CLINICAL ORAL IMPLANTS RESEARCH

Short Communication

Are insertion torque and early osseointegration proportional? A histologic evaluation

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Abstract

Objectives: The objective of this histologic study was to determine the effect of three drilling protocols (oversized, intermediate, and undersized) on biologic responses to a single implant type at early healing periods (2 weeks *in vivo*) in a beagle dog model.

Materials and methods: Ten beagle dogs were acquired and subjected to surgeries in the tibia 2 weeks before euthanasia. During surgery, each dog received three Unitite implants, 4 mm in diameter by 10 mm in length, in bone sites drilled to 3.5, 3.75, and 4.0 mm in final diameter. The insertion torque was recorded during surgery, and bone-to-implant contact (BIC), and bone area fraction occupied (BAFO) measured from the histology. Each outcome measure was compared between treatment conditions with the Wilcoxon signed-rank test. Bonferroni-corrected statistical significance was set to 95%.

Results: Insertion torque increased as an inverse function of drilling diameter, as indicated by significant differences in torque levels between each pair of conditions ($P = 0.005$). BIC and BAFO levels were highest and statistically similar in the recommended and undersized conditions and significantly reduced in the oversized condition ($P < 0.01$).

Conclusions: Reduced drilling dimensions resulted in increased insertion torque (primary stability). While BIC and BAFO were maximized when drilling the recommended diameter hole, only the oversized hole resulted in evidence of statistically reduced integration.

Obtaining primary stability after implant placement has been regarded as one of the essential factors for the achievement of secondary stability (osseointegration). Insufficient primary stability levels result in increased micromotion, and a magnitude of micromotion of more than 50–150 μm results in subsequent soft tissue encapsulation of the implant (Szmukler-Moncler et al. 1998).

Theoretically, it has been suggested that the bone is an elastic material before its yielding point, which is an indication that a certain level of strain can be tolerated due to a relaxation effect (Jimbo et al. 2013a,b). On the other hand, once the strain in the bone exceeds the yielding point, numerous microfractures along with blood capillary overcompression provoke ischemic necrosis or in the worst scenario, complete bone fracture (Bashutski et al. 2009). It has been acknowledged that ischemia and/or pressure necrosis have an impact on rapid bone resorption (Kalebo et al. 1986); however, reports suggest that the living bone can tolerate certain levels of overcompression (beyond the yield strain) without provoking negative bone responses (Perren et al. 1969; Halldin et al. 2011). Based on this theoretical and experimental knowledge and the emerging clinical demands for immediate implant loading, a number of different implant macrodesigns challenge bone mechanical strains limit to obtain maximum primary stability (Irinakis & Wiebe 2009; Trisi et al. 2009; Chowdhary et al. 2013). However, the definite level that would provoke rapid bone loss is uncertain and deserves further investigation.

The objective of this histologic study was to determine whether the alteration of drilling protocols (oversized, intermediate, undersized drilling) present different biologic responses at early healing periods of 2 weeks *in vivo* in a beagle dog model. It was hypothesized that the higher levels of insertion torque would present lower micromotion, and thus, the degree of osseointegration would be proportional to the insertion torque values.

Material and methods

Thirty Unitite (SIN, São Paulo, SP, Brazil) implants of 4.1 mm diameter, 10 mm length, and dual acid-etched surface, previously characterized (Marin et al. 2012), were utilized in this study. Its macrogeometry has been previously presented (Bonfante et al. 2011). Three drilling/instrumentation techniques were used: (i) drilling to a final diameter of 3.75 mm, as recommended by the manufacturer (regular condition); (ii) drilling to a final diameter of 3.5 mm, which is smaller than recommended by the manufacturer (tight condition), and; (iii) drilling to a final diameter of 4.0 mm, being larger than recommended by the manufacturer (overdrilling condition). For the laboratory *in vivo* model, ten adult male beagle dogs with approximately 1.5 years of age were acquired following the approval of the Ethics Committee for Animal Research at Universidade Federal de Uberlandia, Brazil (protocol/approval number CEUA-UFU 082/12).

