Universidade Federal de Uberlândia - UFU
Faculdade de Odontologia
Pós-Graduação em Odontologia

Pablo Pádua Barbosa

Efeito de diferentes macroestruturas e microestruturas sobre a estabilidade primária e secundária de implantes dentários

Effect of different macrostructures and microstructures on the primary and secondary stability of dental implants

Tese apresentada à Faculdade de Odontologia da Universidade Federal de Uberlândia, para obtenção do Título de Doutor em Odontologia na Área de Clínica Odontológica Integrada.

Uberlândia, Dezembro 2021

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Dedicatória

Dedico esta tese primeiramente a Deus a minha família, pais, filhos, irmãos e esposa meu alicerce, meus exemplos e meu amor

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SUMÁRIO

Lista de abreviaturas:

DAS: Double acid-etching and sandblasting

DAS-H: Double acid-etching and sandblasting Hidrophilic

ISQ: Implant stability quotient

RFA: Resonance frequency analysis

RCTS: Randomized controlled clinical trials

PROSPERO: Prospective Register of Systematic Reviews

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

IV: Inverse variance

RR: Risk Ratio

MD: Mean Diference

CI: Confidence intervals

MH: Mantel–Haenszel

CRTgroup: Control group

TESgroup: Test group

RESUMO

A estabilidade primária e secundária são pilares importantes para evolução do processo de osseointegração e para obtenção de sucesso na reabilitação com implantes. Diversos fatores podem influenciar na obtenção desta estabilidade primária e secundária, alguns relacionados ao paciente e outros relacionados aos implantes. A melhoria da micro e macroestrutura dos implantes influenciam diretamente na obtenção de boa estabilidade primária e secundária. Porém ainda há divergência na literatura sobre quais fatores exercem mais influência clínica na estabilidade. Portanto se faz necessário avaliar clinicamente a influência da macroestrutura e microestrutura no processo de obtenção da estabilidade primária e secundária. Dessa forma, essa tese visou, por meio de estudos clínicos e revisão de literatura, avaliar o efeito de superfícies hidrofílicas e de macroestrutura de implantes (com perfil heterógeno de roscas) sobre a estabilidade primária e secundária dos implantes. A tese foi dividida em 3 capítulos. **Objetivo específico 1**: *Estabilidade primária e secundária de implantes com superfície hidrofílica em posterior de maxila: Estudo de clínico randomizado de boca dividida.* Nesse estudo foi avaliado 2 tipos de microestrutura de implantes com a mesma macroestrutura em região posterior de maxila. **Objetivo específico 2***: Existe diferença entre a estabilidade primária, secundária e taxa de sobrevivência em implantes hidrofílicos comparados a não hidrofílicos ? Revisão sistemática meta-análise.* Este estudo analisou os artigos clínicos existentes comparando os resultados da estabilidade primária e secundária e taxa de sobrevivência. **Objetivo específico 3:** *Estabilidade primária e secundária de implantes híbridos com diferentes configurações de roscas.* Estudo clínico controlado e randomizado em modelo de boca dividida. Este estudo analisou implantes com macroestrutura diferentes, sendo dois implantes híbridos um deles com roscas perfurantes e outro com roscas perfurantes e condensantes. Após análises dos resultados desses estudos, pode-se concluir que a macroestrutura teve maior influência clínica na estabilidade primária e secundária comparado a microestrutura. Os estudos clínicos pré-existentes não demonstraram diferença estatística dos implantes hidrofílicos de mesma macroestrutura comparados a não hidrofílicos. Com relação a taxa de sobrevivência, não houve diferença na comparação entre

estudos com superfície hidrofílica comparados a não hidrofílica. Implantes com superfície hidrofílica, porém com diferentes características macroestruturais apresentaram estabilidade diferente durante o processo de osseointegração. É necessário realizar estudos relacionados as microestruturas, em condições as quais, elas possam exercer uma melhoria significativa, como e fatores complicadores, pacientes com doenças no metabolismo ósseo, tabagistas, diabéticos entre outros.

Palavras-Chaves: Estabilidade, macroestrutura, osseointegração, superfícies de implante

ABSTRACT

Primary and secondary stability are important pillars for the evolution of the osseointegration process and for achieving successful in the implant rehabilitation. Several factors can influence the achievement of this primary and secondary stability. Improvements in the micro and macrostructure of implants directly influence the achievement of a good primary and secondary stability. However, there is still a lot of divergence in the literature about which factors exert more clinical influence on the implant's stability. Therefore, it is still necessary to evaluate the influence of macrostructure and microstructure in the process of obtaining primary and secondary stability. Thus, this thesis aimed, through clinical studies and a systematic literature review, to evaluate the effect of a hydrophilic implant surface and a hybrid implant macrostructure (cylindrical-conical with heterogeneous thread profile) on the primary and secondary stability of the implants. The thesis was divided into 3 chapters according to the specific objective that generated the 3 studies in this manuscript. Objective Specific 1: Primary and secondary stability of implants with hydrophilic surface in posterior maxilla: Split-mouth randomized clinical trial. In this study, 2 types of implant microstructure with the same macrostructure in the posterior maxilla were evaluated. Specific objective 2: Is there a difference between primary and secondary stability and survival rate in hydrophilic compared to non-hydrophilic implants? Systematic review meta-analysis. This study analyzed existing clinical articles comparing the results of primary and secondary stability and survival rate. Specific objective 3: Primary and secondary stability of hybrid implants with different thread configurations. Controlled and randomized clinical study in a split-mouth model. This study was an analysis of implants with different macrostructure, a conical compared to a hybrid, with the same microstructure in the maxilla. After analyzing the results of these studies, it can be concluded that the macrostructure had a greater clinical influence on primary and secondary stability compared to the microstructure. Pre-existing clinical studies showed no statistical difference between hydrophilic implants of the same macrostructure compared to non-hydrophilic ones. Regarding the survival rate, there was no

difference when comparing studies with a hydrophilic surface compared to a non-hydrophilic one. Implants with a hydrophilic surface, but with different macrostructural characteristics showed different stability during the osseointegration process. It is necessary to carry out studies related to microstructures, under conditions in which they can exert a significant improvement, such as complicating factors, patients with bone metabolism diseases, smokers, diabetics, among others.

Keywords: Implant surfaces, macrostructure, osseointegration, stability,

1 INTRODUÇÃO E REFERENCIAL TEÓRICO

A estabilidade do implante é fator essencial para o processo de cicatrização, osseointegração e sucesso dos implantes (Ryu *et al.,* 2015). A estabilidade do implante pode ser representada pelo tempo e mecanismo de cicatrização como estabilidade primária e secundária (Simunek *et al.*, 2010). A estabilidade primária é conhecida como retenção mecânica na colocação do implante, enquanto a estabilidade secundária está relacionada à resposta biológica subsequente resultante da consolidação óssea na interface osso-implante (Atsumi *et al.,* 2007).

A modificação das superfícies dos implantes tem sido proposta para potencializar o processo de osseointegração em osso nativo (Buser *et al.,* 2004; Pimentel *et al.,* 2016). Visando reduzir o tempo de realização de procedimentos protéticos (Nicolau *et al.,* 2019), bem como aumentar a previsibilidade de tratamento com implantes osseointegrados em condições clínicas desafiadoras, como osso de baixa densidade, fumantes e / ou pacientes diabéticos não controlados (Sayardoust *et al*., 2013; Khandelwal *et al*., 2014).

Modificações estruturais nos implantes têm propostas para otimizar o processo de osseointegração, modificações podem ser executadas na macroestrutura ou na microestrutura dos implantes (Buser *et al*., 2004; Lang *et al*., 2011; Oliveira *et al*., 2016; Leocádio *et al*., 2020). As modificações na macroestrutura influenciam de forma mais direta a estabilidade primária e a decisão de se estabelecer a aplicação da carga imediata (Torroella-Saura *et al*., 2015; Oliveira *et al*., 2016; Makary *et al*., 2019). As modificações microestruturais estão relacionadas com a aceleração da conversão da estabilidade primária em

secundária devido a estímulos biológicos no processo de osseointegração (Lang *et al*., 2011; Sartoretto *et al*., 2017; Velloso *et al*., 2018; Hamlet *et al*., 2019)

Sobre a macroestrutura, estudos demonstraram que os implantes cônicos têm estabilidade primária superior quando comparados aos implantes cilíndricos (Sakoh *et al.,* 2006; Torroella-Saura *et al*., 2015), podendo também acelerar o processo de osseointegração (Torroella-Saura *et al*., 2015).

Entretanto, esses implantes podem exacerbar o grau de estabilidade primária em ossos mais densos, Além disso, o grau de compressão gerado pelo implante é muito alto e pode causar dano celular local no osso cortical. Sabe-se que compressão muito alta do osso causa morte celular, necrose e, em última análise, pode levar à reabsorção óssea na camada óssea cortical (Soltesz *et al*.,1982; Huiskes *et al.,* 1984). Dessa forma, implantes de estrutura híbrida (Baldi *et al*., 2018), que são cilíndricos em sua porção coronal e cônicos na porção apical, têm sido propostos como alternativa para serem utilizados em qualquer tipo de osso (Leocádio *et al*., 2020; Barbosa *et al*., 2021).

A análise de frequência de ressonância é um método não invasivo indicado para avaliar a progressão da avaliação do processo de osseointegração através da evolução da conversão da estabilidade primária para a secundária (Oliveira *et al*., 2016), sendo assim importante método para determinar o momento em que os implantes alcançaram estabilidade suficiente para serem reabilitados (Almassri *et al.,* 2020).

Apesar dos efeitos descritos das superfícies hidrofílicas no aumento e aceleração da osseointegração, a comparação clínica desses tipos de implantes com as superfícies não hidrofílicas apresenta resultados contraditórios. Revisões sistemáticas anteriores avaliaram o efeito das superfícies hidrofílicas no sucesso

e nas taxas de sobrevivência dos implantes dentários. Makowiecki *et al.,* 2019 mostraram que implantes com alto nível de hidrofilia apresentam redução da perda óssea peri-implantar e altas taxas de sobrevida. Norton & Åström, 2020 também mostraram perda óssea limitada associada a implantes hidrofílicos em 1-5 anos de acompanhamento. No entanto, ambas as revisões compararam implantes com diferentes macroestruturas limitam a compreensão do real efeito das superfícies hidrofílicas no sucesso dos implantes dentários. Além disso, apesar desses bons resultados, isso não é superior aos resultados observados com superfícies não hidrofílicas (Şener-Yamaner *et al.,* 2017; Almassri *et al.,* 2020). Outra revisão de literatura não encontrou diferenças estatísticas em relação a estabilidade primária, secundária e taxa de sobrevivência, quando comparou implantes com mesma macroestrutura e superfícies hidrofílicas comparada a não hidrofílicas (Huthayfa *et al.,* 2020). Isso significa que após o estabelecimento da osseointegração, as superfícies hidrofílicas não agregam vantagens significativas em comparação com outras superfícies.

Apesar de alguns estudos terem demonstrado superioridade na estabilidade primária e secundária na utilização de implantes cônicos, alguns estudos não encontrou diferença na estabilidade de implantes cônicos comparadas a implantes cilíndricos hidrofílicos (Ryu *et al.,* 2015).

Portanto em virtude de resultados divergentes em estudos clínicos, não havendo consenso na literatura, se faz necessário estabelecer melhor a influência dos fatores micro e macrogeométicos dos implantes na obtenção da estabilidade primária e secundária. Sendo necessários a realização mais estudos clínicos especificando comparação microestrutural ou macroestrutural.

E também realizar análises mais detalhadas e atuais dos resultados de estudos existentes, justificando a tese realizada.

2. OBJETIVO GERAL

Avaliar o efeito de uma superfície de implante hidrofílica e de uma macroestrutura de implante híbrida sobre a estabilidade primária e secundária dos implantes e análise de sobrevivência

2.1. Objetivo específico 1*: Estabilidade primária e secundária de implantes com superfície hidrofílica em posterior de maxila: Um estudo clínico controlado randomizado de boca dividida.*

Avaliar, por meio de estudo clínico, se a microgeometria, de superfície hidrofílica, gera melhores resultados clínicos de estabilidade primária e secundária comparados com superfície não hidrofílica em região de posterior de maxila.

2.2. Objetivo específico 2: *Há diferenças entre estabilidade primária, secundária e taxa de sobrevivência de implantes hidrofílicos comparados a implantes não hidrofílicos? Revisão Sistemática de Literatura e Meta-análise.*

Avaliar, por meio de revisão sistemática de literatura e meta-análise, se os estudos clínicos pré-existentes possuem diferenças estatísticas em seus resultados clínicos, com relação a estabilidade primária, secundária e taxa de sobrevivência, comparando implantes com superfície hidrofílica a implantes não hidrofílicos.

2.3. Objetivo específico 3: *Estabilidade primária e secundária de implantes híbridos com diferentes configurações. Um estudo clínico controlado randomizado de modelo de boca dividida.*

Avaliar a influência da macroestrutura de implantes com desing híbrido, com roscas triangulares e quadradas, comparados a híbridos com roscas triangulares, na obtenção clínica da estabilidade primária e secundária e taxa de sobrevivência.

3. HIPÓTESES

Hipótese nula: Superficies hidrofílicas e associação de roscas perfurantes e compressivas não alteram a estabilidade primária e secundária de implantes;
Hipótese alternativa: Superficies hidrofílicas e associação de roscas perfurantes e compressivas alteram a estabilidade primária e secundária de implantes;

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Primary and secondary stability of implants with hydrophilic surfaces in the posterior maxilla: A split-mouth randomized controlled clinical trial.

