Use of a xeno-hybrid bone graft and sticky bone preparation in mandibular regeneration complicated by Actinomyces infection: a case report

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Abstract

Background: **Bone regeneration is essential in oral surgery, particularly in advanced periodontal disease, where teeth are no longer salvageable. Innovative biomaterials like SmartBone® and autologous platelet derivatives have shown promising regenerative potential. However, postoperative infections by *Actinomyces israelii* may compromise outcomes.**
Materials and Methods: **A 52-year-old male with severe periodontal disease in the anterior mandible underwent extractions and grafting with SmartBone® mixed with autologous platelet derivatives using the Sticky Bone Preparation Device (SBPD). Three months post-surgery, localized inflammation occurred and was managed with antibiotics. Histopathological analysis identified *A. israelii*, prompting targeted antibiotic therapy.**
Results: **Despite the infection, the graft maintained structural integrity, and the infection remained localized without fully compromising the regenerative site. After complete healing, four endosseous implants were successfully placed and restored with a fixed metal-ceramic prosthesis. Follow-ups at 8 and 30 months confirmed stable bone integration, healthy mucosa, and no recurrence.**
Conclusion: **This case demonstrates the resilience of SmartBone® in maintaining regenerative function despite opportunistic infection. The xeno-hybrid graft and SBPD enabled successful implant-prosthetic rehabilitation. While the clinical outcome is encouraging, further microbiological studies are necessary to validate the protocol and explore any protective role of the graft material against infection.**

Keywords: Xeno-hybrid bone graft, Sticky Bone Preparation Device, Actinomycosis, Bone regeneration, Periodontal defect.

Introduction

Bone regeneration represents an essential component of modern oral and maxillofacial surgery, allowing for the recovery of bone volumes compromised by inflammatory diseases, chronic infections, or trauma[1]. The aim is to restore bone volume to guarantee oral structures' functionality, stability, and aesthetics, often in preparation for prosthetic-implant rehabilitation [2].

In clinical cases where bone loss is secondary to severe forms of periodontitis and the dental elements are no longer salvageable, the extraction of the involved teeth is followed by regenerative procedures aimed at reconstructing the residual bone volume, with the intent of restoring anatomical integrity and creating the necessary conditions for effective prosthetic or implant rehabilitation [3]. Periodontitis is a chronic inflammatory response localized within the periodontal pocket, caused by bacterial colonization and the accumulation of subgingival plaque. Clinically, it manifests as increased probing depth (PPD) and loss of clinical attachment level (CAL), while radiographically it appears as progressive alveolar bone loss [4]. The regeneration of periodontal tissues represents the final objective, as it guarantees long-term stability [5].

Regenerative techniques, now refined and practical, are based on established biological principles: they require an environment favorable to cell proliferation and differentiation, adequate vascularization, and the availability of a three-dimensional matrix to guide the formation of new bone tissue [6]. Over the last decades, bone graft materials have been developed and widely used to stimulate new bone formation and promote tissue healing. The effectiveness of bone regeneration depends on the quality of the recipient site, the surgical technique, local vascularization, and, crucially, on the type of biomaterial used [7]. Bone grafts act as a three-dimensional structure capable of supporting the adhesion and proliferation of osteogenic cells while maintaining the geometry of the regenerative site [6].

Over the years, a significant evolution of graft materials has been observed, and they can now be classified according to their origin and biological properties into autografts, allografts, xenografts, and alloplastic materials [8]. Autografts, harvested from the patient, possess both osteoinductive and osteoconductive properties and are considered the gold standard. However, harvesting from a second surgical site (intraoral or extraoral) increases operative time and the risk of complications, including infections and delayed healing [8,9]. To overcome these limitations, allografts represent a valid alternative. Derived from a donor of the same species, they are treated through specific processing and sterilization protocols to ensure their safety. The advantages include good availability and the possibility of being shaped in various forms (particulate, blocks, gel, putty) and adaptable to clinical needs. However, allografts may still pose immunological risks and, in rare cases, disease transmission [10]. Xenografts, derived from different species (generally bovine), are subjected to deproteinization processes to eliminate potentially immunogenic organic components. The remaining inorganic matrix retains a natural architecture and a high calcium content, contributing to maintaining the dimensional stability of the regenerated site during the remodeling phases [11]. Finally, alloplastic materials represent a further option. These synthetic substitutes, such as hydroxyapatite, tricalcium phosphate, and bioactive glass, are characterized by different physicochemical properties that give them varying degrees of bioresorbability. These materials, in addition to being osteoconductive, are biocompatible and can be adapted based on the specific regenerative needs of the patient [8].

Among the most innovative materials is SmartBone® (Industrie Biomediche Insubri SA, Mezzovico, Switzerland), a composite bone substitute that combines mineralized bovine bone matrix, biodegradable polymers, and bioactive molecules. Proposed for oral surgery, dental implantology, and maxillofacial applications, it is a CE-marked class III medical device [12]. This xeno-hybrid material shows excellent mechanical and regenerative properties, making it a promising candidate for bone tissue engineering [13]. Clinical and histological studies confirm its effectiveness even under critical conditions, such as direct exposure to the oral cavity, with no signs of infection and good new bone formation. [14].

The regenerative potential can be further enhanced using autologous platelet derivatives such as PRF or compounds like sticky bone, which are enriched with growth factors and obtained through the sticky bone preparation device (SBPD). These concentrates promote angiogenesis, clot stabilization, and stimulate mesenchymal cell migration and differentiation[15,16]. One study showed that combining PRF with bone grafts improves soft tissue healing and alveolar volume preservation[17]. Gheno et al. demonstrated that SBPD® simplifies and accelerates combining bone substitutes with autologous growth factors, while preserving the biological properties necessary for bone healing [15].

