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Clinical Paper
Dental Implants

The efficacy of a tissue-engineered xenograft in conjunction with sodium hyaluronate carrier in maxillary sinus augmentation: a clinical study

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Abstract. PepGen P-15 Putty comprises anorganic bovine bone matrix (ABM) coupled with a synthetic cell-binding peptide, suspended in a sodium hyaluronate carrier. The P-15 portion exhibits a similar structure and properties to the cell-binding region of type I collagen. This study was performed to evaluate ABM/P-15 putty as the sole graft in sinus augmentation. Ten patients for whom both a sinus augmentation and two implants were indicated in the posterior maxilla were enrolled. Bone cores were harvested at 8 and 16 weeks, followed by placement of one implant at 8 weeks and the second at 16 weeks. Twenty collected bone cores were evaluated histologically and by micro-computed tomography. Results showed a significant increase ($P < 0.05$) in bone mineral density at 8 weeks (0.70 ± 0.13 g/cm^3) and 16 weeks (0.97 ± 0.08 g/cm^3) in the graft compared to native (control) bone (0.04 ± 0.02 g/cm^3). There was no significant difference ($P > 0.05$) in the percentage bone volume at the two time intervals (PBV 21.14 ± 4.56 at 8 weeks and 26.33 ± 5.60 at 16 weeks). The average increase in bone height at 16 weeks was 10.55 ± 0.53 mm. It is concluded that PepGen P-15 Putty is capable of conducting and accelerating new bone formation and can successfully support dental implants.

Key words: bone graft; PepGen P-15; sinus augmentation.

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The posterior maxillary edentulous region presents many unique and challenging conditions in implant dentistry. A few of the problematic issues for optimal implant placement include poor bone quality, three-dimensional (3D) bone loss, and a subsequent cascade of exacerbating conditions, such as increased inter-arch space, reverse root to crown ratio, and poor inter-

arch relationships. Simultaneous pneumatization of the maxillary sinus and physiological bone loss secondary to tooth loss further compounds the anatomical deficiency. The magnitude of the deformity has led to a multitude of innovative reconstructive surgical techniques, including sinus grafting for implant reconstruction.[1]

Introduced by Tatum in the mid-1970s, sinus augmentation has become a very popular and predictable procedure over the decades, with success rates in the 90th percentile.[2] A variety of grafting materials have been utilized for sinus augmentation procedures. These include autografts, allografts, xenografts, and growth factors, used alone or in combination.[3–5] While autologous bone remains the gold standard, its use can be limited due to quantity and the potential negative impact of an additional surgery and donor site morbidity.

Improvements in the conduction and induction properties of bone substitutes have progressed rapidly. Collagen, which comprises more than 90% of the spatially fixed matrix of bone, is a major regulator of cell adhesion and osteogenic differentiation. Bhatnagar et al. identified a potent cell-binding domain of type I collagen.[6,7] It has been shown that a 15-residue synthetic peptide (P-15) analogous to the sequence GTPGPQGIAGQRGVV in the α1 (I) chain of type I collagen, binds cells with high affinity.[8] The literature is replete with documentation of the osteoconductive capabilities of anorganic bone matrix (ABM), also known as hydroxyapatite.

Coupling the synthetic clone of the 15-amino acid sequence of type I collagen to the AMB particles facilitates the attachment, migration, and differentiation of cells, similar to the physiological process provided by the collagen molecule. Taking this into consideration, it is expected that bone will be regenerated in an accelerated time compared to unmodified bovine bone.

Recently, the standard powder form of many bone substitutes has been combined with various carrier materials to improve graft handling and physical properties. The effects of these carrier materials on bone formation are still unknown. Sodium hyaluronate is one type of carrier material presently used to improve ABM grafting techniques. In this study, sodium hyaluronate was used with AMB/P-15 to produce a putty form consistency (PepGen P-15 Putty).

The sodium hyaluronate used in this study is chemically identical to that naturally found in humans. Synthetically, it is produced from a bacterial fermentation process and considered a non-animal-derived semi-synthetic material. Hyaluronate is degraded by the lymphatic system. The degraded hyaluronate enters the blood and is then transported to the liver, where it is catabolized. The gel is biodegradable and fully absorbed rapidly. The gel resorption is sufficiently rapid that it does not interfere with bone apposition and formation. In a canine fenestration model, no carrier was observed after 3 weeks.[9] This study used 3D computed tomography (CT scan) analysis to evaluate the bone formation using AMB/P-15 putty as the sole graft material in sinus augmentation.

Materials and methods

A prospective clinical trial was designed and implemented. The study sample comprised a population of 10 patients (eight females and two males; age range 29–59 years), who presented to the Oral and Maxillofacial Surgery Department, Faculty of Oral and Dental Medicine, Cairo University, Egypt. Each of these patients required posterior maxillary rehabilitation with a treatment plan to fabricate a fixed partial denture using two implants. A total of 10 operated sinuses were selected using the following criteria: posterior maxillary alveolar bone height 4 mm or less, naturally opposing teeth or prostheses, medical history void of acute or chronic medical diseases, and non-smoker. All patients enrolled participated in the study from beginning to end.

Consent was obtained after explaining the procedure and possible risks and complications. The graduate advisory committee on human research of the Faculty of Oral and Dental Medicine, Cairo University, Egypt approved the study in accordance with the Declaration of Helsinki.

Preoperative evaluation

Following careful extraoral and intraoral examination of all patients, preoperative CT scans and panoramic radiographs were used to measure the height of the atrophic alveolar ridge and rule out any sinus pathology prior to surgery (Fig. 1). Surgical stents with guided drill holes were fabricated on patient dental models to accurately identify the exact location for grafting and implant placement. This step was also important regarding implant positioning for optimum prosthetic fabrication. Preoperatively, each patient was given a standard dose of 3 g ampicillin/sulbactam (Unasyn) and 8 mg of dexamethasone intravenously. All patients underwent treatment under local anaesthesia (2% lidocaine/1:100,000 epinephrine).

Sinus augmentation procedure

A lateral window approach was used to access all sinus cavities. After sinus membrane elevation, the trap door (bone window) was positioned superior and medially to create and maintain a space for graft placement. Sinus perforations were inadvertently created in two patients.

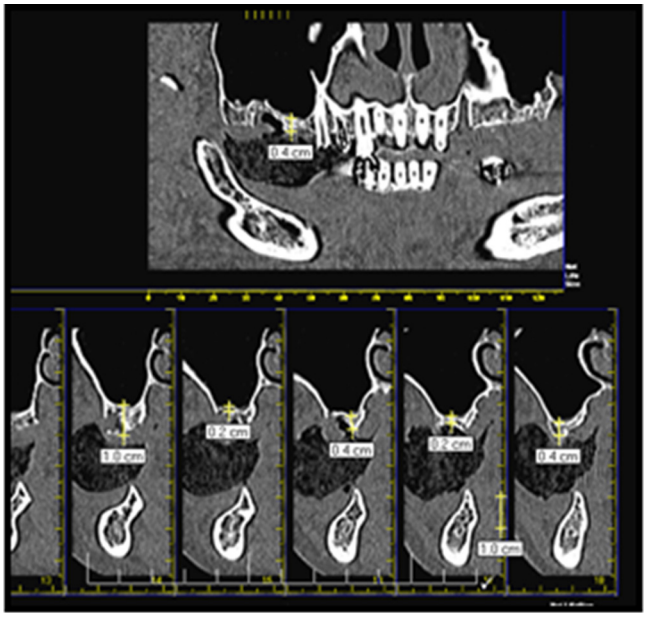

Fig. 1. A preoperative CT scan showing the residual ridge height measurement.