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Karine Câmara Silva

**AVALIAÇÃO DA ESTABILIDADE DE IMPLANTES INSTALADOS
EM ÁREAS PREVIAMENTE SUBMETIDAS À ELEVAÇÃO DO SEIO
MAXILAR UTILIZANDO O BIOMATERIAL BIO-OSS®**

Belo Horizonte
2016

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

Orientador: Prof. Dr. Martinho Campolina
Rabello Horta

Coorientador: Prof. Dr. Maurício Greco Cosso

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COMPOSIÇÃO DA BANCA EXAMINADORA:

- 1- Prof. Dr. Leandro Napier de Souza – UFMG
- 2- Prof. Dr. Rodrigo Villamarim Soares – PUC Minas
- 3- Prof. Dr. Martinho Campolina Rebello Horta – PUC Minas

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Coordenador do Programa de Pós-graduação em Odontologia

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RESUMO

A Análise de Frequência de Ressonância (ARF) tem se mostrado uma técnica viável para o monitoramento da estabilidade do implante ao longo do tempo. O torque de inserção também é um método viável na avaliação da estabilidade primária de implantes. Entretanto, ainda são escassos os estudos que utilizam tais técnicas na avaliação da estabilidade de implantes instalados em áreas de enxerto ósseo de seio maxilar. Nesse contexto, este estudo objetiva comparar a estabilidade primária e a estabilidade secundária, mensuradas pela ARF, de implantes Neodent Titamax Ti® de diferentes comprimentos instalados na região posterior da maxila de áreas previamente submetidas à elevação do seio maxilar utilizando o biomaterial Bio-Oss®. Adicionalmente, também será avaliada a existência de correlação entre ARF e torque de inserção na avaliação da estabilidade primária. Após a instalação dos implantes (doze implantes de 9 mm e oito de 11 mm) em 9 pacientes, o torque de inserção foi mensurado pelo motor Bien Air® (iCHIROPRO) e, em seguida, foi realizada a avaliação da estabilidade com o aparelho Osstell® o qual, através da ARF, determinou o ISQ (Coeficiente de estabilidade do implante). O ISQ foi mensurado pelo mesmo operador em dois momentos: T1) no dia da instalação dos implantes; T2) 90 dias após a instalação dos implantes. Não foram observadas diferenças estatisticamente significantes no ISQ entre T1 e T2 quando os implantes foram agrupados (9 mm e 11 mm) ou quando os implantes de 9 mm foram avaliados separadamente ($p>0,05$). Quando os implantes de 11 mm foram avaliados separadamente, o ISQ foi estatisticamente maior em T2 que em T1 ($p<0,05$). Em T1 os implantes de 9 mm apresentaram ISQ estatisticamente maior que os implantes de 11 mm ($p<0,05$); em T2 os implantes de 11 mm apresentaram ISQ estatisticamente maior que os implantes de 9 mm ($p<0,05$). Não foi observada diferença no torque de inserção entre os implantes de 9 mm e os implantes de 11 mm ($p>0,05$). Não foi observada correlação entre ISQ e torque de inserção para os implantes, independentemente de seu comprimento ($p>0,05$). Estes resultados sugerem que implantes mais longos podem estar associados a um contínuo aumento dos valores de ISQ durante o período de cicatrização, além de indicarem ausência de correlação entre o ISQ e o torque de inserção na avaliação da estabilidade dos implantes.

Palavras-chave: Estabilidade de implantes. Análise de frequência de ressonância. Torque de inserção. Substitutos ósseos. Elevação de seio maxilar.

ABSTRACT

The Resonance Frequency Analysis (RFA) is a viable method used to determine alterations in the implant stability over time. The insertion torque is also a practical method for the evaluation of the primary stability of dental implants. Nevertheless, there are few studies that use such techniques in assessing the stability of implants placed in bone grafting of the maxillary sinus. In this context, this study aims to compare the primary stability and secondary stability, measured by RFA, of Neodent Titamax Ti® implants of different lengths installed in areas of sinus floor elevation using Bio-Oss®, one of the more applied biomaterials in this procedure. The correlation between insertion torque and RFA in assessing the primary stability was also evaluated. Twenty implants were used (12 implants with 9 mm length and 8 implants with 11 mm length), installed in 9 patients in areas previously submitted to sinus floor elevation using Bio-Oss®. After installation of the implants the insertion torque was measured by the Bien Air ® motor (iCHIROPPO). Afterward, the stability was evaluated with Osstell®, that determined the ISQ (Implant stability coefficient) employing the RFA. ISQ was measured by the same operator in two times: T1) on the day of the implant placement; T2) 90 days after implant placement. No statistically significant differences were observed in the ISQ between T1 and T2 when the implants were grouped (9 mm and 11 mm) or when the 9 mm implants were evaluated separately ($p>.05$). Once the 11 mm implants were evaluated independently, ISQ was statistically higher in T2 than T1 ($p<.05$). At T1, the 9 mm implants showed a statistically higher ISQ than the 11 mm implants ($p<.05$). At T2 the 11 mm implants showed a statistically higher ISQ than the 9 mm implants ($p<.05$). No difference was observed in the insertion torque between 9 mm implants and 11 mm implants ($p>.05$). There was no correlation between ISQ and insertion torque of the implants, regardless of its length ($p>.05$). In conclusion, our results suggest that longer implants should be associated with a continuous increase in ISQ values during the osseointegration period and indicate no correlation between ISQ and insertion torque in the evaluation of the stability of implants.

