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EVALUATION THE PRIMARY STABILITY OF DENTAL IMPLANT PLACED IN CLOSED SINUS-LIFTING USING OSSEODENSIFICTION TECHNIQUE

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ABSTRACT

Objective: This study was performed to evaluate the primary stability of dental implants placed in closed sinus-lifting using osseodensification technique. **Subjects and Methods:** Ten patients with missing upper posterior teeth and inadequate bone height at least 5 mm under the floor of the maxillary sinus included in this research, secondary to sinus pneumatization, where there is not enough bone for placement of standard-length dental implant . The average age was (40:70) years old. Stability, bone height and bone density were evaluated during 9 months postoperatively. **Results:** The findings of this study demonstrated that; the mean values of primary stability ISQ were 71.00 \pm 9.64. After 3 months the dental implant was exposed to assess stability, The device used was Ostell® ISQ (Ostell® ISQ, Gothenburg, Sweden), The mean values of ISQ were 72.70 \pm 7.59. According to implant stability, the stability mean values after 9 months were 76.70 6.20, which was statistically different from primary stability (p-value 0.029). **Conclusion:** The osseodensification (OD) technique using Densah® Burs is a different method of treating crestal sinus floor elevation that also has the potential to greatly reduce the amount of time needed to place dental implant at the posterior maxilla while reducing trauma and postoperative discomforts. To validate and develop this crestal sinus lift technique, more studies with long-term follow-up are required.

KEYWORDS: Closed sinus-lifiting, Densah® Bur, Osseodensification (OD) technique, Primary stability.

INTRODUCTION

Treatment of the posterior edentulous maxilla is still a challenge for the implantologist, due to reasons like pneumatization of the maxillary sinus, poor bone density, volume, and difficult access⁽¹⁾. Furthermore, the bone which forms around the osseointegrated implants in this region, does not show very high density, thus in several cases the implant which has successfully osseointegrated may lead to failure after loading in this region ⁽²⁾. To overcome difficulties in residual ridge height and improve the placement of dental implants, the external lateral window method and the internal transalveolar approach are the two main surgical procedures used for sinus floor elevation (SFE) and augmentation. Compared to the external lateral window method, the internal approach is thought to be more conservative and minimally invasive.⁽³⁾.

The effectiveness of treatment in the posterior maxilla is determined not only by the success of sinus elevation, but also by the primary stability

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of the implant, which allows bone apposition on the implant surface without micromovement for osteointegration.⁽⁴⁾.

In 1994, Summers invented the osteotome technique and created bone compaction, which is considered to speed up final bone healing and improve the primary stability of dental implants. ⁽⁵⁾. Büchter et al. claim that in 2005, the osteotome approach had a negative influence on implant stability because it caused microfractures in the peri-implant bone ⁽⁶⁾. Furthermore, the osteotome approach did not improve osseointegration or increase the likelihood of loading single implants right away, according to a 2008 study by Stavropoulos et al. ⁽⁷⁾.

Recently, Densah® Burs (Versah, United states of America) were introduced as a new treatment option for internal transalveolar sinus floor elevation with osseodensification technique (OD) increasing primary implant stability. To improve osteotomies preparation for implant placement Huwais introduce Densah® Burs. His objective was to maintain the healthy bone and create room rather than to remove bone⁽⁸⁾.

Osseodensification is using Densah® Burs is a unique technique that uses a multifluted densifying technique which condenses bone when rotting at 800_1500 Rotation per minute (rpm) in a counterclockwise direction ⁽⁹⁾. Resulting in a densified layer of bone through compaction and auto grafting the implant ⁽¹⁰⁾.

This technique allows enhancing the primary stability of implants inserted in low-density bone by increasing bone–implant contact and increasing bone mineral density around periphery and bottom of the osseodensification holes⁽¹¹⁾. Accordingly, the main aim of this work was to evaluated the safety and effectiveness of using Densah® Burs in closed sinus lifting and observe primary stability of dental implant.

