ABSTRACT

Aim Bone augmentation in the atrophic maxilla is a prerequisite for successful implant rehabilitation. The aim of this study is to evaluate regeneration of bone and to compare the efficacy of PRF in bone regeneration following sinus augmentation surgery in the edentulous posterior maxilla.

Materials and methods A prospective randomized comparative study was conducted at our institution. The study was allocated into 3 groups: Group I, Platelet Rich Fibrin (PRF) as a stand-alone agent; Group II, Autogenous bone graft; Group III, Alloplastic bone graft (Tricalcium phosphate putty). Groups II and III received PRF as an adjuvant.

Results On comparing the post-operative bone height and radiodensity of the augmented region, there was statistical significance in Groups II and III. A 6 month post operative CBCT reveals a better bone regeneration in Group III (Alloplastic bone graft – β-Tricalcium phosphate putty).

Conclusions The results of this study suggest that both autogenous and alloplastic bone grafts are viable graft materials for maxillary sinus augmentation. Platelet rich fibrin, when used as an adjuvant to either alloplastic or autogenous graft enhances bone formation by delivering growth factors at the site of regeneration. However, as a stand-alone agent it failed to provide radiographic evidence of bone formation. The posterior maxilla has always been the most challenging site for implant rehabilitation. There have been various studies, comparing different grafts for successful bone regeneration and stability after implant rehabilitation. Our study aims to search for an ideal grafting material in the maxillary sinus region.

INTRODUCTION

Preservation of the height and width of alveolar bone subsequent to loss of teeth has long been a challenge for effective rehabilitation (1, 2). Any prosthesis will derive its support and stability from either the adjacent teeth or the residual alveolar ridge. Though there are many forms of prosthesis, implant supported prosthesis has been accepted as one of the best options (2). Good osseointegrated implants of sufficient diameter and length remain a pre-requisite for achieving this objective. Physiologically, the alveolar bone undergoes remodeling and resorption after the loss of teeth. This process varies from individual to individual. The degree of resorption grossly varies in different anatomic sites (3). This effect is also largely influenced by the original cause of tooth loss and the technique adopted for tooth extraction. The maxillary ridge resorption is said to be centripetal in nature (2). The maxillary anterior ridge resorption takes place in an upward and backward direction owing to the inclination of the roots of maxillary teeth. The posterior maxilla resorbs in an inward and upward direction making it progressively narrower and smaller (2, 3). In addition, bone resorption in the maxillary posterior region is bidirectional as the ridge resorbs from the crest in an upward direction as well as from the cranial direction due to pneumatization of maxillary sinus (4, 5).

Historically, total maxillary edentulism and posterior free end saddle situations have been addressed with removable prostheses (1, 6). However, with the success of osseointegrated implants, this envelope has been stretched in the last few decades (7). Implants with
adequate size, when placed in good quality bone with a favorable angulation can provide a sound foundation for a near normal dental rehabilitation.

In the posterior maxilla, the residual bone usually has a very thin cortex with large porous cancellous spaces. In addition, the available quantity of bone in all dimensions may be deficient. To overcome the difficulties based on the quantity of bone available, the options are either to augment the bone or to choose an alternative site. The alternative to bone grafting is by engaging the implants either in the maxillary tuberosity or in the pterygoids. In the last decade, specialized longer implants have been designed to engage the zygomatic bone (8). However, all of these remote implants will only support hybrid prostheses.

When bone augmentation becomes the chosen option, the increase in volume of the deficient posterior maxilla is usually achieved by sinus repositioning procedures. Though literature describes various bone augmentation techniques, currently both direct and indirect approaches to the maxillary sinus are practiced (7, 9, 10).

Innovation in material science has revolutionized the clinical application of biomaterials. Autogenous bone graft, which has both osteoinduction and osteoconduction properties, is still considered the gold standard in situations necessitating bone grafting. However, commercial alloplastic materials have been developed over the decades. The latter offer a definitive advantage to the patients by eliminating donor site morbidity. However, most of these materials are osteoconductive in nature (11). In the last 3 decades, concentrates of various growth factors like Platelet Rich Plasma (PRP), Bone Morphogenetic Protein (BMP) and Platelet Rich Fibrin (PRF) have been augmented along with the graft materials to increase the osteogenic potential (12, 13).

Our study aims at assessing the quality and quantity of bone formed within the maxillary sinus after sinus repositioning surgery when augmented with autogenous bone graft and alloplastic material along with Platelet Rich Fibrin (PRF) as an adjuvant. The null hypothesis proposed for this study was "The quality and quantity of bone regeneration after a direct sinus lift procedure is not dependent on the graft material used".

**MATERIALS AND METHODS**

A prospective randomized comparative study was conducted to assess the quality and the quantity of regenerated bone following augmentation of the maxillary sinus.

**Patients selection**

the patients who reported with complaints of edentulism requiring permanent posterior maxilla rehabilitation were included in the study. The grafting material employed for the study was either autogenous or alloplastic in nature. The participants were allocated into three groups based on sequential chronological randomization:

- Group I, Platelet Rich Fibrin (PRF) as a stand-alone agent;
- Group II, Autogenous bone graft + PRF;
- Group III, Alloplastic bone graft + PRF.

Groups II and III received freshly prepared Platelet rich fibrin (PRF) as an adjuvant. The study period was from July 2017 to September 2019 with all the surgical interventions being completed before April 2019 and hence had a minimum follow up of 6 months.

The inclusion criteria for recruiting patients were: Patients presenting with missing maxillary posterior and requiring dental rehabilitation; Patients who have available bone height of 6mm or less between the alveolar crest and the floor of maxillary sinus; Availability of good inter arch space; ASA I & ASA II; Age group – 20 years and above; Mouth opening (Inter-incisal distance) of minimum 35 mm.

The following patients were excluded from the study population: Uncontrolled systemic disease; Smokers; Presence of local pathology; Patients with history of radiotherapy in maxillofacial region; Patients not willing to participate in the study.

**Surgical procedures**

The assessment of maxillary sinus floor was done using a pre-operative orthopantomogram. The treatment plan was done with the planning of implant positions and accordingly the patients were placed into one of the 3 groups.

The surgical procedures (sinus repositioning surgery) were carried out either under local anaesthesia or general anaesthesia. A standardized direct sinus lift procedure was carried out by a single operator (1). The lateral window technique or the crestal approach was employed (1). The position of the maxillary sinus and the level of the sinus floor were assessed preoperatively using an Orthopantomogram (OPG). A crestal incision was placed and a mucoperiosteal flap was reflected to expose the lateral wall of the maxillary sinus. A rectangular window was created in the lateral wall of the maxillary sinus until the maxillary sinus membrane or the Schneiderian membrane was visualized. Using sinus lift curettes, the Schneiderian membrane was separated from the walls and floor of the maxillary sinus. The patency of the maxillary sinus was checked prior to augmentation. The window was then turned up cranially within the sinus along with the membrane so as to create a bony roof for the graft material or the window was removed and replaced back in position following the grafting procedure. The sinus was then grafted with either autogenous or alloplastic graft material (Novabone Putty) reinforced with Platelet Rich Fibrin (PRF). A PRF membrane was placed on the bony window to cover the bone graft. The mucoperiosteal flap was placed back and closure done with 3-0 silk sutures.
The autogenous bone grafts employed in this study were sourced from mandibular symphysis, ramus and iliac crest. Harvesting a mandibular symphysis graft was planned in patients having a good cortical bone volume in the anterior mandible. Standard bone harvesting technique was employed (14). A vestibular incision was employed to approach the symphysis. The incision was made in an apico-lingual direction 3 mm below the mucogingival junction in the lower anterior vestibule and a mucoperiosteal flap was reflected up to the base of the mandible. The superior and inferior osteotomy cuts were made 5 mm inferior to the root apices of the mandibular incisors and 5 mm superior to base of the mandible respectively. Vertical cuts were made connecting the superior and inferior cuts. A rectangular block bone graft of size 3×2 cm was harvested by creating osteotomies perpendicular to the cortex of the mandible. The bone block so obtained was then broken down into smaller pieces to be packed into the maxillary sinus.

The mandibular ramal graft was also harvested under local anaesthesia following the standard protocol (15). The incision was made in the buccal vestibule, medial to the external oblique ridge and was extended anterior and lateral to the retromolar pad. Three osteotomies namely, the external oblique cut, superior ramus cut and the anterior body cut were performed. The depths of these cuts were such that it involved only the outer cortex. A mono-cortical block graft was obtained from the ramus of the mandible. The block graft was broken into smaller pieces for the purpose of packing into the sinus.

The corticocancellous iliac crest graft harvest was performed under general anaesthesia following the standard surgical protocol (16). The iliac region was prepared and sandbag placed under the hip to raise and make the iliac prominence pronounced. Incision was placed over the prominence of the anterior iliac spine. Layerwise dissection was done to expose the iliac crest. Through a medial trapdoor approach, osteotomies were made and a cortico-cancellous bone graft was obtained. Pure cancellous bone particles were obtained by scooping within the iliac bone.

Participants who were randomized to the alloplastic group (Group III) received β-Tricalcium phosphate putty sourced from NovaBone (NovaBone products, LLC, Alachua, Florida) in a cartridge form. It was delivered to the maxillary sinus using a dispensing gun.

The PRF preparation was done according to the Choukroun’s Protocol (18). Each participant received freshly prepared Platelet rich fibrin (PRF); 9 ml of the patient’s venous blood was drawn a few minutes prior to placement and collected in vacutainer tubes without
anticoagulant. The samples were processed in the centrifuge (REMI Laboratories) at 2700–3000 rotations per minute for 12 minutes. A part of it was mixed with autogenous bone particles for packing into the sinus cavity after sinus lift. Another part was compressed between two sterile surfaces to obtain a fibrin membrane which was used for the coverage of the graft material before closure.

An immediate post-operative orthopantomogram was taken to assess the sinus lift done. All the study patients had 6 months follow up with periodic follow up at 1, 3 and 5 months with serial orthopantomograms to assess the bone pattern of the grafted area. At the end of 6 months, a cone beam computed tomography scan was done for implant planning and assessing the radiodensity differences between native bone and the grafted site.

**Statistical analysis**

The observational data were analyzed using SPSS (Statistical Package for Social Sciences) software version 19.0 (IBM Corporation, Armonk, NY, USA). The confidence interval had been set at 95% and the p-value was set for 0.05. A p-value equal to or less than 0.05 was considered significant. The mean height and radiodensity at each interval (1, 3 and 5 months) were analyzed by Kruskal Wallis test. The radiographic height and density achieved over 5 months was analyzed by Friedman test. At 6 months post-operatively, the radiodensity of the native bone and the grafted site of the three groups were compared using Mann Whitney U test.

**RESULTS**

The study included 14 patients, divided into 3 groups who underwent maxillary sinus repositioning surgery (Table 1). The study participants were in the age range of 20-60 years (Table 2). The study population was partially edentulous with either free end saddle or tooth bound saddle (Table 2). Even with the presence of a retained posterior tooth in the arch, there was clinical evidence of ridge resorption and/or radiographic appearance of pneumatization of maxillary sinus. All participants had evidence of pneumatization of the maxillary sinus in panoramic radiographs.

Among the 14 patients, 2 patients received Platelet Rich Fibrin (PRF) as a stand-alone grafting agent (Group I), 6 patients received autogenous bone graft (intra-oral and extra oral sites) along with Platelet Rich Fibrin (PRF) as an adjuvant (Group III) and the remaining 6 patients received alloplastic bone graft material (Novabone Putty) along with Platelet Rich Fibrin (PRF) as an adjuvant (Group II) (Table 3). The radiographic evidence for formation of bone after placement of PRF as a stand-alone graft material in the maxillary sinus was found to be negligible. Therefore, it was abandoned after 2 cases. Our further comparisons were done between Groups II and III.

