

IMPLANT MACRO-DESIGN AND IMPLANT STABILITY: AN EX VIVO STUDY

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Abstract

The aim of the study was to compare the impact of three different implant macro-designs on the primary stability.

25 cylindrical non self-tapping implants (Straumann® SP/TL), 30 hybrid self-tapping implants (Straumann® BL) and 30 tapered self-tapping implants (Straumann® BLT) with the same diameter and length (4.1/10mm) were inserted randomly in 30 different bone bloc types on beef ribs. The assessment of the primary stability was carried out by recording the maximum insertion torque IT (DTA device) and the implant stability quotient ISQ using the resonance frequency analysis RFA (with the Osstell device) for each implant design in a same quality of bone.

In all bone types mingled, BLT implants showed significantly higher mean insertion torque

when compared to TL and BL with respectively 59.97, 48.82 and 31.06 ($p < 0.0001$ each as per the Anova test) and higher mean ISQ with respectively 85.17, 81.60 and 80.67 ($p < 0.0001$ each as per the Anova test). These higher values for the BLT were very important in bone type II and III.

Within the limitation of this study, the tapered self-tapping implant (Straumann® BLT), showed a better primary stability in all types of bone which promises its indication in immediate placement and loading and in immediate loading in soft bone.

The two methods used to assess the primary stability of the different implant macro-designs, the maximum insertion torque and the resonance frequency analysis, showed a weak correlation.

Further clinical studies are required to better evaluate the different biological responses to this enhancement of the primary stability.

Keywords: Dental implant - implant design - insertion torque - primary stability - resonance frequency analysis - animal model.

IAJD 2917;8(2):49-57.

MACRO-DESIGN ET STABILITÉ IMPLANTAIRE : UNE ÉTUDE EX VIVO

Résumé

L'objectif de l'étude était de comparer l'impact de trois différentes macro-géométries d'implants sur la stabilité primaire.

25 implants auto-taroudants cylindriques (Straumann® SP / TL), 30 implants auto-taroudants hybrides (Straumann® BL) et 30 implants auto-taroudants coniques (Straumann® BLT) de même diamètre et longueur (4.1 / 10 mm), ont été insérés de façon aléatoire dans 30 différents types de bloc osseux sur des côtes de bœuf. L'évaluation de la stabilité primaire a été effectuée en enregistrant le couple maximal d'insertion IT (appareil DTA) et le quotient de stabilité des implants ISQ à l'aide de l'analyse de la fréquence de résonance magnétique RFA (avec le dispositif Osstell) pour chaque forme d'implant dans une même qualité d'os.

Dans tous les types d'os confondus, les implants BLT ont présenté un couple d'insertion moyen significativement plus élevé que les TL et BL avec respectivement 59,97, 48,82 et 31,06 ($p < 0,0001$ selon le test Anova) et des valeurs du ISQ plus élevées respectivement avec 85,17, 81,60 et 80,67 ($p < 0,0001$ chacun selon le test d'Anova).

Ces valeurs plus élevées pour l'implant BLT étaient plus remarquables dans les os de type II et III.

Dans la limite de cette étude, l'implant conique auto-taroudant (Straumann® BLT) a montré une meilleure stabilité primaire dans tous les types d'os ce qui promet son indication lors d'une mise en temporisation immédiate, dans une mise en charge immédiate même dans un os de type mou. Les deux méthodes utilisées pour évaluer la stabilité primaire des différentes macro-géométries d'implant, le couple maximal d'insertion et l'analyse de la fréquence de résonance magnétique ont montré une faible corrélation.

D'autres études cliniques sont nécessaires pour mieux évaluer les différentes réponses biologiques à cette amélioration de la stabilité primaire.

Mots-clés: implant dentaire - conception d'implant - couple d'insertion - stabilité primaire - analyse de fréquence de resonance - modèle animal.

IAJD 2917;8(2):49-57.

