

# AUGMENTATION OF THE ANTERIOR MAXILLARY BONY DEFECTS USING CUSTOM- MADE ZIRCONIA MEMBRANES (A CASE SERIES)

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## ABSTRACT

**INTRODUCTION:** Guided bone regeneration (GBR) is the use of membranes to repair various forms of bone deficiencies in a controlled and precise manner.

**OBJECTIVES:** To evaluate a new technique for alveolar ridge augmentation, using custom-made zirconia membranes.

**MATERIALS AND METHODS:** This clinical study was conducted on 10 custom-made zirconia membranes placed in 10 patients having alveolar bone deficiency in the upper anterior jaw region. Radiographic examination was done using cone beam computed tomography (CBCT) preoperatively and 6 months postoperatively.

**RESULTS:** Successful bone gain took place in all cases either in horizontal and/or vertical directions; even when membranes got prematurely exposed, no evidence of infection was observed till the membranes were removed.

All the results were evaluated clinically, radiographically and statistically. Clinically, mild pain and edema occurred and totally subsided 7 to 14 days post-operatively. Radiographically, bone dimensions, either vertically and/or horizontally, have shown remarkable increase.

**CONCLUSIONS:** The tested custom-made zirconia membranes demonstrated good clinical performance and did not show signs of infection, even when exposed prematurely. More research with a larger sample size is required.

**KEYWORDS:** anterior, defects, customized, zirconia, membrane.

**RUNNING TITLE:** Augmenting maxillary defects using custom-made zirconia membranes

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## INTRODUCTION

Various surgical strategies for horizontal and/or vertical bone volume enhancement are readily accessible. Osteodistraction, inlay and onlay bone grafting and GBR treatments are examples of these techniques (1-4).

Concerning the given clinical situation, a number of bone volume enhancement techniques have been proposed to achieve an optimum three-dimensional implant placement. The gold standard for horizontal and/or vertical rehabilitation of the

edentulous ridges is mainly supported by autologous block grafting. In difficult cases, progress in the field of biomaterials or clinical technology led to the inclusion of guided bone regeneration (GBR) (5).

The biological explanation of GBR is that soft tissues are physically excluded from osseous defects and allowing only bone cells to develop and grow into the defect (6). A number of technical

variations have been suggested since its introduction (1,6-11). Nowadays, various types of biocompatible barriers have been developed to enhance the development of new bone. It is intended to stabilize the blood clot and underlying bone graft and thereby reduce the risk that the newly developed crest collapses. Furthermore, the probability of soft tissue creeping into the space is diminished (12-15).

Biocompatibility, cell-occlusive characteristics, integration potentials, mouldability, and stability, are essential aspects of membranes for GBR. As for resorbable membranes, no by-products should be produced, because these could be disruptive to bone regeneration. For a long time, both experimentally as well as clinically, membranes were equal, such as extended polytetrafluoroethylene (ePTFE), collagens, and titanium mesh (16).

Selective laser sintering together with electron beam melting are both examples of rapid prototyping technology, which is used nowadays in conjunction with CBCT imaging and CAD-CAM technology to produce custom-made titanium frameworks for bone augmentation procedures (17-20).

These matrices are patient-specific and are anchored to the edentulous site and serve as stable space-maintaining devices, for the underlying bone graft, to aid in ridge formation. Because of the personalized nature of this technique, it has been demonstrated to substantially decrease the frequency of membrane exposure and intraoperative time as opposed to commercially available titanium mesh (19).

However, additive manufacturing has emerged, also known as three dimensional (3D) printing, which has accelerated the process and substantially reduced the cost of producing custom-made titanium matrices (via electron beam melting or selective laser sintering) which necessitates the use of expensive equipment. The resultant products of the electron beam melting techniques do not possess a smooth surface (21), which necessitates extra polishing time before implantation.

Individualized, non-porous zirconia membranes have been recently described by Malmström et al. to be used for ridge augmentation procedures (22). Zirconia is a biocompatible, chemically inert material that has a wide range of applications in prosthetic and rehabilitative dentistry (23,24).

Because of the prevalence of 5-axis milling machines in dental laboratories, as well as the comparatively higher affordability and abundance of zirconia, the production processes of an accurately milled patient-specific membranes using this material reflects a greater convenient technique than the production of custom-made titanium meshes (25).

Zirconia is used for the production of several dental prosthetics such as zirconia crowns and dental implants. This substance is a polycrystalline ceramic which has several intriguing properties, including being bio-inert and having a high strength and stiffness even at thin thicknesses (23, 26-28). It generates a more favorable fibroblast response, less biofilm adherence, and less inflammatory response than titanium (29).

Therefore, this clinical trial was executed to evaluate the use of custom-made zirconia membranes in bony defects affecting the maxillary anterior region.

## MATERIALS AND METHODS

Appropriate ethical clearance was obtained from Faculty of Dentistry, Alexandria University, and an informed consent was taken from all patients.

### I. Criteria of Patient Selection

This was a prospective clinical trial. It was conducted on 10 custom-made Zirconia membranes placed in 10 patients presented with missing upper

anterior teeth. They were 4 males and 6 females with an average age range from 21- 40 years old. All patients were selected from the outpatient clinic of oral and maxillofacial surgery department, Faculty of Dentistry, Alexandria University.

### Inclusion criteria (5)

1. Patient with anterior maxillary alveolar ridge deficiency (either horizontal, vertical or combined defects) (22,25,30,31).
2. Adequate zone of keratinized gingiva.
3. Patient with sufficient inter-arch space for future dental rehabilitation.
4. Patient age range from 20-40 years.
5. Locally and systemically free.

### Exclusion criteria (32)

1. Patients having an acute odontogenic infection.
2. Poor plaque control (33).
3. Systemic diseases that affect bone turnover such as autoimmune disease, bleeding disorders and uncontrolled diabetes mellitus.
4. Undergoing chemotherapy or radiotherapy.
5. Pregnant or nursing mothers.
6. Smoking.
7. Patient not willing to give consent for the study.

## II. Materials

### Materials

1. All surgical instruments needed for such a procedure.
2. Bone screws (Anton Hipp®, Germany) for membrane fixation.
3. Bovine bone substitute (OneXeno®Graft Bovine, OneGraft®, Germany).
4. Computer aided design-computer aided milling (CAD-CAM) milled ceramic (zirconia) membrane, having a thickness of 0.7mm.

## III. Methods

### 1. Pre-operative phase

#### a. Personal history

The preoperative data was obtained including name, age, gender and telephone number.

#### b. Past medical and dental history

A chart including past medical history, family history, drug history and past dental history was filled out.

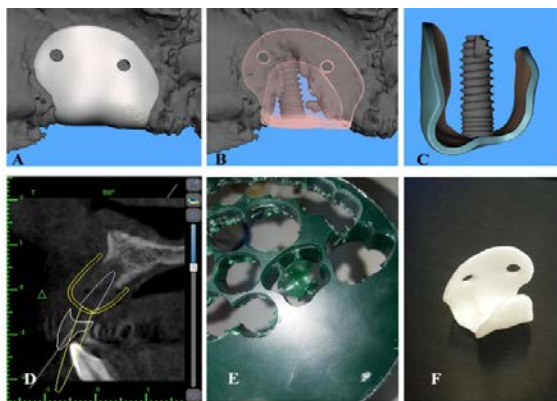
#### c. Clinical examination

- Clinical examination of the oral and tissues, to ensure accurate patient selection.
- Evaluation of the edentulous upper anterior area and the width of the keratinized gingiva.
- Oral hygiene instructions were given to all patients.

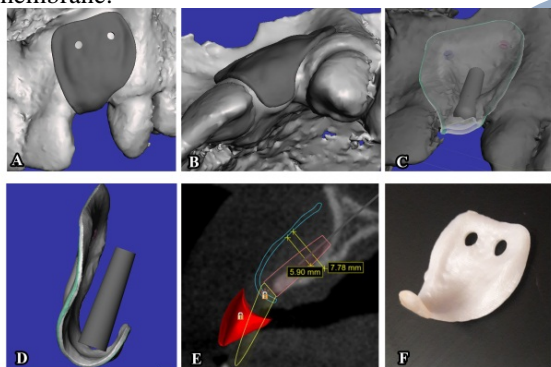
#### d. Radiographic examination

Was obtained by cone beam computed tomography (CBCT) to evaluate bone height, width and therefore; the availability of a future implant placement in the area.

