Evaluation of Flapless Osteotome-Mediated Sinus Floor Elevation with Simultaneous Implant Placement

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Objective: The aim of the present study was to evaluate the predictability and success rate of the flapless osteotome-mediated sinus floor elevation procedure with simultaneous placement of the new OsteoCare™ Maxi Z Flat-End implants without using a bone augmentation material.

Material and Methods: Sixty-four consecutive patients with a minimum of 5-6 mm of residual vertical bone height under the sinus received 108 dental implants protruding in the sinus. The lengths of the implants were 8, 10 and 12 mm. 87 implants had a diameter of 4.5 mm and 21 implants had a diameter of 3.75 mm. A healing period of 6 months was allowed before second stage surgery and the prosthetic phase was begun. The radiographic evaluations and soft tissue measurements were done at 6, 9, and 12 months of the follow-up period.

Results: A total of 105 implants were successfully osseointegrated showing a success rate of 97.22%. Soft tissue healing progressed normally in all patients after implant placement. The mean amount of sinus floor elevation was 3.65 ± 0.84 mm.

Conclusion: The flapless osteotome-mediated internal sinus floor elevation without using a bone augmentation material in conjunction with simultaneous placement of the new OsteoCare™ Maxi-Z Flat-End implants, is a safe and reliable technique. It is indicated when residual bone height under the sinus is of a minimum of 5 mm and a needed amount of sinus floor elevation is up to 4 mm.
Introduction
Oral rehabilitation using implant-supported prostheses in
restoring missing teeth has become an established and
widely used treatment modality in dentistry. The presence of
adequate bone volume at the future implant site is
mandatory for stable biomechanical support of the
osseointegrated implant (1). The posterior maxilla is always a
challenging site for dental implant placement. Pneumatisation
of the maxillary sinus and alveolar bone resorption resulting
from the osteoclastic cells activity following extraction of the
maxillary posterior teeth can lead to horizontal and vertical bone
loss limiting the available amount of bone required for implant placement (2).

A variety of sinus augmentation techniques have been
developed to reconstruct the posterior maxilla when bone
volume is insufficient. There have been two major approaches
utilized for sinus floor augmentation: a modified Caldwell-Luc
(lateral window technique), and a vertical alveolar ridge
augmentation using osteotomes (osteotome technique) (3).

In the lateral sinus lift procedure, a window is created
through the lateral wall of the maxillary sinus; the
Schneiderian membrane is elevated and a bone grafting
material is placed in the created space. This bone
augmentation procedure is considered to be invasive,
time consuming and expensive. Post-operative
complications such as pain and swelling resulting from the
extensive surgical trauma increasing patient's discomfort
after using this technique have also been reported (4).

The osteotome sinus floor elevation procedure (OSFE)
described by Summers in 1994 was considered a less
invasive procedure with decreased operation time and
postoperative discomfort (5). Access to the sinus
membrane is achieved through a crestal approach using a
specific root analog instrument (osteotome). After
performing the initial implant osteotomy drilling,
approximating the sinus floor, an osteotome was inserted
into the osteotomy site and gently tapped, fracturing and
moving the sinus floor superiorly. The fractured sinus bone
was pushed up, reflecting the Schneiderian membrane
followed by insertion of a grafting material. Modifications
to this technique have been studied reporting reduction of
operation time (6). A number of disadvantages and side
effects accompanying these techniques have been
observed including the limitations of the amount of
augmentation of the sinus floor and the volume of bone
created. In addition, the uncontrollable osteotome tapping
force often causes discomfort to the patients during the
surgery (3). In addition, the inability to diagnose a possible
tear in the Schneiderian membrane, which can lead to graft
material or bone spreading into the sinus.

Solutions suggested for such problems directed
researchers towards the use of shorter implants or using
normal length implants with Osteotome-Mediated Sinus
Floor Elevation (OSFE) procedures with or without the use
of bone grafts (7, 8). Special attention to the remaining
bone height (RBH) which should be a minimum of 5 mm
preoperatively in order not to compromise the primary
implant stability was considered (4). Studies conducted in
this field recorded high survival and success rates with
minimal reports of persistent and/or irreversible signs and
symptoms of pain, infection, evidence of peri-implant
radiolucency or progressive crestal bone loss (9).

