

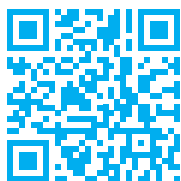
SINUS FLOOR AUGMENTATION BY SINUS-LIFT BALLOON SYSTEM- A 1 YEAR FOLLOW-UP STUDY

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ABSTRACT

A maxillary sinus floor augmentation procedure (also known as sinus lift / sinus procedure) is a surgical technique to augment bone mass in the maxilla which increases the likelihood of successful placement of dental implants. The revolutionary concept of osseointegration is considered highly predictable. Today the implant supported oral restorations are among the most updated treatment options for treating edentulous or partially edentulous jaws opting for a fixed prosthesis. This study aimed to assess the safety and efficacy of a minimally invasive technique for maxillary sinus elevation using the sinus lift balloon system (Zimmer Dental); followed by augmentation of the sinus with cancellous bone allograft (RMTB) and to evaluate the clinical and radiological outcomes of sinus floor augmentation procedure using OPG, over a one-year period.

KEYWORDS : Osseointegration, Schneider's membrane, pneumatization, osteotome, MIAMBE.

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INTRODUCTION:

Oral rehabilitation with implant supported prosthesis is considered the therapeutic procedure of choice for partially or completely edentulous patients. Implant success and primary stability are greatly affected by localized bone density, with implants placed in areas of poorer bone quality associated with high failure rates¹. The posterior region of edentulous maxilla frequently presents insufficient bone for rehabilitation by means of endosseous implants. This might be because of alveolar bone resorption and pneumatization of the maxillary sinus². One method that makes implant placement possible in such difficult situations is the augmentation of maxillary sinus using various graft materials. This procedure involves the detachment of Schneiderian membrane from the maxillary sinus floor, creating a space filled with grafting material, to promote vertical bone augmentation into the maxillary sinus cavity.

In 1994, Summers introduced osteotome sinus floor elevation,



Fig 1- Osteotome sinus floor elevation technique

which is a minimally invasive technique that allows for localized maxillary sinus elevation, in alveolar crest with a residual bone height of 5 - 10 mm³. A minimally invasive technique for sinus membrane elevation (MIAMBE) which is a modification of osteotome technique using balloon inflator secured into the osteotomy site was introduced by Kfir et al (2006)⁴. In this technique, inflation of the balloon elevated the sinus membrane, which was followed by bone augmentation and implant placement. MIAMBE resulted in high procedural success, satisfactory bone augmentation, implant survival and less complication rates. Because it is minimally invasive, this technique may be used as an alternative to the existing sinus augmentation procedures. A wide variety of graft materials have been used to augment bone volume within the sinus: demineralised freeze dried bone allograft (DFDBA), hydroxyapatite preparations, calcium phosphate preparations and xenografts as well as growth factors embedded

with different carrier materials. Irradiated allogenic cancellous bone and marrow particulate grafts randomly sized between 2-3mm have also been used as bone substitute for autogenous bone graft.

AIM OF THE STUDY:

- 1. To assess the safety and efficacy of a minimally invasive technique for maxillary sinus elevation using the Sinus lift Balloon system (Zimmer Dental); followed by augmentation of the sinus with Cancellous Bone Allograft (RMTB).
- 2. To evaluate the clinical and radiological outcomes of sinus floor augmentation procedure using OPG, over a one-year period.

MATERIALS AND METHODS:

The study included a total of 10 patients ,7males and 3 females, aged between 25 to 60 yrs, for implant placement in the edentulous posterior maxilla. Informed written consent to participate in this study was obtained from all patients, after explaining the objectives and protocol of the study, and possible side effects.

INCLUSION CRITERIA:

Patients were selected using the following criteria:

- With a unilateral or bilateral loss of teeth in the maxillary premolar or molar area.
- Crestal bone height greater than 5mm below the sinus floor as determined by an OPG.
- Patients with Class B, division-V (Vertical Defect) were included (ABC classification by Hom-Lay Wang 2008)⁵. a) The bone crest is 6 to 9mm from the sinus floor. b) The bone width is 5mm or more. c) The bone crest is more than 3mm from the adjacent CEJ.
- Patients with good oral hygiene and without any active periodontal disease were selected.

