PONTIFÍCIA UNIVERSIDADE CATÓLICA DE MINAS GERAIS
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Roberta Paula Colen Bustamante

ESTABILIDADE DIMENSIONAL VOLUMÉTRICA DAS HIDROXIAPATITAS XENÓGENA E SINTÉTICA UTILIZADAS COMO ENXERTO NA ELEVAÇÃO DO SEIO MAXILAR: estudo clínico e tomográfico em humanos

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Dissertação apresentada ao Programa de Pós-graduação em Odontologia, da Pontifícia Universidade Católica de Minas Gerais, como requisito parcial para a obtenção do título de Mestre em Odontologia, Área de Concentração: Implantodontia.

Linha de Pesquisa: Propriedades biomecânicas, físico-químicas e biocompatibilidade dos biomateriais e materiais odontológicos.

Orientador: Prof. Dr. Elton Gonçalves Zenóbio

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COMPOSIÇÃO DA BANCA EXAMINADORA:

1- Prof. Dr. Leandro Napier de Souza – UFMG
2- Prof. Dr. Maurício Greco Cosso – PUC Minas
3- Prof. Dr. Élton Gonçalves Zenóbio – PUC Minas

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Belo Horizonte, 27 de setembro de 2016

Prof. Dr. Élton Gonçalves Zenóbio
Orientador

Prof. Dr. Martinho Campolina Rebello Horta
Coordenador do Programa de Pós-graduação em Odontologia

A gravidade explica os movimentos dos planetas, mas não pode explicar quem colocou os planetas em movimento. Deus governa todas as coisas e sabe tudo que é ou que pode ser feito (Isaac Newton).

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RESUMO

A utilização de enxertos para elevação do seio maxilar (ESM) proporciona um reparo ósseo com previsibilidade, no entanto, estudos sobre a estabilidade dimensional destes enxertos são escassos na literatura. Este estudo avaliou por meio da tomografia computadorizada de feixes cônicos (CBCT), o comportamento dimensional dos biomateriais Bio-Oss® *Small* e OsteoGen® após elevação do assoalho do seio maxilar. A metodologia proposta avaliou a variação volumétrica dos biomateriais por meio de imagens tomográficas obtidas nos períodos pré-cirúrgicos (T0), 15 dias de pós-operatório (T1) e 180 dias de pós-operatório (T2); analisadas por meio do software Osirix MD Imaging 6.5 (Pixmeo Genebra, Suíça). A amostra consistiu-se de 10 pacientes (20 seios maxilares) com necessidade de enxerto ósseo bilateral, com distribuição aleatória dos biomateriais em modelo de boca dividida. Para avaliação estatística foi utilizado o teste de Kolmogorov-Smirnov, que provou distribuição normal da amostra e o teste t de Student para análise das alterações volumétricas entre os enxertos e os diferentes períodos de estudo. Como resultado observou-se que para ambos os biomateriais, o volume do enxerto em T2 foi significativamente ($p < 0,05$) menor do que em T1. A variação de volume do enxerto entre T2 e T1 foi maior para o OsteoGen® que para o Bio-Oss® *Small*, sem diferença estatisticamente significativa ($p = 0,138$). Pode-se afirmar que os dois biomateriais utilizados, Bio-Oss® *Small e* OsteoGen®, exibiram mudanças significativas na estabilidade dimensional em 180 dias após a cirurgia. No entanto, quando comparados entre si em relação à alteração volumétrica, não houve diferenças significativas.

Palavras-chave: Elevação de seio maxilar. Substitutos ósseos. Biomateriais. Alterações volumétricas.

ABSTRACT

The use of grafts in maxillary sinus elevation provides a bone repair with predictability. However, dimensional graft changes are few data in the literature. This study evaluated the dimensional behavior of the biomaterials Bio-Oss® *Small* and OsteoGen® after maxillary sinus floor elevation, based on the characteristics and advantages of the bone substitutes, by cone beam computed tomography (CBCT) analysis. The proposed methodology evaluated the volumetric variation of biomaterials through tomographic images obtained in the preoperative period (T0), 15 days after surgery (T1) and 180 days postoperatively (T2); and analyzed it using the OsiriX software 6.5 Imaging (Pixmeo Geneva, Switzerland). The sample consisted up of 5 patients (10 maxillary sinuses) requiring bilateral bone graft, with random distribution of biomaterials in split-mouth model. For statistical analysis we used the Kolmogorov-Smirnov test, which proved normal distribution of the sample and the Student t test for analysis of volumetric changes between the grafts in different times. As a result it was observed that for both biomaterials, the graft volume of T2 was significantly ($p < 0.05$) lower than T1. The volume change of the graft between T2 and T1 was higher for OsteoGen® that for Bio-Oss® *Small* but statistically significant ($p = 0,138$). It can be said that the two biomaterials used Bio-Oss® *Small* and OsteoGen®, exhibited significant changes in dimensional stability at 180 days after surgery. However, when compared with each other in relation to the volume change, there were no significant differences.

Keywords: Maxillary sinus lifting. Bone substitutes. Biomaterials. Volumetric changes.

SUMÁRIO

1 INTRODUÇÃO

A região posterior da maxila compreende os dentes pré-molares e molares que apresentam uma íntima relação com o seio maxilar (JEMT; LEKHOLM; ADELL, 1989; ADELL et al., 1990). Pacientes edêntulos nessa área possuem volume ósseo insuficiente causado pela pneumatização do seio maxilar e reabsorção da crista óssea, com uma redução volumétrica final entre 3-5mm, o que incapacita a inserção de implantes dentários convencionais (PIATTELLI et al., 1999; KAHNBERG; WALLSTROM; RASMUSSON, 2011).

A técnica de elevação da membrana do seio maxilar (ESM) proposta por Tatum em 1977 e publicada por Boyne e James (1980), consiste na preparação de uma janela na parede lateral do seio maxilar, criando uma cavidade a ser preenchida pelo material de eleição para o ganho de volume ósseo.

Recentes estudos da implantodontia são focados em como avaliar o tratamento desses pacientes (CANNIZZARO et al., 2009; COSSO et al., 2014; FAVATO et al., 2015).

Materiais propostos para o enxerto em ESM são autógenos, alógenos, xenógenos e aloplásticos (PIATTELLI et al., 1999; CHIAPASCO; CRICCHIO; LUNDGREN, 2003; SCHLEGEL et al., 2003; ZANIBONI; BOISCO, 2006; CHAVES et al., 2012). O enxerto autógeno permanece considerado como padrão ouro, ideal pelo fato de sua remodelação acontecer sem resistência imunológica, porém restrições ao seu uso devem ser enfatizadas como a morbidade de uma segunda área cirúrgica, assim como seu grau de contração e reabsorção (PIATTELLI et al., 1999; SCHLEGEL et al., 2003, COSSO et al., 2014).

Os substitutos ósseos orgânicos e os biomateriais sintéticos são os mais investigados, entre eles destacam-se a cerâmica de fosfato de cálcio e a hidroxiapatita de origem bovina (HAMMERLE et al., 2008; KNABE et al., 2008). Estes biomateriais devem apresentar as características de biocompatibilidade, serem substituídos pelo tecido ósseo formado e possuir qualidades osteoindutivas ou osteocondutivas (JENSEN et al.,1996).

