ELSEVIER
SAUNDERS

Neurosurg Clin N Am 16 (2005) 629–636

NEUROSURGERY
CLINICS
OF NORTH AMERICA

The Bryan Cervical Disc System

Stephen Papadopoulos, MD

Barrow Neurological Institute, 350 West Thomas Road, Phoenix, AZ 85013, USA

The Bryan cervical disc was originally conceived and developed by Seattle-based neurosurgeon Dr. Vincent Bryan and Alex Kunsler, a local mechanical engineer experienced in designing medical devices. In 1993, they founded Spinal Dynamics, Inc., and initiated the development of the Bryan Cervical Disc System. The goal was to reconstruct a degenerated or herniated cervical intervertebral disc with a functional disc prosthesis that could provide normal motion and physiologic protection of adjacent levels [1–5]. After nearly 10 years of development, mechanical testing, and animal trials, the Bryan cervical disc received approval in Europe in September 2000, and has subsequently been distributed in more than 20 countries outside the United States. To date, more then 8000 Bryan cervical discs have been implanted worldwide. Clinical evaluations of the device in the United States began in May 2002 under an Investigational Device Exemption (IDE) granted by the US Food and Drug Administration (FDA). Enrollment of over 500 patients in the United States IDE trial has been completed and 2-year follow-up data are currently being collected and analyzed in preparation for submission to the FDA.

Description of the Bryan cervical disc

The prosthesis design is based on a proprietary, low-friction, wear-resistant, elastic nucleus. The nucleus is located between, and articulates with, two shaped titanium plates (shells) that are affixed to the vertebral body endplates and provide for normal range of motion in flexion and extension, lateral bending, axial rotation, and translation. A unique flexible membrane surrounds the interior articulating shell surfaces, to separate the internal structures of the device from the external in vivo environment. This compartment is filled with saline at the time of implantation (Fig. 1).

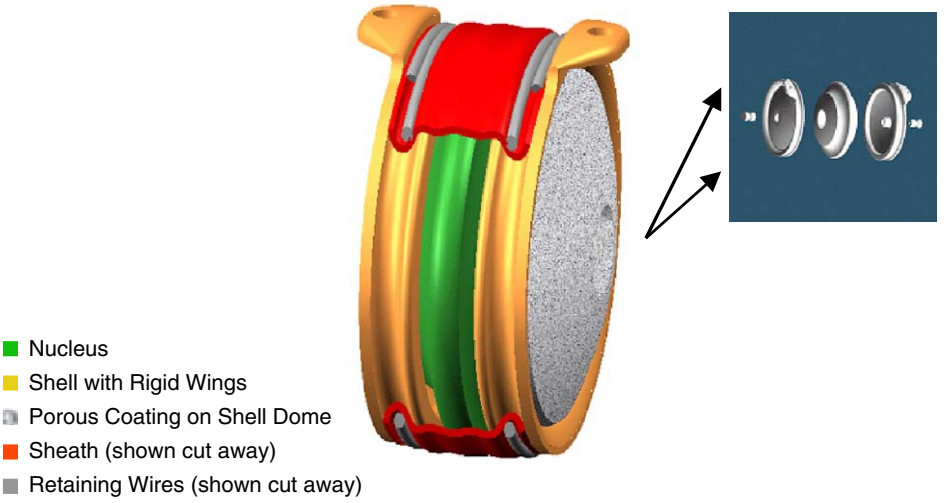
The disc prosthesis endplates are dome shaped with polished, concave, spherical, articulating surfaces. These surfaces conform to and articulate with the convex spherical surfaces of the nucleus and provide a relatively unconstrained range of motion. The nucleus is "fixed" to a "smaller" central post, thus providing physiologic coupled translation–flexion and extension motion. The clinically observed maximum range of motion is 11° of flexion and extension, lateral bending, and 2 mm of translation. Each prosthesis shell is implanted in a precision-machined recess in the vertebral body endplate that exactly matches the geometry of the shell's convex outer surface, capturing the outside edge of each shell inside a contoured interface of bone (Fig. 2). The coefficient of friction at the biarticular nucleus–shell interface is sufficiently low to unload shear stress at the shell–bone interface to allow successful boney in-growth without the need for additional fixation features. This fit provides immediate A/P and lateral stability. Animal studies have shown that long-term fixation is achieved via bone in-growth into the porous surfaces (Fig. 3). The Bryan cervical disc system is manufactured in five sizes, from 14 mm to 18 mm in diameter.