Despite significant advances, infectious complications remain a relevant issue in clinical practice. Among these, infections by *Actinomyces israelii* are a rare but clinically significant occurrence. This anaerobic microorganism, usually part of the oral microbiota, can become pathogenic following surgical interventions, tissue necrosis, or local hypoxic conditions [18]. Actinomycosis often presents as a chronic infection, with the formation of granulomas and pseudotumoral masses, and requires accurate histological diagnosis [19]. One of the most characteristic aspects of this infection is the Splendore–Hoeppli phenomenon, characterized by microorganisms (fungi, bacteria, and parasites) or biologically inert substances surrounded by radiating intensely eosinophilic material. This morphologically unique reaction was first described in sporotrichosis by Splendore and in schistosomiasis by Hoeppli. The eosinophilic material seen in the Splendore–Hoeppli reaction has been described as due to deposition of antigen–antibody complexes and debris from the host inflammatory cells. Microscopically, the Splendore–Hoeppli reaction appears as strongly eosinophilic amorphous material with radiating star-like or club-shaped configurations surrounding or adjacent to the causative agent [20].

Differential diagnosis with other granulomatous infections or neoplastic lesions is often complex, making a multidisciplinary approach necessary. In dentistry and implantology, infection by *Actinomyces* can compromise the effectiveness of bone regeneration and the stability and longevity of implants [21]. Walker M.D. et al. described a case of mandibular osteomyelitis caused by *A. israelii*, highlighting the importance of early histological diagnosis and long-term targeted antibiotic therapy to resolve the clinical picture [22].

The present study aims to describe and analyze a clinical case of bone regeneration in the anterior mandibular sector (region 3.3–4.3) in a 52-year-old patient affected by severe periodontal lesions no longer treatable by conservative therapies. Following the extraction of the compromised dental elements, an immediate bone graft was performed using SmartBone® (Industrie Biomediche Insubri SA, Mezzovico, Switzerland) combined with autologous platelet derivatives, prepared through the SBPD technique. During the healing period, the patient developed a localized chronic inflammatory lesion in region 4.2, subsequently identified as infection by *Actinomyces israelii through histological examination*. The therapeutic management included a surgical revision of the inflammatory focus and administering targeted antibiotics, which allowed complete infection control. At eight months from the regenerative intervention, it was possible to proceed with the placement of six endosseous implants, subsequently prosthetically restored with fixed metal-ceramic rehabilitation.

The objective of this report is to evaluate the effectiveness of the adopted regenerative protocol also in the presence of an infectious complication by an opportunistic pathogen, analyzing the tissue response to the employed biomaterial, the effectiveness of the associated antibiotic therapy, and the clinical success of the implant-prosthetic rehabilitation.

Material and Method

Clinical Case Report and Patient Profile

This case report describes the clinical management of a single patient, A.M., a 52-year-old male in good general health with regular blood tests, particularly regarding bone metabolism. He was affected by severe periodontal disease in the anterior mandibular region (teeth 3.3–4.3). The patient was treated at a specialized dental clinic with immediate bone grafting following the extraction of compromised teeth. The graft material used was SmartBone® combined with autologous platelet derivatives prepared via the SBPD technique. During the healing phase, the patient developed a localized chronic inflammatory lesion at site 4.2, which was subsequently diagnosed by histological analysis as an infection caused by *Actinomyces israelii*. Management involved surgical revision and targeted antibiotic therapy, leading to resolution of the infection. At eight months post-regeneration, placement of six endosseous implants was successfully performed, followed by fixed metal-ceramic prosthetic rehabilitation.

The study was conducted per the revision of the Declaration of Helsinki 2013 and Good Clinical Practice guidelines. After explaining the treatment procedures and data handling, the patient provided written informed consent. SmartBone® is a CE-marked Class III medical device, and all clinical interventions were performed as part of standard care without investigational use; thus, no ethics committee approval was required.

2.2 SmartBone® Graft and SBPD Technique

SmartBone® is a xeno-hybrid composite graft made from bovine-derived cancellous bone mineral matrix, reinforced with resorbable biopolymers and collagen fragments in hydrolyzed gelatin form. Its structure closely mimics autologous bone, supporting remodeling and replacement by the patient's healthy and living bone. In the present clinical case, SmartBone® granules can be combined with autologous platelet derivatives using the SBPD (Sticky Bone Preparation Device) technique to enhance regenerative outcomes. [12,14,23].

The SBPD enables the preparation of "Sticky Bone," a cohesive, growth factor-rich graft created by mixing platelet-rich fibrin (PRF) with bone matrix. The device allows simultaneous centrifugation and mixing, producing a homogeneous, bioactive compound that enhances healing, bone formation, and handling during surgery. In particular, the SBPD optimizes the controlled release of bioactive molecules, such as platelet-derived growth factor, interleukins, and other cellular mediators, essential for healing and bone formation. In clinical practice, the SBPD is used to prepare immediate grafts of SmartBone® granulate, which is mixed with platelet derivatives through the device. This process allows the amalgamation of the bone particulate with the fibrin matrix rich in growth factors, creating a cohesive and highly bioactive graft that can be applied directly to the site of the bone defect [15].

Clinical Procedures and Postoperative Management

The initial clinical evaluation of the anterior mandibular region (dental elements 3.3–4.3) was performed through direct clinical examination, photographic documentation, and digital scanning with the Medit i500 intraoral scanner. Preliminary radiographic diagnostics included a panoramic radiograph (OPT) and high-resolution cone-beam computed tomography (CBCT) using the ACTEON® X-MIND® Trium device. CBCT data were subsequently processed with the OsiriX software to obtain three-dimensional renderings useful for detailed anatomical and volumetric analysis, particularly for identifying residual bone peaks suitable for graft stabilization.

Extraction of the compromised dental elements (from 3.3 to 4.3) was carried out. The extraction sockets were decontaminated using an Nd: YAG laser (Deka). Bone regeneration was performed immediately by grafting granulated SmartBone® mixed with autologous platelet derivatives prepared according to the SBPD technique. The regenerative material was contained and stabilized with a manually shaped titanium mesh (De Ore) and fixed with osteosynthetic screws. Suturing was performed with interrupted 4-0 silk stitches.

