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Effect of Osseodensification on Implants Placed According to the All-On-Four Concept Supporting Immediately Loaded Maxillary Fixed Detachable Restorations (Randomized Clinical Trial)

Alaa Maher Khalifa[1], Ahmed M. Abdelhamid[2], Safeya ElGharabawy[2], and Ahmed M. Hommos[2].

[1] Removable Prosthodontics Department, Faculty of Dentistry, Pharos University in Alexandria, Egypt.
alaa.maher.khalifa@gmail.com

[2] Removable Prosthodontics, Prosthodontics Department, Faculty of Dentistry, Alexandria University, Egypt

ABSTRACT

Background: Rehabilitation of single edentulous maxillary arches with screw-retained prostheses is considered an optimal treatment choice. However, atrophy in the maxillary region may result in deficient bone volume for implants. The "All-on-4" concept offers favorable clinical results for immediate rehabilitation. Primary stability is essential for efficient immediate loading. Different osteotomy procedures were proposed for preparing the implant site. Osseodensification is used to improve the quality of bone and initial stability. **Aim of the study:** To compare and evaluate the effect of osseodensification versus the self-tapping technique on immediately loaded maxillary fixed-detachable restorations retained by implants inserted according to the all-on-four concept. **Materials and methods**: Twelve patients with maxillary posterior atrophy received screw-retained restorations supported by implants placed according to the all–on–four concept. A split-mouth design was conducted, where each patient received two implants inserted using the osseodensification technique and two using the self-tapping technique, followed by immediate loading. Primary stability was evaluated immediately after surgery and at 12 months. Radiographical evaluation of alveolar bone loss was evaluated using CBCT at insertion, 6 months, and 12 months later. **Results**: For primary stability, the highest mean values were recorded in the osseodensified side, while higher amounts of bone loss were measured at the self-tapping side, revealing statistical significance between both groups. **Conclusion:** Osseodensification provides better implant stability and less bone resorption in maxillary arches, improving the chances for immediate loading.

Keywords: Implants, Immediate loading, All-on-four, osseodensification, fixed detachable restorations.

Running title: Effect of osseodensification on immediately loaded maxillary fixed detachable restorations.

Introduction

The restoration of edentulous jaws is commonly and successfully done using fixed detachable implant-supported prostheses. In comparison to removable prostheses, they provide a proven level of long-term predictability, a greater level of patient satisfaction with regard to aesthetics, phonetics, and functioning, along with better psychological acceptance (1).

The viability of loading implants right immediately using a fixed prosthesis was suggested by several clinical trials. Immediate loading has several advantages for the patient, including a shorter period from edentulism to function, the elimination of the need for mobile removable dentures following implant placement, increased self-esteem, and better nutrition due to the rapid establishment of a normal diet (2).

The maxilla tends to develop a retrognathic form due to its divergent pattern of resorption, which might also make implant placement difficult or unsatisfactory from a functional and aesthetic standpoint. Additionally, maxillary sinus pneumatization may also restrict the amount of bone that can be used for a secure and dependable dental rehabilitation supported by implants (3).

The lateral and crestal routes of sinus elevation and bone grafting have been established over the past three decades; however, patient acceptability of these treatments may be limited due to their invasiveness, significant expense, and higher chances of morbidity (4, 5).

In an attempt to address these shortcomings, various clinical options, such as placing implants vertically inside the alveolar bone coupled with distal cantilevers without placing a distal implant, have been suggested; nevertheless, in cases of distal extensions surpassing 15mm, the success rates for this type of treatment have been questionable. The anterior jaw segments provide the dentist with more bone volume than the posterior segments, allowing them to insert lengthier implants, providing greater primary stability via anchoring the apices of the implant within the opposing basal cortical bone (6,7).

Tilting implants have been proposed to treat the atrophic edentulous maxilla without compromising anatomical structures during surgery or resorting to bone augmentation. Additionally, distal implants tilting in full-arch restoration permit a reduction in cantilever length and an increase in how far apart the most posterior and most anterior implant emergences, both of which have various prosthetic benefits (8). The use of lengthier implants and a suitable insertion axis will allow engaging the maximum amount of cortical bone, favoring the accomplishment of sufficient implants' primary stability (9).

Malo et al. (10) in 2003 presented the "All-on-4" approach, which was developed to overcome the restrictions of implant placement in posterior jaw segments with poor bone quality and quantity.

This approach relies on placing 4 implants in the anterior front segment of the jaws to anchor a fixed temporary prosthesis that is fastened and loaded right away. The two most posterior implants are inserted distally and at an angle, while the 2 anterior implants are positioned vertically (10).

An important parameter to consider when selecting an immediately loaded fixed detachable prosthesis is the initial stability. Accomplishment of primary stability, which is crucial for dental implants to succeed, can be significantly impacted by the quality of bone and quantity at the osteotomy site (10, 11).

A sufficient amount of bone in the implant bed is therefore essential to attain optimum stability and enable immediate loading. The maxilla, which has both a quality and quantity deficit in bone, frequently poses challenges in attaining primary stability. Nevertheless, a number of surgical methods were developed to enhance initial stability in these kinds of poor bone density locations. A common route chosen by clinicians is to under-size the osteotomy, particularly in thin ridges, to reserve bone volume and to promote initial stability, yet it does result in a significant level of mechanical strain on the bone (12,13).

Osseodensification, a more recent technique for osteotomy site preparation, has recently been introduced. The use of a densifying bur permits very little plastic deformation of bone while producing very little heat. Osseodensification was first described as a "bone non-extraction approach" by Huwais in 2013. Osseodensification directly increased the amount of implant insertion torques in comparison to self-tapping drilling, which suggests improved primary stability of the implant. The introduction of osseodensification (OD), a non-subtractive drilling technique, allowed for a closer adaptation of the implant to the osteotomy wall and increased primary stability. The unique drills known as "DENSAH Bur" spin in an anti-clockwise direction, compressing bone along the walls of the osteotomy. (14, 15).

Resonance frequency analysis, a noninvasive technique, has been employed to evaluate the implant stability. The simplicity, speed, ease of performance, and lack of potential patient discomfort are the benefits of this approach (16). Improved primary bone-to-implant contact percentage (BIC%) will be attained by attaining more primary stability. Ottoni et al. observed that each 9.8 Ncm increase in torque resulted in a 20% improvement in the survival rate of each implant, which is another indication of implant stability (17, 18).

This split-mouth design study was done to assess primary stability and radiographically assess and compare the effects of osseodensification on immediately loaded maxillary fixed detachable restorations retained by implantsinserted following the all-on-4 concept.

The null hypothesis was that immediately loaded maxillary fixed detachable restorations retained by implants inserted with the osseodensification technique will reveal no difference in clinical and radiographic results in comparison self-tapping technique.

Materials and Methods

This split-mouth design was a randomized clinical trial to evaluate and compare the use of osseodensification versus self-tapping drilling implant placement in immediately loaded maxillary fixed detachable restorations. Approval by the Ethical Committee (IRB NO: 00010556 – IORG 0008839), Faculty of Dentistry, Alexandria University, was obtained before commencing the clinical trial. A sample of twelve edentulous maxillary patients was selected from the Prosthodontic Department, Faculty of Dentistry, Alexandria University. The sample size was determined as 12 participants using MedCalc Statistical Software version 19.0.5. (19,20).

All patients enrolled in this study were systemically healthy, possessing an entirely edentulous maxilla that is posteriorly atrophic, sinus pneumatized, with less than 4 mm of posterior remaining bone height, and adequate bone in the inter-bicuspids area for implant placement with a minimum bone width of 6 mm. Opposing mandibular arch with either a full set of natural dentition or bilaterally restored dentition (19,21).

Each of the 12 maxillary edentulous arches was randomly divided into 2 segments using a computerized method www.randomizer.org. One side received implants using osseodensification, and the other side using self-tapping drilling. The individual allocating the patients was not aware of the allocation sequence (22). Masking/blinding was employed for the patients, and the statisticians were unaware of the segmentation of patients. After being briefed about the procedures, all patients who agreed to take part in the study signed written informed consent.

CBCT (Scanora 3DX Soredex) was used to

determine the remaining bones' quality and quantity, the relation of critical structures to the prospective implants' sites, and the determination of implant position and orientation, using. A CAD/CAM-fabricated surgical guide was created via a dual-scan process. A prefabricated maxillary single complete denture was marked using radio-opaque markers (gutta-percha) at approximately 6-8 sites at different levels in relation to the occlusal plane, corresponding to different tooth positions. A radiographic index was created at centric occlusion to stabilize the denture during the CT scanning procedure. The first scan was done with the radiographic guide placed intraorally in the patient's mouth and biting on the radiographic index, ensuring the correct positioning of the denture. The second scan was done for the radiographic guide outside the patient's mouth. Virtual implants (Blue Sky Plan; Blue Sky bio.) were planned in the maxillary interbicuspid region, two anterior implants, with a length of thirteen mm and a width of 4 mm, were placed axially, while the 2 posterior implants (with the same length and width) were angulated distally at 30º. The CAD/CAM fabricated, three-dimensionally printed, fully-guided surgical guide (Form 2; Formlabs) was used to perform a fully guided drilling procedure.

Local anesthesia 4% lidocaine, was given to the patient. The surgical guide was fitted in place. (Figure 1) Fixation screws were placed to prevent movement of the surgical arch guide duringdrilling. A Tissue punch was used to perform soft tissue punches through the sleeve holes. On one side, the osteotomy preparation was made using the self-tapping technique. Using the Pilot Drill, the osteotomies were prepped to the required depth. Thereafter, traditional self-tapping drills were applied sequentiallyaccording to the implant diameter. For the other osseodensification side, with the pilot drill rotating in a clockwise direction, the implant site was drilled to the specified depth while maintaining profuse irrigation. Afterwards, osseodensification drills (Versah, Densah® Bur system) were used in sequence with the drill motor reversed (counterclockwise direction). For each patient, four implants (Neobiotech, IS-II active) wereinserted in the inter-bicuspid segment, 2 mesial vertical implants and 2 angled implants in the distal position, following the All-on-4 treatment concept. Primary stability was checked using Osstell (Osstell Mentor; Osstell AB) (figure 2). Patients were maintained on oral antibiotics (Augmentin 1gm / 12 hours) and analgesics (Brufen 600mg) for 5 days. Mouthwash was prescribed. Immediately post-implant surgery, the prefabricated removable single denture was provisionalized as an implant-supported fixed detachable denture (19-21). To improve screw access hole orientation, for the inclined implants, angled multi-unit abutments were fastened to the distal implants right away, while straight multi-unit abutments were fastened to the anterior implants (Figure 3). Auto-cure acrylic resin was used to affix temporary cylinders to the provisional denture. Immediately post-surgery, the provisional denture was delivered to the patients. Finally, the occlusion was adjusted.

Figure 1: CAD/CAM fabricated fully guided surgical guide.

Figure 2: OSSTELL® device used to measure primary stability

Figure 3: Multiunit abutments secured to implants.

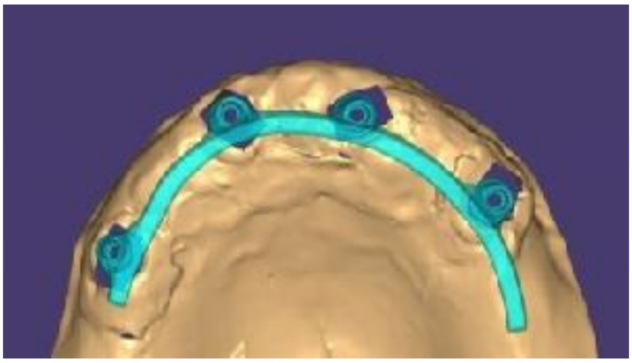

Figure 4: CAD design of the bar substructure

The definitive prosthetic procedure commenced after 4-6 months from placement of the implants. The impression technique selected was open-tray. Implant analogues were used when making the stone casts, and an intraoral verification index was used to confirm the correctness of the replica placements. Wax rims were used to record the patients' maxillo–mandibular bite registration.

The artificial teeth setup was established and verified using a silicone index. The trial dentures' wax-up was verified intra-orally and thenindexed for final processing after the patients' approval. The master cast was then scanned using a desktop bench scanner (company), and the scan was exported as an open file in STL format. ExoCad (exocad GmbH) software was used to design the metal substructure (Figure 4). The metal framework was printed out and tried in intra orally and verified for an accurate fit. Heat-cured acrylic resin was applied to the frameworks in accordance with conventional laboratory protocols, and prefabricated acrylic resin teeth (visio.lign, bredent) were used to veneer the metal substructure. Prosthetic screws were used to secure the prosthesis to the abutments. After that, cotton pellets were used to plug the screw holes, and a light-curable composite resin was applied on top. (Figure 5)

Figure 5: Final delivery of the prosthesis

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Implant stability measures were taken at the time of implant placement and 12 months later, with the help of the Osstell device instrument (Osstell Mentor; Osstell AB), a resonance frequency analysis tool. Implants were fitted with smart pegs, the transducer was placed, followed by taking four measurements from the distal, mesial, lingual, and buccal parts, and the mean was computed. The implant stability quotient (ISQ) is a numerical value between 1 and 100 that is recorded by the Osstell unit. The larger the ISQ value recorded indicates the more stable the implant-bone interface (19, 21). Radiographic evaluation was done at the insertion time, 6 months, and after 12 months (Figure 6). Radiographic assessment of the vertical bone change around each implant using CBCT. Conventional exposure settings (23, 24) and a 0 mm slice thickness

were employed, and images were stored as "digital imaging and communications in medicine" (DICOM) files. Mesiodistally and buccolingually, the implants were intersected in the axial images of the reconstructed CT scan. The resulting imageries offer a cross-sectional perspective to assess buccal and lingual loss of bone, as well as a panoramic overview of each implant to assess mesial and distal loss of bone (23). The images' contrast and brightness were adjusted using the OnDemand3DApp Software (24). The method outlined by Elsyad et al. for evaluating marginal bone loss was used (23). On the mesial, distal, buccal, and lingual aspects of each implant, the marginal vertical bone height was calculated as a

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distance from two fixed points, the implant-abutment connection and the bone-implant contact, and the mean value was calculated.

Figure 6: Post-insertion CBCT.

The Software known as SPSS (Statistical Package for Social Sciences) version 23.0 was used to process and analyze the data.

Results

This study was conducted to clinically and radiographically assess and compare the effect of using the osseodensification drilling technique versus the self-tapping traditional drilling technique on immediately loaded maxillary fixed detachable restorations retained by implants placed following the all-on-four concept. Standard deviation, mean, and range (minimum and maximum) were used to compute quantitative data. The computer was fed data, and the IBM SPSS software package version 20.0 was used for analysis. (IBM Corp., Armonk, NY) (25). To confirm that the distribution was normal, the Shapiro-Wilk test was performed. The terms range (minimum and maximum), mean, standard deviation, and median were used to characterize quantitative data. The results were deemed significant at the 5% level. One test that was employed was the Paired T-test, which compares two periods for quantitative variables that are normally distributed. 2. Wilcoxon signed-rank test: To compare two periods for quantitative variables with aberrant distributions (26).

On comparing the implant stability (ISQ) between the studied groups (Table 1) at baseline and after 12 months of follow-up. The lowest mean values were recorded in the control group (self-tapping side) at baseline (62.21 ± 5.08) and also after 12 months follow up (66.54 ± 6.67) while the highest mean values were recorded in the study group (osseodensified side) at baseline (71.42 ± 2.43) and after 12 months (78.67 ± 3.12) revealing a statistical significance between the two groups and indicating that the osseodensified osteotomies exhibited higher initial stability values enabling them to be safely immediately loaded.

According to measurements from the CBCT, on comparing the bone level changes between the studied groups (Table 2) at baseline, 6 months, and after 12 months of follow-up. The highest mean values were recorded in the control group (standard drilling side) (0.37 ± 0.12) at baseline, (0.63 ± 0.14), and (1.0 ± 0.12) after follow-up for 6 and 12 months, respectively. While the lowest mean values were recorded in the study group (osseodensified side) at baseline (0.30 ± 0.10), after 6 months (0.53 ± 0.16), and after 12 months (0.75 ± 0.20), revealing a statistical significance between the two groups.

Finally, Table 3 highlights the bone level changes when comparing the vertical and angled implants placed in each of the studied groups at baseline, 6 months, and after 12 months of follow-up. At baseline, at 6 months, and after 12 months follow-up, the highest mean values were recorded in the angled group in the control side (0.48 ± 0.04), (0.71 ± 0.11), (1.04 ± 0.13), respectively. The results revealed that angled implants in both the control and study group revealed higher mean values of bone level changes than the vertical implants in both groups. However, the rate of bone loss for the osseodensified side was less than the self-tapping side.

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Table (1): Comparison between the two studied groups according to implant stability (ISQ)

Implant stability (ISQ)	Control (self-tapping) (n = 24)	Study (Osseodensification) (n = 24)	t	p
Baseline				
Mean ± SD.	62.21 ± 5.08	71.42 ± 2.43	8.833*	<0.001*
Median (Min. – Max.)	62.0 (52.0 – 70.0)	71.0 (68.0 – 78.0)		
12months				
Mean ± SD.	66.54 ± 6.67	78.67 ± 3.12	8.405*	<0.001*
Median (Min. – Max.)	65.0 (55.0 – 77.0)	78.0 (74.0 – 86.0)		

SD: Standard deviation **t: Paired t-test**
p: p-value for comparing between Control and Experimental in each position
***: Statistically significant at p ≤ 0.05**

Table (2): Comparison between the two studied groups according to bone level changes in CBCT

Bone changes in CBCT	Control (self-tapping) (n = 24)	Study (Osseodensification) (n = 24)	t	p
Baseline				
Mean ± SD.	0.37 ± 0.12	0.30 ± 0.10	1.968	0.061
Median (Min. – Max.)	0.38 (0.20 – 0.55)	0.31 (0.10 – 0.51)		
6months				
Mean ± SD.	0.63 ± 0.14	0.53 ± 0.16	1.758	0.092
Median (Min. – Max.)	0.62 (0.42 – 0.91)	0.55 (0.29 – 0.81)		
12months				
Mean ± SD.	1.0 ± 0.12	0.75 ± 0.20	4.959*	<0.001*
Median (Min. – Max.)	0.99 (0.87 – 1.3)	0.75 (0.50 – 1.03)		

SD: Standard deviation **t: Paired t-test**
p: p-value for comparing between Control and Experimental in each position
***: Statistically significant at p ≤ 0.05**

Table (3): Comparison between vertical and angled implants according to bone level changes in control and study groups.

	Bone changes in CBCT	Vertical (n = 12)	Angle (n = 12)	t	p
Control (self-tapping)	**Baseline**				
	Mean ± SD.	0.27 ± 0.05	0.48 ± 0.04	24.372*	<0.001*
	Median (Min. – Max.)	0.26 (0.20 – 0.34)	0.47 (0.42 – 0.55)		
	6months				
	Mean ± SD.	0.54 ± 0.11	0.71 ± 0.11	5.394*	<0.001*
	Median (Min. – Max.)	0.54 (0.42 – 0.77)	0.69 (0.58 – 0.91)		
	12months				
	Mean ± SD.	0.96 ± 0.10	1.04 ± 0.13	1.985	0.073
	Median (Min. – Max.)	0.91 (0.87 – 1.20)	1.0 (0.90 – 1.34)		
Study (osseodensification)	**Baseline**				
	Mean ± SD.	0.37 ± 0.07	0.22 ± 0.06	11.218*	<0.001*
	Median (Min. – Max.)	0.34 (0.30 – 0.51)	0.21 (0.10 – 0.33)		
	6months				
	Mean ± SD.	0.68 ± 0.07	0.39 ± 0.07	13.786*	<0.001*
	Median (Min. – Max.)	0.69 (0.57 – 0.81)	0.38 (0.29 – 0.52)		
	12months				
	Mean ± SD.	0.93 ± 0.06	0.57 ± 0.06	18.807*	<0.001*
	Median (Min. – Max.)	0.93 (0.80 – 1.03)	0.56 (0.50 – 0.70)		

SD: Standard deviation, t: Paired t-test.
p: p-value for comparing between Vertical and Angle in each period
***: Statistically significant at p ≤ 0.05**

Discussion

For many years, implantology has made considerable use of conventional drilling techniques. It has some drawbacks, including bone removal, elliptically shaped osteotomy preparation that would have extended the time needed for bone remodelling, and poor initial stability, specifically in low bone density areas. In order to evaluate the initial stability and crestal bone loss around implants placed in the maxilla using conventional self-tapping drilling and osseodensifying drilling techniques, this study was designed (12). The null hypothesis was rejected since the results showed that there was a significance in regards to improved implant stability and less bone loss, favoring the osseodensified side

The split mouth design was adopted as it allows for an objective comparison of the different drill types within each patient, leading to an equal healing potential under equal immunological and microbiological conditions (27,28).

One of the key indicators of effective osseointegration is implant stability. The resistance to cutting of the implant during placement is typically the basis for the clinical judgement of primary implant stability. Resonance frequency analysis (RFA) is a helpful tool to assess the implant loading time since it provides a non-invasive clinical test of implant stability and osseointegration. The Implant Stability Quotient (ISQ), a numerical measure that ranges from 1 to 100, serves as a quantitative representation of the RFA values (27). The Osstell device was used in this investigation to test the implant stability quotient because it is simple, quick, and easy to use, and there is no danger of patient discomfort (15).

The results of this investigation align with those of earlier studies on the primary stability of implants (27,30,31), which found a statistically significant difference between the two drilling procedures. Other studies, however, found no statistically significant difference, even though drilling values obtained with Densah burs were somewhat higher than those obtained with traditional surgical drills (12,32,33). The oseodensified side showed increased primary implant stability. This might be owing to the theory that this method preserves bone in two different ways: first, by compressing cancellous soft bone through its plastic deformation, and second, by autografting bone fragments along the osteotomy's apex and length. This method makes use of specially created drills with more than four lands that gently condense the bone along the osteotomy and have multiple negative rake angles serving as noncutting edges (34). The low density (D3-D4) of the bone in the maxilla and the fact that traditional self-tapping drilling does not permit bone densification may both contribute to the conventional drilling implants' lower primary stability.

In this investigation, a cone beam computed tomography scan was employed since it is a reliable and accurate way to quantify alveolar bone height. Cone Beam CT was therefore utilized in this study to assess marginal bone loss (15). Because, periapical And panoramic radiographs are only twodimensional. Cone beam computed tomography was utilized to evaluate changes in marginal bone level because, because of its 3-dimensional nature, it provides data on bone loss in all aspects (buccally, lingually, mesially, and distally) of the implants (23). After one year of follow-up, vertical bone level changes in the two groups under study did increase, but not significantly, according to a statistical analysis of the radiography results from the current research. This could be brought on by functional stressors in addition to bone remodeling that happens following implant insertion and the bone's response to healing (35,36).

The mean marginal bone loss, after 12 months of follow-up up was somewhat higher in sites where the osteotomy was done using traditional drilling in comparison to the osseodensifying drills. Nonetheless, the difference was found to be insignificant. This may be owing to the fact that densah drills served to autograft the bony chips, acting as nuclei to attract more dense bone formation along the osteotomy wall. These results agree with other similar investigations (12,15) on the other hand another study by Arafat et al. (30) found that there was a significant increase in bone height for both types of drilling perhaps, the difference in those results maybe because unlike arafat, this study was done using computer-guided flapless implant placement, which preserves the intact periosteum and improves blood flow, lowers the risk of early bone resorption, flapless procedure.

The posterior angled implants did, however, exhibit more bone loss than their vertical counterparts in both groups. These results agree with Omori et al. (37), who revealed that, following a year of follow-up, angled implants supporting angulated abutments produced noticeably higher marginal bone loss than those carrying straight abutments. This may be due to several facts, firstly being located in the posterior segment of the arch, where the forces are higher than the anterior segment; secondly, since the forces falling on those angled implants tend to be off-axis (not within the long axis of the implant), both these factors may contribute to the increased bone loss recorded around the angled implants. (38,39)

Conclusion

Osseodensification drilling technique provided higher values of implant stability and less bone loss in comparison to the self-tapping technique, enabling the implants to be immediately loaded successfully, especially in the maxillary arch, where D3, D4 bone is found. Within each group, angled implants showed higher values of bone loss than vertical implants when comparing the osseodensified side and the self-tapping side.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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