PONTIFÍCIA UNIVERSIDADE CATÓLICA DE MINAS GERAIS
Programa de Pós-graduação em Odontologia

Flávia Leite Pereira

VOLUME ÓSSEO FORMADO A PARTIR DO PREENCHIMENTO DO SEIO MAXILAR APENAS COM COÁGULO, ASSOCIADO À INSTALAÇÃO IMEDIATA DE IMPLANTE

Belo Horizonte
2019

Flávia Leite Pereira

VOLUME ÓSSEO FORMADO A PARTIR DO PREENCHIMENTO DO SEIO MAXILAR APENAS COM COÁGULO, ASSOCIADO À INSTALAÇÃO IMEDIATA DE IMPLANTE

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. Maurício Greco Cosso

Belo Horizonte
2019

FICHA CATALOGRÁFICA
Elaborada pela Biblioteca da Pontifícia Universidade Católica de Minas Gerais

Pereira, Flávia Leite
P436v Volume ósseo formado a partir do preenchimento do seio maxilar apenas com coágulo, associado à instalação imediata de implante / Flávia Leite Pereira. Belo Horizonte, 2019.
53 f. : il.

Orientador: Maurício Greco Cosso
Dissertação (Mestrado) – Pontifícia Universidade Católica de Minas Gerais. Programa de Pós-Graduação em Odontologia

1. Seio do maxilar - Cirurgia. 2. Ossos - Transplante. 3. Odontologia - Aspectos estéticos. 4. Reabsorção óssea. 5. Maxila - Cirurgia. 6. Implantes dentários osseointegrados. I. Cosso, Maurício Greco. II. Pontifícia Universidade Católica de Minas Gerais. Programa de Pós-Graduação em Odontologia. III. Título.

CDU: 616.314-089.843

Ficha catalográfica elaborada por Fabiana Marques de Souza e Silva - CRB 6/2086

Flávia Leite Pereira

VOLUME ÓSSEO FORMADO A PARTIR DO PREENCHIMENTO DO SEIO MAXILAR APENAS COM COÁGULO, ASSOCIADO À INSTALAÇÃO IMEDIATA DE IMPLANTE

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

COMPOSIÇÃO DA BANCA EXAMINADORA:

1- Prof. Dr. Leandro Napier de Souza – UFMG
2- Prof. Dr. Leandro Junqueira de Oliveira – PUC Minas
3- Prof. Dr. Maurício Greco Cosso – PUC Minas

DATA DA APRESENTAÇÃO E DEFESA: 30 de setembro de 2019

A dissertação, nesta identificada, foi aprovada pela Banca Examinadora

Prof. Dr. Maurício Greco Cosso
Orientador

Prof. Dr. Rodrigo Villamarim Soares
Coordenador do Programa de Pós-graduação em Odontologia

Dedico este trabalho
À minha amada filha por todo amor e paciência, dentro e fora da barriga.
Aos meus pais pela dedicação e confiança no meu potencial.
Aos meus irmãos pela amizade.
Ao meu marido com quem amo compartilhar a vida e conquistas.

Amo imensamente todos vocês!

AGRADECIMENTOS

A Deus pela saúde e condições físicas de correr atrás dos meus sonhos.

À minha família por sempre acreditar e confiar em mim.

Ao meu querido orientador, Prof. Dr. Mauricio Greco Cosso, por acreditar no meu potencial em formação e por dispensar o seu tempo à nossa pesquisa, que se desenvolveu tranquila graças aoamor de ambos pela cirurgia.

A todos os professores do mestrado, cada um em sua área, seja ela cirúrgica ou protética, que só fizeram meu amor à profissão consolidar ainda mais e meu respeito por essa instituição só aumentar.

Aos funcionários e funcionárias que sempre me receberam com um sorriso.

Aos meus colegas Flávia Greze, Gabriel, Gabriela, Júlia e Sebastião, por ser o braço esquerdo quando o direito faltava e pela amizade que só cresceu, formando essa linda família do Implante.

Aos meus amigos que contribuíram, direta e indiretamente, para mais uma conquista profissional de peso em minha vida.

RESUMO

A cirurgia de levantamento de seio maxilar vem sendo uma opção previsível de tratamento do edentulismo na região posterior da maxila. Diferentes abordagens cirúrgicas foram relatadas na literatura para o aumento da crista alveolar atrófica nessa região. No presente estudo foram avaliados seios maxilares preenchidos apenas por coágulo sanguíneo simultâneo a instalação dos implantes. Seis pacientes edêntulos na área posterior de maxila, que apresentavam remanescente ósseo entre 4 e 7 mm, foram selecionados e um implante Straumann Tissue Level de 4.1 de diâmetro e comprimento de 14 mm foi instalado em cada seio maxilar e a cavidade sinusal foi preenchida apenas com coágulo sanguíneo formado espontaneamente. Os resultados demonstraram que a média da altura óssea residual do rebordo entre o assoalho do seio maxilar e a crista alveolar foi de 4,21 mm desvio padrão=0,81 (variação de 4 a 5,85 mm) antes da cirurgia e 10,5mm desvio padrão=1,35 (variação de 8,5 a 11,9 mm) após 180 dias, representando um aumento médio da altura de 6,35 mm. Considerando o período de avaliação é possível estimar que o preenchimento da cavidade sinusal com coágulo pode promover formação óssea necessária para estabilidade do implante.

Palavras-chave: Elevação do seio maxilar. Enxerto ósseo. Implantes em maxila. Coágulo.

ABSTRACT

Surgery for maxillary sinus lifting has been a predictable option for treating edentulism in the posterior maxilla. Different surgical approaches have been reported in the literature to increase the atrophic alveolar crest in this region. In the present study, maxillary sinuses filled only by blood clot simultaneous to implant placement were evaluated. Six patients with posterior maxillary area with bone remnant between 4 and 6 mm were selected and a Straumann Tissue Level implant of 4.1 diameter and 14 mm length was placed in six maxillary sinuses and the sinus cavity was filled only with blood clot. They underwent a surgical procedure at the Implantology Clinic of the Graduate Program in Dentistry of the Pontifical Catholic University of Minas Gerais. The results showed that the mean residual bone height of the ridge between the maxillary sinus floor and the alveolar crest was 4.21 mm standard deviation = 0.81 (range 4 to 5.85 mm) before surgery and 10.5mm standard deviation = 1.35 (range 8.5 to 11.9mm) after 180 days, representing an average height increase of 6.35mm. Considering the evaluation period, it is possible to estimate that filling the sinus cavity with clot may promote bone formation necessary for implant stability.

Keywords: Maxillary sinus elevation. Bone graft. Maxillary implants. Clot.

