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SUBPERIOSTEAL IMPLANTS FOR THE REHABILITATION OF THE ATROPHIC JAWS

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DEDICATIONS

This work is dedicated to everyone who has walked beside me, held me up, and believed in me even when I doubted myself. This PhD is not only the result of years of study and research, but also of love, patience, and faith - from so many beautiful souls who have shaped my path. To my husband, Artiom, who has stood by me through every moment - through long nights, silent worries, and endless deadlines. Thank you for your understanding and strength, for your patience even when life wasn't easy for you either, and for reminding me that love can survive distance, time, and uncertainty. This achievement is as much yours as it is mine. To my parents - though far away, your love has never failed to reach me. You might not always understand why I've chosen such a demanding and endless path of study, but your pride and unconditional support have been the quiet light guiding me forward. You gave me the roots that allowed me to grow - even far from home. To my sister, Nataly, my tireless listener and unpaid therapist - thank you for hearing every complaint, every tear, every moment of self-doubt. You've reminded me of who I am when I almost forgot. Your empathy and humor have saved me more times than I can count. To my beloved nephews, Aurora and Lorenzo - I carry your laughter in my heart, even when I can't be there in person. I'm sorry for the time we've lost, but every page of this work is written with the thought that one day, you'll know that dreams are worth chasing, no matter how far they take you. To my brother-in-law, Marco - thank you for always being ready to help in any situation, and for making me feel that your home is mine too every time I visit. Your kindness and generosity have truly made me feel part of the family. To Yana - thank you for knowing exactly when to pull me away from my books and for offering the most perfect moments of rest, even if only for a few days, surrounded by your warmth, care, and laughter on the magical island of Sardinia. You have the rare gift of turning any ordinary day into a celebration of life, and I am endlessly grateful for that.

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regardless of others' opinions. You showed me the value of perseverance, integrity, and self-respect - to fight for what I believe in, to hold on when it matters, and to walk away when I am no longer valued. Your example has shaped not only my academic career but also the way I face life itself. To Carlo and Gerry, who patiently guided me through my first steps in scientific writing and research. Thank you for your generosity in sharing your knowledge, for your encouragement when I felt lost, and for helping me transform ideas into real, tangible results. You both taught me that science is not only about data, but about passion, curiosity, and collaboration. To Claudia, Rocco, Sasà, Ale, and all my colleagues from the Department - thank you for turning ordinary days into memories I will always treasure. For the laughter that echoed through the lab when everything felt too heavy, for the friendship that made the struggle feel lighter, and for being there - truly there. You reminded me that even in science, the best discoveries are often found in people.

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1. ABSTRACT

AIMS OF THE STUDY: The primary aim of this study is to evaluate and compare intraoperative and postoperative complications associated with different types of implant placement, focusing on both biological and mechanical issues related to the surgical and prosthetic phases. Secondary aims include: (1) assessment of implant failures, including loss of osseointegration, mechanical failure, or removal due to complications; (2) evaluation of prosthetic failures, such as prosthesis fracture, screw loosening, or loss of passive fit requiring repair or replacement; and (3) measurement of patient satisfaction using validated questionnaires addressing comfort, aesthetics, function, and quality of life, to comprehensively assess treatment success in clinical practice.

MATERIALS AND METHODS: The study was designed as a prospective, multicentre, randomized controlled clinical trial with a parallel two-arm design, aimed at comparing the clinical performance of CAD/CAM subperiosteal implants and conventional implant solutions - including zygomatic, narrow, short, or ultra-short implants - in the rehabilitation of patients with severe jaw atrophy. The study protocol was approved by the CE-AVEC Institutional Review Board (IRB) (Protocol No. 731-2021-DISP-AUSLBO). A total of 22 patients presenting with fully or partially edentulous maxillae and/or mandibles and exhibiting severe alveolar atrophy were enrolled. Eligibility criteria required participants to be 18 years or older, to have provided informed consent, and to demonstrate insufficient bone volume for the placement of at least four standard implants (≥3.5 mm in diameter and ≥6 mm in length) without the need for extensive bone augmentation, as verified through CBCT-based virtual planning. Exclusion criteria included systemic contraindications to surgery, previous intravenous bisphosphonate therapy, uncontrolled diabetes, and other severe systemic diseases. Participants were randomized using the REDCap (Research Electronic Data Capture) platform into two groups of equal size (n = 11 each). The Control Group was treated using conventional implant techniques, such as zygomatic or short/narrow-diameter implants, whereas the Test Group received custom-made subperiosteal implants designed through digital planning and

CAD/CAM technology. Preoperative planning was conducted using CBCT scans, employing RealGuide and PlastyCAD. All patients were planned to be rehabilitated with immediate fixed implant-supported prostheses, provided that adequate primary stability was achieved at the time of surgery. A provisional prosthesis was delivered within 24–48 hours postoperatively, followed by the placement of a definitive CAD/CAM prosthesis after approximately four months. Patients were monitored throughout a structured follow-up period, which included evaluations at 1 week, 14 days, 30 days, 3 months, 6 months, 1 year, 2 years, and 3 years, along with semi-annual maintenance visits thereafter. At each follow-up appointment, clinical and radiographic assessments were performed to record biological and mechanical complications, implant and prosthetic success, and patient-reported outcomes.

RESULTS: A total of 22 patients were included in the study cohort. The demographic profile showed a mean age of 62.2 years (median 63.5 years , range 29-76 years), and the cohort was predominantly female, with 17 patients (77.0%). Baseline clinical risk factors were evaluated, identifying 7 active smokers (31.8%) and 1 patient (4.5%) with a pre-existing diagnosis of diabetes. Procedurally, the 22 cases were split among four implant types: 11 (50.0%) received subperiosteal implants , 5 (22.7%) received zygomatic implants , 5 (22.7%) received short implants , and 1 (4.5%) received a narrow implant. An immediate loading protocol was applied in 21 of the 22 cases (95.5%). The implants were placed in the upper arch in 13 procedures (59%) and the lower arch in 9 (41%). Patients were monitored for a mean duration of 22 months (median 20 months), with follow-up times ranging from 3 to 57 months. For the 11 patients receiving endosseous implants, insertion torque was measured for 44 implants. Zygomatic implants (20 implants) demonstrated the highest primary stability, with a mean insertion torque of 56.15 Ncm and a range of 45–67 Ncm. The 4 narrow implants averaged 44.75 Ncm , while the 20 short implants showed the widest variation (25–45 Ncm) and the lowest mean torque (37.50 Ncm). Insertion torque was not applicable to the 11 subperiosteal cases. The primary clinical endpoint was the incidence of post-operative complications. Overall, 16 patients (72.7%) remained entirely complication-free. Six patients (27.3%) experienced one or more adverse

events , resulting in a total of 7 distinct complications. These included 5 occurrences of mucosititis and 2 of hardware exposure. One patient experienced both types of complications. All 7 adverse events occurred in patients treated with either subperiosteal or zygomatic implants. The subperiosteal group (11 patients) accounted for 5 complications among 4 patients. The zygomatic group (5 patients) had 2 complications in 2 patients. No complications were reported for the short or narrow implant groups. Complication rates varied significantly by risk factor . A dramatic difference was seen based on sex: all 4 male patients (100%) experienced a complication, compared to only 2 of 17 female patients (11.7%). Smokers had a complication rate of 42.8% (3 of 7) , more than double the 20.0% rate (3 of 15) in non-smokers. The single patient with diabetes also experienced a complication (100% rate). Complication onset ranged from 3 months to 3 years post-operatively. Patient satisfaction was evaluated using VAS for pain and the OHIP-14 for quality of life. Post-surgical pain (VAS) scores showed a statistically significant difference between groups ($p = 0.001$). The Zygomatic group reported the highest mean pain ($M = 7.80$) , which was significantly higher than both the Subperiosteal group ($M = 6.27$, $p = 0.021$) and the Short/Narrow group ($M = 4.67$, $p < 0.001$). Oral health-related quality of life (OHIP-14) was assessed longitudinally, with lower scores indicating better outcomes. At prosthesis delivery, the Zygomatic group reported the worst mean score ($M = 39.2$), followed by Subperiosteal ($M = 29.5$) and Short/Narrow ($M = 25.2$). However, all groups showed substantial improvement by the 1-year follow-up, with mean scores dropping to 13.0 for Zygomatic, 9.2 for Subperiosteal, and 7.8 for the Short/Narrow group.

DISCUSSION: Management of severe alveolar ridge atrophy remains a complex challenge in implant dentistry. Traditional multi-stage bone augmentation, while effective, is associated with high morbidity, prolonged treatment, and unpredictable outcomes. Recently, graftless, minimally invasive strategies - including CAD/CAM-fabricated patient-specific subperiosteal implants and alternative anchorage systems such as zygomatic, short, and narrow implants - have emerged as efficient solutions for restoring function and esthetics in severely resorbed jaws. This prospective, multicenter, randomized controlled trial provides the first direct comparison of these approaches, evaluating

postoperative complications, surgical morbidity, and patient-reported outcomes. All implant modalities successfully supported immediate fixed prosthetic rehabilitation. Subperiosteal implants demonstrated intermediate complication rates, primarily localized mucositis and hardware exposure. Zygomatic implants achieved superior primary stability but were associated with higher immediate postoperative pain and inflammation due to more extensive surgical access. Short and narrow implants showed minimal morbidity and no early complications, confirming their suitability when sufficient native bone is available. Patient-reported outcomes, including Visual Analogue Scale (VAS) pain scores and OHIP-14 quality-of-life measures, improved significantly across all groups, with the greatest early discomfort observed in the zygomatic cohort. Risk factors such as male sex, smoking, and diabetes were associated with higher complication rates. Prosthetic complications were reduced with fully digital workflows, though occasional mechanical issues persisted, emphasizing the need for meticulous planning and maintenance. The study highlights the effectiveness of graftless strategies for immediate rehabilitation in severe atrophy while underscoring the importance of individualized treatment planning, patient risk stratification, and rigorous postoperative care.

CONSLUSIONS: Despite encouraging short-term results, further research is essential to validate the long-term biological and biomechanical behavior of subperiosteal implants, optimize digital design and surgical protocols, and better define patient selection criteria. Larger prospective studies with extended follow-up are necessary to confirm their predictability, refine treatment indications, and strengthen their position as a reliable, graftless alternative for advanced atrophic jaw rehabilitation.

2. LIST OF ABBREVIATIONS

GBR – Guided Bone Regeneration

CBCT – Cone Beam Computed Tomography

IRB – Institutional Review Board

REDCap – Research Electronic Data Capture

VAS – Visual Analogue Scale

OHIP-14 – Oral Health Impact Profile – 14 items

CAD – Computer-Aided Design

CAM – Computer-Aided Manufacturing

FEA – Finite Element Analysis

PTFE – Polytetrafluoroethylene

HA – Hydroxyapatite

TCP – β-Tricalcium Phosphate

BCP – Biphasic Calcium Phosphate

Co-Cr-Mo – Cobalt-Chromium-Molybdenum

CaP – Calcium Phosphate

SLM – Selective Laser Melting

PEEK – Polyether Ether Ketone

DICOM – Digital Imaging and Communications in Medicine

STL – Surface Tessellation Language

MPa – Megapascals

SD – Standard Deviation

CRF – Case Report Form

OHI-P – Oral Hygiene Index – Patient

CONSORT – Consolidated Standards of Reporting Trials

DMLS – Direct Metal Laser Sintering

NR – Not Reported

PMMA – Polymethyl Methacrylate

BOP – Bleeding on Probing

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Ti-6Al-4V – Titanium alloy Grade 5

3. INTRODUCTION

3.1. ALVEOLAR BONE REMODELING FOLLOWING TOOTH EXTRACTION

The extraction of the tooth marks not only the physical removal of a dental unit but also the beginning of a complex biological response with profound implications for the surrounding alveolar bone [1,2]. This intervention may cause a range of clinical indications, including extensive dental caries rendering a tooth non-restorable, advanced periodontitis leading to attachment loss and mobility, persistent endodontic infections, traumatic injuries, or developmental anomalies such as impactions [3,4]. Additionally, strategic extractions may be carried out for orthodontic or prosthodontic planning or for medical reasons requiring oral clearance before systemic treatments. Regardless of the cause, extraction initiates a cascade of remodeling processes that alter the local bone structure significantly and irreversibly [5].

The alveolar bone is a highly specialized, tooth-dependent structure that exists primarily to support and anchor teeth [6]. Its preservation is closely tied to the mechanical loading provided by normal mastication and occlusal forces transmitted through the periodontal ligament. Upon tooth removal, this functional stimulation abruptly ceases, triggering a series of catabolic events that result in the atrophy of the alveolar process. The outcome is a predictable loss of both bone volume and architecture, manifested as reductions in ridge width (horizontal dimension) and height (vertical dimension) [7]. The changes are often more pronounced on the buccal aspect due to its thinner cortical plate, particularly in the anterior maxilla [8].

Numerous studies have investigated the temporal dynamics of alveolar bone resorption. One of the most cited is the longitudinal study by Schropp et al. (2003), which revealed that substantial dimensional changes occur within the first twelve months following tooth extraction. Approximately 50% of ridge width can be lost during this period, with the most rapid phase of resorption occurring

within the first three months [9]. This leads to a 5 - 7 mm reduction in width, confirming earlier clinical and histological findings by researchers such as Pietrovsky (1969), Lekovic (1997), and Johnson (1963) [10,11,12]. All these observations emphasize that post-extraction remodeling is not merely a long-term process, but one that is most intense shortly after the extraction event itself.

While the early phase is characterized by rapid and extensive structural changes, bone resorption does not stop after the first year. In the absence of timely prosthetic rehabilitation, bone loss continues progressively, however at a slower rate. Atwood (1971) and Tallgren (1972) demonstrated that residual ridge resorption becomes a chronic condition, particularly evident in completely edentulous patients [13,14]. The mandible is especially susceptible to long-term degradation, with resorption rates as much as four times higher than in the maxilla. This ongoing reduction compromises both the function and esthetics of prostheses over time, presenting serious challenges for long-term oral rehabilitation [15].

To systematically assess the morphological changes following tooth extraction, various classification systems have been developed. One of the most clinically relevant is the classification proposed by Siebert (1983), which categorizes post-extraction alveolar defects into three classes: Class I describes horizontal loss of ridge width without vertical reduction; Class II refers to vertical loss of ridge height with preserved buccolingual dimensions; and Class III represents a combination of both vertical and horizontal defects[16]. Understanding these patterns is essential for selecting appropriate ridge augmentation and soft tissue management techniques in pre-prosthetic or implant therapy (Figure 1).

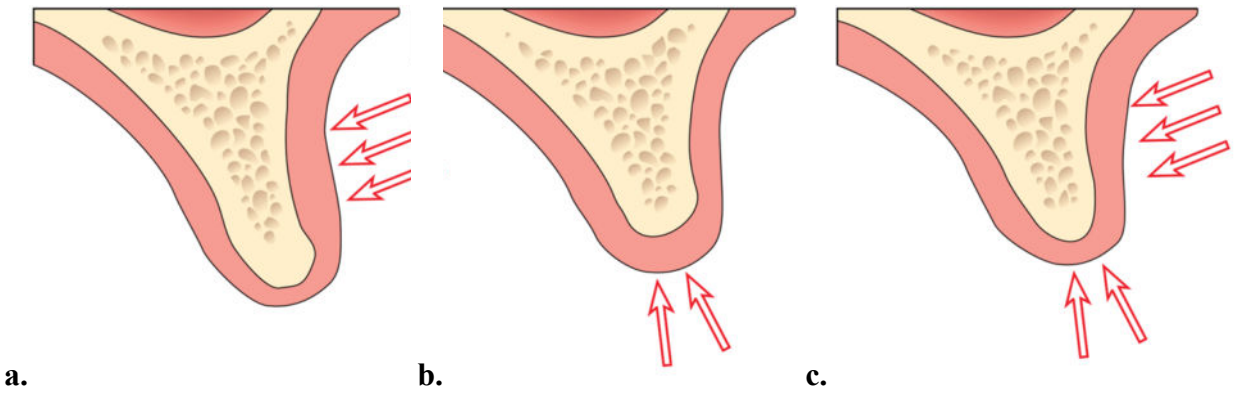


Figure 1. Ridge defect classification according to Seibert (1983): a) Class I describes horizontal loss of ridge width without vertical reduction; b) Class II refers to vertical loss of ridge height with preserved buccolingual dimensions; c) Class III represents a combination of both vertical and horizontal defects.

Among the various configurations encountered in edentulous sites, the so-called ***knife-edge*** ridge represents one of the most diagnostically and therapeutically challenging forms. Characterized by a sharp, narrow bony crest-typically the result of disproportionate resorption of the buccal cortical plate-this ridge type often remains partially obscured beneath seemingly adequate soft tissue contours, which can mislead clinical assessment [13]. Its presence complicates both the mechanical stability of removable prostheses and the planning of implant placement, often necessitating bone augmentation procedures or altered restorative protocols [17].

The importance of recognizing the knife-edge configuration has been highlighted in several attempts to systematically classify residual ridge anatomy. One of the earliest efforts was proposed by Atwood in 1963, who introduced a six-stage continuum based on the degree and progression of resorption. In this system, the knife-edge crest emerges as an intermediate stage-specifically, the fourth order-situated between a high, well-rounded ridge and a low, atrophic form [13] (Figure 2). This transitional morphology reflects both substantial vertical maintenance and a critical loss in horizontal dimension, rendering it structurally inadequate for many conventional restorative approaches [18].

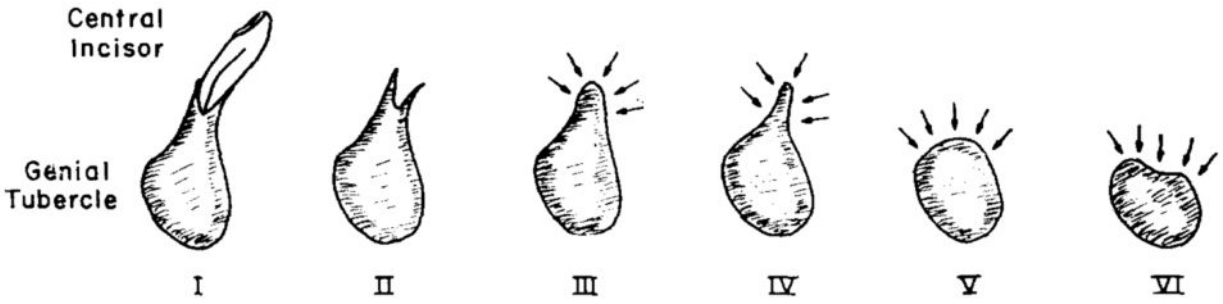


Figure 2. Six orders of mandibular anterior residual ridge form: Order I, pre-extraction; Order II, postextraction; Order III, high well-rounded; Order IV, knife-edge; Order V, low wellrounded; Order VI, depressed (Atwood, 1963).

Another classification (Cawood and Howell, 1988) delineates six morphological classes of completely edentulous ridges based on their clinical presentation and functional implications [19]. The classification begins with Class I, representing the dentate state where the alveolar process is intact, followed by Class II, which describes the ridge immediately following tooth extraction. As healing progresses, the ridge may form into a Class III morphology, which is well-rounded and adequate in both height and width. However, further resorption leads to Class IV, a "knife-edge" ridge that has adequate height but is inadequate in width. More advanced atrophy is seen in Class V, where the ridge becomes flat and is inadequate in both height and width. The final and most severe stage is Class VI, characterized by a depressed ridge form where resorption has progressed to include the loss of basal bone, presenting the most significant rehabilitative challenges.Within their framework, the knife-edge crest is categorized as Class IV, described as possessing sufficient vertical height but lacking adequate buccolingual width. This descriptive presentation is particularly relevant for surgical planning, as it draws attention not only to the insufficiency of bone volume but also to the specific dimension that has been compromised-a factor that directly impacts decisions regarding the need for horizontal augmentation, ridge splitting, or the use of narrow-diameter implants (Figure 3) [19].

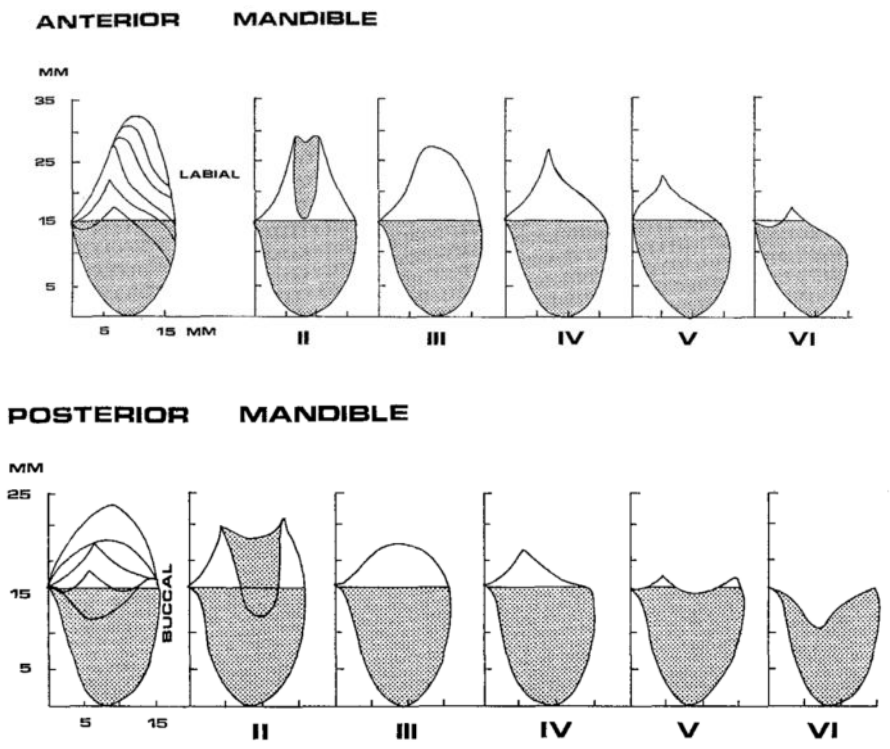


Figure 3. Cawood and Howell's (1988) classification of the edentulous ridge, illustrating the progressive stages of alveolar bone resorption from Class I (dentate) to Class VI (depressed ridge with basal bone loss).

The magnitude of alveolar bone resorption is influenced by a multitude of factors that reflect both systemic and local conditions. Patient-related variables such as age, gender, hormonal status, systemic diseases like diabetes or osteoporosis, and smoking habits can all modulate bone metabolism and healing capacity. Locally, the anatomical morphology of the extraction site, the presence of periapical inflammation, traumatic extraction procedures, and the absence of immediate socket management strategies further contribute to the variability in resorption outcomes. A comprehensive systematic review by Van der Weijden and colleagues (2009) quantitatively assessed post-extraction bone loss [20]. From an initial screening of over 1,300 publications, twelve studies met stringent inclusion criteria. The analysis revealed an average horizontal ridge reduction of 3.87 mm, a mean mid-buccal height loss of 1.67 mm, and a crestal height change of 1.53 mm based on radiographic assessments. Interestingly, despite the vertical reduction, some socket fill was observed, averaging 2.57 mm in

height relative to the original socket floor, reflecting the early stages of immature bone formation and consolidation.

These findings collectively underscore the clinical imperative to anticipate, monitor, and manage post-extraction ridge changes [14]. Understanding the biological mechanisms and temporal profile of bone resorption is foundational not only for academic inquiry but also for evidence-based clinical decision-making-particularly in light of increasing demands for aesthetic and functional rehabilitation via implant-supported prostheses [6].

3.2. BONE AUGMENTATION TECHNIQUES

Implant-supported prosthetic rehabilitation has become a widely accepted and effective treatment modality for edentulous patients, restoring both function and aesthetics. The placement of endosseous dental implants in the maxilla and mandible allows for fixed or removable prosthetic solutions, significantly improving patient quality of life. However, the success of implant therapy is highly dependent on the availability of sufficient alveolar bone volume, which is often compromised in edentulous individuals due to progressive bone resorption following tooth loss. As extensively discussed in previous chapter, following tooth extraction, the alveolar ridge undergoes progressive resorption, both vertically and horizontally, especially in long-standing edentulous cases. When bone volume is insufficient, it becomes impossible to achieve primary implant stability or ideal prosthetically guided positioning. For this reason, numerous bone augmentation procedures have been developed to reconstruct atrophic ridges and allow for successful implant rehabilitation.

The main goal of bone augmentation is to increase the height and/or width of the alveolar ridge to permit stable implant placement in positions that are both functionally and aesthetically appropriate. These augmentation procedures vary in their biological principles, surgical complexity, and clinical indications, but they all aim to restore the anatomy of the jaw to a condition compatible with modern implant therapy.

Among the most widely adopted techniques is Guided Bone Regeneration (GBR), a method that relies on the placement of a bone graft material in the area of the defect and the simultaneous application of a barrier membrane that prevents the migration of epithelial and connective tissue cells into the regenerative space [21,22]. This allows osteogenic and osteoconductive processes to take place undisturbed. GBR can be used for horizontal and vertical augmentation and may be performed simultaneously with implant placement in cases where primary stability is achievable. The membranes used can be either resorbable, such as collagen-based materials, or non-resorbable, such as titanium-reinforced PTFE membranes [23]. The choice depends on the defect's size and shape as well as on the operator's preferences and experience. In all augmentation procedures, the selection of the grafting material is a fundamental step that greatly influences the outcome. The available graft materials can be classified as follows:

- Autografts: Harvested from the same individual, either intraorally (mandibular symphysis, ramus) or extraorally (iliac crest, calvarium). Autogenous bone is osteogenic, osteoinductive, and osteoconductive, and is still considered the "gold standard". However, donor site morbidity and limited availability are major drawback [24].
- Allografts: Derived from human donors (typically cadaveric bone), processed to ensure biocompatibility and sterilization. Allografts are primarily osteoconductive and sometimes osteoinductive depending on preparation (e.g., demineralized freeze-dried bone) [25].
- Xenografts: Bone derived from another species, typically bovine or porcine origin. These grafts provide a stable, slow-resorbing scaffold for bone formation and are widely used in GBR and sinus lifting procedures [26].
- Alloplasts: Fully synthetic materials such as β-tricalcium phosphate (β-TCP), hydroxyapatite (HA), or bioactive glass. These materials are osteoconductive and often used in combination with other grafts to enhance handling and volume stability [27].

Another frequently encountered anatomical limitation concerns the posterior maxilla, where sinus pneumatization and vertical bone resorption reduce the available bone height. In such situations, sinus floor elevation, or sinus lifting, becomes necessary [28]. The procedure can be carried out using a lateral window approach, in which a bony window is opened on the lateral wall of the maxillary sinus and the Schneiderian membrane is carefully elevated. Graft material is then placed into the created submembranous space, and implants may be inserted simultaneously or in a staged manner, depending on the amount of residual bone [29,30]. Alternatively, the transcrestal or osteotome technique allows a less invasive membrane elevation through the implant osteotomy, suitable when residual bone height exceeds 5-6 mm [31]. The choice between these two methods is based on the preoperative radiological assessment of the sinus anatomy and bone volume [32] .

In cases of severe horizontal or vertical deficiencies, onlay bone grafting represents an effective method. This involves the placement of block grafts harvested from the patient's intraoral or extraoral sites onto the deficient ridge. These grafts are then stabilized with osteosynthesis screws, and after a healing period of 4 to 6 months, the implants can be placed [33]. A variation of this technique is inlay grafting, also known as the sandwich technique, where a horizontal osteotomy is performed, and a block of bone is interposed between the basal and superior segments to gain vertical height [34,35].

Another advanced technique used for vertical ridge augmentation is distraction osteogenesis. This method involves a controlled osteotomy followed by the gradual separation of the bone segments using a mechanical distraction device. The resulting gap is progressively filled by newly formed bone as the device is activated over several weeks. This technique is advantageous in that it avoids the use of grafting materials and has been shown to result in stable vertical bone gain [36].

Despite the numerous advantages and clinical successes of bone augmentation techniques, it is important to acknowledge their inherent limitations and potential complications. While these procedures have enabled clinicians to treat previously inoperable cases by restoring bone volume sufficient for implant placement, they also represent an additional surgical phase in the treatment

timeline [37]. This inherently prolongs the rehabilitation process and increases both the biological and financial burden on the patient.

Complications associated with bone grafting procedures may include postoperative infection, wound dehiscence, graft exposure or resorption, donor site morbidity (particularly in autogenous bone harvesting), sinus membrane perforation in sinus lifting procedures, and soft tissue deficiencies leading to graft failure. The success of augmentation depends heavily on patient compliance, surgical skill, and the control of systemic and local risk factors, such as smoking, diabetes, or poor oral hygiene. The resorption rates of grafted materials vary considerably, especially with xenografts and synthetic materials, potentially compromising the volume gained over time [38,39].

In procedures involving large vertical augmentations or complex ridge defects, the predictability of bone volume gain and long-term graft stability may be compromised. Non-resorbable membranes, while offering excellent space maintenance, carry a higher risk of exposure and subsequent contamination, often leading to partial or total graft loss [40]. In sinus floor elevation, membrane perforation remains the most common intraoperative complication, occurring in up to 20 - 30% of lateral window approaches, and may reduce the effectiveness of graft integration if not properly managed [41] .

It must also be stressed that, as a staged surgical approach, bone augmentation inevitably delays the placement of implants by several months in most cases. Even when simultaneous implant placement is feasible, healing periods may still be extended compared to standard implant protocols. In some situations, particularly in elderly patients or those seeking immediate function, this prolonged treatment time can significantly impact patient acceptance and satisfaction [17].

Thus, while bone augmentation procedures remain essential and effective in the management of atrophic ridges, they can have additional drawbacks. Their invasive nature, added surgical

complexity, increased treatment duration, potential morbidity, and cost must all be carefully considered during treatment planning [42].

3.3. ALTERNATIVES TO BONE AUGMENTATION PROCEDURES

Despite the significant advancements in bone augmentation techniques, these procedures are not always the most suitable approach for every clinical case. Bone grafting requires a high level of surgical skill, prolongs treatment time, increases patient morbidity, and is associated with the risk of complications such as graft resorption, infection, or implant failure. In response to these limitations, various graftless strategies have emerged as reliable alternatives for implant-supported rehabilitation, especially in cases of advanced maxillary or mandibular atrophy [42].

Among the most widely studied alternatives are zygomatic implants, which utilize the dense zygomatic bone for anchorage and allow implant placement in severely resorbed posterior maxillae without the need for sinus lifting or vertical bone grafts. These long implants, first introduced by Brånemark, are placed either through or lateral to the maxillary sinus and offer the possibility of immediate loading [43]. However, they require advanced surgical skills and carry risks such as soft tissue inflammation, oroantral communication, or sinusitis [44].

Another widely accepted solution is the use of tilted implants. By placing implants at an angle, clinicians can avoid anatomical obstacles like the maxillary sinus or the inferior alveolar nerve while increasing the anteroposterior spread of support. This concept underlies popular full-arch protocols such as the All-on-4 and All-on-6 approaches, which provide fixed prosthetic rehabilitation with fewer implants and no need for grafting [45]. Tilted implants allow for better load distribution and often enable immediate provisionalization, reducing the overall duration of treatment [46].

Pterygoid implants represent a more posteriorly anchored option in the maxilla. These implants extend through the maxillary tuberosity into the pterygoid process of the sphenoid bone, offering a graftless solution for support in the posterior maxilla [47]. Due to their location, pterygoid implants are

challenging to place and require precise knowledge of anatomy and implant angulation. Nevertheless, when executed correctly, they can significantly enhance the stability of full-arch prostheses and eliminate the need for sinus floor elevation [48,49].

