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Case Report

Custom-Made Horizontal and Vertical Maxillary Augmentation with Smartbone® On Demand™: A Seven-Year Follow-Up Case

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Abstract: The presence of non-sufficient bone height and width requires an increase in the amount of bone available to insert an implant. Different materials are described in the literature, and the "custom-made bone graft approach" is a modern option which currently requires a preoperative stage of studying the bone defect and designing the implant. SmartBone® (SB®) mimics the characteristics of healthy human bone. Thanks to the strong performance, high workability, resistance and shape retention of SB®, it is possible to obtain SmartBone® on Demand™, a bone graft uniquely shaped exactly to patient specifications, produced by following the data precisely and contoured to the bone defect site. The aim of this study was to determine the success over 7 years following a customized SmartBone® on Demand™, a xeno-hybrid bone graft and installation of implants in a maxillary horizontal and vertical atrophy. This case study presents the diagnosis for a 60-year-old male patient requesting the rehabilitation of his edentulous maxilla with dental implants. Preoperative evaluation included the study of photographs, a radiological examination and 3D reconstruction to assess the missing bone, implant size, positioning of implants and anatomical landmarks. Rehabilitation included the insertion of a custom-made xeno-hybrid bone block into the maxilla in order to restore the anatomy prior to the implants' placement. The newly developed bone substitute SB® is a safe and effective material, and its custom-made variant SmartBone® on Demand™ has been shown to be a valid alternative to traditional autologous bone grafting techniques in terms of accuracy, absence of infection/rejection and overall clinical outcome.

Keywords: bone substitute; SmartBone On Demand; custom implants; bone regeneration; xeno-hybrid bone graft

1. Introduction

The treatment of edentulous areas with horizontal and vertical atrophy is among the most complex tasks in oral surgery; the positioning of endosseous implants can be difficult and sometimes even impossible without a staged regenerative approach [1]. However, the reconstruction and augmentation of severely resorbed alveolar ridges are reliable procedures today, with the availability of a wide range of possible grafting biomaterials and techniques [2].

The chosen techniques and biomaterials can significantly affect the outcome of bone regeneration procedures, in terms of both bone formation volume and quality and amount of vital bone. When choosing a bone graft, the surgeon should carefully consider its ultimate effect on healing processes in, and around, the alveolar bone at the endpoint of the procedure [3]. Thus, by choosing the right grafting biomaterial, the surgeon can relevantly contribute to a favorable outcome.

An autogenous bone graft (e.g., harvested from the maxillary tuberosity, the symphysis of the chin or the external oblique line of the mandible) can be considered the gold standard of bone grafts due to its favorable osteogenic ability [4]; autografts, indeed, promote osteogenesis from their own growth factors, which are capable of differentiating cells into osteoblasts [5]. However, donor site morbidity, a long healing period of at least 6 months, graft resorption and a staged approach that necessitates two surgical interventions are considered important disadvantages and can result in avoidable surgical risks. Therefore, clinicians prefer to use commercially available allografts, xenografts or synthetic bone grafts [6]. Donor site considerations require caution in the recommendation of treatment, and a material that is not autologous, but which is equivalent in implant integration suitability, would clearly generate interest. Hence, this category of biomaterial has become the subject of substantial research.

Within this framework, the objective of our approach was to combine the biocompatibility and tissue integration of natural materials with the possibility of accommodating the typical mechanical and physical properties of synthetic ones. Composite grafts mimic the nature of healthy human bone most effectively, as they are both rigid and elastic, compact but porous, dense but viable to cells and vessels. SmartBone® (SB®), a xeno-hybrid developed and manufactured by Industrie Biomediche Insubri SA (Switzerland), was devised according to a new concept in composite approach, building on a base of bovine decellularized bone-derived mineral matrix, reinforced with bioresorbable aliphatic polymers and RGD-containing collagen fragments derived from animal-sourced gelatin (RGD is the acronym of the tripeptide arginine-glycine-aspartic acid). Such a new concept of biomaterial assembly allows the patient's cells to grow quickly and efficiently into the graft, while its biopolymers degrade, providing osteoconduction, supporting osteogenesis and finally ensuring perfect integration via complete remodeling [7–20]. This composite biomaterial resembles human bone microstructure and provides macro-scale properties: an adequate-sized open porosity with a combined rigid-elastic behavior, in combination with surface properties, which ensures cell viability and rapid tissue integration. SmartBone® on Demand™ is the custom-made application of SB® [21,22]. The *.DICOM* (i.e., the file type according to Digital Imaging and Communications in Medicine standard) data from the radiological examination with a cone beam computed tomography were converted into a *.STL* file with dedicated medical software. The data were then used for planning of a personalized bone graft to allow final rehabilitation with an implant-supported bridge. In this case report, it was used to design a patient-specific bone graft to allow a rehabilitation of a bone deficient maxilla with a bridge supported by implants. Surgery was very precise, producing a very satisfactory result both in terms of anatomical and functional reconstruction.

