In vitro biomechanics of cervical disc arthroplasty
with the ProDisc-C total disc implant

DENIS J. DIANGELO, PH.D., KEVIN T. FOLEY, M.D., BRIAN R. MORROW, B.Sc.,
JOHN S. SCHWAB, M.Sc., JUNG SONG, PH.D., JOHN W. GERMAN, M.D.,
AND EVE BLAIR, B.Sc.

Department of Biomedical Engineering, University of Tennessee Health Science Center;
and Image Guided Surgical Research Center, Memphis, Tennessee

An in vitro biomechanical study was conducted to compare the effects of disc arthroplasty and anterior cervical fusion on cervical spine biomechanics in a multilevel human cadaveric model. Three spine conditions were studied: harvested, single-level cervical disc arthroplasty, and single-level fusion. A programmable testing apparatus was used that replicated physiological flexion/extension, lateral bending, and axial rotation. Measurements included vertebral motion, applied load, and bending moments. Relative rotations at the superior, treated, and inferior motion segment units (MSUs) were normalized with respect to the overall rotation of those three MSUs and compared using a one-way analysis of variance with Student–Newman–Keuls test (p < 0.05). Simulated fusion decreased motion across the treated site relative to the harvested and disc arthroplasty conditions. The reduced motion at the treated site was compensated at the adjacent segments by an increase in motion. For all modes of testing, use of an artificial disc prosthesis did not alter the motion patterns at either the instrumented level or adjacent segments compared with the harvested condition, except in extension.

KEY WORDS • biomechanical testing • cervical disc prosthesis • cervical fusion • biomechanics

Approximately 187,000 anterior cervical spine procedures are performed annually in the US.29 Since its description in the 1950s by Cloward8 and Robinson and Smith,40 ACDF has accounted for the majority of these procedures. More recently, the long-term outcome after ACDF has been described in sobering terms. Adjacent-segment degeneration with new, symptomatic radiculopathy occurs after ACDF in 2 to 3% of patients per year on a cumulative basis.25,26 An estimated 7 to 15% of patients ultimately require a secondary procedure at an adjacent level.5 It has been suggested that the increased stress placed on the adjacent segments, particularly the inferior disc, after successful ACDF may increase the rate of future symptomatic disc disease at those segments.8,10,31,38,42,44

Spine surgeons are now becoming interested in alternatives to fusion, such as total disc arthroplasty. The goal in using these devices is to replace the diseased disc while preserving and/or restoring motion at the treated level. The hope is that such devices will help protect patients from experiencing problems in adjacent segments. Although early clinical experience is growing, the biomechanics of cervical disc arthroplasty have not been fully delineated in the literature.

Our objective in the current study was to determine the biomechanics of the ProDisc-C cervical disc prosthesis (Synthes Spine Solutions, West Chester, PA) in an established cadaveric model. Because ACDF remains the standard of care, simulation of a single-level fusion at the implanted site was compared with the harvested and disc-implant conditions.

MATERIALS AND METHODS

Specimen Preparation and Spine Conditions

Six fresh human cadaveric subaxial cervical (C2–T1) spines were procured from the Medical Education Research Institute (Memphis, TN). Three spines were obtained in female and three in male cadavers; the mean age of the specimens was 74.8 ± 3.25 years. Each spine was harvested and immediately double-wrapped in plastic bags and stored at −20°C until the spinal constructs were prepared. Before preparation, the spines were thawed in a refrigeration system for 12 hours. All spines were screened with anteroposterior and lateral radiographs to exclude any specimens with gross osteopenia or anatomical abnormality. Bone density measurements were not done, but any specimen that did not provide adequate screw purchase, as determined by the spine surgeon (K.T.F.), was not used.

The specimens were evaluated sequentially in three dif-
ferent conditions, as follows: 1) harvested; 2) single-level cervical disc prosthesis (ProDisc-C); and 3) single-level (C5–6) fusion. The ProDisc-C cervical implant (Synthes Spine Solutions, West Chester, PA) was used for the disc prosthesis condition. This implant (Fig. 1) consisted of two forged CoCr alloy endplates and an ultra–high molecular weight polyethylene inlay element. The final condition studied was that of the fused spine. Fusion was simulated across the treated level by using custom-designed fixtures (Fig. 2). The fixtures were similar to an external fixation system used by orthopedic surgeons. The remaining vertebrae were left free to move unimpaired. The three different spine conditions are shown in Fig. 3.

