Cervical Arthroplasty: Long-Term Outcomes

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Abstract

Cervical disc arthroplasty (CDA) attempts to preserve normal motion at adjacent segments and in doing so may decrease the incidence of adjacent segment degeneration in comparison with cervical arthrodesis. Since 2006, the United States Food and Drug Administration (FDA) has approved seven CDA prosthetic devices for surgical management of symptomatic cervical spondylosis and disc herniation (seven for 1-level disease and two for two-level disease). Motion-preserving CDA has showed great promise with equivalent quality-of-life outcomes in many long-term comparative studies. Currently, follow-up duration of up to 10 years is available from some of the FDA trials comparing CDA to arthrodesis. In general, study findings have consistently demonstrated that both techniques result in significant clinical improvement by roughly 3 months post-op and that improvement may be maintained at final follow-up. Overall, there exists robust data to support CDA as a viable alternative to arthrodesis in select patients. However, complications such as heterotopic ossification have been reported. In this chapter, we review CDA, with an emphasis on highlighting the published long-term outcomes and complications for this motion-preserving operation in comparison with arthrodesis.

Keywords

Degenerative disc disease · Cervical spondylosis · Disc herniation · Anterior cervical discectomy and fusion · Cervical disc arthroplasty · Heterotopic ossification · Artificial cervical disc · Motion preservation · Adjacent segment degeneration or disease · Bryan cervical disc · Prestige cervical disc · Prestige ST · Prestige LP · Porous Coated Motion · ProDisc-C · Mobi-C · Kineflex-C · Secure-C · Discover artificial cervical disc

Introduction

Degenerative disc disease involving the cervical spine is part of the normal aging process (Traynelis 2004). When degenerative changes occur gradually, they may be asymptomatic; however, in a subset of patients, cervical spondylosis or disc herniation may result in compression of nerve roots or the spinal cord, resulting in radiculopathy, myelopathy, or both (Traynelis 2004). A common surgical treatment for patients with symptomatic cervical spondylosis or disc herniation is anterior cervical discectomy and fusion (ACDF) (Alvin et al. 2014). The ACDF procedure, first described over 50 years ago, has been shown to be safe and clinically efficacious (Alvin et al. 2014; Cloward 1959; Smith and Robinson 1958). However, there is debate about further degeneration at adjacent segments after fusion surgery (Gao et al. 2013; McAfee et al. 2012; Xing et al. 2013; Yin et al. 2013). Specifically, it is currently unclear if adjacent segment degeneration is part of the natural history of cervical spondylosis or whether it is related to the adjacent fused levels. Some studies have shown an average 3% reoperation rate, while other studies report revision rates exceeding 10% after 2 years to treat complications related to the index fusion operation (Hilibrand et al. 1999; Yin et al. 2013). By preserving physiologic cervical motion, one of the goals of CDA is to reduce the incidence of adjacent segment degeneration while maintaining the highly effective results of ACDF in maintenance or improvement of neck pain, arm pain, and myelopathy (Alvin et al. 2014).

The initial clinical experience with CDA began in the 1960s with Ulf Fernstrom, a Swedish surgeon, implanting stainless steel ball bearing prosthetic devices following laminectomy (Fernstrom 1966; Fisahn et al. 2017). A high failure rate and concern for hypermobility and device migration into adjacent vertebral cancellous bone ultimately led the industry back to favoring ACDF (Bertagnoli et al. 2005; Fernstrom 1966; Fisahn et al. 2017). Then later in the 1980s, CDA returned with a design by Cummins, who was developing an artificial disc to address the shortcomings of ACDF regarding motion preservation and adjacent segment degeneration. Cummins' artificial cervical disc was developed in collaboration with the Department of Medical Engineering at Frenchay Hospital in 1989, and resulted in improved clinical outcomes after implantation in appropriately selected patients (Cummins et al. 1998; Traynelis 2004; Wigfield et al. 2002b). After performing the index decompression or discectomy, the main advantage of CDA in comparison to ACDF is the possibility for postsurgical segmental motion preservation, which may prevent the occurrence of adjacent segment degeneration and disease (Alvin et al. 2014).

Since 2006, the United States Food and Drug Administration (FDA) has approved seven CDA prosthetic devices for surgical management of symptomatic cervical spondylosis and disc herniation at a single level (Coric et al. 2018; Gornet et al. 2016). In 2007, the Prestige ST (Medtronic Inc.), a metal-on-metal device made from stainless steel, was the first CDA device to receive FDA approval (Mummaneni et al. 2007). A later version with a low profile modification, the Prestige LP (Medtronic Inc.), was made from a titanium ceramic composite and received FDA approval in 2014 (Gornet et al. 2015). The other five FDA-approved devices are metal (cobalt-chrome or titanium alloy)-on-polymer (polyethylene or polyurethane) designs and include (by order of FDA approval for single-level CDA) ProDisc-C (2008; Synthes Spine), Bryan (2009; Medtronic Inc.), Porous Coated Motion (2012; Cervitech), Secure-C (2012; Globus Medical), and Mobi-C (2013; LDR Medical) (Heller et al. 2009; Hisey et al. 2014; Murrey et al. 2009; Phillips et al. 2013; Vaccaro et al. 2013). Two of these devices, the Prestige LP and Mobi-C, have since received FDA approval for CDA at two adjacent levels.

More recently, long-term studies have been published for these FDA-approved artificial discs and suggest CDA is safe and clinically efficacious in appropriately selected patients. Currently, follow-up duration of up to 10 years is available from some of the FDA trials comparing CDA to ACDF. In general, study findings have consistently demonstrated that both CDA and ACDF result in significant clinical improvement by roughly 3 months post-op and that improvement may be maintained at final follow-up (Davis et al. 2015; Heller et al. 2009; Hisey et al. 2016; Phillips et al. 2013; Radcliff et al. 2016a; Vaccaro et al. 2013; Zigler et al. 2013). CDA was found to produce noninferior results in all the studies for certain outcome variables and even demonstrated statistical superiority for some outcome measures. For single-level CDA, four of the seven discs (Prestige ST, Prestige LP, Bryan, and Secure-C) demonstrated superiority in overall success. Prestige ST showed superiority in three of four outcome variables (neurological success, revision surgery, and overall success), while the other discs showed superiority in ≤ 2 variables (Prestige LP, neurological and overall success; Bryan, Neck Disability Index [NDI] and overall success; Secure-C, revision surgery and overall success; and Pro-Disc C, revision surgery). The Porous Coated Motion (PCM) and Mobi-C discs demonstrated noninferiority for all outcome variables. For two-level (adjacent) CDA, Prestige LP and Mobi-C demonstrated superiority in three outcome variables (NDI, secondary surgery, and overall success), but not neurological success (Turel et al. 2017).

Although the aforementioned devices have met rigorous outcome requirements for FDA approval, there have been reports of complications such as heterotopic ossification (HO; abnormal bone formation around or within the intervertebral disc space) and/or implant migration (Gao et al. 2013; McAfee et al. 2012; Xing et al. 2013; Yin et al. 2013). Therefore, in this review, in addition to summarizing long-term

outcomes, we also report complications associated with CDA for the FDA-approved discs. Although not FDA-approved, we also report outcomes and complications for the Discover artificial cervical disc (DePuy Spine) due to its widespread use outside the United States (OUS). At the end of each section, we specifically report outcome variables (NDI, Visual Analogue Scale [VAS] neck score, VAS arm score, Short Form-36 Health Survey Physical and Mental component scores [SF-36 PCS; SF-36 MCS]) comparing CDA and ACDF, when available. Outcomes for two-level adjacent CDA are also summarized for the FDA-approved Prestige LP and Mobi-C discs.

