

Innovative Bone Scaffold For Reconstructive Oral Surgery

G. Pertici^{1,2} M. Müller¹ S. Maccagnan³ F. Rossi & G. Perale^{1,4}

¹ *Industrie Biomediche Insubri SA, via Cantonale, CH-6805 Mezzovico, Switzerland.*

² *SUPSI, Galleria 2, CH-6928 Manno, Switzerland.*

³ *Gimac Microextruders, via Roma 12, 21040 Castronno (Va), Italy.*

⁴ *DCMIC, Politecnico di Milano, Via Mancinelli 7, 20133 Milan, Italy.*

INTRODUCTION: Autograft is still playing the role of gold standard in critical sized and non-union bone defects in oral and maxillofacial surgeries¹. Hence, adequate bone substitutes for remodelling of native bone tissue are a goal yet to achieve. Indeed, such bone scaffolds should ensure both mechanical stability and strength. Moreover, their intimate structure should have an adequate interconnected porous network for cell and proliferation, while also providing specific signals for bone regeneration².

METHODS: A composite solution, based on a novel concept of biomaterial assembly, bearing cues from both mineral components and polymeric ones, was here followed to develop a new three-dimensional bone scaffold. Hence, a bovine derived mineral matrix was reinforced with biodegradable polymers and bioactive agents through a specific nano-emulsion proprietary bath³: the bovine derived matrix allows maintaining an adequate 3D-structure and porosity; biopolymers permit to achieve good mechanical properties while bioactive agents promote cell adhesion and proliferation. Scaffolds are produced according to GMP standards applying only human-use approved components.

RESULTS & DISCUSSION: Microstructure was evaluated by E/SEM and micro-CT (fig. 1), confirming a strong resemblance with human cortical bone in terms of open mid-sized porosity. Compression tests evidenced a maximum stress capability (20MPa av.) three times higher than best available bovine derived bone, with a four-fold improved Young's modulus (0.2GPa av.). Moreover, further mechanical investigations showed easy shaping by common surgical instruments and high resistance to screws and fixation manoeuvres, thus being feasible to replicate and replace various bone defects. Biological

and histological investigations showed scaffolds to be promising substrates for cell adhesion and growth: citocompatibility and cell viability were positively assessed *in vitro* with standard SAOS-2 and MG-63 line cells. Human adipose tissue derived mesenchymal stem cells were also tested and data showed *in vitro* capability to properly colonize the scaffold and, once induced, to differentiate⁴.

CONCLUSIONS: Experimental data collected gave a positive confirmation of the applicability of this novel composite matrix as scaffold for bone tissue regeneration and of its production process developed therewith. *In vivo* animal trials are in progress on model white New Zealand rabbits.

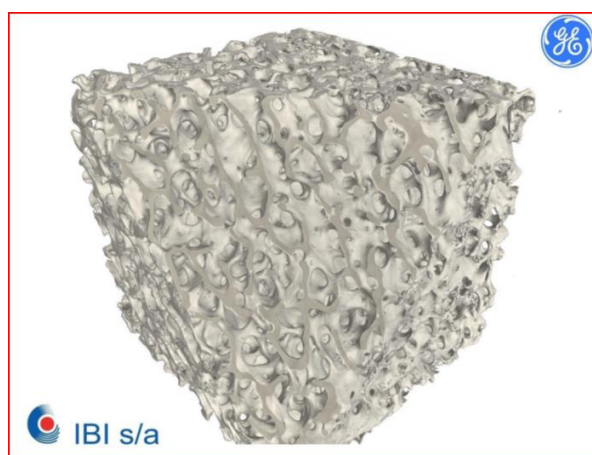


Fig. 1: μ -CT 3D render of new bone scaffold (in cooperation with Phoenix|x-ray, a GE company).

REFERENCES: ¹ J.D. Kretlow, A.G. Mikos (2007) *Tissue Eng.* **13(5)**: 927-938. ² K.E. Kahnberg (2005) *Bone Grafting Techniques for Maxillary Implants*, Blackwell. ³ G. Pertici, *PCT Pat. Appl.* IB2009/007759. ⁴ S. Bardelli et al. (2009) *Regen Med* **4(6)**,S2: 70-71.

ACKNOWLEDGEMENTS: Authors would like to thank Prof. T. Villa for mechanical testing; Prof. G. Carusi for surgical handling tests; Dott. F. Crivelli for histologies.