Interact Surg (2008) 3: 181–186

DOI 10.1007/s11610-007-0038-2

ORIGINAL ARTICLE

The Mobi-C® cervical disc prosthesis: indications, technique and results

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Abstract: The Mobi-C® cervical disc replacement is a semi-constrained prosthesis with a mobile polyethylene insert situated between two chrome cobalt plates. The insert can slide. Overall the Mobi-C® device has five degrees of freedom. The primary indications are as follows: 1) soft herniated discs leading to cervicobrachial pain refractory to conservative treatment; 2) some cases of hard herniated discs if movement has been documented on intra-operative dynamic bending films; 3) much more rarely in cases of spinal cord compression with myelopathy. Technically, centering of the device is facilitated by the dedicated instrument system. Regarding the results, the clinical efficacy is conventional. Mobility is preserved at a minimum 2-year follow-up in 85.5% of the devices. The main mechanical complications are radiological adjacent syndrome and heterotopic ossification (HO), among which even those of class III permit residual movement.

Keywords: Cervical disc prosthesis – Soft cervical herniation – Postoperative mobility – Heterotopic ossifications – Adjacent syndrome

Introduction [1,2]

The Mobi-C® cervical disc prosthesis is a semi-constrained ball-and-socket total disc replacement. In this article, we will successively describe its indications, which are dominated by soft disc herniation associated with cervicobrachial pain, the technique, simplified by the system of instrumentation, the results and the complications involving a multicenter series (335 patients enrolled and 77 patients with a minimum 2-year follow-up).

Description of the device

The Mobi-C® is a metal-on-polyethylene device. It has two plates consisting of cobalt, chromium, 29 molybdenum ISO 5832-12 alloy and an ultra-high-molecular-weight polyethylene mobile insert (Fig. 1). The inner contact surfaces of the superior and inferior plates are spherical and flat, respectively. The mobile insert is self-centering on the inferior endplate. Each movement of the superior plate induces the mobile insert to reposition on the inferior spinal plate. The inner contact surface of the superior plate is spherical, allowing a fully congruent contact surface with the convex spherical dome of the mobile insert. The inner contact surface of the inferior plate is flat and contains two lateral stops that limit the mobility of the mobile insert by contacting the lateral surface of the insert. The lateral stops reduce the potential for the migration of the mobile insert. Both the superior and inferior spinal plates contain two rows of teeth that are located laterally to ensure primary fixation. A titanium and hydroxyapatite plasma ray coating is applied to the bony interface surfaces of the superior and inferior plates. Different plate sizes are available (13 mm × 15 mm, 13 mm × 17 mm, 15 mm × 17 mm, 15 mm × 20 mm, depth × length). Different insert heights are available (4.5, 5, 6, 7 mm) to restore the physiologic height of the disc.

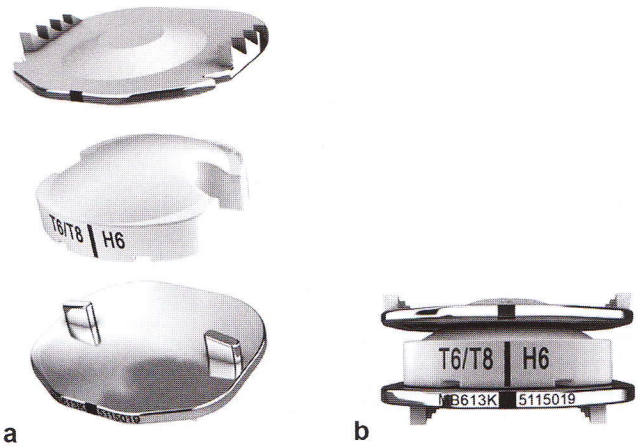

Fig. 1. a: the disc prosthesis including a superior and inferior endplate (inferior endplate has two stops) and a central polyethylene core; b: anterior view of the three parts of the disc replacement assembled

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The device allows for various degrees of mobility that include five independent degrees of freedom, two translational and three rotational. Mean flexion–extension value is 10°, mean lateral bending 10° and mean rotation 8°.

Indications

The disc prosthesis is indicated for soft herniated disc (Fig. 2) or more rarely for hard disc herniation and bone spurs (Fig. 3) when either lead to cervicobrachial pain with neurologic deficit or that fails to respond to conventional conservative treatment. When a soft herniated disc is surgically removed, the surgeon generally penetrates the posterior longitudinal ligament, because we have observed that 80% of operated herniated discs are transligamentous. For hard herniated discs, one should use a high-speed drill to remove the bone spurs from one uncinate process to the other to achieve good intervertebral mobility. In either case, dynamic bending films in flexion and extension show whether mobility still exists in the intervertebral segment scheduled for treatment.

