Efficacy of Beta Tricalcium Phosphate and MacroPore Sheet in Anterior Iliac Crest Reconstruction

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ABSTRACT

Beta-tricalcium phosphate (B-TCP: Vitoss, Orthovita, Malverne, PA) is a newly developed non-weight bearing bone void filler. Blocks of B-TCP are osteoconductive. When combined with autogenous bone marrow aspirate, its substantial wicking capabilities, trap osteoblasts and nutrients, making it additionally osteoinductive and osteogenic.

Ten patients underwent single level anterior cervical corpectomy and fusion procedures (i.e. C5-C7) with dynamic ABC plates (Aesculap, Tuttingen, Germany). Iliac crest autografts, averaging 1.2 cm in depth x 1.4 cm in width x 2.8 cm in length, were harvested, and defects were filled with blocks of B-TCP and MacroPore Sheet (San Diego, CA). 2D-CT scans at 3 and 6 months postoperatively documented progressive fusion characterized by increasing ossification and coalescence of B-TCP particles within the defect; Grade I (50%), Grade II (70%), and Grade III (100%). Outcomes were assessed utilizing a Visual Analog Pain Scale (1-10) and the SF-36 Bodily Pain Scale recorded 3 and 6 months postoperatively.

Postoperative 2D-CT studies of iliac crest reconstructions revealed Grade II (70%) partial fusion within 3 months, and Grade III (100%) complete fusion 6 months following surgery. One patient who developed a hematoma at the operative site demonstrated moderate myositis ossificans on the 2D-CT examination. On the Visual Analog Pain Scale patients demonstrated an average score of 5.2 at three months and 2.0 six months postoperatively. Bodily Pain Scores on the SF-36 showed average preoperative scores of 20, which improved to 35 at three months and 52 at six months postoperatively (higher numbers reflected better outcomes). Patients were followed a minimum of 6 months and average of 12 months postoperatively.

B-TCP proved effective as a bone void filler in iliac crest donor site reconstruction and may supplement autograft and supplant allograft for comparable types of fusions.

Key words: beta tricalcium phosphate, iliac crest fusion

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INTRODUCTION

Synthetic cancellous bone void fillers like Beta Tricalcium Phosphate (B-TCP: Vitoss, Orthovita, Malverne, PA) act as osteoconductive supplements to fusions without load-bearing functions, and are increasingly used instead of allograft. When autogenous bone marrow aspirate is added to round blocks of B-TCP, its unique wicking capability traps osteogenic precursors and nutrients which render it both osteoinductive and osteogenic.

Ten patients with contiguous two-level cervical
Fig. 2: The 6 month postoperative coronal 2D-examination following a single level anterior corpectomy with fusion utilizing a dynamic ABC plate (Aesculap, Tuttlingen, Germany) demonstrates cephalad and caudal fusion of the iliac crest autograft. Note the lack of lucency and presence of bony trabeculation crossing the strut/vertebral body interface. Also observe the length of 2.8 cm and width varying from 12 mm cephalad to 14 mm caudal.

Fig. 1: This 6 month postoperative parasagittal 2D-CT following a single level anterior corpectomy with fusion with dynamic ABC plating (Aesculap, Tuttlingen, Germany) revealed cephalad and caudal fusion of the iliac crest strut autograft. Dimensions of these grafts averaged 1.2 cm in depth, 1.4 cm in width, and 2.8 cm in length.

Harvested iliac crest autografts averaged 1.2 cm in depth, 1.4 cm in width, and 2.8 cm in length. Iliac crest reconstruction was performed utilizing round blocks of Beta Tricalcium Phosphate (B-TCP; Vitoss, Orthovita, Malverne, PA) as a bone-void filler. This was covered with MacroPore Sheet 0.5 mm x 5 cm x 5 cm (San Diego, CA) to contain the B-TCP particles. Drains were placed at the iliac donor site in the latter 8 patients. 2D-CT studies of the iliac crest were successively performed 3 and 6 months postoperatively to grade the progressive coalescence of ossified particles toward fusion; Grade I (50%), Grade II (70%), and Grade III (100%) levels of fusion reflected progressive coalescence of ossified particles. Outcomes were assessed utilizing the Visual Analog Pain Scale (1-10) and the SF-36 (Bodily Pain Scale) 3 and 6 months postoperatively.

**MATERIALS AND METHODS**

Ten patients with moderate myelopathy (Nurick Grade III) exhibited MR and CT-documented contiguous two-level cervical disease with retrovertebral extension; disc disease, spondylosis, and stenosis (Table 1). Single level anterior corpectomy and fusions were performed (i.e. C5-C7).