Short implants-generally defined as implants ≤6 mm in length-have also become a well-documented alternative in the posterior maxilla or mandible where vertical bone height is insufficient [50]. Thanks to improvements in implant surface characteristics and prosthetic connections, short implants have shown survival rates comparable to standard-length implants. They provide a minimally invasive option that avoids both vertical augmentation and proximity to anatomical structures such as the maxillary sinus or the inferior alveolar canal [15,51].

Similarly, narrow diameter implants (< 3.5 mm in diameter) can be considered in cases with limited horizontal ridge width or reduced mesio-distal space, such as in the rehabilitation of narrow edentulous ridges or single anterior teeth [52]. Although they may pose higher mechanical risks under heavy occlusal loads, careful case selection and prosthetic planning can yield predictable outcomes without horizontal bone augmentation [53].

In addition to these well-established options, several other implant types have been explored in the literature as graftless solutions. Basal implants, also known as bicortical or cortical implants, are designed to engage the cortical portions of the bone, such as the basal bone of the mandible or maxilla, which tends to remain stable even after alveolar resorption [54]. These implants are typically placed using flapless or minimally invasive techniques and are often immediately loaded. Though somewhat controversial due to their unique biomechanics and lack of integration with traditional implant systems, basal implants have demonstrated acceptable survival rates in specific clinical contexts [55].

Transnasal implants, as well as implants placed in the nasal floor or the nasomaxillary buttress, have been proposed as alternatives in cases of extreme anterior maxillary atrophy. These extra-alveolar anchorage sites provide dense cortical support and can allow for graftless, full-arch rehabilitation.

However, due to their complexity and close proximity to delicate anatomical structures, these approaches are typically reserved for highly experienced surgeons and remain niche techniques with limited long-term data [56].

The contemporary field of implant dentistry offers a wide spectrum of graftless alternatives to bone augmentation. From anatomical anchorage techniques such as zygomatic, tilted, and pterygoid implants, to prosthetically driven solutions like short, narrow, and cortical implants, clinicians now have multiple options to tailor treatment based on the patient's anatomy, medical condition, and expectations.

3.4. TYPES OF OSSEOINTEGRATION

The fundamental concept of the implant dentistry is osseointegration. This biological phenomenon, first defined and explored by Professor Brånemark in the 1960s, describes the direct structural and functional connection between living bone and the surface of a load-bearing implant, without the interposition of soft tissue [57]. Osseointegration is the critical prerequisite for achieving implant stability and long-term clinical success, and it continues to shape the principles and techniques of surgical and prosthetic implant therapy [58].

Among the major classifications of dental implants, endosseous and subperiosteal systems represent two distinct approaches to engaging the available bone. Endosseous implants, which are inserted directly into the alveolar or basal bone, are the most widely used and extensively studied system in clinical practice today. They derive their support through direct bone anchorage and are designed to integrate biologically within the bone [57]. In contrast, subperiosteal implants rest on the bone surface beneath the periosteum and derive their stability through mechanical fixation, often through the use of screws [59].

The evolution of endosseous implants traces back to Brånemark’s pioneering work, which utilized commercially pure titanium in a threaded cylindrical design. The long-term success of these implants

was demonstrated in edentulous patients and revolutionized the field by establishing a biologically integrated solution for tooth replacement [57]. In the decades that followed, implant design evolved significantly to include variations in shape, taper, thread pattern, and surface characteristics, with the aim of optimizing bone contact and improving healing outcomes. Surface modifications such as sandblasting, acid-etching, and plasma-spraying have been developed to enhance osteoblast attachment and accelerate osseointegration [59-61].

From a biological standpoint, the integration of endosseous implants involves a multistage process that begins with blood clot formation around the implant and progresses to the recruitment of osteogenic cells, deposition of woven bone, and eventual remodeling into lamellar bone in intimate contact with the implant surface. This process ensures the transition from primary mechanical stability to secondary biological stability, and its predictability is the basis for the high success rates associated with endosseous implants.

Subperiosteal implants were originally introduced in the mid-20th century and were widely used until the 1980s [63,64.] These implants offer an alternative pathway for implant rehabilitation, particularly in cases where bone grafting is not feasible or has previously failed. Unlike endosseous implants, subperiosteal achieve mechanical stability through close adaptation to the underlying bone surface and fixation using screws [65].

The principle of osseointegration, whether achieved biologically through endosseous implants or mechanically through subperiosteal designs, remains central to implant dentistry. The choice between these two approaches should be guided by the individual patient's anatomical, systemic, and psychosocial factors. While endosseous implants continue to dominate clinical practice due to their extensive validation and biological integration, subperiosteal implants, revitalized by digital technologies, now offer a compelling alternative for complex cases previously considered untreatable[66].

3.5. EARLY INTRODUCTION OF SUBPERIOSTEAL IMPLANTS

The history of subperiosteal implants is deeply rooted in the early efforts of maxillofacial surgeons and prosthodontists to rehabilitate patients suffering from extreme bone atrophy in edentulous jaws. Before the advent of modern endosseous implants and regenerative techniques, clinicians faced significant limitations in treating severely resorbed alveolar ridges, particularly when conventional dentures offered poor stability. It was within this context that subperiosteal implants emerged as a radical alternative in the mid-20th century, designed to bypass the need for vertical bone height by utilizing the basal bone contours for support [67,68].

The earliest documented development of subperiosteal implants dates back to the 1940s. These early prototypes consisted of custom-cast metallic frameworks placed directly on the surface of the bone and stabilized beneath the periosteum [69]. The foundational concept was to anchor a rigid structure that would protrude through the mucosa and serve as a support for fixed or removable prostheses, without the need for osseointegration [70]. This approach was revolutionary in circumventing the anatomical limitations posed by severe resorption of the maxilla or mandible.

Subperiosteal implants, however, required a complex and invasive two-stage surgical process. The first procedure involved reflecting a full-thickness flap and taking a direct impression of the exposed bone using materials such as plaster, acrylic resin, or irreversible hydrocolloid. This step was often traumatic and prone to inaccuracies due to intraoperative bleeding, tissue distortion, and poor visibility [71,72]. The impression was then used to fabricate a custom metal framework in the laboratory, typically from cobalt-chromium-molybdenum (Co-Cr-Mo) alloy due to its high strength and corrosion resistance. After a healing period of several weeks, the patient underwent a second surgery in which the cast framework was placed over the bone, fixated manually, and allowed to protrude through the mucosa at predetermined abutment locations [72-74].

Several designs of subperiosteal implants were developed over the years, each aiming to improve fit, reduce complication rates, and enhance prosthetic performance. While some frameworks spanned the entire arch in a horseshoe configuration, others were sectional, covering only specific anatomical regions such as the symphysis in the mandible or the anterior maxillary ridge [76]. The fixation was generally achieved through mechanical adaptation to the bone surface and, in later designs, the addition of transosseous fixation screws. Nonetheless, the absence of intimate biological integration between the metal and bone tissues remained a critical limitation. The long-term stability of these devices depended largely on the precision of fit and the integrity of the overlying mucosa [77,78].

The incorporation of bioactive coatings, particularly calcium phosphate (CaP) and hydroxyapatite (HA), has become an increasingly valuable strategy in enhancing the performance of dental implants, including custom subperiosteal frameworks. These coatings are designed to promote a stronger and more stable osseointegration interface, especially critical for subperiosteal implants, which rest on the bone rather than being inserted into it.

Hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$), a naturally occurring mineral form of calcium apatite, is chemically similar to the inorganic component of bone. When used as a coating on titanium or titanium alloy frameworks, HA enhances cellular adhesion, osteoblast proliferation, and early bone apposition [79]. This is particularly relevant for subperiosteal implants where surface contact with the bone is essential for long-term mechanical stability and biological integration, despite the lack of intrabony anchorage [80].

Plasma-sprayed HA coatings or electrophoretic deposition methods have been employed to apply a uniform, porous, and osteoconductive layer on subperiosteal frameworks, aiming to reduce fibrous encapsulation and encourage the formation of bone at the bone-implant interface. These coatings also support angiogenesis and mineralization, both of which are critical for tissue regeneration under the implant [81].

Calcium phosphate coatings, a broader category that includes HA, tricalcium phosphate (TCP), and biphasic calcium phosphate (BCP), provide a resorbable or semi-resorbable interface that can release calcium and phosphate ions over time, stimulating local bone remodeling and integration. These coatings are particularly valuable in atrophic jaws, where the regenerative potential is often compromised, and early stability of the implant is critical [82].

In subperiosteal implant applications, the benefits of CaP/HA coatings include:

- Improved biocompatibility and cellular response at the bone surface;
- Reduced micromotion and enhanced mechanical interlocking due to surface roughness and porosity;
- Accelerated healing times, facilitating early or immediate prosthetic loading;
- Potential reduction in peri-implantitis risk, due to the promotion of a tight bone-implant interface [82].

From a materials perspective, the use of Co-Cr alloys dominated the early decades of subperiosteal implantology due to their availability and favorable mechanical properties. However, these materials posed several drawbacks, including increased rigidity, hypersensitivity reactions in some patients, and difficulties in achieving precise intraoral adjustments. The lack of flexibility and poor biocompatibility contributed to soft tissue irritation, chronic inflammation, and in many cases, partial or complete implant exposure. The frameworks were typically smooth-surfaced and highly polished to reduce bacterial colonization, but this also hindered any potential for soft tissue integration [75].

Clinical outcomes during the early era of subperiosteal implants were varied and often unpredictable. Complication rates were significant, with frequent reports of soft tissue dehiscence, peri-implantitis, infection, mobility of the framework, and eventual failure. These outcomes were especially problematic in the maxilla, where the thin, porous cortical bone and limited keratinized tissue made

retention more challenging [73]. Despite the innovative intent behind subperiosteal solutions, long-term survival was inconsistent, and many cases required removal after several years.

One of the greatest challenges in the early application of subperiosteal implants was the fabrication process itself. Errors in impression taking, delays between surgeries, and imprecision in metal casting often led to frameworks that did not fully conform to the bone, introducing micro-movement under functional load [83]. This, in turn, contributed to bone resorption beneath the implant, soft tissue breakdown, and bacterial invasion. The necessity of a second surgery not only increased patient morbidity but also elevated the risk of wound dehiscence and infection [84].

Despite these issues, subperiosteal implants remained in clinical use for several decades, especially in the United States and parts of Europe, as they represented one of the only fixed solutions for patients with advanced jaw atrophy. By the end of the 20th century, however, subperiosteal implants had virtually disappeared from mainstream practice, relegated to historical interest or salvage cases in patients unsuitable for any other treatment [85]. The lack of long-term clinical data, absence of randomized controlled trials, and high variability in technique further marginalized their role. Nonetheless, the fundamental idea behind subperiosteal support remained clinically sound: a customized framework, stabilized on basal bone, providing prosthetic support when conventional implants are not feasible [86].

In retrospect, the evolution of subperiosteal implants in their pre-digital era was a testament to surgical innovation constrained by the technological limitations of the time. The reliance on manual impression techniques, cast metalwork, and empirical design made the procedure heavily operator-dependent and prone to complications. It is only with the rise of digital imaging, virtual modeling, and precision manufacturing that subperiosteal implants have regained interest - now transformed into a new generation of reliable, customized, and clinically predictable devices [87]. However, to understand this modern renaissance, one must first fully grasp the foundations and shortcomings of their historical development.

3.6. INNOVATIONS IN DENTAL IMPLANTOLOGY

In recent decades, dental implantology has undergone a profound transformation driven by rapid technological progress. These advancements have redefined clinical planning, surgical execution, prosthetic precision, and long-term treatment outcomes. The traditional approaches to implant placement, which often relied heavily on tactile skills, two-dimensional radiographs, and manual fabrication processes, have gradually been replaced or enhanced by digital workflows, computer-guided surgery, biomaterial innovations, and patient-specific implant design [88]. These modern tools have enabled clinicians to approach complex cases with greater predictability and reduced morbidity, opening new possibilities in cases once considered untreatable using conventional methods.

Among the most significant innovations is the integration of three-dimensional imaging technologies, particularly cone beam computed tomography (CBCT). CBCT has become an essential diagnostic tool, allowing for detailed evaluation of alveolar bone anatomy, sinus morphology, nerve positioning, and pathological conditions, all of which are fundamental in planning safe and effective implant surgeries [89]. This imaging modality enables a virtual environment in which surgical plans can be executed with millimetric precision. With the aid of CBCT-derived data, virtual implant planning software allows for the positioning of implants in anatomically optimized locations, taking into account the prosthetic end goal from the earliest stages of treatment planning [90].

These digital plans are often translated into clinical practice through the use of computer-aided design and computer-aided manufacturing (CAD-CAM) protocols. CAD-CAM technology has revolutionized both the surgical and prosthetic phases of implant dentistry. In surgery, it enables the production of custom-made surgical guides that allow for fully guided implant placement according to the pre-defined virtual plan. This has resulted in significantly enhanced accuracy, shorter surgical times, and reduced postoperative discomfort, especially in complex anatomical regions or when placing multiple implants.

In prosthetic rehabilitation, CAD-CAM systems support the fabrication of highly precise frameworks and prosthetic components, tailored to the individual anatomy of the patient. Materials such as titanium, cobalt-chrome, zirconia, and PEEK (polyether ether ketone) can now be milled with submicron accuracy, ensuring a passive fit and reducing the risk of mechanical complications over time. The emergence of monolithic materials and additive manufacturing (3D printing) further extends the possibilities for custom prosthesis fabrication and rapid prototyping. Titanium laser sintering is increasingly used in the production of custom frameworks and patient-specific implants, including modern subperiosteal solutions.

Digital intraoral scanning has further contributed to the shift toward fully digital workflows. This technology eliminates the need for traditional impression materials, enhances patient comfort, and provides high-resolution digital models for immediate use in virtual planning and prosthetic design [91]. The seamless integration between digital planning software, intraoral scanners, and CAD-CAM systems enables a truly synergistic workflow that supports faster delivery, improved communication among team members, and enhanced esthetic and functional results [92].

Another important development has been the evolution of biomaterials, particularly in surface modification of dental implants. Modern implants often feature surface topographies designed to accelerate osseointegration by promoting cellular adhesion and bone growth [93]. Techniques such as sandblasting, acid etching, and laser microtexturing have been widely adopted, and newer approaches involving bioactive coatings-such as calcium phosphate or nanostructured surfaces-continue to be explored for their potential to shorten healing times and improve outcomes, especially in compromised bone situations [94].

Digital surgical planning is also increasingly paired with dynamic navigation systems and robotic assistance, offering real-time feedback and enhanced control during implant placement. While these technologies are still gaining widespread adoption, they represent the future of precision-guided surgery and highlight the field’s trajectory toward minimally invasive and ultra-precise procedures.

A particularly important addition to the modern technological toolkit in implantology is Finite Element Analysis (FEA) [95]. This engineering-based method allows for the simulation and analysis of biomechanical behavior under various conditions. In dental research and clinical planning, FEA enables detailed evaluation of stress distribution in the bone, implants, and prosthetic components under functional loads. For subperiosteal implants in particular, FEA plays a critical role in optimizing the structural design of the metal framework, the number and location of fixation screws, and the anticipated load transfer across the supporting bone surface [96]. By identifying high-stress zones, engineers and clinicians can iteratively modify implant geometry to reduce the risk of micromovements, screw loosening, or bone resorption over time [97].

The implementation of FEA in preclinical phases significantly increases the safety and efficacy of implant-supported rehabilitation, particularly when patient-specific implants are being manufactured. The predictive power of FEA becomes even more crucial in cases of severe atrophy, where the remaining bone volume is insufficient and optimal stress dispersion is paramount to long-term stability. Modern subperiosteal implants benefit enormously from such analyses, as their performance is highly dependent on biomechanical harmony with the bone surface and soft tissue interface [98]. FEA has been instrumental in comparing subperiosteal solutions with alternative treatments, such as zygomatic or short implants, by quantifying differences in mechanical behavior, fatigue resistance, and structural resilience under occlusal loads [99].

Digital surgical planning is also increasingly paired with dynamic navigation systems and robotic assistance, offering real-time feedback and enhanced control during implant placement. While these technologies are still gaining widespread adoption, they represent the future of precision-guided surgery and highlight the field’s trajectory toward minimally invasive and ultra-precise procedures [100].

The synergy between these technological innovations has led to a redefinition of what is possible in implant-supported rehabilitation, particularly for patients with severe bone atrophy or anatomical

constraints. Where in the past such patients would face extended treatment protocols involving invasive bone augmentation and long healing times, contemporary tools now enable alternative, faster, and less invasive solutions. This is particularly relevant for the re-emergence of subperiosteal implants-now redesigned and reimagined through the lens of modern digital dentistry [101].

Whereas early subperiosteal implants were limited by manual fabrication processes and anatomical guesswork, today's systems leverage the full power of digital imaging, CAD-CAM design, and biocompatible materials[102]. These innovations allow for the production of custom-made subperiosteal frameworks that conform precisely to the patient's bone morphology and can be delivered with high predictability in terms of fit and function. The integration of immediate loading protocols, facilitated by the stability and precision of digitally manufactured frameworks, has further enhanced their appeal in full-arch rehabilitations [95].

This transformation-from hand-crafted metal frameworks to patient-specific, digitally designed subperiosteal systems-illustrates the profound impact of technological evolution in contemporary implantology. It is within this context that modern subperiosteal implants have regained clinical relevance, not as a fallback for failure, but as a proactive solution enabled by cutting-edge tools. The next chapter will focus specifically on these new-generation subperiosteal implants, outlining their technical components, manufacturing workflows, clinical indications, and potential for transforming the treatment of severely atrophic jaws [103,104].

3.7. INNOVATIONS IN SUBPERIOSTEAL IMPLANTS

In recent years, subperiosteal implants have undergone a substantial technological revival, emerging as a viable, predictable, and patient-centered solution for the rehabilitation of severely atrophic jaws. This renewed clinical relevance is largely due to the convergence of biomedical innovation, digital design methodologies, and a deeper understanding of biomechanics. While early subperiosteal implants were limited by manual fabrication, imprecise anatomical matching, and lack of predictive

modeling, modern systems benefit from computer-aided design (CAD), computer-aided manufacturing (CAM), finite element analysis (FEA), and biomaterial advances that have dramatically enhanced their performance and reliability [95,105].

The evolution of CAD/CAM technology has allowed for the design of highly individualized implant frameworks that precisely adapt to the contours of the residual bone. These frameworks are manufactured using additive techniques such as selective laser melting (SLM), which constructs the implant layer-by-layer using titanium powder [106]. This method ensures exceptional precision, reproducibility, and biomechanical robustness, thereby significantly reducing surgical complexity and enhancing postoperative outcomes. The result is a customized prosthetic foundation that conforms to the patient's unique anatomy and supports immediate or early loading in many cases [83].

Further, the integration of personalized medicine principles into dental implantology marks a paradigm shift in treatment planning. By incorporating individual anatomical data obtained through CBCT imaging and intraoral scanning, clinicians can now fabricate truly patient-specific implants, thereby reducing surgical trauma and enhancing fit and stability. This personalized approach extends to prosthetic planning as well, enabling seamless transitions from surgical to restorative phases within digital workflows [107].

Among the most critical innovations influencing the long-term success of subperiosteal implants is the application of Finite Element Analysis (FEA). FEA facilitates the simulation of functional loads and the identification of stress concentrations within both the implant and the supporting bone. Given the complex, asymmetrical geometry of atrophic jaws and the mechanical demands placed on full-arch prosthetics, FEA plays an essential role in optimizing design variables such as screw positioning, frame extension, and thickness [98]. This predictive modeling capability allows for biomechanical refinements before surgical placement, minimizing the risk of micromovements, stress shielding, or cortical bone overload that could otherwise compromise osseointegration or lead to early failure.

Additionally, dynamic loading simulations-accounting for realistic chewing forces and time-varying mechanical impacts-reveal that stress magnitudes may increase by 30-60% compared to static or quasi-static analyses. Therefore, ensuring optimal stress distribution becomes essential, especially in patients with limited bone availability. Although clinical studies involving large patient cohorts are still needed for definitive design protocols, in silico modeling enables early-stage evaluations that inform both clinical practice and future research [108].

One persistent challenge has been the lack of standardized design protocols for subperiosteal implants. Currently, parameters such as screw number, placement, wing design, and structural geometry vary widely among systems and manufacturers. This variability can significantly affect outcomes, particularly under dynamic loading conditions, where unbalanced forces can result in mechanical fatigue, screw loosening, or even structural failure. In this context, FEA emerges not only as a design tool but also as a validation mechanism to iteratively test and optimize different configurations [109].

Modern implant surfaces have also benefited from advanced material science. Titanium subperiosteal frameworks are now frequently treated with calcium phosphate (CaP) or hydroxyapatite (HA) coatings to enhance biocompatibility and promote faster osseointegration. These bioactive surfaces support early bone apposition and increase the likelihood of long-term implant stability. Studies suggest that HA coatings, in particular, facilitate stronger bone-implant bonding, even in cases of low bone density or compromised healing capacity [110].

The combined application of these innovations-personalized CAD/CAM frameworks, additive manufacturing, advanced coatings, and FEA-driven optimization-has radically changed the role of subperiosteal implants. No longer considered a last-resort alternative, they now represent a front-line solution for patients with advanced maxillary or mandibular atrophy, who may not be ideal candidates for zygomatic or extensive grafting procedures. These developments not only expand treatment

options but also align with broader trends in digital dentistry, where precision, minimally invasive strategies, and patient-specific care take precedence [111].

In sum, the resurgence of subperiosteal implants in modern implantology is a direct consequence of technological evolution and interdisciplinary integration. These systems exemplify how contemporary tools can revitalize older concepts, transforming them into state-of-the-art solutions with compelling clinical outcomes. As ongoing studies refine design standards and validate long-term success, subperiosteal implants are poised to become an indispensable component of the implant surgeon's toolkit for the rehabilitation of complex cases.

3.8. LITERATURE REVIEW

This comprehensive literature review on subperiosteal implants aimed to synthesize existing knowledge regarding their clinical applications, outcomes, and recent innovations in digital planning, CAD/CAM design, and manufacturing. By critically analyzing the available evidence and identifying gaps in the literature, this review provided a solid scientific foundation for the development of the present research project. It allowed us to better define the study objectives, refine the methodology, and highlight the significance and clinical relevance of evaluating modern subperiosteal implants as a predictable and safe alternative for the rehabilitation of patients with severe jaw atrophy.

Literature Review

The systematic literature review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure methodological transparency and reproducibility. The review protocol was carefully designed to minimize selection bias and to provide a thorough and unbiased evaluation of the available scientific evidence on subperiosteal implants.

Inclusion Criteria

The following criteria were applied for study selection:

- Human clinical investigations, including randomized and non-randomized clinical trials, cohort and case-control studies, case series, case reports, review papers, letters, editorials, expert opinions, and systematic reviews.
- Studies reporting on survival rates, osseointegration, biological or mechanical complications related to subperiosteal implants.
- Studies comparing subperiosteal implants with conventional endosseous implants or alternative rehabilitative approaches.
- No time restrictions were applied, allowing the inclusion of both historical and contemporary studies to capture the full evolution of subperiosteal implant design, fabrication, and clinical outcomes.

Exclusion Criteria

Studies were excluded if they met any of the following conditions:

- Animal or purely in vitro studies without direct clinical relevance.
- Reports focusing exclusively on technical or laboratory aspects without corresponding clinical data or outcome measures.

Search Strategies and Information Sources

A comprehensive literature search was carried out across two major electronic databases: PubMed and Scopus. The strategy combined both controlled vocabulary (MeSH terms) and free-text keywords to ensure a sensitive and inclusive search. The Boolean search string applied was as follows:

((“subperiosteal implants” OR “subperiosteal dental implants” OR “bone-implant interface” OR “custom implants” OR “periosteal implants”) AND (“implant survival” OR “implant failure” OR “long-term success” OR “complications” OR “implant durability” OR “implant prognosis” OR “prosthetic failure” OR “implant failure prognosis”)) AND “humans”. In addition, manual screening

of the reference lists from all included papers was performed to identify any additional relevant studies not captured by the electronic search.

Article Selection

The selection of studies followed a multi-stage screening process:

1. Primary Search Results:

   Screened of all records was performed, retrieved from PubMed (n = 264) and Scopus (n = 452).

2. Duplicate Removal:

   Duplicate records were identified and eliminated using Rayyan software (Rayyan Systems Inc.), resulting in the removal of 476 duplicate entries.

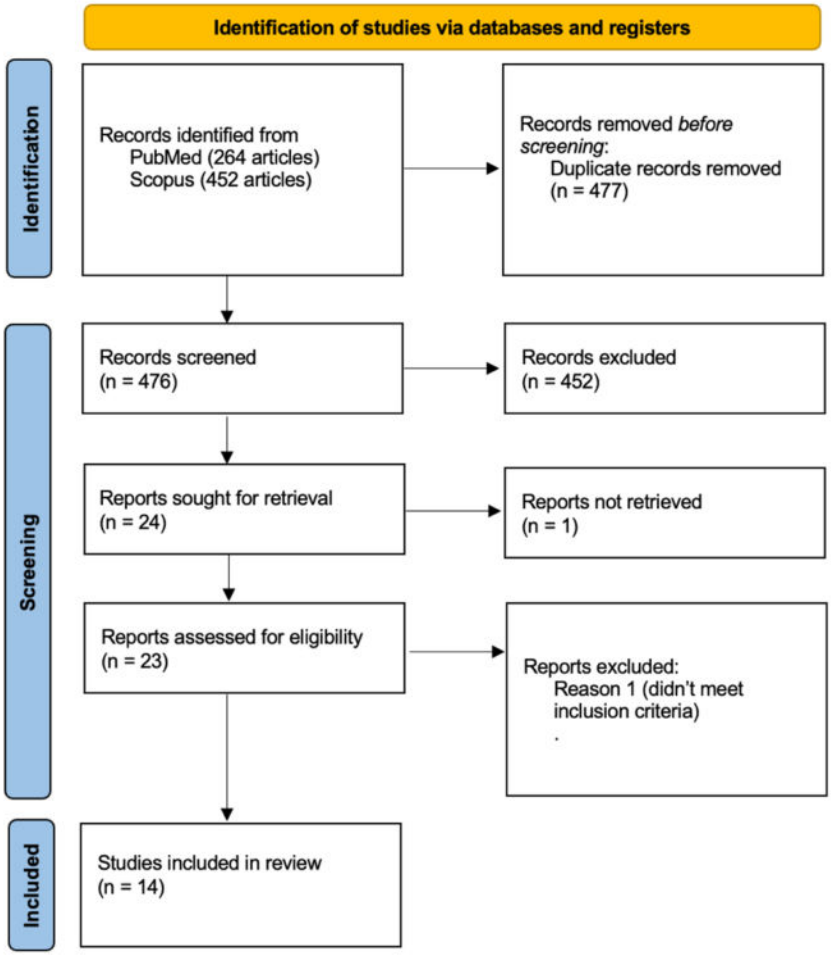
3. Title and Abstract Screening:

   Titles and abstracts were independently assessed for relevance using Rayyan. Studies were classified as *include*, *exclude*, or *uncertain*. A second reviewer (C.B.) served as an arbitrator to resolve any disagreements and to review the articles categorized as *uncertain*. Following this step, 23 studies were deemed eligible for full-text review.

4. Full-Text Evaluation:

   The full-text versions of the selected articles were assessed to confirm eligibility and methodological quality. Studies lacking sufficient clinical data, or failing to report key outcomes such as implant survival, complication rates, or follow-up duration, were excluded.

Ultimately, 14 studies met the inclusion criteria and were selected for data extraction and qualitative synthesis (Flowchart 1) [105,112–124].



Flowchart 1. The flowchart visually represents the systematic selection process for studies included in the review, detailing identification, screening, eligibility, and final inclusion criteria. Fourteen studies met all requirements and were included in the final review.

Data Extraction Process

The data extraction was carried out in a systematic manner to maintain consistency and reliability throughout the review. All relevant details from the included studies were organized into a structured Excel spreadsheet to facilitate comparative analysis. The following parameters were retrieved from each publication:

- Study Characteristics: Authors, publication year, study title, journal, and DOI or web link to guarantee proper identification and referencing of each source.

- Study Design and Population: Research design, number of participants, and geographic location/country to evaluate methodological rigor and external validity.
- Follow-up and Patient Profile: Duration of follow-up, demographic information, treated jaw (maxilla, mandible, or both), and bone status to interpret results across different clinical settings.
- Implant Details: Type of implant material and fixation approach to allow comparison among various design and placement strategies.
- Outcome Measures: Reported survival rates and definitions of success employed in each study to assess clinical effectiveness and implant longevity.
- Complications and Prosthetic Aspects: Recorded complications, type of prosthesis, and levels of patient satisfaction to evaluate functional and subjective treatment outcomes.
- Main Results and Study Limitations: Core findings, clinical relevance, and limitations identified by the authors to appropriately interpret the data.

All extracted data were organized and examined to detect overall trends, recurring patterns, and possible associations between study variables. Quantitative indicators, including survival and complication rates, were summarized descriptively (Table 1).

Author(s), Year	**Study Design**	**Sample**	**Average Age**	**Population**	**Systemic Conditions**	**Follow-up**	**Implant Type/ Implant Brand**	**Survival**	**Success Criteria**	**Complications**
Cerea & Dolcini, 2018	Retrospective	70	**67.8**	Elderly with jaw atrophy	Excluded smokers and bruxists	2 years	Custom-made DMLS titanium; surface not specified; (Eagle-Grid, BTK, Dueville, Vicenza); polished surface	95.8 %	Implant and restoration function	5.7% postop symptoms; 1.4% infection; 8.9% prosthetic issues
Mangano et al., 2020	Case Series	10	**69.6**	Elderly, mandibular atrophy	N/R	1 year	Custom 3D-printed titanium (DMLS); (Iuxta3D ®, BTK, Dueville, Vicenza, Italy); porous surface	100%	Stable fit, no infection	10% discomfort; 20% provisional fractures

Strappa et al., 2022	Case Report	1	**67**	67 y/o female, maxillary atrophy	None	2 years	DMLS titanium alloy; (Eagle-Grid, Eagle-Grid S.r.l.)	100%	No complications	None
Nemtoi et al., 2022	Pilot Study	16	**N/R**	Severe resorption	2 diabetes; 1 cardiovascular case	Several months	DMLS titanium (CBCT-designed); (3D Medica SABETTIMED® and Bone Easy®; polished and rough surface	93.75 %	Stability, integration	1 failure due to infection
Marconcini et al., 2023	Case Report	1	**72**	Elderly, osteoporosis	Osteoporosis	1 year	3D-printed titanium; (3Dfast srl, Padova (Italy); porous surface	100%	Implant stability	None
Onică et al., 2023	Retrospective	36	**59.7**	Edentulous, severe atrophy	NR	6 years	CAD/CAM titanium; (Sisma S.p.A., Piovene Rocchette, Italy)	~25%	Long-term function without complications	Early exposure, mobility in 27/36 cases
Ayhan et al., 2024	Case Report	1	**18**	18 y/o, ectodermal dysplasia	Ectodermal dysplasia	N/A	Custom DMLS titanium; polished and rough surface	N/A	Oral function restoration	None reported
Gellrich et al., 2024	Case Series	4	**N/R**	Severe bone loss	Not specified	Up to 68 mo	Patient-specific titanium framework; IPS Implants. Preprosthetic (KLS Martin Group, Tuttlingen, Germany); polished surface	100%	Stability maintained	None
Ayhan et al., 2024	Retrospective	31	**N/R**	Severe bone loss	NR	15 months	3D-printed titanium; NR	86.7 %	Function, adaptation	Fit issues (23); soft tissue (12); infections (5)
Vaira et al., 2024	Retrospective	17	**61.5**	Posterior mandible atrophy	N/R	7–53 mo	DMLS double-laser titanium; (B&B Dental, San Pietro in Casale, Italy); porous surface	100%	Stable implants	Hypoesthesia (transient); edema
Anitua et al., 2024	Systematic Review	227	**N/R**	Bone atrophy	Included diabetes, cardiovascular,	21.4 mo	Various, mainly titanium; N/A	97.8 %	Functionality maintained	25.6% exposure; 7.5% postop issues

					smoking					
El-Sawy & Hegazy, 2024	Systematic Review	302	**N/R**	Atrophic jaws incl. med. compromised	Included diabetes, hypertension, cancer	17.2 mo	Titanium/PEEK blends in some studies; N/A	95.3 %	Functional with minor issues	11.5% bio issues; 5.9% prosthetic problems
Zielinski et al., 2025	Comparative Study	150	**N/R**	Maxillary atrophy	Included smokers and immunocompromised	≥5 years	CAD titanium; roughened surface in select designs; Mai Implant® (Integra Implants®, Lodz, Poland)	97.1 %	Clinical and prosthetic stability	5.6% peri-implantitis
Santiago et al., 2025	Case Series	3	**62.3**	Maxillary atrophy	N/R	6 months	Custom-designed titanium; NR§	High	Stability, patient satisfaction	None observed

Analysis

The analysis of fourteen studies examining the application of subperiosteal implants in patients with advanced jawbone atrophy demonstrates a combination of favorable clinical outcomes and notable complications, both of which are crucial for evaluating the reliability of this treatment approach. The reviewed studies encompass diverse methodologies, sample sizes, and follow-up durations, providing a comprehensive overview of the efficacy and challenges associated with subperiosteal implant therapy. Most of the examined populations consisted of elderly patients, generally above 60 years of age, reflecting the progressive nature of alveolar bone resorption. This trend aligns with the observations of Anitua et al. and El-Sawy et al., who primarily used subperiosteal implants in older adults unsuitable for conventional implant placement due to severe anatomical limitations [121,122]. Nevertheless, certain investigations, such as that by Ayhan et al. (2024), included younger patients affected by congenital or syndromic disorders, including ectodermal dysplasia, thereby demonstrating the versatility of subperiosteal implants in managing both developmental and age-related bone deficiencies a[121]. Similarly, Cerea et al. (2019) expanded the indications by treating individuals with previous implant failures, supporting the use of subperiosteal implants as a rescue solution for highly compromised cases [112].

