Cervical arthroplasty versus anterior cervical decompression and fusion

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Abstract

Background: Anterior cervical decompression and fusion (ACDF) is a common procedure in neurosurgical practice to manage the cervical cord/nerve roots compression by intervertebral disk herniation / osteophytic formation. However, cervical total disk replacement (TDR) progressively became a feasible alternative to ACDF in surgical practice. This procedure is thought to have many advantages compared to classical ACDF. The aim of the present study is to investigate if TDR is superior as outcome measures than ACDF, by reviewing the published data available to date.

Methods: We searched several electronic databases up to December 2010. Outcomes sought includes pain relief, functional capacity, quality of life, adjacent disk disease, secondary surgeries, kinematics/range of motion, return to work, adverse events, potential candidacy rate for surgery. We selected mainly randomized controlled trials.

Results: Compared to ACDF, TDR has superior or equal clinical outcomes, a lower incidence of adjacent disc disease (radiological +/- clinical), lower rate of secondary revision surgeries, supplemental fixation or adjacent segment reoperation, superior spine kinematics, which is maintained over time, earlier return to work. On the other hand, the presented studies have shown that TDR exposes the patients to more frequent postoperative events and have an inferior candidacy rate compared to ACDF. We did not have access to straight –forward economic data, but TDR seems to be more costly than ACDF.

Conclusions: TDR already represents a well-established technique in the armamentarium to manage the cervical disc herniation, a method required to be handled by any surgeon involved in spinal care.

Keywords: cervical arthroplasy, cervical total disc replacement, Bryan, Prestige, Pro-Disc-C, ACDF

Background

Although anterior cervical discectomy and fusion (ACDF) is the regular management for degenerative cervical disc disease, concerns regarding adjacent level degeneration and loss of motion have suggested that arthroplasty may be a better alternative. This procedure, which occurred quite recently in the armamentarium of therapies in spine surgery, became increasingly interesting for the medical community involved in spinal care. Table 1 figures the rationale of using cervical TDR over classical ACDF.

TABLE 1

Rationale for cervical total disc replacement – comparison with ACDF

Measurement	ACDF	Cervical Total Disc Replacement (TDR)
Spinal segmental motion	Absent	Normal
Incidence of adjacent segment disease	Increased	Decreased
Intraoperative morbidity		
Supplemental instrumentation	Anterior cervical plate	None
Exposure	Equal	Equal
Operative time	Equal	Equal (after learning curve)
Postoperative morbidity		
External immobilization	Rigid cervical collar	None
Return to normal activity	At least one month	As early as 1-2 wks
Pseudarthrosis	Increased	Absent
Instrumentation failure	Minimal	Minimal

Cervical arthroplasy – historical timelines

1934 - Mixter and Barr described operations for the removal of the ruptured intervertebral disc (lumbar)

1943 - Semmes and Murphey published their landmark paper, "The Syndrome of Unilateral Rupture of the Sixth Cervical Intervertebral Disc."

1955 - In 1955, Robinson and Smith briefly described anterior discectomies and interbody arthrodesis for cervical disc

Jan 1964 - The first report of a cervical disc replacement - South African Medical Journal

1966 - Fernstorm tried a method by placing a stainless steel ball into lumber and cervical disc center

1989 - Cummins-Bristol Disc

1990 - Bryan cervical disc

1991 – Clinical trial initiated to investigate Cummins-Bristol Disc

2002 – Pilot study to investigate Frenchay/Prestige cervical disc

2002 – Results of Bryan cervical disc clinical trial were published

2007 – FDA approval for Prestige Disc (Medtronic, Inc.)

2007 – FDA approval for ProDisc-C device (Synthes, Inc.)

2009 – FDA approval for Bryan cervical disc (Medtronic, Inc.)

FDA aproved devices

At the moment, there are three FDA approved devices for cervical disc arthroplasty: Prestige ST (Medtronic), Pro-Disc-C (Synthes) and Bryan (Medtronic) (See Table 1). However, an increasing number of devices with this purpose are in various stages of Institutional Devices Evaluation (IDE) for FDA approval: PRESTIGE LP Cervical Disc (Medtronic); CerviCore (Stryker Spine); PCM (NuVasive, Inc); Advent™ Cervical Disc (Orthofix International N.V.); Activ C disc prosthesis (B. Braun/Aesculap Spine); NeoDisc (NuVasive, Inc); DISCOVER™ Artificial Cervical Disc (DePuy Spine, Inc.); Mobi-C (LDR Spine USA); SECURE®-C Cervical Artificial Disc (Globus Medical Inc); Kineflex-C (SpinalMotion). ClinicalTrials.gov reports 19 on-going IDE trials concerning cervical disc prosthesis

The Prestige ST cervical disc is a metal on metal device. It is made of stainless steel and contains two components- a ball and a trough that articulate. It is attached to the cervical vertebrae with screws. It is manufactured from titanium ceramic composite material. A porous titanium plasma spray coating on the end plate surface facilitates bone in growth and long term fixation.

