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REVIEW ARTICLE

Evidence-based use of arthroplasty in cervical degenerative disc disease

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Abstract

Introduction Cervical disc arthroplasty (CDA) was developed to decrease the rate of symptomatic adjacent-level disease while preserving motion in the cervical spine.

Methods The objectives of this paper are to provide criteria for proper patient selection as well as to present a comprehensive literature review of the current evidence for CDA, including randomized studies, the most recent meta-analysis findings, and long-term follow-up clinical trials as well.

Results Currently, there are several prospective randomized controlled studies of level I of evidence attesting to the safety and efficacy of CDA in the management of cervical spondylotic disease (CSD) for one- or two-level degenerative diseases. These as well as recent meta-analyses suggest that CDA is potentially similar or even superior to anterior cervical discectomy and fusion (ACDF) when considering several outcomes, including dysphagia and re-operation rate over medium-term follow-up. Less robust studies have also reported satisfactory clinical and radiological outcomes of CDA for hybrid procedures (ACDF combined with CDA), non-contiguous disease, and even for multilevel disease (more than 2 levels).

Conclusions Based on this evidence we conclude that CDA is a safe and effective alternative to ACDF in properly selected patients for one- or two-level diseases. Defining superiority of specific implants and detailing optimal surgical indications will require further well-designed long-term studies.

Keywords Spondylotic cervical disease · Cervical arthroplasty · Anterior cervical approaches · Anterior surgery · Discectomy · Arthroplasty

Introduction

Anterior cervical discectomy and fusion (ACDF) has been used successfully for patients with cervical spondylotic disease (CSD) with radicular or myelopathic symptoms since its first description in 1958 [1]. It is a high effective procedure with an excellent safety profile and a very low mortality rate when used in the treatment of one- or two-level diseases [2, 3].

Despite its proven success, ACDF has important drawbacks. Due to its nature as a fusion procedure, it inherently decreases cervical motion [4]. Additionally, the fused level can potentially increase stresses placed on adjacent levels, which may accelerate adjacent-level disease [4]. In this context, cervical arthroplasty (CDA) was developed to maintain motion and decrease the degeneration of segments adjacent to these degenerated levels.

In the USA, the Federal Drug Administration (FDA) is the regulatory agency that requires investigational device exemption (IDE) clinical trials prior to approval of a new technology. The IDE trial consists in prospective controlled clinical trial, multicenter, for producing level I evidence for market approval. That is the reason for the large numbers of level I evidence trials for CDA in the USA. Although IDE clinical trials are developed to analyze safety and effectiveness, due to the large amount of collected information, other studies have also been performed from this data, such as those looking at cost analysis, complication profiles, and patient selection [5].

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Currently, there are seven CDA devices that are FDA approved for one-level disease: Prestige ST, Prestige LP and Bryan (Medtronic Inc.), Prodisc-C (DePuy Synthes, Johnson and Johnson), Secure-C (Globus Medical Inc.), PCM (Nuvasive), and Mobi-C (Zimmer Biomet). For two contiguous levels, only the Mobi-C and Prestige LP are approved [5].

There is an increasing body of literature reports on the outcomes and complications of CDA, as well as trials comparing CDA versus ACDF for several arthroplasty implants with various study designs. The main objective of this paper is to provide the current evidence surrounding CDA in the management of CSD, providing a deep and comprehensive literature review of the main randomized studies, most recent meta-analyses, and long-term follow-up studies of CDA.

Material and methods

A broad literature review of the most recent studies about CDA was performed. We searched for the prospective randomized IDE clinical trials evaluating CDA and also for the recently published meta-analyses. Randomized trials with long-term follow-up were also evaluated. We used the PubMed Database for screening the relevant articles as well as cross-references articles. We presented the results divided into some main topics:

(1) Randomized clinical trials (for one- and two-level diseases)
(2) Evidences from recent meta-analyses (one- and two-level diseases)
(3) CDA versus ACDF considering post-operative dysphagia
(4) Differences of CDA versus ACDF according to patient selection
(5) Reoperation rates of CDA versus ACDF
(6) Ambulatory CDA surgery

Results

Randomized controlled trials

One-level disease

A total of 18 IDE studies were published for one-level cervical CDA. These studies are presented in Table 1, adapted from Nunley et al. 2018 [5].

