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ROLE OF OSSEODENSIFICATION TECHNIQUE IN MANDIDULAR RIDGE EXPANSION (CLINICAL TRIAL)

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ABSTRACT

BACKGROUNd: Osseodensification is a means of biomechanical site preparation. It results in low plastic deformation which preserves the bone, enhances healing and shortens the healing period

OBJECTIVE: Evaluate osseodensification effect for implant site preparation in mandibular narrow ridges using Densah burs in a non-cutting anti-clockwise direction on increasing bone density and ridge width.

MATERIAL AND METHODS: This trial is a clinical trial in which fourteen subjects (30-44 years) with missing mandibular teeth had their implant sites prepared using Densah Bur in an anti-clockwise non-cutting direction. Bone width and density were gauged by using cone beam computed tomography (CBCT) scan before, immediately postoperative and after 4 months. ANOVA with repeated measures and Paired t-tests were used for statistics.

RESULTS: Immediate postoperative bone width increased by 45.16%, 19.72%, 8.51% and 22.27% in the cervical, middle, apical parts and in average, respectively (P<0.001). Four months postoperative bone width increased by 43.92%, 18.72%, 8.51% and 21.66% in the cervical, middle, apical parts and in average, respectively (P<0.001). Bone density increased 10.3% immediately postoperative (P=0.212) and 15.06% after 4 months (P<0.001).

CONCLUSION: Osseodensification technique is effective in increasing ridge width and bone density when used for implant site preparation in mandibular narrow ridges.

DENTAL Implants, Ossseodensification, Mandibular ridge, Densah burs

KEYWORDS: Dental Implants, Ossseodensification, Mandibular ridge, Densah burs

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INTRODUCTION

Success of dental implants is elevated when they are surrounded by sufficient bone. A minimum width of 1mm of bone crest surrounding the implant is necessary to obtain optimal osseointegration and a satisfactory treatment outcome. However, severe and unpredictable ridge resorption frequently occur following a long-standing period after tooth loss which consequently results in extreme difficultly to successfully insert dental implants (1).

Standard drills penetrate into bone efficiently, however, they do not generate a clear-cut circumferential osteotomy where osteotomies might become lengthened and ovoid due to the resultant chatter of those drills. In such instances, implant insertion torque is lessened leading to reduced primary stability and consequently to compromised integration. Moreover, osteotomies that are drilled into areas of narrow bone could result in dehiscence, either on the buccal or lingual aspects, which as well compromises the primary stability and may render bone grafting a must-do procedure. This consequently adds to the costs of the provided treatment as well as the time required for proper healing (2).

Osseodensification is a means of biomechanical site preparation. The non-extraction ridge preparation using osseodensification results in little plastic deformation and consequently conserves the bone. Osseodensification does not scoop out bone tissue contrasting in this matter the conventional drilling systems, instead, it conserves bone substance so that bone tissue is compacted and at the same time autografted in an outwardly expanding direction to create the osteotomy. Accordingly, healing is enhanced, and the healing period is shortened. It is achieved through using trademarked densifying burs that are rotated at a high speed in a non-cutting, reversed direction -known as densifying mode- (3). The descendent surgical force combined with continual irrigation create a temperate compression movement inside the osteotomy that together with the fluting, produce a densified film and plastically expanding the bony ridge. Therefore, a compact layer of bone tissue is established throughout the walls and base of the osteotomy (4).

Concerning ridge enhancement before implant placement, osseodesification has by far been providing promising results, however, till present, research in this area is still lacking. The objective of this trial was to assess the influence of osseodensification for implant site preparation in mandibular narrow ridges using Densah burs in a non-cutting anti-clockwise direction on increasing bone density and ridge width.

MATERIAL AND METHODS

Study design and ethical considerations: This study is a clinical trial with that was conducted after obtaining ethics approval from the Research Ethics Committee (22/1/2017- IRB#: 00010556- IORG#: 0008839), Faculty of Dentistry - Alexandria University, Alexandria, Egypt. Subjects received an explanation of the study's nature then signed 'informed consent' stating that they were willing to participate in the study with an intention of commitment to the follow up appointments.