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Introduction

Immediate implantation and loading are taking considerably their place in the practitioner's planning. The major parameter to achieve a successful immediate loading procedure is an adequate primary stability within strict precautions.

Several studies were conducted to establish clinical guidelines to assure an optimized high insertion torque knowing that the implant macro-design plays an important role. The evidence based data should guide the clinician to enhance the protocol of immediate loading with the adequate implant shape.

The key factor remains the bone density. The distribution of cortical and trabecular bone varies greatly between individual bones, and in various locations within the same bone [1]. In the presence of an adequate cortical bone and a sufficient dense cancellous bone, a better primary stability would lead to an optimized osseo-integration. Even in the presence of very hard cortical bone without any cancellous bone underneath, an implant failure is possible.

Implant design should deal with the diversity of the bone micro-morphology while respecting the physiology. It is incorrect to assume that one implant design and surgical technique will be suitable for all clinical situations. Some implant types and techniques are best used in denser bone, while others perform well in cancellous bone. Understanding how different implant designs and surgical techniques can best be used is a key to success in implant dentistry.

The variation perceived, across the insertion torque values, between conical and cylindrical implants could be explained by the different contact surface area among the thread geometry of these implants. The maximum implant insertion torque depends on the implant geometry, thread form, and implant surface morphology [2].

The aim of this study was to prove the hypothesis that the new Straumann Bone Level Tapered (BLT) implant

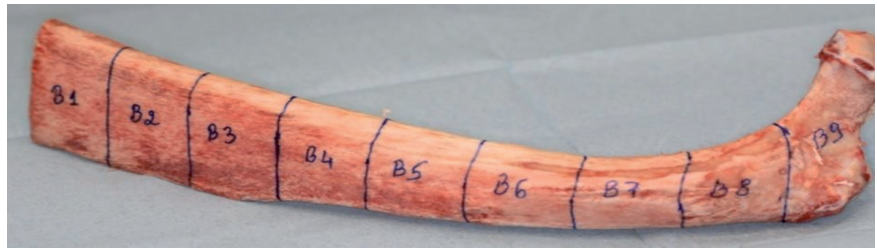


Fig. 1: Beef rib bone labeled.

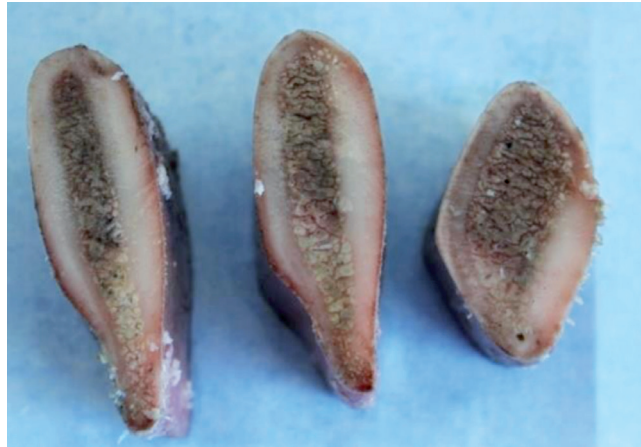


Fig. 2: Blocs cut for the assessment of the bone types.

is more suitable in terms of primary stability in either cancellous bone or fresh extraction socket when compared to Straumann Bone Level (BL) and Straumann Tissue Level (TL).

Materials and methods

Bone specimens and experimental design

Beef ribs bones were retrieved immediately after animals were slaughtered and cleaned from all surrounding tissue until the bone was laid bare. Bone blocks of 30 mm wide and more than 30mm height were obtained by a water-cooled precision diamond saw. Each bloc was labeled in order to keep tracking the implants according to the bone type in which it were inserted (Fig. 1).

Assessment of the bone type

In order to identify the bone type according to Lekholm and Zarb [3] classification, a macroscopic and radiologic analysis were performed

on each bloc and on a sample of 3mm width and in addition according to the feeling of the operator while performing the drillings (Figs. 2, 3 and 4).