Pre-clinical studies

Anderson and colleagues [6,7] have published two pivotal studies that report on the wear characteristics of the Bryan disc in vitro in a cervical spine simulator, and in vivo in goat and chimpanzee models. In the first report, the in

E-mail address: stvpapa@bnaneuro.net

1042-3680/05/$ - see front matter
doi:10.1016/j.nec.2005.06.003



Note: Colors shown are not actual implant colors. Rather, they have been selected to illustrate the various prosthesis components. The wire/sheath/shell interface is fixed and is identical for all designs. The bone/shell interface is also present for all designs.

Fig. 1. Bryan cervical disc.

vitro results of six discs were tested to 10 million or 40 million cycles in a cervical spine simulator by load and motion; an additional three assemblies were tested only to load. Wear debris was reportedly produced at a rate of 1.2 mg/million cycles. Device heights decreased 0.02 mm/million cycles. Debris particles averaged 3.9 microns in diameter and were similar to wear particles found in other arthroplasty wear studies [7].

Local biologic response was reported in two chimpanzees, and both local and distant tissue biologic response was reported in nine goats. 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. Three additional goats had anterior fusion and plating. The plated fusion group exhibited greater metal debris and inflammatory response than the artificial disc 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.

In the second report, Anderson and colleagues [7] examined the wear properties of Bryan disc

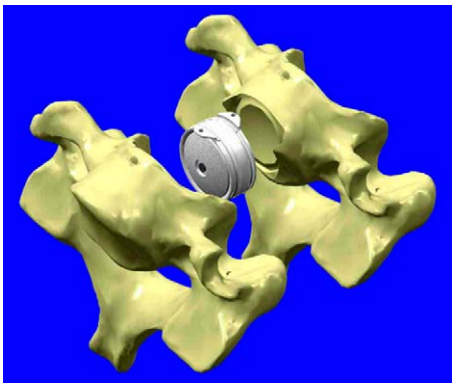


Fig. 2. Endplate preparation for disc implantation.

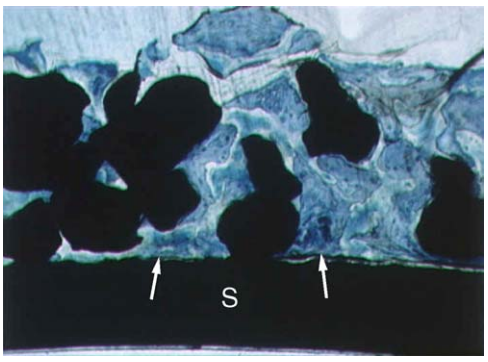


Fig. 3. Bone in-growth demonstrated in preclinical animal studies.

components in a custom cervical spine simulator as well as a goat model. The in vitro model involved simultaneous load and motion in six separate device assemblies with three control devices, and was similar in design to the prior study [6]. Nuclei were measured before and after the test for weight, height, and diameter. Wear debris was assessed with a standardized system. The in vitro wear testing revealed a mean mass loss of 1.76% and a mean height loss of 0.75% after fatigue of 10 million cycles. Particulate debris had a mean diameter of 3.89 microns [8]. There was no dysfunction in the test or load assemblies at 10 million cycles and the polymeric nuclei demonstrated uniform wear on the load-bearing surface with the exception of one sample. Three assemblies were tested to the point of end plate-to-end plate contact, which was observed at 37.7, 39.7, and 40 million cycles respectively. Loss of prosthetic height was linear in relationship to the number of cycles in this model.

Tissues analyzed in the in vivo group included: periprosthetic tissue, draining cervical lymph nodes, spinal canal tissues adjacent to the disc and at the superior and inferior endplates, liver, and spleen. A trend of increasing extracellular wear particles was noted with time, with no appreciable inflammatory response seen at 3, 6, or 12 months. The three animals in the plate/control group all had particulate titanium debris in the periprosthetic tissues, which was much greater in volume than that observed in the Bryan prosthesis animals.

