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REVIEW ARTICLE

Cervical disc replacement — emerging equivalency to anterior cervical discectomy and fusion

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Abstract
Purpose Cervical disc replacement has become an acceptable alternative to anterior cervical fusion for the surgical treatment of cervical spine spondylosis resulting in radiculopathy or myelopathy following anterior discectomy and decompression. This concise overview considers the current state of knowledge regarding the continued debate of the role of cervical disc replacement with an update in light of the latest clinical trial results.
Methods A literature review was performed identifying clinical trials pertaining to the use of cervical disc replacement compared to cervical discectomy and fusion. Single level disease and two level disease were considered. Outcome data from the major clinical trials was reviewed and salient points identified.
Results With lengthier follow-up data becoming available, the equivalence of CDR in appropriately selected cases is becoming clear. This is chiefly manifested by reduced re-operation rates and reduced incidence of adjacent level disease in those treated with arthroplasty.
Conclusion Cervical disc replacement shows emerging equivalence in outcomes compared to the gold standard anterior cervical discectomy and fusion. Further longer term results are anticipated to confirm this trend.

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Introduction

Anterior cervical discectomy and fusion (ACDF) has long been the standard surgical treatment for symptomatic cervical disc herniation and spondylosis with radiculopathy or myelopathy. While this procedure is effective at relieving neural compression and providing symptom relief, there is a reported incidence of clinically significant adjacent level degeneration (ALD) of 3-5 % per year. Cervical disc replacement (CDR) has been developed as a motion-preserving alternative to fusion, with the hope that retained motion at the operative level may reduce ALD.

Design and implant characteristics

Since Fernstrom described the first CDR, a steel ball placed within the native annulus fibrosis, the design of the CDR has changed significantly [1]. The native cervical motion segment exhibits coupled translation and rotation in multiple axes. The range of motion of the cervical motion segment is 5-7° in the coronal and sagittal planes, and less in axial torsion. Stability of the intervertebral segment is conferred by the disc, anterior and posterior longitudinal ligaments, uncovertebral joints, and the posterior ligamentous complex.

The shape of the bearing surfaces may be a ball-and-trough, a semi-constrained metal endplate with a metal-on-polyethylene insert or cross-linked polyethylene annulus. The ball-and-trough allows for rotation and translation in an antero-posterior plane, whereas the semi-constrained (e.g., Mobi C) allows more lateral and antero-posterior translation

of the bearing. Newer 'cushion' designs have a prosthetic annulus with a deformable prosthetic nucleus. The aim of this design is to reduce translation of moving parts, reducing particulate wear particles, and capturing wear particles within the prosthetic annulus in an attempt to avoid secondary osteolysis.

The CDR bearing surface may consist of a metal-on-polyethylene (MoP), metal-on-metal (MoM) or a polyethylene annulus encasing a compressible synthetic annulus. Wear in MoP bearings have been associated with osteolysis and loosening. Metallosis and lymphocytic produced in CDR owing to lower compressive loads, higher number of cycles, and less shear due to a much smaller range of motion. The true incidence of wear related complications in CDR is unknown to date [2].

Retrieval analyses of failed CDRs have shown similar pathological changes as in appendicular joints, with polymetric debris and macrophage-driven inflammation in MoP bearings and lymphocytic reactions with MoM bearings [2–6]. The presence of wear-related complications in MoP and MoM CDR have been associated with endplate impingement [3–6]. Impingement is not completely understood, however, it may be as a result of insertion of an implant in relative extension, implant subsidence, incorrect sizing or excessive discoligamentous resection resulting in increased angulation or translation [5].

Indications and contra-indications

Cervical disc replacement is currently indicated for single- or two-level disc herniation/spondylosis with radiculopathy or myelopathy. Contra-indications include pre-operative instability (>3.5 mm translation or 11° segmental kyphosis), facet joint arthritis, osteoporosis, previous local infection at the surgical site, and ankylosis. CDR should not be performed in cases of congenital stenosis or myelopathy due to retrovertebral cord compression (e.g., OPLL, flavum hypertrophy), since adequate cord decompression is not possible with anterior decompression whilst maintaining the integrity of vertebral endplates. Use of CDR continues to be recommended for individuals meeting the enrollment criteria of the various CDR clinical trials.

