Fixture Length and Primary Stability: An In Vitro Study on Polyurethane Foam

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Abstract: (1) Background: Recently, novel dental implants that are characterized by different levels of surface roughness in the distinct parts of the fixture's body have been introduced in the market. These surface characteristics could affect the primary stability of the implants. The aim of this in vitro study was to compare the primary stability of short and long implants, characterized by multiscale surface roughness, inserted on polyurethane blocks. The secondary aim was to understand if the implant length could be a crucial factor in the decision-making in immediate or rather than delayed loading protocol in the different bone densities. (2) Methods: A total of 20 cylindrical dental implants with a diameter of 5.0 mm were tested for the lengths 6.0 mm (short implants) versus 13.0 mm (long implants) on two different solid rigid polyurethane blocks (20 and 30 PCF). The primary stability was evaluated by measuring the insertion torque value (ITV), the removal torque (RTV), and the resonance frequency analysis RFA. (3) Results: The values of ITV, RTV, and RFA showed the same trend in all measurements. Long implants showed a significantly higher primary stability on 30 PCF blocks that present mechanical properties similar to high-density bone. On the contrary, no relevant differences were found on 20 PCF blocks, which mimic trabecular bone density. (4) Conclusions: The impact of fixture length on the primary stability of implants with multiscale surface roughness is significant in 30 PCF polyurethane corresponding to higher bone density, but not in lower ones.

Keywords: primary stability; resonance frequency; insertion torque; polyurethane foam

1. Introduction

The achievement of primary stability during the dental-implant insertion is the first step toward a successful osseointegration [1]. Indeed, during the healing process, the absence of micromovements higher than 150 μm is fundamental to achieve the formation of new bone [2]; on the contrary, a fibrous tissue of reparation is produced, affecting the implant stability [3]. Moreover, a good glycemic control is fundamental to reduce implant failures in the first stages of healing [4].

Evidence supports the adoption of the second-stage protocol, with submersed implants during the healing stage, if primary stability is low [5]. Other authors suggest to solidarize the implants by means of metallic bars or intraoral electric welders in order to proceed directly to an immediate loading protocol (ILP) [5,6]. The adoption of ILP of dental implants

needs the presence of primary stability [7]. In particular, the literature suggests that, for ILP of full-arch restorations, the achievement of an insertion torque value (ITV) > 30 Ncm is necessary in order to avoid early failures [8,9]. However, with the advent of novel implant surfaces, this value can further be reduced.

The primary stability can be quantified with instruments that measure the frequency of resonance (RFA), such as the Ostell, or by measuring the ITV and the removal torque value (RTV) [10,11].

The primary stability is a direct consequence of the bone density and quality, implant design, and some specific surgical protocols, such as the under-preparation of the implant site, or the use of specific tools for bone osseodensification, could be adopted in order to modify this parameter [1,12].

In particular, the alveolar bone is characterized by an anisotropic behavior, and its mechanical features vary with the site of sampling and the testing orientation [13]; Misch et al. showed, in 1999, that the modulus of elasticity of the bone ranged from 24.9 to 240.0 MPa with cortical plates present, and from 3.5 to 125.6 MPa without cortical plates [14].

However, the use of bone samples for in vitro studies that investigated the factors that influence the primary stability of dental implants has been considered as a possible bias, because of the impossibility to find natural samples with identical mechanical behavior, and also for ethical reasons [15]. In the last few years, the use of an artificial bone substitute, the polyurethane foam, characterized by a very similar mechanical behavior to natural bone, it has been proposed and validated for research in dental implantology [15,16].

The parameters related to the fixture that influence the primary stability are the length, the presence of surface treatments, the shape of the implant, and other factors that could increase the surface area in contact with the bone [17–19]. In particular, recently, the use of fixtures with new superficial treatments that could accelerate the healing phase and/or decrease the bacterial interaction can permit us to achieve clinical success, also by starting by lower values of ITV [20–22]. Is has been shown that the process of double-etching treatment on titanium surfaces (DAE) is able to confer to the samples a multiscale roughness: that is the presence of a concomitant nano- and micro-topografy [20].

Moreover, novel post-processing techniques of the titanium implant permit production fixtures with a surface treatment that is locally differentiated.