Materiais cerâmicos têm sido muito utilizados na reparação óssea de áreas maxilo-mandibulares com considerável reabsorção óssea. São constituídos principalmente de fosfato, carbonato ou sulfato de cálcio. Devido à instabilidade de algumas dessas partículas o espaço entre as mesmas pode não ser preenchido por

osso viável. Estudos recentes sobre a estabilidade de diferentes materiais relataram que quanto maior for o osso residual maior a taxa de sucesso nos procedimentos de ESM (JARAMILLO et al., 2010; FAVATO et al., 2015)

Nesse contexto estudos que proporcionem o maior conhecimento das propriedades e características clínicas e imaginológicas dos substitutos ósseos nos procedimentos de enxertos para ESM são necessários.

2 OBJETIVOS

2.1 Objetivo geral

Avaliar por meio de tomografias computadorizadas de feixes cônicos, a estabilidade dimensional volumétrica dos biomateriais Bio-Oss® *Small* e OsteoGen® na elevação do assoalho do seio maxilar.

2.2 Objetivo específico

Avaliar a alteração dimensional do volume inicial e final em um período de seis meses pós-operatório, dos biomateriais Bio-Oss® *Small* (0.25 – 1mm) e OsteoGen® utilizados como enxertos na elevação do assoalho do seio maxilar, por meio de imagens tomográficas computadorizadas cone beam.

3 ARTIGOS

3.1 Artigo Científico 1

Clinical and CT evaluation of the maxillary sinus elevation using two hydroxyapatites: xenogenous (Bio-Oss ® Small) and Synthetic (OsteoGen®) – Literature Review and case report

Artigo formatado de acordo com as normas de publicação da **Journal of Case Reports in Dentistry** (Qualis B3).

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CLINICAL AND CT EVALUATION OF THE MAXILLARY SINUS ELEVATION USING TWO HYDROXYAPATITES: XENOGENOUS (BIO-OSS ® SMALL) AND SYNTHETIC (OSTEOGEN®) – LITERATURE REVIEW AND CASE REPORT

Roberta Paula Colen Bustamante,[1] Hayder Egg Gomes,[3] Bruno César Ladeira Vidigal,[4] Mário Nazareno Favato,[4] Maurício Greco Cosso,[2] Flávio Ricardo Manzi,[2] e Elton Gonçalves Zenóbio[2]

[1] Mestre em Implantodontia pela PUC Minas, Belo Horizonte, Brasil.

[2] Professor Adjunto IV do Departamento de Odontologia da PUC Minas, Belo Horizonte, Brasil Programa de Mestrado Implantodontia.

[3] Graduado pelo Departamento de Odontologia da PUC Minas, Belo Horizonte, Brasil.

[4] Doutorando pelo Departamento de Odontologia da PUC Minas, Belo Horizonte, Brasil.

Autor Correspondente:

Elton Gonçalves Zenóbio • Av. Dom José Gaspar, 500 – Coração Eucarístico • CEP 30.535-901 • Belo Horizonte • MG Brasil • Telefone: (31) 3319-4414 • E-mail: zenobio@pucminas.br

Abstract

The rehabilitation of the posterior region of the edentulous maxilla is a challenge in implantology. The aim of this study was to evaluate the volumetric dimensional stability of the biomaterials Bio-Oss ® Small (Geistlich, Wolhusen, Switzerland) and Osteogen® (Intra-lock®System) as graft materials after the maxillary sinus lift surgery (SLS) in a clinical case of split-mouth. The proposed methodology evaluated the volumetric change of grafts performed by cone beam tomographic images in the pre-surgical trial periods (T0), 15 days after surgery (T1) and 180 postoperative days (T2). As a clinical outcome, a raise of 12.07mm height of bone on the right side was observed, and 15 mm on the left side, as well as a volume, of 1.38 cm3 on the right side and 2,25 cm3 on the left side, which enabled planning for installation implants. Fifteen days after surgery, the initial volume was 2.57 cm3, and within 180 days after, 2.25 cm3 using 1.5 g Bio-Oss ® Small. The initial volume of Osteogen® obtained was 2.01 cm3, and the final 1.38 cm3 with the use of 3g. Bio-Oss ® Small graft material showed a volumetric change of 12.45%, while the Osteogen® biomaterial showed a change of 31.34%. It was concluded that the two materials can be used similarly in the practice of SLS, and, after six months, both brought sufficient bone volume and vertical height for the installation of dental implants, although the contraction of 18.89% Osteogen® was higher than that of the Bio-Oss ® Small. Longitudinal studies may be conducted to evaluate the impact of stability in implant placement.

Keywords: Maxillary sinus lift. Bone substitutes. Biomaterials. Volumetric changes.

1. Introdução

The absence of bone architecture that favors the installation of implants in the posterior maxilla is a challenge in implantology. It is often necessary to use bone grafts before a rehabilitation with implants in cases of pneumatization of the maxillary sinus and atrophy of the alveolar ridge [1].

Boyne and James [2] described a technique consisting of carrying out a bone window at the side wall of the maxillary sinus, with elevation of the Schneider membrane, then creation of a cavity to be filled with the material of choice for increasing bone volume [3]. As the most widely used technique for increasing available bone at the posterior maxillary, SLS can be associated with a wide variety of graft materials such as autograft, heterogeneous, xenogeneic and alloplastic [4].

The autogenous bone graft, considered the gold standard, is rich in cells and growth factors and features great osteoinductive and osteoconductive properties [5]. Furthermore, it has no immunogenic reaction or revascularization. New bone formation occurs within three to four months. [6]. However, it involves a second surgical site, which increases postoperative morbidity [7,8] and can display a large shrinkage and resorption over time [6,9].

Inorganic bone substitutes and synthetic biomaterials are the most frequently investigated, especially hydroxyapatite (HA) of bovine origin and calcium phosphate ceramics [10,11]. These biomaterials ought to present biocompatibility characteristics, being replaced by formed bone tissue and presenting osteoinductive and / or osteoconductive qualities [12].

This study aims to examine the use of xenogeneic bovine graft Bio-Oss ® Small and alloplastic graft Osteogen® in a split-mouth model after SLS, as well as their characteristics relating to volume stability over a period of 180 days, with a literature review and a case report.

2. Literature Review

2.1 Hydroxyapatite xenogenous Bio-Oss®

Bio-Oss ® (Geistlich, Wolhusen, Switzerland) is characterized by being a no protein bovine bone, sterilized with 75% to 80% porosity, approximately 10 nm diameter. Consisting of crystals cortical and cancellous granules form or cortical and cancellous block shape [12]. This biomaterial has demonstrated high biocompatibility with oral tissue in animals and humans, and meets the criterion of being osteoconductive [13].

Hislop [14] evaluated the use of inorganic bone (Bio-Oss ®) in other applications such as Maxillofacial Surgery, to promote the union of fractures and to repair defects caused by fracture or removal of cysts and orthognathic surgery. They concluded that the material may be used as an excellent interpositional graft, and that the elimination of surgery for removal of autogenous bone block reduces morbidity of the patients.

Piattelli et al. [7] conducted a study employing histological analysis of specimens obtained from maxillary sinus patients who underwent SLS technique with biomaterial Bio-Oss ®. The specimens were obtained in follow-up between 6 months and 4 years post procedure. They concluded that the material had high biocompatibility and ostocondutibilidade, as well as low absorption in humans, such that it can be perfectly used in surgery as a substitute material after SLS.

Mordenfeld et al. [15] performed a histologic and histomorphometric study to evaluate long-term tissue response after the completion of SLS using Bio-Oss ® Small mixed with autogenous bone as grafts. Specimens from the same patients were obtained in follow-up between 6 months and 11 years to evaluate possible resorption. The researchers observed intact presence of the biomaterial used in the period up to 11 years, with minimal resorption during the study period.

