

RADIOGRAPHIC ASSESSMENT OF CRESTAL MAXILLARY SINUS MEMBRANE ELEVATION USING DIFFERENT DENTAL IMPLANT HEIGHTS IN ATROPHIC POSTERIOR MAXILLA

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ABSTRACT

Aim: Evaluation of primary stability, secondary stability and amount of bone gained using trans-crestal osseodensification technique and the standard concave osteotomes at different heights in patients with posterior maxillary sinus pneumatization.

Methods: Thirty-three patients participated in this randomized controlled parallel group clinical experiment and were split into three equal groups: group 1 with a lifting height of 2mm, group 2 with a lifting height of 4mm, and group 3 with lifting height at (6mm), with the same inclusion and exclusion criteria. Three different manipulations were performed using the same technique in the vertically deficient posterior maxilla with simultaneous implant placement at different heights and preserving the Schneiderian membrane intact (Avoidance of perforation). Post-operatively, patients were assessed three days after the surgery, followed by weekly evaluations for the initial month. Subsequently, assessments were conducted monthly up to six months to identify any indications of dehiscence.

Results: Regarding primary and secondary implant stability, no statistical difference was noted between study groups. As for bone gain, there was a highly statistically significant higher mean value of bone height (mm) in pre compared to post, with a mean difference of 4.03 ± 0.28 and p-value ($p < 0.001$).

Conclusions: In managing cases with partial edentulous atrophic posterior maxilla seeking implant, sinus elevation using osteotome with the final apical diameter at various levels (2, 4, or 6 mm) beyond the cortical bone was associated with higher bone gain formation around dental implants.

Trial registration: it is registered by ClinicalTrials.gov with Identifier: NCT05166434 in 21 December 2021.

KEYWORDS: Crestal Membrane Elevation; Dental Implant; Atrophic Posterior Maxilla.

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INTRODUCTION

Difficulties in positioning implants in the posterior maxilla may arise due to factors associated with the maxillary sinus. The sinus may undergo pneumatization due to sinus-related issues, the patient's age, the duration of edentulism at the site, or periodontal bone loss linked to the tooth slated for extraction or already removed¹. Consequently, the height of the crestal bone may be reduced in the superior aspect due to sinus enlargement, in the inferior aspect due to periodontal bone loss, or a combination of both processes. As a result, placing implants becomes challenging due to a lack of adequate bone volume to accommodate the implant^[2].

While short implants are recommended for such clinical scenarios, but there may be inadequate vertical space to accommodate these shorter implants. Additionally, this approach may not be preferred due to potential load issues upon completion of the planned prosthetics^[3]. The literature describes two approaches for increasing crestal bone height. The first is the lateral sinus augmentation, which Boyne described in 1980 after Hilt Tatum initially proposed it in 1974. Surgical skill is required for this complex procedure, which can be adjusted to crestal heights varying from paper-thin to different residual thicknesses^[4].

The second approach, initially documented in 1994 by Summers, employs a crestal method to simplify the surgical procedure for sinus elevation. This method is applicable when there is enough height to ensure implant stability during placement; however, additional height is necessary to integrate the implant fully into the surrounding bone [5-6]. In the crestal approach, there must be adequate bone height to stabilize the implant, as the implant plays a crucial role in tenting up the sinus membrane, facilitating graft maturation into the bone of the host, and encompassing the implant. A minimum height of 4 mm is advised in order to accomplish this goal.^[7]

Although it is generally accepted that the crestal technique can result in a 4 mm height increase, some writers contend that larger height increases—up to a practical gain of 10 mm—are attainable. To avoid any possible contact between the sinus membrane and the pilot drill tip, the authors suggest deducting 2 mm from the estimated height. For example, the pilot drill depth should be set at 5 mm if the height is 7 mm^[8-9]. Because the points of standard osteotomy burs are made for cutting bone, they can accidentally tear the sinus membrane when they come into contact with it, making them unsuitable for sinus elevation treatments.

Safe-ended osteotomy drills, which are intended to gradually raise the membrane during site preparation, are therefore crucial. Although these sinus drills are less dangerous than conventional ones, care must be taken to avoid lifting them too much above the sinus floor in order to avoid creating strain in the membrane, which could tear it as the drill progresses. A physical stop on the drill reduces this risk by preventing inadvertent advancement and guaranteeing procedure safety and controlled drill depth.^[10-11]

This study aims to assess the primary stability, secondary stability and the amount of bone gained associated with the trans-crestal osseodensification technique, utilizing regular concave osteotomes at various heights.

