## ORIGINAL RESEARCH Implantology

# Can implant surfaces affect implant stability during osseointegration? A randomized clinical trial

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**Abstract:** This randomized clinical trial evaluated the insertion torque (IT), primary, and secondary stability of dental implants with different surface treatments during the osseointegration period. Nineteen patients with bilateral partial edentulism in the posterior mandibular region were randomly allocated to two implant brand groups and received implants with different surface treatments in the opposite site of the arch: Osseotite and Nanotite or SLA and SLActive. During implant placement, the maximum IT was recorded using a surgical motor equipped with a graphical user interface. The implant stability quotient (ISQ) was assessed immediately after the IT, and was measured weekly via resonance frequency analysis during 3 months. The data were analyzed by a one-way ANOVA, the Bonferroni test, paired t tests and Pearson's correlation coefficient. The IT values were similar (p > 0.05) for all implant types ranging from  $43.82 \pm 6.50$  to  $46.84 \pm 5.06$ . All implant types behaved similarly until the 28th day (p > 0.05). Between 35 and 56 days, Osseotite and SLActive showed lower ISQ values (p < 0.001) compared to Nanotite and SLA implants. After 56 days, only Osseotite maintained significantly lower ISQ values than the other implants (p < 0.05). After 91 days the ISQ values were significantly higher than the baseline for all four implant types (p < 0.001). The ISQ and IT values were significantly correlated at the baseline and at the final evaluation for Osseotite, Nanotite, and SLActive implants (p < 0.001). After 91 days, ISQ and IT values were only significantly correlated for the Osseotite implants (p < 0.05). All implants types exhibited acceptable primary and secondary stability.

**Keywords:** Dental Implants; Randomized Clinical Trials as Topic; Jaw, Edentulous, Partially.

#### Introduction

In recent decades, scientific progress has enabled widespread clinical applications for dental implants in the domain of oral rehabilitation through the implementation of simplified surgical techniques, innovations in macro- and microgeometry, and surface treatments.<sup>1,2,3</sup>. This evolution has ensured the applicability of these methods with high predictability for most healthy patients, and similar success rates have been seen for both the maxilla and the mandible.<sup>3</sup>



In compromised bone sites, the choice of implants with modified surfaces has directly influenced implant survival rates. Previous studies have shown that the bone quality is directly affected by the surface roughness of the implants. At the start of osseointegration, the adhesion of osteoblasts to the dental implant surface is insufficient to guarantee complete healing. This early adhesion is a prerequisite for osteoblast proliferation by mesenchymal cells. Increasing the surface roughness of the implants thus facilitates the retention of osteogenic cells and enables the faster migration of these cells to the implant surface via osteoconduction.

However, many factors can influence the long-term osseointegration success of implants, especially those related to the host bone availability and micro-architectural properties, the surgical planning, and the dental implant properties.<sup>6,7</sup> Dental implants thus require the implementation of an atraumatic surgical technique to reach primary stability. In addition, their biocompatibility, design, and surface characteristics should be observed to minimize the inflammatory responses, thus contributing to a favorable secondary stability.<sup>6,7</sup>

Modifications of the implant surface topography, structure, chemistry, surface charge, and wettability to achieve increased roughness have important influences on osseointegration.8 The final goal of implant surface modification is to create a more osteophilic surface, i.e., a surface that attracts bone-forming cells.<sup>9,10</sup> Both industry and research groups have examined modified titanium implant surfaces. Much research has focused on subtractive production methods, such as sandblasting and/or acid etching, and on methods involving the deposition of calcium phosphate crystals. Surface chemistry modifications that promote an extensive hydroxylation/hydration of the oxide layer have also been extensively researched, as this procedure should lead an interaction between surface atoms and the water shell around biomolecules, such as proteins.11 Hydrophilic titanium surfaces contribute to the acceleration and enhancement of bone apposition in animal models12 via the adsorption of proteins that impact the initial regulation of cellular adhesion. Finally, the stabilization of blood clots and early vascularization, which can be influenced by the

surface of dental implants, may also play an essential role during the early stages of peri-implant wound healing.<sup>13,14</sup> All the aforementioned modifications to bone-implant interfaces have reduced the healing period involved when using titanium implants.<sup>14,15</sup>

