

LATERAL SINUS LIFT TECHNIQUE USING TREPHINE OSTEOTOMY WITH SIMULTANEOUS IMPLANT PLACEMENT (CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: The lateral approach for sinus floor augmentation using the trephine-osteotomy is a precise surgical technique. For the time being, in implant dentistry, trephine drills have been used instead of conventional drills to conserve the bone during osteotomy.

AIM OF THE STUDY: To evaluate the effectiveness of trephine osteotomy for lateral sinus lifting technique associated with sinus floor augmentation using the autogenous bone resulting from implant drilling using specialized trephine drills.

MATERIAL AND METHOD: In this clinical study, 12 Patients were included and have been subjected to lateral sinus lifting using trephine osteotomy with simultaneous implant placement with delay loading. A bone graft used in sinus floor augmentation has been prepared using autogenous bone resulting from implant site preparation in addition to β -tricalcium phosphate. Patients were followed up both clinically and radiographically for 6 months after surgery. A Panoramic radiograph was performed immediately postoperatively and CBCT was performed 3 months and 6 months postoperatively.

RESULTS: After 6 months, the difference between the primary stability and implant stability was statistically significant as p-value ≤ 0.05 . After 6 months, The mean bone density and the mean vertical bone height were increased by 984.7 ± 276.2 mm and 11.71 ± 0.72 mm respectively.

CONCLUSION: Trephine osteotomy technique in both lateral approach of sinus lifting and implant site preparation allows preservation of autogenous bone. Moreover, the trephine osteotomy technique in the lateral approach of sinus lifting eliminates the use of an absorbable membrane. However, this technique requires proper case selection and is considered sensitive.

KEY WORDS: Trephine Drills, Lateral Sinus Lift, Maxillary Sinus Augmentation, Sinus Osteotomy.

RUNNING TITLE: Trephine osteotomy in lateral sinus lift technique.

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INTRODUCTION

Focal hard and soft tissue dimensional changes are promoted by tooth loss (1). Maxillary sinus approximation, when associated with bone resorption in the maxillary posterior region, complicates dental implant placement in this area (1). In 1970, maxillary sinus augmentation has been suggested by Tatum and in 1980, it was published by Bonye and James (2). In this technique generating a hole in the floor of the maxillary sinus can be done by an unfinished fenestration in the lateral surface of the maxilla to raise the Schneiderian membrane. Then the hole is filled with a bone graft, providing adequate height for the dental implant. In this technique, implant

placement can be done either simultaneously or after sinus graft material integration (3).

The sinus lifting could be achieved either with direct visualization with the lateral osteotomy approach or indirectly with the transcrestal approach (4). The surgeon's skills, the patient's anatomical factors (e.g the residual maxillary alveolar bone height), and the amount of lifting required for implant placement; all these factors affect the type of maxillary sinus elevation technique(5). Before sinus lift surgery, CBCT should be performed to assess bone height below the sinus, alveolar bone width, and sinus anatomy (4). Different techniques: conventional burs (carbide, diamond, and a diamond-studded concave bur),

electropiezo, and specialized drills (trephine drills) are now available to prepare a window in the lateral wall of the sinus (6). Piezotome is a sensitive ultrasonic method used during the window preparation to reduce the chance of membrane perforation as it does not harm the soft tissues(6). As well as it could be used to separate the Schneiderian membrane from the bone during sinus elevation (6).

As a modification of conventional direct sinus lifting, Emtiaz et al., (7) introduced sinus lift procedures using trephine drills (Implant Innovations®, Inc., Ibérica, SL, Barcelona, Spain). As they recommended care during the lateral osteotomy using a trephine is needed to reduce the risk of membrane tearing. The trephines are hollow cylindrical drills with a serrated cutting end that produce a cylinder of bone in the drilling site (7). The produced piece of bone can be used as a barrier membrane or crushed to be used as particulate graft material for sinus floor augmentation(8).