Implants

30 Straumann® Standard Plus (SP) Tissue Level (TL) implants (length: 10 mm; diameter: 4.1 mm), 30 Straumann® Bone Level (BL) implants (length: 10 mm; diameter: 4.1 mm) and 30 Straumann® Bone Level Tapered (BLT) implants (length: 10 mm; diameter: 4.1 mm) were used into the study (Fig. 5).

The drilling protocol was performed and the implants were inserted according to the manufacturer. As standard drilling procedure, a 2.2 mm pilot drill was used at first, followed by 2.8, and 3.5 mm twist drills for the preparation of the TL implants, while an adequate profile drill was used for the BL and the BLT implants.

One implant from each of the three models were inserted into the same



Fig. 3: Lateral x-ray.

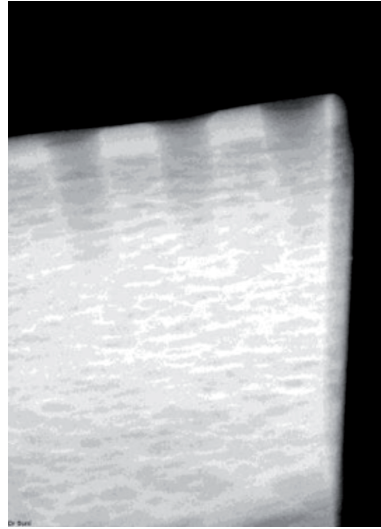


Fig. 4: Frontal x-ray.

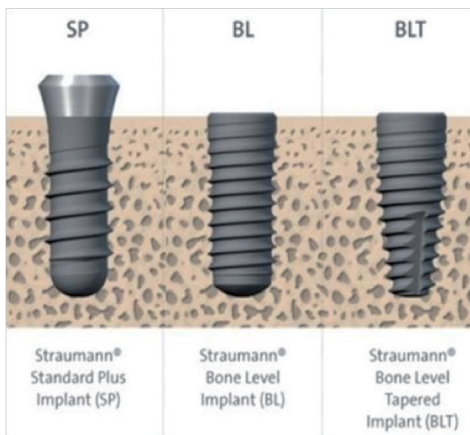


Fig. 5: The three different implant macro-designs.



Fig. 6: The bone rib with the prepared sites showing the variety of bone types.

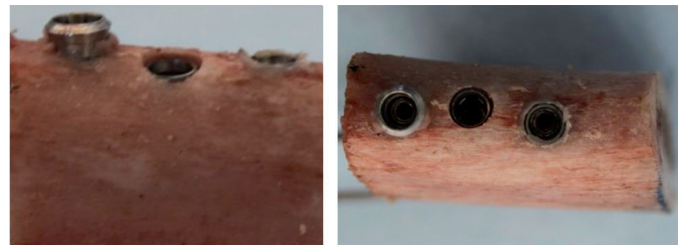


Fig. 7: Implant inserted in the bone blocs with 3mm left in between.

block with a distance in between of 3mm, while 6mm from each side of the block were left to perform a cut of 3mm thickness specimen for the analysis of the bone type (Figs. 6 and 7).

Assessment methods

The maximum insertion torque (IT) was assessed by means of a DTA device (by studio AIP Srl) (Fig. 8). The implant insertion was performed by a digital ratchet linked to a transducer

which is connected to a computer via Bluetooth. A graph shows, on a DTI 2.2 software, the variation of the IT with each rotation, the highest value will be displayed as the maximum insertion torque in Ncm.

Each implant has a relative sheet with all the related data such as the bone block label, the bone type, the implant model and the curve of the insertion torque in Ncm/time.

Each implant was measured, with a "resonance frequency analysis RFA" system leading to the parameter "implant stability quotient" (ISQ) unit using the Osstell™ ISQ device (Osstell, Göteborg, Sweden) (Fig. 9).