Keywords: Implant stability. Analysis resonance frequency. Insertion torque. Bone substitutes. Elevation of maxillary sinus.

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1 INTRODUÇÃO

A estabilidade do implante é necessária para o sucesso da osseointegração e do tratamento protético em longo prazo (BALSHI et al., 2005; SIM; LANG, 2010). A avaliação clínica da estabilidade é baseada em critérios mecânicos, sendo esta representada pela ausência de mobilidade do implante (QUESADA-GARCÍA et al., 2009).

No momento da instalação do implante, a estabilidade gerada pela macroestrutura da superfície do corpo do implante que obtém um embricamento mecânico com o tecido ósseo, é denominada estabilidade primária (SIM; LANG, 2010). Esta é fundamental para osseointegração, já que micromovimentos do implante após sua instalação podem viabilizar a proliferação de tecido conjuntivo fibroso na interface osso-implante, resultando em uma pobre osseointegração (GUPTA; PADMANABHAN, 2013). A estabilidade primária é influenciada por fatores como qualidade e quantidade óssea, design do implante, e técnica cirúrgica (BALSHI et al., 2005; QUESADA-GARCÍA et al., 2009; HERRERO-CLIMENT et al., 2013).

Paralelamente à estabilidade primária, ocorre a formação e remodelação óssea na interface osso-implante durante o período de osseointegração. Este processo é responsável pela estabilidade secundária dos implantes que corresponde à união biológica entre a superfície do implante e o tecido ósseo. Fatores como tipo de superfície do implante e tempo de cicatrização podem influenciar a estabilidade secundária (QUESADA-GARCÍA et al., 2009). Adicionalmente, alterações sistêmicas associadas devem ser consideradas no plano de tratamento de modo a evitar a associação de fatores de risco para a perda de implantes (WAKIMOTO et al., 2012).

Desde a utilização de implantes com carga imediata, a determinação do nível de estabilidade do implante mostrou-se necessária, já que implantes submetidos a este protocolo dependem de um grau de estabilidade primária previamente determinada. Tornou-se então necessário que o profissional medisse a estabilidade do implante no contexto clínico, de modo a quantificar micromovimentos do implante e determinar o risco fracasso do tratamento, especialmente em casos nos quais o paciente apresenta osso de má qualidade (BALSHI et al., 2005; BRIZUELA-VELASCO et al., 2015).

A necessidade de uma técnica não invasiva, confiável e clinicamente aplicável

para medir a estabilidade do implante levou ao desenvolvimento da análise de frequência de ressonância (ARF). A técnica foi introduzida por Meredith e colaboradores em 1996 (MEREDITH; ALLEYNE; CAWLEY, 1996), sendo utilizada como um instrumento de diagnóstico que permitiria o monitoramento de alterações na estabilidade do implante ao longo do tempo (SIM; LANG, 2010).

A ARF utiliza um dispositivo eletrônico disponível com o nome comercial de Osstell®. A técnica emprega um transdutor piezoelétrico que ao ser energizado por um pulso magnético emite um sinal destinado a vibrar o implante. A resistência do implante à vibração é medida pelo dispositivo em Hertz e convertida em ISQ (Coeficiente de estabilidade do implante) que varia numa escala de 1 a 100 (QUESADA-GARCÍA et al., 2009; HERRERO-CLIMENT et al., 2013), sendo que valores elevados (> 60) indicam estabilidade adequada do implante (HSU et al., 2011).

Um estudo *in vitro*, ao avaliar a correlação entre ISQ e micromovimentos do implante, demonstrou que quanto maior o ISQ menor a micromovimentação do implante sob uma determinada carga e que um ISQ de 57 corresponde a micromovimentos de 150 µm, valor este que não deve ser excedido para obtenção e manutenção da osseointegração (BRIZUELA-VELASCO et al., 2015).

Outra técnica proposta para avaliação da estabilidade de implantes é o torque de inserção. Descrito inicialmente por Johansson e Strid (1994) consistem em um método que registra a força necessária para instalação do implante, avaliando a estabilidade primária do mesmo, além de fornecer informações sobre a qualidade óssea local (TURKYILMAZ et al., 2007). O torque de inserção pode ser aferido por meio de um medidor de torque contido no interior da unidade de perfuração ou através de instrumento mecânico ou digital de mensuração de torque (OTTONI et al., 2005).

Como a estabilidade do implante é influenciada pelo embricamento entre o implante e o sítio ósseo receptor, acredita-se que um alto torque de inserção seja desejável para que a integração do implante ocorra de forma efetiva (OTTONI et al 2005). Entretanto, estudos têm levantado a hipótese de que torques de inserção elevados estão associados a atraso no processo de osseointegração, atribuído a uma tensão excessiva gerada na interface osso/implante (NORTON, 2011).

A ARF e o torque de inserção são atualmente as técnicas propostas para o diagnóstico de problemas de estabilidade de um implante, sendo levantada a

hipótese de correlação positiva entre as duas técnicas (BAYARCHIMEG et al., 2013; BRIZUELA-VELASCO et al., 2015). Entretanto, publicações recentes indicam que estas técnicas representam elementos distintos associados à estabilidade primária, podendo induzir o profissional a uma avaliação equivocada das medidas de estabilidade de implantes instalados (SENNERBY; MEREDITH, 2008; DEGIDI et al., 2013; SENNERBY et al., 2015).