The immediate postoperative course was regular, but after about three months, a recurrent inflammatory focus appeared at site 4.2, with purulent discharge. The condition was initially controlled with antibiotic therapy (amoxicillin-clavulanic acid, 1 g every 12 hours). At the site of inflammation, the titanium mesh progressively became exposed, revealing chronic inflammatory tissue in the deeper planes. During this period, the patient wore a provisional removable prosthesis supported by the mucosa, made with FITT material (Functional Impression Tissue Toner).

Ten months after the first procedure, a second surgical intervention was performed, including the removal of the titanium mesh and the excision of the chronic inflammatory mass. Histological analysis of the lesion confirmed the presence of *Actinomyces israelii*, with evidence of a Splendore–Hoeppli reaction, indicating marked bacterial pathogenic activity. Targeted antibiotic therapy with tetracyclines was therefore prescribed for 40 days, along with a chest X-ray to exclude possible systemic dissemination, which turned out negative.

After infection control and tissue healing, four endosseous implants (Dio Implant, 4×8.5 mm) were inserted into the regenerated area. Postoperative CBCT analysis confirmed the correct implant placement in mature, well-structured bone tissue. Forty days after implant surgery, the final prosthetic phase began. Impressions were taken digitally with the Medit i500, and the case concluded with delivery of a fixed metal-ceramic prosthesis.

Results

Clinical and Preoperative Diagnostic Evaluation

The patient presented with severe periodontal compromise in the anterior mandibular region (teeth 3.3–4.3) and reported recurrent inflammatory episodes. The initial evaluation was conducted through clinical examination and documented with photographic images (Figure 1A). The intraoral scan performed using the Medit i500 revealed tooth mobility and loss of periodontal support, confirming the indication for extraction of the involved teeth (Figure 1B).

Orthopantomography (OPT) was initially performed as a routine radiological exam; however, since it did not provide sufficient three-dimensional information (Figure 2A), a CBCT scan (ACTEON® X-MIND® Trium), also a routine diagnostic procedure, was subsequently carried out. The CBCT highlighted severe bone loss in the 33–43 region, with only a few residual bone peaks deemed suitable for regeneration, as indicated by the red line in the corresponding Figure 2B. Furthermore, the 3D rendering performed with OsiriX visually emphasized these findings: the red arrows mark the bone peaks between the canines and first premolars considered for regeneration, while the red and green lines outline the vestibular and lingual bone profiles, respectively (Figure 2C).

Surgical regenerative procedure and postoperative management

The first surgical intervention involved the atraumatic extraction of the compromised teeth and decontamination of the sites using an Nd: YAG laser (Deka®). A graft of granular SmartBone® mixed with autologous platelet derivatives prepared through the SBPD technique was then placed. This combination was chosen to take advantage of both the osteoconductive and mechanical properties of the biomaterial and the biological effect of platelet-derived growth factors, known to stimulate angiogenesis and bone regeneration. The material was contained using a customized titanium mesh from DeOre, fixed with osteosynthetic screws (Figure 3).

The postoperative radiological check (Figure 4A) and the 3D Rendering (Figure 4B) obtained with OsiriX confirmed the graft's correct positioning.

Inflammatory complication

Approximately three months after the procedure, the patient developed a localized inflammatory focus at site 4.2, characterized by three recurring episodes of suppuration. These episodes were initially managed with antibiotic therapy (amoxicillin/clavulanic acid 1g every 12 hours for 6 days). Still, the persistence of the condition led to progressive exposure of the titanium mesh and a clinical diagnosis of localized chronic infection. The mesh became superficialized, and the underlying tissue showed macroscopic signs of chronic inflammation. At this stage, the patient was provided with a mucosa-supported provisional prosthesis using the FITT (Functional Impression Tissue Toner) to preserve the soft tissue architecture while awaiting the second surgery (Figure 5).

Second surgery: lesion resolution and implant rehabilitation

Ten months after the first procedure, a second surgical intervention was performed involving the removal of the titanium mesh and the complete excision of the inflammatory lesion. The overall bone regeneration

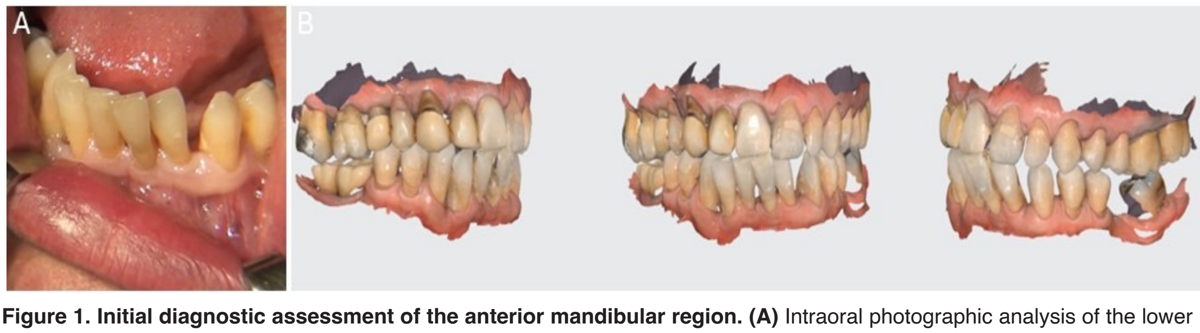

Figure 1. Initial diagnostic assessment of the anterior mandibular region. (A) Intraoral photographic analysis of the lower anterior region reveals dental mobility and severe periodontal compromise. **(B)** Intraoral scan performed with Medit i500 showing the loss of periodontal support in the lower anterior teeth, where the patient reported recurrent inflammatory episodes.

