

EFFICIENCY OF USING OSSEODENSIFICATION PROTOCOL FOR ALVEOLAR RIDGE EXPANSION IN CASES OF ATROPHIC EDENTULOUS ALVEOLAR RIDGES (RANDOMIZED CONTROLLED TRIAL)

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ABSTRACT

Aim: This study aimed to compare the Osseodensification protocol and the conventional alveolar ridge widening technique regarding comfort and efficiency in gaining alveolar ridge width in patients suffering from maxillary horizontal alveolar bone loss.

Materials and methods: This study was conducted on 18 cases suffering maxillary horizontal alveolar ridge width deficiency and seeking dental implant placement. Patients were equally divided into two groups. The first group (study group) in which Osseo-densification protocol was applied using Densah burs. The second group (control group) in which conventional ridge widening technique was done using manual hand driven osteotomes.

Results: The average clinical bone width gain was 2.12 ± 0.40 mm for the osseodensification group, and 1.87 ± 0.35 mm for the osteotome group which indicates statistically insignificant increase in bone gain in osseodensification group in relation to osteotome group. Moreover, the radiographic average bone width gain was 2.10 ± 0.42 mm and 1.59 ± 0.63 mm for the osseodensification and hand osteotome groups respectively. Both groups allowed for immediate dental implant fixture insertion at the expanded osteotomy site. The mean ISQ measurements via Osstell device were 82.17 ± 8.28 and 81.61 ± 7.36 for the osseodensification group and the osteotome group respectively. The average amount of pain was not significantly different between the two groups. An average time of 29.22 ± 6.16 and 32.22 ± 5.07 minutes were required to completely perform the osseodensification procedure and hand osteotome technique respectively.

Conclusion: Osseodensification is an efficient alveolar ridge widening surgical technique that can be used in horizontally deficient maxillary alveolar ridges.

KEYWORDS: Osseodensification, Alveolar ridge expansion, edentulous

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INTRODUCTION

Throughout the years, researchers and dental clinicians have worked hard to find an effective method for restoring missing teeth. Therefore, the search for a better longstanding way to restore missing teeth was a must. Thanks to Brane mark's discovery of osseointegration a possible solution was introduced. An end-osseous implant supported prosthesis became feasible. Since that time, dental implants served a successful way to substitute missing teeth. Dental implants are a dependable and well-documented treatment for rehabilitation of edentulous sites. ⁽¹⁾

Due to its efficiency, dental implant supported prosthesis became the patients first choice for restoring missing teeth. Patients usually desire implant supported fixed restorations that mimic natural teeth. ⁽¹⁾ Nowadays, dental implants have turned out to be the best solution for replacing missing dentition. Dental implant therapy is the gold standard method for restoring edentulous sites. ⁽²⁾

Finally, Osseointegration which is the direct functional and structural union between the dental implant surface and the surrounding bone. The osseointegration is an ankylotic connection between the implant surface and the surrounding bone. ⁽³⁾

A mobile implant will cause the biological pendulum to shift early healing phases towards soft tissue formation around the implant surface, that will consequently lead to fibrous encapsulation of the inserted fixture. ⁽⁴⁾ Primary stability sets the foundation upon which secondary stability will be built until final osseointegration is achieved. High Initial stability of the implant sets the base upon which biological, or secondary, stability is obtained via osteo-conduction and subsequent bone modelling and remodeling. ⁽⁵⁾

Horizontally deficient maxillary alveolar ridges are one of the most challenging regions for dental implants insertion. Atrophied maxillary bone rep-

resents a famous anatomical restriction for implant therapy. ⁽⁶⁾ The reason is the combination between poor bone quality and quantity in such regions. It is difficult to obtain sufficient implant stability in such jeopardized alveolar ridges. Poor nature and deficiency of maxillary ridges are negative factors that diminish -bone-fixture interface connection and adversely affect implant retention. ⁽⁷⁾

