THE INTEREST OF POROUS CELLULAR ALUMINA BIOCERAMICS IN SPINAL SURGERY

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SUMMARY

Objective of the study: To study the behaviour of the porous cellular alumina cervical cages (CERAMIL®), associated with or without anterior osteosynthesis plate fixation depending as needed.

Material and method: The population studied was composed of 61 patients who underwent spinal surgery between May 1999 and October 2003 (48 female patients and 13 male patients with an average age of 49 years at the time of surgery). 74 implants were used with 71 of these being intersomatic cages. 10 patients were operated at 2 levels; C5-C6 and C6-C7 were the levels most often concerned. Patient follow-up was at 1 month, 3 months and 6 months and where possible past 6 months. Clinical and radiological data were available for all patients.

Results: The mean follow-up was 7,2 months. Post-operative clinical data included assessment of neck and arm pain, using a standard visual analogic scale and fusion status determined by the presence of trabecular bridging bone and the disappearance of lucent lines around the implant on plain anteroposterior and lateral cervical radiographs. Two patients required another intervention, allowing intra-operative assessment of the quality of fusion. Symptomatic improvement is consistent with data from the literature, with 54% of the patients free from any form of residual cervical or radicular pain at follow-up, while a zero or very moderate activity restriction was found in 88% of cases. Total bone fusion was obtained on average in 6 months in 58 cases and in all cases at 12 months, including the two patients who required revision.

Discussion: The porous cellular alumina ceramic cage constitutes a perfectly bio-compatible and mechanically stable implant, allowing a good and quality bone fusion. The integration of bone appears satisfactory on the control versions and these type of implants are therefore perfectly adapted to cervical spinal surgery, avoiding the use of an autologous graft that can result in donor site graft complications.

Cervical micro-discectomy with an intersomatic transplant is a well-known procedure of neurosurgeons in the treatment of cervical discopathies (degenerative disc disease), and widely diffused since its original description [3, 5, 8, 9, 16, 21]. The use of an intersomatic transplant is not unanimous, meeting some opponents advocating a simple discectomy, which was able to prove its safety, but not necessarily its long-term results [19,22]. However, in the case of a grafting option, the material of choice remains the autologous bone graft, in spite of the non-negligible morbidity in relation to the sampling area [4, 23, 29, 30]. We report here our experience in the use of porous alumina ceramics in place of autologous bone grafts.

MATERIAL AND METHOD

Between May 1999 and October 2003, 61 patients were operated in the same institution and by the same surgeon using alumina ceramic implants (intersomatic cages or reconstruction blocks) commercialized at this stage by the company M.I.L. *(fig.1).* These bioceramics are of strictly mineral composition, intended for use in medicine, in accordance with the NF S 90-408 standard, and are available in various sizes, varying from 12 to 16 mm in length, from 11 to 16 mm in depth and with variable heights, always asymmetrical, ranging from 4/2 to 6/4 mm.

Fig. 1 – Appearance of unpacked ceramic cages

This type of procedure has benefited patients with a cervical degenerative pathology at one or two levels, constituting a radiologically proven disco-osteophytic bar with radio clinical concordance, or patients with symptomatic disc herniation. The use of associated screw-plate osteosynthesis was not systematic, except in patients with lesions due to trauma or corporectomy.

The average age was 49 years with a minimum age of 21 years and a maximum age of 81 years. The indications were dominated by the treatment of cervico brachial neuralgia rebellious to the usual conservative therapeutics with a minimum duration of evolution of three months and are summarized in (*Table I).* It was a 1-level discectomy-graft in 49 cases, 2 levels in 10 cases, representing the use of 71 intersomatic cages (2 patients had to be re-operated) making it possible to appreciate the quality of integration of the material. The sex ratio was 2.7 in favour of the female sex. All patients were systematically reviewed at 1 month and at least once between 3 and 6 months postoperatively, or more, as often as possible, with an average follow-up of 7.2 months (3-17 months). Two patients underwent corporectomy with reconstruction blocks at (C5) level in 1 case and at 2 levels (C5 and C6) in another case, requiring 3 reconstruction blocks in total. Thus 74 devices have been implanted and represents the basis of this study.