The advantages of sinus augmentation using the trephine osteotomy technique are: (I) less time is needed for performing the lateral window leading to the sinus cavity, (II) trephine osteotomy is a more precise osteotomy, (III) smaller or larger osteotomy can be prepared with several available trephine sizes according to the size and anatomy of the sinus (7), (IV) reducing the surgical cost, as the trephine drills are used on the same handpiece for implant placement(9), and (V) the round bony segment resulting from the lateral window osteotomy will act as a barrier so, there would be no need for a barrier membrane. Thus, the surgical cost will be less (7). Moreover, the repositioned bony window has osteoinductive and osteogenic properties that can lay down bone and stimulates vital bone regeneration (10).

Bone conservation and precise angulation of implant during osteotomy affect the long-term success of implants (11). In 2014, Rai et al.,(12) suggested the use of trephine drills rather than conventional drills to preserve the bone during implant site preparation. After the cortical osteotomy using trephines is complete, the resultant trephine cutting edge is plugging in and encouraged with dense cortical bone; so, bone marrow condensation rather than actual marrow removal takes place(13). This phenomenon is proved by CBCT images obtained using trephines drills for implant osteotomy (13).

The aim of this study is to evaluate the effectiveness of trephine osteotomy during sinus floor augmentation using the autogenous bone resulting from implant trephine drills with a lateral sinus lifting approach.

MATERIALS AND METHODS

All study measures were accomplished with approval from the Ethics research board, Faculty of

Dentistry, Alexandria University. This study has been registered at, clinicaltrials.gov and granted an ID number: NCT04625192.

Study design: The study design is a prospective clinical trial(case series).

Study sample: 12 patients as a total sample size were admitted to the outpatient clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. All patients met the inclusion criteria and signed informed consent before undergoing lateral sinus lift surgery.

Sample size estimation: A minimal total sample size of twelve patients who were indicated for unilateral direct maxillary sinus lifting was assigned to evaluate the effectiveness of trephine osteotomy with an assumed significant difference in the vertical bone height and implant stability after sinus lift procedure with commonly estimated group standard deviations of 1 mm and with 95% confidence level and 80% power using One-sample t-test. (PASS program version 20) (14).

Eligibility Criteria

Regardless of gender, any patient who needed an implant in the posterior maxilla was included. Non-smoker patients with good oral hygiene were selected and their ages ranged between 20-50 years. Patients should be free from any sinus pathoses. If patients had performed a recent extraction it should be performed at least 4 months before sinus lifting. Residual bone height ranged between (4 - 6 mm) while ridge width should not be less than 4 mm.

Exclusion criteria:

- i. Any sinus pathoses (15).
- ii. Any medical condition compromises the surgery (e.g. uncontrolled diabetes) (16).
- iii. Excessive smoking (17).
- iv. Active oral infections (17).
- v. Inferior oral hygiene (16).
- vi. Patients receive radiotherapy or chemotherapy (16).

Procedures

I. Surgical procedure

1. Pre-surgical assessment

A. History (18) included personal history, past medical history, past dental history, and chief complaint.

B. Clinical Examination (18).

Both extraoral and intraoral clinical examinations were performed.

C. Construction of the surgical guide stent (19).

D. Ear, nose, and throat (ENT) consultation (20).

All patients were referred to an ENT specialist for a consultation to exclude any maxillary sinus pathology before the sinus surgery.

E. Radiographic examination (19).

To measure the residual bone height and ridge width panoramic radiograph and cone-beam computed tomography (CBCT) were done

F. Preoperative preparation (18).

Scaling and root planning of the neighboring teeth were done, as it aimed to obtain optimal health for the patient's periodontium. As well as the selection of implant fixture length and width was performed.

2. Surgical procedures (7)

Anaesthesia technique: The surgical area was anesthetized with local anesthesia(2% Lidocaine hydrochloride with adrenaline 1:100,000.) using maxillary vestibular and palatal infiltration techniques.

