

## Clinical Studies

## The prevalence of indications and contraindications to cervical total disc replacement

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**Abstract**

**BACKGROUND CONTEXT:** Although the prevalence of indications and contraindications to lumbar total disc replacement (TDR) has been evaluated, no study to date has quantified the potential candidacy for cervical disc replacement in practice.

**PURPOSE:** To report the potential candidacy rate for cervical TDR from both an academic and private practice spine surgery setting.

**STUDY DESIGN/SETTING:** Retrospective case series.

**PATIENT SAMPLE:** Patient record review of 167 consecutive patients who underwent cervical spine surgery by 1 of 2 orthopedic spine surgeons between January 1, 2003 and January 1, 2005.

**OUTCOME MEASURES:** Evaluation of potential candidacy for cervical TDR, with emphasis on both contraindications and indications.

**METHODS:** In this study, we used the published contraindications and indications listed in trials of four different cervical disc arthroplasty devices: ProDisc-C (Synthes Spine, West Chester, PA), PRESTIGE LP (Medtronic Sofamor Danek, Memphis, TN), Bryan Cervical Disc prosthesis (Medtronic Sofamor Danek, Memphis, TN), and Porous Coated Motion (PCM; Cervitech, Rockaway, NJ). The proportion of patients who met both inclusion and exclusion criteria was calculated. We also examined the proportion of patients who would be candidates for cervical TDR if the indications were expanded to include the treatment for adjacent segment disease (ASD).

**RESULTS:** Of the 167 patients (mean age 50.8 years, range 20–89 years) reviewed, 91.6% (153/167) had fusion surgery and 8.4% (14/167) had nonfusion surgery. Fifty-seven percent (95/167) had absolute contraindications to cervical TDR, and within this group the average number of contraindications was 2.1 (SD=1.2, range 0–5). Forty-three percent (72/167) met the strict inclusion criteria, and had no exclusion criteria. If the indications were expanded to include treatment for ASD, an additional 4.2% (7/167) of the patients would have qualified as candidates for cervical TDR.

**CONCLUSIONS:** Compared with lumbar TDR, total disc replacement may have a larger potential role in the treatment of cervical degenerative conditions, as 43% of patients would have met the strict criteria for TDR candidacy, or 47% if the indications were expanded to include treatment for ASD. © 2008 Elsevier Inc. All rights reserved.

**Keywords:**

Cervical disc replacement; Candidacy; ACDF; Indications

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## Introduction

Anterior cervical discectomy and fusion (ACDF) currently remains the standard treatment for disc herniation and degenerative disc disease (DDD) refractory to conservative therapy. Recently, however, cervical total disc replacement (TDR) has generated significant interest as a potential alternative, because of the well-known risks and complications associated with cervical fusion [1,2]. Biomechanical studies have shown that fusion alters adjacent-level kinematics, resulting in increased biomechanical stresses; this may lead to accelerated degeneration at adjacent segments [3–7]. A recent clinical study reported that disease-free survival rates after ACDF were 89% at 5 years, 84% at 10 years and 67% at 17 years [8]. Further potential morbidities associated with cervical fusion include the possibility of decreased total cervical range of motion, pseudarthrosis, graft donor site morbidity, and instrumentation-related complications [9–15]. Cervical intervertebral disc prostheses, on the other hand, preclude the need for a bone graft and fusion, and are designed to maintain more physiologic spinal kinematics at both the operative and adjacent levels. Given this important theoretical advantage, cautious enthusiasm for cervical TDR continues to expand, whereas the results from clinical trials comparing cervical TDR with ACDF accumulate.

Several recent publications have challenged the predictions that TDR will supplant fusion procedures in the lumbar spine, citing advanced degeneration, central stenosis, and facet arthrosis as the most common reasons patients do not meet the criteria for TDR candidacy [16–18]. The prevalence of contraindications to lumbar TDR in a tertiary referral spine surgery center ranges from 95% to 100% [17,19], but TDR may be indicated in as many as 33% in patients with a diagnosis of DDD [18]. Overall, the precise role and potential utility of TDR technology relative to other available treatment options for spinal disorders remain uncertain, though the results from ongoing clinical trials should help establish its place in the spine surgeon's surgical armamentarium. Given the unexpectedly low percentage of lumbar surgical patients who would qualify for lumbar TDR, the purpose of our study, therefore, was to evaluate the potential utility of cervical disc replacement among consecutive patients who underwent cervical spine surgery from both academic and private practice settings.

