Cervical Disc Arthroplasty

A Technology Overview

ADOPTED BY THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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This *Technology Overview* was prepared using systematic review methodology, and summarizes the findings of studies published as of September 9, 2009 on cervical disc arthroplasty. As a summary, this document does not make recommendations for or against the use of cervical disc arthroplasty and it should not be construed as an official position of the American Academy of Orthopaedic Surgeons. Readers are encouraged to consider the information presented in this document and reach their own conclusions about cervical disc arthroplasty.

The Academy has developed and is providing this *Technology Overview* as an educational tool. Patient care and treatment should always be based on a clinician's independent medical judgment given the individual clinical circumstances.

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This technology overview was developed by an AAOS physician volunteer task force based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This technology overview is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

Disclosure Requirement
In accordance with AAOS policy, all individuals whose names appear as authors or contributors to this technology overview filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to developing the key questions contained within this technology overview.

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FDA Clearance
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SUMMARY OF RESULTS

Summaries of the data pertaining to the four key questions addressed in this Technology Overview are provided. All four questions and the studies included to address each question compare the outcomes of patients treated with cervical disc arthroplasty (CDA) to patients treated with anterior cervical disc fusion (ACDF).

QUESTION #1:

What patient characteristics predict successful outcomes in patients who undergo cervical disc arthroplasty (CDA) compared to patients who undergo anterior cervical discectomy and fusion (ACDF)?

The outcomes of interest for this question included the following: previous surgeries per patient, all demographics available, age, sex, smoking status, workmen's compensation status, narcotic use, opioid use, analgesic use, use of TENS Unit, and any ongoing pain management if evaluated in a study. Most studies considered for this question, did not report or conduct the appropriate statistical analyses such as regression or multiple regression to examine predictive patient characteristics with patients considered to have successful clinical patient-oriented outcomes.

At 24 months, the authors of one Level II study with 147 patients reported no statistically significant difference in the percentage of successful patients treated with CDA compared to successful patients treated with ACDF in regards to the continuation of the use of strong narcotics and muscle relaxants (See Table 7). These results are inconclusive as to what patient characteristics predict successful outcomes in patients treated with cervical disc arthroplasty compared to patients treated with anterior cervical disc fusion.

QUESTION #2:

Do patients with herniated cervical disc who present with arm pain with or without neck pain and are treated with a cervical disc arthroplasty(CDA) have equal or better clinical outcomes than patients treated with anterior cervical discectomy and fusion (ACDF)?

Five level II studies were considered to address this question. Below, we present a brief summary of the results of the outcomes addressed in the studies considered for this overview. Please see pages 12-13 for further information of the following outcomes:

- **Neck Disability Index scores**

  Three of the four studies we included reported that at earlier follow-up durations (1.5-3 months) patients treated with CDA had statistically significantly lower NDI scores than patients treated with fusion. Results at longer follow-up durations are inconclusive.

- **Neck Disability Index success rate**

Two of the three Level II studies we included reported that, at 3 months, patients treated with CDA had statistically significantly higher NDI success rates. No statistically significant differences were reported at later follow-up durations.

- **Neurologic success rate**

  Two of the three Level II studies we included reported that at all follow-up durations there were no statistically significant differences between treatment groups. One Level II study reported that patients treated with CDA had statistically significantly higher neurologic success rates at 12 months.

- **Pain (VAS)**

  - **Neck Pain**

    Four of the five Level II studies we included reported no statistically significant differences in neck pain at earlier follow-up durations (1 – 6 months). One study reported patients treated with CDA had statistically significantly less neck pain than patients treated with ACDF. The results reported at later follow-up durations are inconclusive.

  - **Arm Pain**

    Three of the four Level II studies we included reported no statistically significant differences in arm pain scores at all follow-up durations. One study reported that at 24 months, patients treated with CDA at multiple levels had statistically significantly less arm pain compared to patients treated with ACDF at multiple levels.

- **Short-form-36**

  The results reported by three of the Level II studies included for this overview are inconclusive.

- **Return to Work**

  Two Level II studies we included reported no statistically significant differences in the number of patients who returned to work at 24 months and one study reported similar results for patients returning to “heavy work” at 24 months.

QUESTION #3

Do patients with herniated cervical disc who present with arm pain with or without neck pain and are treated with a cervical disc arthroplasty have equal or better revision rates, and/or complication rates than those treated with anterior cervical discectomy and fusion?

Four level II studies were included for this question. The results of secondary surgical procedures reported by three of the studies are inconclusive as the authors of these studies do not report or measure secondary surgical procedures of patients similarly, and therefore, the results cannot be compared. The results of any adverse events of patients reported by four of the studies considered for this question are also inconclusive.

QUESTION #4

For patients, what is more economical, cervical disc arthroplasty or anterior cervical discectomy and fusion as defined by hospital (LOS) and length of time to return to work (RTW)?

Four Level II studies were included to address this question. No statistically significant differences were reported in the length of hospital stay for patients treated with CDA compared to patients treated with ACDF. Patients treated with CDA returned to work in statistically significantly fewer days (range 14-16 days) than patients treated with ACDF.

INTRODUCTION

The prospect of achieving relief of radicular arm and neck pain, while at the same time maintaining spine segmental motion and thus eliminating adjacent segment degeneration, is very appealing. With the advent of the artificial disc, this scenario may be possible. Increasing numbers of artificial discs are becoming available for use along with a growing body of data with longer follow-up. The question remains however; "Does the currently available evidence answer the question of whether artificial disc replacement is as good as or superior to anterior cervical fusion in relief of neck and arm pain when used to address similar clinical scenarios as anterior cervical fusion?"

Evidence-based medicine utilizes a three legged stool approach to arrive upon appropriate clinical decisions. The best available evidence (1) is incorporated with the (2) physician's experience and (3) patient values to select the best available treatment recommendation for an individual patient. Often, in incorporating newer technology into clinical practice, physician experience is limited and exuberant marketing and unrealistic expectations of the value of a new technique can unduly influence patient values. Given the potential inherent weaknesses of two of three of the legs of the evidence-based medicine triad, the best available evidence becomes that much more important in clinical decision making early in the incorporation of new technology into a clinician's practice. The purpose of this technical review is to examine the best available evidence on cervical artificial disc replacement when compared to the current gold standard of anterior cervical fusion and plating. The AAOS presents this evidence using a process that includes a meticulous literature search combined with a methodical evaluation of relevant manuscripts to present to the reader the best available evidence. It is left to the reader to reach their own conclusions.

METHODS OVERVIEW

This report was developed using the methods of a systematic review[1]. We began by having a panel of physicians frame four Key Questions, and next developed rules (inclusion criteria) for determining what information we would include (The full list of criteria appears in Appendix I); articles were only included if they met the *a priori* criterion. Finally, we conducted comprehensive literature searches (See Appendix II) to ensure that the data we considered are not biased in favor of any particular point of view. Thereafter, we evaluated the quality of the relevant studies (including their methods of analysis) considered and compared their results, and summarized this information. The program TechDig 2.0 (Ronald B. Jones, Mundelein, Illinois) was used to estimate means and variances from studies presenting data only in graphical form. Also, we calculated the variance of the arcsine difference to confirm statistical significance ($p < 0.05$)[2] and converted one-sided probability values to two-sided values in order to consistently compare the results of all the studies included in this overview.

INCLUDED ARTICLES

Our search identified 2054 citations that were potentially relevant to this overview and that could potentially meet our inclusion criteria. Of these, 7 studies[3-9] were included to address the key questions (See Table 1). Six of these studies compared the outcomes of

patients treated with single level cervical disc arthroplasty to patients treated with single level fusion with adjunctive augmentation. One study[6] compared the outcomes of patients treated with cervical disc arthroplasty (CDA) at multiple levels to patients treated with anterior cervical disc fusion (ACDF) at multiple levels.

The majority of the studies in this Overview[4, 6, 7, 8](n= 566) included patients with a herniated cervical disc and/or cervical degenerative disc disease. These studies did not include patients with moderate or severe or "marked" spondylosis. Two studies[3, 9](n=297) included patients with spondylosis and neck or arm pain (radicular) and or functional/neurological deficits [but excluded patients with severe spondylosis or ankylosing spondylitis (chronic spondylosis)]. One study[5], does not report whether or not patients with spondylosis were included.

Table 1. Included studies and corresponding questions

Author	Q1	Q2	Q3	Q4
Heller, et al. 2009	-	●	-	●
Murrey et al. 2009	●	●	●	●
Cheng, et al. 2008	-	●	-	-
Mummaneni, et al. 2007	-	●	-	●
Nabhan, et al. 2007	-	●	-	-
Anderson, et al. 2008	-	-	●	
Riew, et al. 2008	-	-	-	●

• study was included for (x) question
- study not included for (x) question

DEVICE PROPERTIES

The studies included in this overview reported that patients were treated with a metal-on-polymer or metal-on-metal artificial cervical disc; patients treated with disectomy and fusion received an anterior cervical plate with varying adjunct augmentation and with or without a cage (See Table 2). Information regarding the size of the artificial discs used to treat patients in these studies was not reported in detail. Any information the authors reported regarding disc size was given in general terms. Specifically, the authors reported the sizes available for a specific type of the artificial disc but did not disclose the number of patients who received any given size. Nor was disc size compiled for specific groups of patients identified; therefore, disc size information was not useful for this overview.

Table 2. Device properties for patients treated with arthroplasty vs. fusion.

Author	CDA	ACDF
Heller, et al. 2009	metal on polyurethane	plate w/ bone allograft
Anderson, et al. 2008	metal on polyurethane	plate w/ structural allograft
Riew, et al. 2008	metal on polyurethane	plate w/ allograft
Cheng, et al. 2008	metal on polyurethane	plate w/ iliac crest autograft
Mummaneni, et al 2007	metal on metal	plate w/ cortical ring allograft
Murrey, et al. 2009	metal on polyethylene	plate w/ bone allograft
Nabhan, et al. 2007	metal on polyethylene	plate w/ cage[a]

[a] bone graft not specified

DEVICE RECALL INFORMATION

The U.S. Food and Drug Administration have issued recalls associated with two of the devices used to treat patients with CDA or ACDF reported by four of the studies included in this overview. Please see Table 3 and Table 4 for further information regarding the recalls for these devices.

Table 3. FDA recall classifications

Recall class	Recall Description	Recall examples
Class I	Dangerous or defective products that predictably could cause serious health problems or death	Food containing botulinum toxin, food with undeclared allergens, a label mix-up on a lifesaving drug, or a defective artificial heart.
Class II	Products that might cause temporary health problem, or pose only a slight threat of a serious nature	A drug that is under-strength but that is not used to treat life-threatening situations.
Class III	Products that are unlikely to cause any adverse health reaction but that violate FDA labeling or manufacturing laws	A minor container defect and lack of English labeling in a retail food.

