

COMPARISON OF MAGNETIC MALLET VERSUS PIEZOTOME IN CRESTAL WINDOW MAXILLARY SINUS AUGMENTATION FOLLOWED BY DELAYED IMPLANT PLACEMENT (RANDOMIZED CONTROLLED TRIAL)

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ABSTRACT

INTRODUCTION Sinus augmentation is a reliable treatment option to augment alveolar bone deficiency in the posterior maxilla. Historically, lateral or crestal approaches were the most used techniques.

OBJECTIVES to radiographically compare newly formed bone volume in crestal window sinus lift technique using magnetic mallet versus piezotome to augment extremely atrophic posterior maxilla (remaining bone height ≤ 3 mm).

MATERIAL AND METHODS: 20 patients indicated for sinus floor elevation were divided into two equal groups (group A) in whom the crestal window was prepared and elevated via magnetic mallet while in (group B) sinus elevation was done via piezotome. In both groups, sinus augmentation using human particulate allografts were placed via the crestal access window followed by implant placement 6 months later.

Cone-beam computed tomography (CBCT) was done for volumetric and bone density analysis of the newly formed bone in both groups also clinical evaluation was done by comparing the operative time and incidence of postoperative complications.

RESULTS: The newly formed bone height of was 7.4 ± 1.4 mm in group A and 6.75 ± 1.3 mm from the baseline to 6 months postoperative the difference was nonsignificant ($p = 0.849$) when comparing both groups A and B 6 months post-operative.

Bone density was 436.7 ± 99.81 HU in group A and 486.8 ± 106.9 HU in group B ($p = 0.830$) and the difference was nonsignificant between both groups between both groups.

No intraoperative or postoperative complications were observed in either group.

CONCLUSION: crestal window sinus lift performed with magnetic mallet or piezotome is a predictable procedure for maxillary sinus augmentation in severely atrophic posterior maxilla, where postoperative elevation of bone height can be achieved with minimal intra and postsurgical complications.

KEY WORDS: Sinus lifting, Magnetic mallet, Piezotome, dental implants.

RUNNING TITLE: Magnetic mallet versus Piezotome in maxillary sinus augmentation

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INTRODUCTION

The inevitability of alveolar bone resorption both in vertical and horizontal directions following tooth extraction has been well established throughout the literature. (1)

The continuous actions of alveolar ridge atrophy and maxillary sinus pneumatization will lead to inevitable subantral alveolar segment resorption

into a shallow, and sloped ridge which is incapable of accommodating dental implants and bearing the functional strains. (2)

Advanced maxillary resorption can be managed by several surgical options, the most popular of which is lateral window and transalveolar sinus lift with or without bone grafts. (3)

Although transalveolar bone-added osteotome sinus floor elevation (BAOSFE) techniques are more conservative and result in less post-operative pain, there is an increased risk of complications due to the inability to visualize the Schneiderian membrane and there for a “blind” procedure. (3, 4)

Meanwhile, lateral window sinus lift allows direct visualization of the Schneiderian membrane and, it is more invasive; disadvantages include postoperative discomfort, complications, and an increased risk of infection. (5, 6)

Sinus lifting procedure using a crestal window approach was first proposed by Winter et al as an alternative technique allowing one stage implant placement in atrophic maxillary ridges (≤ 4 mm) without bone grafts or membranes. (7)

The rationale for this technique was that it will combine the immediate implant placement and minimal post operative pain of the transalveolar approach with the direct visualization and greater potential of Schneiderian membrane mobilization of the lateral approach. (7)

The technique was further modified by limiting indications only to patients with extremely atrophic maxillae (≤ 3 mm), using piezotome to create crestal bone window followed by two stage implant placement protocol. (8)

Long term clinical results demonstrated that piezotome crestal window sinus lift is a predictable procedure for lifting a maxillary sinus floor less than 2 mm thick, with an average elevation height of 11.73 mm. (9)

Another modification to the technique was introduced utilizing magnetic mallet to create the crestal window osteotomy in atrophied posterior maxilla (≤ 3 mm) and elevation of the attached bone fragment into the sinus followed by sinus augmentation and two stage implant placements 6 months later. (10)