Schlegel et al. [8] proposed a study to compare the use of Bio-Oss ® and autogenous bone as grafts after SLS performed in beagle dogs, sacrificed after 90 and 180 days for histological exam. The authors concluded that the biomaterial can be used for induction of increased bone volume when there is no need for a full regeneration of the bone area, but the use thereof promotes a slow reabsorption.

Chackartchi et al. [16] compared bone formation after SLS with grafts of bovine bone of different granulations--small (0:25 - 1 mm) and large (1 - 2mm)--clinically, histologically and volumetrically in humans. The authors concluded that in the clinical and histological follow-up examinations, there was no significant difference in the results. The two granulations served their purpose. The use of one or another material is simply a professional choice.

Testori et al. [17] proposed a study to compare histology of bone tissue formed after SLS. Bilateral surgery was performed on one sinus with Bio-Oss ®Large and Bio-Oss ® Small. After 6 to 8 months, specimens were obtained for histologic evaluation. The authors reaffirmed the osteoconductive properties of the material in question, and that the use of Bio-Oss ® Large showed a significant increase in the formation of bone tissue.

Cosso et al. [9] evaluated the dimensional graft changes measured by multislice CT after SLS, either with autogenous bone or autogenous bone and hydroxyapatite (HA) mixed, in 10 patients. We used split-mouth methodology to select the patients as follows: control group (CG n = 10 sinuses grafted with autogenous bone) and test group (TG, n = 10 sinuses grafted with HA and autogenous bone mixed to 80:20 w / w). The volumetric dimensional changes of the groups were measured by computed tomography (CT) with 15- and 180-days follow-up by two calibrated examiners.

Both groups showed significant dimensional changes after 180 days ($p < 0.05$). The reduced volume in the test group was lower (25.87%) than in the control group (42.30%) ($P < 0.05$). Both graft materials contributed to an increase in bone volume capacity for installation of dental implants. Furthermore, in 180 days follow -p on the mixture of HA and autogenous bone grafts demonstrated lower absorption and higher dimensional stability when compared to the autogenous bone graft features.

Jensen et al. [18] proposed a study to evaluate the stability of the implants after the SLS using deproteinized bovine bone mineral available in two particle sizes, large and small. They concluded that predictability of the two materials is equal to the SLS technique followed by immediate implant placement.

2.2 Hydroxyapatite Synthetic Osteogen®

Osteogen® is a hydroxyapatite (HA) synthetic, produced in the USA by Intra-Lock® System, which demonstrates slow resorption and is not a ceramic that has osteoconductive properties. The crystalline organization is similar to human bone mineralization in that it does not contain inhibitors such as tricalcium phosphate or pyrophosphate, which are found in the HA ceramics. It consists of elongated crystals attached to a central core. This macrostructure gives it great hydrophilicity and contact surface, facilitating the absorption of extracellular matrix molecules, recruiting osteoprogenitor cells and demonstrating subsequent bone formation [19].

HA ceramic beads are different from crystals of bone and Osteogen®, as evidenced by infrared spectroscopy and diffraction X-rays [20]. The Osteogen® HA crystals are not synthesized at the high temperatures associated with ceramic. Thus, the material does not lose its natural state [Ca 5 (PO 4) 3 {OH)] and maintains its physical and chemical properties similar to human cancellous bone [21,22].

Ricci et al. [23] observed, after twelve weeks of Osteogen® implantation in tibias dogs, intense osteogenic and osteoconductive activity. Whittaker et al. [24] obtained biopsies in grafts within human jawbone with Osteogen® after 6 months, and also observed bone formation around the biomaterial particles.

Valenzuela et al. [19] conducted a study in which bone defects in the alveolar process were treated with bone graft HA not ceramic (Osteogen®) after debridement and exposure of the bone defect. Biopsies were performed at 6 and 12 months, as well as histological sections for observation under optical and electronic microscopy. Trabeculae of cancellous bone surrounding Osteogen® particles was observed, and among them and on the root surface, a fibrous connective tissue. At twelve month follow-up, most implanted particles appeared immersed in lamellar bone tissue.

Artzi et al. [25] reported a clinical study in which Osteogen® was structurally and biologically equivalent to the human bone, and in which the three-dimensional configuration of it (crystal conglomerates) offered more space between particles compared to the ceramic. These spaces facilitate cell and tissue proliferation in the graft material, thus enhancing osseointegration.

Manso et al. [26] evaluated, by clinical parameters and images, the long-term predictability of dental implants that were placed in simultaneous approaches after SLS in posterior regions of atrophic maxillas, using resorbable synthetic graft bioactive and autogenous bone graft. All patients were surgically treated by the same surgeon and received the same technical protocol: graft composed of modified autogenous bone and synthetic bioactive resorbable graft (Osteogen®, Implant, Holliswood, NY).

A total of 160 implants were placed into 57 maxillary sinus of 45 patients (16 men, 29 women). Six months was the minimum time before examination in order to ensure the reactivity of bone tissue. All patients were observed during an average period of 61.7 months (range of 20-132 months) using clinical and radiographic features. The rates of survival and success were 98.05% and 94.85%, respectively. It was concluded that the resorption of advanced rear maxilla with expansion of the maxillary sinus can be safely handled by the SLS approach and simultaneous insertion of the implant using the protocol technical and biomaterials studied.

2.3 Comparative studies Bio-Oss® Osteogen®

Santos et al. [27] evaluated the tissue reaction of two different HA (synthetic and natural) and bioactive glass when implanted in dogs after dental extraction. The first and third upper and lower molars were extracted, on both sides, in six dogs - females. The dental alveolus were randomly divided into four groups: Group 1 - control (not filled), Group 2 - filled with synthetic hydroxyapatite, Group 3 - filled with bovine HA (natural), and Group 4 - filled with bioactive glass. The animals were sacrificed at 4 weeks (n = 2), 8 weeks (n = 2) and 28 weeks (n = 2) after extraction.

The jaw and maxilla of each animal were removed for histological analysis to determine soft tissue reactions, bone neoformation, bone characteristics, and the presence or absence of implanted materials. Most synthetic HA particles demonstrated bone formation on their surfaces, although some particles showed a layer of fibrous connective tissue. The group filled with bovine bone mineral showed portions partially replaced with bone formation. The group filled with bioactive glass showed particles with a thin layer of calcified tissue, but it was absent in some

samples, suggesting complete reabsorption. The bovine HA, in relation to synthetic HA and bioactive glass, demonstrated a greater number of particles covered with bone tissue. All biomaterials interfered with the tissue repair process. Biomaterials exhibit similar behavior.

The use of grafts for SLS provides a predictive biological repair process; however, from the point of view of dimensions, there is still no consistent data in the literature.

Based on the reported characteristics and advantages of bone substitutes, this study investigates the dimensional behavior of Bio-Oss® Small and OsteoGen® biomaterials in maxillary sinus floor elevation.

3. Clinical Case Report

Patient, 52 years old, female, visited the Professional Master in Implant Dentistry of the Pontifical Catholic University of Minas Gerais for rehabilitation with the use of dental implants. In the evaluation of Computed Tomography of Cone Beams, severe posterior bone loss was diagnosed (Figure 1), and pneumatization of the maxillary sinus bilaterally and ESM surgery were indicated. The patient was introduced in a prospective study, and split-mouth model was used to compare two Bio-Oss® Small and OsteoGen® biomaterials, used as ESM grafts. A free and informed consent form informing her of the risks and benefits, authorization and release, of the documentation of the surgical procedure was signed.

