

Intermediate Follow-up After Treatment of Degenerative Disc Disease With the Bryan Cervical Disc Prosthesis: Single-Level and Bi-Level

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Study Design. Prospective, concurrently enrolled, multicenter trials of the Bryan Cervical Disc Prosthesis (Medtronic Sofamor Danek, Memphis, TN) were conducted for the treatment of patients with single-level and two-level (bi-level) degenerative disc disease of the cervical spine.

Objectives. The studies were designed to determine whether new functional intervertebral cervical disc prosthesis can provide relief from objective neurologic symptoms and signs, improve the patient's ability to perform activities of daily living, decrease pain, and maintain stability and segmental motion.

Summary of Background Data. The concept of accelerated degeneration of adjacent disc levels as a consequence of increased stress caused by interbody fusion of the cervical spine has been widely postulated. Therefore, reconstruction of a failed intervertebral disc with functional disc prosthesis should offer the same benefits as fusion while simultaneously providing motion and thereby protecting the adjacent level discs from the abnormal stresses associated with fusion.

Methods. Patients with symptomatic cervical radiculopathy and/or myelopathy underwent implantation with the Bryan prosthesis after a standard anterior cervical-

discectomy. At scheduled follow-up periods, the effectiveness of the device was characterized by evaluating each patient's pain, neurologic function, and radiographically measured range of motion at the implanted level.

Results. Clinical success for both studies exceeded the study acceptance criteria of 85%. At 1-year follow-up, the flexion-extension range of motion per level averaged 7.9 ± 5.3 degrees in the single-level study and 7.4 ± 5.1 degrees in the bilevel study. No devices have been explanted.

Conclusions. Discectomy and implantation of the device alleviates neurologic symptoms and signs similar to anterior cervical discectomy and fusion. Radiographic evidence supports maintenance of motion. The procedure is safe and the patients recover quickly. At least 5 years of follow-up will be needed to assess the long-term functionality of the prosthesis and protective influence on adjacent levels. [Key words: cervical disc prosthesis, ACDF, herniation, spondylosis, degenerative disc disease] **Spine 2003;28:2673–2678**

The concept that interbody fusion of the cervical spine leads to accelerated degeneration of disc levels adjacent to the fusion because of increased stress is widely postulated.^{1,6,8,10,13,16,22,24,28} Therefore, reconstruction of a failed intervertebral disc with a functional disc prosthesis should offer the same symptomatic benefits as decompression and fusion while additionally providing motion and thereby protecting the adjacent level discs from the abnormal stresses associated with fusion by maintaining physiologic motion and kinematics.

The purpose of the study is to determine if unique functional intervertebral cervical disc prosthesis can provide relief from objective neurologic symptoms and signs, improve patient function, decrease pain, and provide motion. This report, which provides an update of previously reported results,¹² describes the first 24 months of results of the single-level clinical investigation and the first 12 months results of the bilevel investigation conducted in several European study centers.

■ Materials and Methods

Device Description. The Bryan Cervical Disc prosthesis, manufactured by Medtronic Sofamor Danek, USA, is a cervical intervertebral disc prosthesis designed to permit motion similar to the normal cervical functional spine unit. The prosthesis is intended to treat stable cervical degenerative disc disease without fusion, thereby providing the patient with the capability for motion at the treated level.

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The device(s)/drug(s) that is/are the subject of this manuscript is/are being evaluated as part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol for indications (The device is intended for use in skeletally mature patients [at least 21 years old] undergoing primary surgery for treatment of mechanically stable, degenerative disc disease of the cervical spine at any one level or two adjacent levels between C3-4 and C-7, as demonstrated by signs and/or symptoms of radiculopathy and/or myelopathy associated with spondylotic foraminal or canal stenosis and/or disc herniations.) and contraindications (The device should not be implanted in patients with an active infection, osteoporosis, radiographic evidence of mechanical instability or the absence of demonstrated motion at the treatment level on preoperative flexion/extension films.).

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Figure 1. The Bryan Cervical Disc Prosthesis (Medtronic Sofamor Danek, Memphis, TN).

