

FIGURE 3: PRE-OPERATIVE RANGE OF MOTION



FIGURE 4: THREE-MONTH RANGE OF MOTION

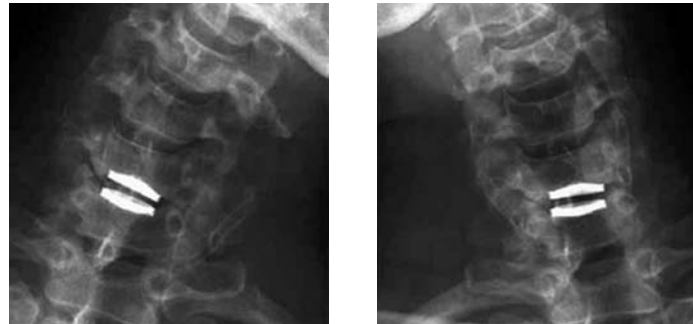


FIGURE 5: TWELVE-MONTH RANGE OF MOTION



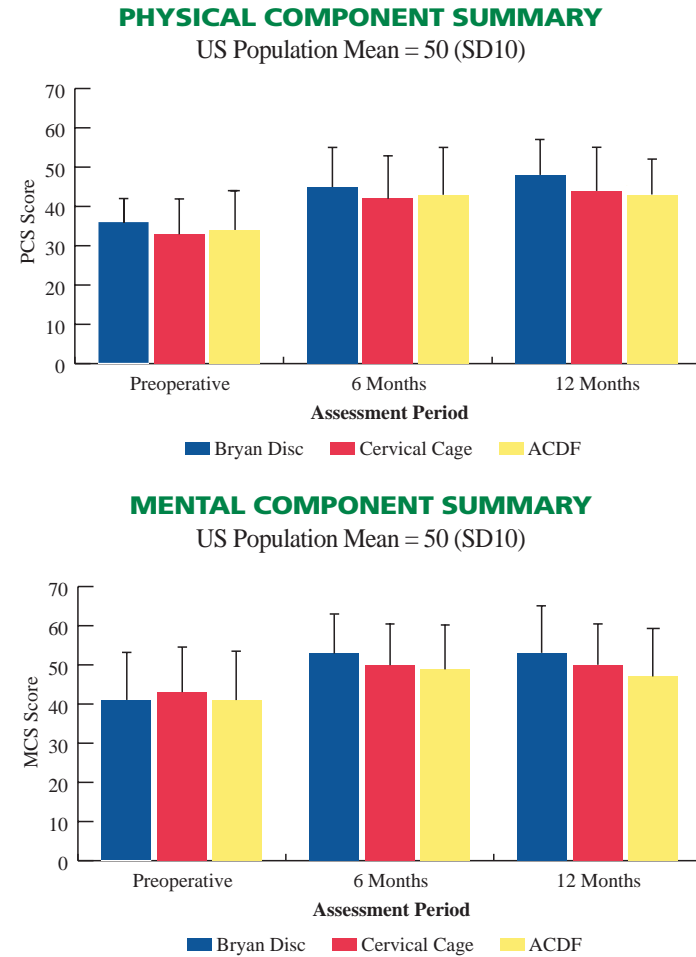
QUALITY OF LIFE RESULTS

SF-36 Health Survey results are presented for the patients reaching the one-year and six-month follow-up periods. Values for each period are presented in the SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores, which utilize U.S. population means to establish normalized scores.

Results for PCS and MCS scores are comparable to results published for single-level fusion and cervical cage subjects in a prospective randomized study conducted for the cervical cage [1]. The results for all patients who reached six and/or twelve-month follow-up are averaged in Figure 6 and compared to patients in the cervical cage study, and those who received an autograft/allograft fusion. At 12 months post-implant, patients with the Bryan prosthesis meet or exceed the U.S. population mean for PCS and MCS scores.

FIGURE 6: COMPARISON OF SF-36 SUMMARY SCORES

(Average with one standard deviation)



Figures for the Cervical Cage and ACDF groups are approximations based on bar charts presented.

CONCLUSIONS

Twenty-seven out of 30 patients (90%) evaluated at one-year follow-up and fifty-two out of sixty patients (86%) evaluated at six-month follow-up were deemed a clinical success (Odom's classification of excellent, good, or fair). At one year, the Bryan prosthesis has a success rate greater than 85% with 95% confidence.

The data clearly shows that properly placed devices do not migrate, and that segmental motion is present. The implantation of the device alleviates pain and improves function based on neurological signs and symptoms at least equivalent to ACDF.

