

NON-GRAFTED MAXILLARY SINUS LIFTING TECHNIQUE UTILIZING THERMOPLASTIC BIORESORBABLE SPACE MAINTAINING MESH

Mamdouh Sayed Ahmed *

ABSTRACT

Non-grafted maxillary sinus floor elevation which is based on the concept of membrane elevation and support either by tenting technique or space maintaining mesh solved the problem of maxillary sinus pneumatization by creating a space for new bone formation with subsequent implant placement in the edentulous posterior maxilla. The aim of this study is to evaluate the predictability of new bone formation after sinus floor elevation using a bioresorbable mesh. Eight patients with sinus pneumatization were selected for implant placement in the edentulous posterior maxilla. Pneumatized sinuses were approached through lateral window technique and the membrane was elevated and sustained with a bioresorbable mesh. All patients were clinically and radiographically evaluated immediately and at 6 months postoperatively. At six months post-operatively, core bone biopsy was performed for histological examination of the formed bone using a trephine drill at the planned implant position. All patients showed uneventful healing and radiographic, clinical and histological evidence of new bone formation and it was concluded that the bioresorbable mesh was reliable and predictable as a space maintaining device.

KEYWORDS: Maxillary sinus, non-grafted sinus lifting, implant, resorbable mesh.

INTRODUCTION

Implant placement in an atrophic maxilla is considered a clinical problem, since bone augmentation is important to allow implant placement with sufficient number and length. The insufficient maxillary bone volume is normally a consequence of ongoing maxillary sinus pneumatization and remodeling of the alveolar bone. Maxillary sinus floor augmentation with

autogenous bone is considered a well established method^[1-3]. However, bone grafts harvested from different sites of the skeleton are accompanied with postoperative morbidities like bruising, swelling, pain, and functional problems at the donor site^[1-6]. Several minimally-invasive surgical methods have also been introduced for maxillary sinus augmentation to limit the morbidity starting at regional autograft, and ending with allogenic, xenogeneic, and alloplastic materials^[7-10].

* Assistant Professor of Oral and Maxillofacial Surgery, Oral and Maxillofacial Surgery Department, Faculty of Oral and Dental Medicine, Cairo University.

In contrast, a number of recent studies described maxillary sinus floor augmentation by simple non-grafted sinus floor elevation utilizing implants to support the elevated membrane without the use of any grafting materials [11-21]. In these studies, the sinus was approached through a lateral window and the membrane was dissected and elevated creating a space for blood clot formation and organization. Implants were then installed through the residual crestal bone to be extended into the maxillary sinus to support and maintain the elevation of the sinus membrane. These Studies have shown that there is a great potential for healing and bone formation in the maxillary sinus without the use of bone grafts or bone substitutes. Bone formation also occurred when closed sinus floor elevation was performed using a transalveolar osteotome technique without placing any graft material in the maxillary sinus [8, 22-24].

The pioneer work of Lundgren et al., in 2004 showed that the elevation of the Schneiderian membrane alone and its stabilization with implants resulted in new bone as the highly vascular, osteogenic potential of the membrane and the antral walls together with scaffold blood clot play an important role in that process. Since the results of non-supported sinus membrane elevation showed collapsed membrane into the created space and limited amount of bone gain, several attempts were made to ensure fixed sinus membrane elevation using titanium screws, resorbable device, hollow hydroxyapatite device, and titanium mesh [14, 25-28].

A space maintaining resorbable or non-resorbable devices for sinus floor elevation were an innovative techniques that aimed to keep the sinus membrane lifted in place for a long term allowing a stable blood clot formation during the postoperative healing stage [15]. The different studies supported non grafted sinus floor elevation technique using different space-maintaining devices opened the door for the present study to evaluate radiographically

and histologically the predictability of new bone formation after sinus floor elevation using a thermoplastic bioresorbable mesh [25-28].

MATERIALS AND METHODS

Inclusion criteria

A prospective study was conducted on a consecutive series of 8 patients that had atrophic edentulous posterior maxilla with maxillary sinus pneumatization. Maxillary sinuses had to be free from any local pathosis or previous sinus surgery. All patients had partial or complete edentulous posterior maxillary ridges and the distance between the crest of the ridge and the floor of the sinus in areas planned for future implantation had to be less than 3 mm. All the patients were entailed about the risk and benefits of the procedure, and approved their participation in written consent.

