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Comparison of BRYAN Cervical Disc Arthroplasty With Anterior Cervical Decompression and Fusion

Clinical and Radiographic Results of a Randomized, Controlled, Clinical Trial

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Study Design. A prospective, randomized, multicenter study of surgical treatment of cervical disc disease.

Objective. To assess the safety and efficacy of cervical disc arthroplasty using a new arthroplasty device at 24-months follow-up.

Summary of Background Data. Cervical disc arthroplasty preserves motion in the cervical spine. It is an alternative to fusion after neurologic decompression, whereas anterior decompression and fusion provides a rigorous comparative benchmark of success.

Methods. We conducted a randomized controlled multicenter clinical trial enrolling patients with cervical disc disease. Ultimately 242 received the investigational device (Bryan Cervical Disc), and 221 patients underwent a single-level anterior cervical discectomy and decompression and fusion as a control group. Patients completed clinical and radiographic follow-up examinations at regular intervals for 2 years after surgery.

Results. Analysis of 12- and 24-month postoperative data showed improvement in all clinical outcome measures for both groups; however, 24 months after surgery, the investigational group patients treated with the artificial disc had a statistically greater improvement in the primary outcome variables: Neck disability index score ($P = 0.025$) and overall success ($P = 0.010$). With regard to implant- or implant/surgical-procedure-associated serious adverse events, the investigational group had a rate of 1.7% and the control group, 3.2%. There was no statistical difference between the 2 groups with regard to the rate of secondary surgical procedures performed subsequent to the index procedure. Patients who received the artificial cervical disc returned to work nearly 2 weeks earlier than the fusion patients ($P = 0.015$).

Conclusion. Two-year follow-up results indicate that cervical disc arthroplasty is a viable alternative to anterior cervical discectomy and fusion in patients with persistently symptomatic, single-level cervical disc disease.

Key words: degenerative disc disease, cervical spine, arthroplasty, fusion, spinal instrumentation. **Spine 2009; 34:101–107**

Anterior cervical discectomy and fusion is a common treatment for patients with radiculopathy and myelopathy. The procedure is well tolerated, and in correctly selected patients, the results are satisfactory in a high proportion of patients. Longer follow-up has revealed that up to 25% of patients may develop recurrent radicular symptoms from adjacent segment degeneration.[1,2] Furthermore, reoperations may be required to treat complications of fusion, such as nonunion, graft collapse, or expulsion. Cervical arthroplasty is a potential substitute for fusion after anterior neural decompression. The original theoretical basis for cervical arthroplasty was that maintenance of motion might decrease the likelihood of adjacent segment disease and avoid other morbidities of fusion.

The BRYAN Cervical Disc (Medtronic Sofamor Danek, Memphis, TN) is one of several cervical disc arthroplasty devices undergoing testing in the United States. After *in vitro* and *in vivo* testing[3–5] demonstrated feasibility and adequate durability, a European prospective clinical trial, which began in 2000, demonstrated acceptable results at 2- and 4-year follow-up.[6–8] Subsequently, in the United States, a prospective, randomized, controlled clinical trial was undertaken to evaluate the safety and effectiveness of the Bryan cervical disc. The indication for surgery was radiculopathy or myelopathy in patients with single-level cervical disc disease. The hypothesis was that arthroplasty would produce outcomes at least equivalent to fusion. We report the 24-month results of this noninferiority trial.

Materials and Methods

Subjects and Study Design

Eligible patients were at least 21-year-old with radiculopathy or myelopathy from single-level cervical disc disease secondary

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The device(s)/drug(s)that is /are the subject of this manuscript is/are being evaluated as the part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol.

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Medtronic sponsored this IDE clinical trial.

