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Randomised Controlled Trial
Dental Implants

Hydrophilic modification of sandblasted and acid-etched implants improves stability during early healing: a human double-blind randomized controlled trial

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Abstract. A randomized controlled trial was performed to evaluate and compare the changes in implant stability quotient (ISQ) of implants of the same brand, design, length, and diameter but with two different surface treatments, placed in the posterior mandible: sandblasted and acid-etched (SAE) and chemically modified SAE (hydrophilic). Twenty implants of the same design, length, and diameter (cylindrical and compressive, 3.75 × 11 mm) but with different surface treatments (control group: 10 SAE; test group: 10 modified SAE) were randomly assigned to placement in the posterior mandibular region in 20 different patients. ISQ values were assessed in a blinded manner for six consecutive weeks. The maximum and minimum ISQ values observed during follow-up were 76.0 and 48.5, respectively, in the test group, and 76.0 and 49.0, respectively, in the control group. There was no statistically significant difference ($P = 0.19$) in ISQ variation for the test group implants (modified SAE). Comparison between the test and control groups revealed a significant difference in the measurements: the ISQ in the test group was higher than that in the control group during the follow-up period (parametric Mann–Whitney test). This study demonstrated that implants with a modified SAE surface installed in the posterior mandible showed higher and faster ISQ stability during the healing period when compared to implants with a SAE surface.

Key words: dental implant; implant stability; osseointegration; randomized controlled trial; implant surface.

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The osseointegration of dental implants is a predictable event with a high success rate[1]. The treatment of the implant surface and the primary stability obtained at the time of the surgical installation are key parameters for the success and speed of osseointegration[1,2]. Recent studies have shown that certain modifications of the surface of dental implants result in faster osseointegration when compared with implants that have only a machined surface[3,4]. The physical modification of the surface of dental implants is usually done by addition or subtraction of micro- or nanoscale materials[5]. Furthermore, chemical modification of the composition of the titanium surface can be done with plasma treatment or by oxidation[6].

One of the benefits of the treatment of the surface of implants is the increased hydrophilicity (wettability). In general, the surface energy is directly associated with the degree of hydrophilicity of the implant[7]. Positively charged surfaces tend to exhibit greater hydrophilicity[8]. Preclinical[4,9] and clinical[10,11] studies have shown that implants with a hydrophilic surface tend to show greater differentiation and cellular aggregation, which significantly increase bone–implant contact (BIC), especially in the early stages of the healing process.

Stability of a dental implant is defined as the absence of movement of the implant at the time of the surgical installation (primary stability) or in the late phase of osseointegration (secondary stability)[12]. One of the most common non-invasive methods used for the assessment of primary and secondary stability is resonance frequency analysis (through the implant stability quotient, ISQ), which was proposed by Meredith et al.[13] in 1996.

Healthcare regulators and professionals are required to provide evidence of the safety and efficacy of products through the use of standardized protocols, in order to dispel controversy and prevent the use of ineffective materials[4]. The aim of this study was to investigate the impact of the surface properties of new commercially available dental implants installed in the posterior mandible.

Materials and methods

Study design

This randomized double-blind controlled trial was conducted in the Department of Periodontology of the Federal Fluminense University between April 2015 and February 2017. The study followed the principles described in the Declaration of Helsinki regarding experiments in humans and was approved by the Ethics Committee of the University Hospital Antonio Pedro. All participants in the study signed an agreement of free and informed consent.

In order to ensure the quality and transparency of this randomized study, the guidelines in the CONSORT Statement were followed[14].

Outcome measure

The primary outcome was the stability of the implants in terms of the ISQ in the test and control groups during 6 weeks of healing.

Inclusion and exclusion criteria

All study participants were informed of the study purpose and procedures, including the potential risks and benefits associated with the therapy. The complete medical and dental history was obtained for each patient. Radiographic examinations were conducted using cone beam computed tomography (CBCT) (i-CAT; KaVo, Joinville, SC, Brazil). Healthy volunteers over 20 years of age, with an edentulous area in the posterior mandibular region, requiring rehabilitation with dental implants, with no history of bone regeneration, with a minimum post-extraction healing period of 90 days, and with a alveolar ridge height $\geq$13 mm and width $\geq$6 mm, were included in this study. Smokers, pregnant women, people with motor difficulties that impede or hamper hygiene or with a history of radiotherapy or use of bisphosphonates, were excluded from this study.

