New micro and macro porous ß-Tricalcium phosphate ceramics as bone regeneration material

Non-autogenous bone replacement materials for guided bone regeneration find increasing acceptance. The development of these materials have been constantly adapted to the latest scientific knowledge. This was the case with the product which has been introduced as a new development, showing osteoconductive properties due to the micro and macro-porous structure. The product and the clinical application are described in conjunction with the product data.

The guided bone regeneration (GBR) in implantology and periodontology is one of the therapy areas of an implant surgery dental office which has most rapidly developed during the past ten years with regard to new development as well as new surgery procedures. Gold standard 1 in augmentation of bone defects is until today the therapy with fresh autogenous bone material which due to the origin has the property of biological activity and an osteoinductive as well as osteoconductive function.

There are, however, certain limits to this therapy which are connected with harvesting of autogenous bone material such as the surgery at another site and the limited amount of bone material especially with elder patients and possible complications at the site.

For this reason, the non-autogenous bone augmentation materials are the therapy of choice today which are suitable to replace autogenous bone. With BioResorb, a synthetic bioresorbable bone augmentation material of phase-free ß-Tricalcium phosphate with interconnecting porosity is available. The material serves as matrix for the entrance of bone regenerative cells (osteoblasts) and allows a bony integration (osteoconductive function). The biocompatibility of this material was documented in several clinical studies. The bioresorption, the complete resorption of BioResorb and the transformation into natural bone (remodelling) takes place according to the regular basic principles of ceramics bone augmentation materials: the physico-chemical decomposition and the direct cellular attack.

New manufacturing process

By a new production process of the manufacturer*, a new generation of phase-free bioresorbable ß-Tricalcium phosphate ceramics was developed which consists of a different interconnecting pore system with macro and micropores (Fig. 1 and 2). The percentage of micropores of an average size of 5 µm and the percentage of macropores with an average size of 500 µm is 30 volume percent each. The size interval of the micropores is 0.5 – 10 µm, and that of the macropores is 50 – 700 µm. The high porosity enhances an improved dynamic regeneration as compared to other bone augmentation materials. The homogenous structure of macro and micropores offers a high capillary function, and the considerably larger surface can be soaked with more blood particles and cells of osteogenous potential. The pore structure allows more room for vascularization than other augmentation materials and provides an improved nutrition of the regenerative material. The considerably larger surface offers more contact for cellular resorption, resulting in a shorter resorption time, so the simultaneous process of resorption and new bone growth is achieved.

The interconnecting micropore system of the granules and especially the macropores are connected by a collagenous fiber network, along with sufficient blood vessels. The collagenous fibers function as guidance for the vessels as well as the newly formed bone, this stimulating the direct apposition of bone on the surfaces of the granules prior to the start of resorption. The macropores facilitate the ingrowth of bone into the material, the osteones grow into the upper layers of the bone augmentation material. The bone regeneration material BioResorb Macro Pore is resorbed completely, simultaneously with new bone growth and allows an accelerated regeneration of the natural vital bone at the defect site.

The new ß-Tricalcium phosphate ceramic material has osteoconductive properties based on the micro and macroporous structure which enable bone defects which would normally not heal in a sufficient way, to regenerate well in good bone quality so that an immediate or a later implant insertion is possible.

Despite the high porosity, BioResorb Macro Pore has an optimal improved stability and high resistance against abrasion. The phase-free purity provides a stable structure and homogenous resorption ability in time under physiological conditions.

Clinical Study

In this context, we refer to the clinical study which was conducted at the Department of Oral and Maxillofacial Surgery at the University of Ulm, Germany, at the Military Hospital, with BioResorb Macro Pore ß-Tricalcium phosphate ceramics with macropores in clinical applications. The study comprises 95 patients (51 male, 44 female) of an average age of 49.4 years, who were treated with the bone augmentation material during a time period of October 1998 to September 2000. 41 patients had bone defects based on non-inflammatory epithelial cysts, with different sizes of bone defects. 54 patients showed inflammation-based epithelial cysts with an average defect size of 2.3 cm x 1.1 cm x 0.8 cm.

The evaluation includes radiograph controls (3, 6 and 9 months post-op), histologic analysis and the clinical healing process. The study was aimed at the pure descriptive evaluation of the bony substitution in the corresponding defects and the wound healing in the patients treated respectively.

The histologic data showed that after nine months post-op no remnants of bone augmentation material were detected. Only a few particles of the material were found in a state of resorption without complication. The remaining particles of the material were nearly completely enclosed by lamellary bone and nearly completely entered by structured bone. The vital stained osteocytes demonstrated vital bone cells.

The clinical healing process in the patient group with non-inflammatory bone defects showed a primary wound healing in 39 of 41 patients. This corresponds with a success rate of 95.2 percent.

The evaluation included the consideration that with increasing defect size the pace of bone regeneration decreases, since the regeneration process is not based on a linear reaction. The defects with a maximum volume of less than 1.5 cm required three months for bony regeneration, defects with a size between 1.5 cm and 2.5 cm six months, and the defects of more than 2.5 cm nine months (Fig. 3).

The ß-Tricalcium phosphate ceramics with macropores tested can be termed as bioinert. There was no connective tissue reaction like an encapsulation during the healing phase detected in any of the patients.

Conclusion

The new bone regeneration material BioResorb Macro Pore of phase-free micro and macroporous ß-Tricalcium phosphate ceramics guarantees a sufficient stability during the transformation into natural bone and final resorption without remnants in a predictable period of time. The demand for a complete regeneration of the bone defect without complication is fulfilled. The optimum biocompatibility of the material eliminates the risk of an unspecific immunologic reaction.

The selection of three granule sizes (200-500 µm, 500-1000 µm, 1000-2000 µm) predetermines this new bone regeneration material for the reconstruction of bone defects – dependent upon the size of the bone defect, the corresponding granule size can be chosen. The use of BioResorb Macro Pore enables a genuine restitutio ad integrum – a reconstruction of the original natural condition.

Fig. 1
SEM image of BioResorb Macro Pore, magnification 1:100

Fig. 2
SEM image of BioResorb Macro Pore, magnification 1:10,000

Fig. 3
Graphic diagram of the radiographic results for evaluation of the bone regeneration structure

relative frequency
size of the defect
3 months
6 months
9 months

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Literature references upon request.

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