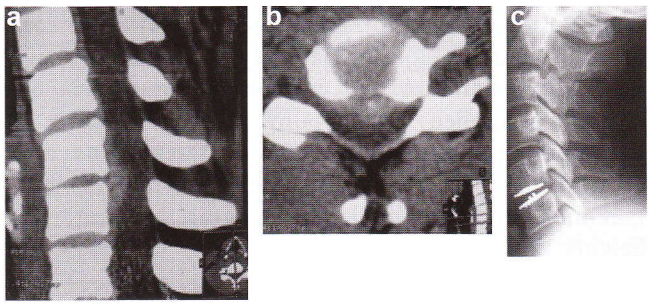

Fig. 2. Ideal indication for the Mobi-C® disc replacement: soft medial herniated C5-C6 disc. a: sagittal CT scanner slice; b: axial CT scanner slice; c: postoperative lateral film

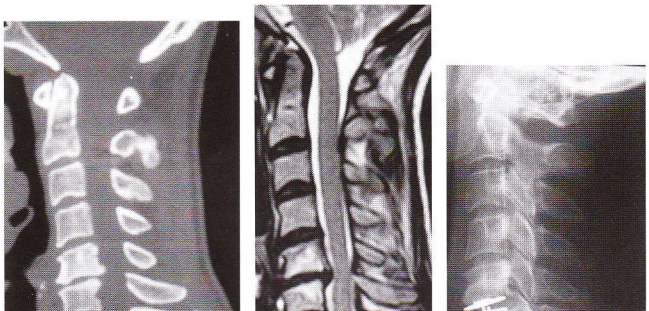

Fig. 3. Indication for the disc replacement in the case of a hard C5-C6 disc herniation. a: sagittal CT scanner slice; b: sagittal MRI slice; c: postoperative X-ray on which is visible that the posterior osteophytes have been burred down, particularly on the inferior endplate of C5

Myelopathy is a much more controversial indication, because it occurs most often in a context of bony stenosis, in which preoperative mobility is limited. Furthermore, it is possible that the residual mobility obtained by the use of a total disc replacement might contribute to the recurrence of osteophytes and hypertrophy of the posterior ligaments. Nevertheless, in our experience, this indication has been retained in a certain number of patients with an acceptable average result.

Technique

The patient is placed in the supine position. The arms are pulled toward the feet with adhesive elastic bands for better visualization of the cervicothoracic junction on lateral views (Fig. 4). Generally, the head is maintained straight with a rolled drape placed under the cervical lordosis. After being centered, an image intensifier is placed under the operative drapes for the duration of surgery. Using the image intensifier for verification, the precise level of the incision is determined. It is made in a skin fold of the neck over the anterior edge of the sternocleidomastoid muscle if only one level is planned (Fig. 5). The incision should be vertical if two or more disc replacements are scheduled to be used. It is important to verify the position of the incision well, notably using a metallic pin (Fig. 6). The vertebrae can be numbered by the counting of the spinous processes, which are usually shorter in C3-C5 (Fig. 4). Right-handed surgeons typically prefer a right approach and vice versa because this facilitates the use of the instruments. Nevertheless, at C7–T1, it is preferable to use a left-sided exposure, because the inferior laryngeal nerve is less exposed to injury on the left than on the right.

When the anterior column is attained, the *longus colli* muscles are carefully dissected. Bone wax is used to stop bone bleeding. Retractors, which are radiotransparent if

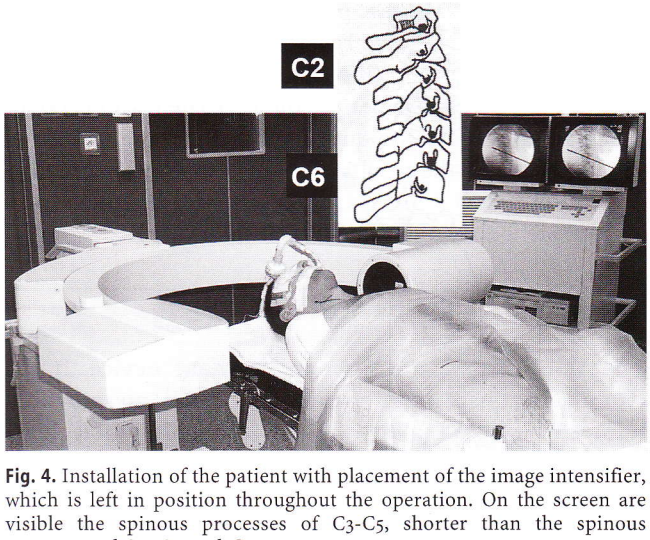

Fig. 4. Installation of the patient with placement of the image intensifier, which is left in position throughout the operation. On the screen are visible the spinous processes of C3-C5, shorter than the spinous processes of C2, C6 and C7

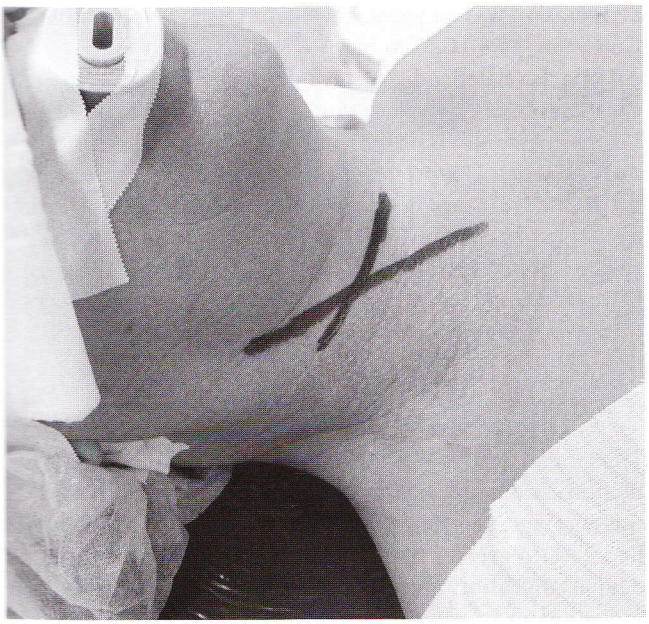

Fig. 5. Example of a horizontal incision in a skin fold of the neck for this exposure of C5-C6. The downward medial oblique line follows the anterior edge of the sternocleidomastoid muscle