Table 4. CDA and ACDF device recall information

Author	Device	Recall Class Number	Recall Number	Reason for Recall	Date Posted
Heller, et al. 2009	ACDF	III	Z-0330-06	Screwdriver handle breakage	Dec. 28, 2005
Mummaneni, et al. 2007	CDA	II	Z-0211-04	Step drills from Lot 25947 may have been mis-etched	Dec. 11, 2003
Mummaneni, et al. 2007	ACDF	II	Z-0138-2008	Implant mis-seating; Variance in size between the trial and the implant could cause the implant to be improperly seated.	Dec. 19, 2007
Mummaneni, et al. 2007	ACDF	III	Z-0330-06	Screwdriver handle breakage	Dec. 28, 2005
Anderson	ACDF	III	Z-0330-06	Screwdriver handle breakage	Dec. 28, 2005
Riew	ACDF	III	Z-0330-06	Screwdriver handle breakage	Dec. 28, 2005

QUALITY OF THE LITERATURE

The quality of evidence is an important and critical step in the systematic review process. In studies investigating the result of treatment, we assessed the quality of the evidence for each outcome at each time point reported in a study, not simply the overall quality of a study. Our approach follows the recommendations of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group[10] as well as others.[11]

We evaluated quality on a per outcome basis rather than a per study basis because quality is not necessarily the same for all outcomes and all follow-up times reported in a study. For example, a study might report results immediately after patients received a given treatment and after some period of time has passed. Often, nearly all enrolled patients contribute data at early follow-up times but, at much later follow-up times, only a few patients may contribute data. In this scenario, one would have more confidence in the earlier data than in the later data. The fact that we would assign a higher quality score to the earlier results reflects this difference in confidence.

We assessed the quality of treatment studies using a two-step process. First, we assigned a level of evidence to all results reported in a study based solely on that study's design. Accordingly, all data presented in randomized controlled trials were initially categorized as Level I evidence, all results presented in non-randomized controlled trials and other prospective comparative studies were initially categorized as Level II. We next assessed each outcome at each reported time point using a quality questionnaire and, when quality standards were not met, downgraded the level of evidence (for this outcome at this time point) by one level.

OUTCOMES CONSIDERED

We preferentially included patient-oriented outcomes over surrogate outcomes. This was partly because patient-oriented outcomes are important to patients and indicate, without the need for extrapolation, whether an intervention is effective.[12] Patient-oriented outcomes include pain, quality of life, ability to perform activities of daily living, and revision surgery. On the other hand, surrogate outcomes substitute for a clinical event of true importance.[12] Common surrogate outcomes include laboratory tests, biomarkers, range of motion, and radiographic findings. Unlike use of patient-oriented outcomes, use of surrogate outcomes can be misleading, and can even make harmful treatments look beneficial.[13] We found patient-oriented evidence for every question.

MINIMAL CLINICALLY IMPORTANT IMPROVEMENT

Wherever possible, we considered the effects of treatments in terms of the minimal clinically important improvement (MCII) in addition to whether their effects were statistically significant. The MCII is the smallest clinical change that is important to patients, and recognizes the fact that there are some treatment-induced statistically significant improvements that are too small to matter to patients. The values we used for MCIIs are derived from a published studies investigating the Visual Analogue Scale, and the Neck Disability Index. [14, 15]

Table 5 MCII of outcomes

Outcome Measure	MCII (points)
Pain – VAS (0-100)	15
NDI -	10.2

The associated descriptive terms in this technology overview and the conditions for using each of these terms, are outlined in the following table:

Table 6 Descriptive terms for results with MCII

Descriptive Term	Condition for Use
Clinically Important	Statistically significant and lower confidence limit > MCII
Possibly Clinically Important	Statistically significant and confidence intervals contain the MCII
Not Clinically Important	Statistically significant and upper confidence limit < MCII
Negative	Not statistically significant and upper confidence limit < MCII
Inconclusive	Not statistically significant but confidence intervals contain the MCII

POWER

To assess the power of an outcome to detect a statistically significant difference we determined whether the number of patients in the study was sufficient to detect a small, medium, or large effect, while assuming an alpha of 0.05 as the significance level, 80% power, and Cohen's definitions of small, medium, and large effects (a small effect is d = 0.2, a medium effect is d = 0.5, and a large effect is d = 0.8).[16] When a study with a non-significant difference was unable to detect a medium or large effect it was categorized as low power. Studies able to detect medium effects or with statistically significant differences were categorized as high power. Six of the seven included studies for this Overview were categorized as having high power and one study[17] was categorized a low powered study.[7]

QUESTION 1:

What patient characteristics predict successful outcomes in patients who undergo cervical disc arthroplasty compared to patients who undergo anterior cervical discectomy and fusion?

SUMMARY OF RESULTS

The outcomes of interest for this question included the following: previous surgeries per patient, all demographics available, age, sex, smoking status, workmen's compensations status, narcotic use, opioid use, analgesic use, use of TENS Unit, and any ongoing pain management if evaluated in a study. Most studies considered for this question, did not report or conduct the appropriate statistical analyses such as regression or multiple regression to examine predictive patient characteristics with patients considered to have successful clinical patient-oriented outcomes.

At 24 months, the authors of one Level II study with 147 patients reported no statistically significant difference in the percentage of successful patients treated with CDA compared to successful patients treated with ACDF in regards to the continuation of the use of strong narcotics and muscle relaxants (See Table 7). These results are inconclusive about what patient characteristics predict successful outcomes in patients treated with cervical disc arthroplasty compared to patients treated with anterior cervical disc fusion.

The results of the included study[3] that addressed this question (See Appendix V) reported unreliable Level II evidence for the outcomes (See Appendix III).

The results of the included study are unreliable because they were reported as a composite measure. Composite outcome measures, such as "overall success" as reported in this included study[3] are unreliable because each individual outcome might not equally influence or contribute to the overall significance of the estimated effects of the given treatment; hence, less important outcomes can be more influential than more serious outcomes (i.e. death and/or serious adverse events). Studies suggest examining the results of the individual outcome measures along with the results of the composite outcome measures to ensure a comprehensive examination of the effects of a given treatment.[18-20]

Other studies considered for this question, did not report or conduct the appropriate statistical analyses or did not compare patients treated with CDA to patients treated with ACDF, therefore these studies were not included (See Appendix V).

STUDY RESULTS

Table 7 Medication use of successful patients

Author	LOE	Treatment Group	N[a, b]	Duration	Medication use [c, d]	p-value Study [e]	p-value AAOS [f]
Murrey et al. 2009	III	CDA	75	24 months	10%	p = 0.1	p = .065
	III	ACDF	72		20.8%		

[a] Number of patients considered an overall success

[b] Overall success defined by the authors as the percentage of patients with Neck Disability Index success (≥15 pt improvement/ reduction from baseline), maintenance or improvement in neurologic status (measured by motor function, sensory function, and tendon function; all three conditions had to be satisfied in order to be considered a success), no serious implant related adverse event or adverse event related to the implant procedure, or secondary surgical procedure.

[c] Medication use includes the use of strong narcotics and muscle relaxants.

[d] Strong narcotics defined as schedule 2 drugs with high abuse and high dependency risk

[e] The authors reported the results of one-tailed tests. We converted the values reported by the authors to two-tailed values.

[f] test of arcsine difference

QUESTION #2:

Do patients with herniated cervical disc who present with arm pain with or without neck pain and are treated with a cervical disc arthroplasty have equal or better clinical outcomes than patients treated with anterior cervical discectomy and fusion?

SUMMARY OF RESULTS

To address this question, we included five studies[3-7] that examined five outcomes (See quality Table 26-Table 30). The data were all Level II except for three of the outcomes reported by Mummaneni et al. The results reported by Mummaneni et al at 24 months were Level III data because patient follow-up at this duration was <80% (see section on quality of literature). Based on this flaw, the outcomes data reported at 24 months were not included to address this question; the NDI, neurologic success and VAS pain results at earlier follow-up durations were included to address this question.

NECK DISABILITY INDEX (NDI) SCORES

Four studies[3-6] reported NDI scores of patients treated with CDA compared to patients treated with ACDF at various follow-up durations (See Table 8 and Figure 1). One study[6] reported NDI results of patients treated with CDA at multiple levels compared to patients treated with ACDF at multiple levels. Patients with lower NDI scores are considered to have less disability when performing activities of daily living compared to patients with higher NDI scores. Three of the four studies reported that, at earlier follow-up durations (1.5 – 3 months), patients treated with CDA had statistically significantly lower NDI scores than patients treated with ACDF but the differences are not considered as clinically important. Results at longer follow-up durations are inconclusive in that one of the four studies reported statistically significant differences in favor of patients treated with CDA at 6 months and one study reported no statistically significant results; two of the four studies reported statistically significant results in favor of CDA at 12 months and at 24 months, two of the three studies reported statistically significant results in favor of patients treated with CDA (Table 8).

NDI SUCCESS RATE

Three studies[3-5] reported NDI success rates as the percentage of patients with ≥15 pt improvement/ reduction from baseline. Two studies [3, 5] reported that, at 3 months, patients treated with CDA had statistically significantly greater NDI success rates than patients treated with ACDF (See Table 9). Three studies reported no statistically significant differences in NDI success rates of patients at later follow-up durations (6 – 24 months). One study[4] reported that, at 24 months, the NDI success rates of patients treated with CDA was statistically significantly noninferior (margin of inferiority, δ = 0.10) to the success rate of patients treated with ACDF(See Table 9).

NEUROLOGIC SUCCESS RATE

Three studies[3-5] reported unreliable (See question #1 for section on composite outcomes) and inconclusive results of neurologic success rates defined as the maintenance or improvement in neurologic status from baseline measured by motor function, sensory function, and tendon function; all three conditions had to be satisfied in order for a patient

to be considered a success. Details were not reported regarding how motor, sensory, and tendon function were measured.

All three studies reported no statistically significant differences in neurologic success rates at earlier follow-up durations (See Table 10). One study reported that at 12 months, patients treated with CDA had statistically significantly greater neurologic success rates than patients treated with ACDF (See Table 10). One study reported that the neurologic success rates of patients treated with CDA were statistically significantly noninferior to patients treated with ACDF at 24 months.

NECK PAIN (VAS)

The results reported by five Level II studies[3-7] are inconclusive. One study[3] reported neck pain results that are incomparable to the results reported by the other studies included to address this question.

Four of the five studies reported no statistically significant differences in the neck pain of patients at earlier follow-up durations (1 – 6 months); one study reported patients treated with CDA had statistically significantly less neck pain than patients treated with ACDF (See Table 11 - Table 12 and Figure 2). At later follow-up durations (12 -36 months), two[4, 6] of the five studies reported patients treated with CDA had statistically significantly less neck pain than patients treated with ACDF but in one of these two studies, patients were treated with either CDA or ACDF at multiple levels of the cervical spine.

One study[3] reported that, at 3 months, patients treated with CDA had statistically significantly less neck pain intensity than patients treated with ACDF; no statistically significant differences in neck pain scores were reported by the authors of this study at all other follow-up durations (See Table 12).

ARM PAIN (VAS)

Five studies[3-7] reported the results of arm pain scores of patients up to 36 months following treatment (See Table 13 - Table 14 and Figure 3). Four studies reported no statistically significant differences in the arm pain scores of patients at 36 months. One study[6] reported patients treated with CDA at multiple levels had statistically significantly less arm pain than patients treated with ACDF at multiple levels.