Clinical outcomes in CDR randomized controlled trials

Single level CDR or ACDF

Five randomized controlled trials have now published results at four to seven years post-enrollment after having previously reported results at earlier time points [7–15]. Each paper reviews the clinical trial of a different CDR prosthesis; all are compared to ACDF performed using an allograft spacer with anterior plating as the control group. The studies have reported outcomes according to improvements in VAS scores for neck and arm, neck disability index (NDI), short-form (SF)-12 or −36 scores or components of (most commonly physical component score (PCS) or mental component score (MCS)). The 'overall success' and 'neurological success' are recorded in each study with success variably defined according to improvements. Most statistical analyses have been designed to prove non-inferiority.

As previously established, when reviewing these studies we have considered the minimum clinically important differences (MCIDs) as follows: NDI 7 points; SF-36 4.1; VAS neck pain 2.5; VAS arm pain 2.5 [16]. We have considered the following to be indicative of significant clinical benefit (SCB): NDI 9.5 points; SF-36 PCS 6.5; VAS neck pain 3.5; VAS arm pain 3.5 [16]. A summary of the latest published clinical results for CDR is seen in Table 1. Where possible exact values are recorded from text but in two instances success rates according to attainment of predefined improvement criteria alone are reported [8, 10]. The benefit of CDR over ACDF reached the MCID for VAS neck and arm pain at a four year follow-up FDA trial published by Sasso et al. [11]. Similarly at seven years, Jannsen et al. and Burkus et al., both demonstrated that CDR resulted in greater reduction of neck pain VAS scores and the difference between CDR and ACDF exceeded the MCID [7, 9].

Several meta-analyses have been published, reporting the clinical results of CDR compared to ACDF. A recent criticism of these is the failure to adhere to AMSTAR, an assessment tool for systematic reviews [17, 18]. However, of the publications reviewed by Tashani et al. the best quality review was published in 2012, which pre-dates four of the most up-to-date reports from the clinical trials.

Boselie et al. provided a systematic review published in the Cochrane Database of Systematic Reviews [19]. They concluded that, while the use of CDR should be restricted to clinical trial settings, there was a tendency for results to be in favour of CDR. They also noted 'high quality evidence that the goal of preservation of segmental mobility in arthroplasty was met'. A further update with five years or more follow-up was deemed necessary, however, the most recent Cochrane Review on the topic was withdrawn [20].

In 2012, Fallah et al. reviewed nine trials consisting of 1778 subjects noting that CDR was associated with a statistically but not clinically significant lower rate of neurologic failure and improvement in VAS neck pain scores [21]. Other measures including VAS arm pain and SF-36 PCS were not significantly different. And the authors conclude no strong evidence to support the routine use of CDR over ACDF while citing the lack of long-term data to support the safety of CDR.

The most contemporary meta-analysis comes from Wu et al. that takes into account four clinical trials with at least four years of follow-up [22]. Long-term improvement in NDI,

Table 1 Clinical outcome results from the most recent publications of randomized trials testing five different CDR prostheses against ACDF

Author/year/ follow-up	Implants	Number enrolled (followed-up)	VAS pain scores neck		VAS pain scores — arm		NDI		Short Form–36 (PCS)		Overall success	Neurologic success
			Pre	Post	PRe	Post	Pre	Post	Pre	Post		
Sasso/ 2011/ 4 years	Bryan cervical disc	242 (181)	75.0	**20.7***†	71.2	**16.6***†	51.4	13.2*†	32.6	48.4*†	85 %	93 %
	Allograft spacer and anterior plate	221 (138)	74.8	**30.6***†	71.2	**22.4***†	50.2	19.8*†	31.8	15.7*†	72.5 %	90 %
Burkus/ 2014/ 7 years	Prestige	276 (212)	68.2	**13.1***†	59.1	12.7*	55.7	18.1*†	31.9	45.1*†	73 %†	88 %†
	Allograft spacer and anterior plate	265 (183)	69.3	**19.4***†	62.4	15.0*	56.4	23.8*†	32.0	43.2*†	60 %†	80 %†
Jannsen/ 2015/ 7 years	ProDisc-C	103 (79)	73.0	**27.3***	63.9	23.2*	53.9	22.0*	34.5	46.7*		88 %
	Allograft spacer +/− local bone and anterior plate	106 (73)	65.7	**22.8***	61	21.2*	52.3	22.0*	35.2	47.3*		89 %
			% patients improving 20 mm		% patients improving 20 mm		% patients improving >20 % baseline score		% patients improving >15 % baseline score			
Phillips/ 2015/ 5 years	PCM cervical disc	211 (160)	72 %*†		81 %*		85 %*†		74 %*			92 %
	Allograft spacer and anterior plate	184 (128)	76 %*†		71 %*		74 %*†		57 %*			86 %
							% patients improving 30 points					
Hisey/ 2015/ 4 years	Mobi-C cervical disc prosthesis	164 (128)	*		*		81 %		*		70 %	
	Allograft spacer and anterior plate	81 (55)	*		*		78 %*		*		59 %	