Before preparation and testing, the bone surfaces of the C-2 and T-1 VBs were cleaned and mounted in cylindrical pots by using an alignment frame to position the cervical spine in a neutral (upright) orientation. The flexion/extension axis was estimated at the anterior aspect of the facet joint of each vertebra. Positioning screws that passed through the sides of the pots initially held the end bodies in place; a low-melting-point bismuth alloy (Small Parts, Miami Lakes, FL) provided final fixation of the end bodies in the pots.

The surrounding paravertebral soft tissues were dissected, with care taken to preserve the spinal ligaments, discs, and bone. Threaded rods were placed into the lateral aspects of the VBs that secured light-emitting diode targets used with the motion tracking system. A single-axis load cell (Transducer Technologies, Temecula, CA) was in line with the shaft of the load actuator. The other end of the single-axis load cell was coupled with fixtures containing a pinned connection and a linear bearing for attaching the cervical spine. The flexion/extension testing arrangement is shown in Fig. 4.

Mounting fixtures added to the biomechanical testing system converted the single controlled input from the load actuator to a coupled motion input (unconstrained translations and rotation in a plane) and a combined loading state (axial compressive force and flexion/extension or lateral bending moment). With the flexion/extension axis of the spine placed eccentric to the load axis of the actuator, a compressive load and flexion/extension bending moment were applied to the upper pot. The specimens were mounted in an inverted neutral orientation with the T-1 pot attached to the upper fixture and the C-2 pot mounted to the lower base fixture, thereby inducing a greater moment at T-1 than at C-2, simulating in vivo conditions. For lateral bending tests, the spine was rotated 90° in the mounting fixtures and the base was unconstrained in axial rotation. A rotational displacement transducer (Data Instruments, Acton, MA) was attached to the upper pinned assembly and measured the global rotation of the spine. The displacement transducer recorded changes in the moment arm length between the upper pot and load axis of the actuator during flexion/extension or lateral bending tests. A separate loading system was used for axial rotation and is shown in Fig. 5.

Nondestructive Testing Protocol and Sequence

Various in vitro testing methods have been used to study the stability of cervical fusion devices. Typical protocols have involved bovine tissue or single-level human cervical motion segment units, and these are usually tested under pure-moment loading conditions. Although pure-moment methods permit ranking between the different fixation systems, they do not replicate physiological conditions. We have developed a testing protocol that dis-
tributes a bending moment across the spinal construct that increases in the caudal direction.2 This protocol has been used to study other cervical fusion15,20 and motion restoration16 devices. The in vitro flexion/extension motion response associated with the modified testing protocol is shown in Fig. 6 and was similar to that in published in vivo data. The nondestructive protocol involves application of a bending moment of 3 Nm with limit checks of 35° total spine rotation, 5-Nm flexion/extension moment at T-1, or an applied load of 75 N. These values were based on our preliminary test findings11 and conformed with the limits used by other researchers.35,36

For each condition listed, the spines were nondestructively tested with flexion/extension, lateral bending, and axial rotation loading. All tests were performed under displacement control. For flexion/extension and lateral bending, the spine offset was 200 mm from the load axis. The testing apparatus was programmed to output a triangular displacement–time waveform of 6.4 mm/second, which corresponded to approximately $2°$/second overall spine motion.

Before the formal testing sequence began, each spine was preconditioned with five cycles at low displacement levels. Each test trial included three loading cycles. Throughout the entire testing sequence the spines were moistened at regular intervals with a normal saline mist.

Fig. 3. Photographs showing the spine conditions tested. Left: Harvested. Center: Cervical disc prosthesis (C5–6). Right: Simulated fusion (C5–6).

Fig. 4. Photographs showing the extension testing set-up. Overview (A) and closeup (B) photographs of mounted spine. For flexion testing, the spine was rotated 180° in the mounting fixtures.
The spines were first tested in the harvested condition. After completion of these tests, a conventional discectomy was performed by the spine surgeon to prepare for disc implantation. After the procedure was completed, the spine was tested in the implanted state. All procedures were performed at the Medical Education Research Institute.

