EVALUATION OF DIRECT SINUS LIFT USING TITANIUM REINFORED MEMBRANE ASSOSIATED WITH SIMULTENEOUS IMPLANT PLACEMENT

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ABSTRACT

INTRODUCTION : Various techniques for maxillary sinus augmentation have been utilized using different materials to improve the autogenous bone formation in maxillary sinus, enhancing proper positioning of dental implants.
OBJECTIVE: The aim of this study is to evaluate the sinus lift procedure using PTFE titanium reinforced membrane to maintain the space formed after schneiderian membrane elevation followed by simultaneous implant placement.
Patients and Methods: This case series was carried out on 12 patients with average age 52.3 years old with posterior maxillary bone 4-6 mm. Implants were placed immediately after sinus lift procedure and the sinus membrane was maintained in position using PTFE titanium reinforced membrane. Patients were followed up for 6 months clinically and radiographically.
RESULTS: All patients except one patient experienced pain and swelling few days after surgery which decreased gradually until completely disappeared one week postoperatively, this single case suffered from infection 3 months after surgery led to implant failure. All patients except the failed case showed a significant increase in bone height, bone density and implant stability.
CONCLUSION: Results in this study have proven the effectiveness of the titanium reinforced PTFE as a space maintainer facilitating new bone formation.
KEYWORDS: Sinus lift, PTFE titanium reinforced membrane, Implant placement.
RUNNING TITLE: Direct sinus lift with titanium reinforced PTFE membrane.

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INTRODUCTION

The loss of upper posterior teeth is considered to be the main cause for patients seeking dental implants. Aside from this, the rehabilitation of posterior maxilla can be difficult due to atrophy of the alveolar ridge vertically and horizontally after the loss of maxillary teeth (1) and pneumatization of maxillary sinus which decreases the vertical bone in posterior maxilla (2).

Since restoration of edentulous posterior maxilla with dental implants has been considered a challenging mission due to the presence of atrophied posterior alveolar ridge, sinus lift procedure with grafting sinus floor by autogenous bone graft after schenideriane membrane elevation was first introduced and reported by Tatum in 1975 and by Boyne and James in 1980 (3).

Autogenous bone is generally considered the superior material for sinus augmentation due to its superior histological performance. However, its main disadvantages are donor area morbidity and graft volume loss, that is why lots of efforts are directed toward using different bone substitutes (xenografts, allografts) and new grafting materials (4).

Various techniques for augmenting sinus floor were described in literature, especially the crestal approach and the lateral window approach. The lateral window approach has been considered as the classical method for augmentation of maxillary sinus floor especially when the remaining alveolar bone height does not grantee primary stability of dental implants. It depends mainly on the quality and the quantity of the remaining alveolar ridge and it can be performed either in a single step where implant can be placed immediately or in two stages with delayed implant placement (5).

Guided bone regeneration (GBR) is a technique used to increase the volume of alveolar bone. It involves the use of a mechanical barrier which protects the underlying space or graft material

while preventing migration of the unwanted soft tissue cells (6).

Barrier membranes, which can be classified as resorbable or non-resorbable, have been developed to perform a range of purposes in clinical applications. Membrane function and selection are ultimately influenced by their biomaterial and physical features. The biological features of the barrier membrane, as well as the treatment needs, are used to determine which membrane to be used (7).

Non-resorbable barrier membranes, such as e-PTFE and d-PTFE, are also available as titanium-reinforced e-PTFE or d-PTFE. The reinforced membrane may be easily shaped to accommodate a variety of bony defects without rebounding, also it provides additional stability in osseous defects that require space maintenance (8).

Our aim in this study was to evaluate osseointergration process after direct sinus lift procedure using titanium reinforced PTFE membrane as a space maintainer associated with simultaneous implant placement.

PATIENTS AND METHODS

Study Design

This study was registered in ClinicalTrials.gov with registration ID number NCT05044260. This case series was conducted on 12 patients needed implant placement for their lost posterior maxillary teeth with limited bone height below the floor of maxillary sinus. All patients received implants and synthetic bone graft after sinus lift using Neobiotech sinus lift kit, sinus lateral approach kit (SLA) along with titanium reinforced PTFE membrane to maintain space after the sinus lift procedure.

