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ORIGINAL RESEARCH

COMPARATIVE EVALUATION OF CUSTOMIZED 3D TITANIUM MESH VERSUS TITANIUM-REINFORCED DENSE POLYTETRAFLUOROETHYLENE(D-PTFE) MEMBRANE IN HORIZONTAL RIDGE AUGMENTATION USING CBCT– A PILOT STUDY

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ABSTRACT

Aim: The study aims to evaluate and compare bone width gain in horizontal ridge augmentation, using customized 3D titanium mesh and titanium-reinforced dense polytetrafluoroethylene membrane(d-PTFE)

Material and methods: Six patients in total were recruited, three patients allocated to Group A (augmented with d-PTFE), and three to Group B (with customized 3D titanium mesh). After 6 months; bone width gain, membrane exposure rates, surgical time, and soft tissue assessment by patient questionnaire were measured.

Result: Significantly higher bone width gain was noted in Group B . Surgical time was higher in Group A. Both groups indicated predictable, acceptable healing outcomes and biocompatibility of the materials used.

Conclusion: Both groups demonstrated satisfactory outcomes but a greater horizontal bone width gain was observed in Group B. Membrane exposure occurred in one patient from Group A during early healing; none noted in Group B. Surgical time was shorter in Group B, indicating efficiency and satisfactory healing. Patient-reported outcomes were favorable, with five out of six patients reporting satisfactory healing. Within the limitations of the study, both materials may be considered as promising options for ridge augmentation. Further studies with bigger sample sizes, arch-specific analysis, and long-term follow-up are required to substantiate these findings.

***Keywords*:** alveolar ridge augmentation, cone-beam computed tomography guided bone regeneration, 3D-printed membrane, titanium mesh, polytetrafluoroethylene.

1 INTRODUCTION

Alveolar bone is a vital tissue that not only anchors the teeth but also provides structural stability for mastication and other oral functions[1]. So, tooth loss results in alveolar bone or ridge resorption either in a buccolingual or apicocoronal direction, and sometimes in a combination of both. This resorption results in loss of over 40% of the height and 60% of the thickness of the alveolar process

majorly within the the first six months of tooth loss [2,3]. Guided Bone Regeneration (GBR) is considered as gold standard[4] in cases of severe bone loss, providing sufficient bone regeneration and implant stability [5]. With the use of barrier membranes and the "cell exclusion" principle, GBR stops soft tissue cells outside the defect, allowing only selective osteoprogenitor cells to proliferate [6,7]. When the alveolar process dimensions are insufficient, dental implant placement may be compromised, hence, horizontal alveolar ridge augmentation is usually required [8-10] to make more bone available. Numerous techniques have been used to achieve consistent horizontal bone growth [11-13] such as the split-crest technique, autologous onlay bone block grafts[14], titanium mesh[15], distraction osteogenesis[16], and several non-resorbable membranes like polytetrafluoroethylene(PTFE).

When comparing with resorbable membranes, non-resorbable membranes have better space-maintenance qualities [17] since they are more rigid and stable, thereby having a slightly more predictable bone formation owing to the longer duration for which the membranes last [18]. The only disadvantage of using a non-resorbable membrane are the chances of exposure from the soft tissue[19]which a thick phenotype may tolerate but a thin phenotype might not. In such cases, resorbable membranes or soft tissue substitutes may be a better alternative. Secondly, the need for a second surgery to remove the said membrane from the site may cause more patient discomfort post procedure. The study aims to evaluate and compare bone width gain after horizontal ridge augmentation, using customized 3D titanium mesh and titanium-reinforced dense polytetrafluoroethylene(d-PTFE) membrane.

2.MATERIALS AND METHODS:

2.1 Study Design and Population

This study was an observational study conducted on patients from the Outpatient Department of Periodontology and Oral Implantology, Sree Balaji Dental College and Hospital, Chennai, India. It was performed after obtaining ethical clearance from the Institution's Ethical Committee with number SBDCH-IEC-CT-/30-08/24-4

Patients included were healthy individuals aged 38 to 60 years, specifically with an adequate keratinized tissue >2mm and inadequate ridge width up to 4-5mm in the anterior region of the jaw, requiring alveolar ridge augmentation for dental implant placement. Patients with any adverse smoking, drug or alcohol use habits, active infection or severe inflammation in the intervention zone, pregnant and lactating mothers, or any other systemic disease or hypersensitivities were excluded.

