

# Cervical Total Disc Arthroplasty

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## Abstract

Symptomatic adjacent segment degeneration of the cervical spine remains problematic for patients and surgeons alike. Despite advances in surgical techniques and instrumentation, the solution remains elusive. Spurred by the success of total joint arthroplasty in hips and knees, surgeons and industry have turned to motion preservation devices in the cervical spine. By preserving motion at the diseased level, the hope is that adjacent segment degeneration can be prevented. Multiple cervical disc arthroplasty devices have come onto the market and completed Food and Drug Administration Investigational Device Exemption trials. Though some of the early results demonstrate equivalency of arthroplasty to fusion, compelling evidence of benefits in terms of symptomatic adjacent segment degeneration are lacking. In addition, non-industry-sponsored studies indicate that these devices are equivalent to fusion in terms of adjacent segment degeneration. Longer-term studies will eventually provide the definitive answer.

## Keywords

- ▶ ACDF
- ▶ cervical fusion
- ▶ cervical arthroplasty
- ▶ adjacent segment

Anterior cervical discectomy and fusion (ACDF) has remained the gold standard treatment of cervical radiculopathy and myelopathy for over 50 years. In 1958, Smith and Robinson first described the ACDF by removing the disc material and subchondral bone and then packing the interspace with iliac crest autograft.<sup>1</sup> That same year, Cloward reported using a cylindrical bone dowel instead of autograft.<sup>2</sup> Because of its reliable and reproducible results, this procedure remained unchanged until the 1990s, when cervical plating was introduced. Despite its excellent clinical outcomes and long follow-up data, the question of adjacent segment degeneration has persisted. This has generated considerable interest in motion preservation technologies of the cervical spine. The tremendous success of total joint arthroplasty in the hip and knee joint has paved the way for multiple cervical disc arthroplasty devices. These devices have shown early promise in motion preservation and improved if not equal outcomes to ACDF.<sup>3</sup> However, the ultimate goal of cervical disc arthroplasty, preventing symptomatic adjacent segment degeneration, has not been unequivocally demonstrated in the current literature.

## Rationale for Motion Preservation

The kinematics of the cervical spine differ significantly from those of the lumbar spine. Most fusions occur between C3 and C7, adjacent to the highly mobile upper cervical region that accommodates approximately half of all cervical motion.<sup>4</sup> Transfer of motion and stress to adjacent levels after a fusion has been extensively studied biomechanically. Schwab et al examined human cadaveric cervical spines from C2 to T1 and assessed the effects of incremental single-level fusions at different regions of the cervical spine.<sup>5</sup> They concluded that motion compensation was distributed among the unfused segments, with significant compensation at the segments adjacent to the fusion. Interestingly, the fusion level determined whether the increased motion was seen at the adjacent level above or below the fusion. When the fusion level was at C3–C4 or C4–C5, significant increases in motion were seen at the level above the fusion. When the fusion level was at C5–C6 or C6–C7, significantly increased motion was seen at the levels above and below the fusion. Greater compensation occurred at the inferior segments than the superior segments for these lower-level

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fusions at C5–C6 and C6–C7. Though this study demonstrated increased motion at the levels adjacent to single-level cervical fusions, it did not conclude that this increased motion was responsible for adjacent segment degeneration.

Radiographic analysis of adjacent segment degeneration has been documented in long-term studies. Baba et al studied 106 patients who underwent ACDF for cervical myelopathy with an average of 8.5 years of follow-up.<sup>6</sup> He found that 25% of patients developed spinal canal stenosis at the level above the previously fused segments. Gore and Sepic followed 121 patients who had undergone an ACDF for an average of 5 years.<sup>7</sup> They found that 25% had new-onset spondylosis, and another 25% had progression of preexisting spondylosis. Neither of these two studies found any correlation between adjacent segment degeneration and clinical symptoms. Matsumoto et al performed a prospective study with 10-year follow-up comparing magnetic resonance imaging (MRI) findings of patients who underwent an ACDF with healthy control subjects.<sup>8</sup> They further subcategorized cervical spondylosis as decreased signal intensity of the disk (DSI), posterior disc protrusion (PDI), disc space narrowing, and foraminal stenosis. Results showed that DSI occurred significantly more in the ACDF group at the C4–C5 level, and PDI occurred significantly more in the ACDF group at all levels except C5–C6. Disc space narrowing and foraminal stenosis occurred significantly more in the ACDF group at C3–C4 and C6–C7, respectively. They concluded that although progression of cervical spondylosis occurred in both groups, ACDF did accelerate adjacent segment degeneration.

