
Clinical Results of a New Resorbable Composite Material for Cervical Cage: 6 Years' Follow-up (Part 2)

17

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Efficiency of corticocancellous autologous bone grafts in cervical interbody fusion has been widely reported since Smith and Robinson [1] or Cloward [2]. Depending on the studies, 70–96 % of the patients develop good or excellent results. However, the use of autologous grafts induces a second operation, generally on the iliac crest, and may be associated with an important morbidity [3]. Moreover, such complications as long term pain syndrome, femorocutaneous nerve damage, infection or secondary fracture has been reported [4–6]. In order to prevent such risks, different bone substitutes are nowadays available. Natural ones like allografts or xenografts [7, 8] have been

studied since decades. With a cancellous-like architecture, their macroscopical structure can help bone ingrowth and lead to satisfying results with regards to bone fusion, both on animal models or humans. But these natural bone grafts still represent a microbiological risk, like AIDS, hepatitis or non-conventional disease transmission. For these reasons, we preferred synthetic materials when choosing a bone substitute. Elaborated from pure chemical compounds, such materials seemed safer to us. Among the family of synthetic materials, calcium phosphate compounds like hydroxylapatite (HA) are probably better known. Intensively studied over the last 20 years [9], such compounds are biocompatible. In a porous form, they facilitate bone cells penetration and lead, as well as allografts or heterografts, to bone healing and fusion with surrounding bone [10–18]. HA is reported to be poorly – or non – resorbable and capable of achieving a long-term correction if sufficient mechanical strength and stability can be obtained. Clinical studies recently confirmed these theoretical findings, in the filling of non load-bearing bone defects or in spinal surgery [16, 19–25]. Tricalcium phosphate (TCP) is completely resorbable in a variable period depending on the porosity and the mass. The advantage of this ceramic is that the resorption occurs in the same time of bone healing and this leads to a complete fusion with at the end only bone in the same way as a Cloward procedure. However, pure HA or TCP ceramic materials are brittle

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and can fracture without prior elastic deformation, leading to the formation of hard debris presenting a risk of spinal cord or nerve root lesion. We have recently developed a composite material composed of b-TCP and lactic acid polymer (PLLA), which has a high breaking strength and a real capacity to withstand plastic and elastic strain. It thus has the major advantage that it can be used under conditions of high biomechanical stress with a low risk of rupture. This could be a serious advantage but there is no study at time to know if this fusion occurs without loss of correction and there is no study to evaluate the rate of complications of such a resorbable material. The objective of this study was to carry out a clinical study to evaluate radiological and clinical results of this new composite cervical interbody cage.

Materials and Methods

Patients were operated with Implants provided by SBM (SBM, Lourdes, France). The cage was made of composite material (material containing 60 % PLA and 40 % TCP) and inside was impacted a tricalcium phosphate ceramic block (porosity: 60 %) that matched the cage size (Fig. 17.1). These material was previously tested and evaluated in an in vitro and in vivo study (see Chap. 19).

Fourty patients, suffering of cervical nevralgia in relation with soft disc herniation, were operated according to the Smith and Robinson



Fig. 17.1 Cervical Cage “Duosorb”™ (SBM, Lourdes, France)

technique [1], Clinical evaluation at pre-op, post-op and each follow-up visit included JOA scoring, neurological evaluation, AP and lateral Xrays with bending films. At 2 years follow-up a CT scan evaluation of the fusion was performed to evaluate the fusion quality and the resorption of the cage and X rays at 4 and 6 years.

Preoperatively templates were used to determine the right size of the implant, and the cages were softly introduced in the disc space. Further insertion was carefully performed with a polyethylene bone impactor. Doing so, the implants were located at the center of the disc, ensuring vertebral end-plates parallelism, which was confirmed via peri-operative radiographic controls. All the patients were stabilized by an anterior titanium plate fixed by four screws and locking mechanism (Zephyr plate, Medtronic, Memphis, USA).

Verticalization was allowed the day after surgery, with no particular care except a soft collar, further maintained during 10 days. A 24 h post-operative radiographic control was performed. Data were collected from a homogenous consecutive series of patients, operated between 2004 and 2005. The same surgeon assumed reviews 1, 3 and 6, 12 months and each year after surgery, then at latest follow-up.

