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Case Report

Jaw's Bone Augmentation with New Generation of Bone Composite Substitute Materials

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Received: April 16, 2019; **Published:** July 15, 2019

Abstract

Introduction: In the process of manufacturing of the new generation of composite biomaterials, the natural mineral bone structures (bovine matrix) are combined with the resorptive biopolymers and cell nutrients (biomolecules with Arg-Gly-Asp sequence). This new concept of the biological materials stimulates the host cells to grow faster and more effective into the graft material while the biomaterials degrade simultaneously ensuring the perfect integration and osteogenesis.

Case Presentation: In this case study we evaluate female patient 57 years old in good medical condition, with edentulous upper jaw. Patient was evaluated anamnestic, clinically and performed CBCT evaluation. Two custom made grafts for the maxilla posterior regions were manufactured. In the second phase we performed the augmentative procedures with positioning and fixation of the grafts and collagen membranes. After period of 9 months, the patient was clinically and roentgenological evaluated. The real enlargement of the bone volume and bone fundament was considered and optimal condition for dental implants insertion created.

Conclusion: The results suggest significant enlargement in the horizontal and vertical alveolar ridge dimensions and excellent consecutive osseointegration of dental implants with satisfactory full-arch functional and esthetic restoration.

Keywords: *Composite Bone Substitutes; 3D Planning, 3D Custom Made Grafts, Vertical and Horizontal Augmentation, Osseointegration*

Introduction

Autologous grafting and distraction osteogenesis are the most commonly used techniques for restoring primarily mandibular defects. Generally, autologous grafts are considered to be "gold standard" in oral surgery and implantology, because of their ability to favor osteogenesis, osteoinduction and osteoconduction. The main problem of autologous grafts is, in certain cases, the severe availability and consecutive morbidity of the donor site. Because of these main reasons, the search for new methods and solutions for bone reconstruction in dental science and clinical practice is more intense.

In the new generation of inventive and intelligent regenerative systems, cutting edge technology meets nature. The new composite bone substrates (Smartbone) have been specially developed for a wide range of indications in oral, maxillofacial surgery and implantology. In the process of production of the new composite biomaterial, natural mineral bone structures (bovine bone matrix) are combined with bioactive resorptive polymers and cellular nutrients (biomolecules with the Arg-Gly-Asp sequence) [1]. This new concept of biological materials encourages the recipient's cells to propagate quickly and efficiently in the graft material itself while biopolymers are decomposing, allowing perfect integration and osteogenesis. At the micromolecular level during the integration of the graft with recipient tissues, complex cascades are initiated precisely from the biomolecules that surround the graft [2]. When migrating cells come in contact with type I collagen, cells secrete enzymes called matrix metalloproteinases (MMPs) in order to denature type I collagen in gelatin (denatured collagen). Once type I collagen is denatured in gelatin, a number of active sequences (RGD sequences) become available to other cells. The RGD (Arg-Gly-Asp) sequences represent attachment domains and become chemotactic for a large number of cells responsible for the formation of granulation tissue (the new tissue formed in the process of bone healing rich in blood vessels). A gelatin coating can provide improved signaling to the cells responsible for the creation of granulation tissue. Collagen-type coatings containing only type I collagen require MMP-1 support for initial conversion of collagen into gelatin, so cells in the early phase must first release MMP-1 in order to change type I collagen into gelatin. Proteins containing Arg-Gly-Asp (RGD) attachment side of the molecule, together with the integrins that serve as their receptors, constitute the cellular recognition systems that promotes cell adhesion. This type of peptide promotes cell adhesion when found in an insoluble form of the surface and inhibits it when presented to the cells in dissolved form.

Composite bone substituents are extremely biocompatible, possess a porous microstructure that is analogous to the human bone with hydrophilic features and promote cell colonization, cell adhesion and osteogenesis. The microstructure in the composite matrix strongly mimics the histological structure of the human bone with a similar porosity of 27%. Through the process of designing within biomedical engineering, the natural variability of bovine matrix micropores is reduced, transforming it into a bone substituent with a homogeneous and regular microstructure.