Sample size calculation, randomization, and blinding

The sample size calculation for this study was conducted using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA). This study had a parallel design, thus the method of randomization used was inter-participant through the system of opaque envelopes. The participants were divided into two groups: the test group (modified sandblasted and acid-etched (SAE) implants) and the control group (SAE implants). All participants in the study were blinded to the type of implant they received.

Surgical procedure

All patients were operated on by the same surgeon (G.V.) under local anaesthesia with mepivacaine 2% (Mepiadre; Nova DFL, Rio de Janeiro, RJ, Brazil). The surgeon was calibrated before the study and used the same surgical protocol for all patients. Preoperative examinations included a clinical examination, diagnostic models, and CBCT. After obtaining the CBCT image, Dental Slice surgical planning software (Bioparts, Brasília, DF, Brazil) was used to determine the correct position of the implant and to make a surgical guide. Twenty implants with the same prosthetic connection (external hexagon) and of the same design, diameter and length (3.75 $\times$ 11 mm) were used. The test group consisted of 10 Titamax Ex Ti Acqua implants (Neodent, Curitiba, Brazil). These implants have a SAE surface and have undergone additional chemical treatment to impart hydrophilic characteristics to the surface (modified SAE). The control group consisted of 10 Titamax Ex Ti NeoPoros implants (Neodent, Curitiba, Brazil). These implants have a SAE surface without hydrophilic characteristics. The implants were installed according to the manufacturer's instructions.

After single-stage installation of the implants, a standard device was connected to the implant platform (SmartPeg; Osstell, Göteborg, Sweden) to allow the determination of the ISQ over a period of 6 weeks, at the following time points: immediately postoperative (T0), 1 week (T1) 2 weeks (T2), 3 weeks (T3), 4 weeks (T4), 5 weeks (T5), and 6 weeks (T6) postoperative. All measurements were conducted by an examiner who was blinded to the implant used.

Suture removal was performed 7 days after the surgery. Antibiotic medication, amoxicillin (875 mg) with potassium clavulanate (125 mg), was prescribed for all participants for 7 days. Dipyrone 1 g every 6 hours was also prescribed in case of pain. Chlorhexidine gluconate 0.12% mouthwash (twice daily for 2 weeks) was also prescribed.

During the healing period, the implants received a healing screw that varied according to the mucosal thickness of the patient, but this never exceeded 2 mm above the gingival level.

Measurement of resonance frequencies and clinical evaluations

After installation of the SmartPeg under the implant, blinded measurements of the ISQ in the buccal–lingual (B–L) and mesial–distal (M–D) directions were conducted for six consecutive weeks. A further clinical evaluation was performed after 2 months, during which the participants were referred to the prosthesis manufacturer. Clinical and radiographic examinations were performed at 12