Maxillary alveolar ridges are usually of less bone quality than mandibular alveolar ridges. The bone quality is higher for the mandible than for the maxilla. ⁽⁸⁾ Therefore, it is more difficult to obtain sufficient implant primary stability in maxillary alveolar ridges. Inadequate primary stability will result in inability to achieve osseointegration. Insufficient primary stability allowing micromotion at the implant-bone interface greater than 150µm prevents osseointegration. ⁽⁹⁾ In a study the researchers concluded that micro-motion of inserted implant fixtures leads to occurrence of fibroplasia as a biologic response in the bone tissue. ⁽¹⁰⁾

Many techniques have been introduced along the past decades to obtain higher implant primary stability and enhanced bone quality and quantity at the potential implant site. One of the most successful and most widely applied techniques is the ridge widening osteotome technique. The technique was introduced to enhance bone quality at low density soft bone sites via bone compression without removing bone. It allowed for gaining width at the osteotomy site in addition to simultaneous implant placement. Moreover, ridge widening resulted in higher implant primary stability. Therefore, a better chance for success. The osteotome technique (OT) was presented to enhance bone-implant interface properties, which would increase the primary stability of implants in low-density bones particularly in the maxilla. ⁽¹¹⁾

The Densah burs through Osseodensification (OD) technique act to efficiently and softly compress bone to create sufficient bone width for implant

placement. In contrast to regular drilling, this method uses densifying burs that have four or more lands and flutes which are capable of compacting bone into marrow spaces.⁽¹²⁾ Utilizing these burs by bouncing motion in counterclockwise rotation under copious irrigation can trigger hydrodynamic compression to densify the bone.⁽¹³⁾

This study aimed to compare the Osseodensification protocol and the conventional alveolar ridge widening/splitting technique regarding comfort and efficiency in gaining alveolar ridge width in patients suffering from maxillary horizontal alveolar bone loss prior to dental implants placement.

MATERIAL AND METHODS:

This study was conducted on 18 implant sites with horizontally atrophied alveolar bone prior to dental rehabilitation with dental implants in Maxilla; in the department of Oral and Maxillofacial Surgery, Cairo University. These patients will be categorized in 2 equal groups.

Inclusion criteria, were absence of systemic conditions that would contraindicate dental implant fixture insertion. Inclusion criteria involved Age ≥ 18 years old. In cases of an initial ridge width ≤ 5 mm that contains ≤ 2 mm of trabecular bone core. Alveolar ridges with narrow crest and wider base. Exclusion criteria were uncontrolled diabetic patients, heavy Smokers, patients suffering from osteoporosis or receiving chemo or radio therapy or suffering from bleeding disorders or from intraosseous lesions at the proposed site of implant, patients with insufficient alveolar bone height less than 10 mm and resorbed ridge with a narrow base.

Method of random sequence was computerized random number generation with Allocation ratio (1:1). Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned. Trial participants, researcher,

supervisors, outcome assessors and statistician were blinded after assignment to interventions.

Auditing of the study design was done by the research committee of the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University. The study was independently reviewed and approved by Ethics committee of scientific research, Faculty of Dentistry, Cairo University. Approval number was (13 9 22). The Evidence-Based committee, Faculty of Dentistry, Cairo University, did the auditing of the study design.

Preoperative Preparations were through Case history: Personal data, Chief complaint and thorough medical history were gathered from all patients via combined questionnaire and verbal conversation, Clinical assessment, preoperative photos and impressions to develop study casts, Laboratory investigations will be conducted (CBC, coagulation profile, random blood glucose, H_{1c}) and Radiographic assessment with cone beam CT and measuring the height and width of the alveolar bone at the region of interest using special software. (Fig. 1)

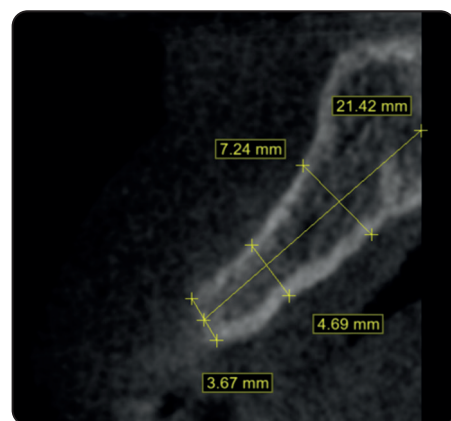


Fig. (1) Preoperative measurements of alveolar ridge.