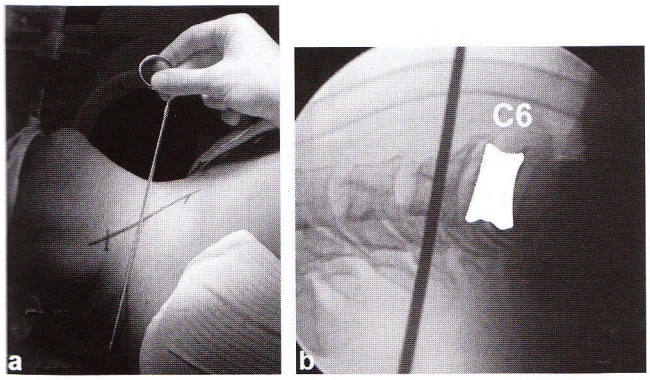

Fig. 6. Intra-operative level verification. a: using a metallic pin placed on the lateral aspect of the neck; b: this pin should be situated over the C5-C6 disc being accessed, so there will be no distortion on the level check

available, are placed under the two *longus colli* muscles. An anterior discectomy is performed, once again after verification that one is at the proper intervertebral level. Fork-like devices varying in width from 15 to 21 mm between the uncinate processes laterally and which have a medial pin are used to determine the middle of the disc (Fig. 7). The upper pin of a Caspar retractor is centered using this medial pin. Opening this retractor permits the surgeon to dissect and excise the disc more posteriorly. However, intervertebral distraction obtained with a Caspar retractor accentuates lordosis, which is a drawback of the device. The dedicated intervertebral retractor provided in the instrumentation permits parallel distraction of the intervertebral endplates and stabilizes the distraction obtained with the Caspar retractor (Fig. 8). At the posterior portion of the disc,

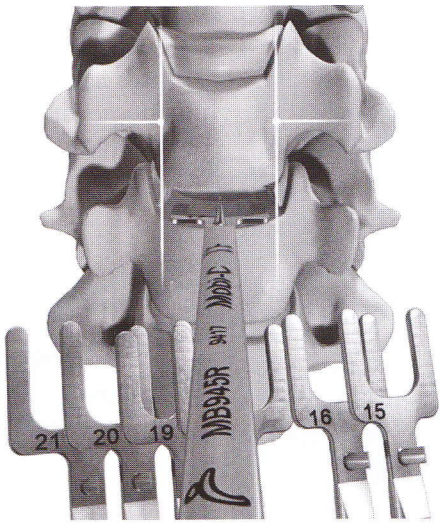

Fig. 7. Centering with the fork-like devices of progressively larger sizes abutting the uncinate processes: vertically under the pin is the middle of the vertebral body where the upper pin of the Caspar retractor is placed

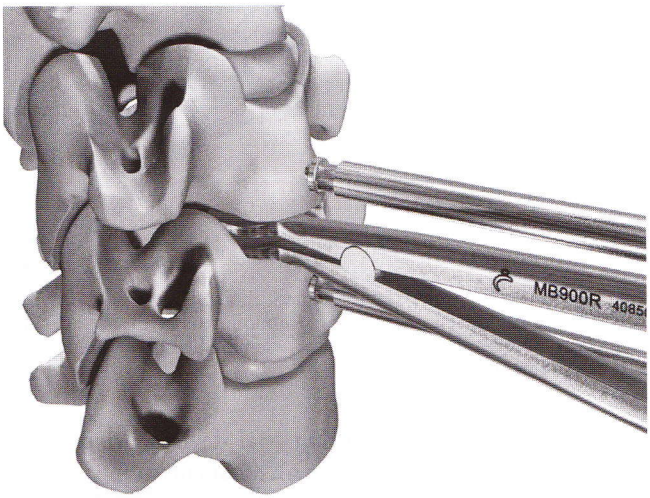

Fig. 8. Double intervertebral body distraction consisting of the intervertebral body distracting endplates, which distract the vertebral endplates horizontally, and the Caspar retractor with a superior and an inferior pin which maintain this parallel distraction

the surgeon cleans the vertebral endplates stopping at the subchondral bone. The surgeon may use a high-speed drill to carefully and progressively remove the upper and lower osteophytes from one uncinate process to the other. The posterior longitudinal ligament is traversed using an osteophyte hook or a small *rongeur* to remove the transligamentous disc herniation when there is one. The fork device used for centering is used to determine the width of the disc replacement. The anteroposterior dimension of the vertebral body is determined with a dedicated sliding measurer. With the width and depth, the size of the disc replacement is chosen as previously defined. The height of the prosthesis remains to be

