Biomechanical studies of an artificial disc implant in the human cadaveric spine

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Object. The authors compared the biomechanical performance of the human cadaveric spine implanted with a metallic ball-and-cup artificial disc at L4–5 with the spine’s intact state and after anterior discectomy.

Methods. Seven human L2–S1 cadaveric spines were mounted on a biomechanical testing frame. Pure moments of 0, 1.5, 3.0, 4.5, and 6.0 Nm were applied to the spine at L-2 in six degrees of motion (flexion, extension, right and left lateral bending, and right and left axial rotation). The spines were tested in the intact state as well as after anterior L4–5 discectomy. The Maverick disc was implanted in the discectomy defect, and load testing was repeated.

The artificial disc created greater rigidity for the spine than was present after discectomy, and the spine performed biomechanically in a manner comparable with the intact state.

Conclusions. The results indicate that in an in vitro setting, this model of artificial disc stabilizes the spine after discectomy, restoring motion comparable with that of the intact state.

Keywords • artificial disc • spinal biomechanics • discectomy • cadaver

Degenerative disc disease associated with disc collapse, herniation, osteophytes, spinal instability, and pain often requires surgical treatment. Current treatments for lumbar DDD generally consist of disc excision with or without fusion.

Unfortunately, fusion procedures are by no means assured of success. Although the incidence of pseudarthrosis is estimated to be less than 10%, this is by no means negligible.5,20,25,29,33 Moreover, these procedures are associated with risks of dural or vascular tears, chronic pain, and stiffness. In addition, following lumbar fusion many patients may eventually suffer from symptomatic degenerative disease rostral or caudal to the fused segments. This accelerated process of degeneration adjacent to a fused segment(s) has been reported in the cervical and lumbar spine and may warrant fusion.14,21,26,31

Implantation of an artificial disc instead of performing fusion at the site of a diseased disc would theoretically restore spinal motion, reestablish stability, and maintain the caliber of the neural foramina, while avoiding the development of adjacent degenerative changes. To this end, artificial disc implants and prosthetic nuclei have been developed, and many have obtained a fairly large amount of follow-up data in Europe; however, they await approval in the US.1–3,6,10,18,22,23,24,32,34

Whereas an artificial disc should allow rotation it must do so without being overly restrictive. In vitro testing of the artificial disc in cadaveric spines helps predict the range of motion of the implant and adjacent spinal segments. In this study we examined biomechanical features of the Maverick artificial disc (Medtronic Sofamor Danek, Memphis, TN; Fig. 1) after implantation in human cadaveric spines. We assessed motion characteristics of the intact lumbar spine after anterior L4–5 discectomy and after artificial disc implantation under quasistatic loading conditions.

Materials and Methods

Seven fresh-frozen human cadaveric spines were obtained from the deeded body program at the Department of Anatomy, University of Iowa. Spines were radiographed in both the anteroposterior and lateral planes to ensure absence of fractures, deformities, and metastatic disease. Bone mineral density was measured in the lateral plane by using dual-energy x-ray absorptiometry with a bone densitometer (QDR-2000; Hologic, Inc., Waltham, MA). Specimens were stored in double plastic bags at −20°C and allowed to thaw at room temperature prior to manipulation. Prior to potting, thawed specimens were carefully denuded of paravertebral musculature, avoiding disruption to spinal ligaments, joints, and discs.

The L2–S1 spine specimen was mounted on a biomechanical testing frame. Pure successive moments of 0, 1.5, 3.0, 4.5, and 6 Nm were applied at L-2 in each axis of rotation (flexion, extension, right and left lateral bending, and right and left axial rotation). These moments were selected as safe loads on the human cadaveric spine based on published data of biomechanical testing.9,15–17 Spinal motion was tracked using the Neuroscience Real Time 3D System.
Load testing was performed with the spine in the intact state prior to any manipulation. Throughout the testing cycle, specimens were kept moist with lukewarm saline.

Experimental Biomechanical Testing Paradigm

The experimental paradigm included seven spines subjected to the following steps.

Step 1. Load testing was performed with the spine in the intact state prior to any manipulation. Throughout the testing cycle, specimens were kept moist with lukewarm saline.

Step 2. After anterior anulotomy, complete L4–5 discectomy was performed with appropriate ring and cup curettes. Posterior osteophytes and the posterior longitudinal ligament were excised while maintaining the integrity of the lateral anulus. Load testing was repeated.

Step 3. The Maverick disc was implanted in the discectomy defect per manufacturer’s specifications. The Maverick implant consists of two Co-Ch-Mo plates with a ball-and-cup design allowing full 360° axial rotation, 16° of bending to all sides, and yielding 32° of total potential motion (Fig. 1 (left)). The nonarticulating surfaces have a keel that engages the vertebral endplates for anchoring, and these are chemically textured and covered with a layer of hydroxyapatite to facilitate adherence to the vertebra. A four-in-one tool was inserted into the disc space to the level of the spinal canal, allowing distraction of the endplates without anular disruption. This spreader allows the measurement of the anteroposterior dimension, the height, and lordosis of the disc space. The endplates were squared off, and a central slot was cut into the adjacent bodies by using a keel and corner chisel that fits into the four-in-one tool. The endplates of the artificial disc come in three sizes: small (25 × 32 mm), medium (27 × 35 mm), and large (30 × 39 mm). Implant heights are available in 10, 12, or 14 mm, and there are three options of lordotic angulation: 6, 9, or 12°. The center of rotation of the artificial disc was 10 mm anterior to its posterior margin. The specifications of the artificial discs are summarized in Table 1. Based on the size of the spine, the largest artificial disc was selected and implanted into the disc space such that the posterior margin of the implant was flush with the floor of the spinal canal and the lateral anulus was stretched but not disrupted (Fig. 1 (right)). Load testing was repeated.

