Primary Stability of a Hybrid Self-Tapping Implant Compared to a Cylindrical Non-Self-Tapping Implant with Respect to Drilling Protocols in an Ex Vivo Model

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ABSTRACT

Background: Modifications of implant design have been intending to improve primary stability. However, little is known about investigation of a hybrid self-tapping implant on primary stability.

Purposes: The aims of this study were to evaluate the primary stability of two hybrid self-tapping implants compared to one cylindrical non-self-tapping implant, and to elucidate the relevance of drilling protocols on primary stability in an ex vivo model.

Materials and Methods: Two types of hybrid self-tapping implants (Straumann® Bone Level implant [BL], Straumann® Tapered Effect implant [TE]) and one type of cylindrical non-self-tapping implant (Straumann® Standard Plus implant [SP]) were investigated in the study. In porcine iliac cancellous bones, 10 implants each were inserted either using standard drilling or under-dimensioned drilling protocol. The evaluation of implant-bone interface stability was carried out by records of maximum insertion torque, the Periotest® (Siemens, Bensheim, Germany), the resonance frequency analysis (RFA), and the push-out test.

Results: In each drilling group, the maximum insertion torque values of BL and TE were significantly higher than SP ($p = .014$ and $p = .047$, respectively). In each group, the Periotest values of TE were significantly lower than SP ($p = .036$ and $p = .033$, respectively). The Periotest values of BL and TE were significantly lower in the group of under-dimensioned drilling than standard drilling ($p = .002$ and $p = .02$, respectively). In the RFA, no statistical significances were found in implants between two groups and between implants in each group. In each group, the push-out values of BL and TE were significantly higher than SP ($p = .006$ and $p = .049$, respectively).

Conclusion: Hybrid self-tapping implants could achieve a high primary stability which predicts them for use in low-density bone. However, there is still a debate to clarify the influence of under-dimensioned drilling on primary stability.

KEY WORDS: animal model, dental implant, maximum insertion torque, Periotest, primary stability, push-out test, resonance frequency analysis

Primary stability, certainly one of the fundamental criteria influencing implant success, depends on especially the geometry of the implants (i.e., length, diameter, shape, and thread) besides the surgical

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technique, volume, and mechanical quality of local bone. The primary stability especially in situations of critical bone quality has been attempted to be optimized by modification of implant design. One suggested approach to enhance primary stability in critical bone quality is to choose a conical implant for insertion to a standard parallel-sided hole. The idea behind this approach is to induce controlled compressive forces in the cortical bone layer, as the implant is inserted. These forces would increase the primary stability of the implant.[1,2] Based on this idea, a new hybrid self-tapping implant has been specifically designed for use in bone of critical quality, which combines the advantages of a conical implant with those of a cylindrical shape. Another approach to enhance primary stability is the adoption of self-tapping thread, removing the need for a separate surgical tap to prepare the implant site, and may improve the implant primary stability and the implant survival rate.[3–5] One proposed use of a self-tapping implant has took place in regions of critical bone quality.[6] The surface area of implant is increased and facilitates to engage marginal and lateral cortical bone to a greater extent. Because self-tapping implants have been widely used and achieved the promising long-term results on evidence,[7–9] a hybrid self-tapping implant is expected also to enable to establish high primary stability. However, the primary stability of a hybrid self-tapping implant has not been clarified.

Under-dimensioned drilling protocol has been proposed in case of estimated low primary stability.[10–12] This is a method to insert the implant into a hole of smaller diameter than usual. This approach has been used in regions of critical bone quality. Compressive forces are set up along the implant-bone interface, which enhance the implant stability. These compressive forces are related to the quality of the bone, the mismatch between the hole and the implant diameter, and are evenly distributed along the length of the implant-bone interface. In contrast to the frequent clinical use of the under-dimensioned drilling with long-term "biological" clinical outcome, almost no data are available on its "mechanical" influence on primary stability.

