Minimally Invasive Sinus Lift Implant Device: A Multicenter Safety and Efficacy Trial Preliminary Results

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ABSTRACT

Purpose: In cases of advanced maxillary sinus atrophy of the bone (pneumatization), the sinus floor has to be augmented in order to obtain acceptable bone volume for implantation. The objective of the present study is to evaluate a new procedure and device, designed as a closed sinus lift using a dedicated dental implant that allows for Schneiderian membrane elevation and the placement of a flowable bone replacement graft.

Materials and Methods: Eighteen patients (8 males, 10 females) underwent 23 procedures. All procedures were completed successfully, with elevation of the sinus membrane and insertion of bone graft and the dental implant at the planned site. No membrane tears were noted. No intraoperative or postoperative adverse events were observed in any of the cases. There were no postprocedural emergency or distress calls.

Results: The patients' average age was 52 (range 38–72). The mean residual alveolar ridge height was 5.5 mm (range 4.0–7.0). The average bone gain was 11.2 mm (range 9–13) after an average healing period of 8.7 months (range 6.7–13.1). All implants achieved clinical stability and prosthetic rehabilitation was uneventful.

Conclusions: A closed sinus floor elevation procedure can be accomplished using a dedicated dental implant that allows for hydraulic elevation of the Schneiderian membrane and placement of a flowable bone replacement graft and dental implant placement all at the same time with minimal patient discomfort.

KEY WORDS: bone grafting, crestal, implant, minimally invasive, sinus lift procedure

INTRODUCTION

With age and edentulism, the maxillary sinus increases in volume (called pneumatization), causing a reduction in the remaining maxillary alveolar ridge. In cases of advanced atrophy of the bone, the remaining bone height is insufficient to support dental implants, and the sinus floor has to be augmented in order to obtain acceptable bone volume for implantation. Nevertheless, patients may refuse the procedure due to cost, fear, or other considerations.[1–7]

Several methods exist for sinus floor augmentation. The lateral window approach, described by Tatum in 1986,[2] is based on opening a window into the sinus (antrostomy) in the buccal bone. Bone graft material is then introduced into the sinus and placed beneath the elevated sinus membrane. The graft material can be an autograft, an allograft, a xenograft, an alloplast, or combinations thereof. It is also called an open sinus lift procedure. Optionally, implant sites can be prepared and implants placed at this stage. More typically, the bone graft is left to mature for 6 to 9 months before introducing implants. The open sinus lift procedure allows the clinician to elevate the sinus floor to the full extent

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necessary. However, this procedure involves a significant amount of trauma to the patient.[1–14]

The osteotome approach was described by Summers in 1994.[1] This method is based on fracturing the floor of the maxillary sinus. It is also called a closed sinus lift. An osteotomy is drilled into the maxilla, stopping 1 to 2 mm below the maxillary sinus floor. An osteotome is then introduced into the osteotomy. The practitioner strikes the osteotome with a mallet to fracture the bone and punch a hole into the sinus, thereby raising the sinus floor. Bone graft material is then introduced into the sinus through the osteotomy, followed by the dental implant. The osteotome approach eliminates much of the trauma and pain of the open approach; however, it is limited in its ability to raise the sinus floor. Therefore, this approach is not always suitable.

Hydraulic sinus condensation was described by Chen and Cha in 2005.[3] This is a variant of the osteotome technique. An osteotomy is initially drilled into the crestal ridge, and fluid pressure from the drilling instrument is used to gently raise the sinus membrane from the sinus floor. After the sinus membrane is raised, it is filled with bone grafting material, and implants are placed.

The present study focuses on a new procedure and device, designed as a closed sinus lift procedure based on a dedicated dental implant. The sinus lift bone augmentation and implant placement are all performed in the same procedure. This technique combines advantages of both the lateral ridge approach and the osteotome sinus lift procedures, where the less invasive advantage of the osteotome technique is combined with the broader access advantage of the lateral window approach. This manuscript presents preliminary results of a multicenter prospective safety and efficacy of human clinical trial of consecutively treated patients.

MATERIALS AND METHODS

The dental implant used in this trial was a self-tapping endosseous dental implant.* It contained an internal channel that allows the introduction of liquids through the implant body and into the maxillary sinus (Figure 1). The device was approved for clinical testing by the ethical committees of the Israeli Ministry of Health and the Romanian Ministry of Health following extensive preclinical and bench testing. The device also has a Conformité Européenne (CE) approval and is allowed for distribution in Europe and Israel.