EXCLUSION CRITERIA:

- Systemic conditions such as uncontrolled diabetes mellitus, hypertension or any other contraindicating systemic complications.
- Patients with immunosuppression and bleeding disorders.

- Patients with orofacial cancer, chemotherapy or head and neck radiotherapy twelve months prior to the surgery.
- Any pathological lesion in the sinus.
- Untreated active periodontitis in neighbouring teeth.
- Patients with long term steroid therapy or bisphosphonate medication.
- Patients who are not current smokers.
- Pregnant women and nursing mothers.
- Any previous history of sinus surgery.
- Patients with any drug abuse including alcohol.

RADIOGRAPHIC EXAMINATION:

Preprocedural panoramic radiographs were used to assess the vertical bone height (VBH) below the sinus lining.

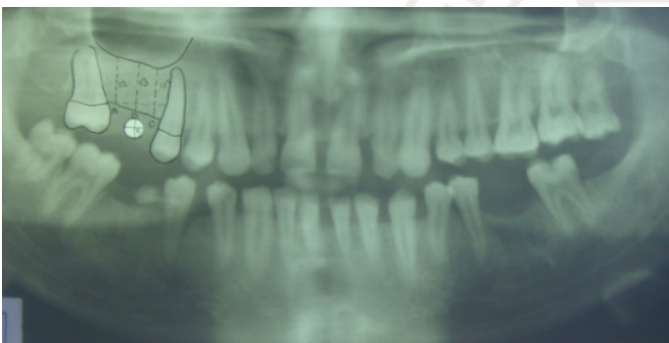


Fig 2 - Tracing of OPG

Digital periapical radiographs were taken before the procedure was initiated. Evaluation of VBH from the alveolar crest (arbitrary horizontal line joining the CEJ of the adjacent teeth) to the floor of the sinus, was done using OPG. The following three points were marked on the arbitrary horizontal line joining the CEJ. • Point A- 2mm from the mesial tooth. • Point B- Midpoint from the line joining point A & C. • Point C- 2mm from the distal tooth. From these 3 points mentioned above, vertical arbitrary lines were drawn to the floor of the maxillary sinus and the values were recorded.

MATERIALS USED:

SINUS-LIFT BALLOON SYSTEM

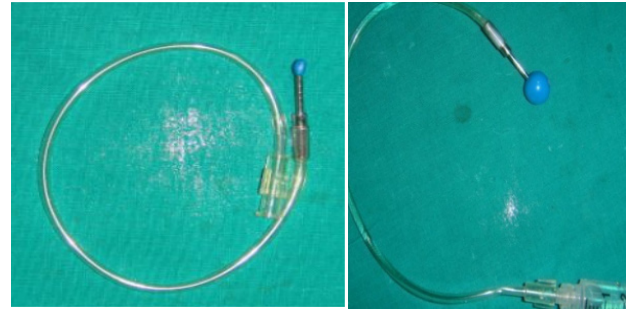


Fig 3a & 3b - Sinus lift balloon system

- The Sinus-lift balloon system (Zimmer Dental) was developed to gently elevate the Schneiderian membrane with minimal trauma and without the use of sharp instruments.
- The apparatus is a pneumatic device consisting of a 5ml syringe, polyvinyl chloride (PVC) tubing and a metal shaft with the tip connected to a latex mini balloon with an inflation capacity of approximately 5cm³.
- The amount of saline placed in the syringe was determined by the number of millimeters the sinus membrane would need to be elevated – 1cc of saline solution corresponds to 6mm (+/- 0.5mm) of membrane elevation.