Criteria for patient selection

Patients Selection was done from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Alexandria.

The patients in this study were chosen according to the following criteria:

Inclusion criteria

Patients of both genders requiring implants placement in atrophied posterior maxilla, age ranges from 40 to 60 years old, patients with good oral hygiene (9), and healthy maxillary sinus free from any pathology (10). The mean crestal bone height was 4.91 mm (11). Patients who were willing and fully capable to comply with the study protocol.

Exclusion criteria

Patients with tumors, chronic sinusitis or rhinitis, mental impairment (12), smoking and parafunctional habits (13, 14) and uncontrolled systemic diseases (15).

Informed consent

Appropriate institutional ethical clearance provided by Faculty of Dentistry Alexandria University Ethical Committee and written informed consent were presented by the patients. All patients were informed of the purpose of the study.

Materials

Implant system (www.Neobiotech.com)

Neobiotech Is-II active implant system.

Surgical kit

Drill length guide, Initial drill, Point lindemann drill, Twist drill, Cortical drill, Cortical tab, Parallel pin and counter sank.

Sinus Lateral Approach kit (SLA) (www.Neobiotech.com)

The Neobiotech sinus lift kit (SLA) was used for direct sinus lift procedure elevating the schniderian membrane. It consists of LS reamers which drill the lateral wall safely and a kit of elevators consists of 3 elevators used to elevate sinus membrane.

Beta tri calcium phosphate (adbone TCP) (www.medbone.eu/en/)

Beta tri-calcium phosphate (ß-TCP) is a biocompatible, osteoconductive , widely used bone grafting material, it is preferred as a synthetic bone substitute due to its chemical stability, bio resorption properties and great mechanical strength , it resorbes gradually within (3-6) months (16,17).

Titanium reinforced PTFE membrane (www.onegraft.com)

ONE Ti-Membrane is non-resorbable PTFE membrane made of MicroPore PTFE and Titanium, it can be easily handled and shaped for tenting and space maintenance, it can be easily fixed by Bone screw, Bone Tac or fixture.

Method

Preoperative phase

The preoperative data were collected, intra oral and extra oral examination were performed, CBCT was done for radiographic examination, scaling was done and oral hygiene instructions were given to the patients.

Operative phase (Surgical phase) (Figure 1, Figure 2 & Figure 3A)

- A direct sinus lift was performed according to Boyne and James on all patients under local anesthetics.
- The mucoperiosteal flap was lifted with a mucoperiosteal elevator exposing the lateral wall of the maxilla.
- To reduce the danger of sinus membrane perforation, SLA kit was used with a careful drilling and saline irrigation while creating the lateral window.
- Once the sinus membrane appeared with its pinkish grey color the drilling was stopped and the membrane elevation was initiated from the inferior border, then it continued along the medial surface of the lateral wall of the sinus and then all around the window boundaries.
- The membrane was carefully elevated from the lateral wall and the floor of the sinus cavity until it reached the upper border of the window and was raised to its new level.

- The elevated membrane resulted in an empty space that was bordered by the elevated membrane superiorly and the floor of the sinus inferiorly.
- The sinus membrane's integrity was checked with the Valsalva maneuver, which involved squeezing the patient's nose and inducing a considerable exhale, where the sinus expanded and deflated, verifying that there were no perforations in its walls.
  The titanium reinforced PTFE membrane was extended 2 mm beyond the borders of the defect, then adapted to fit precisely into the newly created space in an L-shape figure, with one side fixed on the lateral wall with a mini screw, the length of the mini screw that was used to fix the titanium reinforced PTFE was 4 mm and the perforation of the sinus membrane was avoided by guarding the sinus membrane away from the site of fixation using elevator number 3 in SLA sinus lift kit till fixation was done, this step occurred after proper reflection and elevation of the sinus membrane superiorly above the level of the titanium reinforced PTFE was supposed to be fixed and with proper selection of the screw the rest of the screw penetrating the sinus was less than 0.5 mm so the membrane was still intact after the screw fixation while the other side of the titanium reinforced PTFE was pushed inside the cavity supporting the sinus membrane at its new level.
- Sequential drilling of crestal bone was done to allow proper placement of dental implants.
- The Implants were secured in place.
- Beta tri-calcium phosphate (ß-TCP) bone graft was added around the placed implants and covered the lateral window.
- After proper readaptation of the flap, the flap was sutured and secured in its original position with the use of 3-0 silk suture in an interrupted pattern.
- After 7-14 days from the surgery the sutures were removed.

