

# EFFICACY OF A NOVEL ADAPTABLE AND MOLDABLE SYNTHETIC POLYMER, IN OPEN SOCKET PRESERVATION WITHOUT A MEMBRANE: EASE OF USE AND VOLUME PRESERVATION IN ALVEOLAR BONE REGENERATION

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## Abstract

This study evaluates FlexiOss® Dent, a novel biomaterial combining synthetic hydroxyapatite with curdlan, for its potential in dental applications specifically targeting alveolar bone regeneration post-extraction. Alveolar bone volume loss following tooth extraction significantly compromises dental implant viability and presents challenges in predictable prosthetic reconstruction. Traditional bone grafts, including autografts and allografts, are associated with limitations such as donor site morbidity, resorption, immunologic reactions, and ethical concerns related to animal-derived materials. In this single-patient case study, a 45-year-old patient with persistent mandibular pain underwent extraction of tooth 37, followed by socket preservation using FlexiOss® Dent. The biomaterial was hydrated, sectioned, and layered within the socket to provide structural support, promote angiogenesis, and facilitate osteogenesis. Over a 110-day follow-up period, CBCT imaging and histopathological analysis confirmed effective bone regeneration and integration, with no evidence of vertical or horizontal bone resorption. Favorable soft tissue healing and maintenance of alveolar ridge dimensions were also observed, indicating stable integration of the graft. FlexiOss® Dent's moldability, porosity, and non-animal-derived composition support its ethical and clinical advantages over conventional graft materials. These findings suggest that FlexiOss® Dent may represent a promising alternative for alveolar ridge preservation and complex dental reconstructions, although larger controlled studies and long-term evaluations are required to validate its broader clinical applicability.

**Keywords:** FlexiOss® Dent, bone regeneration, alveolar bone, dental reconstruction, synthetic polymer

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## Introduction

The alveolar process, essential for dental development, shapes the orientation and eruption of teeth. However, it is vulnerable to periodontal diseases necessitating multiple tooth extractions. Teeth extractions can significantly cause bone atrophy and reduce alveolar bone volume, which is crucial for dental implant viability [1]. Tooth extraction initiates biological changes due to local inflammation and lack of masticatory stimulation, disrupting periodontal tissue homeostasis and structure. This process, supported by preclinical and clinical evidence, involves rapid alveolar bone resorption and mucosal invagination in the weeks following extraction [2]. Various bone substitutes have been employed to address the loss of alveolar ridge volume, including autografts, allografts, and synthetic fillers, such as hydroxyapatite-based materials, which are particularly prevalent due to their resemblance to bone's inorganic component [3]. These are essential for maintaining the bone structure necessary for prosthetic treatments with implants.

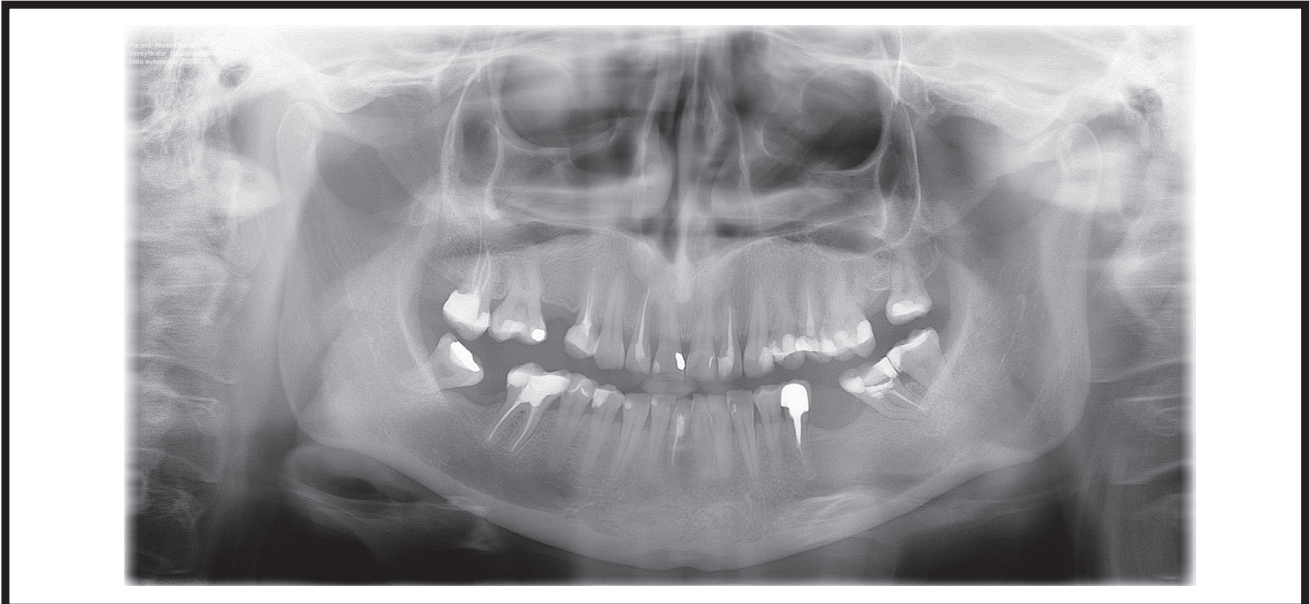
Alveolar socket resorption typically results in a loss of about 3.87 mm in width and 1.67 to 2.03 mm in height within the first three months post-extraction, posing substantial challenges during prosthetic treatments with implants [4]. While soft tissue augmentation has been explored, it often proves inadequate to preserve the alveolar ridge long-term, emphasizing the necessity for bone augmentation and their possible interplay [5]. Maintaining higher residual alveolar bone volume significantly improves dental implant survival. However, complications such as donor site morbidity, graft rejection, resorption, and religious issues are prevalent with current bone graft materials [6]. Additionally, these materials require the meticulous selection and preparation of the correct consistency for augmentation, as well as a time-consuming application process that demands effective stabilization [7].