Bryan Cervical Disc

Vincent Bryan designed the Bryan cervical disc (Medtronic Inc.) in the United States in 1992 (Basho and Hood 2012). The Bryan cervical disc (Fig. 1a) is a non-constrained device consisting of a low-friction, wear-resistant, polyurethane nucleus housed between titanium plates (Bryan 2002). These titanium plates have convex porous ingrowth surfaces that function to support bony fixation of adjacent vertebral end plates. Consistent with the goal of motion preservation, the Bryan disc was designed to allow normal or physiologic range of motion, as well as coupled motion in cervical flexion/extension, lateral bending, rotation, and translation (Bryan 2002). Several studies have reported significant improvement in postoperative standardized outcomes scores (NDI, VAS scores, and SF-36 scores) for Bryan CDA in comparison with ACDF, for both single- and two-level procedures in patients with discogenic cervical radiculopathy and/or myelopathy (although the Bryan disc is not FDA-approved for multilevel CDA) (Cheng et al. 2009, 2011; Coric et al. 2006, 2013; Garrido et al. 2010; Goffin et al. 2003, 2010; Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Lafuente et al. 2005; Leung et al. 2005; Quan et al. 2011; Robertson et al. 2005; Sasso et al. 2007a, b, 2011; Tu et al. 2011; Walraevens et al. 2010; Yang et al. 2008; Zhang et al. 2012). Table 1 summarizes Bryan CDA outcomes data (Alvin et al. 2014; Anderson et al. 2004; Bhadra et al. 2009; Bryan 2002; Cheng et al. 2009; Coric et al. 2006, 2010, 2013; Ding et al. 2012; Duggal et al. 2004; Garrido et al. 2010; Goffin et al. 2003, 2010;

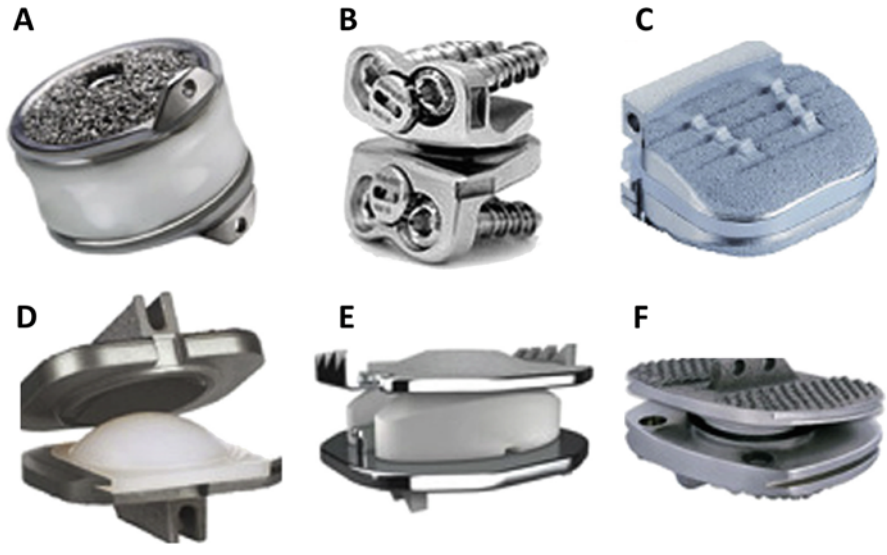

Fig. 1 (**a**) Bryan disc, (**b**) Prestige disc, (**c**) Porous Coated Motion (PCM) disc, (**d**) ProDisc-C disc, (**e**) Mobi-C disc, and (**f**) Kineflex-C disc. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014)

Table 1 Summary of single- and multilevel Bryan disc arthroplasty outcomes for symptomatic cervical spondylosis or disc herniation. Recreated and modified from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Anderson et al. 2004; Bhadra et al. 2009; Bryan 2002; Cheng et al. 2009; Coric et al. 2006, 2010, 2013; Ding et al. 2012; Duggal et al. 2004; Garrido et al. 2010; Goffin et al. 2003, 2010; Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Kim et al. 2008, 2009; Lafuente et al. 2005; Lee et al. 2010; Leung et al. 2005; Pickett et al. 2004, 2006; Quan et al. 2011; Ren et al. 2011; Robertson et al. 2005; Ryu et al. 2010; Sasso et al. 2007a, b, 2011, 2017; Sekhon 2003; Sekhon et al. 2005; Shim et al. 2006; Tu et al. 2011; Walraevens et al. 2010; Wang et al. 2008; Yang et al. 2008; Yoon et al. 2006; Zhang et al. 2012)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/ arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Sasso 2017	RCT	47 (single level)	120 mos	Imp	Imp/Imp			Ib
Coric 2013	RCT	74 (single level)	72 mos	Imp	Imp/Imp			Ib
Zhang 2012	RCT	120 (single level)	24 mos	Imp	Imp/Imp			Ib
Sasso 2011	RCT	463 (single level)	48 mos	Imp	Imp/Imp	Imp	Imp	Ib
Cheng 2009	RCT	65 (all multilevel)	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Garrido 2010	RCT	47 (single level)	48 mos	Imp	Imp/Imp	Imp	Imp	Ib
Heller 2009	RCT	463 (single level)	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Sasso 2007	RCT	115 (single level)	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Hacker 2005	RCT	46 (single level)	12 mos	Imp	Imp/Imp	Imp	Imp	Ib
Coric 2006	RCT	33 (single level)	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Quan 2011	PC	21 (6 multilevel)	96 mos		Imp/Imp			IIb
Ren 2011	PC	45 (6 multilevel)	35 mos	Imp				IIb
Coric 2010	PC	98 (13 multilevel)	24 mos	Imp				IIb
Goffin 2010	PC	98 (9 multilevel)	72 mos	Imp	Imp/Imp	Imp	Imp	IIb
Ryu 2010	PC	36 (single level)	24 mos	Imp	Imp/Imp			IIb
Walraevens 2010	PC	89 (single level)	48 mos					IIb
Bhadra 2009	PC	60 (single level)	31 mos		Imp/Imp			IIb
Heidecke 2008	PC	54 (5 multilevel)	24 mos					IIIb
Kim 2008	PC	47 (8 multilevel)	24 mos	Imp	Imp/Imp			IIb
Wang 2008	PC	59 (single level)	24 mos	Imp	Imp/Imp			IIb
Yang 2008	PC	19 (3 multilevel)	24 mos		Imp/Imp			IIb
Pickett 2006	PC	74 (21 multilevel)	24 mos	Imp	Imp/Imp	Imp	Imp	IIb
Robertson 2005	PC	74 (single level)	24 mos		Imp/Imp	Imp	Imp	IIb
Sekhon 2005	PC	15 (5 multilevel)	24 mos		Imp/Imp			IIb

(continued)

Table 1 (continued)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/ arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Lafuente 2005	PC	46	12 mos	Imp	Imp/Imp	Imp	Imp	IIb
Pickett 2004	PC	14 (1 multilevel)	24 mos	Imp		Imp	Imp	IIb
Duggal 2004	PC	26 (4 multilevel)	12 mos	Imp		Imp	Imp	IIb
Anderson 2004	PC	136 (30 multilevel)	12 mos			Imp	Imp	IIb
Goffin 2003	PC	143 (43 multilevel)	12 mos			Imp	Imp	IIb
Bryan 2002	PC	97 (single level)	24 mos			Imp	Imp	IIb
Ding 2012	R	32 (included multilevel)	49 mos	Imp	Imp/Imp	Imp	Imp	IIb
Tu 2011	R	36 (16 multilevel)	27 mos		Imp/Imp			IIb
Lee 2010	R	48 (single level)	14 mos		Imp/Imp			IIb
Kim 2009	R	51 (12 multilevel)	19 mos	Imp	Imp/Imp			IIb
Shim 2006	R	47 (8 multilevel)	6 mos	Imp	Imp/Imp			IIb
Yoon 2006	R	46 (single level)	12 mos	Imp	Imp/Imp			IIb
Leung 2005	R	90	12 mos			Imp	Imp	IIb
Sekhon 2003	R	7 (2 multilevel)	6 mos	Imp	Imp/Imp			IIb

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Kim et al. 2008, 2009; Lafuente et al. 2005; Lee et al. 2010; Leung et al. 2005; Pickett et al. 2004, 2006; Quan et al. 2011; Ren et al. 2011; Robertson et al. 2005; Ryu et al. 2010; Sasso et al. 2007a, b, 2011, 2017; Sekhon 2003; Sekhon et al. 2005; Shim et al. 2006; Tu et al. 2011; Walraevens et al. 2010; Wang et al. 2008; Yang et al. 2008; Yoon et al. 2006; Zhang et al. 2012). The vast majority of these studies had follow-up duration of up to 2 years; however, some had over 6 years of clinical and radiographic follow-up (Pointillart et al. 2017; Quan et al. 2011).

Long-Term Outcomes for Single-Level Bryan CDA Versus ACDF

In 2012, Zhang and colleagues reported 24-month outcomes for Bryan CDA versus ACDF. Study results demonstrated no significant differences between treatment groups based on mean NDI or median VAS scores (Zhang et al. 2012). These results are consistent with a study by Coric and colleagues (with average follow-up 72 months) that also demonstrated no significant differences between groups based on mean NDI or median VAS scores (Coric et al. 2013). In contrast, Sasso and colleagues reported significantly greater improvement in the CDA cohort based on NDI, VAS neck and arm pain scores, and SF-36 PCS and MCS scores at 48 months post-op (Sasso et al. 2011). Sasso and colleagues also reported an advantage for CDA in comparison with ACDF as measured by 7- and 10-year NDI scores (Sasso et al. 2017). The same authors reported CDA having an advantage over ACDF based on 7-year VAS neck and arm pain scores; however, the comparison was no longer significant at final 10-year follow-up (Sasso et al. 2017).

