

## Composite Biomaterial in Paste for Bone Grafting: A Technical Note

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### Introduction and Background

Currently, bone defects caused by congenital malformations, diseases, trauma or surgical procedures are considered a health problem, particularly in implantoprosthesis rehabilitation and dental and bone maintenance. Bone tissue is currently the second most transplanted tissue worldwide, after blood<sup>1</sup>.

Several biomaterials have been researched and developed in Dentistry, particularly in Guided Tissue Regeneration and Guided Bone Regeneration. The main functions of bone graft material are to provide mechanical support and stimulate bone regeneration, whose final scope is bone replacement. Osseointegration, osteogenesis, osteoconduction and osteoinduction are primordial foundations for the performance of biomaterials in bone grafts<sup>1-3</sup>.

Biomaterials should present several characteristics that elect it in the choice for use. However, there is still no material that includes all these characteristics<sup>1-3</sup>. Biocompatibility, biological safety, low patient morbidity, ease of handling, low immunogenicity, angiogenic potential, plasticity, high volumetric stability, long useful life, resistance to compressive forces, more conservative access so as not to require the use of relaxing incisions and meet the needs of the technique of Guided Bone Regeneration, for the preservation and functionality of alveolar bone for subsequent oral rehabilitation are desired<sup>1-5</sup>.

There are several types of biomaterials and techniques, from autogenous, allogenic, xenografts and synthetic grafts. Each biomaterial or technique has advantages and disadvantages. Autogenous bone is considered the gold standard, although limited in quantity for large defects. In these cases, extraoral areas are recommended as donor sites. These surgeries involve the need for a hospital environment and the participation of other surgeons, such as neurologists or orthopedists. These procedures making the process more expensive and increasing morbidity for patients<sup>1</sup>. Allogenic or xenogenic materials present the risk of prion disease transmission<sup>6,7</sup>. Prion is a protein particle that is undetectable, even by molecular biology diagnostic methods, and is the etiological agent of Bovine Spongiform Encephalopathy ("mad cow disease") in the bovine herd, and of Creutzfeldt-Jakob Disease in the human population<sup>6</sup>. From this perspective, the abolition of the use of bovine bone as a source material for xenografts has been suggested<sup>7</sup>. The use of synthetic ceramic biomaterials such as hydroxyapatite, calcium phosphate, calcium sulfate and tricalcium phosphate derivatives have osteoconductive properties and unlimited supply. When associated with other synthetic bioabsorbable polymers such as polylactic acid, polyglycolic acid or poly (lactic-co-glycolic acid) and polycaprolactone they may also favour bone or tissue growth. In this perspective, the purpose of this article is to present a technical note on a new biomaterial and its characteristics - the composite biomaterial in the form of injectable paste for bone grafts.

### Presentation of the material

The paste composite for bone grafting (Osstion Pasta™, Bioactive Biomateriais S.A., Indaiatuba, Brazil) is a bioabsorbable and biocompatible biomaterial of synthetic origin (Figure 1). It consists of the association of lactic acid and caprolactone constituting the copolymer (PLC), polyethylene glycol, beta tricalcium phosphate, hydroxyapatite and nanohydroxyapatite.

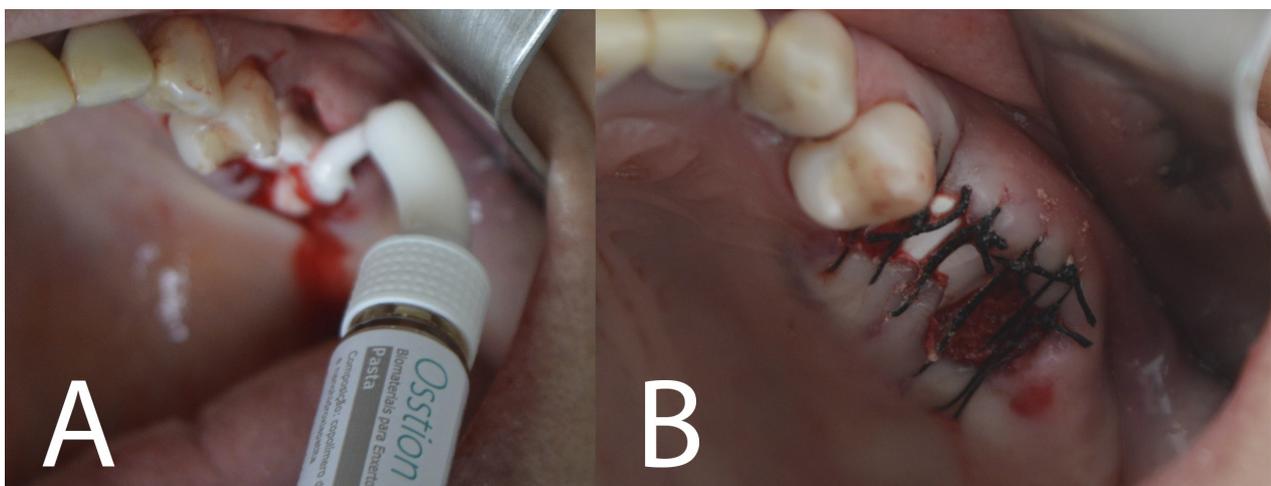
The biomaterial is implantable, sterile, single-use, and recommended for filling small bone cavities, gaps and spaces, besides the reconstruction of bone defects in dental and maxillofacial surgeries, Guided Tissue Regeneration and Guided Bone Regeneration<sup>8</sup>.

