

RIDGE HEIGHT PRESERVATION USING OsteoBiol® Gen-Os (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

Mohamed Shokry* and Nahed Attia**

ABSTRACT

An important question facing most of the clinicians is whether the bone replacements graft help in preserving bone in the post extraction period, and whether they limit or reduce the alveolar bone height shrinkage. The aim of this study was to assess the effectiveness of xenografts (OsteoBiol® Gen-Os) in ridge height preservation using cone beam computerized tomography (CBCT).

Materials and methods: This study out was carried as a randomized controlled clinical trial. Thirty patients requiring extraction of mandibular first molars were enrolled in this study, they are randomly divided into two equal groups, and each consisted of fifteen participants. Group I (study Group): received (OsteoBiol® Gen-Os; Tecnooss srl, Giaveno, Italy) and collaplug following the tooth extraction, while group II (control Group), received (Bio-oss® Geistlich Pharma AG, Switzerland) and collaplug serving as a control group. Vertical ridge changes were studied in the two groups from the time of extraction to four and nine months after the extraction using CBCT.

Results: The mean loss of vertical bone was 0.66 mm $\pm$ 0.071 and 0.567 $\pm$ 0.080 in Groups I and II respectively at 4 months follow up interval, whereas, it was 0.397 $\pm$ 0.057 for the study group and 0.375 $\pm$ 0.055 for the control group at 9 months postoperatively. A non-statistically significant difference was found between the test and control groups.

Conclusion: The use of Osteobiol Gen Os® is effective in ridge preservation. It decreased the loss of alveolar bone vertically following extraction.

INTRODUCTION

Attempts to regenerate lost alveolar bone have been elusive and such a goal is always the dream of both the clinicians and the patients. Loss of alveolar

bone may be attributed to a variety of factors, such as endodontic pathology, periodontitis, facial trauma and aggressive maneuvers during extractions. An adequate alveolar crest is essential for implant placement in terms of esthetics and function. ⁽¹⁾

* Lecturer of Oral and Maxillofacial Surgery, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Alexandria University.

** Professor of Periodontology, Chairperson of Oral Surgical Sciences Department, Faculty of Dentistry, Beirut Arab University.

The extraction socket heals and forms a blood clot which leads to the formation of new bone within 3-4 months. Although bone deposition in the socket continues for several months, it will not reach the crestal level of the neighboring teeth. The specific pattern of resorption after tooth loss is unpredictable. In many cases this resorption process tends to stabilize after a period, whereas in others a continuation of the process eventually results in total loss of alveolar bone.⁽²⁾ Both bone volume and bone density decrease once the functional stresses normally transmitted by natural teeth loss.⁽³⁾

As the interarch distance increases and the height of the available bone decreases, the reduced bone height can make implant placement difficult as it allows only for short fixtures. In cases where alveolar bone height is not lacking, extreme buccolingual resorption can compromise or even preclude fixture placement. This increases the challenge associated with achieving adequate initial stability and/or stability in function. In other words, the severity of the healing pattern may pose a problem for the clinician in 2 ways: it creates an esthetic problem in the fabrication of an implant-supported restoration or a conventional prosthesis; and it may make the placement of an implant challenging if not unfeasible.⁽³⁾

Therefore, maintaining bone quality and quantity in the alveolar ridge during and after tooth removal is critical for assuring good esthetics and functional results and minimizing the need for grafting procedures prior to implant placement.⁽⁴⁾ Furthermore, preserving the existing bone helps the support of both fixed and removable prostheses and ensures successful osseointegration of dental implants. Soft tissue contours follow hard tissue contours; therefore, the clinician must not only prevent bone defects but also repair any defects early in the treatment phase. When grafts are necessary, proper technique is critical to the success of the grafts and final ridge contour.⁽³⁾

The best time to preserve a ridge or to augment a tooth socket is at the time of tooth extraction.

