Section A-Research paper

ASSESSMENT OF GUIDED BONE REGENERATION IN AUGMENTATION OF HORIZONTALLY ATROPHIC MAXILLARY RIDGE USING COLLAGEN MEMBRANE VERSUS USING TITANIUM MESH: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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Abstract

Objective is to assess the guided bone regeneration in augmentation of horizontally atrophic maxillary ridge using collagen membrane with the new Sausage technique versus using titanium mesh.

Material and methods: Two different Barrier membranes were evaluated with GBR ridge augmentation in maxillary atrophic ridge. 20 sites received GBR using native collagen membrane (group 1) covering 1:1 autogenous and anorganic bovine bone mineral (ABBM) bone mixture, and another 20 sites receiving GBR using Ti-mesh with the same mixture of bone.

Results: Postoperative assessment for augmented cases revealed uneventful healing except for six sites in the ti-mesh group. There was a significant increase in alveolar bone width in both techniques at all different bone levels. Also, there were Significant difference between the increase

of bone width in group one than in group two at 6months. Bone area percent was almost 28% for both groups and no evidence of reminants of collagen membrane were found in group1 specimens.

Conclusion: Guided bone regeneration in augmentation of horizontally atrophic maxillary ridge using collagen membrane or titanium mesh with a mixture of 1:1 autogenous and xenograft are viable techniques before implant placement. Titanium mesh is a more technique sensitive and complicated procedure as compared to collagen membrane due to its high rate of postoperative complications.

KEY WORDS: Collagen membrane; Sausage technique; Titanium mesh; Guided Bone Regeneration; anorganic bovine bone mineral.

Introduction

Dental Implants are the treatment of choice for replacing any missing teeth. Some Problems may Hinder this procedure as the thickness of the alveolar process. Guided bone regeneration (GBR) is one of the successful techniques used to restore the horizontal ridge deficiency. However, studies still comparing the barrier membranes used with GBR aiming for the ideal one.

This study is to Assess the guided bone regeneration in augmentation of horizontally atrophic maxillary ridge using collagen membrane with the new Sausage technique™ versus using titanium mesh.

Material and methods:

Forty edentulous sites in Twenty four patients suffering from thin ridge that doesn't allow implant placement. Patients were selected from the outpatient clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry Cairo University. Two different Barrier membranes were evaluated with GBR ridge augmentation in maxillary atrophic ridge. 20 sites received GBR using native collagen membrane (group 1) covering 1:1 autogenous and anorganic bovine bone mineral (ABBM) bone mixture, and another 20 sites receiving GBR using Ti-mesh with the same mixture of bone.

I. Preoperative Assessment:

Case history: Each patient was interviewed in order to obtain a comprehensive history including personal data, medical, surgical history and family history and a written consent was signed. (Appendix 1).

Clinical examination: Overall extraoral and intraoral examination was carried out for all patients. Patients were inspected for inter- arch space, normal covering mucosa and periodontal status of adjacent teeth. Clinical measurements were taken to ensure patient adherence to inclusion criteria prior to further investigations. (Fig 1)

Radiographic examination: A preoperative digital panoramic view with 1:1 magnification and Cone Beam computed tomography (CBCT) scan was ordered for bone width measurements at 2mm, 5mm and 10mm from the top of the crest at the anticipated implant site. (fig 9)

II. Intraoperative surgical procedure:

A full thickness mid crestal incision was made at the intended implant placement site with two vertical releasing incisions. The flap was mobilized to permit tension-free primary closure. Blunt dissection and separation of the elastic fibers at the level of the base of the flap between the two vertical incisions. Then the flap is freely mobile and can be sutured tension free. The recipient site was decorticated using a small round bur, to allow angiogenesis and migration of osteoprogenitor cells from the bone marrow spaces.(Fig 2,3)

Chin Autogenous bone harvesting: Incision was placed 5 to 10 mm below the mucogingival junction at the symphyseal region extended just distal to the mandibular canines bilateral to allow adequate access to bone bed. Bone was harvested using the auto chip makes ACM[(1)] bur which harvest bone chips rich in viable bone cells .(Fig 4)

Bovine bone graft (bio-Oss)[(2)] was mixed with the harvested autogenous chipped bone graft with ratio 1:1 (Fig 5).

Resorbable collagen GBR Sausage Technique Group 1 :

A native collagen membrane was measured and trimmed to the proper size and shape to fit the grafting area putting into consideration the extra volume of the augmented bone. The membrane was fixed at two points at least on the palatal site with titanium bone tacks. The bone mixture was packed on to the thin ridge under the collagen membrane, overfilling was done to compensate for future resorption and the membrane was folded over and fixed in place with additional bone tacks on the labial side. tension free primary closure by Suturing in two lines firm horizontal mattress suture placed 4 mm from the incision line.(Fig 6,7,8)

Titanium mesh membrane Group 2 :

Trim the ti-mesh[(3)] to the proper size and shape. Edges were trimmed and polished to prevent the dehiscence or premature exposure then the mesh was fixed on the labial and palatal sides using 2mm Ti mini screws over the particulate 1:1 bone mixture. Flap advancing and suturing using an apical horizontal mattress suture 4 mm from the incision line. (Fig, 10,11,12)

[(3)] Titanium mesh from Bioinnovation, Brazil.

Figure (1): Photograph showing labial view of the alveolar ridge before grafting case no. 5 (group 1).

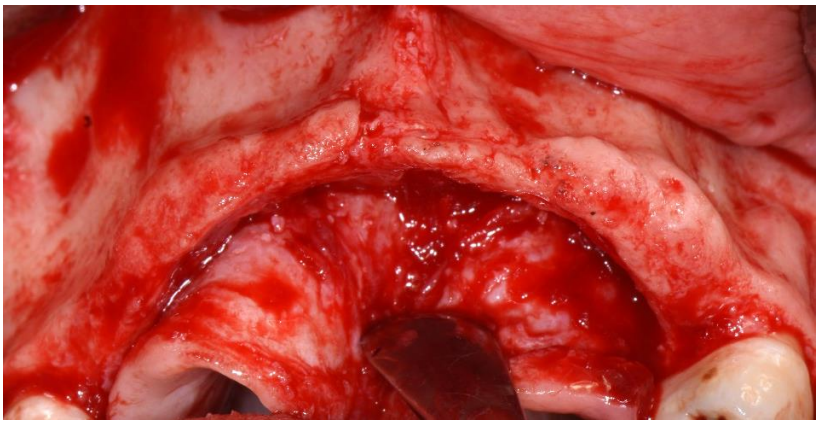

Figure (2): Photograph showing occlusal view of the alveolar ridge before grafting case no.5 (group 1).

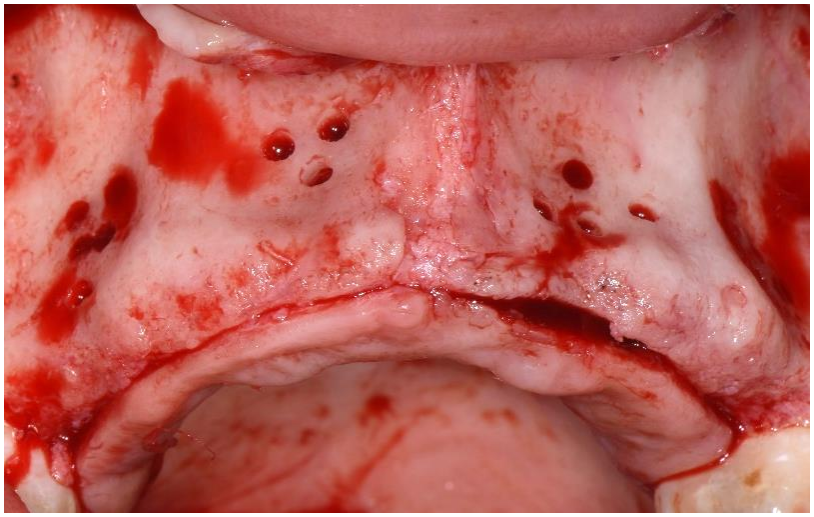

Figure (3): Photograph showing occlusal view of the alveolar ridge decortication before grafting case no.5 (group 1).

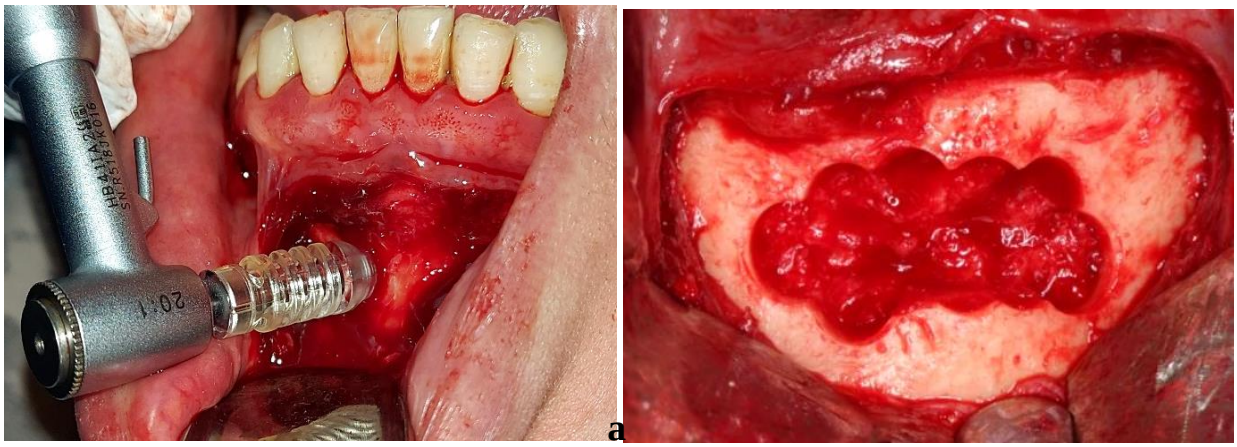

Figure (4): Photograph showing the donor site (chin) after harvesting autogenous bone using ACM Bur. a: (group 2); b: (group 1).

Figure (5): Photograph showing the 1:1 mixture of autogenous bone with bovine Bio-oss graft.

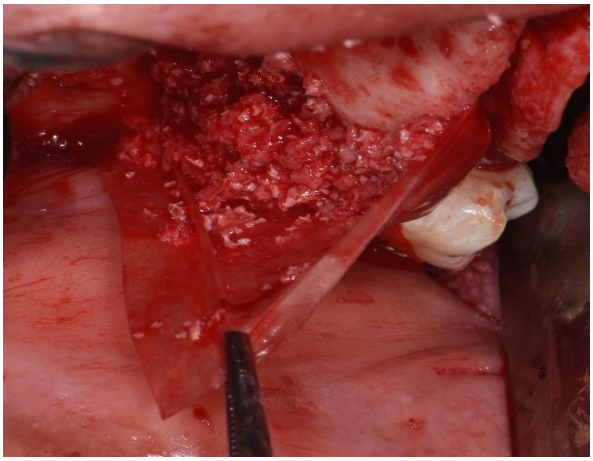

Figure (6): Photograph showing the collagen membrane attached from the palatal side with ti-tacs and bone mixture was being packed underneath. (group 1).

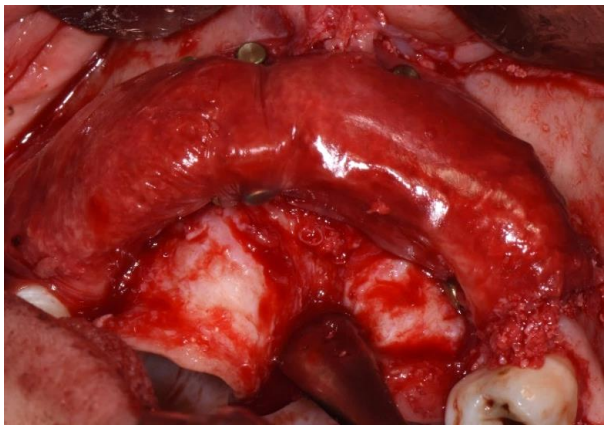

Figure (7): Photograph showing occlusobaccal view of the augmented ridge after overfilling with grafted bone mixture and complete fixation of collage membrane using sausage technique.(group 1).

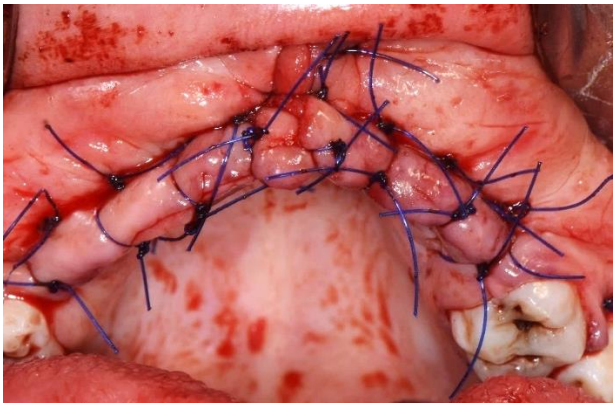

Figure (8): Photograph showing tension free primary closure of the flap using horizontal mattress suture placed 4 mm from the incision line and interrupted sutures in between. (group 1).

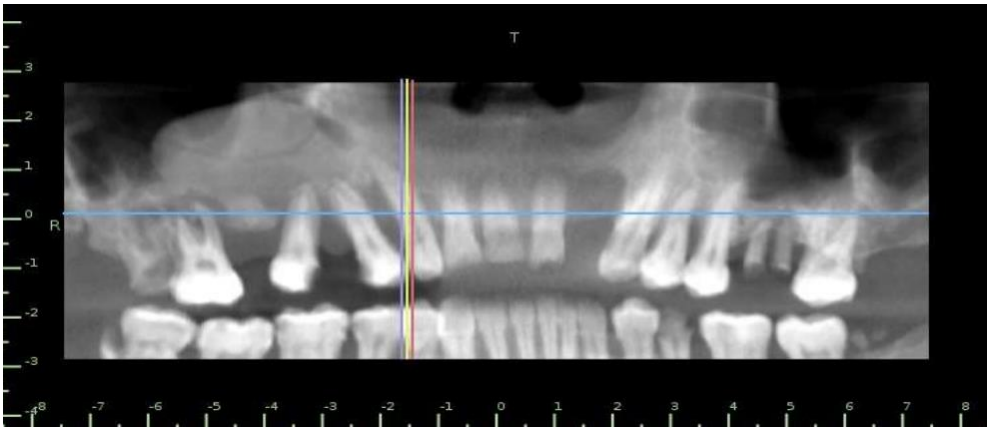

Figure (9): Photoradiograph showing preoperative alveolar ridge with multiple teeth to be extracted, (group 2).

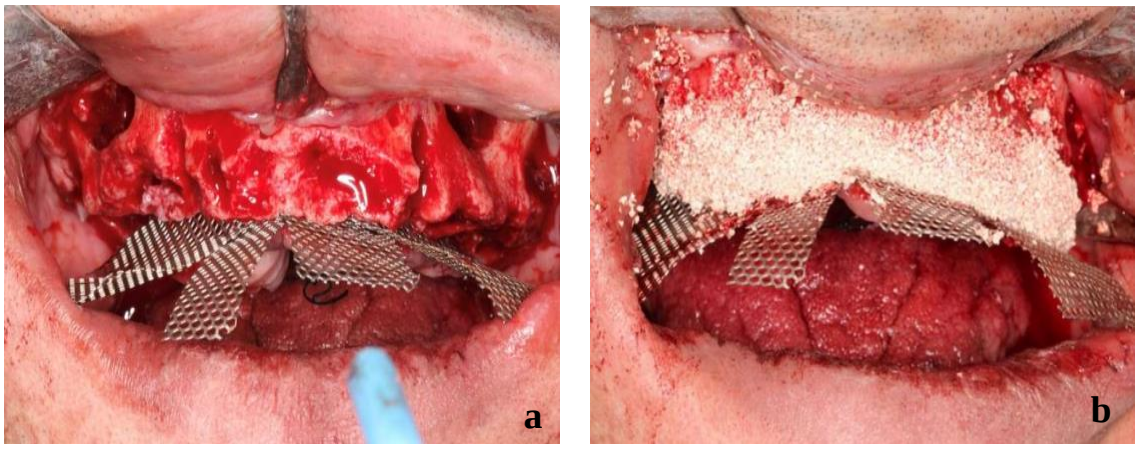

Figure (10): (a) Photograph showing the Ti- mesh attached from the palatal side with screws (b) and bone mixture was added on the defective ridge. (group 2).

Figure (11): Photograph showing fixation of the ti-mesh over the augmented alveolar bone. (group 2).

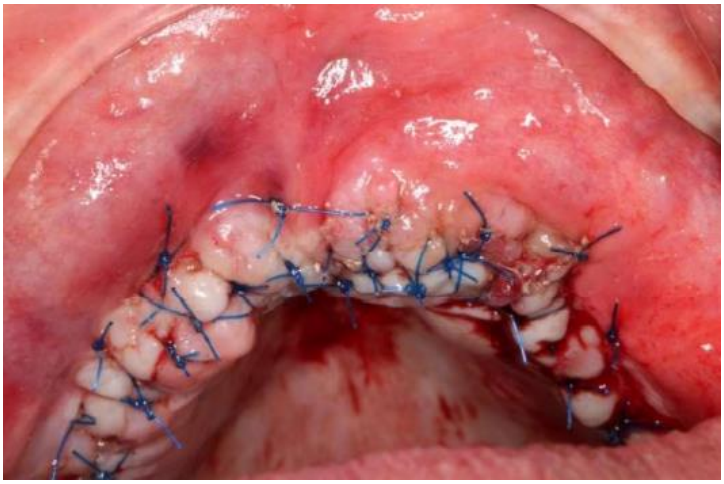

Figure (12): Photo showing occlusal view of the augmented alveolar ridge after suturing the flap with horizontal mattress suture plus interrupted suture to ensure edge closure. (group 2).

III. Follow-up Clinical and radiographic assessment:

Clinical assessment: One week, one month and at six months post-operative clinical assessment of flap healing, presence of any inflammation, infection or membrane dehiscence which is the primary outcome of this study. (Fig 13, 19)

Radiographic assessment: A total of three scans were taken to all patients. Bone width measurements were made on tomographic slices perpendicular to the longitudinal axis of the alveolar crest, 2mm, 5mm and 10mm from the top of the crest at the anticipated implant site.

IV. The second stage surgery:

Reentry after 6 months, Full thickness Flap was elevated to assess clinically the amount of bone width gained and implants with proper diameter were inserted. For the non-resorbable titanium mesh group, the mini screws were removed and the mesh was rolled off the grafted bone.(Fig 14,15,16,17,18)

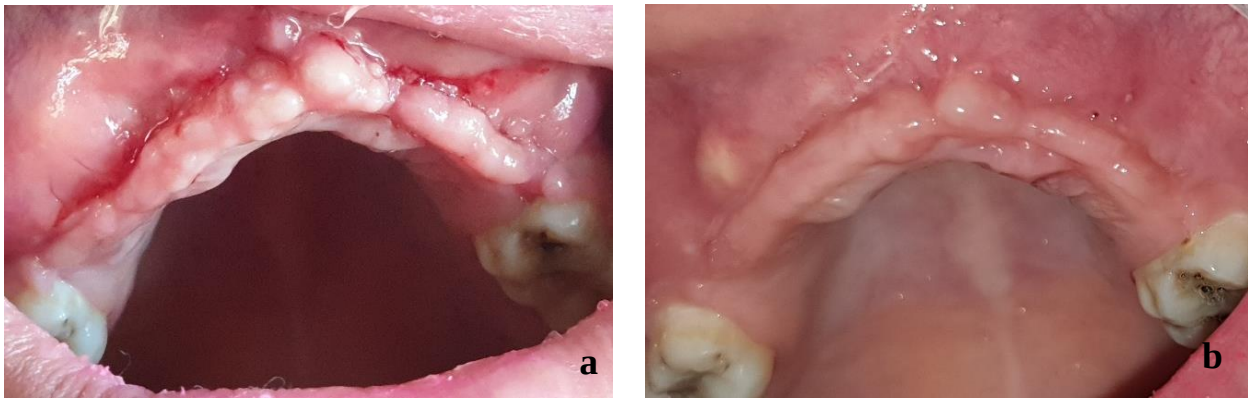

Figure (13): Photographs showing a) post operative clinical assessment for wound healing 1st week postoperatively b) and 6 months post operatively (group 1).

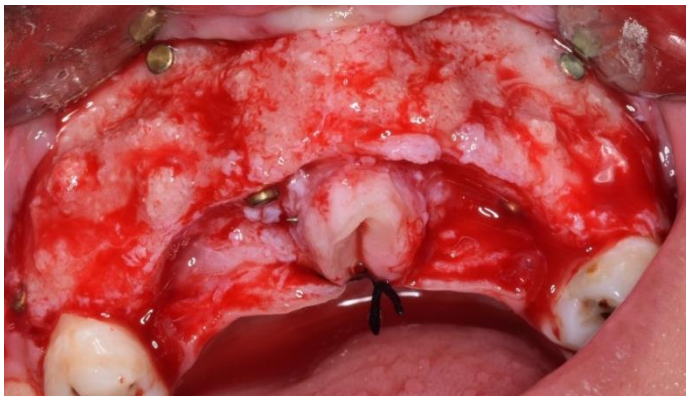

Figure (14): Photograph showing alveolar ridge at reentry after 6 month postoperatively, flap elevation and clinical assessment of the amount of bone width increase. case no 5 (group 1).

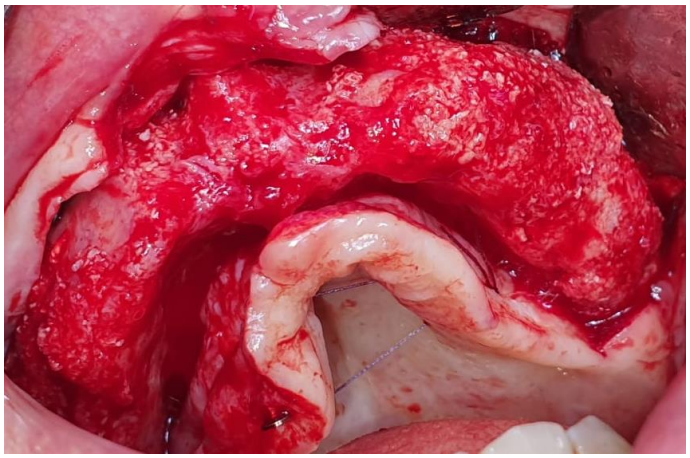

Figure (15): Photograph showing alveolar ridge at reentry after 6 month postoperatively, flap elevation and clinical assessment of the amount of bone width increase. case no 13 (group 1).

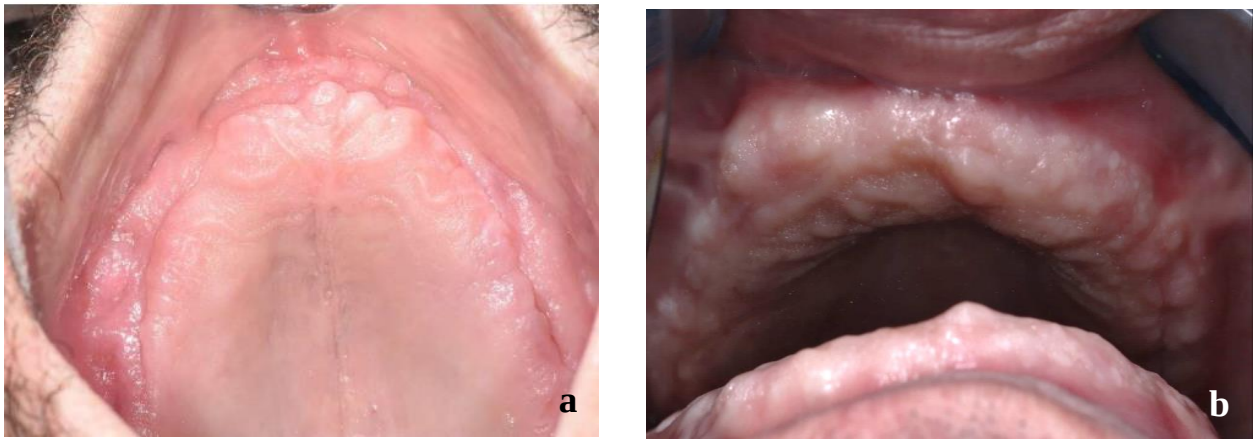

Figure (16): Photographs showing a) post operative clinical assessment for wound healing 1st week postoperatively b) and 6 months post operatively (group 2).

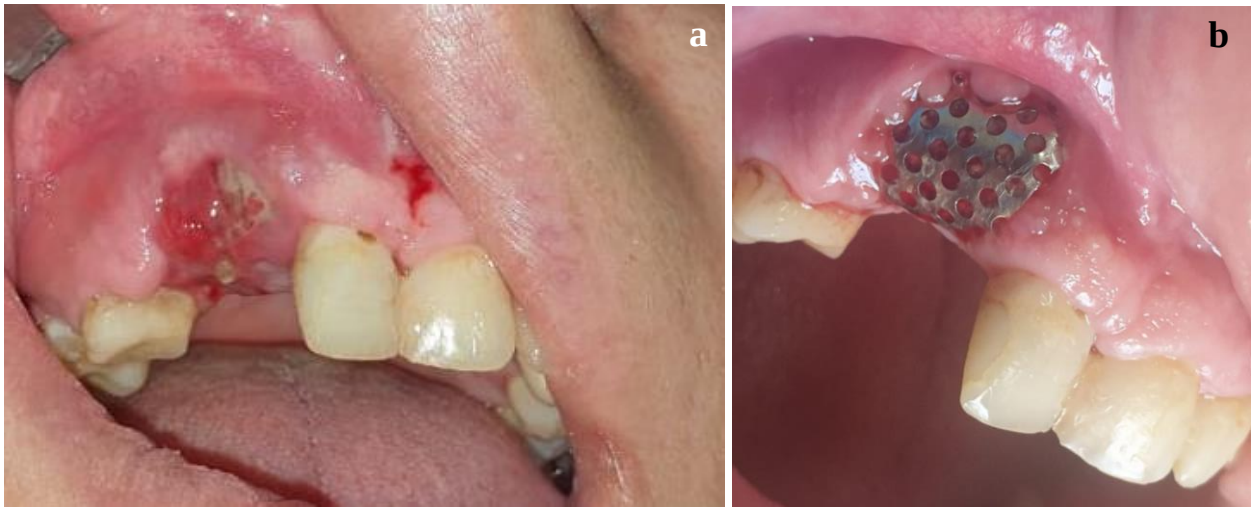

Figure (17): Photographs showing different cases with post operative complications wound healing in Group2.

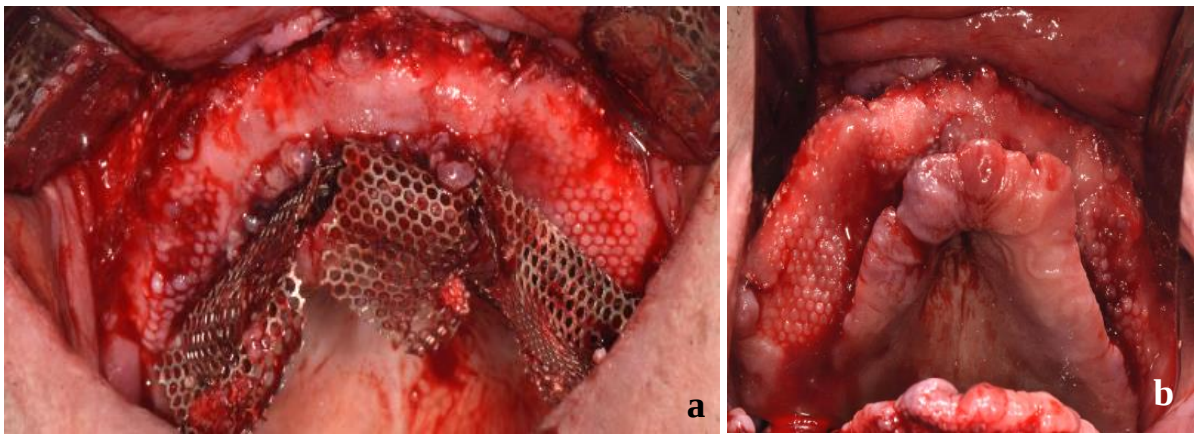

Figure (18): Photograph showing after 6 months postoprstively in case no. 7 group 2 (a) flap elevation and ti-mesh removal, (b) clinical assessment of the amount of bone width increased.

Histomorphometric Analysis:

A core biopsy was obtained by using a 2mm trephine bur from a preplanned implant positioning at the same length and direction of the implant osteotomies for histomorphometric analysis. The core biopsies were sectioned and stained with hematoxylin and eosin (H&E) stain. Sections were examined and photographed with Leica DM 400 light microscopy and a camera using Leica Application Suite-LAS software[(4)] in the Oral Biology Department, Faculty of Dentistry, Cairo University. (Fig 20)

Prosthetic Part:

[(4)] Microscope Software Platform LAS X Life Science © 2022 Leica Microsystems.

Patients Participating in the study completed their prosthetic planning with implant placement. Then after three months of Implant-bone healing, fixed prosthesis was performed according to each case. (Fig 21,22,23)

Statistical analysis:

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data showed parametric (normal) distribution. (Fig 24)

Figure (20): Photograph showing the core biopsy obtained by using a 2mm trephine bur from a preplanned implant position.

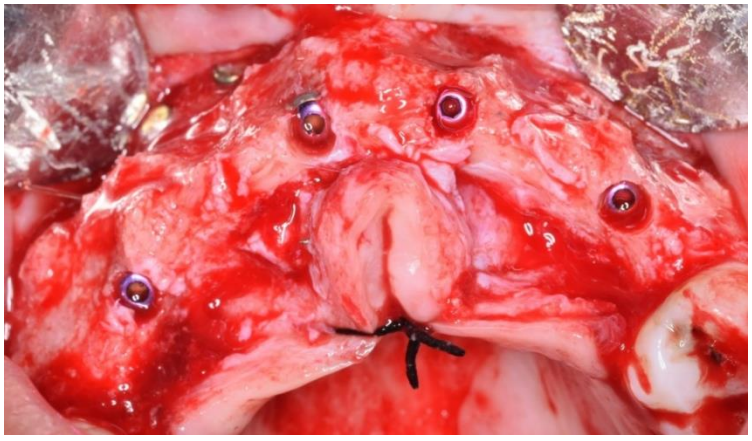

Figure (21): Photograph showing occlusal view for implant placement in augmented regenerated bone at reentry after 6m. Case no.5 (group 1).

Figure (22): Photograph Showing (a) implants with their abutments after healing, (b)Final restoration insertion, case no 5 (group 1).

Figure (23): Photograph Showing (a)implants with their abutments after healing, (b)Final restoration insertion, case no. 7 (group 2).

Results:

Postoperative assessment for augmented cases revealed uneventful healing except for six sites in the ti-mesh group showed signs of inflammation and membrane dehiscence. Statistical analysis showed a significant increase in alveolar bone width in both techniques at all different bone levels.

In the Collagen group At Level 1(L1) a mean bone gain of 3.44(±0.63) mm, Level 2(L2) bone gain of 2.96 (±1.10)mm, and at Level 3(L3) a bone gain of 2.59(±0.66).

In the Ti mesh group the bone gain was at L1 2.54(±0.55) mm , ant L2 2.75(±0.96)mm and at L3 a again of 2.36(±1.78)mm. Also, there were Significant difference between the increase of bone width in group one than in group two at 6months postoperatively at L1 and L3. Where the mean bone width at L1 was 7.29 ± 0.47 mm for Group 1 and was 6.29 ± 0.50 mm for Group 2, and this was Statistically significant with p= 0.001. at L3 The mean bone width was 11.37 ± 0.39 mm for Group 1 and was 10.68 ± 0.83 mm for Group 2, and this was Statistically significant p= 0.029. (Fig. 24, Table 1)

Bone area percent was almost 28% for both groups and no evidence of reminants of collagen membrane were found in group1 specimens. (Fig.25,26)

Variables	**Bone gain**											
	L1				**L2**				**L3**			
	Mean	**SD**	**Min**	**Max**	**Mean**	**SD**	**Min**	**Max**	**Mean**	**SD**	**Min**	**Max**
Group 1 (Collagen membrane)	3.44	0.63	2.50	4.75	2.96	1.10	0.80	4.20	2.59	0.66	1.53	3.50
Group 2 (Titanium mesh)	2.54	0.55	1.81	3.33	2.75	0.96	0.90	4.24	2.36	1.78	-1.62	4.99
p-value	**0.003***				**0.667ns**				**0.709ns**			

Table (1): The mean, standard deviation (SD) values of amount of bone gain of different groups.

*; significant (p<0.05) ns; non-significant (p>0.05)

