Case Series

Minimally Invasive Antral Membrane Balloon Elevation: Report of 36 Procedures

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Background: *The posterior maxillary segment frequently has insufficient bone mass to support dental implants. This registry evaluated the feasibility and safety of minimally invasive antral membrane balloon elevation (MIAMBE), followed by bone augmentation and implant fixation.*

Methods: *Thirty-six consecutive patients referred for posterior maxillary bone augmentation underwent alveolar crest exposure and implant osteotomy followed by MIAMBE (>10 mm). Fibrin and bone particles were injected beneath the antral membrane, implants were placed into the osteotomies, and primary closure was executed at the same sitting.*

Results: *All 36 patients successfully concluded the procedure with no significant procedural complications or discomfort. Procedure time was 48 ± 15 minutes. Incremental bone height consistently exceeded 8 mm, and implant survival of 97% was observed at 6 to 8 months.*

Conclusions: *MIAMBE resulted in high procedural success and satisfactory bone augmentation implant survival and complication rates. Because it is minimally invasive, this procedure may be an alternative to the currently used surgical methods.* J Periodontol 2007;78:2032-2035.

KEY WORDS

Dental implants; maxillary sinus.

Candidates for dental implants of the posterior maxillary segment frequently have insufficient bone mass to support the implants.[1] Traditionally, clinicians have used two approaches to perform bone augmentation in the inferior aspect of the maxillary sinus: the lateral maxillary window approach (“hinge osteotomy”) and the “osteotome technique,”[2] also called bone-added osteotome sinus floor elevation. The latter approach yields a modest bone height increment that can be estimated according to the initial bone height.[3] Moreover, this procedure can be complicated by membrane perforation and tear,[4] which can be minimized with expert technique and dedicated instrumentation.[5] Lateral maxillary window offers a satisfactory average implant survival of 91.8% (ranging from 61.7% to 100%).[6] Compared to the minimally invasive methods, the major shortcomings of this method are potential nerve and vascular injury, requirement of high surgical skills, and patient discomfort. Lateral bone fenestration[7] has limitations similar to hinge osteotomy. Minimally invasive antral membrane balloon elevation (MIAMBE) is a modification of the osteotome technique initially attempted 3 years ago.[8] The MIAMBE is executed via an osteotomy site ≤3.5 mm. This article summarizes the initial experience with this method using non-commercial dedicated prototype equipment.

MATERIALS AND METHODS

Patients

The registry included 36 consecutive patients (mean age: 42 ± 9 years) with edentulous posterior maxillary segment and insufficient bone mass who were referred for bone augmentation and treated between June 2004 and October 2005 in a specialized dental clinic in Petah-Tikva, Israel. Twenty-eight percent were smokers; 50% were female. Baseline bone height was 3.4 ± 2.1 mm. Patients received an explanation of the procedure and signed an informed consent. This was a second cohort treated with MIAMBE.

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Materials

A MIAMBE device (non-commercial prototype) was used in this study. This is a stainless steel tube that connects to the dedicated inflator on its proximal end; it has a screw-in mechanism, which secures the device into the osteotomy site, on its distal end. The balloon is concealed in the distal end until it is inflated (Fig. 1A). Other materials used included a dedicated bone transplant injector; coronary angioplasty inflation syringe‖ filled with diluted contrast material¶ that allows inflation pressure monitoring; autologous platelet-rich fibrin obtained by centrifugation of 40 ml autologous blood divided into four test tubes and centrifuged for 10 minutes at 2,700 rpm; synthetic bone graft;# autologous bone particles collected during drilling by bone filter; and gel.**

Study Protocol

Preprocedural computerized tomography (CT) and panoramic radiographs were used to assess mucosa thickness and pathology, bone height and thickness, sinus structure, and major blood vessels. Periapical radiographs were made before the procedure was initiated.