Several experimental setups and measurement devices have been introduced for the assessment of implant primary stability. Elevated mechanical forces of maximum insertion torque and values of push-out test show the relevance of sufficient primary stability to long-term implant success.[12–15] The extent of matchability of over-elastic forces in push-out test is correlated with the clinical situation.[16] Although these biomechanical measurements can give valuable information on the rigidity of the implant-bone interface, the most critical issue is their invasiveness to the insertion site with no possibility to correlate with intra-individual long-term success. Therefore, noninvasive measurement setups have also been introduced for the diagnosis of immediate, as well as for the prediction of long-term implant stability.[17–19] Periotest® (Siemens, Bensheim, Germany) is designed as an electronic instrument to measure tooth mobility and has also been introduced to test implant stability.[20–22] Resonance frequency analysis (RFA) has been reported to utilize measurement of resonance frequency of a small transducer attached to an implant fixture or abutment.[23–26] Although individual measurements have been investigated extensively in experimental and clinical studies, little is known about the investigation of three different Straumann® implant systems simultaneously by these four measurements.

The first aim of this study was to investigate the primary stability of two hybrid self-tapping implants inserted in cancellous bone in comparison with that of a cylindrical non-self-tapping implant. The second aim was to assess the relevance of an under-dimensioned drilling protocol to primary stability in comparison to a standard drilling protocol.

MATERIALS AND METHODS

Specimens

Bone blocks (approximately $30 \times 70 \times 10$ mm) were obtained by a water-cooled precision diamond saw (EXAKT® Sawing-Grinding System; EXAKT, Norderstedt, Germany). Out of porcine iliac crest specimen, 10 fresh blocks were randomly chosen for this study. After the removal of adjacent soft tissue, the surfaces of the bone blocks were thoroughly cleaned by water rinsing. Every block was checked macroscopically for irregularities, and the thickness of 10 mm was verified using precision calipers. All blocks obtained were immediately used for further investigations.

Implant Insertion and Recording Maximum Insertion Torque

Ten Straumann® Bone Level (BL) implants (length: 10 mm; diameter: 4.1 mm), 10 Straumann® Tapered Effect (TE) implants (length: 10 mm; diameter: 4.1 mm) and 10 Straumann® Standard Plus (SP)

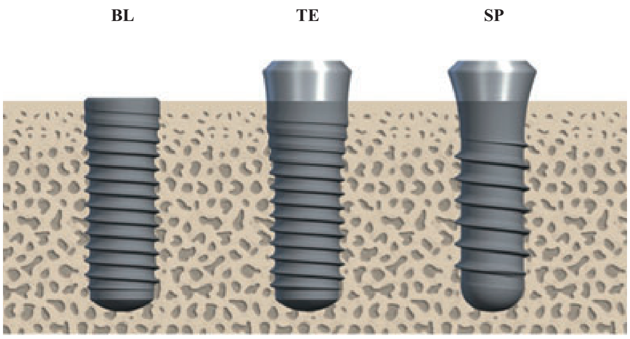

Figure 1 Schematic images of three Straumann implants. BL, Bone Level implant; TE, Tapered Effect implant; SP, Standard Plus implant.

implants (length: 10 mm; diameter: 4.1 mm) were introduced in this study (Figure 1). According to the insertion protocol of the manufacturer, five implants of each type were inserted by the standard drilling protocol into five blocks, while the other five implants were inserted by under-dimensioned drilling into the other five blocks (Figure 2). In the procedure of standard drilling, a 2.3 mm pilot drill was used at first, followed by 2.2, 2.8, and 3.5 mm twist drills for preparation. The drilling procedure penetrated through the 10-mm-thick blocks. In the procedure of under-dimensioned drilling, the last pilot drill was stopped at a depth of 8 mm. During the implant insertion, the maximum insertion torque was recorded by a drilling system (Osseocare™ DEC 601, Nobel Biocare, Göteborg, Sweden).

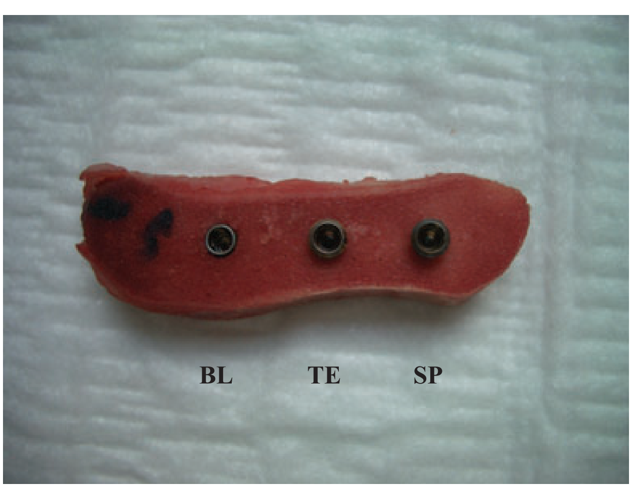

Figure 2 Three different implants inserted in one block of porcine iliac bone. According to the drilling protocols of the manufacturer, each five implants of Bone Level implant, Tapered Effect implant, and Standard Plus implant were inserted by the standard drilling protocol into the five blocks of porcine iliac bone, while the other five implants were inserted by under-dimensioned drilling into the other five blocks. Ten blocks were obtained for the measurements.

