

TRANSCRESTAL SINUS LIFT AND IMPLANT PLACEMENT USING THE SINUS BALLOON TECHNIQUE

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ABSTRACT

INTRODUCTION: Rehabilitation of the edentulous posterior maxilla with dental implants is challenging. The deficient alveolar ridge interferes with implant insertion of adequate length placed in the correct position and with the accurate inclination. The transcresal sinus elevation procedure has become an important preprosthetic surgical procedure for bone creation in the posterior maxilla prior to implant placement.

OBJECTIVES: Clinical and radiographic evaluation of using ballooning technique for sinus lift simultaneous with implant placement.

MATERIALS AND METHODS: A randomized clinical trial was conducted on fourteen patients who were divided into two groups. Patients, with limited bone height below the floor of the maxillary sinus, were selected on the basis of history, clinical and radiographic examination using cone beam computed tomography. In group A, elevation of sinus membrane using ballooning technique without graft material and implants were placed simultaneously. While in group B, after sinus membrane elevation using ballooning technique, augmentation using biphasic calcium phosphate simultaneously with the implant placement were done. The bone density was measured in Hounsfield unit using ondemand3d software of the cone beam computed tomography. Also, the bone height was measured using cone beam computed tomography.

RESULTS: Successful sinus membrane balloon lifting procedures were performed in 14 cases; in both groups there was no sinus membrane perforation. A total of 14 implants were placed. The radiographic examination showed the mean elevated height after 6 months by balloon in group A was 10.43 ± 1.56 mm while in group B was 10.31 ± 1.86 .

CONCLUSIONS: The use of balloon technique to elevate the sinus membrane is a minimally invasive technique and is associated with very little discomfort and complication.

KEY WORDS: Transcresal Sinus lift, balloon, implant, tenting-pole, Biphasic calcium phosphate (BCP).

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INTRODUCTION

Ridge resorption and sinus pneumatization in the posterior maxilla, compounded with poor quality of bone, can compromise implant rehabilitation of the patient (1).

The maxillary sinus elevation procedure has become an important preprosthetic surgical procedure for the creation of bone volume in the edentulous posterior maxilla for the placement of dental implants (2).

Elevation of the sinus membrane through a crestal approach using osteotome technique was introduced by summers in 1994. (3)

The antral membrane balloon elevation (AMBE) technique lifts the sinus membrane with minimal trauma and is particularly useful in areas that are difficult to reach. It is beneficial when teeth are adjacent to the edentulous area that requires augmentation. The AMBE technique is accomplished with a limited incision, minimal mucoperiosteal flap reflection, and a small window. The membrane is elevated to the medial wall of the sinus cavity avoiding sharp dissection around the roots of adjacent teeth. Thus, morbidity, blood loss, operative time, and postoperative pain and complications are reduced when compared with the conventional procedure. Sinus lift surgery is predictable and is usually not technically demanding. However, it is a more difficult surgical technique when teeth are adjacent to the edentulous area. It presents a far lesser challenge in the totally edentulous posterior maxilla (4).

The tenting of the sinus mucous membrane by the implants in the sinus floor is important for the clot formation and subsequent bone formation. The tissue formed by the clot under the elevated membrane is an unstable stage in the

bone formation process, as also discussed by Xu et al. 2005 (5).

Biphasic calcium phosphate (BCP) is a commonly used synthetic bone substitute comprising less soluble hydroxyapatite (HA) and more soluble β -tricalcium phosphate (β -TCP). It is a biocompatible, osteoconductive, and cost-effective biomaterial. The main advantage of BCP is that its chemical composition is similar to that of apatite in biological bone (6).

The aim of this study was clinical and radiographic evaluation of using ballooning technique for sinus lift simultaneous with implant placement.

MATERIALS AND METHODS

Research deign

A randomized clinical trial was conducted on fourteen patients who were selected from those attending the Outpatient Clinic of the Oral & Maxillofacial Surgery department, Faculty of Dentistry, Alexandria University. The patients in group A were with age range from 33-50 years, and the mean of age was 37.43 ± 5.80 . While, the age of the patients in group B range from 32-53years, and the mean of age was 42.29 ± 8.71 . The participants were seeking implantation of their lost posterior maxillary teeth, premolar and molars with limited bone height below the floor of the maxillary sinus, secondary to sinus pneumatization.