This study was conducted with the approval of the Bioethics Committee (No. WLS9/RNW/PFZ3/N/25), as part of the Statutory Project of the Medical University of Warsaw, Department of Oral Surgery. The aim was to investigate FlexiOss® Dent, a novel biomaterial tailored for dental applications using synthetic hydroxyapatite [8, 9]. Combining synthetic hydroxyapatite with curdlan, this non-animal-based polymer avoids the ethical and safety reservations linked to animal-derived grafts and addresses concerns associated with allografts. Notably, as a third-generation hydroxyapatite/glucan composite with good healing properties in vivo, it stands out for its adaptability and moldability, which are necessary properties for addressing bone deficits in dental applications [10]. FlexiOss® Dent's unique composition allows it to absorb fluids, such as a patient's blood or sterile solutions, to become malleable, accurately conforming to and filling bone cavities. Its porosity facilitates expansion within the defect site, enhancing integration and adherence, which are crucial steps for successful alveolar bone resorption after extractions. The following study aims to elucidate the potential of FlexiOss® Dent in regenerating significant alveolar defects and averting atrophy, providing an alternative for patients needing bone augmentation for successful dental implants.

## Materials and methods

### Case presentation

A 45-year-old woman with no significant medical history presented for comprehensive dental treatment due to persistent pain in the mandible. The discomfort was traced to



**FIG. 1.** Panoramic radiograph of tooth 37, the second molar on the left mandible, showing no filling in the mesial root and complex root anatomy. A visible area of osteolysis indicates a periapical cyst, necessitating extraction due to persistent pain and prior endodontic treatment.

tooth number 37, the second molar on the mandible's left side, which had previously undergone endodontic treatment. Diagnostic imaging, including a pantomogram X-ray (FIG. 1), identified a lack of filling in the mesial root, complex root anatomy, and an osteolytic lesion indicative of a periapical cyst, warranting extraction.

#### **Surgical procedure and protocol**

The patient underwent aseptic extraction of tooth number 37. Subsequent management of the alveolar socket involved careful irrigation with saline to eliminate residual bacteria and debris, setting the stage for grafting. Flexi-

Oss® Dent, the sterile synthetic polymer, was selected for its suitability in dental applications. The graft material, characterized by its cylindrical shape, was prepared by immersion in saline, making it malleable for implantation. It was then precisely sectioned into slices to create a layered graft within the socket, a deeper layer for structural support, and a superficial membrane to close the site (FIG. 2).

The FlexiOss® Dent was placed into the socket with careful anticipation of potential volume expansion, and the wound was sutured, allowing for a small gap to account for this expansion (FIG. 3, FIG. 4).



