



Review Article

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Received: May 9, 2018

Revised: August 5, 2018

Accepted: August 28, 2018

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The Option of Motion Preservation in Cervical Spondylosis: Cervical Disc Arthroplasty Update

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Cervical disc arthroplasty (CDA), or total disc replacement, has emerged as an option in the past two decades for the management of 1- and 2-level cervical disc herniation and spondylosis causing radiculopathy, myelopathy, or both. Multiple prospective randomized controlled trials have demonstrated CDA to be as safe and effective as anterior cervical discectomy and fusion, which has been the standard of care for decades. Moreover, CDA successfully preserved segmental mobility in the majority of surgical levels for 5–10 years. Although CDA has been suggested to have long-term efficacy for the reduction of adjacent segment disease in some studies, more data are needed on this topic. Surgery for CDA is more demanding for decompression, because indirect decompression by placement of a tall bone graft is not possible in CDA. The artificial discs should be properly sized, centered, and installed to allow movement of the vertebrae, and are commonly 6 mm high or less in most patients. The key to successful CDA surgery includes strict patient selection, generous decompression of the neural elements, accurate sizing of the device, and appropriately centered implant placement.

Keywords: Cervical disc arthroplasty, Total disc replacement, Adjacent segment disease, Radiculopathy, Myelopathy, Anterior cervical discectomy and fusion

INTRODUCTION

Cervical disc arthroplasty (CDA), or total disc replacement, has been widely accepted as an alternative treatment for cervical disc degenerative disease in the past decade because of its preservation of segmental mobility and the potential to reduce adjacent segment disease (ASD).¹⁻⁴ There were several U. S. Food and Drug Administration (FDA) prospective randomized control trials comparing CDA and anterior cervical discectomy and fusion (ACDF) with 5–8 years follow-up data published.⁴⁻¹⁶ The results of these trials indicate that CDA has a similar success rate in relief of neurologic symptoms with ACDF.^{5,11,13,17} These results also demonstrate effective preservation of segmental mobility in CDA. The average range of flexion/extension of

each treated level is 7–9 degrees.^{7,9,10,12} Studies suggest CDA has a lower incidence of ASD with a reported rate of 0.8% to 2.9%.^{2,18}

CERVICAL ARTIFICIAL DISC

There are many artificial discs provided by different manufacturers which use different designs and materials. An artificial disc is composed of three major parts: upper end plate, articulation core, and lower endplate.

1. Endplate of Artificial Disc

Most artificial discs use 1 of 3 endplate shape designs: spherical, ovate, and rectangular. The endplate design influences the endplate coverage and the extent of bony preparation. There

are now more manufacturers using a convex upper endplate design. This design could fit to the physiological shape of the upper endplate of vertebrae. The materials used for endplates, include Titanium alloy, Cobalt-chromium and stainless steel. Currently, there is no definite conclusion or clinical evidence of the superiority of these 3 materials. However, stainless steel has more artifact in magnetic resonance images than the other 2 materials that make follow-up difficult. The designs for primary stabilization included teeth, keel, fin, spike, and screw with/without endplate coating (porous titanium or hydroxyapatite). Care should be taken to follow the manufacturer's instructions to install the device for adequate osteo-integration.

2. Articulation Core

Most artificial discs use a ball-and-socket articulation design with different materials, including ultrahigh molecular weight polyethylene (metal-on-polymer), stainless steel (metal-on-metal) and ceramic (ceramic-on-ceramic). To date, there has been no report of revision surgery due to device wear-out. Long-term follow-up is still needed, especially focusing on the durability of the articulation core and the reactive response to wear debris. Fixed or mobile core was another design difference of the articulation in these devices. Artificial discs with a mobile core would have an additional degree of freedom, the anterior-posterior translation, which provided significantly more movement between the 2 vertebrae. Owing to the mobile core, the artificial disc could add a movable center of rotation (COR) which should effectively lower the mechanical load over adjacent discs. In the contrast, the artificial discs with a fixed core would only allow a fixed COR that required special address during installation, because they must be installed precisely to replicate the anatomical COR, in order to restore normal kinematics, and mimic physiological motion.^{19,20}

INDICATION AND CONTRAINDICATION

The FDA trials enrolled adult patients who had 1- or 2-level cervical disc disease between C3 to C7, causing refractory radiculopathy, myelopathy or both.⁴ CDA might not be recommended in elderly patients (aged over 60) because they have a higher chance of having pre-existing facet arthropathy that limits the range of motion.

