Evaluation of bone height gain following transcrestal sinus floor elevation using piezoelectric surgery versus the conventional osteotome technique in patients with atrophic posterior maxillae: A Randomized controlled clinical trial

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Abstract:
Background: Although trans-crestal sinus floor elevation (TSFE) has been proven as a predictable surgical procedure to increase the bone height in the posterior maxilla, high-quality evidence comparing TSFE using piezoelectric surgery versus the conventional osteotome technique is limited. The aim of the present study is to evaluate bone height gain following TSFE using piezoelectric surgery versus the conventional osteotome technique.

Subjects and methods: Twenty-four patients with one missing upper posterior tooth with 5-8 mm residual bone height beneath the maxillary sinus were randomly allocated into two groups; TSFE using piezoelectric surgery (test group) and TSFE using osteotomes (control group). CBCT was
used to measure bone height gain after 6 months. Sinus membrane perforation and oral health related quality of life (OHRQoL) were evaluated using appropriate statistical tests.

Results: No statistically significant difference regarding the bone height gain after 6 months between the test (2.22 mm) and control (1.94 mm) groups was found. Only one case of membrane perforation occurred in each group representing a percentage of 8%. Likewise, no statistically significant difference between the test and the control groups regarding OHRQoL was found.

Conclusion: TSFE is a successful technique regardless of the tools used with statistically significant difference between the initial bone height and bone height after 6 months. In addition, there is no statistically significant difference between TSFE using piezoelectric surgery and osteotomes regarding bone height gain after 6 months, membrane perforation and OHRQoL.

Keywords: sinus lift; piezosurgery; osteotomes; crestal approach

Introduction:

Implant placement in the edentulous posterior maxilla is usually a challenging procedure. After tooth loss, atrophy of the alveolar crest and pneumatization of the maxillary sinus occur which limit the quantity of residual bone available for implant anchorage.\(^1\),\(^2\) Sinus floor augmentation is a useful procedure for implant supported restoration in the atrophic posterior maxilla. Sinus floor augmentation can be performed either through a lateral window,\(^3\) or via a crestal access.\(^4\) The selection between these two techniques is based on the remaining residual vertical sub-sinus bone height. Lateral approach of sinus elevation is indicated when the residual bone height is of 4 mm or less, while the crestal approach is used in case of residual ridge of 5-6 mm.\(^5\)

The osteotome mediated sinus floor elevation (OSFE) with subsequent implants placement was first suggested by Tatum \(^6\) and modified by Summers.\(^7\) OSFE is less invasive, traumatic and time consuming than the lateral approach. The osteotome technique for sinus floor elevation uses a set of osteotomes of varying diameters to prepare the implant site. In this technique, drilling in the bone via the crest up to 1 mm apical to the sinus floor then a set of osteotomes are used to perform a
‘green-stick fracture’ of the sinus floor by tapping using a mallet. This leads to sinus membrane elevation creating a tent which provides a space for bone graft placement or blood clot formation. The technique tended also to increase the density of the soft type III and IV maxillary bone through lateral condensation resulting in bone compression and better primary stability of the dental implants.\[7\]

Many long-term studies and systematic reviews have showed that OSFE technique is a highly predictable method for rehabilitation of patients with atrophic posterior maxilla with survival rates ranging from 92 % to 100 %.\[8-11\] However, endoscopic studies have demonstrated the risk of membrane perforation while performing TSFE.\[12, 13\] Moreover, the Summers technique can cause complications as headache and paroxysmal positional vertigo.\[14\]

The piezoelectric internal sinus elevation (PISE) technique was first introduced by Sohn et al.\[15\] Using piezoelectric ultrasonic vibration (25–30 kHz), the piezosurgery device cuts only mineralized structures without cutting soft tissues even in case of accidental contact resulting in a low rate of sinus membrane perforation.\[16\] Another advantage of piezosurgery is its precision as the movement of the piezosurgery tip is very small, so the cutting accuracy is great and the patient’s discomfort is minimal. In addition, the air-water cavitation effect of the piezoelectric device maintains a blood-free surgical field which improves visualization of the surgical field. This technique overcomes the problem of benign paroxysmal positional vertigo (BPPV) caused by malleting during the OSFE.\[17\]

Unfortunately, few randomized controlled clinical trials were done to assess the efficiency of piezoelectric surgery in TSFE and therefore the objective of this study is to evaluate radiographically the amount of bone height gain and clinically the possibility of developing complications after TSFE using piezoelectric surgery versus the conventional osteotome technique.