Many techniques were used to preserve extraction sockets and to augment bone defects following old extractions; they include the use of autogenous bone, bone substitute, a mix of autogenous bone and bone substitute alone or in combination with resorbable or nonresorbable membrane, or by the application of a bioscaffold such as Alvelac or Collaplug.^(1,2,5)

One of the difficult aspects of ridge preservation is choosing an appropriate graft material for the specific site. To determine which material is needed, the clinician should evaluate the size and configuration of the defect and then calculate the amount of bone needed to replace the missing tissue. Conventional periapical and panoramic radiographs, CBCT, CT scans, and various calipers have been used for this purpose.⁽⁵⁾

Bio-oss® Collagen is a combination of purified cancellous natural bone mineral granules and 10% collagen fibers in a block form and is sterilized by γ -irradiation. The collagen facilitates handling of the graft particles and acts to hold the Bio-oss® Collagen at the desired place. The consistency of this material readily allows it to take the shape of the defect. Scientific evidence and a wealth of reported practical experience have also demonstrated that the insertion of Geistlich Bio-oss® in an extraction socket may be the ideal way to preserve the alveolar dimensions.^(5,6)

OsteoBiol® Gen-Os is a bone graft material of porcine, bovine, and equine origin. It is made of carbonated nanocrystal bone mineral and collagen of natural heterologous origin. It is a natural substitute of autogenous or allogeneous bone as it conserves the same intimate structures (matrix, porous form). It is osteoconductive, resorbable, biocompatible, and hygroscopic material. It can also function as a carrier for selected medications and drugs.⁽⁶⁾ Its collagen content facilitates blood clotting and the subsequent invasion of repairing and regenerative cells, favoring the integument of missing bone.⁽⁷⁾

This study was done to evaluate the effectiveness of OsteoBiol® Gen-Os in ridge height preservation following tooth extraction.

MATERIALS AND METHODS

This study was carried out as a randomized controlled clinical trial, it consisted of thirty patients. They were recruited from the Outpatient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, for extraction of the mandibular first molar. The age of the patients that were included in the study ranged between 25 and 45 years. The patients were healthy and free from any uncontrolled systemic disease. The tooth that had to be extracted was unrestorable. On the other hand, patients that had severe periodontal disease, acutely infected extraction sites, uncontrolled systemic diseases, or bone diseases that contraindicated the placement of graft materials were excluded from the study. This study was approved by the institutional review board, and an informed consent was obtained from all patients before their inclusion in the study.

After the sample was conveniently selected to fulfill the inclusion criterion, it was randomly divided into two equal groups each consisted of fifteen patients. Group I (Study group) consisted of fifteen participants in which socket preservation using OsteoBiol® Gen-Os® and collaplug was done immediately following the extraction of a mandibular first molar, on the other hand, the other fifteen participants representing group II (control

group) received Bio-oss® and collaplug for socket preservation. (Figures: 1 a-c).



Fig. (1) a) Osteobiol Gen-oss xenograft, b- Bio-oss xenograft c- Collaplug

After proper clinical and radiographic examination, and before undergoing the surgery, an acrylic stent was fabricated to allow for reproducible and standardized CBCT images at baseline, 4 and 9 months postoperatively. A silicone impression of the quadrant where extraction to be undertaken was done, later wax up of the tooth that was to be extracted was performed (Figure: 4). Then a thin hard thermoplastic sheet was heated and pressed on the vacuum machine over the cast to make the stent. Cold cured acrylic resin was placed into the stent at the site of the tooth to be extracted. Then a cylindrical bur was used to make nine holes in the