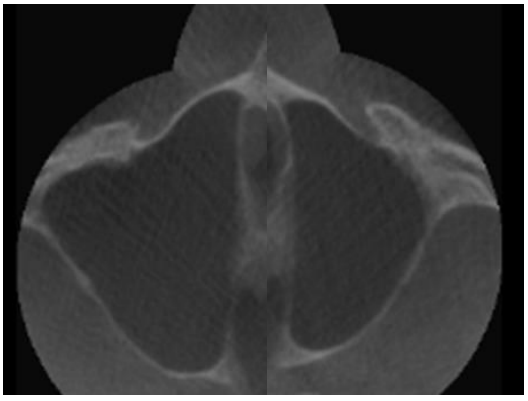

Figure 1: Right maxillary sinus - Left maxillary sinus - axial section

3.1 Surgical protocol

a) Commercial local anesthesia (2% lidocaine with 1:100,000 epinephrine) was administered at an appropriate dose to produce an adequate anesthetic depth. As a prophylactic measure, all patients received 875mg of amoxicillin and potassium clavulanate 1 hour before surgery as well as 7 days postoperatively. In order to manage postoperative edema, patients received a 4 mg dose of dexamethasone 12 hours prior to the procedure, another dose of 4 mg 1 hour before and one last dose of 4 mg 12 hours after the procedure;

b) After anesthesia of the posterior superior alveolar nerve, middle superior alveolar nerve and greater palatine nerve, the region of the maxillary sinus was accessed by making an incision in the top of the crest of the alveolar ridge. Prior relaxing incisions were made in the lateral incisor and later in the maxillary tuber. As a result, a mucoperiosteal flap was obtained and laterally removed. It was fixed by means of sutures at the base of the buccal flap to expose the lateral wall of the maxillary sinus. According to the procedure used (BOYNE; James, 1980), this type of surgical incision meets all the basic principles of oral surgery by appropriately exposing the area to be grafted; [2];

c) Osteotomy of the lateral wall of the maxillary sinus to be grafted using the technique known as Caldwell luc, consists of creating a rectangular window with rounded corners. Its size differs according to the size of the maxillary sinus. This technique should be performed utilizing a round diamond No. 8 bur at low speed with copious saline irrigation. As a result of this, part of the Schneider membrane is exposed;

d) Detachment and careful elevation of Schneider membrane was performed by carefully separating from the inner cortical surface of the maxillary sinus by using a series of specific instruments for this procedure, starting at the bottom wall of the cavity and extending to the anterior, medial and posterior until the planned height is reached. After the osteotomy, the bone portion of the lateral wall that is adhered in the sinus membrane is removed and used as autologous filler material;

e) Protect the side wall of the maxillary sinus by using Bio-Oss® *Small* to fill the maxillary sinus and resorbable membrane Surgidry;
f) The surgical flap is repositioned and sutured with nylon 5.0, a suture without tension;
g) The procedure is repeated on the opposite side of the maxillary sinus, but the graft material used is OsteoGen®.

2.5g of OsteoGen® was used in the right maxillary sinus; 2g of Bio Oss Small® was used in the collateral region; there were no intercurrences during the surgical procedure or post surgically(Figures 2 and 3).

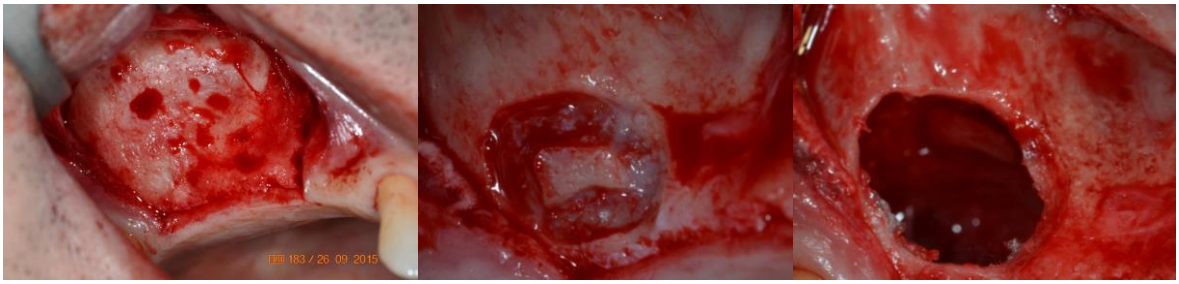

Figure 2: Exposure of the lateral wall of the maxillary sinus and osteotomy of the lateral wall of the maxillary sinus Schneider membrane elevation.

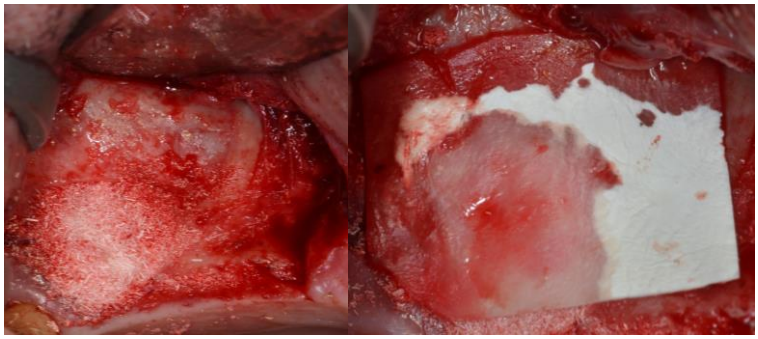

Figure 3: Filling with biomaterial and positioning of the collagen membrane on the graft.

Three CT scans were performed, initially (T0), 15 days after the surgical procedure (T1) and 180 days after (T2) (Figures 4 and 5).

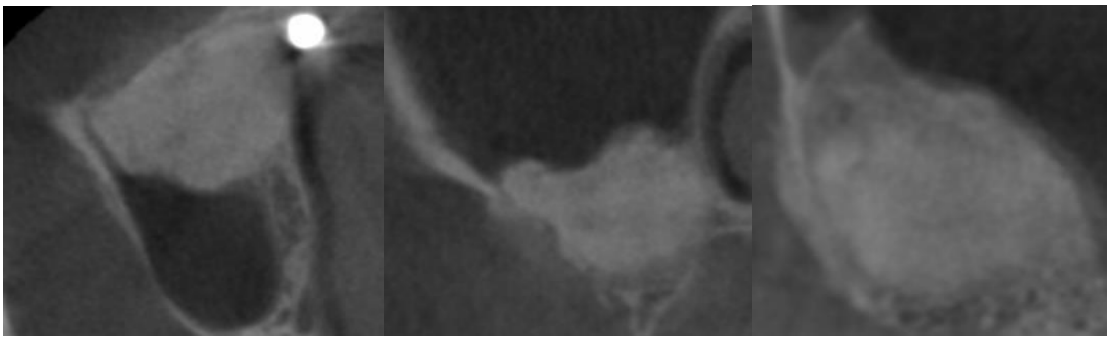

Figure 4: Right side maxillary sinus with OsteoGen® 15 days postoperatively.