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Abstract

Purpose: The aim of this split-mouth randomized clinical trial was to evaluate the primary and secondary stability of implants with hydrophilic surfaces in comparison with implants with conventional surfaces in the posterior region of the maxilla. **Materials and Methods:** Twenty patients with a bilateral edentulous ridge in the posterior area of the maxilla randomly received implants with two types of surfaces: 1) implants with surface modified by double acid-etching and sandblasting (DAS, n= 20); 2) implants with surface modified by double acid-etching and sandblasting, stored in 0.9% saline solution to confer highly hydrophilic properties (DAS-H, n= 20) on the surface. The implants presented the same macrostructure with a hybrid design. The resonance frequency analysis was performed in order to obtain the implant stability quotient (ISQ) using Osstell®. The ISQ analyses were performed just after placement of the implant (Primary stability) and at the 28, 40, and 90 days after the surgical procedure (Secondary stability). **Results:** There were no differences between the DAS and DAS-H surfaces in the primary stability or during the conversion of the primary to the secondary stability, however, there was a reduction in the stability of the implants at the 28-day period, which returned to the baseline level at 40 and 90-days in both surfaces. **Conclusion:** It can be concluded that the surface wettability of implants with hybrid macrostructure did not increase the primary and secondary implant stability in the posterior region of the maxilla.

Keywords: dental implants, implant surface, stability.

Introduction

The modification of implant surfaces has been proposed to enhance the osseointegration process in native bone (1-3) or improve it in grafted areas (4), aiming to reduce the time to perform prosthetic procedures (5), as well as increase the predictability of treatment with osseointegrated implants in challenging clinical conditions such as low-density bone, smokers, and/or uncontrolled diabetic patients (6, 7).

Modifications proposed to improve the physical property of wettability of the implants should be considered (8), since these surfaces may improve the adhesion, proliferation, and osteoblastic differentiation (9, 10), which could accelerate the process of bone formation and mineralization (8, 9).

Double acid-etched and sandblasted surfaces stored in 0.9% saline solution present highly hydrophilic properties (DAS-H)(10). Some preclinical findings in animals showed that implants with a hydrophilic surface increased the removal torque, bone apposition, and healing during the early stages of osseointegration(1, 11, 12), as well as which, osseointegration was improved in grafted areas with different osteoconductive bone substitutes in relation to implants with unmodified surfaces(4). A clinical study has also shown that the degree of osseointegration was superior with hydrophilic surfaces in the early phase in humans(2).

The implant stability quotient (ISQ) is an indirect method of analysis to verify the primary and secondary stability of implants (3, 13-17). However, results have been controversial, since some authors verified higher and faster stability

during the healing period for hydrophilic surface implants (17), while other findings did not evidence better results for clinical stability (6).

The posterior region of the maxilla is considered critical for the obtention of primary stability due to its lower bone density compared to the other regions of the oral cavity, e.g. mandible bone, and this area is more likely to have greater impacts due to the effect of different implant surfaces to achieve bone healing (3). Thus, this area is considered more challenging in obtaining the osseointegration process(18, 19). Therefore, the aim of this split-mouth randomized controlled clinical trial was to evaluate the primary and secondary stability of DAS-H dental implants compared to double acid-etching and sandblasting(DAS) surfaces in the posterior region of the maxilla.

Material and Methods

Ethical Considerations

This study was submitted to and approved by the ethical committee for human research of the under protocol 1.765.515.

Study design and Sample

This split-mouth randomized clinical trial consisted of preoperative preparation of all patients through non-surgical periodontal treatment, biofilm controls, and restorations performed and completed 15 days before the surgical procedure. A tomographic examination was also performed at the same time for planning the surgical procedure.

Twenty patients who had undergone a bilateral edentulous ridge in the posterior region (premolars and molars) of the maxilla participated in this study after signing the informed consent form, and were allocated to two groups: 1) implants modified by double acid-etching and sandblasting (DAS) (Neoporos

surface, Neodent, Curitiba, Brazil), and 2) implants modified by double acid-etching and sandblasting and stored in 0.9% saline solution to confer highly hydrophilic properties (DAS-H) to the surface (Acqua Surface, Neodent, Curitiba, Brazil). The implants presented the same macrostructure, were the same size (3.75 mm x 9.0mm), and had the same prosthetic connection (Morse taper), and design (Hybrid – cylindrical in the cervical and middle portion and conical at the apex portion) (Titamax EX CM, Neodent, Curitiba, Brazil). The selection of the implants to be placed in each surgical site was defined randomly by lot at the time of the surgeries. The program Research Randomizer (https://www.randomizer.org/) was used to draw the implant installation in the first or second quadrant of the posterior region of the maxilla (premolars and molars). The installation sites were drawn bilaterally in a split-mouth design, with a DAS-H implant in the first quadrant and DAS in the second or opposite depending on the draw(Figure 1).

Inclusion and exclusion criteria

To be included in this study the patients were required to be older than 18 years old, with at least one bilateral missing tooth in the posterior region of the maxilla, and the edentulous region was required to present a residual bone border with a minimum width of 5 mm and a minimum height of 9 mm. The patients with the following characteristics were excluded from the study: dental extractions performed less than 6 months before the placement of the implants; presence of severe atrophy of the alveolar ridge; presence of a bone grafting area; presence of a cystic lesion in the alveolar ridge; presence of a tooth included in the alveolar ridge; smokers; decompensated diabetics or with an altered glycemic rate; user of

medications that altered the bone metabolism; patients with active periodontal disease; patients with poor oral hygiene.

Sample size calculation

A pilot study was performed to analyze six patients who had undergone at least one bilateral implant in each posterior region of the maxilla with DAS and DAS-H implants. The ISQ was evaluated in each implant on the mesial, vestibular, distal, and palatal surfaces. The data from this pilot study were normally distributed using the Shapiro-Wilk test and the mean and standard deviation were calculated considering the 90th day after the implant installation. The sample size was calculated by the T test considering DAS (80.0 ± 3.56) and DAS-H (77.0 ± 3.23) implants. The proportion was 1:1, power 0.80, and significance 0.05. The results showed a sample size of 20 implants per group. Thus, as a split-mouth design was used, 20 DAS implants and 20 DAS-H implants (n=40) were installed, considering the right and left posterior region of the maxilla.

Surgical procedure

The patients were locally anesthetized with articaine 4% combined with epinephrine 1: 100.000, using the infiltrative technique. The incision was made linearly over the alveolar ridge, and a mucoperiosteal flap was performed to expose the bone tissue. The acrylic surgical guides were used to facilitate the correct positioning of the implants. The posterior region of the maxilla was selected to install the implants of both groups. The S-max SG 20 contra-angle (NSK Ltd, Tokyo, Japan) was used, mounted on the NSK Surgical Pro surgical engine (NSK Ltd, Tokyo, Japan), for bone perforation and implant placement. The perforations were performed with 1000 rpm with 45Ncm of torque using the manufacturer's surgical kit. The following sequence of drills was used: Spear drill (9 mm of deep);

2.0 mm drill (9 mm deep), 2/3 drill (pilot), and 2.8 drill (7 mm deep). All the implants were placed with the connection positioned 2 mm below the bone crest. The insertion torque values were obtained during the implant placement. The sites were sutured with nylon 5.0 threads and the following post-operative medications were prescribed for all patients: Amoxicillin 500 mg (8/8hs for 7 days), nimesulid 100mg (12/12hs for 3 days), and dipyrone 500mg (6/6hs for 3 days). The sutures were removed 7 days after the surgical procedure.

ISQ Analysis

Resonance frequency analysis was performed in order to obtain the implant stability quotient (ISQ) using Osstell® (OsstellInc, Gotemburg, Sweden). The ISQ analyses were performed immediately after the implant placement and 28, 40, and 90 days after the surgical procedure. In all the follow-up visits, the healing abutments were removed and a smart-peg was connected under the implants. The ISQ measurements were performed on the mesial, vestibular, distal, and palatal surfaces of each placed implant and a mean was calculated. The ISQ and insertion torque assessments performed at the baseline period were considered together as the primary stability, while the assessment of the ISQ during the follow-up until the 90-day period was considered as the secondary stability of the implants.

Statistical Analysis

The data obtained on the insertion torque and ISQ analysis did not present normal distribution according to the Shapiro-Wilk test. The non-parametric Wilcoxon test was used to compare the insertion torque (Ncm) and the ISQ data of the primary and secondary stability between the groups of implants (DAS vs. DAS-H). The Friedman non-parametric test complemented by the Dunn test was

used to evaluate the ISQ scores within each group comparing the different periods of follow-up. The software Graphpad Prism 6 (San Diego, CA, USA) was used to perform the statistical analysis, and all the statistical tests were applied with the significance level set at 5%.

Results

There were no statistical differences between the DAS and DAS-H groups for the primary stability measured by insertion torque, measured by an analog torquemeter (DAS: 26.27 ± 12.22 Ncm; DAS-H: 23.36 ± 14.46 Ncm; $P > 0.05$) and ISQ (DAS: 74.6 ± 6.0; DAS-H: 72.7 ± 6.0; $P > 0.05$). ISQ values for primary and secondary stability can be observed in table 1. There were no differences regarding the ISQ between the groups in any experimental period.

Figure 1 shows the comparisons between periods within the groups. The ISQ mean of the secondary stability reduced significantly in both groups at the 28th day in comparison to baseline (DAS: from 74.6 to 71.9; DAS-H: from 72.7 to 69.4; $p<0.05$). At the 40th day, there was an increase in the ISQ mean values for DAS (74.4) and DAS-H (73.1) groups, with similar means when compared with baseline data (Immediate vs. Day 40) $P > 0.05$. The highest ISQ mean values were obtained at the 90th day for both groups (DAS: 80.1; DAS-H: 79.1), with a statistically significant difference when compared to the other periods $P < 0.05$. In general, the ISQ values in both types of implant reduced at the 28-day period and then improved at the 40 and 90-day periods.

Discussion

The surface of the implants with higher wettability properties has been shown to improve osseointegration with greater bone area and bone-implant contact in the histomorphometric analyses(1, 2, 11, 12); however, some findings

did not demonstrate differences between hydrophilic implants compared to the control group measured by indirect methods such as the ISQ analysis (6). These results are in agreement with our findings that also did not demonstrate a higher degree of primary and secondary stability by the ISQ method in relation to implants with the DAS surface.

It could be seen that the ISQ analysis was not directly correlated with the bone-implant contact analysis performed by histometry(15) and with other mechanical analysis such as the insertion torque(20). This fact could be the reason for the inconsistent data with respect to implant surfaces that promote greater bone-implant contact through voids not demonstrating an effect on ISQ values (3). A pre-clinical study conducted on mini-pigs demonstrated that there were no differences between DAS-H and DAS implants in relation to the ISQ values, however DAS-H implants showed greater bone-implant contact than DAS implants two weeks after the surgical procedure (15). Regarding the distinct values between the insertion torque and ISQ values, previous studies showed that the correlation of these analyses are not significant since the insertion torque measures the locking of the implants at the recipient site while the ISQ measures the micromovements of the implants at the bone (20, 21). The higher values of the ISQ compared with the insertion torque may mean that the implants presented good stability with a low degree of micromovements despite the low density of the maxillary bone where the implants were placed.

An important finding of this study was the reduction in ISQ at the 28-day period in both types of implants, a common finding in other studies that place this period as critical in the establishment of the osseointegration process (3, 6). However, this finding disagrees with clinical studies that show that DAS-H implants

placed in the posterior region of the mandible do not present a reduction in ISQ during the healing phase (13, 17). In our study, the implants were placed in the posterior region of the maxilla which is a region with lower bone density than the mandible (14). It is probable the low-bone densities located in the posterior region of the maxilla jeopardize the transition of the primary to the secondary stability and could be the reason for the ISQ reduction at the 28-day period for the DAS-H implants. However, the reduction in the ISQ noted in both types of surface in this study may not influence the clinical outcomes since the values of the ISQ presented at the 28-day period were higher than 65, which is considered as a value of implants with good stability(13).

Good primary stability has been related as an important factor to obtain success for the establishment of osseointegration(16). Indeed, implants with good primary stability have been shown to present a better bone healing process than implants with reduced primary stability (22). It is probable the good primary stability obtained in our study could explain the absence of differences between the DAS and DAS-H surfaces in the ISQ analysis. Indeed, a clinical study that compared the stability of the implants with similar surfaces tested in this study (SLActive vs. SLA) showed that there were no differences in the ISQ at 0, 28, 42, and 91 days after the implant placement in the mandible (23).

Another point to be discussed is the macrostructure of the implants; since some authors point out that the macrostructure of the implants is a more determining factor for obtaining primary stability (3, 16). The absence of the effect of the DAS-H on the primary stability in our study could possibly be explained based on the macrostructure design, and not on the modification of the implant surface.

Tapered implants revealed greater insertion torque values with greater primary stability than cylindrical implants (16). Additionally, hybrid implants with macrostructure tapered in their lower portion and cylindrical in their middle/coronal portion have been demonstrated to present better primary stability compared with cylindrical implants, which was more evident in cancellous bone (24). The implants used in the present study presented a hybrid macrostructure for both groups, which could directly interfere in the implant primary stability.