Periotest, RFA, and Push-Out Test

Damping capacity assessment (Periotest) was performed. After the mounting of abutments on the inserted implants, the guidelines for the Periotest measurements were followed as given by the manufacturer. In the handpiece, a rod flies at an almost constant speed until it hits the implant. The handpiece is held at a distance of 4 mm from the abutment surface. After the impact takes place, the implant is deflected and the rod is braked. Sixteen defined reproducible impacts with the implant are obtained within a period of 4 seconds. The percussion of the implant with the rod was performed perpendicularly to the longitudinal axis of the implant at the coronal platform of the abutment surface.[27–29] The measurements were performed in triplicate.

Bone resonance frequencies were measured with the Osstell™ resonance frequency analyzer model 6.0 (Integration Diagnostics, Göteborg, Sweden). The placed abutments were removed, and the transducers were mounted on the implants. It was tightened with a screw by hand. The RFA transducer was designed as an offset cantilever beam with an attached piezoceramic element. Exciting these elements vibrates the beam. The excitation signal is a sine wave typically varying in frequency v from 5 to 15 Hz with a peak amplitude of 1 V.[29] The frequency response of the system was measured. The measurements were performed in triplicate.

After the measurements of Periotest and RFA values, the blocks with the implants were transferred to a Zwick UPM 1425 material testing device (Zwick, Atlanta, GA, USA) to measure the axial push-out forces (Figure 3). Taking into account the alignment between load direction and implant, the force was applied to the apical end of the implant in an axial direction, imitating a continuous pull-out mode (0.5 mm/min). The shear strength required to detach the implant from bone was measured. To avoid a possible influence of differences between the blocks, a "normalized push-out force value" was calculated for each group by dividing the individual push-out force value by the mean of the respective bone sample.

Statistics

The statistical analyses were performed using SPSS version 16.0 software (SPSS, Chicago, IL, USA). The

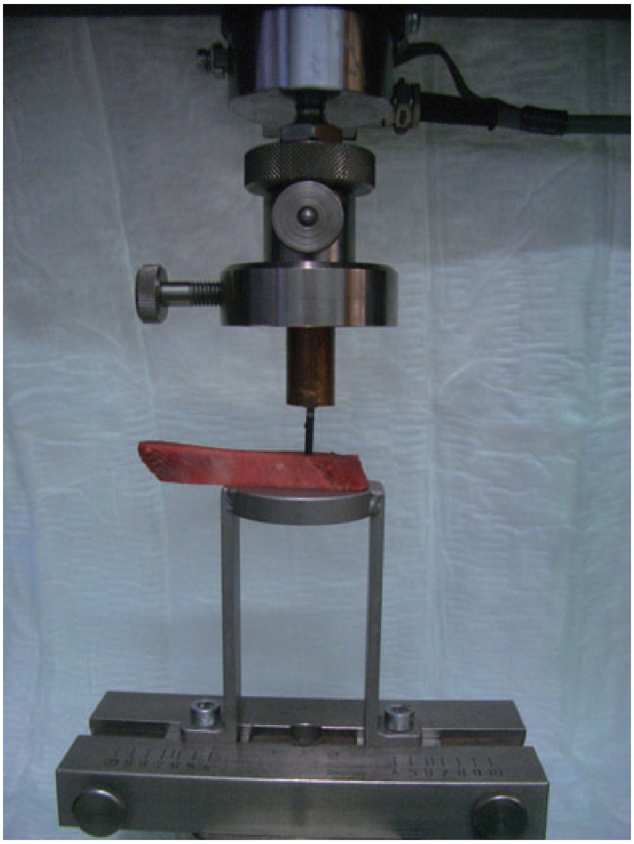

Figure 3 Zwick UPM 1425 material testing device for measurement of the axial push-out forces.

