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Artificial Disc *Versus* Fusion

A Prospective, Randomized Study With 2-Year Follow-up on 99 Patients

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Study Design. A total of 115 patients were randomized in a 1:1 ratio to a Bryan artificial disc replacement (56) or an anterior cervical fusion with allograft and a plate (59).

Objective. The purpose of this study is to examine the functional outcome and radiographic results of this prospective, randomized trial to determine the role of the Bryan artificial cervical disc replacement for patients with 1-level cervical disc disease.

Summary of Background Data. Artificial cervical disc replacement has become an option for cervical radiculopathy. Previous studies have evaluated the efficacy of this alternative without the scientific rigor of a concurrent control population. This study is a pooled data set from 3 centers involved in the U.S. FDA Investigational Device Exemption trial evaluating the Bryan artificial cervical disc.

Methods. The purpose of this study is to examine the functional outcome and radiographic results of this prospective, randomized trial to determine the role of the Bryan artificial cervical disc replacement for patients with 1-level cervical disc disease; 12-month follow-up is available for 110 patients and 24 month follow-up complete for 99 patients. There are 30 males and 26 females in the Bryan group and 32 males and 27 females in the fusion group. The average age was 43 years (Bryan) and 46 years (fusion). Disability and pain were assessed using the Neck Disability Index (NDI) and the Visual Analog Scale (VAS) of the neck and of the arm pain. SF-36 outcome measures were obtained including the physical component as well as the mental component scores. Range of motion was determined by independent radiologic assessment of flexion-extension radiographs. We report a prospective, randomized study comparing the functional outcome of cervical disc replacement to an anterior cervical fusion with results of 99 patients at 2 years. Prospective data were collected before surgery and at 6 weeks, 3, 6, 12, and 24 months after surgery.

Results. The average operative time for the control group was 1.1 hours and the Bryan Group 1.7 hours. Average blood loss was 49 mL (control) and 64 mL (Bryan). Average hospital stay was 0.6 days (control) and 0.9 days (Bryan). The mean NDI before surgery was not statistically different between groups: 47 (Bryan) and 49 (control). Twelve-month follow-up NDI is 10 (Bryan) and 18 (control) ($P = 0.013$). At 2-year follow-up, NDI for the Bryan group is 11 and the control group is 20 ($P = 0.005$). The mean arm pain VAS before surgery was 70 (Bryan) and 71 (control). At 1-year follow-up, Bryan arm pain VAS was 12 and control 23 ($P = 0.031$). At 2-year follow-up, the average arm pain VAS for the Bryan group was 14 and control 28 ($P = 0.014$). The mean neck pain VAS before surgery was 72 (Bryan) and 73 (control). One-year follow-up scores were 17 (Bryan) and 28 (control) ($P = 0.05$). At 2 years: 16 (Bryan) and 32 (control) ($P = 0.005$). SF-36 scores: Physical component- Before surgery Bryan 34 and control 32. At 24 months: Bryan 51 and control 46 ($P = 0.009$). More motion was retained after surgery in the disc replacement group than the plated group at the index level ($P < 0.006$ at 3, 6, 12, and 24 months). The disc replacement group retained an average of 7.9° of flexion-extension at 24 months. In contrast, the average range of motion in the fusion group was 0.6° at 24 months. There were 6 additional operations in this series: 4 in the control group and 2 in the investigational group. There were no intraoperative complications, no vascular or neurologic complications, no spontaneous fusions, and no device failures or explantations in the Bryan cohort.

Conclusion. The Bryan artificial disc replacement compares favorably to anterior cervical discectomy and fusion for the treatment of patients with 1-level cervical disc disease. At the 2-year follow-up, there are statistically significant differences between the groups with improvements in the NDI, the neck pain and arm pain VAS scores, and the SF-36 physical component score in the Bryan disc population.

Key words: Bryan cervical disc, cervical arthroplasty, randomized, prospective, cervical fusion, outcomes. **Spine 2007;32:000–000**

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Anterior cervical discectomy and fusion (ACDF) is a proven intervention for patients with radiculopathy and myelopathy.[1] Because of limitations specific to this procedure, investigators have developed alternatives to fusion that attempt to address kinematic and biomechanical issues.

