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CLINICAL AND RADIOGRAPHIC EVALUATION OF MARGINAL BONE RESORPTION OF ONE-PIECE IMPLANTS IN FULL ARCH REHABILITATIONS WITH FULL DIGITAL APPROACH: A PROSPECTIVE COHORT STUDY.

PhD Coordinator: Prof. Massimo Del Fabbro

Referee: Prof. Carlo Maiorana

PhD Thesis by Mattia Manfredini

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1. INTRODUCTION

In modern dentistry, implantology plays a significant role. Technological advancements continuously reduce the invasiveness of implant surgery and speed up its timelines, providing substantial benefits to patients' quality of life.

In line with that principle, among the new techniques, immediate loading post-extraction implants stand out, allowing the replacement of missing teeth in a single surgical session. It reduces the impact of interventions and accelerates the healing process. Concurrently, digitization through advanced tools such as intraoral scanners and computer-aided design (CAD) software enables detailed and personalized treatment planning, minimizing errors and ensuring optimal results for each patient. The advanced approach eliminates the need for physical models, making the process faster, more accurate, and ergonomic [1, 2].

In addition, guided surgery represents a key advancement, ensuring even greater precision during implant placement. By using 3D imaging and virtual treatment planning, surgeons can create surgical guides that translate the digital plan directly into the clinical procedure. The reduction of human errors enhances accuracy and optimizes the positioning of the implant, particularly in complex cases or when bone availability is limited. The method complements the immediate loading approach by further minimizing invasiveness and improving the predictability of results.

The main objective of this protocol was to evaluate the stability of one-piece immediate loading implants, which eliminate the fixture-abutment interface, through clinical and radiological follow-up, confirming their durability, effectiveness, and predictability.

2. PERI-IMPLANT TISSUES

2.1 ANATOMY AND PHYSIOLOGY OF PERI-IMPLANT TISSUES

The tissues surrounding dental implants, known as peri-implant mucosa, develop during the wound healing process that follows flap closure, whether transgingival implants are placed or during the placement of the healing abutment in the first or second surgical stage in bone-level implants [3]. Mucosal healing leads to the adhesion of soft tissues to the implant components through four distinct phases:

1. Formation and adhesion of a fibrin clot to the implant surface;
2. Absorption of extracellular matrix proteins and connective tissue cells onto the implant surface;
3. Transformation of the clot into granulation tissue;
4. Migration of epithelial cells over the fibrin clot / granulation tissue.

Thus, a transmucosal adhesion system is formed on the implant, consisting of a junctional epithelium and supracrestal connective tissue [4, 5, 6] (See Figure 1).

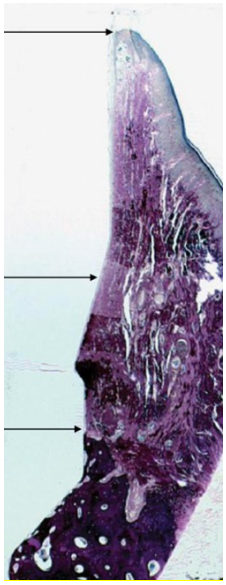

Figure 1: Peri-implant tissues (Lang NP, Lindhe J. Clinical Periodontology and Implant Dentistry, Wiley Blackwell. 2015)

This creates a barrier that prevents bacterial infiltration, which could compromise both the initial healing process and the long-term stability of the implants. The early formation of a durable and efficient seal is essential for the biological protection of the peri-implant structures and for preventing the entry of oral bacteria and their metabolites into the body [7].

Due to its ability to proliferate and migrate over surfaces, the epithelium at the flap incision margin quickly overcomes the fibrin clot after the application of the healing screw or the insertion of the implant. Once it reaches the implant surface, it migrates upward, creating a junctional epithelium approximately 2 mm in length [8].
The presence of granulation tissue attached to the transmucosal surface of the implant components is the main obstacle to further epithelial migration towards the apex. The role of connective tissue in preventing upward epithelial growth has been clearly demonstrated in animal studies; it appears that mature connective tissue appears to more effectively prevent epithelial migration than granulation tissue. Berglundh et al. also hypothesized that upward epithelial migration is interrupted by the interaction between the soft tissue and the titanium oxide layer [6]. Once epithelial cells reach the implant surface, they anchor directly through a basal lamina (<200 nm) and form hemidesmosomes. Hemidesmosomes can form as early as 2-3 days after the beginning of the healing process [9,10].

The junctional epithelium aligned along the peri-implant sulcus is similar to that near the teeth: it shares many structural, ultrastructural, and functional characteristics with corresponding gingival tissue. Studies conducted on humans indicate that the epithelium around implants follows differentiation pathways and functions similar to gingival epithelium. At this level, it is common to find an inflammatory infiltrate composed of T lymphocytes; this phenomenon seems to be due to the presence of a physiological barrier that protects the site from external antigenic stimuli [11,12].
However, the attachment of connective tissue to the implant components differs from that observed in teeth. In periodontal tissues, cementum covers the root up to the cementoenamel junction, providing a substrate into which collagen fiber bundles can deeply penetrate. The dentogingival and dentoalveolar collagen fibers extend laterally,

coronally and apically [13]. In the case of endosseous implants, due to the absence of cementum and the solid consistency of the transmucosal implant components, there is no effective anchorage of the supracrestal connective tissue, but rather a fragile adhesion [6]. The collagen fiber bundles follow a completely different path: they originate from the periosteum of the bone crest and align parallel to the implant surface. This results in a connective tissue adhesion to the implant with weaker mechanical resistance compared to that of natural teeth [6,14]. The absence of a robust connective tissue interface, essential for supporting the epithelium and preventing apical migration, can compromise the success of dental implants. Damage to this interface, caused by mastication or soft tissue instability, can lead to epithelial migration, bone resorption, and the formation of pockets or recessions.

The connective tissue around implants presents a higher concentration of collagen fibers, but fewer fibroblasts and blood vessels compared to natural dental tissue. The differences in vascular supply between teeth and implants are significant. In natural teeth, blood flow to the gingiva comes from two distinct sources: the large supraperiosteal vessels and the vascular plexus of the periodontal ligament. Implants, however, rely primarily on the supraperiosteal vessels for blood supply. Those anatomical differences render the soft tissue around implants similar to scar tissue, with less mechanical and immune resistance, which has relevant clinical implications [15].

Studies on dogs have shown that the pressure of a periodontal probe causes greater penetration around implants compared to teeth, explaining the greater probing depth [3] (Figures 2 and 3).

***Figure 2**: Comparison between peri-implant tissues and periodontal tissues (Babbush, C.A., Dental Implants. The Art and Science, 2011*

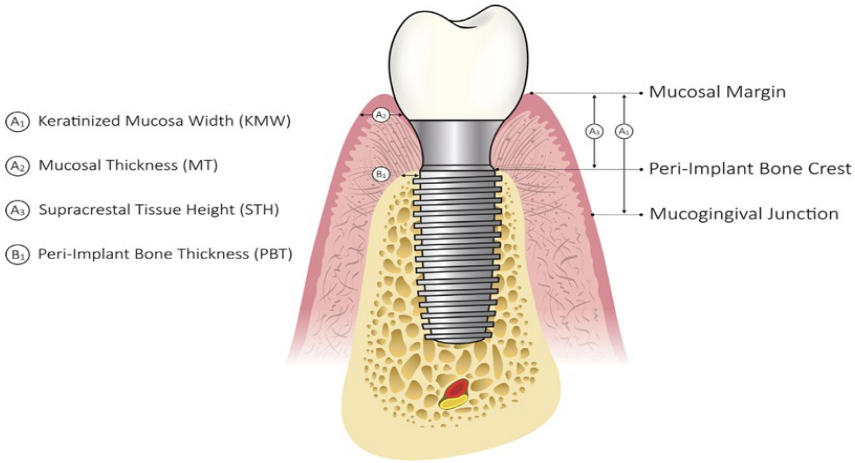

***Figure 3**: Implant phenotype (Gustavo Avila-Ortiz Et Al., The peri-implant phonotype, J Periodontol, 2020)*

The extent of keratinized mucosa (KM) is established as the distance between the mucogingival junction and the free gingival margin. Whether keratinized mucosa is essential for preserving periodontal health has been widely debated. Clinically, a reduced band of KM in natural teeth is often associated with gingival recessions and an inflamed periodontium, suggesting that a certain amount of KM might be necessary for periodontal stability [16].

Lang and Löe, in their 1972 study, deduced that 2 millimeters of KM are needed to maintain the health of periodontal tissues on natural teeth. The same issue has subsequently been raised regarding implants. Since implants and natural teeth have significant anatomical and structural differences, the same conclusions cannot be automatically drawn [17].

The necessity of having a band of keratinized gingiva around dental implants to ensure peri-implant health has been, and still is, a highly controversial topic [18,19,20]. It has been established that the health of the dental implant largely depends on the soft tissue barrier surrounding it. However, it is not entirely clear whether this barrier must necessarily be made of keratinized tissue or lining mucosa. Several studies showed poor plaque management and inflammation of peri-implant tissues around implants with KM < 2 millimeters [21,22]. Conversely, some studies indicated that the absence of an "adequate" band of KM does not negatively affect the health and stability of peri-implant tissues [23].

In a systematic review, Wennström and Derks (2012) concluded that the evidence demonstrating the need for KM around implants was limited, and in a population with adequate maintenance, the presence of KM around implants did not seem to present any advantage. However, the Authors also stated that some patients might experience pain and discomfort during brushing at implant sites with KM < 2 millimeters, which could compromise proper oral hygiene [24]. The hypothesis was later confirmed by a cross-sectional clinical study that demonstrated that patients with peri-implant KM < 2 millimeters exhibited higher levels of brushing discomfort, poorer plaque management, and greater peri-implant inflammation than those with KM ≥ 2 millimeters [25]. Other studies support this thesis, showing that keratinized epithelium offers better sensory insulation, ensuring less discomfort during brushing maneuvers and achieving higher hygiene levels. In light of these considerations, in situations where, following implant placement, there is less than 2 millimeters of KM, the clinician may consider increasing it through a surgical approach [26].

3. MONOPHASIC IMPLANTS

3.1 STRUCTURAL FEATURES

As previously mentioned, since the early stages of modern implantology, two distinct implant configurations emerged: the two-piece design, characteristic of the Branemark School, and the one-piece design, typical of the Schroeder School [27]. Historically, two-component implantology has enjoyed greater popularity and remains the most widely adopted solution today. However, there are still some implant manufacturers offering one-piece implant lines.

This type of implants features a design that structurally combines the transmucosal component and the fixture into a single part. This configuration eliminates the abutment-implant interface, which, according to several studies in the literature, represents a critical area. The junction of the two components inevitably creates an intermediate space that, under mechanical stresses, can cause micromovements of the prosthetic component. These micromovements can lead to both mechanical and biological issues. In contrast, the conical connection appears to significantly minimize the formation of a micro-gap at the implant-abutment interface, leading to an improved seal quality [28].

Bi-component implants primarily present two problems: mechanically, loosening of the fixing screw can occur, and with significant micromovements, the screw itself may even break. Biologically, the major issue is the infiltration of the micro-space between the abutment and fixture by bacteria present in the oral cavity. Each micromovement of the prosthetic interface can generate a flow of liquids containing bacteria and their toxins towards the peri-implant tissues. This bacterial contamination and the resulting microbial flow lead to inflammation of the tissues and consequent tissue loss, both bone and soft peri-implant tissues [29]. The substantial loss of bone tissue can reduce the stability of the implant, potentially compromising its functionality [28]

The aim of the structural characteristics of one-piece implants is precisely to prevent these types of complications.

The one-piece implant system is distinguished by a transmucosal neck, positioning the connection within the soft tissues and thus creating a separation between the

connection and the marginal bone. The concave shape of the transmucosal collar, made possible by the absence of a multi-unit abutment screw, provides additional space for soft tissue maturation and the development of a biological width [30].

Studies showed that the combination of a high-quality implant-abutment connection with a concave collar design leads to a thicker soft tissue seal around the implants [31]. This novel configuration, with the thickened soft tissues provided by the concave neck and the increased distance between the connection and the bone, may serve as protective factors that reduce apical bone resorption, improving both functional and aesthetic outcomes.

Typically, the part emerging from the mucosal tissue has a smooth surface, favorable for soft tissue adhesion, while the portion in contact with bone has a treated surface to improve its bone integration capabilities. The smooth surface of the neck reduces bacterial colonization, enhancing biological protection of the underlying implant surface and promoting long-term marginal bone stability [30].

This type of implants also fits perfectly with fully digital workflows, guided surgery, and immediate loading, avoiding the clinician the difficulties that could arise from using multi-unit prosthetic abutments. Additionally, the shape of the emergence profile and the absence of an implant to abutment connection eliminated the need for a bone profiler to create space for prosthetic components. This allowed for a more conservative approach to preserving hard tissue and resulted in a less invasive and faster surgical procedure, as raising a full-thickness flap for multi-unit abutment placement was not necessary.

3.2 CLINICAL CONSIDERATIONS

Monophase implants, by integrating the transmucosal portion, do not allow submerged healing as originally proposed by the Branemark protocol, enabling the practitioner to avoid the need for subsequent reopening of the surgical site, thereby reducing time and discomfort for the patient. In the literature, the use of one-piece implants is considered both for post-extraction implant insertions and in the presence of intact edentulous sites, depending on the specific clinical case. These implants allow for both immediate and delayed loading protocols [32].

The lack of an internal connection and a connecting screw allows for a reduction in the volume and thickness of the implant neck, creating a better emergence profile and further preserving peri-implant hard and soft tissues [2].

Since the abutment is integrated into the implant itself and thus already present at the time of insertion, its angulation cannot be modified after placement. Therefore, it is crucial to precisely plan the implant placement and execute it with extreme accuracy. Currently, the market offers one-piece implants with angulated transmucosal abutments at various degrees, allowing the practitioner to compensate for situations of implant non-parallelism or angulation relative to the prosthetic superstructure. However, the choice of the transmucosal abutment's angulation must be made during the planning stage before implant insertion.

Scientific literature regarding this type of implants reports excellent results in terms of survival and a low incidence of complications. Prithviraj Dr et al. reported a success rate ranging from 93.2% to 100% with a follow-up of 1 to 3 years [33].

It is often highlighted that there is no statistically significant difference regarding the risk of failure and the onset of peri-implantitis between one-piece and two-piece implants [34].

4. IMMEDIATE LOAD

4.1 SURGICAL TECHINIQUE AND TIMING OF IMPLANT PLACEMENT

In today's society, where there is an increasing emphasis on the importance of timing and aesthetics, the demand from patients to shorten treatment times has significantly grown. In response to the need for optimization, the immediate loading protocol has emerged. To define the concept of immediate loading, it is essential to consider the classification proposed by C.E. Misch et al. in 2004, which outlines different implant loading timelines [35]:

- immediate occlusal loading: involves the full functional occlusal loading of an implant within 1 week of its placement;
- immediate non-functional rehabilitation: entails the placement of implant-supported prostheses within 2 weeks of implant placement without applying direct functional occlusal load;
- early occlusal loading: provides functional loading between 2 weeks and 3 months after implant placement;
- early non-functional rehabilitation: involves the finalization of implant-supported prostheses between 2 weeks and 3 months after implant placement without applying direct functional load;
- delayed occlusal loading: involves the rehabilitation of an implant more than 3 months after its placement.

Subsequently, in 2006, Wang et al. proposed a new definition based on the consensus reached during the International Congress of Implantology (Upper Montclair, New Jersey), where immediate loading was defined as a technique in which the implant supporting the prosthesis is subjected to functional occlusal load within 48 hours of implant insertion. This new definition also distinguishes between immediate rehabilitation for aesthetic purposes, without occlusal contacts, and true functional immediate loading [36].

Analyzing the literature, it emerges that immediate occlusal loading can stimulate bone remodeling and increase peri-implant bone density. However, for an implant subjected

to immediate loading to be successful, it must have excellent primary stability, which depends on its macroscopic morphology, length, diameter, thread characteristics, and the quality and quantity of bone at the surgical site. Brunski and Szmukler-Moncler identified a micromovement tolerance range at the bone-implant interface between 50 and 150 μm, within which primary stability is maintained and osseointegration is favored [37]. In the case of multiple implants, rigid splinting can increase stability and evenly distribute stresses, avoiding areas of occlusal overload.

It should be noted that the bone-implant interface is more vulnerable and at risk of mechanical overload from 3 to 6 weeks after implant insertion due to bone remodeling induced by surgical trauma. It is within this timeframe that, in the absence of signs of infection, failures of immediately loaded implants commonly occur [38].

The disadvantages of immediate loading include the management and organizational complexity of the immediate functionalization of implants, which requires complex logistical planning and can prolong chair time unless the prosthetic phase is postponed to the day after surgery or pre-set digitally. Additionally, there are extra costs associated with the treatment [39].

4.2 RATIONALE FOR USE AND GUIDELINES

In assessing a patient suitable for the immediate loading protocol, it is essential to consider several factors divided into three main categories [13]:

1. **Surgical Factors:** The clinician must choose the most appropriate surgical technique to ensure optimal primary stability, which is the most critical factor for the success of immediate loading. The literature suggests placing implants with a torque of 30 to 50 Ncm to achieve a high success rate. Depending on the patient's bone characteristics, the clinician must select the most suitable implants and appropriately prepare the surgical site to achieve this goal.
2. **Implant-Related Factors:** The application of biomechanics to the study of functional loads transmitted from the fixture to the surrounding bone tissue guided the development of implants with body design and surface characteristics specifically designed to enhance initial mechanical stability and accelerate osseointegration times. The screw-shaped design offers greater mechanical retention and a better ability to

transfer compressive forces. The design and number of threads influence the extent of the biomechanically active surface capable of withstanding forces during immediate loading.