VAS: visual analogue scale; *NDI*: Neck disability index; *PCS*: physical component summary. Scores and results are shown at enrolment and at latest follow-up where available. Success rates as defined by the authors are shown when original values were not available in text — applies to Hisey et al. and Phillips et al. *indicates a statistically significant improvement in outcome measure from baseline. † indicates a statistically significant differeence between the treatment groups at latest follow-up. Results in bold indicate the difference between measures at the latest follow-up are greater than the accepted value for minimum clinically important difference

VAS arm and neck pain, SF-36 PCS, overall success, and neurologic success were all greater in CDR than ACDF.

Two-level CDR vs. ACDF

Evidence for two-level CDR is limited to data for the Mobi-C prosthesis. Davis et al. reported statistically significant improvements of CDR over ACDF for NDI (36.5 vs. 28.5 points) and SF-12 PCS at 4 years, but the difference between interventions meets the MCID only for NDI [23].

Hybrid CDR and ACDF

One systematic review was found reporting on hybrid CDR and ACDF [24]. No conclusions could be reached due the heterogeneity of number of fusion levels, the number of permutations of anatomical locations for each treatment and low numbers reported in very few studies. No randomized clinical trials have included hybrid constructs as a test population.

Range of motion at the operated disc level

In biomechanical testing, CDR has been found to closely mimic the native disc in range of motion. Not surprisingly a significantly higher range of motion is reported in the CDR compared to ACDF [12, 15, 25, 26]. Typically 6-9° of motion can be expected in the coronal and sagittal plane, and motion is preserved but not improved in mid-term follow-up of four to seven years [7, 8, 15, 27]. Boselie et al. concluded in their review that there is high level evidence for motion preservation in CDR but that the long term follow-up still lacks to reveal whether this translates into lower rates of adjacent level surgery [19].

In an in vivo study, Rong et al. reported on 24 patients undergoing CDR with the Prestige LP at C5-6 [28]. Patients were divided in to two groups based on whether they had decreased or increased range of movement post-operatively. In all cases the COR had a cranial shift from pre-operatively but the group with increased range also had a shift in the sagittal plane.

A comprehensive biomechanical study by Gandhi et al. compared the Bryan and Prestige LP CDR [29]. Two Nm moments were applied to intact spines and compared to spines with single level CDR, two level CDR, two level fusions or a hybrid with both CDR and ACDF at adjacent levels. CDR maintained motion at both the index level and the remainder of the spine and under physiologic loads this was close to the intact model.

Adjacent level degeneration

The effect of motion preservation on reduction in ALD is an important potential benefit of CDR over ACDF. Biomechanical theories of ALD have reported increased load transfer to cephalad and caudal intervertebral discs after fusion, resulting in hypermobility, increased intra-discal pressure, and accelerated disc degeneration [30–33].

One study has reported reduced rates of radiographic ALD. Revision surgery for ALD, considered a measurable endpoint for clinical ASD, has been reported to be decreased in CDR compared to ACDF in some studies and not significantly different in other studies [7, 11, 12, 15, 23, 34–36]. Phillips et al. found radiographic ALD in 33 % of patients undergoing CDR compared to 50 % of those with ACDF at 5 years [10].

Recent analysis of the long-term Prodisc-C database, presented but not yet published in full, has shown significantly less progressive radiographic ALD at seven year follow-up in the Prodisc patients as compared to ACDF. In addition, the rate and severity of progressive ALD was seen to inversely correlate with the final range of motion of the surgical level in the CDR patients.

