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Radiolucent cage for cervical vertebral reconstruction: A prospective study of 17 cases with 2-year minimum follow-up

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Abstract In cervical spondylotic myelopathy, extended anterior spinal cord decompression necessitates subsequent stable vertebral reconstruction. Reconstruction with an iliac crest graft and screw-plate fixation gives satisfactory clinical and radiological results, but they are often compromised by morbidity involving the bone harvest. The purpose of this study was to evaluate the contribution to cervical reconstruction of a biocompatible, radiolucent cage combined with screw-plate fixation, making use of bone harvested in situ. This prospective study was performed between July 2000 and March 2001 in eight women and nine men (mean age, 55 years) operated for cervical spondylotic myelopathy. Situated between levels C3 and C6, the cage was inserted after one corporectomy in ten patients, two corporectomies in five patients, and three corporectomies in two patients. The cage consisted of a polyester mesh impregnated with poly-L-lactic acid (PLLA) conferring temporary rigidity to the cage during bony fusion. Clinical and radiological follow-up (plain films, computed tomographic reconstruction in three cases) was performed at 2 months, 6 months, 12 months, 24 months and 36 months, postoperatively, with a mean follow-up of 30 months. Functional results were evaluated according to the Japanese Orthopaedic Association's

scoring system. An independent surgeon assessed the radiological evidence of anterior cervical fusion using the grades proposed by Bridwell [6]. Every patient experienced neurological recovery. At last follow-up, radiological findings were consistent with grade I (complete fusion) in five cases, grade II (probable fusion) in ten cases, grade III (radiolucent halo in favor of non fusion) in one case, and grade IV (graft lysis) in one case with persistent neck pain. In three cases there was screw breakage (two grade II, one grade IV). None of these cases required surgical revision at latest follow-up. In extensive spinal cord decompression through an anterior approach, cervical reconstruction using the present type of cage can achieve clinical results comparable to conventional techniques. The rigidity of the cage meets biomechanical imperatives. Its radiolucency permits one to monitor the course of consolidation, contrary to metal cages. The cases of probable non-fusion and screw breakage were not accompanied by signs of instability on the flexion extension films. This cage meets the biologic and biomechanical imperatives of cervical reconstruction. It obviates complications involving bone harvest.

Keywords Cervical myelopathy · Cervical reconstruction · Mesh cage · Corporectomy · Fusion

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Introduction

In cervical spondylotic myelopathy, extensive decompression of the entire region of compromise spinal cord through an anterior approach is necessary. Spinal stabilization by arthrodesis with internal fixation provides satisfactory results. Since the initial description by Robinson and Smith in 1955 [20], the technique of anterior cervical arthrodesis has progressed. Isolated use of bone grafts, proposed by Bailey and Bagdley [4], Cloward [9], Verbiest [26], and Simmons and Bhalla [23] has often been criticized, notably in traumatic instability, because of the risk of secondary displacement. In the degenerative spine, this type of complication is more rare, and the technique of bone grafts without osteosynthesis can be used after decompression of one level. When decompression is more extensive, complementing with osteosynthesis appears to be preferable [5, 21].

In cervical spondylotic myelopathy, decompression through an anterior approach permits resection of compressive bone spurs and disc lesions, while instrumented arthrodesis contributes to stability and preservation of lordosis. In our experience, the posterior approach is still indicated in extensive decompression when cervical lordosis is preserved and in ossification of the posterior longitudinal ligament, because of its frequent adhesion to the dura mater in the latter disorder.

Arthrodesis with autologous iliac crest graft is considered as the biologic and biomechanical standard in anterior cervical reconstruction [2, 7, 13, 27, 28]. However, morbidity involving the site of graft harvest remains high

and can compromise the often satisfactory clinical result of cervical nerve root and spinal cord decompression [3, 22].

Two alternatives to iliac graft harvest enable cervical arthrodesis after anterior decompression: the use of bone substitutes and the use of cages. Concerning the bone substitutes, although they can be proposed in transdiscal decompression procedures, they appear poorly adapted to extensive cervical reconstruction, because of failure to achieve viable bone. Using titanium cages, one can take advantage of the biologic properties of the autologous bone harvested during the decompression. Furthermore, such cages meet biomechanical imperatives. However, the radiopaque nature of these cages hampers evaluation of the bony fusion; the absolute rigidity increases the risk of stress shielding, and the straight structure is poorly adapted to the physiological curvature of the spine.