The data from these studies suggests that Bryan CDA is at least a viable alternative to ACDF for symptomatic cervical spondylosis and/or disc prolapse. The data also suggests that there is a lower incidence of secondary surgery after CDA (Cheng et al. 2009, 2011; Coric et al. 2006, 2013; Garrido et al. 2010; Goffin et al. 2003, 2010; Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Lafuente et al. 2005; Leung et al. 2005; Quan et al. 2011; Robertson et al. 2005; Sasso et al. 2007a, b, 2011; Tu et al. 2011; Walraevens et al. 2010; Yang et al. 2008; Zhang et al. 2012). A study by Shang and colleagues that focused on "skip" cervical spondylosis provided more evidence for the benefits of Bryan CDA over ACDF (Shang et al. 2017). Also, in a study that utilized a workers' compensation patient cohort, a greater number of CDA patients returned to work at 6 weeks and 3 months after surgery compared to ACDF (Steinmetz et al. 2008).

However, despite the demonstrated benefits of Bryan CDA over ACDF, complications were still reported (Cheng et al. 2009, 2011; Coric et al. 2006, 2013; Garrido et al. 2010; Goffin et al. 2003, 2010; Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Lafuente et al. 2005; Leung et al. 2005; Quan et al. 2011; Robertson et al. 2005; Sasso et al. 2007a, b, 2011; Tu et al. 2011; Walraevens et al. 2010; Yang et al. 2008; Zhang et al. 2012). For example, new anterior osteophyte formation or enlargement, increased narrowing of the intervertebral interspace, new adjacent degenerative disc disease, and calcification of the anterior longitudinal ligament were reported radiological findings indicative of post-CDA adjacent-level disease (Robertson et al. 2005; Yi et al. 2009). The incidence of heterotopic ossification (HO) causing restricted range of movement of the artificial disc prosthesis appears to increase with time, especially in multilevel (bilevel) CDA. Longer follow-up duration after CDA, gender, and age were noted to be risk factors in the development of HO after CDA (Leung et al. 2005).

Preoperative cervical kyphosis is a contraindication to CDA; therefore, post-CDA alignment has been an important topic of interest (Leven et al. 2017; Nunley et al. 2018). Using Bryan CDA for patients with single- and/or two-level symptomatic disc disease, Kim and colleagues studied postsurgical sagittal alignment of the functional spinal unit (FSU), as well as overall sagittal balance of the cervical spine (Kim et al. 2008). Their results demonstrated that Bryan CDA resulted in preserved motion of the FSU, and although the preoperative lordosis (or kyphosis) of the FSU could not always be maintained at during follow-up, the overall sagittal balance of the cervical spine was usually preserved (Kim et al. 2008). Pickett and colleagues reported similar results. Specifically, they also demonstrated preserved motion of the FSU after CDA. Although both the end plate angle of the treated disc space and the angle of the FSU became kyphotic after CDA, overall cervical spine sagittal alignment was preserved (Pickett et al. 2004). Other authors have found that cervical spine sagittal alignment became kyphotic after surgery, but overall lordosis was restored at a later time on follow-up imaging (Yoon et al. 2006). Possible causes of kyphotic changes included "over-milling" at the dorsal end plate, suboptimal angle of disc insertion, structural absence of lordosis in the Bryan disc prosthesis, removal of the posterior longitudinal ligament, and preexisting cervical kyphosis (Yoon et al. 2006).

Cummins/Bristol and Prestige Cervical Discs

Authors of both single- and multicenter studies have reported statistically significant improved postoperative outcomes for Prestige CDA (Fig. 1b), as well as reduced rates of secondary surgery compared to ACDF (Burkus et al. 2010, 2014; Lanman et al. 2017; Mummaneni et al. 2007; Peng et al. 2011; Porchet and Metcalf 2004; Riina et al. 2008; Robertson and Metcalf 2004). In addition to improved neurological success and outcomes, some studies have also demonstrated that Prestige CDA may restore segmental lordosis and preserve segmental motion (Peng et al. 2011). The follow-up duration for many of these studies was 2 years, but up to 7 years of follow-up data was reported (Lanman

Table 2 Summary of single-level Prestige disc outcomes for symptomatic cervical spondylosis or disc herniation. Recreated and modified from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Burkus et al. 2010, 2014; Gornet et al. 2015, 2016, 2017; Lanman et al. 2017; Mummaneni et al. 2007; Peng et al. 2011; Porchet and Metcalf 2004; Riew et al. 2008; Riina et al. 2008; Robertson and Metcalf 2004)

Author/Device	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Gornet 2016 Prestige LP	RCT	545	84 mos	Imp	Imp/Imp	Imp	Imp	Ib
Gornet 2015 Prestige LP	RCT	545	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Burkus 2014 Prestige ST	RCT	541	84 mos	Imp	Imp/Imp	Imp		Ib
Burkus 2010 Prestige ST	RCT	541	60 mos	Imp	Imp/Imp	Imp		Ib
Riew 2008 Prestige ST	RCT	199	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Mummaneni 2007 Prestige ST	RCT	541	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Porchet 2004 Prestige II	RCT	49	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Peng 2011 Prestige LP	PC	115 (includes 1–3 levels)	24 mos	Imp	Imp/Imp	Imp	Imp	IIb
Riina 2008 Prestige ST	PC	19	24 mos	Imp	Imp/Imp			IIb
Robertson & Metcalf 2004 Prestige I	PC	14	48 mos	Imp	Imp/Imp	Imp	Imp	IIb

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Table 3 Summary of two-level (adjacent) Prestige LP disc outcomes for symptomatic cervical spondylosis or disc herniation. (Gornet et al. 2017; Lanman et al. 2017)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Lanman 2017	RCT	397	84 mos	Imp	Imp/Imp	Imp	Imp	Ib
Gornet 2017	RCT	397	24 mos	Imp	Imp/Imp	Imp	Imp	Ib

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

et al. 2017). Tables 2 and 3 summarize Prestige CDA outcomes data (Burkus et al. 2010, 2014; Gornet et al. 2015, 2016, 2017; Lanman et al. 2017; Mummaneni et al. 2007; Peng et al. 2011; Porchet and Metcalf 2004; Riew et al. 2008; Riina et al. 2008; Robertson and Metcalf 2004). Below, we highlight key design steps in the history of Prestige CDA and then summarize one- and two-level outcomes data for Prestige CDA versus ACDF.

In the late 1980s, Cummins introduced a simple ball-and-socket prosthetic cervical joint in an attempt to address some of the problems associated with ACDF (Cummins et al. 1998; Wigfield et al. 2002b). His efforts, in collaboration with the Department of Medical Engineering at Frenchay

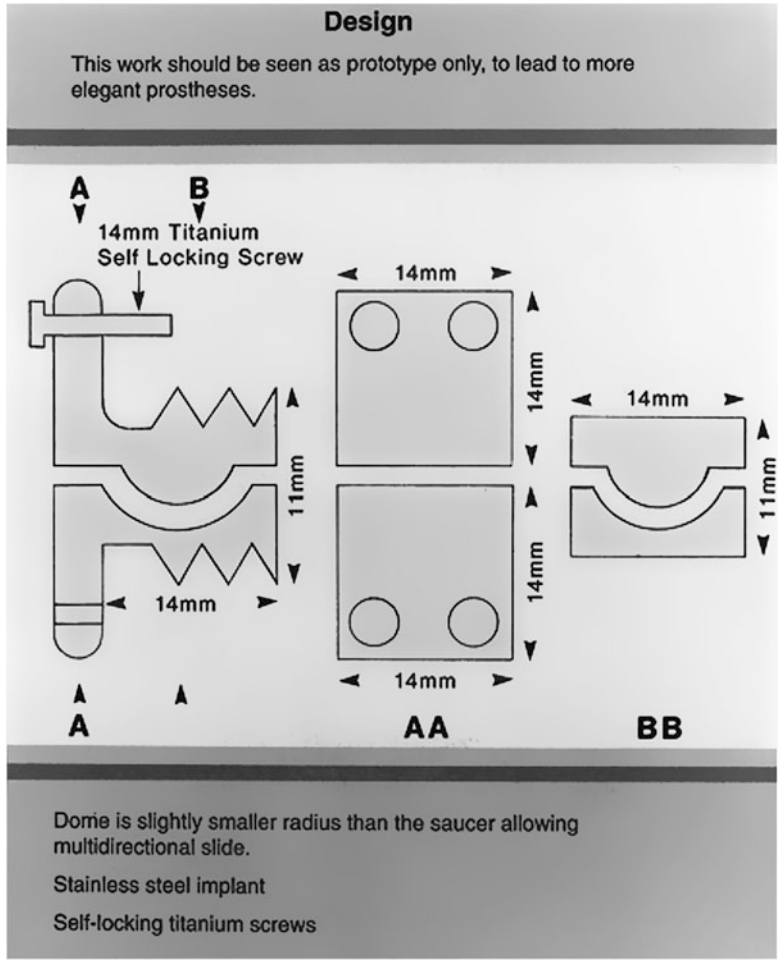

Fig. 2 Prototype design of the Prestige artificial cervical disc composed of stainless steel (made by Mr. Colin Walker at Frenchay Hospital). (Recreated from Cummins et al. Surgical experience with an implanted artificial cervical joint. Journal of Neurosurgery. (Cummins et al. 1998))