The device consists of a polyurethane nucleus designed to articulate with two titanium alloy surfaces (shells). The bone-contacting surface of each shell includes a titanium porous coating to facilitate bony ingrowth and long-term stability. A polyurethane sheath surrounds the nucleus and is attached to the shells, forming a closed compartment. Titanium alloy seal plugs provide for retention of a lubricant. Anterior stops on each shell are designed to prevent posterior migration of the device and a means by which the device can be inserted and, if necessary, removed. The prosthesis is presently configured in five diameters: 14, 15, 16, 17, and 18 mm (Figure 1; The Bryan Cervical Disc Prosthesis (Medtronic Sofamor Danek, Memphis, TN)

Operative Technique. After anterior discectomy, a simple gravitational referencing system is used to establish the center of the disc space. The desired location is found by identifying a point within the surgical site using a system of levels and protractors positioned from the internal anatomic features of the disc space. With the knowledge of the location of the center of the disc space, a milling fixture is positioned appropriately and affixed to the vertebral bodies with bone anchors. The milling fixture precisely controls the locations of the powered cutting instruments that prepare the vertebral body endplates for placement of the prosthesis. The milled concavity of the vertebral endplates exactly matches the geometry of the implant's convex outer surface, capturing the rim of each shell inside a ridge of bone. This precision fit provides immediate anteroposterior, lateral, and torsional stability (Figure 2; The Bryan Cer-

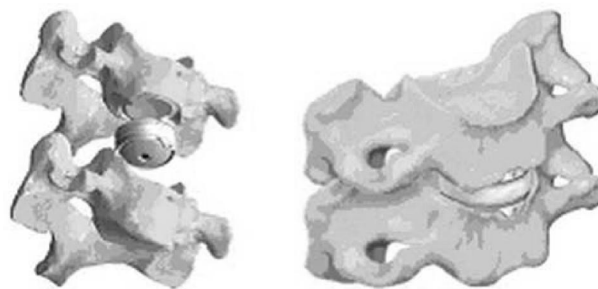


Figure 2. The Bryan Cervical Disc Prosthesis within specially milled vertebral bodies.

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Study Design. Patients were concurrently enrolled in multicenter evaluations of the prosthesis for the treatment of degenerative disc disease of the cervical spine. A clinical study was initiated in January 2000 and evaluated the use of the device in treating single level disease. A second arm of the study was initiated in January 2001 and evaluated treatment of the disease at two adjacent levels. The prospective studies were approved by the ethics committee and, as required, the regulatory agencies for each center. Patient inclusion criteria consisted of disc herniation or spondylosis, with radiculopathy and/or myelopathy, which had not responded to conservative treatment (relative rest, soft collar, physiotherapy, and medication during at least 6 weeks). Exclusion criteria included previous cervical spine surgery involving the use of any other device, axial neck pain as the solitary symptom, significant cervical anatomic deformity or radiographic signs of instability (translational instability of more than 2 mm, angular motion more than 11 degrees greater than either adjacent level), and active infection.

Patient assessments are based on the evaluation schedule and criteria in Table 1. The primary endpoint is classification based on relief of each preoperative symptom (as assessed by the patient using the Cervical Spine Research Society Patient Questionnaire) and relief of each objective neurologic sign (as assessed by the physician in a neurologic examination) associated with the treated level. The Cervical Spine Research Society questionnaire is a comprehensive disease-specific instrument for evaluating the outcomes of treatments for cervical spine conditions.²

Patient data were entered into a database. Results were scored according to a rigorous Odom's Criteria, in which 40

Table 1. Surgeon's Assessments (preoperative, postoperative, 6 weeks, 3 months, 6 months, 1 year, 2 years)

Motor Strength in 5-Point Scale (right and left sides)	Reflexes in 4-Point Scale (right and left sides)	Sensory in 4-Point Scale (right and left sides)	Special Assessments
Deltoids	Biceps	C4 dermatome	Babinski's Sign
Biceps	Triceps	C5 dermatome	Spurling's Sign
Triceps	Brachioradialis	C6 dermatome	Clonus
Wrist extensors	Knees	C7 dermatome	Hoffman's Sign
Wrist flexors	Ankles		
Finger flexors			
Finger abductors			
Patient's Assessments (preoperative, 6 weeks, 3 months, 6 months, 1 year, 2 years)			
Neck pain severity in 6-point scale	Arm pain severity in 6-point scale	Ability to function at activities of daily living in 4-point scale	