General operative procedure:

- Osseodensification ridge expansion:

The procedures were performed on dental chair under local anesthesia* with vasoconstrictor

* Mepicaine, Alexandria Co. for pharmaceuticals, Egypt.

epinephrine 1:100000. Crestal incision was done at the area of interest. Mucoperiosteal flap was elevated. Measurement of residual alveolar ridge width was done using graduated gauge. (Fig. 2) After making narrow Pilot osteotomy, a small disc of 1cm diameter was used to do initial crestal osteotomy. This was followed by using narrowest Densah bur* in counter-clockwise drilling at speed 800-1500 rpm in pumping motion till reaching the desired length. (Fig. 3) Sequential Densah burs in small increments were used till desired diameter reached ridge width. Implant** placement with diameter equal to or slightly (0.7 mm) larger than the initial ridge width was performed. If remaining buccal bone is less than 1mm, bone augmentation*** was performed followed by measuring primary stability by using smartpeg of osstell****. Finally, flap closure with no tension using 4-0 black silk sutures*****.

- Conventional ridge widening:

The procedure was done on dental chair under local anesthesia with vasoconstrictor epinephrine 1:100000. Crestal incision was made with mesial and distal vertical releasing incisions if needed for better exposure. After flap elevation, initial osteotomy with pilot drill at planned implant site was done. Crestal bone cut using disc 1cm in diameter followed by using osteotomes***** in sequential manner to do desired ridge expansion till a length 3 mm less than the desired final implant length. (Fig. 4) Conventional implant drill was used to do the final drill at desired implant length and width size according to the manufacturer. After implant placement, smartpeg of Osstell was placed

* Versah, the Osseodensification company, Michigan, USA.

** V line plus, Vitronex, Italy.

*** CompactBone B., Dentegris dental implant system, Germany.

**** Osstell, Osstell AB, Gothenburg, Sweden.

***** EGYSilk, TAISIER-MED, Egypt.

***** Hand Osteotomes, lama medical, Egypt.

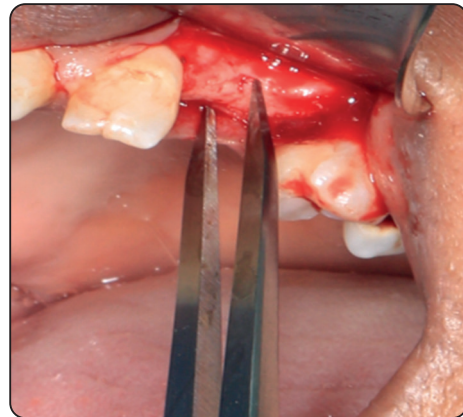


Fig. (2) Clinical measurement of alveolar ridge.

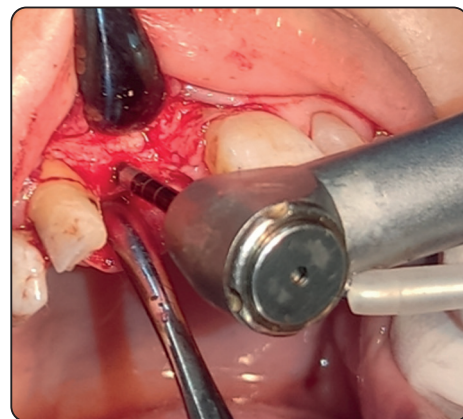


Fig. (3) Sequential use of DENSAH burs.



Fig. (4) Sequential use of osteotomes

to measure primary stability. Finally, flap closure was performed with no tension using 4-0 black silk sutures.

Efficiency of ridge widening technique was assessed by measuring crestal alveolar ridge width gained. Alveolar ridge width was measured clinically in mm using a manual caliber preoperatively, immediate postoperatively. Radiographic measurement was done by CBCT* using a special software** preoperatively and immediate postoperatively.

