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Artículo Original

Histomorphometric Comparison of Bio-Oss vs. Osteodens in Maxillary Sinus Floor Elevation Procedures

Comparación histomorfométrica de Bio-Oss frente a Osteodens en procedimientos de elevación del suelo del seno maxilar

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Abstract

Introduction: The loss of dental elements can lead to excessive bone loss in the posterior maxillary segments, which can limit the placement of dental implants in that area, the pneumatization of the maxillary sinus and the absence of dental elements to keep the bone active are some of the main causes. Among the wide range of available grafting materials, bovine hydroxyapatite has been extensively studied and has shown excellent clinical and histological results. **Materials and methods:** A total of 17 maxillary sinus floor elevations were performed (n = 8 Osteodens, n = 9 Bio-Oss). After a healing period of 6 to 8 months, a block of the grafted area was obtained using trephines and analyzed by histomorphometry. **Results:** The percentage of neoformed bone tissue was higher for Bio-Oss (39.0% ± 11.1) compared to Osteodens (33.4% ± 8.3), while the remaining graft values were slightly lower in Bio-Oss compared to Osteodens (16.3% ± 11.2 and 20.8% ± 12.1, respectively). The proportion of connective tissue was similar in both groups (44.7% Bio-Oss and 45.8% Osteodens). Age, gender, and residual height of the sinus floor did not show statistically significant differences. **Conclusions:** In this study, both graft materials (Bio-Oss and Osteodens) showed no statistically significant differences in their ability to regenerate suitable bone tissue for implant placement after 6 months of healing. Further studies with a larger sample size are needed to validate these results.

Keywords: Bio-Oss, maxillary sinus, graft, histomorphometry, sinus floor augmentation (source: MeSH NLM).

Resumen

Introducción: La pérdida de elementos dentarios puede provocar una excesiva pérdida ósea en los segmentos maxilares posteriores, lo que puede limitar la colocación de implantes dentarios en esa zona, la neumatización del seno maxilar y la ausencia de elementos dentarios que mantengan el hueso activo son algunas de las principales causas. Entre la amplia gama de materiales de injerto disponibles, la hidroxiapatita bovina ha sido ampliamente estudiada y ha mostrado excelentes resultados clínicos e histológicos. **Materiales y métodos:** Se realizaron un total de 17 elevaciones del suelo del seno maxilar (n = 8 Osteodens, n = 9 Bio-Oss). Tras un periodo de cicatrización de 6 a 8 meses, se obtuvo un bloque de la zona injertada mediante trépanos y se analizó

mediante histomorfometría. **Resultados:** El porcentaje de tejido óseo neoformado fue mayor en Bio-Oss (39,0% ± 11,1) en comparación con Osteodens (33,4% ± 8,3), mientras que los valores del injerto remanente fueron ligeramente inferiores en Bio-Oss en comparación con Osteodens (16,3% ± 11,2 y 20,8% ± 12,1, respectivamente). La proporción de tejido conjuntivo fue similar en ambos grupos (44,7% Bio-Oss y 45,8% Osteodens). La edad, el sexo y la altura residual del piso sinusal no mostraron diferencias estadísticamente significativas. **Conclusiones:** En este estudio, ambos materiales de injerto (Bio-Oss y Osteodens) no mostraron diferencias estadísticamente significativas en su capacidad para regenerar tejido óseo adecuado para la colocación de implantes tras 6 meses de cicatrización. Se necesitan más estudios con un tamaño de muestra mayor para validar estos resultados.

Palabras clave: Seno maxilar, Injerto de Hueso Alveolar, Elevación del Piso del Seno Maxilar (fuente: MeSH NLM).