Twenty-five percent of patients undergoing cervical fusion will have new onset of symptoms within 10 years of that fusion.[2] Other reports have helped to shed light on the recurrence of neurologic symptoms and degenerative changes adjacent to fused cervical levels.[3,4] Segments adjacent to a fusion may have an increased range of motion and increased intradiscal pressures.[5,6]

Pseudarthrosis is another complication encountered with anterior cervical fusion procedures. There is an association between the rate of pseudarthrosis and the number of levels fused. Brodke and Zdeblick reported a 97% fusion rate in single-level ACDF, which decreased to 83% with fusion at 3 levels.[7] Bohlman *et al* reported an 11% pseudarthrosis rate in single-level fusions that increased to 27% with multilevel fusions.[1]

Complications associated with autologous iliac crest harvest, traditionally used as a fusion graft in ACDF, are also well documented. Sandu *et al* reported a complication rate of 1% to 25% with such procedures.[8] Complications such as acute and chronic pain, infection, meralgia paresthetica, and pelvic fracture are known to occur at harvest donor sites.[9,10]

Total intervertebral disc replacement (TDR) is designed to preserve motion, avoid limitations of fusion, and allow patients to quickly return to routine activities. The primary goals of the procedure in the cervical spine are to restore disc height and segmental motion after removing local pathology. A secondary intention is the preservation of normal motion at adjacent cervical levels, which may be theorized to prevent later adjacent level degeneration. It avoids the morbidity of bone graft harvest.[11,12] It also avoids complications such as pseudarthrosis, issues caused by anterior cervical plating, and cervical immobilization side effects.

The first cervical disc arthroplasty clinical trial in the United States was the Bryan disc study initiated in May 2002 after a European prospective human clinical trial began in 2000.[13] The results of the European clinical trial, though neither randomized nor controlled, validated the stability, biocompatibility, and functionality predicted by preclinical testing. A prospective, randomized, controlled clinical trial was conducted to evaluate the safety and effectiveness of the Bryan cervical disc in patients with radiculopathy or myelopathy attributable to single-level cervical disc disease. The findings of this study represent a pooled data set of 3 sites from the U.S. FDA Investigational Device Exemption (IDE) study.

■ Materials and Methods

Patients. A total of 115 patients were enrolled and followed prospectively at 3 centers involved in a multicenter, FDA IDE trial for the Bryan cervical disc prosthesis. Patients with symptomatic, cervical radiculopathy or myelopathy refractory to nonoperative interventions were randomized in a 1:1 ratio to a single-level ACDF with allograft and plate (control group) or single-level cervical arthroplasty with the Bryan cervical disc prosthesis (investigational group). Preoperative imaging studies included plain radiographs, magnetic resonance imaging (MRI), and computed tomography (CT). The inclusion criteria were single-level cervical degenerative disc disease causing radiculopathy or myelopathy in skeletally mature patients (21 or older) from C3–C7. Patient's had to fail conservative care for 6 weeks (except for myelopathy cases needing immediate attention). Patients required a Neck Disability Index (NDI) score of ≥30%. The most important exclusion criteria were the presence of significant anatomic deformity, such as moderate to advanced spondylosis, radiographic signs of subluxation (>3.5 mm), or angulation (>11°), or previous cervical procedures at the operative level.

Surgery. Surgical technique was similar in both groups to the point of interbody fusion/arthroplasty. A standard Smith-Robinson approach was made to expose the symptomatic level. The same technique for discectomy and decompression was used for both groups. The uncovertebral joints were left in place unless a portion of it was the cause of neural compression; then just the portion compressing the nerve was removed. Endplate preparation for ACDF was completed with a high-speed burr and an appropriately sized CORNERSTONE SR fibular allograft (Medtronic Sofamor Danek, Inc., Memphis, TN) was placed in the prepared interspace. All ACDF patients underwent anterior cervical plating with the ATLANTIS VISION Cervical Plate System (Medtronic Sofamor Danek, Inc.).

The Bryan cervical disc prosthesis (Medtronic Sofamor Danek, Inc.) is a 1-piece, biarticulating, metal-on-polymer, semiconstrained device with fully variable instantaneous axis of rotation that is not dependent on supplemental fixation.[13,14] It has a unique polyurethane sheath that is designed to contain wear debris and prevent soft tissue ingrowth. Each endplate is porous coated to promote bony ingrowth for long-term device stability. In May 2002, this implant became the first cervical artificial disc replacement performed in the United States. The Bryan disc is comprised of a polyurethane polymeric nucleus sandwiched between 2 titanium alloy clamshell-shaped endplates.[14] There are 2 bearing surfaces, 1 at each nucleus-endplate interface. Because the device is unconstrained (internally) throughout the physiologic range of motion, coupled motions of angulation and translation exist. The polyurethane sheath is attached to the endplates with titanium wires forming a closed compartment. This sheath may promote formation of a surrounding pseudocapsule with time. Sterile saline lubricant is injected into this compartment before implantation and titanium alloy seal plugs seal the compartment. Anterior flanges on each shell prevent posterior migration of the implant. An insertion device engages a hole in each flange to allow easy control of the disc during implantation.

Preparation of the endplates for arthroplasty was accomplished in the standard technique. The Bryan disc milling technique creates 2 concave surfaces *via* a milling jig stabilized by table mounted retractors. Sizing of the Bryan cervical disc was determined with a combination of templates and preoperative radiographic studies including CT. The center of the disc space was determined intraoperatively by a jig that defines the uncovertebral joints and finds the center. With knowledge of the center of the disc space, a milling fixture was anchored to the vertebral bodies. This fixture controlled the cutting tools, which mill the endplates to the exact geometry of the device endplates providing immediate stability.