**FIG. 2.** The proposed layered arrangement of the biomaterial within the alveolar socket, designed to manage potential volume increase after application. The biomaterial is structured in two layers: a deep layer composed of vertical slices for foundational support, and a superficial layer formed as a thin membrane to seal the defect. This configuration helps cushion any expansion of the biomaterial, facilitates blood penetration and angiogenesis, and prevents the intrusion of external fluids and residues into the healing site.



**FIG. 3.** Illustration of the placement of the prepared biomaterial within the alveolar socket. This image demonstrates how the biomaterial is meticulously arranged to conform to the contours of the socket, ensuring optimal contact and integration for effective bone regeneration.



**FIG. 4.** This image shows the placement of sutures to close the wound, with a small gap left intentionally to accommodate potential expansion of the biomaterial and prevent wound dehiscence. The upper layer of the biomaterial seals the wound horizontally.

## Results and Discussion

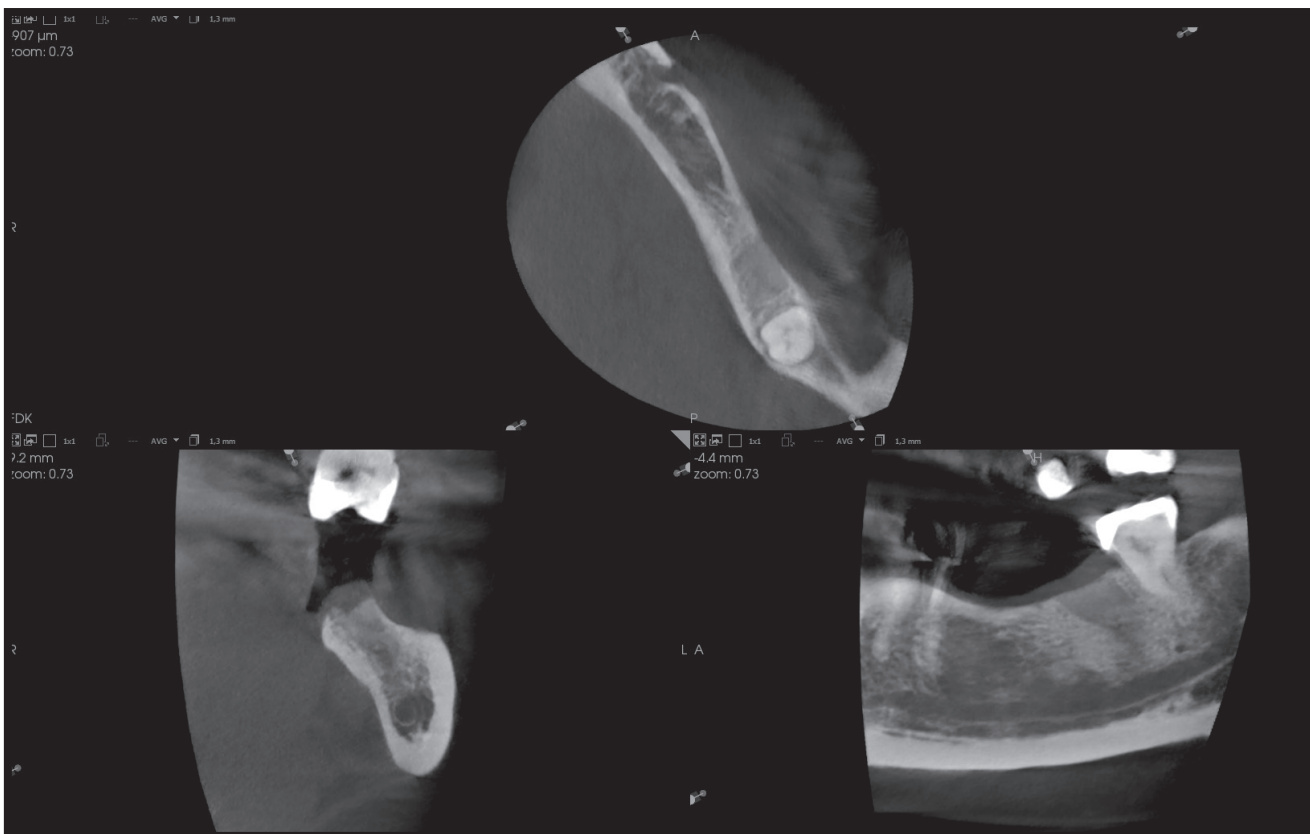
The patient's recovery was monitored, with a 110-day post-operative follow-up that included CBCT scans. These scans confirmed no vertical or horizontal bone resorption and bone density consistent with the surrounding area

(FIG. 5). Histopathological evaluation of a sample taken with a trephine confirmed successful bone regeneration and integration without pathological changes or infection, demonstrating new bone growth (FIG. 6).

