ORIGINAL RESEARCH

Ridge Augmentation with Autogenous Bone Graft and Expanded Polytetrafluoroethylene Membrane using Tenting Screw: A Randomized Controlled Clinical Trial

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Abstract

Background: The study aims to compare non-tenting screw and tenting with a reinforced expanded polytetrafluoroethylene (ePTFE) membrane in horizontal ridge augmentation using an autogenous bone graft.

Material and methods: A randomized controlled clinical trial was conducted between 150 patients needing dental implants. The participants were randomly divided into three study groups; group 1: ridge augmentation using non-resorbable ePTFE membrane only, group2: ridge augmentation using an ePTFE and tenting screw with bone graft Bio-Oss mixed with autogenous bone particles and group 3 (control): ridge augmentation with a bone block. The initial measurement was done at the bone crest at the exact implant site and 10 mm apical to the bone crest. Repeat measurements were recorded after 6 months of healing. Statistical analysis was performed by paired sample t-test and two-way analysis of variance (ANOVA). Statistical significance was considered at $p < 0.05$.

Results: There was a significant gain in the bone in all the three groups postsurgery. Group 3 recorded higher reading at the crest and apical sites when compared to groups 1 and 2 at 6 months (late measurements). The difference in the percentage gain was statistically significant after adjusting for age as well as the initial measurement. The highest gain was seen in group 3 followed by groups 2 and 1.

Conclusion: The membrane with tenting screw group and block bone groups had a significantly higher increase in measurement when compared to the membrane only group. Tenting screw with Bio-Oss can be used in patients with autogenous bone at the donor site.

Clinical significance: Tenting screws in combination with membranes can be used to overcome the limitations posed by the use of membranes alone. It is also a useful method for a patient not consenting for block graft for any medical reason.

Keywords: Autogenous bone graft, Expanded polytetrafluoroethylene, Ridge augmentation, Tenting screw

The Journal of Contemporary Dental Practice (2019): 10.5005/jp-journals-10024-2531

Introduction

Ridge defects are difficult to restore because it needs a three-dimensional reconstruction. The gold standard for reconstructing the segmental bone defects is bone grafts.[1] There are subtypes of bone graft: autograft, allograft, xenograft, synthetic materials and any combination of the previous types. Autogenous bone graft is considered the criterion standard for osseous reconstruction.[2] It minimizes the risk of infection because it does not trigger the immune response.[1] When the autograft becomes vascularized and osseointegrated with the surrounding bone, it will decrease the chance for dislodgment or breakdown. However, harvest requires additional operative time, donor site morbidity. Also, the amount of the transferred bone is limited.[2]

Guided bone regeneration (GBR) is another method to augment the bone defects with no need for another surgical site. GBR is a surgical procedure that uses barrier membranes with or without particulate bone grafts or/and bone substitutes.[3] The principle of GBR is that the barrier membrane will create a space which allows the growth of the cells of the adjacent bone into space and form new bone. Soft tissue will be excluded from the area.[4] It is an attempt to regenerate the alveolar bone of atrophic arches and reconstructing the large osseous defects in the jaws.[5]

The GBR using non-resorbable ePTFE membrane was used for ridge augmentation in different studies. The first use of the non-resorbable membrane for tissue regeneration was in 1984 which was made of ePTFE, (Gore-Tex®).[6] The ePTFE is a biocompatible material and does not elicit foreign body response after implantation, it causes minimal inflammation and allows tissue ingrowth.[7]

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How to cite this article: Johar AO. Ridge Augmentation with Autogenous Bone Graft and Expanded Polytetrafluoroethylene Membrane Using Tenting Screw: A Randomized Controlled Clinical Trial. J Contemp Dent Pract 2019;20(4):409–416.

Source of support: Nil

Conflict of interest: None

Positive outcomes have been shown in a lot of studies when they use the autogenous bone graft and the ePTFE membrane for bone augmentation. Urban et al.[8] found favorable results when they used the non-resorbable ePTFE membrane and autogenous bone graft on 35 patients who required vertical bone augmentation before implant placement. The mean vertical augmentation was 5.5 mm (± 2.29 mm) at membrane removal, and the mean combined crestal remodeling was 1.01 mm (± 0.57 mm) at 12 months. The overall implant survival rate was 100% with a cumulative success rate of 94.7% under loading through the 6 years follow-up period.

Titanium mesh (Ti–mesh) is an alternative method that can be used to overcome the ePTFE membrane drawbacks.[9] Roccuzzo et al.[9] demonstrated that patients could be successfully rehabilitated when a titanium micro-mesh was used to stabilize and protect the autogenous bone graft, even with severely atrophied maxilla.

