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Eight-Year Clinical Follow-Up of Sinus Grafts with Micro-Macroporous Biphasic Calcium Phosphate Granules

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Abstract. Restoring alveolar bone following tooth extraction or pathological diseases is important, and recent efforts have been made to overcome the use of autografts during dental implantation. Although micro-macroporous biphasic calcium phosphate (MBCP™) has performed well in orthopedic procedures, few studies have investigated its use in dentistry. Here, we report a greater than eight-year clinical follow-up of bone regeneration using MBCP™ after sinus grafting. MBCP™ technology is a unique mixture of hydroxyapatite and β-tricalcium phosphate, which displays both macroporosity and microporosity. A total of 25 patients (33 implantation sites) were evaluated by X-rays, and their pre-operative and immediate post-operative bone heights were measured. After approximately six months, dental implantation was performed. Subsequently, X rays were performed each year, and bone height was measured. In all cases, radio-opacity of the implantation area decreased with time, indicating resorption and bone ingrowth at the expense of the MBCP™ material. After one year, the implantation area had the appearance of physiological bone and <11% of height loss was observed. Strikingly, the newly formed bone was preserved after 7–8 years of follow-up, with only <14% of height loss recorded**.** We demonstrate that sinus grafting followed by dental implantation with a resorbable and bioactive synthetic bone graft material (MBCP™ technology) safely and efficiently supports dental implantation.

Introduction

Autologous bone is the gold standard in pre-implant bone reconstruction because it represents a source of osseous matrix, cells, and growth modulating molecules. However, autografts must be harvested at a location distant from the primary surgical site, complicating initial procedures. Therefore, synthetic products have been developed [1,2]. Biphasic calcium phosphate (BCP), which is a mixture of hydroxyapatite (HA) and β-tricalcium phosphate (β-TCP) [2,3], or pure β-TCP have been proposed as reference materials for use in dentistry. For dental implantations, sufficient bone augmentation must be achieved. Thus, sinus lift grafting (SLG) has become a common surgical procedure for attaining increased bone height. The use of synthetic materials, such as calcium phosphate bioceramics, represents an efficient alternative to autologous bone grafts during bone reconstruction. Indeed, BCP has a chemical composition close to biologic bone apatites and has already been used as an effective bone substitute in many human clinical applications [4-10]. Collectively, these studies using BCP with various ratios of HA and β-TCP have demonstrated the bioactivity of these bioceramic materials. This has led to a significant increase in the production and use of BCP-based bone substitute materials in dental, orthopedic, and tissue engineering applications.

The aim of this study was to demonstrate bone regeneration at the expense of micro-macroporous biphasic calcium phosphate (MBCP™) granules during SLG and to investigate long-term ingrowth stability by conducting eight-year patient follow-ups.

Materials and Methods

MBCP™ (Biomatlante SA, Vigneux de Bretagne France) is a mixture of HA and β-TCP (ratio 60/40) that has crystals of high specific surface area (SSA > 4 m^2/g) and granule sizes between 0.5 and 1 mm. In addition, MBCP™ is made up of micropores and macropores that display high interconnection and permeability. The total porosity was 70%, which consisted of 30% micropores and 70% macropores (300–600 µm).

Granules were used during sinus lift augmentation procedures in humans. Patients were treated under local anesthesia by para-apical and palatin infiltration. A crestal incision was made, followed by vertical discharge. The bone window was created via drilling (diamond bur), and the Schneider membrane was then slightly displaced. Classical techniques were used for sinus lift, and 1–2 cc of MBCP™ were delivered. After wetting the granules in sterile water, they were gently packed under the mucosa while taking care of the mucosa lesion. A collagen membrane was subsequently used to close the implantation site. Bone height was evaluated before and after implantation of the bone substitute. Approximately six months later, a second surgical step was performed for dental implantation. Bone height was then measured for up to eight years. Twenty-five patients were recruited for the study between 2004 and 2006, and a total of 33 implantation sites were evaluated.

Results

The mean time of bone grafting before dental implantation was 26 ± 11 weeks. Only one patient received dental implantation after three years; however, in this particular case there was no loss of bone height. The initial mean bone height prior to grafting was 3.5 mm ± 1.7. After SLG, the initial mean height was 17 ± 3 mm. The height measured during the eight-year follow up is reported in Fig. 2. After one year, the height decrease was <11%. After 6–8 years, the loss was <14%, and no significant difference could be observed over time (Fig. 1). The corresponding linear regeression equation was y = 0.0051x + 15.478 (r = 0.0279).