Clinical studies

Goffin and colleagues [9] 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 caused by disc herniation or spondylosis and for whom conservative treatment had failed. Exclusion criteria included previous cervical spine surgery, neck pain as the only symptom, and radiographic evidence of instability. Patient outcomes were determined by the Cervical Spine Research Society (CSRS) patient questionnaire and SF-36 questionnaire, an instrument that measures a patient's general health status and includes physical and mental components. Clinical success rates at 6 months and 1 year were 86% and 90%, respectively. This compares favorably to previously published outcomes in single level antererior cervical fusion patients.

In a follow-up report, Goffin and colleagues [10] have recently published the intermediate results of this multi-center study. The study was expanded to include a second group of patients treated at two adjacent levels. The single-level group contained 103 patients and the bilevel group had 43 patients. At the time of the follow-up report, 100 single-level patients had completed 1-year follow-up evaluation, and 51 patients had completed the 2-year follow-up. In the two-level cohort, 29 patients had reached the 1-year evaluation point. Success rates in the single-level study at 6 months, 12 months, and 24 months were 90%, 86%, and 90%, respectively. In the bilevel study, the success rate at 6 months was 82% and 96% at 1 year. No device failures or subsidence was observed in any patient. At 1-year follow-up, flexion and extension range of motion per level averaged 7.9° in the single-level group and 7.4° in the bilevel group.

Sekhon [11] 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 1 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.

Sasso and colleagues have reported the initial functional outcome results of a three-surgeon cohort of patients entered in the prospective, multi-center, United States IDE trial of the Bryan cervical disc. Multiple outcome measures were used including: neck disability index (NDI), neck pain visual analog pain score (VAS), arm pain VAS, SF-36 physical component (PCS), SF-36 mental component (MCS), and range of motion (ROM) flexion and extension. In this pooled cohort of 115 patients, 56 were randomized to a Bryan artificial disc replacement and 59 were randomized to an anterior cervical fusion with allograft and a plate. The average operative time for the control group was 1.1 hours and the Bryan group 1.7 hours. Average blood loss was similar. Neck disability index scores preoperatively were Bryan 47 and control 49. Twelve-month follow-up data were available for 75 patients (38 Bryan and 37 controls) with NDI's of Bryan 11 and control 19. At 2-year follow-up, 16 patients were available (8 Bryan and 8 control). NDI for the Bryan group was 7 and for the control group, 26. Arm pain VAS preoperatively was Bryan 70 and control 71. At 1-year follow-up, Bryan arm pain VAS was 14 and the control was 22. At 2-year follow-up, the average arm pain VAS for the Bryan group was 7 and control 45. Neck pain VAS preoperatively

was Bryan 72 and control 73. The 1-year follow-up scores were Bryan 19 and control 28. At 2-years the scores again favored the Bryan group: Bryan 10 and control 38. SF-36 scores (physical component) were also notable: preoperative Bryan was 34 and the control 32. At 24-months postoperative, the physical component of the SF-36 had changed to Bryan 51 and control 45. SF-36 mental component scores preoperatively were Bryan 46 and control 49. At 24-months they were Bryan 55 and the control 50. As expected, significantly more motion ($P < 0.006$ at 3, 6, and 12 months) was retained in the disc replacement group than the plated group at the index level. The

