History of cervical disc arthroplasty

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Enthusiasm for cervical disc arthroplasty is based on the premise that motion-preserving devices attenuate the progression of adjacent-segment disease (ASD) in the cervical spine. Arthrodesis, on the other hand, results in abnormal load transfer on adjacent segments, leading to the acceleration of ASD. It has taken several decades of pioneering work to produce clinically relevant devices that mimic the kinematics of the intervertebral disc. The goal of this work is to trace the origins of cervical arthroplasty technology and highlight the attributes of devices currently available in the market. (DOI: 10.3171/2009.6.FOCUS09128)

KEY WORDS • arthroplasty • cervical spine • history of neurosurgery

Cervical Arthroplasty Biomechanics

Biomechanical testing and design configuration of cervical disc prostheses have been key in the development of this technology. Material designs include the following: metal-on-metal, metal-on-polymer, ceramic-on-polymer, polymer composite, or ceramic-on-ceramic designs. Prostheses are further divided into constrained, unconstrained, and semiconstrained types, based on degrees of motion allowed (Table 1). The “best” configuration or design of a cervical artificial prosthesis is one that most closely mimics normal intervertebral disc kinematics. Consensus on which design accomplishes this goal, however, has not been clearly established. Kinematics, wear properties, stiffness, durability, and imaging compatibility are only some of the features that are taken into consideration in the design of these prostheses.

Biomechanical arthroplasty testing, as compared with arthrodesis testing, represents unique challenges. The goal is to measure parameters that accurately depict whether the instrumented spinal segment is behaving similarly to the intact spine. Measuring a simple ROM, which is the most commonly measured parameter in rigid fixation protocols, is insufficient in arthroplasty testing. Adjacent-segment ROM, coupling patterns, facet loading, intradiscal pressures, and postural changes are a few examples of useful biomechanical parameters for full characterization of cervical arthroplasty.

Not addressing these parameters, in our opinion, was a weakness in many of the earlier studies (Table 2). More
Recent studies were able to incorporate advanced testing techniques, including measuring intradiscal pressure and facet loads. Panjabi \(^9\) proposed a “hybrid” protocol for construct testing of spinal arthroplasty. In this technique, a load control is used in normal specimens to determine the limiting angles in each mode, after which displacement control is used for testing the remaining conditions. A potential problem with this method is that fused specimens are forced to undergo unrealistically excessive rotation, and this biases experiments unrealistically in favor of arthroplasty.

In our biomechanics lab at Barrow Neurological Institute, we have designed a specific protocol for gathering more extensive biomechanical data on cervical arthroplasty devices. In addition to simple ROM, we measure coupling patterns, instantaneous axis of rotation, alterations to upright posture, and facet loads by using strain gauges (unpublished data). Both traditional pure-moment loading and more physiological flexion and extension mechanisms were all redesigned. The initial pilot study in 2002 showed that total disc replacement systems allowed for ROM, instantaneous axis of rotation, and coupling patterns that closely mimicked the normal state when compared with fusion. Testing to compare the kinematics of Bryan to Prestige devices is currently underway.

Using this more extensive protocol, we have initiated studies on several of the commercially available cervical devices. In 3 separate studies, we evaluated the kinematics of the cervical spine after insertion of the CerviCore, Pro-Disc C, and Prestige devices (our unpublished data). Comparisons were made to the normal and fused states. Results showed that these total disc replacement systems allowed for ROM, instantaneous axis of rotation, and coupling patterns that closely mimicked the normal state when compared with fusion. Testing to compare the kinematics of Bryan to Prestige devices is currently underway.

Developing and refining biomechanics testing methodologies for better assessment of the kinematics of cervical arthroplasty devices will be key as this technology is further embraced by clinicians and patients alike.