LISTA DE ABREVIATURAS E SIGLAS

ABNT	Associação Brasileira de Normas Técnicas
ARF	Análise de frequência de ressonância
ISQ	Coeficiente de estabilidade do implante
TCFC	Tomografia computadorizada de feixe cônico

SUMÁRIO

1 INTRODUÇÃO

A cirurgia de levantamento de seio maxilar vem sendo uma opção previsível de tratamento do edentulismo da região posterior da maxila, principalmente quando se observam seios pneumatizados e rebordos ósseos severamente reabsorvidos. Diferentes abordagens cirúrgicas, combinadas ou não com enxertos ósseos e com instalação posterior ou simultânea dos implantes foram relatadas na literatura para o aumento da crista alveolar atrófica nessa região (CHEN *et al.,* 2007; ESPOSITO *et al.,* 2010).

Introduzida inicialmente por Tatum (TATUM JÚNIOR; 1977), a técnica de levantamento de seio maxilar consiste na criação de uma janela lateral, com o objetivo de deixar intacta a membrana de Schneider. A membrana é elevada cuidadosamente e a janela óssea deslocada medialmente, criando um espaço que pode ser preenchido por materiais de enxerto (WOOD; MOORE, 1988). A neoformação óssea nesse tipo de abordagem pode também ser alcançada sem a utilização de qualquer biomaterial a partir do potencial do coágulo de sangue. As células mesenquimais progenitoras e células da linhagem osteogênicas presentes na mucosa do seio promovem a diferenciação osteogênica em resposta aos estímulos provenientes do coágulo (ELLEGAARD; BAELUM; KOLSEN-PETERSEN, 2006; LUNDGREN; ANDERSSON; SENNERBY*,* 2003).

Uma das vantagens na utilização da técnica corresponde ao osso ser formado simultaneamente ao processo de cicatrização dos implantes, isso devido à atividade trombogênica, onde a trombina modula a expressão gênica nos osteoblastos, resultando em aumento da expressão de fatores angiogênicos (BLUTEAU *et al.,* 2006). A condição local do seio maxilar com formação do coágulo de sangue em torno dos implantes pode servir como um modelo onde a trombina gerada cliva o fibrinogênio e contribui para a ativação de osteoblastos através da proteinase de receptores ativados. A ativação do sistema de coagulação das plaquetas gera efeitos sobre células de crescimento ósseo, pois contém um número importante de fatores de crescimento, como fatores de crescimento derivados de plaquetas, fatores de crescimento semelhantes a insulina, fatores de crescimento vascular endotelial e fatores de crescimento de fibroblastos que são conhecidos por dar suporte, revascularização e osseointegração (HONG *et al.,* 1999).

Diversos estudos que avaliaram instalação imediata de implantes sem o uso de enxertos ósseos no levantamento de seio maxilar confirmam que esta é uma abordagem confiável e com taxas de sobrevivência dos implantes, que variam entre 97,7 e 100% (STEFANSKI; SVENSSONAND; THOR, 2017; THOR *et al.,* 2007). Um estudo clínico realizado por Zenóbio e colaboradores em 2018 avaliou a contração do coágulo e neoformação óssea após elevação do seio maxilar com implante imediato, sem utilização de enxertos por meio de tomografia computadorizada. Foram utilizados 10 implantes em 10 pacientes com crista óssea residual de altura entre 4 e7 mm na região posterior da maxila. Tomografias foram realizadas após 15 e 180 dias para avaliar a taxa de contração do coágulo sanguíneo e neoformação óssea. A média da altura óssea na região mesial, apical e distal referentes ao implante foram 4,77 mm, 0,77 mm e 5,30 mm respectivamente. O estudo demonstrou uma formação óssea consistente em torno de todos os implantes e embora tenha ocorrido contração média de 16,52% (com desvio padrão de 8,60%) do coágulo sanguíneo, a taxa de sobrevivência dos implantes foi de 100% (ZENÓBIO *et al.,* 2018).

Sob outra pespectiva podemos considerar que a estabilidade primária do implante é uma avaliação relevante no processo de osseointegração. Para que haja formação óssea é necessária a retenção mecânica entre o implante e o osso no momento da instalação (ABRAHAMSSON *et al.,* 2004). Além disso, a estabilidade primária dos implantes pode ser medida de diversas maneiras, como por meio do torque de inserção ou da Análise da Frequência de Ressonância (ARF) (ATSUMI; PARK; WANG*,* 2007; MOLLY, 2006; SACHDEVA; DHAWAN; SINDWANI, 2016).

Na ARF utilizamos o dispositivo Osstell™ (Integration Diagnostics AB, Göteborg, Sweden) para avaliar a estabilidade do implante. Nessa técnica um *SmartPeg* é fixado ao implante ou pilar e o transdutor é excitado por um impulso magnético emitido pelo dispositivo Osstell™ (Integration Diagnostics AB, Göteborg, Sweden) e o coeficiente de estabilidade do implante (ISQ) é calculado a partir do sinal de resposta. Os valores de ISQ podem variar de 1 a 100, onde quanto maior o ISQ, maior a estabilidade. O equipamento tem uma variação na amplitude de aferição de seus valores de 5000 Hz (sugerindo que não há estabilidade primária ou não integração do implante) até 15000 Hz (sugerindo alta estabilidade ou rigidez na integração do implante). A conversão de valores é feita através de um software do próprio equipamento (QUESADA-GARCÍA *et al.,* 2009). Para implantes clinicamente

estáveis são encontrados valores de ISQ de 40 a 80 (APARICIO; LANG; RANGERT, 2006; LACHMANN *et al.,* 2006). Após o período de cicatrização, o osso em contato com o implante é substituído por um novo osso durante o processo de osseointegração, dando origem à estabilidade secundária (ABRAHAMSSON *et al.,* 2004).

Pesquisas mais recente têm procurado encontrar um substituto ósseo ideal que diminua a morbidade cirúrgica e tempo total de tratamento, além de ser capaz de manter as propriedades de osteoindução, osteocondução e células osteoprogenitoras no tratamento de reconstruções ósseas da região posterior da maxila (CHAPPUIS *et al.,* 2013). Na busca de maior fundamentação científica de protocolos de abordagens menos invasivas e com menores custos financeiros, este estudo teve como objetivo avaliar por meio da tomografia computadorizada de feixe cônico o volume ósseo formado após a elevação do seio maxilar e instalação simultânea de implante apenas com coágulo sanguíneo.

2 OBJETIVOS

2.1 Objetivo geral

Este estudo clínico prospectivo longitudinal tem como objetivo geral avaliar, por meio de tomografia de feixe cônico, o volume ósseo formado após a elevação do seio maxilar e instalação simultânea de implante apenas com coágulo sanguíneo formado espontaneamente.

2.2 Objetivos específicos

a) determinar a contração do coágulo pela diferença de volume entre os períodos T1 (15 dias) e T2 (após 180 dias) por meio de tomografia computadorizada;
b) avaliar a variação na altura da crista óssea entre o T1 e T2;
c) avaliar a variação na altura da área correspondente ao coágulo sanguíneo entre T1 e T2;
d) mensurar a variação da estabilidade dos implantes por meio da análise de frequência de ressonância em T1 e T2.