Introduction

The maxillary sinus floor elevation technique is well-documented both clinically and histologically, and it is a viable alternative that allows for the placement of dental implants in cases of excessive bone loss in the posterior maxillary segments due to the pneumatization of the maxillary sinus and the absence of dental elements to keep the bone active are some of the main causes. Maxillary sinus floor elevation procedures through a lateral window approach as part of pre-prosthetic treatment were initially presented by Tatum1 in 1977, and the first publication on this topic was made by Boyne and James2 in 1980. Since then, the technique has continuously evolved in two fundamental aspects: the transition from autologous grafts, which were considered the "gold standard" for a long time, to bone replacement materials (allografts, xenografts, alloplasts); and the development of surgical techniques that simplify the procedure and reduce the risk of intra- and post-operative complications3,4,5,6. Among all bone replacement materials, xenografts (bovine hydroxyapatite) have been rigorously studied. Multiple studies conducted by Testori7, Del Fabbro8, Pjeturson9, Froum10, and Traini11 have shown that it is possible to achieve bone neoformation and implant survival rates in grafted sinuses similar to those observed in native bone. Furthermore, the use of xenografts eliminates the need for a donor site in the patient, reducing the procedure's morbidity12. The loss of dental elements in the posterosuperior segments is often accompanied by a marked loss in the quantity and quality of bone tissue, which can limit the placement of implants in that area. Different procedures have been described to gain height in this sector and thus be able to place them, the most used and best-studied procedures in cases where the height of the remaining crest is less than 4mm is the maxillary sinus floor elevation technique by opening a lateral window and placing material of graft, the use of a wide variety of materials to fill the sinus has been documented, ranging from autologous bone, taken from different donor areas, heterograft, xenograft and alloplastic materials, used alone or in combination with each other14,15. Of these materials, the best results in terms of the rate of bone neoformation and quality of viable neoformed tissue for implant placement were obtained with bovine hydroxyapatite xenografts (Bio-Oss)7,10,11,12,13,20, in turn, it offers the advantage of avoiding a donor area in the patient when compared to an autogenous graft, thus reducing the morbidity of the procedure.

Bovine hydroxyapatite is highly biocompatible, has slow resorption rates, and maintains its osteoconductive properties over a long period, facilitating neoformation and remodeling of bone in the grafted sinus. It has also been demonstrated in various studies that the remaining material particles do not come into contact with the implant surface, thus not interfering with osseointegration mechanisms or triggering an inflammatory reaction in the adjacent tissues16. These qualities make bovine hydroxyapatite an appropriate and reliable material for this procedure.

Methods

The study included partially or completely edentulous patients in the posterior upper regions with native bone height less than 5mm, who have lost ridge bone due to the absence of dental elements, use of maladaptive prostheses, or simply pneumatization of the maxillary sinuses due to edentulism. The patients were of both genders, aged 41 to 80 years, medically healthy or medically compensated without absolute contraindications for surgical procedures. Patients who did not have to have been treated to enter the study with sinus grafting procedures and had healthy maxillary sinuses requiring maxillary sinus floor elevation using the lateral window technique before dental implant placement were included. A prospective histomorphometric study was conducted, involving 17 maxillary sinuses in patients of both sexes (10 females and 7 males).

A successive non-probabilistic sampling method was used, considering only those maxillary sinuses that met the inclusion criteria and allowed for the completion of the predetermined sample size, which was determined based on similar research studies.

Patients who did not meet the detailed inclusion criteria and those who were pregnant or breastfeeding, uncooperative, smokers, alcoholics or substance abusers, and had poor oral hygiene (bacterial biofilm greater than 20% of tooth surface) were excluded from the study.

The maxillary sinus floor elevation procedures were performed by the treating dentists within the framework of the Specialization Program in Oral Implantology at the Círculo Odontológico de Córdoba (2013-2016 cohort). One case was performed in private practice by the program director (Dr. Juan Carlos Ibañez). The biopsy samples were taken by the researcher following the same treatment protocol for patients and samples.

Preoperative antibiotic medication, Amoxicillin with clavulanic acid 1g every 12 hours, starting 24 hours before the procedure and continuing for 7 days postoperatively (Amixen Clavulánico 1g, Bernabó Laboratory), and dexamethasone 5mg drops (Dexalergin, TEVA Laboratory) during the first week after surgery (1 drop in each nostril every 8 hours, followed by 1 drop every 12 hours during the second week). Flurbiprofen 100mg was administered as an analgesic and anti-inflammatory medication every 8-12 hours for five days (Clinadol forte, Gador Laboratory).