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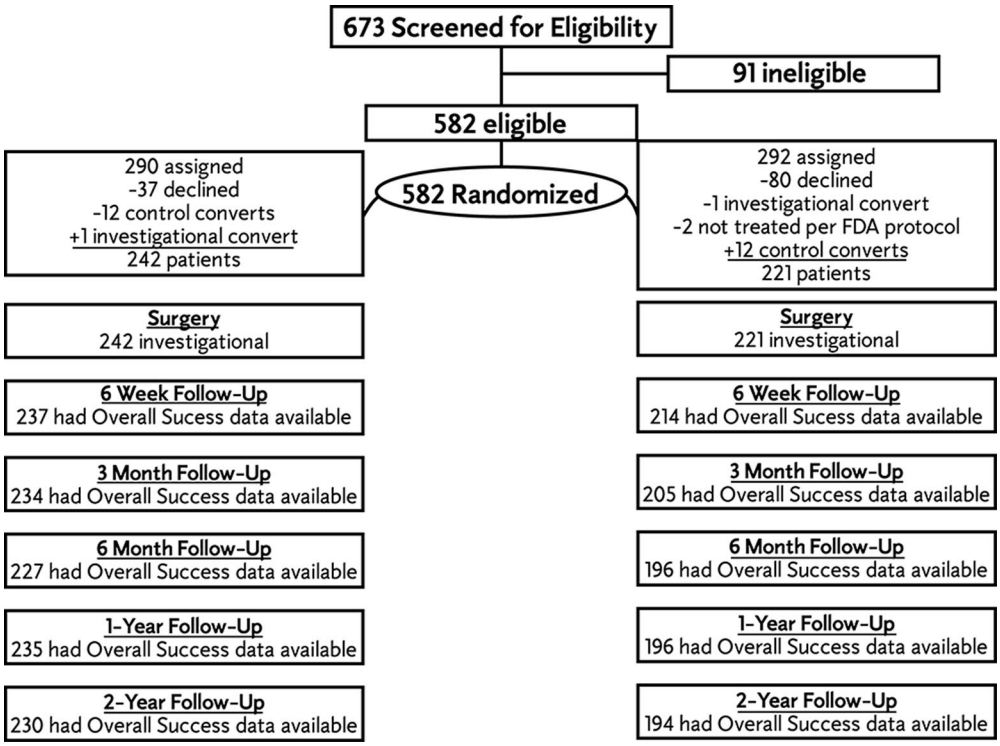

Figure 1. Flow diagram of the exclusion, enrolment, randomization, and follow-up of patients in the study.

to disc herniation that had not responded to at least 6 weeks of nonoperative management, with the exception of cases of myelopathy requiring immediate treatment. Exclusion criteria included marked spondylosis; marked reduction or absence of motion or collapse of the intervertebral disc space of greater than 50% of its normal height; facet joint arthrosis; segmental instability or cervical kyphosis; active infection; metabolic bone disease, such as osteoporosis; known allergy to titanium, polyurethane, or ethylene oxide residuals; concomitant conditions requiring steroid treatment; diabetes mellitus; extreme obesity; pregnancy; inflammatory spondyloarthropathies, such as ankylosing spondylitis or rheumatoid arthritis, and previous cervical spine surgery.

All investigational sites had Institutional Review Board approval, and all patients provided voluntary informed consent to participate in the study. Patients were randomly assigned in a 1:1 ratio to 1 of 2 treatment groups (Figure 1): investigational subjects received an artificial disc, the BRYAN Cervical Disc (Figure 2) and control subjects underwent fusion with anterior cervical plating and a bone allograft (ACDF). The randomization schedule was centrally generated by the study's sponsor, stratified by site and by using a fixed block size of 4. Blinding for investigators and patients was maintained through confirmation of eligibility and informed consent. The surgeries were performed at 30 investigational sites by 65 investigators and co-investigator surgeons. The control group's fusion procedure was standardized by using a commercially available allograft and a single anterior cervical plating system (Medtronic Sofamor Danek). The treatments were similar with neither group requiring co-interventions. Patients in both treatment groups followed a routine postoperative course and the investigational group was allowed to resume nonstrenuous activities as they pleased. Investigational group patients were treated with a 2-week postoperative course of a nonsteroidal anti-inflammatory drug of their surgeon's choice. Because of this difference between the treatment groups and issues related to patient care, further blinding was not practical or ethical. Any decision to provide either soft or hard cervical collars was left to the discretion of the surgeon for both patient cohorts.

