Implants Placed Simultaneously With Lateral Window Sinus Augmentation Using a Putty Alloplastic Bone Substitute for Increased Primary Implant Stability: A Retrospective Study

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Introduction: *The aim of this retrospective study was to evaluate the primary stability of implants placed in significantly pneumatized maxillary sinuses with minimum residual bone height.*

Materials and Methods: *Seventeen patients who had been treated with simultaneous implant placement in sites with <5 mm of vertical bone height using a modified direct sinus lift technique were included. Implants placed in adjacent sites with at least 5 mm of bone height were included as quasi-controls.*

Results: *A total of 30 implants were inserted with a maximum insertion torque number >20 N/cm². Logistic regression analysis failed to show any association between residual bone height and primary implant stability. Implant survival was 96.67% (29/30) during a mean follow-up of 15.74 months post-loading.*

Conclusions: *The diminished preoperative vertical dimensions of the residual ridges did not seem to negatively influence the osseointegration of implants placed in this study. The prerequisite for simultaneous sinus augmentation and implant placement is an adequate primary stability of the implant and not a fixed minimum bone height level. (Implant Dent 2014;23:496–501)*

Key Words: maxillary sinus, simultaneous implant placement, putty, primary implant stability

The lateral window approach for maxillary sinus augmentation was introduced to allow for the placement of implants in maxillary posterior edentulous sites with significant pneumatization of the sinus cavity.[1–3] This technique is considered to be the most predictable treatment modality for the augmentation of the posterior maxilla.[4] Implants placed simultaneously with the lateral window sinus augmentation technique enjoy high success rates that are reported to be similar to implants placed in pristine bone in the maxilla.[5,6]

An 1-stage or 2-stage implant placement approach has been suggested in conjunction with lateral wall maxillary sinus lift procedures. Traditionally, the main prerequisite for simultaneous implant placement with direct sinus lift has been native vertical bone height (VBH) >4 mm or at least 5 mm as measured preoperatively.[7,8] Recent clinical evidence suggests that the placement of implants simultaneously with direct sinus lift in ridges with minimum remaining bone may be a feasible treatment modality as long as adequate primary stability can be ensured.[9]

Many different biomaterials have been proposed for use in sinus augmentation including particulate alloplastic bone substitutes.[10–13] The ongoing development of biomaterials has improved the physical attributes and properties of alloplastic bone substitutes to include novel characteristics such as a moldable putty consistency. A more viscous consistency of the biomaterials used for sinus augmentation could positively affect the primary stability of an implant placed simultaneously with a sinus lift procedure.

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Synthetic putty comprised of calcium, phosphate, and silica particles, an additive phase consisting polyethylene glycol, and a binder phase comprised of glycerin that is available in premixed doses have been reported to exhibit promising results when used for bone augmentation and ridge preservation procedures.[14–16] In addition to being osteoconductive, this biomaterial has been characterized as osteostimulative by the Food and Drug Administration (FDA 510k 2006) because of its ability to stimulate osteoprogenitor cells to produce transforming growth factor, because of the release of silicon.[17]

The potential benefit of the enhanced handling characteristics and the osteostimulative properties of new generation putty biomaterials in sinus augmentation procedures followed by simultaneous implant placement have not been investigated to date.

The aim of this retrospective study was to evaluate the primary stability of implants placed in significantly pneumatized maxillary sinuses with minimum residual bone height, using implants placed in adjacent sites with 5 mm or more bone height as quasi-controls. The primary outcome was maximum insertion torque (MIT) during implant placement. Clinical outcomes and radiographic changes in VBH were calculated as secondary outcomes.

MATERIALS AND METHODS

Data related to age, sex, implant location, intraoperative or postoperative complications, implant stability, implant survival, and radiographic bone changes were recorded. All patients had to fulfill the following inclusion criteria: direct sinus lift with simultaneous implant placement, noncontributory medical history, smoking <10 cigarettes per day, at least 6 months of postloading follow-up, and an implant site with <5 mm of VBH preoperatively in each sinus. Because of the anatomy of the sinus floor next to each site exhibiting minimum residual bone height (<5 mm), adjacent sites that also required implant placement revealed 5 mm or greater VBH. Those sites were included in the evaluation as a separate subgroup and were used as quasi-controls to determine the effect of residual bone height on primary implant stability.