2. Case Report

A healthy 60-year-old male smoker with no contributing medical history was referred to a private practitioner (E.M.) requesting the rehabilitation of his edentulous maxillary region with dental implants. On clinical examination, a marked labial–palatal atrophy was diagnosed (Figure 1).

A cone beam computed tomography (CBCT) scan demonstrated the reduction in the coronal segment of the ridge with progressive apical expansion (Figure 2), and overall was judged still critical also for the use of short implants.

Preoperative evaluation included the study of photographs, a periapical radiographs and 3D reconstruction (building from the CBCT scan) to assess the missing bone, implant size, position of implants and anatomical landmarks. Initially, the rehabilitation included grafting of a molded heterologous bone block in the atrophic area to allow the following rehabilitation with implant-supported bridge.

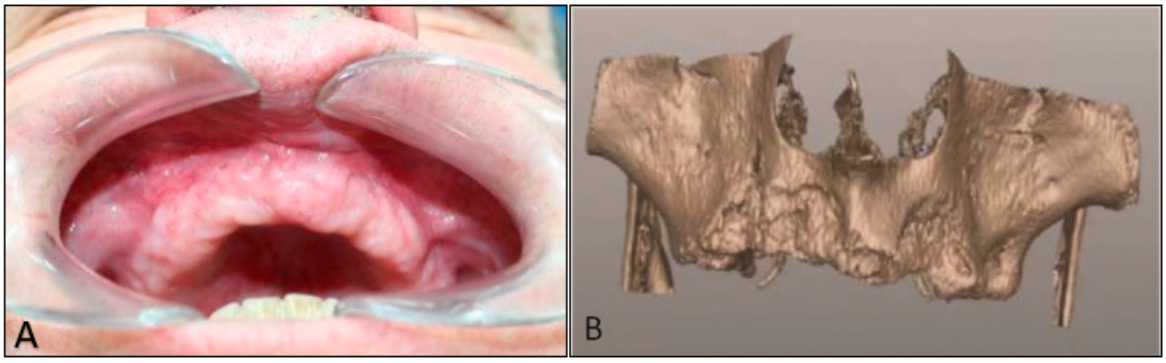

Figure 1. Initial situation of the pre-maxilla: (**A**) soft tissue of the edentulous area, (**B**) 3D CAD reconstruction of the upper jaw atrophy.

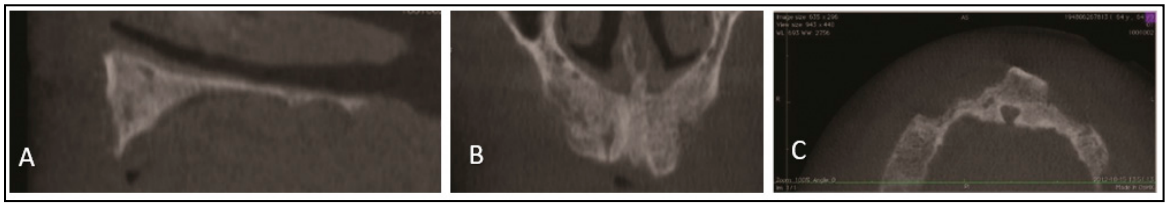

Figure 2. Cone beam computed tomography (CBCT) analysis before surgical treatment showed severe bone atrophy in the pre-maxilla area: (**A**) sagittal view, (**B**) coronal view and (**C**) axial view.

