The Feasibility of Flapless Approach to Sinus Augmentation Using an Implant Device Designed According to Residual Alveolar Ridge Height

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Hydraulic sinus lift and augmentation may be successfully performed using a dedicated implant device designed according to residual bone height (RBH). The aim of this study was to evaluate whether a flapless surgical approach might negatively influence the outcome. A total of 40 consecutive patients (16 men and 24 women) were included in the study, 20 in each group (minimal flap/control versus flapless/study). Inclusion criteria were ≥ 3 mm RBH, ≥ 6 mm width of the residual alveolar ridge according to preoperative cone beam computerized tomography, and ≥ 8 mm buccopalatal keratinized gingiva for the flapless group. Primary outcome parameters included intraoperative membrane perforation. Secondary outcome parameters included postoperative infection, soft tissue healing, bone gain, and short-term dental implant survival. Mean RBH was 4.6 mm. No intraoperative membrane perforations and no postoperative infections were observed. Mean bone gain height was similar for both groups, at 11 mm. Soft tissue healing was observed within 2 months. In all cases, second-stage surgery allowed generation of at least 2 mm of keratinized gingiva buccally. All implants were osseointegrated at second-stage surgery. The use of a flapless approach to maxillary sinus augmentation using an implant device based on RBH yields predictable results.


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The first rule of medicine is *primum non nocere*. As a result, a complete visualization of surgical anatomical landmarks was considered essential when imaging modalities were limited. At the advent of implant dentistry, the available imaging modalities were primarily two-dimensional (periapical and panoramic radiographs). As a result, it was impossible to visualize preoperatively the precise relationships between the different anatomical landmarks. Raising a flap to place dental implants was mandatory to achieve predictable results. The popularization of three-dimensional imaging (eg, computed tomography [CT] and cone beam CT [CBCT]) allowed for a better preoperative assessment. The combination of clinical and radiologic examination allowed the operator predictable planning of the surgery in most cases. However, borderline anatomical cases remained a significant challenge.1–6

Surgery is heading toward minimally invasive intervention, with minimal postoperative morbidity, fewer working days lost, improved healing, and reduced operation time being the main motivations. One application in implant dentistry is flapless implant placement. The prerequisites for such a procedure include sufficient keratinized gingiva and uncompromised bone dimensions in the implantation site. A flapless surgery can be performed...
by placing a dental implant directly through the mucosal tissues without reflecting a flap or by removing a circular gingival punch, performing the surgical implant placement, returning the punch, and placing a securing suture over it. The main risk of such a technique is misdiagnosis of the underlying bone topography, which may increase the risk of implant placement outside the available bone volume. Thermal damage due to compromised access for external irrigation during surgery is an additional concern. Esthetic complications or implant losses might be the unfortunate outcome.1–7

Implant placement in the posterior maxilla is often challenging due to limited available bone volume.8–13 Longer and wider implants may have a biomechanical advantage.14 Sinus augmentation to increase the vertical bone height in the posterior maxilla has become routine in implant dentistry. A flapless approach combined with an implant device based on residual alveolar ridge height has never been described. In the present study, a minimally invasive implant device (Maxillent) was used.11,12 The length of this device is based on the residual bone height (RBH) (13 mm length for 3 to 4 mm RBH, 14.5 mm for 4 to 5.5 mm RBH, and 16 mm for 5.5 to 7 mm RBH).

The purpose of the present study was to evaluate whether sinus augmentation using a RBH-based implant device via the flapless surgical approach may influence the results. Primary outcome parameters included intraoperative membrane perforation. Secondary outcome parameters included postoperative infection, soft tissue healing, bone gain, and short-term dental implant survival.

Materials and Methods

A total of 40 patients (16 men, 24 women) were included in the study, 20 in the control group and 20 in the study group. The mean age was 52 years for the control group and 50 years for the study group. Inclusion criteria were RBH ≥ 3 mm, residual alveolar ridge width ≥ 6 mm as measured by CBCT, and ≥ 8 mm buccopalatal keratinized gingiva for the flapless group. A total of 20 iRaise implants were used for each group.

