

# Graftless Maxillary Sinus Floor Augmentation with Simultaneous Porcine Bone Layer Insertion: A 1- to 5-Year Follow-up Study

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**Purpose:** Evidence suggests that maxillary sinus floor augmentation via a lateral approach can be performed without positioning a bone graft inside, when one or more implants can be placed simultaneously. The aim of this study was to test if the placement of a porcine cortical bone layer underneath the sinus membrane can increase bone formation and implant stability. **Materials and Methods:** One hundred seventy-two patients with posterior maxilla atrophy needing implant rehabilitation were selected. Two hundred six sinus augmentation procedures were performed via a lateral approach, and 295 implants were placed in the same session of the sinus elevation surgery. In all the surgeries, a porcine cortical bone layer was placed underneath the sinus membrane, without using any graft material. After 6 to 7 months of healing, the implants were uncovered, then restored with porcelain-fused-to-metal crowns and monitored with a follow-up of 1 to 5 years. **Results:** The implant cumulative success rate was 95.2%, while the residual bone crest height changed from  $2.67 \pm 1.11$  mm to  $12.54 \pm 1.42$  mm, with an increase of 9.87 mm on average. Marginal bone resorption was 0.83 mm on average after 1 year of loading, while the mean implant stability measured at the moment of implant placement and 6 to 7 months later increased from an implant stability quotient (ISQ) of  $62.61 \pm 5.7$  to an ISQ of  $70.07 \pm 8.2$ . **Conclusion:** This study confirms the validity of the graftless sinus elevation surgery when simultaneous implant placement is performed. The use of a porcine cortical bone layer seems to increase, from a radiologic point of view, the amount of bone around the implants, reducing healing time, cost, and biologic complications for the patient. *Int J Oral Maxillofac Implants* 2020;35:808–815. doi: 10.11607/jomi.7878

**Keywords:** cortical bone layer, implant, posterior maxilla, sinus elevation, sinus graft, sinus membrane

Lateral sinus augmentation is a predictable procedure that is indicated to increase bone volume in patients with posterior maxillary atrophy, with the aim of making implant rehabilitation possible.<sup>1</sup> The idea of using a graftless technique is mainly due to some authors identifying some common possible complications, such as perforation of the sinus membrane, oftentimes associated with spreading of the graft material inside the cavity; infection leading to sinusitis; and surgical morbidity when autogenous bone is harvested from other parts of the body.<sup>2,3</sup> When Lundgren et al first proposed a graftless technique for lateral sinus floor elevation, the protocol included implant placement after elevation

of the sinus membrane, without inserting any grafting material into the sinus.<sup>4,5</sup> Several of the following comparative studies reported no statistically significant difference when using this technique, as opposed to the success rate of implant placement associated with conventional sinus elevation techniques.<sup>6–9</sup>

A histologic study on Capuchin primates demonstrated that implants placed without any intrasinus grafting resulted in new bone formation around the threads as well as osseointegration.<sup>10</sup> However, upon careful analysis of the histologic documentation reported in that article, the sinus membrane was found to have collapsed over the apex of the implants, thus leading to a reduced bone-to-implant contact (BIC).<sup>10</sup> The use of a porcine cortical bone lamina after the elevation of the sinus membrane has been compared in a human study to conventional intrasinus grafting, resulting in pure autogenous bone formation instead of graft-bone integration.<sup>11</sup>

The aim of this prospective study was to evaluate the healing after graftless maxillary sinus augmentation surgery and to evaluate whether a porcine cortical bone lamina can increase the newly formed bony volume by preventing the sinus membrane from collapsing on the sinus floor and implants, thus increasing the BIC and implant secondary stability.

