



Full-arch rehabilitation of severely atrophic maxilla with additively manufactured custom-made subperiosteal implants: A multicenter retrospective study

Luigi Angelo Vaira^{a,b,*}, Andrea Biglio^a, Marco Roy^c, Giovanni Salzano^d, Stefania Troise^d, Vincenzo Abbate^d, Miguel Mayo-Yanez^e, Jerome R. Lechien^{f,g}, Pasquale Piombino^d, Giacomo De Riu^a

^a Maxillofacial Surgery Operative Unit, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy

^b PhD School of Biomedical Science, Biomedical Sciences Department, University of Sassari, Sassari, Italy

^c Poznan University of Medical Sciences Department of Prosthodontics and Gerostomatology, Poznan, Poland

^d Maxillofacial Surgery Operative Unit, University Hospital of Naples 'Federico II', Naples, Italy

^e Otorhinolaryngology, Head and Neck Surgery Department, Complejo Hospitalario Universitario A Coruña (CHUAC), A Coruña, Galicia, Spain

^f Department of Anatomy and Experimental Oncology, Mons School of Medicine, Research Institute for Health Sciences and Technology, University of Mons, Mons, Belgium

^g Department of Otolaryngology-Head Neck Surgery, Elsan Polyclinic of Poitiers, Poitiers, France

ARTICLE INFO

Handling Editor: Emeka Nkenke

Keywords:

Alveolar bone loss
Subperiosteal implant
Maxillary atrophy
Atrophic jaws
Subperiosteal implantation
Dental implant
Oral surgery
Maxillofacial surgery

ABSTRACT

The aim of this retrospective study was to analyze a series of patients who underwent full-arch rehabilitation of the atrophic maxilla using additively manufactured subperiosteal implants, between August 2018 and January 2023, at the Universities of Sassari and Poznan. In total, 36 patients and 72 implants were included, with no implants lost during follow-up, and a success rate of 90.3%. Seven (9.7%) of the implants showed class 1 exposure. Bleeding on probing was detected in 10.4% of the abutments at 6 months, 7.9% at 1 year, 10% at 2 years, 7% at 3 years, and 11.4% at 4 years. No significant bone resorption under the abutments was detected during the whole observation period. Based on the findings from this study, additively manufactured subperiosteal implants could represent a safe and reliable technique for full-arch rehabilitation in patients with severe maxillary atrophy.

1. Introduction

The implant-prosthetic rehabilitation of Cawood and Howell's Class V and VI atrophies of the upper jaw represents a difficult challenge, necessitating multiple surgeries and long rehabilitation times (Rinaldi, 2023). When severe atrophy affects the anterior sectors of the maxilla, Le Fort I osteotomy with autologous bone graft inlays is currently considered the treatment of choice (Schlund et al., 2016; Varol et al., 2016). This approach enables the restoration of a sufficient quantity of bone for implant placement, and allows correction of the Class III malocclusion that often results from anteroposterior resorption of the maxilla. However, the approach requires a major procedure under

general anesthesia, which is associated with a significant rate of complications (Laventure et al., 2022). Additionally, the rehabilitation times are lengthy, and the costs are high, making this approach increasingly less acceptable to patients.

In recent years, there has been growing interest in graftless rehabilitations for atrophic maxillae (Cooper et al., 2020; Choo et al., 2023). This approach aims to reduce rehabilitation times and allows for patient rehabilitation with immediate loading in a single surgical procedure. Regarding full-arch rehabilitation, zygomatic implantology is currently supported by the most substantial scientific evidence (Rosenstein and Dym, 2021).

The placement of four zygomatic implants, possibly combined with

* Corresponding author. Maxillofacial Surgery Operative Unit, Department of Medicine, Surgery and Pharmacy, University of Sassari, Viale San Pietro 43B, 07100, Sassari, Italy.

E-mail address: lavaira@uniss.it (L.A. Vaira).

<https://doi.org/10.1016/j.jcms.2024.06.016>

Received 24 February 2024; Received in revised form 8 April 2024; Accepted 8 June 2024

Available online 10 June 2024

1010-5182/© 2024 The Authors. Published by Elsevier Ltd on behalf of European Association for Cranio-Maxillo-Facial Surgery. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

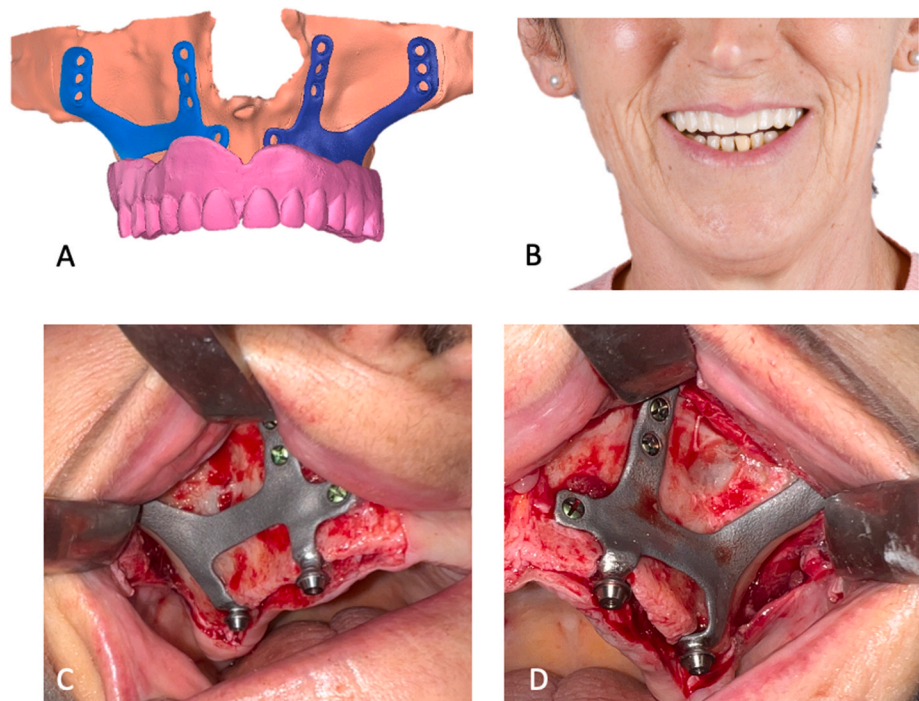


Fig. 1. (A) Digital planning of implant-prosthetic rehabilitation. (B) Postoperative follow-up after 6 months. (C) Insetting of the right implant. (D) Insetting of the left implant.

