



MESTRADO EM ODONTOLOGIA
ÁREA DE CONCENTRAÇÃO EM PERIODONTIA

FÁBIO LUÍS BORGES

**ELEVAÇÃO DA MUCOSA SINUSAL ASSOCIADA À
INSERÇÃO DE IMPLANTES OSSEOINTEGRADOS
SEM A UTILIZAÇÃO DE ENXERTO AUTÓGENO:
AVALIAÇÃO CLÍNICA E RADIOGRÁFICA**

Guarulhos

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**Dissertação apresentada à Universidade
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Mestre em Odontologia, Área de
Concentração em Periodontia.**

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“Não está na natureza das coisas que o homem realize um descobrimento súbito e inesperado; a ciência avança passo a passo e cada homem depende do trabalho de seus predecessores.”

Ernest Rutherford

RESUMO

Estudos prévios mostraram que a elevação da mucosa sinusal concomitantemente à instalação de implantes dentais osseointegráveis sem a utilização de materiais de enxerto pode ser um procedimento previsível. No entanto, não existem estudos controlados que avaliaram esta técnica. O objetivo deste estudo clínico, prospectivo, controlado e randomizado foi avaliar se a elevação da membrana sinusal e a simultânea inserção de implantes dentais osseointegráveis sem enxerto de osso autógeno pode criar suporte ósseo alveolar para permitir o sucesso do implante após um período de 6 meses. A elevação da membrana sinusal e a inserção de implantes dentais osseointegráveis foram realizadas bilateralmente em 15 pacientes. Os seios maxilares foram distribuídos em 2 grupos: grupo teste, com elevação da mucosa sinusal e inserção simultânea de implantes dentais osseointegráveis sem a adição de material de enxerto, e grupo controle, com elevação da mucosa sinusal e inserção simultânea de implantes dentais osseointegráveis com a adição de material de enxerto autógeno intra-oral. Decorridos 6 meses do pós-cirúrgico, os pilares de cicatrização foram instalados. Para cada implante, comprimento do implante inserido no rebordo remanescente, análise de frequência de ressonância (AFR) e ganho ósseo foram obtidos nos tempos 0 e 6 meses após cirurgia. Complicações clínicas não foram observadas, com exceção de duas fístulas/supurações no período pós-operatório para ambos os grupos. Apenas um implante do grupo teste foi perdido, obtendo-se, assim, um índice de sucesso de 96,4% e 100% para os grupos teste e controle, respectivamente. Após cicatrização, a neoformação óssea radiográfica peri-implantar foi observada para ambos os grupos, variando entre $8,3 \pm 2,6$ mm e $7,9 \pm 3,6$ mm para os grupos controle e teste, respectivamente ($p > 0,05$). Os valores de AFR aos 6 meses foram significativamente menores para o grupo controle quando comparados ao tempo 0 ($p < 0,05$). Correlações positivas foram encontradas entre o comprimento do implante inserido no seio maxilar/ganho ósseo e sobrevivência do implante/sinusite ($p < 0,0001$). A técnica de implantes

inseridos simultaneamente à elevação da mucosa sinusal sem enxertos resultou em formação óssea peri-implantar após um período de 6 meses.

Palavras-chave: seio maxilar/elevação, membrana do seio maxilar, enxerto de osso autógeno, implantes dentários

ABSTRACT

Earlier studies have shown that the simultaneous sinus mucosal lining elevation and installation of dental implants without graft materials could be a predictable procedure. Nevertheless, there are no controlled studies that evaluated this technique. The aim of this prospective, controlled and randomized clinical study was to evaluate whether sinus membrane elevation and simultaneous placement of dental implants without autogenous bone graft can create sufficient bone support to allow implant success after 6 months post-surgically. Sinus membrane elevation and simultaneous placement of dental implants were performed bilaterally in 15 patients. The sinuses were assigned in 2 groups: test group, with simultaneous sinus mucosal lining elevation and installation of dental implants *without* graft materials, and control group, with simultaneous sinus mucosal lining elevation and installation of dental implants *with* intra-oral autogenous bone graft. After 6 months of healing, abutments were connected. For each implant, length of implant protruded into the sinus, resonance frequency analysis (RFA) and bone gain were recorded at baseline and at 6-month follow-up. Clinical complications were not observed, except for two postoperative fistulas/suppuration in both groups. Only one implant from the test group was lost, reaching a success rate of 96.4% and 100% for test and control groups, respectively. After healing, radiographic new peri-implant bone was observed in both groups ranging between 8.3 ± 2.6 mm and 7.9 ± 3.6 mm for control and test group, respectively ($p>0.05$). RFA values were lower for the control group when compared with baseline ($p<0.05$). A significant positive correlation was found between the protruded implant length/bone gain and implant survival/sinusitis ($p<0.0001$). Simultaneous sinus mucosa elevation and implant placement resulted in peri-implant bone formation over a period of 6 months.

Key-words: maxillary sinus/augmentation, sinus membrane, autogenous bone graft, dental implants

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1. INTRODUÇÃO JUSTIFICADA

Após a comprovação científica da osseointegração no final da década de 70, definida como “uma conexão direta e estrutural entre osso vivo ordenado e a superfície de um implante submetido a carga funcional”, grandes avanços foram realizados para que cirurgias de implantes dentários se tornassem uma alternativa viável na substituição dos elementos dentários ausentes.

Modificações no desenho estrutural dos implantes e o tratamento mecânico e químico de sua superfície possibilitaram um aumento substancial dos índices de sucesso quando utilizados no tratamento reabilitador oral, fato este amplamente documentado na literatura (ROOS-JÄNSAKER et al., 2006). Tal sucesso sustenta-se em duas condições fundamentais: a existência de um volume ósseo que possibilite a instalação dos implantes em sua posição protética ideal e de um número de implantes em tamanhos variados que faça frente às forças mastigatórias (MISCH, 2000).