3 ARTIGO

Measurement of bone volume formed from maxillary sinus floor filling with clot only, associated with immediate implant placement

Artigo a ser submetido à publicação no periódico **The International Journal of Oral and Maxillofacial Implants**

Normas para submissão de artigos podem ser visualizadas no endereço eletrônico: https://jomi.quintessenz.de/jomi/downloads/authorguidelines_jomi.pdf

Measurement of bone volume formed from maxillary sinus floor filling with clot only, associated with immediate implant placement

Flávia Leite Pereira[1], Júlia Beserra Santiago[1], Bruno César Ladeira Vidigal[2], Vinicius de Magalhães Barros[3], Maurício Greco Cosso[4]

[1] MSc, School of Dentistry, Pontifical Catholic University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil.

[2] Associate Professor and Department of Dentistry, University Center Newton Paiva, Belo Horizonte, Minas Gerais, Brazil.

[3] Associate Professor and Department of Dentistry, Pontifical Catholic University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil.

[4] Associate Professor and Department of Dentistry, Pontifical Catholic University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil..

Correspondence to: Dr. Maurício Greco Cosso, Departamento de Odontologia, Pontifícia Universidade Católica de Minas Gerais, Av. Dom José Gaspar, 500, Prédio 46, Cep: 30535-901, Belo Horizonte, Minas Gerais, Brazil.
Tel: (31) 3319-4414 / (31) 99973-7979E-mail: mmcosso@hotmail.com

Abstract

Introduction: Maxillary sinus elevation surgery has been a suitable option for treating edentulism in the posterior maxilla. Different surgical approaches have been reported in the literature to increase the alveolar ridge atrophy in this area. In the present study, maxillary sinuses filled only by blood clots simultaneous to implant placement were evaluated. **Materials and Methods:** Six edentulous patients in the posterior maxillary area with remnant bone between 4 and 7 mm were selected and a Straumann Tissue Level implant of 4.1 diameters and 14 mm length was placed in each maxillary sinus. The sinus cavity was filled only with spontaneously formed blood clot. **Results:** The results showed that the mean residual bone height of the ridge between the maxillary sinus floor and the alveolar ridge was 4.21 mm, standard deviation = 0.81 (ranging from 4 to 5.85 mm) before surgery and 10.5 mm standard deviation = 1.35 (ranging from 8.5 to 11.9 mm) after 180 days, representing an average height increase of 6.35 mm. **Conclusion:** Considering the evaluation period, it is possible to estimate that the filling of the sinus cavity with clot may promote bone formation necessary for implant stability.

Keywords: Maxillary sinus elevation. Bone graft. Maxillary implants. Clot.

INTRODUCTION

Maxillary sinus augmentation surgery has been a suitable option for treating posterior maxillary edentulism, especially when pneumatized sinuses and severely resorbed bone ridges are observed. Different surgical approaches, whether or not combined with bone grafts and with subsequent or simultaneous implant placement have been reported in the literature to increase atrophic alveolar ridge in this region[1,2].

The maxillary sinus augmentation technique, initially introduced by Tatum Jr.[3], consists of the creation of a lateral window to keep the Schneider membrane intact. The membrane is carefully lifted and the bone window displaced medially producing a space that can be filled by graft materials[4]. Bone neoformation in this type of approach may also be achieved without any biomaterial from the blood clot potential. The progenitor mesenchymal cells and osteogenic lineage cells present in the sinus mucosa promote osteogenic differentiation in response to clot stimuli[5,6].

One of the advantages of using this technique is that the bone is formed simultaneously to the implant healing process due to the thrombogenic activity in which thrombin modulates the gene expression in osteoblasts, resulting in increased expression of angiogenic factors[7]. The local condition of the maxillary sinus with blood clot formation around the implants can serve as a model in which the thrombin generated cleaves the fibrinogen and contributes to osteoblast activation through proteinase-activated receptors. Activation of the platelet clotting system plays a role in the bone growth cells as it contains a significant number of growth factors such as platelet-derived growth factors, insulin-like growth factors, vascular endothelial growth factors, and fibroblasts growth factors, which are known to support, provide revascularization, and osseointegration[8].

Several studies evaluating immediate implant placement without bone grafts in the maxillary sinus augmentation confirm that this is a reliable approach with high implant survival rates. In a clinical study Zenóbio et al.[11] evaluated clot contraction and bone neoformation after maxillary sinus augmentation with the immediate implant without grafts by computed tomography. Ten implants were used in ten patients with a residual ridge bone between 4 and 7 mm in height in the posterior region of the maxilla. CT scans were performed after 15 and 180 days to evaluate the rate of blood clot contraction and bone neoformation. The mean bone height in the mesial, apical, and distal regions related to the implant were 4.77 mm, 0.77 mm, and 5.30 mm, respectively. The study demonstrated consistent bone formation around all implants and although significant blood clot contraction occurred, the survival rate of the implants was 100%.

From another viewpoint, we can consider the primary stability of the implant a relevant evaluation in the osseointegration process[12]. For bone formation, mechanical retention between the implant and the bone is required at the time of placement, and resonance frequency analysis (RFA) is one of the most common methods for this evaluation[13-15].

At the RFA we used the Osstell™ device (Integration Diagnostics AB, Göteborg, Sweden) to evaluate implant stability. In this technique, a Smartpeg is attached to the implant or abutment and the transducer is stimulated by a magnetic pulse emitted by the Osstell™ device (Integration Diagnostics AB, Göteborg, Sweden) and the implant stability coefficient (ISQ) is calculated from the response signal. ISQ values can range from 1 to 100 in which the higher the ISQ, the greater the stability. The equipment has a measuring range from 5000 Hz (suggesting that there is no primary stability or no implant integration) to 15000 Hz (suggesting high

stability or rigidity in implant integration). The values conversion is performed through the equipment software. For clinically stable implants, ISQ values from 40 to 80 are found[16-18].

Recent studies have aimed to find an ideal bone substitute that decreases surgical morbidity and overall treatment time, and that might be able to maintain osteoinduction, osteoconduction, and osteoprogenitor cell properties in the treatment of posterior maxillary bone reconstruction[19]. In the search for a better scientific basis of less invasive and less costly protocols, this study aimed to evaluate, through cone-beam computed tomography, the bone volume formed after maxillary sinus augmentation and the simultaneous implant placement with blood clot only.

MATERIAL AND METHODS

This prospective clinical study evaluated the ridge height and implant stability in maxillary sinuses using only the blood clot as a graft, followed by implant placement in the same surgical area (Figure 1). Ethical standards for scientific research with humans were followed according to the Law 6.638/79 and the Declaration of Helsinki (World Medical Association Recommendation, 2011). This study was approved by the Research Ethics Committee of the Pontifical Catholic University of Minas Gerais (CAAE 16886719.2.0000.5137).

Patients

Six patients were selected at the Implantology Clinic of the School of Dentistry of the Pontifical Catholic University of Minas Gerais between March/May 2018 and the surgeries were performed until December 2018. The inclusion criteria were patients who had partial edentulism and bone height of the remaining alveolar ridge

between 4-7 mm and approximately 6.5 mm width in the posterior region of the maxilla[11,20,21]. Exclusion criteria were: health impairment, patients irradiated in the head and neck, pregnancy, bisphosphonate therapies, immunological diseases, platelet disorders, chronic sinusitis, patients suffering from some pathology in the maxillary sinus, and uncontrolled diabetes.