The Pro-Disc –C cervical disc is a metal on polymer device. It has cobalt-chromium end plates with a central keel for anchorage

to the vertebral bodies and a locking core of ultra high molecular weight polyethylene (UHMWPE) as a central polymer that provides a ball and socket articulation. In order to be compatible with tissue, the endplates are coated a titanium plasmapore.

The Bryan cervical disc is also a metal on polymer device. It is a single piece of a porous coated, clamshell shaped titanium endplates with a polycarbonate, polyurethane core.

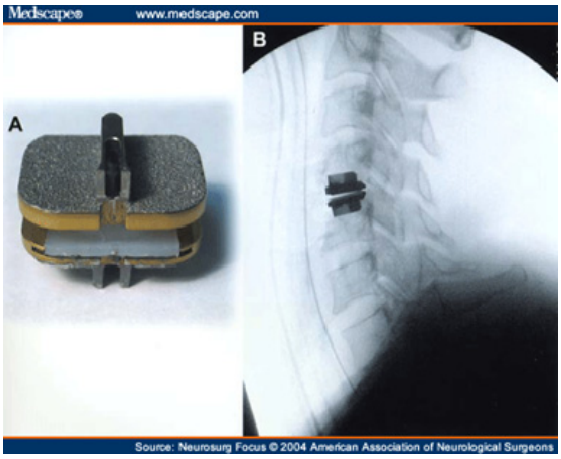

Figure 1 The Prodisc C device. The prosthesis **A** inserted on a patient at C4/C5 level – lateral view **B**

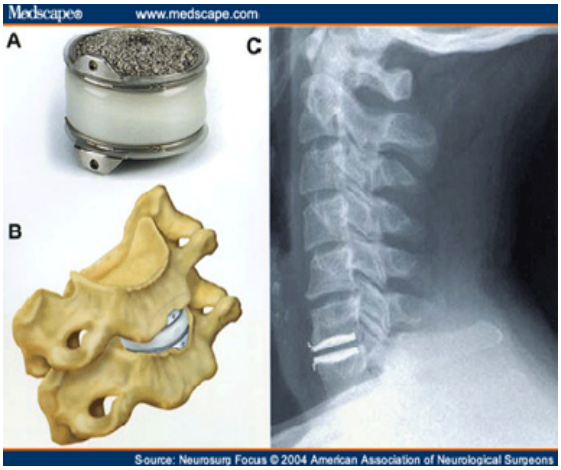

Figure 2 The Bryan device. The prosthesis **A** inserted in vitro **B** and on a patient at C6/C7 level – lateral view **C**

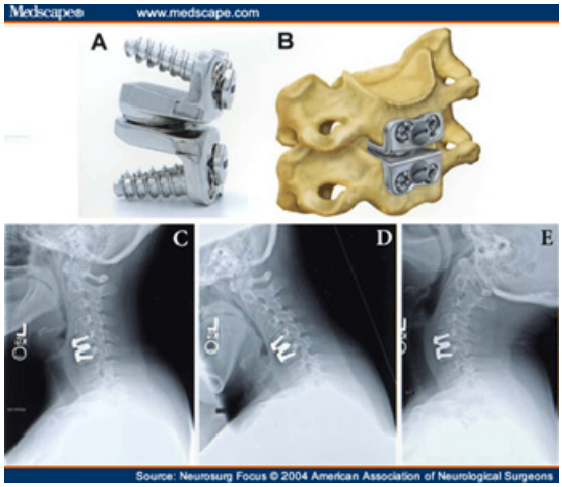

Figure 3 The Prestige device. The prosthesis **A** inserted in vitro **B** and on a patient at C5/C6 level – lateral view **C**, flexion **D**, extension **E**

Methods

We performed a literature review in the following databases: The Cochrane Library and Medline (National Library of Medicine). The review was limited to studies published between 2000 and 2010. The used keywords were: "cervical arthroplasty", "cervical prosthesis", "ProDisc C", "Bryan", and "Prestige". The search plan and the selection and quality ranking of the pertinent studies were carried out and analyzed separately by two persons in a first step and jointly synthesized and discussed in a second step. The studies that had been found were selected according to the quality criteria of the Jadad Score (2000) for randomized controlled trials (7, 8) and the checklist of Downs and Black (1998) for randomized and nonrandomized studies. Only randomized controlled trials, comparing ACDF vs cervical arthroplasty were included. 17 studies were identified.

