ORIGINAL ARTICLE

Clinical Outcomes of Bryan Cervical Disc Arthroplasty A Prospective, Randomized, Controlled, Single Site Trial With 48-Month Follow-up

Ben J. Garrido, MD, Tarek A. Taha, MD, PhD, and Rick C. Sasso, MD

Study Design: Prospective, randomized, controlled. Level 1 evidence.

Objective: To report functional outcomes at 48 months follow-up on prospectively randomized patients to either the Bryan cervical disc prosthesis or anterior cervical discectomy and fusion (ACDF) at a single site.

Summary of Background Data: Surgical treatment of cervical disc pathology can involve discectomy and fusion (ACDF), the gold standard technique. The safety and effectiveness of this procedure has been established and demonstrated in the literature, however, limitations have evolved and alternatives such as disc replacement are being investigated. Intervertebral disc replacement is designed to preserve motion, both at affected and adjacent levels avoiding limitations of fusion such as adjacent level degeneration. New onset degenerative changes and possible recurring neurologic symptoms may be deferred or eliminated with cervical disc replacement. A recent multicenter trial with 24 months follow-up has shown the Bryan disc to compare favorably with ACDF. Continued follow-up is needed to further evaluate and compare functional outcomes in both these cohorts.

Methods: A total of 47 patients were enrolled at our site as part of an ongoing multicenter prospectively randomized study investigating ACDF versus Bryan cervical disc prosthesis. Functional outcomes are now reported at 48 months follow-up for our cohort of participants. Neck disability index score (NDI), VAS neck and arm and SF-36 both physical and mental as well as complications and reoperations will be reported.

Results: Functional outcome data collected at routine follow-up for 48-months has favorably demonstrated improved functional outcomes for NDI, neck/arm pain VAS scores, and the SF-36 physical/mental health component scores for the Bryan arthroplasty and ACDF cohorts. The NDI scores for the Bryan arthroplasty preoperatively was 51 and at 48 months 10. For ACDF preoperative NDI score was also 51 and at 48 months 16.7. At 48 months NDI success, measured by ≥ 15 points NDI improvement demonstrated a 93.3% success for Bryan arthroplasty and an 82.4% success for ACDF. VAS neck pain scores for the Bryan arthroplasty preoperatively was 76.2 and at 48 months was 13.6. VAS neck pain scores for ACDF preoperatively was 80.6 and at 48 months was 28.1. Arm Pain scores were also measured and for the Bryan arthroplasty preoperatively measured 78.8 and at 48 months 10.8. For ACDF arm pain scores preoperatively measured 77.1 and at 48 months 21.7. These outcomes have not been associated with any degradation of outcome measures from 2 to 4 years. During the 48 months of follow-up at our institution we also report 6 secondary surgeries in our control group (ACDF) and only 1 in our investigational group (Bryan). Of the 6 surgeries in the control group performed, 3 or 12% to date were for adjacent level degenerative disease and 1 or 4% for remote level degenerative disc disease. The remaining 2 surgeries were performed on the same patient for a pseudarthrosis. In the investigational group there was only 1 secondary surgery performed to date for adjacent level disease 5%.

Conclusions: At 48 months, cervical arthroplasty with the Bryan cervical disc prosthesis continues to compare favorably to ACDF at our institution. There has been no degradation of functional outcomes from 24 to 48 months for NDI, VAS of neck and arm, and SF-36. There has been a lower incidence of secondary surgeries for the Bryan arthroplasty cohort to date.

Key Words: Bryan cervical disc, cervical arthroplasty, randomized, prospective, ACDF, adjacent level disease

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Anterior cervical discectomy and fusion (ACDF) is well regarded as the surgical gold standard for the treatment of degenerative disc disease of the cervical spine.[1] The procedure provides predictable pain relief however, has been fraught with complications, most notably pseudarthrosis and junctional degeneration, commonly referred to as adjacent level disease.[1,2] Fusion at one level increases motion at adjacent levels along with increased intradiscal pressures.[3,4] This phenomenon can result in symptomatic adjacent level degeneration, which can necessitate reoperation at these levels.[5,6] In fact, the reoperation rates for ACDF have been reported at 2.9% per year.[2] Moreover, 26% of patients will have another

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From the Department of Orthopaedic Surgery, Indiana Spine Group, Indiana University School of Medicine, Indianapolis, IN.
Reprints: Rick C. Sasso, MD, Indiana Spine Group 8402 Harcourt Rd. Suite 400 Indianapolis, IN 46260 (e-mail: rsasso@indianaspinegroup.com).

surgery from recurrent symptoms at 10 years from the index procedure.[2] These findings underscore the concept that while arthrodesis is a good option to relieve symptoms of cervical stenosis, alternative options with more robust longevity may be worth pursuing.

