Biomechanical study of thoracolumbar junction fixation devices with different diameter dual-rod systems

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Object. Advances in the design of a smaller-diameter rod system for use in the thoracolumbar region prompted the authors to undertake this biomechanical study of two different thoracolumbar implants.

Methods. In vitro biomechanical testing was performed using human cadaveric spines. All specimens were loaded to a maximum moment of 5 Nm with 300-N axial preload in six modes of motion. Two types of anterior implants with different rod diameters were applied to intact T10–12 specimens in two groups. The loading was repeated and the range of motion (ROM) was measured. A T-11 corpectomy was then performed and a strain gauge–mounted carbon fiber stackable cage was implanted. The ROM and compression force on the cage were measured, and the mean values were compared between these two groups.

With stabilization of the intact spine, ROM decreased least in extension and greatest in bending compared with the intact specimens. After corpectomy and stabilization, ROM increased in extension by 104.89 ± 53.09% in specimens with a 6.35-mm rod insertion and by 83.81 ± 16.96% in those with a 5.5-mm rod, respectively; in flexion, ROM decreased by 26.98 ± 27.43% (6.35 mm) and by 9.59 ± 15.42% (5.5 mm), respectively; and in bending and rotation, both groups each showed a decrease in ROM. The load sharing of the cage was similar between the two groups (the 6.35-mm compared with 5.5-mm rods): 47.44 and 44.73% (neutral), 49.16 and 39.02% (extension), 61.90 and 56.88% (flexion), respectively.

Conclusions. There were no statistical differences in the ROM and load sharing of the cage when either the 6.35- or 5.5-mm-diameter dual-rod was used.

KEY WORDS • thoracolumbar junction • anterior fixation • dual-rod system • biomechanics • cadaver

VARIOUS lesions such as tumors, infections, and those due to traumatic injury affect the thoracolumbar junction and cause instability. Anterior approaches to the thoracolumbar junction have been frequently undertaken in these cases. The use of spinal instrumentation for anterior-column reconstruction has improved fusion rates, decreased postoperative deformity, and provided the immediate stability at unstable segments.

Anterior instrumentation for the thoracic and lumbar disorders was first applied by Dwyer who used a cable and screw system for scoliosis correction. Zielke and Berthet modified the Dwyer system by substituting a 3.2-mm single-threaded rod with nuts for the cable. Kostuik has reported the use of an anterior spinal fixation system involving a Dwyer–Hall vertebral plate and Harrington distraction rod (the anterior Kostuik–Harrington system) in the treatment of spinal fracture. The development of stiffer one-rod systems include the TSRH and the anterior Isola systems. In the TSRH system, the screws are rigidly attached to a smooth single 6.3-mm rod with a side connection (cantilever beam with a fixed moment arm), which lessens the need for bicortical purchase. In the Isola system, a spiked plate is used for screw fixation with a single 6.3-mm rod. Kaneda and coworkers developed the system in which spiked vertebral plates are attached to the vertebral bodies via screws interconnected by rigid rods. The SRK system (Depuy Spine, Raynham, MA) consists of rods and four constrained bicortical screws, which allow for compression and distraction.

A number of anterior devices have been developed and used for thoracolumbar junction fixation. The two major types—anterior plates and dual-rod systems—have been accepted because of their versatility and ease of application. In general, dual-rod systems may offer greater adjustability and control over screw placement, as well as increased load sharing. Plate systems are designed to be stiffer and less prone to fatigue failure, but there are theo-
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retical concerns and unanswered questions regarding the risk of pseudarthrosis and device-related osteopenia with very rigid spinal implants. For single-rod fixation, increasing the rod diameter neither improves the stiffness nor affects rod/screw strain. The dual-rod fixation design provides higher construct stiffness and less rod/screw strain compared with single-rod fixation. This dual-rod fixation is recommended over single-rod fixation, even if thinner rods are used.

In cases of dual-rod fixation, no data are available to indicate if the rod’s diameter can be reduced while continuing to maintain biomechanical stability. We undertook biomechanical testing of the smaller-diameter rod in the dual-rod systems.