Although the ideal lengths and diameters of implants for immediate loading have not yet been definitively established, early studies indicate that lengths greater than 10 mm are associated with a significant increase in success. An increase of 3 mm in implant length results in a significant increase in the osseointegrable surface area. However, while the use of longer implants contributes to greater initial mechanical stability and increases the osseointegrable surface area, it does not have a significant impact on load distribution at the crestal level, where the maximum stress is concentrated. Therefore, width, more than length, is crucial in selecting an implant for immediate loading, especially in the neck region, where the greatest occlusal stresses occur.

To ensure initial mechanical stability and maximize the contact surface with the bone, it is essential to provide a minimum implant length and the widest diameter possible, compatible with the thickness of the edentulous ridge. Another critical aspect to consider in choosing an implant for immediate loading is the surface treatment. Animal studies demonstrated the advantages of rough surfaces over smooth ones, as they increase the primary stability of the implant and promote greater platelet adhesion, indirectly facilitating the concentration of growth factors in the peri-implant environment. This process, known as contact osteogenesis, accelerates ossification and promotes greater bone colonization on the implant.

3. **Occlusion-Related Elements**: In the practice of immediate loading implantology, an occlusal model characterized by contacts between chewing surfaces without lateral contacts is suggested. The placement of multiple implant pillars allows for an increase in the functional area to distribute masticatory load across the interface surface with the bone tissue, thereby reducing overload on each individual implant. If the prosthetic-surgical study of the patient indicates the need for significant anterior and/or vertical cantilevers to compensate for bone resorption in the sagittal and vertical directions, the use of a greater number of implant pillars will be planned to distribute the biomechanical load. Patients with parafunctions or occlusion impairments should not undergo immediate loading: research by Balshi and Wolfinger showed that approximately 75% of immediate loading failures occur in patients with parafunctions

[40]. Further studies confirmed these results and suggested that these patients, if not excluded from immediate loading, should be strongly informed of the high risk of failure [38].

5. POST-EXTRACTIVE IMPLANT

5.1 THE POST-EXTRACTIVE IMPLANTS

This surgical approach was introduced in 1976 as an alternative to the traditional surgical protocol initially proposed by Brånemark. This therapeutic option offers several advantages, including a reduction in both treatment times and the number of surgical interventions, thereby increasing patient satisfaction. Furthermore, the survival and success rates of post-extraction implants have shown positive results, comparable to those of implants placed in fully healed edentulous ridges.

The data available so far clearly showed that immediate implant placement does not completely prevent bone resorption, although it is still not entirely clear whether immediate implant placement offers significant advantages in terms of healing and tissue maintenance compared to spontaneous healing of the post-extraction socket. The evidence in the literature again is contradictory [41]. For example, Araujo et al., analyzing the healing of post-extraction sockets with and without immediate implant placement in the same maxillary arches, observed that the reduction in buccal bone height after 3 months of healing was similar in both contralateral sites [42].

5.2 INDICATIONS AND CONTRAINDICATIONS OF POST-EXTRACTION IMPLANTS

The primary reason for adopting an immediate implant placement protocol is the extraction of a tooth affected by an untreatable pathology, such as caries, corono-radicular fracture, endodontic lesions, chronic granulomatous periapical infections, untreatable chronic periodontal lesion in patients undergoing periodontal maintenance therapy, or the extraction of impacted or deciduous teeth in cases of agenesis. On the contrary, the presence of an acute inflammatory endodontic or periodontal lesion constitutes an absolute contraindication for immediate implant placement. Other contraindications are related to the inability to achieve adequate primary stability.

Whenever the patient's anatomical characteristics require regenerative techniques, such as moderate or extensive maxillary sinus lift, implant placement is preferably

postponed. Another contraindication is the presence of significant mucogingival defects that require regenerative surgery but cannot be performed simultaneously with implant placement. Finally, the inability to perform an atraumatic extraction suggests postponing implant placement to a subsequent session after the site has adequately matured [42,43,44,45].

5.3 THE IMMEDIATELY LOADED POST-EXTRACTIVE IMPLANTS

The benefit of immediate loading on a post-extraction implant consists of improved soft tissue regeneration around the implant abutment and the opportunity for the patient to achieve an almost optimal aesthetic result from the first surgical procedure. The essential clinical prerequisite for proceeding with immediate loading on a post-extraction implant is achieving optimal initial stability of the implant, with an insertion torque between 40 and 50 Ncm [46,47].

Additionaly, it is essential to ensure centric occlusion with evenly distributed occlusal contacts during the complete arch rehabilitation for fully edentulous patients, while for single or multiple edentulous rehabilitations, it is preferable to keep the restoration in infraocclusion during the osseointegration period [48].

6. DIGITAL DENTISTRY

6.1 THE DIGITAL WORKFLOW

Over time, a gradual and increasingly evident process of digitalization in both production and clinical processes was observed, leading it to significant changes in the traditional workflow. Thanks to various innovations and remarkable technological advancements, workflows, in some cases, are entirely digital, eliminating the need for analog processes throughout the rehabilitation treatment. This digital workflow can be applied to all areas of dentistry but finds its greatest effectiveness in implantology and restorative-prosthetic dentistry.

The first step in this digital path is represented by previsualization and aesthetic analysis technologies, which allow for a digital simulation of the prosthetic project in the pre-operative phase, creating a digital mock-up. The use of those tools greatly facilitates communication with the patient, often resulting in more informed and motivated consent for the rehabilitation plan. To create this simulation, it is necessary to collect complete 2D documentation through photographs or 3D through videos or three-dimensional facial acquisition tools. Benefits of video documentation are the simplification of acquisition processes, the ability to conduct dynamic analysis of mandibular movements and facial expressions of the patient, and easier communication with the patient and colleagues [(1)].

The next phase involves the recording of the dental arches through a digital scan using an intraoral scanner (IOS), which allows real data to be converted into digitally manageable virtual data. In the absence of an intraoral scanner, it is possible to scan the analog impression or plaster models obtained from the analog impression using a laboratory scanner [(49)]. For a more comprehensive diagnostic and rehabilitation approach, intraoral scanning can be integrated with an extraoral scan of the soft tissues. In surgical cases, it is common to integrate the documentation with a CBCT (Cone Beam Computed Tomography) to obtain a precise analysis of the patient's hard tissues. Through specific software, it is possible to combine all this data and create a "digital patient" on which to develop the treatment plan [(50)]. Subsequently, the collected

information needs to be processed using surgical planning or prosthetic design CAD (Computer Assisted Design) software. During surgical planning, implants can be digitally positioned in the most appropriate three-dimensional location. Based on that plan, digital guides can be constructed to assist the clinician in the surgical phase by positioning the implants exactly as planned. The use of these tools helps to reduce surgical complications and improve accuracy. Similarly, there are software programs that allow for the digital design of fully customizable prosthetic restorations starting from the digital intraoral impression. Finally, the designed restorations are produced using specific machinery such as milling machines and 3D printers (CAM, Computer Assisted Manufacturing). At this stage, the process returns to the physical world, where everything that has been designed, developed, and produced through the digital workflow is applied and used in clinical practice [(2)].

In summary, the digital revolution in the field of dentistry has brought several advantages, including:

1. Increased patient motivation: thanks to effective aesthetic previsualization.
2. Improved communication with the patient: regarding the treatment plan.
3. Precision in treatment planning: exploiting three dimensions.
4. Increased safety in implantology: through digital planning and the use of guided surgical guides.
5. Optimization of time.
6. Real-time verification of the scan's accuracy.
7. Reduction of human errors during data collection.
8. Possibility of measurements, corrections, and spatial analyses thanks to the software's functions.
9. Integration and matching of various diagnostic files (STL, DICOM).
10. Simple data archiving.

6.2 CAD-CAM TECHNOLOGIES

The abbreviations CAD and CAM stand for Computer-Aided Design and Computer-Aided Manufacturing, respectively. Originally developed in the 1960s for the

aerospace and automotive industries, those technologies entered the dental field about a decade later. In 1971, Dr. Duret was the first to develop a CAD/CAM device for dental applications, creating crowns based on optical impressions of prosthetic abutments and using numerically controlled milling machines [51,52].

Since then, those technologies have made significant advancements and have become, especially in recent years, an increasingly crucial component in dental workflows. Today, they are used in the production of inlays (such as inlay, onlay, and overlay), dental veneers, crowns, bridges, implant abutments, full-arch prosthetic rehabilitations, orthodontics, and the creation of surgical guides.

In particular, CAD refers to software capable of processing STL files obtained through intraoral or laboratory scanners to digitally construct the desired artifact in a fully customized manner without the use of analog models. Although the available software is numerous and continuously updated, some common features can be identified:

- Modeling Tools: allow the digital design and modeling of the desired artifact using a mouse and keyboard, making it fully customizable.
- Predefined Libraries: include predefined models such as prosthetic elements or implant components, which can be customized through modeling and customization functions.
- Archiving: provides space to store all developed projects, allowing for an organized catalog of all work and the ability to revisit a project over time.

Once the digital modeling phase of the three-dimensional project is completed, it must be physically produced, which is made possible by CAM (Computer-Aided Manufacturing) tools. These tools are divided mainly into two major categories:

- Machines using Additive Manufacturing Technology (AMT): these build objects by adding material layer by layer, typically through 3D printing.
- Machines using Subtractive Manufacturing Technology (SMT): these create objects by removing material from a solid block, typically using milling machines.

6.3 GUIDED SURGERY

It is based on the use of DICOM data derived from Cone-Beam Computed Tomography (CBCT) which, thanks to a specialized software, allows for precise

planning of implant positions based on the patient's bone characteristics, the location of surrounding vital anatomical structures, and the future requirements of the final prosthetic wax-up. More recently, intraoral scans begun to be integrated into the planning phase. In fact, it is possible to overlay images of identifiable structures, such as teeth, obtained from CBCT and intraoral scans, allowing for the creation of a more accurate digital model of the patient's hard and soft tissues through a process known as matching [50].

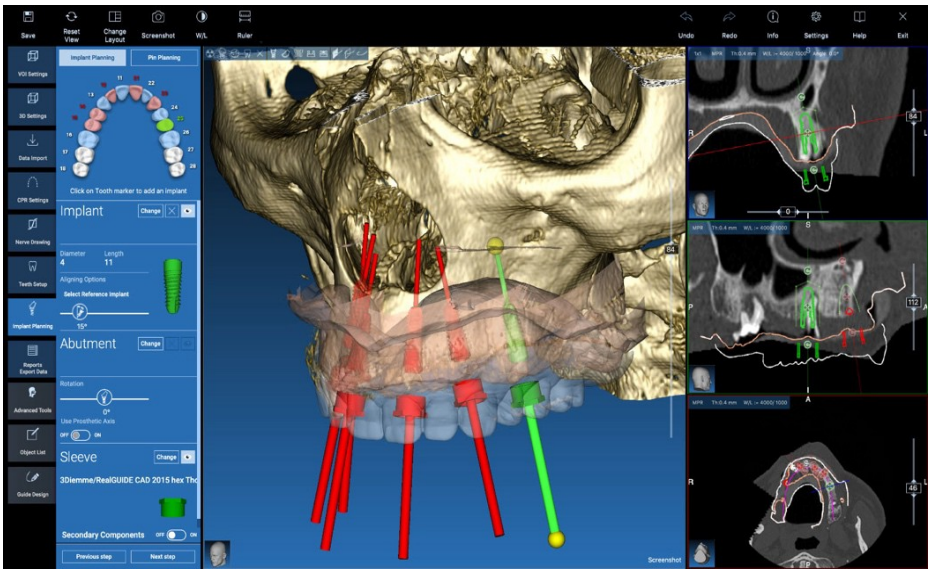

Figure 4: *Planning Software for Guided Implant Surgery*

The foundation underlying guided surgery is the pursuit of dental implant positioning that aligns with the prosthetic wax-up, ensuring maximum precision and accuracy. The advantages of a correct implant placement are numerous and evident, including the reduction of complications related to injuries of the structures vital structures, better long-term stability of the surrounding tissues, optimal aesthetic, prosthetic, and occlusal results. Additionally, adhering to critical parameters such as the distance between implants, the distance between the implant and the tooth, the depth, and the position relative to the cortical bone, has made virtual implant planning an important resource for ensuring treatment success. The next step, after planning, is the creation of surgical guides enabling the surgeon to place the implant exactly in the intended position. Those guides are digitally designed and then fabricated using computer-assisted manufacturing tools such as milling machines or 3D printers [53].

Figure 5: *Surgical Guide for Guided Surgery*

There are different types of surgical guides, or templates, which are distinguished by the type of support or their positioning.

Based on the type of support, we can identify:

• **Tooth-supported surgical guides**: stabilized on the residual teeth of the dental arch.

• **Mucosa-supported surgical guides**: placed on the mucosal surface, mainly used in completely edentulous patients.

• **Bone-supported surgical guides**: positioned in contact with the bone after raising a mucoperiosteal flap.

• **Mini-implant or pin-supported surgical guides**: connected to mini-implants inserted before or during the implant surgery itself.

A systematic review conducted during the 5th Consensus Conference of the International Team for Implantology concluded that bone-supported guides tend to be less precise, as they involve more modifications compared to the planned implant position. Tooth-supported guides, on the other hand, are the most reliable [(54)].

Various surgical protocols for guided surgery have been documented in the literature. Some systems allow guidance for both osteotomy and implant placement (fully guided protocol), while others permit only osteotomy guidance, leaving implant insertion to the surgeon's discretion. In line with the constant interest in less invasive surgery, guided implant surgery can sometimes be performed without flap elevation (flapless surgery). In the procedure, the implant is inserted through the soft tissues without raising a mucoperiosteal flap. This method preserves the blood circulation of the soft tissues, positively affecting their architecture [(55)].

According to a systematic review conducted by Cosyn et al., the flapless approach reduces peri-implant bone remodeling, improves the regrowth of interdental papillae, and facilitates the achievement of satisfactory aesthetic results [56]. Preserving the soft tissues also makes it easier to apply temporary prostheses with good aesthetic and functional results. Additionally, avoiding the elevation of a mucoperiosteal flap keeps the periosteum intact, preserving the osteogenic potential and blood flow to the underlying bone. Conversely, tearing the periosteum can lead to bone remodeling. The technique also involves less morbidity and postoperative discomfort, allowing patients to resume normal oral hygiene practices more quickly. However, not all cases are suitable for the flapless approach. The quality and quantity of the surrounding soft tissues must be carefully evaluated when choosing between flapless and open surgery, as in some cases, flapless surgery may result in the excessive removal of keratinized soft tissue [57].

One of the main benefits of guided surgery is the ability to know the exact position of the implant before its actual insertion. It allows the connection of a prefabricated prosthetic superstructure and immediate loading on the same day of surgery, without the need for intraoperative impressions [58]. The approach leads to significant time savings and reduces patient discomfort. Initially, guided implant procedures were recommended mainly for critical cases. However, over the years, with the increased use of digital tools, guided surgery is becoming more accessible and applicable to everyday clinical practice.

6.4 MODULAR TEMPLATES

Conventional protocols involve the use of an initial dental or mucosal-supported guide, which is initially used to create holes for bone fixation pins. The guide is then removed, any remaining teeth may be extracted, and a subsequent template is stabilized with fixation pins inserted into the holes made by the previous guide. The sequential removal and insertion of pins can cause variations in the direction of the holes due to the elastic rebound of the bone. This can dislocate the surgical guides, which may assume a different position from the planned one, leading to linear and angular deviations. To address this issue, modular templates have recently been introduced,

allowing for the fixation of a base structure that remains in situ throughout the entire procedure [59].

This minimizes repositioning errors and improves the overall precision of implant placement and the workflow predictability. It is important to note that a fixed reference helps the operator transition quickly between various components of the template, reducing surgical and prosthetic times with beneficial effects on postoperative morbidity [60,61].

Another aspect to be considered is the material used to manufacture the overlapping models. Conventional guides are made of PMMA and may undergo deformation or even fracture during implant site preparation due to the pressures exerted on them. To address the problem, modular templates use titanium-reinforced overlapping models, increasing rigidity to reduce the risk of deformation and fracture during the preparation sequence. Another limitation of conventional protocols using closed guides is the inability to adequately cool the drills with saline solution during implant site preparation. It can lead to increased bone temperature with potential deterioration of the healing process. If the bone temperature exceeds 47°C, protein coagulation and microthrombosis occur, resulting in scar tissue formation and subsequent fibrointegration of the implant [62,63]. In contrast, overlapping guides have been designed with open structures, allowing for direct cooling of the drills during site preparation. The quantity and stability of hard and soft tissues play a key role in the long-term success of the rehabilitation. [64]

In conventional guided implantology, surgical guides often obstruct the entire surgical field and their bulky nature limits the management of future peri-implant tissues. The slim design of the base model in modular templates not only provides an excellent view of the surgical area but also allows for intraoperative management the tissues underneath. This is particularly beneficial in cases with thin or suboptimal soft tissue thickness, where splitting of the keratinized mucosa is necessary to ensure long-term success. The open design also allows for better handling of peri-implant tissues, ensuring minimal trauma and maintaining soft tissue integrity during surgery. The enhanced visualization and access contribute to more accurate tissue management, which is crucial for the longevity of the implant.

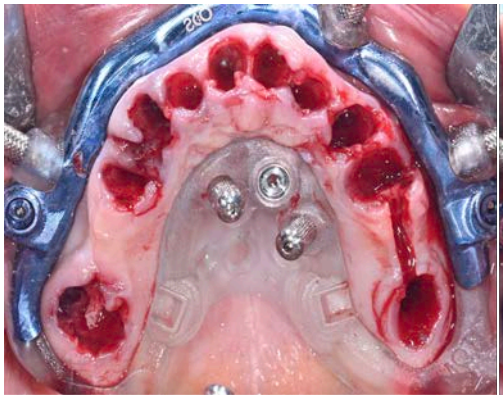

Figure 6: *Base template connected to the positioning tamplate*

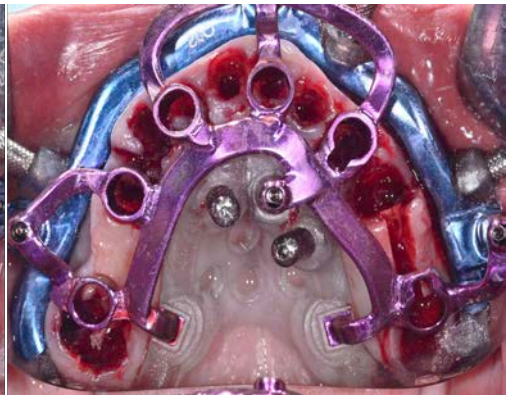

Figure 7: *Base template in position*

For hard tissue management, the stackable templates can be equipped with resective guides that allow for guided osteoplasty as per the pre-surgical digital planning. This ensures precise bone contouring and preparation, which is important for creating an optimal environment for implant placement and integration. Furthermore, One-piece implants used in conjunction with stackable templates eliminate the need for a bone profiler, which is typically required to create space for prosthetic components in two-piece systems. This results in greater bone preservation, particularly at the implant neck, where reduced thickness is possible due to the absence of an internal connection or prosthetic screw [(2)].

