

## Assessment of implants installed in grafted maxillary sinuses after prosthetic rehabilitation

Avaliação de implantes instalados em seios maxilares enxertados após reabilitação protética

Evaluación de implantes instalados en senos maxilares injertados después de rehabilitación protésica

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### Abstract

**Purpose:** To compare the stability and bone loss of implants installed in the maxillary sinus after sinus lift using Bio-oss™ Small and Large, before functional loading (T1) and after it (T2). **Methods:** Ten patients received bone graft in the maxillary sinus in two different granulations: Bio-oss™ Small and Large, with one granulation per sinus. After 8 months, the implants were installed. Prosthesis manufacturing and installation occurred after a six-month. Out of 10 patients, six (13 implants) were selected, with an average age of 53.4 years. The stability was measured with a resonance frequency and all implants installed showed high values in both groups. **Results:** The comparison between times showed a statistical difference with the Bio-oss™ Large particles, in which T1 ( $64.21 \pm 7.41$ ) was lower than T2 ( $69.96 \pm 4.95$ ;  $P=0.003$ ). However, the comparison between the different particle dimensions in the same period didn't show a statistical difference. Regarding marginal bone loss, there wasn't statistical difference between the particle dimensions. There wasn't correlation between stability and marginal bone loss and between the different biomaterial particle dimensions. **Conclusion:** The implants installed in grafted maxillary sinus with both Bio-Oss™ particle dimensions showed similar behavior, allowing implant stability and functional loading.

**Keywords:** Bone grafting; Sinus floor augmentation; Dental implants.

### Resumo

**Objetivo:** Comparar a estabilidade e perda óssea de implantes instalados no seio maxilar após elevação do seio maxilar utilizando Bio-oss™ Small e Large, antes da carga funcional (T1) e após a mesma (T2). **Métodos:** Dez pacientes receberam enxerto ósseo no seio maxilar em duas granulações diferentes: Bio-oss™ Small e Large, com uma granulação por seio. Após 8 meses, os implantes foram instalados. A confecção e instalação da prótese ocorreu após seis meses. De 10 pacientes, seis (13 implantes) foram selecionados, com média de idade de 53,4 anos. A estabilidade foi mensurada por meio da frequência de ressonância e todos os implantes instalados apresentaram valores elevados em ambos grupos. **Resultados:** A comparação entre os tempos mostrou diferença estatística com as partículas Bio-oss™ Large, em que T1 ( $64,21 \pm 7,41$ ) foi menor que T2 ( $69,96 \pm 4,95$ ;  $P=0,003$ ). No entanto, a comparação entre as diferentes dimensões de partículas no mesmo período não mostrou diferença estatística. Em relação à perda óssea marginal, não houve diferença estatística entre as dimensões das partículas. Não houve correlação entre estabilidade e perda óssea marginal e entre as diferentes dimensões das partículas do biomaterial. **Conclusão:** Os implantes

instalados no seio maxilar enxertado com ambas as dimensões de partículas de Bio-Oss™ apresentaram comportamento semelhante, permitindo estabilidade do implante e carga funcional.

**Palavras-chave:** Enxerto ósseo; Levantamento do assoalho do seio maxilar; Implante dentário.

### Resumen

*Propósito:* Comparar la estabilidad y la pérdida ósea de los implantes instalados en el seno maxilar después de la elevación del seno usando Bio-oss™ Small y Large, antes de la carga funcional (T1) y después de ella (T2). *Métodos:* Diez pacientes recibieron injerto óseo en seno maxilar en dos granulaciones diferentes: Bio-oss™ Small y Large, con una granulación por seno. Después de 8 meses, se instalaron los implantes. La fabricación e instalación de prótesis se produjo después de seis meses. De 10 pacientes, se seleccionaron seis (13 implantes), con una edad promedio de 53,4 años. La estabilidad se midió con una frecuencia de resonancia y todos los implantes instalados mostraron valores altos en ambos grupos. *Resultados:* La comparación entre tiempos mostró diferencia estadística con el Bio-oss™ Partículas Grandes, en que T1 ( $64,21 \pm 7,41$ ) fue menor que T2 ( $69,96 \pm 4,95$ ;  $P=0,003$ ). Sin embargo, la comparación entre las diferentes dimensiones de las partículas en el mismo período no mostró una diferencia estadística. En cuanto a la pérdida de hueso marginal, no hubo diferencia estadística entre las dimensiones de las partículas. No hubo correlación entre la estabilidad y la pérdida de hueso marginal y entre las diferentes dimensiones de las partículas del biomaterial. *Conclusión:* Los implantes instalados en seno maxilar injertado con ambas dimensiones de partículas Bio-Oss™ mostraron un comportamiento similar, permitiendo la estabilidad del implante y la carga funcional.

**Palabras clave:** Injerto óseo; Elevación del piso del seno maxilar; Implante dentales.

## 1. Introduction

The absence of teeth promotes bone resorption, which complicates implant installation. The posterior maxillary region is especially critical because of the pneumatization of the maxillary sinus in edentulous patients, resulting in insufficient bone dimensions for implant installation (Scarano et al., 2006). The technique of elevating the maxillary sinus floor membrane associated with the use of biomaterials is the most used method to resolve the deficiencies of bone availability, allowing a satisfactory primary and secondary implant stability with predictable results and high success rates (Dos Anjos et al., 2016; Molon et al., 2019).

The factors that affect implant stability from installation to function include the bone quality of the host area, graft quality, native bone quality, marginal bone progression, bone density, bone hardness, implant design, host tissue preparation, stress direction, load pattern, implant surface, healing time, micromovements, immediate load, implant length, and systemic conditions of the patient. These factors may also change the tissues and the close bone-implant contact (Meijer et al., 1993; Gapski et al., 2003; Romanos et al., 2003; Fanuscu et al., 2004; Waite et al., 2005; Kwon & Kim, 2006; Bornstein et al., 2008; Jung et al., 2009; Degidi et al., 2010; Ingham et al., 2010; Barewal et al., 2012; Gabay et al., 2012; Herrero-Climent et al., 2012; Browaeys et al., 2013; Shen et al., 2015; Wang et al., 2017).

Highlighting graft quality, there is a frequent indication of the xenogeneic graft of bovine origin (DBBM) to procedures of maxillary sinus floor elevation because this material presents osteoconductive characteristics (Hallman et al., 2001; Oliveira et al., 2012), low bone resorption (4.2%) in comparison with the autogenous bone (Shen et al., 2015), mean radiographic bone loss of 0.3 mm over five years (Jung et al., 2009), and high survival and success rates (Oliveira et al., 2012). DBBM has different particle sizes: \* fine granulation (Bio-Oss™ Small-0.25-1 mm; SGP-Geistlich Bio-Oss™) and \* coarse granulation (Bio-Oss™ Large-1-2 mm; LGP-Geistlich Bio-Oss™). A few randomized clinical trials have compared different sizes of DBBM particles for elevating the sinus floor membrane, all with satisfactory results for both particle sizes (Chackartchi et al., 2011; Testori et al., 2013; Dos Anjos et al., 2016; Molon et al., 2019). Anjos et al. (2016) stands out among these studies because the others did not perform assessments after implant installation. (Chackartchi et al., 2011; Molon et al., 2019).

After implants are activated using rehabilitations, they go through a process of adapting to these conditions, which show changes in cervical bone level as a reflex of the exposure of implants to the oral environment. There is also a biomechanical stimulus working on bone tissue remodeling. (Barewal et al., 2012)

Considering the rare studies assessing the stability and marginal bone loss of implants installed in regions previously subjected to maxillary floor elevation with bone regeneration, this prospective, randomized, and controlled split-mouth clinical trial aimed to compare the stability and marginal bone loss of implants installed in maxillary sinuses after elevating the sinus membrane using Bio-Oss™ Small and Large, for six months after implant installation, before functional loading and at 44 months of implant installation after functional loading.

## **2. Methodology**

This a prospective, randomized, and controlled split-mouth trial was approved by the Human Ethics Committee of the UNIARA-(Number 580.869).

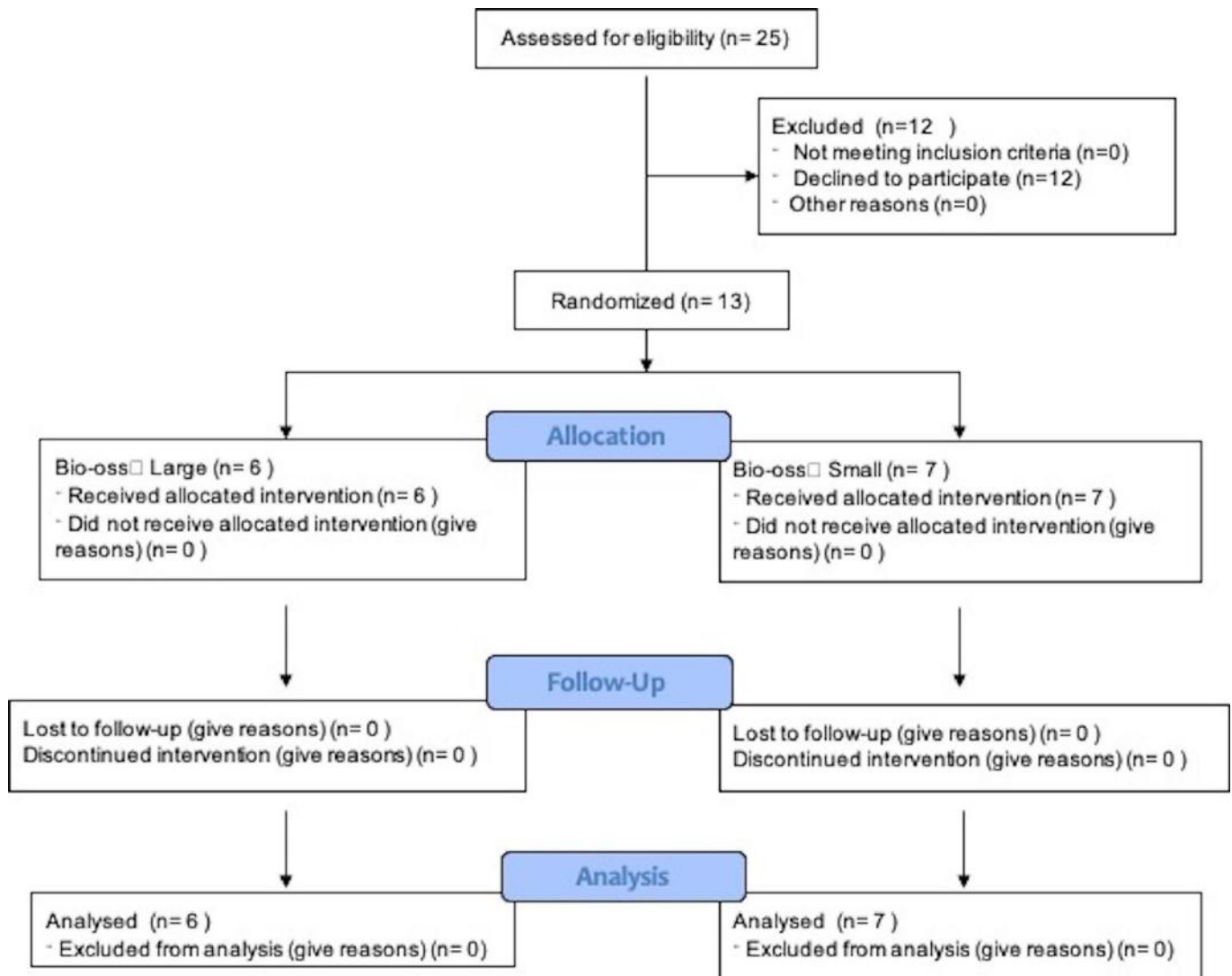
### *Sample*

The study was designed based on previous studies by the team (Dos Anjos et al., 2016; Molon et al.,2019). Ten patients, with a total of 25 implants, partially or completely edentulous, of both sexes, and ages ranging from 20 to 65 years. The patients sought oral rehabilitation using implant-supported prostheses and presented a bilateral deficiency of alveolar bone height in the region of maxillary sinuses, which prevented the immediate implant installation, thus requiring grafting.

The inclusion criteria for selecting the patients were the need for bilateral bone grafting in the region of maxillary sinuses before installing osseointegrated implants. The exclusion criteria were the presence of systemic diseases that could admittedly interfere with the incorporation of grafts and implant osseointegration, smokers, alcoholics, drug users, and the presence of clinical or radiographic signs indicating dentomaxillary lesions that could prevent the graft surgery.

The patients were divided randomly into two experimental groups: \*Small-patients who received, before implant installation, a graft made of a bovine bone mineral matrix with fine granulation(Bio-Oss™ Small-0.25-1 mm; SGP-Geistlich Bio-Oss™); and \*Large-patients who received, before implant installation, a graft made of a bovine bone mineral matrix with coarse granulation(Bio-Oss™ Large-1-2 mm; LGP-Geistlich Bio-Oss™).(Figure 1)

**Figure 1** - Flowchart for exemplification of groups division.



Source: Authors.

### Surgical procedure - Sinus lift

The access and elevation of the maxillary sinus floor membrane and bone grafts were performed after additional and intraoral antiseptics in the surgical field. The anesthetic block of the corresponding area was performed with 2% mepivacaine 1:100,000 epinephrine (DFL, Rio de Janeiro, RJ, Brazil). Next, an incision was made in the bone crest of the edentulous area, as well as two vertical relaxing incisions. Then, the mucoperiosteal detachment and osteotomy of the lateral bone window were performed. After that, the Schneiderian membrane was carefully elevated and the maxillary sinus was filled with either Bio-Oss™ Small or Larger, in the respective maxillary sinus. The lateral access to the sinus wall was occluded by a Geistlich BioGide™ collagen membrane (Wallace & Froum, 2003). The flap was repositioned and sutured with a 5-0 nylon thread.

The patients received postoperative instructions, including the prescription of systemic medications that included antibiotic, anti-inflammatory, and analgesic and topical medication that included 0.12% chlorhexidine digluconate mouthwash.

They were also instructed on the care regarding the maxillary sinus graft surgery. The suture was removed after 15 days and the area operated remained without the influence of a direct load during the entire bone regeneration phase, which lasted eight months.

### Surgical procedure - Implant installation

Eight months after the initial step, the surgical procedure for implant installation was performed. After additional and intraoral antiseptics of the surgical field, local anesthesia was performed similarly to the sinus lift procedure. Next, an incision on the bone crest and mucoperiosteal detachment were performed. The preparation of the surgical bed was standardized following the manufacturer's instructions.

Twenty-five external hexagon cylinder implants were used. They had a prosthetic platform of 4.1 mm of diameter (Conexão Sistemas de Prótese, Arujá, São Paulo, Brazil), 3.75 and 4.0 mm of diameter, and length varying from 8.5 to 13.0 mm. When this phase ended, the suture was performed and instructions about diet, drug prescription, postoperative care, and oral hygiene were provided.

After a six-month interval for osseointegration, the procedures of additional and intraoral antiseptics in the surgical field and anesthesia were performed for the installation of healing abutments on the implants. Next, the fixed prosthesis on the implant was manufactured and installed.

### Follow-up control

The patients were assessed before functional loading - six months after implant installation (T1), and after functional loading - 44 months after implant installation (T2). Implant survival was defined according to Buser et al., and the following parameters were recorded: (1) the absence of pain in the host area, (2) the absence of peri-implant suppuration or infection, (3) a lack of implant mobility, (4) the absence of sulcus bleeding, and (5) a lack of peri-implant radiolucency.

### Implant stability quotient (ISQ)

To assess the integration and stability of implants in the different Bio-Oss™ granulations, after exposing the implants and removing the sealing screw, a Smartpeg (transducer) was coupled to the platform of each implant, and their stability was verified with the Osstell™ (Integration Diagnostics AB, Göteborg, Sweden), which is a non-invasive appliance that allows clinically measuring the stability of an implant by assessing resonance frequency, which is automatically translated by the equipment to an ISQ index ranging from 1 to 100<sup>2</sup>.

The measurements were taken in mesiodistal, distal-mesial, buccolingual, and lingual-buccal directions and a mean per implant was provided at T1 and T2.

### Peri-implant bone level analysis

To measure the bone level in the cervical region, the panoramic radiographs were imported to the Image J software, version 1.51. Next, calibration was performed using the known value of implant length to correlate potential dimensional distortions of panoramic radiographic images.

After calibrating the software, the level of bone contact in the cervical region was measured mesially and distally, at T1 and T2, for both groups. These values were tabulated for posterior statistical assessment.

### Statistical analysis

The ISQ and cervical bone level values were expressed in mean and standard deviation. The data were subjected to the Kolmogorov-Smirnov statistical normality test and, because they were non-parametric data, the Mann-Whitney statistical test was applied. Pearson's correlation coefficient was performed between the ISQ and bone level values at T2.

All statistical tests were assessed at a 5% significance level ( $p < 0.05$ ). The GraphPad Prism software, version 6.0 (GraphPad Software, Inc., La Jolla, California, USA) was used for the statistical analysis and data visualization.

### 3. Results

#### *Clinical information and implant distribution*

Ten patients were subjected to the surgical procedure for lifting the maxillary sinus membrane and, after eight months, the implants were installed, resulting in 25 implants installed. From these, six patients returned for monitoring (with 13 implants) and were included in this study. They were three men and three women with an average age of 53.4 years. Thus, seven implants were installed in the maxillary sinus with Bio-Oss Small™ particles, and six implants were installed in the maxillary sinus with Bio-Oss Large™ particles (Table 1).

All patients in the study had a satisfactory recovery without significant peri-implant changes such as mucositis, peri-implantitis, gingival inflammation, and bleeding, which might interfere with the results.

**Table 1** - Patient demographic data and clinical data related to the implants installed in the maxillary sinus after the augmentation procedure with the different particle sizes of Bio-Oss™; N = 6 patients.

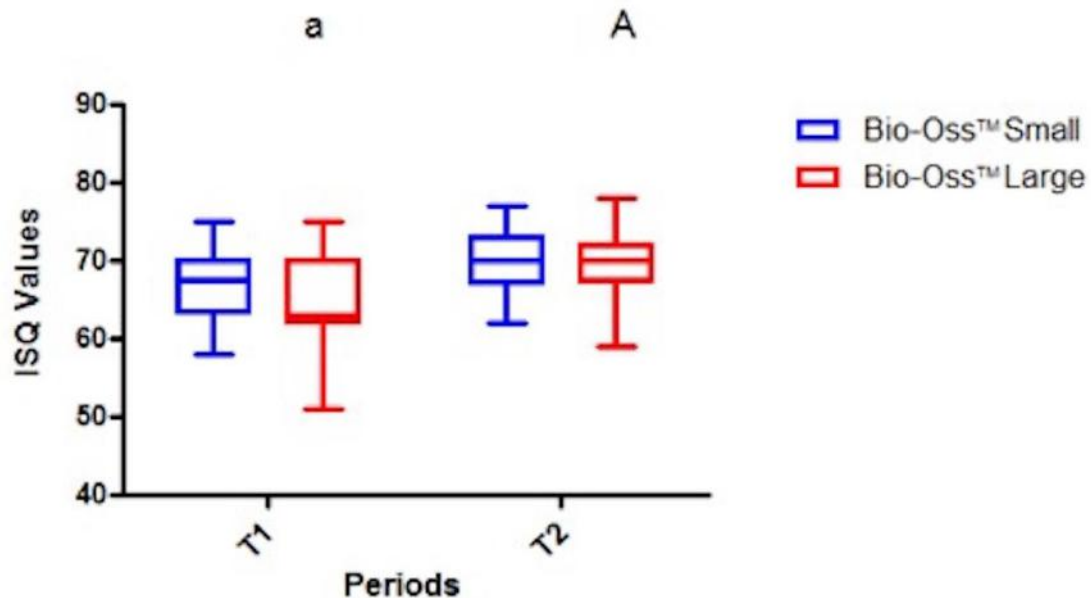
Patient	Sex	Implant Number	Implant Lost	Bio-oss™ Large		Bio-oss™ Small	
				Implant region	Implant length (mm)	Implant region	Implant length (mm)
1	M	2	0	17	3,75x11,5	26	3,75x13,0
2	F	3	0	16	3,75x10,0	26	3,75x8,5
						27	4,0x8,5
3	M	2	0	16	3,75x10	26	3,75x11,5
4	F	2	0	26	3,75x10	16	3,75x10
5	M	2	0	15	3,75x8,5	26	3,75x8,5
6	F	2	0	26	3,75x11,5	16	3,75x11,5

F, female; M, male. Source: Authors.

#### *Stability analysis*

The intra-examiner reproducibility for the ISQ analysis was  $r = 0.937$ . All implants installed in both groups showed high ISQ values at T1 and T2. The comparison between T1 ( $66.95 \pm 5.79$ ) and T2 ( $69.45 \pm 3.86$ ) of the Bio-Oss™ Small particles did not show a statistically significant difference, with  $P = 0.189$ . However, there was a statistical difference with the Bio-Oss™ Large particles with T2 ( $69.96 \pm 4.95$ ) greater than T1 ( $64.21 \pm 7.41$ ) ( $P = 0.003$ ). (Figure 2). The intergroup comparison between the different Bio-Oss™ particle dimensions in the same period did not show a significant statistical difference.

**Figure 2** - Implant stability quotient (ISQ) obtained for Bio-oss™ Small and Bio-oss™ Large particle sizes. Six months after implant installation (T1) and 44 months after implant installation (T2). There was a statistical difference with the Bio-oss™ Large particles with T2 ( $69.96 \pm 4.95$ ) greater than T1 ( $64.21 \pm 7.41$ ) ( $P=0.003$ ;  $a \neq A$ ). The Bio-oss™ Small particles did not present a statistically significant difference at T1 ( $66.67 \pm 6.1$ ) and T2 ( $70.46 \pm 3.36$ ), with  $P=0.189$ . Mann-Whitney at a 5% significance level ( $p < 0.05$ ).



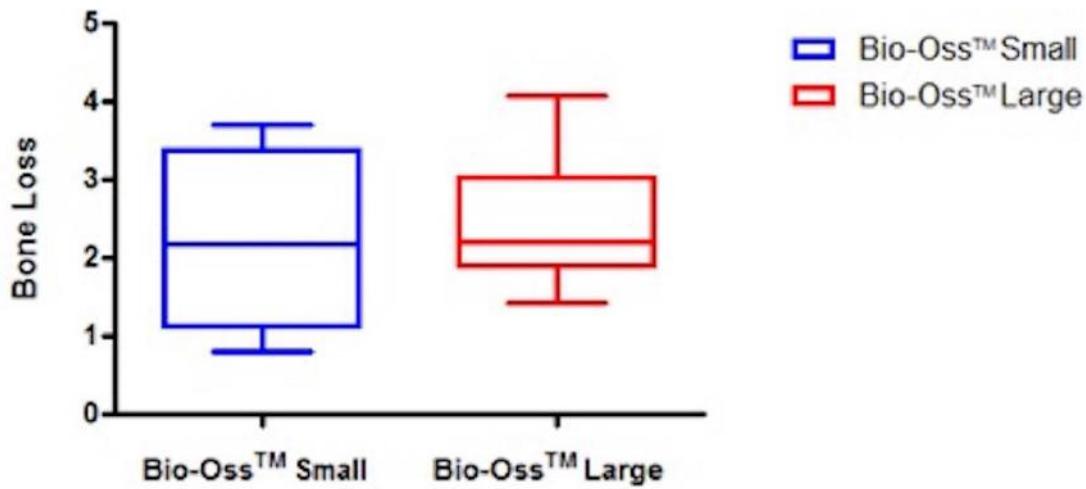
Source: Authors.

#### Peri-implant bone level analysis

The intra-examiner reproducibility for this analysis was  $r=0.918$ . The comparison of marginal bone loss values for Bio-Oss™ Small particles ( $2.22 \pm 1.19$  mm) and Bio-Oss™ Large particles ( $2.44 \pm 0.90$  mm) at T2 didn't show a statistical difference ( $p=0.746$ ). (Figure 3).

Pearson's correlation coefficient test was performed between ISQ and marginal bone loss values, for Bio-Oss™ Small ( $P=0.23$  and  $r=0.76$ ) and Bio-Oss™ Large ( $P=0.88$  and  $r=-0.17$ ), and there wasn't statistically significant correlation between these data.

**Figure 3** - Comparison between the different Bio-Oss™ particle dimensions regarding the marginal bone loss. Mann-Whitney at a 5% significance level ( $p < 0.05$ ).



Source: Authors.

#### 4. Discussion

The lack of studies on implant stability and the behavior of the newly formed bone tissue in bone graft areas led to the search for studies investigating the survival rate, stability, and bone loss of implants installed in the maxillary sinus after elevating the sinus membrane using Bio-Oss™ Small and Large, before functional loading (T1) and after it (T2).

Our results did not show postoperative complications for any particle size and the implant survival rate was 100%. The resonance frequency showed high ISQ values for all implants installed in both groups, at T1 and T2, and there wasn't significant statistical difference between the different Bio-Oss™ particle dimensions. The marginal bone loss for different Bio-Oss™ particles, at T2, didn't show a statistical difference. There wasn't correlation between the ISQ and marginal bone loss and between Bio-Oss™ Small and Large. Thus, our results suggest a skeletal maturation over time and increased implant stability, even after functional loading and with the presence of the saucerization expected after functional loading.

There is a diversity of biomaterials used to lift the maxillary sinus membrane. Autogenous bone is considered the gold standard, mainly due to efficient bone repair, immediate stability, versatility, easy handling, adequate lifespan, providing satisfactory and predictable results, and affordable cost. However, this treatment option requires a two-bed surgical procedure, consequently longer duration and morbidity, and in some cases, it may not obtain sufficient bone volume. (Santos et al., 2013) Thus, alternative treatments have been suggested for sinus lift, highlighting in this article the Bio-Oss, which has a structural similarity to human bone. Its main feature is low resorption, due to the presence of hydroxyapatite in its granules, favoring osteoconduction and reducing its resorption after being placed in the maxillary sinus. (Anjos et al., 2016)

The filling of maxillary sinuses with different Bio-Oss™ granulations has been studied in randomized clinical trials (Oliveira et al., 2012; Testori et al., 2013; Jensen et al., 2015; Anjos et al., 2016; Molon et al., 2019). However, only Anjos et al. (2016) and Jensen et al. (2015) assessed the behavior of implants in grafted sinuses. Anjos et al. (2016) assessed primary stability, resonance frequency, peri-implant bone level, and survival rate of implants installed in maxillary sinuses filled with different DBBM granulations, for six months after implant installation (without prosthetic load), and concluded the size of Bio-Oss™ particles didn't affect implant stability in the maxillary sinus. However, this study did not perform a follow-up after prosthetic loading. Jensen et al., (2015) assessed primary stability and bone-to-implant contact in maxillary sinuses of minipigs



filled with different DBBM granulations for 6 and 12 weeks, and concluded Small and large particle sizes were equally predictable.

Conversely, Testori et al. (2013) compared vital bone formation in maxillary sinuses grafted with different particle dimensions in a histomorphometric study, concluding that there is a greater vital bone formation in maxillary sinuses filled with Bio-Oss™ Large. So far, our study is a pioneer in assessing the follow-up of implant behavior after sinus lift procedures filled with different Bio-Oss™ particles, under prosthetic loading.

After prosthetic loading, the bone around implants goes through a process of saucerization and bone remodeling in all dimension and types of implants, regardless of design, surface type, platform, or prosthetic connection, and this relates to the integration of implants with the gingival epithelium and connective tissue. (Consolaro et al., 2010) Over time, this bone resorption around the implant platform decreases, as long as hygiene and peri-implant conditions are favorable. (Bragger et al., 2004; Consolaro et al., 2010). In our research, implants with different dimensions were used, due to the individualization of the treatment. Research shows that there are no major differences in survival related to implant dimensions after surgical installation, but rather to the prosthetic rehabilitation procedure. The occurrence of failures is mentioned after prosthetic rehabilitation and subjection of the implant to load. Thus, surgical success is not related to the variable implant size, but to adequate prosthetic rehabilitation. (Assaf et al., 2020).

Regarding the biomechanics of implants, after osseointegration, the Bio-Oss™ particles in contact with the titanium surface reduce the mechanical support of implants, presenting only 48.6% of bone-implant contact after five years. (Hass et al., 1998; Iezzi et al., 2008)

Vandamme et al., (2007) have studied whether bone strength under load and mineralization changes the stress-deformation relationship and reduces the risk of microfracture over the years. They concluded that the change in the loading bone strength and mineralization after one year changes the stress-deformation relationship and reduces the risk of microfracture over the years. Thus, mechanical stress may induce a metabolic turnover of the bone based on the changes in osteocyte responses around the implant, resulting in bone remodeling.

Corroborating this, Browaeys et al. (2013) showed an increase in biomechanical stability and, as bone hardness around the implant increases, the stresses are balanced in the surrounding layers, which suggests an increased bone density in this area and consequently increased implant stability. Vandamme et al. (2007) also indicated significantly more osteoid in contact with the implant, which was found for the loaded conditions when compared with no loading. A well-controlled micromovement favorably affected the formation in an implant interface. These results suggest that bone metabolic activity is changed by mechanical stress and that it depends on load conditions. Our results corroborate these researchers, who indicate that functional loading promoted more effective osseointegration and that overload or unfavorable load may contribute to implant failure.

Therefore, there is a loss of integration in this area, which requires caution in selecting the biomaterials used for these reconstructions because they will be highly important for implant longevity. Such biomaterials should offer a satisfactory condition for implant osseointegration and present stability over time, even after functional loading, preventing the loss of implant stability.

To confirm the trends found in this study, further ones should be performed with a larger sample of patients and a longer follow-up.

## 5. Conclusion

Based on the results of this study, it may be concluded that implants installed in maxillary sinuses grafted with both

Bio-Oss™ particle dimensions obtained similar behaviors, allowing implant stability and functional loading.

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