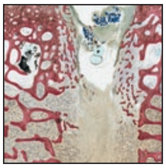
Absence of Healing Impairment in Osteotomies Prepared via Osseodensification Drilling



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This study sought to qualitatively and quantitatively evaluate the effect of osteotomy preparation by conventional (control group) or OD (OD group) instrumentation on osteotomy healing. An incision of 10 cm was made in the anteroposterior direction over the hip in five sheep, and 15 osteotomies were prepared in the left ilium of the sheep (n = 3/sheep). Three different instrumentation techniques were utilized: (1) conventional/regular drilling (R [recommended by manufacturer]) in a 3-step series of a 2-mm pilot, 3.2-mm, and 3.8-mm twist drills; (2) OD clockwise (OD-CW) drilling with Densah Bur (Versah) 2.0-mm pilot, 2.8-mm, and 3.8-mm multi-fluted tapered burs; and (3) OD counterclockwise (OD-CCW) drilling with Densah Bur 2.0-mm pilot, 2.8-mm, and 3.8-mm multi-fluted tapered burs. Drilling was performed at 1,100 rpm with saline irrigation. Qualitative histomorphometric analysis of the osteotomies after 6 weeks did not show any healing impairment due to the instrumentation. Histologic analysis shows bone remodeling and growth in all samples, irrespective of osteotomy preparation technique, with the presence of bone chips observed along the length of the osteotomy wall in sites subjected to osseodensification drilling.

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The placement of dental implants to restore the oral cavity to baseline form and function in patients undergoing edentulous rehabilitation is well established.[1] Successful endosteal implant fixation is required for these devices to support prosthodontic rehabilitation.[1] This fixation is predicated on the direct functional and structural connection between bone and implant after placement, termed osseointegration.[2] Improving on the applications of this principle has been the impetus for implant studies for the last four decades.[3] Moreover, improving osseointegration has several applications for health care, as endosteal implant fixation encompasses fields such as dentistry, hand surgery, spinal surgery, etc, with revision costs of ~$15,000 for hip arthroplasty[4] and ~$1,700 for dental prostheses[5] consequent to implant failures.

Successful osseointegration requires primary stability, the firm interplay between the bony wall defect and implant at the time of instrumentation.[6] The degree of primary stability is dependent on osteotomy dimensions, implant device dimensions, and the amount of strain applied to bone.[7] Osseointegration also requires secondary stability, which is established over time consequent to bone remodeling around the implant during the healing period. Secondary stability is also an

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essential facet of biomechanical fixation, which occurs when cell-mediated bone remodeling occurs towards the implant and apposition of bone and endosteal device.[8] Osseointegration is achieved when newly formed bone is in direct contact with the implant and its surface without any intermediate soft tissue component.[7,9] An array of factors contribute to successful primary and secondary stability, eg, implant design (geometrical configuration, implant coating, or porosity), surgical instrumentation (sequence, speed, and instrumentation technique), and patient health status (host response and quality and quantity of bone).[7] An adequate volume of bone in the implant bed is essential to ensure osseointegration and long-term implant stability. For example, low density bone, as seen in the human maxilla, has limited bone quantity, which can lead to poor bone-to-implant contact, which may negatively impact primary stability[10] and secondary stability. There are different surgical instrumentation techniques currently available for preparing osteotomy sites, including the conventional drilling technique, which is subtractive, as well as a contemporary method called osseodensification (OD), which is nonsubtractive in nature and aims to enhance primary stability.

To address potential limitations of current methods for osteotomy preparation, an alternative approach was explored. This contemporary technique uses an additive method (OD) that utilizes custom-designed burs, which combines current additive concepts for osteotomies with the speed and control of drilling procedures.[11] A unique feature of the OD technique is that rather than eradicating the bone particles, as is common in conventional instrumentation, this instrumentation maintains bone particles by compacting them into the osteotomy wall.[11] Another distinction is in the design of the instrumentation's bur: The burs have a large negative rake angle, which is used as a noncutting edge to allow for increased bone density as the osteotomy expands.[12] In both conventional and OD instrumentation techniques, copious amounts of irrigation lubricate the bur and bone surfaces to minimize damage of adjacent tissue[13,14] due to overheating.[11] OD instrumentation preserves bone bulk and enhances its density by laterally compacting bone via viscoelastic and plastic deformation, and by displacing/autografting bone particles at the walls and apex of the osteotomy.[11] OD can potentially maximize osseointegration of titanium screws through the creation of an autografted bony wall that interacts intimately with the implant, but there are currently no studies in the literature investigating whether the formation of such bony walls through OD drilling acts as a physical barrier and possibly precludes healing at the central regions of the osteotomy.