Prior to general anesthesia, IM atropine sulfate (0.044 mg/kg) and xilazyne chlorate (8 mg/kg) were administered. A 15 mg/kg ketamine chlorate dose was then utilized to achieve general anesthesia. The surgical site was the proximal tibia. Following hair shaving, skin exposure, and antiseptic cleaning with iodine solution at the surgical and surrounding area, a 5-cm-length incision to access the periosteum was performed and a flap reflected for bone exposure. Three implants were placed along the left tibia from proximal to distal in an alternated drilling technique distribution, being interchanged in every tibia to minimize bias from different implantation sites (sites 1 to 3 from proximal to distal). The implants remained *in vivo* for a period of 2 weeks and were allocated in sites 1 to 3 in an equal distribution. This approach resulted in balanced surgical procedures that allowed the comparison of the same number of implants placed under the different drilling technique per time *in vivo*, surgical site (1 through 3), and animal. The implants were placed at distances of 1 cm from each other along the central region of the bone. The implants were inserted in the drilled sites, and the maximum insertion torque was recorded with a portable digital torquemeter (Tohnichi, Tokyo, Japan) with a 200 Ncm load cell for each implant placed.

Following placement, each implant received its proprietary cover screw to avoid tissue overgrowth. The soft tissue was sutured in layers following standard procedures, where the periosteum was sutured with vicryl 4–0 (Ethicon Johnson, Miami, FL, USA) and the skin with 4–0 nylon (Ethicon Johnson). Postoperative antibiotic and anti-inflammatory medication included a single dose of benzyl penicillin benzatine (20,000 UI/kg) IM and ketoprofen 1% (1 ml/5 kg). The animals were euthanized by anesthesia overdose, and the limbs were retrieved by sharp dissection. The soft tissue was removed by surgical blades, and initial clinical evaluation was performed to determine implant stability. If an implant was clinically unstable, it was excluded from the study.

The bones containing the implants were reduced to blocks, and thin sections were prepared as described elsewhere (Marin et al. 2012). The sections were then toluidine blue stained and referred to optical microscopy for bone-to-implant contact (BIC) evaluation at 50X-200X magnification, and bone area fraction occupied (BAFO) between threads in trabecular bone regions at 100X magnification (Leica DM2500M; Leica Microsystems GmbH, Wetzlar, Germany) by means of computer software (Leica Application Suite; Leica Microsystems GmbH) (Coelho et al. 2012).

Statistical analysis

Prior to analysis, the distribution of all outcomes was examined for each drilling condition. These results are shown in box plots. The effect of drilling diameter on all outcomes was determined with the Wilcoxon signed-rank test. Conceptually similar to a paired *t*-test, the Wilcoxon test avoids normality assumptions and is more appropriate to this relatively small sample than the *t*-test, while remaining sensitive to dependencies introduced by this within-subject design. Statistical significance was set experiment-wise at 5% ($\alpha = 0.05$), after Bonferroni correction for three comparisons within each outcome; that is, the per comparison α was 0.0167.

Results

No complication was detected throughout the study, and no implant was excluded due to clinical instability. Qualitative evaluation of the biologic response showed intimate contact between cortical and trabecular bone for all conditions at 2 weeks *in vivo*, including regions which were in close proximity or substantially away from the osteotomy walls (Fig. 2). The thin sections presented an appositional bone healing mode at regions where intimate contact existed between implant surfaces and bone immediately after placement (Fig. 2a–c). These regions comprised the vast majority of the perimeter of implants placed into 3.5-mm (tight) sites (Fig. 2a), and the outer aspects of the threads of implants placed into the 3.75 (recommended, Fig. 2b) and 4.0-mm (overdrilling, Fig. 2c) drilling sites. In contrast to implants placed into 3.5-mm (tight) sites that presented substantial bone remodeling along the perimeter of the implant/bone contact (Fig. 2a), the initial healing pattern observed in proximity of the implant inner thread diameter and drilled walls (forming healing chambers) when implants were placed into the 3.75-mm and 4.0-mm drilling sites followed an intramembranous-type healing mode (Fig. 2b,c).

Fig. 1 shows that insertion torque increased as an inverse function of drilling diameter from 4.0 mm (overdrilling), to 3.75 mm (recommended), to 3.5 mm (tight). A significant difference in torque levels was observed between all conditions (Table 1).

At the 2-week time point, the implants placed into 3.5-mm (tight) drilling sites presented extensive necrotic bone/remodeling areas with bone resorption areas in the region between the implant threads (Fig. 2a). The 3.75 mm (recommended) and 4.0 mm (overdrilling) presented spots of necrotic bone/remodeling areas with bone resorption and a chamber filled with osteogenic tissue between the implant inner diameter and the drilled wall along with newly formed woven bone (Fig. 2b,c). Primary engagement by the threads outer region without extensive necrotic bone areas was observed (Fig. 2a–c).

Fig. 3 shows the highest BIC values for the 3.75 mm (recommended) drilling condition. This level was significantly greater than BIC in the 4.0 mm condition, but statistically similar to levels in the 3.5 mm condition (Table 1). The overdrilling condition was also statistically greater than the 3.5 mm condition. Fig. 4 also shows the highest BAFO levels in the 3.75 mm (recommended) drilling condition; however, only the overdrilling condition presented significantly lower BAFO values relative to the recommended condition after Bonferroni correction (Table 1).

Discussion

Although the insertion torque testing showed that the oversized drilling condition presenting

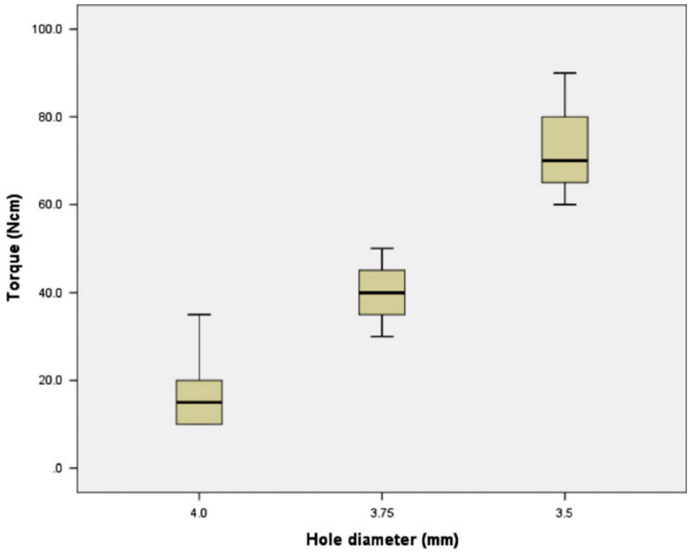

Fig. 1. Insertion torque increase as an inverse function of drilling diameter from 4.0 to 3.75 to 3.5 mm (tight). Note the significant difference in torque levels between all conditions.

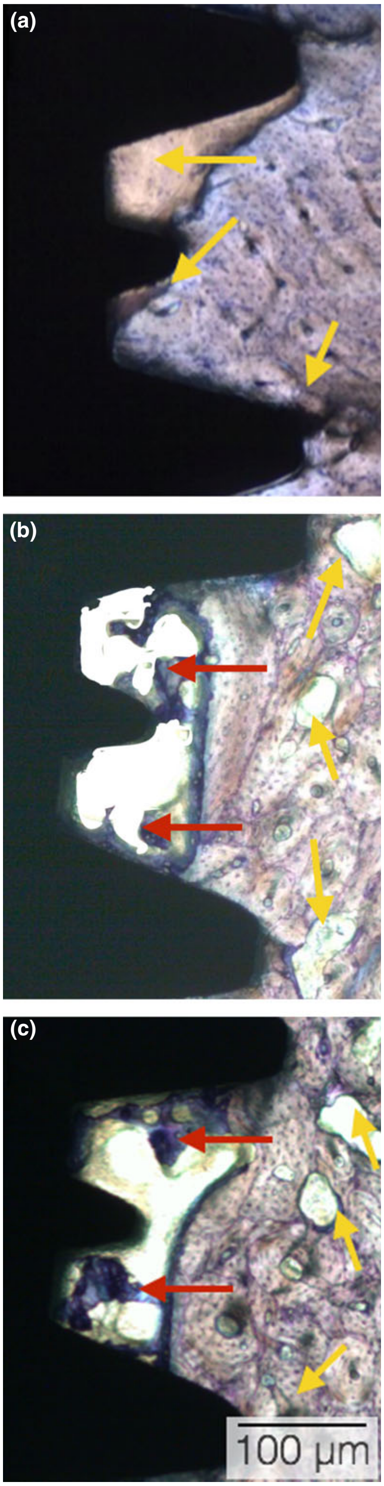

Fig. 2. Optical micrographs at 2 weeks *in vivo* for the (a) tight instrumentation, (b) recommended instrumentation, and (c) overdrilling instrumentation. The red arrows depict newly formed bone at the healing chambers regions; yellow arrows depict bone remodeling regions.

Table 1. **Mean (SD) and Median Torque, bone-to-implant contact (BIC), bone area fraction occupied (BAFO) for each instrumentation condition, and the result of the Wilcoxon test of pair-wise differences**

Measure	Condition	Mean (SD)	Median	Wilcoxon result
Torque	4.0	17.0 (7.9)	15.0	Vs. TI, P = 0.005
	3.75	40.0 (6.2)	40.0	Vs. OV, P = 0.005
	3.5	73.0 (10.9)	70.0	Vs. RE, P = 0.005
BIC	4.0	17.5 (6.6)	15.1	Vs. TI, P = 0.009
	3.75	36.3 (11.3)	36.6	Vs. OV, P = 0.005
	3.5	30.3 (10.1)	33.7	Vs. RE, P = 0.24
BAFO	4.0	24.0 (9.4)	21.7	Vs. TI, P = 0.02
	3.75	50.3 (14.1)	51.3	Vs. OV, P = 0.005
	3.5	37.1 (11.1)	36.5	Vs. RE, P = 0.05

the lowest values and the undersized drilling presenting the highest, the histologic micrographs clearly presented that new bone formation was most active in proximity of the implant surface for the implants placed with the intermediate size drilling protocol. Both the BIC and the BAFO showed that the intermediate drilling protocol presented the highest histomorphometric values, although statistically similar to the lower values of undersized drilling, suggesting that the alteration from primary to biologic stability was most active for this condition. The reasons for the unproportional biologic response could be that the insertion torque values may not necessarily result in the best combination of primary stability and bone compression levels for this specific implant design. It has been suggested that depending on the implant system, the low levels of rotational stability at the time of implant insertion may not be an indication for high micromotion (Norton 2011, 2013; Freitas et al. 2012). Thus, concerning the implant design utilized in the current study, the application of intermediate drilling likely provided low micromotion degrees due to engagement of the outer thread parts along with low degrees of bone compression resulting in higher amounts of bone formation.

Furthermore, in comparison with the overdrilling condition, the space provided between the implant and the bone for the intermediate drilling condition resulted in a better scenario for intramembranous-like bone formation and resulted in direct agreement with Marin et al. (Marin et al. 2010) who showed that healing chamber size does play a role on bone healing kinetics at early implantation times. This is also in accordance with several reports where it was suggested that a closed chamber between the implant and the bone allowed blood fill and subsequent new bone formation compared with press-fit conditions where little to no space was allowed between implant and bone immediately after placement (Berglundh et al. 2003; Coelho et al. 2010). The authors suggested that the bone in direct contact to the implant initially for the press-fit

