

ASSESSMENT OF IMPLANT STABILITY IN IMMEDIATELY LOADED MAXILLARY FIXED DETACHABLE RESTORATIONS USING OSSEODENSIFICATION (RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: Rehabilitation of single edentulous maxillary arches with screw-retained prostheses is considered an optimal treatment choice. However, atrophy in the maxilla 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 preparation of the implant site. Osseodensification is used to improve quality of bone and initial stability.

AIM OF THE STUDY: To compare and evaluate the effect of osseodensification versus 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 retained by implants placed following the all-on-four concept. Split mouth design was conducted whereas each patient received two implants inserted following the osseodensification technique and two utilizing the self-tapping technique followed by immediate loading. Implant stability was evaluated immediately after surgery and 12 months.

RESULTS: Implant stability measures showed the highest mean values in the osseodensified side over the self-tapping, revealing a statistical significance between both groups ($p \leq 0.05$)

CONCLUSION: Osseodensification provides better implant stability in maxillary arches improving the chances for immediate loading.

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

RUNNING TITLE: Effect of osseodensification on immediately loaded maxillary fixed detachable restorations.

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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 regards 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 also may restrict the amount of bone that can be used for a secure and dependable dental rehabilitation supported by implants (3).

The lateral and crestal route 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 has been proposed in order to treat the atrophic edentulous maxilla without compromising anatomical structures during surgery or resolving to bone augmentation. Additionally, distal implants tilting in full-arch restoration permits a reduction in cantilever length and an increase in how far apart are 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 of the maximum amount of cortical bone, favoring the accomplishment of sufficient implants primary stability (9).

Malo et al. in 2003 presented the "All-on-4" approach, it 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. 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 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. With the use of a densifying bur, it 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 "DENSEAH 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 currently 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).

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

The null hypothesis was that immediately loaded maxillary fixed detachable restorations retained by implants inserted with osseodensification technique will reveal no difference in comparison with 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 and an informed consent form was signed by all participants before commencing the clinical trial. A sample of twelve edentulous maxillary patients were selected from Prosthodontic Department, Faculty of Dentistry, Alexandria University. The sample-size was determined as 12 participants using MedCalc Statistical Software version 19.0.5. (17,18).

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-bicuspid area for implant placement with minimum bone width of 6 mm. Opposing mandibular arch with either full set of natural dentition or bilaterally restored dentition (17,19,20).

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 (21). Masking/blinding was employed to the patients and the statisticians were unaware of 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 the quantity, the relation of critical structures to the prospective implants' sites and 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 position. 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 patients 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 length of thirteen mm and width of 4 mm were placed axially, while the 2 posterior implants (with the same length and width) were angulated distally at 30°. 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 during drilling. A Tissue punch was used to perform soft tissue punches through the sleeve holes. For 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 sequentially according 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) were inserted in the inter-bicuspid segment, 2 mesial vertical implants and 2 angled implants in the distal position following to the All-on-4 treatment concept. Primary stability was checked using Osstell (Osstell Mentor; Osstell AB). Patients were maintained on oral antibiotics (Augmentin 1gm / 12 hours) and analgesics (Brufen 600mg) for 5

days. Immediate post-implant surgery, the prefabricated removable single denture was provisionalized as implant-supported fixed detachable denture (17-20). In order 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 2). Auto-cure acrylic resin was used to affix temporary cylinders to the provisional denture. Post-surgery, each patient's previous denture was immediately delivered after occlusal adjustments. Finally, the occlusion was adjusted.

The definitive prosthetic procedure commenced after 4-6 months from placement of the implants. The impression technique selected was open-tray using abutment level impression. Abutment analogues were connected to impression copings and stone casts were poured. An intraoral verification index was used to confirm the correctness of the impression. Wax rims were used to record the patients' maxillo-mandibular bite registration. Artificial teeth setup was established and verified using a silicone index. The trial dentures' wax-up were verified intra-orally and then indexed 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 used to design the metal substructure (figure 3). The Co-Cr metal framework was printed out and tried in intra orally and verified for accurate fit. Heat-cured acrylic resin 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 4). A follow up CBCT was requested to verify the final prosthesis placement (Figure 5)

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, 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 (17, 20).