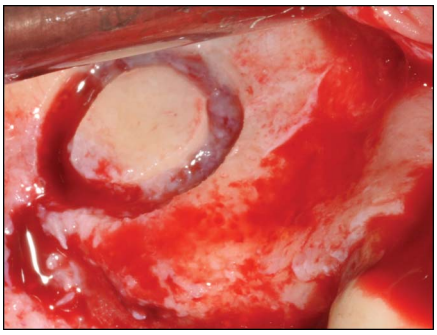

Fig. 1. Intraoperative view of the prepared bony window on the lateral wall of the sinus.

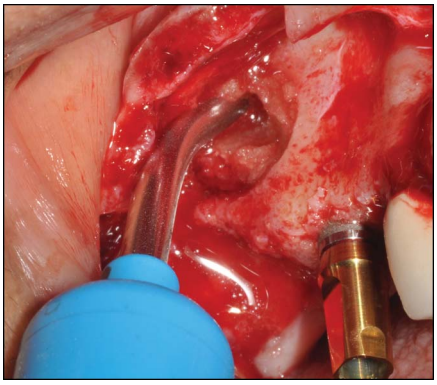

Fig. 3. The putty bone substitute was delivered into the sinus using a cartridge delivery system that simplified the grafting procedure. No premixing was required before its use. An implant in the second premolar position was placed in native bone.

Exclusion criteria included history of acute sinus infection, history of previous maxillary sinus surgery (Caldwell–Luc surgery, direct or indirect sinus lift, etc), and/or medications that may affect bone healing (chronic steroid regimen, oral, or intravenous bisphosphonates, etc).

According to the clinic's protocol, all patients were evaluated preoperatively for the need for sinus augmentation with a cone beam computed tomography (CBCT). The indications for the procedure and possible complications were reviewed with the patients, and all patients agreed to proceed and signed an informed consent. All patients were treated in accordance with the Helsinki Declaration of 1975, as revised in 2000.

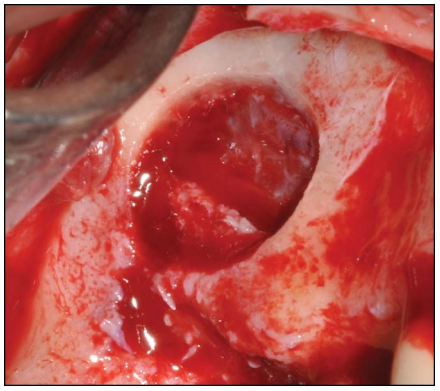

Fig. 2. The outfractured bone wall was kept in saline throughout the procedure. Sinus curettes were used to perform careful elevation of the schneiderian membrane across the floor of the sinus.

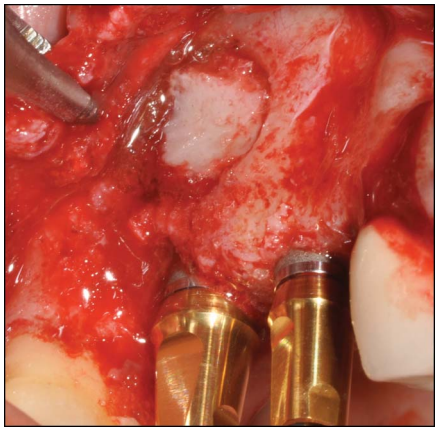

Fig. 4. An implant in the first molar position was placed in the augmented sinus. The outfractured window is replaced in the lateral wall of the sinus.

Modified Surgical Technique

All patients in this study were treated under local anesthesia. Sinus floor elevations were performed as a modification of the outfracture osteotomy technique that was introduced by Cho et al.[18] A full thickness mucoperiosteal flap was elevated in the posterior maxilla, and the lateral window osteotomy was outlined with either a Piezo surgical tip or a number 4 diamond round bur on a rear-exhaust handpiece (Fig. 1). The bony window was outfractured and preserved in sterile saline until the end of the procedure (Fig. 2). After elevation of the sinus membrane, a calcium phosphosilicate (CPS) putty bone substitute (NovaBone Dental Putty; NovaBone Products, Alachua,