2.1. Methods

A two parallel-way approach was followed to design the custom-made grafts using both CBCT scan images, a digital planning using medical software and 3D real modeling with a stereolithographic 3D model. The CBCT images were used to create a virtual upper jaw model to support graft design. Further, in order to demonstrate the goodness of the digital design, files have been replicated and verified in a 3D stereolithographic model [16]. This solid model was mounted onto an articulator. After a diagnostic assembly process, there was an evaluation of the missing bone and the position in which the implants should have been inserted (Figure 3).

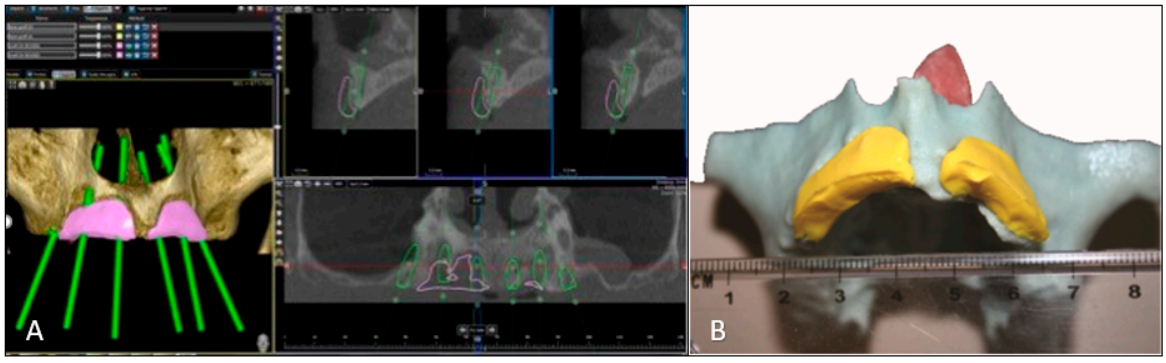

Figure 3. (**A**) Virtual planning of the surgical rehabilitation. (**B**) Stereolithographic model of the 3D resin reconstruction.

2.2. Surgical Phase

The choice of SB® was also driven by its specific properties with regard to mechanical resistance [11] and tenacity to screws. There could be no breakage or loss of stability in the interior bone without a risk of cracks, which would cause mobility and improper healing of the graft into the maxillary defect. After a careful evaluation, it was decided to proceed grafting only the patient's right side.

Surgery was performed according to standard protocols. After the appropriate anesthetic procedures, a crestal incision and a mucoperiosteal flap reflection were prepared. Thanks to the correct releasing incision, these provided ease of access for the operation taking place (Figure 4A). The SmartBone® on Demand™ graft was easily placed on the defect and tightly fixed with two osteosynthesis screws (Figure 4B). A resorbable membrane was then attached, and the mucoperiosteal flap was repositioned in its original position and sutured to cover the heterologous bone block (Figure 4C).

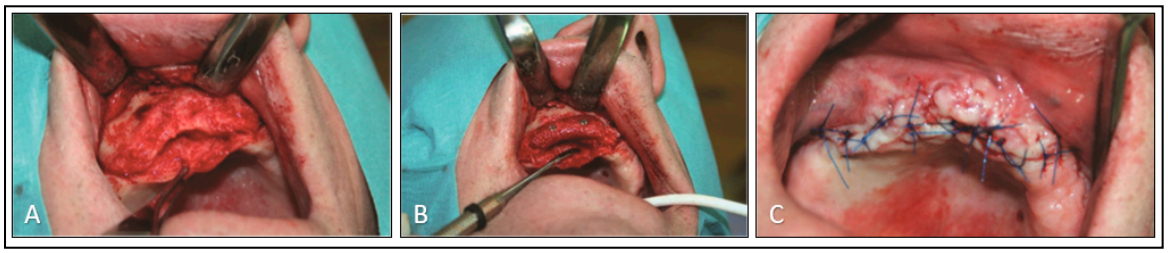

Figure 4. Surgical phase: (**A**) skeletonization of the defect area, (**B**) graft positioning and screws fixation and (**C**) soft tissue sutures.

In the postoperative phase, the patient was prescribed systemic antibiotics (tetracyclines) and anti-inflammatory and analgesics for 7 days. The patient was placed on a regular follow-up and control protocol. A check-up after surgery showed that everything was proceeding well: a CBCT showed a well-adapted integrated graft with signs of new bone formation already after 2 months (Figure 5).

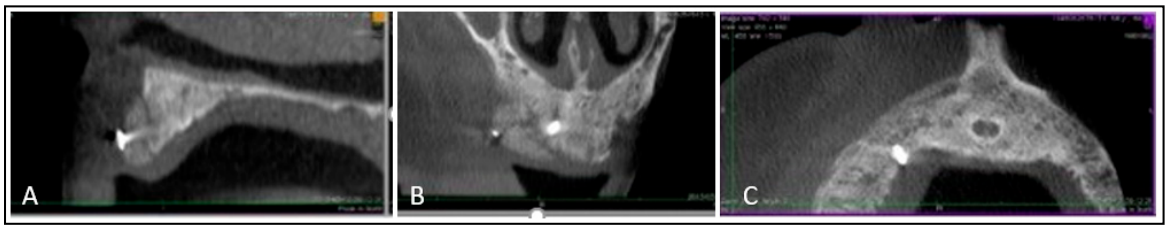

Figure 5. CBCT scan at 2 months after the surgical operation. It shows a good initial integration and stability of the SB® custom graft. (**A**) Sagittal view, (**B**) coronal view and (**C**) axial view.

After a healing period of 8 months, the soft tissue and radiographic findings were clinically good and showed good bone regeneration, suitable for implant placement.

The exemplificative images reported in Figure 6 show evidence of successful integration of the bone graft and its progressive remodeling.

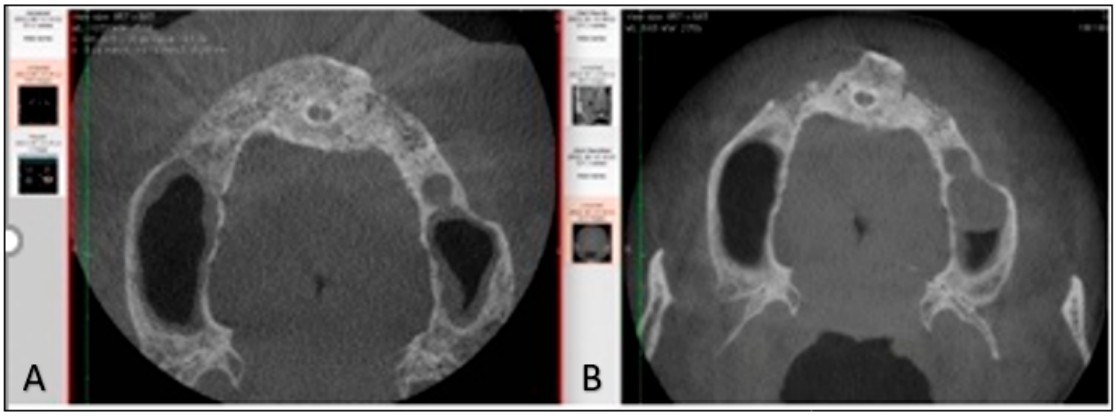

Figure 6. Axial view of the CBCT slide after 8 months following surgery. It shows good osteointegration at the bone material into the recipient site. Good bone density is shown as well. (**A**) Axial view after 8 months of the surgical operation. (**B**) Axial view before the surgical operation.

Seven implants were placed (Figures 7 and 8), and no post-operative complications were recorded at the time of the implant placement surgery.

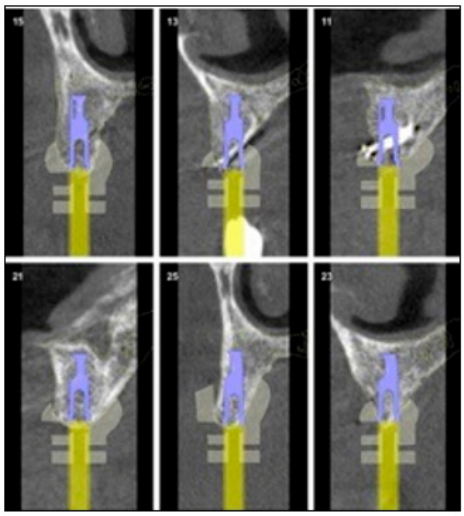

Figure 7. Surgical planning of the implants' placement.

