

## Cervical Total Disc Replacement, Part Two: Clinical Results

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Variations on discectomy and fusion with autologous bone have been attempted with varying success. Successful orthopedic treatment of arthropathies, initially with large joint replacement and more recently with smaller joint replacements, has resulted in a heightened interest in spinal total disc replacement (TDR). Closer attention is being paid to the longer-term effects of spinal fusion, and an increasingly critical approach to assessing short- and long-term surgical outcome is being addressed. A cervical disc replacement should not adversely affect the associated facet joints, adjacent motion segments of the spine, and most important, the neurovascular elements of the spine. The cervical TDR implants with the most extensive clinical experience are the ProDisc-C (Synthes, Oberdorf, Switzerland), the Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, Tennessee), and the Bristol Disc (Medtronic Sofamor Danek, Memphis, Tennessee).

### ProDisc-C

#### Design

The ProDisc-C prosthesis (Fig. 1) was designed to be implanted in a simple surgical procedure with

a few steps. The ProDisc-C restores segmental motion, foraminal height, dynamic function, spinal balance, and stability of the cervical spine. The prosthesis consists of a modular design, two metal plates, and a polyethylene inlay that is safely secured into the lower end plate (snap mechanism). The metal end plates have a keel design for enhanced primary stability and fixation, and the end plate coverage with titanium plasma spray coating allows bony ingrowth and long-term fixation. The polyethylene inlay determines the height of the prosthesis. The prosthesis is designed for en bloc implantation.

#### Indications

Ideal patients for cervical TDR present with degenerative disc disease that has failed extensive non-surgical treatment and is causing combinations of neck pain, myelopathy, and radiculopathy. Cervical TDR in patients with degenerative disease and isolated neck pain without neural compression symptoms is not yet recommended until more clinical data are available. There are several factors that exclude patients from being eligible to have this procedure, such as osteoporosis and osteopenia or other bone metabolic diseases, posterior facet arthropathy, severe myelopathy due to posterior vertebral body spinal cord compression, chronic infections, tumor, metabolic or systemic disease, or pertinent metallic allergies.

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Fig. 1. Illustration of the ProDisc-C. (Courtesy of Synthes, Oberdorf, Switzerland from the surgical technique ProDisc-C © Stratec Medical 2005, Switzerland; with permission.)

### *Surgical approach*

Before surgery, a complete clinical and radiographic assessment must be performed. The patient is situated in a supine position on a fluoroscopic imaging table to allow imaging in anteroposterior (AP) and lateral planes to locate the level of the diseased disc and to control the different surgical steps of the

application. The anterior cervical spine is exposed using a standard-approach, standard retractor system or with the assistance of a specialized anterior spinal retractor system, the Cervical SynFrame (Synthes Spine, Oberdorf, Switzerland). After determining the midline, self-tapping retainer pins are fixed into the vertebral bodies. After application of the retainer, the discectomy is performed and distraction is performed with the distraction forceps. The retainer is adjusted to the distraction forceps accordingly, and the disc-extruded material and the cartilaginous end plates are removed. With a high-speed bur, the anterior and posterior part of the end plate is remodeled into a relatively flat surface. At least 60% to 70% of the natural end plate must be maintained.

After the end plate preparation is completed, specially designed trials that correspond to the height and AP diameter of the sizes available for the ProDisc-C are used to assess sizing under lateral fluoroscopy. After the appropriate size is determined, positioning along the midline is confirmed by AP fluoroscopy. Keel cuts are made using the prosthesis trial as the guide and a keel-cutting chisel. The trial and chisel are removed. Under lateral fluoroscopy, the prosthesis is inserted to an adequate depth. AP and