Follow-up periods across studies varied considerably, ranging from 6 months to 6 years. Extended follow-ups, as reported by Zielinski et al. (2025) and Onică et al. (2024), revealed a higher occurrence of late complications, suggesting potential difficulties in long-term maintenance [116,123]. Conversely, Anitua et al. documented stable results over a 17-month period without any implant loss, and El-Sawy et al. noted comparable success within an average follow-up of 18 months [121,122]. Cerea et al. observed a limited number of soft tissue issues after up to 36 months of observation, reinforcing the importance of prolonged monitoring to fully assess long-term reliability [112]. Collectively, these findings indicate that although short- and mid-term results are encouraging, long-term data remain essential for definitive conclusions.

Reported complications ranged from mild and transient to more serious events affecting treatment success. Early postoperative symptoms - such as discomfort, swelling, and inflammation - were common but generally well controlled, consistent with the experiences described by Anitua and El-Sawy [122]. More severe complications, including infection and implant failure, were less frequent but clinically significant. Ayhan et al. (2024) recorded a 13.3% failure rate predominantly due to infection, and Nemtoi et al. (2022) also identified infection as a principal cause of implant loss [114,118]. Cerea et al. (2019) reported a single implant failure in a smoker, highlighting the influence of patient-related risk factors on clinical outcomes [112]. Collectively, these observations emphasize that success depends strongly on surgical expertise, systemic health, and appropriate postoperative management.

Prosthetic complications - such as misfit or fracture of provisional restorations - were mentioned in several studies. The adoption of fully digital workflows, as described by Anitua, El-Sawy, and Ayhan, was associated with a reduction in prosthetic issues [118,121,122]. These digital processes facilitate precise implant design and accurate anatomical adaptation, leading to improved function and patient satisfaction. Nonetheless, Cerea et al. noted occasional prosthetic complications in early designs, indicating that digital technology, though advantageous, is not without limitations [112].

Among all reported complications, implant exposure was the most frequent. Its exact influence on long-term implant survival and its potential association with peri-implant mucositis remain uncertain. Infection continues to be the most concerning adverse event due to its direct effect on implant loss. Studies by Nemtoi et al. (2022), Ayhan et al. (2024), and Marconcini et al. (2023) all identified infection as the primary cause of early implant failure [114,118,124]. These variable outcomes underscore the importance of refined surgical protocols and the potential value of minimally invasive techniques in minimizing infection risk.

3.9. RESEARCH GAPS

Most studies observed in the previous chapter patients for less than three years, making it difficult to determine the true longevity and maintenance requirements of these implants. Additionally, the majority of research has focused on elderly individuals with age-related bone atrophy, while data on younger populations affected by congenital or syndromic bone deficiencies remain scarce. Expanding the demographic and etiological scope of future studies could clarify how systemic and developmental conditions influence treatment outcomes.

Another critical limitation lies in the lack of standardization across existing research. Considerable variability in study design, surgical techniques, and manufacturing methods hinders direct comparison and synthesis of findings. Establishing unified clinical protocols and consistent reporting criteria would allow for more reliable cross-study evaluation and evidence-based recommendations. Furthermore, although infection and implant exposure were identified as the most frequent complications, their underlying causes - particularly the interplay between implant design, peri-implant soft tissue health, and microbial colonization - are still poorly understood. Targeted studies examining these biological and mechanical factors are essential for improving complication prevention strategies.

Finally, while the adoption of digital workflows has shown potential in reducing prosthetic misfits and improving patient satisfaction, the long-term benefits and limitations of these technologies have yet to be conclusively demonstrated. Comparative clinical trials assessing digital versus conventional fabrication and placement methods are necessary to validate their accuracy, cost-effectiveness, and clinical superiority. Overall, future research should aim to provide standardized, long-term, and biologically grounded evidence to optimize the use of subperiosteal implants in complex atrophic cases.

4. SIGNIFICANCE OF THE STUDY AND CLINICAL RELEVANCE

A critical gap identified through an extensive review of the current scientific literature is the lack of comparative clinical studies evaluating the outcomes of subperiosteal, and conventional endosseous implants in the treatment of severely atrophic jaws. Despite the increasing use of these diverse implant modalities in complex cases, no randomized controlled multicenter trials have been conducted to directly compare their efficacy, safety, and long-term success rates within a unified clinical framework.

The present study seeks to fill this gap by designing and implementing a multicenter randomized controlled clinical trial with a particular emphasis on implant/prosthetic failure, complications and patients' satisfaction. Given that implant failure-whether biological or mechanical-remains one of the most critical indicators of long-term treatment success, this research will offer essential data to inform clinical decision-making, especially in anatomically compromised patients who are not candidates for conventional implant protocols without extensive bone grafting procedures.

By comparing two fundamentally different implant approaches-endosseous implants, including zygomatic implants (which anchor in the zygomatic bone) and traditional implants (placed within the alveolar bone), versus custom-made subperiosteal implants (which rest over the bone beneath the periosteum) - this study will provide valuable insights into their respective indications, biomechanical behavior, complication profiles, and overall clinical performance.

The outcomes of this research are expected to:

- Guide clinicians in choosing the most appropriate implant strategy for patients with severe jaw atrophy;

- Contribute to evidence-based treatment planning, particularly for high-risk and medically complex patients;
- Support the integration of emerging technologies, such as digital planning and CAD/CAM fabrication, into routine clinical practice for subperiosteal implants;
- Improve patients' quality of life by identifying protocols that minimize surgical morbidity, maximize prosthetic function, and reduce long-term complications.

Through its innovative design and comprehensive comparative analysis, this study has the potential to significantly advance the field of dental implantology and redefine therapeutic options for a historically difficult-to-treat patient population.

5. AIM OF THE STUDY

PRIMARY AIM

The primary objective of this study is to assess and compare the intraoperative and postoperative complications that may arise at the time of implant placement or during the post-placement period. These include both biological and mechanical complications related to the surgical procedure and the prosthetic components. Complications will be thoroughly documented throughout the study period to determine the safety and predictability of each approach.

Specifically, the following events will be considered within the scope of the primary outcome:

- **Intraoperative complications** such as surgical difficulty, anatomical injury (e.g., nerve damage), and excessive bleeding.
- **Postoperative complications** including soft tissue inflammation, surgical site infections, early exposure of the implant or framework, screw loosening, peri-implantitis, or prosthetic failure.

By focusing on these events, the study aims to determine whether modern subperiosteal implants-developed through digital planning and CAD/CAM fabrication-can provide a viable and safer alternative to traditional solutions in extreme anatomical conditions.

SECONDARY AIMS

In addition to the primary outcome, the study includes several secondary objectives to offer a comprehensive evaluation of treatment performance:

1. *Implant Failures*

   Assessment of implant survival over the follow-up period, including loss of osseointegration, mechanical failure, or removal due to complications.

2. *Prosthetic Failures*

   Evaluation of prosthetic complications such as fracture of the prosthesis, prosthetic screw loosening, or loss of passive fit, leading to the need for repair or replacement.

3. *Patient Satisfaction*

   Measurement of overall patient satisfaction through validated questionnaires assessing comfort, aesthetics, function, and quality of life. This dimension is critical in evaluating the real-world success of advanced implant treatments, especially when involving high-risk or medically compromised patients.

6. MATERIALS AND METHODS

6.1. Primary and Secondary Outcomes of the Study

Primary Outcome

The principal aim of this clinical trial is to assess and compare the long-term clinical outcomes of immediate-load fixed prostheses supported by subperiosteal implants versus traditional implant solutions for the rehabilitation of severely atrophic maxillae. In particular, the primary outcome centers on the evaluation of intraoperative and postoperative complications that may occur either during the implant placement procedure or in the subsequent postoperative period.

Any pathological event-such as neurological injury, exposure or infection of the medical device, inflammation, fracture or loosening of prosthetic screws, or fracture of the prosthesis itself-will be considered as part of this outcome. All biological or prosthetic complications encountered during the course of treatment will be thoroughly documented. This includes photographic and radiographic records, which will be systematically reported in the "Complications, Protocol Deviations, and Drop-outs Case Report Form (CRF)."

Furthermore, Cone Beam Computed Tomography (CBCT) will be performed at one and three years following prosthetic loading to detect potential complications. These include the presence of subclinical maxillary sinusitis in cases of zygomatic implants or pathological bone resorption due to excessive load in the case of subperiosteal implants.

Secondary Outcomes

The study also investigates a series of secondary objectives, which include implant failure, prosthetic failure, and overall patient satisfaction following treatment. Each of these outcomes is described below:

1. Implant Failure

Implant failure defined as any mechanical or infectious complication requiring the removal of the implant. For zygomatic implants, stability will be clinically evaluated at the time of definitive prosthesis delivery and again at one and three years after prosthetic loading. This will be done by manually testing the implant after prosthesis removal, using a torque of 20 Ncm to tighten the abutment screw. Implants that rotate upon this test will be considered failures and removed accordingly.

Some degree of horizontal mobility in zygomatic implants may be tolerated due to their length and the lack of surrounding bone in the central and coronal regions. Such cases will not be classified as failures, provided the implants maintain functional integration.

For subperiosteal implants, particularly those with reduced length or diameter, implant stability will be assessed by manually attempting to move the prosthesis. The detachment or removal of a segment of the implant structure, or the repositioning of osteosynthesis screws, will not be considered a failure as long as the overall stability of the implant is preserved.

2. Prosthetic Failure

Prosthetic failure will be defined as the inability to deliver or maintain a functioning prosthesis. This may include failure due to implant loss, structural or technical complications in the prosthesis, or complete remake of the definitive prosthesis for any reason deemed clinically necessary.

3. Patient Satisfaction

To evaluate overall patient satisfaction, two validated questionnaires will be used: the Oral Health Impact Profile (OHIP-14) and a Visual Analogue Scale (VAS). These instruments will be administered during follow-up visits at prosthesis delivery and at one year of follow-up and each year of the follow-ups post-loading.

The OHIP-14 questionnaire includes 14 questions assessing functional limitations, discomfort, and self-perceived disability due to oral conditions. Patients will answer the following:

1. Have you had difficulty speaking due to problems with your teeth, mouth, or dentures?
2. Have you noticed a change in taste due to these problems?
3. Have you experienced persistent pain in the mouth?
4. Have you found it difficult to eat certain foods?
5. Have you felt that something was wrong with your mouth?
6. Have you felt tense because of oral problems?
7. Have your eating habits become unsatisfactory?
8. Have you had to interrupt meals due to dental issues?
9. Have you found it hard to relax because of mouth problems?
10. Have you experienced embarrassment?
11. Have you felt more irritable toward others?
12. Have you had difficulty carrying out routine activities?
13. Has your quality of life been reduced?
14. Have you felt completely disconnected from normal activities?

For each item, patients will respond using the following scale:

- 0 = Never
- 1 = Rarely
- 2 = Occasionally
- 3 = Often
- 4 = Very often

This scoring enables a weighted analysis across different categories of functional limitation, helping to determine which aspects of oral health most significantly impact the patient's quality of life. A higher total score indicates a worse impact on oral health-related quality of life.

Visual Analogue Scale (VAS)

Pain will be measured using a Visual Analogue Scale. This consists of a 10 cm calibrated line, either numerical or resembling a thermometer. One end of the scale represents “no pain,” while the opposite end signifies “the worst pain imaginable.” Patients will be asked to mark a point on the line that best reflects their pain level at that moment.

This method is easy to administer, repeatable over time, and intuitively understood by most patients. It allows for a straightforward and consistent assessment of perceived pain throughout the treatment course.

6.2. Study Design

This randomized controlled clinical trial has been developed in response to the current absence of high-quality comparative data evaluating the performance of different implantological strategies-namely zygomatic implants, subperiosteal implants, and conventional endosseous implants-in the rehabilitation of severely atrophic maxillae and mandibles. The study was developed in accordance with the CONSORT guidelines (Consolidated Standards of Reporting Trials) for randomized controlled trials, and it complies with the principles outlined in the Declaration of Helsinki for ethical research involving human subjects. The study protocol received approval from the CE-AVEC Institutional Review Board (IRB) 731-2021-DISP-AUSLBO.

6.2.1. Study Population and Group Allocation

A total of 22 patients were enrolled and randomized equally into two groups:

- **Control Group (n = 11):** Patients were treated using conventional implant techniques. This includes the placement of four zygomatic implants in the maxilla and short and/or narrow-diameter endosseous implants in the mandible, where applicable.
- **Test Group (n = 11):** Patients were treated with custom-made subperiosteal implants, designed using advanced digital workflows and placed in both the maxilla and mandible as needed.

All patients in both groups were rehabilitated with immediate fixed prostheses.

6.2.2. Study Type and Centers

This is a prospective, multicentre, randomized controlled superiority trial with a parallel two-arm design. It is classified as an interventional post-marketing clinical investigation involving medical devices, in full accordance with regulatory guidelines for post-market surveillance.

The study is multicentric, involving two academic surgical centers:

1. Oral Surgery Unit, Dental Clinic, University of Bologna
2. Oral Surgery Unit, University “Magna Graecia” of Catanzaro

The trial has received ethical approval from the competent ethics committee (731-2021-DISP-AUSLBO) and was commence following the acquisition of full regulatory authorization.

6.2.3. Study Timeline

- Start of patient recruitment: Immediately after IRB approval
- Prospective study phase: 1 year (recruitment and treatment)
- Overall study duration: 5 years
    - Including 3-year follow-up phase
    - Followed by data analysis and dissemination of results

6.2.4. Device and Material Provision

All medical devices used in this study-zygomatic implants, custom subperiosteal implants, and narrow-diameter endosseous implants-will be provided free of charge by the sponsor manufacturer (Biotec S.r.l.). Study-specific insurance coverage will be ensured through university research funds.

6.2.5. Eligibility Criteria

Inclusion Criteria:

- Age ≥ 18 years
- Signed informed consent
- Edentulous patients in the maxilla and/or mandible with severe alveolar atrophy, such that placement of at least four standard implants (≥3.5 mm diameter, ≥6 mm length) is not feasible without extensive bone augmentation, as verified by CBCT-based virtual planning

Exclusion Criteria:

- Systemic contraindications to oral surgery
- Head and neck irradiation >70 Gy
- Immunosuppression or immunocompromise
- Ongoing or prior IV bisphosphonate therapy
- Poor oral hygiene or lack of motivation
- Uncontrolled diabetes
- Pregnancy or lactation
- Drug or alcohol dependence
- Severe psychiatric conditions
- Absence of opposing dentition or prosthesis
- Maximal incisal opening <3.5 cm
- Presence of active infections or inflammation in implant sites

All eligible and non-eligible patients, as well as those who decline participation, will be documented along with the specific reason for exclusion or refusal.

6.3. Medical Devices and Their Application in the Study

The present randomized clinical trial incorporates a wide range of advanced medical devices and digital planning technologies in order to ensure precision, predictability, and clinical efficacy in the treatment of patients with severely atrophic jaws. The devices and materials used have been selected for their reliability, scientific support, and compliance with contemporary prosthetic and surgical protocols. All devices are supplied by Biotec S.r.l. (Povolaro di Dueville, Italy), a manufacturer with experience in producing custom and standard dental implants.

6.3.1. Planning Software

Two digital software systems are employed for preoperative planning:

- **RealGuide 5.0:** Utilized for planning surgeries involving zygomatic and traditional implants. This software enables virtual implant positioning based on DICOM files derived from cone-beam computed tomography (CBCT), allowing precise anatomical assessments and simulation of implant placement.
- **PlastyCAD 1.7:** Specifically used for the design and virtual customization of subperiosteal implants. It allows the generation of 3D implant models tailored to the patient's unique bone morphology, ensuring intimate contact with the underlying bone and accurate positioning of prosthetic abutments.

6.3.2. Zygomatic Implants

For patients in the control group undergoing maxillary rehabilitation, BT ZYGOMAX IR (BTK, Biotec SRL, Povolaro di Dueville, IT) implants will be used. These are titanium implants with an internal connection, available in the following lengths: 35, 37.5, 40, 42.5, 45, 47.5, 50, and 52.5 mm,

and with a standard diameter of 3.75 mm. Each patient will received four zygomatic implants (two per zygomatic bone). The implants will be immediately loaded with a provisional fixed prosthesis, provided an insertion torque of at least 40 Ncm is achieved, ensuring primary stability necessary for immediate function.

6.3.3. Custom Subperiosteal Implants

Patients in the test group will be treated with custom-made subperiosteal implants IUXTA-3D (BTK, Biotec SRL, Povolaro di Dueville, IT), produced using CAD-CAM and Selective Laser Melting (SLM) additive manufacturing technology. These titanium implants are designed based on patient-specific bone volumes obtained from CBCT scans, enabling exact adaptation to the anatomical contours of the atrophic jaw. Each subperiosteal implant consists of a single monolithic framework with 3 vertical prosthetic abutments (pillars) emerging through the mucosa. The implant surface undergoes complete mechanical polishing, reducing bacterial adhesion and improving soft tissue integration.

6.3.4. Short and Narrow-Diameter Implants

Where appropriate, Safe and Nano Implants (BTK, Biotec SRL, Povolaro di Dueville, IT) will be used to rehabilitate the mandible or anterior maxilla in control patients. These implants are internally connected and available in:

- Lengths: 10, 12, and 14 mm with 3.3 mm diameter
- Ultra-short options: 5 mm length with diameters of 4.2, 4.8, and 6 mm

A minimum of four implants per patient will be inserted following the same immediate loading protocol, conditional on achieving a minimum insertion torque of 35 Ncm.

6.3.5. Prosthetic Materials

Two types of prostheses will be used across both test and control groups:

- Immediate provisional prostheses: These will be screw-retained, fixed restorations fabricated from reinforced acrylic resin, delivered on the day of surgery to provide aesthetics, function, and psychological benefit during the initial healing phase.
- Definitive prostheses: After the healing and osseointegration phases, patients will receive CAD-CAM milled screw-retained prostheses made from titanium frameworks veneered with composite resin. This combination ensures excellent mechanical resistance, biocompatibility, and long-term clinical success.

6.4. Preoperative Assessment and Digital Planning

6.4.1. Initial Visit and Preoperative Radiographic Evaluation

All patients enrolled in the study undergo an initial comprehensive clinical assessment to determine eligibility based on the predefined inclusion and exclusion criteria. This evaluation includes a detailed anamnesis, oral examination, and review of the patient's medical history, habits, and overall health status. To ensure patient autonomy and adherence to ethical guidelines, each participant is given a minimum of one week to consider participation after receiving all relevant information about the study. Only after this reflection period is the informed consent obtained.A baseline satisfaction questionnaire is administered according to routine clinical practice, aiming to collect subjective data on the patient's initial expectations and quality-of-life parameters prior to treatment.

6.4.2. Randomization Process

Following consent and clinical eligibility confirmation, patients were randomized into one of the two study arms through the REDCap (Research Electronic Data Capture) platform, which ensures methodological rigor and minimizes allocation bias. Two randomization lists were generated-one for

each participating center-to assign patients either to the control group (zygomatic/traditional implants) or the test group (custom subperiosteal implants).

6.4.3. Virtual Planning and 3D Modeling

Preoperative planning relies heavily on digital tools to enhance precision and predictability. Each patient undergoes a cone-beam computed tomography (CBCT) scan, which provides high-resolution three-dimensional imaging of the maxillary or mandibular bone.

These DICOM files are uploaded into specialized software to guide surgical planning:

- RealGuide 5.0 Software: Used for patients in the control group, it allows precise positioning of zygomatic and traditional endosseous implants based on bone volume, quality, and prosthetic needs. Stereolithographic study models are fabricated to assist clinicians in visualizing anatomical constraints and optimizing implant positioning.
- Key Zygomatic Planning Principle: Special attention is paid to placing zygomatic implants crestally rather than palatally, which facilitates better prosthetic emergence profiles and reduces biomechanical complications.
- PlastyCAD Software 1.7 and CAD-CAM Design: For patients in the test group, the IUXTA-3D subperiosteal implants are virtually designed using CAD-CAM systems. The framework is customized to the patient's anatomy, ensuring intimate adaptation to the available basal bone and correct positioning of fixation screws. A prosthetic guide is used during planning to determine the emergence profile of the abutments and to pre-fabricate the immediate provisional prosthesis.

6.5. In vitro study of Subperiosteal Implants

The in vivo segment of this investigation aimed to assess the clinical efficacy and biomechanical performance of subperiosteal implants subjected to functional loading in patients with pronounced

jaw atrophy. Emphasis was placed on practical implementation, examining implant stability, tissue integration, and stress distribution over time. A representative case featuring a markedly resorbed mandible and maxilla was selected, exhibiting typical anatomical features while excluding the most extreme forms of bone loss. Radiographic data in Digital Imaging and Communications in Medicine (DICOM) format were processed to isolate the bone structures using RealGuide 5.2 software. Surface tessellation language (STL) files were generated for the skull segment beneath the orbital cavities (upper region) and the entire mandible (lower region).

The extracted surfaces and volumes underwent refinement to correct minor defects and streamline the geometry, utilizing Meshmixer 3.5. This software also facilitated the reconstruction of cancellous bone where present, as the delineation between cortical and trabecular bone is often indistinct in direct exports from radiographic imaging. Cortical bone thickness was measured across multiple regions, and the cancellous bone volume was derived by offsetting the previously segmented cortical surfaces.

Following conventional design protocols, the juxta-osseous implant was digitally modeled onto the processed STL files. An initial prosthetic framework was drafted to accurately position the abutments and define the loci of masticatory force application. Using Cyborg3D MeshToCAD for reverse engineering, parametric surfaces were reconstructed to enhance compatibility with current modeling software. The mandible, maxilla, and implant files were then converted into STEP format. Further refinements were made in SolidEdge 2022, where additional structural elements such as cortical fixation screws were incorporated. These screws were simplified in design to avoid excessive computational load and unnecessary geometric complexity, which could hinder the clarity and efficiency of the analysis. The subsequent phase of the study concentrated on establishing contact interactions between various components of the system, setting the foundation for biomechanical simulation.

Two distinct types of contact interactions were defined within the model:

- Glued contact: This configuration permanently fuses surfaces, preventing any relative movement or separation.
- Frictional contact: This setup permits sliding and detachment between surfaces, mimicking more realistic biomechanical behavior.

Specific interface zones within the geometric model were paired using connectors, each assigned one of the above contact types:

- Between the bone support and the juxta-osseous implant surfaces, frictional contact was used to replicate natural mechanical interaction.
- Between cortical and cancellous bone regions, glued contact was applied to reflect their physiological continuity.
- Between screw threads and bone surfaces, glued contact was selected to simplify modeling and simulate osseointegration.
- Between the screw underhead and the juxta implant seats, a contact property allowing limited displacement was introduced.
- Between the juxta abutments and the prosthetic structure, glued contact was used to ensure a rigid connection.

Initial simulation parameters were configured to eliminate gaps or penetrations, thereby correcting minor geometric inconsistencies. All materials were modeled as isotropic and linearly elastic, with average bone properties adopted to account for variability due to patient-specific factors such as age, physiology, and pathology.

Meshing was performed using tetrahedral elements tailored to the complexity of each anatomical and implant component. The mesh sizes were defined as follows:

- Cortical bone: 1.5 mm

- Implant support zones: 1 mm
- Cortical screw holes: 0.5 mm
- Cancellous bone: 1.5 mm (general), 1 mm (screw holes)
- Juxta-osseous implant: 0.7 mm (general), 0.5 mm (screw sites)
- Cortical screws: 0.5 mm
- Prosthetic structure: 1.5 mm

These dimensions were selected to ensure precise representation of critical geometries and regions of interest within the finite element analysis (FEA) framework. The term σmax allowable refers to the maximum stress a material can endure. For titanium, this corresponds to its yield strength, while for bone, the value is sourced from literature and represents a threshold below which bone resorption is unlikely.

Mechanical loads were introduced via node displacement across five distinct configurations. Each scenario was independently analyzed to observe how the structural system responded to different points of load application (Figures 4 and 5).

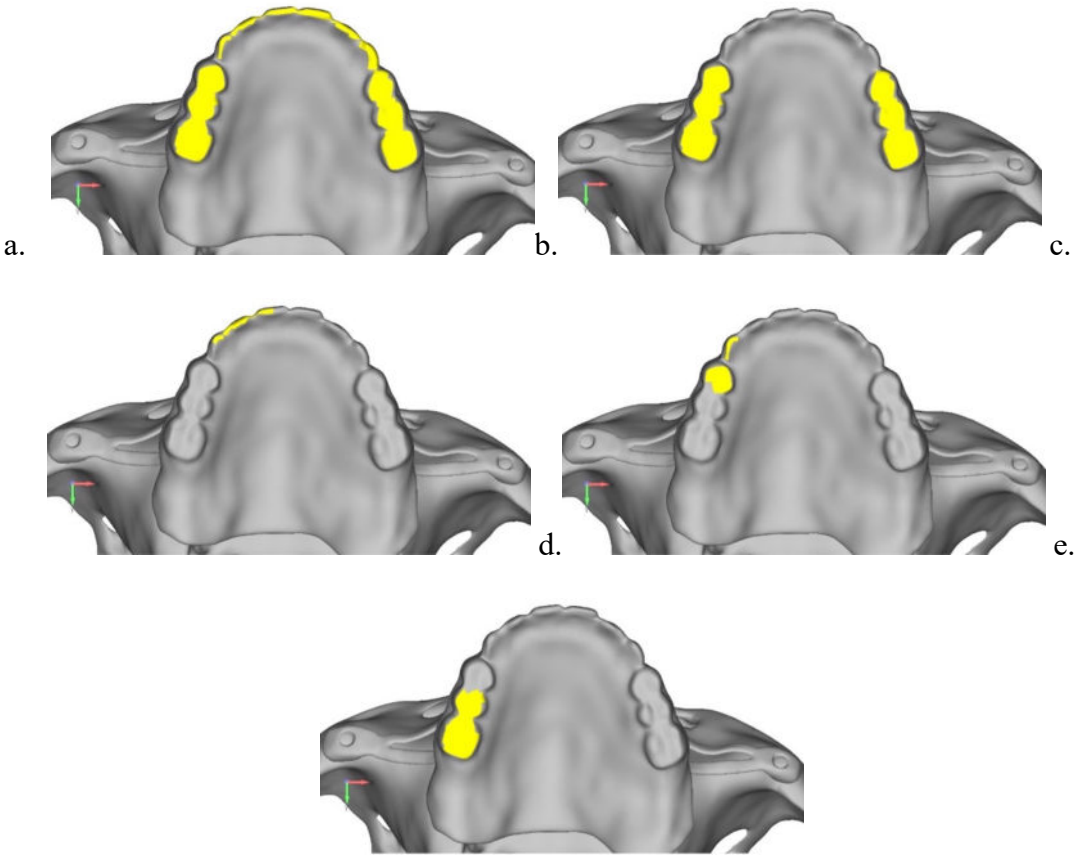


Figure 4. Different types of loads, indicated in yellow, were applied to the upper jaw. (a) Configuration 1: a uniform load is applied, distributed evenly across the entire jaw. (b) Configuration 2: a bilateral load is applied specifically in the molar region. (c) Configuration 3: an anterior unilateral load is applied to one side of the jaw. (d) Configuration 4: a unilateral load is applied in the premolar region. (e) Configuration 5: a unilateral load is applied in the molar region.

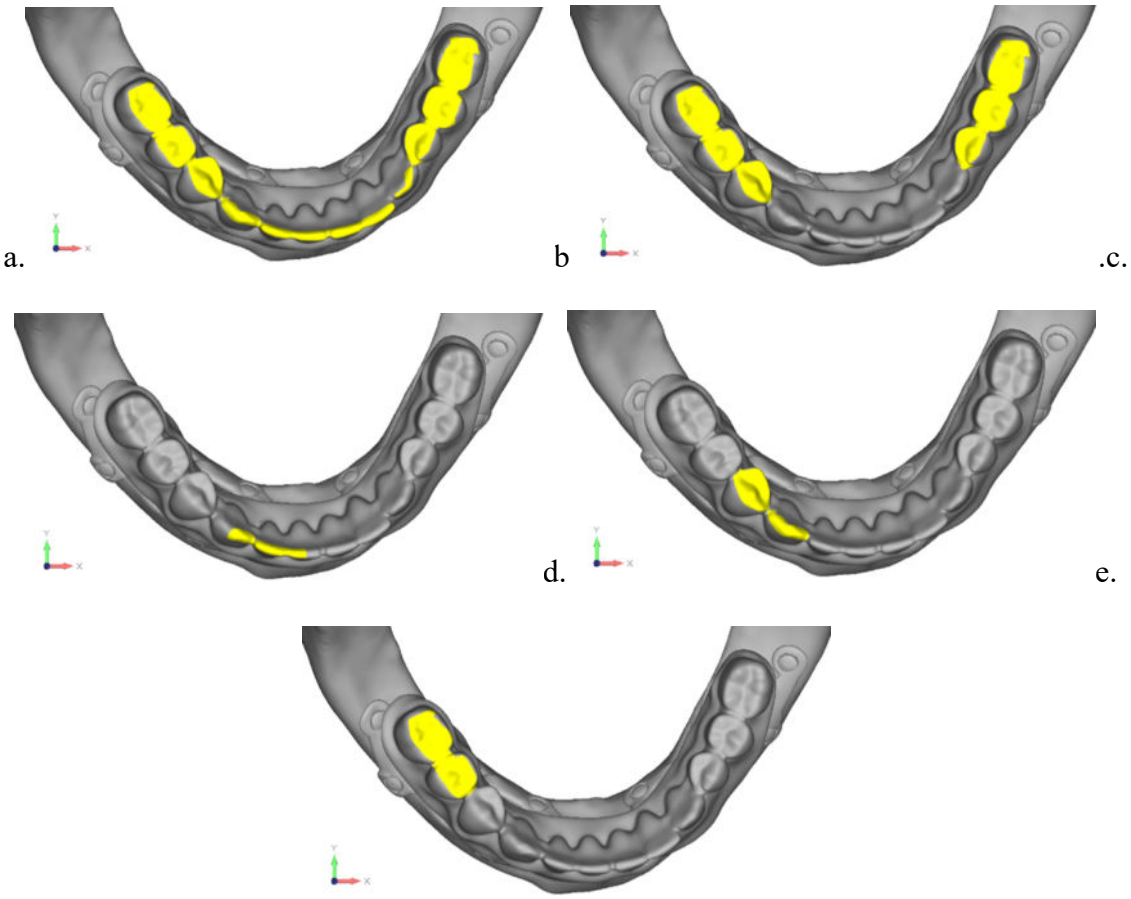


Figure 5. Different types of loads, indicated in yellow, were applied to the lower jaw. (a) Configuration 1: a uniform load is applied, distributed evenly across the entire jaw. (b) Configuration 2: a bilateral load is applied specifically in the molar region. (c) Configuration 3: an anterior unilateral load is applied to one side of the jaw. (d) Configuration 4: a unilateral load is applied in the premolar region. (e) Configuration 5: a unilateral load is applied in the molar region.