SUBJECTS AND METHODS

Study design

It is A prospective randomized clinical study. Ten patients with partial dentition who were selected from the Outpatient Clinic of the Oral and Maxillofacial Surgery Department at the Faculty of Dental Medicine, Al- Azhar University, Boys, Cairo, and Sayed Jalal University Hospital and indicated for implant placement in the posterior maxilla with unilateral maxillary sinus augmentation having undergone the study.

Inclusion criteria

- Because to sinus pneumatization, all study participants had inadequate bone height that was at least 5 mm below the maxillary sinus floor.
- 2. Patients age range of 40 to 70 years.

Exclusion criteria:

- 1. Uncontrolled systemic diseases (such as chemotherapy, radiation, autoimmune disease, or uncontrolled diabetes mellitus) or medications that may affect osseointegration or healing.
- 2. Patients' incapability to undergo minor oral surgical procedures.
- Any individual presenting with maxillary sinus pathosis.
- 4. Patients who have active periodontal disease and inadequate dental hygiene.
- 5. Patients with insufficient vertical inter-arch space.
- 6. Patients with parafunctional habits affecting osteointegration.

Ethical consideration

The Faculty of Dental Medicine (Boys- Cairo (Al-Azhar University) ethics committee accepted the study with ethical code (475/2154).

Patient Consent

Before the study began, each patient gave a signed informed consent form that contained information about the whole procedure. After getting informed consent from the patient, the treatment was done.

Sample size calculation

To study the effect of dental implant placement in closed sinus-lift using osseodensification technique on primary stability (ISQ), paired t test and repeated measures ANOVA were used for comparison between different observation times. According to a previous study by Padhye et al. (2020) ⁽¹²⁾. The mean bone to implant contact affecting stability was 49.6±6.8 originally in comparison to 70.3±13.8 after treatment. A large effect size of approximately 1.5 is expected. Using an actual power (1- β error) 0.95 (95%) and significance level (α error) 0.05 (5%) for two-sided hypothesis test, the minimum estimated sample size was 7 patients in one group⁽¹³⁾.

Preoperative assessment

- 1. *Medical history:* full medical history was obtained from the patients
- 2. Dental history: complete dental history was recorded in order to the attitude of the patients toward dental treatment.

3. Clinical examination:

- A) Intraoral photograph was taken for the selected candidates as a baseline record
- B) Study casts for upper and lower arches to detect vertical inter-arch space and medsio-distal width of missing tooth, after that cast was used to construct surgical guide.
- C) Inspection; to assess the general oral hygiene, occlusion, condition of the existing teeth,

4. Radiographic examination:

a. A preoperative orthopantomogram (OPG) was taken first as a screening method.

b. Cone beam computed tomography (CBCT) is used to measure the height and width of the remaining bone and to assess bone density.

Surgical procedures:

Using 0.12% chlorhexidine gluconate, the patient was instructed to rinse their mouth (orovex, Macro group, Egypt) mouth wash for 1 minute before starting surgical procedures. Then local anesthesia infiltration using Artcaine (Artinibsa, Spain) 4% with 1.100.1000 epinephrine was injected. A crestal incision was made in the center of the crest of the ridge, at the site of tooth to be replaced. By utilizing a No. 15 blade, a full thickness mucoperiosteal flap was created to allow for sufficient access and visualization of the entire ridge crest at the implant site.