Over the past few years, studies on cervical disc arthroplasty as an alternative to ACDF have emerged with promising results.[7–11] The Bryan disc (Medtronic Sofamor Danek, Inc, Memphis, TN) consists of 2 titanium-alloy shells encasing a polyurethane nucleus.[12] Recent results from a multicenter clinical trial have shown that arthroplasty is an effective treatment method for cervical radiculopathy and myelopathy.[9,13] These studies have thus far reported outcomes at 2 years for the Bryan disc versus arthrodesis. Our clinical site analysis now at 4 years will evaluate the postoperative functional outcomes from 24 to 48 months and determine if there is degradation of results with regard to neck disability index (NDI) score, VAS neck/arm pain scores, short form (SF-36) physical/mental scores. Furthermore, we will report all repeat surgeries/failures to date for both cohorts.

MATERIALS AND METHODS

Patients

A total of 47 patients at our site were enrolled in the study. Twenty-one were in the Bryan disc arm, and 26 in the arthrodesis group. These same patients are enrolled in the multicenter IDE trial for the Bryan disc, whose results at the 24 months time point have been published.[10] This data analysis reviews the 4-year time point. All patients had single-level cervical spine disease (C3 to C7) manifesting as radiculopathy or myelopathy and failed nonoperative treatment for at least 6 weeks. Imaging studies included plain radiography, magnetic resonance imaging and computed tomographic scans. Exclusion criteria included all patients with significant anatomic abnormalities, which are defined as an angular deformity greater than 11 degrees, translation greater than 3.5 mm, and/or evidence of advanced spondylosis on x-rays.

Surgery

The surgical approach for the ACDF and the Bryan disc groups were through the Smith-Robinson approach. After the exposure, the diseased disc was excised, along with the posterior longitudinal ligament followed by decompression of the spinal cord and nerve roots.

In the arthrodesis group, the endplates were prepared with a high-speed burr and then the appropriately sized Cornerstone SR fibular allograft (Medtronic Sofamor Danek) was placed in the interspace. The plates used were the Atlantis Vision Cervical Plate system (Medtronic Sofamor Danek).

For the arthroplasty group, the endplates were prepared using the Bryan disc milling jig which creates 2 concave surfaces that accept the titanium alloy metal surfaces of the disc. Theses surfaces allow bony ingrowth for long-term fixation. Appropriate sizing of the disc was done by preoperative templating and intraoperative lateral fluoroscopy, which assured appropriate placement.

Data Collection

Preoperative demographic data, surgical data, and outcomes data were collected on all patients enrolled in the study. Clinical outcome tools included: NDI, arm pain score (VAS), neck pain score (VAS), and SF-36 physical component subscores (PCS), and SF-36 mental component subscore (MCS). Outcomes were evaluated preoperatively and then at 6 weeks, 12 weeks, 6 months, 12 months, 24 months, 36 months, and 48 months. Complications including repeat surgeries have also been collected to date.

RESULTS

Demographic and Surgical Data

Four-year follow-up data were reviewed on the 47 patients who were randomized in a 1:1 ratio to the Bryan disc (N = 21) or the ACDF (N = 26) groups (Table 1). The demographic data for the 2 populations were quite similar. The mean age distributions were 40 for the Bryan disc and 43 for the control ACDF groups. The sex distribution was comparable as well, with 61.9% males and 38.1% females in the Bryan disc arm of the study and 65.4% males and 34.6% females in the ACDF arm (Table 2).

The average time for surgery for the Bryan group was 2 hours and 1.2 hours for the arthrodesis group. The blood loss in the arthroplasty group on average was 80 mL compared with 42 mL in the ACDF group (Table 3). All interventions were done at a single cervical level (Table 3). All levels are considered equivalent in the analysis and the data are analyzed accordingly. The use of a soft collar postoperatively was primarily for comfort and had no bearing on postoperative rehabilitation in either group.

Outcomes Data

Functional outcomes were evaluated at 4 years. The preoperative NDI scores for the Bryan and ACDF groups were comparable at 51.1 and 51.5, respectively. Postoperatively, patients showed an improvement of about 50% in both groups, such that the NDI at the 6 weeks visit were 22.2 (Bryan group) and 26.4 (ACDF group). At 24 months, 21 of the Bryan group patients were available

TABLE 1. Patient Follow-up Status, Bryan vs. ACDF Cohorts

Patient Follow-up	Bryan Cervical Disc	Control
Preoperative	21	26
6 wk	20	25
3 mo	20	25
6 mo	18	24
12 mo	20	22
24 mo	21	25
48 mo	18	20

ACDF indicates anterior cervical discectomy and fusion.