Porém, usualmente o que se encontra são reabsorções ósseas que se caracterizam pela atrofia do tecido ósseo em altura e espessura, podendo variar entre as diferentes regiões da cavidade oral com padrões de reabsorção distintos. A causa mais frequente e responsável por grandes atrofias relaciona-se àquela que ocorre após a perda do elemento dental por ausência de estímulo ao tecido ósseo (CAWOOD & HOWELL, 1988). As reabsorções causadas pela doença periodontal também merecem ser mencionadas, já que podem ocasionar, em seus estágios mais avançados, uma grande redução do volume ósseo, o que impossibilita muitas vezes o uso de implantes osseointegrados sem que manobras de enxertia sejam executadas previamente (CAWOOD & HOWELL, 1991).

Também é importante considerar as características do osso nesta região, geralmente de cortical fina e trabeculado pouco denso, o que contribui para uma menor taxa de sucesso na reabilitação por meio de implantes. A região posterior da maxila é a que possui a menor densidade entre todas as regiões dos maxilares, e essa tende a diminuir com o avanço da idade do

indivíduo, o que torna a região comumente acometida por importantes reabsorções. A este fato, soma-se a pressão positiva exercida nos seios maxilares, que ocasiona o avanço de seus limites com conseqüente diminuição do volume ósseo nesta região. Este processo é denominado de pneumatização dos seios maxilares (CHAVANAZ, 1990).

Neste contexto, torna-se bastante desafiador a reabilitação de maxilares atrofiados em sua região posterior. Tais ocorrências reforçam a necessidade de realizar cirurgias reparadoras que aumentem o volume ósseo da região e que permitam, posteriormente, a instalação de implantes osseointegrados adequados.

Inicialmente, na década de 80, os procedimentos de reconstrução óssea previamente à instalação de implantes osseointegráveis foram descritos com a utilização de enxertos autógenos, ou seja, um fragmento de tecido ósseo do próprio paciente é retirado de uma região denominada área doadora, e colocado em uma região receptora onde há a necessidade de reconstrução (BOYNE & JAMES, 1980). Nesse procedimento, um retalho mucoperiosteal e uma abertura em formato de janela na parede lateral do seio maxilar permitiam o acesso para o descolamento da membrana de Schneider, criando-se um espaço para a aplicação do enxerto de origem autógena. Esses procedimentos apresentaram altos índices de sucesso, em torno de 90%, e são utilizados até hoje com frequência, com altos graus de previsibilidade (WALLACE, 2006; NKENKE & STELZLE, 2009).

Até a presente data, o uso do enxerto autógeno é considerado como o *gold standard* por conter características osteogênicas, osteocondutoras e osteoindutoras (HALLMAN et al., 2001). Vários estudos surgiram com a proposta de tornar esse procedimento menos invasivo, quer pela diminuição e facilidade do acesso cirúrgico, como na técnica proposta por SUMMERS, 1994, quer pela substituição parcial ou total de osso autógeno. Sua utilização representa um segundo leito cirúrgico, ocasionando um aumento do tempo e risco cirúrgico, além dos desconfortos pós-operatórios inerentes a esses procedimentos. Esses desconfortos estão proporcionalmente relacionados à quantidade de reconstrução necessária para a reabilitação do caso clínico, o que define a fonte doadora de enxerto, que pode ser intra-oral, cujas áreas mais utilizadas são sínfise mentoniana e o ramo mandibular (CLAVERO &

LUNDGREN, 2003). Nas grandes reconstruções do tecido ósseo utilizam-se fontes doadoras extra-orais, sendo que as mais relatadas pela literatura são a crista ilíaca, por acesso anterior ou posterior, a tíbia e a calota craniana (CHIAPASCO et al., 2009).

A necessidade de usar fontes extra-orais implica em realizar o procedimento em ambiente hospitalar, com equipe médica auxiliar, procedimentos realizados sob anestesia geral e médicos ortopedistas ou neurologistas para coleta dos enxertos, o que aumenta consideravelmente as custas e a morbidade do tratamento. Por isso, pesquisadores vêm buscando alguma técnica ou algum material que possa substituir os enxertos autógenos, sem que haja comprometimento dos resultados (MANGANO et al., 2009).

O material de enxertia parece ser de fundamental importância para o prognóstico de enxertos. Estudos mostram que diversos biomateriais como osso liofilizado humano, liofilizado bovino, sulfato de cálcio e as hidroxiapatitas possuem limitações específicas em diferentes graus, o que gera incertezas quando ao prognóstico desses enxertos, e que apenas o osso autógeno possui propriedades verdadeiramente osteogênicas, com menor tempo de cicatrização (DEGIDI et al. 2006, BÖECK-NETO et al., 2009).

As proteínas morfogenéticas (ou *bone morphogenetic protein* - BMP), por suas propriedades exclusivas de osseoindução dentre todos os biomateriais, vêm merecendo atenção especial (MANGANO et al., 2009; NKENKE & STELZLE, 2009). Entretanto, seu alto custo ainda inviabiliza sua aplicação.

Já a engenharia tecidual, através do cultivo de células em laboratório, também poderá, em um futuro próximo, ser uma alternativa aos enxertos autógenos (MANGANO et al., 2009)

Com os estudos publicados sobre regeneração tecidual guiada (RTG), verificou-se a possibilidade de se utilizar essa técnica também na região dos seios maxilares. Assim, BRUSCHI et al., 1998, demonstraram a possibilidade de formação de osso ao redor de implantes inseridos dentro do seio maxilar sem qualquer material de enxerto.