After incision and elevation of the mucoperiosteal flap, a rounded osteotomy was done 4 –5 mm away from the most coronal part of the alveolar crest. This osteotomy was performed at approximately 1800 rpm with profuse irrigation using a trephine drill (drill #6 Dentium Advanced Sinus Kit (DASK)) (Figure 1) mounted on a straight implant handpiece. The trephine drill should be placed perpendicular to the lateral wall and bone cutting done without pressure to avoid sinus membrane perforation (Figure 2).

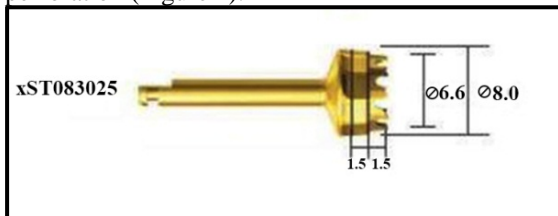


Figure (1): showing DASK drill #6.

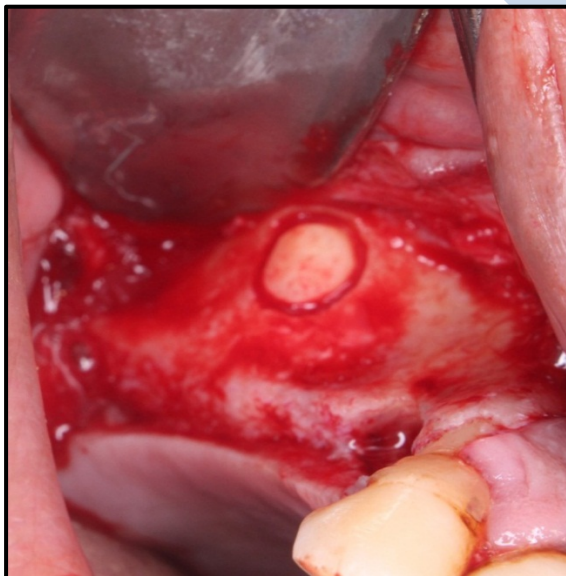


Figure (2): showing lateral sinus wall after lateral window preparation using a trephine.

To commence a fracture of the bone all around the edge of rounded osteotomy, light pressure should be done cautiously. With complete caution, A molt curette had been used to flake the sinus membrane from the inner surface of the rounded bony piece. Using college pliers, the bony piece was separated and placed in a saline solution to be repositioned finally over the bone graft (Figure 3). If sinus membrane perforation occurred, it could be

detected by direct visualization and by Valsalva maneuver (21) (Dentium company, Seoul, Korea.).

At a speed ranging from 800 to 1200 rpm with copious irrigation (external and internal), implant site preparation was done using the trephine drills (Dentium company, Seoul, Korea.). The trephine drills sizes were less than 0.5 mm than the diameter of the placed implant (e.g: 3.5 mm for 4 mm implant) (12). Using an implant stability meter (Osstell ISQ®, W&H Co, Gothenburg, Sweden), primary stability was measured. Bone resulting from drilling implant site was used for grafting the sinus floor in addition to β -tricalcium phosphate bone graft (Ovis Bone BCP (Dentis Implant, Korea)) (Figure 4). Then, the rounded bony piece was repositioned precisely without any gap over the lateral wall osteotomy. It should act as a membrane so, the placement of an absorbable membrane was not needed (Figure 5). Finally, repositioning and suturing of the mucoperiosteal flap were performed.

3. Postoperative instructions and medications

All patients were instructed to put ice packs on the face for the first 24 hours postoperatively, opening the mouth while sneezing, avoid suction by drinking straws, avoid nose blowing or any action that could produce high intranasal pressure or vacuum, perform oral hygiene instructions, Soft diet for the first week and avoid chewing on the surgical site. Sutures were removed two weeks after surgery.

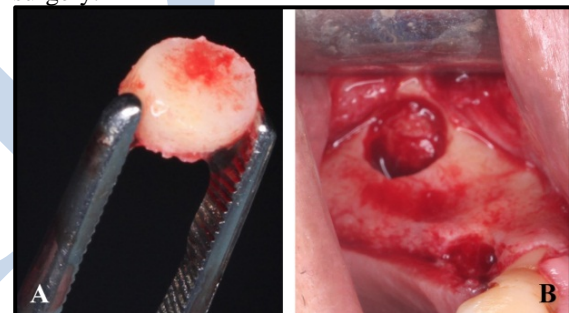


Figure (3): A) showing lateral bony window after separation. B) showing the lateral sinus wall after complete separation of the bony window.

