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Review Article

Cervical Disc Arthroplasty versus Anterior Cervical Discectomy and Fusion: A Systematic Review

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Abstract

Anterior Cervical Discectomy and Fusion (ACDF) is a widely utilized surgical treatment for cervical disc disease. Despite success of ACDF, concerns regarding adjacent segment degeneration led to the design and development of cervical disc arthroplasty (CDA). We performed a systematic review of studies comparing the efficacy and safety profile of CDA versus ACDF. We searched databases PubMed, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) for prospective randomized controlled studies comparing CDA with ACDF with at least 24-month follow-up. Studies were evaluated for level of bias. Data regarding clinical outcomes, postoperative kinematic changes, procedure or device related adverse events and types and rates of secondary surgeries were extracted. A total of 142 articles were retrieved of which 8 articles satisfied the inclusion and exclusion criteria. These eight studies cover five different disc devices (BRYAN, PRESTIGE, ProDisc-C, Kineflex-C and Porous Coated Motion). There are significant differences in some patient reported clinical outcomes favoring arthroplasty over ACDF. Arthroplasty also preserved motion at the operated site while fusion reduced range of motion at the fused segments. The type and rate of adverse events, postoperative complications and secondary surgeries are similar between the two groups. The rate of surgeries for adjacent level degeneration is similar between CDA and ACDF. Cervical Disc Arthroplasty is a viable alternative procedure in the surgical management of cervical disc disease with similar safety profiles and at least equivalent and possibly superior clinical outcomes compared to Anterior Cervical Discectomy and Fusion. There does not appear to be significant differences in reoperation rates for adjacent level degeneration between the two procedure types. Future long-term follow up studies are needed to make a more robust conclusion on the overall effectiveness of CDA.

Keywords: Cervical arthroplasty; Anterior cervical disectomy and fusion; Outcomes; Kinematics; Complications; Adjacent segment disease; Systematic review

Abbreviations: ACDF: Anterior Cervical Discectomy and Fusion; CDA: Cervical Disc Arthroplasty

Introduction

Anterior Cervical Discectomy and Fusion (ACDF) is a standard surgical treatment for symptomatic cervical disc disease that is non-responsive to conservative management [1-5]. Despite the success of ACDF, cervical fusion can reduce segmental motion at the operated level resulting in increased motion at adjacent levels [6-9]. These mechanical changes are believed to produce adjacent segment disease, which may require additional treatments and possibly surgeries [6-8].

These concerns lead to the design and development of cervical disc arthroplasty (CDA) in which a prosthesis allowing for segmental motion is placed in the disc space. It is believed that the preservation of segmental motion at the index site may reduce some of these fusion-related complications [8,10].

Under the FDA Investigational Device Exemption, prospective randomized controlled studies comparing cervical disc arthroplasty with ACDF were initiated in the United States under the FDA Investigational Device Exemption in 2002 [10]. We conducted a systematic review of the prospective randomized controlled studies published between January 1, 2000 and December 1, 2012 that compared cervical arthroplasty versus spinal fusion procedures using patient reported clinical outcomes, postoperative kinematic changes as well as types and rate of postoperative complications.

Materials and Methods

Databases PubMed, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) were searched using the terms “cervical arthroplasty,” “cervical fusion,” and “clinical trial.” The inclusion criteria were articles describing prospective randomized controlled trials that compared patient reported clinical outcomes, kinematic changes and/or types and rate of postoperative complications and secondary surgeries between cervical disc arthroplasty and anterior cervical discectomy and fusion published between January 1, 2000 and December 1, 2012. The exclusion criteria were studies on post hoc, subset and/or subgroup analysis of published clinical trials, studies on data pooled from multiple randomized control trials, preliminary studies where later follow up studies were published, and any studies that did not use statistical comparisons of arthroplasty versus fusion. In an attempt to study long-term differences between CDA and ACDF, studies with follow up results less than 24-month follow-ups were also excluded.

The search algorithm was performed in duplicate and any disagreements were resolved by the senior author.

