

Case Report

Ten-year follow-up in a maxillary sinus augmentation using anorganic bovine bone (Bio-Oss). A case report with histomorphometric evaluation

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Abstract: Several bone grafting materials have been used in sinus augmentation procedures. Bio-Oss (deproteinized and sterilized bovine bone) has shown to have osteoconductive properties and no inflammatory or adverse responses have been published. In spite of these successful results, histologic data regarding bone augmentation using Bio-Oss in humans is scarce. The purpose of this study was to analyse the amount of Bio-Oss ossification in a case of maxillary sinus augmentation, recording and comparing histomorphometric data 8 months, 2 and 10 years after surgery. This long-term histologic evaluation of retrieved specimens has been performed, comparing histomorphometric measures at different times. Eight months after surgery we observed in 20 different thin sections of the specimen a mean amount of bone tissue (including medullar spaces) of 29.8% (and 70.2% of Bio-Oss) \pm 2.6. At 2 years the bone tissue increased to 69.7% \pm 2.7 and 10 years after surgery it was 86.7% \pm 2.8. The comparison of the means for each time has shown a highly significant increasing trend in bone formation associated with Bio-oss resorption: at 8 months, 2 and 10 years.

Several bone grafting materials have been used in sinus augmentation procedures (Pittelli et al. 1999). Bio-Oss (deproteinized and sterilized bovine bone) has shown to have osteoconductive properties and no inflammatory (Wheeler et al. 1996; Valentini et al. 2000) or adverse responses have been published. In spite of these successful results, histologic data regarding bone augmentation using Bio-Oss in humans is scarce.

from the grafting area. A mucoperiosteal flap was elevated, exposing the lateral wall of the left maxillary sinus. The antrum was outlined on the lateral wall of the maxilla with a round bur under copious irrigation. An elevator was used to push the sinus membrane inward and to elevate the lateral wall of the sinus. The membrane was dissected from the floor, the lateral walls and the medial wall of the antrum. The graft material (anorganic bovine bone)

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Material and methods

Surgical procedure

A 60-year-old man (Fig. 1) was treated with a left maxillary sinus augmentation technique as suggested by Kent & Block (1989). After local anaesthesia, an incision was made palatal to the edentulous crest and then continued buccally, at least 3 mm



Fig. 1. The X-ray aspect before surgery.

was placed against the medial wall of the antrum. Three plasma sprayed implants (IMZ™) were inserted, taking care to achieve the primary stability (Fig. 2). Bio-Oss was then applied to completely fill the compartment (Figs 3 and 4) and an e-PTFE membrane was fixed on the lateral wall of



Fig. 2. The IMZ implants placed after the elevation of the sinus membrane.



Fig. 3. The filling of the sinus with Bio-Oss.



Fig. 4. The X-ray aspect after surgery.



Fig. 5. The flaps adaptation and sutures' closure.

the maxilla, covering the grafting material. The soft tissues were sutured obtaining a primary closure (Fig. 5). Three biopsy specimens were taken at 8 months, 2 and 10 years after surgery using a trephine bur and copious irrigation. Cores were taken in the most apical space between the mesial and the middle implant to a depth (in a bucco-palatal direction) of about 4 mm after 8 months, a depth of 8 mm at 2 years and 12 mm at 10 years. The deepest component of the specimens (4 mm) was considered at 2 years and 10 years.

Hystomorphometric evaluation

The samples were immediately fixed in 4% paraformaldehyde phosphate buffer, pH7.4 for 24 h. The specimens were then dehydrated through graded ethanols, cleared in xylene, embedded in paraffin, cut into slices of about 10µm thick and stained with ematoxylin and eosin.

Using a high geometric linearity TV camera, directly applied on a light microscope (obj. magn. 6.3 X), a morphometric-computerized analysis was performed by means of an interactive computerized image analysis system (Kontron-Zeiss/IBAS 2).

The image of the half specimen corresponding was displayed on a TV colour monitor with a resolution of 512 X 512 square pixels; this image was the specimen for interactive editing in the image analyzer.

A suitable computer program for morphometric analysis was defined and then performed.

Results

The error due to the automatic process of hystomorphometric evaluation of each section has been controlled analysing 20 sections for each specimen (8 months, 2 and 10 years).

Eight months after surgery we observed a mean amount of bone tissue (including medullar spaces) of 29.8% (Fig. 6) (and 70.2% of Bio-Oss) ± 2.6. At 2 years (Fig. 7) the bone tissue increased to 69.7% ± 2.7 and 10 years after surgery (Fig. 8) it was 86.7% ± 2.8.

