

Custom-made bone grafts for reconstructive maxillo-facial surgery: a case study

G. Pertici¹, F. Grecchi², G. Perale¹

¹ *Industrie Biomediche Insubri SA, Mezzovico, Switzerland.* ² *Istituto Ortopedico R. Galeazzi, Dept. of Maxillo-facial surgery, Milan, Italy.*

INTRODUCTION: Scaffolds for bone regeneration should ensure both mechanical stability and strength. Moreover, their intimate structure should have an adequate interconnected porous network for cell migration and proliferation, while also providing specific signals for bone regeneration. SmartBone[®] composite solution, based on a novel concept of biomaterial assembly, bearing cues from both mineral components and polymeric ones [1-3], was chosen to develop new patient-specific three-dimensional bone grafts. Indeed, thanks to mechanical performances and to full control over production, custom-made grafts can be produced according to the specific need of each single patient, via digital surgical planning, starting from CT scans.

METHODS: SmartBone[®] technology, a bovine derived mineral matrix reinforced with resorbable biopolymers and bioactive agents [1-3], was applied together with a CAD-CAM manufacturing system to obtain custom-made 3D bone grafts.

The case of a 38-years old Caucasian male with an important traumatic defect of his left zygomatic portion was here investigated: CT scans were acquired; surgical planning together with graft design was performed both on real model (made by 3DiEmme srl, Italy) and digitally (3Diagnosys software, by 3DiEmme srl, Italy); once surgical procedure and grafts had been confirmed, 5axes CAD-CAM manufacturing process (Industrie Biomediche Insubri SA, Switzerland) was used to machine-mill bovine derived mineral matrix into final shapes, which then underwent proprietary physical-chemical reinforcement process prior to packaging and sterilization [1].

After general anaesthesia, surgery began with site preparation along the old scar, including removal of formerly placed cartilage grafts and metal parts. Once receiving site had been properly prepared, custom-made grafts were placed and fixed with standard fixation tools (KLS Martin & Co. GmbH, Germany). Grafted bone substitutes were covered with long lasting resorbable collagen membranes (Tutomesh, by Tutogen Medical GmbH, Germany) and finally muscles and soft tissue layers were sutured back in place. Control CT scans were acquired 2 days and 6 months post surgery.

RESULTS: Surgical planning resulted in the need of three bone grafts: two for the external zygoma and one for orbital pavement, respectively (see Figure 1 left). Surgery was performed as planned and grafts fixation required just few minutes: only 5 screws and 1 plaque easily ensured proper grafts stability (see Figure 1 right).

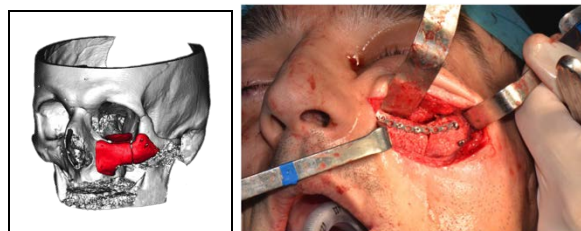


Fig. 1: left – digital planning of the needed grafts; right – surgical fixation of the grafts onto patient.

Facial symmetry was restored, together with a proper orbital alignment. No visual nor neurological outcomes were reported. Post surgical CT scans confirmed correct positioning of grafts (after 2 days) and confirmed graft integration and stability (after 6 months), showing no signs of bone graft volumetric reduction.

DISCUSSION & CONCLUSIONS: a proper surgical planning and a precise design of needed grafts allowed obtaining a very satisfactory reconstruction. SmartBone[®] technology proved being adequate: bone grafts showed extremely high mechanical performances, easily withstanding fixation manoeuvres, while material stability and integration were fully confirmed too.

Moreover, a correct and precise planning, the perfect geometrical matching of grafts with receiving site, ensured by the precise production, and a high performance bone graft, resulted in a relevant reduction of surgical time and, therefore, of surgery-related risks for patient.

REFERENCES: ¹ G. Pertici (2008) *Bone implant matrix and method of preparation of the same*, pat. appl. CH 01997/08. ² S. Bardelli *et al.* (2009) *Clinically-optimized cell culture conditions in combination with a new 3d-scaffold for human msc bone tissue engineering*, Reg. Med, 4(6)-s2:70-1. ³ G. Perale *et al.* (2010) *Bioresorbable bioactive matrix for bone regeneration*, Tissue Engineering Part A, 16(8): A-10.