

# The Use of Artificial Disc Replacement in Degenerative Conditions of the Cervical Spine

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## ABSTRACT

### Purpose of Review

Anterior cervical fusion, the gold standard for reconstruction following anterior cervical decompression, is both safe and effective but potentially accelerates degeneration of adjacent segments. Artificial disk replacement is an emerging technology with the potential to maintain motion and decrease adjacent segment degeneration. Several devices are currently in pilot studies with early and intermediate results reported. This article reviews the current clinical and basic science studies evaluating the Frenchay and Bryan artificial cervical disk replacement devices.

### Recent Findings

Current clinical studies of the Frenchay and Bryan devices have exceeded targeted success rates at six months, one year and two years. Both devices allow maintenance of physiologic motion at the implanted level without increasing motion at adjacent segments. Wear analysis of the Bryan Disc shows a low wear rate and satisfactory biologic response with minimal inflammatory reaction.

### Summary

Early clinical results of disk replacement are comparable to anterior fusion in the same follow-up period. Biomechanical studies indicate that disk replacement does minimize stress at adjacent levels while maintaining normal physiologic segmental motion in the whole cervical spine. Wear analysis supports low wear rates with minimal inflammatory response. Only long-term follow-up will prove if cervical disk replacement is equal or superior to anterior cervical fusion.

## INTRODUCTION

Anterior cervical decompression and arthrodesis, first described by Robinson and Smith [1] in the 1950's, is a very effective and widely accepted treatment for radiculopathy and myelopathy due to cervical spondylosis and herniated cervical disks. Interbody grafting techniques promote foraminal distraction and restoration of normal cervical alignment. The theoretical advantage to obtaining fusion is that the foraminal distraction is maintained, and that decreased motion combined with the resorption of osteophytes minimizes irritation of nerve roots. Despite excellent clinical results, the potential for acceleration of adjacent segment disease is concerning. Several biomechanical studies demonstrate significant increase in shear strain, intradiscal pressure and segmental motion at levels adjacent to anterior fusions [2,3]. Hilibrand et al [4] report that symptomatic adjacent segment disease occurs at 2.9%/year for the first decade after anterior fusion. Often patients require additional procedures to address degeneration of adjacent levels.

Cervical disk replacement is a new technique for reconstruction following anterior cervical decompression. The main proposed advantage for cervical disk replacement is maintenance of segmental motion, which decreases stress transmitted to the adjacent levels and hopefully lessens adjacent segment degeneration. Disk replacement also avoids potential complications specifically associated with fusions such as bone graft morbidity and pseudarthrosis. Earlier return to function is another proposed advantage.

Pointillart [5\*] first described a titanium cervical prosthesis with a carbon-bearing surface that articulated with the endplate of the cephalad vertebrae. This prosthesis “failed” as the eight patients out of ten who had good resolution of neck pain went on to spontaneous fusion within two years. The two patients who maintained motion had significant continued neck pain, one requiring revision to fusion. Currently, there are two devices, the Frenchay disk and the Bryan disk, being investigated in which early clinical data is available. Both devices are inserted by anterior approach and require anterior decompression of neural structures prior to insertion as neither device provides enough distraction to indirectly decompress the foramen or spinal canal. This article will summarize the current available data on these prostheses.

## **FRENCHAY ARTIFICIAL CERVICAL JOINT**

### **History/Design**

In the late 1980's, Cummins [6\*] developed a metal-on-metal ball and socket cervical disk replacement comprised of 316L stainless steel. This device allowed minimal translation. The device components were fixed to the vertebrae by ridges that engage the endplates as well as anterior screws placed in the vertebral bodies.

The Frenchay artificial cervical joint, named for the institution where it was developed, is a modification of the Cummins device which allows more normal physiologic motion. The caudal component, previously the socket, was changed to a shallow ellipsoid saucer which allows both translation and rotation as the cranial ball component glides in the saucer. The incongruous surfaces allow the ball component to passively find the axis of rotation determined by the constraints of the facet joints and the coupled motion of the other vertebral segments. The profile of the screw locking mechanism was lowered making the device less bulky.