The DAS-H surfaces improved the osseointegration compared with the DAS in implants with a cylindrical macrostructure (11, 12). Another preclinical study that compared implants with hybrid and cylindrical macrostructures with a DAS-H surface showed that the implants with a hybrid macrostructure presented a higher insertion torque and percentage of bone-implant contact than the cylindrical implants (25). Thus, the treatment of implant surfaces could be more important to enhance osseointegration in cylindrical implants, in which the primary stability is lower than in hybrid implants.

This study has some limitations that must be taken into account when interpreting our findings. ISQ analysis is a non-invasive method that has been used frequently in studies in the field of implantology, but the lack of correlation with other types of analysis methods used to assess osseointegration(15, 26) raises doubts about the isolated use of this method of analysis as performed in the current study. In addition, this method has not been used for clinical decision-making. As an example, the values of the ISQ throughout the study were above 65, which is the minimum value required for the application of the occlusal load (13), however, the immediate occlusal load was not applied since the majority of the implants tested presented insertion torque lower than 32 Ncm, a parameter commonly used

by clinicians to make the decision about the best moment to apply the occlusal load on the dental implants. Another important limitation was that the implants were not followed after the occlusal load, and it has been shown that loaded implants presented improved osseointegration compared to unloaded implants (27). Thus, the behavior of the DAS-H in loaded conditions requires more investigation.

Conclusion

It can be concluded that the surface wettability of implants with hybrid macrostructure did not increase the primary and secondary implant stability in the posterior region of the maxilla.

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Figures

Figure 1. Study design.

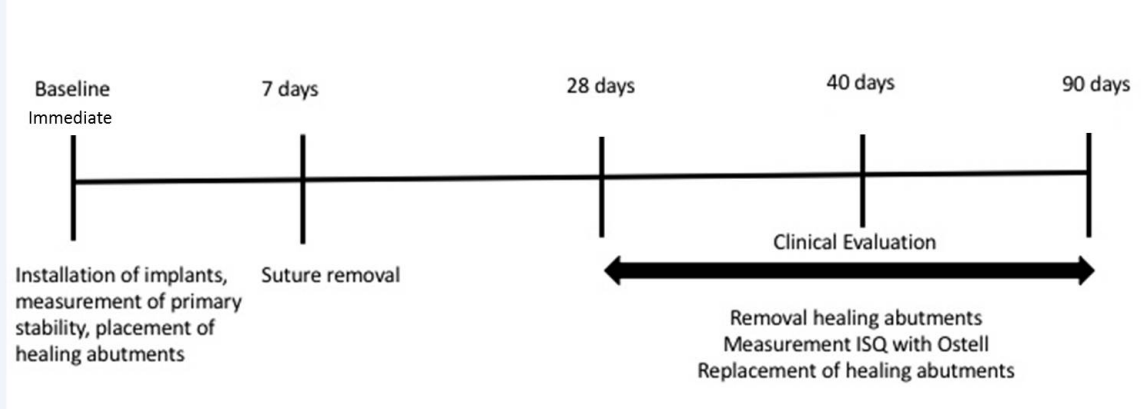


Figure 2. Median and quartiles (minimum and maximum). Different letters indicate statistically significant differences among periods within each group (Friedman test; $p<0.0001$).

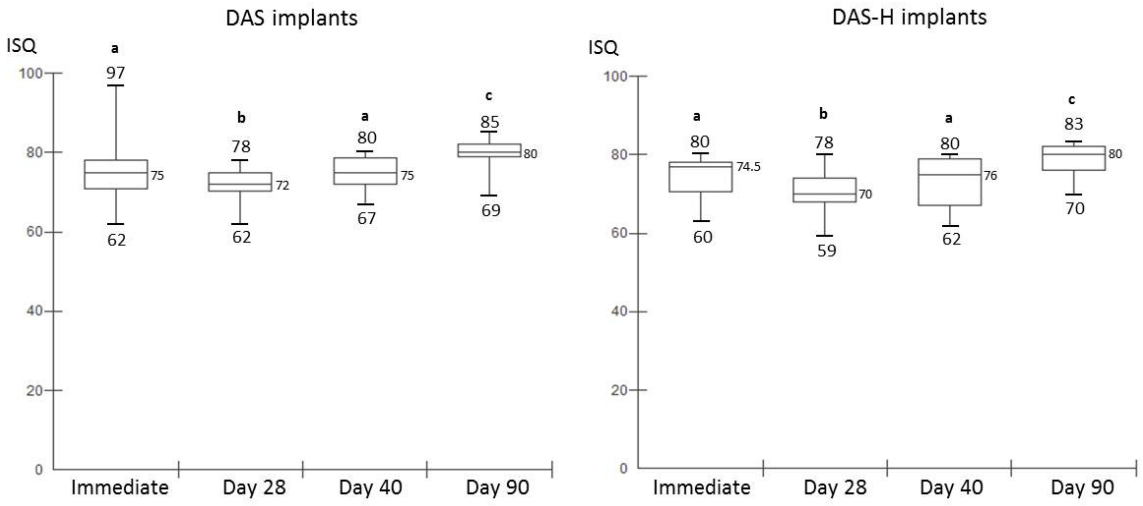
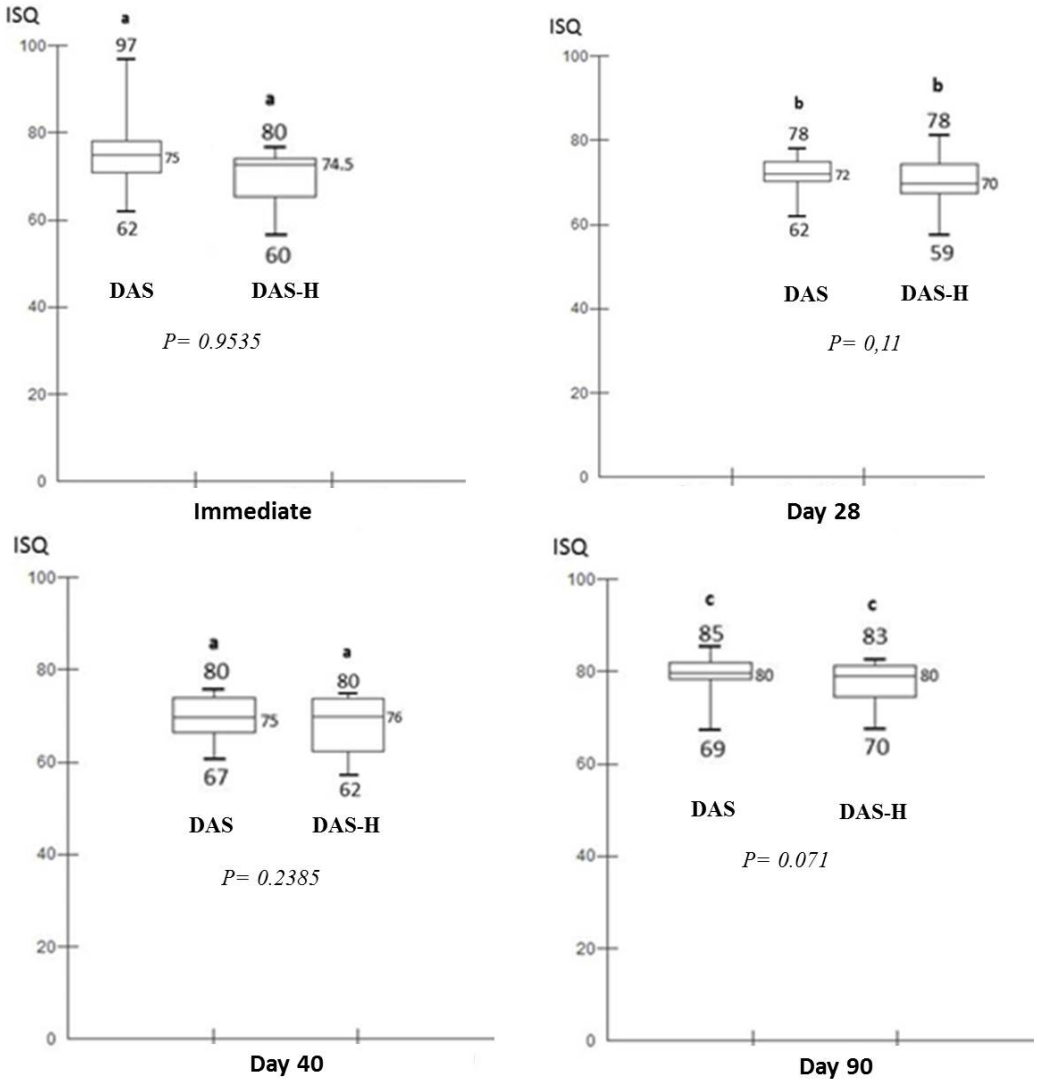
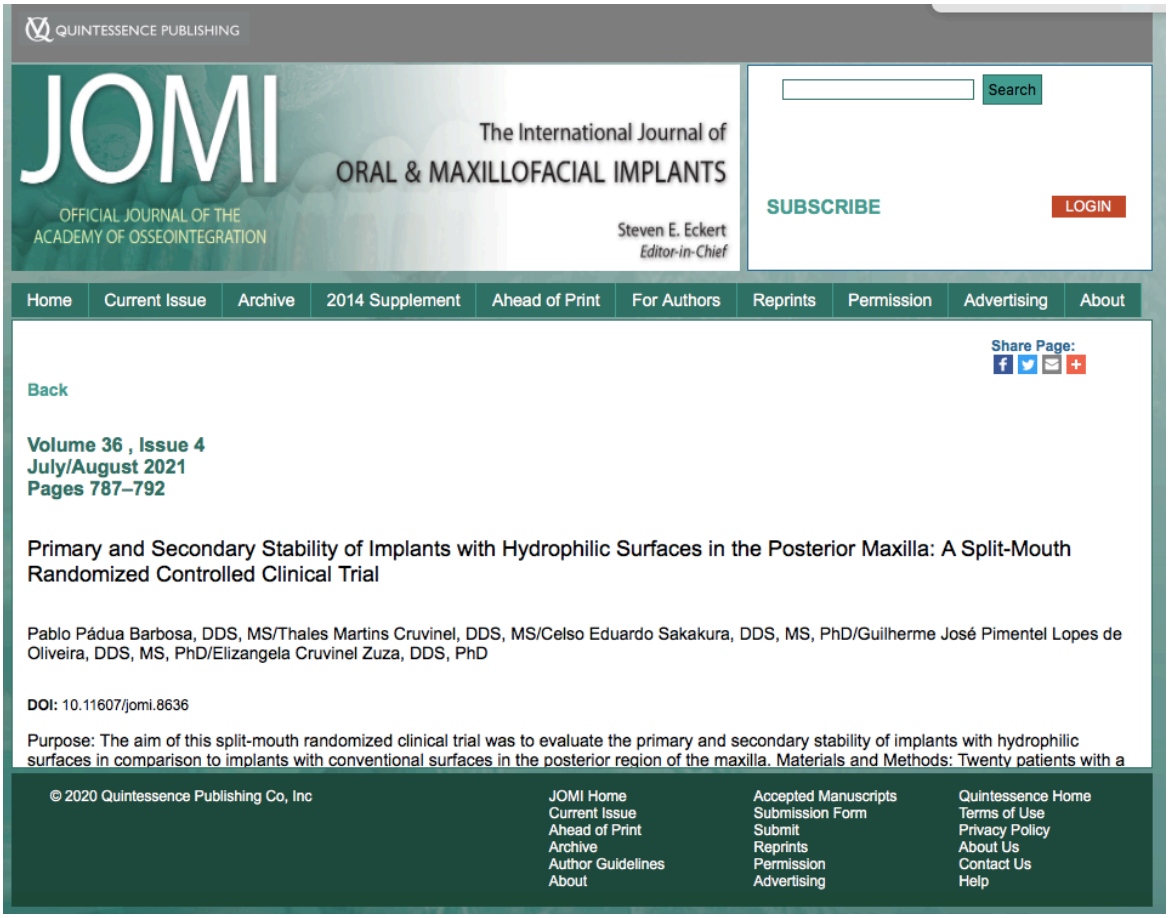


Figure 3. Median and quartiles (minimum and maximum). Identical letters between DAS and DAS-H groups do not indicate statistically significant difference (Wilcoxon test; p > 0.05).



Attachment 1: Cover of the publication attached to the magazine



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Primary and Secondary Stability of Implants with Hydrophilic Surfaces in the Posterior Maxilla: A Split-Mouth Randomized Controlled Clinical Trial

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DOI: 10.11607/jomi.8636

Purpose: The aim of this split-mouth randomized clinical trial was to evaluate the primary and secondary stability of implants with hydrophilic surfaces in comparison to implants with conventional surfaces in the posterior region of the maxilla. Materials and Methods: Twenty patients with a

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4.2 CAPITULO 2 – A ser enviado na Clinical Oral Investigations

Original Paper: Is there a difference in primary and secondary stability and survival of hydrophilic implants compared to non-hydrophilic implants? A systematic review and meta-analysis.

