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# Clinical and radiological assessment of the use of Bio-Gen Mix xenografts in jaw bone defects

## Kliniczna i radiologiczna ocena zastosowania materiału Bio-Gen Mix w ubytkach kości szczęk

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**ABSTRACT**

**Introduction**: Oral surgery management and procedures usually lead to irreversible loss of dentition and typical alveolar ridge bone height and width defects.
The aim of this study was to evaluate the healing of bone defects after the use of Bio-Gen Mix.

**Materials and methods**: The study group consisted of 42 patients treated for dentigeneous cysts, periapical lesions in teeth requiring root apex resection, or patients requiring post-extraction ridge augmentation procedures of Bio-Gen Mix bone replacement xenografts.

**Results**: The results of radiological and clinical assessments were summarized using a 3-grade scale for the assessment of intra-osseous defects as proposed by Gutmann and Harrison, and modified by Taschieri et al.

**Conclusions**: Our studies demonstrate that in the case of small bone deficiency, the use of bone replacement materials such as Bio-Gen Mix is sufficiently effective. The procedure leads to good outcomes, relatively fast bone remodeling, and resulting in bone quality largely appropriate for further prosthetic implantation.

**Keywords**: xenograft; bone graft; guided bone regeneration.

**ABSTRAKT**

**Wstęp**: Tradycyjne metody postępowania i wykonywania zabiegów z zakresu chirurgii stomatologicznej zazwyczaj prowadzą do bezpowrotnej utraty uzębienia i powstania typowego ubytku wysokości i szerokości kości grzbietu wyrostka zębodołowego. Celem niniejszego badania była ocena gojenia się ubytków kostnych po zastosowaniu materiału kościozastępczego Bio-Gen Mix.

**Materiały i metody**: Grupę badaną stanowiło 42 pacjentów leczonych z powodu obecności torbieli zębopochodnych, zmian okołowierzchołkowych przy zębach wymagających przeprowadzenia zabiegu resekcji wierzchołka korzenia oraz pacjentów wymagających poekstrakcyjnych zabiegów augmentacyjnych, jak również zabiegów sterowanej regeneracji kości przed planowanymi zabiegami implantacji z użyciem ksenogennego materiału kościozastępczego Bio-Gen Mix.

**Wyniki**: Wyniki oceny radiologicznej i klinicznej podsumowano za pomocą 3-stopniowej skali oceniającej proces gojenia ubytków śródkostnych, zaproponowanej przez Gutmanna i Harrison, a zmodyfikowanej przez Taschieri i wsp.

**Wnioski**: W przypadku niewielkich deficytów tkanki kostnej wystarczające jest wykorzystanie substytutów kości, chociażby preparatów pochodzenia wołowego, takich jak Bio-Gen Mix. Uzyskuje się w ten sposób dobry rezultat, dość szybką przebudowę tkanki kostnej, której jakość w dużej mierze wystarcza do prowadzenia dalszego leczenia implantoprotetycznego.

**Słowa kluczowe**: materiał pochodzenia ksenogennego; przeszczep kostny; sterowana regeneracja tkanek.

## INTRODUCTION

Traditional dental surgery management and procedures usually lead to irreversible loss of dentition and formation of typical alveolar ridge bone height and width defects. From the very beginning, however, dental surgeons attempted to fill the dental and jaw bone defects using various materials [1]. As late as in the 20th century new inventions opened up new possibilities of replacing missing teeth using dental implants and treating jaw bone defects of various aetiology using biological materials [2]. Thanks to these new methods, bone loss can be reduced significantly. Materials suitable for filling in jaw bone defects are in high demand today, instigating research and the examination of factors promoting optimum bone healing and reconstruction [3]. The use of patients' own tissues is often limited or even impossible. Usually, only small quantities of bone tissue can be collected, particularly from the most common oral collection sites used in outpatient care practice. This is associated with additional strain and risk of intraoperative and postoperative complications, such as bleeding, infections, and chronic pain at the collection site [4].

Therefore, new graft sources were sought in order to provide adequate quantities of implantation materials. Optimum quantities of bone replacement materials can be obtained from materials collected from donors of the same species (allografts), animals (xenografts) or synthetic materials [4, 5].

An appropriate amount of bone replacement material may be provided by natural materials of animal origin, i.e. xenografts.

Bone grafts may be of bovine (e.g. Bio-Oss, Cerabone) or equine (e.g. Bio-Gen) origin. Due to the potential risk of transmission of zoonotic diseases, these materials must be sterile and deproteinated to reduce their significant immunogenic potential, as well as submitted to a multi-hour annealing process for denaturation and carbonization. A negative outcome of these processes consists in a reduction of the osteoinductive potential of materials, as bone morphogenetic proteins are removed along with the other proteins.

The aim of this study was to evaluate the healing of bone defects after the use of Bio-Gen Mix.

## MATERIALS AND METHODS

The study group consisted of 42 patients treated at the Chair and Department of Oral Surgery Lublin Medical University Dental Clinical Centre in the years 2010–2013 for dentigeneous cysts, periapical lesions in teeth requiring root apex resection, or patients requiring post-extraction ridge augmentation procedures, as well as guided bone regeneration procedures before scheduled implantations of Bio-Gen Mix bone replacement xenografts.

Detailed patient interviews and medical histories were collected including diseases, addictions, allergies and hypersensitivities.

Extra- and intraoral clinical examinations were also performed to determine the treatment needs of individual patients, the overall health of their dentition and periodontium, as well as oral hygiene. In order to reduce the potential sources of infection prior to the scheduled surgery procedures, patients were recommended to undergo thorough sanitation of the oral cavity, including conservative, endodontic, periodontic and surgical treatment. Required radiodiagnostic images were acquired before the treatment in all patients. Extraoral dental x-rays and panoramic x-rays were performed as standard diagnostic procedures.

Clinical and radiological assessments of the procedures were performed in all patients immediately after the procedure, as well as 3, 6, and 12 months after the procedure.

## RESULTS

The results of radiological and clinical assessments were summarized using a 3-grade scale for the assessment of intra-osseous defects for the purposes of regenerative surgery [6, 7]. The scale was as follows:

— S – clinical success,

— D – dubious result, dubious positive clinical outcome and/or the presence of pathological clinical symptoms,

— F – failure and/or the presence of pathological clinical symptoms.

Bone defects classified as S should be considered healed, while those classified as D or F should be considered non-healed.

Not all cases could demonstrate a whole remodelling of the implant within the patient's native bone after 12 months;

**TABLE 1. Radiological assessment using the 3-grade scale for the assessment of intra-osseous defects**

| Patient | Procedure | Month 3 assessment | Month 6 assessment | Month 12 assessment |
|---|---|---|---|---|
| 1. | augmentation | S | S | S |
| 2. | augmentation | S | S | S |
| 3. | augmentation | S | S | S |
| 4. | augmentation | S | S | S |
| 5. | augmentation | S | S | S |
| 6. | augmentation | S | S | S |
| 7. | extraction | S | S | S |
| 8. | extraction | S | S | S |
| 9. | extraction | S | S | S |
| 10. | extraction | S | S | S |
| 11. | extraction | S | S | S |
| 12. | extraction | S | S | S |
| 13. | sinus lift | S | S | S |
| 14. | sinus lift | S | S | S |
| 15. | sinus lift | S | S | S |
| 16. | sinus lift | S | S | S |
| 17. | sinus lift | S | S | S |
| 18. | sinus lift | S | S | S |
| 19. | extraction of impacted tooth | F | F | F |
| 20. | extraction of impacted tooth | D | D | D |
| 21. | extraction of impacted tooth | S | S | S |
| 22. | cystectomy | D | D | S |
| 23. | cystectomy | D | D | S |
| 24. | cystectomy | D | D | S |
| 25. | cystectomy | D | D | S |
| 26. | cystectomy | S | S | S |
| 27. | cystectomy | S | S | S |
| 28. | cystectomy | S | S | S |
| 29. | cystectomy | S | S | S |
| 30. | cystectomy | S | S | S |
| 31. | cystectomy | S | S | S |
| 32. | cystectomy | S | S | S |
| 33. | cystectomy | S | S | S |
| 34. | cystectomy | S | S | S |
| 35. | cystectomy | S | S | S |
| 36. | cystectomy | S | S | S |
| 37. | cystectomy | S | S | S |
| 38. | cystectomy | S | S | S |
| 39. | cystectomy | S | S | S |
| 40. | cystectomy | S | S | S |
| 41. | cystectomy | S | S | S |
| 42. | cystectomy | S | S | S |

S – clinical success; F – failure and/or the presence of pathological clinical symptoms; D – dubious result, dubious positive clinical outcome and/or the presence of pathological clinical symptoms

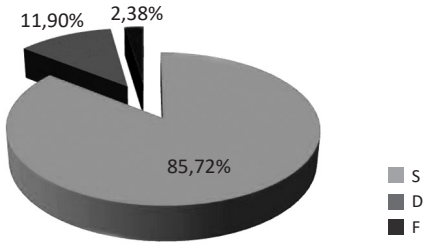


**FIGURE 1.** Month 3 healing assessment

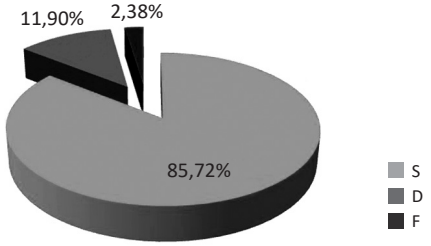


**FIGURE 2.** Month 6 healing assessment

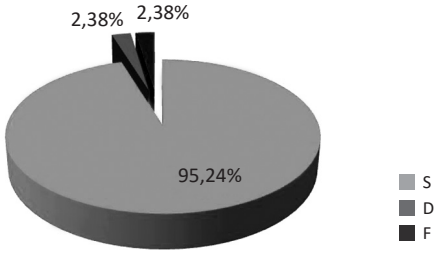


**FIGURE 3.** Month 12 healing assessment

however, such cases were classified into the category S (success), despite the appropriate regeneration rate as no disturbing clinical symptoms were observed. The results are presented in Table 1 and Figures 1–6. No differences were observed in the assessments of the healing process after 3 and 6 months of treatment.