RESULTS

All 10 patients demonstrated partial Grade II (70%) incorporation on CT studies 3 months postoperatively. Complete or Grade III (100%) incorporation was documented within 6 postoperative months (Figs. 3-6). One early patient developed a mild and another a moderate postoperative hematoma
Table 1: Clinical Data for 10 Patients Undergoing Single Level Anterior Corpectomy/Fusion and Iliac Crest Reconstruction Utilizing Beta Tricalcium Phosphate (Vitoss, Orthovita, Malvern, PA) and MacroPore Sheet (San Diego, CA)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Clinical Data (10 Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age</td>
<td>44</td>
</tr>
<tr>
<td>Range of Ages</td>
<td>28-61</td>
</tr>
<tr>
<td>Sex</td>
<td>7</td>
</tr>
<tr>
<td>Males</td>
<td>3</td>
</tr>
<tr>
<td>Follow-Up Average Duration Range</td>
<td>8.5 Months</td>
</tr>
<tr>
<td></td>
<td>6-11 Months</td>
</tr>
<tr>
<td>Single Level ACF</td>
<td>10</td>
</tr>
<tr>
<td>Average Plate Length</td>
<td>46 mm</td>
</tr>
<tr>
<td>Preoperative Nurick Grade</td>
<td>3</td>
</tr>
<tr>
<td>Postoperative Nurick Grade</td>
<td>0</td>
</tr>
<tr>
<td>Average Hospital Stay</td>
<td>3.3 Nights</td>
</tr>
<tr>
<td>Average Weight</td>
<td>195</td>
</tr>
<tr>
<td>Number of Patients over 200 lbs</td>
<td>6</td>
</tr>
<tr>
<td>Average Time to Fusion of Cervical Graft Based on CT Studies</td>
<td>4.65 Months</td>
</tr>
<tr>
<td>Time to CT-documented Fusion of Iliac Crest Graft Utilizing VITOSS</td>
<td>3 months: 70% (Grade II)</td>
</tr>
<tr>
<td></td>
<td>6 months: 100% (Grade III)</td>
</tr>
<tr>
<td>Myositis Ossificans</td>
<td>9</td>
</tr>
<tr>
<td>Absent/Minimal</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Complications of VITOSS Fusion at Iliac Crest Graft Site</td>
<td>1 Moderate Hematoma (No Surgery)</td>
</tr>
<tr>
<td></td>
<td>1 Mild Hematoma (No Surgery)</td>
</tr>
</tbody>
</table>

at the grafting site; myositis ossificans was seen in the latter individual and attributed to the hematoma. All subsequent patients received iliac crest drains for 24-48 hours postoperatively; no further hematomas nor significant myositis ossificans were observed. No additional complications occurred.

Pain on the Visual Analog Pain Scale averaged 5.2 at 3 months and 2.0 at 6 months postoperatively. On the Bodily Pain Scale of the SF-36, scores averaged 20 preoperatively, but increased to 35 at 3 months, 52 at 6 months (the higher the score the better the patient).

**DISCUSSION**

**B-TCP (Vitoss)**

Synthetic bone void fillers/expanders avoid the disease-related complications associated with allograft [5]. The optimal bone expander should provide osteoconduction, osteoinduction, and osteogenesis. B-TCP offers all 3 factors in a single block construct. It is comprised of 39% calcium and 20% phosphorus with a molar ratio of 1.5 [chemical formula is B-Ca3(Po4)2]. Osteoconduction is offered by the B-TCP (Vitoss) scaffold. The mean size of the
B-TCP crystallites is 102 nm, and it closely mimics cancellous bone in its porosity and structure. Interconnecting pores result in a 90% void space, with pore size ranging from 1 micron to 1 mm in diameter. Larger pores (diameters of 100 microns to 1 mm) allow for bone ingrowth and vascularization. Osteoinduction and osteogenesis are provided when B-TCP is combined with bone marrow aspirate; smaller pores with wicking capabilities facilitate fluid transport, homeostasis and the retention of osteoblasts and nutrients [5]. This product is FDA approved as a bone void filler and biocompatible implant.

**Efficacy of B-TCP and Other Bone-Void Fillers in Animal Models**

B-TCP is an effective bone void filler when implanted into the proximal tibias of Sprague Dawley rats, and the tibial metaphyses and femoral condyle cavities of rabbits [1, 3, 8, 10, 11]. B-TCP fusion was verified in some studies utilizing bright-field polarized light microscopy and scanning electron microscopy [3].