FL) was injected directly into the area using a cartridge system (Fig. 3). The novelty of this technique lies in that implants were placed immediately after grafting the sinus cavity with CPS Putty because the physical properties of this biomaterial allow for preparation of the implant osteotomy through the body of the graft. The drilling sequence followed the implant system manufacturer's recommendations with no intent to undersize the osteotomies. The implants were initially engaged into the native bone at the crest of the ridge and then slowly torqued in to engage into the CPS Putty at the apical aspect of the implant osteotomy. Primary stability was recorded as the MIT achieved using a torque wrench for the placement of the implant in its final position. Two distinct torque values were used as reference points (20 and 35 N/cm^2) based on the MIT index,[15] and the MIT for each implant was recorded as greater, equal, or lesser than the reference torque measurements. Cover screws were placed, and the detached bony window was used to cover the osteotomy site (Fig. 4). Primary flap closure was achieved using a single interrupted suturing technique. No membrane was used for the coverage of the bony window.

Patients were followed up at 2 weeks, 4 weeks, and 4 months after the surgery for postsurgical evaluation. Second stage surgery was scheduled at 5- to 6-month postsinus lift. During that appointment, a periapical radiograph was taken to evaluate the amount of postoperative VBH and assess radiographic signs of implant osseointegration. The radiographic measurements were calculated twice by the same examiner at 2 different time intervals, and the means of both measurements were reported. The periapical radiographs were taken by using the long-cone paralleling technique, and the measurements were scaled using known markers (implant length) to correct possible elongation or foreshortening of measurements on the periapical radiographs when compared with CBCT preoperative measurements. Specialized imaging software was used for the above-mentioned adjusted measurements (Dental Imaging Software, version 6.1.7; Carestream Dental LLC, Atlanta, GA).

Table 1. Distribution of Implants Per Site

Implant Dimensions (mm × mm)	Maxillary Implant Sites		
	Second Premolar	First Molar	Second Molar
3.5 × 10.5*	1	0	0
3.5 × 12*	2	0	0
3.8 × 10.5	4	5	0
3.8 × 12	3	1	0
4 × 10.5*	0	5	3
4 × 12*	0	3	0
4.6 × 10.5	0	3	1
5 × 10.5*	0	1	0

*Parallel-walled implant.

Implant survival was evaluated clinically based on the assessment of implant mobility, signs of periimplantitis, and evaluation of subjective symptoms (pain, altered sensation).[19,20] After implant loading, patients were seen for a clinical evaluation after 6 months and were then followed up on an individualized basis that included clinical examinations at least biannually thereafter.

Statistical Analysis

Descriptive statistics were used to evaluate implant survival and primary implant stability. The Wilcoxon matched pairs signed-rank test was used for the evaluation of VBH before and after surgery. The statistical computational level was set at the implant site unit. Logistic regression analysis was performed to investigate the association between preoperative VBH and primary implant stability as assessed by dichotomous evaluation of the MIT ($\geq$35 or $<$35 N/cm^2) for implants included in this study. For statistical modeling purposes, preoperative VBH data on the implant site computational level were treated as independent values. Preoperative VBH was considered as a predictor, and primary implant stability was set as the dependent variable. A P value of <0.05 was established as the threshold of statistical significance for all statistical tests.

RESULTS

Seventeen patients with a median age of 51 years received a total of 30 implants with all patients contributing at least 1 direct sinus lift procedure that fulfilled the inclusion criteria for this

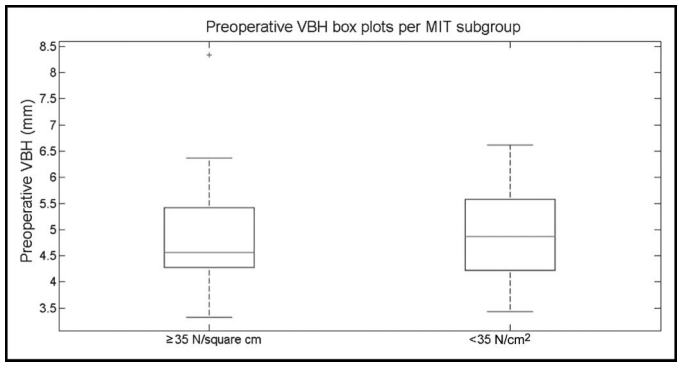

Fig. 5. Each box plot represents the median (red line) and the edges of the box are the 25th and 75th percentiles for the preoperative VBH measurements according to MIT achieved during implant placement. The left subgroup represents VBH values for implants achieving at least 35 N/cm^2 of MIT (n = 19) and the right subgroup for those achieving $<$35 N/cm^2 (n = 12). The whiskers extend to the most extreme data points not considered outliers, and outliers are plotted individually. Note how similar the distribution of preoperative values is in both subgroups. Logistic regression failed to reveal any association between the 2 values (data not shown).

