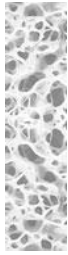




Summary of the Publication:



Synthetic, non-reactive beta-tricalcium phosphate-ceramic (Cerasorb®) for bone regeneration in reconstructive surgery of the jaws. A clinical long term study with review of literature

Horch HH, Sader R, Kolk A
Deutsche Zahnärztliche Zeitschrift 59 (2004) 12, 680-686

Purpose:

The fully synthetic, pure phase β -tricalcium phosphate ceramic Cerasorb®¹⁾, available since 1997, is characterized by its special biocompatibility, resorbability and osteoconductivity. Since 1997 the bone augmentation material was implanted in 152 patients in a prospective long term study under standardized conditions.

Materials and Methods:

From January 1997 to September 2001, bony defects in 152 patients (156 indications) were filled with Cerasorb®¹⁾ granulate (500-2000 μ m). The granulate was mixed with defect blood. Indications were the augmentation of large bony defects after cystectomy, reconstructive dentoalveolar

surgery, sinus floor elevation, alveolar cleft bone grafts, periodontal regeneration as well as other mandibular defects (tumors, apicoectomies, mandibular augmentations, defect filling after harvesting of autologous spongiosa). In cases of a radiologically visible osteolysis of more than 2cm, autologous bone was mixed with Cerasorb®¹⁾ in a ratio of 30-50%. Additional controls followed 4, 12 and 52 weeks post surgery. The duration of the study was 5.25 years.

Results:

In all 156 indications a safe and easy application of the granulate in the defect was possible. In 9.2% of the patients superficial wound healing irritations were observed which led to a partial loss of granulate in 5.9% of the

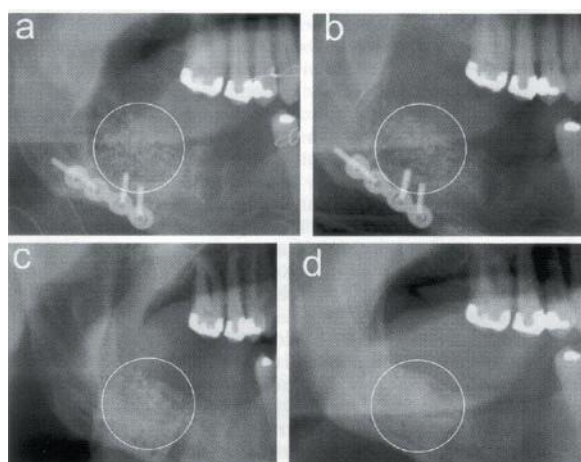


Fig. 1

Figure 1: Pathological mandibular fracture, defect filled with Cerasorb®¹⁾ immediately (a), 1 week (b), 4 months (c) and 12 months (d) after surgery.

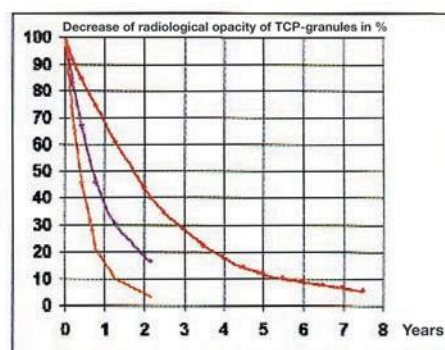


Fig. 2

Figure 2: Decrease of the radiological density of the TCP granulates with (orange) and without (purple) autologous spongiosa in comparison with a β -TCP which does not show the high phase purity ($\geq 99\%$) of Cerasorb®¹⁾ (red).



cases. Owing to cleansing and appropriate care of the region, a secondary wound healing could be achieved without adverse effects to the outcome. In 2% of the cases (3 patients) a total loss of the granulate occurred as a result of a secondary infection after the treatment of extensive mandibular keratocysts. In these patients the total loss was caused by an intraoperative fixation of the endocyst with Carnoy' solution containing acetic acid which may have shifted the pH area of stability. In the other 135 patients (88,8%), an almost complete resorption of the β -TCP granulate with a simultaneous total bone substitution could be observed radiologically and histomorphometrically (see figure 1). The decrease of the radiological density occurred faster with the purephase ($\geq 99\%$) β -tricalcium phosphate Cerasorb®¹⁾ than with older, non pure-phase products (see figure 2). Foreign body reactions were not observed. Mixing Cerasorb®¹⁾ with autologous spongiosa resulted in a more rapid decrease of the radiological density (85% instead of 65%).

Discussion:

Bioactive ceramics based on calcium phosphates or bioglasses have been used as bone defect fillers for decades. Caused by the bioactivity and the osteoconductivity of non resorbable materials, a bonding osteogenesis occurs, but not a full recovery of the defect region to the status as it was before. β -TCP materials are completely resorbed by the body. With the synthetic, highly pure-phase ($\geq 99\%$) ceramic Cerasorb®¹⁾, however, a clinically relevant and defined degradation kinetic was evident.

After resorption of the material, the bone regenerated completely. Trabecular structures were histologically visible. The complete bony substitution of the ceramic is difficult to predict because of the individual influencing factors inherent to the patient. Minimal residues of the ceramic, histologically visible in a study 86 weeks after implantation are clinically irrelevant. In sinus floor elevations, a concomitant insertion of dental implants should be avoided. Because of the initial progressive degradation phase, this procedure can lead to encapsulation of the implant with connective tissue. It is recommended to insert dental implants after advanced degradation and bony substitution of the ceramic after approximately 5-6 months. β -TCP ceramics should be used as a matrix for osteoinductive substances in future. Methods of Tissue Engineering for the cultivation of bone in a bioreactor are also possibilities for such resorbable bone augmentation materials. Deproteinized allogeneic and xenogeneic materials cannot be recommended due to the risk of disease transmission that cannot be entirely ruled out and/or to antigenicity that may lead to rejection or allergic reactions.

Conclusion:

In a study covering 5.25 years, 135 patients were treated with Cerasorb®¹⁾ without risks or problems. An average resorption/degradation time of 12 months could be established. The relevance of the phase purity was confirmed by radiological observations. Insertions of dental implants can be performed after 5-6 months following bony ingrowth and partial decomposition of the ceramic.

¹⁾ Trade name CERASORB® Classic since 2011