Materials

A stock of 0.3 mm thickness bioresorbable mesh (Resorb RX, KLS Martin, Germany) (PDLA) (Poly-D and L-Lactic Acid). A stock of bioresorbable sonic pins and ultrasound welder were utilized [Fig.1A-1B]. A stock of bioresorbable (lyophilized) collagen membrane (Biocollagen, Bioteck, Torino, Italy) and titanium tags for its fixation, Xcelsior water bath device. Schilli Implantology Circle implants (SIC invent AG, Basel, Switzerland).

Preoperative preparation and radiographic examination

A thorough preoperative assessment of all patients was carried out, including history-taking and clinical and radio-graphic examinations (Panoramic and cone beam computed tomography (CBCT) (SCANORA 3D with Auto- Switch; Soredex, Helsinki, Finland) replaced with, with exposure parameters of 85 kVp, 15 mA, and 6 cm field of view (FOW). The preoperative CBCT were performed while the patients were wearing

a radiographic/surgical stent for a standardized surgical planning and follow-up radiographic measurements. A second Implant surgical stent was fabricated by using specific implant sleeves seated on the ridge of the cast in the planned positions of the implants. [Fig.1A-C]

Surgical procedures

1st Surgical Stage (Non-grafted Sinus Lifting)

All patients were instructed to use povidine iodine mouth rinse (Betadine) before the surgical procedures. All procedures were carried out under posterior superior alveolar nerve block and infiltration anaesthesia with mepivacaine hydrochloride and 1:200,000 adrenaline solution (Scandonest 2%; Septodont, France). Maxillary sinus floor elevation using lateral window technique was performed for each patient. A Full thickness mucoperiosteal trapezoidal flap was reflected to expose the lateral wall of the maxilla according to the pre-determined implant treatment plan and fabricated first surgical stent [Fig. 2A]. A round diamond bur was utilized to outline both the inferior and superior horizontal osteotomies to carefully gain access to the Schneiderian membrane.

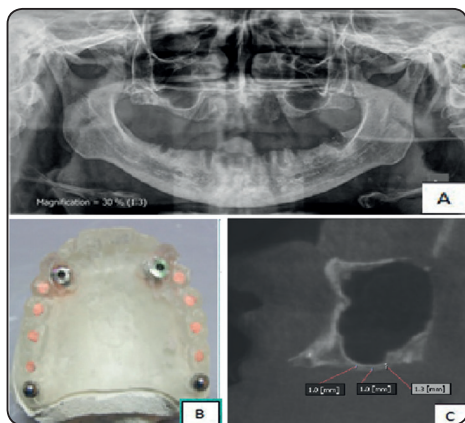


Fig. (1) (A) Pre-operative panoramic radiograph showing severe pneumatization of maxillary sinus, (b) transparent acrylic radiographic/ first surgical stent (c) coronal cut showing remaining alveolar crest 1.0 mm

The inferior osteotomy was approximately 3 mm from the sinus floor while the superior osteotomy was made at 15 mm from the crest. Once the window outline was completed, special sinus lift elevators were utilized to release the lateral bony window with the underlying Schneiderian membrane attached to it from the periphery of osteotomy outline to get a cleavage plane. It was therefore imperative that the membrane be elevated across the sinus floor and up to the medial wall to the level of the proposed implant length. A foil template was trimmed to fit into the superior boundary of the created sinus space reaching the medial wall of the sinus [Fig.2B].

The resorbable mesh was softened in Xcelsior water bath resorbable. The operating temperature range of 158 – 194F (70-90°C) was permitted for use. The mesh was cut guided by the foil template and shaped like S-shaped [Fig.2C]. In order to facilitate the insertion of the bioresorbable mesh and at the same time guaranteed wider Schneiderian membrane elevation, two v-shaped cutbacks were performed at the anterior and posterior margins of the mesh at the points of meeting with the lateral bony window margins which also eliminated the need for further enlargement of the lateral window [Fig. 2D].