Scarce studies demonstrated induction of new bone
formation in the maxillary sinus with achievement of
primary stability and high survival rate using OSFE with
simultaneous implant placement without the use of any
graft material. This concept is based on the evidence that
the blood supply to the osteotomy site created using this
technique permits osseointegration of the implants
without the hindrance of a graft material that must first
resorb before new bone can be formed (4, 10).

The present study was conducted using the new
OsteoCare™ Maxi-Z Flat-End dental implants to evaluate
the predictability of the OSFE without the use of a
grafting material through the minimally invasive flapless
procedure followed by simultaneous implant placement.

Material and Methods: (Figures: Cases 1-3)

Patients' Selection
Sixty-four patients (30 males and 34 females) were included
in the study, their ages ranged between 35 and 72 years
(mean age was 48 years). All patients had one or more
missing teeth in the maxillary posterior region. All patients
included in this study were systemically healthy and had no
condition that might alter the treatment outcome. All the
selected subjects had at least 5 mm residual bone height
(RBH) measured from the crest of the alveolar ridge to the
maxillary sinus floor with the recipient site of the implant free
from any pathological conditions. Criteria for exclusion from
the study were: 1) Patients with history of systemic illness,
drug abuse, catabolic drug or psychiatric disorder; 2) Patients
having insufficient bone quantity and also having insufficient
vertical inter-arch space upon centric occlusion; 3) Patients
in the growth stage with partially erupted teeth; 4) Patients
with parafunctional habits such as bruxism or clenching that might
produce overload on the placed implants; 5) Smokers and
alcoholics were also excluded. All patients who participated
in the study were thoroughly informed about the surgical
protocol and all the risks associated with the procedures and
signed an informed consent form.

Implant Selection
One hundred and eight OsteoCare™ Maxi-Z Flat-End dental
implants were used in this study (OsteoCare™ Implant System,
London, United Kingdom). These implants are self-tapping
tapered two-piece implants with high load buttress thread
design and grit-blasted and acid etched surface.
Figure 1a — Schematic drawing of the soft tissue punching procedure.

Figure 1b — Clinical photo showing the rotary soft tissue puncher.

Figure 2a — Schematic drawing of the flapless osteotomy preparation to the level below the floor of the sinus by 1 mm.

Figure 2b — Clinical photo showing the osteotomy preparation using the 4 mm drill.

Figure 3a — Schematic drawing of using the osteotome to infracture the floor of the sinus.

Figure 3b — Clinical photo of the use of the osteotome with the mallet to infracture the floor of the sinus.
Pre-surgery Evaluation
Local visual examination and palpation to examine the entire oral and peri-oral tissues were carried out. The width of the bone at the future implant site was measured using a graduated bone caliper. Maxillary and mandibular impressions were made and poured into stone casts to check the occlusion and direction of forces with respect to future implant site. Pre-surgical radiographic evaluation with periapical and panoramic radiographs (using paralleling technique) in order to measure the residual bone height and to detect presence of any clinically undetectable pathology was performed.

Surgical Protocol
After administration of local anesthesia, a rotary tissue puncher mounted on a low speed handpiece (50 rpm) was used to remove the tissues overlying the crest of the ridge at the drilling site (Figs. 1a and 1b).

All the drills were mounted on a low speed handpiece and drilling was done under copious normal saline cooling irrigation. Sequential drilling started with the 2.2 mm drill, then the 2.75 mm drill when placing a 3.75 mm implant in soft bone; in case of hard bone, the 3.25 mm drill was used. When placing a 4.50 mm implant, the sequential drilling ended with the 3.25 mm drill in soft bone or the 4.00 mm drill in hard bone. Osteotomy preparation was done up to 1mm below the sinus floor (Figs. 2a and 2b). Sinus floor infracture was then accomplished using the direct sinus floor infracture technique. The corresponding osteotome was used to punch-out the cortical plate of the sinus floor with the adherent membrane to the working length (Figs. 3a and 3b). Immediately after infracture, the implant site was tested for perforation of the sinus membrane by observing the appearance of bubbles of blood coming out through the osteotomy when the patient tries to exhale gently through his nose while his nostrils are pinched.