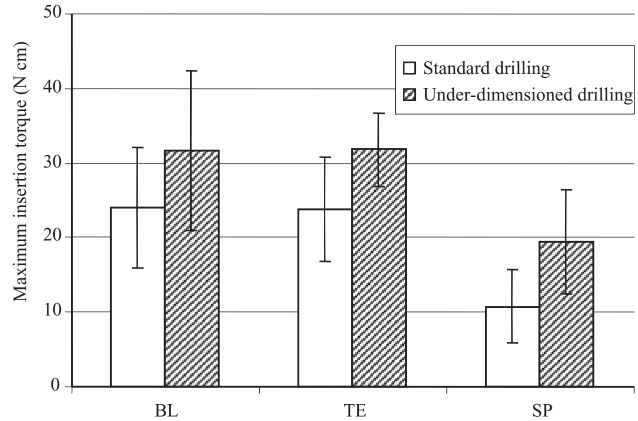

Figure 4 Mean values of maximum insertion torque of implants in the group of standard drilling and under-dimensioned drilling.

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 of less than .05 were considered to be significant.

RESULTS

Measurements of Maximum Insertion Torque

In the group of standard drilling, the mean values of the maximum insertion torque were 24.0 ± 8.1 Ncm for the BL implant and 23.8 ± 7.0 Ncm for the TE implant, compared to 10.8 ± 5.0 Ncm for the SP implant. In the group of under-dimensioned drilling, the values were 31.6 ± 10.7 Ncm for the BL implant and 31.8 ± 5.0 Ncm for the TE implant, compared to 19.4 ± 7.0 Ncm for the SP implant. For the group of standard drilling, the values of the BL implant and the TE implant were significantly higher than that of the SP implant ($p = .014$, one-factor factorial ANOVA). For the group of under-dimensioned drilling, the values of the BL implant and the TE implant were significantly higher than that of the SP implant ($p = .047$, one-factor factorial ANOVA). In the group of under-dimensioned drilling, the values of all three implants were higher than those in the group of standard drilling, although there were no significant differences between the groups (BL implant: $p = .879$; TE implant: $p = .964$; SP implant: $p = .972$, *t*-test). The value of BL implant was nearly similar to that of the TE implant in both groups (Figure 4).

Measurements of Periotest

In the group of standard drilling, the mean values were 15.0 ± 9.6 for the BL implant, 5.3 ± 5.3 for the TE implant, and 8.7 ± 8.5 for the SP implant. In the group of under-dimensioned drilling, the values were 4.3 ± 4.0 for the BL implant, 1.0 ± 3.1 for the TE implant, and 5.3 ± 3.7 for the SP implant. For the group of standard drilling, the values of the TE implant were significantly lower than that of the BL implant or the SP implant ($p = .036$, one-factor factorial ANOVA). For the group of under-dimensioned drilling, the values of the TE implant were significantly lower than that of the BL implant or the SP implant ($p = .033$, one-factor factorial ANOVA). The values of the BL implant and the TE implant were significantly lower in the group of under-dimensioned drilling than those in the group of standard drilling ($p = .002$ and $p = .02$, respectively; *t*-test). In the group of standard drilling, the value of the BL implant was higher than others (Figure 5).

Measurements of RFA

In the group of standard drilling, the mean values were 64.0 ± 7.2 for the BL implant, 62.9 ± 4.5 for the TE implant, and 57.3 ± 7.4 for the SP implant. In the group

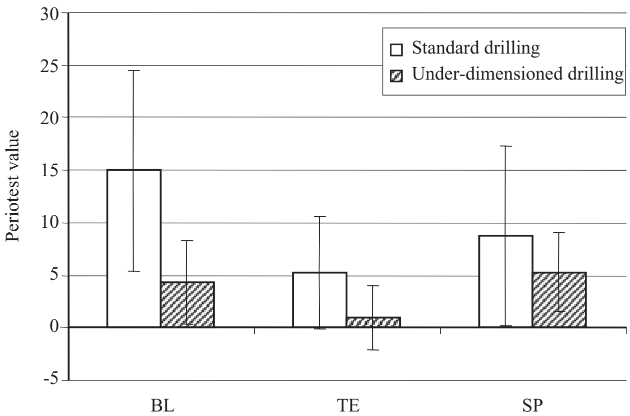

Figure 5 Mean values of Periotest of implants in the group of standard drilling and under-dimensioned drilling.