**Data Management and Analysis**

Signals from the transducers were collected with a dedicated analog-to-digital data acquisition system (National Instruments, Inc., Austin, TX) and sampled at 10 Hz. The data were processed using custom-designed software routines (Labview; National Instruments) and collected in a spreadsheet file for later computational processing and statistical analysis (Sigma Stat; Jandel Scientific, San Rafael, CA). A three-dimensional, noncontact, real-time measurement system was used to track segmental cervical motion for each testing condition.

The vertebral displacement data were simultaneously collected and displayed to the user in real time. The moment applied to the spine at T-1 (designated \( \text{Ma} \)) was determined by calculating the vertical force reported by the inline load cell (designated \( \text{Fa} \)), the total rotation of the upper pot reported by the rotational transducer (\( \text{qr} \)), and the displacement offset (\( \text{da} - \text{ddt} \)) between the upper pot and load axis according to the following formula: 

\[
\text{Ma} = \frac{\text{Fa}(\text{da} - \text{ddt})}{\cos(\text{qr})},
\]

where \( \text{da} \) is the initial offset distance between the load axis and the center of the upper pot.

Measurements of the global rotational motion and applied load data were combined to calculate the overall spine flexibility. Flexibility data were compared at the largest reported end limit of motion common to all spines. Variations in the motion patterns were also analyzed at an end limit of global (C2–T1) moment common to all spine conditions within each specimen by comparing the percent contribution of the rotation at the superior (S), treated (T), or inferior (I) MSUs relative to overall rotation of those three MSUs (S+T+I). The instrumented spine conditions were normalized to the harvested condition to account for intrinsic differences in tissue specimens. To study the effects of the disc-implant or fusion treatments on the adjacent segment biomechanics, the contribution of motion at the remaining segments relative to the overall total motion was normalized to its contribution in the harvested state and then compared.

A one-way analysis of variance with a Student–Newman–Keuls test was used to compare differences in the flexibility and normalized motion data at the treated and adjacent segments. The alpha value was set at 0.05 for all tests. The distribution of the relative rotations of each MSU was also compared across the entire cervical spine.

**RESULTS**

**Global Stiffness and Normalized Flexibility**

Typical global stiffness curves for flexion and extension loading are shown in Fig. 7. The degree of hysteresis between the loaded and unloaded cycles remained similar among the three different spine conditions, indicating that minimal tissue/ligamentous relaxation had occurred throughout the testing sequence. A similar response occurred in lateral bending and axial rotation.

The global flexibility values, or the inverse of stiffness, for the instrumented spine conditions were normalized to the harvested condition and compared at the largest reported applied moment common to all spine conditions; results are given in Tables 1 and 2. Significant differences occurred in extension between the ProDisc-C and harvested (151% of harvested) and ProDisc-C and fusion (151% compared with 109%) conditions, and in right axial rotation there were significant differences between the Pro-
Disc-C and harvested (148% of harvested) and ProDisc-C and fusion conditions (148% compared with 112%).

**Normalized Motion**

The mean rotational values at the treated MSU level of the instrumented conditions were normalized to the harvested condition and compared at common limits of global moment. For the normalized motion data, the rotation at the treated level was expressed relative to the sum of the rotations at the treated, superior adjacent, and inferior adjacent segments. All initial and normalized motion data are given in Tables 3 and 4. Graphs of the normalized motion for combined flexion and extension, right plus left lateral bending, and right plus left axial rotation are shown in Fig. 8. A normalized value identical to the harvested condition equals 1 and can be expressed as equivalent to 100% of the harvested condition. Significant differences between the spine groups and loading conditions are indicated on the charts (Fig. 8) and included in Table 4. The only significant difference between the ProDisc-C and harvested spine conditions occurred in extension (57% of

