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SPECIAL ARTICLE

Custom-made additively manufactured subperiosteal implant

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ABSTRACT

Subperiosteal implants were introduced in the last century. Poor clinical results led those implants to be progressively abandoned. Recently, several Authors suggested a revival of subperiosteal implants as an alternative to regenerative procedures. The purpose of this study was to describe the clinical application of custom-made additively manufactured subperiosteal implant for fixed prosthetic rehabilitation of edentulous maxilla. Plaster models of the upper and the lower arch were scanned, as well as the mock-up. Digital Imaging and Communications in Medicine data obtained from cone beam computed tomography were processed through the thresholding procedure. The design of the subperiosteal implant was drawn on the stereolithographic model and scanned. Once the digital project of the subperiosteal implant was completed, it was sent to additive manufacturing. After the surgery, the patient was strictly monitored for up to 2 years. The outcomes were assessed based on the incurrence of biological and mechanical complications, postoperative complications, and implant survival. The patient did not suffer from postoperative complications. Neither biological nor mechanical complications occurred during the follow-up period. At the end of the study, the implant was still in function. Custom-made subperiosteal implants could be considered as an alternative to regenerative procedures for the rehabilitation of severe bone atrophy. Further studies are needed in the future to confirm the positive outcome.

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KEY WORDS: Dental implants; Alveolar bone loss; Printing, three-dimensional; Cone-beam computed tomography.

Subperiosteal implants were introduced during the ’40 of the last century.[1] In the following years, it took place an evolution of both the clinical procedures and the design.[2-7] Nevertheless, longitudinal studies showed that the subperiosteal implants were related to an high rate of complications, such as recurrent infections, fracture of the implants, resorption of the underlying bone, paresthesia and mobility.[8-13] Longitudinal studies reported the removal of many implants due recurrent infection and structure exposure. Furthermore, the procedure was badly tolerated by patients because it required two stage surgeries. As a consequence, the subperiosteal implants were progressively abandoned[14] in favor of the endosseous implant introduced by Brånemark *et al.*[15]

Endosseous implants have shown long-term high survival rate.[16] However, a certain quantity and quality of bone is necessary for their placement. This means that in case of severe bone at-

rophy regenerative procedures are needed. The most used are guided bone regeneration (GBR) with non-resorbable or resorbable membranes, sinus augmentation, alveolar ridge split, inlay/onlay bone grafting, or distraction osteogenesis.[17] Those procedures are not always predictable, intra- and postoperative complications could afflict the final result and they also require long waiting and add economic costs.[18]

Recently, several Authors suggested a revival of subperiosteal implants.[19-21] The steps required for the production of the subperiosteal implants were totally revised, according to the modern knowledge of oral implant research. The digital technologies in the dental field allow the production of custom made subperiosteal implants though additive manufacturing.

The purpose of this manuscript was to describe the clinical application of custom-made additively manufactured subperiosteal implant for fixed prosthetic rehabilitation of edentulous maxilla.

Study framework

Representative case

All the data of the clinical case were collected from M.C. personal database. The patient was a 67-years-old female with an edentulous maxilla (V Class Cawood & Howell)[22] (Figure 1A). The exclusion criteria were: 1) existence of metabolic bone disease; 2) history of malignancy; 3) history of radiotherapy or chemotherapy for malignancy in the past 5 years; 4) history of autoimmune disease, and long-term steroidal or antibiotic therapy; 5) more than 10 cigarettes per day smoker; and 6) poor oral hygiene. The patient desired to replace her upper removable total prosthesis with a fixed prosthesis on dental implants. The patient agreed to submit a rehabilitation of the upper jaw with a subperiosteal implant (Eagle Grid, Eagle Grid S.r.l, Bergamo, Italy) and the present study.

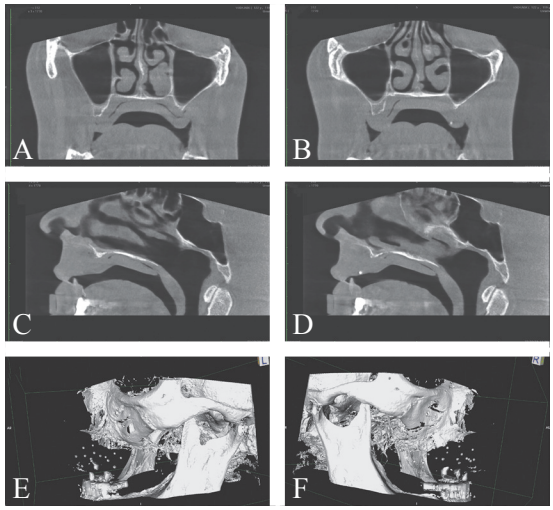

Figure 1.—Cone Beam Computed Tomography (CBCT) evaluation for treatment planning. The different projections (A-D) show the severe bone atrophy of the upper jaw. The 3D reconstruction of the bone anatomy of the upper jaw (E, F).

Digital workflow

Direct impressions of the upper and low arches were taken with polyvinyl siloxane A-type (Express STD, 3M ESPE). The plaster models were scanned and saved as an STL (Standard Tessellation Language) file. The diagnostic wax-up was scanned and saved as an STL file. The dental technician made a resin scan prosthesis, a replica of the wax-up, with fiducial markers in barium. The scan prosthesis was stabilized with silicon during the CBCT exam (0.2mm slice, 15x18 FOV) (Figure 1). Next, the scan prosthesis was scanned with and without the plaster models of the patient.

DICOM data were processed through a thresholding procedure to create a virtual reconstruction of the bone anatomy of the patient. The software used was Real Guide (3DIEMME S.r.l., Cantù, Como, Italy). The file created was used to make a stereolithographic model in resin. The design of the subperiosteal implant was drawn on the resin model with a black pencil. The choice of the color was functional to the subsequent scan, because green and black are the ones that the optical reader catches better. The struts of the subperiosteal implant were located on the maxilla pillars (nasal, canine, and hard palate in the median and paramedian areas). The holes for the fixation screws were strategically placed according to the thickness of the cortical bone. Next, the resin model was scanned, so the project was used to digitally design the subperiosteal implant. The software used was Exocad (exocad GmbH, Darmstadt, Germany) (Figure 2A-D).

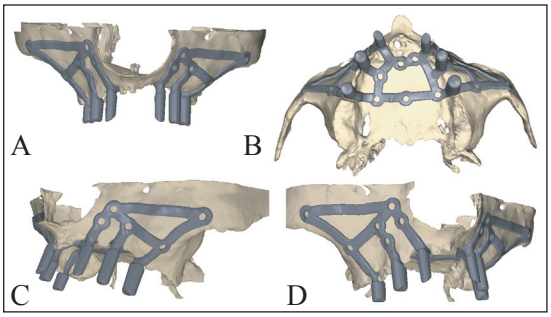

Figure 2.—Digital planning of the subperiosteal implant in different projection (A-D).

Osteotomies were digitally planned to support the parts of the subperiosteal implant that connect the struts with the abutment. It's opinion of the Authors that by preserving most of the bone around the abutment, the healing of the soft tissue improves. As a consequence, the risk of soft-tissue dehiscence could decrease.

Additive manufacturing

The STL file of the subperiosteal implant was sent to a printing facility (Ancorvis S.r.l., Bologna, Italy) for Direct Metal Laser Sintering (DMLS). The material used was titanium grade 5 powder. Once the production was completed, the implant underwent a milling machine process to refine the design of the abutment. In this case, abutments for cement retained prosthesis were used. Next, the subperiosteal implant was cleaned-up and packaged for sterilization (Alticolor S.r.l., Padua, Italy). The surface of the subperiosteal implant was marked with an alphanumeric code, which enables to identify of the technical file of the implant itself. This allows to trace all the information of the digital planning, the additive manufacturing process, and sterilization of the implant itself. All those information represents the declaration of conformity according to European and Italian laws.[23, 24]

Surgery

Local anesthesia was performed by infiltration with 4% articaine containing 1:100 000 adrenaline. A wide crestal incision was executed in a palatal direction to preserve the keratinized tissue. Vertical incisions were made in the median and lateral positions. A full-thickness flap was raised to make visible the areas where the struts of the subperiosteal implant will be fixed. A surgical template in resin was used to carry out the osteotomies digitally planned with a surgical drill. The subperiosteal implant (EagleGrid, EagleGrid S.r.l.) was picked up from the package and the fit was carefully checked. Next, the subperiosteal implant was pushed in position with light percussions using a specific tool, which is part of the Kit Integra (Mech & Human S.r.l., Padua, Italy). The osteosynthesis screws (Kit Integra, Mech & Human S.r.l.) were placed with a torque of 30 Ncm. The flaps were sutured (non-absorbable monofilament 3/0) tension-free and then a temporary prosthesis in PMMA was delivered.

Postoperative instructions were given to the patients: 1) medications (Augmenting 1gr every 12 hours for 6 days; Brufen 600mg each day for 3 days); 2) mouth rinse with chlorhexidine 0.12% 2-3 times a day per 5 days. The sutures were removed 10 days after the surgery.

Clinical outcomes

The main outcomes evaluated in this case were:

- postoperative complications, such as oedema, swelling, bleeding, or hematoma;
- occurrence of mechanical complications and biological complication. In the first group were included fracture of the implant or the prosthesis. Biological complication included recurrent implant infection with/without suppuration, pain, swelling and dehiscence of the soft tissue around the abutments;
- implant survival, which was considered as an implant still in function at the end of the study.

Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

The implant in the patient before mentioned was inserted in December 2019. After the surgery, the patient was monitored with clinical evaluations at 1 month, 6 months, and 2 years. Radiographic evaluations (Orthopantomography) were also taken during the follow-up visits (Figure 3A-C).

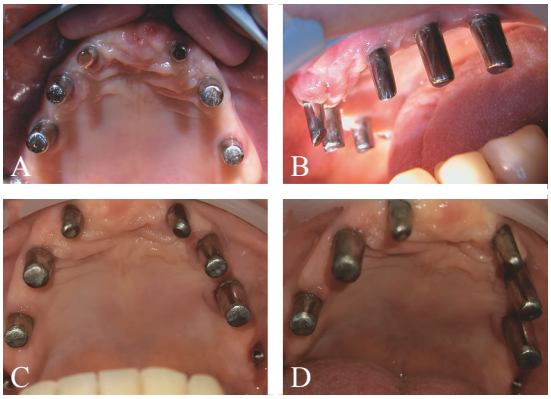

Figure 3.—Clinical evaluations during the follow-up: healing at 6 months (A, B) and at 2 years (C, D) after the surgery.

With regard to the study outcomes, neither biological nor mechanical complications were experienced immediately after the surgery and during the follow-up. No postoperative complications were reported. The clinical evaluations at 6 months and 2 years (Figure 4A-D) showed the implant still in function (implant's survival rate 100%). The soft tissues around the abutment were healthy, as shown by the clinical data reported in Table I, and the patient's satisfaction was very high. The definitive prosthesis was delivered at 6 months (Figure 5). The CBCT exam

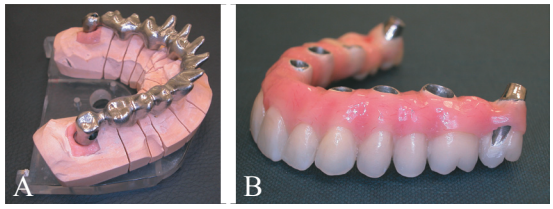

Figure 5.—Definitive prothesis. A) The metal connection structure; B) the definitive Toronto Bridge.

at 2 years after the surgery (Figure 6A-F) shows the intimate contact between the implant and the underlying bone. No bone loss was detected around the struts of the implants.

Discussion

Recently, several studies have re-evaluated the use of subperiosteal implants. All the aspects of the subperiosteal implant were revised according to the knowledge achieved in the field of implant research, related to both materials and biological phenomena. The introduction of new acquisition data technologies (CBCT and intra/extra-oral scanner) and CAD software in the dental field allow the use of additive manufacturing for the production.

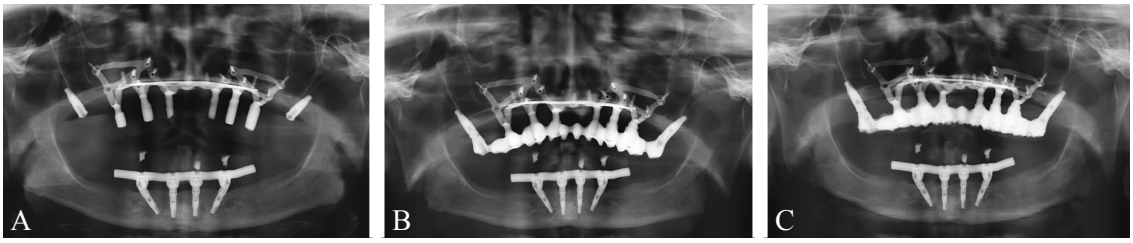

Figure 4.—Radiographic evaluations (orthopantomography) during the follow-up: 1 months (A), 6 months (B), and 2 years (C) after the surgery.

TABLE I.—*Clinical data recorded during the follow-up visits at 6 months and 2 years after the surgery. Six sites were evaluated for each abutment (DV, V, MV, DP, P, and MP).*

	6-months after the surgery						2-years after the surgery					
	1.6	1.4	1.3	2.3	2.4	2.6	1.3	1.4	1.3	2.3	2.4	2.6
PI	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0
	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0
BoP	0 1 0	0 0 0	0 0 0	0 0 0	0 0 0	1 1 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0
	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0
PPD	3 3 2	2 2 3	3 3 3	2 2 2	3 2 3	3 3 3	2 2 2	2 2 3	2 3 3	3 2 2	2 2 2	2 2 3
	3 3 3	2 3 3	3 3 3	2 2 3	2 3 3	2 2 2	2 2 3	2 2 3	2 3 3	2 2 3	2 2 2	2 2 2

PI: Plaque Index; BoP: bleeding on probing; PPD: probing pocket depth.

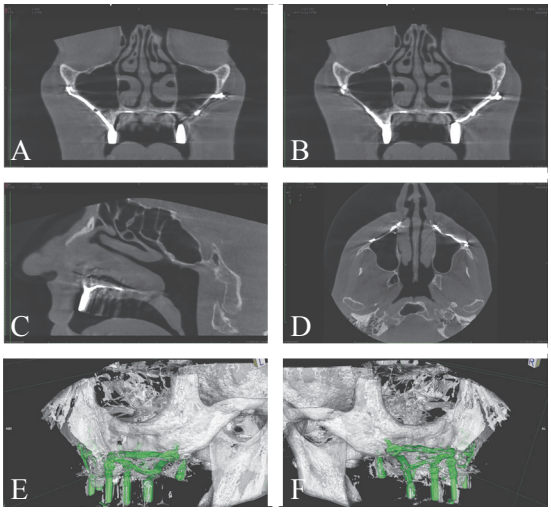

Figure 6.—Cone Beam Computed Tomography (CBCT) evaluation at 2 years after the surgery. The different projection (A-F) showed the good interaction between the implant and the underlying bone.

In the past, subperiosteal implants were made of Vitallium (cobalt-chromium-molybdenum alloy). Currently, this material is replaced by Ti6Al4V alloy because of its better mechanical and biological features. Vitallium has a higher Young's module (210-250 GPa) rather than cortical bone (10-30 GPa).[25] This mismatch causes stress shielding and the resorption of the underlying bone,[26] experienced in the longitudinal studies.[10, 12] Ti6Al4V alloy has a Young's module (110 GPa) closer to the one of cortical bone.[25] Consequentially, his phenomenon could be avoided. Furthermore, this alloy showed a low corrosion rate, low density, and excellent biocompatibility.[27] The histological studies of Cohen *et al.*[28] on animal models have shown that this alloy allows the formation of osseointegration bridges between the implant surface and the underlying bone tissue. This represents a marked difference from the past when subperiosteal implants underwent fibrointegration.[29, 30]

The results of the *in-vitro* and *in-vivo* studies by Cohen *et al.*[28] also demonstrate the superiority, in terms of bone tissue formation, of rough surfaces (etched and sandblasted) compared to smooth ones. At present, various methods have been used to modify the surface roughness of subperiosteal implants. Cerea *et al.*[19] reported his experience with polished through electro-erosion of the subperiosteal implants. Mommaerts[26] increased the surface roughness of the implants through grit-blasting (297 μm aluminia) and etching (oxalic acid). The part of the implants, that faces the soft tissue, was polished to improve the adhesion of fibroblasts. On the contrary, Mangano *et al.*[31] used custom-made subperiosteal implants without surface treatment. The same Authors[32, 33] also suggested that porous surfaces, obtained from additive manufacturing, were able to stimulate both bone ingrowth and soft tissue adhesion. In this study, the subperiosteal implant (Eagle Grid, EagleGrid S.r.l.) did not undergone surface treatment. It is opinion of the Authors that subperiosteal implants could benefit of surface treatment. Nevertheless, further *in-vitro* and *in-vivo* studies are required to investigate the most suitable surface modification process.

In the past, the stability of subperiosteal implants was achieved through the retention offered by specific anatomical landmarks, both for the maxilla and the mandible.[34, 35] The degree of accuracy of the models, obtained from the direct bone impressions, influenced significantly the final stability of the implants. However, this type of stability was not comparable, both in qualitative and quantitative terms, to the bond between the endosseous implants and the surrounding bone. The subperiosteal implants showed certain mobility,[36] which resulted in resorption of the underlying bone.[12] Currently, the design of the subperiosteal implants for the maxilla follows insists on the midfacial pillars of resistance (nasal and zygomatic).[19] In our study, the struts of the subperiosteal implant were located on the vertical pillars of resistance (nasal and zygomatic) and also the transverse ones (palatine in the median and paramedian areas). It is the opinion of the Authors that the use of transverse pillars (in the median and paramedian areas) could confer a greater stability to the implants compared to the design proposed by Mommaerts,[25, 26] which insisted only on the vertical ones. The resistance pillars of the maxilla consist of dense cortical bone, which does not undergo resorption.[20] Surovas[21] suggested that the thickness of the cortical bone above which to place the structure of the subperiosteal implant should be at least 0.8 mm.

The stability of the subperiosteal implants is

achieved through rigid fixation (osteosynthesis screws), which is widely used in the craniomaxillofacial traumatology and reconstructive surgery fields.[20] The osteosynthesis screws allow obtaining a high degree of primary stability,[31] as also confirmed by the FEA analysis.[26, 37] This avoid micro-movements between implant and bone that could compromise the clinical result. In our clinical case, during the digital planning it was possible to establish both the position and type of screw to be used. The choice was based on the proximity to the anatomical structures (*e.g.*, maxillary sinuses).

In our clinical case, the osteotomies were planned in the areas where the struts of the implant's structure connected to the abutments. These areas could represent a weak spot, as described by Mommaerts.[26] The Author reported soft tissue dehiscence around the abutment during the follow-up and this led the author to modify the design of the subsequent implants. It is the authors' opinion that osteotomies, by preserving the mesial and distal bone peaks, allow better healing of both hard and soft tissues. As a consequence, the incidence of soft tissue dehiscence could be reduced. During the follow-up of our clinical case, no such complication occurred.

Several authors have suggested a fully digital workflow of subperiosteal implants.[20, 21, 25, 26] In our study, the design of the implant was first drawn on the stereolithographic model and then scanned to the subsequent digital planning. It is the opinion of the Authors that the first step allows to a better understanding of the needs of the clinical case to the medical engineer, who takes care of the design in CAD software. In addition, it represents an essential element from a medico-legal point of view.

In the past, the subperiosteal implants were produced by lost wax casting metal. First, the design of the structure was drawn on a plaster model obtained from the direct bone impressions. Then the implant was molded with wax and finally cast in metal.[4] Inaccuracies during these analogical steps could afflict the final fit of the implants on the bone and so the clinical result.[34] The Authors interpreted the poor clinical results obtained with subperiosteal implants in the upper jaw due to the lack of precision of the direct bone impressions.[38] Truitt *et al.*[39, 40] were the first to use computed tomography (CT) data to realize a stereolithographic model of the jaws. The subperiosteal implant was molded upon the model and cast in metal.[41] This method eliminated the need for the first surgery required for direct bone impression, reducing the discomfort for the patients. Nevertheless, this procedure had little response due to the lack of interest of the scientific community to subperiosteal implants. Currently, the production of the subperiosteal implant is carried out by additive manufacturing, such as direct metal laser sintering (DMLS) o selective laser melting (SLM).[19, 25, 26] Those techniques allow to create a replica of the STL file of what is digitally designed with a high degree of accuracy.[21] Mangano *et al.*[31] reported a high rate fit of the custom-made subperiosteal implant on the bone, with a mean rating of 7 out of 10. Only two implants had an insufficient fit and that was due to errors during the thresholding procedure because of the presence of scattering from neighboring crown or teeth. This means that problems related to the fit are not due to additive manufacturing procedure but to errors in one of the steps of the digital workflow. Other issues that can afflict the final fit are CT scan data quality, modeling software output quality, and error repair software algorithms.[21] FEA analysis can be performed to focus the area of the subperiosteal implants subjected to higher stress (von Mises) levels according to different occlusal loading.[26, 37] This allows the Author to modify the design of the implant and also reinforce the structure of the implant in those specific areas through additive manufacturing.

Bone atrophy has always been considered one of the major concerns in implant dentistry. Regenerative procedures are required to place endosseous implants, but the results are not always predictable. Postoperative complications could arise, such as membrane exposure.[18] The patient should not wear removable prosthesis because it can afflict the final result of bone regeneration. Furthermore, the procedures need at least two surgeries: the first for bone (and eventually soft tissue) regeneration and the second one for implant placement. The subperiosteal implants could be considered as an alternative to complex

regenerative solutions for the rehabilitation of severe atrophy of the jaws. The main advantages can be summarized as follows:[37] 1) elimination of donor area morbidity for autologous bone grafting; 2) possibility of ambulatory realization; 3) reduction of the time required for the prosthetic loading, since a provisory prosthesis is delivered after the surgery; 4) possibility to treat patient with sinus pathology because the struts avoid the anatomical structure; 5) possibility of maxillofacial reconstructive surgery, as reported by Grecchi *et al.*[42] and Bhargav *et al.*[43]

Limitations of the study

This study has limitations, since it has only one patient enrolled and a short follow-up (1 year). Nevertheless, clinical experience with the modern application of the subperiosteal implants reported in literature is limited.[44] Most of the studies describes case reports with a small number of patients enrolled and a short follow-up. The work of Mangano *et al.*[31] involved 10 patients with a 1-year follow-up. The survival rate was 100%, while the incidence of early complications and late complications amounted, respectively, to 10% and 20%. Mounir *et al.*[45] reported a prospective clinical study involving 10 patients with 1 year follow-up. The patients were divided into two groups, based on the material used for the subperiosteal implants: Ti6Al4V alloy (5 patients) and Polyether Ether Ketone (PEEK) (5 patients). The survival rate at 1 year was 100% in both groups. The retrospective study of Cerea *et al.*[19] is the one with the major number of patients enrolled (70) and with the longer follow-up (at least 2 years). The implant survival rate was 95.8% while the incidence of biological and mechanical complications was, respectively, 1.4% and 8.9%. In the future, further studies with a larger number of patients enrolled and longer follow-up will be required.

Conclusions

Recently, several Authors revised the use of the subperiosteal implants, according to knowledge achieved in implant oral research. The introduction of new acquisition data technologies (CBCT and intra/extra-oral scanner) and CAD software in the dental field allow the use of additive manufacturing. This study, within its limits, showed that the subperiosteal implants could be used as an alternative to regeneration procedures for the rehabilitation of severe bone atrophy. Further studies will be required in the future.

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