Comparison of Single-Level Cervical Fusion and a Metal-on-Metal Cervical Disc Replacement Device

Joseph Riina, MD, Amisha Patel, MS, ATC, LAT, John W. Dietz, MD, Jeffrey S. Hoskins, MD, Terry R. Trammell, MD, and David G. Schwartz, MD

Abstract

Cervical fusion is the common treatment for cervical disc disease but can cause secondary disorders. The Prestige ST cervical disc prosthesis (Medtronic Sofamor Danek, Memphis, TN) was designed to preserve spinal motion to potentially limit the secondary disorders.

In this article, we report 2-year results from a single-center study comparing use of this device with use of anterior cervical discectomy and fusion (ACDF). Nineteen patients were prospectively randomized to receive the device or to undergo ACDF. Twenty-four months after surgery, patients who received the device demonstrated improvement in neck pain, arm pain, and neurologic function. In our cohort, patients who underwent arthroplasty demonstrated greater improvement in neurologic function and neck pain than patients who underwent cervical discectomy and fusion.

Treatment of spinal degenerative disease has long been based on the idea that limiting motion of a pain-producing segment will limit the pain generated by that segment. This concept formed the prevailing philosophy of treatment of degenerative disease of the hip, knee, and shoulder as well, until the advent of total joint arthroplasty. The success of these procedures in treating pain while maintaining motion[1,2] has led investigators to attempt motion-preserving procedures on the spine while removing the pain generator. Recent investigations of treatments based on these principles have been conducted, and results with the lumbar disc prosthesis have been good.[3,4]

Dr. Riina is Orthopaedic Spine Surgeon, Ms. Patel is Research Coordinator, and Dr. Dietz is Orthopaedic Spine Surgeon, Department of Spine Surgery, Indiana Orthopaedic Hospital, Indianapolis, Indiana.

Dr. Hoskins is Orthopaedic Spine Surgeon, Department of Spine Surgery, Orthopaedic Institute of Dayton, Dayton, Ohio.

Dr. Trammell is Orthopaedic Spine Surgeon, and Dr. Schwartz is Orthopaedic Spine Surgeon, Department of Spine Surgery, Indiana Orthopaedic Hospital, Indianapolis, Indiana.

Address correspondence to: Joseph Riina, MD, 8450 Northwest Blvd, Indianapolis, IN 46278 (tel, 317-802-2000; fax, 317-884-5363; e-mail, j.riina@orthoindy.com).

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Like the treatment of lumbar disorders with back pain, fusion using a variety of methods has been the mainstay of treatment for cervical disc disease.[5] Unlike the lumbar spine, however, cervical disc herniation resulting in radicular symptoms is most commonly treated with discectomy and fusion,[1] whereas in the lumbar spine removal of the offending disc fragment generally is curative.

The treatment goal for cervical degenerative disc disease is to decompress the neural structures and to restore normal alignment and disc space height.[6] In the cervical spine, anterior cervical discectomy and fusion (ACDF) has been the standard treatment for degenerative disc disease. Cervical fusion has been proved to increase motion at the adjacent levels of the cervical spine, causing stress and load and an increase in intradisc pressure to the adjacent levels of the fused site.[7,8] These added stresses have been hypothesized to lead to secondary disorders, such as adjacent segment degeneration and pseudarthrosis.[1,8-13] In addition, these stresses may result in accelerated disc degeneration and create mechanical instability in the levels adjacent to the fusion.[14] Previous studies have shown that patients who underwent ACDF then developed adjacent segment disease at a constant rate of 2.9% annually.[7] As a result, a more physiologic procedure that limits these complications by preserving or potentially restoring motion is indicated.

Cervical arthroplasty was designed to achieve these goals. In addition, cervical arthroplasty is performed in an attempt to prevent abnormal stresses from arising after anterior cervical fusion.[14] These issues were the basis for the development of a cervical disc prosthesis that has been evaluated in the United States.

In this article, we report 2-year results from a single-center study comparing use of this device with use of ACDF in the treatment of symptomatic cervical disc disease.