SYMPTOMS	NUMBER OF PATIENTS (%)
Cervicalgia	61 (100)
Systemic unilateral radiculalgia	
C5:	2 (3)
C6:	25 (41)
C7:	20 (33)
C8:	3 (5)
Un-systemized, united or bilateral radiculalgia	9 (15)
NEUROLOGICAL SIGNES	
Motor deficit	10 (16)
Hypoaesthesia	27 (44)
Modification of osteotendinous reflexes	11 (18)

Table 1. Neurological signs and symptoms

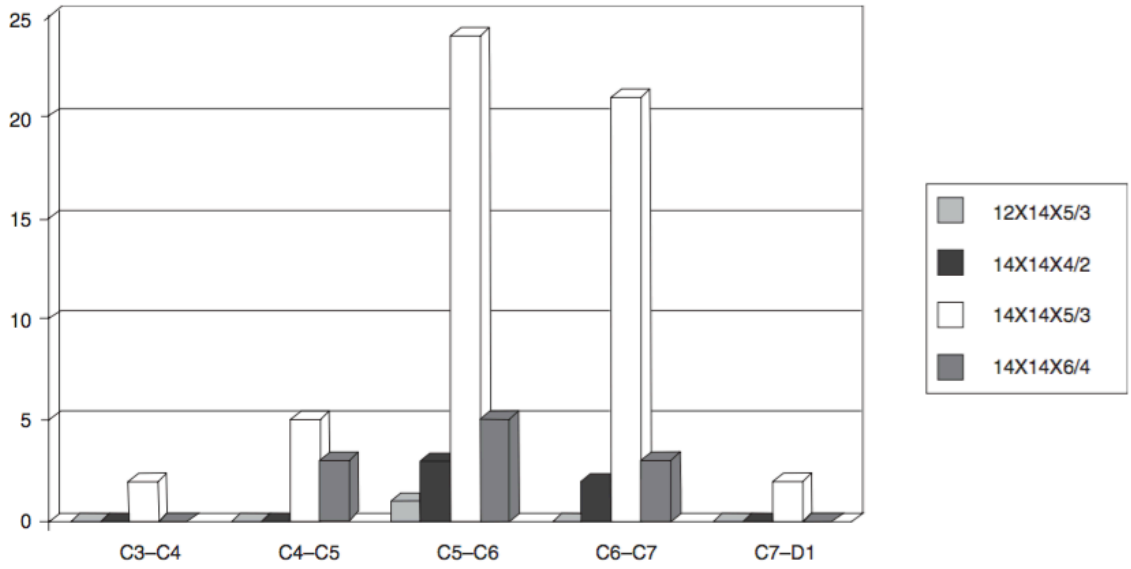


Fig. 2. Type pf implant used and operated levels

The level operated at and the type of implant implanted are shown above in *figure 2.* Assessment of the results, both functional and radiological, was carried out during the most recent consultation, at least 3 months (3 cases) if not most often at 6 months postoperative and is based on the following items:

- Algic relief

Pains were assessed, both in terms of neck pain and the possible existence of systemic radicular pain when it existed, using a standard visual analogue scale (VAS), graded from 0 to 10, with the lowest values representing the most moderate pain: 0 = insignificant or absent pain, 10 = worst pain imaginable [13].

- Functional results

It was evaluated according to the score of Prolo [20] (*Table 2*) with a good result assigned to a score between 8 and 10 and a bad result for a score less than 8.

- Radiological findings

The fusion was assessed on the presence of interosseous bridges and / or the complete disappearance of the radio transparent rim surrounding the implant at least 3 months of its placement on the standard images of front and profile (possibly confirmed at the scanner in case of doubt or shots of poor quality), carried out systematically before the last inspection.

