ± 3.91	11.17 ± 4.17	5.68 ± 2.78	4.86 ± 3.98

All ROM values are presented in degrees.

Table 2

Intact and Construct In-plane and Out-of-plane Range of Motion Averages for Spinal Segments during Lateral Bending

In-plane and out-of-plane range of motion for the upper, mid, and lower thoracic regions of lateral bending are presented here. During lateral bending, the primary plane is the coronal plane; the secondary plane is the axial plane; and the tertiary plane is the sagittal plane. The averages are of the intact and construct cases as groups; however, the statistical analysis was a paired difference test between individual specimens within the group.

Region/ Level	State	RIGHT BENDING			LEFT BENDING		
		Coronal	Axial	Sagittal	Coronal	Axial	Sagittal
T1–T4	Intact	0.69 ± 0.41	5.80 ± 5.19	1.96 ± 2.22	-	-	-
	Construct	1.04 ± 0.56	6.98 ± 4.29	1.91 ± 2.12	-	-	-
T4–T8	Intact	0.70 ± 0.81	3.07 ± 1.92	0.46 ± 0.58	0.63 ± 0.64	2.51 ± 1.93	0.45 ± 0.48
	Construct	0.58 ± 0.44	2.86 ± 1.45	0.62 ± 0.53	0.47 ± 0.38	2.40 ± 1.61	0.59 ± 0.48*
T8–T12	Intact	5.98 ± 3.25	1.94 ± 1.35	2.36 ± 0.94	5.01 ± 3.46	1.54 ± 1.17	1.95 ± 1.33
	Construct	6.35 ± 3.29	1.95 ± 1.51	2.46 ± 1.51	5.40 ± 3.50	1.61 ± 1.46	1.94 ±1.70

All ROM values are presented in degrees.

Table 3

Intact and Construct In-plane and Out-of-plane Range of Motion Averages for Spinal Segments during Flexion/Extension

In-plane and out-of-plane range of motion for the upper, mid, and lower thoracic regions of flexion/extension are presented here. During flexion/extension, the primary plane is the sagittal plane; the secondary plane is the coronal plane; and the tertiary plane is the axial plane. The averages are of the intact and construct cases as groups; however, the statistical analysis was a paired difference test between individual specimen within the group.

Region/ Level	State	FLEXION			EXTENSION		
		Sagittal	Coronal	Axial	Sagittal	Coronal	Axial
T1–T4	Intact	4.12 ± 3.39	7.27 ± 6.05	3.32 ± 4.80	1.91 ± 1.40	7.25 ± 6.14	3.41 ± 4.94
	Construct	3.53 ± 2.77	7.05 ± 6.00	3.29 ± 4.35	1.93 ± 0.94	6.84 ± 6.09	3.65 ± 5.14
T4–T8	Intact	1.75 ± 1.30	3.18 ± 1.87	1.08 ± 1.23	1.18 ± 0.95	3.16 ± 1.89	1.09 ± 1.22
	Construct	1.28 ± 1.64	3.25 ± 1.93	0.92 ± 0.91	1.05 ± 0.92*	3.05 ± 2.06	1.01 ± 1.04
T8–T12	Intact	3.01 ± 1.69	4.62 ± 1.91	1.42 ± 1.24	2.44 ± 1.21	4.57 ± 1.99	1.38 ± 1.28
	Construct	1.14 ± 1.38*	4.03 ± 2.20	1.35 ± 1.93	1.37 ± 1.13*	3.84 ± 2.40	1.48 ± 1.95

The asterisk denotes a significant paired differences in the paired comparison of the range of motion between intact and construct case.

All ROM values are presented in degrees.

Table 4

Intact and Construct Stiffness Averages

Elastic zone stiffness (EZS) and neutral zone stiffness (NZS) for the upper, mid, and lower thoracic regions and motion units T1/T2, T4/T5, and T8/T9 are presented here.

Region /Level	State	RIGHT ROTATION		LEFT ROTATION		RIGHT BENDING		LEFT BENDING		FLEXION		EXTENSION	
		EZS	NZS	EZS	NZS	EZS	NZS	EZS	NZS	EZS	NZS	EZS	NZS
T1–T4	Intact	2.4 ± 1.4	1.5 ± 0.8	4.4 ± 3.9	1.5 ± 0.9	8.5 ± 5.1	-	-	-	2.6 ± 2.2	1.9 ± 1.2	4.6 ± 2.5	0.8 ± 0.6
	Construct	1.9 ± 1.4	1.6 ± 1.2	3.9 ± 3.0	1.5 ± 1.0	8.7 ± 1.3	-	-	-	2.1 ± 2.4	1.8 ± 1.3	3.0 ± 1.3	1.0 ± 0.6
T4–T8	Intact	2.0 ± 1.2	1.2 ± 0.4	5.3 ± 7.2	1.1 ± 0.3	-	-	-	-	5.1 ± 6.1	3.1 ± 1.3	5.7 ± 4.1	3.9 ± 5.0
	Construct	2.1 ± 0.4	1.1 ± 0.4	2.2 ± 0.4	1.1 ± 0.4	-	-	-	-	3.5 ± 1.6	3.3 ± 1.4	8.3 ± 3.9	5.4 ± 4.8
T8–T12	Intact	2.3 ± 2.1	0.7 ± 0.3	3.1 ± 3.3	0.7 ± 0.3	0.9 ± 0.4	2.6 ± 1.2	4.0 ± 5.9	3.3 ± 2.2	1.3 ± 0.3	1.6 ± 1.0	1.9 ± 1.1	1.0 ± 0.7
	Construct	1.6 ± 0.5	0.7 ± 0.4	1.8 ± 0.9	0.7 ± 0.4	1.4 ± 0.7	2.1 ± 0.9	1.8 ± 0.6	4.4 ± 3.4	3.9 ± 2.9	2.3 ± 0.8	5.0 ± 2.0	2.9 ± 2.7

The asterisk denotes a significant paired differences in the stiffness between pre- and post- implantation of the rod system.

All stiffness values are presented in degrees per Newton-meter (°/Nm).