### **Biomechanics**

Biomechanical testing compared intact spines, spines with the Frenchay disk and spines with a fused segment [7]. There was no statistically significant difference in bending stiffness between intact spines and those with the Frenchay device. Also, there were no significant changes in motion characteristics of the other cervical levels in specimens with the Frenchay device. The range of motion in flexion-extension ranged from 18 degrees at C5-6 down to 8 degrees at C2-3 in intact spines, compared with 17 degrees and 7 degrees respectively in the specimens with an artificial disk. The specimens with simulated fusions were significantly stiffer than the intact spines and the motion characteristics of other motion segments were significantly altered. A separate study [8\*] looking at fatigue testing showed no failure at 10 million cycles loading a 12 mm prosthesis to 150 N and a 14 mm prosthesis to 225 N.

### **Clinical Studies**

Wigfield et al [8\*] have recently reported favorable results on a two-year pilot study of the Frenchay disk designed to address the safety of the technique and to assess the stability of, and motion allowed by, the device. They tried to target patients most at risk for adjacent segment disease. Inclusion in the study required radiculopathy or myelopathy due to herniated disk or uncovertebral osteophytes confirmed on CT or MRI scan adjacent to a surgically or congenitally fused segment. An additional inclusion category was for patients with asymptomatic disk degeneration adjacent to the symptomatic level without presence of a fusion. Fifteen patients were enrolled in the study. They concluded that the technique is safe as procedural complications were limited to two cases of transient hoarseness which resolved. Motion was successfully preserved as all patients' radiographically demonstrated motion within an appropriate physiologic range. At two years the mean motion in flexion-extension was 6.5 degrees with a range of 1 to 15 degrees. Anteroposterior translation up to 2 mm was obtained. Device stability was concluded as no devices dislocated. Two of the sixty screws inserted broke midshaft at six months allowing settling of the caudal component. No other cases of settling were noted. The locking screws worked well and no screws backed out. A concerning finding is a lucent line that developed at the junction of the vertebral endplate and the anterior vertebral border suggestive of stress shielding. This lucency did not progress after twelve months. One patient required removal of the device and conversion to fusion for continued neck pain in extension. That device was found to be loose with surrounding fibrous tissue; however, there was no histologic evidence of infection, inflammation or wear debris. Functional improvement was documented by improvements in visual analogue scale arm and neck scores, neck disability index scores and SF-36 short form and SF-36 mental component scores at two-years

compared to preoperative scores. Statistical significance was not obtained due to the small number of patients in the study.

In a separate prospective nonrandomized study, Wigfield et al [9\*] compare the effects of the Frenchay disk and one-level anterior fusion on adjacent segment motion. No significant difference in adjacent segment motion was measured between the two groups preoperatively. Postoperatively, there was a significant increase in adjacent segment motion in the fusion group (mean 9 degree increase) compared to a slight reduction in adjacent level motion noted in the Frenchay disk group. In the fusion group, adjacent segment motion increased 5% at six months and 15% at one year. Subgroup analysis showed that increased motion occurs predominantly in normal rather than degenerative adjacent disks.

## **BRYAN CERVICAL DISK REPLACEMENT**

### Device Design

The Bryan cervical disk is comprised of a polyurethane polymeric nucleus sandwiched between two titanium alloy clamshell-shaped endplates. There are two bearing surfaces, one at each nucleus-endplate interface. The device is unconstrained throughout the physiologic range of motion allowing coupled motions of angulation and translation. Each endplate is porous coated to promote bony ingrowth for long-term device stability. The polyurethane sheath is attached to the endplates with titanium wire forming a closed compartment. This sheath may promote formation of a surrounding pseudocapsule with time. Sterile saline lubricant is injected into this compartment prior to 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 disk during implantation. Five diameters are available: 14, 15, 16, 17 and 18 mm.