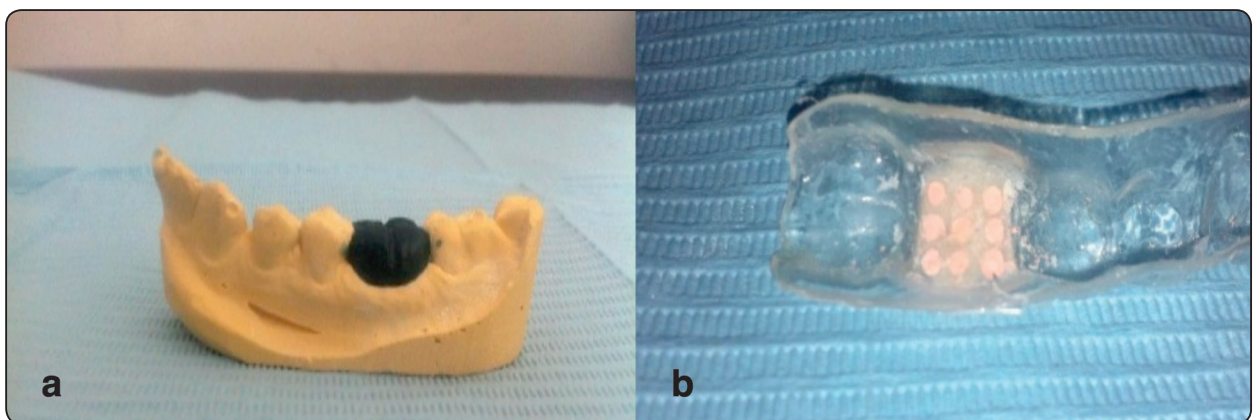


Fig. (2) a- Wax up of the tooth to be extracted, b- Thermoplastic Stent with drilled holes filled with gutta percha.

resin. Three holes were made along the center of the resin and represent a virtual line called line C, three other holes were made to the mesial of line C, and represent a virtual line called line M. Three last holes were made to the distal of line C, and represent a virtual line called line D. Finally gutta-percha was heated and condensed into the holes (Figure: 2 a,b).

Operative procedure:

All procedures were done under complete sterile condition; local anesthesia was used to anesthetize the inferior alveolar nerve, lingual nerve and long buccal nerve using Mepecaine-L (Alexandria Company for Pharmaceuticals, Alexandria, Egypt) local anesthesia.

Extraction was then performed in atraumatic fashion, starting with curved periostomes to detach

the periodontal ligaments surrounding the tooth, then when the tooth became luxated, the extraction was terminated by means of a lower full crown forceps. Once the tooth was extracted, the socket was irrigated with normal saline solution.

For Group I (Study Group), OsteoBiol® Gen-Os was used to fill the extraction socket to the crestal bone level after it has been mixed with normal saline then Collaplug was placed over it and sutured to ensure graft stabilization and protection using 3-0 black silk suture material (Figures: 3-6). For Group II (Control Group), Bio-oss® was used to fill the extraction socket to the crestal bone level then collaplug was placed over it and sutured to ensure graft stabilization and protection using 3-0 black silk suture material.



Fig. (3) Preoperative clinical view of the tooth to be extracted.



Fig. (4) Empty socket after atraumatic extraction



Fig. (5) Socket filled with OsteoBiol® Gen-Os



Fig. (6) Collaplug inserted over the graft and suturing of the extraction socket

Post-operative Phase

Immediately, following the surgery, post-operative instructions were given to patients including cold consumption of foods and drinks and avoiding any mouthwash the day of surgery. All patients were given amoxicillin 1000 mg (Ospamox, Sandoz International Gmdh, Austria) twice daily for seven days and Ponstant Forte analgesics (Mefenamic acid, Pfizer, Australia) when needed. Then, before dismissing the patient, CBCT was done to be used as a baseline evaluation after inserting properly the pre-operatively fabricated stent. All the patients returned to the clinic for clinical post-operative follow up at day three and six post-operatively to evaluate the healing process. Sutures were removed one week after the surgery.

Lately, all patients were followed up radiographically at two intervals, the first four months and the second nine months post-operatively using CBCT. The measurement of the alveolar ridge height detected with the CBCT for each patient at the different follow up periods were recorded and statistically evaluated and analyzed.

Descriptive statistics involved sample distributions of all variables, including means, standard deviations, minimum and maximum values were performed. The Kolmogorov-Smirnov test was used to assess the normality of distribution and the data was found to be normally distributed. Accordingly, the independent t test was used to test the working hypothesis of difference in the alveolar bone loss between the two groups, at different time points. In addition, the paired t test was used to test the difference in bone loss within each group between buccal and lingual aspects of the ridge. A probability of error of 0.05 was considered statistically significant. Data were analyzed using the Statistical Package for Social Sciences (SPSS) Version 20.0.

RESULTS

The study sample included thirty patients, 46.6% were males while 53.4 % were females, with their ages ranged from 25 to 37 years with mean age of 29.2 years (Figure: 7).

