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Comparative Evaluation of Primary Stability between Different Diameters Multi-Scale Roughness Dental Implant by Solid Rigid Polyurethane Simulation

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Abstract: Background: Implant primary stability is determined by screw characteristics and surgical procedure. The aim of the present study was to evaluate, on a polyurethane model, the insertion torque (IT), removal torque (RT), and resonance frequency analysis (RFA) of multi-scale roughness dental implants of different diameters. Methods: Two implant sizes were tested on two polyurethane blocks (20 pounds per cubic foot (PCF) and 30 PCF): 3.0 diameter and 13 mm length and 5.0 diameter and 13 mm length. The IT, RT, and RFA were assessed. Results: A significant difference of IT and RT was present in favor of wider implants at both polyurethane densities. No statistical difference was present between the 5.0 diameter and 3.0 diameter implants at both polyurethane densities. A statistically increased RFA was reported for 5.0 implant 30 PCF polyurethane blocks. Conclusions: Multi-scale roughness dental implants of both diameters showed high insertion torque and primary stability on polyurethane blocks, which is valuable for implant loading protocols.

Keywords: titanium surface; roughness; dental implant; solid rigid polyurethane blocks

1. Introduction

Primary stability is the main clinical condition for the early and long-term success of dental implant osteointegration [1,2]. This clinical condition determines the induction of the healing of the peri-implant tissues and permits the creation of an ankylotic relationship at the level of the bone-to implant interface, new bone formation, and remodeling [1,3].

Dental implant primary stability is defined as the mechanical friction determined by the surface contact of a clinically stable screw with the osteotomy wall during its positioning [4–7].

The presence of micromovements of over than 150 microns has been reported as a condition favorable for soft tissue interposition between the bone and implant surface inducing fibrous integration [8–13]. Bone tissue is a dynamic, highly responsive connective tissue to functional loading [3]. In the literature, it has been reported that stress and strain on stable dental implants are able to induce cortical bone modification, bone–implant contact, and density increase around the screw interface [14,15]. Several different techniques have been described for implant site preparation such as drilling protocols [16–20], osseodensification technique [21–23], ultrasonic piezoelectric device [17,24,25], manual osteocondensation [26], and conventional and under-preparation osteotomy [27,28]. Primary stability is also determined by the macro-geometry and thread shape of the implant [29]. Comparative studies reported, in a polyurethane block simulation, that a cylindrical implant design showed increased insertion torque (IT) and implant stability quotient (ISQ) compared to conical implants [30]. The insertion torque and removal strength are clinically determined by the micro-mechanical interaction between the dental implant and the surrounding bone wall [31]. The minimum insertion torque necessary to achieve implant osseointegration is undefined, while a positioning torque ≥30 Ncm is clinically required for immediate loading protocol into healed bone ridges and post-extraction alveolar sockets [27]. The implant stability quotient (ISQ) is a reproducible, repeatable, and highly predictive measurement for dental implant stability [32]. This procedure has been proposed to evaluate the stability and clinical prognosis of teeth and dental implants in the oral cavity as a cost-effective and non-operator-dependent diagnostic technique [32].

The solid rigid polyurethane bone block has been proposed as a valuable material for orthopedics and maxillofacial medical devices [5,11,33]. The material is available in different densities and microstructures able to simulate the mechanical and physical properties of human bone and its cortical and cancellous components [34]. In the literature, many different materials have been proposed to evaluate dental implants' primary stability such as bovine or pig ribs, rabbit tibiae, sheep mandible, and cadaveric human bone [35–38]. Polyurethane blocks present a uniform density, elastic and strength characteristics, and are unaffected by desiccation [30,39].

The aim of the present investigation was to compare the primary stability between two different diameters' multi-scale roughness dental implants positioned into solid rigid polyurethane blocks of different densities.

2. Materials and Methods

2.1. Polyurethane Foam Blocks

Polyurethane solid rigid blocks represent a validated bone simulator to test the response of dental implants and medical devices in a standardized environment (ASTM F-1839-08) [11,30,39]. Polyurethane blocks present a uniform density, elastic and strength characteristics, and are unaffected by desiccation. Polyurethane presents similar properties to human bone and it requires no special handling or preservation protocol. This synthetic material presented consistent mechanical characteristics. For the present investigation, two different densities of 20–30 pounds per cubic foot (PCF) (D2–D1) of polyurethane solid rigid block (Sawbones, Vashon Island, Washington USA) with a size of 120 × 170 × 30 mm were tested.

2.2. Implant Characteristics

Internal hexagon cylindrical implants (IC, Resista, Omegna VB, Italy) were evaluated in the present investigation (Figures 1 and 2).

The differential multi-scale surface treatments were provided in the coronal, median, and apical portions of the device to increase the osteogenic response of the peri-implant tissues.

The cervical portion was characterized by a smooth machined surface to oppose bacteria adhesion and proliferation. The micro-thread area was provided by a nano-rough surface with Ra < 1 μ. The presence of a textured surface is able to increase the absorption of proteins and the stabilization of blood clots, platelets, and fibrin adhesion in the healing phase, promoting implant osteointegration.

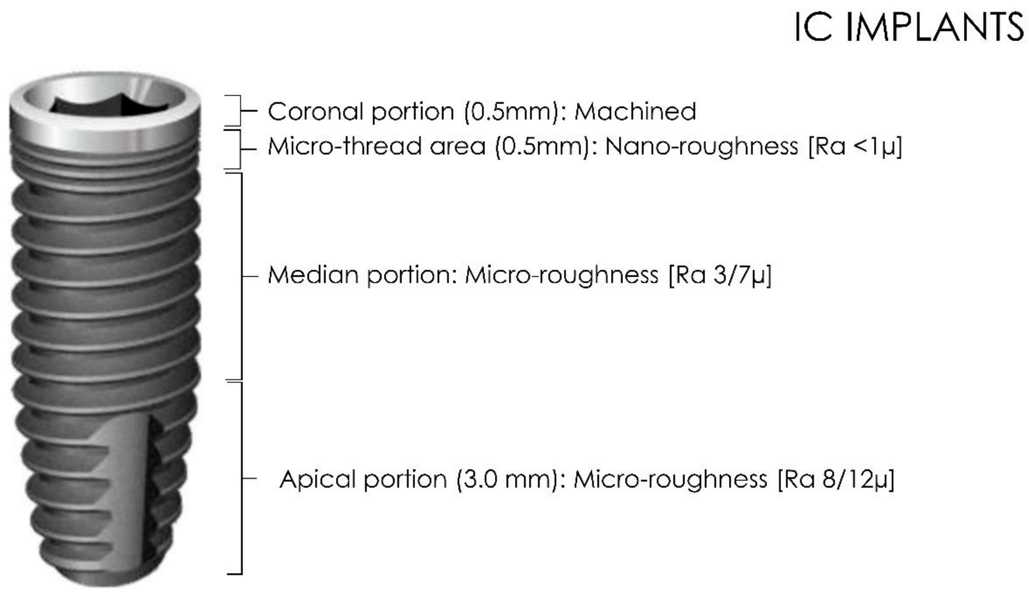

Figure 1. Main characteristics of the dental implants evaluated in the present investigation.

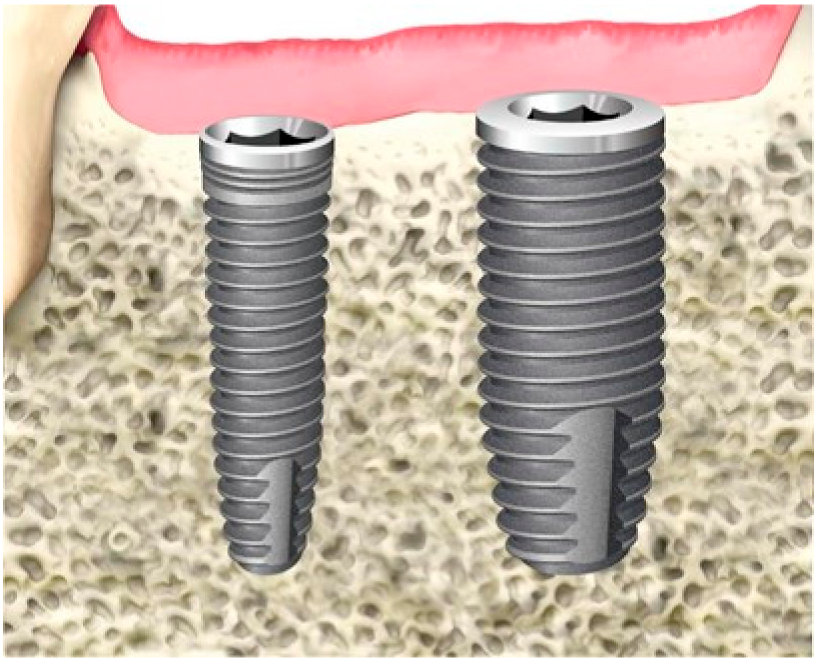

Figure 2. Optimal positioning into the bone tissue of the dental implant tested in the present investigation.

The median part of the implant screw was characterized by a dual acid-etched (DAE) micro-rough surface (mean Ra: 3/7 μ) and the apical portion by a slow dual acid-etched (DAE) micro-rough surface (mean Ra: 8/12 μ).

2.3. Drilling Protocol and Insertion (IT) and Removal Torque (RT) Assessment

A total of 20 dental implants were positioned in the present polyurethane research. Two different solid rigid polyurethane densities were tested (SawBones H, Pacific Research Laboratories Inc, Vashon, WA, USA) (Figure 2). The polyurethane block was characterized by a closed cell range from 96.0% to 99.9%. The 20-pound per cubic foot (lb/ft^3) (PCF) polyurethane density, equal to 0.32 g/cm^3, presented similar rigidity and consistency to D2, and 30 PCF, equal to 0.48 g/cm^3, simulated the rigidity and consistence of D1 bone (Figure 3).

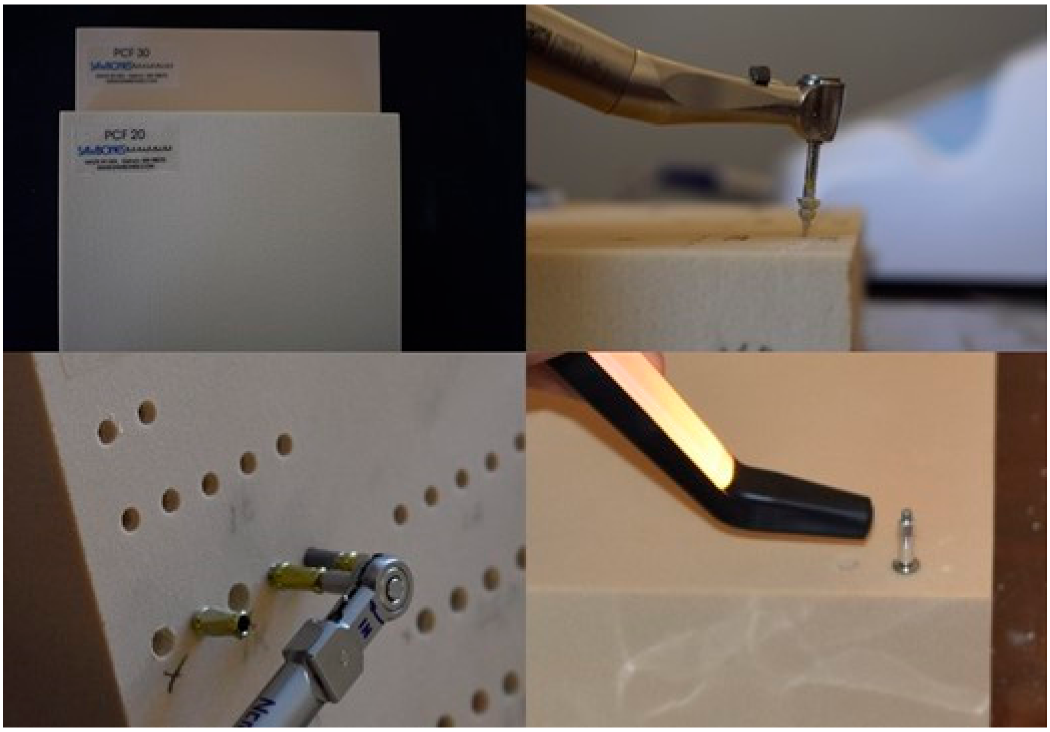

Figure 3. Details of the procedural phase of the experimental protocols.

Polyurethane solid rigid blocks (Sawbones, Vashon Island, Washington DC, USA) with two different densities of 20–30 PCF (D2-D1) were prepared for 3.0 diameter IC implant according to the following drilling protocol: lance drill, 2.0 diameter drill, 2.6 diameter drill, 2.8 diameter drill.

The implant site preparation for the 5.0 diameter IC implant was according to the following drilling protocol: lance drill, 2.0 diameter drill, 2.6 diameter drill, 2.8 diameter drill, 3.2 diameter drill, 3.8 diameter drill, 4.5 diameter drill. The surgical hand-piece was set with a speed of 800 rpm and a torque of 30 Ncm for implant site preparation. After the implant site preparation according to the manufacturer's protocol, the insertion torque and removal torque were recorded by dynamometric analysis during the screw positioning. Torque measurement was assessed with a software package (ImpDat Plus, East Lansing, MI, USA).

2.4. Resonance Frequency Analysis (RFA)

RFA (Osstell, Columbia MD USA) is an electromechanical assessment that is performed by an electronic device that measures the micromovement of an implant for a total of 16 times.

The RFA device is able to self-eliminate the non-compliant pulse offering a reliable and reproducible measurement of the implant micro-mobility.

The measurements are classified according to the implant stability quotient score (ISQ), ranging between 1 and 100:

- Good stability: >70 implant stability quotient (ISQ);
- Medium stability: 60–69 implant stability quotient (ISQ);
- Low stability: <60 implant stability quotient (ISQ).

2.5. Statistical Analysis

The normal distribution of the study data was evaluated by the Kolmogorov–Smirnov test. A one-way ANOVA followed by the Tukey post-hoc test was performed to evaluate the statistical significance of the study variables. The study data were analyzed using the statistical software package GraphPad 8.0 (Prism, San Diego, CA, USA). The statistical significance was set at $p < 0.05$.

3. Results

The mean IT assessment for both groups is presented in Figure 4 and Table 1. The 3.0 IC implant showed a mean IT in 20 PCF and 30 PCF cases of 25.80 ± 0.8367 Ncm and 49.40 ± 2.702 Ncm, respectively ($p < 0.05$). A statistically significant higher IT was reported for the 5.0 IC implant at 20 PCF and 30 PCF with a mean of 51.60 ± 1.049 and 90.00 ± 0.3012 Ncm, respectively ($p < 0.05$).

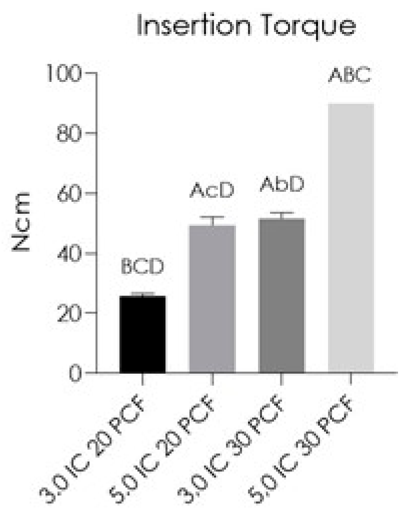

Figure 4. Insertion torque values of the 3.0 IC 20 PCF (A), 5.0 IC 20 PCF (B), 3.0 IC 30 PCF (C) and 5.0 IC 30 PCF (D) dental implants. The intergroup statistical significance comparison results are represented by capital letters ($p < 0.05$) and lowercase letters ($p > 0.05$).

Table 1. Insertion torque values of the 3.0 IC and 5.0 IC dental implants.

INSERTION TORQUE	3.0 IC 20 PCF	5.0 IC 20 PCF	3.0 IC 30 PCF	5.0 IC 30 PCF
Minimum	25.00	45.00	50.00	90.00
25% Percentile	25.00	47.00	50.50	90.00
Median	26.00	50.00	51.00	90.00
75% Percentile	26.50	51.50	53.00	90.00
Maximum	27.00	52.00	55.00	90.00
Range	2.000	7.000	5.000	0.000
Mean	25.80	49.40	51.60	90.00
Std. Deviation	±0.8367	±2.702	±1.949	±0.3012
Std. Error of Mean	0.3742	1.208	0.8718	0.000
Lower 95% CI of mean	24.76	46.05	49.18	90.00
Upper 95% CI of mean	26.84	52.75	54.02	90.00

The mean RT measurements are presented in Figure 5 and Table 2, where the 5.0 IC implant at 20 PCF and 30 PCF showed a statistically significant higher mean RT of 51.60 ± 1.049 and 79.00 ± 11.40 Ncm, respectively ($p < 0.05$). The 3.0 IC implant showed an average RT at 20 PCF and 30 PCF of 24.80 ±1.304 and 46.00 ± 2.345 Ncm, respectively ($p < 0.05$).

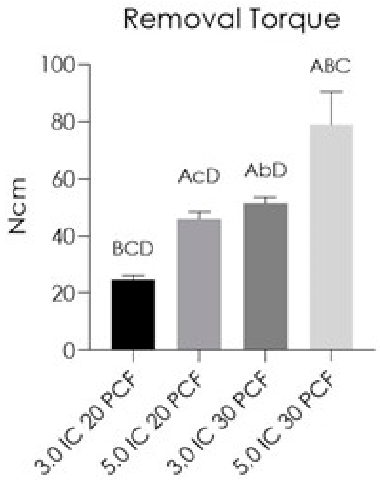

Figure 5. Removal torque values of the 3.0 IC 20 PCF (A), 5.0 IC 20 PCF (B), 3.0 IC 30 PCF (C) and 5.0 IC 30 PCF (D) dental implants. The intergroup statistical significance comparison results are represented by capital letters ($p < 0.05$) and lowercase letters ($p > 0.05$).

Table 2. Removal torque values of the 3.0 IC and 5.0 IC dental implants.

REMOVAL TORQUE	3.0 IC 20 PCF	5.0 IC 20 PCF	3.0 IC 30 PCF	5.0 IC 30 PCF
Minimum	23.00	43.00	50.00	60.00
25% Percentile	23.50	43.50	50.50	70.00
Median	25.00	47.00	51.00	80.00
75% Percentile	26.00	48.00	53.00	87.50
Maximum	26.00	48.00	55.00	90.00
Range	3.000	5.000	5.000	30.00
Mean	24.80	46.00	51.60	79.00
Std. Deviation	±1.304	±2.345	±1.949	±11.40
Std. Error of Mean	0.5831	1.049	0.8718	5.099
Lower 95% CI of mean	23.18	43.09	49.18	64.84
Upper 95% CI of mean	26.42	48.91	54.02	93.16

The mean RFA measurements for both groups are presented in Figure 6 and Table 3.

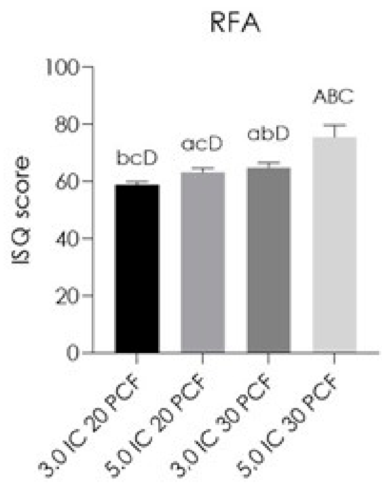

Figure 6. Resonance frequency analysis (RFA) values of the 3.0 IC 20 PCF (A), 5.0 IC 20 PCF (B), 3.0 IC 30 PCF (C) and 5.0 IC 30 PCF (D) dental implants. The intergroup statistical significance comparison results are represented by capital letters ($p < 0.05$) and lowercase letters ($p > 0.05$).

Table 3. RFA values of the 3.0 IC and 5.0 IC dental implants.

