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Volumetric Behaviour of Two Xenogeny Hydroxyapatites Used as A Graft in Maxillary Sinus Floor Lift: Tomographic Study in Humans

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Keywords:

Maxillary sinus elevation; Volumetric analysis; Bovine biomaterial; Equine biomaterial; Bone formation

List of Abbreviations and Acronyms:

2D Two-dimensional; 3D Three-dimensional: HA Hydroxyapatite; LD Right side; LE Left side; ROI Area of interest; T0 Pre-operative; T1 Post-operative (15 days after surgery); T2 Post-operative (180 days after surgery); CT Computed tomography; CTCB Cone bean computed tomography

1. Abstract

This prospective randomized clinical study performed a comparative volumetric analysis of the grafts obtained after maxillary sinus floor elevation, using two xenogens biomaterials: Bio-Oss® and BioGen®, by means of cone beam computed tomography. Graft surgeries were performed in 20 maxillary sinuses of 10 patients, and the selection of biomaterials was done randomly by lot. A total of 40 computed tomographic images, 16 images at 07 (T1) and 16 images at 180 days after surgery (T2) were evaluated using Osirix® MD Imaging 6.5 software (Pixmeo Geneva. Switzerland). The graft volumes obtained during the study periods were correlated. The amount in grams used of each biomaterial was according to the size of the maxillary sinus evaluated before surgery (T0) and the area of prosthetic interest to be rehabilitated. As a result, five patients used 2.0 grams, four patients 1.5 grams and one patient 1.0 grams. The volumetric reduction evaluated at T2 was significant compared to T1, $p < 0.05$, but no significant difference was observed when the biomaterials used were compared. Even with the observed volumetric contraction (17% average), the volume gain through the grafts was sufficient for rehabilitation with the planned implants. This study concluded that both biomaterials used suffered significant volume reduction during the evaluation period. Despite the contraction of the grafts, the volume obtained was sufficient for the installation of dental implants. Follow-up and longitudinal studies are needed to assess the stability of these grafts with implant functions.

2. Introduction

Most edentulous patients in the posterior maxillary area present insufficient bone volume for rehabilitation using implants, due to pneumatization of the maxillary sinus and reabsorption of the

bone crest [1]. In this context, reconstructions of the posterior portion of the maxilla with grafts Bone grafts are performed using different surgical techniques and biomaterials [2]. The technique proposed by [3] and published by Boyne and [4], for elevation of the maxillary sinus floor, consists of preparing a lateral window, elevation of the maxillary sinus membrane creating a cavity that will be filled with the biomaterial of choice for gaining bone volume. The biomaterials proposed for the graft can be allogenic, alloplastic, xenogenic and autogenic [1,5]. THE autogenous graft was considered the reference standard for bone reconstructions [6-13], due to the fact that its remodeling happens without immunological resistance, but the restrictions of its use are morbidity and limitations of the donor area [14,15]. These limitations led to the development of bone substitutes, which have been better developed [16]. In this context, inorganic bone substitutes and synthetic biomaterials have been the most investigated in breast lift surgical procedures jawbone, including calcium phosphate ceramics and hydroxyapatite of bovine origin [17,18]. The most common source of xenografts is bovine origin and as alternative materials of porcine and equine origin have been used. The articles found in the literature on bone substitutes of equine origin have demonstrated good results and ability to induce osteoblastic differentiation cellular, being considered an effective biomaterial in the breast lift technique jaw [19,20]. To evaluate the behavior of these biomaterials, studies such as [21-23]. Analyzed through computed tomography the volumetric changes of the grafts used for elevation of the floor of the maxillary sinus. In this context, this study evaluated through cone beam computed tomography (CBTC) the initial and final volume of the grafts using the bovine xenogeneic biomaterials Bio-Oss® (Geistlich) and equine origin BioGen® (Bioteck), in patients with total edentulism in posterior region of the maxilla requiring maxillary sinus lift surgery bilaterally.