The measurements of the Osstell™ were displayed as ISQ from 1 to 100, where 100 signify the highest implant stability.

The SmartPeg is screwed to each implant and tightened to approxima-



Fig. 8: DTA device for the assessment of the insertion torque.



Fig. 9: Osstell™ device for the assessment of the implant stability quotient.

tely 5 Ncm. The transducer probe was aimed at the small magnet on top of the SmartPeg at a distance of 2 to 3 mm and held stable during the pulsing time until the instrument beeped and displayed the ISQ value. If two ISQ values were displayed simultaneously, their mean value was recorded. Measurements were taken twice in two perpendicular directions. The mean of all measurements was rounded to the nearest whole number and was regarded as representative of the ISQ.

Statistical analyses

The statistical analyses were performed using a software program (SPSS for Windows version 17.0, USA). Statistical significance of the differences between the groups was determined by the one-factor factorial analysis of variance (ANOVA) or the t-test. P-values less than 0.05 were considered to be significant.

The Kolmogorov-Smirnov test showed that the ISQ and the IT were normally distributed. Levene test showed that the variance was not significantly different between

groups. Analysis of variance followed by Tukey (HSD) was conducted to compare the mean ISQ and the mean IT among groups according to bone type.

Results

Measurements of the RFA

In type I bone, the mean of the ISQ values was significantly elevated with BLT implant (84.71 ± 1.80), intermediate with BL implant (81.57 ± 2.23) and lower with TL implant (80.33 ± 4.08). The results were statistically significant ($p=0.030$).

In type II bone, the mean of the ISQ values were the highest for BLT implant (85.50 ± 1.20) and equal for the TL implant (83.14 ± 1.46) and the BL implant (83.50 ± 1.93). The results were statistically significant ($p=0.016$).

In type III bone, the mean of the ISQ values was significantly elevated with BLT implant (85.20 ± 2.60), intermediate with TL implant (81.33 ± 4.10) and lower with BL implant (78.73 ± 7.89). The results were statistically significant ($p=0.009$) (Tables 1 and 2).

In all types of bone, the mean of the ISQ values was significantly elevated with BLT implant (85.17 ± 2.086), intermediate with TL implant (81.60 ± 3.582) and lower with BL implant (80.67 ± 6.025). The results were statistically significant ($p=0.0001$) (Tables 3 and 4).

Measurements of the maximum insertion torque

Despite the fact that the insertion torque at the BL implant group (43.08 ± 22.28) was the smallest compared to the BLT implant (52.50 ± 13.60) and TL implant (53.47 ± 16.26), the mean IT was not significantly different between implants for bone type I ($p=0.560$).

The mean IT was significantly elevated with BLT implant (69.09 ± 31.62), intermediate with TL implant (58.26 ± 29.45) and lower with BL implant (30.29 ± 10.35) for bone type II ($p=0.018$).

The mean IT was significantly elevated with BLT implant (58.50 ± 32.74), intermediate with TL implant (40.98 ± 15.21) and lower with BL implant (26.91 ± 10.61) for bone type III ($p=0.003$) (Tables 6 and 7).

In all type of bone, the mean of the maximum insertion torque values was significantly elevated with BLT implant (59.97 ± 28.738), intermediate with TL

ISQ				
Bone Type	TL	BL	BLT	-p-value
Type I	80.33 ± 4.08 ^a N=6	81.57 ± 2.23 ^b N=7	84.71 ± 1.80 ^c N=7	0.030 ANOVA
Type II	83.14 ± 1.46 ^a N=7	83.50 ± 1.93 ^a N=8	85.50 ± 1.20 ^b N=8	0.016 ANOVA
Type III	81.33 ± 4.10 ^b N=12	78.73 ± 7.89 ^a N=15	85.20 ± 2.60 ^c N=15	0.009 ANOVA

Table 1: ISQ on different bone types.

