

Linear Bone Gain and Healing Complication Rate Comparative Outcomes Following Ridge Augmentation with Custom 3D Printed Titanium Mesh vs Ti-Reinforced dPTFE. A Randomized Clinical Trial

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Received: 22 March 2024 ♦ **Accepted:** 21 June 2024 ♦ **Published:** 31 August 2024

Citation: Giragosyan K, Chenchev I, Ivanova V. Linear bone gain and healing complication rate comparative outcomes following ridge augmentation with custom 3D printed titanium mesh vs Ti-reinforced dPTFE. A randomized clinical trial. Folia Med (Plovdiv) 2024;66(4):505-514. doi: 10.3897/folmed.66.e123766.

Abstract

Aim: The aim of this randomized clinical trial was to compare the qualitative (linear alveolar ridge changes) and quantitative (healing complications) outcomes after guided bone regeneration (GBR) using a custom-made 3D printed titanium mesh versus titanium reinforced dense PTFE membrane for vertical and horizontal augmentation of deficient alveolar ridges.

Materials and methods: Forty patients (40 defect sites) were included in the analysis. The patients were divided into two groups – a test group that received custom made Ti mesh and a control group which received a titanium reinforced dense polytetrafluoroethylene membrane.

This case series documented consecutive patients treated with vertical bone augmentation to facilitate the future placement of dental implants.

The procedure was performed using xenograft and autograft in a ratio of 1:1. Baseline vertical and horizontal deficiencies, acquired bone height and width as well as absolute bone gain (height and width) were recorded radiographically; postoperative complication rate was recorded clinically.

Results: The absolute bone height acquired for the test group was 3.65 ± 1.73 mm, and for the control group - 4.24 ± 2.19 mm; the absolute bone width acquired for the test group was 2.48 ± 1.03 mm and for the control group - 2.60 ± 0.82 mm. Postop complication rate was 33.3% for the test group and 38.9% for the control group.

Conclusion: The use of a custom-made 3D printed titanium mesh for needs of vertical and horizontal guided bone regeneration showed results comparable to those of – Ti d-PTFE both in terms of height and width gain and complication rate.

Keywords

bone grafts, vertical ridge augmentation, titanium mesh

INTRODUCTION

Guided bone regeneration (GBR) with particulate graft has enabled practitioners to offer patients more predictable and long-lasting implant treatment modalities. Despite the evolution of techniques and materials, the regeneration procedure still requires great skill and knowledge on the part of clinicians and cooperation and understanding from the perspective of patients.^[1]

The consensus in the literature is that the location of the defect dictates the choice of barrier membrane.^[2] This is so that sites with a vertical deficiency cannot maintain the stability of the graft during the healing process if a resorbable (in other words, unstable in shape) membrane is placed over them. For these reasons, such cases require the use of a rigid (stable in shape) non-resorbable membrane to be used by the practitioner in Wang's 'PASS' principle of guided bone regeneration.^[3]

Currently, there is enough clinical evidence that titanium reinforced polytetrafluoroethylene (PTFE) membranes are the gold standard for vertical GBR.^[4] Historically, PTFE was used in its expanded variant with pore size $<8 \mu\text{m}$ assisting connective tissue attachment to the membrane, thereby stabilizing the incision line area. Later, dense PTFE was devised with a pore size of $<0.3 \mu\text{m}$ with the intention of protecting the grafted bone in case of wound dehiscence. With the development of mobilization techniques, the lesser concern for postoperative complication enabled the use of Ti-reinforced PTFE meshes^[5], which utilize the vascularization from the periosteum.

Still, one important aspect of the procedure is the graft stabilization for which fixation appliances are used such as bone screws and tacks. Another factor that takes up moderate amount of surgical time is the membrane shaping, especially if the case involves teeth anterior and posterior to the edentulous area. All those reasons led to the creation of the custom printed titanium graft stabilization meshes. The premade medical devices conform to the patients' bony anatomy, the grafted volume can be planned ahead of the surgical procedure and require less fixation appliances, not at the expense of the graft stabilization.

Since custom made 3D printed titanium meshes are a relatively new entity in the field of bone regeneration, we decided to investigate their clinical behavior and compare it to the already established Ti-reinforced PTFE.

AIM

1. To compare the amount of bone height gain in millimeters radiographically, using titanium reinforced dense PTFE membrane vs. patient specific, 3D-printed titanium mesh using a ratio of 50:50 xeno- and autograft.
2. To examine the influence of the two graft stabilization devices on postoperative complications (healing complications).

MATERIALS AND METHODS

This study was designed as an independent, monocentric, parallel group, randomized, controlled clinical trial, in which the variables were prospectively analyzed. The study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of the Medical University of Plovdiv with registration number P-183 (22.01.2021).

The criteria to be evaluated are gained bone height and width, radiographically, after the healing period and the occurrence of healing complications. A statistician calculated that the sample size necessary to obtain statistically significant results for those objectives was 20 subjects per group. In group A, the GBR procedure was carried out using a custom 3D printed titanium mesh - test group, whereas in the control group, the patients received Ti-reinforced d-PTFE membrane.

