ABSTRACT

Aim This in vivo study aims to compare the quantity and quality of bone formation around dental implants inserted following Tatum’s approach with placement of Concentrated Growth Factors (CGF).

Materials and methods This prospective study involved 20 patients requiring maxillary sinus augmentation for missing maxillary first molars. These patients were randomly divided into two groups: one in which sinus augmentation was followed by placement of CGF and simultaneous implant placement and the other in which no grafting material was used also followed by immediate implant placement. Radiographic assessment was carried out six months postoperatively using Cone Beam Computed Tomography (CBCT) to assess the quantity and quality of the new bone formed.

Results CBCT analysis showed a mean bone gain of 3.19 mm in subjects in the test group and 4.47 mm in the control group. Also, a statistically significant difference was noted in bone quality in the test group when compared to controls.

Conclusion This study indicates that direct sinus augmentation with CGF and immediate implant placement is a viable treatment option for the atrophic posterior maxilla. However, further studies are required to validate the quantity of bone formation preferably using Computed Tomography (CT).

KEYWORDS CBCT, CGF, Dental Implants, Maxillary sinus augmentation, Pneumatization of the maxilla.

INTRODUCTION

Teeth loss results in inadequate oral function, positional changes in the natural teeth, loss of structural balance and poor esthetics. Endosseous osseointegrated implants provide successful and predictable outcomes in the rehabilitation of completely and partially edentulous patients. Horizontal and vertical resorption of the bone in the posterior maxilla takes place following the pneumatization of the maxillary sinuses and resorption of the alveolar ridge after extraction of the maxillary posterior teeth (1). Hence, the placement of dental implants in the atrophic posterior maxilla can pose a great challenge. This can be overcome by the augmentation of the floor of the maxillary sinus. A wide range of experimental and clinical studies have evaluated the efficacy of various augmentation techniques and graft materials like xenografts, autografts and allografts for new bone generation (2).

In recent years, human and animal studies have reported the successful augmentation of the maxillary sinus without the need for bone grafting and effective osseointegration of the dental implants (3). Concentrated Growth Factors (CGF) were developed by Sacco in the year 2006. It is produced by centrifuging venous blood, as a result of which the platelets are concentrated in a gel layer, also containing fibrin matrix (4) rich in platelets, growth factors, leukocytes, thereby providing a matrix for angiogenesis, cell migration and tissue remodeling. In a case series by Gheno et al., the authors used xenogenic bone blocks with CGF in both maxilla and mandible, where grafting was required along with simultaneous implant placement; the authors concluded that this technique can be safely performed in the dental office under local anesthesia and is a viable treatment option for regenerative surgery (5). However there are very few studies which have evaluated the quality of the new bone formed around the implants following membrane elevation without the placement of any graft material.

This in vivo study aims to compare the quantity and
quality of bone formation around dental implants placed following Tatum’s approach with placement of CGF alone (6).

MATERIALS AND METHODS

Patients reporting to the department of Prosthodontics at A. B. Shetty Memorial Institute of Dental Sciences (Derlakatte, Mangaluru, India) with the chief request of replacement of missing upper posterior teeth were screened for the study (Fig. 1). Dental and medical histories were obtained. Preoperative Cone Beam Computed Tomography (CBCT) (Fig. 2) (Planmeca ProMax® 3D Mid) were taken to evaluate the bone height, width and the sinus anatomy.

Patients were randomly distributed into two groups.
- Group A: patients in whom CGF was placed after sinus elevation procedure in the space created followed by immediate implant placement.
- Group B: no graft material was placed after sinus elevation procedure.

Surgical procedure

The patients’ own venous blood was transferred into two 4 ml vacutainer tubes and centrifuged (Medifuge, Silfradent) using the following program: 30 seconds acceleration, 2 minutes 2700 rpm, 4 minutes 2400 rpm, 4 minutes 2700 rpm, 3 minutes 3000 rpm, 36 seconds deceleration and stop for making CGF. At the end of the process there were three blood fractions (Fig. 3):
1. upper platelet poor plasma (PPP) layer;
2. middle fibrin-rich gel with aggregated platelets and CGF;
3. lower red blood cell (RBC) layer.

Surgery was performed under local infiltration anaesthesia. A mid-crestal incision was performed in the edentulous area, vertical releasing incisions were made and a full-thickness mucoperiosteal flap was raised.
The lateral window was made using a number 6 sinus scoring bur, to allow the entry of the membrane elevation instruments. The lateral bony wall was not separated from the Schneiderian membrane but lifted along with it. Sequential osteotomies were done for the 3.5 mm implant (Ankylos surgical kit) according to the manufacturer’s instructions. A 3.5 x 11 mm implant was mechanically torqued at a minimum insertion torque of 25 Ncm. CGF was placed in the space created by lifting the sinus membrane after placement of the implant in the test group (Fig. 4). A collagen membrane (Periocol-GTR, Eucare Pharmaceuticals) was placed over the lateral window and interrupted sutures were placed to achieve primary wound closure with Vicryl 3-0 sutures.

Prosthetic procedure
After a healing period of six months, an intra-oral periapical radiograph was taken to check bone formation. Second stage surgery was performed and an abutment level single step closed tray impression was made with putty and light body in the subsequent appointment (Aquasil putty and light body, Dentsply India). Metal-ceramic crowns were fabricated in physiologic occlusion and cemented using zinc phosphate cement (De Tray® Zinc) (Fig. 5).

Radiographic analysis
CBCT scan was done pre-operatively (Fig. 2) and six months post-operatively (Fig. 6). Initial bone quantity was measured in the pre-operative CBCT and the post-operative CBCT was used to measure the new bone formation in the sinus. Also, the quality of bone formed was detected by measuring the Hounsfield Units (HU) adjacent to the first two and last two implant threads.

RESULTS
The data obtained was analyzed using IBM SPSS Statistics Version 22 (Armonk, NY: IBM Corp). Descriptive data were
Bone height and bone quality at the first and last two threads were compared using independent Student’s t-test. P-value <0.05 was considered to be significant. When comparing the quantity of bone formation on the mesial side, it was higher in Group B (4.501±1.03 mm) with a t-value of -3.31 and was statistically significant with a p-value of 0.006; similarly, on the buccal side, it was higher in Group B (5.13±1.2 mm) with a t-value of -0.968 which is statistically non significant with a p-value of 0.346 (Table 1).

Comparison of the bone density on the mesial side at the last two threads between the two groups shows that it is higher in Group A (838.5±372.8 HU) with a t-value of 2.385 and is statistically significant with a p-value of 0.039; similarly, bone density on the distal side at the last two threads between the two groups shows that it is higher in Group A (764.8±340.61 HU) with a t-value of 2.634 and is statistically significant with a p-value of 0.025. Comparing the bone density buccal to the implant, the last two threads between the two groups show that it is higher in Group A (1027.1±325.88 HU) with a t-value of 3.952 and is statistically significant with a p-value of 0.001 (Table 2).

### Table 1: Radiographic assessment of bone quantity formation between the two groups.

<table>
<thead>
<tr>
<th>Difference in bone height</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>t</th>
<th>df</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesial</td>
<td>Group A</td>
<td>10</td>
<td>1.932</td>
<td>2.224774</td>
<td>-3.31</td>
<td>12.73</td>
<td>0.006</td>
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<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>4.501</td>
<td>1.03628</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>Group A</td>
<td>10</td>
<td>2.621</td>
<td>1.762173</td>
<td></td>
<td>18</td>
<td>0.009</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>4.639</td>
<td>1.268871</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palatal</td>
<td>Group A</td>
<td>10</td>
<td>3.864</td>
<td>1.50871</td>
<td></td>
<td>18</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>4.028</td>
<td>1.661631</td>
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<td></td>
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</tr>
<tr>
<td>Buccal</td>
<td>Group A</td>
<td>10</td>
<td>4.417</td>
<td>2.008106</td>
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<td>18</td>
<td>0.346</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>5.135</td>
<td>1.209924</td>
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</tr>
</tbody>
</table>

### Table 2: Comparison of bone quality at the first two and last two threads of the implant six months after implant placement.

<table>
<thead>
<tr>
<th>Group 2 threads mesial</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>t</th>
<th>df</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>Group A</td>
<td>10</td>
<td>593.3</td>
<td>406.752</td>
<td>0.144</td>
<td>11.429</td>
<td>0.888</td>
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<td></td>
<td>Group B</td>
<td>10</td>
<td>573.5</td>
<td>150.832</td>
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<tr>
<td>Second</td>
<td>Group A</td>
<td>10</td>
<td>597.6</td>
<td>315.378</td>
<td>1.077</td>
<td>10.752</td>
<td>0.305</td>
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<td></td>
<td>Group B</td>
<td>10</td>
<td>485</td>
<td>98.879</td>
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<tr>
<td>Buccal</td>
<td>Group A</td>
<td>10</td>
<td>874.2</td>
<td>338.843</td>
<td>2.918</td>
<td>18</td>
<td>0.009</td>
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<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>531.8</td>
<td>151.122</td>
<td></td>
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<tr>
<td>Palatal</td>
<td>Group A</td>
<td>10</td>
<td>1049.8</td>
<td>434.125</td>
<td>2.741</td>
<td>11.045</td>
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<td></td>
<td>Group B</td>
<td>10</td>
<td>652.5</td>
<td>147.303</td>
<td></td>
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<tr>
<td>First 2 threads mesial</td>
<td>Group A</td>
<td>10</td>
<td>838.5</td>
<td>372.889</td>
<td>2.385</td>
<td>9.855</td>
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<td>Group B</td>
<td>10</td>
<td>550.7</td>
<td>81.344</td>
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<tr>
<td>First 2 threads distal</td>
<td>Group A</td>
<td>10</td>
<td>764.8</td>
<td>340.619</td>
<td>2.634</td>
<td>10.082</td>
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<td>Group B</td>
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<td>472.6</td>
<td>83.657</td>
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<tr>
<td>First 2 threads buccal</td>
<td>Group A</td>
<td>10</td>
<td>1027.1</td>
<td>325.887</td>
<td>3.952</td>
<td>18</td>
<td>0.001</td>
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<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>569.3</td>
<td>167.359</td>
<td></td>
<td></td>
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<tr>
<td>Last 2 threads mesial</td>
<td>Group A</td>
<td>10</td>
<td>1020.7</td>
<td>249.157</td>
<td>3.437</td>
<td>18</td>
<td>0.003</td>
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<tr>
<td></td>
<td>Group B</td>
<td>10</td>
<td>655.3</td>
<td>225.735</td>
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</tbody>
</table>
DISCUSSION

