

The efficacy of OsteoBiol Gen-Os® on postextraction alveolar ridge preservation: a blind clinical radiological trial in humans.

Amer Kanj¹, BDS, Nahed Attia², BDS, M.Sc., Ph.D., Rehab El Sherkawy³, BDS, M.Sc., Ph.D.

Abstract

An important issue facing most dental clinicians is whether the bone replacement grafts help in preserving alveolar bone in post-extraction period, and whether they will limit or reduce alveolar bone height's shrinkage, when compared to sites not receiving a graft material.

The aim of this study was to compare post-extraction vertical bone loss between two groups using cone beam computerized tomography (CBCT), where one group received Osteobiol Gen-Os® (xenograft) and CollaPlug® (collagen sponge) and the other group only received CollaPlug®.

Material and Methods: Fourteen patients requiring tooth extraction were enrolled in the study. They were divided in two groups: Group I (study -or test- group of seven patients who received Osteobiol Gen-Os® and CollaPlug®), and Group II (control group of seven patients who only received CollaPlug® in extraction sites). Vertical alveolar ridge changes were studied on CBCT images, in the two groups, from time of extraction to four months following extraction.

Results: Vertical bone loss was significantly less in test group (0.66 ± 0.071 mm) compared to control group (0.967 ± 0.13 mm).

Conclusion: In alveolar ridge preservation, the use of xenograft in conjunction with a collagen sponge is more efficient than the sole use of a collagen sponge, in a fresh extraction socket.

INTRODUCTION

Extraction socket heals and forms a blood clot which leads to the formation of new bone within 3-4 months. Although bone deposition in dental socket continues for several months, it does not reach the crestal level of the neighboring teeth¹. 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 bone². Both bone volume and bone density decrease once the functional stresses normally transmitted by

1. M.Sc. student, Oral Surgical Sciences Department, Faculty of Dentistry, Beirut Arab University, Beirut, Lebanon

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

3. Assistant Professor of Oral Surgery, Oral Surgery Department, Faculty of Dentistry, Cairo University, Cairo, Egypt

natural teeth are lost³.

As interarch distance increases and height of available bone decreases, 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 function³.

Maintaining bone quality and quantity in the alveolar ridge during and after tooth removal is critical for assuring good esthetic and functional results and minimizing the need for grafting procedures prior to implant placement⁴. Furthermore, preserving the existing bone helps supporting both fixed and removable prostheses and ensures successful osseointegration of dental implants. Soft tissue contours follow hard tissue contours; therefor, 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 contours¹.

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.¹

The best time to preserve a ridge or to augment a tooth socket is at the time of tooth removal¹. Many techniques have been 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^{®5}.

OsteoBiol Gen-Os[®] (Tecnoss Srl, Giaveno, Italy) is a corticocancellous porcine bone xenograft. 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 exhibits a structure and composition similar to natural bone⁷. It is an osteoconductive, resorbable, biocompatible, and hygroscopic material. It can also function as a carrier for selected medications and drugs⁶. Its collagen content facilitates blood clotting and the subsequent invasion of repairing and regenerative cells, favoring "restitutio ad integrum" of missing bone. OsteoBiol Gen-Os[®] granules (250-1000 microns granulometry) constitute a cortico-cancellous collagenated bone mix and, microscopically, two weeks after implanting the graft, OsteoBiol Gen-Os[®] granules are covered by newly formed bone and a seam of osteoblasts. Osteocytes in lacunae are visible in the newly formed bone. Advantages of using OsteoBiol Gen-Os[®] is that it expands up to 50% in volume after hydration with sterile saline^{6,7}.

MATERIALS AND METHODS

This study was a blind clinical trial carried out on fourteen patients, where the patients were not informed about the treatment products they were receiving.

They were recruited from the Outpatient Clinic of Oral Surgical Sciences Department/ Division of Oral Surgery, Faculty of Dentistry, Beirut Arab University in Beirut, Lebanon (FD, BAU). Patients in need of extraction of the mandibular first or second molar were eligible.

The age of the patients that were included in the study ranged from 25 to 45 years. Patients were free from any uncontrolled systemic disease. The tooth that had to be extracted was an unrestorable mandibular first or second molar. Exclusion criteria included patients who had severe periodontal disease, acutely infected extraction sites, uncontrolled systemic diseases, or bone diseases that contraindicated the placement of graft materials.