While the theory of motion preservation in CDR lowering the rate of clinically significant ALD seen in ACDF seems to make sense biomechanically, there is insufficient evidence at this point to confirm the efficacy of CDR in preventing clinically significant ALD. One meta-analysis specifically looking at this area of controversy reviewed three papers and found that although there was a lower rate of ALD in CDR the difference was not significant [37].

Survivorship and re-operation rates

Reoperation rates are consistently reported to be lower in CDR than in ACDF. Mid-term re-operation rates are comparable with total hip arthroplasty when performed for osteoarthritis according to national joint registry data. In comparison, the reported all-cause reoperation rate for ACDF in the same studies varied from 4.5-18 % in single level disease [7–10]. Only one RCT reported no difference in re-operation rate at 4 years [11].

The benefit in CDR over ACDF has been supported by meta-analyses, reporting lower re-operation rates in CDR [22, 34]. Wu et al. reported that secondary surgery rates were lower in the CDR groups for both the index (RR 0.45) and adjacent segment (RR 0.53) [22]. A slightly higher re-operation rate was noted by Aragonés et al. — they reported a meta-analysis of 1101 patient undergoing either MoP CDR or ACDF but the difference was not statistically significant [38]. As expected, lengthier follow-up has been linked with increasing cases of adjacent segment degeneration and disease hence the need for ongoing follow-up [39].

ASD is the most common cause of re-operation for ACDF, and revision or supplemental fixation has been more commonly reported in ACDF, largely owing to pseudoarthrosis or implant related complications [40]. In the seven year follow-up

study reported by Jannsen et al., there was a 15 % re-operation rate at the index level following ACDF and 6 % following CDR.

Cost-effectiveness

Menzin et al. reported a direct cost saving of $431 for CDR and an overall cost saving of $6987 over two years when compared with ACDF. The cost benefit was attributed to a higher return to work rate and higher work productivity in the CDR group [41].

A 20-year cost projection by Qureshi et al. for single-level disease reported a $4836 saving ($11,987 vs. $16823) for CDR over ACDF [42]. This study assumed a 5 % pseudoarthrosis rate and 3 % annual revision for ASD for ACDF and a 1.5 % annual hardware failure rate for CDR. By their calculation, CDR would cost $3042 per quality adjusted life year (QALY) compared with $8760 per QALY for ACDF. The limitation in this data is the unknown incidence of ASD in CDR to accurately project 20-year cost-analysis. It is worth noting, however, that the cost per QALY for CDR is well under the generally accepted threshold of $50,000-100,000.

Using a collective administrative claims database Radcliff et al. showed that at 36 months post-operatively, re-operation was significantly greater for patients undergoing ACDF compared to CDR (10.5 % vs. 5.7 %) [43]. This was the main factor in the author's conclusion that the total costs paid by insurers were almost US$5000 less for CDR.

Limitations in interpretation of studies

The main limitations in comparing CDR and ACDF come from the low number of trials with level-1 and −2 evidence, loss to follow-up in these trials, and the lack of long-term (>10 year) data. In level-1 evidence, follow-up rate was lower in the ACDF group than in the CDR group, and may be a potential bias, however, both groups had follow-up at four to seven years of 65-92 % [8, 11, 12, 15]. Longer duration of follow-up is likely needed to better understand the late wear characteristics and wear-related complications associated with CDR.

Additionally, agreement on a definition of what defines success regarding clinical improvement and more uniform reporting of results will aid understanding and allow better comparison between studies as for now there is a degree of heterogeneity clouding some of the interpretation.

Conclusion

In appropriately indicated patients, clinical results of CDR appear to be at least as good as ACDF out to seven years post-operatively, with improvement in established clinical outcome measures and overall success. Improved segmental range of motion and lower rate of radiological adjacent segment disease favor CDR over ACDF. Evolving evidence confirms at least the clinical equivalence of CDR to ACDF, the current gold standard surgical treatment for one to two level cervical disc disease with radiculopathy. Lower re-operation rates, decreased rates or radiographic ASD, and potential cost-effectiveness make CDR an attractive alternative to ACDF in many patients and further long-term findings should be eagerly anticipated.

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