In a systematic review with meta-analysis on sinus floor elevation, different variables influencing the outcomes were analyzed. It was observed that the best results were obtained when implants with a rough surface and membrane on the antrostomies were used. However, no evaluations on different dimensions or position of the antrostomies were performed.

In a split-mouth randomized controlled trial (RCT), 16 patients underwent bilateral sinus floor elevation. Computed tomography scans were taken before surgery and after 6 months of healing. Antrostomies of different dimensions, either 6 × 6 mm (area of 36 mm²) or 8 × 10 mm (area of 80 mm²), were randomly prepared in each patient. The elevated space was filled with deproteinized bovine bone mineral, and the antrostomies were covered by a collagen membrane. No difference was found between the two groups in terms of bone augmentation height.

In another RCT, sinus floor elevation using lateral access was performed in 24 patients. Antrostomies measuring 8 mm (area of ~100 mm²) or 4 mm in height (area of ~50 mm²) were randomly prepared in each patient. The elevated space was filled with deproteinized bovine bone mineral, and the antrostomies were covered by a collagen membrane. No difference was found between the two groups in terms of bone augmentation height.

A strong negative correlation was seen between the window dimensions and

In another clinical study, the influence of the dimensions of the antrostomy on osseointegration of mini-implants placed in the grafted region after sinus floor elevation was evaluated. The smallest window measured 36 mm² and the largest 146 mm². A strong negative correlation was seen between the window dimensions and

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1Department of Oral Implantology, Osaka Dental University, Hirakata city, Osaka, Japan.
2Associate Professor, Department of Medical, Oral and Biotechnological Sciences, University of Chieti-Pescara, Chieti, Italy.
3Full Professor, Department of Medical, Oral and Biotechnological Sciences, University of Chieti-Pescara, Chieti, Italy; Chair of Biomaterials Engineering, Catholic University of San Antonio of Murcia (UCAM), Murcia, Spain.
4Doctor, Corporación Universitaria Rafael Núñez, Cartagena de Indias, Colombia.
5Doctor, ARDEC Academy, Rimini, Italy.

Correspondence to: Dr Karol Ali Apaza Alccayhuaman, ARDEC Academy, Viale Pascoli 67 – 47923 Rimini, Italy. Fax: +39 0541 393444. Email: caroline7_k@hotmail.com

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the presence of new bone. However, in that study, the position of the antrostomy and of its lower margin was not reported. Moreover, data on the osseointegration of implants placed in the augmented antral region at which lateral windows of different dimensions were performed are missing.

Hence, the aim of the present study was to evaluate the osseointegration of mini-implants placed in grafted sinuses with lateral windows of two different dimensions.

The hypothesis was that a higher bone-to-implant contact of the mini-implants would be observed in the group with smaller compared with larger dimensions of the antrostomies.

MATERIALS AND METHODS

The study was approved by the Ethical Committee of the University Corporation Rafael Núñez, Cartagena de Indias, Colombia (protocol #01-2015; May 19, 2015) and performed at the same university. This study reported the histologic outcomes of mini-implants placed in the grafted region 6 months after maxillary sinus elevation. The data from the CBCT analyses from the same group of patients were reported elsewhere.

The Helsinki Declaration was respected, and informed consent was obtained from the patients at the inclusion in the study. The CONSORT indications were followed (http://www.consort-statement.org/).

Study Population

In the present randomized clinical study, the participants were recruited for sinus floor elevation. The inclusion criteria were: (1) residual bone height ≤ 4 mm in a posterior maxilla region; (2) patient’s desire for a fixed prosthetic rehabilitation supported by implants; (3) ≥ 21 years of age; (4) in good systemic health; and (5) not pregnant. The patients were excluded if they presented: (1) systemic and immunologic not-controlled diseases; (2) chemotherapeutic or radiotherapeutic treatment; (3) acute or chronic sinus pathology; (4) previous bone regenerative treatments in the region; (5) bisphosphonates treatment; or (6) heavy smoking habit.

No previous data on osseointegration were available on implants placed in the sinus floor augmented through antrostomies of different dimensions. In the present study, to test the dimensional variations evaluated on CBCT images, a sample size of n = 10 was obtained. Considering a difference in osseointegration of at least 10% to 15%, 10 patients for the group were also considered sufficient to provide a statistically significant difference, if it exists.

Two groups were defined: the large group with antrostomies 8 mm high and the small group with antrostomies 4 mm high.

The allocation of the treatments (8 mm or 4 mm) was randomly assigned. The randomization was performed at randomization.com by an author that did not carry out the sinus floor augmentation (M.F.).