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Conflict of interesting: None

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Abstract

The aim of this systematic review and meta-analysis was to compare the primary and secondary stability, and short-time survival rates of dental implants with different wettability degree (hydrophilic vs. non-hydrophilic surfaces). The specific question was: **Is there a difference in primary and secondary stability and survival of hydrophilic implants compared to the non-hydrophilic implants?.** The review protocol was registered on PROSPERO (CRD42021266722). Four electronic databases (MEDLINE/PubMed, Web of Science, Scopus, and Cochrane Library) and grey literature (ProQuest) were screened for articles published until September 2021 without language or time restrictions. Randomized controlled clinical trials (RCTs) and prospective clinical studies with a hydrophilic surface implant were compared to non-hydrophilic surface implants in the upper or lower jaws. The risk of bias was assessed using Rob 2.0 tool. A meta-analysis was performed by Review Manager 5.4 software considering resonance frequency analysis (RFA) of the average of the implant stability coefficient (ISQ) for each evaluation period (implant placement, 4 , 6 , 8 and 12 weeks of follow-up). In general, there was no difference in the primary and secondary stability of implants with a hydrophilic surface compared to implants with a non-hydrophilic surface, as demonstrated in the meta-analysis in all the evaluation periods. Furthermore, both types of implants presented high level of survival rates. It can be concluded that implants with a hydrophilic surface showed primary and secondary stability similar to implants with a non-hydrophilic surface.

Keywords: Implant stability, implants surface, meta-analysis, osseointegration, survival rates

Introduction

The rehabilitation protocol and success of the prothesis supported by dental implants is dependent of the osseointegration phenomenon that is influenced by host and dental implants factors. (Khandelwal *et al.,* 2014; Makowiecki *et al.,* 2019). Host-related risk factors, such as the quality of bone tissue or the presence of characteristics that alter the metabolism of this tissue, are difficult to control and can impair the survival of implants (Aghaloo *et al*., 2019). Efforts to improve the design of implants and their physicochemical properties have been proposed with the aim of making the osseointegration process predictable in all cases, regardless of the local and systemic conditions provided by the host (Buser *et al.,* 2004; Pimentel Lopes de Oliveira *et al.,* 2016; Nicolau *et al.,* 2019)

Changes in implant surfaces have traditionally been proposed as alternatives to improve the osseointegration process (Jemat *et al.,* 2015; Pimentel Lopes de Oliveira *et al.,* 2016). The surface modifications related to increased roughness and wettability have been shown in clinical and preclinical studies to increase bone-implant contact compared to non-hydrophilic (Buser *et al*., 2004; Lang *et al.,* 2011) or machined surfaces (Pinotti *et al.,* 2018). Furthermore, it has been proposed that implants with high level of wettability (eg.hydrophilic surfaces) can reduce the waiting time for osseointegration (Lang *et al.,* 2011), and could be protective against induced bone resorption by microbial or biomechanical factors, which would increase the survival rate of these implants (Donos *et al.,* 2019; Nicolau *et al.,* 2019).

Despite the described effects of the hydrophilic surfaces on the enhance and acceleration of the osseointegration, the clinical comparison of these type of

implants with the non-hydrophilic surfaces presents contradictory results. Previous systematic reviews evaluated the effect of the hydrophilic surfaces on the success and survival rates of the dental implants. Makowiecki *et al.,* 2019 showed that implants with high level of hydrophilicity presented reduced peri-implant bone loss and high survival rates. Norton & Åström. 2020 also showed limited bone loss associated with hydrophilic implants at 1-5 years of follow-up. However, both reviews compared implants with different macrostructures limits the understanding of the real effect of hydrophilic surfaces on the success of dental implants. Despite these good outcomes, this is not superior than the outcomes observed with non-hydrophilic surfaces (Şener-Yamaner *et al.,* 2017; Almassri *et al.,* 2020). This means that after the establishment of the osseointegration, the hydrophilic surfaces do not add significant advantages compared with other surfaces.

The advantage of using implants with hydrophilic surfaces is related to the reduction in the time required to obtain the osseointegration (Lang *et al.,* 2011; Bang *et al.,* 2014). This property benefits the application of early loading protocols of these implants in clinical situations where immediate loading is not possible (Makowiecki *et al.,* 2017). Resonance frequency analysis is a non-invasive method that is indicated for evaluating the progression of the evaluation of the osseointegration process through the evolution of the conversion from primary to secondary stability (Pimentel Lopes de Oliveir*a et* al., 2016). An important method to determine the moment in the which implants achieved sufficient stability to be rehabilitated (Almassri *et al.,* 2020).

The evolution of the implant's stability involving the hydrophilic and non-hydrophilic surfaces was evaluated in a previous systematic (Almassri et al.,

2020) that showed no differences between these both type of implants at baseline and 3, 6, and 8 weeks. However, the small sample sizes and high methodological heterogenicity of the included studies limited the data interpretation. So, it is necessary to update these data included more studies with high methodological level. Therefore, the aim of this systematic review and meta-analysis was to assess if the hydrophilic implants surfaces are superior to the non-hydrophilic surfaces in the obtaining of the primary stability and in conversion of the primary to the secondary stability in osseointegrated implants.

Material and Methods

Review Protocol and Register

This systematic review was performed according the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline (PRISMA) for conducting of systematic reviews and meta-analysis. This review was also registered at the International Prospective Register of Systematic Reviews PROSPERO (CRD42021266722).

Eligibility Criteria

The specific question of the research hypothesis was formulated based on the PICO strategy was: **Is there a difference in primary and secondary stability and survival of hydrophilic implants compared to the non-hydrophilic implants?** Based on the established criteria, with the population identified by patients who received the two types of implants described. The primary endpoint evaluated was primary and secondary stability and the secondary endpoint was implant survival rates.

The studies included in this systematic review were randomized controlled clinical trials (RCTs) and prospective clinical studies where the implants with a

hydrophilic surface were compared to implants with a non-hydrophilic surface in the upper or lower jaws, studies that two evaluated groups (hydrophilic and non-hydrophilic) implants which had similar diameter, length and the same macrostructure geometry was considered. The studies with the following characteristics were excluded from this review: Animal, in vitro and finite element analysis studies, case reports, case series, and case-control studies. Studies were the implants presented different macrostructures, presence of a very divergent sample size between the groups and the absence of the descriptive data of the stability analysis was also excluded. No language restrictions were applied.

Search strategy

The search of the papers was realized by two independent evaluators (P.P.B, V.M.S) for articles published until September 31, 2021 at the following electronic databases: MEDLINE/Pubmed, Web of Science, Scopus, Cochrane, and grey literature database Proquest. The specific search strategy for each electronic database was presented in Supplemental File 1.

Studies were firstly selected by titles and abstracts that seems to meet the inclusion requirements. Studies that had more than one type of implant evaluated were included, but only the comparison between 2 types (hydrophilic and non-hydrophilic) implants.

One of the authors (C.A.A.L) imported the studies selected in the search strategy into the Rayan program, where the duplicate articles were removed by one author (P.P.B.) and three other authors (P.P.B; V.S; T.M.C) reading the title first, then the abstract and finally the full text and applying the inclusion criteria, they selected the articles for review. In addition, a manual search of articles contained

in the references lists of previous systematic reviews and included articles that had been included was performed. In addition, a search was also made in the ClinicalTrials.gov database.

Data Extraction

One of the authors collected the relevant data from each study (P.P.B) using the Excel software with a table including, number of implants, standard deviation, stability and survival rate data, which was revised by 2 authors (G.J.P.L.O) and (E.P.Z). The data collected included author/year, study design, patients/gender, mean age, number of implants, implant system and dimensions (length and diameter), installation site, loading protocol, primary stability, complications, survival rates, primary and secondary stability and follow-up.

The selected articles were organized according the authorship, year, type of the diameter and length of implants; installation site; loading protocol; primary and secondary stability data; survival rates, patients related complications, and follow-up periods (Table 1).

Risk of bias

One author (P.P.B.) assessed the risk of bias using the Rob 2.0 tool. Rob 2.0 addresses five specific domains: (1) bias arising from the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in measurement of the outcome; and (5) bias in selection of the reported results (Sterne *et al.,* 2019). A bias risk graph was generated demonstrating the judgment (Low, Some Concerns and High risk of bias) for the 5 domains and overall.

Summary measures and Synthesis of Results

The meta-analysis was performed using the Inverse Variance (IV) and Mantel–Haenszel (MH) methods for primary/secondary stability and implants survival rates, respectively. The primary and secondary stability was evaluated through mean difference (MD), while implants survival rates was evaluated using the risk ratio (RR), both analysis with alpha < 0.05 considered as statistically significant with 95% confidence intervals (CI). In the analysis with statistically significant heterogeneity (P < 0.10), a random-effects model was used to assess the evaluated groups; if there was no statistically significant heterogeneity a fixed-effects model was used (Egger and Smith 2001). The analysis was performed using the Reviewer Manager 5.4 (Cochrane Group) software. Resonance frequency analysis (RFA) was evaluated using the average of the implant stability coefficient (ISQ) for each evaluation period (at the time of implant placement, 4, 6, 8 and 12 weeks) of follow-up.

Results

The search in the electronic databases resulted in 1208 selected articles, while the search on the clinicaltrial.gov resulted in the finding of more 13 studies. The studies were imported into the Rayan program where 653 duplicates were removed, and 13 were considered ineligible. After reading the titles and abstract, 506 articles were excluded, leaving 49 clinical studies that were read in full. After this phase, 16 articles were selected for the final evaluation. Then, more 6 articles were removed for the revision before the data extraction due to different reasons: Two of these chosen articles compared different macrostructure (Ryu *et al.,* 2015; Kahramanoglu *et al.,* 2020) , one study presented the implants stability data only in graphics and did not expose the descriptive data and the authors did not answer our queries regarding the raw data, (Novellino *et al.,* 2017); two study had

very divergent sample distributions between the test and control groups very different or heights and diameters of implants between the test and control groups (Guler *et al.,* 2013; CarmoFilho *et al*., 2018); one study evaluated only the hydrophilic surface (Zollnet *et al*., 2008).

Finally, 10 clinical studies were included for data analysis, 8 of these studies were RCTS and 2 of these studies were prospective clinical studies. The search and selection strategy are described in flow diagram. (Figure1).

The total number of patients in all studies was 242, where 527 implants were performed, 263 implants with a hydrophilic surface and 264 implants with a non-hydrophilic surface. (Khandewal *et al*., 2014; Velloso *et al.,* 2018; Siqueira *et al.,* 2018) installed feather implants in the mandible (Shatzle *et al.,* 2009; Barbosa *et al.,* 2021) installed implants only in the maxilla. (Oates *et al*., 2007; Karabuda *et al.,* 2010; Markovic *et al.,* 2016; Tallarico *et al.,* 2019; Tallarico *et al*., 2021) installed implants in both the maxilla and mandible.

Most studies evaluated were with Straumann implants (SLActive compared to SLA) (Oates et al., 2007; Shatzle et al., 2009; Karabuda et al., 2010; Khandewal et al., 2014; Markovic et al., 2016). Three studies analyzed Neodent brand implants Acqua vs. neoporous surfaces (Velloso *et al.,* 2018; Siqueira *et al*., 2018 and Barbosa *et al.,* 2021). Two studies analyzed Hiossen brand implants Sandblasted and acid etched implants vs. hydrophilic implants (Tallarico *et al.,* 2019; Tallarico *et al.,* 2021).

Risk of bias analysis

The bias risk data of each study is described at the figure 2. Five of the papers was considered to present a low risk of bias (Markovic *et al*., 2016, Velloso *et al.,* 2018; Tallarico *et al*., 2019; Tallarico *et al.,* 2021; Barbosa *et al.,* 2021),

four was considered to present high risk of bias (Oates *et al.*, 2007; Shatzle *et al*., 2009; Karabuda *et al*., 2010; Siqueira *et al*., 2018), and one that presented some concerns regarding the bias risk (Khandewal *et al*., 2014).

The majority of the included studies were RCTs were the both type of implants was placed at the same jaw in a split-month model associated with the randomization procedure. Only two the selected studies were prospective (Karabuda *et al.,* 2010; Siqueira *et al*., 2018). However, both of them described a randomization process in the distribution of the implants, but in one study the patients not received the same number of implants (Karabuda *et al*., 2010), while in another study each one of the 11 patients received five implants in the anterior region of the mandible, so the number of each type of the implants was not the same (Siqueira *et al.,* 2018).

Level of evidence

To assess the level of evidence of the studies included in this review, a cocharne GRADEpro tool was used. Among the 10 articles analyzed using the GRADE pro tool, 4 articles were considered to have a moderate level of evidence (Oaetes *et al.,* 2007; Shaztle *et al.,* 2009; Karabuda *et al.,* 2010; Siqueira *et al.,* 2018). The other 6 articles were considered to have a high level of evidence (Khandewal *et al.,* 2014; Markovic *et al.,* 2016; Velloso *et al.,* 2018; Tallarico *et al.,* 2019; Tallarico *et al.,* 2021; Barbosa *et al.,* 2021).

Dental implants stability analysis

It was possible to carry out the meta-analysis that was segmented into different follow-up evaluation periods (Immediate and after 4, 6, 8 and 12 weeks after implant placement). Eight articles that evaluated the stability of the implants at baseline and 4 weeks after the surgical procedure were included in the meta-

analysis (Oates *et al*., 2007; Shatzle *et al.,* 2009; Markovic *et al*., 2016; Velloso *et al* ., 2018; Siqueira *et al* ., 2018; Tallarico *et al.,* 2019; Tallarico *et al .,* 2021; Barbosa *et al.,* 2021), 7 papers were included in the analysis of 6-week (Oates *et al*., 2007; Shatzle *et al.,* 2009; Karabuda *et al.,* 2010; Markovic *et al*., 2016; Velloso *et al* ., 2018 Tallarico et al., 2019; Tallarico et al., 2021) and 8-week follow-up period (Shatzle *et al.,* 2009; Karabuda *et al.,* 2010; Khandewal *et al.,* 2014; Markovic *et al*., 2016; Siqueira *et al.,* 2018; Tallarico *et al.,* 2019; Tallarico *et al.,* 2021). Finally, 4 papers that evaluated the implants stability at the 12-wekk follow-up period was included in the metanalysis (Shatzle *et al.,* 2009; Markovic *et al*., 2016; Siqueira *et al.,* 2018; Barbosa *et al*., 2021).

