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Cervical motion segment replacement

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Introduction

Factors that qualify a degenerative disc process, including herniated nucleus pulposus (HNP), as a disease as opposed to a normal aging process include the age at which the degenerative disease process presents itself and the rate at which it progresses relative to the general population.

Once initiated, degenerative disc disease (DDD) is likely to progress at a more rapid rate than the normal de-

Abstract When symptoms bring to light a cervical spine degenerative disc process that requires surgical intervention, a symptom relieving procedure such as decompression, followed by functional restoration, arthroplasty, offers the benefit of prophylaxis of accelerated spondylosis at the operated level. In addition, by altering the biomechanical stress factors at adjacent levels, theoretically it should offer prophylactic benefit at these levels as well. The design requirements for a cervical disc prosthesis, the importance of precision instrumentation, and technique are described. Mechanical testing, animal testing, the study design for the EU clinical study, and the operative technique are discussed. The clinical 1- and 2-year data to date are presented.

Keywords Cervical vertebrae · Degenerative disc disease · Herniated disc · Intervertebral disc · Joint prosthesis implantation · Spinal fusion · Spondylosis

generative disc aging process. Both the biomechanical and physiologic effects become increasingly more stressful on the component tissues of the functional spine unit (FSU). They may include: alteration in the axis of rotation, altered load sharing, loss of cushioning, hyper- or hypomobility of the FSU, and declining performance of the nutritional supply system.

Thus, the symptomatic presentation of DDD may lead to accelerated degeneration at the affected FSU and secondarily at the adjacent FSUs as well.

In time, the nature of the symptom(s), in combination with neurological impairment, may lead to surgical intervention. Surgical decompression of the neural structures usually results in symptomatic improvement in 6–12 weeks. In the cervical spine an anterior approach (including surgical fusion with grafts or devices) is commonly employed to foster lordosis, maintain intervertebral body spacing, and to address and/or potentially avoid axial pain and pseudarthrosis. Fusion, however, is often performed despite no radiographic evidence of mechanical instability. The need to assess surgical fusion outcome prolongs the outcome assessment period to 12–24 months.

Recently, longer-term outcome data (5–10 years) suggests that there are significant radiographic and clinical consequences associated with fusion. Hilibrand et al. [3] identified symptomatic adjacent-segment disease occurring at an average rate of 2.9% per year during the first 10 post-fusion years for patients in their study group, with two-thirds of those patients requiring reoperation. Goffin et al. [2] identified a 92% rate of adjacent-level radiological degeneration after fusion over a mean of 8.6 years. Brumley et al. [1] identified hypermobility at segments adjacent to a fused segment.

From a surgical perspective, the benefits of an anterior approach to the cervical spine are well appreciated, and for many surgeons it has become a satisfying and successful surgery. Posterior or anterior lateral partial discectomy approaches may be alternatives to an anterior approach as a means to avoid the biomechanical consequences of fusion. Nonetheless, even with decompression alone, the long-term degenerative disease process is left unattended in favor of symptomatic relief.

When deciding upon functional reconstruction, one is selecting a concept and treatment that addresses the symptomatic degenerative disc process as a disease rather than as a symptom that is simply part of the normal aging process. In doing so, one acknowledges the importance of addressing the long-term biomechanical and natural history issues in a prophylactic manner, at both the operated as well as the adjacent FSUs.

Hypothetically, the concept of a fully functional disc prosthesis, which re-establishes more nearly normal biomechanics to the FSU, if introduced early enough in the symptomatic DDD process, should return the biomechanical natural history of the FSU from that of a disease to that of the individual's normal aging process.

Materials and methods

Design requirements

Ideally, a fully functional disc prosthesis should provide a means to re-establish motion, elasticity, and more normal load sharing and rotational axes in a minimally constrained device with immediate, short- and long-term mechanical stability and durability.

Secondly, the device design should not contain features prone to frequent revisions (e.g. screws, etc.).

Fig. 1 Bryan Cervical Disc Prosthesis



Thirdly, the device should permit future interbody fusion options, should they become necessary.