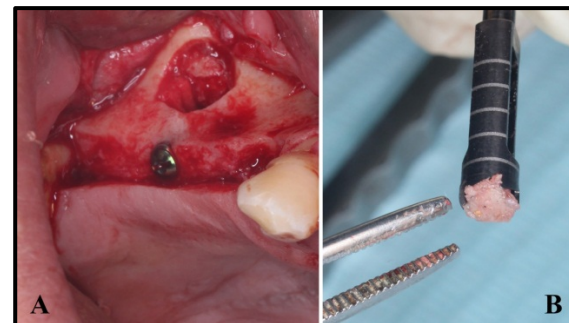


Figure (4): A) showing lifting of the Shenidrian membrane and implant placement.

B) showing autogenous bone resulting from implant drilling.

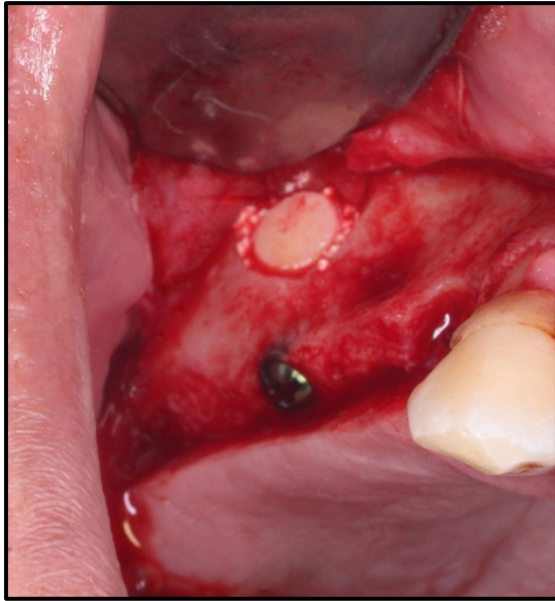


Figure (5): showing bony window being replaced precisely back over the osteotomy site.

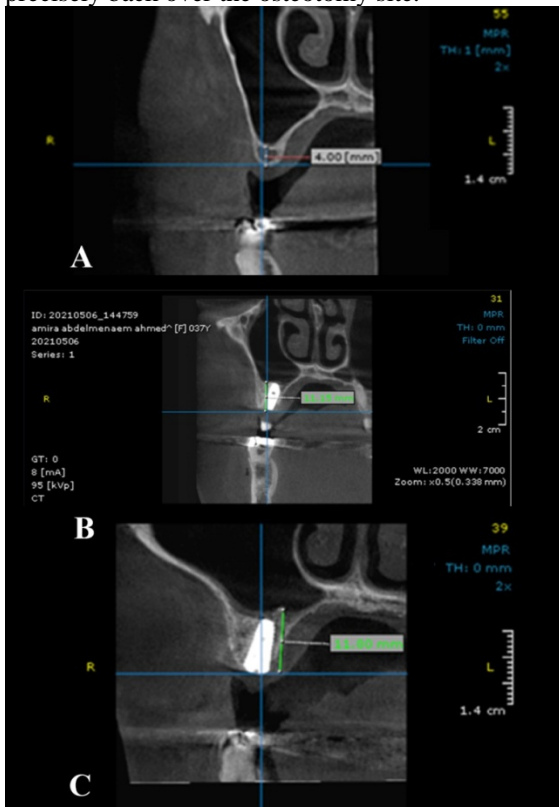


Figure (6): A) Cross-sectional CBCT showing preoperative vertical bone height equals 4 mm. B) Cross-sectional CBCT after 3 months showing vertical bone height equals 11.15 mm. C) Cross-sectional CBCT after 6 months showing vertical bone height equals 11.80 mm.

