Solid radiographic fusion with a nonconstrained device 5 years after cervical arthroplasty

Case report

ROBERT F. HEARY, M.D., IRA M. GOLDSMITH, M.D., KATARZYNA M. GETTO, B.S.N., AND NITIN AGARWAL, M.D.

Department of Neurological Surgery, Rutgers New Jersey Medical School, Newark, New Jersey

Cervical disc arthroplasty (CDA) has been gaining popularity as a surgical alternative to anterior cervical discectomy and fusion. Spontaneous fusion following a CDA is uncommon. A few anecdotal reports of heterotrophic ossification around the implant sites have been noted for the BRYAN, ProDisc-C, Mobi-C, PRESTIGE, and PCM devices. All CDA fusions reported to date have been in devices that are semiconstrained.

The authors reported the case of a 56-year-old man who presented with left C-7 radiculopathy and neck pain for 10 weeks after an assault injury. There was evidence of disc herniation at the C6-7 level. He was otherwise healthy with functional scores on the visual analog scale (VAS, 4.2; neck disability index (NDI, 16); and the 36-item short form health survey (SF-36; physical component summary [PCS] score 43 and mental component summary [MCS] score 47). The patient underwent total disc replacement in which the DISCOVER Artificial Cervical Disc (DePuy Spine, Inc.) was used. The patient was seen at regular follow-up visits up to 60 months. At his 60-month follow-up visit, he had complete radiographic fusion at the C6-7 level with bridging trabecular bone and no motion at the index site on dynamic imaging. He was pain free, with a VAS score of 0, NDI score of 0, and SF-36 PCS and MCS scores of 61 and 55, respectively.

Conclusions. This is the first case report that identifies the phenomenon of fusion around a nonconstrained cervical prosthesis. Despite this unwanted radiographic outcome, the patient’s clinical outcome was excellent.

Key Words • total disc arthroplasty • nonconstrained device • cervical fusion • cervical disc

Anterior cervical discectomy and fusion (ACDF) is the gold standard in the treatment of degenerative disc disease and acute disc herniation, with proven successful outcomes. Excellent clinical and radiographic results have been seen in 85%–95% of all patients.16,17 As some studies show that fusion alters cervical spine biomechanics,4 there has been some debate whether ACDF causes adjacent-segment disease. As a result of this concern, cervical disc arthroplasty (CDA) has emerged as a treatment option that is specifically designed to preserve segmental motion. Several prospective, randomized, controlled clinical trials of CDA compared with ACDF have yielded promising results, and few complications or adverse events have been reported.4,8–10,18,19,21,25,28

Spontaneous fusion following CDA is uncommon, but it has been reported. Reports of spontaneous fusion after CDA with the BRYAN Cervical Disc (Medtronic Sofamor Danek USA, Inc.) by Bartles and Donk as well as Parkinson and Sekhon were published in 2005.2,19 Multiple other articles mention occurrences of high-grade heterotopic ossification (HO) and/or spontaneous fusion after CDA with the ProDisc-C Total Disc Replacement system (Synthes Spine, Inc.), PCM (NuVasive, Inc.), Mobi-C Cervical Disc Prosthesis (LDR Spine USA, Inc.), SECURE-C Cervical Artificial Disc (Globus Medical, Inc.), and PRESTIGE Cervical Disc System (Globus Medical, Inc.).3,6,7,12–14,16,22,24,27 All of the reported cases of fusion involving CDA occurred with devices that are semiconstrained.

We report a case of spontaneous fusion around a nonconstrained device (DISCOVER Artificial Cervical Disc; DePuy Spine, Inc.). To our knowledge, this is the first description of such findings with a nonconstrained cervical prosthetic device.

Case Report

History and Presentation. A 56-year-old healthy
man presented with neck pain and left arm weakness that began following an assault. His symptoms had not improved after 3 months of conservative treatment (including physical therapy). On physical examination, he had weakness of his left triceps, finger extensors, and wrist flexion, along with decreased sensation in the C-7 dermatomes bilaterally. A CT scan demonstrated an autofusion at the C5–6 level (Fig. 1). An MRI of the cervical spine revealed a disc herniation at C6–7, which was greater on the left side (Fig. 2). Plain radiographs, with flexion and extension views, demonstrated no dynamic instability. His clinical status was consistent with a traumatic C-7 radiculopathy. He was otherwise healthy with functional scores on the visual analog scale (VAS, 4.2); neck disability index (NDI, 16); and the 36-item short form health survey (SF-36; physical component summary [PSC] score 43 and mental component summary [MCS] score 47).

Operation. A routine, right-sided, anterior cervical approach was used to perform a microsurgical removal of the C6–7 disc. Electrocautery was used judiciously during the approach for hemostasis. The posterior annulus fibrosus and the posterior longitudinal ligament were resected along with some posterior osteophytes. The dura mater was visualized and noted to be intact. Following the manufacturer’s recommendations for insertion, a DISCOVER disc (size 16.7 mm × 17.2 mm × 6 mm) was inserted. This device was inserted as part of an FDA investigational device exemption (IDE) study. Intraoperative fluoroscopy confirmed proper alignment of the device in the cervical spine. After copious irrigation with normal saline, a standard layered closure was performed.