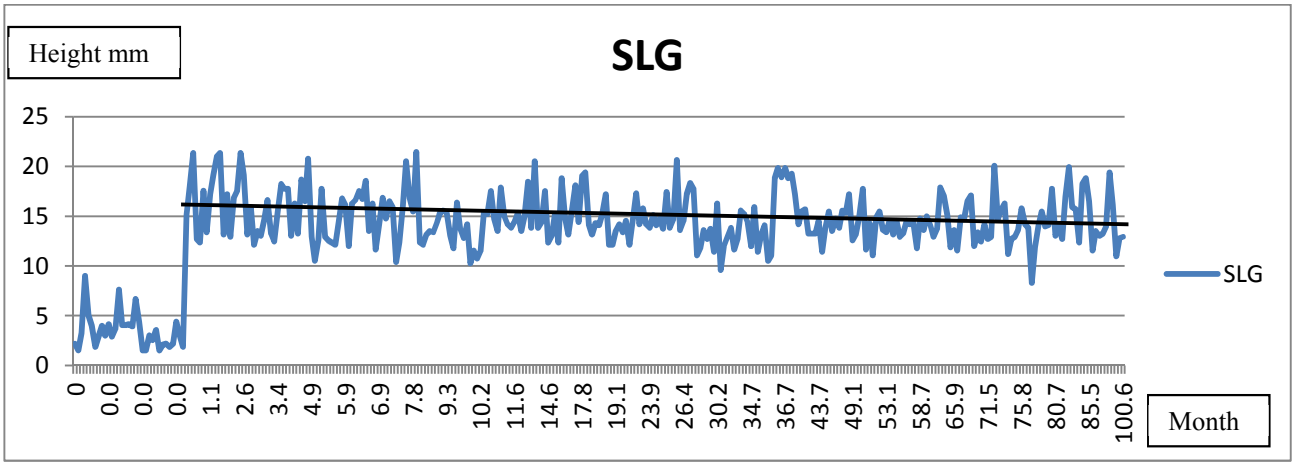

Figure 1. Bone augmentation evolution over time after SLG

In all patients, radiographs revealed newly formed bone with increased density. In addition, we noted high bone density during drilling for dental implantation. For this report, we have displayed the results from a representative patient with two implantation sites (Fig. 2). Reduction in radio-opacity as well as organization of the bone architecture could be observed at the implantation site over time using X-rays (Fig. 3).

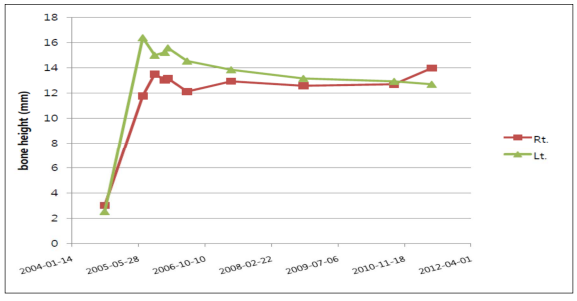

Figure 2. Patient 7138680, regular bone height measurement

Notably, the dental implants displayed good mechanical stability according to classical tests, which were performed after the surgery.