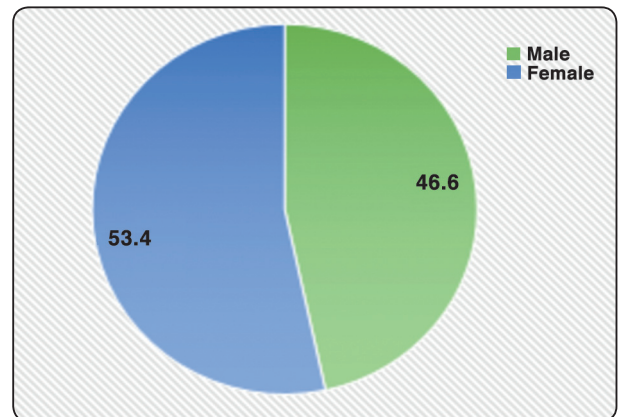


Fig. (7) Pie chart graph showing distribution of the sample according to gender.

Clinical follow-up

Healing of the extraction sockets within both groups was uneventful in all cases and normal color of the overlying mucosa was detected throughout the follow-up period. Moreover, the patients did not complain of any unusual or severe pain. There were no signs of infection, abnormal reaction, wound dehiscence or extrusion of material in any of the patients.

Radiographic follow-up

Table 1, presents the group comparisons using the t test at the 3 different aspects of the ridge in the period extending from baseline to 4 months (Figures: 8, 10: a-c, 11:a-c). The average bone loss at all 9 points differed insignificantly across both groups; the study group resulted in higher bone loss (0.660 ± 0.071 mm) when compared to the control group (0.567 ± 0.080 mm), $p=0.067$. The average bone loss at the buccal aspect of the ridge differed also insignificantly across both groups: the control group (0.600 ± 0.077 mm) resulted in less amount

of bone loss when compared to that of the study group (0.695 ± 0.071 mm), $p=0.073$. Furthermore, the average bone loss at the lingual aspect of the ridge differed insignificantly across both groups: the control group (0.552 ± 0.084 mm) resulted in much less bone loss than the experimental group (0.633 ± 0.079 mm), $p = 0.062$. The difference between the paired measurements (buccal-lingual) in the period between baseline to 4 months was statistically significant within both groups. This difference was 0.0619 ± 0.0356 mm, $p=0.004$ for the study group and 0.0476 ± 0.0325 mm, $p=0.008$ for the control group (Table 2).

When comparing the results among both groups within the interval between 9 months postoperatively to those taken at 4 months postoperatively (table 3), (Figures: 9,12:a-c) it was noted that the average bone loss at all aspects of the ridge was 0.397 ± 0.057 mm for the study group and was 0.375 ± 0.055 for the control group and these results were statistically insignificant ($p=0.069$). For the bone loss on the buccal aspect of the ridge, it was 0.410 ± 0.053 for the study group and less resorption took place within the control group (0.390 ± 0.050 mm), also insignificant statistical difference was observed ($p=0.071$). Finally, on the lingual aspect of the ridge, the bone loss was nearly the same within group I and group II; 0.367 ± 0.046 and 0.367 ± 0.058 respectively ($p=0.051$). The difference between the paired measurements (buccal-lingual) in the period between 4 months to 9 months was statistically significant within both groups (Table 4). This difference was 0.0333 ± 0.0192 mm for the study group and 0.0238 ± 0.0371 mm for the control group ($p= 0.004, 0.032$).

This study showed that the difference in alveolar bone loss between the study group and the control group was statistically insignificant. It was also noted that the resorption was greater in the period extending from baseline to 4 months when compared to the period extending from 4 to 9 months in both

groups. Finally, it was observed that the resorption on the buccal side of the ridge was greater than the lingual side in both groups.

TABLE (1) t-test comparing the alveolar bone loss between baseline and 4 months.

	Group 1	Group2	P
Loss on all aspects	0.660 ± 0.071	0.567 ± 0.080	0.0067
Loss on buccal aspect	0.695 ± 0.071	0.600 ± 0.077	0.0073
Loss on lingual aspect	0.633 ± 0.079	0.552 ± 0.084	0.0062

TABLE (2) The comparison of changes between buccal and lingual aspects between baseline and 4 months.

Group	Buccal	Lingual	Difference	p value
1	0.695 ± 0.071	0.633 ± 0.079	0.0619 ± 0.0356	0.004*
2	0.600 ± 0.077	0.552 ± 0.084	0.0476 ± 0.0325	0.008*

TABLE (3) t-test comparing the alveolar bone loss between 4 months and 9 months

	Group 1	Group2	P
Loss on all aspects	0.397 ± 0.057	0.375 ± 0.055	0.069
Loss on buccal aspect	0.410 ± 0.053	0.390 ± 0.050	0.071
Loss on lingual aspect	0.367 ± 0.046	0.367 ± 0.058	0.051

TABLE (4) The comparison of changes between buccal and lingual aspects between 4 and 9 months.

Group	Buccal	Lingual	Difference	P value
Group I	0.410 ± 0.053	0.376 ± 0.046	0.0333 ± 0.0192	0.004*
Group II	0.390 ± 0.050	0.367 ± 0.058	0.0238 ± 0.0371	0.032*

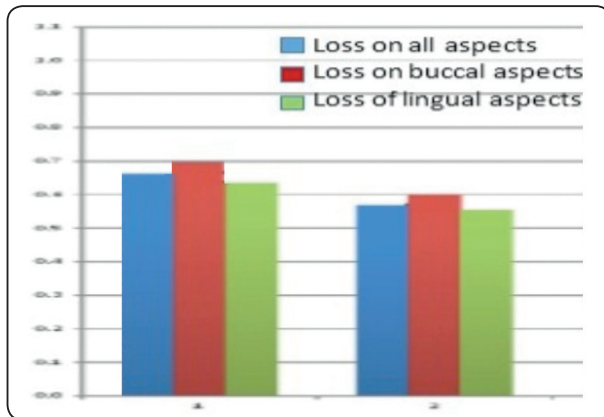


Fig. (8) Bar chart graph showing alveolar bone loss on all aspects, buccal, and lingual aspects of the ridge between base line and 4 months among the two groups.

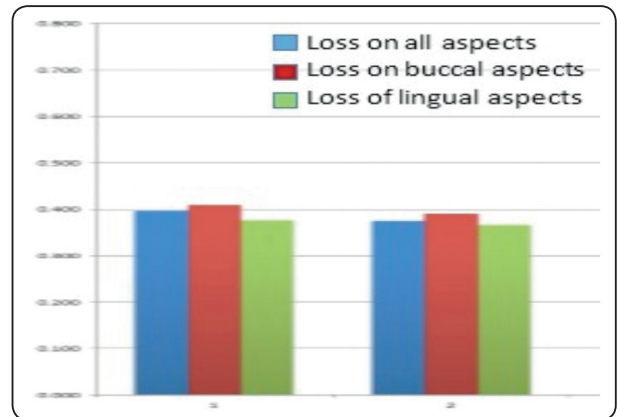


Fig. (9) Bar chart graph showing alveolar bone loss on all aspects, buccal, and lingual aspects of the ridge between 4 months and 9 months among the two groups.

