

RIDGE AUGMENTATION USING AUTOGRAFT AND XENOGRAFT VERSUS XENOGRAFT ALONE WITH SIMULTANEOUS IMPLANT PLACEMENT: A RANDOMISED CLINICAL TRIAL

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Abstract. Aim. To compare the alveolar ridge augmentation using either a 1:1 combination of autograft and bovine graft or bovine graft alone and a slow resorbing collagen membrane with simultaneous placement of implants. **Materials and Methods.** 24 subjects aged 20-60 years with an atrophic, both vertically and horizontally deficient, edentulous space in the esthetic region of the maxilla were randomly assigned into two groups who underwent guided bone regeneration procedures in conjunction with simultaneous implant placement. Group A received a 1:1 combination of autograft and bovine graft and Group B received bovine graft alone. Primary closure and a tension-free flap were achieved. The study subjects were recalled after six months to assess the alveolar bone augmentation by means of cone beam computed tomography (CBCT) imaging. The data that was collected was statistically analyzed. **Results.** The mean alveolar ridge augmentation as seen at 6 months was observed to be 2.09 mm in the vertical dimension and 0.99 mm in the horizontal dimension, respectively, in the Group A subjects. In Group B, a mean vertical augmentation of 1.73 mm and a mean horizontal augmentation of 2.09 mm, respectively, were observed. The difference in mean vertical bone augmentation between the two groups at 6 months as compared to the baseline was statistically insignificant. **Conclusion.** This study demonstrates that alveolar ridge augmentation using a 1:1 combination of autograft and xenograft with immediate implant placement is a viable treatment option for the atrophic esthetic region of the maxilla.

Key words: autograft, guided bone regeneration, resorbable membrane, ridge augmentation, xenograft

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INTRODUCTION

Dental implants have been established as a predictable and viable option in the treatment of the partially and completely edentulous jaws. However, in many cases, there is insufficient bone available for the ideal three-dimensional place-

ment of endosseous implants. Therefore, there is a need to augment the alveolar ridge either before or at the time of placement of dental implants. These augmentation procedures have to be carried out in order to ensure that correct angulations, adequate primary stability and a favorable crown-root ratio can be achieved [1, 2, 3]. Insufficient bone volume and

suboptimum alveolar ridge width and height, if unresolved, post challenges to the outcomes and success of any dental implant treatment [3, 4].

Various surgical techniques and biomaterials have been developed to make the successful placement of dental implants in atrophied alveolar bone possible [3, 4, 5]

Vertical and horizontal alveolar ridge augmentation with block or particulate autografts, distraction osteogenesis or guided bone regeneration (GBR) or a combination of these methods has been documented. However, these procedures, besides being technique sensitive, are also associated with complications such as donor-site morbidity, long-term resorption of the autologous bone and in the case of GBR procedures, exposure of the barrier membrane.

To minimize some of these issues, bone substitutes and resorbable membranes have been studied extensively to help in bone augmentation procedures.

Xenografts are one such bone substitute. Xenografts are derived from non-human sources, primarily, bovine sources. They have osteoconductive properties and are considered to be biocompatible.

Commercially available bovine bone is processed in a way that the organic content is removed to yield natural bone mineral. Anorganic bone of bovine origin consists of a hydroxyapatite skeleton that retains its micro- and macro-porous structure of cancellous and cortical bone that is retained after the extraction of the organic component by low-heat and chemical methods. These graft materials exhibit higher osteoconductive potential, increased cellular adhesion, wound healing and better formation of bone-like tissue as compared to synthetically manufactured materials [3, 4, 5, 6].

The use of a resorbable membrane eliminates the need for a second stage surgery that must otherwise be undertaken in order to retrieve the barrier membrane.

There is a lack of data that exists regarding the efficacy of a deproteinized bovine bone mineral (DBBM) combined with autologous bone for vertical ridge augmentation with GBR surgical techniques using a resorbable membrane [5, 7].