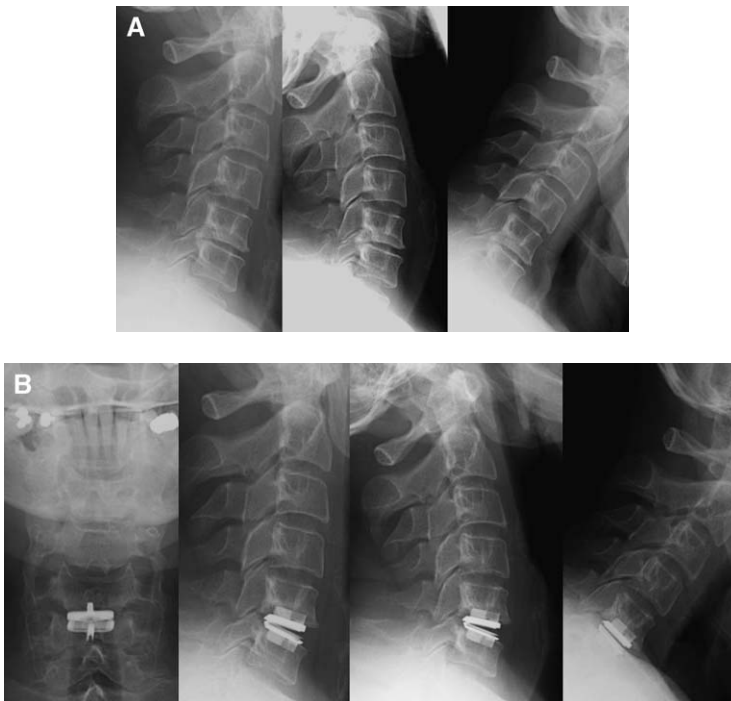


Fig. 2. (A) Preoperative radiographs (lateral, flexion, extension). (B) Postoperative radiographs (AP, lateral, flexion, extension).

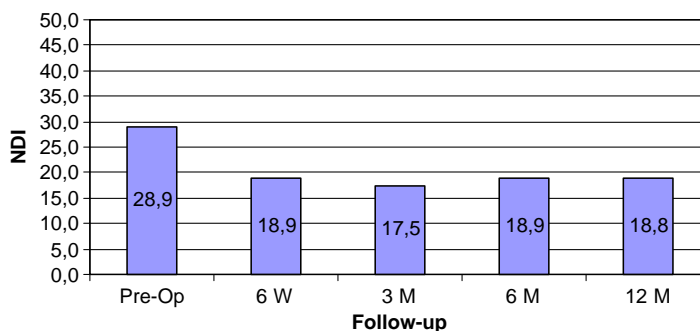


Fig. 3. Preoperative to 12-month follow-up NDI scores for patients with ProDisc-C implantation.

lateral fluoroscopy confirm appropriate placement. The incision is closed, completing the procedure.

### Results

In this study, only patients who had one level of cervical degenerative disc disease were surgically treated with a Prodisc-C implant. Twenty-seven patients with 1-year follow-up were included.

Patients were assessed preoperatively and postoperatively at 3 and 6 weeks and at 3, 6, and 12 months. The primary functional outcomes assessed pre- and postoperatively were disability and pain scores using the Neck Disability Index (NDI) and visual analog scale (VAS) scores. Additional clinical parameters included analysis of pre- and postoperative patient satisfaction, general neck pain, radicular pain, medication usage, and complications.

Pre- and postoperative radiographs (Fig. 2) were obtained in all patients, including AP, lateral, flexion, extension, and lateral bending films. Independent reviewers assessed radiographs for device-related loosening, dislodgment, or subsidence.

The average age of the patients was 49 years (range, 31–66 years) at the time of surgery. Of the 27 patients, 13 were men and 14 were women. Three patients had prior surgery. Most cases were at the operative level of C5-6 (16 patients) and the remaining patients had surgery at C4-5 (2 patients) and C6-7 (9 patients).

The clinical outcome measures (Figs. 3–5) show sustained improvement at 1-year follow-up. The NDI scores show a 35% decrease at 6 weeks postoperatively that steadily continue to 1-year follow-up. Similarly, VAS scores drop 44% by 6 weeks postoperatively and remain constant. Range of motion (ROM) showed a 240% improvement at 1-year follow-up in comparison to the preoperative condition, and more important, ROM returned to a normal functional level of motion at about 10°.

Pain intensity and frequency was assessed in the neck and arms. The frequency and intensity of neck pain decreased similarly from the preoperative assessment by approximately 40%. In the arms, pain frequency and intensity resolved to less than half of the original value.

