Two-Year Follow-up Comparison of Three Surgical Techniques for Implant Placement in Posterior Maxilla with Limited Alveolar Bone Height

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Purpose: The aim of this pilot study was to compare three surgical techniques (bicortical fixation, unicortical fixation, and indirect sinus elevation) for implant placement in the posterior maxilla with limited alveolar bone height. This 2-year follow-up assessment on the implants of a previously published prospective clinical trial compared (1) restoration/implant stability among the three surgical groups, (2) intrasinus bone formation between the bicortical fixation and indirect sinus elevation groups, and (3) implant and prosthetic complications reported among the three groups.

Materials and Methods: For the original prospective study, 38 patients were recruited, exhibiting 7 to 11 mm of alveolar bone coronal to the sinus floor as confirmed by preoperative CBCT; and 45 implants were placed using three randomly assigned surgical techniques. No patient received more than two implants, which were placed in opposite sides of the maxilla and using different surgical techniques. At the 2-year follow-up assessment, 32 patients with 37 implants were evaluated. The 2-year follow-up restoration/implant stability was measured with the Periotest stability measuring device. Intrasinus bone formation was measured from the 2-year follow-up CBCT in comparison to the preoperative CBCT. Clinical examination was also performed to identify loose implants and/or implant crowns and signs of peri-implantitis. Patients were interviewed regarding complications experienced with the study implants/restorations, and electronic charts were thoroughly reviewed to identify records of complications.

Results: No significant difference in restoration/implant stability (Periotest value [PTV]) was seen between the bicortical fixation, unicortical fixation, and indirect sinus elevation groups (–1.69 [0.80], –1.76 [0.80], –2.22 [0.60], respectively, P = .76) at the 2-year follow-up. The indirect sinus elevation group showed more intrasinus horizontal (1.99 [0.17] vs 1.47 [0.16] mm, P = .03) and vertical (3.15 [0.43] vs 2.35 [0.38] mm, P = .13) bone gain compared with the bicortical fixation group. Conclusion: Within the limitations of this study, placing implants using a bicortical fixation surgical technique in moderately limited alveolar bone height (7 to 11 mm) was not significantly different from the other two techniques and may be a feasible option with limited risks while allowing longer implant placement and negating the need for indirect sinus augmentation, which is accompanied by additional expense and surgical morbidity to the patient. Int J Oral Maxillofac Implants 2022;37:171–180. doi: 10.11607/jomi.8302

Keywords: bicortical fixation, intrasinus bone formation, sinus elevation

Improvements in dental implants have made the aesthetic and functional replacement of natural teeth possible. Despite these advancements, the loss of teeth in the posterior maxilla results in the continual resorption of the maxillary alveolar ridge and the pneumatization of the maxillary sinus, diminishing the available bone height for implant placement.1 In addition, bone quality in the posterior maxilla lacks strength because of its low-density medullary characteristics.2 These physical properties of the posterior maxilla provide unique challenges to the surgeon placing implants.

To compensate for this lack of bone quality and quantity in the posterior maxilla, sinus augmentation techniques are often used to create additional bone.3 Among the many factors that affect the ability to achieve initial implant stability, residual ridge height in this region will determine whether a direct or indirect sinus elevation procedure is indicated.1,4 Comlications to the sinus elevation bone graft technique with implant placement include acute sinusitis,3 facial

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congestion, nasal obstruction or discharge, bone loss around the implant, and sinus graft failure.\textsuperscript{5} While sinus augmentation techniques have well-established guidelines, they vary in complexity, invasiveness, extent of intraoperative and postoperative complications, and cost of additional nonautogenous grafting materials.

More recently, shorter implants have been developed, decreasing the need for bone-grafting procedures like sinus augmentation. These procedures provide faster and less-expensive treatment options while reducing patient morbidity. However, debate still exists in the literature as to how the success rates and complications from mechanical stress and peri-implantitis-induced bone loss of these shorter implants compare with implants of greater length.\textsuperscript{7,8}