Materials and Methods

Specimen Preparation

Fourteen fresh human cadaveric T9–L1 specimens were obtained. Radiography was performed to exclude osseous abnormalities, and dual energy x-ray absorptiometry scanning was conducted to evaluate BMD. The muscles of the specimens were removed, with care taken to preserve spinal ligaments and facet joints. The T9–L1 specimens were mounted with polymethylmethacrylate in the potting fixtures of a material testing machine (MTS 858 test system; Bionix, Eden Prairie, MN). Specimens were divided into two groups of seven specimens each, with the mean BMD in each group as close to the average BMD of all specimens as possible. The mean BMD values (± standard deviation) were 0.771 ± 0.147 g/cm (6.35-mm rod) and 0.744 ± 0.133 g/cm (5.5-mm rod). The T-scores were −3.07 ± 1.15 (6.35-mm rod) and −2.96 ± 1.23 (5.5-mm rod).

Biomechanical Testing

Biomechanical stability of the specimens was tested in six different modes of motion: flexion, extension, right and left lateral bending, and right and left axial rotation. For each mode of motion, a moment up to 5 Nm with a 300-N axial preload was applied with a rate of 0.3 Nm/second. To minimize the viscoelastic effect, the specimens were loaded three times and only the results from the third time were taken. The motion between T-10 and T-12 was measured using a motion analysis system (MacReflex; Qualysis AB, Gothenburg, Sweden) with reflective markers placed on T-10 and T-12. The ROM across T-10 and T-12 was evaluated.

Test Sequence

The test sequence was as follows (Fig. 1). 1) Spines were load tested in the intact state prior to any operation. 2) Anterior instrumentation was placed from the T10–12 levels. An anterior fixation device with a 6.35-mm dual rod (the SRK device) was applied in one group of seven specimens. Another device with a 5.5-mm dual rod (Expedium; Depuy Spine) was applied in second group of seven specimens. In the 6.35-mm dual-rod group, 6.25-mm-diameter bone screws were applied, and a length of 40 to 55 mm was selected to achieve a bicortical purchase. These bone screws were connected to two 6.35-mm rods by using set screws. The rods were interconnected by two cross-connectors to prevent translation and axial rotation. In the 5.5-mm dual-rod group, open-head screws 6-mm in diameter were inserted with a bicortical purchase. The screws were connected with a 5.5-mm rod (Fig. 2). The rods were then spanned by two cross-connectors. After complete application of the anterior instrumentation, the load test was conducted with the same magnitude of moment. 3) The rods were removed from the construct with the screws left in the vertebral bodies. A T-11 corpectomy was then performed, a stackable CFC of appropriate height was inserted, and the rod was reapplied. Load testing was then repeated.

Strain Gauge in the CFC

Four strain gauges (model CEA-06-062UW-350-P2; Vishay Micro-Measurements, Raleigh, NC) were attached to the anterior, posterior, left, and right sides of the stackable CFC (DePuy Spine) by using the M-bond 200 (Vishay Micro-Measurements) (Fig. 3). The strain gauges were then connected to a strain gauge signal conditioner (model 2100; Vishay Micro-Measurements), and the strain output signals were recorded by the biomechanical testing machine as a voltage unit. After biomechanical testing, the gauge-mounted cage was removed from the spine specimen and laid under direct compression in a biomechanical testing machine. The strain-output signals were measured, with the compression force ramping from 0 to 500 N. The measured voltage value of the strain-output signal was proportional to the change of the applied compression force. The strain-output voltage was then calibrated to the applied compression force. Hence, the strain-output signal measured during biomechanical testing can also be calibrated to the load transmission through the cage.

Statistical Analysis

With these testing sequences, the biomechanical stability of two different fixation systems was compared. The load transmitted through the CFC could also be compared. Statistical analysis of the evaluated ROM data and cage compression force was performed using the paired-samples t-test with SPSS software (version 10.0; SPSS, Inc., Chicago, IL). The level of significance was set at a probability value of 0.05.

Results

Range of Motion in Intact Spines

In the intact specimens, there was no intergroup difference in ROM in all modes of loading between those in-
strumented with the 6.35-mm rod and those with the 5.5-mm rod. In axial rotation, the ROM was 7.39 ± 1.55˚ for the 6.35-mm rod group and 6.38 ± 1.08˚ for the 5.5-mm rod group (Table 1).

Change in ROM in Anterior Fixation of Intact Spines

After anterior fixation of the intact spines, the ROM decreased irrespective of the type of implants. The decrease was least in extension (5.45 ± 10.85% for the 5.5-mm rod and 23.53 ± 5.13% for the 6.35-mm rod; p = 0.229) and greatest in bending (70.28 ± 5.65% for the 5.5-mm rod and 77.84 ± 5.04% for the 6.35-mm rod; p = 0.409) compared with the intact specimens (Table 1). The decrease in ROM was more prominent in the 6.35-mm rod group, but the difference was not statistically significant (Fig. 4).

Change in ROM in the Corpectomy Model

In the postcorpectomy stabilization model, the change in ROM exhibited different features depending on the mode of loading. In extension, an increase in the ROM occurred in both groups compared with the intact spine. In flexion, bending, and axial rotation, a decreased ROM was evident in both groups compared with the intact spine (Table 1). In extension, ROM in the 5.5-mm rod was 3.99 ± 0.61˚ (an increase of 83.31%) compared with the intact spine. In the 6.35-mm rod, ROM was 4.51 ± 1.11˚ (an increase of 104.89%; p = 0.809) (Fig. 4). In flexion, ROM was 5.87 ± 1.56˚ for the 5.5-mm rod and 2.69 ± 0.99˚ for the 6.35-mm rod (a decrease of 9.59 and 26.98%, respectively; p = 0.07). In bending, the stabilized spines were more rigid in both groups (57.59 and 66.85% for the 5.5-mm rod and 6.35-mm rod groups, respectively; p = 0.290). In axial rotation, ROM was decreased by 3.89% for the 5.5-mm rod and by 22.02% for the 6.35-mm rod (p = 0.647).

Load Sharing of the CFC

The amount of the load transmitted through the CFC was measured on four sides of the stackable cage. In the pure compression mode, the axial compression force of 500 N was applied. The measured values were 223.68 ± 26.9 N (5.5-mm rod) and 237.2 ± 82.35 N (6.35-mm rod), which indicated 44.7% (5.5-mm rod) and 47.4% (6.35-mm rod) of applied force, respectively. In other modes of loading, 300 N of axial preload was applied to the spine. In extension, ROM in the 5.5-mm rod and 147.49 ± 82.46 N (49.1%) for the
6.35-mm rod group. In flexion, 170.65 ± 24.71 N (56.8%; 5.5-mm rod) and 185.71 ± 51.15 N (61.9%; 6.35-mm rod) were measured. These values reflected no intergroup difference (p = 0.865 and p = 0.933, respectively). In lateral bending for the 5.5-mm rod, the force on the graft increased to 433.62 ± 54.21 N (144.5%) on the right side and 97.74 ± 37.62 N (32.6%) on the left side. Similar values (that is, 393.97 ± 93.16 N [right; 131.3%] and 119.11 ± 55.40 N [left; 16%]) were observed for the 6.35-mm rod. Also in axial rotation, there was no intergroup difference in the measured force (Fig. 5).

Discussion

Intact Spine ROM

The ROM of the T11–12 segment has been estimated to be 6 to 20˚ in flexion–extension, 4 to 13˚ in one-side lateral bending, and 2 to 3˚ in one-side axial rotation. Little difference exists between our data and the reported data in the sagittal-plane and coronal-plane ROM, but in terms of axial rotation, ROM was greater in our study. In the horizontal plane, there is 8 to 9˚ of motion in the upper half of the thoracic spine and 2˚ in each interspace of the three lower thoracic and lumbar segments. The rotation angle is related to the spatial alignment of the facet joint.

Changes in ROM After Anterior Fixation of Intact Spines

After anterior fixation of the intact specimens, all modes of motion decreased. Of six modes of motion, the decrease was minimal in extension, which was common in both groups. The anterior fixation devices have less effect on the extension motion than do posterior fixation devices. The anterior implant is located ventral to the instantaneous axis of rotation in the flexion–extension mode; thus it is more affected in flexion than extension. Regardless, strong stiffness on bending and axial rotation was noted in the instrumented spines.

The intact spine is a nondestructive model. The instrumentation used in this nondestructive model is not relevant to clinical situations. This model, however, can be adopted as another model for biomechanical comparison. Although the ROM is easily expected to be decreased after application of instrumentation in the nondestructive model, the extent to which ROM will decrease in each mode may be different between the two groups.