Prosthetic Phase
After a healing period of 6 months (Figs. 5a and 5b), soft tissue punches were used to expose the implants and healing collars were then attached to the implants. The tissues were left to heal for a period of 3-5 days. Impressions were taken using Polyvinylsiloxane material (Cavex, SiliconA, Cavex, Holland) for construction of the final ceramo-metal restorations. The final restorations were checked for shade matching, marginal fitness and occlusion, then permanently cemented using zinc polycarboxylate (Adhesor Carbofine, SpofaDental, Czech Republic).

Postoperative Follow-up and Evaluation
Clinical evaluation:
Each patient was evaluated at 6, 9 and 12 months postoperatively.
Discomfort, pain and tenderness were evaluated according to the signs and symptoms of the patients.

**Evaluation of the condition of the peri-implant tissues:**

- Bleeding on probing was evaluated using papillary bleeding index (PBI) described by Muhlemann 1977 (11) using a periodontal probe.
- Infection, swelling and gingival inflammation were assessed using the gingival index (GI) according to Loe and Silness 1963 (12).
- Probing Depth (PD) was measured according to the standard procedure described by Glavind and Loe 1967 (13) using a periodontal probe with Williams’ calibrations.

Mobility was tested using the Periotest M (Medizintechnik Gulden, Bensheim, Germany) to evaluate the clinical stability. Periotest M values (PTMV) of (-8 to 0) were considered the ideal values that denote successful osseointegration.

**Radiographic evaluation:**

Periapical x-ray films were taken immediately after implant insertion, at 6 and 12 months postoperatively to detect amount of sinus floor elevation, marginal bone level and change in bone density around the implants in the area created by sinus floor elevation calculated as the difference between the residual bone height and the inserted implant length, using the linear measurement system of Digora software (Orion Corporation, Sordex, Finland).

**Statistical Analysis**

Data were presented as mean and standard deviation (SD) values.

The t-test was used to study the changes in Probing depth (PD), Papillary Bleeding Index (PBI), Gingival index (GI) and marginal bone loss. The percentage of change was also calculated. The amount of sinus floor elevation, changes in bone density and changes occurred by time were calculated using the Mann-Whitney U test. Wilcoxon signed-rank test was used to study the changes by time. The significance level was set at \( P \leq 0.05 \). Statistical analysis was performed with SPSS 16.0® (Statistical Package for Scientific Studies) for Windows.

**Results**

Sixty-four patients were included in the study. Forty-four patients had two missing teeth and twenty patients had one missed tooth in the maxillary posterior region, with their sites indicated for implant placement with internal sinus floor elevation. A total of one hundred and eight implants were placed without bone augmentation. The lengths of the implants were 8, 10 and 12 mm. Eighty-seven implants were 4.5 mm in diameter and twenty-one implants were of 3.75 mm in diameter (Table 1). All patients were followed up for 12 months. All implants showed initial stability exceeding 30 N/cm except for 12 implants. Only three implants failed to osseointegrate, which had a diameter of 3.75 mm, lacked the initial stability and were inserted in type D4 bone. These implants were excluded from the study, and the remaining 105 implants were successfully osseointegrated showing a success rate of 97.22%. Complete soft tissue healing was
Case 1

Figure 6a — A panoramic radiograph of a 56 year-old female patient, showing an approximately 6 mm bone height existing below the floor of the maxillary sinus at the area of missing UL6.

Figure 6b — A preoperative clinical photograph showing enough ridge width at the area of UL6.

Figure 6c — Clinical photo showing the use of the osteotome with the mallet to infracture the floor of the sinus.

Figure 6d — Checking of the integrity of the Schneiderian membrane using a blunt osteotomy probe.

Figure 6e — Placement of the OsteoCare™ Maxi-Z Flat-End implant (4.5x10 mm).