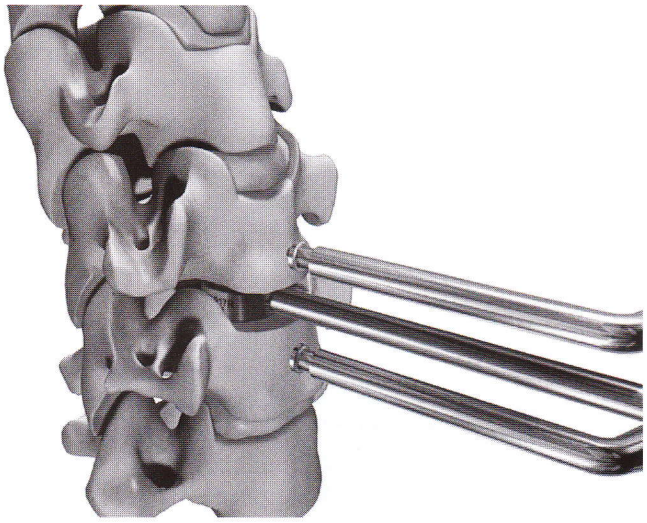

Fig. 9. Placement of the trial disc replacement to determine the prosthesis height, which should be the same as the height of the adjacent discs if they are healthy

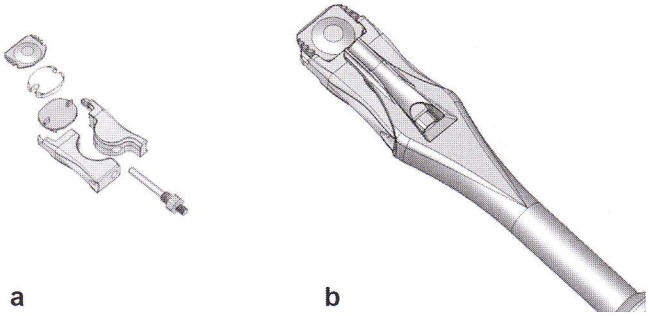

Fig. 10. Sterile and disposable implant holder in which the disc replacement of the chosen size is pre-mounted. a: all of the parts artificially disassembled; b: definitive assembled implant holder and disc replacement

determined. This is done using trial devices, which have heights of 4.5, 5, 6 or 7 mm (Fig. 9). Most commonly, we use the height closest to that of the adjacent disc. The prosthesis is mounted on a dedicated radiotransparent holder and inserted under fluoroscopic guidance (Fig. 10). It should be placed in the center of the vertebral endplates. The operative wound is closed over suction drainage. No external orthosis is needed. The patient is generally discharged 48 hours postoperatively. We believe that use of corticosteroids, which are recommended by some teams to prevent heterotopic ossification (HO), is unnecessary.

Results

Clinical results

Three hundred thirty-five patients have been enrolled in an ongoing prospective multicenter (both orthopedic and neurosurgical units) study in France. Seventy-seven patients (55% women) with 86 disc replacements (multilevel prosthesis in 12%) have completed 2-year follow-up. Mean age at operation was 44 years. Level C5-C6 was involved in 43%, C6-C7 in 35%, C4-C5 in 8% and C5C6 + C6C7 in 8%. Approach-related adverse events were observed in eight cases. The only reoperation to remove the prosthesis involved an adjacent syndrome next to a congenital block. At the mean follow-up of 2 years there was an improvement in Neck VAS from 46 preop to 21 postop, Arm VAS from 64 preop to 23 postop and Neck Disability Index (NDI) from 50% preop to 26% postop. Sixty-nine percent of the patients had a NDI improvement greater than 15 points and 91% said they would accept to undergo the same procedure.

Radiological results

The mean preoperative range of motion (ROM) in flexion-extension was 8.6° and the postoperative ROM was 9° (Figs. 11–12). At last follow-up, 85.5% of the levels had a ROM greater than 3°. There was no subluxation, no device migration and no subsidence. In most cases, the mean center of rotation on lateral X-rays was situated in the posterior half part of the inferior vertebral body in a more physiological position postoperatively than preoperatively [1] (Fig. 13).

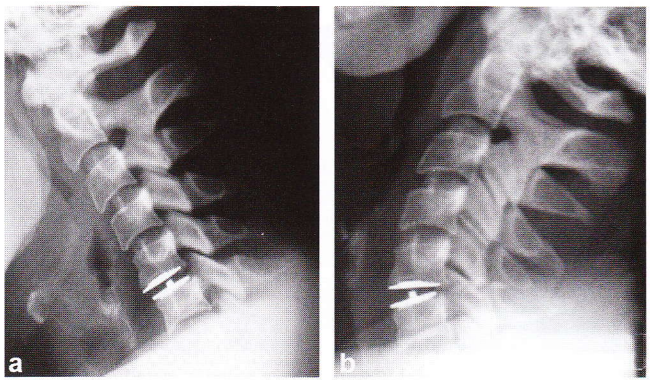

Fig. 11. Dynamic flexion–extension-bending films of a C5-C6 disc replacement implanted 3 years earlier. a: flexion film; b: extension film: one may note the contact between the spinous processes at the operated level

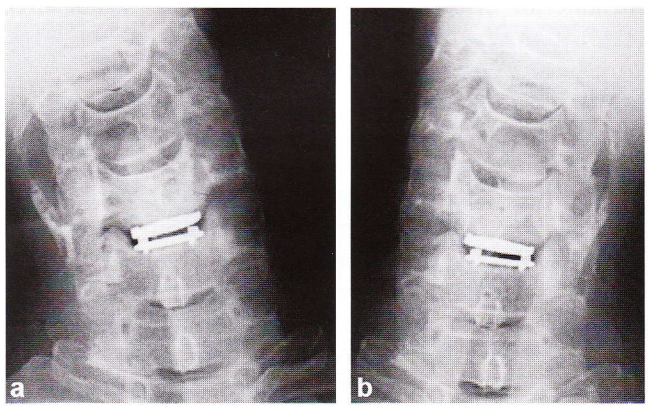

Fig. 12. Follow-up right (Fig. 2a) and left (Fig. 2b) lateral bending films of the same patient