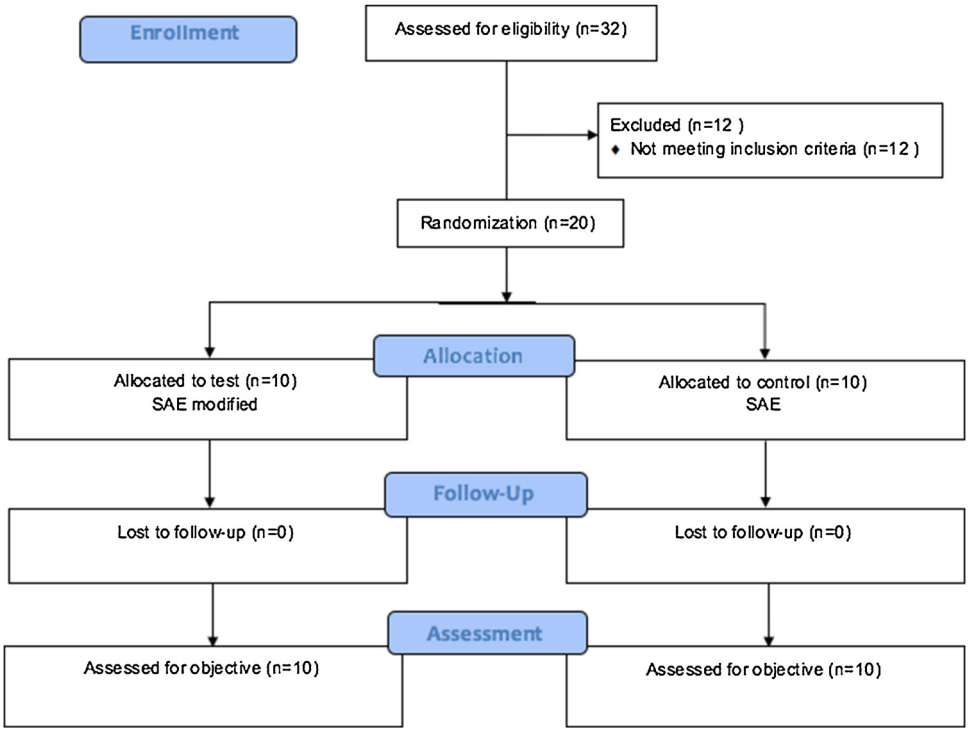

Fig. 1. CONSORT flow diagram showing the recruitment, inclusion, and assignment of the study sample.

months after installation of the implants in order to evaluate implant survival.

Statistical analysis

The normality of the distribution of the mean ISQ values in the test and control groups at the different evaluation time points was evaluated using the Kolmogorov–Smirnov normality test with a significance level of 5%. For the evaluation of the difference in the means between the six measurements in each group, and because the numerical interval measurements were performed in the same set of patients at different times, characterizing the data as dependent or paired, the Friedman non-parametric test was applied, with a significance level of 5%. For direct comparison between the test and control groups at each measurement time point, the non-parametric Mann–Whitney test was applied with a significance level of 5% for each measurement, assuming the non-normality of the values of the measurements and considering the Kolmogorov–Smirnov test applied to the raw data of the experiment.

Results

Sample size calculation

The test power revealed a sample size of at least eight implants in each group, with 80% strength and a significance level of 5%. Considering a dropout rate of 20% in advance, a sample size of 10 implants for each group was adopted.

Population data

A total of 20 participants, nine male and 11 female with a mean age of 37 ± 10.6 years, were recruited into this study between April 2016 and February 2017. The CONSORT flow diagram of participant selection is presented in Fig. 1. All ISQ measurements were conducted for 6 weeks; however the participants were followed up for 12 months with the objective of monitoring the survival of the implants and the final prosthetic rehabilitation.

At each measurement visit, no biological complications or implant losses were observed (100% survival rate). No dropout was recorded during the study. The demographic data (sex and age), implant sites, and bone density classification at the implant sites[15] of the study participants are described in Table 1.

At the time of referral for the preparation of the prosthesis, all implants in the test group and the control group were

Table 1. Demographic data of the study participants.

Variable	Test group	Control group	*P*-value
Age (years)	36.9 ± 10	37.2 ± 11.3	NS
Sex, *n* (%)			
Male	4 (40)	5 (50)	NS
Female	6 (60)	5 (50)	
Sites (bone density)	44 (D3)	37 (D3)	NS
	36 (D3)	36 (D2)	
	36 (D4)	46 (D4)	
	37 (D3)	47 (D4)	
	46 (D2)	36 (D3)	
	36 (D3)	46 (D4)	
	45 (D4)	36 (D3)	
	35 (D3)	46 (D2)	
	36 (D3)	44 (D3)	
	46 (D3)	34 (D3)	

NS, not significant.

clinically osseointegrated. The participants were reassessed at 12 months after implant installation.

Implant stability

The bone density scores at the implant sites, based on the classification of Lekholm and Zarb[15], are presented in Table 1. The scores were found to be equivalent in the two groups (no statistically significant difference; $P = 0.60$, nonparametric Mann–Whitney test at the 5% level of significance).

The maximum and minimum variations in the ISQ observed during follow-up measurements were 76.0 and 48.5, respectively, in the test group, and 76.0 and 49.0, respectively, in the control group. Tables 2 and 3 present the B–L and M–D values, as well as the mean obtained for each participant throughout the follow-up period. Analysis of the test group revealed no statistically significant difference between the seven measurements ($P = 0.19$), with an increase in the ISQ over time. Analysis of the control group revealed a statistically significant difference between the seven measurements ($P = 0.004$), revealing that for the SAE surface, the ISQ value decreased over time.

The mean and standard deviation values of the ISQ measurements for the participants in the test and control groups at the different evaluation time points are presented in Table 4.