All patients were treated using the same surgical technique, which involved maxillary sinus floor elevation through a lateral window approach (Boyne and James, 1980). After local anesthesia (4% carticaine hydrochloride with 1:100,000 epinephrine) was administered, a mucoperiosteal flap was raised to expose the lateral wall of the maxillary sinus. An osteotomy window was created using piezoelectric surgery, and the bone window was rotated inward into the sinus after careful dissection of the Schneiderian membrane. The space created by membrane elevation was filled with bovine graft material. The control group was grafted with particulate bovine inorganic bone (Bio-Oss, Geistlich AG, Wolhusen, Switzerland), and the experimental group was grafted with particulate bovine hydroxyapatite (Osteodens E, Pharmatrix, Argentina). Both materials were mixed only with the patient's blood collected from the surgical site. After filling the space created by sinus membrane elevation, the lateral window was closed using a bilayer porcine collagen membrane (BioGide, Geistlich, Wolhusen, Switzerland).

After a healing period of 6 to 8 months, at the time of dental implant placement, a full-thickness flap was raised, and in the proposed implant sites, a block of bone tissue was obtained (in a coronal-apical direction, in the place where the implant should be placed according to the planning and surgical guide) using a trephine (Fixum, Argentina) with an external diameter of 3mm and immediately fixed in 10% formaldehyde. The samples were processed for histomorphometric analysis to compare the behavior of the two graft materials (Osteodens and Bio-Oss).

Image Pro-Plus v4.52 software was used for area measurements. The measurements were performed on digitized microscopic images of the biopsies at 40X magnification (panoramic sections, Fig. I). The digitization was carried out using a Carl Zeiss optical microscope (imager A2) with an incorporated camera (Carl Zeiss -Axiocam Ic 5). In cases where panoramic magnification was insufficient to determine the observed tissue type in a particular area, higher magnifications (100X and 200X) were used.

Descriptive statistical analysis was performed on the data, including measures of central tendency (mean) and dispersion (standard deviation). As an exploratory analysis, mean values of tissue percentages were compared using parametric tests (Student's t-test). Additionally, the correlation between tissue percentages and age and residual height factors was evaluated. Finally, adjusted models (generalized linear regression models) were used to determine the magnitude of the effects that factors (gender, patient age, residual height, and biomaterial) had on the proportion of different tissues measured in the biopsy sections. The level of statistical significance was set at $P<0.05$ for all tests.

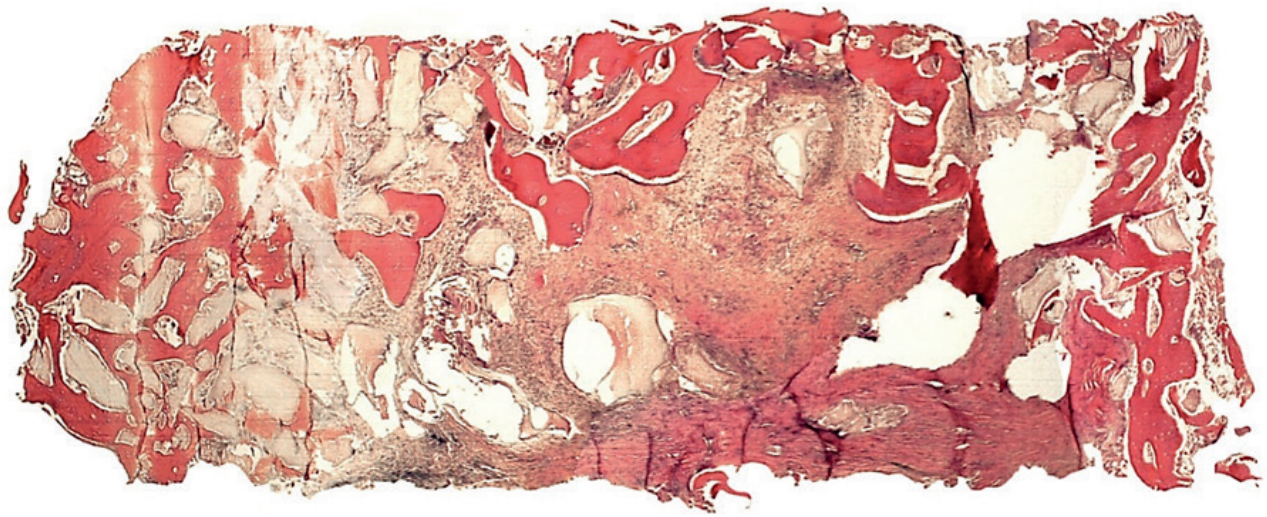

Fig. I. Panoramic image (40X magnification) of a longitudinal section of a biopsy. Sample from case 7526 (2) - Osteodens.