Bone in the posterior maxilla consists of a cortical plate associated with the alveolar ridge and a second cortical plate associated with the maxillary sinus floor. It is widely thought that implants in the posterior maxilla are more stable when both cortical plates are engaged.\textsuperscript{9} In vitro and animal studies have reported favorable results for bicortical fixation over unicortical fixation.\textsuperscript{10,11} Bicortical fixation has been shown to have greater implant stability, 20\% to 50\% greater stress reduction under various loading conditions,\textsuperscript{9,11,12} and no difference in marginal bone loss compared with unicortical implant anchorage.\textsuperscript{9} Preliminary clinical research for bicortically placed implants has demonstrated promising results.\textsuperscript{13}

To better plan and assess implant success, several technologies are available to measure bone density and implant stability. CBCT has been available since the mid-1950s, and its application in dentistry has expanded significantly with the advent of implant dentistry.\textsuperscript{14} CBCT radiography has the ability to assess cross-sectional bone morphology and bone density more accurately than panoramic or periapical radiographs.\textsuperscript{14} A pilot study found significant relationships among CBCT-based bone density, maximum insertion torque, and primary implant stability measured by resonance frequency analysis and suggested that preoperative CBCT bone density might serve as an objective diagnostic tool.\textsuperscript{15} The noncontact Osstell device (Integration Diagnostics) produces an implant stability quotient (ISQ) value ranging from 1 to 100, which is mathematically converted from the resonance frequency analysis against a SmartPeg, which is adapted to the internal interface of the implant.\textsuperscript{16} Another tool to measure osseointegration of dental implants is the Periotest (Medizintechnik Gulden), a tapping instrument, which has shown improved results over radiographs in predicting implant success.\textsuperscript{17} The Periotest has a value (PTV) between –8 and +50; values greater than 10 indicate implant failure.\textsuperscript{18} Because implant-supported crowns were mainly cement-retained in this clinical study, the Periotest provides an advantage over the Osstell device in its ability to measure 2-year follow-up implant stability without removing these cement-retained restorations.

To achieve bicortical stabilization in limited posterior maxillary ridge height, surgical drills with vertical stoppers can be used to control the amount of implant apex protrusion into the sinus. Self-threading implants are then inserted by maintaining intimate contact between implant threads and the dense sinus floor without additional bone graft materials. To the authors’ knowledge, this technique has not been tested for its safety and efficacy compared with other conventional sinus elevation techniques. The aim of the original pilot prospective study was to compare the primary and secondary implant stability (measured by Osstell) of 45 implants from 38 patients, which were placed using three different surgical techniques (bicortical fixation, unicortical fixation, and indirect sinus elevation) in the posterior maxilla with limited alveolar bone height, and its results have been previously published.\textsuperscript{19} The aim of the present 2-year follow-up assessment study on the implants previously placed during the prospective clinical study was to compare (1) restoration/implant stability (measured by Periotest) among the three surgical groups, (2) intrasinus bone formation between the bicortical fixation and indirect sinus elevation groups, and (3) implant and prosthetic complications reported among the three groups.

MATERIALS AND METHODS

The study protocol was approved by the Institutional Review Board at the University of Minnesota. This 2-year follow-up assessment study presents the findings of a prospective single-center clinical trial.

Patients

Patients were recruited from the Graduate Periodontology program, Graduate Prosthodontics program, and Faculty Dental Practice clinic at the University of Minnesota and treated between March 2010 and July 2013. Two-year follow-up CBCTs were taken between April 2013 and September 2016.

Eligible volunteers were partially edentulous in the maxillary posterior region, met the standard criteria for implant placement, and had a residual 7 to 11 mm of bone height coronal to the sinus floor as confirmed by preoperative CBCT scan for diagnosis and treatment planning. Exclusion criteria consisted of smoking, overall health contraindication to implant surgery, sinus augmentation procedures, and implants with bone dehiscence and/or fenestration at the time of placement.
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Phase 1 Protocol
A periapical radiograph was used to perform an initial screening assessment of ridge height. Once a patient met the inclusion criteria and agreed to participate in the study, a preoperative CBCT scan of the maxilla was taken prior to surgical placement of the implant. Patients were then randomly assigned into one of three surgical implant placement protocols: group 1—bicortical fixation (self-threading implants intentionally engaging the sinus floor up to 2 mm into the sinus without graft; drill stoppers were utilized during osteotomy preparation); group 2—unicortical fixation (short implants placed in proximity to the sinus without sinus floor involvement); and group 3—indirect sinus elevation technique using osteotome with bone graft (Fig 1).