---

**TABLE 1**

*Flexibility data in cadaveric spines tested in various conditions*

<table>
<thead>
<tr>
<th>Test</th>
<th>Harvested</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moment</td>
<td>Global Rotation</td>
<td>Moment</td>
<td>Global Rotation</td>
<td>Moment</td>
</tr>
<tr>
<td>flexion</td>
<td>2.88 ± 0.55</td>
<td>31.30 ± 7.36</td>
<td>2.81 ± 0.54</td>
<td>32.67 ± 4.51</td>
<td>2.83 ± 0.52</td>
</tr>
<tr>
<td>extension</td>
<td>1.86 ± 1.07</td>
<td>27.68 ± 6.40</td>
<td>1.82 ± 1.04</td>
<td>39.29 ± 1.94</td>
<td>1.84 ± 1.04</td>
</tr>
<tr>
<td>lt lat</td>
<td>3.51 ± 0.18</td>
<td>26.67 ± 6.74</td>
<td>3.46 ± 0.23</td>
<td>27.24 ± 7.37</td>
<td>3.45 ± 0.21</td>
</tr>
<tr>
<td>rt lat</td>
<td>3.25 ± 0.78</td>
<td>26.75 ± 6.17</td>
<td>3.25 ± 0.84</td>
<td>28.59 ± 5.74</td>
<td>3.22 ± 0.84</td>
</tr>
<tr>
<td>lt axial</td>
<td>4.00 ± 0.24</td>
<td>16.29 ± 2.99</td>
<td>3.96 ± 0.22</td>
<td>21.52 ± 6.86</td>
<td>4.01 ± 0.26</td>
</tr>
<tr>
<td>rt axial</td>
<td>3.95 ± 0.16</td>
<td>17.07 ± 5.01</td>
<td>3.97 ± 0.13</td>
<td>24.66 ± 5.91</td>
<td>3.99 ± 0.11</td>
</tr>
</tbody>
</table>
Changes in MSU Contribution

Treated MSU Level. The rotation of the surgically treated MSU level (C5–6), expressed as a percentage of the overall global rotation (C2–T1) for the ProDisc-C and fused spines, was normalized to its corresponding contribution in the harvested condition. This ratio, calculated as follows: ([C5–6 rotation of surgically treated spine]/[C2–T1 rotation of treated spine]) divided by ([C5–6 rotation of harvested spine]/[C2–T1 rotation of harvested spine]) is shown in Figs. 10 through 12 for the combined loading conditions. There were no significant differences between the ProDisc-C and harvested conditions at the treated MSU level. Nevertheless, significant differences occurred between the fusion model and both the ProDisc-C and harvested conditions for all loading modes combined.

Adjacent MSU Levels. The changes in the MSU contribution at the remaining segments are also shown in Figs. 10 through 12. Significant differences between the harvested and ProDisc-C conditions only occurred in combined left plus right lateral bending at C2–3 and C6–7. Nevertheless, significant differences occurred between the harvested and fusion conditions in combined flexion plus extension at C3–4 and C6–7, in combined left plus right axial rotation at C6–7. Significant differences between the ProDisc-C and fusion conditions occurred in flexion plus extension at C3–4 and C4–5, in combined left plus right lateral bending at C6–7, and in left plus right axial rotation at C6–7.

DISCUSSION

Biomechanical Testing Protocols

The two most common methods for studying cervical spine mechanics in vitro are load control and displacement control.23 For load control, a pure or constant moment is incrementally applied to the spine and the spine is loaded in one motion plane at a time. For displacement control, the translations and rotations of the end VBs are controlled. In this study we controlled the displacement of the spine by using custom fixtures that induced a “moment distribution” throughout the spine similar to the in vivo situation.

The question arises as to which testing method better replicates the in vivo motion behavior of the cervical spine

### TABLE 2

<table>
<thead>
<tr>
<th>Test</th>
<th>Normalized ProDisc/Harvested</th>
<th>Normalized Fusion/Harvested</th>
</tr>
</thead>
<tbody>
<tr>
<td>flexion</td>
<td>1.11 ± 0.27</td>
<td>1.09 ± 0.23</td>
</tr>
<tr>
<td>extension</td>
<td>1.51 ± 0.37†</td>
<td>1.09 ± 0.25†</td>
</tr>
<tr>
<td>lt lat</td>
<td>1.10 ± 0.41</td>
<td>1.05 ± 0.19</td>
</tr>
<tr>
<td>rt lat</td>
<td>1.10 ± 0.15</td>
<td>1.07 ± 0.13</td>
</tr>
<tr>
<td>lt axial</td>
<td>1.35 ± 0.41</td>
<td>1.04 ± 0.20</td>
</tr>
<tr>
<td>rt axial</td>
<td>1.48 ± 0.36†</td>
<td>1.12 ± 0.15†</td>
</tr>
</tbody>
</table>

† Denotes significant difference between the ProDisc and fusion conditions.
* Denotes significant difference from the harvested condition.

