

Technical Focus

BIO-GEN: *IN VIVO* DIMENSIONAL CHARACTERIZATION AND KINETIC REMODELING ASSESSMENT

Bio-Gen is dimensionally analogous to the deproteinized bovine bone but remodels faster.



From the Bioteck Academy Editorial Office

Bone regeneration in implantology may involve the use of bone substitutes of animal origin as scaffolds which, ideally, should resorb and be completely replaced with newly-formed bone tissue by the osteoclast/osteoblast system¹.

In clinical practice, optimal remodeling kinetics depend on various factors and are, therefore, case-specific: it is important that the oral surgeon have at his/her disposal materials with different remodeling kinetics, so that he/she may choose the graft that best meets the patient's needs. Deproteinized bovine bone (Bio-Oss, Geistlich) is one of the most used biomaterials of animal origin. It is known, however, that it is characterized by slow remodeling kinetics, due to the high temperatures to which it is subjected during the antigen removal process.

Bioteck has developed a graft of equine origin, Bio-Gen, which is obtained with the use of an enzymatic treatment capable of removing antigens without the use of such high temperatures. Pre-clinical evaluations have allowed the in-depth study of its dimensional characteristics and remodeling kinetics.

1. Perrotti V., et al. Human osteoclast formation and activity on a xenogenous bone mineral. J Biomed Mater Res A, 90(1), 238-246 (2009).

Materials

This study compared two bone substitutes of different origin and preparation methodology.

Bio-Gen is a material of equine origin, made non-antigenic with the use of a biotechnologically advanced enzymatic treatment (Zymo-Teck process), which results in partially denaturated collagen. The material is then made sterile by irradiation with Beta-rays.

The format analyzed in this study is Bio-Gen Mix (BGM), composed of a mixture of cancellous and cortical bone granules in equal measure.

Bio-Oss is a granular material composed of cancellous bone of bovine origin. It undergoes thermal treatment at high temperatures that makes the graft non-antigenic. There is a complete absence of collagen. The material is then sterilized using Gamma-rays.

Histological and histomorphometric analysis carried out by the Thin Section Laboratory, DISBIOC Department, University of Milan, Italy

Histomorphometrical Analysis
Bio-Oss vs. Bio-Gen

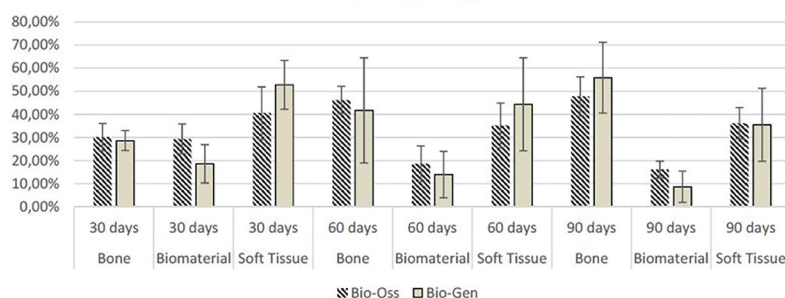


Fig. 1 – Results of histomorphometric analysis: the percentage of newly-formed bone tissue for both materials increases with time, without significant differences between the two. With the use of Bio-Gen, the percentage of residual biomaterial is reduced by a significantly higher margin than with the use of Bio-Oss. The percentage of soft tissue 90 days after the procedure is the same.

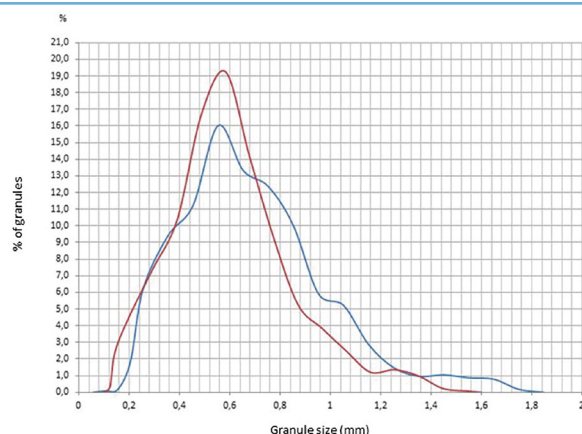


Fig. 2 – Results of the dimensional analysis with SEM: Bio-Gen (blue line) and Bio-Oss (red line) are essentially analogous.

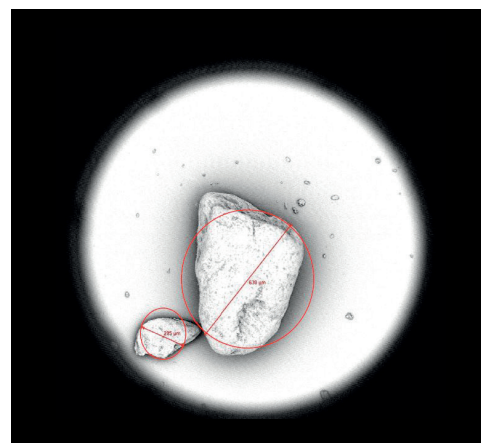


Fig. 3 – Dimensional evaluation of the granules with SEM: an example of how the diameters of the analyzed granules were calculated.