Regarding prosthetic advantages, the pre-designed and pre-fabricated provisional prosthesis can be screwed onto the base model. This eliminates the need for intraoperative impressions and means that the prosthesis placement is not solely dependent on occlusal keys. Additionally, the higher precision achieved by connecting the provisional prosthesis to the base model reduces the gap between the titanium structure and the temporary abutments. Consequently, a reduced amount of resin is used in the voids, eliminating material contraction during polymerization and thereby enhancing the precision of the prosthetic fit [(65)].

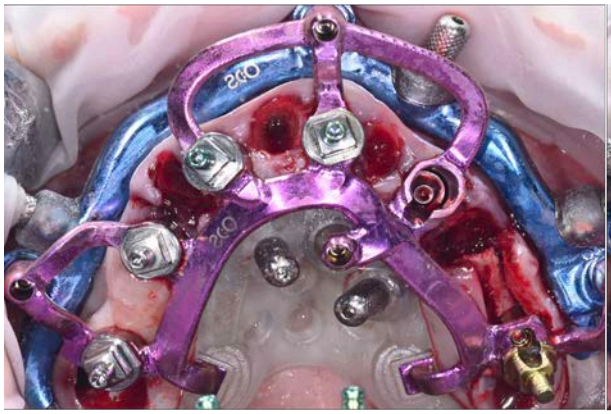

Figure 8: *Implants' placement in planned position*

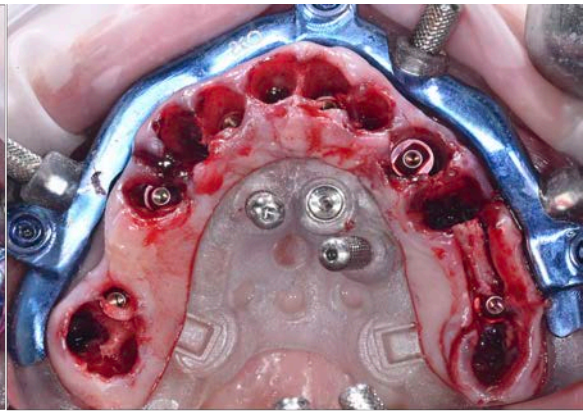

Figure 9: *Implants' placement without base template*

A potential limitation of modular templates is that their successful implementation depends on the clinician's expertise in both the planning and surgical phases, as there is a learning curve associated with fully digital workflows. Additionally, discrepancies between the planned and actual implant positions remain an unresolved challenge, impacting the accuracy of the workflow. The proper integration of digital technologies across clinical, surgical, and prosthetic procedures could mitigate information loss that may occur with traditional manual approaches, thus enhancing the precision of rehabilitation [66]. Furthermore, long-term studies are required to fully validate the advantages of stackable templates compared to conventional computer-guided workflows.

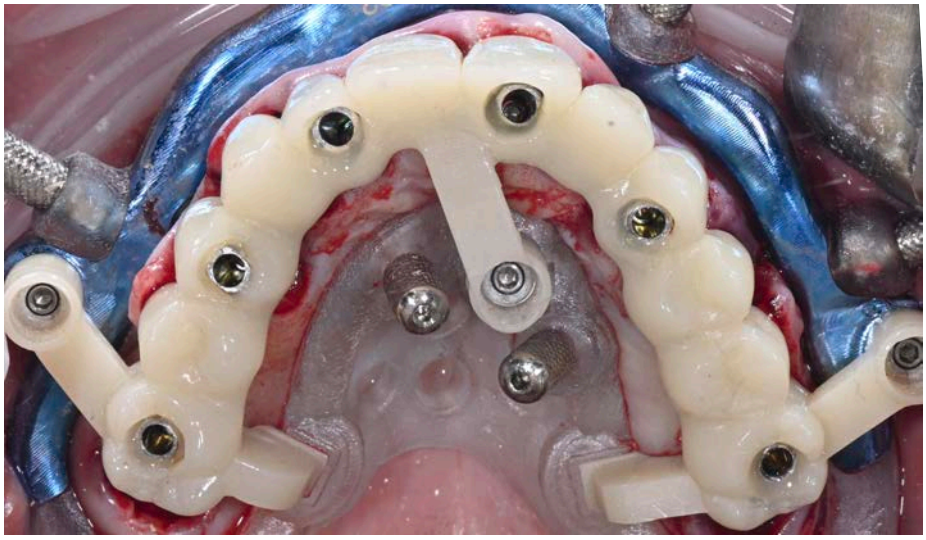

Figure 10: *Provisional prosthesis connected to base template*

7. BONE REMODELING AND BONE LOSS

7.1 PERI-IMPLANT MARGINAL BONE STABILITY

Peri-implant marginal bone stability is one of the key factors for evaluating the long-term success of dental implant therapy. Traditionally, marginal bone loss (MBL) up to 2 mm during the first year of function, followed by a maximum of 0.2 mm annually, has been considered acceptable [67].

However, modern improvements in implant design and surgical protocols led to better preservation of peri-implant bone during the initial phase of physiological remodeling. In particular, for subcrestally placed implants, it is critical to distinguish between bone remodeling and bone loss, as these processes represent distinct biological phenomena with different clinical implications.

7.2 BONE REMODELING AND PERI-IMPLANT DISEASE

Numerous studies demonstrated a direct correlation between physiologic bone remodeling and the risk of future peri-implant diseases. In 2015, Galindo-Moreno et al. identified that peri-implant bone loss greater than 0.44 mm within 6 months postloading is a strong predictor of further bone loss progression over time [68].

Additionally, in 2021, a long-term prospective study by Windael et al. highlighted that marginal bone resorption $\geq$ 0.5 mm after 1 year of function increases the odds of developing peri-implantitis by 5.43 times over a 10-year period [69].

More recently, it was proposed that radiographic MBL $\leq$ 0.5 mm after 6 months of prosthetic loading should be considered a success criterion for osseointegrated implants [70].

This evolving understanding of peri-implant bone dynamics reinforces the importance of early detection and precise evaluation of bone changes around implants.

7.3 BONE REMODELING VS BONE LOSS

The measurement of bone changes around implants differs significantly depending on the implant's position relative to the bone crest. For equicrestally or supracrestally placed implants, marginal bone loss is commonly measured as the vertical distance between the implant-abutment junction (IAJ) and the most coronal bone-to-implant contact visible on radiographs.

However, for subcrestally placed implants, the method looks inappropriate, as bone extends above the IAJ. Therefore, to accurately assess peri-implant bone changes around subcrestal implants, two distinct measurements must be employed:

- Bone Remodeling: The distance between the crestal bone and the IAJ.
- Bone Loss: The distance between the IAJ and the first radiographically visible bone-to-implant contact.

Those measurements allow clinicians and researchers to distinguish between the remodeling process, which supports peri-implant soft tissues, and the true bone loss, which impacts the implant's stability and osseointegration [71].

7.4 MEASUREMENT OF BONE CHANGES

Bone coronal to the IAJ and bone apical to the IAJ should be entirely distinguished, as each region undergoes dynamic changes in response to different stimuli. These changes have not been sufficiently investigated but are likely associated with distinct biological behaviors.

- Bone remodeling: bone remodeling occurs coronal to the IAJ, involving the portion of the bone that supports peri-implant soft tissue. The process may involve supracrestal tissue height formation and could potentially modify the vertical mucosal thickness around transmucosal components. Once completed, the remodeling enhances tissue stability around the prosthetic abutment by supporting the peri-implant mucosa. Importantly, in normal conditions, this kind of bone remodeling does not typically reduce the osseous support provided by the microrough implant surface.
- Bone loss: Bone resorption apical to the IAJ, on the other hand, involves partial exposure of the implant surface and represents true marginal bone loss (MBL). The

process compromises the implant's osseous support and is more insidious due to the risk of exposing the implant to the oral environment, which increases the likelihood of peri-implant diseases, including peri-implantitis. The exposure of the implant surface is a critical risk factor for the onset and progression of peri-implant pathosis [68,70].

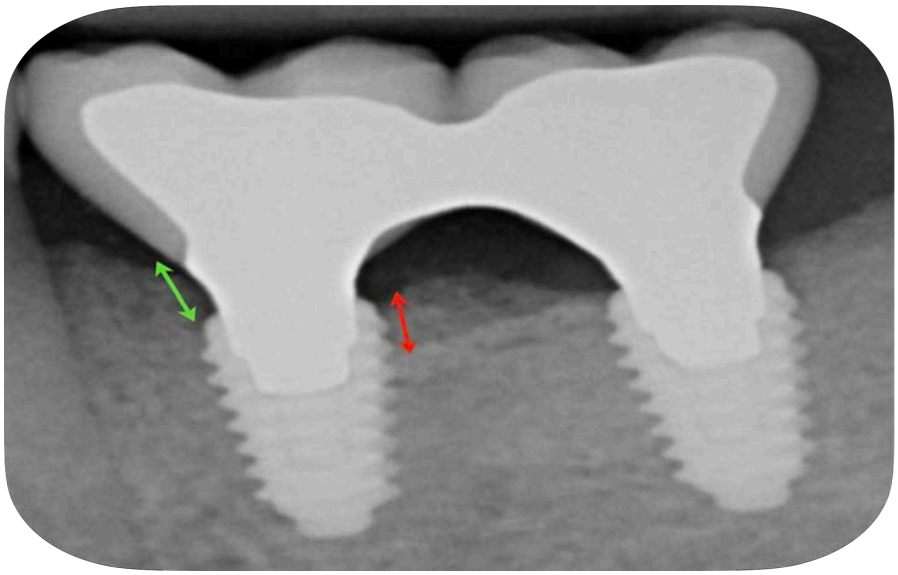

Figure 11: *A radiographic view highlights the bone remodeling area (Green) and bone loss area (Red)).*

7.5 CLINICAL CONSIDERATIONS

The differentiation between bone remodeling and bone loss is not only biologically significant but also clinically crucial. Understanding that those are two distinct processes provides clinicians with the knowledge necessary to develop appropriate therapeutic strategies. For instance, early detection of excessive bone loss apical to the IAJ can signal the onset of peri-implant complications, such as peri-implantitis, allowing for timely intervention. Conversely, bone remodeling coronal to the IAJ can be seen as a natural adaptive process that helps establish soft tissue stability.

Moreover, research indicates that peri-implant bone loss greater than 0.44 mm within the first 6 months postloading, or ≥ 0.5 mm after 1 year, significantly increases the risk of peri-implantitis over the long term. This finding underscores the need for early monitoring of marginal bone loss as a prognostic marker for the overall success of dental implants.

Subcrestal implant placement offers several clinical advantages, particularly in terms of aesthetic outcomes and protection against microbial colonization. However, this approach requires a nuanced understanding of the biological processes surrounding the implant, including the distinction between bone remodeling and bone loss. By integrating these concepts into clinical practice, practitioners can improve long-term implant stability and reduce the risk of peri-implant diseases [71].

8. MATERIALS AND METHODS

8.1 STUDY DESIGN

Prospective observational cohort study, utilizing medical devices, monocentric, and spontaneous.

In this study, patients presenting with complete or partial edentulism (where the remaining teeth are deemed non-restorable) and requiring rehabilitation with implant-supported prostheses in the mandibular or maxillary arch are recruited following evaluation with Cone Beam Computed Tomography (CBCT). Patients must have sufficient bone thickness for guided implant placement without the need for horizontal bone augmentation.

CBCT scans are performed at a reference center using the same equipment and settings for all patients. Each scheduled surgical procedure is conducted by two experienced operators to avoid potential operator-related bias. The surgical technique and materials used are standardized for all patients to exclude potential biases related to component variability. All cases are planned using the same digital workflow and monophasic implant system.

The procedures outlined in this study are part of the standard clinical practice for patients requiring full-arch implant prosthetic rehabilitation.

8.2 SETTING

The monophasic implants used are produced FIXO (Oxy Implant Dental System, Via Nazionale Nord, 21, 23823 Colico Piano LC) with CE code number CE0051.

Currently, this monophasic implant is the only one on the market specifically designed for guided surgery and full arch rehabilitations, with prosthetic components available at inclinations of 0°, 17°, and 30° as part of a one-piece system.

Digital workflow management is conducted using the surgical-prosthetic design software RealGUIDE™ (3DIEMME Bioimagin Technologies)

8.3 INCLUSION CRITERIA

■ Age ≥ 18 years.

■ Presence of complete edentulism, intercalated partial edentulism, or distal partial edentulism where the remaining teeth in the mandibular or maxillary arch are deemed non-restorable due to periodontal compromise, second-degree mobility, destructive caries, or prosthetic needs, with horizontal bone dimension > 6 mm. Non-restorable teeth are those that cannot be preserved due to periodontal damage, mobility of the second degree, destructive caries, or prosthetic requirements. For patients with non-restorable teeth, post-extraction implants can be placed in prosthetically relevant sites where the vestibular bone component is present and regeneration is not required.

■ Any extraction/loss of teeth must have occurred at least 2 months before the planned intervention, with complete clinical and radiographic healing of the extraction sites.

8.4 EXCLUSION CRITERIA

Local Factors:

- Plaque Index (FMPS - Full Mouth Plaque Score) ≥ 25%;
- Bleeding Index (FMBS - Full Mouth Bleeding Score) ≥ 25%;
- Local inflammation affecting the mucosa;
- Presence of erosive mucosal diseases;
- Presence of bone lesions;
- History of prior radiotherapy and/or chemotherapy in the cervico-facial area;
- Extraction sites not fully healed and/or less than two months post-extraction;
- Parafunctional patients with bruxism;
- Patients with insufficient daily oral hygiene.

Systemic Factors:

- Patients with known collagen allergy;
- Patients with uncontrolled systemic diseases;
- Presence of chronic pathological conditions requiring antibiotic prophylaxis, such as rheumatic fever, bacterial endocarditis, cardiac valve anomalies, etc.;
- Medical conditions requiring prolonged use of steroid medications and/or bisphosphonates;
- History of leukocyte dysfunction or deficiency;
- History of coagulation disorders;
- History of renal insufficiency;
- Patients with physical and/or mental disabilities that impede proper and adequate oral hygiene;
- Patients with substance abuse issues, including alcohol or drug abuse;
- Patients with HIV;
- Smokers (> 10 cigarettes per day);
- Presence of conditions or circumstances that could interfere with the patient's proper participation in the study, such as non-cooperation;
- Pregnant patients.

8.5 OPERATIONAL PROTOCOL

8.6

First Visit

Clinical and radiographic evaluation is conducted and the patient's eligibility for inclusion in the research protocol is assessed. During the first visit, the patient is informed about full-arch rehabilitation using a full digital approach. Patients who consent to data collection pre- and post-treatment are divided according to the following criteria: Group A includes fully edentulous patients, while Group B consists of partially edentulous patients with at least two remaining teeth with sufficient stability (≤ mobility grade 1), which will be extracted. Both groups will follow different digital workflows, although they will be rehabilitated with the same monophasic implants.

The operational protocol is explained, and the patient receives the necessary documentation (informed consent, informational sheet, personal data processing consent form, privacy notice, and letter for the referring physician).
If the patient agrees to participate in the research study, the therapeutic process and the procedures as outlined in the clinical practice are then initiated.

Second Visit for Group A

- Acquisition of signed documentation;
- Execution of photographic status

- Prescription of CBCT;
- Acquisition of intraoral scans;

Using the obtained information, the technician creates a digital diagnostic wax-up. Based on this wax-up, a resin prototype is produced using CAM technology (either milled or 3D-printed) to verify function and aesthetics, as digitally designed by the technician, directly on the patient. This prototype is equipped with radiopaque markers and is used as a radiological template during the CBCT acquisition.

Third Visit for Group A

The aesthetic and functional parameters are evaluated through the fitting of the prototype created by the technician.
Once the prosthetic proposal is validated, a CBCT is performed, followed by the digital design of the implant positions. If the proposal is not acceptable, the aesthetic and functional parameters must be corrected before proceeding with the surgical planning.
The clinician digitally positions the implants necessary for the correct surgical plan.
The technician creates the surgical guide required for the guided placement of the designed implants.
Additionally, the technician fabricates the prosthesis in reinforced PMMA with a metal core made of titanium or cobalt-chrome, according to the wax-up validated by the prototype trial.

Second Visit for Group B

- Acquisition of signed documentation;
- Execution of photographic status;
- Prescription of CBCT, which the patient will undergo with cotton rolls placed between the arches to separate them and enhance the readability of occlusal margins;
- Acquisition of intraoral scans of the upper and lower arches, as well as the arches in maximum intercuspation.

Using the obtained information, the lab creates a digital diagnostic wax-up. This wax-up is analyzed digitally by overlaying 2D photographic images with the 3D file of the wax-up. This allows for previewing the aesthetic outcome of the new prosthetic rehabilitation to the patient.

If the prosthetic proposal is deemed valid, the implant positioning is digitally designed. If not, the aesthetic and functional parameters must be corrected before proceeding with surgical planning.

The clinician digitally positions the implants necessary for the correct surgical plan.

The technician creates a modular surgical guide, initially configured with a dental support to properly position the base of the guide, which is then secured with pins. The coronal portion of the guide can be removed for tooth extractions and later replaced with a new component that guides implant preparation and placement. Alternatively, the technician may create two separate guides: one with dental support for guided placement of fixation pins and another for guided implant placement after the removal of the remaining teeth.

Additionally, the lab fabricates a provisional prosthesis in PMMA reinforced with a metal core made of titanium or cobalt-chrome, according to the wax-up validated by the digital trial conducted during the second visit.

Surgical Procedure:

A pre-medication with Diazepam drops is administered. Local anesthesia is achieved through block infiltrations of mepivacaine 20 mg/ml with epinephrine 1:100.000.

Group A

The surgical guide, necessary for the guided placement of the implants, is positioned inside the patient's mouth. Proper fit is ensured by the occlusal portion of the guide, which aligns with the antagonist arch teeth.
When a flapless surgical approach is chosen, a mucotome is used as the first bur. Otherwise, mucoperiosteal flaps are elevated as needed, since the base structure of the guide provides ample space for incising, reflecting, and performing subsequent surgical maneuvers on the soft tissues. Implant sites are prepared using a sequence of dedicated burs guided by the cannulas on the surgical guide. Implant placement is then performed, with guidance ensured by the contact between the implant mount and the cannula of the surgical guide. Implants are inserted according to the manufacturer's instructions with a torque of at least 35 Ncm. The system's mounters feature a screw that allows removal of the mounting device at the end of the angled implant insertion. The screw must align with a slot on the sleeve edge to enable the use of a dedicated screwdriver. After removing the mounters, the fixation pins and the surgical guide are also disengaged.
Provisional cylinders, pre-cut by the technician to the correct height, are placed over the implants. A provisional prosthesis in PMMA with a titanium or cobalt-chrome metal core is then fixed onto these cylinders using dual-cure composite resin. The prosthetic profiles are refined to ensure access for home oral hygiene maneuvers. Access holes are sealed with Teflon and light-cured flow composite.
Occlusal adjustments are performed where needed.
The patient is recalled for follow up visits at 7, 14, and 28 days, following standard clinical practice.

Group B

The surgical guide is first positioned in its dental support configuration, securing the base with fixation pins. The most coronal portion of the guide is then removed, and the residual teeth are extracted. The second component of the guide is mounted and fixated to the base, which remains in position due to the pins. This second

configuration allows for guided implant preparation and placement.
If two separate guides are used instead of a stackable guide, the first guide, which supports the teeth, is utilized to place the fixation pins, which then serve to properly align the second guide, which provides mucosal support and facilitates guided implant placement. During the interval between the use of the two guides, the residual teeth are removed. Implants are inserted according to the manufacturer's instructions with a torque of at least 35 Ncm. The surgical guide is then removed. In the post-extraction sites, alveolar volume maintenance is performed using deproteinized bovine bone. If necessary, due to insufficient soft tissue thickness, a connective tissue graft harvested from the palatal area is performed.
Provisional cylinders, pre-cut by the technician to the correct height, are placed on the implants. The provisional prosthesis, made of PMMA with a titanium or cobalt-chrome metal core, is then fixed onto these cylinders using dual-cure composite resin. The prosthetic profiles are refined to ensure access for home oral hygiene. Access holes are sealed with Teflon and light-cured flow composite.
Occlusal adjustments are performed where needed.
The patient is recalled for follow-up visits at 7, 14, and 28 days, in accordance with standard clinical practice.

Definitive Prosthesis

First Appointment

After a 6 months healing period, a definitive full-arch prosthesis is fabricated using a digital workflow. The provisional prosthesis is scanned to transfer functional and aesthetic information to the technician. To maintain the same vertical dimension, a scan of the buccal surfaces of the maxillary arches in occlusion is performed. The provisional prosthesis is then removed.
For the maxillary arch, due to the presence of abundant keratinized tissue and reference points provided by the palatine rugae, along with minimal tissue mobility, an optical impression with an intraoral scanner can be obtained after placing the Scan Bodies.
At the mandibular arch, it is advisable to first perform a scan of the soft tissues without

Scan Bodies. This initial scan will be used by the technician to create a custom scanning guide.

The role of the scanning guide is to stretch the tissues, establish a stable connection between the Scan Bodies placed on the implants, reduce distortion of the arch curvature, and provide recognizable geometric shapes for the scanner to ensure a smooth and continuous scan.

Second Appointment

This appointment is necessary if a scanning guide has been created. The guide is placed in the patient's mouth along with the Scan Bodies. Following this, an intraoral scan is performed using the scanner.

Third appointment

The lab fabricates an alluminium bar prototype, used to test passive fit. The passive fit of the bar is assessed both clinically and radiographically.
An acrilyc restoration is used to test the aesthetic and functional values of the prototype. Any required modification is communicated to the technician.

Fourth Appointment

The final prosthesis is delivered, featuring a milled titanium framework, a monolithic tetragonal zirconia dental portion, and a milled pink PMMA gingival portion. The three components are then assembled using a sandwich technique and cemented with a composite resin. Clinical and radiographic passive fit checks are performed, along with occlusal adjustments in both static and dynamic conditions. Once the prosthesis is validated for both aesthetic and functional parameters, the abutment screws are torqued to 30 Ncm as per the manufacturer's instructions. The screw access holes are sealed with Teflon and light-cured composite resin. Subsequent appointments for follow-up evaluations are scheduled at 1, 2, and 3 years, during which outcome parameters of the study will be collected.

8.7 END POINTS

a) Stability of Peri-Implant Bone Tissue:

The stability of peri-implant bone tissue is assessed using panoramic radiographs (OPT), with measurements taken mesially and distally to the implants. For each case the postoperative panoramic radiograph is considered as the baseline and follow up radiographs are used for measurements.
Radiographs are taken immediately post-op, at 3 months post op and after 1 year before the beginning of the final prosthesis fabrication.
If the radiographs are not in digital format, the images are scanned and digitized at a resolution of 1200 dpi.

The marginal bone level, defined as the distance between the most apical point of the smooth neck of the fixture and the first visible contact point between bone and implant, is measured mesially and distally for each implant with 10-15x magnification using image analysis software (ImageJ v 1.49, NIH, Bethesda, MA, USA). (Figure 6, 7).

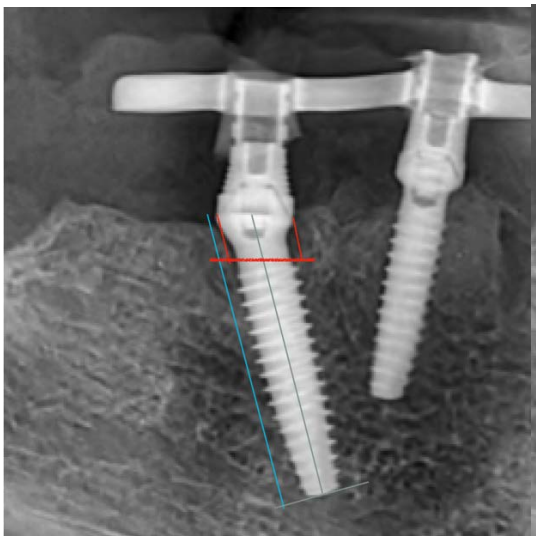

Figure 6

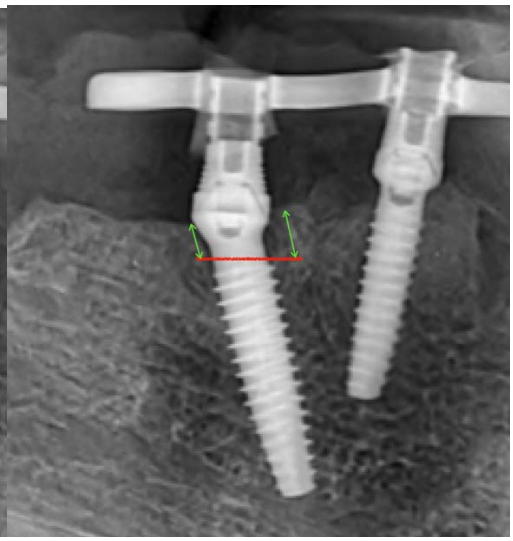

Figure 7

The length of the implant is used as a known distance to calibrate and determine the exact distortion and magnification of the images. Calibration is repeated for each

implant.

Customized calibration is required for each implant angle and platform type as they differ in the smooth collar portion and the height of the prosthetic platform. Dimensional analysis of the implants provided by the company were used to ensure reliable measurements.

If the bone level is located more apically compared to the prosthetic shoulder, a value preceded by a "+" sign is assigned. Conversely, if the bone level is more coronal compared to the prosthetic shoulder, the measurement is preceded by a "-" sign.

All measurements are performed by two examiners. In the event of a disagreement, the measurement is repeated and the results are discussed until a unanimous agreement is reached.

b) Post-operative morbidity

the Post-operative morbidity is assessed through the completion of a specific questionnaire. This questionnaire is filled out by the patient starting 6 hours after the implant placement surgery (before taking any prescribed medications) and continues until the third post-operative day. According to international scientific literature (310), a 100 mm visual analog scale (VAS) with endpoints at each extreme is used to record:

1) The intensity of post-operative pain on the day of surgery, as well as on days 1, 2, and 3 following the surgery. The scale ranges from 0, indicating no pain, to 100, indicating extreme pain:

0 No pain 100 Extreme pain

2) The severity of swelling on the day of surgery, and 1, 2, and 3 days after surgery. A score of 0 corresponds to no swelling, while 100 corresponds to extreme swelling.

3) 0 no swelling 100 Extreme swelling

4) The intensity of bleeding on the day of surgery, and 1, 2, and 3 days after surgery. A score of 0 corresponds to no bleeding, while 100 corresponds to extreme bleeding;

5) 0 No bleeding 100 Extreme bleeding

6) The patient's perception of the procedure on a scale from acceptable (0) to very unpleasant (100).

0 Acceptable 100 Very unpleasant

The patient is asked to mark on a visual analog scale (VAS) the point that best represents the intensity of each parameter. Once the point's position is recorded, the distance from the origin to the marked point is measured in millimeters, with the maximum possible score being 100 mm. The questionnaire is collected during the first postoperative follow-up, 7 days after surgery.

8.8 STATISTICAL CONSIDERATION

A descriptive analysis of all variables under study will be performed, with data presented as means and standard deviations for normally distributed data, and as medians and interquartile ranges for non-normally distributed data.

For sample size calculation, a specific software (G*Power 3.1, Heinrich-Heine University, Düsseldorf, Germany) was used with the two-tailed Wilcoxon signed-rank test considering the primary outcome. An average bone resorption of 1.06 ± 0.9 mm between baseline and one year of follow-up was assumed, based on the most recent scientific publication on radiographic assessment of peri-implant bone remodeling for monophasic implants. Assuming a mean bone resorption of 1.06 ± 0.9 mm, a significance level of 5%, and an effect size of 1.17, a sample size of 13 patients is

required to achieve a statistical power (1-β) of 95%.

Regarding the primary outcome (which is the radiographic assessment of peri-implant bone tissue stability over time) the bone levels at baseline will be compared with those at follow-up. Data related to resorption will be organized and analyzed using a statistical electronic database (IBM SPSS Statistics 24.0, IBM Corp, Armonk, NY). Each implant will be considered as the statistical unit of reference.

The Shapiro-Wilk test was initially applied to assess the normality of the data distribution. Based on the results, if the data were normally distributed, parametric tests were used for the subsequent analyses.

To compare marginal bone loss (MBL) values during the study period (Baseline and 1 year), an independent samples t-test was used for comparisons between two independent variables (maxilla vs. mandible and native vs. post-extraction bone). For comparisons involving more than two groups (implant angulation: 0°, 17°, 30°), a one-way ANOVA was employed. Tukey's post-hoc test was applied for multiple comparisons.

As for the evaluation of intra-group differences (within the same group over time), paired samples t-tests were used to compare MBL between Baseline and 1 year for both the maxilla and mandible, as well as for each implant angulation group.

In cases involving repeated measurements across time (Baseline vs. 1 year), a two-way repeated measures ANOVA was performed to assess interactions between time and implant angulation. Bonferroni correction was applied for post-hoc comparisons.

The significance level for all tests was set at $\alpha = 0.05$.

As for the secondary outcome, which is post-operative morbidity, the Independent T-test will be used to assess statistically significant differences between data reported by patients in Group A and Group B.

8.9 MATERIALS

In the present protocol, one-piece implants from the Fixo® line, produced by Oxy Implant Dental System Italia® (Biomec colico lc, Italy), were used. These implants are characterized by the structural integration of the transmucosal abutment and the implant fixture, creating a single component with significant mechanical and biological qualities.

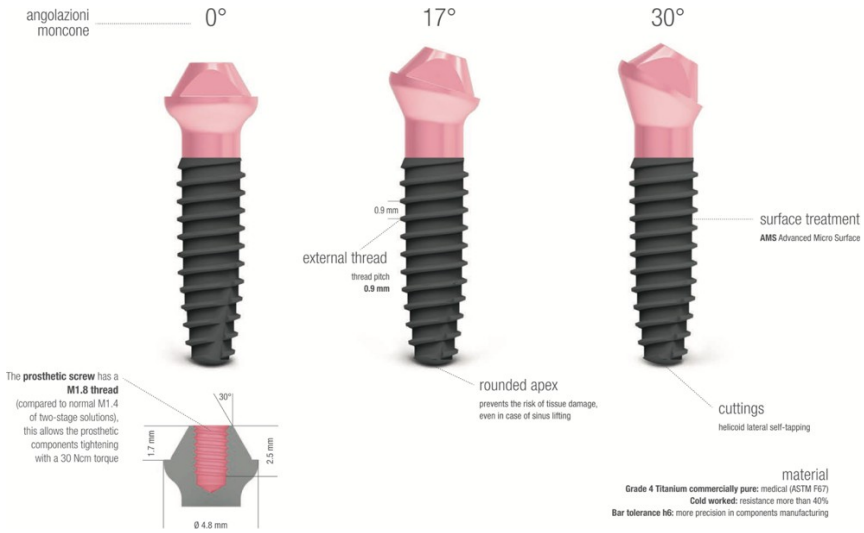

Figure 8: Fixo Implant Line (Oxy Implant Dental System Italia®)

The cited implants are available with angled abutments in three different inclinations: 0°, 17°, and 30°. The design allows the clinician to address any misalignment issues resulting from either straight or angled placement of the implant fixture while meeting the required aesthetic and functional criteria. The narrow diameter of the Fixo implants, combined with the precise coaxial alignment between the fixture and abutment, makes them ideal for use in guided surgery. Those characteristics facilitate smooth and interference-free passage through the surgical guide sleeve. The considered implant system is equipped with specialized mounters that also allow the insertion with angled abutments, ensuring that the fixture is perfectly aligned with the insertion axis.

Figura 9: Mounter for Fixo Implant System, Oxy Implant Dental System Italia®

The alignment between the angled abutment and the fixture reduces the lever arm in load-bearing situations, resulting in decreased biomechanical stress on the marginal bone and a reduced risk of peri-implant bone resorption.

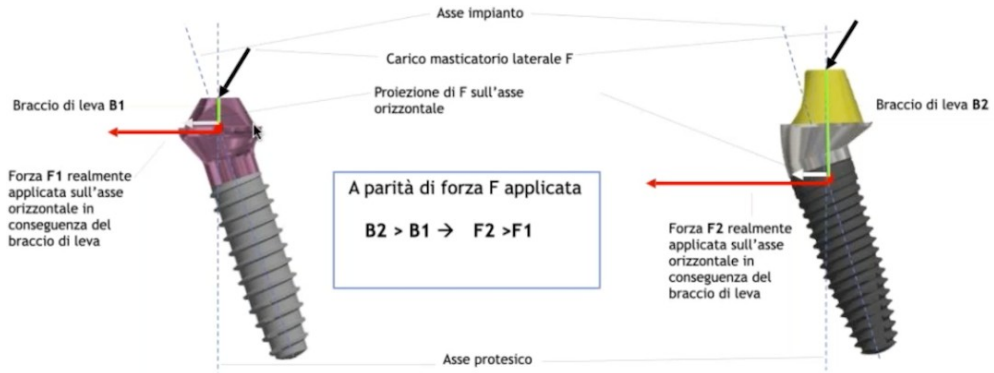

Figura 10: Comparison of the force system generated by a lateral masticatory load in a Fixo implant with an angled abutment versus a two-piece implant with an angled abutment.

The Fixo implant line includes four different diameters: 3 mm, 3.5 mm, 4 mm, and 4.5 mm, with various lengths ranging from 7 mm to 17 mm depending on the type of fixture. Among these, the Fixo mini line is distinguished by diameters of 3 mm and 3.5 mm, with lengths of 10 to 13 mm for the smaller diameter and 8.5 to 15 mm for the 3.5 mm diameter. This line only includes fixtures with 0° and 17° abutments, with no 30° angulation available. A notable feature is the chamfer diameter of the integrated abutment, which is only 4 mm (compared to 4.8 mm in the classic Fixo line), making them ideal for aesthetic zones.

All Fixo implants feature a pink transmucosal component to blend with soft tissues, even in cases of thin phenotypes. The component is available in two configurations: short (2 mm in height) and long (3 mm in height). The Fixo mini implants are available only in the short configuration. The transmucosal component accommodates an M1.8 prosthetic screw that allows for a torque of 30 Ncm.

All Oxy Implant implants are made of Grade 4 Titanium, while the prosthetic components are made of Grade 5 Titanium. The surface treatment of the Fixo line implants, known as AMS (Advanced Micro Surface), is consistent across all implant lines produced by Oxy Implant Dental System Italia® (Figure 11).