Maxillary sinus floor augment procedure

The surgical procedures were performed by a single qualified surgeon. Patients received pre- and postoperative instructions for proper oral hygiene control and oral antibiotic treatment (amoxicillin 500 mg, two tablets one hour before the procedure and maintenance of one tablet every 8 hours for ten days), an oral corticosteroid (Dexamethasone 4 mg, one tablet 12 hours before and one hour before the procedure), one pain reliever (acetaminophen 750 mg, one tablet every 6 hours for three days). Patients were instructed to rinse their mouth with chlorhexidine (0.12%) twice daily for 15 days.

Implants placement

Dental implants were placed following the Straumann® Standard Plus (SP) Tissue Level (TL) Implant Surgical Protocol with 14 mm in length and 4.1 diameter.

The sutures were removed 15 days after the surgical procedure and the area was not exposed to any direct loading during the whole bone regeneration phase.

Tomographic analysis

Each patient underwent three cone-beam computed tomography (CBCT) examinations: preoperative (T0), 15 days (T1), and after 180 days (T2)[11,23]. The

images were taken with a 0.5 mm thick KODAK 9500 Cone Beam 3D System Carestream Health, Inc. (Rochester, NY) device with collimation bone filter.

Preoperative examination (T0) evaluated sinus anatomy and alveolar ridge length for implant placement. The scanned exams were reconstructed and exported in a Digital Imaging and Communication in Medicine (DICOM) file format and imported into the Osirix MD®Imaging 6.5 CT-scan software (Pixmeo, Geneva, Switzerland).

Volumetric evaluation

Images were evaluated and blood clot volumetric measurements were performed according to Nunes et al.[22], in which the authors compared the blood clot area volume in sinus augmentation surgery. A trained radiologist manually delimited the length of the clot by the coronal section and used the pencil tool from the OsirixMD® Imaging 6.5 software (Pixmeo Geneva, Switzerland). After, the volume was calculated with the Compute Volume tool.

Volume measurement was performed using the area sum technique, a method for calculating CT sequential image volume. This method requires manual definition of the clot perimeter with a computer mouse in each CT section to its full coverage (Figure 1). For each section, the software calculates the volume in cm^3 within the defined area, considering the slice thickness. The individual volume of each slice is added to the volume of the preceding sections. When the area is completely defined in sequential images, the software's volumetric function is triggered and the final result obtained automatically is equal to the total volume. These procedures were performed in all individuals 15 and 180 days after the surgical intervention[23].

Linear assessment

The linear measurements were based on Zenóbio et al.[11] e Borges et al.[24] and were performed in the coronal section that allowed to evaluate the mesial and distal area of the implant. The evaluations were performed in three sections: the implant center (LC), 1.2 mm mesial (LM) e 1,2 mm distal (LD). Software tools were used to standardize the measurements, having as reference the section in which the entire implant area was visualized. Linear measurement of the bone ridge (CO) was also measured at T1, referring to the residual bone height of the ridge in the area where the implant was placed. At T2, the bone height measurement (CO2) was based on the distance from the ridge to the most superior portion of the final bone height (Figure 2).

Resonance frequency analysis

After implant placement, stability evaluation was performed using a device (Osstell®; Integration Diagnostics, Gothenburg, Sweden). For this measurement, a SmartPeg (SmartPeg® Type 04, No. 100350; Osstell AB, Gothenburg, Sweden) was attached to the implant and the device's probe was placed close to it without touching it. This SmartPeg is stimulated by a magnetic pulse, the pulse generates a resonant frequency as a response by which the implant stability value in the instrument is calculated. Three measurements were performed, from which the median value was used for data analysis. ISQ measurements were performed in a standardized manner by a trained examiner at two moments: immediately after implant placement (T1) and 180 days after implant placement (T2)[25].

Statistical analysis

The normal distribution of the data of the variables analyzed was confirmed by the Shapiro-Wilk test. The variables were then compared in different periods using the paired t-test with a significance level of 5% ($p < 0.05$).

Analyses were performed using the GraphPad Prism 6.05 software (GraphPad Software, San Diego, California, USA).

RESULTS

Patient characteristics

A total of six patients was included in this study (Table 1), five females and one male, aging from 38 to 71 years [mean age 58.42 (SD ± 10.43)]. Four of the patients were partially edentulous and two were edentulous in the maxilla (Table 1).

A total of six implants were placed into the maxillary sinus augmentation region (Table 1). During the healing period, the patients partially edentulous did not use temporary removable dentures and the edentulous patients received a relining (Dentusoft; GDK Densell) in the temporary denture. All implants had the same diameter (4.1 mm) and length (14 mm). The survival rate of implants placed six months after reopening was 100%.

Cone-beam computed tomography analysis

A total of 18 CBCTs was obtained from six patients to evaluate the dimensional changes of the graft (Figure 2). The results of CBCT analysis are described in Tables 2 and 3.

Linear assessment of remaining edge

The linear CO1 at T1 ranged from 3.67 to 5.85 mm (mean 4.21 mm SD ± 0.81). After 180 days, there was an increase in CO2, ranging from 8.52 to 11.96 mm (mean 10.56 mm SD ± 1.35), representing an average increase of 6.35 mm (CO2) (Table 2). The comparison between T1 and T2 ($p < 0.05$) performed by the paired T-test demonstrated a significant difference, presenting a $P = 0.0001$.

Linear assessment

The linear measurements LM, LC, and LD were performed at T1 and T2 and compared between the two periods. LM1 presented an average of 7.19 mm with SD ± 4.37 and LM2 6.12 mm with SD ± 2.67, with a reduction of 1.07 mm. The LC1 measure presented an average of 8.86 mm with SD ± 0.94, and LC2 8.86 mm with SD ± 1.62, showing a similarity between them in both periods. The linear measurement LD1 presented an average of 9.38 mm with SD ± 0.88 and LD2 6.34 mm with SD ± 1.44, with a reduction of 3.04 mm. The comparison between the difference in linear measurements at T1 and T2 ($p < 0.05$) performed by the paired T-test did not show any significant difference (Table 2).

Volumetric evaluation

The results of the CBCT analysis are shown in Table 3. The clot volume observed immediately after the surgical procedure (T1) varied between 0.13-0.47 cm^3 and its mean value was 0.24 cm^3 with SD ± 0.12. After six months of healing (T2), the clot volume ranged from 0.12-0.41 cm^3 with a mean value of 0.29 cm^3 with SD ± 0.009. The paired T-test did not show any significant difference between T1 and T2 ($p < 0.05$), presenting a $P = 0.12$ (Table 3).