For these reasons, we have developed and assessed a new type of radiolucent vertebral cage, solid but flexible to compression and easy-to-cut: "Biocage" vertebral cages (Cousin Biotech). The purpose of this prospective study was to perform a radiological and clinical assessment of "Biocages" implanted in 17 patients between July 2000 and March 2001.

Materials and methods

This prospective study included 17 patients (nine men and eight women) who underwent surgery for symptomatic, cervical spondylotic myelopathy between July 2000 and March 2001 (Table 1). The average age at intervention was 55 years (range, 30–80 years).

Table 1 Demographic parameters (JOA Japanese Orthopaedic Association score)

Case	Sex	Age (years)	Level of corporectomy	Smoker	JOA		JOA Recovery rate	Grades of fusion at 24 months	Lordosis C2–C7 (degrees)	
					Preop	Postop			Preop	Postop
1	F	60	C5–C6	No	13	15	50	II	13	13.5
2	M	62	C5	Yes	9	15	75	I	12	13.5
3	F	59	C5–C6	No	10	14	57	I	14	14.5
4	F	48	C5–C6	No	14	17	100	II	10	19
5	F	80	C4–C5	No	11	13	33	I	8	12
6	F	67	C5	No	11	12	17	II	15	20
7	M	56	C5	No	10	14	57	II	14	14.5
8	F	52	C6	No	12	16	80	II	10	11.5
9	M	71	C4–C5–C6	Yes	11	14	50	II	10	14.5
10	F	66	C6	No	10	15	71	I	11	12.5
11	F	45	C6	No	14	17	100	II	10	13
12	M	41	C5	No	12	17	100	II	20	15
13	M	44	C5	Yes	13	16	75	II	14	15.5
14	M	49	C4–C5	No	10	14	57	III	13	15
15	M	30	C4	No	11	14	50	I	13	16
16	M	47	C6	No	14	17	100	II	11	13
17	M	64	C5	No	10	16	86	IV	8	9

Fig. 1a–c Surgical technique. **a:** cutting the cage, **b:** morselized bone graft in the cage, **c:** cage and anterior plate. **a** The Biocage was cut to be 2–3 mm longer than the measurement provided by a slide gauge; **b** the cage was contoured, and the cutting angles were slightly oblique at the extremities to maintain anatomical cervical lordosis; and **c** bone was compressed in the cage, and the blood contained in the morselized bone graft was evacuated in the cage jig

Three of the 17 patients were cigarette smokers. Mean follow-up was 30 months (range, 24–36 months). The operative indication was a somewhat extensive, symptomatic cervical spondylotic myelopathy.

The vertebral cage was implanted after one corpectomy in ten cases, two corpectomies in five cases and three corpectomies in two cases. Every case involved levels between C3 and C6, inclusive. The shape of the vertebral Biocage is tubular and bent. The bending simulates the anatomical curvature of the spine. The structure of the cage is obtained using wide-mesh-woven polyester tissue closed by a seam, giving the implant its tubular shape. A thread impregnated with barium sulfate is inserted in the seam for easy location of the cage during radiological verification, while preserving its radiolucency. Impregnation of the tube with a solution of poly-L-lactic acid (PLLA) affords the cage's rigidity. As the PLLA disappears, the lateral openings of the cage become available, permitting bony recolonization.

The constraint of the cage, corresponding to the load applied for a given surface, is 1.5 daN/mm² for the empty cage and 3.8 daN/mm² for the cage filled with bone. The elasticity of the materials used reduces the stress-shielding effect. Concerning the surgical technique, decompression was achieved through an anterior approach. Once exposure was obtained, discectomies adjacent to the vertebral body were performed. The corpectomy was performed alternately using a micro-drill, permitting the bone dust mixed with blood to be gathered with a curette, and a gouge supplying more compact and more voluminous osseous fragments.

Resection of the posterior longitudinal ligament permitted satisfactory decompression of the nerve root and spinal cord. The precise length necessary was measured using a slide gauge. Concerning depth, we systematically used cages 12 mm in diameter, leaving a margin of security between the cage and the dura mater.

The Biocage was cut to be 2–3 mm longer than the measurement provided by a slide gauge. The cage was contoured, and the cutting angles were slightly oblique at the extremities to maintain anatomical cervical lordosis (Fig. 1).

Bone was compressed in the cage, and the blood contained in the morselized bone graft was evacuated in the cage jig. During cage placement, cranial traction was applied to lengthen the space into which the cage was implanted in compression. This arthrodesis was systematically instrumented with an anterior screw plate secured to the adjacent vertebrae. The wound was closed with re-approximation of two anatomic planes over a suction drainage system. The patient returned to the upright position the day after the intervention, protected by a soft cervical collar.