Table 2. Patient Demographics

	Single Level		Bi-Level	
Number of patients	103		43	
Age range	26–79		28–62	
Gender	Male	Female	Male	Female
	42	61	25	18
Clinical diagnosis*				
Radiculopathy	96		38	
Myelopathy	14		10	
Primary cause*				
Herniation	81		13	
Spondylosis	34		38	

* Several patients presented with multiple diagnoses and/or causes.

individual neurologic assessments (*e.g.*, right- and left-side biceps muscle strength, right- and left-side C7 dermatome, *etc.*) and 15 individual patient assessments (*e.g.*, neck pain at the end of the day, ability to care for oneself in bathing and dressing, *etc.*) are compared with their individual baseline preoperative assessments. Outcomes were then categorized as follows:

- **Excellent**
Improvement in most (at least 80%) of the preoperative signs and symptoms, with little deterioration (not more than 10%)
- **Good**
Improvement in some (at least 70%) of the preoperative signs and symptoms, with some deterioration (not more than 15%)
- **Fair**
Improvement in half (at least 50%) of the preoperative signs and symptoms, with some deterioration (not more than 20%)
- **Poor**
Improvement in few (less than 50%) of the preoperative signs and symptoms, or significant deterioration (more than 20%)

A literature review of anterior cervical discectomy and fusion was conducted to establish an anticipated success rate for the study.^{3–5,7,8,11,14,17–21,23,25,27} Statistical analysis was performed on data reported in relevant articles, which established a success (excellent, good, or fair) rate of 73%. On the basis of this analysis, a success rate of 85% was set as the acceptance criteria for the study.

■ Results

Study Enrollment

A total of 103 patients underwent implantation and were followed-up in the single-level study and 43 patients were in the bi-level study. In all cases, neural compression was verified by performing computed tomography or magnetic resonance imaging and a neurologic assessment. In the single-level study, 100 patients have reached their 12-month follow-up visit and 51 patients have reached their 24-month follow-up visit. In the bilevel study, 29 patients have reached their 12-month follow-up and one patient reached the 24-month follow-up. Table 2 details the demographic variables of the patients. Patients with complete clinical and radiographic data are summarized. An independent board-certified radiologist

Table 3. Summary of Clinical Results

Follow-Up (mo)	No. of Patients	Excellent (%)	Good (%)	Fair (%)	Poor (%)
Single Level					
6	92	66 (72)	6 (6)	11 (12)	9 (10)
12	89	62 (70)	7 (8)	7 (8)	13 (14)
24	49	32 (65)	2 (4)	10 (21)	5 (10)
Bi-Level					
6	34	18 (53)	6 (18)	4 (11)	6 (18)
12	26	20 (77)	1 (4)	4 (15)	1 (4)

analyzed the radiographs to determine range of motion and assess device migration and/or subsidence.

Operative Data

Operative times for the procedure were calculated after removing the first two surgeries for each investigator, which accounts for surgeon training. Operative time for the single level surgery averaged 125 ± 51 minutes and bilevel surgery averaged 158 ± 53 minutes (recorded as skin to skin). The total number of days from surgery to discharge averaged of 3.5 ± 2.2 days for the single level study and 3.6 ± 6.2 days for the bilevel study. Length of stay varies by country and hospital, in accordance with local standards. No restrictive postoperative management has been found to be necessary.

Neurologic Symptoms and Signs

Table 3 summarizes clinical results based on relief of preoperative symptoms (as assessed by the patient) and relief of neurologic signs (as assessed by the surgeon) for 6-month, 1-year, and 2-year follow-up visits.