Primary stability was measured clinically after performing ridge expansion and insertion of the implant fixture at the previously prepared site via placement of smartpeg and OSSTELL device (Fig. 5).

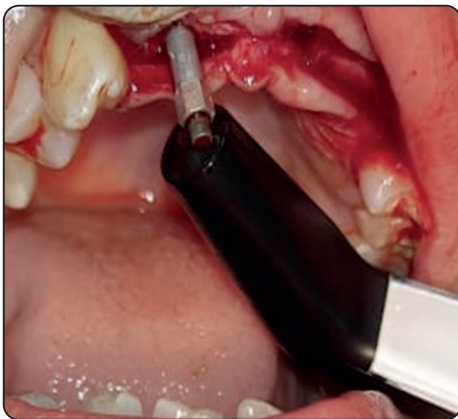


Fig. (1) Preoperative measurements of alveolar ridge.

Pain: The degree of pain the patient had experienced during performing each ridge widening technique was assessed via a graded visual scale. Each patient was given a scale of numbers from one to ten. Patients were instructed to choose number that resembles the pain they had experienced during the surgery. They were informed that the bigger the chosen number the greater the experienced pain.

Length of surgical procedure: A stop watch was used to count the time of the surgical procedure

* Planmeca ProMax 3D Mid, Helsinki, Finland.

** Blue sky plan version 4.11.2 (64 bit), Software, blue sky bio company, United States.

in minutes from the moment of starting the ridge expansion technique and till suturing was done.

- Post-operative care:

Penicillin*** antibiotic was prescribed for 1 week, anti-inflammatory**** twice a day for 1 week and antiseptic***** mouth wash for 1 week. Cold fomentation was applied for the first 24 hours followed by warm fomentation the following days.

Frequency and percentage values were analyzed using Fisher's exact test. Numerical data were tested for normality by viewing data distribution and by using Shapiro-Wilk's test. Pain score data were non-parametric and were presented as median and interquartile range (IQR) values and were analyzed using Mann-Whitney U test. Other data were normally distributed, were presented as mean, standard deviation values (SD) and were analyzed using independent and paired-t-tests for inter and intragroup comparisons respectively. Agreement analysis was done using intraclass correlation coefficient (ICC) and Bland-Altman plot. The significance level was set at $p < 0.05$ within all tests. Statistical analysis was performed with R statistical analysis software version 4.3.2 for Windows.*****

RESULTS

This study included a total of 18 patients, that were equally and randomly allocated to each of the tested groups (i.e., 9 cases each). Fourteen of the patients were females and four were males. The Osseo densification group contained 6 females and 3 males. The conventional osteotome group involved 8 females and 1 male. The patients ages range was 21-56 years with an average age range

*** Augmentin 1g, Medical Union Pharmaceuticals (MUP), Egypt.

**** BRUFEN 400 (Ibuprofen 400 mg), Kahira Pharm. & Chem. Ind. Co., Egypt

***** OROVEX ,MACRO Group Pharmaceuticals (Macro Capital), Egypt.

***** R Core Team (2024). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.

of (32.67±12.02) years for the osseodensification group and (38.00±12.71) years for the conventional osteotome group.

Preoperative radiographic findings

Patients’ examination included preoperative CBCT analysis which showed horizontal alveolar ridge deficiency at the proposed site of dental implant fixture insertion. The radiographic pre-operative alveolar ridge width measurement at the crest of the ridge ranged between 3.10- 5.16mm. The average mean of preoperative crestal alveolar ridge width in the whole study was (4.08±0.59) (mm). In the osseodensification group, the range of radiographic pre-operative bone width was (3.26-4.91) (mm) and the average mean was (3.94±0.50) (mm). The conventional osteotome group had a range of (3.10-5.16) (mm) and the average was (4.22±0.65) (mm). All ridges had a narrow crest and a wider base in form with bone height not less than 10mm in length. No intraosseous boney lesions were present at the desired sites at the time of radiographic examination (Table 1).