Em um achado de formação óssea espontânea, LUNDGREN et al., 2003, relataram a formação óssea ocorrida após a remoção de cisto dentro da cavidade do seio maxilar. No ano seguinte, LUNDGREN et al., 2004, publicaram estudo mostrando a possibilidade dessa técnica em um estudo que utilizou 19 implantes inseridos em 12 seios maxilares. Após o levantamento da mucosa do seio maxilar, os implantes foram inseridos e a janela óssea, que fora removida para se obter o acesso à cavidade sinusal, foi recolocada em sua posição original. Os autores discutiram a neoformação óssea ao redor dos implantes segundo o processo de regeneração tecidual guiada na qual a presença de coágulo sanguíneo alojado em um compartimento ósseo auxiliado pela manutenção mecânica da membrana sinusal pelos implantes, formando uma “tenda”, resultou em formação de tecido ósseo peri-implantar. Os autores comentaram, ainda, que a reposição da parede óssea removida para o acesso à cavidade sinusal funcionava como uma barreira rígida para evitar o crescimento de tecido mole para dentro da cavidade sinusal.

Em um estudo utilizando macacos, PALMA et al, 2006, avaliaram histologicamente a formação óssea ao redor de implantes inseridos na cavidade sinusal enxertada com osso autógeno e apenas coágulo sanguíneo. Nesse estudo, os autores compararam a formação óssea ao redor de implantes, sendo que essa neoformação foi significativamente maior nos implantes de superfície anodizada ($p < 0.05$), embora a neoformação ocorresse também ao redor de implantes de superfície lisa.

Posteriormente, THOR et al, 2007, observaram um ganho médio de 6,51 mm ao redor de implantes inseridos no seio maxilar sem qualquer material de enxerto e somente com a presença de coágulo sanguíneo. Nesse estudo, houve 41% de perfuração da membrana de Schneider, com apenas um (1) implante perdido dentre os 44 instalados. Os autores mostraram, ainda, que a porção apical do implante apresentava ausência de neoformação óssea, provavelmente devido à movimentação pneumática da cavidade sinusal, que empurrava a mucosa sinusal elevada contra a porção apical dos implantes.

Embora a técnica de utilização de implantes inseridos concomitantemente à elevação da mucosa sinusal com preenchimento com

coágulo sanguíneo apresente ótimos resultados, ainda não há, na literatura, estudos controlados e randomizados que avaliem, de maneira sistemática, esta técnica clínica de elevação de seio maxilar.

2. PROPOSIÇÃO

O objetivo deste estudo é avaliar, clínica e radiograficamente, a neoformação óssea ao redor de implantes osseointegrados inseridos em seios maxilares sem a inserção de enxerto ósseo.

3. Artigo Científico

Simultaneous sinus membrane elevation and dental implant placement without autogenous bone graft: a 6-month follow-up study

(artigo preparado segundo as normas do *Clinical Implant Dentistry and Related Research*)

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Running title: Sinus mucosal lining elevation without bone graft

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ABSTRACT

Background: Earlier studies have shown that the simultaneous sinus mucosal lining elevation and installation of dental implants without graft materials could be a predictable procedure. Nevertheless, there are no prospective, controlled and randomized studies that evaluated this technique.

Purpose: The aim of this prospective, controlled and randomized clinical study was to evaluate whether sinus membrane elevation and simultaneous placement of dental implants without autogenous bone graft can create sufficient bone support to allow implant success after 6 months post-surgically.

Material and Methods: Sinus membrane elevation and simultaneous placement of dental implants were performed bilaterally in 15 patients in a split-mouth design. The sinuses were assigned in 2 groups: test group, with simultaneous sinus mucosal lining elevation and installation of dental implants without graft materials, and control group, with simultaneous sinus mucosal lining elevation and installation of dental implants with intra-oral autogenous bone graft. After 6 months of healing, abutments were connected. For each implant, length of implant protruded into the sinus, resonance frequency analysis (RFA) and bone gain were recorded at baseline and 6 months follow-up.

Results: Clinical complications were not observed, except for two postoperative fistulas/suppuration in both groups. Only one implant of test

group was lost, reaching a success rate of 96.4% and 100% for test and control groups, respectively. After healing, radiographic new peri-implant bone was observed in both groups ranging between 8.3 ± 2.6 mm and 7.9 ± 3.6 mm for control and test group, respectively ($p > 0.05$). RFA values were lower for the control group when compared with baseline ($p < 0.05$). A significant positive correlation was found between the protruded implant length/bone gain and implant survival/sinusitis ($p < 0.0001$). The technique applied (placing implants simultaneously to sinus membrane elevation without graft material) resulted in bone formation over a period of 6 months.

Conclusions: Implants placed simultaneously to sinus membrane elevation without graft material resulted in bone formation over a period of 6 months.

Key-words: maxillary sinus/augmentation, sinus membrane, autogenous bone graft, dental implants.

INTRODUCTION

Dental implant therapy has become an excellent and safe treatment modality for a conservative and esthetic alternative to solve partial and total edentulism. When the patient presents deficient alveolar ridges, however, this deficiency could jeopardize the placement of dental implants, mainly in the posterior maxilla, due to loss of alveolar bone and increased maxillary sinus pneumatization.

The maxillary sinus grafting procedure has been used for occlusal rehabilitation with prosthetic appliances placed over dental implants in the posterior maxilla. A plethora of researchers (for review see^{1,2}) have evaluated different bone grafting materials inserted in the maxillary sinus cavity. However, recent studies³⁻⁹ have shown that the simple elevation of the Schneiderian membrane can induce bone formation at the maxillary sinus.