The information of the treatment allocation was revealed to the surgeon at the time of the surgery, opening sealed opaque envelopes. The patients were blinded to the dimensions of the antrostomy. The histologic slides were coded so that the histologic outcomes assessor was blinded to the large and small group allocation.

Clinical Procedures

Detailed information about the clinical procedures are described in a previous report. Briefly, after having injected local anesthesia, the flaps were raised and the antrostomies of 8 or 4 mm in height were prepared using a sonic-air instrument (Sonosurgery TKD). The elevated space was filled with collagenated corticocancellous porcine bone (OsteoBiol Gen-Os, 250 to 1,000 µm, Tecnoss), and a collagen membrane (OsteoBiol Evolution, 0.3 mm, Tecnoss) was placed on the antrostomy. The flaps were subsequently sutured. The sutures were removed after 1 week.

After 6 months of healing, a mini-implant, 8 mm long and 2.4 mm in diameter (Sweden & Martina), with a moderately rough surface (ZirTi, Sweden & Martina), was placed at the crestal level and in a submerged fashion in the position of the definitive implants, located in the grafted region. Three months later, biopsy specimens containing the mini-implants were harvested with a trephine bur with 3.5 mm of internal and 4 mm of external diameters (GA33M, Bontempi Strumenti Chirurgici). The trephine was used in an eccentric mode. Definitive implants were subsequently placed in the same position.

Postoperative Therapy

Antibiotic therapy was prescribed, based on amoxicillin 875 mg and clavulanic acid 125 mg twice per day for 6 days, and ibuprofen 400 mg three times per day for 3 days. Mouthrinses with 0.12% chlorhexidine three times a day for 10 days were also recommended.

Histologic Preparation

The biopsy specimens were fixed in 10% formalin, and afterward dehydrated in an ascending series of alcohol. Consequently, the specimens were incorporated in a glycol-methacrylate resin (Technovit 7200 VLC, Kulzer) and polymerized. The sections were performed following the long axis of the mini-implants, and ground sections of ~30 µm of width were obtained. The staining was carried out with acid fuchsins and toluidine blue.

Histomorphometric Evaluation

Before performing the measurements, a calibration was done with another author (D.B.), and K > 0.9 of interrater
agreement was achieved. Two histomorphometric measurements were performed for each histologic slide by a well-trained examiner (K.A.A.A.), who was blinded to the allocations code. Mean values were calculated for the two measurements. High-resolution photographs with $100 \times$ magnification were taken at an Eclipse Ci microscope (Nikon Corporation) equipped with a motorized stage (EK14, Nikon Corporation). The measurements were performed at $100 \times$ magnification with the software NIS-Elements D 5.11 (Laboratory Imaging, Nikon Corporation).

The histometric measurements were performed from the most coronal (B) to the most apical contact (A) of the bone to the mini-implant surface. The measurements included the following tissues in contact with the mini-implant surface: newly formed bone, old bone (preexisting bone), marrow spaces, and residues of xenograft granules. The region of interest for the morphometric measurements was included between A and B and a region up to 400 µm from the mini-implant surface. A point-counting method was employed (Schroeder and Münzel-Pedrazzoli) using a lattice with squares of 75 µm superposed over the histologic images. The tissues included in the evaluation were as follows: new bone, old bone (preexisting bone), marrow spaces, and residues of xenograft granules. The total mineralized bone was calculated as the sum of new and preexisting bone for both histometric and morphometric data.

### Data Analysis

The primary outcome variable was new mineralized bone for both histometric and morphometric data. The other outcome variables were considered as secondary ones.

#### RESULTS

Twenty-four volunteers were enrolled in the study. Perforations were observed in four sinuses, three of which were protected with a collagen membrane, and the patients were maintained in the study; however, one patient was excluded for the dimensions of the perforation. Three patients did not follow the timing scheduled for the CBCTs, so they had to be excluded. Biopsy specimens were retrieved from 20 patients, 10 for each group ($n = 10$; Fig 1). Twelve patients were women and eight men, with a mean age of $56.6 \pm 9.5$ years. The area of the antrostomy as evaluated clinically was approximately $49 \text{ mm}^2$ and $98 \text{ mm}^2$ at the small and large groups, respectively, with the difference being statistically significant. Bone quality at implant site preparation was mostly of type III, with the exclusion of two sites presenting type II and type IV, respectively. All mini-implants were stable at placement.

At the biopsy specimen retrieval, the mini-implants were maintained within the trephines and appeared to be located eccentrically in respect to the trephine. This procedure was applied to reduce the dimensions of the biopsy specimens and of the donor sites, and yet to retain enough tissue at one side for the histologic evaluation (Figs 2a and 2b).