RBH-Based Implant Device

The dental implant used in this trial was a self-tapping endosseous dental implant11,12 (Fig 1). It contains an internal channel that allows the introduction of liquids through the implant body and into the maxillary sinus. The introduction of saline initially allows hydraulic lifting of the sinus membrane. The same channel allows for the introduction of the bone graft into the space created by the hydraulic lifting. The portal of entry to the internal channel must be positioned above the alveolar crest to allow the assembly of the fluid insertion connector. Thus, a fixed-length port crestal to the implant channel is required, to allow prosthetic connection. This part is similar for all the implants used and is approximately 9 mm. The length of the apical part of the implant is based on RBH. Therefore, the length of the implant (ranging from 13 to 16 mm) should be as follows: 13 mm for RBH ≤ 4 mm, 14.5 mm for RBH 4 to 5.5 mm, and 16 mm for RBH 5.5 to 7 mm. The device was approved for clinical testing by the ethical committees of the Israeli Ministry of Health following extensive preclinical and bench testing (study approval number HTA5284). The device also has a Conformité Européenne (CE) approval from Health Canada and is approved for distribution in Europe, Canada, and Israel.
Surgical Procedure

Preoperative imaging demonstrating at least 3 mm residual alveolar ridge height was a prerequisite (Fig 2). Prophylactic antibiotics were administered (1 g amoxicillin, 1 hour before the procedure). The patient performed a mouthrinse for 1 minute with chlorhexidine gluconate 0.2% solution prior to surgery. In the flap group, surgery commenced with local anesthesia and a crestal incision, without vertical extensions, along the maxillary ridge. Relatively small full-thickness mucoperiosteal flaps were reflected buccally and palatinally. Flapless surgery was performed by placing a dental implant directly through the mucosal tissues without reflecting a flap or by removing a circular gingival punch (Fig 3), placing the implant, and then returning the punch and securing it with a suture. For the flapless cases, the gingival thickness was measured using a University of North Carolina (UNC) probe. The thickness (2 to 3 mm) was added to RBH. The osteotomy site was marked with a small round bur. An osteotomy was started at the implantation site with a 3.2-mm twist drill to a depth of 3 mm. The stopper of this drill allowed drilling up to 3 mm in the alveolar bone in minimal flap and flapless cases. The second drilling was done with a flat-tip drill up to 1 to 2 mm below the sinus membrane, as measured by the preoperative CBCT. In some cases (minimal flap or flapless), the operator used drill stoppers to accurately drill to the planned point under the sinus floor; in other cases, the operator used a freehand drill with depth marking only. A periapical radiograph with a depth guide was performed to verify the drilling angulation and depth. The osteotomy site was widened to the desired diameter with the full drilling sequence for a 4.2- or 5.0-mm-diameter implant. The sinus floor was weakened/opened using a drill with an active diamond tip designed to atraumatically penetrate the sinus floor under the sinus membrane without damaging the membrane. The implant was inserted into the osteotomy until it reached the end of the prepared osteotomy. It was then slowly advanced until the sinus floor was penetrated (approximately 1 mm) (Fig 4). A periapical radiograph was performed in some cases to determine whether the implant penetrated the sinus floor. A saline syringe (0.9% sodium chloride sterile saline solution) was connected to the implant via the tubing port. Saline solution was gently injected through the implant and into the sinus (Fig 5). Typically, 2 to 3 mL of saline was required, depending on the size of the sinus, the number of implants, and the required elevation.

For the flapless cases, the implant had to overcome the additional gingival height to allow tube connection. As a result, implant length was chosen according to the results of RBH + soft tissue thickness according to the previously mentioned rules. For cases with RBH + soft tissue 5.5 to 7 mm, the implant was first inserted in the sinus floor to allow sinus penetration and then withdrawn to enable tube connection. The cylindrical design allowed this movement without compromise to initial stability with a RBH of at least 5.5 mm. For some cases, conventional osteotomes were used to penetrate the sinus floor. The implant was then introduced up to a point that enabled tube connection (implant apex not reaching the sinus floor).
The saline solution was retracted back into the syringe, and the syringe was disconnected from the tubing port. Slight bleeding was noted in the retracted saline solution. The blood was observed in the tubing on stopping the injection or slightly draining fluid. This phenomenon was a further indication that the implant tip penetrated the cortex. Although blood may also originate from the osteotomy site, it can be speculated that it originated from the severed blood vessels connecting the sinus membrane to the sinus bony walls due to the dilution in 2 to 3 mL of saline.

Sinus membrane integrity was assessed as follows. At the end of drilling, the Valsalva test was performed. If the result was negative, the procedure continued. During saline or graft insertion, the patient was asked to report any feeling of fluids inside the nose or throat. Bleeding from the nose or oropharynx was clinically assessed. Whenever doubt arose regarding membrane integrity, a CBCT was performed.