Non-hydrophilic implant surfaces have also enhanced bone apposition during the initial healing period and have shown favorable results when early-load protocols are applied.<sup>11</sup> The mechanisms involved are based on a bone-bonding phenomenon involving an interdigitation of the cement line matrix of the bone with surface features of the underlying implant.<sup>13</sup> Jonge et al.,<sup>9</sup> showed an increased adhesion of osteoblast-like cells to such coatings in an in vitro study. Calcium phosphate (CaP) coatings are known to promote in vitro cell attachment and the production of extracellular matrix (ECM), whereas in vivo studies have confirmed the increased osteoconductive properties of CaP coatings when such implants were compared to non-coated implants. 16,17 This favorable property of CaP coatings is thought to be related to the similarity in chemical composition between synthetic CaP and natural CaP. Despite this chemical similarity, the deposited coatings do not show structural or biological similarity with bone tissue because natural bone also contains an organic matrix of collagen and non-collagenous proteins. Therefore, new techniques such as the electrostatic spray deposition of CaP have been explored in an attempt to promote osteoconductivity and osteogenesis and enhance osseointegration. Electrostatic CaP might be able to induce osteoblast attachment and consequently support cell differentiation and proliferation.<sup>18</sup>

Various studies<sup>4,5,19</sup> have measured macro-, micro-, and nanoscale surface features of oral implants to investigate how these structures influence bone repair. However, very little is known about the clinical effects of modified physicochemical implants surfaces, especially regarding their primary stability, although it has been proven that primary stability can be enhanced by surface treatments.<sup>20</sup> Currently, a large number of implant surface treatments are available.<sup>8</sup> However, the effects of these treatments on primary or secondary stability during the early stages of osseointegration are still debated.<sup>21</sup> This longitudinal randomized clinical trial evaluated the

primary and secondary stability and the insertion torque of dental implants with four different surfaces during the healing process.

### Methodology

#### **Experimental design**

This double-blind split-mouth randomized clinical trial was conducted in accordance with the Helsinki Declaration, 2008, following the Consolidated Standards of Reporting Trials Statement (CONSORT)<sup>22</sup> and aimed to evaluate the insertion torque and implant stability of dental implants with four different implant surfaces in the posterior region of the mandible. This study was performed at the dental clinic of the São Leopoldo Mandic Dental Research Center (Campinas / SP) and was approved by the Ethics Research Committee of this research center under protocol number 2010/0262. All patients enrolled in this study signed informed consent forms and provided medical health histories before treatment.

The sample size calculation was based on the implant stability quotient (ISQ) means and SD of SLA RN (76.5  $\pm$  6.5) and SLActive (78.8  $\pm$  3.20) groups at 12 weeks recorded in a previous study<sup>25</sup>. The following parameters were used: the smallest expected difference between the means; the standard deviation of the difference between the means; a beta error of 20%, an alpha error of 5% and an effect size of 0.91, as indicated by a sensitivity analysis. These calculations indicated that each group should include a minimum of 20 implants.

The following inclusion criteria were applied: ASA type I patients without physiological, biochemical or psychiatric illnesses, non-smokers, D2 and/or D3 class bone density,<sup>23</sup> bone quantity class A and/ or B,<sup>24</sup> and bilaterally edentulous in the mandibular region. Patients with poorly controlled diabetes, a recent history of heart surgery, heart attack, stroke, or the recent use of anticoagulant drugs or the long-term use of bisphosphonate medication were excluded from the study. Furthermore, patients who required bone grafting, barrier membranes, or immediate loading were also excluded from the study. Finally, any dental implant that did not reach an insertion torque of 30 Ncm during the installation was removed

from the analyzed dataset. Prior to surgery, patients received a comprehensive periodontal examination. All patients underwent a periapical and panoramic radiograph of the prospective areas for implant placement to determine the implant length. The bone site thickness was clinically evaluated using a bone measuring caliper. When the bone quantity or quality was unclear, a computerized tomogram of the elected hemi-arch was performed before surgery.

Four implant types of two brands comprised the four groups under study: Group I - Osseotite® (prepared using double acid etching; Biomet-3i, West Palm Springs, FL); Group II - Nanotite® (prepared using double acid etching with the discrete nanoscale deposition of CaP crystals; Biomet-3i, West Palm Springs, USA); Group III - SLA® (prepared using jets of corundum particles followed by acid etching; Straumann AG - Basel, Switzerland); and Group IV -SLActive® (chemically activated by surface blasting with corundum followed by acid etching, made hydrophilic by washing under a N<sub>2</sub> atmosphere with isotonic acid and subsequently immersed in NaCl, Straumann AG - Basel, Switzerland). All implants had a cylindrical body with similar dimensions: diameters of 4.0-4.1 mm and implant lengths of 8-11.5 mm. The implant length was selected according to the bone availability. The dental implants in group I and II had triangular threads with small/short thread pitches and cutting apex, while implants of groups III and IV had triangular threads with pitch wide/long holes and apex threads. The drilling protocols followed were those recommended by the manufacturers.

To randomize the patients and implant surface treatments, we used a computer-generated list created by an independent researcher (RMMM). The implant selection was determined by allocating the implant brand (Biomet-3i or Straumann) and the implant surface in each posterior hemi-arch according to the list generated by the algorithm. The patient and the single calibrated evaluator were blinded with respect to the location of each implant in the mandibular arch.

The insertion torque (IT) values were determined as the maximum torque value (Ncm) reached at the end of the implant insertion. The IT was measured using a surgery drilling unit (Kavo Koncept Surg, Kavo do Brasil, Joinvile, Brazil) equipped with a

graphical user interface with an accurate display of maximum torque (up to 80 Ncm) and a motor speed fitted with a 27:1 surgical contra-angle (KAVO Dental GmbH, Biberach, Germany). After the final seating of the implant, a type 17 or type 45 Smartpeg® was installed, and resonance frequency analysis (RFA) was performed to record the primary stability (PS) using an Osstell Mentor® device (Ostell/Integration Diagnostics, Goteborg, Sweden). The implant stability quotient values (ISQ) were recorded in the buccal and the mesial directions, both oriented perpendicular to the transducer. The ISQ value for each implant surface was then calculated as the mean value of the two faces. The secondary stability (SS) of the implant was also recorded on a weekly basis between 7 and 91 days post-surgery

Straight healing abutments were inserted after implant installation. The incision was sutured with 5.0 Nylon (Bioline Fios Cirúrgicos Ltda, Anápolis, Brazil) using simple interrupted stitches, which were removed one week after surgery (Figure 1). All patients were instructed to follow a doughy-like and cold diet during the first three days after surgery. To control biofilm accumulation, the patients were instructed to use a soft toothbrush and a mouthwash containing 0.2% chlorhexidine digluconate twice

daily during the first week. These instructions were reinforced at each follow-up. All patients received a prescription for Azithromycin (500 mg, 1 tablet every 24 hours for 3 days) starting 1 hour before surgery. In addition, dexamethasone (4 mg, 1 tablet every 24 hours for 3 days) and Lisador or Paracetamol (500 mg, 1 tablet every 6 hours for 5 days) were prescribed after the surgery.

#### Statistical analysis

The data were first analyzed using one-way ANOVA. The Bonferroni test was then used to compare implant surface treatments at different time points, and paired t tests were used to compare each implant surface treatment between the time points. Pearson's correlation coefficients (r) between the IT and ISQ were calculated. The significance level was set at 5% for all analyses.

#### Results

A flow chart for the study is shown in Figure 2. A total of 80 implants were installed in 19 patients (12 women and 7 men) with a mean age of 46.7 years. No patients were lost during the follow-up period. All dental implants had similar dimensions,

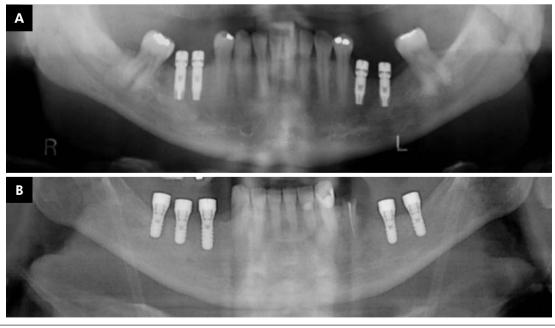


Figure 1. Split-mouth clinical design: a.) Osseotite x Nanotite; b) SLA x SLActive

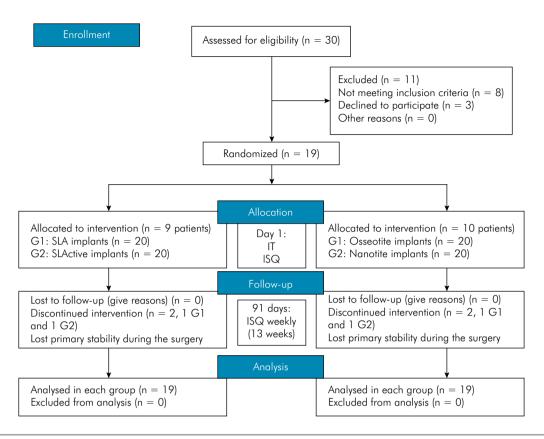


Figure 2. Consort flow diagram.

with diameters that varied from 4.0 to 4.1 mm and with lengths between 8 and 11.5 mm. The implants used in this study are listed according to their commercial brand, dimensions, and surfaces in Table 1 and are graphically shown according to the edentulous region of the posterior mandible in Figure 3. Four implants, one in each group, did not reach the minimum insertion torque (IT) of 30 Ncm required. No significant differences (p > 0.05) were observed between the insertion torque values according to the implant type. The obtained IT values (mean  $\pm$  sd) were as follows: Osseotite = 44.47  $\pm$  6.64; Nanotite = 46.84  $\pm$  5.06; SLA = 43.82  $\pm$  6.50 and SLAactive = 43.95  $\pm$  6.14.

All implant types behaved similarly until the 28th day (p > 0.05). After 35 days, Osseotite and SLActive implants showed significantly lower ISQ values than Nanotite and SLA implants (p < 0.001), and this difference persisted until 56 days. After 56 days, Osseotite maintained significantly lower ISQ values (p < 0.05) than the other implant types. After

**Table 1.** Distribution of implants used in the study according to their commercial brands and dimensions (n = 80).

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Surface	Dimension of implants (mm)						
Surrace	4.0 x 8.5	4.0 x 10	4.0 x 11.5	4.1 x 8.0	4.1 x 10		
Osseotite	2	10	8	х	х		
Nanotite	5	10	5	x	x		
SLA	x	x	х	4	16		
SLActive	х	Х	х	8	12		

91 days, the ISQ values for all analyzed implant types were significantly higher than the primary ISQ value (p < 0.001). SLA and SLActive exhibited the highest ISQ values (p < 0.001), and Osseotite had the lowest values (p < 0.001). Table 2 lists the correlation coefficients between ISQ and IT values at critical time points. At the baseline evaluation, IT and ISQ were significantly correlated for all evaluated implant types except SLA types (p > 0.05). At 91 days, IT was significantly correlated with ISQ only for the Osseotite implants (p < 0.0002).

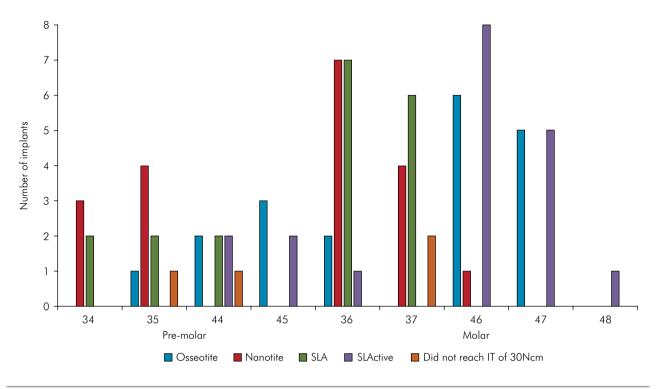


Figure 3. Distribution of the implant sites.

**Table 2.** Correlation between IT and ISQ in the critical time points.

Implant surfaces	Time Intervals (days)					
	0	21	42	63	91	
Nanotite	0.83451	0.61083	0.68315	0.65956	0.48054	
	<.0001S	0.0055\$	0.0013S	0.0021S	0.0373NS	
Osseotite	0.91995	0.75725	0.72751	0.69178	0.75407	
	<.0001S	0.0002\$	0.0004\$	0.0010S	0.0002\$	
SLA	0.43911	0.58010	0.28658	0.45557	0.11381	
	0.0778NS	0.0146S	0.2648NS	0.0661NS	0.6636NS	
SLActive	0.85445	-0.10194	-0.09812	0.05133	0.13903	
	<.0001S	0.6780NS	0.6894NS	0.8347NS	0.5703NS	

S: Significant correlation; NS: non-significant correlation.

Figures 4 and 5 show the implant stability as a function of time. The intra-group comparisons showed an ISQ minimum at 21 days for the SLActive implants (78.8  $\pm$  2.6), and their ISQ was significantly higher at 63 days (80.2  $\pm$  2.4). The minimum ISQ for the SLA (79.5  $\pm$  2.8) and Nanotite implants (78.4  $\pm$  3.2) occurred at 28 days, and the ISQ increased gradually from 42 days onwards. The Osseotite implants showed the lowest mean ISQ at 35 days (75.5  $\pm$  5.6), and the

ISQ then increased significantly and continuously until 91 days.

#### **Discussion**

A wide diversity of implant brands currently exists, and many types of materials have been developed by research scientists and private industry. Therefore, organized comparative information for clinicians is

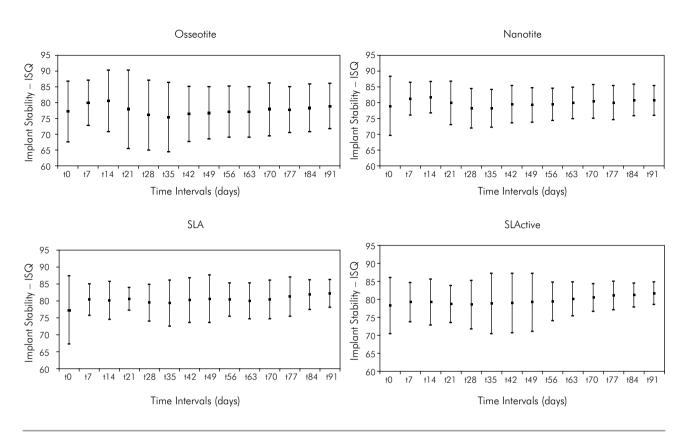
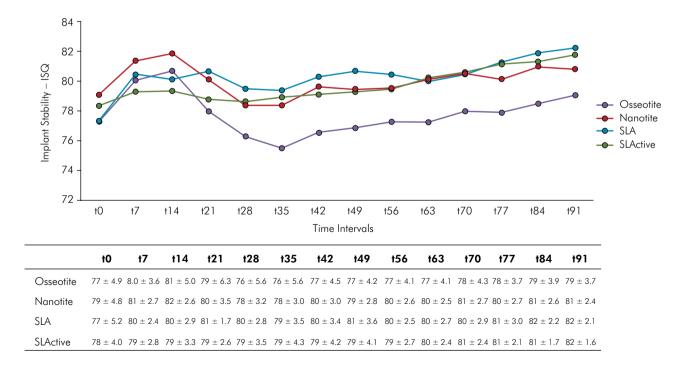


Figure 4. Range of Implant stability values (Mean, upper, and lower interval) as a function of time according to the implant types.



**Figure 5.** The ISQ of all implant surfaces as a function of time (mean  $\pm$  SD).

essential to enable the rapid and accurate selection of implant systems with optimal cost-benefit ratios. Therefore, our clinical trial adopted a split-mouth design to control for possible confounding factors, such as patient-specific characteristics related to bone-healing capacity, general health condition, and habits. During the 90-day follow-up of this study, the studied Osseotite, Nanotite, SLA and SLActive implants all showed acceptable primary and secondary stability with ISQ means above 75. However, when we compared the different implant types, Osseotite presented the lowest ISQ values.

Our results show a high implant stability profile for all studied surfaces across all evaluated times (Figures 4 and 5). These results are similar to those reported by Han et al.<sup>25</sup> in a study that determined the influence of surface type and diameter on the stability of implants during the early phase of osseointegration for SLActive and SLA implants. These authors also reported that after 12 weeks, no significant differences were found for ISQ values depending on surface or implant diameter. This behavior was attributed to the time dependency of bone remodeling observed at the initial stage. Therefore, bone shape and remodeling toward the implant surfaces interferes with the bone-implant contact interface.<sup>15,26</sup>

To standardize the sample population to control for confounding factors, we selected homogenous bone sites and implants with similar dimensions, which contributed to our favorable ISQ results. Sim and Lang<sup>27</sup> investigated the influence of bone density structure, implant length, and the position of the measuring instrument on resonance frequency analyses and concluded that variations in the ISQ values are not related to the position of the measuring instrument. Instead, the bone structure and implant length around the implant mainly influences ISQ. The small variation in implant length (8-11.5 mm) may have influenced the ISQ values. Unfortunately, it is impossible to completely control for this potential confounding factor as the variation is determined by the available lengths for each brand. Moreover, in the clinical study by Sim and Lang,<sup>27</sup> the ISQ values for implants with lengths of 8 and 10 mm were significantly different only at the time of surgery. Furthermore, because the number of implants used

per group in this study was relatively low and the implants were grouped irrespective of the bone type, it is difficult to determine to what degree the implant length is a predictive factor for ISQ. In this RCT, only 7 of 40 installed implants were short in the 3i brand subgroups, while 12 of 40 implants in the Straumann subgroups were short. The correlations between IT and ISQ in this study (Table 2) suggest that the implant length might influence the relationship between IT and ISQ over time as the smallest number of short implants (n = 2) was installed in the Osseotite implants group, and this group presented significant correlations between ISQ and IT at all critical time intervals during healing.