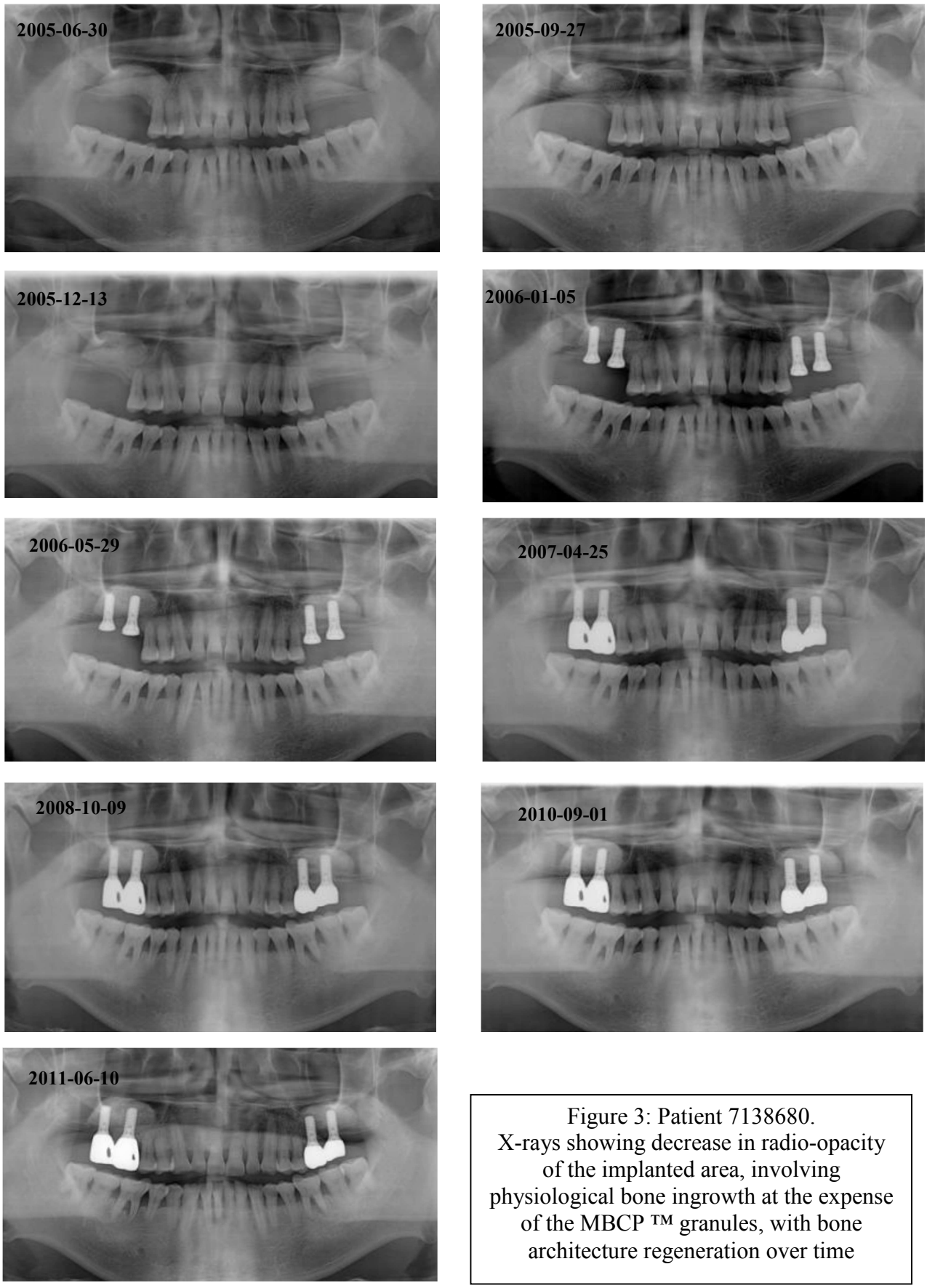

Figure 3: Patient 7138680.
X-rays showing decrease in radio-opacity of the implanted area, involving physiological bone ingrowth at the expense of the MBCP ™ granules, with bone architecture regeneration over time

Discussion

Insufficient bone volume is a common problem encountered during dental implantation. Therefore, maxillary sinus augmentation using bone grafts is often required to make implant placement possible [11]. However, selecting an appropriate synthetic bone substitute is an important decision. HA is not sufficiently resorbed for promoting bone regeneration, and β-TCP is too soluble to prevent progressive bone height loss, while HA/TCP mixture (BCP) are able to control the resorption and bone ingrowth at the expense of the bioceramic [3]. Therefore, effective bioceramics must display controlled resorption over time along with high osteogenic activity to support bone augmentation and long-term stability of the dental implant. This study confirms efficient resorbability of MBCP™ over time, allowing new bone to form at the expense of the bioceramic granules. As a result, long-term bone height stability can be observed, which offers an advantage for mechanical support of the dental implant following SLG. Thus, the use of MBCP™ technology delivers efficient regeneration of bone architecture, which is required for physiological bone reconstruction by synthetic bone substitutes.

Conclusions

After 6–8 months, sinuses that had been filled with MBCP™ granules displayed enough bone ingrowth to support dental implants. Moreover, the bone architecture remained suitable for mechanical stability over time. Strikingly, no significant loss of bone height was observed after eight years.

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