

# THE EFFECTS OF OSSEODENSIFICATION Vs MOTOR-DRIVEN EXPANDERS' TECHNIQUES ON PERI-IMPLANT BONE DENSITY

## (A RANDOMIZED CLINICAL TRIAL)

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### ABSTRACT

**BACKGROUND:** Poor bone volume in the alveolar ridge resulting from long edentulism can be observed after the first year of tooth loss as decreased ridge width forcing an improper placement of the dental Implants without additional surgical procedures to reconstruct the original anatomy of the alveolar crest. Osseo-densification is a suitable biomechanical technique to overcome this possible obstacle, which uses a counterclockwise, non-cutting densifying bur utilizing a non-subtractive densifying method to increase the peri-implant bone density and expand the alveolar ridge at the same time.

**OBJECTIVES:** To compare and measure the changes in the peri-implant bone density with osseodensification (OD) and rotary expanders' techniques with simultaneous implant placement.

**MATERIALS AND METHODS:** Fourteen patients requiring implant placement in the anterior maxillary region till the premolar region were randomly selected and divided into two groups (seven patients per group), the control group was operated on with the rotary expanders' technique, and the test group was operated on with the osseodensification (OD) technique. The Radiographical evaluation was performed preoperative and postoperative (immediate, 6 months) to assess the changes of the peri-implant bone density.

**RESULTS:** Statistical analysis of the radiographical evaluation proved that the densifying burs enhanced the peri-implant bone density more than the rotary expanders, where the mean peri-implant bone density of densifying burs values were ( 758.8 preoperative, 1013.1 immediate postoperative, and 1170.0 after 6months ).

**CONCLUSION:** Within the limitations of this study, results allow the conclusion: both rotary expanders and osseodensification burs improve the peri-implant bone density, but without a significant difference.

**KEYWORDS:** Endosseous implants, Osseo-densification, Expanders, poor bone density.

**RUNNING TITLE:** Osseo-densification Vs expanders on peri-implant bone density.

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### INTRODUCTION

Poor bone volume in the alveolar ridge resulting from bone resorption due to long-term edentulism, untreated chronic infection, or dental trauma can be observed after the first year of tooth loss as a decreased ridge width forcing an improper placement of the endosseous implants in a suitable position without additional augmentative surgical procedures, and it is considered a challenging clinical situation (1).

Poor biomechanical bone quality is common in human maxilla. In D3 or D4 bone types, achieving sufficient primary stability of inserted implants is challenging due to poor bone value percentage (%BV) around dental implants, resulting in increased early implant failure (2).

Different surgical options have been suggested to regain bone width after horizontal bone resorption and to increase peri-implant bone density in a low-density bone. Summers reported an expansion of the edentulous ridge and placement of implants without removing the bone by using a series of expanders to achieve the desired dimensions and to preserve the existing bone by utilizing the biomechanical

properties of soft bone elasticity (3). Bone condensation and expansion, therefore, is suggested to be indicated in the upper maxilla, due to its poor density and the thin buccal cortical plate (4).

The rotary expanders technique is an alternative technique to the hand osteotomes (5). Rotary expanders aim to increase the density of the cancellous bone in the apicoronal and buccolingual dimensions (6). Taking advantage of the bone's viscoelasticity and enhance implant primary stability. Rotary expanders have several advantages over the augmentation technique, that allows gradual expansion of the ridge with less liability to fracture. It decreases the operating time, and it eliminates the problems that occurred with augmentation like membrane exposure or bone graft infection, as there is no need to harvest bone (7).

Osseo-densification is an established biomechanical site preparation technique. The concept is based on a non-subtractive multi-stepped drilling protocol, resulting in the densification of the osteotomy site to enhance primary

stability by using a counterclockwise rotating, densifying bur with large negative rake angles (non-cutting edge) (8).

They can densify by rotating counter-clockwise (densifying mode) at 800-1200 rotation per minute (rpm), and drill bone in a clockwise direction (cutting mode). This technique is coupled with external irrigation giving a gentle compression inside the osteotomy creating a densified layer through the compaction-autografting technique (9). It allows the recoil of bone back to the implant surface apically and laterally (10).