### TABLE 3

<table>
<thead>
<tr>
<th>Test</th>
<th>Harvested S+T+1</th>
<th>Treated</th>
<th>ProDisc S+T+1</th>
<th>Treated</th>
<th>Fusion S+T+1</th>
<th>Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>flexion</td>
<td>17.79 ± 7.81</td>
<td>6.84 ± 4.20</td>
<td>21.99 ± 3.23</td>
<td>9.46 ± 1.99</td>
<td>17.85 ± 4.10</td>
<td>0.34 ± 0.30</td>
</tr>
<tr>
<td>extension</td>
<td>14.56 ± 4.26</td>
<td>4.95 ± 1.30</td>
<td>18.92 ± 3.05</td>
<td>3.76 ± 1.90</td>
<td>11.50 ± 3.50</td>
<td>0.15 ± 0.13</td>
</tr>
<tr>
<td>lt lat</td>
<td>13.55 ± 3.79</td>
<td>5.01 ± 2.30</td>
<td>14.16 ± 3.64</td>
<td>5.37 ± 3.20</td>
<td>10.77 ± 3.15</td>
<td>0.46 ± 0.42</td>
</tr>
<tr>
<td>rt lat</td>
<td>9.90 ± 2.20</td>
<td>3.76 ± 1.48</td>
<td>13.99 ± 1.82</td>
<td>4.72 ± 2.91</td>
<td>9.16 ± 2.27</td>
<td>0.26 ± 0.27</td>
</tr>
<tr>
<td>lt axial</td>
<td>7.10 ± 1.93</td>
<td>3.88 ± 2.24</td>
<td>12.19 ± 6.16</td>
<td>5.78 ± 4.75</td>
<td>7.43 ± 2.70</td>
<td>0.95 ± 0.44</td>
</tr>
<tr>
<td>rt axial</td>
<td>9.22 ± 4.24</td>
<td>3.42 ± 1.06</td>
<td>14.02 ± 5.26</td>
<td>7.14 ± 4.48</td>
<td>8.95 ± 3.34</td>
<td>0.68 ± 0.37</td>
</tr>
</tbody>
</table>

*S+T+I = overall data for superior, treated, and inferior segments combined.
and would thus be better suited to delineate differences between disc arthroplasty and fusion instrumentation. Miura, et al., recently described a method for simulating in vivo cervical spine kinematics by using a preload and pure-moment protocol. Application of a follower load was used in conjunction with a pure moment. The follower load concept directs a compressive load through the center of rotation of each MSU. In their study, the rotational axis was placed near the lateral masses and remained fixed for the flexion and extension tests. Nevertheless, the instant axis of rotation position was based on three cited studies, none of which included an analysis of the propagation of error associated with the theoretical instant axis of rotation calculation itself, nor were the instant centers determined over small ranges of cervical motion (that is, 2 to 3° increments). We have previously shown that the instant axis of rotation error can be large (as high as ±10 mm) for small angular changes (2 to 3°) and that the instant axis of rotation position is significantly different in flexion and extension. In the end, use of the follower load restricts the spine from following its natural path.

The flexion/extension motion response obtained using Miura and colleagues’ pure-moment protocol with a follower load is shown in Fig. 13, along with a mean in vivo data set and the MSU rotational patterns from our testing protocol. No significant difference was reported between the pure-moment response and the in vivo data. Nevertheless, the combined mean flexion/extension rotational values did not always follow the in vivo pattern and in some instances went in the opposite direction or remained constant across multiple MSU levels (Fig. 13) at the region where the predominant amount of motion occurs in the cervical spine (that is, C4–5 and C5–6). Furthermore, the trend in Miura and colleagues’ data indicates that if the sample size were increased, significant differences would exist between the pure-moment response and the in vivo response.

Using displacement control methods to apply a moment distribution across the cervical spine produced an in vitro motion response (Fig. 13) that matched the in vivo pattern. Therefore, this method should be used when studying the effects of nonfusion instrumentation on spine biomechanics. When using this protocol to evaluate disc arthroplasty, the motion of the spine at the superior, implanted, or inferior MSUs was comparable to the harvested condition.