Meta-analysis revealed no significant difference between hydrophilic and non-hydrophilic implants in terms of primary stability during implant placement (baseline) analysis (P = 0.81; MD: 0.24; CI: -1.74 to 2.22; Fig. 3A). A significant heterogeneity was observed (P = 0.0006; I^2 = 73%). Therefore, we performed a new baseline analysis excluding one study that present a large difference between groups (Markovic et al. 2016). In this new analysis, the absence of difference was maintained (P = 0.69; MD: -0.26; CI: -1.54 to 1.02), but a low heterogeneity and non-significant was observed (P = 0.56; I^2 = 0%) (Figure 3B).

Regarding the others follow-ups, the analysis performed revealed no difference for implant stability between hydrophilic surface when compared to non-hydrophilic surface implants during 4 weeks (P = 0.84; MD: -0.11; CI: -1.14 to 0.92; Fig. 4), 6 weeks (P = 0.92; MD: -0.05; CI: -1.09 to 0.98; Fig. 5), 8 weeks (P = 0.52; MD: 0.27; CI: -0.54 to 1.07; Fig. 6), and 12 weeks (P = 0.79; MD: 0.13; CI: -0.86 to 1.13; Fig. 7). These analyzes showed low heterogeneity without significance P > 0.10.

Survival rates

Two of the included studies did not present the survival rates data (Shatzle *et al*., 2009 e Siqueira *et al.,* 2018). The other studies showed that the both types of implants presented good outcomes regarding this parameter since 6 of them showed 100% of survival rates (Oates *et al*., 2007; Markovic *et al*., 2016; Velloso *et al*., 2018; Tallarico *et al.,* 2019; Tallarico *et al.,* 2021; Barbosa *et al.,* 2021). Only two studies reported one implants lost each (Karabuda *et al.,* 2010 e Khandewal *et al.,* 2014), giving a survival rate of 97,7% and 98% for hydrophilic and non-hydrophilic, respectively.

Regarding the meta-analysis due to the absence of failures for most of studies, only two studies were estimable. The data showed no difference between different surfaces in terms of implants survival rates during short-term follow-up (P = 1.00; RR: 1.00; CI: 0.15 to 6.87; low heterogeneity – P: 0.33; I^2 = 0%; Fig. 7).

Discussion

The surface of implants has been the focus of technological improvements in order to speed up the osseointegration process and reduce the waiting period for installation of the prostheses (Makowiecki *et al.*, 2017). Indeed, a myriad of implants surfaces modifications have been showed to improve the osseointegration compared with implants with no surface treatment (Pinotti *et al.,* 2018; De Tulio *et al*., 2020). Comparing implants with different surfaces modifications, the hydrophilic surface deserves highlight since it has been showed superiority compared with non-hydrophilic surfaces due to the enhance and acceleration of the osseointegration (Buser *et al.,* 2004; Lang *et al.,* 2011; Bang *et al*., 2014; Sartoretto *et al.,* 2015), however, the information that showed

this improvement in the osseointegration related with the hydrophilic surfaces are provided by histological analysis (Buser *et al.,* 2004, Lang *et al.,* 2011, Sartoretto *et al.,* 2015).

Although the histological findings demonstrate this superiority of hydrophilic surfaces, the present review did not demonstrate that this advantage at the microscopic level reverted to clinical benefits, as there were no differences in the primary and secondary stability of implants with these surfaces compared to implants without a high degree of wettability. This fact occurred because most of the clinical studies used in this review did not find differences between these surfaces in the evaluated periods (Oates *et al*., 2007; Karabuda *et al.,* 2010; Khandelwal *et al.,* 2014; Sener-Yamaner *et al*., 2017; Barbosa *et al.,* 2021). An important point in understanding these results is that studies demonstrating the superiority of hydrophilic implant surfaces occur in the earliest periods of healing (Buser *et al.,* 2004; Lang *et al*., 2011), and even one of the clinical studies that were included in this review, which demonstrated superiority in the secondary stability of implants with a hydrophilic surface, they occurred only up to the fourth week after implant placement (Oates *et al.,* 2007).

An important confounding factor when clinically analyzing the effect of different surface modifications on the osseointegration process is the lack of standardization in the macrostructure of the implants (Carmo-Filho *et al.,* 2018). Morphological patterns such as thread shape (Falco *et al*., 2018; Leocádio *et al.,* 2020), and body shape (Torroella-Saura *et al.,* 2014; Atieh *et al.,* 2018) are some elements that increase the primary stability of implants (Atieh *et al.,* 2018; Leocádio *et al.,* 2020). As the evolution of the secondary stability of implants depends on the initial locking (Monje *et al.,* 2019), the non-standardization of

these macroscopic implant patterns makes it impossible to isolate the understanding of the effects of the implant surfaces on the osseointegration process.

The findings of this study of the absence of differences in the stability of implants with different degrees of wettability may mean that evolutions in the macrostructure of the implants reduce the importance of the hydrophilic microstructure clinically (Torroella-Saura *et al*., 2014; Leocádio *et al.,* 2020). The influence on the osseointegration of hydrophilic surfaces may have greater significance in low quality bone (eg. maxilla, patients with risk factors), and the justification for using this surface in any circumstance has not demonstrated a significant improvement in the clinical outcomes.

Regarding the survival rate, only two studies lost an implant and did not have a 100% survival rate for the periods evaluated (Karabuda et al.,2010 ; Khandewal *et al.,* 2014). Karabuda *et al.,* 2010; had 97.7% for hydrophilic ModSLA implants and Khandewal *et al*., 2014 had 98% for non-hydrophilic SLA implant. One study did not report results for survival rate (Shatzle *et al.,* 2009). No statistical differences were found in this review between the survival rates for hydrophilic and non-hydrophilic implants.

Within the limitations of our study, it was demonstrated that there are no statistical differences regarding primary and secondary stability, and survival rates for implants with a hydrophilic surface and the same macroestructure. More randomized controlled clinical trials must be performed under more challenging clinical conditions in order to improve the understanding of the clinical indications in which hydrophilic surfaces may provide more consistent benefits.

Conclusion

It can be concluded that implants with a hydrophilic surface showed primary and secondary stability similar to implants with a non-hydrophilic surface.

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Figure legends

Figure 1: PRISMA Protocol Agreement Search Strategy Preferred Reporting Items for Systematic Review and Meta-Analysis.

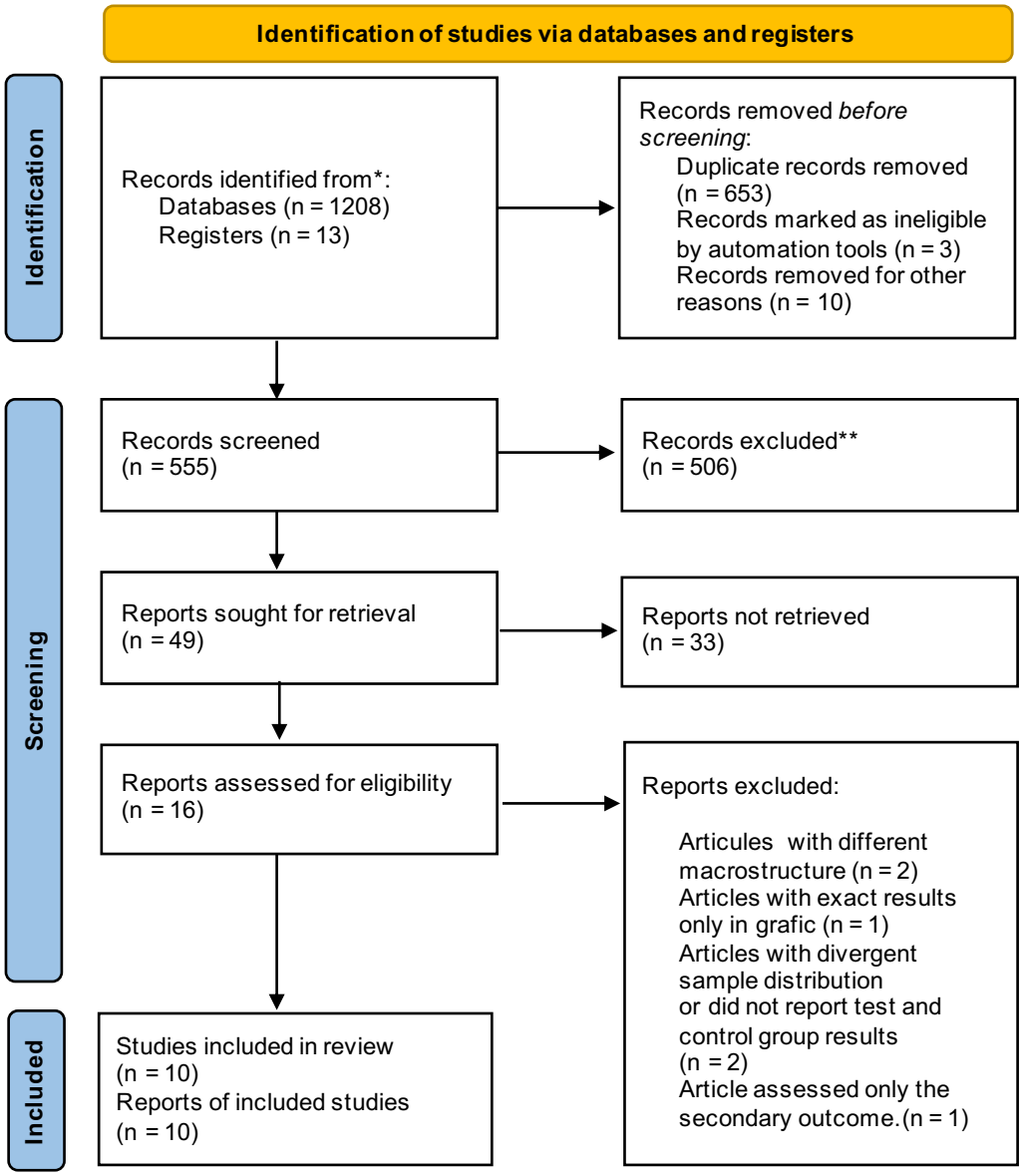


Figure 2: Risk of Bias Analysis tool Rob 2.0

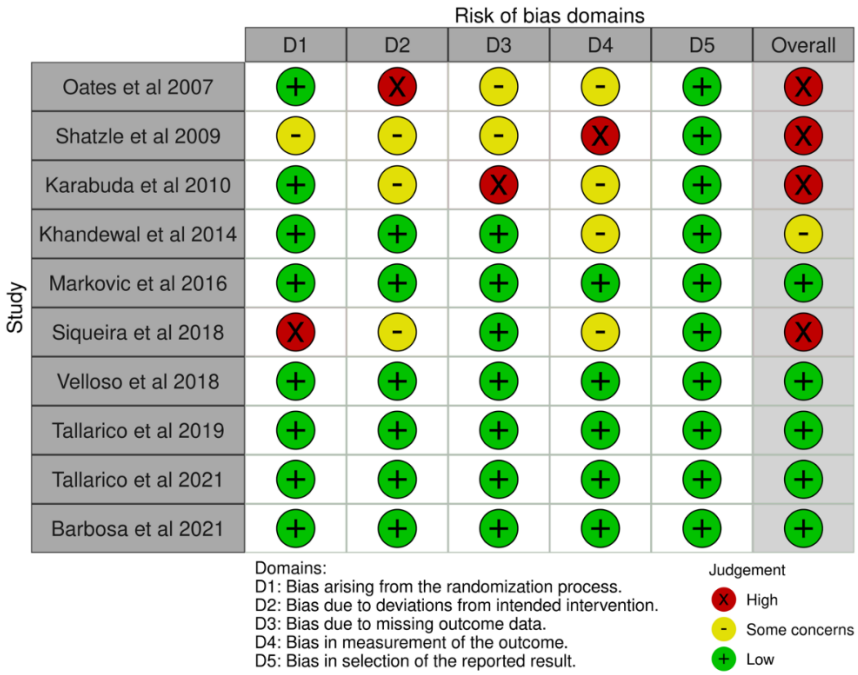
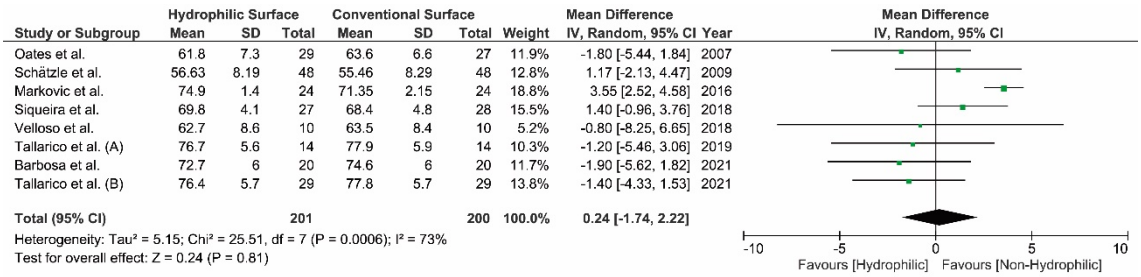


Figure 3 – Forest plot of baseline of hydrophilic in comparison with non-hydrophilic dental implants for implant stability (A) Random analysis with high heterogeneity;

A)



(B) Fixed analysis with low heterogeneity after remove study of Markovic et al. of analysis.