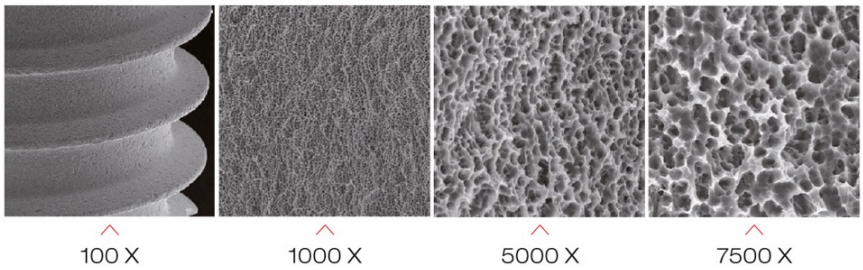

Figure 11: Surface Treatment of the Fixo Implant Line at Different Magnifications

This treatment was developed to accelerate the biological response of cellular adhesion, thereby optimizing the process of osseointegration. It is achieved through chemical attachment processes, decontamination, and cold Argon plasma treatment. These combined processes result in a surface with a high degree of cleanliness, characterized by homogeneous microporosity with peak distances on the order of a few microns, smaller than cellular dimensions. This significantly enhances the adhesion of osteoblastic cells and promotes osteogenesis. These factors are crucial for achieving better implant anchorage in bone, higher insertion torque values, and consequently higher clinical success rates.

9. CLINICAL CASES

Clinical case n.1 - mandibular edentulism and resective surgery

Figure 12: Initial extraoral photographs with the removable complete denture

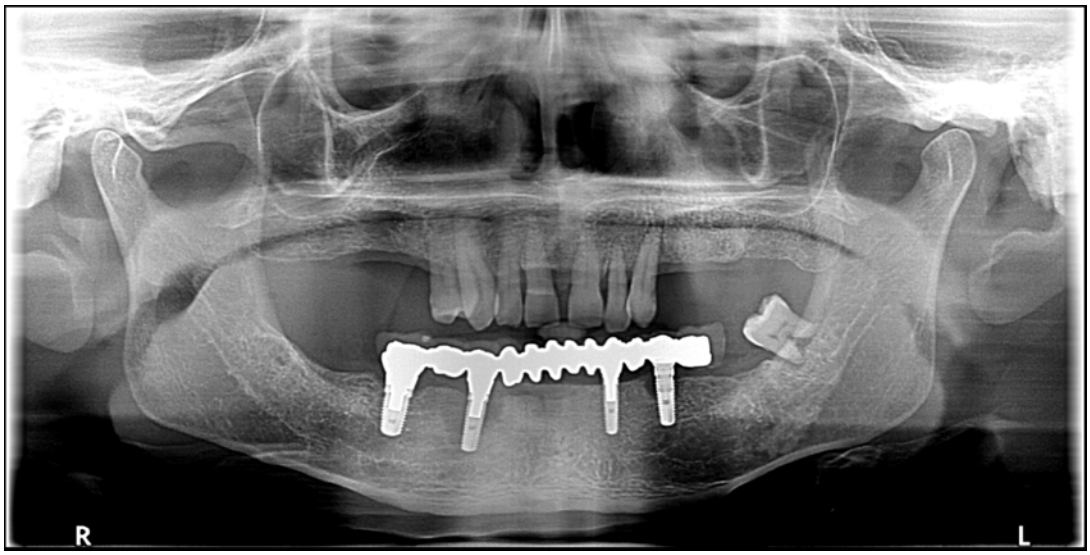

Figure 13: Initial panoramic X-ray showing implants with peri-implantitis and non-recoverable tooth 38

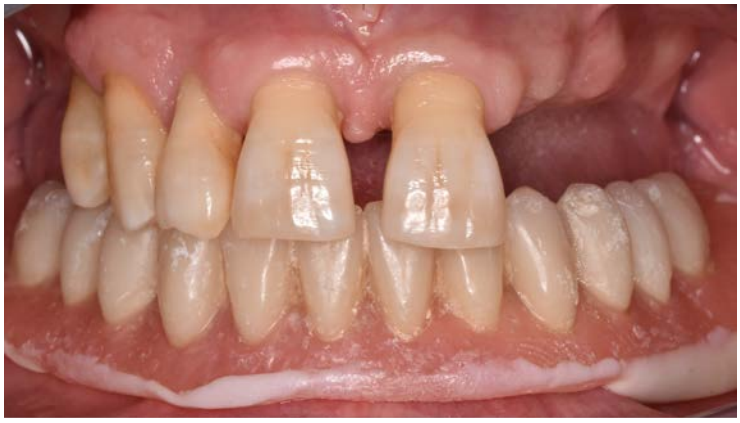

Figure 14: Intraoral photograph with provisional lower prosthesis

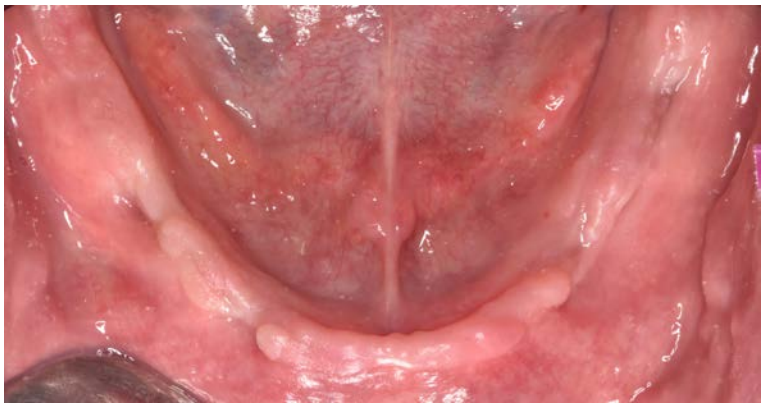

Figure 15: Intraoral photograph of edentulism pre-surgery

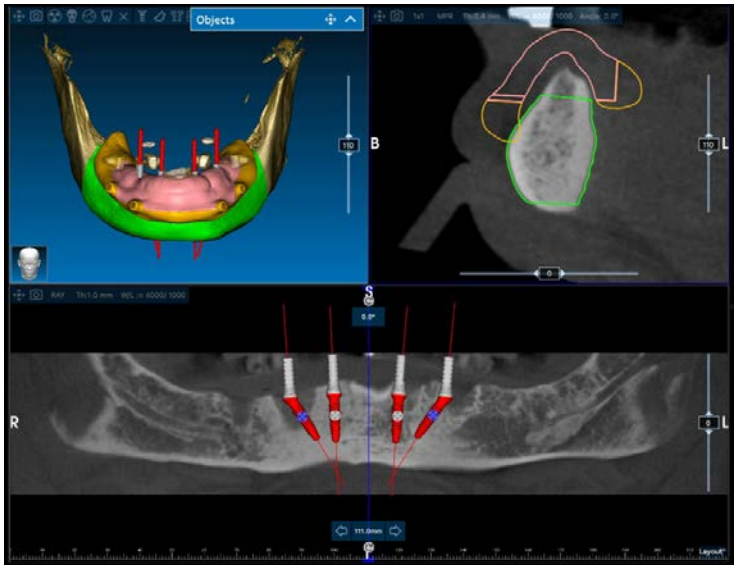

Figure 16: Guided Surgery Planning

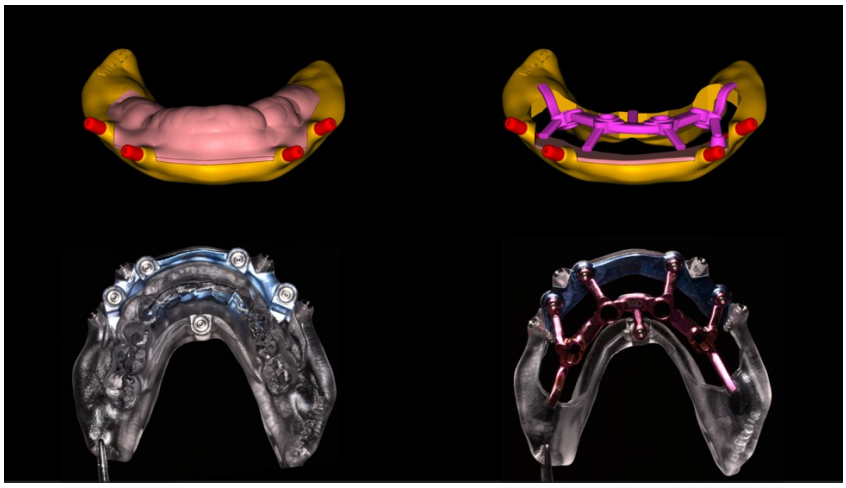

Figure 17:Design and Fabrication of a Modular Surgical Guide

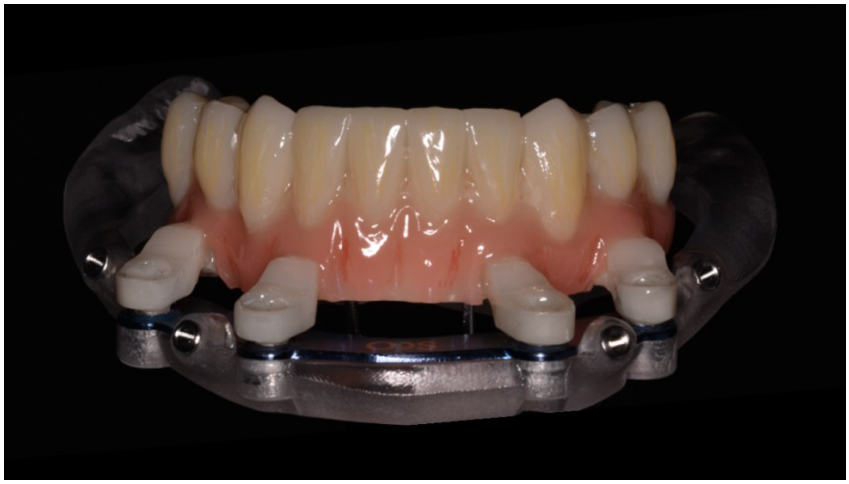

Figure 18: Modular Surgical Guide with Temporary Prosthesis in Position

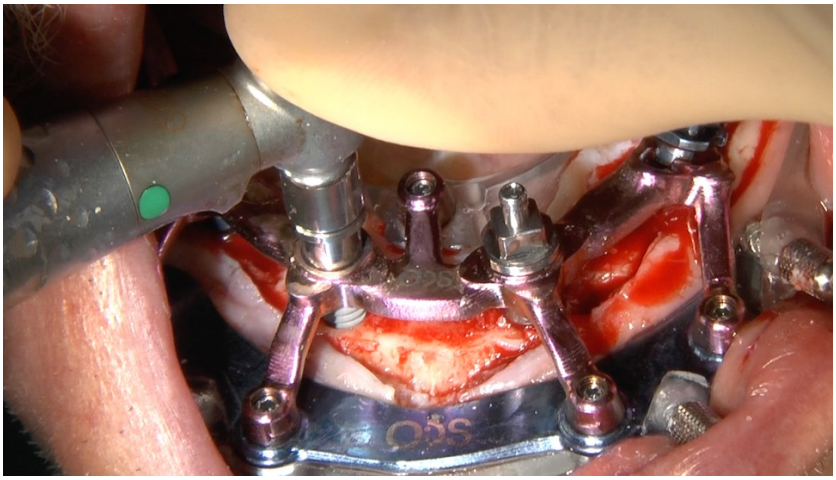

Figure 19: Implant Placement Using Surgical Guide

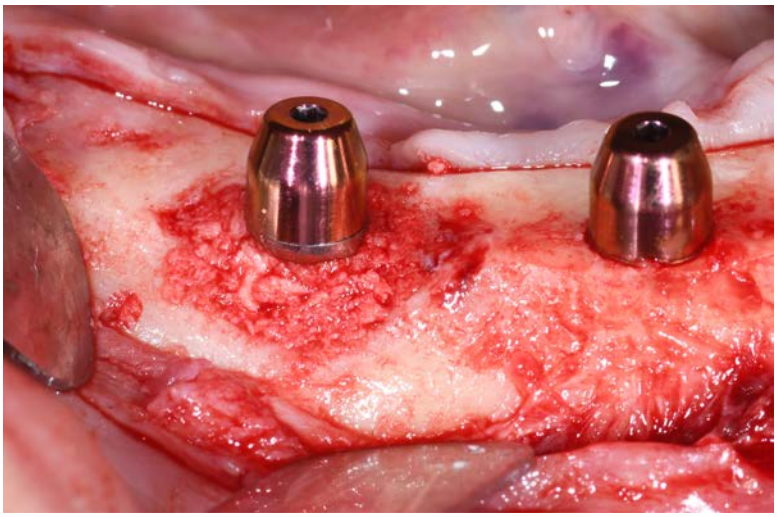

Figure 20: Implants Placed with Healing Abutments in Position (Detail)

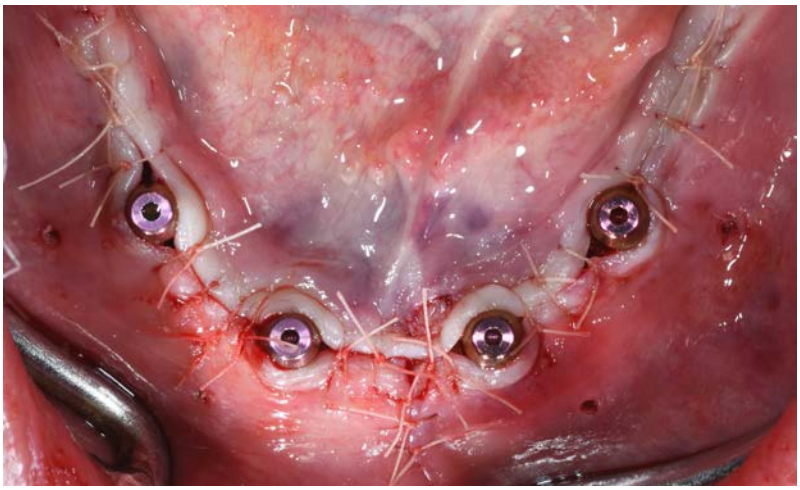

Figure 21: Implants Placed with Healing Abutments in Position

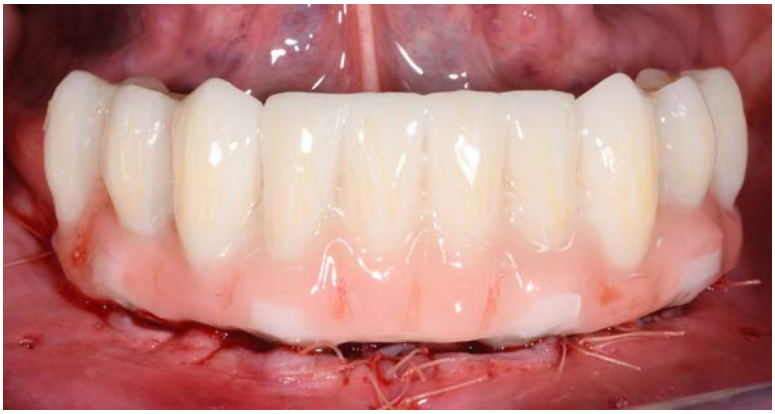

Figure 22: Screwed Temporary Prosthesis

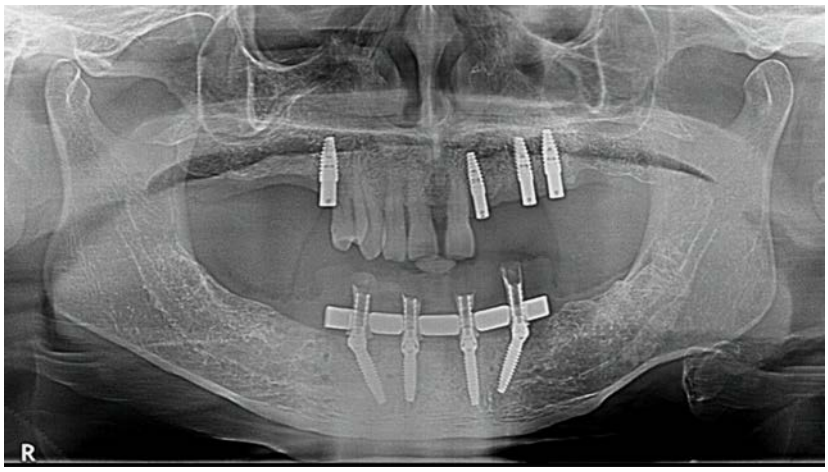

Figure 23: Post-Delivery Temporary Prosthesis Control OPT

Clinical case n.2 - partially dentate patient

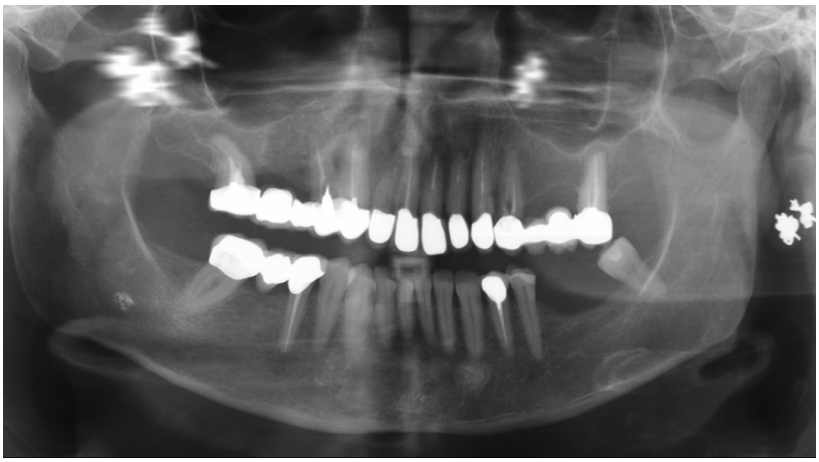

Figure 24: Initial panoramic X-ray showing non-recoverable teeth in the upper arch