Hospital, led to the development of a prosthetic cervical disc constructed entirely of stainless steel with congruent surfaces and no point loading (Fig. 2) (Cummins et al. 1998; Traynelis 2004; Wigfield et al. 2002b). The Cummins disc occupied 11 mm of the intervertebral space and was secured to the vertebral bodies above and below the index level with screws (Traynelis 2004). Between 1991 and 1996, 22 Cummins discs were implanted in 20 "end-stage" patients who lacked motion over multiple cervical levels because of congenital block vertebrae or prior surgical fusion. On follow-up, two patients lacked motion at the index level. This was attributed to the relatively large implant size which may have caused over-distraction of the facet joints (Cummins et al. 1998). Although there were implant problems such as screw breakages, patients experienced clinical improvement (those with radiculopathy improved, and those with myelopathy improved or stabilized) (Cummins et al. 1998).

The work of Cummins set the foundation for the development of the next generation of artificial cervical discs. The next CDA device was developed in 1998 and was referred to as the Frenchay artificial cervical joint (Fig. 3) (Traynelis 2004; Wigfield et al. 2002b).

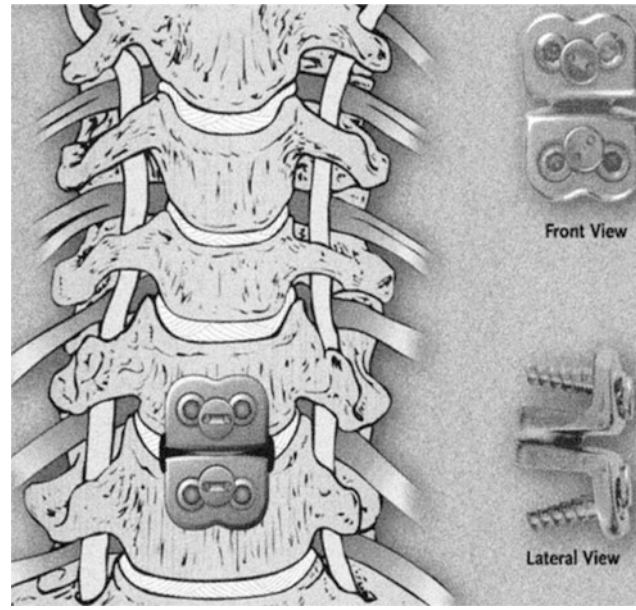

Fig. 3 The two articulating components of the Frenchay artificial cervical joint (or Prestige I) are shown with the bone and locking screws. (Recreated from Wigfield et al. The New Frenchay Artificial Cervical Joint: Results From a Two-Year Pilot Study. Spine (Phila Pa 1976). (Wigfield et al. 2002b))

Medtronic ultimately purchased the Frenchay disc, and it was renamed as Prestige (Medtronic Inc.) (Nunley et al. 2018). This device had some similarities to the prior Cummins joint but was redesigned with a trough rather than a ball-and-socket for articulation. Also, the lower component of the joint was redesigned for translation within three degrees of freedom for both translation and rotation (Wigfield et al. 2002b). Together, these design changes allowed more physiologic motion (anterior-posterior translation coupled with flexion/extension) (Traynelis 2004; Wigfield et al. 2002b). Wigfield and colleagues prospectively evaluated the Frenchay artificial joint in a cohort of 15 patients with cervical radiculopathy or myelopathy from cervical disc herniation or posterior vertebral body osteophytes (Wigfield et al. 2002b). Over the duration of their 2-year study, the Frenchay CDA maintained motion and intervertebral height at the index levels, there were no cases of dislocation screw backout, and clinical outcomes scores improved (Wigfield et al. 2002b).

The next iteration of Prestige CDA, Prestige II, was developed in 1999 (Traynelis 2004). This device had roughened end plate surfaces to promote bony ingrowth for long-term stability (Traynelis 2004). The Prestige II was the first artificial cervical disc to be compared to ACDF (non-instrumented arthrodesis with autograft) in a prospective randomized trial of patients with symptomatic single-level primary cervical disc disease (Porchet and Metcalf 2004; Traynelis 2004). Data after 2 years of follow-up demonstrated improvement in most outcome measurements that favored CDA over ACDF (Porchet and Metcalf 2004). Also, motion analysis demonstrated favorable results in the CDA cohort (motion was maintained in the CDA cohort compared to ACDF patients who displayed no significant motion) (Porchet and Metcalf 2004).

The next Prestige disc, Prestige ST, became available in 2002 (Traynelis 2004). The surfaces of the device contacting the end plates were grit-blasted to promote bone osteointegration (Traynelis 2004). In comparison with its predecessor, there was a 2 mm reduction in the height of the device's anterior flanges (Traynelis 2004). The Prestige ST ball-and-trough articulation design, combined with its angulation between the base and anterior portions of the device, allowed more physiologic motion comparable to normal cervical vertebrae (Traynelis 2004). Mummaneni and colleagues performed a

multicenter, prospective, randomized, non-inferiority clinical trial comparing the Prestige ST to ACDF (Mummaneni et al. 2007). The Prestige CDA patients maintained physiological segmental motion and had improved clinical outcomes (summarized below) and reduced rates of secondary surgery compared to ACDF (Mummaneni et al. 2007). Burkus and colleagues demonstrated that the Prestige ST disc maintained improved clinical outcomes (summarized below) and segmental motion after implantation after 5 years post-op (Burkus et al. 2010). Rates of reoperations for adjacent segment degeneration trended lower in the CDA cohort in comparison with the ACDF group, but the differences were not statistically significant (Burkus et al. 2010).

The Prestige LP is the latest generation in the Prestige family of cervical discs (Traynelis 2004). The FDA-approved Prestige LP disc (for both single- and two-level symptomatic cervical spondylosis or disc herniation) is a non-constrained ball-in-trough, metal-on-metal articulation made of a titanium ceramic composite. The unique titanium ceramic composite material is highly durable and results in less artifact during CT and MRI scans (Traynelis 2004). Also, the porous titanium plasma spray coating on the end plate surface facilitates bone ingrowth and long-term fixation (Traynelis 2004). Long-term outcomes for the Prestige family of discs are summarized below.

Long-Term Outcomes for Single-Level Prestige CDA Versus ACDF

Prestige LP: In 2015, Gornet and colleagues reported 24-month outcomes for Prestige LP CDA versus ACDF: NDI and VAS neck and arm scores were noninferior, and SF-36 MCS was noninferior as well as statistically superior (Gornet et al. 2015). Gornet and colleagues reported continued success for Prestige LP CDA versus ACDF at 84 months: NDI and VAS scores were still noninferior, SF-36 PCS was noninferior, and SF-36 MCS was noninferior as well as statistically superior (Gornet et al. 2016).

Prestige ST: Outcomes at 24 months for Prestige ST CDA versus ACDF demonstrated no differences in NDI, VAS neck score (which had been significantly better for the CDA group at 12 months), VAS arm score, and SF-36 PCS and MCS (Mummaneni et al. 2007; Riew et al. 2008). Burkus and colleagues reported outcomes at 60 months for Prestige ST CDA versus ACDF: NDI was significantly better, VAS neck score was significantly better, VAS arm score had no significant difference, SF-36 PCS had no significant difference, and SF-36 MCS comparison was not reported (Burkus et al. 2010, 2014). Later in 2014, Burkus and colleagues reported 84-month outcomes for Prestige ST CDA versus ACDF, and the results were similar to previously reported 60-month outcomes except the SF-36 PCS score for the CDA group was now significantly improved compared to the ACDF treatment group (Burkus et al. 2014).

