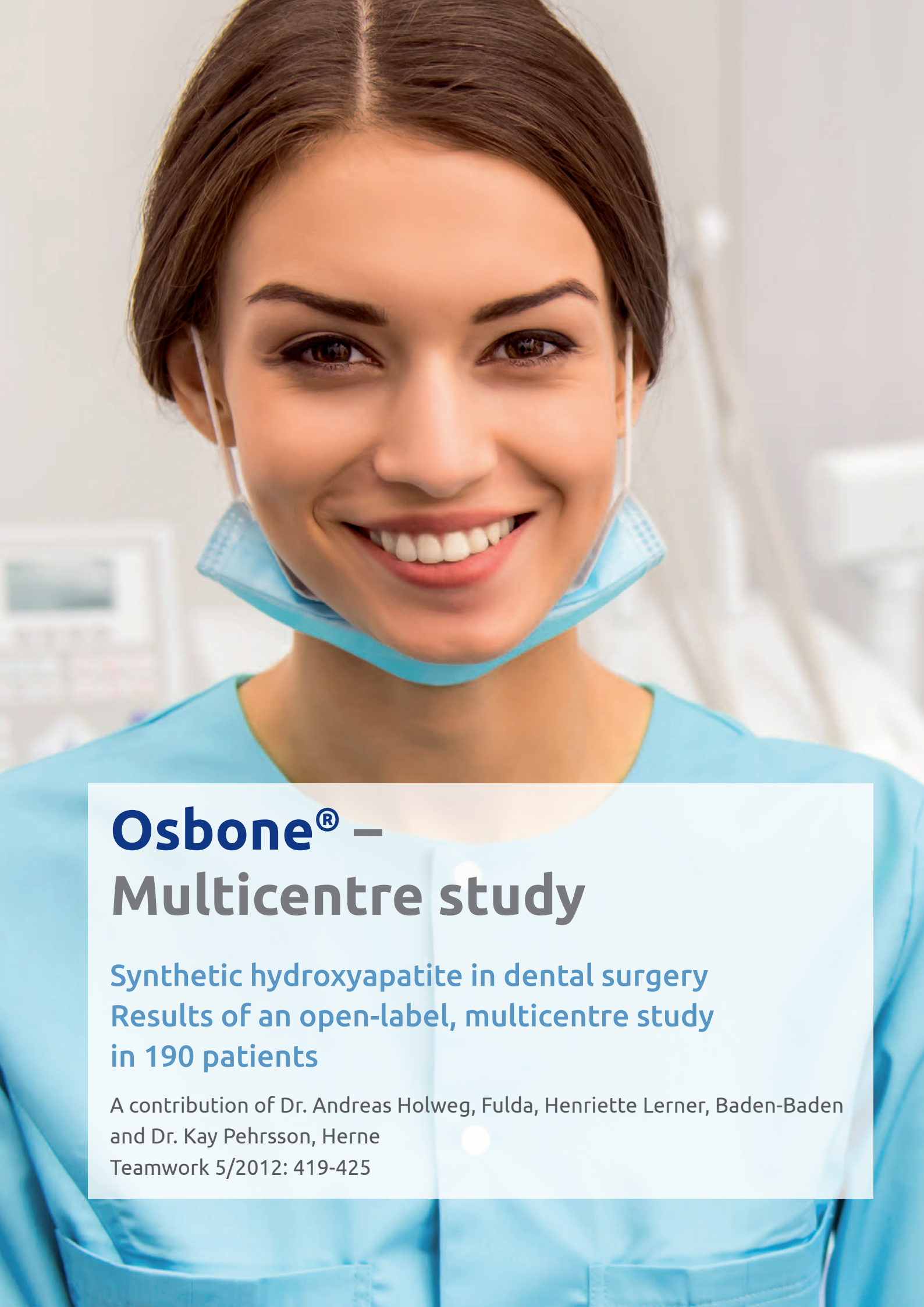
Literature service

Osbone®-Multicentre study

curasan
Regenerative Medicine



Osbone® – Multicentre study

Synthetic hydroxyapatite in dental surgery Results of an open-label, multicentre study in 190 patients

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Introduction

There is a considerable demand for bone regeneration or augmentation materials (BRM) in the field of dental medicine, especially in oral and maxillofacial surgery. While fresh autologous bone exhibits the highest biological potency, the necessary second intervention and its associated complications, the relatively limited availability, the additional logistical effort and potential forensic consequences when using this type of bone alone have to be considered.