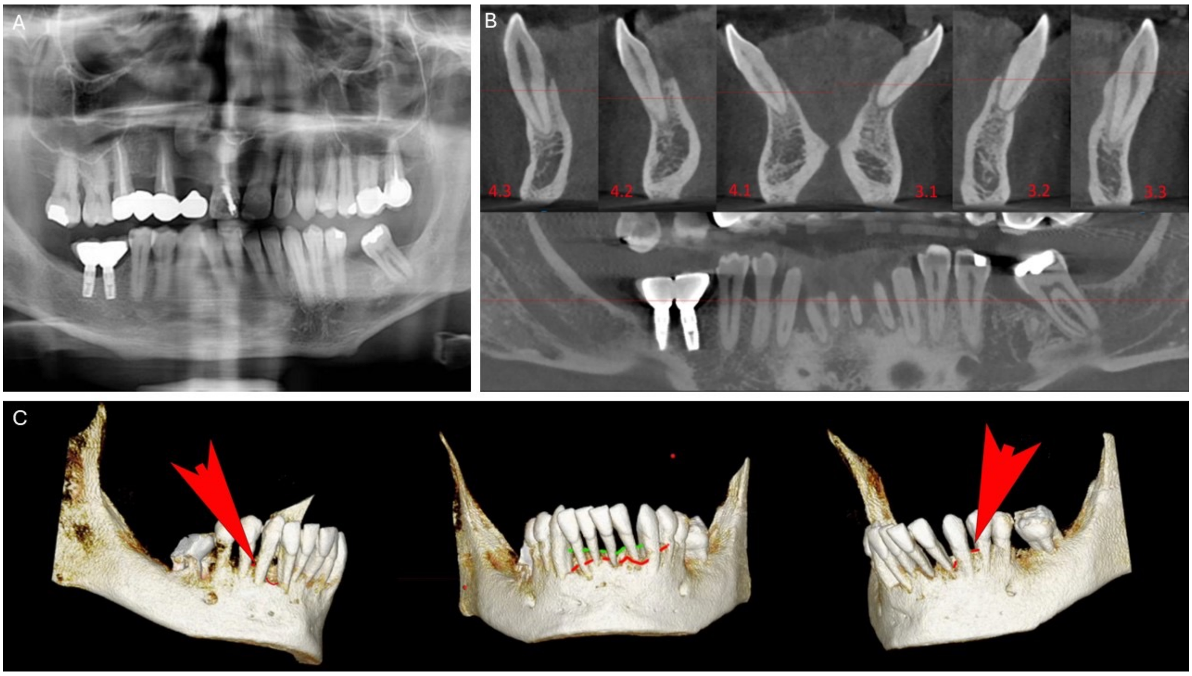

Figure 2. Preoperative evaluation of the anterior mandibular region. (A) Preoperative orthopantomography (OPT): routine imaging that does not allow for accurate three-dimensional analysis. **(B)** CBCT scan acquired with Acteon X-MIND® Trium highlights the severe bone loss in the 3.3–4.3 region. The red line indicates the residual bone peaks selected for regeneration. **(C)** 3D rendering with OsiriX graphically emphasizes the CBCT findings. Red arrows point to the bone peaks between the canines and first premolars; the red line outlines the buccal bone profile, while the green line represents the lingual profile.

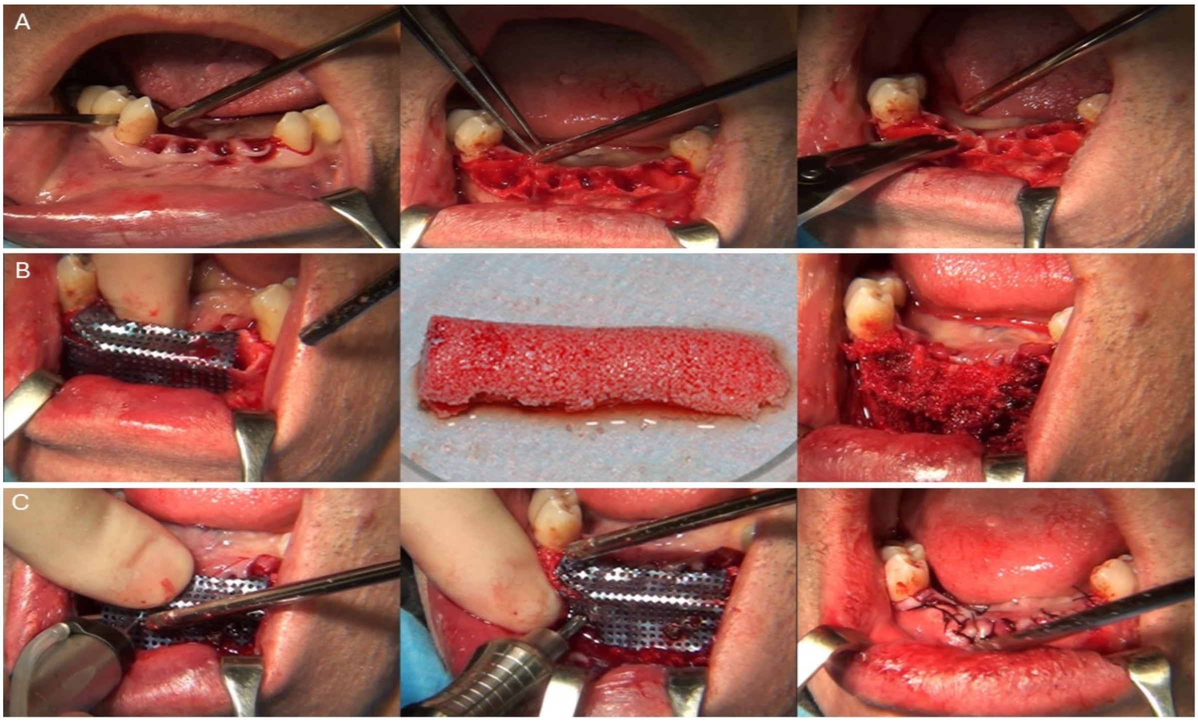

Figure 3. Surgical protocol for regenerative material application. (A) Initial surgical phase: atraumatic tooth extractions and smoothing of the residual alveolar processes. **(B)** Preparation and application of the regenerative material (Sticky Bone and SmartBone®) followed by shaping of the titanium mesh. **(C)** Fixation of the titanium mesh with osteosynthetic screws and suturing with 4/0 silk interrupted stitches.

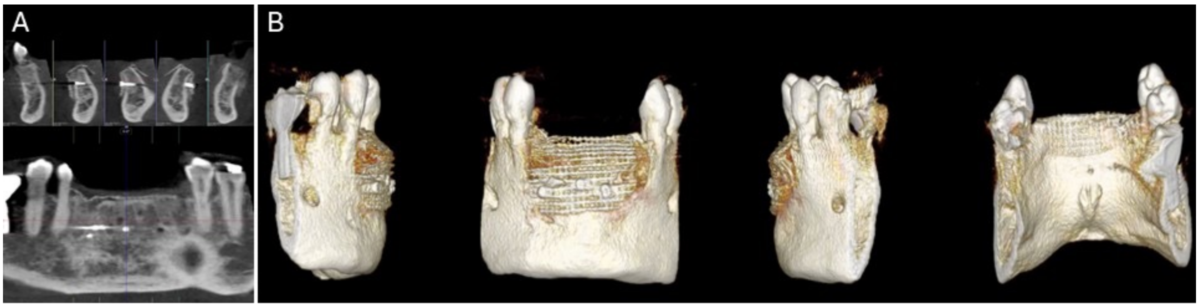

Figure 4. Postoperative assessment of graft placement. (A) Postoperative radiographic control showing the correct placement of the regenerative material. **(B)** Postoperative 3D rendering with OsiriX confirming accurate three-dimensional positioning of the graft.

Figure 5. Clinical appearance of the mucosa at 3 months. Exposure of the titanium mesh and clear signs of chronic inflammation at site 4.2, 10 months after the first surgery.

was satisfactory, with good peripheral corticalization and preservation of bone volumes. It is important to emphasize that the infection and inflammation remained localized and well-contained, with no evidence of spread into the newly formed bone tissue or adjacent anatomical structures, thus allowing optimal removal of the inflamed tissue and implant integration within the newly formed bone (Figure 6).

Figure 6. Pre-second surgery CBCT. Radiological analysis for implant planning shows good bone regeneration with well-developed peripheral corticalization. The red arrows indicate the contaminated region, which appears confined and not expanded within the newly formed bone.

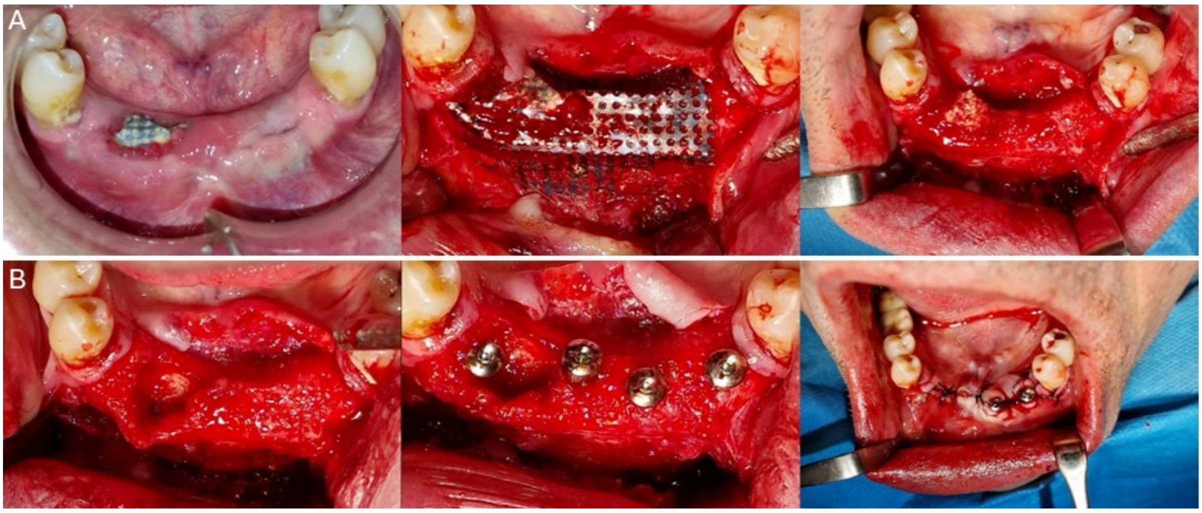

Figure 7. Second surgery. (A) The initial stages of the second surgery show the removal of the titanium mesh and the identification of a well-defined mass where inflammatory episodes occurred. **(B)** The inflammatory lesion is removed, and four endosseous implants (4 × 8.5 mm) Dio Implant are placed, followed by suturing of the surgical wound.

The initial phases of the second surgery involved removing the titanium mesh and the well-defined inflammatory lesion. Subsequently, four endosseous implants (Dio Implant, 4 × 8.5 mm) were placed, followed by suturing the surgical wound (Figures 7).
The tomographic analysis using CBCT confirmed the correct positioning of the four endosseous implants. The images show that the implants were placed in mature, well-structured bone, demonstrating proper three-dimensional integration. The distribution of the implants adheres to the criteria of parallelism and inter-implant distance, which are essential for ensuring the long-term stability of the prosthetic (Figure 8).

Histological analysis and targeted therapy

The excised tissue was subjected to histological analysis, which revealed the presence of Actinomyces israelii, a gram-positive anaerobic microorganism known for its ability to cause chronic granulomatous infections in both soft and hard tissues, with the presence of the Splendore–Hoeppli phenomenon, characteristic of the local immune response to active infections (Figure 9-10). Based on the histological findings, a 40-day antibiotic therapy with tetracyclines was prescribed, as these antibiotics are known to be effective against Actinomyces spp. A pulmonary evaluation was also carried out through chest radiography to exclude hematogenous dissemination of the pathogen, which returned negative.