Janssen et al. reported the results of prospective randomized IDE clinical trials comparing the Prodisc-C with ACDF [24]. At seven years, a follow-up rate of 92% was achieved (152 of 165). There were no significant differences in demographic factors, follow-up rate, and patient-reported outcomes between the groups. Authors reported that neurological status was improved or maintained in 88% (Prodisc-C) and 89% (ACDF) of the patients. However, only seven (7%) of 103 patients required a new surgery in the CDA group compared with 19 (18%) of 106 patients in the ACDF group ($p = 0.0099$), with similar rates of device-related adverse effects between the groups.

A ten year follow-up study comparing the Bryan cervical disc with ACDF was published by Ghobrial et al. [25]. The data was pooled secondarily with 84-month follow-up of the Prestige cervical disc. The overall success rate with Bryan was reported in 81.3% of the cases versus 66.3% of the ACDF group ($p = 0.005$), without loss of motion preservation (8.69^{o} versus 0.6^{o}). There were no statistical differences in the re-operation rate at adjacent levels up to 120 months of follow-up (9.7% with Bryan and 15.8% with ACDF—$p = 0.146$), but when combining the data from Bryan and Prestige ST, the CDA group at 84 months of follow-up had a lower rate of secondary surgery at the adjacent levels (6.9% versus 11.7%, $p = 0.023$).

Two-level disease

Six IDE studies were published for two-level CDA. These studies are presented in Table 2 (adapted from Nunley et al. 2018) [5].

Lanman et al. reported outcomes at 84 months of a randomized trial comparing CDA (209 patients) versus ACDF (188 patients) for two adjacent levels [32]. CDA was performed using the Prestige LP cervical disc. The CDA group had statistical superiority over ACDF for overall success (observed rate 78.6% vs 62.7%; posterior probability of superiority [PPS] = 99.8%), Neck Disability Index success (87.0% vs 75.6%; PPS = 99.3%), and neurological success (91.6% vs 82.1%; PPS = 99.0%). There was no statistically difference in adverse effect up to 84 months. Finally, patients in the CDA group had a significantly lower rate of re-operation at the operated levels (4.2%) than the fusion group (14.7%) (LHR 1.29 [95% CI − 2.12 to − 0.46]). Authors concluded that the Prestige LP was an alternative to fusion at 84 months of follow-up.

Evidences from recent meta-analyses

One-level disease

Although the 24 US IDE studies presented in Tables 1 and 2 included one- or two-level CDA trials, studies with CDA for multilevel surgeries (> 2 levels), CDA after a previous cervical spine surgery and hybrid treatment with ACDF and CDA, were published in the last several years as well [33–35].

In 2018, Luo et al. performed a meta-analysis of randomized controlled trials comparing the rate of adjacent segment degeneration of CDA versus ACDF [36]. A total of 21 studies with a minimum 48 months of follow-up were included and

Table 1 Summary of the 18 published US IDE studies published for one-level cervical arthroplasty [5]

Author	Year	Study design	Cervical disc	Follow-up	Number of patients
Mummaneni et al. [6]	2007	Prospective Multicenter Randomized Control	Prestige ST	2	276 CDA vs 265 ACDF
Murrey et al. [7]	2009	Prospective Multicenter Randomized Control	Prodisc-C	2	103 Prodisc-C (R) vs 106 ACDF vs 136 Prodisc-C (CDA)
Heller et al. [8]	2009	Prospective Multicenter Randomized Control	Bryan	2	242 CDA vs 221 ACDF
Burkus et al. [9]	2010	Prospective Multicenter Randomized Control	Prestige ST	5	276 CDA vs 265 ACDF
Delamater et al. [10]	2010	Prospective Multicenter Randomized Control	Prodisc-C	4	103 Prodisc-C (R) vs 106 ACDF vs 136 Prodisc-C (CDA)
Coric et al. [11]	2011	Prospective Multicenter Randomized Control	Kineflex-C	2	136 CDA vs 133 ACDF
Sasso et al. [12]	2011	Prospective Multicenter Randomized Control	Bryan	4	242 CDA vs 221 ACDF
Phillips et al. [13]	2013	Prospective Multicenter Randomized Control	PCM	2	218 CDA vs 185 ACDF
Vaccaro et al. [14]	2013	Prospective Multicenter Randomized Control	Secure-C	2	151 CDA vs 140 ACDF
Zigler et al. [15]	2013	Prospective Multicenter Randomized Control	Prodisc-C	5	103 Prodisc-C (R) vs 106 ACDF vs 136 Prodisc-C (CDA)
Burkus et al. [16]	2014	Prospective Multicenter Randomized Control	Prestige ST	7	276 CDA vs 265 ACDF
Hisey et al. [17]	2014	Prospective Multicenter Randomized Control	Mobi-C	2	164 CDA vs 81 ACDF
Janssen et al. [18]	2015	Prospective Multicenter Randomized	Prodisc-C	7	103 Prodisc-C (R) vs 106 ACDF vs 136 Prodisc-C (CDA)

