EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
VOL. 71, 2061:2070, JULY, 2025
PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360
ORAL SURGERY
Submit Date : 08-04-2025 • Accept Date : 29-05-2025 • Available online: 10-07-2025 • DOI : 10.21608/edj.2025.373686.3441

XENOGRAFT VS XENO - ALLOGENIC COMPOSITE GRAFT USING THE TENTPOLE TECHNIQUE FOR RECONSTRUCTION OF HORIZONTAL RIDGE DEFICIENCIES: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Dental implants are the gold standard for treatment of edentulous spaces especially with the introduction of the tent-poling technique. This study aims to compare the use of xenografts VS xeno-allogenic grafts with tenting screws for reconstruction of horizontally deficient ridges.

Methodology: 19 patients were included in the study with 30 different implant sites randomly assigned to the study (receiving a combination of xeno-allogenic bone graft) or the control group (receiving xenografts) for the defective alveolar ridge. The 1st stage surgery included the placement of 1.5 mm self drilling tenting screws perpendicular to the outer cortical plate. The 2nd stage surgery was 6-9 months later during which the tenting screw was removed and the osteotomy site prepared. CBCTs were ordered preoperatively, 6 months postoperatively and after implant placement. Histomorphometric assessment was carried out for the core biopsy retrieved.

Results: One case (excluded from the study) showed partial wound dehiscence with severe graft loss & required a second grafting procedure. In 2 of the cases complete screw-head coverage by bone was noted on the 2nd surgery. Histomorphometric assessment showed 43% mean bone content in the study group while it was only 33% in the control group postoperatively. 81% of the former and 72% of the latter was vital bone. Radiographically, statistically-significant bone gain was noted within each group but was statistically insignificant between the groups.

Conclusions: Within the limitations of the study, it can be concluded that the type of bonegraft has no significant impact on bone gain with the tentpoling technique.

KEYWORDS Tentpoling, Xenograft, Allograft, horizontal alveolar ridge defect, dental implant

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INTRODUCTION

Dental implants are considered the gold standard for treatment of edentulous spaces including those of the maxillary and mandibular regions. Lack of sufficient bone volume required for proper osseointegration of the dental implants has led to a myriad of research discussing methods to improve remaining ridge height, width or both[1]. Onlay grafting, sandwich osteotomies and sinus lifting/ augmenting are only a few examples of these research propositions[2]. Sinus augmentation is usually the treatment of choice in cases of deficient posterior ridge height and was first proposed by Tatum and has since led to the development of several editions to simplify and improve the initial surgical procedure. The use of the lateral approach (historically known as the Caldwell Luc procedure) to augment the sinus is based on the access of the sinus membrane laterally, lifting it and either adding a grafting material or leaving it tented. The choice of approach is based on the ridge condition where a thinner/shorter ridge is an indication for a lateral approach sinus augmentation procedure [3]. The approaches researched for sinus augmentation further lead to the idea of tenting over the implant ; where the implant was used to lift the Schneiderian membrane causing a space which would later fill with bone. The tenting technique was then further researched in other maxillary and mandibular ridge deficiencies[4-6]. Tent poling is said to cause regain of bone quantity partially by preventing soft tissue contracture over the graft and therefore reducing graft resorption[9].

The grafting materials that are used to augment alveolar ridges include autogenous bone (from intraoral or extraoral sites), xenograft, allografts or a mix of these. Autogenous bone being osteogenic, osseoinductive and osteoconductive is the best choice but carries the increased risk of a second surgical site with its morbidity, bleeding time and longer surgical time[7]. Xenografts – especially those of bovine origin- are commonly used due to the biocompatibility and similarity to human bone [8-9].

Tenting dental implants is a reported procedure that allows for bone fill in the created gap (5). The tenting procedure creates a space which attracts bone forming cells and studies in the literature have reported sufficient bone formation with tented implants in sinus lifts (6) and vertical ridge augmentation (10).

The aim of this study is to compare the use of xenografts VS xenografts with allogenic grafts with tenting screws for reconstruction of horizontally deficient alveolar ridges.

METHODOLOGY

The current research protocol was approved by the institutional ethical committee and review board at, faculty of dentistry, Cairo University (Approval No. 32-1-24). All clinical procedures involving patients were conducted according to "Ethical Principles for Medical Research Involving Human Subjects" based on Helsinki declaration of the World Medical Association [11]. This study was designed as a prospective, randomized, single blind, clinical and radiographic study, and in adherence with CONSORT guidelines [12].

Inclusion criteria:

- Missing tooth / teeth in maxilla or mandible with horizontal ridge deficiency of <= 4 millimeters
- Evidence of fair periodontal health with no active periodontal disease in adjacent teeth
- Non relevant history of medical illnesses that could affect bone and wound healing (e.g. uncontrolled diabetes mellitus, osteoporosis, renal osteodystrophy…etc.)
- Willingness to participate in the study and attend prescribed follow-up appointments.

Exclusion criteria:

- Ridge deficiency of more than 4 millimetres
- Pregnant and lactating females
- Smokers
- Patients on active treatment with anti-resorptive or anti-neoplastic medication such as bisphosphonates, chemotherapeutic agents, and monoclonal antibodies (e.g. Denosumab)
- Patients who had history of radiation therapy for head and neck cancer in the previous year

The sample size for the study was determined using an online statistical calculator (13). Accordingly, for 80% statistical power along with a two-sided level of significance of 5% (alpha level 0.05) to be achieved , sample size of at least 8 grafting sites was needed for each group. Patients were randomly assigned to each group based on the type of bone graft (Group A –; Group B –), by picking lots from an opaque container all the surgical procedure were carried out with the same operator. The current study was conducted on 19 patients (9male/10 female) with localized horizontal alveolar ridge defects underwent surgery. The patients presented to the outpatient clinic requiring dental rehabilitation . A total of 30 dental implants are to be inserted.

Preoperative assessment

1 –clinical assessment

The standardized clinical evaluation for patients indicated for implant treatment is performed for all patients (including general oral condition, remaining teeth health status , interarch distances and Soft tissue and keratinized mucosa,,,,,etc).

Radiographic assessment

CBCT was carried out preoperatively for assessment of bone volume, density and surrounding tissues at the area planned for implant/s placement. Bone width buccolingually or buccopalataly was measured at 2 levels . First at 1 mm and the second at 5 mm away from crest of the ridge.

The patients were then randomly allocate to a group ; Group I (Study group : xenograft +allograft) or Group II (control group : xenograft) Figure 1.

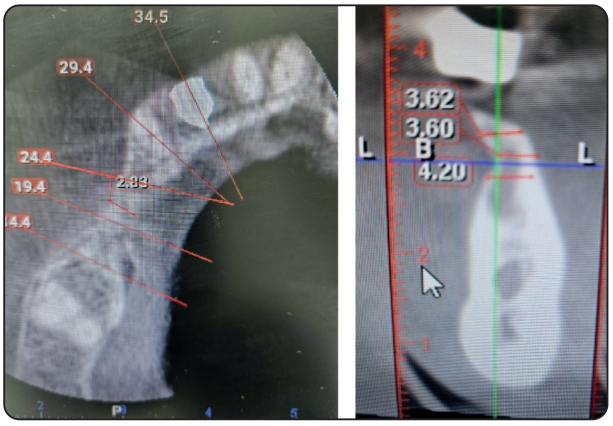

Fig. (1) Preoperative CBCT image showing horizontal alveolar ridge deficiency the measurement of the ridge requiring augmentation (2.83 mm)

Operative procedures

1st stage surgery:

The patients used Chlorhexidine Gluconate 0.1% mouthwash before surgery. Local anesthesia (Articaine 4% with 1:100000 epinephrine) was injected with a nerve block procedure according to the location (maxillary / mandibular). The incision was made crestally down to bone and the periosteum was reflected to expose the alveolar ridge. Fenestrations were made in the ridge using a carbide round bur under copious irrigation with saline solution 0.9%. one or more 1.5mm self drilling was placed perpendicular on the outer cortical plate of bone leaving 3–4mm outside the bone to support the resorbable membrane. According to the group of the patient (study vs control); bone grafts were placed in the defective ridge surrounding a screw to tent the mucosa. The study group received a 1:1 mixture of bovine derived xenograft *(CopiOs Cancellous particulate xenogrft – Zimmer Tutogen medical GmbH Industriestrase 6, 91077Neunkirchen*

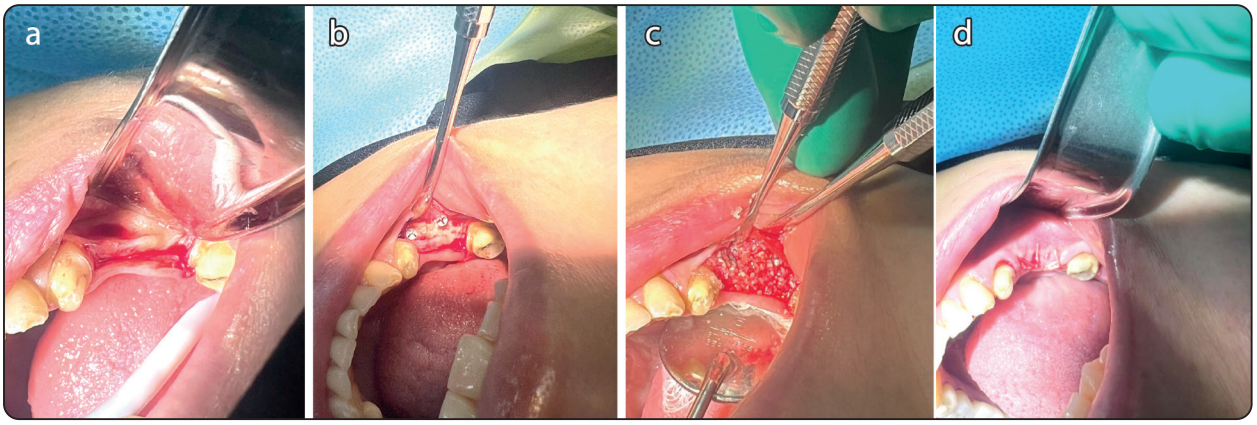

Fig. (2) : a) intraoperative picture of exposed alveolar ridge ready for augmentation, b): screws in place for tenting, c): bone graft placed according to which group (Group I xeno+allo graft , Group II xenograft only) d): suturing of flap back in place with vicryl 4-0

a.Br. Germany) and allogenic graft while the control group had received xenograft alone. The soft tissue flap was repositioned and sutured in place using vicryl 3-0 interrupted sutures. (Figures 2 a-d)

The patients were instructed to apply ice packs for the first 6 hours postoperatively. NSAIDS were prescribed 3 times daily for 4 days. Broad spectrum antibiotic was prescribed (3 times daily for 5 days). Oral hygiene measures and mouthwash were instructed and the patients were told to avoid negative pressure such as using a straw or nose blowing. The patients were recalled weekly then at 1,3, and 6 months postoperatively. Clinical assessment of the surgical sites was done to ensure absence of inflammation and infection. CBCTs and 4 months were made and the bone width was re measured at these time points for comparison (Figure 3).

Second stage surgery (after 6-9 months)

Second stage surgery was performed 6-9months after the 1st stage surgery. It involved removal of the tenting screw *(Tenting screw KLS Martin TENTING SCREW, MAXDRIVE, DF, 1.5x9MM, 4MM. KLS Martin Platz 1 · 78532 Tuttlingen)* and preparation of the osteotomy for implant placement *(Straumann® Bone Level Implantatlinie Institut Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland)* (figures 3-4).

- Core biopsy with 2.0 trephine bur was collected at each implant site and were subjected for histology and histomorphometrical analysis
- Implant osteotomy was drilled with implant consequential drills)
- A trephine bur was used to acquire a bone biopsy
- The implant was installed using ratchet wrench
- Cover screw was applied.
- Finally, the flap was returned into position and sutured using 3/0 vicryl suture.

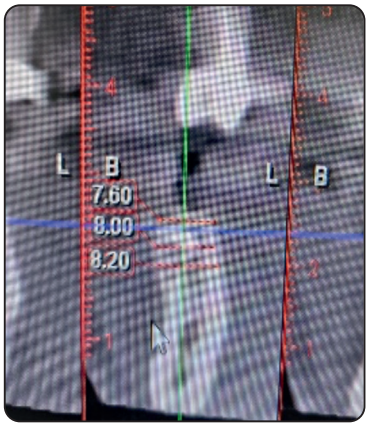

Fig. (3) Postoperative radiographic assessment showing the bone gain at both levels from the alveolar ridge crest

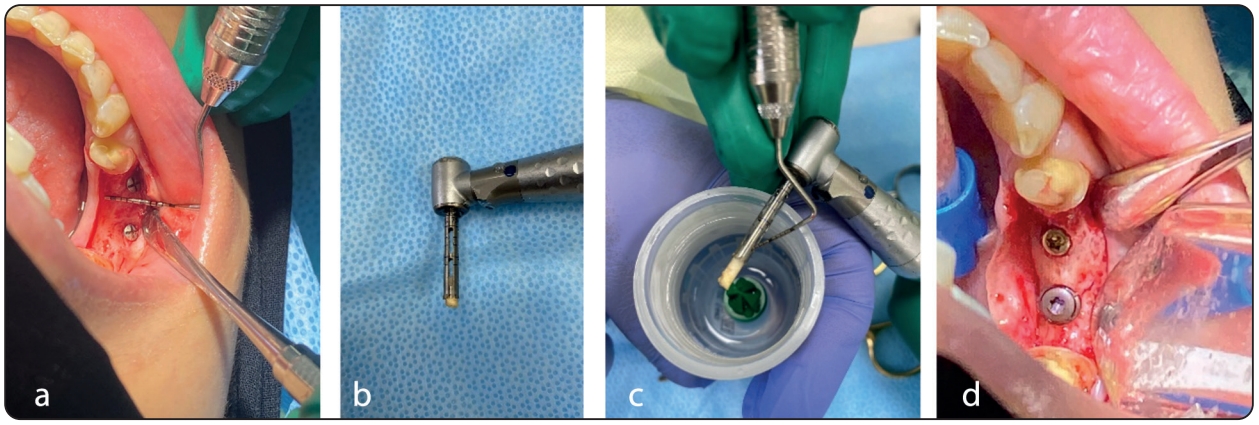

Fig. (4) a) Assessment of ridge width postoperatively, b): 2.0 trephine bur for core biopsy, c) The bone core prepared for histological assessment , d) Implants placed and cover screws secured in place.

Followup:

CBCT was repeated at 6 months to assess bone density and compare the data between the groups. On implant placement a core biopsy was made and sent for histopathologic assessment. These were also used for comparison of bone formation quality and quantity between the groups.

Statistical analysis: Statistical analysis was performed using SPSS (Statistical package for the social sciences) version 15, Echosoft corp., U.S.A. Data were represented as mean ± standard deviation. Paired sample student t-test was used to compare each pair of the studied variables within the studied group of patients. Independent sample t test was used to compare variables between the two studied groups. The test result was considered statistically significant if the P- value was equal or less than 0.05.

RESULTS

The mean patient age was 50.06 years (range 35 to 62 yrs). 7 patients required rehabilitation of a deficient mandible and 12 patients had required augmentation of the partially edentulous maxilla. Of the 19 patients, 8 patients had 2 or more missing teeth with moderate to severe horizontal defects of the maxillary alveolar ridge

Clinical findings:

One patient had partial wound dehiscence bilaterally. It was treated with conservative care with oral hygiene maintenance and oral rinse for 4-month healing period. Severe graft loss was noted on the retake of the patient. The patient required a second graft procedure using onlay autogenous bone graft and was excluded from the study results. In 2 patients, complete coverage of the screw head by bone was noted. All screws were removed, and ridge width was clinically evaluated to be larger than 6 mm at all sites of implant placement. A total of 30 implants was placed into the grafted ridges at locations predetermined by with a surgical stent Straumann implants (Straumann, Basel, Switzerland). Twenty implants were placed in the maxilla and 10 were placed in the mandible. Two stages surgical implant protocol was used to place all implants. Average Insertion torque of 40 N/cm was utilized for implants placement. All implants were allowed a waiting period of at least 3 months before the restoration phase. After 3 to 4 months of integration, all implants were noted to be clinically and radiographically integrated. Implants have been successfully restored in all patients. Follow-up examinations have indicated stable and healthy peri-implant tissue and bone levels. Bone cores were harvested from all patients for histologic

evaluations. In addition, 10 of the grafted specimens underwent histomorphometric analysis 5 of each belong to the first group and the others belongs to the second group.

Histological results

All cores showed good integrity with a good cancellous bone pattern and good connectivity of the trabeculae. The new bone formation had surrounded mineralized allograft formed bridges resulting in a good cancellous bone. However , the Bio-Oss particles was still non-resorbed in both groups.

The histology of the xenograft alone showed higher inflammation with more areas showing non viable bone (osteocytes absence in lacunae) together with more marrow inflammation with acute and chronic cells compared to the composite graft. High-power images showed excellent integration of new bone formation and particles of mineralized allograft. All grafted sites consisted of more viable bone. Histomorphometric analysis of the specimens revealed a mean bone content of 43% in the composite graft group whereas it was reduced significantly to 33% in xenograft group. Of this bone, the mean vital bone content was 81% in the composite graft group while it was 72% in xenograft group. (Figures 5-7)

Group 1 with 50 x magnification

Group 1 with 400 x magnification showing

Radiographic results:

The cross-sectional views showed horizontal bone gain buccal of implants in the range of 2.9–3.7 mm(figure 8). The histological evaluation confirmed new bone formation with osteoblastic rimming

Radiographic analysis was performed propeartively 6 months postoperatively after grafting and after implant placement using CBCT. The cross-sectional images were utilized to measure the bone width bucccolingually at 2 levels . level 1 where the measurement was carried out 1 mm below the crest of alveolar ridge and level 2 where measurement was carried out 5 mm below the crest of alveolar ridge

The alveolar ridge width at level 1 (1 mm below crest of the ridge) for group 1 before surgery ranged from 1.98 to 3.15 mm with mean 2.03±1.1 mm. The alveolar ridge width after 6 months ranged from 6.2 to 7.3 mm with mean 6.6±0.65 mm. The width gain ranged from 3.5 to 4.02 mm with mean 3.63±0.41 mm which was statistically significant (Table 1).

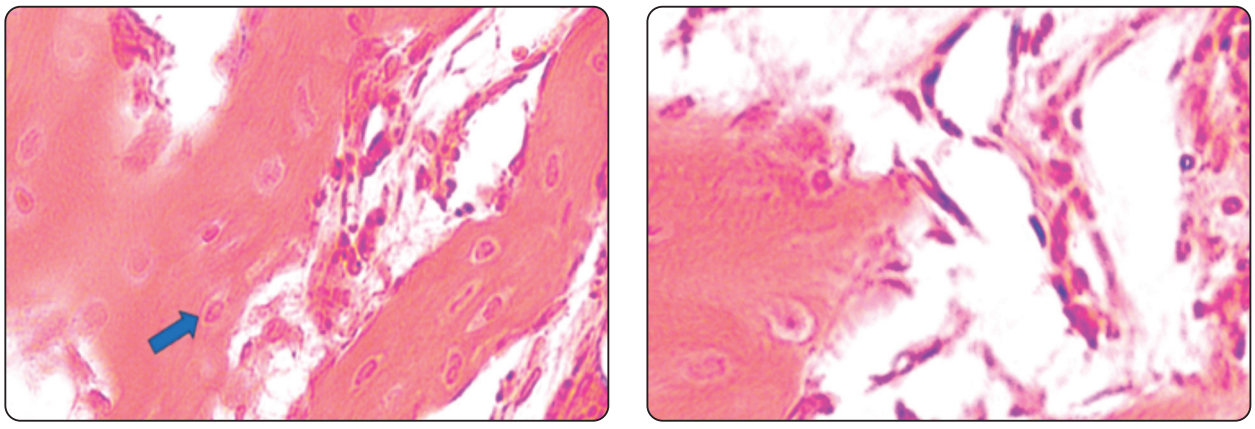

Fig. (5-6) Histological images of 50x magnification (left) and 400x magnification (right) showing osteocytes around areas of non-resorbed graft material and inflamed tissues contains blood vessels

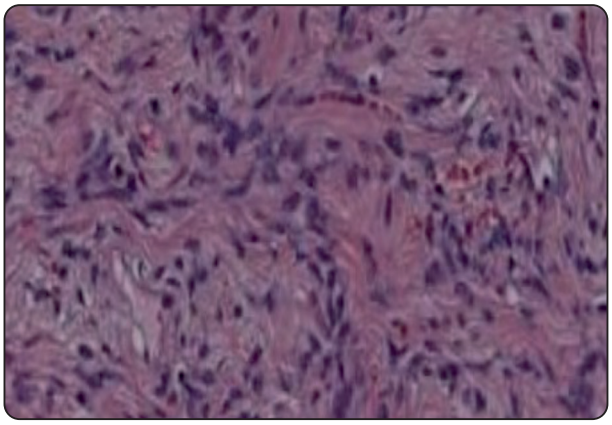

Fig. (7) Showing radiographic image of pre and postoperative CBCT cuts showing bone gain in a mandibular deficient ridge (left) and a maxillary case (right).

TABLE (1) The descriptive statistics of radiographic variables group 1 level 1

	Before surgery	After 6 months	Width gain	P value
Mean	2.03	6.6	3.63	0.0001
SD	1.1	0.65	0.41	
Max	3.15	7.3	4.02	
Min	1.98	6.2	3.5	

The alveolar ridge width at level 1 (1 mm below crest of the ridge) for group 2 before surgery ranged from 2.2 to 3.65 mm with mean 2.98±0.85 mm. The alveolar ridge width after 6 months ranged from 6.01 to 6.9 mm with mean 6.3±0.47 mm. The width gain ranged from 3.2 to 3.9 mm with mean 3.33±0.5 mm which was statistically significant. (Table 2).

TABLE (2) The descriptive statistics of radiographic variables group 2 level 1

	Before surgery	After 6 months	Width gain	P value
Mean	2.98	6.3	3.33	0.0001
SD	0.85	0.47	0.5	
Max	3.65	6.9	3.9	
Min	2.2	6.01	3.2	

The alveolar ridge width at level 2 (4mm below crest of the ridge) for group 1 before surgery ranged from 3.1 to 4.65 mm with mean 3.78±1.69 mm. The alveolar ridge width after 6 months ranged from 6.95 to 7.73 mm with mean 7.1±0.55 mm. The width gain ranged from 3.12 to 3.81 mm with mean 3.46±0.36 mm which was statistically significant (Table 3).

TABLE (3) The descriptive statistics of radiographic variables group 1 level 2

	Before surgery	After 6 months	Width gain	P value
Mean	3.78	7.1	3.46	0.0001
SD	1.69	0.55	0.36	
Max	4.65	7.73	3.81	
Min	3.1	6.95	3.12	

The alveolar ridge width at level 2 (4 mm below crest of the ridge) for group 2 before surgery ranged from 3.7 to 4.05 mm with mean 3.83±0.23 mm. The alveolar ridge width after 6 months ranged from 6.72 to 7.9 mm with mean 6.9±0.91 mm. The width gain ranged from 3.01 to 3.65 mm with mean 3.43±0.21 mm which was statistically significant (Table 4).

TABLE (4) The descriptive statistics of radiographic variables group 2 level 2

	Before surgery	After 6 months	Width gain	P value
Mean	3.83	6.9	3.43	0.0001
SD	0.23	0.91	0.21	
Max	4.05	7.9	3.65	
Min	3.7	6.72	3.01	

Comparison between alveolar bone gain at both levels between both groups showed statistical insignificant difference as shown in table 5

		Difference	t-test	P	
Level 1	Preoperative	0.95	2.00	0.06	No statistically significant difference
	6 months postop	-0.3	–1.16	0.09	No statistically significant difference
	Width gain	-0.3	–1.43	0.08	No statistically significant difference
Level 2	Preoperative	0.05	0.57	0.57	No statistically significant difference
	6 months postop	-0.2	–0.4	0.69	No statistically significant difference
	Width gain	-0.03	0.23	0.82	No statistically significant difference

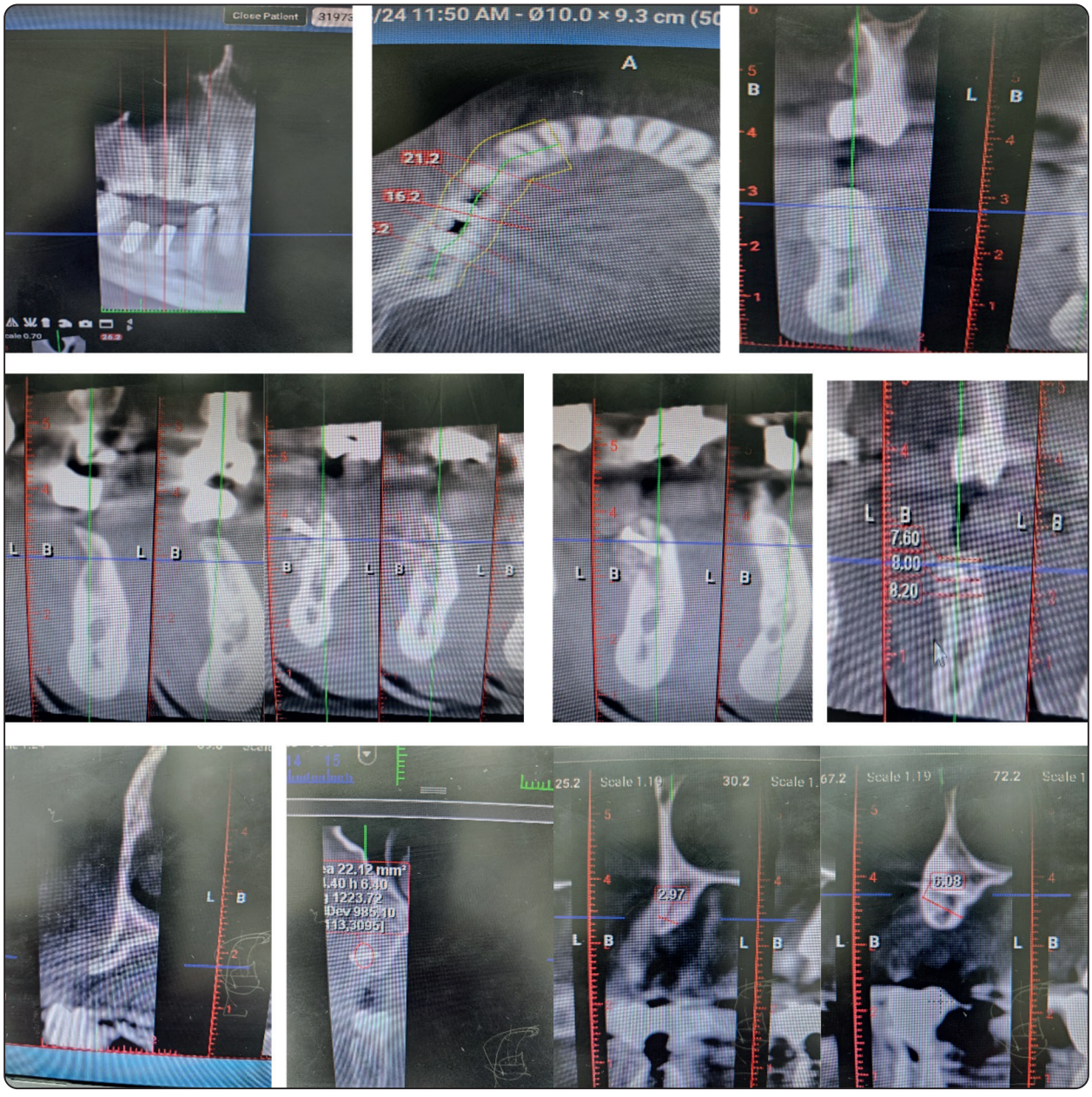

Fig. (8) Showing the radiographic images of pre and postoperative images of some of the cases included in the study

DISCUSSION

A total of 19 patients were treated in this study with a total of 30 implant sites. They were divided into 2 groups a study group and a control group (n=15); where the study group received 1:1 mixture of bovine derived xenograft and allogenic graft and the control group received xenograft alone. Both grafting procedures were accompanied by a tenting procedure using a titanium screw extending 3-5 mm beyond the alveolar ridge. A total of 30 implants were placed with 15 implants placed per group.

The tentpole technique is now a commonly used technique for deficient alveolar ridges. It is based on the idea of the extending crew acting as a space maintainer between the native bone and the soft tissue . the advantage of this technique is that it provides sufficient, stable bone gain. It has been widely reported for use in vertical and horizontal deficient ridges.

In our study we provide evidence of its use for horizontally deficient alveolar ridge . there is no consensus so far on the type of bone graft to be used with tentpoling for the best results.

We therefore compare the use of Xenograft vs Xenograft+Allograft to assess the bone gain with tentpoling the maxillary and mandibular horizontally deficient ridges. Results of our study show an average bone gain of 3.63mm on the study group vs 3.33mm for the control group. This was found to be statistically insignificant. These results are relatable from data from literatiuure which stated that tentpolong on its own allows for a bone gain of an average of 2.45mm midridge , while xenograft alone is reported to provide bone gain of an average of 4 mm. it would be expected that the combination would increase the total bone gain but logically the extending screw is the limit of the bone gain and the stability of the newly formed bone is very important.

With these results it can be concluded that the type of bone graft has minimal influence on the bone gain in the horizontal alveolar ridge augmentation. It is therefore recommended to use the cheaper, less complicated option. We might recommend the use of xenograft with tenting in both ridges generally to provide acceptable bone gain. Although more healing time is probably required due to less resorption rate in xenograft, composite graft with allograft added to xenograft might fasten the time of healing and allow early implant placement.

Tentepole technique for horizontal alveolar bone augmentations provide simple, reliable, less complicated and excellent prognosis for both maxillary and mandibular bony defects

Further research with more cases can allow further insights into the reasons for these results and assess the different bone grafts in different horizontal or vertical defective ridges.

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