Postoperative phase

I- Postoperative instructions

- For the first 24 hours, all patients were directed to apply cold packs for 10 minutes every 30 minutes.
- Oral hygiene guidelines, including teeth brushing with a gentle brush and mouthwash containing 0.1 percent chlorhexidine gluconate (3 times per day for two weeks).
- For the first 24 hours avoidance of any negative or positive pressure, such as spitting hardly, blowing one's nose or even sipping through a straw.

II- Postoperative medications including

Medical regimen included

- Non-steroidal anti-inflammatory, analgesic, antipyretic : Diclofenac potassium 75 mg/amp/3ml I.M. injection every 12 hours for the first 24 hours(Cataflam , Novartis Pharmaceuticals Corporation, www.novartis.com).
- Non-steroidal anti-inflammatory, analegesic : Diclofenac 50 mg tablet ,3 times daily for 5 days (Cataflam , Novartis Pharmaceuticals Corporation, www.novartis.com)
- Anti-inflammatory and anti-edematous : trypsin 300 i.u. + chymotrypsin 300 i.u., 3 times daily for 2 weeks (Alphintern, Amoun company, www.amoun.com).
- Antibiotic: Amoxicillin Clavulanate 1 gm every 12 hours (Augmentin, Galaxo Company, www.us.gsk.com).
- Nasal decongestant: Oxymetazoline HCl 0.25% nasal drops (every 8 hours for 7 days) (Oxymet, L.perrigo Company, www.perrigo.com).
- Chlorohexidine Gluconate 0.1 percent mouthwash was prescribed (3 times per day for two weeks) (Hexitol, ADCO, www.adcopharma.com).

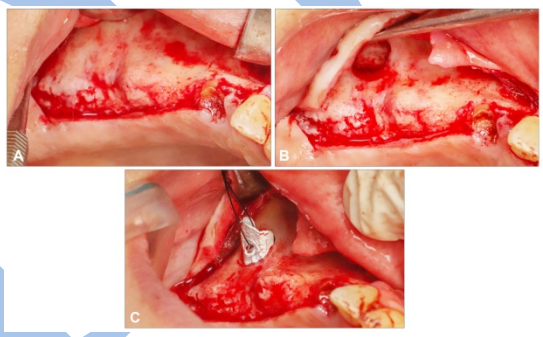

Figure 1 : A) Flap reflection. **B)** Window creation by SLA kit. **C)** Titanium reinforced PTFE membrane insertion.

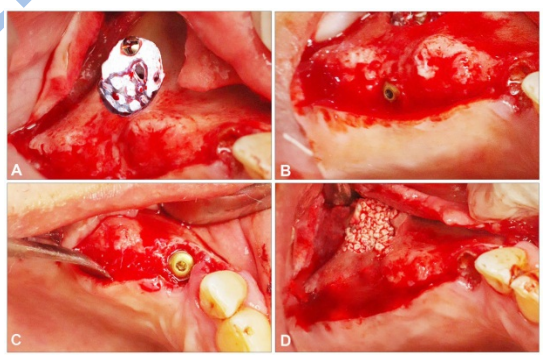

Figure 2: A) Titanium reinforced PTFE membrane fixation. **B)** Implant placement. **C)** Implant placement. **D)** Bone graft placement

Postoperative follow up

a) Clinical evaluation

Postopertive pain, swelling or infection (18)

The patients were checked after 48 hours, one week, two weeks, one month and then monthly until six months for the presence or absence of pain, tenderness, discomfort, signs of bleeding, hematoma, infection or even membrane exposure.