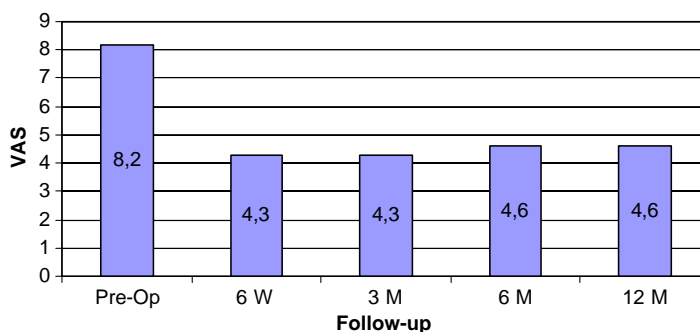


Fig. 4. Preoperative to 12-month follow-up VAS scores for patients with ProDisc-C implantation.

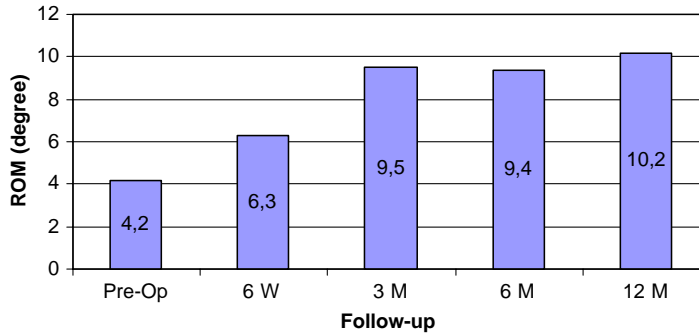


Fig. 5. Range of motion, preoperative to 12-month follow-up.

Patient satisfaction levels at 1-year follow-up were completely satisfied (52%), satisfied (36%), and not satisfied (12%). More patients initially reported being completely satisfied, but this rate dropped by approximately 20% over the first year. The percentage of patients who reported being satisfied rose during the year of follow-up by approximately 10%. At 3-week follow-up, none of the patients reported being not satisfied, but the percentage increased during follow-up.

There were no device-related complications in this study. The authors recorded no cases of loosening, subsidence, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurologic injuries caused by the implant components, or infection. There were no approach-related complications such as intraoperative fractures, hematomas, dural tears/leaks, postoperative airway compromise, esophageal or tracheal disruption, laryngeal nerve injury, or sympathetic nerve dysfunction. The authors observed no spontaneous fusions at the affected or adjacent levels.

#### Discussion

Because many of the new designs have the potential to become a standard of practice in medical care of degenerative disc disease, it becomes imperative to understand the biomechanical environment of the cervical spine and how each design works within that environment. Although well-controlled prospective, randomized studies are currently underway and provide excellent short-term data, long-term results truly show the advantage of arthroplasty over arthrodesis. This short series offers a glimpse into the clinical basis for arthroplasty and elucidates the lack of complications and short-term issues with cervical

arthroplasty. It is hoped that long-term data will support the theory that arthroplasty reduces the incidence of adjacent-level disease because it restores functional motion, thereby maintaining normal loads at the adjacent levels.

#### Bryan Cervical Disc

##### Design

The Bryan Cervical Disc prosthesis consists of a low-friction polyurethane nucleus surrounded by a polyurethane sheath and situated between two titanium alloy shells. The biarticulating metal-on-polymer disc possesses elasticity and little compressibility and allows for unconstrained motion and translation through normal ROM. The prosthesis is axially symmetric, allowing for similar ROM in sagittal plane motion and in lateral bending.

Axial rotation of the Bryan disc is unconstrained. Preliminary biomechanical studies suggest a mobile center of rotation [1], allowing the device to accommodate a range of preoperative center-of-rotation values without subjecting the facets and ligaments to abnormal stresses. Abnormal shifting of the center of rotation following spinal arthroplasty has been implicated in recent reports of facet pain associated with prosthesis positioning [2].