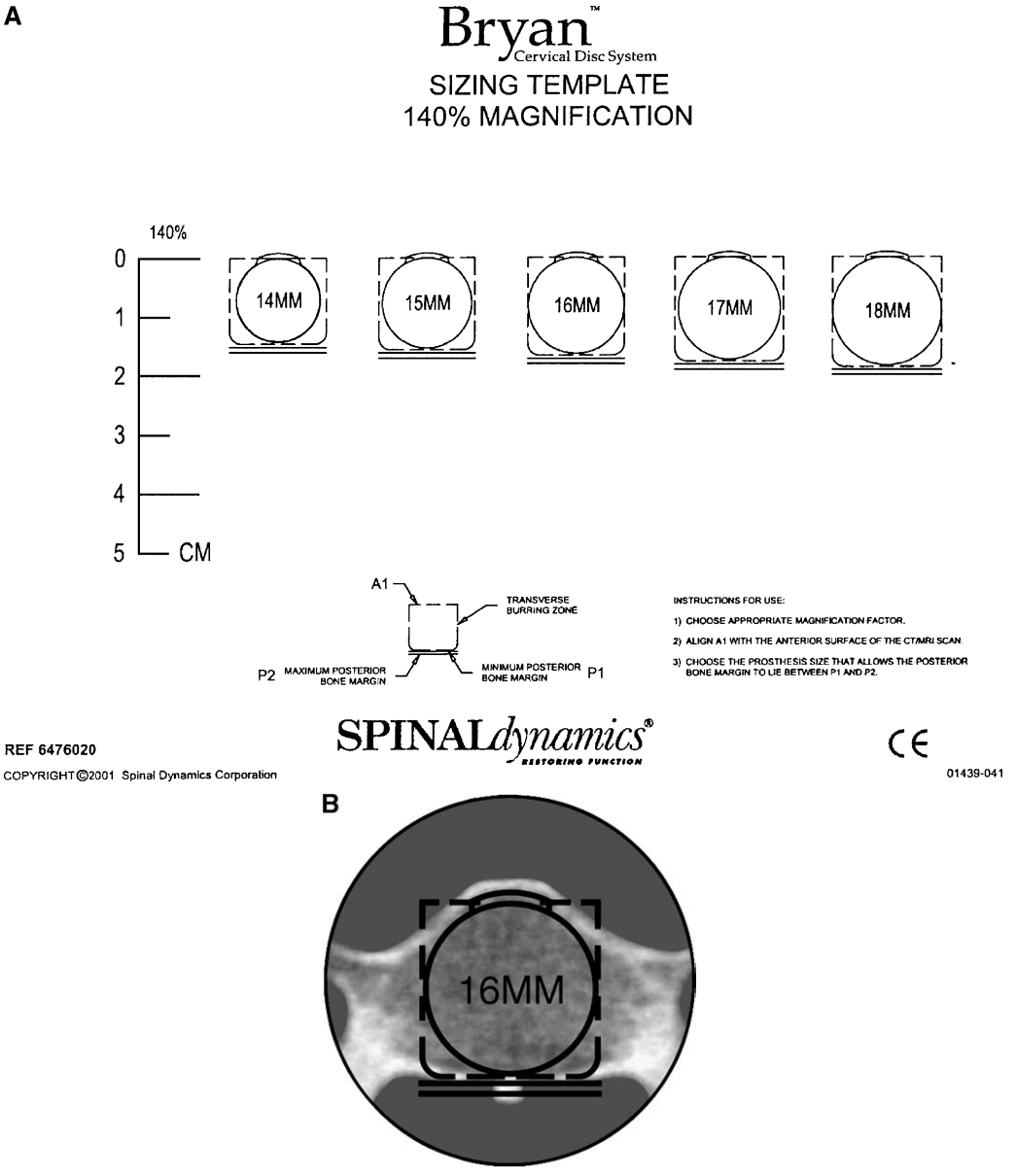


Fig. 4. (*A*) Template range of sizes for Bryan cervical disc. (*B*) Template overlay on axial CT scan at the index disc space. (Courtesy of Medtronic Sofamor Danek, Inc, Cervitech, Synthes Spine, and Stryker, with permission. Bryan Cervical Disc System incorporates technology developed by Gary K. Michelson, MD. CAUTION: Investigational devices limited by United States Federal Law to investigational use.)

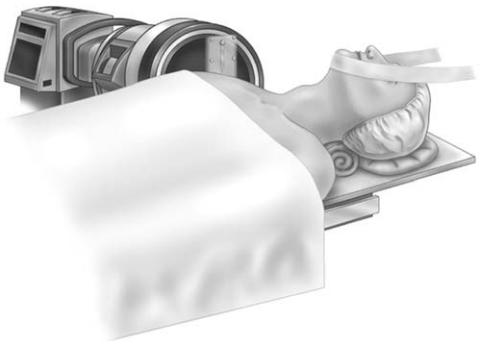


Fig. 5. Patient neutral position.

disc replacement group retained an average of 6.7° at 12 months. In contrast, the average range of motion in the fusion group was 2.0° at the 3-month follow-up and gradually decreased to 0.6° at 24 months. This data strongly suggests that the Bryan disc replacement compares favorably to single level anterior cervical arthrodesis at the intervals studied.