All applied loads were static and vertically directed, simulating masticatory forces of 500 N. To mitigate the risk of bone resorption, a stress threshold of 50 MPa was established based on literature values (Table 1). The upper jaw model was stabilized by constraining the sectional surfaces of the cranial region. Nodes located on these surfaces were fully restricted, locking all degrees of freedom. This constraint was implemented using a “rigid” element, which linked peripheral nodes to a central reference node. As a result, all connected nodes remained fixed relative to the global coordinate system (Figure 6).

Type of material	Elastic module E (MPa)	Poisson coefficient	σmax Maximum allowable (Mpa)
Cortical bone	13700	0.3	50
Trabecular bone	1370	0.3	-
Titanium Gr5 (load model)	101000	0.34	950
Titanium Gr5 (bar)	101000	0.34	970
Resin for prosthetics	3000	0.3	-
Muscle simulators	25	0.4	-

Table 2. The characteristics of the material and the mesh adopted from the literature.

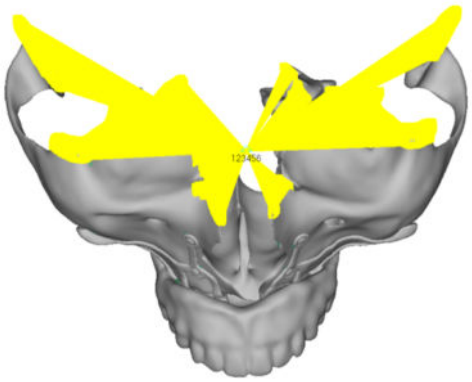
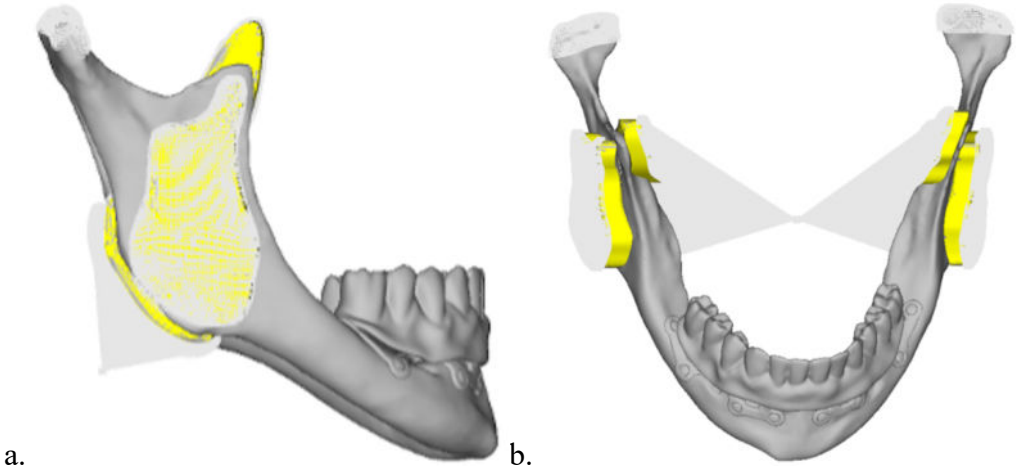


Figure 6. An image of the upper model, showing the "rigid" element in yellow and the central node with all six degrees of freedom locked (translations in x, y, z and rotations in x, y, z).

A distinct modeling strategy was employed for the mandible. To simulate the influence of muscular forces, the mandible was constrained using elastic pads composed of a material with significantly lower elastic modulus compared to the other components in the model. These pads were anchored to the reference system, forming a flexible interface between the anatomical structure and the constraint. At the level of the condyles, hinge-like constraints were introduced to permit rotational movement of the joint. This configuration allowed for a more physiologically accurate distribution of stress within the bone. As in the upper model, "rigid" elements were utilized to link surface constraints to individual nodes (Figure 7).



a. b.

Figure 7. (a) Visualization of the lower jaw model. Elastic pads were linked to a central node, which was fully constrained across all six degrees of freedom - three translational (x, y, z) and three rotational (x, y, z). (b) The nodes at the condylar regions were connected to two distinct nodes - one for each condyle - each restricted to translational movement only. This configuration effectively simulated a hinge mechanism representing the mandibular joint.

The workflow commenced with the segmentation of DICOM files to produce STL representations of the skull and mandible. These models were subsequently refined and simplified using Meshmixer to correct minor imperfections and streamline geometry. The cancellous bone structure was reconstructed, and cortical bone thickness was measured across selected regions. The juxta-osseous implant was then digitally integrated onto the processed STL models, with additional design elements incorporated using Cyborg3D and SolidEdge CAD platforms. Contact interactions were defined, employing both glued and frictional connections to simulate realistic biomechanical behavior. All materials were treated as isotropic and linearly elastic, and the model was meshed using tailored element sizes to capture anatomical and structural detail. A vertical static load of 500 N was applied, and a bone stress threshold of 50 MPa was established to safeguard against resorptive effects.

As previously outlined, multiple loading scenarios were implemented to assess biomechanical responses. In the initial model (V0), the configuration producing the highest stress concentrations was identified. Although all subsequent models were evaluated under the same loading conditions,

geometric optimization was guided by the most critical configuration. Stress values are reported in megapascals (MPa).

Upper Jaw Models

- Model V0: Analysis revealed that load configuration 3 - representing anterior loading on the right side - generated the most pronounced stress levels (Figure 8 a,b). In contrast, configurations 1 and 2, which applied forces across the full dentition and posterior teeth respectively (Figures 9 and 10), resulted in significantly lower stress. Importantly, no structural concerns were noted for the juxta-osseous implant. Even under configuration 3, stress peaks reached 500 MPa only in highly localized regions, remaining below the failure threshold for titanium produced via laser melting.
- Model V1: Posterior screws were introduced to redistribute stress away from the anterior region, achieving a more balanced load distribution. This modification notably reduced the burden on the palatal screw, which had previously been overstressed (Figure 11). The posterior screw now bore the highest stress, but only a limited portion of the screw hole exceeded 50 MPa, with the affected area significantly reduced (Figure 12 a,b).
- Model V2: Designed as a variant of V1, this configuration aimed to stabilize the posterior region using screws oriented vestibularly rather than palatally (Figure 13). Mechanical behavior closely mirrored that of V1, leading to the decision to continue development based on the V1 configuration (Figure 14a,b).
- Model V3: Building on insights from V1, this iteration focused on enhancing anterior anchorage. Two additional screws were placed anterior to the nasal spine to alleviate stress on the frontal screws (Figure 15). However, the modification yielded minimal improvement: stress levels on the frontal screws remained unchanged, though pressure on the anterior crestal support dropped below 35–40 MPa (Figure 16a,b).
- Model V4: The previously added screw was repositioned toward the frontal process and vertically aligned with adjacent screws, allowing both arms of the first and second abutments

to connect to it (Figure 17). This adjustment proved more effective than V3, reducing stress on surrounding screws and support structures. The region exceeding 50 MPa near the screws became more localized, and crestal support stress levels fell within the acceptable range of 30–35 MPa (Figure 18a,b).

- Model V5: This model explored the impact of connecting the two hemi-implants. A frontal connecting bar was added while the palatal bar was removed (Figures 19 and 20a,b). The goal was to evaluate whether such a connection influenced implant stability or stress distribution.
- Model V6: This configuration featured two independent hemi-arches without any connecting element. Results showed that the presence or absence of a connecting bar had no measurable effect on stress distribution. In all prior models, the connecting bar exhibited negligible stress, and its removal in V6 did not alter the biomechanical behavior of either the bone or the implant (Figure 21 and Figure 22 a,b).

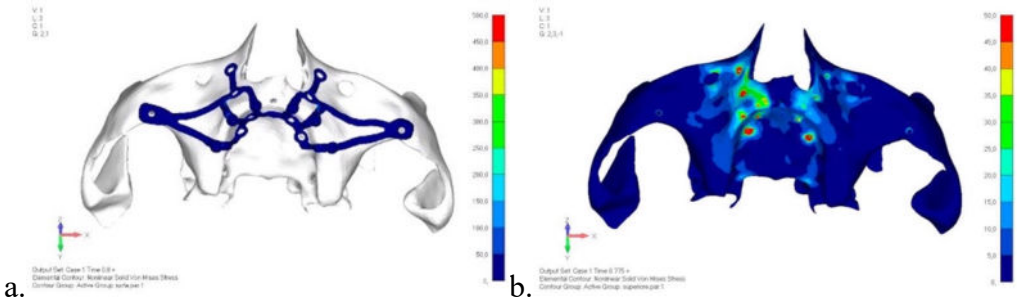


Figure 8. (a) Structural layout of the subperiosteal implant in upper jaw model V0. (b) Visualization of model V0 under the most critical loading scenario - anterior unilateral force applied to the right side.

Figure 9. Upper jaw model V0 under load configuration 1, representing the least critical scenario with force evenly distributed across the full dental arch.

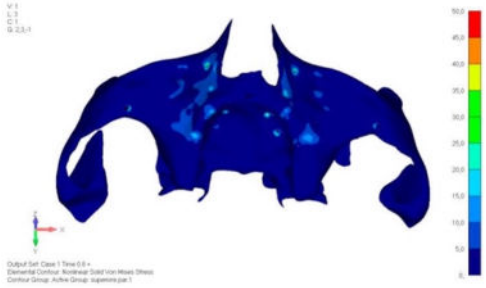


Figure 10. Upper jaw model V0 subjected to load configuration 2, representing a low-stress scenario with force applied exclusively to the posterior dentition.

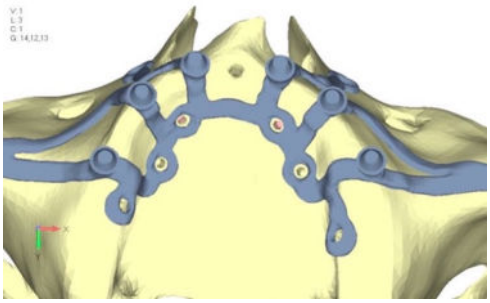


Figure 11. Structural design of the subperiosteal implant in upper jaw model V1, featuring added posterior screws to alleviate anterior stress and promote a more uniform load distribution.

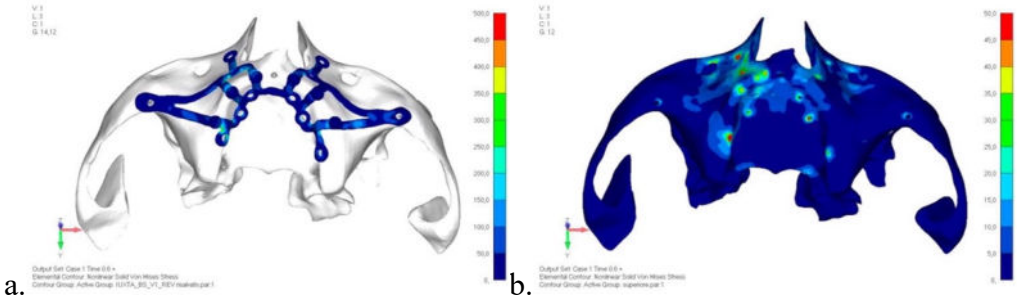


Figure 12. (a) Structural design of the subperiosteal implant in upper jaw model V1. (b) Stress distribution in model V1 showing reduced anterior loading due to the addition of posterior screws.

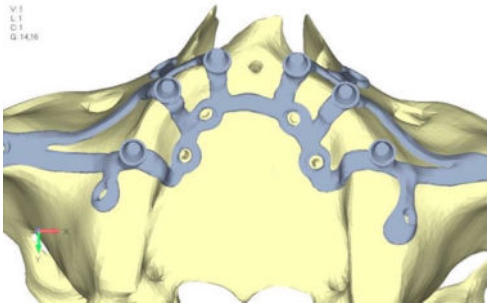


Figure 13. Design of upper jaw model V2 featuring posterior screws oriented vestibularly instead of palatally.

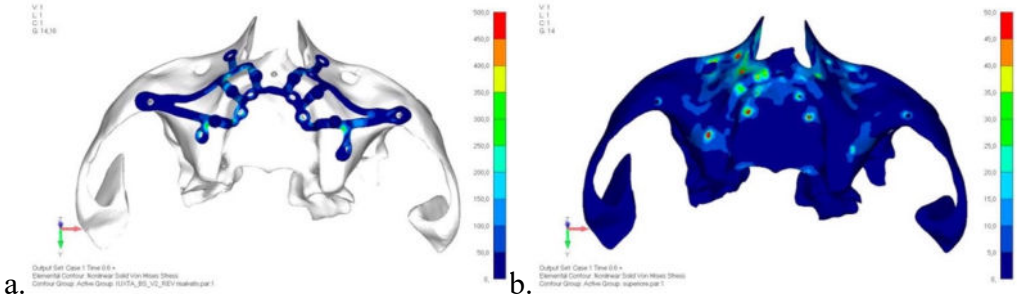


Figure 14. (a) Subperiosteal implant configuration in upper jaw model V2. (b) Load distribution pattern in model V2, demonstrating mechanical behavior comparable to model V1.

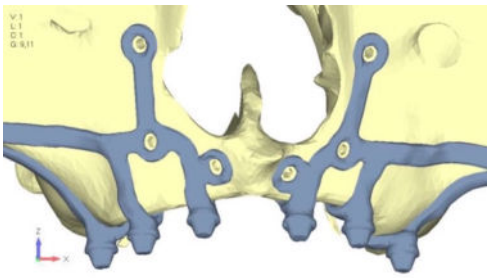
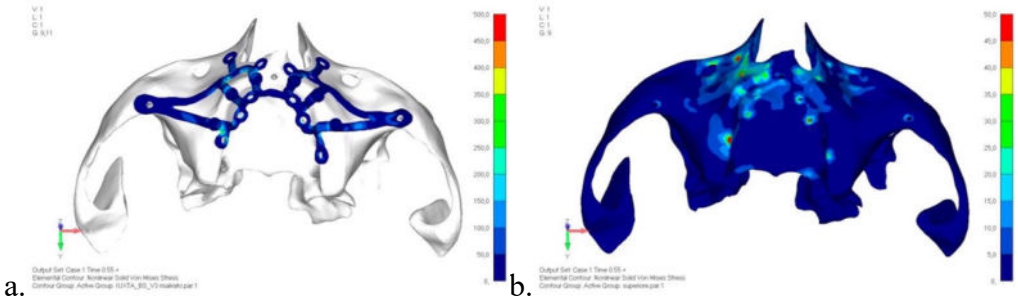


Figure 15. Structural layout of upper jaw model V3 with anterior screws positioned vestibularly to optimize anchorage.



a. b.

Figure 16. (a) Structural design of the subperiosteal implant in upper jaw model V3. (b) Stress analysis of model V3 with an optimized anterior section featuring additional screws; frontal screw stress levels remained unchanged.

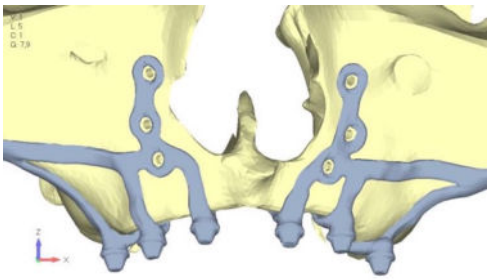
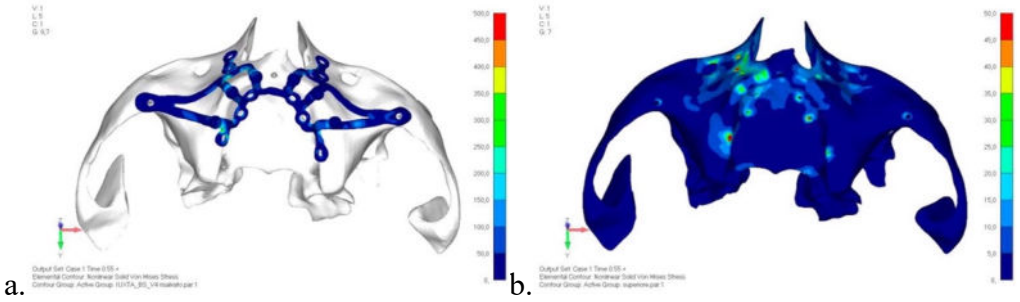


Figure 17. Design of upper jaw model V4, where the newly added screw was repositioned toward the frontal process and vertically aligned with adjacent screws, allowing both abutment arms to anchor to this point.



a. b.

Figure 18. (a) Implant configuration in upper jaw model V3. (b) Stress distribution in model V4 reveals localized areas exceeding 50 MPa near the screws, while crestal support stress levels remain within the acceptable range of 30–35 MPa.

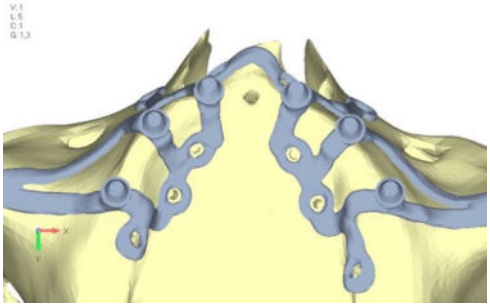
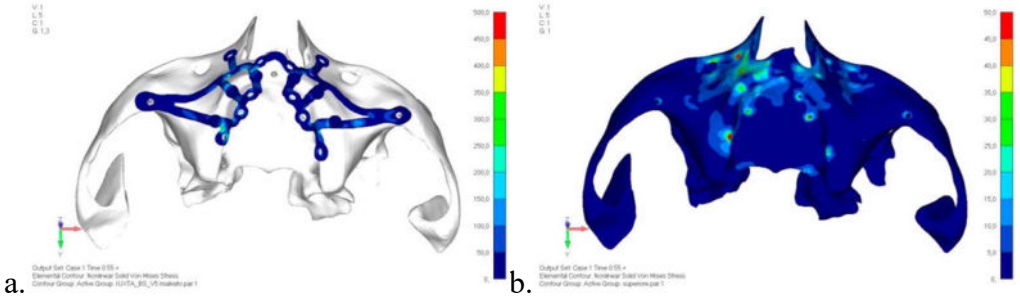


Figure 19. Structural layout of upper jaw model V5, incorporating a frontal connecting bar between the two hemi-implants and omitting the palatal bar to assess its impact on implant behavior.



a. b.

Figure 20. (a) Structural configuration of upper jaw model V5. (b) Stress distribution in model V5 featuring a frontal connecting bar between the two hemi-implants.

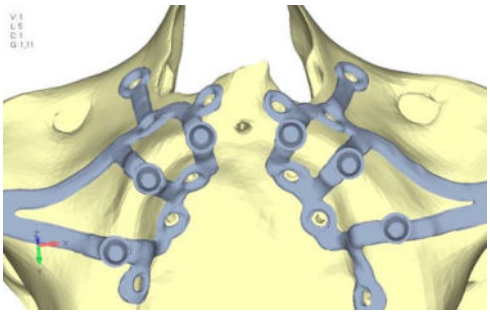


Figure 21. Design of upper jaw model V6, composed of two separate hemi-arches without any connecting element.

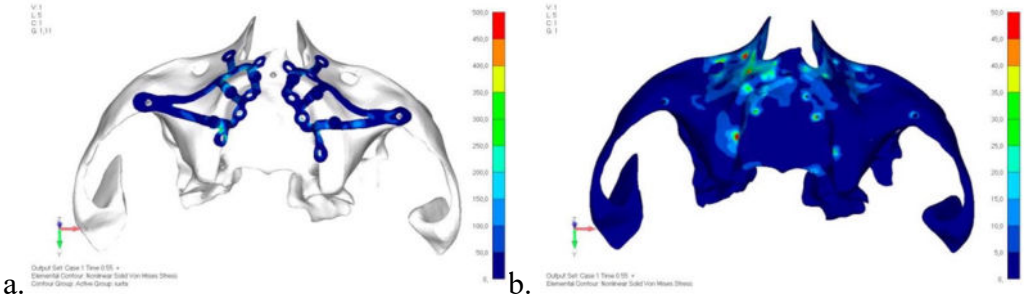


Figure 22. (a) Implant layout in upper jaw model V5. (b) Stress analysis in model V6 showing that bone and implant behavior remains unchanged despite the absence of a connecting bar.

Lower jaw

A methodology consistent with the upper jaw analysis was applied to the mandible, evaluating multiple load configurations to identify the most demanding scenario.

- Model V0: This baseline model features two independent hemi-arches. The stress patterns observed closely resemble those in the upper jaw. Load configuration 3 - representing anterior chewing on the right side - produced the highest stress levels (Figure 23a,b). In contrast, configurations 1 and 2, which distributed forces across broader regions, resulted in reduced stress on both the implant and surrounding bone (Figures 24 and 25). Importantly, peri-implant bone stress remained within acceptable limits and was notably lower than in the upper jaw. Even under the most critical loading, peak stress reached 250 MPa, maintaining a safe

margin. However, in configuration 3, stress levels exceeding 50 MPa were observed in distant regions such as the condyles and posterior alveolar process.

- Model V1: This iteration introduced two anterior crestal appendages intended to improve load distribution in the frontal region (Figure 26). However, the modification did not yield biomechanical benefits. From a clinical standpoint, the placement of crestal screws poses challenges for soft tissue management, increasing the risk of dehiscence and implant exposure (Figure 27 a,b).
- Model V2: The anterior portion of the implant was redesigned by extending vestibular arms connected to the first abutment (Figure 28). This aimed to enhance flexibility and promote load transfer through structural support rather than screw fixation. Despite the design change, stress levels near the screw holes remained comparable to those in model V1 (Figure 29 a,b).
- Model V3: To alleviate stress on the frontal screws, an additional screw was added, redistributing the load from the anterior abutment across three screws instead of two (Figure 30). This adjustment improved stress distribution, reducing the volume of material exposed to stress levels above 50 MPa near the screw sites (Figure 31 a,b).
- Model V4: Building on model V3, a posterior screw was added in the vestibular region to further optimize load distribution (Figure 32). This modification effectively reduced stress concentrations, although the posterior alveolar region - particularly around the newly added screw - remained under notable stress. This was attributed to the anatomical geometry rather than the screw itself (Figure 33a,b).
- Model V5: Retaining the geometry of model V4, this version incorporated two connecting bars - one lingual and one vestibular (Figure 34) - to compare the behavior of a monolithic implant versus a split design. Results mirrored those from the upper jaw: the connecting bars did not enhance stability. Both bars exhibited near-zero stress, indicating no load transmission through these elements (Figure 35 a,b). Once again, the prosthesis played a key role in reinforcing the system via the abutments.

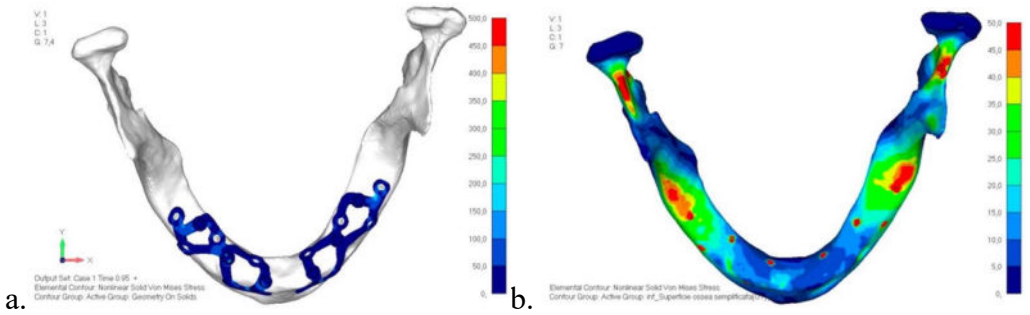


Figure 23. (a) Structural design of the subperiosteal implant in lower jaw model V0. (b) Load configuration representing anterior chewing on the right side, identified as the most critical scenario for the lower jaw.

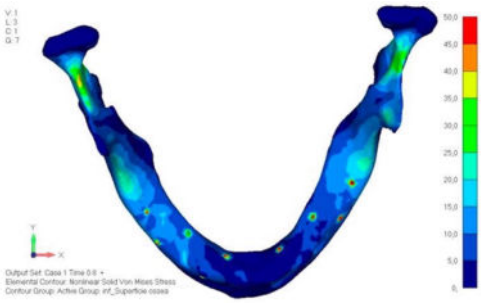


Figure 24. Load configuration 1 applied to lower jaw model V0, with force distributed across a broad area.

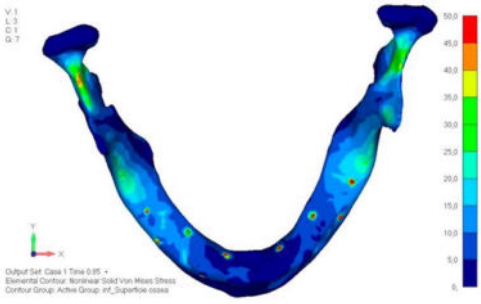


Figure 25. Load configuration 2 applied to lower jaw model V0, targeting posterior regions with reduced stress concentration.

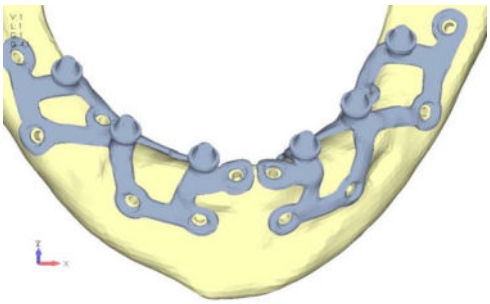


Figure 26. Structural design of lower jaw model V1 featuring two anterior crestal appendages intended to improve load distribution.

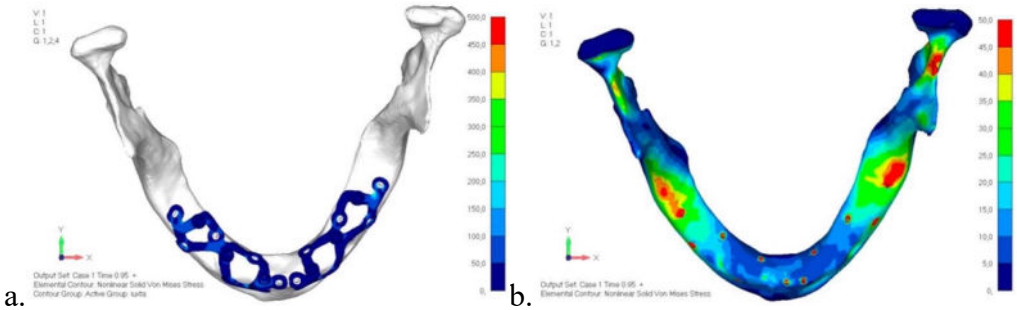


Figure 27. (a) Implant configuration in lower jaw model V1. (b) Stress analysis reveals no significant improvement in load distribution with the added crestal appendages.

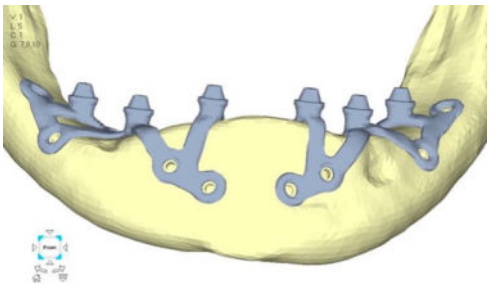


Figure 28. Design of lower jaw model V2 incorporating extended anterior vestibular arms connected to the first abutment.

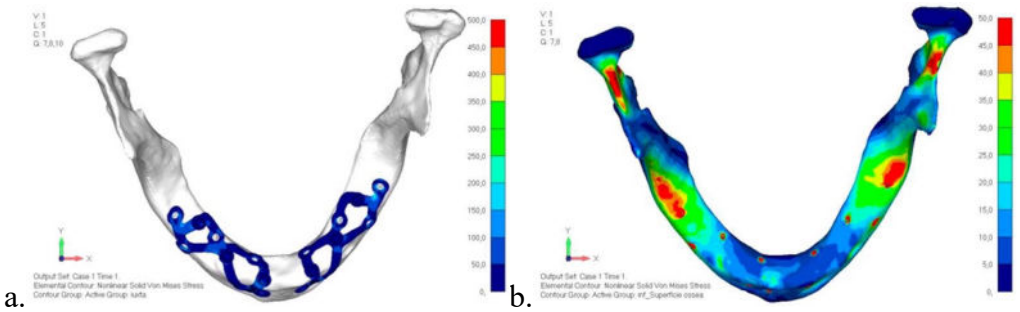


Figure 29. (a) Implant layout in lower jaw model V2. (b) Stress levels near screw holes remain comparable to those in model V1.

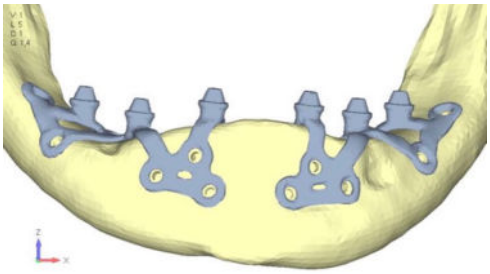


Figure 30. Lower jaw model V3 redesigned with an additional anterior screw to distribute abutment load across three fixation points.

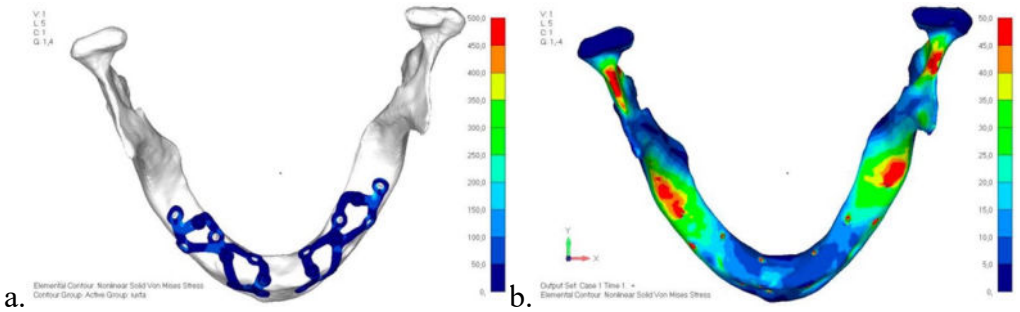


Figure 31. (a) Implant configuration in model V3. (b) Stress analysis shows reduced high-stress zones around screw sites compared to previous models.

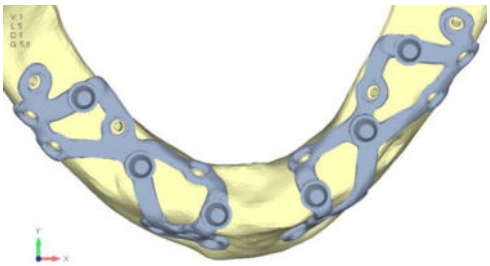
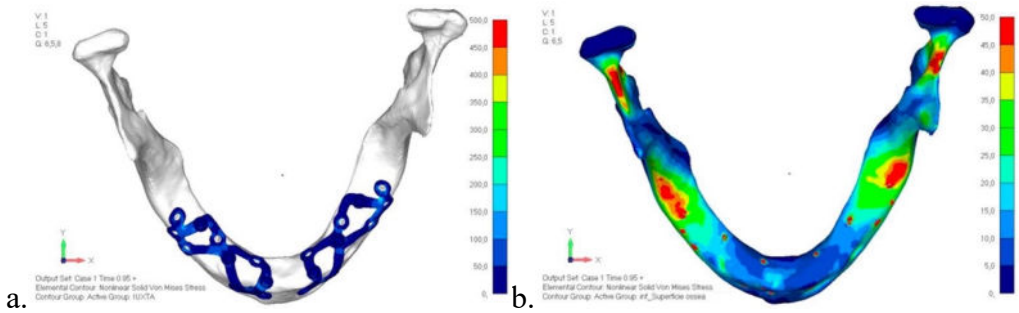


Figure 32. Lower jaw model V4 derived from model V3, featuring an added posterior screw oriented vestibularly to enhance anchorage.



a. b.

Figure 33. (a) Implant design in model V4. (b) Stress remains elevated in the posterior alveolar region, particularly around the newly added screw.

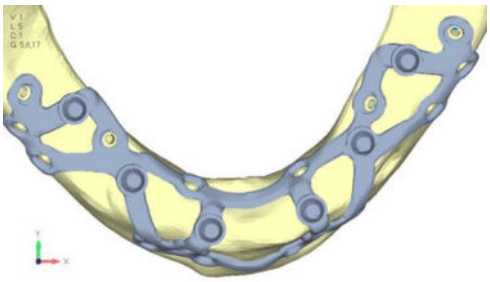


Figure 34. Lower jaw model V5 retaining the geometry of model V4, with the addition of two connecting bars - one lingual and one vestibular.

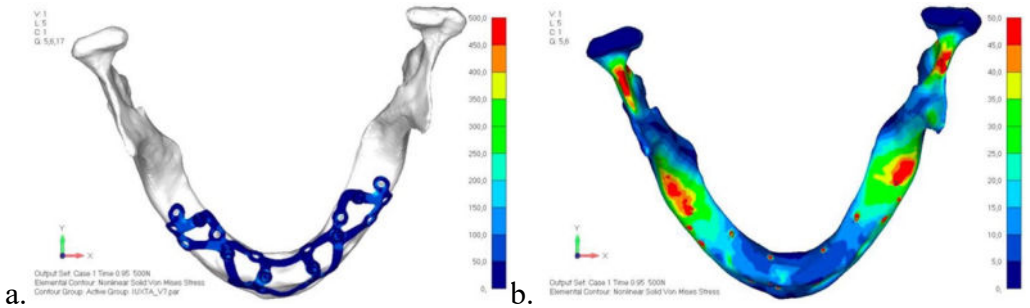


Figure 35. (a) Structural layout of model V5. (b) Stress analysis indicates minimal force transmission through the connecting bars, confirming their negligible biomechanical contribution.

The present study investigated the biomechanical behavior of juxta-osseous implants under simulated masticatory loading. For both maxillary and mandibular models, the most demanding stress configuration occurred when the load was applied anteriorly. The analysis demonstrated that the metallic framework of the juxta-osseous implant effectively resisted functional forces, with no critical stress concentrations observed. Nonetheless, achieving proper implant fixation proved to be a key factor for biomechanical stability. No significant differences were detected between the one-piece and two-piece implant configurations in either model. The prosthetic component played a vital role in reinforcing and stabilizing the overall structure. Despite these encouraging findings, clinical studies are necessary to confirm and validate the biomechanical outcomes observed in this investigation.

6.6. Surgical and Prosthetic Protocols

Preoperative Measures

Before surgery, patients perform a one-minute rinse with 0.2% chlorhexidine mouthwash to reduce bacterial load in the oral cavity. Prophylactic antibiotics were administered 1 hour before the surgery:

- Standard: *2 g Amoxicillin*
- In case of penicillin allergy: *600 mg Clindamycin*

All surgical procedures were performed under local anesthesia, using either 4% Articaine with 1:100.000 epinephrine or 3% Mepivacaine, administered as infiltration or nerve block depending on the surgical site and patient needs. Conscious sedation was used selectively, typically with intravenous Midazolam, to ensure patient comfort and compliance. Prior to flap elevation, anesthesia and sedation were administered. A full-thickness mucoperiosteal flap was then carefully incised, including releasing incisions when necessary, and reflected to allow complete visualization of the underlying alveolar bone, facilitating accurate surgical access and planning.

Implant Placement

- In the control group, zygomatic implants and/or short/narrow-diameter implants were inserted according to preplanned trajectories using surgical guide, with insertion torque monitored to ensure adequate primary stability (≥40 Ncm) required for immediate loading.
- In the test group, the custom subperiosteal implant were carefully positioned over the atrophic jaw bone. The pre-manufactured titanium framework were secured with osteosynthesis screws in predetermined bone support areas. The emergence of transmucosal abutments were verified for passive fit and proper prosthetic orientation.

Immediately following implant placement, patients in both groups receive a screw-retained reinforced acrylic provisional prosthesis, fabricated prior to surgery based on digital planning and prosthetic simulation.

6.6.1. Surgical Protocol for Zygomatic Implants

The surgical approach for the placement of zygomatic (BT ZYGOMAX IR; BTK, Biotec SRL, Povolaro di Dueville, IT) implants follows a structured and anatomically guided protocol to ensure accurate three-dimensional positioning, optimal primary stability, and the possibility of immediate prosthetic loading.

Surgical Access and Anatomical Landmarks

A mid-crestal incision is performed to gain access to the maxillary bone. The mucoperiosteal flap was elevated sufficiently to expose key anatomical reference points, including the infraorbital foramen and the notch between the zygomatic arch and the lateral/medial surfaces of the frontal process of the zygomatic bone. A bone window approximately 10 x 5 mm were created, extending from the lateral wall of the maxillary sinus to the base of the zygomatic bone. Particular attention were paid during this phase to gently elevate and preserve the respiratory epithelium lining the sinus cavity.

Positioning Considerations

Whenever anatomical conditions allow, implants were positioned extra-sinusally, avoiding direct invasion of the sinus cavity. The emergence profile of the implant is planned to be crestal rather than palatal, optimizing prosthetic trajectory and reducing functional complications. A retractor were strategically placed in the zygomatic notch between the zygomatic arch and the frontal process to assist in the accurate three-dimensional alignment of the drills and implants.

Osteotomy Preparation

Osteotomy began using a spherical burr at 800 rpm under constant, abundant irrigation with sterile saline to minimize thermal damage. This is followed by the use of 3.75 mm cylindrical abrasive burs, rotating at 500 rpm, which help define the osteotomy path along the lateral wall of the maxillary sinus. Subsequent drillings were performed using spiral drills of 2.8 mm and 3.2 mm in diameter, operated at 600 rpm, with the goal of penetrating the outer cortical layer of the zygomatic process. Drill depth were carefully controlled to ensure a trajectory that optimizes apical engagement while maintaining parallelism and emergence orientation.

Implant Selection and Insertion

The appropriate implant length was determined using a dedicated depth gauge to match the anatomical configuration of each zygomatic bone. Implants were inserted at low speed (15-25 rpm) to allow precise control and to minimize the risk of overheating or microfracture.The goal was to

achieve a minimum insertion torque of 40 Ncm to allow immediate loading, while not exceeding 65 Ncm, beyond which deformation of the implant head could occur. Four zygomatic implants were placed in total-two per zygoma-maintaining a minimum distance of 1 cm between the apices of the two implants on the same side, which helps distribute functional forces and reduces the risk of cortical bone resorption or implant convergence.

Management of Inadequate Primary Stability

In cases where one or more implants fail to reach the minimum required 40 Ncm insertion torque, those implants were left in situ unloaded for a period of four months, allowing for osseointegration before they are connected to the prosthetic superstructure. Suturing was carried out using either resorbable 4-0 polyglactin 910 (Vicryl) or non-resorbable 5-0 polypropylene (Prolene) sutures, selected according to tissue thickness and surgical site, employing interrupted or horizontal mattress techniques to ensure precise adaptation and tension-free closure of the flap margins.

Patients rehabilitated with zygomatic implants receive additional instructions to protect the maxillary sinus and prevent sinus-related complications:

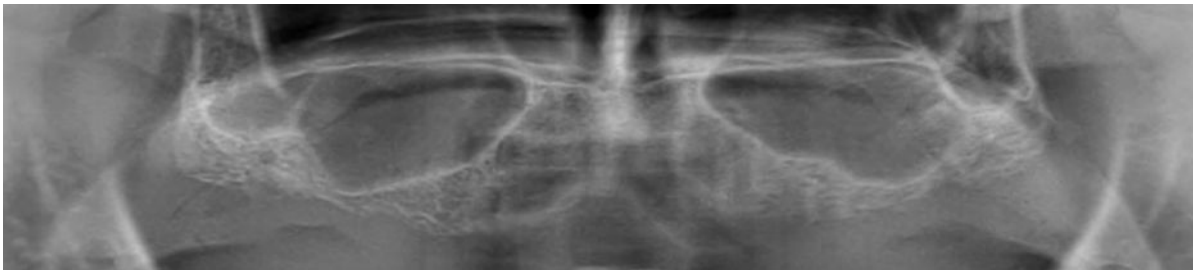
Post-Operative Instructions

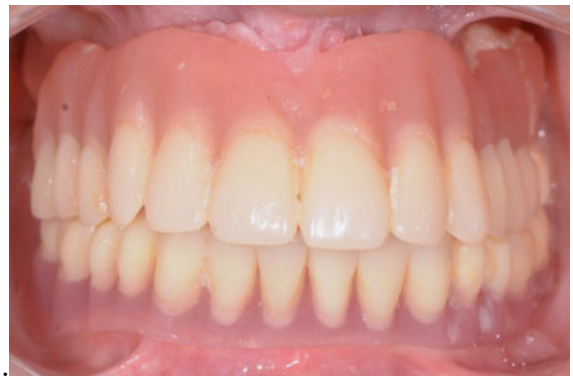
- Antibiotic Therapy: Amoxicillin 1 g orally three times daily for 5 days is prescribed as first-line treatment. For patients with beta-lactam allergies, Clindamycin 300 mg three times daily for 5days is recommended.
- Analgesia: Ibuprofen 600 mg is advised up to three times daily during meals for one week. Patients are instructed to avoid taking analgesics if they experience no pain.
- Oral Hygiene: Patients should perform rinses with 0.12% Chlorhexidine mouthwash twice daily for two weeks to maintain mucosal hygiene and minimize bacterial colonization.
- Diet: A soft diet is recommended for the first two weeks post-surgery to reduce mechanical trauma to the surgical sites.

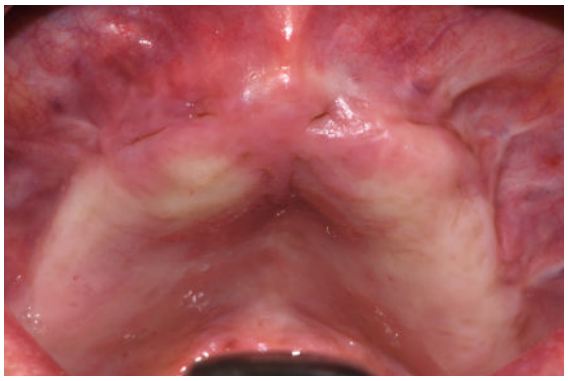
- Nasal Decongestants: Administration of nasal decongestant drops (e.g., Otrivin) at a dosage of 5 drops three times daily for two weeks helps reduce mucosal swelling and maintain sinus patency.
- Pressure Avoidance Measures: Patients are instructed to avoid blowing their nose, to use straws when drinking, and to keep their mouth open during sneezing. These measures serve to reduce intra-sinus pressure fluctuations that could jeopardize surgical outcomes.

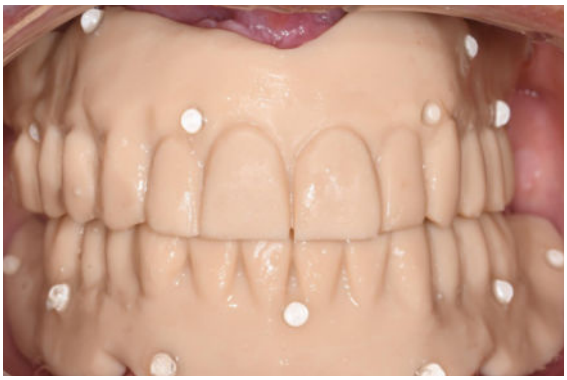
6.6.2. Prosthetic Procedures Following Zygomatic Implant Placement

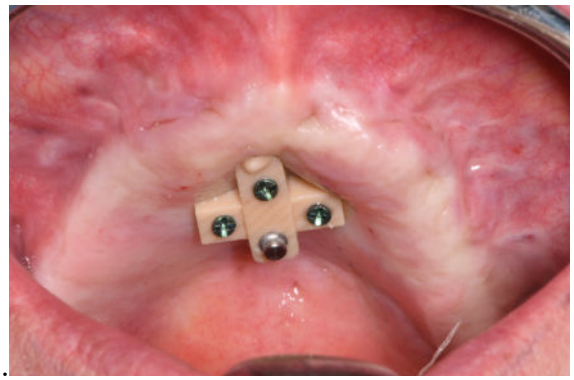
Following implant placement, angled BT4 IR abutments at 45° or 55° (BTK, Biotec SRL, Povolaro di Dueville, IT)were connected to the zygomatic implants to ensure proper prosthetic orientation. Subsequently, the surgical flaps were sutured to promote optimal healing. A layer of dental rubber dam material is placed over the soft tissues to isolate the surgical site, and a conventional or digital (utilized scan abutments) impression were taken using a rigid impression material to capture accurate implant positions. A reinforced screw-retained provisional resin prosthesis was then fabricated and delivered to the patient by the following day (from 24 – to 48 hours after the surgery), ensuring immediate functional and esthetic rehabilitation (Figure 36).

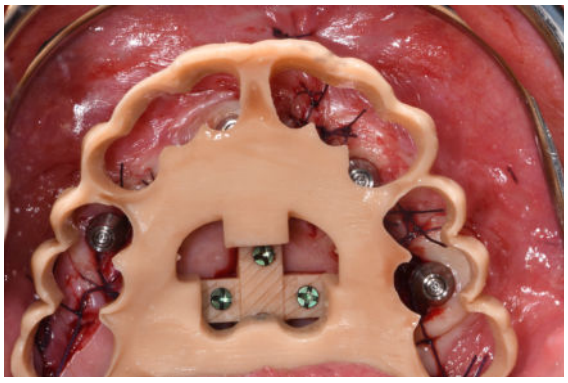
a. 

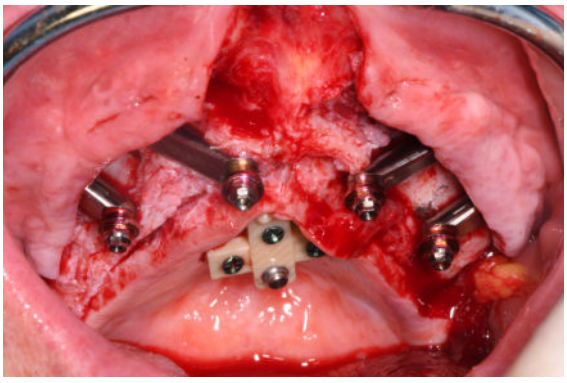
b . 

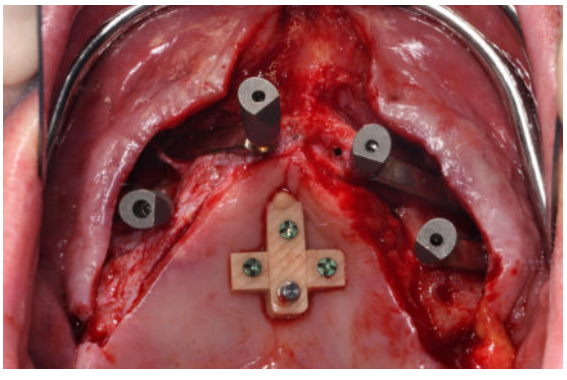
c. 

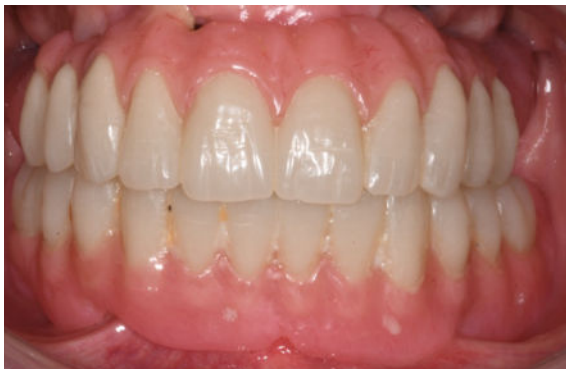
d. 

e . 

f. 

g. 

h. 

i. 

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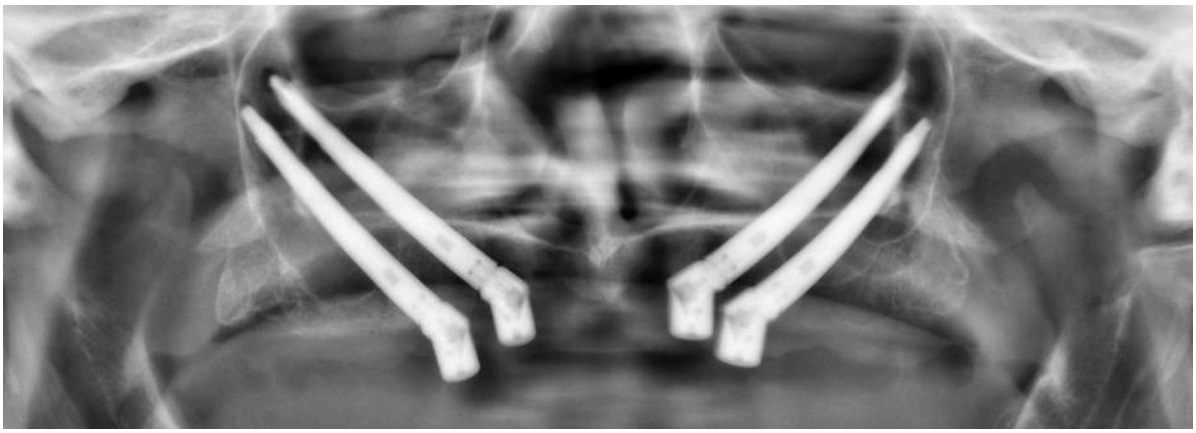

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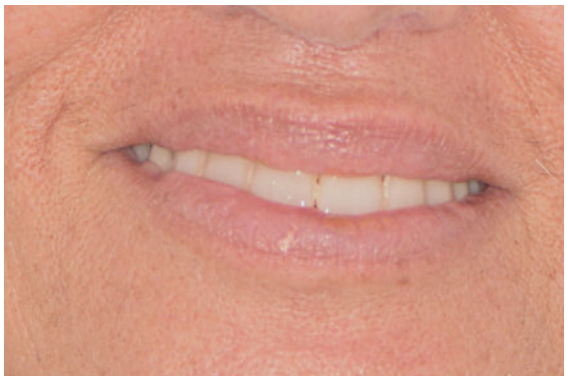

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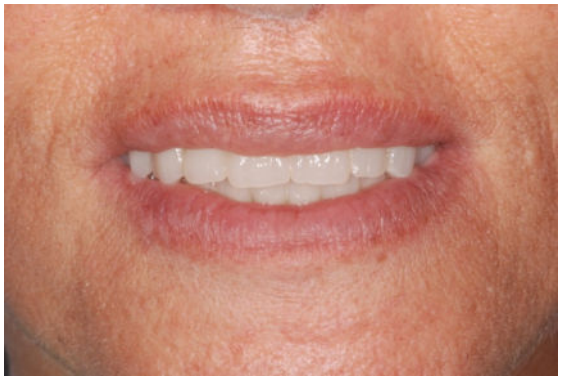


Figure 36 (Case 1). Clinical and radiographic workflow of maxillary full-arch rehabilitation using zygomatic implants. a) Panoramic radiograph of the edentulous maxilla. b) Intraoral view of the patient wearing the existing complete removable prosthesis. c) Clinical view of the fully edentulous upper jaw. d) Provisional prosthesis with adjusted vertical dimension of occlusion (DVO) and marked reference points for CBCT scanning. e) Intraoral positioning of the radiographic reference tool on the palate. f) Placement of the surgical guide in the maxilla. g) Intraoperative view following placement of four zygomatic implants (BT ZYGOMAX IR; BTK, Biotec S.R.L., Povolaro di Dueville, Italy). h) Positioning of the scan abutments for digital impression. i) Intraoral view of the screw-retained provisional prosthesis. j) Postoperative panoramic radiograph showing implant positions. k) Preoperative clinical view of the patient's smile. l) Postoperative smile following delivery of the provisional prosthesis.

6.6.3. Surgical Technique for Subperiosteal Implant Placement

The surgical placement of subperiosteal implants (IUXTA-3D; BTK, Biotec SRL, Povolaro di Dueville, IT) involved a crestal incision extending from tuber to tuber across the maxilla and from retromolar space to retromolar space of mandible. This incision was accompanied by extensive releasing incisions to ensure sufficient flap mobility and full exposure of the underlying bone. In cases involving the maxilla, the anterior palate was elevated by carefully detaching the soft tissue, which necessitates the intentional transection of the incisive nerve to allow complete access for implant placement.

Once full exposure of the bone anatomy is achieved, the custom-manufactured implant-produced with CAD-CAM technology for precise adaptation was carefully positioned onto the osseous surface. The implant was then fixed in place with titanium screws (BT Screws, BTK, Biotec SRL, Povolaro di Dueville, IT) anchored into the main bony support pillars, as identified during preoperative virtual planning. In cases of bone irregularities and to accurately position the implant pillars of the subperiosteal implant, osteotomies were performed using surgical guides derived from the digital planning workflow (BTK, Biotec SRL, Povolaro di Dueville, IT).The implant were then fixed in place with titanium screws anchored into the main bony support pillars, as identified during preoperative virtual planning. Following implant fixation, the mucosal flaps were repositioned and sutured around six transmucosal posts that remained exposed intraorally to permit subsequent prosthetic rehabilitation. Suturing was carried out using either resorbable 4-0 polyglactin 910 (Vicryl) or non-resorbable 5-0 polypropylene (Prolene) sutures, selected according to tissue thickness and surgical site, employing interrupted or horizontal mattress techniques to ensure precise adaptation and tension-free closure of the flap margins.

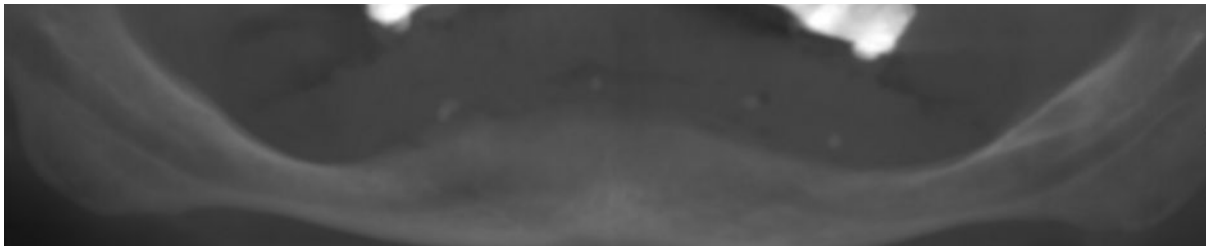
Post-Operative Instructions

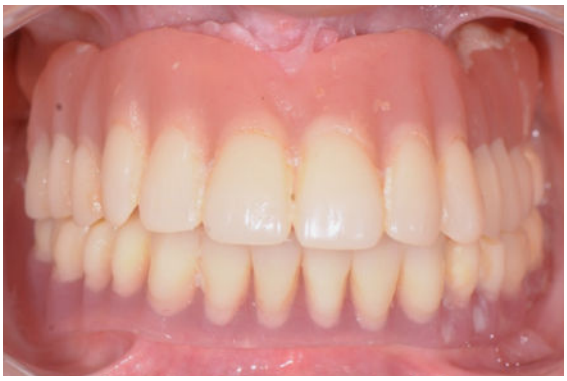
To optimize healing and reduce the risk of infection and complications, patients are provided with detailed post-operative care instructions as follows:

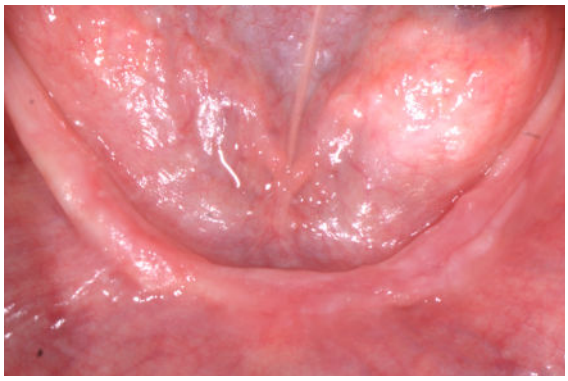
- Antibiotic Therapy: Amoxicillin 1 g orally three times daily for 5 days were prescribed as first-line treatment. For patients with beta-lactam allergies, Clindamycin 300 mg three times daily for 5 days is recommended.
- Analgesia: Ibuprofen 600 mg was advised up to three times daily during meals for one week. Patients are instructed to avoid taking analgesics if they experience no pain.
- Oral Hygiene: Patients should perform rinses with 0.12% Chlorhexidine mouthwash twice daily for two weeks to maintain mucosal hygiene and minimize bacterial colonization.
- Diet: A soft diet was recommended for the first two weeks post-surgery to reduce mechanical trauma to the surgical sites.

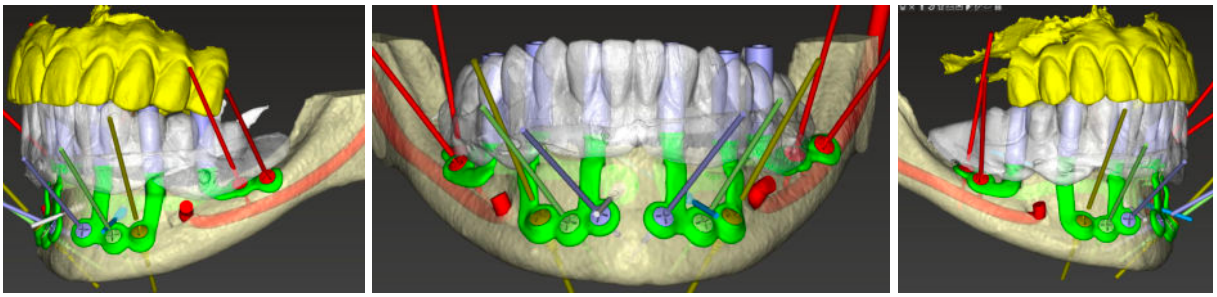
6.6.4. Prosthetic Procedures Following Subperiosteal Implant Placement

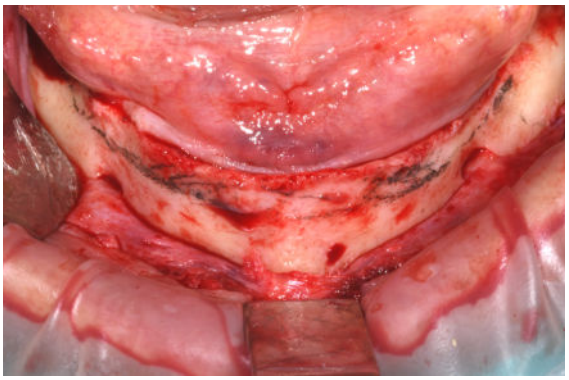
Following the placement and fixation of the subperiosteal implant framework, the transmucosal abutment posts (BTK, Biotec SRL, Povolaro di Dueville, IT) were connected to ensure proper prosthetic alignment and emergence profile. The mucoperiosteal flaps were then repositioned and sutured with tension-free adaptation to promote optimal soft tissue healing. After achieving hemostasis, scan abutments were securely attached to the transmucosal posts, and a digital impression of the arch was obtained using an intraoral scanner to accurately capture the position and morphology of the abutments. The digital file was subsequently transferred to the laboratory for computer-aided design and fabrication of a reinforced, screw-retained provisional resin prosthesis, which was delivered to the patient the following day (from 24 to 48 hours after the surgery), allowing for immediate functional and esthetic rehabilitation (Figure 37, 38 and 39).

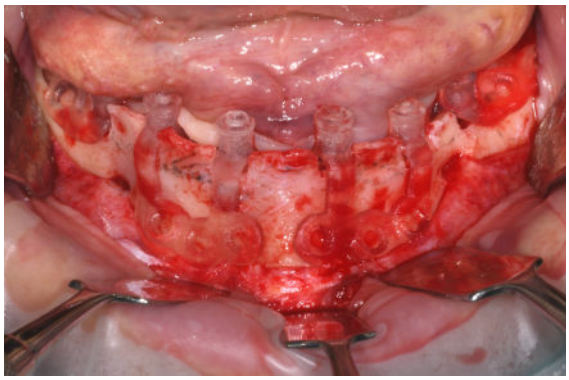
a. 

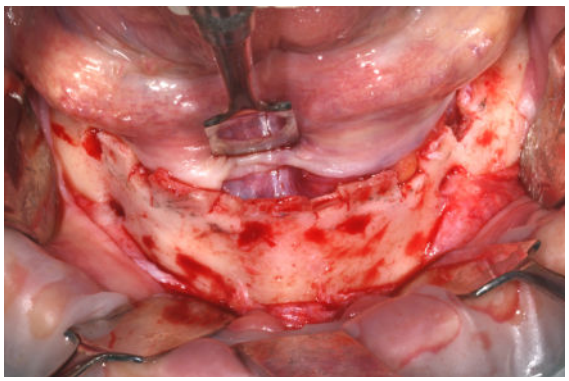
b. 

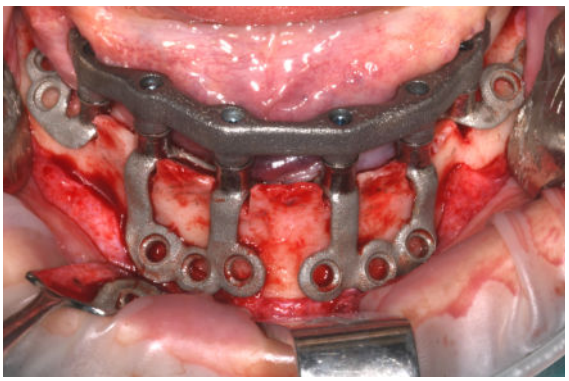
c. 

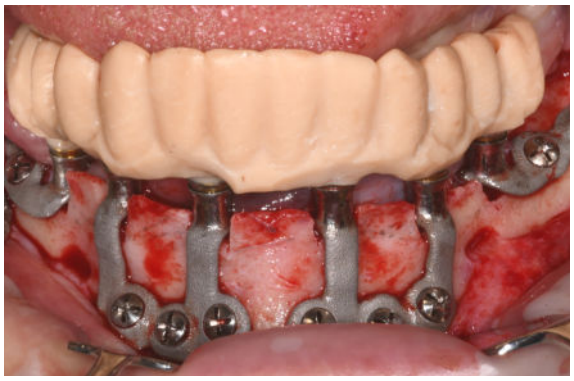
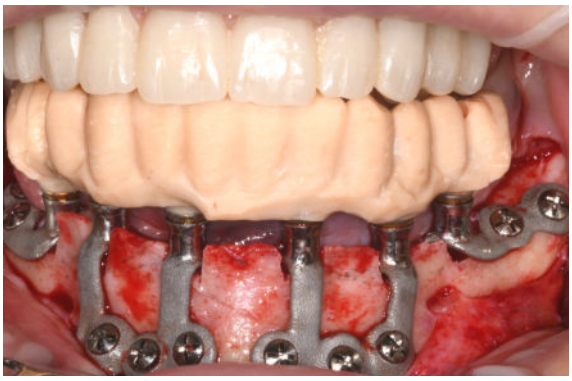
d. 

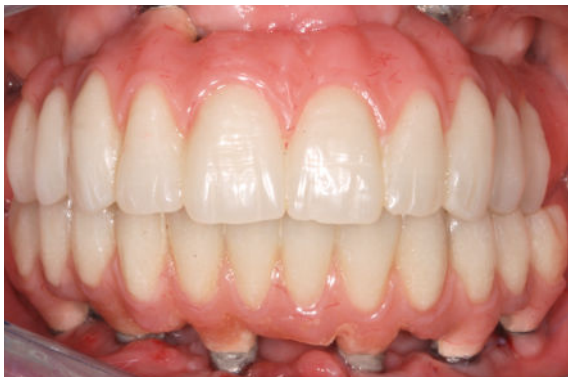
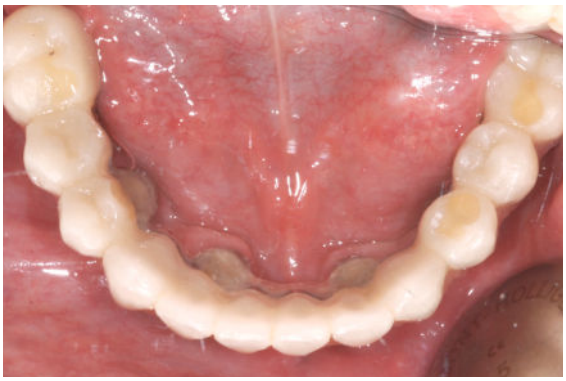
e. 

f. 

g. 

h. 

i.  j. 

k.  l. 

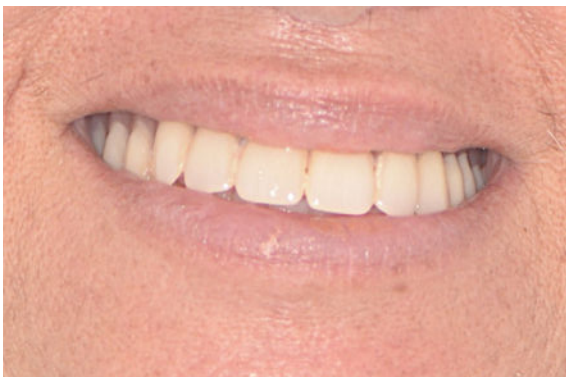
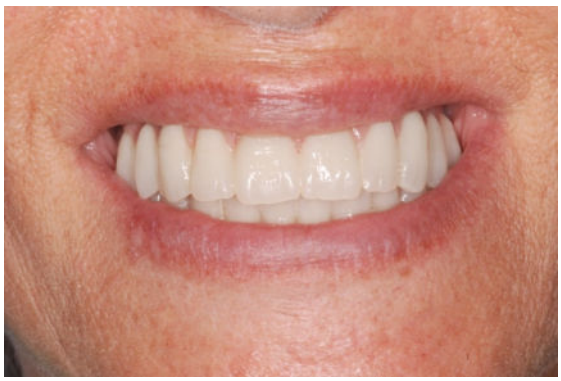
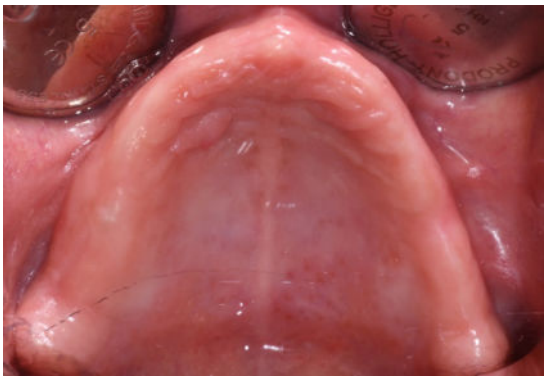
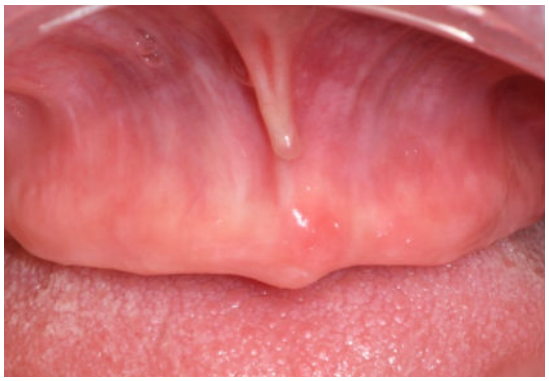
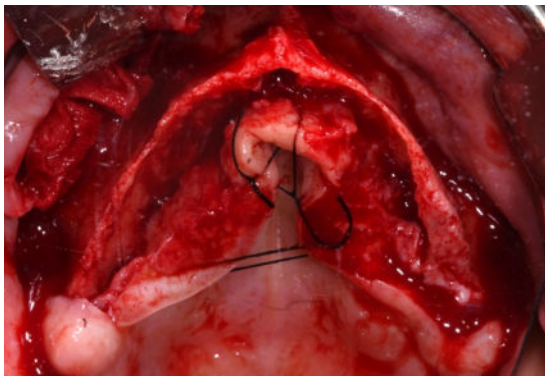
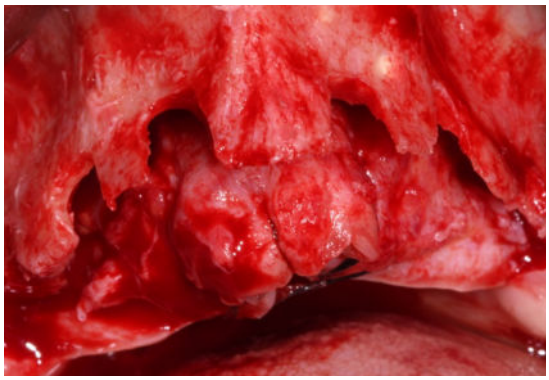
m.  n. 

Figure 37 (Case 2). Clinical and radiographic workflow of mandibular full-arch rehabilitation using subperiosteal implants. a) Panoramic radiograph of the edentulous mandible. b) Intraoral clinical photo of the patient wearing the existing complete removable prosthesis. c) Clinical photo of the fully edentulous mandibular ridge. d) Digital modeling of the customized subperiosteal framework with planned fixation screws. e) Intraoral intra-surgical clinical photo of the edentulous mandibular ridge following the sull-thickness flap elevation. f) Intraoperative fitting of the resin subperiosteal framework template (IUXTA-3D, BTK, Biotec S.R.L., Povolaro di Dueville, Italy) for adaptation verification. g) Intraoral

photo of osteotomies performed according to the digital surgical plan and guide template. h) Intraoral photo of the definitive metal framework positioned with a connecting verification bar to ensure proper parallelism. i) Intraoral photo of the seated metal framework and the screw-retained provisional prosthesis on the mandible. j) Intraoral photo of the mandibular provisional prosthesis in occlusion with the maxillary prosthesis. k) Intraoral photo three weeks postoperatively showing the provisional prosthesis in function. l) Occlusal intraoral view of the mandibular provisional prosthesis. m) Extraoral view of the patient's smile before surgery. n) Extraoral view after surgery showing the final esthetic outcome (1 year of follow-up).

a.  b. 

c.  d. 

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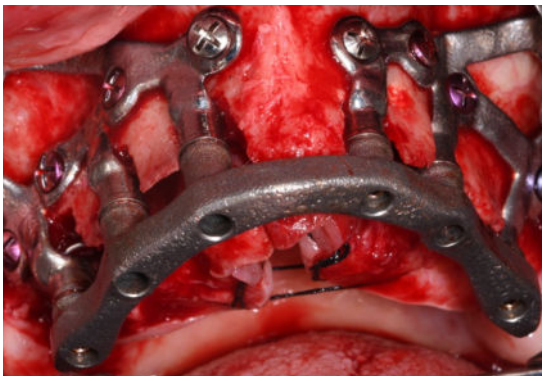
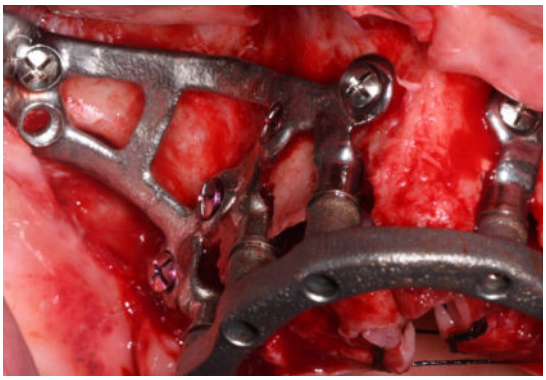
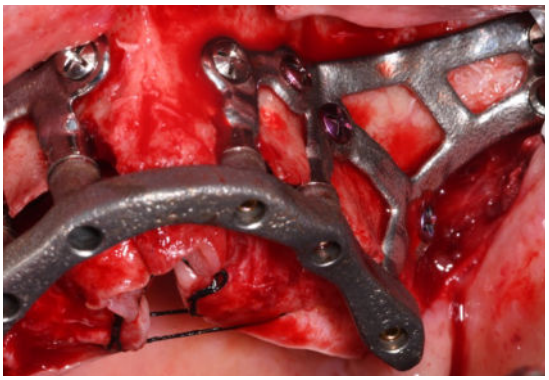
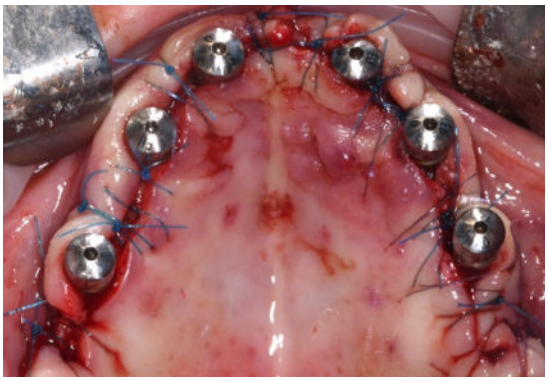
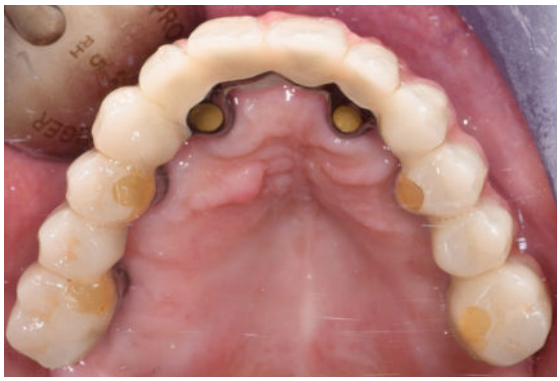
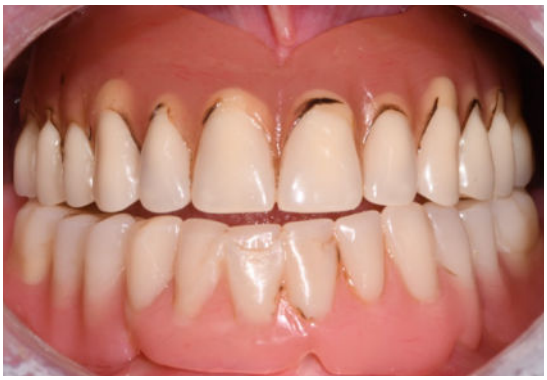
f. 

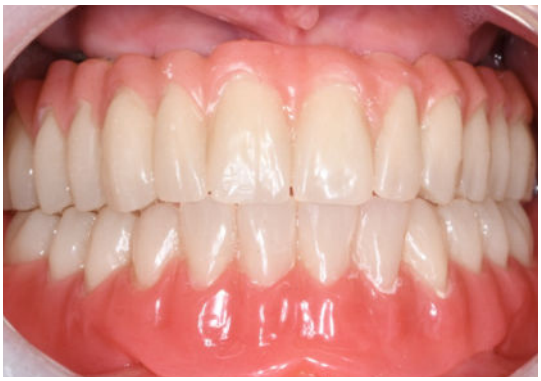
g. 

h. 

i. 

j. 

k. 

l. 

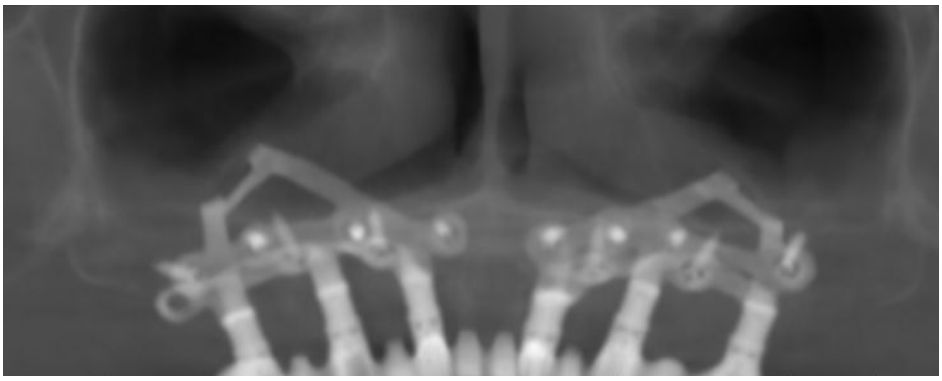
m. 

Figure 38 (Case 3). Clinical and radiographic workflow of maxillary full-arch rehabilitation using subperiosteal implants. a) Intraoral occlusal view of the fully edentulous maxilla.b) Buccal clinical view of the edentulous maxillary ridge. c) Intraoperative view of the edentulous maxilla following full-thickness flap elevation. d) Intraoral view of the osteotomies performed according to the digital surgical plan and guide template. e) Extraoral view of the customized metal framework before placement on the edentulous ridge (IUXTA-3D; BTK, Biotec S.R.L., Povolaro di Dueville, Italy). f) Intraoral view of the definitive metal framework positioned with a connecting verification bar to ensure correct parallelism. g) Intraoral view of the right lateral extension of the framework with fixation screws in place. h) Intraoral view of the left lateral extension of the framework with fixation screws in place. i) Occlusal view showing the healing abutments and sutured flaps. j) Occlusal view of the screw-retained provisional prosthesis. k) Buccal clinical view of the patient wearing the old complete removable prosthesis. l) Buccal clinical view of the newly positioned fixed provisional prosthesis in the maxilla and the opposing mandibular complete removable prosthesis with adjusted vertical dimension of occlusion (DVO) (1 year of follow-up). m) Postoperative panoramic radiograph of the maxilla following subperiosteal implant placement.

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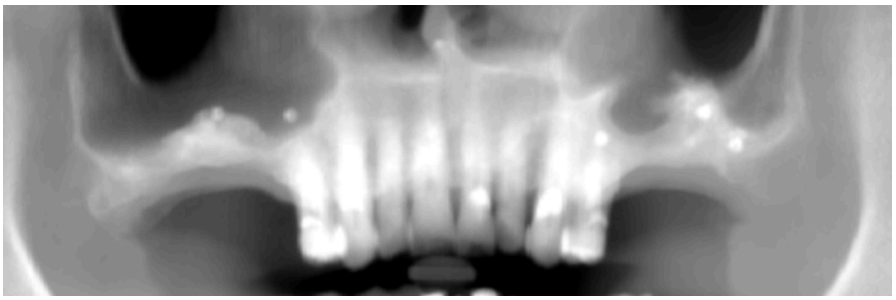

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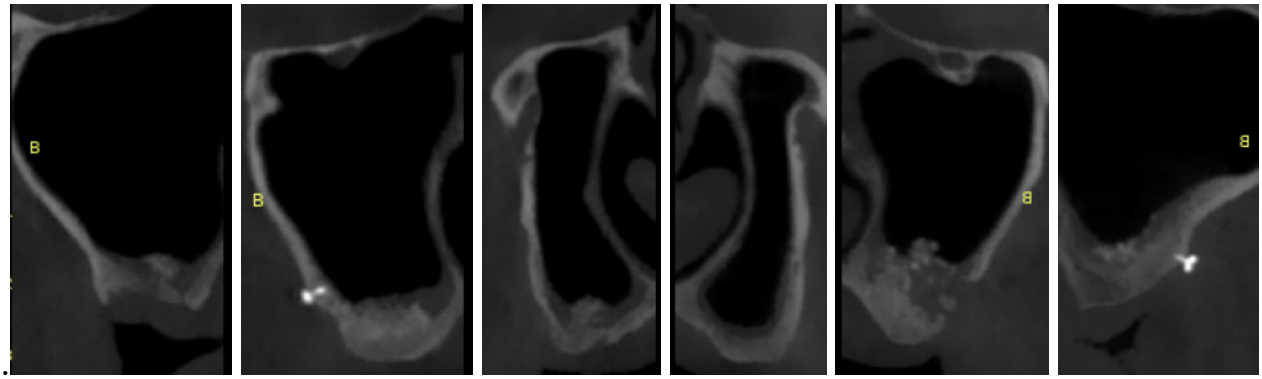

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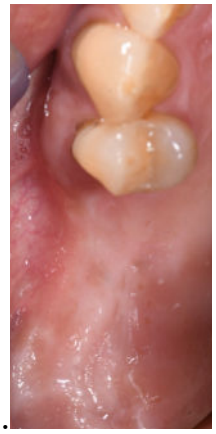

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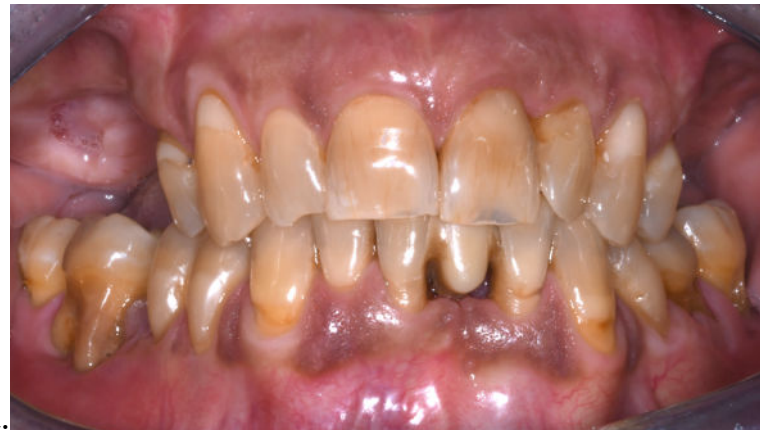

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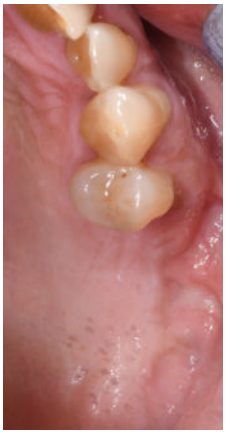

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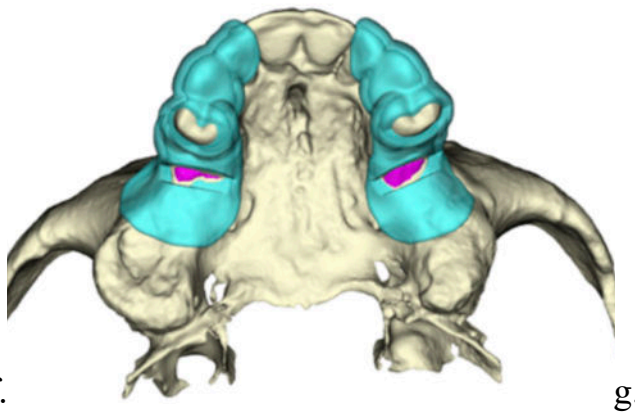

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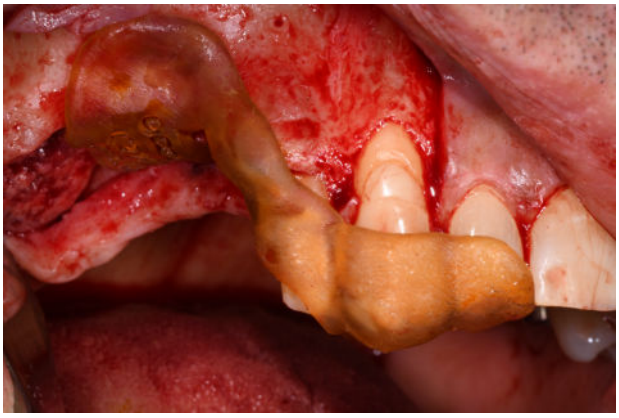
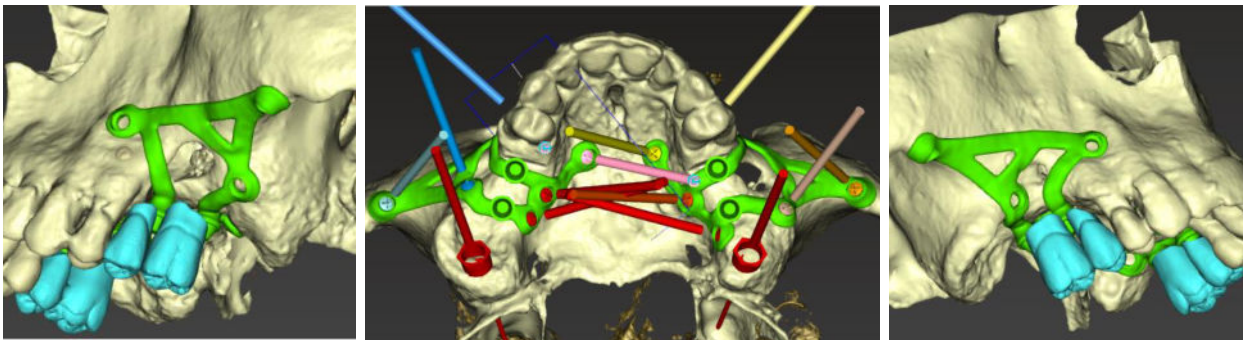
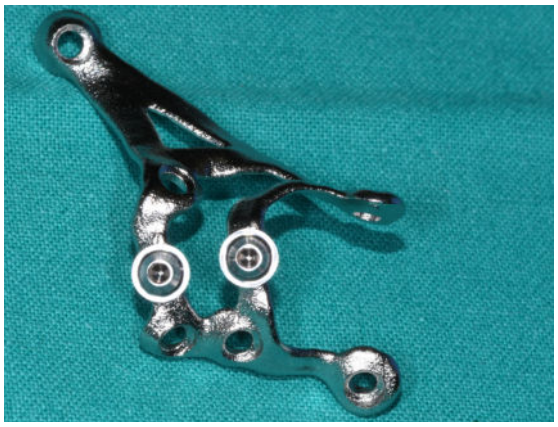
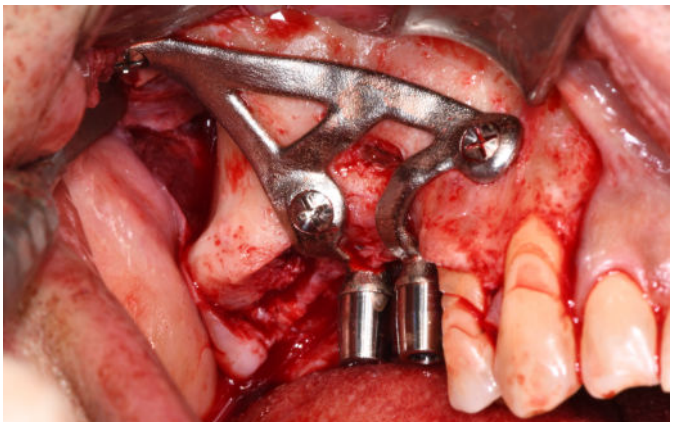
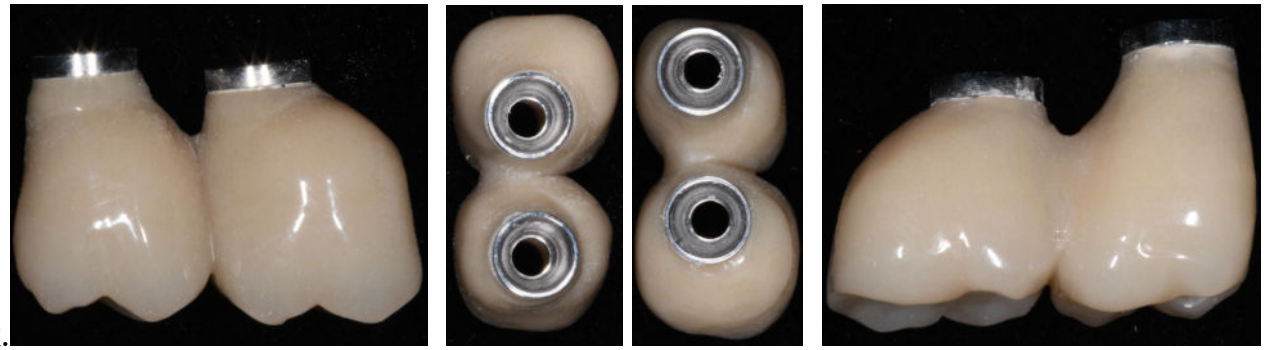
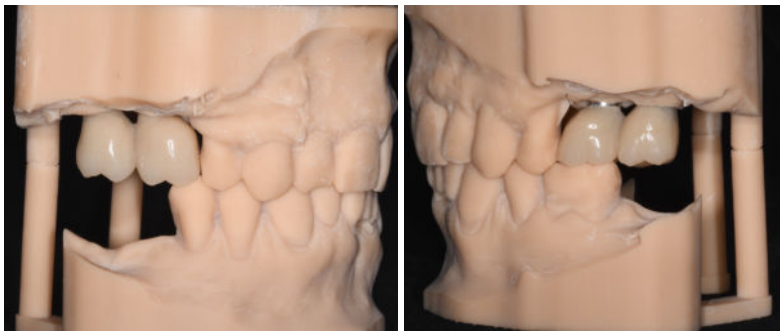


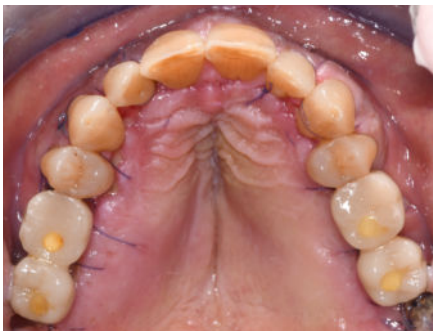
h. 

i. 

j. 

k. 

l. 

m. 

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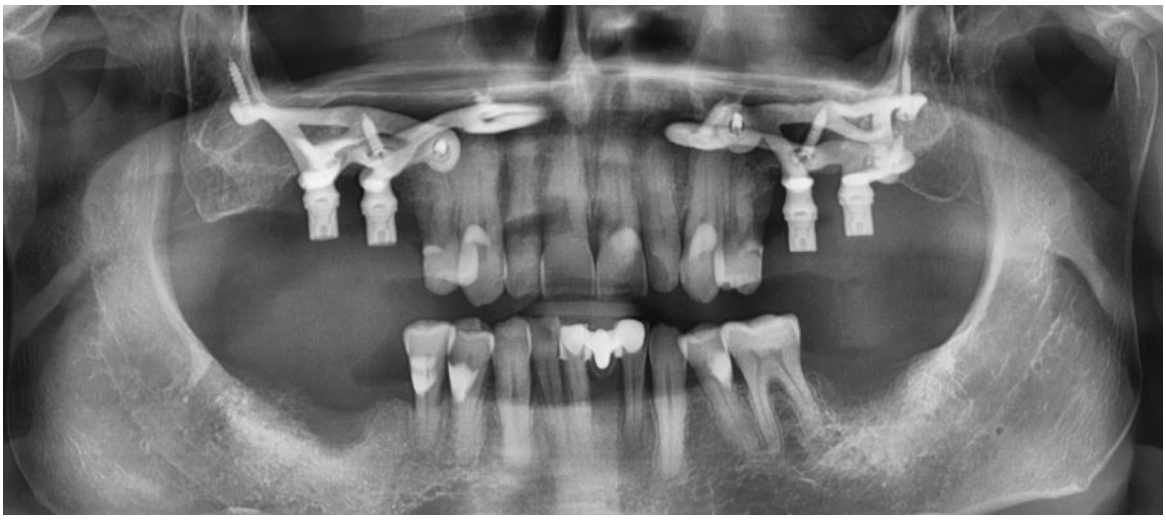

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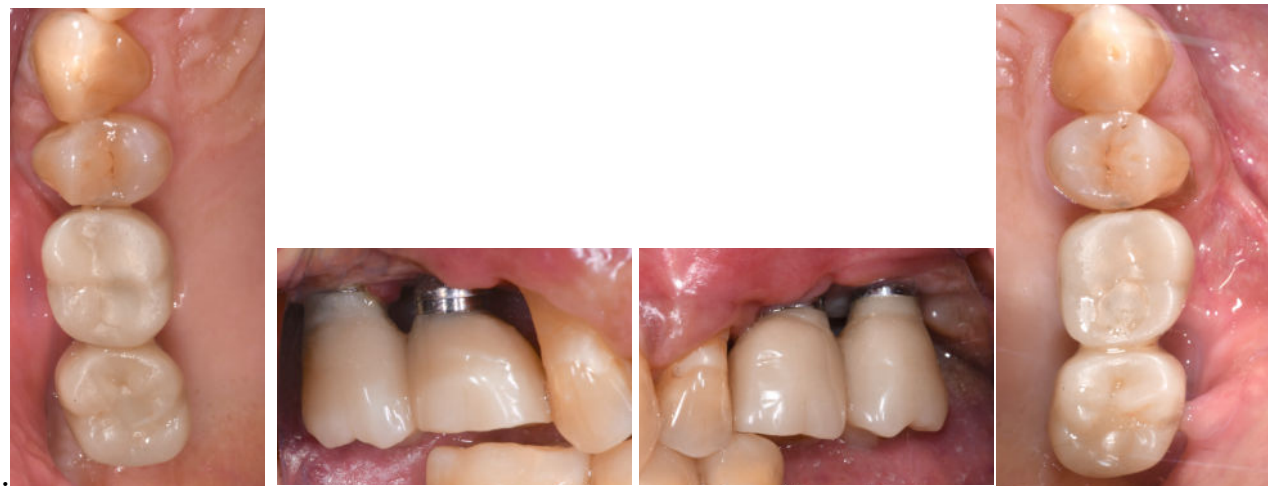


Figure 39 (Case 4). Clinical and radiographic workflow of maxillary rehabilitation using subperiosteal implants in posterior areas. a) CBCT panoramic reconstruction of the partially edentulous maxilla showing posterior bone deficiency. b) CBCT cross-sectional views illustrating the degree of alveolar bone resorption and the residual bone volume in the posterior regions. c) Intraoral occlusal view of the partially edentulous maxilla on the posterior right side. d) Intraoral buccal view showing the patient in centric occlusion. e) Intraoral occlusal view of the partially edentulous maxilla on the posterior left side. f) View of the digitally designed surgical templates for the edentulous ridges (RealGuide 5.0, 3Diemme, Italy). g) Intraoperative view showing the positioned surgical guide used for ridge alignment and reference during framework planning. h) Digital planning of the customized subperiosteal titanium framework (right, left, and occlusal views) illustrating the distribution and

angulation of fixation screws. i) Fabricated titanium framework (IUXTA-3D; BTK, Biotec S.R.L., Povolaro di Dueville, Italy) prior to surgical placement. j) Intraoperative view of the adapted and fixated metal framework on the right posterior maxilla. k) Buccal and occlusal views of the provisional crowns immediately after extraoral fabrication. l) Provisional crowns positioned on the master cast before intraoral delivery. m) Occlusal view after surgery showing flap closure with sutures and provisional crowns in place. n) 3 years follow-up panoramic radiograph confirming precise framework adaptation and stable implant fixation. o) Clinical photograph 3 years postoperatively showing the definitive prosthesis, demonstrating long-term functional stability and satisfactory esthetic integration.

6.6.5. Surgical Protocol for Narrow and Short/Ultra-short Implant Placement

Narrow implants with a diameter of 3.0 mm, as well as short implants measuring 4 mm in diameter and 4 mm in length (Safe and Nano Implants; BTK, Biotec SRL, Povolaro di Dueville, IT), were placed following a prosthetically guided approach. The procedure began with a crestal incision and the elevation of a full-thickness mucoperiosteal flap to expose the underlying alveolar bone. A surgical guide template, fabricated based on the prosthetic planning, was utilized to ensure precise implant positioning and angulation. Implant site preparation followed the standard protocol outlined in the manufacturer's instructions for use. Sequential osteotomy drills of increasing diameter were employed to prepare the implant sites. To maximize primary stability, the osteotomy sites were intentionally underprepared relative to the implant dimensions. During implant insertion, the implant motor is set to deliver a maximum insertion torque of 40 Newton - centimeters, ensuring adequate mechanical stability without compromising the surrounding bone. The implants were positioned with the implant collar's transition zone aligned at the crestal bone level. The collar portion of the implant was maintained at the level of the surrounding bone to promote optimal soft tissue integration and crestal bone preservation.

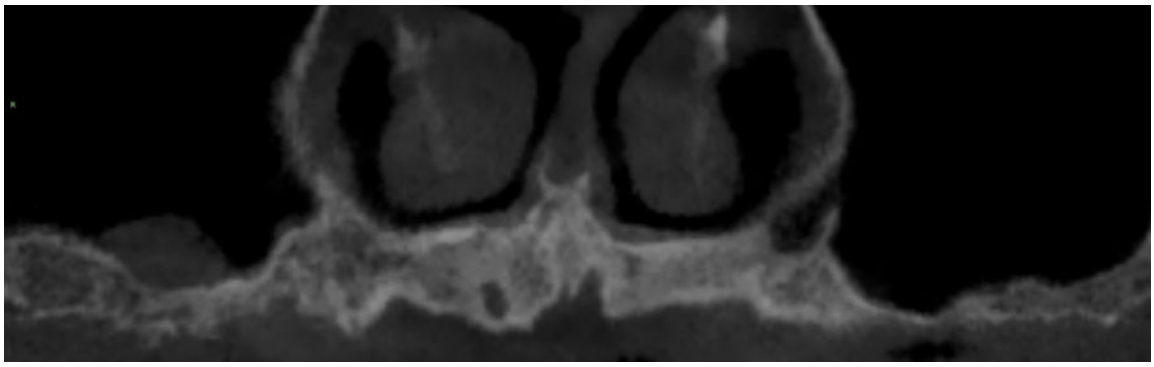
Post-Operative Instructions

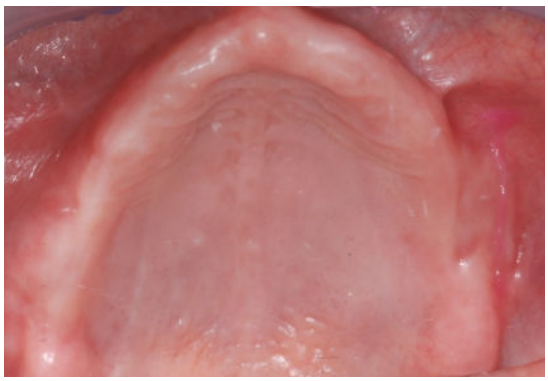
To optimize healing and reduce the risk of infection and complications, patients were provided with detailed post-operative care instructions as follows:

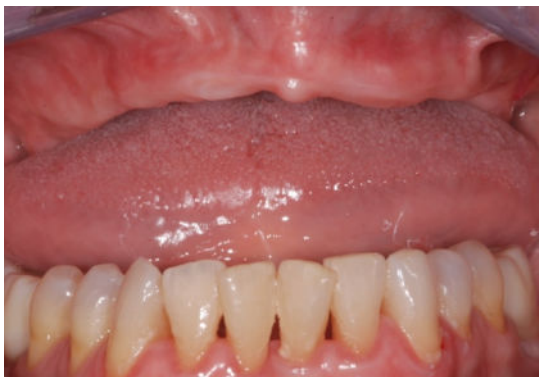
- Antibiotic Therapy: Amoxicillin 1 g orally 3 times daily for 5 days was prescribed as first-line treatment. For patients with beta-lactam allergies, Clindamycin 300 mg three times daily for five days was recommended.
- Analgesia: Ibuprofen 600 mg is advised up to 3 times daily during meals for one week. Patients were instructed to avoid taking analgesics if they experience no pain.
- Oral Hygiene: Patients should performed rinses with 0.12% Chlorhexidine mouthwash twice daily for two weeks to maintain mucosal hygiene and minimize bacterial colonization.
- Diet: A soft diet was recommended for the first two weeks post-surgery to reduce mechanical trauma to the surgical sites.

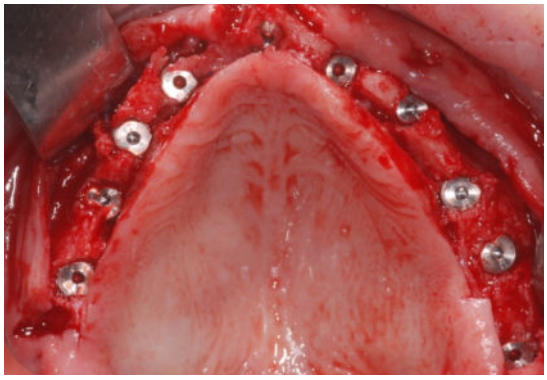
6.6.6. Prosthetic Procedures Following Narrow and Short Implant Placement

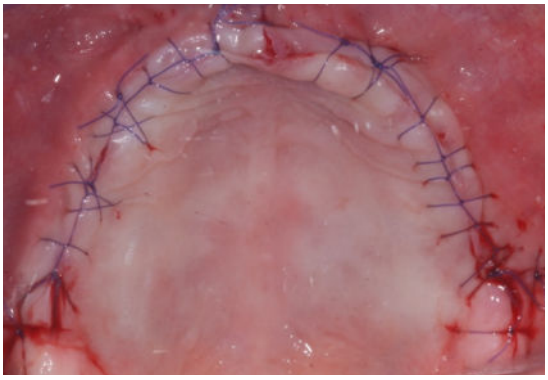
Following the surgical placement of the narrow or short/ultra-short implants, the scan abutments were placed (BTK, Biotec SRL, Povolaro di Dueville, IT), and a digital impression was obtained using an intraoral scanner to precisely capture implant positions and surrounding soft tissue morphology. The digital files were immediately transferred to the dental laboratory, where a computer-aided design (CAD) workflow was utilized to fabricate a screw-retained provisional resin prosthesis. The provisional restoration was produced through computer-aided manufacturing (CAM) and delivered to the patient within 24 hours of surgery. The prosthesis was carefully adapted intraorally, ensuring passive fit, proper occlusal contacts, and satisfactory esthetics. This immediate provisionalization allowed for early functional loading and soft tissue conditioning while maintaining patient comfort and treatment continuity (Figure 40 and 41).

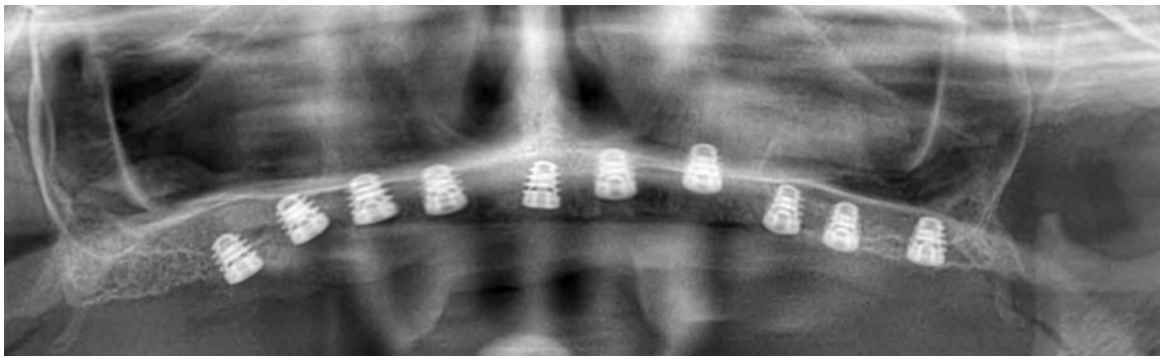
a. 

b. 

c. 

d. 

e. 

f. 

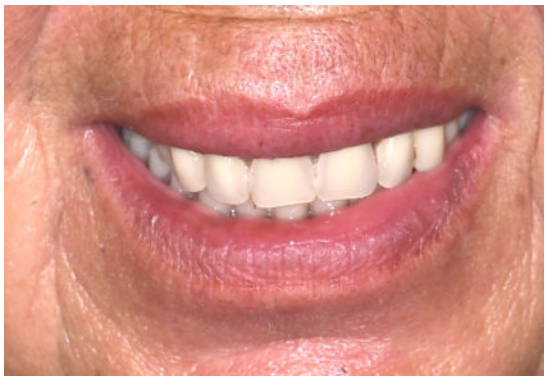
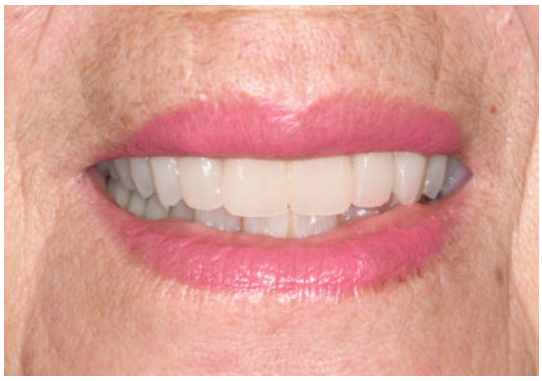
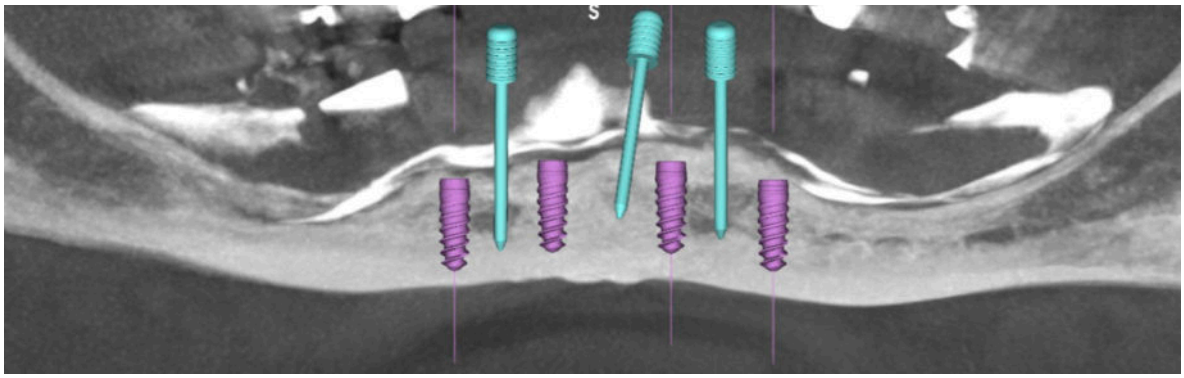
g.  h. 

Figure 40 (Case 5). Clinical and radiographic workflow of maxillary full-arch rehabilitation using short implants. a) Preoperative CBCT scan of the edentulous maxilla showing advanced alveolar bone resorption and reduced vertical bone height. b) Intraoral occlusal view of the edentulous ridge demonstrating adequate soft tissue conditions. c) Buccal view of the maxillary ridge highlighting the degree of bone atrophy. d) Intraoral view of the positioned short implants (Nano Implants D4.8 mm-L5 mm; BTK, Biotec S.R.L., Povolaro di Dueville, Italy) placed according to the digital surgical plan. e) Occlusal view after flap closure with resorbable 4-0 Vicryl sutures ensuring proper adaptation. f) Postoperative panoramic radiograph (OPT) confirming correct implant positioning and angulation. g) Preoperative extraoral photograph of the patient with the existing removable prosthesis showing reduced vertical dimension. h) Postoperative extraoral photograph after delivery of the screw-retained provisional prosthesis demonstrating restored esthetics and function (4-month follow-up).

a. 

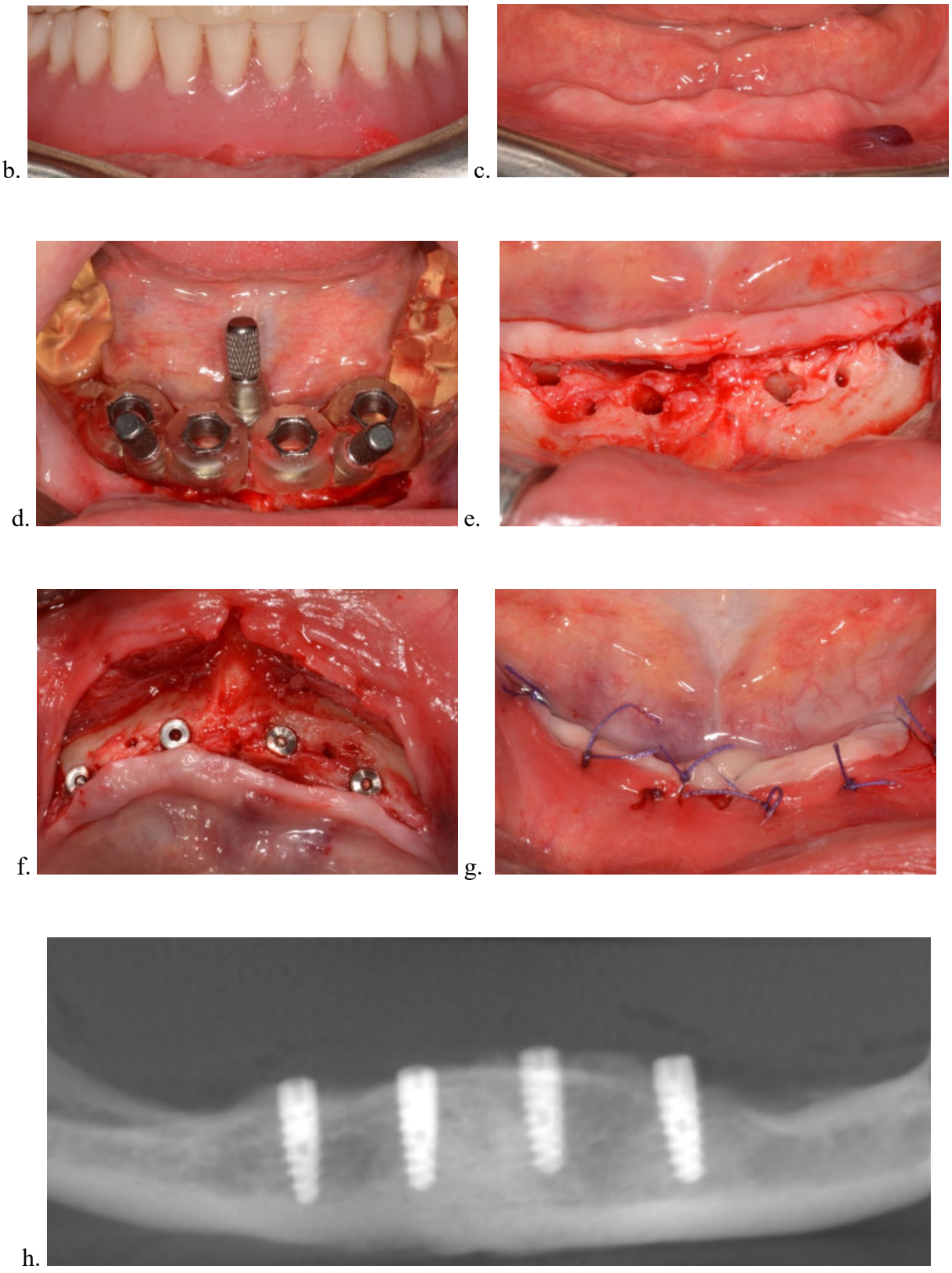


Figure 41 (Case 6). Clinical and radiographic workflow of mandibular full-arch rehabilitation using narrow implants. a) Preoperative CBCT scan of the edentulous mandible showing advanced alveolar bone resorption and reduced vertical bone height, along with digital planning for fixation pin

positioning and the placement of four short implants (BT Safe Bone MTH, Ø3.3 × 10 mm; BTK, Biotec S.R.L., Povolaro di Dueville, Italy). b) Intraoral buccal view of the patient wearing the old removable prosthesis. c) Buccal view of the atrophic mandibular ridge highlighting the extent of bone deficiency. d) Intraoral view showing the positioned surgical guide prior to implant placement. e) Intraoperative view of the osteotomy sites prepared according to the digital surgical plan. f) Occlusal view following implant placement. g) Flap closure with resorbable sutures ensuring proper adaptation of the soft tissues. h) Postoperative CBCT scan confirming correct implant positioning and angulation.

6.7. Follow-Up and Prosthetic Adjustments

- 3 Days Post-Delivery: Patients are recalled for an initial evaluation of peri-implant soft tissue healing and occlusal assessment to identify any necessary adjustments.
- 10 Days Post-Delivery: A follow-up appointment is scheduled for suture removal and to reinforce oral hygiene instructions.
- 1 Month Post-Delivery: Patients return for a comprehensive check of peri-implant tissues and occlusion, accompanied by professional oral hygiene reinforcement.
- 3 Months Post-Delivery: Conventional implant-level impressions are taken at the abutment level for zygomatic implants to fabricate the definitive prosthesis.

6.8. Definitive Prosthesis Delivery

Four months after the placement of the provisional restoration, once satisfactory soft tissue maturation and functional adaptation are achieved, the definitive screw-retained prosthesis is fabricated and delivered. The final prosthesis is designed using CAD/CAM technology to ensure an accurate passive fit over the subperiosteal or endosseous framework. It typically consists of a titanium base structure that provides mechanical strength and long-term stability, veneered with composite or ceramic materials for optimal esthetics, wear resistance, and biocompatibility.

The framework is milled from grade V titanium alloy (Ti-6Al-4V), chosen for its superior mechanical strength, corrosion resistance, and biocompatibility. The veneering layer is composed of microhybrid composite resin or high-performance polymer (such as PMMA or PEEK-based composites), which provides favorable esthetics, low weight, and shock absorption under functional loads. In cases requiring enhanced esthetics, ceramic veneering (lithium disilicate or feldspathic porcelain) may be employed for anterior regions. The combination of these materials ensures both biomechanical durability and natural appearance.

During the delivery appointment, the passive fit of the framework is verified both clinically and radiographically before final screw tightening. Occlusal contacts are adjusted to distribute functional loads evenly across the arch, minimizing stress concentrations on the implants and surrounding bone. Once the prosthesis is secured, screw access channels are sealed with composite resin.

Occlusal contacts are meticulously refined to achieve even bilateral distribution in centric relation and to minimize lateral interferences during excursive movements. This occlusal scheme reduces the risk of overload and mechanical complications such as screw loosening or framework fracture.

Comprehensive oral hygiene instructions are reinforced, emphasizing the use of interdental brushes, water flossers, and antimicrobial mouth rinses to maintain peri-implant health. Patients are also educated on recognizing early signs of mechanical or biological complications, such as screw loosening or mucosal inflammation. Finally, patient satisfaction is recorded through structured questionnaires assessing comfort, esthetics, speech, and overall functional performance.

6.9. Maintenance and Follow-Up Visits

A structured maintenance program is implemented to support the long-term success of the rehabilitation. Patients are scheduled for recall visits every six months, or more frequently if risk factors such as smoking, history of periodontitis, or parafunctional habits are identified.

At each maintenance appointment, peri-implant soft tissues are evaluated for inflammation, bleeding on probing (BOP), plaque accumulation, and mucosal stability. Radiographic control (periapical or panoramic) is performed annually to monitor marginal bone stability and framework adaptation. Torque verification of prosthetic screws is routinely conducted at the 6-month visit and subsequently on an annual basis to ensure continued mechanical integrity.

Professional mechanical debridement is performed using non-abrasive plastic or titanium-coated instruments and low-abrasion polishing pastes to avoid scratching the prosthetic surfaces. The occlusion is reassessed to detect any premature contacts or changes in load distribution, which could lead to biomechanical complications.

This comprehensive follow-up strategy ensures biological health, mechanical stability, and patient satisfaction over time, promoting the longevity and success of the implant-supported rehabilitation.

Visit	Timing	Procedures
Visit 1	Screening (Before Study)	Eligibility assessment, informed consent, medical history collection, CBCT evaluation
Visit 2	1 week before surgery	Professional oral hygiene
Visit 3	Surgery day	Implant placement, CBCT, clinical photos, digital impressions, provisional prosthesis delivery within 48 hours
Visit 4	7 days post-op	Clinical examination, clinical photos
Visit 5	14 days post-op	Suture removal, clinical examination, clinical photos, Oral Hygiene Index-Patient (OHI-P) questionnaire completion
Visit 6	30 days post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, OHI-P questionnaire, periodontal charting

Visit 7	3 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, periodontal charting
Visit 8	6 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, periodontal charting
Visit 9	12 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, OHI-P questionnaire, periodontal charting
Visit 10	24 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, OHI-P questionnaire, periodontal charting
Visit 11	36 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, OHI-P questionnaire, periodontal charting
Visit 12	48 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, OHI-P questionnaire, periodontal charting
Visit 13	60 months post-op	Clinical evaluation, clinical photos, soft tissue healing assessment, OHI-P questionnaire, periodontal charting

6.10. Blind Evaluation Parameters

The following parameters were assessed in a blinded manner by an independent evaluator (statistician) at the time of delivery of the prostheses and subsequently at 1-, 2-, 3-, 4-, and 5-year post-loading intervals to ensure objective longitudinal comparison:

1. Patient Satisfaction

   The subjective satisfaction of each patient regarding the prosthetic rehabilitation was systematically evaluated using a standardized questionnaire (OHIP) and visual analogue scale (VAS). The assessment encompassed multiple domains, including overall comfort, masticatory efficiency, phonetics, esthetic appearance, and psychological well-being

following prosthetic rehabilitation. This data allowed for a comprehensive analysis of patient-centered outcomes and long-term satisfaction trends over the follow-up period.

2. Implant Stability

At each follow-up interval, the definitive prosthesis was carefully removed under sterile conditions to permit individual assessment of implant stability. The mechanical stability of the zygomatic and conventional implants was evaluated by applying a controlled reverse torque of 15 Ncm to the prosthetic abutments using a calibrated torque wrench. No mobility or rotation was expected to occur if osseointegration had been preserved. Any perceptible movement or loss of resistance was recorded as indicative of potential biological or mechanical compromise. The evaluation was performed without exceeding the reverse torque threshold to prevent implant or abutment damage.

In addition to torque testing, clinical examination was performed to assess peri-implant tissue health, including absence of pain, inflammation, or exudation, and radiographic analysis and continuity of bone-to-implant contact. All findings were documented using standardized clinical forms and radiographic templates to allow for consistent longitudinal comparison.

6.11. Statistical Analysis

All patient data were collected, tabulated, and entered into a database for statistical analysis. The analysis was planned to be primarily descriptive, with exploratory analyses to identify potential associations between patient/procedural factors and clinical outcomes.

Descriptive Statistics

Descriptive statistics were planned to summarize all baseline variables.

- Continuous variables, such as patient age, insertion torque, and follow-up duration, would be assessed for normality. Data would be presented as mean\pm standard deviation (SD) if

normally distributed, or as median and interquartile range (IQR) if non-normally distributed. Minimum and maximum values (range) would also be reported.

- Categorical variables, including sex, treatment center, smoking status, diabetes, implant type, and loading protocol, would be summarized using frequencies (n) and percentages (%).

The primary outcomes - the overall incidence of complications and the frequency of specific complication types (e.g., mucosititis, hardware exposure) - would also be reported as frequencies and percentages.

Inferential and Comparative Analysis

To investigate potential risk factors for complications, a comparative analysis was planned. The cohort would be stratified into two groups: "Complications (Yes)" and "Complications (No)."

- For categorical factors (e.g., Smoking vs. Non-smoking, Implant Type, Diabetes Yes/No, Loading Protocol), the association with complication occurrence would be assessed using the Chi-squared test or, more likely given the small sample size and low expected cell counts, the Fisher’s Exact Test.
- For continuous factors (e.g., patient age, insertion torque), the difference between the complication and no-complication groups would be assessed. An independent samples t-test would be used for normally distributed data, while a Mann-Whitney U test would be used for non-normally distributed data.

All statistical tests would be two-tailed, and a p-value of < 0.05 would be considered the threshold for statistical significance. All analyses would be conducted using standard statistical software (StataSoftware).

7. RESULTS

A total of 22 patients were included in the study cohort. The mean age of the patients at the time of surgery was 62.2 years, with a median age of 63.5 years. The patient ages ranged from 29 to 76 years. The sex distribution within the cohort was not evenly balanced, consisting of 17 female patients (77.0%) and 5 male patients (23.0%).

The vast majority of patients (n=20, 90.0%) were treated at Centre 1 (Bologna), while the remaining 2 patients (9.1%) were treated at Centre 2 (Catanzaro). A complete summary of these baseline characteristics is presented in Table 3.

Characteristic	Category	Count (N=22)	Percentage (%)
Total Patients		**22**	**100%**
Age (Years)	Mean	62.2	
	Median	63.5	
	Range (Min-Max)	29 - 76	
Sex	Female	17	77.0%
	Male	5	23.0%
Treatment Centre	Centre 1 (Bologna)	20	90.0%
	Centre 2 (Catanzaro)	2	10 %

Table 3. Patient Demographic Profile.

The systemic health profile and lifestyle risk factors of the 22-patient cohort were evaluated, with findings detailed in Table 4. A significant portion of the study population consisted of non smokers. 7 patients (31.8%) were active smokers, while the remaining 15 patients (68.2%) were non-smokers.

In addition to smoking habits, the prevalence of diabetes mellitus was also assessed. One patients (4.5%) had a pre-existing diagnosis of diabetes. Consequently, the majority of the cohort, 21 patients

(95.5%), were non-diabetic. These figures indicate that a substantial subset of the patients presented with one or more significant clinical risk factors.

Risk Factor	Status	Count (N=22)	Percentage (%)
Smoking	Yes (Smoker)	7	31.8%
	No (Non-smoker)	15	68.2%
Diabetes	Yes	1	4.5%
	No	21	95.5%

Table 4. Patient Clinical Risk Factor Prevalence.

The surgical and prosthetic characteristics for the 22 procedures are summarized in Table 5. Four distinct categories of implants were utilized across the cohort. Subperiosteal implants were the most common, accounting for exactly half of all cases (n=11, 50.0%). Zygomatic implants and short implants were used with equal frequency, with 5 cases each (22.7%). A single patient (4.5%) received a narrow implant. Regarding the prosthetic protocol, an immediate loading strategy was overwhelmingly preferred, applied in 21 of the 22 cases (95.5%). Only one patient (4.5%) underwent a 3-month delayed loading protocol. The anatomical location of the implants was also recorded. 13 procedures (59%) were performed in the upper arch and 9 (41%) in the lower arch. An additional 8 cases (36.3%) were specified as being in specific quadrants.

Characteristic	Category	Count (N=22)	Percentage (%)
Implant Type	Subperiosteal	11	50.0%
	Zygomatic	5	22.7%
	Short	5	22.7%
	Narrow	1	4.5%
Implant Loading	Immediate	21	95.5%

	3 months	1	4.5%
Jaw	Upper Arch	13	59%
	Lower Arch	9	41%
	Specific Quadrants	8	36.3%

Table 5. Implant and Procedural Characteristics.

A summary of the post-operative monitoring period for the entire 22-patient cohort is presented in Table 6. Patients were followed for a mean duration of 22 months. The median follow-up time was 20 months. The close alignment of the mean and median values indicates that the follow-up data is relatively symmetrically distributed, without significant skewing from extreme outliers.

This consistency is observed despite a very wide range in monitoring times. The data includes patients with very short-term outcomes, with a minimum follow-up of only 3 months, as well as patients with substantial long-term data, with the maximum follow-up extending to 57 months (4 years and 9 months). This broad observation window provided a comprehensive view of both early and long-term outcomes.

Statistic	Follow-up Duration (in Months)
Mean	22 months
Median	20 months
Minimum	3 months
Maximum	57 months (4 years and 9 months)
Total Patients	22

Table 6. Patient Follow-up Duration Statistics.

The primary clinical endpoint assessed was the incidence of post-operative complications across the entire follow-up period for the 22-patient cohort. The findings, as summarized in Table 7, reveal that the majority of patients (N=16), representing 72.7% of the study population, remained entirely complication-free.Conversely, 6 patients (7 complications), corresponding to 27.3% of the cohort, experienced one or more adverse events or complications at some point after their procedure. This establishes an overall complication rate of just over one in four patients for this study.

Outcome	Count (N=22)	Percentage (%)
Patients with 1 or more complications	6	27.3%
Patients with 0 complications	16	72.7%

Table 7. Overall Patient Complication Rate.

A detailed breakdown of the specific biological complications observed in the 6 affected patients is provided in Table 8. A total of 7 distinct complication events were recorded. The most frequently observed complication was mucosititis, which accounted for 5 of the events. Hardware exposure was the other complication type identified, occurring 2 times. The total of 7 events among 6 patients indicates that one patient experienced both mucosititis and hardware exposure.

Biological Complication Type	Frequency (Total=7)
Mucosititis	5
Hardware Exposure	2

Table 8. Frequency and Type of Biological Complications

Insertion torque values recorded during surgery were analyzed and are presented in Tables 9a and 9b. Insertion torque was successfully measured for a total of 44 endosseous implants. All measured implants achieved a torque of at least 25 Ncm.

- BTK, BT Zygomax (Zygomatic Implants): 5 patients received a total of 20 zygomatic implants (4 per patient). This group demonstrated the highest and most consistent primary stability, with an average insertion torque *per implant* of 56.15 Ncm (Range: 45–67 Ncm). The average torque *per patient* was similarly high at 56.65Ncm.
- BTK, Safe implants (Narrow Implants): 1 patient received 4 narrow implants. This procedure achieved an average torque of 44.75 Ncm (Range: 38–55 Ncm).
- BTK, Nano implants (Short Implants): 5 patients received a total of 20 short implants. This group showed the widest variation in torque values, ranging from 25 Ncm to 45 Ncm. The average torque *per implant* was 37.50 Ncm. One patient in this group (with 10 implants) had a lower mean torque of 34.70 Ncm, while another (with 2 implants) had a higher mean torque of 44.00 Ncm. Overall, across all 44 measured implants, the mean insertion torque was 46.64, indicating excellent overall primary stability for the endosseous implants used in the study.