Changes in ROM in the Corpectomy Model

In the postcorpectomy stabilization model, ROM increased in extension only and exhibited a decrease in other modes of loading. Because of the compression provided by the anterior instrumentation and the flexion-limiting effect of the graft, stabilized spines were significantly more

<table>
<thead>
<tr>
<th>Mode of Motion</th>
<th>Intact Specimen (A)</th>
<th>Intact &amp; Fixed (% change)</th>
<th>CFC &amp; Fixation (% change)†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>extension</td>
<td>1.83 ± 0.30</td>
<td>1.67 ± 0.19</td>
<td>1.85 ± 0.47</td>
</tr>
<tr>
<td>flexion</td>
<td>5.57 ± 1.47</td>
<td>4.18 ± 0.87</td>
<td>-5.45 ± 10.85</td>
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<tr>
<td>bending (lt &amp; rt)</td>
<td>7.11 ± 1.59</td>
<td>6.89 ± 1.71</td>
<td>2.83 ± 1.29</td>
</tr>
<tr>
<td>rotation (lt &amp; rt)</td>
<td>6.38 ± 1.08</td>
<td>7.39 ± 1.55</td>
<td>-58.15 ± 5.98</td>
</tr>
</tbody>
</table>

* Values are presented as the means ± standard deviations. A = 5.5-mm rod group; B = 6.35-mm rod group.
† The percentage of change is the value that is calculated compared with the intact specimen.
rigid in flexion than in extension.\(^\text{12}\) In some reports on the use of the SRK device and Z-plate, however, the extension angle decreased after stabilization compared with that measured in the intact spine. In axial rotation, ROM has been reported to increase;\(^\text{12}\) however, it decreased in our specimen. We believe this to be due to the application of the preload. In White and Panjabi’s report,\(^\text{26}\) the spine became less stiff in flexion and stiffer in axial rotation as a result of the addition of the preload.

In our study, a maximum of a 5-Nm pure bending moment was applied to the specimen. The rationale for selecting this low-level moment was based on the theory that a cadaveric spine devoid of muscle absorbs approximately 1% of the estimated total 471-Nm moment exerted during routine load-lifting activities.\(^\text{16,24}\) In previous studies, investigators have applied pure moments up to 10 Nm.\(^\text{10,24}\) Preliminary studies by Ogon, et al.,\(^\text{19}\) and Tawackoli, et al.,\(^\text{24}\) however, have shown that loads beyond 5 Nm lead to failure. In vivo estimation of bending moments made in the earlier studies by other authors\(^\text{1,24}\) were higher than those observed in the present study, mainly because of the decreased stiffness of the cadaveric specimens.

**Load Sharing of the CFC**

The load-sharing capacity of the anterior instrumentation after corpectomy varied inversely to the stiffness, ranging from 63 to 89%.\(^\text{5}\) Some investigators have reported that the load sharing of the graft may be as low as 34%.\(^\text{11}\) The stiffer the implant, the more minimal the load sharing of the graft. The presence of the CFC contributed to the overall construct stiffness in all instrumentation systems, particularly in lateral bending and flexion–extension. The compressive force applied by the construct allows the sharing of the load with the spine or interbody strut. This can be enhanced by spinal distraction and subsequent placement of the interbody graft. The construct may then be compressed onto the previously placed interbody strut graft. This allows for the following: 1) increased security of the interbody strut graft–mortise interface; 2) sharing of the load between the implant and the strut graft; and 3) augmentation of bone healing–enhancing forces.\(^\text{2}\)

A spinal implant placed in distraction bears most of the axial load; one placed in compression, however, it shares the axial load with the graft. If enough compression is applied, the spinal implant could conceivably bear no load during an individual’s assumption of the upright position. In our study, the CFC was inserted after corpectomy and then completion of the anterior instrumentation was done. At completion, the compression was applied. The forces that were measured at the CFC ranged from 39 to 61.9% of the applied axial load, except for lateral bending, and exhibited no significant intergroup difference. This means that similar forces were applied at the completion of the anterior instrumentation. Short-segment fixation places much less stress on the longitudinal device, thus resulting in little difference in load sharing related to the size of the rod.

