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# Osseodensification outperforms conventional implant subtractive instrumentation: A study in sheep

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ABSTRACT

Osseodensification is a surgical instrumentation technique where bone is compacted into open marrow spaces during drilling, increasing implant insertion torque through densification of osteotomy site walls. This study investigated the effect of osseodensification instrumentation on the primary stability and osseointegration of as-machined and acid-etched implants in low-density bone.

Six endosteal implants were inserted bilaterally in the ilium of five sheep totaling 60 implants ($n = 30$ acid-etched and $n = 30$ as-machined). Each animal received three implants of each surface. The osteotomy sites were prepared as follows: (i) subtractive conventional-drilling (R): 2 mm pilot, 3.2 mm and 3.8 mm twist drills; (ii) osseodensification clockwise-drilling (CW), and (iii) osseodensification counterclockwise-drilling (CCW) with Densah Burs (Versah, Jackson, MI, USA) 2.0 mm pilot, 2.8 mm, and 3.8 mm multi-fluted tapered burs. Insertion torque, bone-to-implant contact (BIC) and bone-area-fraction occupancy (BAFO) were evaluated. Drilling techniques had significantly different insertion torque values (CCW > CW > R), regardless of implant surface. While BIC was not different as a function of time, BAFO significantly increased at 6-weeks. A significantly higher BIC was observed for acid-etched compared to as-machined surface. As-machined R-drilling presented lower BIC and BAFO than acid-etched R, CW, and CCW. New bone formation was depicted at 3-weeks. At 6-weeks, bone remodeling was observed around all devices. Bone chips within implant threads were present in both osseodensification groups. Regardless of implant surface, insertion torque significantly increased when osseodensification-drilling was used in low-density bone. Osseodensification instrumentation improved the osseointegration of as-machined implants to levels comparable to acid-etched implants inserted by conventional subtractive-drilling.

## 1. Introduction

Endosseous dental implants have been used as a predictable treatment option for the rehabilitation of partial and complete edentulism with high long-term survival rates [1,2]. Osseointegration is defined as the direct anchorage of an implant by the formation of bony tissue around it without growth of fibrous tissue at the bone-implant interface [3]. It is achieved after surgical placement of an implant through bone modeling-remodeling processes around the metallic device [4,5].

An essential aspect of osseointegration is implant primary stability, which is directly related to bone density [6,7], surgical drilling protocol [8], implant surface texture, and geometry [9]. Primary stability is the mechanical bone-implant interlocking that only takes place upon successful fixation of an implant, and is essential for bony fixation because it prevents excessive implant micromovement [10]. Machined implants are known to achieve predictable osseointegration specially in areas of optimal bone density [11]. Hence, dental implants have adopted over the years more aggressive thread designs, specific drilling protocols and roughened surfaces to optimize primary stability and osseointegration in areas of reduced bone density [12]. Once cell-mediated remodeling takes place, primary stability decreases over time in benefit of the secondary stability, which is characterized by bone-implant anchoring

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due to new bone formation over time resulting from bone apposition [12].

Despite the higher levels of primary and secondary stability observed in low bone density [13], textured implant surfaces have shown one main concern compared to machined surface implants. Some textured implant surfaces seems more prone to bacterial colonization and disinfection of contaminated surfaces is more challenging, with reports showing more peri-implant bone loss for rough (1.04 mm), compared to minimally rough implant surfaces (0.86 mm) [14,15]. While peri-implantitis is of multifactorial origin [16], it is prudent to attempt to prevent peri-implantitis by controlling all known potential systemic and local etiologic factors [17,18]. Therefore, given the positive long-term results of as-machined implant surfaces, the use of surgical instrumentation strategies targeted at improving early host response, specially in areas of low bone density, remains open to further development.

Once primary stability is assured, bone remodeling becomes vital for secondary stability establishment as it can be directly related to patient factors and implant surface characteristics [19], such as: surface energy, composition, topography and roughness [20,21]. Machined implant surfaces represents the starting point of implant surface design and it has been used for decades according to classical protocols in which several months were required for osseointegration [22]. Improving implant surface biocompatibility and osseoconductive properties through topographic pattern modifications has been shown to increase not only the bone-implant contact but also biomechanical interaction, resulting in accelerated bone healing and bone apposition rate, and consequently, earlier biological fixation [23].

Drilling technique is another major aspect to be considered when primary stability prompt establishment is expected. Several surgical techniques aiming to increase the primary stability, particularly in low-density bone have been published [24–26]. However, all of them compare subtractive drilling activity performed under the assumption that bone must be removed and excavated. Increased stability may be achieved with various degrees of under preparation of the osteotomy. In general, the combination of increasing implant diameters with reduced osteotomy dimensions result in proportionally increased insertion torque levels during implant placement [27,28].

On the other hand, osseodensification drilling technique is based on the concept of a non-subtractive multi-stepped drilling process through burs that allow bone preservation and autografting compaction along the osteotomy wall [29]. The densifying bur presents a cutting chisel and tapered shank allowing it to progressively increase the diameter as it is moved deeper into the osteotomy site, controlling the expansion process. Also, drilling can be operated in both counterclockwise (CCW) and clockwise (CW) rotation directions at high drilling speeds. The counterclockwise drilling direction is more efficient at the densification process and is utilized in low-density bone, while the clockwise drilling direction is suitable for higher-density bone [30]. Osseodensification drilling provides an environment that enhances primary stability due to compaction auto grafting and the presence of residual bone chips [29–31]. Furthermore, besides improved primary stability, bone densification may accelerate new bone growth through osteoblasts nucleating on the instrumented bone [30,32].

The effect of osseodensification drilling techniques comparing as-machined and surface textured implants has not yet been determined. Consequently, the quantification of the biomechanical and biological basis is warranted in order to evaluate if there is synergism between surgical technique and implant surface texture. The objective of this study was to evaluate the effect of osseodensification on the primary implant stability and progression of osseointegration (3 and 6 weeks) of as-machined (M) or surface textured (grit blasted/acid-etched) (A) dental implants.

## 2. Materials and methods

A total of 60 conic shaped implants (Ti-6Al-4 V) presenting progressive power threads, 4.0 mm in diameter and 10 mm in length (Emfils D2, Itu, SP, Brazil), were included in the present study. The surfaces included in the present study comprised two different groups: as-machined (M) and grit-blasted/acid-etched (A) [27]. The surface texture was achieved by blasting the surface with aluminum oxide followed by dual acid etching [33]. The implants were sterilized by gamma-radiation.

### 2.1. Preclinical in vivo model

This *in vivo* study was performed according to the ethical approval from the Institutional Animal Care and Use Committee under ARRIVE guidelines. A translational, large preclinical animal model was chosen. Also, aiming to increase the statistical power and decrease the number of animals, the iliac crest of the sheep hip model was used. Due to animal size, all experimental groups were nested within each subject. Five female sheep weighing approximately 120 pounds were used in the study. Six implants were inserted into the ilium of each animal, bilaterally, resulting in a total of 60 implants ($n$ = 30/group; as-machined and acid-etched). While samples that remained *in vivo* for 3 weeks were placed in the left side, the right side consisted of implants for 6 weeks evaluation.

Prior to surgery, anesthesia was induced with sodium pentothal (15-20 mg/kg) in Normasol solution into the jugular vein of the animal and maintained with isofluorane (1.5–3%) in $O_2/N_2O$ (50/50). ECG, $SpO_2$, end tidal $CO_2$, and body temperature with a circulating hot water blanket for regulation were used to monitor animals. The surgical site was shaved and treated with iodine solution prior to the surgery. First, an incision of approximately 10 cm was made along the iliac crest, followed by dissections of fat tissue until muscular tissue was reached. Aiming ilium bone exposure, dissection of muscular plane with sharp dissection and the application of a periosteal elevator was performed. Three different osteotomy techniques were conducted: (i) subtractive regular drilling (R) in a 3 step series of a 2.0 mm pilot, 3.2 mm and 3.8 mm twist drills; (ii) clockwise drilling (CW) with Densah Bur (Versah, Jackson, MI, USA) 2.0 mm pilot, 2.8 mm, and 3.8 mm multi fluted tapered burs; and (iii) osseodensification counterclockwise drilling (CCW) with Densah Bur (Versah, Jackson, MI, USA) 2.0 mm pilot, 2.8 mm, and 3.8 mm multi fluted tapered burs. Drilling was performed at 1.100 rpm under saline irrigation. To minimize location bias, experimental group distribution was interpolated as a function of the animal subject, allowing the final comparison of the same number of as-machined and acid-etched implants placed in sites 1 through 6 by R, CW, and CCW surgical drilling at both 3 and 6 weeks (Fig. 1). The insertion torque of each implant was performed to the cortical level and the values were measured and recorded using a digital torquemeter (Tohnichi STC-G, Tohnichi, Japan). Layered closure with nylon 2–0 for skin and Vicryl 2–0 for muscle was performed. Cefazolin (500 mg) was intravenously administered pre-operatively and post-operatively. After recovery, food and water *ad libitum* was offered to the animals. Then, the animals were sacrificed by anesthesia overdose and samples were retrieved by sharp dissection.

### 2.2. Histologic procedures and histomorphometric analysis

The process for histological and histomorphometric analyses comprised step-by-step dehydration in ethanol and methyl salicylate, followed by a final embedding in methylmethacrylate (MMA). According to a pre-established methodology [34], non-decalcified histological sections were prepared: 300 μm thickness samples were cut using a slow-speed precision diamond saw (Isomet 2000, Buehler Ltd. Lake Bluff, IL, USA). Each section of the tissue was then glued to an acrylic plate by a photolabile acrylate-based adhesive (Technovit 7210 VLC

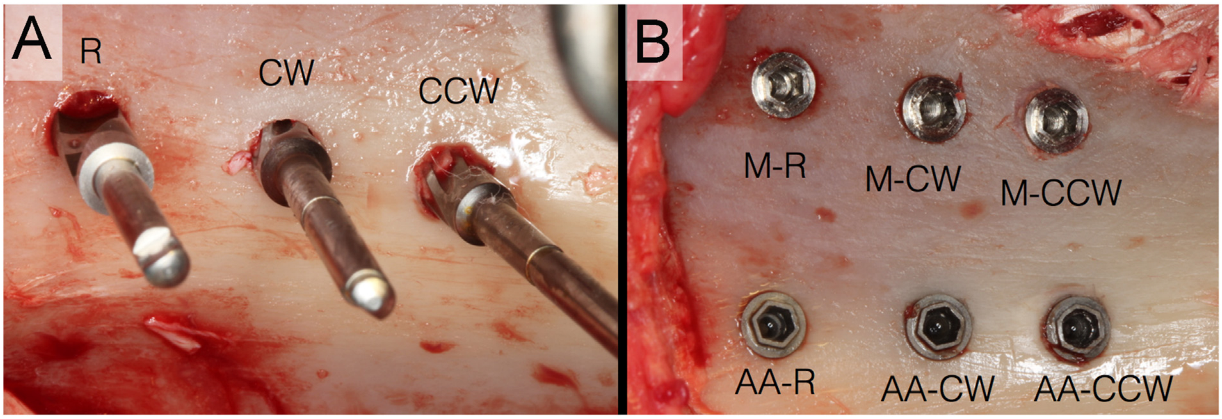


**Fig. 1.** Exposed ilium illustrating A) subtractive conventional-drilling (R), osseodensification clockwise-drilling (CW), and osseodensification counterclockwise-drilling (CCW). B) All study groups: M-R (machined conventional-drilling); M-CW (machined osseodensification clockwise); M-CCW (machined osseodensification counter clockwise); AA-R (acid etched conventional-drilling); AA-CW (acid etched osseodensification clockwise); AA-CCW (acid etched osseodensification counter clockwise).

adhesive, Heraeus Kulzer GMBH, Wehrheim, Germany). After that, grinding and polishing process under copious water irrigation with increasingly finer grit silicon carbide (*SiC*) abrasive papers (600, 800, and 1200) (Metaserv 3000, Buehler Ltd., Lake Bluff, IL, USA) to a thickness of approximately 30 μm was performed. Subsequently, the samples were stained with Stevenel's Blue and Van Giesons's Picro Fuschin (SVG) stains and scanned *via* an automated slide scanning system and specialized computer software (Aperio Technologies, Vista, CA, USA). For histomorphometric evaluation, an imaging analysis software (ImageJ, NIH, Bethesda, MD) was used to quantify and evaluate osseointegration parameters around the peri-implant surface: bone-to-implant contact (BIC) and bone area fraction occupancy (BAFO) [30,31].

### 2.3. Statistical analysis

The histomorphometric and biomechanical testing data are presented as mean values with corresponding 95% confidence interval values (mean ± 95% CI). %BIC, %BAFO and insertion torque data were collected and statistically evaluated through linear mixed model with fixed factors of implant surface treatment (M and A), time *in vivo* (3 and 6 weeks), surgical drilling technique (R, CW, CCW) and a random intercept. After administering a significant omnibus test, post-hoc comparison of the three drilling method means was gathered using a pooled estimate of the standard error. Preliminary analyses have shown indistinguishable variances in the study of all three dependent variables (Levene test, all $p > 0.25$). The analysis was accomplished using IBM SPSS (v23, IBM Corp., Armonk, NY).

## 3. Results

Insertion torque as a function of surface treatment showed ~49 N·cm and ~46 N·cm for acid-etched surface (A) and as-machined group (M), respectively, and revealed no statistical significance ($p = 0.498$) (Fig. 2A). The recorded insertion torque values were approximately 10 N·cm for R technique and showed subsequent increases, for CW (~53 N·cm) and CCW (~78 N·cm) (Fig. 2B), with data indicating statistical significance as a function of technique (CCW > CW > R, $p < 0.005$). When insertion torque was evaluated as a function of surface treatment combined with drilling technique, a consistent decrease in insertion torque was observed irrespective of implant surface where CCW > CW > R (Fig. 2C).

Evaluating %BIC as a function of time (3 *vs.* 6 weeks), no statistical significance was noted ($p = 0.577$) (Fig. 3A). Bone-to-implant contact (%BIC) for the acid-etched surface (A) group was observed to be significantly higher in comparison to as-machined group (M) ($p = 0.001$) with %BIC levels being ~40% greater for the implants which had the acid-etched surface (Fig. 3B). No significant differences were observed between drilling techniques when data was collapsed over time and surface treatment ($p = 0.148$) (Fig. 3C). When surface was collapsed over drilling technique and evaluated as a function of time, the acid-etched (A) group presented significantly higher %BIC values than the as-machined (M) surfaces at both time points ($p < 0.01$) (Fig. 3D). Collapsing BIC data over time *in vivo*, results demonstrated that BIC values for the CCW and CW groups were comparable to all acid-etched implant drilling groups while the R drilling for machined groups resulted in significantly lower %BIC values ($p < 0.01$) (Fig. 3E). Statistical evaluation considering all drilling techniques, both implant surfaces, and times *in vivo* depicted that at 3 weeks the as-machined R drilling technique presented significantly lower %BIC values than acid-etched R, and CCW/CW osseodensification drilling techniques irrespective of surface treatment ($p = 0.01$) (Fig. 3F). At 6 weeks, machined implants inserted through R drilling technique presented significantly lower values than any of the acid-etched implant groups and was also significantly lower than the machined implants inserted into CCW drilled sites ($p < 0.02$).

The effect of time in %BAFO values showed a significant increase in values from 3 to 6 weeks *in vivo* ($p = 0.014$) (Fig. 4A). No significant differences were depicted between acid-etched and machined surfaces when %BAFO values were collapsed over time and drilling technique ($p = 0.053$) (Fig. 4B). Additionally, there was no statistical significance in %BAFO when results were collapsed over implant surface and time when analyzed as a function of drilling technique ($p = 0.330$) (Fig. 4C). No differences in %BAFO values between surfaces were observed as a function of time collapsed over drilling technique ($p > 0.30$) (Fig. 4D). Nevertheless, when assessing the factors of surface treatment and drilling technique collapsed over time, as-machined (M) implants placed in osteotomies prepared with regular (R) drilling technique resulted in significantly lower %BAFO levels in comparison to R acid-etched implants and CW and CCW osseodensification techniques irrespective of surface treatment (Fig. 4E).

Statistical evaluation of %BAFO levels with respect to all factors showed that at 3 weeks the as-machined implants placed within the R drilling technique osteotomies presented lower amounts of %BAFO compared to the other surgical techniques (Fig. 4F). Similarly, at 6 weeks, the as machined (M) implants placed in R drilling technique osteotomies presented lower values compared to any other group.

Histological evaluation indicated osseointegration of all implants. Regardless of the implant surface treatment and surgical technique, the pattern of osseointegration presented extensive remodeling around the

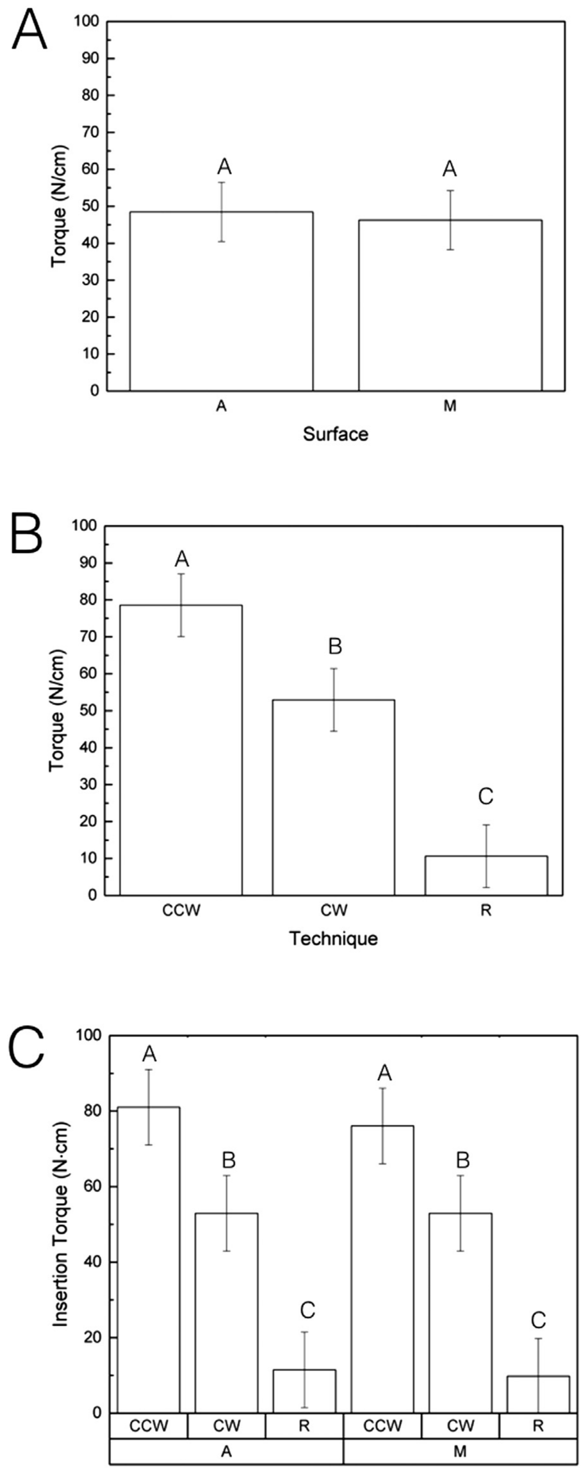


**Fig. 2.** Statistical summary for (A) insertion torque as a function of implant surface treatment (data collapsed over drilling technique); (B) insertion torque as a function of surgical technique (data collapsed over surface treatment); and (C) insertion torque as a function of surface treatment and drilling technique. Same letters represent statistically homogenous groups. Data presented as mean ± 95%CI.

cortical shell, as sites of bone resorption and new bone formation were observed in close proximity to the implant surface. Qualitative analysis of the R drilling technique revealed new bone growth in both the cortical and trabecular regions with a notable lack of bone fragments present, while histological images of the osseodensification drilling techniques (CW and CCW) revealed a presence of bone chips to a lower (CW) and higher (CCW) extent (Figs. 5 and 6). The presence of bone chips was more notable among the CCW surgical technique samples, as these bone chips were present along the length and within the threaded regions of both types of surface treatments. Regardless of the surface treatment or the cutting direction of the surgical technique employed, the bone chips acted as bone nucleating entities bridging natural bone and the implant surfaces. Representative micrographs for the acid-etched and machined implant groups are presented in Figs. 5 and 6, respectively.

## 4. Discussion

Surgical instrumentation for dental implant placement is one of the most important steps that can influence osteotomy accuracy and degree of primary and secondary stability [12]. However, there are limited studies focused on this aspect of implant placement in the literature. This study assessed the effect of osseodensification drilling techniques (CCW and CW) relative to regular subtractive drilling by insertion torque measurement, bone-to-implant contact (%BIC) and bone area fraction occupancy (%BAFO) as a function of time (3- and 6-weeks remained *in vivo*) and surface treatment (as-machined and acid-etched). Histomorphometric results indicate that the experimental osseodensification drilling techniques (especially CCW) and implant surface treatment positively influences the osseointegration process.

Poor density bone (types 3 and 4) is commonly seen in posterior jaw [35], especially in elderly patients that represents a high percentage of implant treatment seekers. Implant primary stability can be influenced by cortical bone thickness, quality and quantity of trabecular bone and implant geometry, and implant surface roughness [20,36]. Consequently, satisfactory primary stability in low density bone is difficult to be reached and higher rates of implant failure are usually observed in those cases [37,38]. In order to increase predictability of osseointegration in areas of poor bone density, the use of textured implant surfaces have been recommended in a recent systematic review [11]. The sheep hip model was selected for this study for the assessment of implant placement in areas of low bone density [24,32,39]. This model suitably represents low density bone and it is effective in evaluating the influence of osseodensification drilling techniques on the improvement of primary, as well as, secondary stability [30,40].

The concept of attempting to improve bone quantity and quality around implant osteotomy sites through different surgical procedure is not innovative. Bone condensation with osteotomes for osteotomy preparation [41] and/or significantly undersize of the implant osteotomy have been previously used [28,42,43]. On the other hand, osseodensification drilling technique, which drives bone compaction in the osteotomy site wall, using specially designed burs comprises an innovative surgical instrumentation approach. Conceptually, improved primary stability using this technique is related to presence of residual bone chips forming an autograft wall around the osteotomy perimeter, by creating an "implant lamina dura". Furthermore, there are no reports of negative bone response from micro fractures or extensive modeling-remodeling process related to excessive bone strain affecting osseointegration [30]. These bone chips act as autografts, nucleating new bone formation as observed in this study and also reported elsewhere [30].

In this study, increased insertion torque in osseodensification drilling techniques when compared to R subtractive technique are consistent with previous findings that implants inserted using osseodensification instrumentation had statistically higher biomechanical performance than implants inserted with conventional subtractive drilling [44]. On the progressive power threaded implants used in the present experiment, counterclockwise technique (CCW) demonstrated significant higher insertion torque values than clockwise (CW) rotation direction, supporting previous data that more efficient densification is exerted by counterclockwise rotation [30]. On the other hand, surface treatment did not influence the recorded insertion torque values. This

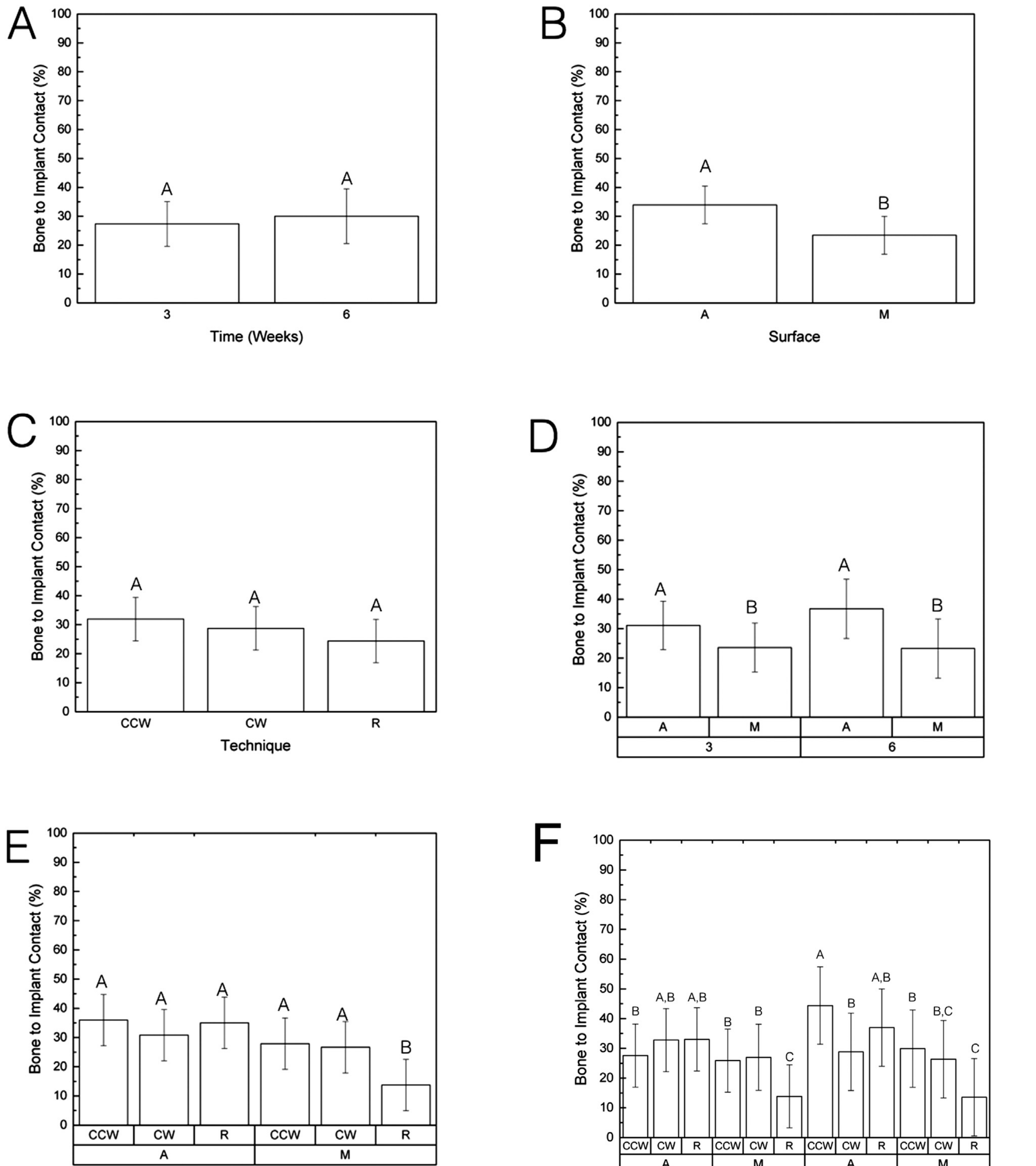


**Fig. 3.** Statistical summary for %BIC as a function of (A) time, (B) implant surface, (C) surgical technique, (D) implant surface and time (collapsed over surgical technique), (E) surgical technique and implant surface collapsed over time. (F) Statistical summary for %BIC with all factors depicted. Same letters represent statistically homogenous groups. Data presented as mean ± 95%CI.

finding is significant as it demonstrates that the association between improved implant thread design and osseodensification can overcome lower insertion torque values of machined implant surfaces in areas of low bone density when placed by conventional subtractive drilling techniques. Hence, machined implants when combined with osseodensification may experience at least similar osseointegration success rates of textured implants in low bone density.

The overall bone-to-implant contact (%BIC) percentages were not significantly different when comparing 3 and 6 weeks time points. This can be attributed to initial interlocking between implant and bone. Adequate osteotomy size relative to the implant geometry provided immediate and intimate contact with surrounding bone without excessively surpassing bone compressive strain levels [42]. A significant difference was observed when bone area fraction occupancy percentage

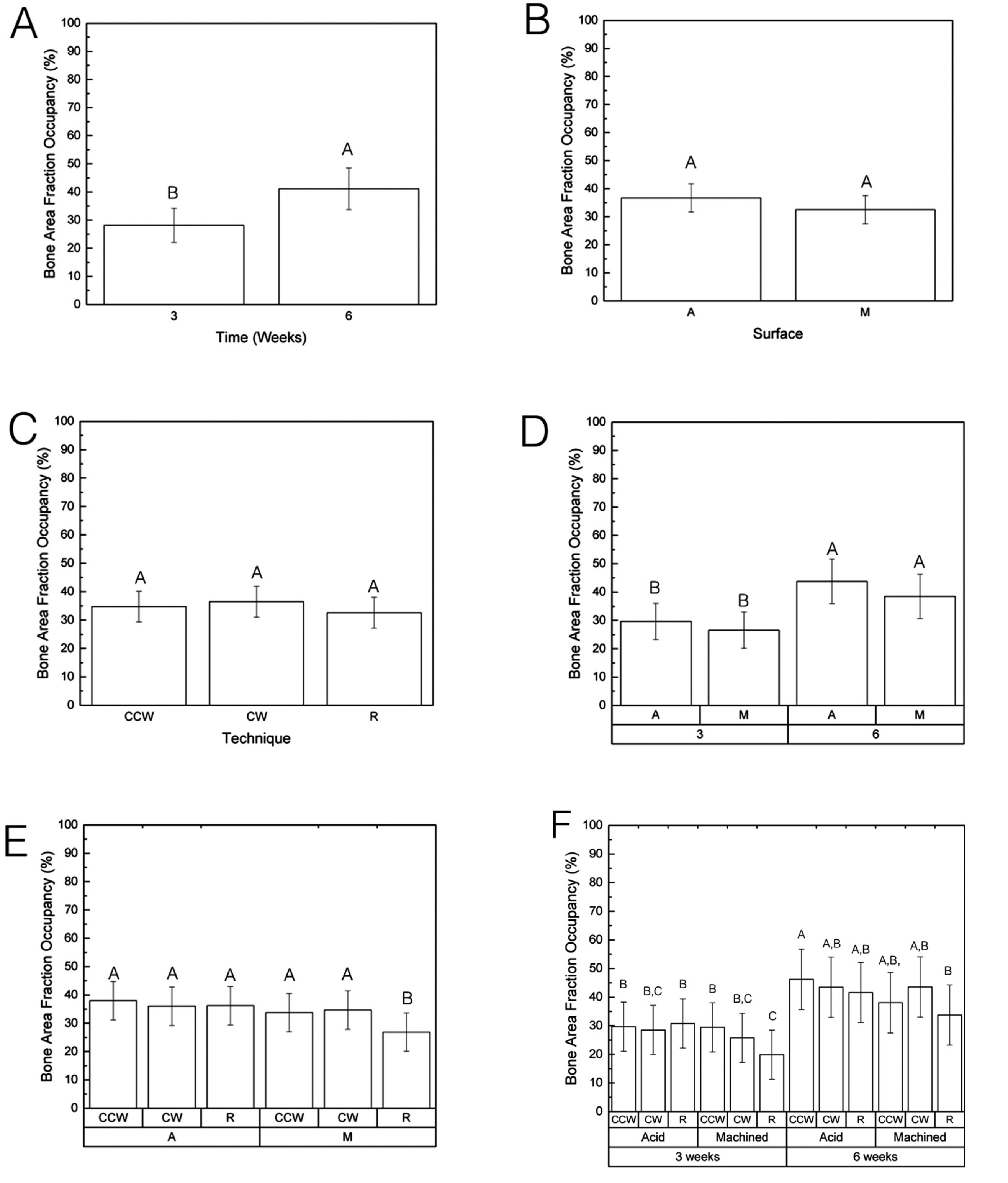


**Fig. 4.** %BAFO statistical summary as a function of (A) time, (B) implant surface, (C) surgical technique, (D) implant surface and time (collapsed over surgical technique), (E) surgical technique and implant surface collapsed over time. (F) Statistical summary for %BAFO with all factors depicted. Same letters represent statistically homogenous groups. Data presented as mean ± 95%CI.

(%BAFO) was analyzed as a function of time. Higher degrees of healing are expected over time for all drilling techniques and surfaces, however, histological micrographs of osseodensification samples revealed that compacted bone chips acted as nucleating surfaces that bridged implant and surrounding bone and were not detrimental to osseointegration [30].

Although previous studies considering different implant configurations have reported significantly higher levels of bone-to-implant contact (%BIC) and bone area fraction occupancy percentage (%BAFO) for osseodensification techniques [30], no significant difference was evidenced when CCW and CW techniques were compared to R subtractive drilling in the present study. Nonetheless, %BIC and %BAFO results

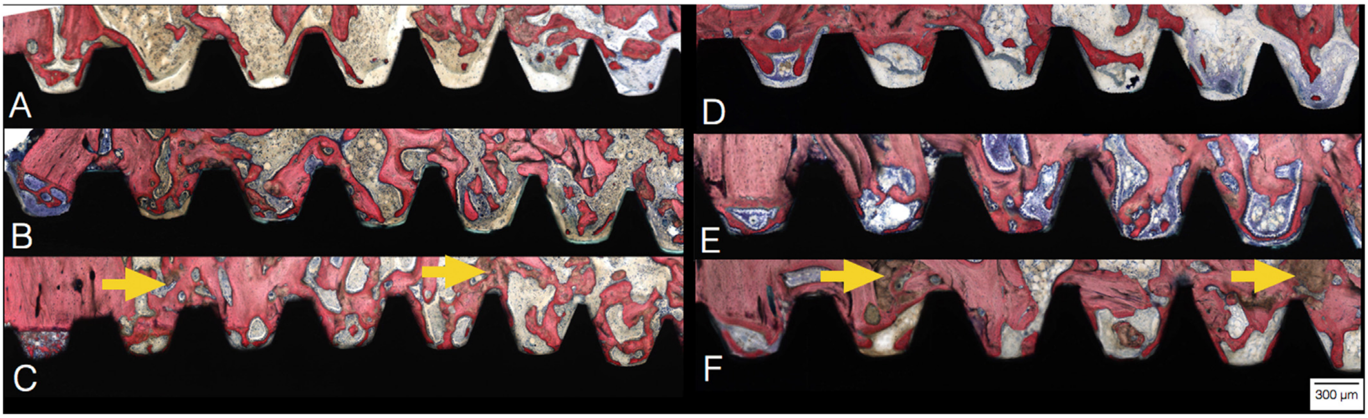


**Fig. 5.** Histological micrographs of as-machined implants at 3 and 6 weeks, A–C and D–F, respectively; (A and D) represent the R-drilling, (B and E) osseodensification clockwise drilling (CW), and (C and F) osseodensification counter clockwise drilling techniques.

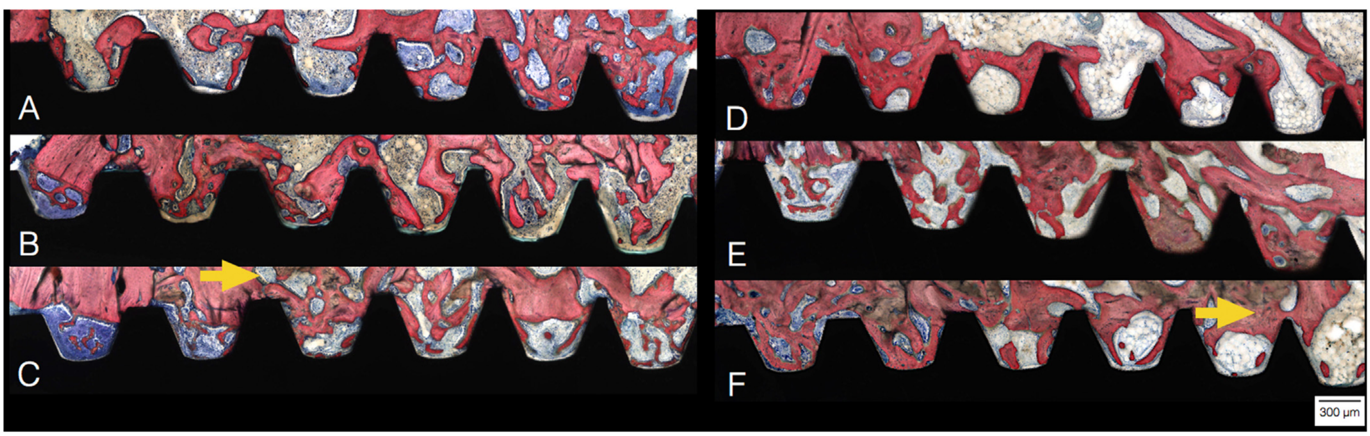


**Fig. 6.** Histological micrographs of acid-etched implants at 3 and 6 weeks, A–C and D–F, respectively; (A and D) represent the R drilling, (B and E) osseodensification clockwise drilling (CW), and (C and F) osseodensification counter clockwise drilling techniques.

when data were collapsed only over time depicted that as-machined R drilling technique presented significantly lower %BIC values than acid-etched R and CCW and CW drilling techniques regardless of surface treatment. The absence of significant difference between drilling protocols when all data are collapsed can be attributed to surface treatment since bone-to-implant and bone area fraction occupancy percentage levels were higher for acid-etched surface than for as-machined. Implant surface treatment is advantageous during initial phase of wound healing since it is directly related to increased biocompatibility and osseoconductive properties of surface that enhances bone apposition [45].

Acid-etched surfaces have previously shown higher percentage of bone-to-implant contact when compared to conventional as-machined [46]. Nonetheless, a notable result is evidenced when as-machined CCW and CW drilling %BIC were significantly higher than R as-machined and not significantly different from acid-etched groups, unequivocally pointing that despite the osseoconductive disadvantage from the lack of surface treatment for as-machined implants, the osseodensification surgical technique compensated for the differences in the surface osseoconductivity. In other words, CW and CCW osseodensification drilling of implant osteotomies resulted in not only higher insertion torque values but also higher %BIC and %BAFO of machined implants, when compared to R drilling of roughened implants in low bone density. It can be assumed that machined implants when associated with osseodensification drilling techniques may experience at least the same, if not higher, predictability of osseointegration in areas of low bone density.

Dental implant rehabilitation is a well-established treatment with high success rates in long-term studies, up to 90% [1,2]. Few studies concerning to low-density bone and primary stability provided by osseodensification drilling techniques have been published, despite its applicability in oral rehabilitation. More *in vivo* and clinical studies are warranted in order to better understand the osseointegration dynamics at the cell and molecular level when osseodensification is used.

## 5. Conclusions

In low-density bone, regardless of surface treatment, conical progressive power threaded endosteal implants inserted *via* osseodensification surgical technique presented higher insertion torque values. Also, association of osseodensification techniques to machined surface implants resulted in osseointegration levels presented by surface textured implants placed by means of subtractive drilling technique (R) demonstrating that drilling technique significantly increases early osseointegration of machined surface devices to levels comparable to surface textured devices.

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## Conflict of interest

The authors declare that they have no competing interests.

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