The study was done on 18 partially edentulous patients who need vertical bone augmentation of at least 4 mm. Meshes and screws were removed after a mean interval of 4.6 months, and 37 endosseous implants were successfully placed. The mean vertical bone augmentation obtained was 4.8 mm (range 4–7 mm).

Space maintenance over bone is a central issue for successful GBR. The extent of augmentation can be limited due to the compressibility of some graft materials, so support must be provided under the membrane because most of the membranes are not rigid enough to resist collapsing.[4] Numerous successful reports have been published to provide support to the membranes such as using of tenting pins or screws extending several millimeters above the crest, or a combination of implants and pins.[4] The tenting screw can gain 3.5–7 mm of bone height. The amount of regenerative bone depends on the distance from the tenting screw head to the residual bone.[10] Additional advantages of tenting screw include time and ease of screw placement, one surgical site, minimal morbidity, and space maintenance for the GBR materials.

This study is to compare between the non-tenting screw and tenting screw with a titanium reinforced ePTFE membrane in horizontal ridge augmentation using an autogenous bone graft. The null hypothesis was that there is no difference in the ridge augmentation achieved by the use of tenting screws in comparison to ePTFE membrane and bone block.

Materials and Methods

Study Design and Study Population

A randomized controlled clinical trial was conducted among 150 patients who reported to KAU Dental Clinics in the period from 2010 to 2015 for replacement of missing tooth with an implant.

Ethical Approval and Informed Consent

Ethical approval was obtained from the institutional review board of KAU. Written informed consent was obtained from all the patients after a thorough explanation of the protocol in English as well as their native language before being enrolled in the trial.

Inclusion Criteria

- Single or multiple missing teeth that needed replacement with a dental implant.
- Anterior or posterior edentulous zone which exhibits ridge deficiency, Sebert class I (buccolingual) direction only.
- Time after extraction was a minimum of 6 month.
- Patient age range from 20 to 50 years.
- The absence of periodontal disease on the remaining teeth.

Exclusion Criteria

- Patient with diabetes type I or II
- History of smoking
- History of osteoporosis, any metabolic bone disease or collagen disease.
- Medication that might affect the bone/collagen remodeling like cortisone or bisphosphonate.
- Pregnancy
- History of failed prior ridge augmentation procedure

Study Groups

Fifty patients (25 male and 25 female) were randomly allocated into three study groups:

- *Group 1:* Ridge augmentation using a non-resorbable membrane, expanded polytetrafluoroethylene (ePTFE) only (control group) (Figs 1A and B)
- *Group 2:* Ridge augmentation using ePTFE and tenting screw with bone graft (BIO OSS mixed with autogenous bone particles obtained by bone shaving from the intraoral site) (Figs 2A and B)

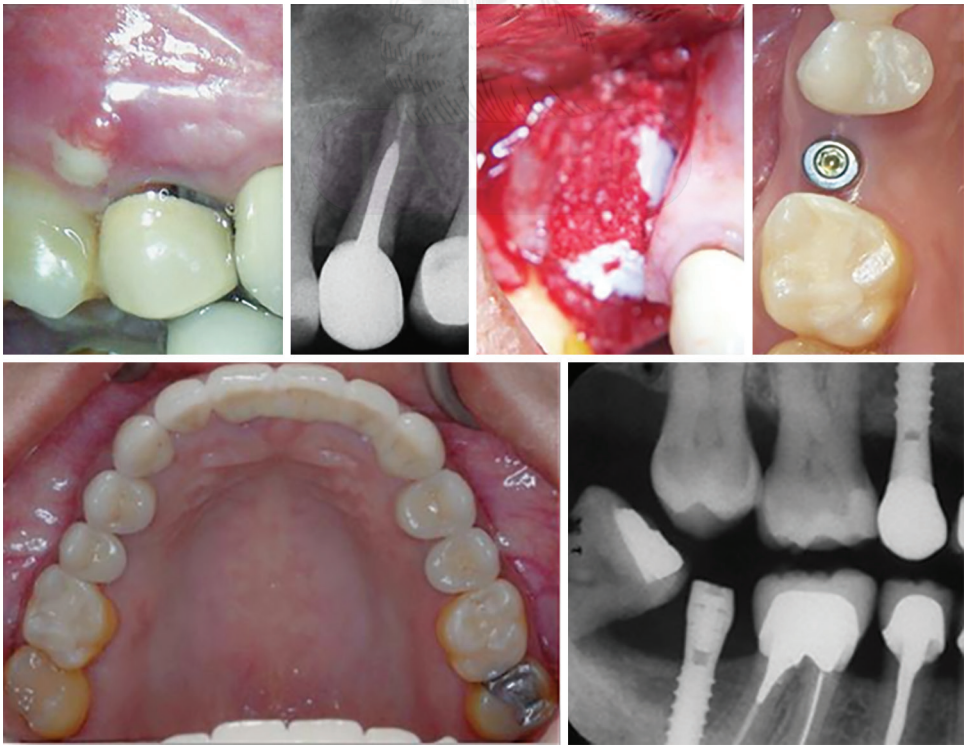

Fig. 1A: Case 1, ridge augmentation using a non-resorbable membrane, expanded polytetrafluoroethylene (ePTFE) only (control group)

