

# SCIENTIFIC ABSTRACTS

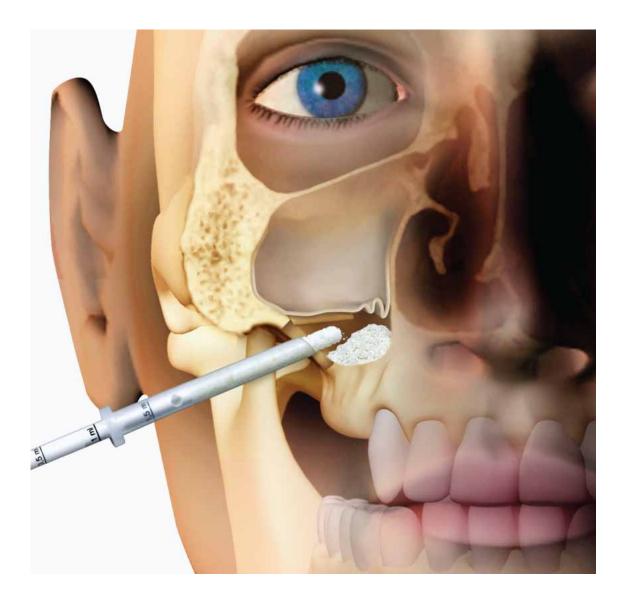
# INTERNATIONAL PUBLICATIONS ON OSTEOBIOL® BIOMATERIALS



REGENERATION SCIENCE

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# Osteo Biol® by Tecnoss

REGENERATION SCIENCE





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BONE SUBSTITUTE OsteoBiol® Apatos

# Histologic and ultrastructural analysis of regenerated bone in maxillary sinus augmentation using a porcine bone-derived biomaterial

#### ABSTRACT

In case of an insufficient bone volume in the posterior maxilla, maxillary sinus floor augmentation procedures are used. Even if several different materials have been proposed for sinus augmentation procedures, it is still not clear which graft materials are clinically most suitable for bone regeneration. Autogenous bone is considered to be the gold standard, but its main disadvantages, especially those related to the patient's discomfort, produced a quest for a bone substitute that could be used in bone regeneration techniques and induce a predictable and rapid healing of the tissues at the interface with dental implants.

The aim of the present study was to report the results of light microscopy (LM) and transmission electron microscopy (TEM) in specimens retrieved 5 months after sinus floor augmentations using a porcine bone-derived biomaterial in the form of granules (OsteoBiol® Apatos, Tecnoss®, Giaveno, Italy). 10 patients were included in this study. After maxillary sinus augmentation using this biomaterial, 10 specimens were retrieved after 5 months and processed to be observed under light microscopy (LM) and transmission electron microscopy (TEM). At the same time, implants have been placed, planning second-stage surgery after 5 months.

After 5 months, the clinical observation revealed that all implants were stable and the x-rays showed the presence of bone around and above the implants placed in the augmented maxillary areas. The light microscopy observation showed that most of the particles were surrounded by newly formed bone and that mainly compact bone was present at the interface. Moreover, the bone biomaterial interface showed a close contact between the porcine bone particles and the surrounding bone that had mainly features of mature bone with numerous osteocytes. Newly formed bone area was  $36\pm2,8\%$ , marrow spaces were  $38\pm1,6\%$ , while residual graft material was  $31\pm1,6\%$ . Under TEM, all phases of bone formation (osteoid matrix, woven, and lamellar bone) were observed in proximity with the biomaterial particles.

#### CONCLUSIONS

The findings of this study show that this cortical porcine bone-derived biomaterial is biocompatible and can be used for maxillary sinus augmentation procedures, promoting bone formation without interfering with the normal reparative bone processes and implant osseointegration. Based on these results, the Authors concluded that "these findings could increase the scientific knowledge of the clinician for understanding the biologic interactions occurring in proximity of a porcine bone substitute, showing that bone in contact with it presents all the phases of bone formation and shows features similar to the pre-existing osseous tissue, thus indicating the biocompatible properties of this graft".





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LASL

# Porcine bone used in sinus augmentation procedures: a 5-year retrospective clinical evaluation

#### ABSTRACT

Inadequate bone height in the lateral part of the maxilla is a contraindication for implant surgery and the rehabilitation of the edentulous posterior maxilla with dental implants often represents a clinical challenge.

The aim of this study was to evaluate from a clinical point of view the maxillary sinus augmentation using porcine bone. This study included 121 healthy patients (71 women and 50 men), all candidates for augmentation in the posterior maxilla. After the elevation of the sinus membrane, the maxillary sinus was filled with sterilized porcine cortico-cancellous mixed bone particles (OsteoBiol® Apatos, Tecnoss®, Giaveno, Italy). In 20 cases a perforation of the sinus membrane occurred, but without clinical complications and all the membrane perforations were successfully repaired with a collagen membrane (OsteoBiol® *Evolution*, Tecnoss®) and showed uneventful healing. After a 4- to 6-month healing period, sandblasted and acid-etched implants were inserted. All grafted sinuses healed well without major complications and did not show occurrence of symptoms indicating possible maxillary sinusitis and the cumulative survival implant rate was 92% after a mean loading time of 5 years.