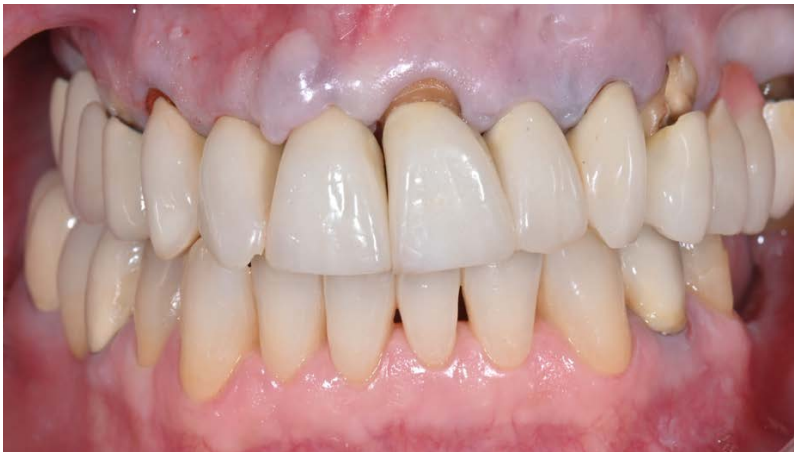

Figure 25: Frontal view of the dentition at baseline

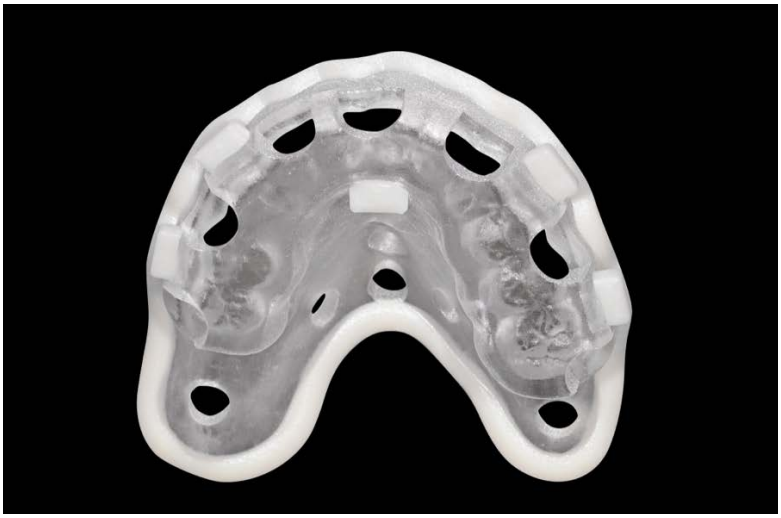

Figure 26: radiological template

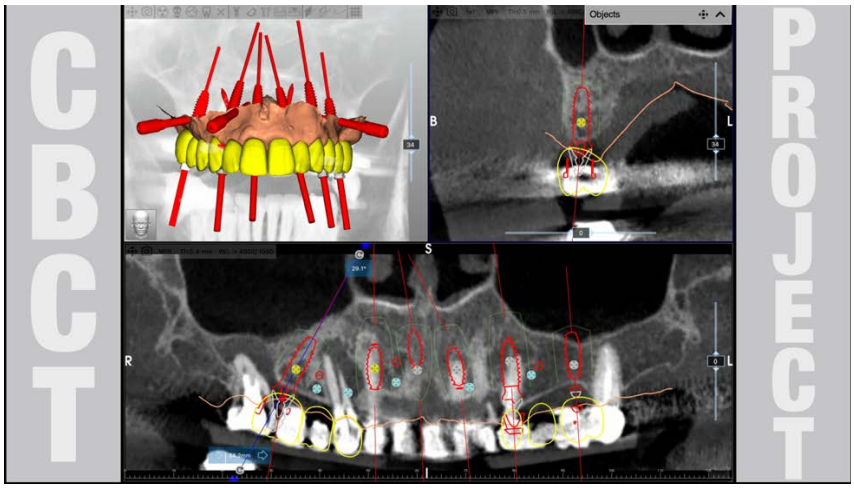

Figure 27: Guided Surgery Planning

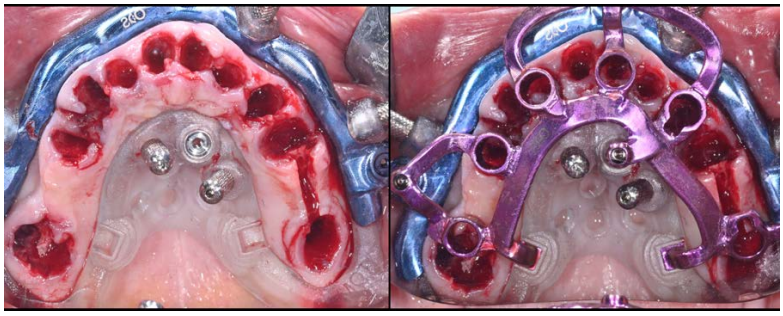

Figure 28a: Occlusal view of the base guide after teeth extraction

Figure 28b: Occlusal view of the implant insertion guide mounted on the base guide

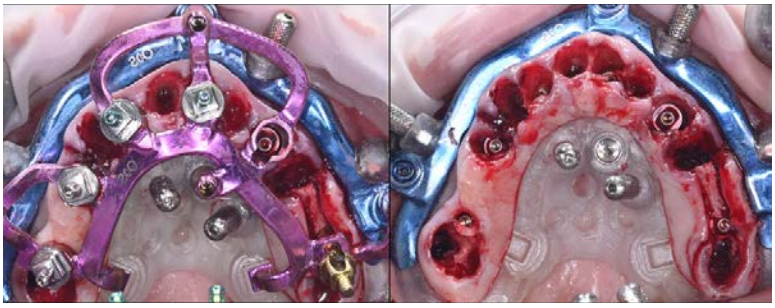

Figure 29a: Implant insertion guide mounted on the base plate and five fixtures inserted

Figure 29b: Occlusal view of Implants inserted

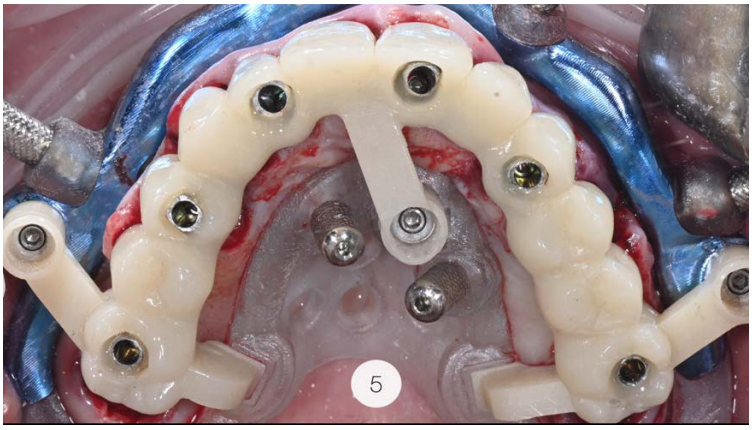

Figure 30: Occlusal view of the provisional Prosthesis mounted on the base guide

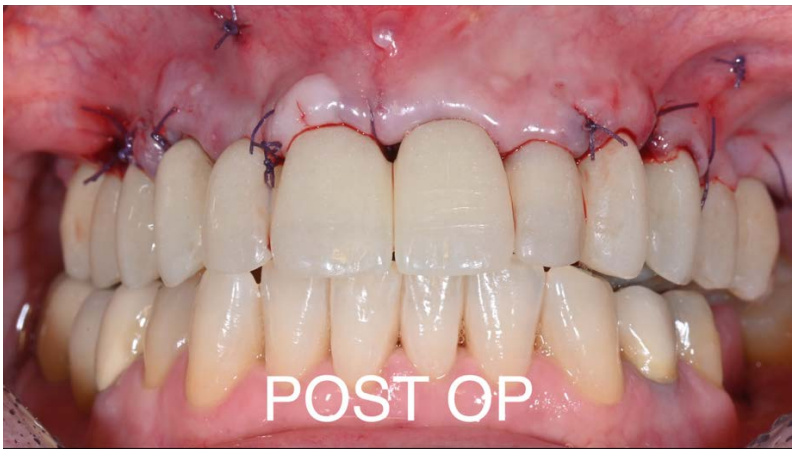

Figure 31: Frontal view of the provisional prosthesis at post-op

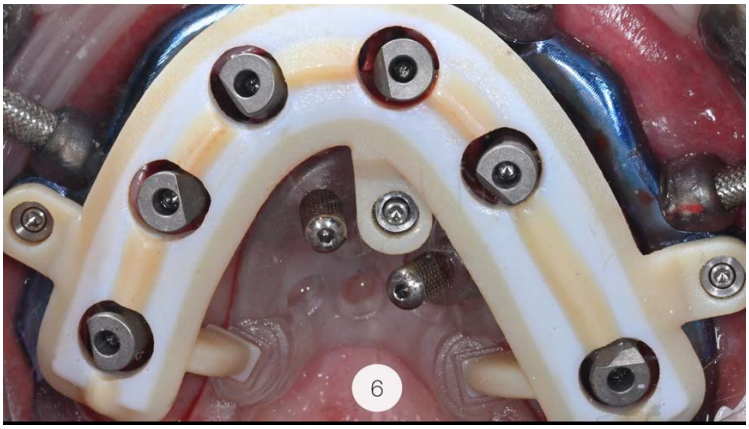

Figure 32: Occlusal view of the number guide mounted on the base guide

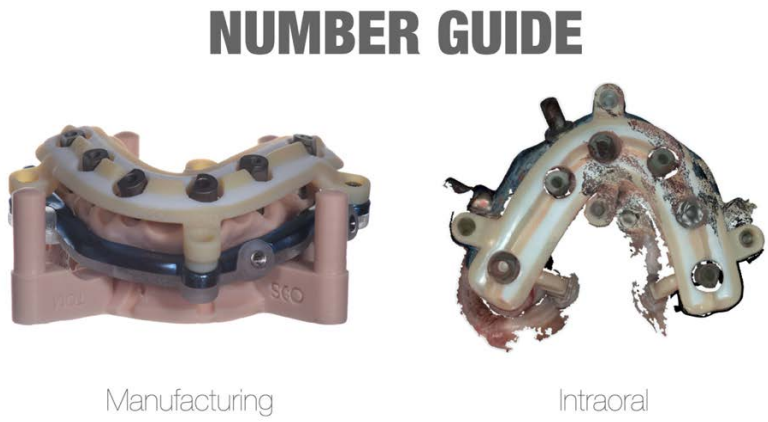

Figure 33: number guide manufacturing and digital scan

Figure 34: Frontal view of the provisional prosthesis at 2 weeks post-op

Clinical case n.3 - maxillary edentulous patient

Figure 35: Initial extraoral photographs with the removable complete denture

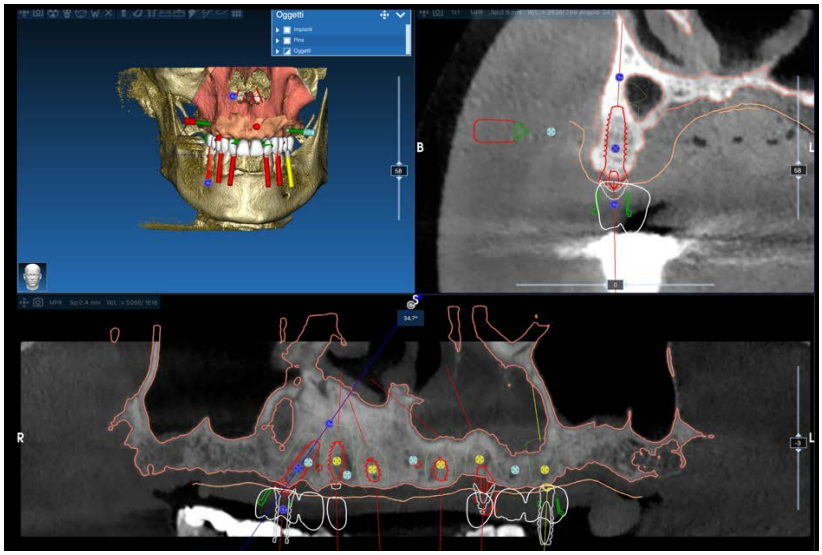

Figure 36: Guided Surgery Planning

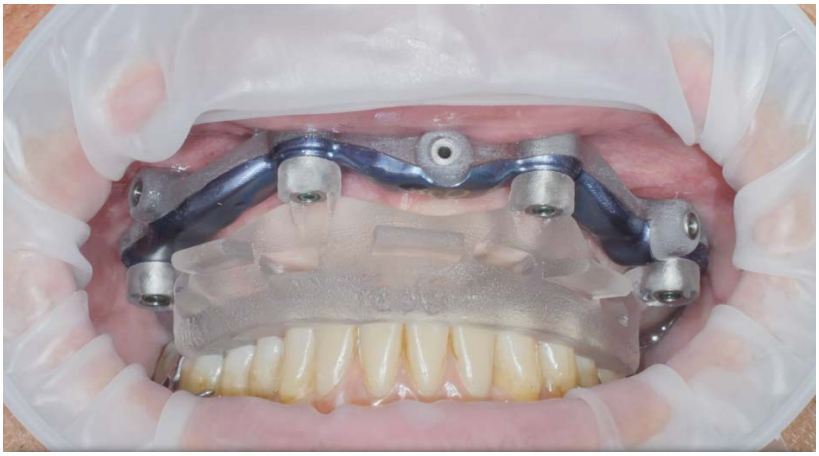

Figure 37: Frontal view of the base guide positioning using a stackable module in intercuspation with lower arch

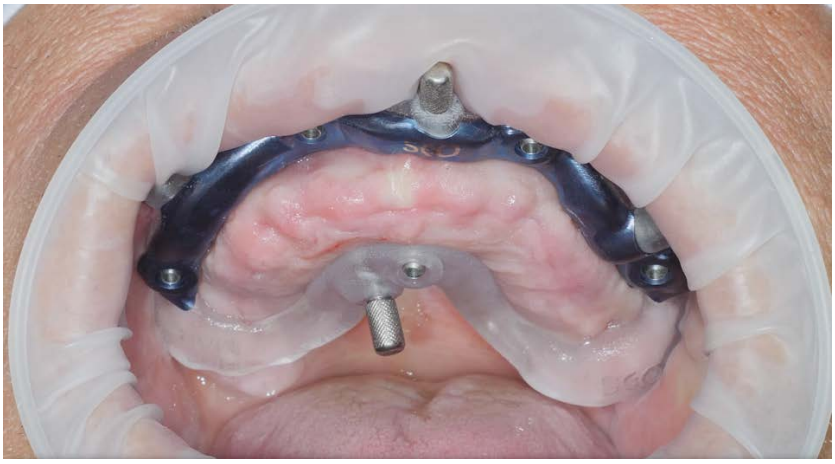

Figure 38: Occlusal view of the base guide and stabilization pin inserted

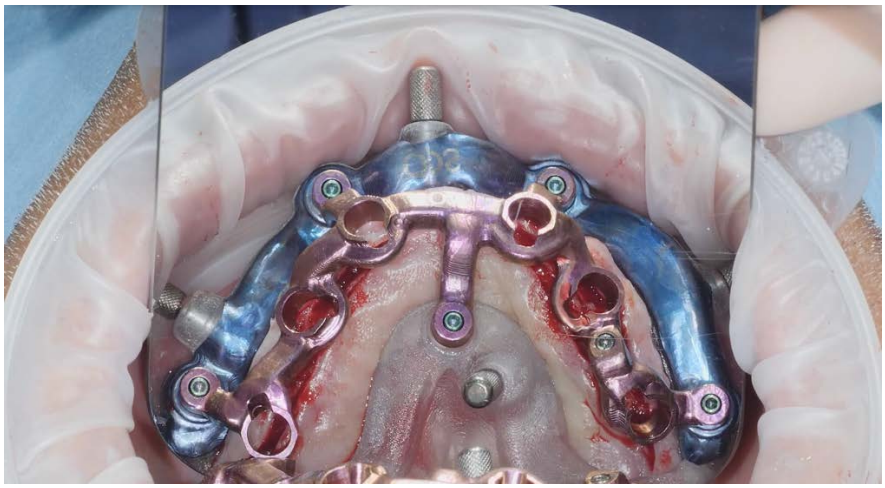

Figure 39: Occlusal view of the base guide and fixtures insertion guide

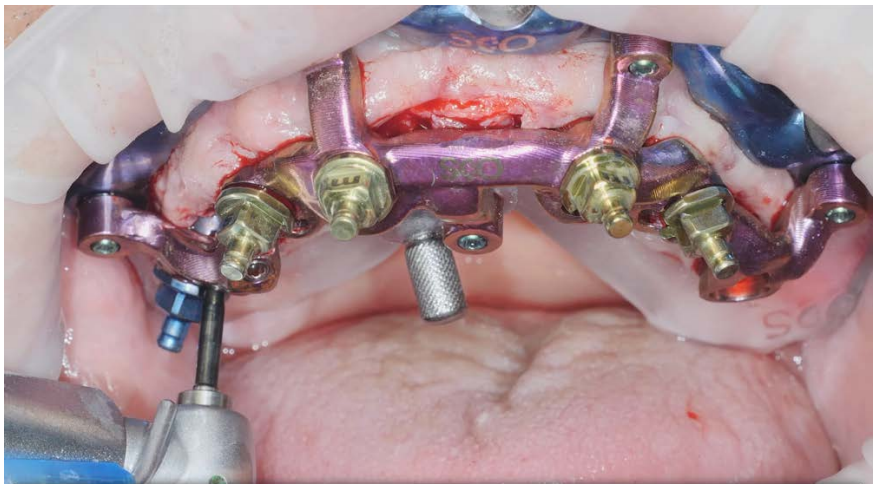

Figure 40: Frontal view fixtures inserted and the unscrewing of the insertion guide