Closed Sinus membrane lifting and Implant insertion:

The implant position was marked by a pilot drill through the surgical guide to preserve the integrity of the bone surrounding it, using a pilot drill, drill to the depth determined within an around 1.0 mm safety zone from the sinus floor (Clockwise drill speed 800-1500 rpm with copious irrigation). A periapical radiograph was acquired to verify the osteotomy's location and angulation. started with the Densah® bur (Versah, USA) (2.3), set the drill motor to Densifying Mode (anticlockwise drill speed 800-1500 rpm with liberal irrigation), and begin drilling to create the osteotomy by modulating pressure with a pumping motion until you reach the sinus floor. Once you feel the haptic feedback of the bur reaching the dense sinus floor, stop drilling. When the bur has reached the dense sinus floor and haptic feedback has been obtained, used the next wider Densah® Bur (3.0) (Versah, USA) to insert it into the osteotomy that was previously made. Then, continue to advance the sinus floor in 1 mm increments by maintaining pressure modulation with a pumping motion (Maximum advancement

past the sinus floor at this stage must not exceed 2.0 mm in the first time). For final desired width for implant placement, an additional 2.0 mm of vertical depth and 2.0 mm of membrane lift were achieved using the final diameter Densah® Burs (Versah, USA) (3.5mm) in the osteotomy. The bone was then pushed toward the apical end and started to gently lift the membrane and autograft-compacted bone.

Furthermore, the integrity of the sinus membrane were investigated using direct visual inspection and asked the patient to blow through the nose after blocked his nostrils and looking for air bubbles or mist on the mirror. The suitable width and height implant (4*10mm, Neobiotec, Korea) has been placed into the desired depth with the drill motor and screwed manually to reach the maximum manual torque then continue with ratchet wrench to seat the implant into its final position.

Primary implant stability was evaluated by Resonance frequency analysis (RFA) through using Osstell® device after implant placement, according to the manufacturer's instructions, the smart peg was attached to the implant, ISQ value were recorded, ISQ scale ranging from 1 to 100. Cover screws were placed over the implants and the flaps were replaced and sutured. An immediate postoperative periapical radiograph was taken to verify final position of the implant.

Postsurgical medication:

- Amoxicillin-clavulanic acid (Augmentin, Medical Union Pharmaceuticals, Egypt) 1 gm tablets (b.d.s) was prescribed with Metronidazole (Flagyl, Sanofi-Aventis, Egypt) 500 mg tablets (t.d.s) for 7 days.
- Ibuprofen (Brufen, Abott Laboratories, Cairo, Egypt.) 600 mg tablets (t.d.s) 3 times for 3 days and then when necessary.
- Instructions were directed to the patient to rinse her/his mouth with 0.12% chlorhexidine gluconate (orovex, Macro group, Egypt) mouth

wash for 1 minute to refrain from mechanical plaque mouths twice daily for 14 days.

• Nasal decongestant: Xylometazoline HCL (Otrivin, Novartis Pharma AG, Switzerland) nasal drops were used (t.d.s) 3 times a day for 5 days to avoid rebound effect.

Post-operative evaluation:

A) Biomechanical evaluation:

Implant stability:

All implants were assessed for Implant Stability Quotient (ISQ) immediately after insertion, as according to the manufacturer's instructions. The device used was Ostell[®] (Gothenburg, Sweden) ISQ. All implants were evaluated for stability at 3 and 9 months later. The results are represented as ISQ values.

B) Radiographic parameters:

- 1. A periapical radiograph was taken after implant placement immediately.
- 2. CBCT was done for scanning the implant site at 3 and 9 months to assess:
- A) Bone density (Hounsfield unit) around implant was assessed relatively by in the three different areas were measured at the apical, middle, and coronal areas and the mean value was used in Statistical analysis.
- B) The amount of vertical bone height gained was measured post-operatively and compered with gained bone height after 3 and 9 months.

Statistical analysis

All entered data were processed and analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were shown as mean± standard deviation (SD). Qualitative data were shown as frequency and percentage.



FIG (1) (A) preoperative photo. (B) after incision and full mucoperiosteal flap elevation. (C) a periapical radiograph showing guide pin was placed in the osteotomy site. (D) photograph of 3.5mm Densah® bur toward apical end and lifting the sinus membrane up to 2mm past the sinus. (E) Photograph showing Measurement of primary stability was immediately performed after implant placement. (F) Photograph showing flap closure with black silk suture 3.0. (G) an immediate post-operative periapical radiograph showing tinting of sinus membrane by dental implant. (H) Radiographic view 9 months postoperative showing coronal section of CBCT.

