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*Preliminary Study*

# New titanium mesh design method in customized bone regeneration of the jaws: preliminary study on a sample of 11 patients

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**DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.**

## ABSTRACT

**The aim of this study is 1) to present a new method of virtually-designed custom made scaffolds to be employed in customized bone regeneration (CBR) for segmental jaw atrophies and 2) to evaluate long-term clinical results in terms of bone regeneration success and implant rehabilitation success. A total of 11 patients with edentulousness and bone atrophy in a localized area of the mandible or the maxilla were recruited for the study. To fulfill the research inquiries, CT images of the pre-regeneration mandibular or maxillary arch of each patient were collected. A dedicated Mevislab 2.4 software was employed to virtually design custom bone regeneration meshes designed to fit the atrophic sector of each patient's mandible or maxilla. Subsequently, a second Meshmixer software was used to refine the margins of each of the designed meshes. All patients underwent oral surgery, during which a mixture of autologous and heterologous bone in a 1:1 proportion was grafted into the atrophic site, a custom-made mesh was placed, and a resorbable membrane was inserted. The mesh was removed after this procedure, and implant rehabilitation was performed. All patients underwent the bone regeneration procedure, with eight undergoing titanium mesh removal. A total of seven patients completed implant rehabilitation. Average horizontal bone augmentation was 3.525 ± 1.36 mm; average vertical bone augmentation was 4.45 ± 2.22 mm. Implant survival was 92.85%. During the healing phase, complications occurred in 9.09% of patients. The use of dedicated software, Mevislab 2.4 and Meshmixer, for titanium mesh design is an accurate, predictable, effective, and quick-to-use method. The learning curve for design is uncomplicated and rapid. Mesh exposure does not necessarily lead to bone graft failure; this complication can be treated by chlorhexidine aids.**

## INTRODUCTION

Conceived and introduced by Dahlin in 1988, Customized Bone Regeneration (CBR) (1, 2) is a bone regeneration technique used in dental and maxillofacial fields to recreate adequate bone tissue regeneration as a preliminary step to the placement of dental implants in implant-retained jawbone rehabilitation (3–7). Generally, bone defects are due to post-extraction sites, post-excision cyst sites, bone sites damaged by peri-implantitis, or sequelae of dental trauma in childhood (8). CBR requires three-dimensional augmentations of the alveolar ridge. Given that implants require an adequate tissue quantity surrounding the implant surface, proper implant placement cannot be separated from adequate bone rehabilitation.

Whatever the defect to treat (5, 9), two fundamental elements are mandatory in successful bone regeneration: bone augmentation materials and membranes. In recent years, several bone regeneration techniques using different materials, both resorbable and non-resorbable, have been proposed to restore bone volumes for implant placement (10, 11), given that nowadays, the minimal bone quantity is related to the type of implant rehabilitation being considered for the specific patient (12).

Tables I and II show that multiple regeneration materials and resorbable scaffolds are available for CBR (13-15); titanium meshes are classified as non-resorbable scaffolds (16-20). Titanium mesh creates and maintains the space necessary for bone regeneration: it protects the bone defect from the proliferation of rapid epithelial and connective tissue cells (6, 21) so that osteoprogenitor cells are capable of growing. CBR is a promising method for the rehabilitation of alveolar bone defects due to its replicable protocol and excellent results achieved in the long term.

**Table I**. *Resorbable and non-resorbable membranes.*

| REASORBABLE MEMBRANES | | NON-RESORBABLE MEMBRANES |
|---|---|---|
| Biological Origin | Synthetic Origin | Synthetic Origin |
| Collagen I and III<br>Silk | Ac. Polylactic (PLA)<br>Ac. Polyglycolic acid (PGA)<br>Ac. Polylactic + Polyglycolic<br>Polyurethane<br>Polyethylene glycol (PEG)<br>Polyester (POE) | Politetrafluoroetilene (PTFE)<br>Expanded Politetrafluoroetilene (e-PTFE)<br>Dense Politetrafluoroetilene denso (d-PTFE)<br>Expanded Polytetrafluoroethylene (e-PTFE) + Titanium<br>Grade 2 Titanium modelled at the time of surgery<br>Custom-made Titanium |