Patients were evaluated at protocol-defined intervals: preoperative, surgery/discharge, 1.5-, 3-, 6-, 12-, and 24-month after surgery. Patient retention exceeded 90% at each postoperative interval. The patient follow-up rates at 12 and 24 months were 93.1% and 91.6%, respectively. The premarket

Figure 2. The BRYAN Cervical Disc system is a composite-type artificial disc with 2 anatomically shaped metal plates.

approval application submitted to FDA by the study sponsor was based on an interim analysis; however, this report includes the final follow-up data gathered at 24 months.

Outcomes Assessment

Pain and function were assessed using the neck disability index (NDI),[9,10] the SF-36,[11] and numerical rating scales for neck and arm pain. The patient completed these outcomes measures without assistance. The investigator or ancillary staff member recorded standardized neurologic examinations, including motor, sensory, and reflexes. Neurologic success required maintenance or improvement of all 3 neurologic parameters (motor, sensory, and reflexes). Protocol radiographs were obtained before surgery, before hospital discharge, and at 3, 6, 12, and 24 months after surgery. All images were stored centrally and read by independent radiologists. All adverse occurrences were recorded prospectively, categorized, evaluated for causality, and graded for severity using World Health Organization criteria.[12] All were then reviewed for accuracy of categorization, causality, and severity by an independent physician.

The primary endpoint for the study was a composite measure termed "overall success," which comprised the primary effectiveness and safety measures. To be considered an overall success, patients had to achieve all of the following: a ≥15-point improvement in their NDI scores, maintenance or improvement in their neurologic status, no serious adverse events related to the implant or implant/surgical procedure, and no subsequent surgery or intervention that is classified as "failure." Overall success was predefined in the protocol, based on FDA's recommendation and guidance for Investigational Device Exemption clinical trials for spinal devices.

Investigational patients were evaluated for angular range of motion using the Cobb technique on dynamic radiographs. For each measurement, the means from 2 reviewers were calculated and used for analysis.

For control patients, successful fusion was defined as ≤4° of angular motion on lateral flexion and extension radiographs, the presence of bridging trabecular bone between the vertebrae being fused, and the absence of any radiolucent zones spanning more than 50% of the allograft surface. Two independent radiologists assessed the radiographs. In the event of disagreement about fusion healing, a third independent reading was obtained.

Statistical Methods

This clinical trial was based on a noninferiority hypothesis—that is, the overall success rate of the investigational group was statistically noninferior to the control group's rate. A δ value of 0.10 was used as the noninferiority margin, with overall success at 24 months defined as the primary study end point. The sample size of 225 patients per treatment arm was calculated with a significance level of 0.05 and a power of 80% and equal expected rates in overall success in the 2 groups, based on the primary study hypothesis. Importantly, the superiority hypothesis was also predefined. If noninferiority were established, then superiority would also be examined without the need to adjust for the statistical multiplicity because it was a closed test procedure. For adverse events, additional surgical procedures or interventions, and surgery and hospital information, the null hypothesis was that the 2 groups were the same.

The primary analysis dataset consisted of all patients who received 1 of the study treatments. Statistical comparisons were primarily based on the observed and recorded follow-up data. A small number of patients required an additional surgical procedure (removal, revision, or supplemental fixation); their outcomes were recorded as a treatment failure for overall success—the primary study endpoint. For other outcome variables, the observation before the second surgery was used for all future evaluation periods. Intent-to-treat analysis was not employed as the primary method because it could not be considered *a priori* as a conservative method for a noninferiority trial.

