

## “CUSTOMIZED TITANIUM MESH VERSUS TITANIUM REINFORCED MEMBRANE IN LOCALIZED ALVEOLAR RIDGE AUGMENTATION WITH SIMULTANEOUSLY DELAYED IMPLANT PLACEMENT” A RANDOMIZED CLINICAL STUDY

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### ABSTRACT

**Aim:** To compare two different alveolar ridge augmentation (ARA) approaches applied in conjunction with delayed dental implants regarding the enhancement of the buccolingual alveolar ridge width and the changes in alveolar crestal level radiographically.

**Materials and Methods:** 20 patients participated in this study; two groups received particulate bone graft simultaneously with delayed implant placement. Ten patients had received Customized titanium mesh (CTi) and ten patients had received titanium (Ti) reinforced membrane.

**Results:** Regarding the buccolingual ridge width by CBCT. Comparing the value of pre-post percent change between groups, revealed no statistically significant difference. In both groups, comparing pre and post value of buccolingual ridge width revealed a statistically significant increase. Regarding changes in alveolar crestal level by digital periapical radiography. In both groups, comparing pre and post value of alveolar crestal bone revealed no statistically significant difference.

**Conclusion:** Customized titanium mesh can be used successfully for ARA performed simultaneous with delayed implant placement as it enhances buccolingual alveolar ridge width and prevent alveolar crestal resorption.

**KEYWORDS:** Customized titanium mesh, Delayed implant, Guided bone regeneration, Ridge defect, Ti-reinforced membrane

### INTRODUCTION

Successful implant therapy relies on a proper bone volume at the insertion site. (*Chipasco et al., 2006*). The presence of a bone width of at least

1–1.5 mm on both the buccal and lingual / palatal sides of the implant is required to achieve sufficient osseointegration and a successful treatment outcome (*Scipioni et al., 1994; Nedir et al., 2004; Suh et.*

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*al., 2005; Baffone et al., 2013; Bengazi et al., 2014*). After removal of the tooth, the alveolar ridge undergoes significant remodeling cycle. It was defined in a systematic analysis that the mean width reduction of the alveolar ridge is 3.8 mm during the six months after tooth extraction, and the mean height reduction is 1.2 mm (*Tan & Wong, 2012*).

Bone augmentations may take place simultaneously with (combined approach) or before (staged approach) placement of implants. The combined approach is favored if allowed by the clinical situation, since this strategy results in reduced morbidity, time and cost of treatment for the patient (*Benic & Hammerle, 2014*).

Guided bone regeneration (GBR) is based on guided tissue regeneration principles (GTR) (*Nyman et al., 1980*). GBR involves placing an occlusal barrier in such a way as to prevent the invasion of non-bone-forming cells from the surrounding soft tissues into the defect and at the same time allow time and space to repopulate the defect by the bone forming cells (*Dahlin et al., 1990, 1998; Donos et al., 2004*).

By using non-resorbable membranes (polytetrafluoroethylene ; PTFE), the fill of defects was greater than the resorbable membranes, taking into account the following characteristics of PTFE membranes: better space provision effect, regulated barrier function time and absence of inflammatory resorption that negatively affects tissue regeneration (*Hammerle & Jung, 2003*).

Titanium mesh (Ti-mesh) is another non-resorbable material valid for alveolar bone repair. In **1969, Boyne et al.** inaugurated a titanium mesh to restore large osseous discontinuity defects. Titanium micromesh protect and preserve densely packed bone graft in the defects. It is the most resilient structurally in the membrane armamentarium, which ensured its function in protecting the graft, maintaining space until its removal, in addition to supporting the angiogenesis and cell ingrowth (

**Lim et al., 2015**). **Raquel et al., 2016**, found that horizontal ridge augmentation with titanium meshes performed simultaneously with dental implants was promising.

Owing to its high strength and rigidity, low density and corresponding low weight, its ability to withstand high temperatures and its corrosion resistance, titanium has been commonly used in various surgical applications (*Degidi et al., 2003*). Another common characteristic of the commercially available Ti-mesh membranes is their (millimeter range) macroporosity. This is believed to play a critical role in sustaining blood flow, and is believed to promote healing by enhancing wound stability through tissue integration and allowing extracellular nutrients to disperse through the mesh (*Weng et al., 2000*). In a systematic review by **Briguglio et al., 2019**, the use of particulate bone grafts with titanium mesh represented a successful method for the reconstruction of atrophic sites.

Ti-mesh provides an excellent approach for bone regeneration over other forms of membranes. However, the application of traditional Ti-mesh to a defect involves several steps: bending, trimming, and fixation. These processes are technically complex, time-consuming and have a strong impact on the regenerative outcomes (*Rakhmatia et al., 2013*). The present study applied a newly developed form of Ti-mesh; this customized Ti-mesh (CTi-mesh) is ready for different types of defects and has stabilizing components that allow them to be easily fixed to the fixture of the implants. It was anticipated that Ti-meshes could be easier to control with this new design and thus minimize possible technical errors. CTi mesh approach postoperative follow-up showed that when it was used in simultaneous implant and grafting, the implant was stable with excellent osseointegration and the bone resorption at the surgical area was reconstructed (**Jegham et al., 2017**).

Hence, the purpose of this study was to determine the effect of a newly designed, self-stabilizing Ti-mesh on buccal bone regeneration around the dental

implant compared to non resorbable Ti-reinforced dense-PTFE membrane

## AIM OF THE STUDY

### Primary objective:

To compare two different approaches applied in conjunction with delayed dental implants regarding the enhancement of the buccolingual alveolar ridge width using cone beam computed tomography (CBCT).

1st approach: is the placement of customized titanium mesh (CTi- mesh )

2nd approach: is the placement of Ti-reinforced dense-PTFE membrane

### Secondary objective:

To compare the formerly described approaches regarding the changes in alveolar crestal level (ACL) by digital periapical radiography (parallel technique).

## SUBJECTS AND METHODS

### Patient selection

Twenty patients were selected from the outpatient clinic in faculty of dentistry Ain shams university at the department of oral diagnosis, oral medicine and periodontology. The research ethics committee of Ain shams university faculty of dentistry had reviewed and accepted the proposal of the study. All patients received detailed written information about the study nature and treatment protocol then signed an informed consent form.

### Inclusion criteria

- Medically free according to Burkett’s health medical history questionnaire (*Glick et al., 2008*).

- Single missing maxillary anterior tooth or premolar with history of extraction not less than 6 months.
- The buccolingual dimensions of the alveolar ridge allowed implant insertion but with slight bony dehiscence exposing the crestal 2-3 threads of the implant fixture which necessitated simultaneous bone augmentation at the same time of the implant insertion (Class 2 or 3 *Benic & Hammerle, 2014*).
- The radiographic buccolingual width of the coronal third of the alveolar ridge ranges from 4 to 5 mm and it was measured at 2 points 3mm and 5mm apical to the alveolar crest then the mean was calculated while the radiographic buccolingual width of the apical third ranged from 9 to 13mm and this was measured at point 8 mm and 10 mm apical to the alveolar crest then the mean was calculated.
- Dimensions mesiodistally shouldn’t be less than the mesiodistal width of the missed tooth crown.
- Males or females from 20 to 40 years.
- Patients were not receiving any systemic drugs at the time of the examination and for at least four weeks prior to the study.
- Patients did not receive any drugs during the follow up period.

### Exclusion criteria:

Smokers; residual infections in the edentulous area or apparent infection in a neighboring tooth; poor oral hygiene; cases that need staged augmentation approach (Class 4 and 5 *Benic & Hammerle, 2014*).

### Patient grouping

The twenty patients were divided into two groups: Ten patients, (Group 1, Test group) ARA was performed using customized titanium mesh\*.

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\* Cti mesh neobiotech

Ten patients, (Group 2, Control group) ARA was performed using non resorbable titanium reinforced membrane\*.

### Pre surgical preparation:

Preoperative analysis included complete patient history, clinical examination, clinical photographs Fig (1).

Preoperative radiographic examination was done to the edentulous area using cone beam computed tomography (CBCT). One week before the implant placement, professional debridement and oral hygiene instructions were given to the patients.

Clinical re-evaluation of the case was done before starting the surgical procedures and any case that didn't follow the instructions was excluded.

### Surgical procedures

Two surgeries were carried out for each patient; the bone augmentation and the implant placement were held in the same visit, and the second surgery was to remove the membrane or mesh after 4 months. After administration of local anesthesia, para-crestal horizontal incision technique using surgical blade number 15, was applied placing the line of incision

toward the palatal aspect of the edentulous ridge in the maxilla. Sulcular incision was done buccal and palatal around the teeth mesial and distal to the edentulous area. Vertical releasing incisions mesial and distal extending beyond mucogingival junction were then performed followed by, full thickness flap elevation (Fig 2).

Initial drilling (800-1000 Rpm,30 N) was done using a pilot drill supplied in the implant surgical kit. After checking the position and the direction of the drill, sequential drilling was continued until reaching the final drill equivalent to the desired implant size. The implant\*\* was installed till the implant platform was 2\_3mm apical to the cementoenamel junction of neighboring teeth. A cover screw was secured over the implant after placement. The expected class 2 or 3 dehiscence defect was obtained (*Benic & Hammerle, 2014*) Fig (3).

Graft material (particulate bone xenograft) Hypro-oss\*\*\* in both groups was placed at the defect site Fig (4).

For the test group: after particulate graft placement, CTi mesh was placed and fixed with the cover screw, no need for additional screw, only adapt & burnish the margins Fig (5).



Fig. (1) Pre-operative clinical photo.



Fig. (2) Full thickness flap elevation.

\* Ti 250 Osteogenicsbiomedical inc.USA

\*\* Neo Biotech dental implant (IS-II active Fixture).

\*\*\* Hypro-Oss Granules (500-1000 Lm). Bioimplon GmbH, Friedrichliststr,27, 35398 Giessen, German.



For the control group: Ti. reinforced membrane was adapted over the grafted site. Then membrane tacks were used to assist the membrane stability one tack palatally and two tacks on mesial and distal of the buccal side of the membrane Fig (6).

Periosteal releasing incisions were performed, to aid in primary tension-free closure using interrupted 4-0 polypropylene suture.



Fig. (3) Dehiscence defect



Fig. (4) Xenograft bone covering the dehiscence.

**Post-operative care**

Post-operative medications were prescribed to all patients, including amoxicillin and clavulanic acid (*Hibiotec , Amoun, Egypt*) (1 g every 12 hours for 5 days) , non-steroidal anti-inflammatory drug (ibuprofen 600 mg for a maximum of twice a day (*Brufen, Kahira, Egypt*) and chlorhexidine mouth



Fig. (5) CTi mesh covering the defect.



Fig. (6) Ti-reinforced membrane covering the defect.



Fig. (7) after prosthesis delivery

rinse (*Hexitol, ADCO, Egypt*) 0.12% (twice a day). The patient is placed on warm saline rinses starting at the second day for the first 2-3 weeks to encourage normal flap healing without disturbing migrating cells (*Huynh et al., 2016*).

Oral hygiene measures were given to the patients and they were instructed to refrain from removing

plaque by mechanical means at the surgical sites for 2 weeks and shouldn't use any removable partial denture during the first 4 months.

Sutures were removed 2 weeks postoperatively (Rojo et al., 2016). After 4 months, professional debridement was done then after one week, crestal incision was made after anaesthetizing the area with infiltration and removal of mesh or membrane was performed. Healing abutment was placed for two weeks. Then the prosthetic procedures started 2 weeks after healing abutment.

### Radiographical Assessment

#### A) Radiographic evaluation of buccolingual alveolar ridge width changes:

Image reconstruction was performed using i-CAT software. Baseline CBCT was performed 1 week before the surgery. The second CBCT was performed four months after augmentation during prosthetic steps. (Gluckman & Du Toit, 2014). On the same CBCT, 3 sagittal views were used for evaluation and at each sagittal view 2 buccolingual measures were taken.

#### B) Radiographic evaluation of alveolar crest level changes:

This was performed using digital periapical radiograph using long-cone paralleling technique. Baseline measure: Day zero, immediately after implant insertion;  $ACL_1$ . Follow up measure: Month 4, 1 week before removal of mesh/ membrane and placement of healing abutment;  $ACL_2$ .

ACL represent the distance from the apex of the implant (fixed reference point) to the first implant-shoulder to bone contact. To determine ACL changes by time, ACLs were measured mesially and distally to each implant and the mean of both represent  $ACL_1$  at zero day and  $ACL_2$  at 4 months.

### Statistical Analysis

Values were presented as mean and standard

deviation (SD), median, min. max and confidence intervals. Data were explored for normality using Kolmogorov-Smirnov test of normality. The results of Kolmogorov-Smirnov test indicated that most of data of CBCT were normally distributed (parametric data), while digital paralleling data were non-parametric.

For CBCT, Unpaired t test was used for intergroup comparisons, while paired t test was used for intragroup comparisons.

Mann Whitney U test was used for intergroup comparison regarding paralleling results and percent change of CBCT and paralleling, while Wilcoxon signed rank was used for intragroup comparison of paralleling results

## RESULTS

### 1- Alveolar ridge buccolingual width changes by CBCT:

#### a-Comparison between groups

- *Pre-treatment*, Independent t test revealed no significant difference between groups ( $p=0.318$ ) (Table 1).
- *Post treatment*, Independent t test revealed no significant difference between groups ( $p=0.394$ ) (Table 1).

A greater percent increase was recorded in Ti reinforced group. Mann Whitney U test revealed no significant difference between groups ( $p=0.354$ ) (Table 1).

- *b. Comparison between the radiographical buccolingual width within the same group:*
- **In CTI group**, comparing pre and post value of buccolingual width using paired t test revealed a significant increase ( $2.56\pm 0.86$ ), ( $P=0.00$ ) (Table 2).
- **In Ti reinforced group**, comparing pre and post value of buccolingual width using paired t

test revealed a significant increase (2.65±0.95), (P=0.00) (Table 2).

**2- Changes in alveolar crestal level by digital periapical radiograph:**

*a) Comparison between groups:*

- *Pre-treatment*, a higher median value was recorded in Ti reinforced group. Mann Whitney U test revealed no significant difference between groups (p=0.444) (Table 3).
- *Post treatment*, a higher median value was recorded in Ti reinforced group. Whitney U test revealed no significant difference between groups (p=0.630) (Table 3).

A greater median value of percent decrease was

recorded in Ti reinforced group. Mann Whitney U test revealed no significant difference between groups (p=0.963) (Table 3).

*b) Comparison of alveolar crestal level by digital periapical radiography within the same group:*

- **In CTi group**, comparing pre and post value of alveolar crestal bone level using Wilcoxon signed Rank test revealed the same median value, with no significant difference, (P=0.075) (Table 4).
- **In Ti reinforced group**, comparing pre and post value of alveolar crestal bone level using Wilcoxon signed Rank test revealed a decrease in the median value after treatment, with no significant difference, (P=0.310) (Table 4).

TABLE (1) Descriptive statistics and comparison of values of changes in radiographical buccolingual width by CBCT pre –post, difference and percent change after treatment in both groups.

Groups		Buccolingual width pre	Buccolingual width post	Difference Between pre-post	Percent change
CTi group	Mean	4.87	7.42	2.56	55.37
	Std. Error of Mean	.31	.27	.29	7.21
	Median	4.80	7.60	2.80	65.22
	Std. Deviation	.92	.80	.86	21.64
	95 % CI	4.16-5.57	6.81-8.04	1.89-3.22	38.74-72.01
	Minimum	3.50	6.30	1.00	14.29
	Maximum	7.00	8.50	3.50	80.00
Ti reinforced group	Mean	4.44	7.09	2.65	63.15
	Std. Error of Mean	.27	.27	.32	9.39
	Median	4.30	7.10	3.00	73.81
	Std. Deviation	.82	.81	.95	28.16
	95 % CI	3.81-5.07	6.47-7.71	1.91-3.38	41.51-84.80
	Minimum	3.50	5.50	1.20	23.15
	Maximum	6.09	8.40	2.56	55.37
Comparison between groups	t	1.03	0.88	0.21	---
	P	0.318ns	0.394ns	0.836ns	0.354ns

*Significance level p≤0.05, ns=non-significant*

*95% CI=95% confidence interval*

*Independent t test was used to compare buccolingual width values between groups.*

*Mann-Whitney U test was used to compare difference and percent change after treatment between groups.*

TABLE (2) Comparison of values of buccolingual width pre –post within the same group (paired t test).

