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Subperiosteal Digitally Manufactured Implant Combined with Guided Pterygoid Fixation for Rehabilitation of the Severely Atrophic Maxilla

Schiroli Guido [1], Covani Ugo [2], Giammarinaro Enrica [2,*], Roberto Marra [3], Sandi Andrea [4], Simone Marconcini [5] and Rupnik Carlo [6]

[1] Private Practice, 16121 Genova, Italy; guido.schiroli@gmail.com
[2] Istituto Stomatologico Toscano, 55041 Comune di Camaiore, Italy; covani@covani.it
[3] Private Practice, 80121 Naples, Italy; dr.robertomarra@gmail.com
[4] 3D Fast, 35121 Padova, Italy; andrea@sandi.it
[5] Saint Camillus International University of Health Sciences, 00131 Rome, Italy; simosurg@gmail.com
[6] Private Practice, 85310 Budva, Montenegro; rupnik@itcc-mne.com
* Correspondence: e.giammarinaro@gmail.com

Abstract

Background: Severe maxillary atrophy remains a major challenge for implant-supported rehabilitation, often requiring complex grafting procedures or zygomatic implants associated with increased surgical morbidity. Advances in digital planning and additive manufacturing have enabled the development of patient-specific subperiosteal implants supported by cortical bone anchorage. Materials and Methods: This study presents a fully digital workflow combining customized subperiosteal implants (SP3D) with guided pterygoid fixation (PT3D) to achieve stable distal support and allow immediate loading in severely atrophic maxillae. Results: Nine patients presenting with advanced maxillary atrophy were treated using computer-assisted design, guided surgery, and immediate prosthetic rehabilitation. All implants were successfully placed according to the digital plan, achieving stable fixation through bilateral pterygoid engagement. No major intraoperative or postoperative complications were observed. Immediate loading was performed in all cases with stable prosthetic outcomes during the follow-up period (average follow-up period was 12.7 months). Conclusions: The combined SP3D–PT3D approach represents a minimally invasive alternative for full-arch rehabilitation in extreme maxillary atrophy, potentially reducing the need for bone grafting while improving surgical predictability and biomechanical stability.

Keywords: subperiosteal implant; atrophic maxilla; digital workflow

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1. Introduction

Rehabilitation of the edentulous maxilla using fixed implant-supported prostheses represents a predictable and well-established treatment when adequate residual bone volume allows placement of conventional endosseous implants. Since the introduction of osseointegration by Brånemark in the early 1980s, implant-supported fixed restorations have become the gold standard for treatment of edentulous jaws [1].

However, patients presenting with advanced maxillary atrophy—commonly corresponding to Cawood and Howell class V or VI conditions—often exhibit insufficient bone height and width for placement of conventional or short implants [2]. In these situations,

removable prostheses frequently fail to provide satisfactory functional stability, masticatory efficiency, and patient acceptance, significantly affecting quality of life [3].

Historically, two principal surgical strategies have been adopted to manage severe maxillary atrophy: extensive autologous bone grafting procedures and zygomatic implant placement. Reconstruction using extraoral donor sites such as the iliac crest or calvarium may restore bone volume but requires additional surgical morbidity, hospitalization, prolonged healing periods, and staged rehabilitation protocols. Furthermore, long-term volumetric resorption and reduced predictability in severe defects remain relevant clinical concerns [4].

Zygomatic implants, introduced in the early 1990s, have progressively emerged as an alternative approach by providing anchorage in dense zygomatic bone and frequently allowing immediate loading protocols [5]. Long-term survival rates comparable to conventional implants have been reported [6]. Nevertheless, zygomatic implant surgery remains technically demanding, often requiring advanced surgical expertise and extensive anatomical exposure [7]. Implant trajectories may involve trans-sinus or extra-sinus pathways in proximity to critical anatomical structures, potentially leading to complications such as sinusitis, oroantral communication, soft-tissue dehiscence, and complex retreatment scenarios [8]. Additionally, many procedures require general anesthesia and hospital-based settings.

These limitations have renewed interest in alternative solutions capable of reducing surgical invasiveness while maintaining biomechanical stability and prosthetic predictability.

Subperiosteal implants represent one of the earliest concepts in implant-supported rehabilitation. Originally introduced in the 1940s, these devices consisted of custom metal frameworks resting on cortical bone surfaces beneath the periosteum [9]. Conventional fabrication required direct intraoperative bone impressions followed by casting procedures, frequently resulting in inaccurate adaptation, increased infection risk, and mechanical complications [10]. With the widespread success of endosseous implants, subperiosteal systems were progressively abandoned.