Inclusion and exclusion criteria

The inclusion criteria were as follows:

- vertical insufficiency that would result in poor crown-to-implant ratio
- edentulous regions with a height of $\leq 7 \text{ mm}$ and a width of $\leq 4 \text{ mm}$
- combined horizontal with vertical defects
- capacity to understand and accept the written conditions of the study.

The exclusion criteria were as follows:

- insufficient oral hygiene
- smoking habit
- acute local and systemic infections
- uncontrolled systemic disease
- patients who underwent radiotherapy
- patients, undergoing immunosuppressive therapy or immunocompromised patients.

After standard patient history was taken, the patients were placed in either group with the use of a simple randomization technique, carried out by a coin toss. The study subjects were enrolled, planned, and treated from 2021 to 2023: 20 patients were assigned to the test group (Ti mesh) and 20 patients to the control group (Ti d-PTFE). Each patient received written information and provided written consent before any study-related procedure.

Digital planning and device production

All candidates for the study underwent a CBCT procedure, where the baseline data for the available bone height and width was gathered.

The DICOM data of the subjects that were designated to the test group was sent to a company that has division for designing and manufacturing patient specific titanium printed medical devices (Biotec Srl). The company then transferred the DICOM files obtained from the CBCT in stereolithography (STL) format (**Fig. 1**).

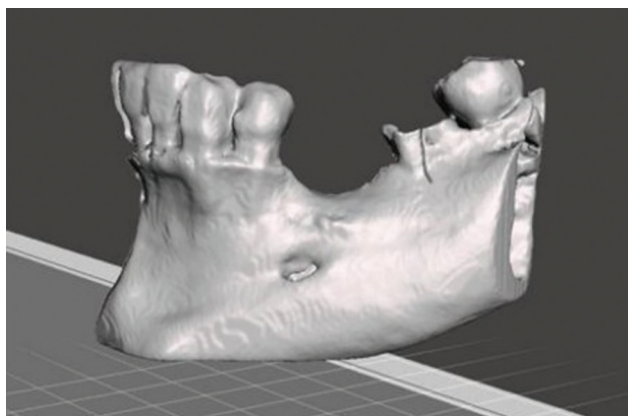


Figure 1. Stereolithographical model of an atrophic alveolar ridge.

From there on, the insufficient bony tissues were recreated virtually, and a mesh-like structure was designed over the simulated “regenerated tissue” (Fig. 2). In addition to that, the openings for the placement of the fixation screws were located away from any vital structures to avoid their impairment. When the digital process was finished, the firm contacted us and asked if any changes needed to be made. The process ended with us agreeing (in writing) to the digital design of the mesh, which gave our partners a green light regarding the manufacturing process which consisted of 3D printing the mesh through the process of select laser sintering (Fig. 3).

From there on, the patients from the test and control group were scheduled for the identical surgical procedure.

Surgical procedure

Written consent was obtained from all patients before the surgery. After anesthesia, the procedure began with a mid-crestal incision in keratinized tissue, which was extended buccally two teeth away (Fig. 4a) and lingually (Fig. 4b) one tooth away from the edentulous site creating the so called “asymmetrical flap”.^[6] From there on, vertical releasing incisions were created alongside the line angles of the teeth involved in the sulcular incision.

Since one of the principles for successful guided bone regeneration is primary intention closure, the flaps needed to be mobilized to facilitate the soft tissue closure over the additionally placed bony tissue. The buccal flap was extended with a simple periosteal releasing incision. In the mandibular cases the lingual flap’s length was managed according to the varying anatomical zones, composing its structure (Fig. 5).

The lingual flap is divided in three zones as proposed by Urban et al.^[7]: the first zone is the retromolar area (Fig. 6a) from which the soft tissue is only reflected with a periosteal elevator; the second zone involves the mylohyoid area (Fig. 6b), and its management involves blunt dissection of the superficial fibers of the muscle; and lastly the third zone – premolar region (Fig. 6c) – in which the tissues are mobilized by a simple periosteal releasing incision.

The aftermath of this intricate lingual flap management technique is a three-fold increase of its length (Fig. 7).

The rest of the surgery involved, perforating the cortical plate of the atrophic alveolar ridge to facilitate angiogenesis

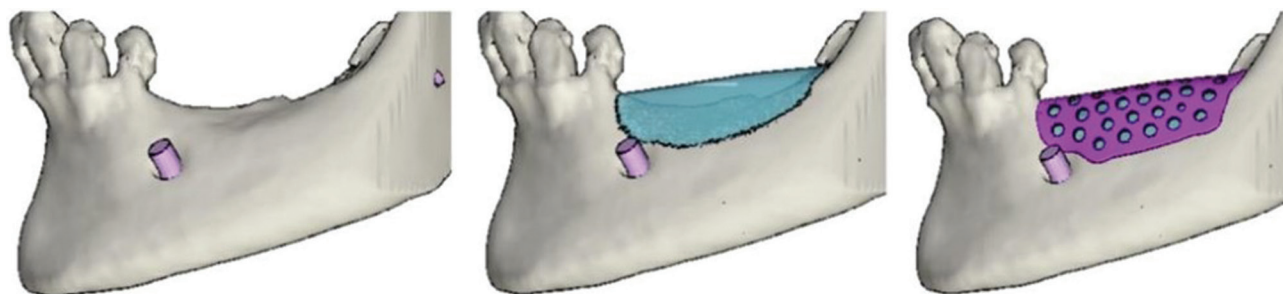


Figure 2. Regenerated tissue over atrophic ridge and design of the patient specific mesh.