This technique was based on the concept that the lifting of the sinus membrane and the establishment of a compartment with a blood clot could result in new bone around the inserted implants in similar way that bone graft materials maintain the augmented space and promote osteogenesis.⁴ Maxillary sinus augmentation as well as bone regenerative procedures share similarities and both are coordinated processes involving various biological factors.¹⁰ Blood supply and angiogenesis play an important role in guided bone formation.^{11,1} Indeed, the blood clot contain many growth factors, such as fibroblast growth factor (FGF), transforming growth factor (TGF), bone morphogenetic proteins (BMP), insulin-like growth factor (IGF), platelet-derived growth factor (PDGF), and vascular endothelial growth factor (VEGF),

that are expressed during skeletal development and induced in response to injury. These factors are believed to regulate the repair of bone tissue.^{13,14} Some of these molecules are also involved in angiogenesis (i.e. FGF, TFG, VEGF).¹⁴ Complementary, it was shown that cells derived from explants of Schneiderian membrane can express markers of osteoprogenitor cells.¹⁵

In addition, the contact of the whole blood with the titanium surface generates thrombin.¹⁶ Thrombin that is generated by coagulation cascade not only cleaves fibrinogen but also contributes to activation of osteoblasts via proteinase-activated receptors, which, with the platelets may have several effects on bone growth.

Together, these observations show that the simultaneous elevation of sinus membrane and implant placement could be a feasible clinical procedure. However, to date, there are not controlled human studies that evaluated this technique. Therefore, the aim of this prospective, controlled randomized study was to evaluate the simultaneous sinus membrane elevation and implant placement without autogenous bone grafts after a 6-month follow-up.

MATERIAL AND METHODS

Patient Population

Seventeen subjects (11 females and 6 males, mean age 57.9 years) presenting bilateral edentulous area in posterior maxilla were enrolled in this study. The sinuses, in a split mouth design, were assigned in 2 groups: a control group consisting of $n = 17$ sinuses that received simultaneous sinus

membrane elevation, autogenous bone graft and implant placement, and a test group consisting of $n = 17$ sinuses that received simultaneous sinus membrane elevation and implant placement without graft material. Tossing a coin was used to determine which sinus was assigned as control or test sinus side.

Calculation of the sample size was based on a series of previous studies.^{7,17} A difference of 20% or 1mm in bone reformation (height of new bone formed around implants placed into maxillary sinus), with a common standard deviation of 3mm between sinus lifting approaches was set, as the present split mouth study design (with or without graft materials in) is not available in the literature. With an α of 0.05 and $1-\beta$ of 0.80, a sample of at least 14 subjects was considered desirable.

The study protocol was explained to each subject and a signed informed consent was obtained. The Institutional Clinical Research Ethics Committee of Guarulhos University approved this study protocol (# 152/09).

Exclusion Criteria

Subjects were excluded if they were smokers and if they had residual sinus floor of less than 3mm height, maxillary sinus pathology, a chronic medical disease or condition that would contraindicate dental surgery (e.g., diabetes, uncontrolled hypertension, history of head and neck radiation), moderate to severe chronic periodontitis in the remaining teeth (i.e., suppuration, bleeding on probing in more than 30% of the subgingival sites or any site with probing depth > 5mm), absence of primary stability of the

inserted implant in the residual bone and large sinus membrane perforation (> 3mm) during mucosal sinus elevation procedure.

Sinus membrane elevation

All subjects received oral prophylaxis treatment before surgery. Panoramic radiographs and dental computer tomography scans - CT (I-Cat, KaVo Dental GmbH, Biberach, Germany) were taken of all patients. The residual alveolar bone height was measured before surgery. All patients received antibiotics (amoxicillin 875mg and sulbactan 125mg) and steroidal anti-inflammatory (dexamethasone 8mg) prior to the surgery. The bilateral maxillary sinus augmentation was performed under local anesthesia on the same day. According to the CT of the patient and anatomical landmarks, a horizontal crestal incision and two vertical incisions extending beyond the mucogingival junction were performed. A full-thickness flap was reflected in order to expose the maxillary sinus lateral bone wall. Under constant irrigation with sterile saline solution, an osseous window of approximately 15mm x 10mm was demarked, using a round diamond coated bur. The bone in the center of the window was left attached to the sinus membrane. The Schneiderian membrane was carefully dissected and elevated using specially designed elevators, and the bony wall was gently pushed inside the sinus cavity forming the roof to the secluded compartment. The sinus membrane was released without any tension to provide an adequate compartment for the autogenous bone graft (control side) or blood clot (test side). Two trained surgeons (FLB and JAS) performed all surgeries.

Autogenous bone graft

Autogenous bone grafts from the symphysis area or the mandibular ramus, depending on the volume of maxillary sinus and availability of donor area, were obtained via an intraoral incision. A modified 8.0mm length and 6mm diameter trephine bur (INP, São Paulo, SP, Brazil), under constant sterile saline irrigation, were used to harvest the donor site and provided a milled bone. The bone grafts were stored in saline solution until they were placed inside the sinus of the control group.

Implant placement

Screw-shaped implants with sandblasted acid-etched surface, 4.00 mm diameter and 15 to 18mm length (Conus, INP, São Paulo, SP, Brazil) were used in this study. Implants sites were marked using a surgical template. The templates were based on the diagnostic waxing with perforations on the longitudinal axis, on the premolar and molar regions, according to ideal position of final implant supported restorations.

Initial implant stability was optimized by using an under-preparation technique: drilling through the residual bone using a 2.0mm twist drill followed by a 2.8mm and 3mm drill was performed, just enough to enable the initial insertion of implant in the surgical site.

The autogenous bone, in the control group, was placed at the superior aspect of the sinus against the medial aspect of the grafted compartment created in the sinus cavity. The graft was condensed at each stage. The dental implants were placed to half of their total length. Then, following the condensation of the graft, the dental implants were seated in their final

positions, to avoid empty spaces in the sinus cavity. Any remaining graft material was placed over the exposed implant surfaces.

Once the coagulum was observed underneath the elevated sinus mucosa of the test group (without autogenous bone graft), the implants were finally placed, as shown in figure 1.