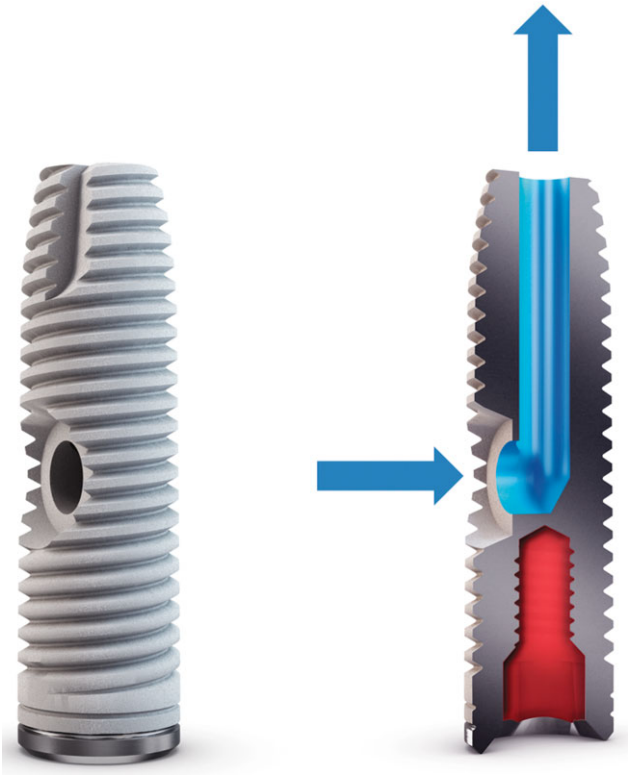

Figure 1 iRaise™ (Maxillent Ltd, Herzliya, Israel) sinus lift implant and internal channel.

Study participants were healthy volunteers in need of a sinus floor augmentation. Participants were screened for inclusion/exclusion criteria at enrollment and signed an informed consent form according to the ethical committee approval.

Inclusion Criteria

The inclusion criteria were the following:

- Age 18 years or above
- In need of sinus floor augmentation
- Residual bone height of approximately 4 mm or more as observed by radiographic survey
- At least 3 months postloss of teeth in the intended sinus augmentation location
- Sinus appears healthy in radiographic survey
- No general health contraindications

Exclusion Criteria

Patients were not eligible for this study if any of the following criteria were met:

*iRaise™ by Maxillent Ltd, Herzliya, Israel.

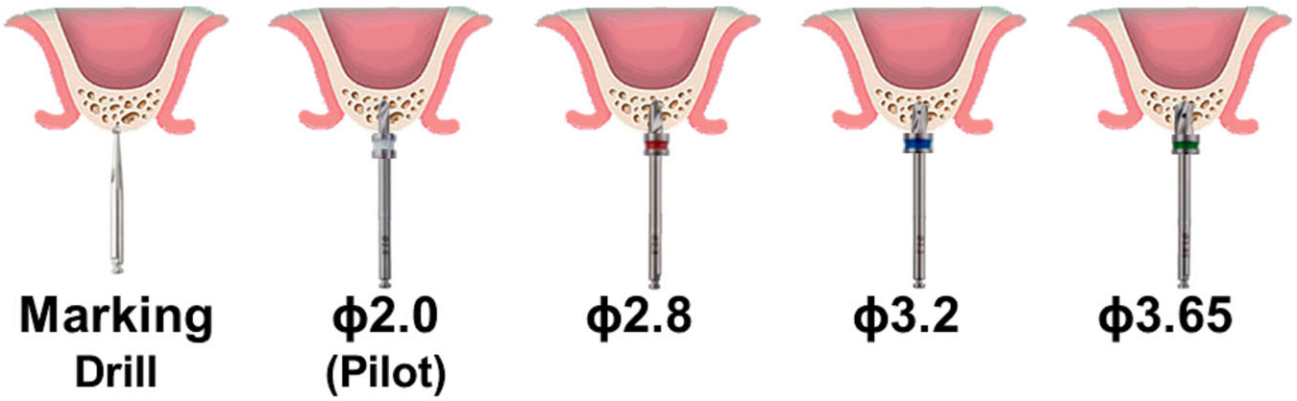

Figure 2 Full drilling sequence.