Few biomechanical studies have been conducted to analyze the effects of disc arthroplasty on cervical joint biomechanics in a multiple-body cadaveric model. We have previously analyzed the biomechanical properties of the Prestige cervical disc under flexion/extension and lateral bending conditions by using the modified testing protocol. McAfee, et al., investigated the role of the posterior longitudinal ligament following discectomy, anterior disc replacement, and anterior disc arthrodesis. The porous coated motion prosthesis was used as the disc replacement device. In their study the different spine conditions

<table>
<thead>
<tr>
<th>Test</th>
<th>Normalized ProDisc/Harvested</th>
<th>Normalized Fusion/Harvested</th>
</tr>
</thead>
<tbody>
<tr>
<td>flexion</td>
<td>1.35 ± 0.51*</td>
<td>0.05 ± 0.04†</td>
</tr>
<tr>
<td>extension</td>
<td>0.57 ± 0.22†</td>
<td>0.04 ± 0.05†</td>
</tr>
<tr>
<td>lt lat</td>
<td>1.05 ± 0.37*</td>
<td>0.13 ± 0.12†</td>
</tr>
<tr>
<td>rt lat</td>
<td>0.92 ± 0.47*</td>
<td>0.07 ± 0.05†</td>
</tr>
<tr>
<td>lt axial</td>
<td>1.07 ± 0.88*</td>
<td>0.29 ± 0.15†</td>
</tr>
<tr>
<td>rt axial</td>
<td>1.26 ± 0.41*</td>
<td>0.24 ± 0.20†</td>
</tr>
</tbody>
</table>

* Denotes significant difference between the ProDisc and fusion conditions.
† Denotes significant difference from the harvested condition.
were tested under the pure-moments method by using a shortened (C3–7) spine model. Although pure-moment methods permit relative comparisons among the different spine conditions, they do not replicate physiological conditions and are less suitable for biomechanical testing of arthroplasty or nonfusion devices. In addition, use of fewer spinal segments further limited the analysis of the adjacent-segment biomechanics.

**Clinical Experience**

The issue of adjacent-segment disease in the cervical spine has recently been reviewed by Azmi and Schlenck. It should be emphasized that the problem of adjacent segment degeneration may be best managed by avoidance of ACDF. Patients with unilateral radicular symptoms who require surgery may very well be best served by posterior cervical foraminotomy and not ACDF. Whether it is performed in a minimally invasive manner or as an open procedure, posterior cervical foraminotomy has a high success rate with respect to alleviation of radicular symptoms, and it preserves spinal motion. For patients with bilateral radicular symptoms, significant ventral cord compression, or significant axial neck pain, ACDF remains the standard of care. These patients constitute a group of individuals who may potentially benefit from cervical disc arthroplasty to minimize symptomatic adjacent segment degeneration and the need for future surgical intervention. It has been argued that adjacent-segment disease represents progression of the underlying disease of cervical spondylosis and may not necessarily be related to the biomechanical effects of successful fusion. Despite this contention, radiological follow-up studies, biomechanical studies, and clinical experience indicate that the presence of a successful ACDF places increased strain on the adjacent levels and may accelerate the degenerative process. The ultimate test of this proposition will be the long-term clinical outcomes of cervical disc arthroplasty.

Fig. 9. Bar graphs showing the mean relative MSU rotations.

Fig. 10. Bar graphs showing the percent contribution of flexion/extension MSU rotations of each MSU level of the implanted and fused spines, normalized to their respective rotational contribution in the harvested state. * = significant difference with the harvested condition; # = significant difference between the ProDisc-C and fusion conditions.

D. J. DiAngelo, et al.

Neurosurg. Focus / Volume 17 / September, 2004
The concept of cervical disc replacement is not new: the initial clinical efforts are attributed to Fernstrom, Reitz and Joubert, and Alemo-Hammad. Over the last decade, clinical experience with the Cummins artificial cervical joint and the Bryan Cervical Disc prosthesis (as described by Goffin, et al.) have been reported.

The Cummins artificial cervical joint is a stainless steel ball-and-socket joint that allows some translation. It requires internal fixation with AO screws similar to those used for anterior cervical plating. The device is inserted after a standard anterior cervical discectomy and resection of posterior osteophytes as needed. The initial clinical experience includes implantation of 22 single-sized devices in 20 patients for myelopathy, radiculopathy, and axial pain. Two patients underwent implantation of two devices, one as a primary procedure, and the second patient received the device in a staged procedure. Nineteen of the 20 patients had either a congenital fusion or had undergone a previous surgical fusion. Sixteen of the patients reported pain relief, whereas three had continued pain. One patient sustained a transient hemiparesis related to a drill injury. Screw pullout, screw breakage, and joint subluxation were all reported. One device was ultimately explanted. Joint motion was shown to be present up to 5 years postsurgery. No patient required further surgery at an adjacent motion segment. Wear debris and bone incorporation into the device were not observed. The report by Cummins, et al. demonstrated that a stainless steel joint can be implanted in the cervical spine. Suggested future refinements of the device include development of multiple sizes, a decreased profile, and a total of four screws for better fixation.

