A systematic review with meta-analysis on sinus floor elevation reported that the optimal implant survival rate was obtained using implants with a rough surface and covering the antrostomy with a membrane. This procedure may improve the healing and the outcome. However, further studies reported inconclusive results with regard to the efficacy and the need to cover the antrostomy window.

In a randomized clinical trial, similar results in new bone formation were observed histologically 6 months after sinus floor augmentation both with and without the use of a membrane in collagen to cover the antrostomy. It has been further shown in an experiment in rabbits that the use of a collagen membrane did not prevent an incomplete healing of the antrostomy, as shown both at the histologic and microtomographic analyses. Moreover, a clinical study showed that the collagen membrane did not prevent the migration of the biomaterial through the antrostomy. With an aim to improve the healing at the antrostomy and guarantee the closure during and after healing, the reposition of the bony window on the antrostomy was proposed. In a study in rabbits, maxillary sinus augmentation was performed bilaterally. At one sinus, the bone window was rearranged at the antrostomy,
while the other one was protected with a collagen membrane. Higher and faster bone growth was seen at the repositioned bone plate sites in comparison to the antrostomy with a membrane. In a similar experiment in rabbits, at the test sites, a cyanoacrylate glue was applied to fix the bone window at the antrostomy after sinus floor augmentation. While the healing inside the augmented sinuses was similar in both groups, at the antrostomies, the repositioned bone window was incorporated into the new bone formed within the elevated spaces. At the collagen membrane sites, the healing was incomplete, and the antrostomies presented residual defects.

The dimensional variations after sinus floor elevation were evaluated on cone beam computed tomography (CBCT) images in two randomized clinical trials. Different positions and dimensions of the antrostomies were applied and studied. It seemed clinically relevant to also study how the covering of the antrostomy with a collagen membrane may affect the dimensional variations within an augmented sinus floor.

Hence, the aim of the present study was to evaluate the dimensional variations after elevation of the maxillary sinus floor and the healing of the antrostomy left unprotected or protected by a collagen membrane.

**MATERIALS AND METHODS**

The Declaration of Helsinki on medical protocols and ethics was followed for the present study. The protocol was approved by the Ethical Committee of the University Corporation Rafael Nuñez, Cartagena de Indias, Colombia (protocol #02-2015; May 19, 2015), where the study was conducted. Signed informed consents were collected. The Consort checklist was followed for this report (http://www.consort-statement.org/). The study was registered at ClinicalTrials.gov (https://clinicaltrials.gov/) with the following identifier: NCT03899688.

**Study Population**

To calculate the sample size, the data from a radiographic evaluation on height variation during the first year of healing were used, and n = 10 for each group (20 patients) was considered sufficient. An author not involved in the surgery performed the randomization (M.F.). Sealed and opaque envelopes containing the assignments were opened after the placement of the filler material within the elevated space, and the assignment was revealed to the blinded surgeon (D.B.).

For the inclusion criteria, the following had to be satisfied: (1) edentulous zone in the posterior regions of the maxilla; (2) sinus floor height of ≤ 4 mm; (3) request for a fixed prosthesis on implants; (4) age ≥ 21 years; (5) good general health; (6) no contraindications for oral surgery procedures; and (7) not pregnant.

For the exclusion criteria, the following parameters were adopted, if present: (1) systemic disorder; (2) chemotherapeutic or radiotherapeutic treatments; (3) smoking of > 10 cigarettes/day; (4) acute or chronic sinusitis; and (5) bone augmentation procedures in the region of treatment.

**Biomaterial Used**

The filler material was Cerabone granulate 1.0 to 2.0 mm (BoTiss Biomaterials) composed of a ceramic consisting of hydroxyapatite (pentacalcium hydroxide trisphosphate) produced from bovine cancellous bone in a high-temperature process (> 1,200 ºC). The xenograft presents a macroporosity of a dimension included within a range of 100 to 1,500 µm. The membrane used to cover the antrostomy at the control sites was Collprotect membrane (BoTiss Biomaterials) made of porcine collagen obtained from the corium. Both biomaterials are distributed by Straumann.