These fourteen patients were divided into two equal groups of seven patients as follows:

Group A: elevation of sinus membrane using ballooning technique was done without graft material and implants were placed simultaneously.

Group B: after sinus membrane elevation using ballooning technique was done, augmentation using biphasic calcium phosphate simultaneously with the implant placement was done.

Patients were selected on the basis of history, clinical and radiographic examination using CBCT to fit the following.

Inclusion criteria

- Acceptable inter-arch space for the future prosthesis.
- A ridge height at the site of implantation of 4-7 mm.

Exclusion criteria

Patients with immunologic diseases, uncontrolled diabetes mellitus maxillary sinus inflammations or other contraindicated systemic conditions were excluded.

This study was performed after the approval of research ethics committee, Faculty of Dentistry, Alexandria University, and informed consent form was signed from each patient after discussing oral and written explanation of the treatment plan about sinus lifting and implant placement procedures.

MATERIALS

1. Antral membrane elevation balloon (Dentium, Seoul, South Korea)

The Dentium sinus lift balloon was developed to gently elevate the Schneiderian membrane with minimum trauma and without the use of sharp instruments. The apparatus is a pneumatic device consisting of a 5 ml syringe, connected to a latex mini balloon with an inflation capacity of approximately 5 mm (Figure 1)



Figure (1): Antral membrane elevation balloon

2. Bone graft (Dio Seoul, South Korea)

Biphasic calcium phosphate (BCP) that was used in the present study for maxillary sinus augmentation is based on a balance between a more stable phase (HA) $Ca_{10}(PO_4)_6(OH)_2$ and a more soluble phase (β -TCP) $Ca_3(PO_4)_2$.

It is a fully synthetic bone substitute and consists of 60% HA and 40% β -TCP in a hard sintered mixture. It is 90% porous with interconnected pores of 100-500 microns in diameter. The particle size varies between 250-1000um.

3. Implant system (Dentium, Seoul, South Korea)

Dentium s-clean super line implant system with rounded apex, different diameters (4.4, 5), and lengths (8, 10, 12, mm) were used in this study.

4. Osteotome kit (Medesyrl, Italy)

The type of osteotome that was used in the present study consists of concave tips with ergonomic handle facilitates the control of instrument, with a special lock device for fine and easy adjustment to the required measures using the L key, and with different colors indicating the different diameters (2.7, 3, 3.7, 4, 4.5, 5). Surgical mallet was used to

apply gentle tapping on the osteotome to allow controlled fracture of the sinus cortical layer.

METHODS

1. Preoperative phase

A. Clinical examination

Patients' data were collected; name, gender and age, medical history and dental history were taken. All patients were subjected to extra oral examination; lymph node examination and examination of the area above the maxillary sinus for the presence of any tenderness or swelling. Also intra-oral examination to determine the condition of the edentulous maxillary area and the opposing dentition. The oral mucosa of the edentulous area was examined for color, texture, firmness and thickness, the buccal vestibule and the palate were examined for the presence of any pathologic condition.

B. Radiographic examination

Cone beam computerized tomography (CBCT) was performed for all patients preoperatively as treatment planning and diagnostic tools to measure the vertical height of the bone, bone density, and to select the suitable diameter and length of the implant.

C. Ear, nose and throat (ENT) consultation

All patients were referred to an ENT specialist for consultation to exclude any maxillary sinus pathology prior to surgery.

D. Diagnostic Cast and surgical stent

Alginate impression had been taken and stone cast was made and surgical stent constructed. The final prosthesis design, optional abutment number and location, have been determined.

Surgical phase

Surgery was performed under local anesthesia (2% lidocaine hydrochloride-epinephrine 1:100,000; Huons Co., Seoul, Korea). Anesthesia was achieved by maxillary vestibular infiltration and middle/posterior superior alveolar nerve block.

An incision was made, 2 to 3 mm on the palatal side of the crest of the ridge with two vertical releasing incisions. Flap was reflected to fully expose the crestal alveolar ridge wall of the maxillary Sinus.