The search terms for cervical arthroplasty versus ACDF generated a total of 142 articles in 3 databases. From the 142 articles, 111 articles were excluded due to duplicates and failure to satisfy the inclusion criteria. From the remaining 31 articles, 23 articles were excluded on the basis of our exclusion criteria (Figure 1). The remaining 8 articles were included in this systematic review (Table 1).
The articles were assessed for level of bias using the 12 criteria recommended by the Cochrane Back Review Group. Studies with a high risk of bias was defined as having met fewer than 6 of the 12 criteria while low risk of bias was having met 6 or more criteria [11].

Data regarding clinical outcomes measured with patient reported questionnaires, postoperative changes in kinematics measured with imaging, as well as types and incidence of complications and secondary surgeries (including rate of adjacent segment disease) that compared ACDF with CDA for a minimum of 2 year follow-up were extracted from each of the selected papers and included in this systematic review.

### Results

The 8 studies comparing cervical arthroplasty with anterior cervical fusion investigated the BRYAN (Medtronic Sofamor Danek; Memphis, Tennessee), PRESTIGE (Medtronic Sofamor Danek; Memphis, Tennessee), ProDisc-C (Synthes USA Products, LLC, West Chester, PA) Kineflex-C (SpinalMotion Inc., Mountain View, CA) and Porous Coated Motion devices (Cervitech, Inc., Rockaway, NJ). Two of the eight studies have high risk of bias (Table 1).

### CDA versus ACDF: Patient reported clinical outcomes

There were 7 studies comparing patient-reported clinical outcomes between ACDF and CDA patients with a minimum of 24-month follow up (Table 2). The assessment tools utilized in these studies included the Neck Disability Index (NDI), Visual Analogue Scale (VAS) for neck and/or arm pain and Short Form 36 (SF-36).

Three of the studies compared ACDF with CDA (BRYAN device). Two of the three studies had relatively small sample size. Zhang et al. compared VAS arm/neck pain and NDI scores between patients with single level cervical disc disease who received the BRYAN prosthesis versus ACDF at 1.5, 3, 6, 12 and 24 months after the surgery. There was only one significant between-group difference in VAS neck pain score that favors CDA over ACDF at the 24-month follow-up time point [12].

Cheng et al. conducted a similar 3-year follow up study also comparing arthroplasty with the BRYAN device versus ACDF using

### Table 1: Included articles on cervical disc arthroplasty versus anterior cervical discectomy and fusion.

<table>
<thead>
<tr>
<th>Author Name</th>
<th>Prosthesis Investigated</th>
<th>Number of Subjects (Arthroplasty/Fusion)</th>
<th>Level of Bias (Cochrane Back Review Group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zigler and Delamarter, 2012 [19]</td>
<td>ProDisc-C</td>
<td>103/106</td>
<td>Low Risk of Bias</td>
</tr>
<tr>
<td>Zhang et al., 2012 [12]</td>
<td>BRYAN</td>
<td>56/53</td>
<td>Low Risk of Bias</td>
</tr>
<tr>
<td>Cheng et al., 2011 [13]</td>
<td>BRYAN</td>
<td>41/42</td>
<td>Low Risk of Bias</td>
</tr>
<tr>
<td>Sasso et al., 2011 [14]</td>
<td>BRYAN</td>
<td>242/221</td>
<td>Low Risk of Bias</td>
</tr>
<tr>
<td>Coric et al., 2011 [18]</td>
<td>Kineflex-C</td>
<td>136/133</td>
<td>High Risk of Bias</td>
</tr>
<tr>
<td>McAfee et al., 2010 [20]</td>
<td>PCM</td>
<td>151/100</td>
<td>High Risk of Bias</td>
</tr>
<tr>
<td>Burkus et al., 2010 [16]</td>
<td>PRESTIGE</td>
<td>144/127</td>
<td>Low Risk of Bias</td>
</tr>
</tbody>
</table>

Abbreviations: JOS (Japanese Orthopedics Association Scale), MCS (Mental Component Summary), NDI (Neck Disability Index), PCS (Physical Component Summary), SF-36 (Short Form 36), VAS (Visual Analog Scale)