6 subjects were randomly allocated in a 1:1 ratio, by a coin-toss method, according to the inclusion and exclusion criteria. After the nature of study was explained to all subjects, and informed consent obtained, the six patients were divided into two groups; Group A: inadequate ridge of 4-5 mm, treated with titanium reinforced d-PTFE (Cytoplast Ti-150) and Group B: inadequate ridge of 4-5mm, treated with 3D titanium mesh.

After 6 months, secondary surgical interventions followed by CBCT analysis were done to evaluate the gain in ridge width, membrane exposure, and surgical time. The parameters have been measured both at baseline and after 6-month period.

2.2 Sample size estimation

A standard formula for comparing two means was employed [20]: $n = \frac{(\sigma_1^2 + \sigma_2^2)}{(Z_{1-\alpha/2} + Z_{1-\beta})^2} \times \frac{1}{\Delta^2}$

where σ12σ_1^2 and σ22σ_2^2 are the variances of the two groups, Z1−α/2=1.96Z{1 -α/2} = 1.96 corresponds to a 95% confidence interval (α = 0.05), Z1−β=0.84Z{1 -β} = 0.84 corresponds to a power of 80%, and Δ is the clinically significant effect size, estimated at 0. 48. Based on these parameters, the total estimated sample size was 6 patients.

2.3 Pre-operative measurements:

In cone beam computed tomography (CBCT) images, bone density and ridge width were assessed at 0, 2, 4, and 6mm from the crest, drawn parallel to the alveolar bone. A perpendicular line that intersects gives the width of the alveolar bone (Figure 1 a-d, 2 a-d).

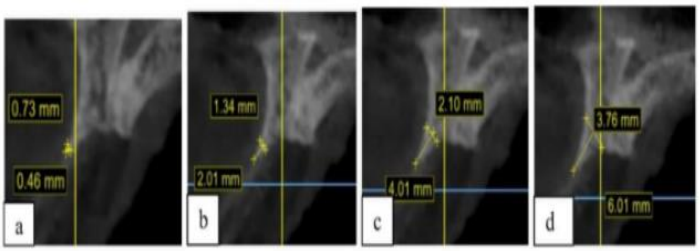

Figure1. Measurements of pre-op CBCT in group A measured at 0mm, 2mm, 4mm, 6mm from the crest a) pre-op measurement at the level of 0.46mm from the crest 0.73mm width is present, b) pre-op measurement at the level of 2.0mm from the crest 1.34mm width is present, c) pre-op measurement at the level of 4.0mm from the crest 2.10mm of width, d) pre-op measurement at the level 0f 6.0mm from the crest gives 3.76mm of width.

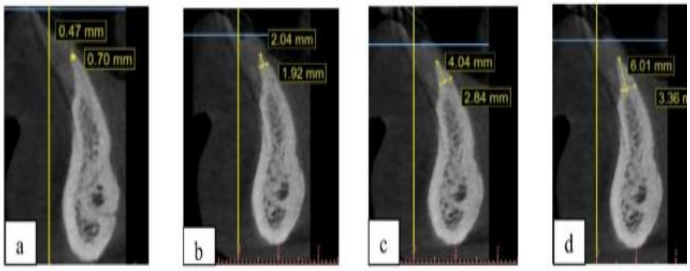

Figure 2. Measurements of pre-op CBCT in group B measured 0mm, 2mm, 4mm, 6mm from the crest a) at the level of 0.47mm from the crest 0.70mm width is present, b) at the level of 2.0mm from the crest 1.92mm width is present, c) at the level of 4.0mm from the crest 2.84mm of width, d) at the level of 6.0 mm from the crest gives 3.36mm of width.

2.4 Surgical procedure:

After informed consent was obtained, before the surgical procedure, patients underwent scaling and root planning, and preoperative antibiotics were administered to minimize the risk of infection. Patients were asked to rinse with 0.12%– 0.2% chlorhexidine (CHX) gluconate mouthwash twice daily for two weeks before and after the procedure to reduce bacterial load and enhance soft tissue healing.

Patients were well prepared for the surgical procedure, and local anesthesia was injected, followed by a mid-crestal incision. Two vertical releasing incisions made at the mesial and distal ends and reflected beyond the defect to provide adequate access for graft placement. For additional mobility along the alveolar ridge, slightly on the palatal/lingual side to preserve the vestibular soft tissue for tension-free closure, periosteal releasing incisions were made on the inner surface of the flap.

GROUP A: Augmentation with Ti-reinforced D-PTFE- After placing the bone graft over the defect, d-PTFE membrane was placed and stabilized using screws. The flap is carefully approximated to avoid gaps or exposure of the bone graft/membrane and sutured (Vicryl 5-0). (Figure 3)

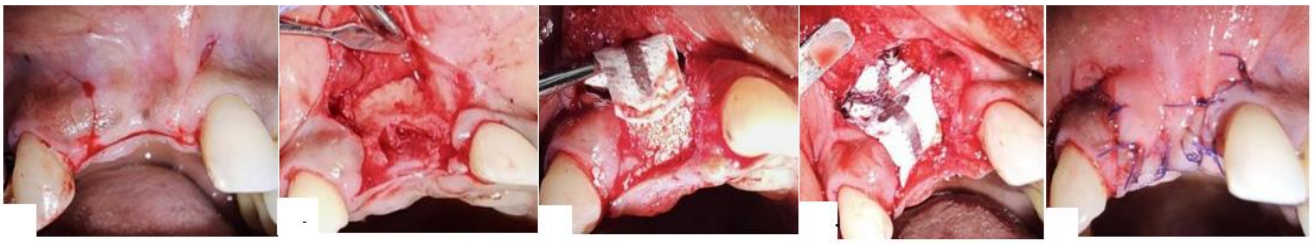

Figure 3. Group A- Surgical procedure a) Midcrestal incision followed by 2 vertical incisions, b) Full thickness flap raised with bony defect, c) Followed by debridement, graft placed, d) Cytoplast Ti reinforced PTFE membrane placed and stabilized with screws, e) Approximated coronally and sutured with vicryl 4-0

GROUP B: Augmentation with customized 3D titanium mesh (Figure 4)- A customized 3D titanium mesh was placed and stabilized using screws, followed by bone graft condensed over the defect. PRF and membrane were placed over the mesh (Figure 5).

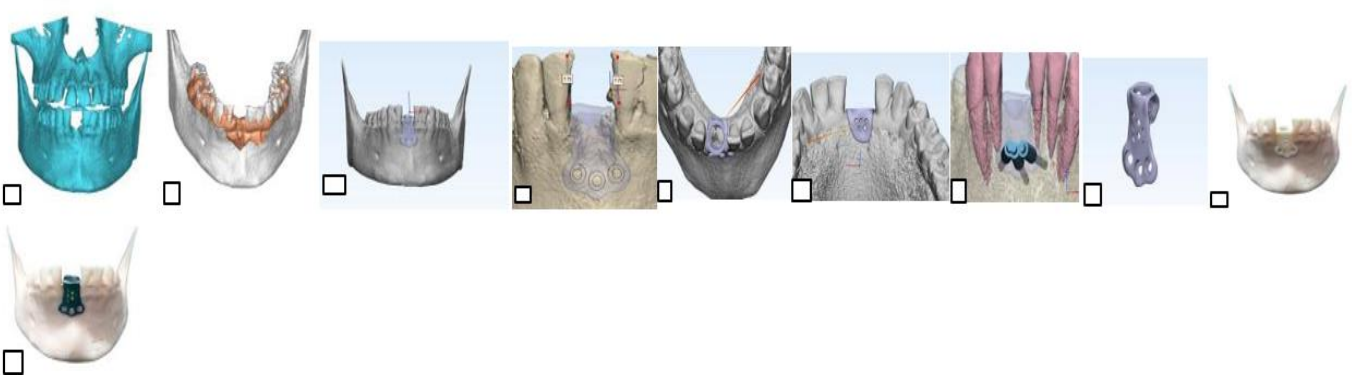

Figure 4. Designing and printing of customized 3-D titanium mesh: a) Segmentation - Conversion of Dicom files to STL file (2D to 3D), b) Superimposition of intra oral scan on the Mandible STL file to evaluate the soft tissue height and width, c) Designing of customized Alveolar Augmentation mesh, d) Measurement to make sure it's at the level of CEJ of adjacent teeth, e) Occlusal sleeve for placing dental implant without removing the mesh after successfully osseointegration, f) Lingual hook design extension for better initial stability while fixing, g) Pre-determined position, size, length and angulation of surgical screws for fixation, h) Final mesh design of the patient specific defect, i)Prototype were created to check the fit of mesh over the defect, j)Final mesh designed and printed

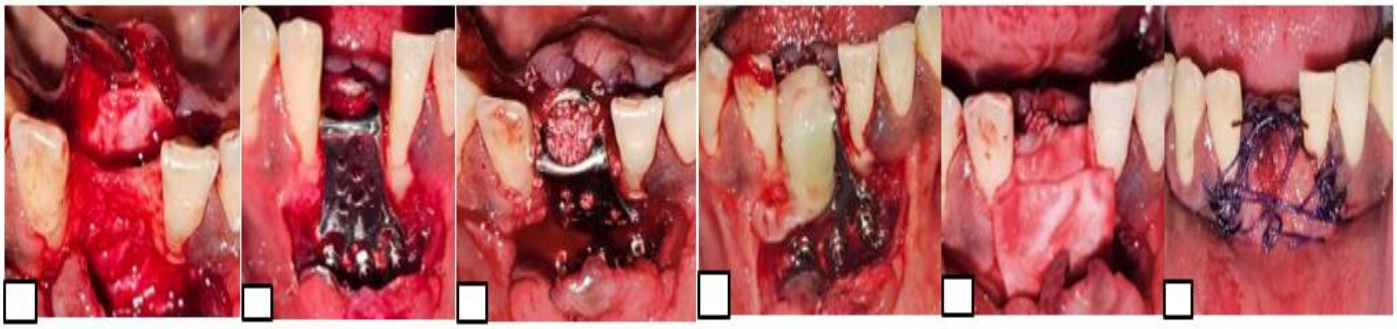

Figure 5. Group B- Surgical procedure a) full thickness flap raised, b) fabricated customized Ti-mesh placed and stabilized with mini screws, c) graft placed over the defect, d) PRF placed over the mesh, e) membrane is placed over the mesh, f) flaps were coronally advanced and sutured.

Patients were instructed to avoid mechanical trauma (e.g., brushing, chewing hard foods) near the surgical site. Follow-up was scheduled at intervals of 1 week, 3 weeks, and 6 months to evaluate for inflammation, soft tissue dehiscence, or membrane exposure.

2.5 Post-operative measurements

In CBCT images, bone density and ridge width were assessed as it was at baseline measurements; at 0, 2, 4, and 6mm from the crest, also measured at various time intervals immediately post-operative, 3, and 6 months post-surgery (Figure 6a-d, 7a-d).

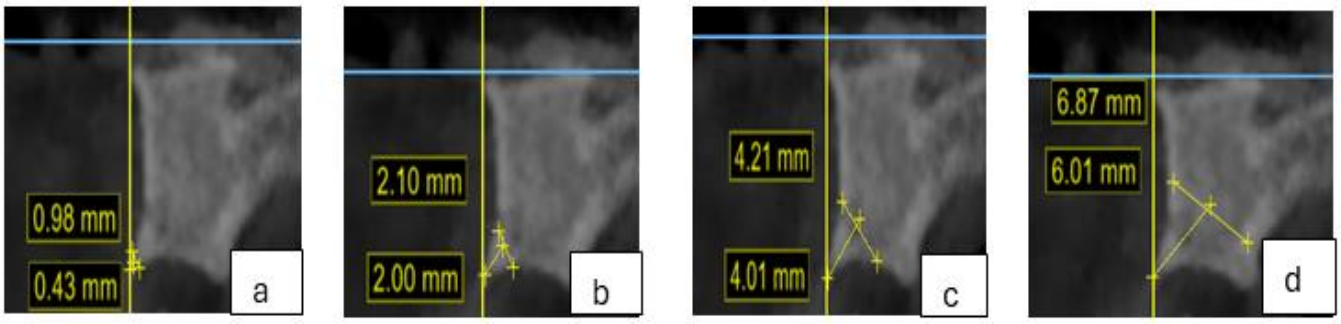

Figure 6. Measurements of post-op CBCT in group A measured at 0mm, 2mm, 4mm, 6mm from the crest
a) pre-op measurement at the level of 0.43mm from the crest 0.98mm of width is present, b) post-op measurement at the level of 2.0mm from the crest 2.10 mm width is present, c) post -op measurement at the level of 4.0mm from the crest 4.21 mm of width, d) post-op measurement at the level 0f 6.0mm from the crest gives 6.87mm of width.

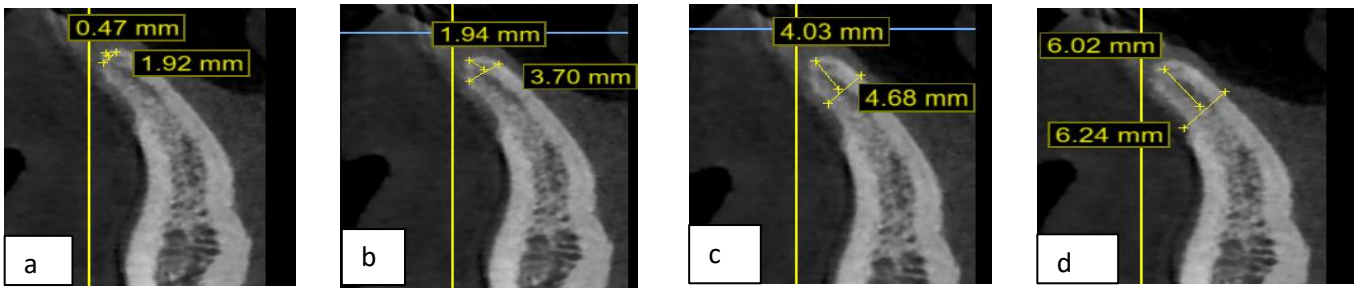

Figure 7. Measurements of post-op CBCT in group B measured 0mm,2mm,4mm,6mm from the crest
a) post -op measurement at the level of 0.47mm from the crest 1.92mm of width is present, b) post-op measurement at the level of 2.0mm from the crest 3.70 mm width is present, c) post -op measurement at the level of 4.0mm from the crest 4.68 mm of width, d) post-op measurement at the level 0f 6.0mm from the crest gives 6.24mm of width.

Membrane exposure was assessed clinically during the postoperative follow-up visits at 1 week, 3 weeks, and 6 months. The surgical site was examined for any signs of early or late membrane exposure, inflammation, or dehiscence, and findings were documented accordingly (Figure 8).

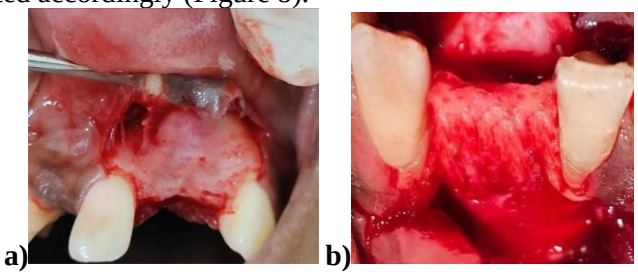

Figure 8. Post-operative (surgical re-entry) at 6 months a) GROUP A (D-PTFE), b) GROUP B (CUSTOMIZED 3D TI-MESH)

Surgical time analysis was made with a stopwatch to record the total duration of the procedure, from anesthesia administration, flap elevation, bone graft and membrane placement, flap closure, and suturing. Patients were asked to fill out a questionnaire reporting patient-related outcomes, the data was represented graphically with descriptive analysis. (Figure 9)

Patient questionnaire for Soft Tissue Evaluation

Patient questionnaire for Soft Tissue Evaluation

Section A: General Information

1. Name/Code:
2. Age:
3. Gender: ☐ Male ☐ Female ☐ Other

Section B: Patient-Centered Soft Tissue Parameters

Please answer the following questions based on your current experience after the ridge augmentation procedure.

1. **Do you notice any swelling or puffiness in the treated area?**
   - ☐ No
   - ☐ Mild
   - ☐ Moderate
   - ☐ Severe
2. **Do you experience pain or tenderness in the treated area now?**
   - ☐ No
   - ☐ Occasionally
   - ☐ Frequently
   - ☐ Constantly
3. **Have you noticed any bleeding from the gums in the treated area?**
   - ☐ No
   - ☐ Occasionally while brushing
   - ☐ Frequently
   - ☐ Spontaneous bleeding
4. **How would you rate the appearance of the gums (color and texture) in the treated area?**
   - ☐ Normal and healthy
   - ☐ Slightly red/swollen
   - ☐ Uneven/irregular texture
   - ☐ Unnatural or concerning appearance
5. **Do you feel any exposure of material kept inside the treated area?**
   - ☐ No
   - ☐ mild
   - ☐ moderate
   - ☐ Severe

Section A: General Information

1. Name/Code: __ __ _ _ _ _
2. Age: __ _
3. Gender: ☐ Male ☐ Female ☐ Other

Section B: Patient-Centered Soft Tissue Parameters

Please answer the following questions based on your current experience after the ridge augmentation procedure.

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☐ No
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☐ Moderate
☐ Severe

2. Do you experience pain or tenderness in the treated area now?

☐ No
☐ Occasionally
☐ Frequently
☐ Constantly

3. Have you noticed any bleeding from the gums in the treated area?

☐ No
☐ Occasionally while brushing
☐ Frequently
☐ Spontaneous bleeding

4. How would you rate the appearance of the gums (color and texture) in the treated area?

☐ Normal and healthy
☐ Slightly red/swollen
☐ Uneven/irregular texture
☐ Unnatural or concerning appearance

5. Do you feel any exposure of material kept inside the treated area?

☐ No
☐ mild
☐ moderate
☐ Severe

3.RESULTS

Bone density changes at 0, 2, 4, and 6 mm (Table 1) showed no statistically significant differences between the control group (Ti-reinforced d-PTFE) and the test group (customized 3D titanium mesh) at baseline or postoperative assessments ($p>0.05$). However, intragroup comparisons revealed significant postoperative bone density gains at all levels in both groups ($p<0.05$), except at 0 mm in the control group, where the change was not significant ($p=0.072$). The test group demonstrated highly significant improvement at 0 mm ($p=0.003$), and consistent significant increases at 2, 4, and 6 mm. The control group also showed significant postoperative increases at 2 mm ($p=0.031$), 4 mm ($p=0.007$), and 6 mm ($p=0.027$). Overall, while both augmentation techniques improved bone density, intergroup comparisons did not reveal statistically significant differences. Further bone gain was measured in both groups and as the depth increased, a higher gain was noted in this both groups and was not statistically significant for 2 mm, 4 mm, and 6 mm (Table 2). Both groups demonstrated bone gain at all depths. Group A improved from 0.78 to 1.25 mm at 0 mm and from 3.53 to 5.94 mm at 6 mm. Group B showed greater gains, increasing from 0.67 to 1.78 mm at 0 mm and from 3.54 to 5.80 mm at 6 mm. Overall, both groups benefited, with the test group showing a more consistent improvement (Table 3). Membrane exposure has been recorded in one patient in Group A treated with d-PTFE (Cytoplast-150) at an interval of 3 weeks post-operative. Table 4 shows the occurrence of the membrane exposure, with no statistical significance (p=1.000). The surgical time for

Group A was 77.6667 minutes (mean value), which is less when compared to the surgical time for Group B, which was 139.667 minutes (mean value), showing a statistically significant ($p<0.005$) difference (Table 5).

TABLE 1. Bone density: Intragroup and intergroup comparison at 0mm, 2mm, 4mm and 6mm level

	CONTROL GROUP	TEST GROUP	t-value	p-value†
	AT 0 mm LEVEL			
PRE-OPERATIVE	0.7800±0.17059	0.6733±0.12220	0.880	0.428
POST OPERATIVE	1.25±0.37643	1.7833±0.18717	2.197	0.093
t-value	3.529	19.521		
p-value‡	0.072	0.003*		
	AT 2mm LEVEL			
PRE-OPERATIVE	1.5400 ± 0.27221	1.5733 ± 0.37220	0.125	0.906
POST OPERATIVE	2.7167± 0.55609	3.1033 ± 0.59501	0.822	0.457
t-value	5.584	11.566		
p-value‡	0.031*	0.007*		
	AT 4mm LEVEL			
PRE-OPERATIVE	2.2200 ± 0.28931	2.7133 ± 0.31005	2.015	0.114
POST OPERATIVE	4.0333± 0.30600	4.1167± 0.61533	0.210	0.0833
t-value	12.222	6.271		
p-value‡	0.007*	0.024*		
	AT 6mm LEVEL			
PRE-OPERATIVE	3.5267 ± 0.27737	3.5400 ± 0.17088	0.071	0.947
POST OPERATIVE	5.9367 ± 0.97767	5.8000 ± 0.71077	0.196	0.854
t-value	5.920	4.559		
p-value‡	0.027*	0.045*		

Control group - Augmentation with Ti-reinforced D-PTFE; Test group - Augmentation with customized 3D titanium mesh; SD – Standard deviation. All values are expressed as Mean ± SD. The statistical test used: †Unpaired t-test and ‡Paired t-test; level of significance: *p ≤ 0.05 is considered statistically significant

TABLE 2. Bone Gain: Intragroup comparison in Group A and Group B using paired t-test

Depth	Pre-op Mean (SD)	Post- op Mean (SD)	Bone Gain (Post – Pre)	t-statistic	p-value
	GROUP A				
0 mm	0.78 ± 0.171	1.25 ± 0.376	+0.47	3.53	0.0717
2 mm	1.54 ± 0.272	2.72 ± 0.556	+1.18	5.58	0.0306*
4 mm	2.22 ± 0.289	4.03 ± 0.306	+1.81	12.22	0.0066*
6 mm	3.53 ± 0.277	5.94 ± 0.978	+2.41	5.92	0.0274*
	GROUP B				
0 mm	0.67 (0.122)	1.78 (0.187)	+1.11	19.52	0.0026*
2 mm	1.57 (0.372)	3.10 (0.595)	+1.53	11.57	0.0074*
4 mm	2.71 (0.310)	4.12 (0.615)	+1.41	6.27	0.0245*
6 mm	3.54 (0.171)	5.80 (0.711)	+2.26	4.56	0.0449*