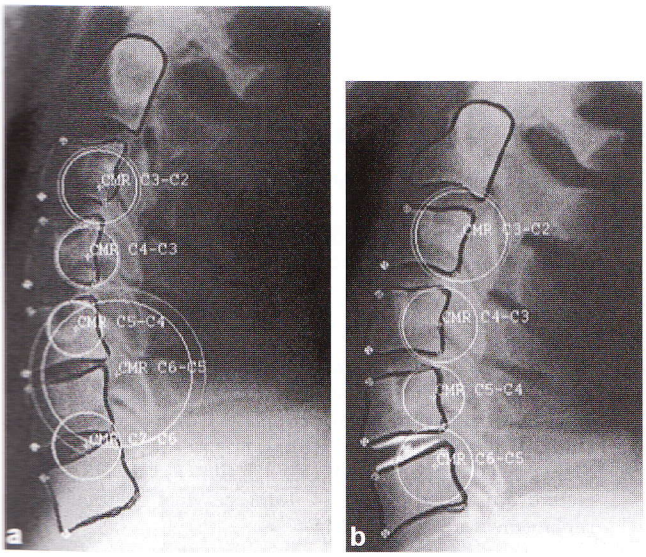

Fig. 13. Comparison of the instantaneous centers of rotation: a: intraoperatively; b: postoperatively; one may note the normalization of the instantaneous centers of rotation

Complications

The primary complications of cervical disc replacements are adjacent syndrome and HO.

Adjacent syndrome

Assessment of an adjacent syndrome is difficult, because one must distinguish radiological adjacent syndromes with abnormal imaging features on follow-up films, clinical adjacent syndromes consisting in neck pain and/or cervicobrachial pain, and surgical adjacent syndromes that necessitate revision surgery for severe discomfort. The frequencies of these three types of adjacent syndromes are obviously very different:

- around 90% for radiological adjacent syndromes;
- 15% for clinical adjacent syndromes;
- scarcely 5% for surgical adjacent syndromes.

Most studies, including the series reported by Robertson et al. [3], are consistent with the fact that cervical disc replacements reduce the number of adjacent syndromes with respect to cervical arthrodesis without eliminating them entirely. In our series, degenerative changes at the upper and lower functional adjacent levels have been assessed. Seventy-eight/76 patients at 2 years have been analyzed. It means theoretically 136 levels to be analyzed, but because of the same technical difficulties as in HO assessment at the index levels, only 110 levels could be evaluated.

The results are as follows: 5/65 upper adjacent levels show a slight degradation at 2-year follow-up, and the same was observed for 5/45 lower adjacent levels.

It means ten new degenerative changes/110 levels at 2-year follow-up (9.1%).

HO

HO in the vicinity of disc replacements are problematic. They can be classified into four classes according to McAfee as well as to Mehren et al. [4] (Table 1). Some authors believe that HO could be caused by use of high-speed drills, while others hypothesize that bleeding near the *longus colli* contributes to this complication. Some clinicians think that HO might be prevented by anti-inflammatory agents, based upon observations involving total hip replacements. Obviously, one should make use of surgical exposures that spare perivertebral structures as much as possible and perform rigorous hemostasis of bony bleeding. In our series, we have observed a certain number of cervical disc replacements with class II bony bridges (incomplete anterior bridging) and even some

Table 1. Distribution of the implanted levels 2 years of the surgery according to the McAfee and Mehren classification for HO

	Number of levels (%)
Class 0	25 (32.9)
Class I	9 (11.8)
Class II	33 (43.4)
Class III	3 (3.9)
Class IV	6 (7.9)

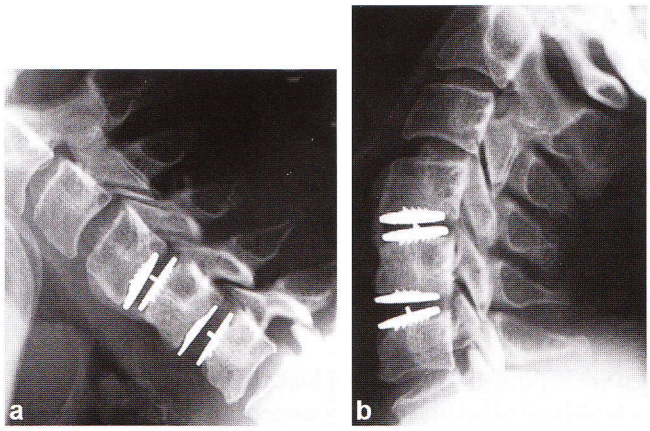

Fig. 14. Image of a bony bridge between C4 and C5 in a patient operated 3 years earlier with a double disc replacement at C4-C5 and C5-C6; one may note mobility almost as extensive as that of the underlying adjacent level despite the bony bridging (grade 3 in the classifications of McAfee and Mehren)

class III bridges (complete anterior bridging), nonetheless with preservation of flexion–extension and lateral bending mobility (Fig. 14). With disc replacements that are less constrained than the Mobi-C®, anterior bony bridging leads to complete fusion of the vertebrae. Taken together, classes 0, I and II represent 88.1% of the index levels and 98.5% of these levels (66/67) have a ROM $\geq 3^{\circ}$ at 2 years. Thus, although bone is present outside or inside the discal space, motion is not affected, even after 2 years.