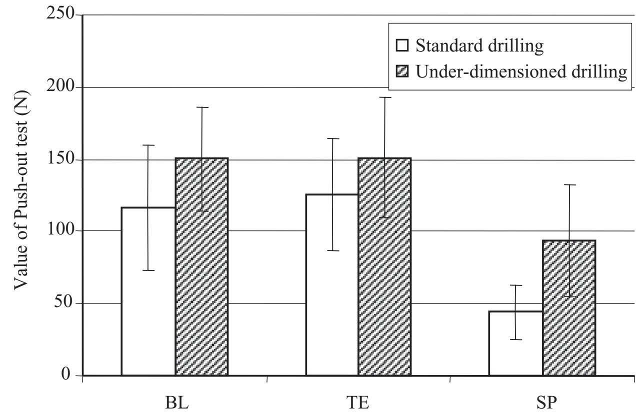

Figure 7 Mean values of push-out test of implants in the group of standard drilling and under-dimensioned drilling.

of under-dimensioned drilling, the values were 60.3 ± 9.0 for the BL implant, 66.1 ± 4.1 for the TE implant, and 62.1 ± 6.6 for the SP implant. All values of the three implants were not clearly different in both groups (Figure 6). For the group of standard drilling, any statistically significances were not found between the implants ($p = .065$, one-factor factorial ANOVA). For the group of under-dimensioned drilling, any statistically significances were not found between the implants in each group of standard drilling or under-dimensioned drilling ($p = .126$, one-factor factorial ANOVA). For individual implants, there were no significant differences between the groups (BL implant: $p = .099$; TE implant: $p = .943$; SP implant: $p = .928$; *t*-test).

Measurements of Push-Out Test

In the group of standard drilling, the mean values were 116.6 ± 43.0 N for the BL implant and 125.8 ± 39.1 N for the TE implant, compared to 44.0 ± 19.1 N for the SP implant. In the group of under-dimensioned drilling, the values were 150.4 ± 35.9 N for the BL implant and 151.2 ± 41.7 N for the TE implant, compared to 93.2 ± 38.8 N for the SP implant. In each group, the values of the BL implant and the TE implant were significantly higher than that of the SP implant ($p = .006$ and $p = .049$, respectively; one-factor factorial ANOVA). By trend, the values of the three implants were higher in the group of under-dimensioned drilling than those in the group of standard drilling, although there were no significant differences between the groups (BL implant: $p = .892$; TE implant: $p = .825$; SP implant: $p = .983$; *t*-test). The values of the BL implant were nearly similar to that of the TE implant in both groups (Figure 7).

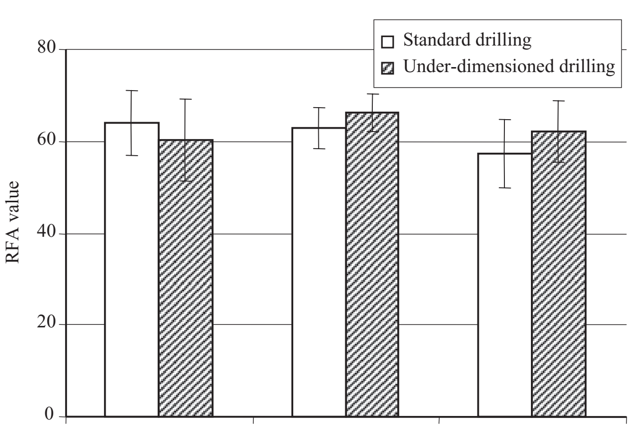

Figure 6 Mean values of resonance frequency analysis of implants in the group of standard drilling and under-dimensioned drilling.