Insertion of the TDR was accomplished under lateral fluoroscopy to assure adequate depth. Before inserting the Bryan disc, the implant was filled with saline as an initial lubricant. The prosthesis was then placed into the milled interspace. Before closure of the incision, appropriate placement of a TDR was confirmed with anteroposterior and lateral fluoroscopic imaging.

Data Collection. Preoperative demographic data, surgical data, and outcomes data were collected on all patients. Clinical

outcome tools included: NDI, Arm Pain Score (VAS), Neck Pain Score (VAS), and SF-36. Outcome assessments were made before surgery and at 6 weeks, 3 months, 6 months, 12 months, and 24 months. Radiographic angular motion at the target level was tracked on digital radiographs using quantitative motion analysis software (QMA, Medical Metrics) to calculate the functional spinal unit motion parameters tool by 2 blinded, trained observers.

Primary outcome measures were the pain and functional assessment data using patient self-report instruments, the NDI and SF-36 questionnaires, as well as numerical rating scales (VAS) for neck and arm pain. Radiographic measures were included as secondary endpoints. Investigational patients were evaluated with respect to maintenance of functional spinal unit height, implant subsidence, anteroposterior implant migration, and angular motion at the implanted and adjacent disc spaces.

Statistical Analysis. For continuous variables, statistical comparisons between the treatment groups were performed by using analysis of variance (analysis of variance) and for categorical variables, the Fisher exact test was used. A paired *t* test was used to assess the statistical significance of postoperative score change from the preoperative in SF-36, NDI, and neck and arm pain measures. It was also used for analysis of motion scores at the target level when change from preoperative angulation was recorded.

■ Results

Demographic and Surgical Data

A total of 115 patients were randomized in a 1:1 ratio to either a Bryan cervical disc (N = 56) or an anterior cervical fusion with allograft and a plate (N = 59). There were 30 males and 26 females in the Bryan group and 32 males and 27 females in the fusion group. The average age was 43 years (Bryan) and 46 years (control). No statistically significant differences were noted in the demographics of the investigational and control populations. No differences in demographics, such as age, percent of males, height, weight, smoking history and percent worker's compensation, were present between groups ($P > 0.05$) (Table 1). T1

The average operative time for the control group was 1.1 hours and the Bryan Group 1.7 hours. Average blood loss was similar (49 mL control, 64 mL Bryan). Average hospital stay was 0.6 days (control) and 0.9 days (Bryan).

Table 1. Demographic Information

Variable	Investigational (N = 56)	Control (N = 59)	P*
Age (yr)			0.015
N	56	59	
Mean	42.5	46.1	
SD	7.8	7.8	
Minimum	25.1	29.4	
Maximum	64	66.9	
Height (in.)			0.728
N	56	59	
Mean	67.9	67.7	
SD	3.5	3.7	
Minimum	60	61	
Maximum	74	77	
Weight (lbs.)			0.343
N	56	59	
Mean	173.6	180.8	
SD	42.6	39.2	
Minimum	110	100	
Maximum	312	282	
Gender [N (%)]			1
Male	30 (53.6)	32 (54.2)	
Female	26 (46.4)	27 (45.8)	
Race [N (%)]			0.469
White	53 (94.6)	56 (94.9)	
Black	0 (0.0)	0 (0.0)	
Asian	0 (0.0)	1 (1.7)	
Hispanic	1 (1.8)	2 (3.4)	
Other	2 (3.6)	0 (0.0)	
Marital status [N (%)]			0.968
Single	4 (7.1)	5 (8.5)	
Married	45 (80.4)	48 (81.4)	
Divorced	6 (10.7)	6 (10.2)	
Separated	1 (1.8)	0 (0.0)	
Widowed	0 (0.0)	0 (0.0)	
Education level [N (%)]			0.562
<High school	6 (10.7)	8 (13.6)	
High school	13 (23.2)	18 (30.5)	
>High school	37 (66.1)	33 (55.9)	
Tobacco used [N (%)]			0.635
Yes	12 (22.2)	10 (16.9)	
No	42 (77.8)	49 (83.1)	
Alcohol used to relieve neck pain [N (%)]			1
Yes	2 (3.7)	3 (5.1)	
No	52 (96.3)	56 (94.9)	
Preoperative work status [n (%)]			0.838
Currently working	41 (73.2)	42 (71.2)	
Not working	15 (26.8)	17 (28.8)	

*For continuous variables, *P* values are from ANOVA; and for categorical variables, they are from Fisher exact test.