SHORT FORM-36

Three studies[4-6] reported the SF-36 physical component summary (PCS) scores and two studies reported the mental component summary (MCS) scores up to 24 months following treatment. One of the three studies[4] reported that patients treated with CDA had statistically significantly greater improvements in PCS and MCS scores up to twelve months following treatment but the difference was not statistically significant at twenty-four months (See Table 12 and Table 15). One of three studies[5] reported no statistically significant differences in PCS and MCS scores at all follow-up durations. Two studies[4, 5], categorized as having high power, report conflicting results at 6 months; one study reported statistically significant results where as the second study reported no statistically significant results. One study[6] reported that, at 12 and 24 months, patients

treated with CDA at multiple levels had statistically significantly higher PCS scores than patients treated with ACDF at multiple levels (See Table 15, Table 16,; Figure 4. Figure 5).

RETURN TO WORK

Two studies[3, 4] reported no statistically significant difference in the percentage of patients who returned to work at 24 months and one study[3] reported similar results for patients returning to heavy work (See Table 17). Please see question #4 for the results of patient's length of time to return to work.

STUDY RESULTS

Table 8. Neck Disability Index scores [a b]

Author	Treatment	N	Baseline	1 week	1.5 months	3 months	6 months	12 months	18 months	24 months
Heller, et al. 2009 [c, f]	CDA	242	51.4 (nr)	nr	*22.5 (nr)**	*17.6 (nr)*	*16.1 (nr)*	*15.1 (nr)*	nr	*16.2 (nr)*
	ACDF	221	50.2 (nr)	nr	***31.2 (nr)***	***22.4 (nr)***	***21 (nr)***	***18.8 (nr)***	nr	***19.2 (nr)***
Murrey, et al. 2009 [d]	CDA	103	53.9 (15.0)	nr	29.1 (18.5)	*21.7 (16.7)*	23.0 (19.3)	22 (20.4) ‡	21.2 (19)	21.4 (20.2)
	ACDF	106	52.2 (14.5)	nr	30.7 (16.4)	***25.9 (19.8)***	22.2 (20.1)	21.7 (18.5) ‡	22.2 (18.5)	20.5 (18.4)
Mummaneni et al, 2009 [c, f]	CDA	276	55.7 (nr)	nr	27.1 (nr)	20.7 (nr)	21.7 (nr)	20.6 (nr)	nr	-
	ACDF	265	56.4 (nr)	nr	32.1 (nr)	26.8 (nr)	24.5 (nr)	23.4 (nr)	nr	-
Cheng, et al. 2008 [e]	CDA	30	50 (nr)	21.3 (nr)	nr	19.7 (nr)	14.3 (nr)	*12 (nr)*	nr	*11 (nr)*
	ACDF	32	51 (nr)	24.0 (nr)	nr	20.2 (nr)	19.2 (nr)	***18 (nr)***	nr	***19 (nr)***

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion; ANOVA, analysis of variance; ANCOVA, analysis of covariance.

[a] Data are presented as mean and standard deviation (SD) unless otherwise indicated.

[b] NDI range of scores is 0-100

[c] ANCOVA, pre-op score used as covariate.

[d] Wilcoxon rank-sum test

[e] ANOVA

[f] Heller et al and Mummaneni et al reported the results of one-tailed tests. For comparability, we converted the values reported by both authors to two-tailed values.

* "nr" refers to "not reported"

‡ Authors report no statistical significant difference but do not provide p-value.

▪ Number of patients at baseline

Values presented in bold italic are significantly greater than CDA; $p \leq 0.05$

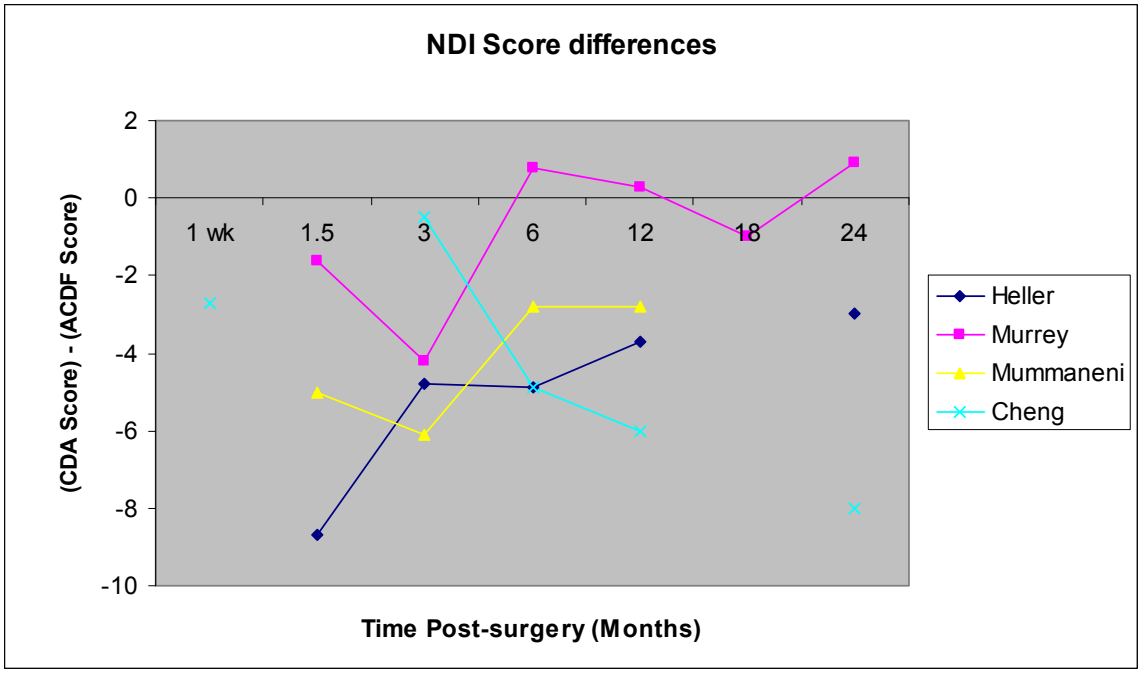


Figure 1. Difference between mean NDI scores for the CDA and ACDF groups over time.

* A negative score indicates improved function in favor of the CDA group and positive score indicated improved function for the ACDF group.

Table 9 Neck Disability Index success rates

Author	Duration	N CDA:ACDF	CDA % of patients	ACDF % of patients	p-value [a] study[b]	p-value [a] AAOS [b]
Mummaneni, et al. 2007	1.5 months	531 (274:257)	75.4%	68.40%	p = 0.104	p = 0.069
Mummaneni, et al. 2007	3 months	498 (257:241)	86.7%	73.80%	***p = 0.008****	***p ≤ 0.01****
Murrey, et al. 2009	3 months	202 (101:101)	nr*	nr	***p = 0.001****	n/a
Mummaneni, et al. 2007	6 months	492 (259:233)	81.4%	77.20%	p = 0.27	p = 0.248
Mummaneni, et al. 2007	12 months	493 (265:228)	82.2%	79.10%	p = .215	p = .962
Heller, et al. 2009	24 months	423 (229:194)	86.0%	78.9%	p = 0.07	p = 0.053
Murrey, et al. 2009	24 months	191 (99:92)	79.80%	78.30%	p = 0.892	p = 0.729
Heller, et al. 2009[d]	24 months	423 (229:194)	86.0%	78.9%	***p = 0.002***	n/a

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion.
[a] The authors reported the results of one-tailed tests. For comparability, we converted the values reported by both authors to two-tailed values.
[b] *P*-values are for Fisher exact test unless otherwise indicated.
[c] *P*-values reported from test of arcsine difference.
* "nr" refers to "not reported."
Values presented in bold italic are statistically significant; p ≤ 0.05.
[d] *P*-values reported from tests of noninferiority.

Table 10 Neurological success rates

Author	LOE	Duration	N CDA:ACDF	CDA % of patients	ACDF % of patients	p-value [a] study[b]	p-value [a] AAOS [c]
Heller, et al. 2009	II	1.5 - 12 months	423 (229:194)	nr*	nr	ns‡	n/a±
Mummaneni, et al. 2007	II	3 months	498 (257:241)	92.0%	87.0%	p = 0.136	p = .086
Murrey, et al. 2009	II	6 months	209 (103:106)	94.6%	85.1%	p = .092	n/a
Mummaneni, et al 2006	II	6 months	492 (259:233)	92.5%	90.0%	p = .318	p = .315

Author	LOE	Duration	N CDA:ACDF	CDA	ACDF	p-value [a]	
				% of patients		study[b]	AAOS [c]
Mummaneni, et al 2006	II	12 months	493 (265:228)	92.5%	85.0%	***p = .024***	***p = .009***
Murrey et al. 2009	II	24 months	209 (103:106)	90.9%	88.0%	p = .638	p = .404
Heller, et al. 2009	II	24 months	423 (229:194)	93.9%	90.2%	p = 0.222	p = 0.161
Heller, et al. 2009 [d]	II	24 months	423 (229:194)	93.9%	90.2%	***p< 0.002***	n/a

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion.
[a] All three studies reported the results of one-tailed tests. For comparability, we converted the values reported by the authors to two-tailed values.
[b] *P*-values are for the Fisher exact test unless otherwise indicated.
[c] *P*-values reported from test of arcsine difference.
[d] *P*-values reported from tests of noninferiority.

Table 11 Neck Pain (VAS) [a, b, c]

Author	LOE	Duration	N CDA:ACDF	CDA	ACDF	p-value[d]
				Mean (SD)		
Heller, et al. 2009 [d, e]	II	Baseline	463 (242:221)	75.4 (19.9)	74.8 (23.0)	p = .765
Mummaneni, et al. 2007 [e]	II	Baseline	541 (276:265)	67.6 (nr)	68.6 (nr)	nr
Nabhan, et al 2007 [f]	II	Baseline	41 (20:21)	60 (12.0)	62 (9.0)	p = 0.1
Cheng, et al. 2008 [f]	II	Baseline	62 (31:34)	73 (nr)	71 (nr)	nr
Nabhan, et al. 2007	II	Immediate post-op	41 (20:21)	35 (6.0)	29 (7.0)	nr
Heller, et al. 2009 [d, e]	II	1.5 months	451 (237:214)	32.7 (nr)	37.5 (nr)	***p = 0.034***
Mummaneni, et al. 2007 [e]	II	1.5 months	531 (274:257)	16.6 (nr)	19.9 (nr)	p = 0.06
Heller, et al. 2009	II	3 months	439 (234:205)	27.1 (nr)	32.8 (nr)	***p = 0.012***
Mummaneni, et al. 2007	II	3 months	498 (257:241)	13.3 (nr)	17.6 (nr)	p = 0.296
Heller, et al. 2009	II	6 months	423 (227:196)	24.1 (nr)	32.7 (nr)	***p <0.002***

Author	LOE	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value[d]
Mummaneni, et al. 2007	II	6 months	492 (259:233)	17.6 (nr)	19 (nr)	p = .61
Heller, et al. 2009	II	12 months	431 (235:196)	23.6 (nr)	28.1 (nr)	p = 0.084
Mummaneni, et al. 2007	II	12 months	493 (265:228)	15.7 (nr)	19.4 (nr)	p = 0.07
Nabhan, et al 2007	II	12 months	40 (19:21)	14 (2.0)	15 (3.0)	nr
Cheng, et al. 2008 [f]	II	12 months	62 (30:32)	19 (nr)	25 (nr)	nr
Heller, et al. 2009	II	24 months	424 (230:194)	23 (nr)	30.3 (nr)	***p = 0.018***
Cheng, et al. 2008 [f]	II	24 months	62 (30:32)	15 (nr)	26 (nr)	***p = 0.012***
Nabhan, et al 2007	II	36 months	40 (19:21)	17 (4.0)	25 (4.0)	p = 0.1

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion; ANCOVA, analysis of covariance.