Resonance frequency analysis

The ISQ values were evaluated in all implants at both times (T1 and T2) and presented a greater variation in T1 between 39-77 ISQ with an average of 53.33 and SD ± 14.80 and a smaller variation between 60-78 ISQ with 72.67 and SD ± 5.75 at T2, with a mean increase between both periods (Table 4).

The comparison between the difference in ISQ at T1 and T2 ($p < 0.05$), performed by the paired T-test, demonstrated a significant difference, presenting a $P = 0.0236$ (Table 4).

DISCUSSION

The literature reports that the maxillary sinus augmentation technique with immediate implants without graft filled only by the blood clot is indicated for vertical maxillary augmentation in the posterior region and presents high success rates, besides offering treatment in only one stage, reducing morbidity, time, and costs[1,5,6,9,10,26,27]. However, studies evaluating the dimensional stability through analysis of linear and volumetric measurements by cone-beam tomography examinations such as those performed in this study are scarce.

Bone substitutes of various origins (autogenous, xenogeneic, or allogeneic) have been suggested for sinus grafts; however, different studies have shown the formation of new bone without direct use of any graft material around the implant[9,11,28]. We can consider the autogenous grafting (bone remodeling period of 6 months) or allograft (bone remodeling period from 9 to 12 months) favorable to increase the sinus floor, as it allows the placement of the implants only in a second surgical stage[10,26,29].

This approach was considered to be an autologous treatment, raising the hypothesis that the new bone formation would arise from the immediate placement of the dental implant under the membrane, supporting it and promoting a spontaneous filling in the region by the blood clot. Thus, this clot with osteogenic potential osteoprogenitor cells can migrate, proliferate, and differentiate into osteoblasts and regenerate new bone through the healing process[5,6,9,10,11,26,28,29].

The criterion for surgical selection required for primary implant stabilization is a residual ridge height of at least 4 mm. Studies have shown that the evaluation criteria involve implant mobility and, when present, it should be considered a failure factor leading to the need for implant removal [6,9,10,11,20]. Therefore, we calculated the survival rate of the implants after the time elapsed between their placement until the last follow-up visit at 6 months postoperatively and we obtained 100% osseointegration.

Through the approach of lateral osteotomy and augmentation of the Schneiderian membrane as high as possible, 14 mm implants were simultaneously placed, enabling membrane stabilization and favoring blood clot stability. Thor et al.[9], identified that longer implants (13-15 mm) would be suitable for the success of the new bone formation to prevent the membrane collapse in the implant and threaten the bone formation around them. Thus, the simultaneous placement of implants would function as a tent.

The mean gain in the newly formed bone height is an aspect that can be assessed by comparing the linear measurements of the initial postoperative period and the follow-up over longer periods. In the study by Bassi et al.[26], when comparing the newly formed bone height in the initial postoperative period and the 51-month follow-up, demonstrated that the average gain was 5.63 mm. According to the

authors, over time the tendency for a higher degree of mineralization is due to the physiological stimuli that the masticatory function exerts on the implant, promoting greater peri-implant bone maturation. In our study, linear measurements compared between 15 and 180 days showed an average height gain of 6.35 mm, representing less than one millimeter of gain greater than the previous study.

Follow-up studies by Thor et al.[9], Altintas et al.[30], and Zenóbio et al.[11] evaluated the postoperative period from 6 to 27 months, demonstrating the linear gain in bone height and an average success rate of 97.7% in the implants. In the present study, when comparing the analyses, we conclude that this technique brings us security with high success rates.

In this study, the ISQ was statistically higher when compared between the T1 and T2 periods, showing higher values than those reported in the literature (mean 72.67 ± 5.75). The absence of previous evaluation studies in different periods for the same surgical technique shows that 180 days were appropriate for the osseointegration of the implant, even when the initial ISQ values were low. Safe ISQ values were found, which allowed us to identify secondary stability in 100% of patients[31].

In the current scientific scenario, there are precise imaging methods for greater reliability of results, the TCFC has the great advantage of providing accurate images of both hard and soft tissue in the same scanner. These images allowed us to define the volume and total length of the graft within 15 days after the sinus augmentation procedure and compare it to the volume and length after 180 days. TCFC is a reliable technique for 3D visualization of volume changes and linear measurements. In the volumetric evaluation methodology used in this study using the software OsiriX® MDImaging 6.5 (Pixmeo Geneva, Switzerland), measurements of

the hypodense images of the clot in the maxillary sinus were obtained to be compared at different times. The outcomes shown in the literature provide us with reliable data on linear measurements through CT in the implant field[11,21,27].

In a clinical study, Zenóbio et al[11]. evaluated clot contraction and bone neoformation after maxillary sinus augmentation with the immediate implant without grafts by computed tomography. Ten implants were used in ten patients with a residual bone ridge between 4 and 7 mm in height in the posterior region of the maxilla. CT scans were performed after 15 and 180 days to evaluate the rate of blood clot contraction and bone neoformation. The mean bone height in the mesial, apical, and distal regions related to the implant were 4.77 mm, 0.77 mm, and 5.30 mm, respectively. The study demonstrated consistent bone formation around all implants and although significant blood clot contraction occurred, the survival rate of the implants was 100%[11].

In the present study, the differences between the two periods in the volume and length measurements of the clot-related area associated with the bone remnant varied. Postoperative follow-up of 15 days and 6 months was chosen for the evaluation of image evolution to determine short and long term healing, as it has been frequently used in other studies[5,6,11,27]. The success rate of maxillary sinus augmentation without bone grafts is evidenced as well as the success rate of conventional techniques and after several reports in the literature, this technique has gained visibility[27].

CONCLUSION

Considering the sample of this study, the results seem to demonstrate that sinus graft with only blood clot is a viable and safe technique. We will need a larger patient sample so that we can more safely validate this technique.

REFERENCES

1. Chen TW, Chang HS, Leung KW, Lai YL, Kao SY. Implant placement immediately after the lateral approach of the trap door window procedure to create a maxillary sinus lift without bone grafting: a 2-year retrospective evaluation of 47 implants in 33 patients. J Oral Maxillofac Surg. 2007 Nov;65(11):2324-8.
2. Esposito M, Piattelli M, Pistilli R, Pellegrino G, Felice P. Sinus lift with guided bone regeneration or anorganic bovine bone: 1-year post-loading results of pilot randomized clinical trial. Eur J Oral Implantol. 2010;3(4):297-305.
3. Tatum H Jr. Maxillary and sinus implant reconstructions. Dent Clin North Am. 1986 Apr;30(2):207-29.
4. Wood RM, Moore DL. Grafting of the maxillary sinus with intraorally harvested autogenous bone prior to implant placement. Int J Oral Maxillofac Implants. 1988;3(3):209-14.
5. Ellegaard B, Baelum V, Kølsen-Petersen J. Non-grafted sinus implants in periodontally compromised patients: A time-toevent analysis. Clin Oral Implants Res. 2006 Apr;17(2):156-64.
6. Lundgren S, Andersson S, Sennerby L. Spontaneous bone formation in the maxillary sinus after removal of a cyst: coincidence or consequence? Clin Implant Dent Relat Res. 2003;5(2):78-81.