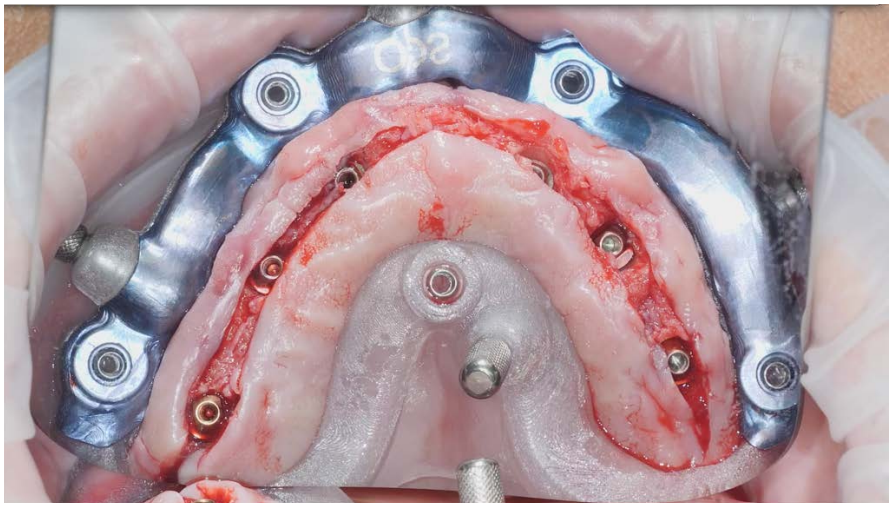

Figure 41: Occlusal view of the base guide and fixtures inserted

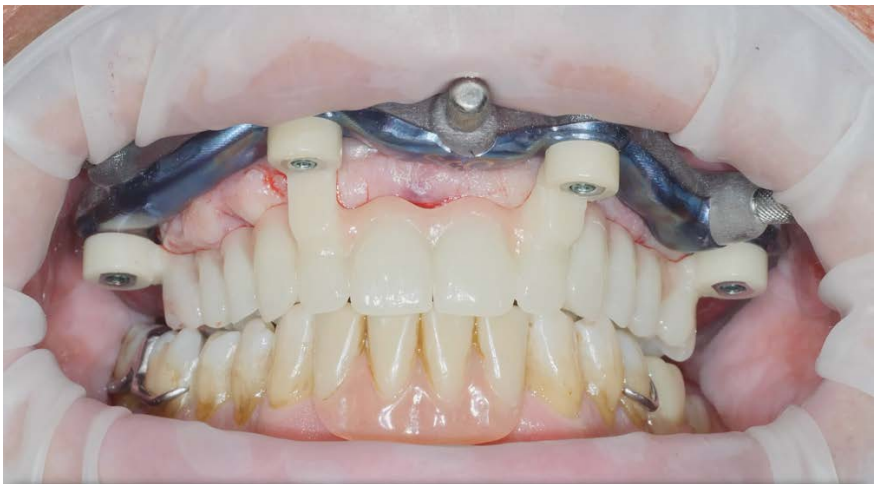

Figure 42: Provisional Prosthesis mounted on the base guide

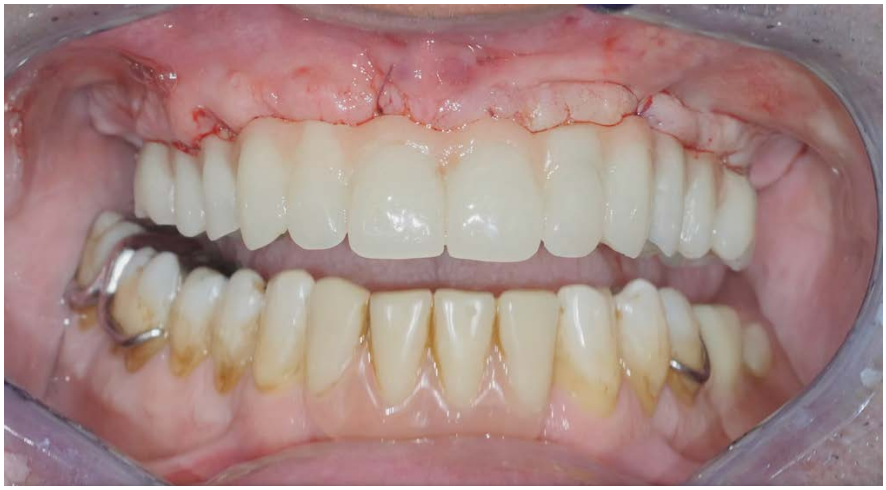

Figure 43: Frontal view of provisional prosthesis post-op

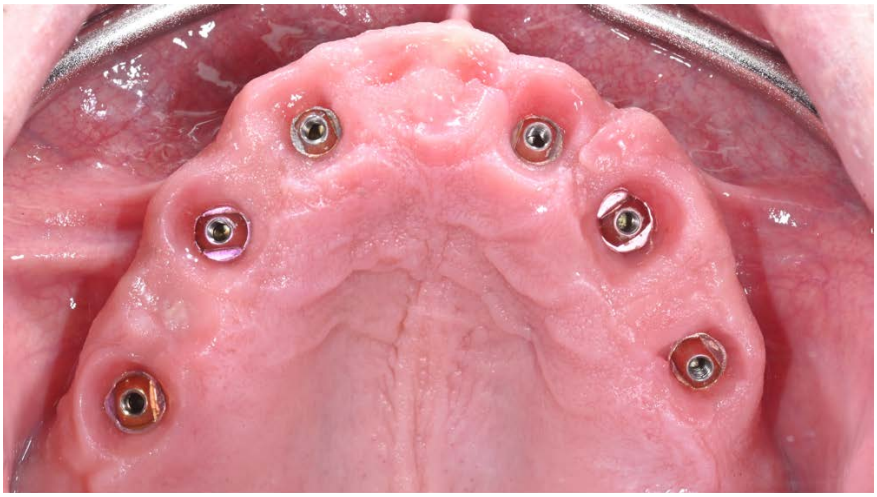

Figure 44: Occlusal view of soft tissues at definitive proshesis delivery

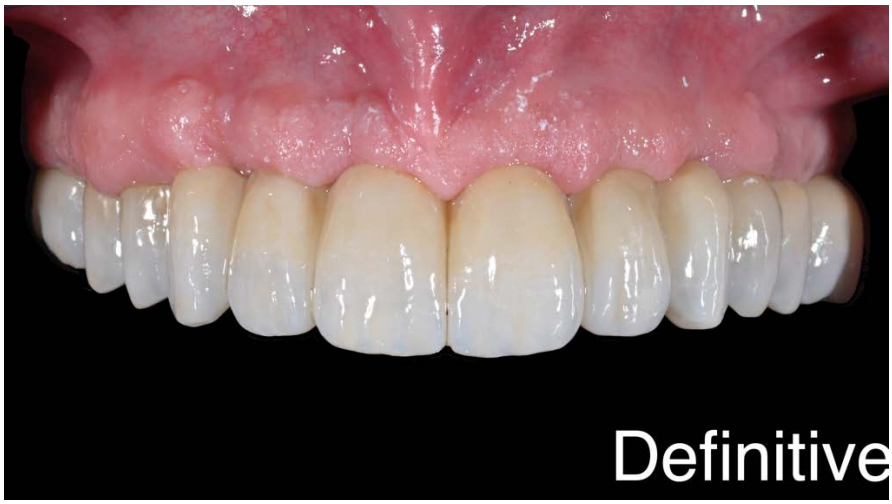

Figure 45: Frontal view of definitive proshesis delivery

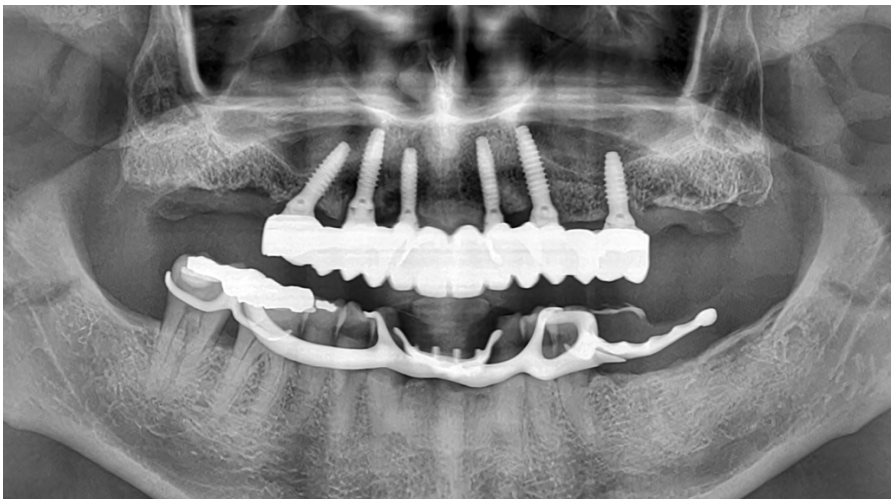

Figure 46: Post-Delivery definitve Prosthesis Control OPT

10. RESULTS

The primary objective of this study is to examine the stability of perimplant bone tissue, assessed through the measurement of marginal bone loss (MBL) around one-piece implants inserted using guided surgery with a full digital workflow for full-arch rehabilitations. Marginal bone level, defined as the distance between the most apical part of the smooth neck of the fixture and the first visible point of contact between bone and implant, was measured mesially and distally for each implant using 10-15x magnification with an image analysis program (ImageJ v 1.49, NIH, Bethesda, MA, USA). The nominal length of each implant was used as a known distance to calibrate and determine the exact distortion and magnification of the images. Calibration was repeated for each individual implant. To compare peri-implant bone resorption values during the study period (baseline/follow-up), the Independent T-test was used for parameters involving up to two independent variables (arch considered and insertion site [healed bone or extraction socket]), while one-way ANOVA was applied for parameters involving more than two variables (angulation of the integrated abutment). The significance level was set at 5% ($\alpha = 0.05$). None of the 108 osseointegrated implants examined in this study experienced failure or prosthetic complications of any kind.

The secondary outcome of the study is the assessment of post-operative morbidity using a specific questionnaire where patients are asked to indicate on a VAS scale a representative value of pain, swelling, and bleeding at 5-6 hours post-operation, the following day, 2 days, and 3 days after the intervention. Patients are also requested to rate their perception of the procedure using the VAS scale, with values ranging from 0 (Acceptable) to 100 (Very Unpleasant). The mean value for each parameter is calculated from the obtained data. The Independent T-test was used to assess the existence of statistically significant differences between the data reported by patients in Group A and Group B.

a) Peri-Implant Bone Tissue Stability

The mean Marginal Bone Loss (MBL) calculated for 108 one-piece implants inserted across 26 different clinical cases using an immediate loading protocol with a full digital approach is 1.300 mm ± 0.090 mm (mean ± SD).

The results showed no statistically significant differences in MBL concerning the arch of insertion, implant diameter, abutment angulation, or insertion site.

b) Post-Operative Morbidity

Patient	5-6 Hours Post-Surgery (D)	5-6 Hours Post-Surgery (G)	5-6 Hours Post-Surgery (S)	Day 1 (D)	Day 1 (G)	Day 1 (S)	Day 2 (D)	Day 2 (G)	Day 2 (S)	Day 3 (D)	Day 3 (G)	Day 3 (S)	Perception of the Procedure
1	50	10	10	40	10	0	40	10	0	30	10	0	30
2	20	15	10	30	20	0	30	15	0	10	0	0	10
3	15	5	25	15	5	5	10	5	0	5	5	0	10
4	5	0	0	5	0	0	2	0	0	0	0	0	5
5	10	0	10	5	5	0	0	10	0	0	10	0	10
6	30	10	15	20	5	5	20	10	5	15	10	5	25
7	25	15	20	25	15	10	25	15	10	20	10	5	20
8	35	20	25	30	20	15	30	20	15	30	20	10	30
9	10	5	10	10	5	5	10	5	0	10	5	0	10
10	20	15	10	15	10	5	15	10	5	15	10	5	15
11	50	25	30	40	30	20	40	25	20	40	25	20	35
12	5	0	5	5	0	0	5	0	0	5	0	0	5
13	30	15	20	25	15	10	25	15	10	25	15	10	20
14	25	10	15	20	10	5	20	10	5	20	10	5	25
15	40	20	30	35	20	15	35	20	15	35	20	10	35
16	15	5	10	15	10	5	15	10	5	15	10	5	10
17	10	5	5	10	5	0	10	5	0	10	5	0	5
18	20	10	15	20	15	5	20	15	5	20	15	5	15
19	35	20	25	30	25	15	30	25	15	30	25	15	30
20	40	25	30	35	25	20	35	25	20	35	25	20	35
21	30	15	20	25	15	10	25	15	10	25	15	10	30
22	25	10	15	20	10	5	20	10	5	20	10	5	25
23	15	5	10	15	10	5	15	10	5	15	10	5	10
24	5	0	0	5	0	0	5	0	0	5	0	0	5
25	20	10	15	20	10	5	20	10	5	20	10	5	15
26	50	25	30	45	30	25	45	30	25	45	30	25	40
27	40	20	25	35	25	20	35	25	20	35	25	20	35

Tab. 4 Table for Assessment of Postoperative Morbidity

Data collected through the questionnaire regarding pain, swelling, bleeding, and perception of the procedure indicate very low values, reflecting the minimally invasive nature of the procedures and the high level of patient satisfaction. No adverse postoperative events such as abnormal bleeding or swelling, nor pain that could not be adequately managed with pharmacological treatment, were reported in any of the cases presented. Nearly all patients reported discontinuing analgesic medication after 3 days post-surgery.

As for pain, the average values recorded are: on the day of the surgery (25.00), on day 1 (22.04), on day 2 (21.56), and on day 3 (19.81).

For swelling, the average values recorded are: on the day of the surgery (11.67), on day 1 (12.96), on day 2 (12.96), and on day 3 (12.22).

For bleeding, the average values recorded are: on the day of the surgery (16.11), on day 1 (7.78), on day 2 (7.41), and on day 3 (6.85).

These data demonstrate that pain tends to be higher in the first 2 days, gradually decreasing over the next 2 days. Swelling, on the other hand, shows consistent values across the first two days, with a slight decrease on day 3. Bleeding starts higher on the day of the surgery and progressively decreases across the next few days.

When comparing the average values reported by patients in Group A (completely edentulous) with those in Group B (partially edentulous), a statistically significant difference is observed in pain and swelling levels on day 2. Both are higher in partially edentulous patients. This difference is hypothesized to be due to the need for extractions of remaining teeth during the same surgical session as implant placement in these patients. Additionally, in Group B, alveolar preservation using deproteinized bovine bone and possible soft tissue grafts is performed during the same session.

The tolerable postoperative course, combined with the ability to achieve a fixed rehabilitation with good aesthetics in a single session, contributes to a very manageable perception of the treatment for the patients. No patient reported an unpleasant perception of the procedure. The average value for the perception of the operation is 20.

11. DISCUSSION

The present study investigates the impact of one-piece implants on the rate of peri-implant bone resorption over time. The rationale for such an approach lies in the elimination of the fixture-abutment interface in these implants, which numerous studies have identified as a critical area influencing the outcome of rehabilitation [63].

Biologically, that interface represents a region where bacteria can infiltrate and proliferate. Micromovements generated during chewing in a two-piece abutment-implant connection cause a phenomenon known as the "pumping effect," which expels resident bacteria and their toxins from this space to the surrounding bone, triggering an inflammatory process that can lead to peri-implant bone resorption [28].

The repetitive chewing movement, similar to a pump, aids the accumulation of bacteria and biological debris in the peri-implant tissues, increasing the risk of inflammation and complications such as peri-implantitis and marginal bone resorption. The process can compromise the long-term stability of the implant and the health of the surrounding soft and hard tissues. The consequences of the resorption include decreased implant stability, soft tissue recession with aesthetic defects, and exposure of threads, which can be easily colonized by bacteria, significantly increasing the risk of peri-implant disease [72]. Those effects are more pronounced in components with a flat-to-flat connection, whereas they are reduced in more stable conometric connections, where micromovements are minimized [73].

Monobloc implants, which integrate the implant component and the prosthetic abutment into a single structure, offer a significant advantage in this context. Their connection-free configuration eliminates micromovements at the junction between implant and abutment, drastically reducing the possibility of bacterial infiltration. This feature provides greater stability and a more effective biological seal, protecting peri-implant tissues from infections and bone resorption. Clinical studies demonstrated that monobloc implants significantly reduce the incidence of peri-implant complications compared to biphasic systems. The absence of the fixture-abutment interface in one-piece implants provides a solid biological basis for long-term peri-implant bone stability [74].

Thickening of soft tissues promoted by the characteristics of the transmucosal component, combined with the increased distance of the prosthetic connection from the bone, acts as a protective factor limiting marginal bone resorption [2]. Additionally, due to the absence of a MUA, the use of bone profiler burs to create space for the intermediate prosthetic component was not required. It resulted in a more conservative approach towards hard tissue and a less invasive, faster procedure. The absence of an internal MUA-implant connection and a connection screw enables reduction in the volume and thickness of the implant collar, ensuring a better emergence profile, thus contributing to greater preservation of peri-implant soft and hard tissues [75]. The use of this type of prosthetic platform is considered more "tissue-friendly" compared to biphasic implants where a separate Multi-Unit Abutment (MUA) is mounted, primarily due to its more compact design and reduced diameter. The diameter of the FIXO platform is only 4.8 mm, and 4.0 mm for the mini versions, which is significantly smaller than traditional MUAs. A narrower diameter offers several advantages. First, it reduces invasiveness towards the surrounding soft tissues, improving healing and the stability of peri-implant tissues by providing more space for tissue maturation. The anatomical emergence profile of the FIXO platform further contributes to improving soft tissue integration, promoting a natural seal that reduces the risk of bacterial infiltration and inflammation [31].

The results of the present research show an average Marginal Bone Loss (MBL) of 1.300 mm ± 0.090 mm across 108 cases, with a follow-up of 1 year. These results align with current literature on one-piece implants and meet the implant success criteria defined by Albrektsson, which stipulate a resorption of 1.5 mm during the first year of loading and 0.2 mm per year thereafter [67, 76, 77].

Considering the x-ray taken at baseline (3 months after the day of surgery) the MBL observed during the first year is higher due to primary bone remodeling necessary to stabilize the supra-crestal soft tissues. It should be noted that 42 from the 108 implants were placed in post-extraction sites. Literature suggests that implant placement in post-extraction sites does not prevent bone resorption, predicting a vertical ridge resorption of approximately 1.24 mm at 6 months [78,79].