The drilling site was marked initially by the pilot drill in the center of the alveolar crest. Drilling of the site of implant by using drills at least up to 4.5 mm in diameter to allow entry of balloon, and the bed was then enlarged until reaching to the determined diameter of the final drill. Drilling was done using the drills with stopper to keep 1mm of remaining bone to be fractured later by the osteotome.

Osteotomes were used to be corresponded to implant lengths, and the diameters of the osteotomes were smaller than that of correspondent implant by 0.5 mm. The osteotome was inserted into the osteotomy, and gentle tapping was applied by surgical mallet to allow controlled fracture of the sinus cortical layer. It was manifested by changing in the voice resonance and tactile sense of the surgeon.

The latex balloon was fitted to a catheter used to insufflate the balloon. Before placing it within the bone bed, correct functioning of the balloon was checked by insufflating it several times. The balloon was inserted in the subantral space, performing progressive, slow and controlled insufflations with saline solution.

The integrity of the sinus membrane was confirmed by asking the patient to blow through the nose after pinching the nostrils, and looking for mist on the mirror.

According to the manufacturer, 1cc of the saline will elevate sinus membrane by 5 mm, so the sinus membrane was detached to the desired height in each case. The sinus lift was performed with simultaneous dental implants placement at the same visit. (Figure 2)

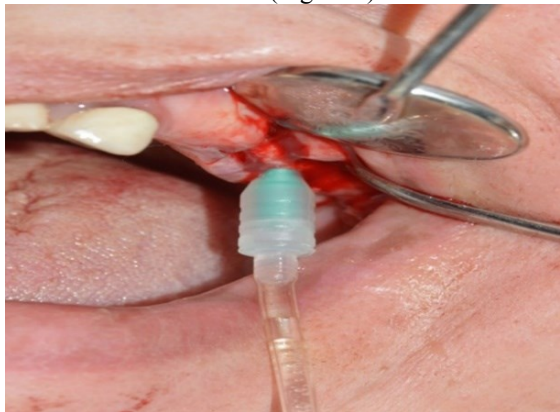


Figure (2): Insertion of the sinus balloon for lifting of the sinus membrane.

Group A, elevation of sinus membrane using ballooning technique was done without graft material and implants were placed simultaneously. (Figure 3)

Group B, the bone graft was placed into the osteotomy by using excavator and then condensed into the elevated sinus using elephant foot instrument and implants were placed simultaneously. (Figure 4)

The cover screw was placed into its position, and tightened using screw driver. The mucoperiosteal flap was replaced and sutured by simple interrupted suture technique, using (Black silk suture 3/0, ETHICON SETA, B-1130 Brussels, Belgium).



Figure (3): Placement the implant without graft material.



Figure (4): augmentation of sinus by biphasic calcium phosphate.

Postoperative Instructions

- The patients were instructed to apply cold fomentations and avoid hot drinks during the first day and hot fomentations during the second day.
- The patients should avoid chewing hard food at implant site.
- If coughing occurs, it should be done with the open mouth to relieve pressure within the sinus.
- Oral hygiene recommendations about the use of regular antiseptic mouthwash three times daily starting on the 2nd postoperative for 10 days (Chlorhexidine HCL 0.12%, Hexitol Mouth wash, the arab drug Co., Cairo, Egypt), and also soft bristle toothbrush was recommended.

Medications

1. Broad spectrum antibiotic; Amoxicillin 875mg, Clavulanic acid 125mg tablets (Augmentin 1 gm Smithline Beecham Pharmaceutical Co., Bentford, England) in combination with metronidazole 500mg tablets (Amrizole 500 mg tablets, Amriya Pharmaceutical Industries, Egypt) twice daily for 5 days to avoid post-operative infection
2. Non-steroidal anti-inflammatory analgesic in the form of diclofenac potassium (Cataflam 50mg tablets, Novartis Pharma AG, Basle, Switzerland) 50mg tablets 3 times daily for 7-10 days to avoid the possibility of inflammation, edema and pain.
3. Ephedrine nasal drops (Otrivin spray/nasal Drops 10ml, Novartis Pharma AG, Basle, Switzerland) were given 3-5 times daily for 5 days.