The height of sinus repositioning achieved was measured immediately post-surgery using ImageJ software (Rasband, W.S., ImageJ, U. S. National Institutes of Health, Bethesda, Maryland, USA). The bone height maintained was measured at 1 month, 3 months and 5 months post-operatively. The height achieved at 1 month post-surgery was not statistically significant in between the groups. The height appeared to be consistent in Group III (Alloplastic bone graft + PRF) and resorption was found in the 3 month and 5 month follow up OPG in Group II (Autogenous bone graft + PRF) (Table 4, Fig. 2). The density measurement in panoramic radiographs was carried out in grey values using ImageJ software by NIH (Rasband, W.S., ImageJ, U. S. National Institutes of Health, Bethesda, Maryland, USA). The radiodensities of the inferior part of the maxillary sinus was measured at a standardized distance of 7 mm from the crest of the alveolar ridge in the pre-treatment radiograph to set a baseline density. The radiodensity of native bone was also measured at the level of the crest of the alveolar bone as well as the change of the native bone after 6 months of bone grafting. Both Alloplastic bone graft material (Group II) and Autogenous bone grafts (Group III) were observed to show an increased density (p = 0.003, p = 0.002 respectively) as compared to the preoperative

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**TABLE 1** Details of age, number and gender of participants.

<table>
<thead>
<tr>
<th>Age group (yrs)</th>
<th>Male</th>
<th>Female</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-30</td>
<td>3</td>
<td>0</td>
<td>21.5</td>
</tr>
<tr>
<td>30-40</td>
<td>2</td>
<td>1</td>
<td>21.5</td>
</tr>
<tr>
<td>40-50</td>
<td>5</td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>50-60</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>3</td>
<td>100</td>
</tr>
</tbody>
</table>

**TABLE 2** Type of edentulism within the study group.

<table>
<thead>
<tr>
<th>Edentulism Type</th>
<th>Partial</th>
<th>Complete</th>
<th>Total (%) (saddle type)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free end saddle</td>
<td>10</td>
<td>1</td>
<td>11 (78.5%)</td>
</tr>
<tr>
<td>Tooth bound saddle</td>
<td>3</td>
<td>0</td>
<td>3 (21.5%)</td>
</tr>
<tr>
<td>Total (edentulism)</td>
<td>13 (92.8%)</td>
<td>1 (7.2%)</td>
<td>14 (100%)</td>
</tr>
</tbody>
</table>

**TABLE 3** Group distribution in the study participants.

<table>
<thead>
<tr>
<th>Group</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR</td>
<td>2</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>AU + PR</td>
<td>2</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>AL + PR</td>
<td>2</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

PR- Platelet Rich Fibrin, AU – Autogenous Bone, AL – Alloplastic bone
Assessment of bone regeneration after sinus augmentation

The density of grafted bone in Hounsfeld units was measured via CS3D software (Carestream Dental LLC, Atlanta, GA, USA) at 6 months after sinus repositioning surgery. The mean density of Group III is 470HU. The autogenous group (Group II) had a mean density of 369HU. On comparison using Mann Whitney U test, the density of the alloplastic graft material was found to be statistically significant (Table 6). On comparing the radio-densities of native bone and grafted bone, in a 6 months post-operative Cone Beam CT scan, a statistically significant increase in the density of alloplastic bone graft material was observed (Table 6).

Our results demonstrate that both alloplastic and autogenous bone grafts show significant bone regeneration when used to augment the maxillary sinus. Although the radiodensity of alloplastic material is superior to the autogenous graft materials, this could be attributed to the tendency of autogenous grafts to resorb and remodel. Further long term studies are needed to completely understand the pattern of resorption of the grafted bone and the factors responsible for it.

