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 bilateral edentulous ridge in the posterior area of the maxilla randomly received implants with two types of surfaces: *(1)* implants with the surface modified by double acid-etching and sandblasting (DAS, n = 20); and *(2)* implants with the 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 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 28 days, which increased significantly at 40 and 90 days in both surfaces. ***Conclusion:*** It can be concluded that the surface wettability of implants with a hybrid macrostructure did not increase the primary and secondary implant stability in the posterior region of the maxilla. *Int J Oral Maxillofac Implants 2021;36:787–792. doi: 10.11607/jomi.8636*

Keywords: dental implants, implant surface, stability

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] and 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

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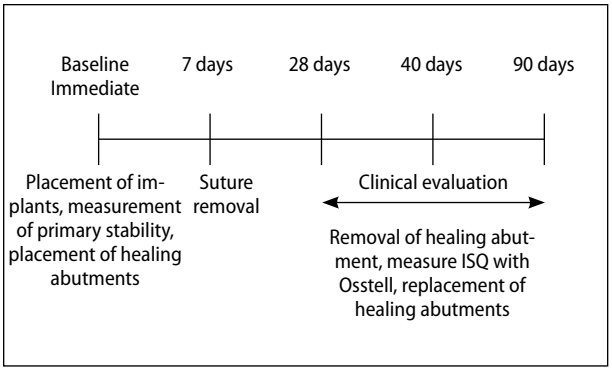

Fig 1 Study design.

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 with the other regions of the oral cavity, eg, mandibular 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 with double acid-etching and sandblasting (DAS) surfaces in the posterior region of the maxilla.

MATERIALS AND METHODS

Ethical Considerations

This study was submitted to and approved by the ethical committee for human research of the University Center of the Educational Foundation of Barretos 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), 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). The implants presented the same macrostructure, were the same size (3.75 mm × 9.0 mm), 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). 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 placement in the first or second quadrant of the posterior region of the maxilla (premolars and molars). The placement 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 (Fig 1).

Inclusion and Exclusion Criteria

To be included in this study, the patients were required to be older than 18 years of age, 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, users of medications that altered the bone metabolism, patients with active periodontal disease, and 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 placement. 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 .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

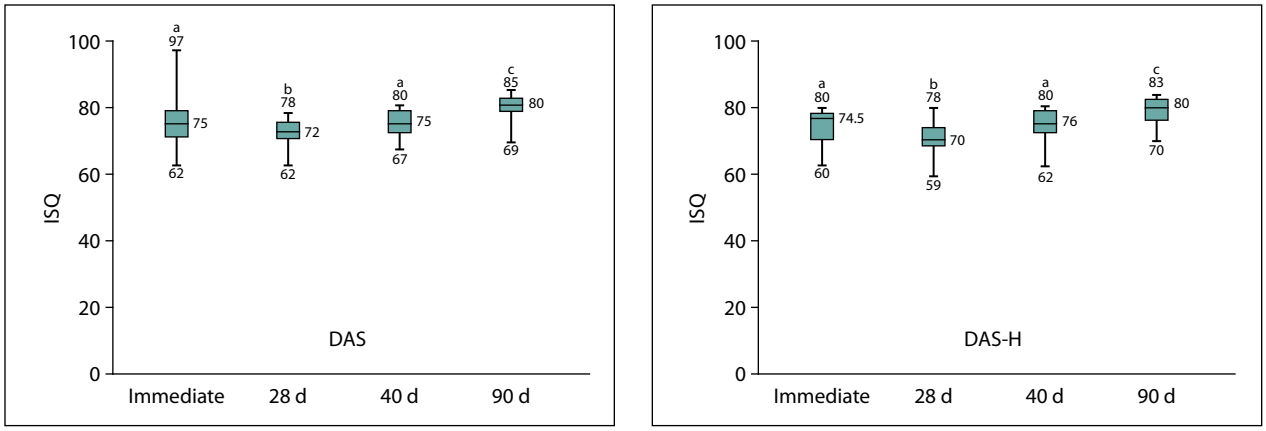

Fig 2 Median and quartiles (minimum and maximum). Different letters indicate statistically significant differences among periods within each group (Friedman test; $P < .0001$).