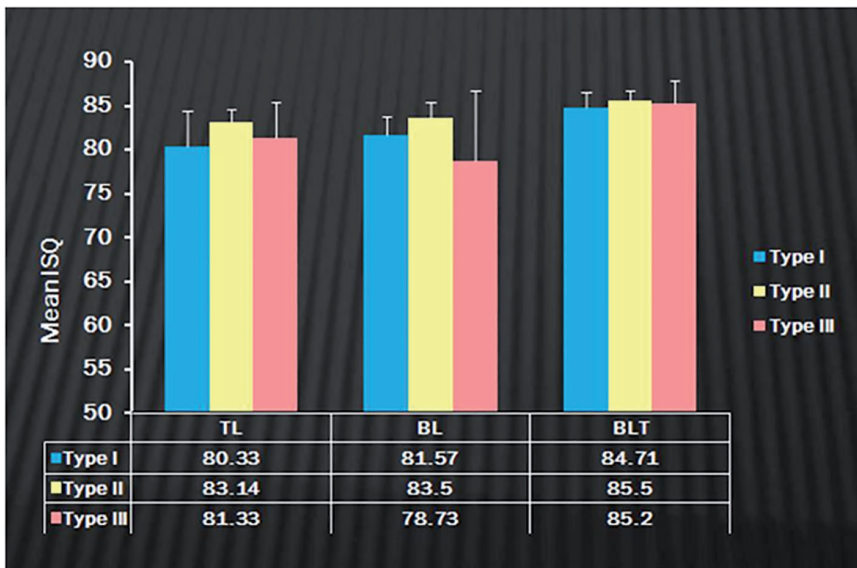


Table 2: ISQ on different bone types.

		N	Mean	Std. Deviation	-p-value
ISQ	TL	25	81.60 ^a	3.582	<0.0001 ANOVA
	BL	30	80.67 ^a	6.025	
	BLT	30	85.17 ^b	2.086	

Table 3: ISQ on all bone types.

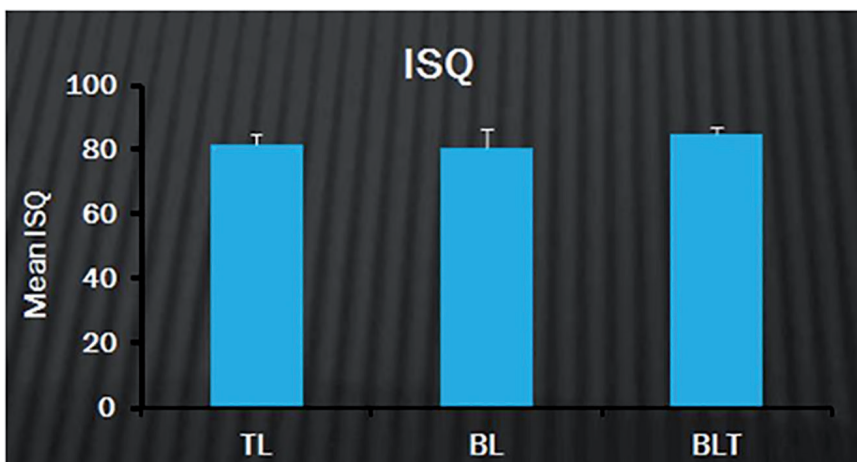


Table 4: ISQ on all bone types.