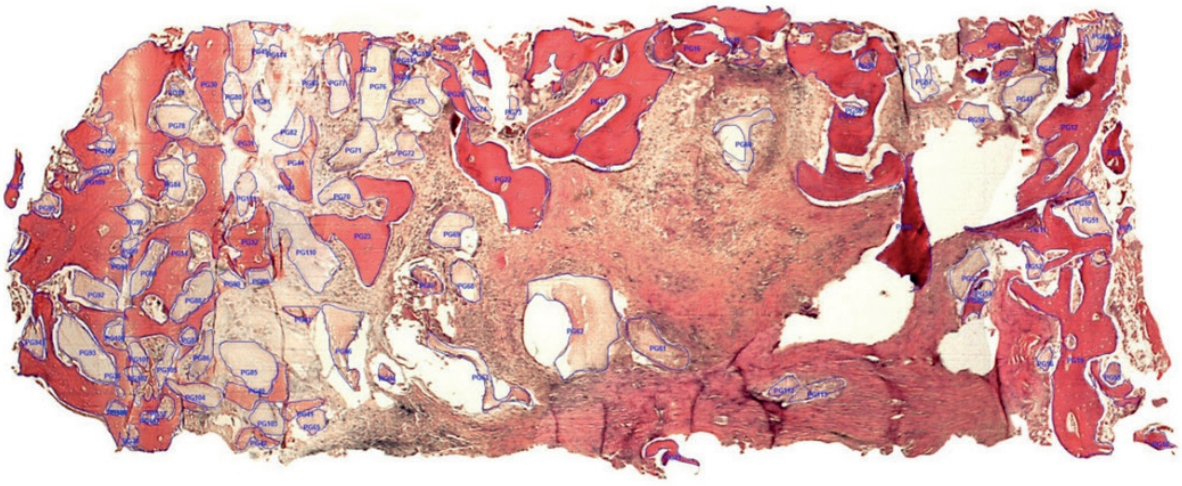

Fig. II. Measurements were performed on the panoramic image (40X magnification). Case 7526(2). The references within each measured zone (PGxx) indicate the number of Polygon xx delimited, which are associated with certain tissues.

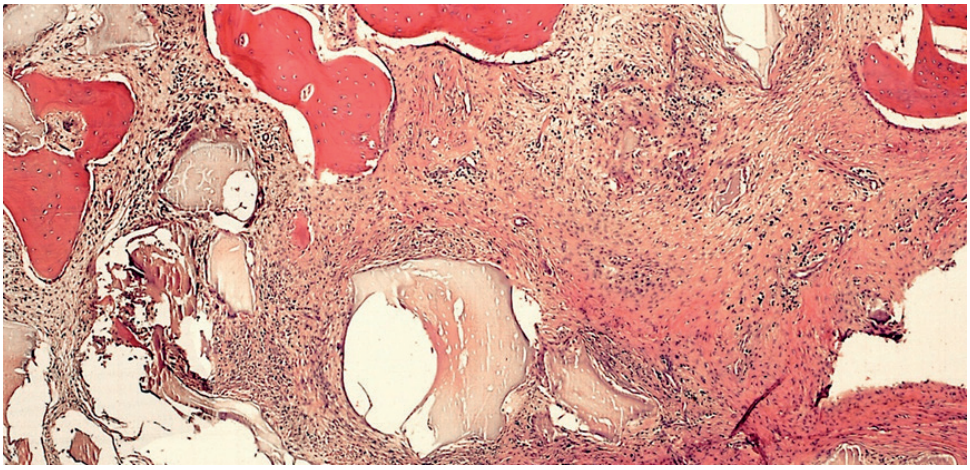

Fig. III. The same section as Figure I, but at higher magnification (100X). Ref: NB: neo-formed bone, RG: remnant Graft, CT: connective tissue.

