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Randomised controlled clinical trial of augmentation of the alveolar ridge using recombinant human bone morphogenetic protein 2 with hydroxyapatite and bovine-derived xenografts: comparison of changes in volume

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Abstract

The aim of this randomised controlled clinical trial was to assess the early efficacy of bone morphogenetic protein-2 with hydroxyapatite granules (BMP-2/hydroxyapatite) on augmentation of the alveolar ridge, by comparing changes in volume with those associated with the use of an inorganic bovine-derived xenograft (BDX). We studied 20 patients who were divided into two groups using a table of random numbers, and BMP-2/hydroxyapatite and BDX were applied accordingly. Computed tomographic (CT) images and panoramic radiographs were obtained immediately after operation and four months later. CT images were reconstructed in three dimensions to measure volumetric changes, and linear measurements were made on panoramic images. The mean (SD) absorption rates for BMP-2/hydroxyapatite and BDX were 13.2 (8.8)% and 13.8 (20.5)%, respectively. While the mean value did not differ significantly between the two materials, the SD was higher in the BDX group than in the BMP-2/hydroxyapatite group. No clinically important complications occurred in either group. We conclude that both BMP-2/hydroxyapatite and BDX were effective in augmenting the alveolar ridge, but BMP-2/hydroxyapatite seemed to be more useful in complicated bone defects.
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Keywords: Bone morphogenetic protein; Hydroxyapatite; Bovine-derived xenograft; Alveolar ridge augmentation; Volume change; Clinical trial

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Introduction

Alveolar bone loss as a result of tooth loss, infection, trauma or resection of a tumour requires reconstruction of bony defects to allow implantation of teeth. The presence of adequate bone to surround an implant is essential for successful implantation, and various techniques have been developed and used for the regeneration of alveolar bone.[1] Guided regeneration is one of the most popular procedures done in the outpatient department at dental hospitals, and it has been further advanced by the development of substitute materials. The autogenous bone graft (autograft) is known to have the best prognosis of various bony substitutes, and is still considered the gold standard for most applications because it is superior to other materials in the promotion of osteogenesis.[2,3] Despite this, an autograft has some limitations including the requirement for an additional operation at the donor site, increased risk of complications, and restriction of supply.[3–5] Substitute bone grafts – including various kinds of allogenic, xenogenic, and alloplastic materials – have therefore been used alone or in combination for guided bony regeneration.

Unlike the conventional bone substitutes that are osteoconductive or osteoinductive, growth factors such as bone morphogenetic proteins (BMP), have proved to have a powerful osteoinductive capacity and have been investigated as new graft materials for bony regeneration. They are one of the most potent cytokines present in the tissues and organs, and they play an important part in the development and regeneration of bone by acting as a powerful inducer of mesenchymal progenitor cells that differentiate into osteoblasts.[6–10] Early recombinant human BMP (rhBMP) is produced in mammalian cells such as Chinese hamster ovary cells but is not particularly productive and is expensive. However, the mass production of rhBMP using prokaryotic expression systems such as *Escherichia coli* has made it possible to use rhBMP cheaply.[11,12] The use of rhBMP-2 for augmentation of the maxillary sinus and localised augmentation of the alveolar ridge in oral and maxillofacial surgery was approved by the Food and Drug Administration in 2007.[3–5,13,14] Since then there have been many clinical studies of rhBMP-2, but to our knowledge most of them were case reports, with only a few controlled clinical trials.[10,15,16]

The aim of the present randomised controlled clinical trial (RCT) was to assess the early efficacy of rhBMP-2 delivered with hydroxyapatite granules, by focusing on the change in volume in augmentation of the alveolar ridge compared with that resulting from an inorganic bovine-derived xenograft (BDX).

Material and methods

This study was a single-blinded RCT at a single centre: the Department of Oral and Maxillofacial Surgery in Yonsei University Dental Hospital. The protocols used were approved by the Institutional Review Board for Clinical Research at Yonsei University Dental Hospital (approval no. 2-2015-0001) and conformed to the Helsinki Declaration and the Good Clinical Practice guidelines. Written informed consent was obtained from all patients who took part.

Materials used

The BMP-2/hydroxyapatite (Novosis-Dent, CG Bio, Gyeonggi-do, Korea) that was used in the experimental group comprised hydroxyapatite granules (0.5 g; granule size, 0.6∼1.0 mm; pore size, 200∼250 μm), lyophilised *E-coli*-derived rhBMP-2 (ErhBMP-2, 0.5 mg), and distilled water (0.5 ml). After the ErhBMP-2 had been dissolved in sterile distilled water it was gently mixed with the granules for more than 10 minutes so that it would be evenly distributed into the pores. BDX (Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland; 0.5 g/bottle; small granules, 0.25∼1.0 mm) was applied in the control group. The amount of graft material used depended on the size of the particular defect.

Subjects

Ten subjects were studied in each group. As there have to our knowledge been few RCT of augmentation of the alveolar ridge with BMP-2, this study was designed as a therapeutic exploratory clinical trial to evaluate the efficacy and safety of BMP-2/hydroxyapatite, and to compare it with BDX. The number of subjects was calculated based on the clinical and radiological experience of the operator and the results of previous research. The inclusion and exclusion criteria are shown in Fig. 1.

Randomisation

Patients were randomly assigned to the groups by a statistician using block randomisation. Computer-generated random numbers were given to subjects, and the surgeon was given the treatment assigned on the day of operation. The patients enrolled were unaware of the treatment.

Timetable and operations

The trial was conducted in four periods (Fig. 1), and a single surgeon did all the operations under local anaesthesia. The technique used for guided bony regeneration differed from the conventional one that uses crestal, vertical, and releasing incisions and a barrier membrane. Instead we used the envelope method, which comprises a vestibular incision and raising the periosteal space for graft material. This technique can prevent the spread of the graft, and reduces the risk of complications such as wound dehiscence. After the envelope has been formed, the operator makes several holes with a fissure bur for decortication at the recipient sites, and fills the envelope with graft material. No membrane is used, and the periosteum is kept intact. Horizontal mattress sutures with 4/0

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