#### CONCLUSIONS

The results of this study show that porcine bone can be used with success in sinus floor augmentation procedures, and rougher-surfaced implants are probably preferable. These findings are in accordance with other studies that showed that porcine bone has good biocompatibility and osteoconductive properties, with osteoblastic seams forming bone directly on the biomaterial surface and with no histologic signs of adverse reactions.



# OsteoBiol

#### LATERAL ACCESS SINUS LIFT

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ORIGINAL ARTICLE Clinical Implant Dentistry and Related Research 2011; 13(1):13-18

#### Grafted with

BONE SUBSTITUTE OsteoBiol® Apatos

MEMBRANE OsteoBiol® Evolution

# Maxillary sinus augmentation in humans using cortical porcine bone: a histological and histomorphometrical evaluation after 4 and 6 months

#### ABSTRACT

Bone substitutes, such as allografts, xenografts, and alloplasts, have been proposed in several augmentation procedures as an alternative to autogenous bone. Although autogenous bone is considered as the gold standard, its use has several disadvantages: a limited availability, a tendency to partially resorb, the need for an additional surgery, and the increased morbidity.

Among the bone substitutes available on the market, OsteoBiol® Apatos (Tecnoss<sup>®</sup>, Giaveno, Italy) is a xenogeneic bone substitute consisting of sterilized cortical porcine bone in form of particles with a high porosity and with a diameter ranging from 600 to 1000  $\mu$ m. This biomaterial is similar to human bone, and it has been reported, in humans, to be osteoconductive, well integrated in the host site and incompletely resorbed after 5 months, and with no signs of adverse reactions in a rabbit study. All sinuses have been augmented with porcine cortical bone particles (Apatos) mixed with sterile saline solution and blood. A resorbable membrane (OsteoBiol® Evolution, Tecnoss®) was positioned while closing the packed sinus window. The aim of the present study was to perform histologic and histomorphometric evaluation of 77 specimens retrieved 4 or 6 months after sinus augmentation using cortical porcine bone augmentation material. The specimens were processed to be observed under light microscopy. Histomorphometric measurements after 6 months showed:  $31,4\pm2,6\%$  newly formed bone,  $34,3\pm3,1\%$  marrow spaces,  $37,6\pm2,2\%$ residual graft.

The results of the evaluations confirmed the good biocompatibility and high osteoconductivity of this porcine biomaterial. Most of the grafted biomaterial particles were surrounded by newly formed bone, and no gaps or connective, fibrous tissues were found at the biomaterial-bone interface. There were no sign of inflammatory or other adverse reactions in the bone formed.

#### **CONCLUSIONS**

The present results show that cortical porcine bone is a biocompatible, osteoconductive biomaterial than can promote the formation of new bone, even in maxillary sinus augmentation procedures, without interfering with bone regeneration.

As this was a histological and histomorphometrical study only, in their conclusions the Authors anticipated that the long-term outcomes - that will be reported in a separate manuscript - were satisfactory in comparison to studies using other graft materials.





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# Comparative histological results of different biomaterials used in sinus augmentation procedures: a human study at 6 months

#### **ABSTRACT**

As demonstrated by several studies, sinus augmentation is a predictable treatment for atrophy of the posterior maxilla and different bone substitutes have been used in sinus floor augmentation. However, only few studies compared the performances of the different kinds of grafts and so a current issue is the definition of the best filling material for the sinus cavity. Therefore, the aim of this study was to perform a histological and histomorphometric evaluation, in humans, of specimens retrieved from sinuses augmented with phycogene HA (Algipore<sup>®</sup>, DENTSPLY-Friadent, Mannheim, Germany), macroporous biphasic calcium phosphate (MBCP®) (Leone, Firenze, Italy), calcium carbonate (Biocoral®, Leader-Novaxa, Milan, Italy), collagenized porcine cortico-cancellous bone (OsteoBiol® Apatos Cortical, Tecnoss<sup>®</sup>, Giaveno, Italy) ABB (Bio-Oss<sup>®</sup>, Geistlich, Wohlhusen, Switzerland). A total of 30 sinus augmentation procedures were performed and in every case, 100% biomaterial was used. 15 patients were scheduled for bone reconstruction procedures including sinus augmentation and implant insertion. For the examination, a total of 60 bone cores, 2 for each augmented sinus, 12 for every biomaterial, were retrieved. At low power magnification, it was possible to observe that many grafted particles were bridged by newly formed bone and in some portions of the specimens, graft particles appeared to be lined by newly formed bone, without gaps at the bone-particle interface and with no sign of inflammatory cells and multinucleated giant cells. In the porcine bone group, few peripheral osteocytic lacunae, present in the biomaterial, appeared to be filled with osteocytes; around some particles, osteoblasts could be seen, while actively depositing unmineralized osteoid matrix.