Prestige II: In 2004, Porchet and colleagues reported outcomes at 24 months for Prestige II CDA versus ACDF: NDI was statistically equivalent, VAS neck score statistical equivalence could not be shown between treatment groups, VAS arm score was statistically equivalent, and no significant differences were demonstrated for SF-36 PCS and MCS (Porchet and Metcalf 2004).

Long-Term Outcomes for Two-Level Adjacent Prestige LP CDA Versus ACDF

Gornet and colleagues reported 24-month outcomes for Prestige LP CDA versus ACDF at two levels: NDI was statistically superior, VAS neck score was noninferior, VAS arm score was noninferior, SF-36 PCS was noninferior, and SF-36 MCS was not reported (Gornet et al. 2017). Lanman and colleagues reported similar results for 84-month CDA outcomes: VAS neck score was statistically superior, SF-36 PCS was statistically superior, and SF-36 MCS was noninferior (Lanman et al. 2017). Although there was no statistically significant difference in the overall rate of implant- or procedure-related

adverse events for up to 84 months post-op, the trend favored the CDA treatment cohort (Lanman et al. 2017).

Porous Coated Motion (PCM) Cervical Disc

The Porous Coated Motion (PCM) device (Cervitech) is a non-constrained artificial cervical disc that was originally invented by McAfee and then was improved upon by Helmut Link and Arnold Keller (Fig. 1c) (Pimenta et al. 2004). It has a unique biomechanical design feature that incorporates a large radius ultrahigh-molecular-weight polyethylene bearing surface attached to the inferior vertebrae. This allows the device more physiologic translational motion in an arc, which is consistent with the natural motion of the cervical spine (Pimenta et al. 2004). The porous ingrowth material is composed of two ultra-thin layers of titanium with electrochemically coated calcium phosphate (Pimenta et al. 2004). The pore size was designed to match the bony trabecular architecture of the cervical vertebra (Pimenta et al. 2004).

Pimenta and colleagues reported the results of a pilot study performed between December 2002 and October 2003 in which 82 PCM devices were implanted in 53 patients. Significant improvements in all scores were seen postoperatively (NDI, VAS pain scores, and Treatment Intensity Gradient Test). One device migration of 4 mm was seen at 3 months and was observed (no reoperation). Eighty percent of patients had a good or excellent result at 1 week, improving to 90% of patients having a good or excellent result by 1 month (Odom's criteria), and this result remained stable 3 months after surgery (Pimenta et al. 2004). Later in 2007, Pimenta and colleagues published the first prospective CDA study to show significantly improved clinical outcomes for multilevel compared to single-level CDA (PCM disc) (Pimenta et al. 2007). Table 4 is a summary of PCM CDA outcomes data (Alvin et al. 2014; Delamarter et al. 2010; Phillips et al. 2009, 2013, 2015; Pimenta et al. 2004, 2007).

Long-Term Outcomes for Single-Level PCM CDA Versus ACDF

The FDA randomized controlled trials comparing PCM CDA vs. ACDF were performed by Phillips and colleagues (Phillips et al. 2013, 2015). The study cohort consisted of patients 18–65 years of age with single-level symptomatic cervical spondylosis (radiculopathy and/or myelopathy) unresponsive to nonoperative treatment. This included patients with prior non-adjacent or adjacent single-level fusion operations. The 24-month outcomes demonstrated that NDI was significantly better, VAS neck and arm scores were not significantly different, and SF-36 PCS and MCS were not significantly different for PCM CDA compared to ACDF (Phillips et al. 2013). The patients with PCM CDA had lower rates of prolonged dysphagia, greater patient satisfaction, and superior overall success compared to ACDF (Phillips et al. 2013).

In 2015, Phillips and colleagues reported 60-month outcomes for PCM CDA vs. ACDF: NDI was significantly better, VAS neck score was significantly better, VAS arm score was not significantly different, and SF-36 PCS and MCS were significantly better (Phillips et al. 2015). PCM CDA patients also had a lower rate of radiographical adjacent-level degeneration and a trend toward fewer secondary surgeries (Phillips et al. 2015). The authors interpreted the results of these studies to support PCM CDA as a viable and sustainable alternative to ACDF in appropriately selected patients (Phillips et al. 2015).

ProDisc-C Cervical Disc

The ProDisc-C (Synthes Spine) is an artificial cervical disc designed with these principles in mind: implant stability, ease and safety of insertion, minimal end plate disruption, and optimization of functional range of motion (Fig. 1d). These principles and design characteristics were investigated in several studies, and clinical outcomes are summarized in

Table 4 Summary of single- and multilevel Porous Coated Motion (PCM) disc outcomes for symptomatic cervical spondylosis or disc herniation. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Phillips et al. 2009, 2013, 2015; Pimenta et al. 2004, 2007)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Phillips 2015	RCT	110	60 mos	Imp	Imp/Imp	Imp	Imp	Ib
Phillips 2013	RCT	342	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Phillips 2009	PC	152	12 mos	Imp	Imp/Imp			IIb
Pimenta 2007	PC	140 (69 multilevel)	NR	Imp	Imp/Imp	NR	NR	IIb
Pimenta 2004	PC	53 (25 multilevel)	NR	Imp	Imp/Imp	NR	NR	IIb

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Table 5 Summary of single- and multilevel ProDisc-C disc outcomes for symptomatic cervical spondylosis or disc herniation. Recreated and modified from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Bertagnoli et al. 2005; Chin et al. 2017; Delamarter et al. 2010; Janssen et al. 2015; Kelly et al. 2011; Kesman et al. 2012; Mehren et al. 2006; Murrey et al. 2009; Nabhan et al. 2007; Peng et al. 2009; Suchomel et al. 2010; Zigler et al. 2013)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Janssen 2015	RCT	209	84 mos	Imp	Imp/Imp	Imp	Imp	Ib
Zigler 2013	RCT	209	60 mos	Imp	Imp/Imp	Imp	Imp	Ib
Kesman 2012	RCT	44	84 mos	Imp	Imp/Imp	Imp	Imp	Ib
Kelly 2011	RCT	199	24 mos					Ib
Delamarter 2010	RCT	345	48 mos	Imp	Imp/Imp	Imp	Imp	Ib
Murrey 2009	RCT	209	24 mos	Imp	Imp/Imp	Imp	Imp	Ib
Nabhan 2007	RCT	49	12 mos		Imp/Imp			Ib
Suchomel 2010	PC	54 (10 multilevel)	48 mos		Imp/Imp			IIb
Mehren 2006	PC	54 (20 multilevel)	12 mos	Imp	Imp/Imp			IIb
Bertagnoli 2005	PC	16 (4 multilevel)	12 mos	Imp	Imp/Imp			IIb
Peng 2009	R	166	24 mos	Imp	Imp/Imp			IIb
Chin 2017	R	110	24 mos	Imp	Imp/Imp			III

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Table 5 (Alvin et al. 2014; Bertagnoli et al. 2005; Chin et al. 2017; Delamarter et al. 2010; Janssen et al. 2015; Kelly et al. 2011; Kesman et al. 2012; Mehren et al. 2006; Murrey et al. 2009; Nabhan et al. 2007; Peng et al. 2009; Suchomel et al. 2010; Zigler et al. 2013). The

specific advantages of the ProDisc-C device include the absence of anterior plate fixation hardware, preservation of osseous end plates, immediate keel fixation stability, and the possibility of multilevel application. Biomechanically, the ProDisc-C implant is considered to represent a ball-and-socket/semi-constrained design with a fixed axis of rotation (Bertagnoli et al. 2005). DiAngelo and colleagues performed an in vitro biomechanical study to compare the effects of ProDisc-C CDA and ACDF in a multilevel human cadaveric model. Their results demonstrated that ACDF decreased motion at the index level in comparison with CDA (DiAngelo et al. 2004). The reduced motion at the index level was compensated at adjacent segments by an increase in motion. ProDisc-C CDA did not alter the motion patterns at either the index or adjacent levels compared with control (except in extension) (DiAngelo et al. 2004). Long-term outcomes from the FDA trials comparing ProDisc-C CDA to ACDF are summarized below.

Long-Term Outcomes for Single-Level ProDisc-C CDA Versus ACDF

In 2007, Nabhan and colleagues reported no significant difference in 12-month VAS neck and arm scores for ProDisc-C CDA versus ACDF (Nabhan et al. 2007). Later in 2009, Murrey and colleagues reported no significant differences in all outcome variables (NDI, VAS neck and arm scores, SF-36 PCS and MCS) at 24 months post-op (Murrey et al. 2009). This trend continued in 2010 with Delamarter and colleagues reporting 48-month outcomes for ProDisc-C CDA versus ACDF: NDI and VAS neck and arm scores were still not significantly different (Delamarter et al. 2010). However, in 2013, Zigler and colleagues reported 60-month outcomes for ProDisc-C CDA vs. ACDF and found that NDI and VAS neck scores were significantly better (VAS arm score, SF-36 PCS, and SF-36 MCS were not significantly different) (Zigler et al. 2013). Then at 84 months post-op, two studies demonstrated no significant difference in all outcome variables for ProDisc-C CDA versus ACDF (Janssen et al. 2015). For these two studies, the VAS and SF-36 scores showed noninferiority of the Prodisc-C group, which trended toward statistical superiority (Kesman et al. 2012).

