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Original Article

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An in vitro evaluation on polyurethane foam sheets of the insertion torque, removal torque values, and resonance frequency analysis (RFA) of a self-tapping threads and round apex implant

Margherita Tumedei[1], Adriano Piattelli[1,2,3], Antonello Falco[4], Francesco De Angelis[1], Felice Lorusso[1], Maristella Di Carmine[5] and Giovanna Iezzi[1]

Abstract
The dental implant primary stability and micromovement absence represent critical factor for dental implant osseointegration. The aim of the present in vitro investigation was to simulate the bone response on different polyurethane densities the effect of self-tapping threads and round apex implant geometry. A total of 40 implants were positioned in D1, D2, D3 and D4 polyurethane block densities following a calibrated drilling protocol. The Insertion, removal Torque and resonance frequency analysis (RFA) means were calculated. All experimental conditions showed insertion torque values >30 Ncm. A significant higher insertion torque, removal and RFA was present in D1 polyurethane. Similar evidences were evidenced for D3 and D4. The effectiveness of

[1] Department of Medical, Oral and Biotechnological Sciences, University of Chieti-Pescara, Via dei Vestini, Chieti, Italy
[2] Chair of Biomaterials Engineering, Catholic University of San Antonio de Murcia (UCAM), Av. de los Jerónimos, Guadalupe, Murcia, Spain
[3] Fondazione Villa Serena per la Ricerca, Città Sant'Angelo (PE), Italy
[4] Private Practice, Pescara (PE), Italy
[5] Private Practice, Loreto Aprutino (PE), Italy

Corresponding author:
Margherita Tumedei, Department of Medical, Oral and Biotechnological Sciences, University "G. D'Annunzio" of Chieti-Pescara, Via dei Vestini, 31-66100 Chieti (CH), Italy.
Email: margytumedei@yahoo.it

the present study suggested a valuable clinical advantage for self-tapping threads and round apex implant using, such as in case of reduced bone density in the posterior maxilla

Keywords
Dental implant, polyurethane blocks, primary stability

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Introduction

The implant-supported restorations represent a viable and highly predictable treatment for total or partial edentulisms.[1,2] It is well-known that the primary stability is an essential clinical requisite for dental implant osseointegration.[3,4] This clinical parameter is correlated to numerous factors such as the density of the bone tissue, the micro-and macro-geometry of the implant, the adoption of underpreparation or osseodensification drilling protocols.[5–8]

In literature, a local poor bone density is associated to an increase of the early implant failure and loss of osseointegration.[9–11] In the same way, a poor bone density is associated to a more difficult primary stability achievement.[12–15] Comuzzi et al. reported that, in standardized condition on low-density polyurethane study, the macro-geometry induced the main effect on the primary stability, while the osseodensification drilling procedure produced the more visible effect on stability in presence of a residual cortical bone.[16] Moreover, Gehrke et al. reported the key role of the implant macro-geometry on a sheep study, while the self-tapping and round apex macro-geometry is able to influence significantly the percentage of new bone formation and the deposition of highly vascularized osteogenic matrix within the marrow spaces,[17] where the number and thickness of bone trabeculae increase with the loading of the dental implants.[18] In vivo, no radiographical and hystological evidence in crestal bone resorption were present were evident between the osseodensification procedure,[19–21] the drilling technique[22] and ultrasonic device approach.[23]

Misch et al. classified the type IV bone as a histotype characterized by a more represented cancellous bone with an almost complete absence of the cortical component.[24] This variant seems to be more widespread in the posterior maxillary region.[24,25]

On the contrary, the type I bone is characterized by a more expressed bone cortical component and is typical of the mandible symphysis.[24,26] The intermediate histotypes are represented clinically with a discrete local anatomical variability between the upper and lower jaws in relation to several aspects such as the age of the patient, the metabolism health and the functional loading of the region.[24,26]

The insertion torque measurement and resonance frequency analysis (RFA) by implant stability quotient (ISQ) Scale has been proposed to evaluate clinically the stability of the implant during the positioning procedure in relation to their high reproducibility.[27,28]

In literature, an optimal insertion torque range between 30 Ncm and 50 Ncm has been correlated to increased new bone formation and bone-implant contact.[27] Moreover, an ISQ >70 has been considered an optimal clinical effectiveness for one-stage loading for splinted or single implant.[27]

On the contrary, a ISQ <60 is associated to a decreased of implant stability and the indication for a two-stage loading protocol.[27]

The polyurethane simulation has been proposed as a standardized study model for implant mechanical test by the American Society for Testing and Materials International (ASTM) with

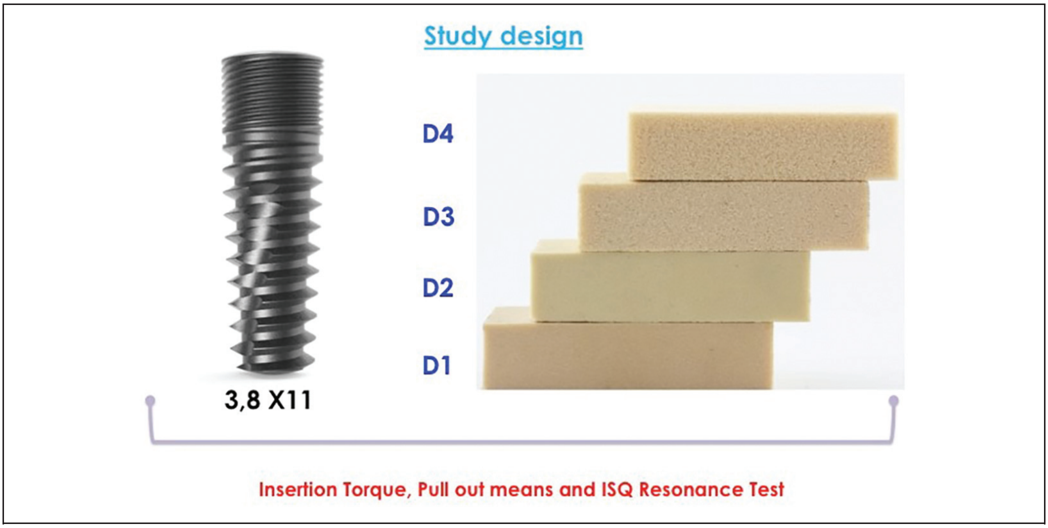

Figure 1. Polyurethane simulation study design. D1 bone: 40 pounds per cubic foot polyurethane block (pcf); D2 bone: 30 pcf polyurethane block; the D3 bone: 20 pcf polyurethane block; D4 bone: 10 pcf polyurethane block.

a high affinity and accuracy of the bone tissue substrate.in terms of density, elastic module, compression and traction load.[29]

The aim of the present study was to evaluate the stability of a self-tapping and round apex implant on a polyurethane in vitro simulation.

The null hypothesis of no difference of insertion torque, removal and RFA between the different polyurethane densities was tested.

Materials and methods

Polyurethane bone simulation

Different densities of synthetic solid rigid polyurethane homogeneous bone blocks (SawBones H, Pacific Research Laboratories Inc., Vashon, Wash) were used for the present investigation to simulate the bone histotypes of the jaws (Figure 1). As reported by a recent study of Comuzzi et al.,[30,31] the D1 bone was simulated with the 40 pounds per cubic foot block (pcf), the D2 with the 30 pcf block, the D3 and D4 respectively with 20 and 10 pcf block according to the Misch classification.

Implant characteristics

A total of 40 implant 3.8 mm diameter and 11 mm length (Way miX, Geass Pozzuolo del Friuli, Italy) was positioned on the polyurethane blocks, 10 screw for each experimental condition. The implant presented a surface treatment of laser roughening and the macro-design was characterized by a conical geometry with a cervical microthreads area of 2.5 mm. The body of the implant presented self-tapping threads and round apex. The screw was provided by an internal hexagon implant-abutment connection (Figure 2). The four experimental condition followed the same drilling protocol with the 2.5 diameter drill followed by the 3.8 diameter final drill at 800 rpm

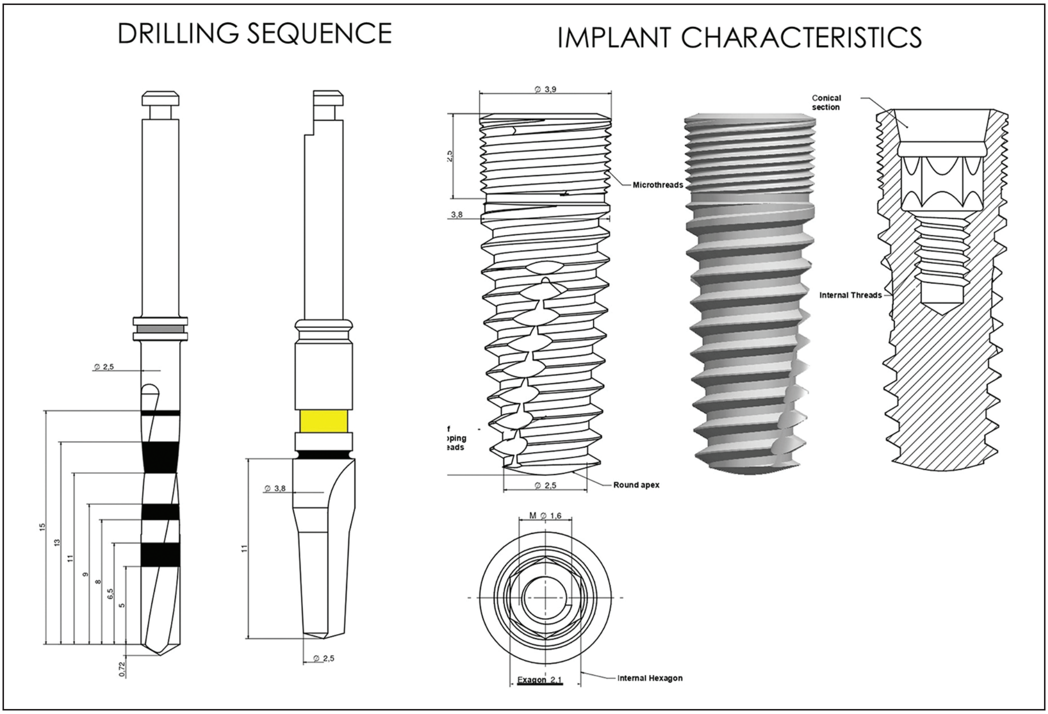

Figure 2. Drilling sequence protocol and main screw characteristics of the implant used in the present investigation.

and 30 Ncm torque by calibrated dynamometric motor integrated to the universal testing machine (Imada, Japan) (Figures 2–3). The final work length of 11 mm and a constant calibrated force rate of 9.0 N was electronically applied to the handpiece to standardize the implant drill preparation. The implant insertion torque was calculated following a positioning speed of 50 rpm. The removal was recorded by the high precision electronic dynamometric to evaluate the extraction resistance of the implant from the preparation site.

RFA stability measurement

The resonance frequency analysis (RFA) was performed by the Implant stability Quotient analytical method by a dedicated electronic device (Osstell, Gothenburg Sweden) after the screw positioning.

The implant stability quotient (ISQ) scale range was from 0 to 100 and classified as low stability (<60 ISQ), Medium (60–70 ISQ), and High stability (>70 ISQ). For each specimen, the RFA measurement was repeated two times for each specimen (Figure 4).

Statistical analysis

The Insertion Torque, Pull out means and ISQ Resonance Test means were statistically analysed between the four study groups. The normality was evaluated by Kolmogorov-Smirnov test and the

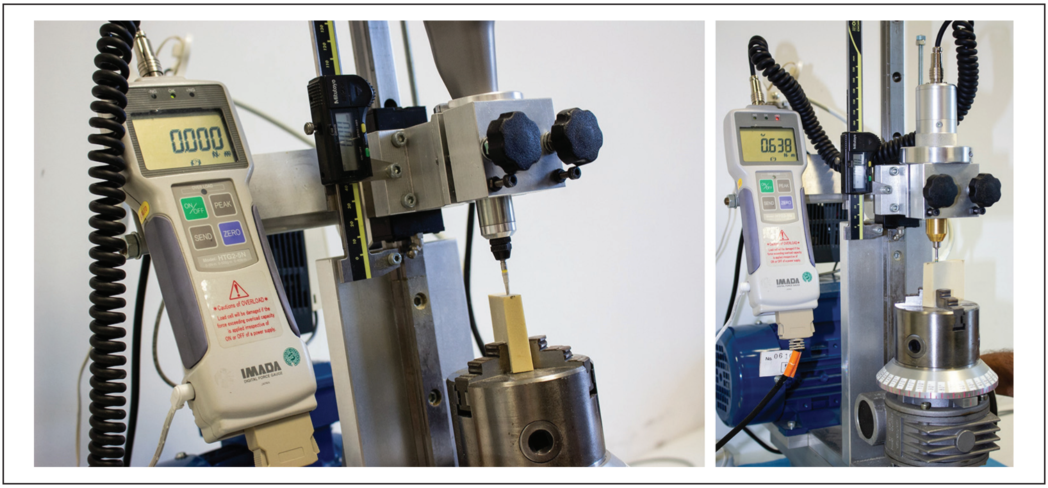

Figure 3. Implant site drilling by Universal testing machine (left). Calibrated dental implant positioning sequence (right).

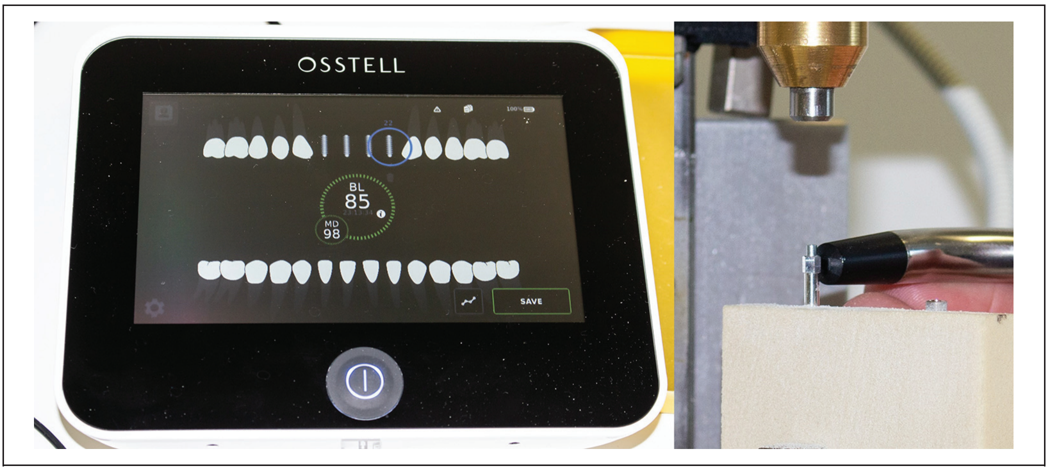

Figure 4. RFA measurement of dental implant stability after the screw positioning.

one-way ANOVA followed the Sidak multiple comparisons post-hoc test for heterogeneous variances was evaluate the study data by the software package GraphPad 6.0 (Prism San Diego, CA, USA) statistical package. The level of significance was set at $p < 0.05$.

Results

No evidences of micro-cracks were observed in the cervical portions of the polyurethane-implant interface. Mean values for Insertion Torque values are presented in Table 1 (Figure 5). The insertion torque means were higher for D1 group (mean 135.1 $\pm$ 6.324) ($p < 0.01$) (Table 2).

Table 1. Summary of insertion torque, removal and rfa measurements. No statistical differences of insertion torque and pull out were detectable for D3 and D4 groups ($p > 0.05$). A significant difference of insertion torque, pull out and rfa analysis were evidenced for all comparison groups ($p < 0.05$) (One-way Anova, mean, standard deviations).

	Insertion Torque [Ncm]		Removal Torque [Ncm]		RFA ISQ Scale	
Groups	Mean	DS	Mean	DS	Mean	DS
D1	135.1	6.324	30.79	4.686	70.20	5.613
D2	92.92	30.57	24.87	2.898	70.45	2.339
D3	45.79	2.731	13.71	1.196	60.75	3.706
D4	36.89	6.969	13.70	1.523	51.50	4.143

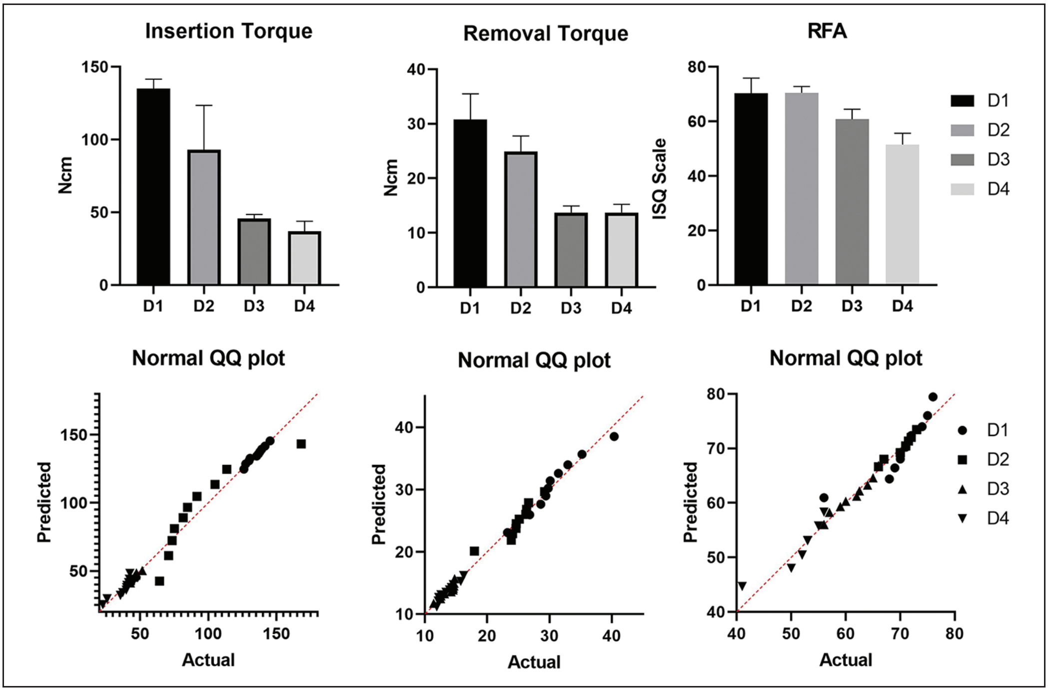

Figure 5. Bar graph of insertion torque, removal and rfa measurements. No statistical differences of insertion torque and pull out were detectable for D3 and D4 groups ($p > 0.05$). A significant difference of insertion torque, pull out and rfa analysis were evidenced for all comparison groups ($p < 0.05$).

The removal values are presented in Table 3, where showed a statistically significant difference between the study groups with the highest values for D1 group (mean: 30.79 $\pm$ 4.686) ($p < 0.01$) (Table 1–3, Figure 5).

The implant micromovement analysis by ISQ resonance test is reported in Figure 5. No statistical differences were present between D1 and D2 groups and between D3 and D4 ($p > 0.05$) (Table 1–4, Figure 5).

Table 2. Summary of insertion torque groups comparison (One-way Anova-Sidak post-hoc test, mean, standard deviations).

Insertion Torque	Mean Diff.	95.00% CI of diff.	Adjusted P Value
D1 vs. D2	42.19	−3.819 to −0.7306	<0.0001
D1 vs. D3	89.31	2.631 to 5.719	<0.0001
D1 vs. D4	98.22	−5.469 to −2.381	<0.0001
D2 vs. D3	47.13	4.906 to 7.994	<0.0001
D2 vs. D4	56.04	−3.194 to −0.1056	<0.0001
D3 vs. D4	8.907	−10.43 to 28.24	0.6056

Table 3. Summary of removal torque groups comparison (One-way Anova-Sidak post-hoc test, mean, standard deviations).

Removal Torque	Mean Diff.	95.00% CI of diff.	Adjusted P Value
D1 vs. D2	5.925	2.408 to 9.442	0.0003
D1 vs. D3	17.08	13.56 to 20.60	<0.0001
D1 vs. D4	17.09	13.57 to 20.61	<0.0001
D2 vs. D3	11.16	7.640 to 14.67	<0.0001
D2 vs. D4	11.17	7.650 to 14.68	<0.0001
D3 vs. D4	0.01000	−3.507 to 3.527	>0.9999

Table 4. Summary of RFA groups comparison (One-way Anova-Sidak post-hoc test, mean, standard deviations).

RFA	Mean Diff.	95.00% CI of diff.	Adjusted P Value
D1 vs. D2	−0.2500	−5.212 to 4.712	0.9991
D1 vs. D3	9.450	4.488 to 14.41	<0.0001
D1 vs. D4	18.70	13.74 to 23.66	<0.0001
D2 vs. D3	9.700	4.738 to 14.66	<0.0001
D2 vs. D4	18.95	13.99 to 23.91	<0.0001
D3 vs. D4	9.250	4.288 to 14.21	<0.0001

Discussions

The primary implant stability represents the clinical main condition that could determine the long-term success of implants osseointegration and is deeply influenced by the implant surface geometry.[12,32,33]

In the present study, the RFA was chosen as a nondestructive, noninvasive, and repeatable quantitative evaluation of implant stability that is independently of the implant system used.

The effectiveness of the present study showed significant differences between the experimental conditions, so the tested null hypothesis of the present investigation was rejected.

In the present investigation the self-tapping and round apex implant tested showed in all conditions an insertion torque >30 N, that is commonly considerated[AQ1] an optimal clinical positive predictive index for implant stability.[34,35]

In the simulated condition of D1, higher the insertion torque mean >130 N associated to increased removal and Rfa values were reported.

Consolo et al. reported on sheep mandible similar histological aspects of the peri-implant bone tissue between low torque (<25 Ncm) and high torque (>100 Ncm) after 8 and 12 weeks.[36]

The authors reported that high implant insertion torque did not induce adverse reaction in cortical bone and does not lead to implant failure.[36]

Reasonably, the drilling technique represents an essential factor for the implant success in the D1 mandible symphysis, where the reduced cancellous bone and vascularization and the thermal effect generated by the implant site preparation could represent a cause of early implant failure.[37–40]

Piattelli et al. reported that the microscopical thermal damage of peri-implant tissues is characterized by aspects of bone sequestra; no regeneration of the peri-implant tissues and presence of mature bone; inflammatory infiltrate at the level of the implant-bone interface; no stable peri-implant bone clot; bacteria colonization and necrotic bone.[41]

On the other side, the poor density bone benefits a self-tapping thread geometry in order to a favourable implant positioning.[42,43] In fact, in case of low bone density, the obtaining of implant primary stability and screw anchorage is more difficult.[44]

In this way, the presence of the round apex is able to generate a gently apical compression able to increase the implant stability and a conservative Schneider's membrane lift in case of maxillary sinus augmentation.[45]

Low initial stability in type IV bone corresponds to lower insertion torque, pull out and rfa means, that clinically could induce the adoption of a more conservative two-stage loading approach, mostly in case of single implant restoration.[11]

The implant-splinted rehabilitation for a one-stage loading approach is preferable with careful control of the chewing function, presence of parafunctions and bruxism.[46]

Chrcanovic et al. reported in a multilevel mixed retrospective study on 10 096 implants implant failure rate of 13·0% for bruxers. The bruxism was considered a statistically significantly risk factor to implant failure as well as implant length, implant diameter, implant surface, bone quantity, bone quality, smoking and the intake of proton pump inhibitors.[46]

Conclusions

The evidences of the present study suggested that self-tapping implants is highly recommended. Especially in case of low-density maxillary bone, where the achievement of implant primary stability is clinically more difficult.

Author contributions

The conception and design of the study (AP, GI), acquisition of data (MT FL) analysis and interpretation of data (AP, AF, MT) drafting the article (AP, MT, MD), revising it critically for important intellectual content (MT, MD, AF, FD) final approval (AP, GI).

Declaration of conflicting interests

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ORCID iD

Margherita Tumedei https://orcid.org/0000-0001-8770-5297

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