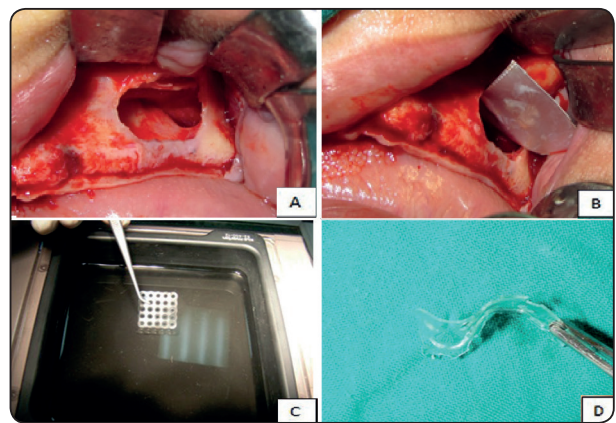


Fig. (2) (A) A clinical photograph showing the lateral window completely outlined. (B) A foil template for measuring superior dimension of the new sinus floor. (C) The Bioresorbable mesh while being softened in the Xcelsior water bath device. (D) Bioresorbable mesh after bending to the S-shape form.

The mesh was then fixed to the lateral wall of the maxilla above the superior osteotomy with resorbable sonic Pins 2.1x 4mm, by ultrasound (Sonic Welder) [Fig.3A-C]. resorbable (lyophilized) collagen membrane was utilized to cover the lateral window of the sinus [Fig. 3D], and was adjusted in place by nails then fixed using titanium tags. [Fig.3D] The soft tissue flap was readapted and sutured using interrupted and matters sutures (3-0 resorbable vicryl).

2nd surgical Stage (Implant Insertion)

All patients were re-called 6 month post-operatively for implant insertion. The patients were instructed to use povidine iodine mouth rinse (Betadine) before the surgical procedures. All procedures were carried out under posterior superior alveolar nerve block and infiltration anesthesia with mepivacaine hydrochloride and 1:200,000 adrenaline solution (Scandonest 2%; Septodont, France). A crestal incision was performed followed by a minimal mucoperiosteal flap elevation enough to expose only the crestal bone and avoiding flap extension over previous lateral sinus window. First, a core bone biopsy specimens were obtained from all the implantation sites using a trephine bur (2mm in diameter) guided by the implant surgical stent.

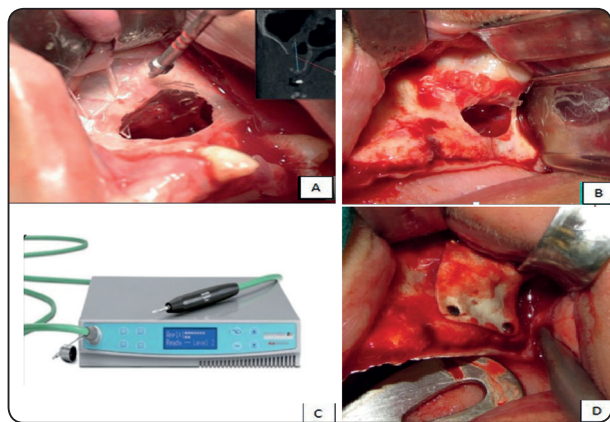


Fig. (3) (A, B) A clinical photograph showing drilling for fixation of the resorbable mesh. (c) ultrasound welder for fixation of the resorbable sonic pins. (D) covering of the lateral window with a collagen membrane stabilized with titanium tacks.

The specimens were collected in 10% formalin [Fig. 4A-B]. Secondly, a specific implant condensers were used for preparation of implant osteotomy sites instead of rotary surgical drills to improve bone quality and minimize bone removal. This was followed by installing a larger implant diameter than the final condenser to achieve a better primary stability [Fig. 4C-D]. Finally the flap was readapted and sutured and postoperative medications and instruction were prescribed for all patients.

Postoperative instructions

The patients were instructed to apply ice-packs over the surgical area for 20 minutes every hour for the next 6 hours immediate postoperatively and to rinse their mouth with warm saline solution starting on the second day avoiding any positive or negative pressure on the nasal cavity (e.g., nose-blowing, drinking using straw, spitting, and breathing down) for the first 24 hours especially after the sinus lifting surgical procedure.

Radiographic Assessment

During the follow-up period, CBCT scans were obtained immediately postoperative sinus lifting (within 1 week), and at six month immediately postoperative implant placement to evaluate bone regeneration along the sinus floor.