2.1. Pneumatization of the Maxillary Sinuses

Tooth loss induces expansion of the maxillary sinus, possibly creating a union between the sinus floor and the crest of the remaining alveolar ridge [24]. This expansion is related to the height and length of the breast, rather than depth [25]. After tooth extraction, a 25% reduction is observed in the crest volume during the first year, reaching 40-60% of length during the first three years [26]. Discussed the anatomy, physiology and mechanisms of bone grafting, as well as materials to be used for grafting to raise the floor of the maxillary sinus, where he emphasized that the reason for performing this technique has with the aim of restoring a sufficient amount of alveolar bone so that implants are successfully placed. Many biomaterials have been recommended for the maxillary sinus floor lifting procedure and the ideal graft should be non-toxic, non-antigenic, non-carcinogenic, resistant, resilient, easy to manufacture, capable of allowing tissue adhesion, resistant to infection, available and inexpensive.

2.2. Hydroxyapatite of Bovine Origin

Bio-Oss® (Geistlich®) is a highly hydroxyapatite of bovine origin. purified and biocompatible, chemically and structurally comparable to bone human [5,27,28]. Processed at high temperatures, the organic and protein components of bovine bone are eliminated and its amorphous inorganic components are converted into hydroxyapatite. During sintering, the bovine trabecular bone microstructure is preserved, as evidenced by traces of lacunae in the osteocyte network; a chain of sub-micropores is grouped in the mineralized structure of the matrix. The general structure and pore morphology (pore size, percentage and interconnectivity) individual) are similar to mineralized human bones and serve as a support that allows the entry of osteogenic cells for bone growth [29,30].

2.3. Hydroxyapatite of Equine Origin

performed a comparative histochemical study in humans using autogenous bone and autogenous bone associated with equine bone for lifting of the maxillary sinus floor, resulting in higher values of microvascular density were found in the bone grafted sites autologous with significant difference between control and autologous ($p < 0.01$) and control versus autologous + equine ($p < 0.01$) [31]. They concluded that the mixture of autologous bone with equine bone is biocompatible and that this form of graft is associated with new formation of blood vessels during the healing phase, which has been shown be of extreme importance to bone formation [32]. Examined the bone regeneration potential of a mineral matrix derived from equine bone, for elevation of the maxillary sinus with the aim to rehabilitate the posterior region of the maxilla in a series of cases. The selected 10 patients with 12 maxillary sinus lifts. Histological results after 6 months demonstrated a large amount of newly formed vital bone in the intimate contact with residual graft particles. An average of 23.4% new bone formation was assessed after 6 months. It compared favorably to Previous results of xenografts for maxillary sinus lift. Qualitative and quantitative results from this case series suggest regeneration bone comparable to grafts derived from bovine bone within 6 months.

2.4. Volumetric Stability of Biomaterials

Shanbhag and Stavropoulos (2014) conducted a systematic review of the change volumetric analysis of sinus grafts with different biomaterials in humans, in relation to time, using 3D images. 12 studies were analyzed (n = 234), being 7 control studies and 5 uncontrolled studies with high risk of bias, using different types of grafting materials. Autogenous bone was used both particulate or block, bone substitutes were used alone or combined with other materials, such as “compositegrafts”. All studies showed volumetric changes in the grafts over time, generally after a short period of observation (ranging from 6 months to 6 years). Autogenous bone showed a higher resorption rate in 45% of cases in 77 sinus

grafts (after 6 months and more than 2 years). The resorption rate of bone substitutes alone or combined was relatively lower (18 to 22% in 142 cases) after a period of similar time. All studies showed a large reduction rate volumetric. There was no significant difference in volumetric reduction between the different biomaterials used. This volumetric loss does not appear to compromise the placement or survival of implants.