RESULTS

No infectious complications were reported. Two patients had to be re-operated: one, for a break of the screw that occurred 15 months after the intervention while the fusion appeared correct on the control plates; the other in connection with a partial dislocation of the implant *(cf. case 2).* During this re-intervention, under pressure from the patient and the attending physician, a perfect ossification with no residual mobility at the level of the instrumented segment was observed, with a new plate placed in place of the previous one, with screws of greater length creating a bi-cortical fastening. The dramatic result on the alleged residual dysphagia raises a more than serious doubt about a probable underlying psychological problem, not elucidated to date, the patient having been regularly checked since then for other problems without any residual complaint at this level.

ECONOMIC	FUNCTIONAL
E1 : Complete invalidity	F1 : Total incapacity (worse than prior to operation)
E2 : Incapacity to work, including retirement activities	F2 : Cervicalgia, brachialgia or persistent paraesthesia, preoperative motor deficit unchanged
E3 : Necessary to change employment	F3 : Moderate cervico brachial neuralgia and / or paraesthesia and / or slight motor weakness
E4 : Capacity to work (same employment but part time)	F4 : Persistent paraesthesia, no cervico brachial neuralgia
E5 : Capacity to work with no restrictions	F5 : Total recovery

Table 2. Prolo score

Algic relief

The distribution of the recorded results is collated in *(Table 3).* Cervicalgia was found in all pre-operative patients and in only 45% at the last contact, with an average score at VAS, from 6.7 to 1.72 post-operatively. In pre-operative surgery, more than 9 patients out of 10 had radiculalgia in the upper limbs, while only 41% still complained of post-operative upper limb pain, of which only 2 patients were algic at level 7 or 8 of VAS, with the mean score increasing from 7.05 pre-operative to 2.1 post-operatively. In total, 54% of patients no longer complained of any post-operative pain in the neck or upper limb.

Neurological results

Ten patients had moderate to severe neurological deficit in preoperative surgery, 4 of which were related to cervicarthrosis myelopathy. The deficit was expected to improve or disappear in two patients with spinal cord injury and to disappear completely in 4 patients with radicular deficiency.

Functional results

Pre-operatively, 80% of patients reported moderate to severe discomfort, with disruption of any occupational activity in 65% of cases. Correlated to the Prolo score, there were 7 poor results (E2F2: 2, E2F3: 2, E2F4: 2 and E3F4: 1) with no return to work in 5 pre-operative patients, 4 of which relate to the consequences of an accident at work.

Radiological results

In 58 cases, the fusion, assessed on the criteria used, was confirmed within an average of 6 months, and in all cases with a sufficient follow-up, at 15 months, including patients requiring re-operation. The two patients who underwent corporectomy, using a reconstruction block, saw a complete internalization of their graft, in one case this was at 7 months, the follow-up of the other patient was insufficient (4 months) to confirm a complete consolidation (contact lost with patient, the clinical result at the last contact was however satisfactory).

VAS Score	NUMBER OF CASES (%)			
	CERVICALGIA		RADICULALGIA	
	Pre-operative	Post-operative	Pre-operative	Post-operative
Pain:				
Extreme (9-10)	12 (20)	0 (0)	14 (23)	0 (0)
Severe (7-8)	24 (40)	1 (2)	30 (49	2 (3)
Moderate (5-6)	18 (30)	5 (8)	13 (21)	8 (13)
Mild (2-4)	7 (10)	21 (35)	2 (3,5)	15 (25)
None (0-1)	0 (0)	34 (55)	2 (3,5)	36 (59)
Score:				
Average	6,7	1,72	7,05	2,1
Median	7	1	7	1
Minimum	2	0	0	0
Maximum	10	7	10	8
**VAS : Visual Analogue Scale*				