Each self-threading implant (Astra Tech OsseoSpeed TX, Dentsply Sirona Implants) was randomly assigned to one of the three surgical techniques, with a maximum of two implants per patient. If a patient had two implants, they were placed using different randomly assigned surgical techniques and in different quadrants. In the event that a patient was randomized to receive a unicortical fixation technique, yet the ridge height and width required an implant size that was unavailable in the manufacturer’s repertoire, the patient was placed in the next randomization group. The subsequent subject enrolled was then assigned to the group that was previously skipped due to limitations of existing implant sizes. The recruiting investigator (A.H.) was strictly blinded to the allocation of the surgical techniques until the CBCT was reviewed and the patient’s enrollment in the study was completed. Figure 2 is a schematic of the study design. Refer to Hsu et al19 for the clinical procedure, preoperative and postoperative instructions, and stage-two surgery (implant exposure surgery). Vertical stoppers and clinical application of the bicortical fixation surgical technique are presented in Fig 3.
Patients were recalled after approximately 2.5 years from the implant placement date for assessment of the dental implants. At this appointment, a 2-year follow-up CBCT was taken using $0.2 \times 0.2 \times 0.2$-mm voxel size on an i-CAT CBCT unit (i-CAT). All CBCT assessments were made on the i-CAT viewing software. From this CBCT, ridge height, intrasinus implant protrusion, crestal bone loss, and vertical and horizontal intrasinus bone gain were measured. Alveolar ridge height and intrasinus implant protrusion were measured once each on panoramic (mesiodistal) view and cross-sectional (buccopalatal) view of the CBCT. Crestal bone loss and vertical and horizontal intrasinus bone gain measurements were taken on the mesial and distal (from the panoramic view) and buccal and palatal (from the cross-sectional view) aspects of the implants. To locate the limits of vertical and horizontal bone gain, a $0.4 \times 0.4$-mm measurement tool to assess Hounsfield Unit (HU) was moved across from the implant, alveolar bone, sinus floor, and new bone growth areas to the sinus membrane and empty sinus cavity. The HU typically changed from 2,500 (implant), 900, 500, 300, 100, and 0 (water) to –150 or lower (fat/air). An HU value of
100 was used as a threshold of gained bone. From the magnified, saved panoramic and cross-sectional view images with four HU 0.4 × 0.4-mm markers, the vertical bone gain was measured from the preoperative original sinus floor to the vertical bone gain HU markers using specialized software (ImageJ). With this technique, the horizontal bone gain was also measured from the implant surface to the horizontal bone gain HU markers (Fig 4). Eight total measurements (four aspects [buccal and palatal, mesial and distal] of implants × vertical and horizontal bone gains) were made from panoramic (mesiodistal) and cross-sectional (buccopalatal) views per implant. Because some of the bicortical fixation and indirect sinus elevation group implants showed that the original sinus floor had moved superiorly in the 2-year follow-up CBCT, the preoperative CBCT image was overlapped onto the 2-year CBCT image, and the original sinus floor was traced on the 2-year CBCT images using the “layer opacity” function tool of Photoshop Element 11 (Adobe). Intrasinus implant protrusion and vertical and horizontal bone gain were measured from the original sinus floor, not from the changed sinus floor of the 2-year follow-up CBCT images.

In addition, at the 2-year assessment appointment, three repeated Periotest measurements were taken on the buccal and palatal aspects of the implant crown, totaling six PTV measurements per implant. All Periotest measurements were taken at the mid-crown level as perpendicular as possible to the implant crown. Clinical examination was also performed to identify loose implants and/or implant crowns and signs of peri-implantitis. Patients were asked for any complications experienced with the study implants, and electronic charts were thoroughly reviewed to find the complication records. Two researchers collected all 2-year follow-up data (R.W., W.S.), and two researchers (Y.H., W.S.) did all CBCT measurements together.