Additionally, the prosthesis system must include precision instrumentation to ensure proper localization and preparation of the prosthesis interbody site.

Finally, the design requirements must recognize the critical role of the surgeon in applying appropriate indications to patient selection, employing prophylactic medications and closely adhering to prescribed surgical technique while, through knowledge, understanding, and skill, making adjustments for the variations in anatomic and degenerative conditions encountered from patient to patient.

The device

The Bryan Cervical Disc prosthesis (see Fig. 1) contains a proprietary, low-friction, wear-resistant, unique polyurethane nucleus. The nucleus is located between, and articulates with, shaped titanium plates (shells) that include convex porous ingrowth surfaces, to allow bony fixation to the adjacent vertebral endplates. The design provides for a normal range of motion (ROM) in flexion/extension, lateral bending, rotation and translation, as well as coupled motions. While prosthesis motion is unconstrained through the normal ROM, special geometric features provide soft limits to this range. Additionally, a unique flexible membrane surrounds the interior articulating shell surfaces, to separate the internal structures of the device from the external *in vivo* environment, and to contain a lubricant.

Testing

Extensive laboratory and animal testing was performed to adequately determine and demonstrate the safety of the functional disc prior to initiating clinical trials. *In vitro* testing, including static and fatigue evaluations, was conducted on the components, subassemblies, and final devices to evaluate and establish the prosthesis' mechanical performance limits under "worst-case" conditions. The testing included evaluation of prosthesis stability, utilizing a mechanical cervical spine simulator to determine the long-term functionality and durability of the prosthetic system. This simulator subjected the device to dynamic load and motion profiles representative of normal *in vivo* conditions. Other bench and cadaver studies were conducted that included testing to ensure the functionality of the surgical instrumentation system.

Pre-clinical animal studies were conducted to study the *in vivo* performance of the prosthesis and the surgical instrumentation. The studies were conducted following the principles of laboratory animal care. An adult chimpanzee survivor model was selected as the most appropriate, because of its similarity to the human in cervical spinal anatomy, morphology, and biomechanics. Three independent studies evaluated device safety in a total of 12 animals, with up to 6 months follow-up. The results showed that the prosthesis was stable and provided motion at the operated level. Fluorochrome labeling demonstrated bone ingrowth into the prosthesis shells. Additionally, a goat study, utilizing 16 animals, was undertaken to evaluate the biologic response to any particulates in sur-

rounding tissues, lymph nodes, liver, spleen, dura mater, and spinal cord. At 6 months, no inflammatory response was demonstrated in any of the tissues. When combined with extensive in vitro testing, the robust chimpanzee and goat study results collectively demonstrated device safety and supported the initiation of clinical trials during the first week of January 2000. The operative procedures represent the combined work of nine neuro- and orthopedic surgeons at seven centers in Europe.

Study design

Patients were concurrently enrolled in a multi-center evaluation of the prosthesis for the treatment of single-level DDD of the cervical spine. The prospective study was approved by the ethics committee and, as required, the regulatory agencies for each center. As such, the study was conducted in accordance with the Declaration of Helsinki. Patient inclusion criteria included disc herniation or spondylosis, with radiculopathy and/or myelopathy that had not responded to conservative treatment. Exclusion criteria included pre-

Table 1 Patient assessments, carried out preoperatively, postoperatively, and at 6 weeks, 3 months, 6 months, 1 year, and 2 years

Motor strength on a five-point scale (right and left sides)
Deltoids
Biceps
Triceps
Wrist extensors
Wrist flexors
Finger flexors
Finger abductors
Gait on a four-point scale
Reflexes on a four-point scale (right and left sides)
Biceps
Triceps
Brachioradialis
Knees
Ankles
Sensory function on a four-point scale (right and left sides)
C4 dermatome
C5 dermatome
C6 dermatome
C7 dermatome
Neck pain severity on a six-point scale
Arm pain severity on a six-point scale
Ability to function with respect to activities of daily living on a four-point scale

Table 2 Patient demographics (n=97)