The aim of osseo-densification is the compaction of bone that will be in immediate contact with the implant leading to high primary stability due to physical interlocking between the bone and the implant and the nucleation of the osteoblasts emitted from the endosteum of the micro-fractured bone-trabeculae in contact with the implant leading to faster new bone growth formation (11).

the drilling protocol for osseo-densification is variable according to the implant type and bone density. The decision to densify or cut is related to the specific biomechanical bone quality of the implant site. The drilling of the highly-dense bone is achieved by rotating the drills in a clockwise direction at 800-1200rpm. (12).

The aim of the study was to compare the effect of osseo-densification and the rotary expanders on the peri-implant bone density with simultaneous implant placement.

## MATERIALS AND METHODS

*Informed consent:* The study was performed after gaining the approval of the Research Ethics Committee, Faculty of Dentistry, Alexandria University.

All patients participating in this study were informed about the clinical procedure, possible risks, and complications before being enrolled in the study.

### *Study design*

The study was established as a randomized clinical trial with two parallel arms. The randomized clinical trial comprised 14 patients with a horizontal deficiency in the anterior maxillary ridge till the premolar region not less than 3mm. Both genders, whose ages ranging from 25 to 45 years, were selected from the Outpatient Clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

### *Criteria for patient selection*

#### *Inclusion criteria*

Patients requiring implant placement in the anterior maxilla till the premolar region. They aged between 25-45 years, with crestal maxillary alveolar ridge width not less than 3mm, and good oral hygiene evaluated by applying Oral Hygiene Index Simplified (OHI-S) (13).

#### *Exclusion criteria*

Atrophic ridge (2mm or less) with no interposition of cancellous bone between the buccal and palatal plates.  
Heavy smokers, untreated periodontal disease, and acute oral infections.

Uncontrolled metabolic diseases.

History of radiotherapy to the head and neck region or treatment with bisphosphonates.

Pregnant or breastfeeding women,

Female patient taking oral contraceptive pills (14,15,16).

The surgical site needs to be grafted.

### *Materials*

Materials used in this study comprise the following:

Osseo-densification Densah burs (Versah, LLC: 2500 West Argyle Street, Suite 300 Jackson, Michigan 49202 Tel: 844-711-5585 www.Versha.com)

Implant system (Dentium Co Ltd #214, 105, Gwanggyo-ro, Yeoungtong-gu, Suwon-si, Gyeonggi-do, Korea Tel: +82-31-888-5431 www.dentium.com): two-piece implant with conical hex implant/abutment connection, round tapered design, and implant healing abutments.

RS kit ® (ridge spreader): (Dentium Co Ltd #214, 105, Gwanggyo-ro, Yeoungtong-gu, Suwon-si, Gyeonggi-do, Korea Tel: +82-31-888-5431 www.dentium.com)

Osstell ISQ-mentor device and smart pegs (Osstell AB, Stampgatan 14, 411 01 Göteborg, Sweden Phone: Tel: +46313408250 www.osstell.com)

3D Imaging device (Morita R100 cone beam 3D imaging system) (Morita 3DX; J Morita Mfg corp., Kyoto, Japan.)

CBCT analyzing software (OnDemand3D, Cybermed Inc., Seoul, Korea).

### *Methods*

#### *Pre-surgical phase*

Patient's history: which included personal data, past medical, and dental history.

Clinical examination (Figure 1, Figure 2)

It was performed both extraorally and intraorally (17). We assessed the status of oral hygiene by using the Oral Hygiene Index Simplified (OHI-S) (13), in which we examined only 6 teeth surfaces (4 posterior and 2 anterior teeth).

This index included; the Debris Index (DI-S), and the Calculus Index (CI-S), in which each index has a certain score and criteria, then we added the two indices to get the overall(OHI-S) score; in which the score (0.0- 1.2) means good oral hygiene and any patient scoring above this value was excluded.

#### *Pre-operative impressions*

To evaluate the relation between the maxillary and mandibular arches, the prosthetic options, and measure the inter-arch space (18).

#### *Radiographic examination (Figure 1, Figure 2)*

Radiographic examination was performed by using cone beam 3D imaging system (Morita 3DX; J Morita., Kyoto, Japan), and CBCT analyzing software (OnDemand 3D version 1.0, Win 32 edition) to detect implant position, angulation, measure the ridge width, and the peri-implant bone density at the planned implant site (19).

Firstly, we standardized the settings of the CBCT device (preoperative, immediate postoperative, and 6 months postoperative). The scan was done with field of view (FOV) W 100mm x H 50mm with 0.160mm isometric voxel size. The tube voltage was 90KV (kilovoltage), 8 mA (Milliampere), and the exposure time was 20 seconds.

By using OnDemand 3D software, we selected from the implant database a virtual implant that matches the same dimensions, type, and position of the actual implant to be placed at the planned implant site, then the mean of the peri-implant bone density value was calculated automatically.

#### *Surgical protocol*

The oral cavity was prepared using 0.12% chlorohexidine mouth rinse for 30 seconds before surgery.

Local anesthesia: Labial and palatal infiltrations were administered by local anesthesia (2% Mepivacaine ) at the implant site.

Slightly palatal para-crestal incision with full-thickness flap reflection to expose the surgical site was performed by using No.15 blade, and sharp periosteal elevator.

The patients were randomly separated into 2 groups:

**In Group I (7 patients):** each patient received one implant in the anterior maxilla till the premolar region. (Figure 3).

The implant site was prepared using the motor-driven expanders' technique.

The first pilot drill at 700-900 rpm with copious irrigation was rotated in a clockwise direction till reaching the desired length. Then we consecutively expanded the osteotomy site till reaching the full length and adequate diameter.

Before we shifted to the next expander, we waited about 10-20 seconds after each half turn by ratchet wrench to give enough time for bone expansion.

The expander was pulled-out from the osteotomy site in an anticlockwise direction.

The implant was placed in the osteotomy socket, then it was put to the full depth inside the socket by using the torque wrench

After implant placement, the smart peg was connected to the implant, by using the Osstell® mentor ISQ readings were obtained.

The cover screw was placed followed by the closure of the flap using 3/0 silk suture (GMS® (surgical suture, non-absorbable, braided) Ghatwary medical GMS, 2<sup>nd</sup> industrial zone, Borg El Arab El Gadida city-Alex Egypt).

**In Group II (7 patients):** each patient received one implant in the anterior maxillary ridge till the premolar area, and the implant site was prepared using the osseo-densification technique (Figure 4).

The pilot drill at 800-1200 rpm was rotated in a clockwise direction with copious irrigation till reaching the desired length.

Sequential using of larger Densah® drills rotated in an anti-clockwise direction (non-cutting mode) at 800-1500 rpm with copious irrigation in a bouncing motion up and down till reaching the full length and adequate diameter.

The implant was placed in the osteotomy socket, then it was put to the full depth inside the socket by using the torque wrench.

After implant placement, the smart peg was connected to the implant, by using the Osstell® mentor ISQ readings were obtained.

The cover screw was placed followed by the closure of the flap using 3/0 silk suture (GMS® (surgical suture, non-absorbable, braided) Ghatwary medical GMS, 2<sup>nd</sup> industrial zone, Borg El Arab El Gadida city-Alex Egypt).

#### Post-surgical phase

##### Post-surgical care:

All patients were instructed to avoid chewing hard food on the operation side, Apply ice packs over the area for the 1<sup>st</sup> day and then warm packs for the next two days, after a week the sutures were removed.

All patients were advised to take the following medications, which include:

Antibiotics (Augmentin®- GlaxoSmithKline-Australia)( Amoxicillin+ clavulanic acid 1gm-Sigma Pharmaceutical Industries- Mounfia- Egypt) every 12 hours for five days (20).

Non-steroidal anti-inflammatory drugs ( Cataflam (Diclofenac potassium 50mg) Novartis pharma, AG, Basel, Switzerland) every eight hours for five days.

0.12% chlorhexidine mouth rinse (Chlorhexidine 125mg / 100ml, concentration 0.125%: Arabic drug company, ADCO.) for seven days.

##### Evaluation and follow-up:

Patients were followed-up clinically and radiographically for 6 months.

##### Clinical evaluation:

Post-operative pain: It was assessed daily for the 1st week, then, weekly for the 1st month using a 10-point Visual Analogue Scale (VAS) (21).

Presence or absence of postoperative complications: assessment of any subjective sensation at each visit, peri-implant infection with suppuration, presence, or absence of radiolucency around the implant.