In the single-level study, of the 92 patients with complete clinical data at the 6-month follow-up, 83 (90%) were classified as excellent, good, or fair. At 1-year, the scores were excellent, good, or fair for 76 out of 89, or 86%, of the patients. Of the 49 patients with complete clinical data at 2-year follow-up, 44 (90%) were classified as excellent, good, or fair.

In the bilevel study, of the 34 patients with complete clinical data at the 6-month follow-up, 28 (82%) were classified as excellent, good, or fair. At 1 year, the scores were excellent, good, or fair for 25 out of 26, or 96%, of the patients. One patient in the bi-level study presented with discrete signs and symptoms of recurrent myelopathy at the 1-year follow-up visit. A spiral CT, performed at the visit, suggested redevelopment of posterior midline osteophytes at the operated level, at least to some extent. However, because of the absence of an immediate postoperative CT scan, it cannot be proven that these osteophytes were really fully resected during the operation, although the surgeon confirms that the posterior ligament was widely opened.

These results are greater than the targeted success rate of 85% excellent, good, or fair, based on a meta-analysis of anterior cervical discectomy and fusion literature.

Complications

In the single-level study, there were three reinterventions at the treatment level. They included an evacuation of a prevertebral hematoma, a posterior foraminotomy without device involvement to treat residual symptoms, and a posterior decompression to treat residual myelopathic symptoms. Regarding the residual myelopathy complication, the patient's preoperative duration of symptoms was more than 2 years before the initial surgery and the reintervention was not performed by one of the study investigators. In one patient, the wrong level was initially operated on, with a subsequent report of unresolved pain that was corrected by follow-up surgery in which a second device was implanted at the targeted level. After the second operation, temporary dysphonia occurred. One patient reported pain in the right shoulder, right arm, and in the sternum region approximately 6 months after surgery. An MRI ruled out any remaining neural compression. Another patient remarked about unresolved nonspecific shoulder pain on the left side. One patient in the single-level study required a second device implant at an adjacent level 21 months after the initial surgery because of radiculopathy caused by disc herniation. After the second surgery, which was performed with an approach from the opposite side, the patient experienced severe dysphonia caused by bilateral vocal cord paralysis. The investigator attributed it to bilateral recurrent nerve compression resulting from excessive retraction.

In the bi-level study, one patient experienced a cerebral spinal fluid (CSF) leak while decompressing posteriorly. In addition, there were four reinterventions at the treatment level that included an evacuation of an epidural hematoma, an evacuation of a prevertebral hematoma, a repair of a pharyngeal tear/esophageal wound

incurred during intubation and an anterior decompression caused by ongoing nerve root compression. This last reintervention required revision surgery for decompression of residual foraminal stenosis and the device was repositioned. There have been no device failures or device explants in either study.

Radiographic Results

Complete radiographic follow-up data has been obtained in the single level study for 89 patients at 6 months, 90 patients at 1 year, and 46 patients at 2 years. In the bi-level study, complete radiographic data were obtained for 38 patients (73 levels) at 6 months, and 26 patients (49 levels) at 1 year. Data were unavailable for several levels because of obscured radiographs at lower cervical levels.

Device Position

Device position is measured using lateral radiographs at each follow-up interval. Subsidence of the device into the milled vertebral endplates has not been observed in any patients. Evidence of temporary anterior/posterior device migration was detected in one patient and suspected in a second patient in the single level cohort. This was because of a deficiency in the endplate milling process that occurred in the first study cases. Radiographic analysis confirmed that a full concavity was not milled in some of the initial surgeries. The issue was corrected with improvements to the instrument system. Evidence of migration was also detected in one patient in the bi-level study in which the implanted level was unstable before surgery. However, migration greater than 3.5 mm has not been observed in any patients; this threshold is based on the definition of segmental integrity.^{9,26}