We tracked information about the following parameters: clinical outcome,

adjacent disc disease, kinematics, secondary surgeries, return to work, adverse events.

Clinical outcome: TDR superior to ACDF

Some studies reported superior results TDR vs ACDF in terms of clinical outcome. Garrido BJ et al. investigated 47 patients randomly managed by ACDF and TDR. At 48 months follow-up they found improved functional outcomes for NDI (Neck Disability Index), neck/arm pain VAS scores, and the SF-36 physical/mental health component scores for both the Bryan arthroplasty and ACDF cohorts. There has been no degradation of functional outcomes from 24 to 48 months for NDI, VAS of neck and arm, and SF-36 (5). They found superior results for cervical arthroplasty group. Heller JG et al. studied 563 patients (242 TDR vs 221 single-level ACDF). At 24 months follow-up the investigational group patients treated with the artificial disc had a statistically greater improvement in the primary outcome variables: NDI score ($P = 0.025$) and overall success ($P = 0.010$) compared to ACDF group (6). In another study, Riina J et al. operated 19 patients randomly using TDR and ACDF and follow them for 24 months. Patients who underwent arthroplasty demonstrated greater improvement in neurologic function and neck pain than patients who underwent cervical discectomy and fusion (15). Finally, Sasso RC et al. managed 115 patients randomized in a 1:1 ratio to ACDF or TDR. At 24 months follow up, the investigational group had statistically significant ($P<0.05$) improvements as assessed by the Neck Disability Index, the Neck Pain Score, and SF-36 Physical component scores. The improvement in the Mental Component Subscore values for the BRYAN and control groups was equivalent at 24 months ($P=0.055$). Arm pain relief was similar in both groups ($P=0.152$) (17, 18).

Clinical outcome: no differences TDR vs ACDF

On the other hand, there are studies showing no differences in clinical outcome post ACDF vs TDR. Bhadra AK et al. studied 60 patients: (15 TDR, 15 plate and tricortical autograft, 15 plate, cage, and bone substitute, 15 cage only) at 31 months follow up. The clinical outcome in terms of VAS of neck and arm pain and SF12 physical and mental score improvement ($P=0.001$) were comparable in all four techniques (3). In another study, Buchowski JM et al. analyzed 199 patients: 106 patients (53%) TDR vs 93 (47%) ACDF at 24 months follow up (4). Patients in both the arthroplasty and arthrodesis groups had improvement following surgery; furthermore, improvement was similar between the groups, with no worsening of myelopathy in the arthroplasty group. Kim SW et al. had 105 patients with 63 TDR placed in 51 patients and 54 patients operated with ACDF, 26 single level , 28 double level at 19 months follow up (9). There was clinical improvement within each group in terms of VAS and NDI scores from pre-op to final follow-up, but not significantly between the two groups for both single (VAS $p=0.8371$, NDI $p=0.2872$) and double (VAS $p=0.2938$, NDI $p=0.6753$) level surgeries. Murrey D et al. operated 209 patients (106 ACDF; 103 TDR) and follow them for 24 months (13). NDI and SF-36 scores, VAS neck pain intensity and frequency as well as VAS arm pain intensity and frequency were significantly less compared with pre-surgery scores at all follow-up visits for both the treatment groups ($p<.0001$).

Neurologic success (improvement or maintenance) was achieved at 24 months in 90.9% of ProDisc-C and 88.0% of fusion patients (p=.638). However, at 24 months, there was a statistically significant difference in medication usage with 89.9% of ProDisc-C patients not on strong narcotics or muscle relaxants, compared with 81.5% of ACDF patients. 49 patients were randomly managed by Nabhan A et al. with ACDF or TDR (14). At 36 months follow-up, after both procedures, a significant pain reduction in neck and arm was observed, without significant differences between both groups.