Intra-operative findings

The applied alveolar ridge expansion techniques were both conservative and efficient. A limited envelope flap design was sufficient to complete the surgical procedure successfully. The need for adding bone graft material was limited to only two cases during the whole study.

Concerning ridge width, the two techniques successfully provided a sufficient amount of crestal alveolar ridge width gain for implant fixture insertion. The measured initial clinical crestal ridge width for

both groups ranged between (3-5 mm), for Densah bur group the average width was (3.67±0.62) (mm), for osteotomes group it was (3.92±0.68) (mm) and overall, it was (3.79±0.65) (mm) (Fig. 6).

The average clinically measured bone width gain showed a higher width gain value of (2.12±0.40) (mm) for the osseodensification technique, than for the osteotome technique (1.87±0.35) (mm). Yet the difference was not statistically significant (p=0.183) (Fig. 7).

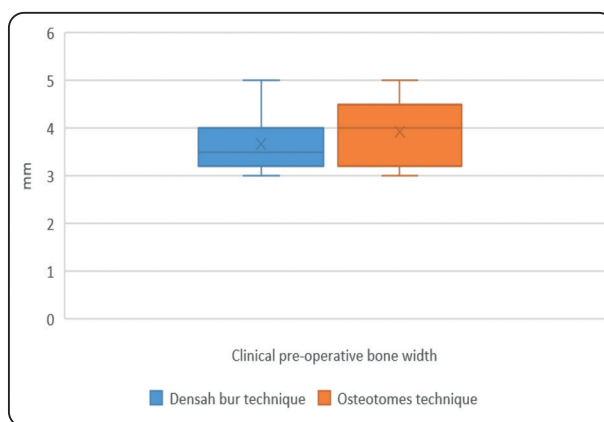


Fig. (6) Box plot showing clinical pre-operative bone width

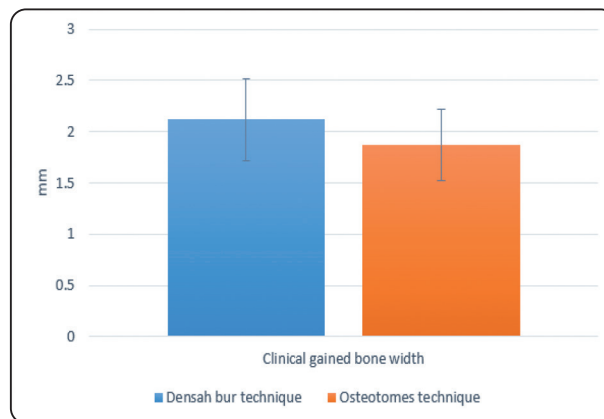


Fig. (7) Bar chart showing mean and standard deviation values for gained clinical bone width (mm).

TABLE (1) Summary statistics for radiographic pre-operative crestal bone width (mm).

Group	Measurement Range (mm)	(mean±SD) (mm)
OD technique	(3.26-4.91)	3.94±0.50
Osteotomes technique	(3.10-5.16)	4.22±0.65
Total	(3.10-5.16)	4.08±0.59

Both groups allowed dental implant fixture insertion at the expanded osteotomy site. The inserted implants showed high primary stability in both groups. The osseodensification technique (82.17 ± 8.28) (ISQ) had a higher average stability than the conventional osteotome technique (81.61 ± 7.36) (ISQ). Still the difference was not statistically significant ($p=0.882$). That value of primary stability is considered to be sufficient and an indicator for a successful dental implant placement surgical procedure (Figure 8).