## CONCLUSIONS

Based on the findings, the Authors concluded that "the results of the present study have shown that all these biomaterials can be used with success in maxillary sinus augmentation procedures showing good biocompatibility and osteoconductive properties, with osteoblastic seams forming bone directly on the biomaterial surface and with no histological signs of adverse reactions".



# Regeneration of human bone using different bone substitute biomaterials

## ABSTRACT

In order to compensate for a lack or loss of bone tissue, it is possible to use bone substitute biomaterials (BSBs) available as inorganic or organic, natural or synthetic materials. Ideally, a BSB should have specific biological and clinical peculiarities.

The aim of this study was to evaluate and compare the in vivo behavior of different biomaterials, placed in humans, by means of two mathematical indexes, one used to examine bone regeneration processes and the other for the assessment of bone density structure obtained after regeneration.

13 different BSB were considered in the present analysis, and among them there was a collagenized porcine bone (OsteoBiol® Apatos Cortical, Tecnoss<sup>®</sup>, Giaveno, Italy) and a cortico-cancellous porcine bone (OsteoBiol® Apatos Mix). 295 patients were included in the study and almost all the cases were sinus augmentation procedures; one case was of alveolar socket regeneration and one case of an implant retrieved for fracture.

The data belonging to previously published studies have been analyzed using innovative mathematical models to evaluate the bone regenerative index (Br) and the structural density index (Ds).

The results showed that after 6 months the regenerated bone showed a D3 bone type. After several years, the regenerated bone type was D2, with an evident increase in the density of the regenerated bone over time. Moreover, the values of Br were higher for combined biomaterials indicating a fewer amount of residual particles and marrow spaces, while the values of Ds were higher for anorganic bovine bone indicating a greater new bone formation and a lesser amount of marrow spaces. After 20 years, the bone regenerated using hydroxyapatite still had a D4 bone quality.

#### CONCLUSIONS

Based on the results of the evaluations performed, the Authors concluded that "the clinical implications of the present observation appeared to be irrelevant in cases for which the BSBs were used with the aim to restore or augment bone for aesthetic/prosthetic reasons without implant placement. Instead, for those cases in which the use of BSBs was an essential pretreatment for implant prosthetic restorations, it was necessary to take into consideration that the augmented bone, after 6 months of healing, had on average a structure like poor D3 type bone and represented one-third of the space filled by BSBs. Finally, none of the evaluated biomaterials seemed to be an ideal BSB".

#### LATERAL ACCESS SINUS LIFT

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> ORIGINAL ARTICLE Clinical Oral Implants Research 2016 Sep;27(9):1106-22

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# Histomorphometric outcomes after lateral sinus floor elevation procedure: a systematic review of the literature and meta-analysis

# ABSTRACT

Very often, the progressive resorption of the alveolar bone caused by tooth loss in the posterior maxilla needs a bone augmentation procedure in order to increase the available bone volume for the placement of dental implants needed to support a fixed prosthetic rehabilitation.

In literature it has been reported that the lateral approach sinus floor elevation (LASFE) can be safely applied in cases of posterior maxilla atrophy, leading to a high implant survival rate.

The aim of the present systematic review of the literature and meta-analysis was to investigate the histomorphometric outcomes of LASFE (Lateral approach sinus floor elevation) surgery in order to evaluate different bone substitute materials (AB, autogenous bone; BB, Bovine bone, AG, allograft; FDBA, freeze-dried bone allograft; HA, hydroxyapatite; PB, porcine bone; PRP, platelet-rich plasma) performances related to new bone formation. After an electronic and manual search, 84 articles were included in the quantitative synthesis and 16 of them in the meta-analysis of comparative studies. Taking into consideration the articles selected, a total of 1846 subjects were treated, and a total of 2224 biopsies were taken and examined. Recorded data were statistically analyzed evaluating percentage of new bone volume, residual biomaterial, and connective/soft tissues in the biopsies. The results show that the use of autogenous bone (AB) alone led to a significantly higher new bone formation if compared with bovine bone (BB) alone (P = 0.04), while no significant difference was found when the latter was compared with a mixture of AB and BB (P = 0.52). Grafts composed of BB showed significantly greater new bone formation as compared to hydroxyapatite (HA) (P < 0.001) while a mixture of tricalcium phosphate (TCP) and HA achieved better outcomes than BB (P < 0.001). PB alone showed at six months a new bone volume range between 31.4% and 43.9%.

#### CONCLUSIONS

None of the biomaterials used for LASFE procedures demonstrated a significant and predictable superiority regarding new bone formation. The observation that, in comparative studies, the amount of new bone volume was higher for AB than for BB could not be confirmed by clinical results and so it seems that when donor site morbidity is a concern, BB and a mixture of TCP and HA could be considered as predictable alternative with promising results. Anyway, the Authors concluded that "more randomized, controlled clinical trials providing individual data about the characteristics of the analyzed specimen (size and site of biopsy) and of the residual bone height before intervention may help to achieving a deeper knowledge of the histologic behavior of biomaterials in LASFE procedures".