2.5. Volumetric Analysis Method

To evaluate bone grafting procedures in reconstructive surgeries maxillofacial, it is important to have reliable and accurate diagnostic methods, capable of determining the longitudinal survival of bone grafts. In this context, computed tomography can assess the correlation between the actual measurements of the bone grafts and the volumes measured later for determine the accuracy of this type of examination [33.34], in a multislice tomographic study on changes dimensional after elevation of the maxillary sinus floor compared bone autogenous to autogenous bone plus hydroxyapatites in the periods of 15 and 180 days. The average volume obtained from the evaluated biomaterials had changes significant differences between the groups at 180 days. They concluded that the two types of graft enabled anchoring of dental implants and that the tomography protocol computerized for volumetric evaluation of bone grafts is a method safe and accurate, providing consistent data [35]. Evaluated the impact of maxillary sinus volume on dimensional changes of different grafting biomaterials in elevation of the floor of the maxillary sinus, by means of multislice computed tomography. Comparison of 4 biomaterials using pre-surgery tomography and 15 days after surgery and 180 days after surgery. No correlation was observed between total breast volume maxilla and the dimensional alteration of the different grafts and also reported on the use of computed tomography in this study was highly efficient for volumetric evaluation. Rehabilitation of the atrophic alveolar ridge is always a clinical approach difficult to resolve. Surgery to gain bone height can be made difficult by lack of surface and blood nutrition during the initial phase of regeneration bone. Heterologous biomaterials and bone substitutes are used as alternatives to autogenous bone due to the limitations, disadvantages and morbidity associated with use of autogenous bone. In view of this, this research is relevant, as it carried out a comparative study in humans between a biomaterial little reported in the literature (BioGen®) with a widely used biomaterial (Bio-Oss®) and their respective volumes obtained for maxillary sinus elevation.

3. Objectives

3.1. General Objective

To assess the initial and final volume of xenografts used in elevation of the floor of the maxillary sinus, using the biomaterials, Bio-Oss® (Geistlich) - bovine origin and BioGen® (Bioteck) – origin equine.

3.2 Specific Objectives

a) correlate the initial bone volume obtained at T1 (7 days post-graft) and the final volume obtained at T2 (180 days post-graft), to evaluate the volumetric differences between T1 and T2 and whether there is a significant difference between bovine and equine xenogeneic biomaterials.

4. Material and Methods

4.1. Sample

This study was submitted and approved by the Ethics and Research Committee in Humanities of the Pontifical Catholic University of Minas Gerais (PUC Minas) under the number CAAE 11332319.9.0000.5137 (ANNEX A). All patients attended to the inclusion and sample selection criteria.

4.1.1. Inclusion Criteria

a) patients have pneumatization of the maxillary sinus, presenting bone remains less than 5 mm in height, with the need for bone grafting on both sides to increase alveolar ridge in height allowing the installation of implants bilaterally osseointegrable;

b) agree to participate in the research according to the application form. free and informed consent (ANNEX B).

4.1.2. Exclusion Criteria

a) smoking patients;

b) age under 18 and over 75;

c) patients with systemic alterations that contraindicate the procedure surgical such as: immunological diseases, uncontrolled diabetes mellitus, alcoholism, heart valve prostheses (recently installed), metal joint prostheses and primary endocarditis. The criteria for local exclusions were: maxillary sinus pathologies, maxillary sinus surgeries Caldwell Luc type preview, presence of septa that may hinder the sinus membrane detachment procedure, sinuses extremely narrow and unfavorable intermaxillary relationship, absence of periodontal disease; d) patients who do not agree to participate in the research, without this harm your service. Ten patients were selected, and all presented pneumatization of the maxillary sinuses and bone remnants of less than 5 mm and which required bone grafts for future implant installation. This study was performed split-mouth. This sample was divided into 2 groups: Bio-Oss® Group (10 maxillary sinuses) and BioGen® Group (10 maxillary sinuses), where the choice of sides was performed randomly. After evaluation of the patient and the tomography initial computerized, the quantity in grams of biomaterials was planned used in each case, according to the extension of the maxillary sinus and the area necessary for regeneration. The quantity in grams of each biomaterial was same in each patient, but there was variation between them. In 5 patients 2.0 grams were used, in 4 patients 1.5 grams and in 1 patient 1.0 grams. The biomaterials used for the grafting procedure were: Bio-Oss® - Geistlich, inorganic cancellous bovine bone graft in granules recognized by Ministry of

Health (ANVISA registration 806969930002), and BioGen® - Bioteck, inorganic cancellous equine bone graft in granules recognized by the Ministry Health (ANVISA registration 10349760020). The evaluations were performed using computed tomography in the postoperative period after 07 and 180 days, according to the surgery protocol of Master's degree in Implantology from the Pontifical Catholic University of Minas Gerais.