Figure 3. Printed patient specific titanium meshes.

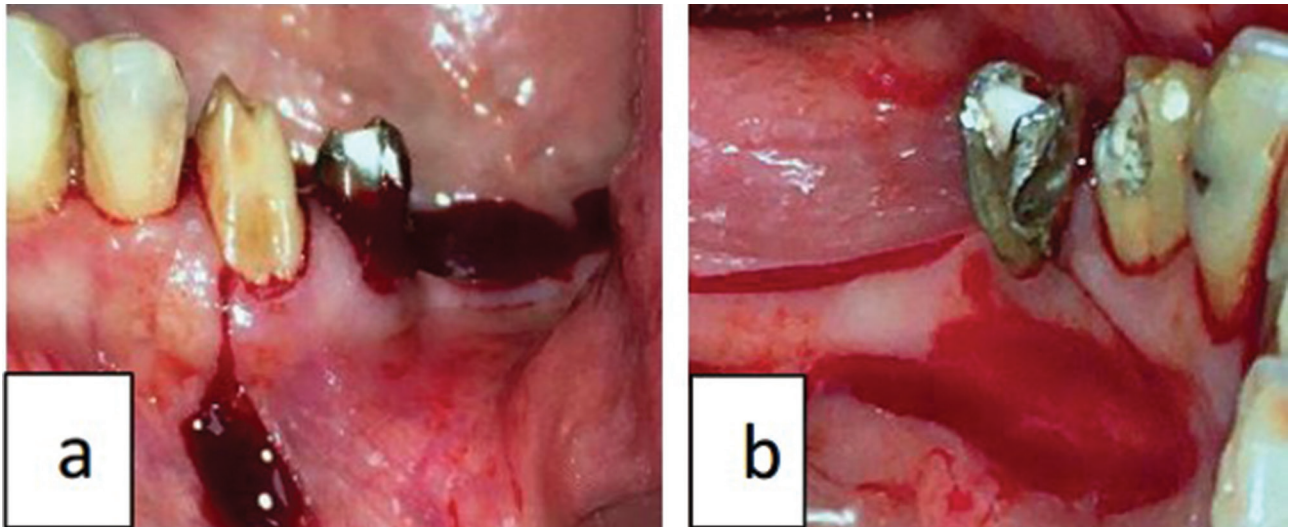


Figure 4. Midcrestal and sulcular incision: a) buccal view; b) lingual view.

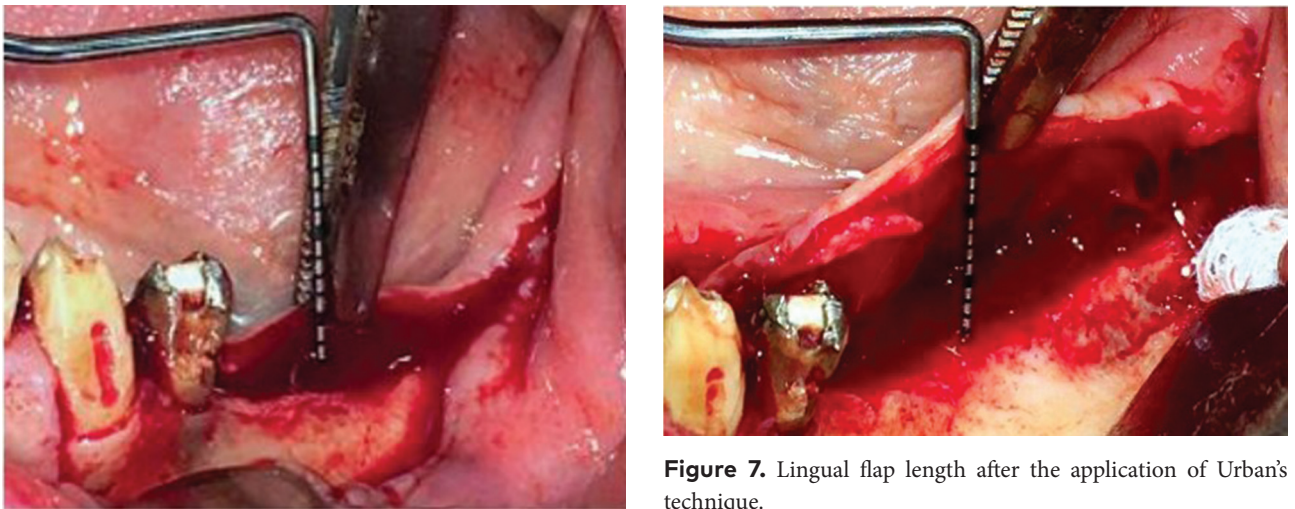


Figure 5. Initial length of lingual flap.

Figure 7. Lingual flap length after the application of Urban's technique.