DISCUSSION

To our knowledge, this is the first report of the primary stability of hybrid self-tapping implants using four different ex vivo measurements. If the group of standard drilling and that of under-dimensioned drilling are defined as separately, the surgical techniques, drilling protocols, and utilized bone quality were kept constant in this study. Therefore, most of the differences between the stability values of the investigated implants are likely to be related to the characteristics of the implant design. In this study, measurements of the maximum insertion torque, the two widespread noninvasive techniques (i.e., Periotest and RFA), and finally push-out test were carried out in order to evaluate the primary stabilities of three different Straumann implants in cancellous bone of porcine iliac crest. The better these parameters, the higher the primary stability would be expected, which is still one of the fundamental criteria for the development of successful osseointegration.[1,30–32] Using maximum insertion torque and push-out test, the results revealed a significantly higher stability of hybrid self-tapping implants in both drilling groups, compared to that of a cylindrical non-self-tapping implant. Primary stability is influenced by the geometry of the implant.[29] A hybrid self-tapping implant has been designed, combining the advantages of a cylindrical implant with those of a conical shape, as well as the self-tapping thread. Because seminal studies show the advantage of conical implant and self-tapping thread for the primary stability,[1,2,7–9] a hybrid self-tapping implant could be expected to achieve better values of the four measurements for primary stability. On the other hand, because a cylindrical non-self-tapping implant features a reduced thread, it was assumed that the implant could achieve the low values of the conducted measurements. Therefore, based on these results in an ex vivo model congruent with our expectation, we believe that in clinical use, a hybrid self-tapping implant could also accomplish the proper primary stability enough for stable osseointegration with long-term implant success even in soft bone such as D4 quality. In the comparison between the two different drilling groups, as could be expected, the measurements of maximum insertion torque and push-out test in the group of under-dimensioned drilling showed the higher values for all three implants than those in the group of standard drilling, although the clearly statistical significances were not found between the groups. The elevation of values can be attributed to the difference of drilling on implant bed preparation, because other conditions were quite the same in both drilling groups. Thus, this rises the possibility that the under-dimensioned drilling increases the primary stability of implants in cancellous bone.

The measurements of Periotest did not show the significantly better stability of BL implant in any drilling group. In the well-standardized conditions of this experimental setup, the Periotest values seemed to be as effective in assessing this special parameter. However, objections have been reported on the clinical use of the Periotest method.[33–36] Although a good inter-examiner reliability has been reported, a number of variables have been reported to have an influence on the Periotest values. They can be increased or decreased by changes in the implant diameters, vertical measuring point on the implant abutment, handpiece angulation, and horizontal distance of the handpiece from the implant. The existence and the influence of such variables cannot be ruled out, although this study was performed by one investigator and they were kept to a minimum as possible. Therefore, the differences between the group of standard drilling and that of under-dimensioned drilling concerning implant stability might become less pronounced. The significant decreased values for hybrid self-tapping implants were found in the group of under-dimensioned drilling, compared to those of standard drilling. Therefore, only using the measurement of Periotest, the benefit of under-dimensioned drilling can be markedly documented, to enhance primary stability. No statistically significant differences were found between the group of standard drilling and that of under-dimensioned drilling using the other three measuring methods.

The RFA did not show any significant differences of hybrid self-tapping implants or cylindrical non-self-tapping implant for both drilling groups. These results are compatible with the previous studies in which a poor association of RFA was found between conical implant and cylindric screw-type implants.[12,37,38] On the other hand, the results conflict with previous studies that found significant differences between dense and soft bone for RFA.[39] 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.[29] Exposed implant height above the marginal bone and bone quality has been reported to be particularly correlated to primary stability of the implant.[17,37,40,41] The length of the implant with the transducer was kept constant in this study. One explanation may be that all implants were inserted in cancellous bone of porcine iliac crest specimen, but cortical bone seems to influence more remarkably on difference of RFA values.[38,42,43] Because of the high density, cortical bone has a higher elastic modulus than cancellous bone. If implant fixation is a mechanical interlock caused by surface irregularities and geometry variations of the implant, cortical bone is probably harder to deform because the protruding parts of the implant will be restricted in the mineralized interface bone.[44] Combined with the possible compressive character mentioned earlier, a positive hypothesis for under-dimensioned drilling can be made for further studies to investigate the effects on primary stability of BL implant inserted by under-dimensioned drilling protocol into cortical bone by these four measurements.

CONCLUSION

In this ex vivo model, hybrid self-tapping implants could achieve a promising primary stability suggesting sufficiently further osseointegration. Measurements of maximum insertion torque and push-out test demonstrate adequately the enhancement of primary stability. The measurement of Periotest reveals the usefulness of under-dimensioned drilling for enhancement of primary stability in cancellous bone. Clinical data have to show if a significant benefit of under-dimensioned drilling on implant success can be achieved.

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CONFLICT OF INTEREST

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