## Materials and methods

### Patient selection and data collection

After Investigational Review Board approval, we retrospectively reviewed the medical records of 167 consecutive patients who underwent cervical spine surgery by one of two orthopedic spine surgeons (K.R.C., S.A.R.) between January 1, 2003 and January 1, 2005. The cohort of surgical patients was comprised of patients evaluated and treated at an academic tertiary referral center, as well as those evaluated

and treated in a private practice spine referral center. Patients underwent elective procedures only if their condition was refractory to 6 months of conservative therapy, including lifestyle modification, physical therapy, medications, orthotic treatment, spinal injections, acupuncture, and/or chiropractic manipulation. Any patient presenting with an emergent spine-related condition underwent a comprehensive preoperative evaluation, including appropriate radiologic and laboratory studies, by a multidisciplinary medical team before undergoing surgery. All 167 clinical records, operative notes, and radiographic imaging results were reviewed by an orthopedic resident (J.D.A.) to identify the patient's age, gender, clinical diagnosis, relevant radiographic findings, and surgical procedures performed.

### Contraindications to cervical TDR

Although the guidelines for candidacy are not universally agreed on, for the purposes of the current study, we used the published contraindications and indications listed in trials of four different cervical disc arthroplasty devices: ProDisc-C (Synthes Spine, West Chester, PA), PRESTIGE LP (Medtronic Sofamor Danek, Memphis, TN), Bryan Cervical Disc prosthesis (Medtronic Sofamor Danek, Memphis, TN), and Porous Coated Motion (Cervitech, Rockaway, NJ) [20–24]. A summary of these contraindications are listed in Table 1 and are also in agreement with the previously published guidelines described by McAfee [24]. Particular attention was paid to the nature of the compressive anatomy, and whether it was disc material or osteophytes. In the latter case, spondylosis (defined as the presence of osteophytes) is considered an indication for cervical TDR, however, spinal stenosis by hypertrophic spondylarthrosis, or severe spondylosis (defined as bridging osteophytes, a loss of disc height greater than 50%, or absence of motion [less than 2°]), was considered a contraindication.

### Indications for cervical TDR

In addition to determining the proportion of patients with contraindications to cervical TDR, we also determined the proportion of patients without contraindications who also met inclusion criteria. Such patients were considered candidates for cervical TDR. The inclusion criteria for cervical TDR are similar to those generally agreed on for ACDF. These include patients without contraindications who have cervical DDD causing radiculopathy or myelopathy, and radiographic evidence for a compressive lesion characterized by 1) disc herniation with radiculopathy, 2) spondylotic radiculopathy, 3) disc herniation with myelopathy, or 4) spondylotic myelopathy [20–24] (Table 2). Other radiographic indications for cervical TDR include decreased intervertebral disc height of at least 4 mm, with or without scarring, thickening of the annulus fibrosus, and the presence of osteophytes [24].

Table 1

Summary of contraindications to cervical TDR

≥3 vertebral levels requiring treatment
Cervical instability (translation >3 mm and/or >11° rotational difference to that or either adjacent level)
Known allergy to implant materials (titanium, polyethylene, cobalt, chromium, and molybdenum)
Cervical fusion adjacent to the level to be treated
Posttraumatic vertebral body deficiency/deformity
Facet joint degeneration
Neck or arm pain of unknown etiology
Axial neck pain as the solitary presenting symptom
Severe spondylosis (bridging osteophytes, disc height loss >50%, and absence of motion <2°)
Osteoporosis/osteopenia
Prior surgery at the level to be treated
Active malignancy; any patient with history of invasive malignancy, unless treated and asymptomatic for at least 5 years
Systemic disease (AIDS, HIV, Hepatitis B or C, and Insulin-dependent diabetes)
Other metabolic bone disease (ie, Paget's and osteomalacia)
Morbid obesity (BMI>40 or weight>100 lb over ideal body weight)
Pregnant or trying to become pregnant in next 3 years
Active local/systemic infection
Presently on medications that can interfere with bone/soft tissue healing (ie, steroids)
Autoimmune spondyloarthropathies (rheumatoid arthritis)

TDR = total disc replacement.