BONE GRAFTS



Fig 4 - Bone graft

Irradiated allogenic cancellous bone and marrow particulate bone graft (Rocky Mountain Tissue Bank, Denver, Co) randomly sized between 2 to 3mm has been used as a bone substitute for sinus augmentation in this study. It is a trabecular allograft obtained from the spinal column and treated with 2.5

and 3.8 megarads of radiation.

SURGICAL TECHNIQUE:

Under local anesthesia, alveolar mid-crestal horizontal incision was



Fig 5 - Incision placed

placed in the edentulous site and connected with sulcular incision of adjacent teeth. Mucoperiosteal flap was elevated exposing alveolar crest of the bone. No vertical releasing incision was used and the flap was reflected not exceeding the alveolar ridge. Cortical perforation was done using a round bur, followed by pilot drill reaching about 1mm short of the sinus floor (After radiographic verification of the sinus floor with digital periapical radiographs). Sequential expansion of the osteotomy site was achieved

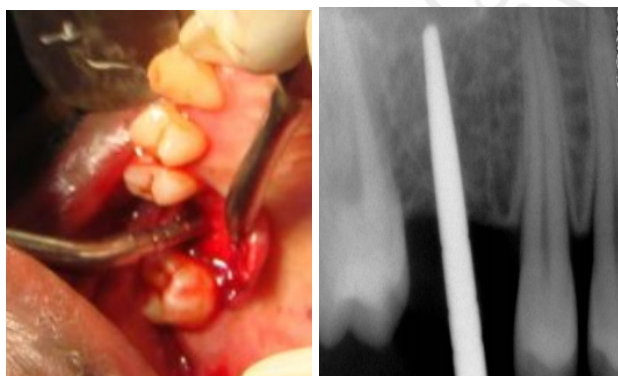


Fig 6a & 6b - Flap elevated and pilot drilling of the surgical site done

using a series of osteotomes (from 3.8mm to 5mm) in graduated diameters, to laterally condense the low density maxillary bone. Care was taken to gently penetrate the sinus floor and slightly elevate the Schneiderian membrane to allow 3mm of access for the deflated balloon. Valsalva maneuver is followed. The sinus lift balloon was anchored and secured into the osteotomy site. Then the balloon was

slowly inflated with gentle inflating pressure with

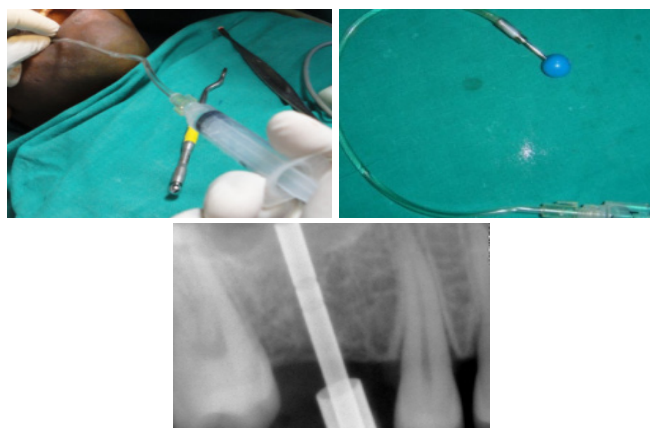


Fig 7a,7b & 7c - Balloon inflation of the surgical site done

normal saline (1cc of saline solution corresponds to 6mm of membrane elevation). Digital periapical radiographs were taken to assess the balloon inflation and the extent of sinus floor elevation at the surgical site during the procedure. Once the desired elevation (usually greater than 10mm) was obtained, the balloon was deflated. A second test of membrane integrity was done by Valsalva manoeuvre. Irradiated allogenic cancellous bone and marrow (RMTB) was filled under the elevated sinus membrane using bone condensers. Simple interrupted sutures were placed using 3-0 silk suture material.



Fig 8 - Flap sutured

Post-operative instructions and antibiotic coverage were given. Patients were examined after a week and suture removal was done. The grafted sinus was allowed to heal for 6 months.