Alternatively a variety of synthetic and biological materials is available that differ from one another in terms of porosity, surface structure and absorption kinetics. Hydroxyapatites (HA), for example, have been used as BRM throughout the entire skeletal system for many decades. In principle a distinction is made between products that are synthesised from the minerals calcium and phosphate and products of allogeneic or xenogeneic origin. Os**bone**® granules (curasan AG) consist of purely synthetically manufactured, phase-free hydroxyapatite. According to recent findings from bone regeneration research, Os**bone**® possesses the following properties: Interconnecting, open multiporosity (approximately 80 %), polygonal granular structure and high similarity to human cancellous bone.

The aim of this multicentre study pursuant to § 23b German Medical Devices Act (MPG) was to gain further insights into the benefit, efficacy and tolerability of Os**bone**® for various indications in dental and oral surgery.

Material and methodology

The prospective, multicentre study was conducted in Germany by experienced oral surgeons and implantologists. Patients with the following preoperative diagnoses or indications were to be enrolled in the study: alveolar defect, apical resection, implant bed preparation, filling of cysts, sinus floor elevation, periodontal pocket and other similar indications.

After collecting the medical history and performing a baseline physical examination (including radiographs if possible), as well as obtaining informed consent for the procedure, the following was documented: treatment administered (type of intervention; amount and grain size of the Os**bone**® granules used; additional measures such as mixing in PRP [platelet-rich plasma] or PMC [platelet mediator concentrate]; use of a membrane; soft tissue closure; etc.) and the follow-up examinations performed 1-2 weeks postoperatively as well as after approximately three, six, nine and twelve months and sometimes later – depending on the progress of regeneration and healing.

Results

A total of 32 dental as well as oral and maxillofacial surgeries throughout Germany took part in the study. The observation period lasted from May 2010 to May 2012 (first treatment day of first patient, last follow-up of last patient). The documentation sheets of a total of 190 patients (107 female, 83 male) aged 20 to 83 years (mean age: 53.15 years, median 54 years; no age given for n = 4 patients) were analysed.

The most common diagnoses with 75 instances was atrophy of the alveolar ridge, followed by „non-salvageable tooth“: 25, periodontitis: 18, history of root canal treatment/apical resection: 14, history of tooth loss: 13, cyst surgery: 13; other nominations included e.g.: alveolar defect, post-trauma tooth loss, root fracture.

Augmentation was performed at a total of 458 locations: first quadrant: 150, second quadrant: 179, third quadrant: 63, fourth quadrant: 66. The majority of augmentations was performed at site 26 (n = 44), following by site 16 (n = 37). The most commonly performed intervention was sinus floor elevation.

Os**bone**® granules with a grain size of 0.25–1 mm were used in 128 cases, while a grain size of 1–2 mm in size was used in 71 cases. The amounts used were: 1.0 g in 107 patients, 0.5 g (n = 51), 2.0 g (n = 19), 1.5 g (n = 8), 3.0 g (n = 4), 4.0 g (n = 3), and 5.0 g (n = 1).

Os**bone**® was mixed with autologous bone in 36 patients. Other interventions included PRP (n = 27), PMC (n = 3) and fibrin from autologous blood (n = 10).

Antibiotics were given preoperatively in 73 cases or postoperatively in 131 cases, most commonly clindamycin (n = 74), followed by amoxicillin (50) and amoxicillin clavulanate (11). The duration of antibiotic therapy varied between two and 14 days, most commonly it was three days (n = 31), five days (n = 24) and seven days (n = 36). 137 patients performed regular mouthrinses, mostly with chlorhexidine (n = 95) or Meridol (n = 30).

A total of 128 interventions involved use of a membrane: 107 resorbable, 15 non-resorbable and six instances of titanium mesh.

In 117 patients, the implant was primarily placed on the day of defect filling or augmentation; in 37 patients, it was placed between 14 and 304 days post-operatively (mean: 159.3 days; median: 161 days); no data were available for 36 patients (as no implantation was performed here). Altogether, 400 implants were placed, most commonly at sites 15, 16 as well as 25 and 26.

