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VERTICAL AND HORIZONTAL GUIDED BONE REGENERATION (GBR) USING CUSTOMIZED MESHES WITH OR WITHOUT RESORBABLE MEMBRANES: Preliminary results of a Randomized Clinical Trial

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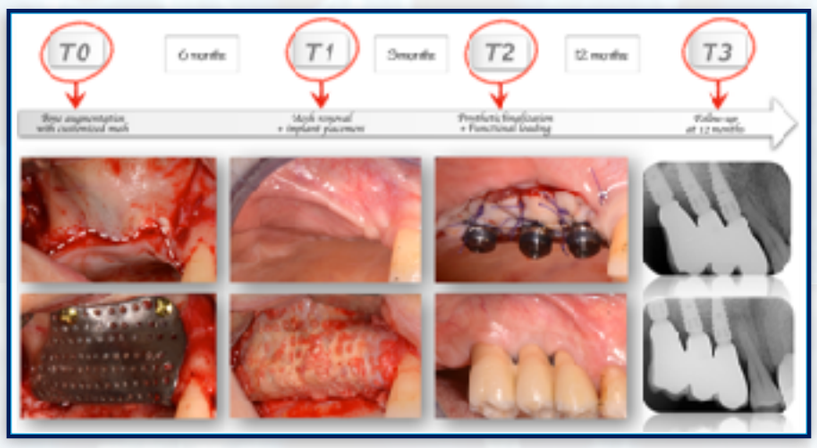
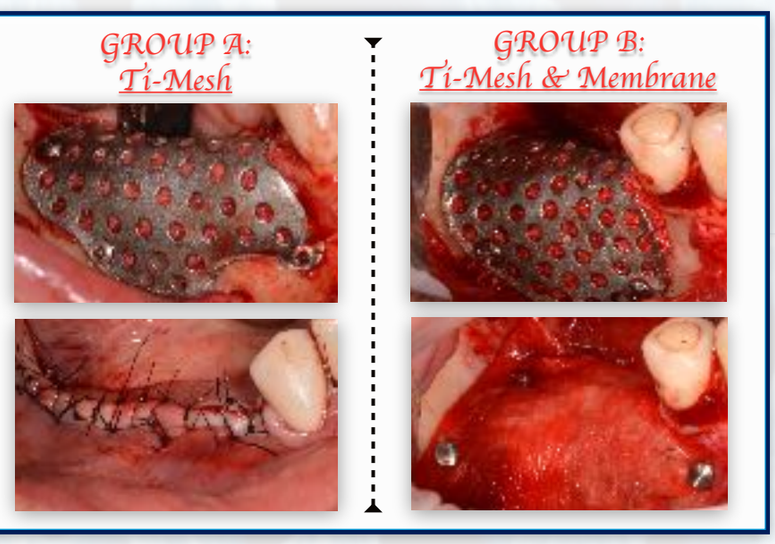
BACKGROUND. & AIMS

The presence of alveolar ridge deficiencies is considered a major limitation to achieve an implant-prosthetic restoration with high aesthetics and stability over time. Guided Bone Regeneration (GBR) can be considered an effective solution for bone augmentation. The most advanced technology of GBR is the customized titanium mesh (Ti-mesh), which is developed with a fully digital work flow system. The aim of this randomized clinical trial is to compare complications rates and bone augmentation rates after GBR using customized mesh with collagen membrane versus customized mesh alone.



MATERIALS AND METHODS

30 patients with horizontal and/or vertical bone defects during reconstructive surgery (t0), were randomly divided into two study groups: 15 patients were treated by means of a custom-made mesh (**3D-mesh BTK, Biotec, Vicenza, Italy**) without collagen membrane (group a – control group), while 15 patients were treated by means of a custom-made titanium mesh with a collagen membrane (**Cytoplast RTM, Osteogenics, deore materials, Verona, Italy**) (group b – test group). All sites were grafted with a mixture 50:50 of autogenous bone, harvested from the external oblique ridge of the mandibular rams using a bone scrape (**Safescraper, Meta, Deore, Verona, Italy**) and xenograft (**Z-core, Osteogenics, Deore, Verona, Italy**). Primary closures (with **Cytoplast PTFE suture, Osteogenic, Deore, Verona, Italy**) of surgical sites were obtained to ensure a submerged healing of the meshes. After 6 months (t1), re-entry surgery was completed to remove the meshes, evaluate the augmented volume and to place implants (**BT SAFE, BTK, Biotec, Vicenza, Italy**) in the augmented sites. After 3 months (t2), soft tissue management was accomplished with implant exposure and a connective tissue graft, before prosthetic restoration (t3). Data collection included surgical and healing complications, planned bone volume (pbv) and reconstructed bone volume (rbv), pseudo-periosteum type, bone density, implant success, and crestal bone loss. Statistical significance was set at a=0.05.