The Software known as SPSS (Statistical Package for Social Sciences) version 23.0 was used to process and analyze the data. Standard deviation, mean, and range (minimum and maximum) were

used to compute quantitative data. The computer was fed data, and IBM SPSS software package version 20.0 was used for analysis. (IBM Corp., Armonk, NY) (22). 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. (23).

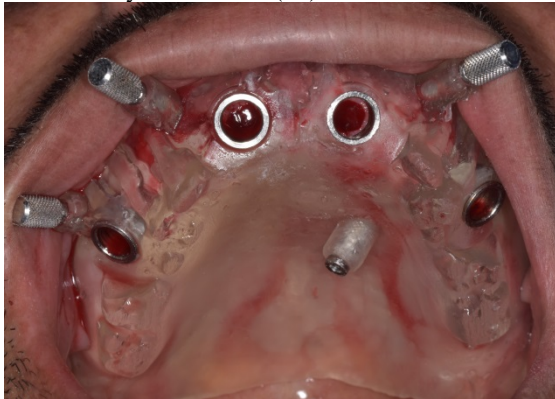


Figure 1: CAD/CAM fabricated fully guided surgical guide.

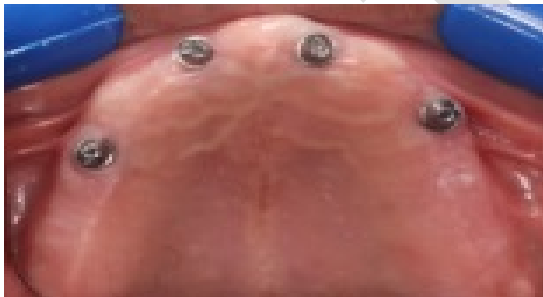


Figure 2: Multiunit abutments secured to implants.

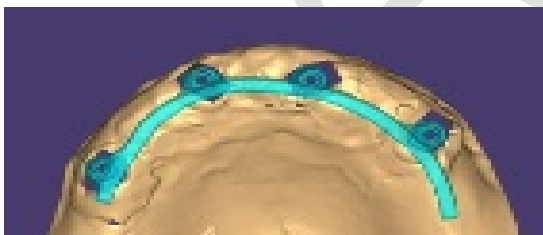


Figure 3: CAD design of the bar substructure.



Figure 4: Final delivery of the prosthesis.

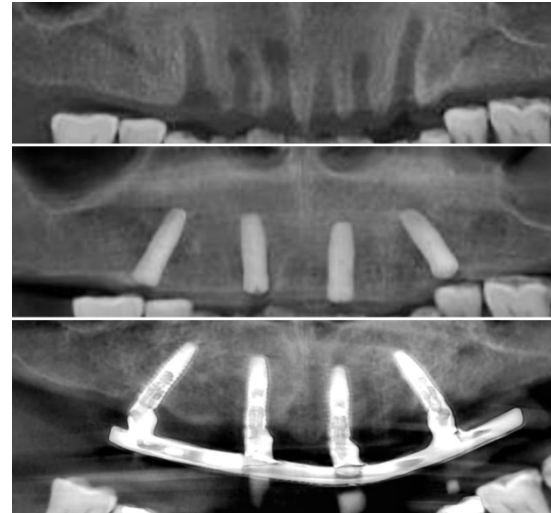


Figure 5: Follow-up CBCTs.

RESULTS

When the implant stability (ISQ) was compared regarding the vertical and angled implants between both studied groups at base line and after 12 months follow up the following was revealed (table 1). At baseline, the lowest mean values were recorded in the control group (self-tapping side) for the angled implants (62.0 ± 5.0) followed by the vertical implants (62.42 ± 5.38) and also after 12 months follow up for the angled and vertical implants respectively (66.42 ± 6.86) and (66.67 ± 6.77). While the highest mean values were recorded in the vertical implants of the study group (osseodensified side) after 12 months (79.08 ± 3.90) followed by the angled implants (78.25 ± 2.18) revealing a statistical significance ($p \leq 0.05$) between both groups for each the vertical and angled implants.