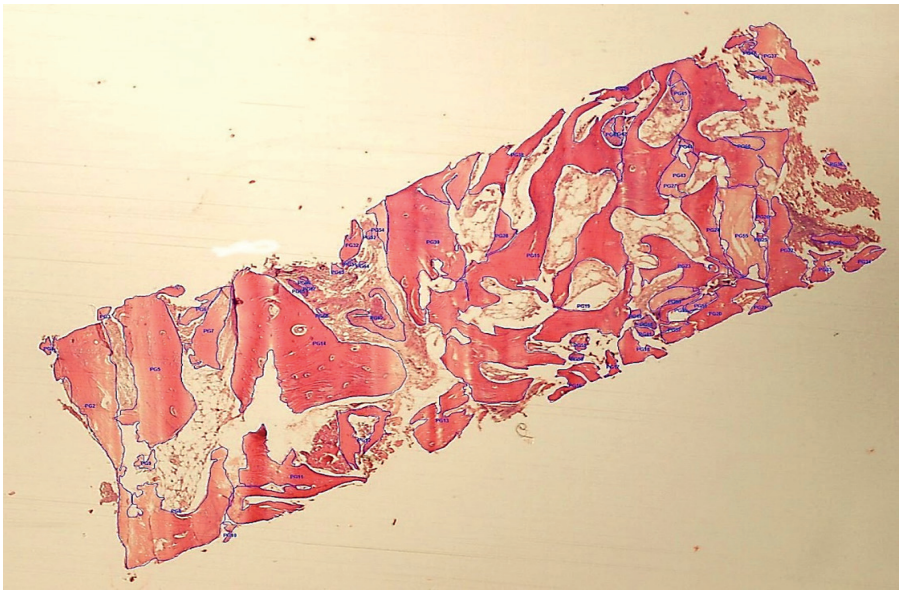

Fig. IV. Measurements performed on the panoramic image (40X magnification). Case 7657(2). The references within each measured zone (PGxx) indicate the number of Polygon xx delimited, which are associated with certain tissues - Bio Oss.

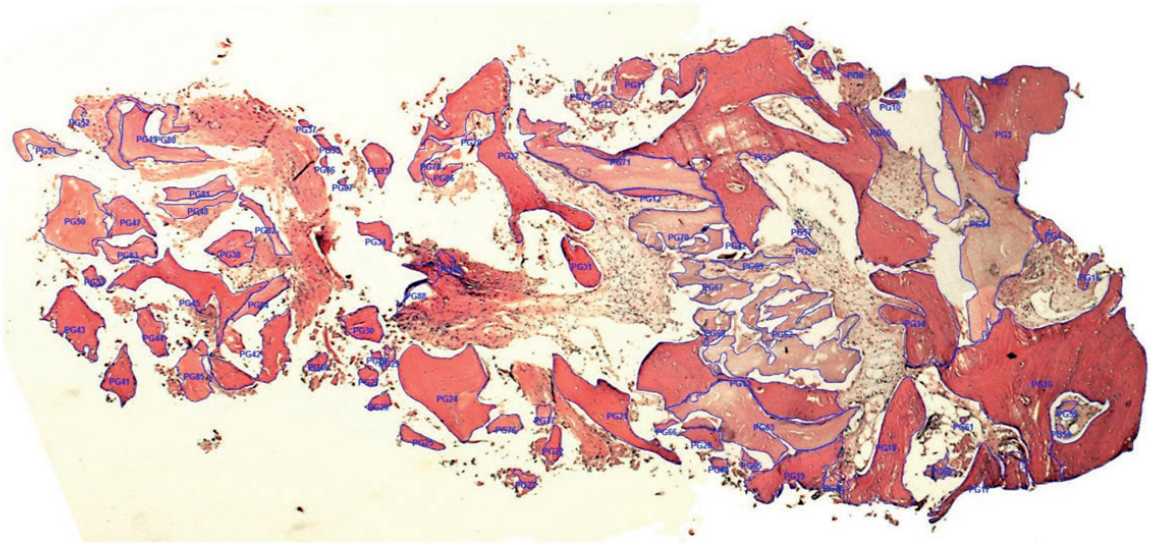

Fig. V. Measurements performed on the panoramic image (40X magnification). Case 7657 (1). The references within each measured zone (PGxx) indicate the number of Polygon xx delimited, which are associated with certain tissues – Bio Oss.

The study was conducted in compliance with the Personal Data Protection Law No. 25326, the Provincial Law No. 9694 of Córdoba, Argentina, and the Good Clinical Practice Guidelines of ANMAT (National Administration of Drugs, Foods, and Medical Devices), as well as the ethical guidelines for biomedical research and experimentation in human subjects (Declaration of Helsinki 2008). Therefore, all patients who participated in the research study signed an informed consent form to protect their identity and personal data. The protocol was approved by the Research Ethics Committee of UCC (Universidad Católica de Córdoba).