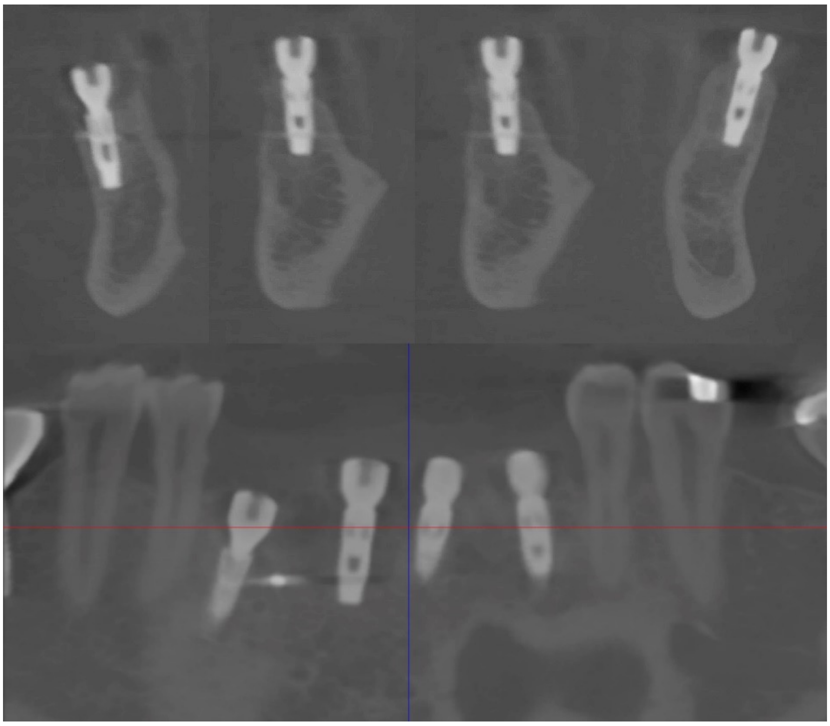

Figure 8. Post-operative CBCT of implant placement. CBCT view confirms the correct positioning of the four implants in mature and well-structured bone.

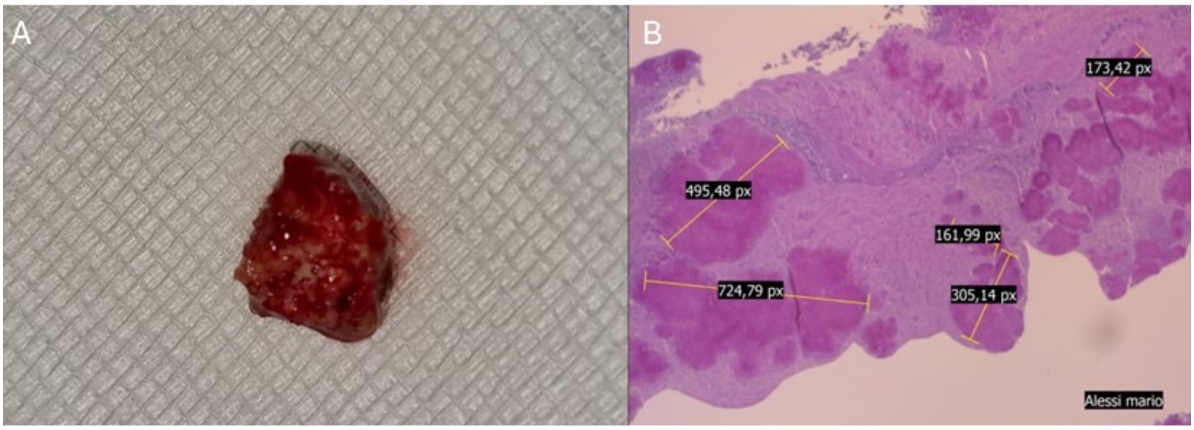

Figure 9. Histological examination. (A) Extracted an inflammatory lesion involving the regeneration tissue. **(B)** Histological analysis highlights the presence of *Actinomyces israelii* with Splendore–Hoeppli phenomenon, indicative of a strong local immune response and active pathogenicity of the bacterial agents.

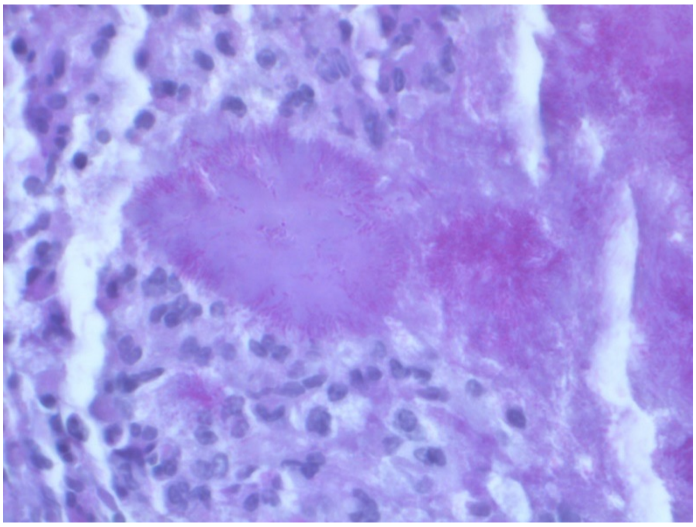

Figure 10. Histopathology of the typical SH reaction. There is cylindrical clubbing around filaments of bacteria (Actinomyces) extending out at the colony's edge. PAS D stain, original magnification × 1000.

Final Prosthetic Rehabilitation

Forty days after implant placement, the definitive prosthetic phase was initiated. The impressions were retaken using the Medit i500 scanner (Figure 11A), followed by the successful placement of a definitive metal-ceramic fixed prosthesis (Figure 11B). Clinically, the mucosa showed good superficial epithelialization, consistent with a practical regenerative course, and no inflammatory recurrence was observed six months after the end of therapy.