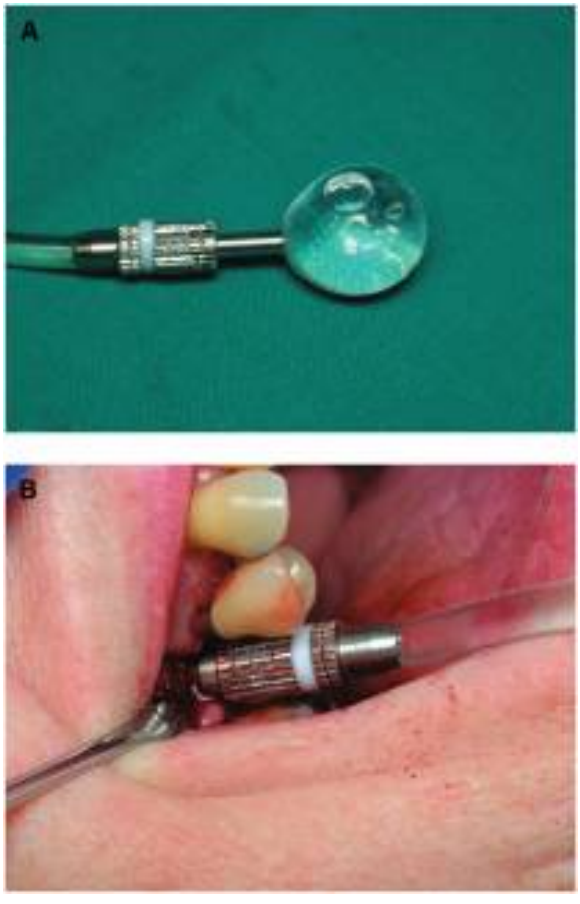

Figure 1.
A) *MIAMBE device with balloon inflated.* ***B)*** *MIAMBE device in vivo fixation.*

A preprocedural non-steroidal anti-inflammatory agent and amoxicillin and clavulanate potassium, 875 mg twice daily, were initiated 24 hours prior to the procedure.

Nitrous oxide and oxygen inhalation sedation were administered if the patient consented. Local anesthesia (infiltration of posterior superior alveolar nerve and greater palatine nerve) was performed with articaine 4%.†† Forty milliliters of the patient's blood was obtained by venous puncture and processed to obtain platelet-rich fibrin. A horizontal full-thickness flap with palatal bias (to preserve keratinized tissue) was performed, followed by a minimal (2 to 3 mm) mesial vertical incision to expose the alveolar crest. An implant osteotomy (using a pilot drill of 2 mm reaching 1 to 2 mm short of the sinus floor) was enlarged by sequential osteotome upsizing (number 1: 2.3 to 2.7 mm; number 2: 2.7 to 3.1 mm). The sinus floor was gently broken. After examining the integrity of the sinus membrane by Valsalva maneuver and direct visualization, the gel was injected to enhance lubrication.

The dedicated MIAMBE device was screwed in up to 0.5 mm superior to the sinus floor. The balloon was slowly inflated with the dedicated inflator-syringe using contrast media (50% contrast material diluted with normal saline) with inflating pressure not exceeding 2 atm (Fig. 1B). The balloon inflation and sinus floor elevation were evaluated by sequential periapical radiographs. Once the desired elevation (usually >10 mm) was obtained, the balloon was deflated. A second test of membrane integrity was done as mentioned above. A mix of autologous fibrin (obtained from the patient's centrifuged blood), bone particles (collected by suction), and synthetic bone speckles‡‡ was injected with a dedicated syringe under the elevated antral membrane. After bone transplantation, implants of 3.75 to 5 mm in diameter were screwed in via osteotomies, and primary closure was performed. Drilling osteotomy and bone implantation were repeated in adjacent areas to optimize results. Patients were discharged with celecoxib 200 mg (single dose) for pain relief and amoxicillin and clavulanate potassium, 875 mg twice daily for 7 days. Sutures were removed within 7 days. At 6 months postprocedure, follow-up CT and panoramic and periapical radiographs were performed; prosthetic rehabilitation was initiated 3 weeks after implant exposure.