Statistical Analyses

Descriptive statistics were expressed as frequencies, percentages, or mean and standard error (SE), as appropriate by surgical techniques. The P value for comparing three surgical techniques was calculated using a generalized linear mixed model to account for within-subject correlation. The correlation between follow-up measures and baseline characteristics was assessed by the Pearson correlation coefficient or Spearman correlation coefficient (r) using the bootstrap method to account for within-subject correlation. The bootstrap median and a confidence interval computed from the 2.5th and 97.5th percentiles were presented. Adjusted analysis was done using a generalized linear mixed model to compare follow-up measures among surgical techniques controlling for the variables, which were statistically significantly associated with outcome measures. Both intent-to-treat and per-protocol (as-treated) analyses were performed, and the results did not differ substantively. Per-protocol analyses have been reported to reduce confusion. All analyses were carried out using the SAS system (v. 9.4; SAS Institute) and R (v. 3.5.2; R Foundation for Statistical Computing). All P values were two-sided, and .05 was considered statistically significant.

RESULTS

Thirty-eight patients and 45 implants were initially recruited for the original prospective clinical study. At the 2-year follow-up evaluation, a total of 32 patients with 37 implants were enrolled. The research subject/implant enrollment and follow-up summary is presented in Table 1. Six patients resulting in eight implants were dropped from the study between the stage-two surgery and the 2-year follow-up assessment. Minor implant and prosthetic complications were reported and are summarized in Table 1.

Table 2 compares patient and implant data among three groups measured both at the preoperative and 2-year follow-up (average of 911 days from stage-one surgery) points. Baseline data showed that the HU of preoperative CBCT bone density was lowest in the bicortical group (P = .02), which may be related to the finding that bicortical fixation implants were placed primarily in first and second molar sites. All groups showed comparable crestal bone loss (0.28 to 0.33 mm, P = .62) at the 2-year follow-up.

Two-year follow-up restoration/implant stability measured with Periotest showed no significant differences (P = .76) between three groups, even though the trend repeated that the indirect sinus elevation group had the highest primary stability measurement during the implant placement surgery (Table 3). The indirect sinus elevation group had significantly more horizontal bone gain (1.99 vs 1.47 mm, P = .03) but not so significant vertical bone gain (3.15 vs 2.35 mm, P = .13) compared with the bicortical fixation group (Table 3).

Table 4 shows that the preoperative ridge height measured from the periapical radiograph had a significant positive correlation with 2-year follow-up restoration/implant stability Periotest measurement (stability increases as the PTV value approaches −8). In addition, intrasinus implant protrusion showed a significant positive correlation with vertical intrasinus bone gain. However, there was no significant correlation between primary and secondary implant stability measured with Osstell and 2-year follow-up restoration/implant stability measured by Periotest.

Table 5 illustrates that the indirect sinus elevation group showed clinically detectable sinus floor location and shape changes in 63.6% of cases, while only 28.6%
### Table 1 Research Subject/Implant Enrollment and Follow-up Summary