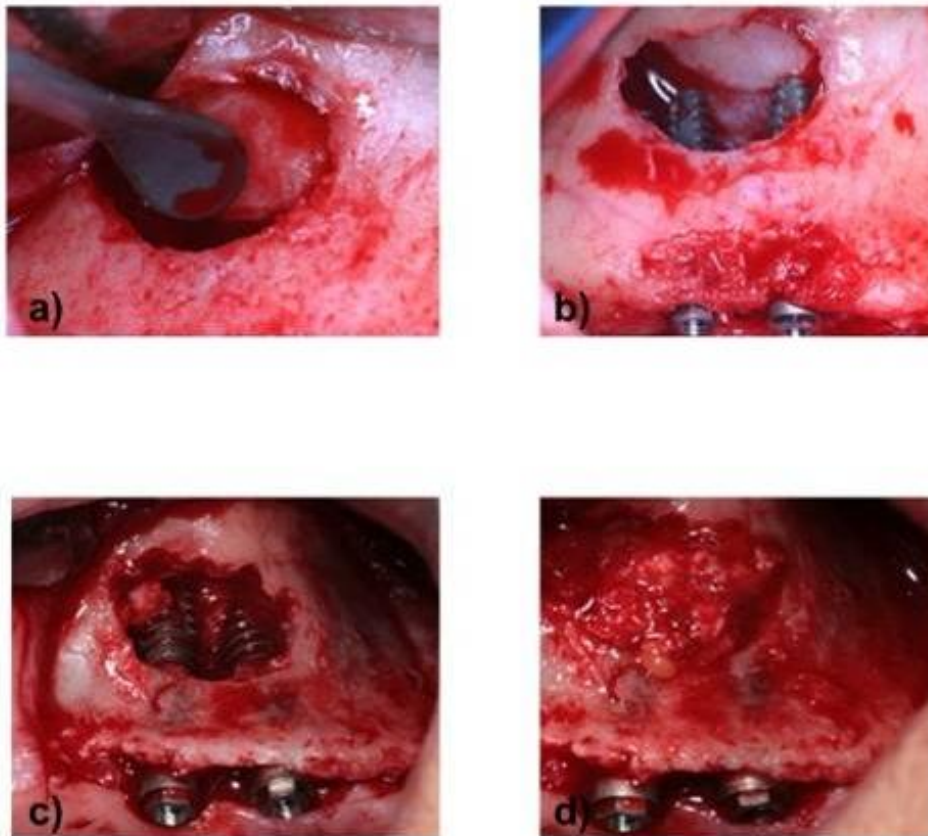


Figure 1: Clinical view of **a)** lateral bone wall pushed into the sinus cavity; **b)** simultaneous sinus membrane elevation and implant placement without autogenous bone graft; **c)** simultaneous sinus membrane elevation and implant placement; **d)** autogenous bone graft inserted over the implants.

Following the implant placement, a polypropylene membrane (INP, São Paulo, SP, Brazil) was applied to cover the lateral wall osteotomy of the sinuses of control and test groups. The membrane was adjusted to extend

circumferentially 5 to 8mm over the adjacent alveolar bone, avoiding ingrowths of the soft connective tissue. To allow flap apposition and closure after placement, incisions were made buccally and palatally after membrane placement. Primary wound closure was achieved with horizontal mattress sutures alternated with interrupted sutures to ensure a submerged healing procedure in dental implants.

Postoperative care

Postoperative care consisted of a 0.12% chlorhexidine mouthrinse twice a day for 14 days without mechanical cleaning at the surgical areas. Anti-inflammatory medication (dexamethasone, 4 mg) was administered once a day and appropriate analgesia (paracetamol, 750 mg) for 3 days following surgery in order to reduce postoperative swelling and pain. A postoperative antibiotic regimen with amoxicilin and sulbactan was prescribed during 7 days. Nylon sutures were removed 14 days after surgery. The existing upper removable prosthesis was adapted with soft tissue conditioner and was worn after a healing period of 4 weeks. Occlusal adjustments and soft tissue conditioner were performed when necessary. Professional plaque control supplemented this healing phase every month, during 6 months.

Postsurgically events as membrane exposure, sinusitis and paresthesia were recorded in each recall visit.

Implant stability and CT measurements

Immediately after the implant placement (baseline) and at second stage surgery (6 months after maxillary sinus augmentation), the resonance

frequency analysis-RFA (Osstell, Integration Diagnostics, Savadale, Sweden) was used to measure the primary stability of the implant. The transducer (smartpeg type 1) was hand-screwed into the implant body. For every series of RFA measurements, the ISQ values (unit of RFA) were recorded. An ISQ value between 1 and 100 was given where 1 is the lowest and 100 the highest. A mean of ISQ value was calculated for each implant based on one measurement of each implant, and then of each group. The RFA was measured at baseline and 6 months after therapy.

Three computed tomography (CT) datasets were acquired for every patient, at baseline, 14 days and 6 months after maxillary sinus augmentation procedures. The CT data were transferred in the DICOM format to specific implant navigation software (I-Cat Vision, Kavo Dental). This format allows a 3D reconstruction of the maxilla. Moreover, this software enables, through segmentation tools, to measure bone crest height along transversal sections, corresponding to the longitudinal axis of the implant, before and after maxillary augmentation.

A single trained examiner performed all measurements in order to evaluate the changes in height of maxillary sinus floor for each implant. The sinuses were evaluated in order to assess the radiographic parameters: 1) average of residual sinus floor measured in the initial CT ($A1+A2/2$); 2) the height of endosinus bone gain, defined as the mean height of new bone ($B1+B2/2$); 3) the linear distance of the buccal and palatal sinus wall ($C1+C2/2$); 4) the length of the implant protruded into the sinus after surgery ($D1+D2/2$). These measurements were taken and then averaged per implant, and then per group, as shown in figure 2.