7. Bluteau G, Pilet P, Bourges X, Bilban M, Spaethe R, Daculsi G, et al: The modulation of gene expression in osteoblasts by thrombin coated on biphasic calcium phosphate ceramic. Biomaterials. 2006 May;27(15):2934-43.
8. Hong J, Andersson J, Ekdahl KN, Elgue G, Axén N, Larsson R, et al: Titanium is a highly thrombogenic biomaterial: Possible implications for osteogenesis. Thromb Haemost. 1999 Jul;82(1):58-64.
9. Thor A, Sennerby L, Hirsch JM, Rasmusson L. Bone formation at the maxillary sinus floor following simultaneous elevation of the mucosal lining and implant installation without graft material: an evaluation of 20 patients treated with 44.J Oral Maxillofac Surg. 2007 Jul;65(7 Suppl 1):64-72.
10. Stefanski S, Svensson B, Thor A. Implant survival following sinus membrane elevation without grafting and immediate implant installation with a one-stage technique: anup-to-40-month evaluation. Clin Oral Implants Res. 2017 Nov;28(11):1354-1359.
11. Zenóbio EG, Cardoso LD, Oliveira LJ, Favato MN, Manzi FR, Cosso MG. Blood clot stability and bone formation following maxillary sinus membrane elevation and space maintenance by means of immediate implant placement in humans. A computed tomography study. J Cranio-Maxillo-Fac Surg. 2018. doi: 10.1016/j.jcms.2018.10.004. In Press.
12. Abrahamsson I, Berglundh T, Linder E, Lang NP, Lindhe J. Early bone formation adjacent to rough and turned endosseous implant surfaces. An experimental study in the dog. Clin Oral Implants Res. 2004 Aug;15(4):381-92.
13. Molly L. Bone density and primary stability in implant therapy. Clin Oral Implants Res. 2006 Oct;17 Suppl 2:124-35.

14. Atsumi M, Park SH, Wang HL. Methods used to assess implant stability: current status. Int J Oral Maxillofac Implants. 2007 Sep-Oct;22(5):743-54.
15. Sachdeva A., Dhawan P, Sindwani S. assessment of implant stability: methods and recent advances.Brit J Med Res. 2016;12(3):1-10.
16. Quesada-García MP, Prados-Sánchez E, Olmedo-Gaya MV, Muñoz-Soto E, González-Rodríguez MP, Valllecillo-Capilla M. Measurement of dental implant stability by resonance frequency analysis: A review of the literature. Med Oral Patol Oral Cir Bucal. 2009 Oct;14(10):e538-46.
17. Lachmann S, Jäger B, Axmann D, Gomez-Roman G, Groten M, Weber H. Resonance frequency analysis and dampening capacity assessment. Part 1: an in vitro study on measurement reliability and a method of comparison in the determination of primary implant stability. Clin Oral Implants Res. 2006 Feb;17(1):75-9.
18. Aparicio C, Lang NP, Rangert B. Validity and clinical significance of biomechanical testing of implant/bone interface. Clin Oral Implants Res. 2006 Oct;17 Suppl 2:2-7.
19. Chappuis V, Buser R, Brägger U, Bornstein MM, Salvi GE, Buser D. Long-term outcomes of dental implants with a titanium plasma-sprayed surface: a 20-year prospective caseseries study in partially edentulous patients. Clin Implant Dent Relat Res. 2013 Dec;15(6):780-90.
20. Hagi D, Deporter DA, Pilliar RM, Arenovich T. A targeted review of study outcomes with short (< or = 7 mm) endosseous dental implants placed in partially edentulous patients. J Periodontol. 2004 Jun;75(6):798-804.

21. Jensen SS, Terheyden H. Bone augmentation procedures in localized defects in the alveolar ridge: Clinical results with different bone grafts and bone substitute materials. Int J Oral Maxillofac Implants. 2009;24 Suppl:218-36.
22. Nunes FAS, Pignaton TB, Novaes AB Jr, Taba M Jr, Messora MR, Palioto DB, et al. Evaluation of a bone substitute covered with a collagen membrane for ridge preservation after tooth extraction. Clinical and tomographic randomized controlled study in humans. Clin Oral Implants Res. 2018 Apr;29(4):424-433.
23. Cosso MG, de Brito RB Jr, Piattelli A, Shibli JA, Zenóbio EG. Volumetric dimensional changes of autogenous bone and the mixture of hydroxyapatite and autogenous bone graft in humans maxillary sinus augmentation. A multislice tomographic study. Clin Oral Implants Res. 2014 Nov;25(11):1251-1256.
24. Borges FL, Dias RO, Piattelli A, Onuma T, Gouveia Cardoso LA, Salomão M, et al. Simultaneous sinus membrane elevation and dental implant placement without bone graft: a 6-month follow-up study. J Periodontol. 2011 Mar;82(3):403-12.
25. Strnad J, Urban K, Povysil C, Strnad Z. Secondary stability assessment of titanium implants with an alkali-etched surface: a resonance frequency analysis study in beagle dogs. Int J Oral Maxillofac Implants. 2008 May-Jun;23(3):502-12.
26. Bassi AP, Pioto R, Faverani LP, Canestraro D, Fontão FG.Maxillary sinus lift without grafting, and simultaneous implant placement: a prospective clinical study with a 51-month follow-up. Int J Oral Maxillofac Surg. 2015 Jul;44(7):902-7.
27. Lundgren S, Andersson S, Gualini F, Sennerby L. Bone reformation with sinus membrane elevation: a new surgical technique for maxillary sinus floor augmentation. Clin Implant Dent Relat Res. 2004;6(3):165-73.

28. Cricchio G, Sennerby L, Lundgren S. Sinus bone formation and implant survival after sinus membrane elevation and implant placement: a 1 to 6-year follow-up study. Clin Oral Implants Res. 2011 Oct;22(10):1200-1212.
29. Sohn DS, Kim WS, An KM, Song KJ, Lee JM, Mun YS. Comparative histomorphometric analysis of maxillary sinus augmentation with and without bone grafting in rabbit. Int J Oral Maxillofac Implants. 2008 May-Jun;23(3):502-12.
30. Falah M, Sohn DS, Srouji S. Graftless sinus augmentation with simultaneous dental implant placement: clinical results and biological perspectives. Int J Oral Maxillofac Surg. 2016 Sep;45(9):1147-53.
31. Altintas NY, Senel FC, Kayıpmaz S, Taskesen F, Pampu AA. Comparative radiologic analyses of newly formed bone after maxillary sinus augmentation with and without bone grafting. J Oral Maxillofac Surg. 2013 Sep;71(9):1520-30.
32. Tajima N, Ohba S, Sawase T, Asahina I. Evaluation of sinus floor augmentation with simultaneous implant placement using platelet-rich fibrin as sole grafting material. Int J Oral Maxillofac Implants. 2013 Jan;28(1):77-83.