### Analyses performed

After data collection, three analyses were performed. First, the percentage of patients who were contraindicated was determined, using the aforementioned criteria. Second, the percentage of patients who were candidates (ie, had no contraindications and met inclusion criteria) was calculated. Finally, we examined the proportion of patients who would have qualified for cervical TDR if the indications were expanded to include the treatment for adjacent segment disease (ASD), a situation for which cervical TDR may ultimately be indicated and has already been performed [20,22]. Although cervical TDR is not currently indicated to treat adjacent segment degeneration, some authors have proposed that one of the main advantages of cervical TDR compared with ACDF may be its ability to more safely treat adjacent segment degeneration [24,25]. One of the main problems in trying to achieve a fusion adjacent to a previous fusion is the difference in stiffness properties of the solid fusion below, and the open disc space above [25]. Pimenta et al. reported excellent results using a Porous Coated Motion (Cervitech, Rockaway, NJ) cervical disc replacement to treat 10 patients with adjacent segment degeneration above a prior fusion (eight from a previous surgical fusion and two from congenital Klippl-Feil fusions) [22]. Other potential drawbacks of cervical fusion in the treatment of ASD, for which cervical TDR may provide a safer alternative are 1) the need to use a plate in the extension of the initial fusion may increase the risk for postoperative swelling and dysphagia and 2) increased risk for pseudarthrosis and continued pain [25].

### Statistical analysis

The mean, standard deviation, and range of contraindications present in all patients were calculated. All data analysis was performed using Microsoft Excel 2002 (Microsoft Inc., Redmond, WA). Student *t* tests were

performed to detect any statistical difference between groups. Statistical significance was set at the  $\alpha=.05$  level.

### Results

The charts of 167 consecutive patients who had cervical spine surgery were reviewed. The mean age was 50.8 years ( $SD=12.2$  years; range 20–89 years). There were 93 men with a mean age of 50.9 years ( $SD=12.6$  years; range 22–89 years) and 74 women with a mean age of 50.8 years ( $SD=11.8$  years; range 20–82 years). Of the 167 patients who underwent surgical procedures, 91.6% (153/167) had fusion surgery and 8.4% (14/167) had nonfusion surgery. Of the patients who underwent fusion procedures, 42% (70/167) underwent iliac crest bone graft harvesting, a procedure which some authors have suggested may cause significant postoperative morbidity [9,26]. A summary of the surgical procedures performed on patients is listed in Table 3. There were 14 patients who underwent both a nonfusion and a fusion procedure.

On review of the 167 consecutive patients treated with cervical spine surgery, 57% (95/167) did not meet appropriate criteria to undergo TDR and were considered absolute contraindications. The average number of contraindications to cervical TDR in this group was 2.1 ( $SD=1.2$ , range 0–5). The most common clinical contraindication to TDR in this patient cohort was an operative level greater than or equal to three

Table 2

Indications for total disc replacement

Symptomatic cervical disc disease at one or two vertebral levels between C3–T1 confirmed by imaging (magnetic resonance imaging [MRI], computed tomography [CT], or myelography) showing herniated nucleus pulposus (HNP), spondylosis, or loss of disc height
Failed ≥6 weeks of conservative therapy
Between 20 and 70 years of age
No contraindications

Table 3  
Summary of surgical procedures performed

Surgical procedure	Number of surgical procedures (%) N=181
ACDF	69 (38)
Posterior cervical decompression (laminectomy) and fusion	22 (12)
Posterior cervical decompression (laminectomy) without fusion	7 (4)
ORIF	6 (3)
Combined anterior and posterior fusion	11 (6)
Corpectomy with anterior cervical plate	55 (31)
Laminotomy	1 (0.6)
Foraminotomy	9 (5)
TDR	1 (0.6)

ACDF = Anterior cervical decompression and fusion; ORIF = Open reduction and internal fixation; TDR = Total disc replacement.

(n=47) (Fig. 1). Seventeen patients underwent surgery for symptomatic adjacent segment degeneration. The second analysis revealed that 72/167 patients (43%) who were candidates for cervical TDR possessed no contraindications and meeting all inclusion criteria. If the indications for cervical TDR were expanded to include treatment for adjacent segment degeneration, then an additional seven patients would have qualified for cervical TDR for a total of 79/167, or 47% (Fig. 2). There were no statistical differences identified between the two surgeons for any of the above outcomes.

## Discussion

Compared with cervical fusion, disc replacement offers the theoretical biomechanical advantage of preservation of motion at the operative level which reduces stresses at the adjacent level [4]. Maintenance of physiologic motion,

and prevention of increased stresses, may protect the adjacent level from late degeneration [7,27]. Although cervical fusion alters adjacent-level kinematics, TDR has been shown to cause a normalization of load transfer and kinematics at adjacent levels when compared with fusion [3–5]. Wigfield et al. recorded stress profiles in adjacent-level intervertebral discs after TDR and found that, compared with fusion, they were similar to those observed in non-treated, intact specimens, thereby suggesting an advantage of TDR surgery compared with spinal fusion [6]. Dmitriev et al. showed that cervical TDR maintains adjacent-level intradiscal pressures, and maintains preoperative level kinematics to the operative level [27].