**Clinical Procedures**

An antrostomy of approximately 5 mm in height and 10 mm in length was prepared using a sonic-air surgical instrument (Sonosurgery TKD). The sinus membrane was elevated, and the space obtained underneath the sinus mucosa was filled with the xenograft. A collagen membrane was arranged covering the lateral access only at the randomly selected control sites, and the flaps were sutured. The day before and for a total of 6 days, amoxicillin 875 mg with clavulanic acid 125 mg twice a day was prescribed. Analgesic drugs were recommended if needed, and mouthrinses with 0.12% chlorhexidine for 10 days were performed. The sutures were removed after 7 days, and all patients received maintenance care for the full duration of the study.

Six months later, mini implants (Sweden & Martina), 2.4 mm in diameter and 8 mm in length, were placed in the location of definitive implants for further investigations.

**CBCT Imaging Analyses**

Details on CBCT imaging procedures, landmarks used, and measures taken were also reported in a previous article. Briefly, CBCTs were taken before surgery (T0), and 1 week (T1) and 9 months (T2) after surgery. The radiographic evaluations were carried out with i-Dixel 2.0 software (J. Morita Corporation). The method of measurement included the use as reference of a line drawn following the floor of the nose both in the coronal (axis X; Fig 1) and in the lateral (axis Z; Fig 2) views. The floor of the nose roughly corresponded to the level of the palatal-nasal recess (PNR). The following
landmarks were used for measurements in the coronal view (Figs 1 to 4): C, top of the bone crest; F, sinus floor; A, posterior superior alveolar artery (PSAA; or intraosseous anastomosis); the medial (MW) and lateral (LW) walls of the sinus; and the upper (UM) and lower (LM) margins of the antrostomy.

Several measurements were carried out (Table 1). The elevated areas in the coronal and lateral views were calculated by subtracting or adding to the areas measured at T0, the residual or exceeding areas measured at T1 and T2, respectively. For references and measurements, see also Table 1.
Data Analysis
The primary outcome variable was the change in height of the elevated sinus space in the medial, middle, and lateral regions. The secondary outcome was the change of the area in the elevated zone. All tomographic evaluations were performed twice by a well-trained examiner (K.A.A.A.) who was blinded to the protocol. The intraexaminer agreement was > 0.9. Mean values of the two measurements were obtained. Mean values and standard deviations were calculated for each variable. The differences between the two groups were analyzed using the Mann-Whitney test included in the statistics software SPSS (IBM). The level of significance was set at \( \alpha = .05 \).

RESULTS
The study started in February 2015 and ended in December 2018, and 20 patients were included.

Two perforations were detected during surgery, one of 5 mm in dimension in the membrane group, and one of 2 mm in dimension in the no-membrane group. Both perforations were covered with a piece of collagen membrane before filling the elevated space with the bone substitute.

No complications were detected during healing, and no dropouts were registered. The radiographic documentation was available for all 20 patients so that \( n = 10 \) was reached for the tomographic evaluation. Demographic and clinical data are reported in Table 2.

CBCT Imaging Evaluation
Coronal View. The anatomical data evaluated at T0 (before surgery) are depicted in Table 3, including balcony height, evaluated at T1 (1 week after surgery). No statistically significant differences were disclosed between the two groups. The mean distance between the x-axis and the bone crest was 13.0 ± 3.8 mm and 12.5 ± 1.6 mm in the membrane and no-membrane groups, respectively.

The middle region height increased 12.5 ± 3.8 mm in the membrane group and 11.9 ± 3.6 mm in the no-membrane group, as evaluated at T1 (Table 4; Fig 5). After 9 months from surgery, losses of 0.6 mm and 0.8 mm were registered, respectively. No statistically significant differences were found.

Correspondingly, the loss of area between T1 and T2 was 12.7% ± 17.5% in the membrane group, and 15.3% ± 15.7% in the no-membrane group (Table 5). Again, no statistically significant differences were disclosed.