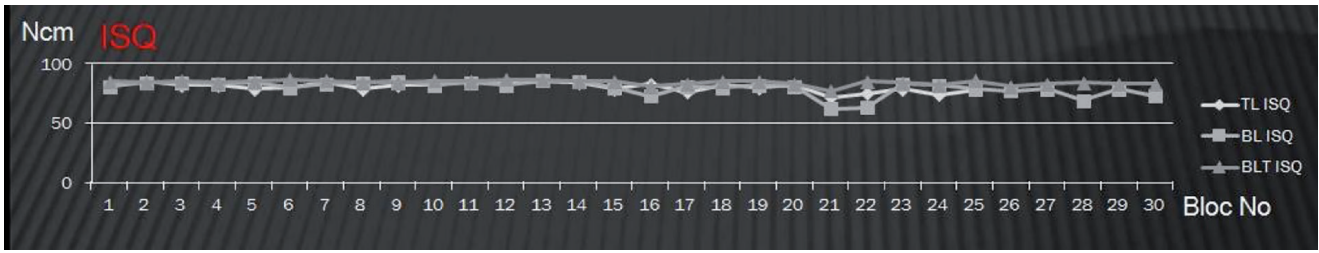


Table 5: ISQ on all bone types.

IT				
Bone Type	TL	BL	BLT	-p-value
Type I	53.47 ± 16.26 N=6	43.08 ± 22.28 N=5	52.50 ± 13.60 N=7	0.560 ANOVA
Type II	58.26 ± 29.45 ^b N=7	30.29 ± 10.35 ^a N=8	69.09 ± 31.62 ^c N=8	0.018 ANOVA
Type III	40.98 ± 15.21 ^b N=12	26.91 ± 10.61 ^a N=13	58.50 ± 32.74 ^c N=14	0.003 ANOVA

Table 6: IT values (Ncm) on different bone types.

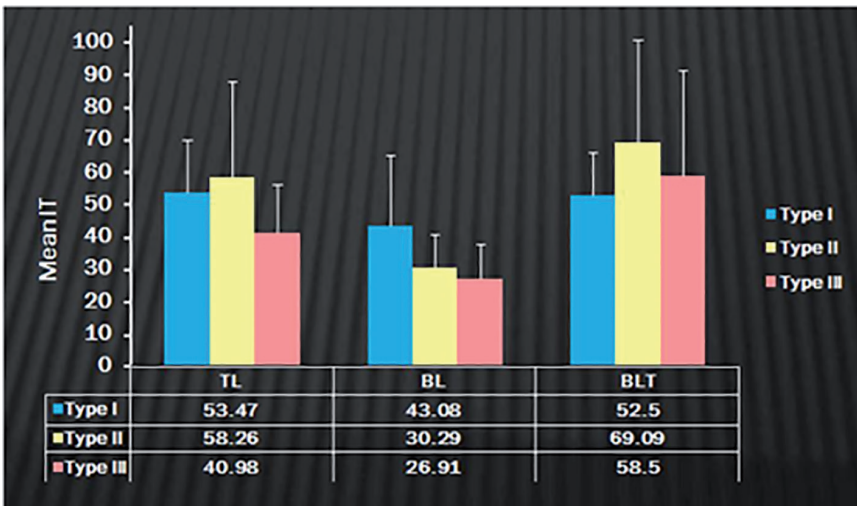


Table 7: IT values (Ncm) on different bone types.

		N	Mean	Std. Deviation	-p-value
IT	TL	25	48.82 ^b	20.977	<0.0001 ANOVA
	BL	26	31.06 ^a	14.194	
	BLT	29	59.97 ^c	28.738	

Table 8: IT values (Ncm) on all bone types.

implant (48.82± 20.977) and lower with BL implant (31.06 ± 14.194). The results were statistically significant with p<0.0001 (Tables 8 and 9).

Discussion

Efficacy of root formed implants over parallel-sided implants placed in compromised bone sites either extraction tooth sockets [4] or type IV bone [5] has been demonstrated.

Alternative designs for a dental implant have been derived using shape optimization techniques based on biological adaptive growth.

The new designs, which include smooth thread shoulder, can significantly reduce the stress concentration at the neck of the implant.

Square thread implants generating the least shear force were found to have greater bone to implant contact and higher reverse torque when compared with V shaped and reverse buttress implants [6].