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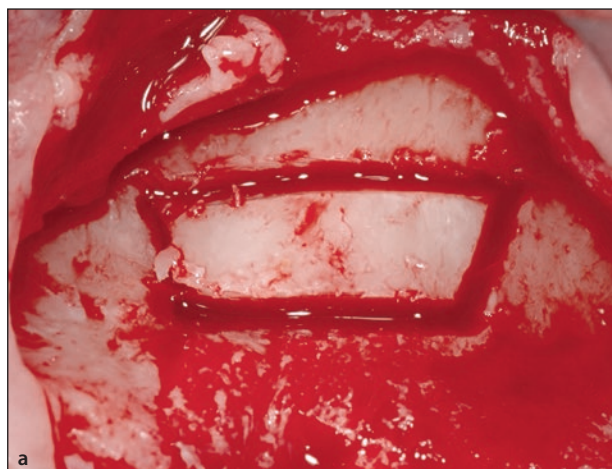
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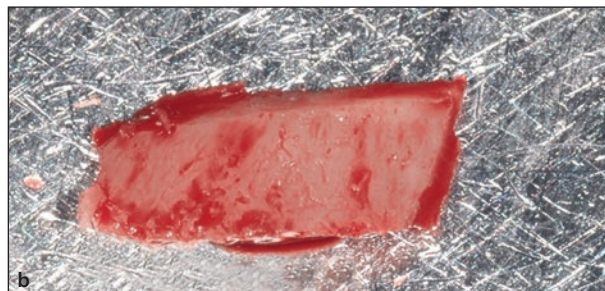
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**Fig 1a (left)** Intraoperative image showing the trapezoidal-shaped bone window of the lateral wall of the sinus.

**Fig 1b (below)** The bone dowel just removed from the lateral wall of the sinus.



## MATERIALS AND METHODS

One hundred ninety patients with posterior maxillary atrophy needing implant rehabilitation were selected. Two hundred six lateral sinus elevation procedures were performed, and 295 implants were placed during the same surgery. In 188 procedures, a porcine cortical bone lamina (Lamina Soft Fine, OsteoBiol, Roen) was placed underneath the sinus membrane, without using any grafting material, and one or two 13-mm-long implants (Biomet 3i Implant Innovation) were placed. Uncovering was carried out 6 to 7 months after the first surgery, and provisional screw-retained implant-supported fixed dental prostheses (FDPs) were loaded. Single- and multiple-unit porcelain-fused-to-metal FDPs were fabricated. Patients were followed up every 6 months from 1 to 5 years.

### Patient Selection

Both male (97) and female (93) patients were included in this study. The mean age of the study group was  $64.2 \pm 3.6$  years. None of the selected patients was taking medications (eg, bisphosphonates) or had medical conditions that could affect intraoperative and postoperative risk and outcome (ie, noncompensated diabetes or cardiac conditions, bleeding disorders, substance abuse). Even though smoking constitutes a risk factor for surgery failure, 42 smoker patients (ie, > 10 cigarettes/day) were included in the present study, after having been informed of the higher failure risk. All patients were devoid of signs of sinus tract, acute inflammation, and/or neoformations. All selected patients were referred to an otorhinolaryngologist for further examination before proceeding to surgery.

Only patients missing one maxillary second premolar or first molar were included in the study, provided that no fixed or removable prosthesis was present. All patients were scanned with cone beam computed

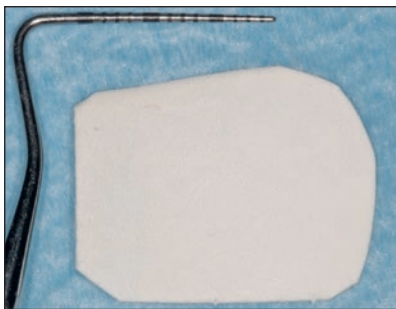
tomography (CBCT) to assess bone volumes in the three dimensions. Minimum vertical height was assessed to be 1 mm (up to 4.9 mm), and a minimum thickness of 6.2 mm was measured to allow the placement of implants with a minimum diameter of 4 mm. Patients were also informed about all surgical aspects regarding the procedure, and specific consensus was obtained prior to beginning treatment.

All patients were prescribed 1 g amoxicillin/clavulanic acid (Augmentin, GlaxoSmithKline) twice a day, starting the day before surgery for 6 days, and an analgesic (ibuprofen, 600 mg) was prescribed as needed. All patients were prescribed 0.12% chlorhexidine mouthwashes starting 3 days before surgery, up until 14 days after surgery, 3 times a day, for 1 minute after brushing.

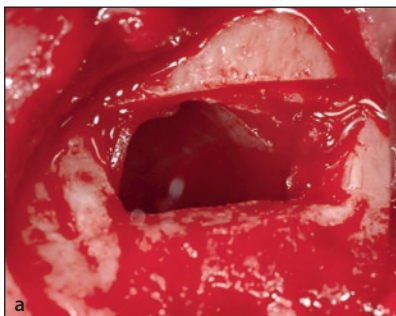
All surgeries were conducted in accordance with the 1975 Declaration of Helsinki, as revised in 2013, for biomedical research involving human subjects.