Comparison between the test group and the control group showed no statistically significant difference in the measurement results at T0 ($P = 0.85$) or T1 ($P = 0.52$). In contrast, significant differences in measurements were found at T2 ($P = 0.03$), T3 ($P = 0.04$), T4 ($P = 0.03$), T5 ($P = 0.03$), and T6 ($P = 0.03$), revealing that the ISQ in the test group was higher than that in the control group at each of these five evaluation periods.

Considering the ISQ behaviour for the test and control groups as a function of the time of measurement, a comparison between the two linear regression curves was performed. The curve of the test group showed a positive correlation and a statistically significant difference in relation to time ($r = 0.94$ and $P = 0.001$), i.e., as time passed the ISQ increased. Conversely, the curve of the control group showed a negative and statistically significant correlation with time ($r = -0.62$ and $P = 0.1307$), i.e., the ISQ tended to decrease over time. Figure 2 shows the mean ISQ values of the test and control groups at the different follow-up times.

Table 4. Mean ISQ values of the participants in the test and control groups.

Measurement	Test		Control	
	Mean	SD	Mean	SD
T0	62.7	8.6	63.5	8.4
T1	65.1	5.9	62.9	8.9
T2	64.9	8.3	59.2	8.6
T3	65.9	6.6	58.5	8.1
T4	66.3	5.5	59.1	7.7
T5	66.9	5.8	60.4	7.4
T6	67.1	5.9	61	7.2

ISQ, implant stability quotient; SD, standard deviation.

Discussion

This prospective, clinical, randomized, and double-blind study confirmed the hypothesis that the modified (hydrophilic)

Table 2. ISQ measurements obtained in the B–L and M–D directions for the modified SAE surface.

Patient	T0			T1			T2			T3			T4			T5			T6		
	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean
1	49	56	52.5	69	70	69.5	70	77	73.5	74	75	74.5	70	68	69.0	63	63	63.0	62	63	63.0 [62.5]
2	60	60	60.0	63	64	63.5	59	43	51.0	62	55	58.5	64	58	61.0	64	60	62.0	64	60	62.0
3	71	68	69.5	70	70	70.0	72	70	71.0	71	67	69.0	73	68	70.5	74	74	74.0	74	74	74.0
4	76	76	76.0	66	63	64.5	69	69	69.0	67	67	67.0	70	70	70.0	74	74	74.0	74	73	74.0 [73.5]
5	74	75	74.5	72	70	71.0	72	70	71.0	73	70	71.5	71	70	70.5	69	68	68.5	69	68	69.0 [68.5]
6	56	54	55.0	69	64	66.5	49	48	48.5	68	69	68.5	69	69	69.0	71	70	70.5	71	69	70.0
7	55	52	53.5	56	53	54.5	68	69	68.5	59	55	57.0	60	56	58.0	62	60	61.0	62	61	62.0 [61.5]
8	66	65	65.5	75	70	72.5	55	50	52.5	75	71	73.0	75	71	73.0	76	70	73.0	76	70	73.0
9	59	55	57.0	60	56	58.0	59	64	61.5	61	54	57.5	61	56	58.5	61	57	59.0	61	58	60.0 [59.5]
10	64	63	63.5	62	60	61.0	59	57	58.0	63	62	62.5	64	63	63.5	64	64	64.0	64	64	64.0

ISQ, implant stability quotient; B–L, buccal–lingual; M–D, mesial–distal; SAE, sandblasted and acid-etched; T0, immediately postoperative; T1, 1 week postoperative; T2, 2 weeks postoperative; T3, 3 weeks postoperative; T4, 4 weeks postoperative; T5, 5 weeks postoperative; T6, 6 weeks postoperative.

Table 3. ISQ measurements obtained in the B–L and M–D directions for the SAE surface.