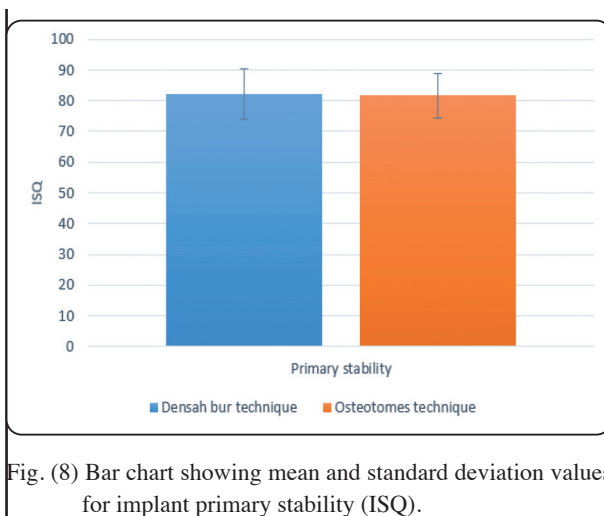


Fig. (8) Bar chart showing mean and standard deviation values for implant primary stability (ISQ).

Regarding pain Local anesthesia was profound and effective throughout the working time. Patients experienced some discomfort when malleting was performed to prepare the osteotomy site via the hand osteotome technique. Median pain score measured with the osteotomes technique [6.00 (4.00)] was higher than that of OD technique [4.00 (2.00)]. However, the average amount of pain was not statistically significantly different between the two groups ($p=0.073$).

Both techniques were not time-consuming procedures. An average time of (29.22 ± 6.16) minutes was required to completely perform the Osseo densification procedure. The average length measured in the osteotomes technique was higher (32.22 ± 5.07) minutes. Yet the difference was not statistically significant ($p=0.276$). That is why the osseodensification maneuver was found to be statistically not significantly faster than the hand osteotome when used to achieve alveolar ridge expansion.

Post operative radiographic findings

Crestal alveolar ridge expansion has occurred in all cases. The newly obtained ridge width was enough to accommodate the pre-planned implant diameter. The average bone width gain value was higher for the osseodensification technique. The average values were (2.10 ± 0.42) (mm) and (1.75 ± 0.33) for the osseodensification and hand osteotome groups respectively. Statistically there was no major difference between the two techniques ($p=0.067$) (Figure 9).

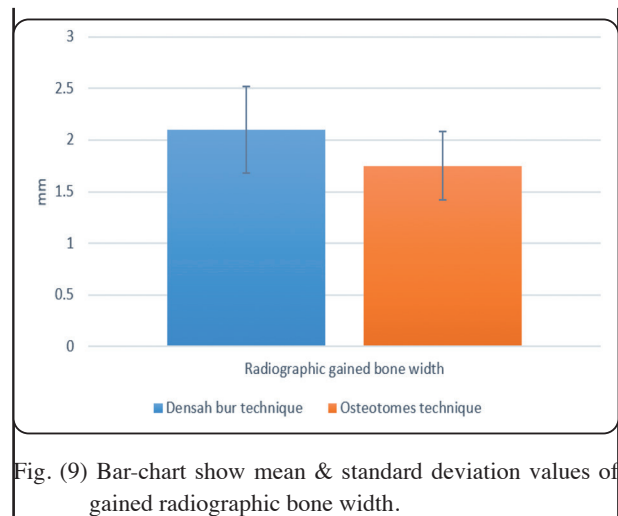


Fig. (9) Bar-chart show mean & standard deviation values of gained radiographic bone width.

According to clinical and radiographic results, the average crestal expansion was slightly higher in the OD group. Still the difference between the two groups was not statistically significant.

There was no significant difference between clinical (1.99 ± 0.39) (mm) and radiographic (1.84 ± 0.58) (mm) ($p=0.243$), and the agreement between both measurements was strong and statistically significant ($ICC=0.626$, $p<0.001$). The Bland-Altman plot showed that that the mean difference between clinical and radiographic measurements is 0.7 mm, indicating a slight negative bias, with radiographic method tending to produce slightly lower measurements. The data points exhibited uniform spread, within the limits of agreement (-0.57 and 0.70) (mm) with no indication of proportional bias (Table 2).

TABLE (2) Agreement between clinical and radiographic measurements

(mean±SD) (mm)		Difference (95%CI)	t-value	p-value	ICC (95% CI)
Clinical gained width	Radiographic gained width				
1.99±0.39	1084±0.58	0.15 (-0.11:0.40)	1.21	0.243ns	0.626 (0.036:0.858)

ICC: Intraclass correlation coefficient. CI: confidence interval. *: Significant ($p < 0.05$). ns; non-significant ($p > 0.05$).