Materials and Methods

Study Design

After we obtained approval from the US Food and Drug Administration and the institutional review board at our center, patients consented to be part of the study. They completed screening forms (Pain Scale, Neck Disability Index [NDI]) so we could determine their eligibility. The screening forms were evaluated by the enrolling physician. Initial selection criteria included patients with cervical disc

Figure 1. The Prestige ST cervical disc prosthesis (Medtronic Sofamor Danek, Memphis, Tenn), a dynamic stainless steel device, is inserted into the intervertebral disc space. The disc allows segmental spinal motion through a ball-and-trough mechanism and maintains disc space height. Image provided by Medtronic.

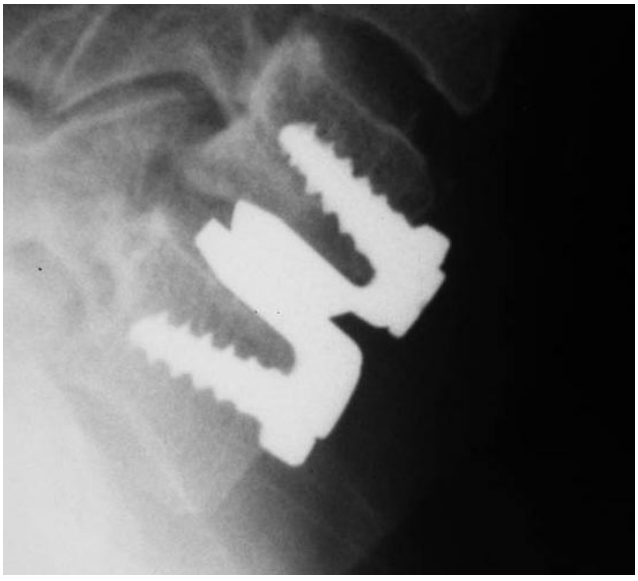

Figure 2. Lateral x-ray of patient who had the motor vehicle accident (MVA) after surgery. Image provided by Medtronic.

disease (defined as intractable radiculopathy, myelopathy, or both) with at least one of the following conditions producing symptomatic nerve root or spinal cord compression (or both) documented by patient history (ie, neck or arm pain, functional deficit, or neurologic deficit) and by radiographic studies (herniated disc or osteophyte formation). Patients who had C3–C4 to C6–C7 disc involvement at only a single level and whose disease did not improve after 6 weeks of nonoperative treatment or who had progressive signs of spine or nerve root compression were then considered eligible for the study. Additional criteria included being at least 18 years old, having had a preoperative NDI score of 30 or more, not being pregnant, and being willing to adhere to the study plan and sign the informed-consent form. Patients were instructed to return for follow-up 6 weeks after surgery and then at 6 months, 12 months, and 24 months. A minimum of 6 months follow-up was required to be included in this study, and all patients completed the 24-month follow-up. Exclusion criteria are listed in Table I. Patients who met all the selection criteria and consented to the study were randomly assigned to receive the artificial cervical disc or undergo ACDF.

Device Description

The Prestige ST cervical disc prosthesis (Figure 1), manufactured by Medtronic Sofamor Danek (Memphis, TN) and approved by the US Food and Drug Administration on July 16, 2007, is a dynamic stainless steel device that is inserted into the intervertebral disc space. Consisting of 2 metal plates that interface through a ball-and-trough mechanism, the device permits segmental spinal motion and maintains disc space height. The anterior surfaces of the device are affixed to the vertebral bodies by 4 bone screws held in place by 2 locking screws (Figure 1).

The Atlantis anterior plate, also manufactured by Medtronic Sofamor Danek, is a titanium alloy implant that is fixed to the vertebral bodies with either fixed- or variable-angle cancellous screws. This plate, used in ACDF, provides temporary spinal stabilization while the cervical spine is being fused.

If the patient was in the fusion arm of the study, Cornerstone SR (Medtronic, Memphis, TN) cortical bone was placed and instrumented anteriorly with an Atlantis plate (Medtronic, Memphis, TN).

Surgical Technique

ACDF (Control Group). The patient was positioned supine on the operating table with the head positioned in slight extension. A standard Smith-Robinson approach to the cervical spine was used. Once the cervical spine was exposed, the longus colli muscles were retracted bilaterally. Self-retaining retractor blades were used to optimize visualization to perform the surgical procedure. The blades were placed below the longus colli muscles bilaterally. A discectomy was performed with curettes, pituitaries, kerrisons, or a high-speed burr to decompress the spinal canal. An operating microscope was used to improve visualization, and a 6-0 curette was used to decompress the spine further. The endplates were then prepared with a high-speed burr.