**Table II**. *Bone augmentation materials.*

| BONE AUGMENTATION MATERIALS | |
|---|---|
| Autografts | Obtained from the same individual. |
| Allografts | Obtained from another individual within the same species. |
| Xenografts | Obtained from another species. |
| Alloplastic materials | Synthetically derived |

A site treated by CBR heals similarly to a fracture. In the first days, the hemostasis phase occurs with the formation of a blood clot; the coagulation cascade leads to a fibrin clot that stops the bleeding. In the following three weeks, macrophages remove the clot, and granulation tissue takes place; this tissue is rich in blood vessels and allows the migration of endothelial and mesenchymal cells. The third phase involves osteoconduction; finally, preosteoblasts migrate toward the site where bone neoformation will occur. The fourth phase occurs after four to six weeks with the formation of primary bone, known as woven bone or woven bundle bone, which is the result of rapid expansive growth (up to 60μm per day) to fill the spaces initially occupied by blood clots (22). Subsequently, the woven bone will be remodeled and replaced with secondary lamellar-structured bone from the sixth week of the healing process.

The aim of the study is to describe a new design method of scaffolds for customized bone regeneration. The study also aims to compare the advantages and disadvantages of this protocol. We were interested in verifying whether the in-house-project of scaffolds results in better surgical planning and saves time in scaffold design and fabrication. Furthermore, this preliminary study is meant to pave the way for realizing resorbable scaffolds and have them printed with type I and III collagen bio-inks (23, 24).

## MATERIALS AND METHODS

A preliminary retrospective longitudinal study was conducted on a sample of 11 patients with edentulous mandibular or maxillary sectors with residual bone size inferior to 8mm in height and 5mm in width. These parameters made the mandible unsuitable for implant treatment. Medical history and CT scans were collected for each patient enrolled in the study. Titanium meshes were designed following the steps described below.

### *Mesh design*

Preliminary design steps were performed in Mevishlab 2.4, then Meshmixer was employed to finalize mesh contours. Detailed design phases are presented below.

1. *Selection of region of interest.* Using a visualization tool to analyze the three-dimensional CT image in the three orthogonal planes, the operator selects the orthogonal plane of work and the minimum volume affected by the defect (Region of Interest, ROI), which will be the subject of guided bone regeneration (Fig. 1).

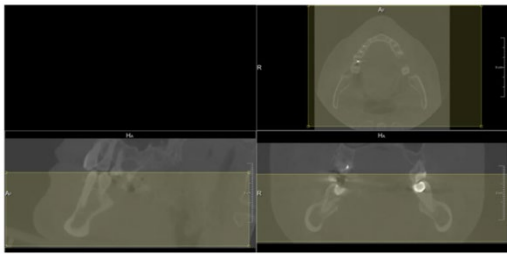

**Fig. 1**. *Region of Interest (ROI) selection on CT.*

2. *Hard Tissue Segmentation.* This step is accomplished through a semiautomatic procedure called Region Growing, which requires the operator to select one or more voxels defined as seeds and the range of Hounsfield values (Fig. 2).

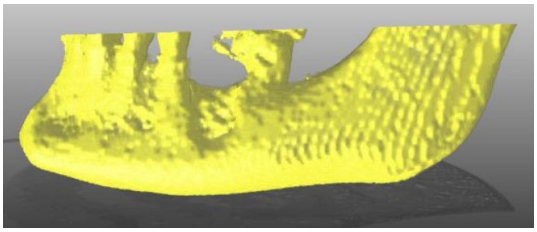

**Fig. 2**. *Mandibular segmentation: a 3D model of the mandible is created by the dedicated software Mevishlab 2.4.*

3. *Membrane profile design.* The design of the three-dimensional membrane profile is accomplished by interpolation of two-dimensional figures drawn by the operator in specific sections of interest. The operator performs several steps in each section:
   Step 1. The initial step is delineating the fundamental contour, represented by an ellipse of variable dimensions (Fig. 3).
   Step 2. The subsequent step involves the positioning of the contour, which can be enhanced through the application of rototranslation operations (Fig 3).

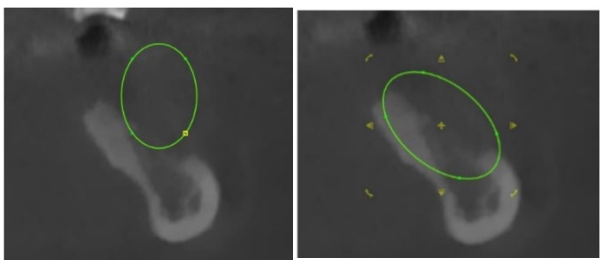

**Fig. 3.** *Delineation of the fundamental contour.*

Step 3: The contour shape is modified.
The shape of the ellipse can be modified to align with the patient's morphology through a variety of operations, including scaling, local deformations with variable size, augmentation, and/or subtraction of areas drawn freehand (Fig. 4). In order to facilitate the design process, the operator may utilize measurement tools that provide the distance in millimeters between two user-selected image points.

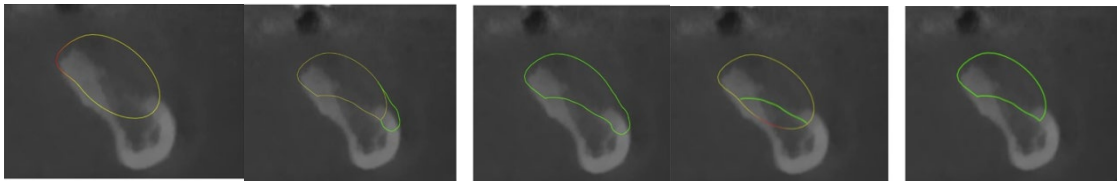

**Fig. 4**. *The contour shape is modified.*

4. *Interpolation*. The two-dimensional shapes thus created will then undergo an interpolation process, resulting in a three-dimensional object (Fig. 5). The hard tissue will be subjected to a morphological dilation filter with a spherical kernel of variable size, determined by the operator. The "object" will then be subtracted from the volume obtained from the interpolation operation (Fig. 6). The accuracy of the work is verified using a three-dimensional rendering tool that allows simultaneous visualization of the three objects: the original CT, the segmentation result (hard tissue), and the membrane profile (Fig. 7). The fusion of the three objects can then be visualized by roto translation or zoom operations, clipping according to orthogonal planes, and orthogonal plane transparency operations. In addition, the tool allows for the variation of the degree of transparency of the three objects, which aids in the analysis.

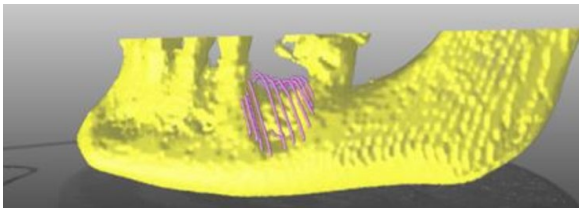

**Fig. 5**. *Design before interpolation.*

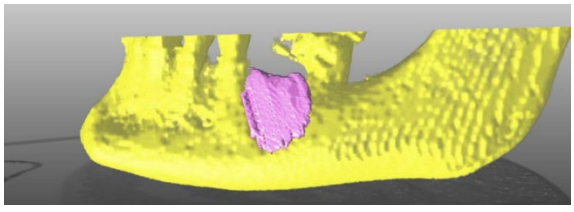

**Fig. 6.** *Result after interpolation.*

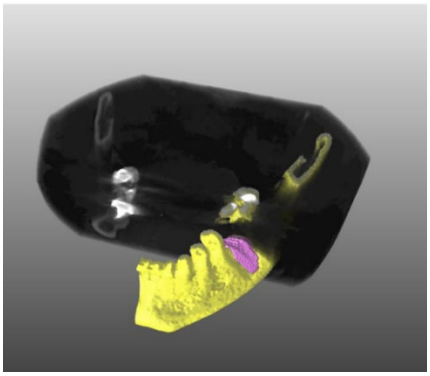

**Fig. 7**. *Rendering tool in three dimensions.*

5. *Thickening*. The obtained profile is then processed by means of a morphological dilation filter with a variable-size spherical kernel (3 voxels in x, y, z). This process creates an initial design of the membrane (Fig. 8).

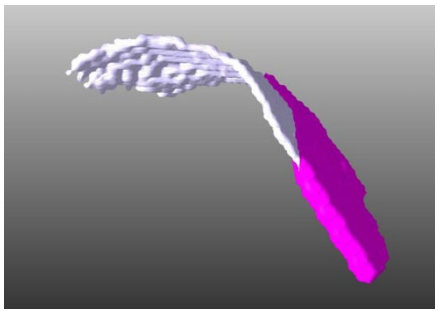

**Fig. 8**. *Membrane thickening.*

6. *Finishing the design in Meshmixer*. The final stage of the design process consists of completing the surface obtained in Meshmixer. The final shape is achieved by using dedicated tools within the software, including Flatten, Inflate, RobustSmooth, and ShrinkSmooth, which all aim to sculpt 3D objects (Fig. 9).

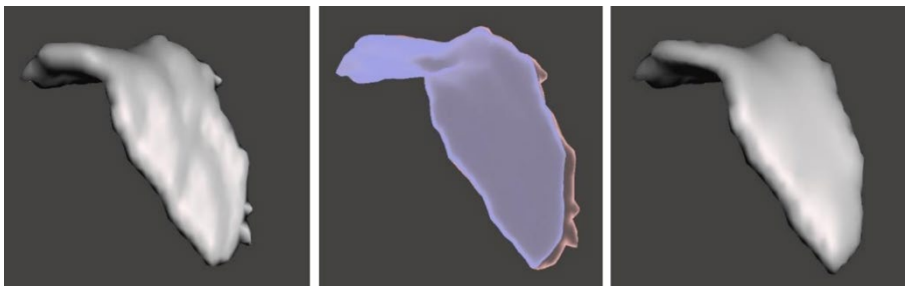

**Fig. 9**. *Membrane refinement with Meshmixer.*

The mesh design is finally checked by the team of oral surgeons who will perform the CBR procedure. Once the virtually designed membrane is deemed ready for printing, it is sent to the manufacturing company. It is sterilized in a steam autoclave and ready for clinical use.

*Scaffold printing*

The pivotal point of the study was scaffold printing using a BIOX Cell Ink 3D printer and bio-inks. As described in the previous paragraph, the scaffolds are designed starting from the TC scan; once the project is completed, the scaffolds are ready to be printed. The BIO X 3D printer represents a significant advance in 3D printing, developed to enable the fabrication of complex objects using biological and biocompatible materials. This printer combines the precision of printing with the ability to work with biomaterials, paving the way for new applications in regenerative medicine (Fig. 10).


**Fig. 10**. *Bio X printer.*

Its robust structure provides a stable foundation for printing; components might be added to customize the printing process. With a touchscreen display, the user interface enables intuitive control of the printing process, from material loading to parameter configuration. The printer works with diverse biological materials, including hydrogels, biocompatible polymers, and live cells. This printer is designed to maintain the integrity of biological materials during the extrusion process, thereby ensuring high cell survival and uniform distribution of materials. It is equipped with three bioink ports. These features allow for independent or simultaneous use with other features, with a single or multiple materials. The printer parameters can be modified by the operator; sensors are in place to detect the working pressure and working temperature. The pressure that can be used is up to 700 kPa, and the temperature can be set from 7°C to 60°C for the base up to 250°C for the upper portion. The printer is also equipped with an advanced cooling system that ensures the rapid solidification of the material, thereby enabling the creation of complex geometries without deformation (Fig. 11).

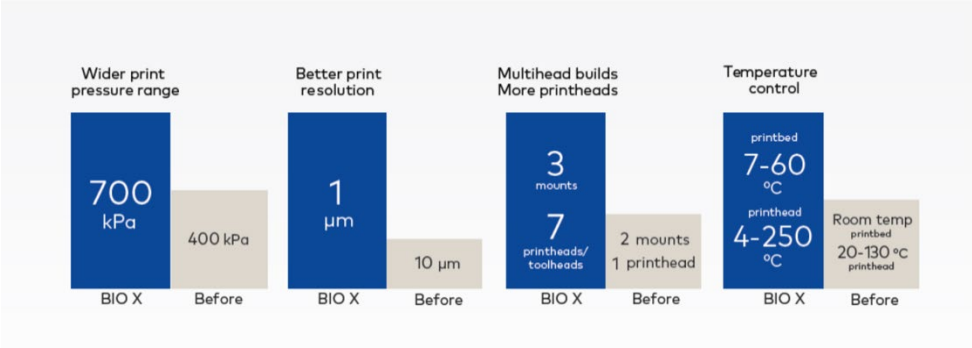


**Fig. 11**. *Bio X printer parameters; previous printer characteristics are indicated in grey.*

*Surgical technique*

The initial incision should be designed in accordance with the extent and location of the site undergoing CBR in a manner that increases bone volume while respecting adjacent anatomic structures such as the maxillary sinus, nerve structures, vascular structures, and ligaments. A mucoperiosteal flap with a wide base allows for an adequate blood supply. The periodontal condition of adjacent teeth and their prosthetic support should also be considered. The healing process is positively affected by making a full-thickness incision avoiding tissue compression during mobilization of the flap and a marginal incision, especially if one is in an esthetic area. When the titanium grid / resorbable scaffold is inserted, it is essential to ensure that the periosteum and flap are not damaged or perforated and that mobilization of the flap is passive. The incision should be made in a manner that allows for the comfortable placement of the scaffold, considering the presence of a larger graft volume. Following suture removal and throughout the course of wound healing, the soft tissue situation was clinically monitored on a regular basis to detect the presence of dehiscence or signs of inflammation at an early stage.

In case a titanium non-resorbable mesh is used, after a healing period of approximately nine to twelve months, the mesh is removed. The same initial incision line is recommended to be used when removing the mesh. Following the preparation of the mucoperiosteal flap, a well-vascularized volume increase and possible osteoblast/osteocyte growth through the grid can be observed. The grid is mobilized via the facilitated removal function by lateral extrusion movements without affecting the achieved bone augmentation.

## RESULTS

Of the 11 patients involved in the study, 7 were female, and 4 were male (Table III); 5 were treated for atrophies in the upper jaw, and 6 were treated for mandibular atrophies. All patients performed the bone regeneration procedure, 8 performed titanium mesh removal, and 7 completed implant rehabilitations.

**Table III**. *Results of patients involved in the study.*

| Patient | Gender | Age | CBR site |
|---|---|---|---|
| 1 | F | 43 | 22-23-24 |
| 2 | F | 51 | 36 |
| 3 | F | 62 | 13-11-23-24 |
| 4 | F | 51 | 36 |
| 5 | F | 48 | 11-12-13-14 |
| 6 | M | 49 | 14-15-16 |
| 7 | F | 49 | 36 |
| 8 | M | 55 | 46 |
| 9 | M | 36 | 46 |
| 10 | M | 58 | 15-12-22-25 |
| 11 | F | 38 | 11-12 |

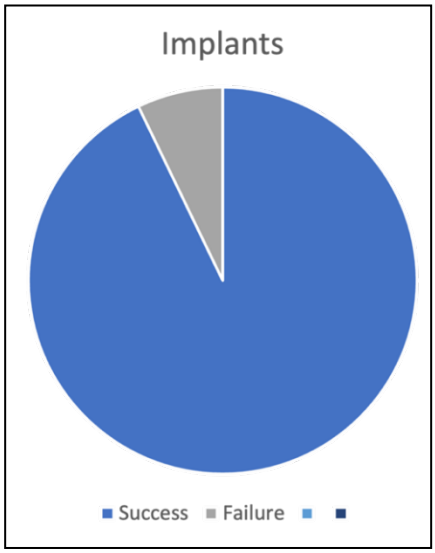


**Fig. 12**. *Implant survival.*

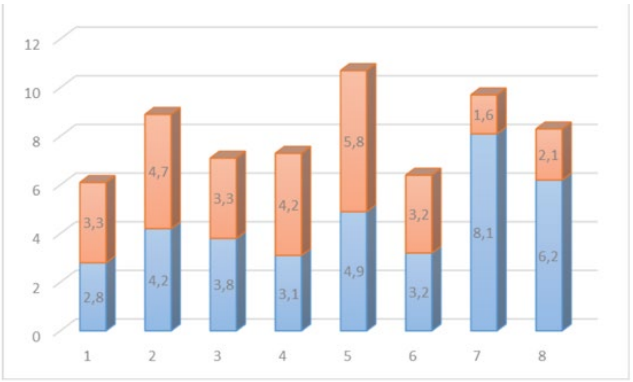


**Fig. 13.** *In blue, the initial width of the alveolar ridge. In red is the extent of width augmentation after treatment.*

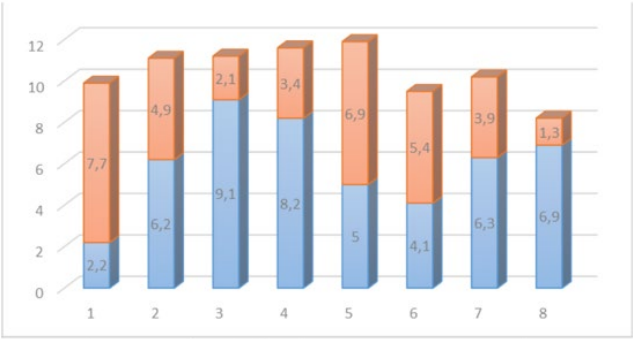


**Fig. 14**. *In blue, the initial height of the alveolar ridge. In red is the extent of height augmentation after treatment.*

Each patient had a CBCT performed to study atrophy and to allow for a titanium mesh design. The surgeries were performed under loco-regional anesthesia using one of the following surgical techniques for flap setup;

"ridge incision", "poncho technique," and "modified poncho technique". A non-resorbable YXOss CBR titanium membrane was used, filled with a mixture of homologous/heterologous bone in a 50:50 ratio as graft material, and covered with a resorbable membrane.

All patients were followed in the healing phases; of these, 8 patients completed the regenerative phase. Seven patients undertook the implant-prosthetic phase. The healing phase was smooth in the 9-12 months postoperatively; therefore, the implants were placed at the same time as the titanium mesh removal surgery. Only one patient reported membrane exposure during the healing period; the complication was treated with chlorhexidine 0.2% mouthwash and chlorhexidine 1% gel. Fourteen dental implants were placed, and only one implant was lost less than 1 year after placement. No other implants were lost after that. On average, patients after the implant-prosthetic phase were followed for 4 and 6 months (minimum follow-up of 3 years and 6 months, maximum follow-up of 5 years and 6 months).

CT scans performed before and after guided bone regeneration surgery evaluated bone augmentation in terms of change in horizontal and vertical measurement of the bone itself.

The mean horizontal augmentation was 3.525 ± 1.36 mm; the mean vertical augmentation was 4.45 ± 2.22 mm. Implant survival was 92.85%. Complications during the healing phase were 9.09%.

## DISCUSSION

Guided bone regeneration of horizontal and vertical defects is a challenging surgical procedure, particularly in the presence of extensive bone atrophy (10). Studying residual bone tissue's morphology, quantity, and quality is essential to successfully plan customized bone rehabilitation and achieve satisfactory rehabilitation goals.

A review of the literature by Patil indicates that both resorbable and non-resorbable membranes are effective in guided bone regeneration (25). According to the literature, type I and III collagen is the most widely used material for resorbable membranes (26, 27). It is mainly obtained from animals such as pigs or cattle. The use of this material has several advantages. For instance, there are fewer postoperative complications, the resorbable scaffold is not exposed during the healing process, and it does not require a second surgical procedure to remove the membrane. However, it has disadvantages, including poor stiffness, which necessitates the use of dedicated screws or specific sutures to maintain the scaffold in its appropriate position. Additionally, there is a lack of control over resorption over time, with resorption varying between 4 and 24 weeks. Finally, the authors stated that micromovement of the resorbable scaffold is possible during the healing phases (26).

This study hypothesizes the possibility of printing custom-made scaffolds with type I and III collagen bio-inks, which have already been approved for use on humans. In addition to the previously described advantages, the use of custom-made resorbable membranes could reduce operative time, considering that the scaffolds available in commerce are resorbable, have standardized dimensions, and the operator must modify them to fit the site to be regenerated during surgery. Furthermore, precise custom-made support could reduce the problem of micromovements during the healing phases. Moreover, the surgeon might be able to directly modify the scaffolds, taking into account the importance of soft tissue and noble oral cavity structures that must not be damaged in surgical procedures (28), coming to a point where scaffolds could also be in-house made (29).

Today, the only custom-made scaffolds for guided bone regeneration available in the commerce are titanium meshes. The fabrication process for these membranes involves several steps and takes approximately 21 days.

The operator's role in these stages is to forward CT files of less than 128MB in size to the manufacturing company and then request design changes. In our study, the operator himself utilizes the software to virtually create the custom-made scaffold, and this step requires a far shorter time, which is estimated to be of approximately two to three days. In most cases, the time required for the scaffold design depends on the intricacy of the bone atrophy to be regenerated. The following passage will be scaffold-printing with bio-inks, and the patient will then undergo surgical intervention. According to Troeltzsch (30), the utilization of resorbable membranes is associated with a reduced incidence of complications in comparison to titanium meshes, with a rate of 10.2% in the former versus 21% in the latter, which is an additional advantage of in-house projecting and printing of resorbable scaffolds to be used in CBR. The feasibility of our design is also confirmed using easily manageable programs like Mevislab 2.4 and Meshmixer. To confirm the research, continuing the CBR study by printing the membranes in collagen and experimenting with them on patients is recommended.

Regarding the experiment on CBR with titanium mesh, the decision to use a 50:50 mixture of autologous and heterologous bone was guided by the results found in the literature; in fact, Troeltzsch states that in GBR procedures, bone formation in the regenerated areas increased by 33.1% ± 14.9% with the use of allogeneic grafts and 56% ± 25.6% with the use of autologous grafts mixed with other graft material. In the same work, the average horizontal gain was 3.7 mm ± 1.2 mm with a difference of 2.2 mm ± 1.2 mm using synthetic material alone and 4.5 mm ± 1 mm using a mixture of autologous/heterologous bone (30).

In the present study, the mean horizontal bone gain was 3.525 ± 1.36 mm, a value consistent with the average result obtained by Troeltzsch and higher than his horizontal bone gain obtained using only synthetic material.

In their literature review, Rasia Dal Polo et al. evaluated the reliability of titanium mesh in GBR procedures by considering 17 articles; the author found a mean horizontal gain of 4.36 ± 1.29 mm and a mean vertical gain of 4.91 ± 2.35 mm, which is in line with our results for a mean horizontal gain of 3.525 ± 1.36 mm and a vertical gain of 4.45 ± 2.22 mm. The variability may be due to the small case series of our study (31, 32).

In terms of complications, only one titanium mesh was found to be exposed during the healing period in the present study, and such a limited percentage of complications was probably due to treatment with chlorhexidine 0.2% mouthwash and chlorhexidine 1% gel. In fact, no titanium mesh was removed prior to the predetermined bone healing period.

In terms of implant survival, the results obtained here are also better than those reported in literature, with a survival rate of 92.85% at a mean follow-up of 4 years and 6 months, compared to 89.9% found by Rasia Dal Polo at a mean follow-up of 9 months. The positive result is likely to confirm the viability of the applied method (31).

## CONCLUSIONS

The use of dedicated software, Mevislab 2.4 and Meshmixer, for titanium mesh design is an accurate, predictable, effective, and quick-to-use method in customized bone regeneration. The operator acquires sufficient expertise with the software in relatively short time, making the learning curve rapid and uncomplicated.

Future research will focus on the comparison between the size of a resorbable-3D-printed scaffolds to the size of titanium meshes. Preliminary results seem to confirm the validity of this procedure, owing to the almost negligible discrepancy between traditional titanium mesh and resorbable-3D-printed membranes.

According to the findings of this study, mesh exposure does not necessarily lead to bone graft failure; anyway, this is a possible complication that can be promptly treated by chlorhexidine aids.

To substantiate the efficacy of this procedure, further research and clinical employment of new technologies are recommended.

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