O torque de inserção mensura a resistência mecânica friccional do leito receptor ao avanço apical do implante e à rotação no eixo longitudinal. Já o ISQ considera a rigidez de contato do implante ao sítio receptor e sua resistência ao deslocamento lateral (SENNERBY et al., 2015). Achados que indicam proporção direta entre torque de inserção e ISQ (em que a aplicação de um maior torque é capaz de aumentar o ISQ e fornecer uma maior estabilidade primária) são controversos, tendo em vista que alguns estudos demonstraram relação direta entre estas variáveis (TURKYILMAZ et al., 2009; BRIZUELA-VELASCO et al., 2015), enquanto outros não encontraram esta correlação (AKÇA et al., 2010; FUSTER-TORRES et al., 2011).

Em implantodontia, tem se mostrado cada vez mais frequente a utilização dos enxertos ósseos de forma a viabilizar a instalação de implantes em sítios com perda óssea acentuada. Regiões maxilares posteriores superiores edêntulas geralmente apresentam redução do volume ósseo, tanto em largura quanto em altura por atrofia e pneumatização do seio maxilar. Perda óssea acentuada pode representar uma barreira anatômica à reabilitação protética da maxila, pela ausência de suporte ósseo para a estabilidade adequada do implante (BALLERI et al., 2002; CALVO-GUIRADO et al., 2010).

Diversos materiais têm sido utilizados como substitutos ósseos atuando como uma estrutura de suporte que sustenta o volume inicial sendo estes progressivamente substituídos por novo osso (MARTINEZ et al., 2010). Diferentes substitutos ósseos incluindo aloenxertos, xenoenxertos e materiais aloplásticos têm sido utilizados na elevação do seio maxilar de forma isolada ou em diferentes combinações (SILVESTRI et al., 2013).

Sendo a ARF e o torque de inserção as técnicas mais utilizados na avaliação da estabilidade de implantes, torna-se importante avaliar a correlação entre os resultados obtidos por esses dois métodos.

2 OBJETIVOS

2.1 Objetivo geral

Avaliar, pela análise de frequência de ressonância (ARF) e pelo torque de inserção, a estabilidade de implantes instalados na região posterior da maxila em áreas previamente submetidas à elevação do seio maxilar.

2.2 Objetivos específicos

- a) comparar a estabilidade primária e a secundária, mensuradas pela análise de frequência de ressonância (ARF), de implantes Neodent Titamax Ti® de diferentes comprimentos instalados na região posterior da maxila em áreas previamente submetidas à elevação do seio maxilar;
- b) avaliar a existência de correlação entre os resultados obtidos pela análise de frequência de ressonância (ARF) e pelo torque de inserção na avaliação da estabilidade primária, de implantes Neodent Titamax Ti® de diferentes comprimentos instalados na região posterior da maxila em áreas previamente submetidas à elevação do seio maxilar.

3 ARTIGO

Assessment of dental implants stability by the resonance frequency analysis and the insertion torque in areas previously submitted to maxillary sinus elevation

Os resultados desse trabalho foram compilados na forma de artigo a ser submetido ao periódico **Clinical Oral Implants Research** (Qualis A1), de acordo com as normas do periódico, que podem ser acessadas em: [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1600-0501/homepage/ForAuthors.html](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1600-0501/homepage/ForAuthors.html)

**ASSESSMENT OF DENTAL IMPLANTS STABILITY BY THE RESONANCE
FREQUENCY ANALYSIS AND THE INSERTION TORQUE IN AREAS
PREVIOUSLY SUBMITTED TO MAXILLARY SINUS ELEVATION**

Karine Câmara Silva

Paulo Eduardo Alencar Souza

Elton Gonçalves Zenóbio

Maurício Greco Cosso

Martinho Campolina Rebello Horta

Graduate Program in Dentistry, Pontifical Catholic University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil.

RUNNING TITLE: IMPLANTS STABILITY IN AREAS OF MAXILLARY SINUS
ELEVATION

Corresponding author:

Martinho Campolina Rebello Horta

Pontifical Catholic University of Minas Gerais - Department of Dentistry

Av. Dom José Gaspar 500 - Prédio 45 – Sala 110

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

Phone: (+55) 31 33194341- Fax: (+55) 31 33194166

E-mail: martinhhorta@pucminas.br

Summary

Objective: To compare the primary and secondary stability, measured by Resonance Frequency Analysis (RFA), in implants of different lengths installed in areas submitted to maxillary sinus elevation and, additionally, to evaluate the existence of a correlation between RFA and implant insertion torque.

Material and methods: Twenty implants (twelve implants of 9 mm and eight implants of 11 mm) were implanted in areas submitted to maxillary sinus elevation. The insertion torque was measured by the Bien Air® engine. Osstell®, through RFA, determined the ISQ (Implant Stability Quotient) at two times: the day of implant installation (T1) and 90 days after implant installation (T2).

Results: No significant differences were observed in the ISQ between T1 and T2 when the 20 implants were grouped, nor when the 9 mm implants were evaluated separately. In contrast, when the 11 mm values were evaluated separately, the ISQ was significantly higher in T2 than in T1 ($p < 0.05$). In T1, 9 mm implants had a higher ISQ than 11 mm ones ($p < 0.05$), whereas in T2 the implants of 11 mm showed a statistically higher ISQ than the 9 mm implants did ($p < 0.05$). There was no significant statistical difference in insertion torque between 9 mm and 11 mm implants ($p > 0.05$), nor was there a correlation between ISQ and insertion torque ($p > 0.05$).

Conclusions: The findings suggest that, when installed in areas previously submitted to maxillary sinus elevation, longer implants (11 mm) presented a significant increase in ISQ values during the healing period. This phenomenon was not observed for shorter implants (9 mm). Finally, we did not observe any correlation between the stability measurements obtained by RFA and implant insertion torque.

