Triosite® Bioactive Ceramic Bone Graft Substitute

A Cost Effective Bioactive Approach to Bone Augmentation

zimmer | trauma
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In orthopaedics and traumatology, surgeons are often faced with reconstruction of lost, diseased or damaged bone. Traditionally, the use of autologous grafts has been considered ideal, however the supply of material is restricted, and harvesting autograft bone requires additional trauma and pain to the patient and associated blood loss. Allograft material may be available via local or regional bone banks, however its performance is considered to be inferior to auto-grafts and there is potential for the material to act as a vector for microbiological contamination.

Synthetic Solution

There is a need for a biocom patible synthetic material that can be used to replace or augment graft material. Ideally, the material should become integrated with the surrounding bone tissue and ultimately be replaced by new healthy bone, as is seen with autologous graft.

Triosite Bone Graft Substitute is a bioactive calcium phosphate ceramic composed of hydroxyapatite (HA) and tricalcium phosphate (TCP). It has micro- and macropores and supplied in both block and granular form. The material is soluble and gradually dissolves in the body, seeding new bone formation as it releases calcium and phosphate ions into the biological milieu. With time, the porous structure becomes completely infiltrated with, and replaced by healthy viable bone.

Triosite Bone Graft Substitute possesses the unique properties of controlled bioactivity and solubility as a result of its chemical composition. It consists of an optimum balance of the more stable phase of HA and more soluble TCP.

Triosite Bone Graft Substitute is indicated to augment or substitute for bone graft in nonloadbearing clinical applications.

Proven Clinical Benefits*

The effectiveness of *Triosite* Bone Graft Substitute as has been critically evaluated in a large prospective randomized study involving 341 patients undergoing posterior spinal fusion with associated instrumentation[1]. The performance of *Triosite* Bone Graft Substitute was characterized by:

- Equivalent clinical outcome to autologous bone graft
- Fewer spinal wound healing problems than autologous grafts
- Avoidance of donor site pain and infections
- No allergenic reactions

Histological analysis of biopsies containing *Triosite* Bone Graft Substitute show that it provides a favorable scaffolding for the stimulation and growth of new bone, and gradual incorporation into the fusion mass. Progressive *Triosite* Bone Graft Substitute resorption involved the same amount of well-differentiated bone ingrowth. It should be noted, however, that *Triosite* Bone Graft Substitute must be surrounded by and covered with host bone. As with other prosthetic materials, extensive contact with soft tissues can lead to fibrous encapsulation and delay or prevent full incorporation and replacement by bone.

* See publications at the end of this brochure.

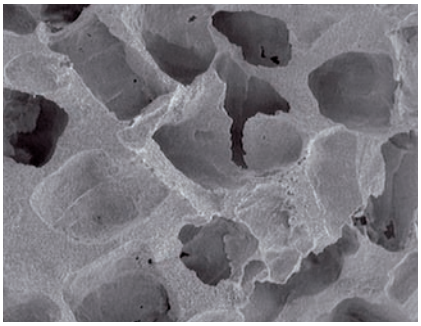

Figure 1
Macropores (300–600 microns), which are a network of interconnected spaces and allow the biological infiltration and cellular colonization by osteoblasts and osteoclasts. (Data on file at Biomatlante)

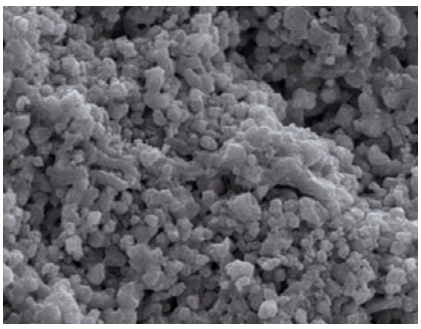

Figure 2
Micropores (<10 microns) which are the intercrystalline spaces where dissolution and recrystallization take place.
(Data on file at Biomatlante)

***Triosite* Bone Graft Substitute has also been used successfully in other clinical situations, such as the filling of pathogenic or mastoid cavity bone defects[2, 3], and to replace bone in the treatment of long-bone fractures[4].**

An Overview of Triosite Biphasic Ceramic Bone Substitute

Hydroxyapatite is stoichiometrically equivalent to the crystals of biological apatite found in natural bone. However, many chemical substitutions are found in biological apatite, such as calcium carbonates, which lead to imperfections in the crystal structure affecting size shape and particularly dissolution properties. Of all the synthetic calcium phosphate ceramics, hydroxyapatite is one of the least soluble and bioactive[5].