Groups		Paired Differences					t	P
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference			
					Lower	Upper		
CTI Group	pre - post	2.56	.86	.29	1.89	3.22	8.91	.00*
Ti reinforced Group	pre -post	2.65	.95	.32	1.91	3.38	8.32	.00*

Significance level  $p \leq 0.05$ , \*significant

TABLE (3) Descriptive statistics and comparison of values of alveolar crestal level (ACL) pre –post and difference after treatment in both groups (Mann whitney U test).

Groups		ACL pre	ACL post	Difference Between pre-post	Percent change
CTI group	Mean	12.00	11.49	-.51	-4.33
	Std. Error of Mean	.25	.36	.23	1.94
	Median	11.50	11.50	-.36	-3.13
	Std. Deviation	.75	1.09	.68	5.82
	95 % CI	11.42-12.58	10.65-12.32	-1.04-.01	-8.80-.14
	Minimum	11.50	10.12	-1.38	-12.00
	Maximum	13.00	13.00	.48	4.17
Ti reinforced group	Mean	12.15	11.67	-.48	-3.67
	Std. Error of Mean	.29	.40	.44	3.56
	Median	12.07	11.87	-.45	-3.52
	Std. Deviation	.83	1.13	1.26	10.07
	95 % CI	11.46-12.85	10.73-12.62	-1.53-.57	-12.09-4.75
	Minimum	10.68	10.33	-2.41	-18.54
	Maximum	13.00	13.77	1.63	13.43
Comparison between groups	P	.444ns	.630ns	.961ns	.963ns

Significance level  $p \leq 0.05$ , ns=non-significant

95% CI=95% confidence interval

TABLE (4) Comparison of values of alveolar crestal level (pre –post) within the same group (Wilcoxon signed Rank test).

Groups	ACL	Paired Differences					P
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
					Lower	Upper	
CTI group	pre - post	.51	.68	.23	-.01	1.04	0.075ns
Ti reinforced group	pre -post	.48	1.26	.44	-.57	1.53	0.310ns

Significance level  $p \leq 0.05$ , ns=non-significant



## DISCUSSION

The GBR therapeutic technique requires the surgical positioning of a cell occlusive membrane facing the bone surface (*Dahlin et al., 1988*). The membrane provides an area for the osteoprogenitor cells (*Linde et al., 1993; Karring et al., 1993*).

This study included 20 patients who were allocated into two different groups. Sample size determination based on a 0.05 power 0.8. The power of this study =80% - confidence = 95%. Accepted error = 5%.

The age group was between 20-40 years while older patients were excluded as the aging process involves changes in a person 's physiological, pathological, social, and psychological conditions (*Rowe & Kahn, 1987*).

To prevent any adverse effects of smoking on the final outcome, all patients in our study were non-smokers, the evidence showed that smokers are at higher risk of implant failure, peri-implantitis (*Cochran et al., 2009; Lin et al., 2014*). All patients were systemically free and received no systemic antibiotics or corticosteroids to avoid any effects on bone metabolism and periodontal status, and to standardize the capacity for healing (*Glick et al., 2018*).

The buccolingual dimensions of the alveolar ridge which had been chosen in this study allowed implant insertion but with slight bony dehiscence exposing the buccal crestal 2-3 threads of the implant fixture which necessitated simultaneous bone augmentation at the same time of the implant insertion (Class 2 or 3 *Benic & Hammerle, 2014*).

In this study, dental implants were limited to maxillary anterior and premolar areas owing to better visibility than the lower jaw (*Adell, 1974; Breine and Branemark, 1980; Adell et al., 1981*).

Regarding the timing of GBR, in our research a single-stage protocol was followed and the

reconstructive GBR procedure was performed simultaneously with the implantation to reduce total treatment time and overall invasiveness of the surgical procedure (*Hellem et al., 2003*). This was made possible by the fact that the horizontal bone defect was mild (Class 2 or 3 *Benic & Hammerle, 2014*), the edentulism was restricted to a single tooth of the maxilla, and the amount of graft necessary to fill the defect was limited, due to the volume taken up by the implant itself.

Of the more widely known materials, the high density polytetrafluoroethylene (d-PTFE) selected in our study provides separation between the soft tissue and the grafted bone, helps to seal the wound if the primary union is not achieved and stabilize the graft to support new vessels' growth (*Strietzel et al., 2006; Hoffmann et al., 2008*).