Table 1. Demografic and clinical data of the patients

Pacients	Age	Gender	Partial/Total Edentulism	Jaw Side	Surgical Complications
1	63	F	Partial	L	Não
2	62	F	Partial	R	Não
3	71	M	Partial	R	Não
4	60	F	Total	R	Não
5	53	F	Partial	R	Não
6	38	F	Total	R	Não

F=feminine; M=male; R=right; L=left.

Table 2. Linear graft measurements in T1 e T2

	LM1	LM2	LC1	LC2	LD1	LD2	CO1	CO2
Mean between patients	7,19	6,12	8,86	8,86	9,38	6,34	4,21	10,56
SD	4,37	2,67	0,94	1,62	0,88	1,44	0,81	1,35
Graft mean reduction (mm)	1,07		0,0		3,04		+6,35	

Values are expressed as mean, standard deviation and graft reduction. Linear measurements were evaluated in millimeters (mm). Differences of each graft measurements between the two times in each group were calculated by paired t-tests.

Table 3. Graft volumetric measurements in T1 e T2

	MV1	MV2
Mean between patients (cm^3)	0,24	0,29
Min./max. (cm^3)	0,13-0,47	0,12-041
SD	0,12	0,09
SE	0,04	0,04

Values are expressed as mean, min/max., standard error. Graft volume was calculated in cubic centimeters (cm^3). Differences in graft volume between the two moments in each group were calculated by paired t-tests. Not statistically significant difference between T1 and T2 (P=0,2431). Abbreviations: MV1 = volumetric mean at time 1; MV2 = volumetric mean at time 2. V. min = minimum value; V. Max = maximum value, SD = standard deviation; EP = standard error of the mean.

Table 4. Measures of implant stability coefficient (ISQ) in T1 e T2

	ISQ1	ISQ2
AVERAGE	53,33	72,67
SD	14,80	5,75
V.min./V.max. (ISQ)	39 - 77	62 - 77
Value of P*	**0,0236**	

The resonance frequency analysis of the implant was represented in ISQ. The differences in ISQ between the two moments in each group were calculated by paired t-tests**. *** Statistically significant difference between T1 and T2 (P = 0.0236). Abbreviations: ISQ1 = implant stability coefficient at time 1; ISQ2 = implant stability coefficient at time 2; V.min = minimum value; V.max = maximum value, SD = standard deviation.

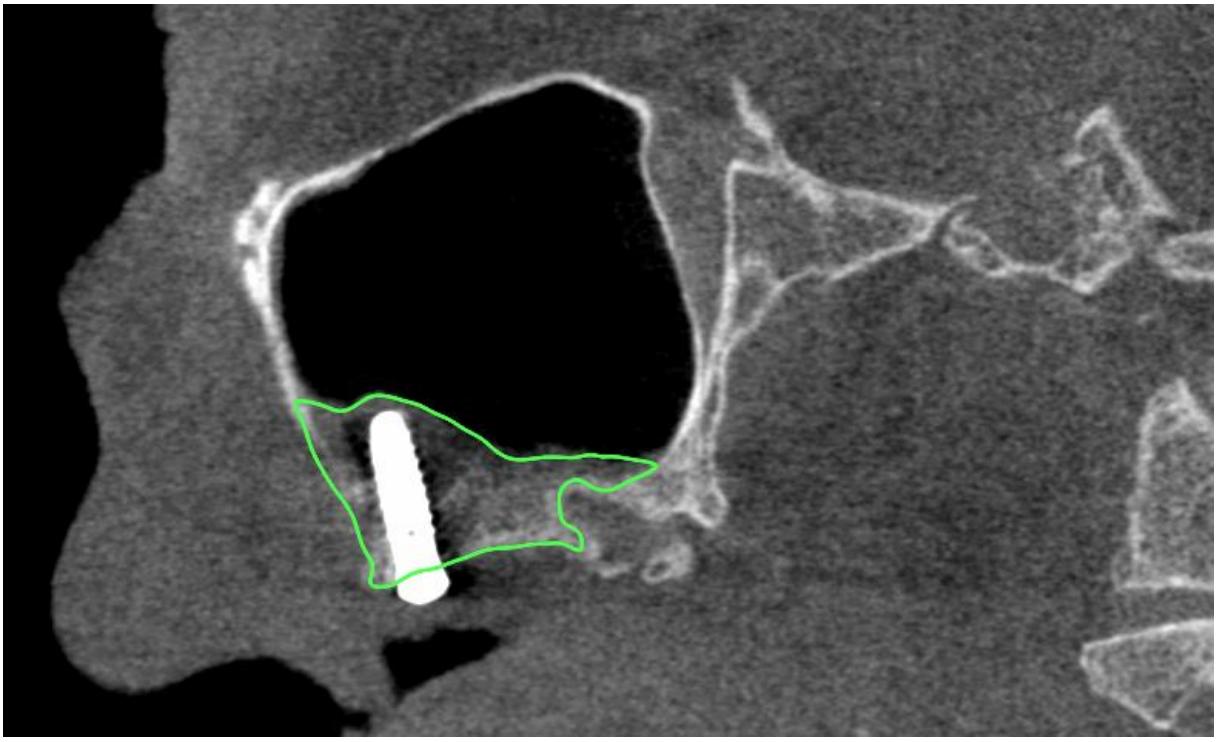

Figure 1. Sagittal section T2

Caption: Demarcation (green) delimiting the entire length of the graft promoted by the clot in the sagittal T2 – weighted view.

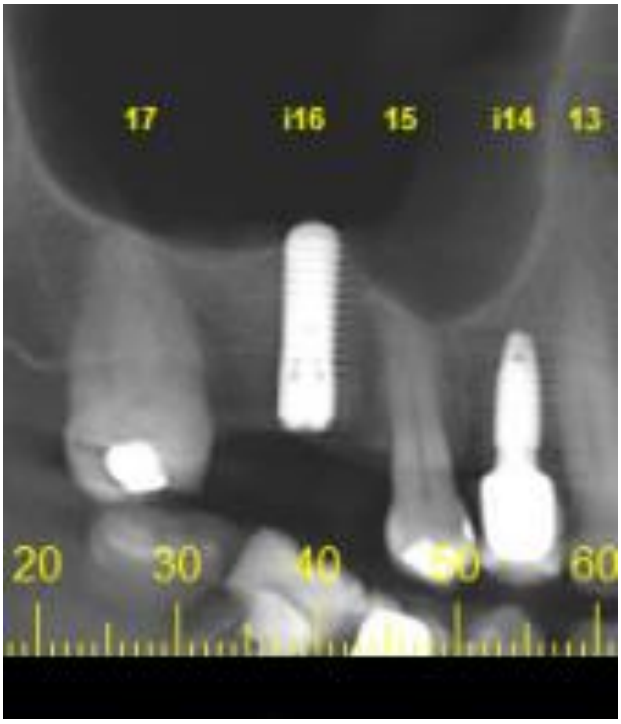

Figure 2. panoramic image of TC, T2

4 CONSIDERAÇÕES FINAIS

Concluímos que este estudo descreveu uma alternativa viável para instalação imediata do implante apenas com preenchimento espontâneo de coágulo no interior do seio maxilar. Podemos afirmar que houve uma alta taxa de sucesso e diminuição da morbidade cirúrgica associada a enxertos autógenos, bem como algumas das limitações de outros materiais de enxerto.