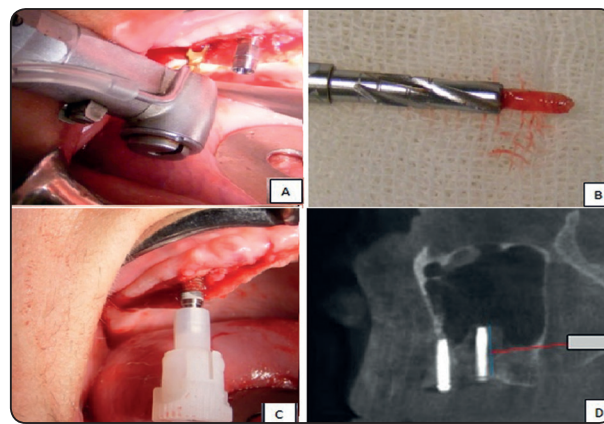


Fig. (4) (A) A clinical photograph showing the core biopsy harvesting from the sinus by using 2.0 mm trephine bur. (B) Core bone biopsy specimen.(c) implant insertion in the prepared osteotomy site. (D) Six month postoperatively dome shape bone built up.

Preoperative linear measurements of the residual alveolar bone height were measured from the alveolar crest to the sinus floor along all the radio-opaque markers (ROMs; gutta percha). Immediately postoperatively, the linear measurements were made along the same ROMs from the crest to the preserved buccal cortical plate of the lateral window that was became above the radiolucent resorbable mesh. At six month postoperatively, the regenerated bone height was measured from the crest to the level of regenerated bone "Bone gain". Volumetric measurements of new bone formation were calculated through measuring the difference between sinus volumes immediately and six months post-operatively. Based on the anatomical fact that the maxillary sinus is pyramidal in shape with an almost square base oriented medially and an apex located in the zygomatic bone, the sinus volume was geometrically calculated by the following equation: Volume of the maxillary sinus Pyramid = Base Surface Area x 1/3 Height =

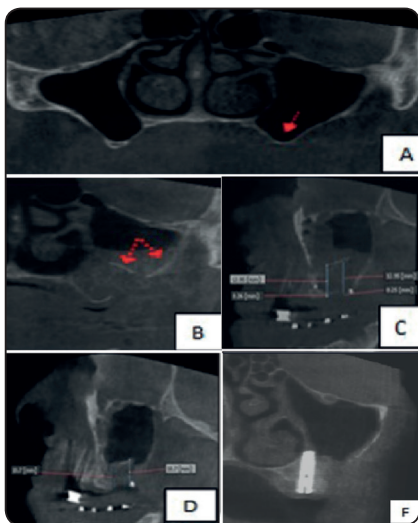


Fig. (5) (A) Preoperative coronal snapshot showing sinus pneumatization and alveolar bone resorption leaving only the cortex, alveolar height is less than 2.0 mm. (B-C) Immediately postoperative sagittal and coronal snapshots showing radiopaque shadows filling the sinus with preservation of the buccal cortical plate of the lateral window (red arrow). (D-F) Six months postoperative snapshots showing regenerate bone height and implant placement.

(Antro-posterior (Depth) x Cranio-caudal (Width) x Medio-lateral (Height))/ 3

Histological and Histomorphometric Assessment

The obtained bone biopsy was then decalcified and processed according to a standardized protocol of Ethylene di amine tetra acetic acid (EDTA) and formic acid combination. Then specimens were embedded longitudinally into paraffin blocks and oriented in a standardized way for labeling. The blocks were cut into longitudinal 5 micro-mm thick section using a manual rotary microtome, and stained with Mayer's hematoxylin and eosin stain (H&E) for histological analysis. The percentage area of bone trabeculae was estimated using Leica Quin 500 analyzer computer system. The cursor was used to outline the areas of bone trabeculae, which were then masked by a blue binary color that could be measured by the computer. The image analyzer was calibrated automatically to convert the measurement units (pixels) produced by the image analyzer program into actual micrometer units. The percentage area of bone trabeculae was estimated in 5 different fields on each slide using magnification (x200). Mean values of bone trabeculae and standard deviation were calculated.

Statistical Analysis

The statistical analysis of the data was performed using SPSS (Statistical package for the social sciences). Data were represented as mean + standard deviation. One sample Kolmogorov-Smirnov test (K-S) was used to examine the normality of data distribution. In all tests result were considered statistically significant if the p-value was equal to or less than 0.05.

RESULTS

This study included a total of 8 patients with atrophic edentulous posterior maxilla with sinus pneumatization (three males and five females) with an average age of 36 years (range 19–53 years) (Table 1).

