Augmentation and Defect Reconstruction with a New Synthetic Pure-Phase Beta-Tricalcium Phosphate (Cerasorb® M) in Oral and Craniomaxillofacial Surgery

An open trial in 289 patients

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Introduction

Dental implants have become a generally accepted treatment modality in the prosthodontic management of edentulous and partially dentate patients. An adequate bone volume for accommodating root form implants and adequate primary implant stability ensuring implant osseo-integration are key for a successful outcome.

Therefore in many cases there is an increasing need for bone grafting and reconstruction. Autografts and xenografts, which have widely been used for this purpose, no longer meet what is expected of a safe bone grafting material – not only because of the potential residual risks inherent in biologic materials. While bone autografts continue to be the "gold standard" for many users, their functionality as a bone grafting material as well as the associated donor site morbidity and the risk of persistent damage to the patients are increasingly given critical attention, all the more so as a number of suitable synthetic grafting materials has been around for some time now.

Material and Methods

In a mono-center open trial, between September 2004 and December 2005, void filling or bone grafting was performed in all candidate patients with the new pure-phase beta-tricalcium phosphate, CERASORB® M (granule sizes 500–1000 µm and 1000 – 2000 µm) alone or in combination with autogenous bone. The synthetic bone regenerating material's distinguishing features are its interconnecting open multiporosity and its polygonal granule structure (micro-, meso- and macropores). In the meantime, Cerasorb® is used as world-wide standard for ß-TCP (ICDD).

Before applying the CERASORB® M granules the surrounding viable bone was invariably freshened vigorously, at times using a burr, and the granules were soaked in the fresh blood oozing from the wound. Occasionally, PRP (platelet-rich plasma) was also applied.

Depending on the conditions encountered, the grafting material was covered with a resorbable (Epi-Guide®) or non-resorbable (TefGen™ [1]) membrane for GBR (guided bone regeneration).

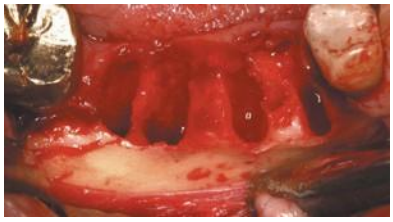

Fig. 1 a

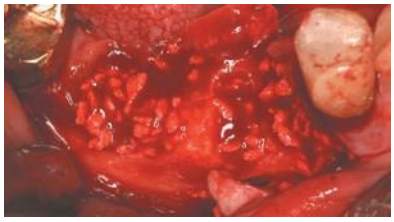

Fig. 1 b

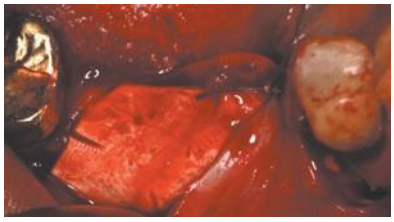

Fig. 1 c

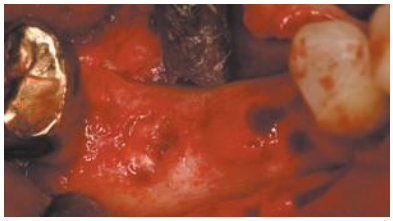

Fig. 1 d

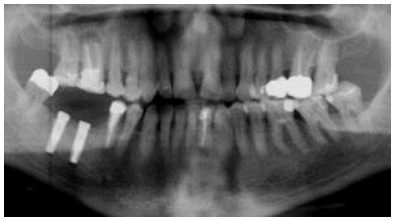

Fig. 1 e

1a) Post extraction

1b) Post grafting with CERASORB®M

1c) Coverage with Epi-Guide® membrane

1d) Exposed alveolar ridge 6 months post grafting

1e) OPG post implant placement

After adequate reconstruction or augmentation the patients enrolled in this study received one-stage or two-stage cylindrical or root form titanium implants (3i Implant Innovations Inc., USA).

All patients were followed up clinically and radiologically at the following times: Clinical follow-up/removal of sutures at one week; digital OPG at 3 and 6 months. The longest follow-up time was about 12 months.

Results

Membranes for GBR were used in 84 patients. Twenty-three of them were non-resorbable (TefGen™ [1]), while 61 were resorbable (Epi-Guide®).

Three groups of bone defects were distinguished by size: up to 1.5 ccm, 1.5 to 2.5 ccm and more than 2.5 ccm. Defects of more than 5.0 ccm were considered to be "critical size".

123 patients presented with defects of up to 1.5 ccm. In 92 of them the bone grafting material was completely replaced by bone at 3 months, in the remaining 31 at 6 months.

106 patients showed defects of 1.5 to 2.5 ccm. In 71 of them the material was completely resorbed at 6 months, in the remaining 35 at 6 to 9 months.

60 patients had defects of more than 2.5 ccm, some of them of more than critical size up to about 7 ccm. In all of them homogenous consolidation was seen radiologically at 6 to 12 months.

Late follow-ups were invariably radiologic. Bone biopsies were obtained from 23 patients, who had undergone vertical ridge augmentation, sinus lifting and reconstruction of extraction sockets, during implant surgery after 3, 6 and 9 months. Some of these biopsies were evaluated histologically. These did not show any histomorphologic evidence of bone loss by phagocytosis or foreign body reactions.

The figures 1a-e show a clinical example.

Discussion

Fresh bone autografts are known to have the best growth and healing potential. They would continue to be the gold standard for reconstructing defects and would, no doubt, be the ideal material, if harvesting them would not disrupt the routine in the practice setting to a considerable extent. Various donor sites are available. No matter what the donor site, graft harvesting invariably requires minor or major secondary surgery. The rate of potential donor site complications can apparently be reduced by a subtle technique. But it is still reported to lie between 20% and 30%. This shows that synthetic bone regenerating materials also are an alternative to bone autografts cost wise.

Recently Szabo and coworkers showed in a multicenter split-mouth trial the absence of histologic and histomorphometric differences between Cerasorb® [1] and autogenous bone grafting at the time of implant placement 6 months after grafting.

In principal one can distinguish between synthetic or semi-synthetic grafting materials, or of bovine (animal) or human donor origin. The latter, i.e. bank bone, is uncontestedly associated with some residual risks for both the surgeon and the patient. A potential transmission of BSE, foreign proteins and priones as well as the potential sequels of grafting with bovine material has been reported in the literature. Additionally there is a recent German court decision (OLG Stuttgart, 2005) mandating more comprehensive information of patients, who are candidates for grafting with bovine materials. Furthermore there is a risk of "stigmatizing" patients receiving bovine grafts as legally unfit for organ and blood donations at least in some counties/states.

Conclusions

CERASORB® M is an ideal synthetic material for use in dental practice. As it is fully synthetic, it does not expose surgeons and patients to the risks inherent in materials of biologic origin, i.e. potential allergy, infection, "stigmatization", nor does it require extensive preprocedure patient information. It is characterized by ease of handling, optimal applicability and retention. Rapid resorption and simultaneous formation of new bone facilitate reconstruction even in problem patients, in those requiring immediate implant placement despite a reduced bone volume and – needless to say – in candidates for implant placement 4 to 6 months post reconstruction, depending on the site grafted.

[1] TefGen-Membranes are not availabele since 2008. The non-resorbable Cytoplast TXT-200 Membranes [produced by Osteogenics, USA, distributed (in some countries) by RIEMSER Arzneimittel AG] are a very good alternative.

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