The cortical endplate was left intact, and the cartilage was removed. Once the endplates were parallel, the disc space was sized with a template, and an allograft spacer of an appropriate size was chosen. A bone graft holder and mallet were used to tap the bone graft into the discectomy site. Fluoroscopy was used to verify placement. Any osteophytes and soft tissue on the adjacent vertebral bodies were removed to allow the Atlantis plate to sit evenly

Table I. Exclusion Criteria

- Cervical spine condition other than symptomatic cervical disc disease requiring surgical treatment at the involved level
- Cervical instability as defined by flexion-extension x-rays showing more than 3.5 mm of sagittal plane translation or more than 20° of sagittal plane rotation
- Metabolic disease or malignant bone disease
- More than 1 cervical level requiring surgery or having a fused level adjacent to the level being treated
- Any previous surgical intervention at the involved level
- Previously diagnosed with osteopenia or osteomalacia
- Postmenopausal non–African American women older than 60 and weighing less than 140 lb
- Postmenopausal women who have sustained a nontraumatic hip, spine, or wrist fracture
- Men older than 70
- Men who are older than 60 and have sustained a nontraumatic hip, spine, or wrist fracture
- Level of bone mineral density was a T score of –3.5 or a T score of –2.5 with vertebral crush fracture
- Spinal metastases
- Overt or active bacterial infection (local or systemic)
- Severe insulin-dependent diabetes, chronic or acute renal failure, or prior history of renal disease
- Fever (documented oral temperature of 101°F) at time of surgery
- Documented allergy or intolerance to stainless steel, titanium, or a titanium alloy
- Mentally incompetent patients, prisoners, pregnant women, alcohol and/or drug abusers, or recipient of drugs that may interfere with bone metabolism within 2 weeks before the planned date of spinal surgery (except routine perioperative anti-inflammatory drugs)
- History of endocrine or metabolic disorder known to affect osteogenesis or condition requiring postoperative medications that interfere with the stability of the implant or fusion (ie, steroids)
- Received treatment with an investigational therapy within 28 days before implantation surgery or had treatment planned for a time during the 16 weeks after artificial cervical disc implantation

Table II. Scaling System for Motor Function, Sensory Function, and Reflexes for Neurologic Status

	Description	Number Scale
Motor function	Normal (active movement, against full resistance)	9
	Active movement, against some resistance	4
	Active movement, against gravity	3
	Active movement, gravity eliminated	2
	Palpable or visible contraction	1
	Total paralysis	0
Sensory function	Normal (present)	9
	Impaired	1
	Absent	0
Reflexes	Normal and hyporeflexic	9
	Hyperreflexic (severe)	2
	Hyperreflexic (moderate)	1
	Absent or trace	0

on the anterior cortex. The anterior plate was temporarily stabilized. Then, screw holes were drilled with a bit, and screw length was determined by a depth gauge. A tap was used to tap into the vertebral bodies. The screws were placed in each screw hole, and a final tightening was done sequentially to ensure that the plate was applied evenly and firmly. All lock screws were tightened to lock the screws to the plate. The position of the graft and plate were then checked with fluoroscopic imaging, the retractors were removed, and the incision was closed.

Artificial Cervical Disc (Investigational Group). Patients in the investigational group were positioned the same way as in the control group. A transverse skin incision was made. Between the trachea and esophagus (medially) and the carotid sheath (laterally), an avascular dissection plane was created. Handheld retractors were used to expose the anterior vertebral column and longus colli muscles. The self-retaining retractor blades were placed below the longus colli muscles. A discectomy was performed at the involved level, and osteophytes were removed using pituitaries, curettes, and/or kerrisons. The spine was placed in the neutral position before endplate preparation. For this group, the endplates were prepared by a freehand technique using a Midas Rex drill (Medtronic Sofamor Danek, Forth Worth, TX) and curettes. The same endplate preparation was done for both arms of the study. Then, the disc replacement trials were used to verify the correct contour with the anterior vertebral bodies and endplates. The artificial cervical disc was held in place with the holder. Once this disc was placed in the site, the distraction was released, and the inserter was removed. Disc placement was verified with fluoroscopy. Two pairs of screws were placed in the superior and inferior aspects of the device. Locking screws were placed over each pair of screws. Final placement of the implant was verified with fluoroscopy. Range of motion was tested to ensure that the disc was functioning appropriately. The retractors were removed and the wound closed.