The Bryan Cervical Disc prosthesis consists of two titanium shells enclosing a polyurethane nucleus. Implantation of the device requires milling of the endplates after establishing the center of the disc space by using a gravitational reference system. The milling affords a precision fit such that the milled surfaces match the titanium shells’ outer surface. This allows the shells to be protected by a rim of bone and provides immediate stability. Goffin, et al. reported the initial clinical experience with the Bryan Cervical Disc prosthesis in 103 patients who underwent...
single-level implantation and 43 who underwent bilevel implantation.

Patients were enrolled if they needed treatment of radiculopathy or myelopathy and were excluded only if they needed treatment of axial neck pain. In the single-level study, 90% of patients were classified as having attained excellent, good, or fair outcomes at 2 years. In the bilevel study, 96% of patients were classified as having attained excellent, good, or fair outcomes at 1 year. Reported reasons for repeated operation included the following: evacuation of prevertebral hematomas (two patients), evacuation of an epidural hematoma, posterior foraminotomy for residual symptoms, posterior decompression for residual myelopathy, repair of a pharyngeal tear caused by intubation, and anterior decompression. No device failures have been reported. The device provided more than 2° of motion at 2 years in 93% of the patients who received single-level implants and in 86% of the ones who received bilevel implants at 1 year. It was believed by the investigators that the results equaled or surpassed those achieved with ACDF, based on a metaanalysis of the literature. Nevertheless, the clinical experience does not constitute a randomized clinical trial of cervical disc arthroplasty and ACDF, which would be ideal.

Both the Cummins and the Bryan devices have distinct advantages and disadvantages. The Cummins device has a relatively high rate of instrumentation-related complications, including device subluxation, whereas the Bryan device appears to be well tolerated at 1 to 2 years. The Cummins device is easily implanted, whereas the Bryan device requires a precise milling process. The ultimate evaluation of the success of both devices will depend on long-term follow up with documentation of adjacent-segment degeneration when compared directly with results in patients undergoing ACDF. It is likely that a minimum of 5 years of follow up will be required before any conclusions regarding adjacent-segment disease can be made. As with any new surgical procedure, time will be the final arbitrator.

CONCLUSIONS

Although pure-moment protocols are more commonly used to evaluate spinal fixation hardware, they are less suitable for evaluating spinal arthroplasty or nonfusion devices. An improved testing protocol that replicated the in vivo motion behavior of the cervical spine was used to study the biomechanics of a disc prosthesis in vitro. Under this protocol the ProDisc-C implant maintained the biomechanical integrity of the cervical spine. Nevertheless, simulation of fusion significantly reduced motion at the surgical site, which was compensated for by increased motion at the adjacent segments. This increased motion at the adjacent segments may accelerate degeneration of adjacent disc segments.

In this biomechanical study we have emphasized the maintenance of normal motion at all segments of the spine with placement of the cervical prosthesis, compared with decreased motion of the adjacent segments after surgical fusion. Use of a prosthetic total disc replacement device such as the ProDisc-C to treat symptomatic degenerative cervical disc disease may minimize or alleviate the adjacent-segment disease associated with fusion surgery. Prosthetic disc replacement may become a viable alternative to cervical fusion for the surgical treatment of mechanical neck pain.

Acknowledgments

We thank the Medical Educational Research Institute in Memphis, Tennessee for the use of their surgical facilities and tissue. We are grateful for assistance with manuscript preparation by Henry Bonin.

References

Biomechanics of artificial cervical disc arthroplasty


Manuscript received July 7, 2004. Accepted in final form August 16, 2004. This work was funded in part by Synthes Spine Solutions (West Chester, PA).

Address reprint requests to: Denis J. DiAngelo, Ph.D., Department of Biomedical Engineering, University of Tennessee Health Science Center, 920 Madison Avenue, Suite 1005, Memphis, Tennessee 38103. email: ddiangelo@utmem.edu.