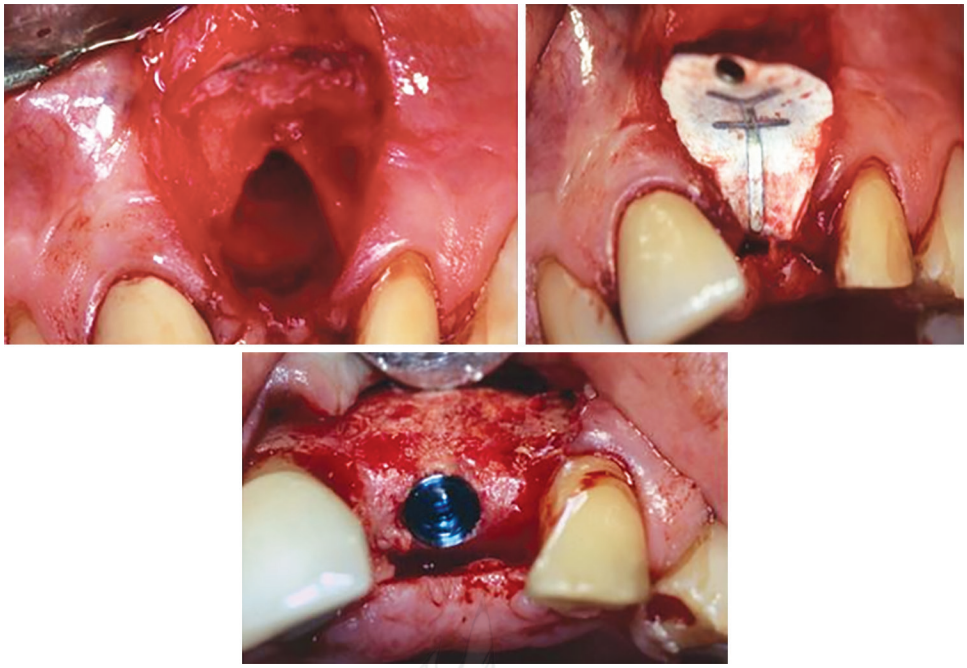

Fig. 1B: Case 2, ridge augmentation using a non-resorbable membrane, expanded polytetrafluoroethylene (ePTFE) only (control group)

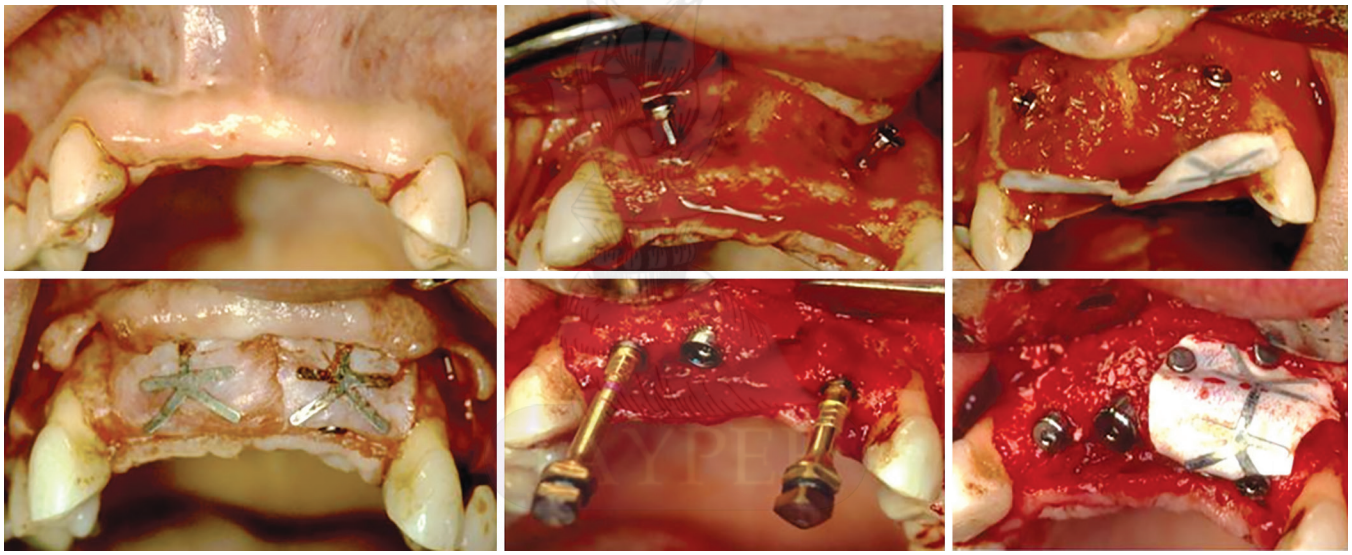

Fig. 2A: Case 1, ridge augmentation using ePTFE and tenting screw with bone graft (BIO OSS mixed with autogenous bone particles obtained by bone shaving from the intraoral site)

- *Group 3:* Ridge augmentation with autogenous bone block harvested from an intraoral site (Figs 3A–C).

Oral Outcome Measurements

Initial measurement at the bone crest at the exact implant site and 10 mm apical to the bone crest was determined by the surgical stent. The second set of measurements was recorded after 6 months of healing at the same sites.

The surgical stent was used as a guide to standardize both measurements using an electronic automated poly gauge that gives the measurement at the site where bone graft is going to be placed.

Surgical Procedure

Patients were prescribed prophylactic antibiotics for 7 days. Ibuprofen was given as an anti-inflammatory and analgesic. Chlorhexidine was given as mouth rinse antiseptic solution.

After the local anesthesia was given using xylocaine 2% with 1:100000 epinephrine, crestal incision was done, and the flap was reflected. Before the surgical intervention, the crestal and apical bare bone measurements were obtained. A buccal plate of bone was perforated using small rose head bur. Bone graft was harvested from an intraoral site at maxillary tuberosity for all patients in group 2. For group 3, the chin area and ascending ramus were the intraoral donor site.

Bleeding points were established, and the protocol was followed to augment the bone according to the assigned group. A single operator performed all the surgeries to reduce surgical variability. All the measurements were recorded by a single operator to minimize variability.

There was no blinding nor concealment of allocation.

Surgical and healing complications were recorded. Complications were noted in three cases in group 2 and were handled by applying chlorhexidine to the exposed membrane.

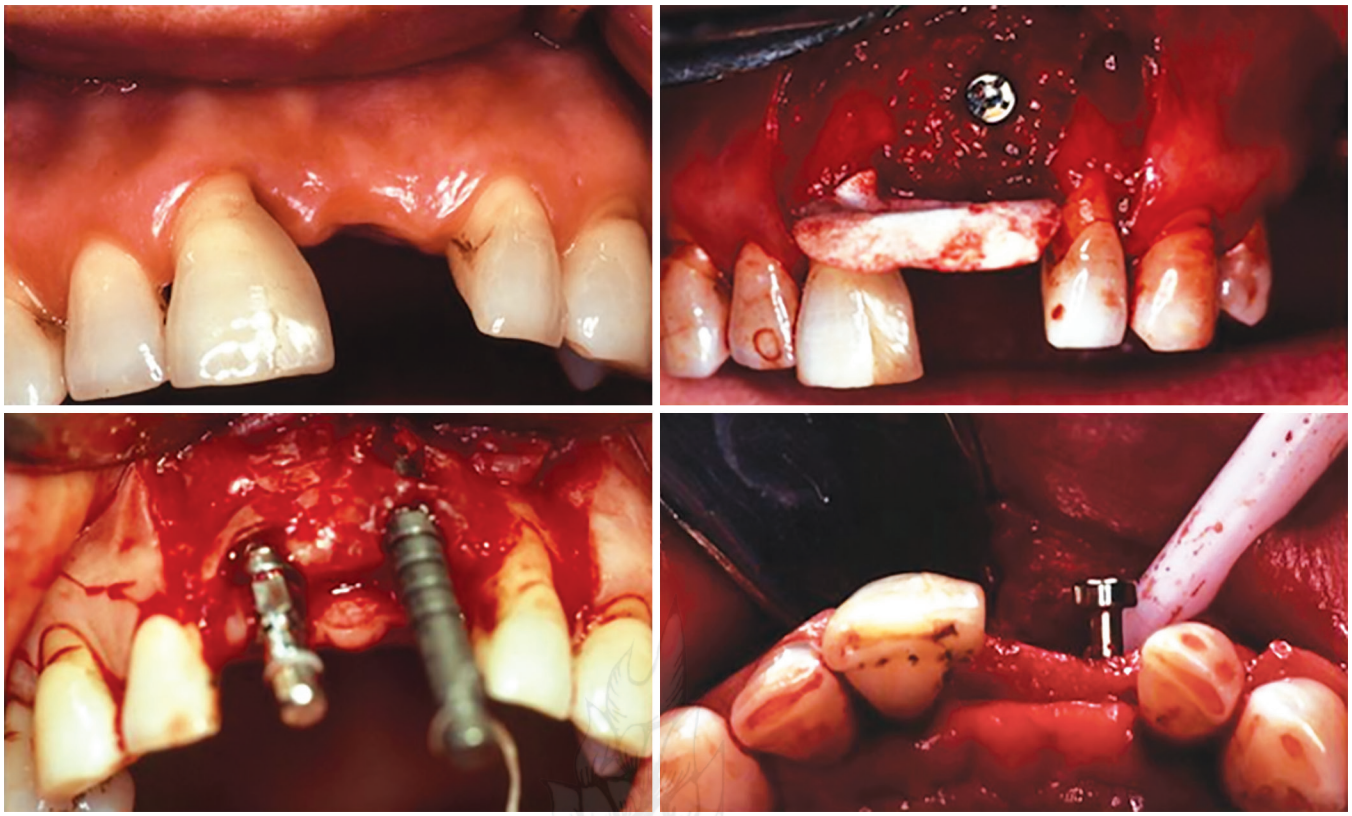

Fig. 2B: Case 2, ridge augmentation using ePTFE and tenting screw with bone graft (BIO OSS mixed with autogenous bone particles obtained by bone shaving from the intraoral site)

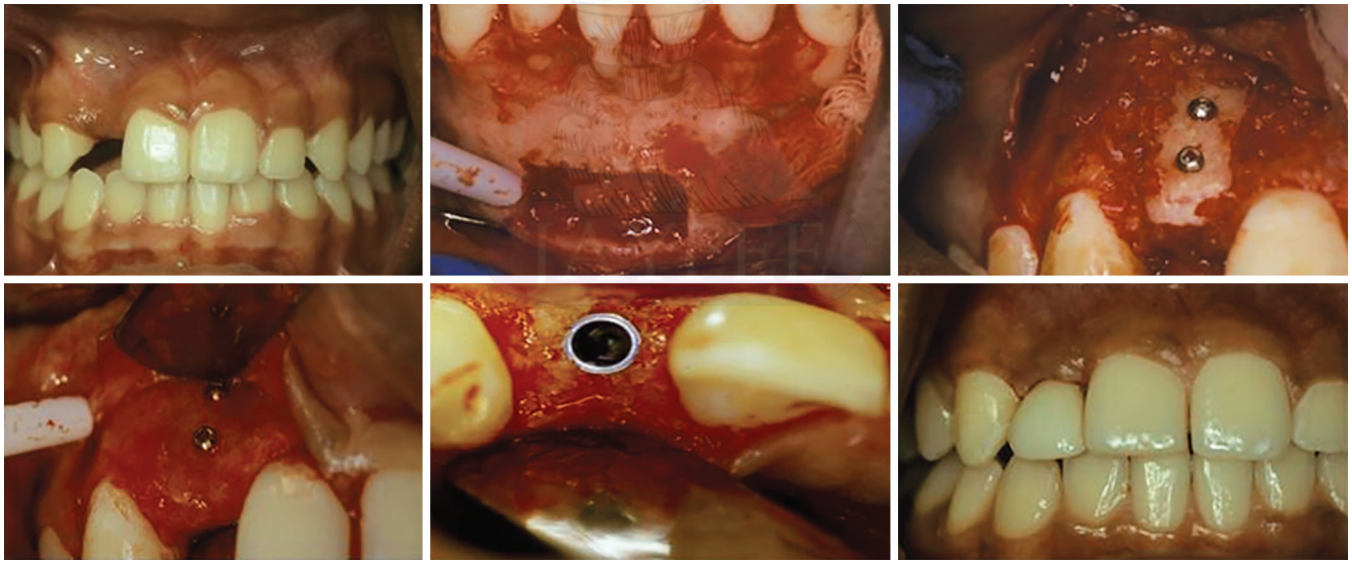

Fig. 3A: Case 1, ridge augmentation with autogenous bone block harvested from an intraoral site

All procedures were performed by the recommendations of the Declaration of Helsinki (2008) for investigations with human subjects. No dropouts presented during the entire period of observation. After 6 months, all the implants were loaded with fixed dental prosthesis (FDP) or a single crown as per the treatment plan of each patient.