To compare patients' demographic and preoperative measures, an analysis of variance was used for continuous variables and Fisher exact test was used for categorical variables. For comparing postoperative mean scores or mean score improvements measured in continuous scales, such as NDI scores, analysis of covariance was used with the preoperative score as the covariate. For assessing statistical significance of improvement in the outcome measures within each treatment group, a paired *t* test was used. For comparing days to return to work in the 2 treatment groups, the Kaplan-Meier life table method was used. For comparing success or event rates, Fisher exact test was used for assessing the superiority hypothesis. A *z*-test was used for assessing noninferiority.

One-sided *P* values were reported for most clinical outcomes as defined in the protocol except for surgery and return-to-work data, adverse events, and additional surgical procedures, which were 2-sided. A *P* value of <0.05 was customarily considered as significant.

Results

Preoperative Comparison

From May 2002 to October 2004, 463 enrolled subjects were randomly assigned to the study groups and received the study devices: 242 to the investigational group and 221 to the control group (see Figure 1). Baseline characteristics of the patients and preoperative clinical measures were similar in the 2 groups except for the mean SF-36 mental component summary scores, body mass index, and range of motion (Table 1). We do not believe the differences were clinically significant.

NDI

Statistically significant reductions ($P < 0.001$) in NDI scores were noted for the investigational (34.7 ± 20.5 at 24 months) and control (30.6 ± 19.8 at 24 months) groups at every follow-up interval (Figure 3). However, the investigational group had significantly greater score improvements at all intervals than the control group ($P = 0.025$ at 24 months). The proportion of the investigational group who had a >15-point reduction in NDI scores, a criterion for overall success, was statistically higher than that of the control group at each follow-up interval (Table 2).

Neck and Arm Pain

Statistically significant reductions in both arm and neck pain from baseline scores ($P < 0.001$) occurred in both groups at each follow-up interval (Figure 4A, B). Although similar arm pain reduction was seen in both groups, the investigational group showed significantly greater improvement in neck pain at all postoperative intervals.

Table 1. Baseline Characteristics and Preoperative Severity of Disease

Variable	Investigational Group (n = 242)	Control Group (n = 221)	P*
Patient characteristics			
Mean age (range) yr	44.4 (25–78)	44.7 (27–68)	0.723
Mean body-mass index, mean (SD)	26.6 (4.8)	27.6 (5.0)	0.027
Male (%)	45.5	51.1	0.228
Working (%)	64.5	65.0	0.923
Preoperative disease severity			
Neck disability index scores, mean (SD)	51.4 (15.3)	50.2 (15.9)	0.392
Arm pain scores, mean (SD)	71.2 (19.5)	71.2 (25.1)	0.976
Neck pain scores, mean (SD)	75.4 (19.9)	74.8 (23.0)	0.765
SF-36 physical component summary scores, mean (SD)	32.6 (6.7)	31.8 (7.2)	0.208
SF-36 mental component summary scores, mean (SD)	42.3 (12.5)	44.6 (11.6)	0.041
Range of motion (deg)†, mean (SD)	6.5 (3.4)	8.4 (4.5)	<0.001
Neurological abnormality (%)	99.6	98.6	0.352

*For continuous variables, probability values were based on an analysis of variance. For categorical variables, they were based on Fisher exact test.
†Range of motion is based on flexion-extension radiographs.

SF-36 Summary Scores

At 24 months, the mean postoperative SF-36 physical component summary and mental component summary scores had significantly improved for the investigational and control groups, but no statistical differences were present between groups (Figure 4C, D). At earlier time intervals, 1.5 to 12 months, improvements were significantly greater in the investigational group.

Neurologic Success

Rates of neurologic success were similar for both treatment groups at all follow-up intervals. At 24 months, neurologic success occurred in 93.9% of investigational and 90.2% of control patients (Table 2).

Return-to-Work Status

Before surgery, 65% of patients in both study arms were employed. Although at the earlier time periods of 1.5 and 3 months after surgery, a greater percentage of patients in the investigational group had returned to work, there were no differences between the groups at 24 months: 76.8% of investigational patients and 73.6% of control patients. Overall, the median return-to-work intervals were significantly different (Wilcoxon test, $P = 0.015$): 48 days for investigational patients and 61 days for the control group.

