Simultaneous Sinus Membrane Elevation and Dental Implant Placement Without Bone Graft: A 6-Month Follow-Up Study

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Background: Previous studies have shown that simultaneous elevation of the sinus mucosal lining and placement of dental implants without graft materials can be a predictable procedure. Nevertheless, few prospective, controlled, and randomized studies have evaluated this technique. The aim of this prospective, controlled, and randomized clinical study is to evaluate whether sinus membrane elevation and simultaneous placement of dental implants without autogenous bone graft can create sufficient bone support to allow implant success 6 months post-surgically.

Methods: Sinus membrane elevation and simultaneous placement of dental implants were performed bilaterally in 15 patients in a split-mouth design. The sinuses were assigned to two groups: the test group, with simultaneous sinus mucosal lining elevation and placement of dental implants without graft materials; and the control group, with simultaneous sinus mucosal lining elevation and placement of dental implants with intraoral autogenous bone graft. After 6 months of healing, abutments were connected. For each implant, length of implant protrusion into the sinus, resonance frequency analysis, and bone gain were recorded at baseline and 6 months follow-up.

Results: Clinical complications were not observed, except for two postoperative fistulas and suppuration in both groups. Only one implant of the test group was lost, reaching a success rate of 96.4% and 100% for the test and control groups, respectively. After healing, radiographic new peri-implant bone was observed in both groups ranging between 8.3 ± 2.6 and 7.9 ± 3.6 mm for the control and test groups, respectively (P > 0.05). Resonance frequency analysis values were lower for the control group compared to baseline (P < 0.05). However, these values were similar at 6 months (P > 0.05). A significant positive correlation was found between the protruded implant length/bone gain and implant survival/sinusitis (P < 0.0001).

Conclusion: Implants placed simultaneously to sinus membrane elevation without graft material resulted in bone formation over a period of 6 months. *J Periodontol 2011;82:403-412*.

KEY WORDS

Dental implants; guided bone regeneration; sinus elevation.

ental implant therapy has become an excellent and safe treatment modality for a conservative and esthetic alternative to solve partial and total edentulism. When the patient presents deficient alveolar ridges, however, this deficiency could jeopardize the placement of dental implants, mainly in the posterior maxilla, because of alveolar bone loss and increased maxillary sinus pneumatization.

The maxillary sinus grafting procedure has been used for occlusal rehabilitation with prosthetic appliances placed over dental implants in the posterior maxilla. A plethora of researchers ^{1,2} have evaluated different bone-grafting materials inserted in the maxillary sinus cavity. However, studies ³⁻¹⁰ have shown that the simple elevation of the Schneiderian membrane can induce bone formation at the maxillary sinus.

This technique was based on the concept that the lifting of the sinus membrane and the establishment of a compartment with a blood clot could result in new bone around the inserted implants in a similar way that bone-graft materials maintain the augmented space and promote osteogenesis. ⁴ Maxillary sinus augmentation and bone regenerative procedures share similarities and both are coordinated processes involving various biologic factors. ¹¹ Blood supply and angiogenesis play an important role in guided bone formation. ^{12,13} Indeed, the

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blood clot contains many growth factors, such as fibroblast growth factor, transforming growth factor, bone morphogenetic proteins, insulin-like growth factor, platelet-derived growth factor, and vascular endothelial growth factor (VEGF), which are expressed during skeletal development and induced in response to injury. These factors are believed to regulate the repair of bone tissue. ^{14,15} Some of these molecules are also involved in angiogenesis (i.e., fibroblast growth factor, transforming growth factor, and VEGF). ¹⁵ Complementarily, it was shown that cells derived from explants of Schneiderian membrane can express markers of osteoprogenitor cells. ¹⁶

In addition, the contact of the whole blood with the titanium surface generates thrombin.¹⁷ Thrombin that is generated by coagulation cascade not only cleaves fibrinogen but also contributes to activation of osteoblasts via proteinase-activated receptors, which with the platelets may have several effects on bone growth.