The objective was to qualitatively and quantitatively evaluate the effect of osteotomy preparation by conventional (control group) or OD (OD group) instrumentation on osteotomy healing. The hypothesis tested is that there is no healing impairment when using OD relative to conventional drilling methods.

Materials and Methods

After receiving approval from the Institutional Animal Care and Use Committee (IACUC), five ewes were acquired and housed for a period of ~5 days for acclimation prior to any surgical procedures. All surgical procedures were conducted under strict sterile conditions and general anesthesia as follows: animals were injected with sodium pentothal (15 to 20 mg/kg) in Normasol solution in the jugular vein. The anesthesia was sustained using isoflurane (1.5% to 3%) in O2/N2O (50/50). Furthermore, vital signs of animals were monitored via ECG, SpO2, and end tidal CO2. The designated site for surgical osteotomy preparation was shaved and prepared with iodine solution.

An incision of 10 cm was made in the anteroposterior direction over the hip, and 15 osteotomies were prepared in the left ilium of the sheep (n = 3/sheep). Three different instrumentation techniques were utilized: *(1)* conventional/regular drilling (R [recommended by manufacturer]) in a 3-step series of 2-mm pilot, 3.2-mm, and 3.8-mm twist drills; *(2)* OD clockwise (OD-CW) drilling with Densah Bur (Versah) 2.0-mm pilot, 2.8-mm, and 3.8-mm multi-fluted tapered burs; and *(3)* OD counterclockwise (OD-CCW) drilling with Densah Bur 2.0-mm pilot, 2.8-mm, and 3.8-mm multi-fluted tapered burs. Drilling was performed at 1,100 rpm with saline irrigation. At the end of the surgical procedure, areas of site preparation were sutured using vicryl 2-0 for muscle and nylon 2-0 for skin. Cefazolin (500 mg) was administered as a choice of antibiotic preoperatively and postoperatively via intravenous injection to reduce incidence of postoperative complications (ie, infection, inflammation, etc). Furthermore, food and water were provided ad libitum to the animals postoperatively.

All sheep were euthanized at 6 weeks postsurgery with an overdose of anesthetics. The ilium of each sheep was removed en bloc. Samples were dehydrated in a series of steps from 70% to 100% ethanol and subsequently embedded in methyl methacrylate (MMA). After polymerization, the embedded samples/blocks were approximately cut into thin section slices, ~300 μm (Isomet, 2000, Buehler), which were then glued onto histologic slides (Technovit 7210 VLC adhesive, Heraeus Kulzer). Slides were ground and polished under constant water irrigation using a series of silicon carbide (SiC) abrasive papers (Buehler) to approximately 100-μm thick on a grinding machine (Metaserv 3000, Buehler). Finished slides were stained using Stevenel's blue and Van Gieson fuchsin (SVG) in order to differentiate the soft tissue and mineralized tissue.[15,16] Slides were scanned (Aperio Technologies) for histomorphometric analysis via image software (ImageJ, NIH). Histologic slides were first qualitatively assessed followed by quantitative analysis. The quantitative assessment, bone-area-fraction-occupancy (BAFO), was executed on slides that were scanned and exported to digital images. The digital histologic images of the bone within the osteotomy were subjected to thresholding, ultimately quantifying as a function of area. The analysis was completed by a single operator who was blinded to the experimental groups.

Statistical Analyses

Statistical analysis between the control (Regular [R]) and experimental groups (OD-CW and OD-CCW) was analyzed using SPSS software (v23, IBM). Normality test was conducted via Kolmogorov-Smirnov test. Data illustrated that homogeneity of the three dependent variables was met. A mixed model analysis was used to test the effects of drilling techniques on BAFO, and a two-sample *t* test was performed. Statistical significance was set at $\alpha = .05$.

Results

There were no signs of postoperative complication at surgical sites, and all animals were retained throughout the study. Qualitative histomorphometric analysis of the osteotomies did not show any healing impairment due to the instrumentation. All osteotomies, independent of the instrumentation, resulted in bone remodeling and growth (Figs 1a, 2a, and 3a). The standard instrumentation (R), which served as the control, displays initial bone ingrowth, mainly at the trabecular region towards the apex and lateral walls of the osteotomy (Fig 1a). A histologic slide viewed with a higher magnification (Fig 1c) gives a visual representation at the apex region with bone beginning to remodel. The two experimental groups OD-CW (Fig 2) and OD-CCW (Fig 3) had the presence of bone chips along the wall of the osteotomy. The bone chips were primarily found at the apical region of the osteotomy in the OD-CW group, which is seen in Fig 2a and in higher magnification in Fig 2c. The OD-CW group had more pronounced autografting along the walls of the osteotomy compared to the R group (Fig 2b). The OD-CCW group presented a healing pattern similar to its analogous counterpart (OD-CW), but one stark difference between the two was the presence of residual bone chips. Unlike in the OD-CW instrumentation, the OD-CCW had bone chips present through the length of the osteotomy walls (Fig 3a). As seen at higher magnification in Fig 3b, the chips were well attached and embedded into the osteotomy wall. Further qualitative evaluation of the OD-CCW indicated a more concentrated amount of bone chips in the apical region of the osteotomy, as indicated by the arrows in Fig 3c. Furthermore, at this region the bone chips were highly compacted into the surrounding wall. Irrespective of group and the presence of autografts, bone healing occurred throughout the osteotomy volume. The autografted bone presented as nucleating surfaces for new bone formation.

The histologic slides were subjected to quantitative analysis of BAFO, as a function of instrumentation (R, OD-CW, OD-CCW). The mean BAFO value (%) for R instrumentation was ~11.5%, while both OD techniques (OD-CW and OD-CCW) resulted with statistically homogeneous values: 11.3% and 9.1%, respectively ($P = .78$) (Fig 4).

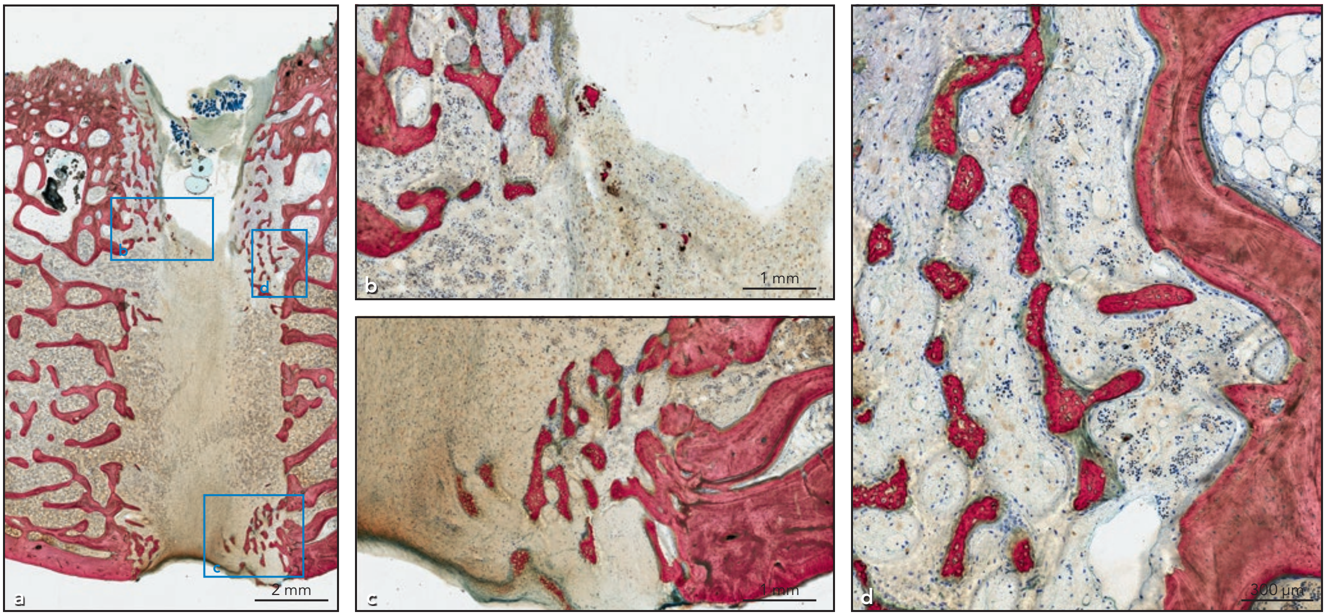

Fig 1 *Histologic image representing regular instrumentation.* (a) *Overall view of the osteotomy created, with three regions of interest (ROI, blue boxes): higher magnifications of* (b) *upper left inset,* (c) *lower right inset (illustrating initial healing from the osteotomy outer perimeter inwards), and* (d) *upper right inset (illustrating the outer perimeter inwards). Samples stained with Van Gieson's fuchsin and Stevenel's blue.*

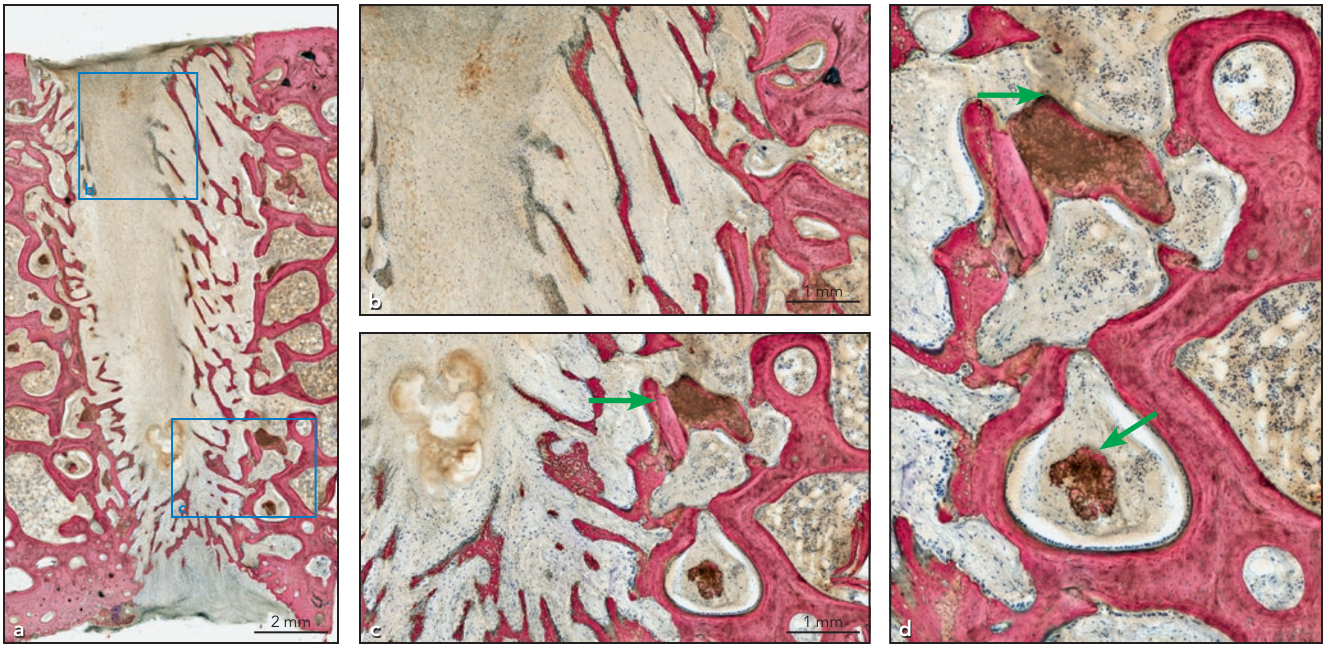

Fig 2 *Histologic image representing OD-CW instrumentation.* (a) *Overall view of the osteotomy created depicts the formation of an autograft bone wall around the osteotomy perimeter, with two primary regions of interest (ROI, blue boxes). Higher magnifications of* (b) *upper inset and* (c) *lower inset depict new bone formation occurring from the osteotomy's outer perimeter towards the center of the defect.* (d) *High-resolution inset of* (c) *zoomed in on the bone chips. The green arrows indicate a remaining bone chip. Samples stained with Van Geison's fuchsin and Stevenel's blue.*

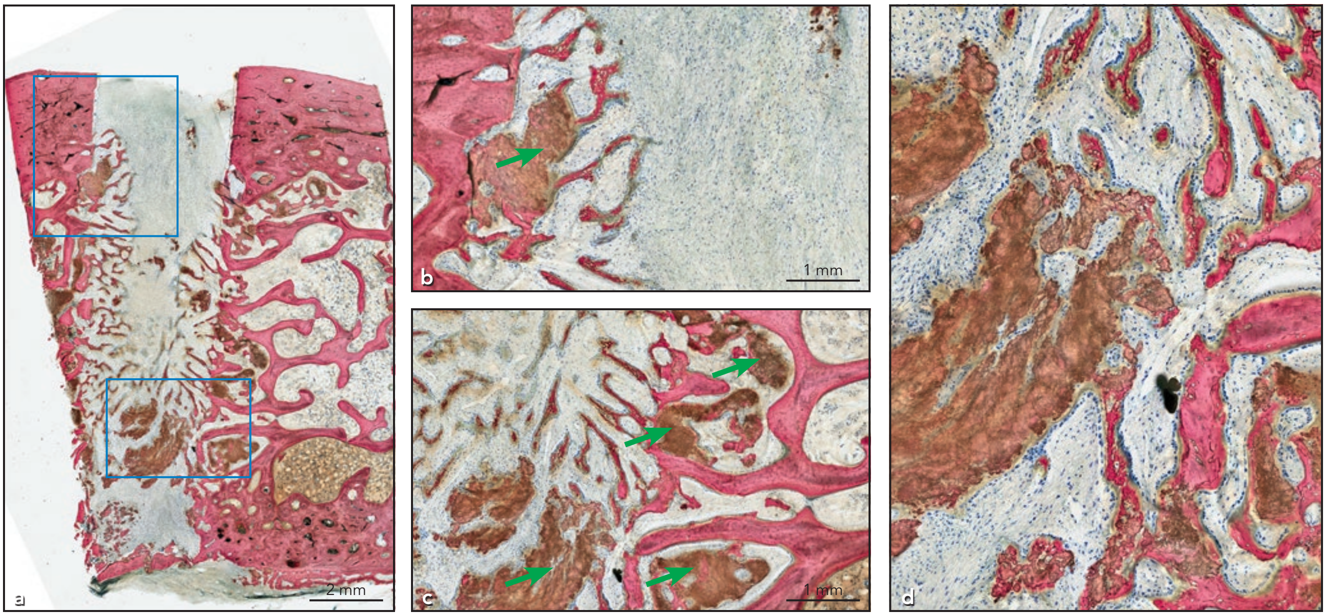

Fig 3 *Histologic image representing OD-CCW instrumentation.* (a) *Overall view of the osteotomy created depicts the formation of an autograft bone wall around the osteotomy perimeter, with two primary regions of interest* (ROI, blue boxes). *Higher magnifications of* (b) *upper inset and* (c) *lower inset depict new bone formation occurring from the osteotomy's outer perimeter towards the center of the defect.* (d) *High-resolution inset of the highlighted region in inset* (c) *focused on the remaining bone chips. The green arrows indicate a remaining bone chip. Samples stained with Van Gieson's fuchsin and Stevenel's blue.*

Discussion

While previous studies have based their investigations on analyzing OD and its effects on implant placement, the present work evaluated OD drilling effects on healing in empty osteotomies. The maintenance and compaction of autogenous bone during OD osteotomy preparation (drilled using the Densah bur in either the clockwise or counterclockwise orientation) has been shown to have a positive effect on scenarios where implant devices are in proximity of the densified bone walls, providing primary mechanical stability and accelerated healing.[3,17–19] The Densah bur design, when operated in the clockwise direction, allows for initial subtractive drilling, and once

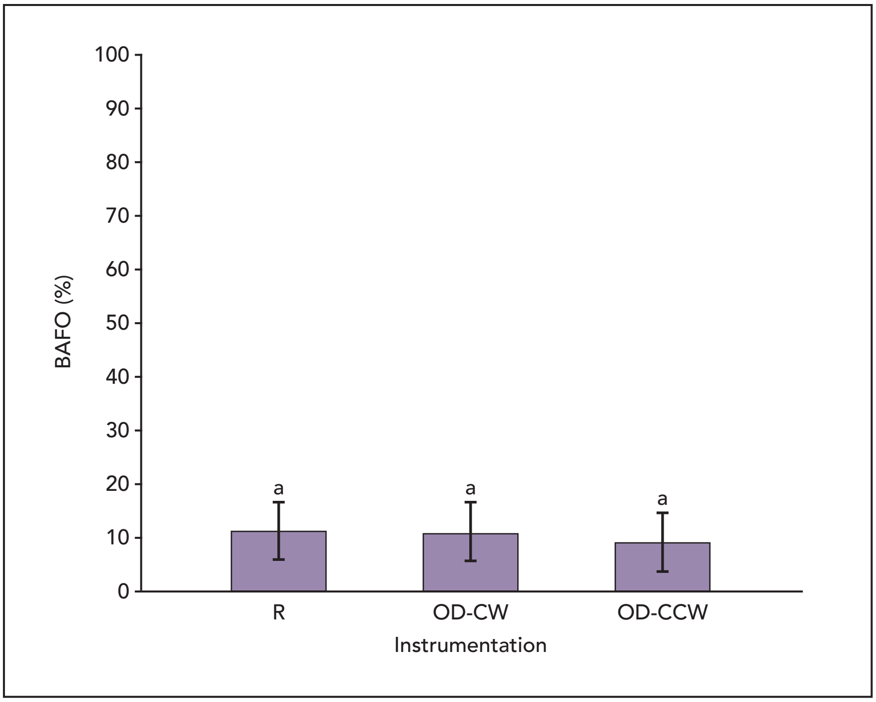

Fig 4 *Bar graph representing bone area fraction occupancy (BAFO) as a percentage of three drilling techniques (mean ± 95% confidence interval). Letters represent statistically homogeneous groups.*

its closed-ended flutes are filled with bone particles, densification takes place. Such an instrumentation method has been recommended by the manufacturer in high-density bone types in order to avoid excessive bone compression during instrumentation and due to high implant insertion torque. On the other hand, OD in the counterclockwise direction is recommended in low-density bone types, as the Densah bur design allows for additive instrumentation that is meant to create a bony wall for improved initial stability. The present study design aimed to address the degree of bone regeneration of the three drilling protocols, to validate the osteotomies' healing potential. Leaving the osteotomy 'open' permitted the authors to test the hypothesis that OD is not detrimental to healing at central regions of the defect.

Traditional subtractive drilling instrumentation has been utilized in an overwhelming majority of the literature pertaining to implant fixation.[20–23] Though subtractive drilling is widely utilized, it has limitations, such as when "excavating" bone leads to increased modeling time[11] and the loss of viable bone fragments at the bone-implant interface that bridges the gap between the implant bed and implant surface. The lessened volume of bone can potentially lead to a scenario where implant failure is more likely.

The results strongly indicate that the OD protocols had no negative influence on bone healing relative to the conventional protocol, and thus the hypothesis was accepted. The histologic outcomes (BAFO) of the control drilling were compared with OD-CW– and OD-CCW–drilled osteotomies. The results of histometric analyses, as indicated by the BAFO values, confirmed that there are no healing differences when utilizing different instrumentations. Additionally, from a histomorphologic standpoint, there was no indication of necrosis, inflammation, scarring, or dehiscence of bone present within the walls of the osteotomy, which further supports the fact that OD poses no harm to bone healing. The current study identified that bone healing and initial modeling/remodeling in the OD-CW and OD-CCW instrumentation were similar to the regular conventional drill. The data suggest that different drilling methods and techniques (ie, conventional vs OD) can generate similar bone growth patterns within the central regions of the osteotomy.

Conclusions

While the presented results, which are based on BAFO alone, are strongly indicative that OD drilling does not impair bone defect healing, the present study lacks shorter and longer endpoints, and supplementary analyses to qualitatively and quantitatively address healing pathways are warranted for further investigation.

Acknowledgments

The authors reported no conflicts of interest related to this study.

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