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SMARTBONE® ON DEMAND™ APPLIED TO A POST TUMORAL LARGE SPHENO-ORBITAL RECONSTRUCTION

After almost two years of positive clinical feedback, in November 2013, the innovative bone substitute SmartBone® made it possible to successfully engage in a great maxillo-facial surgical challenge. Thanks to a profitable collaboration between the Swiss biomedical company Industrie Biomediche Insubri SA and the renowned University of Modena a complex large spheno-orbital reconstruction case was accomplished using a revolutionary approach. The outstanding biomechanical and microstructural properties of SmartBone®, that in these last two years has obtained great results in the dental field and in reconstructive surgery, have allowed the surgeons of the University of Modena to treat the case with excellency and promising results.

The treatment of anterior and lateral skull base tumours has always constituted a complex surgical challenge: extensive bony demolitions produce aesthetic deformities that need accurate reconstructions. Indeed, highly destructive procedures increased the need to introduce new reconstructive techniques. Wide defects, *e.g.* those involving more than a single orbital wall, have to be reconstructed with solid tissues such as autologous grafts or alloplastic materials. Surgical visual limits impairments may reduce the possibility to properly repair the three-dimensional bony architecture of the craniofacial skeleton: because of the nonlinear nature of the bone in the craniofacial skeleton, even small degrees of error can lead to poor outcomes.

Here we investigated the innovative application of SmartBone® on Demand™ in a case of skull base reconstructive surgery: the use of custom-made bone grafts for these cases is not previously reported in literature.

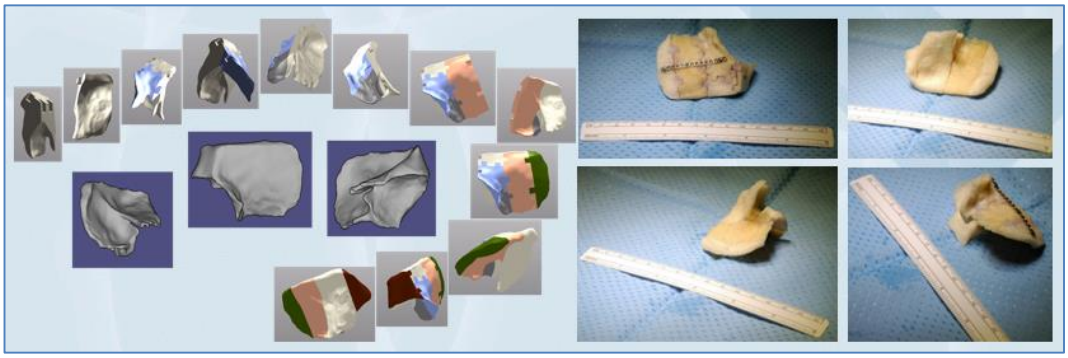

Fig. 1: Assembly of the six pieces that composed the bone graft; digital assembly (left), SmartBone® assembly during the surgery (right).

Innovations applied to this case were multiple: based on high resolution patient CT scans, virtual surgery and computer-aided design were used to plan resection; sterile plastic models of the resected area were created to physically guide the surgery at highest precision. A contralateral disease-free skull base was used as a reference and a mirroring technique was used to create the ideal grafts, which were then manufactured accordingly using the new composite custom-made bone grafts SmartBone® on Demand™. SmartBone® is highly resistant to shaping and offers high tenacity to screws and surgical fixation manoeuvres thanks to its inner composite nature: it is obtained combining natural mineral bone structures with biopolymers and cell nutrients through proprietary nanotechnological processes.

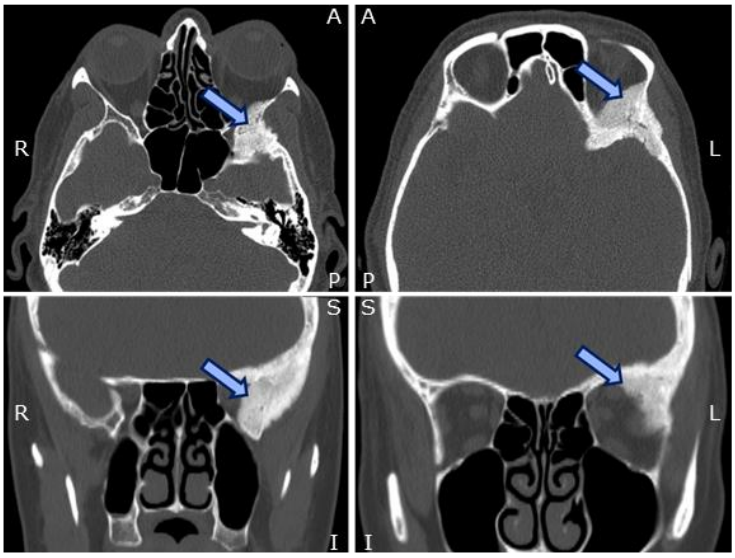

Fig. 2: Patient's initial condition. The arrows indicate the cancerous bone. CT scan (without contrast) 131 mA, 120 kV.

The patient underwent resection of a meningioma in the spheno - orbital-temporal region: the use of surgical guides allowed a precise removal of cancerous bone; neurosurgery was then performed to resect the meningeal involved district, which was reconstructed with membranes.

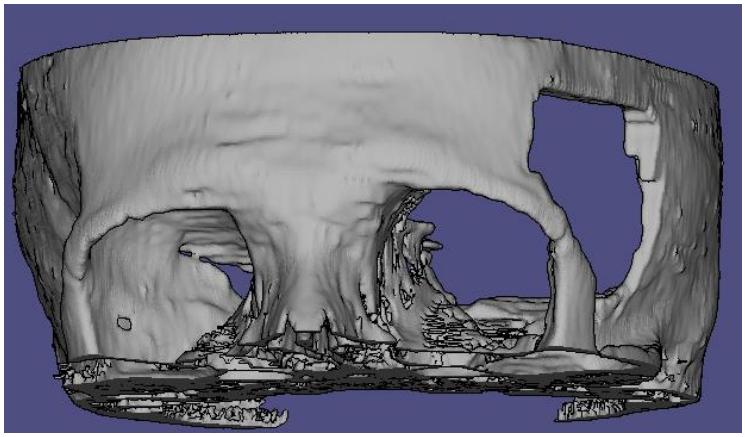

Fig. 3: Patient's initial condition, 3D render model.

SmartBone® on Demand™ grafts were then very precisely grafted into the destination site.

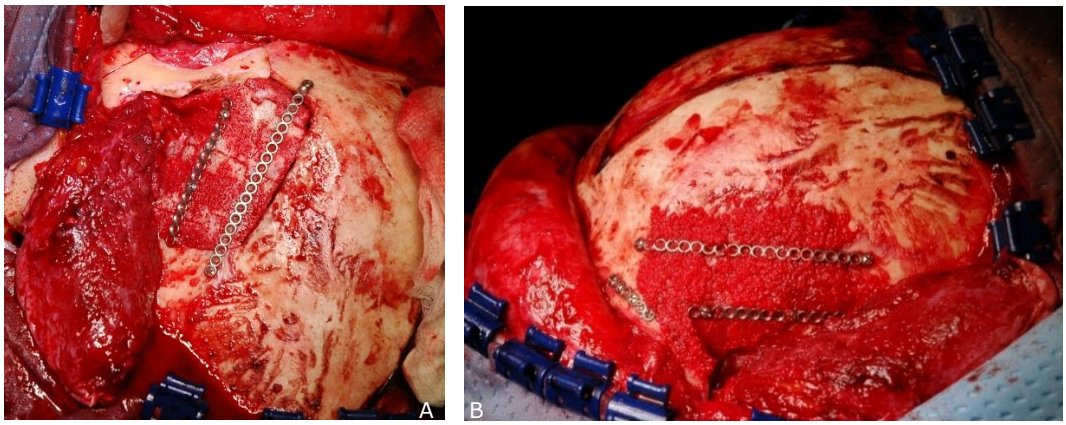

Fig. 4: SmartBone® placement and fixing with surgical straight plates for bone fixation. In figure B, the graft is covered with SmatBone® Microchips to fill the space between the native bone and the graft. This procedure allows a perfect contact that promotes SmartBone®'s osteointergration.

During follow-up, neither cerebrospinal fluid leakage nor intracranial infections were registered. Postoperative CT scans showed excellent stability and integration of SmartBone® on Demand™ grafts; postoperative morphological results are very satisfactory.

Outcomes confirm the high reliability and accuracy of virtual surgical planning and graft design, which, together with the high performances of SmartBone®, allow the production of very precise and stable custom-made grafts and, finally, addressing the previously unmet needs in skull base reconstructive surgery.

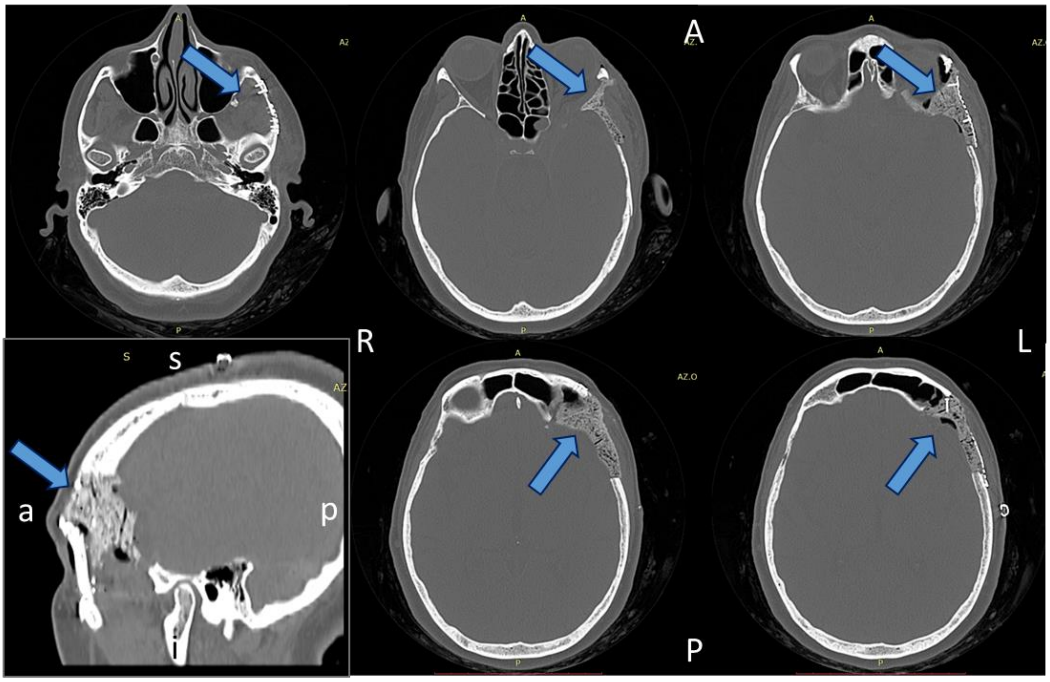

Fig. 5: First follow up time point 11 days after surgery. The arrows indicate the graft. CT scan (without contrast) 250 mA, 120 kV.

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