##### Clinical results

Goffin et al [3] provided the first report of a large clinical series of patients treated with the Bryan Cervical Disc prosthesis. This multicenter, pro-

spective cohort described preliminary results with insertion of the disc following anterior cervical discectomy for single-level degenerative disease. Patients with radiculopathy or myelopathy were recruited for the study. Although the investigators described 97 patients undergoing implantation with the device, clinical outcome data were reported for only 60 patients, with 30 reaching the 1-year post-operative end point. The outcome tools that were used included the Cervical Spine Research Society Assessment Scale and Short Form-36 (SF-36); results were reported using modified Odom's criteria. Success, defined by the investigators as excellent, good, or fair, was reported in 86% of patients at 6 months and 90% at 1 year. These promising clinical outcomes, however, are a result of the adequacy of neural decompression and are independent of the prosthesis. Perhaps more important, preserved ROM at the site of surgery was reported in 93% of patients at 6 months and in 88% at 1 year. No device failures, subsidence, or explantations were described. Device migration was detected in 1 patient and suspected in another. This migration was attributed to incomplete milling of the end plates. Approach-related complications were also described [3].

A follow-up study by Goffin et al [4] reported longer follow-up on the single-level group and early clinical results with two-level implantation of the Bryan Cervical Disc. ROM analysis demonstrated preserved sagittal plane motion in 88% of single-level and 86% of two-level patients at 1 year, whereas clinical outcomes were rated as excellent, good, or fair in over 90% of patients ( $n = 89$ ) at 1 year [4]. More recently, follow-up on this group of patients

showed that 45 of 73 (62%) single-level patients with 2-year follow-up had "excellent" outcome, with 7 patients scored as good, 13 as fair, and 8 as poor [5]. SF-36 physical and mental component summary scores were significantly improved by 3 months post-operatively, and this improvement was maintained up to 2 years. Sagittal plane motion equal to or greater than  $2^\circ$  remained present in 88% of patients at 2 years [5]. Similarly encouraging results were reported for the two-level cohort, with 21 of 30 (70%) patients with 1-year follow-up outcome scored as excellent, 3 scored as good, 5 as fair, and 1 as poor. SF-36 scores again improved postoperatively, although the statistical significance was not reported [5].

A smaller prospective cohort confirmed preservation of motion and significant improvement in standardized clinical outcome tools including the NDI and SF-36. In this study, Duggal et al [6] also compared outcomes in patients suffering from soft disc herniations with those patients with spondylotic ridging causing foraminal stenosis. No statistically significant difference was found with respect to outcome scores between the two groups. In addition, when outcomes in patients undergoing arthroplasty for myelopathy were compared with patients who had radiculopathy, no difference in outcome or complication rate was found.

A functional disc prosthesis, which adequately mimics the in vivo function and biomechanics of an intervertebral disc, may be able to restore the functional spine unit and prevent subsequent adjacent segment degeneration. The authors recently assessed the in vivo kinematics of the Bryan artificial disc in a

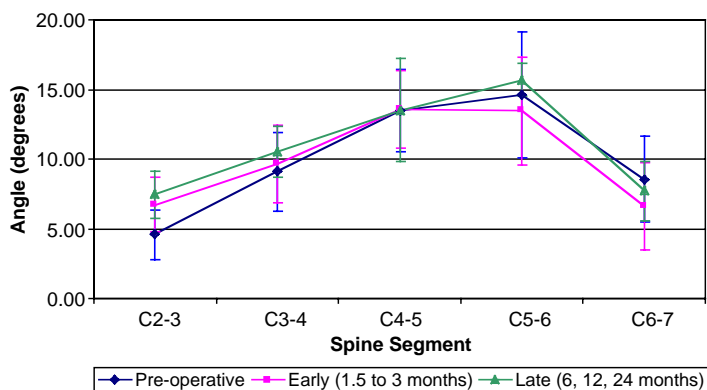


Fig. 6. Sagittal rotation for patients with a single C6/C7 prosthesis. The relative contribution of each spinal segment to global spinal motion did not change significantly following arthroplasty.