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Advantages

The Bio-Oss and Bio-Gen biomaterials were compared at dimensional level, and their remodeling kinetics was studied in animals.

The dimensional distribution of the granules was analyzed with a Scanning Electron Microscope (SEM); no differences between the materials were found.

For the study *in vivo*, the materials were grafted in bone defects created in the dental arches of "Yucatan" miniature pigs. Histological and histomorphometric analysis was carried out on biopsies obtained 30, 60 and 90 days after the graft, to measure the quantity of newly-formed bone tissue, the quantity of residual biomaterial, and the level of inflammation in the tissues adjacent to the graft. The values corresponding to the two biomaterial grafts were compared with suitable statistical tests.

The quantity of new bone tissue increased with time, without statistically significant differences between the two biomaterials. There were differences, however, in the quantity of residual biomaterial: in the sites that received the Bio-Gen graft, residual

biomaterial quantities were significantly lower compared to the sites grafted with Bio-Oss. The percentage of soft tissue was not statistically different in the two cases. Since the presence of a lower percentage of residual biomaterial compared to newly-formed bone tissue indicates faster kinetics of the biomaterial replacement with newly-formed bone, this result allows us to say that the Bio-Gen bone graft undergoes faster remodeling.

The level of inflammation in the tissues at 30 and at 60 days after the graft was reduced in both the sites that had received the Bio-Gen graft and in those where Bio-Oss had been grafted. Thirty days after the procedure, the sites that had received the Bio-Gen graft presented a slightly higher level of inflammation than those grafted with Bio-Oss; at 90 days, however, the inflammation was gone in both sites.

This study showed how the Bio-Gen graft is analogous to the Bio-Oss graft with regard to both the size of the granules and the ability to form new bone tissue; it presents, however, faster remodeling kinetics.

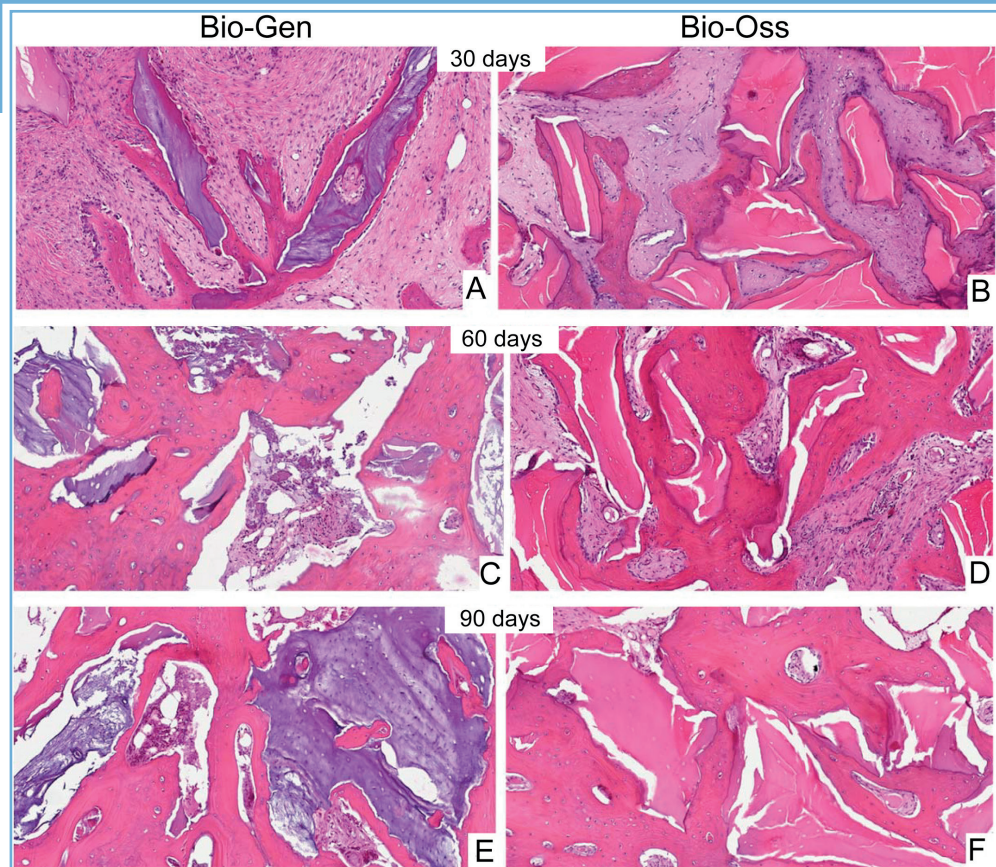


Fig. 4 – Histomorphometric analysis of the grafted materials, Bio-Gen and Bio-Oss, 30, 60 and 90 days after the procedure. We may observe: (A, B) biomaterial particles surrounded by a thin layer of bone tissue being formed; (C, D) biomaterial particles surrounded by newly-formed bone tissue that tends to grow, forming bone bridges between different particles to create an organized mineralized tissue; (E, F) particles integrated within wide areas of newly-formed tissue.



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