Table 1 (continued)

Author	Year	Study design	Cervical disc	Follow-up	Number of patients
		Control			
Phillips et al. [19]	2015	Prospective Multicenter Randomized Control	PCM	5	218 CDA vs 185 ACDF
Gornet et al. [20]	2015	Prospective Multicenter Nonrandomized Control	Prestige LP	2	280 CDA vs 265 ACDF
Hisey et al. [21]	2015	Prospective Multicenter Randomized Control	Mobi-C	4	164 CDA vs 81 ACDF
Hisey et al. [22]	2016	Prospective Multicenter Randomized Control	Mobi-C	5	164 CDA vs 81 ACDF
Gornet et al. [23]	2016	Prospective Multicenter Nonrandomized Control	Prestige LP	7	280 CDA vs 265 ACDF

analyzed according to the standard Cochrane systematic review criteria. The pooled data reported 37 re-operations (2.6%) in 1414 CDA patients and 75 re-operations (6%) in 1247 patients who underwent ACDF. Their analysis of these results showed that CDA had significantly lower adjacent segment disease than the fusion group (OR = 0.57, 95% CI 0.44 to 0.73, $p < 0.00001$), with no obvious heterogeneity ($p = 0.26$, $I^2 = 17\%$), and also fewer adjacent segment re-operations (OR = 0.43, 95% CI 0.29 to 0.64, $p < 0.0001$) with no obvious heterogeneity ($p = 0.13$, $I^2 = 34\%$).

Dong et al. in 2017 performed a comprehensive meta-analysis to evaluate re-operation rates and adjacent segment motion between CDA versus ACDF [37]. A total of 29 randomized trials were included. Adjacent segment re-operation was evaluated in 21 studies; for 0–24 months of follow-up, re-operation was lower in the CDA group (OR = 0.53, 95% CI [0.30, 0.93], $p < 0.05$). After 24 months of follow-up, the re-operation rate in the CDA was reduced by 70% compared with ACDF (OR = 0.30, 95% CI [0.20, 0.44], $p < 0.01$)—this advantage of the lower adjacent segment re-operation in CDA compared with ACDF increased with increasing follow-up.

Zhu et al. evaluate the reported rate of adjacent segment disease of CDA compared with ACDF in a meta-analysis [38]. A total of 14 randomized studies were included with a minimum two years of follow-up (1696 patients in the CDA group versus 1529 in the ACDF group). They reported fewer re-operations in the CDA group compared with the ACDF (OR = 0.47, 95% CI [0.32, 0.70], $p < 0.0002$).

Two-level disease

Zhao et al. performed a meta-analysis in 2018 to compare the safety and efficacy of CDA versus ACDF for two contiguous levels [39]. A total of 2715 patients from nine randomized controlled trials and two cohort controlled trials were included. Pooled analysis indicated that CDA was superior do ACDF in Neck Disability Index, visual analog scale for neck, SF-12 physical component summary (PCS), overall clinical success, and patient satisfaction and also for device-related adverse event, adjacent segment degeneration, and subsequent surgical intervention. There were no significant differences between CDA and ACDF for neurological deterioration, visual analog scale for arm pain, and mental component score.

CDA versus ACDF considering post-operative dysphagia

The most common adverse effect after anterior cervical surgery is post-operative dysphagia. Some degree of dysphagia is reported in more than 50% of the cases in prospective studies [40]. The aetiology is multifactorial, including oesophageal denervation, soft tissue swelling/edema, plate prominence, haematoma, and nerve root injuries [41]. A few studies have analyzed the differences in dysphagia among patients who had CDA versus those who had ACDF. Smucker et al. specifically evaluated the incidence of long-term dysphagia in CDA

Table 2 Summary of the six published US IDE studies published for two-level cervical arthroplasty [5]