<table>
<thead>
<tr>
<th>Group</th>
<th>Non grafted sinus</th>
<th>Post operative</th>
<th>Friedman test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (PR)</td>
<td>3.80</td>
<td>7.50</td>
<td>7.25</td>
<td>6.50</td>
</tr>
<tr>
<td>II (AU+PR)</td>
<td>2.54</td>
<td>9.05</td>
<td>9.02</td>
<td>8.83</td>
</tr>
<tr>
<td>III (AL+PR)</td>
<td>3.57</td>
<td>11.07</td>
<td>11.05</td>
<td>10.92</td>
</tr>
</tbody>
</table>

TABLE 4 Comparison between the preoperative and postoperative bone height.

<table>
<thead>
<tr>
<th>Group</th>
<th>Native / Grafted</th>
<th>Mean HD</th>
<th>SEM</th>
<th>Mann Whitney U test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Native</td>
<td>437.00</td>
<td>140.00</td>
<td>0.00</td>
<td>0.121</td>
</tr>
<tr>
<td></td>
<td>Grafted</td>
<td>129.00</td>
<td>9.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Native</td>
<td>572.00</td>
<td>105.92</td>
<td>15.000</td>
<td>0.631</td>
</tr>
<tr>
<td></td>
<td>Grafted</td>
<td>501.33</td>
<td>137.94</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>Native</td>
<td>439.83</td>
<td>13.03</td>
<td>3.00</td>
<td>0.016</td>
</tr>
<tr>
<td></td>
<td>Grafted</td>
<td>369.67</td>
<td>20.76</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

HD – Hounsfield density, SEM – Standard error of mean

TABLE 5 Comparison between pre and post-operative radiodensity up till 5 months postoperatively.

FIG. 2 Preoperative (A) and 5 months postoperative OPG (B) of a participant of group III depicting the bone regeneration following sinus augmentation.
DISCUSSION

The posterior maxilla has always been the most challenging site for implant rehabilitation owing to the horizontal and vertical bone loss coupled with pneumatization of the maxillary sinus (19,20). The most challenging factors are the poor quality of bone, decreased volume and density giving a porous cancellous type of bone with minimal or no corticated margins. Implant site preparation is a prerequisite to implant placement and needs to be included as part of the treatment plan.

The paranasal sinuses are rudimentary at birth and develop as the cranial bones mature. The maxillary sinus is the first of the paranasal sinuses to develop. They are initially medial to the orbits, and later descend below the orbits. As the maxilla develops, the maxillary sinuses enlarge. Eventually, the sinus is filled with air by a physiologic process called pneumatization (4). After the loss of maxillary teeth, this process of pneumatization is unobstructed. It starts encroaching upon the alveolar bone and is one of the primary causes of decreased ridge height in the posterior maxilla (5). The literature reports various factors that influence pneumatization process which include heredity, configuration of the craniofacial skeleton, history of previous surgeries involving the sinus, influence of hormones and even the pressure of air within the sinus cavity. Age and loss of teeth also contribute to this condition (4).

Augmentation of the maxillary sinus with an appropriate material to aid in bone regeneration is predictably the sine qua non for preparation of the posterior maxilla for successful placement and stability of implants. The technique of maxillary sinus grafting was originally developed by Tatum and coworkers in 1975 (10, 21). An alveolar crest access to the maxillary sinus was used by Tatum. A modified Caldwell-Luc procedure, where a bone window was created on the lateral wall of the maxillary sinus and in-fractured to elevate the intact sinus membrane gained popularity, was followed (1). The chosen bone graft was placed in the area which was previously occupied by the inferior one-third of the pneumatized maxillary sinus. This procedure provided adequate bone in the posterior maxilla, which permitted various implant placement options (7). In 1980, Boyne et al. demonstrated significant bone formation after augmenting with autogenous cancellous bone chips (22). In 1984, Misch modified this technique by developing a combination procedure of sinus augmentation and blade-vent implant placement (6). Currently, two techniques of sinus grafting namely, the lateral window technique and the sinus intrusion osteotomy technique (crestal) are in use (19, 23).