Relative contraindications for CDA are kyphotic deformity, facet arthropathy, instability (i.e., more than 2- to 3-mm translation/subluxation on dynamic lateral radiographs), ankyloses, ossification of posterior longitudinal ligament, and osteoporosis.

4-8,10-12,14,17

CLINICAL CONSIDERATIONS

The design rationale for CDA is to replace the diseased disc which is causing radiculopathy while preserving segmental motion at the index level. For cervical spondylotic myelopathy (CSM), some surgeons advocate fusion to limit motion to enhance recovery. It is not clear whether there are differences in patients' neurological recovery or outcome with myelopathy versus radiculopathy when treated with CDA. The FDA trials also enrolled patients with myelopathy and demonstrated similar improvements of myelopathy in both ACDF and CDA patients. There is some evidence showing that CDA is also effective in the management of 1- or 2-level CSM.²¹⁻²³ Although the present data seem promising, the true effect of CDA in the management of cervical myelopathy requires further investigation.

PREOPERATIVE EVALUATION

Evaluation by both magnetic resonance imaging (MRI) and computed tomography (CT) is helpful before CDA surgery. MRI is useful in evaluation of spinal canal stenosis as well as foraminal stenosis. Preoperative CT scans are helpful in the detection of ossification of the posterior longitudinal ligament (OPLL), calcified disc, osteophytes, and facet arthropathy. In patients with OPLL or calcified disc, anterior discectomy could be associated with a higher risk of durotomy. In most published literature, OPLL is listed as a relative contraindication for CDA. Furthermore, a preoperative CT scan is particularly useful for detection of facet arthropathy. If the facet joint is severely degenerated or fused, there is little chance to preserve motion after CDA surgery.

Both cervical anteriorposterior and lateral radiographs, including dynamic views, are helpful in the evaluation of cervical alignment and segmental mobility. Patients with pre-existing cervical kyphosis, anteriorposterior translation or subluxation are not good candidates for CDA surgery, because it is not likely for CDA to correct cervical alignment.²⁴ On the other hand, instrumented ACDF is well accepted for the correction of cervical kyphosis by using lordotic interbody bone grafts.

The most common level of CDA surgery is C5-6, followed by C4-5 and C6-7. Compared to other subaxial levels, C3-4 CDA was reported to have a higher incidence of heterotopic ossification (HO) with uncertain cause.²⁵ There were also a few case reports of C7-T1 CDA which is technically feasible but

rarely indicated. To date, there have been no reports of CDA at C2–3.

For patients who had any kind of prior neck surgery (i.e., ACDF or thyroid surgery), preoperative endoscopic surveillance of vocal cord movement should be considered. If bilateral vocal cord movement is normal, approach from the virgin side is suggested to avoid risk of esophagus injury. If there is pre-existing unilateral vocal cord palsy, CDA should be performed via the same side to prevent bilateral vocal cord palsy which may require tracheostomy to protect the airway.

SURGICAL TECHNIQUE

General anesthesia with either an oral or a nasal endotracheal tube and prophylactic antibiotics are recommended for all patients undergoing CDA. The nasal endotracheal tube is considered when C3–4 CDA surgery is planned since it may allow easier retraction of the trachea. Intraoperative neuro-monitoring and perioperative steroids are options that may be considered.

Positioning is the first step for successful CDA. The patient should be placed in a supine position, without head rotation in neutral or slightly lordotic alignment. Adequate cushioning underneath the neck is helpful to achieve appropriate alignment. In obese patients, chin or shoulder traction would be helpful for better visualization of the target level. After positioning, a lateral fluoroscopy image is necessary to assure visualization of the target level and location of the skin incision. An anterior-posterior fluoroscopy view is sometimes useful to confirm the patient's neck is in an orthogonal position.