US Investigational Device Exemption study

In May 2002, an Investigational Device Exemption was granted by the FDA for clinical evaluation of the Bryan Cervical Disc System. The trial is designed to demonstrate equivalence with the ''gold standard'' anterior discectomy and interbody fusion with plate fixation, and with a primary patient outcome endpoint at time intervals up to 24 months. Trial enrollment was completed in 2004.

Study design

The Bryan Cervical Disc System is designed for use in patients diagnosed with degenerative disease of the sub-axial cervical spine having radicular or myelopathic symptoms and signs, with or without axial neck pain. The study is designed to establish the safety and effectiveness of the prosthesis as compared with the control group representing the current standard of care. Five hundred and fifty patients were included and equally randomized into a treatment arm, treated with implantation of the Bryan Cervical Disc System and a control group treated with discectomy, decompression, and the ATLANTIS Cervical Plate System (Medtronic Sofamor Danek, Memphis, Tennessee) with allograft.

Inclusion criteria for the trial:

- The patient requires surgical treatment at one level (C3-4 to C6-7) for disc herniation with radiculopathy

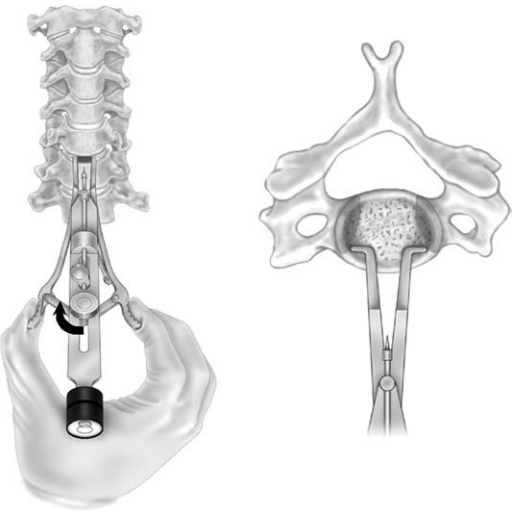


Fig. 7. Determination of mid-line.

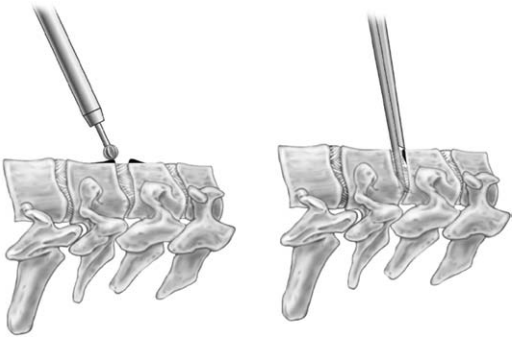


Fig. 6. Anterior endplate preparation.

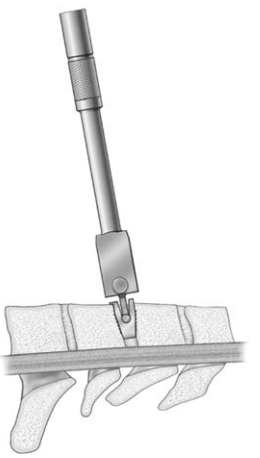


Fig. 8. Sagital wedge.

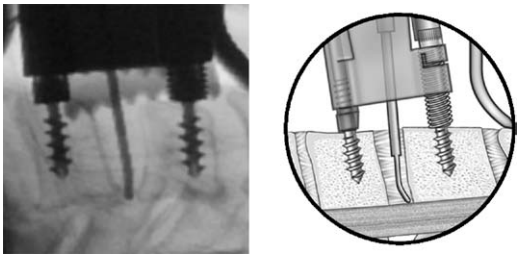


Fig. 9. Determination of depth and implant diameter.

- Spondylotic radiculopathy
- Disc herniation with myelopathy
- Spondylotic myelopathy
- Failed conservative treatment for 6 weeks, except for myelopathy that requires immediate intervention
- Diagnosis confirmed using CT, or myelography and CT, or MRI
- At least one clinical sign (ie, abnormal reflex, decreased motor strength, or abnormal dermatome sensitivity)
- Skeletally mature (at least 21 years old)

An active systemic infection or infection at the operating site, metabolic bone disease, and known allergy to titanium, polyurethane, or ethylene oxide residuals would lead to exclusion of a patient. Other exclusion criteria include: concomitant conditions requiring steroid treatment, diabetes mellitus requiring daily insulin management, extreme obesity, pregnancy, axial neck pain as the solitary symptom, and previous cervical spine surgery.