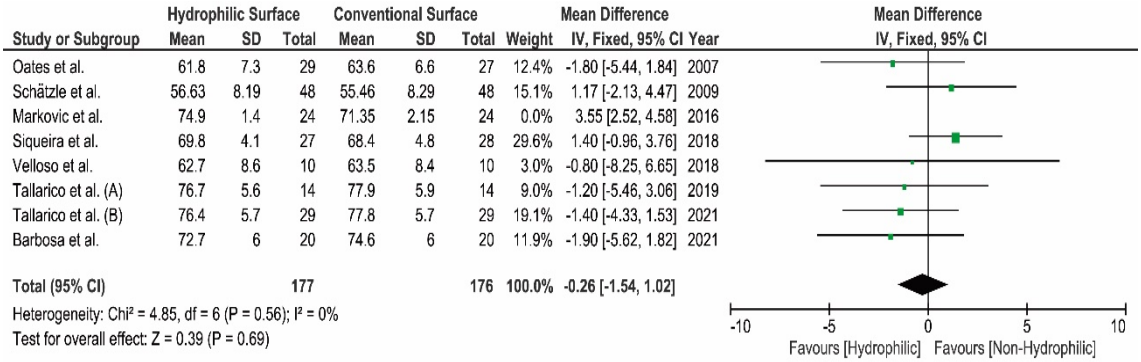


Figure 4 – Forest plot of 4 weeks of hydrophilic in comparison with non-hydrophilic dental implants for implant stability.

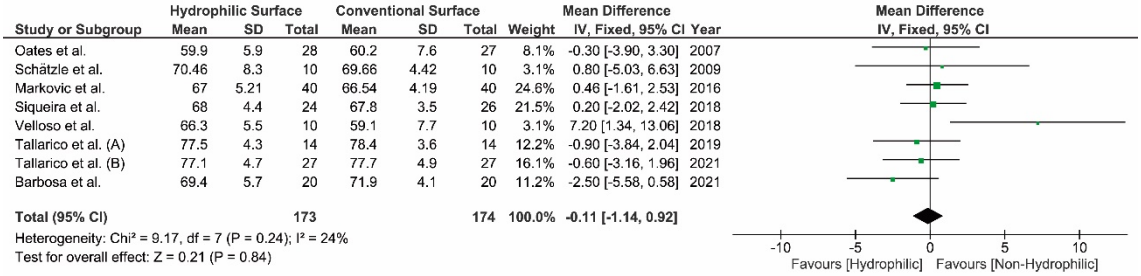


Figure 5 – Forest plot of 6 weeks of hydrophilic in comparison with non-hydrophilic dental implants for implant stability.

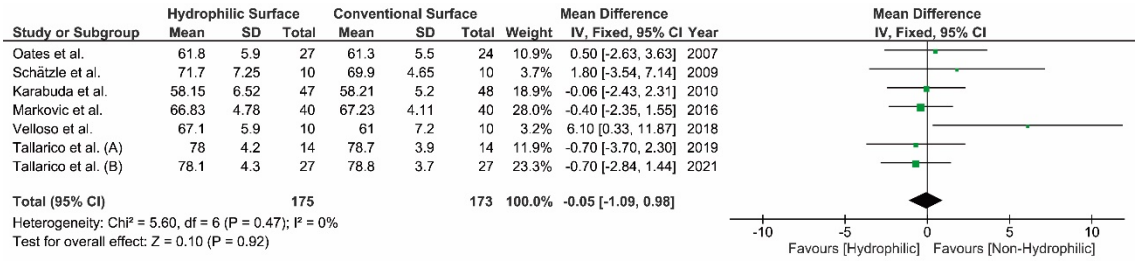


Figure 6 – Forest plot of 8 weeks of hydrophilic in comparison with non-hydrophilic dental implants for implant stability.

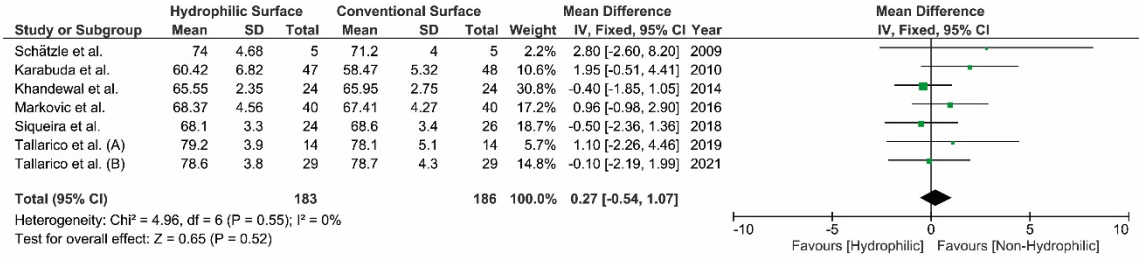


Figure 7 – Forest plot of 12 weeks of hydrophilic in comparison with non-hydrophilic dental implants for implant stability.

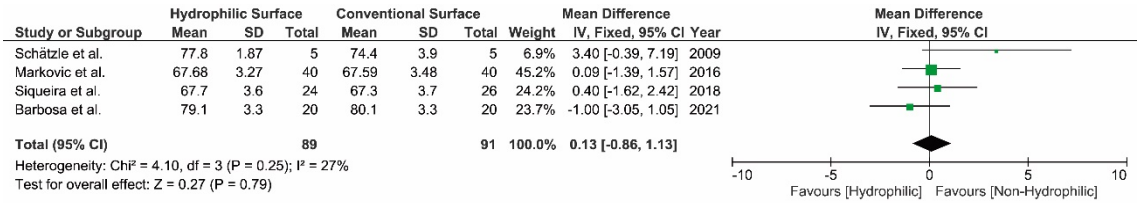


Figure 8 – Forest plot of hydrophilic in comparison with non-hydrophilic dental implants for implants survival rates.

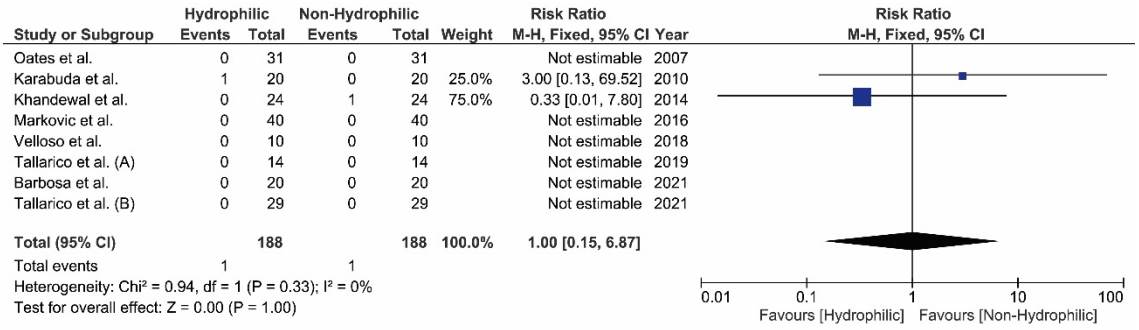


Table:

Table 1

Table 1: Description of the study design of the selected studies.

Author/ Year	Study Design	Patient, n Gender	Mean age, years	Implants, n	Implant system/Diameter/ Lenght	Installation site	Loading Protocol	Primary stability	Complications, n (type of complications)	Survival rates of implants, n (%)	Follow-up, months
Oates et al 2007	RCT	**31** 22 Fe 9 Ma	61.1	62 31: ModSLA 31: SLA	Straumann® Standard Plus 4.1/10 or 8 mm	50 Mandible and 12 Maxilla /	Conventional	Primary outcome	No	100%	B,1,2,3,4,5,6 Weeks
Schätzle et al 2009	RCT	**40 19 Ma 21Fe**	27.9	40 20: ModSLA 20:SLA	Straumann® Standard Plus 4..1/ 4,2 mm comprimento	Maxilla	Conventional	Primary outcome	No	Not Informed	B, 1,2,3,4,5, 6,7,8, 10,12 Weeks
Karabuda et al 2010	Prospective RCT	**22 15 Fe 7Ma**	46.68	96 48:ModSLA 48:SLA	Straumann® Standard Plus 4.1/4,2mm	Mandibule and Maxilla	Conventional	Primary outcome	No	97,7% ModSLA 100% SLA	1,3,6 Weeks
Khandewal et al 2014	RCT	**24 15Fe 9Ma**	57.3	48 24:SLA 24:SLActive	Straumann® Standard Plus 4.1/ 8,10mm	Mandibule	Conventional	Primary outcome	Diabetes mellitus type 2	100% SLActive 98% SLA	B,8,16
Markovic et al 2016	RCT	**20 16 Ma 4 Fe**	63,8	80 40: SLA 40:SLActive	Straumann® Standard Plus 3.3mm diameter	38:Mandibule and 42:Maxilla	Conventional	Primary outcome	Anticoagulants	100%	B,1,2,3,4,5,6,8,12
Velloso et al 2018	RCT	**20 9 Ma 11 Fe**	37	20 10TitamaxEX Neoporos 10Titamax Ex acqua	Neodent 3.75/11	Mandibule	Conventional	Primary outcome	No	100%	B,1,2,3,4,5,6
Siqueira et al 2018	Prospective Clinical	**22 11Ma 11Fe**	58,3	55 28Titamax Ex Neoporos 27Titamax ExAcqua	Neodent 3,75	Mandibule	Immediate	Primary outcome	No	NR	B, 10d,2,4,8,12
Tallarico et al 2019	RCT	**14 1Ma 13Fe**	58,3	28 14 Hiossen SAE 14Hiossen NH	Hiossen (NR)	4 Mandibule 10 Maxilla	Conventional	Primary outcome	No	100%	B 1,2,3,4,5,6
Tallarico et al 2021	RCT	**29 7 Ma 22 Fe**	59.9	58 29 SAE 29NH	Hiossen	11Mandibule 18 Maxille	Conventinal	Primary outcome	No	100%	B,1,2,3,4,5,6,7,8
Barbosa et al 2021	RCT	**20**	NR	40 20 Titamax EX Neoporos 20 Titamax EX acqua	Neodent	20 Maxille	Conventional	Primary outcome	No	100%	B,4,6,12

Supplementary material 1 – Search strategy in the different electronical databases

PUBMED

#1 ((((((("Dental Implants"[Mesh]) OR ("Dental Implants")) OR ("Dental Implant")) OR ("Dental Prosthesis, Implant-Supported"[Mesh])) OR ("Dental Prosthesis, Implant- Supported")) OR ("Dental Implantation, Endosseous"[Mesh])) OR ("Dental Implantation, Endosseous")) OR ("Dental Implant-Abutment Design"[Mesh])) OR ("Dental Implant-Abutment Design")

#2 ((((((((("Wettability"[Mesh]) OR ("Wettability")) OR ("Hydrophilic")) OR ("Hydrophilicity")) OR ("Hydrophilicities")) OR ("Chemically Modified")) OR ("SLActive")) OR ("Thommen Inicell")) OR ("Acqua")) OR ("Hiossen")) OR ("Surface Treatment*")) OR ("Surface Modification*")

#3 ((((((("Hydrophobic") OR ("Hydrophobicity")) OR ("Hydrophobicities")) OR ("Sandblasted and Acid-etched")) OR ("Sand-blasted")) OR ("Acid-etched")) OR ("Sandblasted, large grit, and acid etched")) OR ("SAE")) OR ("SLA")

#4 ((((((((((("Osseointegration"[Mesh]) OR ("Osseointegration")) OR ("Implant Stability

Quotient")) OR ("ISQ")) OR ("Stability")) OR ("Survival"[Mesh])) OR ("Survival")) OR ("Success")) OR ("Failure*")) OR ("Complication*")) OR ("Bone Resorption"[Mesh])) OR ("Bone Resorption")) OR ("Bone loss")) OR ("Bone level")

#1 AND #2 AND #3 AND #4

Web of Science

#1 TS=("Dental Implants") OR TS=("Dental Implant") OR TS=("Dental prosthesis, implant supported") OR TS=("Dental implantation, Endosseous") OR TS=("Dental Implant-Abutment Design")

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#4 TS=("Osseointegration") OR TS=("Implant Stability Quotient") OR TS=("ISQ") ORTS=("Stability") OR TS=("Survival") OR TS=("Success") OR TS=("Failure*") OR TS=("Complication*") OR TS=("Bone Resorption") OR TS=("Bone loss") OR TS=("Bone level")
#1 AND #2 AND #3 AND #4

Scopus

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KEY ("Complication*") OR TITLE-ABS-KEY ("Bone Resorption") OR TITLE-ABS-KEY ("Bone loss") OR TITLE-ABS-KEY ("Bone level")

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Cochrane

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#8 "Hydrophilicity" 164

#9 "Hydrophilicities" 1

#10 "Chemically Modified" 101

#11 "SLActive" 38

#12 "Thommen Inicell" 0

#13 "Acqua" 70

#14 "Surface Treatment*" 241

#15 "Surface Modification*" 54

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1896

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#33 "Failures" 10782

#34 "Complications" 154397

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#37 "Bone level" 901

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PROQUEST

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4.3 CAPITULO 3 A ser enviado na Clinical Oral Implants Research

Original Paper: Primary and secondary stability of hybrid implants with different thread configurations and hydrophilic surface. A split-mouth randomized controlled trial

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Conflicts of interest: None

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Abstract

The aim of this split-mouth randomized controlled trial was to evaluate the primary and secondary stability of hybrid implants with different thread configurations and hydrophilic surfaces. Twenty patients with a partially edentulous maxilla were selected. These patients received two types of implants with the same hydrophilic surface: CTR group: Cylindrical implant in the coronal and middle portion and tapered in the apical portion with perforating threads; TES group: Cylindrical implant in the coronal portion and tapered in the apical and middle portion with perforating and condensing threads. The primary and secondary stability parameters were measured by insertion torque and resonance frequency analysis at the time of implant placement and 7, 28, 56, and 90 days after the surgical procedure. It was found that the implants in the TES group presented higher primary stability values at the time of implant placement, due to the higher ISQ and insertion torque, than the implants in the CTR group. It was also verified that the implants in the TES group presented higher ISQ values than the implants in the CTR group in all follow-up periods. Hybrid implants with perforating and condensing threads demonstrated greater stability than hybrid implants with only perforating threads.

key-words: Implants design, stability, osseointegration.