Magnetic mallet is a new modality for osteotomy preparation which is a magneto-dynamical instrument assembled into a hand piece energized by a power control device, delivering forces by the timing of application. (11, 12)

It depends on transforming electromagnetic energy into kinetic energy that sends a shock wave of 90 daN/8 ms. through the osteotome to contact the maxillary sinus floor for only 80–100 μ s (1 Newton = 0.2248 lb. 1 daNewton = 10 Newtons. 1 lb. = 454 g). (11)

Magnetic mallet could provide a safe modality to create the crestal osteotomy as it delivers controlled magnitude of force through the osteotome tip to cut the crestal bone automatically without the risk of heat generation or sinus membrane perforation. (10, 12)

This study aimed to radiographically compare newly formed bone volume in crestal window sinus lift technique using magnetic mallet versus piezotome to augment extremely atrophic posterior maxilla (remaining bone height ≤ 3 mm).

MATERIAL AND METHODS

Study design

This study was a randomized controlled clinical trial with a 1:1 allocation ratio. It was set up and reported according to the CONSORT guidelines.

Study sample and Sample size estimation

The minimal sample size was calculated using GPower version 3.1.9.2 based on a previous studies aimed to describe the results in which a two-stage CSA technique was used in patients with 2 to 4 mm of bone height.

Based on their results, adopting a power of 80% ($\beta=0.20$) to detect a standardized effect size in difference of new vertical bone height and level of significance 5% (α error accepted =0.05), the minimum required sample size was found to be 8 patients per group (number of groups=2) (Total sample size=16 patients).

Anticipating dropout rate of 20%, so, sample size was increased to 10 patients per group (number of groups=2) (Total sample size=20 patients).

Patient selection

Twenty patients aged between 30 and 60 years of age attending outpatient clinics at oral and maxillofacial surgery department Alexandria university with severe ridge atrophy in the posterior maxilla (≤ 3 mm) were enrolled in this study.

Patients with acute maxillary sinusitis, presence of infection or periapical lesions in adjacent teeth, alcoholism and medically compromised patients with medical conditions contraindicating elective dental surgery were excluded from the study. Participants were equally divided and randomly allocated into two groups A (magnetic mallet) & B (piezotome) using a computer-generated random list (Random Allocation Software 2.0 by Informer Technologies, Inc.)

https://random-allocation-software.software.informer.com/2.0/#google_vignette

Preoperative assessment
Full personal data and Past dental and medical history recorded in detail were collected from each patient. Clinical examination was performed both extra orally and intraorally by inspection and palpation to detect any swelling, asymmetry, malocclusion, presence of any ulceration, hypertrophy, or draining sinuses.

Preoperative Radiographic examination
Using orthopantomogram first for the selected

patients, followed by cone beam computed tomography (CBCT) for evaluation of bone width and height in addition to sinus anatomical variation.

Surgical procedure

Flap elevation

All patients were treated under local anesthesia. A full mucoperiosteal flap was elevated with crestal incision using blade no.15 followed by full mucoperiosteal flap reflection.

Patients were divided into 2 groups: Group A included 10 patients in whom crestal window sinus lifting was done using magnetic mallet. Group B included 10 patients in whom crestal window sinus lifting was done using piezotome.

Crestal Bone Window preparation

Group A (magnetic mallet group) Figure 1

A rectangular window of adequate size was created on the edentulous bone crest with the magnetic mallet avoiding sinus membrane perforation.

The magnetic mallet (Metaergonomica Srl Devices manufacturer Via Montenero, Italy) was set to mode number 1 (65daN at 120Ms).

The rectangular-shaped trapdoor of carved bone was gently tapped with osteotomes mounted on the magnetic mallet to push it inside the sinus cavity. The sinus membrane was carefully detached all around the trapdoor to create a space from the lateral to the mesio-distal walls using sinus membrane elevators.

Group B (piezotome group) Figure 2

Bone osteotomy was made with a piezoelectric device (SATELEC A company of ACTEON Group, Italy) followed by detachment of the bone fragment along and elevation of detached Schneiderian membrane into the new upper position. In both groups, once the space achieved after sinus elevation is sufficient, The allograft (Lyoplast, Russia) was placed to maintain the apically displaced sinus membrane in place to accommodate an 8 mm implant in the second stage.