There are a number of radiographic exclusion criteria: significant cervical anatomical deformity, such as ankylosing spondylitis and rheumatoid arthritis; moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion or collapse of the disc space $>50\%$ of its normal height; radiographic signs of subluxation >3.5 mm and angulation of the disc space more than 11° greater than adjacent segments and significant kyphotic deformity also prevent inclusion into the study.

Fig. 10. Endplate milling.

Patients will be followed for 2 years after surgery. Outcome assessment at 2 years, and at certain time points before, include a neurological exam, anterior-posterior (AP) and lateral cervical spine x-rays, and a variety of validated outcome instruments such as the NDI and SF-36, and a quality of life and health status assessment looking at neck, arm, and shoulder pain, work status, and requirement of pain medications.

Implantation technique for the Bryan cervical disc

To achieve precise placement of the artificial disc, an alignment procedure and instrumentation has been developed based on the use of a simple gravitational referencing system. This system establishes a virtual axis in the intervertebral disc space that is used to position a machining fixture, which is fastened to the anterior vertebral surfaces. This fixture precisely controls the location and movement of custom-powered cutting instruments, which prepare the vertebral endplates with the shell geometry oriented in the proper A/P, midline, and angular position. Implantation encompasses four steps: (1) patient preparation, (2) discectomy and decompression, (3) disc alignment, and (4) implantation.

Patient preparation

On preoperative axial CT images the correct prosthesis size is determined using the Bryan cervical disc template (Fig. 4a). CT images should be obtained parallel to the disc spaces and bony spurs and ridges should not be included when selecting the template size (Fig. 4b). The patient is in supine AP position on the operating room table and C-arm fluoroscopy is used to identify the target disc space (Fig. 5). A standard anterolateral approach is used to expose the operative level.

Discectomy and decompression

Lateral and cephalad/caudal retractors are used for exposure and retraction of the surrounding tissues. Next, the approximate center of the target disc is identified and the incision template is used to mark the annulus fibrosus for the width of excision, using the previously determined

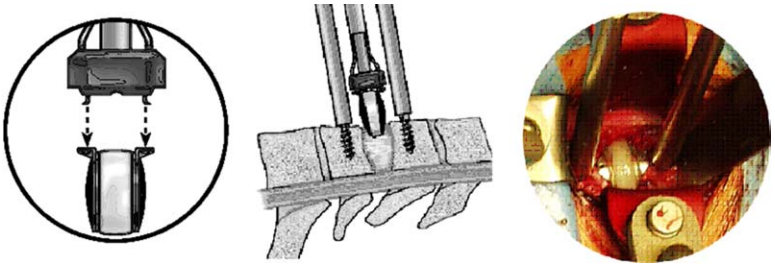


Fig. 11. Final implant placement.

prosthesis size. The section of the annulus between the marks is excised. The discectomy is completed using Kerrison rongeurs, pituitary forceps, and curettes. Bony osteophytes are removed using a similar technique and appropriate neural decompression is accomplished. Interbody distractors may be placed for completion of posterior decompression and removal of the posterior longitudinal ligament as needed.

The anterior surface of the vertebral body is prepared by removing all excess anterior osteophytes. Additionally, the anterior "lip" of the superior endplate is resected with a Kerrison rongeur to provide adequate access to the interbody disc space (Fig. 6).

Alignment

Next, the transverse centering tool is inserted into the disc space and its tips are expanded until they contact the lateral soft tissue margins (Fig. 7). The centering level is placed on the tool and adjusted until the bubble is centered in a lateral direction. Using the sliding pointer as a guide, the center point of the cephalic vertebral body is marked. The sagittal wedge is placed into the disc space so that its center is in line with the mark previously made on the cephalad vertebral body (Fig. 8). The wedge should be placed deep enough so that the stop contacts the anterior vertebral body. This is confirmed with an x-ray.

The milling guide is then slid onto the sagittal wedge until it contacts the caudal vertebral body.