Subjects and Methods:

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Study Design:

The present study is a single-center, prospective, single-blinded randomized parallel two-arm controlled clinical trial. The present study was approved by the Research Ethics Committee of Faculty of Dentistry, Cairo University (ID. 19-6-23). The CONSORT guidelines for clinical trials were followed. Each subject participating in the study signed an informed written consent form. The clinical trial was registered on www.ClinicalTrials.gov (ID. NCT03944811). The primary outcome of the current study is the bone height gain; the secondary outcomes included implant stability, sinus membrane perforation, and OHRQoL.

Sample Size Calculation:

Based on a previous study [18], the mean bone height gain was 2.5 mm (Standard deviation (SD) 1.5) for the osteotome group. As no randomized controlled clinical trials that compared both groups was done before, the minimum clinically important difference was estimated by a clinical expert (main supervisor) to be 2 mm. Using power 80 % and 5% significance, a sample size of 10 implants in each group was needed. This number was increased to a sample size of 12 implants in each group to compensate for any losses during follow-up. Sample size calculation was achieved using PS: Power and Sample Size Calculation Software Version 3.1.2*.

Patients’ Selection:

Patients were recruited from the outpatient clinic of Oral Medicine, Oral Diagnosis and Periodontology department, Faculty of Dentistry, Cairo University. The following inclusion criteria were applied: Residual bone height ranged from 5 mm to 8 mm, a minimum of 6 mm bone width at the edentulous site, systemic and local condition compatible with implant placement and sinus floor elevation, adequate inter-occlusal space of 8-10 mm, motivated and hygiene conscious.

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The patients were excluded on the basis of: uncontrolled diabetes mellitus or other systemic disorders, any habits that jeopardize the osseointegration process, such as current smokers, rhinitis or sinusitis, and parafunctional habits that produce overload on implant.

Treatment Allocation and Allocation Concealment:

Each patient was randomly assigned to either the test (PISE) or the control (OSFE) group using a computer-generated randomization list† with a 1:1 allocation ratio. Allocation concealment was done utilizing sequentially numbered opaque sealed envelopes that contained the treatment group to which the participant will be assigned. The envelope was opened by the main supervisor after local anaesthesia administration at the surgical site. This study is single-blinded because the evaluator of the study variables and outcomes were blinded. Due to the nature of the procedures, it was not possible to blind the researcher and the participants for the treatment protocol.

Treatment Protocol:

A thorough history and medical evaluation were done before the initiation of treatment. Cone-beam computed tomography (CBCT) was done to perform accurate measurements in three dimensions and to evaluate the contents of the sinus accurately. All the patients underwent presurgery screening and initial periodontal therapy.

Local anesthetic was applied to all the patients participating in this study. A para-crestal incision, then two vertical incisions at the mesial and distal neighboring teeth down to muco-buccal fold were done and a mucoperiosteal flap was elevated, exposing the buccal bone and the crest of the ridge. Implant drills‡ were mounted on a low-speed handpiece and osteotomy preparation was

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‡ OsteoCare™ Implant System, London, United Kingdom
done under copious normal saline solution. Sequential drilling started with the 2.2 mm drill, then the 2.75 mm drill and ended with the 3.25 mm drill in soft bone or the 4 mm drill in hard bone.

The osteotomy site was prepared 0.5 mm short of the existing maxillary sinus floor.

For the test group, piezosurgery device§ was used. Two special diamond coated ultrasonic tips with internal irrigation were used in the study; SCL2D tip (diameter 2.1-2.9 mm) or SCL4D tip (diameter 2.4-3.5 mm). The selection of the tip used depended on the osteotomy site width. The selected tip was used through the osteotomy site for thinning out of the remaining bone below the sinus floor using minimal pressure (figure 1).

For the control group, Flat end osteotome** of appropriate size was introduced through the osteotomy to in-fracture the floor of the sinus by light malleting (figure 2).

