

Efficacy of Osseodensification versus Expander Technique for Alveolar Ridge Expansion: A 3-Years Randomised Controlled Trial

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Abstract

Osseodensification is a new implant-site osteotomy preparation technique that expands the alveolar ridge by compacting bone autografts. To evaluate the possible different outcomes between osseodensification and expander techniques, 14 female patients were assigned randomly and equally into 2 groups; each to receive an implant at a maxillary premolar or molar site. Seven implants were placed using osseodensification and the other 7 were placed using ridge expander technique. Clinical and radiographic outcomes of each technique were recorded at implant placement time, loading time, 6, 12, 36 months after loading. The degree of ridge expansion, implant stability by resonance frequency analysis (RFA), peri-implant pocket depth (PPD), modified sulcus bleeding index (mSBI), and marginal bone height (MBH) were studied at these time intervals.

Three years of post-loading follow up, all implants were successful; Osstell device reflected RFA values of stable well-osseointegrated 14 implants. No significant difference found between both groups in regard to PPD, mSBI, or MBH (P value > 0.05). The degree of ridge expansion achieved with osseodensification was significant ($P=0.0001$) at the occlusal point but insignificant ($P=0.423$) at the apical point when compared to the expander technique.

Both techniques showed favourable clinical outcomes and could preserve the narrow maxillary ridge with no need for bone graft. Simultaneous ridge expansion and implant placement can shorten the treatment time, overcome the risk of cross-infection and reduce the treatment cost. However, future trials on larger scale and longer follow up periods are required for further conclusive recommendations.

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Introduction

Survival of dental implants relies mainly on the bone quality and quantity. The posterior area of the upper jaw, represents the lowest rates of implant success because of inadequate bone quality.^{1,2} Bone quality and quantity can be improved by ridge augmentation or expansion. Ridge bone might be expanded with osteotomes, expanders or by splitting technique.³ Guided bone regeneration (GBR) using different bone sources or substitutes still presents some

common post-operative complications.⁴ However, distraction osteogenesis and ridge splitting techniques are other effective approaches to expand the ridge width with relatively lower risk of post-operative complications.⁵

In 1986, Tatum developed the osteotome technique which was incorporated into clinical practice to address the deficiency in bone width.⁶ It involves lateral and apical compression of the alveolar ridge along with an expansion of the buccal and lingual cortical plates, to increase the ridge width and place an implant with a suitable diameter. This technique was further improved to allow for wider clinical applications. It can achieve many goals such as; concurrent implant placement, shorter treatment period, and no required bone graft. However, some limitations of ridge spreading technique do exist, such, as; possible fracture of the buccal or lingual cortical plates. In addition, possible excessive angulation

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of the implant would result when employing this technique in an over-angleded aveolar ridge.⁵

Osseodensification is a technique that evolved in 2013 by Huwais and was developed to prepare a non-extraction site for implant placement. Densah burs (Densah®, Versah, LLC, Jackson, Michigan, USA) were developed with special design to increase bone density while expanding the aveolar ridge and scooping out insignificant quantity of bone. These burs share the advantages of osteotomes and drills, in terms of greater tactile sensitivity and speed with decreased heat generation to maintain healthier bone and enhance implant osseointegration.⁷ Densah burs were devised with a negative rake angle that is large enough to allow for non-reductive cutting. Their design creates hydrodynamic waves to simultaneously condense and expand the alveolar bone. Thereby, they function as compaction autografting tools at the osteotomy site, therefore, they enhance periimplant bone density and implant stability.⁸

In this three-year clinical trial, we document the possible different outcomes between osseodensification and ridge spreading techniques when used for osteotomy site preparation with simultaneous implant placement at the posterior maxilla.

Materials and methods

Patients

Methodology was reviewed by an independent statistician. The Declaration of Helsinki on medical protocol and ethics was followed to plan and conduct this study. This trial was performed at the Oral Surgery Clinic and was approved by the university Ethical Review Board (approval number: 08042016).

A sample size of 14 subjects (14 implants in total) was calculated before starting the study to give a power of 80% (alpha, two-tailed, was set at 0.05). Block randomization was used to generate a random sequence of allocation for the study groups. Patients were assigned to each group based on the random sequence list and the time of enrolment. This trial did not employ blinding of either clinicians or patients and no patients had access to the study plan or outcomes. The assigned implant placement technique was disclosed to patients for ethical reasons and to the clinicians to follow the

surgical protocol of each technique. Fourteen participants were assigned randomly into two equal groups. Group 1 comprised 7 sites subjected to osteotomy preparation with osseodensification technique while group 2 comprised 7 sites subjected to osteotomy preparation with bone expander technique. Each of the 14 recruited female patients signed an informed consent after being assigned to her group.

The inclusion criteria included the presence of: adequate horizontal and vertical bone at the future implant site, opposing occlusion, non-salvageable maxillary premolar or molar, good oral hygiene, no medical limiting condition. The exclusion criteria included the presence of: teeth close to the future implant site that are periodontally or endodontically compromised, no opposing dentition; inadequate oral hygiene and chronic medical condition, such as; hemorrhagic disease or uncontrolled diabetes. Smokers, alcohol abusers and bruxers were excluded from this study.

Each patient was examined comprehensively and each implant was treatment planned using diagnostic models and pre-operative CBCT (Fig 1A, Fig 1B, Fig 3A and Fig 3B). All patients were instructed for oral hygiene and received adequate periodontal scaling before surgery.

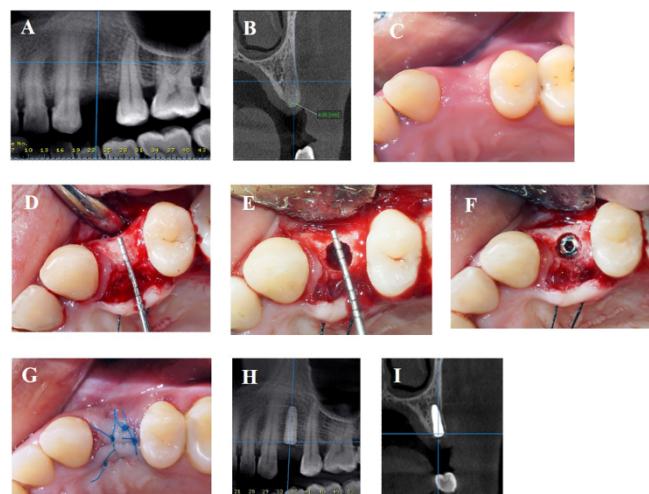


Figure 1. Shows series of photographs and radiographs of a patient who received an implant at a missing maxillary left first premolar, associated with osseodensification technique. Series A and B, preoperative CBCT radiographs show the planned osteotomy site; (A) a panoramic view and (B) a cross-sectional view. Series C, an intraoperative preoperative photograph

shows a missing maxillary left first premolar. Series D, an intra-operative photograph shows the initial buccopalatal (BP) ridge dimension after flap elevation and reflection. Series E, an intra-operative photograph shows the osteotomy site after complete expansion; a periodontal probe marks an increase in the BP dimension compared to Series D. Series F, an intra-operative photograph shows the implant inserted in place with its cover screwed on. Series G, an intra-operative photograph shows primary flap closure. Series H and I, immediate postoperative CBCT radiographs show the implant inserted at the planned site; (H) a panoramic view and (I) a cross-sectional view.

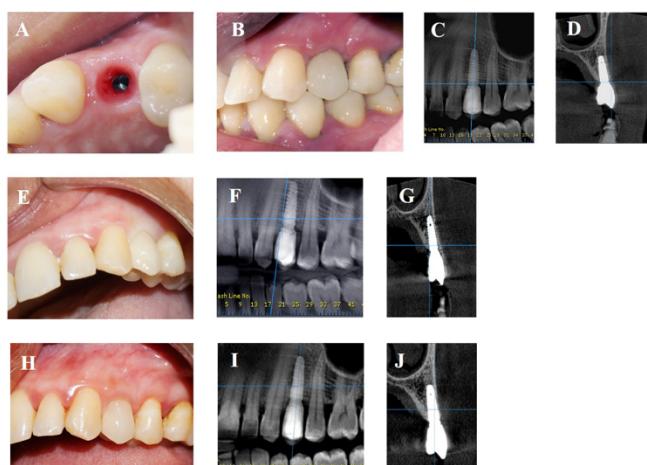


Figure 2. Shows series of photographs and radiographs of a patient who received an implant at a missing maxillary left first premolar, associated with osseodensification technique at the abutment connection time; 4 months after implant placement (T_1) and at the follow up appointments 12 (T_3) and 36 (T_4) months after implant loading. Series A, a photograph shows gingival healing 2 weeks after abutment placement. Series B, intraoral photograph taken at loading time (T_1) to show the final PFM restoration and the gingival contour in a buccal view. Series C and D, CBCT radiographs taken at loading time (T_1) to show the implant, bone and final PFM restoration; (C) a panoramic view and (D) a cross-sectional view. Series E, an intraoral buccal view photograph taken 12 months after loading time (T_3) to show the final PFM restoration and the gingival contour. Series F and G, CBCT radiographs taken 12 months after loading time (T_3) to show complete healing with satisfactory bone quality and quantity around the implant restored by a PFM restoration; (F) a

panoramic view and (G) a cross-sectional view. Series H, an intraoral buccal view photograph taken 36 months after loading time (T_4) to show the final PFM restoration and the gingival contour. Series I and J, CBCT radiographs taken 36 months after loading time (T_4) to show satisfactory bone quality and quantity around the implant and the PFM restoration; (I) a panoramic view and (J) a cross-sectional view.

Surgical procedures

Fourteen two-piece sandblasted acid-etched (SLA) endossous implants (Dentium Co., Seoul, Korea) were placed to restore 14 missing maxillary premolars or molars in 14 female patients. After administration of local anesthesia (Artinibsa; Inibsa, Lliça de Vall, Spain), a crestal incision for a full-thickness mucoperiosteal flap was prepared and reflected buccally and palatally to expose the alveolar ridge at the implant site. For the first group, the implant site preparation was performed using densah burs (Densah®, Versah, LLC, Jackson, Michigan, USA), rotating counterclockwise at high speed rotation (800-1500 rpm) with copious saline irrigation, beginning with the smallest densah bur diameter. Repeated lifting off and reapplying pressure with a pumping motion are necessary when feeling the haptic feedback of the bur pushing up out of the osteotomy till reaching the desired depth. Thereafter, the implant bed was widened using densah burs in small increments, allowing ridge expansion to the desired diameter.⁹ Figures 1 and 2 present series of radiographs and photographs of a patient who received an implant at the site of a missing maxillary left first premolar, after ridge expansion with osseodensification technique.

In the second group, the implant site was prepared using the screw expanders (MCT Bone Expander, Mr.Currete Tech., South Korea). The first screw was inserted manually by Manual Knob, then screwed in, in a clockwise direction by Ratchet Wrench to the desired depth. It is preferred to wait approximately 10 to 20 seconds after each half turn to give sufficient time for expansion to take place, allowing for bone flexure while compressing the buccal and palatal bony plates, simultaneously. Thereafter, the expander was turned into an anti-clockwise direction and pulled out of the osteotomy site, then, the successive larger expander was used until reaching the desired length and width. All the

expansion steps were performed with copious saline irrigation.¹⁰ Figures 3 and 4 present series of radiographs and photographs of a patient who received an implant at a missing maxillary right first premolar site after ridge expansion with expander technique. The presented cases achieved different amounts of ridge expansion (Table 1, Fig 1D, 1E, Fig 3D and 3F). Thereafter, the implant was driven into the prepared implant bed with stable pressure, and complete implant placement was achieved with the coupling ratchet wrench. Then, a cover screw was installed on each implant (Fig 1F and Fig 3G) and the mucoperiosteal flap was closed using interrupted 4.0 black silk sutures (Fig 1G and Fig 3H).

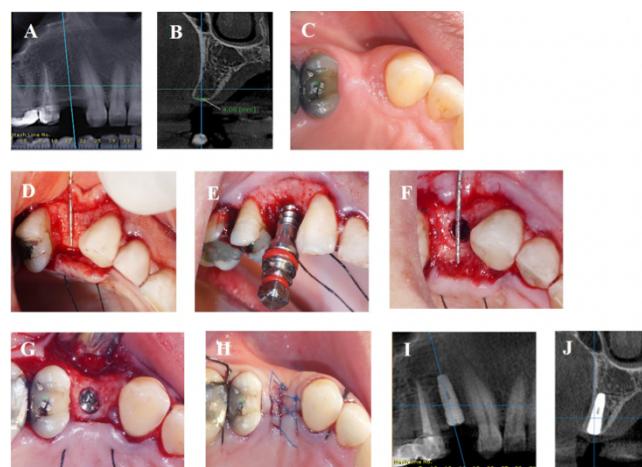


Figure 3. Shows series of photographs and radiographs of a patient who received an implant at a missing maxillary right first premolar, associated with expander technique. Series A and B, preoperative CBCT radiographs show the planned osteotomy site; (A) a panoramic view and (B) a cross-sectional view. Series C, an intraoperative photograph shows a missing maxillary right first premolar. Series D, an intra-operative photograph shows the initial buccopalatal (BP) ridge dimension after flap elevation and reflection. Series E, an intra-operative photograph shows the third expander (red = Ø 3.4 mm) inserted up to the planned implant length (11.5 mm). Series F, an intra-operative photograph shows the osteotomy site after complete expansion; a periodontal probe marks an increase in the BP dimension as compared to Series D. Series G, an intra-operative photograph shows the implant inserted in place with its cover screwed on. Series H, an intra-operative photograph shows primary flap

closure. Series I and J, immediate postoperative CBCT radiographs show the implant inserted at the planned site; (I) a panoramic view and (J) a cross-sectional view.

Ridge Width (mm)		Expanders group (N= 7 implants)		Osseodensification group (N= 7 implants)		P value
		Mean	±SD	Mean	±SD	
Initial	Occlusal Point	4.84	0.75	4.30	0.71	0.187
	Apical Point	8.14	2.28	6.58	1.27	0.140
Final	Occlusal Point	5.92	0.77	6.16	0.54	0.522
	Apical Point	9.01	2.33	7.61	1.49	0.206
Expansion	Occlusal Point	1.08	0.23	1.86	0.27	0.0001*
	Apical Point	0.87	0.22	1.03	0.50	0.423

Table 1. Ridge expansion values of expander (N= 7 implants) and osseodensification (N= 7 implants) groups; measured as the difference in alveolar ridge width (in millimeters) between the initial ridge width and the width measured after expansion (at time of surgery), at fixed occlusal and apical points. *Significant difference at P < 0.05.

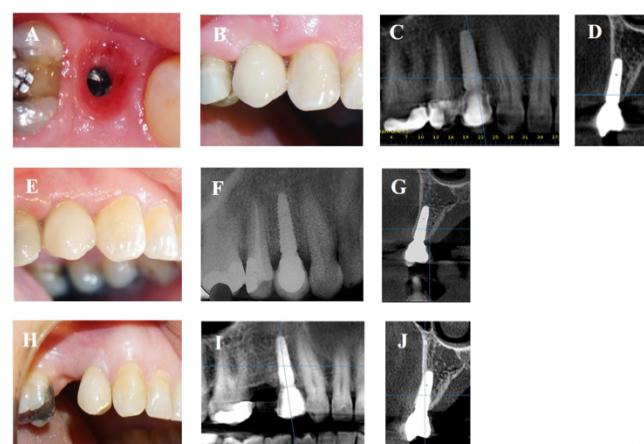


Figure 4. Shows series of photographs and radiographs of a patient who received an implant at a missing maxillary right first premolar, associated with expander technique at the abutment connection time; 4 months after implant placement (T₁) and at the follow up appointments 12 (T₃) and 36 (T₄) months after implant loading. Series A, a photograph shows gingival healing 2 weeks after abutment placement. Series B, intraoral photograph taken at loading time (T₁) to show the final PFM restoration and the gingival contour in a buccal view. Series C and D, CBCT radiographs taken at loading time (T₁) to show the implant, bone and final PFM restoration; (C) a panoramic view and (D) a cross-sectional view. Series E, an intraoral buccal view photograph

taken 12 months after loading time (T_3) to show the final PFM restoration and the gingival contour. Series F and G, CBCT radiographs taken 12 months after loading time (T_3) to show complete healing with satisfactory bone quality and quantity around the implant restored by a PFM restoration; (F) a panoramic view and (G) a cross-sectional view. Series H, an intraoral buccal view photograph taken 36 months after loading time (T_4) to show the final PFM restoration, gingival contour and a missing maxillary right second premolar. Series I and J, CBCT radiographs taken 36 months after loading time (T_4) to show satisfactory bone quality and quantity around the implant and the PFM restoration; (I) a panoramic view and (J) a cross-sectional view.

Immediate post-operative CBCT scans were taken and analyzed to act as a baseline for comparison with future follow up scans (Fig 1H, 1I, Fig 3I and 3J). Patients were prescribed Amoxicillin 500 mg capsules every 8 hours for 7 days and Diclofenac potassium 50 mg tablets for pain. Oral hygiene instructions were reinforced and patients were advised to eat soft food for 3 days post-surgery and to avoid traumatizing the surgery site. Sutures were removed 14 days after surgery and patients presented for evaluation after 2 weeks, then monthly. After a healing period of 4 months, a crestal incision was made to expose the implant platform and a healing abutment was installed, then the soft tissue was sutured around it. Approximately after two weeks, gingival healing was achieved (Fig 2A and Fig 4A) and an open-tray polyvinyl sialoxane impression was taken with a laboratory analogue for the fabrication of a cement-retained porcelain-fused-to-metal crown, which was delivered to each patient after another week (Fig 2B and Fig 4B).

Clinical Outcomes

All patients were examined at baseline (implant placement, T_0), loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading, for evaluation of the following clinical outcomes:

1. Implant stability was recorded using Osstell ISQ device (Integration Diagnostics AB, Göteborg, Sweden). Stability values were interpreted based on the manufacturer's guide. ISQ is a scale from 1 to 100 that has a nonlinear correlation to micromobility. Scales >70 ISQ mean high stability, scales between

- 60 and 69 mean medium stability and scales <60 ISQ are considered low stability.
2. Peri-implant pocket depth (PPD) was measured from the pocket base to the gingival margin with a plastic periodontal probe. The probe was inserted at the mid-buccal/mesial/palatal/distal sites around each implant; in a line parallel to the vertical axis of the implant until the blunt edge of the probe contacted the pocket base.
3. Modified sulcus bleeding index was evaluated according to the criteria established by Mombelli et al.^{11, 12} These criteria included; a score of 0 when there is no bleeding along the gingival margin; a score of 1 when an isolated bleeding spot is seen; a score of 2 when a confluent red line of blood forms at the gingival margin; and a score of 3 when bleeding is heavy at the gingival margin.

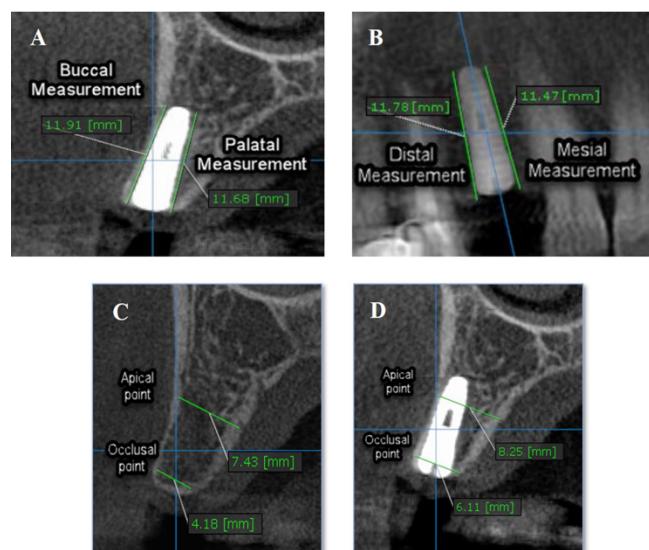


Figure 5. shows series of CBCT radiographs. Series A, a cross-sectional view with two lines drawn parallel to the implant, starting at the crest of the buccal and palatal plates of bone and ending at the apical level of the implant, marginal bone height was measured (in millimeters). Series B, a panoramic view shows the measured mesial and distal bone heights (in millimeters). Series C and D show cross-sectional views to illustrate ridge expansion evaluation, with ridge width measurements (in millimeters) before and after ridge expansion and implant placement, at both the occlusal (1 mm apical to the alveolar crest) and apical (8 mm from the first point) points.

Radiographic outcomes

CBCT radiographs were taken to evaluate the changes in the marginal bone level at baseline (implant placement, T₀), loading time (T₁), 12 (T₃), and 36 (T₄) months after loading. All patient scans were performed with a Planmeca ProMax® 3D unit (Planmeca OY, Helsinki, Finland), using a fixed imaging parameter at each scan. All DICOM data were analyzed using OnDemand3D software (Version 1, CyberMed, Seoul, South Korea).

- Marginal Bone Height (MBH) Assessment¹³: The implant was used as a reference by adjusting the cross-section and panoramic long axes at the center of the implant and bisecting it; to show the buccolingual and mesiodistal dimensions, respectively. In a CBCT cross-sectional view, a line was drawn just parallel to the implant, starting at the crest of the buccal plate of bone and ending at the apical level of the implant. The height was recorded in millimeters and the same process was repeated at the palatal direction, Fig 5A. The panoramic view was utilized to calculate the mesial and distal bone heights in millimeters, Fig 5B.

-Assessment of Ridge Expansion¹⁴: For each implant, the alveolar ridge width was measured at two points, Fig 5C and 5D. The first was placed 1 mm apical to the alveolar crest, and was called the occlusal point of the ridge. The second point was in the middle zone, 8 mm from the first point and was called the apical point.

Statistical analysis

Patients' records and information were collected from the beginning through the end of the study and saved on the main computer in the office of the principal investigator. Only the 4 researchers who participated in this study were given access to this information. Data was collected and tabulated in a Microsoft Excel Worksheet and reviewed individually by the 4 researchers. Thereafter, data was anonymously provided to an independent statistician for analysis. Data was analyzed using the SPSS software (version 22.0; IBM Corporation, NY, USA) to obtain descriptive and analytical statistics. Analysis of data was done using independent sample t-test to compare the two groups and dependent t-test to compare the implant site at different time intervals. Results are shown as mean \pm standard deviation (SD) values and the level of significance was set at P < 0.05.

Results

Demographic data

Results were reviewed by an independent statistician. The 14 female patients who met the inclusion criteria of this study had an age range of 20 – 58 years and a mean age of 41.4 years. In this study, the 14 implants replaced 7 single missing maxillary first premolars, 4 single missing maxillary second premolars, and 3 single missing maxillary first molars. In the osseodensification group, the patients' mean age was 36.43 (\pm 8.48) years while in the expander technique group, the mean age was 45.86 (\pm 8.56) years.

All implants had the same length (11.5 mm), however, their diameters differed as follows: 3.75 mm (8 implants = 57.1%), 4.3 mm (2 implants = 14.3%), 4.5 mm (3 implants = 21.4%) and 5 mm (1 implant = 7.1%). All implants exhibited successful signs of osseointegration while being followed up at loading time (T₁), 6 (T₂), 12 (T₃), and 36 (T₄) months after loading.

Four clinicians participated in scoring measurements and collecting data. Inter-rater reliability was measured by finding no significant difference among the 4 clinicians' scores. Intra-rater reliability was measured by comparing the 4 clinicians' scores of the same measurements when re-scored after 2 weeks interval (test re-test reliability index), R = 0.94.

Assessment of ridge expansion

The results of ridge expansion are shown in Table 1. In the expander group, the mean degree of ridge expansion at the occlusal point was 1.08 (\pm 0.23) mm and 0.87 (\pm 0.22) mm at the apical point, with a significant difference at both points (P=0.001), Table 6.

In the osseodensification group, the mean degree of ridge expansion at the occlusal point was 1.86 (\pm 0.27) mm and 1.03 (\pm 0.50) mm at the apical point with a significant difference (P=0.001 at the occlusal point and 0.002 at the apical point), Table 6. The ridge expansion achieved in the osseodensification group was significant (P=0.0001) at the occlusal point but not (P=0.423) at the apical point, when compared to the expander group, Table 1.

Implant stability

Resonance frequency analysis (RFA) showed increased values of implant stability quotient (ISQ) with time, in both groups, Table 2. In the expander technique group, the mean ISQ

value started as 59.28 (± 13.14) at T_0 to reach 71.07 (± 9.58) at T_4 , and the difference was significant when comparing ISQ values within the expander group, ($P<0.05$), except when T_0 was compared to T_1 , Table 6. On the other side, in the osseodensification group, the mean ISQ value started as 69.50 (± 10.50) at T_0 to reach 77.64 (± 7.40) at T_4 , and the difference was significant when comparing ISQ values within the osseodensification group, ($P<0.05$), except when T_0 was compared to T_1 , Table 6. There was no difference ($P>0.05$) between the two groups in regard to implant stability when compared at different time intervals, Table 2.

Time point	Implant stability quotient (ISQ) values				P value	
	Expanders group (N= 7 implants)		Osseodensification group (N= 7 implants)			
	Mean	$\pm SD$	Mean	$\pm SD$		
T_0	59.28	13.14	69.50	10.50	0.134	
T_1	61.36	10.45	70.29	6.57	0.080	
T_2	68.64	9.41	75.36	6.81	0.152	
T_3	69.28	10.45	76.57	7.52	0.160	
T_4	71.07	9.58	77.64	7.40	0.177	

Table 2. Implant stability quotient (ISQ) values of expander (N= 7 implants) and osseodensification (N= 7 implants) groups at baseline (implant placement, T_0), loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading. No significant difference was found between both groups at any time point. Statistical significance at $P < 0.05$.

Time points	Peri-implant Pocket Depth (PPD) Values				P value	
	Expanders group (N = 7 implants)		Osseodensification group (N = 7 implants)			
	Mean	$\pm SD$	Mean	$\pm SD$		
T_1	1.57	0.37	1.89	0.59	0.248	
T_2	1.82	0.61	2.00	0.69	0.617	
T_3	1.86	0.78	2.32	0.85	0.307	
T_4	2.29	0.64	2.75	0.38	0.080	

Table 3. Peri-implant pocket depth (PPD) values of expander (N= 7 implants) and osseodensification (N= 7 implants) groups at loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading. No significant difference was found between both groups at any time point. Statistical significance at $P < 0.05$.

Time points	Modified Sulcus Bleeding Index (mSBI) Values				P Value	
	Expanders group (N= 7 implants)		Osseodensification group (N= 7 implants)			
	Mean	$\pm SD$	Mean	$\pm SD$		
T_1	0.07	0.12	0.04	0.09	0.552	
T_2	0.29	0.30	0.36	0.28	0.657	
T_3	0.14	0.13	0.29	0.17	0.109	
T_4	0.47	0.37	0.39	0.19	0.657	

Table 4. Modified sulcus bleeding index (mSBI) values of expander (N= 7 implants) and osseodensification (N= 7 implants) groups at loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading. No significant difference was found between both groups at any time point. Statistical significance at $P < 0.05$.

Time points	Marginal Bone Height (MBH) Values				P Value	
	Expanders group (N= 7 implants)		Osseodensification group (N= 7 implants)			
	Mean	$\pm SD$	Mean	$\pm SD$		
T_0	Mesial	11.39	0.31	11.30	0.54	
	Distal	11.53	0.31	11.51	0.47	
	Buccal	11.05	0.43	10.98	0.38	
	Palatal	11.36	0.34	11.43	0.41	
T_1	Mesial	11.03	0.31	11.00	0.53	
	Distal	10.77	0.33	10.76	0.66	
	Buccal	10.60	0.32	10.53	0.43	
	Palatal	11.18	0.28	11.18	0.37	
T_3	Mesial	10.82	0.27	10.68	0.59	
	Distal	10.57	0.28	10.33	0.47	
	Buccal	10.39	0.29	10.35	0.43	
	Palatal	11.00	0.23	10.94	0.28	
T_4	Mesial	10.42	0.40	10.34	0.61	
	Distal	10.22	0.34	10.05	0.38	
	Buccal	10.19	0.39	10.06	0.37	
	Palatal	10.73	0.35	10.55	0.31	

Table 5. Marginal bone height (MBH) values of expander (N= 7 implants) and osseodensification (N= 7 implants) groups at baseline (implant placement, T_0), loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading. No significant difference was found between both groups at any time point. Statistical significance at $P < 0.05$.

Peri-implant pocket depth

Peri-implant pocket depth (PPD) values had increased with time, Table 3. In the expander group, the PPD mean value started as 1.57 (± 0.37) mm at T_1 to reach 2.29 (± 0.64) mm at T_4 and the difference was significant ($P<0.05$) only between T_1 and T_4 , Table 6. On the other side, in the osseodensification group, the PPD mean

value started as 1.89 (± 0.59) mm at T_1 to reach 2.75 (± 0.38) mm at T_4 and the difference was significant ($P < 0.05$) between T_1 and T_4 & T_3 and T_4 , Table 6. There was no difference ($P > 0.05$) between the two groups when the PPD values were compared at different time points, Table 3.

Variables		Time points	P-value	
			Expanders group (N= 7 implants)	Osseodensification group (N= 7 implants)
Ridge Expansion	Occlusal point	Initial – Final	0.001*	0.001*
	Apical Point	Initial – Final	0.001*	0.002*
Implant Stability		$T_0 - T_1$	0.497	0.628
		$T_1 - T_2$	0.006*	0.003*
		$T_2 - T_3$	0.035*	0.043*
		$T_0 - T_3$	0.006*	0.009*
		$T_0 - T_4$	0.002*	0.007*
		$T_3 - T_4$	0.017*	0.006*
Peri-implant Pocket Depth		$T_1 - T_2$	0.345	0.510
		$T_2 - T_3$	0.864	0.336
		$T_1 - T_3$	0.431	0.095
		$T_1 - T_4$	0.008*	0.051*
		$T_3 - T_4$	0.111	0.049*
Modified Sulcus Bleeding Index		$T_1 - T_2$	0.200	0.360
		$T_2 - T_3$	0.231	0.358
		$T_1 - T_3$	0.457	0.018*
		$T_1 - T_4$	0.055	0.008*
		$T_3 - T_4$	0.022*	0.356
Marginal Bone Height	Mesial	$T_0 - T_1$	0.020*	0.002*
		$T_1 - T_3$	0.016*	0.017*
		$T_0 - T_3$	0.009*	0.002*
		$T_0 - T_4$	0.003*	0.000*
		$T_3 - T_4$	0.003*	0.001*
	Distal	$T_0 - T_1$	0.001*	0.015*
		$T_1 - T_3$	0.004*	0.030*
		$T_0 - T_3$	0.001*	0.001*
		$T_0 - T_4$	0.000*	0.0001*
		$T_3 - T_4$	0.012*	0.002*
	Buccal	$T_0 - T_1$	0.001*	0.007*
		$T_1 - T_3$	0.040*	0.051*
		$T_0 - T_3$	0.001*	0.007*
		$T_0 - T_4$	0.000*	0.000*
		$T_3 - T_4$	0.004*	0.001*
	Palatal	$T_0 - T_1$	0.005*	0.011*
		$T_1 - T_3$	0.001*	0.013*
		$T_0 - T_3$	0.001*	0.001*
		$T_0 - T_4$	0.000*	0.000*
		$T_3 - T_4$	0.004*	0.000*

Table 6. Significant differences ($P < 0.05$) at different follow up time points within each group, in regard to ridge expansion, implant stability, peri-implant pocket depth, modified sulcus bleeding index, marginal bone height. Implants were followed up at baseline (implant placement, T_0), loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading. *Statistical significance at $P < 0.05$.

Modified sulcus bleeding index

The modified sulcus bleeding index (mSBI) of both groups are shown in Table 4. In

the expander group, the difference between mSBI scores was significant ($P=0.022$) between T_3 and T_4 but was insignificant ($P>0.05$) among all other time points, Table 6. On the other side, the osseodensification mSBI values showed significant ($P<0.05$) differences between T_1 and T_3 & T_1 and T_4 but showed insignificant ($P>0.05$) difference among all other time points, Table 6. There was no significant ($P>0.05$) difference between the two groups when the mSBI values were compared at different time points, Table 4.

Marginal bone height

The CBCT scans taken at all time intervals showed no peri-implant radiolucency, Fig 2 and 4. Marginal bone height (MBH) values of both groups are shown in Table 5. In general, BMH values were declining in both groups from baseline time (T_0) to 36 months after loading (T_4). The differences among MBH values within each group were significant ($P < 0.05$), Table 6, however, the difference between the MBH values of the two groups was insignificant ($P>0.05$) at all time point, Table 5.

Discussion

This clinical trial evaluated the outcomes of delayed implant placement simultaneously with either osseodensification or expander technique for ridge expansion at the posterior maxilla. The clinical and radiographic outcomes were assessed and compared at baseline (implant placement, T_0), loading time (T_1), 6 (T_2), 12 (T_3), and 36 (T_4) months after loading. Here, we report three years of success of 100% of the implants placed with both techniques.

Osseodensification technique produced significant expansion at the occlusal level ($P=0.0001$) when compared to the conventional expander technique, Table 1. However, there was no significant difference between the outcomes of both techniques in terms of implant stability, peri-implant pocket depth, modified sulcus bleeding index and marginal bone height, at any time point.

Several techniques were proposed to increase the alveolar ridge width, to accommodate dental implants with ideal dimensions. These techniques include, guided bone regeneration (GBR), onlay block grafts, and alveolar distraction osteogenesis techniques.¹⁵ Most of these approaches require waiting time ranging between 6 to 12 months, a second site of

surgery, increase the morbidity and elevate the treatment cost with less than 100% success rate.¹⁶

Ridge splitting and bone spreading techniques provide treatment alternatives to bone grafting and guided bone regeneration.¹⁷ These techniques were significantly modified since they have been described by Summers.¹⁸⁻²⁰ Thereafter, the use of screw expanders and osseodensification techniques were introduced.¹⁰ This trial compared the clinical and radiographic outcomes of dental implants placed simultaneously with either osseodensification or traditional expander technique at a single missing maxillary premolar or molar. We planned for reasonable expansion of maxillary narrow ridge sites to yield better outcomes, in terms of implant stability and bone quality and quantity as compared to the traditional techniques. Our data demonstrate significant increase in the bone width at the implant site, on the occlusal and apical ridge levels, in both groups, Table 6.

Interestingly, our expander group exhibited less bone width gain which was significant when compared to osseodensification group. This might be explained by the screw expander criteria, such as; metal rigidity and thread pattern. These criteria require slow insertion of the expander to avoid production of high friction heat which can damage the alveolar bone. Therefore, allowing the bone to expand depending on its elastic capacity. In addition, avoiding excessive pressure when using the expanders, is crucial to minimize the risk of cortical bone fracture, this in turn, limits the expansion achieved.²¹ Chan et al, reported an overall mean width gain of 2 mm at the occlusal point and 0.79 mm apical to the crest when they restored 11 maxillae with 20 implants simultaneously with expander technique.²² Furthermore, Guillemant et al, reported a mean width gain of 1-2 mm during assessment of radiological sections in a similar study.²¹ Similar expansion techniques reported alike bone width gain.¹⁶⁻¹⁸ Cortes et al, treated 21 patients using bone screws and immediate implant placement and reported 2.5 mm of ridge width gain, however, most of their implants (33.3%) exhibited buccal bone dehiscence and required bone graft augmentation.²³ Mazzocco et al, reported 1.5 mm horizontal bone gain at the coronal portion and 1.6 mm under the crest of the bone by 5 mm when they used motorized expanders and guided

bone regeneration, without implant placement.²⁴ Similarly, Rahpeyma et al, treated 25 resorbed ridges with 82 dental implants and reported 2 mm ridge width gain after ridge splitting and bone augmentation.²⁵

Densah burs are designed with a large negative rake angle and multiple flutes. During osseodensification, these burs create hydrodynamic waves which simultaneously densify and expand the osteotomy site.⁹ Trisi et al, inserted 20 implants in the iliac crests of 2 sheep and reported 30% expansion in the iliac ridge width and increase in the bone volume percentage when compared to conventional drilling.⁸ In addition, densah burs can operate at high speed rotations (800 - 1200 rpm), an advantage that provides the practitioner with the haptic feedback to control the drilling force in accordance with the density of the bone. This results in shorter procedure time, improved tactile sensation and visibility, and better control of the axis and depth of the implant bed.⁹

In our study, we report significant increase in implant stability over the study time, in both groups as measured by resonance frequency analysis. This might have been affected by two main factors; the increased degree of osseointegration of the implants and the increased maturation of the surrounding bone, both factors occur naturally with time.²⁶

Modified sulcus bleeding index (mSBI), is a clinical indicator of inflammation. Both groups showed elevated mSBI scores, however, there was no evidence of developing peri-implantitis. Many factors were suggested to affect the gingival and periodontal health around dental implants, such as; inaccuracy regarded to variations among practitioners recording the mSBI.^{27,28} In this study, 4 clinicians scored measurements and collected data, independently and no significant differences were found among their scores.

The peri-implant pocket depth (PPD) is an important criterion in evaluating the periodontium health. Increased PPD values in this study, may be caused by reflecting a full-thickness mucoperiosteal flap, which might have led to a more apically positioned junctional epithelium around the implant.²⁹ Open wounds heal slowly with significant scarring due to peri-implant vascularity impairment.³⁰ In this trial, we used the full thickness mucoperiosteal flap to preserve the gingival/mucosal tissues from laceration during

expansion and implant placement, and to minimize the risk of possible infection. The full thickness flap allows proper monitoring of the buccal bone for identification of fenestration or dehiscence.³¹

In this study, we report marginal bone height (MBH) results that are similar to Nishioka et al.,³² and Rodriguez-Martinez et al.³³ In general, BMH values have significantly ($P<0.05$) decreased in both groups from baseline time (T_0) to 36 months after loading (T_4), Table 6, however, there was no difference ($P>0.05$) between the MBH values of both groups, Table 5. MBH is affected by several factors, such as; a) full thickness flap elevation which may interfere with revascularization of the peri-implant bone due to the stripping of the periosteum,¹³ b) bone expansion and spreading which exert pressure on the thin cortical plates and affect their blood supply and flow,²¹ and c) the resorption pattern of the maxilla which normally occurs more on the buccal bone side.

The present study has multiple limitations which include small sample size, limited follow up time and enrollment of female patients only which indicates that this study was not sampled from a well-defined population. Our inclusion and exclusion criteria limited the sample size, however, including only females in this study occurred by chance. Clinical outcomes are always affected by multiple variants which include age, sex, diet, anatomical considerations and health factors. This study presents valuable information on the applicability of osseodensification technique; however, wider pool of patients and long-term clinical trials will reveal more accurate and conclusive recommendations."

Conclusions

Within the limitations of the current study, there is no clinical relevant differences observed between osseodensification and screw expander techniques. Both expansion techniques show preserved alveolar bone in 14 narrow maxillary ridges with no bone grafting required. Ossodensification group gained significant ridge expansion at the occlusal point, when compared to the conventional expander group. Bone grafting to increase the bone quality and quantity of the future implant site is not required with osseodensification. Therefore, inclusion of

osseodensification with simultaneous implant placement, in the clinic, can offer shorter treatment time, minimize the risk of cross-infection and reduce the treatment cost.

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Declaration of Interest

The authors claim no financial interest, either directly or indirectly, in the products or information listed in the paper.

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