### Sinus Floor Elevation Protocol

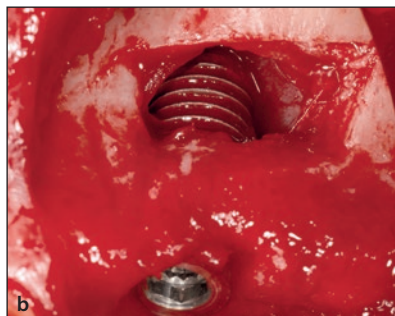
After anesthesia, a trapezoidal full-thickness flap, including at least one mesial and distal tooth in the edentulous space, was elevated to expose the lateral wall of the maxillary sinus. A trapezoidal-shaped bone window was first outlined, using a piezoelectric-mounted micro-saw (OT12s, Piezosurgery 3, Mectron), and then detached using a Lucas surgical curette (Hu-Friedy) and stored in saline solution (Figs 1a and 1b). Then, the sinus membrane was carefully elevated from the sinus walls using an intrasinus elevator (710 #10 Round eac, Henry Schein). At this point, a porcine cortical bone lamina (Lamina Soft Fine,  $25 \times 25 \times 0.5$  mm, OsteoBiol, Roen) was first hydrated for 5 minutes in saline solution and then cut using surgical scissors and placed inside the sinus underneath the sinus membrane (Figs 2 and 3a). If membrane perforation occurred during removal of the bony window or elevation of the sinus membrane, no attempt was made to close it.



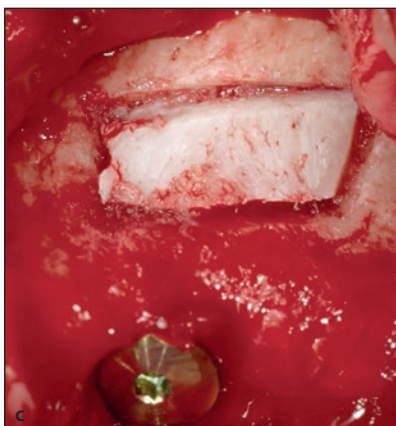
**Fig 2** The porcine cortical bone layer trimmed and hydrated for 5 minutes in saline solution.



**Fig 3a** The elevated sinus membrane and the porcine cortical bone layer placed inside the sinus underneath it.



**Fig 3b** The implant placed into the sinus underneath the porcine cortical bone layer.



**Fig 3c** The detached bone window replaced in the lateral wall of the sinus using cyanoacrylate surgical glue.



**Fig 3d** Implant stability measured with the Osstell Mentor device.

### Implant Placement and Stability Assessment

Implant perforations were underprepared to achieve good primary stability. One or two 13-mm-long implants (T3 Implant, Zimmer Biomet) were placed during each surgery. Diameter (4 or 5 mm) was chosen depending on the residual available ridge (Fig 3b). Since, for 18 patients, it was impossible to reach satisfactory primary implant stability, a staged approach was preferred. After retrieval of the implants, an organic bovine bone graft (Bio-Oss, Geistlich) was placed in the sinus, and the implant would be placed up to 8 months later. If primary stability after implant placement was optimal, as for all the other patients, the detached bone window was placed back in its original position and stabilized using cyanoacrylate surgical glue (Histoacryl, B. Braun Surgical) (Fig 3c). The flap was sutured with a resorbable Vicryl 4-0 (Johnson and Johnson/Ethicon) suture to achieve tension-free wound closure.

### Prosthesis Fabrication and Follow-up

Uncovering was scheduled 6 to 7 months after the first surgery, and an impression was taken and sent to the laboratory for the fabrication of provisional screw-retained single- and multiple-unit FDPs. Among all patients, 101 had only one implant placed, and hence, a single FDP (73 molars, 44 premolars); 89 had two implants with a two-crown prosthesis including the second premolar and first molar. Definitive prostheses were screw-retained porcelain-fused-to-metal FDPs (Fig 4). The screws were tightened according to the manufacturer's instructions with 20 Ncm. The patients were enrolled in a strict hygiene program and followed up every 6 months for up to 5 years.

### Measurements

Implant stability quotient (ISQ) was measured using the Osstell Mentor device (Osstell). Resonance frequency analysis right after surgery ( $RFA_1$ ) and at uncovering ( $RFA_2$ ) was recorded with reference to the mesiodistal and buccolingual sides of a specific peg, and mean values were calculated (Fig 3d).

Residual crestal bone height (RCBH) under the sinus floor was measured using CBCT imaging and analysis software (EZ Dent-1 imaging software, Vatech) before sinus surgery ( $RCBH_1$ ) and repeated 6 months later ( $RCBH_2$ ) to evaluate new bone growth (Figs 5 and 6).