Recent histologic and histomorphometric studies indicate that particulate grafts that contain autogenous bone may be particularly suited for earlier implant placement because of their relatively quick healing property (24-26). However, the ideal graft, implant materials and their techniques are still an area of study and debate. Since the mid-1980s, numerous techniques have evolved describing their advantages in sinus repositioning procedures. The procedures vary in terms of the initial surgical approach, the type of grafting material or source of autogenous bone, and the type of implant material. Currently, there are two surgical protocols for sinus repositioning surgery which are either the 1-step or the 2-step technique. The 1-step procedure is the technique where maxillary sinus repositioning surgery, sinus grafting and implant placement is done simultaneously. The 2-step procedure is the technique where a 6 month waiting period is given for the sinus graft to mature and allow for bone regeneration before placing the implants (10). Many authors have reported good initial results with the one-step as well as the two-step procedures (23, 27, 28).

The criteria for determining when either the 1-step or 2-step procedure should be used, however, have generally been universal (10). These criteria have called for the two-step procedure to be used for situations involving anything less than 5 mm of alveolar bone height and for the 1-step procedure to be reserved only for patients with bone heights of 5 mm or more (9, 10). We chose our study criteria based on this. A two-step procedure was followed for all our study participants. A period of 6 months was allowed for graft maturation. A Cone Beam Computed Tomography (CBCT) Scan was done after this period, primarily for the planning of implant rehabilitation. This also helped in the quantitative and qualitative assessment of the grafted material.

According to available literature, concentrates of growth factors added along with graft material theoretically improved the quality of bone formed (29). The alpha granules of platelets secrete growth factors like Platelet Derived Growth Factor (PDGF), Vascular Endothelial Growth Factor (VEGF), and Transforming Growth Factor (TGF). These factors are hypothesized to stimulate cell proliferation, matrix remodeling and angiogenesis (30, 31). Concentrates of platelets were initially used in Transfusion Medicine for the prevention and treatment of hemorrhage resulting from thrombocytopenia. The standard platelet concentrate for transfusion medicine was Platelet Rich Plasma (PRP). PRP was in use for about one and a half decades for promoting wound healing and bone regeneration. There were reported incidents of immunogenic reactions attributed to the addition of thrombin in the preparation process of PRP (30, 32). In 2005, Choukroun et al. described a second generation platelet concentrate which was termed Platelet Rich Fibrin (PRF). Since then PRF has been used as a viable material for bone defects (30, 31, 33). Various studies have been conducted comparing the bone regenerative capacity of PRP and PRF when mixed with grafting materials (34). Choukroun’s PRF gained popularity as it is a single step procedure. Moreover, no chemical agents were needed during its preparation process. By altering the speed of the centrifuge, variations in this platelet
In the 20th century, many grafting materials have been used for augmentation of the sinus cavity (15, 16, 17, 19). The alloplastic graft materials, particularly tricalcium phosphate used in our study, seem to be excellent agents for bone regeneration in the sinus. Tricalcium phosphate helps in both space maintenance after the sinus membrane has been repositioned superiorly and has osteoconductive property which helps in bone formation in the region (17). Our study shows a statistically significant difference in the density of alloplastic graft material when compared to the native bone.

The limitation of our study is the lack of histological evidence of the quality bone formed and need for long term follow up for assessment of implant stability. We intend to extend this study for a further period and include all these factors.

CONCLUSION

Our study compared the regenerative potential of both autogenous and alloplastic graft materials augmented with PRF. Although PRF as a stand-alone agent did not show radiographic evidence of bone regeneration, as an adjuvant it was proven to be a valuable augmentation agent in sinus repositioning surgery. Quantitatively both alloplastic and autogenous graft materials reinforced with PRF showed promising results with maintenance of bone height up to 6 months which is considered to be the period for bone remodeling. Qualitatively, alloplastic material maintains the radiodensity whereas autogenous material showed varying degrees of radiodensity depending on the source of the graft. This suggests that both graft materials are stable after augmenting with PRF with the autogenous grafts undergoing remodeling at a faster pace. More extensive research studies are required on a long term basis to demonstrate successful osseointegration of implants onto the grafted site and assess the functional stability of implants in the grafted sinus for many years.

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Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

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