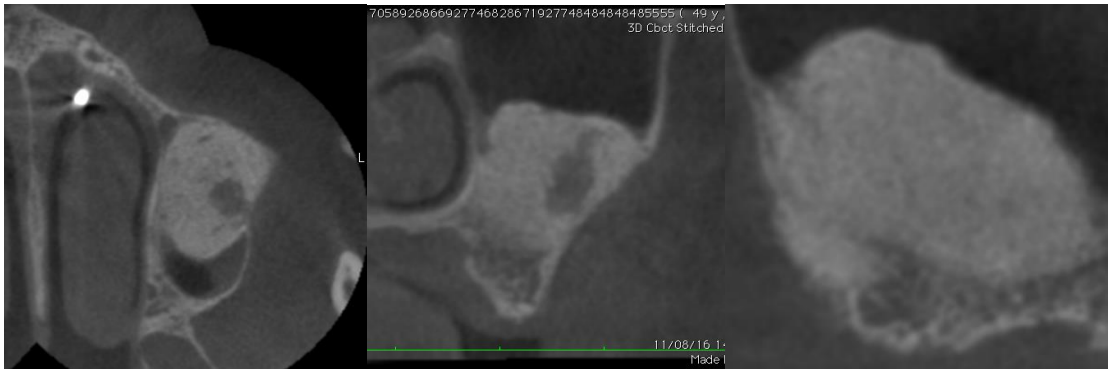

Figure 5: Left-side maxillary sinus with Bio-Oss® Small 15 days postoperatively.

Clinically, no intercurrence was observed in the biomaterials used. An increase in bone volume was observed, with a height of 12.07 mm on the right side and 15 mm on the left, as well as volume of 1.38 cm3 on the right side and 2.25 cm3 on the left side, which made it possible to plan for implant installation. The evaluation of the volumetric change, as well as the amount of Bio-Oss® Small and OsteoGen® biomaterials, are described in Table 1.

Table 1: Evaluation of volumetric change of biomaterials

	Amount of Material (g)	Volume cm^3 15 days	Volume cm^3 180 days	Volumetric change %
Left Side (Bio-Oss® *Small*)	1,5	2,57	2,25	12,45
Right Side (OsteoGen®)	3	2,01	1,38	31,34

5. Discussion

The present study reported a clinical case of the ESM surgical technique using Bio-Oss® Small in the right maxillary sinus and OsteoGen® in the left sinus. The evaluation of the volumetric alteration of biomaterials was obtained 180 days after surgery. The volume change was 12.45% for Bio Oss® Small and 31.34% for OsteoGen® in the left and right sinus, respectively. Even with this change and the quantity of material, the patient could be rehabilitated through implants. In cases where the pneumatization of the maxillary sinus is greatly exacerbated, a significant amount of OsteoGen® may be required for there to be a gain in height and volume of bone structure. Comparative studies of Bio-Oss® Small and OsteoGen® used in ESM procedures have not yet been published in the literature. However, in a study by Santos et al. [27], who evaluated the tissue reaction of two different HAs (synthetic - OsteoGen® and natural - Bio-Oss®) and bioactive glass when implanted in dogs shortly after the extraction, concluded that all biomaterials interfered with the tissue repair process and presented similar behavior at the end of their bone repair. Although many biomaterials are used for ESM procedures, the ideal material has not yet been identified, but the vast majority of them have provided sufficient bone height and volume for the installation of osseointegrative implants in the posterior maxilla region. Another issue that could be addressed would be the cost. Bio-Oss® Small is twice the cost of OsteoGen®, so opting for non-ceramic HA could represent an economic advantage, mainly for the patient, but the necessary amount of OsteoGen® to obtain a Similar volume to Bio-Oss® Small is greater as well.

6. Conclusion

The two materials can be used as grafts in the practice of maxillary sinus floor augmentation, and the procedures result in similar material behaviors. Six months follow-up showed bone volume and sufficient vertical height for the installation of dental implants, despite a 18.89% higher contraction of OsteoGen® compared to Bio-Oss® Small. Longitudinal studies should be conducted to assess the impact of this variability on the stability of the installation of the implants, as well as the predictability.

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3.2 Artigo Científico 2

A volumetric dimensional stability evaluation of xenogenous and synthetic hydroxyapatites Bio-Oss ® *Small* and OsteoGen®, used as grafts after sinus floor augmentation in humans: a clinical and tomographic study

Artigo formatado de acordo com as normas de publicação da **Revista Clinical Oral Implants Research** (Qualis A2).

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A VOLUMETRIC DIMENSIONAL STABILITY EVALUATION OF XENOGENOUS AND SYNTHETIC HYDROXYAPATITES BIO-OSS ® SMALL AND OSTEOGEN®, USED AS GRAFTS AFTER SINUS FLOOR AUGMENTATION IN HUMANS: a clinical and tomographic study

Roberta Paula Colen Bustamante

Bruno César Ladeira Vidigal

Mário Nazareno Favato

Flávio Ricardo Manzi,

Mauricio Greco Cosso

Elton Gonçalves Zenóbio

Programa de Pós-graduação em Odontologia, da Pontifícia Universidade Católica de Minas Gerais, Belo Horizonte, Minas Gerais, Brasil.

Palavras-chave: Elevação de seio maxilar. Substitutos ósseos. Biomateriais. Alterações volumétricas.

Endereço para correspondência:

Elton Gonçalves Zenóbio

Pontifícia Universidade Católica de Minas Gerais - Departamento de Odontologia

Av. Dom José Gaspar 500 – Coração Eucarístico

Belo Horizonte - MG - Brasil - CEP: 30535-901

Telefone: (31) 33194414

Email: zenobio@pucminas.br

Abstract

Objective: This study evaluated the dimensional behavior of the biomaterials Bio-Oss Small® and Osteogen® after sinus lift surgery (SLS). This is elevation of the maxillary sinus floor, using computed tomography tapered beam (CTCB).

Methods: Ten patients (20 maxillary sinuses) with a bilateral bone graft with random distribution of biomaterials in a split-mouth model were evaluated. The measurements were performed with: tomographic images obtained in the preoperative period (T0), and 15 days (T1) and 180 days postoperatively (T2). They were analyzed using the OsiriX Imaging 6.5 software (Pixmeo Geneva, Switzerland). The Kolmogorov-Smirnov test was used, which showed a proved normal distribution in the sample. The Student's t-test was used for analysis of volumetric changes between the grafts and at different periods.

Results: With both biomaterials, the volume of the grafts in T2 was significantly lower than in T1 for both biomaterials ($p < 0.05$). The volume change of the graft between T2 and T1 was higher for Osteogen® than for Bio-Oss ® Small, but not statistically significant.

Conclusion: Both biomaterials can be used to SLS once it was obtained, after 6 months, bone volume and sufficient vertical height for installing implants. Fewer Bio-Oss ® Small was required to fill the same area compared to Osteogen®. Longitudinal studies should be conducted to assess the impact of this change to the placement and preservation implants.

Keywords: maxillary sinus lift, bone substitutes, biomaterials, volumetric changes

Introduction

In cases of patients with this edentulous in the posterior regions of the maxilla, there might be insufficient bone volume caused by pneumatization of the maxillary sinus and bone resorption of the crest. Remaining bone <5 mm makes insertion conventional dental implants impossible (Adell et al. 1990; Jemt et al. 1989; Piattelli 1999, Kahnberg et al. 2011, Gorla et al. 2015.).