Marginal bone level (MBL) changes were assessed using digital periapical radiographs taken using the parallel technique at implant placement ( $MBL_1$ ), at definitive prosthesis delivery ( $MBL_2$ ), and after 1 year of loading ( $MBL_3$ ), using a customized holder (Fig 7). All radiographs were viewed in digital radiographic imaging software (DBSWIN Imaging Software, Durr Dental SE) and evaluated by one of the authors.

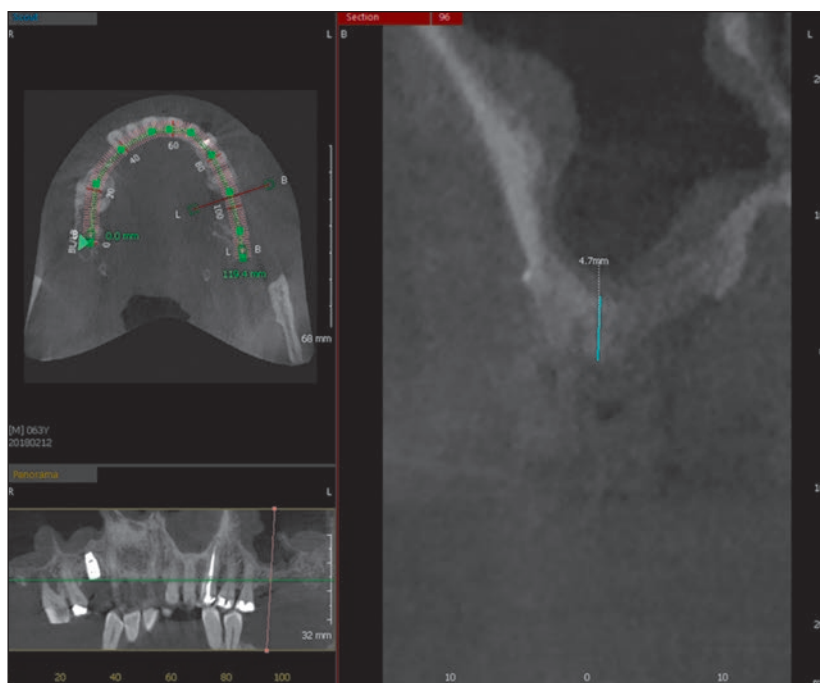




**Fig 4 (above)** Porcelain-fused-to-metal crown the day of the final cementation.

**Fig 5 (right)** Preoperative CBCT scan showing residual RCBH<sub>1</sub>.

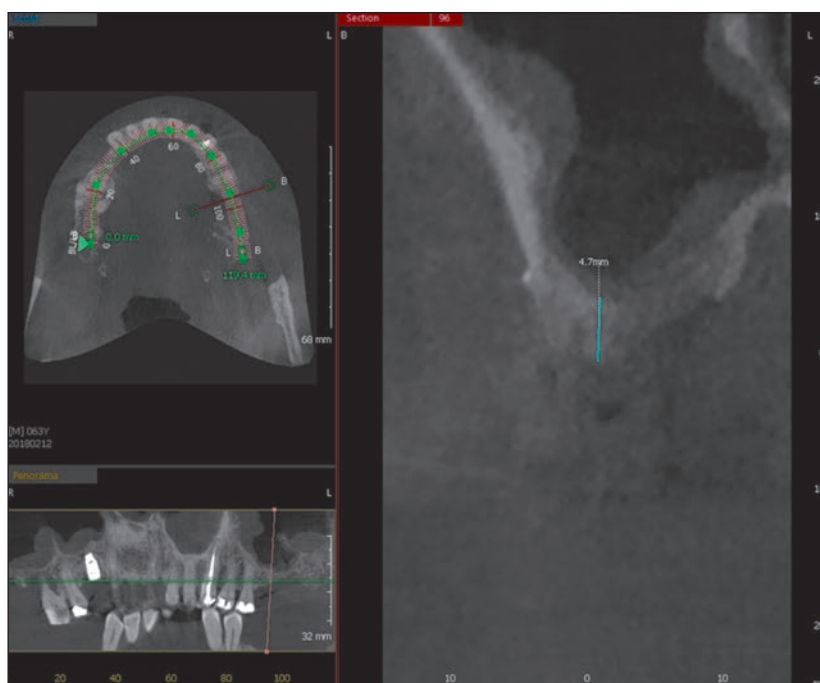
**Fig 6 (bottom right)** CBCT scan showing new bone growth 6 months after implant placement (RCBH<sub>2</sub>).



## RESULTS

Two hundred six sinus elevation surgeries using a lateral approach were performed on 190 patients (93 women and 97 men). Among these, 172 patients had 295 implants (65 were 5 mm in diameter; 230 were 4 mm in diameter) positioned during the same session of the graftless lateral sinus elevation surgery. In particular, 16 patients had bilateral surgery, for a total of 32 graftless lateral sinus elevations, while the remaining 156 patients had single graftless lateral sinus elevation surgery. In 18 patients, all scheduled for single sinus surgery, it was impossible to achieve satisfactory primary implant stability ( $< 40$  Ncm), so implants were retrieved, and a second surgery was scheduled to place 4-mm-diameter implant(s). Among the 295 implants placed, 73 were placed in 42 smoker patients.

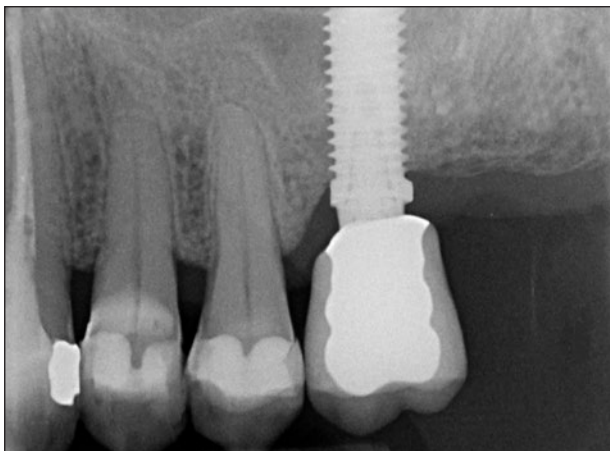
Patients were called for a hygiene session and check-up at least every 6 months. During the follow-up period, 46 patients (24%) stopped attending check-ups after 1 year, 42 patients (22%) after 2 years, 39 (21%) after 3 years, 32 (17%) after 4 years, and only approximately 16%



of patients (31) complied with the follow-up protocol up to 5 years. No clinical or radiologic sinus complications occurred either during the healing phase, or during the follow-up period, except nose bleeding during the hours following surgery, and some swelling and bruises, which generally healed within 1 week.

## ISQ

The immediate (RFA<sub>1</sub>) ISQ average value was  $62.61 \pm 5.7$ , which increased to a mean  $70.07 \pm 8.2$  ISQ at uncovering (RFA<sub>2</sub>).



**Fig 7** Radiograph showing marginal bone loss at the implant-abutment junction (MBL<sub>3</sub>). CBCT slice at 1-year follow-up shows stability of the peri-implant bone and sinus lift.



**Fig 8** CBCT slice at 1-year follow-up shows stability of the peri-implant bone and sinus elevation.

### Implant Cumulative Success Rate

Out of the 295 implants placed in the same session of the graftless lateral sinus elevation surgery, 14 implants failed in 12 patients with an implant cumulative success rate (CSR) of 95.26%. All failures occurred at connection of the abutment or during the provisional prosthetic phase. With respect to smoker patients, 7 implants failed out of 73, with an implant success rate of 90.42% vs 96.85% in the nonsmoker group, where there were 7 failures out of 222.

No failures occurred in patients who had two-stage lateral sinus elevation surgery and grafting and delayed implant placement.