### Early Experience

**First Artificial Cervical Device**

Ulf Fernstrom is credited with implanting the first artificial cervical device, in 1966. \(^{11}\) The implant was a stainless steel ball bearing prosthesis that was implanted in both lumbar and cervical regions of the spine. In total, Fernstrom inserted 191 lumbar spheres and 13 cervical spheres. During the same time, another group from South Africa was experimenting with the Fernstrom type device in the cervical spine. \(^{29}\) The primary indications were headaches and cervicobrachialgia. Clinical follow-up, however, demonstrated unacceptable rates of device subsidence, migration, and adjacent-segment hypermobility. \(^{28}\) Given these failures, interest in cervical arthroplasty diminished in favor of arthrodesis techniques developed by Smith and Robinson. \(^{31}\)

**The Cummins-Bristol Disc**

Given the popularity and widespread use of lumbar arthroplasty devices in the 1980s and 1990s, principally in Europe, the feasibility of motion preservation in the cervical spine gained renewed interest. One of the first prototypes was designed by B.H. Cummins at the Frenchay Hospital in Bristol, UK, in 1989. In a 2004 review, Le et al. \(^{20}\) described this as a 2-piece, metal-on-metal device composed of stainless steel. The articulating surface was a ball-and-socket design with 2 (initially 1) anterior anchoring screws that fixed each piece of the device to the adjacent vertebral bodies. Initial clinical results in the 18 patients available for follow-up were encouraging, however, with 3 cases of screw pullout, 1 of screw breakage, and 1 subluxed joint. \(^{4}\) Persistent dysphagia was reported in all 18 patients.

**The Prestige Disc**

Due to the high hardware failure rate and high-profile design of the Cummins-Bristol device, the prosthesis was redesigned and reintroduced as the Frenchay cervical disc. The articulating surface of the lower piece, the profile of the entire device, and the anterior locking mechanisms were all redesigned. The initial pilot study in 2002 demonstrated favorable results, with lower complication rates. \(^{34}\) With these initial results, further studies were undertaken to examine the efficacy of this device (later acquired by Medtronic, Inc., and renamed the Prestige Disc [Fig. 2]), with particular interest in progression of ASD. \(^{35}\) In 2007, the first randomized clinical trial in the US was performed to compare outcomes of Prestige disc implantation versus fusion. The results demonstrated that segmental motion was maintained with the device at 24 months as well as improved clinical outcomes, and found

### TABLE 1: Cervical arthroplasty devices available in the US as of 2006

<table>
<thead>
<tr>
<th>Name of Device</th>
<th>Manufacturer</th>
<th>Classification</th>
<th>Biomaterials</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCM</td>
<td>NuVasive, Inc., San Diego, CA</td>
<td>semiconstrained</td>
<td>CCM end plate w/ UHMWPE inlay</td>
</tr>
<tr>
<td>ProDisc-C</td>
<td>Synthes Spine, West Chester, PA</td>
<td>semiconstrained</td>
<td>CCM end plate w/ UHMWPE inlay</td>
</tr>
<tr>
<td>Bryan</td>
<td>Medtronic, Ltd., Memphis, TN</td>
<td>unconstrained</td>
<td>titanium alloy shells w/ polyurethane nucleus</td>
</tr>
<tr>
<td>Prestige ST, Prestige LP</td>
<td>Medtronic, Ltd., Memphis, TN</td>
<td>unconstrained</td>
<td>metal-on-metal (ST device: stainless steel; LP device: titanium ceramic composite)</td>
</tr>
<tr>
<td>Kineflex-C</td>
<td>Spinal Motion, Inc., Mountain View, CA</td>
<td>semiconstrained</td>
<td>CCM metal-on-metal</td>
</tr>
<tr>
<td>CerviCore</td>
<td>Stryker Spine, Allendale, NJ</td>
<td>semiconstrained</td>
<td>CCM metal-on-metal</td>
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</tbody>
</table>

* According to information in the article by Traynelis. Please note: not all devices are FDA approved.
### TABLE 2: Peer-reviewed cervical arthroplasty biomechanics studies*