Discussion

In the present study, sinus floor augmentation with anorganic bovine bone was

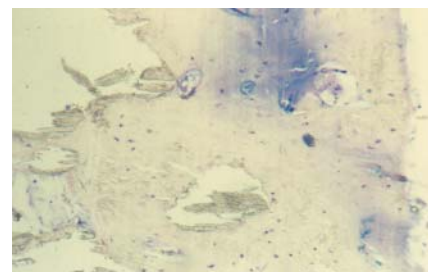


Fig. 6. The hystologic aspect 8 months post-op. The specimens are stained with ematoxylin and eosin.

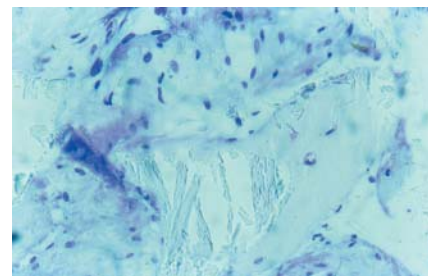


Fig. 7. The hystologic aspect 2 years post-op. The specimens are stained with ematoxylin and eosin.

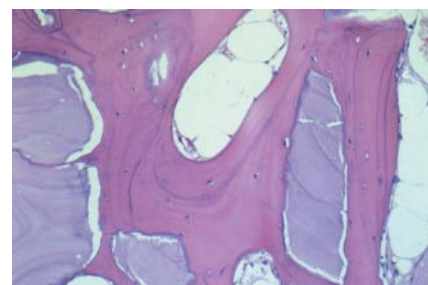


Fig. 8. The hystologic, aspect 10 years post-op. The specimens are stained with ematoxylin and eosin.

evaluated. Many authors (Lundgren et al. 1996; Piattelli et al. 1999; Valentini et al. 2000) have concluded that the sinus-lift augmentation technique is a safe and effective method to increase bone volume in the maxilla. The histologic data on bone formation and clinical success rates confirm that the ideal graft material for sinus-lift augmentation is autogenous bone (Valentini et al. 2000).

In spite of this, Bio-Oss has been shown to be highly biocompatible with oral hard tissues in animals and humans and to have

Table 1. The amount of bone formation at different times

8 months	20 months	10 years
29.800% ± 2.567	69.7% ± 2.677	86.7% ± 2.849

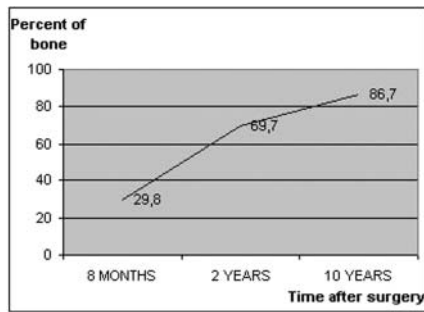


Fig. 9. The new bone formation in the 10-year follow-up period.

the properties of an osteoconductive material (Pinholt et al. 1991; Berglundh & Lindhe 1997). New bone has been detected over exposed implants using Bio-Oss in association with membranes (Zitzman et al. 1997). The amount of newly formed bone after 6 months in cases treated with maxillary sinus augmentation using Bio-Oss varies from $14.7\% \pm 5.0\%$ to $33.1\% \pm 12.4\%$ (Wheeler et al. 1996; Yildirim et al. 2000, 2001).

In our case report, all three specimens (8 months, 2 and 10 years after surgery) the Bio-Oss particles were surrounded by newly formed lamellar bone (Figs 6, 7 and 8), showing processes of slow resorption.

The potential metabolization of Bio-Oss by osteoclasts could be confirmed by the progressive increase in relative bone volume (Table 1, Fig. 9) until the biopsy at the tenth year after surgery. After 8 months the bone tissue represented the 29.8% of the total new volume (and Bio-Oss $100\% - 29.8\% = 70.2\%$). In the next 16 months (until the second year) 56.8% of the residual Bio-Oss was substituted by bone and, from the second year until the tenth, similarly the 56.1% of the grafting material was replaced by lamellar bone, showing a markedly faster process of resorption in the first period after surgery. In fact, until the second year a speed of resorption (SR) of 3.55% per month was observed. This value decreased consistently

in the following 8 years with a mean value of 0.58% per month, which is 6.12 times slower than the initial SR.

Résumé

Différents matériaux de greffe osseuse ont été utilisés dans les processus d'épaissement du plancher sinusal. Les propriétés ostéoconduites et l'absence de réponse négative ou inflammatoire ont été rapportées pour le Bio-Oss® (os bovin stérilisé et déprotéiné). Malgré ces succès, des données histologiques concernant l'épaissement osseux par le Bio-Oss® chez l'humain restent rares. Le but de cette étude a été d'analyser la quantité d'ossification du Bio-Oss® dans un cas d'épaissement du plancher sinusal en notant et comparant les données histomorphométriques huit mois, deux ans et dix ans après la chirurgie. Huit mois après la chirurgie, dans 20 coupes fines différentes une quantité moyenne de tissu osseux (incluant les espaces médullaires) de 29.8% (et 70.2% de Bio-Oss®) $\pm 2.6\%$ a été observée. Après deux années, le tissu osseux augmentait à $69.7 \pm 2.7\%$ et dix ans après la chirurgie à $86.7 \pm 2.8\%$. Durant une décennie la comparaison des moyennes à chaque moment a indiqué une tendance très significative de l'augmentation de la formation osseuse associée à la résorption graduelle du Bio-Oss®.