Results

The present statistical analysis was conducted based on the percentage values of newly formed or remodeled bone tissue (NB), graft residue (GR), and connective tissue (CT) for each of the 17 histological sections evaluated in this study. These percentages were obtained from measurements made using the Image Pro-Plus v4.52 morphometry software on digitized biopsy images. Table 1 summarizes the information using central tendency values (mean) and dispersion (standard deviation) for each experimental group. The overall percentages of remaining filler material were slightly lower in Bio-Oss compared to Osteodens (16.3% and 20.8%, respectively), while the average percentage of newly formed tissue was higher in Bio-Oss (39.0%) compared to Osteodens (33.4%). The proportion of connective tissue was similar in both groups (Bio-Oss 44,7% and Osteodens 45,8%). Therefore, the percentage of remaining tissue, which is the sum of new bone and residual graft, was very similar in the two biomaterial groups: 55.3% for Bio-Oss and 54.2% for Osteodens (Fig. I).

When statistically analyzing the percentage values of each tissue using T-tests (Student's t-test), the differences observed between both material groups were not significant in all cases ($p>0.05$) (NB: $p=0.26$; GR: $p=0.44$; CT: $p=0.81$).

Other variables analyzed were sex, age, and residual ridge height before the procedure, among which no statistically significant differences were observed (Tables 2, 3, 4, and 5), except when comparing the residual height of the sinus floor before surgery according to patient's sex, resulting in $p=0.026$.

The residual height was significantly greater in women (mean of 3.6 mm) compared to their male counterparts (mean of 2.0 mm), showing a statistically significant difference ($p=0.026$; $p<0.05$).

Discussion

The use of bovine hydroxyapatite as a graft material in maxillary sinus lift procedures is a well-documented technique [7,10,11,12,14,15,18,19], which allows for the placement and subsequent rehabilitation of dental implants in atrophic posterior upper segments. In this study, two types of bovine hydroxyapatite were compared: Bio-Oss and Osteodens, and the percentages of new bone formation, remaining graft material, and connective tissue were not statistically significant. There are no histomorphometric studies available in the literature on Osteodens used as a graft material in maxillary sinuses.

There are also no studies evaluating the effects of gender and age on the final results. Regarding the variable of residual sinus floor height, it is only mentioned in some studies as an inclusion criterion (<4-5mm height), but not its influence on the outcomes. In similar studies, Portelli, M. Cicciu, and M. Gherlone E.[17] conducted a histomorphometric evaluation comparing two different bone substitutes: Bio-Oss (bovine hydroxyapatite) and Re Oss (synthetic hydroxyapatite + polylactic acid, ac. + polyglycolic acid). They operated on 10 maxillary sinuses with a residual floor height of 4mm, and

Table 1. Percentages of histological tissues according to biomaterial: Mean ± standard deviation. In each case, the p-values resulting from the contrasts between groups are shown.

Biomaterial	Newly Formed Bone	Remaining Graft	Connective Tissue
Bio-Oss (n9)	**39,0** ± 11,1	**16,3** ± 11,2	**44,7** ± 11,6
Osteodens (n8)	**33,4** ± 8,3	**20,8** ± 12,1	**45,8** ± 7,6
Test T (Sig.)	*p = 0,26*	*p = 0,44*	*p = 0,81*

Table 2. Histological tissue percentages according to sex: Mean ± standard deviation. The resulting p-values from the group comparisons are shown for each case.

Sex/Histological Tissues	Newly Formed Bone	Remaining Graft	Remaining Graft Connective Tissue
Females (n 10)	**38,3** ± 11,4	**15,0** ± 11,8	**46,8** ± 10,8
Males (n 7)	**33,6** ± 8,2	**23,4** ± 9,8	**43,0** ± 8,0
Test T (Sig.)	p = 0,36	p = 0,14	p = 0,45

Table 3. Patient age according to implanted biomaterial: Count (n); Mean; Standard deviation (SD); Minimum and Maximum. Values are expressed in years.

