Cone beam computed tomography assessment on the influence a collagen membrane placed subjacent the sinus mucosa after maxillary sinus floor augmentation. A randomized clinical trial.

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Conflict of Interest Statement

The authors declare no conflict of interest regarding this study. Tecnoss srl, Giaveno, Italy will provide all biomaterials. Sweden & Martina SRL, Due Carrare, Padua, Italy and ARDEC Academy, Ariminum Odontologica s.r.l., Rimini, Italy will cover the costs of the study.
Abstract

**Aim:** to seek for differences in dimensional variations of augmented maxillary sinuses with or without the placement of a collagen membrane subjacent the sinus mucosa.

**Material and Methods:** After the elevation of the maxillary sinus mucosa, a collagen membrane with standard dimensions will be placed at the test sites subjacent the sinus mucosa and the elevated space will be filled with a xenograft, both test and control groups. A collagen membrane will be placed to cover the antrostomy at both groups and sutures will be provided to close the wound. CBCTs will be taken for all patients before surgery (T0), after 1 week from sinus floor augmentation (T1) and after 9 months of healing (T2). Dimensional changes over time of soft and hard tissues will be evaluated on the CBCTs.
Introduction

The perforation of the sinus mucosa during sinus floor augmentation is a complication that has been reported in several clinical1-4 and experimental studies5,6 with an occurrence that varies between 10 and 55%. Dislodgement of the biomaterial and sinusitis may represent a consequence of the perforation.2 Small perforations may not require any treatment because, after the elevation and relaxation of the sinus mucosa, the margin of the perforation may collapse together and close the defect.7 Perforations of larger dimensions may be closed using sutures1,8,9 or fibrin glue.1,8,10 Collagen membranes were also used to protect the perforations of the sinus mucosa and good outcomes have been claimed.3,4,11-16 Several experimental studies have been performed to evaluate histologically the influence of a collagen membrane placed subjacent the sinus mucosa in the absence5,16 or presence of perforation17 and no differences were seen in the healing outcomes. However, there is still a lack of clinical information about how the placement of a collagen membrane between the sinus mucosa and the graft may influence dimensional variations and healing at augmented maxillary sinuses. Hence, the aim of this randomized clinical trial will be to seek for differences in dimensional variations of augmented maxillary sinuses with or without the placement of a collagen membrane subjacent the sinus mucosa.

Material and methods

The protocol was approved by the Ethical Committee of the University Corporation Rafael Núñez, Cartagena de Indias, Colombia (protocol #03-2015; 4 December
2015) and the Declaration of Helsinki on medical protocols and ethics will be followed. This study will be submitted for registration to ClinicalTrials.gov PRS (https://clinicaltrials.gov) to obtain the NCT. The patients will be informed about the procedures and the possible complications and signed informed consents will be obtained. The Consort checklist will be followed for this study (http://www.consort-statement.org/).

**Study population**

For the present randomized clinical trial, all recruitments, surgeries and follow-ups will be carried out at the University Corporation Rafael Núñez, in Cartagena de Indias (Colombia). To calculate the sample size, the data from an article that assessed the variations over time in height of the augmented sinuses were used.\(^\text{18}\) It was calculated that an n=10 was sufficient to show differences, if exist. An author not involved in the surgeries will perform the randomization process (MF). The assignments will be sealed within opaque envelopes that will be opened after the completion of the elevation of the sinus mucosa.

The following inclusion criteria have to be fulfilled:

(i) presence of an edentulous atrophic zone in the posterior segment of the maxilla;

(ii) height of the sinus floor \(\leq 4\) mm;

(iii) desiring a prosthetic restoration of the zone using a fix prosthesis supported by implants;

(iv) \(\geq 21\) years of age;

(v) good general health;

(vi) no contraindication for oral surgical procedures;
(vii) not being pregnant.

The patients will be excluded if they:

(i) present a systemic disordered;
(ii) had a chemotherapeutic or radiotherapeutic treatment;
(iii) are smokers >10 cigarettes per day;
(iv) have an acute or a chronic sinusitis;
(v) had a previous bone augmentation procedures in the zone of interest.

Biomaterial used

The filler material will be a collagenated corticocancellous porcine bone granules (Gen-Os, 250–1000 µm, OsteoBiol, Tecnoss, Giaveno, Italy).

The membrane used subjacent the sinus mucosa at the test sites and to cover the antrostomy at both test and control sites the control sites will be an equine collagen membrane (Evolution, 0.3 mm, OsteoBiol, Tecnoss).

Clinical procedures

The lateral wall of the maxillary sinus will be exposed and osteotomies of about 6 mm in height and 10 mm long will be prepared using a diamond insert (SFS 109 029), Komet-Brasseler-GmbH, Germany) mounted on a sonic-air surgical instrument (Sonosurgery® TKD, Calenzano, Fi - Italy). The sinus mucosa will be elevated and, at the test sites, a collagen membrane will be placed subjacent the sinus mucosa. Subsequently, the elevated space will be filled with the xenograft both at the test and control sites. A collagen membrane will be used to protect the antrostomies and the soft tissues wounds will be sutured.

Amoxicillin 875 mg with clavulanic acid 125 mg twice a day for 6 days, non-steroidal anti-inflammatory drugs as needed, and mouth rinses with 0.12%
chlorhexidine three times a day for 10 days will be recommended. The sutures will be removed after 7 days, and the patients will be enrolled in a maintenance program for the full extent of the study.

**CBCT imaging procedures**
Cone bean computed tomographies (CBCTs) will be taken at three different periods: before the sinus floor elevation (T0); one week (T1) and 9 months (T2) after surgery.

**CBCT imaging analyses**
All radiographic evaluations will be performed with the software i-Dixel 2.0 (J. Morita Corporation, Kyoto, Japan). As references, a line drew following the floor of the nose will be used both in the coronal view (axis X) and in the lateral view (axis Z).

**The Results Data Element Definitions**
The following parameters will be evaluated: mucosa thickness, bone crest height, nasal floor height from the base of the sinus, superior posterior alveolar artery height and diameter, sinus width, distance between the inferior margin of the antrostomy and the base of the sinus, antrostomy height, sinus length in the lateral view, the largest length of the xenograft/ hard tissue in the lateral view.

The variation in height and area of the elevated region will be evaluated among the CBCT taken in the various periods of healing.
Outcomes measures

Primary outcome: Changing in height of the elevated zone.

Description: Measurements will be assessed in the medial, middle and lateral regions of the elevated zone using the cone beam computerized tomographies (CBCTs) taken in various periods. Comparisons among the CBCTs of each participants will be performed.

Timeframe: The CBCTs will be taken before surgery (T0) and 1-week (T1) and 9 months (T2) after surgery.

Secondary outcome: Changing in mucosa thickness.

Description: Measurements will be assessed in the cone beam computerized tomographies (CBCTs) taken in various periods. Comparisons among the CBCTs of each participants will be performed.

Timeframe: The CBCTs will be taken before surgery (T0) and 1-week (T1) and 9 months (T2) after surgery.

Other pre-specified outcomes: (C-F) bone crest height, (X-F) nasal floor height, (A-C) anastomosis height and (AD) its diameter, (XW) sinus width, (LM-F) balcony height, (LM-UM) window height, (ZW) sinus length, (ZE) the largest length of the xenograft/ hard tissue, T0 X-area and T0 Z-area.

Description: Measurements will be assessed in the medial, middle and lateral regions of the elevated zone using the cone beam computerized tomographies (CBCTs) taken in various periods. Comparisons among the CBCTs of each participants will be performed.

Timeframe: The CBCTs will be taken before surgery (T0) and 1-week (T1) and 9 months (T2) after surgery.
Data analysis

The radiographic measurements will be performed twice by a well-trained researcher that will be blinded about the differences in the protocols. Mean values will be obtained between the two measurements and used for analyses. Mean values and standard deviations (SD) will be calculated for each outcome variable. Differences between the groups will be analyzed using the Mann-Whitney test. The level of significance will be set at α=0.05.

References


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