Intraoperatively, antibiotic prophylaxis, intravenous Solumedrol to prevent edema, and a class II analgesic were administered.

Table 2 Classification in grades of anterior fusion proposed by Bridwell

Grade I (definite)	Fused with remodeling and trabeculae
Grade II (probable)	Graft intact, not fully remodeled and incorporated through; no lucencies
Grade III (probably not)	Graft intact, but a definite lucency at the top or the bottom of the graft
Grade IV (no)	Definitely not fused, with resorption of bone graft and collapse
Grade V (unable to assess)	

Mean blood loss was 220 ml (110–400 ml). Clinical and radiological follow-up (plain films, and, in three cases, computed tomographic reconstruction) was performed at 2 months, 6 months, 12 months, 24 months and 36 months postoperatively. At final follow-up, all patients underwent interview and physical examination. Clinical findings were scored according to the criteria for evaluation of treatment of cervical myelopathy proposed by the Japanese Orthopaedic Association (JOA score) [15]. The JOA scoring system was adapted to a European population. A recovery rate was calculated by Hirabayashi's method [15].

The curvature of the cervical spine was determined by measuring the angle formed by two lines extending from the posterior borders of the second and seventh cervical bodies, in the neutral position. The radiological images were evaluated by an independent surgeon using the classification in grades of anterior fusion proposed by Bridwell [6] (Table 2).

Results

In the immediate postoperative period, neurological examination was normal in every case, and the radiographic work-up confirmed the appropriate positioning of the vertebral cage. There was no complication during the immediate postoperative period. Clinically, 16 patients had complete relief from the neurological symptoms, without associated neck pain at last follow-up. Two patients had abnormal persistence of the neck pain, which began to diminish later than anticipated from experience. This pattern was not accompanied by radiological abnormalities (normal flexion–extension films) and resolved after prolonged use of a Minerva collar. At last follow-up, one patient experienced worsening of neck pain. This was the patient who had radiological signs of non fusion.

Fig. 2 At last follow-up, **a** five patients had a radiological assessment of grade I (complete fusion); **b** ten had grade II (probable fusion); **c** one had grade III (radiolucent halo, probable non-fusion); and **d** one had grade IV (bone graft lysis)

Overall clinical results

The average preoperative and postoperative scores (JOA) were 11 points and 15 points, respectively, with a mean improvement rate of 68%. At last follow-up, five patients had a radiological assessment of grade I (complete fusion); ten had grade II (probable fusion); one had grade III (radiolucent halo, probable non fusion); and one had grade IV (bone graft lysis) (Fig. 2). Sagittal CT reconstruction performed in three cases confirmed the ranks of fusion observed on plain films. In three patients, there was screw breakage, which was accompanied in one case by a grade IV result and in two cases by a grade II result. At the last follow-up, there was a maintenance of measured cervical lordosis, with 12.1° on average (to 8° from 20°) into the preoperative stage and 14.2° at 2 years (to 9° from 20°). None of these patients required surgical revision at latest follow-up.

Discussion

In cervical reconstruction, after extensive decompression through an anterior approach, the use of an iliac crest graft

associated with screw-plate fixation gives satisfactory results, both clinically and in terms of the quality of bony fusion achieved [2, 7, 13, 27, 28]. However, the morbidity of the iliac bone harvest can often tarnish these results. According to Arrington et al. [3], on the average there are minor complications (superficial infections, hematoma, cosmetic problems, etc.) of the donor site in 10% of cases and major complications in 5.8% of cases, requiring therapeutic modifications, surgical revision, and prolongation of the duration of hospitalization. Silber et al. [22] observed that 26.1% of patients reported pain of the donor site, with visual analog scale values between 3.8 and 10 on a scale of 10. The use of vertebral cages responds to biomechanical imperatives and, by use of bone harvested in situ during the corpectomy, avoids complications involving the bone harvest.

Currently available cervical reconstruction cages are made of metal, which hinders radiological monitoring of bony fusion [1, 11, 12, 18, 24]. M.E. Madj et al. [18] studied the efficacy and safety of titanium cages associated with an anterior plate in cervical reconstruction. Thirty-four patients (mean age, 51 years) were treated by corpectomy and implementation of titanium cages filled with morselized,

autologous bone harvested from the vertebral bodies. In 30 cases, an anterior plate was used in the arthrodesis (a plate was added when the decompression involved two levels or more). Average follow-up was 32 months, consisting of clinical and radiological examinations. Pseudarthrosis was found in 3% of the patients. The authors of that study stressed several advantages of vertebral cages, including avoidance of graft harvest from the iliac crest and, *de facto*, the related complications. They also emphasized the efficacious alternative of a cage with plate fixation, as opposed to conventional autologous bone grafts, in terms of immediate, solid support for the anterior column. They noted the infrequency of complications involving the material.