Outcomes Data

For all of the following functional outcomes measures, both groups demonstrated statistically significant improvement compared with preoperative values. The *P* values relate to differences between groups at follow-up. Preoperative scores between groups were all statistically similar.

NDI before surgery was 47 (Bryan) and 49 (control). Twelve-month follow-up data were available for 110 patients (55 Bryan and 55 control) with NDI 10 (Bryan) and 18 (control) ($P = 0.013$). At 2-year follow-up, 99 patients were available (49 Bryan and 50 control). NDI for the Bryan group was 11 and the control Group 20 ($P = 0.005$). In addition to the group-to-group differences noted, both groups demonstrated a significant improvement in comparison to their preoperative scores ($P < 0.001$) (Figure 1). F1

Neck pain VAS before surgery was 72 (Bryan) and 73 (control). Twelve-month follow-up data were available for 110 patients (55 Bryan and 55 control) with VAS 17 (Bryan) and 28 (control) ($P = 0.05$). At 2-year follow-up, 99 patients were available (49 Bryan and 50 control). VAS for the Bryan group was 16 and the control Group 32 ($P = 0.005$) (Figure 2). In addition to the group-to-group differences noted, both groups demonstrated a significant improvement in comparison to their preoperative scores ($P < 0.001$). F2

Arm pain VAS before surgery was 70 (Bryan) and 71 (control). Twelve-month follow-up data were available

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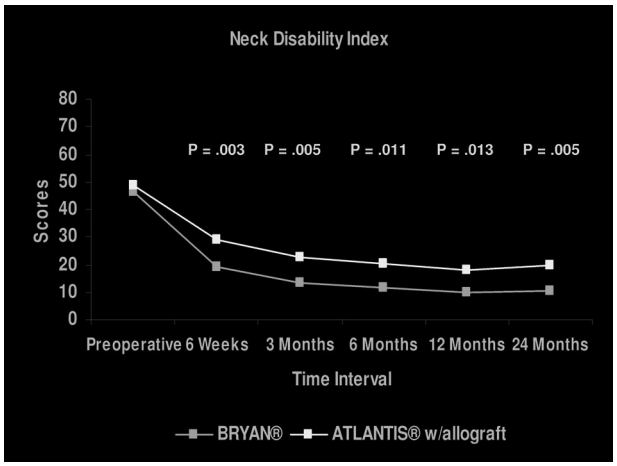

Figure 1. NDI scores.

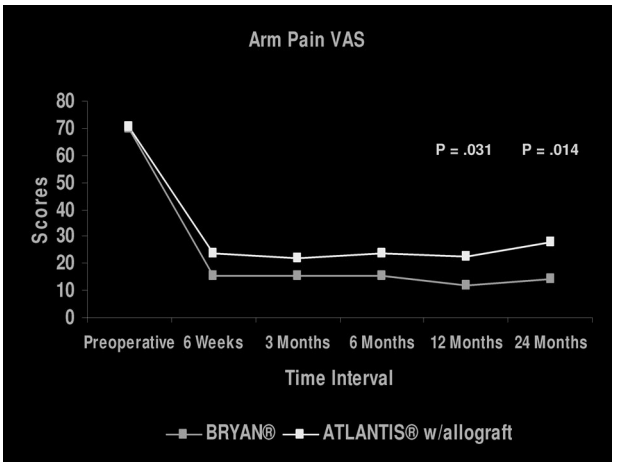

Figure 3. Arm pain VAS scores.

for 110 patients (55 Bryan and 55 controls) with Bryan arm pain VAS 12 and control 23 ($P = 0.031$). At 2-year follow-up, 99 patients were available with the arm pain VAS for the Bryan Group 14 and control 28 ($P = 0.014$). In addition to the group-to-group differences, both groups demonstrated a significant improvement in comparison to their preoperative scores ($P < 0.001$) (Figure 3). F3

SF-36 scores (Physical Component) were also notable: preoperative Bryan 34 and control 32. Twelve-month follow-up Physical Component Score data were available for 110 patients (55 Bryan and 55 control) with Physical Component Score 51 (Bryan) and 47 (control) ($P = 0.031$). At 24 months after surgery, the physical component of the SF-36 had changed to: Bryan 51 and control 46 ($P = 0.009$) (Figure 4). SF-36 Mental Component Scores were before surgery: Bryan 46 and control 49. By 24-months they were: Bryan 54 and control 52 (Figure 5). The group-to-group Mental Component Scores difference was not significant at 24-months ($P > 0.05$). F4 F5