4.2. Patient Selection

Patient selection was carried out at the planning clinic Department of Dentistry at the Pontifical Catholic University of Minas Gerais. The selected patients were waiting for dental rehabilitation through osseointegrated implants in the maxilla. After clinical examination, anamnesis, tomographic analysis of the maxillary sinus and agreement with the terms of consent, planning was carried out surgical, medication prescription and scheduling of the procedure.

4.3. Medication Protocol

a) Amoxicillin 875 mg + Potassium Clavulanate 125 mg: Intake of 2 tablets 1 hour before the procedure and continue taking 1 tablet every 12 hours for 10 days in a row;

b) Dexamethasone 4 mg: Take 1 tablet 12 hours before and 1 tablet 1 hour before the procedure;

c) Budesonide 50 mcg intranasal: Continuous use starting 2 days before procedure and stop 15 days later, completing 17 days of use of the medication, applying 1 spray into each nostril every 12 hours;

d) Paracetamol 750 mg: Take 1 tablet every 6 hours for 3 days, or as long as there is pain.

4.4. Surgical Technique Protocol

a) asepsis of the operating field, local anesthesia (Lidocaine 2%) with anesthetic associated with vasoconstrictor (epinephrine) and appropriate dose for total absence of pain for the patient;

b) surgical incision complying with all the basic principles of oral surgery, appropriately exposing the recipient area to be grafted;

c) oval-shaped osteotomy of the lateral wall of the maxillary sinus to be grafted, using the modified Caldwell Luc technique, using a drill low speed diamond spherical with copious irrigation of solution sterile saline;

d) careful detachment and lifting of the sinus membrane;

e) deposition without condensation in the surgical pocket of Bio-Oss® - Geistlich or BioGen® - Bioteck for maxillary sinus filling (choose randomized);

f) tension-free suture with 5.0 nylon thread;

g) post-operative and medication recommendations;

h) patient monitoring.

4.5. Postoperative Control

Patients were followed up in the clinical postoperative period for 10 days. With postoperative tomography assessment in 7 days and clinical follow-up 30, 60, 90, 120 days. A second postoperative CT scan at 180 days was carried out.

4.6. Obtaining Images

Patients underwent preoperative panoramic radiography, and initial tomography was requested, prior to surgical intervention to planning and after 7 and 180 days of the procedure. The CT scans computerized scans were performed to assess the volume of graft placed in the interior of the maxillary sinuses in order to measure the degree of volumetric change between the two repair times, and guide the installation of future implants.