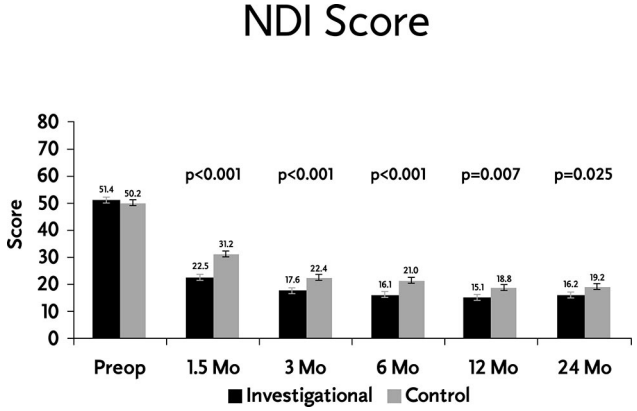

Figure 3. Comparison of mean neck disability index scores between investigational and control groups. *P* values are from analysis of covariance, with patient's preoperative score as a covariate. One-sided *P* values are reported.

Adverse Events

Serious adverse events, WHO grade 3 or 4, during the 2-year follow-up period occurred in 31.0% of investigational patients and 27.6% of control patients. Most were related to general medical conditions and unrelated to the surgical procedure, implant, or cervical spine disease. The percentages of patients experiencing any type of adverse event determined to be either implant-associated or implant/surgical procedure-related were 2.9 and 5.4 for the investigational and control groups, respectively. More importantly, only 1.7% of the investigational and 3.2% of the control patients were determined to have experienced either implant-related or implant/surgical-procedure-related serious adverse events. The differences in all of these adverse events between groups were not statistically significant.

Secondary Surgical Procedures

Within the 24-month duration of follow-ups, secondary surgical procedures at the treated level were performed in 2.5% of investigational patients (1 revision, 3 removals, and 2 reoperations) and in 3.6% of the control patients (3 removals, 1 reoperation, and 4 supplemental fixations). These rates were low in both groups and the difference was not statistically significant.

Radiographic Outcome Measures

The mean preoperative range of motion was 6.5° for the investigational group and 8.4° for the control group. At 2 years after surgery, range of motion was 8.1° ± 4.8° in the investigational group. Fusion was successful in 94.3% of control patients.

Overall Success

At 24 months, overall success was achieved in 82.6% (95% CI: 77.1%–87.3%) of the patients in the investigational group and 72.7% (95% CI: 65.8%–78.8%) in the control group (Table 2 and Figure 5). This difference of 9.9% (95% CI: 2.0%–17.9%) was statistically signif-

Table 2. Neck Disability Index, Neurologic, and Overall Success at 24 Months

Period	Investigational Group (n = 242)*	Control Group (n = 221)*	*P*	
			Noninferiority† (δ = 10%)	Superiority‡
Neck disability index success ([mtequ]15-point improvement from preoperative)				
Success	197 (86.0)	153 (78.9)	<0.001	0.035
Failure	32 (14.0)	41 (21.1)		
Neurological success (maintenance or improvement from preoperative)				
Success	215 (93.9)	175 (90.2)	<0.001	0.111
Failure	14 (6.1)	19 (9.8)		
Overall success				
Success	190 (82.6)	141 (72.7)	<0.001	0.010
Failure	40 (17.4)	53 (27.3)		

*Results are based on no. of patients observed at follow-up.
†Noninferiority *P* were calculated by *z*-test.
‡One-sided superiority *P* were obtained by Fisher exact test.

icant ($P = 0.010$). A similar difference was noted at the 12-month follow-up interval ($P = 0.004$).