Target-Level Motion Analysis

Cervical vertebral bodies were tracked on the digital radiographs using quantitative motion analysis software (QMA, Medical Metrics) to calculate the functional spinal unit motion parameters. The mean preoperative angular motion of the Bryan and fusion group was 6.43° ± 3.42° and 8.39° ± 4.54°, respectively. The difference was not statistically significant. As expected, significantly more motion (3, 6, 12, and 24 months) was retained in the disc replacement group than the plated group at the index level. The disc replacement group retained an average of 7.3° at 12 months and 7.9° at 24 months. In the 24-month Bryan group, this did not represent a statistically significant change from the preoperative measured angulation at the target level ($P > 0.05$). (Figure 6) In contrast, the average range of motion in the fusion group was 1.3° at the 3-month follow-up and gradually decreased to 0.6° at 24 months, a significant change from the preoperative measurements ($P < 0.0001$). F6

Complications

Over the 24-month follow-up period, a total of 6 subsequent surgical interventions were performed in the study population (4 control, 2 investigational). All subsequent surgical interventions were performed by the initial treating surgeon at the discretion of that surgeon. One patient in the control group required a posterior cervical fusion

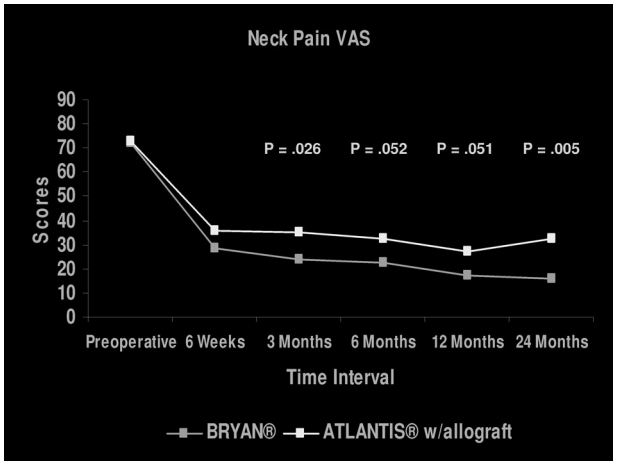

Figure 2. Neck pain VAS scores.

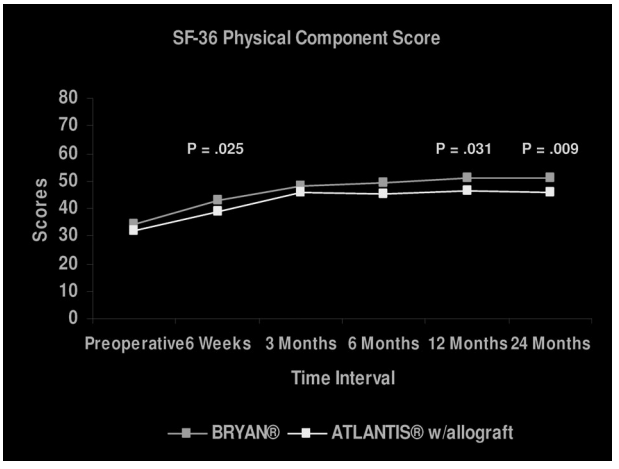

Figure 4. SF-36 Physical component scores.

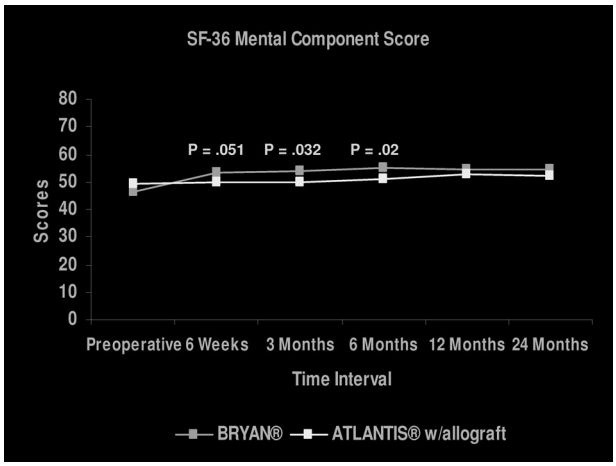

Figure 5. SF-36 Mental component scores.

for symptomatic nonunion. Another patient in the control group required revision ACDF for nonunion, which was performed with rhBMP-2 and revision anterior cervical plating. Two patients in the control group required ACDF for adjacent level disease during the 24-month period.

Two patients in the investigational group required ACDF for adjacent level disease during the 24-month follow-up period. There were no incidents of radiographic or clinical implant complications noted at the target surgical levels (Bryan disc replacement) in the investigational group. There were no intraoperative complications, no vascular or neurologic complications, no spontaneous fusions, and no device failures or explantations in the Bryan cohort.

■ Discussion

Our study demonstrates significant improvement (investigational group *vs.* control group) in multiple outcome measures at 12 and 24 months, including NDI, neck pain VAS, arm pain VAS, and SF-36 Physical Component Score. Although both surgical groups had statistically significant improvement in all outcome measures at 24 months with respect to their preoperative scores, the outcome-based group to group comparison at the follow-up intervals is highly suggestive of the benefit of the investigational implant in the 24-month period examined by this study.