Hence, this study was planned to augment the edentulous ridge in the maxillary esthetic region using a 1:1 combination of autograft and bovine graft along with a resorbable collagen membrane and comparing it with the use of only bovine graft and a resorbable collagen membrane with simultaneous placement of endosseous implants.

MATERIALS AND METHODS

Participant Selection

A sample of 24 subjects aged 20-60 years with an atrophic, both vertically and horizontally deficient, edentulous space in the esthetic region of the maxilla were recruited from the out-patient, Department of Periodontology and Department of Oral Implantology, A.B. Shetty Memorial Institute of Dental Sciences, Mangalore, India. A written, informed consent was obtained from all the participants. Ethical clearance was obtained from the institutional ethics committee.

Subjects were included if they had an atrophic edentulous site in the esthetic region of the maxilla, no history of any systemic disease and good oral hygiene (OHI-S Score 0.0-1.2) [8].

The study subjects were excluded if there was any history of tobacco use or the presence of a local, active infection. Pregnant/Lactating women were also excluded.

The participants were randomly assigned into two groups, Group A and Group B, of 12 participants each. The participants were masked to which group they were assigned. Based on the group to which the study subject belonged, the graft was introduced into the graft site. Group A received a 1:1 combination of autograft and bovine graft and Group B received bovine graft alone.

A preoperative CBCT (ProMax 3D Mid®, Planmeca, Helsinki, Finland) was taken to assess the alveolar bone level at baseline. Standard protocols were used: Small Field of View 4x5cm, Volume 201x201x251, Exposure time 12 seconds at 90 kVp and 8 mA. Routine blood investigations, oral prophylaxis and assessment of occlusal equilibrium were carried out. The study subjects were instructed to adopt meticulous home care measures to maintain good oral hygiene.

The study subjects were then scheduled for surgery.

Surgical Procedure

The subjects were prescribed a course of 500 mg Amoxicillin thrice a day starting a day prior to the day of implant surgery. All the instruments that were used in the surgical procedure were sterilized. The surgical site was anesthetized with the administration of a 2% Lignocaine with 1:80,000 adrenaline local anesthetic solution. A slightly palatally-placed crestal incision and sulcular incisions around the adjacent teeth were given along with a vertical releasing incision distal to the defect site. A full thickness mucoperiosteal flap was elevated to about 5 mm apical to the bone defect. Periosteal releasing incisions were also given to enable primary closure and a tension-free flap.

Using a round bur, decortication holes were made at the atrophied edentulous site. Following this, sequential osteotomy was carried out using the sequential drills as per the implant manufacturer's guidelines (Ankylos C/X®, Dentsply Sirona). A 3.5 mm diameter endosseous implant was then placed into the prepared osteotomy. The cover screw was positioned. Instead of a tenting screw, a 2 mm sinus membrane screw (Ankylos C/X®, Dentsply Sirona) which has a diameter of 6 mm was threaded into the cover screw. This was done to facilitate 'tenting' of the collagen membrane. (Figure 1) A slow-resorbable, bilayer collagen membrane (BioGide®, Geistlich Pharma) was placed with the membrane extending at least 2 mm apical to the bone defect. This collagen membrane was tacked down on the buccal side using titanium tacks (Frios®, Dentsply Sirona).

Based on the group to which the study subject belonged, that is, Group A or Group B, the bone graft was introduced into the graft site. The graft was packed and the collagen membrane that was previously tacked on the buccal aspect was used to cover this graft material before being tacked on the palatal aspect. The autograft in Group A was obtained using a trephine from the same site. (Figure 2)

Primary closure and a tension-free flap were achieved by the means of the periosteal releasing incisions and the placement of sutures. First, horizontal mattress sutures were placed. This was followed by simple interrupted sutures.