e. Digital, manufacturing and sterilization methods (Fig.1)(Fig.2)



**Figure (1):** a) Finished membrane design on software on top of the deficient alveolar ridge. b) See-through membrane design to visualize its fit and position of future implant to be placed. c) Virtual membrane design with future implant to be placed (sagittal view). d) Sagittal cut of membrane on preoperative CBCT e) Trial wax milled membrane. f) Milled and sintered zirconia membrane.



**Figure (2):** a) Finished membrane design on software on top of the deficient alveolar ridge (labial view). b) Finished membrane design on software on top of the deficient alveolar ridge (incisal view). c) See-through membrane design to visualize its fit and position of future implant to be placed. d) Virtual membrane design with future implant to be placed (sagittal view). e) Sagittal cut membrane on preoperative CBCT. f) Milled and sintered zirconia membrane

1. CBCT scans were done for the edentulous upper anterior areas and surrounding dentition and structures for all patients.
2. Patient's Digital Imaging and Communications in Medicine (DICOM) data obtained from CBCT scan was imported into Bluesky Plan software in order to generate a virtual prosthetic plan for the exact future implant and prosthesis position and angulation onto which the virtual ridge augmentation step will be done.
3. Bone and teeth were segmented using the threshold function.
4. Afterwards, artificial teeth were added on the most acceptable prosthetic position on the

edentulous span. Then implants were added from the software library. Hence, prosthetic-driven implant positioning was implemented.

5. Virtual implant along with the segmented bone and teeth were exported as STLs from the Bluesky Plan software (Blueskybio, Illinois, US) and then imported into Autodesk Meshmixer software (Meshmixer, Autodesk Inc., US)
6. On meshmixer, bone was virtually augmented using sculpt tools in order to create at least 1.5mm of virtual bone all around the virtual implant.
7. Then the membrane was designed using the Separate and Extrude functions. The thickness generated was 0.7mm.
8. Afterwards, screws were virtually added as cylinders with dimensions corresponding to the used microscrews. Screw holes were then created by using Boolean difference operation in the software.
9. Finally the designed membrane was exported as a stereolithography (STL) model.

**10. Milling stage:**

- A trial wax-milled membrane was done first to compensate for any software or milling errors which might occur when milling the zirconia membrane itself.
- Membrane was milled from a zirconia disc (Dental Direct®, Germany)
- Both the wax trial and the zirconia membrane were milled using a 5-axis milling machine (Roland DWX 50®, Japan).
- The dimension of the processed membrane is expanded automatically by in order to compensate for the sintering shrinkage.
- Sintering was done at a temperature of 1500°C using a high-temperature furnace (Zirkon Zahn®, Italy).

**11. Sterilization technique (22)**

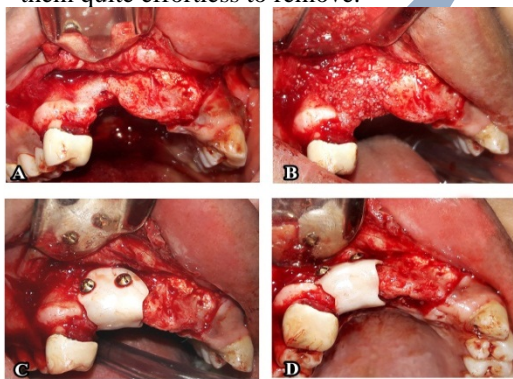
- Cleaning in an ultrasonic bath after sintering was done using 70% alcohol for 15 min.
- Then the membrane was placed in an autoclave and sterilized, prior to usage, using the 134 °C temperature program.

**2. Operative phase (Fig.3)(Fig.4)**

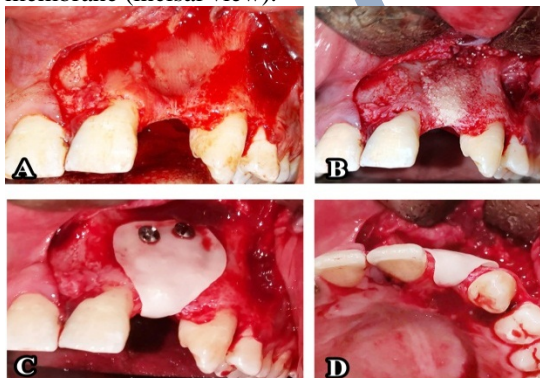
- Infiltration anaesthesia labially and palatally and/or infra orbital block was given along the targeted area.
  - Beveled paracrestal incision was done with scalpel blade number 15.
- Vertical incisions were placed 2 teeth mesial and 2 teeth distal to the edentulous area.
- Full thickness flap reflection done using the periosteal elevator.
- Membrane adaptability was checked over the targeted site to check its adaptability and fit to the bone margins surrounding the bony defect.



- Decorticotomy points done, using round surgical bur, to promote bleeding.
- Mixing the bovine bone substitute with sterile saline solution.
- Placement of the bone graft over the bony defect and then placement of the membrane over the bone graft.
- Placement of self-tapping fixation screws through their holes in the membrane.
- Periosteal releasing incisions were done to allow for soft tissue approximation without tension.
- Periosteal sutures were taken as a way to relief more tension away from the incision line, this was done using vicryl sutures 5/0.
- Mucosal sutures were taken using vicryl sutures 4/0.
- After 6 months of healing, surgical re-entry was performed by reflecting full-thickness mucoperiosteal flap and removal of the fixation screws together with the zirconia membrane then a PRF (Platelet Rich Fibrin) membrane was sutured to the edges of the soft tissue defects.
- It was discovered that the membranes have not been attached to the underlying bone or the surrounding tissues that enclosed them, making them quite effortless to remove.



**Figure (3):** A reflected flap to visualize the severe vertical bone defect. **b)** Xenograft application. **c)** Membrane fixed with 2 titanium screws labially. **d)** Application and fixation of the zirconia membrane (incisal view).



**Figure (4):** a) reflected flap to visualize the severe horizontal bone defect. **b)** Xenograft application. **c)** Membrane fixed with 2 titanium screws labially.

**d)** Application and fixation of the zirconia membrane (incisal view).

**3. Post-operative phase**

**a) Early postoperative care**

- No rinsing or hot drinks for 24 hours.
- Oral hygiene instructions.
- Sutures were removed 7 days post-operatively.

**b) Postoperative medication**

- Amoxicillin 857mg clavulanate 125mg (Augmentin: GlaxoSmithKline, UK.) 1 gm every 12 hours for 7 days.
- Metronidazole 500mg (Flagyl: GlaxoSmithKline, UK.) every eight hours for 7 days.
- Diclofinac potassium 50mg (Cataflam: Diclofenac Novartis-Switzerland.) every eight hours for 7 days.
- All patients were instructed to rinse their mouth using chlorhexidine (Hexitol: Arabic drug company, ADCO, Egypt) antiseptic mouth wash 0.12%.

**4. Follow up phase**

**a) Clinical evaluation**

The patients were followed up clinically post-operatively every 48-72 hours for the first 2 weeks then weekly for one month and then every 3 weeks for the rest of the healing period (6 months) regarding: Presence/absence of membrane instability, flap dehiscence, exposed membrane, bone graft loss outside the flap, infection, hematoma or laceration, and any post-operative complications.

**b) Radiographic evaluation**

A CBCT was done 6 months postoperatively to assess dimensions of newly formed bone and its density.

**5. Statistics**

All of the obtained data were statistically analyzed and presented in the form of tables, graphs and charts using the IBM Statistical Package for Social Science (SPSS) software version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, and standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

**RESULTS**

A total of 10 zirconia membranes were placed in 10 patients presented with missing maxillary anterior teeth and they were indicated for implant placement but suffering from deficient alveolar ridge bone volume. The selected patients were 4 males and 6 females with age range from 21 to 40 years with mean of 29.60 ± 6.83 years. The follow-up time was 6 months.

Successful bone gain took place in all cases either in a horizontal and/or vertical dimension; even when membranes got prematurely exposed, no signs of infection were present till the membranes were removed. All GBR procedures healed uneventfully.

**1. Pain**

After surgery, 1 patient experienced moderate pain (VAS=2), 4 patients experienced pain between annoying and uncomfortable (VAS=3) and 3 patients experienced uncomfortable pain (VAS=4) and 2 patients experienced nagging troublesome pain (VAS=5) at surgical site for 1-3 days duration postoperatively.

There was a statistically significant decrease in pain intensity among patients in the second week postoperatively (P=0.004)

**2. Edema**

All patients suffered from mild to moderate edema, which subsided totally by the second week post-operatively. That was due to the relative complexity of the surgical procedure.

There was a statistically significant decrease in edema among patients in the second week postoperatively (P=0.004)

**3. Post-operative complication (Table 1) (Fig.5)**

Premature membrane exposure occurred but without any evidence of infection or loss of bone graft material outside the membrane during the whole follow-up period, except for the first case done in our study.

**4. Radiographic results to assess gained bone volume (Table 2) (Fig.6)**

Successful bone gain took place in a horizontal dimension only, in six cases, where they had deficient alveolar ridge bone thickness but sufficient alveolar ridge height for a future implant placement.

Bone gain was also accomplished successfully in both horizontal and vertical dimensions in the rest of the four cases in our study.

**Table (1):** Descriptive analysis of the studied cases according to time of membrane exposure (n=10)

	N	Min. – Max.	Mean ± SD.	Median (IQR)
<b>Time of membrane exposure (weeks)</b>	<b>10</b>	1.0 – 16.0	5.80 ± 5.53	3.0 (1.0–11.0)

IQR: Inter quartile range SD: Standard deviation

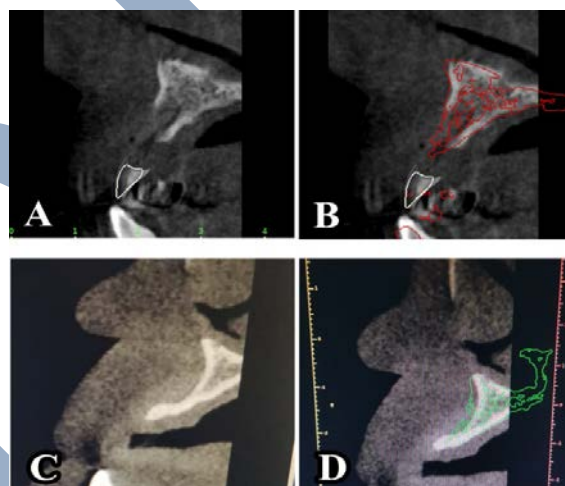


**Figure (5):** Prematurely exposed zirconia membrane.

**Table (2):** Distribution of the studied cases according to gained bone volume (n=10)

Bone gained	No.	%
<b>Bone gained</b>		
Horizontal only	6	60.0
Horizontal and vertical	4	40.0
<b>Bone gained Vertical (mm)</b>	<b>(n=4)</b>	
Min. – Max.	4.0 – 7.0	
Mean ± SD.	5.58 ± 1.26	
Median (IQR)	5.67 (4.67–6.50)	
<b>Bone gained Horizontal (mm)</b>	<b>(n=10)</b>	
Min. – Max.	0.0 – 3.93	
Mean ± SD.	2.18 ± 1.05	
Median (IQR)	2.20 (1.80–2.60)	

IQR: Inter quartile range  
SD: Standard deviation



**Figure (6):** a) Sagittal cut for deficient alveolar ridge (before). b) Overlap of postoperative newly formed ridge on top of the preoperative CBCT.

c) Sagittal cut for deficient alveolar ridge (before). d) Overlap of postoperative newly formed ridge on top of the preoperative CBCT.

The mean value of vertical bone gain in our study is 5.58 ± 1.26mm and the mean value for horizontal bone gain is 2.18 ± 1.05mm.

**Evaluation techniques**

Measurement of the bone volume gained using overlay of the DICOM data from the preoperative and postoperative CBCT scans. These were analyzed through the Import Scan Appliance function in Blueskyplan software (Blueskybio, Illinois, USA).

After opening the prosthetic plan done on the preoperative CBCT scan, Import Scan Appliance option is selected and the patient's postoperative DICOM data is selected and uploaded for further processing, to be overlapped upon the pre-existing preoperative CBCT scan.

The software process revealed the amount of bone volume gained postoperatively in three dimensions

compared to the same area in the preoperative CBCT scan.

#### 6. Radiographic results to assess bone density (Table 3)

The mean bone density value for newly formed bone postoperatively was  $806.39 \pm 206.76$  HU, which is equivalent to bone density levels of D2 (850-1250 HU) and D3 (350-850 HU) bone types, as proposed by the bone density classification by Misch.

**Table (3):** Descriptive analysis of the studied cases according to bone density post-operative (n=10)

	N	Min. – Max.	Mean $\pm$ SD.	Median (IQR)
<b>Bone density newly formed bone (HU)</b>	9	504.30 – 1213.0	806.39 $\pm$ 206.76	835 (656.5–856)

IQR: Inter quartile range  
Standard deviation

SD:

#### Evaluation techniques

To guarantee uniformity in measuring bone density in the CBCT software, an estimated 1-mm square Region of Interest (ROI) will be chosen for assessment at each site where the newly gained bone was formed. The ROI is mostly made of trabecular bone (34).

#### 6. Histology

Histological evaluation of the gingival soft tissue of one of the cases studied showed the overlying soft tissue to be of normal histological appearance despite premature membrane exposure.

#### Evaluation techniques

A part measuring 3x3mm of the overlying keratinized gingiva only was removed, related to an exposed underlying zirconia membrane.

## DISCUSSION

In the last several decades, guided bone regeneration techniques have advanced significantly. A basic GBR method entails using a barrier to separate the site and shield the underlying blood clot and bone graft (5,14,35,36). It has been disclosed that an optimum barrier stabilizes the graft and also prevents epithelial and connective tissue cells from seeping into the grafted location from the bordering soft tissues (16,37).

The chance of using a perfectly biocompatible material that can be easily customizable for each situation, simple to use, and resistant to microbial colonization, opens up new and significant opportunities for zirconia to be used as a material for GBR (30).

As for its unique characteristics as a barrier material, Zirconia was chosen because as opposed to titanium, it induces a more favorable fibroblast response, lower biofilm adherence as well as lower inflammatory reaction. While biologically more favorable than titanium, it is brittle in nature

and if less than 0.5 mm in terms of thickness, it can sustain stress but cannot be reshaped, nor it is a flexible material (30).

Zirconia membrane thickness was uniform in all cases (=0.7mm) as done by Malmström et.al in their study.

Both mesio-distal and labio-palatal dimensions were variable from one case to another according to the three-dimensional morphology of the bony defect and amount of bone augmentation needed for an optimal three-dimensional future implant placement.

Only one case in our study has undergone immediate GBR with the custom-made zirconia membrane following extraction of teeth #11, #12 and #13.

One case has undergone GBR with the custom-made zirconia membrane after about 3 years of extraction of teeth #12 and #13.

Rest of cases has undergone this technique after recent extractions of upper anterior teeth by about 6-8 weeks

All cases have received zirconia membrane with xenograft bone substitute underneath and were left to heal for 6 months postoperatively, also on membrane removal appointment, also all cases received PRF membrane sutured to the edges of the soft tissue defect.

Periosteal sutures were done in 7 cases out of 10 and have proved to delay the onset of premature membrane exposure.

Our very first case to be done had complications occurring in the form of premature membrane exposure 1 week postoperatively and membrane was removed three months postoperatively due to loss of bone graft material outside the surgical site, most probably due to: faulty membrane design (thickness of membrane was more than the proposed thickness of 0.7mm, was over contoured, no periosteal sutures were taken and therefore; there was tension along the incision line which later lead to a soft tissue dehiscence due to muscle pull in this area. As for the management of this case, PRF membrane was placed and sutured to edges of soft tissue defect after membrane removal and the patient was followed for three weeks till complete healing occurred.

The following two cases we tried to modify both the flap and the membrane design in an attempt to solve the complication of the premature exposure which occurred in the first case.

The first modification to be done was to make the incision line palatally based, that was done so that the mucosal sutures are away from any tension made by the lip movement. Unfortunately, premature exposure occurred 1 week postoperatively along the palatal incision line, that was most probably due to decreased blood supply to the palate and its tough mucoperiosteum.



The next modification to be done was to design the membrane with a lesser palatal extension. Also, premature exposure occurred 1 week postoperatively and that was also most probably due to absence of periosteal sutures taken before final flap closure.

One of the positive things about zirconia membranes, if they are accurately designed, is that although premature exposure occurs; no loss of bone graft material outside the flap takes place. That is due to the precise fit of the membrane to the bony defect, its stability, as it is fixed with 2 titanium screws labially, and its adapted edges to the host bone thus preventing the escape of the bone graft material outside the membrane if premature exposure occurred.

Periosteal sutures were taken in all of the following cases using vicryl 5/0 sutures and a noticeable delay in premature membrane exposure occurred, which ranged in onset from 2 weeks to 16 weeks postoperatively.

All cases were followed up for 6 months postoperatively, and that was relatively similar to the follow up period proposed by F.Mandelli et. al in their clinical trial which had a range of 3-7 months, and also the follow-up period proposed by Heikal et. al in their study which was 6 months for all cases, and Hofferber et. al case report where they left the membrane in place for 6 months for one case and 8 months for the other case.

Thickness of zirconia membrane in all cases were the same (=0.7mm) which is similar to the thickness used in the pilot study done by Malmström et al.

One case in our study was similar to a case done by F.Mandelli et al as regards to the onset of premature zirconia membrane exposure which was 1 month postoperatively.

As regards to the percentage of the total cases where premature zirconia membrane exposure occurred in our study, that was not comparable to any previous study working on zirconia membranes for GBR treatments; and that may be due to that our study is the first to use zirconia membrane for GBR procedures in the maxillary anterior region. This area in the oral cavity is anatomically characterized by strong muscle pull due to lip movement.

As for the sterilization technique, it was done following the sterilization steps done in the pilot study executed by Malmström et al.

On removal of the zirconia membrane, a soft tissue layer below the membrane was detected clinically in all cases, his observation has previously been investigated with the use of both custom-made titanium and zirconia matrices/ sheets (19, 22, 38).

This layer was histologically studied previously by Malmström et al. in their study, and it was found to be a periosteal-like tissue due to its origin between the newly gained bone and the zirconia membrane, where it showed connective tissue with no

inflammatory reaction and bone trabeculae were observed on the edges.

Also the histology of the newly formed bone under the zirconia membrane was previously studied by F. Mandelli et al in their study, where it showed new formation of blood vessels starting from the periosteal layer or from the connective tissue layer laying above the periosteal layer, and this observation might be a reason for the observed increased osteogenic potential. Comparable histological findings were observed by Malmström et al where they found normal osteoblastic and osteoclastic activity in a mature marrow stroma with dilated vessels having thin walls.

Regarding the vertical bone gain in our study, the resultant average was equal to  $5.58 \pm 1.26$ mm which is considered to be higher than the average vertical bone gain results of a study done by Malmström et al which was equal to 2.9mm and another study made by Hofferber et al which was equal to 3mm in one case in their study.

Concerning the horizontal bone gain, the average outcome of the results in our study was equal to  $2.18 \pm 1.05$  mm which is nearly similar to the results of one case in a case report executed by Hofferber et al which was equal to 3mm.

As for the density of newly formed bone, the results of the cases in our study gave an average of  $806.39 \pm 206.76$  HU which is considered to be higher than the results of cases in a study done by Heikal et al which gave an average of 371.3 HU.

To measure dimensions of newly formed bone in both vertical and/or horizontal dimensions, CBCT overlay technique was done, this technique was also used in the pilot study executed by Malmström et al.

## CONCLUSION

Although custom-made zirconia membranes showed to be technique-sensitive when used in the maxillary anterior region, it proved to be a stable space-maintaining device to be used in GBR procedures, maintaining bone graft material through-out the whole healing period, and even when prematurely exposed, it showed excellent soft tissue reaction and postoperative successful bone gain radiographically.

## Conflict of Interest

The authors declare that they have no conflict of interest.

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