Patients were prescribed: Amoxicillin 875 mg + Clavulanic acid 125 mg (Augmentin: manufactured by, GlaxoSmithKline, England.) twice for 5 days in combination with Metronidazole 500mg (Flagyl: GlaxoSmithKline, UK) every 8 hours for 5 days. In addition to, Diclofenac potassium 50mg (Cataflam:

Novartis-Switzerland.) every 8 hours for 5 days and Ephedrine hydrochloride + Naphazoline nitrate 0.5% (Deltarhino nasal spray: Global Napi Pharmaceutical, GNP.) every 6 hours for 5 days. Also, Chlorhexidine antiseptic mouth wash (Hexitol: Arabic drug company, ADCO) starting from the next day 3 times daily.

4. Follow-up

Both clinical and radiographical follow-up was performed for 6 months.

A. Clinical evaluation

I. Postoperative pain (22) was scored daily in the 1st 3 three days using a 10-point Visual Analogue Scale (VAS).

II. Postoperative edema (23) was assessed in the 1st postoperative week using a grading system.

III. Presence of postoperative complications: e.g bleeding, epistaxis, sinusitis, and peri-implantitis(23) were observed clinically during the patients' visits after surgery.

IV. Implant stability: By using implant stability meter (Resonance Frequency Analysis) (Osstell™) implant stability was assessed immediately and after 6 months.

B. Radiographic evaluation

A panoramic radiograph was performed immediately postoperatively and cone-beam computed tomography (CBCT) was performed at 3 and 6 months postoperatively to assess the following:

i. Bone density

The bone density (mean, standard deviation, minimum and maximum) was evaluated radiographically by using OnDemand3D™ software.

ii. Vertical bone height

- CBCT Cross sections preoperative, 3 months, and 6 months postoperative were compared.
- Bone height was measured from the level of the alveolar bone crest to the cortical sinus floor.

Statistical analysis of the data

All the collected data were statistically analyzed and presented in tables, graphs, and charts using the IBM Statistical Package for Social Science (SPSS)* version 20 (14). The level of significance was set at 5%. Number and percent were used to describe qualitative data. The normality of distribution was confirmed using the Kolmogorov Smirnov test. To describe the quantitative data, we used rang, mean, median, and standard deviation. ANOVA with repeated measures and Paired T-test were used for the normally distributed quantitative data and to compare between more than two periods. Wilcoxon signed ranks test was used for abnormally distributed quantitative variables and to compare between two periods. Friedman test was used for abnormally distributed quantitative variables and to compare between more than two periods.

RESULTS

A total of 12 patients were presented with unilateral missing maxillary posterior teeth indicated for maxillary sinus lifting and implant placement. The selected patients were of both sexes (8 females and 4 males) and their ages ranged between 23-47 years with a mean of 35.08 ±8.21 years.

A. Clinical evaluation

1. Postoperative pain

The pain was evaluated for 3 days after surgery using a Visual Analogue Scale (VAS). The mean pain score of the first day was 3.58 ± 1.16. On the second day, three patients scored (VAS=1) and nine patients experienced mild pain. On the third day, eleven patients experienced no pain and one patient experienced mild pain. There was a statistically significant difference between the pain on the first and third day postoperatively at p ≤ 0.05

2. Edema

Edema was measured for all patients in the 1st postoperative week. On the 3rd day, 9 patients experienced mild edema which manifested as intraoral swelling confined to the surgical field while 3 patients experienced moderate edema which manifested as extraoral swelling confined to the surgical area.

3. Postoperative complications

Both intraoperative and postoperative complications such as Schneiderian membrane perforation (SMP), bleeding, periimplantitis, and postoperative sinusitis were evaluated. Sinus membrane perforation occurred in one patient and this patient experienced epistaxis on the first and second days of the surgery. No patients experienced intraoperative epistaxis. No patients showed any signs of postoperative sinusitis or periimplantitis.