In this study, one implant surface of each tested sample group was lost due to a low initial insertion torque. Nevertheless, the mean IT values showed that the bone quality of the bone site provided a favorable prognosis in terms of bone anchorage, allowing the adoption of an immediate loading protocol. Alsaadi et al.,<sup>28</sup> and Turkyilmaz et al.,<sup>29</sup> also reported that bone density affected the primary implant stability. Furthermore, they found a significant correlation between insertion torque and PS as measured by RFA and concluded that these methods are effective for evaluating implant stability.

Although the insertion torque of the different implant surfaces did not significantly differ (p > 0.05), they showed a strong correlation with the ISQ values at all evaluated times. However, the correlation between the primary and secondary stability as evaluated by resonance frequency analysis and the installation torque has only been observed in a few studies, and the obtained results appear contradictory. 30,31,32,33,34. Factors such as a lack of homogeneity of the implant receptor site, differences in bone density, drilling techniques, friction coefficient during implant installation, thread geometry and implant shape, implant surface treatment, and even the model used for statistical analysis can influence the relation between torque and resonance frequency analysis.35 A recent systematic review by Lages et al.,36 found no correlation between insertion torque and primary stability, indicating that a high insertion torque does not necessarily correspond to a high ISQ.

With regard to the biological behavior of implant surfaces, Ostmann et al.37 emphasize that while new surface textures such as those achieved by nanoscale calcium phosphate incorporation improve early setting and morphometric bone formation in preclinical studies and human studies; however, these surfaces only have a clear cost-benefit outcome when immediate loading is applied. The clinical implications of our results are consistent with this statement and indicate that implants with different surfaces can reach similar implant-bone interface rigidity, despite a small but significant ISQ difference at approximately 35 days. Thus, when a fast rehabilitation using immediate loading is not required, clinicians should prioritize evaluating the patient's characteristics and their surgical experience over evaluating the implant surface modifications available on the market.

Regarding hydrophilic surfaces, Novellino et al.,38 suggest that hydrophilic surface implants osseointegrate faster than sandblasted and acid-etched implants. In addition, these authors demonstrated that the ISQ of hydrophilic implants increased 2.24 times faster than implants treated with blasting and acid etching. However, in our longitudinal clinical study, it was shown that Nanotite® (double acid-etched with the discrete nanoscale deposition (DCD®) of CaP crystals), SLA® (sandblasted Al<sub>2</sub>O<sub>3</sub> cored and acid-etched) and SLActive® (chemically treated sandblasted and acid-etched surfaces with hydrophilic properties) induced higher biological activity than Osseotite® (double acid-etched) surface implants at the end of the 91-day evaluation period. Furthermore, both the SLA® and SLActive surface implants were superior to the Nanotite® surface (P<0.05). Gupta and Padmanabhan<sup>39</sup> argue that primary implant stability is a mechanical phenomenon that is related to the local bone quality and quantity, implant type, surgical techniques used, and installation. The application of a simple, clinically applicable noninvasive tool to evaluate implant stability and osseointegration is considered highly desirable. Therefore, the clinical applicability of resonance frequency analysis (RFA) should be encouraged as a tool to test implant suitability for immediate loading protocols (ISQ  $\geq$ 70), 6 to dictate biologic prognosis, and for monitoring the long-term behavior of implants.

Although this RCT was able to detect different bone behavior during the osseointegration period for the various studied implant surfaces, this prospective clinical study was conducted using a relatively small sample size, examined implants with small length variations, and used a short follow-up time. We therefore suggest that future studies investigate these effects between 21 and 42 days after installation. During this period in the healing process, we noticed a subtle reduction in stability for all chemically inactive surfaces. Our results provide useful clinical information that can be investigated using different time frames. For instance, the secondary implant stability of the Osseotite implants was lower than the other implant surfaces only after 42 days of healing. All other tested implant surfaces showed a slight reduction in the ISQ values after installation, reaching minimum stability levels at 21 days post-operation and increasing from 63 days onwards.

#### Conclusion

Osseotite, Nanotite, SLA, and SLActive implant types all exhibited acceptable primary and secondary stability. The most important interval for osseointegration occurred at approximately 35 days for the Osseotite and SLActive implants.

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