Discussion

Anterior discectomy and fusion has been clinically successful with high patient satisfaction rates for decades. Therefore, it serves as a rigorous benchmark for comparison. Cervical disc replacement after anterior neurologic decompression may be an alternative to fusion in selected patients. In this randomized, controlled study, we compared clinical outcomes of similar groups of patients treated with 1 of these 2 treatment methods—either single-level ACDF or artificial cervical disc implantation. Despite being designed and powered as a noninferiority study, the results demonstrate significantly better improvements in overall success and some other key clinical endpoints in arthroplasty patients at 24-months follow-up.

To evaluate the safety and efficacy of a new surgical treatment, the study design employed a rigorous and appropriate control group. ACDF is the most prevalent surgical procedure in use today for these patients.

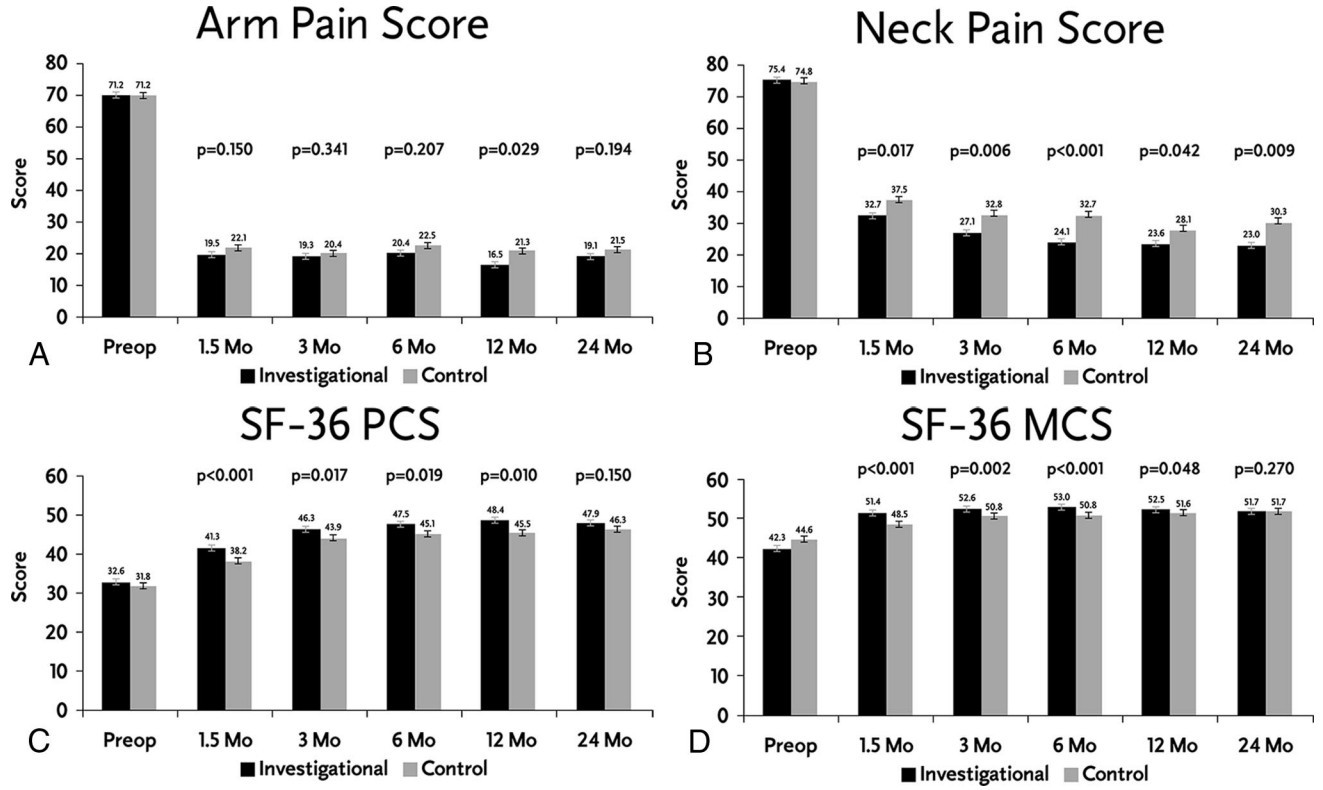

Figure 4. Comparison of outcomes between investigational and control groups. (**A,**) Comparison of mean arm pain scores between investigational and control groups. (**B,**) Comparison of mean neck pain scores between investigational and control groups. (**C,**) Comparison of mean SF-36 Physical Component Summary scores between investigational and control groups. (**D,**) Comparison of mean SF-36 Mental Component Summary scores between investigational and control groups. *P* values are from analysis of covariance, with patient's preoperative score as a covariate. One-sided *P* values are reported.