Follow-up phase

Clinical evaluation

Early clinical evaluation

Evaluation of Schneiderian membrane perforation.

The integrity of the sinus membrane was evaluated by valvula maneuver after elevation of the membrane by balloon technique. This was confirmed by asking the patients to blow through the nose after pinching the nostrils, and looking for mist on the mirror.

Implant Stability

It was measured by using torque wrench for both groups at implant placement time, and after 4 months postoperative at prosthetic loading phase.

Postoperative complications

a. Pain

It was measured through visual analogue scale ⁽⁷⁾ after 24 hours, 3 days, and 7 days postoperatively.



b. Edema

Facial edema was evaluated by tape method described by Gabka and Matsumara ⁽⁸⁾ at immediate post-operative period, and at 2nd, 3rd, and 7th days postoperatively. Two measurements were made. The first measurement was between tragus, lip commissure and the second measurement was between lateral corner of the eye, lower border of the mandible.

c. Infection

The wound was examined after 2 days, 3 days, and 7 days for signs and symptoms of infection including redness, swelling, and discharge.

Prosthetic phase

Definitive porcelain fused to metal restorations were delivered to all patients for both groups on the 4th postoperative month.

Delayed clinical evaluation

1. Mobility of the implant according to Mickney and Koth (9)

Mobility was tested using back and forth pressure by two instrument handles at final abutment placement. Implant mobility indicates lack of osseointegration. Therefore, mobility was used as a specific diagnostic test pointing to loss of osseointegration and being decisive in making the decision to remove the affected implant.

The clinical implant mobility scale is:

Scale 0 : Absence of clinical mobility with 500g in any direction.

Scale 1 : Slight detectable horizontal movement.

Scale 2 : Moderate visible horizontal mobility up to 0.5 mm.

Scale 3: Severe horizontal movement greater than 0.5 mm.

Scale 4: Visible moderate to severe horizontal movement and any visible vertical movement.

2. Peri-implant probing depth according to Glavind and Loe (1967) (10)

Probing pocket depth refers to the distance from the gingival margin to the bottom of the pocket at one month and three months after loading. Mesial and distal pockets were measured from the buccal aspect as close as possible to contact points while facial and lingual pockets were measured at the midline of the implant.

Probing was made with pressure sensitive plastic periodontal probe used for determination of peri-implant probing depth, to avoid undue tissue damage and over extension into the healthy tissue.

3. Bleeding on probing according to Muhleman (1977) (11)

Bleeding on probing was measured at one month and three months after loading. This is a sensitive indicator for the severity of the gingival inflammation it discriminates different degrees of bleeding which is provoked by sweeping the sulcus using a blunt periodontal probe under light finger pressure from the base of the papilla to its tip along the tooth distal and mesial aspects.

Grade 0: No bleeding.

Grade 1: Only bleeding point is observed.

Grade 2: Several isolated bleeding points or small areas of blood.

Grade 3: Interdental triangle filled with blood.

Grade 4: Profuse bleeding spreading towards the marginal gingiva.

Radiographic evaluation

CBCCT was used for all patients at immediate postoperative period for baseline measurement and at 6 months after implant placement to assess bone density and bone height.

The bone density was measured in Hounsfield units using ondemand3d software of the cone beam computed tomography. Also, the bone height was measured using the tools of cone beam computed tomography. The bone height was measured mesially and distally to the implant from the most coronal point of bone to implant contact to the most apical point of contact between bone and implant, and then the mean of the mesial and distal measurements was taken. The measurements of bone height were taken immediately postoperative and after six months.

STATISTICAL ANALYSIS

Data were presented as mean and standard deviation (SD) values. Paired-test was used to compare between preoperative and postoperative bone height. Wilcoxon signed ranks-test was used to compare between preoperative and postoperative bone density. The significance level was set at $P \leq 0.05$.

