A Novel Osseous Densification Approach in Implant Osteotomy Preparation to Increase Biomechanical Primary Stability, Bone Mineral Density, and Bone-to-Implant Contact

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Purpose: *It is essential to have sufficient bone bulk and density at the implant site in order to achieve good bone-to-implant contact and primary stability, which are crucial for osseointegration. A new osteotomy preparation technique was recently introduced that uses a bone preservation method that creates a layer of compacted bone along the surface of the osteotomy. The hypothesis of this study was that this novel technique would increase primary implant stability, bone mineral density, and the percentage of bone at the implant surface compared with drilling technique.* ***Materials and Methods:*** *A total of 72 osteotomies were created in porcine tibial plateau bone samples using three preparation techniques: standard drilling; osseous extraction drilling with a new tapered, multi-fluted bur design; and osseous densification with the same multi-fluted bur rotating in a reversed direction that preserved and created a compacted layer of bone. The surgical process (temperature increase, drilling force, and torque), mechanical stability during the insertion and removal of 4.1-mm and 6.0-mm diameter implants (implant torque and stability quotient), and bone imaging (scanning electron microscopy, microcomputed tomography measurement of bone mineral density, and histomorphology) were compared among the three preparation techniques.* ***Results:*** *Osseous densification significantly increased insertion and removal torques compared to standard drilling or extraction drilling. No significant differences in implant stability quotient readings or temperature increases were demonstrated among the three groups. Although the same bur was used for extraction drilling and osseous densification techniques, the osseous densification osteotomy diameters were smaller than both the extraction drilling and standard drilling osteotomies due to the spring-back effect of bone elastic strain created. Imaging methods documented a layer of increased bone mineral density around the periphery of osseous densification osteotomies. The percentage of bone at the implant surface was increased by approximately three times for implants prepared with osseous densification compared with standard drilling.* ***Conclusion:*** *This study confirmed the hypothesis that the osseous densification technique would increase primary stability, bone mineral density, and the percentage of bone at the implant surface compared with drilling. By preserving bulk bone, it is hypothesized that the healing process will be accelerated due to the bone matrix, cells, and biochemicals that are maintained in situ and autografted along the surface of the osteotomy site. The healing response requires further study in vivo.* Int J Oral Maxillofac Implants 2016; (10 pages). doi: 10.11607/jomi.4817

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Endosseous implants have demonstrated success rates of more than 90% over the past 10 years[1] and implant stability is considered to be one of the most important factors in that success.[2] There are many factors that can affect initial biomechanical primary stability, such as the drilling or osteotome surgical preparation technique,[3,4] bone type and bone mineral density,[5] and the diameter, length, taper, threading, and surface design parameters of the implant.[6,7] Osseointegration is defined as a direct structural and functional connection between living bone and an implant surface and is considered a prerequisite for implant loading and long-term clinical success.[8] Two frequently cited factors affecting osseointegration are the direct bone-to-implant contact at the microscopic level[9] and the quality and quantity of the histologic structure of bone at the implant interface, which is strongly correlated with bone mineral density.[10] Increased primary stability and maintaining the bulk of bone mineral and collagen material has been shown to accelerate the healing process after surgery.[11–13] Therefore, it is important for endosseous implant success to preserve bone bulk and to maintain the bone's histologic structure during the preparation of an osteotomy.

Drilling is a widespread osteotomy preparation technique that involves the cutting and extraction of bone tissue to create a cylindrical osteotomy that will receive an implant fixture.[14] The medical profession has generally adapted commercially available instruments that have been developed for drilling in other materials.[15] Drills, sometimes called drill bits or burs, consist of a specified length and diameter shank. At the end there is a pointed chisel edge and cutting lips that extend to the outer diameter of the drill. The shank includes spiral guides called *lands* and channels called *flutes* that remove debris from the hole. Along each flute there is a secondary cutting edge that has a positive angle called the *rake* to remove a small thickness of material with the rotational pass of each flute. Twist drills designed for the most efficient cutting of bone usually have two or three flutes with cutting edges that have a 25- to 35-degree rake angle. However, the removal of bone during drilling can compromise implant fixation stability and pullout strength.[16] Bone drilling may also lead to other clinical complications, such as heat generation–induced necrosis if sufficient cooling and irrigation is not applied,[17] drill-tip skiving along the bone surface,[18] or vibration as the cutting resistance vector is constantly changing due to unhomogenous bone properties, which can compromise the geometric accuracy of the osteotomy.[19] For more than a decade, clinicians have been asking for improvement in bone drilling and preparation.[20]

Several techniques have been introduced to prevent bone tissue from being sacrificed during the osteotomy preparation process. The undersized preparation drilling technique has been shown to improve the early fixation of oral implants in both clinical and histologic studies[21,22]; however, this improvement did not translate directly to improved peri-implant bone volume[23] and did not allow an enhanced healing process.[24] Bone compaction utilizing the osteotome technique was introduced by Summers to increase the primary stability of dental implants without removing bone tissue[25] and is believed to improve final bone healing.[26,27] On the other hand, Buchter et al reported the osteotome technique led to decreased implant stability and related this effect to microfractures that were created in the peri-implant bone.[28] Stavropoulos et al also reported that the osteotome method had a deleterious effect on osseointegration.[3] Ridge expansion and spreading utilizing screw-type expanders are other reported techniques to expand bone and create an osteotomy without removing any bone stock but rather displacing it.[29] On the other hand, buccal plate fracture during this procedure may affect implant insertion stability.[30]

Osteotome techniques and undersized drilling have been shown to create a layer of compacted bone at the implant interface, which increases primary stability of low-density cancellous bone.[31,32,33] However, these techniques also present limitations during surgery. The repeated impacting of a mallet is required to advance the Summers osteotome, which is a traumatic technique that may be difficult for the surgeon to control and in some cases can result in unintentional displacement, fracture, or patient side effects such as vertigo.[34] Expander drills offer an atraumatic technique but may be cumbersome or difficult for the surgeon to use because the threading pattern creates direct coupling between feed rate and expansion rate, which limits the surgeon's control.

A new osteotomy preparation technique, osseous densification, has recently been introduced. This bone preservation technique is made possible with a specially designed bur that has many lands with a large negative rake angle, which work as noncutting edges to increase the density of the bone as they expand an osteotomy.[35] These densifying burs have four or more lands and flutes that smoothly compact the bone (Fig 1). Densifying burs are novel surgical devices as they are designed to have a cutting chisel edge and a tapered shank, so as they enter deeper into the osteotomy they have a progressively increasing diameter that controls the expansion process.[36] These burs are used with a standard surgical engine and can densify bone by rotating in the noncutting direction (counterclockwise at 800–1,200 rotations per minute) or drill bone by rotating in the cutting direction (clockwise at 800–1,200 rotations per minute).

This new technique's proposed method of bone compaction is through the application of controlled deformation due to rolling and sliding contact along the inner surface of the osteotomy with the rotating lands of the densifying bur. The bone deformation occurs through viscoelastic and plastic mechanisms when the load is controlled beneath the ultimate strength of bone. Copious amounts of irrigation fluid during this procedure provide lubrication between the bur and bone surfaces and eliminate overheating. A recommended technique is for the surgeon to utilize a bouncing motion of the bur in and out of the osteotomy, which will induce a pressure wave ahead of the point of contact. The irrigation fluid that is then forced into the osteotomy may also facilitate autografting of bone particles along the inner surface of the osteotomy. The autografting supplements the plastic bone compaction to further densify the inner walls of the osteotome.[34] The surgeon can safely control the osseous densification process because the bur-to-bone contact applies an opposing axial reaction force that is proportional to the intensity of the force applied by the surgeon. This gives the surgeon haptic feedback to control force based on the bone density that is encountered and to facilitate the strain-rate controlled plastic deformation that compacts the bone and expands the osteotomy.

The purpose of this study was to validate the biomechanical properties of osseous densification as a novel osteotomy preparation technique that a surgeon can use to safely and efficiently prepare low-density regions with a layer of compacted bone at the implant interface. The hypothesis was that osseous densification would increase primary stability, bone mineral density, and the percentage of bone at the implant surface compared with drilling with standard drills or drilling with the newly designed bur.

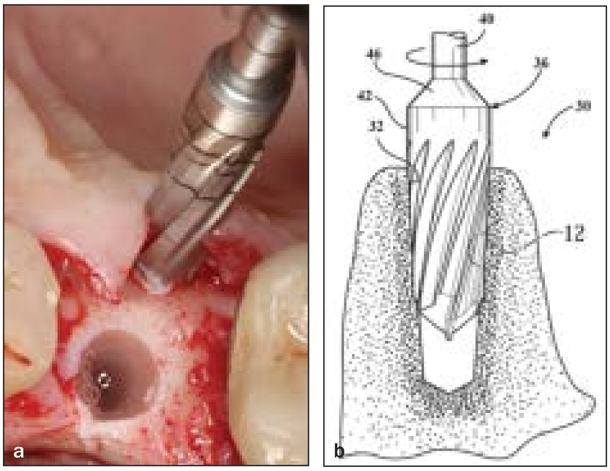

Fig 1 *(a)* The densifying bur preparation of an implant site in bone through osseous densification, a nonextraction technique that creates a layer of compacted bone along the surface of an osteotomy *(b)*, reprinted from Huwais[36] with permission).

MATERIALS AND METHODS

Experimental Design

Commercially available drills were used to prepare the implant osteotomy in the control group following standard drilling methods. This process included a five-step series starting with a 1.7-mm pilot drill and followed by twist drills that had a tapered design and maximum diameters of 2.2, 3.2, 4.2, and 5.2 mm. For the experimental groups, a series of new, multi-fluted tapered burs (Densah, Versah) with maximum diameters of 2.8, 3.8, 4.8, and 5.8 mm (Fig 1) were used. In the first experimental group, the implant osteotomy site was prepared by osseous extraction drilling by operating the surgical motor in a clockwise direction (cutting mode) to remove bone in a manner analogous to a standard rotary drill. In the second experimental group, the implant osteotomy site was prepared by osseous densification with the same burs running in a reversed, counterclockwise direction that did not extract bone (densifying mode).

Specimens

A total of 72 implant sites were prepared in 12 porcine tibial plateau bone samples. The bone samples were prepared by removing the articular surface and subchondral bone layers (approximately 15-mm thickness) to expose the cancellous bone. They were mounted in epoxy potting. Groups of three osteotomies (anterior, central, and posterior) randomized for each of the osteotomy preparation techniques were aligned in rows on the medial and lateral sides of the proximal tibias with a minimum spacing of 6 mm between osteotomies (Fig 2).

Osteotomy Procedure

Precisely controlled and quantified procedures were used to create osteotomy sites for the insertion of straight original design Brånemark implants. The bone samples were mounted in a custom clamping system and attached to a materials testing system (ElectroPlus E10000, Instron) (Fig 2). A surgical drilling mechanism with irrigation, controllable motor speed, and a torque limiter (WS-75, Biomet 3i) was mounted to the crosshead of the materials testing system. A biaxial load cell (Dynacell, Instron) was used to measure the maximum applied force and torque during the osteotomy preparation procedures. Five steps, each of a different diameter, were used to progressively enlarge the osteotomies. The materials testing system was programmed for displacement control with a cyclic constant linear rate into and back out of the osteotomy at six progressive depths until the target depth of 14 mm was achieved (Fig 3). Heat generation was measured during the osteotomy preparation procedures by inserting a thermocouple into the bone, approximately 1 mm away from the edge of the final osteotomy diameter (Fig 2).

Biomechanical Stability

The primary stability of 4.1-mm and 6.0-mm implants (11-mm length) were compared between groups (n = 8) by measuring the insertion and removal torques with the load cell and implant stability quotient with a resonance frequency analysis system (Osstell). After the third diameter step osteotomy was completed, a 4.1-mm diameter implant was inserted into the osteotomies. Then the 4.1-mm implant was removed and the progressive osteotomy enlargement continued,

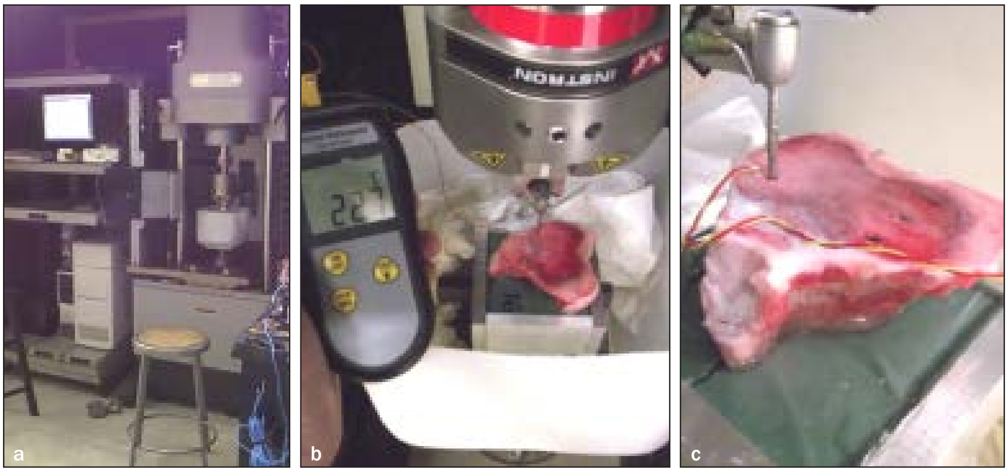

Fig 2 *(a)* Materials testing machine setup. *(b)* Potted bone sample and drill motor installed in custom fixtures and temperature probe installed in bone adjacent to the drilling site. *(c)* Location and spacing of implant sites across the tibial plateau.

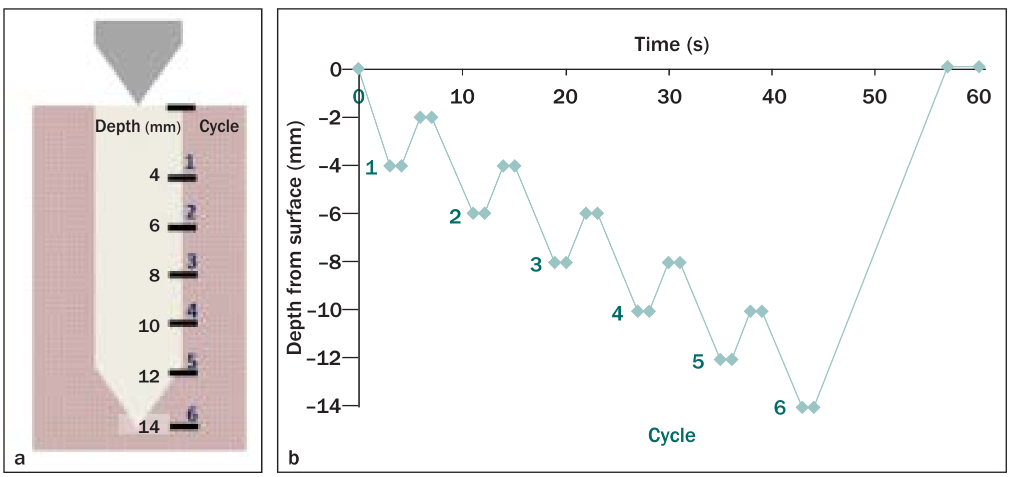

Fig 3 Materials testing machine program for creating a 14-mm osteotomy using the clinical bouncing technique with six cycles completed at progressive depths with a 1-mm/sec linear rate and 1-second pause at each minimum and maximum depth.

followed by the insertion of the 6.0-mm implant and biomechanical stability measurement.

Microcomputed Tomographic Imaging

Osteotomy preparations were created in eight additional tibia specimens with similar procedures, but the drilling process was halted at each of the progressive diameter steps without insertion of an implant. These specimens were used to determine the densified crust thickness increase between each diameter step. The morphology and density of the bone was imaged using microcomputed tomography. High-resolution slices were aligned along the axis of the osteotomies with a voxel resolution of 90 µm. Regions of interest were selected and the bone mineral density was quantified as a function of distance from the edge of the osteotomy and depth using Microview software (Parallax Innovations). The diameter of the osteotomies and crust thicknesses at the coronal and apical depths were measured with or without spacers inserted immediately after the osteotomy preparation.

Histomorphology

Morphologic characterization of the compacted bone was conducted using histology. Nondecalcified samples with 4.1- or 6.0-mm implants inserted into sites created with each osteotomy preparation technique were sectioned along the center axis through the implant and processed for histology. The slices were stained with toluidine blue and microradiographs were also created from each section. Images were obtained with optical microscopy at ×10 and ×50 magnification. The crust thickness and mean percentage of bone in contact with the implant was measured with ImageJ software (National Institutes of Health) along the entire length of the implant surface and at the apex from the ×50 images.

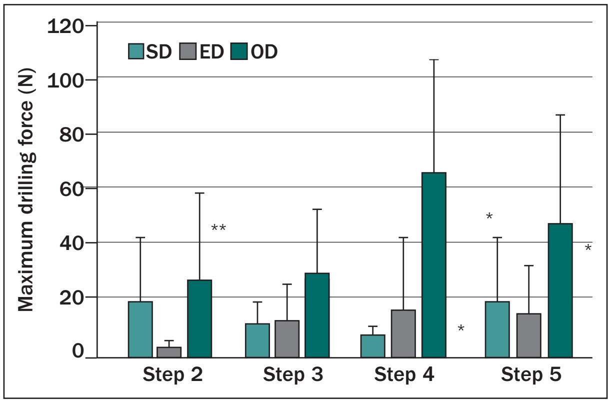

Fig 4 Measured maximum penetration force during each drilling step. *Significantly different than osseous densification (OD) and different than extraction drilling (ED) based on a one-way ANOVA. SD = standard drilling.

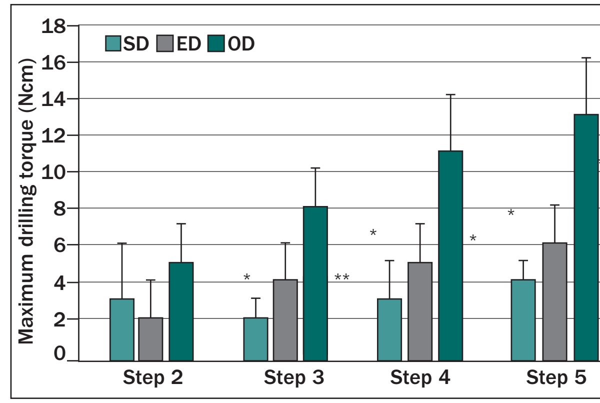

Fig 5 Measured maximum torque during each drilling step. *Significantly different than osseous densification (OD) and different than extraction drilling (ED) based on a one-way ANOVA. SD = standard drilling.

Statistical Comparisons

Quantitative biomechanical and temperature data are expressed as mean ± standard deviation and are based on groups with three samples each. Differences in temperature, drilling force, or drilling torque at each diameter step and differences in the insertion or removal torque of each diameter implant were compared among groups with one-way analysis of variance (ANOVA) statistical comparisons with Bonferroni post hoc tests. A level of $P > .05$ was considered significant.

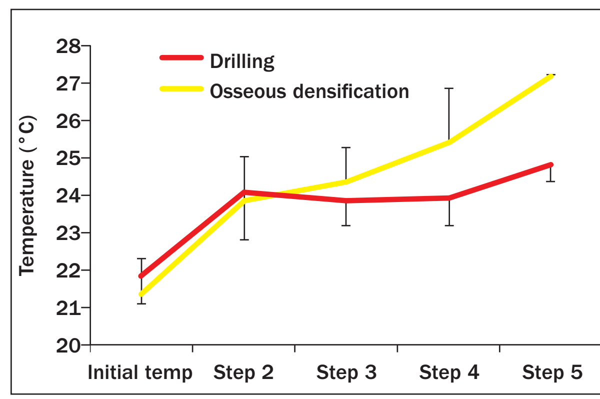

Fig 6 Mean and standard deviation of the temperature during the drilling and osseous densification techniques at each diameter step.

RESULTS

Osteotomy Procedure

During the drilling process with various diameter steps, the osseous densification technique was shown to increase the required penetration force and torque compared to standard drilling and extraction drilling (Figs 4 and 5). Force and torque during osseous densification was somewhat correlated with the expansion-step diameter so that the higher values occurred during the last two steps. There were few differences in the drilling force and torque between the standard drilling and extraction drilling techniques, which also had little correlation with the diameter steps. The two drilling techniques produced an increase of approximately 3°C for step 5 (Fig 6). Although osseous densification produced higher maximum temperatures than drilling, the maximum temperature increase of step 5 was also limited at approximately 6°C.

During standard drilling and extraction drilling there were substantial bone particulates that were washed out of the osteotomies by the irrigation fluid and bone material that remained in the flutes of the drills when they were removed from the osteotomy. On the other hand, little bone material was excavated from the osteotomy by either of these mechanisms during the osseous densification technique.

Biomechanical Stability

The osseous densification insertion and removal torques were significantly increased for both implants compared to standard drilling or extraction drilling (Fig 7). The maximum osseous densification insertion torque for the 4.1-mm implant was 49 ± 24 Ncm and for the 6.0-mm implant was 108 ± 56 Ncm, which were approximately double the insertion torques of the standard drilling and extraction drilling techniques. The maximum osseous densification removal torques for 4.1-mm and 6.0-mm implants were 31 ± 17 Ncm and 85 ± 49 Ncm, respectively, which were also more than double the removal torques of the standard drilling and extraction drilling techniques. There were no significant differences in implant stability quotient measurements between groups.

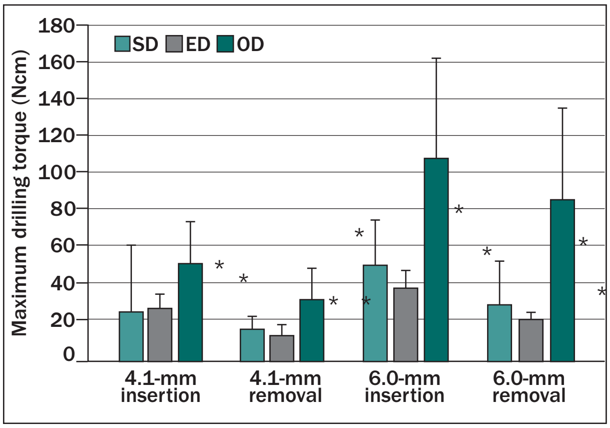

Fig 7 Measured maximum 4.0-mm and 6.1-mm implant insertion and removal torques. *Significantly different than osseous densification (OD) based on a one-way ANOVA. SD = standard drilling; ED = extraction drilling.

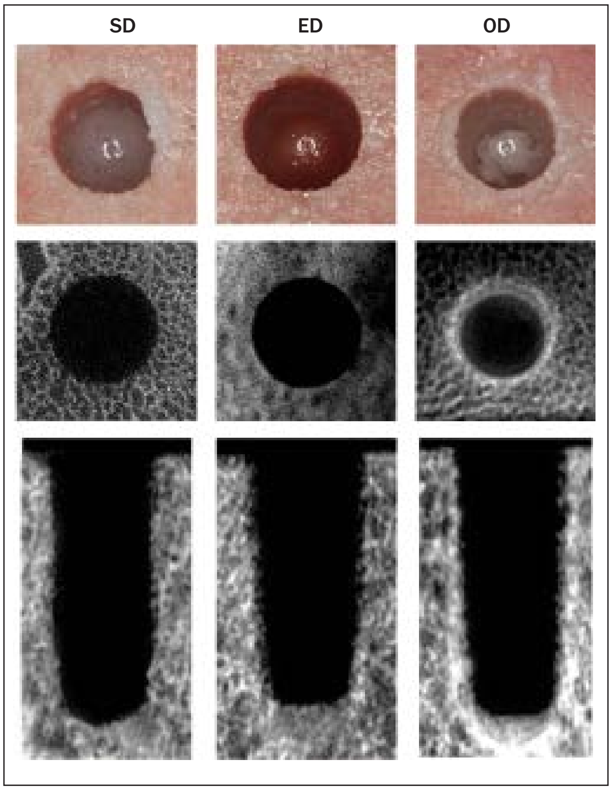

Fig 8 *(a)* Surface view of 5.8-mm standard drilling (SD), extraction drilling (ED), and osseous densification (OD) osteotomies. *(b)* Microcomputed tomography midsection and *(c)* cross section.

μCT Imaging

Although the Densah burs had larger diameters (4.8–5.8 mm from apex to top for the largest step) than the standard bur (4.2–5.2 mm), the diameters of the osseous densification osteotomies were approximately 0.5 mm smaller than standard drilling osteotomies. There were also slight differences between diameters of osteotomies created with the extraction drilling and osseous densification techniques, even though the same bur was used for both procedures. The smaller osteotomy diameters of the osseous densification technique demonstrates that elastic strain recovery occurs after this osteotomy preparation technique when the bur is removed from the osteotomy.

There was a crust of compacted bone with increased bone mineral density around the periphery of osseous densification osteotomies, but relatively constant bone mineral density around osteotomies created through drilling (Fig 8). Prior to insertion of the implant the crust of increased bone mineral density around the periphery of osseous densification osteotomies was 0.1 to 0.3 mm along the edges and 0.5 to 1.0 mm at the bottom. After insertion of the implant or a spacer, the bone mineral density was increased around the periphery of osteotomies created by all the osteotomy preparation techniques. After implant insertion the crust thickness of the osseous densification osteotomies was increased to 0.4 to 0.9 mm along the edges of the implant, while the standard drilling osteotomies had a crust of 0.2 to 0.6 mm.

HISTOLOGY

Bone morphology at the implant interface was imaged by staining histologic sections with toluidine blue and with microradiographs (Fig 9). These images show that the percentage of bone at the implant surface was increased with the osseous densification technique compared to drilling. Mean bone percentage went from 26% to 72% for the 4.1-mm implant and from 22% to 64% for the 6.0-mm implants prepared with standard drilling versus osseous densification, respectively. The osseous densification technique autografted bone particles into the trabecular pores along the walls and at the bottom of the osteotomy.

DISCUSSION

This study demonstrates that the osseous densification technique increases primary stability and the percentage of bone at the implant surface by creating a crust of increased bone mineral density around the osteotomy site. The implants placed into osseous densification osteotomies had significantly increased insertion and removal torques. Although penetration forces and torques during osseous densification were slightly increased compared to drilling, this study demonstrated that this new osteotomy technique is clinically similar to drilling. There were relatively small increases in temperature when irrigation and a bouncing surgical method were used, demonstrating that this technique is safe.[17]

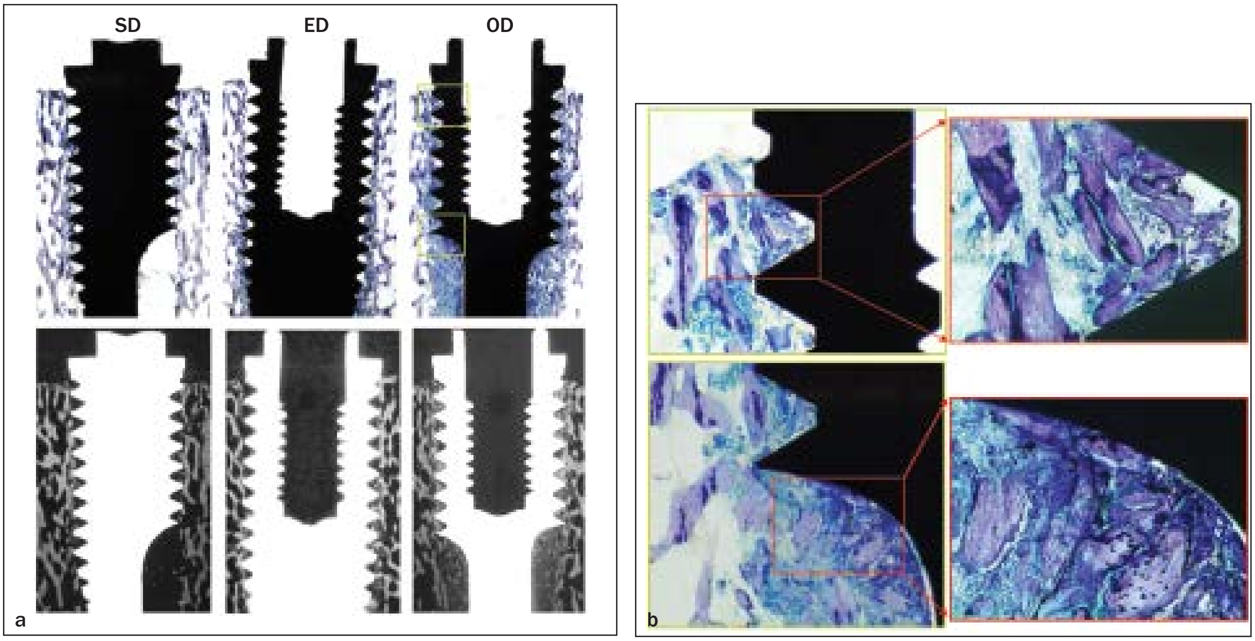

Fig 9 *(a)* Histology sections of standard drilling (SD), excavation drilling (ED), and osseous densification (OD) osteotomies stained with toluidine blue (×10). *(b)* Microradiograph sections of the same implants. Higher magnification (×50 and ×100) histology at the bone surface and apical crust regions near the osseous densification implant.

The osseous densification preparation technique preserves bone bulk in two ways: compaction of cancellous bone due to viscoelastic and plastic deformation, and compaction autografting of bone particles along the length and at the apex of the osteotomy. There are other, previously discussed osteotomy techniques that compact bone through deformation, and impaction autografting has been used to improve stability of total hip replacements.[37] The philosophy of these techniques runs counter to the outcome of bone drilling, that healthy bone should be maintained, especially in regions where the density is already compromised.

The quality and quantity of bone at the implant interface is linked to the success rate of osseointegration.[10] The mechanical properties of bone are related not only to mineral density but also to the architectural distribution and collagen integrity.[38] Collagen gives bone its toughness and its ability to dissipate energy[39]; therefore, collagen integrity has been found to be directly linked to bone plasticity.[40] The plastic deformation of bone occurs as a gradual change that is dependent on time and strain rate.[41,42] The fluid content of bone also plays an important role in determining bone viscoelasticity.[43] Osseous densification is essentially a burnishing process that redistributes material on a surface through plastic deformation.[44] The bur's counterclockwise rotation causes the lands to slide across the surface of the bone with a compressive force less than the ultimate strength of the bone. Since fresh, hydrated trabecular bone is a ductile material, it has a good capacity for plastic deformation. The irrigation fluid and fluid content of the bone help this process by creating a lubrication film between the two surfaces to reduce friction and more evenly distribute the compressive forces.

Osseous densification was shown to increase the percentage of bone at the implant surface by increasing the bone mineral density in the peri-implant region. Bone compaction has been shown by many studies to improve early fixation stiffness and strength of dental implants[25,31,32] and in other orthopedic applications.[37,45–47] The osteotome and other compaction techniques have been shown to increase the density of cancellous bone,[26,47] allowing for a larger surface area of interdigitation with the implant[31,33] and therefore higher frictional resistance as measured by the insertion torque.[48] Compacted bone has been shown to maintain its histologic structure, which is directly linked to increased bone-to-implant contact[10] and increased primary stability.[49]

Implant stability depends on direct contact between the implant surface and the surrounding bone so that micromotions at this interface are reduced. The amount of micromotion is determined by the bone density around the implant.[50] In low-density bone, as was investigated in the current study, drilling procedures that remove bone inevitably lead to low insertion torques and further reductions in bone mineral density. In these cases, early loading of the implant will cause micromotion and may lead to a failed bone healing response.[51] Cancellous bone stiffness and strength are proportional to bone mineral density.[52] With reduced bone mineral density there is a higher risk that the remaining bone will reach or exceed the bone's microdamage threshold. If microdamage does occur, the bone remodeling unit may require 3 or more months to repair the damaged bone area.[53] On the other hand, bone compaction techniques have been shown to increase insertion torque and bone density and therefore reduce micromotion.[54] While there is an inverse correlation between insertion torque and micromotion,[55] in soft bone Trisi et al were not able to achieve more than 35 Ncm of peak insertion torque.[54] In the current study, osseous densification increased the insertion torque with a 4.1-mm implant to approximately 49 Ncm, up from approximately 25 Ncm with the standard drilling technique. The percentage increase in insertion torque of the 6.0-mm implant was even greater with osseous densification versus drilling. High insertion torque is particularly important in achieving a good clinical outcome with early or immediate loading.[56]

The spring-back effect has been documented as a response of compacted bone that reduces the osteotomy to a smaller diameter when the osteotome is removed.[57] In the current study, when the osseous densification osteotomy was left empty during microcomputed tomography imaging, the diameter was reduced to approximately 91% of the bur diameter. While much of the compaction of cancellous bone is permanent deformation that occurs due to its plastic behavior when loaded beyond the yield point,[58] the spring-back is due to the viscoelastic portion of the deformation.[57] Viscoelasticity is a time-dependent process, so in order to achieve bone compaction of this nature, it is necessary to apply stress in a time-controlled manner.[43,59] Osseous densification occurs in a slow, incremental process that is carefully controlled by the surgeon, in contrast to the impaction process of Summer's osteotome. The viscoelastic recovery of the osteotomy demonstrates that there are residual strains created in the bone's surface during this preparation technique. The residual strain in the bone creates compressive forces against the implant, therefore increasing the bone-to-implant contact and primary stability,[31,57] which have been shown to promote osteogenic activity through a mechanobiologic healing process.[60] This reverse compression applied to the implant by the bone is also likely responsible for the much higher removal torques that were generated with osseous densification compared to drilling. High insertion torque is an indication of good primary stability and is necessary to achieve early or immediate loading.[61] Other studies that placed implants into compacted bone have shown that increased primary stability and bone-to-implant contact leads to improved bone healing.[12,26]

This study was designed to validate the osseous densification technique's improvements in bone biomechanics in vitro. The porcine tibia cancellous bone that was used in this study represents a tissue model that was somewhat homogenous with a simple geometry. However, it does not represent the anatomical shape of the mandible or maxilla and had no cortical bone layer. Only one implant design, the straight Brånemark implant, was investigated. This implant design was chosen for this study because its gross geometry did not contribute to increased primary stability, as might be the case with more advanced tapered implants. The drilling depth of 14 mm was set to eliminate the possibility that the implant would bottom out, which might have influenced the insertion torque and implant stability quotient measurements. The pumping method in this study was precisely controlled by a materials testing machine, as opposed to the clinical scenario when a surgeon will have the flexibility to control the applied pressure and therefore the rate at which the osseous densification process occurs. The surgical process' parameters, such as drilling speed, torque, force, feed rate, and heat generation, as well as bleeding and other factors, may also affect the healing process in vivo. Further in vivo investigations are required to address how the increased primary stability, autografted bone particles, and compacted bone will affect healing response during the implant's transition from primary to secondary stability.

CONCLUSIONS

This study confirmed the hypothesis that the osseous densification technique would increase primary stability, bone mineral density, and the percentage of bone at the implant surface compared with drilling technique. Osseous densification was shown to increase the insertion and removal torques of the implants compared to standard drilling and extraction drilling. This demonstrates increased implant primary biomechanical stability.[54] The new technique was also shown to have similar clinical safety to drilling when proper rotary speed, penetration speed, and irrigation are used. Trabecular bone compaction produced during the osseous densification technique created a smaller osteotomy than drilling due to spring-back recovery of viscoelastic deformation when the bur was removed from the osteotomy. The bone mineral density of the osseous densification sites were increased by both compaction and autografting bone along the periphery and at the apex of the osteotomies. The percentage of bone at the implant surface was similarly increased in the osseous densification sites compared with standard drilling and extraction drilling. By preserving the bone bulk with the osseous densification technique, it is hypothesized that the healing process will be enhanced due to the autografted bone matrix, cells, and biochemicals along the osteotomy site. Further histologic healing investigations are needed to test and examine this hypothesis.

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