The center of the disk space is determined intraoperatively using a gravitational referencing system. With knowledge of the center of the disk space, a milling fixture is anchored to the vertebral bodies. This fixture controls the cutting tools which mill the endplates to the exact geometry of the device endplates providing immediate stability.

### Clinical Studies

Goffin et al [10] 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 disk herniation or spondylosis failing at least six 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 > 2mm or > 11 degrees of angulation compared to 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 [11\*\*] have recently published the intermediate-term results of this multicenter study. The study was expanded to include a second arm evaluating the treatment of two adjacent levels. The single-level arm had 103 patients enrolled with 100 reaching the one-year mark and 51 reaching two-year follow-up. The bilevel study arm was comprised of 43 patients with one-year data completed on 29 patients and two-year data available on one 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 six months was 82% and 96% at one year. No device failures or subsidence was observed in any patient. At one-year follow-up flexion-extension range of motion per level averaged 7.9 degrees in the single-level arm and 7.4 degrees in the bilevel arm.

In the single-level study, three 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 appro-

ropriate level. The other patient developed a second symptomatic disk 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.

Temporary anteroposterior device migration was detected in one 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 greater than 3.5 mm, the radiographic threshold of segmental stability, was not observed.

Sekhorn [12] reported early results of nine patients with cervical spondylotic myelopathy who were treated with anterior decompression and reconstruction with the Bryan Disc. Follow-up ranged from one to 17 months. On average the Nurick grade improved by 0.72 and Oswestry Neck Disability Index scores improved by 51.4 points. Improvement in cervical lordosis was noted in 29% of the patients. No complications were reported.

### Wear Analysis

Failure of total joint arthroplasty has been largely attributed to wear debris from polymer-bearing surfaces. Wear debris induces an intense cellular inflammatory response which results in the production of cytokines that cause resorption of bone. This process, known as aseptic loosening, leads to destabilization and mechanical failure of the joint. The possibility of a similar process occurring after cervical disk replacement is concerning especially given the polymeric bearing nucleus of the Bryan Disc. In addition, the unknown effects of wear debris and inflammatory response in the spinal canal around neural structures are worrisome.

Anderson et al [13\*\*] have published a pivotal study that reports on the wear characteristics of the Bryan Disc in vitro in a cervical spine simulator, and the in vivo biologic response in goat and chimpanzee models. In the in vitro study, six disks were tested to 10 million or 40 million cycles in a cervical spine simulator by load and motion, while an additional three assemblies were tested only to load. Wear debris was produced at a rate of 1.2 mg/million cycles. At 10 million cycles, there was 0.75% weight loss of the prosthesis. Device heights decreased 0.02 mm/million cycles. Debris particles averaged 3.9  $\mu$ m in diameter and were similar to wear particles found in other arthroplasty wear studies.

The local biologic response was examined in two chimpanzees, while both local and distant tissue biologic response was studied in nine goats. Three additional goats had anterior fusion and plating. Local wear debris was found in one chimpanzee and four goats; however, no inflammatory response was seen in any animal. Some animals had wear debris in loose connective tissue and in the epidural space without evidence of inflammation. One goat had debris particles in the lumbar spine; however, they were at the extreme margins and not incorporated in the tissue indicating they may have been artifactual. The plated fusion group exhibited greater metal debris and inflammatory response than the artificial disk group. Given their findings, the authors conclude that the low in vitro wear rate and lack of inflammatory response in vivo predict satisfactory long-term performance.

### CONCLUSION

Although far from being an accepted standard, the concept of artificial disk 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 is going to be necessary to prove that this technology supercedes the current gold standard of anterior fusion. Biomechanical studies demonstrate that disk replacement creates less adjacent 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 disk 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 true reality of this will only be borne out with more follow-up time. Obviously, the jury is still out on this technology, but early reports suggest the verdict may be promising.

## REFERENCES AND RECOMMENDED READING

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