RESULTS

In this study, sinus lifts were performed on fourteen patients. The selected patients in group A were 2 males and 5 females, their age ranged from 33-50 year, and the mean of age was 37.43 ± 5.80 . In Group A, 3 patients replaced second premolars, and 4 patients replaced first molars. Three patients received 3 implants of 8 mm in length and 5 mm in width, and 2 patients received 2 implants of 10 mm in length and 4.5 mm in width, and 2 patients received 2 implants of 12 mm in length and 5mm in width. While the selected patients in group B were 1 male and 6 females, their age ranged from 32-53 years, and the mean of age was 42.29 ± 8.71 . In Group B, 2 patients replaced second premolars, and 5 patients replaced first molars. Two patients received 2 implants of 8 mm in length and 4.5 mm in width and 1 patient received 1 implant of 12 mm in length and 4.5 mm in width, and 4 patients received 4 implants of 10 mm in length and 5mm in width.

Early clinical evaluation

Evaluation of Schneiderian membrane perforation

Schneiderian membrane perforation didn't occur in any case of this study in both groups.

Implant Stability

All implants were stable during implant placement, and the mean in group A was 42.14 ± 7.56 . While, the mean in group B was 45.0 ± 8.16 . Also, the implants were stable at implant placement time, and after 4 months postoperative at prosthetic loading phase. The mean in group A was 51.43 ± 4.76 , while the mean in group B was 52.86 ± 3.93 .

Postoperative complications

a. Pain index

Pain indices in both groups were ranging from 0-2 during 24 hours to 0-1 at the 3th post-operative day, and while no pain was recorded since the 7th day postoperatively till the rest of the follow up period.

b. Infection

No wound infection was present in both groups post operatively in all of the cases.

Delayed clinical evaluation

1. Implant Mobility

Implant mobility was recorded in both groups; which revealed absence of mobility of implants during prosthetic loading phase. Mobility score was zero.

2. Peri-implant probing depth

Their pocket probing depth measurement at one month and three months after loading for both groups. It was recorded in (Table 1).

On the one month, the mean probing depth scores for the group A was 2.14 ± 0.24 with a minimum recorded value of 2.00 and a maximum recorded value of 2.5, while the mean probing depth scores for the group B was 2.29 ± 0.27 with a minimum recorded value of 2.00 and a maximum recorded value of 2.5. This difference in the probing depth score between the group A and group B was found to be statistically insignificant.

On the three months, the mean probing depth scores for the group A was 1.82 ± 0.12 with a minimum recorded value of 1.75 and a maximum recorded value of 2.00, while the mean probing depth scores for the group B was with 1.93 ± 0.12 a minimum recorded value of 1.75 and a maximum recorded value of 2.00. This difference in the probing depth score between the group A and group B was found to be statistically insignificant.

Table (1): Comparison between the two studied groups according to probing depth.

| Probing depth | Study (n = 7) | Control (n = 7) | t ₁ | p ₁ |
|--------------------------------------|---|-------------------------------------|----------------|----------------|
| After 1 month | | | | |
| Min. – Max. | 2.0 – 2.50 | 2.0 – 2.50 | | |
| Mean ± SD. | 2.14 ± 0.24 | 2.29 ± 0.27 | 1.044 | 0.317 |
| Median | 2.0 | 2.50 | | |
| After 3 months | | | | |
| Min. – Max. | 1.75 – 2.0 | 1.75 – 2.0 | | |
| Mean ± SD. | 1.82 ± 0.12 | 1.93 ± 0.12 | 1.643 | 0.126 |
| Median | 1.75 | 2.0 | | |
| t₂ (p₂) | 6.971*($<0.001^*$) | 4.804*(0.003^*) | | |

t₁, p₁: t₁ and p₁ values for Student t-test for comparing between the two studied groups

t₂, p₂: t₂ and p₂ values for Student t-test for comparing between 1 month and 3 months

*: Statistically significant at $p \leq 0.05$

3. Bleeding on probing

Bleeding on probing was measured at one month and three months after loading.

For group A, mean bleeding index score at 1 month after loading was 1.57 ± 0.53 with minimum recorded value of 1.0 and maximum recorded value of 2.0. While, Mean bleeding index score at 3rd month after loading was 0.43 ± 0.53 with minimum recorded value of 0.0 and maximum recorded value of 1.0. This difference in bleeding index scores from one to three month was found to be statistically significant.

