Int. J. Oral Maxillofac. Surg. 2017; xxx: xxx–xxx
https://doi.org/10.1016/j.ijom.2017.11.016, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper
Pre-Implant Surgery

Comparative study of volumetric changes and trabecular microarchitecture in human maxillary sinus bone augmentation with bioactive glass and autogenous bone graft: a prospective and randomized assessment

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Abstract. The aim of this study was to compare the volumetric changes and the new bone microarchitecture in human maxillary sinuses augmented with bioactive glass (Biogran) alone, bioactive glass combined with autogenous bone graft (1:1), or autogenous bone graft alone. Twelve maxillary sinuses were grafted with bioactive glass (group 1), nine with bioactive glass mixed with autogenous bone graft 1:1 (group 2), and 12 with autogenous bone graft (group 3). Patients underwent cone beam computed tomography 15 days after the procedure to determine the initial volume of the graft (T1) and again 6 months later (T2). Biopsies were obtained at the time of dental implant placement and were subjected to micro-computed tomography. The volumetric change was 44.2% in group 1, 37.9% in group 2, and 45.7% in group 3 ($P > 0.05$). The trabecular microarchitecture results showed that the materials used in groups 1 and 2 were good bone substitutes. However, the addition of 50% bioactive glass to autogenous bone graft improved the microarchitecture of the graft. Furthermore, the results for volumetric changes indicated that bioactive glass, its association with autogenous bone graft in a 1:1 ratio, and autogenous bone graft alone have similar resorption.

Key words: maxillary sinus augmentation; bioactive glass; bioactive glass added to autogenous bone graft; bone graft resorption; trabecular bone microarchitecture.

Accepted for publication 29 November 2017

0901-5027/000001+07

The aim of maxillary sinus augmentation is to restore the ideal bone height, enabling dental implant placement[1]. Some studies have proposed the use of bone substitutes to contribute to the maintenance of bone volume and new bone formation in the maxillary sinus[2–7]. The autogenous bone graft is still the most predictable and favourable for bone grafting because of its osteogenic, osteoinductive, and osteoconductive properties[8,9]. However, the use of this graft implies the need for another surgical site, which can increase morbidity for the patient; therefore, it should be chosen for specific cases[10,11].

Other bone substitutes have been used to augment the maxillary sinus height, including allogeneic grafts, alloplastic grafts, and combinations of these with autogenous bone grafts[1,12]. The ideal bone substitute has to work as a template for bone formation in three dimensions and should have certain properties: be biocompatible, promote osteogenic cell attachment, bond to the host bone without intermediary fibrous tissue, have an interconnected porous structure, be degradable, share the mechanical load with the host bone, and be sterilizable[13]. Furthermore, it is important that the new bone formed is strong enough to anchor the dental implants and support the masticatory forces[14].

One of these biomaterials is bioactive glass, a bioactive ceramic with osteoconductive properties that was developed by Professor Larry Hench in 1969 and approved by the United States Food and Drug Administration in 1996. It has all of the necessary characteristics except porosity[13,15]. A commercial form of this material is Biogran (Biomet 3i, Palm Beach Gardens, Florida, USA), a resorbable bioactive ceramic of 300–355 μm particle size and composed of silicon dioxide (SiO_2; 45%), calcium oxide (CaO; 24.5%), sodium oxide (NaO_2; 24.5%), and phosphorous pentoxide (P_2O_5; 6%)[16,17].

It is important to evaluate the dimensional changes in bone grafts placed in the maxillary sinus, because shrinkage occurs during graft healing. Studies analysing bone graft remodelling after sinus floor augmentation with simultaneous implant placement have been performed previously[18–20]. However, when it is not possible to install the dental implants simultaneously, cone beam computed tomography (CBCT) represents the best method for evaluating volumetric bone changes[21]. This examination offers three-dimensional (3D) visualization, allowing real volumetric measurements to be obtained during the bone healing phase[22].

