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The manufacture of synthetic non-sintered and degradable bone grafting substitutes

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A new synthetic bone grafting substitute (NanoBone®, ARTOSS GmbH, Germany) is presented. This is produced by a new technique, the sol-gel-method. This bone grafting substitute consists of nanocrystalline hydroxyapatite (HA) and nanostructured silica (SiO_2). By achieving a highly porous structure good osteoconductivity can be seen. In addition, the material will be completely biodegraded and new own bone is formed. It has been demonstrated that NanoBone® is biodegraded by osteoclasts in a manner comparable to the natural bone remodelling process.

Key words: bone grafting substitutes, sol-gel-method

INTRODUCTION

The application of bone grafting substitutes is of increasing interest for dental and craniofacial surgery. The substitutes should promote the formation of new natural bone, while the external material should be degraded. To achieve this result the optimal bone grafting substitute must be degraded in the way natural bone is always degraded — bone remodelling. Through this natural process a permanent regeneration and optimisation of the skeletal system *in vivo* takes place [1].

In the past mostly ceramic materials, especially those based on hydroxyapatite (HA) and β-tricalcium phosphate (β-TCP), were used to treat osseous defects. The reason for this is that a large fraction of human bone consists of hydroxyapatite in its inorganic phase. The conventional bioceramics of animal or synthetic origin were produced in methods where sintering on temperatures between 1100°C to 1500°C occurred. This sintering results in a higher density of the material and decreasing porosity [2, 3]. In addition, connectivity between the pores is lost to a considerable degree. The result is decreased osteoconductivity and poor or no degradation of the biomaterial, which remains at the site of implantation. Very often HA particles can be found clinically many years later. The disadvantage of this behaviour is the negative impact of mechanical properties and sometimes the problem of chronic resorptive inflammation.

THE CONCEPT OF NANOBONE®

NanoBone® is produced by the sol-gel-method [4]. It was approved in Europe (CE-certificate) in January 2005. In the manufacture of NanoBone® the temperature is always below 700°C, so that no sintering of the nanocrystalline hydroxyapatite takes place. During the sol-gel-method nanocrystalline hydroxyapatite is introduced into the SiO_2-sol and homogeneously distributed. The silica forms a nanoporous scaffold during the gel transition and connects

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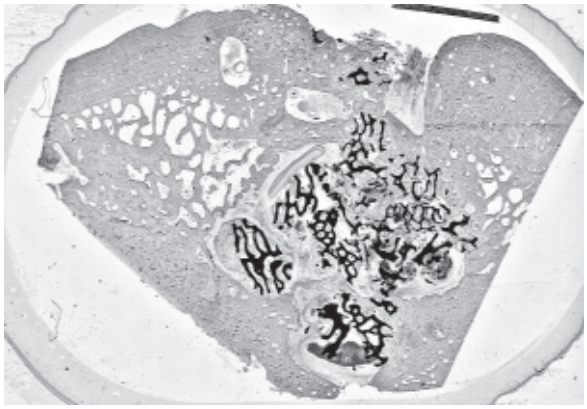

Figure 1. Sintered hydroxylapatite after 8 months. A degradation of the biomaterial is observable. An encapsulation of the particles can be seen.

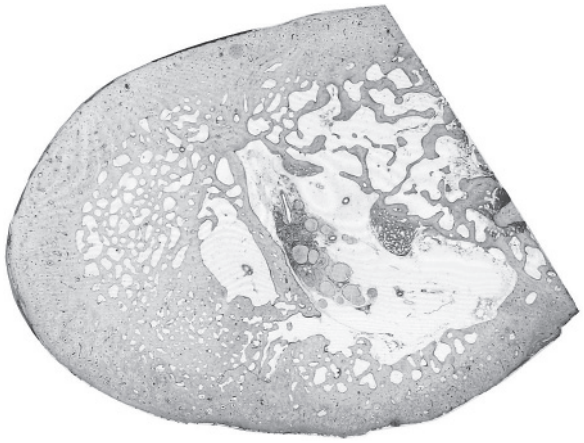

Figure 2. After 8 months NanoBone® is almost completely degraded. Compacta and spongious bone have been formed.

the loosely packed hydroxyapatite crystallites. Through the disappearance of the solvent during the drying process at 200°C a formation of pores in the micrometre range occurs. Afterwards a highly porous granulate is produced. Because of the high porosity and loose packaging of the granulate (in a "fir-cone shape") the solid content is approximately only 20 volume percent. In contact with the patient's blood during the operation approximately 80 volume percent is filled with the patient's own material. In particular, the patient's own proteins can enter the nanopores of the new bone grafting material.

ANIMAL EXPERIMENTS

Conventional sintered bone grafting substitutes and the new biomaterial NanoBone® were tested in clinical trials on mini-pigs from Goettingen. A perforating critical size defect in the region of the anterior mandible with a volume greater than 5 cm^3 was, therefore, created. There was no contact with the oral cavity or the teeth system. After 8 months the animals were sacrificed. Histological cuts were prepared and histomorphometrically analysed (Fig. 1).

In the defects treated with sintered HA an encapsulation of the biomaterial was observed. Defects treated with NanoBone® were almost completely healed (Fig. 2). The new bone grafting substitute was almost completely degraded by osteoclasts. In parallel to this new bone tissue in the former defect region was formed and new compacta and spongious tissue can be seen.

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