Whereas, mean bleeding index score for group B at 1 month after loading was 1.57 ± 0.53 with minimum recorded value of 1.0 and maximum recorded value of 2.0. While, Mean bleeding index score at 3rd month after loading was 0.57 ± 0.53 with minimum recorded value of 0.0 and maximum recorded value of 1.0. This difference in bleeding index scores from one to three month was found to be statistically significant.

It was found that there was no significant difference between the two groups.

Radiographic evaluation

Assessment of Bone Density

In both groups, there was increase in the bone density from immediate post-operative to 6 months postoperative. (Table 2)

For group A, the bone density range at immediate post-operative was 220.0 HU– 247.0HU. While After 6 months, bone density range was 385.0HU – 680.0HU. With change percentage of 83.5% (Figure 5). While in group B, bone density range at immediate post-operative was 295.0HU – 331.0HU. Whereas, bone density range after 6 months was 385.0HU – 682.0HU. With change percentage of 39.03%. (Figure 6)

Comparison between group A and group B revealed that there was no significant difference in density of the new formed bone around implants after 6 months.

Assessment of Bone Height in both groups, there was increase in the bone height from immediate post-operative to 6 months postoperative. (Table3)

The minimum bone height with sinus balloon technique in group A at immediate postoperative was 4 mm, and maximum of bone height was 7 mm. While the minimum gained bone height at 6 months after operation was 8.50 mm and, maximum of bone height was 12.30mm. Which changed significantly when compared with immediate postoperative bone height, with change percentage of 82.0%. While the minimum bone height with sinus balloon technique in group B at immediate postoperative was 4 mm and, maximum of bone height was 7 mm. While the minimum gained bone height at 6 months after operation was 8.50 mm and, maximum of bone height was 12.30mm. Which changed significantly when compared with immediate postoperative bone height, with change percentage of 83.8%

Comparison between group A and group B revealed that there was no significant difference in bone height of the new formed bone around implants after 6 months.



Figure (5): photo radiograph of 6 months cone beam C.T in study group.



Figure (6): photo radiograph of 6 months' cone beam C.T in control group.

DISCUSSION

The present study was designed for clinical and radiographic evaluations using ballooning technique for sinus lift simultaneous with implant placement. In our study the cases were divided equally into two groups. In group A, elevation of sinus membrane using ballooning technique was done without graft material and implants were placed simultaneously. While, in group B, after sinus membrane elevation using ballooning technique was done, augmentation using biphasic calcium phosphate simultaneously with the implant placement was done.

Table (2): Comparison between the two studied groups according to bleeding.

| Bleeding | Study (n = 7) | | Control (n = 7) | |
|----------------------------------|----------------|------|-----------------|------|
| | No. | % | No. | % |
| After 1 month | | | | |
| 1 | 3 | 42.9 | 3 | 42.9 |
| 2 | 4 | 57.1 | 4 | 57.1 |
| Min. – Max. | 1.0 – 2.0 | | 1.0 – 2.0 | |
| Mean ± SD. | 1.57 ± 0.53 | | 1.57 ± 0.53 | |
| Median | 2.0 | | 2.0 | |
| Z ₁ (p ₁) | 0.0 (1.000) | | | |
| After 3 months | | | | |
| 0 | 3 | 42.9 | 3 | 42.9 |
| 1 | 4 | 57.1 | 4 | 57.1 |
| Min. – Max. | 0.0 – 1.0 | | 0.0 – 1.0 | |
| Mean ± SD. | 0.57 ± 0.53 | | 0.57 ± 0.53 | |
| Median | 1.0 | | 1.0 | |
| Z ₁ (p ₁) | 0.0 (1.000) | | | |
| Z ₂ (p ₂) | 2.646*(0.008*) | | 2.646*(0.008*) | |

Z₁, p₁: Z₁ and p₁ values for Mann Whitney test for comparing between the two studied groups

Z₂, p₂: Z₂ and p₂ values for Wilcoxon signed ranks test for comparing between 1 month and 3 months

*: Statistically significant at p ≤ 0.05

Many studies (12-13) discussed the relevance of using a biomaterial during a sinus lift to reconstruct a significant bone volume for implantation or at least maintain space for bone regeneration. The sinus cavity shows a high osteogenic potential and it is very strong model of an osteogenic chamber for bone regeneration. Thus, sinus lift without grafted bone material, even in residual bone height <5 mm, is a very natural and attractive approach. The conduction of crestal sinus lift is the natural consequence and evolution of the quantitative and qualitative success of the crestal sinus lift with an osteotome using no grafting material.