## DISCUSSION

According to Dominiak and Łysiak [8], the first prerequisite for the management algorithm in intra-osseous defect repair is to determine the size of the defect. The literature provides the concept of a critical size defect, i.e. a defect that can not be spontaneously filled by normal bone tissue. Animal studies determined the critical dimension to be 5 mm [9, 10]. In clinical practice the diameters of bone defects after the enucleation of inflammatory cyst lesions are rarely smaller than 5 mm.

In our studies the largest dimension (diameter) of all defects was always larger than 5 mm.

Many authors bring up the question of the choice of the material to replace the lost bone tissue. Established years ago as the old standard, autologous bone graft seems to remain the optimum solution despite the growing availability of materials characterized by continuously improved properties [11, 12, 13, 14, 15, 16].

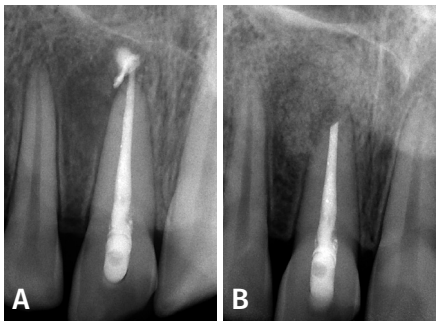


**FIGURE 4.** A cyst in the region of tooth 11, status after lesion extraction (A); resection of tooth 11 root tip and augmentation using Bio-Gen Mix (B)

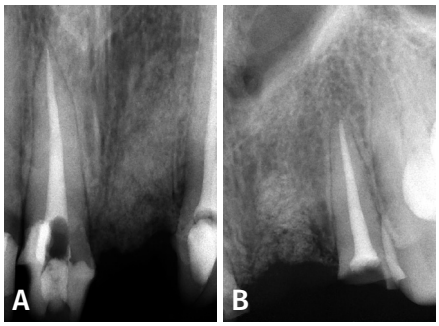


**FIGURE 5.** Dental alveolus after extraction of tooth 21 and augmentation with Bio-Gen Mix (A); 12 months after augmentation with Bio-Gen Mix (B)

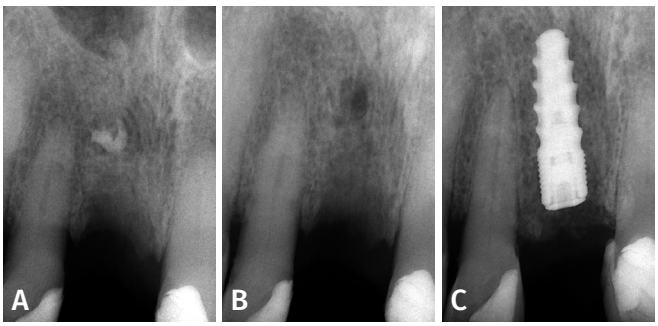


**FIGURE 6.** Status post surgical extraction of tooth 11 (A); status post augmentation with Bio-Gen Mix (B); 12 months after augmentation and implant placement in tooth 11 region (C)

Today, the question of bone replacement materials of natural or synthetic origin is being raised in many studies.

Many authors, e.g. Kozakiewicz et al. [17], Ray et al. [18], Merkx et al. [19, 20], Traini et al. [21], Bashara et al. [22], Jensen et al. [23], Šponer et al. [24], Cestari et al. [25], report the possibility of using bone replacement materials of various types in diverse clinical settings.

When analyzing the choice of materials, some authors bring up the potential risks of transmission of infectious agents, particularly viruses such as HCV, HBV, and HIV, or prion proteins. The use of autogeneic bone appears to be a rational choice in many cases, as these risks are thus eliminated.

Our studies demonstrate that in the case of small bone deficits, the use of bone replacement materials, e.g. materials of bovine origin, such as Bio-Gen Mix, is sufficiently effective. The procedure leads to good outcomes, relatively fast bone

remodelling, and resulting bone quality largely appropriate for further prosthetic implantation.

## CONCLUSIONS

1. Due to the high demand for augmentation procedures, guided tissue and bone regeneration procedures are dynamically evolving, leading to improved bone replacement materials and new management procedures.

2. Some bone grafting materials may be alternatives to autogeneic bone grafts. A high role is ascribed to xenogeneic materials.

3. The choice of appropriate method and material for augmentation of hard tissues prior to scheduled implantation is largely affected by the operator's experience and intuition, as well as by the amount of the remaining bone tissue.

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