- Poor dental hygiene
- Acute infection requiring antibiotics at the time of screening
- Acute or chronic sinus pathology
- History of a sinus augmentation in the past in the relevant sinus
- Known allergies to metal alloys
- History of alcohol or drug abuse within the last 2 years
- Heavy smokers (10 or more cigarettes per day)
- Compromised general health

Surgical Procedure

The distance from the maxillary crest to a point 1 to 2 mm below the Schneiderian membrane was calculated, using the preoperative radiographic imaging. Prophylactic antibiotics were administered (1 g of amoxicillin, 1 hour before the procedure). The patient performed a mouth wash for 1 minute with chlorhexidine gluconate 0.2% solution. Surgery commenced with local anesthesia and a crestal incision, without vertical extensions, along the maxillary ridge. Relatively small full thickness mucoperiosteal flaps were reflected. The osteotomy site was marked with a small round bur. An osteotomy was started at the implantation site with a 2-mm twist drill to a depth up to 1 to 2 mm below the Schneiderian membrane, as measured by the preoperative radiograph. A periapical radiograph with a depth guide was performed in order to verify the drilling angulation and depth. The osteotomy site was widened to the desired diameter with the full drilling sequence for either a 4.2 or 5.0 mm–diameter implant (Figure 2). The length of the implant (ranging from 14 to 17 mm) was selected based on the residual bone height: a 14-mm length implant was used for bone heights of up to 5 mm, a 15.5-mm length implant was used for bone heights of up to 6.5 mm, and a 17-mm length implant was used for bone heights of up to 8 mm.

The implant was first inserted into the osteotomy until it reached the end of the prepared osteotomy. The implant was then slowly advanced until the sinus floor was penetrated (approximately 1 mm). A periapical radiograph was performed in some cases in order to determine whether the implant penetrated the sinus floor (Figure 3). A saline syringe (0.9% sterile saline solution) was connected to the implant via the tubing port. Saline solution was gently injected through the implant and into the sinus (Figure 4). Slight bleeding was noted in the retracted saline solution. This phenomenon served as a further indication that the implant tip penetrated the cortex. The blood was observed in the tubing upon stopping the injection or slightly draining fluid (Figure 5). Typically, 2 to 3 cm^2 of saline was

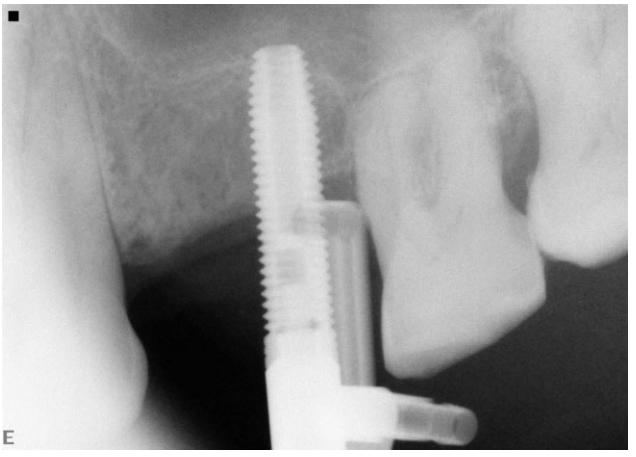

Figure 3 Sinus floor penetration.

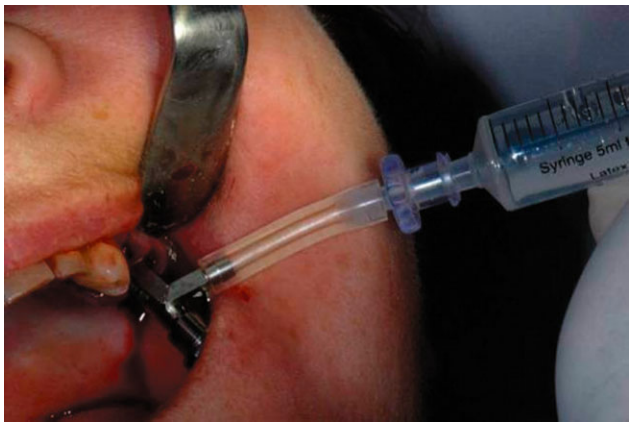

Figure 4 Introducing saline solution via the implant to lift the sinus membrane hydraulically.