Although ACDF remains one of the more rewarding and successful treatment options for patients with spinal disorders, the long-term consequences of cervical fusion are also potentially significant. Hilibrand et al. reported that the rate of ASD 10 years after ACDF was 26.4% or roughly 2.9% per year; however, the authors concluded that these changes were more likely attributable to the natural history of underlying DDD rather than from increased stress adjacent to the fusion [28]. In contrast, a recent study by Robertson et al. reported on clinical and radiographic outcomes from 232 patients who underwent either ACDF or cervical TDR using the Bryan Artificial Cervical Disc. At 2 years, ACDF was associated with a significantly higher rate of both radiographic and clinical ASD [29]. When revision surgery is required for symptomatic adjacent segment degeneration, it often includes decompression and extension of the fusion and insertion of a longer plate. This procedure is potentially fraught with complications including a risk for pseudarthrosis, dysphagia, recurrent laryngeal nerve injury, esophageal injuries, instrumentation-related issues, and the possible

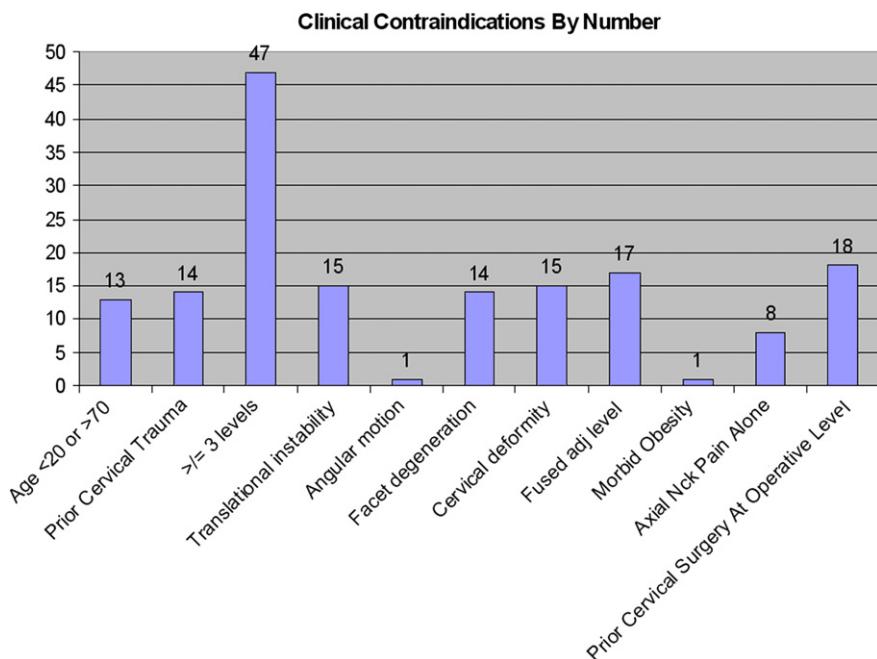


Fig. 1. Most common contraindications to cervical total disc replacement (TDR).

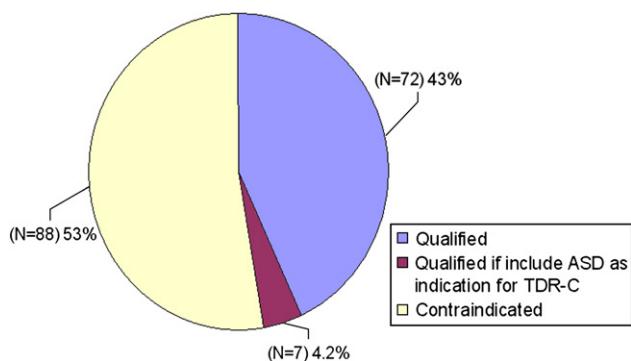


Fig. 2. Proportion of cervical total disc replacement (TDR) candidates.

need for iliac crest bone graft [25,30]. Complications after iliac crest bone grafting include postoperative infection, pelvic fracture, sacroiliac joint injury, inferior gluteal artery injury, and chronic donor site pain. In a retrospective analysis of 1,191 iliac crest bone graft harvest cases, postoperative complications developed in 20% of patients and 55% of patients had chronic donor site pain at 1-year follow-up [7]. In the current study, iliac crest bone graft was used in 42% of patients who underwent fusion procedures. Disc replacement may obviate some of these problems by precluding the need to achieve a fusion or the need for autograft bone, by preventing or delaying the onset of adjacent segment degeneration, and, therefore, may be a more suitable treatment for ASD.