The role of the sinus membrane itself is unclear, but are recent study in primates indicated the presence of a potential of mesenchyme cells in the sinus membrane that might allow for bone formation (15).

The selected patients were systemically free from any disease or systemic condition to avoid any systemic influence on bone formation or bone resorption, and this was in accordance with an 11 years' retrospective study performed by Moy et al (16) in 2005 who concluded systemic disease as high risk factor for implant failure.

Also, patients in this study were selected free from any sinus pathosis after ear nose and throat (ENT) consultation. This is in agreement with a study conducted by Torretta et al (17) in 2013, which recommended that a careful multi-tasking preoperative management, including an ENT assessment is useful in patients undergoing sinus membrane elevation.

In presented study, Schneiderian membrane perforation didn't occur in any case of this study, and this was

confirmed clinically in all cases by valvula maneuver. Absence of Schneiderian membrane perforation in all cases could be attributed to the non-traumatic surface of the balloon and gentle slow inflation of sinus balloon. In the control group, CBCT showed uniform distribution of the bone substitute material around the dental implants, identical consistent dome shape of the bone substitute and no leakage of bone particles from sinus membrane space into the sinus cavity space. This finding was supported by Soltan and Smiler.2005 (18).

Table (3): Comparison between the two studied groups according to bone density.

| Bone density | Preoperative | Immediate postoperative | After 6 months | F | p |
|--------------------------|--|-------------------------|-----------------|---------|---------|
| Study (n = 7) | | | | | |
| Min. – Max. | 220.0 – 247.0 | 220.0 – 247.0 | 385.0 – 680.0 | | |
| Mean ± SD. | 235.5 ± 11.07 | 235.5 ± 11.07 | 432.14 ± 109.62 | 24.692* | <0.001* |
| Median | 235.0 | 235.0 | 385.00 | | |
| Sig. bet. Periods | p ₁ =-, p ₂ =0.003*, p ₃ =0.003* | | | | |
| Control (n = 7) | | | | | |
| Min. – Max. | 220.0 – 279.0 | 225.0 – 280.0 | 385.0 – 682.0 | | |
| Mean ± SD. | 240.14 ± 20.38 | 243.43 ± 19.23 | 434.57 ± 109.47 | 20.134* | <0.001* |
| Median | 235.0 | 238.0 | 390.00 | | |
| Sig. bet. Periods | p ₁ =0.001*, p ₂ =0.004*, p ₃ =0.004* | | | | |
| t(p) | 0.521(0.612) | 0.937(0.367) | 0.041(0.968) | | |

F: F test (ANOVA) with repeated measures

Sig. bet. Periods was done using Post Hoc Test (LSD) for ANOVA with repeated measures

p₁: p value for comparing between Preoperative and Immediate postoperative

p₂: p value for comparing between Preoperative and After 6 months

p₃: p value for comparing between Immediate postoperative and After 6 months

*: Statistically significant at p ≤ 0.05

In the current study, all implants were stable during implant placement, and the mean in group A was 42.14 ± 7.56. While, the mean in group B was 45.0 ± 8.16. Also, the implants were stable during abutment tightening, and the mean in group A was 51.43 ± 4.76 While, the mean in group B was 52.86 ± 3.93. Similar inferences was drawn by Zitzmann et al (19) in 1998 when they compared three different methods of sinus floor elevation in 30 patients designed for implant treatment in resorbed posterior maxilla.

In the current study, there was no significant postoperative pain with minimal edema in both groups throughout the follow up phase. The Pain indices in both groups were ranging from 0-2 during 24 hours to 0-1 at the 3th post-operative day, and while no pain was recorded since the 7th day postoperatively till the rest of the follow up period. This was coinciding with Hu X et al. (20) in 2009, in their study where they observed minimal postoperative swelling and pain, resulting in patient comfort and reduction of analgesic use.