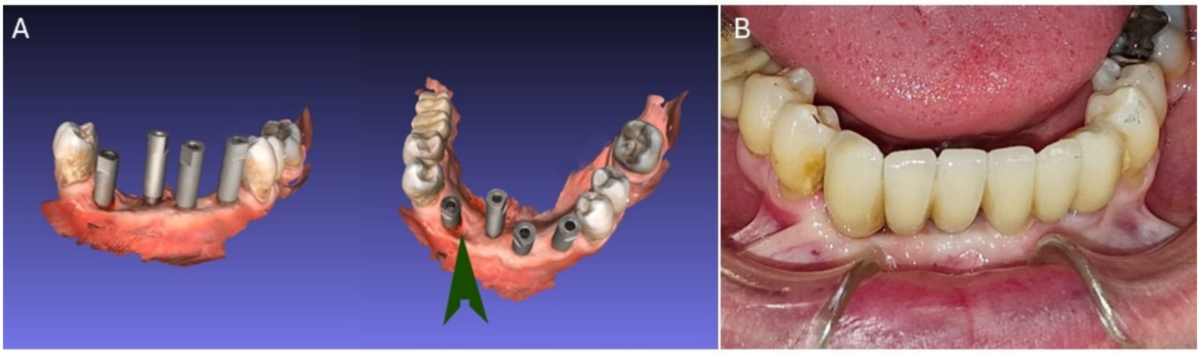

Figure 11. Final prosthetic restoration. (A) Digital impression obtained with Medit i500; the green arrow highlights the mucosal depression remaining from the previous actinomycosis infection, indicating good superficial mucosal epithelialization. **(B)** Final prosthesis with metal-ceramic fixed restoration: functional rehabilitation and no inflammatory signs.

At the 8-month postoperative follow-up, a CBCT scan was performed to evaluate bone stability and implant integration in the anterior mandibular region. The scan reveals excellent osseointegration of the four endosseous implants, with clear evidence of mature and compact bone surrounding each fixture. In cross-sectional and panoramic reconstructions, the regenerated bone appears structurally homogeneous and well-corticalized. The vertical bone levels are preserved, and the buccal and lingual cortices show continuity, confirming the long-term success of the regenerative protocol using SmartBone® and SBPD. No residual signs of the previous Actinomyces-related lesion are visible, and the peri-implant tissues appear stable and inflammation-free (Figure 12).

At the 30-month postoperative follow-up, a CBCT scan was performed to assess the long-term stability of the regenerated bone and the four endosseous implants in the anterior mandibular region. The scan confirms stable osseointegration, with the implants firmly anchored in dense and mature bone. Both cross-sectional and panoramic views reveal that the regenerated bone maintains a homogeneous structure with well-defined corticalization of the buccal and lingual plates. Vertical bone levels are preserved, and there are no radiological signs of peri-implant bone loss or pathological alterations. The peri-implant tissues remain healthy and inflammation-free, demonstrating the regenerative procedure's long-term success with SmartBone® and SBPD (Figure 13).

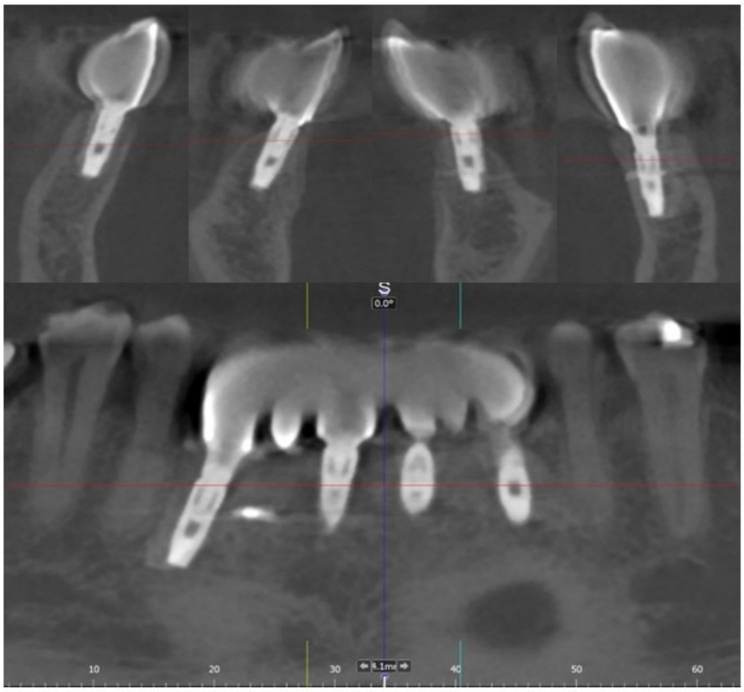

Figure 12. CBCT scan at 8-month follow-up. The radiological image shows successful osseointegration of the four implants and stable regenerated bone in the anterior mandible. No pathological findings are present.

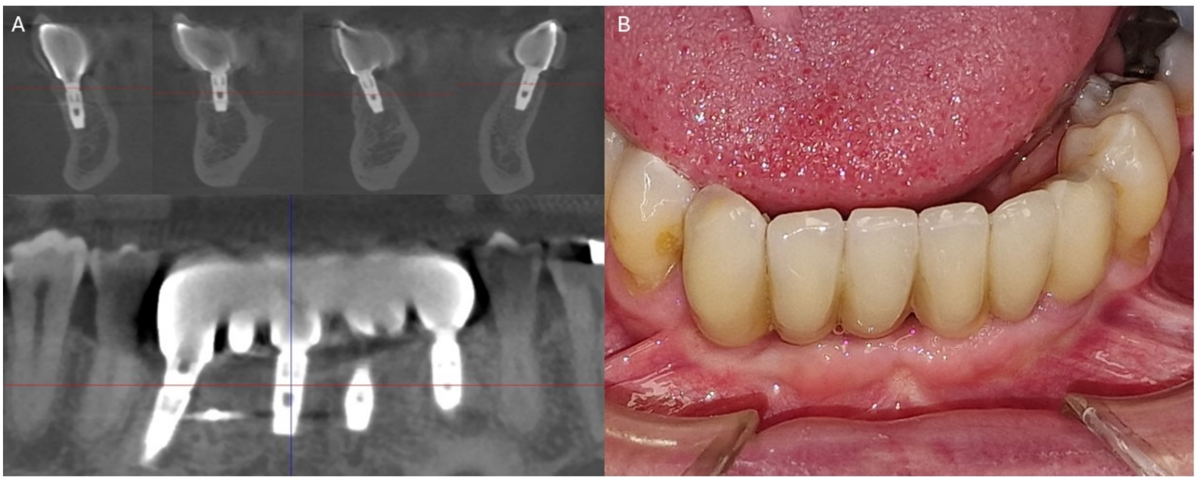

Figure 13. 30-month follow-up. (A) A CBCT scan showed stable osseointegration of the four implants with preserved bone levels and intact cortical plates. **(B)** Clinical view revealing healthy peri-implant soft tissues and stable prosthetic rehabilitation.