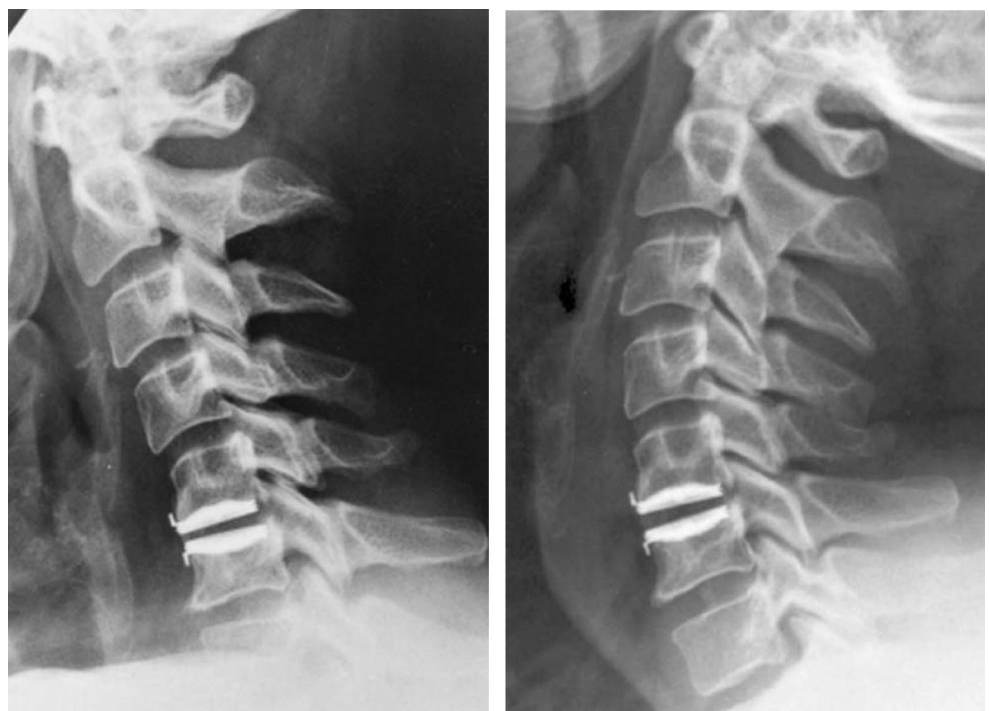


Figure 3. Flexion (right) and extension (left) radiographs show the angulation achieved by the implanted FSU.

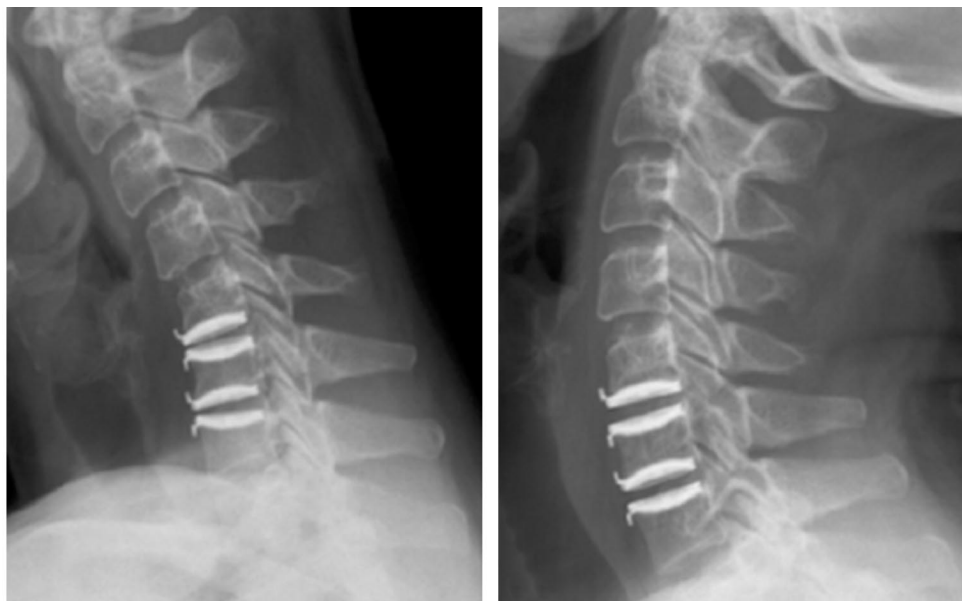


Figure 4. Flexion (right) and extension (left) radiographs show the angulation achieved by the implanted FSUs.