A resorbable collagen membrane was fixed over the alveolar crest to maintain the graft in position and prevent soft tissue invasion, followed by Closure of the flap with 4/0 proline suturing material. The integrity of the Schneiderian membrane was tested by the Valsalva maneuver. Also Operating time: from the start of crestal window osteotomy to graft application was measured.

Intraoperative evaluation

Intraoperative evaluation of sinus membrane integrity using the Valsalva maneuver was done on all patients in both groups without any signs or symptoms of perforation.

Operative time Table 4.3 Figure 4.4

Operative time in both groups was calculated starting from crestal window osteotomy till membrane elevation and allograft placement.

Postoperative pain evaluation

Post-operative pain was measured 24 hours after surgery using a visual analog scale (VAS). The participants were instructed to point to the position on the line between faces to indicate how much pain they might feel.

In this system, the total scores range from 0 to 100 based on measuring the distance in millimeters from the left end bar to the mark made by the subject on the 10 cm line anchored by happy to sad faces, with a higher score indicating more severe pain.

Implant placement.

38 implants (vitronex Implant system, Italy) with 4.2 mm diameter and 8.5 mm lengths were used in this study 6 months after maxillary sinus lifting.

A calibrated torque wrench (vitronex implant, Italy) was used to drive the implant into the osteotomy 1 mm below the bone crest.

Maximum insertion torque was recorded for each implant measured in Newton centimeters (Ncm)

Radiographic evaluation

A CBCT was obtained preoperative and after six months to assess the volume of newly formed bone, increase in vertical bone measurement at the grafted site, and Bone density.

The CBCT images were all obtained from the same machine Orthophos XG (Sirona Group, Bensheim, Germany) set at 85 kV and 4 mA, with a 14 s exposure time.

Vertical bone height was measured from the crest of the ridge to the floor of the sinus at the grafted site 6 months post-operative T1 and compared to the preoperative measurements T0.

The difference in bone height between T1 and T0 represents the height of newly formed bone TN. (Figure 3,4)

$$T1-T0=TN$$

Bone density was measured 6 months postoperative by selecting 3x3 mm region of interest (ROI) within the grafted area using on-demand software (DEXIS, Australia) which automatically calculated the average bone density within the ROI in grayscale value (GSV). (Figure 4,5)

Statistical analysis of the data

Data was fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). The Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR). The significance of the obtained results was judged at the 5% level.

The used tests were.

1 - Student t-test

For normally distributed quantitative variables, to compare between two studied groups.

2 - Paired t-test

For normally distributed quantitative variables, to compare between two periods.



Figure 1: group A (magnetic mallet group)
 (A & B) Para crestal incision made with no 15blade followed by full mucoperiosteal flap elevation
 (C) Magnetic mallet split osteotome used to outline a rectangular osteotomy on the crest of the ridge
 (D) The rectangular osteotomy is made with 2 mm safety margin from the buccal and palatal side
 (E) Magnetic mallet cutting osteotome used to deepen the rectangular osteotomy to reach the sinus membrane
 (F) Detachment of the sinus membrane and inward displacement of the bone widow
 (G) Inspection of the sinus membrane for any perforation and performing valsalva maneuver
 (H & I) Augmentation f the maxillary sinus with allograft to maintain space and promote new bone formation
 (J) Closer of the wood with 000 prolene sutures

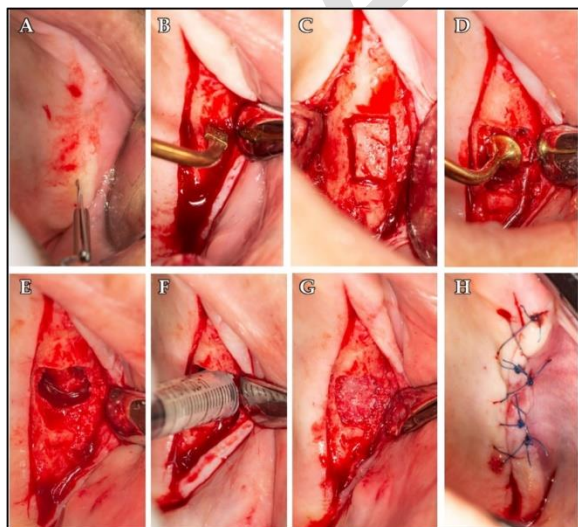


Figure 2: Group B (piezotome group)

(A) Para crestal incision made with no 15blade followed by full mucoperiosteal flap elevation
 (B) Piazotome used to create a rectangular osteotomy on the crest of the ridge and up to the sinus membrane
 (C) The rectangular osteotomy is made with 2 mm safety margin from the buccal and palatal side
 (D) Detachment of the sinus membrane and inward displacement of the bone widow
 (E) Inspection of the sinus membrane for any perforation and performing valvaser maneuver
 (F & G) augmentation f the maxillary sinus with allograft to maintain space and promote new bone formation

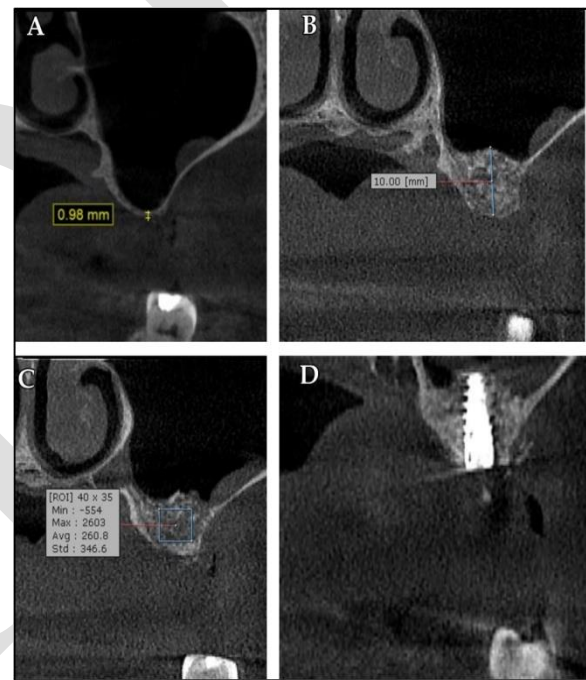


Figure 3: Group A (magnetic mallet group)
 (A) Pre operative CBCT showing vertical bone height measuring 0.98 mm
 (B) 6 months post operative CBCT showing vertical bone height measuring 10 mm
 (C) ROI showing average bone density of 260 HU
 (D) 8 mm implant inserted at 35 Ncm torque 6 months postoperative



Figure 4: Group B (piezotome group)
 (A) Pre operative CBCT showing vertical bone height of 3.5 mm
 (B) 6 months post operative showing vertical bone height of 7.89 mm
 (C) 8 mm implant inserted at 35ncm torque 6 months postoperative

RESULTS

Twenty patients aged between 30 and 60 years of age attending outpatient clinics at oral and maxillofacial surgery department Alexandria university with severe ridge atrophy in the posterior maxilla (≤ 3 mm) were enrolled in this study

The subjects were eight males and twelve females divided equally into two groups. group A magnetic mallet group and group B piezotome group. 38 implants (vitronex Implant system, Italy) with 4.2 mm diameter and 8.5 mm lengths were used in this study 6 months after maxillary sinus lifting

The volume of newly formed bone
 The newly formed bone volume in group A was 3.54 ± 0.55 mm³ and in group B 2.18 ± 0.43 mm³ ($p = 0.001$). The difference was significant within each group 6 months post-operative compared to the preoperative value, but the difference was nonsignificant ($p = 0.965$) when comparing both groups A and B 6 months post-operative.

Bone height gain (Table 1)
 Radiographic image analysis in this study attested to an increase in height of available bone 7.43 ± 1.4 mm in group A and 6.75 ± 1.3 mm in group B from the baseline to 6 months postoperative allowing insertion of 8.5 mm implants ($p = 0.001$) The difference was significant within each group 6 months postoperative compared to the preoperative values. However, the difference was nonsignificant ($p = 0.849$) when comparing both groups A and B 6 months post-operative.

Bone density (Table 1)
 Bone density was 436.7 ± 99.81 GSV in group A and 486.8 ± 106.9 GSV in group B ($p = 0.830$) and the difference was nonsignificant between both groups between both groups.

Intraoperative evaluation
 Intraoperative evaluation of sinus membrane integrity using Valsalva maneuver was done on all patients in both groups without any signs or symptoms of perforation.

Table 1: Bone hight gain and bone density

6 months	Group A (n = 10)	Group B (n = 10)	p
Bone density			
Min. – Max.	280.0 – 623.0	345.0 – 658.0	0.830
Mean \pm SD.	436.7 ± 99.81	486.8 ± 106.9	
Bone gain			
Min. – Max.	5.0 – 11.0	6.0 – 11.0	0.849
Mean \pm SD.	7.43 ± 1.4	6.75 ± 1.3	

Operative time (Table 2)
 Operative time in both groups was calculated starting from crestal window osteotomy till membrane elevation and allograft placement. It was found to be 12.90 ± 3.45 minutes for group A and 10.6 ± 1.90 minutes for group B. ($p = 0.081$) and the difference was nonsignificant between both groups.

Table 2: comparison between Operative time in group A and group B

Operative time	Group A (n = 10)	Group B (n = 10)	p
Min. – Max.	10.0 – 20.0	8.0 – 15.0	0.081
Mean \pm SD.	12.90 ± 3.45	10.60 ± 1.90	

Postoperative pain evaluation
 Post-operative pain was measured 24 hours after surgery using a visual analog scale (VAS). The means of VAS values for group A were 42.20 ± 12.70 (range: 0-100) and 48.40 ± 13.83 (range: 0-100) for group B, respectively with statistically nonsignificant differences between both groups ($P = 0.032$).

Implant placement. (Table 3)
 All the 36 implants placed in this study 18 implants in group A and 18 implants in group B were used. The mean insertion torque for the magnetic mallet group (group A) was 32.5 ± 10.1 While the mean insertion torque for piazotome group (group B) was 30 ± 8.5 p-value was 0.556.

No significant differences between the two groups were recorded.
 All implants were loaded 4 months later without incidence of failure

Table 3: Comparison between insertion torque and ISQ value in group A and group B

	Group A (n = 10)	Group B (n = 10)	p
Insertion tourq			
Mean \pm SD.	32.5 ± 10.1	30 ± 8.5	0.556
Median (Min. – Max.)	35 (15 – 45)	32.5 (15 – 40)	

DISCUSSION

In this study a comparison between magnetic mallet and piezotome to create the crestal window osteotomy followed by sinus membrane elevation and sinus augmentation

Crestal window sinus lifting was first introduced by Winter et al (8, 9) as an alternative to the lateral window approach that allows for direct visualization of the osteotomy site from the crest of the ridge rather than the lateral window and allows for simultaneous sinus lifting and implant placement in the severely atrophic posterior maxilla.

Soardi CM et al (8, 9) suggested three modifications to reduce the risk of perforation and maximize alveolar bone height gain at the grafted site.

First, limiting the use of the technique to alveolar bone height of 2 mm or less to facilitate Schneiderian membrane elevation and visualization. (8, 9)

Secondly, a Piezo surgery instrument was used to open the window instead of a conventional hammer and mallet to minimize the risk of membrane perforation. (8, 9)

Finally, a delayed instead of simultaneous implant placement approach is used to provide adequate time for bone remodeling at the grafted site. (8)

The crestal window sinus lifting technique combines the less invasive potential of the traditional crestal approach, with better accessibility to elevate the sinus membrane and adequate hematic support for the graft of the lateral window approach. (13)

Additionally, the crestal window sinus lifting technique could reduce the risk of damage to the posterior alveolar artery which was detected in 73.2% of all 225 patients, in a study conducted by Shams N et al. (14, 15)

Piezotome is a well-documented modality for maxillary sinus augmentation both in crestal and lateral approaches with high cutting efficiency and safety against membrane perforation. (16, 17)

Chiriatic et al. (18) had shown that reduced inflammatory response with the use of piezoelectric surgery improves healing after the surgical procedure which helps in stabilizing the bone graft and improves new bone formation.

Jordi C. et al' (19) compared rotating instruments and piezoelectric devices and found that conventional rotary instruments were associated with a perforation rate of 24%, the piezoelectric devices with 8% perforation rate leading to a statistically significant difference between both modalities ($p < 0.05$).

Although the osteotome-mediated sinus elevation technique was a predictable procedure with

minimal discomfort for patients suffering from pneumatization of the maxillary sinus, Bjarni E et al (20) reported that increased failure rate was associated with deficient available bone height.

With the introduction of magnetic mallets as a reliable alternative to conventional rotary instruments for implant site preparation, it was suggested to be used for crestal window osteotomy. (12)

Magnetic mallet provides precise cutting with controlled force to reduce surgical site morbidity as the blade is only cutting the bone in the form of a calibrated shock wave contacting the bone in a milliseconds. (10, 21)

Malleating approach for sinus elevation provides high axial and radial movement control of the tip of the osteotome, with a limited number of calibrated shock waves resulting in better condensation, especially in softer bone. (10, 12, 21)

Also, magnetic mallet is a non-rotating instrument that will eliminate heat generation during the osteotomy preparation negating the use of irrigation which will improve healing and surgical site visibility. (11)

Radiographic image analysis in our study attested to an increase in height of available bone 7.4 ± 1.4 mm in group A and 7.75 ± 1.3 in group B mm from the baseline to 6 months postoperative which is higher than conventional crestal approach and comparable to the lateral approach. (22, 23)

Giudice et al (24) reported similar results of bone height gain (7.8 mm, ± 0.86 mm) which is greater than the average of the osteotome technique in a 60-month clinical and radiological follow-up evaluation of transrectal sinus lift in atrophic maxillary ridge.

Starch-Jensen T et al (25) in a meta-analyses of 102 studies assessing absolute and relative volumetric changes following maxillary sinus augmentation, have found inevitable volumetric reduction of the augmented area following maxillary sinus floor augmentation regardless of the grafting material.

Gultekin et al (26) found that reduced grafting volume after maxillary sinus augmentation did not appear to compromise the survival rates of implants in a 2 years follow-up because most of the graft resorption appeared in the first 6 months postoperative followed by volume stability.

The newly formed bone exhibited adequate density and volume comparable to normal bone density in the posterior maxilla in both groups which was sufficient to accommodate an 8mm implant 6 months postoperatively with 35 Ncm insertion torque. (25)

CONCLUSION

Within the limitations of this study, we concluded that crestal window sinus lift performed with magnetic mallet or piezotome is a predictable procedure for maxillary sinus augmentation in the severely atrophic posterior maxilla, that can be achieved with minimal intra and postsurgical complications.

No significant statistical difference between magnetic mallet and piezotome methods used for crestal window sinus lifting in terms of newly formed bone volume and quality or intra operative or post-operative complications .

Longer intra-operative time was observed with magnetic mallet due to longer learning curve of the device and need for adequate accessibility to the surgical site.

Also we found the magnetic mallet to be a reliable tool due to its precise cutting, lack of heat generation and minimal trauma to the bone so it can be used in variable surgical procedures with high safety and predictable results

Declarations section

All authors certify that they have not received any funding and have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Ethical Approval and Consent to participate.

The research protocol was approved by the Research Ethics Committee of Alexandria University Faculty of Dentistry (IRB No. 001056 –IORG 0008839) prior to any research-related activities.

The study abided with the Declaration of Helsinki and other ethical guidelines adopted by the Research Ethics Committee of Alexandria University Faculty of Dentistry.

The study was first registered with Cochrane south Africa for clinical trials on (06 / 01 / 2023) regeneration number (PACTR202301774017220) <https://pactr.samrc.ac.za/>

Informed consent was acquired from all participants in the study prior to any surgical intervention detailing the surgical procedures and any possible complications. All patients consented to the use of all collected data including photographs, x rays and personal records collected during this study.

List of abbreviations

CBCT: Cone beam computed tomography

DICOM: Digital Imaging and Communications in Medicine

ROI: region-of-interest

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