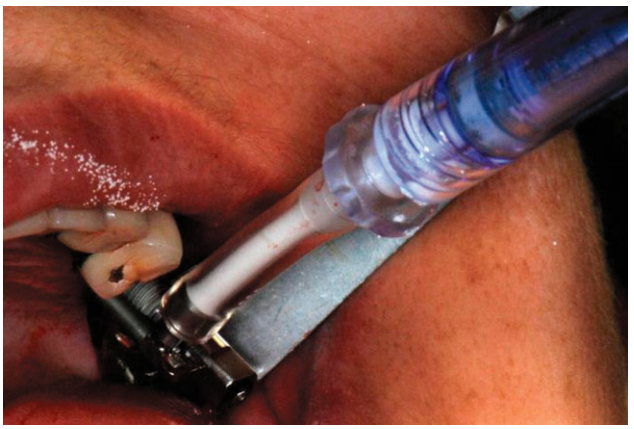

Figure 6 Introducing bone graft liquid into the sinus.

required, depending on the size of the sinus, the number of implants, and the required elevation. The saline solution was retracted back into the syringe and the saline syringe was disconnected from the tubing port. A flowable bone graft filled syringe was then connected to the tubing port. The desired volume of bone graft material was then slowly injected through the implant into the sinus (Figure 6). The amount of bone graft ranged from 1 to 3 cm^2, average 2.1 cm^2. The bone graft syringe was subsequently disconnected from the tubing port and then the applicator and tubing together were disconnected from the implant. The implant was then fully inserted through the osteotomy into the bone graft until the coronal aspect of the implant was aligned with the maxillary alveolar crest (Figure 7). The gingival flaps were then sutured. The patient was instructed to perform mouth rinsing 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): 3 × 500 mg amoxicillin for 7 days.

The primary outcomes of the study were the following:

- Safety of the procedure as determined by the lack of adverse events
- Success of the augmentation as determined by bone height gain

The occurrence of adverse events (during the implantation procedure or following implantation) related to the procedure was recorded. The integrity of the Schneiderian membrane was evaluated by the lack of nasal discharge of the injected saline fluid: the maxillary sinus is in direct communication with the nasal cavity through the antral ostium. This communication is

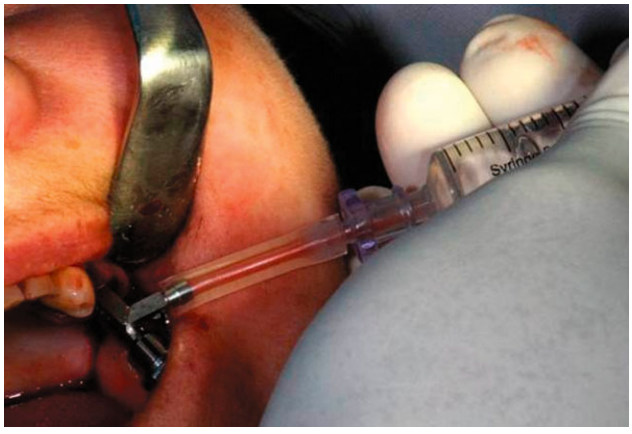

Figure 5 Blood observed in retracted saline solution.

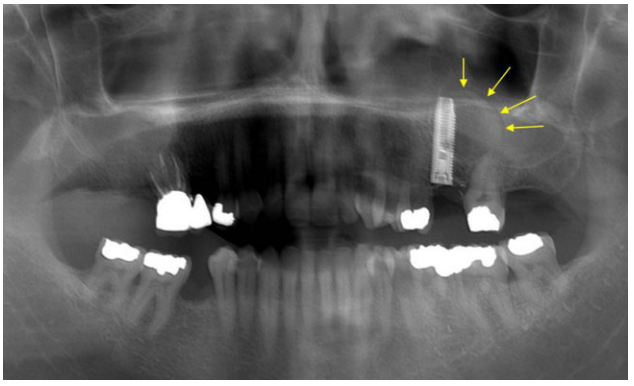

Figure 7 iRaise™ fully inserted within the osteotomy and the submembrane cavity. The cavity is filled with bone graft material, raising the membrane in a rounded shape.