The new bone formation in the maxillary sinus can be analysed using histological measurements obtained from two-dimensional (2D) sections[23]. Nevertheless, the 3D assessment of bone biopsies can also provide information on the trabecular bone structure and its microarchitecture[24]. One means of analysing these parameters is micro-computed tomography (micro-CT), which is considered the 'gold standard' method because it is non-destructive and provides high-resolution images of the bone structure[25].

The aim of this study was to evaluate bioactive glass (Biogran) used alone or in combination with autogenous bone graft in a 1:1 ratio, compared to autogenous bone graft alone in maxillary sinus augmentation. The analyses were conducted through the assessment of volumetric bone changes on CBCT evaluation and the trabecular bone microarchitecture on micro-CT evaluation.

The study hypotheses were: (1) H0 (null hypothesis), that bioactive glass will show less resorption than autogenous bone graft; (2) H1 (alternative hypothesis 1), that the addition of 50% of autogenous bone graft to bioactive glass will improve the trabecular bone microarchitecture.

Materials and methods

Patients with an edentulous posterior maxilla were invited to participate in this study. The number of samples required in each group was determined by statistical power test, performed at the website http://www.lee.dante.br and based on the results of a previous study[26]. The difference in the average to be detected was 11.9%, with a standard deviation of 9.57, at the significance level of 5% and with 80% power in a one-tailed hypothesis test.

The inclusion criteria encompassed patients with a maxillary sinus bone height (pristine bone) of less than 5 mm, who required bone grafting to allow dental implant placement. Patients were excluded if they presented any uncontrolled systemic diseases, periodontitis, any pathologies in the maxillary sinus, were smokers, or had received radiation treatment to the face, head, or neck.

CBCT scans were performed to evaluate all maxillary sinuses prior to treatment. The autogenous bone grafts were harvested from the mandibular symphysis or retromolar region. Anatomical structures next to these areas, such as tooth roots and the mandibular canal, were identified on CBCT scans.

Twenty-nine patients (35 maxillary sinuses) met the eligibility criteria and were invited to participate in this research. These patients were divided into three groups: group 1 comprised 11 patients (13 maxillary sinuses) grafted with bioactive glass alone (Biogran); group 2 comprised eight patients (10 maxillary sinuses) grafted with bioactive glass mixed with autogenous bone graft in a 1:1 ratio; group 3 comprised 10 patients (12 maxillary sinuses) grafted with autogenous bone graft alone (control group). There was no association between the side of the maxillary sinus and the grafting material used. Randomization was performed by drawing lots to decide which sites would be grafted with each material. This was done by a clinical assistant, who was not involved in the surgeries or in the data evaluation.

Surgical procedures

This prospective study was approved by the institutional ethics committee and was performed at Araçatuba Dental School from March 2014 to July 2016. The autogenous bone block grafts were harvested under local anaesthesia (lidocaine 2% with epinephrine 1:100,000; DFL, Taquara, RJ, Brazil) and milled with a bone crusher (Neodent, Curitiba, PR, Brazil), as recommended by Pereira et al.[27]. The maxillary sinus bone augmentation was performed in accordance with the surgical procedure of Boyne and James[28]. Postoperatively, 500 mg of amoxicillin (EMS, São Paulo, SP, Brazil) three time per day was prescribed to reduce the chance of infection, as well as 500 mg paracetamol (EMS, São Paulo, SP, Brazil) four times per day for the management of pain. One patient in group 2 presented a maxillary sinus infection and was excluded from the study, and one patient in group 1 did not return for follow-up; thus, the final analysis included 12 maxillary sinuses for group 1, nine for group 2, and 12 for group 3.

Evaluation of the volumetric change

CBCT scans were obtained to determine the bone graft volume. The first scan was performed 15 days after the maxillary bone augmentation procedure, determining the initial volume (T1). The second scan was performed 6 months after the procedure (after 6 months of bone graft healing), determining the final volume

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