Das et al. [11] retrospectively studied 38 patients (mean age, 46 years), 28 having undergone a discectomy, and ten a corpectomy. All had had arthrodesis with cylindrical titanium cages filled with autologous bone graft harvested from the operative site and screw-plate fixation. Clinical and radiological follow-up was performed postoperatively at 3 months, 6 months, and 12 months, then yearly. Mean follow-up was 16 months. Fusion was defined indirectly by the absence of both segment mobility and breakage of the fusion hardware. According to this definition, fusion was considered achieved in 100% of the patients. In the opinion of those authors, the classic technique of decompression followed by arthrodesis with an iliac crest graft provides satisfactory results in 80% of cases, and the rate of pseudarthrosis ranges 6–8% for one level and 15–46% for treatment of several levels. In their opinion, the advantages of combining titanium cages with an anterior plate included better preservation of cervical lordosis, shorter convalescence, better resistance to axial-compression-force load, and the possibility of “recycling” the bone from the corpectomy, thus avoiding iliac crest harvest.

Riew et al. [19] assessed the use of titanium cages in cervical vertebral reconstruction. In 54 patients with a follow-up of 2 years, they observed no displacement of the material, no infection, and no neurological deficit. In their opinion, the fusion rate was comparable to that of conventional techniques. Two patients required surgical revision for pseudarthrosis. Both cases involved decompression of several levels in patients who smoked.

Van Dijk et al. [25] evaluated the consequences of the rigidity of cages on the rate of lumbar interbody fusion. Three types of cages were implanted in 15 sheep at the L3–L4 level: three titanium cages with a resistance to axial compression of 700 kN/mm, six rigid PLLA cages with an axial resistance of 4 kN/mm and six flexible PLLA cages with a resistance of 2 kN/mm. These cages were filled with autologous iliac crest. After 6 months, the rate of fusion was significantly higher with the PLLA cages than with the titanium cages of the same shape. The histological analyses at 3 months and 6 months of radiolucent areas corresponded to developing endochondral bone. The substantial reduction in the rigidity of PLLA cages with

respect to that of titanium cages increased the arthrodesis fusion rate. However the biologic tolerance of PLLA degradation by-products needs to be confirmed by long-term studies.

Our series is not easily comparable with that of Van Dijk [25], because the cage used is a polyester covered with PLLA, whereas the study of Van Dijk relates to cages in PLLA. However, the reduction in the rigidity of the cage appears to be a factor supporting the osseous consolidation.

In the present series, there was one case of hardware breakage with radiological signs of non fusion at last follow-up. This patient experienced worsening of neck pain. Shortly after the operation, this patient was the victim of an accident severe enough to cause a fracture of the acetabulum. Radiological follow-up of the cervical spine performed soon after the accident was normal. At last follow-up, the dynamic bending films showed no evidence of instability. Although a decision to propose surgical revision has not yet been made, the diagnosis of non fusion has been retained in this patient.

The other two cases of osteosynthesis screw breakage were not accompanied by deterioration in clinical status. Plain films showed probable fusion (grade II) in both patients. The dynamic bending films showed no sign of instability. In these two cases, even though fusion appears to have been achieved, hardware failure may reflect pseudarthrosis and radiological monitoring should be prolonged. As with metal cages, the present cage provides good primary stability and obviates the necessity of iliac crest grafts, reducing both operative duration and complications related to graft harvest.

The potential advantages of the present cage over metal cages include:

1. Straightforward sectioning of the cage, facilitating adaptation to the extent of vertebral resection
2. Relative flexibility permitting compressive stress on the graft during loading, contributing to consolidation
3. Radiolucency allowing follow-up of fusion
4. Bioresorbable constituent initially blocks the openings of the Biocage, facilitating compaction of the bone graft filling and maintaining it in place. Reopening of these orifices with time permits secondary extension of bony fusion around the graft

Conclusion

This PLLA cage appears to meet the biologic and biomechanical imperatives of cervical reconstruction after extensive decompression. A prospective study comparing this cage with iliac crest grafts in cervical reconstruction is currently underway to confirm the quality of the arthrodesis obtained, the biologic tolerance of the cage, and the advantage gained by eliminating complications related to harvesting iliac crest grafts.

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