Age range	26–79 years
Gender	41 men, 56 women
Clinical diagnosis ^a	Radiculopathy (n=90); myelopathy (n=13)
Primary etiology ^a	Herniation (n=75); spondylosis (n=33)
Duration of symptoms	6 wk. (n=6); 3 mo. (n=18); 6 mo. (n=24); 1 yr (n=15); 2 yr. (n=14); 2 yr. (n=20)
Levels implanted	C3–C4 (n=0); C4–C5 (n=11); C5–C6 (n=42); C6–C7 (n=44)
Size implanted	14 mm (n=22); 15 mm (n=21); 16 mm (n=25); 17 mm (n=20); 18 mm (n=9)

^a Several patients presented with multiple diagnoses and/or etiology

vious cervical spine surgery involving any other device, axial neck pain as the solitary symptom, significant cervical anatomical deformity or clinical instability, and active infection. Patients gave their informed consent before participating in the study.

Patient assessments are based on the evaluation schedule presented in Table 1. The primary endpoint is classification based on relief of preoperative symptoms, as assessed by the patient using the Cervical Spine Research Society (CSRS) and SF-36 patient questionnaires, and relief of objective neurological signs, as assessed by the physician in a neurological examination, associated with the treated level.

Data were entered into a database and, in accordance with a scoring algorithm, assessments were calculated to determine relief of neurological symptoms and signs. Results were scored according to a modified version of Odom's Criteria, and categorized as follows:

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

Radiographs were analyzed independently to determine ROM and assess device migration and/or subsidence.

Study enrollment

A total of 97 devices were implanted. In all cases, neural compression was verified using computed tomography (CT) or magnetic resonance imaging (MRI) and a neurological assessment. Complete clinical and radiographic data are available on 97 patients. As of late January 2002, 49 of the patients have been followed for 1 year and 10 patients have been followed for 2 years. Table 2 details the demographic variables of the patients.

The duration of preoperative symptoms ranged from 3 weeks to more than 2 years.

Operative technique

The prosthesis is implanted using a proprietary surgical procedure that is an extension of current anterior cervical discectomy and fusion (ACDF) procedures. Following initial discectomy, surgical instruments utilize a simple gravitational referencing system to establish a virtual axis in the intervertebral disc space that is used to position a milling fixture, which is then fastened to the anterior vertebral surfaces. This fixture controls the location and movement of the powered cutting instruments that prepare the vertebral end-

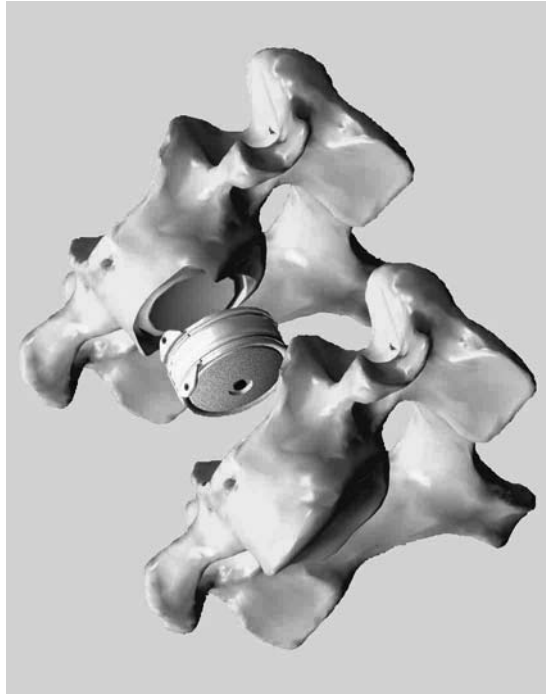


Fig. 2 Disc prosthesis and precisely milled concavity in the vertebral body

plates for placement of the prosthesis. The milled vertebral end-plates exactly match the geometry of the shell's convex outer surface, capturing the rim of each shell inside a ridge of bone (see Fig. 2). This tight fit provides immediate antero-posterior and lateral stability.