Introduction

Dental implants have been used extensively in oral rehabilitation of all types of edentulism (Belser *et al*., 2009; Souza *et al.,* 2018). However, despite the high survival and success rates, failures still occur, which may be associated with mechanical or biological factors that occur mainly in the first year of the implant in function, especially at the critical moment for achieving osseointegration (Lin *et al.,* 2018).

One controllable factor linked to success in osseointegration is the achievement of good primary stability, which makes secondary stability a more predictable event (Faot *et al.,* 2019; Makary *et al.*, 2019). Structural modifications in the dental implants have been proposed to optimize the osseointegration process, and these modifications can be performed in the macrostructure or microstructure of the implants (Buser *et al.,* 2004; Lang *et al.,* 2011; Oliveira *et al.,* 2016; Leocádio *et al.,* 2020). Changes in the macrostructure more directly affect primary stability and the decision to establish immediate load application (Torroella-Saura *et al.,* 2015; Oliveira et al., 2016; Makary *et al.,* 2019), while microstructural modifications are related to the acceleration of the conversion from primary to secondary stability due to biological stimuli in the osseointegration process (Lang *et al.,* 2011; Sartoretto *et al.,* 2017; Velloso *et al.,* 2018; Hamlet et al., 2019)

Regarding the macrostructure of the dental implants, previous studies have shown that tapered implants present higher primary stability than cylindrical implants (Sakoh *et al.,* 2006; Torroella-Saura *et al.,* 2015), and this effect may

also affect the acceleration of osseointegration (Torroella-Saura *et al.,* 2015). However, tapered implants can exacerbate the degree of primary stability in denser bones (Baldi *et al.,* 2018). Thus, implants with a hybrid structure; cylindrical in the coronal portion and tapered in the apical portion, have been proposed as an alternative to be used in any type of bone density (Leocádio *et al.,* 2020; Barbosa *et al.,* 2021), which could simplify the clinician's decision-making regarding the type of macrostructure to be used in different clinical conditions. Furthermore, modification in the shape of the implant threads has been proposed, to perforate and compress the surgical site in order to improve and control primary stability of the hybrid implants (Leocádio *et al.,* 2020). However, these implants can exacerbate the degree of primary stability in bones. Thus, the objective of this clinical trial was to evaluate the primary and secondary stability of hybrid implants with different thread configurations.

Material and methods

Ethical considerations and patient selection

This split-mouth randomized controlled clinical trial was approved by the ethical committee of the University of Santa Fé do Sul, Brazil (CAAE: 37995520.7.1001.5428). The study protocol was registered in the Brazilian Registry of Clinical Trials (ReBEC - U1111-1263-9721). In addition, this study followed the ethical precepts set out in the Declaration of Helsinki.

Twenty patients undergoing installation of at least one pair of implants participated in this study. The patients were selected according to the following inclusion criteria: 1) Aged between 18 and 60 years; 2) Requiring multiple, bilateral or unilateral rehabilitation with osseointegrated implants; 3) Sufficient

bone available for installation of a conventional size implant; 4) Good systemic health.

Patients with the following characteristics were excluded from this study: 1) Smokers; 2) Uncompensated diabetics; 3) Patients who are chronic users of medications (e.g., bisphosphonates, immunosuppressants, anti-inflammatory drugs) or with pathologies that alter bone metabolism; 4) Patients who chronically use anti-inflammatory drugs and antibiotics; 5) Bruxism; 6) Chemical dependency; 7) Pregnant or who want to get pregnant in the next year; 8) History of radiotherapy treatment in the head and neck region.

To calculate the sample size, the stability of the implants measured by resonance frequency analysis was used as the primary variable. A study comparing the stability of implants with different macrostructures (Cylindrical vs. Tapered) demonstrated an expected standard deviation for this analysis of 5.19 (Torroela-Saura *et al.,* 2015). Considering a minimum clinically relevant difference for the ISQ of 5 points and setting the β power at 0.90 and type I error at 0.05, it was determined that at least 15 patients would be necessary to carry out this study.

Surgical procedure and groups

After performing the local anesthesia technique, a full-thickness mucoperiosteal flap was opened to expose the ridge. The milling procedure was carried out under abundant irrigation with saline solution and in accordance with the implant manufacturer's recommendations. The implant sites were randomly allocated to receive one of the two implant types. The implants in the control group (CTR) were cylindrical implants in the middle and coronal portion and tapered in the apical portion with perforating threads (Titamax EX®, Neodent, Curitiba, Brazil)

and the implants in the test group (TES) were cylindrical in the coronal portion and conical in the apical and middle portion with perforating and condensing threads. (Helix®, Neodent, Curitiba, Brazil) (Figure 1). The implants had a diameter of 3.75 mm and a length of 9 mm (CTR) or 10 mm (TES), presented morse taper connection, and were installed 2mm subcrestally. Randomization was performed by applying a randomization table at the time of perforation of the site for implant placement (random.org).

After insertion of the implants, the surgical site was sutured with 5.0 nylon threads (Ethicon, Johnson & Johnson, Brazil). Post-operative care included oral application of amoxicillin (500mg) for 7 days, nimesulide (100mg) for 5 days, and sodium dipyrone (500mg) for 3 days. Additionally, 0.12% chlorhexidine gluconate-based mouthwash was prescribed for 14 days. The sutures were removed after 7 days. The healing cap was installed and maintained for a period of 90 days after implant placement, when the implants were submitted to prosthetic loading.

Analysis of stability of the dental implants

At the time of implant placement, primary stability was measured through insertion torque and resonance frequency analysis using the Osstell® device (Osstell AB, Göteborg, Sweden). The system includes the use of a specific SmartPegTM for each implant, which is fixed to the implant by an integrated screw. The SmartPegTM is then excited by a magnetic impulse from the measuring probe of the portable instrument and the implant stability coefficient (ISQ) is calculated. The results are displayed on the instrument, varying on a scale from 1 to 100, in that the higher the ISQ number, the greater the stability of the implant. Stability measurements were obtained on four faces of each implant

(buccal, palatal, distal, and mesial) and the mean of the results was considered the stability value of each implant. The ISQ evaluation was measured again 7, 28, 56, and 90 days after implant placement (Figure 2).

Statistical analysis

GraphPad Prism 6 software (San Diego, CA, USA) was used to perform the statistical analysis of this study. Numerical data from stability analyses demonstrated normal distribution according to the Shapiro-Wilk test. The comparisons between the groups of implants in each follow-up period were evaluated using the paired t-test. Longitudinal data within each group of implants were evaluated using repeated measurements ANOVA complemented by the post-hoc Tukey test. All tests were applied with a confidence level set at 95%.

Results

Forty-eight implants were installed in the posterior maxillary region in 20 patients (6 men and 14 women). Patients received 2 (16 patients) or 4 implants (4 patients), with 24 implants placed in the CTR group and 24 implants placed in the TES group. During the evaluation period, one implant in the CTR group was lost, which generated a survival rate of 95.83% for implants in the CTR group and a 100% survival rate in the TES group. The lost implant was replaced by another implant from the CTR group, but the patient was removed from the follow-ups, because the patient was diagnosed with sinusitis after a medical consultation. Thus, 46 implants placed in 19 patients were included in the final evaluation (Figure 3, Table 1).

The implants in the TES group presented higher insertion torques than the implants in the CTR group, measured by an analog torquemeter (36.92 ± 16.50 Ncm2 vs. 28.00 ± 14.40 Ncm2) $P < 0.05$. In addition, implants in the TES group

had higher ISQ values than implants in the CTR group at baseline (63.61 ± 9.44 vs. 40.59 ±7.46), 7 days (68.67 ± 7.60 vs. 41.55 ± 9.07), 28 days (68.61 ± 5.98 vs. 47.90 ±13.10), 56 days (74.09 ± 3.96 vs. 55.85 ± 13.18), and 90 days (75.45 ± 4.02 vs. 63.47 ± 6.92) after implant placement. The implant stability increased in both types of implants over the follow-up period ($p<0.05$).

Discussion

In the current study, implants with a hybrid macrostructure, associating perforating and condensing threads, presented greater primary stability and acceleration of the conversion from primary to secondary stability compared to hybrid implants with only perforating threads. These findings suggest that implants in the TES group may increase predictability in establishing osseointegration at its most critical moment, and make protocols for early implant loading safer. In fact, TES implants also had a higher survival rate than CTR implants.

The success of dental implants is directly influenced by the level of primary stability after implant placement (Atieh *et al.,* 2018), and the implant macrostructure plays an important role in achieving primary stability (Sakoh *et al.,* 2006; Leocádio *et al.,* 2020). The shape of implants and the thread configurations influence this parameter, as demonstrated in previous studies in which tapered implants presented greater stability than cylindrical implants (Torroela-Saura *et al.,* 2015; Atieh *et al.,* 2018). The implants used in the current study have a hybrid macrostructure in which there is an association of a cylindrical shape in the coronal portion and a tapered shape in the lower portion, and this type of implant macrostructure has also been shown to present superior stability to cylindrical implants (Toyoshima *et al.,* 2015; Leocádio *et al.,* 2020).

Taking into account the data obtained on primary stability in this study, both implants presented adequate values of insertion torque, which demonstrates the effectiveness of this type of implant format in obtaining locking even in low density bone such as in the posterior region of the jaw.

Regarding the shape of the implant threads, studies have shown that different thread configurations present better results depending on the type of bone where the implants are installed (Pérez-Pevida *et al.,* 2020; Yamaguchi *et al.,* 2020). Triangular or sharp threads reduce bone resistance during implant insertion by inducing cuts in the bone structure, which facilitate implant placement in high density bone (Trisi *et al.,* 2015; Ramkumar *et al.,* 2020). On the other hand, the condensing square threads compress the bony trabeculae and increase locking in bone with low density (Falco *et al.,* 2018; Pérez-Pevida *et al.,* 2020). The TES implant presents the association of these two types of threads, the perforating triangular threads are located in the apical portion, while the square condensing threads are located at the coronal portion and this characteristic may explain the superiority in the primary stability of the TES implants compared with the CTR implants.

Primary stability is a good predictor of the osseointegration process, and this requirement has been used as a determining factor for the best time to apply prosthetic loading (Faot *et al.,* 2019; Makary *et al.,* 2019; Faot *et al.,* 2019). In fact, implants in the TES group showed higher levels of secondary stability throughout the study, which corroborates other studies that emphasize the importance of primary stability in achieving faster and more predictable osseointegration (McCullough & Klokkevold, 2017). It is likely that the greater stability obtained in TES implants makes this type of implant safer for immediate

or early loading protocols in low density bone, but this hypothesis needs to be tested in the future.

Another important aspect for the evolution of the osseointegration process is the characteristics of the implant surfaces (Barbosa *et al.,* 2021). In this study, both implants had a hydrophilic surface, with double acid etching and sandblasting before being kept in isotonic solution. Histological analysis of bone-implant contact has shown that this surface accelerates the osseointegration process in preclinical (Buser *et al.,* 2004; Sartoretto *et al.,* 2017) and clinical (Lang *et al.,* 2011) studies, compared to implant surfaces with similar surface treatment but without the same level of high wettability. This acceleration in osseointegration is related to increased osteogenesis, which is increased on this type of surface due to the greater adhesion of undifferentiated mesenchymal cells (Hotchkiss *et al.,* 2019) and stimulation in the differentiation and activity of osteoblasts, which increase bone formation rates (Bang *et al.,* 2014). However, the clinical superiority of the hydrophilic surface in primary stability and its conversion to secondary stability has not been confirmed in clinical studies (Markovic *et al.,* 2017; Barbosa *et al.,* 2021). It is possible that in clinical situations where implants achieve good primary stability the importance of the type of surface used is reduced. In fact, although the implants in the current study presented the same surface, the transition process from primary to secondary stability occurred differently due to the different macrostructural characteristics of the tested implants.

This study has some limitations that must be taken into account when interpreting the obtained findings. The implants were not subjected to occlusal loading, and it is known that loading can stimulate the acceleration of the

osseointegration process (Esaki *et al.,* 2012). In addition, long-term assessments to determine whether these different macrostructures significantly impact implant success and survival are also needed. Finally, the lengths of the implants used were different (TES – 10 mm vs. CTR – 9 mm), but this characteristic does not seem to significantly impact the stability of the implants (Oliveira et al., 2016).

Conclusion

Hybrid implants with perforating and condensing threads demonstrate greater stability than hybrid implants with only perforating threads.

Acknowledgment

This study was funded by the Neodent's research assistance program (20.0731-3).