Studies evaluating the options of grafts for maxillary sinus membrane elevation (ESM) were proposed in the last decades trying to evaluate the behavior of the bone grafts and of different biomaterials. (Piattelli 1999; Hallman et al. 2002; Cricchio & Lundgren 2003; Schlegel et al. 2003; Chiapasco et al. 2006; Chaves et al. 2012; Yang et al. 2013; Cosso et al. 2014; Favato et al. 2015; Gorla et al. 2015; Wu et al. 2016)

Inorganic bone substitutes and synthetic biomaterials are the most investigated, foremost among them the hydroxyapatite (HA) of bovine origin and calcium phosphate ceramics (Jensen et al. 1996; Hammerle et al. 2008; Knabe et al. 2008; Cannizzaro et al. 2009; Jaramillo et al. 2009; Cosso et al. 2014; Favato et al. 2015).

The use of grafts for maxillary sinus elevation provides a predictive biological repair process, however, from the point of view of dimensional changes there is still no consistent data in the literature

Material and Methods

The study was approved by the Ethics Committee, number CAAE 49796115.4.0000.5137.

Panoramic radiographs were made of 50 patients for initial screening of maxillary remaining bone crest availability. Patients that were smokers, or had autoimmune diseases, diabetes mellitus, alcoholism, stress, active periodontal diseases or diseases of the maxillary sinus were excluded. Patients with less than 5 mm of bone remaining between the crest of alveolar ridge and associative maxillary sinus were included.

The final sample consisted of patients: two men and four women, aged between 21 and 70 years. Computerized tomography (CBCT) was requested for all patients for preoperative evaluation.

As a surgical and therapeutic protocol, the methodology described by Cosso et al. (2014), except for the grafts, that by means of a random lottery and referenced in a table to choose the biomaterial OsteoGen® or Bio-Oss® Small for ESM procedure in the split-mouth model. At 15 and 180 days following the ESM surgery, computerized tomography was performed to evaluate the volumetric changes. The 64-bit software OsirixMD® (Pixmeo, Geneva, Switzerland) was used for image analysis. A single trained and calibrated radiologist manually delineated the graft image using the program and automatically set all sagittal, axial, and coronal sections of the image. The graft area was measured in all slices with a thickness of 0.25 mm and a distance of 1 mm between the slices. The graft area was automatically calculated with OsiriXMD® software tool. The volume was calculated automatically by the program, generating a geometric figure showing the total volume of the graft (Figure 1). A new measurement and geometric image of the graft were performed on the tomographic image 180 days following surgery, then compared to the volume that was obtained 15 days postoperatively.

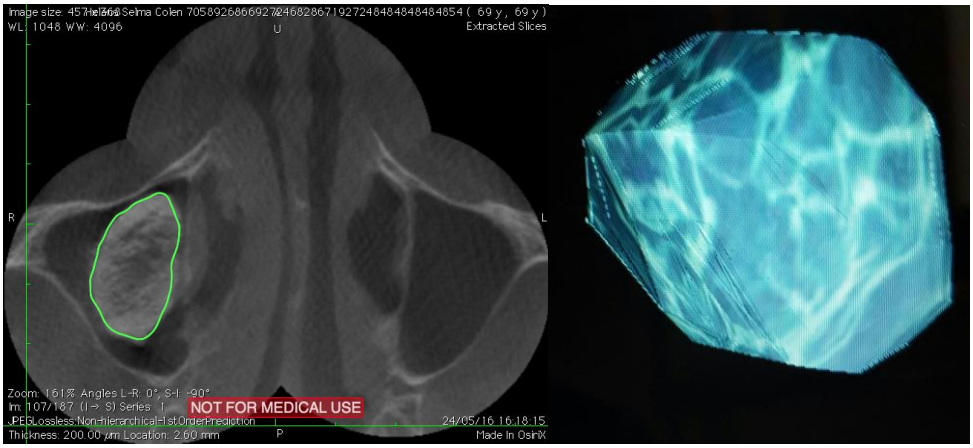

Figure 1. Manual delimitation of the graft and geometric figure of the total volume of the graft

The data were evaluated using the Kolmogorov-Smirnov normality test, which showed a normal distribution. The paired t-test, with significance of 5%, was used to evaluate and compare the changes in the volume of the OsteoGen® and Bio-Oss® Small, biomaterials used in the grafts between T1 and T2. The analyses were performed using Minitab Statistical Software 16.0 software (Minitab Inc. State College, Pennsylvania).

Results

The mean graft volume in T2 was lower than in T1, demonstrating volumetric reductions over the analyzed period. This difference is statistically significant, according to table 1 ($p < 0.05$).

Table 1. Mean, standard deviation and mean deviation of graft volume compared to T1 and T2

Biomaterial	T1		T2		Mean Deviation (T2-T1)	Value (*P*)
	Mean	SD*	Mean	SD*		
Bio-Oss® *Small*	3,203	1,228	2,753	1,345	0,525	<0,05
OsteoGen®	1,960	0,868	1,557	0,850	0,327	<0,05

***** *Standart Deviation*

No statistically significant volumetric difference was found when the mean volume changes were compared between grafts with Bio-Oss® Small and OsteoGen® biomaterials (Table 2).

Table 2. Percentage ratio of the contraction of Bio-Oss® *Small* and OsteoGen®

	Bio-Oss® *Small*		**OsteoGen®**	
	QUANTITY(g)	CONTRACTION (%)	QUANTITY (g)	CONTRACTION (%)
Patient 1	2	8,1	4	6,64
Patient 2	3	7,54	3	25
Patient 3	2	18,84	3	29,16
Patient 4	2,5	0,85	1,8	16,18
Patient 5	1	53,36	2	26,76
Patient 6	1,5	12,45	3	31,34

The graft volume variation (graft volume difference between T2 and T1) was higher for OsteoGen® than for Bio-Oss® Small. However, this difference was not statistically significant (p = 0,795; Table 3).

Table 3. Paired t-test and comparison between biomaterials

Biomaterial	Mean	Standard deviation	Mean deviation	Value (P)
Bio-Oss® *Small*	-0,450	0,343	0,140	0,795 (n.s.)
OsteoGen®	-0,403	0,216	0,088	

P value obtained by paired T-test: Bio-Oss® Small VS OsteoGen®
N.s. = not significant

Discussion

For the prospective split-mouth experimental model, no studies comparing the use of Bio-Oss® Small and OsteoGen® in maxillary sinus lift procedures were found in the literature, but individual analyses of animal and human studies have been considered in the discussion of these results.

In the present study, the choice of hydroxyapatites was based on the biological behavior described by Santos et al. (2010), which evaluated the tissue reaction of two different HAs (synthetic - OsteoGen® and natural - Bio-Oss®) through histological analysis.They concluded that all biomaterials interfered with tissue repair process and showed similar behavior in relation to bone formation.

Regarding the behavior of these biomaterials in maxillary sinus elevation, Ayna et al. (2016) recently demonstrated that, after 14 years of preservation, the graft region with residual Bio-Oss granules, interspersed with neo-formed bone tissue, was observed by histological and micro-radiographic analysis. Thus, there is strong evidence that the newly-formed bone was distributed throughout the bone substitute material around all of its granules.

Numerous studies have evaluated the behavior of bovine HA in the maxillary sinus using the LS surgical technique, determining that the biomaterial can be perfectly used for induction of bone volume increase because it presents high

biocompatibility and ostoconducibility. Piattelli et al. [7], Mordenfeld et al. [15] Schlegel et al. [8] Chackartchi et al. [16], Testori et al. [17]

For the analysis of graft images after maxillary sinus elevation, we can compare the results of the present study with those of Sbordone et al. [18] who evaluated the long-term bone remodeling of autografts, particulate and block, over a period of six years by means of computed tomography.