Traditionally, the stability of dental implants is considered to be directly correlated with the length; however, the insertion of long implants requires the presence of a greater quantity of bone, and if not present, the patient must undergo difficult bone-augmentation procedures, or more invasive interventions, such as the insertion of pterygoid or zygomatic fixtures [23,24]. However, the insertion of long implants increases the risk of invasion of fragile structures, such as the mandibular canal, the mental foramen, and the maxillary sinus [25,26]. Moreover, a recent consensus report concluded that the survival rate of shorts (<6 mm) vs. standard implants is quite similar, and in the case of reduced bone, short implants are a valid option, also because they prevent the patients from the risk of complications associated with bone-grafting procedures [27].

In a previous study, we have shown that multiscale-roughness dental implants of 3.0 and 5.0 diameters showed high insertion torque and primary stability on polyurethane blocks, and this is valuable for implant-loading protocols [28].

Our hypothesis is that, with the advent of multiscale roughness surfaces, such as the DAE ones, the parameter of length could have a minor influence on primary stability in respect to machined implants. If this hypothesis would be confirmed, it could be possible to proceed with an immediate loading protocol (ILP) also in the case of reduced bone height, without the necessity of regenerative procedures.

The aim of this in vitro study was to compare the primary stability of short and long implants, characterized by a multiscale surface roughness, inserted on polyurethane blocks of different densities.

The secondary objective was to understand what implant length would permit us to achieve the higher primary stability in high and low bone densities.

2. Materials and Methods

2.1. Implant Characteristics

A total of 20 titanium implants ASTM Grade 4 (ISO Standard 5832/2), cylindric, 5.0 mm diameter and 2 different lengths (Resista, Verbano, Italy), external exagon (EC), were inserted at a constant distance of 5 mm each on polyurethane blocks.

All implants tested were characterized by a multiscale roughness and a surface treatment locally differentiated in 4 different portions, starting from the implant neck [28]. In particular, the cervical portion was characterized by a machined surface with a micro-roughness of Ra < 1 μ. The rest of the body of the fixture was characterized by a dual acid-etched (DAE) surface, in which the median Ra was 3/7 μ and the apical portion had a mean Ra of 8/12 μ.

The tested implants had 2 different lengths:

(a)   Shorts: 6.0 mm;
(b)   Longs: 13.0 mm.

For each type of implant, a total of 10 fixtures were used, i.e., 5 inserted in the polyurethane block 20 PCF and 5 inserted in the block 30 PCF.

2.2. Polyurethane Foam Blocks

Two different types of solid rigid polyurethane foam (SawBones H, Pacific Research Laboratories Inc., Vashon, WA, USA) with homogeneous densities were selected for the present investigation, in order to mimic different bone densities [29]. The polyurethane blocks used for the experiment have the dimensions 4.0 cm × 13.0 cm × 18.0 cm (Figure 1).
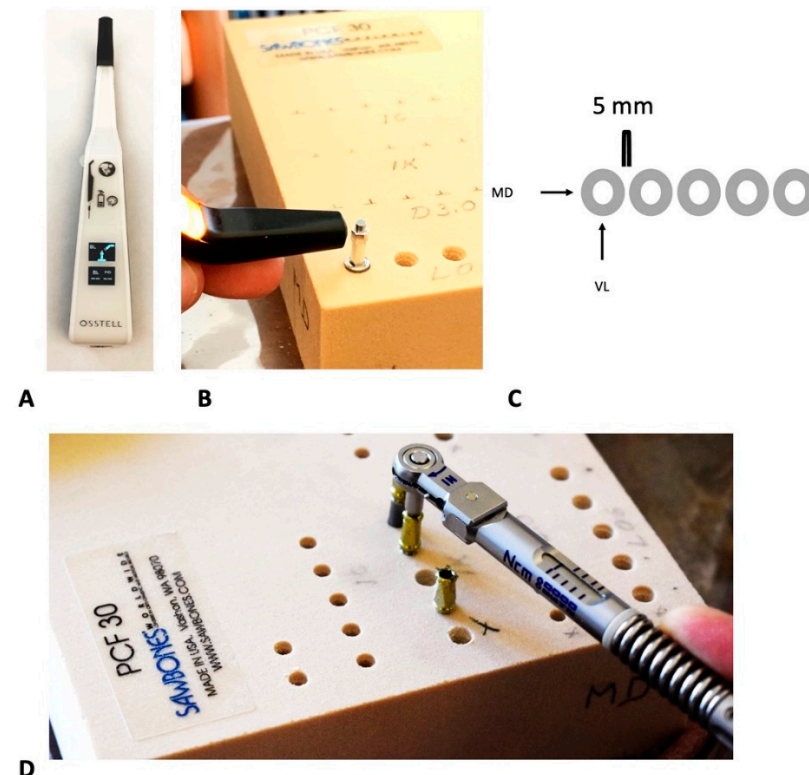
Figure 1. Evaluation of the primary stability of the two types of implants by means of the RFA measurement (**A**,**B**) that was performed in two different directions (**C**), and the recording of the insertion torque value (ITV) and removal torque value (RTV) by using a specific dynamometric ratchet CRD (**D**).

2.3. Drilling Protocol

The implant cavities were prepared without irrigation, in accordance with the Manufacturer instructions (Resista, Verbano, Italy).

The surgical hand-piece was set with a speed of 600 rpm and a torque of 30 N cm for the implant site preparation. A pilot drill FI50 (Cortical Drill—Ø 5.0 mm) was used first, and it was inserted along its entire length for implants long 13.00. A pilot drill FI35 (Cortical Drill—Ø 3.5 mm) was used for implants long 6.00.

Then the following surgical drills were used consecutively: C20 (FC 2018 Cylindrical Drill—Ø 2.0 mm-Long 18 mm), C26 (FC 2618 Cylindrical Drill—Ø 2.6 mm-Long 18 mm), C32 (FC 3218 Cylindrical Drill—Ø 3.2 mm-Long 18 mm), C38 (FC 3818 Cylindrical Drill—Ø 3.8 mm-Long 18 mm) and C42 (FC 4218 Cylindrical Drill—Ø 4.2 mm-Long 18 mm). The length of implant site preparation was the same of the implants inserted, 6.0 and 13.0 mm.

The use of Resista Drill Stoppers—Titanium Grade 5 of 6 and 13 mm lenght—permitted a precise implant site preparation, for the insertion of the two types of implants.

The primary stability of the implants was evaluated by measuring the following parameters:

- Insertion Torque value (ITV) in Ncm;
- Resonance frequency analysis (RFA) in implant stability quotient score (ISQ);
- Removal Torque (RT) in Ncm.

2.4. RFA Stability Measurement

The resonance frequency analysis (RFA) was measured through a dedicated electronic device (Osstel, Columbia, MD, USA) after the screw positioning (Figure 1A,B). The screwing of the transducer on the fixtures was performed always by the same calibrated operator in order to decrease the risk of bias [1]. The RFA was measured in two different points for each implant that were perpendicular each other in order to verify if there were differences (Figure 1C):

- Mesio-distal (MD);
- Vestibulo-lingual (VL).

2.5. Insertion and Removal Torque Values

Insertion and removal torque was measured by using a specific dynamometric ratchet CRD (Resista, Verbano, Italy; see Figure 1D).

The peak force measured at implant loosening was scored as the torque-out value [30].

2.6. Statistical Analysis

Statistical analysis was performed by using SPSS for Windows version 21 (IBM SPSS Inc., Chicago, IL, USA). A *t*-test (Student's *t*-test) was used to compare the parameters analyzed in the study for intra- and inter-group analysis. The threshold was set at $p = 0.05$. In order to analyze the impact of the implant length, in different bone densities, results were stratified in the following:

- Long vs. short implants in 20 PCF;
- Long vs. short implants in 30 PCF.

In order to analyze the impact of bone density on primary stability of implants of the same length, results were stratified in the following:

- Long implants in 20 PCF vs. 30 PCF;
- Short implants in 20 PCF vs. 30 PCF.

3. Results

The results of the primary stability measurements of short implants on 20 PCF polyurethane blocks showed values of RFA-VL of 56.800 (±3.962) ISQ, RFA-MD of 56.800 (±2.864) ISQ, ITV of 49.400 (±17.643), and RTV of 36.800 (±5.069). Long implants showed values of RFA-VL of 62.600 (±2.074) ISQ, RFA-MD of 63.200 (±1.095) ISQ, ITV of 45.800

(±2.774), and RTV of 42.600 (±2.073). The statistical analysis showed significant differences only for the RFA measurements (Figure 2A).
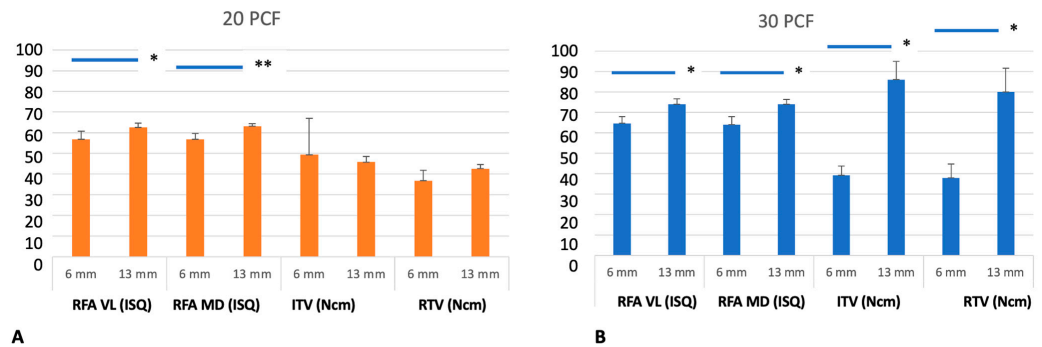
Figure 2. Measurements of primary stability on polyurethane blocks of 20 PCF (**A**) and 30 PCF (**B**); * *p*-value = 0.027, and ** *p*-value = 0.005.