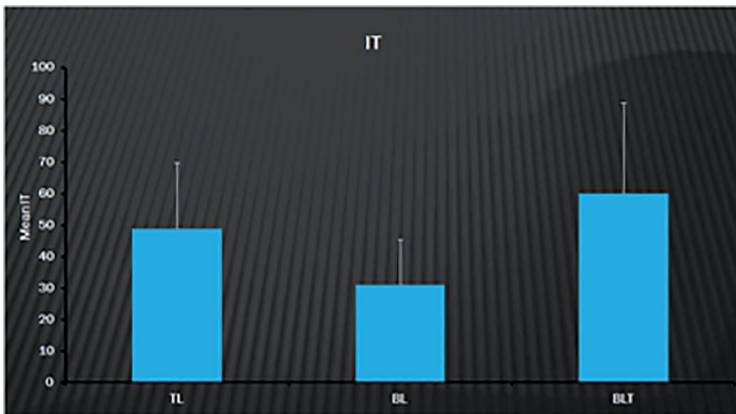


Table 9: IT values (Ncm) on all bone types

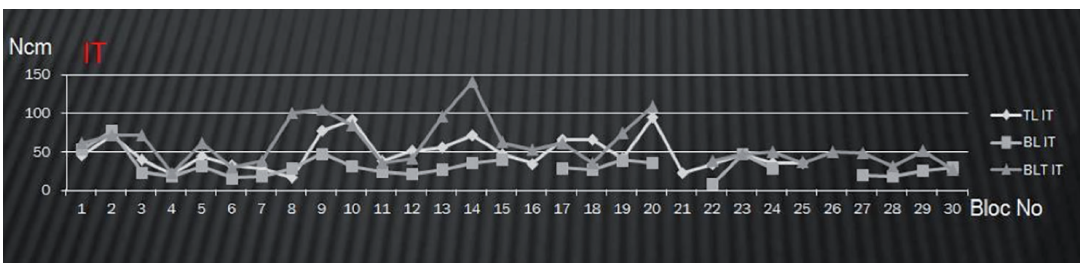


Table 10: IT values (Ncm) on all bone types.

Studies showed that maximum effective stress decreased as screw pitch decreased and implant length increased [7]; Interestingly, some considered 0.8mm as the optimal thread pitch for achieving primary stability [8].

When primary stability is a concern, as in cancellous bone, increasing the implant surface area by using implants with smaller pitch might be beneficial [9]. The most favorable configuration in terms of implant stability appeared to be the single-threaded one [10].

Greater thread depth may be an advantage in areas of softer bone and higher occlusal force because of the higher functional surface area in contact with bone [11].

The use of cutting flutes increases the self-tapping ability of the implant tip [5].

The bowl-fluted design has the least flute space to store the squeezed bone chips, so both insertion torque and bending strength were significantly higher [12].

The conical implant with bowl flutes is the optimal design, with a lower resistance to initial insertion and higher stability, for final instrumentation [12].

It is common practice to use "under dimensioned" drilling in an attempt to increase the primary stability. Although smaller drilling dimensions might increase primary stability, a greater amount of a necrotic "dieback" and interfacial remodeling will take place, potentially decreasing implant stability over time until secondary stability has been achieved through new bone formation between the implant surface and pristine bone [13].

Many papers stated that high implant insertion torque produces compression and distortion on the peri-implant bone. This has been claimed to induce deleterious effects on the local microcirculation, which may lead to bone necrosis and possibly to failure of the implant.

Contradictory results showed by Trisi et al. in 2011 [14]; they stated that high implant insertion torque in

dense cortical bone with an under-drilling protocol does not induce bone necrosis or implant failure, but it does increase the primary stability of implants, which is extremely important in immediate loading protocols.

According to Rea et al. [15], high torque values for the immediate loading procedures were not necessary. Probably, low torque values were sufficient to obtain primary stability and to provide better osseointegration than high torque value.

Presently, various diagnostic analyses have been suggested to define implant stability. Non-destructive methods include percussion test, radiography, cutting or insertion torque test while placing implants, periotest, and resonance frequency analysis (RFA).