Together, these observations show that the simultaneous elevation of sinus membrane and implant placement could be a feasible clinical procedure. However, to date, there are few controlled human studies that have evaluated this technique. Therefore, the aim of this prospective, controlled, randomized study is to evaluate the simultaneous sinus membrane elevation and implant placement without autogenous bone grafts after a 6-month follow-up.

MATERIALS AND METHODS

Patient Population

Between February and August of 2009, 17 subjects (six males and 11 females; mean age: 57.9 years) presenting to the Oral Implantology Clinic, Guarulhos University, Guarulhos, Brazil, with bilateral edentulous area in the posterior maxilla were enrolled in this study. The sinuses, in a split-mouth design, were assigned to two groups: a control group consisting of 17 sinuses, which received simultaneous sinus membrane elevation, autogenous bone graft, and implant placement; and a test group consisting of 17 sinuses, which received simultaneous sinus membrane elevation and implant placement without graft material. A coin toss was used to determine which sinus was assigned as control or test sinus side.

Calculation of the sample size was based on a series of previous studies. 7,18 A difference of 20% or 1 mm in bone reformation (height of new bone formed around implants placed into maxillary sinus), with a common standard deviation of 3 mm between sinus lifting approaches, was set because the present splitmouth study design (with or without graft materials) is not available in the literature. With an α of 0.05 and 1- β of 0.80, a sample of \geq 14 subjects was considered desirable.

The study protocol was explained to each subject and a signed informed consent was obtained. The Institutional Clinical Research Ethics Committee of Guarulhos University approved this study protocol (#152/09).

Exclusion Criteria

Subjects were excluded if they were smokers and if they had a residual sinus floor of <3 mm height; maxillary sinus pathology; a chronic medical disease or condition that would contraindicate dental surgery (e.g., diabetes, uncontrolled hypertension, or history of head and neck radiation); moderate to severe chronic periodontitis in the remaining teeth (i.e., suppuration, bleeding on probing in >30% of the subgingival sites, or any site with probing depth >5 mm); absence of primary stability of the inserted implant in the residual bone; and large sinus membrane perforation (>3 mm) during the mucosal sinus elevation procedure.

Sinus Membrane Elevation

All subjects received oral prophylaxis treatment before surgery. Panoramic radiographs and dental volume tomography|| (DVT) were taken of all patients. All patients received antibiotics (amoxicillin, 875 mg, and sulbactan, 125 mg) and a steroidal anti-inflammatory (dexamethasone, 8 mg) before surgery. The bilateral maxillary sinus augmentation was performed under local anesthesia on the same day. According to the DVT of the patient and anatomic landmarks, a horizontal crestal incision and two vertical incisions extending beyond the mucogingival junction were performed. A full-thickness flap was reflected to expose the maxillary sinus lateral bone wall. Under constant irrigation with sterile saline solution, an osseous window of approximately 15 × 10 mm was demarked, using a round diamond-coated bur. The bone in the center of the window was left attached to the sinus membrane. The Schneiderian membrane was carefully dissected and elevated using specially designed elevators, and the bony wall was gently pushed inside the sinus cavity, forming the roof to the secluded compartment. The sinus membrane was released without any tension to provide an adequate compartment for the autogenous bone graft (control side) or blood clot (test side). Two experienced and trained surgeons (FLB and JAS) performed all surgeries.

Autogenous Bone Graft

Autogenous bone grafts from the symphysis area or the mandibular ramus, depending on the volume of maxillary sinus and availability of the donor area, were obtained via an intraoral incision. A modified 8-mm length and 6-mm diameter trephine bur, under constant

| I-Cat, KaVo Dental, Biberach, Germany.

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sterile saline irrigation, was used to harvest the donor site and provided a milled bone. The bone grafts were stored in saline solution until they were placed inside the sinus of the control group.

Implant Placement

Screw-shaped implants with sand-blasted acid-etched surface, 4-mm diameter and 15- to 18-mm length, were used in this study. Implant sites were marked using a surgical template. The templates were based on the diagnostic waxing with perforations on the longitudinal axis, on the premolar and molar regions, according to ideal position of final implant-supported restorations.

Initial implant stability was optimized by using an under-preparation technique: drilling through the residual bone using a 2-mm twist drill followed by a 2.8- and 3-mm drill was performed, just enough to

enable the initial insertion of the implant in the surgical site.

The autogenous bone, in the control group, was placed at the superior aspect of the sinus against the medial aspect of the grafted compartment created in the sinus cavity. The graft was condensed at each stage. The dental implants were placed to half of their total length. Then, after condensation of the graft, the dental implants were seated in their final positions to avoid empty spaces in the sinus cavity. Any remaining graft material was placed over the exposed implant surfaces. Once the coagulum was observed underneath the elevated sinus mucosa of the test group (without autogenous bone graft), the implants were finally placed (Fig. 1).

After implant placement, a polypropylene membrane was applied to cover the lateral wall osteotomy of the sinuses of the control and test groups. The membrane was adjusted to extend circumferentially 5 to 8 mm over the adjacent alveolar bone, avoiding ingrowths of the soft connective tissue. To allow flap apposition and closure after placement, incisions were made buccally and palatally after membrane placement. Primary wound closure was achieved with horizontal mattress sutures alternated with interrupted sutures to ensure a submerged healing procedure in dental implants.

Postoperative Care

Postoperative care consisted of a 0.12% chlorhexidine mouthrinse twice a day for 14 days without mechanical cleaning at the surgical areas. Anti-inflammatory

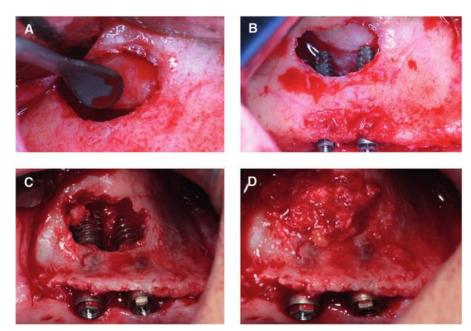


Figure 1.Clinical view of **(A)** lateral bone wall pushed into the sinus cavity, **(B)** simultaneous sinus membrane elevation and implant placement without autogenous bone graft, **(C)** simultaneous sinus membrane elevation and implant placement, and **(D)** autogenous bone graft inserted over the implants.

medication (dexamethasone, 4 mg) was administered once a day and appropriate analgesia (paracetamol, 750 mg) was administered for 3 days after surgery to reduce postoperative swelling and pain. A postoperative antibiotic regimen with amoxicillin and sulbactan was prescribed for 7 days. Nylon sutures were removed 14 days after surgery. The existing upper removable prosthesis was adapted with soft tissue conditioner and was worn after a healing period of 4 weeks. Occlusal adjustments and soft tissue conditioner were performed when necessary. Professional plaque control supplemented this healing phase every month, for 6 months.

Post-surgical events, such as membrane exposure, sinusitis, and paresthesia, were recorded in each recall visit.

Implant Stability and DVT Measurements

Immediately after the implant placement (baseline) and at second-stage surgery (6 months after maxillary sinus augmentation), resonance frequency analysis (RFA)** was used to measure the primary stability of the implant. The transducer (smartpeg type 1) was hand-screwed into the implant body. For every series of RFA measurements, the implant stability quotient (ISQ) values (unit of RFA) were recorded. An ISQ value between 1 and 100 was given where 1 is the

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- Bone heal, INP.
- ** Osstell, Integration Diagnostics, Savadaled, Sweden.

lowest and 100 the highest. A mean of ISQ value was calculated for each implant based on one measurement of each implant, and then of each group. The RFA was measured at baseline and 6 months after therapy.

Three DVT datasets, with a resolution of 0.3-mm voxel, were acquired for every patient at baseline, 14 days, and 6 months after maxillary sinus augmentation procedures. The DVT data were transferred in the DICOM format to specific implant navigation software. †† This format allows a three-dimensional reconstruction of the maxilla. Moreover, this software enables, through segmentation tools, the measurement of bone crest height along transversal sections, corresponding to the longitudinal axis of the implant, before and after maxillary augmentation.

A single, masked, trained examiner (ROD) performed all measurements to evaluate the changes in the height of maxillary sinus floor for each implant. The sinuses were evaluated to assess the radiographic parameters: 1) average of residual sinus floor measured in the initial DVT (at baseline, before implant placement) (A1+A2/2); 2) the height of endosinus bone gain, defined as the mean height of new bone (B1+B2/2); 3) the linear distance of the buccal and palatal sinus wall (C1+C2/2); 4) the length of the implant protruded into the sinus after surgery (D1+D2/2). These measurements were taken and then averaged per implant, and then per group (Fig. 2).

In addition, bone density of grafted areas was evaluated 6 months after the augmentation procedures. Density measurements (Hounsfield unit [HU]) were taken 6 months after surgery to compare the degree of maturation or mineralization of new bone obtained according to each group using the peri-implant bone area in the protruded implant area on the maxillary sinus.

Statistical Analyses

The mean and standard deviation of the value of RFA and radiographic data were calculated for each implant and then for each group. The data for the most protruded implant into the sinus were also measured for both groups. Mann-Whitney U test was used to calculate the differences between groups for the radiographic and RFA variables. Wilcoxon rank test was used to evaluate the intragroup differences between RFA values at baseline and 6 months post-therapy. The χ^2 test was used to calculate the dichotomous variables (i.e., presence or absence of suppuration, membrane exposure, lateral window closure, and implant survival). Spearman correlation was used to evaluate the possible correlations among the clinical and radiographic variables. The unit of analysis was the patient and the level of significance was 0.05.

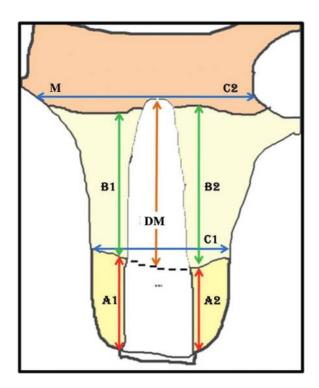


Figure 2. Schematic drawing of an implant inserted into the sinus cavity. To evaluate the changes in height of maxillary sinus floor for each implant, the sinuses were evaluated to assess the radiographic parameters: 1) average of residual sinus floor measured in the initial DVT (AM = A I +A2/2); 2) the mean height of endosinus bone gain, defined as the mean height of new bone (BM = B I +B2/2); 3) the average of linear distance of the buccal and palatal sinus wall (CM = C I +C2/2); and 4) the mean length of the implant protruded into the sinus after surgery (DM = D I +D2/2).

Table I.

Position and Length of Implants Used in the Study

	Position									
Length (mm)	18	17	16	15	14	24	25	26	27	28
Control 18 15		2 3	2 4	2		2	2	l 3	I 3	I
Test 15 18	ı	3 2	5 I	I	I		I	5 1	5 1	I

RESULTS

Maxillary Sinus Augmentation

Fifteen of 17 patients were followed throughout the study period. One patient presented pus inside the maxillary sinus at the time of the surgery, and one

^{††} I-Cat Vision, KaVo Dental.

had a mucosal sinus perforation >5 mm. A total of 30 sinus-lift procedures were performed in 15 patients. Fifty-four implants were placed (Table 1). Sinus mucosal perforations <2 mm were observed in two sinuses, one in each group. These perforations were left without sutures or membranes.

A



Figure 3.Clinical view of test side **(A)** at baseline and **(B)** 6 months after surgery. Note that the lateral window is completely closed.

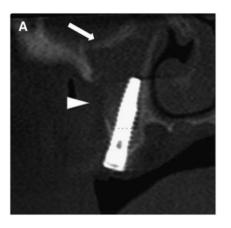




Figure 4.Radiographic view of Figure 3. **A)** At baseline, the lateral bone window of the maxillary osteotomy pushed inside the sinus (arrow) and the open wall (arrowhead). **B)** Note that 6 months post-surgery the lateral wall is closed (arrowhead) and the lateral bone window was used as the "roof" of the secluded cavity (arrow).

Postoperative Control

Two postoperative wound infections, one in each group, occurred 3 to 4 weeks after the maxillary sinus augmentation. Both exhibited suppuration, and they were solved with polypropylene membrane removal and irrigation with 0.12% chlorhexidine. Additional

surgery was not needed. Membrane exposure was present in 25% of all the cases in both groups (P>0.05) and membranes were removed without surgical intervention. Exposures occurred after a period of 3 to 4 months post-surgery.

In addition, no patient presented any paresthesia or altered sensation in the donor area. Oral function was not affected in all treated patients. Data were measured according to questionnaire forms answered by the patients 6 months after surgery.

Implant Uncovering and Implant Survival

At implant uncovering, the remaining membranes were removed and visual evaluation of the lateral window of the maxillary osteotomy was performed (Figs. 3 and 4). Four sinuses presented an incomplete closing of the lateral window: one in the control group and three in the test group (P>0.05).

One implant in the test group was removed because of a lack of osseointegration. This loss was observed in the patient who presented sinusitis. The implants placed in the sinus where membrane perforation was observed presented good clinical stability (data not shown). The 53

Table 2.

Mean (SD) of Clinical and Radiographic Variables of Implants Placed in Control and Test Groups

Group	Residual Alveolar Bone Around Placed Implants (mm)	Buccal and Palatal Distance (mm)	Length of Implant Protruded into the Sinus (mm)	Proportion of Bone Gain: Residual Alveolar Bone	Bone Gain (mm)	Bone Density (HU)
Control	5.34 (2.34)	10.62 (1.61)	8.20 (2.40)	1.37 (0.81)	8.31 (2.60)	207 (143.58)
Test	5.89 (2.89)	10.65 (2.98)	8.95 (3.50)	1.46 (1.07)	7.91 (3.60)	194.42 (84.75)

Mann-Whitney test (P>0.05).

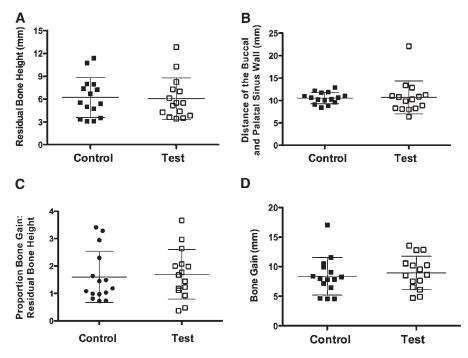


Figure 5. Scatter dot-plot with mean \pm SD of the most protruded implant in each group (n = 15 implants per group) of all radiographic variables. **A)** Residual alveolar bone (millimeters). **B)** Buccal and palatal distance (millimeters). **C)** Proportion of bone gain: residual alveolar bone. **D)** Bone gain (millimeters). Mann-Whitney test (P >0.05).

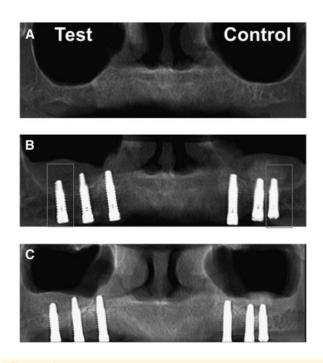


Figure 6.
Panoramic view of sinuses of the test and control groups at (A) baseline, (B) 14 days after surgery, and (C) 6 months. Note the new bone formation around the implant.

remaining implants, in both groups, were clinically stable. The implant survival rate was 96.4% and 100% in the test and control groups, respectively.

DVT Evaluation

Table 2 and Figure 5 present the radiographic variables. No difference was found between groups in both comparisons (general and the most protruded into the sinus). The DVT images showed implants protruding, on average, 8 mm into the sinus (P > 0.05). In all patients, radiographic evidence of new bone formation in the elevated sinus area was seen. Both sides of implants, in a varied range, were covered with new bone, independent of the evaluated group (Figs. 6 and 7). The new bone formation was 8.3 \pm 2.6 mm and 7.9 \pm 3.6 mm in the control and test groups, respectively (P > 0.05). The distance between the buccal and palatal bone wall (CM, Fig. 2) was also similar in both groups (P > 0.05).

The average bone density in the areas of the control and test groups

was 207 ± 143.58 and 194.42 ± 84.75 HU, respectively (P>0.05).

Positive correlations were detected to length of implant protruded into the sinus and bone gain (P < 0.0001; $r^2 = 0.635$), and lateral window closure and bone gain (P < 0.05; $r^2 = 0.551$) for both groups. In addition, absence of sinusitis was correlated with implant survival (P < 0.0001; $r^2 = 0.704$).

Resonance Frequency Analysis

ISQ is presented in Figures 7 and 8. RFA data were obtained only from the implants placed in the sinus area. Implant stability measurements at baseline showed a mean ISQ value of 57.34 for all implants, with higher means to implants placed in the control group (P > 0.05). After healing of 6 months, the ISQ value showed a decrease in these values in both groups (P < 0.05) compared to baseline, but significant for only the control group. These values ranged between 51 and 50 ISQ for the control and test groups, respectively. However, there was not a significant difference between groups after 6 months (P > 0.05).

DISCUSSION

The present data show that simultaneous sinus membrane elevation and dental implant placement with or without autogenous bone graft presents the J Periodontol • March 2011 Borges, Dias, Piattelli, et al.

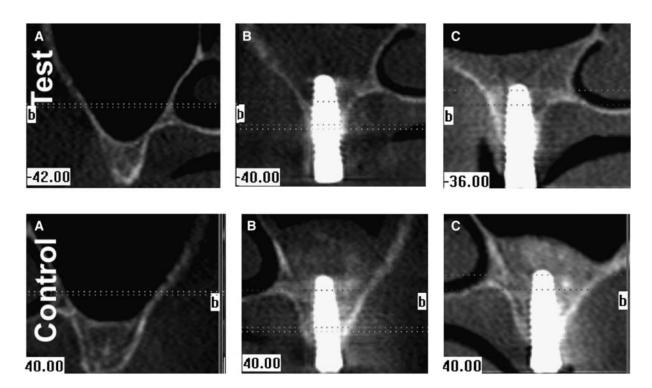


Figure 7.

Cone-beam tomography of the square determined in Figure 6B of the test and control (with autogenous bone graft) groups at **(A)** baseline, **(B)** 14 days after surgery, and **(C)** 6 months.

same results in a 6-month follow-up. Bone formation was evident in all patients, except in the patient who presented an acute post-surgery sinusitis. This patient also lost one implant during the initial healing period in the test group. These results agree with previous studies in humans^{4,6,7,10} and animals^{8,9} who also obtained, in a varied range, new bone formation in the maxillary sinus augmentation without bone grafts.

Although these results are based on recent studies,^{4,7} the idea of placing implants inside the maxillary sinus without bone grafts is not new. Previous studies^{19,20} developed in the early 1980s reported bone formation at the apical portion of dental implants placed in maxillary sinus after carefully raising the sinus membrane. Thereafter, other studies^{21,22} also showed that the careful lining of the sinus membrane allowed new bone formation around the implant placed in maxillary sinus cavity, through remaining alveolar bone crest approach. However, these techniques have bone formation limited to 3.5 to 4 mm.