The results of the primary stability measurements of short implants on 30 PCF polyurethane blocks showed values of RFA-VL of 64.600 (±3.286), RFA-MD of 64.000 (±3.937), ITV of 39.200 (±4.549), and RTV of 38.000 (±6.708). Long implants showed values of RFA- VL of 74.000 (±2.645), RFA-MD of 74.000 (±2.345), ITV of 86.000 (±8.944), and RTV of 80.000 (±11.726). The statistical analysis showed significant differences between short and long implants only for all the parameters analyzed (Figure 2B). Comparing the values of primary stability measurements of long implants on 20 and 30 PCF densities, we see that all measurements showed statistically significant differences, with implants inserted on 30 PCF characterized with a significant higher value with respect to those inserted in 20 PCF (Figure 3A). On the contrary, concerning shorts implants, statistical differences were found for RFA, but no significant differences were found for ITV and RTV (Figure 3A).
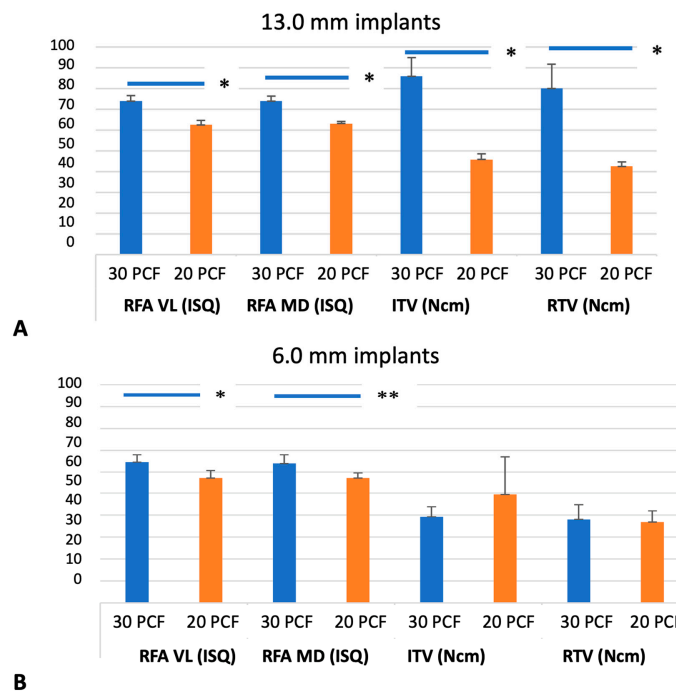
Figure 3. Measurements of primary stability of long implants (**A**) and shorts (**B**) implants on polyurethane blocks of 20 and 30 PCF. * *p*-value < 0.01; ** *p*-value < 0.05. RFA-VL = vestibulolingual resonance frequency analysis (ISQ); RFA-MD = mesio-distal resonance frequency analysis (ISQ); ITV = insertion torque value (Ncm); RTV = removal torque value (Ncm).