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Figure legends

Figure 1: A) TES implant; B) Placement of the TES implant; C) CTR implant; D) Placement of the CTR implant; E) Resonance frequency analysis

Figure 2: Flowchart showing the study design

Figure 3: Flow diagram of the study.

Figure 4: Location of implants

Figure 1: A) TES implant; B) Placement of the TES implant; C) CTR implant; D) Placement of the CTR implant; E) Resonance frequency analysis

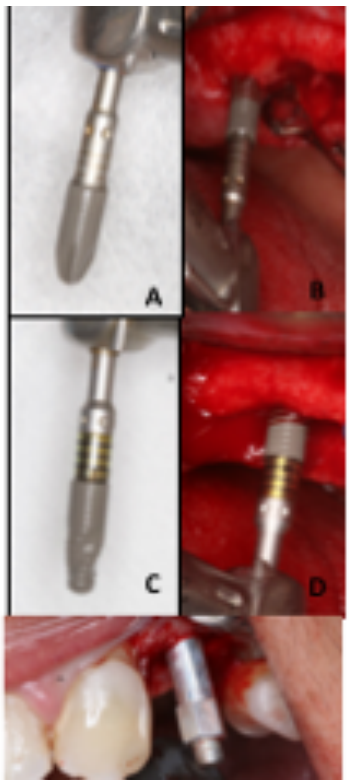


Figure 2: Flowchart showing the study design

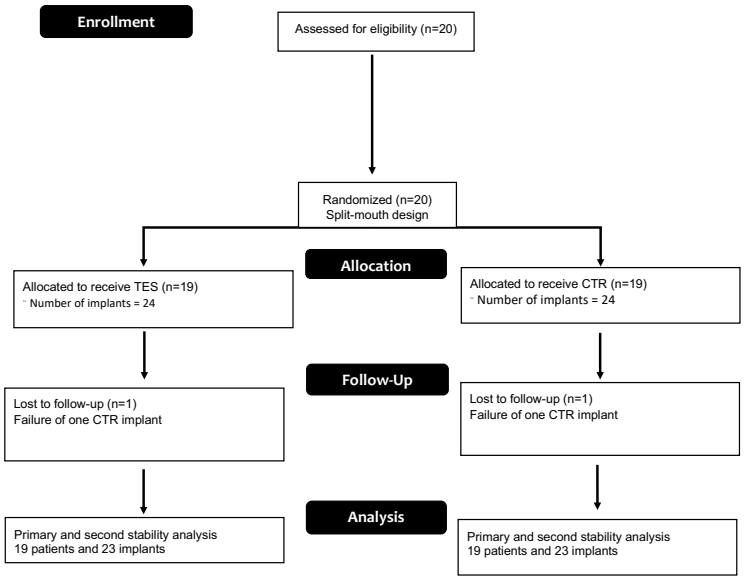


Figure 3: Flow diagram of the study.

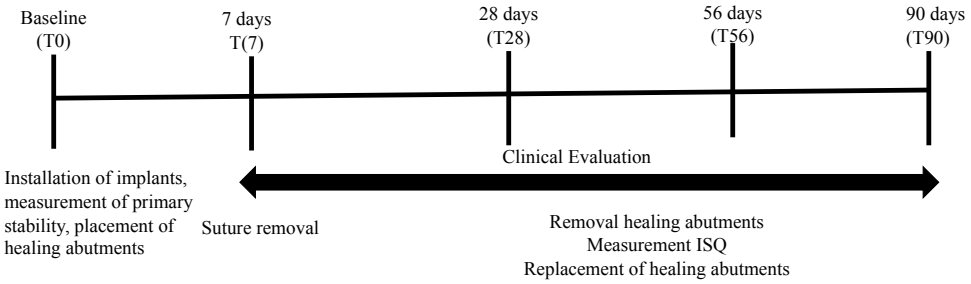
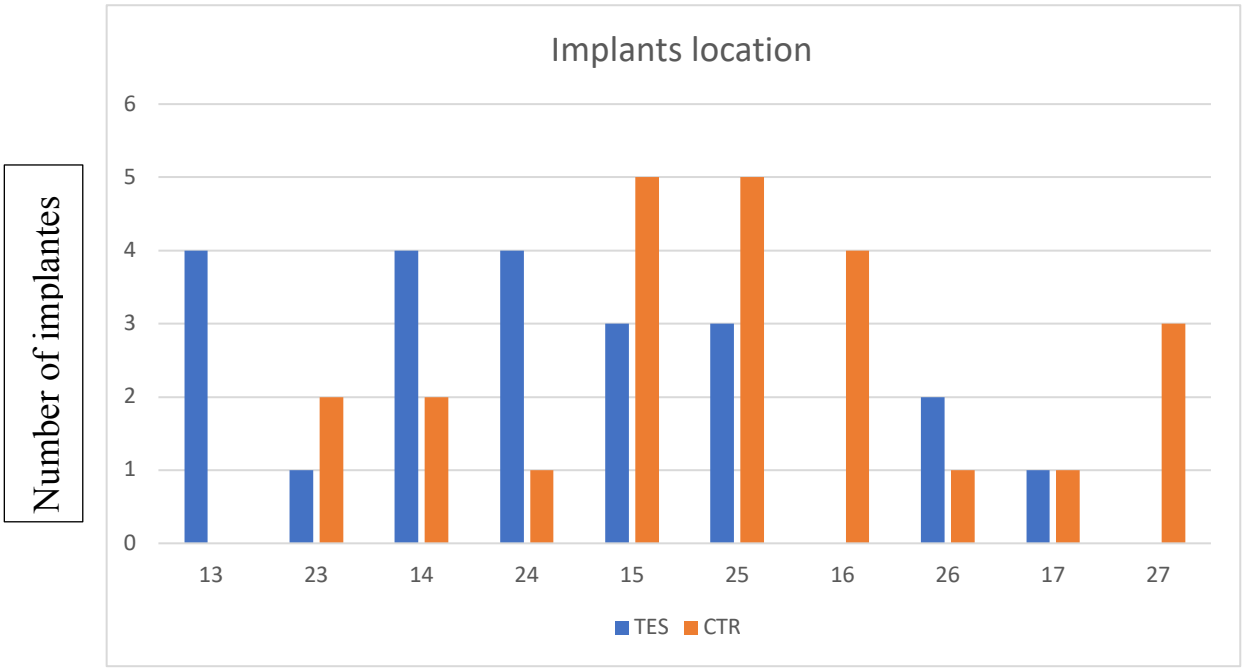


Figure 4: Location of implants



5. CONSIDERAÇÕES FINAIS

De acordo com os estudos que compõem essa tese, pôde-se concluir que a macroestrutura testada, exerceu maior influência clínica no aumento da estabilidade primária e secundária, quando comparado ao efeito da microestrutura de implantes com superfície hidrofílica. O tratamento de superfície induzindo aumento da molhablidade, apesar de aumentar o ângulo de contato entre osso e implante e acelerar o processo de osseointegração, induzindo uma resposta celular, conforme já descrito em estudos anteriores, não foi suficiente para demonstrar uma melhoria significantemente clínica no aumento da estabilidade primária e secundária.

É necessário avaliar a justificativa da indicação deste tipo de tratamento de superfície para todos os tipos ósseos, tendo em vista o custo do processo de fabricação e o valor agregado a compra do implante pelo cirurgião. Em situações de normalidade com pacientes saudáveis, os tratamentos de superfície convencionais tem demonstrado bons resultados. Entretanto deve-se obter evidência do benefícios da utilização deste tipo de tratamento superfície, em

situações de fatores de risco relacionados ao pacientes, como doenças no metabolismo ósseo, pacientes quimioterápicos, radioterápicos, diabéticos e tabagistas. Tais estudos auxiliaram na análise de vantagens que estas superfícies podem demonstrar nessas situações.

Existem outros fatores que influenciam na estabilidade primária relacionados ao paciente como, qualidade óssea e relacionados ao procedimento cirúrgico como, tipo de fresagem e outros fatores necessitam também de mais evidências científicas.

As evidências obtidas nesse estudo podem auxiliar na indicação do melhor tipo de implante, de acordo com a necessidade de aceleração do carregamento protético, ou da melhoria de travamento necessária para reabilitação de implantes em áreas de osso de baixa qualidade.

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ANEXOS:

ANEXO 1: Parecer do comitê de ética primeiro artigo

FUNDAÇÃO EDUCACIONAL DE BARRETOS - FEB

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA
Título da Pesquisa: Avaliação clínica do coeficiente de estabilidade de implantes com superfície hidrofílica.

Pesquisador: celso eduardo sakakura
Área Temática:
Versão: 1
CAAE: 60348716.5.0000.5433
Instituição Proponente: Fundação Educacional de Barretos - FEB
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER Número do Parecer: 1.765.515

Apresentação do Projeto:

Boca dividida, randomizado, onde em um lado os paciente receberção implantes convencionais e do outro implantes com superfície hidrofílica ambos produtos comercializados no mercado brasileiro

Objetivo da Pesquisa:

Objetivo Primário:
Este estudo visa avaliar clinicamente, através da mensuração do coeficiente de estabilidade do implante (ISQ), a estabilidade de implantes de superfície hidrofílica (Acqua, Neodent), comparados a implantes com superfície convencional (Neoporos, Neodent). Buscando possíveis diferenças no tempo de obtenção da estabilidade necessária para carregamento protético e também uma possível obtenção de
um maior coeficiente de estabilidade (ISQ) nos implantes com superfície hidrofílica.

Avaliação dos Riscos e Benefícios:

Riscos:
Não se apresentam riscos que fujam da normalidade da instalação cirúrgica de implantes, tendo em vista que os implantes estão disponíveis no mercado com a devida aprovação pela ANVISA e as indicações são comuns ao tratamento

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reabilitação com implantes odontológicos.
Benefícios:
O presente estudo irá contribuir para o esclarecimento das vantagens do uso de implantes com superfície hidrofílica, recém introduzido no mercado, com avaliação clínica de suas possíveis vantag

Comentários e Considerações sobre a Pesquisa:

De acordo.

Considerações sobre os Termos de apresentação obrigatória:

De acordo.

Conclusões ou Pendências e Lista de Inadequações:

De acordo.

Considerações Finais a critério do CEP:
Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
A	PB_INFORMAÇÕES_BÁSICAS_DO_P ROJETO_693204.pdf	11/05/2016 08:42:06		Aceito
Projeto Detalhado / Brochura Investigador	0.docx	06/05/2016 18:38:39	celso eduardo sakakura	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.docx	06/05/2016 18:37:51	celso eduardo sakakura	Aceito
Folha de Rosto	0000.pdf	05/05/2016 10:45:17	celso eduardo sakakura	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Endereço: Av. Professor Roberto Frade Monte, 389
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ANEXO 2: Parecer comitê de ética terceiro artigo:

Attachments:1 human research ethics committee

FACULDADES INTEGRADAS DE SANTA FÉ DO SUL - FISA/FUNEC

Continuação do Parecer: 4.479.556

seguintes termos: Termo de Anuência Institucional (TAI), Termo de Consentimento Livre e Esclarecido (TCLE) e o Termo de Assentimento (TA) assinados, impreterivelmente até o dia 17/12/2021. Modelo do relatório está no site: http://unifunec.edu.br/comite-de-etica-em-pesquisa

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_1601629.pdf	14/12/2020 18:58:22		Aceito
Outros	Declaracao_ps_iturama.pdf	14/12/2020 18:57:42	PABLO PADUA BARBOSA	Aceito
Declaração de Instituição e Infraestrutura	TERMODEANUENCIAINSTITUCIONAL. docx	14/12/2020 18:51:50	PABLO PADUA BARBOSA	Aceito
Declaração de Instituição e Infraestrutura	TERMODEANUENCIAINSTITUCIONAL FUNEC.docx	14/12/2020 18:45:40	PABLO PADUA BARBOSA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEUnifunecPabloretificado.docx	14/12/2020 18:45:13	PABLO PADUA BARBOSA	Aceito
Outros	DeclaracaoodeanuenciainstitucionalFOU FU.pdf	14/12/2020 18:44:05	PABLO PADUA BARBOSA	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoMacroestruturaImplantesatualiza dopareceCEP.docx	14/12/2020 18:43:08	PABLO PADUA BARBOSA	Aceito

Parecer Anterior	CartarespostaaopareceristaPablo.doc	13/12/2020 13:41:16	PABLO PADUA BARBOSA	Aceito
Folha de Rosto	folhaDeRostoPablo.pdf	04/08/2020 20:32:30	PABLO PADUA BARBOSA	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

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Continuação do Parecer: 4.479.556

SANTA FE DO SUL, 21 de Dezembro de 2020

Assinado por:

Marisa Lídia Azevedo Silva (Coordenador(a))

ANEXO 3: Comprovação da Publicação do primeiro artigo Qualis A2

QUINTESSENCE PUBLISHING

JOMI
OFFICIAL JOURNAL OF THE ACADEMY OF OSSEOINTEGRATION

The International Journal of ORAL & MAXILLOFACIAL IMPLANTS

Steven E. Eckert
Editor-in-Chief

Volume 36 , Issue 4
July/August 2021
Pages 787–792

Primary and Secondary Stability of Implants with Hydrophilic Surfaces in the Posterior Maxilla: A Split-Mouth Randomized Controlled Clinical Trial

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Purpose: The aim of this split-mouth randomized clinical trial was to evaluate the primary and secondary stability of implants with hydrophilic surfaces in comparison to implants with conventional surfaces in the posterior region of the maxilla. Materials and Methods: Twenty patients with a