The surgical approach for CDA is similar to the standard ACDF approach. A transverse skin incision along a pre-existing skin crease is adequate for exposure of up to 2 disc levels. Sharp dissection of soft tissue between the carotid sheath and the strap muscle leads to an avascular plane. By blunt dissection through the avascular plane, the trachea and esophagus are pushed medially to expose the prevertebral retro-pharyngeal space. The bilateral longus coli muscles are dissected and detached slightly along the medial border. Self-retaining retractor blades can be inserted beneath the longus coli muscles for protection of the esophagus medially and the carotid sheath laterally. After setup of the retractor, the endotracheal cuff may be deflated and partially re inflated immediately to prevent barotrauma to the trachea and recurrent laryngeal nerves. Caution should be taken during dissection to avoid injury to the superior and recurrent laryngeal nerves, which may lead to postoperative hoarseness and

dysphagia.

After confirmation of the target level by intraoperative fluoroscopy, precise midline determination of the vertebral body should be done by either recognizing anatomic features or by using anterior-posterior fluoroscopy. The authors prefer the use of distraction pins placed into the midline of vertebral bodies to facilitate discectomy with gentle retraction. For CDA, resection of the posterior longitudinal ligament is recommended for thorough decompression of the dura.²⁶ Moreover, the authors suggest resection of the bilateral uncovertebral joints to ensure decompression of the bilateral neural foramen.²⁶ Since CDA aims at preservation of segmental motion, it is a necessity to ensure decompression of both neural foramen in order to prevent nerve impingement during neck motion. Unlike conventional ACDF, which partially relies on indirect decompression by distraction of the disc space, CDA depends solely on direct decompression. Thus, generous decompression of the dura and bilateral neural foramen is crucial to avoid recurrent radicular symptoms during extreme motion after CDA.

To achieve the best outcome of CDA surgery, each artificial disc should be installed properly, including sizing, centering, and positioning. Thus, midline acquisition and proper endplate preparation is important. The endplate preparation helps primary stability of the artificial disc. Care must be taken that the endplate should not be violated too much during decompression, otherwise the risk of implant migration or subsidence increases. There are many types of artificial discs on the market and each one has specialized fixation mechanisms, such as keel, fin, teeth, or screws. There is no definite report that demonstrates superiority of one device over another. Surgeons should follow the manufacturer's specific instructions and select the proper height and the largest footprint that is closest to the physiologically functioning disc. Most artificial discs are 5–6 mm high and surgeons should note that overly high CDA may inhibit segmental motion by splaying the facet joints.

1. Case Illustration

A 43-year-old male presented with neck pain and left-sided radiculopathy that was refractory to medical management for more than 3 months. The symptoms were aggravated during neck extension. There were also mild symptoms of cervical myelopathy, which were referable to a disc herniation at C5–6 demonstrated by MRI. The preoperative CT scan also confirmed the stenosis with marginal osteophyte at C5–6 and ruled out ossification of posterior longitudinal ligament (Fig. 1). The preoperative lateral flexion and extension radiographs demonstrat-