TABLE (1) Showing the demographic characters of the studied patients.

Patient number	No. of Implants	Age	Gender
1	4	34	Female
2	4	53	Female
3	4	19	Female
4	4	38	Male
5	2	53	Male
6	3	32	Male
7	2	25	Female
8	2	28	Female

Clinical Findings

A total of 8 sinus membranes had been elevated and sustained with a bioresorbable mesh fixed superiorly to the lateral maxillary wall with resorbable pin and the lateral sinus window was covered with collagen membrane. One case showed bleeding during outlining the lateral window which was controlled intraoperatively by application of a gentle pressure. Another case showed Schneiderian membrane small perforation during early dissection of the membrane which was managed by careful dissection around the perforation and folding the rest of the membrane over this small perforation. The early postoperative follow up went uneventful without any complication regarding infection, dehiscence, mesh exposure, or bleeding, with only minimal tenderness at the site of surgery. The wound had completely healed after 7 to 10 days when the sutures were removed. Patients were clinically assessed on regular bases with the following intervals one day, 1week, 2week, 1month, 3month and 6month post-operatively till construction of the final restoration with no signs or symptoms of tenderness, sinusitis, or mesh exposure in all the

cases. All core bone specimens harvested from the planned implant sites showed adequate rigidity during harvesting and during retrieval from the trephine drill. A total of 15 implants were placed in the eight elevated sinuses at the planned implant sites according to pre-operative work-up without intra-operative complications and all implants showed a adequate primary stability during its installation.

Radiographic Results

Preoperative CBCTs of all patients showed severe maxillary sinus pneumatization reaching the alveolar crest leaving the alveolar bone almost as cortical shell with no trabecular pattern at the sites intended for implant insertion (1 to 2 mm, mean 1.5mm) [Fig. 5A].

Immediate postoperatively, a radiopaque shadow filling the sinus (suggesting hematoma formation) was seen in all cases above and below the meshes level, with variable size haphazardly distributed radiolucent shadows were seen within the filling defects of hematoma. A thin radiopaque line representing the buccal cortical plate of the lateral bony window (trap door) was revealed. The trap door was short from the medial wall of the sinus making a V shape outline with the zygomatic buttress [Fig. 5B-C]. Six months postoperatively, bone regenerate appeared as a flat or concave radiopacity [Fig. 5D-F]. Post-operative regenerated bone height showed elevation of Schneiderian membrane from 9.5mm to 18.9 mm; with the mean was $14.3\text{mm} \pm 3.23\text{mm}$ immediately and 9.5mm to 19.5 mm, with the mean was $13.88\text{ mm} \pm 3.52\text{ mm}$ six months postoperatively. (Table 2) [Fig. 6A]

Histological Results

Clinical interpretation of the retrieved core bone biopsies showed that the entire core was regenerate bone formation. The H&E examination under Light Microscope (LM) for all section of the core biopsies revealed the following; the sections were impressive for new vascularization in the

form of small capillary and small caliber blood vessel, mostly arteriolar in nature. New cortical bone formation was evident surrounded actually by osteoblastic rimming, and also the presence of large lacunae in the bone spicules. The bone trabeculae were interconnected through the entire length of the core from the mucosal to the sinus side. No presence of inflammatory cells were seen in all sections. The marrow spaces were all vascular. There was no

evident of original native bone from the apical view of the course examination, i.e. the entire core had neither old Haversian system, nor course woven bone differentiation. Multiple osteoblastic bone cratering was seen. In capping of the bone specimen newly formed spicules had been remodeled, the fibro collagen septation had plumb fibroblastic infiltration around most of marrow spaces [Fig. 6B].

TABLE (2) Showing the descriptive statistics of the bone height.

	Min	Max	Mean +/- St.Dev	P value
Preoperative	1	2.1	0.32 +/- 1.2	0.001
Post-operative	9.5	18.9	3.2 +/- 14.3	
6 months	9.5	19.5	3.5 +/- 13.88	