4.7. Volumetric Analysis

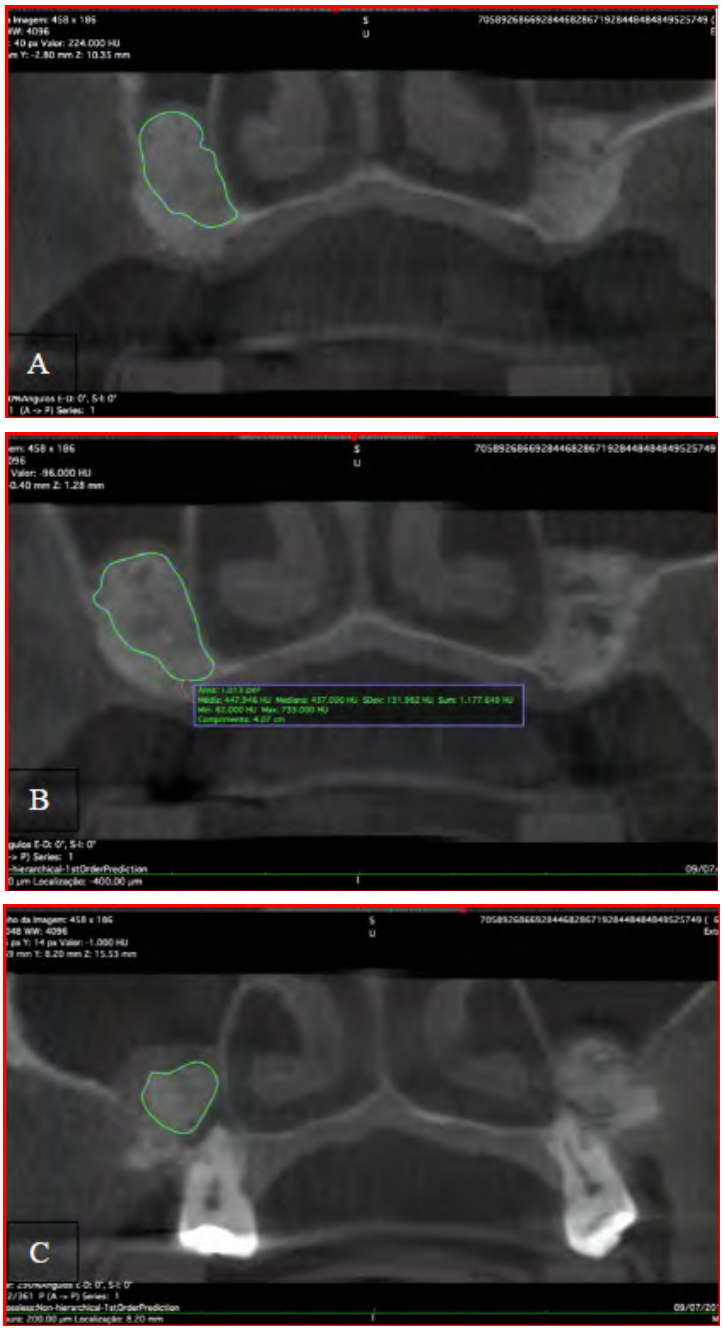
The computer program Osirix® 8.5 (Pixmeo, Geneva, Switzerland) was used to analyze the images obtained from the studied areas, comparing the initial volume of the biomaterial used, with steps 07 days and 180 days after the graft, as well as volumetric changes between these times. They were performed coronal, sagittal and axial reconstructions to obtain the volume, and the coronal section was chosen for volume analysis. From the coronal sections, the cursor was positioned on the cut that begins to see the presence of the image of the graft, and the ROI (Region of Interest) is selected (Figure 1A). As the cuts are moving to the most posterior region, new ROIs were selected, until reach the last cut that has the presence of the graft. 6 ROIs were selected in each breast and at each time point studied (T1 and T2) (Figure 1B and 1C). For each slice, the software calculates the volume within the identified area of interest in cm3, taking into account the thickness of the slice. When the total volume of the grafts was fully delimited in the images sequentially, the volumetric function of the software was activated (Figure. 2A and 2B) and the total graft volume was obtained in cm3 automatically. This procedure was carried out through training and calibration with a Kappa (k) index of 0.78.

4.8. Statistical Analysis Method

Statistical analysis of the data was performed using statistical software PRISM FIVE for Mac OS X (version 5.0a; GraphPad Software 2008). The tests normality Kolmogorov-Smirnov, D'Agostino & Pearson and Shapiro-Wilk, were carried out to assess the normality of data distribution. A level of significance level of 5% was adopted. To compare the means of the Bio-Oss® groups and BioGen® and the evaluation periods T1 and T2, the paired T-test was used.