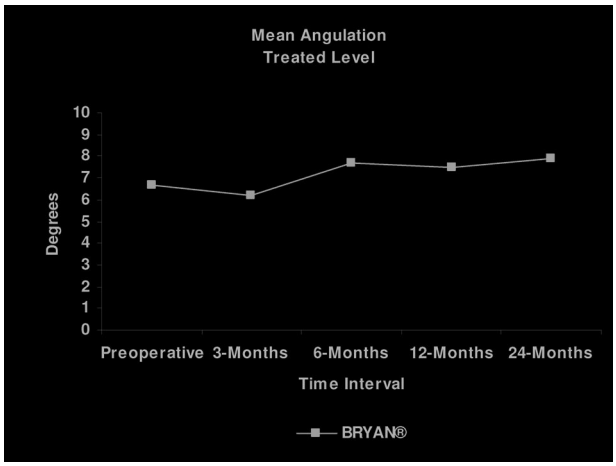

Figure 6. Mean flexion-extension angulation of the Bryan disc.

Our results with regard to surgical outcomes are similar to those of other investigators and represent the largest single randomized, controlled, prospective series of patients with Bryan disc arthroplasty followed to 24 months. Goffin *et al*[13] reported early results of a multicenter study of the Bryan disc performed at single levels in 60 patients for the treatment of radiculopathy or myelopathy due to disc herniation or spondylosis failing at least 6 weeks of conservative treatment. Exclusion criteria included previous cervical spine surgery, axial neck pain as the sole symptom, significant anatomic deformity, and radiographic evidence of instability (translation >2 mm or >11° of angulation compared with the adjacent level). Patient outcomes were determined by the Cervical Spine Research Society and SF-36 instruments. Clinical success rates at 6 months and 1 year were 86% and 90%, respectively, exceeding the study's targeted success rate of 85%.

In a separate report, Goffin *et al*[15] have recently published the intermediate-term results of this multicenter study. The study was expanded to include a second arm evaluating the treatment of 2 adjacent levels. The single-level arm had 103 patients enrolled with 100 reaching the 1-year mark and 51 reaching 2-year follow-up. The bilevel study arm was comprised of 43 patients with 1-year data completed on 29 patients and 2-year data available on 1 patient. Success rates in the single-level study at 6 months, 12 months, and 24 months were 90%, 86%, and 90%, respectively. In the bilevel study, the success rate at 6 months was 82% and 96% at 1 year. No device failures or subsidence was observed in any patient. At 1-year follow-up, flexion-extension range of motion per level averaged 7.9° in the single-level arm and 7.4° in the bilevel arm.

Anderson *et al* described the follow-up results of 73 patients who had >2-year follow-up status on a 1-level Bryan disc arthroplasty.[14] Forty-five of these patients were rated as excellent, 7 as a good, and 13 as fair. Only 8 patients had a poor rating at the 2-year follow-up. SF-36 functional outcome data demonstrated significant improvement from preoperative to 3-month postoperative time points. These outcomes remained stable 24 months after surgery. There was no radiographic evidence of subsidence of implants. A total of 89% of all patients had at least 2° of motion at 1 and 2 years. Average range of motion was 8°. There was 1 early anterior device migration associated with a partially milled cavity.

Sekhon[16] reported early results of 9 patients with cervical spondylotic myelopathy who were treated with anterior decompression and reconstruction with the Bryan disc. Follow-up ranged from 1 to 17 months. On average, the Nurick grade improved by 0.72 and Oswestry NDI scores improved by 51.4 points. Improvement in

cervical lordosis was noted in 29% of the patients. No complications were reported.

In another small prospective study, Duggal *et al* reported on 26 patients undergoing single- or two-level implantation of the Bryan artificial cervical disc for treatment of cervical degenerative disc disease resulting in radiculopathy and/or myelopathy.[17] Patients were evaluated radiographically and *via* NDI and SF-36 at regular intervals. Segmental sagittal rotation from C2–C3 to C6–C7 was measured using quantitative motion analysis software. A total of 30 Bryan discs were placed in 26 patients. Follow-up duration ranged from 1.5 to 27 months, with a mean duration of 12.3 months. A statistically significant improvement in the mean NDI scores was seen between preoperative and late postoperative follow-up evaluations.