Statistical Analysis

Mean angular rotations ± SDs in response to pure moments of 0, 1.5, 3, 4.5, and 6 Nm are provided in Table 2. The mean BMD of the spines was 0.625 ± 0.038 g/cm² (range 0.561–0.678 g/cm²) (Table 3).

Results

The spine specimens were obtained in four female and three male individuals who, at the time of death ranged in age from 60 to 93 years (mean 82.4 ± 13.4 [SD] years). The mean BMD of the spines was 0.625 ± 0.038 g/cm² (range 0.561–0.678 g/cm²) (Table 3).

Discectomy was associated with an increase in motion related to load in all directions (Table 2, Fig. 2). In flexion, discectomy was associated with a significant increase in rotation compared with the intact state at 1.5 Nm (p = 0.0152) and 3 Nm (p = 0.0177). Discectomy was also associated with significantly more flexion than both the intact and artificial disc–implanted states at 4.5 Nm (p = 0.0057) and 6 Nm (p = 0.0047). In extension, the increase in motion after discectomy was significantly greater than that in the intact and implanted spines with loads of 3 Nm (p = 0.0021), 4.5 Nm (p = 0.0054), and 6 Nm (p = 0.0030). Compared with the intact and artificial disc–implanted states, discectomy yielded an increase in right (p = 0.0024) and left (p = 0.0987) axial rotation with a load of 1.5 Nm (Table 2, Fig. 2 (center)). In right axial rotation with loads of 3, 4.5, and 6 Nm, discectomy was associated with increases in motion compared with the intact state (p = 0.0031, 0.0219, and 0.0195, respectively). In left axial rotation, an increase in motion of the discectomy spines compared with the intact and artificial disc–treated spines was also observed with loads of 3, 4.5, and 6 Nm (p = 0.1153, 0.1194, and 0.1373, respectively). In right and left lateral bending, the increases in motion associated with discectomy compared with the intact and artificial
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TABLE 1
Dimensions of the artificial discs placed at L4–5*

<table>
<thead>
<tr>
<th>Experimental Spine No.</th>
<th>04</th>
<th>06</th>
<th>07</th>
<th>08</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>size</td>
<td>sm</td>
<td>med</td>
<td>lg</td>
<td>sm</td>
<td>lg</td>
<td>med</td>
<td>lg</td>
</tr>
<tr>
<td>height (mm)</td>
<td>12</td>
<td>10</td>
<td>12</td>
<td>12</td>
<td>10</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>plate (*)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inferior</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>superior</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>total†</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>6</td>
<td>6</td>
<td>9</td>
<td>6</td>
</tr>
</tbody>
</table>

* Lg = large; med = medium; sm = small.
† The total degrees of lordosis is the sum of the lordotic angulation of the superior and inferior plates.

Mean Flexion and Extension of L-4 Relative to L-5 in Response to Discectomy and AD Implantation
Mean Right and Left Axial Rotation of L-4 Relative to L-5 in Response to Discectomy and AD Implantation
Mean Right and Left Lateral Bending of L-4 Relative to L-5 in Response to Discectomy and AD Implantation

Fig. 2. Graphs demonstrating mean flexion and extension motion (left); right and left axial rotation (center); and right and left lateral bending (right) of L-4 relative to L-5 in response to L4–5 discectomy and artificial disc implantation. AD = artificial disc.

Discussion

Over the years, several disc designs have been proposed. Some have undergone assessment in formal clinical trials in the US. Implants are widely varied and include spherical implants, spring-loaded artificial discs, rubberized implants located between metal plates, nucleus pulposus replacements, polyethylene slip-core center joints (SB Charité; DePuy-Spine, Raynham, MA), the polyethylene core ball-and-socket design (Prodisc; Synthes Spine, Paoli, PA), or the metal-on-metal design (Maverick). Some of these implants, such as the SB Charité and Prodisc have been the subject of 10 to 15 years of clinical follow-up review in Europe, whereas others are undergoing clinical studies in the US. The goal for the artificial disc is that it would replicate the biomechanical performance of the natural disc without major fluctuations.