TABLE 2. Demographic Patient Summary, Bryan vs. ACDF Cohorts

Demographic Summary	Bryan Cervical Disc	Fusion Control
N	21	26
Age (y)	40.0	43.3
Weight (lbs)	177.0	187.8
Male (%)	61.9	65.4
WC P (%)	4.8	0.0
Litigation (%)	0.0	0.0
Alcohol (%)	5.0	3.8

ACDF indicates anterior cervical discectomy and fusion.

for follow-up and showed an NDI of 12.4 (75% decrease from preop), whereas 25 of the ACDF patients available for follow-up had an NDI of 19 (63% decreases from preop). Follow-up at 48 months showed an NDI of 10.1 (80% decrease from preop) in the Bryan group compared to an NDI of 15.9 (69% decrease from preop) in the ACDF group. The 48 months follow-up rate was 18 patients (86%) in the Bryan group and 20 (77%) in the ACDF group. The NDI success, or ≥ 15 points improvement in NDI at 48 months was 93.3% for the Bryan arthroplasty and 82.4% for ACDF cohort.

Neck pain scores were also evaluated between the 2 groups. Treatment resulted in a decrease in neck pain scores in both the Bryan disc and ACDF groups. Preoperative scores were 76.2 and 80.6 and had dropped at 6 weeks follow-up to 32.3 and 39.2. The scores dropped further at 24 and 48 months (17.9 and 33.8 at 24 mo and 13.6 and 28.1 at 48 mo for Bryan and ACDF cohorts, respectively). These results indicate that there was an improvement of 82% compared with 67% in the Bryan versus the ACDF groups (Figs. 1, 2).

The next disability index evaluated was arm pain. Preoperatively, arm pain score averages rated at 78.8 and 77.1 for the Bryan and the ACDF groups. Again, improvement was noted postoperatively with a change in the score rates to 16.3 and 22.8 at 6 weeks. Twenty-four month follow-up showed a decrease to 15.7 (Bryan) and 23.2 (ACDF), whereas the 4-year time point showed scores of 10.8 (Bryan) and 21.7 (ACDF). The data suggest

TABLE 3. Surgical and Hospitalization Data, Bryan vs. ACDF Cohorts

	Bryan Cervical Disc	Fusion Control
OR time (h)	2.0	1.2
EBL (mL)	80.0	41.8
Treatment levels (%)		
C3-C4	0.0	0.0
C4-C5	0.0	3.8
C5-C6	28.6	53.8
C6-C7	71.4	42.3
LOS (d)	1.1	0.2
External orthosis (%)		
None	28.6	11.5
Soft collar	66.7	84.6

ACDF indicates anterior cervical discectomy and fusion.

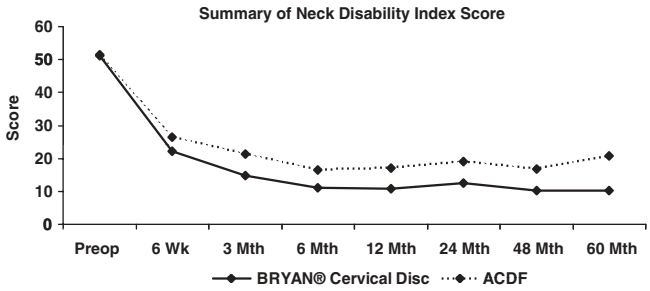

FIGURE 1. Neck disability index score. Patients treated with anterior cervical discectomy and fusion (ACDF: dotted line) and Bryan disc arthroplasty (solid line).

an 86% decrease in arm pain in the Bryan group compared with 73% in the arthrodesis group at 4 years (Fig. 3).

SF-36 PCS were 33.1 (Bryan) and 31.4 (ACDF) preoperatively. Improvements by 26% (Bryan) and 33% (ACDF) were noted postoperatively at 6 weeks. There was a further 50% improvement at the 24 months period (51.2 for Bryan and 49 for ACDF), which was maintained at 48 months (49.4 for Bryan and 47.4 for ACDF). The data indicate that the 2 interventions produce comparable results with respect to SF-36 PCS (Fig. 4).

Similar results were seen with the SF-36 MCS data. Preoperative scores were 43.2 (Bryan) and 46.3 (ACDF) preoperatively. At 6 weeks, these scores showed slight improvements to 52.4 (Bryan) and 47.2 (ACDF). Unlike the SF-36 PCS, the scores remained minimally changed at the 24 months period (52.3 in Bryan and 50.7 in ACDF) but like the SF-36 PCS, these changes were maintained at the 4-year follow-up time point (53.5 in Bryan and 52.1 in ACDF). Therefore, at 4 years, there was a 24% improvement in SF-36 MCS in the Bryan group compared with 13% in the arthrodesis group (Fig. 5).