Recent advances in cone-beam computed tomography (CBCT), digital imaging, and CAD–CAM technologies have fundamentally transformed this historical concept. Contemporary digitally designed subperiosteal implants can now be planned entirely within a virtual environment using precise three-dimensional reconstructions of patient anatomy [11]. Additive manufacturing through selective laser melting (SLM) enables the fabrication of patient-specific titanium frameworks with highly accurate bone conformity and complex biomechanical geometries not achievable with traditional casting techniques [12]. Early clinical reports have demonstrated encouraging outcomes with digitally manufactured subperiosteal implants in severely atrophic maxillae, frequently allowing immediate loading protocols with acceptable complication rates [13].

In parallel, the pterygoid region has gained increasing relevance as a site for posterior implant anchorage due to the presence of dense cortical bone formed by the maxillary tuberosity, palatine pyramidal process, and pterygoid process of the sphenoid bone [14]. Engagement of the pterygoid lamina provides favorable biomechanical support and reduces distal cantilever forces. However, placement of pterygoid implants remains anatomically demanding because of limited surgical access and proximity to vascular and neural structures, including the pterygoid venous plexus and descending palatine artery [15]. Minor deviations in drilling angulation or depth may compromise cortical engagement or increase surgical risk.

Static computer-guided surgery has significantly improved accuracy in conventional implantology by translating digital planning into controlled intraoperative execution [16].

Nevertheless, currently available guided systems are primarily designed for endosseous implants and are not readily integrated with complex subperiosteal frameworks.

The SP3D system described in the present study represents a digitally engineered subperiosteal implant designed to combine extensive cortical surface support with triangulated screw fixation and guided distal fixation in the pterygoid region. The associated PT3D device functions simultaneously as a stabilization system and a static surgical guide, enabling controlled osteotomy preparation and reproducible engagement of the pterygoid lamina according to the digital plan.

This integrated approach aims to redefine subperiosteal implant biomechanics by transforming the implant framework into an active guided surgical platform rather than a passive resting structure.

The objective of the present study is therefore to describe the digital workflow, implant design principles, and standardized surgical protocol of the SP3D–PT3D system and to report the early clinical and radiological outcomes obtained in a consecutive series of patients affected by severe maxillary atrophy.

2. Materials and Methods

2.1. Study Design and Patient Selection

This prospective descriptive case series included nine consecutive patients (five females and four males) presenting with advanced maxillary atrophy requiring fixed implant-supported rehabilitation. Patient age ranged from 57 to 76 years.

All treatments were performed at a single surgical center using a standardized clinical and digital workflow based on the SP3D subperiosteal implant protocol combined with guided pterygoid fixation (PT3D system).

Inclusion criteria were:

Severe maxillary atrophy classified as Cawood and Howell class V or VI;
Indication for fixed full-arch or partial rehabilitation;
Insufficient bone volume for placement of conventional endosseous implants;
Patient refusal or contraindication to extensive augmentation procedures, including iliac crest grafting, calvarial grafting, or zygomatic implants.

All patients provided written informed consent for surgical treatment, postoperative imaging, and use of anonymized clinical data for scientific purposes. The study was conducted in accordance with the Declaration of Helsinki.

2.2. Preoperative Imaging and Digital Data Acquisition

Each patient underwent cone-beam computed tomography (CBCT) scanning using a standardized protocol (3D Accuitomo 170, Morita, Kyoto, Japan) with voxel size ranging between 0.2 and 0.3 mm.

CBCT acquisition was performed with the patient wearing a radiographic prosthesis and occlusal bite incorporating fiducial markers to enable accurate prosthetically driven alignment.

Intraoral optical scans of both arches and soft tissues—or high-resolution scans of conventional casts when required—were obtained and exported in STL format.

DICOM datasets derived from CBCT imaging and STL surface scans were imported into a digital planning environment (RealGuide®, 3Diemme, Cantù, Italy). Multimodal registration and segmentation procedures were performed using dedicated software platforms (v.20.0, Mimics®, Materialise NV, Belgium), generating a unified three-dimensional representation of hard and soft tissues.

Particular attention was dedicated to the reconstruction of the maxillary tuberosity and visualization of the cortical boundaries of the pterygoid process to allow accurate distal fixation planning.

2.3. Digital Implant Design and SP3D Planning Protocol

Implant design was performed according to the SP3D protocol, aimed at achieving multi-vectorial biomechanical stabilization through broad cortical support and triangulated fixation (Geomagic Freeform Version: V2025.1 Hexagon AB Stoccolma, Svezia). The device should have embraced the basal bone both buccally and palatally in a "U" fashion.

