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Influence of an Alternative Implant Design and Surgical Protocol on Primary Stability

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The purpose of this *in vitro* study was to evaluate the influence of a new proposal of implant design and surgical protocol on primary stability in different bone densities. Four groups were tested (n=9): G1 - tapered, cone morse, Ø 4.3 mm x 10 mm in length (Alvim CM); G2 - experimental tapered; G3 - cylindrical, cone morse, Ø 4.0 mm x 11 mm in length (Titamax CM) and G4 - experimental cylindrical. The experimental implants were obtained from a design change in the respective commercial models. The insertion was performed in polyurethane (PU) blocks 0.24 g/cm^3 (20 pcf) and 0.64 g/cm^3 (40 pcf), according to different surgical protocols. The primary stability was measured by means of insertion torque (IT) and pullout test. Data were analyzed by ANOVA, Tukey's test (α=0.05) and Pearson's correlation. For IT and pullout, conventional and experimental implants showed no difference between them when inserted in the 20 pcf PU ($p>0.05$). In the 40 pcf PU, the modified implants exhibited greater IT ($p<0.05$) and lower pullout ($p<0.05$) compared to the respective conventional models. The implant design tested associated with the surgical protocol, positively influenced primary stability in higher density bones.

Key Words: dental implants, design, bone densities, surgical protocol, torque.

Introduction

The main current research goals is to develop an implant design that provides timeless stability in bone tissue (1-3), restoring the physiological, systemic functions and quality of life to edentulous patients in a short period of time (4). However, there are few implants and types of biomaterials that are fully characterized and understood before marketing (5).

The surface treatment is frequently reported in the literature as the main criterion to assist the osseointegration process, while a significantly smaller number of studies have evaluated how the aspects of design and surgical technique interfere in this process. To ensure the success and survival of the implant, the variables involved as macro geometry, bone quantity and quality and surgical technique must be evaluated together (6), since they have direct relation with the initial stability, prerequisite for cell differentiation and tissue healing (2,4).

The macro geometry of the implant is an important biomechanical factor and is closely related to the initial contact with the bone tissue, proper distribution of loads and support of forces during the function (7-9). In the presence of poor bone quality, achieving optimal stability is a challenge for clinicians, and it is often necessary to change the surgical protocol and adapt the design characteristics of implants to the bone conditions. In this case, although two different parameters are under consideration, their contribution to osseointegration cannot be considered separately (2,10).

Thus, in clinical situations where bone quality is critical, it becomes necessary to understand the influence of macro geometry to achieve good primary stability (8,11). There are numerous design proposals available in the dental market, which vary depending on the size, type of thread, prosthetic connection and shape (12), such as the tapered, which induces controlled compressive forces and promotes better fixation (11).

Self-tapping implants are viable in situations of immediate loading and low density bone regions, since the presence of chamfers or edges in the apical third facilitates the surgical technique and increases its survival rate (7-8,13). On the other hand (4,14,15), studies have demonstrated significant reduction in insertion torque in the presence of notches, according to these authors, due to friction loss, there is a decrease in compression with the bone tissue and an increase in the shear strength.

Small design changes, together with the close research/industry relationship constantly transform laboratory findings into commercial models without the prior realization of basic and clinical research. The lack of a sequential approach in designing a new implant model still causes many knowledge gaps, challenging dental surgeons and engineers to address the interaction of parameters such as macro geometry, surgical technique, and bone density in a broad and objective manner (2,5).

Thus, the present study proposes a combining changes in the macro geometry and surgical technique in experimental implants in order to assess the primary stability of the new proposal, compared to commercial models, using a polyurethane blocks of different densities.

Material and Methods

Implants

For this study 36 Neodent® implants (Curitiba, Parana, Brazil) were used, divided into four groups (n=9): G1 - tapered, cone morse, Ø 4.3 mm x 10 mm length (Alvim CM); G2 - experimental tapered; G3 - cylindrical, cone morse, Ø 4.0 mm x 11 mm in length (Titamax CM) and G4 - experimental cylindrical. The experimental implants were obtained from a design change in their respective commercial models by extending the three pre-existing grooves in the apical third up to the level of the prosthetic platform (8) (Fig. 1).

Polyurethane Blocks and Surgical Protocol

In order to standardize the bone characteristics polyurethane blocks (PU) were used (National bones, Sao Paulo, Brazil) according to ASTM F1839/08, with the following dimensions: 15x15x30 mm at densities of 0.24 g/cm3 (20 pcf = pounds per cubic foot 20) and 0.64 g/cm3 (40 pcf = pounds per cubic foot 40). According to the classification proposed by Lekholm and Zarb (16), 20 pcf PU simulates the bone types II and III, and the 40 pcf PU simulates the bone type I (17).

All implants were individually inserted into the bone blocks by a trained professional. An independent observer, blinded to the study, assessed the placement accuracy. The drilling was performed with a Surgical Electric Motor MC 101 (Dentscler®, Ribeirão Preto, São Paulo, Brazil), adjusted to a torque of 45 N and 1350 rpm. The drilling protocol followed the manufacturer's recommendations for commercial implants, for experimental models, the proposal made was to change the original protocol by reducing the number of drills used (Table 1).

Figure 1. Design of implants: A: G1; B: G2; C: G3; D: G4.

Primary Stability Analysis

The implants were inserted from the lowest (20 pcf) to the highest (40 pcf) PU density, so the increasing density could not affect the morphological structure of the screws. To insert the implants, each PU block was placed on the bench vise and the implant was installed according to the surgical protocol described above. The IT measurement was performed using a manual torque wrench (Neodent®) with the respective set of implants and insertion keys.

In addition to IT, the pullout assay was performed according to ASTM F543. Each implant, in PU blocks, was attached to a universal testing machine (EMIC® model DL-10000N, São José dos Pinhais, Paraná, Brazil) using a device specifically designed for this study. After positioning the set PU blocks/implant in the machine, an axial traction force was applied with a constant velocity of 2 mm/min with a 200 Kg load cell. For all implants, a preload of 10 N and a 30-s settling time was used. The data for the maximum pullout force were obtained using Tesc 1.13 Software.

After the normality of the data was verified by the Kolmogorov-Smirnov test, analysis of variance (ANOVA) followed by the Tukey test (α=5%) was used.

To verify the correlation between the methods used in the analysis of primary stability, the Pearson's correlation was used.

In Pearson's analysis:

Values > 0.70 (positive or negative) indicate a strong correlation.

Values ranging from 0.30 to 0.70 (positive or negative) indicate a moderate correlation.

Values 0 to 0.30 indicate a weak correlation.

The tested null hypotheses were that there would be no influence of a new implant design and surgical protocol on the primary stability.

Results

Insertion Torque

The experimental implants inserted in the 20 pcf PU, did not present statistical differences in relation to the respective commercial models, tapered (p=1.000) and cylindrical (p=0.274). In the 40 pcf PU the experimental implants, tapered (p=0.000) and cylindrical implants

Table 1. Drilling protocol used for each group of implants

G1	Lance	2.0	3.5	4.3	-	-
G2	Lance	2.0	3.5	*	-	-
G3	Lance	2.0	2/3	3.0	3.3	3.3/4.0
G4	Lance	2.0	2/3	3.0	*	*

(*) Indicate not using the cutter. In each line, the values are diameter of implants in mm.

(p=0.016) showed significantly higher insertion torque compared to the respective commercial models (Fig. 2).

Pull out Test

In the 20 pcf PU there was no statistical difference between the experimental and commercial implants, tapered (p=0.848) and cylindrical (p=0.089). In the 40 pcf PU, the experimental tapered (p=0.000) and cylindrical implants (p=0.021) presented significantly lower pullout values compared to the respective commercial models (Fig. 3).

Insertion Torque Correlation x Pullout Test

The two methodologies used in the study showed positive moderate correlation p 0.413.

Discussion

Aspects of implant design, surgical technique and bone quality affect the osseointegration process. Although different variables are under consideration, their contribution to the healing process can not be assessed in isolation. Only the design does not guarantee the success and survival of the implant, its performance can improve or worsen due to other factors such as bone quantity and quality, surgical technique and patient health. Therefore, the interaction of these three parameters has been discussed widely and objectively in the study.

The null hypothesis of this study was rejected, since the change in design and surgical protocol altered primary stability. The combination of threads and sharp edges along the longitudinal extension transformed the implants into a self-drilling devices that facilitate the surgical technique, decrease the manipulation of the bone tissue, favor cellular retention and proliferation along its surface and improves the primary stability without impairing the distribution of forces before the application of loads (7,8).

An ideal surgical technique should be able to prepare the bone bed carefully and avoid overheating by providing adequate preparation for implant stability (18). A recent study (19) showed that individualized surgical protocols, such as the use of bone condensation, undersized perforations and tapered implants, may increase primary stabilityThe experimental implants evaluated were inserted using the underpreparation technique, in which the insert is held in a smaller diameter hole than usual, by generating compressive forces along the interface with the bone tissue, resulting in greater stability (20-23). This method facilitates the technique, reduces surgical time and bone tissue removal, a fundamental factor for the healing response, since less bone removal reduces friction and contributes to primary stability (11,24).

Depending on the diameter of the last drill in relation to the implant, macro design and micro design, and bone density, different insertion torque values can be obtained. Many of the manufacturers already recommend undersized surgical protocols to improve stability, especially in bone with lower density (13). However, the exact amount of subpreparation is not specified in the literature and often depends on the perception of the dentist in the surgical procedure (25), since, depending on the clinical situation, the protocol customization is necessary (18). Based on this, the drilling protocol for the modified implants has been modified, allowing the use of a smaller number of drills to achieve greater stability due to its characteristic design.

Reducing the number of drills during the preparation is beneficial to the healing process (4,26). The drilling of the bone in several stages generates significantly higher temperatures than the single-step technique (27), leading to the formation of a necrotic area around the preparation site, proportional to the amount of heat generated. In

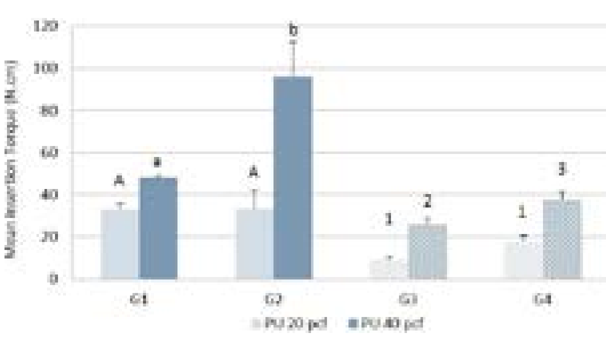

Figure 2. Mean insertion torque (N.cm) of the implant groups at the different densities of polyurethane. Note: In figure 2, the G1 obtained means of 33.00 (2.91) N.cm for 20 pcf PU and 47.88 (1.36) N.cm for 40 pcf PU; G2 33.12 (9.23) N.cm for 20 pcf PU and 96.11 (16.35) N.cm for 40 pcf PU; G3 9.44 (0.72) N.cm for 20 pcf PU and 25.77 (3.03) N.cm 40 pcf PU; G4 17.44 (3.16) N.cm for 20 pcf PU and 37.77 (5.65) N.cm for 40 pcf PU.

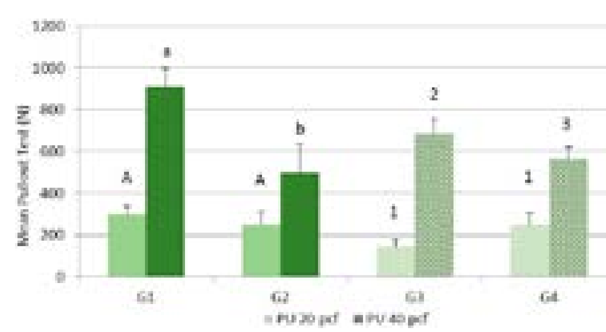

Figure 3. Mean pullout test (N) of the implant groups at the different densities of polyurethane. Note: In figure 3, the G1 obtained means of 298.18 (37.54) N for 20 pcf PU and 910.37 (85.79) N for 40 pcf PU; G2 246.74 (67.31) N for 20 pcf PU and 500.01 (133.91) N for 40 pcf PU; G3 143.52 (35.48) N for 20 pcf PU and 687.38 (71.48) N 40 pcf PU; G4 246.13 (63.85) N for 20 pcf PU and 565.56 (56.17) N for 40 pcf PU.

addition, multiple perforations increases the removal of bone tissue, while for improving the primary stability, the bone must be moved laterally (24) and not removed.

In low density bones, limited primary stability (25) the healing time and higher failure rates require (2,28) a broader analysis that correlates the different variables involved. In the study, for 20 pcf PU, changing the format and surgical protocol, with reduction of a one drill for the experimental tapered implant and of three drills for the experimental cylindrical did not cause a significant increase in primary stability, measured by IT and pullout test. On the other hand, the insertion of the experimental implants in the 40 pcf PU promoted an improvement in the primary stability, evaluated by IT. This demonstrates that the design has different performances, depending on the bone density and surgical technique (29), reaffirming the need for a comprehensive approach to these variables when designing an implant.

Although the design change did not increase insertion torque in the lower density polyurethane, the values obtained were similar to those of the respective conventional models. The results of the present study were different to those reported in other studies (4,15), which associated the significant reduction of insertion torque to the presence of bevels in self-drilling implants, according to them, due to the loss of friction, decrease of the compression with the bone tissue and increase of the shear force.

The experimental models showed significantly lower values than the conventional ones for the maximum pullout force. This may be associated with the extended formation of grooves, which despite increasing the cutting capacity and facilitating insertion, may have decreased the contact surface and the frictional forces in the implant/bone (4,14), since the shear stress generated with the pullout test is obtained as a function of the external diameter and effective length of the implant in contact with the bone tissue (30,31).

The type of material used for insertion should also be considered. As polyurethane is an inorganic polymer, it does not promote condensation reaction (22) as the bone tissue. In this case, the torque generated during surgical installation causes the material to break into smaller particles, reducing the contact surface of the implant and (23-24) decreasing primary stability when assessed by the pullout test. Although the maximum force was lower in modified models, the values obtained from 246.74 N for the conical and 500.01 N for the cylindrical are considered satisfactory for the stability of the implant. A study carried out on rabbit tibiae found pullout values similar to those observed in the study, even after 12 weeks of osseointegration (31).

In recent years, a number of implant systems have been introduced to the market, but few studies have investigated new implant designs under a full-blown approach to the influence of design, surgical technique, and bone density (5). Although in vivo studies should be performed to confirm the efficacy of experimental implants evaluated, the results obtained demonstrated advantages in its use, such as favorable primary stability and benefits of the surgical technique, even in bones of lower density. An alternative implant design and surgical protocol evaluated showed advantages in relation to the conventional implants tested, with respect to primary stability and facilitating the surgical technique.

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Resumo

O objetivo deste estudo *in vitro* foi avaliar a influência de uma nova proposta de design de implante e protocolo cirúrgico na estabilidade primária em diferentes densidades ósseas. Foram testados quatro grupos (n=9): G1 - cônico, cone morse, Ø 4,3 mm x 10 mm de comprimento (Alvim CM); G2 - experimental cônico; G3 - cilíndrico, cone morse, Ø 4,0 mm x 11 mm de comprimento (Titamax CM) e G4 - experimental cilíndrico. Os implantes experimentais foram obtidos a partir de uma mudança no design dos respectivos modelos comerciais. A inserção foi realizada em blocos de poliuretano (PU) 0,24 g/cm^3 (20 pcf) e 0,64 g/cm^3 (40 pcf), de acordo com diferentes protocolos cirúrgicos. A estabilidade primária foi aferida por meio do torque de inserção (TI) e ensaio de arrancamento. Os dados foram analisados por ANOVA, teste de Tukey (α=0,05) e correlação de Pearson. Para TI e arrancamento, os implantes convencionais e experimentais não mostraram diferença entre si quando inseridos na PU de 20 pcf (p>0,05). Na PU de 40 pcf, os implantes modificados exibiram maior TI (p <0,05) e menor arrancamento (p <0,05) em relação aos respectivos modelos convencionais. O design do implante testado associado ao protocolo cirúrgico, influenciou positivamente a estabilidade primária em ossos de maior densidade.

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