The new generation of composite bone substitutes offers impressive mechanical performance that allows precise shaping, high volume stability, excellent stability during fixation, resistance to extreme loads, rigid and elastic mechanical behavior at the same time. Their clinical indications include sinus lift procedures, vertical and horizontal bone augmentation, preservation of post-extraction alveoli, augmentation of intrabone defects and peri-implant defects [3,4].

Modern composite materials are presented in various forms adapted for the most appropriate clinical use (microgranules, blocks, special U, C, L shapes, cylindrical or wedge shaped grafts). With the help of modern computer-assisted and computer-aided surgery and 3D design software solutions a precise manufacturing of composite bone substitutes can be done. By using this method a restoration of complex bone defects is enabled.

Aim of the Study

The main and key goal of the case study was to evaluate effective and real enlargement of the bone volume in horizontal and vertical projection in the edentulous maxilla, with 3D custom made grafts with new composite bone substitute materials and their direct impact on functional and esthetic results.

Case Presentation

The following case describes the treatment of a 50-year-old female with edentulous maxilla (Figure 1).

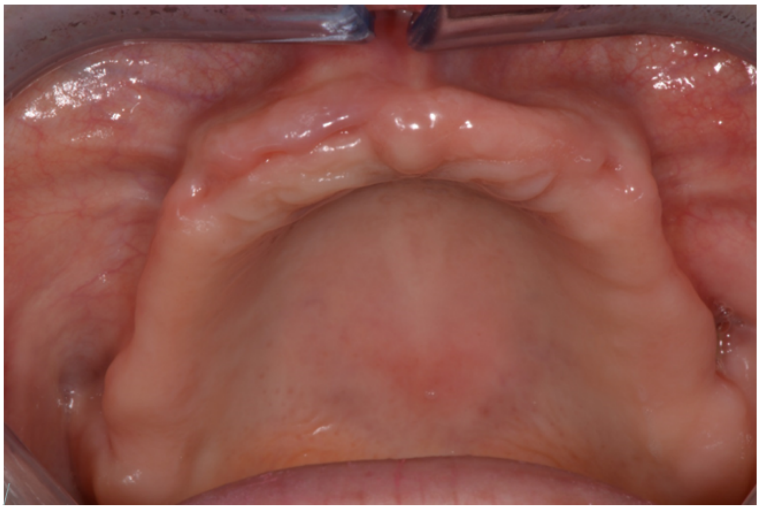
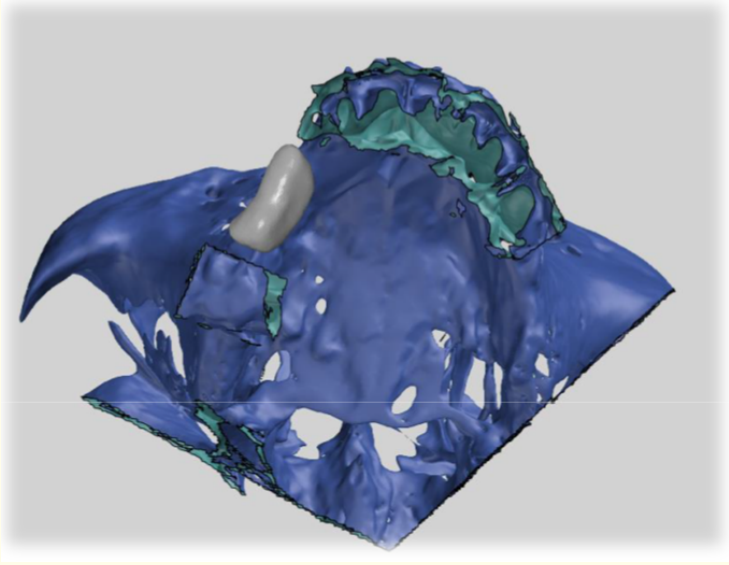


Figure 1: *Intraoral view of the edentulous maxilla.*

Patient was evaluated anamnestic, clinically and roentgenographically (CBCT). The 3D dental scanning visualizes most precisely bone deficiencies and their anatomomorphological limitations in the upper jaw. It was evident that major bone augmentation in height and width was indicated, in order to enable prosthetic-driven implant placement.

Treatment plan was well established and also the following augmentative surgical procedures. After being carefully informed of the treatment and its potential outcomes, the patient accepted it.

A treatment plan involving two custom made smartbone blocks was created using CAD/CAM technology for bilateral posterior maxilla augmentation (Figure 2 and 3).



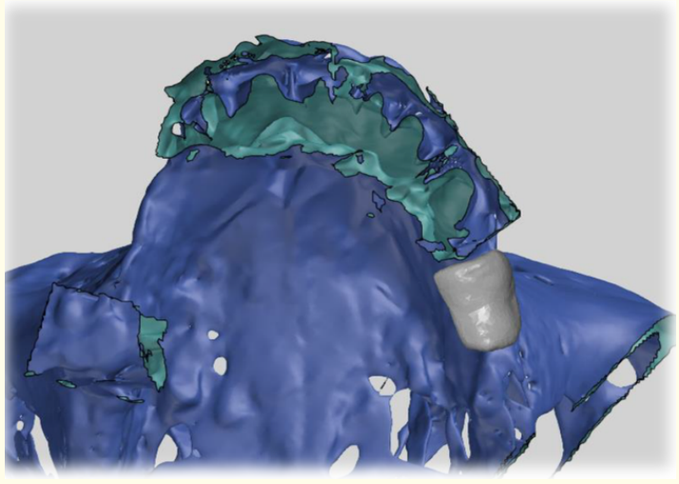


Figure 2 and 3: *3D images of the specially designed software solutions for two custom made smartbone blocks in posterior maxilla.*

Based on 3D dental scans, bone insufficiency in the vertical and horizontal direction was precisely visualized, as well as the volume and size of bone defects and their ratios with the anatomical structures in the upper jaws. With the help of the software analysis, a virtual plan of therapy was created.

In this particular case all benefits from the modern computer-assisted and computer-aided surgery, specially designed software solutions, 3D designs were used. This 3D designs and creation of custom made grafts for solving complex bone defects were manufactured in the computer science centre in IBI S.A (industrie biomediche insubri S.A.) in Switzerland.

The size and shape were approved after a few corrections in the virtual model by the international team. Then the custom made graft was approved for production.

Patient was provided with preventive antibiotic and anti-inflammatory prophylaxis according to protocols for prophylaxis in augmentative surgical techniques.

After the application of local anaesthesia and preparation of the operative field, a mucoperiosteal flap was created and intraoperative bone insufficiency in a horizontal and vertical direction was visualized. The recipient site was prepared using a special bone transfer surgical set into an adequate bed for the application of the composite bone substituent. The creation of "micro perforations" (preparation of bleeding holes) in cortical bone of the recipient site, improves the capacity of vascularisation and fast graft osseointegration (Figure 4).

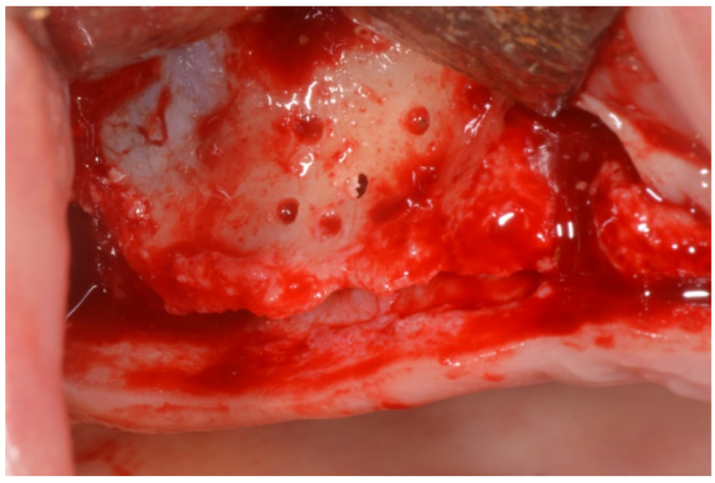


Figure 4: *Intraoral view of the surgical recipient site.*

The soft tissues were expanded respectively, allowing the subsequent complete closure of the operative wound and graft. Next is the appropriate bearing for the surgical screws providing close contact of the graft and perfect fit, with the natural bone and firm fixation of the graft (Figure 5 and 6). After the application of the graft, the possible sharp angles of the graft material must be eliminated and its maximum adaptation with the anatomy of the surrounding natural bone is ensured. It is not recommended by the manufacture to mix this type of graft material with other types of biomaterials. This type of graft materials also indicates the obligatory application of the barrier collagen membrane (Figure 7).