<table>
<thead>
<tr>
<th>Time points</th>
<th>Bicortical fixation implants</th>
<th>Unicortical fixation implants</th>
<th>Indirect sinus elevation implants</th>
<th>Research subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage-one surgery</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>38</td>
</tr>
<tr>
<td>Stage-two surgery</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>38</td>
</tr>
<tr>
<td>Crown delivery</td>
<td>14</td>
<td></td>
<td>14</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>1 patient went outside for a crown.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 implant developed buccal bone loss and extracted (failure) in endometrial cancer patient.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 patient went outside for a crown.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-year follow-up</td>
<td>14</td>
<td></td>
<td>12</td>
<td>32</td>
</tr>
<tr>
<td>Dropped implants/subjects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failures</td>
<td>0</td>
<td>1 extracted due to severe buccal bone loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complications</td>
<td>1 crown dislodgment 1 sinus floor thickening</td>
<td>1 screw loosening</td>
<td>1 vertigo symptom at Stage-one surgery.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 implant was in a terminally ill patient, and his daughter decided to withdraw.</td>
<td></td>
<td>1 implant was opposite side of the terminally ill patient who withdrew.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 patient had no transportation and decided to withdraw.</td>
<td></td>
<td>1 patient was opposite side of the terminally ill patient who withdrew.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 implant was opposite side of endometrial cancer patient who withdrew.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 implant was opposite side of the terminally ill patient who withdrew.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 patient was relocated, could not be reached</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 2 Preoperative and 2-Year Follow-up Patient and Implant Baseline Information and Outcome Measures of Three Implant Surgical Technique Groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Bicortical fixation (n = 14)</th>
<th>Unicortical fixation (n = 12)</th>
<th>Indirect sinus elevation (n = 11)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operation (Pre-Op) age (y)**</td>
<td>59.86 (3.23)</td>
<td>59.75 (3.49)</td>
<td>52.91 (3.64)</td>
<td>.30</td>
</tr>
<tr>
<td>Sex (n (%))**†</td>
<td>8 (57.14)</td>
<td>5 (41.67)</td>
<td>4 (36.36)</td>
<td>.66</td>
</tr>
<tr>
<td>Pre-Op PA ridge height (mm)</td>
<td>8.61 (0.43)</td>
<td>9.57 (0.44)</td>
<td>9.17 (0.52)</td>
<td>.32</td>
</tr>
<tr>
<td>Pre-Op PA bone density (Al eRD; mm)</td>
<td>6.73 (0.42)</td>
<td>7.02 (0.47)</td>
<td>7.55 (0.44)</td>
<td>.27</td>
</tr>
<tr>
<td>Pre-Op CBCT ridge height (mm)</td>
<td>8.85 (0.35)</td>
<td>10.06 (0.37)</td>
<td>9.18 (0.39)</td>
<td>.08</td>
</tr>
<tr>
<td>Pre-Op CBCT bone density (HU)</td>
<td>310.55 (39.23)</td>
<td>513.34 (45.28)</td>
<td>418.89 (40.17)</td>
<td>.02*</td>
</tr>
<tr>
<td>Implant location (n (%))†</td>
<td></td>
<td></td>
<td></td>
<td>&lt; .01*</td>
</tr>
<tr>
<td>First premolar: #5,12</td>
<td>0</td>
<td>4 (33.33)</td>
<td>1 (9.09)</td>
<td></td>
</tr>
<tr>
<td>Second premolar: #4,13</td>
<td>3 (21.43)</td>
<td>7 (58.33)</td>
<td>2 (18.18)</td>
<td></td>
</tr>
<tr>
<td>First molar: #3,14</td>
<td>8 (57.14)</td>
<td>1 (8.33)</td>
<td>8 (72.73)</td>
<td></td>
</tr>
<tr>
<td>Second molar: #2,15</td>
<td>3 (21.43)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Implant diameter (mm)</td>
<td>4.65 (0.14)</td>
<td>4.19 (0.15)</td>
<td>4.72 (0.16)</td>
<td>.04*</td>
</tr>
<tr>
<td>Implant diameter (n (%))‡§</td>
<td></td>
<td></td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>3 (23.08)</td>
<td>8 (80.00)</td>
<td>3 (27.27)</td>
<td></td>
</tr>
<tr>
<td>5.0 mm</td>
<td>10 (76.92)</td>
<td>2 (20.00)</td>
<td>8 (72.73)</td>
<td></td>
</tr>
<tr>
<td>Implant length (mm)</td>
<td>11.50 (0.38)</td>
<td>8.22 (0.40)</td>
<td>11.67 (0.45)</td>
<td>&lt; .01*</td>
</tr>
<tr>
<td>Post-Op PA intrasinus implant protrusion (mm)</td>
<td>3.53 (0.29)</td>
<td>–1.62 (0.33)</td>
<td>3.69 (0.32)</td>
<td>&lt; .01*</td>
</tr>
<tr>
<td>Follow-up interval (d): stage-one surgery to follow-up CBCT</td>
<td>915.36 (51.99)</td>
<td>894.81 (59.86)</td>
<td>924.25 (50.29)</td>
<td>.82</td>
</tr>
<tr>
<td>Follow-up CBCT intrasinus implant protrusion (mm)</td>
<td>3.04 (0.33)</td>
<td>2.92 (0.38)</td>
<td>.78</td>
<td></td>
</tr>
<tr>
<td>Follow-up CBCT crestal bone loss (mm)</td>
<td>0.29 (0.09)</td>
<td>0.28 (0.11)</td>
<td>0.33 (0.09)</td>
<td>.62</td>
</tr>
</tbody>
</table>

*Indicates statistically significant differences.

**The table presents person-level characteristics; because 5 patients had 2 implants and different surgical techniques were used for each implant, these patients are counted twice, once for each pertinent technique.

†Since variables are categorical, n (%) was presented instead of average (SE).

§3.5 and 4.5 mm are omitted due to small sample size.

Pre-Op = pre-operation; Post-Op = post-operation; Al eRD = aluminum equivalent radiodensity; HU = Hounsfield Unit; PA = periapical radiograph; CBCT = cone beam computed tomography.