study. One of the 17 patients reported being a smoker with a frequency of <10 cigarettes per day. No patients experienced any complications associated with the sinus surgery or implant placement. There were no visible perforations of the Schneiderian membrane in any of the cases. The preoperative ridge height ranged from 3.32 to 8.14 mm with 63.3% of the sites placed in the severely resorbed ridges (<5 mm, n = 19) subgroup and the remaining placed in the adjacent sites (≥5 mm, n = 11). All implants were placed simultaneously with the sinus lift procedures. Tapered BioHorizons implants (Tapered Internal; BioHorizons, Birmingham, AL) were placed in 15/30 sites, while 15/30 sites received parallel-walled implants from the same manufacturer (Internal; BioHorizons). The dimensions of the implants placed are presented in Table 1. Adequate primary stability was achieved in all cases with at least 35 N/cm^2 of MIT recorded for 19/30 implants (63.3%), whereas the MIT was <35 N/cm^2 in 11/30 implants placed (36.7%). In all cases (100%), at least 20 N/cm^2 of MIT were achieved. Logistic regression analysis failed to show any significant difference in the MIT achieved during implant placement between the severely resorbed subgroup (<5 mm) and the subgroup including the adjacent implant sites (≥5 mm) ($P > 0.05$) (Fig. 5).

All implants were left to heal submerged for 5.6 ± 0.3 months. At the second stage appointment, the mean VBH was 13.34 mm (±1.74 mm) as seen on postoperative radiographs. The difference between the initial VBH and the bone height at the time of loading displayed a highly statistically significant difference ($P < 0.001$) (Table 2). Patients were monitored for a mean duration of 15.54 months (7 months minimum and 34 months maximum). During the follow-up period, 29 of a total of 30 placed implants remained functional, for an implant survival rate of 96.67%. The only implant lost was a 3.8 × 10.5-mm implant placed at site 14 in a 63-year-old nonsmoker women. Three implants were placed simultaneously with the direct sinus lift in this patient at sites 14, 15, and 16 with the 2 latter remaining successfully osseointegrated after 10 months of follow-up.

Table 2. Increase in Vertical Bone Height at 6-month Postsurgery (Mean ± SD)

Preoperative bone height	4.91 ± 1.03
Postoperative bone height	13.34 ± 1.74
Difference	8.43 ± 2.08*

*Highly statistically significant ($P < 0.0001$).

DISCUSSION

This retrospective study aimed at investigating clinical results from simultaneous placement of implants during direct maxillary sinus lift procedures in extremely resorbed ridges. The primary outcome was primary stability for implants placed with the proposed sinus augmentation technique. All implants achieved good to optimal primary stability; and interestingly, the bone height at baseline was not found to be a predictor of primary implant stability in our sample. The survival of implants placed was found to be 96.77% after at least 6 months of observation with a mean follow-up of 15.54 months.

Among the first researchers to introduce this clinical concept were Peleg et al[21] who placed 160 implants simultaneously with the augmentation of maxillary sinuses with a residual alveolar bone height between 3 and 5 mm. Similar to our results, they did not report any postoperative complications or radiographic evidence of crestal bone loss around the implants after uncovery at 9-month postsurgery.

The benefits of simultaneous implant placement include reduced waiting time for the patient and the benefit of a single surgical procedure. Recently, Cha et al[9] have also disputed the dogma of simultaneous implant placement in the posterior maxilla during sinus lift procedures only when at least 5 mm of native supportive bone are available for implant anchorage. In their large-scale retrospective study, they reported on 262 implants placed in ridges with a minimum residual bone height versus 200 implants placed in sites with greater than 5 mm of residual bone height.[9] Their findings of similar success rates in both subgroups indicated that the prerequisite for simultaneous sinus augmentation and implant placement is adequate primary stability of the implant and not a minimum amount of pre-existing bone height.[9] In our study, we achieved at least 20 N/cm^2 for all implants placed with almost 66% achieving at least 35 N/cm^2 using a novel approach for grafting the maxillary sinus. When using this technique, we did not find the preoperative VBH to be a predictive value of primary implant stability. The presented results are contradictory to the findings of a comparative animal study that found initial implant stability to be associated with residual bone height and implied that a threshold of 6 mm should be considered for simultaneous implant placement in sinus elevation surgeries with particulate bone grafts for predictable osseointegration.[22]

