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## Adjacent segment disease requiring reoperation in cervical total disc arthroplasty: A literature review and update



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### Ki-Eun Chang\*, Martin H. Pham, Patrick C. Hsieh

Department of Neurological Surgery, University of Southern California, 1200 N State Street, Suite 330, Los Angeles, CA 90033, USA

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#### ABSTRACT

*Objective:* To evaluate the difference in rate of reoperation for adjacent segment disease (ASD) between anterior cervical decompression and fusion (ACDF) and total disc replacement (TDR). *Method:* A systematic review of literature was performed using PubMed, clinicaltrials.gov, and various other search engines. Nine studies met the inclusion criteria and were used to report an estimated overall rate of reoperation secondary to ASD for both ACDF and TDR. *Results:* Forty-six clinical trials were identified after the initial search, and 9 studies met our inclusion criteria. Although the data was not pooled due to significant variation in level of evidence and length of follow-up, the overall rate of reoperation for ASD in the TDR cohort of patients analyzed in our review was 3.1% (range: 0–7.1%) with a follow-up between 24 and 80 months. In contrast, the reoperation rate for ASD in the ACDF control was 6.0% (range: 1.0–11.9%). *Conclusion:* The average reoperation rate for ASD was 3.1% for the TDR across all studies, which was lower than the reoperation rate of 6.0% in the ACDF group. Further studies and follow-up data are still needed to determine if cervical TDR preserves adjacent segment motion more efficiently than the natural history of the disease, and if it will be a durable option when compared to the already excellent results of ACDF.

#### 1. Introduction

Anterior cervical discectomy and fusion (ACDF) is a wellestablished and familiar technique for treating cervical degenerative disc disease [1]. However, one unfortunate long-term complication is the development of adjacent segment disease (ASD) in about 25% of patients within 10 years of the index operation [2]. In an attempt to address this concern, a myriad of motion preserving techniques, such as cervical total disc replacement (TDR), have been proposed as an alternative to ACDF [3].

The use of cervical TDR has significantly increased in the past few decades [4] ever since early Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trials demonstrated its safety and efficacy [5,6]. The basic argument behind its use over fusion procedures was to offer the same anterior neural decompression while preserving segmental motion, thereby eliminating adjacent level stress and subsequent deterioration. However, ASD was still reported in a majority of the early results, and reoperation rates after prolonged follow-up are still pending [7]. Through this

\* Corresponding author.

E-mail address: ki.chang14@gmail.com (K.-E. Chang).

review, we attempt to address the question "does motion preserving surgery for cervical radiculopathy/myelopathy prevent or reduce the reoperation rate for ASD in the long term?" by analyzing and reporting the most recent data through an extensive systematic literature search.

#### 2. Materials/methods

#### 2.1. Selection of papers for review

We conducted a systematic search using the Medline (PubMed) database for literature published through July 2015. Our PICO question is listed in Table 1 and the initial PubMed search phrase was (("adjacent segment disease" [All Fields] AND "reoperation" [All Fields]) AND "cervical disc replacement" [All Fields]) OR "total disc arthroplasty" [All Fields]) OR "motion preservation surgery" [All Fields]) OR "cervical arthroplasty" [All Fields]). Additional searches across multiple databases (PubMed, Google Scholar, ClinicalTrials.gov) were performed using specific device names to identify the most recent data regarding our index question.

We included studies evaluating adult patients with symptomatic cervical degenerative disease who underwent cervical motion sparing operations and had follow-up of at least



Abbreviations: ASD, adjacent segment disease; ACDF, anterior cervical decompression and fusion; TDR, total disc replacement.

#### Table 1

	Inclusion criteria	Exclusion criteria
Population of interest	Adult patients who had surgery for: – Cervical spondylotic myelopathy – Cervical radiculopathy – Symptomatic cervical disc herni- ation/degeneration – Symptomatic cervical spinal stenosis	<ul> <li>Pediatrics/ adolescents</li> <li>Tumor</li> <li>Infection</li> <li>Severe deformity</li> <li>Trauma</li> </ul>
Intervention	Cervical motion-sparing operations: – Arthroplasty/total disc replacement – Foraminotomy – Microforaminotomy – Diesys – Laminoplasty – Laminectomy	
Comparison	Fusion: – Anterior – Posterior – Combined	
Outcome	Clinical ASD (cASD) Reoperation for cASD	
Study design	Randomized controlled trials Prospective Cohort studies Retrospective reviews Meta-analysis	Case series/reports Cadaveric studies Animal studies Biomechanical studies Small studies ( <i>n</i> < 10) Studies with <2 year follow-up Non-English language

24 months. Since our primary endpoint was to evaluate the rate of reoperations due to ASD, we eliminated studies that did not report rates of reoperation. The search was limited to human studies written in the English language. When there were multiple reports on the same patient cohort, the study with the longest follow-up was used. Full-text articles meeting the inclusion criteria were reviewed by 2 independent investigators (KC, MP). For the purposes of this review, ASD was defined as clinically symptomatic radiographic degeneration of adjacent segments. We described the rates of radiological and clinical ASD if the authors reported it in the original study.