METHODS

With the ID NCT05166434, this randomized controlled parallel-group clinical trial was listed on clinicaltrials.gov. The following approval number, 31021, was issued by Cairo University's Faculty of Dentistry's Research Ethics Committee. The Helsinki Declarations on the Ethical Guidelines for Human Subjects in Medical Research were adhered to in this investigation.

Sample size:

The sample size was determined by PS software. For the primary outcome, which is bone gain formation around dental implants, it was found that eleven patients per group were deemed appropriate. The total sample size for the study includes thirty-three patients distributed across three groups. The statistical power is set at 80%, and the significance level (α error probability) is 0.05. The effect size to be detected was estimated based on the mean and standard deviation of the variable of interest obtained from relevant scientific literature ^[12].

Study population:

Patients of both genders with partial edentulous atrophic posterior maxilla seeking implant rehabilitation. Ages ranging from 25-60 with alveolar bone height ranging from 4–6mm and minimum width of 6 mm. Sufficient inter-arch space and healthy mucoperiosteum and periodontium. Patients with systemic diseases that will affect the bone healing, with sinus problems or previous attempts of sinus lifting were excluded.

For all patients, a comprehensive review of the medical and dental histories, followed by a thorough clinical examination was performed. Each patient underwent a preoperative cone beam computer tomography (CBCT) scan conducted as investigative and planning step. This detailed imaging allowed

for the precise calculation of the needed vertical bone gain within the maxillary sinus (Fig. 1).

Intra-operative procedures:

All operations were performed under local anesthesia, using mepivacaine HCl (2%) with levonordefrin 1:20 000 infiltrations (Scandonest 2%; Septodont, Saint- Maur-des-Fossés, France). The patients were asked to rinse with antiseptic mouth wash containing 1 % povidone iodine (Betadine mouth wash, Mundipahrma, Cairo, Egypt). Implementation of a crestal incision line followed by reflection of buccal and palatal full thickness muco-periosteal flaps, exposing the crestal part of the alveolar ridge. (Fig. 2).

Figure (2): Clinical photographs Showing Pre-Operative Residual ridge and Mucoperiosteal Reflection for 2 mm Group (A&B), 4 mm group (C&D) and 6mm group (E&F).

In order to prepare the implant site, a pilot drill was used to designate the drilling sites at the alveolar crest. The drill was then inserted 0.5 to 1.5mm below the sinus floor. The initial sinus up-fracture was then started by gradually expanding the preparation region both horizontally and vertically using concave-tipped osteotomes of increasing diameter. Bone was compressed laterally and apically with each larger osteotome insertion, and the gathered bone chips were pushed under the tented membrane to reach the required height.

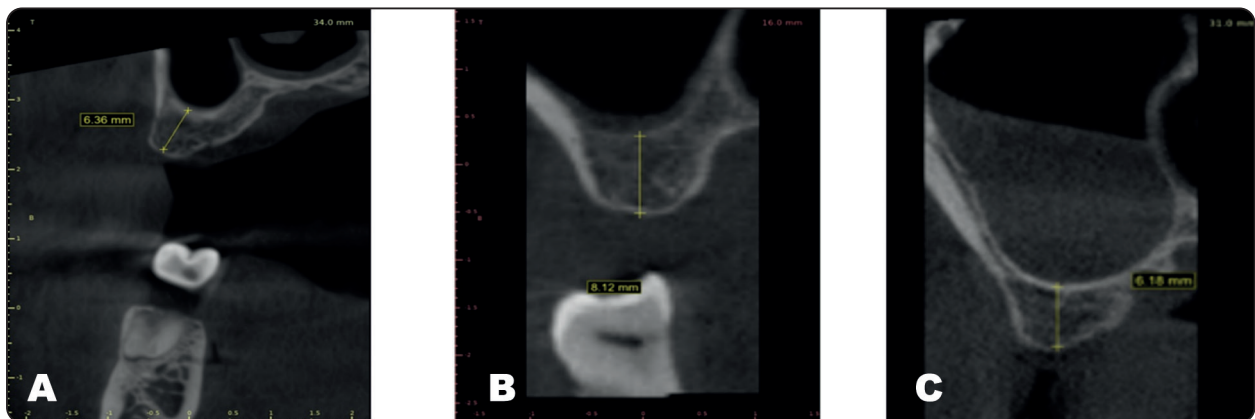


Fig. (1) Cross-Section CBCT photographys showing Pre-Operative Residual ridge and Crestal Incisions for 2 mm Group (A), 4mm group (B) and 6mm group (C).

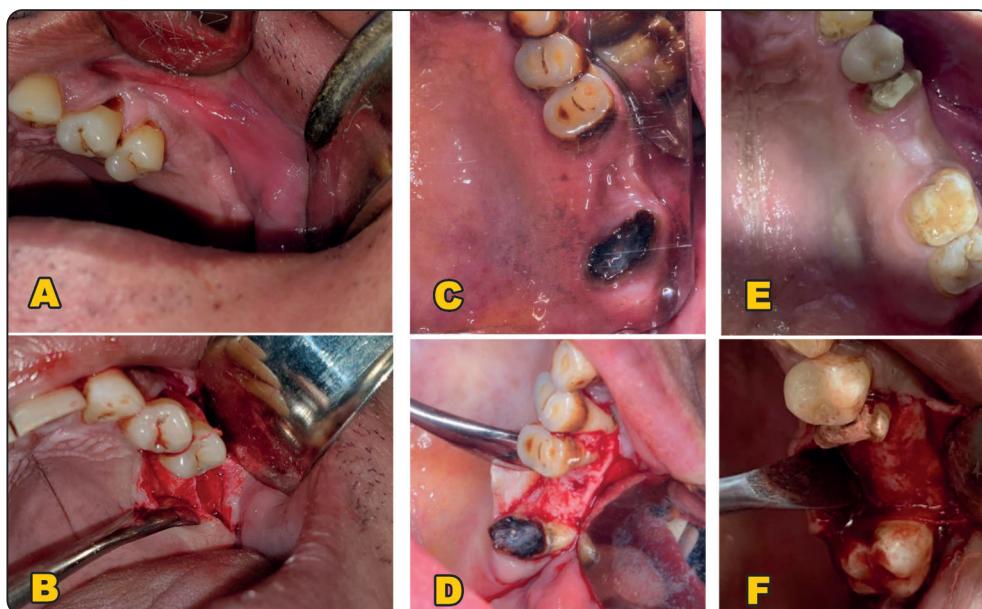


Fig. (2) Cross-Section CBCT photographs showing Pre-Operative Residual ridge and Crestal Incisions for 2 mm Group (A), 4 mm group (B) and 6mm group (C).

During malleting, the osteotome was advanced gradually in each consecutive elevation to reach the desired height according to each study group as Follows: 2mm, 4mm and 6mm height groups (Fig. 3 A, C, and E)

Primary stability has been checked immediately after Nickle Titanium dental implant insertion using the MEGA ISQ®* Ostell Device OSTELL device and the flap was sutured to obtain primary closure (Fig. 4).

Postoperative care and medications:

Patients were evaluated 3 days postoperatively and weekly thereafter for the first month, the patients were also present at 3rd month, and finally the Secondary stability was checked by the MEGA ISQ® Ostell Device at 6 months postoperative. (Fig. 5).

Radiographic assessment

This was achieved by Cone beam CT (CBCT) scan After 6 months post-operatively (Fig. 6). to bone gain along the sinus floor, together with pre-

operative CBCT make a total of two CBCT Scans for each patient.

To measure bone gain, a horizontal line was inserted and was fixed as a reference point in the pre and post CBCT slices, (usually between the adjacent teeth Cusps around dental implant), then a perpendicular line at the half of previous drawn line is inserted to the crest of the ridge. The reason for this add a reproducible method to ensure maximum accuracy for measurement using the same point before and after dental implant insertion on the same CBCT slice. (Fig. 6&7).

Statistical analysis

The statistical software for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA), was used to evaluate the recorded data. In the case of parametric (normal) distribution, the quantitative data were displayed as mean $\pm$ standard deviation and ranges, whereas non-parametric (non-normally distributed) variables were displayed as median with inter-quartile range (IQR). Qualitative variables were also displayed as percentages and numbers. Using the Shapiro-Wilk and Kolmogorov-Smirnov tests, the data were examined for normality. The

* MEGA ISQ is manufactured by MegaGen Implant Co., Ltd., Gyeongbuk, South Korea.

tests listed below were conducted: The post-hoc test and a one-way analysis of variance (ANOVA) were employed when comparing more than two means: Multiple comparisons between various variables were conducted using Tukey's test. When comparing related samples, the paired sample t-test of significance was employed. Only when the predicted count in any cell was less than five was the

Chi-square test used to compare groups with qualitative data; otherwise, Fisher's exact test was used instead. A 95% confidence interval and a 5% acceptable margin of error were established. Therefore, a p-value of less than 0.05 was deemed significant, a p-value of less than 0.001 was deemed extremely significant, and a p-value of more than 0.05 was deemed inconsequential.

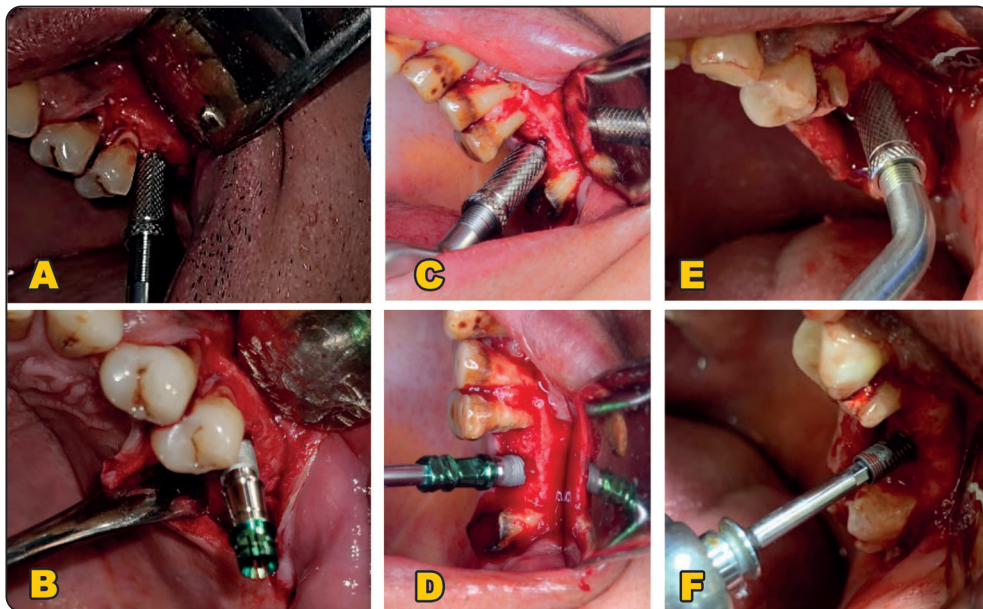


Fig. (3) Clinical photographs Showing Pre-Operative Residual ridge and Crestal Incisions for 2 mm Group (A&B), 4 mm group (C&D) and 6 mm group (E&F).

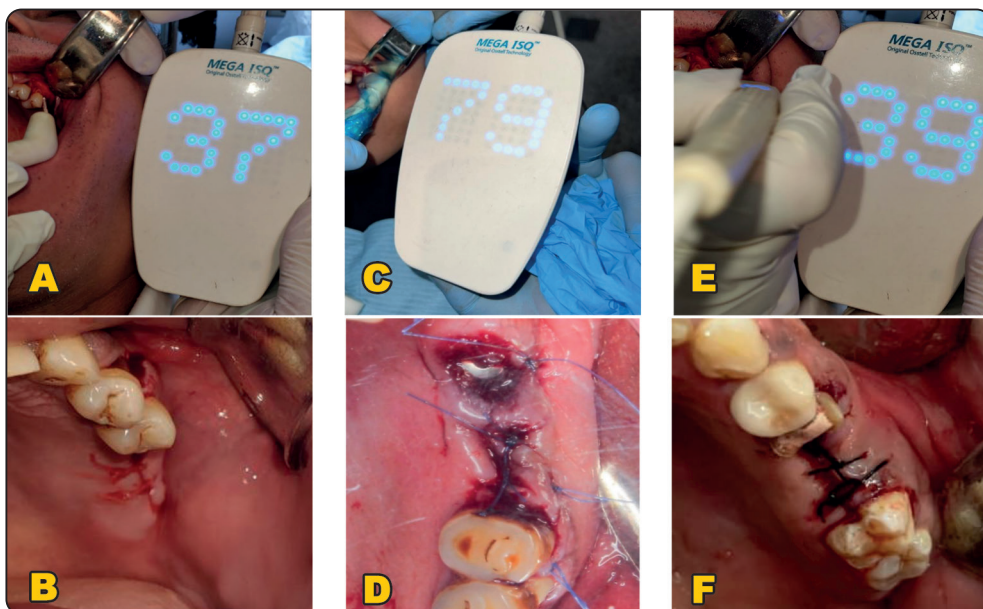


Fig. (4) Clinical photographs Showing Primary Stability measurement and Flap Closure for 2 mm Group (A&B), 4 mm group (C&D) and 6mm group (E&F).

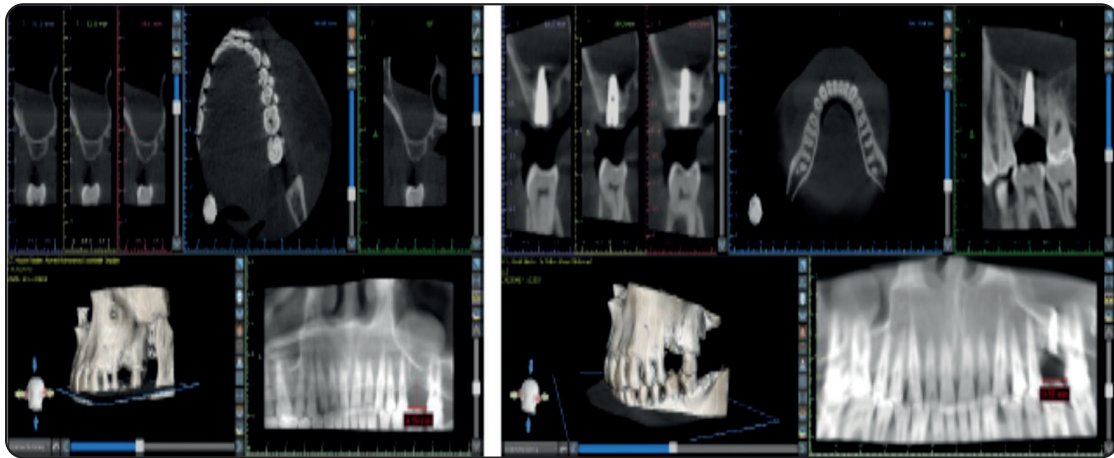


Fig. (6) Reference points insertion to ensure same position Cross-section Position for Bone Gain measurement.

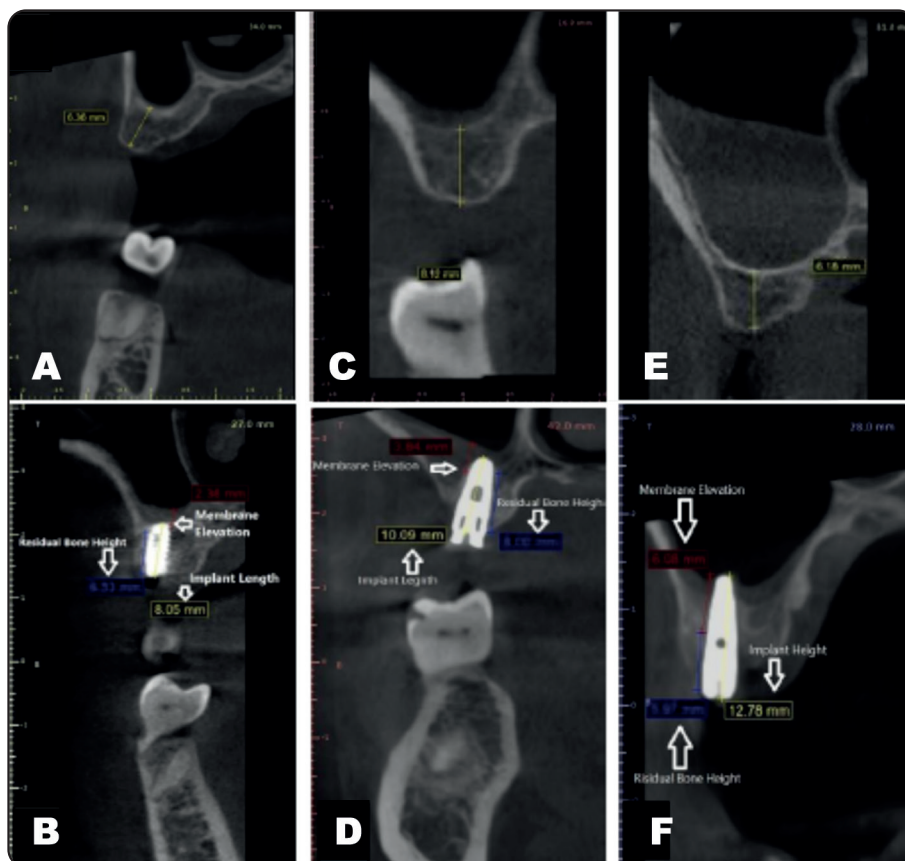


Fig. (7) Cross sectional CBCT Showing Pre and Post-Operative Bone Gain measurement for 2 mm Group (A&B), 4 mm group (C&D) and 6mm group (E&F).

RESULTS

Our goal was to evaluate the bone gain and both primary and secondary stability attained by the trans-crestal Osseo densification approach using regular concave osteotomes at different altitudes. Three groups of 33 patients were selected and assigned to the 2 mm lifting group (n=11), the 4 mm lifting group (n=11), and the 6 mm lifting group (n=11).

The mean age of the included patients was 37.09 ± 8.73 years. There was female predominance with female to male ratio of about 1.54:1.

Concerning primary and secondary stability, there was a highly statistically significant value of secondary stability ISQ compared to primary stability ISQ within each group, with a mean difference of 20.88 ± 1.72 and p-value ($p < 0.001$).

For inter-group statistical interpretation, there was

no statistically significant difference between groups according to primary stability ISQ and secondary stability ISQ, with a p-value ($p > 0.05$). (Table 1).

As for bone gain, there was a highly statistically significant higher mean value of bone height (mm) in pre-operative compared to post-operative, with a mean difference of 4.03 ± 0.28 and p-value ($p < 0.001$). However, higher bone gain was noted among cases of sinus elevation with the final apical diameter at the level of 6 mm beyond the cortical bone. Table 2.

This table shows highly statistically significant higher bone gain "mm" in the 6 mm Group as 5.80 ± 0.73 , followed by the 4 mm Group 3.95 ± 0.83 and the lowest value in the 2 mm Group 2.35 ± 0.55 , with p-value ($p < 0.001$).

TABLE (1) Comparison between groups according to stability.

Stability	Group LHat (2mm) (n=11)	Group LHat (4mm) (n=11)	Group LHat (6mm) (n=11)	Testvalue	p-value
Primary stability ISQ	8.33 ± 53.73	8.03 ± 61.64	11.37 ± 55.64	2.136	0.136
Secondary stability ISQ	3.14 ± 77.09	4.11 ± 78.64	5.38 ± 77.91	0.355	0.704
Amount of change	6.25 ± 23.36	4.33 ± 17.00	5.17 ± 22.27	1.329	0.280
p-value#	<0.001**	<0.001**	<0.001**		

TABLE (2) Comparison between groups according to bone height (mm).

Bone Height (mm)	Group LH at (2mm) (n=11)	Group LH at (4mm) (n=11)	Group LH at (6mm) (n=11)	Test value	p-value
Pre	$0.90 \pm 7.93A$	$0.85 \pm 6.89B$	$0.42 \pm 5.93C$	19.514	<0.001**
Post	$0.95 \pm 10.29B$	$1.17 \pm 10.84B$	$0.65 \pm 11.74A$	6.562	0.004*
Bone Gain (mm)	$0.55 \pm 2.35C$	$0.83 \pm 3.95B$	$0.73 \pm 5.80A$	65.341	<0.001**
p-value#	<0.001**	<0.001**	<0.001**		

DISCUSSION

Especially when it comes to the maxillary sinus, implant placement in the posterior maxilla might be difficult. The length of edentulism at the location, the patient's age, periodontal bone loss related to the tooth that will be or has been pulled, and sinus problems are some of the many variables that may affect the pneumatization (enlargement) of the sinus. These factors contribute to the complexity of the surgical procedure and must be carefully considered during treatment planning to ensure successful outcomes ^[13].

Consequently, the crestal bone height in the posterior maxilla may be reduced both superiorly due to sinus enlargement and inferiorly due to periodontal bone loss. The interaction of these two processes can result in diminished bone height at the crest, posing challenges for successful implant placement. This underscores the importance of a thorough understanding of the individual patient's anatomical and dental history when planning and executing implant procedures in the posterior maxilla ^[6].

Therefore, the placement of implants becomes challenging because there is an inadequate amount of available bone to accommodate the implant. While short implants are suggested for such clinical scenarios, there may be insufficient height to place even these shorter implants. Additionally, opting for short implants might not be the preferred approach due to concerns related to load-bearing issues upon completion of the planned prosthetics ^[3].

A sufficient bone height is required for the crestal approach in order to support the implant, which is essential for tenting up the sinus membrane. The graft can develop and become a part of the host bone thanks to this tenting activity, which covers the entire implant. To achieve this successfully, it has been suggested that a minimum height of 4 mm is necessary. ^[14]

There is a general agreement that the crestal approach can achieve a height increase of 4 mm. However, some authors argue that greater increases

in height, up to a potential gain of 10 mm, can be accomplished with this technique ^[15], with clinical success rates exceeding 93%, as reported in the literature ^[16]. Therefore, this study was undertaken with the aim of assessing Secondary stability and bone gain in the trans-crestal osseodensification technique using standard concave osteotomes at various height elevations in patients exhibiting pneumatization of the posterior maxillary sinus.

This randomized controlled clinical trial was on thirty-three patients who were divided into three equal groups: the first group with a lifting height of (2mm); the second group with a lifting height of (4mm) and the third group with lifting height of (6mm), with the same inclusion and exclusion criteria. Three different manipulations were performed using the same technique (osseodensification) in the vertically deficient posterior maxilla with simultaneous implant placement at different heights with preservation of the Schneiderian membrane intact (Avoidance of perforation). Patients underwent evaluations three days postoperatively, followed by weekly assessments in the first month. Additionally, radiographic assessments were conducted using cone beam computed tomography scans at the Six-month postoperative mark to measure the vertical bone changes ^[17-18].

Our study revealed that sinus elevation using osteotomes of the final apical diameter at various levels was associated with significant stability of dental implants measured by Ostell Device. The secondary stability ISQ was highly statistically significantly higher compared to primary stability ISQ 77.88 ± 4.22 vs. 57.00 ± 9.69 .

Also, sinus elevation using osteotome with the final apical diameter at different levels in all groups (the 2 mm, 4 mm, and the 6 mm group) beyond the cortical bone was associated with higher bone gain formation around dental implants, i.e., " highly statistically significant higher mean value of bone height (mm) in pre comparing to post-intervention"; 10.95 ± 1.10 vs. 6.92 ± 1.10 .

No difference was noted between study groups (using osteotome with the final apical diameter at various levels 2, 4, or 6 mm) regarding the stability of dental implants: 23.36 ± 6.25 vs. 17.00 ± 4.33 vs. 22.27 ± 5.17 .

However, higher bone gain was noted among cases of sinus elevation with the final apical diameter at the level of 6 mm beyond the cortical bone: 5.80 ± 0.73 A vs. 3.95 ± 0.83 B vs. 2.35 ± 0.55 C.

De Melo et al., 2014 and Yamada et al., 2013 suggested that the utilization of bone substitutes may significantly contribute to the promotion of intra-sinus bone gain by acting as a scaffold and/or maintaining space, thus preventing the collapse of the sinus membrane^[19-20].

Nevertheless, Si et al. (2015) found no histologic benefits of employing bone substitutes for intrasinus bone gain during the sinus elevation surgery^[21]. The study's findings may be impacted by the type of implant surface and the degree of implant penetration into the maxillary sinus above the residual bone height (RBH). In fact, a specific implant surface might perform better than another in terms of encouraging the growth of new bone.

Furthermore, a 2013 study by Si et al. pointed out that the amount of space the implant creates beneath the sinus membrane may have an impact on how much new bone grows. Additionally, the reported follow-up periods frequently appear insufficient for doing thorough long-term assessments, and many of the studies that are now available rely on a two-dimensional radiographic study of intrasinus bone alterations.^[22]

Furthermore, according to Santoro and Pippi (2018), it is currently difficult to ascertain whether intrasinus bone gain varies between intermediate and non-intermediate implants placed using the osteotome technique, or between single, double, or multiple adjacent sinus elevation procedures, based on the data currently available. Furthermore, it is yet unknown if the kind of final implant rehabilitation—such as single vs full-arch rehabilitation—

could affect the amount and stability of intrasinus bone gain over the long run. Therefore, it is necessary to conduct randomized controlled trials (RCTs) to examine if these different parameters could affect intrasinus bone gain in the short to long term.^[23]

Choosing an 8-mm-length implant would be the most prudent option when a 2- to 3-mm bone growth is expected with a 4- to 5-mm residual bone height (RBH). According to Ferrigno et al. (2006) and Pjetursson et al. (2009), using an implant that is 10 or 12 mm long may also be appropriate when working with a 6- to 7-mm RBH.^[8-9]

After a 3-year period, the mean intrasinus bone gain surpasses 2 mm in approximately 80% of procedures without grafting and 100% of procedures with grafting. These findings align closely with those reported by Nedir et al. in 2016, who observed intrasinus bone gain exceeding 2 mm in 93.8% of procedures without grafting and 100% of those with grafting^[24].

Compared to treatments including grafting material, sinus elevation techniques without grafting consistently displayed favorable dimensional improvements, resulting in a larger relative intrasinus bone growth. Grafting procedures, on the other hand, only showed negative percentage changes between the first and last follow-up. Because there is a dearth of research with long follow-up periods, these results are based on a small number of studies. Interestingly, Nedir et al. (2016) found a 20% intrasinus bone increase during the first and tenth follow-up years after analyzing 25 sinus elevation procedures without grafting.^[24]

Similarly, Si et al. found that between the first and fifth follow-up years in 2016, there was a 25.31% increase in procedures without grafting and a 10.96% decrease in procedures with grafting. Significantly atrophic ridges in a more recent randomized controlled experiment (RCT). Additionally, they observed a dimensional drop in procedures with and without grafting from the first to the fifth follow-up years of 4% and 2.5%, respectively.^[21]

Only two randomized controlled trials (RCTs) with an initial mean crestal height of less than 5 mm—Nedir et al. in 2017 and Si et al. in 2013—among the chosen studies allowed for a comparison of the outcomes of the two methods. Both studies showed high implant survival rates up to three years following surgery (range from 90.0% to 94.1% and 95.0% to 95.2%, respectively), with no statistically significant differences found ^[21,24].

These findings align with those of other studies and a recent meta-regression analysis by Lai et al. in 2010, Chao et al. in 2010, Pommer et al. in 2014, and Stavropoulos et al. in 2007, indicating that the residual crestal height may not definitively impact short- and medium-term implant success, some authors advise employing the sinus elevation osteotome technique in cases where there is a minimum residual bone height (RBH) of at least 6 mm ^[2,7,25,26].

Importantly, conclusions about the long-term success of the osteotome technique applied to greatly atrophic residual ridges are hampered by the small number of RCTs (Tan et al., 2008; Weber et al., 2009; Zitzmann and Scharer, 1998), their comparatively short follow-up periods, and the frequent lack of local bone density assessment. ^[18,27,28]

Emmerich et al. in 2005 and Rodoni et al. in 2005 reported a 100% implant survival rate, which is comparable to or greater than that observed in previous studies involving sinus floor elevation. They concluded that the insufficient height of the residual alveolar ridge is not a significant factor contributing to implant failure. Instead, factors such as trauma, infection, or contamination during surgery may play a role in unfavorable outcomes ^[12,29].

According to Lai et al., in 2008, implants placed using a closed sinus lift technique with osteotomes and without bone grafts can achieve good primary stability. They noted that the stability curve might experience a dip between 1- and 6 weeks post-operation, but overall, implants in the atrophic posterior maxilla using closed sinus lift alone, without grafting, can exhibit predictable and uneventful osseointegration ^[30].

The Osseodensification approach offers the potential to prepare the osteotomy site inadequately without digging considerable volumes of bone, resulting in increased BIC and 70 implant stability in low-density locations (posterior maxilla). This notion was supported by the findings of Lahens et al., 2016, who found increased bone-to-implant contact while utilizing a Densah bur.

According to Trisi et al. (2016), the Densah bur is able to improve trabecular density by compacting bone as an auto-graft in the osteotomy walls. Compared to standard osteotomies, it improves the percentage of bone volume and bone-implant contact for dental implants implanted into low-density bone, which may aid in osseointegration and implant stability ².

Kumar and Narayan (2017) concluded that using a Densah bur in densifying mode can elevate the sinus membrane with autografting without causing perforation. However, Wang et al. (2017) found that osseodensification improved the peri-implant bone's apparent density but did not enhance primary stability or bone-implant contact. ^[11]

Effluence is generated ahead of the point of contact by hydrodynamic wave motion caused by fluid pumping and high-speed counterclockwise drill rotation. As revealed by Wang et al., 2017, After the sinus floor is penetrated by a densifying bur, the irrigation solution and bone debris play a crucial role in hydraulically elevating the sinus membrane ^[17].

Using the densifying mode, plastic bone formation continues even after a traumatic osteotomy preparation. As a result, there is more biomechanical energy available for bone-to-implant contact as the inner walls of the osteotomy bounce back toward the center. In order to improve intra-osseous densification, Meyer and Huwais (2014) state that lateral compaction entails pushing small pieces of displaced trabecular bone both laterally and apically during implant preparation ^[32].

Finally, Mandelaris et al., 2010 stated that a pre-surgical stent was placed in cases to enable optimal

implant placement, resulting in a favorable distribution of forces directed to implant and prosthetic components [33].

CONCLUSIONS

From our study, we can conclude that:

1. Sinus elevation using osteotome with the final apical diameter at different levels (2, 4, or 6 mm) beyond the cortical bone was associated with higher bone gain formation around dental implants.
2. Sinus elevation using osteotome with the final apical diameter at various levels was associated with significant stability of dental implants measured by Ostell Device in ISQ.
3. The higher bone gain was noted among cases of sinus elevation with the final apical diameter at the level of 6 mm beyond the cortical bone. However, no difference was noted between study groups (using osteotome with the final apical diameter at various levels 2, 4, or 6 mm) regarding stability of dental implants.

Declarations

- **Ethics approval and consent to participate:** “This study was authorized by the Research Ethical Committee at Faculty of Dentistry, Cairo University with number 31021. Informed consent was waived by the ethics committee Research Ethical Committee at Faculty of Dentistry, Cairo University.”.
- **Availability of data and materials:** The datasets utilized and analyzed during the current study are available from the corresponding author on reasonable request.
- **Competing interests:** There are no conflicts of interest.
- **Funding:** This work was entirely self-funded; no grants were obtained for it.

- **Authors' contributions:** Maher Mohammed wrote the manuscript. The data entry and collecting were done by Mohammed Atef. The project was directed by Mohammed Khashaba. The final manuscript was evaluated and approved by each author.

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