Postoperative Course. The patient experienced complete resolution of both his neck and arm pain shortly after the surgery. His motor examination status improved over the next several months; at his 2-year follow-up, he was pain free and had only minor weakness (Grade 5–5) remaining in his left hand. His clinical outcome was superb; however, the postoperative radiographic parameters were not as successful. Cervical spine radiographs, with flexion and extension views, were acquired at 2 and 6 weeks; 3 (Fig. 3) and 6 (Fig. 4) months, and 1 and 2 (Fig. 5) years postoperatively. By 1 year after the operation, there was concern on plain radiographs about fusion across the operative level. The 2-year postoperative CT scans, obtained as part of the FDA IDE protocol, demonstrated a complete fusion around the prosthesis (Fig. 6). At his 5-year follow-up evaluation, cervical spine radiographs, with flexion and extension views, clearly demonstrated fusion across the operative level (Fig. 7). There was also evidence of HO at the adjacent C5–6 level. Clear bridg-
Fusion after arthroplasty with a nonconstrained device

ing trabecular bone, around the DISCOVER implant, was evident across the C6–7 segment. Postoperative functional outcomes scores at the 60-month follow-up evaluation were as follows: VAS score of 0; NDI score of 0; and SF-36 PCS and MCS scores of 61 and 55, respectively.

Discussion

Fusions across segments treated by CDA are known to occur. To date, all of the devices that have fused are semiconstrained.21,27 By definition, a device is considered to be “constrained” if it includes a mechanical stop within the physiological range of motion; “semiconstrained” if there is a mechanical stop outside of the normal range of motion; and “unconstrained” if the implant has no mechanical stop at all.10,28

Our case study describes a complete fusion around a prosthesis that is classified as nonconstrained. This device design preserves greater amounts of segmental motion than a semiconstrained design. As such, this represents the first reported case where, despite no mechanical stop incorporated as a part of the device, a complete radiographic arthrodesis was demonstrated on both plain films and CT scans at long-term follow-up.

Despite the promising, short-term clinical results after CDA, there has been a recent increase in the reporting of HO around the prosthesis (Table 1). Heterotopic ossification is commonly defined as a formation of bone outside the skeletal system. This phenomenon is widely known in the field of total hip or knee arthroplasty and has been classified by McAfee et al. for lumbar total disc replacement.15 The 5-grade system is as follows: Class 0, no HO; Class I, HO present, without affecting the intervertebral space; Class II, HO with new bone formation in the disc space, without blocking or articulating between the adjacent-level endplates; Class III, bridging ossifica-

Fig. 4. Plain radiographs, with flexion (left) and extension (right) views, taken 6 months after the index surgical procedure. A comparison of the position of the spinous processes at the extremes of neck motion (flexion and extension) demonstrates 0.5 mm of motion, which is consistent with what many neurosurgeons would deem to be within the limits denoting fusion.

Fig. 5. Plain radiographs with flexion (left) and extension (right) views, taken 2 years after the index surgical procedure. A comparison of the position of the spinous processes at the extremes of neck motion (flexion and extension) demonstrates 0 mm of motion and bridging trabecular bone consistent with fusion.

Fig. 6. Reconstructed CT scans taken at the FDA IDE protocol time point of 2 years postoperatively. Left: Solid arthrodesis present with bridging trabecular bone clearly visualized ventral to the C6–7 DISCOVER device; Class IV HO is also apparent at the C5–6 level. Right: Solid bony arthrodesis is apparent around the lateral edges of the DISCOVER device on the coronal view, which demonstrates a symmetrical midline placement of the device.

Fig. 7. Plain radiographs with flexion (left) and extension (right) views, taken 5 years after the index surgical procedure. Well-corticated fusion is present across the ventral disc space, and no motion can be detected when comparing the positioning of the spinous processes on the views at the extremes of neck motion (flexion and extension).
TABLE 1: Cervical disc arthroplasty devices with FDA approval

<table>
<thead>
<tr>
<th>Device</th>
<th>Company</th>
<th>Date Approved</th>
<th>Design†</th>
<th>HO Reported*</th>
</tr>
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<tbody>
<tr>
<td>ProDisc-C Total Disc Replacement</td>
<td>Synthes Spine, Inc.</td>
<td>12/17/2007</td>
<td>semiconstrained28</td>
<td>yes5</td>
</tr>
<tr>
<td>PRESTIGE Cervical Disc System</td>
<td>Medtronic Sofamor Danke USA, Inc.</td>
<td>07/16/2007</td>
<td>semiconstrained1</td>
<td>yes11</td>
</tr>
<tr>
<td>BRYAN Cervical Disc</td>
<td>Medtronic Sofamor Danke USA, Inc.</td>
<td>05/12/2009</td>
<td>semiconstrained28</td>
<td>yes5</td>
</tr>
<tr>
<td>SECURE-C Cervical Artificial Disc</td>
<td>Globus Medical, Inc.</td>
<td>09/28/2012</td>
<td>semiconstrained10</td>
<td>yes23</td>
</tr>
<tr>
<td>PCM Cervical Disc System</td>
<td>NuVasive, Inc.</td>
<td>10/26/2012</td>
<td>semiconstrained2</td>
<td>yes20</td>
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<tr>
<td>Mobi-C Cervical Disc Prosthesis</td>
<td>LDR Spine USA, Inc.</td>
<td>08/07/2013</td>
<td>semiconstrained26</td>
<td>yes5</td>
</tr>
</tbody>
</table>

* Citation refers to the study in which design was described and/or HO was reported.

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