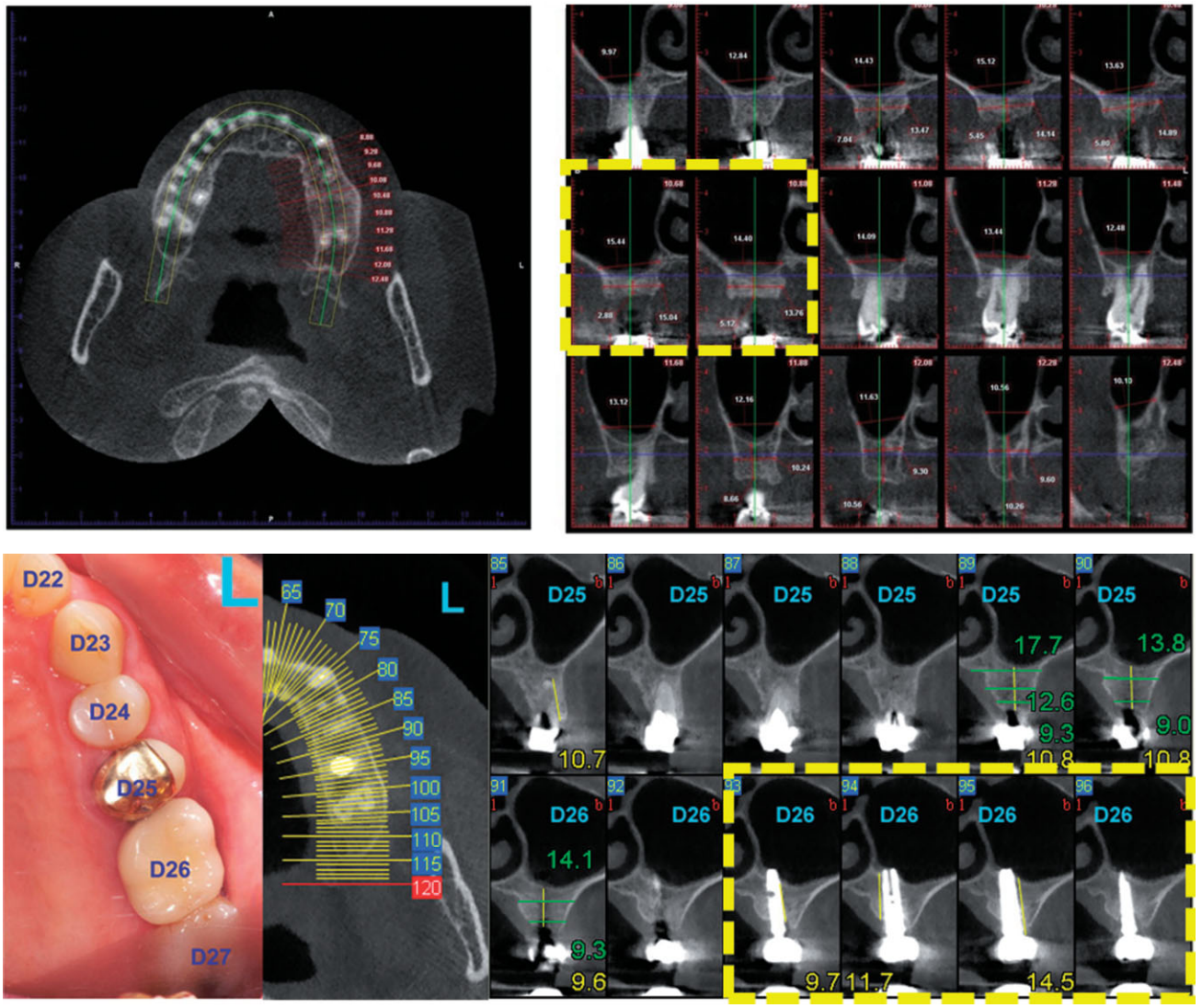

Figure 8 *Top*: preoperative Cone Beam Computed Tomography (CBCT) images – implant location marked by yellow outline. *Bottom*: CBCT images after final restoration, 19 months postoperatively.

further facilitated by the patient's reclining position. Therefore, in case of a breach in the integrity of the Schneiderian membrane, the saline fluid that is injected during the procedure will be identified by its discharge through the nose.