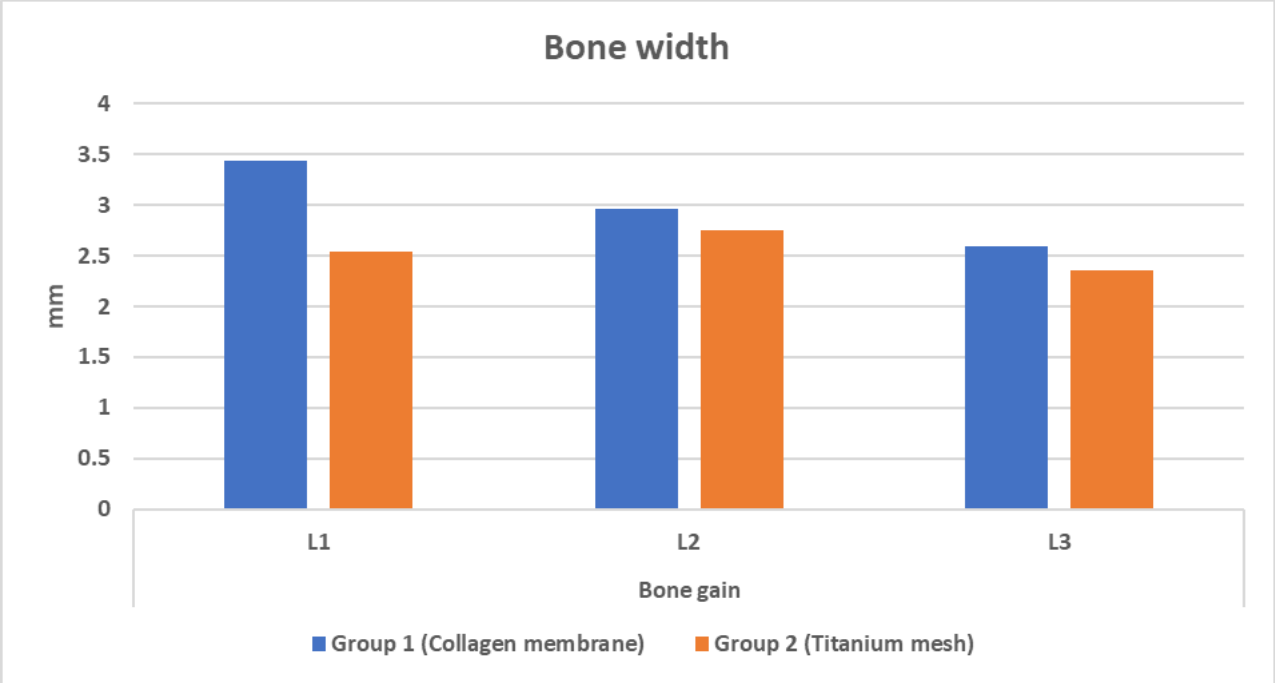

Figure (24): Bar chart representing bone gain comparing the two groups at the three different bone levels.

I) Histological Results:

Twelve specimens were examined histologically, seven from the collagen group and five from ti-mesh group. Not all specimens where successfully collected and examined due to difficulty to retrieve a sound and solid core biopsy from all cases. The core blocks were taken at 6months post operatively during re-entry for implant placement using a 2.0 mm trephine bur.

Histomorphometric analysis of the specimens collected from both groups revealed considerable amounts of new bone formation. The newly formed bone trabeculae forming a trabecular network with interconnected marrow cavities. In some areas, the newly formed bone were formed of cellularized woven bone displaying randomly distributed osteocytes with wide lacunae space. No haversian systems were detected in the newly formed bone in the defect area.

In the collagen group (group 1), the bone area percentage represents a mean of 27.92% of the specimen, the xenograft residual particles 23.97% and marrow space 48.13%. The xenograft was connected with a network of newly formed bone of various degree of maturation. There was no histological evidence of the collagen membrane .

In the Ti-mesh group (group 2), the bone area percentage represents a mean of 27.2% of specimen, the residual particles of the xenograft 23.8% and marrow spaces 48.8%.

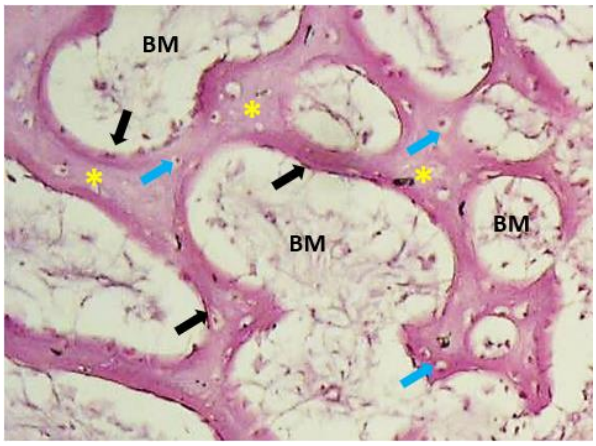

Figure (25): Photograph showing an overview of the histologic section of the collagen group (group1) showing: bone trabeculae containing islands of woven bone (yellow asterisks), osteoblast (black arrows), blue arrow (osteocyte) and marrow cavities (BM) *(H & E, Orig. Mag. 400).*

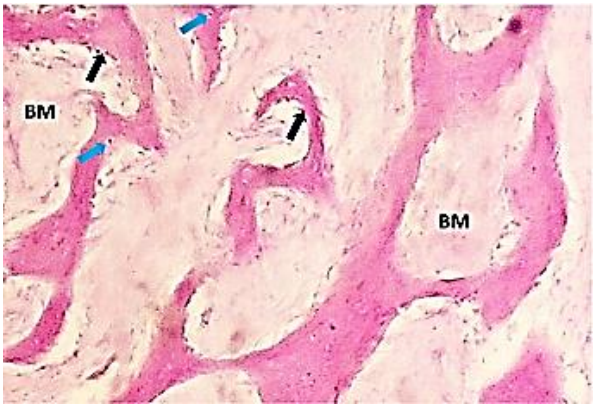

Figure (26): Photograph showing an overview of the histologic section of the Ti-mesh group (group2) group showing: bone trabeculae containing islands of woven bone (yellow asterisks), osteoblast (black arrows), blue arrow (osteocyte) and marrow cavities (BM) *(H & E, Orig. Mag. 400).*

Discussion:

In this study we used GBR instead of Bone blocks as particulate bone undergoes better bone remodeling unlike the blocks which need longer period of time to revascularize and anastomose with augmented bed as agreed by **Khoury F et al. (2007)**. No complications were recorded with the donor site harvesting or flap healing in all cases involved in this study.

Pure Autogenous bone as graft material will resorb very fast as agreed in most of the studies by **Jovanovic SA (1992), Urban (2013), Beretta (2015)** and **Meloni et al. (2017)**. And their studies proved better bone gain by using mixture of autogenic and xenogeneic bone graft with ratio 1:1 to overcome the resorption problem of pure autogenous graft and to provide the graft with osteoconductive properties.

Also a systematic review by **Aludden et al. (2017)** agreed with the same graft ratio. The review tested if there is a difference between using bovine (bio-oss) alone or mixed with particulate autogenous bone graft with ratio 50:50 in lateral ridge augmentations. His results were in agreement with using the 50:50 bio-oss mixture with autogenous bone as more amount of newly formed bone, bone width gain of the alveolar process and short-term implant survival rate were better than using the bio-oss alone.

There are two membrane types used in our study a resorbable versus the non resorbable membrane used for holding the graft material in position . **Antoun et al. (2001)** agreed with the presence of significant less resorption in the group using onlay graft and membrane than the group using onlay graft alone.

In group A the membrane used was bilayer non cross-linked collagen membrane Bio-Gide® in agreement with **Urban and his sausage technique.** The Sausage techniques played an important role in preserving the uniformity of the augmented ridge. has certain advantages as: the membrane adapts itself after wetting its edges with saline or the patient's blood, after wetting it could be stretched to an extent that it could be adapted in the patient's mouth to the desired morphology and edges could be cut easily. The collagen membrane elasticity allows mechanical stable augmented ridge and allows adding more graft material using the sausage technique. **Urban (2013)**. The biodegradation of the bilayer non cross-linked collagen membrane was rapid as agreed by **Jie Liu and David G**. in their review 2014. In this study no membrane remnants were observed during re-entry after 6m in all cases. Postoperative complications as membrane exposure, inflammation or infection were not observed in any of the cases involved in this study which come in agreement with **Urban et al. (2009)**, **Hammerle et al. (2008)**, **Simion et al. (1997)**, and **Zitzmann NU et al. (1997)**.

In group B the non-resorbable membrane used to protect the augmented ridge was ti-mesh. The Ti-mesh can be shaped in a three dimensional way, more over the presence of pores

do not block the blood supply to reach the grafted bone as agreed and used by **Pier P. Poli et al. (2014)** in his retrospective clinical study.

In this study our primary outcome was the difference between the post operative complications resulting from the use of two famous membranes in thin ridge augmentation using same bone graft mixture .In Group A (resorbable collagen membrane group) no post operative complications were observed till six months postoperatively.

unlike the rate of membrane exposure was 28.62% for the cross-linked collagen membrane group and 20.74% for the non-cross linked collagen membrane group. It is not statistically significant between the two groups but the results favor the non-cross linked over the cross linked group due to the less exposure rate of this group. **B. Wessing et al. (2017)**, also **Meloni and Urban et al. (2016)** 13.6% of the cases showed collagen membrane exposure two weeks postoperatively.

Fourteen out of twenty augmented sites of group B (ti-mesh group) healed uneventfully. Six other sites were presented with soft tissue healing complications. Three of these sites showed membrane dehiscence after the first two weeks of healing. Therefore, 30% of the cases showed postoperative complications and These results agreed with the results of **F. Briguglio et al. (2019)** in his systematic review published that 81 exposed meshes out of 154 cases (52%) and it was the most frequent complication. Also agreed with **Uehara et al. (2015)** obtained 70% exposed mesh of which six early exposures at 3-4 months postoperatively.

The secondary outcome in this study was to compare the amount of horizontal bone gain between the two groups., in group 1 (collagen membrane) the mean bone width was 3.85± 0.40mm preoperatively and increased to 7.29 ±0.47mm after 6 months postoperatively. These results where nearly in comparison with the results by **Hammerle et al. (2008)** where 3.2mm width increased to 6.9mm.

Also in **Urban et al. (2013)**, case series ridges with mean width 2.19± 0.64mm were increased to 5.68± 1.42mm with lateral ridge augmentation using collagen membrane and GBR.

Another study by **Silvio Mario et al. (2019)** where the average bone width in 18 patients treated with collagen membrane and GBR was 4mm or less and the average bone gain reached 5.03± 2.15mm. In group 2 (ti-mesh) the mean bone width was 3.75 ± 0.39mm preoperatively and increased to 6.29 ± 0.50mm after 6 months postoperatively These results were comparable to **Marco Rasia et al. (2014).** Also, in a case report by **H Jegham et al. (2017)**, the bone width was less than 5mm at the implant site which was augmented by GBR and ti-mesh as a membrane to be increased to 7mm at four month postoperatively when the mesh was removed.

In the present study, the histomorphometric analysis showed xenograft particles incorporating within the newly formed bone in the grafted alveolar ridge in the specimens collected from both groups. the bone area percentage in group 1 and group 2 were 27.92% and 27.2% respectively which considered a relatively good percentage of new bone formation. According to the systematic review done by **Barallat L. et.al2014**, this average percentage (±28%) was in acceptance with the studies of **(Istvan A. et al. 2013**, **Iasella et al. 2003; Heberer et al. 2008; Alkan et al. 2013; Gholami et al. 2012; Lee et al. 2009; Vance et al. 2004; Norton et al. 2003; Carmagnola et al. 2003)**, where membrane reached 28%. On the other hand, Nam et.al.2011 only reached 10.4 ±4.6% of new bone formation. While **Artzi et al. (2000)** and **Crespi et al. (2011)** reach 46.3±9% and 39.6±9.4 respectively of percentage bone gain.

Conclusion:

Guided bone regeneration in augmentation of horizontally atrophic maxillary ridge using collagen membrane or titanium mesh with a mixture of 1:1 autogenous and xenograft are viable techniques before implant placement. Titanium mesh is a more technique sensitive and complicated procedure as compared to collagen membrane due to its high rate of postoperative complications.

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