O coágulo formado a partir da elevação da membrana de Schneider foi o suficiente para formação óssea no interior do seio, tendo o implante funcionado como suporte na forma de uma tenda da membrana, possibilitando a osseointegração do implante após sua estabilidade primária.

REFERÊNCIAS

ABRAHAMSSON, I. *et al.* Early bone formation adjacent to rough and turned endosseous implant surfaces. An experimental study in the dog. **Clinical Oral Implants Research,** v.15, p. 381-392, 2004.

APARICIO, C.; LANG, N.P.; RANGERT, B. Validity and clinical significance of biomechanical testing of implant/bone interface. **Clinical Oral Implants Research,** v.17, Suppl. 2, p. 2-7, Oct. 2006.

ATSUMI, M.; PARK, S.H.; WANG, H.L. Methods used to assess implant stability: current status. **The International Journal of Oral &Maxillofacial Implants,** v.22, n.5, p. 743-754, Sept./Oct. 2007.

BLUTEAU, G, *et al.* The modulation of gene expression in osteoblasts by thrombin coated on biphasic calcium phosphate ceramic. **Biomaterials,** v.27, n.15, p. 2934-2943, May 2006.

CHEN, T.W. *et al.* Implant placement immediately after the lateral approach of the trap door window procedure to create a maxillary sinus lift without bone grafting: a 2-year retrospective evaluation of 47 implants in 33 patients. **Journal of Oral and Maxillofacial Surgery,** v.65, n.11, p. 2324-2328, Nov. 2007.

CHAPPUIS, V.*et al.* Long-term out comes of dental implants with a titanium plasma-sprayed surface: a 20-year prospective case series study in partially edentulous patients. **Clinical Implant Dentistry and Related Research,** v.15, n.6, p. 780-790, Dec. 2013.

ELLEGAARD, B.; BAELUM, V.; KØLSEN-PETERSEN, J. Non-grafted sinus implants in periodontally compromised patients: A time-to-event analysis. **Clinical Oral Implants Research,** v.17, n.2, p. 156-166, Apr. 2006.

ESPOSITO, M. *et al.* Sinus lift with guided bone regeneration or anorganic bovine bone: 1-year post-loading results of pilot randomized clinical trial. **European Journal of Oral Implantology,** v.3, n.4, p. 297-305, 2010.

HONG, J.*et al.* Titanium is a highly thrombogenic biomaterial: Possible implications for osteogenesis. **Thrombosis and Haemostasis,** v.82, n.1, p. 58-64, July 1999.

LACHMANN, S. *et al.* Resonance frequency analysis and dampening capacity assessment. Part 1: an in vitro study on measurement reliability and a method of comparison in the determination of primary implant stability. **Clinical Oral Implants Research,** v.17, n.1, p. 75-79, Feb. 2005.

LUNDGREN, S. *et al.* Bone reformation with sinus membrane elevation: a new surgical technique for maxillary sinus floor augmentation. **Clinical Implant Dentistry and Related Research,** v.6, n.3, p. 165-173, 2004.

LUNDGREN, S.; ANDERSSON, S.; SENNERBY, L. Spontaneous bone formation in the maxillary sinus after removal of a cyst: coincidence or consequence? **Clinical Implant Dentistry and Related Research,** v.5, n.2, p. 78-81, 2003.

MOLLY, L. Bone density and primary stability in implant therapy. **Clinical Oral Implants Research,** v.17, Suppl. 2, p. 261-267, Oct. 2006.

QUESADA-GARCÍA, M.P. *et al.* Measurement of dental implant stability by resonance frequency analysis: A review of the literature. **Medicina Oral, Patologia Oral y Cirurgia Bucal**, v.14, n.10, p. e-538-546, Oct. 2009.

SACHDEVA, A.; DHAWAN, P.; SINDWANI, S. Assessment of implant stability: methods and recent advances. **British Journal of Medicine & Medical Research** v.12, n.3, p. 1-10, Jan. 2016.

STEFANSKI, S.; SVENSSONAND, B.; THOR, A. Implant survival following sinus membrane elevation without grafting and immediate implant installation with a one-stage technique: anup-to-40-month evaluation. **Clinical Oral Implants Research,** v.28, n.11, p. 1354-1359, Nov. 2016.

TATUM JÚNIOR, H. Maxillary and sinus implant reconstructions. **Dental Clinics of North America,** v.30, n.2, p. 207-229, Apr. 1986.

THOR, A. *et al.* Bone formation at the maxillary sinus floor following simultaneous elevation of the mucosal lining and implant installation without graft material: an evaluation of 20 patients treated with 44. **Journal of Oral and Maxillofacial Surgery,** v.65, n.7, p. 64-72, July 2007.

WOOD, R.M.; MOORE, D.L. Grafting of the maxillary sinus with intraorally harvested autogenous bone prior to implant placement. **The International Journal of Oral & Maxillofacial Implants**, v.3, n.3, p. 209-214, 1988.

ZENÓBIO, E.G. *et al.* Blood clot stability and bone formation following maxillary sinus membrane elevation and space maintenance by means of immediate implant placement in humans. A computed tomography study. **Journal of Craniomaxillofacial Surgery,** Oct. 2018. Doi.org/10.1016/j.jcms.2018.10.004.

ANEXO A - Termo de Consentimento Livre e Esclarecido

Termo de Consentimento Livre e Esclarecido

Título do Projeto: VOLUME ÓSSEO FORMADO A PARTIR DO PREENCHIMENTO DO SEIO MAXILAR APENAS COM COÁGULO, ASSOCIADO À INSTALAÇÃO IMEDIATA DE IMPLANTE

Prezado Senhor (a), XXXXXX

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 seios maxilares onde nada será inserido apenas coágulo sanguíneo em formação após abertura da janela óssea. A técnica utilizada aqui se enquadra dentro dos pré-requisitos exigidos à pesquisa. E por ter características que consideramos necessárias para realização do estudo, venho por meio desse convidá-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.

O objetivo desse estudo é avaliar por meio de tomografias computadorizadas, a estabilidade e volume ósseo formado a partir da cirurgia conhecida por aumentar o 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.

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, 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)".

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.

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.

O conhecimento adquirido com esta pesquisa poderá beneficiar você, bem como outros seres humanos, com informações e orientações futuras em relação à estabilidade e formação óssea estudados na técnica de levantamento de seio maxilar. Assim como, diminuir custos e tempo de tratamento após esta técnica.

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:

Departamento de Odontologia

Av. Dom José Gaspar, 500 - Fone: 3319-4517 - Fax: 3319-4517

CEP 30535.901 - Belo Horizonte - Minas Gerais - Brasil

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

Belo Horizonte, 28 de agosto de 2019

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,XXX XXX 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: