Original Article

Radiographical and histological evaluation of bioactive synthetic bone graft putty in sinus floor augmentation: A pre- and post-intervention study

ABSTRACT

Objective: The main objective is to evaluate the quantity and quality of bone formed after use of bioactive synthetic bone graft putty in sinus augmentation and to radiographically and histologically evaluate increase in alveolar bone height in augmented sinus.

Materials and Methods: It is a pre- and post-intervention study of 15 patients (present at both baseline and at 6 months) with 80% power and 95% confidence level.

Results: The mean increase in alveolar bone height is 7.08 ± 1.42 mm ranging from 5.6 mm to 10.7 mm. It is evident from the data that there has been increase in alveolar bone height postbone graft augmentation. $P < 0.001$ shows that increase in alveolar bone height is highly significant as compared to preoperative bone height. The mean postoperative density is 525.43 ± 104.18 hounsfield unit ranging from 649 HU to 350 HU. This is also a D3 quality bone as per Misch classification. The mean difference in alveolar bone density is 104 ± 125.16 HU. $P = 0.0053$ shows that increase in alveolar bone density is significant as compared to preoperative bone density.

Conclusion: Bioactive synthetic bone graft putty yields sufficient quantity of mineralized tissue for implant placement in patients with 2–6 mm of alveolar bone height before grafting. Histologically, it has shown that it has good osteoconductive properties and good quality of bone is formed within 6 months of its augmentation.

Keywords: Dental implant, histological evaluation, sinus augmentation, synthetic bone graft

INTRODUCTION

Insufficient bone volume is a common problem encountered in rehabilitation of posterior maxilla with implant-supported prosthesis. The bone available for implant placement may be limited by the presence of maxillary sinus together with loss of alveolar bone height. Loss of alveolar bone height following tooth loss is an ongoing process due to loss of functional stimulation in the crestal region and apparently continuing pneumatization of the sinus.[1]

Published clinical studies of implant survival in the posterior maxilla have been universally unsatisfactory with failure rates of 35% or higher for short implants.[2]

The material used in this study (i.e., bioactive synthetic bone graft putty) has been used successfully in various clinical situations in dentistry such as extraction sockets and periodontal defects. It has four components: regular calcium phosphosilicate particulate (55%), smaller-sized calcium phosphosilicate particulate (14%), and binder composed of phosphoethylene glycol (12%) and glycerin (19%).

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This present study was undertaken to evaluate the specific use of bioactive synthetic bone graft putty in sinus augmentation. It was done to evaluate the quantity and quality of bone formed with the use of this graft material. The quantity of bone formed was evaluated radiographically and histological evaluation was done to assess the quality of new bone formed. The study was done as a two-staged procedure, wherein sinus lift surgery was done in the first stage and trephine biopsy was taken from the planned implant site, 6 months after the first surgery. This provided adequate time for graft to heal and thereafter for histological analysis.

MATERIALS AND METHODS

It is a pre- and post-intervention study. Sample size has been calculated with alveolar bone height as the primary outcome variable, for a pre- and post-intervention study. Considering mean standard deviation of alveolar bone height at the baseline as 4 ± 2.5 mm, anticipating at least 50% increase in alveolar bone height in 6-month postintervention (i.e., 6 ± 3.0 mm at 6 months) to detect this difference with 80% power and 95% confidence level, we require minimum of 13 evaluable patients (present at both baseline and at 6 months). Considering some loss to follow-up, we enrolled 15 patients in the study [Table 1].

Ethical dimension

Whole project outline was presented to the Ethical Committee, All India Institute of Medical Sciences (AIIMS), New Delhi, and prior clearance was achieved before taking up the case. Informed and written consent from the patient was obtained before inclusion in the study.

Inclusion criteria

The inclusion criteria were as follows:

1. Patients requesting dental implant placement at the time of rehabilitation of posterior maxilla
2. Healthy male or female between 18 and 65 years of age with inadequate bone height in the posterior maxilla (<6 mm) (confirmed by Dentascan)
3. Patients who were willing to delay implant placement up to 6 months and were available for follow-up visits up to 9 months.

Table 1: Parameter for data collection

Preoperative	Intraoperative	Postoperative
Age/sex	Quantity of putty placed	Immediate postoperative orthopantomograph - quantity of putty
Teeth present	Intraoperative complication documentation	1 week: Clinical sign of any wound infection
Periodontal health of remaining teeth		After 6 months: Dentascan for - Height, width, and density of bone
Duration of patient being edentulous		Biopsy outcomes of quality of bone
Height, width, and density of bone		Histomorphometric analysis

Exclusion criteria

The exclusion criteria for this study were:

1. Patients who have received and failed a previous maxillary sinus augmentation procedure
2. Patients with acute or chronic sinus disease
3. Patient who are nursing or pregnant
4. Patients on long-term chronic immunosuppressant therapy
5. Patients with smoking habits
6. Patients who have had a significant radiation exposure
7. Diabetic patients and patients with significant medical history and on medication that compromise results (i.e., corticosteroids, bisphosphonate, etc.)
8. Patient refuses to give consent.

Methodology

The study was divided into two stages:

- Stage 1: The sinus augmentation surgery was performed
- Stage 2: The second surgery was carried out after 6 months when the augmented area was ready for implant placement. Trephine biopsy was taken just before implant placement. This was subjected to histopathological examination.

Radiographic assessment of the edentulous site: A radiographic analysis was carried out by using orthopantomogram (OPG): Initially, an OPG was taken to gain information about remaining alveolar bone height in posterior maxilla and to rule out any pathology at edentulous site as well as adjacent teeth.

Dentascan: Once the satisfactory results were obtained from OPG, three-dimensional Dentascan was done to determine the exact residual alveolar bone height, width, and density and to rule out any sinus pathology.

Surgical procedure

Prophylactic antibiotics were given 1 h before the surgery and the surgery was performed under local anesthesia. A crestal incision was made on the palatal aspect of the maxillary posterior edentulous ridge from the tuberosity to one tooth anterior to the anterior wall the maxillary sinus. Anterior vertical relief incision was made at least 10 mm anterior to the anterior vertical wall of antrum. Posterior vertical relief incision was made on the distal end of the crestal incision. The facial full-thickness mucoperiosteal flap was reflected to

expose the complete lateral wall of the maxilla and a portion of zygoma.

Lateral access window

The overall design of the lateral access window was determined after a thorough review of the Dentascan. Osteotomy cut for bony window was created by piezoelectric device (Piezotome 2, Satelec, Acteon, New Delhi, India). The inferior scoreline of the rectangular access window on the lateral maxilla was placed approximately 2–5 mm above the level of antral floor (which was 5–10 mm from the crest). The superior scoreline was made approximately 8–10 mm above the inferior scoreline. The anterior vertical line of the access window was scored approximately 5 mm distal to anterior vertical wall of the antrum. The distal vertical line was scored approximately 15 mm from the anterior vertical line. The corners of the access window were kept round [Figure 1].

Sinus membrane elevation

A flat-ended metal punch was used to gently fracture the lateral-access window from the surrounding bone, while still attached to the sinus membrane. A sinus membrane elevator was then introduced through the lateral access window along the inferior border. Once the mucosa of the antral floor was elevated, the lateral, distal, and medial wall of sinus was addressed. Bone graft putty about 0.5 cc in volume was placed into the space so created with the help of gun and bone graft cartridge [Figure 2]. Sutures were placed with good approximation. Immediate postoperative radiographs (OPG) were taken to estimate the amount of graft material [Figure 3]. Postsurgical instructions and medications (antibiotics and analgesics) were given.

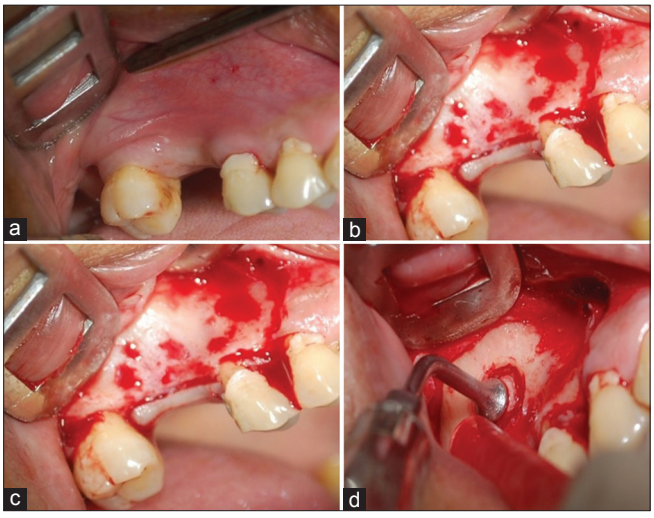

Figure 1: Clockwise (a) A crestal incision was made on the palatal aspect of the maxillary posterior edentulous ridge from the tuberosity to one tooth anterior to the anterior wall the maxillary sinus. (b and c) The facial full-thickness mucoperiosteal flap was reflected to expose the complete lateral wall of the maxilla. (d) A flat-ended metal punch was used to gently fracture the lateral-access window from the surrounding bone, while still attached to the sinus membrane

Follow-up visit: 1 week

On the 7th postoperative day, evaluation of the surgical site was done for any sign of infection and suture removal was done.

Follow-up visit: 6 months

Dentascan was done to estimate increased alveolar bone height and density of newly formed bone. Trephine biopsy of augmented site with 2 mm trephine bur was done at the time of implant placement. Dental implant was placed. The bone biopsy was sent for histopathological examination for qualitative analysis [Figures 4 and 5].

RESULTS

A prospective clinical study

There were in total 15 patients with 15 sides (10 right and 5 left) enrolled in our study, all fulfilling the above-mentioned inclusion criteria. No dropouts were observed during the course of the study.

Evaluation of preoperative alveolar bone height

Dentascan was done preoperatively to evaluate the exact remaining alveolar bone height in deficient posterior maxilla [Figure 6]. The mean preoperative alveolar bone height was 4.15 ± 1.23 mm ranging from 2.1 mm to 5.8 mm. The mean preoperative alveolar bone density was 418.94 ± 103.92 HU ranging from 310 HU to 588 HU.

Comparison of pre- and post-operative alveolar bone height

Postoperatively (after 6 months), Dentascan was done and increase in alveolar bone height in posterior maxilla, after bone graft augmentation was evaluated.

The mean postoperative height is 11.23 ± 1.25 mm ranging from 9.5 mm to 14.8 mm.

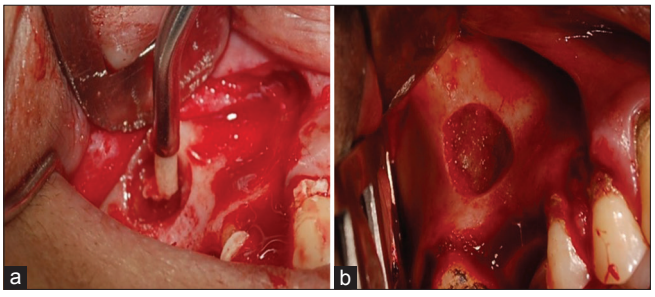

Figure 2: (a and b) Once the mucosa of the antral floor was elevated, the lateral, distal, and medial wall of sinus was addressed. Bone graft putty about 0.5 cc in volume was placed into the space so created with the help of gun and bone graft cartridge

The mean increase in alveolar bone height is 7.08 ± 1.42 mm ranging from 5.6 mm to 10.7 mm. It is evident from the data that there has been increase in alveolar bone height postbone graft augmentation. $P < 0.001$ shows that increase in alveolar bone height is highly significant as compared to preoperative bone height [Table 2].

The mean postoperative density is 525.43 ± 104.18 HU ranging from 649 HU to 350 HU. This is also a D3 quality bone as per Misch classification.

The mean difference in alveolar bone density is 104 ± 125.16 HU.

It is evident from the data that there has been increase in alveolar bone density postbone graft augmentation. $P = 0.0053$ shows that increase in alveolar bone density is significant as compared to preoperative bone density [Table 3].

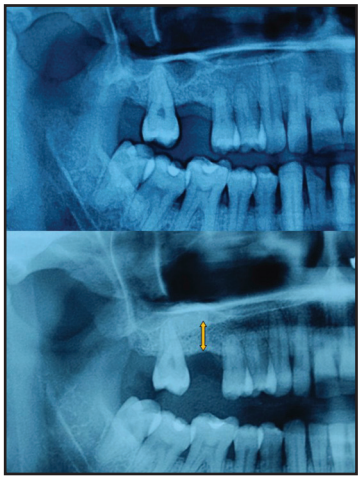

Figure 3: Pre- and post-operative orthopantomogram

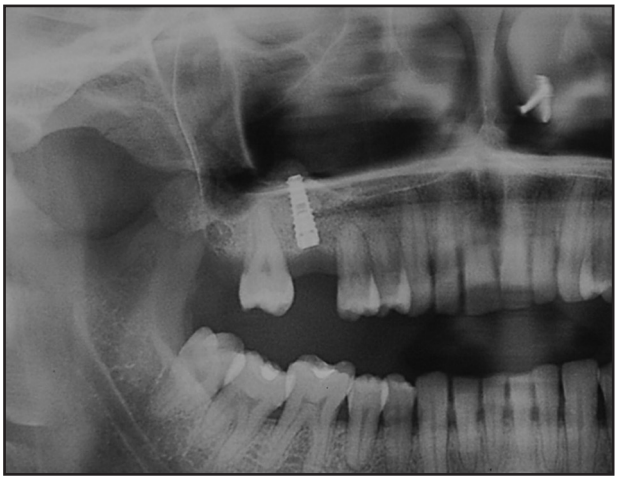

Figure 5: Implant placement at 6-month postoperatively

Tissue processing and analyses

The histopathological evaluation of the bone biopsy was carried out in Department of Pathology, AIIMS, New Delhi. Specimens were decalcified in ethylenediaminetetraacetic acid (10%) for a period of 1 week. After dehydration in graded series of ethanol, the specimens were embedded in paraffin, sectioned (3–5 μm sections), and stained with hematoxylin-eosin. Examinations were performed in a

Figure 4: Trephine biopsy of augmented site with 2 mm trephine bur was done at the time of implant

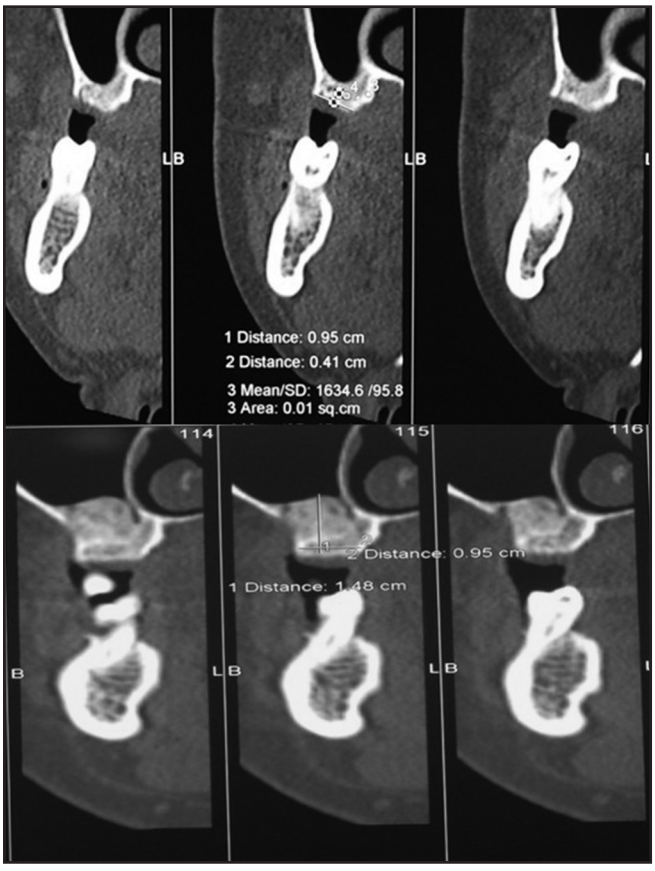

Figure 6: Pre- and post-operative Dentascan

Research light microscope (Model 80i, Nikon Corporation, Japan).

Histomorphometric measurements were performed in order to calculate the percentages (i.e., area fraction) of mineralized bone, residual graft materials, and soft-tissue components (i.e., connective tissue and/or bone marrow) 6 months after the sinus augmentation procedure. The stained specimens were photographed under Digital camera QCam (Q Imaging, Surrey, Canada) with inbuilt image grabber card. The images were processed and analyzed using Image-Pro Plus image analysis software version 7 (Media Cybernetics corporation, USA) to assess the percentages of different components. Images of the selected fields from the hematoxylin and eosin-stained slides were captured and stored in tagged image file format. Ten such consecutive images from each case were captured. The images on the monitor screen were outlined by a semiautomatic tracing system using the computer mouse the histological evaluation showed that the residual graft particles were surrounded by newly formed bone which presented features of mature bone, with well-organized lamellae and numerous small osteocytic lacunae. Blood vessels were found both in the mineralized part and in the soft tissues. It was also found that an active resorption of the grafted bone was taking place [Figure 7].

Histomorphometric evaluation

- In all the 15 samples, the area of the newly formed bone ranged from 29.71% to 59.37% with a mean of 42.35 ± 8.77%
- The percentage of residual grafted area ranged from 6.62% to 32.58% with a mean of 14.75 ± 7.86 and
- The soft tissue percentage ranged from 30.75% to 55.7% with a mean of 42.77 ± 8.11.

DISCUSSION

Sinus lift surgery is a standard surgical procedure used to increase the alveolar bone volume in deficient posterior maxilla, so that it provides good support and strength for stabilization of implants with adequate dimension. It was first performed by Dr. Hilt Tatum in mid-1970s and from there on it has become the most popular procedure to augment the deficient posterior maxilla.

The present study evaluated the performance of bioactive synthetic bone graft putty in bone formation, qualitatively and quantitatively in sinus augmentation procedure. The osteoconductive properties of bioactive glass have been documented in various clinical studies.[3,4]

In our study, the bony window was created with the help of piezoelectric device. Conventionally, motor-driven handpiece with bur is used to make window in the lateral wall of maxillary sinus. However, one of the most common complications of sinus lift surgery is sinus membrane perforation (35%). The sinus membrane perforation most commonly occurs during preparation of bony window due to accidental dipping of the bur into the sinus. Baldi *et al*.[5] and Li *et al*.[6] concluded in their study that piezosurgery provided less discomfort for the patient and greater convenience for the surgeon. They also found out that piezosurgery has advantages such as cut precision, greater intraoperative control, clear surgical site, and selective cut of the mineralized tissues with preservation of soft tissues. The ultrasonic insert permits gentle sectioning of bone without damage to the sinus membrane.

The advantage of obtaining the sample from the proposed implant site is that we analyze the same area of the newly formed bone where implant is to be placed. This also prevents us from making unnecessary another site for obtaining the biopsy. The internal diameter of the trephine bur used was

Table 2: Comparison between pre- and post-operative alveolar bone height

Variable	Preoperative	Postoperative	*P*
Alveolar bone height	4.15±1.23	11.23±1.25	<0.001

Paired *t*-test was applied

Table 3: Comparison between pre- and post-operative alveolar bone density

Variable	Preoperative	Postoperative	*P*
Alveolar bone density	418.94±103.91	525±104.18	0.0053

Paired *t*-test was applied

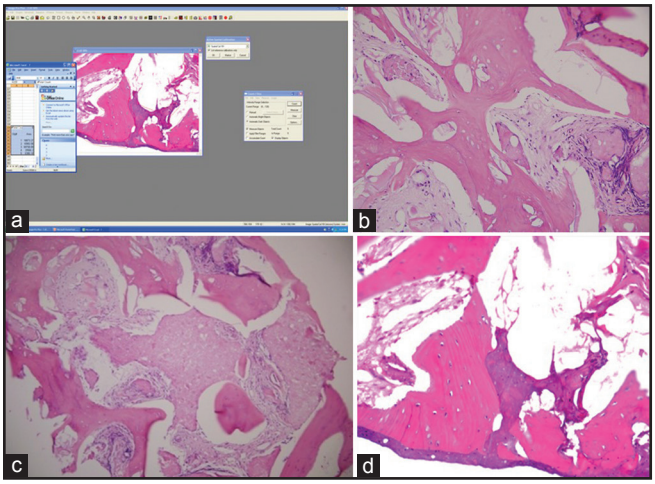

Figure 7: Clockwise manner. (a) The images were processed and analyzed using Image-Pro Plus image analysis software version 7 (Media Cybernetics corporation, USA) to assess the percentages of different components. (b, c and d) The histological evaluation showed that the residual graft particles were surrounded by newly formed bone which presented features of mature bone, with well-organized lamellae and numerous small osteocytic lacunae. Blood vessels were found both in the mineralized part and in the soft tissues

2 mm and the external diameter was 3 mm. We placed implants with diameter either equal to 3.75 mm or more than that. Kolerman *et al*.[7] also used the similar dimension trephine bur in their study.

CONCLUSION

One of the key determinants of successful sinus lift surgery is alveolar bone height. Sufficient alveolar bone height allows for placement of implant with adequate length.

Dentascan was done preoperatively and postoperatively, 6 months after sinus augmentation procedure. The mean preoperative alveolar bone height was 4.15 ± 1.23 mm and the mean postoperative alveolar bone height was 11.23 ± 1.25 mm. The mean increase in alveolar bone height was 7.08 ± 1.42 mm. Our result corresponds to that of Cordioli *et al*.[3] In their study, the mean increase in mineralized tissue height was 7.1 ± 1.6 mm after comparing presurgical CT scans with those performed 9–12 months following sinus augmentation procedure. The bone graft material used in their study was bioactive glass (Biogram) in combination with autogenous bone. Li *et al*.[6] also reported a mean increase of 7.5 ± 0.9 mm in alveolar bone height after grafting the sinus with a xenograft (Bio-Oss).

In our study, since the mean postoperative alveolar bone height is 11.23 ± 1.25 mm, it allowed placement of implants with adequate length in posterior maxilla. It also provided sufficient volume of mineralized tissue for primary stability of implants.

The internal structure of bone is described in terms of quality or density, which reflects a number of biomechanical properties, such as strength and modulus of elasticity. The density of the available bone in an edentulous site is a determining factor in treatment planning, implant design, surgical approach, healing time, and initial progressive bone loading during prosthetic reconstruction.

In our study, the mean preoperative density was 418.94 ± 103.92 HU. This is a D3 quality of bone according to Misch classification, which is generally found in posterior maxilla. The postoperative density of newly formed bone after sinus augmentation was 525.43 ± 104.18 HU. Now, this is also a D3 quality bone. The difference in pre- and postoperative density of bone is statistically significant ($P = 0.0053$), but clinically, there is not much difference since both are D3 quality bone. In a study done by Altintas *et al*.,[8] mean postoperative density after sinus augmentation was 254.91 HU ranging from 174 to 510 HU. Postoperative CT scan was performed 6 months after sinus augmentation. Bone graft used in this study was allogeneic mineralized bone graft. Recently, bone density is better demonstrated by histomorphometric analysis of bone biopsy samples of the grafted areas.

In our study, bone graft material used was prehydrated corticocancellous porcine bone. Biopsies were harvested 6 months after the sinus augmentation procedure. Acocella *et al*.[9] found a mean of 40.57 ± 4.22% of new bone formation in biopsies harvested 3 months after sinus augmentation surgery. The bone graft material used was corticocancellous fresh frozen bone chips. As reported with other composites graft, Wallace *et al*.[10] and Wheeler *et al*.,[11] prolonged healing periods may be required to allow bone maturation and complete resorption and substitution by bone of all graft particles.

In the present study, the presence of bands of osteoid tissue in the biopsy cores indicated that bone formation was still taking place after a healing period of 6 months.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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