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# Implant stability after sinus floor augmentation with deproteinized bovine bone mineral particles of different sizes: a prospective, randomized and controlled split-mouth clinical trial

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*Abstract.* The aim of this study was to compare implant stability after maxillary sinus floor augmentation using small- or large-sized particles of Bio-Oss. Ten partially edentulous patients requiring bilateral maxillary sinus floor augmentation were enrolled. The subjects were assigned randomly to one of two experimental groups: maxillary sinus was filled with 0.25–1 mm particle size (small particles) and the contralateral side was filled with 1–2 mm particle size (large particles). After 8 months, a total of 25 implants were placed in the two maxillary sinuses. Primary implant stability was measured immediately after implant placement (T0) using a torque controller and resonance frequency analysis (RFA). Six months after implant placement (T1), the implant stability was measured again. There were no postoperative complications in either particle size group, and the success rate for implant survival was 100%. All implants showed good primary stability as evidenced by high torque for the implant insertion in both groups. RFA revealed high ISQ values for all implants installed in both groups at T0 and T1. These results indicate that the size of the Bio-Oss particles (small and large) did not influence implant stability in the maxillary sinus. Indeed, small and large particles of Bio-Oss presented optimal properties, supporting their possible use as osteoconductive grafts.

Key words: bone graft; sinus floor augmentation; Bio-Oss; dental implants; maxillary sinus.

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The use of osseointegrated implants to restore function and patient aesthetics provides predictable treatment outcomes, and these implants have a high survival rate.[1–3] However, crestal bone resorption after tooth extraction and/or pneumatization of the maxillary sinus leads to insufficient vertical and horizontal bone dimensions for the rehabilitation of posterior missing teeth with osseointegrated implants.[4] Sinus floor augmentation with autogenous bone or bone substitutes is a surgical approach that allows the installation of implants of a suitable length: the sinus membrane is elevated, enabling the interposition of bone graft materials before or simultaneously with implant placement, increasing the bone height in the posterior edentulous maxilla for long-term implant stability.[5]

A variety of bone substitutes and autogenous bone grafts are used to fill the newly formed space in the maxillary sinus.[4–7] The autogenous bone graft still represents the gold standard for grafting materials because of its osteogenic, osteoconductive, and osteoinductive proprieties. However, it presents some drawbacks mainly related to the high morbidity associated with graft harvesting, limited availability, and the need for two or more surgical sites in the case of bilateral sinus augmentation.[8] Consequently, bone materials that could replace the use of autogenous bone are required. Autogenous bone has gradually been associated with and/or substituted by different types of biomaterial, with the aim of increasing patient acceptance and minimizing patient morbidity. These materials include deproteinized bovine bone mineral (DBBM), human deproteinized bone matrix, tricalcium phosphate, hydroxyapatite, and bioactive glass particles.[6,7]

DBBM is a material widely used for sinus floor augmentation due to its similarity to human bone, predictable treatment outcomes, and promising rate of bone formation.[6] The deproteinization process results in the removal of protein and organic components, thus preventing immunological rejection of the DBBM after placement; the remaining material is mainly hydroxyapatite, and this acts as a scaffold for new bone formation, characterizing it as an osteoconductive material.[6] Several human studies reported in the literature have shown the use of DBBM for maxillary sinus floor augmentation to be histologically associated with active bone neoformation.[9–14] Previous studies have also recommended a healing period of 8 months for this type of material when used as the only grafting material in the maxillary sinus.[9,15,16] Optimal outcomes in terms of implant survival have been demonstrated for implants placed in the maxillary sinus filled with DBBM, and this material can be considered a safe and predictable graft material for sinus floor augmentation.[17] However, only a few studies have compared different sizes of DBBM for sinus floor augmentation,[4,18] and no study appears to have used resonance frequency analysis (RFA) to evaluate implant stability following the use of different particle sizes of DBBM.

RFA is a commonly used method to evaluate implant osseointegration and is indicative of treatment success. This is a non-invasive method of measuring dental implant stability that can be used for routine periodical evaluations. The implant stability quotient (ISQ) is calculated. This has a value that ranges between 0 and 100, where a high ISQ value indicates greater stability and a low value indicates a reduced integration between the implant and the surrounding bone. This measurement is achieved with the RFA apparatus and the technique has been designed to reflect the bone–implant interface. Estimates of implant stability using RFA are highly correlated with maximum insertion torque.[19]

The aim of this prospective, randomized and controlled split-mouth clinical trial was to compare the stability of implants placed in the maxillary sinus after sinus floor augmentation using small-sized (0.25–1 mm) and large-sized (1–2 mm) particles of Bio-Oss, by means of RFA, immediately after implant placement (T0) and at 6 months (T1) after implant installation. The working hypothesis was that there would be a statistically significant difference in implant stability, relative to the parameters examined, between augmentations using the large particles of Bio-Oss and those using the small particles, due to the expected larger spaces between the granules with the larger particles; these spaces could favour the formation of more bone between the DBBM particles when compared to the small particles.

## Materials and methods

This prospective, randomized and controlled split-mouth clinical trial was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement.[20] The protocol was approved by the institutional ethics committee on human research before patient enrolment. Each subject was fully informed about the treatment and its implications, and written informed consent was obtained from all patients prior to the commencement of treatment.

### Patient characteristics

A total of 10 partially edentulous patients presenting to the implantology department were enrolled in this study; six were male and four were female, and they ranged in age from 30 to 65 years (average age 48.34 years). For inclusion in the study, the patient had to require bilateral maxillary sinus floor augmentation and have a residual alveolar bone crest height of 2–4 mm (based on panoramic images), for implant placement in a two-stage approach. Patients were excluded if they had a compromised general health condition or any condition known to modify bone metabolism that would primarily affect bone and soft tissue healing, including chemotherapy and uncontrolled diabetes.[21] Smokers and alcohol and drug abusers, and any subject suffering from any pathology in the maxillary sinus, were also excluded from the study.

The patients included in this study were assigned randomly (by a random table created by panoramic radiography before the surgical procedures) to two experimental groups to be grafted with two different particle sizes of DBBM (Bio-Oss; Geistlich Pharma AG, Wolhusen, Switzerland). One maxillary sinus was filled with small particles (particle size 0.25–1 mm) and the contralateral side with large particles (particle size 1–2 mm).

### Maxillary sinus floor augmentation procedure

Prior to the sinus lifting surgery, conventional panoramic radiographs were obtained to evaluate the maxillary sinus and the residual vertical bone height. The procedure was performed under local anaesthesia (mepivacaine 2% and epinephrine 1:100,000; DFL, Rio de Janeiro, RJ, Brazil). A crestal incision was made in the maxillary edentulous area, followed by two vertical incisions extending both mesial and distal to the lateral sinus wall, as described previously.[5] The mucoperiosteal flap was detached to fully expose the maxillary lateral sinus wall. A lateral window approach was accomplished according to the technique first described by Boyne and James.[22] Briefly, an oval window was created, the cortical bone wall was detached, and the Schneiderian membrane was gently elevated with the aid of special curettes (Hu-Friedy, Chicago, IL, USA). Small and large particles of Bio-Oss were inserted

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