POST-OPERATIVE RADIOGRAPHIC EVALUATION:

During the 3 months and 6 months follow-up

period, radiographic assessment



Fig 9 - post-operative IOPA

of the vertical bone gain in the augmented sites was done using OPG at the three reference points (A, B, C).

STATISTICAL ANALYSIS:

The paired 't' Test was adopted to evaluate the significance of differences in the mean bone height (MBH)

RESULTS:

- Clinically, no complications were observed during or after the surgical procedure.
- No signs and symptoms of maxillary sinus pathology
- There was a significant increase in the mean bone height (MBH) post-operatively at the 3 months follow-up period.
- Point A- 2.3mm,
- Point B -3.2mm,
- Point C- 1.8mm
- Which consistently increased during the 6 months follow-up period (point A- 2.7mm, point B- 3.34 mm, point C-2mm)

DISCUSSION:

First introduced by Dr. Hilt Tatum in 1974,⁶ sinus lining elevation was done using inflatable catheters between 1975 – 1979. Boyne and James⁷ authored the first publication on the technique in 1980 - when they published case reports of autogenous grafts placed into the sinus and allowed to heal for 6 months, which was followed by the placement of

implants.

The present study was undertaken to assess the safety and efficacy of a minimally invasive technique (MIAMBE) for maxillary sinus elevation using the sinus lift balloon system (Zimmer Dental); followed by augmentation of the sinus with irradiated cancellous bone allograft (Rocky Mountain). The implant placement was planned after a six-month follow-up period. It is generally preferred to delay implant placement by several months after the grafting phase, to allow adequate graft maturation. In the present study, the radiographic assessment was based on panoramic radiographs. Although CT scan is considered to be the most accurate means for the diagnosis of sinus pathologies and for the evaluation of sinus membrane thickness, periapical and panoramic radiographs were also frequently used to diagnose radiodensities and mucosal cysts (Casamassimo PS1980)⁸. OPG can only be used for the assessment of bone height because it offers only a two-dimensional view, therefore volume measurement could not be assessed. There was a significant increase in the mean bone height (MBH) post-operatively at the 3 months follow-up period, which consistently increased during the 6 months follow-up period at the 3 reference points (A, B, C). This study utilized irradiated allogenic cancellous bone and marrow graft (RMTB) for augmentation of the sinus. It has been shown that among all available allografts, irradiated bone is most similar to autogenous bone, demonstrating rapid replacement & consistent establishment of a reasonable ratio of new bone⁶. NS Soltan et al (2005)⁹ reported antral membrane balloon elevation via a lateral bone fenestration. The procedure was highly successful and predictable. Xiulian Hu et al (2009)¹⁰ assessed the efficacy and safety of MIAMBE followed by bone grafting and implant placement in 28 patients. MIAMBE can be used as a predictable alternative to the invasive sinus augmentation procedures which are currently in use.

CONCLUSION:

Within the limits of this study, the following conclusions have been elucidated:

- MIAMBE is safe and effective for maxillary sinus augmentation. The procedure yielded satisfactory bone augmentation results.

- This procedure eliminates the complications, discomfort and also shortens the surgical time.
- Particulate irradiated cancellous bone allograft (RMTB) augmentation was biocompatible and seemed to improve new bone formation in sinus grafting. It can be used as a substitute for autogenous grafts in sinus augmentation procedures.

Thus, it is appropriate to conclude that, sinus floor elevation using “Sinus-lift Balloon System (Zimmer Dental)” has obvious advantages, paving way for maximal augmentation of the sinus for successful implant placement in future. Because it is minimally invasive, this technique may be used as an alternative to the currently employed maxillary sinus augmentation methods. However, further controlled clinical trials with large sample size, advanced radiographic and histomorphometric analysis should be executed to evaluate the effectiveness and safety of this technique compared to other sinus augmentation procedures.

FINANCIAL SUPPORT AND SPONSORSHIP:

Nil

CONFLICTS OF INTEREST:

There are no conflicts of interest.

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