The inserted implants showed high primary stability in both groups. The osseodensification technique (82.17±8.28) (ISQ) had a higher average stability than the conventional osteotome technique (81.61±7.36) (ISQ). The difference was not statistically significant ($p=0.882$).

DISCUSSION

The conventional ridge widening technique via hand osteotomes and the new osseo-densification technique using specially designed Densah burs drills are claimed to provide sufficient alveolar ridge width along with enhancing osseointegration in horizontally deficient maxillary alveolar ridges. Osteotomy site preparation using osteotomes preserves bone, safe and accelerates osseointegration. ⁽⁶⁾

Osseodensification is said to boost osseointegration of titanium fixtures and, promote significant ridge expansion outcomes at low density bone sites through establishing of autografted implant bed osteotomy walls. ^(1,7) Both the osteotome ridge widening technique and the new OD technique depends on the viscoelastic nature of bone. Osteotomes make use of osseous viscoelasticity which enables compression and manipulation. ⁽¹⁴⁾ OD counts on viscoelastic features of the bone particles that allow for conservative compression of the osseous tissue. ⁽¹⁵⁾

In alliance with this study findings there are numerous examples in the literature showing the efficiency of hand osteotomes in performing

alveolar ridge expansion in poor quality bone regions. The osteotome ridge widening technique is one of the oldest and most trusted surgical maneuvers introduced for dental implants insertion in deficient soft alveolar ridges. Ridge expansion via osteotomes is applied on a broad scale among clinicians to enhance bone features at the implant bed and ensure obtaining the desired outcomes of the therapy. ⁽¹⁶⁾ It was stated that OD, OT and UD have presented remarkably higher ISQ values than conventional drilling. ⁽¹⁷⁾

The high levels of implant primary stability obtained with the OT was related to its effect on bone at the prepared site. The osteotome ridge widening technique works by causing compression and compaction of trabecular bone. The results of hand osteotome action are increased bone density and higher implant to bone contact; therefore, higher implant primary stability is obtained. Compacted and compressed trabeculae of bone surrounding fixtures were seen via computerized micro-tomographs at sites prepared by osteotomes. ⁽¹⁶⁾ Some studies proved by histological examination increased bone to implant connection at osteotomies prepared via the osteotome technique. ⁽¹⁸⁾

More over other authors claimed that the compressed bone after using osteotomes has the potential of new bone formation more than the regular bone prepared by conventional drilling methods. A repair mechanism known as “regional acceleratory phenomena” is expected to be activated by trauma induced by osteotomes action

of condensing bone. Trabecular bone formation is induced by mechanical stimuli which can increase bone remodeling up to 50 folds.⁽¹⁹⁾

Some studies mentioned that bone compression via hand osteotomes causes increase in bone density without disturbing the blood supply. In fact, new spaces are produced for formation of new blood vessels. Moreover, they stated that by applying suitable forces; bone is allowed to expand without even endangering the osteocytes. Nkenke and his colleagues stated that marrow spaces are displaced by compressing trabecular bone. The resultant displacement allows for new spaces to be formed for angiogenesis. Therefore, higher bone density is obtained without affecting the bone blood supply.⁽²⁰⁾

On the other hand, in a systematic review carried out by EL-Kholey and EL-Komy the authors mentioned that some studies concluded that the OT does not enhance implant primary retention than conventional drilling. It was stated that condensing bone via hand osteotome does not support implant stability.⁽²¹⁾ Another systematic review cited that some papers concluded higher implant primary stability to be obtained by conventional drilling rather than osteotomes preparations. Osteotome ISQ levels scored an average of 5.2 values less than conventional drilling readings, which denotes higher stability for implants inserted by conventional drilling method.⁽¹⁷⁾ The decreased primary stability in OT cases was related to the aggressiveness of the technique. Some authors claimed that the OT is an aggressive surgical maneuver. They mentioned that the technique of hammering an osteotome against bone is traumatic to the bone. Osseo-condensation via striking against hand osteotomes induces surgical trauma.⁽²²⁾