Post-operative instructions were given to all the participants. The subjects were instructed to complete

the course of 500 mg Amoxicillin and were also prescribed 50 mg Diclofenac sodium twice a day for three days to prevent postoperative infection and pain. The subjects were also instructed to rinse with a 1:1 dilution of 0.12% twice daily for two weeks post-operatively.

Subjects were recalled after 2 weeks for suture removal and for the fabrication of an adhesive bridge which was to serve as a temporary prosthesis for 6 months.

The study subjects were recalled after six months to assess the alveolar bone augmentation by means of CBCT images. The Planmeca Romexis® was used to evaluate the CBCT images. (Figure 3 and Figure 4)

Microsoft Excel and IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp was used for statistical analysis. Due to the limited sample size, only a descriptive statistical analysis was carried out. Mean, median, quartile range and standard deviation were used to evaluate the observations.

Unpaired t-test was used to find the difference between the values of the groups as it was following normal distribution. A value of $P < 0.05$ was considered to be statistically significant.

RESULTS

A total of 24 subjects, 17 males and 7 females, with a mean age of 36.9 years were included in this study. Of the 24 implants, one implant belonging to Group A was lost due to peri-implantitis after three weeks.

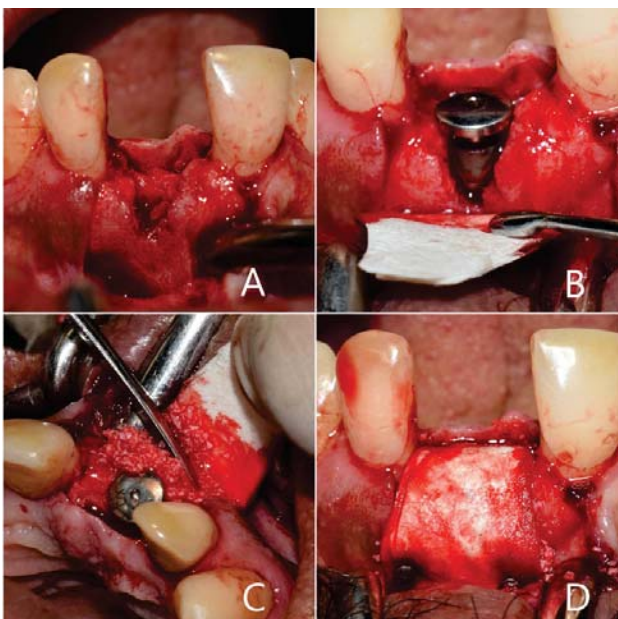


Fig. 1. A: Bone defect visualization, **B:** Implant placement, **C:** Surgical site grafted (occlusal view), **D:** Surgical site grafted (buccal view)

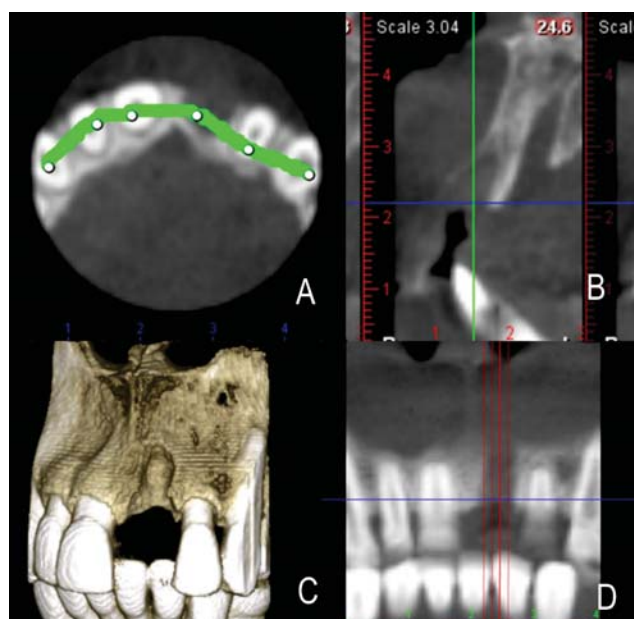


Fig. 2. A: Axial section, **B:** Coronal section, **C:** 3D reconstruction, **D:** Sagittal section

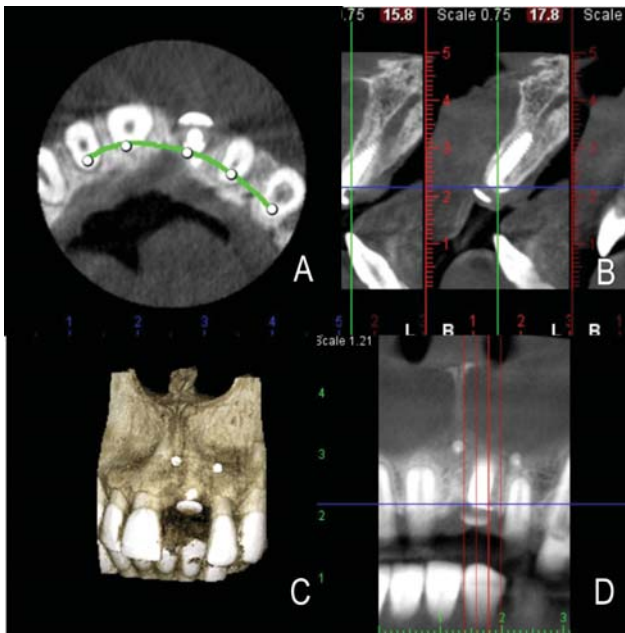


Fig. 3. A. Axial section, B. Coronal section, C. 3D reconstruction, D. Sagittal section

Ten subjects in Group A were followed up to 6 months, whereas eleven subjects were followed up in Group B. Of the 21 cases, marginal bone loss was seen in two subjects, each of both groups.

In Group A, the mean pre-operative alveolar ridge dimensions were 9.62 mm in the vertical dimension and 3.85 mm in the horizontal dimension. The mean alveolar

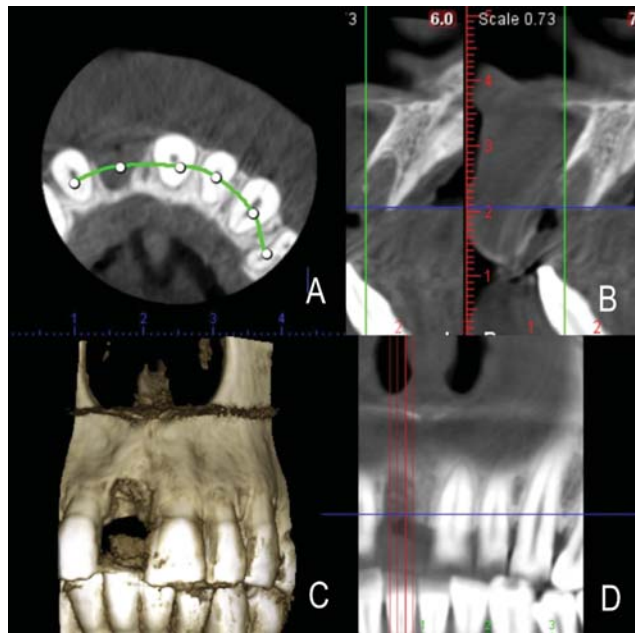


Fig. 4. A. Axial section, B. Coronal section, C. 3D reconstruction, D. Sagittal section

ridge augmentation as seen at 6 months was observed to be 2.09 mm in the vertical dimension and 0.99 mm in the horizontal dimension. In Group B, the mean pre-operative alveolar ridge dimensions were 10.64 mm in the vertical dimension and 3.68 mm in the horizontal dimension. A mean vertical augmentation of 1.73 mm and a mean horizontal augmentation of 2.09 mm were observed (Figure 5, Table 1, Table 2, Graph 1).

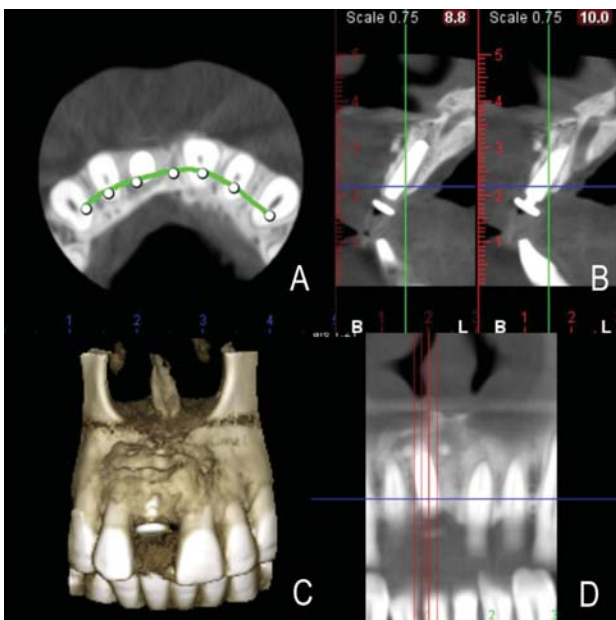


Fig. 5. A. Axial section, B. Coronal section, C. 3D reconstruction, D. Sagittal section

1.	Figure 1: A: Bone defect visualization; B: Implant placement, C: Surgical site grafted (occlusal view); D: Surgical site grafted (buccal view)
2.	Figure 2: Pre-op. Group A; A. Axial section; B. Coronal section; C. 3D reconstruction; D. Sagittal section
3.	Figure 3: Pre-op. Group B; A. Axial section; B. Coronal section; C. 3D reconstruction; D. Sagittal section
4.	Figure 4: 6 Months post-op. Group A; A. Axial section; B. Coronal section; C. 3D reconstruction; D. Sagittal section
5.	Figure 5: 6 Months post-op. Group B; A. Axial section; B. Coronal section; C. 3D reconstruction; D. Sagittal section
6.	Graph 1: Pre-op and 6 months post-op inter-group comparison

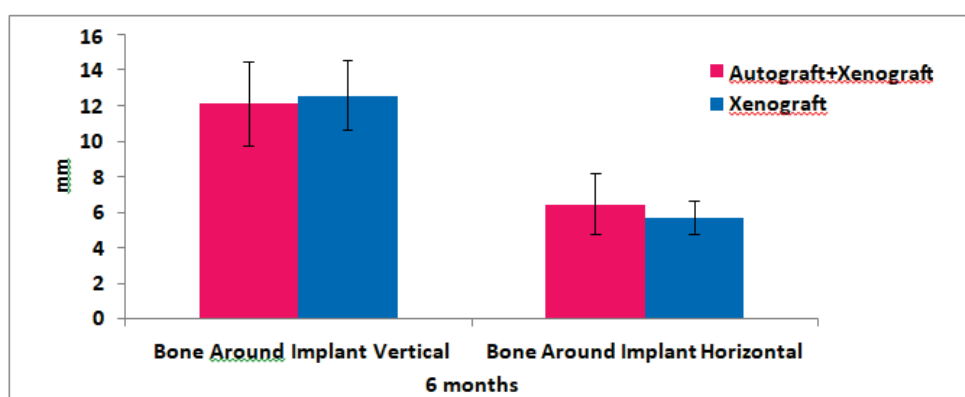
Table 1. Comparison of available bone (vertical and horizontal) between the two groups at baseline

	Group	N	Mean	Std. deviation	Mean difference	t	P	95% Confidence interval of the difference	
								Lower	Upper
Available bone (vertical) baseline	Autograft+Xenograft	12	9.62	3.59	-1.02	-.722	0.479	-3.97	1.94
	Xenograft	12	10.64	2.63					
Available bone (horizontal) baseline	Autograft+Xenograft	12	3.85	1.35	0.16	.336	0.741	-0.85	1.18
	Xenograft	12	3.68	0.71					