##### Radiographic evaluation:

Cone-beam computed tomography was performed to assess Bone density surrounding the dental implant immediately after implant surgery. By using OnDemand 3D software, the virtual implant that mimics the placed implant was selected, then it was superimposed over the placed actual implant. The mean of the peri-implant bone density value was measured automatically. A comparison is drawn between (group I) and (group II) in terms of their effect on the peri-implant bone density. Actually, this procedure is repeated after 6 months of implant placement.

##### Final prosthesis:

Definitive porcelain fused to metal restoration was delivered after 6 months.

##### Statistical analysis

Data were collected and analyzed using IBM SPSS software package version 20.0 (Armonk, NY: IBM Corp). The tests used in this study are as follows:

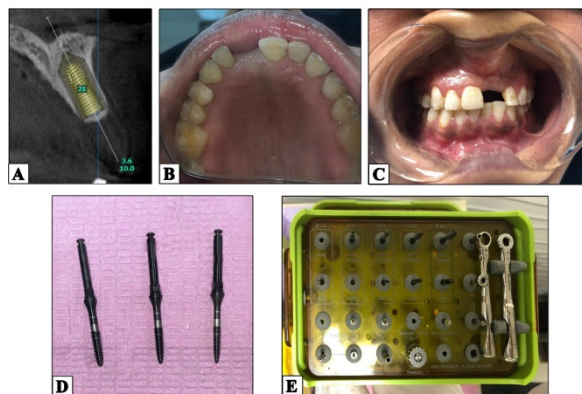
Chi-square test: compares between the different groups (categorical variables).

Student t-test: compares between the two studied groups (quantitative variables).

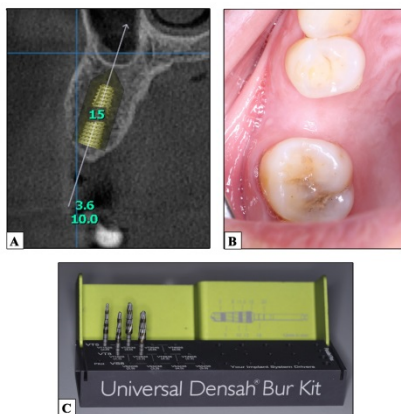
Paired t-test: compares between two periods (quantitative variables).

ANOVA with repeated measures: compare between more than two periods (quantitative variables).

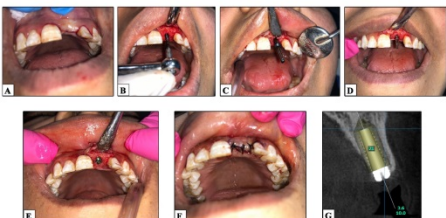
Post Hoc test (Bonferroni adjusted): for pairwise comparison. The significance of the obtained results was considered at the 5% level.



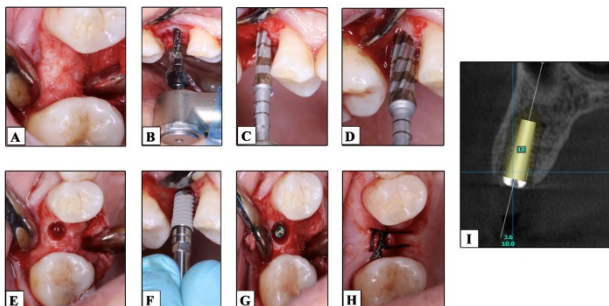
**Figure (1):** Pre-operative clinical and radiographic examination for control group.



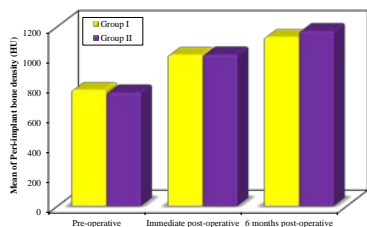
**Figure (2):** Pre-operative clinical and radiographic examination for study group.



**Figure (3):** Sugrical sequence for motor-driven expanders technique.



**Figure (4):** Sugrical sequence for osseodensification technique.



**Figure (5):** Comparison between the two studied groups according to mean of Peri-implant bone density.

**RESULTS**

**Demographic data:**

14 patients, whose ages ranged from 25 to 45 years, (6 males and 8 females), requiring implant placement in the anterior

maxilla till the premolar region were assessed in this study. The patients were randomly separated into 2 groups, in the control group; 7 patients received a single implant using the motor-driven expanders’ technique, and study group; 7 patients received a single implant using the osseo-densification technique. (Table 1)

All patients were followed up for 6 months and the results were documented in terms of clinical evaluation and radiographic evaluation.

**Clinical evaluation:**

The post-operative pain was evaluated clinically for the first week, then weekly for the first month using Visual Analogue Score (VAS), where it was noticed lower in group II (Study Group) than Group I (Control Group), but without a significant difference between them. The mean values of the r-VAS scores for Group (I) at 6hr,12hr were  $9.40 \pm 0.84$  mm and  $8.20 \pm 1.48$  mm respectively, and for Group (II) were  $9.40 \pm 0.70$  mm and  $8.0 \pm 1.25$  mm at the same time.

The number of analgesic pills taken postoperatively did not differ significantly between the two groups.

**Radiographic evaluation:** The peri-implant bone density was measured in Hounsfield Units (HU), regarding the mean peri-implant bone density values, and standard deviation at the preoperative, immediate postoperative, and 6 months postoperative periods

**In Group I (rotary expanders’ technique):**

Pre-operatively, the mean peri-implant bone density value was (723.9HU) in the immediate postoperative period, and the mean peri-implant bone density value was (975.1HU), while in the 6 months postoperative period, the mean peri-implant bone density value was (1128.5HU). Thus, it was revealed that a significant increase in the peri-implant bone density along the evaluation periods, where ( $p<0.001$ ). (Table.2)

**In Group II (Osseo densification technique):**

The mean peri-implant bone density values in the pre-operative and immediate postoperative periods were (739HU) and (1019.7HU) successively, while after 6 months postoperatively, the mean of peri-implant bone density value was (1170HU). Therefore, there was a significant increase in the peri-implant bone density along the evaluation periods, where ( $p<0.005$ ). (Table.2)

Comparison between the mean peri-implant bone density of the two groups in the evaluation periods using Hounsfield Units (HU)

The mean peri-implant bone density values in Group I and II were ( 774.8HU and 758.8HU) preoperatively, and (1009.6HU and 1013.1HU) in the immediate postoperative period. However, in the 6 months postoperatively, in Group I, the mean peri-implant bone density value was (1128.5HU), and in Group II was (1170HU). These readings revealed that Group (II) enhanced the peri-implant bone density in the immediate and 6 months postoperative periods more than Group (I). On the other hand, there was no significant difference in the mean peri-implant bone density between the two groups, whether in the immediate postoperative period or the 6 months postoperative period  $p =0.683$ ,

P-value considered significant if  $p< 0.05$ . ( Table.3) & (Figure 5)

**Table (1):** Comparison between the two studied groups according to demographic data.

	Group I (n = 7)		Group II (n = 7)		Test of Sig.	p
	No.	%	No.	%		
Sex					$\chi^2=$ 1.167	0.592
Male	2	28.6	4	57.1		
Female	5	71.4	3	42.9		
Age (years)					t= 1.377	0.194
Min. – Max.	26.0 – 40.0		28.0 – 42.0			
Mean ± SD.	33.29 ± 4.39		36.79 ± 5.10			

**Table (2):** Comparison between the different periods according to mean of Peri-implant bone density.

Mean of Peri-implant bone density (HU)	Pre-operative	Post-operative		F	p
		Immediate	6 months		
Group I (n = 6)				42.899*	<0.001*
Min. – Max.	430.7 – 971.1	761.1 – 1150.3	924.0 – 1386.6		
Mean ± SD.	723.9 ± 211.5	975.1 ± 160.5	1128.5 ± 162.1		
Sig. bet. periods	p <sub>1</sub> =0.002*, p <sub>2</sub> =0.004*, p <sub>3</sub> =0.013*				
Group II (n = 6)				22.532*	0.005*
Min. – Max.	336.4 – 844.1	885.8 – 1275.5	995.9 – 1491.9		
Mean ± SD.	739.0 ± 198.7	1019.7 ± 144.8	1170.0 ± 179.7		
Sig. bet. periods	p <sub>1</sub> =0.036*, p <sub>2</sub> =0.011*, p <sub>3</sub> =0.001*				

**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 studied periods

p<sub>1</sub>: p value for comparing between **Pre-operative** and **Immediate post-operative**

p<sub>2</sub>: p value for comparing between **Pre-operative** and **6months post-operative**

p<sub>3</sub>: p value for comparing between **Immediate** and **6months post-operative**

\*: Statistically significant at p ≤ 0.05

**Table (3):** Comparison between the two studied groups according to mean of Peri-implant bone density.

Mean of Peri-implant bone density (HU)	Group I (n = 7)	Group II (n = 7)	t	p
Pre-operative			0.140	0.891
Min. – Max.	430.7 – 1079.9	336.4 – 877.3		
Mean ± SD.	774.8 ± 235.3	758.8 ± 188.8		
Immediate post-operative			0.042	0.967
Min. – Max.	761.1 – 1216.5	885.8 – 1275.5		
Mean ± SD.	1009.6 ± 172.6	1013.1 ± 133.3		
6 months post-operative	(n = 6)	(n = 6)	0.420	0.683
Min. – Max.	924.0 – 1386.6	995.9 – 1491.9		
Mean ± SD.	1128.5 ± 162.1	1170.0 ± 179.7		

**t: Student t-test**

p: p value for comparing between the studied groups

## DISCUSSION

The density of available bone of an edentulous ridge is an important factor in implant selection, surgical approach (22). Moreover, it affects primary stability (23), and long-term implant survival (24).

Multiple studies suggested that the failure rate of dental implants is related to the quality of the bone (25). In D3 or D4 bone types as in maxilla (26), the bone percentage value (%BV) is poor. Therefore, we need to improve the density of the bone tissues that will be in contact with the implant surface to obtain high primary stability (27). This can be achieved through the modification in the surgical protocol as in the osseo-densification technique, whose protocol is a non-subtractive multi-stepped drilling-based protocol (28) using burs with negative rake angles (non-cutting edge) to increase the bone density (29).

In our study, a total of 14 patients, whose ages range between 25 & 45 years, in need of a dental implant in a horizontally deficient maxillary ridge (from anterior to the premolar area), were selected from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

In this study, Group ( I ) has recorded one implant failed after two months of its placement. This is due to the pre-operative misdiagnosis of the bone type radiographically and this is in agreement with Strietzel FP et al., where two implants failed from a total of 22 during the unloaded period, due to improper evaluation of bone quality. (30). Hence, assessment of bone quality has an important role before using the osteotome technique, as they concluded that the best bone types suitable for osteotome technique are class III and IV according to Lekholm and Zarb classification (1985).

Furthermore, in Group (II) also, we recorded a failure of one implant one month postoperatively, due to the excessive drilling force applied during preparation, according to Koutouzis et al. (2019) reported failure of two implants out of 28 implants, both two weeks postoperatively, but in the mandibular jaw. (31)

In this study, CBCT were taken for each patient in the evaluation periods (pre-operative, immediate postoperative, and 6 months postoperative) to measure the changes in the peri-implant bone density. Preoperatively, CBCT is important for preoperative analysis, treatment planning, and anatomical consideration. (32,33). In fact, it is also considered a good substitute for CT (computerized tomography), due to its lower cost, better resolution images, and lesser dose of radiation. (34,35)

In Group (I), it was revealed that there is a significant increase in the peri-implant bone density in the immediate postoperative and 6 months postoperative periods, as the rotary expanders exert lateral compression on the trabecular bone. This results in increasing bone density which is in proportion to the degree of compression, and this is in line with Butcher et al., (36).

The Densah drills have an increasing effect on the peri-implant bone density in the immediate postoperative and 6 months postoperative periods. This is as the Densah burs compact bone of the osteotomy site rather than excavate it (compaction-autografting technique). In addition, the compacted bone that in direct contact with the implant surface acts as a nucleation center for new bone formation resulting in faster osseointegration. Furthermore, this enhances the physical interlocking between the instrumented bone and the implant surface. Actually, this is consistent with Trisi P et al., (37).

Accordingly, the increase in bone density indicated that there was an effective new bone formation, remodeling, and maturation as well as enhancement in the architecture of the peri-implant bone density which improved osseointegration (38).

## CONCLUSIONS

Within the limitations of this study by its small sample size, the results suggest an improvement in the peri-implant bone density with densifying burs more than rotary expanders, but without a statistically significant difference.

Conflict of interest

The authors declare that they have no conflicts of interest.

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