Additional outcomes included the following:

- Success/failure of the implantation procedure
- Success/failure of the inserted endosseous implants
- Clinical stability of the dental implant after 6 to 9 months
- Determining the height of bone augmentation, as measured by panoramic and/or computerized tomography radiographs (Figure 8)

RESULTS

Eighteen patients (8 males, 10 females) participated in the present study. Five patients (one male and four females) underwent bilateral procedures, so that a total of 23 procedures were performed. Age ranged between 38 to 72, average 52. Twenty-three sinus lift implants were inserted. Implant diameter was 4.2 mm (18 implants) or 5 mm (five implants). Implant length ranged between 14 and 17 mm, average 16.3 mm. Three different flowable grafting materials were utilized and included an allograft putty material[†] (five procedures),

[†]DBX by Musculoskeletal Transplant Foundation, Edison, NJ, USA.

an allograft gel[‡] (13 procedures), and an alloplast consisting of a mixture of hydroxyapatite and beta-tricalcium phosphate granules in a hydrophilic polymer solution[§] (five procedures).

Implant locations were the maxillary right first molar site (11 cases), the maxillary left first (one case) and second (one case) premolar sites, and the maxillary left first molar site (10 cases). The mean residual alveolar ridge height was 5.5 mm (range 4.0–7.0). The mean bone height gain at second-stage surgery was 11.2 mm, ranging between 9.0 and 13.0 mm, providing a total height of 14 to 19 mm with an average of 16.7 mm. The cases were evaluated after 6.7 to 13.1 months with an average of 8.7 months (note that in some cases, the second stage occurred at a later time frame than the 6 to 9 month specified in the protocol, due to patient availability).

All procedures were completed successfully, with elevation of the sinus membrane and insertion of bone graft and the dental implant at the planned site. No membrane tears were noted. No intraoperative or postoperative adverse events were observed in any of the cases. The patients did not require any unusual postoperative care such as additional pain control medication or medication for swelling beyond what is generally used for implant placement without sinus elevation or bone grafting. Furthermore, there were no postoperative emergency or distress calls.

All patients underwent second-stage implant surgery. All exposed implants achieved clinical stability.

DISCUSSION

This study reports on the outcome of a minimally invasive, single-appointment procedure for maxillary bone augmentation and implant placement. The procedural goals of this modification of the osteotome technique were met: sinus augmentation and implant placement in a prospective cohort of patients treated without any major procedural-related complications in a consecutive patient population. Taking into account the successful clinical outcomes and lack of adverse events, this study supports a very high benefit to risk ratio. Furthermore, the clinical experience in the two-center study supports an expanded study of the use of this implant and procedure in a larger patient population. No specific concerns or special precautions were identified during the course of the current experience that would suggest concerns for patients or at-risk groups of patients that would meet the current inclusion/exclusion criteria. Because the mean preprocedural bone height in this series was equal to or greater than 4 mm, there are no data regarding the applicability of this technique in extremely thin and atrophic (eggshell) maxillary bone.

The 23 procedures yielded satisfactory bone augmentation without patient complication. However, follow-up was over a relatively short-time period of 6 to 9 months following implant placement. Longer-term follow-up is required to evaluate the ability of the implants placed in this procedure to support longer-term functional loading. All procedures were performed under local anesthesia and no patients required an unusual course of postoperative analgesia. Therefore, the use of this technique eliminates some of the complications and discomfort associated with the traditional lateral window sinus graft procedure[4,8–13] and has the potential to shorten the time to implant exposure and loading due to the simultaneous placement of bone graft and endosseous dental implant.

A recent meta-analysis[15] regarding the osteotome technique concluded that "short-term clinical success/survival of implants placed with an osteotome sinus floor elevation technique seems to be similar to that of implants conventionally placed in the partially edentulous maxilla." These authors implied that prospective clinical trials are required to evaluate the long-term outcome of the traditional osteotome technique similar to what will be required for this modified osteotome technique. Another minimally invasive sinus lift procedure performed with a hydraulic sinus condensing technique had favorable results in a single-center study but appears not to have been widely accepted.[3]

The 23 cases performed in this patient cohort resulted in no detectable membrane perforation and no unusual adverse events. The mechanical properties of the Schneiderian membrane may explain the lack of detectable membrane perforation in the present study. Pommer and colleagues and Pommer and Watzek have demonstrated in human cadavers that the Schneiderian membrane is perforated at a mean tension of 7.3 N/mm^2, while the pressure exerted manually with saline in a 5-cm^2 syringe is limited to approximately 0.2 N/mm^2 (two atmospheres); thus, the risk of membrane perforation appears to be extremely low.[16,17] Therefore, this

[‡]Grafton™ DBM Gel by Osteotech Inc., Eatontown, NJ, USA.
[§]MBCP Gel by Biomatlante s.a., Vigneux de Bretagne, France.

technique using a specially designed implant, where the advantage of an osteotome technique is combined with an advantage of a lateral window technique, appears to be a safe and effective way to execute an antral membrane elevation and posterior maxillary bone augmentation. Relative to a lateral window procedure, the current technique appears to be minimally invasive. The patients in this two-center prospective consecutively treated population experienced minimal discomfort and the patients were able to be functionally restored in a shorter time period than patients treated with a two-stage sinus grafting technique.