Figure 6f — Seating of the implant by using the 2.2 hexdriver and a ratchet wrench.

Figure 6g — Checking the initial stability with the 30N/cm torque wrench.

Figure 6h — Immediate postoperative photo after fixation of the cover screw.
generally uneventful in all patients after implants placement. The patients reported minimal postoperative swelling and pain experiences with no occurrence of hematoma and minimal need for analgesics. These results were revealed by clinical and radiographic evaluation. (Figures: Cases 1-4)

Clinical evaluation:

1) Discomfort, Pain and Tenderness:

All patients suffered from very mild discomfort during the first postoperative week but from that time on, no other complaints/symptoms were reported.

<table>
<thead>
<tr>
<th>Implant Diameter</th>
<th>Implants’ Length</th>
<th>Number of Implants Used</th>
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</thead>
<tbody>
<tr>
<td>3.75 mm</td>
<td>10 mm</td>
<td>10</td>
</tr>
<tr>
<td>3.75 mm</td>
<td>12 mm</td>
<td>11</td>
</tr>
<tr>
<td>4.5 mm</td>
<td>8 mm</td>
<td>27</td>
</tr>
<tr>
<td>4.5 mm</td>
<td>10 mm</td>
<td>29</td>
</tr>
<tr>
<td>4.5 mm</td>
<td>12 mm</td>
<td>31</td>
</tr>
</tbody>
</table>

Table 1: The number of implants used with their diameters and lengths

2) Condition of the peri-implant tissues:

I. Papillary Bleeding Index (PBI)
Statistical analysis of PBI scores was done for all patients and the results revealed a mean and standard deviation values of $0.83 \pm 0.45$ after 9 months and $0.81 \pm 0.43$ after 12 months as shown in Table (2). Change by time showed a statistically significant decrease after 12 months with recorded P-value of 1.000. Comparison between percentages of changes in PBI showed no statistically significant difference between 9 months and 12 months with P-value of 0.769.

II. Probing depth (PD)
Statistical analysis of probing depth scores was done for all patients showing a mean and standard deviation values of $2.17 \pm 0.26$ mm after 9 months and $1.96 \pm 0.27$ mm after 12 months as presented in Table (2). Change by time reported a statistically significant decrease in mean PD after 12 months with a mean difference of $-0.19$ and SD of 0.11 showing a P-value of 0.001. There was no statistically significant difference in % of change in PD from 9 to 12 months.
III. Infection, Swelling and Gingival Inflammation

These were assessed using the Gingival Index (GI). Statistical analysis of GI scores was done for all patients showing a mean and standard deviation values of 0.93 ± 0.27 after 9 months and 0.52 ± 0.12 after 12 months. There was no statistically significant difference through the periods of the study. The results of GI scores are shown in Table (2). Change by time reported a statistically significant decrease in mean GI after 12 months with a mean difference of -0.38, SD of 0.24 and a recorded P-value of 0.011. There was no statistically significant difference between percentages of changes in GI along the different time periods.

IV. Mobility

Statistical analysis of Periotest M values revealed that the mean and standard deviation records were -2.66 ± 2.07 after 6 months and -2.82 ± 2.12 after 12 months. There was no statistically significant difference from 6 to 12 months as shown in Table (3). Change by time reported a statistically significant decrease in mean Periotest M values after 12 months with a mean difference of -0.11 and SD of 0.09 resulting in a P-value of 0.017. There was no statistically significant difference between % of change in Periotest M values between 6 and 12 months.
Figure 7a — A panoramic radiograph of a 52 year-old female patient, showing an approximately 6 mm bone height existing below the floor of the maxillary sinus at the area of missing UR6.

Figure 7b — A preoperative clinical photograph showing enough ridge width at the area of UR6.

Figure 7c — Clinical photo showing the use of the osteotome to infracture the floor of the sinus.

Figure 7d — Immediate postoperative photo after implant placement.

Figure 7e — Immediate postoperative periapical radiograph showing the implant with the fractured bone around its apex.

Figure 7f — A 6-months postoperative clinical photograph.