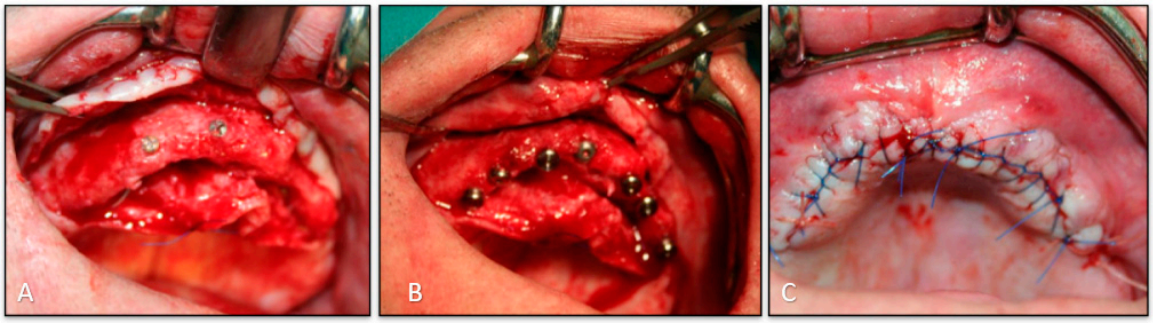

Figure 8. Surgical implants placement. (**A**) Bone quality after the re-opening, (**B**) positioning of seven implants and (**C**) suture of the soft tissue.

Following implant placement, bone samples were harvested for histological analysis. The exemplificative histology segment presented in Figure 9 shows SmartBone® vs newly formed tissue (H/E staining method): a thin trabecular bone with a mature lamellar structure is evident, and no reactions to foreign bodies are present.

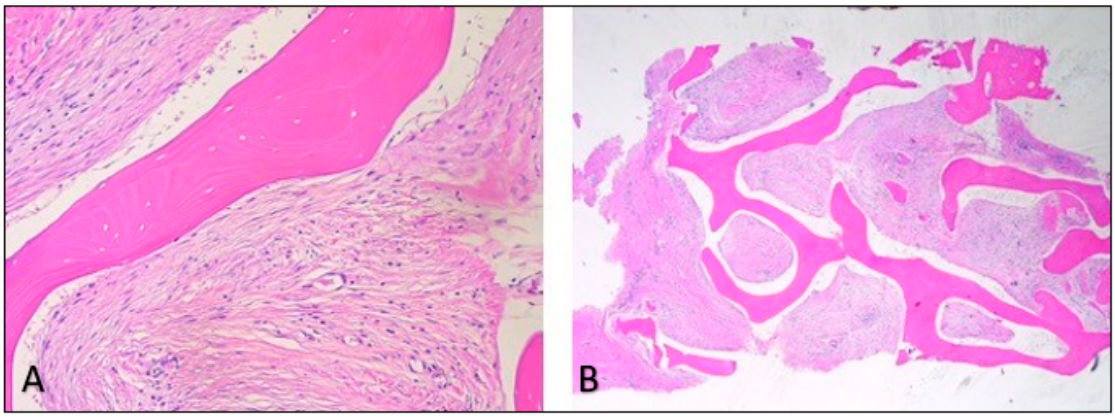

Figure 9. Histology (200×) segment: (**A**,**B**) show substitution of the SB®, and the osteogenesis has formed a lamellar bone with cement lines; a lot of osteocytes inside the lacunae and a good angiogenesis are evidenced.

The final restoration was completed 11 months after implant placement (Figure 10). Healing was uneventful, and the patient claimed to have minimal swelling and almost no pain. The patient was periodically recalled and followed up for 1 year after the prosthetic restoration. He remained a light smoker, but this condition appeared not to have significantly affected bone remodeling and overall long-term clinical outcome.

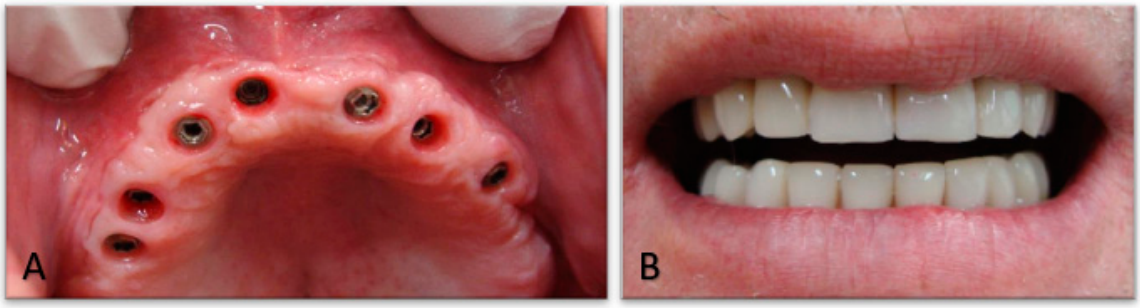

Figure 10. (**A**) Soft tissue, (**B**) final prosthesis placement.

The success and realization of the therapeutic program has provided the patient with the comfort of a rehabilitated set of teeth and the resulting advantages. A seven-year follow-up (Figures 11 and 12) demonstrates the long-term stability of custom graft rehabilitation by using SB® biomaterial.

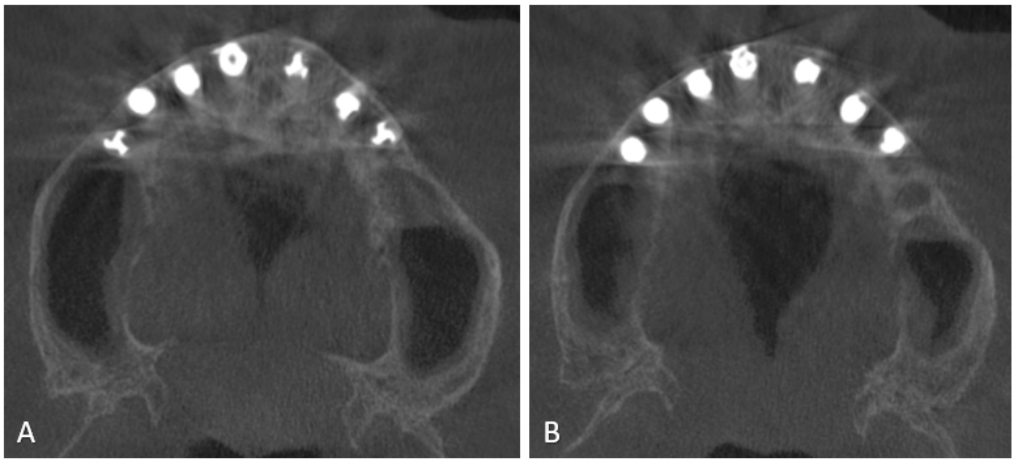

Figure 11. (**A**,**B**) CBCT slices of a seven-year follow-up after surgery.