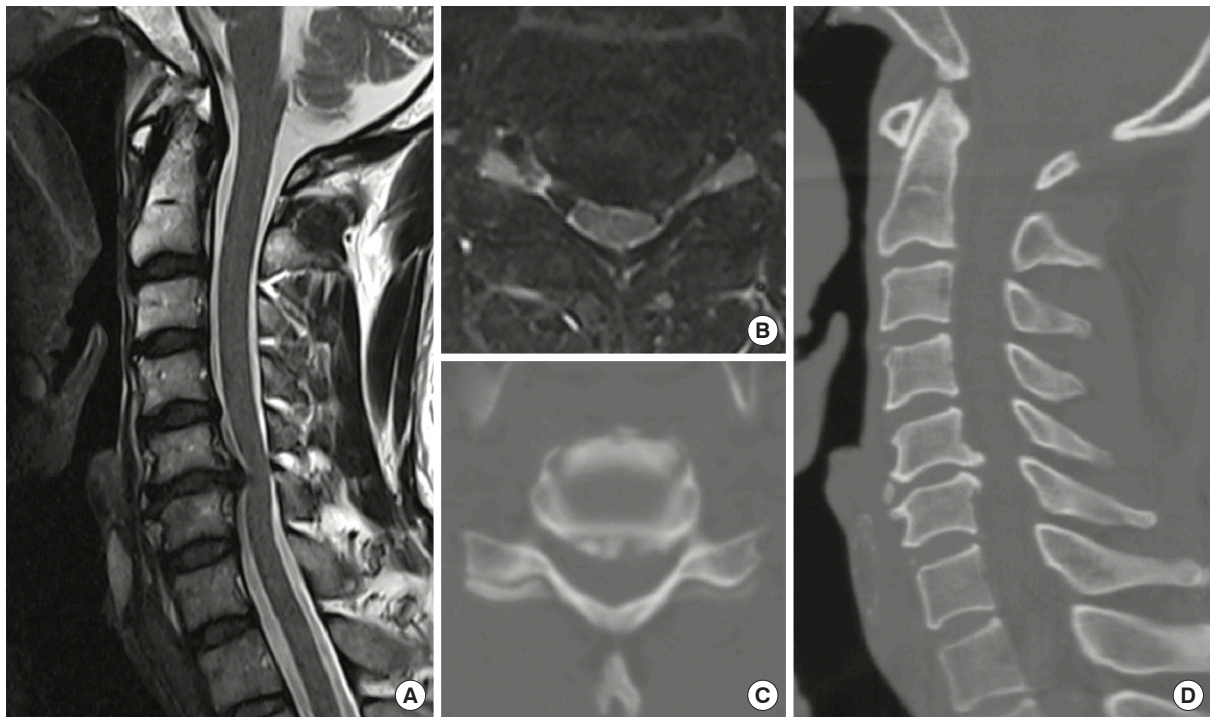


Fig. 1. Preoperative magnetic resonance images (sagittal and axial view over C5–6, A and B), computed tomography (axial view over C5–6 and sagittal, C and D).

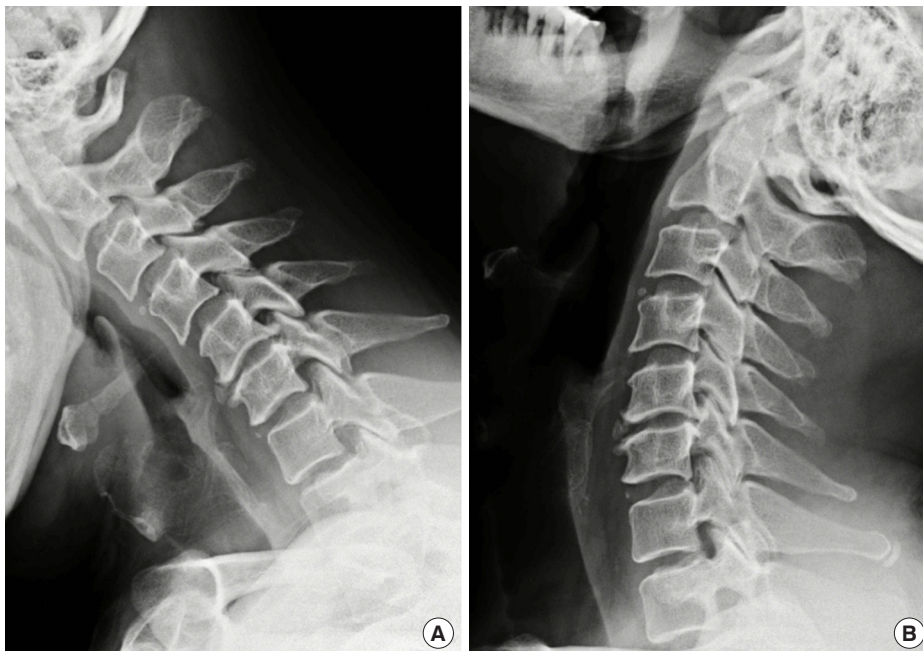


Fig. 2. Preoperative lateral dynamic radiographs: flexion (A) and extension (B).

ed a normal range of motion (Fig. 2).