Keywords: Biomaterials, Bone implant interactions, Clinical research, Sinus floor elevation

Introduction

Dental implants have become a predictable treatment modality that has been widely used in the rehabilitation of edentulous areas. The primary stability achieved shortly after implant installation is a prerequisite for the success of osseointegration, as well as one of the main factors that influence the survival rates of the implants (Frieder et al., 1991; Meredith 1998; Lioubavina-Hack et al. 2006). The primary stability consists of the frictional contact between the implant and the bone of the receptor site (Fini et al., 2004). Factors such as implant geometry, surgical technique, bone quantity, and bone quality influence primary stability (Meredith 1998; Quesada-García et al., 2009). After implantation, a sequence of events in the osseointegration process occurs at the bone / implant interface, leading to a reduction in primary stability (Fini et al., 2004), which is gradually replaced by the secondary biological stability provided by deposition of newly formed bone around the implant body (Atsumi et al., 2007).

The stability of the implant can be assessed clinically by non-invasive quantitative methods such as insertion torque (Johansson & Strid 1994) and Resonance Frequency Analysis (RFA) (Meredith et al., 1997). Described by Johansson & Strid (1994), the insertion torque registers the torque required for implant installation. A high insertion torque indicates that the implant is well fixed and mechanically stable (Johansson & Strid 1994; Nedir et al., 2004).

RFA was introduced by Meredith et al. (1997) as a technique in which the rigidity at the bone/implant interface is calculated from the resonance frequency as a reaction to the oscillations that impinge on the bone / implant system. RFA measurements are performed by the Osstell® apparatus and are expressed in ISQ (Stability Coefficient of Implant), indicating a stability degree on a scale of 1 (less stability) to 100 (greater

stability) (Sennerby & Meredith 2008). The technique allows the monitoring of changes in stability and stiffness at the implant / bone tissue interface, from the time of implantation to the final stages of osseointegration (Zix et al., 2008; Kahraman et al., 2009).

Although RFA and insertion torque are associated with the assessment of implant stability, these techniques measure distinct mechanical characteristics. The insertion torque measures the frictional mechanical resistance generated at the bone / implant interface during the rotational movement of the implant on the longitudinal axis, in the apical direction. The RFA, whose result is expressed in ISQ, represents the contact rigidity of the implant with the receptor bone bed and its resistance to lateral displacement (Brizuela-Velasco et al., 2015).

In this context, studies evaluating the possible correlation between insertion torque and RFA have been conducted, and these describe contradictory results as positive correlation (Türkyilmaz 2006; Türkyilmaz et al., 2009; Brizuela-Velasco et al., 2015) or absence of correlation (Friberg et al., 1999; Da Cunha et al., 2004; Akça et al., 2010; Fuster-Torres et al. 2011).

Thus, the present study aims to compare the primary stability and secondary stability, measured by RFA, of Neodent Titamax Ti® implants of different lengths installed in the posterior maxilla in areas previously submitted to maxillary sinus elevation, as well as to evaluate the existence of a correlation between the results of the RFA and the insertion torque in the evaluation of the primary stability of the implants.

Material and methods

Study Design

This Clinical Observational Study evaluated 20 implants (twelve 9 mm implants and eight 11 mm implants), installed in 9 patients previously submitted to maxillary sinus elevation using Bio-Oss® biomaterial (Figure 1). The patients were selected at the Implant Dentistry Clinic of the Graduate Program in Dentistry of the Pontifical Catholic University of Minas Gerais. This study was approved by the Research Ethics Committee of the Pontifical Catholic University of Minas Gerais (CAAE 53955215.0.0000.5137).

Inclusion and exclusion criteria

Patients previously submitted to maxillary sinus elevation using Bio-Oss® biomaterial after a 6-month follow-up period were included in the study. The following exclusion criteria were adopted: I) patients presenting any type of systemic disease that contraindicated surgical procedures at the time of installation of the dental implants; II) smokers; III) patients with active periodontal disease; IV) patients showing a graft remnant that made impossible to install implants at least 9 mm long and 3.75 mm in diameter (graft remnant after the repair period and evaluated by computed tomography).

Surgical procedure

Patients were submitted to face antisepsis with chlorhexidine gluconate (2%) and oral solution with chlorhexidine mouthwash (0.12%) and local anesthesia with 2% lidocaine and epinephrine (1/100,000). The surgical procedure was performed according to the protocol of the Neodent company (Curitiba, Brazil). With the use of

the Bien Air® engine (iChiropro, Bienne, Switzerland), 20 Titamax Ti implants with an external hexagonal interface, a diameter of 3.75 mm, and a length of 9 mm or 11 mm were installed in the posterior region of the maxilla previously submitted to elevation of the maxillary sinus using Bio-Oss® biomaterial.

Measurement of insertion torque

The Bien Air® electronic motor (iChiropro, Bienne, Switzerland) was used to measure the insertion torque of the implants at the time of installation. This motor was designed to register the insertion torque (expressed in N • cm) at the same time as the implant installation. The recording of the insertion torque was completed as soon as the implant reaches its final position and its rotation was interrupted by friction with the peri-implant bone tissue.