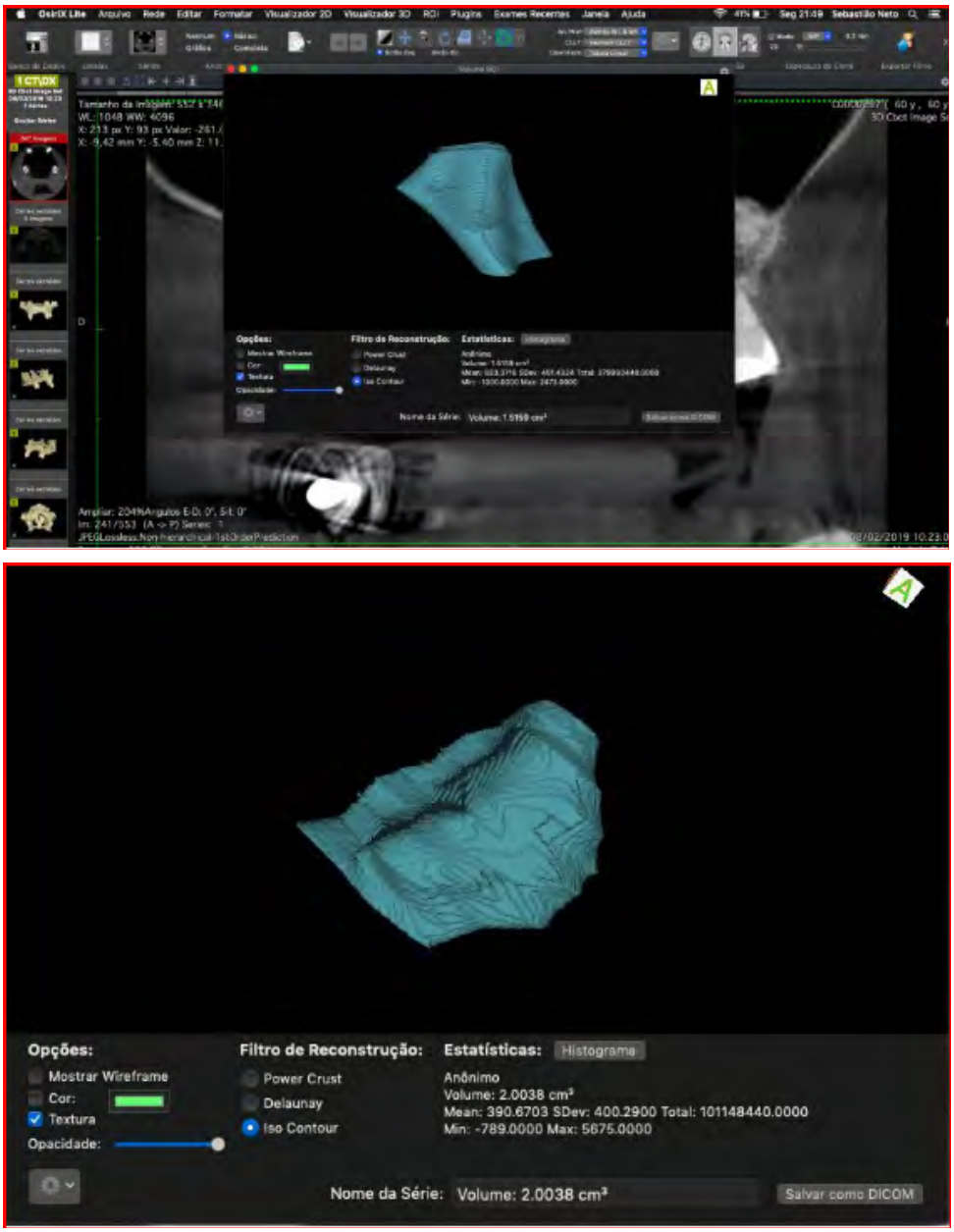
5. Conclusion

This study concluded that the biomaterials used suffered significant volume reduction during the evaluated period, without significant difference between them. Despite the contraction of the grafts, the final volume obtained was sufficient for the installation of the planned implants. Follow-up and longitudinal studies are necessary to evaluate the stability of these grafts with the functions of implants in equine HA.



Legend: A) Marking of the first area of interest; B) Marking of the intermediate areas of interest; interest; C) Marking the last area of interest.

Figure 1: Region of Interest (ROI) Selection.



Caption: A) Volumetric analysis; **B)** 3D reproduction of the area of interest.

Figure 2: Volumetric analysis of selected sections.

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