(n = 40) were placed, 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 place the implants of both groups. The S-max SG20 contra-angle (NSK) was used, mounted on the NSK Surgic Pro surgical engine (NSK), for bone perforation and implant placement. The perforations were performed at 1,000 rpm with 45 Ncm of torque using the manufacturer's surgical kit. The following sequence of drills was used: Spear drill (9 mm 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 postoperative medications were prescribed for all patients: amoxicillin 500 mg (8/8 hours for 7 days), nimesulid 100 mg (12/12 hours for 3 days), and dipyrone 500 mg (6/6 hours 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 ISQ using Osstell (Osstell). 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 baseline were considered together as the primary stability, while the assessment of the ISQ during the follow-up until 90 days 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 nonparametric 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 nonparametric 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 was used to perform the statistical analysis, and all the statistical tests were applied with the significance level set at .05.

RESULTS

There were no statistical differences between the DAS and DAS-H groups for the primary stability measured by insertion torque (DAS: 26.27 ± 12.22 Ncm; DAS-H: 23.36 ± 14.46 Ncm; $P > .05$) and ISQ (DAS: 74.6 ± 6.0; DAS-H: 72.7 ± 6.0; $P > .05$).

Figure 2 shows the comparisons among periods within the groups. The ISQ median of the secondary stability was reduced significantly in both groups at the 28th day in comparison to the baseline (DAS: from 75 to 72; DAS-H: from 74.5 to 70; $P < .05$). At the 40th day, there was an increase in the ISQ median values for the DAS (75) and DAS-H (76) groups, with similar medians

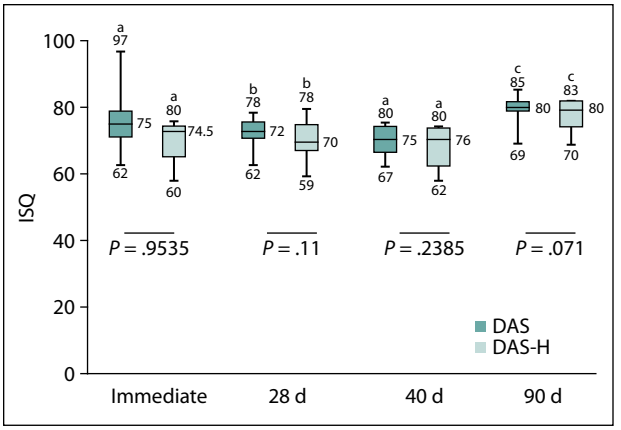

Fig 3 Median and quartiles (minimum and maximum). Identical letters between DAS and DAS-H groups do not indicate statistically significant difference (Wilcoxon test; $P > .05$).

compared with baseline data (immediate vs day 40; $P > .05$). The highest ISQ median values were obtained at the 90th day for both groups (DAS: 80; DAS-H: 80), with a statistically significant difference compared to the other periods ($P < .05$). In general, the ISQ values in both types of implants were reduced at 28 days and then increased at 40 and 90 days.

Figure 3 shows that both groups (DAS and DAS-H) showed similar median values at baseline (immediate) and at 28, 40, and 90 days, with no statistical significant difference between groups ($P > .05$).

DISCUSSION

The surface of implants with higher wettability properties has been shown to improve osseointegration with greater bone area and bone-to-implant contact in histomorphometric analyses[1,2,11,12]; however, some findings did not demonstrate differences between hydrophilic implants compared with the control group measured by indirect methods such as the ISQ analysis.[6] These results are in agreement with the present findings, which 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-to-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-to-implant contact through voids not demonstrating an effect on ISQ values.[3] A preclinical study conducted on minipigs 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-to-implant contact than DAS implants 2 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 micromovement 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 28 days 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 the present 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 that 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 28 days for the DAS-H implants. However, the reduction in the ISQ noted in both types of surfaces in this study may not influence the clinical outcomes since the values of the ISQ presented at 28 days were higher than 65, which is considered to be 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 that the good primary stability obtained in the present 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 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 this is a determining factor for obtaining primary stability.[3,16] The absence of the effect of the DAS-H on the primary stability in the present 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 that is 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-to-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.

The present study has some limitations that must be taken into account when interpreting the findings. ISQ analysis is a noninvasive 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 present 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 with unloaded implants.[27] Thus, the behavior of the DAS-H in loaded conditions requires more investigation.

CONCLUSIONS

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

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