Age/Biomaterial	n	**Mean**	SD	Minimum	Maximum	T-Test
Bio-Oss	9	**58,8**	6,3	47	65	p=0,25
Osteodens	8	**64,9**	14,0	41	80	
Total	17	**61,6**	10,7	41	80	

Table 4. Age of patients according to sex: Count (n); Mean; Standard deviation (SD); Minimum and Maximum. Values expressed in years.

Sex/Biomaterial	n	**Mean**	SD	Minimum	Maximum	T-Test
Women	10	**65,0**	9,2	54	80	p=0,17
Men	7	**56,9**	11,6	41	70	
Total	17	**61,6**	10,7	41	80	

Table 5. Residual height of the sinus floor before surgery according to biomaterial: Count (n); Mean; Standard deviation (SD); Minimum and Maximum. Values expressed in mm.

Residual Height/Biomaterial	n	**Mean**	SD	Minimum	Maximum	T-Test
Bio-Oss	9	**3,22**	1,48	1,00	5,00	p=0,47
Osteodens	8	**2,63**	1,85	1,00	6,00	
Total	17	**2,94**	1,64	1,00	6,00	

Table 6. Residual height of the sinus floor before surgery according to sex: Count (n); Mean; Standard deviation (SD); Minimum and Maximum. Values expressed in mm.

Residual Height/Sex	n	**Mean**	SD	Minimum	Maximum	T-Test
Women	10	**3,60**	1,78	1,00	6,00	p=0,026
Men	7	**2,00**	0,82	1,00	3,00	
Total	17	**2,94**	1,64	1,00	6,00	

the results obtained in terms of percentage of different tissues were as follows: Residual graft: Bio-Oss 16%, Re Oss 10.05%; new bone formation: Bio-Oss 27.5%, Re Oss 44.45%; remaining connective tissue: Bio-Oss 56.5%, Re Oss 45%. This difference in the residual height of the sinus floor between the sexes is a circumstantial finding in the sample taken, to the knowledge of the authors there is no precedent on the subject and would require a broader statistical study that is beyond the objectives of this paper.

Lee, J. Shin, H., and Yun, J.18 conducted a randomized clinical trial (RCT) using bovine hydroxyapatite (Bio-Oss) as the control versus porcine hydroxyapatite (THE Graft) as the test material in 15 maxillary sinuses. They obtained the following histological results: Newly formed bone - Bio-Oss: 26.15%, THE Graft:

29.77%; Residual graft Bio-Oss: 25.1%, THE Graft: 15.24%; Fibrovascular tissue - Bio-Oss: 48.11%, THE Graft: 55%.

Cordaro, Bosshardt, Rao, and Chiapasco19 conducted a randomized study comparing Bio-Oss versus Bone Ceramic (beta-tricalcium phosphate) in 48 maxillary sinuses of 37 patients (23 Bio-Oss and 25 Bone Ceramic). The average residual ridge height was 5mm, and the healing period was 6 to 8 months. Samples were taken using 3.5mm diameter trephine burs from implant sites, and the percentages of obtained tissues were: Newly formed bone 19.8% (Bio-Oss), 21.6% (Bone Ceramic); Residual graft 37.7% (Bio-Oss), 26.6% (Bone Ceramic); Connective tissue 42.5% (Bio-Oss), 51.8% (Bone Ceramic).

De Molon et al.20 histologically evaluated maxillary sinus augmentations performed with Bio-Oss using two different particle sizes. They treated 10 patients bilaterally (20 maxillary sinuses), grafting one side with small particles (0.25-1mm) and the contralateral side with large particles (1-2mm). After an 8-month healing period, biopsy samples were taken from sites perpendicular to the implant axes. The patients ranged from 30 to 65 years old, and the initial sinus floor height was equal to or less than 5mm. The percentages of obtained tissues were: Newly formed bone 36.7% (large particles), 36.1% (small particles); Residual graft 38% (large particles), 32.4% (small particles); Connective tissue 23.8% (large particles), 30.4% (small particles).

Froum, Wallace, et al. 21 compared histomorphometrically Bio-Oss versus Bio-Oss + PDGF (recombinant human platelet-derived growth factor). After a healing period of 7 to 9 months, they treated 12 patients bilaterally (24 maxillary sinuses) with a residual sinus floor height of <5mm. Samples were taken from non-implanted areas, and the following results were observed: Newly formed bone 21.4% (Bio-Oss), 19.5% (Bio-Oss + PDGF); Residual graft 40.3% (Bio-Oss), 35.5% (Bio-Oss + PDGF); Connective tissue 38.4% (Bio-Oss), 44.2% (Bio-Oss + PDGF).