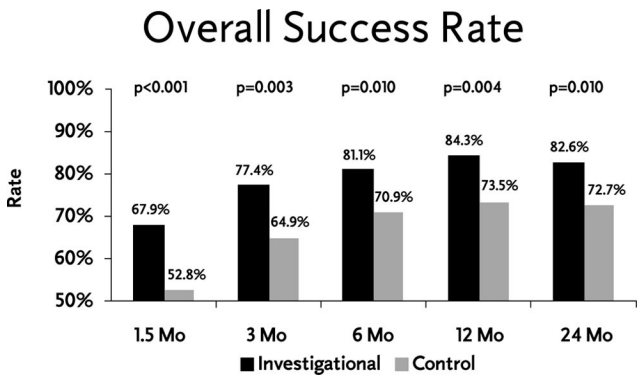

Figure 5. Comparison of overall success rates between the investigational and control groups. *P* values are from Fisher exact test. One-sided *P* values are reported.

Patients offered enrollment were all candidates for surgery because of the severity and persistence of their signs and symptoms and failure of nonoperative therapy for a minimum of 6 weeks. In fact, an unintended benefit of this and other clinical trials of similar technologies provides an unprecedented examination of the benefits of ACDF.

The degree of clinical improvement in both study groups compares favorably with the results of the nonrandomized European clinical trial of the BRYAN Cervical Disc.[7] Because the NDI was not used in the European clinical trial, the only comparable measure of patient outcomes is SF-36 scores. The SF-36 results are consistent with improvements in function as measured by the NDI and pain scale. In addition, significant improvement in the mental health scores most likely reflected a decrease in pain and return to social function. Interestingly, the improvements in both the investigational and control treatment groups, as measured by the SF-36, are greater than or equal to those seen after total hip and knee arthroplasty. Puschak *et al*[13] conducted a meta-analysis of SF-36 outcomes in patients undergoing extremity arthroplasty, comparing the results with those in our cervical arthroplasty patients. In a paper presented at the Spine Arthroplasty Society (May 2007), they reported significantly greater improvement in the SF-36 physical and mental component scores of the cervical arthroplasty patients than in the hip or knee arthroplasty patients. The rate of adverse events was similar to or better than that in the arthroplasty patients in the European study. The only patient with a perioperative spinal cord injury was in the control group. Secondary surgery rates were also similar or less frequent in the investigational group. As with any other mobile prosthesis, long-term follow-up will be needed to determine if wear effects on the bearing surfaces or other issues will result in late failure.

Arthroplasty patients returned to work 13 days earlier than fusion patients. This difference was significant for the arthroplasty group. Obviously, the primary determinant of this was the surgeon's discretion. However, despite the earlier return, there were no increases in adverse events, suggesting that shortening the interval does not pose a risk to patients. Although it remains to be determined if a similar shortening for the fusion patients is possible, ACDF is a procedure with a long history and a well established record. It may be unlikely for surgeons to change their patients' return-to-work intervals, knowing that some may have adverse events associated with physical activity. We, therefore, believe that the data demonstrate the safety of an earlier return-to-work date for arthroplasty patients. This observation may be of importance to patients, employers, and public health policy makers.