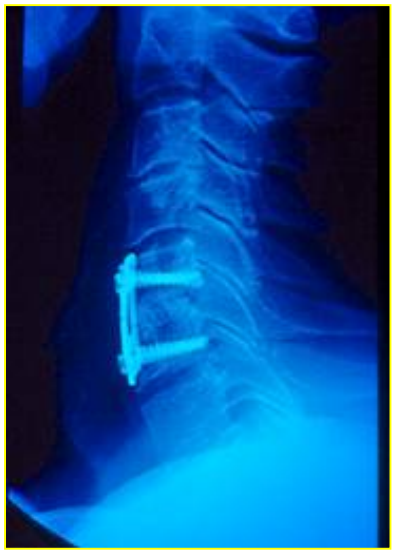
*Table 3. Score VAS**

CLINICAL ILLUSTRATION

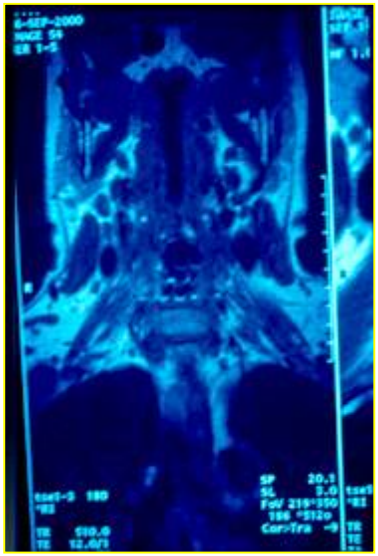
Case n° 1

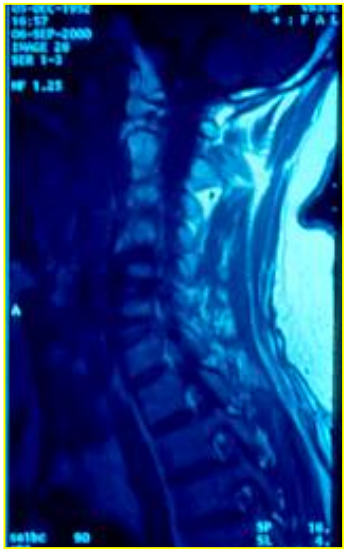
Patient of 47 years old, farmer, victim to a fall off a horse in February 1999 with cervical traumatism in flexion. Rapid installation of left cervico brachial neuralgia, C6 topography, non deficient, associated with moderate cervicalgia. Conservative treatment ineffective, including the use of morphine. The intensity of the radicular pain was rated at 7 on the VAS. The radiological findings reveal a C5-C6 discopathy evolved on the standard X-ray images, while the CT scan reveals a partially calcified left C5-C6 disc herniation, on an old osteophytic bar. The intervention occurred on the 10/11/1999 with the realization of a discectomy graft, using an implant of average size (14x14x5/3). Immediate post-operative relief with residual pain rated at 0 on the VAS at last consultation. The post-operative control images at 3 months show a complete internalization of the implant, confirmed by MRI performed at 10 months post-operatively.

Rx. Control post-op



IRM post-op





Case n°2

Patient of 73 years presenting a cervico brachial neuralgia, disabling right, badly systematized for several months, with usual therapeutics deemed ineffective. MRI shows a large, straight C3-C4 disc herniation, partially migrated downwards towards the arm. The intervention took place on the 21/07/2003 with the placement of a graft size 14X14X5/3. Immediate relief with interruption of the taking of analgesics. Occurrence of secondary pain after a violent sneezing crisis occurred a dozen days after surgery. The radiological control images show a partial dislocation of the implant, associated with a fracture in the cortex of the anterior cortex of the vertebra C3. A re-intervention allowed the repositioning of the implant that had already showed partial ossification. Persistence of moderate cervicalgia, rated at 3 on the VAS after the 2nd intervention.

DISCUSSION

The classic interosseous grafting procedure without associated osteosynthesis is well known and well accepted, giving satisfactory results in degenerative pathology [5, 8-10, 16, 21, 23]. A cervical kyphosis, or at least a loss of physiological lordosis, may be the consequence of a pseudoarthrosis in the case of a graft and, if it seems more frequent in case of simple discectomy, its real incidence remains unknown although the association with an osteosynthesis seems to reduce the risk of it occurring [14, 30]. In the case of a graft, the use of an autologous bone graft remains the reference, although the intrinsic morbidity in the graft catchment area is not negligible and has led to the search for other solutions [4, 11, 18, 23, 27, 29], the most widespread being based on micro or macro porous substitutes, which are supposed to reproduce bone trabeculae as closely as possible. The mechanism of internalization of this type of implant has been studied at the ultra-structural level by electron microscopy at the university of Annaz [2]: The mechanism of colonization by osteoblasts is by means of emission of pseudopods at the level of the micro pores of the substances studied, the progressive adhesion allowing the secondary constitution of true cell bridges, premise to the secondary osteogenesis. This mechanism seems to be retained for all types of porous implants studied.