Complications

The entire data set for both operative groups was analyzed for complications to date. A total of 6 patients required reoperation from the index procedures; a total of 7 procedures, 6 procedures in the control and 1 in the investigational cohort were performed (Fig. 6). One participant from the control group developed a painful

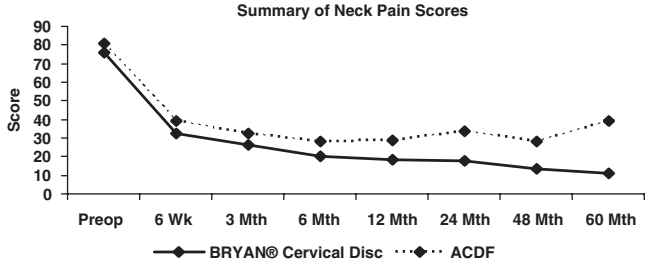

FIGURE 2. Neck pain scores. Patients treated with anterior cervical discectomy and fusion (ACDF: dotted line) and Bryan disc arthroplasty (solid line).

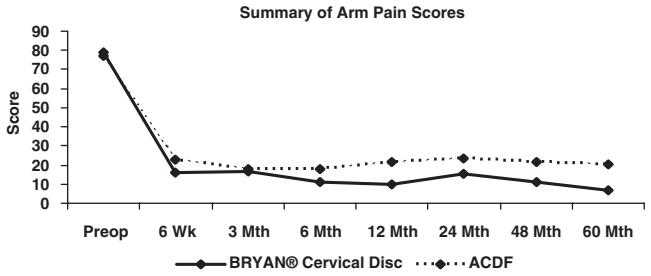

FIGURE 3. Arm pain scores. Patients treated with anterior cervical discectomy and fusion (ACDF: dotted line) and Bryan disc arthroplasty (solid line).

pseudarthrosis and underwent 2 procedures, a facet neurotomy and a posterior fusion at the same level. Three (12%) others in the control had adjacent level disease and 1 (4%) had nonadjacent level disease . The single re-operation in the investigational cohort was indicated for adjacent level disease as well. These were all addressed with arthrodesis at the diseased level.

DISCUSSION

A multicenter prospective, randomized study with 2-year follow-up for artificial cervical disc replacement versus fusion did show statistical differences between the groups.[11] For 1-level cervical artificial disc replacement, improved functional outcomes were demonstrated for NDI, NDI success (≥ 15), and neck pain VAS scores. The purpose of this study was to provide updated 4 years follow-up data for our centers cohort of participants. Most importantly after reviewing the data we continue to see a favorable outcome for the artificial disc cohort without any degradation of outcome measures from 2 to 4 years. Although not statistically significant due to insufficient power, clinically we continue to see an established favorable trend for artificial disc replacement with regard to NDI, NDI success, neck/arm pain VAS scores, and the SF-36 scores. All of these outcome measures improved from the 2 to 4-year postoperative time point. Most interesting of all, when we look at secondary surgical procedures performed there have been 6 surgeries for the control group and only 1 for the

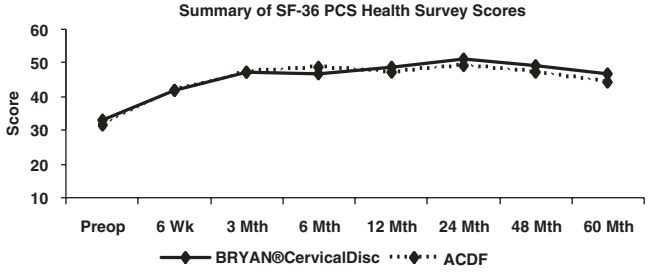

FIGURE 4. SF-36 physical component subscores (PCS) health survey scores. Patients treated with anterior cervical discectomy and fusion (ACDF: dotted line) and Bryan disc arthroplasty (solid line).