RFA	3.0 IC 20 PCF	5.0 IC 20 PCF	3.0 IC 30 PCF	5.0 IC 30 PCF
Minimum	58.00	61.00	62.50	68.00
25% Percentile	58.00	62.25	63.00	72.25
Median	58.50	63.50	65.50	77.00
75% Percentile	60.00	64.25	66.25	78.00
Maximum	60.50	64.50	67.00	78.50
Range	2.500	3.500	4.500	10.50
Mean	58.90	63.30	64.80	75.50
Std. Deviation	±1.084	±1.351	±1.789	±4.257
Std. Error of Mean	0.4848	0.6042	0.8000	1.904
Lower 95% CI of mean	57.55	61.62	62.58	70.21
Upper 95% CI of mean	60.25	64.98	67.02	80.79

The 3.0 IC implant showed a mean implant stability quotient (ISQ) value at 20 PCF and 30 PCF of 58.90 ± 1.084 and 63.30 ± 1.351, respectively ($p > 0.05$). The 5.0 IC implant at 20 PCF showed a mean value of 64.80 ± 1.789 ($p < 0.05$). A statistically significant higher RFA measurement was reported for the 5.0 IC implant at 30 PCF with an average ISQ value of 75.50 ± 4.257. The aim of the present investigation was to evaluate the primary stability of cylindrical multi-scale roughness dental implants of two different diameters.

4. Discussion

The rationale of the present investigation was to evaluate the effect of different sizes of implant diameter on primary stability through a standardized simulation on an artificial polyurethane model. The implant choice was made in accordance with the recent and most diffused macro-geometry and internal prosthetic platform for endosseous implants in order to preserve the experimental repeatability and reduce the study variables [40].

The choice of the appropriate implant diameter is clinically determined by prosthetic factors, aesthetics, the residual thickness of the bone ridge, and the distance between adjacent elements [41]. A minimum distance of 1.4–2mm should be always maintained between the marginal bone and the implant surface [42]. The implant positioning could be affected by anatomical features such as knife-edged alveolar ridges that require a regenerative approach [42,43]. Primary stability is determined by different mechanical and frictional factors such as absence of micromovements, implant design, screw size and diameter, bone quality, and surgical technique [1,15].

The adoption of an increased implant diameter of 1 mm is able to induce a higher surface contact area percentage with the surrounding tissues by between 30% and 200%, which could actively influence the primary stability and the functional bone stress distribution [44].

In the present investigation, both dental implant diameters showed a high insertion torque value (>25 Ncm). Moreover, no significant difference in terms of ISQ stability was present at both 20 PCF and 30 PCF polyurethane densities ($p > 0.05$).

Clinically, the presence of optimal primary stability also with a reduced dental implant diameter could represent a determining factor that could contribute to the rehabilitation of regions with limited prosthetic space and/or bone thickness [45,46]. This effectiveness could be further improved by adopting solidarized implants for an immediate or delayed protocol of functional loading [6].

Multi-scale roughness represents a surface treatment able to create differentiated roughness levels in the various parts of an implant screw. The most common implant surface treatments are machining, sandblasted surfaces, acid-etched treatment, lasered surfaces, and anodized titanium surfaces [47,48]. The coronal part is critical for potential early bacteria colonization of the peri-implant tissue [49]. Rodriguez and Baena et al. reported in vitro that machined titanium and nano-roughness surface are able to reduce the bacterial adhesion of *Aggregatibacter actinomycetecomitans*, *Streptococcus mutans*, and *Streptococcus sanguis* strains [49]. Moreover, the authors reported the lowest amount of bacterial contamination for the nano-roughness surface. It is well known in the literature that the micro-roughness surface rugophilia is a key factor for the induction of osteogenic actors' activity [49,50]. Several studies reported in animal experiments that implant micro-roughness is associated with higher bone-to-implant contact compared to machined implants [51–54]. In this way, implant surface treatment is important to create wettability and an optimal environment for early stabilization of blood clots and for supporting the integration healing of the implant [55,56]. Blood and proteins' adsorption seems to be related to direct bone osteogenesis from the implant surface oriented to the implant site bone wall [3]. Distance osteogenesis is associated, in the literature, to machined topography, with an osteogenesis vector oriented from the old bone to the implant surface [3].

5. Conclusions

In conclusion, both of the diameters tested for multi-scale roughness dental implants positioned in synthetic bone models showed enhanced primary stability that is valuable for implant loading protocols. The larger implant diameter should be preferred in the case of bone volume availability to obtain higher primary stability.

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