Abutment positions were prosthetically driven and located primarily in canine and first molar regions corresponding to principal load-bearing zones. The framework geometry incorporated horizontal and oblique connecting arms designed to distribute functional loads and increase resistance to torsional and bending forces.

Primary fixation sites included:

Anterior nasal spine anchorage;
Peri-abutment triangulated screw configurations;
Bilateral distal fixation in the pterygoid region.

It is crucial to highlight that the one placed in the pterygoid region was a fixation screw and not an implant. The length was always 19 mm and the diameter 2 mm.

The internal surface of the framework was maintained with a micro-rough texture to increase frictional stability against bone, whereas the external surface was polished to minimize soft-tissue irritation.

The finalized implant framework was exported as an STL file and manufactured in Ti-6Al-4V titanium alloy using selective laser melting (SLM) technology (TruPrint 2000, TRUMPF Additive Manufacturing; Print Genius 150, Prima Additive, Collegno, Italy) (Figure 1).

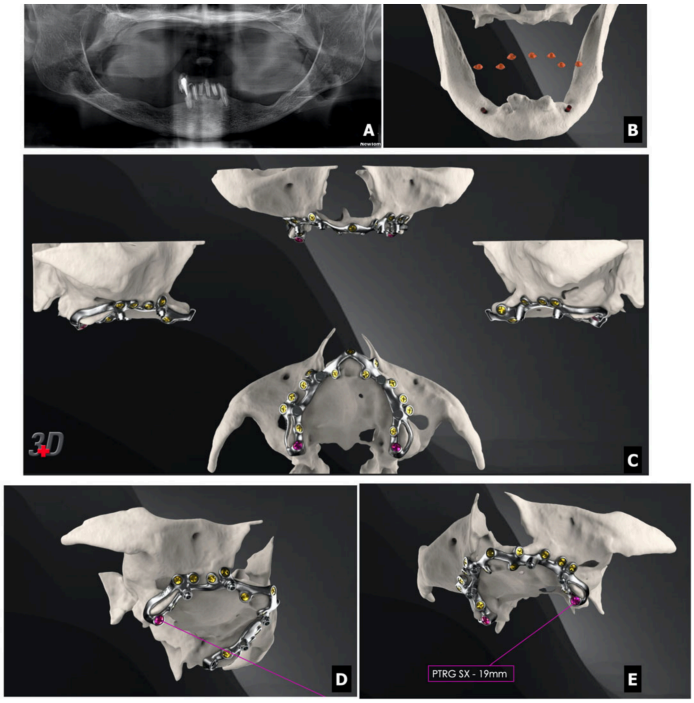

Figure 1. (**A**) Pre-op panoramic radiograph of an atrophic patient treated with a custom subperiosteal implant. (**B**) Three-dimensional reconstruction of the edentulous ridges. (**C**) 360° view of the custom implant framework design. (**D**) Detail of the left pterygoid fixation. (**E**) Detail of the right pterygoid fixation.

2.4. PT3D Guided Stabilization Device

A dedicated laser-melted cobalt–chromium device (PT3D—Pterygoid 3D) was digitally designed and rigidly coupled to the subperiosteal framework.

The PT3D device fulfilled three primary functions:

Stabilization and handling of the implant during placement;
Prevention of framework deformation during screw tightening;
Static guidance of pterygoid osteotomies.

Distal metallic sleeves integrated into the PT3D device guided drilling toward the pterygoid lamina according to the preplanned trajectory. Depth-control mechanisms ensured cortical engagement while preventing over-instrumentation and minimizing risk to adjacent anatomical structures.

2.5. Guided Pterygoid Fixation Planning

The digitally planned pterygoid trajectory originated from a safe entry point at the maxillary tuberosity and extended toward the cortical lamina of the pterygoid process.

Virtual planning defined:

Drilling angulation;
Osteotomy depth;
Screw length;
Cortical engagement point.

These parameters were directly transferred intraoperatively through the PT3D-guided sleeves, allowing reproducible execution independent of freehand estimation.

2.6. Immediate Prosthetic Protocol

Integrated prosthetic connections were incorporated into the implant design to allow immediate loading.

All patients received screw-retained provisional PMMA prostheses supported by a prefabricated SLM-manufactured cobalt–chromium bar (“3D bar”) delivered on the day of surgery.

2.7. Postoperative Evaluation and Accuracy Analysis

Postoperative CBCT scans were obtained using the same imaging device employed preoperatively.

Digital segmentation and three-dimensional superimposition between planned and postoperative datasets were performed using identical software environments to evaluate:

Adaptation of the framework to the maxillary surface;
Accuracy of pterygoid screw trajectory;
Engagement of the pterygoid cortical lamina.

Accuracy assessment was performed qualitatively through spatial correspondence analysis between planned and achieved implant positioning.

2.8. Surgical Procedure

All surgical interventions were performed under local anesthesia, with or without conscious sedation, in both partially and fully edentulous patients.

The surgical workflow followed a standardized sequence defined by the SP3D–PT3D protocol and was supported by a set of digitally manufactured auxiliary devices designed to transfer virtual planning accurately to the clinical setting.

2.9. Incision Planning and Flap Design

A digitally designed incision guide manufactured by three-dimensional printing (PA12 material) was used intraoperatively to identify the precise emergence sites of the implant abutments.

Linear mucosal incisions were performed directly over the planned abutment locations, allowing elimination of vertical releasing incisions and minimizing flap extension. This approach reduced surgical morbidity while preserving vascular supply to surrounding tissues.

Limited mucoperiosteal flaps were elevated only in correspondence with the cortical areas intended for framework support. Unlike zygomatic implant surgery, no exposure of the lateral maxillary wall, sinus cavity, or zygomatic buttress was required.

Anatomical replicas and implant duplicates were used intraoperatively to verify adequate bone exposure prior to definitive implant placement.

2.10. Implant Positioning and Initial Stabilization

The SP3D subperiosteal implant was positioned with the PT3D stabilization device preassembled to the framework before insertion.

The coupled system facilitated controlled handling and ensured passive adaptation of the framework onto the maxillary cortical surface.

Fixation followed a predefined tightening sequence to prevent distortion and maintain positional accuracy:

Placement of the anterior nasal spine fixation screw, establishing a primary positional reference;
Insertion of bilateral posterior buccal screws adjacent to distal abutments;
Progressive placement of remaining fixation screws around load-bearing abutments using an alternating bilateral sequence.

This staged fixation protocol ensured stable framework seating prior to distal guided osteotomy preparation.

2.11. Guided Pterygoid Osteotomy

After preliminary stabilization of the implant, pterygoid osteotomies were performed through the metallic sleeves integrated into the PT3D device.

The guide maintained predefined angulation and drilling depth according to digital planning. Depth-controlled drills allowed engagement of the cortical lamina of the pterygoid process while minimizing the risk of overpenetration and injury to adjacent anatomical structures.

Following osteotomy preparation, the PT3D stabilizer was removed, and long fixation screws were manually inserted into the pterygoid cortical bone under tactile control.

The guided sequence ensured that distal fixation was achieved only after complete stabilization of the framework, preventing displacement during drilling.

2.12. Immediate Prosthetic Loading

After completion of fixation, implant stability was verified clinically.

A screw-retained provisional prosthesis fabricated in polymethyl methacrylate (PMMA) and bonded to a prefabricated cobalt–chromium SLM-manufactured bar was delivered on the same day of surgery, enabling immediate functional loading (Figure 2).

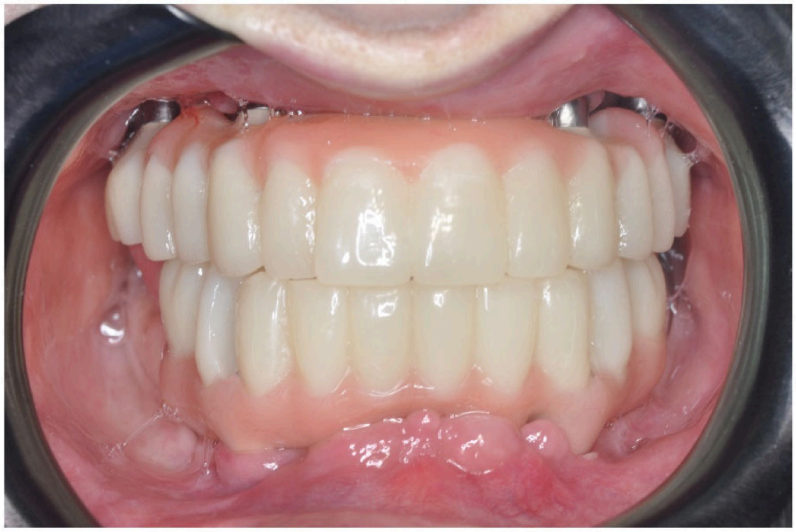

Figure 2. Intraoral photograph showing the immediate prosthetic rehabilitation.

2.13. Postoperative Protocol and Accuracy Verification

Patients were recalled on the first postoperative day for occlusal adjustment and radiographic evaluation.

Postoperative CBCT scans were acquired using the same imaging device employed during preoperative planning. Bone and metallic structures were segmented separately, and a three-dimensional comparison was performed between the planned and postoperative datasets. To establish a common coordinate system, the planned maxilla was aligned to the postoperative maxilla using a best-fit registration based exclusively on stable bony surfaces. After registration, the planned and actual positions of the pterygoid screws were individually superimposed. For each screw, a longitudinal axis was defined from the center of the screw head to the apex, allowing precise calculation of spatial deviations along the X, Y, and Z axes. Accuracy was assessed according to geometrical tolerancing principles, which enabled independent evaluation of positional and angular deviations. A cylindrical tolerance zone centered on the planned screw axis was generated to quantify the overall spatial discrepancy between the planned and postoperative trajectories, providing a standardized and reproducible assessment of surgical accuracy.

2.14. Outcomes Evaluation

Implant survival: An implant was considered successful at the 12-month mark if it remained functional and stable, showed no mobility, pain on percussion, or signs of peri-implant disease or exposure. Survival was verified after temporary prosthesis removal.

Prosthesis success: Defined by stable, pain-free function without mobility. Stability was evaluated during each follow-up by applying pressure with opposing instruments.

Any mechanical or biological complication was noted if present. Soft tissue dehiscence was considered biological; if the dehiscence was associated with infection, the occurrence was considered a major event.

3. Results

All nine planned SP3D subperiosteal implants were successfully placed according to the preoperative digital planning protocol (Table 1).

Table 1. Demographic and clinical characteristics of the included patients.

Patient ID	Age (Years)	Sex	Maxillary Condition	Follow-Up (Months)	Complications	Loading Protocol	Number of Fixation Screws
P01	63	M	Partial edentulism	16	None	Immediate	7
P02	72	M	Total edentulism	14	None	Immediate	15
P03	67	F	Total edentulism	13	Tuber exposure at 14 months, without infection	Immediate	15
P04	78	F	Total edentulism	12	None	Immediate	15
P05	71	M	Partial edentulism	12	Soft tissue exposure at 4 months, without infection	Immediate	7
P06	69	F	Total edentulism	12	None	Immediate	15
P07	64	F	Total edentulism	12	None	Immediate	15
P08	67	F	Total edentulism	12	None	Immediate	15
P09	73	M	Total edentulism	12	None	Immediate	

A total of eighteen pterygoid fixation screws were inserted using the PT3D-guided approach. Implant placement and distal fixation were achieved in all patients without intraoperative complications.

3.1. Surgical Outcomes

No intraoperative vascular injury, neural impairment, or uncontrolled bleeding events were recorded.

Framework stabilization was achieved in every case through the planned triangulated fixation pattern combined with bilateral pterygoid fixation. Passive adaptation of the implant framework to the maxillary cortical surface was clinically confirmed during surgery, with no evidence of deformation or positional instability during screw tightening.

All procedures were completed under local anesthesia with or without conscious sedation.

3.2. Radiological Accuracy

Postoperative CBCT analysis followed by three-dimensional digital superimposition demonstrated high correspondence between planned and achieved implant positioning.

In all cases:

Guided drilling maintained the planned angulation and depth.
Engagement of the pterygoid cortical lamina was radiologically confirmed.
No clinically relevant deviation from the planned screw trajectory was observed (Figure 3).

Digital comparison confirmed intimate adaptation of the framework to the underlying osseous anatomy. A summary table is presented below (Table 2).

Table 2. Mean translational deviations (mm) along the three spatial axes between planned and post-op implant positions.

Axis	X (mm)	Y (mm)	Z (mm)
Right side (DX)	0.1097	0.2087	0.9260
Left side (SX)	0.4683	0.5199	1.3073
Overall (TOT)	0.2890	0.3643	1.1166

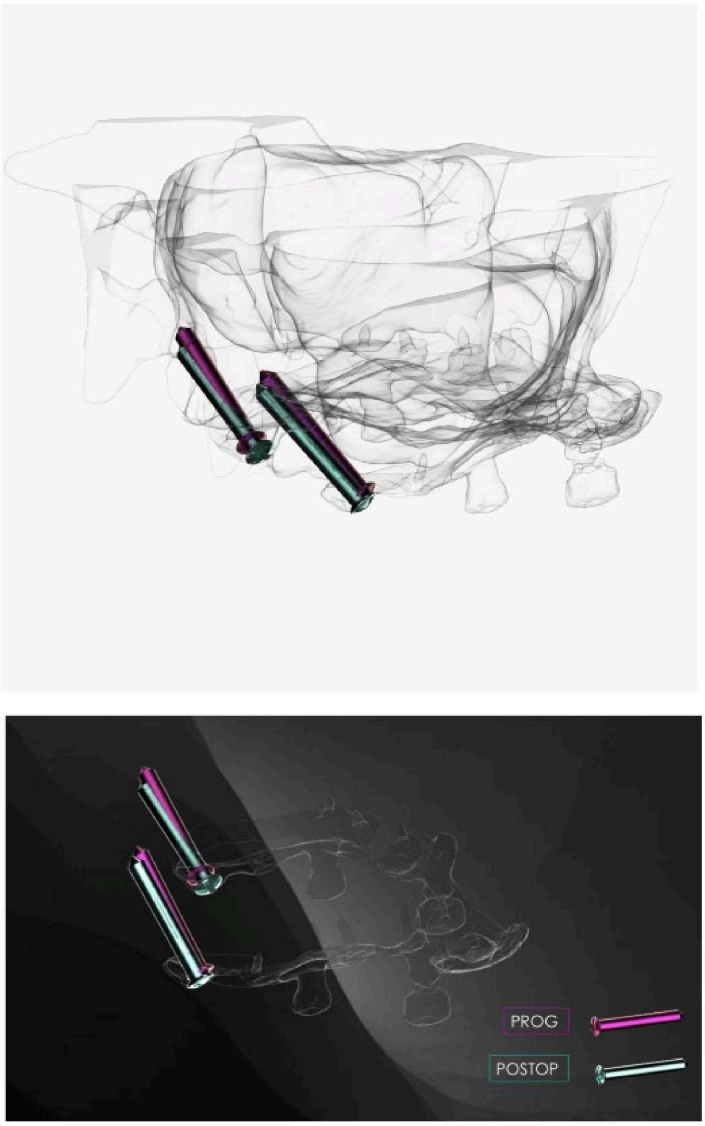

Figure 3. Three-dimensional superimposition: planned and post-op positions of the pterygoid screw fixation.

3.3. Soft-Tissue Healing and Biological Response

Postoperative healing was uneventful in the majority of patients.

Soft-tissue adaptation around transmucosal abutments appeared favorable, with the absence of infection, suppuration, or inflammatory complications during the observation period.

One patient presented a limited early framework exposure without signs of infection or implant mobility. No surgical revision or implant removal was required (Figure 4).

3.4. Prosthetic Outcomes

Immediate loading was successfully performed in all cases through screw-retained provisional prostheses delivered on the day of surgery.

All provisional restorations remained stable throughout the observation period, providing satisfactory functional rehabilitation, phonetics, and patient comfort.

No prosthetic loosening, fracture, or loss of stability was observed.

The average follow-up period was 12.7 months.

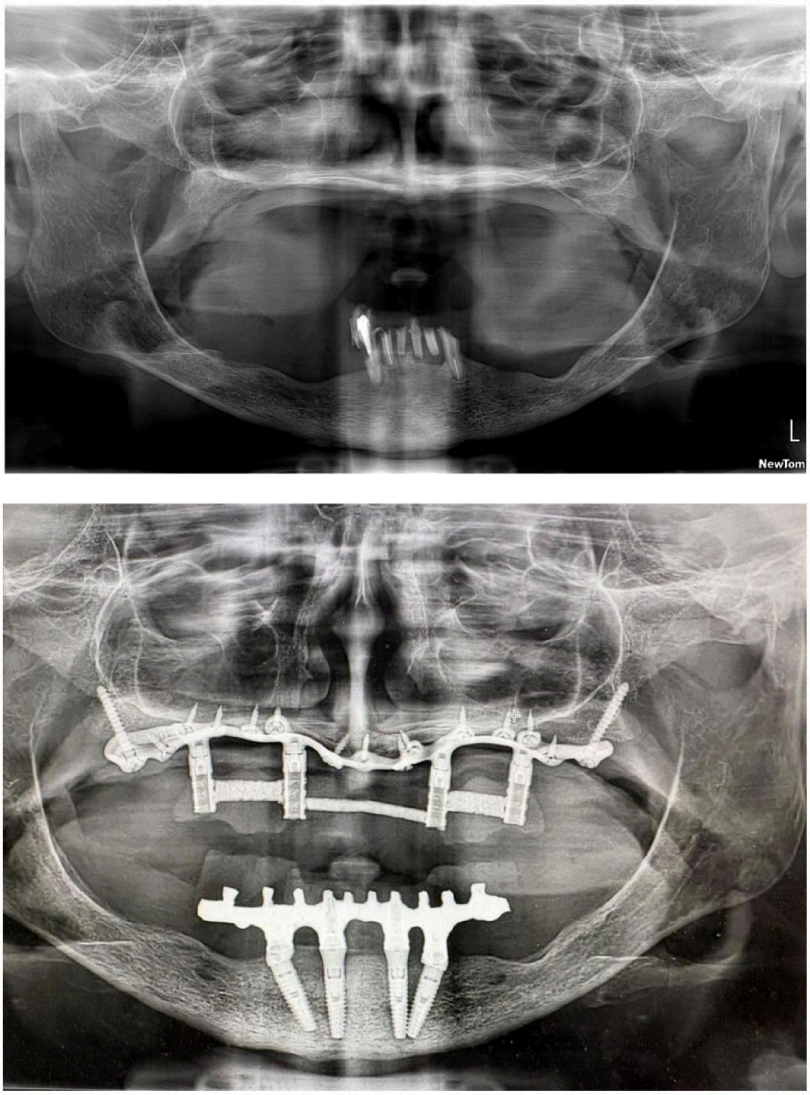

Figure 4. Comparison of preoperative and postoperative panoramic radiographs.

4. Discussion

Rehabilitation of the severely atrophic maxilla remains one of the most demanding challenges in implant-supported fixed prosthodontics [17]. When residual bone volume becomes insufficient for conventional endosseous implant placement, treatment strategies traditionally rely on extensive bone augmentation procedures or zygomatic implant anchorage [18]. Although both approaches demonstrate clinically acceptable survival rates, they are associated with increased surgical invasiveness, technical complexity, and biological morbidity [19].

The present study introduces a digitally designed subperiosteal implant system integrating guided pterygoid fixation, representing a conceptual evolution rather than a simple modification of historical subperiosteal implants.

4.1. From Passive Frameworks to Active Guided Platforms

Traditional subperiosteal implants functioned primarily as passive load-bearing frameworks resting on cortical bone surfaces. Their clinical limitations were largely related to inaccurate fabrication methods and insufficient mechanical stabilization.

The SP3D–PT3D system fundamentally modifies this concept. Through digital planning and selective laser melting manufacturing, the implant framework becomes an actively stabilized multi-anchor platform combining:

Broad cortical surface support;
Triangulated fixation patterns;
Prosthetically driven abutment positioning;
Guided distal cortical engagement.

The addition of guided pterygoid fixation transforms the implant from a resting structure into a surgically guided biomechanical system capable of controlled load distribution across multiple anatomical regions.

4.2. Biomechanical Rationale of Pterygoid Engagement

The pterygoid process represents one of the densest cortical regions of the posterior maxilla and has long been recognized as a reliable anchorage site in implantology. However, conventional pterygoid implant placement remains technically demanding due to limited surgical access and proximity to critical vascular structures [20].

In freehand procedures, minor deviations in angulation may compromise cortical engagement or increase surgical risk. By digitally encoding trajectory, angulation, and drilling depth into the PT3D-guided device, distal fixation becomes independent of operator estimation and reproducible across procedures.

This approach allows posterior stabilization without sinus involvement and reduces reliance on long trans-anatomical implants. From a biomechanical perspective, distal cortical fixation contributes to a reduction in cantilever forces and improves resistance to torsional loading during mastication.

The present implant design incorporates a monolithic multivectorial framework extending from the premaxilla to the maxillary tuberosity, with vestibular and palatal fixation, tripod-supported prosthetic pillars, and guided pterygoid fixation. This integrated biomechanical configuration enhances load distribution and resistance to multidirectional masticatory forces, while the electropolished surface may reduce the risk of infection in the event of partial soft-tissue exposure.

4.3. Comparison with Zygomatic Implant Rehabilitation

Zygomatic implants currently represent a well-established solution for extreme maxillary atrophy and have demonstrated long-term clinical success [21]. Nevertheless, their placement requires advanced surgical expertise, extensive anatomical exposure, and frequently general anesthesia.

The SP3D–PT3D approach differs conceptually by avoiding sinus traversal and orbital proximity while enabling treatment under local anesthesia. Preservation of anatomical structures may reduce surgical morbidity and maintain future retreatment options.

Importantly, the present system should not be interpreted as a replacement for zygomatic implants but rather as an additional therapeutic option within the armamentarium for managing severe maxillary atrophy. Patient-specific anatomical conditions, surgeon experience, and risk assessment remain decisive factors in treatment selection.

Compared with zygomatic implant rehabilitation, the subperiosteal approach offers several surgical and clinical advantages. Zygomatic implant placement typically requires extensive surgical exposure, including the infraorbital nerve region and zygomatic buttress, often necessitating general anesthesia, hospitalization, and advanced maxillofacial surgical expertise. In addition, the proximity of osteotomies to the orbit is associated with the risk of intraoperative and postoperative complications, including infraorbital nerve injury, orbital damage, chronic sinusitis, implant exposure, and oroantral communications. By

contrast, custom-made maxillary subperiosteal implants can generally be placed under local anesthesia in an outpatient setting without exposure of the infraorbital foramen or extensive zygomatic dissection. This results in reduced surgical morbidity, lower postoperative discomfort, and a complication profile mainly limited to occasional implant exposure, which is often not associated with infection and rarely requires intervention. Furthermore, implant failure does not usually result in permanent anatomical damage, allowing predictable retreatment when necessary. However, further studies with a randomized design, comparison with the zygomatic approach, and a longer follow-up period are needed to confirm the present results.

4.4. Role of Digital Workflow and Surgical Reproducibility

A central aspect of contemporary implantology is the ability to transfer virtual planning accurately into clinical execution [22]. The integration of digitally manufactured auxiliary devices within the SP3D–PT3D workflow enables controlled positioning, stabilization during fixation, and guided osteotomy preparation [23].

By converting the subperiosteal implant itself into a static surgical guide, the system reduces procedural variability and enhances reproducibility. Such standardization represents a critical step toward evidence-based adoption of complex reconstructive procedures [24].

4.5. Biological Considerations

Limited flap elevation, polished external surfaces, and intimate adaptation of the framework to cortical bone appeared to favor soft-tissue healing in the present series. The absence of infection or implant mobility and the occurrence of only one minor exposure suggest acceptable early biological tolerance.

Modern additive manufacturing technologies allow accurate bone conformity while maintaining structural rigidity, potentially reducing micromotion at the bone–implant interface compared with historically fabricated subperiosteal designs [25].

4.6. Limitations

The principal limitation of this study is the limited sample size and relatively short observational period. Although early clinical and radiological outcomes are encouraging, long-term survival and mechanical behavior must be validated in larger prospective cohorts.

Finite element analysis and fatigue testing will be essential to further investigate stress distribution and long-term load performance of this multi-anchor configuration.

4.7. Future Perspectives

Digitally designed patient-specific implants may represent a transitional step toward personalized skeletal anchorage systems. This protocol showed promising preliminary clinical feasibility and short-term stability.

Future investigations should evaluate long-term biomechanical stability, peri-implant tissue response, and comparative outcomes versus established reconstructive approaches.

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Institutional Review Board Statement: The present study is a retrospective observational case series involving nine consecutive patients treated with standard-of-care surgical procedures. No experimental intervention beyond routine clinical practice was performed. All patient data were fully anonymized prior to any analysis. The study was conducted in full accordance with: The Declaration of Helsinki (WMA, last amended by the 75th General Assembly, Helsinki, October 2024), specifically Paragraphs 9 and 10, constituting the primary binding international ethical framework for medical research; Article 16 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Council of Europe, Oviedo Convention, 1997; ratified by Italy), governing the protection of persons involved in research; Article 82 of EU Regulation 2017/745 on Medical Devices (MDR), under which retrospective observational studies based on anonymized clinical data collected in the context of standard care are explicitly excluded from the scope of clinical investigations requiring prior Ethics Committee authorization. On the basis of the foregoing international and EU regulatory framework, directly applicable irrespective of the national jurisdiction of the authors or the seat of the publisher, formal IRB approval is not required for this category of study.

Informed Consent Statement: Patient consent was waived due to the retrospective observational case series of the study and the use of anonymized data.

Data Availability Statement: Data are available upon request.

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Conflicts of Interest: Authors Schiroli Guido, Roberto Marra, and Rupnik Carlo are in private practice. Author Sandi Andrea is the CEO of 3D Fast. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Abbreviations

The following abbreviations are used in this manuscript:

CBCT	Cone-Beam Computed Tomography
SLM	Selective Laser Melting
SP3D	Subperiosteal 3D Implant System
PT3D	Pterygoid 3D Guided Stabilizer Device
Ti-6Al-4V	Titanium Alloy (Grade V)
Co-Cr	Cobalt–Chromium Alloy
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
STL	Standard Tessellation Language (3D Surface File Format)
DICOM	Digital Imaging and Communications in Medicine
PMMA	Polymethyl Methacrylate
FEA/FEM	Finite Element Analysis/Finite Element Method
PA12	Nylon 12 High-strength Thermoplastic Polymer

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