### Table 2: Summary of Patient Reported Outcomes (Arthroplasty versus Anterior Cervical Discectomy and Fusion).

The 8 studies comparing cervical arthroplasty with anterior cervical fusion investigated the BRYAN (Medtronic Sofamor Danek; Memphis, Tennessee), PRESTIGE (Medtronic Sofamor Danek; Memphis, Tennessee), ProDisc-C (Synthes USA Products, LLC, West Chester, PA) Kineflex-C (SpinalMotion Inc., Mountain View, CA) and Porous Coated Motion devices (Cervitech, Inc., Rockaway, NJ). Two of the eight studies have high risk of bias (Table 1).
year follow up by Sasso et al. [14] measured clinical outcomes between CDA (BRYAN device) and ACDF using NDI, SF-36 and neck/arm pain scores measure at postoperative time points 1.5, 3, 6, 12, 24 and 48 months in patients with single level cervical disc disease. CDA patients had significantly better NDI, neck pain scores at all follow up time points relative to ACDF patients. There were small but significant differences in the improvement of the arm pain score that favored CDA over ACDF at 12 and 48 months following the procedure. There were also significantly different SF-36 physical component scores favoring CDA over ACDF at all follow up time points except for 24 months. There were no significant differences in the two groups for percentage of patients returning to work at 6 weeks. Rate of overall success, defined as a 15-point improvement in the NDI score, neurologic improvement and no serious adverse events, was significantly higher in the CDA group than ACDF at all time points [14].

Two studies compared CDA with PRESTIGE device versus ACDF also using patient reported questionnaires. The smaller study by Pochet and Metcalf compared clinical outcomes between CDA and ACDF using NDI, VAS neck/arm pain and SF-36 mental and physical component scores using patients with single level cervical disc disease. The study found that both treatment groups experience significant improvements in NDI and VAS neck/arm pain scores relative to preoperative baseline scores at 6, 12 and 24 months. This study did not find any significant differences in NDI, VAS and SF-36 scores between CDA and ACDF at any postoperative time point [15].

A larger 5-year follow-up study by Burkus et al. compared CDA with PRESTIGE and ACDF using SF-36, NDI, Neck/Arm pain scores as well as return to work status at 1.5, 3, 6, 12, 24, 36 and 60 months postoperative time points in patients with single level cervical disc disease. The NDI scores significantly favored CDA over ACDF at 1.5 and 3 months following the surgery. Although the NDI scores assessed between 6 months to 2 years following the procedures are not significantly different, the differences in NDI scores significantly favored CDA over ACDF at 3 and 5-year postoperative time points. Neck pain scores significantly favored usage of PRESTIGE device over ACDF at 1.5 and 3 months as well as 1 and 2-year postoperative time points. Arm pain scores were not significantly different between the two groups at any time points. SF-36 scores are similar between the two groups and were significantly different only at the 3-year postoperative time point. There were no significant differences between group differences in return to work status at 5 years following the procedure [16].

Zigler et al. compared CDA with ProDisc-C device versus ACDF in a five-year follow-up study using patients with single level cervical disc disease. There were no significant differences between the two treatment groups for percent change of NDI from baseline scores or absolute NDI score at 2 or 5 years following the procedure. There were also no significant between-group differences in VAS neck pain intensity and frequency scores at 2 years following the surgery. However, the study detected significant differences in VAS neck pain intensity and frequency favoring CDA over ACDF at the 5 year follow up. VAS arm pain intensity and frequency scores were similar between the two treatment groups at 2 and 5 years. There were no significant differences in SF-36 physical and mental component scores at 2 and 5 year follow up time points [17].