Several complications were observed in our investigation: 4 control, 2 investigational. In the investigational group, 2 patients went on to require surgical intervention at adjacent levels for symptomatic pathology refractory to nonoperative means. In the control group, 2 patients required surgical intervention at adjacent levels, 1 patient required surgical revision for nonunion, and 1 patient required supplemental posterior cervical fusion. Our complications may be compared with those described in the series reported by Goffin *et al*. In the single-level study,[13] 3 patients required subsequent surgical intervention. These procedures included the evacuation of a prevertebral hematoma, a posterior foraminotomy for residual compression, and a posterior laminectomy for residual myelopathy. Four subsequent procedures were required in the bilevel study: evacuation of a prevertebral hematoma, evacuation of an epidural hematoma, repair of a pharyngeal/esophageal injury caused by intubation, and an anterior decompression due to residual nerve root compression. Two patients developed dysphonia after second procedures. One patient initially had a device placed at a wrong level and developed temporary dysphonia after a device was placed at the appropriate level. The other patient developed a second symptomatic disc 21 months after the index procedure and developed severe dysphonia from bilateral vocal cord paralysis after a second device was placed from a contralateral approach.

In the intermediate Goffin *et al* study,[15] temporary anteroposterior device migration was detected in 1 patient and suspected in another. This migration was felt to be due to inadequate endplate milling early in the study. This issue was corrected with modification of the instrument system. Migration >3.5 mm, the radiographic threshold of segmental stability, was not observed.

While it is difficult to draw statistically relevant conclusions from few reoperative complications observed in our series, it is probable that the long-term follow-up of this cohort will yield further data. In the interim, reoperative rates have been reported in other series and are relevant to the discussion.

Anderson *et al*[18] studied reoperation rates following arthroplasty and cervical spine arthrodesis. Their randomized, prospective, controlled study analyzed data from multiple IDE trials including: U.S. PRESTIGE and Bryan IDE trials, European Bryan (single-level), and PRESTIGE trials. Additional arthrodesis data were obtained from the control group of the AFFINITY Cervical cage. A total of 649 arthroplasties and 580 control arthrodesis patients were analyzed.[18] The follow-up period for the arthroplasty and arthrodesis groups was comparable and ranged from 6 weeks to 28 months. Among the arthroplasty patients, there were 12 (1.8%) reoperations out of 649, with 10 (1.5%) at the same level, and 4 (0.6%) at another level (some pts had a redo at the same level plus another level done). In the arthrodesis group, 21 (3.6%) underwent a reoperation. 9 (1.6%) were at the same level, and 13 (2.2%) were at a different level. The difference in reoperation rates was just less than significant ($P = 0.055$). Reoperations at the treated level were similar but reoperations at an adjacent level were significantly higher for the arthrodesed patients ($P = 0.01$). Their results suggest, in the short-term (follow-up <28 months), reoperations are more common following arthrodeses than arthroplasties of the cervical spine. This was thought to be due to a greater number of reoperations at adjacent levels following arthrodesis.[18]

One of the primary goals of cervical disc replacement is to reproduce normal kinematics after implantation. Our investigation noted preservation of angular motion at the target level at 24 months. This statistically significant finding mirrors the findings of other investigators. Duggal *et al* have demonstrated preservation of motion in Bryan treated spinal segments (mean range of motion, 7.8° for up to 24 months postsurgery).[17] The relative contribution of each segment to overall spinal sagittal rotation differed depending on whether the disc was placed at C5–C6 or C6–C7. Overall cervical motion (C2–C7) was moderately increased on late follow-up evaluations.[17]

A few retrospective evaluations of patients with cervical myelopathy treated with anterior decompression and artificial disc replacement are available. Results from these studies are favorable. It does appear that patients with cervical myelopathy may be treated with a cervical disc replacement and experience successful outcomes. Sekhon[16] concluded that, at least in the short-term, cervical myelopathy treated by Bryan cervical disc arthroplasty resulted in excellent outcomes.

Bertagnoli *et al* reported on the early results after ProDisc-C (Synthes Spine, Inc., West Chester, PA) cervical disc replacement.[19] Patients with mild myelopathy were included; however, severely myelopathic patients were excluded. The conclusions were that mild myelopathy can be satisfactorily treated with cervical arthroplasty.[19]

The closest look at the use of artificial disc replacement for the surgical treatment of myelopathy is by Riew *et al* who undertook a prospective, randomized, multicenter investigation to determine the effectiveness of cervical arthroplasty for cervical myelopathy.[20] The patients were a subset of those enrolled in the FDA IDE

study for the Bryan and Prestige artificial cervical disc replacements. All patients with a diagnosis of myelopathy were evaluated. Myelopathy was defined as hyperreflexia or clonus or Nurick grade ≥1. None of these patients had retrovertebral cord compression from pathologies such as ossification of the posterior longitudinal ligament. Of the 542 patients in the Prestige trial, 108 had myelopathy. Fifty-eight of these were randomized to arthroplasty while 50 underwent an ACDF. Of these, 55 arthroplasty and 39 ACDF patients had a minimum 1-year follow-up; 11 arthroplasty and 14 ACDF patients had 2-year follow-up. Of the 465 patients in the Bryan trial, 93 had myelopathy. Forty-nine of these were randomized to arthroplasty, while 44 underwent an ACDF. Of these, 42 arthroplasty and 32 ACDF patients had a minimum 1-year follow-up; 18 arthroplasty and 15 ACDF patients had 2-year follow-up.