4. Implant stability

Implant stability was evaluated for all implants using the Ostell device, immediately postoperatively and after 6 months. The mean ISQ value recorded postoperatively was 68.08 ± 2.75. The mean ISQ recorded after 6 months was 80.75 ± 4.14 where the minimum ISQ value was 74 and the maximum recorded ISQ value was 85. There was a statistically significant difference between the primary stability and implant stability after 6 months at p ≤ 0.05. (Table1)

i. Radiographical evaluation

1. Bone density

The mean preoperative bone density was 280.6 ± 71.67 Hounsfield Units (HU). After 3 months the minimum bone density value was 604.9 HU and the maximum recorded bone density value was 849.9HU. The mean bone density recorded after 6 months was 984.7 ± 276.2 where the minimum bone density value was 640.3 and the maximum recorded bone density value was 1200 HU. There was a statistically significant difference between the bone density on the 3 studied periods (p ≤ 0.05).

2. Vertical bone height

The mean preoperative residual bone height was 5.18 ± 0.77mm. After 3 months, the mean vertical bone height became 11.02 ± 0.93 where the minimum vertical bone height was 10.0 mm and the maximum vertical bone height was 13.20 mm. While after 6 months, the mean vertical bone height was 11.71 ± 0.72 with the values ranging between 11.0 – 13.50mm. The difference was found to be statistically significant at p ≤ 0.05 (Table 2).

Table (1): Comparison between the two studied periods according to stability (n = 12).

Stability	Immediate	After 6 month	t	p
Min. – Max.	64.0 – 72.0	74.0 – 85.0		
Mean ± SD.	68.08 ± 2.75	80.75 ± 4.14	11.410*	<0.001*
Median (IQR)	68.0 (65.50 – 70.0)	81.50 (77.50 – 84.50)		

IQR: Inter quartile range

t: Paired t-test

p: p value for comparing between the two studied periods

*: Statistically significant at p ≤ 0.05

Table (2): Comparison between the three studied periods according to vertical bone height gained (n = 12).

Vertical bone height gained	Before	After 3 months	After 6 months	F	p
Min. – Max.	4.0 – 6.0	10.0 – 13.20	11.0 – 13.50		
Mean ± SD.	5.18 ± 0.77	11.02 ± 0.93	11.71 ± 0.72	302.84	<0.001*
Median (IQR)	5.35 (4.40 – 6.0)	11.0 (10.50 – 11.0)	11.50 (11.25 – 12.0)		
Sig. bet. periods	p ₁ <0.001*, p ₂ <0.001*, p ₃ <0.001*				

IQR: Inter quartile range

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using Post Hoc Test (adjusted Bonferroni)

p: p value for comparing between the three studied periods

p₁: p value for comparing between before and after 3 months

p₂: p value for comparing between before and after 6 months

p₃: p value for comparing between after 3 months and after 6 months

*: Statistically significant at p ≤ 0.05

DISCUSSION

When pneumatization occurs, sinus floor augmentation is performed to restore the posterior maxilla allowing implants placement to support single crowns or a fixed prosthesis (24,25). There are two approaches for sinus floor augmentation: the direct (lateral /external approach) or the indirect (crestal /internal approach) (25,26). Osteotomy through the lateral wall of the zygomatic buttress

bone of the maxilla followed by elevation of the Schneiderian membrane and placement of graft material is the conventional technique for maxillary sinus augmentation (2,27). This technique is secure, expected, and effective to increase bone volume in the posterior maxilla, with a long-term success rate (28-30). Nowadays, the use of trephine drills in implant dentistry is greatly increased. In 2002, Emtiaz et al.,(7) described a different surgical procedure using trephines for the lateral approach of sinus augmentation. Less surgical time and easy procedures were mentioned as advantages of the lateral sinus approach using trephine burs. Moreover, no additional instruments are needed for example additional handpieces, chisels, mallets, and piezotome equipment. But, the author declared that care is needed during lateral window preparation to decrease the risk of sinus membrane tearing (7).

In 2014, Rai et al.,(12) suggested that the use of trephine drills instead of conventional drills will maintain the bone during osteotomy. The advantages of trephine drills used for implant site preparation were highlighted as trephine burs save more than 40 % of the bone during implant drilling, are time-saving, easy to be used with minimum injury to the bone.