For each of the patients, we have postoperatively evaluated the clinical benefits of surgery and possible sequels : dysphagia, radicular or cervical residual pain. Correction (disc height and kyphotic/lordotic deformation), displacement and/or fracture of the implant, radiolucent line, dynamic mobility of the vertebrae (flexion/extension X-Rays) were radiologically assessed at each examination. The resorption of the material was evaluated radiographically by an independent radiologist in four stade: no resorption, partial resorption (inferior to 50 %); major resorption (more than 50 %); complete resorption. Finally, twenty patients got a CT evaluation of the fusion at 2 years follow up.

Results

Twenty patients included in the study were all followed at 2 years, mean age 48 years, average follow-up 28 months (Min 18/Max 47). The main

syndrome at first examination was cervical pain (30 %), radicular syndrome (60 %), myelopathic syndrome (15 %). A single level fusion was performed in all the patients.

From a clinical point of view, we observed one dysphagia. Improvement in initial pain syndrome was noted for 80 % of the patients. Radicular pain syndrome is present at latest follow-up for 15 % of the patients, as residual cervical syndrome is noted for 40 % of the patients. Complete disappearance of pain occurred for 80 % of the patients who initially presented radicular syndrome and for 50 % of the patients who presented preoperative cervical pain.

Radiological findings evidenced that 95 % of the patients conserved initial correction, with neither measurable (<1 mm) loss of disc height nor kyphotic lordotic evolution of the curve. One patient showed impaction of the implant inside the lower vertebra with a 3 mm loss of disc height. In 100 % of our observations, no measurable (<1 mm) implant displacement was observed at latest follow-up. Flexion/extension X-ray showed no mobility of the grafted level(s) for all the patients, for whom fusion was considered to be acquired. A moderate radiolucent dark line was observed in two of our observation in contact with one vertebral end plates. Its thickness decreased over time, and becomes invisible at 6 months and at latest follow-up. No visible signs of implant resorption was noticed using routine x rays at 6 months follow up.

No cyst or lysis were detected on CT scan analysis. The quantity of new bone formation at the cage level was evaluated as 62.6 % (12.4 sd) of the volume of the cage at 2 years. No infection, no neurological complications were reported.

Discussion

In animal studies histological examinations indicated clearly that pure PLLA implants were systematically surrounded by a layer of conjunctival tissue containing large numbers of macrophages, irrespective of the length of implantation, whereas bone tissue grew in direct contact with composite implants during the first few months and matured gradually until the end of the study

period with no marked macrophage activation. The composite material under investigation is thus more favorable for bone consolidation *in vivo* than pure PLA and has identical properties to those of pure b-TCP ceramics. This result is not particularly surprising if we consider the properties of the materials in the composite separately. We know that pure lactic acid-based polymers are not cytotoxic or inflammatory *in vitro* [4, 8, 24, 26–30] but are capable of causing an inflammatory reaction *in vivo* [4, 8, 26, 30–33], as confirmed by clinical observations [10, 18, 19, 34–36]. Pure b-TCP, on the contrary, promotes bone healing by osteoconduction, becoming surrounded by healthy bone tissue containing active osteogenous cells, with no intermediate fibrous layer. It is, thus, conceivable that composite materials such as those we studied have a “hybrid” biological behavior that becomes closer to that of pure tricalcium phosphate as the mineral content increases.

This clinical series showed that fusion occurred within regular time period. No inflammatory reaction was noted confirming *in vivo* study. Radiolucent line in two cases disappeared quickly which might the sign of progressive bone healing process around the implant. No loss of disc height was noted at latest follow up assessing the good behaviour of the implant when an anterior plating is performed. This preliminary results needs further studies to confirm strength retention properties of the implant and its resorption rate over time. We haven't observed radiological resorption of the cage during the time of the study despite significant resorption was seen in animal study. This could be attributed to the neutralization effect of the anterior plate decreasing the stresses applied on the cage. Since no loss of correction was observed we can admit that the mechanical properties of the cage was maintained during this period otherwise screw mobilization would probably have appeared.

Conclusion

This new composite material eliminates the inflammation reaction induced by the use of PLA alone and promotes new bone formation. The ceramic block guarantees the maintenance of the disc height and its slow resorption

allows long term fusion and stability. At the end this combination provides the same results as tri-cortical iliac crest graft without the disadvantages of the bone harvesting site. Further clinical studies are requested to confirm these results.

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