Postoperative Care

For both groups, a soft collar was used overnight. Patients stayed in the hospital for 23 hours and were then discharged home. After discharge, disc patients did not wear collars;

Table III. Neurologic Status[a]

Period	Variable	n (%) Investigational (N = 10) Success	Investigational (N = 10) Failure	Control (N = 9) Success	Control (N = 9) Failure
6 months	Motor	7 (100.0)	0 (0.0)	8 (100.0)	0 (0.0)
	Sensory	7 (100.0)	0 (0.0)	8 (100.0)	0 (0.0)
	Reflexes	7 (100.0)	0 (0.0)	8 (100.0)	0 (0.0)
	Overall	7 (100.0)	0 (0.0)	8 (100.0)	0 (0.0)
12 months	Motor	9 (100.0)	0 (0.0)	7 (100.0)	0 (0.0)
	Sensory	8 (88.9)	1 (11.1)	6 (85.7)	1 (14.3)
	Reflexes	9 (100.0)	0 (0.0)	6 (85.7)	1 (14.3)
	Overall	8 (88.9)	1 (11.1)	5 (71.4)	2 (28.6)
24 months	Motor	9 (100.0)	0 (0.0)	7 (100.0)	0 (0.0)
	Sensory	7 (77.8)	2 (22.2)	6 (85.7)	1 (14.3)
	Reflexes	8 (88.9)	1 (11.1)	6 (85.7)	1 (14.3)
	Overall	7 (77.8)	2 (22.2)	5 (71.4)	2 (28.6)

[a]Success for each component was defined as maintenance or improvement from before surgery for all elements and success for overall neurologic status: all successes of the 3 components.

Table IV. SF-36 Scores for Investigational (I) and Control (C) Groups

Variable	Mean (SD) Preoperative I (n = 10)	Preoperative C (n = 9)	12 Months I (n = 9)	12 Months C (n = 6)	24 Months I (n = 9)	24 Months C (n = 7)	Change From Preoperative I (n = 9)	Change From Preoperative C (n = 7)
Physical Component Summary	28.5 (8.1)	25.9 (4.2)	42.2 (12.4)	40.2 (10.3)	40.6 (13.8)	44.3 (11.5)	12.6 (15.9)	17.4 (13.1)
Mental Component Summary	40.1 (14.7)	45.0 (11.8)	50.3 (15.2)	52.3 (5.5)	51.1 (12.6)	46.0 (7.1)	12.0 (15.1)	2.4 (9.7)
Physical Function	38.0 (26.9)	37.4 (15.7)	69.4 (26.3)	73.3 (26.2)	67.2 (36.1)	75.7 (34.0)	32.8 (45.6)	35.0 (34.2)
Role-Physical	11.1 (31.6)	0.0 (0.0)	47.2 (50.7)	50.0 (35.4)	52.8 (47.5)	50.0 (43.3)	41.7 (58.6)	50.0 (43.3)
Pain Index	18.4 (13.7)	18.1 (12.7)	62.8 (27.3)	46.2 (28.8)	58.3 (22.9)	59.9 (31.1)	42.4 (22.9)	42.9 (33.5)
General Health Perception	58.6 (22.1)	66.6 (18.9)	68.2 (23.7)	70.8 (18.4)	63.0 (24.3)	70.3 (19.8)	5.9 (19.7)	2.4 (22.6)
Social Function	36.3 (24.6)	26.4 (22.9)	73.6 (33.3)	75.0 (13.7)	76.4 (24.6)	67.9 (18.9)	41.7 (28.6)	41.1 (28.6)
Mental Health	53.2 (26.3)	63.1 (18.4)	72.4 (26.7)	76.0 (13.1)	74.2 (24.2)	75.4 (13.4)	22.7 (28.4)	14.3 (15.1)
Role-Emotional	53.3 (50.2)	74.1 (43.4)	74.1 (43.4)	83.3 (18.3)	77.8 (37.3)	52.4 (42.4)	29.6 (42.3)	–19.0 (42.4)
Vitality	22.0 (14.4)	24.4 (11.8)	58.9 (16.9)	55.0 (24.3)	52.8 (22.8)	50.7 (24.4)	31.7 (29.9)	28.6 (27.6)

ACDF patients were allowed to wear collars for comfort only. Disc patients were given a nonsteroidal anti-inflammatory drug to use after surgery, as per study protocol.