Average and standard error are presented; except as indicated.
of bicortical fixation cases showed a detectable change. The amount of changes of the two groups were similar (1.9 vs 2.0 mm, respectively). In all cases, the sinus floor was shown to move apically.

Additional comparisons were made between male and female subjects and between implant locations assessing vertical and horizontal intrasinus bone gain and implant stability. No significant differences were seen among the sexes and comparing first premolar, second premolar, first molar, and second premolar sites with these variables (data not shown).

**DISCUSSION**

Preoperative and 2-year follow-up baseline patient variables were quite similar, but implant variables were not similar among the three groups. Even though
randomization charts were used to allocate one of the three surgical techniques to the enrolled patients/implants, due to the limited repertoire of implant size, the majority of the unicortical fixation group implants were placed in premolar sites, while more bicortical fixation and indirect sinus elevation group implants were in molar sites. This may be the reason for significant differences of preoperative CBCT bone density (HU, \( P = .02 \)) and implant diameters (mm, \( P = .04 \)) among the three groups, showing the lowest HU in the bicortical fixation group (310.55) and the highest HU in the unicortical fixation group (513.34), and the smallest diameter in the unicortical fixation group (4.19 mm) and the largest diameter in the indirect sinus elevation group (4.72 mm; Table 2).

Restoration/implant stability by PTV at the 2-year follow-up was not expected to be significantly different among the bicortical fixation, unicortical fixation, and indirect sinus elevation groups because both primary stability (71.4, 69.6, and 75.9, respectively) and secondary stability (79.9, 80.0, and 80.0, respectively) by ISQ were comparable.\(^\text{19}\) Current 2-year follow-up data confirmed the present authors’ expectations (Table 3). The bicortical fixation implant placement surgical technique was able to achieve comparable implant stability through the 2-year follow-up point, even though bicortical fixation implants were mainly placed in lower CBCT HU density bone, such as first and second molar sites (Table 2).

Greater intrasinus bone formation was expected in the indirect sinus elevation group compared with the bicortical fixation group, as the former surgical technique included added bone graft material and the latter bicortical fixation did not. The results showed that the expectation was mostly correct (Table 3). Even though the average intrasinus bone gain differences were not large in the horizontal (0.5 mm) and vertical (0.8 mm) dimension, the difference was quite consistent between the two groups. Whether these statistically significant differences of <1 mm in bone gain translate into clinically significant differences will require long-term assessment.

An average vertical bone gain of 2.35 mm in the bicortical fixation group (with no bone graft) is in agreement with other studies showing a minimum of 2 mm intrasinus radiographic bone gain using the osteotome technique in this study. In a 2-year follow-up using osteotome sinus elevation without grafting material, the mean implant protrusion of 3.8 mm resulted in 2.5 mm (SD: 1.5 mm) intrasinus bone gain at the 6-month CBCT postoperative evaluation.\(^\text{22}\) While this reported gain by He et al\(^\text{22}\) is similar to the present nongrafted bicortical fixation group, these data are based on mesial and distal averages, while the present study included all four aspects (buccal, palatal, mesial, and distal) of measurements. Other osteotome indirect sinus elevation studies have reported significantly higher intrasinus vertical bone gain: 3.17 mm in grafted and 3.07 mm in nongrafted sites at the 36-month follow-up.\(^\text{23}\) 4.8 mm in grafted and 3.8 mm in nongrafted sites at the 5-year follow-up,\(^\text{24}\) and as much as 6 mm vertical bone gain in the grafted site.\(^\text{25}\)

Few studies reported intrasinus horizontal bone gain. In the present study, horizontal bone gain (indirect sinus elevation with graft group of 1.99 mm [0.17] vs bicortical group of 1.47 mm [0.16], \( P = .03 \)) was measured perpendicular to the implant surface at the level ranging between the apex of the implant and the sinus floor. This differs from the study by Nishida et al\(^\text{26}\) of osteotome with graft, which calculated the horizontal bone gain at the height of the implant apex from one side of the bone via the whole diameter of the implant (5-mm implants were used) to the other side of the bone. Their horizontal bone gain measured after 6 months of healing was on average 10.7 ± 3.4 mm, which can be broken down as approximately 2.85 mm (= [10.7 – 5]/2). This is approximately 0.86 mm more horizontal bone gain compared with the present indirect sinus elevation with bone graft group.