Statistical Analysis

The data were entered in Microsoft Office Excel worksheets and analyzed using software IBM statistical package for social sciences version 20.0 (IBM Statistics, SPSS, Chicago, USA). The normality of the data was assessed using the Kolmogorov–Smirnov test while Levene's test for equality of error variances was used to analyze the homogeneity of error variances. Descriptive statistics were calculated as frequencies and percentages or means and standard deviations. Paired t-test was used to compare repeated measures at initial and late periods for each study group. Percent change in ridge measurement was calculated as: [(late measurement–initial measurement)/initial measurement)*100] and was

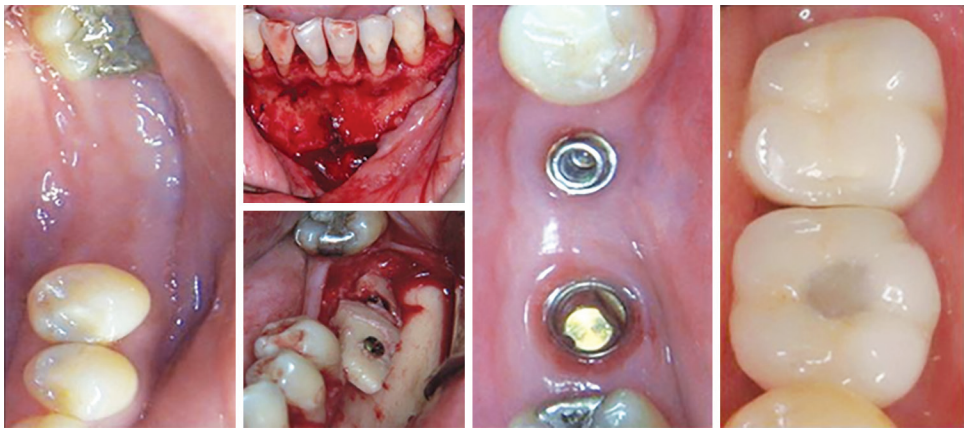

Fig. 3B: Case 2, ridge augmentation with autogenous bone block harvested from an intraoral site

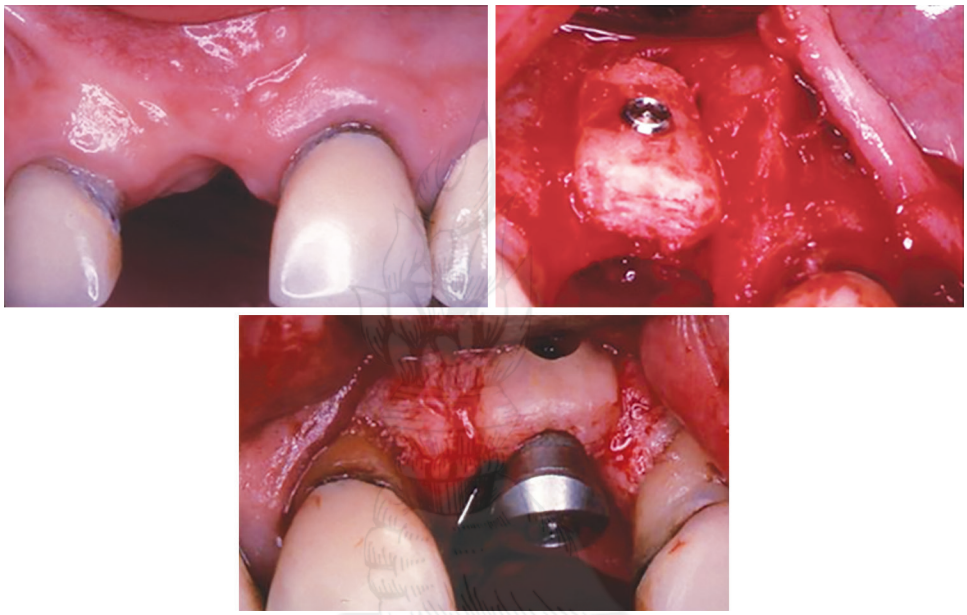

Fig. 3C: Case 3, ridge augmentation with autogenous bone block harvested from an intraoral site

compared among the study groups using regression analysis with adjustment for age and initial measurement. Means and 95% confidence intervals were calculated followed by a comparison of means using Bonferroni adjustment for multiple comparisons. Statistical significance was set at $p < 0.05$.

Results

The present study was conducted among 150 (75 males and 75 females) participants randomly divided into three study groups. The mean age of the participants in group 3 was 31.02 ± 6.61 years which was significantly higher than those in groups 1 and 2 (Table 1). Intergroup comparison of apical and cervical ridge measurements (mm) revealed that there was a statistically significant difference between the study groups at both initial and late measurements (Table 2). For initial measurements, group 1 had a higher reading, whereas, for the late measurements group 3 had a higher reading. Also, intragroup comparison revealed that there was a statistically significant increase in the ridge measurement at the end of 6 months in all the three study groups. (Table 2).

Table 1: Distribution of the study participants based on age and gender

		Study group			
Variables		*Group1 (n = 50)*	*Group 2 (n = 50)*	*Group 3 (n = 50)*	*p value*
Age	Range	20–42	20–42	20–43	0.02*
	Mean (SD)	27.62 (5.42)[a]	28.78 (6.32)	31.02 (6.61)[a]	–
Gender	Male n (%)	25 (50)	25 (50)	25 (50)	–
	Female n (%)	25 (50)	25 (50)	25 (50)	–

*Statistically significant at $p < 0.05$; [a], significant post hoc analysis

Table 2: Inter and intragroup comparison of initial and late measurements (at 6th month)

		Study group			
		Group1 (n = 50)	*Group 2 (n = 50)*	*Group 3 (n = 50)*	
		Mean (SD)	*Mean (SD)*	*Mean (SD)*	*p value (ANOVA)*
Apical	Initial	3.81 (0.24)[a]	3.66 (0.22)[a]	3.63 (0.23)[a,b]	0.000*
	Late	7.5 (0.46)[a,b]	9.45 (0.35)[a,b]	11.30 (0.54)[a]	0.000*
(Paired t) *p* value		0.000*	0.000*	0.000*	
Cervical	Initial	3.82 (0.24)[a]	3.66 (0.26)[a]	3.62(0.26)[a,b]	0.000*
	Late	7.42 (0.48)[a,b]	9.94 (0.39)[a,b]	11.41 (0.66)[a]	0.000*
(Paired t) *p* value		0.000*	0.000*	0.000*	

*Statistically significant at $p < 0.05$, [a,b]Significant post hoc analysis

Table 3: Comparison of percent change in measurements adjusted for age and initial measurements

	Study groups % (95% confidence interval)			
	Group1 (n = 50)	*Group 2 (n = 50)*	*Group 3 (n = 50)*	*p value*
Cervical	102.32 (97.81–106.83)[a,b]	170.46 (166.16–174.79)[a,b]	211.50 (207.06–215.95)[a,b]	<0.001*
Apical	105.90 (102.08–109.71)[a,b]	169.62 (165.96–173.28)[a,b]	202.16 (203.28–210.79)[a,b]	<0.001*

*Statistically significant at $p < 0.05$, [a,b]Significant post hoc analysis

The percentage change in the measurements was compared using regression analysis and the confounding factors considered were age and the initial measurements. It was observed that there was a statistically significant difference in the percentage change in the ridge measurements at both cervical and apical sites. The maximum gain (211% cervically and 202% apically) was observed in the 3rd group followed by the 2nd group and 1st group (Table 3).

Discussion

This randomized controlled clinical trial was conducted to compare the ridge augmentation achieved by the use of tenting screws in comparison to ePTFE membrane and bone block. It was observed that there was a significantly higher gain in the tenting screw group as compared to the membrane only group, but the increase was significantly lower than the bone block group. Hence, the null hypothesis is partially rejected.

At baseline, patients showed a significant difference in the initial ridge measurements. Hence this was considered as a confounding variable for comparison of the percentage change in the ridge measurements. A significant increase in ridge measurement was detected in this study when comparing the initial and late measurements. This finding was observed in the three surgical procedure groups. This difference was detected using a paired sample t-test. These results were anticipated since the investigators chose the surgical procedures that are well known to give positive results.[3]

Comparison of outcomes according to the surgical procedure was carried out to answer the research question of which one of these surgical procedures provide the best ridge augmentation results. A significant difference in the late ridge measurements at the crest and apical sites between the different surgical procedures was observed.

There was a significant difference in the mean age of the patients enrolled in the three surgical procedure groups, which might affect the osteogenic potential among patients.[11] Therefore, the investigators used regression analysis to control for age as a confounding variable in testing the effect of the procedures on the ridge measurement and found that age did not play a role in the detected significant difference in measurements due to the surgical procedures.

Post hoc results (pairwise) analysis showed that the membrane group recorded significantly lower readings at the crest and apical sites when compared with the membrane and tent group as well as the bone block group. To allow for granting the extent of successful augmentation procedures, investigators compared the percent increase in ridge measurement between the surgical procedures at each measurement site and found that the membrane and tent group and block bone groups had significantly increased in measurement when compared to initial measurement.

After tooth extraction, loss in height and width of the alveolar process resulted in narrowing and shortening of the remaining ridge.[12] The resorption and remodeling of the alveolar ridge after tooth removal is a natural healing phenomenon, which is physiologically undesirable and possibly inevitable and can negatively impact implant placement. Treatments for replacing missing teeth has changed radically.[13]

The notion of restorative implants in dentistry is well accepted. It is important to have sufficient bone to achieve long-term stability to long-term dental implants.[10,14]

In the past, the resultant ridge deformities would often impede favorable placement of endosseous implants, which may lead to biomechanical and aesthetic problems.[15] Today, it is possible to regenerate bone in locations and quantities to permit favorable implant position in almost every restorative application.