Any signs and symptoms of sinusitis were also checked in all patient during the follow up period.

b) Implant stability (19)

Implant stability quotient (ISQ) was measured by using Osstell (Ostell company), (https://www.ostell.com) immediately postoperatively and after 6 months.

c) Radiographic evaluation

Cone beam Computed tomography (CBCT) was taken immediately and six months after surgery, On Demand 3d software (On demand 3d software, Cyber Med Company, www.ondemand3d.com) was used to assess:

1- Bone formation in sinus floor.

2- Height and density of bone.

d) Prosthetic phase (Figure 3b, Figure 4)

After 6 months from implant placement the final prosthesis was placed.

RESULTS

The 12 selected patients were of mean age 50 ±2.4 years old, the patients were of both genders 7 females and 5 males, they required sinus lift procedure with simultaneous implant placement, the missing teeth were upper right 5 and 6 in seven patients, upper left 6 and 7 in two patients while three patients had a free end saddle starting from the upper right canine, the minimum amount of crestal bone in all patients was between (4-6 mm).

Clinical evaluation

1. **Pain**

Pain was evaluated 48 hours ,1 week then one month after the operation using the VAS scale from 0 to 10 ("0" is pain free and"10" is extremely severe pain).

After surgery the mean postoperative pain for the selected patients were 7.67 ±0.78 48 hours after surgery, 2.67 ±0.89 one week after surgery and 0.25 ±0.87 one month after surgery.

2. **Swelling or infection**

All patients experienced no infection except one patient who suffered from infection 3 months after surgery. All patients except one patient experienced swelling, edema and discomfort 48 hours after surgery then those signs decreased gradually till they totally disappeared by one week after surgery. The patient who suffered from intermitted pain swelling and infection with pus discharge throughout the first 3 months the implants failed eventually and subsequent removal for the graft, membrane and implants was done.

3. **Measurement of Implant Stability by Osstell™**

Implant stability quotient was measured in all patients using the resonance frequency analysis technique by Osstell™ device immediately after implant placement and after 6 months. Through the collected data the mean implant stability was 62.83 ±2.66 immediately and was 73.09 ±3.27 after six months, this difference was found to be statistically significant with p value <0.001 (Tables 1).

Radiographic Evaluation (Figure 5)

1. **Assessment of bone height**

Data were collected regarding the crestal bone height preoperatively and 6 months postoperatively of all implants. The mean of bone height values, standard deviation and percentage of change of the phases are shown in (Tables 2).

In the preoperative phase, the mean bone height value was 4.92 ±0.79, after 6 months the mean bone height value was 9.13 ±1.13. These differences were statistically significant with (p <0.001).

2. **Assessment of bone density**

Data were collected regarding bone density preoperatively and 6 months postoperatively of all implants. The mean of bone density values, standard deviation and percentage of change of the phases are shown in (Tables 3).

In the pre-operative phase, the mean bone density value was 621.3 ±84.03 HU, after 6 months the mean bone density was 728.7 ±93.90 HU. The differences were statistically significant with (p <0.001).

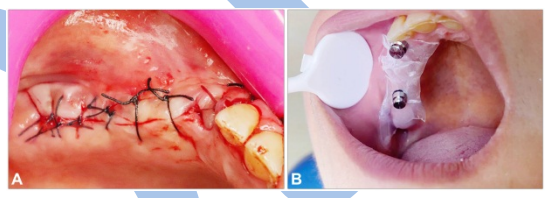

Figure 3: A) Suturing. **B)** Abutment with attachments in place.