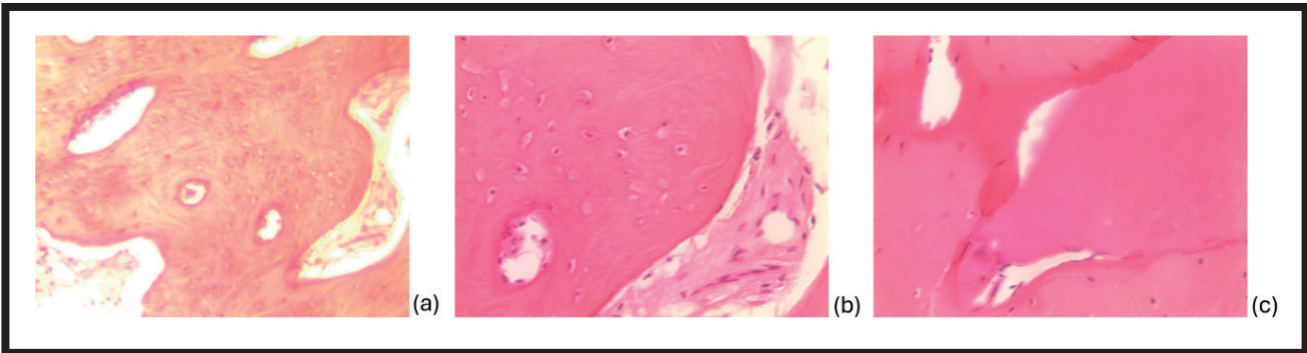
The mucous membrane remained healthy throughout the healing process with no signs of inflammation, and soft tissue levels stayed consistent with those pre-extraction (FIG. 7). The FlexiOss® Dent material remained stable, with no displacement, and sutures were intact and removed after two weeks, suggesting no dehiscence. The exposure of the mucoperiosteal flap showed bone with uniform macroscopic structure as in adjacent areas to the graft, mechanically uniform, hard, and not crumbling. The patient experienced a favorable recovery with no reported discomfort, and the integrity of the regenerated bone was maintained, meeting the treatment objectives.

In this case report, the successful regeneration of alveolar bone can be attributed to several key factors that were carefully considered during the treatment process. The use of FlexiOss® Dent, a synthetic polymer designed for dental applications, played a pivotal role. Its successful application was previously observed in a study on dogs, in which the treatment with FlexiOss® Dent showed strengthened mucosal structures without inflammation or dehiscence and demonstrated accelerated bone formation and filling of alveolar sockets within just three weeks post-extraction [11].

The absence of both vertical and horizontal bone resorption 110 days post-operation is a significant finding, as it suggests that this hydroxyapatite/glucan bone filler is not only effective in promoting bone regeneration, but also in preventing the common post-extraction issue of bone atrophy. To date, researchers have evaluated various ridge preservation methods in controlled studies with mixed results, and clear guidelines for choosing techniques and materials in clinical practice are still lacking [12]. The limitations of



**FIG. 5.** Key aspects of the augmented area: 1. Bone level shows no vertical resorption. 2. Ridge width remains intact with no horizontal resorption. 3. Bone density matches that of the surrounding tissue. 4. Structural analysis reveals no foreign bodies present.



**FIG. 6. Microscopic analysis of decalcified bone specimens, H&E staining: (a) Visible bone trabeculae and marrow spaces. Within the bone trabeculae, osteocyte lacunae are visible. (10× magnification); (b) decalcified specimen at higher magnification, with remnants of a biostatic bone graft and newly formed trabeculae with visible osteocyte lacunae, indicating bone remodeling (40× magnification); (c) dynamic bone formation processes observable, with osteocyte lacunae, elongated osteogenic cells, and osteoblasts initiating osteoid encapsulation (40× magnification).**