The contradictory results may be partially explained by the different consistency of the bone grafts used in the 2 studies.[22] The technique used in our study exploits the clinical characteristics of a recently introduced putty alloplastic bone substitute. CPS putty was used to graft the sinus cavity intraoperatively before the placement of the implant. After the fill of the maxillary sinus, osteotomies were initiated on the alveolar ridge, and implants were placed though the osteotomies. During the insertion of the implant in the augmented sinus through the osteotomies, the CPS putty acted as a viscoelastic medium that transfers the resistance of the cortical bony walls of the sinus to the inserted implant similarly to the function of cancelous bone during implant placement in an intact ridge, thus increasing its primary stability. It is assumed that the primary stability of the implant was obtained from its anchorage in the remaining crestal bone and in the putty present in the augmented sinus cavity because no attempt was made to use techniques such as bone condensation or undersizing of the osteotomy. Undersizing of the osteotomy was avoided to prevent the inherent risk of fracture of the fragile residual crestal bone because of excess torque generated during implant placement. Another important factor that may deem the use of putty bone substitutes as preferable to modifications to the drilling protocol, such as undersizing of the osteotomy, is

the damaging effect of undersizing the bone-implant interface.[23] Coelho et al[23] investigated the effect of various undersizing protocols with descending final drill diameters for the placement of 4.0 mm in diameter implants in the radii of dogs. They found that undersizing was associated with areas of necrotic bone areas in the coronal threads of the tapered implants, while the recommended drilling protocol resulted in chamber spaces between the implant threads and prepared alveolar bone that were filled with osteogenic tissue at 1-week postplacement. Results of this study showed that there was an inversely proportional relationship between the insertion torque because of undersizing and removal of torque values for the implants that lead the authors to conclude that excessive stress because of undersizing of the osteotomy leads to compromised secondary implant stability.[23]

Comparable with our technique, Mazor et al[24] presented results of a similar technique where a rigid bone cement was successfully used to allow for the anchorage of implants simultaneously placed in the atrophic maxilla with adequate primary stability. The viscoelastic characteristics that putty bone substitutes enjoy and their simplicity of placement and their enhanced graft particle containment[25] allowed us to proceed with placement of the graft and completion of the sinus lift procedure before preparation of the implant bed, allowing the surgeon to have a better tactile sense during the implant surgical procedure. Regarding the histological outcome of sites grafted with CPS putty, the retrospective design of this study did not include reports of histological analyses, yet a plenitude of human clinical studies have verified the osseous regenerative potential of CPS putty.[14,26,27] Histomorphometric results from the use of CPS putty in well-contained defects have been very promising with ranges of percentage of vital bone from 31%[27] to 49%[14] depending on the healing time. Additionally, previous histological studies have verified the positive effect of CPS particles in the percentage of vital bone present in extraction sockets and in augmented maxillary sinuses.[28,29]

In conclusion, there is a moderate level of evidence in the literature to support a shift in decision-making process for simultaneous placement of implants in conjunction with direct maxillary sinus lift in severely resorbed ridges. Yet, the empirically dictated threshold is still used nowadays, and no clear consensus has been reached.[8] Initial primary stability seems to be a more pivotal factor in implant success rather than the vertical bone dimensions of the residual ridge. Additional prospective controlled studies are required to verify our findings and provide definitive guidelines for implant placement simultaneously with sinus lift procedures.

CONCLUSIONS

Within the limitations of this study, we conclude that:

1. The placement of implants simultaneously with direct maxillary sinus lift in severely resorbed posterior maxillary sites is a viable treatment option when adequate primary stability can be achieved.
2. The diminished preoperative vertical dimensions of the residual ridges did not seem to negatively influence the osseointegration of implants placed in this study.
3. The prerequisite for simultaneous sinus augmentation and implant placement is adequate primary stability of the implant and not a fixed minimum bone height level.
4. Clinicians may benefit from the use of the proposed technique for attaining adequate primary stability.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

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