pterygoid implants or an implant at the level of the nasal spine, allows for the rehabilitation of severe atrophies of the upper jaw with a medium-term implant survival rate of 90–95% (Lan et al., 2021; Ramezanzade et al., 2021; Brennand Roper et al., 2023). However, the placement of zygomatic implants requires adequate surgical skills, a thorough understanding of the region's anatomy, and high patient compliance, especially if performed with conscious sedation alone. It is also associated with a significant rate of severe complications, such as orbital perforations, ocular damage, infraorbital nerve injury, maxillary sinusitis, and peri-implantitis at the zygomatic buttress level (D'Agostino et al., 2021; Gabriele et al., 2023). For these reasons, it is a technique limited to a few professionals, and difficult to disseminate widely in the field of dentistry. The implant emergence is also determined by the shape of the zygoma and upper jaw and, even with the extra-sinus technique, is often very palatal. Finally, in many cases of upper jaw atrophy, the zygomatic arches are also atrophic, making the placement of two zygomatic implants impossible or highly complex.

In 2017, a novel approach to subperiosteal implantology for graftless rehabilitation of the maxilla in cases of atrophy or postablative defects was introduced and advocated by Mommaerts (2017) and Gellrich et al. (2017). This innovative concept leverages the advancements in CAD/CAM and laser melting technologies to create tailor-made implants. The design of these implants is such that they can be rigidly fixed onto the maxillary pillars, effectively addressing and overcoming the traditional limitations associated with this rehabilitation method.

To date, the literature offers only a limited amount of data concerning the functional outcomes of rehabilitations with subperiosteal implants (Cerea and Dolcini, 2018; Van den Borre et al., 2021; Nemtoi et al., 2022; Van den Borre et al., 2022; Dimitroulis et al., 2023). Consequently, there are no consensual guidelines regarding the design of the implant or the type and location of fixation. Additionally, there is a scarcity of information on the possible complications and their management, and about the short- and long-term functional outcomes of these procedures. The aim of our study was to retrospectively analyze a series of patients who underwent full-arch rehabilitation of the atrophic maxilla using additively manufactured subperiosteal implants.

2. Materials and methods

This retrospective multicenter study included consecutive patients with Cawood and Howell Class V and VI atrophy of the maxilla, who underwent full-arch rehabilitation with additively manufactured subperiosteal implants, between August 2018 and January 2023. The study was conducted in the Maxillofacial Surgery Operative Unit of the University Hospital of Sassari and the Department of Prosthodontics and Gerostomatology of Poznan University of Medical Sciences. All the patients were followed up for a minimum of 1 year, with regular clinical and radiological evaluations. Given its retrospective nature, the study was exempt from approval by the ethical committee (Poznan University of Medical Sciences ethical committee, protocol number 64/24). The reporting of this study adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2007).

2.1. Digital planning and implant manufacturing

All the patients were subjected to cone-beam computed tomography (CT) of both the maxilla and mandible. These scans had a slice thickness of 0.1–0.3 mm and covered a comprehensive field of view, encompassing the whole maxilla, including the entire cheekbones. The CT scans were performed using a radiological template with radiopaque markers, based on the prosthetic planning. The study further involved acquiring digital impressions of both dental arches and the radiological template used during the CT scan. For each participating center, an experienced prosthodontist prepared and executed the prosthetic plan. The resulting DICOM and STL files were forwarded to B&B Dental (San Pietro in Casale, Italy), the company tasked with fabricating the implant.

The DICOM files from the CT scans were processed using B&B Dental's GS software, enabling the 3D reconstruction of bone segments. These 3D images were refined to eliminate scatter and other inaccuracies. The STL files, including those of the dental arches and the diagnostic wax-up, were then integrated with the 3D jaw model. Next, the 3D files were imported into Meshmixer software (Autodesk, San Rafael, CA, USA) for the implant's design, based on the surgeon's instructions and



Fig. 2. (A) Insetting of the right implant. (B) Insetting of the left implant. (C) Immediate loading of the temporary prosthesis. (D) Follow-up at 6 months.

previous finite element analysis conducted by other authors (Mommerts, 2019; De Moor et al., 2022). In every instance, the rehabilitation process was planned with the implementation of two distinct implants, one for each side. Each implant featured two arms with osteosynthesis screw holes: one arm on the nasomaxillary pillar and the other on the maxillomalar pillar, extending to the anterior face of the zygomatic arch. The positioning of the screw holes was determined based on the underlying bone thickness, with at least two holes planned for each arm.

All implants were equipped with multiunit abutments integrated into the implant structure. These abutments were placed in slots created in the alveolar crest, allowing them to rest deeper relative to the residual basal bone in order to prevent further resorption beneath the abutments. The length and orientation of the abutments were matched with the diagnostic wax-up and the gingival thickness, as determined from the arch scans. A chrome-cobalt surgical guide was fabricated to allow for the preparation of slots in the alveolar crest. On the palatal side, the abutments were solidified by a palatal connection with a screw hole, if the underlying bone thickness allowed. Finally, the 3D models of the bones, gums, prostheses, and implants were reimported into the B&B Dental GS software for the surgeon's final review and approval (Fig. 1).

Following the surgeon's endorsement of the project, the implant was crafted from grade V titanium using advanced double-laser melting technology (MYSINT100; Sisma, Piovene Rocchette, Italy). The implant was then subjected to a sintering process in an oven (Nabertherm GMBH, Lilienthal, Germany), initially at 840 °C for 4 h and subsequently at 500 °C for an additional 2 h. This step was crucial to ensure the titanium's stability and eliminate any porosity, without altering the implant's dimensions. The abutments were precisely shaped using a five-axis milling machine (Datron D5; Datron, Milford, NH, USA), and the

MUA's internal threads were created as needed. To remove any contaminants, the subperiosteal implant was thoroughly cleansed with the organic acid DOWCLEN 1601 (Dow Chemicals Corporation, Midland, MI, USA) and then sterilized. The templates for carving out slots in the alveolar crest to fit the abutments were milled from cobalt chrome (Datron D5; Datron, Milford, NH, USA), chosen for its durability and ease of handling. In the final stage, a stereolithography model of the maxilla was produced in resin using a 3D printer (Stratasys Objet 30; Stratasys, Eden Prairie, MN, USA) and handed over to the surgeon for reference.

2.2. Surgery

The surgeries included in this series were performed by four different surgeons (LAV, AB, MR, and GDR), using local anesthesia complemented by superficial intravenous sedation with diazepam. The surgical procedure is presented in Video 1. The local anesthesia was administered using articaine with 1:100 000 adrenaline. The infraorbital nerve and zygomatic nerves were blocked extraorally to ensure anesthesia of the upper front of the surgical field. Intraorally, anesthesia was applied to the upper vestibular fornix and then on the palatal side blocking the greater palatine and nasopalatine nerves. In all cases, the use of two separate implants entailed handling one surgical field at a time.

Supplementary data related to this article can be found online at <https://doi.org/10.1016/j.jcms.2024.06.016>

For each side, a full-thickness incision of the mucosa was made at the level of the alveolar crest with two vestibular releases, one at the midline and one posterior, at least 5 mm from the most distal abutment. The incision was made 2–3 mm palatally, to reposition a sufficient layer of

Table 1
Patients' characteristics.

Patient ID	Age	Gender	No. of abutments		No. of screws		Duration of surgery (minutes)	Implant- or prosthetic-related complications	Follow- up (months)
			Right	Left	Right	Left			
1	53	M	3	3	7	6	122	None	64
2	56	M	3	3	6	6	95	None	60
3	61	F	4	4	5	6	110	Class 1 exposure	56
4	64	F	3	3	6	6	89	None	56
5	71	M	3	3	6	7	92	None	53
6	59	F	3	3	6	6	134	None	49
7	58	F	3	3	6	6	87	None	48
8	67	M	3	3	5	6	84	Delayed episode of zygomatic region edema	44
								Class 1 exposure	
9	62	F	2	2	7	5	75	None	42
10	70	M	3	3	7	6	83	Class 1 exposure	40
11	52	F	2	2	6	7	112	Class 1 exposure	37
12	58	F	2	2	6	5	91	None	36
13	61	M	2	2	6	6	65	None	33
14	67	F	2	2	7	6	102	Infection, with loosening of one screw	31
								Class 1 exposure	
15	60	M	2	2	6	5	86	Class 1 exposure	30
16	58	F	2	2	5	5	82	None	28
17	51	F	2	2	6	7	76	Delayed episode of zygomatic region edema	28
18	55	F	2	2	7	7	92	None	26
19	71	M	2	2	6	7	99	Class 1 exposure	25
20	69	M	2	2	6	6	103	Breakage of the provisional prosthesis	24
21	62	F	2	2	5	6	87	None	23
22	60	F	2	2	7	6	78	None	23
23	56	M	2	2	7	7	64	Delayed episode of zygomatic region edema	21
24	57	F	2	2	6	6	71	None	20
25	63	M	2	2	5	5	68	None	20
26	58	F	2	2	6	6	95	None	20
27	67	F	2	2	6	6	84	Delayed episode of zygomatic region edema	19
28	53	M	2	2	7	7	135	None	18
29	62	F	2	2	6	6	81	None	17
30	61	F	2	2	7	6	75	None	16
31	67	F	2	2	6	5	79	Delayed episode of zygomatic region edema	14
32	57	F	2	2	5	6	88	Delayed episode of zygomatic region edema	14
33	59	M	2	2	6	6	96	None	13
34	69	F	2	2	6	6	82	None	12
35	57	M	2	2	5	5	74	None	12
36	53	F	2	2	7	5	84	None	12

keratinized gingiva on the vestibular side of the abutments. After the incision, a full-thickness flap was raised on both the palatal and vestibular sides. The dissection of the maxilla, in this first phase, did not extend beyond the alveolar crest area, in order to accommodate the crestal preparation template. Using this template, slots for the abutment housing were prepared, deep enough to reach the basal bone. In the more distal sites, the crest preparation could reach the sinus membrane, which needed to be carefully preserved and detached in such cases. In the event of perforations, a resorbable membrane was placed under the abutment.

Once the crestal preparation was complete, the skeletonization of the upper maxilla was completed by proceeding upwards to identify and preserve the infraorbital nerve and completely detach the nasomaxillary pillar and the zygomatic buttress. This maneuver could be facilitated by cutting the more anterior insertions of the masseter muscle. The subperiosteal implant was then inserted and its fitting checked. Rigid fixation was achieved with 2 mm-diameter grade V titanium osteosynthesis screws (B&B Dental, San Pietro in Casale, Italy). The length of the screws was based on the underlying bone thickness, and varied between 10 mm and 14 mm at the zygomatic buttress, between 4 mm and 6 mm at the nasomaxillary pillar, and between 4 mm and 8 mm at the palate. If a screw did not provide a sufficiently strong closure torque, a 2.3 mm-diameter safety screw was used. Each implant was fixed with at least two screws per pillar, to ensure sufficient primary stability for immediate loading (Fig. 2A and B). After fixation was completed, the implant structure was covered using resorbable membranes or cortical laminae, or by transposing the Bichat's fat pad. The mucosa was then passivated using periosteal releases and sutured.

After the surgery, all patients received a prescribed course of antibiotics (amoxicillin with clavulanic acid, 1 g twice daily for a duration of 6 days), along with pain relief medication. Immediate loading was performed in all the cases (Fig. 2C and D), with a fixed provisional prosthesis screwed into the MUA. The definitive prosthesis was provided 6 months following the surgical procedure, after the soft tissues had undergone adequate conditioning. All patients were prescribed a soft diet for the first 15 days and then advised to avoid harder foods until the final prosthesis was delivered.

2.3. Evaluation protocol

Every patient was subject to both clinical and radiological monitoring postsurgery, with a focus on identifying any complications. Complications were categorized according to Clavien–Dindo classification (Dindo et al., 2004). Evaluations of the soft-tissue health surrounding the abutments were conducted 6 months postsurgery during the final prosthesis fitting, and subsequently every 6 months. The peri-implant bleeding on probing (BOP) was assessed at six different points around each abutment (these points being mesiobuccal, mid-buccal, distobuccal, mesiolingual, midlingual, and distolingual). This assessment followed a four-grade scale, as outlined by Mombelli (Mombelli, 2005), ranging from 0 (indicating no bleeding) to 3 (denoting severe and extensive bleeding upon probing). Additionally, the exposure level of the implant structure was evaluated using a five-point scale: no exposure (score 0); exposure of the abutment's vertical arm (score 1); exposure of the implant's horizontal arm (score 2); exposure of both the horizontal arm and at least one osteosynthesis

screw (score 3); and exposure of the implant, accompanied with mobility (score 4). Each level was further divided into two subgroups, A and B, based on the presence or absence of painful or inflammatory symptoms (Vaira et al., 2024).

CT scans were conducted 10 days postsurgery, again at 6 months, and thereafter on an annual basis. These scans were crucial for the study, particularly for evaluating the extent of bone resorption beneath the abutments — a method previously established for upper jaw rehabilitation (Van den Borre et al., 2021). The degree of resorption at each abutment was determined by comparing CT scans taken 10 days after surgery (T0) with those at 6 months (T1), and at 1 (T2), 2 (T3), 3 (T4), and 4 (T5) years.

On the basis of the parameters collected, the success rate of the implants was determined by modifying the criteria of Albrektsson et al., (1986), established for endosseous implantology: implant that is immobile when tested clinically; radiography that does not demonstrate evidence of bone resorption around more than one screw per maxillary buttresses; no evidence of maxillary sinusitis if not present before the surgery; bone loss that is less than 0.2 mm annually after the implant's first year of service; no persistent pain, discomfort, or infection; no evidence of exposure of the implant structure, whether symptomatic or not.

2.4. Statistical analysis

The statistical analysis was conducted using Jamovi, an open-source statistical software, version 2.3.18.0, which is available at www.jamovi.org. The data are represented both as absolute numbers and as percentages of the total. For quantitative variables, descriptive statistics are presented as mean values along with their standard deviations. To analyze the differences in bone resorption under the abutments, Student's *t*-test for paired samples was utilized. This involved comparing the measurements taken at the initial time point (T0) with those at subsequent time points — T1, T2, T3, T4, and T5. A *p*-value of less than 0.05 was considered statistically significant, within a 95% confidence interval.

3. Results

In total, 36 patients (comprising 72 implants), consecutively operated on between August 2018 and January 2023, were included and retrospectively analyzed. The cohort included 22 women and 14 men, with an average age of 61.1 years (ranging from 51 to 71 years) and a mean follow-up of 30.1 months (range 12–64 months), as detailed in Table 1. Of these cases, 34 presented with complete edentulism at the time of surgery, while two cases involved patients with residual endosseous implants with periimplantitis, which were removed during the surgical procedure. No major complications were observed during the surgeries. There was one instance of poor implant fitting on an abutment, attributed to an inaccurate assessment of the residual bone level in the implant removal site during the surgery. The average duration of the surgeries was 89.4 min, ranging from 64 to 135 min.

The most common postoperative sequelae were edema and bruising in the infraorbital region, which fully resolved within the first few weeks after surgery. Thirteen patients experienced temporary hypoesthesia of the infraorbital nerve, which completely resolved by the 6-month follow-up. One case involved altered skin sensitivity in the region of the zygomatic buttress and the temporal area, which also fully resolved within the 6-month follow-up period. One patient had a breakage of the provisional prosthesis, which was replaced without further complications. No other issues related to either the provisional or final prosthesis were reported. From 15 days after the operation, no patient reported chewing difficulties when taking the prescribed diet, and in all cases it was possible to return to a diet that included even the hardest foods after the delivery of the definitive prosthesis.

In four previously uneventful cases, varying from 2 to 23 months

Table 2
Bone resorption under the abutments — results of statistical analysis.

Observation time	Bone gap (mm) Mean ± SD	Paired-samples <i>t</i> -test		
		Statistic	DF	<i>p</i> -value
T0 versus T1 (<i>N</i> = 164)				
T0	0.374 ± 0.2227	−0.857	163.0	0.392
T1	0.385 ± 0.191			
T0 versus T2 (<i>N</i> = 164)				
T0	0.374 ± 0.227	0.492	163.0	0.623
T2	0.368 ± 0.187			
T0 versus T3 (<i>N</i> = 100)				
T0	0.373 ± 0.212	−1.603	99.0	0.112
T3	0.398 ± 0.182			
T0 versus T4 (<i>N</i> = 68)				
T0	0.365 ± 0.216	−1.522	67.0	0.133
T4	0.372 ± 0.219			
T0 versus T5 (<i>N</i> = 44)				
T0	0.373 ± 0.212	−1.857	43.0	0.070
T5	0.389 ± 0.209			

SD: standard deviation; DF: degrees of freedom; T0: 10 days after surgery; T1: 6 months after surgery; T2: 1 year after surgery; T3: 2 years after surgery; T4: 3 years after surgery; T5: 4 years after surgery.

postoperatively, patients experienced an episode of asymptomatic edema in the region of the zygomatic buttress, which completely resolved with antibiotic and corticosteroid therapy, without recurrence of the issue. There was one case of infection of the implant at the level of the zygomatic buttress; a CT scan revealed loosening of one of the osteosynthesis screws, and the issue completely resolved following antibiotic therapy and screw removal. No implants were lost during follow-up. Overall, 19 complications categorizable according to Clavien–Dindo were detected: grade 1 in 14 cases, grade 2 in 4 cases, and grade 3a in one case.

Throughout the observation period, seven implants (9.7%) showed class 1 exposure (i.e. exposure of the abutment's vertical arm). In every case, exposure was observed within the first year following surgery, without any associated inflammatory symptoms. All instances were managed conservatively through the topical application of chlorhexidine and routine professional oral hygiene maintenance. These exposures were closely monitored over time, showing stability in five cases and regression in two cases, with one case experiencing complete resolution. Six months postoperation, 17 out of 164 abutments (10.4%) exhibited BOP, with 13 cases rated as 1 (indicating a single isolated spot) and four cases rated as 2 (indicating a continuous line of bleeding). After 1 year, BOP was observed in 13 out of 164 abutments (7.9%), rated as 1 in 10 cases and 2 in three cases. Two years into the follow-up, BOP was noted in 10% of the abutments assessed (10 out of 100), with eight cases receiving a score of 1 and two a score of 2. Six (scored as 1 in four cases and 2 in two cases) and five (scored as 1 in three cases and 2 in two cases) instances of BOP were detected during the 3-year (7% of 86 abutments) and 4-year (11.4% of 44 abutments) follow-up evaluations, respectively.

In every instance, follow-up cone-beam CT scans conducted 10 days postsurgery, 6 months later, and yearly thereafter, consistently indicated that the implants remained stable, with evidence of screw loosening in only four cases (0.9% of 434 screws). When examining the space between the implant and the underlying bone at the abutments, there were no notable changes observed from the initial postsurgery CT scans through to the follow-ups at 6 months (*p* = 0.392), 1 year (*p* = 0.623), 2 years (*p* = 0.112), 3 years (*p* = 0.133), and 4 years (*p* = 0.070), as detailed in Table 2.

Overall, the 72 implants included in the study had a survival rate of 100% and a success rate of 90.3%.

4. Discussion

Subperiosteal implants were first proposed in the 1940s by Dahl, but

due to technical difficulties, the necessity for two surgeries, poor fitting of the implants, and resorption of the alveolar bone beneath the abutments over time, their use never became widespread. In 2017, a new generation of subperiosteal implants was introduced, leveraging technological advancements in digital planning and the ability to manufacture implants using laser melting (Gellrich et al., 2017; Mommaerts, 2017). This new design was based on finite element analysis, taking into account the distribution of masticatory forces on the maxillary resistance pillars (De Moor et al., 2022; Zielinski et al., 2023). Since then, the use of subperiosteal implants has been described in various reports for the rehabilitation of patients with severe atrophies (Cerea and Dolcini, 2018; Nemtoi et al., 2022; Van den Borre et al., 2022; Dimitroulis et al., 2023) or post-resection defects (Korn et al., 2021; Cebrián Carretero et al., 2022; De Riu et al., 2023) of the upper jaw.

However, data on the short- and medium-term functional outcomes of subperiosteal implants are scarce, based on small case series, and involve non-homogeneous types of rehabilitation. Cerea and Dolcini reported a series of 70 implants used for sectorial and total rehabilitations of the maxilla and mandible, noting three cases of implant failure at 2 years (Cerea and Dolcini 2018). Nemtoi et al. (2022) and Dimitroulis et al. (2023) reported their experiences with the rehabilitation of atrophic jaws using subperiosteal implants, with average follow-ups of 6 and 22.4 months, respectively, each reporting the loss of one implant in series of 16 and 21 implants, respectively. Also in these studies, the type of rehabilitation varied widely, including partial or total edentulism of both the maxilla and mandible.

In our series, which included only full-arch rehabilitations of the upper jaw, no implant was lost, with an implant survival rate of 100% at an average follow-up of 30.1 months. One patient developed an infection, with CT scans revealing loosening of one of the zygomatic screws, which resolved after its removal. In four cases, patients experienced isolated episodes of delayed edema in the zygomatic region, which completely regressed with cortisone therapy and was not associated with screw issues on CT scans.

This study demonstrated that the rehabilitation of severe atrophies of the upper jaw is a reliable technique, with a high success rate in the short and medium term. The design of the implant is fundamental to the success of the procedure. All implants used in this study, made of porous grade V titanium, were designed based on previous studies on finite element analysis to optimize masticatory load on the implant structure and on the osteosynthesis screws, and to reduce stress shielding on the bone surfaces. The holes on the zygomatic arm of the implant were designed to lie on the anterior face of the zygoma. This has a triple advantage: first, the detachment of the zygoma is less extensive; second, the screws are inserted at a favorable insertion angle, reducing the difficulty of tissue retraction; third, it is possible to use longer screws (12–14 mm) by exploiting the major axis of the zygomatic arch.

Unlike previous studies, full-arch rehabilitation was achieved with two separate implants rather than a single one, as suggested by Mommaerts (2019). This presents several advantages: it is possible to manage one operative field at a time, reducing bleeding and the spread of local anesthetic; the detachment of the upper jaw is more limited compared with that required to insert a single implant; there is no need for extensive detachment of the palatal fibromucosa and sacrifice of the nasopalatine nerve; in case of infection problems with part of the implant, only the affected part needs to be removed.

One of the issues with first-generation subperiosteal implants was that the abutments rested on remnants of alveolar bone, which, over time, were subject to further resorption, risking exposure and implant failure. A significant advantage of virtual planning is the possibility to provide housing carved into the residual alveolar ridge, so that the abutment can rest directly on the basal bone, which is less prone to resorption over time. In this series, great care was taken during the planning of the interventions to remove any possible remnants of alveolar bone and provide the abutment with as regular a bone support as possible. With these precautions, bone resorption beneath the

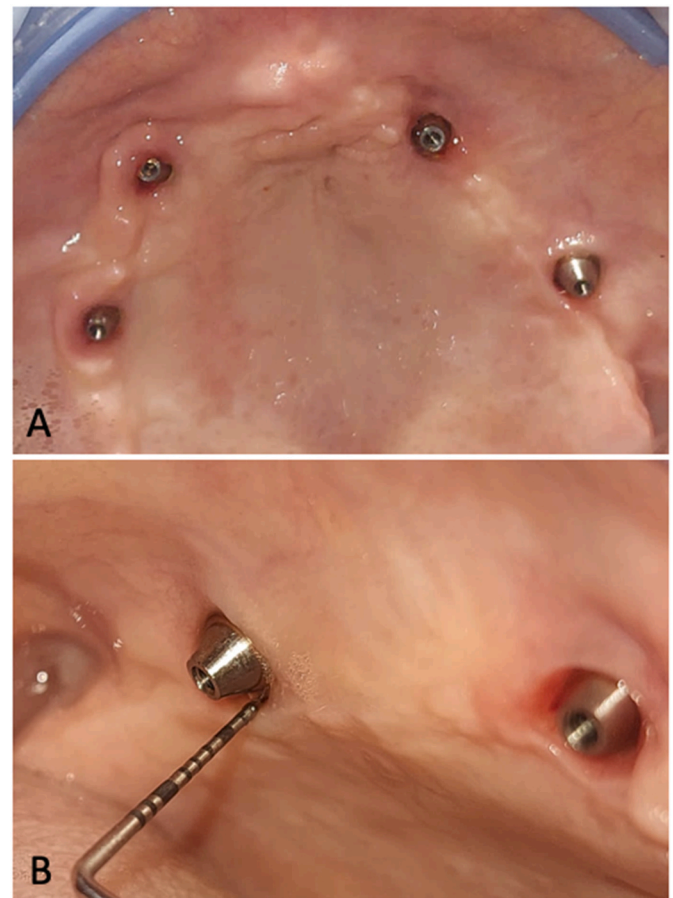


Fig. 3. (A) Soft-tissue healing at 24 months postoperatively. (B) No evidence of bleeding on probing at 2-year follow-up.

abutments was not significant throughout the observation period, even in implants with at least 4 years of follow-up. This confirms the findings of de Moor et al. (de Moor et al., 2022) in a prospective study with a 12-month follow-up, which detected an average resorption of 0.2 mm, comparable to that reported for endosseous implants. The fitting of the implant depends strictly on the precision of the CT scan, while any sources of error introduced by dental elements or residual implants need to be extracted during the procedure. In cases where the abutments are placed in the site of extractions, it is advisable to proceed with dental extraction before performing the CT scan or, if this is not possible, to plan for a very deep abutment slot, reaching to the bottom of the socket.

In our series, seven implants (9.7%) had exposure of the vertical arm above the abutments without signs of mucositis (Fig. 3). This complication is common and has been reported by other authors (Nemtoi et al., 2022; Dimitroulis et al., 2023; Van den Borre et al., 2023) with a frequency ranging from 6.5 to 23.8%, and does not appear to undermine the survival of the implant or be perceived as a problem by the patient (Van den Borre et al., 2022). Such cases are subjected to professional oral hygiene protocols and recession monitoring, reserving possible surgical treatment only for symptomatic cases (Van den Borre et al., 2022; Herce-López et al., 2024). In some cases, conservative treatment can lead to an improvement or a complete regression in the recession.

Our series demonstrated a significant reduction in the number of exposures over time (Table 1) following the implementation of measures to thicken the soft tissues on the vestibular aspect. The incision technique has evolved, transitioning from a crestal incision to a slightly palatal incision, which leaves a thicker strip of keratinized mucosa on the vestibular side of the abutments. It is crucial that the strip of palatal mucosa does not exceed a thickness of 2–3 mm, considering it is

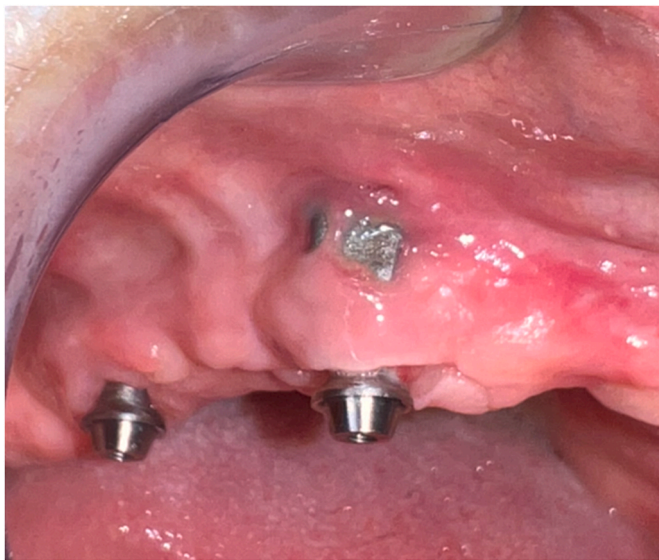


Fig. 4. Evidence of class 1 exposure of the implant structure, without associated inflammatory symptoms.

vascularized by the angiosome of the greater palatine artery, and thus, if overly thick, it may be prone to ischemia and necrosis. Further thickening of the soft tissues above the implant was achieved using collagen membranes or by covering the implant structure with Bichat's fat pad, which was harvested and fixed to the lateral margin of the pyriform notch. This approach also allowed for the projection of the paralateral nasal area, which is often underprojected in patients with severe maxillary atrophy (Rubio-Bueno et al., 2013). The periimplant soft tissues generally exhibited a satisfactory state of health (Fig. 4), with less than 10% of the abutments showing BOP, which was always of minor severity, across all observation periods.

The main limitations of our study were its retrospective nature and the relatively small patient cohort, which may have limited the reliability of the results. While some patients were followed up for more than 4 years, this duration was insufficient to conclusively assess the long-term outcomes of subperiosteal implant rehabilitations. Continuous monitoring of soft-tissue health is imperative, as it plays a vital role in ensuring a proper seal around the abutments, which is key to preventing implant exposure and mitigating bone loss. Furthermore, the surgeries were performed by four different surgeons, all highly skilled, which could have introduced a degree of variability in the outcomes. Nonetheless, all surgeons adhered to the same surgical and planning protocol, and no significant differences were observed in the duration of surgery or complication rates among them. Finally, at present there are no shared and validated success criteria for subperiosteal implants. In this study, some of the accepted criteria for endosseous implantology were modified and used. In the future it will be necessary to establish specific success criteria for subperiosteal implantology.

5. Conclusions

Based on the findings of this study, additively manufactured subperiosteal implants have proven to be a safe technique for full-arch rehabilitation in patients with severe maxillary atrophy. The patient series exhibited a 100% implant survival rate and a 90.3% success rate, with an average follow-up of over 2 years, demonstrating the technique's reliability in the short to medium term. Further studies with longer follow-up periods are needed to monitor bone resorption and the health status of the soft tissues beyond 5 years, to determine if these promising results can be sustained over the long term.

Funding

This research was funded by the University of Sassari Fondo di Ateneo per la Ricerca 2019–2020.

Competing interests

All authors report no conflicts of interest.

Ethical approval

The study received ethical approval exemption from the Poznan University of Medical Sciences ethical committee (protocol number 64/24).

Acknowledgements

The authors would like to thank Claudio Banzi and Alan Betti for their technical support and for reviewing the section on digital planning.

References

- Albrektsson, T., Zarb, G., Worthington, P., Eriksson, A.R., 1986. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *Int. J. Oral Maxillofac. Implants* 1, 11–25.
- Brennand Roper, M., Vissink, A., Dudding, T., Pollard, A., Gareb, B., Malevez, C., et al., 2023. Long-term treatment outcomes with zygomatic implants: a systematic review and meta-analysis. *Int. J. Implant Dent.* 9, 21.
- Cebrián Carretero, J.L., Del Castillo Pardo de Vera, J.L., Montesdeoca García, N., Garrido Martínez, P., Pampín Martínez, M.M., Aragón Niño, I., et al., 2022. Virtual surgical planning and customized subperiosteal titanium maxillary implant (CSTMI) for three dimensional reconstruction and dental implants of maxillary defects after oncological resection: case series. *J. Clin. Med.* 11, 4594.
- Cerea, M., Dolcini, G.A., 2018. Custom-made direct metal laser sintering titanium subperiosteal implants: a retrospective clinical study on 70 patients. *BioMed Res. Int.* 2018, 5420391.
- Choo, S.H., Glickman, R.S., Wiedemann, T.G., 2023. Graftless implantology as a forward-looking clinical concept for highly atrophic maxillary arches. *Comp. Cont. Educ. Dent.* 44, 74–79.
- Cooper, L.F., Thalji, G., Al-Tarawneh, S., 2020. Are nongrafting solutions viable for dental implant treatment in limited bone volume? *Comp. Cont. Educ. Dent.* 41, 368–376.
- D'Agostino, A., Lombardo, G., Favero, V., Signoriello, A., Bressan, A., Lonardi, F., et al., 2021. Complications related to zygomatic implants placement: a retrospective evaluation with 5 years follow-up. *J. Cranio-Maxillo-Fac. Surg.* 49, 620–627.
- De Moor, E., Huys, S.E.F., van Lenthe, G.H., Mommaerts, M.Y., Vander Sloten, J., 2022. Mechanical evaluation of a patient-specific additively manufactured subperiosteal jaw implant (AMSJI) using finite-element analysis. *Int. J. Oral Maxillofac. Surg.* 51, 405–411.
- De Riu, G., Soma, D., Biglio, A., Raho, M.T., Mura, D., Michelon, F., et al., 2023. Primary reconstruction of total maxillectomy with custom-made subperiosteal implant and temporal muscle flap: a case report. *Appl. Sci.* 13, 6269.
- Dimitroulis, G., Gupta, B., Wilson, I., Hart, C., 2023. The atrophic edentulous alveolus. A preliminary study on a new generation of subperiosteal implants. *Oral Maxillofac. Surg.* 27, 69–78.
- Dindo, D., Demartines, N., Clavien, P.A., 2004. Classification of surgical complications. *Ann. Surg.* 240, 205–213.
- Gabriele, G., Chisci, G., Cascino, F., Ricci, N.M., Marruganti, C., Ferrari, M., 2023. Technique-related survival rate and complications of zygomatic implant placement: a systematic review and meta-analysis. *Int. J. Oral Maxillofac. Implants* 38, 855–875.
- Gellrich, N.C., Zimmerer, R.M., Spalthoff, S., Jehn, P., Pott, P.C., Rana, M., Rahlf, B., 2017. A customised digitally engineered solution for fixed dental rehabilitation in severe bone deficiency: a new innovative line extension in implant dentistry. *J. Cranio-Maxillo-Fac. Surg.* 45, 1632–1638.
- Herce-López, J., Pingarrón, M.D.C., Tofé-Povedano, Á., García-Arana, L., Espino-Segura-Illa, M., Seira-Gil, R., Rodado-Alonso, C., et al., 2024. Customized subperiosteal implants for the rehabilitation of atrophic jaws: a consensus report and literature review. *Biomimetics* 9, 61.
- Korn, P., Gellrich, N.C., Jehn, P., Spalthoff, S., Rahlf, B., 2021. A new strategy for patient-specific implant-borne dental rehabilitation in patients with extended maxillary defects. *Front. Oncol.* 11, 718872.
- Lan, K., Wang, F., Huang, W., Davó, R., Wu, Y., 2021. Quad zygomatic implants: a systematic review and meta-analysis on survival and complications. *Int. J. Oral Maxillofac. Implants* 36, 21–29.
- Laventure, A., Lauwers, L., Nicot, R., Kyheng, M., Ferri, J., Raoul, G., 2022. Autogenous bone grafting with conventional implants vs zygomatic implants for atrophic maxillae: a retrospective study of the oral health-related quality of life. *J. Stomatol Oral Maxillofac Surg* 123, e782–e789.

- Mombelli, A., 2005. Clinical parameters: biological validity and clinical utility. *Periodontol* 2000 39, 30–39.
- Mommaerts, M.Y., 2017. Additively manufactured sub-periosteal jaw implants. *Int. J. Oral Maxillofac. Surg.* 46, 938–940.
- Mommaerts, M.Y., 2019. Evolutionary steps in the design and biofunctionalization of the additively manufactured sub-periosteal jaw implant “AMSJI” for the maxilla. *Int. J. Oral Maxillofac. Surg.* 48, 108–114.
- Nemtoi, A., Covrig, V., Nemtoi, A., Stoica, G., Vataavu, R., Haba, D., Zetu, I., 2022. Custom-made direct metal laser sintering titanium subperiosteal implants in oral and maxillofacial surgery for severe bone-deficient patients — a pilot study. *Diagnostics* 12, 2531.
- Ramezanzade, S., Yates, J., Tuminelli, F.J., Keyhan, S.O., Yousefi, P., Lopez-Lopez, J., 2021. Zygomatic implants placed in atrophic maxilla: an overview of current systematic reviews and meta-analysis. *Maxillofac Plast Reconstr Surg* 43, 1.
- Rinaldi, M., 2023. *Implants and Oral Rehabilitation of the Atrophic Maxilla*. Springer, Cham. <https://doi.org/10.1007/978-3-031-12755-7>.
- Rosenstein, J., Dym, H., 2021. Zygomatic implants: a solution for the atrophic maxilla: 2021 update. *Dent. Clin.* 65, 229–239.
- Rubio-Bueno, P., Ardanza, B., Piñas, L., Murillo, N., 2013. Pedicled buccal fat pad flap for upper lip augmentation in orthognathic surgery patients. *J. Oral Maxillofac. Surg.* 71, e178–e184. <https://doi.org/10.1016/j.joms.2012.11.012>.
- Schlund, M., Nicot, R., Lauwers, L., Raoul, G., Ferri, J., 2016. Le Fort 1 osteotomy and calvarial bone grafting for severely resorbed maxillae. *J. Cranio-Maxillo-Fac. Surg.* 44, 859–867.
- Vaira, L.A., Biglio, A., Salzano, G., Abbate, V., Lechien, J.R., De Riu, G., 2024. Implant-prosthetic rehabilitation of the atrophic posterior mandible with additively manufactured custom-made subperiosteal implants: a cohort study. *Int. J. Oral Maxillofac. Surg.* <https://doi.org/10.1016/j.ijom.2024.01.003>.
- Van den Borre, C., Rinaldi, M., De Neef, B., Loomans, N.A., Nout, E., Van Doorne, L., et al., 2021. Radiographic evaluation of bone remodeling after additively manufactured subperiosteal jaw implantation (AMSJI) in the maxilla: a one-year follow-up study. *J. Clin. Med.* 10, 3542.
- Van den Borre, C., Rinaldi, M., De Neef, B., Loomans, N.A.J., Nout, E., Van Doorne, L., et al., 2022. Patient and clinician-reported outcomes for the additively manufactured sub-periosteal jaw implant (AMSJI) in the maxilla: a prospective multicentre one-year follow-up study. *Int. J. Oral Maxillofac. Surg.* 51, 243–250.
- Van den Borre, C., De Neef, B., Loomans, N.A.J., Rinaldi, M., Nout, E., Bouvry, P., et al., 2023. Soft tissue response and determination of underlying risk drivers for recession and mucositis after AMSJI implantation in the maxilla. *Int. J. Oral Maxillofac. Implants.* <https://doi.org/10.11607/jomi.10490>.
- Varol, A., Atali, O., Sipahi, A., Basa, S., 2016. Implant rehabilitation for extremely atrophic maxillae (Cawood Type VI) with Le Fort I downgrafting and autogenous iliac block grafts: a 4-year follow-up study. *Int. J. Oral Maxillofac. Implants* 31, 1415–1422.
- von Elm, E., Altman, D.G., Egger, M., Pocock, S.J., Gøtzsche, P.C., Vandenbroucke, J.P., STROBE Initiative, 2007. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 335, 806–808.
- Zielinski, R., Sowinski, J., Piechaczek, M., Okulski, J., Kozakiewicz, M., 2023. Finite element analysis of subperiosteal implants in edentulism — on the basis of the Mal Implant® by Integra Implants®. *Materials* 16, 7466.