The patient then underwent 1-level CDA with ProDisc-C Vivo (DePuy Synthes Spine, Inc., Raynham, MA, USA). The

surgery went smoothly, and his symptoms were completely relieved after surgery. The postoperative radiographs taken at 6 months demonstrated good mobility (Figs. 3, 4). There were no

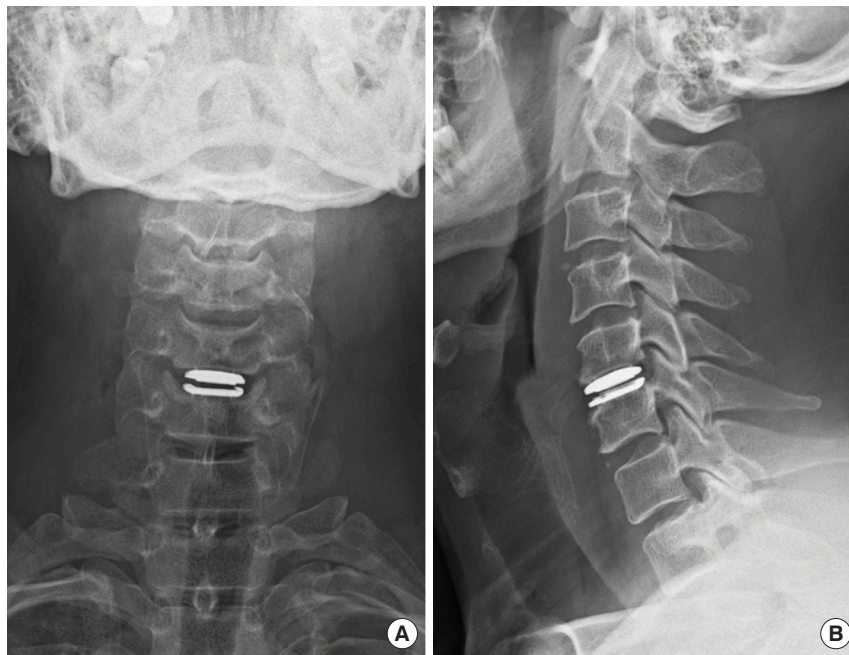


Fig. 3. Immediate postoperative radiographs: anterior-posterior (A) and lateral (B).

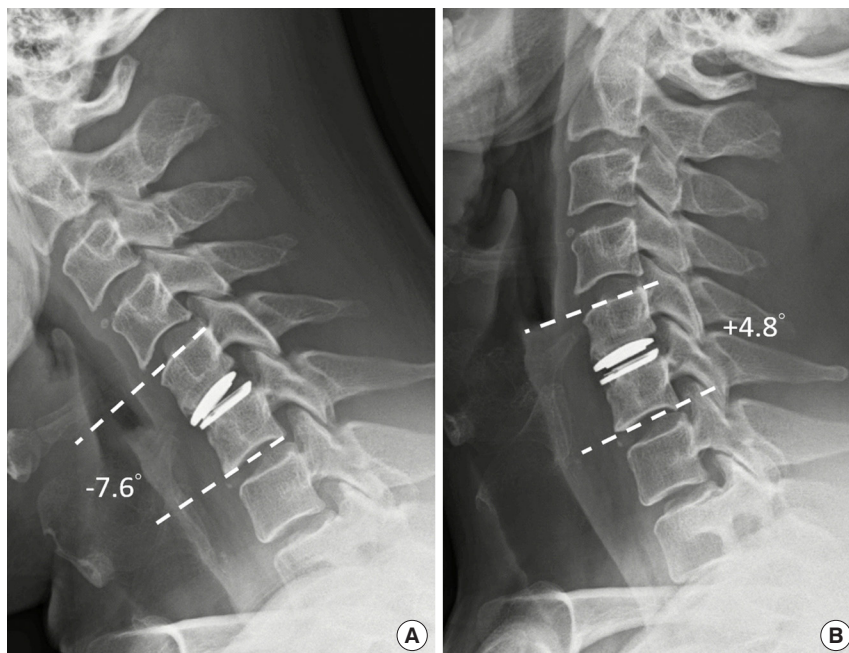


Fig. 4. Postoperative 6 months lateral dynamic radiographs: flexion (A) and extension (B).

complications and reoperations.