However, within each studied group when comparing the vertical to the angled implants (table 2) the highest mean values were recorded for the vertical implants of the osseodensified side after 12 months (79.08 ± 3.90). On the other hand, when comparing the implant stability (ISQ) between the studied groups (table 3) at base line and after 12 months 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 ($p \leq 0.05$) between the two groups and indicating that the osseodensified osteotomies exhibited higher initial stability values enabling them to be safely immediately loaded.

Table (1): Comparison between the vertical and angled implants within the two studied groups according to Implant Stability (ISQ)

Implant stability (ISQ)	Vertical		Angled	
	Control (self-tapping) (n = 12)	Study (osseodensification) (n = 12)	Control (self-tapping) (n = 12)	Study (osseodensification) (n = 12)
Baseline				
Mean ± SD.	62.42 ± 5.38	72.25 ± 2.67	62.0 ± 5.0	70.58 ± 1.93
Median (Min. – Max.)	62.50 (52.0 – 68.0)	72.0 (70.0 – 78.0)	60.50 (55.0 – 70.0)	70.0 (68.0 – 75.0)
t (p)	t=6.480*(<0.001*)		t=6.011*(<0.001*)	
12months				
Mean ± SD.	66.67 ± 6.77	79.08 ± 3.90	66.42 ± 6.86	78.25 ± 2.18
Median (Min. – Max.)	66.0 (55.0 – 77.0)	78.50 (74.0 – 86.0)	64.0 (60.0 – 77.0)	78.0 (75.0 – 83.0)
t (p)	t=6.168*(<0.001*)		t=5.497*(<0.001*)	

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

Table (2): Comparison between Vertical and Angled implants according to implant stability (ISQ) in each the control (self-tapping) and the study (osseodensification) group.

	Implant stability (ISQ)	Vertical (n = 12)	Angled (n = 12)	t	p
Control (self-tapping)	Baseline				
	Mean ± SD.	62.0 ± 5.38	62.42 ± 5.0	0.428	0.677
	Median (Min. – Max.)	62.50 (52.0 – 68.0)	60.50 (55.0 – 70.0)		
12months					
Study (osseodensification)	Baseline				
	Mean ± SD.	72.25 ± 2.67	70.58 ± 1.93	1.311	0.051
	Median (Min. – Max.)	72.0 (70.0 – 78.0)	70.0 (68.0 – 75.0)		
12months					
	Mean ± SD.	79.08 ± 3.90	78.25 ± 2.18	0.931	0.372
	Median (Min. – Max.)	78.50 (74.0 – 86.0)	78.0 (75.0 – 83.0)		

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

Table (3): 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 Study in each position
 *: 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 re-modelling, and poor initial stability, specifically in low bone density areas (12). 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. 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. In this study the patients selected for enrollment had edentulous maxillae opposed by dentate mandibular arches. These patients were particularly indicated to receive implant retained prosthesis while also benefiting from osseodensification in order to be able to withstand forces generated by the opposing natural teeth and to validate the use of densah burs. (24,25).

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 (24,26). The Osstell device was used in this investigation to test the implant stability quotient because it is simple, quick, and simple 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 (24,27,28), which found a statistically significant difference between the two drilling procedures. Other studies, however, found no statistically significant difference, despite the fact that drilling values obtained with Densah burs were somewhat higher than those obtained with traditional surgical drills (12,29,30). The osseodensified 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 (31). 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.

The posterior angled implants did however exhibit less values of ISQ than their vertical counterparts in both groups, these results agree with studies who revealed that, following a year of follow-up, angled implants supporting angulated abutments showed less stability than those carrying straight abutments (32,33,34). This may be due to a number of 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 less values of stability around the angled implants. (35)

Following 12 months of recovery and follow-up, both groups' average ISQs increased. Value changes correspond to modifications in the bone-implant interaction. Improved results seen in the osseodensified side maybe 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 (15,27) on the other hand another study by Sultana et al. (12) found that there was an insignificance between both types of drilling perhaps, the difference in those results maybe because unlike Sultana et al, 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, enhancing primary stability.

Further studies with a larger sample size and longer period of follow up are needed to verify the results of the current study.

CONCLUSION

Osseodensification drilling technique provided higher values of implant stability 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.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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