Mean values and standard deviation (SD) are reported in the text, while in the tables, 25th, 50th (median), and 75th percentiles are also reported. The Mann-Whitney test was used to analyze differences between the large and small groups using $\alpha = .05$. 

### CONSORT 2010 flow diagram.

![ CONSORT 2010 flow diagram.](image)
New bone and marrow spaces were found around and in contact with the mini-implants, and optimal osseointegration of the mini-implant surface to the newly formed bone was observed (Figs 3a and 3b). Old preexisting bone was still present in the crestal region (Fig 3c), and in some instances was still in contact with the implant surface (Fig 3d). Residues of xenograft were observed, consolidated into newly formed bone (Fig 4a), and in some instances in close contact with the implant surface, with no bone interposed (Fig 4b).
Histometric Measurements

The new mineralized bone in contact with the mini-implant surface was found at proportions of 41.1% ± 19.5% and 42.8% ± 13.2% at the large and small groups, respectively (P = .940) (Table 1, Fig 5). The preexisting bone was present at proportions of 1.9% ± 3.5% at the large and 8.1% ± 7.5% at the small groups (P = .014), which promoted a total amount of mineralized bone of 43.1% ± 21.3% and 51.0% ± 11.2%, respectively (P = .450). The marrow spaces were found at percentages of 56.4% ± 21.3% and 43.1% ± 16.4% in the large and small groups, respectively (P = .226). Residues of xenograft were represented by 0.6% ± 1.1% in the large group and 5.9% ± 9.5% in the small group (P = .098). No osteoclasts and no inflammatory cells were seen on the residual xenograft surface.

Morphometric Measurements

Marrow spaces were the most represented tissue around the mini-implants, reaching fractions of 60.5% ± 10.5% and 49.7% ± 12.2% (P = .130) (Table 2; Fig 6). Newly formed bone was found at percentages of 31.7% ± 8.2%, and 34.0% ± 7.9% (P = .623) in the large and small groups, respectively. Preexisting bone was present in fractions of 2.4% ± 3.1% in the large group and 7.8% ± 9.4% in the small group (P = .131), contributing
to an amount of total mineralized bone of 34.1% ± 9.2% and 41.9% ± 11.1%, respectively. Residual xenograft was still present in low proportions, with 2.5% ± 3.3% in the large group, and 7.3% ± 6.7% in the small group (P = .129). Vessels were represented by 2.9% ± 2.4% and 1.2% ± 1.0% in the large and small groups, respectively (P = .103).

**DISCUSSION**

In the present study, similar surgical procedures, bone filler, collagen membrane, and mini-implants were used in both the large and small groups. However, antrostomies of different dimensions were prepared, and no differences were found between the two groups in terms of new bone-to-implant contact and new bone density around the mini-implants. This, in turn, means that the dimensions of the antrostomy had no influence on the histologic outcomes in relation to new bone formation.

The present results are not in agreement with the data reported in a clinical study in which 24 sinus floor elevations were performed in 21 patients. It was shown that the larger the lateral window, the lower the percentage of vital bone formed, presenting a strong negative correlation (r = –0.62). However, when the data for windows below 80 mm² were evaluated, no linear relationship was obtained (r ~ 0.12). Moreover, in that study, the distance of the lower margin of the antrostomy from the sinus floor was not considered in the evaluations. The importance of leaving portions of the lateral wall to promote bone formation at the base of the sinus floor, which is an important region in which the implant will be inserted and will integrate, should be emphasized.

The sinus bone walls represent the most important source for new bone formation; thus, it is important to completely expose the bone walls around the grafted region during sinus mucosa elevation, and to leave portions of the lateral walls (balcony) above the sinus floor.

The data from the clinical and tomographic assessments of the present study had been reported in a previous article. The mean height of the bone crest as evaluated on the tomography images was ~3.5 to 3.6 mm, while the base of the antrostomies was located at ~3.7 to 4.0 mm from the sinus floor, hence leaving part of the lateral bone wall as protection of this region. The total distance of the base of the antrostomy from the alveolar crest, and from the coronal margin of the mini-implants, was ~7.3 to 7.5 mm. This means that most of the mini-implant body, which was 8 mm long, was protected by the lateral wall, while only a small portion of the apex was located, as a mean value, slightly above the base of the antrostomy in both groups. These similar clinical conditions in the two groups that resulted below the lower margin of the antrostomy might have contributed to obtain similar outcomes. However, the present study does not report histologic data of the regions above the apex of the implants, located at the level of the antrostomies.

In the present study, the mini-implants had a moderately rough surface, and they were placed 6 months after surgery and analyzed histologically. It was shown that the larger the lateral window, the lower the percentage of vital bone formed, presenting a strong negative correlation (r = –0.62). However, when the data for windows below 80 mm² were evaluated, no linear relationship was obtained (r ~ 0.12). Moreover, in that study, the distance of the lower margin of the antrostomy from the sinus floor was not considered in the evaluations. The importance of leaving portions of the lateral wall to promote bone formation at the base of the sinus floor, which is an important region in which the implant will be inserted and will integrate, should be emphasized.

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after sinus floor elevation. A mean osseointegration of ~41% to 43% was observed.

The results are in agreement with another study in which, however, mini-implants with a turned surface were used. Sinus floor elevation was performed using deproteinized bovine bone matrix (DBBM) alone, or autogenous bone alone, or 80% of autogenous bone mixed with 20% of DBBM. The mini-implants were placed after 6 to 9 months in the lateral wall of the sinus, within the grafted region. After a further 6 months, biopsy specimens were retrieved, and the mini-implants were found integrated with a bone-to-implant contact ranging between 31.6% and 54.3%.

Both the present study and the aforementioned study evaluated the histologic healing of mini-implants placed at least 6 months after sinus floor elevation, which means they were placed into healed sites containing vital bone. These clinical conditions within the augmented sinus floor might be considered similar to that of an edentulous alveolar ridge. This means that the healing processes should also be similar, even though in the present study, the hard tissue was composed of newly formed bone and xenograft residues. This also means that bone formation will occur from multiple regions around the implants in both the augmented sinus floor and the alveolar bone crest. In such conditions, the osteoconductive properties of the implant surface have an impact on osseointegration, but up to a limited extent. However, in the case of simultaneous implant placement, the surface might play a very important role, as shown in other clinical studies in which mini-implants were placed immediately after sinus floor elevation.

In clinical studies, mini-implants with a moderately rough surface (sandblasted large-grit acid-etched [SLA]) were placed immediately after sinus floor elevation, performed using biphasic calcium phosphate (BCP) or DBBM. Biopsy specimens were retrieved after 6 to 8 months. A bone-to-implant contact ranging from ~35% to 38.4% or ~55% to 65% was found. However, when mini-implants with a turned surface were placed at the time of sinus floor elevation, a bone-to-implant contact of 2% and 10% was observed at the sites augmented with allograft or autograft, respectively.

In the present study, low amounts of residual xenograft were observed after 9 months of healing, showing a trend of slightly higher amounts at the small compared with the large groups. This might be related to a higher loss of biomaterial through the large compared with the small antrostomies. This is in agreement with another study that evaluated the influence of the dimensions of the lateral window on the healing in the elevated space after sinus floor elevation. A positive correlation between the dimensions of the antrostomy and the percentages of residual biomaterial was observed.

Particles of residual xenograft were found in contact with the implant surface in the present study. Obviously, this contact was obtained at the time of implant placement, performed 6 months after sinus floor elevation. No resorptive processes and bone formation occurred to separate this residual xenograft from the implant surface during the following 3 months of healing. In a previous report, biopsy specimens without mini-implants were retrieved 9 months after sinus floor elevation performed using a corticocancellous porcine bone, and residual xenograft was found at proportions of ~15%. In the present study, only 7.3% and 2.5% of xenograft was found at the small and large groups, respectively. These lower percentages, compared with those of the aforementioned study, might be related to possible resorptive processes triggered by the placement of the mini-implants, which might have contributed to the xenograft resorption during the 3 months of healing after placement. It should be mentioned that the placement of an implant as well as its surface generate a strong cellular and immunologic reaction in the surrounding tissues.

The height of the antrostomy should be considered in relation to the position of the posterior superior alveolar artery (PSAA). In fact, an injury to this artery might be responsible for intraoperative hemorrhagic events. A limitation of the present study that should be considered is that the length of the mini-implants used did not reach the whole region of the antrostomy. Longer mini-implants could have been used. However, it must be considered that the use of longer mini-implants would have required a higher elevation of the sinus floor, more filler material to be used, and a more invasive surgical procedure to retrieve the mini-implants.

Further studies should be performed to explore other variables, such as antrostomy dimensions or the use of different bone fillers.

CONCLUSIONS

The outcomes from this study showed that the dimensions of the antrostomy did not influence the histologic healing at implants placed 6 months after sinus floor augmentation. No higher bone-to-implant contact at the mini-implants was observed in the group with smaller compared with larger dimensions of the antrostomies.

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