Adjacent disc disease

One major advantage claimed for TDR is the absence of adjacent disc disease. This condition occurs following ACDF, due to the additional mechanical stress over the discs adjacent to the ACDF site. Two reports investigated the adjacent disc disease occurrence in TDR vs ACDF. Kim SW et al. studied 105 patients. 63 TDR were placed in 51 patients. A single level procedure was performed in 39 patients and a two-level procedure in the other 12 (9). Fifty-four patients underwent ACDF, 26 single level cases and 28 double level cases. Mean follow-up was 19 months. Statistically significant ($p<0.0001$ and $p=0.0172$) differences in the trend of intervertebral height measurements between the two groups were noted at all levels except for the anterior intervertebral height of single level surgeries at the upper ($p=0.1264$) and lower ($p=0.7598$) adjacent levels as well as posterior intervertebral height for double level surgeries at the upper ($p=0.8363$) adjacent level. Radiological change was 3.5 times more observed for the ACDF group. In another study the patients were treated with the Affinity Anterior Cervical Cage System (158) or the Bryan Artificial Cervical Disc (74) (16). Follow-up period was 24 months. Fusion was associated with a significant increase in x-ray film-based changes of adjacent-disc disease ($p = 0.009$, odds ratio [OR] 2.44). In the cage fusion series, the incidence of symptomatic adjacent-level DDD was statistically greater than that in the group treated with the artificial disc ($p = 0.018$).

Secondary surgeries

We also investigated the rates of secondary surgeries needed to fix complications such as: adjacent disc disease or pseudarthrosis. Garrido BJ et al. studied 47 patients randomly managed with ACDF or cervical arthroplasy, at a follow up of 48 months. 6 additional surgeries were needed in ACDF group (3 adjacent level, 1- remote level and 2 for pseudarthrosis) and one surgery in TDR group for adjacent level (5). Heller JG et al. investigated 563 patients (242 TDR vs 221 single-level ACDF) and follow them for 2 years. There was no statistical difference between the 2 groups with regard to the rate of secondary surgical procedures performed subsequent to the index procedure (6). In another study (13), two hundred nine patients were randomized and treated (106 ACDF; 103 ProDisc-C). Patients were assessed pre- and postoperatively at six weeks, 3, 6, 12, 18, and 24 months. There was a statistically significant difference in the number of secondary surgeries with 8.5% of fusion patients needing a re-operation, revision, or supplemental fixation within the 24 month postoperative period compared with 1.8% of ProDisc-C patients (p=.033). Finally, in Mummaneni et al. study five hundred forty-one patients with single-level cervical DDD and radiculopathy were enrolled at

32 sites and randomly assigned to one of two treatment groups: 276 patients in the investigational group underwent anterior cervical discectomy and decompression and arthroplasty with the PRESTIGE ST Cervical Disc System (Medtronic Sofamor Danek); 265 patients in the control group underwent decompressive ACDF. Eighty percent of the arthroplasty-treated patients (223 of 276) and 75% of the control patients (198 of 265) completed clinical and radiographic follow-up examinations at routine intervals for 2 years after surgery. The arthroplasty group had a statistically significant lower rate of secondary revision surgeries ($p = 0.0277$) and supplemental fixation ($p = 0.0031$). Rate of adjacent-segment reoperation was significantly lower in the investigational group as well ($p = 0.0492$, log-rank test) (11, 12).

Kinematics / range of motion

One advantage of TDR vs ACDF seems to be a better kinematics, with larger range of motion by keeping the operated vertebral segment mobil. The following studies were published in this regard. Kim SW et al. studied 105 patients. 63 TDR were inserted in 51 patients. A single level ACDF procedure was performed in 39 patients and a two-level procedure in the other 12. 54 patients underwent ACDF, 26 single level cases and 28 double level cases. Mean follow up period was 19 months. Overall, ROM and intervertebral height was relatively well maintained during the follow-up in the Bryan group compared to ACDF. Regardless of the number of levels operated on, significant differences were noted for overall ROM of the cervical spine ($p<0.0001$) and all other levels except at the upper adjacent level for single level surgeries ($p=0.2872$). Statistically significant ($p<0.0001$ and $p=0.0172$) differences in the trend of intervertebral height measurements between the two groups were noted at all levels except for the AIH of single level surgeries at the upper ($p=0.1264$) and lower ($p=0.7598$) adjacent levels as well as PIH for double level surgeries at the upper ($p=0.8363$) adjacent level (9). Radiological change was 3.5 times more observed for the ACDF group. Sasso RC et al. treated 463 patients (221 ACDF and 242 TDR). The follow up was at 24 months. Significantly more motion was retained in the disc replacement group than the plated group at the index level (Sasso & Best, 2008; Sasso et al., 2008. The disc replacement group retained an average of 7.95 degrees at 24 months. The preoperative motion was 6.43 degrees and there was no evidence of degradation of motion over 24 months. In contrast, the average range of motion in the fusion group was 1.11 degrees at 3-month follow-up and gradually decreased to 0.87 degrees at 24 months. The preoperative motion was 8.39 degrees. Murrey D et al., managed 209 patients (106 ACDF vs 103 TDR). Results show that at 24 months postoperatively, 84.4% of ProDisc-C patients achieved a more than or equal to 4 degrees of motion or maintained motion relative to preoperative baseline at the operated level (13). Nabhan A et al. studied 49 pts 1:1 randomized TDR vs ACDF at a follow up of 36 months. The range of motion of the treated segment with prosthesis remained unchanged 3 years after surgery in comparison to the 1-year result (14). The prosthesis shows a significant segmental motion in contrast to the fusion group at each RSA examination time ($p < 0.05$). Finally, Mummaneni PV et al. investigated 541 patients (276 TDR vs 265 ACDF) (11, 12). At 24 months the

cervical disc implant maintained segmental sagittal angular motion averaging more than 7 degrees. In the investigational group, there were no cases of implant failure or migration.