Our results on motion suggest that the presence of HO does not have significant influence impact on motion at the index level, as mean ROM remains quite constant from 6 to 24 months after the surgery.

Considering the classes IV (six levels) and III (three levels), they can be regarded as non-functional prostheses, as motion is blocked (ROM $\leq 3^{\circ}$). However, in these eight patients, clinical outcomes are not altered compared to overall population, even at 2 years FU.

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Internat Surg (2008) 3: 201–204
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DOI 10.1007/s11610-008-0086-2

ORIGINAL ARTICLE

Baguera cervical disc prosthesis

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Abstract A new high performance tool, the disc prosthesis, endows the degenerative cervical rachidian pathology. It allows us to fill the fusions' lacunas by protecting the adjacent levels from an accelerated degeneration while preserving the anatomical and physiological characteristics of the cervical spine, especially its mobility. At the present time, there exist several models of cervical disc prosthesis on the market. We have tested some of them such as the Bryan®, the Prestige® and the Prodisc®. We have currently chosen the Spineart Baguera®C. In this article, we are going to present our experience of this prosthesis which was implanted in 49 patients between February and December 2007.

Keywords: Degenerative discopathy – Cervical disc prosthesis – Mobility

Introduction

The anterior cervical discectomy and fusion represents today the gold standard for treating degenerative pathology at the cervical level.

However, some studies [1,2] tend to show a more or less pejorative evolution of the patients who have benefited of this technique, concerning the contiguous levels of the one operated, especially accelerated discarthrosis degeneration with the necessity to intervene in time.

The total disc replacement method is a new tool in the therapeutic stock at the spine surgeon's disposal. It enables to bypass the ACDF's limits and it is more physiological because it maintains the operated segment's mobility and enables a better strain distribution on the contiguous disc levels as well as on the zygapophysis.

Furthermore, it is more anatomical by conserving the cervical lordosis and restoring the disc's height, which allows a good radicular decompression.

Patient and method

Between 2003 and 2006, we have implanted 40 prostheses in 25 patients, principally the Bryan®, the Prestige® and the Prodisc® [3].

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Our study showed that there are no significant differences between the implanted models.

Since February 2007, our choice was the Spineart Baguera®C mainly because of the simplicity of its implantation.

Fifty-three prostheses implanted between February and December 2007 in 49 patients:

- 18 men and 31 women;
- average age of 38 (28-57);
- C4-C5 = 7;
- C5-C6 = 23;
- C6-C7 = 17;
- C4-C5 + C5/C6 = 2;
- C5-C6 + C6/C7 = 4.

The Baguera® (Fig. 1) is a prosthesis made of two titanium plates covered by Dimolith® with a high-density polyethylene mobile nucleus.

Surgical procedure

The patient is placed supine, the head left straight in slight extension (Fig. 2). The incision is made preferably