Zusammenfassung

Für den chirurgischen Eingriff einer Sinusbodenaugmentation sind verschiedene Knochentransplantate verwendet worden. Bio-Oss (entproteinisierter und sterilisierter Rinderknochen) hat osteokonduktive Eigenschaften gezeigt und bis heute sind keine Berichte über entzündliche oder allergische Reaktionen veröffentlicht worden. Trotz diesen erfolgreichen Anwendungen, sind histologische Daten vom Menschen über Knochenaugmentationen mit Bio-Oss selten.

Ziel: Das Ziel dieser Studie war, das Ausmass der Ossifikation von Bio-Oss an einem Fall von Sinusbodenaugmentation zu analysieren. Man erhob dazu histomorphometrische Daten 8 Monate, sowie 2 und 10 Jahre nach dem chirurgischen Ersteingriff.

Material und Methode: Diese histologische Langzeituntersuchung erfolgte mit Hilfe von zu verschiedenen Zeitpunkten entnommenen Biopsien, welche dann histomorphometrisch vermessen und verglichen wurden.

Resultate: 8 Monate nach der Chirurgie entdeckten wir auf den 20 dünnen Schnitten der Biopsie einen mittleren Knochengewebanteil (Markräume eingeschlossen) von $29.8\% \pm 2.6$ (und 70.2% Bio-Oss). Nach 2 Jahren wuchs der Knochengewebanteil auf 69.7 ± 2.7 und nach 10 Jahren waren es $86.7\% \pm 2.8$.

Zusammenfassung: Der Vergleich der Mittelwerte wäh-

rend 10 Jahren zeigt einen signifikanten Trend zur Knochenbildung einhergehend mit der Bio-Oss-Resorption.

Resumen

Se han utilizado diversos materiales de injerto en los procedimientos de elevación del seno. El Bio-Oss (hueso bovino desproteinizado y esterilizado) ha demostrado tener propiedades osteoconduivas y no se han reportado reacciones inflamatorias o adversas. A pesar de estos resultados exitosos, los datos respecto a aumento óseo usando Bio-Oss en humanos son escasos.

Objetivos: El propósito de este estudio fue analizar la cantidad de osificación de Bio-Oss en un caso de elevación del seno maxilar, recogiendo y comparando los datos histomorfométricos tras 8 meses, 2 años y 10 años de la cirugía.

Material y métodos: Este estudio histológico a largo plazo de especímenes recogidos se ha llevado a cabo comparando medidas histomorfométricas en momentos diferentes.

Resultados: Ocho meses tras la cirugía observamos en 20 secciones finas de los especímenes una cantidad media de tejido óseo (incluyendo espacios medulares) de 29.8% (y 70.2 de Bio-Oss) ± 2.6 . A los 2 años el tejido óseo se incrementó hasta 69.7 ± 2.7 y 10 años tras la cirugía fue del 86.7 ± 2.8 .

Conclusión: La comparación de las medias para cada momento mostró una tendencia creciente altamente significativa en la formación ósea asociada con la reabsorción de Bio-Oss: a los 8 meses, 2 años y 10 años.

要旨

数種類の骨移植材料が上顎洞増多術に用いられている。Bio-Oss (除蛋白滅菌牛骨) は骨伝導性があり、炎症性や有害反応は無いことが示されてきた。このような成功にもかかわらず、ヒトにおいて Bio-Oss を用いた骨増多に関する組織学的データはほとんどない。

目的: 本研究の目的は、上顎洞増多術において術後 8 ヶ月後、2 年後及び 10 年後の組織学的データを記録し、比較することによって、Bio-Oss の骨化の量を分析することであった。

材料と方法: 採集した標本の長期の組織学的評価は、異なる時点の組織形態測定を比較することによって行った。

結果: 術後 8 ヶ月後に標本の 20 の異なる薄切片において、骨組織の平均量は 29.8% (及び Bio-Oss が 70.2%) ± 2.6 であった。2 年後に骨組織は $69.7\% \pm 2.7$ 、術後 10 年後には $86.7\% \pm 2.8$ に増加していた。

結論: 8 ヶ月後、2 年後、10 年後の各時点の平均値を比較すると、Bio-Oss の吸収と相関した骨形成の極めて有意な増加傾向が認められた。

キーワード: 上顎洞増多術、無機質牛骨、Bio-Oss

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