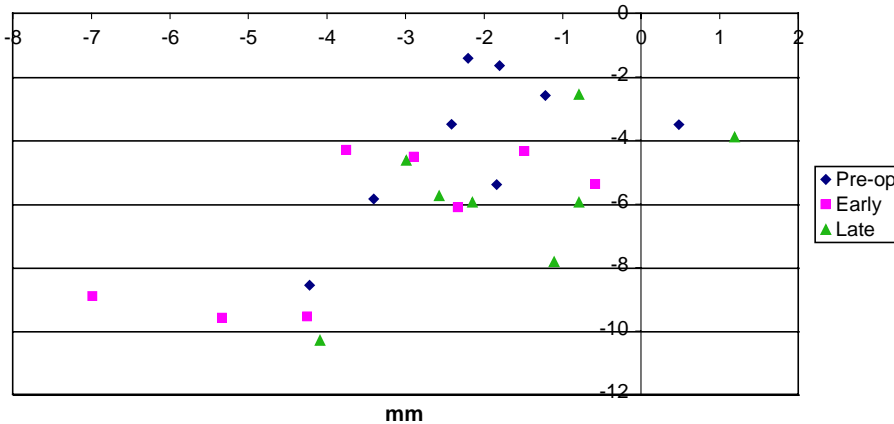


Fig. 7. C5-6 COR for patients with single C5-6 prosthesis. Preoperative center-of-rotation values (COR) plotted in  $(x,y)$  pairs show wide variability. The prosthesis was able to accommodate a similar range postoperatively, with no significant change in the distribution of the center-of-rotation locations.

prospectively enrolled cohort of 20 patients (24 discs) using quantitative motion analysis software to analyze intervertebral motion. Sagittal ROM, centers of rotation, horizontal translation, and disc height were not significantly altered following disc replacement compared with the preoperative state. The relative contribution of each spinal segment to sagittal rotation was preserved (Fig. 6).

The center of rotation at the level of surgery and at the adjacent levels was also preserved following arthroplasty (Fig. 7) [1].

These results suggest that the Bryan Cervical Disc replacement can preserve the preoperative kinematics of the cervical spine.

### Complications

Complications reported following insertion of any cervical prosthesis may be divided into those specific to the prosthesis and those associated with anterior cervical discectomy [7,8]. Cerebrospinal fluid leak, esophageal injury, and wound hematomas were reported in the European studies, with an overall complication rate of 6.3% per operated level [4]. Inadequate neural decompression requiring repeat surgery was reported in 3 of 146 cases. Reported complications specific to the Bryan Cervical Disc, however, include anterior and posterior migration, end plate kyphosis, and failure to maintain motion [4,9]. The unconstrained nature of the disc has resulted in cases of worsened cervical kyphosis when implanted in patients with straight or kyphotic cervical curvatures, particularly those with a preopera-

tive focal kyphosis at the operated segment [10]. No cases of subsidence or device failures have so far been reported in over 5500 implants worldwide [5].

### Bristol Disc

#### Evolution

In the late 1980s, Brian Cummins, a neurosurgeon at Frenchay Hospital (Bristol, United Kingdom) tried to address the problem of maintaining motion in the cervical spine following surgery by introducing a simple ball-and-socket type of cervical joint. It was made out of type-316 stainless steel and had an upper hemispherical component that sat in a reciprocating lower cup, the two components secured to their respective vertebrae by means of anterior flanges and screws. In the first clinical trial, however, problems encountered included joint subluxation, screw pullouts, and screw fractures. The Cummins joint was redesigned by Gill to allow more physiologic motion to occur. Translation and rotation was achieved with the upper vertebral component being permitted to passively find its own axis of rotation as determined by the facet joints and coupled motion of adjacent vertebrae. The lower vertebral component had a shallow elliptic concavity rather than a reciprocating concave hemisphere on which the upper component could glide with point contact. In addition, the screw locking mechanism was redesigned to incorporate the Orion locking system (Medtronic Sofamor Danek). The overall bulk of the construct



Fig. 8. Illustration of the two articulating components of the Bristol Disc without bone screws or locking screws. The lower component with the ellipsoid saucer is on the right.

was reduced. This new device was referred to as the Bristol Disc (Fig. 8).

#### *The Bristol Disc pilot study*

The aim of the pilot study was to assess the safety of the surgical technique, to closely monitor patients receiving the joint for evidence of adverse events, and to evaluate the clinical stability of the device and the ability of the implant to preserve segmental motion in the cervical spine. Secondary outcome measures of pain scores for neck and arm pain, myelopathy scores, and SF-36 scores were also assessed.