Some studies have shown that although bone density was increased no enhancement in implant initial retention was obtained with OT. In a study carried out by L. Wang and his colleagues they provided evidence that condensation can densify bone. Still, the densified bone did not offer better

connection with the implant nor did it support retention.⁽²³⁾

Regarding bone expansion some studies were carried out to evaluate the amount of ridge gained after applying the OD technique. In alliance with this study, Koutouzis and his colleagues concluded that OD can produce alveolar ridge expansion. Osseodensification can change ridge size and allow ridge expansion. They also mentioned that expansion values are larger at crests of narrow ridges that are rich in spongy bone.⁽²⁴⁾

Concerning implant primary stability, in congruence to the results of this study; several studies in the literature have reported high implant primary stability to be obtained after applying the OD technique. However, most of those studies stated significantly higher implant primary stability at sites prepared via OD technique than that obtained at hand osteotomes prepared sites. In a systematic review comparing the influence of different surgical maneuvers on implant's initial retention. The authors declared that in comparison to conventional drilling OD provided the second highest increase in implant primary stability while, OT caused only moderate increase. The OD group scored values of 10 ISQ higher than CD while OT group records were greater by only 6 ISQ.⁽¹⁷⁾

Studies have shown 90% reduction in the diameter of empty osteotomy sites prepared via OD technique.⁽¹⁵⁾ The reduction is explained to be caused by the spring back effect which causes soft maintainable compressive forces against the inserted implant. The outcome is increase in primary stability. The compacted bone tends to return to its normal position prior to applying the OD protocol.⁽²⁴⁾ This causes bone to be smoothly compressing against the inserted implant fixture.

Continuing with pain and length of surgical procedure. Both factors were measured to test the possible draw backs of both techniques in terms of patient satisfaction and technical difficulties. The literature had presented multiple studies that stated

the OT to be an inconvenient surgical technique. Some papers mentioned that the hammering action is unpleasant for the patients. ⁽¹⁸⁾ Other authors considered the osteotome technique to be hard for the operator. It is a very difficult and operator dependent technique, with a substantial learning curve. ⁽²⁵⁾ The results obtained from this thesis showed that the OD technique was generally less painful and less time consuming than the hand osteotome method. Still, there was no statistically significant difference between the two surgical procedures. Suggesting that both techniques are almost similar regarding to patient acceptance and easiness of clinical application.

That insignificant statistical difference between the two techniques could be deceiving. To illustrate, the results of this thesis also showed that labial bone fracture had occurred in one of the osteotome cases. A complication presented in this study which is in alliance to the literature in regards to possible risks of applying the OT for alveolar ridge expansion. Ridge expansion via Hand driven osteotomes is an aggressive maneuver that carries higher potential risks of bone fracture. ⁽¹⁾ On the other hand, no complications had been reported in the OD group during the study. A finding that could suggest that the OD technique might be a safer and more predictable surgical technique for alveolar ridge expansion.

CONCLUSIONS

Osseodensification is an efficient alveolar ridge widening surgical technique and can provide sufficient alveolar ridge width and good implant primary stability. OD is a reliable alternative surgical maneuver for conventional osteotome technique to place dental implants in deficient maxillary alveolar ridges.

More researches are required to study the effects of the OD technique on maintaining high implant stability during the initial healing phases and, time required for bone healing to occur around implants placed via the OD protocol.

ACKNOWLEDGMENTS

Mohamed Magdy Mostafa was responsible for patients recruitment, preparation and performance of surgical procedures and data collection and entry. Tarek Ibrahim El Ghareeb supervised the project. Mohamed Ashraf Ahmed and Ahmed Salah were responsible for data curation and Implementation. All authors reviewed the final draft and approved it.

There are no conflicts of interest. We confirm that the manuscript has been read and approved by all named authors and the order of authors listed in the manuscript has been approved by all of us.

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