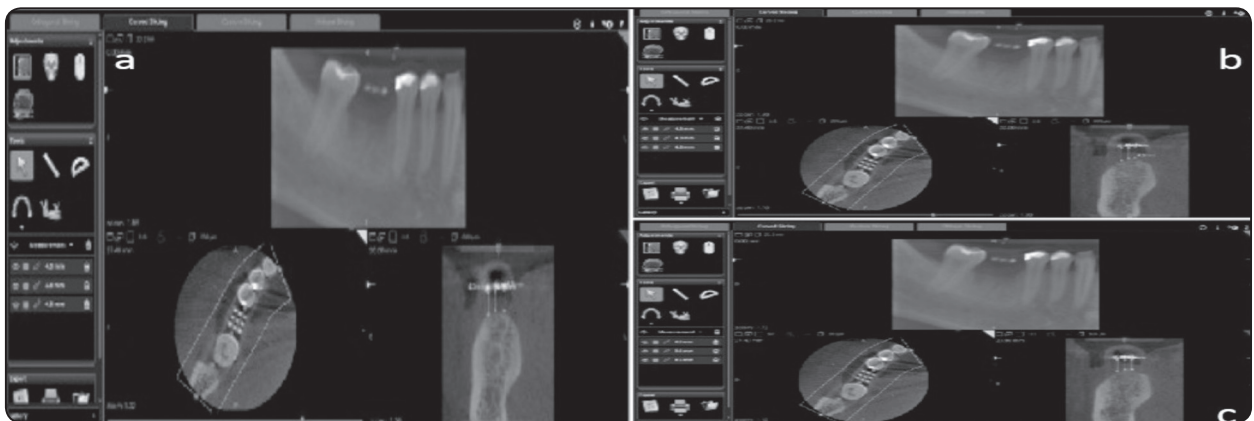


Fig. (10) a- CBCT image passing through virtual line D at baseline, b- CBCT image passing through virtual line C at baseline, c- CBCT image passing through virtual line D at baseline

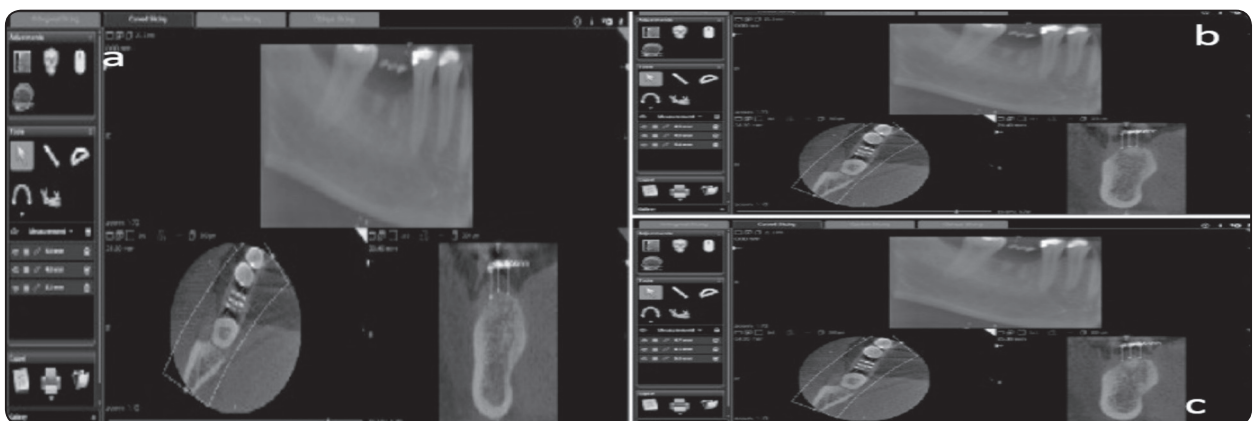


Fig. (11) a- CBCT image passing through virtual line M at 4 months, b- CBCT image passing through virtual line C at 4 months, c- CBCT image passing through virtual line D at 4 months