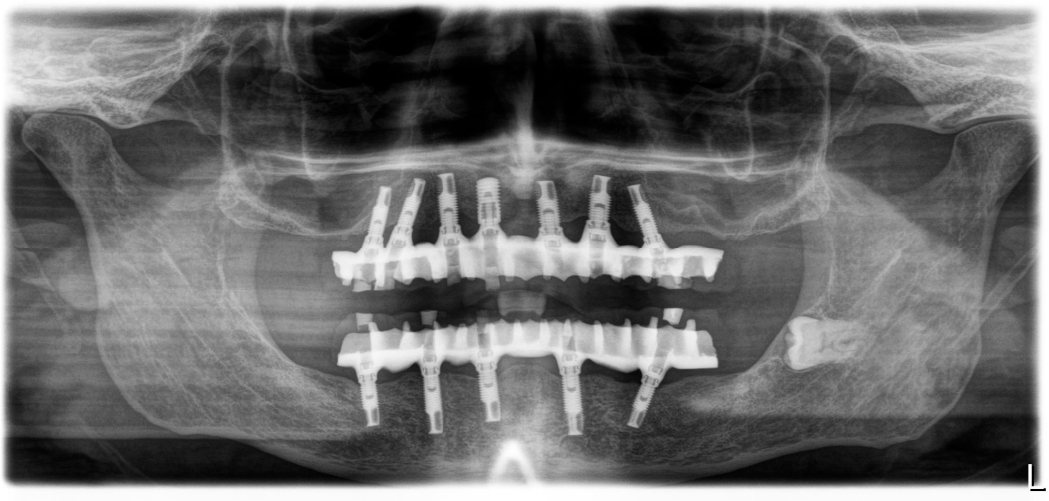

Figure 12. orthopantomogram (OPG), a seven-year follow-up after surgery.

3. Discussion

Numerous bone-grafting options exist to match various needs related to specificity of defects and patient's initial clinical conditions, from autografts to alloplasts, including xenografts and composite biomaterials [6,12,23,24]. The ideal graft material is described as a substance that will change into regular bone under functional loading without resorption and offers the ability to form new bone, either osteoconductively or osteoinductively, to enable the support of dental implants [5,6]. Therefore, autologous bone implantation has been widely adopted for decades because of the superior osteogenic properties of native bone grafts [13]. Autologous grafts are considered a gold standard for reconstruction because of their bioactivity, mechanical competence and immediate cellular function. However, the restricted volume of bone accessible to harvest intra-orally along with donor site morbidity and other known drawbacks have been widely calling for alternative methods in the last decades that range from xenografts to synthetic biomaterials [6,12,23,24]. Growing interest is given to hybrid biomaterials as their composite nature allows them to offer better performances from both the biomechanical perspective and the clinical outcome [6]. Similarly, custom-made solutions are now entering the market area as the long-term tendency is to drift towards patient-specific approaches. In this complex and wide framework, the here presented case highlights both the use of a xeno-hybrid material and a custom-made bone block. Indeed, SB® mimics the characteristics of healthy human bone, including very high biocompatibility, adequate open and interconnected porosity, high mechanical performance and hydrophilicity. In particular, thanks to the strong performance, high workability, resistance and shape retention of SB®, it is possible to obtain SmartBone® on Demand™, a custom-made bone graft uniquely shaped exactly to patient specifications. A custom-made bone graft for the reconstruction of a bone defect is a modern option that currently needs a preoperative stage of studying the bone defect and designing the implant [15], overall, offering interesting and clinically very positive options in lieu of using standard techniques for high-volume ridge augmentations. SmartBone® on Demand™ is indeed produced by following the data precisely, and it is contoured to fit the bone defect site. Moreover, surgery is very precise, and the operation time is significantly shorter than that required for a conventional graft, overall, minimizing surgical risks in favor of patients benefit. In addition, also noteworthy, the composite nature of SB® allows a complete remodeling over time, which, for example, is not recorded while just using simply bovine bone grafts [25]. Finally, a seven-year detailed follow-up is extremely rare to have [6,25].

4. Conclusions

The reconstruction of bone defects in oral surgery is a significant challenge due to the requirements both for complex shape and load-bearing capacity. The case report presented here shows the long-term success of a custom-made xeno-hybrid bone graft being a safe and effective biomaterial. SmartBone® on Demand™ has indeed shown to be a valid alternative to traditional autologous bone grafting techniques, in terms of accuracy, absence of infection/rejection and above all overall clinical outcome, proven by very long term volume stability here recorded over 7 years of follow-up and also histologically by formation of new healthy bone via complete remodeling process.

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Conflicts of Interest: Giuseppe Perale is among shareholders of I.B.I. SA, the Swiss company owning intellectual property rights on SmartBone® and SmartBone® on Demand™, manufacturing and commercializing it. Carlo F. Grottoli works for the same company. The remaining authors declare no conflict of interest.

Consent to Participate: The patient signed an informed-consent form to document that he understood the aims of the study and authorized the use of his data for research purposes. All procedures were performed in strict accordance with the recommendations of the Declaration of Helsinki, as revised in Fortaleza (2013), for investigations with human subjects, and followed good clinical practices and ISO14155 prescriptions.

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