One study in our systematic review evaluates CDA with Kineflex|C device versus ACDF. Coric et al. conducted a randomized controlled trial with minimum of 2-year follow up using patients with single level cervical disc disease. The rate of overall success, defined as preservation or improvement in neurologic status, minimum of 20% improvement in NDI, no device failure, no reoperations and no major adverse events, was significantly higher in the Kineflex|C group than the ACDF patients in this cohort at the 24 month follow up. However, there were no significant differences in NDI between the two groups at any postoperative time point up to the 2-year follow up. Improvements in VAS scores were also similar between the two groups at all time points up to 2 years following the procedures [18].

CDA versus ACDF: Kinematic changes

Six of the studies compared changes in segmental motion at the operated level between patients undergoing CDA versus ACDF for at least 24-month follow-ups (Table 3). Two studies included results on segmental motion of CDA versus ACDF but did not publish data up to the 24 month follow up and thus the kinematic data from that study was not included in this review. These six studies evaluated the BRYAN, PRESTIGE, ProDisc-C and Kineflex|C devices.

Cheng et al. used radiographic analysis to measure flexion-extension range of motion (ROM) of patients who underwent CDA versus ACDF [13]. At the three-year follow up, the average flexion-extension ROM in the fused segments of the ACDF group was significantly lower relative to preoperative levels while the ROM of the operated segments in the BRYAN group is not significantly different from preoperative measurements [13]. As expected, the ROM of operated segments of the BRYAN group was significantly higher than that for ACDF at the three year follow up [13]. Zhang et al. also found that the flexion-extension ROM at the operated site to be significantly greater in the BRYAN group relative to that for the ACDF group at 12 and 24 months following the procedure [12]. Furthermore, the absolute mean change of ROM from preoperative baseline was significantly greater in ACDF than CDA at postoperative 24 months [12]. The larger four-year follow up study by Sasso et al. examining the flexion-extension ROM of the cervical spine found that the ROM in BRYAN patients was significantly higher than baseline measures at all time points after postoperative 3 months [14]. In contrast, patients who underwent fusion demonstrated a mean decrease in ROM at the four-year follow up [12].

Burkus et al. examined segmental motion in patients who underwent CDA with the PRESTIGE device versus those with ACDF. As expected, ACDF patients experienced a decrease in angular motion while PRESTIGE patients are able to maintain angular motion [16].

Zigler et al. determined the flexion-extension ROM in ProDisc-C and ACDF patients. The flexion-extension ROM at the operated level was preserved in ProDisc-C patients at the 2 and 5 year follow up time points while ROM in ACDF patients was significantly reduced at 2 and 5 years [17].

Coric et al. measured ROM in patients receiving Kineflex|C versus those who underwent ACDF. The ROM for Kineflex|C patients initially decreased at 3 months relative to preoperative baseline measures but was significantly greater than the preoperative ROM at 12 and 24 months follow up times. In contrast, ACDF patients in that study had significantly reduced ROM relative to preoperative baseline at all follow-up time points [18].

CDA versus ACDF: Adverse events, postoperative complications and secondary procedures

Eight of the studies addressed the types and incidence of postoperative complications (Table 4). Complications that were addressed included adjacent segment disease, postoperative dysphagia, device failures, revision procedures, and supplemental fixation.
Cheng et al. found that BRYAN patients had fewer complications than those undergoing ACDF [13]. Specifically, the incidence of dysphagia was significantly lower in the BRYAN group than ACDF patients. There were 3 cases of pseudarthrosis in the ACDF group and no cases of device failures or explantation in the BRYAN group [13]. There was one case of reoperation in the BRYAN group and 4 cases of reoperation in the ACDF group in Zhang et al. specifically, the one case of reoperation in the BRYAN group was due to radiculopathy at adjacent segments while 3 of the 4 ACDF reoperations were due to adjacent segment disease [12]. The last ACDF reoperation was due to disc herniations [13].

Sasso et al. only reported serious World Health Organization (WHO) grade 3 and 4 complications between the 2-year and 4-year follow up visits. Forty-four patients in the BRYAN group had 63 adverse events while 36 patients in the fusion group had 64 adverse events. These differences were not significant. There were only nine secondary surgeries (3.7%) and ten secondary surgeries (4.5%) involving the operated level and the differences are again not significant. The rates of secondary surgeries involving adjacent levels were also similar between the two treatment groups [14].