In our paradigm, the ALL and anterior anulus fibrosus were excised during discectomy. Because of the loss of the tethering effect of the ALL and anterior anulus, we observed significant increases in flexion and extension during loads of 3, 4.5, and 6 Nm (Table 2, Fig. 2). Whereas more flexion is allowed in the absence of the disc, conversely, the absence of the ALL allows less restriction on extension. In the axial plane, discectomy, after removal of the ALL and posterior longitudinal ligament, was also associated with an increase in rotation (Table 2, Fig. 2 center). In right and left lateral bending, although there was an increase in motion from the intact state, these increments were not statistically significant (Table 2, Fig. 2 right), which is not surprising because the lateral anulus was intact and tethering the spine in the coronal plane. These results are comparable with those reported in similar studies in which discectomy was performed via an anterior approach. After implanting the artificial disc, motion in all six directions was reduced such that there was no significant difference between the intact and artificial disc–implanted spine regardless of load in any direction. This decrease in motion or rigidity is caused by tensing the remaining anulus while still allowing motion, which are results of the artificial disc’s ball-and-socket feature.

The authors of in vitro tests involving prosthetic nucleus implants have reported results similar to ours and to other investigators of artificial disc implants. In vitro test-
ing in human cadaveric lumbar spines was conducted with dual artificial nucleus implants, which consist of polymeric hydrogel encased in woven high-tenacity polyethylene jackets that allow water absorption. Testing with loads of 0.5 to 7 Nm in six directions showed that the nucleus implant restored spinal stability after discectomy to the level of the intact spine. Biomechanical testing has also involved a flexible nucleus implant made from a poly-methyl siloxane polymer that have been assessed in cadaveric in vitro calf and human lumbar spines have shown an increase in motion and intradiscal pressure at the operated level.11–13,21,26,31 It is anticipated that the artificial nucleus restored, to the level of the intact state. The potential benefits of such a device await confirmation of randomized clinical trials which are currently underway.

In our load-controlled testing setup, the motion at the L3–4 segment was measured as a means of determining experimental errors. No changes were observed in these conditions, lumbar spinal stability in all three planes after discectomy.21,26,31 It is anticipated that the development of expedited DDD at levels adjacent to a fused spinal segment. It is suspected that this increase in motion and intradiscal pressure accompanying fusion may contribute to the development of expedited DDD at levels adjacent to a fused spinal segment.21,26,31 It is anticipated that the implantation of the artificial disc in place of instrumentation and fusion may contribute to reducing the incidence of adjacent-segment degenerative disease that often accompanies the latter.

In summary, analysis of our results indicates that in an in vitro setting, this model of artificial disc restores spinal motion after discectomy to levels similar to those of the intact state. The potential benefits of such a device await confirmation of randomized clinical trials which are currently underway.

### References


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### TABLE 2

**Mean Angular Rotations at L4–5 and L3–4 at 6 Nm**

<table>
<thead>
<tr>
<th>Level</th>
<th>Flexion (°)</th>
<th>Extension (°)</th>
<th>Axial Rotation (°)</th>
<th>Lat Bending (°)</th>
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</thead>
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<tr>
<td>L4–5 level</td>
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<tr>
<td>Intact</td>
<td>6.21 ± 6.72</td>
<td>−4.67 ± 3.57</td>
<td>4.26 ± 1.48</td>
<td>2.42 ± 4.58</td>
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<td>Discectomy</td>
<td>14.28 ± 9.36</td>
<td>−15.35 ± 8.34</td>
<td>7.62 ± 2.81</td>
<td>10.52 ± 15.56</td>
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<tr>
<td>AD Implant</td>
<td>8.67 ± 5.94</td>
<td>−7.66 ± 4.91</td>
<td>5.99 ± 2.43</td>
<td>7.94 ± 9.02</td>
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<tr>
<td>L3–4 level</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>5.79 ± 4.95</td>
<td>−2.14 ± 1.13</td>
<td>1.72 ± 1.28</td>
<td>3.40 ± 2.01</td>
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<tr>
<td>Discectomy</td>
<td>6.47 ± 4.71</td>
<td>−3.38 ± 2.35</td>
<td>1.77 ± 0.56</td>
<td>2.46 ± 1.10</td>
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<tr>
<td>AD Implant</td>
<td>6.56 ± 5.30</td>
<td>−2.33 ± 1.61</td>
<td>1.43 ± 1.07</td>
<td>2.51 ± 1.56</td>
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</table>

*Values are presented as the means ± SDs. Abbreviation: AD = artificial disc.*

### TABLE 3

**Summary of age, BMD, and sex for all spine specimens used in this study**

<table>
<thead>
<tr>
<th>Experimental Spine No.</th>
<th>Characteristic</th>
<th>04</th>
<th>06</th>
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<th>11</th>
<th>12</th>
<th>Mean ± SD</th>
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</thead>
<tbody>
<tr>
<td>BMD (g/cm²)</td>
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<td>0.61</td>
<td>0.649</td>
<td>0.561</td>
<td>0.647</td>
<td>0.678</td>
<td>0.629</td>
<td>0.601</td>
<td>0.625 ± 0.038</td>
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<td>Age (yrs)</td>
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<td>62</td>
<td>60</td>
<td>87</td>
<td>90</td>
<td>92</td>
<td>87</td>
<td>86</td>
<td>80.57 ± 13.53</td>
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<tr>
<td>Sex</td>
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<td>M</td>
<td>M</td>
<td>F</td>
<td>M</td>
<td>F</td>
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