ISQ measurement

After the implants were installed, the evaluation of their primary stability was performed using the Osstell® device. This apparatus, through the RFA, then determined the ISQ. For this measurement, a specific Smartpeg for the implant model used was adapted to the implant, and the device was brought close to it without touching it, following the manufacturer's recommendations. Three measurements were performed, separated by intervals of 5 seconds, from which the median value was used to analyze the data. The RFA measurements were made by the same operator at two points in time: T1) immediately after implant installation, and T2) 90 days after implant installation.

Statistical analysis

A D'Agostino-Pearson normality test showed that the data of the variables Implant Stability Quotient (ISQ) and insertion torque have a normal distribution.

The paired t-test was performed to assess the existence of differences in ISQ between T1 and T2. This analysis was performed separately: a) for implants grouped independently of their length (9 mm or 11 mm), b) for the 9 mm implants, and c) for the 11 mm implants.

A Student's t-test was performed to assess any differences in ISQ between the 9 mm implants and the 11mm implants. This analysis was performed separately on T1 and T2. A Student's t-test was also performed to assess the existence of differences in T1 insertion torque between the 9 mm implants and the 11mm implants.

The Pearson correlation test was used to evaluate the existence of a correlation between ISQ and "insertion torque" in T1. This analysis was performed separately: a) for implants grouped independently of their length (9 mm or 11 mm), b) for the 9 mm implants, and c) for the 11 mm implants.

The level of significance was set at 5%. Analyses were performed using GraphPad Prism 6.05 software (GraphPad Software, San Diego, California, USA).

Results

In T1, when the implants were grouped (9 mm and 11 mm), the ISQ presented a mean of 62.55 and a standard deviation of 8.88. In T2, this variable had a mean of 62.60 and a standard deviation of 10.81. No statistically significant difference was observed in the ISQ between T1 and T2 ($p > 0.05$; Table 1; Figure 2A).

When the 9 mm implants were evaluated separately, the ISQ presented a mean of 65.83 in T1 and a standard deviation of 6.74. In T2, this variable had a mean of 58.67 and a standard deviation of 11.80. No statistically significant difference was observed in the ISQ between T1 and T2 ($p > 0.05$; Table 1, Figure 2B).

When the 11 mm implants were evaluated separately, the ISQ presented a mean of 57.63 in T1 and a standard deviation of 9.84. In T2, this variable had a mean of 68.50 and a standard deviation of 5.65. The ISQ was statistically higher in T2 than in T1 ($p < 0.05$, Table 1, Figure 2C).

When evaluating the existence of differences in ISQ between 9 mm and 11 mm implants in T1, the 9 mm implants had a statistically higher ISQ (65.83 ± 6.74) than the 11 mm implants did (57.63 ± 9.84) ($p < 0.05$, Table 1, Figure 2D). In T2, the 11 mm implants had a statistically higher ISQ (68.50 ± 5.65) than the 9 mm implants did (58.67 ± 11.80) ($p < 0.05$, Table 1, Figure 2E).

In the insertion torque evaluation, no statistically significant difference was observed between the 9 mm (28.93 ± 5.24) and the 11 mm (27.39 ± 4.40) implants ($p > 0.05$, Figure 2F).

No correlation between ISQ and insertion torque was observed in T1 for implants grouped independently of their length ($p > 0.05$, $r = 0.17$, Figure 2G), for those of 9 mm ($p > 0.05$, $r = 0.10$, Figure 2H) or for those of 11 mm ($p > 0.05$, $r = 0.13$, Figure 2I).

Discussion

The purpose of the present study was to evaluate, through RFA and insertion torque, the stability of implants installed in the posterior region of the maxilla in areas previously submitted to maxillary sinus elevation using Bio-Oss®.

Mechanical tests and radiographic examinations, as well as histological and histomorphometric analyses, are used to evaluate osseointegration at the bone-implant interface. In particular, insertion torque and RFA are methods used for clinical evaluation of primary implant stability (Degidi et al., 2013).

In general, ISQ values are predictive of implant stability when evaluated repeatedly over a period of time (Zix et al., 2005). The measurement of ISQ at two points in time (T1 and T2) represents a way of comparing the primary stability and secondary stability of implants (Katsoulis et al., 2012). In the present study, primary stability was measured at time of implantation (T1) and after 3 months (T2) to assess the possible impact of changes that occur around implants during osseointegration. When the implants were grouped (9 mm and 11 mm), no statistically significant difference was observed in the ISQ between T1 (62.55 ± 8.88) and T2 (62.60 ± 10.81) ($p > 0.05$, Table 1, Figure 2A). Similar results were found by Rabel et al. (2007), whose study evaluated the stability of two implant systems and found no significant difference between the mean values of ISQ obtained in the immediate postoperative period and after 3 months of osseointegration when considering the total number of implants.

Rasmusson et al. (2012), in a prospective study, compared the stability of implants installed in grafted and ungrafted areas. Patients submitted to bilateral maxillary sinus elevation with particulate bone showed an initial ISQ of 61.1 ± 5.5 , a result similar to that found in our study, where we obtained a mean ISQ value at T1 of 62.55 ± 8.88 . In addition, as observed in our study, no statistically significant difference was found between the values of ISQ obtained in the first and second measurements (T1 and T2), when considering the total number of implants.

Antunes et al. (2013), when conducting a study in dogs to evaluate the stability of implants installed in bone defects treated with Bio-Oss®, obtained a mean initial ISQ value of 66.22 and a final value (after two months) of 63.00, similar values to those found in our study.