Operative data were compiled on 97 procedures.

Results

Table 3 summarizes the clinical success results based on relief of preoperative symptoms (as assessed by the patient) and relief of neurological signs (as assessed by the surgeon) for the 1-year and 2-year follow-up periods.

Of the 46 patients rated for clinical success at 1-year follow-up, 40 (87%) were classified as a clinical success (excellent/good/fair). This result is better than the targeted success rate of 85% excellent/good/fair. Three patients with incomplete scores (one with an incomplete patient questionnaire, two with incomplete neurological forms) were disregarded in this scoring analysis.

At 2 years, the scores were excellent, good, or fair for eight out of nine, or 89%, of the patients. This result is

better than the targeted success rate of 85%. One patient did not fully complete a patient questionnaire and was not evaluated for 2-year clinical success.

Complications

One patient experienced temporary dysphonia. One patient reported pain subsequent to the 3-month follow-up. This was due to failure to remove a lateral osteophyte, as well as to a 3-year history of preoperative dermatomal pain. A foraminotomy was performed in this case. The device, its position and its function remained good throughout, and it was considered to be unrelated to the symptom.

One patient reported pain in the right shoulder, right arm, and in the sternum region, approximately 6 months after surgery. An MRI examination ruled out any remaining neural compression. Another patient remarked on unresolved non-specific shoulder pain and left axial pain.

One surgical intervention at the target space occurred approximately 26 h post surgery. A standard drainage catheter had loosened and ceased draining. Subsequently, the patient experienced pain and shortness of breath. The re-operation revealed a hematoma, which was evacuated; no active bleeding was detected. The intervention was uneventful and the patient responded well.

There have been no device failures or device explants.

Radiographic results

Radiographic follow-up data were obtained for 43 (of 49) patients with 1 year's follow-up, and ten (of ten) patients with 2 years' follow-up. An independent radiologist assessed all radiographs.

Device position

After each follow-up visit, lateral radiographs were measured to ensure that device instability did not occur. Based on the accuracy of measuring plain radiographs, and as measured in fusion cage studies, 2 mm was considered the detection threshold. Subsidence has not been observed in any patients. Evidence of anterior/posterior device migration over 2 mm was detected in one patient; however, migration greater than 3 mm has not been observed. In this patient, the milled concavity had not been created, due to nearly mechanical failure in the cutting instrument.

Table 3 Clinical success results based on patient's assessment of relief of preoperative symptoms and surgeon's assessment of relief of neurological signs

Follow-up	Clinical success % (n)	Sample size	Excellent % (n)	Good % (n)	Fair % (n)	Poor % (n)
One year	87 (40)	46	70 (32)	4 (2)	13 (6)	13 (6)
Two years	89 (8)	9	78 (7)	–	11 (1)	11 (1)

Fig. 3 Preoperative range of motion (ROM) in a 29-year-old man implanted with a 17-mm prosthesis at the C5-6 level