RESULTS

Implant stability:

Implant stability	Range	Mean±SD	Paired Sample t-test		
			MD±SE	t-test	p-value
Primary stability	51-85	71.00±9.64			
After 3 months	60-84	72.70±7.59	-1.70±2.05	-0.829	0.428
After 9 months	64-83	76.70±6.20	-5.70±2.20	-2.595	0.029*

* p-value <0.05 significant

The results of this study revealed that; the mean values of primary stability ISQ were 71.00 ± 9.64 . After 3 months the dental implant was exposed to assess stability, The device used was Ostell® ISQ (Ostell® ISQ, Gothenburg, Sweden), The mean values of ISQ were 72.70 ± 7.59 . There was a statistically significant difference in stability mean values after 9 months were 76.70 ± 6.20 compared to primary stability according to implant stability, with p-value 0.029. Table (1): Comparison between after implant insertion of implant stability and other measurements "After 3 months and After 9 months".

Bone Height

The crest of the alveolar ridge and the floor of the maxillary sinus were measured using CBCT postoperatively after 3 months of surgery and 9months following implant placement, and the results were compared to pre-operative measurements. Preoperatively, the mean bone height was 5.78 ± 0.57 mm, after 3 months of surgery, it increased to 9.92 ± 0.69 mm and after 9 months later, it was 9.60 ± 0.99 mm.There was statistically significant difference in mean value after 3 months and after 9 months compared to pre-operative according to bone height "ml", with p-value <0.001.

TABLE (2) Bone height preoperatively,3 months and 9months postoperatively.

Bone height (ml)	Range	Mean±SD	Paired Sample t-test		
			MD±SE	t-test	p-value
Pre-operative	5-7.2	5.78±0.57			
After 3 months	9-11.4	9.92±0.69	-4.14±0.17	-24.154	<0.001**
After 9 months	8.2-11.7	9.60±0.99	-3.82±0.22	-17.484	<0.001**

**p-value <0.001 highly significant.

DISCUSSION

To place dental implant in the posterior maxilla in patients with insufficient bone height, a variety of techniques have been discussed in the literature to improve local bone volume. Many techniques, including lateral sinus lifting, guided bone regeneration (GBR), and only block grafts have been recommended for this purpose. The majority of these operations have prolonged (6–12 month) waiting times, higher morbidity rates, and multiple surgical procedures that are more expensive for the patient ^(14,15,16).

A very popular technique for implant rehabilitation of the posterior maxilla involves elevating the maxillary sinus by the crestal approach, which has a satisfactory outcome in terms of grafting method and long-term implant survival rate (ISR) ^(17,18). Summers described osteotome-mediated sinus floor elevation (OMSFE) in 1994 ⁽¹⁹⁾. The original approach has undergone a lot of adjustments during the past two decades.

The purpose of this study was to determine if using an osseodensification burs (OD) for crestal sinus floor elevation would be more effective than using conventional methods in terms of implant stability and patient satisfaction.

Multiple studies have demonstrated that when using crestal sinus floor elevation procedures, the residual bone height (RBH) appears to have the greatest impact on implant survival. With the exception of two implants that were placed in the posterior maxilla and had at least 5 mm of subantral residual bone height, all implants included in the present study were successfully osseointegrated, this finding was supported by Kumar and Nrayan in their study in 2017 during crestal approach sinus floor elevation using Densah burs⁽²⁰⁾.

The clinical mobility of an implant is measured by its implant stability, which also serves as an indirect indicator of osseointegration because primary implant stability obtained after insertion is need for a predicted osseointegration ⁽²¹⁾. It is accomplished on two levels: the primary which is done at the time the implant placement and is mostly made from mechanical engagement of cortical bone. Biological stability is provided by secondary stability that results from bone remodeling surrounding the implant ^(22,23). By evaluating the ISQ value, which evaluates the axial stability of the implant in different directions, primary stability could be assessed at the time of insertion ^(24,25).