Outcome Instruments

Patients completed the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) to document their general health status before surgery and 6 months, 12 months, and 24 months after surgery. SF-36 has a Physical Component Summary (PCS) and a Mental Component Summary (MCS). In this study, success as measured with the SF-36 was defined as postoperative maintenance or improvement in status in comparison with preoperative status. Frequency and intensity of neck and arm pain were measured on a visual analog scale.[15] A numerical rating scale was used to assess arm pain frequency and intensity.[15] The NDI questionnaire was used to measure cervical pain and disability associated with activities of daily living.[15] Neck pain scores, arm pain scores, and NDI scores were obtained 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. Success for neck pain and arm pain was described as preoperative score – postoperative score ≥ 0. Success as measured with the NDI was described as preoperative score – postoperative score ≥ 15.

Another outcome component, neurologic status, was based on 3 parameters: motor function, sensory function, and reflexes. A score for each parameter was calculated (Table II). Preoperative values were compared with values obtained 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. Neurologic outcome was determined to be successful if postoperative score – preoperative score ≥ 0. Overall success requires success in each of the 3 individual parameters: motor function, sensory function, and reflexes. Failure in any of these was considered an overall failure in neurologic outcome. Success in each category (motor, sensory, reflex) was defined as maintenance or improvement in each element.

The foraminal compression test (reproducing pain) was performed before surgery and 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. If application of an axial load on the patient's head produced pain, the test was positive; if pain was not produced, the test was negative.

Patient satisfaction questionnaires were administered 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. A Likert scale was used for the 3 questions.

Success for patient satisfaction was defined as a response of *definitely true* or *mostly true*. All patients were asked one question to address the perceived effect of their surgical treatment. Success was defined as a response of *completely recovered, much improved,* or *slightly improved*.

X-Rays

Anteroposterior, lateral, flexion, and extension views were used to determine radiographic success. These x-rays were taken before surgery and at all postoperative visits (Figure 2).

For the investigational group, radiographic success or maintenance of motion was defined as (1) more than 4° of angular motion based on lateral flexion-extension films, (2) without evidence of bridging trabecular bone forming a continuous bony connection with the vertebral bodies while (3) maintaining at least the same disc height after surgery as before surgery, as measured by the linear distance from the inferior endplate of the level above to the superior endplate of the level below at the level of the posterior vertebral body cortex, accounting for differences in magnification. Overall height of the implant was also measured to determine if any wear could be calculated from the initial postoperative films to the most recent postoperative films.

For the control group (ACDF patients), radiographic success was defined as fusion based on bridging trabecular bone at 6, 12, or 24 months after surgery with up to 4° of angular motion based on lateral flexion-extension x-rays, plus no evidence of radiolucency covering more than 50% of the superior or inferior surface of the graft.

Statistical Analysis

The demographic data recorded were age, height, weight, sex, race, marital status, educational level, worker compensation status, spinal litigation, tobacco use, alcohol use, and preoperative work status. Analyses of variance (ANOVA) were performed to determine *P*s. The Fisher exact test was used for categorical variables.

Neck pain scores, arm pain scores, and NDI scores used *P*s (from paired *t* tests) for change from preoperative in each group. Overall success was defined as meeting 5 criteria: (1) postoperative NDI score improvement of at least 15 points, (2) maintenance or improvement in neurologic status, (3) disc height success, (4) no serious adverse event classified as implant-associated or implant/surgical procedure-associated, and (5) no additional surgical procedure.

Results

Subjects

Nineteen patients (10 disc patients, 9 ACDF patients) enrolled in the study. For the investigational (disc) patients (2 males, 8 females), mean age was 40.8 years (SD, 8.8 years), mean height was 66.9 in (SD, 3.2 in), and mean weight was 184.4 lb (SD, 47.0 lb); 5 (50%) of these patients were smokers and used alcohol. For the control (ACDF) patients (3 males, 6 females), mean age was 38.1 years (SD, 4.9 years), mean height was 66.9 in (SD, 4.2 in), and mean weight was 171.4 lb (SD, 49.0 lb); 4 (44.4%) of these patients were smokers and used alcohol.