Table 2. Comparison of bone around implant (vertical and horizontal) between two groups at 6 months

	Group	N	Mean	Std. deviation	Mean difference	t	P	95% Confidence interval of the difference	
								Lower	Upper
Bone around implant (vertical) 6 months	Autograft+Xenograft	12	12.09	2.38	-0.48	-.476	0.641	-2.639	1.676
	Xenograft	12	12.57	1.79					
Bone around implant (horizontal) 6 months	Autograft+Xenograft	12	6.44	1.73	0.73	1.097	0.299	-.762	2.226
	Xenograft	12	5.71	.81					

Graph 1: Comparison of bone around implant (vertical and horizontal) between two groups at 6 months



It was demonstrated that alveolar ridge augmentation with immediate implant placement is a viable treatment option for the atrophic esthetic region of the maxilla.

DISCUSSION

The results demonstrated the effectiveness of a surgical protocol for vertical and lateral alveolar ridge augmentation by means of a slow-resorbable, bilayer collagen membrane in conjunction with either a 1:1

combination of bovine graft and autograft or bovine graft alone.

The immediate post-operative healing was observed to be uneventful with no complications, such as infection, hemorrhage or any neurosensory disturbances. The study subjects reported some amount of post-operative swelling with the maximum swelling seen at 48 hours. The swelling gradually reduced over the course of the week. Any post-operative pain, as reported by the subjects, was primarily linked with the sutures placed across the vertical releasing incisions.

Numerous studies over the years have demonstrated fairly predictable and successful vertical and horizontal augmentation of the atrophied alveolar ridges. The majority of these studies, however, did not pair the ridge augmentation procedure with simultaneous implant placement. The combined approach of GBR and simultaneous implant placement reduces patient morbidity, treatment time and costs. However, cases must be chosen carefully with primary importance given to whether or not the surfaces of the implant that are initially exposed can be covered by regenerating bone such that the implant can successfully osseointegrate [9, 10].

Most studies that attempted vertical alveolar ridge augmentation employed the use of a non-resorbable membrane in conjunction with the bone substitute. Hammerle and Jung [9], in their systematic review on the various barrier membranes available, enumerated certain advantages and disadvantages to the use of resorbable membranes in GBR procedures. Zitzmann et al [11] conducted a study to compare the efficacy of a resorbable collagen membrane, Bio-Gide®, to that of a non-resorbable PTFE membrane (Gore-Tex®) in conditions where implant surfaces were exposed. 25 split-mouth subjects were treated in a way that one defect site was treated with the resorbable membrane and the other with the non-resorbable membrane. The bone graft used in all the defects was Bio-Oss®, a bovine graft. The defect characteristics such as size, morphology and type were studied at baseline and at the time of re-entry. On analysis, both groups showed a statistically significant difference in terms of bone regenerated when compared to their respective baseline values. However, there was no statistically significant difference between the amounts of bone regeneration seen between the two groups.

Besides eliminating the need for a secondary surgical procedure for retrieval of the barrier membrane, resorbable membranes have the added advantage of improved soft tissue healing. Bioresorbable membranes also reduce the risk of infection that may follow bacterial contamination of open microstructures in cases of membrane exposure. This is possible due to the rate of resorption of these membranes. However, these resorbable membranes are associated with a reduced amount of bone fill. This reduced bone fill is attributed to the reduced 'space-making' ability and the reduced control the clinician has over the time, taken for these membranes, to resorb and maintain their barrier function as compared to the more rigid, non-resorbable membranes. Another disadvantage associated with the currently available bioresorbable membranes is that they are not rigid enough to

maintain the required space unless facilitated by the morphology of the bone defect. These membranes lose their mechanical strength over time. If the bone defects are unable to maintain space by themselves, the bone regeneration procedure is invariably unsuccessful [11, 12]. To counter this property of the bioresorbable membranes, a sinus membrane screw of 2 mm height and 6 mm diameter was used in this study to cause 'tenting' of the membrane.