Study Endpoints

This registry's feasibility and efficacy primary endpoint was successful conclusion of the initial procedure (including >10 mm antral membrane elevation, bone

‖ Merit Medical, Galway, Ireland.
¶ Ultravist 370, Schering, Berlin, Germany.
# Bi-Ostetic, Berkeley Advanced Biomaterials, San Leandro, CA.
** Fisiograft, GHIMAS, Casalecchio di Reno, Italy.
†† 3M ESPE DENTAL, Seefeld, Germany.
‡‡ Bi-Ostetic, Berkeley Advanced Biomaterials.

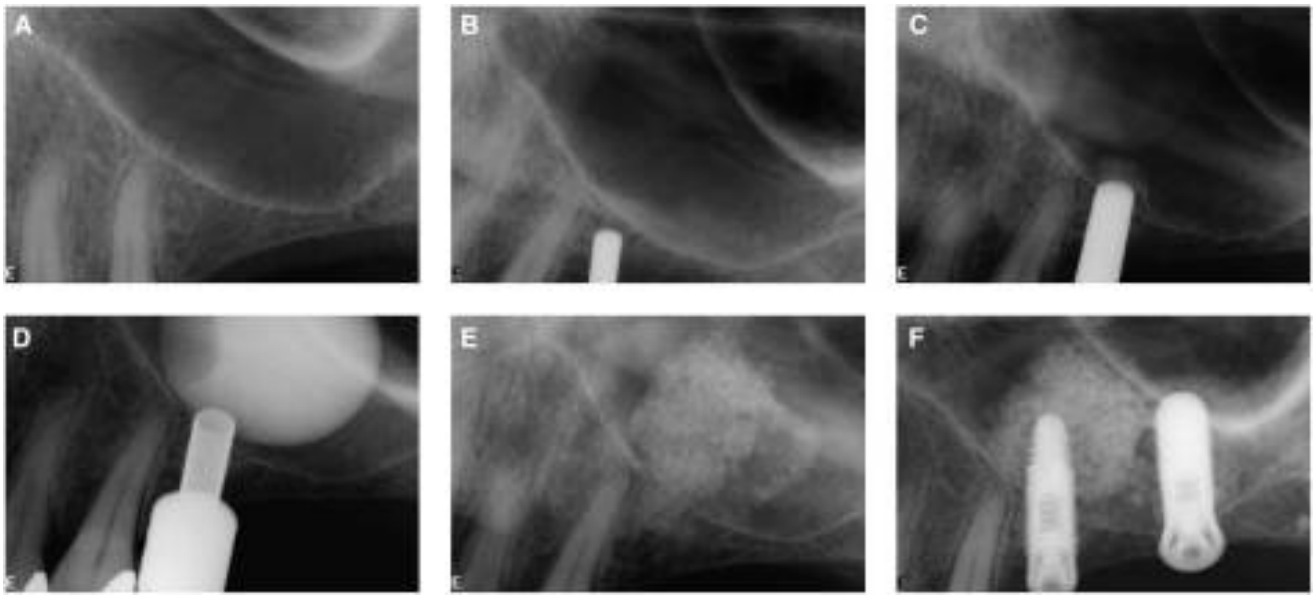

Figure 2.
Radiographs showing the MIAMBE procedure. ***A)*** *Preprocedural.* ***B)*** *Drilling.* ***C)*** *Osteotome.* ***D)*** *Balloon inflation.* ***E)*** *Bone transplantation.* ***F)*** *Implant fixation.*

grafting, and implant fixation). The primary safety endpoint was major complications (including severe bleeding, infection, nerve injury, and prolonged [>7 days] disability). Procedure time, implant failure, and bone height at 6 months also were monitored.

RESULTS

Primary Endpoint: Procedural Success

Primary procedural success was accomplished in 35 of the 36 patients (97.2%) (Table 1). One procedure was modified because of minor membrane tear, and was executed successfully using an alternative osteotomy site at the same sitting. No other complications or adverse events were recorded.