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>Device</th>
<th>Control Type</th>
<th>No. of Specimens</th>
<th>Conditions Tested &amp; Level</th>
<th>Outcome Measures</th>
<th>Results</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>McAfee et al., 2003</td>
<td>PCM load</td>
<td>7</td>
<td>normal; C5/6 discectomy sparing PLL; device implanted; device removed &amp; PLL resected; device replaced; device removed &amp; graft placed; plate placed</td>
<td>ROM</td>
<td>no significant differences between normal &amp; PCM-implanted conditions; PLL resection does not alter biomechanics when PCM device implanted</td>
<td>highlights significance of PLL in uninstrumented procedures</td>
<td>no adjacent-level data; data reported do not separate flexion &amp; extension (combined data are presented)</td>
<td></td>
</tr>
<tr>
<td>DiAngelo et al., 2003</td>
<td>Prestige displacement</td>
<td>4</td>
<td>normal; C5/6 prosthesis; simulated fusion</td>
<td>global stiffness &amp; ROM</td>
<td>fusion decreases motion at replaced level; prosthesis does not provide adjacent-level ROM</td>
<td>axial rotation not studied; fusion specimens forced similar displacement to nonfused specimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puttlitz et al., 2004</td>
<td>Pro-Disc-C load</td>
<td>6</td>
<td>normal; C4/5 prosthesis</td>
<td>ROM, coupling patterns</td>
<td>prosthesis mimicked normal ROM</td>
<td>tested w/ &amp; w/o preload</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DiAngelo et al., 2004</td>
<td>Pro-Disc-C displacement</td>
<td>6</td>
<td>normal; C5/6 prosthesis; simulated fusion</td>
<td>stiffness &amp; ROM</td>
<td>fusion decreases motion at replaced level; prosthesis does not; 35% more flexion occurred w/ disc vs normal (statistically insignificant), 43% less extension w/ disc vs normal (significant)</td>
<td>robotic actuator mimics in vivo loads</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kotani et al., 2005</td>
<td>disc prototype load</td>
<td>7</td>
<td>normal; C5/6 prosthesis; graft; graft + plating</td>
<td>ROM &amp; NZ</td>
<td>prosthesis maintained ROM &amp; NZ vs normal in axial rotation &amp; lateral bending; disc allowed greater ROM (but not NZ) vs normal in flexion &amp; extension</td>
<td>adjacent-segment ROM quantified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dmitriev et al., 2005</td>
<td>PCM displacement (hybrid)</td>
<td>10</td>
<td>normal; C5/6 prosthesis; graft; graft + plate</td>
<td>ROM + NZ C5/6; ROM + intradiscal pressures at C4/5 &amp; C6/7; ROM; NZ</td>
<td>intradiscal pressure at adjacent levels similar to normal after prosthesis, significantly increased after graft or graft + plate; ROM &amp; NZ at index level mimicked normal after disc replacement, but significantly decreased after inserting graft or graft + plate</td>
<td>adjacent-level ROM &amp; intradiscal pressures analyzed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>McAfee et al., 2006</td>
<td>PCM load</td>
<td>6</td>
<td>normal; discectomy; radical discectomy; PCM; unilateral uncovertebral resection + PCM; bilateral uncovertebral resection + PCM</td>
<td>ROM; NZ</td>
<td>ROM &amp; NZ mimicked normal condition, except in axial rotation w/ bilateral uncovertebral resection</td>
<td>graded anterior resections studied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chang et al., 2007</td>
<td>Prestige, Pro-Disc-C displacement</td>
<td>18</td>
<td>normal; prosthesis; graft + plating, C6–7</td>
<td>ROM, IDP, facet loads</td>
<td>increased IDP level above in fused specimens; facet loads increased w/ arthroplasty in extension</td>
<td>facet loads, IDP measurements</td>
<td>only 1 strain gauge used in facet load measurements</td>
<td></td>
</tr>
</tbody>
</table>

* IDP = intradiscal pressure; NZ = neutral zone; PLL = posterior longitudinal ligament.
a reduced rate of secondary surgeries compared with ACDF. In July 2007, the Prestige disc was approved by the FDA for the treatment of intractable radiculopathy and/or myelopathy caused by a herniated disc between the C-3 and C-7 levels. The initial device (Prestige ST) was a metal-on-metal construct composed of stainless steel. The newer Prestige LP model (fifth-generation Prestige model) is composed of a titanium-ceramic composite that is MR imaging-compatible. A porous titanium plasma spray coating is designed to facilitate bone in-growth. This model is currently being evaluated in an FDA IDE trial.

The Bryan Disc

The Bryan cervical disc (Medtronic, Inc.) was designed in the 1990s by the American neurosurgeon Vincent Bryan from Seattle. The device consists of 2 titanium alloy shells articulating with a polyurethane core (Fig. 3). Like the Prestige disc, it is a considered an unconstrained device. This device is not held in the disc space with any hardware, and it requires a tight fit of the prosthesis into a milled concavity. Bone ingrowth eventually bonds the metallic device faces to the vertebrae. The first multicenter trial evaluating the safety and efficacy of