Mobi-C Cervical Disc

The Mobi-C cervical artificial disc (LDR Medical) is a semi-constrained, bone-sparing prosthetic device (Fig. 1e) (Davis et al. 2015; Kim et al. 2007). The implant is composed of two cobalt-chromium-molybdenum alloy shells with an ultrahigh-molecular-weight polyethylene mobile insert facilitating five independent degrees of freedom (Davis et al. 2015; Kim et al. 2007). The mobility of the polyethylene insert decreases the transmission of the constraints on the bone-implant interface and reduces the constraints of the posterior facet joints (Kim et al. 2007). The implant has lateral self-retaining, incline-shaped teeth that were designed to support reliable vertebral end plate anchorage and stability (Kim et al. 2007). Tables 6 and 7 summarize Mobi-C CDA outcomes data (Bae et al. 2015; Beaurain et al. 2009; Davis et al. 2013, 2015; Guerin et al. 2012; Hisey et al. 2014, 2015, 2016; Huppert et al. 2011; Kim et al. 2007; Lee et al. 2012; Park et al. 2008, 2013; Radcliff et al. 2016a). The Mobi-C disc has FDA approval for both single- and two-level symptomatic cervical spondylosis and/or disc disease. Long-term outcomes from the FDA trials are summarized below.

Long-Term Outcomes for Single-Level Mobi-C CDA Versus ACDF

Hisey and colleagues reported 24-, 48-, and 60-month outcomes in multicenter, prospective, randomized, controlled FDA investigational device exemption clinical trials comparing Mobi-C CDA to ACDF in the treatment of

Table 6 Summary of FDA single-level (and other multi-level) Mobi-C cervical disc outcome studies. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Bae et al. 2015; Beaurain et al. 2009; Davis et al. 2013, 2015; Guerin et al. 2012; Hisey et al. 2014, 2015, 2016; Huppert et al. 2011; Kim et al. 2007; Lee et al. 2012; Park et al. 2008, 2013; Radcliff et al. 2016a)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Hisey 2016	RCT	245	60 mos	Imp	Imp/Imp			Ib
Hisey 2015	RCT	245	48 mos	Imp	Imp/Imp			Ib
Hisey 2014	RCT	245	24 mos	Imp	Imp/Imp			Ib
Lee 2012	PC	28 (9 multilevel)	24 mos	Imp	Imp/Imp			IIb
Huppert 2011	PC	231 (56 multilevel)	24 mos	Imp	Imp/Imp	Imp	Imp	IIb
Beaurain 2009	PC	76 (9 multilevel)	24 mos	Imp	Imp/Imp	Imp	Imp	IIb
Park 2013	R	75 (16 multilevel)	40 mos	Imp	Imp/Imp			IIb
Park 2008	R	53	20 mos	Imp	–/Imp			IIb
Kim 2007	R	23 (7 multilevel)	6 mos		Imp/Imp			IIb

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Table 7 Summary of FDA two-Level Mobi-C cervical disc outcomes for symptomatic cervical spondylosis or disc herniation. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Bae et al. 2015; Beaurain et al. 2009; Davis et al. 2013, 2015; Guerin et al. 2012; Hisey et al. 2014, 2015, 2016; Huppert et al. 2011; Kim et al. 2007; Lee et al. 2012; Park et al. 2008, 2013; Radcliff et al. 2016a)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Radcliff 2016	RCT	330	60 mos	Imp	Imp/Imp			Ib
Bae 2015	RCT	413 (225 multilevel)	48 mos	Imp	Imp/Imp			Ib
Davis 2015	RCT	291	48 mos	Imp	Imp/Imp			Ib
Davis 2013	RCT	330	24 mos	Imp	Imp/Imp			Ib
Guerin 2012	PC	40	24.3 mos	Imp	Imp/Imp	Imp	Imp	IIb

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PC* prospective cohort, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

symptomatic degenerative disc disease in the cervical spine (single level). The results demonstrated similar findings at each of these time points, namely, there were no significant differences in NDI or VAS neck and arm scores (Gornet et al. 2015; Hisey et al. 2014, 2015).

Table 8 Summary of single-level Kineflex-C cervical disc outcomes for symptomatic cervical spondylosis or disc herniation. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Coric et al. 2011, 2013, 2018)

Author	Design	n	Follow-up	NDI	VAS neck/arm	SF-36 PCS	SF-36 MCS	Design LoE
Coric 2018	RCT	269	60 mos	Imp	Imp/Imp			Ib
Coric 2013	RCT	74	48 mos	Imp	Imp/Imp			Ib
Coric 2011	RCT	269	24 mos	Imp	Imp/Imp			Ib

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Table 9 Single-level Secure-C cervical disc outcomes for symptomatic cervical spondylosis or disc herniation (Vaccaro et al. 2013)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Vaccaro 2013	RCT	380	24 mos	Imp	Imp/Imp	Imp	Imp	Ib

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

Long-Term Outcomes for Two-Level Adjacent Mobi-C CDA Versus ACDF

In 2013, Davis and colleagues reported 24-month outcomes for Mobi-C CDA versus ACDF at two adjacent levels: NDI was significantly better, and although VAS neck score was significantly improved at 3 and 6 months postoperatively, there were no statistically significant differences at any other time point. Also, there were no significant differences between treatment groups for VAS arm scores at any time point (Davis et al. 2013). Later in 2015, Davis and colleagues reported similar results at 48 months post-op: NDI was significantly better, but there were no significant differences in VAS neck and arm scores between treatment groups (Davis et al. 2015). For 60-month outcomes, Radcliff and colleagues reported that NDI was significantly better, and although there was more improvement in VAS neck and arm scores for the CDA group, the difference was not statistically significant (Radcliff et al. 2016a).

Kineflex-C Cervical Disc

The Kineflex-C artificial cervical disc (SpinalMotion Inc.) is a cobalt-chrome on cobalt-chrome alloy (metal-on-metal) semi-constrained device (Fig. 1f) (Coric et al. 2011). It is composed of three pieces (two end plates and a mobile center that translates within a retention ring). There is a midline keel on the device's end plate that provides immediate fixation, and the end plates are coated with a titanium plasma spray to promote bony ingrowth for long-term fixation (Coric et al. 2011). Table 8 summarizes Kineflex-C CDA outcomes data (Coric et al. 2011, 2013, 2018). Long-term outcomes for the FDA trials comparing Kineflex-C CDA and ACDF are summarized below.

Long-Term Outcomes for Single-Level Kineflex-C CDA Versus ACDF

Coric and colleagues reported 24- and 48-month outcomes for Kineflex-C CDA versus ACDF and found no significant differences between treatment groups based on NDI or VAS scores (Coric et al. 2011, 2013). However, clinical success (maintenance or improvement in neurological exam, minimum of 20% improvement in NDI, no device failure, no reoperation at the index level, no major device-related adverse event) was significantly higher in the Kineflex-C group compared to ACDF (Coric et al. 2011). Recently, Coric and colleagues reported clinical

Table 10 Summary of single- and multilevel Discover disc outcomes for symptomatic cervical spondylosis or disc herniation. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Du et al. 2011; Fang et al. 2013; Li et al. 2013; Miao et al. 2014; Rozankovic et al. 2017; Shi et al. 2016; Skeppholm et al. 2015)

Author	Design	Study size	Follow-up duration	NDI	VAS neck/ arm scores	SF-36 PCS	SF-36 MCS	Design LoE
Rozankovic 2017	RCT	105	24 mos	Imp	Imp/Imp			Ib
Skeppholm 2015	RCT	137 (43 multilevel)	24 mos	Imp	Imp/Imp			Ib
Shi 2016	PC	128	24 mos	Imp				IIb
Miao 2014	PC	79 (23 multilevel)	31.6 mos		Imp/Imp			IIb
Li 2013	PC	55	24 mos	Imp	Imp/Imp			IIb
Du 2011	PC	25 (1 multilevel)	15 mos	Imp	Imp/Imp			IIb
Fang 2013	R	18	15 mos		Imp/Imp			IIb

Imp improved, *LoE* level of evidence, *MCS* mental component score, *NDI* neck disability index, *PCS* physical component score, *R* retrospective, *RCT* randomized controlled trial, *SF-36* short form-36, *VAS* visual analogue scale

success was significantly improved for the Kineflex-C CDA group compared to ACDF at 60 months post-op (Coric et al. 2018). Also, the results demonstrated there were no significant differences between treatment groups in terms of reoperation/revision surgery or device-/surgery-related adverse events during the 5 years of follow-up (Coric et al. 2018).

Secure-C Cervical Disc

The selectively constrained Secure-C artificial cervical disc (Globus Medical) is an anterior articulating intervertebral device comprised of two cobalt-chrome alloy serrated end plates and a sliding polyethylene central core. The end plates have a titanium plasma spray coating on its bone-contacting surface to promote long-term bony ingrowth (Vaccaro et al. 2013). The Secure-C artificial cervical disc is designed for motion in flexion/extension up to 30 ± 15°, lateral bending up to 20 ± 10°, and sagittal translation of up to ±1.25 mm (Vaccaro et al. 2013). There is less available FDA trial outcomes data (compared to the aforementioned discs) comparing Secure-C CDA to ACDF (Table 9) (Vaccaro et al. 2013).

Long-Term Outcomes for Single-Level Secure-C CDA Versus ACDF

Overall success results (improvement of at least 25% in baseline NDI, no device failure requiring revision, and absence of major complications [major vessel injury, neurological damage, or nerve injury]) demonstrated statistical superiority of the randomized Secure-C group compared with the randomized ACDF group at 24 months post-op (Vaccaro et al. 2013). There was noninferiority of the randomized Secure-C group at all postoperative time points (up to 24 months) for both (1) 25% or more and (2) 15-point or more improvement in NDI (Vaccaro et al. 2013). Also, the study demonstrated statistical noninferiority of Secure-C compared to ACDF for VAS neck and arm pain scores (and also statistical superiority for VAS neck pain) (Vaccaro et al. 2013).

Discover Cervical Disc

The non-constrained Discover artificial cervical disc (DePuy Spine) is an MRI-compatible ball-and-socket design consisting of two end plates manufactured from titanium alloy and

a polyethylene core (Du et al. 2011; Shi et al. 2016). The inferior end plate is a two-piece design with an ultrahigh-molecular-weight polyethylene insert and features a spherical bearing surface that allows motion in all rotational directions (Du et al. 2011). The Discover disc has a 7° lordotic angle split evenly between the superior and inferior end plates for restoration of lordosis at the index level (Du et al. 2011). Table 10 summarizes Discover CDA outcomes data (Du et al. 2011; Fang et al. 2013; Li et al. 2013; Miao et al. 2014; Rozankovic et al. 2017; Shi et al. 2016; Skeppholm et al. 2015). In contrast to the aforementioned artificial cervical discs, the Discover disc is not approved by the FDA; however, its widespread use for CDA warrants a brief summary of its outcomes.

Long-Term Outcomes for Single- and Multilevel Discover CDA Versus ACDF

In 2017, Rozankovic and colleagues reported 24-month outcomes for Discover CDA vs. ACDF (single level): NDI and VAS neck and arm scores were significantly improved compared to ACDF (Rozankovic et al. 2017). In contrast, Skeppholm and colleagues did not find significantly better 24-month outcomes for CDA compared to ACDF based on NDI scores. In contrast to the Rozankovic study, the Skeppholm study included patients with multilevel cervical disc degeneration who received CDA at adjacent levels, which could explain the difference in results (Skeppholm et al. 2015).

Summary of Complications Associated with Cervical Disc Arthroplasty

Biomechanical and clinical studies suggest that the rate of adjacent segment degeneration (ASDG; *radiographic* evidence of degeneration at the adjacent level) is significantly higher for ACDF compared to CDA (Baba et al. 1993; Chang et al. 2007; Coric et al. 2010; DiAngelo et al. 2003; Dmitriev et al. 2005; Eck et al. 2002; Matsunaga et al. 1999; Nunley et al. 2018; Park et al. 2011; Puttlitz et al. 2004; Reitman et al. 2004; Wigfield et al. 2002a). However, rates of adjacent segment disease (ASDI; development of new *clinical* symptoms correlating with adjacent segment degeneration) between CDA and ACDF continue to be debated. Jawahar and colleagues found no difference in the incidence of ASDI between CDA and ACDF. On the contrary, there has been growing evidence from other long-term follow-up studies and meta-analyses that suggest CDA may reduce ASDI and reoperation rates in comparison with ACDF (Gao et al. 2013; Ishihara et al. 2004; Jawahar et al. 2010; McAfee et al. 2012; Robertson et al. 2005; Upadhyaya et al. 2012).

Other adverse outcomes associated with CDA include heterotopic ossification (HO), delayed fusion around cervical disc prosthesis, asymmetric end plate preparation resulting in postoperative kyphosis, and reduction in caudal vertebral body height (Yi et al. 2010). Rates of HO with the FDA investigational device exemption publications have been reported, and grade 4 HO rates are as high as 13% (Gornet et al. 2016; Hisey et al. 2016; Janssen et al. 2015; Nunley et al. 2018; Radcliff et al. 2016a). Table 11 is a summary of the commonly reported complications associated with CDA in the literature (Alvin et al. 2014; Anderson et al. 2004; Beaurain et al. 2009; Bertagnoli et al. 2005; Bhadra et al. 2009; Bryan 2002; Cheng et al. 2011; Coric et al. 2006, 2011; Ding et al. 2012; Du et al. 2011; Duggal et al. 2004; Garrido et al. 2010; Goffin et al. 2003, 2010; Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Huppert et al. 2011; Kelly et al. 2011; Kesman et al. 2012; Kim et al. 2007, 2008, 2009; Lee et al. 2010; Leung et al. 2005; Li et al. 2013; Mehren et al. 2006; Mummaneni et al. 2007; Murrey et al. 2009; Nabhan et al. 2007; Park et al. 2008, 2013; Peng et al. 2009, 2011; Phillips et al. 2013; Pickett et al. 2004; Pimenta et al. 2004, 2007; Porchet and Metcalf 2004; Quan et al. 2011; Ren et al. 2011; Riew et al. 2008; Riina et al. 2008; Robertson and Metcalf 2004; Robertson et al. 2005; Ryu et al. 2010; Sasso et al. 2011; Sekhon 2003; Sekhon et al. 2005; Shim et al. 2006; Suchomel et al. 2010; Tu et al. 2011; Walraevens

Table 11 Summary of cervical disc arthroplasty complications. Recreated from Alvin et al. Cervical arthroplasty: a critical review of the literature. The Spine Journal. (Alvin et al. 2014; Anderson et al. 2004; Beaurain et al. 2009; Bertagnoli et al. 2005; Bhadra et al. 2009; Bryan 2002; Cheng et al. 2011; Coric et al. 2006, 2011; Ding et al. 2012; Du et al. 2011; Duggal et al. 2004; Garrido et al. 2010; Goffin et al. 2003, 2010; Guerin et al. 2012; Hacker 2005; Heidecke et al. 2008; Heller et al. 2009; Huppert et al. 2011; Kelly et al. 2011; Kesman et al. 2012; Kim et al. 2007; 2008, 2009; Lee et al. 2010, 2012; Leung et al. 2005; Li et al. 2013; Mehren et al. 2006; Mummaneni et al. 2007; Murrey et al. 2009; Nabhan et al. 2007; Park et al. 2008, 2013; Peng et al. 2009, 2011; Phillips et al. 2013; Pickett et al. 2004; Pimenta et al. 2004, 2007; Porchet and Metcalf 2004; Quan et al. 2011; Ren et al. 2011; Riew et al. 2008; Riina et al. 2008; Robertson and Metcalf 2004; Robertson et al. 2005; Ryu et al. 2010; Sasso et al. 2011; Sekhon 2003, 2005; Shim et al. 2006; Suchomel et al. 2010; Tu et al. 2011; Walraevens et al. 2010; Wang et al. 2008; Yang et al. 2008; Yoon et al. 2006; Zigler et al. 2013)