PUBLISHED CLINICAL STUDIES

Since the beginning of this century, there have been several prospective, randomized, and controlled clinical trials of the

FDA, comparing CDA to the standard ACDF surgery. These published clinical trials have demonstrated the safety and effectiveness of CDA in 1- and 2-level cervical disc herniation and spondylosis, as good as instrumented ACDF (Table 1). Moreover, these artificial discs for CDA from various manufacturers unanimously demonstrated preservation of the segmental mo-

Table 1. Summary of FDA-IDE trials

Device	Author	Year	Manufacturer	Study type	Level	Population	Follow-up (yr)	ROM	Secondary surgery	High grade HO*
Bryan	Heller ⁷	2009	Medtronic	FDA-IDE prospective randomized Controlled trial	1	242 Bryan vs. 221 ACDF	2	8.4°	Index level: 2.5% vs. 3.6%	N/A
Bryan	Sasso ³⁶	2017	Medtronic	FDA-IDE prospective randomized Controlled trial	1	24 Bryan vs. 23 ACDF	10	N/A	Index level: 4.5% vs. 0% Adjacent level: 4.5% vs. 32%	N/A
Bryan Kineflex C	Coric ¹⁷	2013	Medtronic Spinal Motion	FDA-IDE prospective randomized Controlled trial	1	41 CDA vs. 33 ACDF	4	8.6°	Index level: 2.4% vs. 0% Adjacent level: 4.9% vs. 3%	17%
Kineflex C	Coric ³⁷	2018	Spinal Motion	FDA-IDE prospective randomized Controlled trial	1	136 Kineflex C vs. 133 ACDF	5	10.6°	8.2% vs. 8.3%	26.1%
Prestige ST	Mummaneni ⁹	2007	Medtronic	FDA-IDE prospective randomized Controlled trial	1	276 Prestige ST vs. 265 ACDF	2	7.59°	1.8% vs. 5.2%	N/A
Prestige ST	Burkus ¹³	2014	Medtronic	FDA-IDE Prospective randomized controlled trial	1	276 Prestige vs. 265 ACDF	7	6.75°	Index level: 4.8% vs. 13.7% Adjacent level: 4.6% vs. 11.9	10%
Prestige LP	Gornet ⁵	2015	Medtronic	FDA-IDE prospective nonrandomized trial	1	280 Prestige LP	2	7.5°	5%	9.6%
Prestige LP	Gornet ⁶	2017	Medtronic	FDA-IDE prospective randomized Controlled trial	2	209 Prestige LP vs. 188 ACDF	2	6.92°; 6.85°	Index level: 2.4% vs. 8% Adjacent level: 2.4% vs. 3.2%	16.1%–19.7%
Prestige LP	Lanman ⁸	2017	Medtronic	FDA-IDE prospective randomized Controlled trial	2	209 Prestige LP vs. 188 ACDF	7	Around 6.5°†	Index level: 4.2% vs. 14.7% Adjacent level: 6.5% vs. 12.5%	32.5%–34.4%
Mobi-C	Davis ¹⁴	2013	LDR Medical	FDA-IDE prospective randomized Controlled trial	2	225 Mobi-C vs. 105 ACDF	2	10.1°, 8.3°	3.1% vs. 11.4%	10.1%–11.5%
Mobi-C	Radcliff ¹¹	2016	Zimmer biomet	FDA-IDE prospective randomized Controlled trial	2	225 Mobi-C vs. 105 ACDF	7	10.2°	Index level: 4.4% vs. 16.2% Adjacent level: 3.7% vs. 13.6%	N/A
ProDisc-C	Murrey ¹⁰	2009	Synthes	FDA-IDE prospective randomized Controlled trial	1	103 ProDisc-C vs. 106 ACDF	2	9.36°	1.9% vs. 8.5%	N/A
ProDisc-C	Loumeau ³⁸	2016	Synthes	FDA-IDE prospective randomized Controlled trial	1	41 ProDisc-C vs. 22 ACDF	7	> 7°	0% vs. 27.3%	56%

FDA-IDE, U. S. Food and Drug Administration-Investigational Device Exemption; ROM, range of motion; HO, heterotrophic ossification; ACDF, anterior cervical discectomy and fusion; CDA, cervical disc arthroplasty; N/A, not available.
*Incidence of HO differed from detection method. † Approximation from figure.