Range of Motion Results

Postoperative Cobb angle measurements of the functional spinal unit (FSU) at the implant level demonstrated motion of the device in flexion/extension (Figures 3 and 4).

The average range of motion for single-level and bi-level patients at 6 months, 12 months, and 24 months is found in Table 4. In addition, the number of patients that demonstrated flexion/extension range of motion equal to or greater than 2 degrees is also presented. Two degrees is the threshold that clearly establishes motion without question of measurement error because of radiographic image magnification and/or distortion as used in fusion case studies.^{10,15} At the 1-year follow-up, 88% of the patients in the single-level and 86% of the patients in the bi-level study exhibited motion equal to or greater than 2 degrees. At the 2-year follow-up, 93% of the patients in the single-level study exhibited motion equal to or greater than 2 degrees.

Quality of Life Results

SF-36 Health Survey results are presented for the patients reaching the 6-month, 1-year, and 2-year follow-up periods. Values for each period are presented in the SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores, which use

Table 4. Flexion and Extension Range-of-Motion

Follow-Up (mo)	Number of Levels	ROM $\geq 2^\circ$ (%)	ROM $< 2^\circ$	Average \pm SD (degrees)
Single Level				
6	89	86 (97)	3	8.3 \pm 4.5
12	90	79 (88)	11	7.9 \pm 5.3
24	46	43 (93)	3	9.0 \pm 4.9
Bi-Level				
6	73	72 (99)	1	7.3 \pm 4.1
12	49	42 (86)	7	7.4 \pm 5.1

United States population means to establish normalized scores. The average results for all patients who reached 6-, 12-, and 24-month follow-up are found in Table 5.

Discussion

In the single-level study, 44 out of 49 patients (90%) evaluated at the 2-year follow-up, 76 out of 89 patients (86%) evaluated at 1-year follow-up and 83 out of 92 patients (90%) evaluated at 6-month follow-up were deemed a clinical success (Odom's classification of excellent, good, or fair). At 2 years, the Bryan prosthesis has a success rate greater than or equal to 85% with 95% confidence using a single sample binomial hypothesis test.

In the bi-level study, 24 out of 25 patients (96%) evaluated at 1-year follow-up and 27 out of 33 patients (82%) evaluated at 6-month follow-up were deemed a clinical success (Odom's classification of excellent, good, or fair).

Although not required in the original study design, follow-up CT scans were obtained from several patients in the single-level arm of the study to assess bony ingrowth of the shells at the 2-year follow-up period. Evaluation of the CT scans revealed several instances of anterolateral paravertebral ossification. Both retrospective and prospective studies have been initiated to investigate this phenomenon, for which results will be published at a later date. In light of the knowledge accumulated over

Table 5. Quality of Life Data

Follow-Up (mo)	Single Level		Bi-Level	
	PCS	MCS	PCS	MCS
Before operation	36.1 \pm 6.4	41.0 \pm 12.1	37.4 \pm 7.2	35.5 \pm 10.5
6	45.3 \pm 10.3	52.2 \pm 10.5	44.1 \pm 9.2	44.7 \pm 12.9
12	46.9 \pm 10.1	50.0 \pm 12.4	47.0 \pm 10.7	46.1 \pm 12.5
24	46.6 \pm 10.9	52.9 \pm 10.6	No data	No data

decades of total hip replacement regarding paravertebral bone formation, including its prevention and treatment, a proactive detailed investigation of paravertebral bone appears warranted in the spine.

The data clearly show that properly placed devices do not migrate, and the device allows for segmental motion. The implantation of the device alleviates pain and improves function based on neurologic signs and symptoms at least equivalent to ACDF. At least 5 years of follow-up will be needed to assess the long-term functionality of the prosthesis and protective influence on adjacent levels.

■ Key Points

- A cohort of patients with single- and bi-level degenerative disc disease of the cervical spine were concurrently enrolled in a prospective, multicenter, clinical trial of the Bryan Cervical Disc Prosthesis.
- Intermediate results indicate subjects experienced relief from preoperative symptoms and of objective neurologic signs associated with the treated level.

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