Then for both groups, assessment of sinus membrane perforation using osteotomy blunt probe. Twenty-four Maxi-Z Flat-End dental implants†† were used in this study (14 implants 4.5 mm x 8 mm and 10 implants 4.5 mm x 10 mm). All implant insertions were performed by use of a hand ratchet and was seated until the platform flushed with the crestal bone (Figure 3). The cover screw was then placed and tightened to seal the internal hex of the implant. Mucoperiosteal flap was repositioned, and suturing was completed using 4/0 silk suture.

Postoperatively, the patients were informed to avoid strenuous activity. A cold compress was placed superficially on the skin overlying the surgical site for the first 24 hours. The patients were asked to maintain soft diet for one week to avoid trauma to the surgical site. After 24 hours, the patients started chlorhexidine rinses twice daily for two weeks. Also, the patients were informed to sneeze and cough with mouth open. In addition, patients were informed not to exhale and not to bend over. The patients were also instructed that blowing the nose and using straws were

§ NSK VarioSurg, Tokyo, Japan
** OsteoCare™ Implant System, London, United Kingdom
†† OsteoCare™ Implant System, London, United Kingdom

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Augmentin 1000 mg capsules were prescribed twice daily for 5 days to avoid possibility of infection.

After a healing period of six months, implants were exposed surgically, healing abutments were placed and suturing was done. One week later, impressions were taken using Polyvinylsiloxane material and the final crowns were fabricated and cemented (figure 4).

Figure (1): Thinning out of the sinus floor by SCL4D ultrasonic tip.
Figure (2): In-fracture of the sinus floor using osteotome

Figure (3): Implant placement.

Figure (4): Final crown delivered.

Outcome Measurements:

Radiographic measurements:
A comparison was made between the preoperative CBCT radiographs and the 6-month postoperative CBCT radiographs. The raw data set obtained from the CBCT scanning were imported to a special third-party software‡‡ for secondary reconstruction. For standardization of measurements in CBCT, fusion was used where each image (primary and secondary) was given a colour code for identification. The preoperative image was fused to the postoperative image by first using manual registration through anatomical landmarks. Registration (superimposition) was completed automatically by the software allowing the best possible accuracy (Figure 5).

Briefly, the initial bone height, measured from the preoperative CBCT images showed the vertical distance from the cortex bone under the maxillary sinus floor to the alveolar bone crest. The new bone level from the 6-month postoperative CBCT images was measured vertically from the most coronal to most apical of the bone-implant contact area. Bone height gain was measured by subtracting the initial bone height from the bone height after 6 months.

![Figure (5): Superimposition of the postoperative image on the preoperative image.](image)

Clinical measurements:

The patient’s OHRQoL was assessed using oral health impact profile-14 (OHIP-14) questionnaire one week and two weeks postoperatively. The questionnaire uses 14 items to capture measures of seven dimensions: functional limitation, physical pain, psychological discomfort, physical

‡‡ Ondemand 3D, Seoul, South Korea

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disability, psychological disability, social disability, and handicap. Each dimension is measured by two questions. Responses to the items was recorded by using a five-point Likert scale: (0, never); (1, hardly ever); (2, occasionally); (3, fairly often); (4, very often). OHIP-14 score is calculated by adding up the answers of all 14 items, with the total score ranging from 0 to 56.\textsuperscript{[19]}

Statistical analysis:

Numerical data were described as mean and standard deviation (SD). Nominal data were reported as frequency and percentage. Numerical data were explored for normality using Kolmogorov-Smirnov test and Shapiro-Wilk test. In the case of normally distributed numerical variables (age, bone height, bone height gain, membrane elevation, implant stability), a comparison between both groups was done using independent t-test, and between different outcome data in each group with paired t-test. For non-normally distributed variables (OHIP-14), Mann Whiney U test was utilized for comparisons between groups and Wilcoxon signed-rank test for intra-group comparison. Nominal data were analysed using Fisher's exact test. All tests were two-tailed and P-value less than or equal 0.05 was be considered statistically significant. Data were analysed using a statistical software\textsuperscript{§§}.

Results:

Twenty-four patients, aged 25-65 years were included at first. No patients dropped out during the follow-up period. Thus, 12 patients in the test group, and 12 patients in the control group completed the study and their data were used for statistical analysis.