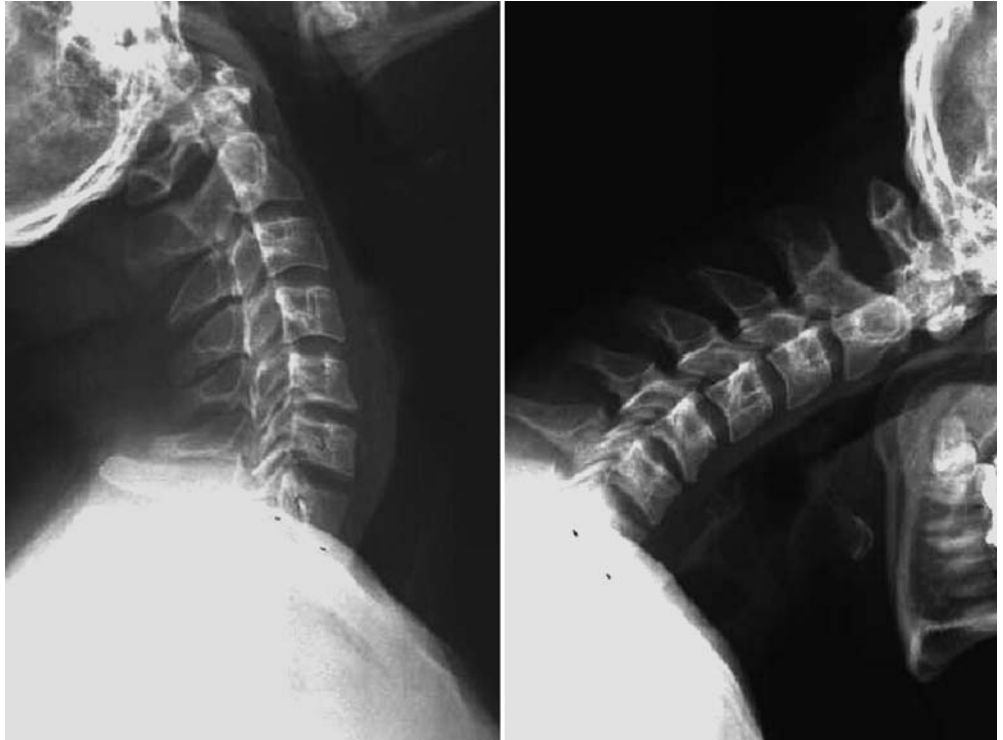
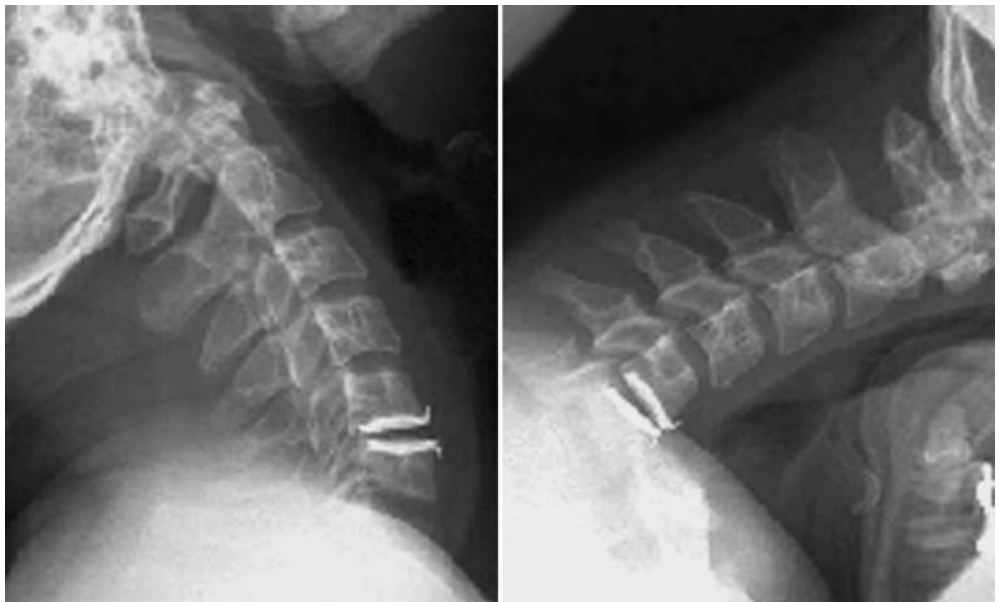


Fig. 4 Twelve-month postoperative ROM in the same man as Fig. 3



Range of motion results

Postoperative Cobb angles for flexion/extension of the FSU at the implant level demonstrated motion of the device in flexion/extension.

At 1 year, 38 out of 44 patients, or 86%, demonstrated flexion/extension ROM equal to or greater than 2°. In four patients ROM measured 1°; the radiograph for the remaining patient was not interpretable. The ROM for pa-

tients at 1 year averages just over 8°, with a standard deviation of 5°.

At 2 years, ten out of ten patients, or 100%, demonstrated flexion/extension ROM equal to or greater than 2°. The ROM for patients at 2 years averages just over 11°, with a standard deviation of 5°. Motion was observed in all patients, and there was no evidence of spondylotic bridging.