From the presented data, no statistically significant differences in MBL were observed based on the insertion arch, abutment angulation, or insertion site (healed bone or post-

extraction socket).

The significant heterogeneity of protocols used in the literature on one-piece implants makes it challenging a data comparison and identify a mean value for Marginal Bone Loss (MBL). Structural differences in implant components and variations in measurement reference points contribute to this heterogeneity.

Systematic reviews available in the literature, given this considerable variability, cannot currently confirm the superiority of one-piece implants over two-piece components in terms of peri-implant bone stability [77].

In the study, measurements were taken from the most coronal part of the smooth neck of the fixture to the first visible bone-implant contact. This point was chosen to ensure greater reliability. The prosthetic shoulder of the implant was not used for bone loss measurements as most implants were placed with the prosthetic shoulder at the crestal or subcrestal level. The Fixo® implant line features a smooth transmucosal component of variable height (from the start of the anodized surface to the prosthetic shoulder), depending on whether the Short or Long type is selected. Therefore, if the implant is placed with the prosthetic shoulder at the crestal level, minimal bone resorption is compatible with implant health as the rough part of the fixture ensuring osseointegration remains fully surrounded by bone. The surface characteristics of the transmucosal component are designed for adhesion and stabilization of supra-crestal soft tissues. The absence of a connection between the smooth transmucosal collar and the fixture itself further helps to prevent bacteria adhesion from the rough part of the implant, reducing the risk of bone resorption.

Regarding the prosthetic benefits of one-piece implants, the lack of a fixture-abutment connection eliminates risks of screw loosening or fracture, thereby reducing the overall number of prosthetic complications. Screw loosening or fracture has been observed in several studies, as reported by a recent review by Patzelt et al. the use of an oversized prosthetic screw (1.8 mm) in the FIXO system allow for a tightening torque of 30 Ncm, ensuring immediate and secure stability for the prosthesis. The oversized screw, compared to the more common 1.4 mm standards in two-stage implant systems, offers several advantages that help prevent complications such as screw loosening or fracture. The larger screw can handle higher occlusal forces, reducing the likelihood of deformation or breakage over time [80].

One-piece implants find their best use in guided surgery, when achieving a perfect positioning and inclination of the prosthetic components is possible. The use of guided surgery further contributes in making the procedure less invasive. Digital case planning and complete guided surgery minimize unexpected events. With the pre-surgical planning of the exact implant positions, the technician can provide the clinician with a provisional that can be easily adapted and screwed onto the newly placed implants without the need for an additional intraoperative impression. This approach minimizes patient discomfort and the overall perception of the procedures performed [81]. A new type of modular surgical guides has been adopted for this system.

Modular surgical guides offer greater accuracy by reducing the risk of mispositioning. Traditional guides are typically positioned using pins, with their holes serving as landmarks for repositioning the guide itself. The procedure becomes necessary when there are elements that are initially used to position the guide but must be extracted before implant placement. Stackable guides offer greater accuracy compared to removable ones in several key aspects related to stability, three-dimensional precision, and error reduction in the surgical process. Stackable guides remain fixed in the planned position thanks to a "base" guide that is not removed throughout the duration of the procedure, avoiding the involuntary displacements that can occur with removable guides [82]. In this configuration a precise positioning of the base guide is mandatory and is ensured using special pins: smooth fixation pins are screwed into the guide and securely tightened, improving stability during surgery. Fixation pins, with a smooth portion entering the bone and a threaded portion that locks into the guide, offer a significant advantage in terms of precision compared to completely smooth pins [83,84].

The combination of mechanical characteristics provides greater stability to the surgical guide during the implant procedure, reducing the risks of micromovements and deviations, which are critical factors for ensuring the correct execution of the surgical plan. The smooth part of the pin, which penetrates the bone, minimizes bone trauma during insertion, avoiding excessive damage to the bone tissue and improving the interface between the pin and the bone. It allows for stable anchorage without causing excessive stress or micro-fractures. Furthermore, the smooth portion facilitates easy

removal of the pin at the end of the procedure, as it does not create excessive resistance during disengagement. On the other hand, the threaded portion that locks into the guide ensures a solid and stable fixation of the guide to the skeletal structure. The threads create a secure mechanical interface between the pin and the guide, minimizing guide micromovements during surgery, even small movements of the guide can lead to implant positioning errors. Conversely, the use of completely smooth pins does not provide the same level of stable locking, making the guide more susceptible to unintended shifts during drilling or implant insertion, resulting in a loss of precision.

A titanium reinforcement is used to prevent the flexion of the bar (blue bar). The implant guide is made of milled titanium, ensuring greater resistance to fracture. Integrating titanium reinforcement in surgical guides is a key strategy for improving overall precision during implant surgery by reducing the flexion of the guide and increasing its fracture resistance. Thanks to its excellent mechanical properties, titanium provides a solid and rigid structure that stabilizes the guide during critical surgical stages such as drilling and implant insertion, preventing deviations or errors. Flexion of the guide, if not adequately controlled, can cause implant positioning errors. The phenomenon often occurs with less rigid guides or those made from materials lacking adequate reinforcement, especially in complex clinical situations where stability and precision are crucial. As reported in clinical studies, the addition of titanium reinforcement allows the guide to maintain its shape and position, preventing micromovements during drilling and minimizing three-dimensional deviations. In fact, titanium has a high modulus of elasticity, meaning it is less susceptible to deformation under load compared to softer materials like resins or plastics commonly used in guide manufacturing. Moreover, titanium is also used in the drilling holes ensuring a greater resistance to burs damage from a biomechanical standpoint, titanium offers an optimal combination of lightness and strength, making it an ideal material for surgical guides that need to be both maneuverable and resistant. Titanium's ability to resist flexion during implant insertion helps keep the guide firmly in place, leading to reduced three-dimensional deviations and better control over implant depth and angulation.

Modular guides also allow for a clear visualization of soft tissues which can be managed with the base guide in position. Unlike monolithic or removable guides, which can limit surgical access, modular guides allow specific parts of the guide to be

disassembled and reassembled during surgery, facilitating more complex surgical maneuvers such as guided bone regeneration (GBR) or the treatment of soft tissues.

A particularly useful aspect of modular guides is the ability to maintain a stable guide for implant insertion even after flap elevation, that allows the surgeon to perform procedures such as bone augmentation, defect removal, or soft tissue graft management without losing the precision of the planned implant placement. Clinical studies showed that the use of modular guides ensures better integration between regenerative and implant surgery, reducing the risk of deviations or errors in implant placement.

In the case of hard tissue regeneration, such as GBR, the use of stackable guides allows the surgeon easy access to the bone area for the placement of membranes or grafts, while still maintaining the precision needed for implant placement. According to Vercruyssen et al., the use of these guides during combined bone augmentation procedures avoids the need for repeated adjustments to the guide, improving the overall effectiveness of the procedure. Furthermore, once the regeneration phase is complete, the guide can be easily repositioned to ensure correct implant insertion [85].

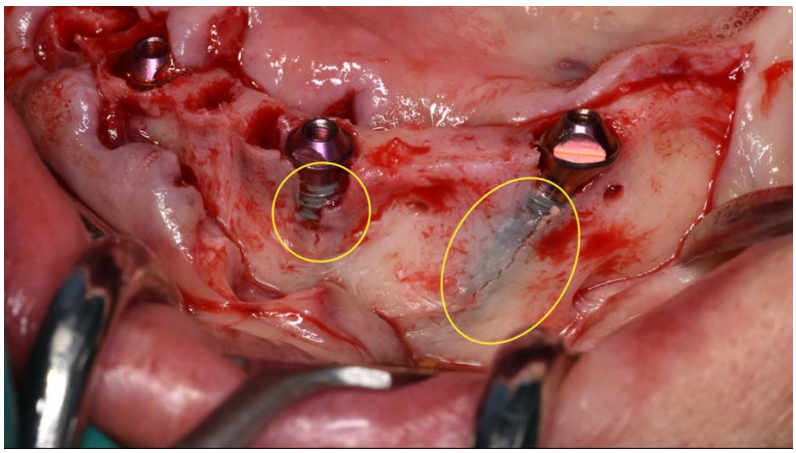

Figure 47: Frontal view of fixtures inserted with a buccal dehiscence

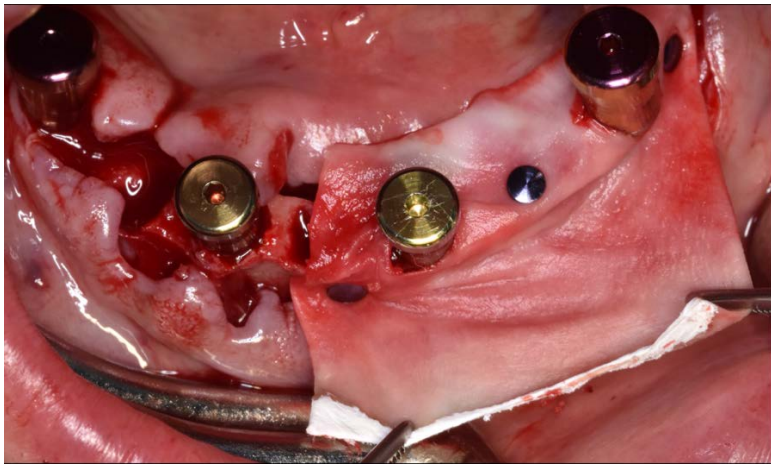

Figure 48: Occlusal view of membrane fixation

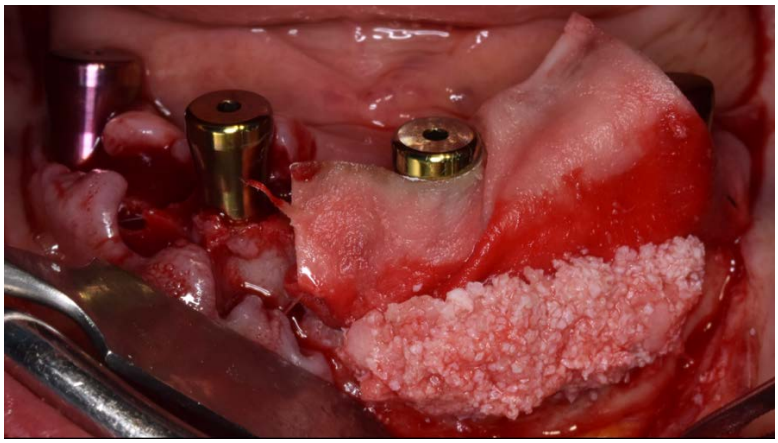

Figure 49: View of bone graft positioning

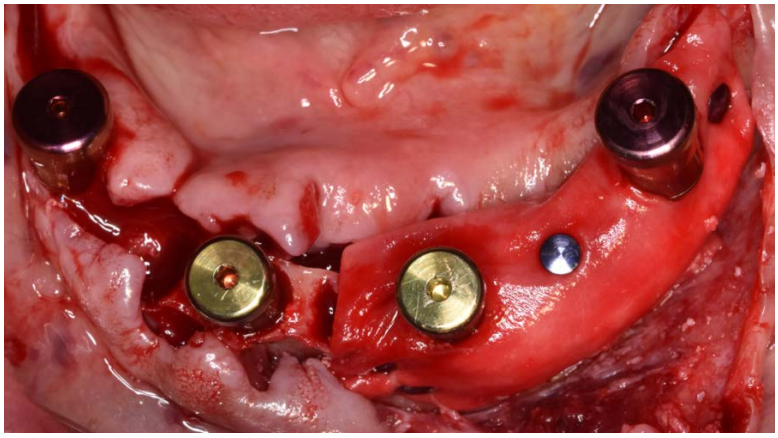

Figure 50: Occlusal view of membrane positioned in final position

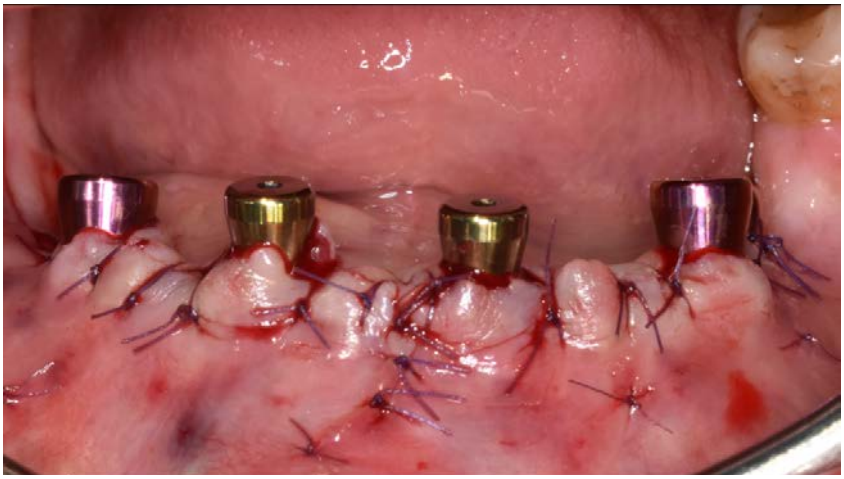

Figure 51: Frontal view after multi layer suturing

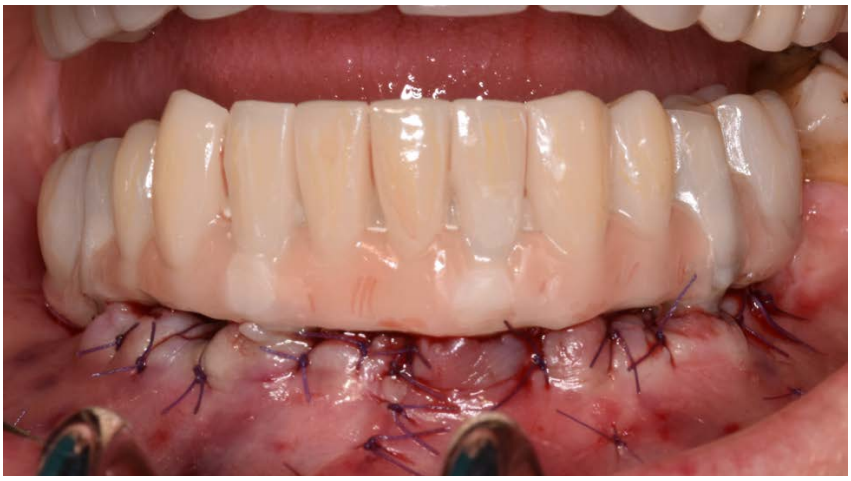

Figure 52: Frontal view after provisional prosthesis delivery

Figure 52: Frontal view at 3 months post-op

Even in the management of soft tissues, such as peri-implant flaps or gingival graft techniques, stackable guides offer greater control. Removing parts of the guide to gain direct access to soft tissues and prepare the site for potential soft tissue grafts or for improving the gingival biotype is possible. This is particularly crucial in situations where it is necessary to correct the size or quality of soft tissues around the implant to enhance long-term esthetic and functional stability.

Another advantage of the use of a base guide is that it serves a purpose at the end of the surgery where the prosthetic load begins, the provisional prosthesis is screwed onto the guide following the original design rather than following maximum intercuspation to ensure greater precision.

After positioning the prosthesis using supports directly anchored to the surgical guide, a direct connection is created between the digital design plan and the clinical reality. In other words, the guide supports act as a physical guide to precisely reproduce the planned prosthesis position, following the parameters defined in the digital design software. This approach ensures that the final prosthesis position aligns with the one envisioned during pre-surgical planning, including orientation, angulation, and depth. As a result, differences between the digital plan and the clinical reality are minimized, ensuring greater accuracy compared to positioning based solely on occlusion.

The collected data regarding post-operative morbidity reflect the low invasiveness of the surgical maneuvers, resulting in a complication-free and well-tolerated postoperative period. In no case did patients report pain that could not be controlled with pharmacological therapy. No postoperative complications such as abnormal swelling or bleeding were recorded. Regarding average values of pain, swelling, and bleeding, the second day showed significantly higher average values of pain and swelling in partially edentulous patients compared to completely edentulous patients. This discrepancy is hypothesized to be due to the need to perform extractions of residual elements and possible soft tissue grafts during the same surgical session as implant placement. On a scale from 0 to 100, where 0 corresponds to "Acceptable" and 100 to "Very Unpleasant," patients reported an average perception score of 15 for the operation. This result is highly reassuring and justifies the operative choices made in this protocol.

Among the limitations of the present study is the fact that measurements were performed using panoramic radiographs, which are less accurate compared to endoral x-ray taken with a parallel tube technique and centering devices, or CBCT. The operational protocol used is limited to guided surgery, and the use of a one-piece implant needs to obtain sufficient primary stability, as transmucosal healing would otherwise be unpredictable. The under-preparation of the site and its management entirely depend on the clinician's experience, as friction between various components, such as mounters and sleeves (often caused by the engagement of implant threads in the prepared bone before these two components are coupled) complicates the perception of insertion torque, particularly concerning longer fixtures.

12. CONCLUSIONS

The presented data indicate an average Marginal Bone Loss (MBL) of 1.300 mm ± 0.090 mm. The reported values align with Albrektsson's success criteria and are consistent with existing literature on one-piece implants [67, 76, 77]. The most recent systematic review comparing MBL between one-piece and two-piece implants, does not reveal any statistically significant difference in peri-implant bone resorption between the two types of implants [59, 63].

Regarding the digital workflow applied in the present protocol, the results highlight an excellent patient perception with favorable biological responses post-intervention. The findings confirm that a digital workflow and the associated pre-visualization and pre-organization can reduce surgical time and the number of required interventions, thereby improving patient perception. Furthermore, it enhances intraoperative safety and organization for the clinician, reducing associated stress.

However, full digital workflows necessitate extensive knowledge and experience due to the numerous steps involved to ensure a smooth protocol. Additionally, advanced surgical expertise is required to properly manage site under-preparation to achieve sufficient implant stability and the resulting insertion torque. For the above mentioned reasons, guided surgery using one-piece implants for immediate loading with a full digital workflow is recommended for experienced clinicians.

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