The next step is to determine the milling depth. This will confirm the implant diameter chosen with the templates before the procedure. The milling depth gauge is inserted and confirmed with intraoperative fluoroscopy (Fig. 9).

Disc implantation

The milling disc is sized specifically to match the size of the prosthesis to be implanted. The milling handpiece is attached to the drive system—the

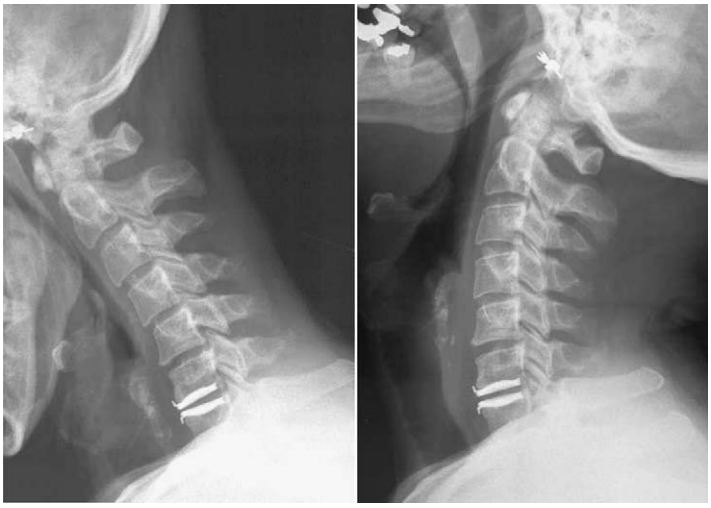


Fig. 12. Post-op flexion and extension X-rays.

cutter surface is facing caudal through the caudal guide slots—and using continuous irrigation, the drive system is activated. The handpiece should be pivoted gently back and forth until the stop on the guide is reached (Fig. 10). The corresponding maneuver is repeated for the cephalad endplate.

The disc space is now ready for implantation of the disc. The prosthesis has an open port through which sterile saline is then filled with a syringe. While holding the prosthesis compressed, a seal plug is threaded into the open port. The prosthesis is then attached to the implant inserter by placing the inserter tongs into the holes in the shell flanges. The disc is then inserted into the prepared disc space; gentle tapping may be necessary (Fig. 11). A standard cervical disc closure follows. Flexion and extension x-rays may be obtained immediately and in routine follow-up (Fig. 12).

References

[1] Eck JC, Humphreys SC, Lim TH, et al. Biomechanical study on the effect of cervical spine fusion on adjacent-level intradiscal pressure and segmental motion. Spine 2002;27(22):2431–4.

[2] Fuller DA, Kirkpatrick JS, Emery SE, et al. A kinematic study of the cervical spine before and after segmental arthrodesis. Spine 1998;23(15):1649–56.

[3] Goffin J, Geusens E, Vantomme N, et al. Long-term follow-up after interbody fusion of the cervical spine. J Spinal Disord Tech 2004;17(2):79–85.

[4] Hilibrand AS, Carlson GD, Palumbo MA, et al. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. J Bone Joint Surg Am 1999;81(4): 519–28.

[5] Wigfield C, Gill S, Nelson R, et al. 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; 96:17–21.

[6] Anderson PA, Rouleau JP, Bryan VE, et al. Wear analysis of the Bryan Cervical Disc prosthesis. Spine 2003;28:S186–94.

[7] Anderson PA, Sasso RC, Rouleau JP, et al. The Bryan Cervical Disc: wear properties and early clinical results. Spine Journal: Official Journal of the North American Spine Society 2004;4(6 Suppl): 303S–9S.

[8] Gelb H, Schumacher HR, Cuckler J, et al. In vivo inflammatory response to polymethylmethacrylate particulate debris: effect of size, morphology, and surface area. J Orthop Res 1994;12(1):83–92.

[9] Goffin J, Casey A, Kehr P, et al. Preliminary clinical experience with the Bryan Cervical Disc Prosthesis. Neurosurgery 2002;51(3):840–5; discussion 845–7.

[10] Goffin J, Van CF, van LJ, et al. Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level. Spine 2003;28(24):2673–8.

[11] Sekhon LH. Cervical arthroplasty in the management of spondylotic myelopathy. J Spinal Disord Tech 2003;16(4):307–13.