In the lumbar spine, Huang et al. reported the first epidemiological study to investigate the prevalence of contraindications to TDR and found that 95% of patients had one or more contraindications to lumbar disc replacement surgery [19]. The authors concluded that widespread enthusiasm for TDR may be premature, as only 5% of patients seen were indicated for disc replacement surgery. Wong et al. recently concluded that all patients in their series (which included academic and private practice, orthopedic surgeons, and neurosurgeons) had at least one contraindication to lumbar TDR [17]. Two recent studies from our institution report a similar low percentage of lumbar TDR candidacy, ranging from 0.5% to 5%, although up to 33% of patients with DDD may be candidates [18,31]. These surprising results led us to investigate whether or not the same would hold true for the potential utility of TDR in the cervical spine.

Our results suggest a very different trend in the cervical spine. In examining the practices of two orthopedic spine surgeons (one academic and one private practice) over a 2-year period, and applying a universal set of criteria compiled from the published series of four different cervical disc prostheses, we found that 43% of patients undergoing cervical spine surgery would have qualified for cervical TDR. This is roughly nine times the proportion of patients who would have qualified for lumbar TDR, which implies that TDR may have a larger role in the treatment of cervical degenerative

conditions compared with lumbar degenerative conditions. The most likely explanation for the increased proportion of TDR candidates in the cervical spine is that cervical TDR is designed to treat radiculopathy or myelopathy usually stemming from disc herniation and nerve root compression, a common diagnosis which can be fairly reliably and reproducibly identified using magnetic resonance imaging, computed tomography, or myelography [22,24,32]. Both TDR and ACDF can reliably facilitate the removal of the offending disc material and osteophytes, restore intervertebral disc and neuroforaminal height, and stabilize the motion segment (either by fusion or by maintenance of motion) with excellent and predictable results [33]. In contrast, lumbar TDR is currently designed primarily to treat disabling low back pain secondary to isolated DDD in the lumbar spine (not radiculopathy) [24,34]. Back pain stemming from the lumbar spine, however, may be attributable to many other pathologies besides the intervertebral disc that may be a potential source of pain including facet arthrosis, herniated nucleus pulposus, lumbar instability, sagittal imbalance, or psychosocial factors, among others. It is likely that our limited abilities to reliably incite the disc as the sole pain generator leads many surgeons to fuse the entire motion which would treat any offending disc, facet, or instability problems in one operation. As such, there are bound to be fewer patients with low back pain that is attributable solely to a degenerated disc, and hence, fewer patients for whom lumbar TDR is the best treatment option. With improved diagnostic techniques, however, perhaps it will be possible to better predict success with TDR in the future.

When the indications of cervical TDR were expanded to include patients with adjacent segment degeneration, the proportion of cervical TDR candidates rose to 47%. Two authors recently discussed the potential advantages of cervical TDR over fusion in not only the prevention of ASD, but in its treatment [24,25]. If 47% of the roughly 250,000 cervical fusions that take place annually in the United States are replaced by cervical TDR, on average 117,500 cervical TDR procedures would be performed annually. Clearly, if cervical TDR is used properly and without irresponsible extension of indications, the potential utility of this novel technology in the treatment of cervical pathologies is significant.

Although cervical TDR has the potential to be a significant addition to the spine surgeon's armamentarium, there are significant unknowns related to the long-term survival of the implant. Known complications of cervical TDR include implant migration, heterotopic ossification, and recurrent radiculopathy resulting from progression of spondylosis [22,24,25,30]. Unknown potential complications in cervical TDR include implant subsidence, loosening, metallic or polyethylene failure, systemic release of metallic ions, allergic reaction, visceral or neurologic injuries, and infection [32]. The results from long-term follow-up studies will be necessary to fully understand the immediate and late complications that accompany cervical TDR.

Limitations of the current study include the fact that the practices of two orthopedic surgeons, but no neurosurgeons, were analyzed. Wong et al., however, recently showed no difference between the proportion of lumbar TDR candidates when examining variables such as academic versus private practice, and orthopedic surgeons compared with neurosurgeons [17]. Another limitation inherent to the study design is that the experience from the two surgeons in our group cannot possibly be expected to exactly duplicate the practice patterns of spine surgeons throughout the country. Rather, by evaluating the practice patterns of an academic and private practice spine surgeon, our results provide only an initial glimpse into the potential utility of this novel technology in practice. Only after indications, relative contraindications, and absolute contraindications are further elucidated will we know the true utility of cervical TDR.

In conclusion, 43% of patients seen in the practice of two orthopedic spine surgeons would have qualified for cervical TDR (ie, no contraindications and met inclusion criteria). When the indications were expanded to include treatment for adjacent segment degeneration, the percentage of qualifiers rose to 47%. This represents a significant increase in the candidacy for cervical TDR compared with lumbar TDR, which has a candidacy rate of perhaps 5%.

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