By 12 months, gait improved for both the arthroplasty and arthrodesis groups. In the Prestige study, 39% of the arthroplasty and 33% of the ACDF patients had improvement in their gait. No one in either group had clinical deterioration and 61% of the arthroplasty and 67% of the ACDF group had maintenance of their gait. Of the patients with 2-year follow-up, 46% *versus* 50% (arthroplasty *vs*. ACDF) noted improvement, 54% *versus* 50% noted maintenance of their gait, and there was no clinical deterioration in either group. Arm and neck pain VAS scores, NDI, and SF-36 Physical and Mental Component Scores all improved from baseline at 6, 12, and 24 months. There was no statistically significant difference between the arthroplasty and arthrodesis groups. There were no revisions in the arthroplasty group while there was 1 removal and 1 reoperation (foraminotomy) in the ACDF group.

In the Bryan study, 45% of the arthroplasty and 30% of the ACDF patients had improvement in their gait. No one in the arthroplasty group deteriorated clinically, while 1 in the ACDF group worsened; 55% of the arthroplasty and 67% of the ACDF group had maintenance of their gait. Of the patients with 2 year follow-up, 50% *versus* 38% (arthroplasty *vs*. ACDF) noted improvement, 50% *versus* 62% noted maintenance of their gait, and there were no deteriorations in either group. Arm and neck pain VAS scores, NDI, and SF-36 Physical and Mental Component Scores all improved from baseline at 6, 12, and 24 months. There was no statistically significant difference between the arthroplasty and arthrodesis groups.

The above results suggest that arthroplasty is equal to ACDF at treating cervical myelopathy. At 3, 6, 12, and 24 months, the improvement in gait, as well as all the various outcome measures, was equivalent between the arthroplasty and arthrodesis groups. These results suggest that, for focal retrodiscal pathology causing cervical myelopathy, arthroplasty is an effective treatment. It should be noted, however, that none of these patients had diffuse retrovertebral compression, such as from ossification of the posterior longitudinal ligament.

It is clear from preliminary studies that cervical myelopathy can be successfully treated by artificial disc replacement. It is extremely important, however, to understand the appropriate indications, and it is critical to recognize the contraindications for cervical arthroplasty. The suitable situation is quite narrow: a focal disc herniation without retrovertebral compression, without significant facet pathology, and without multilevel stenosis. The vast majority of patients with myelopathy are not candidates for cervical arthroplasty due to multilevel pathology or significant degeneration. Long-term follow-up studies are essential to fully understand the role of cervical arthroplasty. The FDA IDE studies of arthroplasty *versus* ACDF will eventually provide these important long-term data for us to understand the appropriate indications for this new technique.

■ Conclusion

Although far from being an accepted standard, the concept of artificial disc replacement is gradually becoming a reality. The possibility of being able to minimize adjacent segment degeneration is exciting; however, much more intermediate and long-term outcome-based data are going to be necessary to prove that this technology supersedes the current gold standard of anterior fusion. Biomechanical studies demonstrate that disc replacement creates less adjacent level strain than fusion. Hopefully, with time, long-term studies will prove that this correlates to a lower incidence of adjacent level degeneration.

Recent clinical reports show promising early data suggesting that artificial disc replacement is comparable to fusion at least in the short-term. Wear studies suggest that there may be less potential for aseptic loosening than in large joint arthroplasty, although the reality of this will only be borne out with more follow-up time. While early reports of success in the United States with the TDR suggest that the intended effects are being achieved, the final results of arthroplasty with these devices and of cervical arthroplasty are pending the outcomes of long-term studies.

This study demonstrates the favorable outcomes of cervical disc arthroplasty using the Bryan disc in comparison to the "gold-standard" (ACDF) at 24 months. Follow-up in this study is similar in duration to published data of many other cervical arthroplasty devices under investigation in U.S. trials. Intermediate and long-term data collection will ultimately determine the feasibility of this device and technique for patients with cervical radiculopathy and myelopathy.

■ Key Points

- This is a prospective, randomized, controlled study evaluating the Bryan cervical disc replacement *versus* anterior cervical fusion for the treatment of 1-level cervical radiculopathy and myelopathy.

- At 2 years of follow-up, the Bryan disc group demonstrated statistically significant improvements in the neck disability index, the neck pain and arm pain visual analog pain scores, and the SF-36 physical component score.
- There were no intraoperative complications, no vascular or neurologic complications, no spontaneous fusions, and no device failures or explantations in the Bryan cohort.
- The disc replacement group retained an average of 7.9° of flexion-extension at 24 months.

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AUTHOR QUERIES

AUTHOR PLEASE ANSWER ALL QUERIES **1**