Return to work

One important issue to be taken into account is the professional outcome of this kind of patient following to TDR or ACDF. We found three studies reporting this kind of data. Heller JG et al. used Bryan devices (6). 563 patients were enrolled (242 TDR vs 221 single-level ACDF). They have data at 24 months follow-up. Patients who received the artificial cervical disc returned to work nearly 2 weeks earlier than the fusion patients (P = 0.015). Steinmetz MP et al.,(19) used Prestige ST and Bryan devices. They studied 1004 patients and follow them for 24 months. At 6 weeks and 3 months, significantly more patients in the arthroplasty group were working compared with the fusion group. At 6 months and later, there was no significant difference in return-to-work rates. Overall, patients returned to work at a median of 101 days after arthroplasty, compared with 222 days after ACDF. Mummaneni PV et al. analyzed 541 pts. - 276 pts TDR (Prestige ST) vs 265 ACDF(11, 12). The patients in the investigational group returned to work 16 days sooner than those in the control group.

Adverse events/ dysphagia

Two studies analyzed the adverse effects related to the cervical disk surgery, either by using ACDF or TDR. McAfee PC et al., 2010 (10) used porous-coated motion (PCM) device in 151 patients and compared them with a control group of 100 ACDF patients. The patients were followed for 12 months. The incidence of postoperative dysphagia and the long-term resolution of the dysphagia was greatly improved in the PCM group compared with the instrumented ACDF control group. Anderson PA et al., 2008 (1) reported four hundred sixty-three (463) patients having cervical radiculopathy and or myelopathy at a single level which were treated at 31 sites. A total of 242 patients received the disc and 221 patients had anterior cervical discectomy and fusion. All patients were evaluated before surgery and at 1.5, 3, 6, 12, and 24 months after surgery . No differences in overall medical events occurred between groups. Surgically related events occurred more frequently in the investigational group secondary to more complaints of postoperative dysphagia and late medical events occurred more frequently in the investigational patients. However, the more severe World Health Organization Grade 3 and 4 events occurred more frequently in the arthrodesis patients related to treatment of pseudarthrosis and persistent symptoms. Significantly, more cervical spine reoperations occurred in the fusion group. Only one spinal cord injury occurred and it was in the arthrodesis group and no patients had deep infection or death related to either procedure.

Potential candidacy rate for cervical TDR

Auerbach JD et al , 2008 (2) reviewed 167 consecutive patients who underwent cervical spine surgery. The authors 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 (Medtronik Sofamor Danek, Memphis, TN), Bryan Cervical Disc prosthesis (Medtronik Sofamor Danek, Memphis, TN), and Porous Coated Motion (PCM;

Cervitech, Rockaway, NJ). 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 non-fusion surgery. 57 % 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). 43% (72/167) met the strict inclusion criteria, and had no exclusion criteria. If the indications were expanded to include treatment for adjacent segment disease (ASD), an additional 4.2% (7/167) of the patients would have qualified as candidates for cervical TDR. This study is very interesting, highlighting the fact that ACDF covers as surgical solution a larger group of patients than TDR.

Conclusions

Summarizing, compared to ACDF, TDR has superior or equal clinical outcomes, a lower incidence of adjacent disc disease (radiological +/- clinical), lower rate of secondary revision surgeries, supplemental fixation or adjacent segment reoperation, superior spine kinematics, which is maintained over time, earlier return to work. On the other hand, the presented studies have shown that TDR exposes the patients to more frequent postoperative events and have an inferior candidacy rate compared to ACDF. We did not have access to straight –forward economic data, but TDR seems to be more costly than ACDF. Our final conclusion is that TDR already represents a well-established technique in the armamentarium to manage the cervical disc herniation, a method required to be handled by any surgeon involved in spinal care.

Abbreviations

TDR – total disc replacement;
ACDF – anterior cervical decompression and fusion;
NDI – neck disability index;
VAS - visual analog scale;
DDD – degenerative disc disease;
ROM – range of motion

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