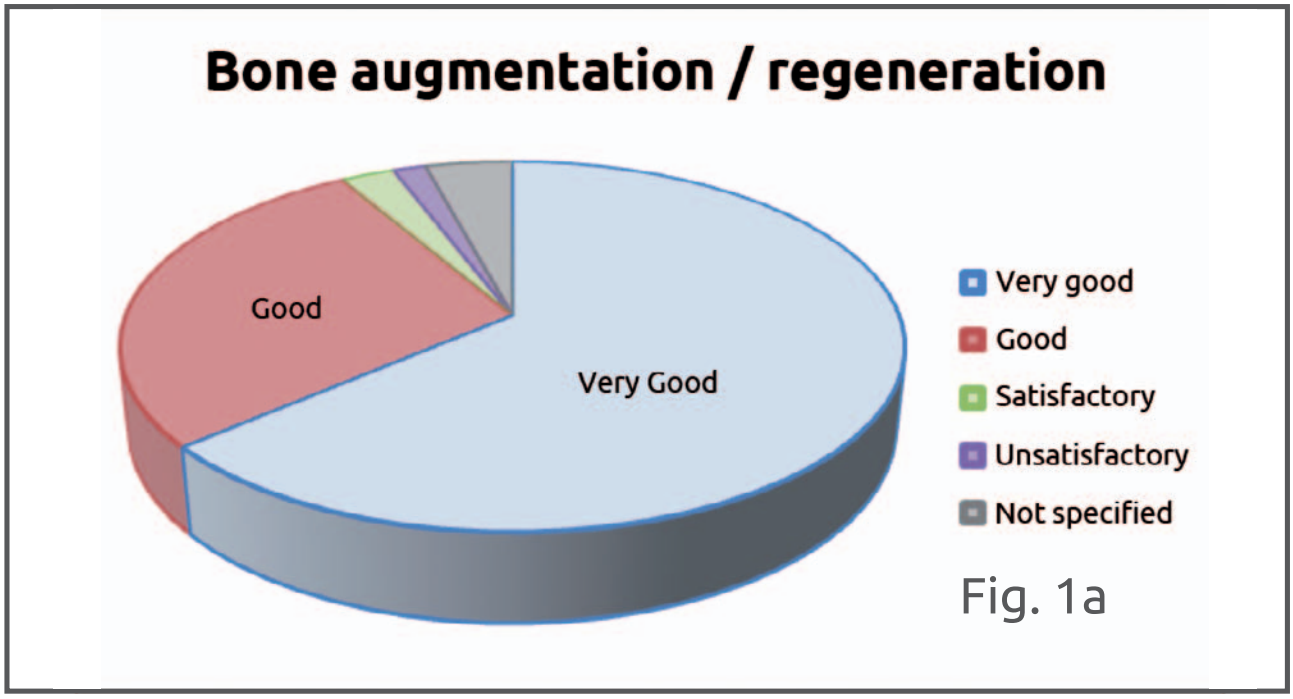
At the time of implantation, the available bone at the insertion site was assessed as follows:

Optimal	Good	Limited suitability	Unsuitable	Unspecified (as no implant was placed)
36	68	47	2	37

In 61 documentation forms, primary implant stability at the time of placement was reported at 20 Ncm, or >20 Ncm in 93 cases (no data available for 36 cases, see above).

Irregularities were observed in only a small number of patients at the individual follow-up visits, namely sinusitis on the contralateral side, exposed titanium mesh (requiring removal of the mesh and granules), purulent infection with granule loss, removal of membrane fragments required, fistula at the surgical site, pressure pain at the surgical site, which were treated with the appropriate therapeutic measures during the further course and healed without complications.

The final overall assessment of the clinical outcome of the defect filling or augmentation and of the tolerability is shown in Fig. 1.