The indications for employing corrective or reconstructive surgical techniques may be functional and aesthetic and may involve both hard and soft tissues. Sufficient bone must be present to allow placement of an implant of appropriate dimensions in a stable and correct orientation to allow construction of a successful prosthesis. Thus, investigators of this research aimed at comparing

techniques of ridge augmentation that could provide adequate bone that allow an efficacious placement of an implant.

Investigators applied three corrective approaches; the first was using autogenous bone graft only, the second using non-resorbable expanded polytetrafluoroethylene membrane (ePTF) only, and the third approach using a combination of ePTF and tenting screw with bone graft.

The first approach, bone block grafts is the gold standard approach for ridge bone regeneration; it was developed years ago and is still promoted as the best approach to intraoral osseous regeneration. The osteogenic potential of autogenous block grafts is one of the major considerations in promoting this type of graft as the gold standard.[11]

However, on lay graft procedures are often traumatic, time-consuming, and costly, they involve multiple sites, and have considerable documented morbidity.[3] An alternative to the gold standard, considering the osteogenetic, osteoinductive, and osteoconduction properties, the best technique is still considered the autograft, which can be intraoral or extraoral.

The second approach is GBR. It was introduced as a therapeutic modality aiming to achieve bone regeneration, via the use of barrier membranes.[16] Expanded polytetrafluoroethylene (e-PTFE) is considered the gold standard of non-resorbable membranes; it has been the most frequently used material for periodontal and bone regeneration.[16] It is a chemically stable and biologically inert polymer, featuring a porous structure and flexible form. It resists microbiological and enzymatic degradation and does not elicit immunologic reactions.[17]

The use of non-resorbable membranes (ePTFE–expanded polytetrafluoroethylene membranes) is a quite traditional and pure approach of GBR.[18] It allows to have rigid protection of the regenerative bone chamber and sometimes to perform the bone regeneration with blood as sole grafting material. Unfortunately, these membranes are difficult to use and can bring complications such as soft tissue dehiscence during the healing period and membrane bacterial contamination. Also, membrane removal during implant placement requires extensive surgical exposure of the newly formed bone.[18,19]

The central issue for successful GBR is space maintenance over bone. However, most membranes do not have the rigidity to resist collapsing, so support must be provided under the membrane. Bone grafts of various types have long been used for that purpose.[20] Further, the compressibility of some graft materials might limit the extent of augmentation.[21] A more reliable space maintainer for the membrane is actual structural support. Tenting pins or screws extending several millimeters above the crest have shown a notable success to provide support for membranes.[22,23]

Implants are screws with improved design and surfaces and can be considered as optimized large osteosynthesis screws. If these screws are used as tent pegs or supporting regenerative pillars in many surgeries to maintain and protect the regenerative bone compartment, then they logically impact the way bone is guided and regenerated. This introduced the concept of screw-guided bone regeneration (S-GBR). Thus, the third approach the investigators applied was the combination of implants and screws, and bone graft to test for its ridge augmentation properties.

Ideally, the surgeon would like to harvest bone from a site that is close to the defect site. This essentially affords the possibility of one surgical site rather than two.[24] The literature highlights the positive aspects of the autologous intraoral grafts regarding hospitalization, anesthetic techniques, bone resorption, and esthetic aspects. Intraoral harvesting procedure may be performed on an outpatient basis and with local anesthesia or conscious sedation. This type of harvesting is also facilitated by the reduced morbidity and lack of cutaneous scars. The most commonly used intraoral sites are symphysis, ramus of the mandible and retromolar trigone and tuber maxillae. While the graft from the tuber maxillae is less used because it provides mainly cancellous bone, rich in cells, but with weak consistency, investigators of this research chose it as an easily accessible surgical area.[25]

The following conclusions can be drawn from the present study:

- All three surgical techniques lead to significant ridge augmentation at 6 months.
- There was a statistically significant difference in the percentage gain in the ridge at both crestal and apical sites between the three surgical procedures.
- Maximum gain was seen in the bone block group followed by the membrane and tenting screw, and the least gain was observed in the ePTFE membrane only group.

Clinical significance

Many techniques exist for effective bone augmentation. The approach largely is dependent on the extent of the defect and specific procedures to be performed for implant reconstruction. It is most appropriate to use an evidence-based approach when a treatment plan is being developed for bone augmentation cases.

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