Insertion torque values have been used to measure the bone quality in various parts of the jaw during implant placement [5]. Insertion torque alone may be used as an independent stability measurement, but it may also act as a variable, affecting implant

stability. In a different light, insertion torque is a mechanical parameter generally affected by surgical procedure, implant design and bone quality at implant site.

The resonance frequency analysis (RFA) offers a clinical, noninvasive measure of implant and bone stiffness and is presumed to be an indirect measure of osseointegration. Clinically, RFA values vary based on three elements: the stiffness of an implant as a function of the geometry and material composition, the stiffness of the implant-tissue interface which is dependent on the bone-to-implant contact area and the height of the implant above the bone and finally the stiffness of the surrounding tissue which is determined by the non-uniform ratio of cortical and cancellous bone and the inherent bone density.

According to this study and in theory, the existence and the influence of many variables cannot be ruled out, although this study was performed in order to keep it as minimum as possible.

In the consistency of the parameter's uniformity, the current study was conducted in a way to minimize all kind of variables in order to concentrate the parameters around the macro-design of the different implants and giving each task of the protocol to one investigator and by assuring an accuracy of each of the process as during the drilling, the insertion torque assessment, the RFA recording or the data collection.

The fidelity of the identification of the different types of bone was assured by analyzing the sectional cuts, the x-rays and the evaluation felt by the investigator during the drilling.

The goal of using different types of bone was to detect the effectiveness of each macro-design in different situations.

The better are these parameters (ISQ and IT), the higher the primary stability would be expected. This will be one of the fundamental criteria for the development of successful osseointegration.

Following many studies showing the effect of cylindrical and hybrid design on the primary stability, the hybrid self-tapping implant was expected to achieve better values of the two measurements.

On the other hand, because a cylindrical non self-tapping implant features a reduced thread, it was assumed that the implant would achieve the low values of the conducted measurements.

Surprisingly, this TL implant showed a very good insertion torque and a higher primary stability than expected.

The measurements did not show significant better stability of BL implant in any drilling group.

In comparison between bone types, the IT and ISQ values showed higher results with all the implants design on bone type II compared to bone type III blocs while the bone type I blocs did not show statistically significant differences.

The BLT implant showed remarkable values in bone type II and III recorded with the IT device. This disappointment with bone type I blocs is justified by the fact that it is no need to enhance the

macro-design features since the main parameter of the primary stability which is the bone is at his highest stiffness.

However, contradictions have been reported on the clinical use of the RFA methods of measurements. While IT values correlated higher with bone volume fraction (BV/TV) than ISQ values, at 88.1% and 68.9% levels, respectively. IT is more sensitive in terms of revealing biomechanical properties at the bone-implant interface in comparison with ISQ [4].

On the other hand, the results conflict with previous studies that found significant differences between dense and soft bone for RFA [16]. More-over upon Meredith et al. [17], the use of RFA measurement seems to be appropriate for assessing reliable data on implant stability, because

variables during the standardized measurements are kept to a minimum.

Cortical bone seems to influence more remarkably on difference of the RFA values, since it measures the stiffness of the surrounding bone which do not necessarily reflect a high insertion torque or a high primary stability.

In the current study a mild correlation between the two methods of assessment was revealed. Based on these results in an ex vivo model congruent with our expectations, we believe that in

clinical use, this BLT hybrid self-tapping implant could also accomplish a primary stability enough

for stable osseointegration with long-term implant success even in soft bone such as D4 quality and especially in fresh extraction sockets [18].

Conclusion

Within the limitation of the present study, the new implant macro-design tested, the tapered self-tapping implant (Straumann® BLT), showed a better primary stability in all types of bone which promises its indication in immediate placement and loading and in immediate loading in soft bone.

The two methods used to assess the primary stability of the different implant macro-designs, maximum insertion torque and the resonance frequency analysis, showed a weak correlation.

A clinical in vivo study is required to better evaluate the different biological responses to this primary stability enhancement.

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