Table 2. Other studies for different clinical scenario

Cervical disc	Author	Year	Study type	Treatment	Follow-up (mo)	Population	Result
Bryan	Tu ³³	2011	Retrospective	1- and 2-level	12	36 Bryan	The HO had an incidence at 48.1% per level, and did not affect clinical outcomes
Bryan	Tu ²⁹	2012	Retrospective	1- and 2-level	24	75 Patient	Shell kyphosis and inadequate endplate coverage have adverse effects on the formation of HO after CDA
Bryan	Wu ³	2012	Retrospective	1-Level	45.5	16 Soft disc herniation 24 Spondylosis	Soft disc herniation and spondylosis had similar clinical outcomes. However, the spondylosis group had more HO significantly less HO.
Bryan	Wu ²⁷	2012	Retrospective control	1- and 2-level	46.2	42 1-level CDA 28 2-level CDA	There were more HO in the 2-level CDA patients than the 1-level, although the clinical outcomes were similar
Bryan	Wu ²⁸	2013	Retrospective	Multilevel	38.3	36 1-level CDA 27 2-level CDA 23 2-level CDA+1 level ACDF	Patients with multi-level CDA had similar clinical outcomes than that with single-level CDA
Bryan Prestige LP	Fay ³⁴	2014	Retrospective control	1- and 2-level	36.4	72 Myelopathy 53 Radiculopathy	Patients with cervical myelopathy had similar outcomes than that with radiculopathy after CDA.
Bryan	Fay ³⁹	2014	Retrospective control	2-Level	40	37 Bryan 40 ACDF	For patients with 2-level cervical disc herniation and spondylosis, CDA could preserve segmental mobility and yielded similar outcomes than ACDF.
Bryan	Tu ³²	2015	Retrospective	1- and 2-level	38.7	53 CDA with NSAID use 22 CDA without NSAID use	Postoperative NSAIDs use could be associated with less HO
Bryan Prestige LP	Chang ³⁰	2015	Retrospective age- and sex-matched control	1- and 2-level	29.6	Traumatic disc herniation 15 CDA 15 ACDF	In patients with traumatic cervical disc herniation, CDA yielded similar outcomes as ACDF
Bryan Prestige LP ProDisc-C	Chang ²⁵	2016	Retrospective control	1-Level	60	11 C3-4 CDA 77 non-C3-4 CDA	There were more HOs after CDA at C3-4
Prestige LP ProDisc-C	Chang ²³	2016	Retrospective	3-Level	18	Cervical spondylotic myelopathy with OPLL 15 hybrid ACCF (for OPLL)+CDA (for disc)	Hybrid CDA has satisfactory clinical outcome in patient of CSM with OPLL
Bryan Prestige LP ProDisc-C	Chang ²²	2016	Retrospective control	1-Level	30	Degenerative disc disease with IISI: 22 IISI, 69 without IISI	CDA was similarly effective for patients with or without IISI
Bryan Prestige LP ProDisc-C Nova	Chang ²¹	2017	Retrospective control	3-Level	28.4	Congenital cervical stenosis 20 hybrid CDA (2-level CDA+1-level ACDF), 17 3-level ACDF	CDA was as effective as ACDF for patients with congenital cervical stenosis.
Prestige LP	Chang ²⁴	2017	Retrospective	1-Level	27.7	50 Prestige	Segmental mobility and overall cervical alignment had no influences on the clinical outcomes after CDA. However, patients with increased segmental mobility had less HO formation

HO, heterotrophic ossification; CDA, cervical disc arthroplasty; ACDF, anterior cervical discectomy and fusion; NSAID, nonsteroidal anti-inflammatory drugs; OPLL, ossification of the posterior longitudinal ligament; IISI, increased intramedullary signal intensity.

bility at the indexed levels for many years.^{4,12} The averaged range of motion in these clinical trials were approximately 7 to 10 degrees. To date, the published trials were on patients who had CDA surgery for up to 2 consecutive levels from C3 to C7 and followed for up to 10 years. Furthermore, some studies suggested lower incidences of ASD in patients who underwent CDA than patients who underwent ACDF. Along with the growth of promising results published, the use of CDA has gained popularity in the past decade. There is a good chance that more applications and designs of CDA would continue to push forward the field of surgical management in cervical spondylosis.