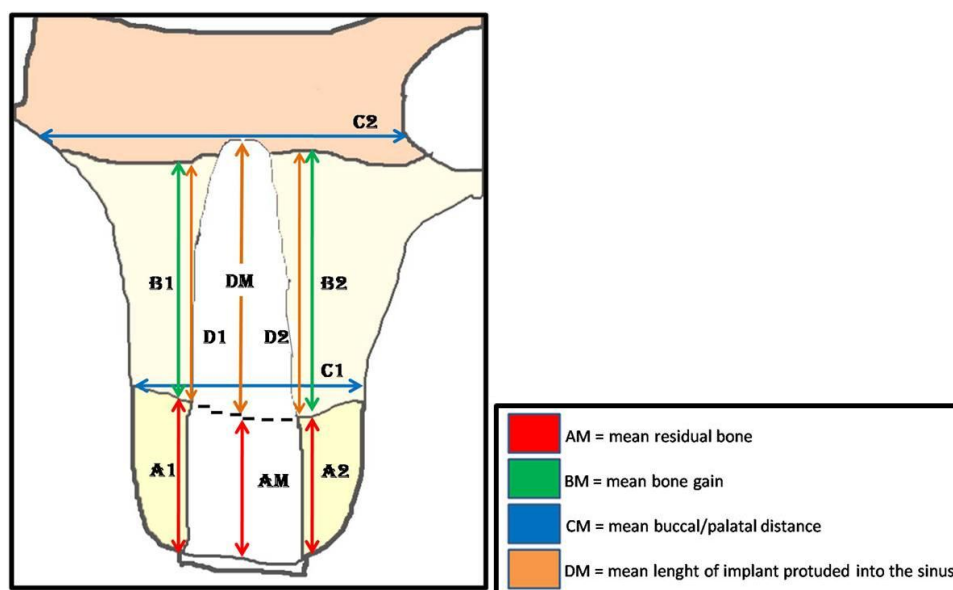


Figure 2: Schematic drawing of an implant inserted into the sinus cavity. To evaluate the changes in height of maxillary sinus floor for each implant, the sinuses were evaluated in order to assess the radiographic parameters: 1) average of residual sinus floor measured in the initial CT ($AM = (A1 + A2) / 2$); 2) the mean height of endosinus bone gain, defined as the mean height of new bone ($BM = (B1 + B2) / 2$); 3) the average of linear distance of the buccal and palatal sinus wall ($CM = (C1 + C2) / 2$); 4) the mean length of the implant protruded into the sinus after surgery ($DM = (D1 + D2) / 2$)

Statistical analysis

The mean and standard deviation of the value of RFA and radiographic data were calculated for each implant and then for each group. Mann-Whitney U test was used to calculate the differences between groups for the radiographic and RFA variables. Wilcoxon's rank test was used to evaluate the intra-groups differences between RFA values at baseline and 6 months post-therapy. The χ^2 test was used to calculate the dichotomously variables, i.e., presence or absence of suppuration, membrane exposure, lateral window closure and implant survival. Spearman correlation was used to evaluate the

possible correlations among the clinical and radiographic variables. The unit of analysis was the patient and the level of significance was 0.05.

RESULTS

Maxillary sinus augmentation

Fifteen out of 17 patients were followed throughout the study period. One patient presented pus inside the maxillary sinus at the time of the surgery and one had a sinus perforation greater than 5mm. A total of 30 sinus lift procedures were performed in 15 patients. Sinus mucosal perforations < 2mm were observed in two sinuses, one in each group (Table 2). Fifty-four implants were placed (Table 1).

Table 1: Position and length of implants used in the study.

18		2	2	2		2	2	1	1	1
15		3	4					3	3	
Length (mm)										
Control										
Position	18	17	16	15	14	24	25	26	27	28
Test										
Length (mm)										
15		3	5	1	1		1	5	5	1
18	1	2	1					1	1	

Table 2. Mean (standard deviation) of clinical and radiographic variables of implants placed in control and test group. Mann-Whitney Test and χ^2 test ($p>0.05$).

Group	Sinusitis (%)	Membrane Perforation(%)	Lateral window closed (%)	Exposition of membrane (%)	Bone Gain (mm)	Length of implant protruded into the sinus (mm)	Buccal/palatal Distance (mm)
Control	0	4.23 (1.96)	96.60 (1.98)	54.34 (4.23)	8.31 (2.60)	8.20 (2.40)	10.62 (1.61)
Test	7.14(2.62)	7.23 (2.34)	82.12 (3.9)	58.44 (4.88)	7.91 (3.60)	8.95 (3.50)	10.65 (2.98)

Postoperative control

Two postoperative wound infections, one in each group, occurred 3-4 weeks after the maxillary sinus augmentation. Both exhibited suppuration, and they were solved with membrane removal and irrigation with 0.12% chlorhexidine. Additional surgery was not needed. Membrane exposure was present in more than 50% of the cases and they were removed without surgical intervention (Table 2). These exposures happened after a period of 2-4 months after surgery.

In addition, no patient presented any paresthesia or altered sensation in the donor area. Oral function was not affected in all treated patients.

Re-entry surgery and implant survival

At abutment surgery, the remaining membranes were removed and visual evaluation of the lateral window of the maxillary osteotomy was performed. Four sinuses presented an incomplete closing of the lateral window: one in the control group and three in the test group (Table 2).

One implant in the test group was removed due to a lack of osseointegration. This loss was observed in the patient that presented sinusitis. The 56 remaining implants, in both groups, were clinically stable. The implant survival was 96.4% and 100% to test and control, respectively.