Sample size estimation: Sample size estimation was made in the Medical Research Institute- Alexandria University using http://powerand sample size. com/Calculators/Compare -2-Proportions/2-Sample-Equality. Upon on the calculations made, initially, a total of 12 subjects represented the required sample for this study. The sample size was then increased to 14 subjects to make up for possible dropouts (5).

Participants: Fourteen adult patients of both genders with missing mandibular teeth were chosen from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry- Alexandria University, in the period between January and November 2018. A patient was considered eligible for the study if he/she matched the following criteria:

Inclusion criteria: Age range 20-50 years; Missing mandibular teeth; Edentulous area should have a minimum of six months healing following extraction; Narrow ridge according to Misch and Judy (6) classification (1987) (B+/-w) as measured from the CBCT; Good oral hygiene; Sufficient interocclusal space; Adequate regenerated gingival tissue.

Exclusion criteria: Inadequate horizontal or vertical space for prosthesis; Acute infection at edentulous site; Sites that would require a bone graft; Parafunctional habits; Uncontrolled systemic illnesses that might affect implant success (Such as uncontrolled diabetes or osteoporosis); Current receiving of chemo/radio therapy; Consumption of medications that might influence bone turnover or mucosal healing (steroids, bisphosphonates); Periodontal diseases; Osteoporosis; Heavy smoking (10 or more cigarettes per day); Alcohol/drug addiction; Pregnancy, breastfeeding or women on oral contraceptives; inability to commit to follow-up appointments.

Intervention: (Figure 1)

Presurgical phase: Personal data, medical history and dental history -including cause of extraction- were all collected and recorded. Extra and intra oral clinical examination were done to exclude any swelling, asymmetry, malocclusion, ulcerations, hypertrophy or draining sinuses (7). Full mouth scaling was done, then finally, preoperative photographs were taken, and Cone Beam Computed Tomography (CBCT) was made to determine preoperative ridge width (8).

Surgical phase: Infiltration anesthesia using 1.8 ml 4% of Septocaine with 1:100,000 epinephrine (Septodont); crestal incision with reflection of complete thickness flap to expose 2.5 - 3 mm of the crestal alveolar ridge (verified by direct measurement) ; marking the implant site ; creating a preliminary pilot osteotomy with a pilot drill mounted on a surgical handpiece and motor through clockwise spinning at a speed of 900-1200 RPM reaching full depth; radiographs using paralleling pins to confirm the angulation between implants and adjacent teeth; expanding the osteotomy using DENSAH™ Bur VT2535 (Versah, LLC) in a non-cutting manner in an anti-clockwise direction at a speed of 900-1200 RPM-densifying mode- (9); placing the implant 3,6 mm diameter (Dentium Co Ltd); flap closure using absorbable Vicryl (000) surgical sutures (Johnson & Johnson - USA) (10). (Figure 2)

Postsurgical phase

Postoperative instructions and medications: Subjects were informed to avoid mouth rinsing, hot foods and/or drinks for twenty-four hours after surgery and were advised to use cold packs immediately for 8 hours postoperative (20 minutes application and 20 minutes off). Subjects were also prescribed an antibiotic containing amoxicillin with clavulanic acid□ (Augmentin, Galaxosmithkline- Australia) 1000 mg every 12 hours for 7 days and a non-steroidal anti-inflammatory drug of 50 mg potassium diclofenac (Cataflam, Novartis pharma-Switzerland) three times each day for 5 days (11, 12).

Wound healing: After one week, removal of sutures and wound examination to exclude any signs of infection, inflammation, wound dehiscence or hardware exposure (13).

Radiographic evaluation: CBCT was done immediately postoperative and after 4 months (8). Bone density assessment was done using grey scale from CBCT Ondemand program. (Figure 3)

Final prosthesis: After four months: The cover screw was disconnected, and healing abutment was made tighter to help gum tissue around the implant site heal faster. After six months: Healing abutment was removed and dual abutment was tightened, also, an addition silicone impression material was used to make impression. Finally, a porcelain fused to metal crown was delivered to all subjects.

Statistical analysis: The IBM SPSS software version 20.0 (Armonk, NY: IBM Corp) was used for analyzing data. For Qualitative data, representation was done through number and percentage. Kolmogorov-Smirnov test was used to confirm normal distribution. Quantitative variables were demonstrated using mean, standard deviation, range, median and interquartile range. Level of significance was judged at P value≤ 0.05. Repeated ANOVA and paired t-tests were appropriately used to detect changes occurring over time.

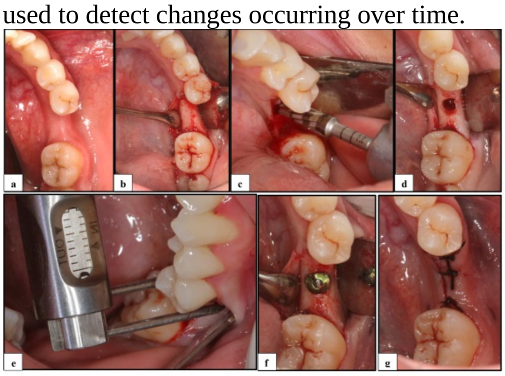

Figure 1: a: Pre-surgical clinical assessment. b: Full-thickness flap reflection to expose the surgical site using a sharp periosteal elevator. c: Implant site preparation using Densah Burs (rotating counter-clockwise direction in densifying mode). d: Implant site prepared using Densah Burs. e: Gauge caliber after osseodensification. f: Implants placed with cover screws. g: Single interrupted sutures after implant placement

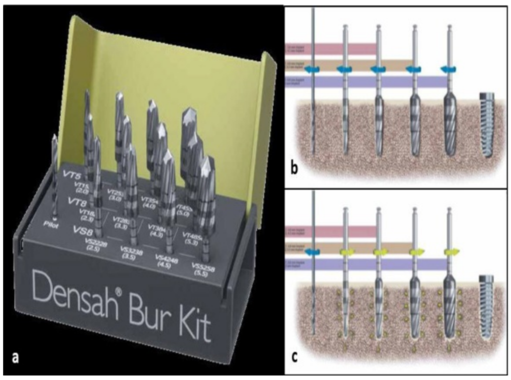

Figure 2:a: The complete kit of 13 Densah drills. b: The Densah drills will cut when run in a clockwise direction at 800-1,500rpm. c: Running the drills counter-clockwise produces the densification effect

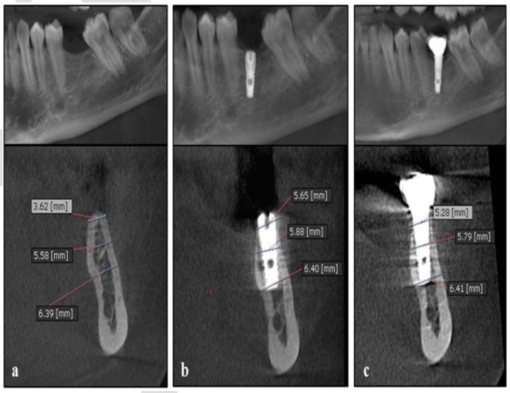

Figure 3: a: Pre-operative CBCT. b: Immediate post-operative CBCT. c: 4 months post-operative CBCT.

RESULTS

Demographics: Fourteen patients aging 30-44 years with mean age (36.0 ± 4.72) of both genders (7 males and 7 females) represented the study sample. (Table 1)

Outcome assessment:

Bone width (cervical area): Comparing to baseline measurements, a significant increase in the bone width was seen immediately postoperative as well as after 4 months by 45.16% and 43.92%, respectively (P<0.001). There was no statistically significant difference between cervical bone width immediately after implant placement and 4-months after (P=1.000). (Table 2)

Bone width (middle area): Comparing to baseline measurements, there has been a significant increase in the bone width immediately postoperative as well as after 4 months by 19.72% and 18.72%, respectively (P<0.001). However, on comparing the bone width measurements in the middle area after 4 months to measurements immediately after implant placement, a significant decrease was noted by 0.83% (P=0.004). (Table 2)

Bone width (apical area): Comparing to baseline measurements, a significant increase in the bone width was seen immediately postoperative as well as after 4 months by 8.51% for both time points (P<0.001). There was no statistically significant difference between apical bone width immediately after implant placement and 4-months after (P=1.000). (Table 2)

Average bone width: Comparing to baseline measurements, a significant increase in the average bone width was seen immediately postoperative as well as after 4 months by 22.27% and 21.66%, respectively (P<0.001). Changes in average bone width immediately after implant placement and 4-months after were not significant (P=0.627). (Table 2)

Bone density: Comparing to baseline, bone density has increased immediately postoperative by 10.3%, however this increase was insignificant (P=0.212). There has been an increase in the bone density after 4 months by 15.06% compared to preoperative measurements. Such increase was significant statistically (P<0.001). (Table 3)

Table 1: Distribution of the studied cases according to demographic data (n=14).

Demographic data	No.	%
Sex		
Male	7	50.0
Female	7	50.0
Age (years)		
<35	7	50.0
≥35	7	50.0
Min. – Max.	30.0 – 44.0	
Mean ±SD.	36.0 ±4.72	
Median (IQR)	35.50 (32.0 – 40.0)	

Table 2: Changes of cervical, middle, apical and average bone width over time compared to baseline.

	Bone Width			**F**	**p**
	Pre-operative	**Immediate**	**4-months**		
Cervical					
Min. – Max. Mean ± SD. Median (IQR)	3.31 – 4.91 4.03 ± 0.56 4.0 (3.52–4.69)	5.21 – 6.72 5.85 ± 0.40 5.85 (5.61–6.11)	5.09 – 6.82 5.80 ± 0.52 5.72 (5.42–6.06)	210.567*	<0.001*
Sig. bet. periods	p_1<0.001*, p_2<0.001*, p_3=1.000				
Middle					
Min. – Max. Mean ± SD. Median (IQR)	3.90 – 6.61 5.02 ± 0.90 4.85 (4.31–5.82)	4.91 – 6.91 6.01 ± 0.68 6.16 (5.42–6.71)	4.82 – 6.89 5.96 ± 0.69 6.12 (5.42–6.69)	103.603*	<0.001*
Sig. bet. periods	p_1<0.001*, p_2<0.001*, p_3=0.004*				
Apical					
Min. – Max. Mean ± SD. Median (IQR)	4.20 – 7.60 5.76 ± 1.09 5.32 (5.02–6.71)	4.98 – 7.68 6.25 ± 0.88 6.07 (5.82–6.92)	4.91 – 7.82 6.25 ± 0.93 6.06 (5.81–6.89)	21.839*	<0.001*
Sig. bet. periods	p_1=0.001*, p_2=0.001*, p_3=1.000				
Average					
Min. – Max. Mean ± SD. Median (IQR)	3.80 – 6.31 4.94 ± 0.83 4.72 (4.27–5.81)	5.18 – 7.05 6.04 ± 0.62 6.12 (5.62–6.47)	5.09 – 7.09 6.01 ± 0.66 6.03 (5.52–6.43)	141.776*	<0.001*
Sig. bet. periods	p_1<0.001*, p_2<0.001*, p_3=0.627				

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using Post Hoc Test (adjusted Bonferroni)

p: p value for comparing between the three studied periods

p_1: p value for comparing between Pre-operative and Immediate

p_2: p value for comparing between Pre-operative and 4 months

p_3: p value for comparing between Immediate and 4 months

*: Statistically significant at p ≤ 0.05

Table 3: Changes in bone density over time compared to baseline

Bone density	Pre-operative	Immediate	4 months	t	p
Min. – Max.	550.0 – 1112.0	632 – 1160	689.0 – 1203.0		
Mean ± SD.	778.57 ± 187.31	867.96 ± 182.44	895.86 ± 184.44	22.565*	<0.001*
Median (IQR)	745.0 (622.0–972.0)	832.96 (710.0–1079.0)	856.50(734.0–1104.0)		
Sig. bet. periods	p_1=0.212, p_2<0.001*, p_3=0.690				

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using Post Hoc Test (adjusted Bonferroni)
p: p value for comparing between the three studied periods
p_1: p value for comparing between Pre-operative and Immediate
p_2: p value for comparing between Pre-operative and 4 months
p_3: p value for comparing between Immediate and 4 months
*: Statistically significant at $p \leq 0.05$

DISCUSSION

The present trial was carried out in order to assess the influence of osseodensification for implant site preparation in mandibular narrow ridges using Densah burs in a non-cutting anti-clockwise direction on increasing bone density and ridge width.

For successful implant placement, a minimum of 1 mm trabecular bone should be present between the cortical plates in order to guarantee the necessary 1.5 mm of cortical and cancellous bone on both sides of the divided ridge, thus, allowing the bone to feast and maintaining satisfactory blood supply. Scipioni et al. (14) recommended ridge augmentation in cases where the buccolingual bone width is 3-6 mm. Therefore, attempting to deal with narrow ridges, the target ridge width in the current study was 3-5 mm.

According to Clementini et al., smoking leads to bone loss around implants which sooner or later leads to implant failure, so, subjects in this trial were chosen to be non-smokers. (15) Likewise, implants in people with parafunctional habits including clenching and bruxism are subjected to extensive duration of forces with a direction that is more horizontal than axial. Manfredini et al. linked that to mechanical complications and implant failure (16). Based on this, selected subjects in this trial were all free of any parafunctional habits.

Bornstein et al. (17) and Bernaerts et al. (18), explained in details the worth of CBCT in implantology beginning with preoperative investigations passing through treatment planning till reaching postoperative evaluation. The lesser radiation dosage, comparatively low costs and the relative grey density values of its images, all of which make it an advantageous alternative for computerized tomography (CT) (19, 20). Hence, in our trial, CBCT was done for all subjects pre-operatively, immediately postoperatively and later after 4 months in order to track the degree of ridge expansion as well as the changes in the density of bone surrounding the implant.

Regarding the surgical procedures in this study, surgeries were conducted under local anesthesia. All patients had a horizontal mid-crestal incision through the attached gingiva for implant insertion similar to Kim et al. (21) and Fickl et al. (22)
Socket closure was cautiously performed using a 3(000) silk suture which was particularly important to avoid postoperative infection and/or inflammation and ensure that epithelial down growth or alveolar crest bone loss does not occur while healing (23).

The results of the current trial revealed that there was a substantial increase in the ridge width as well as ridge density compared to baseline measurements. Such findings were in harmony with the findings of the recent study performed by Isik et al. in 2020 (24), where after placing 22 implants using osseodensification technique, the average alveolar bone width was increased significantly from 3.5 to 5 mm (24).
Osseodensification probably preserves bone bulk through two ways: compacting cancellous bone because of plastic and viscoelastic deformation and through compacting fine autograft bone particles all throughout the walls of the osteotomy and also at the apex (25). Trisi et al. (26) claimed that the fine boney particles along the osteotomy walls and amongst the implant flutes act as initiators for new boney growth which in turn enhance secondary stability. Besides, creating an osteotomy in a non-extraction site without digging-out the precious bone leads to conserving the bone bulk along with its collagen and vascular supply, all of which are crucial for new bone formation and remodeling (27, 28).

The results of this trial eagerly suggest that the osseodensification drilling technique does not influence bone healing in a negative manner, but instead, it may be valuable in enhancing the width and density of bone in narrow ridges as a means of site preparation before implant placement.

This study, nevertheless, has its limitations. The short follow-up period together with the small sample size included in the trial might have provided inaccurate results. For this reason, well designed clinical trials including a larger number of patients, perhaps involving a control group as well along with a longer follow-up period are strongly recommended in order to confirm the worth of using osseodensification in cases with narrow ridges.

CONCLUSIONS

Considering the limitations of the study, it can be concluded that osseodensification technique is effective in increasing ridge width and bone density when used for implant site preparation in mandibular narrow ridges.

CONFLICT OF INTEREST

The authors affirm no interest conflicts.

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