CONFLICT OF INTEREST STATEMENT

This study was supported by a grant from Maxillent Ltd, Herzliya, Israel. Drs. Barbu and Slavescu report no financial relationships related to any products involved in this study. Dr. Better serves as the medical director of Maxillent. Drs. Cochran and Chaushu are on the scientific advisory board for Maxillent.

REFERENCES

1. Summers RB. A new concept in maxillary implant surgery: the osteotome technique. Compendium 1994; 15:152, 154–156, 158 passim; quiz 162.
2. Tatum H, Jr. Maxillary and sinus implant reconstructions. Dent Clin North Am 1986; 30:207–229.
3. Chen L, Cha J. An 8-year retrospective study: 1,100 patients receiving 1,557 implants using the minimally invasive hydraulic sinus condensing technique. J Periodontol 2005; 76:482–491.
4. Katranji A, Fotek P, Wang HL. Sinus augmentation complications: etiology and treatment. Implant Dent 2008; 17:339–349.
5. Solar P, Geyerhofer U, Traxler H, Windisch A, Ulm C, Watzek G. Blood supply to the maxillary sinus relevant to sinus floor elevation procedures. Clin Oral Implants Res 1999; 10:34–44.
6. Raghoebar GM, Timmenga NM, Reintsema H, Stegenga B, Vissink A. Maxillary bone grafting for insertion of endosseous implants: results after 12–124 months. Clin Oral Implants Res 2001; 12:279–286.
7. Garg AK. Augmentation grafting of the maxillary sinus for placement of dental implants: anatomy, physiology, and procedures. Implant Dent 1999; 8:36–46.
8. Raghoebar GM, Batenburg RH, Timmenga NM, Vissink A, Reintsema H. Morbidity and complications of bone grafting of the floor of the maxillary sinus for the placement of endosseous implants. Mund Kiefer Gesichtschir 1999; 3 (Suppl 1):S65–S69.
9. Regev E, Smith RA, Perrott DH, Pogrel MA. Maxillary sinus complications related to endosseous implants. Int J Oral Maxillofac Implants 1995; 10:451–461.
10. Schwartz-Arad D, Herzberg R, Dolev E. The prevalence of surgical complications of the sinus graft procedure and their impact on implant survival. J Periodontol 2004; 75:511–516.
11. Testori T, Wallace SS, Del Fabbro M, et al. Repair of large sinus membrane perforations using stabilized collagen barrier membranes: surgical techniques with histologic and radiographic evidence of success. Int J Periodontics Restorative Dent 2008; 28:9–17.
12. Mardinger O, Poliakov H, Biteltum I, Nissan J, Chaushu G. Patient's perception of recovery after sinus floor augmentation – a prospective study. J Periodontol 2009; 80:572–576.
13. Levin L, Herzberg R, Dolev E, Schwartz-Arad D. Smoking and complications of onlay bone grafts and sinus lift operations. Int J Oral Maxillofac Implants 2004; 19:369–373.
14. Jensen OT. The sinus bone graft. 2nd ed. Hanover Park, IL: Quintessence Publishing (IL), 2006; ISBN: 0867154551.
15. Emmerich D, Att W, Stappert C. Sinus floor elevation using osteotomes: a systematic review and meta-analysis. J Periodontol 2005; 76:1237–1251.
16. Pommer B, Unger E, Sütö D, Hack N, Watzek G. Mechanical properties of the Schneiderian membrane in vitro. Clin Oral Implants Res 2009; 20:633–637.
17. Pommer B, Watzek G. Gel-pressure technique for flapless transcrestal maxillary sinus floor elevation: a preliminary cadaveric study of a new surgical technique. Int J Oral Maxillofac Implants 2009; 24:817–822.