In the present study, when the 9 mm implants were evaluated separately, no statistically significant difference was observed in the ISQ between T1 and T2 ($p > 0.05$, Table 1, Figure 2B). However, when the 11 mm implants were evaluated separately, a statistically higher ISQ in T2 than in T1 was found ($p < 0.05$, Table 1, Figure 2C). According to Olsson et al. (2003) and Balshi et al. (2005), implants installed with high levels of primary stability do not reach the initial level of stability at a later second measurement (secondary stability). These authors also observed that implants with lower levels of primary stability tend to maintain or exceed the initial stability level at a later time. The findings of these authors are in line with our results, which showed that, even if the 9 mm implants had a statistically higher ISQ in T1 than the 11 mm implants did ($p < 0.05$; Table 1, Figure 2D), after a 3-month period (T2), they did not reach the initial level of stability, instead presenting a statistically lower ISQ than the 11 mm implants had ($p < 0.05$; Table 1, Figure 2E). In fact, only the 11 mm implants showed a statistically significant increase in the ISQ from T1 to T2 ($p < 0.05$; Table 1, Figure 2C).

Since there was a statistically significant difference in ISQ between the 9mm (58.67 ± 11.80) and 11mm (68.50 ± 5.65) implants ($p > 0.05$, Table 1, Figure 2E) in T2 (3 months after implantation), our results suggest that implant length was a factor that influenced ISQ values during osseointegration, considering that: 11mm implants exhibited a statistically significant increase in the ISQ from T1 (57.63 ± 9.84) to T2 (68.50 ± 5.65) ($p < 0.05$, Table 1, Figure 2C); the 9 mm implants did not show a

statistically significant difference in ISQ when comparing T1 and T2 ($p < 0.05$, Table 1, Figure 2B). Sim & Lang's (2010) longitudinal evaluation of the factors that influence RFA in Straumann implants of 8 and 10mm in length showed, during osseointegration, a continuous increase in ISQ values in 8mm implants and no significant alteration of ISQ in implants of 10 mm, the opposite results of those observed in our study.

In the present study, insertion torque values were recorded during implant installation, with no difference in insertion torque between 9mm implants and 11mm implants ($p > 0.05$; Figure 2F). These values were also used to evaluate the existence of a correlation between ISQ and insertion torque. No correlation was observed between ISQ and insertion torque at T1 for the implants evaluated, independently if they were grouped (9 mm and 11 mm implants, $p > 0.05$, $r = 0.17$, Figure 2G) or separated into 9 mm implants ($P > 0.05$, $r = 0.10$, Figure 2H) and 11 mm ($p > 0.05$, $r = 0.13$, Figure 2I). An absence of association between ISQ and insertion torque was also found in previous studies. Stubinger et al. (2015), in a study carried out on an animal model, found no correlation between the measures of torque (insertion and removal) and ISQ values. Friberg et al. (1999), when comparing insertion torque and ISQ measured in implants installed in the maxilla, found a significant correlation only in the cervical third of the implants. However, its final results also showed no general correlation between insertion torque and ISQ. Da Cunha et al. (2004), using two implant systems that were implanted in the maxilla and submitted to immediate loading, did not observe a correlation between the values of insertion torque (obtained by OsseCare® motor) and ISQ (measured by Osstell®) either. Dagher et al. (2014) evaluated the existence of a correlation between RFA, insertion torque, and BIC (bone-implant contact) in implants with four different surfaces (SLA®,

SLActive®, TiUnite®, and Euroteknika®). A significant positive correlation between RFA and insertion torque was found only in the SLA group. Regardless of the type of implant surface, there was no correlation between RFA and BIC or between insertion torque and BIC. The absence of a correlation between RFA and insertion torque observed in our study and in the previously reported studies can be explained by the fact that, although RFA and insertion torque assess the primary stability of implants, these methods represent distinct characteristics: RFA is associated with resistance to bending stress, which resembles the direction of the clinical load, and the insertion torque represents resistance to shear forces (Sennerby & Meredith 2000). However, studies that show a positive correlation between ISQ and insertion torque are also described in the literature (Kahraman et al., 2009, Turrizilmaz et al., 2009, Brizuela-Velasco et al). In this context, in a clinical study, Türkyilmaz et al. (2006) also found a positive correlation between ISQ and insertion torque.

The main limitation of our study is its limited sample size. Regardless, our results are similar to those of previous studies where a correlation between the stability measurements obtained by RFA techniques and insertion torque was not observed.

In conclusion, the results showed that, when installed in areas previously submitted to maxillary sinus elevation, longer implants (11 mm) presented a significant increase in ISQ values during the healing period. This phenomenon was not observed for shorter implants (9 mm). Finally, we did not observe any correlation between the stability measurements obtained by RFA and implant insertion torque.

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Table 1. Mean and standard deviation of the ISQ of implants grouped (9 mm and 11 mm), implants of 9 mm, and implants of 11 mm.

Implants	T1		T2		Mean of differences	<i>p value</i> ¹
	Mean	SD	Mean	SD	(T2-T1)	
9 and 11 mm	62.55	8.88	62.60	10.81	0.05	n.s.
9 mm	65.83	6.74	58.67	11.80	-7.16	n.s.
11 mm	57.63	9.84	68.50	5.65	10.87	<0.05
	<0.05		<0.05			

¹ p value obtained by the paired t-test: T2 *versus* T1

² p value obtained by the Student's t-test: 9 mm *versus* 11 mm

n.s. = not significant (p >0.05)