For this study, a minimum of 6 months of follow-up was required for inclusion in the results. One patient from each group did not come to the 6-month postoperative visit (1 moved out of state, 1 was incarcerated). In addition, 1 ACDF patient subsequently underwent fusion at an adjacent level. For the remaining 16 patients (9 disc patients, 7 ACDF patients), outcome measures were performed. $P<.05$ was considered significant.

Surgical Information

In the investigational group, 5 patients (50%) were treated at C5–C6, and 5 were treated at C6–C7. In the control group, 1 patient (11.1%) was treated at C4–C5, 5 (55.6%) were treated at C5–C6, and 3 (33.3%) were treated at C6–C7. Mean operative time was longer for the investigational group (2.0 hours; SD, 0.4 hour) than for the control group (1.6 hours; SD, 0.4 hour). For both groups, hospital stay was approximately 23 hours. Group differences in blood loss and operative time were not statistically significant.

Neck Pain

Before surgery, mean neck pain score was higher for the investigational group (74.8; SD, 19.4; n = 10) than for the control group (71.6; SD, 26.0; n = 9). Two years after surgery, mean neck pain score dropped to 17.9 (SD, 24.1) for the investigational group (n = 9) and 17.4 (SD, 22.1) for the control group (n = 7). The preoperative–postoperative difference in scores was 2.7 points larger for the investigational group than for the control group. Both groups had 100% neck pain success rate (preoperative score – postoperative score ≥ 0).

Arm Pain

Before surgery, mean arm pain score was lower for the investigational group (69.1; SD, 26.29) than for the control group (72.7; SD, 24.7). Two years after surgery, mean arm pain score dropped to 17.2 (SD, 23.1) for the investigational group and 8.6 (SD, 14.6) for the control group. The preoperative–postoperative difference in scores was 12.2 points smaller for the investigational group than for the control group. The investigational group had a 77.8% success rate, and the control group had a 100% success rate (preoperative score – postoperative score ≥ 0).

Neck Disability Index

Before surgery, mean NDI score was lower for the investigational group (65.6; SD, 11.7) than for the control group (60.2; SD, 11.7). Two years after surgery, mean NDI score dropped to 18.9 (SD, 16.8) for the investigational group and 22.3 (SD, 13.5) for the control group. The preoperative–postoperative difference in scores was 8.8 points larger for the investigational group than for the control group. The investigational group had a 100% success rate, and the control group had an 85.7% success rate (preoperative score – postoperative score ≥ 15).

Neurologic Status

Two years after surgery, success rates for the investigational group (n = 7) were 100% for motor function and reflexes and 77.8% for sensory function and overall; success rates for the control group (n = 5) were 100% for motor function, 85.7% for sensory function and reflexes, and 71.4% overall. This information is summarized in Table III.

Foraminal Compression Test

Two years after surgery, all patients in the investigational group had a negative foraminal compression test; only 1 patient (14.3%) in the control group had a positive test.

Radiographic Success Rates

For the investigational group, overall radiographic success rates were 77.8% (n = 7) 1 year after surgery and 87.5% (n = 7) 2 years after surgery. No patient had any signs of bridging bone. Seven patients (87.5%) had more than 4° and less than 20° of angular motion. For the control group, the success rate was 100% both 1 and 2 years after surgery.

Functional Spinal Unit Success Rate

Success was defined as anterior or posterior (postoperative score – 6-week score ≥ –2.) For the investigational and control groups, the success rate was 100% both 1 and 2 years after surgery.

Summary of SF-36 Success Rates

The SF-36 success rate was defined as postoperative score – preoperative score ≥ 0. At 24 months, PCS success rates were 77.8% for the investigational group (n = 7) and 100% for the control group (n = 7), and MCS success rates were 66.7% for the investigational group (n = 6) and 57.1% for the control group (n = 4). The groups' Physical Function success rates were similar: 88.9% for investigational (n = 8) and 85.7% for control (n = 1). The control group's Role-Physical success rate (100%) was higher than that of the investigational group. Table IV lists the SF-36 scores for the investigational and control groups.