A loss of granules of graft through the antrostomy was observed in three cases in the no-membrane group, while only one case in the membrane group presented few granules outside the antrostomy.

The sinus mucosa increased in width after 1 week by 3.1 ± 4.0 mm and 3.8 ± 6.7 mm in the membrane and no-membrane groups, respectively. At T2, the sinus mucosa width regressed to values lower than those encountered at T0 (Table 6).

After 9 months of healing, a closure of the antrostomy was found in two cases in the membrane group and in three cases in the no-membrane group. A corticalization of the new sinus floor was seen only in the three cases of the no-membrane group.

Lateral View
The length of the sinus (ZW) was 21.7 ± 8.6 mm in the membrane group and 18.6 ± 5.8 mm in the no-membrane group. The loss of area occupied by the

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Table 2  Demographic and Clinical Data

<table>
<thead>
<tr>
<th>Group</th>
<th>Sex</th>
<th>Age (y)</th>
<th>Smokers</th>
<th>Side</th>
<th>Window height (mm)</th>
<th>Window length (mm)</th>
<th>Window area (mm²)</th>
<th>Balcony (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mb</td>
<td>4 men; 6 women</td>
<td>56.0 ± 7.5</td>
<td>None</td>
<td>5 right; 5 left</td>
<td>5</td>
<td>10.9 ± 2.6</td>
<td>45.7 ± 6.5</td>
<td>4.4 ± 1.1</td>
</tr>
<tr>
<td>No-Mb</td>
<td>2 men; 8 women</td>
<td>54.7 ± 11.8</td>
<td>None</td>
<td>6 right; 4 left</td>
<td>5</td>
<td>10.6 ± 2.4</td>
<td>44.3 ± 12.1</td>
<td>4.3 ± 1.3</td>
</tr>
</tbody>
</table>

Table 3  Radiographic Anatomical Data in Coronal View Taken at Different Periods

<table>
<thead>
<tr>
<th>Group</th>
<th>Bone crest height (C-F) at T0</th>
<th>Sinus height (X-F) at T0</th>
<th>Distance X-C</th>
<th>Sinus width (XW) at T0</th>
<th>Palatal-nasal recess angle (deg)</th>
<th>PSAA height (A-C) at T0</th>
<th>PSAA diameter at T0</th>
<th>X-area at T0</th>
<th>Balcony height (LM-F) at T1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mb</td>
<td>2.1 ± 1.0</td>
<td>10.9 ± 3.8</td>
<td>13.0 ± 3.8</td>
<td>17.5 ± 5.8</td>
<td>125.5</td>
<td>15.7 ± 2.3</td>
<td>1.1 ± 0.4</td>
<td>126.0 ± 63.0</td>
<td>4.5 ± 0.9</td>
</tr>
<tr>
<td>No-Mb</td>
<td>2.9 ± 1.0</td>
<td>9.6 ± 1.5</td>
<td>12.5 ± 1.6</td>
<td>15.6 ± 3.7</td>
<td>124.7</td>
<td>15.7 ± 3.1</td>
<td>1.2 ± 0.4</td>
<td>106.7 ± 28.3</td>
<td>4.2 ± 0.9</td>
</tr>
</tbody>
</table>

Data in millimeters, grades (PNR angle) or square millimeters (X-area). \( P < .05 \). T0 = before surgery; T1 = 1 week; T2 = 9 months; IA= intraosseous anastomosis.
hard tissue within the elevated space was 7.9% ± 19.8% and 11.9% ± 10.4%, respectively (Table 5). No statistically significant differences were found.

**DISCUSSION**

The influence on dimensional variations of the use of a collagen membrane to protect the antrostomy after maxillary sinus floor augmentation was assessed on CBCTs. A trend of higher loss of dimension was observed in the no-membrane group compared with the membrane group. A total closure of the antrostomy was found only in a few cases in both groups.

At T0, the initial bone crest height was 2.1 mm and 2.9 mm in the membrane and no-membrane groups, respectively. At the tomographic evaluation after 1 week, the top of the biomaterial in the middle aspect

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**Table 4**  
**Floor Augmentation Heights in Coronal View Evaluated at Medial, Middle, and Lateral Aspects of the Sinus at Various Periods of Observation**

<table>
<thead>
<tr>
<th>Group</th>
<th>Medial wall</th>
<th>Middle aspect</th>
<th>Lateral wall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mb</td>
<td>T1</td>
<td>T2</td>
<td>Δ T1 – T2</td>
</tr>
<tr>
<td>9.6 ± 3.1</td>
<td>8.8 ± 3.2</td>
<td>−0.8 ± 1.2</td>
<td>12.5 ± 3.8</td>
</tr>
<tr>
<td>No-Mb</td>
<td>7.6 ± 3.5</td>
<td>7.0 ± 3.2</td>
<td>−0.6 ± 2.0</td>
</tr>
</tbody>
</table>

Data in millimeters. P < .05. T1 =1 week; T2 = 9 months; Δ = difference.

**Table 5**  
**X- and Z-areas at T0, Elevated Area at T1 and T2, and Shrinkage (mm²) and Percentages (%) of Elevated Areas Between T1 and T2, in Coronal and Lateral Views**

<table>
<thead>
<tr>
<th>Group</th>
<th>T0 X-area and T0 Z-area</th>
<th>Elevated area at T1</th>
<th>Elevated area at T2</th>
<th>Δ T1 – T2 (mm²)</th>
<th>Δ T1 – T2 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronal view</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mb</td>
<td>126.0 ± 63.0</td>
<td>120.8 ± 43.3</td>
<td>110.8 ± 44.8</td>
<td>−10.0 ± 9.1</td>
<td>−12.7 ± 17.5</td>
</tr>
<tr>
<td>No-Mb</td>
<td>106.7 ± 28.3</td>
<td>113.8 ± 42.0</td>
<td>98.3 ± 35.1</td>
<td>−14.7 ± 12.7</td>
<td>−15.3 ± 15.7</td>
</tr>
<tr>
<td>Lateral view</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mb</td>
<td>187.8 ± 87.9</td>
<td>162.1 ± 42.1</td>
<td>151.1 ± 46.5</td>
<td>−11.1 ± 26.6</td>
<td>−7.9 ± 19.8</td>
</tr>
<tr>
<td>No-Mb</td>
<td>157.5 ± 42.9</td>
<td>149.6 ± 58.6</td>
<td>133.4 ± 42.8</td>
<td>−19.5 ± 23.4</td>
<td>−11.9 ± 10.4</td>
</tr>
</tbody>
</table>

P < .05. T1 = 1 week; T2 = 9 months; Δ = difference.

**Table 6**  
**Sinus Mucosa Thickness at Various Periods of Evaluation**

<table>
<thead>
<tr>
<th>Group</th>
<th>T0</th>
<th>T1</th>
<th>T2</th>
<th>Δ T1 - T0</th>
<th>Δ T2 – T1</th>
<th>Δ T2 – T0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mb</td>
<td>3.3 ± 3.5</td>
<td>6.4 ± 6.4</td>
<td>1.7 ± 1.5*</td>
<td>3.1 ± 4.0</td>
<td>−4.7 ± 5.4</td>
<td>−1.5 ± 2.5</td>
</tr>
<tr>
<td>No-Mb</td>
<td>2.9 ± 3.3</td>
<td>6.8 ± 6.0</td>
<td>1.0 ± 0.7*</td>
<td>3.8 ± 6.7</td>
<td>−5.8 ± 6.0</td>
<td>−1.9 ± 3.6</td>
</tr>
</tbody>
</table>

Data in millimeters. *P < .05; none of the differences was statistically significant between Group A and Group B. T1 = 1 week; T2 = 9 months; Δ = difference.
was identified at 12.5 mm and 11.9 mm above the sinus floor, at the membrane and no-membrane sites, respectively. After 9 months of healing, a vertical reduction < 1 mm was observed in both groups. The increased height of the sinus floor was included between 11 and 12 mm in both groups so that, incorporating the original dimension of the sinus floor, a total height of 14 mm was available for implant placement.

The pentacalcium hydroxide trisphosphate used for augmentation allowed the shrinkage of the augmented space to be contained to 8% to 15% in 9 months of healing. The vertical and horizontal shrinkage of the augmented sinus depends on the biomaterial used, as shown in a systematic review that considered the volume reduction of various filler materials. The higher shrinkage was observed when autogenous bone was used. When a collagenated corticocancellous porcine shrunken bone was used for sinus floor elevation, a vertical reduction of 1.4 to 3 mm and a dimensional shrinkage of approximately 18% to 25% of the augmented sinuses were observed after 9 months of healing.

In the present study, the reduction in height and dimensions was higher in the no-membrane compared with the membrane groups in the middle and, especially, in the lateral aspects, even though the difference did not reach statistical significance. This might be related to a higher loss of xenograft through the antrostomy in the group without a membrane. Nevertheless, a lack of biomaterial through the antrostomy was also described with the use of collagen membranes both in experimental and human studies.

In the present study, the floor of the nose was used as a reference (x-axis and z-axis) and approximately corresponded to the PNR that represents an important clinical reference. A proper elevation of the sinus mucosa at the palatal aspect allows the exposure of the sinus bone walls, which is an essential source of new bone. The mean top level of the biomaterial at the palatal aspect was located 1.3 to 2.6 mm below the x-axis, not reaching the PNR. It has to be considered that when the vertical distance between the sinus floor and the PNR is too short, the elevation of the mucosa beyond the PNR might be required. In such cases, the angle formed between the palatal and nasal walls will be of great importance. In fact, PNR < 90 degrees is considered a risk indicator in sinus floor elevation for possible perforations of the mucosa during the procedures of detachment from the bone walls. In the present study, in three cases in the no-membrane and four cases in the membrane groups, the sinus mucosa was elevated beyond the PNR, as evaluated at the 1-week CBCTs. In none of these cases was the angle < 100 degrees.

The position and the diameter of the PSAA has clinical relevance because the location of the osteotomy may include the artery, and depending on its diameter, possible damage to this vessel may create a hemorrhage that might require an additional surgical treatment to interrupt the bleeding. In the present study, an air-sonic device was used for antrostomy preparation, and two small perforations of the sinus mucosa were observed. Such devices have been proven to decrease the incidence of perforations of the sinus mucosa as well as damage to the soft tissues, including vessels.

The mucosa width after 1 week of healing doubled the dimensions. This agrees with various other reports. In previous studies, it was shown that after 9 months of healing, the width of the mucosa regressed to the original dimensions. In the present study, the sinus mucosa thickness was 2.9 to 3.3 mm before surgery, which was thicker compared with that reported in the studies cited above. This was due to some sinuses that presented a width > 4 mm in both groups. After 9 months of healing, the width of the sinus mucosa was approximately half of that registered before surgery. This reduction mostly occurred to the mucosa that were originally > 4 mm.

The main limitation of the study was the lack of histologic data describing the healing after 9 months and long-term results. Other studies have compared the results after sinus floor elevation performed with or without a membrane covering the antrostomy. In one of these studies, patients underwent bilateral sinus floor elevation, and nonresorbable membranes were used to cover only one antrostomy, while the other window was left without coverage. More vital bone and higher implant survival were observed in the membrane group. In another similar study, 64 sinus floor elevations were performed in 51 patients. The lateral windows were covered with resorbable or nonresorbable membranes or left uncovered. More vital bone was found in the membrane groups. However, a systematic review with meta-analysis could not find differences in vital bone content in both protected and unprotected antrostomies.

Another limitation was the small number of patients included. A larger sample might have allowed a statistically significant difference to be reached at least in relation to the area loss. No pins were used to stabilize the collagen membrane, so a possible dislocation of the membrane might have affected the healing.

CONCLUSIONS

This study has shown limited effects of the protective coverage of the antrostomy with a collagen membrane on dimensional variations over time.
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vestigator of ARDEC Academy. All the other authors declare no
conflicts of interest regarding this study.

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