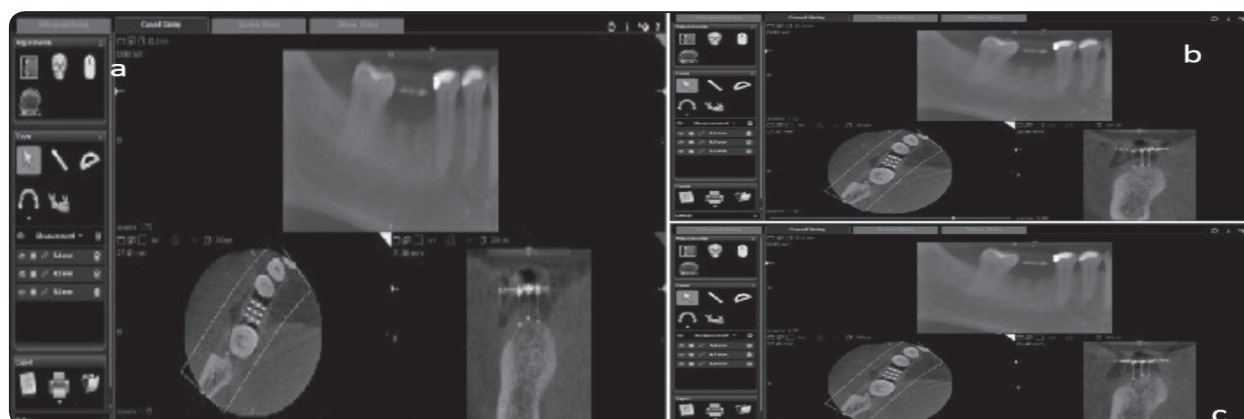


Fig. (12) a- CBCT image passing through virtual line M at 9 months, b- CBCT image passing through virtual line C at 9 months, c- Figure 21 : CBCT image passing through virtual line D at 9 months

DISCUSSION

Ridge preservation is a procedure undertaken at the time of tooth extraction and is designed to minimize external resorption of the alveolar ridge and maximize bone formation within the socket.⁽⁴⁾ According to a study conducted by Garg (2000)⁽⁸⁾, the best grafting material that is also known as the gold standard bone grafting material is the autogenous bone graft, as it is osteoconductive, osteoinductive, osteogenic, and lacks possible immunologic risks. On the other hand there are certain limitations of using autogenous grafts due to the limited amount and the need for a second surgical site which usually results in postsurgical pain and morbidity. To overcome the limitations of autogenous bone graft alternative materials became available in the market including xenografts, allografts, and synthetic alloplastic materials.⁽⁹⁾

Therefore, the present study evaluated the effectiveness of (OsteoBiol® Gen-Os; Tecnooss srl, Giaveno, Italy) in alveolar bone height preservation following tooth extraction. In group I (Study Group); the socket was filled with xenograft (OsteoBiol® Gen-Os and collagen sponge (Collaplug), and in group II (Control Group) the socket was filled with (Bio-oss® Geistlich Pharma AG, Switzerland) and collagen sponge (Collaplug).

The results of the alveolar bone height preservation varied among the two groups during the follow up period intervals. It was also noted that the resorption was greater in the period extending from baseline to 4 months when compared to the period extending from 4 to 9 months in the two groups. The resorption of the buccal side of the ridge was greater than the lingual side within both groups.

Many studies were made to assess the importance of ridge preservation techniques following extraction using different types of bone grafts and membranes.^(1,2,5) The present study noted that there was no statistical significance in alveolar bone height loss between groups I and II at different time intervals, and these results come in accordance to a study conducted by Barone et al. (2008)⁽¹⁰⁾ who compared the results of alveolar ridge preservation using corticocancellous porcine bone with collagen membrane to extraction without ridge preservation, over a period of seven months. The results showed that the mean vertical bone loss on the buccal and lingual side were less on preserved sites when compared to non preserved sites, also vertical bone loss on the buccal aspect is more than that on the lingual one. The results of the present study come in accordance with these results; thus the decreased bone loss is attributed to the use of xenograft which acts as an osteoconductive scaffold that preserves the socket following extraction.

However our study was not in accordance with the study conducted by Vance et al. 2004 ⁽⁴⁾ who compared the use of anorganic bovine matrix (BioOss) with a membrane to DFDBA with a mixture of calcium sulfate and and carboxymethyl cellulose (CalMatrix), and noted a gain in bone height in the bovine matrix group. The difference in the results between the two studies may be attributed to the use of the membrane rather than the Collaplug, because the membrane resorbs slower than the plug thus further preventing epithelial proliferation and in term preserving the socket further more when compared to Collaplug.

The results of the present study noted a reduction in the amount of alveolar bone loss, however the loss of alveolar bone height was inevitable in all both groups. This is in agreement with the study conducted by Morjalia et al. (2014)⁽⁵⁾, where the objective of the study was to assess whether the use of a graft and/or membrane post-tooth extraction improves healing of the site dimensionally, radiographically, and/or histologically, and they concluded that socket intervention therapies did reduce alveolar ridge dimension changes after extraction, yet the use of different types of bone graft substitutes did not completely prevent alveolar dimensional losses and this is attributed to the osteoclastic activity in the period following extraction which will result in bone loss.