[a] Data are presented as mean and standard deviation (SD) unless otherwise indicated.

[b] Reported results calculated by multiplying the intensity score by the frequency score.

[c] The range for neck pain scores is 0-100 points.

[d] Heller et al and Mummaneni et al reported the results of one-tailed tests. For comparability, we converted the values reported by both authors to two-tailed values.

[e] ANCOVA, pre-op score used as covariate.

[f] Values converted to scale for comparability.

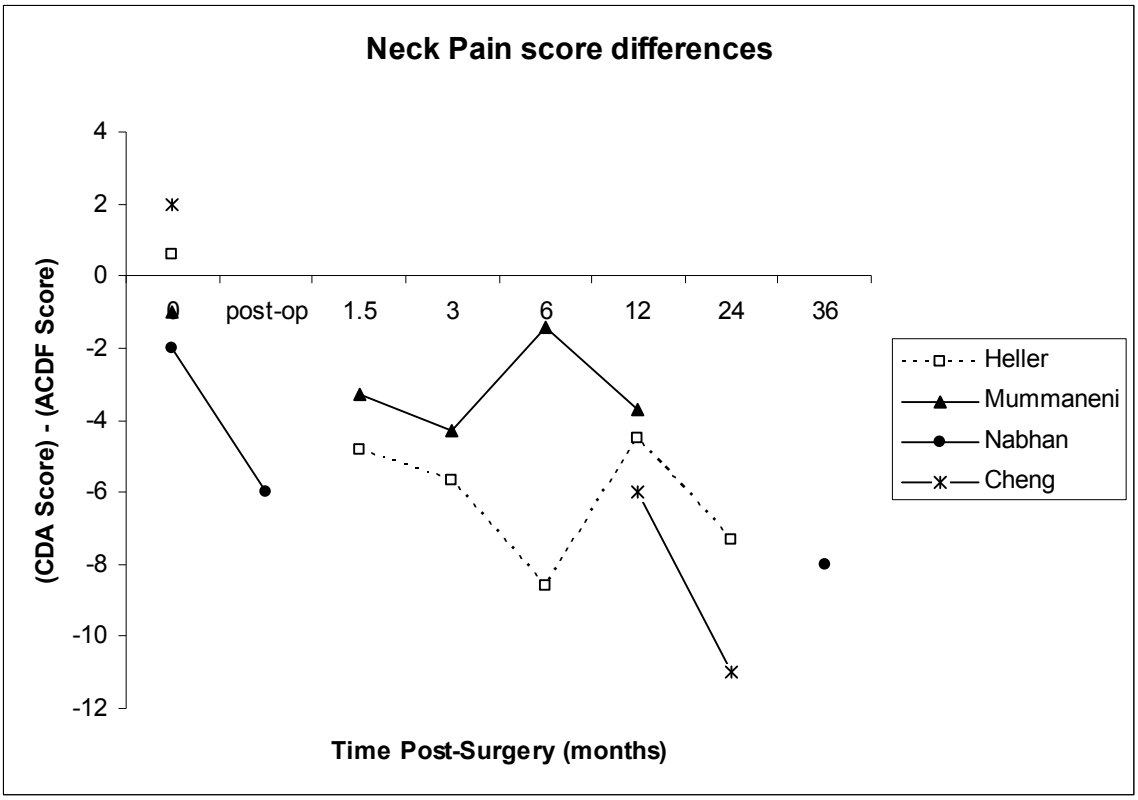


Figure 2. Difference between mean neck pain scores for the CDA and ACDF groups over time.

* A negative score indicates improved function in favor of the CDA group and positive score indicates improved function for the ACDF group.

Table 12. Neck pain intensity and frequency (VAS)[a]

Author	LOE	Outcome	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value[b]
Murrey, et al. 2009	II	Neck Pain - Intensity	1.5 months	209 (103:106)	30.5 (24.9)	25.6 (21.3)	ns*
Murrey, et al. 2009	II	Neck Pain - Frequency	1.5 months	209 (103:106)	37.9 (30.6)	33.1 (28.3)	ns
Murrey, et al. 2009	II	Neck Pain - Intensity	3 months	209 (103:106)	24.1 (24.1)	27.2 (24.6)	***p <.05****
Murrey, et al. 2009	II	Neck Pain - Frequency	3 months	209 (103:106)	34.1 (33.8)	36.6 (33.6)	ns
Murrey, et al. 2009	II	Neck Pain - Intensity	6 months	209 (103:106)	27.4 (27.7)	27.4 (26.6)	ns
Murrey, et al. 2009	II	Neck Pain - Frequency	6 months	209 (103:106)	37.9 (36.6)	35.9 (33.8)	ns
Murrey et al. 2009	II	Neck Pain - Intensity	12 months	209 (103:106)	25.1 (28.7)	27.2 (26.6)	ns
Murrey et al. 2009	II	Neck Pain - Frequency	12 months	209 (103:106)	34.3 (36.9)	36.9 (34.3)	ns
Murrey, et al. 2009	II	Neck Pain - Intensity	18 months	209 (103:106)	25.1 (25.4)	25.9 (25.4)	ns
Murrey, et al. 2009	II	Neck Pain - Frequency	18 months	209 (103:106)	30.8 (33.6)	34.3 (33.1)	ns
Murrey, et al. 2009	II	Neck Pain - Intensity	24 months	209 (103:106)	25.6 (28.2)	24.4 (26.6)	ns
Murrey, et al. 2009	II	Neck Pain - Frequency	24 months	209 (103:106)	34.1 (35.9)	30.6 (33.6)	ns

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion.
[a] Data are presented as mean and standard deviation (SD) unless otherwise indicated.
[b] Wilcoxon rank-sum test.
* "nr" refers to "not statistically significant; authors do not report p-value.
Values presented in bold italic are significantly greater than CDA; $p \leq 0.05$.

Table 13. Arm pain (VAS)[a]

Author	LOE	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value[b]
Heller, et al. 2009	II	Baseline	463 (242:221)	71.2 (19.5)	71.2 (25.1)	p = 0.392
Mummaneni, et al. 2007[c]	II	Baseline	541 (276:265)	59 (nr)	62.9 (nr)	nr
Nabhan, et al. 2007	II	Baseline	41 (20:21)	73 (14.0)	72 (15.0)	P = 0.1
Cheng, et al. 2008	II	Baseline	62 (30:32)	71 (nr)	72 (nr)	nr
Nabhan, et al. 2007	II	Immediate post-op	41 (20:21)	18 (4.0)	16 (4.0)	nr
Heller, et al. 2009	II	1.5 months	451 (237:214)	19.5 (nr)	22.1 (nr)	p = 0.3
Mummaneni, et al. 2007[c]	II	1.5 months	531 (274:257)	13.3 (nr)	13.3 (nr)	p = 1.0
Heller, et al. 2009[c]	II	3 months	439 (234:205)	19.3 (nr)	19.9	p = 0.682
Mummaneni, et al. 2007	II	3 months	498 (257:241)	12 (nr)	12.4 (nr)	p = 0.638
Heller, et al. 2009	II	6 months	423 (227:196)	20.4 (nr)	22.5 (nr)	p = 0.414
Mummaneni, et al 2007	II	6 months	492 (259:233)	14.3 (nr)	13.3 (nr)	p = 1.0
Heller, et al. 2009	II	12 months	431 (235:196)	16.5 (nr)	21.3 (nr)	p = 0.058
Mummaneni, et al. 2007	II	12 months	493 (265:228)	14.8 (nr)	15.7 (nr)	p = 0.496
Nabhan, et al. 2007	II	12 months	41 (20:21)	14 (2.0)	15 (3.0)	p = 0.06
Cheng, et al. 2008	II	12 months	62 (30:32)	18 (nr)	24 (nr)	ns‡
Heller, et al. 2009	II	24 months	424 (230:194)	19.1 (nr)	21.5 (nr)	p = 0.388

Author	LOE	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value[b]
Nabhan, et al. 2007	II	24 months	41 (20:21)	12 (3.0)	19 (2.0)	nr
Cheng, et al. 2008	II	24 months	62 (30:32)	14 (nr)	27 (nr)	***p = 0.013***
Nabhan, et al. 2007	II	36 months	41 (20:21)	12 (3)	17 (2)	p = 0.06

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion
[a] Data are presented as mean and standard deviation (SD) unless otherwise indicated
[b] Wilcoxon rank-sum test
[c]Heller et al and Mummaneni et al reported the results of one-tailed tests. For comparability, we converted the values reported by both authors to two-tailed values.
* "nr" refers to "not statistically significant; authors do not report p-value
‡ "ns" refers to "not statistically significant; authors do not report p-value
Values presented in bold italic are significantly greater than CDA; $p \leq 0.05$

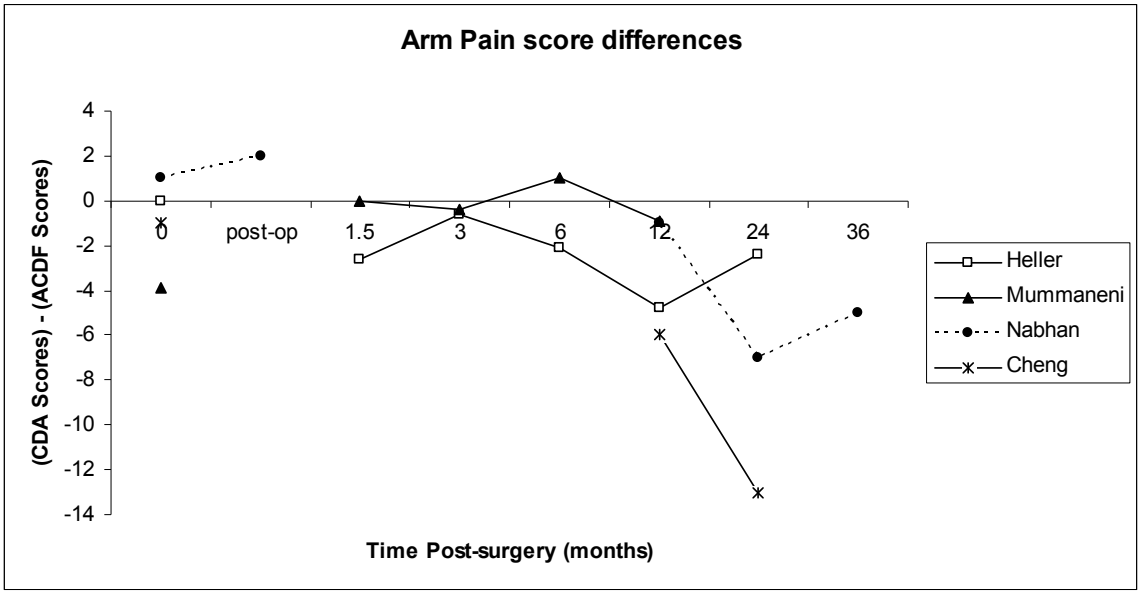


Figure 3. Difference between mean arm pain scores for the CDA and ACDF groups over time.
* A negative score indicates improved function in favor of the CDA group and positive score indicates improved function for the ACDF group.