Significant at $p < 0.05$

TABLE 3. Bone gain: Intergroup comparison between Group A and Group B using Welch's t-test

Depth	Group A (Mean)	Group B (Mean)	t-statistic	p-value
0 mm	0.47	1.11	-4.42	0.0266*
2 mm	1.18	1.53	-1.42	0.2413
4 mm	1.81	1.40	1.53	0.2119

6 mm	2.41	2.26	0.23	0.8270

TABLE 4. Membrane Exposure in Group A and Group B

		Membrane Exposure		Total	Chi Square	p- value†
		Absent	Present			
GROUP	CONTROL GROUP	2	1	3	1.200	1.000
	TEST GROUP	3	0	3		
Total		5	1	6		

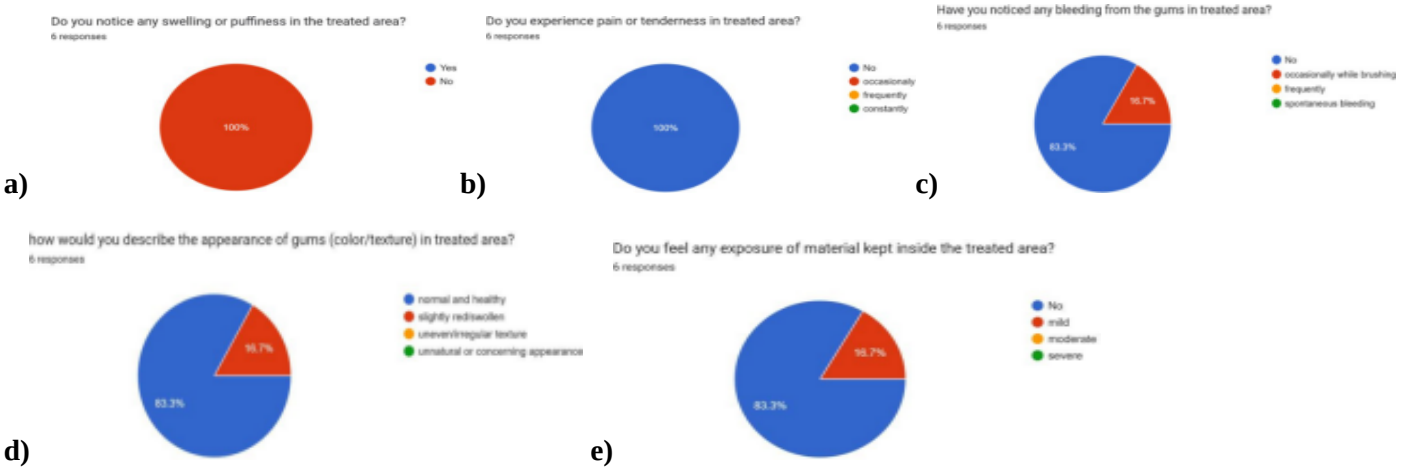
†Chi square-test; level of significance: *p ≤ 0.05 is considered statistically significant

TABLE 5. Time taken for surgical procedure: Comparison between Group A and B

	CONTROL GROUP	TEST GROUP	t-value	p-value†
Timing for completion of the procedure	139.667 ±14.50287	77.6667± 15.30795	5.093	0.007*

†Unpaired t-test; level of significance: *p ≤ 0.05 is considered statistically significant Patient-reported soft tissue health status including color, contour, and tissue adaptation, remained stable in the majority of cases, indicating predictable healing outcomes and acceptable biocompatibility of the materials used(Graph 1a-d). Graph 1a: No patients experienced swelling or puffiness in the treated area; 1b: No patients experienced pain or tenderness in the treated area; 1c: 16.7% noticed bleeding from the treated area; 1d: most of the patients did not feel anything unusual in the treated area; 1e: 16.7% noticed mild exposure over the treated area.

GRAPH 1. Patient-reported outcomes- questionnaire



a) Do you experience pain or tenderness in the treated area now? b) Do you notice any swelling or puffiness in the treated area? c) Have you noticed any bleeding from the gums in the treated area d) How would you describe the appearance of the gums (color and texture) in the treated area? e) Do you feel any exposure of material kept inside the treated area?

4. DISCUSSION

Alveolar ridge reduction is a long-term and irreversible process that involves the gradual bone loss in the area where a tooth has been removed and can significantly affect the amount and density of the remaining bone, which can pose challenges for prosthetic and dental implant treatments. Thereby, strategies that speed up "socket healing and bone production to preserve remaining alveolar bone are desired [2,3]. The search for the right material for bone transplantation remains difficult. Autogenous bone grafts remain the "gold standard" for grafting of bone because of osteoinduction properties and enhanced healing capability. However, they have their drawbacks, such as post-operative discomfort, restricted availability of harvest material, donor site morbidity for the patient, and longer surgical times.