A significant difference was shown between right and left in lateral bending. In right lateral bending, the left-sided implant functioned as a tension band, restricting the...
spinal bending to the right of the CFC. The right-bending moment added to the compression force of the CFC. The load sharing of the cage was shown to be increased up to 433.62 N.

Preload Application

To make an in vitro biomechanical test meaningful, the physiological preload that is estimated to be applied in vivo should be considered. In the in vivo state, the preload has two origins. First, there is the direct compressive load due to the weight of the body above the spinal segments. Second, because the center of gravity of the supported weight is anterior to the spine, the spinal segment is also subjected to large flexion (bending) moments that are counterbalanced by the ligament and back muscle forces. The mean compressive load in the standing position, a contribution of body weight and muscle forces in the L3–4 region, was reported by Nachemson and by Wilke, et al., to be 500 N, which was determined by direct measurement of intradiscal pressure.

In the present paper, we used a preload of 300 N at the T9–L1 segments. It is crucial to maintain the preload path within a small range around the centers of rotation of the spinal segments. The thoracolumbar spine has been shown to support compressive preloads as great as 975 N without sagittal-plane damage when the preload was applied along the natural curvature of the spine through estimated centers of rotation. Patwardhan, et al., used a path that approximated the tangent to the curve of the spine (follower load path) to apply preload in the cadaveric study.

Our method of application was that of vertical compression directed to the posterior one third of the vertebral body, not the follower load path. Vertically applied preloads are thought to produce artificial forces and moments as the specimen rotates. However, because the curvature of the tested spines was nearly straight, with little curve, the distance between the load direction and the center of rotation was thought to be negligible. Although vertical preload was used, the artifact would not be significant. If the preload path is remote to the center of rotation, it can induce artifact moment at the spinal segments; the preload vector may not be perpendicular to the midplane of each disc, inducing shear forces at those segments.

In a study reported by Tawackoli, et al., the flexibility in bending (flexion–extension) of the ligamentous T9–L3 region decreased as compressive preload increased from 75 to 975 N. In an investigation conducted by Stanley and colleagues in which T2–sacrum cadaveric specimens were used, the authors found that the T11–L1 flexion–extension range increased when 0 to 400 N of preload was applied, and no change was seen when the preload force was between 400 and 800 N. In the report published by White and Panjabi, the spine became less stiff in flexion and stiffer in axial rotation as a result of the addition of the preload. The addition of the preload may have lessened the rotational mobility seen in our study compared with that reported by others.

Anterior Fixation

The roles of anterior fixation are to increase the rate of fusion, minimize the chance of translational deformity, and share the load transmitted to the anterior column. To have a load-sharing capacity, the construct requires short-fixed or applied moment arm–cablebeam constructs. The implant construct also should be placed in a compression mode, which causes the load to be shared between the graft and the construct.

To achieve maximum rigidity in an anterior spinal construct, the ideal device should provide graft compression with the aid of four bicortical screws constrained to the rods, such as the SRK and Expedium systems. The placement of anterior screws may fail to support axial loads effectively because of parallelogram translational deformation. A simple inward insertion of the screws should prevent construct failure of this mechanism. This creates a quadrilateral
frame construct that resists torsional deformation of the rods. Three or more cross-links offer no significant advantage over two. In general, the two cross-links should be placed roughly at the junctions of the middle third of the construct and the two terminal thirds of the construct.

Rods of various diameters are currently used in anterior thoracolumbar fixation devices—that is, a 6.3-mm single rod in the TSRH and anterior Isola systems, a 4-mm single rod in the Bad Willungen Mets device, double rod (4 mm and 6 mm) in the Cotrel-Dubousset-Hopf system, and another double rod (4.75 mm) in the Kaneda Anterior Scoliosis System. For single-rod fixation, increased rod diameter neither improved the stiffness nor affected rod/screw strain. The dual-rod fixation provides a higher construct stiffness and less rod/screw strain compared with single-rod fixation. Thus, dual-rod fixation is recommended over single-rod fixation alone, even if thinner rods are used.

Conclusions

There were no statistical differences in the ROM and load sharing of the CFC between the 6.35-mm dual-rod group and the 5.5-mm dual-rod group. The use of the 5.5-mm rod did not weaken the biomechanical stiffness in the dual-rod system. With regard to cross-connectors, a similar degree of stiffness can be maintained with the simpler type, which encompasses two thirds of the entire rod circumference.

References