Patient	T0			T1			T2			T3			T4			T5			T6		
	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean	B–L	M–D	Mean
1	63	61	62.0	75	75	75.0	70	73	71.5	68	70	69.0	68	72	70.0	70	75	72.5	71	75	73.0
2	73	73	73.0	72	73	72.5	69	68	68.5	61	58	59.5	56	57	56.5	55	57	56.0	56	57	57.0 [56.5]
3	53	60	56.5	53	59	56.0	50	61	55.5	53	62	57.5	55	62	58.5	60	65	62.5	60	65	63.0 [62.5]
4	74	71	72.5	65	60	62.5	65	62	63.5	48	50	49.0	56	59	57.5	51	56	53.5	52	57	55.0 [54.5]
5	75	77	76.0	73	77	75.0	75	76	75.5	75	74	74.5	75	74	74.5	74	74	74.0	75	74	75.0 [74.5]
6	55	48	51.5	50	49	49.5	75	76	75.5	50	52	51.0	50	48	49.0	55	52	53.5	55	53	54.0
7	57	54	55.5	56	52	54.0	54	51	52.5	52	51	51.5	55	52	53.5	56	54	55.0	56	55	56.0 [55.5]
8	59	57	58.0	57	63	60.0	74	70	72.0	53	58	55.5	53	57	55.0	58	58	58.0	58	59	59.0 [58.5]
9	62	72	67.0	60	68	64.0	54	60	57.0	58	65	61.5	57	64	60.5	57	65	61.0	57	65	61.0
10	62	64	63.0	60	60	60.0	62	57	59.5	55	56	55.5	56	56	56.0	58	57	57.5	59	58	59.0 [58.5]

ISQ, implant stability quotient; B–L, buccal–lingual; M–D, mesial–distal; SAE, sandblasted and acid-etched; T0, immediately postoperative; T1, 1 week postoperative; T2, 2 weeks postoperative; T3, 3 weeks postoperative; T4, 4 weeks postoperative; T5, 5 weeks postoperative; T6, 6 weeks postoperative.

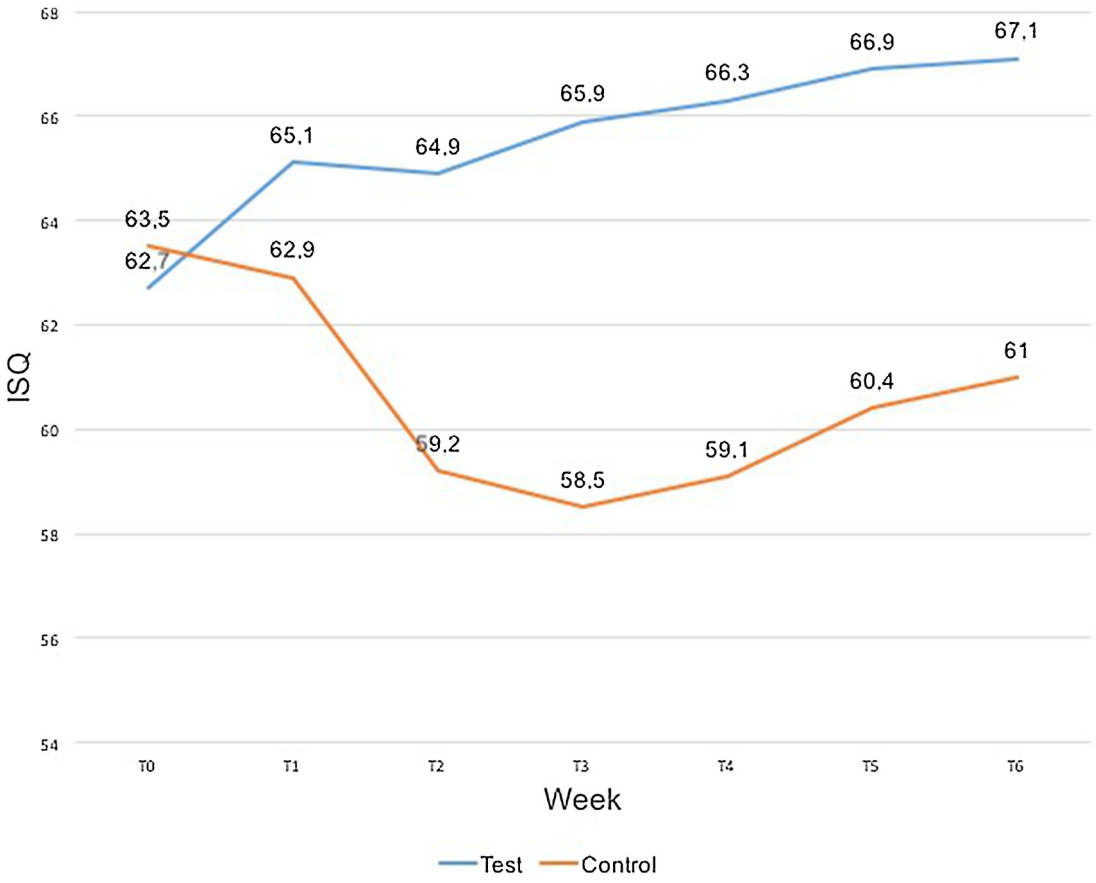

Fig. 2. Implant stability quotient (ISQ) of the test and control groups during follow-up.