In recent years, customized 3D titanium meshes and titanium-reinforced dense polytetrafluoroethylene (d-PTFE) membranes have been utilized in horizontal ridge augmentation procedures. 3D titanium meshes facilitate digital workflow through CAD/CAM technologies, enabling preoperative planning and fabrication tailored to anatomical needs, which enhances surgical precision and patient-specific treatment. On the other hand, titanium-reinforced dense polytetrafluoroethylene (d-PTFE) membrane combines the mechanical benefits of titanium for space maintenance with the biological advantages of bacterial impermeability and soft tissue compatibility, making it highly effective for GBR in horizontal ridge augmentation [4-6].

Aludden HC et.al, Troeltzsch M et.al, Sanz-Sánchez I et.al, and Cucchi et.al [8-10,21] report no added benefit from resorbable membranes, which aligns with our findings, where customized 3D titanium meshes achieved favorable bone gains and d-PTFE membranes offered no significant advantage. While Buser D et.al, Sumi Y et.al, and Sagheb K et.al [22-24] emphasized the regenerative potential of PTFE membranes, they also highlighted greater mechanical stability and surgical efficiency with customized titanium meshes, consistent with our observation of shorter surgical time. In vertical augmentation studies, mixed results were reported, but overall, the current evidence suggests that both approaches support bone regeneration, although customized titanium meshes may provide superior stability and surgical predictability [25-28].

In the present study, out of 6 cases, membrane exposure has been recorded in one patient in Group A. Though the study includes patients with adequate keratinized tissue width and vestibular depth, there could be several other factors associated with failure or membrane exposure in this study. The observed membrane exposure in the maxillary region may be attributed to inherent anatomical and physiological differences between the maxilla and mandible [29,30]. Additionally, the thin, mobile maxillary mucosa, combined with constant functional forces from the perioral muscles, predisposes the flap to micromotion and ischemia, increasing the risk of early dehiscence and exposure of membrane. In contrast, the mandible's denser D1 cortical bone and enhanced vascular network provide greater mechanical stability and resistance to soft tissue breakdown, which leads to the absence of exposure in mandibular cases in this study [31]. Although, the use of customized 3D titanium mesh has gained increasing attention due to their structural advantages, highlighting the role of 3D printing technology in enhancing space maintenance, precision, and patient-specific strategies [32]. Literature reveals that both titanium mesh or d-PTFE membrane have satisfactory soft tissue outcomes postoperatively.

Thereby, in the present study, a self-reported soft tissue evaluation was utilised. Despite the promising results, one major limitation remains the potential for titanium mesh exposure, which can lead to complications such as infection and delayed healing [33,34]. Secondly, fabrication of the customized 3D titanium mesh can become a financial burden to the patients.

This small sample reduced the statistical power of the study and limited the generalizability of the findings. Secondly, although both groups included a combination of maxillary and mandibular sites, this anatomical variation may have acted as a confounding factor. Moreover, the study did not include a separate, arch-specific analysis, which limits definitive conclusions about the comparative performance of the materials in different jaw regions. However, the results can be assumed as baseline pilot data so that future research can focus on evaluating the long-term outcomes of both customized titanium meshes and d-PTFE membranes in a larger sample size, particularly regarding implant stability in augmented sites and the management of titanium mesh exposure. In the near future, innovations could pave the way so that customization of the 3D titanium meshes could be done with easy access and at low cost.

5.CONCLUSION

Both treatment modalities demonstrated satisfactory bone width gain, but increased gain was evident in patients treated with customized 3D titanium mesh. The surgical time was observed to be shorter in the customized 3D titanium mesh group. Membrane exposure occurred in one patient from the d-PTFE group during the early healing phase. In addition, both groups indicated predictable healing outcomes and acceptable biocompatibility of the materials used, as supported by patient-reported postoperative questionnaire. Overall, both membranes appear to be probable alternatives for horizontal ridge augmentation, with favorable clinical outcomes. Future

studies with bigger samples, arch-specific comparisons, and long-term follow-up are needed to validate these preliminary observations and better assess the material-specific risks and benefits.

DECLARATIONS

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Competing Interests:

Ethical Approval:

The study was approved by the appropriate ethics committee and conducted according to relevant guidelines and regulations.

Informed Consent:

Not applicable.

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