Fig. 1. *Left:* Photograph of the pure-moment, flexibility apparatus. When the piston of the servohydraulic test frame is raised, tension is exerted on the loop of string, applying equal and opposite forces separated by a small distance to the fixture on the specimen. *Right:* Photograph of the flexion-compression apparatus. Weights hung from a belt looped around the specimen apply a constant follower load of 70 N; when the motor is activated, the belt drives the specimen into flexion or extension while keeping the follower load directed axially.
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This device was conducted in Europe. The investigators found that clinical success at 6 months and 1 year after implantation was 86 and 90%, respectively. At 1 year, there was no evidence of hardware failure, but there was 1 case of device migration that did not warrant revision surgery. Other European studies further demonstrated the efficacy of the Bryan device, even with bilevel implantation. Available data from the current US IDE trial are promising. In a recent publication, the investigators found that at 24 months after surgery, the patients in the investigational group treated with the artificial disc had a statistically greater improvement in the primary outcome variables compared with the control group (single-level ACDF). There was a 1.7% rate of implant-associated or implant/surgical procedure–associated serious adverse events in the investigational group, compared with 3.2% in the control group. Patients who received the artificial cervical disc returned to work nearly 2 weeks earlier than the patients who underwent fusion.

The ProDisc-C Device

The ProDisc-C device (Synthes, Inc.) was invented by Dr. Thierry Marnay of France. It was designed to parallel the ProDisc-L device used in lumbar arthroplasty. It is a semiconstrained device composed of CCM end plates, with a UHMWPE articulating surface (Fig. 4). Two keels on each external surface facilitate anchoring into the vertebral end plates. Results of the FDA IDE trial were recently published. Investigators found that neck pain intensity and frequency as well as arm pain intensity and frequency assessed using the visual analog scale were statistically lower at all follow-up time points compared with preoperative levels (p < 0.0001), but were not different between treatments (disc group vs ACDF group). Neurological success (improvement or maintenance) was achieved at 24 months in 90.9% of ProDisc-C and 88% of fusion patients (p = 0.638). There was a statistically significant difference in the number of secondary surgeries, with 8.5% of fusion patients needing a repeat operation, revision, or supplemental fixation within the 24-month postoperative period, compared with 1.8% of ProDisc-C patients (p = 0.033). In this study, the authors concluded that ProDisc-C is a safe and effective surgical treatment for patients with disabling cervical radiculopathy due to single-level disease, and that clinical outcomes after Pro-
Disc-C implantation were either equivalent or superior to those same clinical outcomes after fusion. The ProDisc-C was approved by the FDA in December 2007.

The PCM Device

The PCM device was invented by Paul McAfee, an orthopedic spine surgeon from Baltimore. The PCM is a 2-piece device consisting of a CCM end plate with a UHMWPE inner core. Its hallmark is a broad radius of curvature that allows for more end-plate support laterally. The device is coated with a titanium calcium phosphate coating to optimize end-plate anchorage. Initial results from McAfee’s group are promising. This group’s results from a pilot study in which 82 cervical disc arthroplasties were implanted in 53 patients demonstrated significant improvements in the indices examined. There was 1 device migration that did not require revision surgery. An FDA IDE study is ongoing. In 2009, NuVasive (NuVasive, Inc.) acquired this device.

The CerviCore Device

The CerviCore device (Stryker Spine) is a semi-constrained, metal-on-metal prosthesis. The articulating surface is saddle-shaped (Fig. 5), with 2 keels containing spikes present on each end plate. The saddle-shaped articulation is intended to provide different kinematics during lateral bending than during flexion and extension, as is seen naturally. Testing in our laboratory (unpublished data) showed that this particular total disc replacement system effectively preserves ROM and kinematics in the cervical spine. An FDA IDE trial is ongoing.

Conclusions

The last several decades have witnessed notable milestones in the development of cervical disc arthroplasty. The ultimate goal is to construct a device that stabilizes the involved segment, preserves motion, and mimics the kinematics of a healthy intervertebral disc. Given the evidence of adjacent-segment failure associated with arthrodesis, as well as encouraging results thus far from various clinical and biomechanical studies, the drive for further development of the cervical arthroplasty field is likely to continue.

Disclosures

The Spinal Biomechanics lab at Barrow Neurological Institute of St. Joseph’s Hospital and Medical Center in Phoenix has received research funding from Medtronic Sofamor Danek, Synthes Spine Company, and Stryker Spine for biomechanics testing of cervical arthroplasty devices.

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