There also have been a retrospective series of studies that addressed issues that the FDA trials could not specify (Table 2). For example, patients with soft disc herniation or less degeneration would have less HO than those patients with spondylosis or calcified discs after CDA.³ Patients with multilevel disc herniations had higher chances of development of HO after CDA than that with single-level disease, though the clinical outcomes were all very similar.^{27,28} Furthermore, choosing the exact size of an artificial disc and precise placement of the device, including accurate centering and alignment, were the fundamentals of successful CDA surgery.²⁹ Surgical techniques for CDA are far more demanding than ACDF, since the surgery aims to restore the physiological range of motion while maintaining stability. It is also not uncommon to see that some patients could yield an increased range of motion at the level of index, though the global lordosis of the cervical spine was rarely altered after CDA.²⁴ These studies (Table 2) also demonstrated some extended indications of CDA, including congenital cervical stenosis and traumatic disc herniations that did not cause ligamentous injury or bony destruction.^{30,31}

POSTOPERATIVE MANAGEMENT, CLINICAL OUTCOMES, AND COMPLICATIONS

1. Heterotopic Ossification

The postoperative management of CDA is very similar to that of ACDF except that a neck collar is not necessary in CDA patients. Nonsteroidal anti-inflammatory drugs are often prescribed to most CDA patients to reduce the chance of HO.³² The incidence of HO varies from series to series and depends on the method of detection. HO refers to undesired ectopic bone formation around the artificial disc that might jeopardize function of the artificial disc. HO has been considered as a complication or an adverse event of CDA surgery in most published

series. There was a higher incidence of HO formation after CDA in patients with spondylosis compared to those patients with soft disc herniation.³ It seems that HO is a consequence of continuously on-going degeneration, like the marginal spur, that develops as a normal physiological reaction to stabilize the arthritic spine. Common ways to lower the incidence of HO include copious irrigation to remove bone dust when implanting a CDA and waxing the exposed surface of cancellous bone, as well as giving nonsteroidal anti-inflammatory medication post-operatively for 2 weeks.^{3,29,32,33}

2. Surgical Outcome

Currently, most available data for CDA surgery comes from FDA-Investigational Device Exemption trials which enrolled adult patients with 1- and 2-level cervical herniated discs, degenerative disc disease, and spondylosis with a follow-up to 8 years. The FDA trials demonstrated that CDA has similar outcomes with ACDF in relief of neurologic symptoms and is associated with less reoperation and adverse events. However, it is unclear that patients with unilateral radiculopathy have similar results as those with spondylotic myelopathy. The FDA trials did not provide stratified data and subgroup analysis on this issue.

The advantage of motion preservation in CDA surgery becomes more obvious in the management of multilevel patients. The results of the CDA trials demonstrated motion preservation at 7 to 9 degree for each level during flexion and extension. For patients who underwent one level ACDF, a loss of 7 to 9 degree range of motion might be unnoticeable. However, 2- or 3-level ACDF often limits neck mobility and brings inconvenience in daily activity. There were a few reported series of CDA surgery for multilevel (more than 2) degenerative disease causing radiculopathy, myelopathy or both.^{3,21-23,25,28,34,35} The results seem satisfactory, but more long-term follow-up is still needed, including studies of hybrid constructs combining fusion and arthroplasty.

The future application of CDA might include patients with more than 2-level degenerative disc disease and combined use of ACDF or corpectomy with CDA as a hybrid construct. Currently, manufacturers provide artificial discs with a variety size of different heights and footprints. However, one size cannot fit all patients. Using an improper small size of artificial disc comes with inadequate endplate coverage and an overly high CDA may splay the facets to inhibit motion. In the foreseeable future, custom made artificial discs with 3-dimensional printing could precisely help fit the CDA into each individual patient.

CONCLUSION

In selected patients, CDA spares the need for arthrodesis after anterior discectomy and yields excellent clinical outcomes compared with ACDF. The best currently available data support use of CDA in 1- and 2-level cervical disc disease causing radiculopathy or myelopathy that is refractory to medical management. Further study may expand the application of CDA for cervical stenosis caused by different pathologies or multiple diseases. As the techniques, materials and designs of these CDA devices continue to improve, the utilization of CDA is likely to be more prevalent in the future.

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