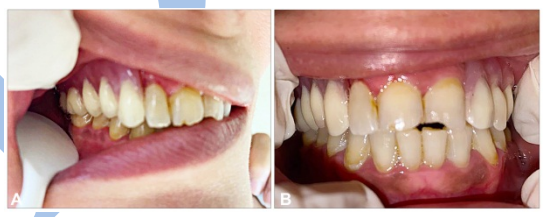

Figure 4: Final prosthesis.

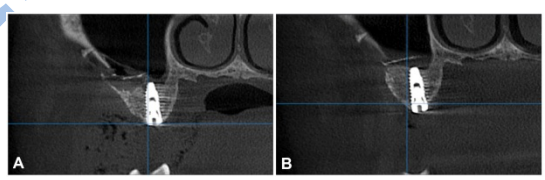

Figure 5:) Immediate postoperative CBCT. **B)** CBCT 6 months postoperatively.

Table (1): Comparison between the two studied periods according to implant stability (n = 12)

Implant stability	Immediate	6 months	T	p
Min. – Max.	60.0 –68.0	69.0 –77.0		
Mean ± SD.	62.83 ±2.66	73.09 ±3.27	10.595*	<0.001*
Median (IQR)	63.0 (60.0 –65.0)	74.0 (70.0 –76.0)		

IQR: Inter quartile range SD: Standard deviation t: Paired t-test

p: p value for comparing between the two studied periods

*: Statistically significant at p ≤ 0.05

Table (2): Comparison between the two studied periods according to bone height (n = 12)

Bone height (mm)	Immediate	6 months	T	P
Min. – Max.	4.0 –6.0	7.50 –10.60		
Mean ± SD.	4.92 ±0.79	9.13 ±1.13	22.298*	<0.001
Median (IQR)	5.0 (4.0 –5.50)	9.20 (8.15 –10.15)		

IQR: Inter quartile range SD: Standard deviation t: Paired t-test
p: p value for comparing between the two studied periods
*: Statistically significant at $p \leq 0.05$

Table (3): Comparison between the two studied periods according to bone density (n = 12)

Bone Density (Hu)	Immediate	6 months	T	P
Min. – Max.	485.0 –722.1	523.1 –865.0		
Mean ± SD.	621.3 ±84.03	728.7 ±93.90	9.403*	<0.001*
Median (IQR)	640.0 (553.1 –685.0)	722.1 (706.6 –787.9)		

IQR: Inter quartile range SD: Standard deviation t: Paired t-test
p: p value for comparing between the two studied periods
*: Statistically significant at $p \leq 0.05$

DISCUSSION

Since endosseous implant placement is considered to be a challenging task in posterior edentulous maxilla because of the pneumatization of maxillary sinus. Various techniques for maxillary sinus augmentation have been introduced with impressive success rates in order to develop these sites for implant placement. The process of new bone formation is still not fully understood but it is believed that the osteogenic properties of maxillary sinus lining play the main role in the process of new bone formation (20, 21-25). The tent pole technique that was described by Lundgreen in 2004 proved that the elevation of the scheniderian membrane alone without any grafting material can lead to new bone formation (26). But Scala et al illustrated that the unsupported scheniderian membrane collapses and limits the amount of bone gain, which necessitates the importance of space maintainers in bone formation (21).

Polytetrafluoroethylene is a widely used material in general surgery (vascular prosthesis, aortobifemoral bypass, ect.) (27), also all the biomaterials that are PTFE-based are considered to be bioinert, so when they are introduced to biological tissues, they do not induce tissue reaction (28). In this current study we aimed to assess the capability of the titanium reinforced PTFE membrane to act as a space maintainer device after Schneiderian membrane elevation, to promote new bone formation. The use of flexible titanium frameworks to reinforce PTFE membranes allow them to be easily shaped and adapted to a variety of defects. These frameworks offer more stability in supracrestal bone deficiencies, extensive dehiscence areas surrounding dental implants, and allow better preservation of the regenerated area during the healing phase (23). So it was easily shaped into an L shape where the longer arm was inside the sinus to hold the scheniderian membrane in place.