Independent radiographic interpretations identified a bone graft nonunion rate of approximately 6% among the control group patients at 24 months after surgery. Range of motion in arthroplasty patients increased slightly throughout the study period. This finding compares favorably with the results reported by others.[14–17] No spontaneous fusions were identified in the investigational patients during the 24-month follow-up duration of the study. Range-of-motion values measured radiographically can be influenced by the patient's motivation, radiographic techniques, or unknown factors. Neck pain or stiffness or anxiety with no anatomic or mechanical cause can influence radiographic measurements. The measurement technique itself is also subject to variation. Thus, one must recognize that a small range-of-motion value does not always indicate mechanical inability of the device to move or a spontaneous fusion. Because of these influences, a patient may show differing values at different follow-up evaluations. In our study, 7% to 8% of patients had range-of-motion values of 2° or less at each follow-up interval; however, none had a value of 2° or less at all examinations. The reason for a lower rate of spontaneous fusions in our study compared with the European study may be that investigational patients were prescribed nonsteroidal anti-inflammatory medication for 2 weeks after surgery. Also, unlike the European study of Goffin *et al*[7] that reported 11% of single-level arthroplasty patients had less than 2° of motion at 1 year, we excluded patients with significant spondylosis who may have a greater likelihood of spontaneous fusions.

The as-treated analysis was defined *a priori* as the primary analysis because the study was designed primarily as a noninferiority trial, for which an intent-to-treat analysis is not usually considered a conservative approach, as compared with a superiority trial. As shown in Figure 2, there were 12 patients in this study who were randomly assigned to the investigational group but received the control treatment instead because of anatomic and technique difficulties during the surgeries. Such cases included 4 patients who were found intraoperatively to have a disc space smaller than the smallest available Bryan implant size. There were 5 patients in whom we were unable to obtain the required intraoperative radiographic visibility at the C6–C7 level thus preventing safe implant placement. There was also a patient who was

randomized to the control group, but mistakenly received the investigational treatment.

We performed a form of intent-to-treat analysis for the primary study endpoint (overall success) where these patients were grouped according to the original randomization. The intent-to-treat analysis showed that the overall success rate was 82.2% (95% CI; 76.7%–86.8%) in the investigational group and 72.7% (95% CI; 65.6%–79.0%) in the control group. The difference of 9.5% (95% CI; 1.4%–17.5%) was statistically significant ($P = 0.014$). These results are very similar to those from the primary analysis. It indicates the robustness of the study conclusions.

This randomized clinical trial of a surgical device is not without other potential weaknesses. An important weakness of the study was the unexpected problem that 117 patients were randomly assigned but declined participation in the study before receiving the assigned treatment. Thirty-seven of these patients would have received the investigational treatment and 80 were potential control patients. One of the main reasons for the dropouts was dissatisfaction with the randomization, with 32 patients in the control group, as compared with 0 in the investigational group, which contributed to the disparity between the groups. In retrospect, the authors recommend when performing randomized controlled studies where patient risk and approach are similar, that randomization occur at the time of surgery. This method was successfully employed in subsequent artificial cervical disc trials, such as the ProDisc-C study,[18] and in our opinion, does not violate ethical concerns.

It is difficult to assess whether the dropouts before surgery potentially incurred biases in this study. Statistical comparisons for demographic and baseline measurements, however, were performed to compare the patients who dropped out before surgery with those who did receive study treatments. We found that the patients who did not undergo their surgery in the study seemed similar to those who underwent surgery in the study.

In summary, in this prospective, randomized clinical trial comparing the results of disc replacement using a Bryan cervical disc with those of fusion in the treatment of single-level disc herniations causing radiculopathy or myelopathy, the composite overall success, and some other patient-reported outcome measures indicated that the Bryan cervical disc treatment achieved statistically superior results. In addition, the investigational group returned to work sooner. Thus, the authors believe that the current investigation provides high-level quality of evidence supporting the safety and effectiveness of the Bryan cervical disc prosthesis at 2 years of follow-up.

■ Key Points

- The investigational group patients treated with the artificial disc had a statistically superior improvement in NDI scores than the control group.
- Investigational group patients had a significantly higher rate of overall success.
- Arthroplasty patients returned to work 13 days earlier than fusion patients.

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