The intrasinus implant protrusion/vertical bone gain of the indirect sinus elevation and bicortical fixation groups were 2.92/3.15 and 3.04/2.35 mm, respectively (Tables 2 and 3). As the average implant protrusion of 3.04 mm was longer than the average vertical bone gain of 2.35 mm, there were more cases where the implant apex was not surrounded by new bone formation in the bicortical fixation group compared with the indirect sinus elevation group, which usually had bone surrounding the apex of implants. An implant protruding in a controlled manner using the bicortical fixation technique had the potential to preserve the integrity of the sinus membrane, creating a tent-shaped space under the membrane that would be filled by a blood clot. This bone formation around the longer implant could provide a biomechanical advantage in areas with limited bone quantity like the posterior maxilla, compared with a shorter implant placed with a unicortical fixation technique, and potentially increase chances for long-term survival. Long-term follow-up data are necessary, however, to assess the implications of increased intrasinus implant protrusion as well as implant apexes not surrounded by new bone when implants are placed using the bicortical fixation surgical technique.

One interesting finding was that clinically noticeable preoperative sinus floor location and shape change has been identified in 7 of 11 cases (63.6%) in the indirect sinus elevation group and 4 out of 14 cases (28.6%) in the bicortical fixation group (Table 5). The osteotome technique used for indirect sinus elevation purposely creates
a green stick fracture of the sinus floor, which is subsequently elevated with bone graft material. The noted sinus floor elevation in the bicortical fixation group was not intentional but may be a result of the undersized sinus floor opening fracturing upward as a larger-diameter self-threading implant is inserted. The average amount of displacement in those clinically noticeable cases was similar for the bicortical fixation and indirect sinus elevation groups (2.0 and 1.9 mm, respectively) and presented as a broad-based elevation across the sinus floor rather than showing an abrupt localized sharp shape change.

Several limitations of this study were recognized by the authors. Measuring intrasinus vertical and horizontal bone gain between preoperative and 2-year follow-up CBCTs was a difficult task. Several recent studies have reported intrasinus bone gain by comparing preoperative and follow-up CBCT images, using various linear or volumetric measurement methods, such as the average of the mesial-distal aspect, buccal-lingual aspect, or all four aspects.22,26,27–29 In the present study, the 0.4 × 0.4-mm² HU measuring cursor was used as a marker to delineate margins of vertical and horizontal bone formation at the mesial, distal, buccal, and palatal aspects of the implant. In the absence of consensus regarding the most appropriate intrasinus bone measuring technique, combining four aspects of linear measurements that are easier to reproduce and to interpret clinically may provide an encompassing depiction of intrasinus bone gain.

At the 2-year recall visit, the Periotest measurement was taken from the definitive restoration. The vertical position of the Periotest measurement on the crown could not be precisely controlled for, and with the posterior position of the implant crowns, a perpendicular angle from the Periotest sensor to the crown was often difficult to achieve. Studies show implant stability by PTV can be affected negatively when the vertical height of the Periotest contact point is further away from the top of the implant.30 Because a majority of definitive restorations were cement-retained, it was not feasible to remove restorations and place SmartPegs to take Osstell measurements and be consistent with primary and secondary implant stability measurements done in the phase 1 study.

Another limitation of this study was that the amount of crossover from one treatment to another, as well as loss to follow-up, was not accounted for in the power analysis, and thus, the sample size may have been too small. An investigation with a larger sample size would be beneficial to confirm the findings of this study.

CONCLUSIONS

Within the limitations of this study, no significant differences were seen in 2-year follow-up restoration/implant stability and complications reported between the three implant surgical groups. The indirect sinus elevation group showed significantly more intrasinus vertical and horizontal bone gain compared with the bicortical fixation group, even though the differences were small (0.8 mm and 0.52 mm, respectively), and its clinical significance is unknown. As a result, placing implants with a bicortical fixation surgical technique in a maxillary alveolar ridge with moderately limited height (7 to 11 mm) may be a feasible option with limited risk of complications. The use of the bicortical fixation technique would allow for longer implant placement and negate the need for indirect sinus augmentation with additional expense and surgical morbidity to the patient.

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