After the patients were examined and appeared to fit the inclusion criteria, they were informed about the nature and aim of the whole procedure, and each patient was asked to sign an informed consent form declaring that he/she accepted to be involved in the research study.

Before undergoing the surgery, a stent was fabricated to allow for reproducible and standardized CBCT images at baseline and 4 months postoperatively. A silicone impression of the quadrant where extraction was to be undertaken was made, later wax up of the tooth that was to be extracted was done (Figure 1).

Then, a thin hard thermoplastic sheet was heated and pressed on the vacuum machine over the cast to make the stent (Figure 2). Cold cured non-radiopaque acrylic resin (Alike) 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 resin: three holes were made along the center of the resin and represented a virtual line called line C, three other holes were made to the mesial of line C, and represented a virtual line called line M. Three last holes were made to the distal of line C, and represented a virtual line called line D (Figure 3). Finally, gutta-percha was heated and condensed into the holes, and provided the radiopaque points in the stent of CBCT images.

After clinical examination, a pre-operative periapical radiograph was taken for the site of extraction for all the patients (Figure 4). They were informed about the nature and aim of the whole procedure, and each



Fig. 1. Wax up of the tooth to be extracted.



Fig. 2. Thermoplastic Stent.



Fig. 3. Drill holes made into the resin of the stent.



Fig. 4. Preoperative radiograph of a perforated first right molar to be extracted.



Fig. 5. Preoperative view of the tooth to be extracted.



Fig. 6. Empty socket after tooth extraction.



Fig. 7. Socket filled with OsteoBiol Gen-Os®.



Fig. 8. Collaplug inserted over the graft.



Fig. 9. Suturing with interrupted sutures.

patient was asked to sign the informed consent form.

Patients were divided into two groups randomly, where a coin was tossed to allocate each patient in either of the two groups. Group I and Group II. Group I (Study group) consisted of seven patients who needed extraction of mandibular first or second molar tooth where Osteobiol Gen-Os® was used to fill the extraction socket up to crestal bone level, immediately after extraction, then CollaPlug®* (Zimmer Dental, Carlsbad, California, USA) was used to cover the grafted socket and suturing using interrupted sutures was finally performed (figures 5-9).

* CollaPlug® is an absorbable collagen wound dressing for extraction sites.

Group II (Control group) consisted of seven patients who needed extraction of mandibular first or second molar. After extraction, CollaPlug® was used to cover the extraction socket and interrupted suturing was then performed over the CollaPlug®.

Surgical procedures were performed under complete sterile conditions and local analgesia (2% lidocaine with 1/100,000 epinephrin) was administered to all patients, prior to surgery. Extraction was minimally traumatic. Once the tooth was extracted, socket cleaning was performed with a surgical curette and under copious irrigation with chilled saline. Patients were instructed to return back to the FD, BAU clinic if any problem arises. All patients were prescribed

amoxicillin 1000mg, twice daily for 7 days.

Immediately after surgery and before dismissing the patient, CBCT (as a base line evaluation) was done, after inserting the stent in patient's mouth and ensuring that it was properly placed into accurate position.

All patients returned to FD, BAU clinic for clinical postoperative follow-up at days 3 and 6 postoperatively, to evaluate the healing process. Sutures were removed one week after the surgery.

CBCT measurements of alveolar ridge height recorded at 4 months were compared to the CBCT measurements recorded at baseline for each patient, and were statistically evaluated and analyzed. Measurements were recorded at each of the nine points marked on the stent, by drawing a line measuring the distance from radiopaque gutta-percha on CBCT image to the point of intersection with adjacent bone. Measurement at each point was compared between baseline period and four months post-extraction (Figures 10-15).

Statistical Analysis:

Kolmogorov-Smirnov (K-S) test of normality indicated that the data was normally distributed. Therefore, the independent t test was used to compare bone loss between the two groups and the paired t test was applied to study the difference between buccal and lingual bone loss amount within each group. P values of less than 0.05 were considered to be statistically significant. All the statistical analyses were performed using the Statistical Package for Social Sciences Version 21.0 (Armonk, NY: IBM Corp.) (SPSS*).

RESULTS

Table 1 addresses the group comparisons using the t test at 3 different aspects of the alveolar ridge during the period extending from baseline to 4 months. The average bone loss at all 9 points differed significantly between the groups ($p < 0.0001$) with larger amount of bone loss in the control group (0.967 ± 0.131 mm) compared to the study group (0.660 ± 0.071 mm).

Similarly, average bone loss at buccal aspect of

Table 1. Comparison of alveolar bone loss in mm (mean $\pm$ SD)

	Group 1	Group 2	p
Loss on all aspects	0.660 $\pm$ 0.071	0.967 $\pm$ 0.131	< 0.0001
Loss on buccal aspect	0.695 $\pm$ 0.071	1.005 $\pm$ 0.148	0.001
Loss on lingual aspect	0.633 $\pm$ 0.079	0.919 $\pm$ 0.109	< 0.0001

Table 2. Comparison of alveolar bone loss in mm (mean $\pm$ SD) between buccal and lingual aspects within each group.

Group	Buccal	Lingual	Difference	p value
1	0.695 $\pm$ 0.071	0.633 $\pm$ 0.079	0.0619 $\pm$ 0.0356	0.004*
2	1.005 $\pm$ 0.148	0.919 $\pm$ 0.109	0.0857 $\pm$ 0.0634	0.012*

the ridge was significantly higher in the control group (1.005 ± 0.148 mm) than in the experimental group (0.695 ± 0.071 mm). Same for the lingual aspect of alveolar ridge, where bone loss in the control group was 0.919 ± 0.109 mm, significantly larger than the study group where average bone loss was 0.633 ± 0.079 mm.

Resorption on buccal side of the ridge was found to be greater than on lingual side in both groups. This difference was 0.0619 ± 0.0356 mm for group 1 and 0.0857 ± 0.0634 mm for group 2 (Table 2).

The difference between 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 for group 1 and 0.0857 ± 0.0634 mm for group 2 (Table 2).

This clinical radiological study showed that the difference in alveolar bone loss between study group and control group was statistically significant. It was also observed that resorption on buccal side of the ridge was greater than on lingual side, in both groups.

DISCUSSION

The present trial evaluated the efficiency of Osteobiol Gen-Os® in alveolar ridge height preservation following tooth extraction.

Patients randomly allocated to the experimental group (n=7) received a xenograft (OsteoBiol Gen-Os®) and collagen sponge (CollaPlug®), whereas patients in control group (n=7) had the socket filled only with a collagen sponge (CollaPlug®). Results of the alveolar bone height preservation varied among the two groups,

* IBM SPSS statistics is an integrated family of products that addresses the entire analytical process, from planning, to data collection, to analysis, reporting, and deployment.

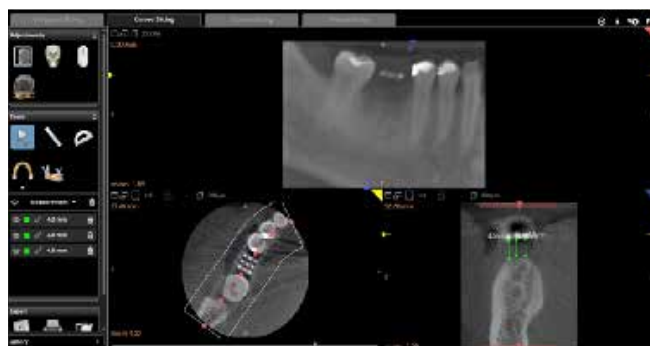


Fig. 10. CBCT image passing through virtual line M at baseline.

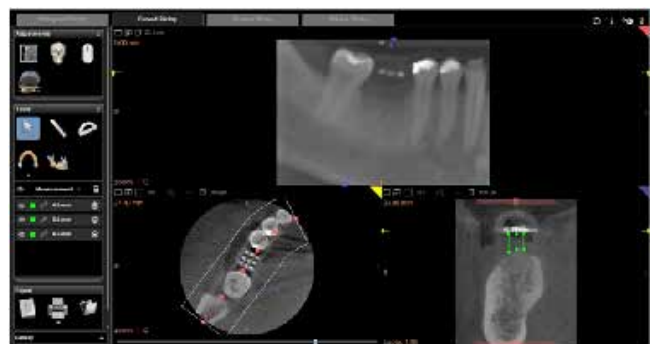


Fig. 12. CBCT image passing through virtual line D at baseline.

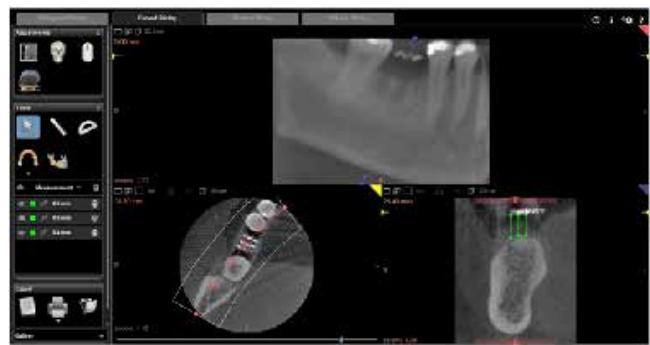


Fig. 14. CBCT image passing through virtual line C at 4 months.

four months after surgery.

Our results showed that there is statistical significance in alveolar bone loss between study group and control group between baseline and 4 months, and these results were similar to those of a study conducted by Barone and associates⁸ who compared the results of alveolar ridge preservation using corticocancellous porcine bone with collagen membrane to extraction without ridge preservation. However, our study was not in accordance with the study conducted by Vance and co-workers⁹ who compared the use of anorganic bovine

** DFDBA = Demineralized Freeze-Dried Bone Allograft

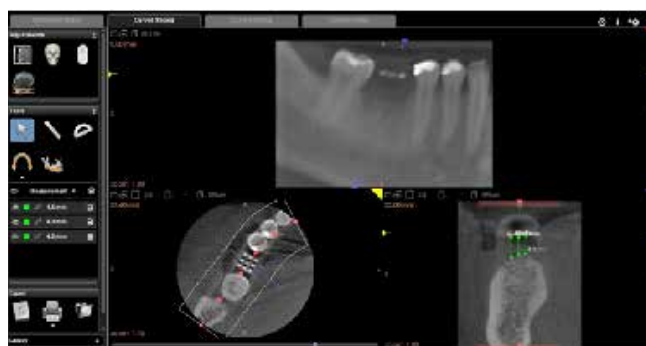


Fig. 11. CBCT image passing through virtual line C at baseline.

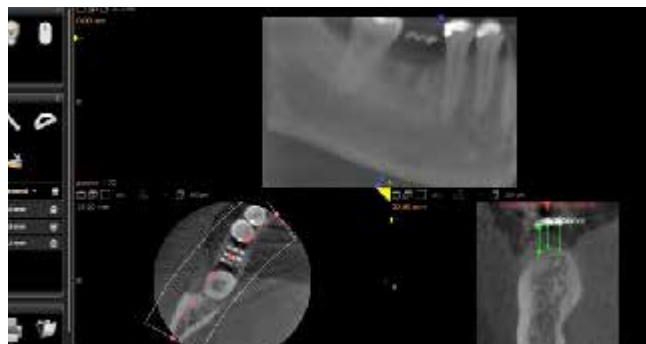


Fig. 13. CBCT image passing through virtual line M at 4 months.

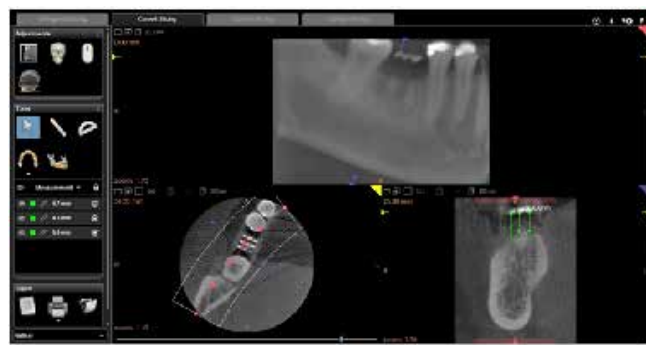


Fig. 15. CBCT image passing through virtual line D at 4 months.

matrix with a membrane to DFDBA** with a mixture of calcium sulfate and carboxymethyl cellulose, and noticed a gain in bone height in the bovine matrix group.

Our present study showed that alveolar bone height loss on lingual walls was less than that on buccal ones and this trend was noticed in both groups of the trial. This finding agrees with the results of the studies conducted by Chen and Buser¹⁰, Araújo and Lindhe¹¹, Cardaropoli and co-workers¹², and Van der Weijden and associates¹³, who reported that vertical ridge height loss was more pronounced on buccal side when compared to lingual one.

The results of our study proved a reduction in the

amount of alveolar bone loss, however, loss of alveolar bone height was inevitable in both groups, which comes in accordance with Morjaria and co-workers¹⁴ who stated that socket intervention therapies did reduce alveolar ridge dimension changes after extraction, but were unable to prevent alveolar resorption.