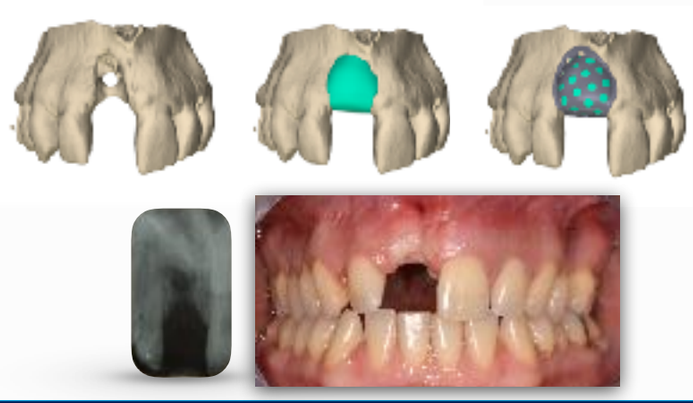


DATA ANALYSIS & RESULTS

Up to date, All patients underwent to T0: 15 belonging to group a and 15 belonging to group b. 26 out 30 patients underwent to T1 and were considered for statistical analysis. Two early and two late exposure of the meshes were observed in the control group (27%); one abscess without exposure and one early exposure were noted in test group (20%). Mean values of pbv and rbv in the control group were 1.11cc and 0.85cc; while, in the test group, 1.25cc and 1.09cc, respectively. The regeneration rates in both study groups were 76.6% and 87.2%, giving a significant statistical difference (p=0.046). Pseudo-periosteum type and bone density were not statistically different over the 2 groups (p=0.67). No implants were lost over time and crestal bone loss were less than 1.5mm in both groups (p<0.001), resulting in success rates of 100%. Finally, statistical analysis revealed significant differences in bone density between the mandible and maxilla(p=0.03).

SURGICAL PROTOCOL

Digital Planning and Mesh Modeling



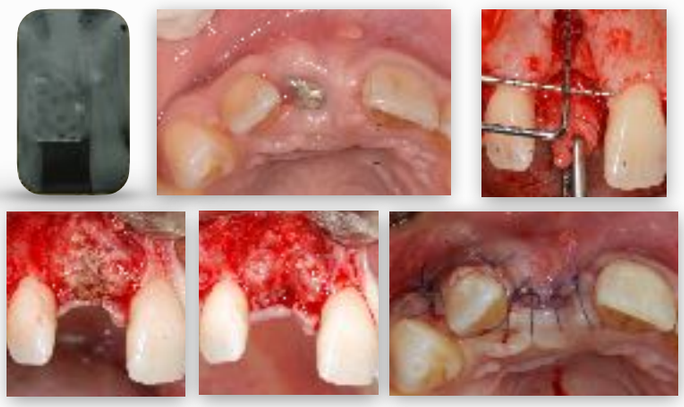
SURGICAL PROTOCOL

Flap Design and Flap Elevation

Bone Harvest and Mesh Fitting

SURGICAL PROTOCOL

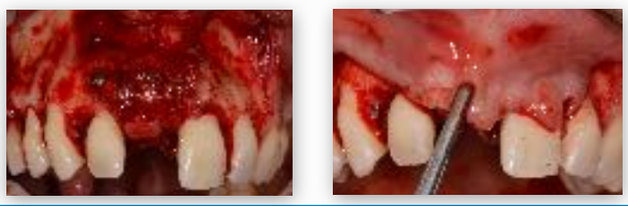
Exposure and Mesh Removal



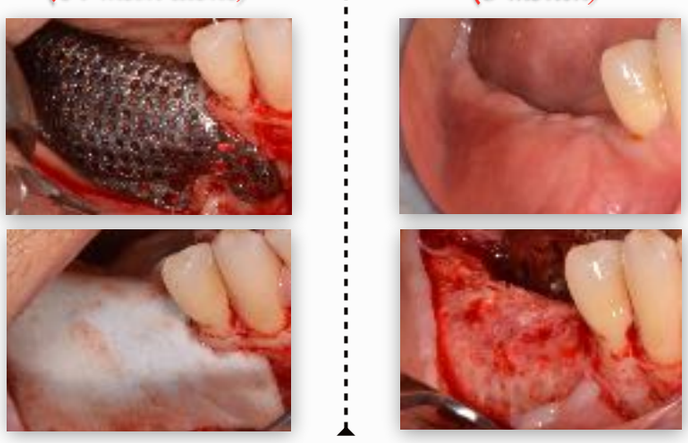
SURGICAL PROTOCOL

Graft and Mesh Fixation

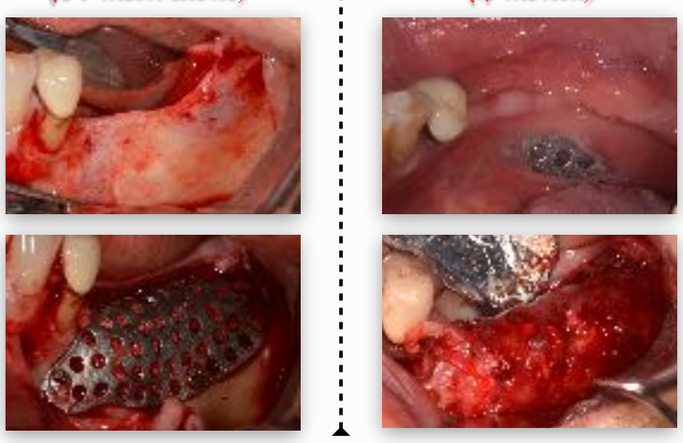
Membrane Fixation & Flap Passivation



Reconstructive Surgery (Ti-mesh alone) — Re-entry Surgery (6 month)



Reconstructive Surgery (Ti-mesh alone) — Re-entry Surgery (4 month)



	TECHNICAL COMPLICATIONS	SURGICAL COMPLICATIONS	HEALING COMPLICATIONS	TOTAL COMPLICATIONS
Group A	1 mesh fracture 1 not precise fitting 13%	0%	2 Early exposure 2 Late exposure 27%	40%
Group B	2 mesh fracture 1 not precise fitting 20%	1 Paresthesia 7%	1 Early Exposure 1 Abscess 13%	40%
Total	17%	3%	20%	

CONCLUSIONS & CLINICAL IMPLICATITONS

The results of this randomized clinical trial showed that GBR using customized mesh is a reliable and predictable solution for bone augmentation of alveolar ridges. Both approaches result in interesting outcomes in vertical and horizontal defects. Complication and regeneration rates seem to be better in group with mesh and collagen membrane compared to mesh alone; however, data on GBR with customized meshes need further investigation to draw meaningful conclusions.

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