Simion et al. [13] undertook a study to evaluate the efficacy of a 1:1 combination of deproteinized bovine bone material (DBBM) and autogenous bone graft in association with an expanded-polytetrafluoroethylene (ePTFE) membrane for vertical alveolar ridge augmentation. The study supported the use of this 1:1 combination of DBBM and autogenous bone chips for vertical ridge augmentation by the means of guided bone regeneration. The regenerated bone was believed to lead to proper osseointegration of the dental implants inserted either at the time of the regenerative procedure or after a healing period of around six months. It was also noted that DBBM undergoes resorption at a slower rate. This reduced rate of resorption of the DBBM particles enhances the stability of regenerated bone in the long-term. As reported by Boyne, radiographic analysis after a period of 4 years showed a 60% reduction in alveolar bone height in cases treated with autologous bone alone. Whereas, in the same time frame, cases, treated with a mixture of autologous bone chips and DBBM in the ratio of 1:1, exhibited a reduction of alveolar bone height of around 20%.

In a study conducted by Urban et al., an average gain of 5.45 mm in vertical height of the alveolar ridge was observed. These observations were similar to those obtained by Simion et al. This concluded that the use of a titanium-reinforced non-resorbable membrane in combination with a mixture of anorganic bovine bone-derived mineral and autologous particulated bone for vertical augmentation was a successful treatment modality.

Kao et al. [14] reported a clinical procedure that was undertaken to restore an edentulous site that had undergone severe bone destruction. Vertical and horizontal ridge augmentation was carried out followed by implant placement. The GBR was carried out using a titanium-reinforced, ePTFE membrane along with tenting screws, which was combined with a mixture of autograft and allograft. A second-stage surgery was carried out to retrieve the non-resorbable membrane after a healing period of 6 months following which, endosseous implants were placed. An increase in bone dimensions of 8.0 mm in the vertical dimension and 7.0 mm in the horizontal dimension

was observed in the edentulous space. An 18-month follow-up showed stable marginal bone level and healthy peri-implant tissue.

From these reported studies, it is evident that vertical ridge augmentation using GBR techniques are an effective and fairly predictable reconstruction technique. However, the process of harvesting autologous bone grafts is associated with the need for a secondary donor site, increased operating time and increased costs.

The results of the present study demonstrated the possibility of supracrestal alveolar bone augmentation using a surgical technique that involves harvesting of the autologous bone from the defect site itself using a trephine. This helped eliminate the need for a secondary surgical site. The use of a resorbable collagen membrane also eliminated the need for a secondary surgical procedure to retrieve the non-resorbable mesh/membrane [15].

The bone regeneration seen in both the groups was similar to the vertical bone gain as reported by previous studies. The alveolar ridge augmentation obtained enabled better 3-D positioning of the implants and a better crown-root ratio. This in turn improved the biomechanical and esthetic outcomes.

In the present study, the regenerated bone was only analyzed radiographically. Further studies on the histologic and histomorphometric parameters are required to evaluate the nature of the regenerated bone and the implant-tissue interface that is created. At this stage, the behavior of the implants and the regenerated bone has not been studied. The results of this study have to be further validated by future randomized clinical trials with increased sample sizes that also study the stability of the regenerated bone and the implants in the long term under occlusal load.

CONCLUSION

On analysis of the collected data, it was observed that ridge augmentation using autograft and bovine graft and using bovine graft alone with simultaneous implant placement showed a statistically significant increase in the horizontal dimensions but not the vertical dimension.

Both groups showed an increase in alveolar ridge dimensions after 6 months as compared to the baseline observations. However, the inter-group results were not statistically significant.

It was demonstrated that alveolar ridge augmentation with immediate implant placement is a viable treatment option for the atrophic esthetic region of the maxilla.

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