The simultaneous Schneiderian membrane elevation and implant placement performed in our study shows results comparable to the aforementioned studies. ^{19,21,22} An extensive bone formation around implants was observed, almost covering all of the apical portion of the implant. The bone gain ranged between 8.3 and 7.9 mm for the control and test

groups, respectively, in agreement with previous studies. 18,23

It must be pointed out that maxillary sinus pneumatization could be the result of positive intrasinus air pressure caused by respiration, and this pressure might promote resorption and new pneumatization after maxillary sinus augmentation. 18,24 However, in the present study, both sinus groups do not present resorption affecting the apical portion of the implants after ≥6-month follow-up. This finding may be supported, in part, by two alterations made in the technique advocated by Lundgren et al.⁵ First, the present study pushes the lateral bone window inside the sinus cavity, using this thin bone as the "roof" of the secluded cavity. This bone wall was mechanically supported by the dental implants as a space maker for guided bone regeneration. Second, it could be hypothesized that membrane avoided the soft tissue ingrowths in the sinus cavity, as shown in previous studies. ^{23,24} These alterations could, together, establish proper pneumatic conditions, different from the earlier data, where the apical portion of some implants was not covered by new bone. Complementarily, the exposition of the membrane in the oral cavity did not jeopardize bone augmentation, probably because of the characteristics of the polymer. Most non-resorbable membranes become infected when exposed to the oral cavity. However, the polypropylene

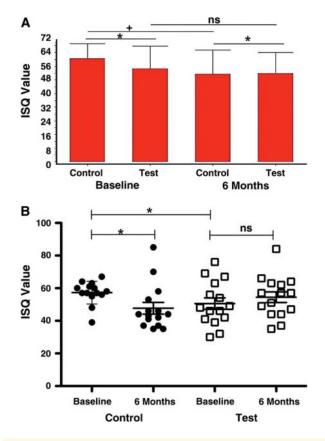


Figure 8. Mean and standard deviation of ISQ values of implants of control and test sinuses at baseline and 6 months of **(A)** all implants and **(B)** the most protruded implant inside the sinus. Mann-Whitney test (* P < 0.05); Wilcoxon rank test (+ P < 0.05). P < 0.050. P < 0.051.

membrane used in this study is comparable to those used to treat intraperitoneal infection.²⁵

In addition, this technique does not use bone grafts inside the sinus cavity. Autogenous bone is the gold standard, but its use is limited by donor-site morbidity, sparse availability, and uncontrolled resorption. 26-28 Previous studies have shown the importance of implant surface topography at micrometer scale on trombogenic activity¹⁷ and the length of implants on the success rate. ²⁹ This trombogenic activation results in the recruitment, migration, and differentiation of progenitor osteogenic cells. These cells are provided by the Schneiderian membrane and exposed bone in the sinus cavity. VEGF is probably the most important player in the vascular formation during angiogenesis. 30 VEGF is an endothelial-specific growth factor that promotes angiogenesis by stimulating endothelial cell differentiation, proliferation, and migration,³¹ and plays an important role in bone remodeling by attracting endothelial cells and osteoclasts, and by stimulating osteoblast differentiation.³²

Complementarily, it is reported that RFA can provide objective evaluation of implant stability, possibly

demonstrating evidence for the extension of implant osseointegration.^{33,34} Therefore, the present data demonstrate that the use of ISQ values range between 54.2 and 60.6 to implants placed in test and control sinus, values very similar to Hallman et al.,³⁵ who found an ISQ value of 66.2 (range: 53 to 76) in implants placed in grafted sinus. However, it could be speculated that the difference between ISQ values of the control and test sides at baseline (P < 0.05) was caused by the presence of autogenous bone graft in the control sinuses. Because the bone graft must be added before the dental implant placement to allow proper graft condensation, this fact might have influenced the results; instead, after a 6-month healing, there was no difference between groups. In addition, the lower means of ISQ values after the 6-month period could be related to the initiation of the new bone formation.^{35,36} The present study also demonstrates a high survival rate for simultaneous implant placement in both groups. The success rate ranged between 96.4% and 100%, similar to previous reports. 1,2,26,29

CONCLUSIONS

Simultaneous sinus membrane elevation and implant placement, with or without bone graft, reach a comparable bone gain and implant survival at 6-month follow-up. However, more long-term clinical data with the implants under loading conditions are needed to draw a more definitive conclusion.

ACKNOWLEDGMENTS

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