Table 14. Arm pain intensity and frequency (VAS)

Author	LOE	Outcome	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value[a]
Murrey, et al. 2009	II	Arm Pain - Intensity	1.5 months	209 (103:106)	22.7 (28.3)	17..3 (23.7)	ns*
Murrey, et al. 2009	II	Arm Pain - Frequency	1.5 months	209 (103:106)	25.2 (31.6)	20.4 (28.3)	ns
Murrey, et al. 2009	II	Arm Pain - Intensity	3 months	209 (103:106)	15.8 (22.7)	18.8 (27.5)	ns
Murrey, et al. 2009	II	Arm Pain - Frequency	3 months	209 (103:106)	17.6 (27.0)	19.8 (28.8)	ns
Murrey, et al. 2009	II	Arm Pain - Intensity	6 months	209 (103:106)	19 (28.5)	18.8 (22.5)	ns
Murrey, et al. 2009	II	Arm Pain - Frequency	6 months	209 (103:106)	19.8 (30.3)	22.3 (29.8)	ns
Murrey, et al. 2009	II	Arm Pain - Intensity	12 months	209 (103:106)	17.2 (26.5)	22.5 (30.1)	ns
Murrey, et al. 2009	II	Arm Pain - Frequency	12 months	209 (103:106)	18.2 (30.1)	27.5 (36.9)	ns
Murrey, et al. 2009	II	Arm Pain - Intensity	18 months	209 (103:106)	18.2 (25)	19.2 (24.5)	ns
Murrey et al. 2009	II	Arm Pain - Frequency	18 months	209 (103:106)	18.4 (26.0)	22.4 (29.3)	ns
Murrey, et al. 2009	II	Arm Pain - Intensity	24 months	209 (103:106)	19.9 (26.5)	17.3 (23.5)	ns
Murrey, et al. 2009	II	Arm Pain - Frequency	24 months	209 (103:106)	20.6 (27.5)	22.4 (31.3)	ns

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion

[a] Wilcoxon rank-sum test

*"ns"refers to "not significant"; authors do not report p-value

Table 15. SF-36 physical component scores [a]

Author	LOE	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value
Heller, et al. 2009	II	Baseline	463 (242:221)	32.6 (6.7)	31.8 (7.2)	p = 0.416
Mummaneni, et al. 2007	II	Baseline	541 (276:265)	32 (nr) *	32.2 (nr)	nr
Cheng, et al. 2008	II	Baseline	62 (30:32)	35 (nr)	34 (nr)	nr
Heller, et al. 2009 [b c]	II	1.5 months	451 (237:214)	41.3 (nr)	38.2 (nr)	***p < 0.002***
Heller, et al. 2009	II	3 months	439 (234:205)	46.3 (nr)	43.9 (nr)	***p = 0.034***
Heller, et al. 2009	II	6 months	423 (227:196)	47.5 (nr)	45.1 (nr)	***p = 0.038***
Mummaneni, et al. 2007 [b c]	II	6 months	492 (259:233)	43.6 (nr)	43.1 (nr)	p = .159
Heller, et al. 2009	II	12 months	431 (235:196)	48.4 (nr)	45.5 (nr)	***p = 0.02***
Mummaneni, et al. 2007	II	12 months	493 (265:228)	44.6 (nr)	43.6 (nr)	p = .157
Cheng, et al. 2008	II	12 months	62 (30:32)	49 (nr)	46 (nr)	***p = 0.033***
Heller, et al. 2009	II	24 months	424 (230:194)	47.9 (nr)	46.3 (nr)	p = 0.3
Cheng, et al. 2008	II	24 months	62 (30:32)	50 (nr)	45 (nr)	***p = 0.013***

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion
[a] Data are presented as mean and standard deviation (SD) unless otherwise indicated
[b] Heller et al and Mummaneni et al reported the results of one-tailed tests. For comparability, we converted the values reported by both authors to two-tailed values.
[c] Results based on ANCOVA; pre-op score used as covariate
* "nr" refers to "not reported"
Values presented in bold italic are statistically significant in favor of CDA; $p \leq 0.05$

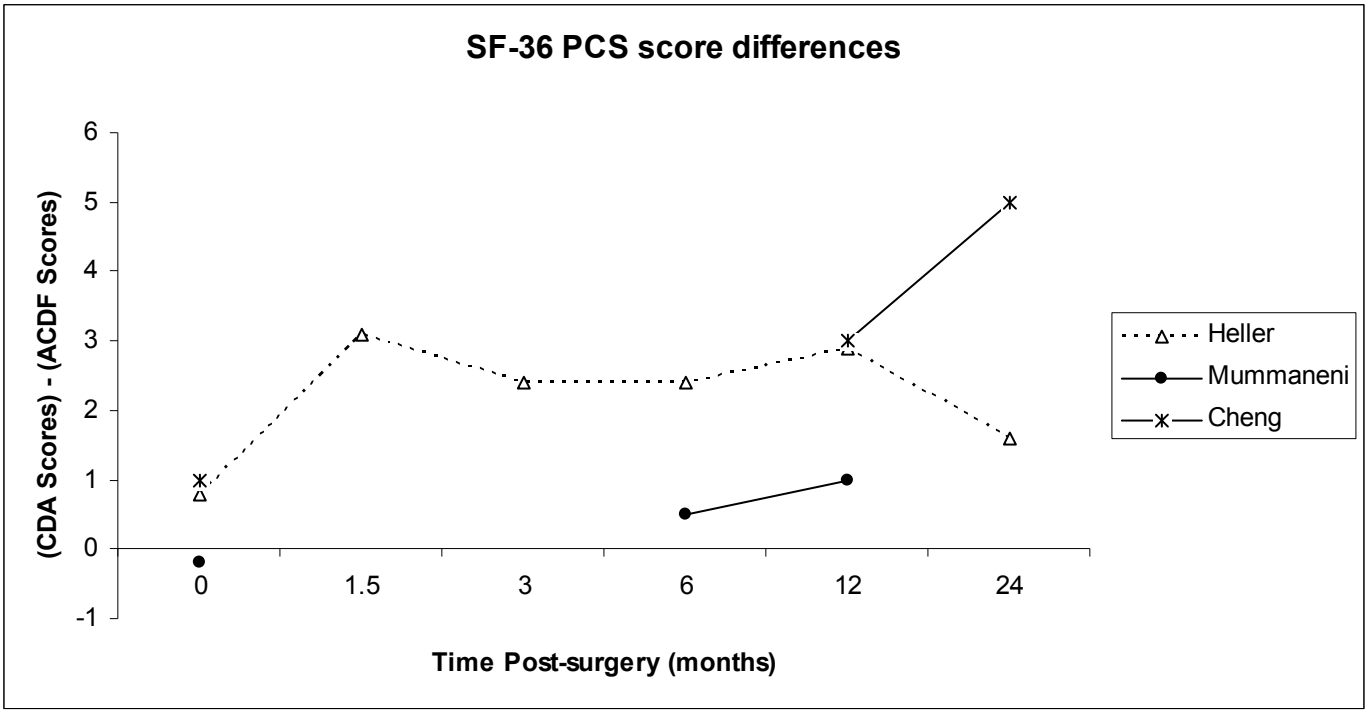


Figure 4. Difference between SF-36 scores for the CDA and ACDF groups over time.

* A positive score indicates improved function in favor of the CDA group and negative score indicates improved function for the ACDF group.

Table 16. SF-36 mental component scores [a]

Author	LOE	Duration	N CDA:ACDF	CDA Mean (SD)	ACDF Mean (SD)	p-value [b, c]
Heller, et al. 2009	II	Baseline	463 (242:221)	42.3 (12.5)	44.6 (11.6)	p = .08
Mummaneni, et al 2007	II	Baseline	541 (237:257)	45.5 (nr)*	42.8 (nr)	nr
Heller, et al. 2009	II	1.5 months	451 (237:214)	51.4 (nr)	48.5 (nr)	***p <0.002***
Heller, et al. 2009	II	3 months	439 (234:205)	52.6 (nr)	50.8 (nr)	***p = 0.004***
Heller, et al. 2009	II	6 months	423 (227:196)	53 (nr)	50.8 (nr)	***p <0.002***
Mummaneni, et al 2007	II	6 months	492 (259:233)	49.3 (nr)	49.5 (nr)	p = 1.0
Heller, et al. 2009	II	12 months	431 (235:196)	52.5 (nr)	51.6 (nr)	p = 0.096
Mummaneni, et al. 2007	II	12 months	493 (265:228)	50.6 (nr)	49.2 (nr)	p = .105
Heller, et al. 2009	II	24 months	424 (230:194)	51.7 (nr)	51.7 (nr)	p = 0.54

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion; ANCOVA, analysis of covariance.

[a] Data are presented as mean and standard deviation (SD) unless otherwise indicated [b] Heller et al and Mummaneni et al reported the results of one-tailed tests. For comparability, we converted the values reported by both authors to two-tailed values.

[c] Results based on ANCOVA; pre-op score used as covariate

* "nr" refers to "not reported"

Values presented in bold italic are statistically significant in favor of CDA; $p \leq 0.05$

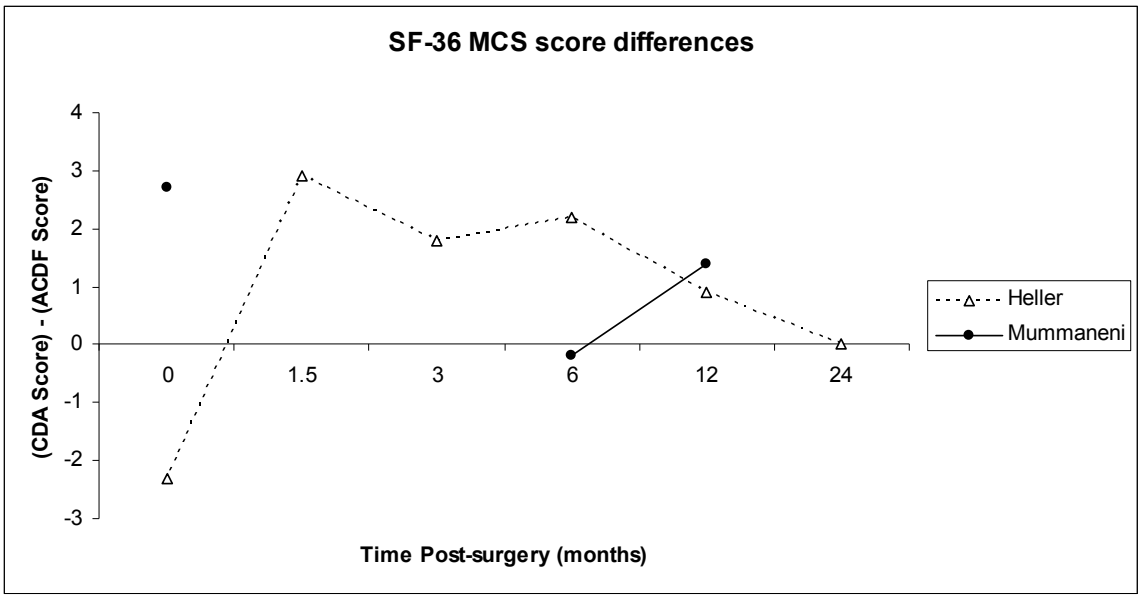


Figure 5. Difference between SF-36 scores for the CDA and ACDF groups over time.

* A positive score indicates improved function in favor of the CDA group and negative score indicates improved function for the ACDF group.

Table 17. Percentage of patients who returned to work

Author	LOE	Outcome	Duration	N CDA:ACDF	CDA %	ACDF %	p- value [a]
Heller, et al. 2009	II	Return to work	24 months	301 (157:144)	76.8%	73.6%	p = .483
Murrey, et al. 2009	II	Return to work	24 months	175 (87:88)	82.8%	80.0%	p = .71
Murrey, et al. 2009	II	Return to heavy work	24 months	115 (54:61)	48.1%	44.7%	p = 0.75

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion

[a] p-value reported from test of arcsine difference

QUESTION #3

Do patients with herniated cervical disc who present with arm pain with or without neck pain and are treated with a cervical disc arthroplasty have equal or better revision rates, and/or complication rates than those treated with anterior cervical discectomy and fusion?

SUMMARY OF RESULTS

To address this question, we included four Level II studies[3, 5, 6, 8] that reported secondary surgical procedures, adverse events and complications of patients treated with CDA at a single level or ACDF at a single level and one study[6] reported the complications of patients treated with either CDA or ACDF at multiple levels.(See quality Table 31 and Table 32). One study[3] reported unreliable results due to the use of a composite measure (See question #1 for discussion of composite outcomes).

SECONDARY SURGICAL PROCEDURES

Three Level II studies reported inconclusive and incomparable results of secondary surgical procedures of patients treated with CDA or ACDF at 24 months. Secondary surgical procedures included revisions, supplemental fixation, implant removal and reoperations (See Table 18).

One of the three studies[3] included reported unreliable results of the device success rate of patients treated with CDA compared to patients treated with ACDF(See Table 18) (See question #1 for explanation of the reliability of composite measures). One[8] of the three studies reported no statistically significant differences in the overall reoperation rates of patients treated with CDA compared to patients treated with ACDF (See Table 18). This study also reported that statistically significantly fewer patients treated with CDA required reoperations at any level of the cervical spine. The author reported that the difference was statistically significant but AAOS calculations cannot confirm this (See Table 18). One[6] of the three studies reported no secondary surgical procedures occurred in patients treated with CDA at multiple levels compared to patients treated with ACDF at multiple levels.

ADVERSE EVENTS

The results reported by four Level II studies[3, 5, 6, 8] regarding the number of adverse events of patients treated with CDA compared to the adverse events of patients treated with ACDF are inconclusive. One study[8] excluded complications or any adverse events "not meaningful" to the treatment and that had no affect on the results of patients (i.e. post-op facelift surgery or being hit with a golf ball). Two studies reported the severity of adverse events based on the World Health Organization (WHO) severity scale. See Table 19 for information and description of each grade.

One[3] of the four studies reported that at 24 months, there is no statistically significant difference in the number of adverse events that occurred in patients treated with CDA compared to patients treated with ACDF (See Table 20). One[5] of the four studies reported, that at 36 months, patients treated with CDA had statistically significantly fewer

serious adverse events than patients treated with ACDF but AAOS calculations cannot confirm this (See Table 20).

One study[8] reported that within the peri-operative period, patients treated with CDA had statistically significantly more surgical related adverse events or acute neurologic adverse events (Grades 1-4). The authors report the difference as statistically significant, but AAOS calculations cannot confirm this (See Table 21 and Table 22). One[5] of the four studies reported that, within the peri-operative period, no statistically significant differences in the number of patients with adverse events (See Table 21). One[6] of the four studies reported that one patient treated with CDA at multiple levels had a deep vein thrombosis and one patient treated with ACDF at multiple levels had dysphagia.

STUDY RESULTS

Table 18. Device success and the percentage of patients with secondary surgical procedures at 24 months

Author	LOE	N CDA:ACDF	Outcome	CDA %	ACDF %	p-value	
						Study	AAOS [a]
Murrey et al. 2009	II	209 (106:103)	Device Success [b]	98.1%	91.5%	p = 0.06 [c]	***p = 0.028***
Anderson, et al. 2008	II	463 (242:221)	Reoperation (cervical)[d]	5.4%	7.7%	***p = 0.045***	p = 0.311
Anderson, et al. 2008	II	463 (242:221)	Reoperation[e] (thoracolumbar)	7.0%	8.1%	p = 0.56	p = 0.775
Anderson, et al. 2008	II	463 (242:221)	Reoperation (Total)	7.0%	8.1%	p = 0.15	p =0.649
Cheng, et al. 2008	II	62 (30:32)	Revisions	0%	0%	n/a*	n/a

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion.
[a] p-value reported from test of arcsine difference.
[b] The percentage of patients who *did not* require reoperation, revision, supplemental fixation or implant removal.
[c] Murrey et al reported the results of one-tailed tests. For comparability, we converted the values reported by the authors to two-tailed values.
[d]Reoperation at the index, adjacent, or both levels of the cervical spine.
[e]Reoperation in the upper extremity, shoulder, carpal tunnel, ulnar nerve transposition, thoracic outlet release.
Values presented in bold italic are statistically significant; $p \leq 0.05$.
"n/a" refers to "not applicable."

Table 19. World Health Organization (WHO) adverse events severity scale

Grade	Description
1	Events that did not require medical treatment and had no effect on the outcome
2	Events may have required non-operative treatment but had no effect on the outcome
3	Events that required medical treatment or may have had a long-term health effect
4	Events required operative treatment, were life threatening, resulted in permanent disability, or caused death

Table 20. Adverse event success and percentage of patients with an adverse event

Author	LOE	N CDA:ACDF	Duration	Outcome	CDA (%)	ACDF (%)	p- value Study	p- value AAOS[a]
Murrey et al. 2009	II	209 (106:103)	24 months	Adverse event success rate [b]	97.1%	93.4%	p=0.66[c]	p = 0.21
Anderson, et al. 2008	II	463 (242:221)	36 months	Serious adverse events [d e]	30.2%	36.2%	p = .012	p =0.168

[a] p-value reported from test of arcsine difference.
[b] Patients without adverse events related to the implant or the surgical procedure; patients considered as an implant related failure had a serious or life threatening adverse events at the index treatment level.
[c] Murrey et al reported the results of one-tailed tests. For comparability, we converted the values reported by the authors to two-tailed values.
[d] Serious adverse events; World Health Organization (WHO) grades 3 or 4.
[e] Serious adverse events include severe neck/arm symptoms, thoracolumbar pain, headaches and pseudoarthrosis.

Table 21. Total surgical and neurologic adverse events

Author	LOE	N CDA:ACDF	Duration	Adverse event	CDA (%)	ACDF (%)	p-value Study	p-value AAOS [a]
Anderson, et al. 2008	II	463 (242:221)	Peri-operative	Adverse Events –Total [b]	33.9%	29.0%	***p = 0.023***	p = .254
Mummaneni, et al 2007	II	541 (276:265)	Peri-operative	Adverse Events -Total	6.20%	4.20%	ns*	p= .289
Anderson, et al. 2008	II	463 (242:221)	Peri-operative	Anesthesia [c]	3.3%	2.3%	p = 0.15	p = .294
Anderson, et al. 2008	II	463 (242:221)	Peri-operative	Medical [d]	10.3%	9.1%	p = 0.13	p = .642
Anderson, et al. 2008	II	463 (242:221)	Peri-operative	Technical [e]	0.8%	0.9%	p = 0.15	p = .927
Anderson, et al. 2008	II	463 (242:221)	Peri-operative	Surgical [f]	16.1%	13.6%	p = 0.06	p = 0.442
Anderson, et al. 2008	II	463 (242:221)	Peri-operative	Acute Neurologic change	3.3%	3.2%	p = 0.15	p = .993

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion

[a] p-value reported from test of arcsine difference

[b] Total adverse events included anesthesia [c] medical [d], technical [e], surgical [f], and acute neurological adverse events [g]

[c] Anesthesia adverse events include airway/re-intubation, eye abrasion/symptoms, forearm compartmental syndrome, and oral cavity injury adverse events

[d] Medical adverse events included cardiovascular, infection, dermatologic/allergy, psychiatric, genitourinary, pulmonary, musculoskeletal, endocrine, central nervous system, cancer, and death

[e] Technical adverse events included any drill failure, malposition, technical problems, and wound contamination.

[f] Surgical adverse events included cerebral spinal fluid leak, superficial and deep wound infection, intra-operative bleeding, hematoma, hematoma evacuation, and dysphagia/dysphonia adverse events.

[g] Acute neurologic events included sensory changes in the upper and lower extremities, motor changes in upper extremities, myelopathy, and spinal cord injury.

Values presented in bold italic are significantly greater than CDA; $p \leq 0.05$

* "ns" refers to not statistically significant; authors do no report p-value.

Table 22. Neurologic adverse events

Author	LOE	N CDA:ACDF	Duration	Adverse Event	CDA (%)	ACDF (%)
Anderson, et al. 2008	II	463 (242:221)	peri-operative	sensory/upper extremities	2.1%	1.8%
Anderson, et al. 2008	II	463 (242:221)	peri-operative	motor/upper extremities	0.4%	0.5%
Anderson, et al. 2008	II	463 (242:221)	peri-operative	myelopathy	0.0%	0.5%
Anderson, et al. 2008	II	463 (242:221)	peri-operative	spinal cord injury	0.0%	0.5%
Anderson, et al. 2008	II	463 (242:221)	peri-operative	sensory/lower extremities	0.8%	0.0%

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion

QUESTION #4

For patients, what is more economical, cervical disc arthroplasty or anterior cervical discectomy and fusion as defined by hospital (LOS) and length of time to return to work (RTW)?

SUMMARY OF RESULTS

Four Level II studies [3-5, 9] were included to address this question (See quality Tables 30 and 31). Three Level II studies[3, 5, 9] reported the average length of hospital stay and two studies[4, 5] reported the length of time to return to work for patients treated with CDA compared to patients treated with ACDF.

The studies included to address both questions did not report patient level data that would allow for appropriate correlation analyses; therefore, no association between adverse events, length of hospital stay and time to return to work can be provided.

LENGTH OF HOSPITAL STAY

Three studies[3, 5, 9] reported no significant difference in the length of hospital stay for patients treated with CDA compared to patients treated with ACDF (See Table 23).

RETURN TO WORK (DAYS)

Two studies[4, 5] reported that patients treated with CDA returned to work in significantly fewer days (range 14-16 days) than patients treated with ACDF (See Table 24).

STUDY RESULTS

Table 23 Length of hospital stay (days)

Author	LOE	Outcome	N (CDA:ACDF)	CDA Mean (SD)	ACDF Mean (SD)	p-value
Murrey et al. 2009	II	Length of stay (days)	209 (103:106)	1.4 (1.18)	1.3 (0.83)	p = 0.788
Riew, et al. 2008	II	Length of stay (days)	88 (47:41)	1.2 (0.5)	1.6 (1.4)	p = 0.058
Mummaneni, et al 2007	II	Length of stay (days)	541 (276:265)	1.1 (nr)*	1.0 (nr)	p = 0.041

Abbreviation: CDA, cervical disc arthroplasty; ACDF, anterior cervical disc fusion
*"nr"refers to "not reported"

Table 24 Return to work (median days)

Author	LOE	Outcome	N CDA:ACDF	CDA Median (variance)	ACDF Median (variance)	p-value
Heller, et al. 2009	II	Return to work (days)	301 (157:144)	48 (nr)*	61 (nr)	***p = 0.015***
Mummaneni , et al 2007	II	Return to work (days)	350 (183:167)	45 (nr)	61 (nr)	***p = 0.022***

"nr" refers to "not reported"
Values presented in bold italic are significantly greater than CDA; $p \leq 0.05$

Appendix I

INCLUSION CRITERIA

We used the following criteria to determine whether studies should be included in this systematic review:

- Study must be of cervical disc arthroplasty or artificial disc or anterior cervical fusion.
- Article must be a full article report of a clinical study (i.e., retrospective case series, medical records review, meeting abstracts, historical articles, editorials, letters, and commentaries are excluded)
- Study must appear in a peer-reviewed publication
- Study should have 10 or more patients per group
- Study must be of humans
- Study must be published in English
- Study must be published in or after 1966
- Study results must be quantitatively presented
- ≥80% of the enrolled study population must be 18 years of age or older
- For any given follow-up time point in any included study, there must be ≥ 50% patient follow-up (if the follow-up is >50% but <80%, the study quality will be downgraded by one Level)
- For any included study that uses "paper-and-pencil" outcome measures (e.g., SF-36), only those outcome measures that have been validated will be included
- Study must not be an in vitro study
- Study must not be a biomechanical study
- Study must not have been performed on cadavers

Appendix II

DATABASES SEARCHED AND SEARCH STRATEGIES

To identify studies for this Overview we searched PubMed, EMBASE, CINAHL, and the Cochrane Library through May 1, 2009 and September 9, 2009.

Our PubMed search strategy was:

"bryan disc" OR "Bryan cervical disc" OR "prestige cervical disc" OR ((Cervical Vertebrae[mh] OR ((disc[tiab] OR vertebra*[tiab] OR neck pain[mh]) AND cervical[tiab])) AND (Prostheses and Implants[mh] OR Prosthesis Implantation[mh] OR replacement[tiab] OR arthroplasty[tiab] OR "Arthroplasty, Replacement"[mh:noexp])) AND English[lang] AND 1966:2009[pdat] NOT ((animal[mh] NOT human[mh]) OR cadaver[mh] OR comment[pt] OR editorial[pt] OR letter[pt] OR addresses[pt] OR news[pt] OR "newspaper article"[pt] OR "historical article"[pt] OR "case report"[title] OR "retrospective case series"[tiab])

Our EMBASE search strategy was:

'bryan disc' OR 'Bryan cervical disc' OR 'prestige cervical disc' OR (('cervical spine'/de OR ((disc OR vertebra* OR 'neck pain'/de) AND cervical)) AND ('prostheses and implants'/de OR 'implantation'/de OR replacement OR arthroplasty OR arthroplasty/de))AND ([article]/lim OR [conference paper]/lim OR [review]/lim) AND [english]/lim AND [humans]/lim AND [embase]/lim NOT (cadaver/de OR 'case report':ti)

Our CINAHL strategy was:
("bryan disc" or "Bryan cervical disc" or "prestige cervical disc" or ((MH "cervical spine" OR ((disc or vertebra* or MH "neck pain") AND cervical)) and (MH "prostheses and implants" or replacement or arthroplasty or MH "arthroplasty, replacement")) and LA English not (PT "editorial" or PT "letter" or PT "case study" or TI "case report")

Our Cochrane Library search strategy was:

cervical AND (((disectomy OR fusion) AND prognos*) OR replacement OR prosthesis OR arthroplasty)

ACDF prognostic factors
Our PubMed search strategy was:

(ACDF[tiab] OR (anterior[tiab] AND (Cervical Vertebrae[mh] OR cervical[tiab]) AND (discectomy[tiab] OR diskectomy[tiab] OR diskectomy[mh] OR decompression[tiab]) AND (fusion[tiab] OR fused[tiab] OR arthrodesis[tiab] OR Spinal Fusion[mh]))) AND (incidence[mh:noexp] OR mortality[mh] OR "follow up studies"[mh:noexp] OR prognos*[tw] OR predict*[tw] OR incidence[tw] OR follow-up[tw] OR risk[tw]) AND English[lang] AND 1966:2009[pdat] NOT ((animal[mh] NOT human[mh]) OR cadaver[mh] OR comment[pt] OR editorial[pt] OR letter[pt] OR addresses[pt] OR

news[pt] OR "newspaper article"[pt] OR “historical article”[pt] OR “case report”[title] OR “retrospective case series”[tiab])

Our EMBASE search strategy was:

('ACDF' OR (anterior AND ('cervical spine'/de OR cervical) AND (discectomy OR diskectomy OR 'intervertebral diskectomy'/de) AND (fusion OR fused OR arthrodesis OR 'anterior spine fusion'/de))) AND ('disease course'/ OR risk* OR diagnose* OR follow-up OR 'physical diseases, disorders and abnormalities'/exp/dm_ep OR outcome) AND ([article]/lim OR [conference paper]/lim OR [review]/lim) AND [english]/lim AND [humans]/lim AND [embase]/lim NOT (cadaver/de OR ‘case report’:ti)

Our CINAHL strategy was:

(ACDF or (anterior and (MH "cervical spine" or cervical) and (discectomy or diskectomy or MH "diskectomy") and (fusion or fused or arthrodesis or MH "spinal fusion"))) and (MH “incidence” or MH “mortality” or MH “Prospective Studies” or prognos* or predict* or incidence or "follow up" or risk) and LA English not (PT "editorial" or PT "letter" or PT "case study" or TI "case report")

Our Cochrane Library search strategy was:

cervical AND (((disectomy OR fusion) AND prognos*) OR replacement OR prosthesis OR arthroplasty)

Appendix III

STUDY QUALITY CHECKLISTS

When determining the quality of the evidence, we begin by considering study design. Better study designs are given higher ratings (i.e. randomized control trials are initially evaluated as Level I studies and non-comparative case series are initially evaluated as Level IV studies). The quality checklist is then used to determine if there are flaws that could influence the outcomes in a study. The checklist is completed for each outcome the study reports. It is also completed for each time point that a study reports. For example, if a study reports two outcomes at three different times, the checklist is completed six times.

Items are answered "Yes", "No", or "Not Reported". "Not applicable" is not an acceptable answer for any of the items except when evaluating a crossover trial and the question is about such a trial.

To score the checklist for a study that is a randomized controlled trial, prospective, non-randomized controlled study, retrospective comparative (i.e., controlled) study, or a case series, each "No" answer is scored as –1, and each "Not Reported" as –0.5. If 1 or more points is deducted, the study is downgraded by one Level *for that outcome*. Studies can only be downgraded by one level. We never downgrade two (or more) levels. Preference is always given to patient-oriented outcomes. If data for surrogate outcomes is examined, the data should be downgraded one level for the surrogate outcome.

To score the checklist for prognostic studies, prospective multiple regression studies start at Level I and retrospective multiple regression studies start at Level II. They are scored as indicated above using the checklist for prognostic studies.

For joint registries, if the reviewer answers "no" to any question or "unclear" to two or more questions, the registry is downgraded one level.

RANDOMIZED CONTROLLED TRIALS

1. Did the study employ stochastic randomization?
2. Was there concealment of allocation?
3. Were subjects blinded to the treatment they received?
4. Were those who assessed/rated the patient's outcomes blinded to the group to which the patients were assigned?
5. Was there more than 80% follow-up for all patients in the control group and the experimental group on the outcome of interest?
6. Did patients in the different study groups have similar levels of performance on ALL of the outcome variables at the time they were assigned to groups?
7. For randomized crossover studies, was there evidence that the results obtained in the study's two *experimental* groups (in period 1 and 2) did not differ?
8. For randomized crossover studies, was there evidence that the results of the two *control* groups (in period 1 and 2) did not differ?

PROSPECTIVE NON- RANDOMIZED CONTROLLED STUDIES

1. Were the *characteristics* of patients in the different study groups comparable at the beginning of the study?
2. Did patients in the different study groups have similar levels of performance on ALL of the outcome variables at baseline?
3. Were all of the study's groups concurrently treated?
4. Was there more than 80% follow-up for all patients in the control group and the experimental group on the outcome of interest?
5. Did the study avoid collecting control group data from one center and experimental group data from another?
6. For crossover studies, was there evidence that the results obtained in the study's two experimental groups (in period 1 and 2) did not differ?
7. For crossover studies, was there evidence that the results of the two control groups (in period 1 and 2) did not differ?

RETROSPECTIVE COMPARATIVE (I.E., CONTROLLED) STUDIES

1. Was there less than 20% difference in completion rates in the study's groups?
2. Were all of the study's groups concurrently treated?
3. Was the same treatment given to all patients enrolled in the experimental and
4. Were the same laboratory tests, clinical findings, psychological instruments, etc. used to measure the outcomes in all of the study's groups?
5. Were the follow-up times in all of the study's relevant groups approximately equal?
6. Was there more than 80% follow-up for all patients in the control group and the experimental group on the outcome of interest?
7. Did the study avoid collecting control group data from one center and experimental group data from another?
8. Did patients in the different study groups have similar levels of performance on ALL of the outcome variables at the time they were assigned to groups?
9. Were the *characteristics* of patients in the different study groups comparable at the beginning of the study?

CASE SERIES

1. Was enrollment in the study consecutive?
2. Was there more than 80% follow-up for all patients on the outcome of interest?
3. Were the same laboratory tests, clinical findings, psychological instruments, etc. used to measure the outcomes in all patients?
4. Were the patients instructed/not given concomitant or adjuvant treatments?
5. Were the follow-up times for all patients approximately equal?

PROGNOSTIC STUDIES

1. Were the variables of interest clearly identified in the Methods section?
2. Were all variables of interest discussed in the Results section?
3. Were there sufficient patients per variable? (use 10 as a rule)
4. Were there sufficient events per variable? (use 10 as a rule)
5. If coding of variables is used, is the coding scheme described or unambiguous?

6. Collinearity has been tested or there is no obvious potential for collinearity?
7. Was the fitting procedure explicitly stated?
8. Were any goodness-of-fit statistics reported?
9. Was the model subjected to a test of validation?

JOINT REGISTRIES

1. Is submission of data to the registry mandatory?
2. Is the registry population-based?
3. Have the registry data been validated against hospital patient records or state/territory health department records?
4. Does the registry ensure >90% of the patients are captured in the database?
5. Does the registry perform statistical quality control measures to ensure the quality of the data?
6. Does the registry perform checks to ensure that the diagnosis of patients who are in the registry is correct OR is the diagnosis unambiguous?