Author	Disc	HO (%)	ASDI (%)[a]	ASDG (%)[a]	Other (%)[a]
Cheng 2011	Bryan	2.4	None	None	Dysphagia (2.4)
Tu 2011	Bryan	50	None	None	None
Lee 2010	Bryan	27	None	None	None
Ryu 2010	Bryan	52.8	None	None	None
Yang 2008	Bryan	None	None	None	None
Shim 2006	Bryan	None	None	None	Op failure (17)
Hacker 2005	Bryan	None	(4.6)	None	Dysphonia (4.5)
Lafuente 2005	Bryan	None	None	None	Dysphonia (7)
Leung 2005	Bryan	17.8	None	None	None
Ding 2012	Bryan	None	None	23	None
Quan 2011	Bryan	47.6	19	19	None
Ren 2011	Bryan	4.4	None	None	None
Garrido 2010	Bryan	None	5	None	Reoperation (6.7)
Bhadra 2009	Bryan	13	None	None	None
Kim 2009	Bryan	None	None	None	None
Heidecke 2008	Bryan	29	None	None	None
Kim 2008	Bryan	None	None	None	None
Wang 2008	Bryan	None	None	None	None
Sasso 2007	Bryan	None	5.4	None	Reoperation (3.5)
Coric 2006	Bryan	None	None	None	None
Yoon 2006	Bryan	None	None	None	None
Duggal 2004	Bryan	None	None	None	None
Pickett 2004	Bryan	None	None	None	None
Sekhon 2003	Bryan	None	None	None	None
Zhang 2012	Bryan	12.5	1.6	None	Reoperation (1.6)
Sasso 2011	Bryan	None	4.1	None	Reoperation (3.7)
Coric 2010	Bryan	5.6	1.7	None	Reoperation (7.5)
Goffin 2010	Bryan	None	4.1	None	Reoperation (8.2)
Walraevans 2010	Bryan	34	None	None	None
Heller 2009	Bryan	None	None	None	Reoperation (2.5)
Pickett 2006	Bryan	2.7	None	None	Reoperation (5.4)
Robertson 2005	Bryan	None	1.3	17.5	None
Sekhon 2005	Bryan	None	None	None	None
Anderson 2004	Bryan	None	None	None	Reoperation (2.2)
Goffin 2003	Bryan	None	None	None	Reoperation (2.0)
Bryan 2002	Bryan	None	None	None	None
Peng 2011	Prestige	None	None	None	None
Riina 2008	Prestige	None	None	None	None
Burkus 2010	Prestige	3.2	2.9	None	Reoperation (10.5)

(continued)

Table 11 (continued)

Author	Disc	HO (%)	ASDI (%)[a]	ASDG (%)[a]	Other (%)[a]
Riew 2008	Prestige	None	None	None	Reoperation (1.9)
Mummaneni 2007	Prestige	None	1.1	None	Reoperation (1.8)
Porchet 2004	Prestige	None	None	None	None
Robertson 2004	Prestige	None	None	None	None
Phillips 2013	PCM	38	39.1	None	None
Pimenta 2007	PCM	0.7	None	None	Reoperation (2.2)
Pimenta 2004	PCM	None	None	None	None
Suchomel 2010	ProDisc-C	88	None	None	None
Peng 2009	ProDisc-C	None	None	None	None
Nabhan 2007	ProDisc-C	None	None	None	None
Mehren 2006	ProDisc-C	57	None	None	None
Bertagnoli 2005	ProDisc-C	None	None	None	None
Zigler 2013	ProDisc-C	None	None	None	Reoperation (2.9)
Kesman 2012	ProDisc-C	None	None	None	None
Kelly 2011	ProDisc-C	None	None	None	None
Murrey 2009	ProDisc-C	2.9	None	None	Reoperation (1.9)
Guerin 2012	Mobi-C	27.7	None	None	None
Lee 2012	Mobi-C	77.3	None	None	None
Park 2013	Mobi-C	94.1	None	None	None
Beaurain 2009	Mobi-C	67	None	9.1	Dysphagia (10.5)
Park 2008	Mobi-C	None	None	None	None
Kim 2007	Mobi-C	None	None	None	None
Huppert 2011	Mobi-C	62	None	None	Reoperation (2.6)
Coric 2011	Kineflex-C	None	None	9	Reoperation (5)
Li 2013	Discover	18	None	7.2	None
Du 2011	Discover	None	9	None	None

[a]Complication rate reported for the arthroplasty investigational cohort
ASDI adjacent segment disease, *ASDG* adjacent segment degeneration, *HO* heterotopic ossification, *PCM* porous coated motion

et al. 2010; Wang et al. 2008; Yang et al. 2008; Yoon et al. 2006; Zigler et al. 2013).

Metal Ion Toxicity

Articulating prosthetic implants are subject to wear and corrosion following implantation. An advantage of metal-on-metal bearings is the substantially lower volumetric wear debris when compared with conventional metal-on-polyethylene bearing couples. A concern regarding any metal-on-metal CDA (e.g., Prestige LP CDA) is that patients may have increased serum metal ion concentrations after surgery since implant wear can lead to local and systemic transport of metal debris (Coric et al. 2018; Gornet et al. 2016). Toxicology-related sequelae from chronically elevated metal ion levels have not been determined. In support of CDA, a 5-year randomized control trial (comparing single-level Kineflex-C CDA with ACDF) demonstrated that serum ion levels (cobalt and chromium) were significantly lower than the levels that merit monitoring (Coric et al. 2018). However, several case studies have reported some early local effects of wear debris (Cavanaugh et al. 2009; Gornet et al. 2016; Hacker et al. 2013).

Patient Selection

CDA is associated with high success rates when performed for appropriately selected patients. However, complications may occur with

improper patient selection, technical errors, or progression of underlying cervical disease (Leven et al. 2017; Nunley et al. 2018; Nunley et al. 2012). Current indications for CDA in the United States (largely dictated by FDA approval of the various prosthetic devices) include skeletally mature patients with cervical radiculopathy and/or myelopathy at a single or two adjacent levels without severe facet joint degeneration, instability, malalignment or kyphosis, or severe neck pain only (Leven et al. 2017; Nunley et al. 2018). Other contraindications include retrovertebral compression (i.e., congenital stenosis or ossification of the posterior longitudinal ligament) and spondyloarthropathies (ankylosing spondylitis) (Leven et al. 2017; Nunley et al. 2018). Patients with a severe axial neck pain due to facet degeneration should be counseled appropriately since these symptoms may not improve after CDA (Leven et al. 2017). Also, some authors have recommended a disc height of 3 mm or greater for adequate disc space access and removal (Ding and Shaffrey 2012). Placing an oversized implant into a collapsed disc space can potentially place excessive forces through the facet joints and lead to worsening of axial neck pain (Ding and Shaffrey 2012).

Cost Efficacy

Although many studies have demonstrated successful treatment with CDA, economic analysis and health costs are also important determinants for obtaining insurance coverage in the United States (Nunley et al. 2018). Therefore, recent studies have focused on analyzing the incremental cost-effectiveness of CDA in comparison with the ACDF. Ament and colleagues reported the incremental cost-effectiveness ratio of CDA compared to ACDF at 2 years post-op for two-level disease was $24954/quality-adjusted life year (QALY). This value is considered to be well within the commonly accepted threshold of $50000/QALY (Ament et al. 2014). Ament and colleagues updated their cost utility analysis at 5 years post-op and reported that the incremental cost-effectiveness ratio for CDA continued to remain below this $50000/QALY threshold (Ament et al. 2016).

In 2014, McAnany and colleagues analyzed 5-year outcomes data and reported cost benefits of CDA compared to ACDF (McAnany et al. 2014). The CDA cost-effectiveness ratio was $35976/QALY compared to $42618/QALY for ACDF (McAnany et al. 2014). In two studies by Radcliff and colleagues, the results suggested that CDA was also the more cost-effective treatment over ACDF (Radcliff et al. 2015, 2016b). Using 3-year data, they found that the total costs paid by insurers for CDA were $34979 compared to $39829 for ACDF. This difference may have been from readmissions and reoperations, which were higher for the ACDF cohort (Radcliff et al. 2015). In another study which analyzed 7-year data, Radcliff and colleagues reported continued cost benefits of CDA over a range of scenarios (Radcliff et al. 2016b).

In 2016, Ghori and colleagues performed a Markov analysis to evaluate the societal costs of ACDF versus CDA in a theoretical cohort of 45–65-year-old patients (Ghori et al. 2016). Their results demonstrated that the long-term costs for CDA were less expensive throughout the model's age range (Ghori et al. 2016). Factors driving lower costs included lower perioperative costs, earlier return to work, and lower reoperation rates (Ghori et al. 2016).

Conclusions

Total cervical disc replacement attempts to preserve normal motion at adjacent segments and in doing so may decrease the incidence of adjacent segment degeneration and disease. Motion-preserving CDA has showed great promise with equivalent quality-of-life outcomes to ACDF in many long-term comparative studies. However, complications such as heterotopic ossification have been reported to occur with some frequency, but the ultimate clinical consequences or implications (in comparison with ACDF) are yet to be determined. Overall, there exists robust data to support CDA as a

viable alternative to ACDF in select patients, but further investigation and continued long-term comparison between CDA and ACDF is warranted.

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