CT evaluation

Table 2 presents the radiographic variables. No difference was found between groups. The CT images showed that implant protruding, on average, 8 mm into the sinus ($p>0.05$). In all patients, radiographic evidence of new bone formation in the elevated sinus area was seen. Both sides of implants, in a varied range, were covered with new bone, independently of the evaluated group (Figures 3 and 4). The new bone formation was 8.3 ± 2.6 mm and 7.9 ± 3.6 mm in the control and test groups, respectively ($p>0.05$). In some cases, mainly in the test group, the new bone tissue was not seen at the apical implant area. The distance between the buccal and palatal bone wall (DM, Figure 2) was also similar in both groups ($p>0.05$).

Positive correlations were detected to length of implant protruded into the sinus and bone gain ($p<0.0001$; $r^2=0.635$) and lateral window closure and bone gain ($p<0.05$, $r^2=0.551$) for both groups. In addition, sinusitis was correlated with implant survival ($p<0.0001$, $r^2=0.704$)

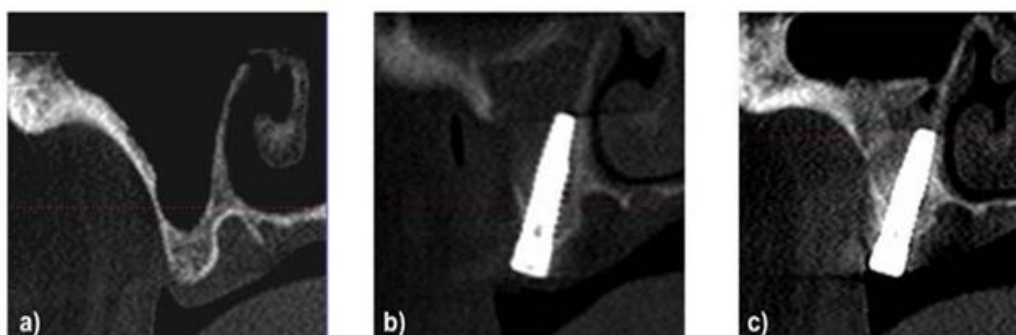
Figure 3**Figure 4**

Figure 3: Computed tomography (CT) of test group at a) baseline, b) 14 days after surgery and c) 6 months. Note the new bone formation around the implant.

Figure 4: Computed tomography (CT) of control group (with autogenous bone graft) at a) baseline, b) 14 days after surgery and c) 6 months.

Resonance Analysis Frequency (RFA)

The Implant Stability Quotient (ISQ) is presented in Figure 5. RFA data were obtained only from the implants placed in the sinus area. Implant stability measurements at baseline showed a mean of ISQ value

of 57.34 for all implants, with higher means to implants placed in the control group ($p>0.05$). After healing of 6 months, the ISQ value showed a decrease in these values in both groups ($p<0.05$) when compared with baseline, but significant for only the control group. These values ranged between 51 ISQ and 50 ISQ, for control and test groups, respectively. However, there was not a significant difference between groups ($p>0.05$).

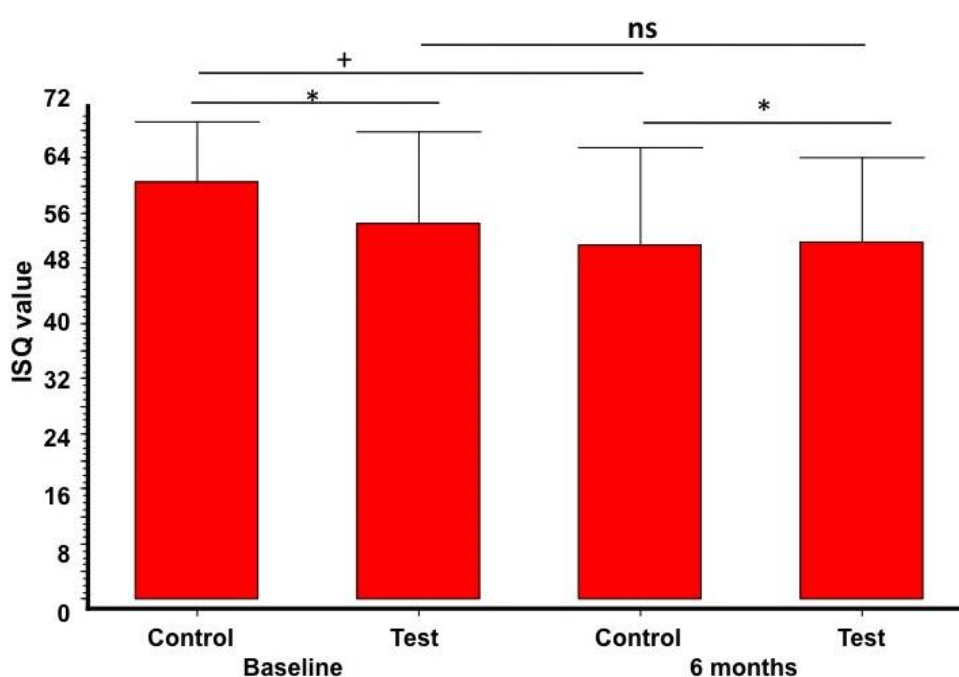


Figure 5: Mean and standard deviation of ISQ values of implants of control and test sinuses at baseline and 6 months. Mann-Whitney Test ($*p<0.05$); Wilcoxon Rank Test ($+p<0.05$), ns=non-significant.

DISCUSSION

The present data showed that the simultaneous sinus membrane elevation and dental implant placement with or without autogenous bone graft presented the same results in a 6-month follow-up. Bone formation was

evident in all patients, except in that patient that presented an acute post-surgery sinusitis. This patient also lost one implant during the initial healing period in the test group. These results agree with previous studies in humans^{4,6,7} and animals^{8,9}, who also obtained, in a varied range, new bone formation in the maxillary sinus augmentation without bone grafts.