Hilibrand et al's landmark work on symptomatic adjacent segment degeneration followed 374 patients for a maximum of 21 years.<sup>9</sup> They found that symptomatic adjacent segment degeneration occurred at a relatively constant rate of 2.9% per year for the first 10 years after surgery. Kaplan-Meier survivorship analysis predicted that 25.6% of patients would have symptomatic adjacent segment disease 10 years postoperatively. Symptomatic adjacent segment degeneration was more likely to occur at C5–C6 and C6–C7. In addition, patients who underwent a multilevel arthrodesis were significantly less likely to develop adjacent segment degeneration than those who underwent a single-level fusion. The authors concluded that adjacent segment degeneration was likely related to the natural history of cervical spondylosis and not the fusion itself.

## Evolution of Cervical Total Disc Arthroplasty

The aforementioned studies underscore the conundrum surgeons face when performing an ACDF. It has provided excellent clinical results for decades, yet the question of adjacent segment degeneration continues to spur interest in motion-preserving technology. Currently, nine different cervical total disc arthroplasty devices have completed the Food and Drug Administration (FDA)-regulated Investigational Device Exemption (IDE) clinical trial. These devices have evolved significantly over time, incorporating principles of both orthopedics and tribology.

The first cervical artificial disc was implanted by Ulf Fernstrom in 1966.<sup>10</sup> It consisted of a stainless-steel ball-

bearing prosthesis and was used in both the cervical and lumbar spines. It was implanted in over 250 patients, but later fell out of favor because of unacceptably high failure rates. The device caused hypermobility and was found to erode into the vertebral end plate and body. Cervical arthrodesis procedures developed by Smith and Robinson increased in popularity and sidelined arthroplasty devices for the next 2 decades.

Use of lumbar arthroplasty devices in the 1980s spurred renewed interest in cervical motion preservation. In 1989, Cummins designed a stainless steel metal-on-metal cervical artificial disc in Bristol, UK. It was a stainless steel, ball-and-socket design with two anchoring screws. Initial clinical results in the 18 patients also showed unacceptably high failure rates: three cases of screw pullout, one of screw breakage, one subluxed joint, and persistent dysphagia reported in all 18 patients.<sup>11</sup> It was redesigned and reintroduced as the Frenchay cervical disc. The Frenchay had better clinical results and was purchased by Medtronic and renamed the "Prestige Disc."<sup>12</sup> In 2007, the Prestige Disc was approved by the FDA for treatment of cervical radiculopathy and/or cervical myelopathy between C3 and C7.

The Bryan cervical disc was designed in 1992 by an American neurosurgeon, Vincent Bryan. It is a metal-on-plastic design, consisting of two titanium alloy shells with a polyurethane core. A polyurethane sheath surrounds the nucleus and is filled with saline, mimicking synovial fluid and containing any potential wear debris. Unlike the Prestige, the Bryan disc is not secured into the disc space with any hardware; it required a "press-fit" after milling of the endplates. In 2007, the Bryan disc completed a multicenter FDA IDE trial.

The Pro-disc C was designed by Dr. Marnay of France. It consists of a cobalt-chromium-molybdenum end plates (CCM) with an ultra-high-molecular-weight polyethylene (UHMWPE) articulating surface. Two keels on each surface anchor the Pro Disc C to the vertebral end plates, paralleling the design of the lumbar arthroplasty device, the Pro Disc L.

The Porous Coated Motion Disc Prosthesis, or PCM device, was designed by Dr. Paul McAfee of Baltimore. It is also composed of CCM end plates that articulate with an UHMWPE inner core. The outer surface of the end plates are serrated and coated with titanium/calcium phosphate, thus allowing for bony ingrowth. Initial fixation is that of a press-fit mechanism. Its broad radius of curvature is thought to provide more end-plate support laterally. In 2009, this device was purchased by Nuvasive, Inc. (San Diego, CA).

Multiple other devices are in development and will likely come to market: Cervicore (Stryker, Kalamazoo, MI), Discocerv (Scientix, Maitland, FL), and NeoDisc (Nuvasive). The Kineflex-C (Spinal-Motion, Inc., Mountain View, CA), a cobalt-chrome metal-on-metal semiconstrained disc with a mobile center core, utilizes midline keels for immediate fixation. The variations in design and implantation have given surgeons multiple devices to choose from, and the number will continue to grow.

## Literature Review

Each of these designs attempts to closely mimic the kinematics of the native cervical disc in the hopes of preserving

motion and preventing degeneration of the adjacent segments. Multiple prospective, randomized, multicenter studies have examined the indications and outcomes of these devices, with varying results.

Mummaneni et al performed a perspective, randomized multicenter study to evaluate the Prestige ST with ACDF.<sup>13</sup> Their study included 541 patients: 276 in the investigational group underwent anterior cervical arthroplasty with the Prestige II, and 265 patients in the control group underwent a single-level ACDF. Patients were followed for regular intervals and up to 24 months postoperatively. Primary outcome measures included neck disability index score (NDI), neurological success, short form (SF)-36, supplementary surgical procedures, relief of neck and arm pain, and return to work.

Improvements in the NDI score were significantly in favor of the arthroplasty group at 6 weeks and 3 months, but lost significance at 12 and 24 months. SF-36 PCS (physical component summary score) and MCS (mental component summary score) were not significantly different between the two groups. Employment status was not different between the two groups at the end of the study, but the investigational group returned to work on average 16 days earlier. Neck pain was significantly improved in the investigational group up to 12 months, but there were no differences in regards to arm pain between the two groups. Their results showed a significantly lower reoperation rate for adjacent segment degeneration in the arthroplasty group, but no criteria were given for its clinical or radiographic diagnosis. Neurological success, defined as a greater than or equal to 15-point improvement in the NDI and maintenance or improvement in neurological status, was significantly higher in the control group at 12 and 24 months. Overall, their results showed early benefits in the arthroplasty group that become insignificant at 24 months. These results should be interpreted with caution as the follow-up rates in this study were low: 80% in the investigational group and 75% in the control group.

Murrey et al examined the Pro Disc-C versus ACDF for symptomatic one-level cervical disease in a prospective, multicenter randomized study.<sup>14</sup> The patient follow-up in this study was excellent: 94.8% for the control group and 98% for the investigational group. Their results showed no statistically significant differences between the two cohorts at 24 months for visual analog scale (VAS) neck and arm, SF-36, NDI, or neurological success. Operative times and blood loss were significantly higher in the arthroplasty group. There was a significant difference in strong narcotic use between the groups, favoring arthroplasty. In addition, there was a significant difference in the number of secondary surgeries between the two groups, favoring arthroplasty: 8.5% of fusion patients required a reoperation, revision, or supplemental fixation within the 24-month postoperative period, compared with 1.8% of the arthroplasty group. Overall, the study demonstrated essentially equivalent short-term outcomes between the two groups.

Heller et al performed a prospective, randomized, multicenter study comparing single-level ACDF with Bryan cervical disc arthroplasty.<sup>15</sup> At 24-month follow-up, the disc arthroplasty group had statistically greater improvement in the primary outcome variables: NDI scores and overall success

(greater than or equal to 15-point improvement in the NDI scores, maintenance or improvement of neurological status, no serious adverse events related to the implant/surgical procedure, and no subsequent surgery or intervention classified as "failure"). Neck and arm pain improved significantly in both groups from baseline, but the arthroplasty group had a significantly greater reduction in neck pain. Adverse events and SF-36 scores showed no significant difference between the two groups. The investigational group returned to work ~2 weeks earlier than the control group, but there was no significant difference in the return to work rates at 2 years postoperatively. Though this study concluded that cervical arthroplasty with the Bryan disc is a viable alternative to ACDF for single-level disease, several shortcomings of the study are noteworthy. Twelve patients who were assigned to investigational group received the control treatment because of anatomic constraints: four had a disc space smaller than the smallest available Bryan disc, five could not have the C6–C7 disc space adequately visualized with intraoperative radiography and therefore could not have the Bryan disc safely implanted, and one mistakenly received the control treatment. There is no mention of the remaining two patients. Another area of concern is the fact that 117 patients who were randomized declined participation in the study before receiving their assigned treatment. Though the authors comment that there were no statistical differences in demographics and baseline measurements between the group of patients who dropped out and those who participated, such a high number of dropouts inevitably introduced bias into the results.

Garrido et al, whose patients were part of the aforementioned study, reported outcomes on their cohort of patients at 48 months.<sup>16</sup> Primary outcome measures were NDI, VAS neck and arm, and SF-36 scores and complications and reoperations. Their data demonstrated improved outcomes in both the arthroplasty group for all outcome measures except the SF-36 physical component score. However, due to their small sample size, the study was underpowered and failed to reach statistical significance in any outcome measure.

Recently, Coric et al performed a prospective, randomized multicenter study evaluating 2-year outcomes of the Kineflex C artificial cervical disk with ACDF for single-level disease.<sup>17</sup> Primary outcome measures such as the VAS pain scores and overall clinical success were all significantly in favor of the arthroplasty group. NDI improved significantly in both groups, but there was no significant difference between groups at the 2-year end point. Adjacent segment degeneration was evaluated from "a quantitative analysis of disc height and an independent radiologist's subjective assessments" based on a previously published qualitative and quantitative analysis of disc height.<sup>18</sup> Though radiographic evidence of severe adjacent segment degeneration was significantly lower in the arthroplasty group, reoperation rates at the adjacent levels showed no significant difference between groups. Based on the published data, the authors cannot conclude any difference between the symptomatic adjacent-level disease between the two cohorts.

In one of the few non-industry-sponsored studies, Nunley et al performed a prospective, multicenter study evaluating

170 patients with symptomatic cervical spondylosis at one or two levels.<sup>19</sup> Subjects received either an ACDF or one of three different types of artificial discs. The types of artificial discs used were not specified. Primary outcome measures included NDI, neurological examination, and visual analog pain scores up to 48 months after surgery. Patients who had radiographic and/or MRI evidence of spondylosis at levels other than the index levels to be treated were excluded from the study. Patients with persistent postoperative symptoms were investigated for adjacent segment degeneration and underwent advanced imaging, neurophysiology, and subsequent active interventions. They authors concluded that the risk of developing adjacent segment degeneration was equivalent between the two cohorts at a median of 38 months postoperatively. Patients with osteopenia and concurrent lumbar degenerative disease were significantly more likely to develop adjacent segment degeneration.

## Conclusion

Over the course of the next few years, motion preservation devices for the cervical spine will continue to increase in number and complexity. Many of the current randomized, prospective studies conclude that disc arthroplasty is a “viable alternative” to ACDF, citing improved outcomes in their cohort of patients in the short term. Late failure of arthroplasty devices, as demonstrated in total knee and total hip arthroplasty, are of real concern and require long-term studies to define. In today’s health care environment, superior, not equivalent, outcomes will be required for a true paradigm shift in the surgical treatment of cervical spondylosis. If these devices can clinically demonstrate reduced rates of symptomatic adjacent segment degeneration in long-term studies, only then will they truly become the standard of care.

### Disclosures

Rahul Basho, None  
Kenneth A. Hood, None

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