The present study showed that the loss of bone height on the lingual walls was less than that on the buccal walls, this was seen in both groups of the study. The results were in accordance with a study conducted by Chan et al (2013).⁽¹¹⁾ Our study showed that there is statistical significance when comparing buccal alveolar bone loss to lingual alveolar bone loss in both groups, where the buccal bone height loss was always greater. In addition it also came in agreement with the studies conducted by Cardaropoli et al. (2003) ⁽¹²⁾ Araujo et al. (2005) ⁽¹³⁾, and Vander Weijden et al. (2009) ⁽¹⁴⁾ who

reported that the vertical ridge height loss was more pronounced on the buccal when compared to the lingual portion.

CONCLUSIONS

The use of OsteoBiol® Gen-Os helps in diminishing the loss of alveolar bone and preserving the socket following extraction, and showed statistical significance when compared to the control group, however it did not completely prevent alveolar bone dimension loss.

REFERENCES

1. Shakibaie-M B. Comparison of the effectiveness of two different bone substitute materials for socket preservation after tooth extraction: a controlled clinical study. *Int J Periodontics Restorative Dent*. 2013; 33(2):223-8.
2. Heberer S, Al-Chawaf B, Jablonski C, Nelson JJ, Lage H, Nelson K. Healing of ungrafted and grafted extraction sockets after 12 weeks: a prospective clinical study. *Int J Oral Maxillofac Implants*. 2011; 26(2):385-92.
3. Karthik K, Sivaraj S, Thangaswamy V. Evaluation of implant success: A review of past and present concepts: *J Pharm Bioallied Sci*. 2013; 5(Suppl 1): S117–S119.
4. Vance GS, Greenwell H, Miller RL, Hill M, Johnston H, Scheetz JP. Comparison of an allograft in an experimental putty carrier and a bovine-derived xenograft used in ridge preservation: A clinical and histologic study in humans. *Int J Oral Maxillofac Implants* 2004; 19(4):491-7.
5. Morjaria KR, Wilson R, Palmer RM. Bone healing after tooth extraction with or without an intervention: a systematic review of randomized controlled trials. *Clin Implant Dent Relat Res* 2014; 16(1):1-20.
6. Lindhe J, Cecchinato D, Donati M, Tomasi C, Liljenberg B. Ridge preservation with the use of deproteinized bovine bone mineral. *Clin Oral Implants Res*. 2014; 25(7):786-90.
7. Festa VM, Addabbo F, Laino L, Femiano F, Rullo R. Porcine-derived xenograft combined with a soft cortical membrane versus extraction alone for implant site development: a clinical study in humans. *Clin Implant Dent Relat Res*. 2013; 15(5):707-13.
8. Garg AK. The use of platelet-rich plasma to enhance the success of bone grafts around dental implants. *Dent Implantol Update*. 2000; 11(3):17-21.

9. Figueiredo A, Coimbra P, Cabrita A, Guerra F, Figueiredo M. Comparison of a xenogenic and an alloplastic material used in dental implants in terms of physiochemical characteristics and in vivo inflammatory response. *Mater Sci Eng C Mater Biol Appl*. 2013 1; 33(6):3506-13.
10. Barone A, Aldini NN, Fini M, Giardino R, Guirado JLC, Covani U. Xenograft versus extraction alone for ridge preservation after tooth removal: A clinical and histomorphometric study. *J Periodontol* 2008; 79: 1370-7.
11. Chan HL, Lin GH, Fu JH, Wang HL. Alterations in bone quality after socket preservation with grafting materials: a systematic review. *Int J Oral Maxillofac Implants*. 2013; 28(3):710-20.
12. Cardaropoli G, Araujo M, Lindhe J. Dynamics of bone tissue formation in tooth extraction sites. An experimental study in dogs. *J Clin Periodontol* 2003; 30:809–18.
13. Araujo MG, Lindhe J. Dimensional ridge alterations following tooth extraction. An experimental study in the dog. *J Clin Periodontol* 2005; 32:212–8.
14. Van der Weijden F, Dell’Acqua F, Slot DE. Alveolar bone dimensional changes of post-extraction sockets in humans: a systematic review. *J Clin Periodontol*. 2009; 36(12):1048-58.