The product is presented in ready-to-use single syringes, including an optional silicone applicator tip. The silicone tip is flexible and makes the posterior regions of the mouth more accessible. The packaging has three self-adhesive labels containing information necessary for traceability and the manufacturing process, expiry date and batch number. The product and packaging are sterilized by gamma radiation, under strict and meticulous manufacturing process. It should be stored in a clean and dry place at room temperature (15 to 30°C / 59 to 86°F) in order to maintain its physical and chemical integrity. The product has a white and pasty appearance. The sticky viscosity is particularly important, keeping the paste in the desired bone cavity<sup>8</sup>.

The paste interacts rapidly with the blood clot, promoting direct contact with the ceramic elements of the product. The material is gradually absorbed and integrated during the bone repair process. Over the course of weeks, the new tissue grows in the desired location. As it is an absorbable product, the need for a second surgical procedure, normally required to remove non-absorbable materials, is eliminated. The paste favours the possibility of precise application of the biomaterial in the injured area, offering excellent handling properties and biological performance. It may be used alone, or in association with autologous materials or other biomaterials. The consistency of the product provides easy adaptation and adherence to the defect and allows complete permeation of the blood. It is recommended to cover the paste with a membrane (collagen or synthetic) as a mechanical barrier (Figure 2). Likewise, it is necessary that the soft tissue flap completely covers the membrane avoiding tension, cracking, or ischemia of the mucoperiosteal flap<sup>8</sup>.



**Figure 1:** Primary packaging of the composite biomaterial in the form of injectable paste for bone grafting (Osstion Pasta™, Bioactive Biomaterials).



**Figure 2:** Insertion of the biomaterial Osstion Pasta™ in the post-extraction alveolus (A) and covering of the surgical bed with polypropylene membrane (B).

The indications for use of the composite in paste have been summarised in Table 1. The product is presented in the form of injectable paste. It acts in the filling of small bone spaces and defects, located at the interface of grafts and host bone. The product is gradually absorbed and integrated during the bone repair process, being totally reabsorbed in up to 90 days. As it is a polymeric based composite, the biomaterial is radiolucent. The basic precepts of surgical procedures are considered, such as oral and gingival health, satisfactory oral hygiene prior to the procedure, and prophylactic antibiotic administration (American Heart Association protocol). The paste should not be used in patients who present hypersensitivity or allergic reactions to the components of the product; and in the presence of localized infection or near the surgical site. The product is not recommended for use in patients with hemostasis, coagulation or healing disorders; patients with autoimmune diseases, bone tumours, renal dysfunction, osteopenia or severe osteoporosis; alcoholics, smokers and drug addicts; pregnant or lactating women. The paste is not designed to be used in locations subject to tension, torsion or flexion<sup>8</sup>.

**Table 1:** Indications for use of the composite biomaterial in paste (Osstion Pasta™).

Clinical Indications
Filling of bone and intraosseous defects with at least 3 walls
Filling cavities and alveolus after tooth extraction
Filling of bone dehiscences
Sinus lift with immediate implant
Periodontal defects
Cystic cavities
Repair of marginal and periapical bone defects

It is important to emphasize the need of complete removal of granulation tissue, fibrous or necrotic, followed by abundant washing of the bone cavity with sterile saline solution and cooled to expose the defect. In the absence of blood or clot, the bone cavity should be decorticalized in order to provide direct contact of the product with the vital and bleeding bone tissue. Implant installation, in two-stage surgical procedures, should be performed considering primary fixation and implant stability<sup>8</sup>.

No drug interactions have been reported with the material. The product does not present adverse reactions or side effects. Possible complications may occur as a result of the surgical procedure, such as infection, edema, sensitivity and painful symptomatology, gingival recession, gingival bleeding, resorption with loss of bone crest height. The persistence of signs and symptoms must be reported to the dental surgeon. Disposal should respect the sanitary measures of each country, and should be discarded in hospital waste<sup>8</sup>.

## Conclusions

The development of new biomaterials and technologies is encouraged by the clinical needs routinely observed in Dentistry. The paste composite for bone grafting Osstion Pasta™ (Bioactive Biomaterials) is promising due to its biological characteristics and nature and its ease of use, indicated in the filling of cavities and bone defects.

## Conflict of Interest

The authors declare no conflict of interest.

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