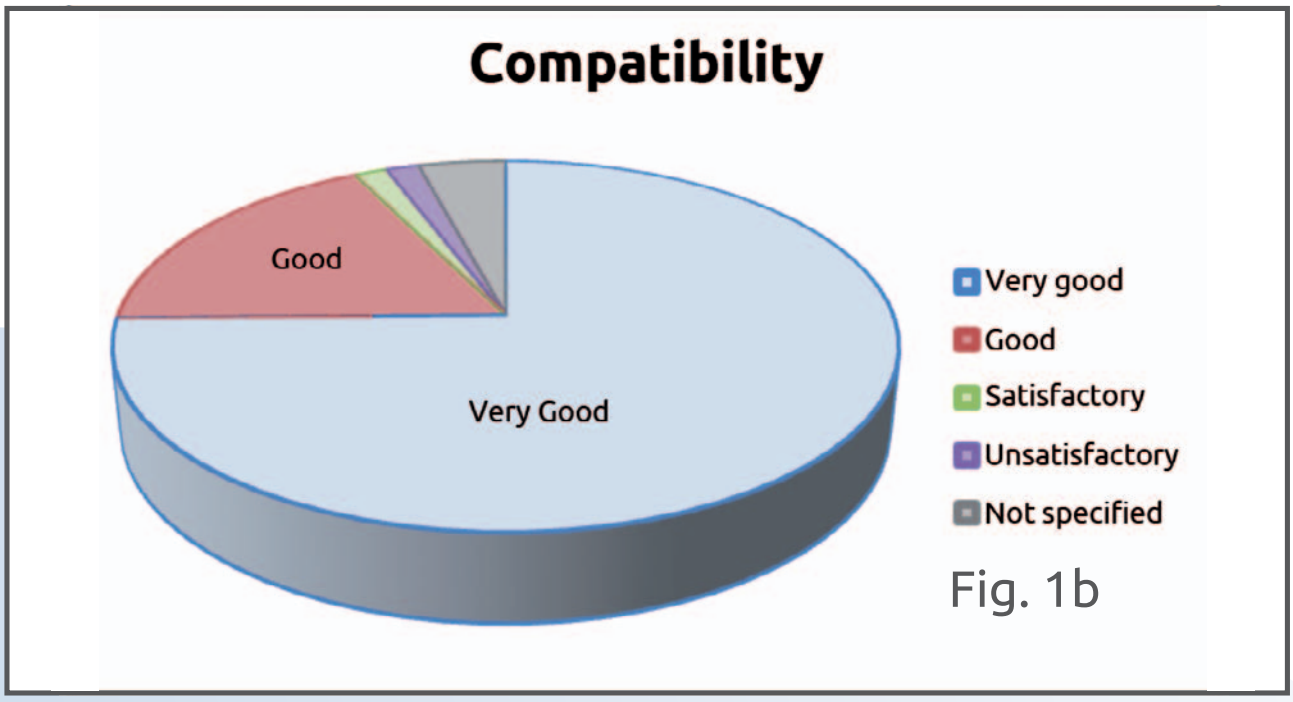


Fig. 1a und 1b: Overall evaluation of efficacy and tolerability

Fig 1a and 1b: curasan AG

Discussion

The indication-conform use of bone replacement and regeneration materials is part of the daily practice in oral surgery. The products used today, such as HA and β-TCP, are available as granules and are not suitable for stabilising implants in cases of severe atrophy.

Smaller bone defects, however, can often be augmented with BRM at the same time as the implantation. Use of TCP for this purpose is limited. This material may absorb prematurely in vestibular augmentation sites. HA is more suitable for this purpose, as it has slower absorption kinetics and degrades only slightly and over an extended period of time.

Because of its porosity of 80 per cent, corresponding to that of human cancellous bone, Os**bone**® promises rapid vascularisation with high stability. For ideal regeneration of larger bone defects, the current literature suggests a minimum pore size of 200–400 µm in order to achieve sufficient neovascularisation and osteoconduction with formation of mineralised tissue within the scaffold. For the penetration of individual bone cells, a lower threshold of 80 µm is indicated.

In this context, an important aspect is the degree of ‚interconnectivity' of the pores within a particle BRM. These are conditions that Os**bone**® fulfils, as the new bone replacement material was developed under the proviso to mimic the cancellous bone structure as closely as possible in order to provide the most suitable structures for osseointegration. Micro-CT images show that the average pore diameter is 500 µm, with beam widths of 150 µm on average.

In an in-vivo comparative study of various BRMs characterised by different porosity and absorption kinetics, Os**bone**® was studied for 18 months in sheep bones.

Throughout the entire study, the material exhibited excellent osteoconductivity and biocompatibility in critical-size defects. The Os**bone**® granules showed excellent bone-to-particle contact and very good bone integration and particle degradation, whereas the ceramic particles were not completely resorbed after 18 months.

However, this is exactly what they were designed for, as they were developed for indications where increased mechanical stability is required. Furthermore, there were no inflammatory or local or systemic toxic reactions at any time during the study.