The use of coral implants, initially praised for their excellent integration rate, quickly proved its lack of long-term effectiveness. Thalgott et al. [27] reported a 100% internalization rate on 26 instrumented patients in 1999 and a "pain control" estimate of 75.8%, strongly recommending the use of coral as a bone substitute, McConnell et al. [17], in a prospective study comparing the results of the coral with that of the autologous implants, reported a rate of fragmentation of the implants in 89% of the cases (versus 11% for the autologous grafts), with secondary displacements in 50% of the cases. More recently, Agrillo et al. Have shown that the common use of coral and carbon cages could give interest to this type of substitute [1].

Hydroxyapatite ceramics, both bovine and synthetic, have also been widely used [15, 26]. Linhart et al. [15] have recently drawn attention to the possibility of degradation of the mechanical performance of this type of product, sometimes occurring long after their pose. Finally, the lactic acid derivatives, which have the theoretical interest of a more or less total bio-resorption of the implant with time [24], seem to have had for the moment only a fairly limited diffusion.

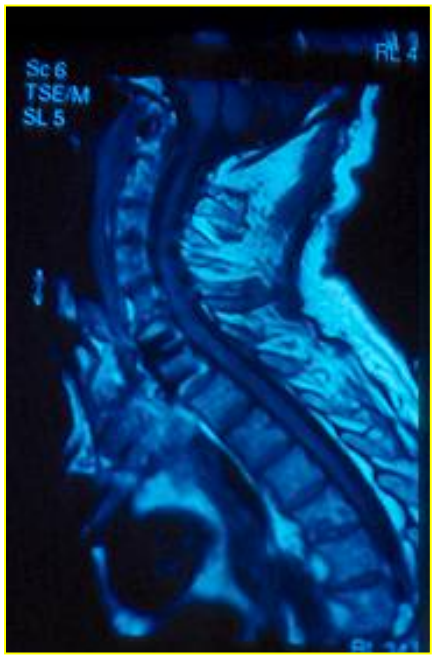
Porous cellular alumina cages seem to be an interesting alternative solution. Presented with a geometry adapted to the human anatomy *(Figure 1),* they have an anterior-posterior slope opposing posterior displacement after placement, and respecting the physiological cervical lordosis irrespective of the size of the selected implant. Their constituent material is made from a suspension of alumina particles (mean diameter 0.5 µm) dispersed uniformly in an aqueous medium containing organic binders.

The suspension thus obtained then impregnates a cellular polymeric structure, pre-cut to the desired shape. The ensemble is dried in an oven and then "decanted" by a suitable pyrolysis technical treatment, making it possible to eliminate any form of organic substance (binders, dispersants, cellular polymer). The implant is finally densified by sintering at high temperature, which makes it possible to obtain the desired mechanical properties [7, 12, 28].