Implant Type	**Total Procedures**	**Total Implants Measured**	**Mean Torque (Ncm)**	**Std. Deviation (Ncm)**	**Torque Range (Min-Max) (Ncm)**
BTK, Iuxta 3D Implants	11	0	N/A	N/A	N/A
BTK, BT Zygomax	5	20	56.15	6.45	45 - 67
BTK, Safe implants	1	4	44.75	7.37	38 - 55
BTK, Nano implants	5	20	37.50	5.61	25 - 45
Overall	**11 (with torque)**	**44**	**46.64**	**10.70**	**25 - 67**

Table 9a. Insertion Torque Statistics by Implant (N=44 Implants).

Implant Type	Patient/Procedure	Implants per Patient	Mean Torque per Patient (Ncm)
BTK, Iuxta 3D	11 Patients	0	N/A
BTK, BT Zygomax	Zygomax Patient 1	4	52.50
	Zygomax Patient 2	4	52.25
	Zygomax Patient 3	4	59.75
	Zygomax Patient 4	4	57.25
	Zygomax Patient 5	4	61.50
	Zygomax Group Avg (5 Patients)	**4.0**	**56.65**
BTK, Safe implants	P1	4	44.75
	Safe Group Avg (1 Patient)	**4.0**	**44.75**
BTK, Nano implants	P1	10	34.70
	P2	2	42.50
	P3	3	39.00
	P4	3	37.67
	P5	2	44.00
	Nano Group Avg (5 Patients)	**4.0**	**39.57**
Overall (11 Patients)		**4.0**	**47.81**

Table 9b. Insertion Torque Statistics by Patient / Procedure (N=11 Patients).

The occurrence of complications was analyzed by stratifying the cohort based on the implant type received, with the results presented in Table 10. This cross-tabulation details the distribution of the 7 total complications among the four different implant categories. Complications were observed in two of the four implant groups. The subperiosteal group (n=11) accounted for 5 complications among 4 patients (a 36.4% patient-level complication rate). One patient experienced two complications at different time points. In the zygomatic implant group (5 patients), 2 patients (40.0%) experienced a complication. No complications were reported for any of the 5 patients who received short implants or for the single patient who received a narrow implant. All 7 adverse events recorded in the study occurred in patients treated with either subperiosteal or zygomatic implants.

Implant Type	**Total Patients**	**Total Implants**	**Patients with Complications**	**Complication Rate (Patient-Level)**	**Complication Type(s)**
Subperiosteal	11	N/A	4	71.4%	3 Mucositis and 2 Hardware Exposure
Zygomatic	5	20	2	28.6%	2 Mucositis
Narrow Implants	1	4	0	0.0%	None
Short Implants	6	24	0	0.0%	None
Total	**22**	**48 Implants**	**6**	**27.3%**	**5 Mucositis, 2 Hardware**

Table 10. Complications by Implant Type.

An analysis of complication rates was performed by stratifying the 22-patient cohort by procedural and demographic risk factors. The findings are summarized in Table 11. A dramatic and highly

significant difference was observed based on sex. All 4 male patients (100%) in the study experienced a complication. In stark contrast, only 2 of the 17 female patients (11.7%) experienced a complication. Smoking status also showed a clear difference in outcomes. The 7 patients identified as smokers had a complication rate of 42.8% (3 of 7). This was more than double the 20.0% rate (3 of 15) observed in the non-smoking group. Regarding the loading protocol, 21 of the 22 patients underwent immediate loading, and all 6 of the study's complications occurred within this group (a 28.6% rate). The single patient who received a delayed loading protocol (0.0%) did not experience any complications. The data for diabetes shows 1 patient was identified as diabetic, and that patient experienced a complication (100% rate). No patients were listed in the non-diabetic category. The "Age Group" data was not available for analysis.

Risk Factor	**Category**	**Total Patients (N=22)**	**Patients with Complications**	**Complication Rate (%)**
Loading Protocol				
	Immediate Loading	21	6	28.6%
	Delayed Loading	1	0	0.0%
Smoking				
	Smoker (Yes)	7	3	42.8%
	Non-Smoker (No)	15	3	20.0%
Diabetes				
	Diabetic (Yes)	1	1	100%
	Non-Diabetic (No)	0	0	0.0%
Sex				
	Female	17	2	11.7%
	Male	4	4	100%
Age Group				

	≥ 65 years	8	3	37.5%
	< 65 years	14	3	21.4%

Table 11. Complications in Relation to Patient Factors and Loading Protocol.

A detailed breakdown of the adverse events is presented in Table 12. A total of 7 distinct complications were recorded among 6 patients. The most frequently observed complication was Mucositis, which occurred 5 times, followed by exposure, which occurred twice. These 7 events were distributed among the 6 patients, indicating one patient (P2) experienced two separate complications (Mucositis and Hardware exposure), while the other five patients experienced one each. All recorded complications were associated with two implant types:

- Subperiosteal: 5 complications (4 patients)
- Zygomatic: 2 complications (2 patients)

The time of onset for these complications varied significantly, with the earliest event (Mucositis) recorded at 3 months and the latest (Mucositis) recorded at 3 years post-operatively (Figure 43).

Patient ID	Implant Type	Complication Type	Time of Onset
P1	Subperiosteal	Mucositis	3 year
P2	Subperiosteal	Mucositis	3 months
	Subperiosteal	Hardware exposure	1 year
P3	Subperiosteal	Mucositis	2 year
P5	Subperiosteal	Hardware exposure	10 months
P12	Zygomatic	Mucositis	1 year
P13	Zygomatic	Mucositis	1 year

Summary			
	Total Complications	7	

Table 12. Timing of Complication Occurrence.

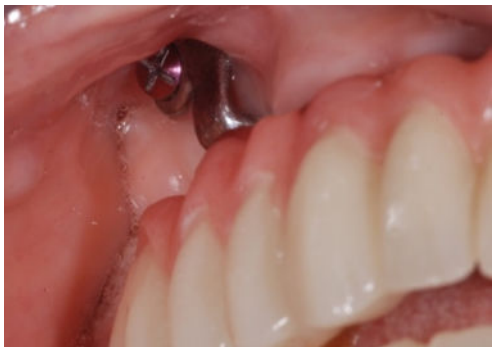
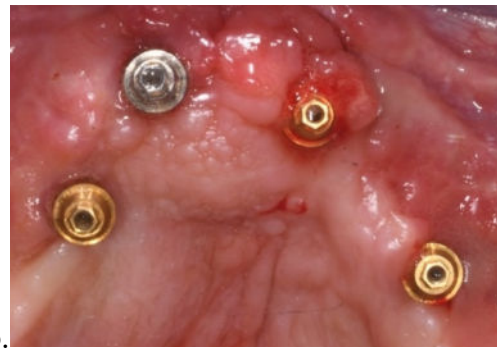
a.  b. 

Figure 43. Examples of complications: (a) hardware exposure of the subperiosteal implant in the upper right maxilla; (b) peri-implant mucositis affecting the zygomatic implant.

A specific protocol was followed to resolve these adverse events:

- Mucosititis: For cases of early mucosititis, a non-surgical approach was used, consisting of Chlorhexidine 0.2% rinses for 2 weeks. In more persistent cases, the protocol involved removal of the prosthesis to allow for a thorough professional debridement and plaque removal of the implant components and surrounding tissues.
- Hardware Exposure: Patients presenting with hardware exposure were managed conservatively. This involved placement in a follow-up program with periodic X-rays, professional prophylaxis, and reinforcement of oral hygiene instructions to maintain the site and prevent further progression.

A total of 22 patients, rehabilitated with four different implant types, were assessed. For statistical comparison, patients were categorized into three groups: Subperiosteal (n=11), Zygomatic (n=5), and Short/Narrow (n=6, comprising 5 short implants and 1 narrow implant). Patient satisfaction was evaluated using a Visual Analogue Scale (VAS) for post-surgical pain and the Oral Health Impact Profile (OHIP-14) questionnaire for quality of life at longitudinal follow-ups (Table 13 and 14). Post-

surgical pain was assessed once per patient using the VAS (0-10, where 10 = "worst pain imaginable"). The Zygomatic implant group reported the highest mean pain score (M = 7.80, SD = 0.84), while the Short/Narrow implant group reported the lowest (M = 4.67, SD = 0.82).

Tables 15 and Graph 1 provides a descriptive summary of these VAS scores by implant group. A one-way ANOVA was conducted to compare pain scores between the three groups. The analysis revealed a statistically significant difference in mean VAS scores, $F(2, 19) = 10.34$, $p = 0.001$. Post-hoc comparisons using Tukey's HSD test indicated that the mean VAS score for the Zygomatic group (M = 7.80) was significantly higher than both the Subperiosteal group (M = 6.27, $p = 0.021$) and the Short/Narrow group (M = 4.67, $p < 0.001$). The difference between the Subperiosteal and Short/Narrow groups was not statistically significant ($p = 0.052$).

Patient ID	Implant Type	Total Follow-Up	VAS Score (0-10)
P1	Subperiosteal	4 years	6
P2	Subperiosteal	2 years 6 months	7
P3	Subperiosteal	3 years 5 months	5
P4	Subperiosteal	3 years 5 months	6
P5	Subperiosteal	1 year	7
P6	Subperiosteal	1 year	5
P7	Subperiosteal	2 years	6
P8	Subperiosteal	2 years	8
P9	Subperiosteal	2 years	7
P10	Subperiosteal	7 months	5
P11	Subperiosteal	7 months	6
P12	Zygomatic	1 year 9 months	8
P13	Zygomatic	1 year 2 months	7

P14	Zygomatic	1 year 9 months	9
P15	Zygomatic	1 year	8
P16	Zygomatic	1 year 2 months	7
P17	Narrow	3 months	4
P18	Short	4 months	5
P19	Short	1 year 6 months	4
P20	Short	4 years 9 months	6
P21	Short	2 years 4 months	5
P22	Short	1 year 6 months	4

Table 13. VAS Pain Score (Out Of 10) Taken From Each Patient After Their Surgery.

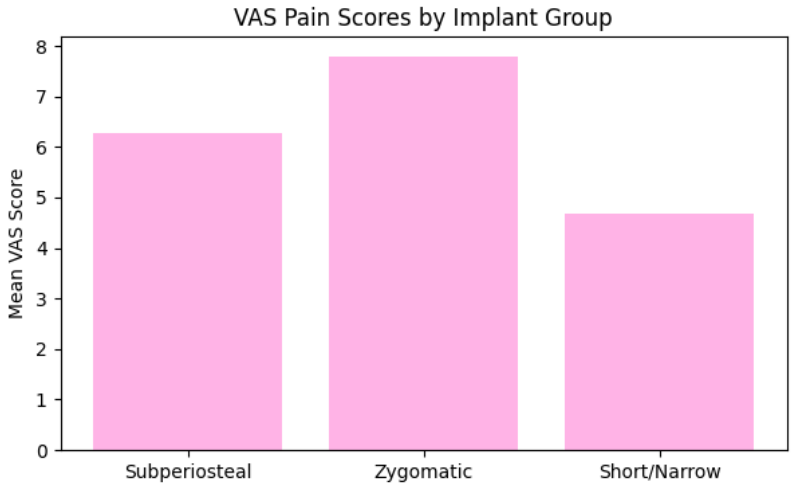
Patient ID	Implant Type	Total Follow-Up	OHIP at Delivery	OHIP at 1 Year	OHIP at 2 Years	OHIP at 3 Years	OHIP at 4 Years
P1	Subperiosteal	4 years	32	10	6	4	4
P2	Subperiosteal	2 years 6 months	28	8	5	N/A	N/A
P3	Subperiosteal	3 years 5 months	35	12	7	5	N/A
P4	Subperiosteal	3 years 5 months	30	9	6	6	N/A
P5	Subperiosteal	1 year	25	7	N/A	N/A	N/A
P6	Subperiosteal	1 year	29	10	N/A	N/A	N/A
P7	Subperiosteal	2 years	33	11	8	N/A	N/A
P8	Subperiosteal	2 years	31	9	7	N/A	N/A

P9	Subperiosteal	2 years	27	8	5	N/A	N/A
P10	Subperiosteal	7 months	24	N/A	N/A	N/A	N/A
P11	Subperiosteal	7 months	26	N/A	N/A	N/A	N/A
P12	Zygomatic	1 year 9 months	40	14	N/A	N/A	N/A
P13	Zygomatic	1 year 2 months	38	12	N/A	N/A	N/A
P14	Zygomatic	1 year 9 months	42	15	N/A	N/A	N/A
P15	Zygomatic	1 year	39	13	N/A	N/A	N/A
P16	Zygomatic	1 year 2 months	37	11	N/A	N/A	N/A
P17	Narrow	3 months	22	N/A	N/A	N/A	N/A
P18	Short	4 months	19	N/A	N/A	N/A	N/A
P19	Short	1 year 6 months	23	6	N/A	N/A	N/A
P20	Short	4 years 9 months	34	10	7	4	3
P21	Short	2 years 4 months	28	7	5	N/A	N/A
P22	Short	1 year 6 months	25	8	N/A	N/A	N/A

Table 14. OHIP-14 Score (Out Of A Maximum Of 56) For Each Patient At Each Required Time Point.

Implant Group	n	Mean VAS Score (0-10)	Std. Deviation (SD)
Subperiosteal	11	6.27	1.10
Zygomatic	5	7.80	0.84
Short/Narrow	6	4.67	0.82
Total	**22**	**6.36**	**1.33**

Table 15. Post-Surgical Pain (VAS) Scores by Implant Group.

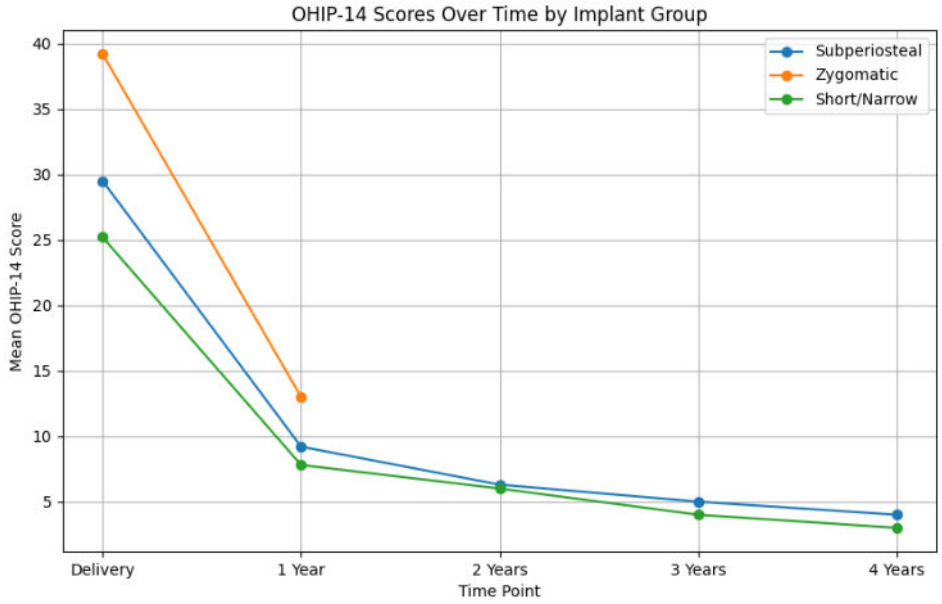


Graph 1. Average post-surgical pain scores by implant type, highlighting higher discomfort in the zygomatic group.

Oral health-related quality of life was measured using the OHIP-14 questionnaire (total score 0-56, where 0 = “no impact” and 56 = “severe impact”). Questionnaires were administered at prosthesis delivery and at subsequent annual follow-ups, according to each patient’s follow-up duration. Table 16 presents the longitudinal mean OHIP-14 scores for all groups at each available time point. As shown, the number of patients (n) eligible for follow-up decreases at later time points (Table 16 and Graph 2).

Implant Group	n (at Delivery)	At Prosthesis Delivery	At 1 Year	At 2 Years	At 3 Years	At 4 Years
Subperiosteal	11	29.5 ± 3.8	9.2 ± 1.6 (n=9)	6.3 ± 1.1 (n=7)	5.0 ± 1.0 (n=3)	4.0 (n=1)
Zygomatic	5	39.2 ± 1.9	13.0 ± 1.4 (n=5)	N/A (n=0)	N/A (n=0)	N/A (n=0)
Short/Narrow	6	25.2 ± 5.6	7.8 ± 1.7 (n=4)	6.0 ± 1.4 (n=2)	4.0 (n=1)	3.0 (n=1)

Table 16. Longitudinal OHIP-14 Total Scores (Mean ± SD) by Implant Group and Time.



Graph 2. Longitudinal improvement in oral health-related quality of life across implant groups over time (Lower scores indicate better oral health–related quality of life).

8. DISCUSSION

The management of severe alveolar ridge atrophy continues to represent one of the most demanding and complex aspects of implant dentistry. Traditionally, the gold standard for achieving fixed prosthetic rehabilitation in such cases involved extensive, multi-stage bone augmentation procedures aimed at recreating sufficient alveolar volume to permit conventional endosseous implant placement. However, these interventions are often associated with increased morbidity, prolonged treatment times, higher costs, and unpredictable outcomes in severely resorbed jaws. In recent years, the clinical paradigm has shifted toward graftless, minimally invasive solutions that seek to restore function and esthetics without the need for extensive reconstructive surgery [121]. Among these, the reintroduction and technological evolution of patient-specific, CAD/CAM-fabricated subperiosteal implants - alongside the established use of alternative anchorage systems such as zygomatic implants - have significantly broadened the therapeutic possibilities for patients with advanced maxillomandibular atrophy, offering reliable and efficient alternatives to conventional augmentation-based protocols [122].

The present prospective, multicenter, randomized controlled clinical trial aims to fill a critical void highlighted in the existing literature - namely, the absence of high-quality comparative evidence assessing the safety, clinical efficacy, and patient-reported outcomes of contemporary graftless rehabilitation strategies within a unified, methodologically robust framework. While numerous case reports and retrospective series have demonstrated promising results for both customized subperiosteal implants and alternative anchorage methods such as zygomatic, short, and narrow implants, the lack of direct comparative trials has limited the establishment of clear clinical guidelines[125, 51]. Therefore, the primary objective of this investigation was to evaluate and compare the incidence of intraoperative and postoperative complications associated with custom-made subperiosteal implants (IUXTA-3D) versus conventional endosseous implant approaches - including zygomatic, narrow-diameter, and short implants - in the rehabilitation of severely atrophic maxillae

and mandibles. To the best of our knowledge, this is the first study to directly compare these distinct implant types within a randomized controlled design.

Overall, the findings of this randomized clinical trial indicate that all treatment modalities were capable of achieving successful immediate-loading protocols, providing stable, fixed prosthetic rehabilitation in patients presenting with severe maxillomandibular atrophy. Nonetheless, the comparative analysis revealed distinct clinical profiles among the different implant types, particularly regarding surgical morbidity, postoperative discomfort, and the incidence and nature of complications. These variations underscore the importance of individualized treatment planning, where the selection of a specific implant solution should be guided not only by anatomical and biomechanical factors but also by patient-specific risk profiles and tolerance for surgical invasiveness. The comparative assessment of complication patterns across implant types provides valuable insight into the biological and technical behavior of each graftless modality under clinical conditions. Differences in intraoperative challenges, postoperative healing responses, and early functional adaptation reflect the inherent contrasts in design principles, surgical approach, and load distribution mechanisms between subperiosteal, zygomatic, and endosseous implant systems [99].

Complications following implant therapy ranged from mild, self-limiting events to more serious issues that could affect overall treatment success. Early postoperative symptoms, including pain, swelling, and inflammation, were commonly observed but generally manageable, consistent with reports from Anitua and El-Sawy [122]. More significant complications, such as infection and implant failure, occurred less frequently but remain clinically significant. For instance, Ayhan et al. (2024) reported an implant failure rate of 13.3%, predominantly due to infection, and Nemtoi et al. (2022) also identified infection as a major contributor to early implant loss [114,118]. Cerea et al. (2019) described a single case of implant failure in a smoker, highlighting the influence of patient-specific risk factors [112]. These observations emphasize that the success of implant rehabilitation depends heavily on surgical technique, systemic health status, and postoperative management.

Prosthetic complications, such as ill-fitting restorations or fractures of provisional prostheses, have also been reported in multiple studies. The implementation of fully digital workflows by Anitua, El-Sawy, and Ayhan was associated with fewer prosthetic issues [117,121,122], likely due to the enhanced precision of CAD/CAM-fabricated components and better anatomical adaptation, which in turn improves clinical outcomes and patient satisfaction. Nonetheless, Cerea et al. noted occasional prosthetic failures, particularly with earlier implant designs, emphasizing that digital workflows, while advantageous, do not entirely eliminate mechanical complications [112].Among all complications, implant exposure remains the most frequently encountered, although its long-term impact on implant survival and its potential link to mucositis remain poorly defined. Infection continues to be a primary concern, as it directly affects implant longevity. Several studies, including Nemtoi et al. (2022), Ayhan et al. (2024), and Marconcini et al. (2023), identified infection as a leading cause of early implant loss [114,115,117]. These varying findings highlight the importance of standardized surgical protocols and suggest that minimally invasive techniques may help mitigate infection risk.

It is also important to note that the heterogeneity of the literature - including differences in implant designs, manufacturing techniques, and surgical approaches - makes comparisons challenging. While in vitro studies, particularly those using finite element analysis with realistic virtual models, provide valuable insights into the biomechanical behavior of subperiosteal implants, additional clinical studies with longer follow-up are needed to fully evaluate long-term outcomes and establish evidence-based guidelines [121].

The results of the present study are consistent with the literature, within the subperiosteal cohort (n = 11), five complications occurred in four patients, corresponding to a patient-level complication rate of 36.4% [122]. The predominant issues included localized mucositis and limited hardware exposure. In the zygomatic group (n = 5), two complications were documented in two patients (40.0%), both characterized by mucositis without further sequelae. In contrast, the subgroup treated with conventional endosseous approaches - comprising short and narrow implants (n = 6) - reported no

postoperative complications throughout the observation period. This distribution of adverse events underscores the intrinsic variability in surgical morbidity among graftless rehabilitation strategies and reflects the distinct biological and technical demands associated with each implant design and placement protocol. Subperiosteal implants require adaptation beneath the periosteum over a wide area, which can increase soft-tissue tension and risk of mucosal exposure, while zygomatic implants involve more extensive dissection and sinus proximity, predisposing to localized inflammation. By contrast, short and narrow endosseous implants are less invasive, preserve native soft tissue, and maintain a more predictable mucosal seal, resulting in lower early complication rates.

The incidence of mucositis and hardware exposure in the custom subperiosteal group highlights a central, long-recognized challenge associated with this implant type. Subperiosteal implants depend entirely on the integrity of the peri-implant soft tissue seal at the transmucosal posts (pillars) for maintaining long-term biological stability, as they are non-osseointegrated frameworks resting directly on the bone surface. Our findings are consistent with recent evidence from Anitua et al. (2024), who reported notable rates of implant exposure in additively manufactured subperiosteal implants, and El-Sawy & Hegazy (2024), who documented biological complications in similar cohorts [121,122]. The comparatively higher rate observed in our subperiosteal cohort may reflect the rigorous, randomized selection of high-risk patients with severe atrophy who were not candidates for conventional endosseous rehabilitation, as well as the relatively short follow-up period (mean 22 months). Complications such as hardware exposure and mucositis, which developed between 3 months and 2 years postoperatively, likely reflect biological tension at the soft-tissue/framework interface, which can be exacerbated by local trauma, plaque accumulation, and patient-related factors including smoking or systemic health status.

Despite the precision afforded by the CAD/CAM, Selective Laser Melting (SLM) fabrication process of the IUXTA-3D system - which mitigates the ill-fitting and micromotion issues observed in older cast-generation implants - the fundamental biomechanical and soft-tissue challenge remains.

Mechanical polishing of the transmucosal surfaces was intended to reduce bacterial adhesion and improve soft-tissue integration; however, the observed mucositis cases demonstrate that the peri-implant environment surrounding the six prosthetic pillars is inherently susceptible to inflammatory events. These findings reinforce the necessity of rigorous maintenance protocols, including professional debridement and patient hygiene reinforcement, as indispensable measures for the long-term success of patient-specific subperiosteal solutions.

The zygomatic group, while successfully achieving immediate loading due to superior primary stability (mean insertion torque 56.15 Ncm), was associated with the highest levels of immediate postoperative pain (VAS mean: 7.80) and a notable incidence of mucositis. The statistically significant difference in post-surgical pain between the Zygomatic group (M = 7.80) and the Subperiosteal group (M = 6.27, p = 0.021) represents a key finding, highlighting the greater immediate postoperative discomfort associated with the more invasive zygomatic implant procedure.. The surgical placement of multiple long zygomatic implants is inherently more invasive, requiring reflection of the maxillary sinus, access to the zygomatic and pterygoid bones, and manipulation of several anatomical structures. This extended surgical complexity is directly correlated with greater immediate postoperative discomfort compared with the subperiosteal approach or the less invasive narrow/short endosseous implants. These observations are consistent with the established morbidity profile of zygomatic implantology reported in the literature, which highlights elevated risks of soft-tissue inflammation, sinus-related events, and postoperative discomfort. The two complications recorded in this cohort were limited to mucositis. The palatal emergence of zygomatic implants, coupled with the use of complex prosthetic platforms incorporating 45° or 55° angled abutments, presents specific challenges for patient hygiene and professional maintenance. These factors contribute to localized soft-tissue inflammation, emphasizing the need for rigorous peri-implant care in zygomatic rehabilitation.

The finding that the Short/Narrow implant group experienced zero complications is highly relevant for clinical decision-making. This group also reported the lowest post-surgical pain score (M = 4.67, SD = 0.82) and had the lowest average insertion torque (Safe 44.75Ncm and Nano 37.50). The relative success and low morbidity of this cohort confirm that, when sufficient native bone is present - even if minimal (i.e., adequate for short or narrow implants) - this represents the preferred, least invasive, and most patient-friendly approach. However, it is important to emphasize that patients in this group were carefully selected based on strict inclusion criteria that precluded the need for extensive bone augmentation. Had bone grafting been required, morbidity and complication rates would predictably increase, consistent with observations reported in the literature. A striking and clinically significant finding of this study is the disproportionate distribution of complications according to patient-related factors, which warrants careful consideration.

Sex: All four male patients in the cohort (100%) experienced a complication, compared to 2 out of 17 female patients (11.8%). While the total number of male patients is small, this marked difference suggests the presence of unmeasured biological or behavioral factors influencing outcomes. Potential explanations include differences in bone quality, greater masticatory forces producing higher mechanical stress, or variations in oral hygiene compliance. Although these observations must be interpreted cautiously due to the limited sample size, they indicate that sex-specific stratification may be valuable in future, larger trials to clarify underlying mechanisms.

Smoking and Diabetes: The data also reinforce the well-established impact of systemic risk factors on implant outcomes. Smokers experienced a complication rate of (42.8%), more than double that of non-smokers (20.0%), consistent with prior literature linking smoking to increased implant failure and peri-implant disease. Similarly, the single patient with diabetes experienced a complication (100% for that subgroup), highlighting that even advanced implant technologies, such as CAD/CAM-fabricated subperiosteal implants, cannot fully overcome biological risks associated with systemic conditions.

Beyond complications, a central goal of this research was to evaluate the patient-perceived success of these advanced rehabilitations. The Visual Analogue Scale (VAS) revealed a statistically significant difference in postoperative pain among the groups ($F(2, 19) = 10.34$, $p = 0.001$). The Zygomatic group reported the highest mean pain score (mean 7.80), reflecting the extensive surgical intervention required, which involves raising a large full-thickness flap, creating a bone window, and accessing the posterior maxilla up to the zygoma. The Subperiosteal group reported intermediate pain (mean = 6.27). Although this approach is more invasive than conventional endosseous placement, the use of a custom-designed frame and the avoidance of extensive drilling into dense zygomatic bone likely contributed to the lower pain levels compared with the zygomatic approach. Nevertheless, surgery still necessitated extensive flap reflection and, in the maxilla, intentional transection of the incisive nerve to achieve proper exposure. The Short/Narrow group experienced the lowest pain mean = 4.67), confirming the low-morbidity advantage of conventional implant techniques when sufficient bone volume allows a less invasive procedure. The longitudinal assessment of Oral Health Impact Profile (OHIP-14) scores demonstrated a substantial and rapid improvement in oral health–related quality of life across all three implant groups. At the time of provisional prosthesis delivery, all groups reported elevated OHIP-14 scores, reflecting significant pre-existing disability and the immediate post-surgical impact (Zygomatic: 39.2 ± 1.9; Subperiosteal: 29.5 ± 3.8; Short/Narrow: 25.2 ± 5.6). Critically, by the 1-year follow-up, mean scores had dramatically decreased to 13.0 ± 1.4 (Zygomatic), 9.2 ± 1.6 (Subperiosteal), and 7.8 ± 1.7 (Short/Narrow), respectively. This marked reduction confirms the transformative potential of immediate fixed prosthetic rehabilitation in severely atrophic jaws, irrespective of the underlying implant modality. The ability to transition patients from a severely edentulous state to a functional fixed prosthesis within 24–48 hours significantly improves function, comfort, and psychological well-being, as validated by the OHIP-14 results. While all groups converged toward excellent scores by the one-year mark, the Zygomatic group started with the worst mean baseline score (39.2 ± 1.9), consistent with their higher reported post-surgical pain. Conversely, the Short/Narrow group began with the lowest baseline OHIP-14

score (25.2 ± 5.6), supporting the notion that less invasive procedures are associated with better early patient-perceived outcomes and reinforcing the preference for minimally invasive approaches whenever feasible.

Strengths, Limitations, and Future Directions:

Strengths of this study include the prospective, multicenter randomized design, which provides robust comparative data across multiple graftless rehabilitation strategies, and the standardized use of CAD/CAM subperiosteal implants (in vitro FEA part of the study), enabling reproducible clinical insights. Limitations include the small sample size (n = 22), which restricts the statistical power for subgroup analyses, the relatively short follow-up period (mean 22 months), and the strict patient selection criteria, which may limit generalizability to the broader population with severe atrophy.

Future studies should include larger, multi-institutional cohorts with longer follow-up, assess the long-term survival of subperiosteal implants compared with conventional endosseous systems, and evaluate cost-effectiveness and patient-reported outcomes across diverse populations. Additionally, investigating biological and mechanical risk factors, such as bone quality, soft-tissue thickness, and occlusal loading, will help refine patient-specific treatment planning.

9. CONCLUSIONS

Despite the encouraging short-term results observed in this study, further investigation is crucial to validate the long-term biological and biomechanical performance of subperiosteal implants. While current evidence supports their clinical reliability and patient satisfaction, data on long-term osseous stability, peri-implant tissue response, and load distribution under functional conditions remain limited. Understanding these parameters through extended follow-up and histological or finite element analyses would help clarify how subperiosteal frameworks integrate and behave under dynamic masticatory forces. Equally important is the continued refinement of digital design and surgical workflows. Advancements in CAD/CAM accuracy, surface treatment optimization, and patient-specific prosthetic connections could further reduce complications such as mucositis and hardware exposure. Defining precise patient selection criteria - considering factors such as bone morphology, soft-tissue quality, and systemic health - will enhance treatment predictability and minimize biological risk. Therefore, larger-scale, multicenter prospective studies with long-term observation are needed to substantiate the promising outcomes presented here and establish standardized, evidence-based clinical protocols. These efforts will be crucial in consolidating subperiosteal implants as a dependable, graftless alternative for the rehabilitation of patients with advanced maxillomandibular atrophy.

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