The maxillary sinus is supplied by three arteries, the infraorbital artery, the posterior superior alveolar artery and posterior lateral nasal artery. The posterior lateral nasal artery is in a close relation with the sphenopalatine artery and may anastomose with the facial or other nasal arteries. Also extra blood supply can be provided through the intraosseous sources in the medial wall of maxillary sinus. This arterial supply enhances the blood supply to the added bone graft, the created space, also promotes blood clot formation with subsequent bone regeneration (29).

In this study the blood clot and bone graft preservation was governed by the stable tenting of the maxillary sinus membrane by titanium reinforced PTFE which led to stabilization of bone graft and blood clot volume which followed by subsequent bone regeneration, Xu et al in 2005 found that the blood colt decreased in volume in the first few weeks of healing, besides the biodegradable property of beta-tricalcium phosphate these indicates the importance of usage of a space holder to prevent the pumping pressure of the scheniderian membrane and to allow a proper bone regeneration process (30).

In our study the titanium reinforced PTFE was used as a space maintainer after maxillary sinus membrane elevation while beta-tricalcium phosphate bone graft was used as scaffold under the non resorbable membrane, the radiographic evaluation revealed that the resorbtion of the grafting material and its replacement by new bone was 6 months after the operation because β-TCP which is a widely used bone substitute material exhibits a fast biodegradation and absorption due to its lower Ca/P ratio (31).

In this current study all patients experienced pain and swelling which decreased gradually until they completely disappeared one week after surgery except one patient who experienced intermitted pain, infection and pus discharge occurred 3 months after surgery, infection is not one of the most common sinus lift complications but still one of possible complication that can be caused due to bad oral hygiene, contaminated implant surface or

infection of the grafting material (32). Graft infection is rare but it is a reported complication with incidence up to 4.7% (33). That is why the patient who suffered from infection 3 months after surgery underwent a complete removal of the graft, membrane and implants after proper examination of CBCT and this was agreed by Peleg et al., (34) in his study investigating immediate implants placed in augmented maxillary sinuses, he found that the cause of 61.4% of implant failure was due to the presence of postoperative infection, where complete removal of the graft and failed implants were necessary with systemic antibiotics administration to reduce the damage that may occur (35).

Since the issue of whether or not to cover the osteotomy window with collagen membrane is still debatable, some authors preferred to cover the osteotomy to rule out non-osteogenic connective tissue infiltration and prevent the escape of graft particles from the grafted site, while others demonstrated that collagen membrane coverage is not necessary (36). The window of the osteotomy in this study was left uncovered with collagen membrane which gave the periosteum the chance to express its direct osteogenic effect on the bone graft and this was in agree with the finding of Atef et al in (2014) (37). As no membrane was used to cover the window in his study minor encleftation was found in the window of maxillary sinus but it did not affect the density or the width of bone. This encleftation was explained by Tawil and Mawla in (2001) (38) as the adult periosteum tends to have a fibrinogenic nature once elevated from the bone surface.

The Results of this study showed a proper postoperative increase in the height of bone and its density with a significant increase in implant stability. Thor et al studied maxillary sinus augmentation by tenting technique and his results revealed that the mean bone of height gained was 6.51mm when the average of remaining bone height was 5.5 mm (39). Also Leblebicioglu documented in his study that the amount of bone gained was less than the present study with an average bone gain 3-4 mm while in the current study the bone height was almost doubled by mean of 9.13 ±1.13 mm six months after surgery while the mean of bone height was 4.92 ±0.79 mm preoperatively. In Leblebicioglu's study using tenting technique the amount of bone formed was around the apex only (40) while in our study CBCT showed that the bone formation was over the whole area beneath the titanium reinforced PTFE membrane.

Results of our study showed that the process of bone formation was still not completed as the amount of bone formed in the CBCT did not reach the titanium reinforced PTFE, indicating that more time is needed to allow the bone to fill the whole area created under the membrane.

CONCLUSION

Results in this study have proven the effectiveness of the titanium reinforced PTFE as a space maintainer facilitating new bone formation.

Conflict of Interest

The authors declare that they have no conflict of interest.

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