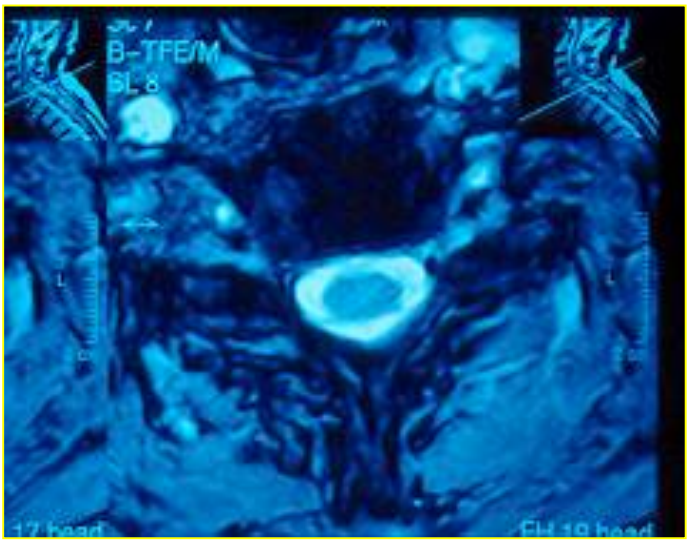
The finished material has an open and interconnected porosity of between 200 and 600 µm, very similar to natural bone, and a total pore volume of 60% for an average mechanical strength of 20 to 60 MPa, depending on the implants [7]. It is also completely inert and free from any form of cytotoxicity, which can be established on murine fibroblasts and macrophages [7]. There is thus a material which lends itself well to what can be expected from a reliable alternative to autologous bone without having the well known disadvantages of other substitutes of animal origin (coral, mother-of-pearl, bone [4, 15, 17, 23, 27] as well as synthetic products (calcium phosphates, hydroxyapatite ...) [29]. It is a material of suitable purity, with high mechanical strength, non-resorbable and bio-inert, offering to the bone a structure favouring its regrowth thanks to a controlled open cellular porosity. The walls of the pores serve as a guide for the bone and fibrous cells by directing their proliferation: the tissue does not encounter any obstacle, which promotes neoformation, the implant thus becoming an integral part of the bone [2, 7, 12].

The excellent quality of bone integration was confirmed in direct vision during the two re-interventions, confirming in one case the total integration of the implant and in the other case the start of integration, the implant was partially dislocated forward and its mobilization proved very difficult, despite the use of an intersomatic retractor. The perfect integration found in 58 of the cases of inter-body implantation, even at two levels, also argues in this sense, confirmed remotely by nuclear magnetic resonance imaging, when it was performed, most often for a cause other than simple evolutionary monitoring.

IRM post-op. (2years) Sagittal T1



IRM post-op. (2years) Transversal T2



The rate of pseudarthrosis seems to increase with the number of grafted levels [5, 25], and can be limited by the addition of an osteosynthesis plate, which has the further advantage of contributing to the correct restitution of a cervical lordosis function [21]. No case of pseudoarthrosis was found in our short series; It is true, however, that no patient has received a gesture at more than two stages using this type of implant and that these were too few (10 cases) to be truly demonstrative.

The only other comparable study available in the literature, using the same type of implant, is that of Bové [6], on the assessment of femoral osteotomy wedges in orthopaedic surgery. It covers 50 patients, with a mean follow-up of 16 months, the criteria for radiological assessment of fusion being comparable to ours, basically based on the radiographic disappearance of the clear border surrounding the implant. Radiologically the fusion could be asserted at 6 months in 48 cases, the other two obtaining a complete fusion at 8 and 13 months, that corresponds to our own results.

The shape and qualities of the implants is deemed as a considerable asset in terms of time saving, an autologous bone graft obviously requires a lot more processing time on demand, and ultimately increasing the operating time. The mean operative time at one level in our series was 67 min, including the cases that required the placement of an associated osteosynthesis plate (55% of cases). Our experience proves that the association with an osteosynthesis plate is far from being systematically necessary with the use of this type of implant, but must be decided on a case-by-case basis, particularly in the case of a particularly mobile segment or in the case of lack of predictable patient compliance in the post-operative period: the wearing of a collar for post-operative restraint and support is therefore necessary in all cases, combined with the adapted physiotherapy.

CONCLUSION

An implant intended to replace an autologous bone graft must be capable of meeting a number of requirements: it must be an inert, non-resorbable product, enabling high-quality bone re-habitation, resulting in mechanically sustainable bone consolidation. These characteristics seem to be fulfilled by the porous cellular alumina bioceramic implants that we have been using for more than 5 years in daily practice. These results perfectly cover those reported by other authors in non-spinal orthopaedic surgery.

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