Although these results are based on recent studies,^{4,7} the idea of placing implants inside the maxillary sinus without bone grafts is not new. Previous studies, developed in the early 80's by BRÄNEMARK et al.¹⁸ and BOYNE & JAMES¹⁹, reported bone formation at apical portion of dental implants placed in maxillary sinus after carefully raising of the sinus membrane.

Thereafter, BRUSCHI et al.²⁰ and SUMMERS,²¹ also showed that the careful lining of the sinus membrane allowed new bone formation around the implant placed in maxillary sinus cavity, through remaining alveolar bone crest approach. However, these techniques have bone formation limited to 4 to 5 mm.

The simultaneous Schneiderian membrane elevation and implant placement performed in our study showed better results, compared with the aforementioned studies.^{18,20,21} An extensive bone formation around implants was observed, almost covering all the apical portion of the implant. The bone gain ranged between 8.3mm and 7.9mm for control and test groups, respectively. Previous studies^{17,22} that evaluated different graft materials in maxillary sinus augmentation and simultaneous implant placement reached similar results.

It must be pointed out that maxillary sinus pneumatization could be caused by positive intra-sinus air pressure due to respiration and this pressure might promote resorption and new pneumatization after maxillary sinus augmentation.^{17,23} However, in the present study, both sinus groups do not present resorption, at least after a 6-month follow-up. This finding may be supported, in part, by two alterations made in the technique advocated by LUNDGREN et al.⁵ Firstly, the present study pushed the lateral bone window inside the sinus cavity, using this thin bone as “roof” of the secluded cavity. This bone wall was mechanically supported by the dental implants as a space maker for guided bone regeneration. Secondly, utilizing membrane that avoided the soft tissue ingrowths in the sinus cavity allowed not only a better blood clot organization but also stabilization for closure of the lateral window, as shown in previous studies.^{22,23} These alterations could, together, establish proper pneumatic conditions, different from the earlier data,⁷ where the apical portion of some implants were not covered by new bone.

In addition, this technique do not use bone grafts inside the sinus cavity. Autogenous bone is the gold standard, but its use is limited by donor-site morbidity, sparse availability, and uncontrolled resorption.^{24,25,26} Another advantage of this sinus lifting technique was the use of sandblasted acid etched implants with 15 and 18 mm length. Previous studies have shown the importance of implant surface topography at micrometer scale on trombogenic activity¹⁶ as well as the length of implants in success rate.²⁷ This trombogenic activation results in the recruitment, migration and differentiation of progenitor osteogenic cells. These cells are provided by the Schneiderian membrane and exposed bone in the sinus cavity. The VEGF is probably the most

important player in the vascular formation during angiogenesis.²⁸ VEGF is an endothelial-specific growth factor that promotes angiogenesis by stimulating endothelial cell differentiation, proliferation, and migration,²⁹ and plays an important role in bone remodeling by attracting endothelial cells and osteoclasts, and by stimulating osteoblast differentiation.³⁰ The involvement of VEGF in bone formation is also suggested by its interaction with humoral factors that regulate bone homeostasis³¹ and by its role, not only in bone angiogenesis but also in different aspects of bone development, including chondrocyte differentiation, and osteoblast and osteoclast recruitment.²⁹ Moreover, osteoblasts and osteoblast-like cells have been shown to be able to produce VEGF.³⁰ Bone formation is closely linked to blood vessel invasion and therefore, the angiogenesis plays a pivotal role in all regenerative processes.^{13,14,28-30} VEGF may act indirectly or directly to increase recruitment of mesenchymal stem cells through an enhancement of vascular permeability, which may facilitate migration of host mesenchymal stem cells to the bone regeneration site.¹³ VEGF activity is essential for normal angiogenesis and appropriate callus formation and mineralization in response to bone injury.

Complementary, it is reported that RFA can provide objective evaluation of implant stability, possibly demonstrating evidence for extending of implant osseointegration.³² Therefore, the present data demonstrated that the use of ISQ values ranged between 54.2 and 60.6 to implants placed in test and control sinus, values very similar to HALLMAN et al.³³ that found a ISQ value of 66.2 (range from 53 to 76) in implants placed in grafted sinus. However, it could be speculated that the difference between ISQ values of

control and test sides at baseline ($p < 0.05$) was due to the presence of autogenous bone graft in the control sinuses. As the bone graft must be added before the dental implant placement to allow a proper graft condensation, this fact might have influenced the results, instead, after a 6-month healing, there was no difference between groups. In addition, the lower means of ISQ values after the 6-month period could be related with the initiation of the new bone formation.³⁴ The present study also demonstrated a high survival rate for simultaneous implant placement in both groups. The success rate ranged between 96.4 and 100%, similar to previous reports.^{1,2,24,28}

In conclusion, simultaneous sinus membrane elevation and implant placement, with or without bone graft reach a comparably bone gain and implant survival at 6 months follow-up. However, more long-term clinical data are needed to draw a more definitive conclusion.

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4. CONSIDERAÇÕES FINAIS

A reabilitação de áreas posteriores da maxila, principalmente após a perda do elemento dental, torna-se complexa devido à pneumatização do seio maxilar. Embora sejam vários os tratamentos e tipos de enxerto para a regeneração desta região, ainda não há um consenso sobre qual técnica apresenta melhor previsibilidade e melhor taxa de sobrevivência dos implantes. A técnica do preenchimento da cavidade sinusal com coágulo sanguíneo e inserção simultânea de implantes mostrou-se eficaz na neoformação óssea peri-implantar, pelo menos, 6 meses após a terapia cirúrgica. No entanto, apesar dos resultados apresentados serem animadores, são necessários estudos longitudinais que possam fornecer maiores detalhes sobre a taxa de sobrevivência destes implantes após função. Outros estudos que possam avaliar as macro e micro estruturas dos implantes, bem como sua eficácia em pacientes fumantes, poderão contribuir para predizer seu sucesso clínico.

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