### Intraoperative Complications Related to the Lateral Sinus Elevation Procedure

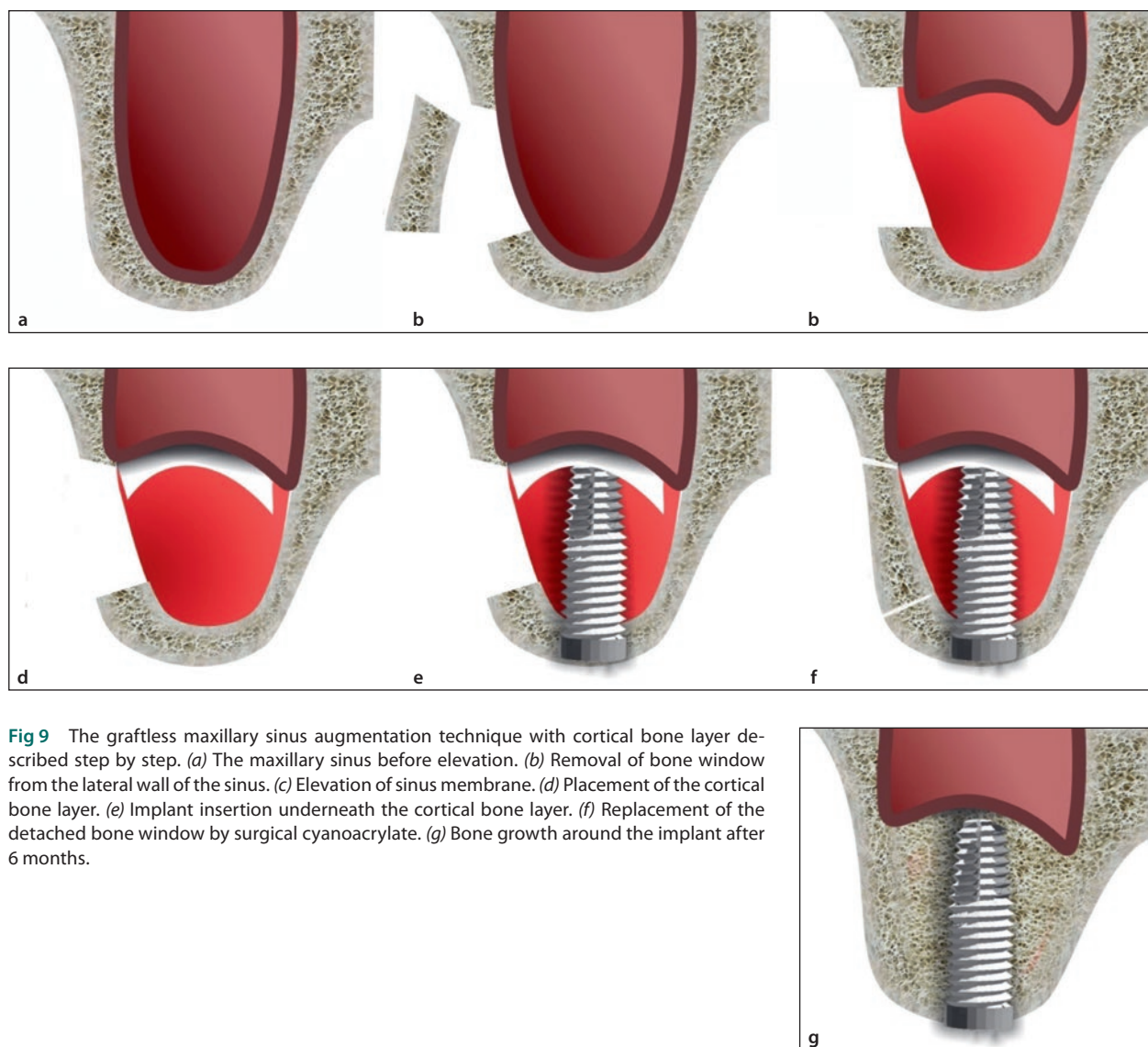
Among 206 lateral sinus elevation procedures, 100 perforations of the sinus membrane occurred. None of the perforations exceeded 7 mm, and they mostly occurred during insertion of the lamina (88%). In some cases, perforations occurred during access to the sinus, ie, detachment of the bony window (5%) and membrane elevation (7%). Among 140 implants placed in sinuses carrying a membrane perforation, 9 failed, leading to an implant success rate of 93.5% vs a 96.78% success rate among the 155 implants placed with intact membranes. As mentioned, the success rate among implants placed in a second surgery was 100%.

The RCBH<sub>1</sub> measured before surgery went from 1 to 4.9 mm, with a mean value of  $2.67 \pm 1.11$  mm. Thickness of the bone ridges stood between 6.2 and 8.3 mm. No other bone augmentation procedure was performed. RCBH<sub>2</sub> measured 6 months after implant placement was 9.1 and 15.2 mm, with a mean value of  $12.54 \pm 1.42$  mm, showing new bone formation of 9.87 mm on average.

The MBL measured on the periapical radiographs, which was  $0.10 \pm 0.2$  mm at implant placement (MBL<sub>1</sub>), was recorded at  $0.77 \pm 0.57$  mm at definitive prosthesis (MBL<sub>2</sub>), and at  $0.93 \pm 0.67$  mm after 1 year of loading (MBL<sub>3</sub>), with an average total marginal bone loss of 0.83 mm after 1 year of loading.

## DISCUSSION

Sinus elevation surgery without using a bone graft was first described in 1997 by Ellegard et al to emphasize sinus elevation efficacy in periodontally compromised patients.<sup>12</sup> In 2003, Lundgren et al<sup>4</sup> described the step-by-step procedure for graftless maxillary sinus augmentation, comparing it to the standard graft procedure modified by Boyne and James in 1980.<sup>1</sup> Lundgren et al also found spontaneous bone formation from the sinus floor after removing a maxillary sinus cyst, which led to the hypothesis that the establishment of a void space filled by a blood clot may yield bone apposition, following the principles of guided tissue regeneration.<sup>13</sup> This hypothesis was later confirmed with a histologic study on animals showing bone formation around machined and oxidized implants with sinus membrane elevation not associated with any kind of bone grafting.<sup>10</sup> In addition, the results did not show significant differences in terms of implant stability compared with techniques including autogenous bone graft, indicating the osteoinductive potential of the sinus membrane.<sup>14,15</sup> Although results seemed promising, no bone was found above the apical part of the implants, probably due to the direct contact with the sinus membrane. In another thorough histologic investigation on primates, Jungner et al found that osteoinduction seemed to start from



**Fig 9** The graftless maxillary sinus augmentation technique with cortical bone layer described step by step. (a) The maxillary sinus before elevation. (b) Removal of bone window from the lateral wall of the sinus. (c) Elevation of sinus membrane. (d) Placement of the cortical bone layer. (e) Implant insertion underneath the cortical bone layer. (f) Replacement of the detached bone window by surgical cyanoacrylate. (g) Bone growth around the implant after 6 months.

the bottom of the sinus floor, instead of the sinus membrane, regardless of the technique used.<sup>16</sup>

The present study was conducted by only one surgeon (R.L.), thus standardizing the technique. In all procedures, a porcine cortical bone lamina (Lamina Soft Fine, 25 × 25 × 0.5 mm, OsteoBiol, Roen) was used as a barrier to prevent the sinus membrane from collapsing over the implant, thus increasing the long-term BIC (Figs 9a to 9g). The use of decalcified porcine cortical bone layers is well documented in guided bone regeneration around implants. Its rigidity makes it a good barrier to hold the sinus membrane and to prevent the underlying grafting material from spreading in the sinus cavity and from entering the sinus in case of perforation.<sup>17,18</sup> As it becomes flexible after hydration, it can be shaped and adapted to the morphology of the defect.

In a recent study, Scarano et al used a 3-mm-thick porcine cortical bone layer in lateral sinus floor elevation to prevent the sinus membrane from collapsing, without using bone graft. In their study, the porcine cortical bone lamina was also bent to cover the access window.<sup>11,19</sup> The same authors also investigated the influence of bone grafting with the same technique, and found that patients who also had bone graft placed under the cortical lamina had better outcomes in terms of bone formation and reduced surgery duration. Yet, the formation of autogenous bone, without interposition of grafting material, might be considered an advantage. The mean 9.87 mm of bone formation found while conducting the present study may be held as a very satisfactory result, which is probably due to the simultaneous implant insertion, which was not included



in the protocol used by Scarano et al.<sup>11</sup> In fact, the implant seemed to function as a tenting screw, thus creating more space to be colonized by the blood clot.

The success and predictability of graftless lateral sinus elevation procedures has been reported by several authors.<sup>20</sup> Borges et al found no statistical difference in terms of implant success rate and new bone formation when comparing the placement of intraoral autogenous bone graft versus no graft material after lining of the sinus membrane and immediate implant placement.<sup>21</sup> A recent systematic review and meta-analysis on the effectiveness of maxillary sinus floor elevation and immediate implant placement without the use of grafting material reported a cumulative average implant success rate of 97% and an average gain in bone height of 4.7 mm, over an average period of 39.4 months.<sup>6</sup> Other systematic reviews confirmed these results, reporting a predictable amount of bone formation in maxillary sinus augmentation, and an implant success rate ranging from 79% to 100%, with a 0- to 143-month follow-up.<sup>22</sup> The study with the longest follow-up is that of Cricchio et al, who reported a 98.7% implant success rate from 1 to 6 years on 189 implants placed with the graftless maxillary sinus augmentation technique.<sup>23</sup> The present study confirms the data of the previous authors, showing an implant CSR of 95.26%, which is similar to that obtained when using standard sinus floor augmentation with graft material.<sup>24</sup>

The average new bone formation of approximately 9.87 mm after 6 to 7 months in combination with a 0.83-mm marginal bone loss after 1 year of loading that was found in the present study seem to improve the results reported by Cricchio et al, who reported 5.3 mm of intrasinus new bone formation on average after 6 months of healing.<sup>23</sup>

The relevant rate of perforations in the present study is higher compared with that reported in previous literature. The success rate of implants placed in sinuses with perforations was 93.5% compared to a 96.8% success rate of implants placed in sinuses with intact membranes. Although these results are similar to those of other authors, most studies do not highlight a statistical difference in terms of implant success rate in cases of sinus membrane perforation after the graftless maxillary sinus augmentation technique.<sup>25</sup> Moreover, the high rate of perforations may be due to the learning curve regarding the insertion of the porcine cortical bone inside the sinus without perforating the membrane. In fact, approximately 80% of perforations occurred during the placement of the lamina, 100% of which occurred in the first 2 years of use of this technique. For this purpose, it was useful to place a sinus elevator to protect the sinus membrane during the placement of the porcine cortical bone layer. Moreover, wrapping the softened lamina around the handle of a mirror, and using the latter as a

carrier to place the lamina inside the sinus, showed that this material easily adapts itself under the sinus membrane, while reducing the risk of damaging it.

Another advantage of using a graftless technique for maxillary sinus augmentation was the absolute lack of infective complications. When infection occurs, in addition to pain, complications can include pus leak through the nose or the wound, which might lead to the need for surgical removal of the graft, and hence, failure of the procedure.<sup>26</sup> The need for graft removal is mostly because the graft contamination in a secluded environment is very difficult to treat with standard antibiotics. On the other hand, the absence of grafting material in the sinus allows systemic antibiotics to reach the clot quickly through the blood stream, thus preventing a sinus infection.<sup>27</sup>

In this work, to facilitate the placement of the bone window back in its original position, the osteotomy was performed in a trapezoid shape by using a piezoelectric device (OT12s, Piezosurgery 3, Mectron) with the tip tilted at 45 degrees, performing a bevel on the four sides. The cyanoacrylate only served to avoid micro-movements of the bony lid or its migration inside the sinus cavity. In a couple of patients, the integration of the bony window was checked clinically by detaching the flap deeper at uncovering, after at least 6 months postsurgery, and all windows checked were found to be perfectly healed. This procedure was also used by Lundgren et al in their first article on graftless maxillary sinus augmentation,<sup>4</sup> as suggested by a previous histologic study on rabbits.<sup>28</sup> The authors compared the use of the homologous bone window versus a collagen membrane over the lateral window and found an increase in bone formation associated with faster healing when the removed bony window was replaced over the sinus.

The main limitation of this technique is the presence of a minimum amount of residual bone to achieve sufficient primary stability. On the other hand, this limitation does not seem to be overcome by bone chip grafting in terms of primary stability. If this cannot be achieved, the authors suggest a staged approach. In the 18 patients in whom it was impossible to stabilize the implant(s), the main reason seemed to be the reduced residual bone volume (< 1.5 to 1 mm). Given this limitation, the authors recommend selecting standard- or large-diameter, preferably threaded, implants with a rough neck, to achieve optimal primary stability, and considering a two-stage protocol for patients with residual bone ridges lower than 1.5 mm. To increase the BIC, implants with 4- and 5-mm diameter and 13-mm length were used in all patients. Implants would only be loaded after a minimum of 6 months. This is another important advantage of the graftless maxillary sinus augmentation technique, as it is not necessary to wait for the integration of a heterologous bone substitute, which takes

approximately 10 months when used alone inside the sinus.<sup>29</sup> In fact, the healing time of elevated and grafted sinus floors strictly depends on the height of the residual ridge, and hence, on the volume of the void that needs to be filled by new bone formation, which is also the main limitation of the graftless technique. Yet, as ISQ values of  $70.07 \pm 8.2$  were found in the present study, which allowed uncovering after only 6 or 7 months, the absence of grafting material to be integrated seemed to be advantageous in terms of healing time. The osseointegration of the implants was also confirmed by the increased residual crestal bone height measured on the CBCT scan after a 6- to 7-month healing time.

## CONCLUSIONS

The graftless maxillary sinus augmentation technique using porcine cortical bone lamina is a predictable and effective procedure. In particular, the porcine cortical bone lamina placed over the implant seems to effectively prevent the sinus membrane from collapsing on the sinus floor and to increase the amount of bone around the implant.

## ACKNOWLEDGMENTS

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