Discussion

Bone regeneration represents one of the most significant challenges in oral and maxillofacial surgery, especially in cases where tissue damage is caused by chronic inflammatory diseases, such as advanced periodontitis [3]. In such contexts, restoring bone volume is necessary for aesthetic and functional purposes and constitutes an essential prerequisite for long-term implant-prosthetic rehabilitation [24]. The evolution of biomaterials, particularly the introduction of advanced bone substitutes such as SmartBone®, has made it possible to address even the most complex cases with greater predictability and safety [15].

SmartBone® is configured as a xeno-hybrid bone substitute, designed to mimic autologous bone's mechanical and biological properties. By combining a mineralized bovine bone matrix with biodegradable polymers and collagen fragments, the material aims to offer a dual function: mechanical support and regenerative stimulus [12]. In the clinical case presented, the use of SmartBone® associated with autologous platelet derivatives obtained through the SBPD technique demonstrated remarkable efficacy in regenerating the anterior mandibular region, even in the presence of particularly unfavorable conditions [15].

An exciting aspect is the material's response in the context of an infection by *Actinomyces israelii*, an opportunistic microorganism known for its ability to cause chronic granulomatous infections [19]. In our case, the infection appeared approximately three months after the regenerative procedure, with the onset of a localized inflammatory lesion in the 4.2 region. Despite the infection, which could have compromised the entire regenerative process, the tissue response remained surprisingly contained. The inflammation did not spread to the surrounding newly formed bone tissue, maintaining good volumetric and structural integrity.

The infection was effectively managed through surgical revision and targeted antibiotic therapy (tetracyclines for 40 days). The treatment allowed complete control of the clinical situation without needing to remove or replace the entire regenerative graft, as often occurs in severe infectious complications. The localization of the infection and the absence of systemic dissemination (confirmed by negative chest radiographs) confirm not only the promptness of diagnosis and therapy but also the material's capacity to confine the inflammation in a limited area. This finding may suggest that SmartBone®, besides providing osteoconductive support, may also contribute to limiting the spread of infection. However, it must be emphasized that it is impossible to state with certainty that the material itself actively contained the infectious process. The favorable outcome may have been influenced by multiple factors, including the patient's immune response, antibiotic treatment timeliness, and the microorganism's limited virulence.

To validate this hypothesis, future studies involving controlled experimental models will be necessary, in which the evolution of infection is observed in the presence and absence of specific regenerative materials. Integrating microbiological testing could help clarify whether materials such as SmartBone® play a passive role (e.g., physical barrier) or an active one (e.g., indirect antimicrobial effect) in containing infections.

After the infection was resolved and the tissue healed, four endosseous implants were placed, which were successfully osseointegrated into mature and well-structured bone tissue. The prosthetic phase, completed with a fixed metal-ceramic rehabilitation, further confirmed the stability and quality of the regenerated bone. The eight-and-thirty-month follow-up showed clinically healthy mucosa, with good epithelialization and no signs of inflammatory recurrence.

Despite the promising results obtained, it is essential to highlight some limitations of the study. First, the results cannot be generalized as a single clinical case report. Individual variability, both in terms of immune response and regenerative capacity, limits the ability to draw definitive conclusions about the efficacy of the therapeutic protocol. In light of these results, the need for further investigations becomes clear. Controlled clinical studies on larger patient cohorts are essential to validate the effectiveness of the adopted protocol.

This case highlights the potential of SmartBone®, combined with autologous platelet derivatives, to achieve successful bone regeneration even in challenging conditions complicated by localized infection. The favorable outcome, including stable implant placement and long-term tissue integration, suggests the protocol's clinical promise.

Conclusion

In conclusion, the clinical case described shows a favorable clinical outcome in a complex scenario, thanks to the combined use of SmartBone® and autologous platelet derivatives. The bone regeneration proved stable and well integrated, allowing for complete implant-prosthetic rehabilitation, even in a localized infectious complication caused by *Actinomyces israelii*, which remained well circumscribed and manageable.

These results suggest that the adopted regenerative protocol may be effective even in the presence of opportunistic infections, without compromising graft integration. However, as this is a single clinical case, general conclusions cannot be drawn. Controlled clinical studies on a larger patient cohort will therefore be necessary. Moreover, to clarify the possible role of the material in containing infection, more in-depth microbiological and immunological studies will be required.

Author Contributions

All authors contributed to the manuscript's conceptualization, design, and writing. All authors have read and agreed to publish the final version of the manuscript.

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This research received no external funding.

Data Availability Statement

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

GP is the shareholder and manager of the company that manufactures SmartBone®, and CFG is the manager of the same company. These affiliations did not influence the design, execution, or interpretation of the research.

Industrie Biomediche Insubri SA, the manufacturer of SmartBone®, did not sponsor the study. There was no financial support or commercial involvement in the execution of this research. The authors conducted all experimental work, data collection, and interpretation independently.

Consent to Participate

The patient signed an informed consent form to document that he understood the study's aims and authorized the use of her data for research purposes. All procedures were performed in strict accordance with the recommendations of the Declaration of Helsinki, as revised in Fortaleza (2013), for investigations with human subjects, and followed good clinical practices and ISO14155 prescriptions.

Ethics Committee Approval

The study described in this article was conducted using SmartBone®, a CE-marked medical device, within the framework of standard post-marketing clinical follow-up studies, in compliance with ISO 13485:2016. Under this regulatory context, specific approval from an ethics committee or an institutional review board (IRB) was therefore not required.

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