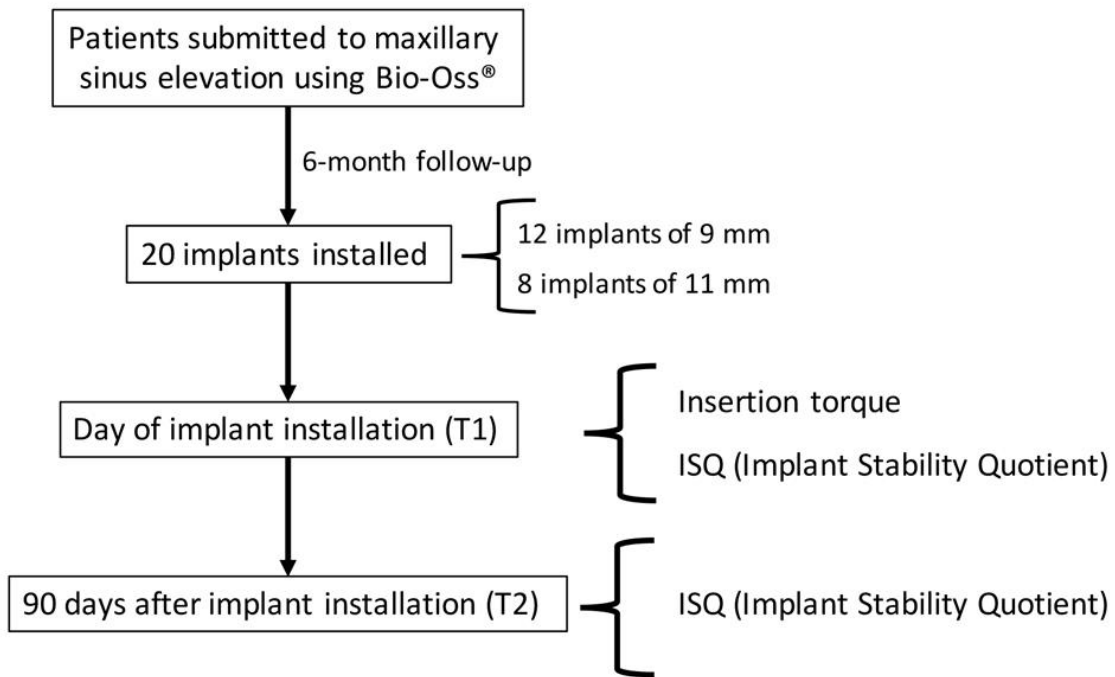


Figure 1. Study design.