The study by Porcher and Metcalf on the PRESTIGE disc detected 19 adverse events in the ACDF group with the majority of these adverse events classified as WHO Grade 2 suggesting that they did respond to therapy or rest. Similarly, 17 adverse events were registered in PRESTIGE patients and the majority of these events responded to therapy. Overall, there are no significant differences between the two groups [15].

The larger study on the PRESTIGE disc by Burkus et al. found that the rates of postoperative dysphagia and dysphonia are similar between ACDF and PRESTIGE patients. Patients who received ACDF were significantly more likely to undergo revision procedures, supplemental fixation, and elective removals relative to PRESTIGE patients. While the rate of implant removal was lower in PRESTIGE patients, the differences were not significant. There were no significant differences in the percentage of patients requiring treatment for adjacent level disease between the two treatment groups [16].

Zigler et al. detected similar rates of implant-related complications in ProDisc-C patients (1%) and ACDF patients (2.8%). The rates of surgery-related adverse events such as dysphagia, edema, gastrointestinal or dural tears were also similar between the two groups. The rate of secondary surgeries at the 5-year postoperative time point was significantly higher in ACDF patients (11.3%) relative to ProDisc-C patients (2.9%). In the ACDF group, nine of the 16 reoperations included an adjacent level and were due to symptomatic adjacent level degeneration. In contrast, there were only 3 reoperations in the ProDisc-C group in which 2 of the reoperations involve adjacent levels to address adjacent level degeneration [17], [19].

The study by Coric et al. on Kineflex-C device detected a significantly higher rate of severe adjacent level deterioration in the ACDF group relative to the Kineflex-C group. However, the percentage of adjacent level surgeries was similar between the two groups. The incidence of index-level reoperations was also similar. ACDF patients, however, did have a higher rate of postoperative dysphagia relative to Kineflex-C patients although the statistical significance was not published [18].

The study by McAfee et al. compared the severity and incidence of postoperative dysphagia in between CDA with Porous Coated Motion (PCM) Prosthesis versus ACDF using patients with single level cervical disc disease. Both treatment groups had relatively high rates.
of postoperative dysphagia at 6 weeks. However, patients receiving the PCM device who developed postoperative dysphagia recovered sooner relative to ACDF patient who develop the same complication. Specifically, the incidence of dysphagia is significantly lower in the PCM group relative to ACDF group at 1.5, 3, 12 and 24-month follow up times. As expected, a significantly greater percentage of PCM patients had long-term resolution of their dysphagia relative to ACDF patients [20].

Discussion

Anterior Cervical Discectomy and Fusion is a widely utilized surgical treatment for cervical disc disease that is non-responsive to conservative treatments [1-5]. Although the success of ACDF has been widely documented in the literature, the loss of segmental motion at the fused segments is believe to contribute towards the development of adjacent segment degeneration [6-9]. Cervical Disc Arthroplasty was designed to replace the disc space with a device that is able to maintain segmental motion thereby reducing mechanical changes to the adjacent segments [8,10]. The hope is that CDA would reduce the incidence of ACDF-related complications such as adjacent segment disease and pseudoarthrosis.

Under the FDA investigational device exemption, there have been several prospective randomized controlled trials that evaluated postoperative outcomes of CDA versus ACDF [10]. Systematic reviews and meta-analyses of these clinical trials may provide a robust assessment of this relatively novel technology.

A Cochrane Review published in 2012 compared outcomes between CDA and ACDF in patients with single level cervical degenerative disc disease. The review identified nine randomized controlled trials that compared clinical outcomes, kinematic changes and rates of revision procedures at the index site and secondary surgeries for adjacent segment degeneration between the two procedure types. Although the review detected some significant differences in clinical outcomes and kinematic changes favoring arthroplasty over fusion, the review failed to show that arthroplasty significantly lowers the incidence or severity of adjacent segment disease. In turn, cervical arthroplasty was concluded to be a potential viable alternative to cervical fusion but was not considered a superior option [21].