REFERENCE DOCUMENTS

- [1] R.J. Hacker et al, "A Prospective Randomized Multicenter Clinical Evaluation of an Anterior Cervical Fusion Cage," Spine, Vol. 25, No 20, pp 2646-2655.
- [2] F.P. Castro et al, "A Cost Analysis of Two Anterior Cervical Fusion Procedures," Journal of Spinal Disorders, Vol. 13, No. 6, pp 511-514.

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Technical Monograph

Bryan™ Cervical Disc Prosthesis

Initial Experience and Results from an Ongoing Prospective Clinical Study

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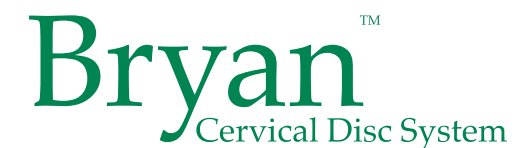
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SUMMARY

Fifty-two out of sixty patients (86%) evaluated at six-month follow-up and twenty-seven out of 30 patients (90%) evaluated at one-year follow-up have exceeded the anticipated study success derived from literature (Odom's classification of excellent, good, or fair).

Postoperative Cobb angle measurements of the functional spinal unit at the implant level demonstrated motion of the device in flexion/extension averaging about 9°. No cases of device ankylosis or adjacent instability occurred.

INTRODUCTION

The concept that interbody fusion of the cervical spine leads to accelerated degeneration of adjacent disc levels due to increased stress from the fusion is widely postulated. Therefore, reconstruction of a failed intervertebral disc with a functional disc prosthesis should offer the same benefits as decompression and fusion while simultaneously providing motion and thereby protecting the adjacent level discs from the abnormal stresses associated with fusion by maintaining physiological motion and kinematics.

The purpose of this study is to determine if a unique functional intervertebral cervical disc prosthesis can provide relief from objective neurological symptoms and signs, improve patient function, decrease pain, and provide motion. This report reviews the first 20 months of the study (patients implanted from January 5, 2000 to September 12, 2001). Follow-up is provided for patients at six months and one year.

METHODS AND MATERIALS

Device Description

The Bryan Cervical Disc prosthesis, manufactured by Spinal Dynamics Corporation, 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.

The device consists of a polyurethane nucleus designed to fit between 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.

The prosthesis is presently configured in five diameters: 14, 15, 16, 17, and 18 mm.

FIGURE 1



Study Design

Patients were concurrently enrolled in a multi-center evaluation of the prosthesis for the treatment of single-level degenerative disc disease of the cervical spine. The prospective study was 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. Exclusion criteria included previous cervical spine surgery involving any other device, axial neck pain as the solitary symptom, significant cervical anatomical deformity or clinical instability, 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 preoperative symptoms (as assessed by the patient using the Cervical Spine Research Society and SF-36 Patient Questionnaires) and relief of objective neurological signs (as assessed by the physician in a neurological examination) associated with the treated level.

TABLE 1: PATIENT ASSESSMENTS

(Pre-op, post-op, 6 weeks, 3 months, 6 months, 1 year and 2 years)

Patient data was entered into a database. Results were scored according to a modified Odom's Criteria, and categorized as follows:

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

Radiographs were analyzed independently to determine range of motion and assess device migration and/or subsidence.

Study Enrollment

A total of 97 devices were implanted. In all cases neural compression was verified using CT or MRI. Neurological assessment was coordinate with the compressive pathology. Sixty of the patients have been followed for six months; thirty patients have been followed for one year. Table 2 details the demographic variables of the patients.

The duration of pre-operative symptoms ranged from 3 weeks to greater than two years. The primary diagnosis was herniation with radiculopathy in 62%, spondylosis with radiculopathy in 20%, herniation with myelopathy in 5%, spondylosis with myelopathy in 3%, and multiple symptoms in 10%.

TABLE 2: PATIENT DEMOGRAPHICS (97)

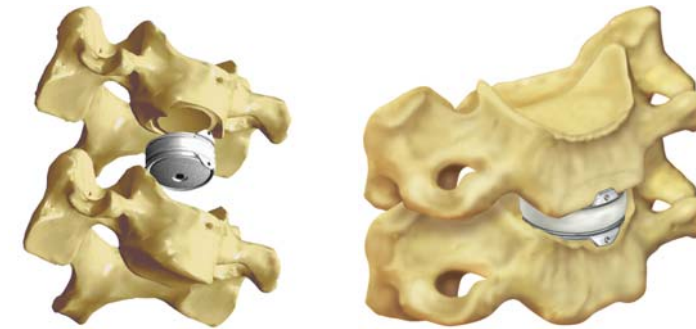
Age Range	26 to 79				
Gender	41 Male		56 Female		
Clinical Diagnosis	Radiculopathy 78		Myelopathy 8		
Levels Implanted	C3-C4 0	C4-C5 11	C5-C6 42	C6-C7 44	
Size Implanted	14mm 22	15mm 21	16mm 25	17mm 20	18mm 9

OPERATIVE TECHNIQUE

Following initial discectomy, surgical instruments utilize a simple gravitational referencing system to establish a virtual axis in the intervertebral disc space that is used to position a milling fixture.