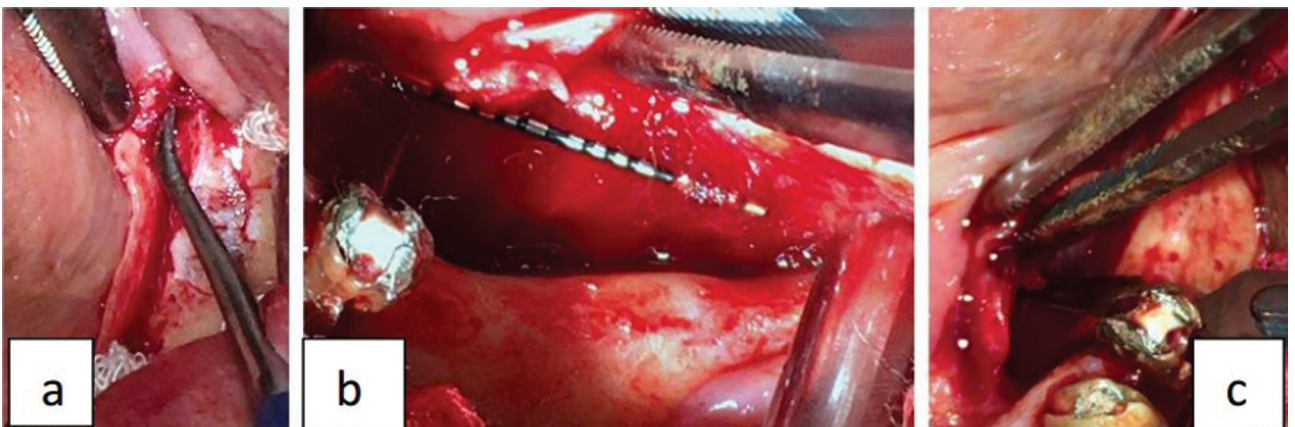


Figure 6. Lingual flap management: a) retromolar region; b) mylohyoid part; c) premolar area.

and harvesting autogenous bone from the oblique line of the mandible with a scraper and mixing it with a xenograft in a ratio of 1:1. This bony mixture was placed either on the inner surface of the mesh in the case of the patients from the test group (Fig. 8a) or on the atrophic ridge in the cases involving Ti d-PTFE membrane (Open Tex-TR, Purgo) (Fig. 8b). After that the meshes/membranes were stabilized with titanium screws (Myungsung CNM).

The surgical procedure ends with a bilayered closure of the augmented region with PTFE sutures – horizontal mattress approximately 8 mm to 10 mm away from the wound edges and coronal to them – simple interrupted sutures (Biotex, Purgo). The patients were given postoperative instructions and were prescribed antibiotics (augmentin 100 mg) and NSAIDs (nimesil 100 mg). Sutures were left undisturbed for 2–3 weeks and the augmented bone was left to heal for at least 6 months. At re-entry, flaps were

elevated, the screws and membranes/meshes were removed and implants (Megagen; Anyridge implants) were placed in the healed sites (Fig. 9).

Data collection

Alveolar ridge height and width were recorded before the surgical procedure. Adjacent anatomical structures were used as reference points to position the coronal slices of the CBCT. After that the values were cumulated separately and a mean baseline height and width were documented for every patient. After the healing period, the same process was repeated, using the same anatomical landmarks and post-procedure mean height and width were recorded and later compared quantitatively (Fig. 10). As for the healing complications, they were assessed qualitatively using the classification by Fontana et al.^[8]

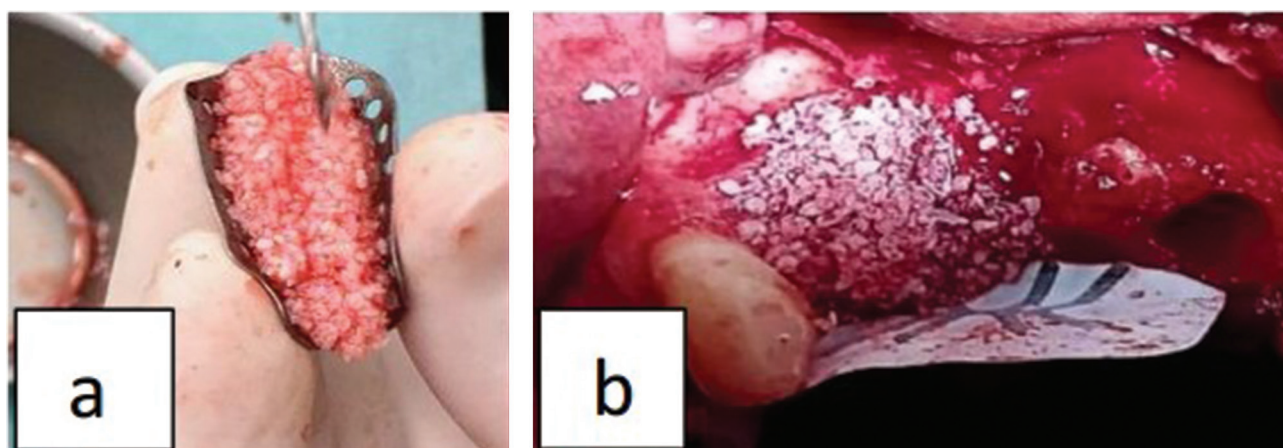


Figure 8. Placement of bony tissue: a) in titanium mesh; b) on top of atrophic ridge with Ti-PTFE membrane, supporting on the posterior.

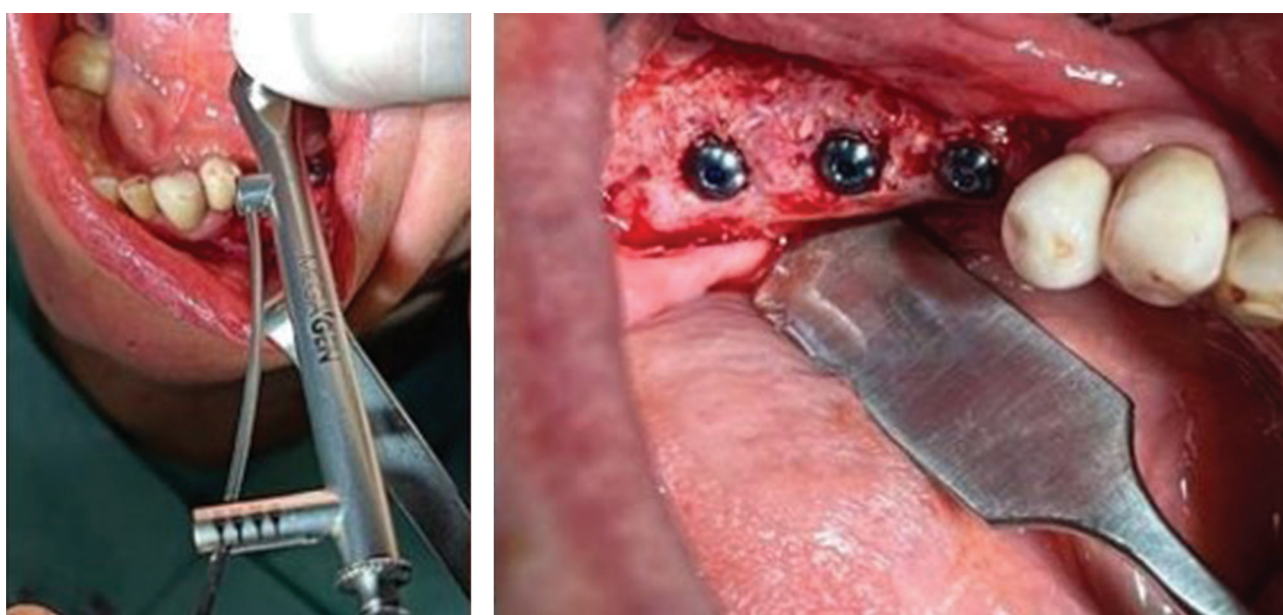


Figure 9. Placement of implants in augmented ridge.

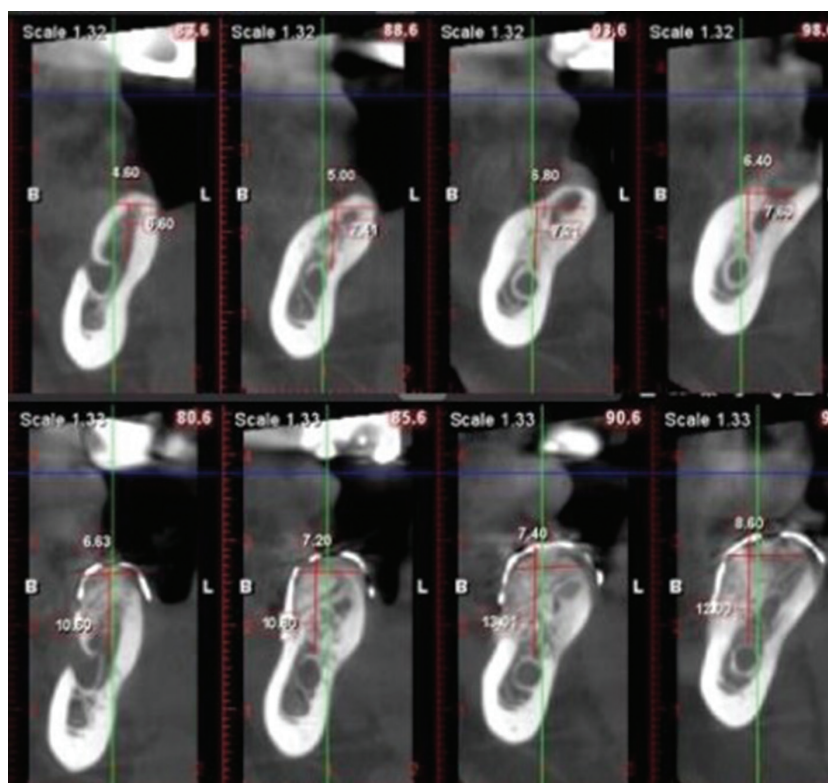


Figure 10. Pre- and post-op measurement of height and width.

Statistical analysis

We used the Minitab statistical software (2022) to estimate the power of a two-sample *t*-test with a sample size of 20 in both study groups. We entered the following parameters: sample size =20, type I error =0.05, assumed minimal difference =2.5, and assumed standard deviation =2.6. The calculation yielded a power of 0.893, indicating almost a 90% accuracy of correctly rejecting a true null hypothesis. The data were analyzed using SPSS v. 27 (2020). Continuously measured variables were screened for normality using the Shapiro-Wilk test. In the presence of normal distributions, the mean values and standard deviations (SDs) were reported, and between-group comparisons were carried out with the independent samples *t*-test. Non-normally distributed variables were described with median values and interquartile ranges (IQRs), and the Mann-Whitney U test was used to compare the groups. The categorical data were presented as numbers and percentages (%), and relationships were determined through the chi-square test and Fisher's exact test. All statistical tests were two-tailed and performed at a type I error (α) of 0.05.

RESULTS

Vertical bone gain

The alveolar ridge height values, including baseline, acquired, and absolute gain, were normally distributed in both groups, and the results were illustrated through individual value

plots in **Fig. 11**. There was no significant difference ($p=0.567$) in the mean baseline height between the Ti-mesh group (9.21 ± 2.67 mm) and the control group (9.82 ± 3.29 mm). The Ti-mesh group's acquired height was 12.86 ± 3.14 mm versus 14.07 ± 3.14 mm in the control group ($p=0.295$). There was no significant difference in the absolute bone gain (acquired – baseline) for the Ti-mesh group (3.65 ± 1.73 mm) and that for the control group (4.24 ± 2.19 mm) ($p=0.400$).

Horizontal bone gain

While the alveolar ridge width values for the baseline and acquired measures were not normally distributed, the absolute width gain had a normal distribution in both groups. Because of this, box plots were used to show the findings for the first two variables (**Fig. 12a**) and individual value plots for the absolute width gain (**Fig. 12b**). The median baseline width for the Ti-mesh group was 3.07 mm (IQR=1.15) compared to 2.88 mm (IQR=0.77) for the control group ($p=0.580$). The acquired width had a median of 5.79 mm (IQR=0.33) in the Ti-mesh group and a median of 5.72 mm (IQR=0.54) in the control group. The mean absolute bone gain (acquired – baseline) for the test group amounted to 2.48 ± 1.03 mm and to 2.60 ± 0.82 mm for the control group ($p=0.719$).

Complications rate

The overall complications rate in the two groups is illustrated in **Fig. 13a**, and the distribution of the complications according to Fontana's classifications is given in **Fig. 13b**.

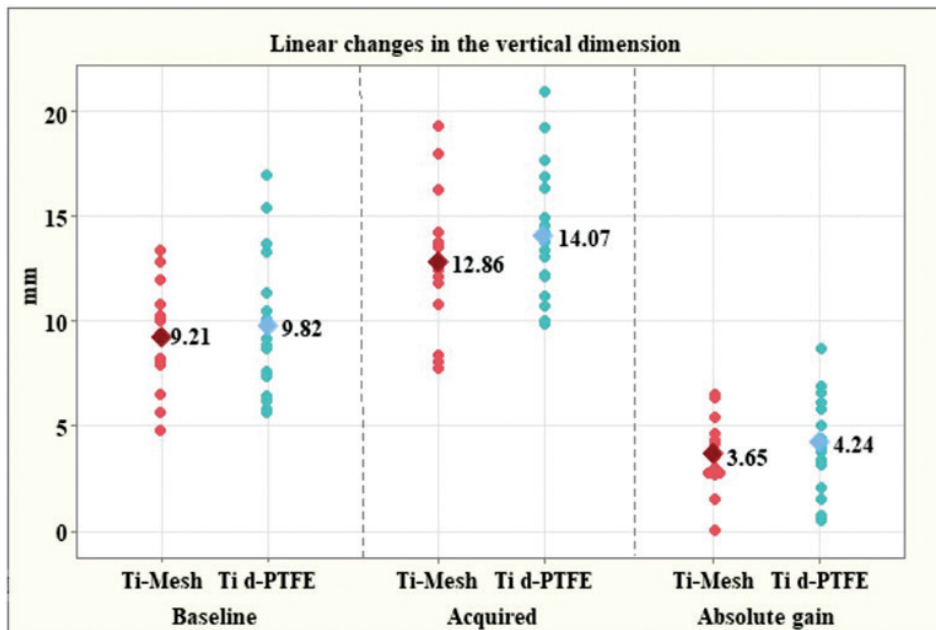


Figure 11. Linear changes in the vertical dimension.

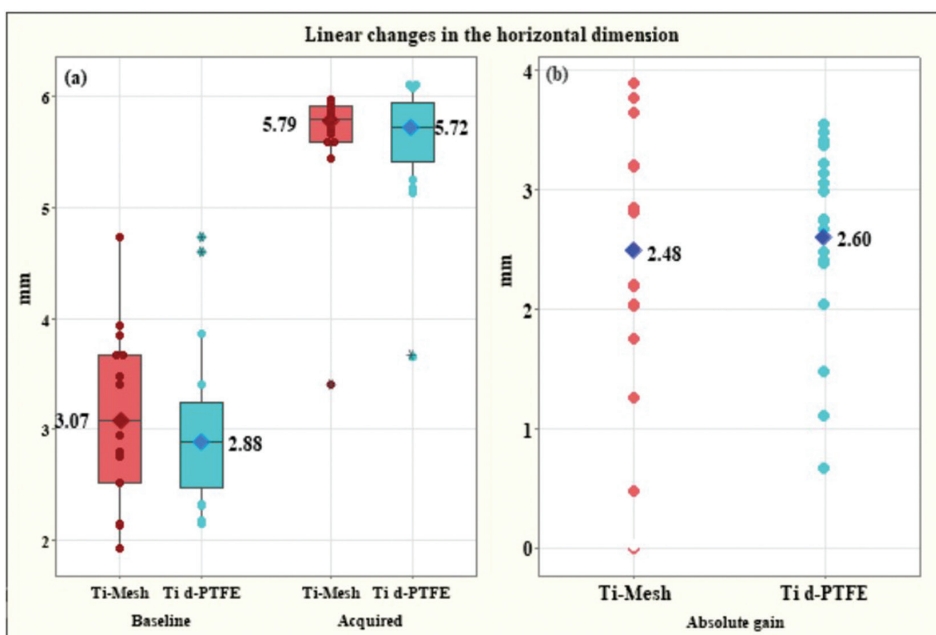


Figure 12. Linear changes in the horizontal dimension

DISCUSSION

The combined vertical and horizontal defect limit the choice of a membrane for guided bone regeneration to three options – titanium reinforced PTFE (d-/e-), titanium mesh (standard/ custom) and a collagen membrane, supported by tenting screws or osteosynthesis plates. In the current study, the scope of our investigation was directed towards clinical and radiographic results with the use of Ti d-PTFE (control group) and custom-made 3D printed Ti mesh (test group).

Since angiogenesis is the main pillar for any tissue growth, we evaluated whether the macroporosity of the Ti-mesh (pores >2 mm, which allows for additional vascularization from the periosteum) would lead to better regenerative outcomes when compared to the higher cell occlusive Ti d-PTFE (pores <0.3 μm). The other aspect of our study was concerned with the investigation whether the individual fit of the custom designed 3D printed titanium mesh would lead to a lesser complication rate than a PTFE membrane that has to be trimmed to facilitate graft stabilization.

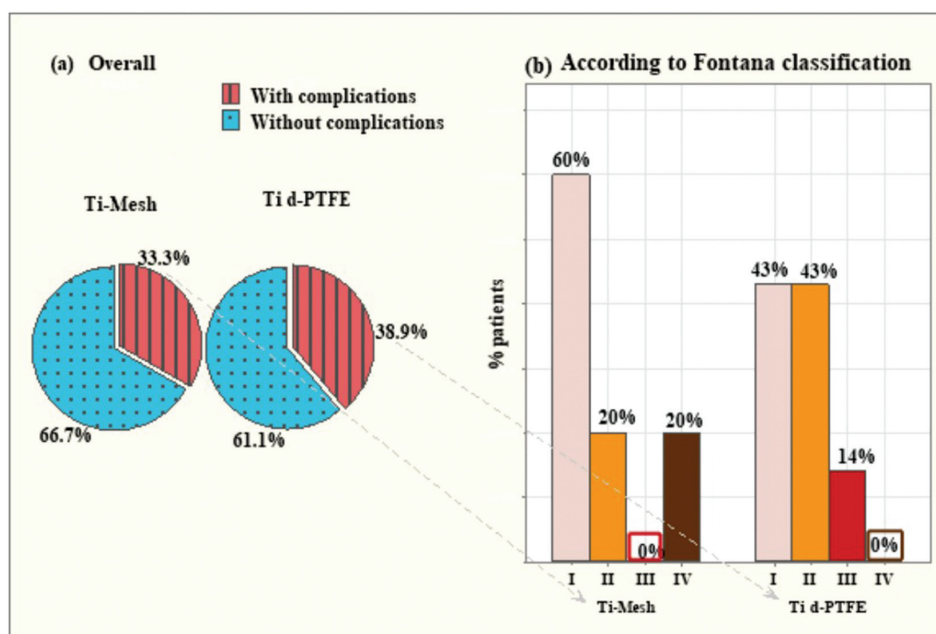


Figure 13. a) Overall complications rate; b) Complications rate according to Fontana classification.

Linear changes discussion

The differences in our results, regarding vertical and horizontal absolute bone gain in the two groups, were small and statistically insignificant. The bone gain, recorded by our group was comparable with the results of other authors using custom printed titanium meshes^[9-12] or Ti d-PTFE membranes^[13-15]. The literature also shows several studies that surpass the bone gain achieved by us in our study with 3D printed meshes^[16-19] or with Ti d-PTFE membranes^[20,21].