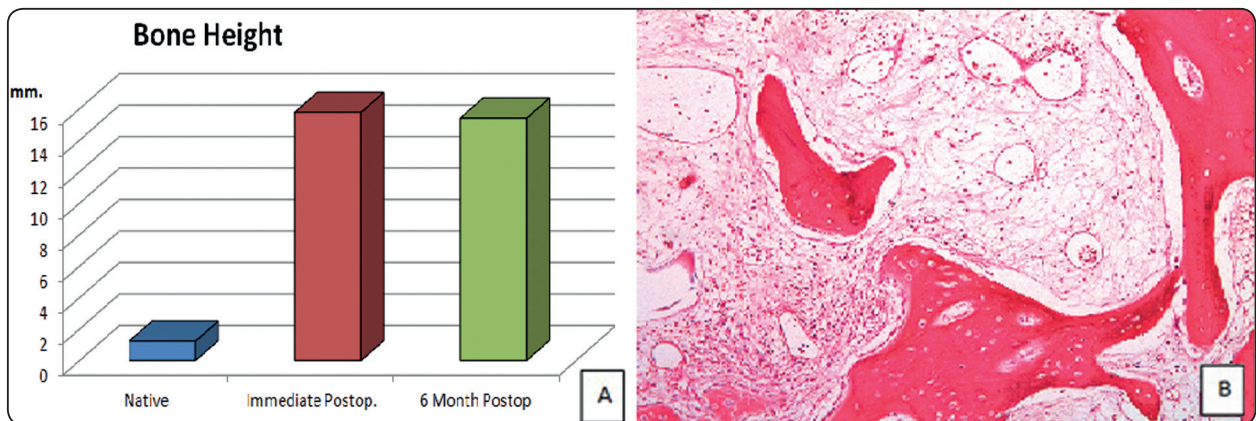


Fig. (6) (A) Graph showing the gained bone height immediately and 6 months postoperatively. (B) A photomicrograph of the regenerated bone inside the resorbable mesh (H&E-X100).

DISCUSSION

Non grafted maxillary sinus. Floor elevation techniques eliminate the need for different types of grafting materials with their associated complications as donor site morbidity regarding autogenous bone grafts or delayed resorption with subsequent limitation of implant osseointegration regarding bone substitutes. The cumulative studies over the past two decades proved that the non-grafted sinus floor elevation with immediate implant placement “Tenting technique”, revealed limited new bone formation owing to the possibility of Schneiderian membrane collapse. This subsequently opened a door of new concept of non-grafted mesh sustained sinus membrane elevation which could be now given the name fixed tenting.^[19,21,29,30]

The resorbable mesh was chosen in the present study owing to the following advantages; first, it consists of poly D- lactide and L-lactide acid as both components are present in the same proportion, that allow a predictable and safe biological degradation process through hydrolysis without any signs or symptoms of irritation, inflammation or foreign body reactions. Second, it can be easily and flexibly adapted after insertion in the heating water bath, and once it's cooled down the material turns rigid again without any sharp edges if compared with titanium meshes, so this mesh can maintain its smooth S-shape after adaptation without any deformation.^[31,32]

The S-shape adaptation of the resorbable mesh guaranteed maximum elevation of Schneiderian membrane in relation to the level of the superior osteotomy of lateral window, and thus preserving lateral sinus wall and allowed insertion of longer implants (14.5 mm).

Resorbable mesh fixation using resorbable sonic pins and ultrasound welder guaranteed its maximum stability for longer time if compared with other resorbable space maintaining devices giving a

chance for blood clot accumulation in the statically created space with subsequent organization and new bone formation.^[25,26]

In the current study; Trap-door of the lateral bony window with elevation of the Schneiderian membrane from the floor and medial wall of the sinus was performed in all cases in order to guarantee complete supporting of the membrane till the medial wall and to be able to identify the trap door cortical bone (above the mesh) as a radiopaque reference line in the CBCT cuts for linear measurement of the elevated membrane immediately postoperative especially as this resorbable mesh is not radiographically visible in the CBCT cuts.

The incidence of perforation of the Schneiderian membrane in the present study was 12.5%. Various methods have been proposed to deal with this complication, from leaving them untreated, suturing of the Schneiderian membrane, and sealing with resorbable collagen membranes or fibrin glue. The reported incidence of perforation in the literature ranges from 10 to 60% of cases.^[33,34]

There are 3 arteries; all are ultimate branches of the maxillary artery that supply the maxillary sinus. The posterior superior lateral nasal artery is relatively close to the sphenopalatine artery and may anastomose with the facial or other nasal arteries. It can course intra-osseously in the medial wall of the sinus. This fact presents the theoretical potential for a significant bleeding complication during lateral approach sinus elevation surgery which was found in one sinus of this study. However, it positively increases the blood supply to the created sinus space that enhance the blood clot formation with subsequent new bone regeneration.^[16,35]