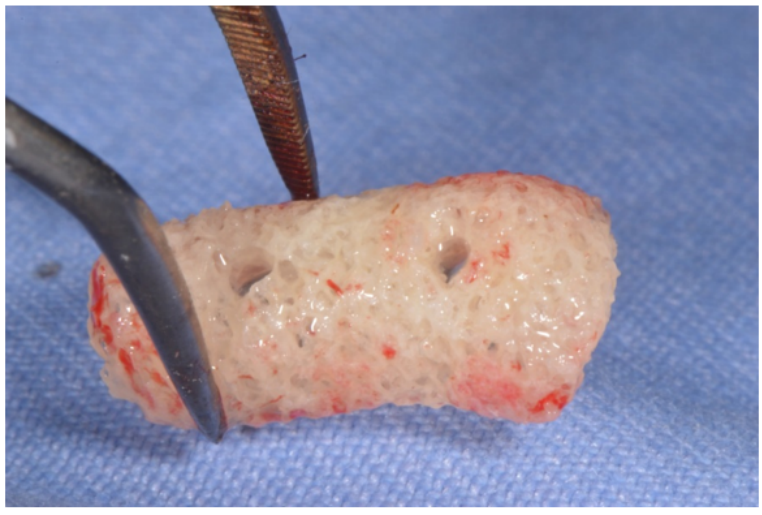


Figure 5: *Custom made smartbone block.*

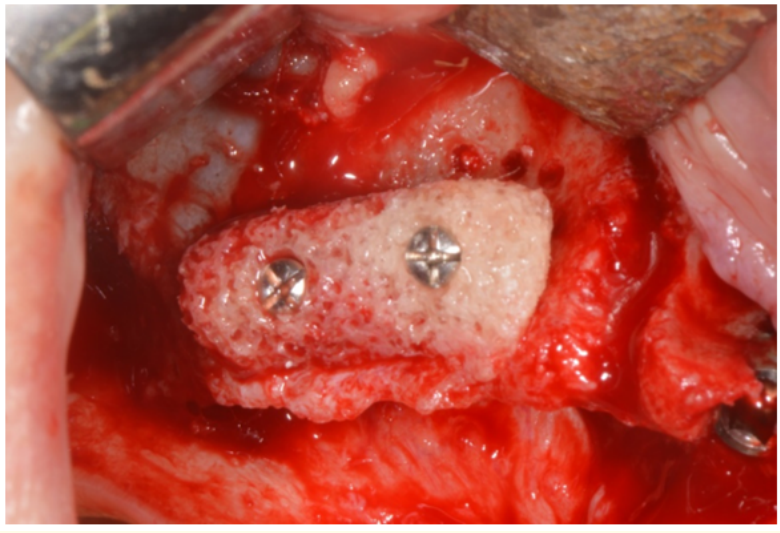


Figure 6: *Fixation of the graft with smartbone surgical screws.*

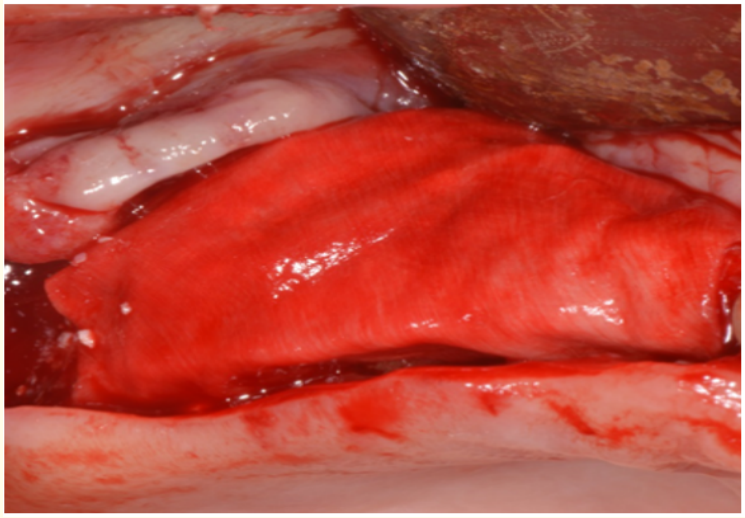


Figure 7: *Collagen membrane coverage.*

After placing the membrane, soft tissues were returned to the original position, which ensures good closure without tension of the operative wound (Figure 8). Tension free wound closure is one of the most important factors for achieving integration and healing of the smartbone block. After the surgical procedure it is important to avoid tissue stress to ensure high oxygen levels in the postoperative wound.

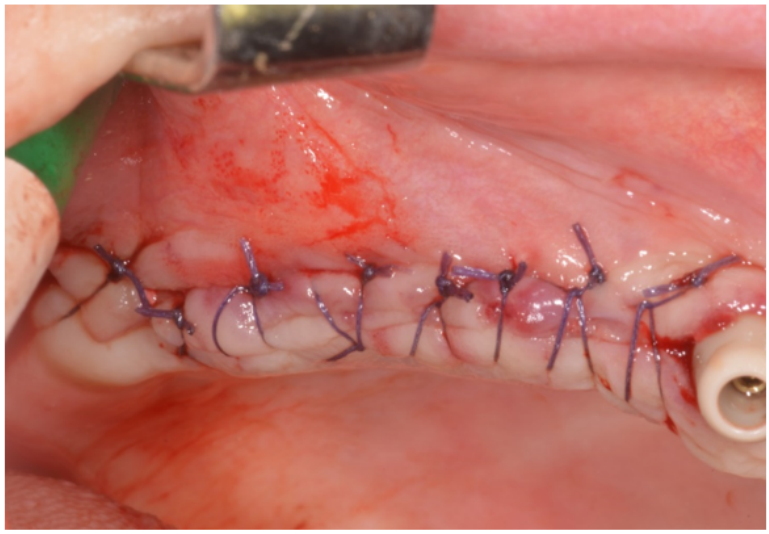


Figure 8: *Surgical wound closure.*

In postoperative period, the appropriate postoperative measures according to the protocol for postoperative care were recommended. Postoperatively, the patient was prescribed antibiotics, anti-inflammatory medications and painkillers. The healing period was uneventful with only minor swelling, pain and discomfort.

After nine months of augmentative surgery procedure, the patient was clinically and radiologically evaluated to assess the real and effective increase in bone volume and bone foundations. CT scanning confirmed the high tissue integration of new composite bone substituents without the presence of a demarcation line between the graft and the natural bone and the normal morphometric structure was present.

The density of the newly formed bone was over 500 HU. The values of the alveolar bone in the augmented part were measured in two directions- horizontal and vertical and were compared with the values obtained prior to the application of the graft material (Figure 9).

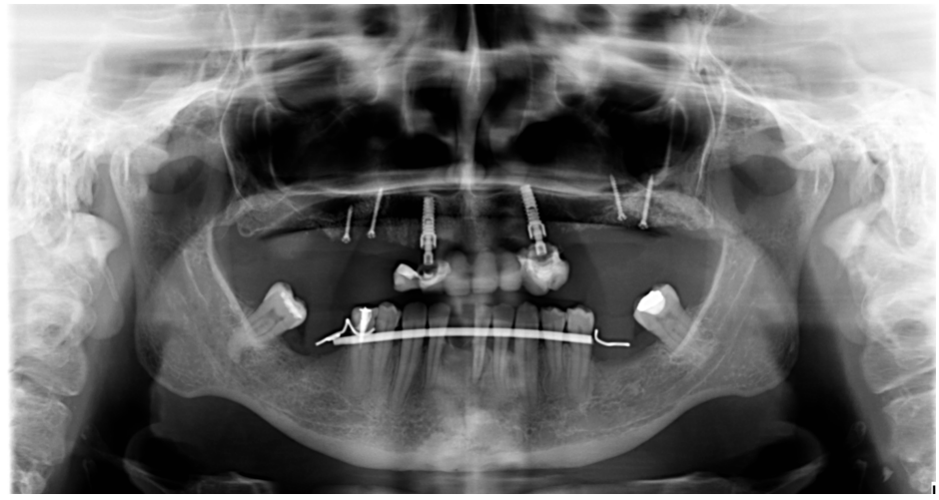
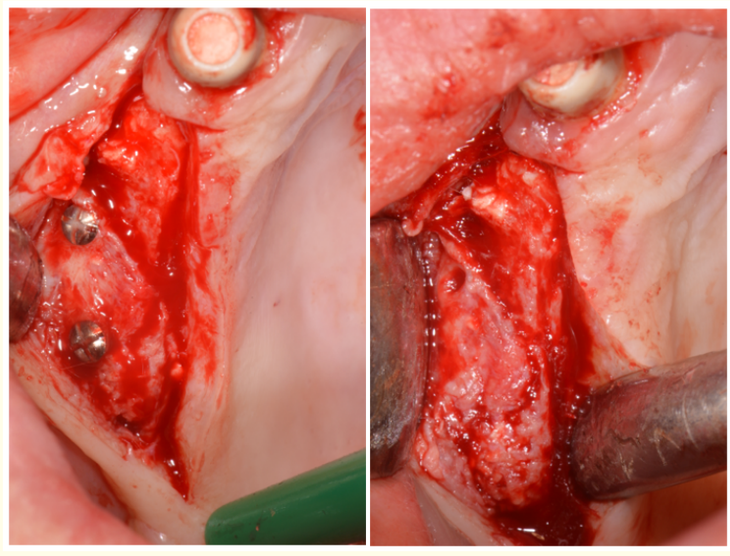


Figure 9: *9 months postoperative panoramic view.*

After confirming the results obtained, patient continued with further implant-prosthetic treatment plan, the second stage surgery (re-entry) and implant placement. There were no signs of resorption of the smartbone blocks which were fully integrated, the heads of the smartbone screws were at the same level of the blocks and the fixation screws were removed prior to implant placement. The final prosthodontic restoration, zirconium bridge, was delivered two months after insertion of the temporary bridge and five months after implant placement (Figure 10-15).

Discussion

The current clinical gold standard for treatment of critical sized bone defects and vertical and horizontal bone insufficiency still remains autograft bone. Although autografts are advantageous for immunocompatibility, they carry a wide spectrum of risks (general anesthesia, complex surgical maneuvers, secondary infections, fractures, and pain and donor site morbidity) that can lead to a high percentage of failures (more than 10%) [5].



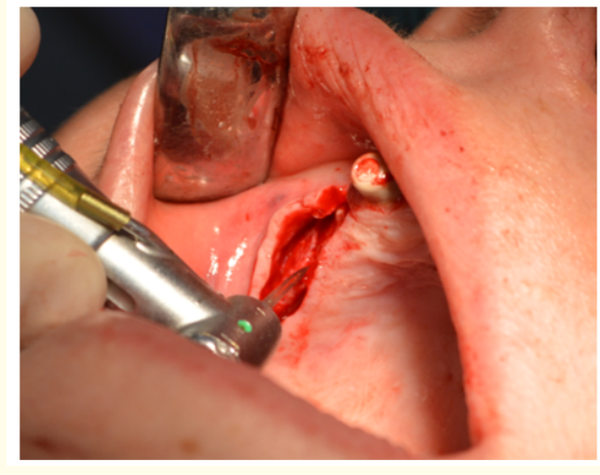


Figure 10-12: *Second stage surgery, re-entry and implant placement.*

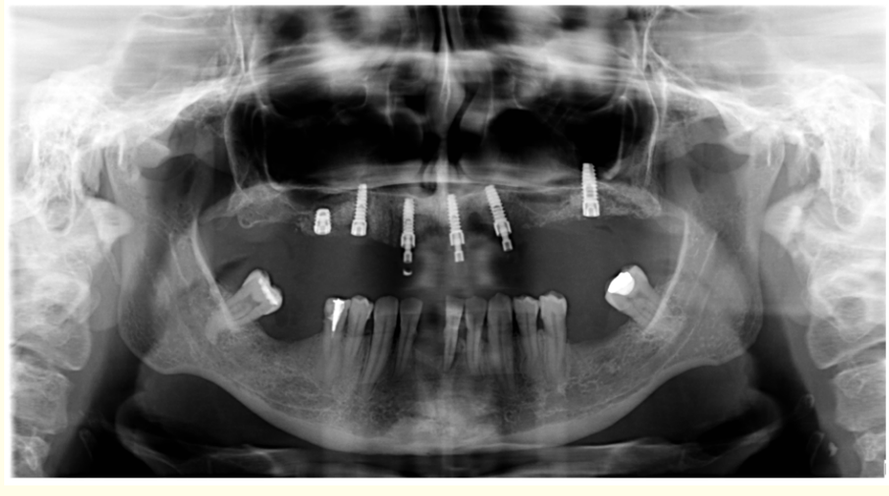


Figure 13: *Postoperative panoramic view.*

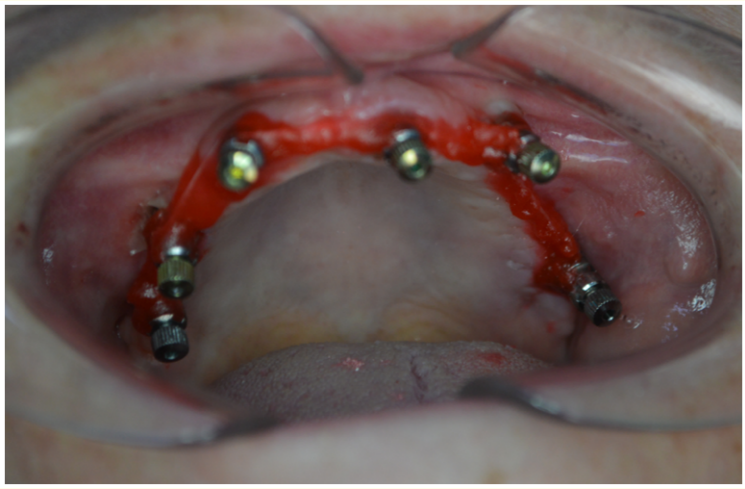


Figure 14: *Prosthodontics phase.*

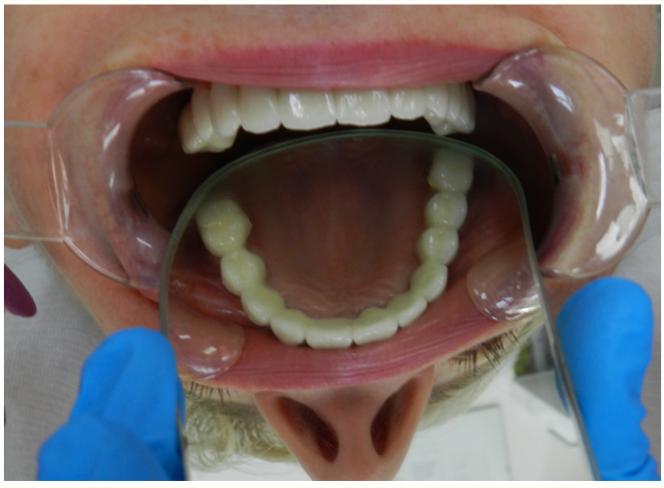


Figure 15: *Definite implant-supported prosthesis.*

Adequate bone substitutes that promote an efficient remodeling of the native bone tissue can be chosen from the wide spectrum of solutions divided into three main categories: allografts, i.e. bone segments taken from cadavers, acellularized and sterilized; xenografts, i.e. bone segments taken from animal bones (cows, horses, pigs, etc.) acellularized and sterilized and synthetic scaffolds.

Scientific research is progressively leading to the evaluation of other alternatives than allografts, because they imply a higher risk, since disease transmission between humans is more likely than transmission between animal and human [6].

The current focus, thus, still remains on xenografts vs. synthetic biomaterials. The new "composite" approach is considered as the most promising as far as it will mimic a healthy human bone [7].

Smartbone is bioengineered medical device that mimics the human bone microstructure (adequate sized open porosity of 27 - 30%) with a combined rigid-elastic behavior and with surface properties that ensures cell viability and colonization in order to obtain remarkable and fast tissue integration. The key features of new composite biomaterial smartbone are high mechanical performances, high hydrophilicity and high tissue integration.

Smartbone has high mechanical performances, close to those of a human healthy bone (rigid elastic behavior, adequate elastic modulus, proper load bearing resistance, ability to be precisely modeled by all types of surgical tools, tenacity to fixation screws and heavy surgical maneuvering resistance). High hydrophilicity enables absorption of blood full of mesenchymal stem cells. High tissue integration means high level of cell viability, proliferation and osteoconduction.

The new developed composite material is composed of a bovine bone derived matrix, biocompatible and biodegradable biopolymers (polyesters) and cell nutrients (polysaccharides). The homogeneous polymeric coating helps to reinforce the structure by adding an elastic component, reduces the porosity mimicking the healthy human bone and protects the graft from the reabsorption during the first inflammation healing period. Polymeric fraction is subject to a complete degradation which occurs in an average of 18 week (approximately in four months).

The presence of cell nutrients makes the surface very viable for cells, promotes cell adhesion and increases the graft wettability, making it highly hydrophilic [8].

Grafts undergo heavy stresses and loads as far as they need to be shaped and cut before being placed and to withstand drilling and fixing of osteosynthesis screws. They must remain mechanically stable offering a strong mechanical bond and high surface contact with the host tissue in order to achieve better tissue integration [9].

The standard way to assess the mechanical behavior of a bone graft is with the mono-axial compression test, which allows to calculate maximum stress resistance (breaking stress) and Young's modulus (i.e. elastic module) [10].

Smartbone graft owns excellent mechanical performance in the terms of capability of very precise shaping by surgical instruments, the absence of powder and debris formation during modeling and a very high resistance to screws and fixation maneuvers. The mechanical stability and the surface contact between the graft and host tissue are determining the future success of the tissue integration.

The purpose behind coating mineral matrix with polymeric fraction comes from the necessity to have higher mechanical properties together with suitable microstructure, on one side, and to improve hydrophilicity for good cell adhesion, on the other [9,11].

Biological osteointegration of a smartbone graft is accelerated due to its characteristics: extreme biocompatibility, fast blood absorption, cell attractiveness and high mechanical stability.

Bone generally has the ability to regenerate completely if provided the space into which to grow (bone graft). As native bone grows, it will replace the graft material completely. The biologic mechanisms that provide a rationale for bone grafting with composite grafts like smartbone are osteoconduction and osteoinduction.

Osteoconduction occurs when the bone graft material serves as a scaffold (framework) for guiding the reparative growth of the natural bone. Osteoinduction is defined as ability to stimulate osteoprogenitor cells to differentiate into osteoblasts that subsequently begin new bone formation.

Smartbone not only serves as a scaffold but also triggers the formation of new osteoblasts, promoting faster integration of the graft [12]. Smartbone graft integration is expected in an average of a 12 month time window.

It covers all forms and shapes from fine microchips and granules to big blocks 15 x 30 x 60 mm.

Smartbone is specifically designed for large variety of bone regeneration applications: vertical and horizontal bone augmentations, sinus lift procedures, intrabony defects and peri-implant defects. Also custom made bone grafts can be used in oral and maxillofacial reconstructive surgery.

Innovations applied to our clinical case report were multiple based on CBCT scans, virtual planning and surgery and computer-aided design. Postoperative CT scans showed excellent stability and integration of custom made grafts, with satisfactory bone density of the grafted areas.

Virtual surgical planning and graft design together with high mechanical performance of new composite biomaterials allow creation of precise and stabile custom made grafts.

Conclusion

Significant and stabile enlargement in horizontal and vertical alveolar ridge dimensions and excellent consecutive osseointegration of dental implants can be expected with combination of digital 3D planning and creation of custom made grafts by computer-aided design with newest composite biomaterial representatives.

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Volume 18 Issue 8 August 2019