Titanium-reinforced d-PTFE membranes have been used for structural durability preserving the required space and promoting the stability of the graft. (*Cytoplast barrier membranes. Osteogenics; updated 2014*). For tenting and space maintenance this membrane can be moulded and shaped.

In this study customized titanium mesh (CTi) were used (test group) secured in place by the implant fixture component itself (cover screw). Studies found that titanium mesh protects and retains closely packed bone graft and found no invasion or displacement of the graft by the soft tissues that surround the titanium mesh. In addition to supporting angiogenesis and cell development, it is the most structurally resilient in the membrane armamentarium which ensured its role in protecting the graft, maintaining space until removal (*Von Arx and Kurt, 1998; Her et al., 2012; Lim et al., 2015*).

Another common feature of CTi mesh is its macro-porosity, in the millimeter range (around 1 mm) (*Lim et al., 2015*). *Chvapil et al., (1969)*, suggested that pores require more than 100 µm for the rapid penetration of highly vascular connective tissue and that smaller pores appear to fill with more

avascular tissue. Other studies have shown that macropores play a critical role in maintaining blood supply and in allowing extracellular nutrients to spread across the mesh (*Weng, et al., 2000*).

The present study showed non-significant differences in all of the radiographical parameters between groups at baseline, this is of importance as it indicates that there was no difference in selection and exclusion criteria at the beginning of the study between both groups, a finding that ensured comparable treatment outcomes during the follow up periods.

Intra group statistical analysis demonstrated that from baseline to four months, the two treatment modalities revealed statistically significant increase in alveolar ridge buccolingual width. Regarding group one of CTi mesh; this was in accordance to systematic review by *Briguglio et al., 2019*, which showed that the regenerative procedures performed through the use of particulate grafts associated with a titanium mesh represented a predictable method for the rehabilitation of atrophic sites.

Regarding the intra group statistical analysis of group 2 Ti-reinforced membrane; this was in accordance to *Urban et al., 2014*, using titanium reinforced d-PTFE in ridge augmentation, which discover that all treated defect sites exhibit excellent bone formation and none of the cases demonstrated bone resorption throughout the follow up period.

Intra group statistical analysis regarding the alveolar crestal level (ACL) revealed no statistically significant change in the ACL in both treatment modalities. Regarding CTi mesh group; this was in accordance to previous literature, *Bartolomeo et al., 2001*, which found no unwanted effects on crestal bone levels using titanium micromesh used simultaneous with implant placement.

Regarding Ti-reinforced membrane group; this was in accordance to previous study where follow-up radiographs taken up to 24 months after GBR

using Ti-reinforced d-PTFE simultaneous with implant placement showed complete maintenance of the peri-implant bone crestal levels without any sign of bone resorption. The grafted site was perfectly able to support the functional loading of the implant (*Cucchi and Ghensi, 2014*).

Inter group comparison of percent change of radiographical alveolar ridge buccolingual width between the two groups revealed the mean of the CTi group was +55.37% and the Ti-reinforced group was +63.15 % which by statistical analysis showed no statistically significance difference; these results were confirmed by the systematic review performed by *Milinkovic & Cordaro in 2014*.

Inter group percent change of ACL between the two groups revealed the median value of the CTi group was -3.13 and the Ti-reinforced membrane was -3.52 which by statistical analysis showed no difference.

Finally, there is no statistically significant difference between the two groups radiographically both in the alveolar bone buccolingual width changes and alveolar crestal level changes. But as our study were investigating volumetric dimensional changes rather than quality of the new formed bone, the quality of regenerated bone between groups may differ taking in consideration the pseudo-periosteum found in the Ti-reinforced membrane group after membrane removal and not found in the mesh group. Unfortunately, we didn't analyze bone quality which is recommended to be carried in further studies.

## CONCLUSION

Customized titanium mesh can be used successfully for alveolar ridge augmentation performed simultaneous with delayed implant placement as it:

1. Enhance buccolingual ridge width of the alveolar ridge.
2. Prevent alveolar crestal resorption.

3. Could provide superior defect stability evidenced by the absence of the ti-mesh associated pseudo-periosteum.

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