Author	Year	Study design	Cervical disc	Follow-up	Number of patients
Davis et al. [26]	2013	Prospective Multicenter Randomized Control	Mobi-C	2	225 CDA vs 105 ACDF
Davis et al. [27]	2014	Prospective Multicenter Randomized Control	Mobi-C	3	225 CDA vs 105 ACDF
Davis et al. [28]	2015	Prospective Multicenter Randomized Control	Mobi-C	4	225 CDA vs 105 ACDF
Radcliff et al. [29]	2016	Prospective Multicenter Randomized Control	Mobi-C	5	225 CDA vs 105 ACDF
Gornet et al. [30]	2017	Prospective Multicenter Nonrandomized Control	Prestige LP	2	209 CDA vs 188 ACDF
Lanman et al. [31]	2017	Prospective Multicenter Nonrandomized Control	Prestige LP	7	209 CDA vs 188 ACDF

versus ACDF using modified Bazaz Dysphagia [42]. Severity questionnaires with a minimum five years post-operative assessment. A total of 15 of 22 (68%) patients completed the questionnaires after long-term follow-up, with no reports of dysphagia, and 18 of 25 (72%) of the patients who had an ACDF completed the questionnaires, five of 18 (28%) reporting some degree of dysphagia ($p = 0.042$). Authors concluded that long-term dysphagia was less common in CDA than in ACDF patients. Potential explanations of these differences may be the use of a plate in the ACDF group that may affect oesophageal motility (while CDA may be considered zero-profile) and motion preservation in the arthroplasty group, which may affect deglutition.

Differences of CDA versus ACDF according to patient selection

ACDF is a procedure used for almost all kinds of patients with cervical disc pathology. It may be used in patients with segmental instability, poor bone quality, severe facet joint degeneration, and also severe OPLL [43]. On the other hand, CDA has many specific considerations prior to surgical indication. The vast majority of the IDE clinical trials included patients with single-level disc disease, a good bone density (such as a T score > 1.5), without severe facet joint degeneration, with a reasonable disc height (some authors suggested at least 3 mm), no evident instability, without segmental kyphosis, without OPLL and ankylosing spondylitis, and also without inflammatory, metabolic, or neoplastic disease [33, 43, 44].

CDA may also be used for cervical myelopathy. Gornet et al. recently reported the long-term outcome (7 years) of a clinical trial analyzing two level CDA versus ACDF in 287 patients with radiculopathy alone and 110 patients with myelopathy alone or associated with radiculopathy [23]. There were no statistical differences between the groups for NDI, neck pain, or arm pain. Both groups had similar proportions of stability or improvement in neurological status, and there were no statistical differences between secondary surgery at the index levels or adjacent levels. They concluded that CDA was a safe and effective treatment for patients with myelopathy.

Reoperation rates of CDA versus ACDF

While arthroplasty appears to decrease the incidence of adjacent-level reoperation, the differences are not as much as was hoped for. In our review, the difference at five years ranged from 2 to 3% to 11.1–14.7% (arthroplasty vs fusion, respectively), at seven years from 6.9 to 11.7%, and at ten years from 9.7 to 15.8% [13, 21, 45–49]. While these are certainly not negligible benefits, they are not as large as one

might have expected from some of the literature that have touted the benefits of arthroplasty. In fact, in only one study, by Delamarter et al., did the difference in adjacent-level re-operation rate between fusion and arthroplasty exceed 10% (11.7%; Table 3) [45]. All the other studies reporting the re-operation rates found a difference in re-operation rates between fusion and arthroplasty that were in the single digits. If we assume that arthroplasty does not alter the normal biomechanics of the index and adjacent levels, then the adjacent-level re-operation rate following arthroplasty should be similar to subjects who never had surgery. Then, the difference in the adjacent-level re-operation rate between disc replacement and fusion would be due to the fusion procedure and not the natural history. On the other hand, it is possible that the arthroplasty procedure also alters the normal biomechanics such that it too increases the adjacent-level re-operation rate compared to the natural history. Unfortunately, there is no study that we are aware of that has compared the adjacent-level re-operation rates for arthroplasty versus natural history.

In Table 3, we report adjacent-level surgery rates at different follow-up periods in which artificial disc replacement and ACDF were compared. Rates of adjacent-level re-operation are noted.