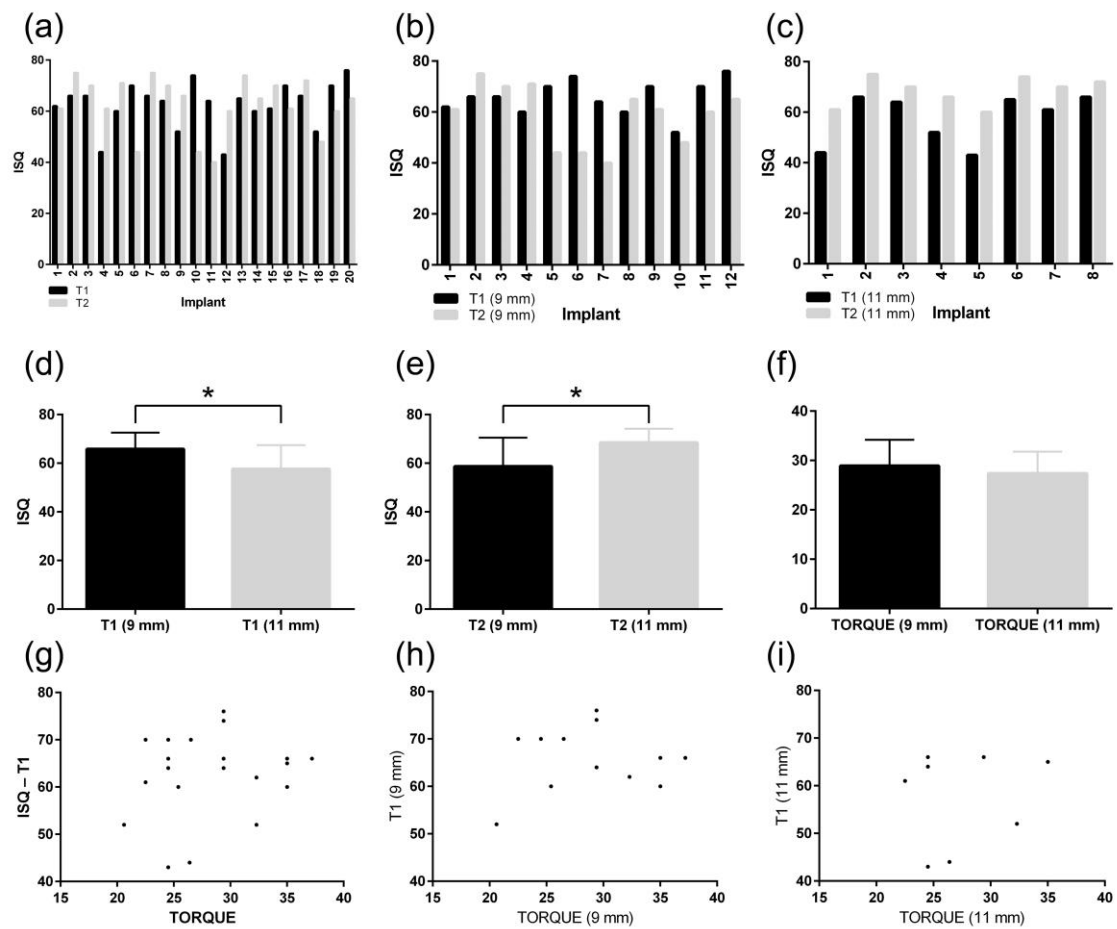


Figure 2. ISQ in T1 and T2 in: the twenty implants evaluated (9 mm and 11 mm implants) (a); the twelve 9 mm implants (b); the eight 11 mm implants (c). Mean and standard deviation of: the ISQ in T1 and its comparison between 9 mm and 11 mm implants (* $p < 0.05$) (d); the ISQ in T2 and its comparison between 9 mm and 11 mm implants (* $p < 0.05$) (e); the insertion torque and its comparison between 9 mm and 11 mm implants (f); Dispersion diagram of the correlation between ISQ and insertion torque in T1 of: implants of 9 mm and 11 mm (g); implants of 9 mm (h); implants of 11 mm (i).

4 CONSIDERAÇÕES FINAIS

Avaliamos a estabilidade primária e secundária de implantes Neodent Titamax Ti®, de diferentes comprimentos, instalados em sítios submetidos à elevação de seio maxilar. A estabilidade primária foi mensurada por meio do torque de inserção e também pela análise de frequência de ressonância (ARF), os métodos mais empregados na literatura. A estabilidade secundária foi mensurada pela ARF. Consideramos também relevante avaliar a existência de correlação entre os valores obtidos por esses dois métodos, durante a avaliação da estabilidade primária. Nossos resultados nos permitem concluir que, na região posterior da maxila, em áreas previamente submetidas à elevação de seio maxilar:

- a) implantes mais longos, com comprimento de 11 mm, apresentaram aumento estatisticamente significativo do ISQ durante o período de osseointegração;
- b) implantes mais curtos, com comprimento de 9 mm não apresentaram diferenças estatisticamente significantes no ISQ durante o período de osseointegração;
- c) implantes de 9 mm e 11 mm, quando avaliados conjuntamente, não apresentaram diferenças estatisticamente significantes no ISQ durante o período de cicatrização;
- d) não foi observada correlação entre ARF e torque de inserção na avaliação da estabilidade primária, independentemente do comprimento do implante.

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ANEXO A - Parecer Consubstanciado do CEP

PONTIFÍCIA UNIVERSIDADE
CATÓLICA DE MINAS GERAIS -
PUCMG



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO DA ESTABILIDADE DOS IMPLANTES INSTALADOS EM PACIENTES SUBMETIDOS À ELEVAÇÃO DO SEIO MAXILAR POR MEIO DE DIFERENTES BIOMATERIAIS

Pesquisador: Karine Camara

Área Temática:

Versão: 1

CAAE: 53955215.0.0000.5137

Instituição Proponente: Pontifícia Universidade Católica de Minas Gerais - PUCMG

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.476.294

Apresentação do Projeto:

Trata-se de um Estudo Clínico Observacional no qual serão selecionados pacientes da Clínica de Implantodontia do Programa de Pós-graduação em Odontologia da Pontifícia Universidade Católica de Minas Gerais, submetidos à cirurgia de elevação do seio maxilar com diferentes biomateriais. Serão instalados implantes de conexão externa na região posterior da maxila, submetida previamente à elevação do seio maxilar. Após a instalação dos implantes será realizada a avaliação da estabilidade.

Objetivo da Pesquisa:

Objetivos:

- Avaliar a estabilidade de implantes instalados na região posterior da maxila em áreas onde foram realizadas elevação do seio maxilar utilizando os biomateriais Bio Oss e Cerasor.

Avaliação dos Riscos e Benefícios:

Riscos: O objeto da pesquisa não representa nenhum risco aos participantes nem altera o curso do tratamento reabilitador.

Benefícios: A Análise de Frequência de Ressonância (ARF) tem se mostrado uma técnica viável (não

Endereço: Av. Dom José Gaspar, 500 - Prédio 03, sala 228

Bairro: Coração Eucarístico **CEP:** 30.535-901

UF: MG **Município:** BELO HORIZONTE

Telefone: (31)3319-4517

Fax: (31)3319-4517

E-mail: cep.proppg@pucminas.br

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Continuação do Parecer: 1.476.294

invasiva, confiável e clinicamente aplicável) que permite o monitoramento de alterações na estabilidade do implante ao longo do tempo.

Comentários e Considerações sobre a Pesquisa:

Relevante.

Considerações sobre os Termos de apresentação obrigatória:

Folha de rosto OK

Termo de consentimento presente

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:

Aprovado.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_P ROJETO_644363.pdf	08/03/2016 21:17:36		Acelto
Folha de Rosto	Folhaderosto.pdf	08/03/2016 21:13:56	Karine Camara	Acelto
TCLE / Termos de Assentimento / Justificativa de Ausência	Termodeconsentimentodols.doc	07/03/2016 23:43:33	Karine Camara	Acelto
Orçamento	ORCAMENTO.doc	24/12/2015 18:13:12	Karine Camara	Acelto
Projeto Detalhado / Brochura Investigador	ProjetoPesquisa.doc	24/12/2015 18:11:58	Karine Camara	Acelto
Cronograma	CRONOGRAMA.doc	24/12/2015 18:11:16	Karine Camara	Acelto

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

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

PONTIFÍCIA UNIVERSIDADE
CATÓLICA DE MINAS GERAIS -
PUCMG



Continuação do Parecer: 1.476.294

BELO HORIZONTE, 04 de Abril de 2016

Assinado por:
CRISTIANA LEITE CARVALHO
(Coordenador)

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

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