**Human Application of B-TCP as Bone Void Filler**

In human clinical trials, B-TCP is effective as a non-weight-bearing bone void filler and/or supplement to autologous bone grafting, supplanting allograft [6, 7, 9]. When B-TCP was employed in 6 patients who sustained fractures of the calcaneus, X-ray obtained 2 months later documented fusion without aberrant inflammatory responses or foreign body reactions [7]. In a prospective randomized trial involving intertransverse process lumbar fusions, autogenous iliac crest bone alone was placed on one side while autogenous laminectomy bone supplemented with B-TCP (ratio 1:1), was placed on the other side; fusion rates for both sides were comparable [6]. For 50 patients undergoing multilevel laminectomies and intertransverse process non-instrumented and instrumented fusions, fusion masses included B-TCP (Vitoss) alone or iliac crest autograft supplemented with B-TCP (Vitoss) [9]. Of 32 patients evaluated 5-7 months postoperatively, 100% exhibited adequate fusion on plain X-rays alone. B-TCP proved useful as a bone filler over the transverse processes and the posterior iliac crest donor site.
patients (35-three months 52-six months postoperatively) were similar to those observed for 23 patients in the previous series undergoing iliac reconstruction with MacroPore and allograft (30-three months, 40-six months) [4].

CONCLUSION

Iliac crest reconstruction with B-TCP (Vitoss) and MacroPore Sheet yielded 100% 2D-CT-documented fusion 6 months postoperatively, and comparable outcomes on both the Visual Analog Scale and SF-36 (Bodily Pain Scale). B-TCP (Vitoss) appears to be a viable bone void filler and an effective alternative to allograft when utilized in conjunction with MacroPore Sheet for iliac crest reconstruction.

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REFERENCES


Reviewer's comment : Tetsuya Morimoto, M.D.
Department of Neurosurgery, Osaka Police Hospital, Osaka, Japan

An iliac crest has been used as a bone graft in a variety of spinal surgeries. Autografts represent the maximum available biologic potential, pose no immunologic considerations, and obviate the concern for transfer of disease, especially infection, from donor to recipient. But, donor site complications such as lateral thigh neuralgia and fracture should not be underestimated.

Various synthetic hydroxyapatite (HA) and tricalcium phosphate (TCP) crystalline or ceramic preparations have been manufactured with the intention of duplicating some of the biologic and biomechanical composition and responses attributable to bone. We congratulate that Dr. Nancy et al have proved B-TCP (VITOSs) to be an appropriate substitute for iliac crest reconstruction in a clinical situation.

Cost effectiveness also must be considered for this kind of treatment. In case of small harvest size, iliac crest reconstruction using this material is seemingly unnecessary.

Reviewer's comment : Masanori Ito, M.D.
Department of Neurosurgery, East Tokyo Metropolitan Hospital, Tokyo, Japan

Dr. Epstein provides a valuable application of Beta-tricalcium phosphate (B-TCP) to a viable bone void filler in an iliac crest donor site. Although the need for fusion after anterior cervical decompression remains controversial (Sonntag and Klara, 1996), many neurosurgeons prefer fusion rather than no fusion. A variety of materials have been used in anterior cervical interbody fusion surgery, such as autografts, allografts, ceramics, titanium cages, plates, and so on. In this study, the author used the iliac bone and cervical plate. The autogenous iliac bone is a favorite standard, but it is not always of good quality in the elderly, smokers, and hemodialysis patients, and it also involves graft-site-related problems such as donor site pain, infection, and pelvic fracture.

This paper has demonstrated the effectiveness of Beta-tricalcium phosphate (B-TCP) as viable bone void filler in iliac crest donor site reconstruction in ten patients who underwent anterior cervical corpectomy and fusion with cervical plate. This procedure resulted in complete fusions 6 months following surgery shown by 2D-CT, and significantly reduced postoperative donor site pain based on the Visual Analog Pain Scale and Bodily Pain Scale of the SF-36. Furthermore, the author stated that this surgical procedure appear to be an effective alternative to allografts with instrumentation that many US neurosurgeons are widely performing (Matthew, T et al., 2002).

There have been three generations of artificial bone: the first generation is sintered hydroxyapatite (HAP) and A-W glass ceramics, the second generation is porous material and Ca-P cement, and the third is the material together with a complex of bone growth factors and bone cells. Three materials for bone replacement have been invented since the 1970s. It was demonstrated that recombinant bone morphogenetic protein-2 and B-TCP impregnated together in the cages was better than an autograft or B-TCP in spinal bone fusion, and that B-TCP was a good carrier with rh-BMP-2 in the experimental study (Ohyaana et al., 2004). One can attempt the use of B-TCP combined with rh-BMP-2 for iliac crest reconstruction.