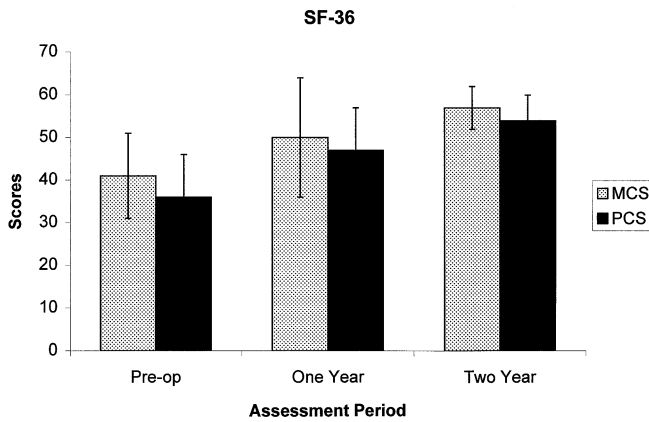


Fig. 5 SF-36 Quality of Life results for the patients reaching the 1-year and 2-year follow-up periods

Illustrative case

The patient illustrated in Fig. 3 and Fig. 4 – a 29-year-old man – was implanted with a 17-mm prosthesis at the C5-6 level. This patient's ROM increased by 4° (from 17° preoperatively to 21° at 12 months postoperatively).

Quality of life results

The SF-36 Health Survey results are presented in Fig. 5 for the patients reaching the 1-year and 2-year follow-up periods. Values for each period are presented in the SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores, which utilize US population means to establish normalized scores. All PCS/MCS scores are norm based, with the general population mean equal to 50 and the standard deviation equal to 10. At 1-year post-implant, patients had PCS scores just under the US mean (47), but that represents a 31% improvement over the average preoperative PCS scores. At 2 years post-implant, patients with the Bryan prosthesis met or exceeded the US population mean for PCS and MCS scores.

Discussion

Though the 1- and 2-year data to date compare favorably with equivalent data for the ACDF procedure, this should come as no surprise, as the patient's symptomatic relief is

obtained principally from the decompression, which is essentially the same in both ACDF and cervical spine arthroplasty procedures. What is noteworthy, however, is the fact that increased axial pain has not been noted in the prosthetic FSUs of DDD patients. This likely is related to facet unloading and movement of the axis of rotation to a location that is closer to normal, following insertion of an appropriately sized prosthesis.

Two of the poor outcomes noted in the 1-year results were in patients whose preoperative radicular symptom of pain had been present for 12–24 months. In two myelopathic patients whose outcome was fair, deficits persisted though no progression was observed (note: cases in which patients/investigators did not complete all 55 combined questions from the questionnaires and forms were automatically excluded from the outcome scoring).

Overall, motion of the FSU postoperatively was similar to that seen preoperatively. No subsidence, device migration or mechanical instability was noted when the device was implanted into properly prepared endplates. No bridging spondylosis has been seen to date, including the first ten patients followed for 2 years. Good movement, which did not diminish over time, has been demonstrated in all ten cases at 2 years. Patient satisfaction has been high, with no postoperative restrictions on activities of daily living (ADL). External orthoses were not required. Studies subsequent to the E.U. series showed the presence of some evidence of paravertebral ossification in about 30% of patients. This finding was profoundly reduced in frequency and degree in patients receiving NSAIDs postoperatively for 2 weeks.

Conclusion

Cervical spine arthroplasty can be expected to address the symptoms and signs of DDD within the outcome assessment period of 2 years at least as well as ACDF. The device instrumentation and technique offer the advantage of treating the disease aspects of the degenerative disc process by providing for continued motion and a more normal biomechanics. It would be desirable for cervical spine arthroplasty to favorably influence the rate of progress and age of onset of future symptoms. If this proves to be the case, it will in effect return the individual's degenerative disc disease process to that of their natural aging process. This will require at least 5–10 years to evaluate.

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