Secondary Endpoints

The procedure time was 48 ± 15 minutes. Only two of 72 implants failed (1 and 3 weeks after the procedure) during the minimal follow-up of 6 months. Patients needed very little medical attention: no patient required additional pain control medication or medication for swelling alleviation. There were no postprocedural emergency or distress calls.

Demonstrative Case

Figure 2 illustrates the step-by-step, technical aspects of the procedure.

Table 1.

Results of 36 Patients Undergoing MIAMBE

	Current Study
Primary procedural success (%)	97.2
Major complications (%)	0
Initial bone height (mm; mean ± SD)	3.4 ± 2.1
Final bone height (mm; mean ± SD)	12.9 ± 3.5
Final bone height, range (mm)	8 to 18
Implants per patient (N; mean ± SD)	1.81 ± 0.41
Implant diameter, range (mm)	3.75 to 5
Implant length, range (mm)	13 to 17.1
Minor complications	1 membrane tear
	2 implant failures
Procedure time (minutes; mean ± SD)	48 ± 15
Rejected implants at 6 months (N)	2
Implant exposure and rehabilitation at 6 to 8 months (%)	100
Follow-up (months; mean ± SD)	13 ± 6

DISCUSSION

This study reports on a minimally invasive, single-sitting procedure for maxillary bone augmentation and implant placement. The procedural goals of this modification of the osteotome technique were met: procedural success approaching 100%, without any major procedural-related complications in a non-selective cohort.

Although no patients were excluded, previous sinus surgery is a relative contraindication to all antral membrane elevation methods. With the MIAMBE method, we successfully treated patients with septum in the maxillary sinus, which has a relatively higher rate of membrane tear in surgical series. Because the mean preprocedural bone height in this series was 3.4 mm, there are not sufficient data regarding the efficacy of this method (or any other any maxillary bone augmentation method) in extremely thin and atrophic (eggshell) maxillary bone.

The procedure yielded satisfactory bone augmentation, which resulted in acceptable implant durability at 6 months. This procedure is highly successful and has a relatively short learning curve. Moreover, the procedure is not time or resource consuming.

This procedure eliminates the complications and discomfort associated with traditional hinge osteotomy and has the potential to abbreviate the time to implant exposure and functionality.

Soltan and Smiler[7] described antral membrane balloon elevation via a lateral bone fenestration. That approach is not minimally invasive. The investigators stated (but do not substantiate with any data) that this modification of hinge osteotomy is "... highly successful, and predictable, and is likely to reduce pain, bleeding, infection, and other morbid symptoms often associated with sinus lift procedures."

Another minimally invasive method has been subjected to considerable research; the osteotome technique yielded a very modest and somewhat variable extent of bone regeneration. This method is clearly inferior to the lateral window approach if the initial height is ≤4 mm.[9] The osteotome technique, even when applied selectively[10] and endoscopically controlled, yields modest antral membrane elevation, requires considerable skills, and frequently may result in membrane tear.[3] A recent meta-analysis[11] 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 investigators implied that prospective, randomized clinical trials are required to evaluate the long-term outcome and various surgical modifications of the osteotome technique. Other minimally invasive methods, such as the hydraulic sinus condensing technique, had favorable results in a single-center study[12] but have never been accepted widely.

CONCLUSIONS

MIAMBE seems to have a high procedural success, a low rate of membrane perforation, and a very acceptable complication rate. It seems to be a safe and effective way to execute antral membrane elevation and posterior maxillary bone augmentation. The procedure truly is minimally invasive, is associated with minimal discomfort and disability, probably requires a relatively short learning curve, and provides the patient with early functional implants.

ACKNOWLEDGMENTS

Dr. Efraim Kfir has patented and developed the MIAMBE modification of the osteotome technique; the described device is not under any commercial manufacturing or use. This report was not supported by any external funding.

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