Joints were inserted between C3-4 and C6-7. No postoperative wound or periprosthetic infections were encountered. Motion was preserved and ranged between  $3^\circ$  and  $12^\circ$  (mean,  $6.5^\circ$ ) at 2 years (Fig. 9). Translation in an AP direction of up to 2 mm was achieved. All the joints stayed in place in the intervertebral space and there was no incidence of joint dislocation. Comparing data at 24 months with preoperative data from the questionnaires indicated improvement in all aspects of patient function and quality of life.

No changes in any of the categories of assessment reached statistical significance due to the small number of patients in this pilot study. Employment status improved. CT myelograms were performed on 4 patients and gave excellent imaging. None of the patients with CT myelograms demonstrated any neural compromise associated with the prosthesis. One patient had the joint removed after 12 months but her symptoms remained unchanged despite achieving a stable interbody fusion. Motion of the joint was maintained in all the remaining 14 patients at 24 months. Good stability of the prosthesis was

demonstrated in all 14 patients with the device at 24 months.

It was necessary to be cautious of attaching too much significance to data arising from the questionnaires completed in this study. Most of the patients had a chronic history of neck disability punctuated by several previous interventions by a variety of clinicians. Some patients had taken part in pain management programs with limited success over preceding years. Hence, although the study entry criteria were strict, a far-from-homogeneous cohort was involved in this study. It was considered essential to gain as much information as possible about this device even if the small numbers involved made data interpretation limited. This study demonstrated that a prosthetic cervical joint that permits normal cervical spinal kinematics of rotation, angulation, and translation could be safely inserted. The study did not demonstrate any adverse effect occurring at adjacent vertebral levels [11].

#### *Refined designs and improved clinical trials*

During the initial pilot study, the Bristol Disc was renamed Prestige (Medtronic Sofamor Danek). Design modifications resulted in a reduced-profile product with bone ingrowth surfaces and a range of sizes (12 or 14 mm AP dimension with heights of 6 or 8 mm). The new discs were named Prestige II. The limitations of the pilot study called for more controlled clinical studies.

A multicenter, prospective, randomized controlled study was conducted. Four centers, from the United Kingdom, Belgium, Switzerland, and Australia, were involved. Fifty-five patients were enrolled in the study, with 27 receiving the Prestige II disc and 28 receiving fusion. Patients were eligible only if their sole diagnosis was degenerative disc disease affecting a single cervical intervertebral disc between



Fig. 9. Flexion (*left*) and extension (*right*) radiographs showing the degree of angulation achieved by the Bristol Disc (in this case, a total of  $9^\circ$  of movement).

C4-5 and C6-7 inclusive and if they had never previously undergone cervical spinal surgery. As in previous studies, patients were assessed clinically, radiologically, and using an array of validated psychometric tests including the NDI, the SF-36, and a VAS relating to neck and arm pain. Adverse events were recorded and assessed according to World Health Organization recommendations. There was no significant difference in the number or distribution of adverse events between the two groups. At 12 months, the Prestige II disc maintained angular motion with a mean value of 5.9°. Both groups of patients showed improvement in NDI scores at 24 months compared with preoperative scores. Similarly, there were improvements in VAS scores and in general health status as assessed by the SF-36. The joint and fusion patients achieved similar scores. Based on these results, the use of the Prestige II disc is as safe and as efficacious as the standard Smith-Robinson fusion procedure [12]. The four-center study was the first to compare disc replacement technology with fusion in a prospective, randomized fashion.

## Summary

Spine arthroplasty is a growing subspecialist area of spinal surgery. There are great opportunities for new materials, devices, and technology to emerge. TDR in the cervical spine offers the opportunity to preserve functional motion and maintain balance. It is postulated that arthroplasty may reduce adjacent-level disease more than traditional surgical treatment methods. The other advantages to this surgical option are immediate implant stability, no complications due to nonunion, and no need for graft harvesting.

The Bryan Cervical Disc is a metal-on-polymer implant with some elastic properties and a relatively mobile center of rotation. The Bristol Disc is a semi-constrained metal-on-metal prosthesis allowing AP translation motion of up to 2 mm. The ProDisc-C is a semiconstrained metal-polyethylene design allowing pure rotary motion that may stress the facet joints. Although there are no long-term data available yet,

these three cervical prostheses appear promising in the nonfusion treatment of cervical degenerative disc disease.

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