In the present study, no wound infection was present post operatively in both groups and radiographic evaluation by CBCT 6 months postoperatively revealed the absence of any fluid level or inflammatory process. This is in agreement with a study conducted by Mazor.Z (21) in 2012,

where they observed that the use of antral membrane balloon elevation minimizes the postoperative swelling and infection.

In this study, implant mobility was recorded in both groups, which revealed absence of mobility of implants during prosthetic loading phase. Mobility score was zero in both groups. Our findings were consistent with result of Sani *et al.* (22) in 2008.

In the current study, there was reduction in the values of the mean probing pocket depth in both groups. In group A, the range was 2-2.5 at one month, and at three months the range was from 1.75-2. While in group B, the range was 2-2.5 at one month, and the range was 1.75-2 at three months. After loading, when both groups were compared with each other, there was statistically insignificant. Also, regarding bleeding on probing, the bleeding in probing was absent around the implant in group A and group B at 1, and 3 months after loading, and when both groups were compared with each other, there was no statistical significance. These findings were in agreement with Schmitt and Zarb (23) in 1993, who showed pocket depth ranges between 1–2 mm in 92.3 % of cases which was considered normal pocket depth around implant, and Bleeding on probing was absent around implants.

Norton & Gamble (24) in 2001 suggested that bone density can be evaluated using Hounsfield units. In the present study, the density of the new bone formed around implants in group A after 6 month ranged from 385.0HU – 680.0 HU and with a significant change in bone density around the implants comparing to the immediate postoperative bone density around the implants that ranged from 220.0HU – 247.0 HU. With a mean percentage of change 83.5%. While, in the group B, bone density around the implants 6 month postoperatively ranged from 385.0HU – 682.0 HU and with a significant change in bone density around the implants in comparison with the immediate postoperative bone density around the implants that ranged 220.0HU – 279.0 HU. With a mean percentage of change 79.2%. There was no significant difference between the two groups, and both groups were comparable to that of bone normally present in the maxilla.

This is in agreement with the results of Sogó *et al.* (25) in 2012, who studied the bone density of the posterior maxilla in 30 patients, and they concluded that the bone in the posterior maxilla was classified as D3 (350–850 HU) or D4 (150–350 HU) according to Misch's classification, comprising 50% and 32% of the entire regions, respectively.

In current study, the minimum bone height with sinus balloon technique in group A at immediate postoperative was 4 mm, and maximum of bone height was 7 mm. While the minimum gained bone height at 6 months after operation was 8.50 mm and, maximum of bone height was 12.30mm. Which changed significantly when compared with immediate postoperative bone height, with a mean percentage of change 82.0%.

This is in agreement with the result of Sohn *et al.* (26) in 2008, first demonstrated evidence of new bone formation in human maxillary sinuses with sinus membrane elevation alone and simultaneous implant placement.

In presented study, the minimum bone height with sinus balloon technique in group B at immediate postoperative was 4 mm and, maximum of bone height was 7 mm. While the minimum gained bone height at 6 months after operation was 8.50 mm and, maximum of bone height was 12.30mm.

Which changed significantly when compared with immediate postoperative bone height, with a mean percentage of change 83.8%.

The result of our study was similar to the study given by Milan *et al.* (27) in 2008, who showed that implants placed using three different techniques of sinus augmentation were successful, with equal survival rates after an observation period of at least 3 years.

The use of balloon technique for sinus membrane elevation is safe and reduces both intraoperative and postoperative complications, and it does not require placement of additional bone grafting material.

CONCLUSIONS

From the results of this study we can conclude that the use of balloon technique to elevate the sinus membrane is a minimally invasive technique, and it is associated with very little discomfort and complications. This study showed that simultaneous sinus lift and implantation using ballooning technique is a reliable procedure which reduces postoperative complications. Sinus floor elevation maintained with an implant without the use of graft material is a secure and reliable method for promoting natural bone formation, and it does not require placement of additional bone grafting material.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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