In this study, lateral sinus lifting was performed on all patients using trephine osteotomy in lateral window preparation with simultaneous implant placement. Also drilling for implant placement done by trephine drills and the autogenous bone resulting from drilling was used for augmenting the maxillary sinus floor in addition to β -tricalcium phosphate bone graft. So far, to the best of our knowledge, no prospective evaluation has been carried out for the effectiveness and applicability of using autogenous bone (resulting from trephine drilling of the implant site) in direct sinus floor surgeries done by trephine lateral approach osteotomy.

Concerning the postoperative clinical evaluation, all patients experienced mild to moderate pain on the first day postoperatively. Scarano et al., obtained an average postoperative pain score of 3.703 on (VAS) scale on the second day of a study performing lateral sinus lifting using the traditional trapezoidal flap whereas in our study there was a significant difference with an average score of 2.42 ± 1.08 on the second day (31). The postoperative pain decreased by the third day to reach 0.50 ± 0.67 .

Osstell device was used to measure implant stability for all implants, immediately and after 6 months postoperatively. There was a statistically significant difference between the primary stability and implant stability after 6 months at $p \leq 0.05$. Jelušić et al. obtained similar results in their study where the average ISQ values 4 months after sinus augmentation were 78.9 ± 6.3 . As declared in the literature, ISQ numbers greater than 70 suggest high implant stability and a high success rate of the placed implant (32).

Evidence of osteogenesis was recorded as the mean preoperative bone density was 280.6 ± 71.67 Hounsfield Units (HU) and after 6 months the mean bone density became 984.7 ± 276.2 . We used in our study autogenous bone in addition to β -TCP which has only osteoconductive properties. Okada et al.,(33) declared that during the first year after direct sinus lifting, β -TCP was gradually displaced by newly formed bone. Sohn et al., (34,35) reported in their study (lateral approach of sinus lifting) that the repositioned bony window has osteoinductive properties without using a bone graft. Kim et al.,(36) have been proved from their clinical study on sinus augmentation through a lateral approach that all cases showed complete bone union between the replaceable bony window and the lateral wall of the sinus without any fibrous connective tissue formation.

With the aid of OnDemand 3D software, all the measurements of vertical bone height were performed. CBCT was done at 3 months and 6 months. A statistically significant bone height gain was obtained after 6 months with an average of 11.71 ± 0.72 mm at $p \leq 0.05$ with the values ranging between 11.0 – 13.50mm. In 2019 Arora et al.(37), recorded a mean vertical bone height gain of 11.23 ± 1.25 mm with values ranging between ranging 9.5 - 14.8 mm. Nevertheless, Starch et al.,(38) reported in their systematic review of the maxillary sinus augmentation, a significant reduction in the vertical bone height after augmentation during the first year.

Despite the positive results in terms of pain, edema, implant stability, vertical bone height, and bone density, complications such as sinus membrane perforation occurred. One patient experienced sinus membrane perforation during lateral window preparation. Membrane perforation was managed immediately by the placement of a resorbable collagen membrane and the surgical procedures were completed. Shim et al.,(39), reported in their study one perforated maxillary sinus membrane using trephine osteotomy in the lateral approach of maxillary sinus augmentation, and this coincides with our study.

Furthermore, according to these findings, there was a statistically significant difference in bone height and density after using bone resulting from drilling implant site with trephine drills in direct sinus lift surgeries (done by trephine lateral window osteotomy).

CONCLUSION

Trepine osteotomy technique in both lateral approach of sinus lifting and implant site preparation allows preservation of autogenous bone. Moreover, the trephine osteotomy technique in the lateral approach of sinus lifting eliminates the utility of a barrier membrane by repositioning the lateral bony window over the grafted bone. Using

trepine drills resulted in a satisfactory outcome in terms of postoperative pain, edema, implant stability, bone density, and vertical bone height gained. However, this technique requires proper case selection and is considered a sensitive technique.

Conflict of Interest

None.

Funding

None.

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