In order to enhance the bioactivity of hydroxyapatite, it can be combined with tricalcium phosphate, which is soluble and reactive in biological terms. By controlling the relative proportions of these constituents it is possible to produce a ceramic with precise biological properties.

Based upon several studies[6, 7, 8], Zimmer selected a balance of 60% HA and 40% TCP for *Triosite* Bone Graft Substitute because it appears to provide the optimum performance in terms of controlled resorption and osseous substitution.

The porosity of the material also has a marked influence on its solubility and bioactivity[9], so the physical properties of *Triosite* Bone Graft Substitute are also carefully controlled. The pores in *Triosite* Bone Graft Substitute can be divided into two categories: the micropores (Fig. 2) and the macropores (Fig. 1).

At the microscopic level, biological fluids seep through micropores, and become enriched with calcium and phosphate ions which are released during dissolution of TCP. As the solution becomes saturated, crystals of biological apatite precipitate in the spaces and bond the substrate together[10, 11, 12] integrating non-collagenic proteins like growth factors and osteogenic molecules. An increase in the mechanical properties of the biomaterial/tissue construct is apparent[13].

At the histological level, viable lamellar bone (O) is deposited directly onto the surfaces of the ceramic scaffold (Fig. 3). Over time the lamellar bone is remodelled to Haversian bone (H), which also gradually replaces the *Triosite* Bone Graft Substitute particles (T) (Fig. 4).[14, 15]

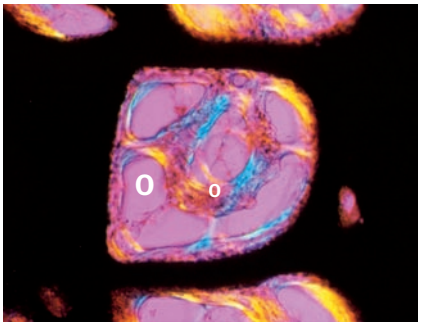

Figure 3
Lamella bone (O, area in pink)

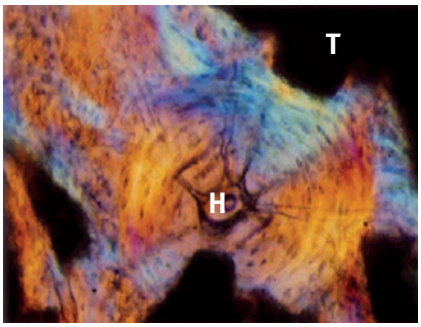

Figure 4
Haversian bone (H)
Triosite Bone Graft Substitute particles (T)

Technical Properties

Triosite Bone Graft Substitute is a high-purity ceramic which is synthesized using a special process involving high-temperature sintering.

Typical Composition	60% Hydroxyapatite ($Ca_{10}(P0_4)_6(OH)_2$) 40% Tricalcium Phosphate ($Ca_3(P0_4)_2$)
Ca:P ratio (by mass)	1.6
Purity	$<$ 50 ppm Heavy Metals
Porosity	60–70%
Pore Size	Macropores = 300–600 microns Micropores $\leq$ 10 microns

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Triosite Sticks

Size (mm)	Quantity	REF
5.0 × 5.0 × 10.0	Box of 2	00-1109-113-01
5.0 × 5.0 × 10.0	Box of 4	00-1109-113-02
5.0 × 5.0 × 20.0	Box of 2	00-1109-114-01
5.0 × 5.0 × 20.0	Box of 4	00-1109-114-02

Triosite Cones

Size (mm)	Quantity	REF
8.0	1	00-1109-085-15
12.0	1	00-1109-132-15

Triosite Osteotomy Wedges

Size (mm)	Quantity	REF
3.0 × 6.0*	1	00-1109-000-36
4.0 × 8.0*	1	00-1109-000-48
5.0 × 10.0*	1	00-1109-005-10
6.0 × 12.0 *	1	00-1109-006-12

Triosite Granules

Size (mm)	Quantity	REF
0.5–1.0	2 cc	00-0060-130-00
2.0–3.0	10 cc	00-1109-115-01
2.0–4.0	16 cc	00-1109-115-02
2.0–3.0	5 cc	00-1109-005-03

Triosite Disks

Size (mm)	Quantity	REF
25.0 × 5.0	1	00-1109-005-25

* Note: Wedges are 30 mm × 30 mm square. Dimensions quoted in the product description relate to minimum and maximum thickness; the latter is a good approximation of the wedge angle.

CE 0123

Manufacturer: Biomatlante
Distributor: Zimmer GmbH

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Lit. No. 06.01314.012 – Ed. 01/2008 ZHUB
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