Demographic Results:

The mean age in the test group was 47.42 ± 9.78 years old while for the control group, the mean age corresponded to 46.17 ± 9.68 years. Difference in mean age between groups is statistically insignificant (P = 0.938). As for the gender distribution, 42% of the test group are males while

\textsuperscript{§§} SPSS version 26, BM Inc., Chicago, IL.
58% are females, while 50% of the control group are males and 50% are females. The differences in proportions are statistically insignificant (P = 1).

Radiographic Results:

Within both treatment groups, there was statistically significant difference between initial bone heights versus bone height after 6 months [Table 1]. The mean initial bone height of the sample subjects in the control group is 6.81 ± 0.95 mm which is slightly higher than that of the test group 6.59 ± 0.87 mm [Table 2]. Difference in mean initial bone height between two groups is statistically insignificant (P = 0.563).

Regarding the bone height at 6 months, the mean bone height after 6 months of the sample subjects in the test group is 8.81 ± 0.70 mm which is slightly higher than that of the control group 8.75 ± 0.99 mm [Table 2]. Difference in mean bone height between groups is statistically insignificant (P = 0.870). While the mean bone height gain after 6 months of the sample subjects in the test group is 2.22 ± 0.5 mm which is higher than that of the control group 1.94 ± 0.78 mm [Table 3]. Difference in mean bone height gain between groups is statistically insignificant (P = 0.314).

Clinical results:

Membrane perforation:

The frequency of occurrence of membrane perforation in subjects in both treatment groups is 8%. The difference between both groups was statistically non-significant (P = 1.00) [Table 4].

OHRQoL:

After week 1, the mean OHIP-14 score in the test group was 7.25 ± 2.93 while the value was 7.75 ± 3.47 in the control group. In this context, the difference between both groups was
statistically insignificant (P = 0.661). For the OHIP-14 mean values after 2 weeks, the test group was 1.25 ± 1.96 and the control group was set at 1.58 ± 2.27. Similarly, there was no statistically significant difference between both groups after 2 weeks (P = 0.649) [Table 5].

Table (1): Comparisons within each group at different follow ups regarding bone height

<table>
<thead>
<tr>
<th>Study groups</th>
<th>Bone height</th>
<th>Mean (SD)</th>
<th>P value</th>
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<tbody>
<tr>
<td>Test group</td>
<td>Initial bone height</td>
<td>6.59 (0.87 mm)</td>
<td>&lt;0.001</td>
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<td></td>
<td>Bone height after 6 months</td>
<td>8.81 (0.70 mm)</td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>Initial bone height</td>
<td>6.81 ± 0.95 mm</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Bone height after 6 months</td>
<td>8.75 ± 0.99 mm</td>
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</table>

Significance at p-value ≤0.05. SD – standard deviation

Table (2): Comparison between two groups regarding initial bone height and bone height at 6 months

<table>
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<th>Outcome</th>
<th>Study groups</th>
<th>Mean (SD)</th>
<th>P-value</th>
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</thead>
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<tr>
<td>Initial bone height</td>
<td>Test group</td>
<td>6.59 (0.87 mm)</td>
<td>0.563</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>6.81 ± 0.95 mm</td>
<td></td>
</tr>
<tr>
<td>Bone height after 6 months</td>
<td>Test group</td>
<td>8.81 (0.70 mm)</td>
<td>0.870</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>8.75 ± 0.99 mm</td>
<td></td>
</tr>
</tbody>
</table>

Significance level at p-value ≤0.05. SD – standard deviation

Table (3): Comparison between the two groups regarding bone gain at 6 months
Table (4): Comparison between the two groups regarding membrane perforation percentages

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study groups</th>
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<th>No</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane perforation</td>
<td>Test group</td>
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<td>11</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>1</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

Significance level at p-value ≤0.05.

Table (5): Comparison of oral health impact profile-14 scores between study groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 (Test)</td>
<td>7.25 (2.93)</td>
<td>0.661</td>
</tr>
<tr>
<td>Group 2 (Control)</td>
<td>7.75 (3.47)</td>
<td></td>
</tr>
<tr>
<td>2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 (Test)</td>
<td>1.25 (1.96)</td>
<td>0.649</td>
</tr>
<tr>
<td>Group 2 (Control)</td>
<td>1.58 (2.27)</td>
<td></td>
</tr>
</tbody>
</table>