Table 3:
The mean and standard deviation (SD) values of Periotest M at 6 and 12 months periods of the study

<table>
<thead>
<tr>
<th>Standard Deviation (SD)</th>
<th>Mean</th>
<th>Period</th>
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<tbody>
<tr>
<td>2.07</td>
<td>-2.66</td>
<td>6 months</td>
</tr>
<tr>
<td>2.12</td>
<td>-2.82</td>
<td>12 months</td>
</tr>
</tbody>
</table>

3) Radiographic Evaluation:

I. Marginal bone loss
The data collected from the measurements of the marginal bone loss at the mesial and distal aspects of all implants was taken immediately after implant insertion at six months and at twelve months postoperatively. The first crestal thread was the reference for readings. The mean and standard deviation values of marginal bone loss were
0.34 ± 0.17 mm after 6 months and 1.02 ± 0.11 mm after 12 months as presented in Table (4).

There was a statistically significant increase in mean marginal bone loss after 12 months with a mean difference of 0.66 and SD of 0.15 with a recorded P-value of 0.005.

II. Amount of sinus floor elevation

Amount of sinus floor elevation was calculated as the difference between the residual bone height and the inserted implant length. The mean and standard deviation values of the amount of sinus floor elevation were 3.65 ± 0.84 mm.

III. Change in bone density

The data collected from the measurements of the change in bone density around all implants in the area created by sinus floor elevation was taken immediately after implant insertion (baseline readings) at six and twelve months postoperatively.

Statistical analysis revealed the mean and standard deviation values of change in bone density to be 32.4 ± 5.5 immediately postoperative, 75.6 ± 1.4 after 6 months and 76.7 ± 1.6 after 12 months. The data of the change of bone densities are shown in Table (5).

<table>
<thead>
<tr>
<th>Period</th>
<th>Mean</th>
<th>Standard Deviation (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediately postoperative</td>
<td>32.4</td>
<td>5.5</td>
</tr>
<tr>
<td>6 months</td>
<td>75.6</td>
<td>1.4</td>
</tr>
<tr>
<td>12 months</td>
<td>76.7</td>
<td>1.6</td>
</tr>
</tbody>
</table>
Discussion

Sinus floor augmentation techniques have expanded the indications of dental implant treatment, allowing the placement of dental implants in the posterior maxilla where, often, an inadequate bone height of residual ridge exists because of alveolar bone resorption and maxillary sinus pneumatization following tooth extraction (14). In Tatum’s initial technique which was utilized for sinus augmentation, access to the sinus floor was through the ridge crest. This approach was gradually abandoned in favor of a window through the lateral wall of the alveolus (Caldwell-Luc operation), which seemed more versatile and practical. With the introduction of the osteotome sinus floor elevation technique by Summers in 1994(5), extensive changes in antral morphology and function have

Case 3

Figure 7k — 6-months postoperative periapical radiograph after cementation of the crown.

Figure 8a — A panoramic radiograph of a 53 year-old male patient, showing an approximately 6 to 8 mm bone height existing below the floor of the maxillary sinus at the area of missing UR5 and UR6.

Figure 8b — Immediate postoperative periapical radiograph after the osteotome-mediated sinus floor elevation and placement of 2 OsteoCare™ Maxi Z Flat-End implants.

Figure 8c — 6-months postoperative periapical radiograph of the successfully osseointegrated implants, showing the endo-sinus bone gain and bone trabeculations around the apical part of the implants.

Figure 8d — 12-months postoperative periapical radiograph showing stability of the new bone formation around the 2 dental implants.
not been anticipated (15). Few studies and case reports performing the OSFE technique without using a grafting material followed by simultaneous implant placement reported high success and survival rates in respect to the remaining bone height (4, 10).