Ambulatory CDA surgery

There have been recent published reports about the safety of performing CDA in the ambulatory surgery centre (ASC) setting. Gornet et al. reported a sample of 145 patients who had one or two level CDA in an ASC, comparing the results with 438 who had the procedure as outpatients (0 or 1 night stay) and 65 as inpatients (2 or more nights) [50]. This retrospective study reported that ASC patients had shorter surgical times compared with outpatients or inpatients for one-level and two-level cases. There were no hospital admissions and no subsequent surgery for ASC patients. Authors concluded that CDA may be performed in ASC in selected patients.

Discussion

Initial studies of CDA date back to the work of Ulf Fernstrom since he implanted the first artificial disc in 1966. These devices, which he implanted in the cervical and lumbar spine, were stainless steel ball implants; unfortunately, the procedure had unsatisfactory outcomes and high complication rates, which limited its widespread appeal [51]. It was not until the 1990s that CDA became popularized with the marketing of the Frenchay disc, later renamed the Prestige (Medtronic Inc.) and the Bryan disc (Medtronic Inc.). Bolstered by a series of publications on their outcomes, these devices ushered in the next generation of CDA.

In 1999, Hilibrand et al. described symptomatic adjacent-level degeneration (SALD) due to degeneration of segments adjacent to the site previously surgically treated [52]. In this study of 374 patients with CSD, 25.6% developed SALD during ten years of follow-up and 72% of them required surgical treatment (about 2.2% per year or a 19.2% risk in 10 years). The aetiology of SALD is still unclear, but is likely due to the natural aging process, with acceleration due to the

Table 3 Subsequent surgery after CDA or ACDF—results of some studies considering re-operation rates

Study and length of follow-up	Study design	Adjacent-level re-operation for CDA vs ACDF	Total re-operation rate of CDA vs ACDF
Phillips et al. [13] 2 years of follow-up	Prospective, multicenter, randomized, clinical trial	–	5.2.% vs 5.4%
Delamarter RB and Zigler J. [45] 5 years of follow-up	Prospective, randomized, clinical trial	3% (2/72) and 14.7% (9/61)	–
Blumenthal et al. [46] 24 to 98 months (mean of 55.1 months)	Post hoc analysis of data collected from multiple prospective randomized studies	4.8% vs 13.5%	8.3% vs 21%
Hisey et al. [22] 4 years of follow-up	Prospective, randomized, controlled, multicenter trial	–	3% vs 9.9%
Jackson et al. [47] 5 years of follow-up	Prospective, randomized, multicenter, unblinded clinical trial	2.2% vs 11.1% one-level 3.4% vs 11.4% two-level	4.5% vs 17.3% one-level 7.3% vs 21% two-level
Coric et al. [48] 5 years of follow-up	Prospective, randomized, multicenter study	–	8.1% vs 8.3%
Loumeau et al. [49] 7 years of follow-up	Prospective, randomized, multicenter study	0% CDA vs 9% ACDF (2/22)	0% CDA vs 27.3% ACDF (6/22)
Ghobrial et al. [25] 7 years of follow-up	Prospective, randomized trial	6.9% vs 11.7%	–
Ghobrial et al. [25] 10 years of follow-up	Prospective, randomized trial	9.7% vs 15.8%	–

longer lever arm increasing intradiscal pressure adjacent to the fusion. The rationale of CDA is to maintain cervical alignment as well as preserve motion in the treated levels, and simultaneously decreasing intradiscal pressure and facet overload in the adjacent levels, with an extrapolated idea from motion preservation techniques used in lower extremity joint replacements [53–55].

In general, CDA results have been shown to be at least similar or even superior to clinical outcomes after ACDF in short- and medium-term follow-up [56–59]. Pointillart et al. have reported that a sustained clinical improvement was possible even after 15 years of follow-up with the Bryan artificial disc, despite some degree of degeneration at the index and adjacent levels [60].

Limitations of all meta-analyses are variation of the artificial disc designs that may change adjacent segment ROM and also reoperation rates, different surgeons, different results after sensitivity analysis, and publication bias. Finally, the vast majority of the randomized studies are sponsored by the manufactures of the artificial discs, which may also require some caution when analyzing the clinical results.

Conclusions

There is robust evidence regarding the safety and efficacy of CDA, especially for one- or two-level diseases in well-selected patients. There are many different types of prostheses, and the exact surgical indications for CDA are evolving; further studies can help elucidate superiority of certain implants and better evidence about patient selection. However, in many clinical scenarios in appropriate patients, when performed technically well, we believe CDA is a safe and effective alternative to ACDF with several potential benefits.

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