The volume and density of the grafts were compared over time by determining a percentage of residual bone graft. There were no statistically significant differences between the two groups, but the groups showed different behaviors in relation to reabsorption, which was 39.2% for the particulate graft, and 21.5% for the graft in the block. This suggests that the bone graft in block in the maxillary sinus elevation produces better results in relation to the maintenance of the bone volume.

In the study by Cosso et al., the dimensional changes in grafts after SLS using autogenous bone or a mixture of autogenous bone and hydroxyapatite (HA) was compared with multi-slice CT scans over a period of 180 days. Both groups showed significant dimensional changes after the 180-day period ($p < 0.05$) and all graft materials contributed with an increase in bone volume capacity for the installation of osseointegrated implants. This is similar to the results obtained in the present study.

Gorla et al. (2015) compared the use of autogenous bone, beta-phosphate tricalcium and a mixture of both in SLS procedures by computerized tomography of conical beams (CTCB) by OsiriX software. The present study observed that b-TCP can be used safely in the SLS, as shown by tomographic evaluation of the obtained graft volume after six months of follow-up. It has the advantage of not requiring a donor site, thus minimizing risks and avoiding greater morbidity. However, they

suggested that studies using this methodology over a longer evaluation period, should be made. Hstomorphometric and immunohistochemical studies should also be conducted.

OsteoGen® granules (Intra-lock®System) are much smaller than Bio-Oss® Small (Geistlich, Wolhusen, Switzerland). The granulometry of non-ceramic synthetic HA ranges from 300-400 µm, whereas unprocessed bovine bone varies from 0.25 to 1 mm (Ohno et al. 2013). When setting up a study similar to ours, synthetic HA OsteoGen® may be considered a disadvantage.

Table 4. Comparison between the quantity of biomaterial used and the initial volume obtained

	BIO-OSS SMALL		**OSTEOGEN**	
	INITIAL QUANTITY (g)	INITIAL VOLUME (cm^3)	INITIAL QUANTITY (g)	INITIAL VOLUME (cm^3)
PATIENT 1	2	3,8	4	3,31
PATIENT 2	3	5,3	3	1,6
PATIENT 3	2	3,29	3	1,7
PATIENT 4	2,5	2,33	1,8	1,73
PATIENT 5	1	1,93	2	0,71
PATIENT 6	1,5	2,57	3	2,01

However, in the analysis of the cost of each biomaterial, there was no difference, since Bio-Oss® Small is marketed at twice the cost of OsteoGen®.

No studies were found in the literature that correlate the amount of material used with the percentages of graft contraction. Comparison can be very advantageous when using such differing granulometry materials.

In conclusion, the two materials can be used for SLS, because six months post-operatively, a sufficient volume and bone height were obtained for the planning and the installation of implants. However, the results showed a lower reabsorption rate for the Bio-Oss ® Small, suggesting that it is more stable in relation to the increase of bone volume in the SLS procedures, confirming findings in the literature.

Compared to OsteoGen®, a smaller amount of Bio-Oss® Small was required to fill the same area.

There are no consistent data in the literature on the use of Osteogen® in maxillary sinus floor elevation procedures. Based on the results and the previously analyzed literature, there is a consensus that Bio-Oss® provides good safety and its efficacy is reliable.

Longitudinal studies should be performed to evaluate the impact of the volumetric reduction observed on each biomaterial in relation to implant placement.

Acknowledgment

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The authors declare no conflicts of interest related to this study.

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4 CONSIDERAÇÕES FINAIS

O presente estudo avaliou a alteração dimensional do volume inicial e final em um período de 6 meses, dos biomateriais Bio Oss *Small*® (0.25 - 1mm) e OsteoGen® na elevação do assoalho do seio maxilar, por meio de tomografia computadorizada cone beam.

Pode-se afirmar que os dois biomateriais utilizados, Bio-Oss® *Small* e OsteoGen®, exibiram mudanças significativas na estabilidade dimensional 180 dias após a cirurgia. No entanto, quando comparados entre si em relação à alteração volumétrica, não houve diferenças estatisticamente significativas. Em conclusão, os dois materiais podem ser utilizados para a ESM uma vez que após 6 meses havia volume e altura óssea vertical suficiente para a instalação de implantes dentários. Menor quantidade de Bio-Oss® *Small* foi necessária para preencher a mesma área comparada ao OsteoGen®. Estudos longitudinais devem ser realizados para avaliar o impacto desta redução volumétrica na colocação dos implantes.

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ANEXO A - Parecer Consubstanciado do CEP

PONTIFÍCIA UNIVERSIDADE CATÓLICA DE MINAS GERAIS - PUCMG

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: ESTABILIDADE DIMENSIONAL DAS HIDROXIAPATITAS XENÓGENA E SINTÉTICA UTILIZADAS COMO ENXERTO NA ELEVAÇÃO DO SEIO MAXILAR EM HUMANOS: Estudo clínico e tomográfico multislice.

Pesquisador: Roberta Paula Colen Bustamante

Área Temática:

Versão: 2

CAAE: 49796115.4.0000.5137

Instituição Proponente: Pontifícia Universidade Católica de Minas Gerais - PUCMG

Patrocinador Principal: Pontifícia Universidade Católica de Minas Gerais - PUCMG

DADOS DO PARECER

Número do Parecer: 1.403.308

Apresentação do Projeto:

A utilização de enxertos para elevação do seio maxilar proporciona um processo biológico de reparo com previsibilidade, no entanto, sob o ponto de vista das alterações dimensionais ainda não existem amplitude de dados na literatura. Será realizado um estudo de caso prospectivo, utilizando-se uma amostra de 20 pacientes portadores de área desdentada posterior bilateralmente que apresentem osso remanescente entre a crista do rebordo alveolar e o assoalho do seio maxilar inferior a 4 mm de altura, que necessitem de enxerto ósseo particulado no seio maxilar para posterior instalação de implantes. Os biomateriais utilizados para o procedimento de enxertia serão o Bio-Oss® e Osteogen® A avaliação será realizada por meio de tomografia computadorizada multislice.

Objetivo da Pesquisa:

O objetivo geral é avaliar por meio de tomografias computadorizadas, a estabilidade dimensional dos biomateriais Bio-Oss® e OsteoGen® na elevação do assoalho do seio maxilar.

Avaliação dos Riscos e Benefícios:

Riscos: Todo procedimento cirúrgico envolve riscos de complicações trans e pós-operatórias que dependem tanto do procedimento em si quanto do paciente. Para minimizar estes riscos faz-se de

Endereço: Av. Dom José Gaspar, 500 - Prédio 03, sala 228
Bairro: Coração Eucarístico **CEP:** 30.535-901
UF: MG **Município:** BELO HORIZONTE
Telefone: (31)3319-4517 **Fax:** (31)3319-4517 **E-mail:** cep.proppg@pucminas.br

suma importância uma anamnese detalhada e um planejamento cirúrgico bem definido. Seguindo esses critérios os riscos são minimizados. Há também o risco relativo ao resultado obtido. Embora os biomateriais estudados estejam fundamentados no estado da arte atual, ainda há a necessidade de mais estudos longitudinais que garanta previsibilidade dos mesmos. Sendo assim pode haver perda parcial ou total do enxerto em seio maxilar.

Benefícios: Este estudo tem grande potencial de gerar bem estar qualidade de vida aos indivíduos participantes. Do ponto de vista dos objetivos da pesquisa existe o benefício da contribuição científica em relação à técnica e biomateriais estudados.

Comentários e Considerações sobre a Pesquisa:

Pesquisa relevante.

Considerações sobre os Termos de apresentação obrigatória:

Os termos de apresentação obrigatória foram anexados e estão de acordo com as normas vigentes. O pesquisador responsável arcará com as despesas relativas aos exames radiográficos.

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:

Pela aprovação do projeto.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_593421.pdf	01/02/2016 09:23:09		Aceito
Declaração do Patrocinador	CARTA_DE_RESPONSABILIDADE_FINANCEIRA.docx	01/02/2016 09:22:14	Roberta Paula Colen Bustamante	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	termo_de_consentimento_livre_e_esclarecido.pdf	03/10/2015 01:28:11	Roberta Paula Colen Bustamante	Aceito
Projeto Detalhado / Brochura Investigador	projeto_detalhado.pdf	03/10/2015 01:27:04	Roberta Paula Colen Bustamante	Aceito
Folha de Rosto	folha_de_rosto.pdf	03/10/2015 01:25:45	Roberta Paula Colen Bustamante	Aceito

PONTIFÍCIA UNIVERSIDADE CATÓLICA DE MINAS GERAIS - PUCMG

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BELO HORIZONTE, 04 de Fevereiro de 2016

Assinado por:
CRISTIANA LEITE CARVALHO
(Coordenador)

Endereço: Av. Dom José Gaspar, 500 - Prédio 03, sala 228
Bairro: Coração Eucarístico **CEP:** 30.535-901
UF: MG **Município:** BELO HORIZONTE
Telefone: (31)3319-4517 **Fax:** (31)3319-4517 **E-mail:** cep.proppg@pucminas.br

ANEXO B - Termo de Consentimento Livre e Esclarecido

Título da Pesquisa: ESTABILIDADE DIMENSIONAL DAS HIDROXIAPATITAS XENÓGENA (BIO-OSS® *SMALL*) E SINTÉTICA (OSTEOGEN®) UTILIZADAS COMO ENXERTO NA ELEVAÇÃO DO SEIO MAXILAR EM HUMANOS: estudo clínico e tomográfico multislice

1) Introdução

Você está sendo convidado a participar de uma pesquisa que estudará dois biomateriais utilizados na técnica de Levantamento de Seio Maxilar. Será realizado esse procedimento nos dois seios maxilares onde será inserido o biomaterial escolhido através de sorteio aleatório entre os lados direito e esquerdo. Os biomateriais utilizados nessa pesquisa serão o Bio-Oss® *Small* e o OsteoGen®. Você foi selecionado(a) porque se enquadra dentro dos pré-requisitos exigidos à pesquisa. E por ter características que consideramos necessárias para realização do estudo, venho por meio dessa convida-lo a participar desse estudo, que consiste em se submeter ao procedimento cirúrgico de levantamento de seio maxilar bilateral e autorizar o acesso a seus exames que o (a) Sr(a) realizará através do banco de dados

Este Termo de Consentimento pode conter palavras que você não entenda. Peça ao pesquisador que explique as palavras ou informações não compreendidas completamente.

2) Objetivo

O objetivo desse estudo é avaliar por meio de tomografias computadorizadas, a estabilidade dimensional dos biomateriais Bio-Oss® *Small* e OsteoGen® na elevação do assoalho do seio maxilar. Se concordar em participar deste estudo você assinará esse termo consentindo se submeter ao procedimento e permitindo o uso dos exames realizados como fonte de informação para a pesquisa.

3) Riscos e desconfortos

Todo procedimento cirúrgico envolve riscos de complicações trans e pós-operatórias que dependem tanto do procedimento em si quanto do paciente. Para minimizar estes riscos faz-se de suma importância uma anamnese detalhada e um

planejamento cirúrgico bem definido. Seguindo esses critérios os riscos são minimizados. Há também o risco relativo ao resultado obtido. Embora os biomateriais estudados estejam fundamentados no estado da arte atual, ainda há a necessidade de mais estudos longitudinais que garanta previsibilidade dos mesmos. Sendo assim pode haver perda parcial ou total do enxerto em seio maxilar. Todos os cuidados inerentes a radiação ionizante , serão devidamente controlados de forma adequada dentro do princípio de ALARA e das normas de proteção radiológica. Os exames serão realizados de acordo com a Comissão Nacional de Energia Nuclear (CNEN) e PORTARIA Nº 453 DO MINISTÉRIO DA SAÚDE, Agencia Nacional de Vigilância Sanitária (ANVISA)". Sua participação é muito importante e voluntária e, consequentemente, não haverá pagamento por participar desse estudo. As informações obtidas nesse estudo serão confidenciais, sendo assegurado o sigilo sobre sua participação em todas as fases da pesquisa, e quando da apresentação dos resultados em publicação científica ou educativa, uma vez que os resultados serão sempre apresentados como retrato de um grupo e não de uma pessoa. Você poderá se recusar a participar ou a responder algumas das questões a qualquer momento, não havendo nenhum prejuízo pessoal se esta for a sua decisão. Todo material coletado durante a pesquisa ficará sob a guarda e responsabilidade do pesquisador responsável pelo período de 5 (cinco) anos e, após esse período, será destruído

4) Benefícios

A perda dos dentes gera grande desconforto e muitas vezes constrangimento ao indivíduo. Associada à perda dental está à reabsorção óssea principalmente na maxila. Essa condição clínica muitas vezes inviabiliza a reabilitação oral com implantes osseointegráveis. Nessa perspectiva considera-se que este estudo tem grande potencial de gerar bem estar qualidade de vida aos indivíduos participantes. Do ponto de vista dos objetivos da pesquisa existe o benefício da contribuição científica em relação à técnica e biomateriais estudados. A participação na pesquisa não acarretará gasto para você, sendo totalmente gratuita. O conhecimento adquirido com esta pesquisa poderá beneficiar você, bem como outros seres humanos, com informações e orientações futuras em relação à estabilidade

dimensional dos biomateriais estudados na técnica de levantamento de seio maxilar. Para todos os participantes, em caso de eventuais danos decorrentes da pesquisa, será observada, nos termos da lei, a responsabilidade civil. Você receberá uma via deste termo onde consta o telefone e o endereço do pesquisador responsável, podendo tirar suas dúvidas sobre o projeto e sua participação, agora ou a qualquer momento.

Pesquisador responsável: Roberta Paula Colen Bustamante
Departamento de Odontologia
Av. Dom José Gaspar, 500 - Fone: 3319-4517 - Fax: 3319-4517
CEP 30535.610 - Belo Horizonte - Minas Gerais - Brasil

Este estudo foi aprovado pelo Comitê de Ética em Pesquisa envolvendo Seres Humanos da Pontifícia Universidade Católica de Minas Gerais, coordenado pela Prof.ª Cristiana Leite Carvalho, que poderá ser contatado em caso de questões éticas, pelo telefone 3319-4517 ou e-mail cep.proppg@pucminas.br.

O presente termo será assinado em 02 (duas) vias de igual teor.

Belo Horizonte, 28 de agosto de 2015

Dou meu consentimento de livre e espontânea vontade para participar deste estudo.

_____

Nome do participante (em letra de forma)

_____
Assinatura do participante ou representante legal
Data:

Eu, comprometo-me a cumprir todas as exigências e responsabilidades a mim conferidas neste termo e agradeço pela sua colaboração e sua confiança.

_____
Assinatura do pesquisador
Data: