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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

into the respective sinus cavities and a resorbable collagen membrane (Bio-Gide; Geistlich Pharma AG) was applied to cover the entire obturated lateral window, as per the protocol established by Wallace and Froum.[23]

After surgery, all patients received postoperative instructions for good oral hygiene control and were prescribed oral antibiotics (amoxicillin, 500 mg three times a day for a week) and an oral anti-inflammatory (nimesulide, 100 mg twice a day for 5 days). They were also advised to rinse their mouth with chlorhexidine (0.2%) for 14 days. The sutures were removed 7 days after the surgical procedure, and the area was not subjected to any direct loading during the entire bone regeneration phase. All patients were checked every month to verify the healing process. Any alteration during the postoperative follow-up was recorded.

Implant installation

Eight months after the sinus floor augmentation procedure, dental implants were installed in both maxillary sinuses. Under local anaesthesia (mepivacaine 2% and epinephrine 1:100,000; DFL), a full thickness flap was raised to expose the alveolar bone, and the receptor area was prepared according to the manufacturer's protocol (Conexão Sistemas de Prótese Ltda, Aruja, Sao Paulo, Brazil). Twenty-five double acid-etched, commercially available implants (MasterPorous; Conexão Sistemas de Prótese Ltda) with an external tapered connection were placed by the same experienced surgeon.

Thirteen implants were placed in the maxillary sinus filled with small particles of Bio-Oss and 12 implants were placed in the sinus filled with large particles of Bio-Oss. All implants had the same diameter (3.75 mm), and the implant length ranged from 8.5 mm to 13.0 mm. Immediately after implant placement (T0), the insertion torque of each implant was recorded using a torque controller (Conexão Sistemas de Prótese Ltda) and the implant stability was recorded using a RFA device. Subsequently, healing caps were installed and the flaps were repositioned and sutured. Patients received oral hygiene instructions and postoperative medication (amoxicillin, 500 mg three times a day for a week; nimesulide, 100 mg twice a day for 5 days; sodium dipyrone 500 mg four times a day for 3 days, in the case of pain). Six months after implant placement (T1), transepithelial healing abutments were installed and the implant stability was again recorded, as described below.

Follow-up control

Patients were evaluated immediately after implant installation (T0) and at 6 months after implant placement (T1). Implant survival was defined according to Buser et al.,[24] and the following parameters were recorded: (1) absence of pain in the receptor area, (2) absence of peri-implant suppuration or infection, (3) lack of implant mobility, (4) absence of sulcus bleeding, and (5) lack of peri-implant radiolucency.

Implant stability quotient (ISQ)

The implant stability coefficient, i.e. RFA, was measured with a RFA device (Osstell; Integration Diagnostics, Gothenburg, Sweden). SmartPegs were used to measure the implant stability at T0 and T1. The RFA device determines the resonance frequency of a peg, which can be attached to the implant with the aid of a cylindrical holder.[19,25] The Osstell apparatus makes contact-free measurements over a range of frequencies by exciting the SmartPeg, which starts to vibrate when the highest and lowest resonance frequencies occur. The measurements were performed in the mesiodistal, distomesial, buccal-lingual, and lingual-buccal regions and the mean values were used, as described previously.[19] The ISQ value, displayed on the screen of the analyzer, ranges between 1 and 100; a high ISQ value indicates great stability and a low value indicates a reduced integration between the implant and the surrounding bone. The average values obtained were recorded in a spreadsheet. If unstable osseointegration is present, the vibrations will be high and a low ISQ value will be measured.[19] All ISQ measurements were performed in a standardized manner by one experienced, blinded, and calibrated examiner, who was masked to the treatment protocol.

Radiographic examination

To evaluate the effect of bone tissue and implant length on stability at T0 and T1, the length of each implant (in millimetres) fixed in the grafted area (intrasinus bone graft) and fixed in the pristine alveolar bone (non-grafted sites) was measured. For this evaluation, panoramic radiographs were taken after implant placement. Digital radiographs were imported into image analysis software (UTHSCSA ImageTool version 3.0) and measurements were performed in a standardized manner by one blinded and calibrated examiner, who was masked to the original treatment protocol. For software calibration, the known sizes of the implants were used to correct image distortion. Errors in the radiographic measurements were evaluated per patient by means of duplicate recordings of one randomly selected implant. After image acquisition, one randomly selected implant was measured twice and the mean and standard deviation measurement recorded in a spreadsheet. The measurements were repeated for all patients with a 1-day interval between analyses. The highest level of the pristine bone and the length of the implant that lay in the bone were then calculated. The length values (%) of each implant in contact with the pristine bone and in contact with the intrasinus bone graft were correlated with the ISQ values obtained, in order to determine the role of bone conditions in the primary and biological stability of the implants. The ISQ values at the two time points evaluated were also correlated with the implant length (in millimetres) in order to determine whether its size is capable of interfering in the primary and biological stability of the implants.

Statistical analysis

GraphPad Prism version 6.0 software (GraphPad Software, Inc., La Jolla, CA, USA) was used for the statistical analysis and visualization of data. All data were expressed as the mean ± the standard error of the mean (SEM). The intra-examiner reproducibility with consideration to the ISQ and radiographic measurements was assessed at baseline. The analyses were repeated for five patients with a 1-h interval between examinations, and the data were submitted to the Pearson correlation test. After testing for a normal distribution (Kolmogorov–Smirnov test), differences were analyzed by Student *t*-test for the insertion torque, ISQ values, and radiographic measurements. In addition, correlations between the ISQ and insertion torque values, between the percentage of implant length installed in pristine bone and ISQ values, and between the implant length (in millimetres) and ISQ values at T0 and T1 were investigated for the two groups using Pearson's rank correlation coefficient. A further non-parametric model (linear regression) was used to explore the association between ISQ values and any single variable of interest. Differences were considered significant at $P < 0.05$.

Results

Patient characteristics

Maxillary sinus floor augmentation was performed bilaterally in 10 participants. One side, selected randomly, was filled with small particles of Bio-Oss and the contralateral side was filled with large particles. Implants were placed after a minimum period of 8 months. After the procedure, during the 240-day healing time, the patients did not wear any provisional removable partial denture or fixed prosthesis. After this healing time, 25 implants were placed; 12 were installed in the maxillary sinus filled with large particles and the other 13 in the contralateral side. None of the implants inserted was lost during the postoperative period. Peri-implant infection, implant mobility, sulcus bleeding, and peri-implant radiolucency were not observed in any of the patients included in this study. No perforations of the maxillary sinus membrane were noted.

Primary implant stability

The insertion torque of each implant was recorded using a torque controller immediately after implant placement. All implants installed in the maxillary sinus presented high insertion torque values, suggesting that all implants had great primary stability. Comparing the insertion torque at T0 between sites with small particles and large particles of DBBM, no statistically significant difference was found ($P > 0.05$): small particles 37.92 ± 12.33 N·cm and large particles 35.0 ± 9.77 N·cm (Fig. 1). The correlation between ISQ values and primary implant stability (insertion torque values) was not significant for small particles ($P = 0.09$) or large particles ($P = 0.45$) (Fig. 2).

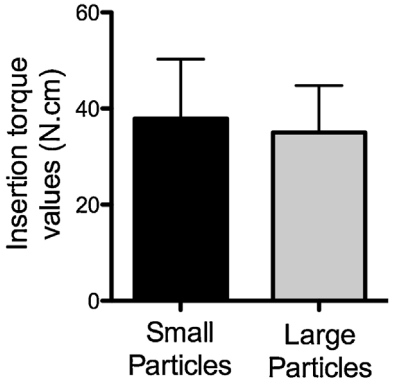

Fig. 1. Insertion torque values (N cm) obtained for small and large particle sizes of Bio-Oss immediately after implant placement; no statistical difference was found between the sizes ($P > 0.05$).

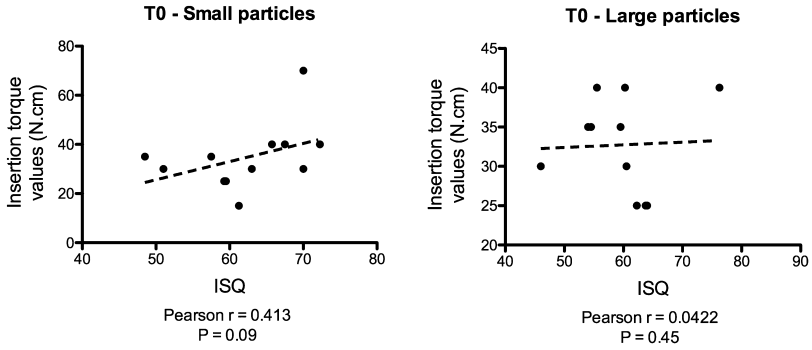

Fig. 2. Correlation between the implant stability quotient (ISQ) and insertion torque values (N cm) at T0. The correlation was assessed using Pearson's correlation coefficient. No statistically positive correlation was found between the ISQ and the insertion torque values for either small particle sizes ($P = 0.09$) or large particle sizes of deproteinized bovine bone mineral ($P = 0.45$).

ISQ analysis

The intra-examiner reproducibility for the ISQ analysis was $r = 0.937$. RFA was performed at T0 (immediately after implant placement) and at T1 (6 months after implant placement) for each group. All implants installed in both groups (small and large particles) demonstrated high RFA values at T0 and T1. No statistically significant difference was found between small particles at T0 (62.9 ± 6.8) and T1 (63.5 ± 5.4) and large particles at T0 (59.7 ± 7.6) and T1 (62.1 ± 7.4) (Fig. 3).

Radiographic measurements

The intra-examiner reproducibility for ISQ analysis was $r = 0.918$. The length of each implant (in millimetres) fixed in the grafted area (intrasinus bone graft) and fixed in the pristine alveolar bone (non-grafted site) was measured. No statistically significant differences were found between the implant lengths inserted in the pristine alveolar bone (3.7 ± 0.9 mm and 2.3 ± 0.5 mm for small and large particle sizes, respectively) and implant lengths inserted in the intrasinus bone graft (7.98 ± 1 mm and 9.75 ± 0.7 mm for small and large particle sizes, respectively), as evidenced in Fig. 4. At least two-thirds of the implant length was inserted into the bone graft material placed in the maxillary sinus for the majority of the implants installed. No correlation was found between ISQ values and the percentage of the implant length fixed to pristine bone between small and large particles of graft material (Fig. 5). At implant placement (T0), a statistically significant positive correlation was found between ISQ values and implant length ($P = 0.0142$) for small particle sizes of DBBM. No statistically significant correlations were found at T1 for either small ($P = 0.0567$) or large particle sizes ($P = 0.4881$) (Fig. 6).

Discussion

The aim of this prospective clinical study was primarily to compare implant stability after maxillary sinus floor augmentation filled with small-sized (0.25–1 mm) or large-sized (1–2 mm) particles of Bio-Oss immediately after implant placement (T0) and at 6 months after implant installation (T1). This study compared the different particle sizes of Bio-Oss for sinus floor augmentation by means of RFA. There were no postoperative complications

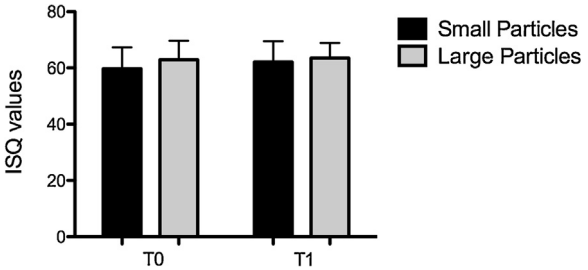

Fig. 3. Implant stability quotient (ISQ) values obtained for small and large particle sizes of deproteinized bovine bone mineral graft immediately after implant placement (T0) and at 6 months after implant installation (T1); no statistically significant differences were found between the groups ($P > 0.05$).

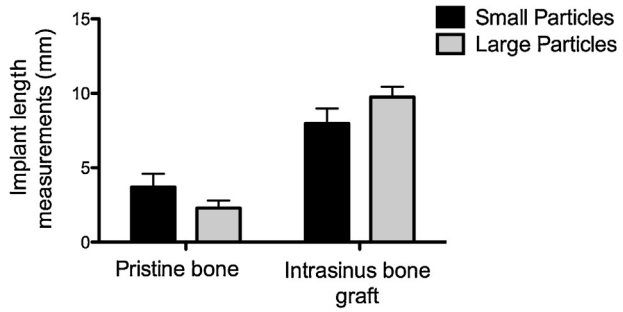

Fig. 4. Implant length measurements (in millimetres) performed on panoramic radiographs of implants fixed in pristine alveolar bone (non-grafted bone) and fixed in the grafted area (intrasinus bone graft). No difference was found between the two particle size groups for either the non-grafted area or the grafted area ($P > 0.05$). At least two-thirds of the implant length was installed in the grafted area.

in either particle size group, and the success rate for implant survival was 100%. All implants showed great primary stability as evidenced by high torque values for implant insertion in both groups. The RFA revealed high ISQ values for all implants installed in both groups at T0 and T1, but with no statistically significant difference between them. No correlations were found between ISQ and primary implant stability, or between ISQ and the percentage of the implant length fixed to pristine bone between the small and large particles of graft material. At implant placement (T0), a statistically significant positive correlation was found between ISQ values and implant length for small particle sizes of DBBM.

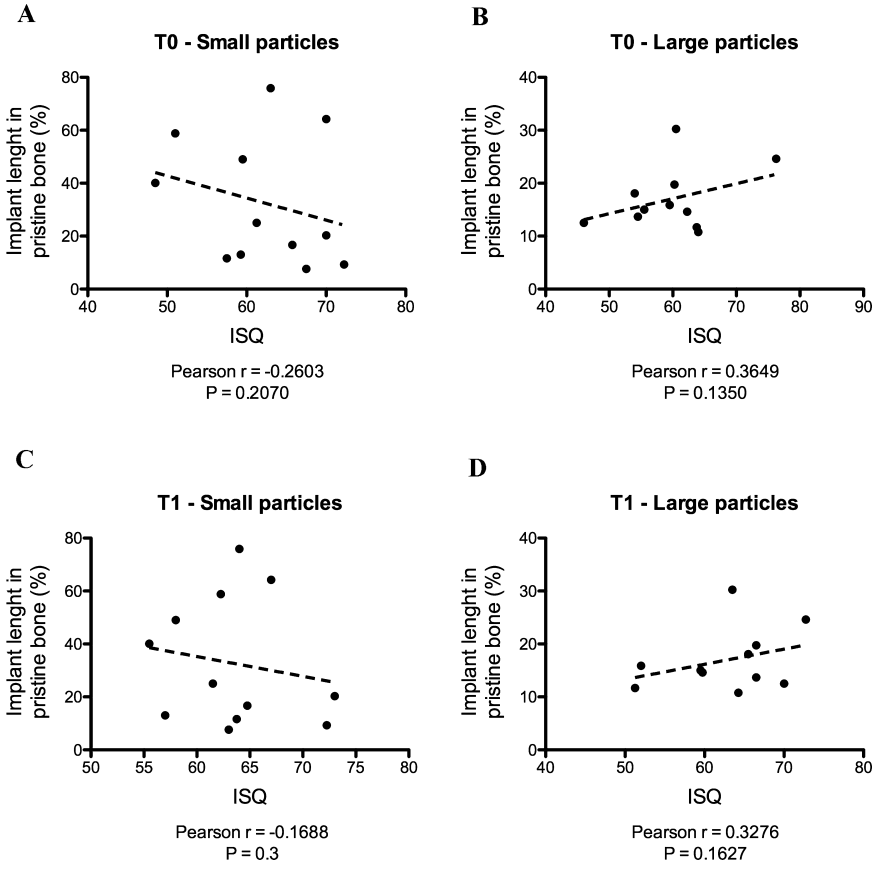

Fig. 5. Correlation between implant stability quotient (ISQ) values and the percentage of implant length installed in the pristine alveolar bone. The correlation was assessed using Pearson's correlation coefficient. No statistically significant correlation was found between groups and periods. Immediately after implant placement: (A) small particles, (B) large particles. After 6-months of follow-up: (C) small particles, (D) large particles.

Bio-Oss (Geistlich Pharma AB) is a low-resorbable DBBM, physically and chemically very similar to human bone, presenting 75–80% porosity, in the form of cortical granules (approximately 10 μm) and a large-mesh interconnecting system acting as a scaffold that allows angiogenesis, osteoblast cell migration, and consequently the formation of new bone.[26] It is commercially available in two different particle sizes of 0.25–1 mm and 1–2 mm, and is considered one of the preferred DBBM graft materials for maxillary sinus floor augmentation.[27] Although Bio-Oss, the most popular DBBM material, has often been utilized as a bone substitute, few studies have addressed the effect of the different particle sizes in sinus floor augmentation.[4,18] Furthermore, there appear to be no studies reported in the literature that have utilized RFA to measure implant stability in the sinus floor augmented with two different particle sizes of Bio-Oss.

To study the progression of implant stability, RFA was performed in the present study immediately after implant placement and at 6 months after implant installation through measurement of the ISQ as a function of stiffness of the bone–implant interface.[28] The ISQ value is influenced by the firmness of the fixation, degree of osseointegration, geometry of the implant (length and width), and hardness of the bone.[19] Previous studies have shown that ISQ values ranging from 57 to 82 (mean value 67) represent great implant stability and a complete process of implant osseointegration.[19,29] In the present study, all implants evaluated presented ISQ values of around 60 or higher (Fig. 3) at T0 and T1, demonstrating optimal implant stability for both groups, with no statistically significant difference between them. This result demonstrates that both particle sizes of Bio-Oss present optimal osteoconductive properties, supporting their possible use as the sole graft material for maxillary sinus floor augmentation. The present data suggest that a site undergoing sinus augmentation with the technique described can offer a satisfactory environment for great primary implant stability, with appropriate maturation of the bone graft for both particle sizes of DBBM.

A previous study evaluated the primary stability by means of RFA of 80 implants installed in 14 patients in sites that had undergone sinus floor augmentation filled with Bio-Oss (63 implants) and in non-grafted sites (17 implants).[30] The authors concluded that the grafted sites demonstrated higher RFA values and positive

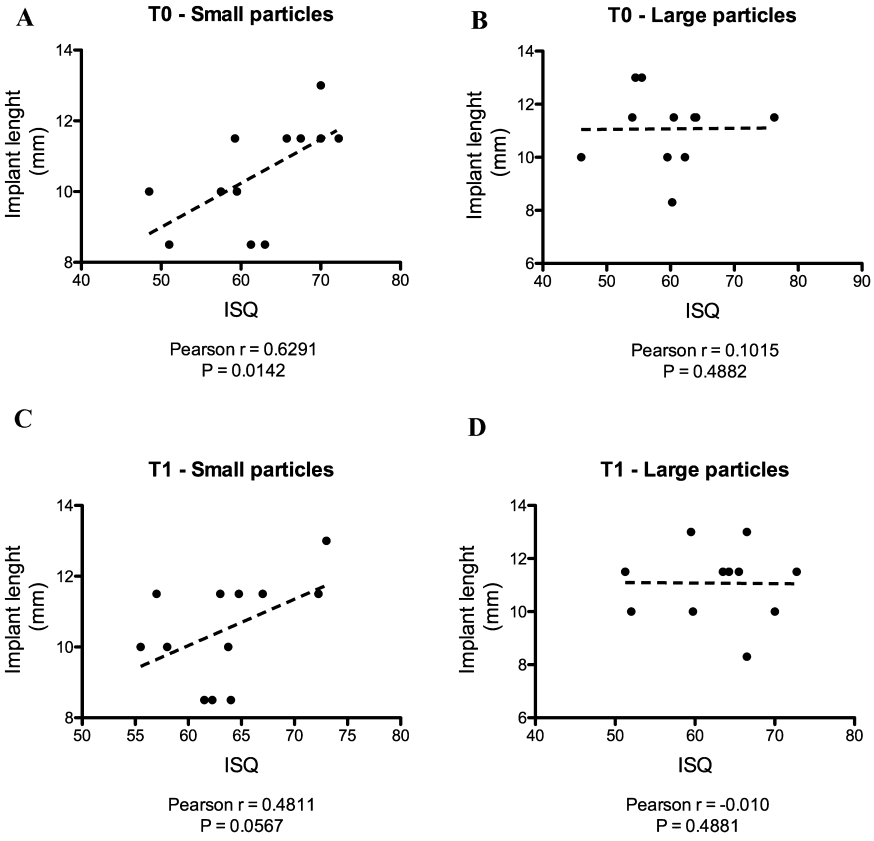

Fig. 6. Correlation between implant stability quotient (ISQ) values and the length (in millimetres) of the implants installed. The correlation was performed using Pearson's correlation coefficient. A statistically positive correlation was found between the ISQ values and implant length for small particle size deproteinized bovine bone mineral at T0. No positive correlation was found at T1 for either group. Immediately after implant placement: (A) small particles, (B) large particles. After 6-months of follow-up: (C) small particles, (D) large particles.

correlations between ISQ and implant diameter, implant length, and diameter of the last bur used compared to the non-grafted site after 6 months of healing. Data from the present study closely resemble those of Degidi et al.,[30] who found high ISQ values for implants installed in grafted sites at 6 months postoperative. However, the present study did not show significant correlations between ISQ values and the percentage of the implant length fixed to pristine bone between the small and large particles of graft material, and this finding could possibly be explained by the similarity between the residual bone and the DBBM graft after 8 months of healing, as reported in previous studies.[9,15,16] Accordingly, Friberg et al. suggested that RFA points to the cervical portion of the implant (crestal third of the implant) as the most important region in determining the mean ISQ value,[31] which could explain the lack of correlation between the percentage of implant length fixed to pristine bone and ISQ values in this study.

Here, the lack of a positive correlation between insertion torque values achieved with the torque controller at T0 and ISQ values plays an important role in the clinical situation. Primary implant stability is the main factor to be measured when immediate implant loading is being considered, since primary stability represents a pivotal factor for bone repair and secondary stability of the implants, which might contribute to better implant osseointegration. According to previous studies, primary stability is related to bone quality and quantity, implant design, and surgical technique.[32,33] The results of this study suggest that primary implant stability could be achieved with RFA instead of using a torque controller, since high ISQ values were found for both groups at T0. In the clinical situation, RFA could provide a more accurate value of implant stability, which might help in the decision regarding immediate provisionalization of the prosthesis. Furthermore, ISQ values could be used to monitor and assess DBBM graft maturation during the post-operative period.

A recent study in humans evaluated the amount of newly formed bone after sinus floor augmentation using small (0.25–1 mm) and large (1–2 mm) particles of DBBM by means of clinical, micro-computed tomography, and histomorphometric analyses.[4] The authors showed that there were no differences between these two particle size preparations in any of the analyses performed and they concluded that both DBBM preparations present satisfactory results. The data from the present study parallel the observations made by Chackartchi et al.[4]: no differences were found for all the analyses, suggesting that Bio-Oss is a viable and safe biomaterial with predictable treatment outcomes, and is a promising material for new bone formation, independent of the particle size. However, a positive correlation was found in this study for ISQ values and implant length (in millimetres) at T0 for small particle sizes of Bio-Oss. This finding closely resembles those of a previous study in which a positive correlation was found between implant length and RFA, and this seems to be an important factor for primary implant stability at least at the time of implant placement (T0).[30]

A recent study by Testori et al. assessed the effect of DBBM particle size on vital bone formation following maxillary sinus floor augmentation in humans.[34] The histomorphometric analysis showed a statistically significant increase in vital bone formation when the larger particle size of DBBM was used (26.77 $\pm$ 9.63%) when compared to the small particle size (18.77 $\pm$ 4.74%). This result would seem to be related to the small sample size of that study when compared to the study by Chackartchi et al.[4] and the present study.

The results of this study disproved the null hypothesis. It was clearly demonstrated that both small and large particle sizes of DBBM presented high insertion torque and high primary implant stability at the time of implant installation and after 6-months of follow-up, without a statistically significant difference between them. Both sizes performed equally well and allowed adequate implant length installation after maxillary sinus floor elevation.

There is a clinical advantage to the fact that implant stability is the same with both small and large particle sizes of DBBM graft following sinus floor augmentation. Vital bone formation around small and large particle sizes seems to be similar when used in the maxillary sinus,[4] or higher with a larger particle size.[34] As the present data are translated to the clinical setting, two factors should be considered before the selection of the DBBM graft particle size. First, the volume of graft material in a 2-g bottle of large

particle Bio-Oss is 7.2 ml. The volume of a 2-g bottle of small particle Bio-Oss is 4.2 ml. It is therefore evident that fewer grams of DBBM will be necessary, and a lower cost realized, to complete a sinus floor augmentation procedure if the large particle size of Bio-Oss is used. Second, the selection of small- or large-sized particles of Bio-Oss is dependent on the personal preference of the clinician, size of the maxillary sinus, residual alveolar bone, number of implants required, sinus anatomy, presence of membrane rupture, and the patient's socio-economic status. It is important to note that the length of the implants fixed in the residual alveolar bone (non-grafted area) in this study was similar in the two groups for small and large particle sizes (3.7 ± 0.9 mm and 2.3 ± 0.5 mm) and thus even with low residual bone present, both particle sizes of Bio-Oss resulted in a high success rate.

In summary, using RFA to measure implant stability in humans after maxillary sinus floor augmentation using two different particle sizes of Bio-Oss, it was found that there is no clinical difference between these two preparations. Moreover, no positive correlation was found between ISQ values and the percentage of implant length fixed in the non-grafted area. Accordingly, both particle sizes present optimal properties, supporting their possible use as osteoconductive grafts when used as the sole grafting material in maxillary sinus floor augmentation. This randomized clinical trial showed that primary implant stability was not influenced by the particle size (small or large) of DBBM.

Funding

None.

Competing interests

None.

Ethical approval

Approval for this study was obtained from the institutional ethics committee on human research (protocol #580.869) before patient enrolment. In addition, written informed consent was obtained from each subject who participated in the study.

Patient consent

Subjects were fully informed about the treatment and implications, and written informed consent was obtained prior to the commencement of treatment.

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