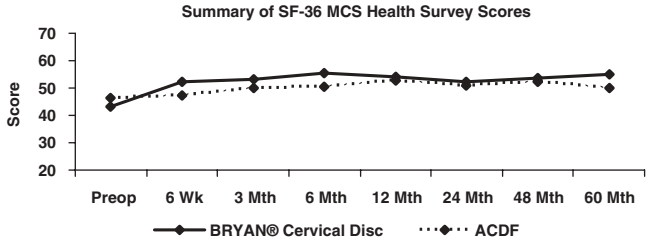

FIGURE 5. SF-36 mental component subscore (MCS) health survey scores. Patients treated with anterior cervical discectomy and fusion (ACDF: dotted line) and Bryan disc arthroplasty (solid line).

investigational group. Of the 6 surgeries performed in the control group, 3 were for adjacent level disease, 1 for nonadjacent level disease, and the other 2 on the same patient for pseudarthrosis. This included a facet neurotomy and posterior cervical fusion. In the investigational group there was only 1 secondary surgery performed for adjacent level disease (Fig. 6). We do believe that long-term multicenter data will confirm our clinical differences in a statistically significant manner.

ACDF has historically been the gold standard treatment for patients experiencing cervical radiculopathy and/or myelopathy refractory to nonoperative measures. The safety and effectiveness of this procedure have been established and demonstrated in the literature, however, limitations have evolved and subsequently alternatives such as disc replacement are being investigated. Such innovative technology has addressed kinematic and biomechanical factors in cervical spine motion. Intervertebral disc replacement is designed to preserve motion, both at affected and adjacent levels, and avoid limitations of fusion. Hilibrand et al[2] have described adjacent level degeneration in patients having undergone cervical fusion at a rate of 2.9% of patients per annum. Thus, at 4 years we should expect about a 12% reoperation rate for adjacent level degeneration for our arthrodesis cohort. Our study showed that the adjacent level degeneration reoperation rate for the Bryan cohort to date is 5%. In the ACDF cohort the reoperation rate for adjacent level disease is 12% to date. The remote degenerative disease for our ACDF cohort resulted in a 15% reoperation rate to date. Thus, the control reoperation rate for adjacent level disease is consistent with historical results while the Bryan cohort is lower.

New onset degenerative changes and possible recurring neurologic symptoms may be deferred or eliminated with cervical disc replacement. Whether such changes occur as a result of the normal aging process or secondary to altered biomechanical environment is a topic of much controversy and debate. Fuller et al[4] and Eck et al[3] have showed altered biomechanics in the cervical spine after fusion and significantly increased intradiscal pressures at adjacent levels with flexion after simulated fusion at C5 to C6, respectively. Thus, it can be argued that spinal fusion can accelerate the normal degenerative process by creating abnormal adjacent

SecondarySurgicalProcedures

PT	Treated Level	Additional Surgery	Timeperiod of 2nd Surgery	Classified As	Treatment Group
JA17	C5-6	PCF C5-6	6 months	Supplemental Fixation	Control
JA17	C5-6	FACET NEUROTOMY PROCEDURE C4-5 THRU C6-7	12 months	Other Target and Adjacent levels	Control
JA23	C6-7	ACDF @ C4-C5 ON 4-12-05	24 months	Other Non-adjacent level	Control
JA54	C6-7	ACDF C5-C6	24 months	Other Adjacent level	Investigational
JA15	C5-6	ACDF C6-7-REMOVAL OF PLATE C5-C6	36 months	Elective Removal	Control
JA05	C5-6	ACDF C4-5	60 months	Other Adjacent level	Control
JA55	C5-6	ANTERIOR FUSION C6-7 DISKECTOMY C6-7	48 months	Other Adjacent level	Control

AQ5 **FIGURE 6.** Secondary surgical procedures for both control and investigational cohorts to date .

activity. In addition, potential complications related to fusion such as pseudarthrosis, anterior plate problems, and morbidity associated with bone graft harvest may be avoided. Cervical disc arthroplasty is designed to provide physiologic motion and eliminate abnormal loading stresses at adjacent levels that lead to accelerated degeneration.

Our study continues to demonstrate clinical improvement in all functional outcome measures for the investigational group at 48 months as did the multicenter trial at 24-month follow-up. This continues to support the clinical benefit of the investigational implant examined by this study. There is no degradation in functional outcome from 24 to 48 months, in fact in every category the outcome improved. Limitations of our study are the low number of participants to demonstrate a potential statistical difference. This preliminary data, however, demonstrates no further degradation of results measured at 48 months for the investigational group at our study site.

The above results are encouraging that artificial disc replacement may progressively replace the accepted "gold standard" (ACDF). Although not statistically significant, there does appear to be a clinical favorable outcome regarding functional outcomes and adjacent segment disease for the arthroplasty cohort. The possibility to minimize adjacent segment degeneration and not contribute to nor accelerate the normal aging process with motion preservation technology is very exciting. Longer term, multicenter studies will be required to definitively prove that cervical arthroplasty does statistically correlate with a lower incidence of adjacent level degeneration and overall better outcomes.

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