Significance level at p-value ≤0.05. SD – standard deviation

Discussion:
Although the OSFE technique is a highly predictable method for rehabilitation of patients with atrophic posterior maxillae with survival rates ranging from 92 % to 100 %, [8-11] this technique can cause complications such as Schneiderian membrane perforation during drilling and BPPV caused by damage to the internal ear due to usage of the sinus osteotomes and mallet to break the sinus floor. [20]

Many modifications were proposed for the OSFE to reduce the rate of membrane perforation. Piezoelectric surgery has gained popularity as it can cut hard tissues with great precision and less trauma resulting in a very low rate of sinus membrane perforation. In addition, the air-water cavitation effect of the piezoelectric device sustains a blood-free surgical field which improves visualization. [23]

The possibility of sinus floor augmentation with or without a grafted material is vigorously debated. In the present study, no grafting material was used and the new bone formation around the apical part of the implants came from the bony walls of the sinus, similar to an extraction socket. [21,22] This means that elevation and tenting of the sinus membrane alone induce formation of bone beyond the original skeletal sinus contour. No significant differences in survival rates have been found whether grafting material was used or not. [8,9]

In the present study, there was a statistically significant difference between the initial bone height (6.59 ± 0.87 mm) and bone height after 6 months (8.81± 0.70 mm) in the test group with an endo-sinus bone gain of 2.22 mm. This is in accordance with the results reported by Baldi et al. [23] who found a statistically significant difference between the initial bone height (5.5 mm) and bone height after 1-year (12.4 mm) with an endo-sinus bone gain of 6.9 mm after PISE. The greater amount of bone gain in the latter study may be due to the use of composite bone graft which maintained the endo-sinus space around implants beneath the elevated membrane.

In the control group, on the other hand, there was also a statistically significant difference between the mean initial bone height (6.81 ±0.95 mm) and the mean bone height after 6 months (8.75 ± 0.99
mm) with an endo-sinus bone gain of 1.94 mm. This is consistent with the results found by Shi et al. [24] who reported a mean endo-sinus bone gain of 2.7 mm after OSFE. Similarly, the results of the present study were supported by the systematic review and meta-analysis performed Ye et al. [8] which reported a mean endo-sinus bone gain of 2.2 mm after OSFE.

Moreover, in the present study, there was no statistically significant difference in the amount of bone gain (2.22 mm versus 1.94 mm) in the test and control groups, respectively. This is in agreement with the results reported by Baldi et al. [23] who reported a mean endo-sinus bone gain of 6.9 mm and 6.5 mm for the PISE and OSFE, respectively with no statistically significant difference between both groups. In addition, the results of our study are consistent with those reported by Radvar et al. [25] who reported no statistically significant difference between PISE and OSFE regarding the mean endo-sinus bone gain (2.2 mm vs 3 mm), respectively.

Sinus membrane perforation is considered the most common complication during TSFE procedures. Intraoperative Schneiderian membrane perforation increases the possibility of postoperative site infection, sinusitis, and implant failure. [26] In the present study, no significant difference regarding the perforation of Schneiderian membrane was found between the test and the control groups. Only one case of membrane perforation occurred in each group representing a percentage of 8%. These results are in accordance with results obtained by Baldi et al. [23] who found no statistically significant difference between the PISE group (0%) and the OSFE group (8%). In addition, our results are in agreement with those revealed by Kühl et al. [27] who claimed that no statistically significant difference regarding the membrane perforation rate between the OSFE group (8%) and the PISE group (25%). The higher perforation rate in the latter study may be due to the inclusion of cases with residual bone height less than 5 mm below the sinus.

Finally, to the best of our knowledge, there are no previous studies that compared between the PISE and the OSFE regarding OHRQoL. In the present study, no statistically significant difference was found between the test and the control groups regarding OHIP-14 scores at one week (7.25 versus 7.75) and two weeks (1.25 versus 1.58) after the surgery, respectively. The only study done by
Radvar et al. [24] showed no statistically significant difference between the piezoelectric surgery group and the osteotome group regarding the patient reported outcomes using the visual analogue scale.

Conclusions

From this study, it can be concluded TSFE is a successful technique regardless of the tools used with statistically significant increase in the bone height after 6 months. Moreover, no statistically significant difference between TSFE using piezoelectric surgery and osteotomes regarding bone height gain after 6 months, implant stability, membrane perforation and OHRQoL was found.

References:


