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Original Article

Radiographic Assessment Following Maxillary Bone Augmentation Using Patient Specific Titanium Meshes Loaded with Bone Marrow Aspirate Mixed with Xenograft versus Xenograft Mixed with Autografts Only: A Randomized Clinical Trial

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Abstract

Aim: The aim of the study is to evaluate the efficacy of three-dimensional bone augmentation in maxillary atrophied alveolar ridges by comparing the utilization of bone marrow aspirate concentrate along with a mix of autograft and xenograft versus autograft and xenograft alone. utilizing patient-specific titanium meshes. **Subjects and methods:** Ten patients experiencing severe vertical and horizontal deficiencies in the entire maxillary arch underwent guided bone regeneration. Utilizing specialized software, virtual bone augmentation were performed for the deficient ridge across the entire maxillary alveolus. This process involved generating virtually augmented models to guide the preoperative prebending of titanium meshes. In the study group, prebent meshes were filled with a combination of xenograft and bone marrow aspirate concentrate (BMAC). Conversely, in the control group, the meshes were loaded with xenograft mixed solely with autograft in a 1:1 ratio. **Results:** All patients experienced uneventful wound healing. Six months postoperatively, Cone Beam Computed Tomography (CBCT) scans were conducted for each patient, revealing a higher Mean vertical bone gain in the Study group (3.46 ± 0.89 mm) while the Control group showed (2.57±0.96 mm). The Mean horizontal bone gain in the Study group (3.80±1.20 mm) while the Control group was (3.91±0.89 mm). **Conclusion:** The difference between the study and control group in both vertical and horizontal bone gain was not statistically significant. Three-dimensional bone augmentation using prebent titanium meshes loaded with xenograft with bone marrow aspirate concentrate could be a reliable less morbid technique.

Keywords: Radiograph, BMAC, maxilla, titanium mesh, bone gain, vertical augmentation, horizontal augmentation.

I. INTRODUCTION

In the dynamic field of oral and maxillofacial surgery, enhancing outcomes in three-dimensional bone augmentation for the maxilla is a considerable challenge. This randomized clinical trial aims to thoroughly assess and compare two approaches to bone augmentation, emphasizing both quantity and quality. Specifically, the study investigates the use of patient-specific titanium meshes, integral to guided bone regeneration, loaded with a combination of bone marrow aspirate and xenograft versus the conventional method of employing xenograft mixed solely with autografts.

Maxillary bone deficiencies, stemming from various causes such as trauma, congenital anomalies, or tooth loss, often necessitate advanced bone augmentation techniques to establish a secure foundation for subsequent dental implant placement. The selection of graft materials and the augmentation strategy design are critical factors influencing procedure success. While xenografts and autografts have conventionally been utilized in bone augmentation, the incorporation of bone marrow aspirate, enriched with regenerative potential, presents an innovative avenue for improving bone regeneration outcomes.(Chen and Buser, 2014)

One of the frequently employed techniques for grafting in the maxillary region is guided bone regeneration (GBR), which is an uncomplicated and versatile approach. This method entails the utilization of barrier membranes to establish an isolated environment, thereby facilitating the controlled and organized regrowth of bone. These membranes act as protective barriers, impeding the infiltration of soft tissue into the designated area, while concurrently facilitating the migration of osteogenic cells and allowing for undisturbed bone regeneration.

Success of GBR hinges on several key elements, including the selection of appropriate barrier materials, grafting materials, and a meticulous understanding of the surrounding anatomical structures. As the field continues to evolve, advancements in biomaterials and surgical techniques contribute to the refinement and efficacy of GBR procedures.

Extraoral bone grafting is a highly prevalent practice, especially in cases where there is a need for substantial amounts of bone to be added. The utilization of extraoral donor sites eliminates the necessity for multiple intraoral harvesting procedures, which may not yield an adequate amount of graft material.

The utilization of donor sites situated within the oral cavity, such as the mandibular symphysis and ramus, provides the notable benefit of being in close proximity to the recipient site. This proximity allows for a reduction in surgical morbidity and simplification of the graft harvest process. These intraoral donor sites offer autogenous bone, which is recognized for its inherent ability to generate new bone tissue, and are frequently preferred for augmentations on a smaller scale.(Idrontino and Valente, 2016)

On the other hand, extraoral donor sites, including the iliac crest, calvarium, and tibia, provide a robust source of bone grafts with considerable volume. Although extraoral grafts may involve a more invasive harvest procedure, they are particularly advantageous for extensive ridge deficiencies, offering a greater quantity of graft material.(Ebraheim NA, Elgafy H, 2001)

II. SUBJECTS AND METHODS

This randomized clinical trial, with a split-mouth design, consisted of 10 patients who had complete maxillary edentulism and deficient alveolar ridges in both vertical and horizontal dimensions. The selection of participants was based on the specified inclusion criteria. In order to reconstruct the maxillary ridge, one half was augmented using a combination of bone marrow aspirate concentrate (BMAC) and xenograft, while the opposite side was reconstructed using a mixture of autogenous bone grafts and xenograft. These reconstructions were supported by pre-bent titanium meshes, contained within 3D printed

models. Each treatment modality was administered to 20 arches (10 patients) in this randomized controlled study.

The candidates for this split-mouth randomized clinical trial were recruited from the outpatient clinics of the Department of Oral and Maxillofacial Surgery, Faculty of Oral and Dental Medicine, Cairo University, Egypt. Patients were screened for inclusion based on the study criteria of complete maxillary edentulism with alveolar ridge atrophy.

This study received ethical approval from the Cairo University Institutional Review Board on February 22, 2022 and was registered on ClinicalTrials.gov (NCT05400044) on May 27, 2022. The individual deidentified participant data can be made available upon request to the corresponding author.

Enrollment of the first participant occurred on May 30, 2022 and the final participant was recruited on June 20, 2022. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki regarding research ethics and protection of human subjects. All participants provided written informed consent prior to enrollment.

The inclusion criteria were adult patients 20-45 years old with completely edentulous atrophic maxillary ridges, good oral hygiene, and no comorbidities or oral pathosis that could impair bone healing. Exclusion criteria were systemic conditions that could compromise healing, active oral infection, and poor oral hygiene.

This split mouth study randomized treatment of the right and left sides of the maxilla in each patient. Allocation concealment was achieved using opaque sealed envelopes containing the group assignment for each side. The sequence generation and envelope preparation were carried out to remove bias. Patients were registered and then an envelope was selected to reveal the right and left side group allocation per the random sequence. The statistical analyst was blinded to group assignment; however, the assessors, participants, and surgeons were not blinded due to the nature of the surgical interventions.

A comprehensive medical and dental history was obtained from all patients, including their chief complaint, dental condition, medical history, oral hygiene status, interarch space, mucosal tissue biotype, status of opposing dentition, and maxillomandibular dimensions and relationship. Clinical evaluation included palpation to assess for swelling, undercuts, or tenderness. Preoperative cone beam computed tomography (CBCT) scans were acquired for each patient using Planmeca ProMax 3D (Helsinki, Finland) to evaluate the vertical and horizontal dimensions of the deficient alveolar ridges and confirm study eligibility based on deficiency criteria.

The CBCT scans were acquired in DICOM format and imported into Mimics software (Materialise, Leuven, Belgium) to reformat the images and reconstruct 3D virtual models of the recipient sites. These models were digitally augmented to the desired dimensions. The virtual augmented models were then imported into 3-Matic software (Materialise) to design the surgical guides and meshes. Implant placement was simulated by virtually placing an 8mm long x 3.5mm wide implant to assess needed bone graft volume. The implants and meshes were digitally positioned based on the planned occlusion and buccopalatal tooth positions of the opposing arch.as shown in Fig 1.

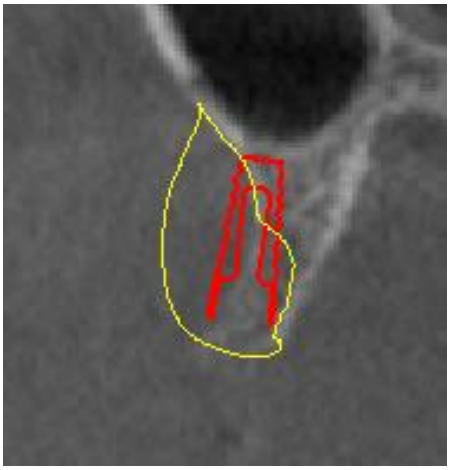

Figure 1: Cross-sectional cut showing virtual implant placement (red), and the required virtual augmentation (Yellow).

The required bone augmentation volume was calculated based on the implant positions and mesh contours. A 1.5mm safety zone surrounding each implant was modelled to ensure adequate bone width/height for implant placement. An additional 1.5mm over-contouring was added to account for pseudo-periosteum formation. As shown in Fig 2.

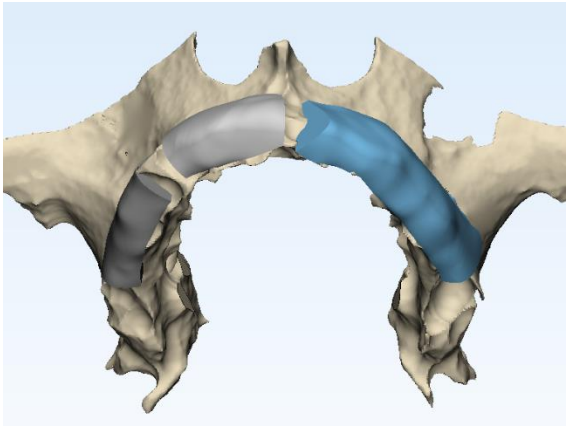

Figure 2: 3D model on the software showing the desired virtual augmentation.

Upon completing the computer-aided design (CAD), the STL files were 3D printed as surgical guides. The titanium meshes were pre-bent on these models before surgery. The 3D printed models were cold sterilized in CIDEX solution for intraoperative reference. The pre-bent titanium meshes were autoclave sterilized before surgery to maintain shape and avoid distortion.

Surgical Intervention:

The surgical field was prepared by scrubbing and draping the patient using standard sterile protocol with Povidone-Iodine antiseptic (Betadine, Avrio Health). Local anaesthesia using Articaine hydrochloride 4% with epinephrine 1:100,000 (ARTINIBSA, Inibsa) was infiltrated for bleeding control and to avoid reflexes during general anaesthesia. A palatal paracrestal incision was made with full thickness labial flap reflection. A distal releasing incision was extended from the end of the paracrestal incision with slight divergence. The mucoperiosteal flap was elevated and reflected labially, with slight elevation of the palatal flap to the boundaries of the planned titanium mesh placement based on the 3D surgical plan. The contour of the pre-bent titanium mesh was verified prior to fixation. All surgical instruments contacting the bone marrow aspirate were heparinized by rinsing and coating to prevent clotting. The anterior iliac crest bone marrow aspiration site was prepared by scrubbing, draping and prepping with Povidone-Iodine antiseptic using standard sterile technique.

Bone marrow aspiration:

A 15-blade stab incision was made 2cm posterior to the anterior superior iliac spine to access the anterior iliac crest. A specialized trocar shown in Fig 3 was used to penetrate the cortical bone to a depth of 4-5cm at the midpoint while applying gentle but firm pressure with alternating clockwise and counterclockwise motion.

A plastic syringe containing anticoagulant citrate dextrose solution formula A (ACD-A) was prepared. The trocar was removed leaving the cannula in place, and the ACD-A syringe was

attached to aspirate the bone marrow. The ACD-A and marrow were mixed together. Up to 30mL was aspirated from each site for a total of 60mL.

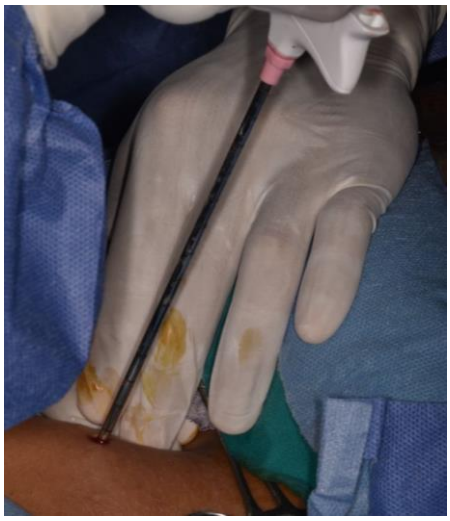

Figure 3: Bone marrow aspiration using a specialized trocar-cannula assembly.

After completing aspiration, the cannula was removed, and the stab incision was closed with a single interrupted absorbable 4-0 polyglycolic acid suture. The aspirate was transferred into sterile vacuum blood collection tubes. As shown in Fig 4.

Figure 4: Bone marrow collected into vaccum tubes.

The aspirate underwent double centrifugation, first at 2400 rpm for 10 minutes to separate plasma, buffy coat and red blood cells. The plasma and buffy coat were extracted and centrifuged again at 3400 rpm for 6 minutes to isolate the buffy coat. The buffy coat and remaining plasma were gently agitated to create the bone marrow aspirate concentrate (BMAC).

The BMAC was mixed with sterile cancellous bovine bone particles 0.5-1mm in size. This mixture was loaded into the patient-specific 3D printed titanium mesh, which was fixed in place with 2.0mm mini screws. As shown in Fig 5.

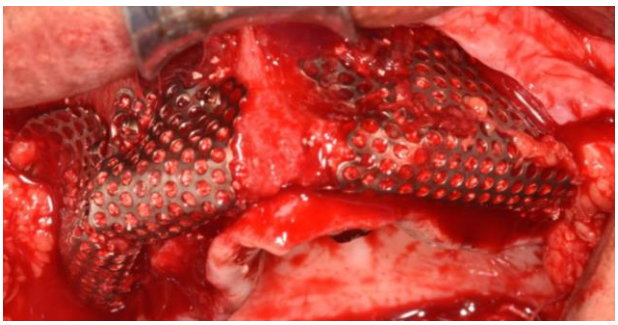

Figure 5: Titanium mesh fixed in place.

Control group

For autogenous bone harvesting, a supraperiosteal vestibular flap was raised using a 15 blade to expose the mentalis muscle. The incision was extended from canine to canine, starting 5mm above the mucogingival junction superiorly and extending to the inferior mandibular border inferiorly.

A full thickness mucoperiosteal flap was reflected to expose the entire symphysis region. An autobone chip maker (ACM) bur was used to harvest autogenous bone particulate from the chin. This was mixed in a 1:1 ratio with sterile cancellous bovine bone particles 0.5-1mm in size.

The autogenous-bovine bone mixture was moistened with sterile saline and loaded into the patient-specific 3D printed titanium mesh. The mesh was then fixed in place with 2.0mm mini screws.

Second stage

The second stage surgery was performed 6 months after the initial ridge augmentation procedure. The bone was surgically exposed and implant osteotomies were sequentially drilled using a graduated implant drilling kit (Dual Implants, Titan industries, Egypt). Implant dimensions were selected based on the height and width of the augmented alveolar ridges achieved from the first surgery.

Bone gain assessment was made by superimposition of the preoperative and 6-month postoperative CBCT scans. The preoperative CBCT data was exported and then imported into the postoperative scan aligned to a coloured STL surface. The anterior nasal spine and pterygoid plates were used as anatomical reference points for alignment and scaling. As shown in *Fig 6.*

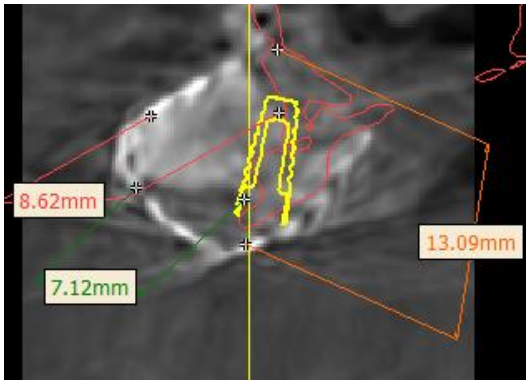

Figure 6: shows a postoperative cross-sectional cut with the preoperative dimensions (red colour) superimposed and the virtual implant (yellow colour) placed in the desired position.

Measurements were taken at planned implant sites for the central incisors, canines, and first molars. At each site, the vertical and horizontal bone dimensions were recorded on both the preoperative and superimposed postoperative scans to quantify bone gain. This allowed comparison of ridge dimensions before and after augmentation at the mapped implant locations.

III. RESULTS

A total of 20 arches (10 patients) were recalled after 6 months for the follow up visits and radiographic assessment of the bone gain in both groups.

For horizontal bone gain, the study group had a mean gain of 3.48 ± 0.87 mm compared to 4.10 ± 0.68 mm in the control group. The difference in mean horizontal bone gain between groups was also not statistically significant (p=0.090). (table 1).

The mean vertical bone gain was 3.48 ± 0.60 mm in the study group and 2.92 ± 0.79 mm in the control group. Although the study group demonstrated greater mean vertical bone gain, the difference between groups was not statistically significant (p=0.085). (Table 2).

Table 1: Mean and standard deviation (SD) values for patient's Horizontal bone gain measured radiographically in mm in both groups

Group	Minimum	Maximum	Mean	SD	Mean difference	*t value*	*p*-value
Study	**1.88**	**4.85**	**3.80**	**1.20**	**-0.118**	**-0.188**	**0.855 ns**
Control	**3.35**	**5.70**	**3.91**	**0.89**			

Table 2: Mean and standard deviation (SD) values for patient's Vertical bone gain measured radiographically in mm in both groups.

Group	Minimum	Maximum	Mean	SD	Mean difference	*t* value	*p*-value
Study	**2.15**	**4.58**	**3.46**	**0.89**	**0.889**	**1.579**	**0.149 ns**
Control	**1.23**	**3.70**	**2.57**	**0.96**			

IV. DISCUSSION

Extraoral sites, particularly the iliac crest, can provide greater quantities of high-quality bone compared to commonly used intraoral donor sites. Iliac crest grafts offer benefits including large volumes of cancellous and cortical bone, relatively easy surgical access, flexibility to conform to the recipient site, and low surgical risk (Nkenke E, 2014). However, iliac crest harvesting has higher associated morbidity versus intraoral bone grafts. Iliac crest grafts also exhibit high resorption, with up to 50% loss of the initial graft volume. Common complications from iliac crest harvest include sensory disturbances from lateral femoral cutaneous nerve injury, seroma, and hematoma. Additional drawbacks are the cutaneous scar and potential for temporary disability or growth pattern disruption in younger patients.(Zins JE, 1983).

Rickert et al. conducted a comparative analysis in which they examined the effectiveness of utilizing bovine bone mineral in conjunction with either autogenous bone or autogenous stem cells for maxillary sinus floor augmentation. Notably, the researchers found no noteworthy disparities in terms of bone-to-graft contact between the two groups. Consequently, they deduced that the combination of bovine bone mineral and autogenous stem cells serves as a successful composite graft for maxillary sinus augmentation, displaying commensurate levels of new bone formation when contrasted with the conventional approach of employing autogenous bone grafts obtained from the iliac crest. Additionally, the utilization of minimally invasive stem cells obviates any potential complications associated with donor site morbidity stemming from autogenous bone graft harvesting.(Rickert et al., 2011)

Mounir et al. conducted a study and determined that cortical bone shells derived from both the retromolar, and symphyseal chin mandibular donor sites present viable alternatives for alveolar ridge augmentation, as they promote sufficient bone formation. The cortical shells obtained from the symphyseal chin exhibit superior quality in terms of the content of lamellar bone. Conversely, the retromolar cortical shells exhibit acceptable new bone formation, primarily characterized by a woven architecture. Utilizing either of these intraoral sites eliminates the risk of extraoral donor site morbidity associated with the harvesting of iliac crest bone. (Mounir et al., 2021)

Mohammed Atef et al. found that titanium meshes provided superior horizontal bone augmentation compared to native collagen membranes for severely atrophic maxillary ridges. The titanium meshes were able to maintain the augmented space and provided improved bone quantity and quality. They attributed the better outcomes with titanium meshes to the increased graft stability and scaffolding provided by the rigid structure. (Atef, 2020).

The outcomes of this investigation correspond with the discoveries made by Atef et al., who similarly examined the enhancement of the horizontal ridge in the maxillary arch by utilizing titanium meshes as opposed to collagen membranes. Atef et al. revealed a substantial increase in the width of the alveolar bone using both techniques, with an average gain of approximately 4.0 mm in the collagen group and 3.7 mm in the titanium mesh group. Similarly, the

present investigation exhibited a comparable gain in horizontal bone width, with averages of 3.80 ± 1.20 mm in the experimental group and 3.91 ± 0.89 mm in the control group.(Atef, 2020)

V. CONCLUSION:

The difference between the study and control group in both vertical and horizontal bone gain was not statistically significant. Three-dimensional bone augmentation using prebent titanium meshes loaded with xenograft with bone marrow aspirate concentrate could be a reliable less morbid technique.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors

Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry-Cairo university on:22/2/2022, approval number: 1222

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