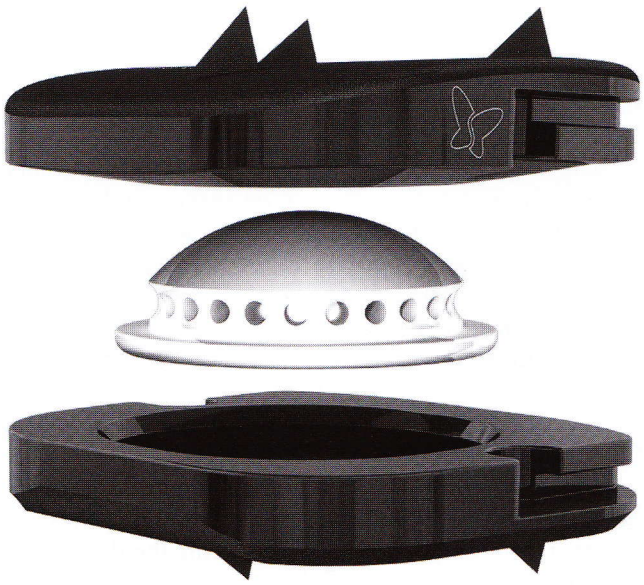

Fig. 1. Spineart Baguera®C

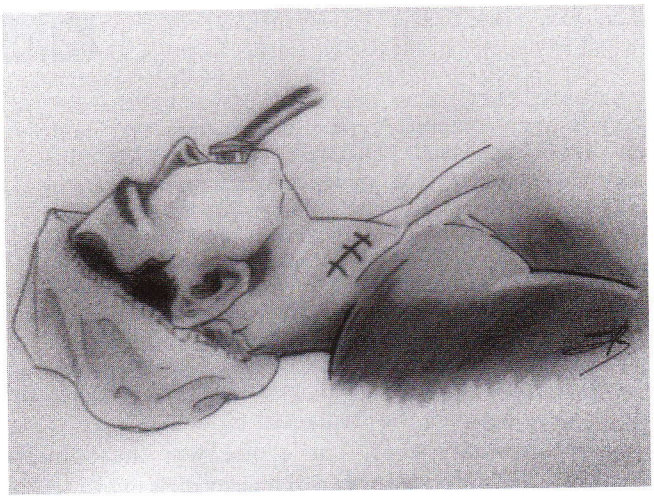

Fig. 2. Drawing of the patient's position: head straight in extension

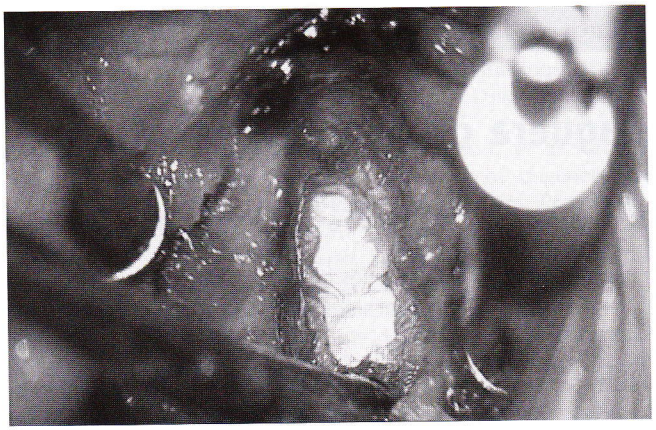

Fig. 4. Complete discectomy and posterior decompression with dura mater exposure

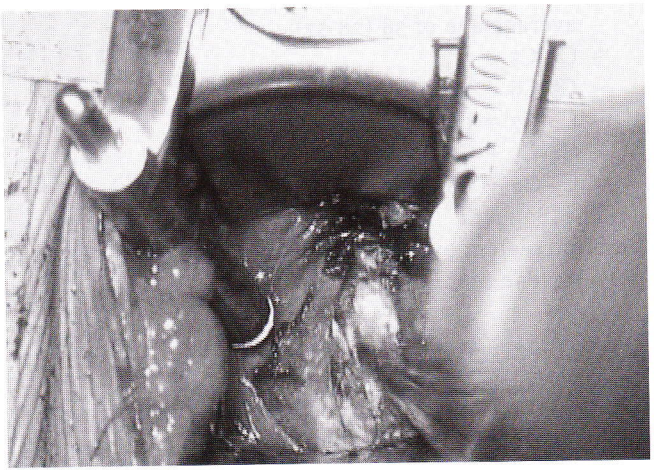

Fig. 3. Early times of the discectomy: opening with the tenotome

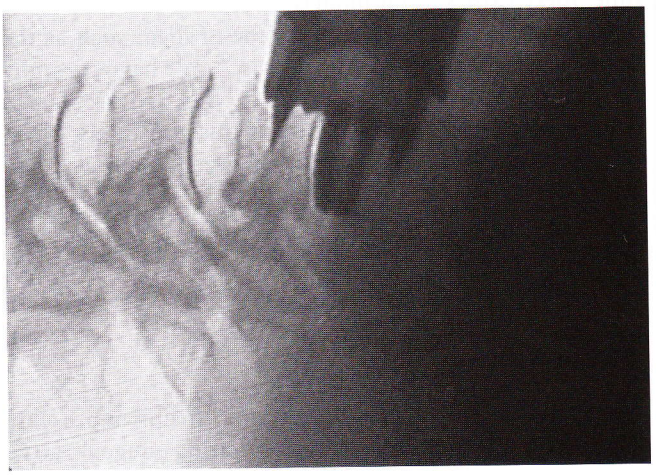

Fig. 5. Fluoroscopic control during the disc prosthesis implantation

for esthetic reasons in a pleat of the neck on the right-hand side, centered on the disc's level previously located by fluoroscopy.

The incision is made following the platysma's fibers. A blunt finger till the pre-vertebral surface and the deep cervical fascia performs the dissection of the space between the aero-digestive visceral sheath and the vascular-nervous sheath. After opening the deep cervical fascia, we detach the *longus colli* muscle of its median vertebral insertions facing the disc level concerned, then, under fluoroscopic control, we screw rods parallel to the two plates neighboring the disc allowing inserting the Caspar separator.

The discectomy is made with a tenotome (Fig. 3), completed with a curette in order to revive the plates and the unci. The Caspar separator performs the division.

The posterior decompression is achieved by opening the posterior longitudinal ligament uncovering the dura mater (Fig. 4), enabling then the extraction of possible soft hernias and even osteophyte's ablation by using a thin-lipped Kerisson Rongeur.

An uncusectomy is performed on its posterior third [4], which allows a good mobility as well as a lateral decompression in order to prevent a contact between the prosthesis and the roots.

The prosthesis size calibration will be done by inserting phantoms, then, once the size has been chosen, we proceed with the prosthesis implantation under fluoroscopic control to make sure of its proper positioning and the absence of any posterior protrusions (Fig. 5).

Results

The hospitalization lasted about 3 days, with simple postoperative consequences, no infection nor compressive haematoma.

Our clinical evaluation was carried on the brachial and cervical VAS, the neck disability index (NDI) and the SF36 scale.

The brachial VAS passed from a 7 average; preoperative limits (0-10) to 1.6 (0-8) in postoperative.

The cervical VAS passed from 6 (0-10) to 1.7 (0-7).

The NDI passed from a 45 average (0-84) to 14.8 (0-36).

The SF36 at M3 showed an average of 100.4 (80-140).

These results are comparable with those obtained with the other prosthesis types tested in our department.

Discussion

The cervical disc prosthesis seems to be a better alternative to the bone graft fusion techniques or intersomatic cages.

The technique's medical indications [5] are quite limited, they being reserved only for degenerative discopathy (Figs. 6-8) with vertebral arthrosis signs among patients aged from 18 to 65 years.

There also exist borderline indications still in debate, which are the cervicarthrosic myelopathy and the isolated cervicodynias.

The installation was greatly simplified thanks to the surgical procedure's evolution and the surgical tools put at our disposal.