Primary stability can affect the outcome of therapy because it helps us choose the best clinical treatment plan among the different surgical and prosthetic protocol options since high primary stability makes loading more predictable.

All of the implants in the present study had ISQ values ranging from 71.00 ± 9.64 showing acceptable primary stability, which is critical for the success of dental implants ^{(21).} The initial stability obtained was insufficient to enable an immediate functional loading protocol for implants; this may be due to poor bone quality in posterior maxilla, which has been reported in the literature ^(26,27,28,29).

A positive significant correlation was found between bone density (calculated using computed tomography) and ISQ values, according to Turkyilmaz et al. He claimed that the higher ISQ values recorded (70.5_+6) were due to the higher quality of the anterior mandible, the surgical method without pre-tapping, and the roughened-surface implant used ⁽²⁵⁾. After confirming stability three months following implant insertion, ISQ values showed a slight decrease, and stability values then increased after 6 and 9 months from insertion, indicating a significant difference between implant stability observed after 3 months and initial stability, stability after 6 months, and stability after 9 months. The differences in ISQ readings are result of the biologic alterations at the bone implant interface. This result is compatible with what is discussed in the literature^(25,30,31).

In comparison to conventional drilling and the Summers osteotome technique, Huwais and Meyer (2014) developed the bone compaction technique using a Densah bur and said that it enhanced insertion torque, increased bone-to-implant contact, and thus produced higher primary stability ⁽¹¹⁾. A study by Lahens et al. (2016) showed considerably increased bone-to-implant contact for Densah bur, has supported this study ⁽³²⁾.

In their 2017 study, Kumar and Narayan concluded that utilizing Densah burs in densifying mode allowed for the elevation of the sinus membrane with autografting without any perforations ⁽²⁰⁾. According to Huwais et al. (2018), osseodensification has the ability to lift the sinus membrane. This is based on a retrospective study with a 5-year follow-up and a 97% implant survival rate ⁽³³⁾.

Osseodensification has the ability to provide autogenous bone grafting for improved implant stability while also enabling osteotomy preparation with elevation of the sinus membrane and reduced risk of perforation. The following technical procedures are combined to produce these capabilities:

Fluid pumping with counterclockwise drill rotation create hydrodynamic waves that cause effluence in front of the point of contact. When the densifying bur has reached the sinus floor, irrigation fluid and bone fragments help to hydraulically elevate the sinus membrane ⁽³³⁾. As a result of plastic bone deformation that persists from the relatively non-traumatic osteotomy preparation (high speed drilling in densifying mode), which enables the

inner walls of the osteotomy to spring back toward its center, osseodensification osteotomy diameters were found to be smaller than conventional osteotomies prepared with the same burs. As a result, more mechanical energy is generated for contact between the bone and the implant ^{(34).}

In the present study, all the implants had ISQ values > 60 at the time of the first measurements, suggesting that Densah bur produced accepted primary stability, which is a necessary for implant success. The ISQ changing mode indicated that, at 8 weeks following surgery, implant stability could reach that at placement. ISQ levels decreased after 2 and 4 weeks, which may be related to bone remodeling caused by the advanced deformation of existing bone and the initiation of new bone formation. Which was agreed with the histological explanation provided by Barewal et al. in 2003 for the process of osseointegration⁽³⁵⁾.

CONCLUSION

The osseodensification (OD) technique is a different method of treating crestal sinus floor elevation that also has the potential to greatly reduce the amount of time needed to treat the posterior maxilla while reducing trauma and postoperative discomforts. Densah® burs can be used to lift closed sinus in a straightforward, safe, and predictable manner with less morbidity without the need of forceful hand tapping. It would enable improved implant stability and effective sinus lift while preserving the sinus membrane. To confirm and enhance this crestal sinus lift procedure, more instances with long-term follow-up are required.

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