#### 2.2. Data extraction and analysis

The following data were extracted from the selected articles: study design, patient demographics, follow-up duration and rate, device name and manufacturer, incidence of ASD as a percent (%) (sum of superior and inferior levels/No. of patients), and the reoperation rate for ASD (specified as reoperations for non-index levels). The data was not pooled since the criteria for radiographic adjacent segment disease (rASD) and clinical adjacent segment disease (cASD) was not consistent and studies varied considerably in the level of evidence and length of follow-up.

#### 3. Results

#### 3.1. Study selection

The initial PubMed search produced 335 results, of which 46 were clinical trials with adequate control. Each abstract was then carefully evaluated using our inclusion criteria. Thirty-eight studies were excluded for various reasons, most commonly involving an unclear indication for reoperation. The 8 selected studies were mostly FDA/IDE trials comparing 8 separate artificial discs with

ACDF (Table 2). In addition to our systematic PubMed search, we reviewed alternative databases such as ClinicalTrials.gov and FDA.gov to comprise a list of new and/or established artificial discs and conducted a PubMed and Google Scholar search using the key words "(the respective device name)," "adjacent segment disease," and "reoperation." Although this search method generated many of the same articles as the original search, one new study met the inclusion criteria, yielding a total of 9 studies qualifying for extensive review.

#### 3.2. Device specific reoperation rates for ASD

#### 3.2.1. Medtronic Prestige

Mummaneni and colleagues performed a FDA/IDE clinical trial comparing TDR with the Prestige artificial disc to conventional ACDF. Two-year data found a significantly higher rate of surgical intervention for ASD in the ACDF group (2.9% (ACDF) vs. 1.1% (TDR)) [8]. Burkus et al. then presented the 5-year data of the same cohort with a follow-up rate of 52.2% (127 patients) for the Prestige group and 47.9% (144 patients) for the ACDF group. The incidence of adjacent-level surgery for ASD was lower with Prestige TDR compared to ACDF (2.9% vs. 4.9%, respectively, p = 0.376), although the difference was not statistically significant [9]. The most recent 7-year follow-up of the same cohort demonstrated that the reoperation rates involving adjacent segments were still lower in the Prestige group compared to control, now with statistical significance (4.6% vs. 11.9%, p = 0.008). The follow-up rate for both groups combined was 73% [5].

#### 3.2.2. Medtronic Bryan

Sasso et al. [10] conducted a FDA/IDE, prospective, multicenter randomized-control trial (RCT) comparing the Bryan artificial cervical disc to ACDF for the treatment of persistent radiculopathy or myelopathy due to single-level cervical disc herniation or spondylosis. Two hundred and forty-two patients were randomized to the Bryan disc group (vs. 221 ACDF). At 4 years, the follow-up rate for the Bryan group was 85.1% (vs. 72.5% in ACDF). The reoperation rate for ASD was equivocal in both groups (4.1% vs. 4.1%).

Zhang et al. [11] reported on their 2 year experience with the Bryan disc through a multicenter RCT in China. The TDR group consisted of 56 patients (vs. 53 in ACDF) and the reoperation rate for ASD was 1.8% (vs. 5.7% ACDF). The rate of ASD itself was not reported and the mean follow-up was 24 months.

#### 3.2.3. Depuy-Synthes ProDisc-C

Delamarter et al. [12] conducted a prospective randomized trial to determined the reason for, and rates of, secondary surgical intervention in patients treated with ProDisc-C or ACDF. A total of 209 patients (103 in ProDisc-C group, 106 in ACDF) were randomized and treated at 13 different institutions. The 5-year follow-up rates were 72.7% for the ProDisc-C group and 63.5% for the ACDF group. A total of 2 patients in the ProDisc-C group underwent 2 operations for ASD (2/103, 1.9%), while 6 patients in the ACDF group underwent 8 reoperations for ASD (6/106, 5.7%). The time to reoperation for the two ProDisc-C patients was 16.5 and 31 months. The rate of radiographic ASD was not reported.

#### 3.2.4. NuVasive PCM

Phillips et al. conducted a prospective, multicenter, randomized FDA approved IDE trial to evaluate the safety and efficacy of PCM Cervical Disc compared to ACDF for single level degenerative spondylosis. Unlike previous IDE trials, they included patients with prior nonadjacent or adjacent single level fusions (approx. 12% of the study population). Two hundred and twenty-four patients were randomized into the PCM group and 218 received surgery

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