However, there is a risk, in time, of a mobility loss due to calcifications therefore restraining the prosthesis' movements [6].

Time will tell us if the operated levels' mobility will persist and if the adjacent levels are preserved.

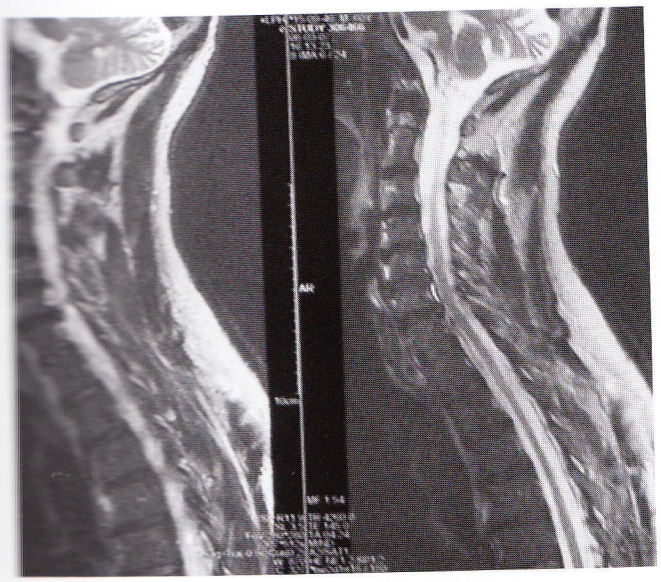

Fig. 6. MRI sagittal cuts of a 51-year-old patient presenting cervical disc hernia C6-C7

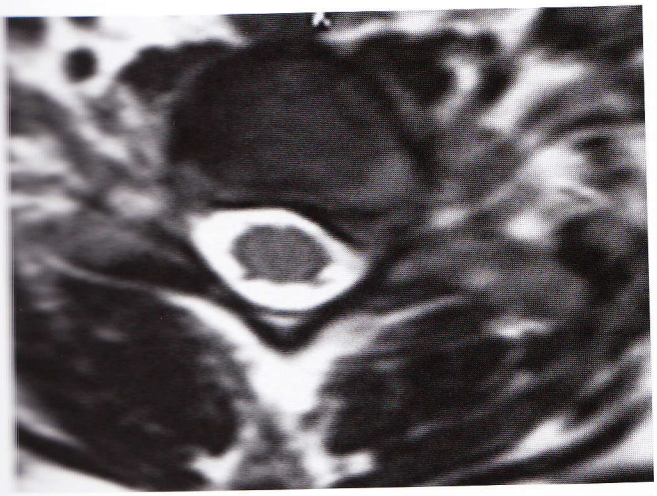

Fig. 7. MRI axial cut of the same patient showing the left posterolateral disc hernia with a C7 radicular conflict

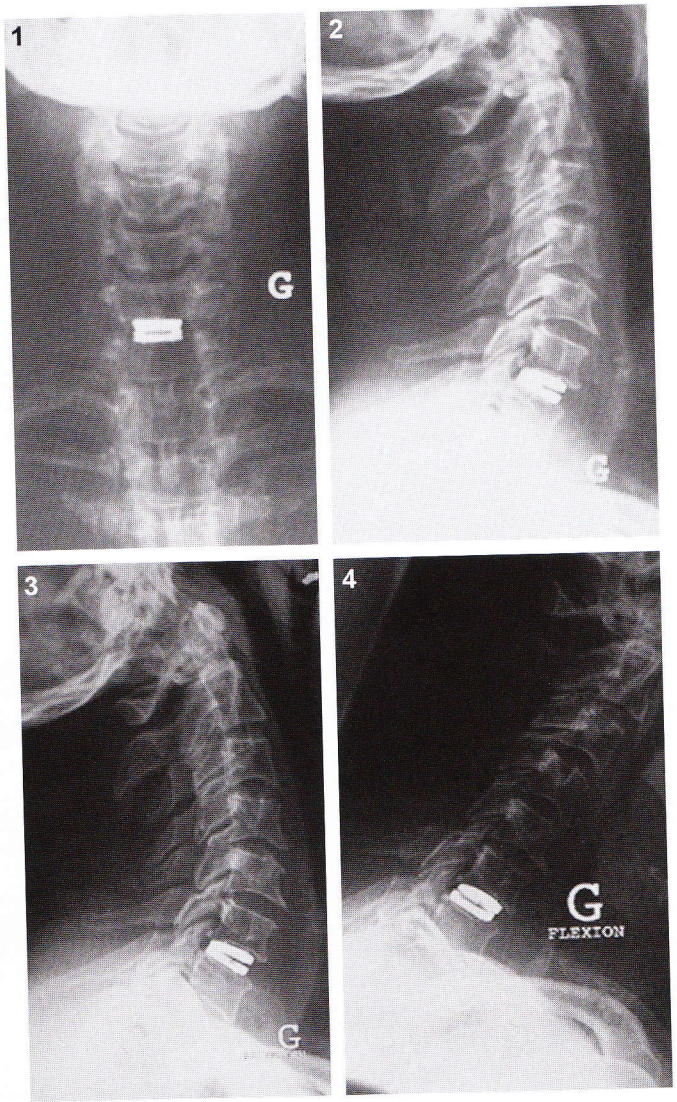

Fig. 8. Postoperative radiography of the same patient showing the intact lordosis and the operated level mobility: (1) facing; (2) profile in neutral position; (3) profile in extension; (4) profile in flexion