Patients included in this study were selected having at least 5 mm residual bone height measured from the crest of the ridge up to the maxillary sinus floor. It was documented that initial fixation of the implant is derived from the residual alveolar ridge; therefore, a minimum of 5 mm of preoperative bone height has been suggested (5). A residual bone height (RBH) of less than 5 mm can be associated with reduced primary implant stability (6). Primary stability of the implants in this study was achieved after complete seating of the implants into place except for 12 implants. The achievement of the primary stability is because the maxillary cortical and cancellous bone covered by the preserved periosseous connective tissues, is elastic and closes back on the implants to become tightly adapted to their surfaces as previously explained by Jung et al 2010 (10). As the crestal osteotome approach involves a blind elevation of the sinus floor, the incidence of membrane perforation, detectable or undetectable, is a concern. However, in the present study, membrane integrity was tested by the Valsalva maneuver (6) as well as with a blunt osteotomy probe and no incidence of perforation was reported.

A high success rate of 97.22% was reported in this study. This success rate was comparable to that obtained after conventional implant placement in non-sinus augmented sites (3). Only 3 implants failed to osseointegrate, which were due to the lack of initial stability, small sized implant diameter (3.75mm) or the type D4 bone in which the implants were inserted. The new bone formation around the apical part of the implants comes from the bony walls of the sinus, similar to an extraction socket. Bone formation requires the recruitment, migration, and differentiation of osteogenic cells into osteoblasts. It is likely that mesenchymal stem cells migrated from the bone marrow in the underlying alveolar bone and possibly, from tissue fragments displaced during the surgery into the blood filled sinus were the source of new bone formation as explained by Dong-Seok et al 2008 (2). This means that elevation and tenting of the sinus membrane alone was sufficient to induce formation of bone beyond the original skeletal contour of the sinus (4).

Soft tissue healing was generally uncomplicated in all patients included in this study. All patients experienced only mild discomfort during the first week, which was attributed to the pressure resulting from bone expansion. As previously mentioned, patients reported minimal postoperative swelling and pain experiences with very little need for medications and analgesics. This aligns with previous results by Azfar et al., 2006 and Zahran et al., 2010 who concluded that the use of the flapless approach for implant placement minimizes the postoperative pain and complications (16, 17).

Figure 9a — 12-months postoperative periapical radiograph showing stability of the new bone formation around an OsteoCare™ Maxi-Z Flat-End implant placed by the OSFE procedure in 72 year-old male patient.

Figure 9b — 12-months postoperative clinical photo of the cemented final ceramo-metal crown showing the healthy peri-implant soft tissue condition.
One of the most valuable techniques employed to study the biological aspect of prosthesis is the estimation of the peri-implant parameters. One can consider the mucosal response to be correlated to marginal bone loss and loss of osseointegration. In the present study, the papillary bleeding and the gingival index scores were recorded at nine and twelve months respectively indicating absence of inflammation throughout the evaluation period.

Mobility indicates absence of complete osseointegration. In this study, there was absence of mobility throughout the evaluation period, which was confirmed by the obtained Periotest M values.

The amount of sinus floor elevation in the present study was calculated as the difference between the residual bone height and the inserted implant length. The mean amount of sinus floor elevation was 3.65 ± 0.84mm. Radiographic analysis of the successful implants showed that an increase of 4 mm of available bone is possible with this procedure. Although the osteotome technique enables the surgeon to raise the sinus membrane internally through an implant osteotomy site, the quantity and predictability of more than 4 mm of bone augmentation could be limited due to the elasticity of the Schneiderian sinus membrane.

Conclusion

Within the context of this study, it can be concluded that the flapless osteotome-mediated internal sinus floor elevation without using a bone augmentation material in conjunction with simultaneous implant placement is a safe and reliable technique which could be used as an alternative treatment modality for the external lateral window sinus elevation technique if the residual bone height under the sinus is of a minimum of 5-6 mm and the needed amount of sinus elevation is up to 4 mm.

The new OsteoCare™ Maxi-Z Flat-End implants with their osteotome counterparts can be successfully used for the internal maxillary sinus floor elevation procedure with simultaneous implant placement.

Disclosure:

Prof. Amr Zahran is the scientific consultant for OsteoCare™ Implant System (UK) and is involved in the designing of the whole range of the Maxi Z dental implants. All other authors claim to have no financial interest in this product.

References:


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