Lee, Chen, and Darby22 conducted a clinical and histomorphometric study of maxillary sinus floor elevation procedures using Bio-Oss. They treated 25 patients with an initial sinus floor height of <5mm, and after 9 months of healing, biopsy samples were taken using 3.5mm diameter trephine burs from implant sites. The following results were obtained: Newly formed bone 19%, Residual graft 40%, Connective tissue 41%.

Valentini, P., Abensur, D., and Wenz, B.23 carried out a study on 15 patients, operating on 20 maxillary sinuses (2 patients bilaterally) using Bio-Oss as the graft material. Biopsies were taken from only 3 sinuses at 6 months, and the same procedure was repeated at 12 months. In this study, the samples were not taken at the implant sites but perpendicularly to the ridge crest. The results obtained were as follows: At 6 months, newly formed bone was 21.08% (Bio-Oss), 39.17% medullary tissue; At 12 months, newly formed bone was 27.55% (Bio-Oss), 27.07% (Bio-Oss), 45.44% medullary tissue.

Schmitt, Moest, and Lutz24 compared Bio-Oss versus Bio-Oss plus autogenous bone (1:1) in 19 patients aged 33 to 62 years with an initial sinus floor height of ≤4mm. After a healing period of 5-6 months, samples were obtained from the implant sites, and the tissue percentages were observed as follows: Newly formed bone 26% (Bio-Oss), 27.5% (Bio-Oss + autogenous bone); Residual graft 31.2% (Bio-Oss), 28.4% (Bio-Oss + autogenous bone); Connective tissue 42.8% (Bio-Oss), 44.1% (Bio-Oss + autogenous bone).

Lee, Y., Shin, S., and Kim,25 studied the histological and histomorphometric reaction of bone to bovine hydroxyapatite (Bio-Oss) in maxillary sinus elevation procedures at 6 and 12 months of healing. They treated a total of 10 patients from whom 14 biopsy samples were retrieved. At 6 months, samples were taken from the implant sites using a 2mm internal diameter trephine bur, and at the following 6 months (12 months after grafting), samples were repeated from sites parallel to the implants at a distance of 2 to 3mm. Defects were filled with Bio-Oss. The values obtained in this study at 6 months were: Newly formed bone - 18.4%, Residual graft - 29.8%, Connective tissue - 52%. At 12 months, the values were: Newly formed bone - 26.6%, Residual graft - 28.7%, Connective tissue - 44.7%.

Shirmohammadi, Roshangar, and colleagues26 conducted a comparative study between Bio-Oss and Ostim (nanocrystalline synthetic hydroxyapatite) mixed with 20% autogenous bone from the tuberosity. They treated 9 patients bilaterally (18 maxillary sinuses) and took samples for histological analysis from implant sites after 5 months of healing. The results showed 21.9% newly formed bone in the Bio-Oss group and 25.34% in the Ostim group. The amount of residual graft was 33.13% (Bio-Oss) versus 20.8% (Ostim), and the remaining connective tissue was 45% in the Bio-Oss group and 54% in the Ostim group.

Pasquali, Texeira, and colleagues27 conducted a histomorphometric comparison between Bio-Oss and Bio-Oss + concentrated bone marrow obtained from the iliac crest in maxillary sinus floor elevation procedures in 8 patients bilaterally. The following results were obtained: Newly formed bone - 27.3% (Bio-Oss), 55.5% (Bio-Oss + concentrated bone marrow); Residual graft - 22.8% (Bio-Oss), 6.3% (Bio-Oss + concentrated bone marrow); Connective tissue - 49.9% (Bio-Oss), 38.5% (Bio-Oss + concentrated bone marrow).

Many materials were used throughout the dental practice, particularly this Osteodens material of bovine origin used in this work, there are no publications, this is the reason and originality of this work.

Conclusion

It can be concluded that both materials used (Bio-Oss and Osteodens) as graft material in maxillary sinus floor elevation procedures did not show statistically

significant differences in their ability to regenerate suitable bone tissue for implant placement after 6 months of healing.

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