SAE surface tends to maintain the ISQ over time and promotes faster osseointegration when compared to the SAE surface. The modified SAE surface showed a positive response regarding implant stability during the most critical period for osseointegration, with increased ISQ values at weeks 2, 3, 4, 5, and 6, while the control group showed a decrease in these values at the respective evaluation time points.

The generally observed changes in implant stability over time reflect the biological changes associated with the bone–implant interface[17]. A decrease in implant stability during the first days after surgical installation is commonly observed and is associated with physiological bone remodelling due to surgical trauma[18]. In contrast, the increase in ISQ value over time reflects bone apposition at the bone–implant interface[19].

In this study, the increasing ISQ values in the test group during the follow-up period suggest that the greater hydrophilicity of the implant surface optimized the healing process and bone repair. Other studies investigating the performance of hydrophilic surfaces have also observed satisfactory results in animal models[4,6] and in humans[11,17]. The surfaces of conventional implants are kept dry and in direct contact with air, which decreases the surface energy and renders them hydrophobic due to the adsorption of carbon and hydrocarbons. This feature decreases the wetting of the implant by the surrounding biological environment and consequently hinders the aggregation of proteins to induce cellular responses[20]. In addition, hydrophilic surfaces are conducive to a higher gene expression, osteoblastic stimulation, bone mineralization, and early osseointegration[21]. In this way, the greater surface energy present in the hydrophilic surfaces tends to accelerate the substitution of the primary bone stability (mechanical) for the secondary bone stability (biological)[22].

Numerous factors can influence the stability of implants, e.g., diameter, length, design, and region of installation[23]. In this study, standardization of the possible variables was ensured: the implants installed were of the same design, diameter, and length. In addition, other variables such as the participants' sex, age, and bone density did not differ significantly between the test group and the study group. The initial maximum and minimum ISQ values of the test group (76.0 and 48.5) and the control group (76.0 and 49.0) were also comparable, which allowed for similar biological conditions in the healing process.

The results of this study demonstrated that in the test group, there was no decrease in the ISQ during the first 6 weeks of postoperative follow-up. This suggests that the osseointegration process occurred faster when compared to that in the control group. However, the study data did not allow us to determine whether the quality of the final osseointegration differed between the groups. Only histomorphometric data could have shown the quality of the BIC interface, but it was not possible to conduct the necessary examinations on the participants included in this study for ethical reasons. Nevertheless, animal testing has shown that in addition to faster osseointegration, the hydrophilic surfaces also demonstrate a higher rate of BIC[4,9].

Treatments that can maintain the stability of implants in the initial postoperative period and accelerate osseointegration represent a significant improvement in

clinical practice. The use of implants with hydrophilic surfaces carries the real possibility of shortened waiting periods for prosthetic loading and consequently a decrease in the total treatment time. Bornstein et al.[21] observed a high survival rate (96.4%) of implants with a hydrophilic surface that underwent early prosthetic loading (third week) in the posterior mandibular region. Another study also investigating early loading (third week) of implants with a hydrophilic surface in the posterior maxillary region, obtained a survival rate of 100%[24]. The loading period in these previous studies is congruent with the findings of the present study, which showed that there was a higher increase in ISQ values for the test group (modified SAE surface) from the third week, suggesting safety for early loading.

All implants used in this study had similar characteristics, with the exception of the surface. In addition, all were installed in the posterior mandible region. Although different ISQ measurements were observed during the study, the most important factor is that the stability increased with time, and significantly more rapidly in the test group than in the control group. Although this subject is currently being studied a great deal, more randomized clinical trials are required to scientifically confirm that the modified SAE surface accelerates osseointegration and reduces failures in the initial healing phase[25].

In conclusion, this study demonstrated that implants with a modified SAE surface installed in the posterior mandibular region, showed higher and faster ISQ stability during the healing period when compared to implants with a SAE surface.

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Competing interests

The authors declare that there was no conflict of interest during the elaboration of this study.

Ethical approval

This study was approved by the Ethics Committee of the University Hospital Antonio Pedro under Certificate of Presentation for Ethical Consideration No. 55264116.90000.5243.

Patient consent

Written participant consent was obtained.

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