In our systematic review, we have identified eight articles that compared patient reported clinical outcomes, postoperative kinematic changes as well as types and incidence of postoperative complications between CDA and ACDF. These eight articles evaluated a variety of cervical disc devices (BRYAN, PRESTIGE, ProDisc-C, KinflexC, and Porous Coated Motion) and presented follow up results ranging from 2 to 5 years after the surgery. In contrast, the 2012 Cochrane Review comparing outcomes between CDA and ACDF reported follow-up results ranging from 3 months to two years after the surgery [21]. Some of the articles in our review [14,16,17] reported longer and more recent follow up data from randomized clinical trials whose earlier results were included in the Cochrane Review. In turn, our study offers a longer follow up comparison between ACDF and CDA [21].

There are significant differences in some patient reported clinical outcomes favoring the usage of arthroplasty over fusion. However, it is important to note that other clinical outcomes were either similar between the two treatment groups or failed to demonstrate significant differences consistently in multiple follow up intervals or in different studies. None of the studies showed that arthroplasty resulted in inferior clinical outcomes relative to ACDF. In turn, our review suggests that the clinical outcome following cervical arthroplasty is at least equivalent and possibly superior to that for ACDF. Although the studies did not discuss the postoperative management of CDA or ACDF patients, it is important to note that the postoperative care of patients who undergo anterior cervical spine surgery (such as the usage of collars) may also affect clinical outcomes of these procedures.

As expected, all of the studies that examined postoperative kinematic changes using radiographic methods showed that CDA preserved segmental motion at the index level while ACDF patients had reduced ROM at the fused site and increased motion at adjacent levels. However, the studies in our review did not consistently demonstrate significant differences in rate of reoperations for adjacent level disease suggesting that preservation of segmental motion at the index level does not necessarily translate into prevention of adjacent level degeneration. Further follow-up studies with longer follow up are needed to determine if CDA is able to significantly reduce this complication.

All of the studies that evaluated postoperative complications showed the incidence and types of adverse events are similar between the two treatment groups. In some instances, the rate of adverse events is actually higher in fusion patients relative to those who received CDA. In particular, the rate of postoperative dysphagia, a common problem in anterior cervical spine surgeries, is lower in patients who received artificial discs. In turn, this review suggests that the safety profile of CDA is at least equivalent and perhaps superior relative to that for ACDF.

The motivation behind the design and adoption of cervical disc arthroplasty is the reduction of adjacent segment disease. While our review shows that cervical disc arthroplasty preserves motion at both the index and adjacent levels, it fails to show that this motion preservation translates into a significant reduction of adjacent segment disease. In turn, although studies show that some of the clinical outcomes following CDA are superior relative to that for ACDF, the primary objective of cervical disc arthroplasty has not yet been demonstrated. It is also important to note while current studies show similar safety profiles between CDA and ACDF, the rates of long-term complications of cervical disc arthroplasty, such as prosthesis wear and tear, are still unknown. Nevertheless, the promising results from these clinical studies along with patient perceptions that cervical arthroplasty, the more novel technology, is inherently superior compared to traditional ACDF suggest that cervical arthroplasty will continue to be a popular viable alternative procedure in the surgical management of cervical disc disease.

There are several limitations to our review. We limited our search to articles published in English and therefore may have some selection bias. Also, we chose out studies strictly based upon the interventions investigated and not based upon patient characteristics and therefore the patient population of this review is heterogeneous. Furthermore, the eight studies also investigated different devices that may have different efficacies and therefore may have contributed to variability of the results and conclusion of the review. We also did not perform a meta-analysis of the data and therefore we do not have quantitative statistical comparisons between CDA and ACDF.

Our review suggests that CDA is a viable alternative procedure to ACDF with similar safety profiles as well as equivalent and possibly superior clinical outcomes. Although CDA preserves motion at the index site and does not increase ROM at adjacent levels, it is unclear whether this reduces adjacent segment disease. More studies are needed to establish long-term differences between CDA and ACDF.
References


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