This fixture precisely controls the powered cutting instruments that prepare the vertebral endplates for placement of the prosthesis. The milled vertebral endplates exactly match the geometry of the implant's convex outer surface, capturing the rim of each shell inside a ridge of bone. This tight fit provides immediate A/P and lateral stability.

FIGURE 2



OPERATIVE TIMES

Operative times for the procedure were calculated after removing the first two surgeries for each investigator, which accounts for surgeon training.

Table 3 below displays all reported operative times for the Bryan implant procedure as averaged with one standard deviation (SD). The times for ACDF autograft, modified cage with plate (TSM: titanium surgical mesh), and the Cervical Cage, as published in Hacker (1) and Castro (2) are provided for comparison.

TABLE 3: COMPARISON OF LENGTH OF SURGERY

Average MIN (SD)

Bryan Prosthesis	ACDF with Iliac Autograft	TSM Cage With Plate	Cervical Cage
126 (52)	180 (14)	132 (6)	92 (*)

(*) Standard deviation not published.

HOSPITAL LENGTH OF STAY

The total number of days from surgery to discharge ranged from one (1) to ten (10) days. The average was 3.6 days with a standard deviation of 2.2 days. Table 4 provides a site-to-site comparison of the post-surgery length of stay (surgery to discharge). Length of stay varies by country and hospital, in accordance with local standards. No restrictive post-operative management has been found to be necessary.

TABLE 4: SITE-TO-SITE COMPARISON OF LENGTH OF STAYS

Average Days (standard deviation)

All Sites	Belgium	Germany	France (#1)	Italy	Sweden	France (#2)
3.6 (2.2)	4.5 (1.5)	10 (0)	5 (1.0)	2 (1.0)	4 (1.5)	1 (0)

CLINICAL RESULTS

Neurological Symptoms and Signs

Complete clinical and radiographic data was available on 86 patients. Table 5 summarizes clinical results based on relief of preoperative symptoms (as assessed by the patient) and relief of

neurological signs (as assessed by the surgeon) for six-month and one-year follow-ups.

Of the 30 patients scored for clinical success at one-year follow-up, 27 (90%) were classified as excellent/good/fair. This result is greater than the targeted success rate of 85% excellent/good/fair, based on a statistical analysis of literature data.

At six months, the scores were excellent, good, or fair for 52 out of 60, or 86%, of the patients. Of the 60 patients scored with six-month follow-up, 41 were classified as excellent for clinical success. Of the 19 remaining patients, 5 were classified as good, 6 as fair, and 5 as poor.

TABLE 5: SUMMARY OF CLINICAL RESULTS

Follow-up (months)	Excellent	Good	Fair	Poor	Not Scored
6	41 (68%)	5 (8%)	6 (10%)	5 (8%)	3 (5%)
12	24 (80%)	1 (3%)	2 (7%)	3 (10%)	0

COMPLICATIONS

There were three patients that reported unresolved pain (i.e., pain present prior to surgery was still present following surgery), one leading to an additional surgical intervention. A posterior foramenotomy was performed, without device involvement. One patient reported pain in the right shoulder, right arm, and in the sternum region approximately six months after surgery. An MRI ruled out any remaining neural compression. Another patient remarked about unresolved non-specific shoulder pain on the left side.

There have been no device failures or device explantations.

RADIOGRAPHIC RESULTS

Radiographic follow-up data has been obtained for 24 (of 30) patients at one year and 57 (of 60) patients at six months. An independent radiologist assesses all radiographs.

Device Position

Device positioning is measured in lateral radiographs at each follow-up interval. Subsidence has not been observed in any patients. Evidence of anterior/posterior device migration was detected in one patient, however, migration greater than 3mm has not been observed in any patients; this threshold is based on the accuracy of measuring plain radiographs.

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. The range of motion for patients at six months averages just under 9° with a standard deviation of 4°. Fifty-three out of 57 patients demonstrated flexion/extension range of motion equal to or greater than 2°. Four patients had radiographs that were not interpretable for that data. Two degrees is the threshold that clearly establishes motion without question of measurement error due to radiographic image magnification and/or distortion. Motion was observed in all patients and there was no evidence of spondylotic bridging.

The range of motion for patients at one year averages just over 9° with a standard deviation of 6°. Twenty-one out of 24 patients, or 88%, demonstrated flexion/extension range of motion equal to or greater than 2°. Two patients measured 1°; the radiograph on the remaining patient was not interpretable. Motion was observed in all patients with no evidence of spondylotic bridging.