STUDY QUALITY

QUESTION #1

Table 25. Medication use

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	Medication use	1.5 -24	CDA vs. ACDF	Level II	●	●	○	○	●	●

QUESTION #2

Table 26. Neck Disability Index

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	NDI score	1.5 -24	CDA vs. ACDF	Level II	●	●	○	○	●	●
Heller, et al. 2009	NDI score	1.5- 24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Heller, et al. 2009	NDI success	24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Mummaneni, et al. 2007	NDI score	1.5 -12	CDA vs. ACDF	Level II	●	●	○	×	●	●
Murrey, et al. 2009	NDI success	3 - 24	CDA vs. ACDF	Level II	●	●	○	○	●	●
Mummaneni, et al. 2007	NDI success	1.5 - 12	CDA vs. ACDF	Level II	●	●	○	×	●	●
Cheng, et al. 2008	NDI score	3-24	CDA vs. ACDF (multi-level)	Level II	×	×	×	×	●	●

Table 27. Study quality - Neurologic success

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	Neurologic success	6 - 24	CDA vs. ACDF	Level II	●	●	○	○	●	×
Heller, et al. 2009	Neurologic success	24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Mummaneni, et al. 2007	Neurologic success	3-12	CDA vs. ACDF	Level II	●	●	○	×	●	●

Table 28. Study quality - Pain (VAS)

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (Months)	Treatment(s)	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	Pain (VAS) - Intensity	1.5 - 24	CDA vs. ACDF	Level II	●	●	○	○	●	×
Murrey, et al. 2009	Pain (VAS) - Frequency	1.5 - 24	CDA vs. ACDF	Level II	●	●	○	○	●	×
Heller, et al. 2009	Pain (VAS)	1.5 - 24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Mummaneni, et al. 2007	Pain (VAS)	1.5 - 12	CDA vs. ACDF	Level II	●	●	○	×	●	●
Nabhan, et al. 2007	Pain (VAS)	Post op -36	CDA vs. ACDF	Level II	●	●	●	×	●	●
Cheng, et al. 2008	Pain (VAS)	12 -24	CDA vs. ACDF (multi-level)	Level II	×	×	×	×	●	●

Table 29. Study quality - SF-36

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment(s)	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Heller, et al. 2009	SF-36 PCS	1.5-24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Heller, et al. 2009	SF-36 MCS	1.5 - 24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Cheng, et al. 2008	SF-36 PCS	12 - 24	CDA vs. ACDF (multi-level)	Level II	×	×	×	×	●	●

Table 30. Study quality - return to work

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	Return to Work	n/a	CDA vs. ACDF	Level II	●	●	○	○	●	○
Murrey, et al. 2009	Return to Heavy Work	n/a	CDA vs. ACDF	Level II	●	●	○	○	●	○
Heller, et al. 2009	Return to Work	n/a	CDA vs. ACDF	Level II	●	●	○	○	●	○

QUESTION #3

Table 31 Study quality - secondary surgical procedures

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	Device success	24	CDA vs. ACDF	Level II	●	●	○	○	●	×
Anderson, et al. 2008	Reoperation	24	CDA vs. ACDF	Level II	×	×	×	×	●	●
Cheng, et al. 2008	Revision	36	CDA vs. ACDF (multi-level)	Level II	×	×	×	×	●	●

Table 32 Study quality- adverse events

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment	Level of Evidence	Stochastic Randomization Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Anderson et al. 2008	Adverse Events	36 months	CDA vs. ACDF	Level II	×	×	×	●	●
Cheng, et al. 2008	Adverse events	24 months	CDA vs. ACDF (multi-level)	Level II	×	×	×	●	●

QUESTION #4

Table 33 Study quality - length of hospital stay (days)

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration (months)	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Murrey, et al. 2009	LOS	n/a	CDA vs. ACDF	Level II	●	●	○	○	●	●
Riew, et al. 2008	LOS	n/a	CDA vs. ACDF	Level III	●	×	×	●	○	●
Mummaneni, et al. 2007	LOS	n/a	CDA vs. ACDF	Level II	●	●	○	×	●	●

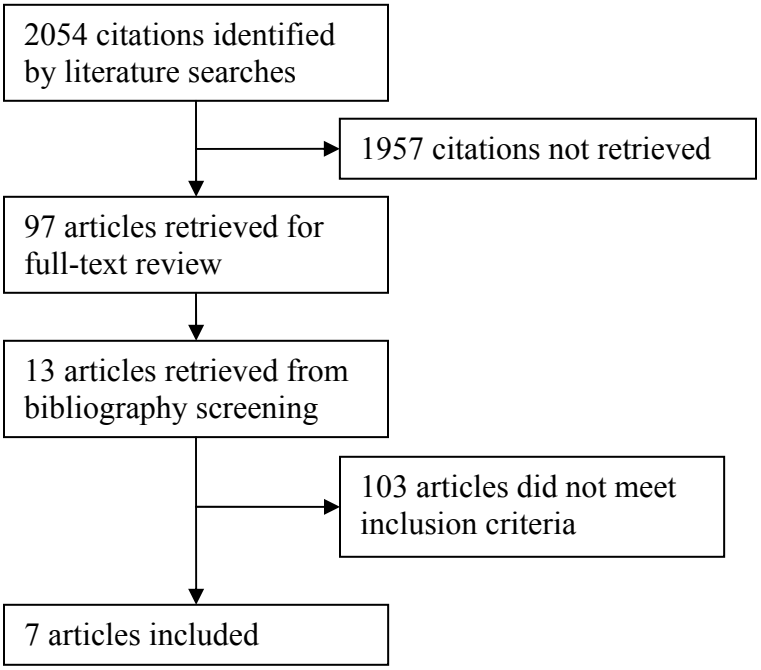
Table 34 Study quality - time to return to work

● = Yes ○ = No × = Not Reported
n/a = not applicable

Author	Outcome	Duration	Treatment	Level of Evidence	Stochastic Randomization	Allocation Concealment	Patients Blinded	Those rating outcome Blinded	Follow Up - 80% or more	All groups have similar outcome performance at entry
Heller, et al. 2009	Return to work	1.5- 24	CDA vs. ACDF	Level II	●	●	○	○	●	○
Murrey, et al. 2009	Return to Work	24	CDA vs. ACDF	Level II	●	●	○	○	●	●
Murrey, et al. 2009	Return to Heavy Work	24	CDA vs. ACDF	Level II	●	●	○	○	●	●

Appendix IV

STUDY ATTRITION



APPENDIX V

DOCUMENTATION OF APPROVAL

AAOS Task Force Draft Completed	January 15, 2010
Manufacturer Review Completed	February 22, 2010
AAOS Guidelines and Technology Oversight Committee	February 24, 2010
AAOS Evidence Based Practice Committee	February 24, 2010
AAOS Council on Research, Quality Assessment, and Technology	March 3, 2010
AAOS Board of Directors	March 8, 2010

AAOS BODIES THAT APPROVED THIS TECHNOLOGY OVERVIEW

Guidelines and Technology Oversight Committee
The AAOS Guidelines and Technology Oversight Committee (GTOC) consists of sixteen AAOS members. The overall purpose of this Committee is to oversee the development of the clinical practice guidelines, performance measures, health technology assessments and utilization guidelines.

Evidence Based Practice Committee
The AAOS Evidence Based Practice Committee (EBPC) consists of ten AAOS members. This Committee provides review, planning and oversight for all activities related to quality improvement in orthopaedic practice, including, but not limited to evidence-based guidelines, performance measures, and outcomes.

Council on Research, Quality Assessment, and Technology
To enhance the mission of the AAOS, the Council on Research, Quality Assessment, and Technology promotes the most ethically and scientifically sound basic, clinical, and translational research possible to ensure the future care for patients with musculoskeletal disorders. The Council also serves as the primary resource to educate its members, the public, and public policy makers regarding evidenced-based medical practice, orthopaedic devices and biologics, regulatory pathways and standards development, patient safety, occupational health, technology assessment, and other related areas of importance.

The Council is comprised of the chairs of the AAOS Biological Implants, Biomedical Engineering, Evidence Based Practice, Guidelines and Technology Oversight, Occupational Health and Workers' Compensation, Patient Safety, Research Development, and US Bone and Joint Decade committees. Also on the Council are the

AAOS second vice-president, representatives of the Diversity Advisory Board, the Women's Health Issues Advisory Board, the Board of Specialty Societies (BOS), the Board of Councilors (BOC), the Communications Cabinet, the Orthopaedic Research Society (ORS), the Orthopedic Research and Education Foundation (OREF), and three members at large.

Board of Directors
The 17 member AAOS Board of Directors manages the affairs of the AAOS, sets policy, and determines and continually reassesses the Strategic Plan.

Appendix VI

TASK FORCE

Michael Zindrick MD, Chair
Hinsdale Orthopedic Associates
550 W Ogden Avenue
Hinsdale IL 60521-3157

Mitchel B Harris, MD
The Brigham & Women's Hospital
75 Francis St PBB A2
Dept of Orthopedic Surgery
Boston, MA 02115

Steven Craig Humphreys, MD
Center for Sports Medicine and Orthopaedics
2415 Mc Callie Avenue
Chattanooga, TN 37404-1144

Patrick T. O'Leary, MD
Loyola University Medical Center
Department of Orthopaedic Surgery
McGuire Center St 1700
Maywood IL 60153

Gary Schneiderman, MD
Sutter Neuroscience Medical Group
2800 L ST#500
Sacramento, CA 95816-5616

AAOS Staff:
Charles M. Turkelson, PhD
AAOS Director of Research and Scientific Affairs
6300 N River Road
Rosemont, IL 60018

Janet L. Wies, MPH
AAOS Manager, Clinical Practice Guidelines

Laura Raymond MA
AAOS Lead Research Analyst

Guidelines and Technology Oversight Chair:
William C. Watters, III MD
Houston Bone and Joint Clinic
6624 Fannin #2600
Houston, TX 77030

CONFLICT OF INTEREST

All members of the AAOS task force disclosed any conflicts of interest prior to the development of the key questions for this technology overview. Conflicts of interest are disclosed in writing with the American Academy of Orthopaedic Surgeons via a private on-line reporting database.

- **Michael Richard Zindrick, MD** 1 (Salt Creek Surgery Center); 3 (DePuy, A Johnson & Johnson Company; Orthofix, Inc.); 5A (Orthofix, Inc.); 7 (Orthofix, Inc.). Submitted on: 12/11/2009. [+]
- **Mitchel B Harris, MD** 7 (AO; DePuy, A Johnson & Johnson Company; Medtronic Sofamor Danek; Synthes; OMeGA). Submitted on: 10/06/2009 and last confirmed as accurate on 10/29/2009. [+]
- **Steven Craig Humphreys, MD** 3 (Biomet); 5A (Biomet; Medtronic). Submitted on: 02/12/2009. [+]
- **Patrick Timothy O'Leary, MD** (n) Submitted on: 01/26/2009 and last confirmed as accurate on 10/28/2009. [+]
- **Gary A Schneiderman, MD** 1 (Fort Sutter Surgery Center; Spider Tek LLC); 3 (DePuy, A Johnson & Johnson Company); 5A (DePuy, A Johnson & Johnson Company; Medtronic; Spineview). Submitted on: 10/19/2009. [+]

[+] **Disclosure Items Answered:** (n) = Respondent answered 'No' to all items indicating no conflicts. 1=Board member/owner/officer/committee appointments; 2= Medical/Orthopaedic Publications; 3= Royalties; 4= Speakers bureau/paid presentations;5A= Paid consultant or employee; 5B= Unpaid consultant; 6= Research or institutional support from a publisher; 7= Research or institutional support from a company or supplier; 8= Stock or Stock Options; 9= Other financial/material support from a publisher; 10= Other financial/material support from a company or supplier.

Appendix VII

Reference List

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