A flowable bone graft–filled syringe (MBCP Gel, Biomantlante) was then connected to the tubing port. The desired volume of bone graft material was slowly injected through the implant into the sinus (Fig 6). The amount of bone graft ranged from 1 to 3 cm³, averaging 2.3 cm³.

The bone graft syringe was subsequently disconnected from the tubing port, and the applicator and tubing were disconnected from the implant. The implant was fully inserted through the osteotomy into the bone graft until the coronal aspect of the implant was aligned with the maxillary alveolar crest. Additional implants were placed (Fig 7). Bone graft emerging from the second osteotomy or bone graft remnants on the surgical drill served as further reassurance of sinus membrane integrity. The gingival flaps were then sutured. When a circular gingival punch was used, the soft tissue was repositioned and a securing suture was placed over it (Fig 8).
Following the procedure, the patients were instructed to rinse for 1 minute with 0.2% chlorhexidine solution twice a day for 10 days. Postoperative analgesia was used as needed. Nose drops (topical decongestants such as oxymetazoline) were used in the relevant nostril twice a day for a week. Antibiotics were prescribed at the clinician’s discretion (as usually given in bone grafting procedures): 500 mg amoxicillin three times a day for 7 days.

Second-stage surgery was performed after 6 to 9 months. Keratinized gingiva of at least 2 mm buccal to the implant was verified prior to flap elevation. There was no need for soft tissue augmentation procedures. All implants were rehabilitated with fixed implant-supported prostheses (Fig 9).

Results

The primary outcome parameter was intraoperative membrane perforation. Secondary parameters included postoperative infection, soft tissue healing, bone gain, and short-term implant survival. Mean residual alveolar ridge height was 4.6 mm, with a range of 3 to 7 mm. Mean bone height gain was 11 mm for the study group and for the control group. There were no intraoperative complications, difficulties in introducing fluids, or postoperative complications. Complete soft tissue healing was observed within 2 months. Second-stage surgery was performed, allowing keratinized gingiva of at least 2 mm buccally. All implants were osseointegrated at the second-stage surgery.

Discussion

The expectations and preferences of patients seeking dental implants today are high. When asked, they mention treatment predictability and fixed implant-supported prostheses as their main demands. They want shorter treatment duration without increasing failure rates and/or postoperative morbidity. Patients are willing to pay the additional costs associated with CT and new surgical techniques, especially those offering minimally invasive treatment alternatives.15

The present study supports the use of a minimally invasive implant device in a minimally invasive technique (flapless approach) for maxillary sinus augmentation with simultaneous implant placement. The operator was able to predictably elevate the sinus membrane, introduce bone graft, and place implants that are at least 13 mm long in a single intervention. With this protocol, more patients may be willing to undergo the sinus augmentation procedure.

The use of preoperative CBCT measurements allowed accurate preoperative planning, enabling a flapless approach. CBCT-guided transalveolar sinus floor elevation technique with simultaneous implant installation was recently assessed.16 Preoperative CBCT was used to guide a flapless surgical procedure. All patients were provided with fixed implant-supported prostheses. No implants were lost after surgery and follow-up. It was concluded that flapless transalveolar sinus lift procedures guided by preoperative CBCT can be used successfully to enable placement.

The results of the present study are comparable with previous studies reporting on the outcome of flapless crestal hydraulic or balloon-assisted sinus floor elevation with
simultaneous implant placement.\textsuperscript{17,18} Flapless crestal sinus floor elevation was reported as safe and effective, decreasing surgical discomfort and trauma.

The effect of flapless implant surgery on soft tissue profile was previously assessed.\textsuperscript{19} The results indicated that creeping attachment (ie, soft tissue recovery) occurred within 2 months after surgery. The study suggests that flapless implant surgery provides esthetic soft tissue results. A similar result was observed in the present study (complete soft tissue healing within 2 months) allowing good soft tissue manipulation at second-stage surgery. Another study concluded that both flapless and flap implant placement protocols resulted in high success rates. A flapless protocol provided a better short-term esthetic result, but no long-term advantages were seen.\textsuperscript{20} The present study described a good outcome for the soft tissue in the posterior maxilla.

The present study demonstrated that use of the flapless approach achieves successful results. However, it is recommended only for those practitioners with advanced clinical experience, especially using the iRaise device in a flap approach.

Conclusions

The use of a minimal flap or flapless approach to maxillary sinus augmentation using a RBH-based transcresittal implant device yields predictable results. Minimal changes in the surgical protocol are required for the flapless approach.

Acknowledgments

The authors reported no conflicts of interest related to this study.

References