An interesting observation can be made with regards to the distribution of the results from our test and control groups. In our control group, the linear results for vertical and horizontal gain appear in a wider range in comparison with the mean value, whereas the exact opposite observation can be made for the regeneration parameters from the subjects of the test group. It could be hypothesized that the use of a graft stabilization device such as a custom designed titanium mesh leads to more predictable outcomes due to its “built-in” vertical and horizontal parameters. With that being said, the larger diameter of the openings on the surface of the titanium lattice structure did not show statistically significant increase of the regenerated tissue due to “dual vascularization” (bone marrow and periosteal blood vessels).

However, when the correlation of the linear results from different studies regarding GBR is examined, it should always be taken with a grain of salt. The gathered data from systemic reviews on the subject^[22,23] show immense heterogeneity – every author has a different understanding of a baseline and acquired bone height and width, and the compared measurements were done both clinically and radiographically. A recommendation for future research could be finding or developing an objective and universal mea-

surement method for the documentation and juxtaposition of linear regenerative bone changes.

Complication rate discussion

Healing complications after GBR procedures are not an uncommon event. This is mostly because the soft tissues must cover the additional bone volume and the tension in the suture line could be a reason for a wound dehiscence and subsequent graft destabilization. Our study unfortunately did not lack post-op complications which proved to be detrimental to the outcome of the regenerative procedure. However, the complication rate between the two group showed no statistical significance and the custom fit of the mesh in the test group failed to show superiority in the inquiry for a better graft stabilization device. Quantitatively, our results with regards to complications in the test group^[19,24] and in the control group^[14,25] were comparable to those of other studies.

Another interesting observation with regards to the clinical behavior of the mesh/membrane, and the related *ph-mediated* resorption of the graft, could be made. The results of our study concluded that Ti d-PTFE performed better in the case of an early exposition of the membrane. This could be because their microporosity maintains the integrity of the bone graft, at least to some extent. Contrary to that, the mesh structure does not provide any protection for the augmented volume at all. When late exposures were examined however, the roles were reversed. The fact that a thick protective layer of “pseudoperiosteum” (largely composed of natural connective tissue) was formed over the graft surface in the subjects from the test group led to less infection in the dehisced sites. In comparison, the exposed synthetic PTFE led to acute infection of the adjacent soft tissues sooner or later.

CONCLUSION

The use of a custom-made 3D printed titanium mesh for vertical guided bone regeneration showed results comparable to those of the gold standard – Ti d-PTFE.

The vertical ridge augmentation procedure is a highly sensitive technique and the choice of a non-resorbable graft stabilization device is not of significance for its outcome.

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Сравнительные результаты линейного прироста костной ткани и частоты осложнений при заживлении после аугментации альвеолярного гребня с использованием индивидуальной 3D-печатной титановой сетки по сравнению с армированным титаном dPTFE. Рандомизированное клиническое исследование

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Дата получения: 22 марта 2024 ♦ **Дата приемки:** 21 июня 2024 ♦ **Дата публикации:** 31 августа 2024

Образец цитирования: Giragosyan K, Chenchev I, Ivanova V. Linear bone gain and healing complication rate comparative outcomes following ridge augmentation with custom 3D printed titanium mesh vs Ti-reinforced dPTFE. A randomized clinical trial. Folia Med (Plovdiv) 2024;66(4):505-514. doi: 10.3897/folmed.66.e123766.

Резюме

Цель: Целью данного рандомизированного клинического исследования было сравнение качественных (линейные изменения альвеолярного гребня) и количественных (осложнения заживления) результатов после направленной костной регенерации (GBR) с использованием индивидуальной титановой сетки, напечатанной на 3D-принтере, и армированной титаном плотной мембраны PTFE для вертикальной и горизонтальной аугментации дефектных альвеолярных гребней.

Материалы и методы: В анализ были включены сорок пациентов (40 участков дефекта). Пациенты были разделены на две группы – тестовая группа, которая получила индивидуально изготовленную титановую сетку, и контрольная группа, которая получила армированную титаном плотную мембрану из политетрафторэтилена.

В этой серии случаев были задокументированы последовательные пациенты, прошедшие лечение с помощью вертикальной аугментации кости для облегчения будущей установки зубных имплантатов.

Процедура была выполнена с использованием ксенотрансплантата и аутогенного трансплантата в соотношении 1:1. Исходные вертикальные и горизонтальные дефициты, приобретённая высота и ширина кости, а также абсолютный прирост кости (высота и ширина) регистрировались рентгенологически; частота послеоперационных осложнений регистрировалась клинически.

Результаты: Абсолютная высота кости, полученная для тестовой группы, составила 3.65 ± 1.73 mm, а для контрольной группы – 4.24 ± 2.19 mm; абсолютная ширина кости, полученная для тестовой группы, составила 2.48 ± 1.03 mm, а для контрольной группы – 2.60 ± 0.82 mm. Частота послеоперационных осложнений составила 33.3% для тестовой группы и 38.9% для контрольной группы.

Заключение: Использование индивидуальной 3D-печатной титановой сетки для нужд вертикальной и горизонтальной направленной регенерации кости показало результаты, сопоставимые с результатами – Ti d-PTFE как с точки зрения прироста высоты и ширины, так и частоты осложнений.

Ключевые слова

костная пластика, вертикальная аугментация гребня, титановая сетка