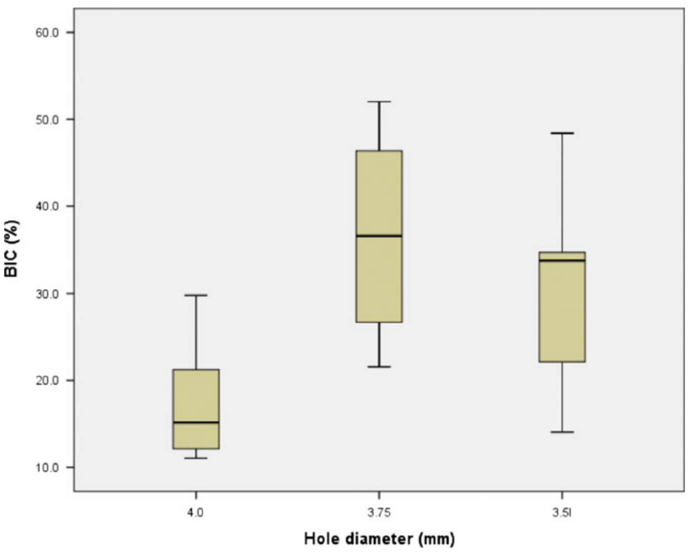

Fig. 3. The highest bone-to-implant contact values was observed for the 3.75 mm drilling condition. This level was significantly greater than the 4.0 mm condition, but statistically similar to levels in the 3.5 mm condition. The overdrilling condition was also statistically greater than the 3.5 mm condition.

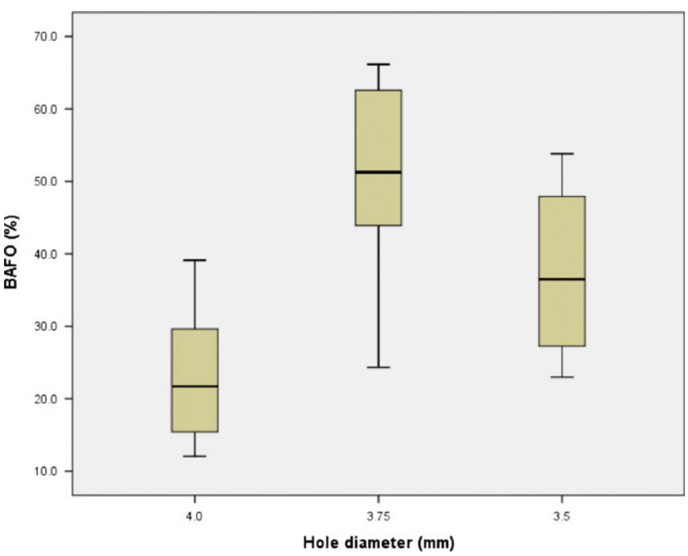

Fig. 4. The highest bone area fraction occupied (BAFO) levels were observed in the 3.75 mm drilling condition. Note that only the overdrilling condition presented significantly lower BAFO values relative to the recommended condition.

condition seemed to first undergo bone resorption before new bone was formed. Therefore, the biologic process observed for the undersized drilling in the current study at the time of 2 weeks *in vivo* might have been an ongoing bone remodeling procedure. The 2-week time observation was selected because initial new woven bone formation has shown to be evident for this animal model and surgical site (Giro et al. 2013; Witek et al. 2013).

The oversized drilling condition presented the lowest histomorphometric values, and this may be due to the gap generated between the implant to the osteotomy wall, which was evident in all histologic sections for that condition. The distance between the implant and the bone was wider than the intermediate condition, which may require more time for bone regeneration at these large healing chambers. Furthermore, the low levels of primary stability may not have been the optimal basis for bone formation. This has been indicated in our previous study that the less stable implant created by overdrilling do not contribute to subsequent osseointegration (Jimbo et al. 2013a,b).

At the early time point of 2 weeks, the insertion torque values and osseointegration are not proportional and the initial hypothesis was rejected. However, it must be stressed that the results obtained can only be applied for this specific implant design. More information is needed to clarify the influence of implant design and drilling protocols to obtain an optimal surgical set-up for different implants. Also, it must be acknowledged that a high degree of primary stability seems to be one of the prerequisites for successful immediate loading (Esposito et al. 2007). However, the ideal combination of insertion torque, implant design parameters, and surgical techniques required to achieve high primary stability and first-rate early bone response is yet to be determined.

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