Patient Satisfaction

Twenty-four months after surgery, all patients in the investigational group were satisfied with the results of their surgery, 88.9% believed the surgery helped as much as they thought it would, and 100% indicated they would have the surgery again for the same condition. Of the patients in the control group, 85.7% were satisfied with the results of their surgery and indicated they would consider having the surgery again for the same condition.

Patient's Perceived Effect of Surgical Treatment

Twenty-four months after surgery, 33.3% of patients in the investigational group felt *completely recovered,* and 66.7% felt *much improved*. Similarly, 28.6% of patients in the control group felt *completely recovered,* and 71.4% felt *much improved*.

Discussion

Cervical discectomy plus fusion has been the mainstay of treatment for cervical spine degenerative disease resulting in radicular symptoms, myelopathic symptoms, or both. An anterior approach with bone graft is the current standard for achieving fusion. Complications arising from this treatment, primarily adjacent segment degeneration, have led investigators to experiment with motion-preserving technology, specifically disc replacement. Although the long-term success of replacement devices in preventing adjacent segment degeneration is hypothetical, several ongoing studies, including those involving the cervical disc prosthesis, are attempting to address this issue.

For an artificial disc to be successful, it should have natural spinal kinematics and be able to maintain biomechanical parameters and pressures at the treated level and entire spine.[13,14] In addition, when the disc is inserted, the procedure should be safe and uncomplicated and should not add a lot more time to the surgery as compared with anterior fusion.[14] Clinical success of the artificial disc should produce outcomes as good as, if not better than, those already achieved with ACDF with or without plating.[6] Complications of artificial cervical discs include inadequate disc placement, implant failure, and joint subluxation.[14]

Surgical Outcomes

Artificial cervical discs with a ball-and-trough design, like the Prestige ST disc, provide a physiologic motion at the center of the ball.[13] The artificial disc must be accurately placed in the intervertebral disc space to avoid exposing the facet joints and ligaments to additional abnormal stresses.[13] Spinal arthroplasty has been shown to increase facet pain when the artificial disc presents with abnormal shifting of the center of rotation.[13]

According to our results, blood loss and operative time were similar in the investigational and control groups (group differences were not statistically significant). In addition, both groups did not have any serious adverse events related to the implant or surgery.

Clinical Outcomes

Two years after surgery, 100% of investigational patients but only 85.7% of control patients were satisfied with the results of their surgery. The artificial disc showed no wear on x-rays and no signs of implant instability.

Previous investigators found that, compared with ACDF patients, artificial disc patients had larger NDI, SF-36, neck pain, and arm pain changes from before surgery to 24 months after surgery.[15] Our SF-36 results were different. At 24 months, our disc patients had larger changes in neck pain, more improvement in neurologic function, and significant improvement in arm pain, though ACDF patients had larger changes in arm pain (relieved or diminished arm pain). Group differences were not statistically significant. According to our inclusion criteria, patients had to have both neck pain and arm pain; those presenting with neck pain alone or arm pain alone were excluded. Given our

small cohort, disc patients' results were at least equivalent to those of ACDF patients for the treatment of neck pain, arm pain, and neurologic function.

Our disc patients' having more arm pain 24 months after surgery may have resulted from some surgeons' not removing osteophytes bilaterally. As some surgeons would, they treated the osteophytes as in a cervical fusion procedure, in which removal is not always required. In arthroplasty procedures, however, osteophyte removal is required because of continued nerve irritation.

Overall, disc patients had larger changes in MCS scores, including General Health Perception, Social Function, Mental Health, Role-Emotional, and Vitality scores. ACDF patients had larger changes in PCS scores, including Physical Function and Role-Physical scores. The groups had equal changes in Pain Index scores.

Duggal and colleagues[14] indicated that spinal arthroplasty may be suitable for patients who present with increased risk for adjacent segment disease, that these patients would present asymptomatic spondylotic changes at the adjacent levels or other spinal levels, and that there is little evidence that spinal arthroplasty is beneficial when the chief symptom is neck pain. However, results from our single-center study showed that neck pain improved more for disc patients than for ACDF patients.

Radiographic Outcomes

According to previous studies, the high success rates of single-level discectomy and fusion with and without plating vary from 76% to 100%.[6] Our ACDF group achieved a 100% fusion rate. ACDFs have been shown to increase the motion at the adjacent segment to the level fused, which can accelerate disc degeneration.[16] The resulting increased motion has been found to cause conditions such as disc herniations, instability, spinal stenosis, spondylosis, and facet joint arthritis.[16]

Although determination of motion across artificial discs is objective (flexion-extension x-rays), results nevertheless rely heavily on patients' cooperating while being x-rayed.[13] Other factors influencing accuracy of plain films are patient discomfort, lack of effort, out-of-plane motion, and imaging technique.[13] Flexion and extension x-rays have been reported to have poor reliability, and quantitative accuracy is limited. All these factors influence the accuracy of motion calculations.[13] Additional care should be taken to ensure that patient positioning, instructions, and patient movement are consistent from patient to patient and from visit to visit.

Study Limitations

Our study was limited to results from a single center that was part of a multicenter prospective randomized clinical trial. Results from the multicenter trial will be published later to update the medical community on the outcomes of artificial disc versus ACDF (the current gold standard) in the treatment of cervical disc degeneration. A second limitation of the study is that patients randomized to the control group may have felt that the technology they received was inferior to what the investigational patients received, and this feeling may have affected their SF-36 results.

Conclusions

We found that neurologic function and neck pain were better addressed with the artificial cervical disc, but arm pain was better addressed with ACDF. Patients in both groups improved over their initial complaints. The disc performed at least as well as ACDF, according to our single-center results. Both groups were successful, according to the criteria set forth in the study to determine overall success.

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References

1. Cummins BH, Robertson JT, Gill SS. Surgical experience with an implanted artificial cervical joint. *J Neurosurg.* 1998;88(6):943-948.
2. Delamarter RB, Fribourg DM, Kanim LE, Bae H. ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. *Spine*. 2003;28(20):S167-S175.
3. Bao QB, McCullen GM, Higham PA, Dumbleton JH, Yuan HA. The artificial disc: theory, design and materials. *Biomaterials.* 1996;17(12):1157-1167.
4. Zigler JE. Clinical results with ProDisc: European experience and U.S. investigation device exemption study. *Spine* 2003;28(20):S163-S166.
5. Wigfield CC, Gill SS, Nelson RJ, Metcalf NH, Robertson JT. The new Frenchay artificial cervical joint: results from a two-year pilot study. *Spine*. 2002;27(22):2446-2452.
6. Hermann AM. Geometric results of anterior cervical plate stabilization in degenerative disease. *Spine.* 2004;29(11):1226-1234.
7. Robertson JT, Papadopoulos SM, Traynelis VC. Assessment of adjacent-segment disease in patients treated with cervical fusion or arthroplasty: a prospective 2-year study. *J Neurosurg Spine*. 2005;3(6):417-423.
8. Reitman CA, Hipp JA, Nguyen L, Esses SI. Changes in segmental intervertebral motion adjacent to cervical arthrodesis: a prospective study. *Spine.* 2004;29(11):E221-E226.
9. Eck JC, Humphreys SC, Lim T-H, et al. Biomechanical study on the effect of cervical spine fusion on adjacent-level intradiscal pressure and segmental motion. *Spine.* 2002;27(22):2431-2434.
10. Hilibrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg Am.* 1999;81(4):519-528.
11. Wigfield C, Gill S, Nelson R, Langdon I, Metcalf N, Robertson J. Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. *J Neurosurg (Spine).* 2002;96(1 suppl):17-21.
12. Yue WM, Brodner W, Highland TR. Long-term results after anterior cervical discectomy and fusion with allograft and plating: a 5- to 11-year radiologic and clinical follow-up study. *Spine*. 2005;30(19):2138-2144.
13. Pickett GE, Rouleau JP, Duggal N. Kinematic analysis of the cervical spine following implantation of an artificial cervical disc. *Spine*. 2005;30(17):1949-1954.
14. Duggal N, Pickett GE, Mitsis DK, Keller JL. Early clinical and biomechanical results following cervical arthroplasty. *Neurosurg Focus*. 2004;17(3):E9.
15. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus*. 2004;17(3):E6.
16. Schwab JS, Diangelo DJ, Foley KT. Motion compensation associated with single-level cervical fusion: where does the lost motion go? *Spine*. 2006;31(21):2439-2448.