In clinical use, the vestibular simultaneous augmentation with hydroxyapatite in grade I and II mandibular atrophy has proven useful, since the material is not as quickly resorbed in the buccal region as e.g. tricalcium phosphate.

With regard to materials that are biological in origin it must also be considered that, when using purely synthetic bone regeneration materials such as Os**bone**®, patients need not be informed of any potential complications related to bone harvesting and transplantation, as well as problems of tissue rejection or potential allergisation or residual infection risks, as would be the case if materials of bovine origin were used.

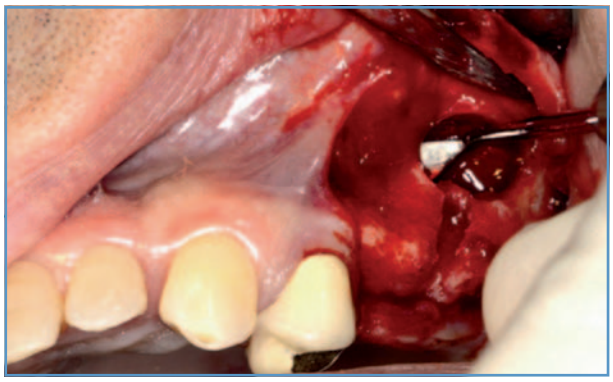


Fig. 2a: External sinus floor elevation according to Tatum, preparation of the mucosa of the maxillary sinus.

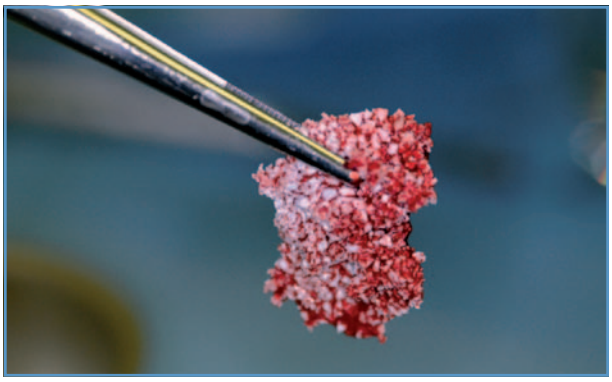


*Fig. 2b: Os**bone**® granule-autologous blood mixture.*

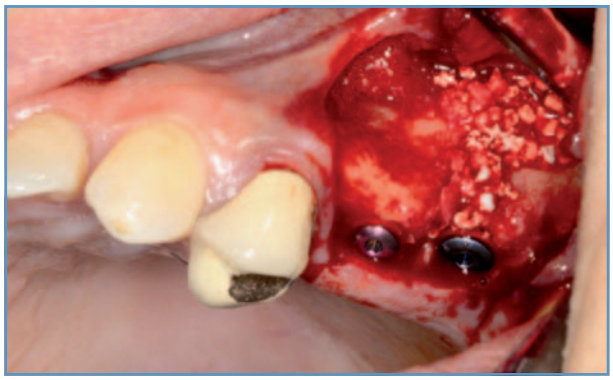


*Fig. 2c: Complete defect filling after introduction of Os**bone**® granules.*

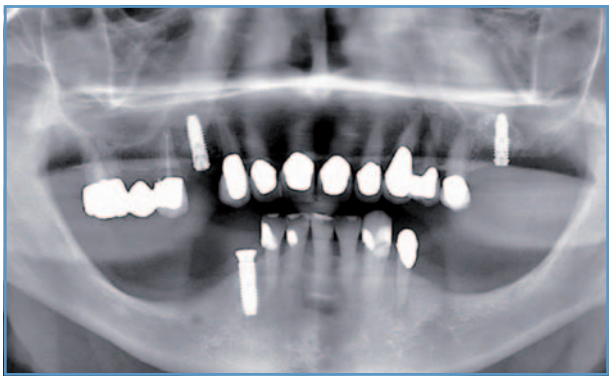


Fig. 2d: X-ray image six months postoperatively, prior to exposure and final treatment: good osseointegration of the implants, residual granules at site 26 visible.

Conclusion

The new bone substitute Os**bone**® is particularly well-suited for use in indications where increased mechanical stability is required, as it offers ideal structures for osseointegration, possesses slow resorption kinetics and exhibits excellent biocompatibility.

Fig. 2a-d: Dr. K. Pehrsson, Herne

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