Blood clot preservation with subsequent new bone regeneration under the elevated sinus floor was governed by two factors. The first was the fixed tenting of the sinus membrane which played an important role in stabilization of the blood

clot volume and subsequent bone formation. This finding is in agreement with the findings of Xu et al., in 2005, who found that the newly formed blood clot decrease significantly in volume during the first weeks of healing, indicating the importance of the a fixed tenting of Schneiderian membrane to decrease its pumping pressure.⁽²⁹⁾ The second factor was the coverage of lateral window by collagen membrane which wasn't installed in the study of **Atef et al.**,^[28] that inversely affect his results if compared with that of the current study. This is also in agreement with findings of **Marinucci et al.**,^[37] who found that collagen membrane, enhance the secretion of type I collagen, TGF- b1 and alkaline phosphatase, and may promote bone regeneration through their activity on osteoblasts. Thus, it could be supposed that the good results are not only caused by the mechanical shielding of the lateral sinus window against the ingrowth of soft tissue, but are also due to membrane-specific features which support new bone formation regarding quality and quantity.^[36-37]

The observed neovascularization in histological examination was impressive for its accompaniment with significant neogenesis of particular bone lamellae. The bone lamellae were seen filling the entire core from the coronal end up to the depth of the sinus. These entire features indicate that there was an active process of bone formation and maturation. **Enlow** stressed that the sinus lining possessed a bone remodeling capability of depository and resorption reforms. However, the lack of osteoclastic activity in the bone sections of this study could be explained as that the increased depository effect of Schneiderian membrane was apparently obvious at that stage of bone (before implant loading).^[7,18,38-41]

The immediate post-operative CBCT have shown haphazardly distributed radiolucencies below the mesh. This was attributed to shrinkage of the formed blood clot during the first healing stage. However, the flat or concave radiopacity of

bone regenerate could be attributed to the laminar follow effect of air going in and out the sinus thus massaging the upper surface of regenerate bone (after complete degradation of resorbable mesh).

In the present study, the preoperative mean residual alveolar ridge height was 13.88 mm + mm, which means that the bone gain was multiplied 7 times. The mean volume of the regenerate bone in the current study was 54.36 + 15.94%. On comparing these results with the finding of Thore et al., and Atef et al.,^[28] were significantly higher. This may be attributed to the use of collagen membrane and the fact that the preoperative mean residual alveolar ridge height in their cases was 2 mm.^[28,30]

Finally, although this study was considered a continuation of the study of **Atef et al.**,^[28] in evaluation of the non-grafted sinus lifting techniques, a significant major differences were followed to move this technique further forward. These differences were as follow: using resorbable mesh as tendency for using biodegradable materials in the maxillofacial regions, coverage of the lateral window with a collagen resorbable membrane aiming to enhance bone regenerate quality, most importantly selecting cases with nearly resorbed alveolar ridge so that the retrieved bone core biopsy actually represent a total bone regenerate (no native bone) reflecting the predictability of this technique, and shaping of the mesh in the S-shape to ensure maximum ridge gain the center of the ridge for subsequent implant placement while simultaneously minimizing the dimensions of the lateral bony window. However, some question have been raised concerning the need for long term follow up of the regenerate bone, as after the complete degradation of the resorbable mesh, this bone will be exposed to the laminar follow effect of air going in and out sinus thus massaging the upper surface of regenerate bone that similar to the ebbing and tide forming waves on the water surface.

Finally the finding of this study showed that non-grafting sinus lift technique using space maintaining bioresorbable mesh is a reliable method of maxillary sinus augmentation. However, there is a need for long term follow up to evaluate maintenance of the bone regenerate after degradation of the bioresorbable mesh.

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Competing interests

The authors declare that they have no significant competing financial, professional, or personal interests that might have influenced the performance or pre-sentation of the work described in this manuscript.

Ethical approval

All patients were selected from the outpatient clinic of the Department of Oral and Maxillofacial Surgery, Faculty of Oral and Dental Medicine, Cairo University. The present study was approved by the Ethics Committee of the Faculty of Oral and Dental Medicine, Cairo University.

Patient consent

Written consent was obtained from all patients for the use of their clinical photographs as a scientific demonstration in this paper. All authors have viewed and agreed to the submission.

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