The placement of dental implants in the posterior atrophic maxilla can be a great challenge owing to the inadequate volume of bone. The augmentation of the maxillary sinus can be done via two approaches: the crestal approach or a lateral window approach (3). It is believed that bone substitutes do not play a major role in bone formation after the direct sinus elevation procedure and the Schneiderian membrane itself has osteoprogenitor cells which facilitate bone formation (7).

In this study, a lateral window approach was employed for the sinus augmentation procedure. Fibrin-rich blocks with CGF were placed between the floor of the sinus and the elevated membrane. In the control group, sinus augmentation was followed by immediate implant placement without any graft material.

CGF was prepared with the patients' own venous blood, thereby avoiding the risk of cross-contamination commonly associated with biomaterials or synthetic materials (8). CGF is known to quicken bone formation along with guided bone regeneration in sinus grafts (9, 10). It releases growth factors such as Platelet Derived Growth Factors (PDGF), Vascular Endothelial Growth Factors (VEGF), Insulin-like Growth Factors and Transforming Growth Factor β -1 (TGF) (11). In comparison to its predecessors (PRP) it does not require addition of any blood clotting factors, thus reducing risk of any allergic reactions.

The disadvantages of sinus augmentation using a bone substitute include infection of grafting material, as a result of which the rate and amount of new bone formation is reduced. Another setback with allogeneic and xenogeneic bone grafting materials is that certain groups of the population may not agree to the use of these materials on religious grounds. Whereas, the only disadvantage with CGF is that 20-60 ml of patients' venous blood is needed. Since it is an invasive procedure, an informed consent should be obtained.

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The new bone formation was measured radiographically by CBCT. Mesial, distal, buccal and palatal values were recorded. The mean bone gain was found to be 3.193 mm in the test group, whereas, in controls it was 4.47 mm. The value for the control group was similar to the study carried out by Chen et al. (11), who reported an average bone gain of 4.5 mm.

When considering the mean total bone height, it was 8.079 mm in the test group. Whereas, in the control group it was 10.2 mm, which was lesser than the length of the implants used. The values for the test group are in contrast to that obtained by Sohn et al., who claim to have achieved a mean bone height of 9.53 mm in a similar study (3). The loss in bone height of 2.921 mm in the control group can be attributed to the collapse of the Schneiderian membrane over the implant apex. This may be due to the pressure created during respiration, additionally it can be due to the early dissolution of CGF.

When comparing the quality of bone formed, the test group showed better statistically significant bone quality as compared to the control group which can be attributed to the faster bone formation with CGF as observed by Kim et al. (4).

No complications were reported in this study during the follow-up period of 6 months, thus indicating a 100% success rate, which is comparable in outcome to several similar studies (1, 3, 12, 13).

Among the techniques used by various authors, Smiler et al. described the use of non-resorbable hydroxyapatite, bovine cortical hydroxyapatite (Bio-Oss), resorbable hydroxyapatite (OsteoGen), and freeze-dried demineralized bone powder and granules for sinus augmentation and reported consistent bone growth in all experimental groups (4, 6). Sohn et al., Altintas et al., Cricchio et al., Chen et al., Thor et al. and Sani et al. used the lateral window approach for sinus augmentation followed by immediate implant placement without the use of any grafts with successful results (1, 2, 12, 13, 14). Whereas Hanao et al., de Oliveira et al. and Dikicier et al. advocated the use of patients' venous blood after sinus augmentation which has shown positive results (15, 16, 17). Kassolis et al., in an experiment have shown the use of PRF with FDBA (Freeze-Dried Bone Allograft) after sinus augmentation as a successful treatment option (17). Mazoz et al. concluded that the use of PRF after sinus augmentation is also possible (16).

CONCLUSION

The following results were achieved.

1. A mean bone gain of 3.194 mm was seen in the test group, whereas it was 4.47 mm in the control group.
2. A statistically significant difference in the bone densities was detected between the test and the control group, the test being higher.
3. 100% implant survival.

Within the limitations of this study, it can be concluded that direct sinus elevation with CGF alone is a viable treatment option with successful osseointegration and can be carried out in patients who are not willing to receive bone graft substitutes. However, the quantity of bone formation was not satisfactory and further studies, preferably with the use of a CT scan, are required to validate the results.
REFERENCES


