

## Micro-CT, Histological and Histomorphometric analysis of bone tissue after GBR using customized titanium meshes with or without resorbable membranes. RCT.

**Lucia Tedeschi<sup>1</sup>, Sofia Bettini<sup>2</sup>, Raffaele Dontati<sup>3</sup>, Antonino Fiorino<sup>4</sup>, Alessandro Cucchi<sup>5</sup>**

<sup>1</sup> Department of Biomedical and Neuromotor Sciences (DIBINEM), University of Bologna, Bologna, Italy

<sup>2</sup> Maxillofacial Surgery and Odontostomatology Unit, Implant Center for Edentulism and Jawbone Atrophies, University of Milan, Milano, Italy

<sup>3</sup> Private practice, Lucca, Italy

<sup>4</sup> Department of Neuroscience and Reproductive and Odontostomatological Sciences, "Federico II", University of Naples, Naples, Italy.

<sup>5</sup> Private practice, Bologna, Italy

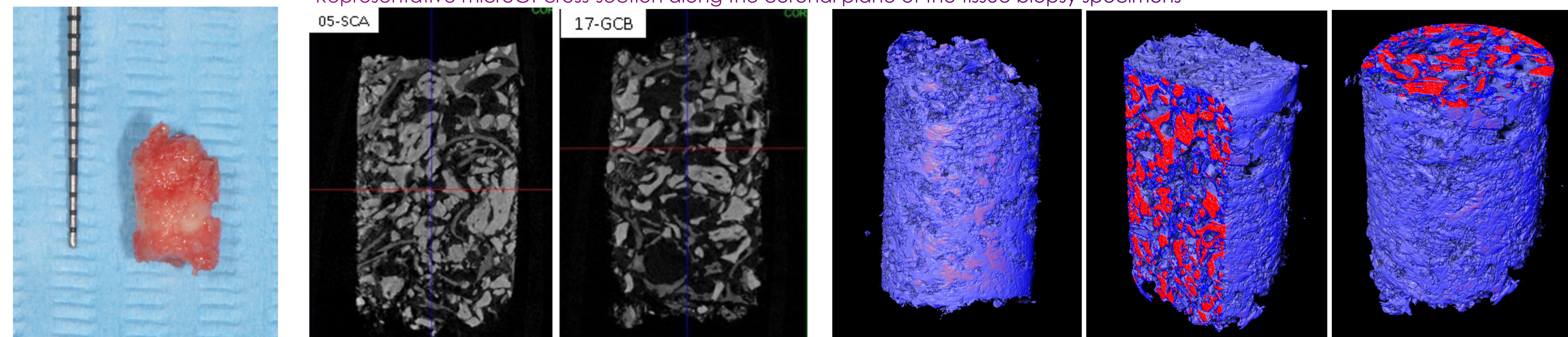
### BACKGROUND AND AIM

GBR is one of the most used techniques for the regeneration of bone defects. Nowadays, using 3D CAD/CAM technologies, it is possible to obtain customized titanium meshes, used as barrier devices. In the literature there are only a few studies reporting micro-CT, histological and histomorphometric analysis after GBR and there are no studies about the role of resorbable membranes over titanium meshes. This randomized non inferiority clinical trial aimed to compare the augmented bone through 3D micro-CT, histological and histomorphometric analysis using custom-made titanium meshes with and without collagen membrane.

### METHODS AND MATERIALS

The study included 30 patients randomly assigned to two study groups: 15 were treated with titanium mesh alone (M-) and 15 with titanium mesh covered with resorbable membrane (M+). During surgery (T0), a 50:50 mixture of autogenous bone and high-porosity xenograft was used to fill the customized titanium meshes before the fixation. In each VOI the following parameters were evaluated: percent tissue/total volume for soft tissue (ST/TV), all bone (AB/TV) residual biomaterial (MATV/TV), proportion bone surface/total volume in relation to all bone (AB\_BS/TV), trabecular thickness (TbTh), number (TbN) and 3D space (TbSp) in new bone, old bone and all bone using micro-CT analysis. Histological and histomorphometric analysis included bone tissue % (B), biomaterial % (Mat), soft tissue % (St), and osteoid matrix % (OM), and osteoid/bone ratio (O/B); measurements of trabecular perimeters were also calculated. The aforementioned parameters were evaluated through a bony tissue biopsy 6 months after surgery (reopening surgery).

Representative microCT cross-section along the coronal plane of the tissue biopsy specimens



### RESULTS

20 out of 30 samples were suitable for histological and histomorphometric analyses: 9 (M-) and 11 (M+) and 25 for micro-CT analysis: 13 (M-) and 12 (M+). No statistically significant differences were observed between the two study groups for any of the variables ( $p > 0.05$ ), therefore the test group was neither inferior nor superior to the control group. The bone biopsies were mainly represented by non mineralized tissue ( $51.98 \pm 11.40\%$ ), followed by bone tissue ( $34.82 \pm 10.13\%$ ), and finally biomaterial particles ( $13.9 \pm 6.14\%$ ). Higher percentages of bone in mandible were found with a mean estimated difference of  $11.46\%$  ( $p=0.011$ ). The study groups showed a slight difference only in osteoid matrix/bone ratio. The differences between mean rates in the two groups (95% C.I.) were  $3.98\%$  ( $-6.90$  to  $14.87$ ) for non-mineralized tissue,  $-0.96\%$  ( $-10.78$  to  $8.85$ ) for bone tissue,  $3.04\%$  ( $-8.80$  to  $2.72$ ) for biomaterial and  $-0.39\%$  (range  $-3.72$  to  $2.94$ ),  $-1.08\%$  (range  $-12.94$  to  $10.77$ ),  $0.19\%$  (range  $-5.01$  to  $5.38$ ),  $1.76\%$  (range  $-4.99$  to  $8.52$ ) for ST/TV, AB/TV, MATV/TV, AB\_BS/TV respectively.

### CONCLUSION

The 3D micro-CT, histological and histomorphometric analysis showed that test group proved to be neither inferior nor superior to the control group in almost all measured parameters. Therefore, within the limits of the present study, the coverage of customized titanium meshes with resorbable membrane did not determine a significant difference in the distribution of tissues in regenerated bone.