**FIG. 7. The mucous membrane post-healing, showing no signs of inflammation and maintaining soft tissue levels consistent with those before the extraction of tooth 37. The membrane's healthy appearance indicates successful recovery.**

traditional bone graft materials, such as autografts and allografts, often come with risks of donor site morbidity, graft rejection, resorption, or ethical and religious problems [6]. Hydroxyapatite bone fillers provide a viable alternative with its synthetic composition, potentially reducing these risks. The limits of using hydroxyapatite alone, such as low fracture resistance, were overcome by incorporating polymers [13]. Hydroxyapatite-based fillers, such as nano-crystalline hydroxyapatite or hydroxyapatite incorporated into hydrogels, have shown enhanced healing capabilities and are more effective in promoting new bone growth in the alveolar ridge [14, 15]. Studies explored scaffold-based bone regeneration approaches using a 3D-printed, osteoinductive, and osteoconductive hydroxyapatite scaffold engineered for controlled resorption and enhanced with growth factors. These studies showed promising results in preclinical models for reconstructing intraoral bone defects prior to dental implant placement [16, 17]. The cost-effective and non-animal-derived polymer, B-glucon, is used in FlexiOss® Dent, a moldable biomaterial comprising synthetic hydroxyapatite and curdlan, a glucose-based glucon polysaccharide. Additionally, its cylindrical shape, conducive to dental surgery, allowed for ease of manipulation and placement within the alveolar socket.

Another factor contributing to the success of the grafting procedure was the application approach. The treatment

facilitated optimal conditions for angiogenesis and osteogenesis by creating a vertical layer for structural support, a superficial membrane layer to seal the defect, and leaving a small gap when suturing the site anticipating the biomaterial's expansion. Appleford et al. [18] developed a hydroxyapatite scaffold that mimics trabecular bone structure. This scaffold demonstrated significant blood vessel growth and bone formation when used in dogs for up to 12 weeks [18]. This application approach, coupled with the biomaterial's porosity, allowed for its expansion, which improved its integration and adhesion to the defect walls. Hydroxyapatite scaffolds with specific pore sizes significantly enhanced both angiogenesis and osteogenesis, demonstrating the importance of scaffold architecture in supporting tissue regeneration [19]. The patient's satisfactory report of no post-operative discomfort and the maintenance of bone volume and structure shows both the biomaterial's effectiveness and the treatment protocol's soundness. The adaptability and ease of placement of FlexiOss® Dent paved the way for innovative dental practices. Its features are crucial for enhancing angiogenesis, a critical factor in bone healing and regeneration, thus underscoring the significance of FlexiOss® Dent in modern dental procedures.

While the successful outcome of this case study provides promising evidence of the efficacy of FlexiOss® Dent, it is essential to recognize the inherent constraints of case study research. The findings derived from a single patient's experience offer a valuable proof of concept and an in-depth understanding of the clinical application of FlexiOss® Dent. However, these findings serve as an initial step, and although insightful, they may not be universally applicable across all patient demographics and clinical scenarios without further investigation and corroboration through larger-scale studies. In addition, while the case showed no immediate complications, the long-term behavior of FlexiOss® Dent in the dynamic oral environment, which faces mechanical stresses and bacterial exposure, remains to be comprehensively understood. One challenge was ensuring the material's integration without interference from the patient's oral hygiene habits or lifestyle factors that could affect healing. Managing patient expectations and adherence to post-operative care protocols also required careful consideration. To address these limitations, future research should involve larger cohorts with diverse demographics to validate the findings. Additionally, controlled

studies examining the long-term stability and resilience of FlexiOss® Dent against everyday functional loads will be essential.

## Conclusions

This case report contributes to the growing body of evidence that supports using synthetic biomaterials like FlexiOss® Dent in dental bone regeneration. While the results are promising, further research with a larger sample size and long-term follow-up would be beneficial to establish the material's efficacy and potential broader applications. Comparative studies involving traditional graft materials could also provide deeper insights into the relative advantages of using synthetic polymers like FlexiOss® Dent in various clinical scenarios. Additionally, investigating the interactions between FlexiOss® Dent and the surrounding soft tissue will provide a more holistic understanding of its integration into the dental matrix.

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## Author Contributions

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- B – Collection and / or assembly of data – Artur Kamiński, Szymon Wróblewski
- C – Data analysis and interpretation – Szymon Wróblewski
- D – Writing the article – Kornel Krasny
- E – Critical revision of the article – Kornel Krasny
- F – Final approval of the article – Kornel Krasny

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