4. Discussion

In order to evaluate the impact of the length of dental implants on the primary stability, the measurements of short vs. long implants on RFA, ITV, and RTV were measured on polyurethane blocks of 20 and 30 PCF that mimic the bone density of the Misch's classes D3 and D2, respectively, of 0.32 and 0.48 g/cm^3 [9,12,14,25,31,32]. Moreover, the compressive strength range (MPa) of the 20 and 30 PCF polyurethane block are very similar to the cortical bone strength that ranged between 130 and 200 MPa, while lower values are reported for the trabecular bone that ranges between 0.1 and 16 MPa. The use of polyurethane foam as a bone substitute to perform orthopedic tests has been validated since 2001 by the ASTM F1839-01 Standard Specification. Since then, many studies have been published on this material, especially in orthopedics. As shown by Calvert et al., the use of polyurethane as a bone substitute for in vitro studies permits the use of a material characterized by similar mechanical properties to trabecular bone, such as the stress–strain curve, but, at the same time, the availability of a material that is always the same from lot to lot. In this way, it is possible to repeat the tests without the risk of bias connected with the use of a substrate that changes properties from one sample to another, such as natural bone [33–36]. This type of fixture has a novel multiscale roughness and double-etched surface that is characterized by a remarkable decrease in *Streptococcus oralis* biofilm formation in respect to machined and single-etched titanium [20]. The measurements of the resonance frequency analysis by using the Ostell device permitted us to obtain an objective evaluation of the primary stability by monitoring the changes in the stiffness and stability at the implant–tissue interface [1]. Considering that we found no significant differences between the RFA measurements in the mesio-distal (MD) and vestibulo-lingual (VL) direction, we here discuss these results as a single value. The RFA is influenced by many parameters, firstly by the specific implant system adopted, and, currently, no specific thresholds of ISQ ranges permit to distinguish between failures or successful implants [37]. The literature shows that an ISQ < 45 indicates a poor primary stability, and values >65 are considered to be the most favorable for implant stability [1,38]. In particular, in accordance with the manufacturer and the previous literature, the Ostell measurements can be used to classify the implant stability as good with ISQ > 70, medium with ISQ 60–69, and low with ISQ < 60 [24,39,40]. The results of this work showed significantly higher RFA values for long implants, with respect to the short ones, in all conditions. In particular, on D2 bone density, the RFA values were 74 ISQ for long implants, which could be also immediately loaded as single implants; on the contrary, short implants showed average values of 64 ISQ and would be considered for immediate loading only for total splinted restorations. On the contrary, for low bone densities (20 PCF), although there were significant differences between the RFA values of the long and short implants, these results should be considered with caution. Indeed, the average RFA value of short implants was 56.8 ISQ, which is very near the threshold of 60 ISQ that distinguishes between low- and medium-stability implants. So, independently, by the length on D3 bone, the implant stability of all fixtures could be considered as medium, and, consequently, they could be immediately loaded only in the case of total splinted restorations; on the contrary, a second-stage protocol should be considered.

A recent review of the literature showed no significant differences in the survival rate at 1 and 3 years between low- and high-ITV implants [41]. However, in the case of immediately loaded single implants, Ottoni et al., in 2005, showed a correlation between ITV and the survival rate: an ITV value of 20 Ncm caused the failure of 90% of the implants; consequently, they suggested a minimum ITV of 32 Ncm to achieve the osseointegration [42]. ITV is a biometric parameter that can be influenced by several conditions, such as the size of the recipient site, the morphology and the quality of the bone, the macro and micro design of implants, and the surgical technique. ITV has an important clinical significance for the immediate loading protocol: the literature suggested minimum values of ITV of 30 Ncm for full-arch restorations, 45 Ncm for implants supporting partial-arch restorations and 60 Ncm for single teeth [43–45]. However, in our retrospective study, we found no statistical differences in the survival rate of implants immediately loaded with different

types of prosthetic rehabilitations with an average ITV of 61.300 vs. 24.030 Ncm [17]. In this study, both short and long implants in 20 and 30 PCF showed values of ITV higher than 39 Ncm. Consequently, for a total immediate prosthetic restoration on multiscale-roughness dental implants splinted together, the length of the implants would be not important, independently by the bone density. As suggested by Meredith et al., an ITV that is between 25 and 30 Ncm is a perfect balance between primary stability and a reduced risk of excessive force that could cause bone resorption and further necrosis [46–48]. In D2 bone density, the use of long implants permitted us to reach ITV values of more than 85 Ncm, which could be immediately loaded also as a single implant restoration. On the contrary, we should act with caution for the immediate loading of short implants in D2 bone and implants in D3 bone, independently from the implant length. The measurements of the removal torque showed the same trend of the ITV, even though it showed lower values, as is in accordance with the previous literature [49]. A limitation of this in vitro study is that natural bone is characterized by an anisotropic behavior, contrary to polyurethane foam, which is isotropic. Future studies will make a comparison between this in vitro model and preclinical and clinical results.

5. Conclusions

Longer implants permitted us to achieve significantly higher values of primary stability in respect to the short ones only on 30 PCF blocks. The ITV and RTV showed no significant differences between long and shorts implant on 20 PCF blocks; all implants showed medium stability that could be considered for immediate loading only in the case of totally splinted restorations, so the implant length seemed to be a relevant factor for immediate loading only on high bone density.

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