Festa and associates¹⁵ studied the efficacy of porcine-derived xenograft (OsteoBiol® Gen-Os; Tecnooss srl, Giaveno, Italy) combined with a soft cortical membrane (OsteoBiol® Lamina; Tecnooss srl, Giaveno, Italy) in implant site development, and compared them to extraction with no graft. They implemented their study on 15 patients who required double extraction of contralateral premolars. Test sites included 15 sockets treated with OsteoBiol® Gen-Os with OsteoBiol® Lamina, while corresponding control sites (extraction - alone sites) were left without grafting. Horizontal and vertical ridge dimensions were recorded at baseline and 6 months after extractions. Authors concluded that "the placement of a porcine xenograft with a membrane in an extraction socket can be used to reduce the hard tissue reabsorption after tooth extraction, compared with extraction-alone sites".

Although our study was a well-controlled prospective one, it had some limitations, mainly the small sample size. In addition, a longer follow-up period would certainly give more insight about the trend in alveolar bone loss after teeth extractions.

CONCLUSION

The use of OsteoBiol Gen-Os® in conjunction with CollaPlug® helps in minimizing post-extraction alveolar bone loss and preserving the height of extraction socket, when compared to the sole use of CollaPlug® alone, following extraction. However, it does not completely prevent alveolar dimension loss.

Further research is warranted, but on a larger number of patients and for a longer period, in order to better understand the variables that affect alveolar bone loss and preserve alveolar ridge height after dental extractions.



REFERENCES

- 1- Garg AK. Augmentation and grafting of the maxillary anterior alveolar ridge. Rationale and clinical application. In: Garg AK. *Bone Biology, Harvesting, Grafting for Dental Implants: Rationale and Clinical Applications* Quintessence Publishing Company Inc. 2004;213-240.
- 2- Tallgren A. The continuing reduction of the residual alveolar ridges in complete denture wearers: A mixed longitudinal study. *J Prosthet Dent* 1972;27(2):120-32.
- 3- Brånemark PI, Gronahl K, Worthington P: Osseointegration and autogenous onlay bone grafts. *Quintessence* 1; 6; 2001.
- 4- Garg AK: Preservation, Augmentation, and reconstruction of the alveolar ridge. *Dent Implantol Update* 2001;12(11):81-5.
- 5- Kahnberg KE, Rasmusson L, Zellin G: *Bone Grafting Techniques for Maxillary Implants* Published by Blackwell Munksgaard, 2005:1-18.
- 6- Ramirez-Fernandez M, Calvo-Guirado JL, Delgado-Ruiz RA, Maté-Sánchez del Val JE, Vicente-Ortega V, Meseguer-Olmos L. Bone response to hydroxyapatites with open porosity of animal origin (porcine [OsteoBiol®mp3] and bovine [Endobon®]): a radiological and histomorphometric study. *Clin. Oral Implants Res* 2011 Jul;22(7):767-773.
- 7- Figueiredo A, Coimbra P, Cabrita A, Guerra F, Figueiredo M. Comparison of a xenogeneic and an alloplastic material used in dental implants in terms of physico-chemical characteristics and in vivo inflammatory response. *Mater Sci Eng C Mater Biol Appl* 2013 Aug 1;33(6):3506-3513.
- 8- Barone A, Aldini NN, Fini M, Giardino R, Calvo Guirado JL, Covani U. Xenografts versus extraction alone for ridge preservation after tooth removal: A clinical and histomorphometric study. *J Periodontol* 2008 Aug;79(8):1370-1377.
- 9- 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 Jul-Aug;19(4):491-497.
- 10- Chen S, Buser D. *ITI Treatment Guide .Volume 3 :Implant placement in postextraction sites :treatment options.* Berlin: Quintessence Publ Co 2008;19:5-11.
- 11- Araújo MG, Lindhe J. Dimensional ridge alterations following tooth extraction. An experimental study in the dog. *J Clin Periodontol* 2005 Feb;32(2):212-218.

- 12- Cardaropoli G, Araújo MG, Lindhe J. Dynamics of bone tissue formation in tooth extraction sites. An experimental study in dogs. *J Clin Periodontol* 2003 Sep;30(9):809-818.
- 13- 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 Dec;36(12):1048-1058.
- 14- 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 Feb;16(1):1-20.
15. Festa VM, Addabbo F, Laino L, et al. 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 Oct;15(5):707-713.

Correspond with:**Amer Kanj**

amerkan@hotmail.com