A novel approach to manage Schneiderian membrane perforation in the maxillary sinus floor augmentation: The "Sinus Pack" technique. Histomorphometric analysis. Part 2/3

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Abstract: Purpose: This retrospective study examined the histomorphometrical outcomes resulting from managing Schneiderian membrane perforation during maxillary sinus floor augmentation using two different approaches and relating the results to perforation size. **Methods:** 19 subjects (7 males, 12 females, mean age 53.3±10.5 years), who experienced a sinus membrane perforation during lateral sinus lift procedure, were enrolled. Perforations were addressed utilizing either the "Sinus Pack" technique (test group, 11 subjects) or collagen membranes with absorbable sutures (control group, 8 subjects). The "Sinus Pack" consisted of a combination of collagenic porcine bone, polyunsaturated fatty acids, and a biocompatible synthetic copolymer, wrapped in a resorbable porcine mesenchymal collagen membrane. Histomorphometry outcomes of both techniques were compared. **Results:** The percentage of vital bone was significantly higher with the "Sinus Pack" approach (44.5% ± 19.8%) compared to the control group (26.3% ± 21.2%) (P= 0.045). (*Am J Dent* 2024;37:18A-20A).

Clinical significance: The "Sinus Pack" approach for managing sinus membrane perforations appears to be effective and advantageous, as it has resulted in optimal histomorphometric outcomes, indicating a significant increase in vital bone.

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Introduction

The maxillary sinus floor augmentation is one of the most popular surgical procedures for increasing the available bone, to allow for implant placement. This procedure was first described in the early 1980s and has undergone some modifications over the years to improve the predictability of the outcome and minimize intraoperative complications and patient discomfort.[1,2] It can be performed by crestal[3,4] or lateral[5,6] approach. Among intraoperative complications, accidental membrane perforation is the most common (10%-56%) during sinus lift surgery.[7]

In addition to radiographic and clinical evaluation, the effectiveness of a sinus augmentation procedure is assessed by the level of viable bone growth after graft maturation and the sustained success rates of implants within that bone over time.[8] Functional remodeling and progressive replacement of the grafting material with vital tissue are required for successful graft consolidation.[9] This procedure necessitates the existence of a stable scaffold, adequate angiogenesis (blood supply), and the migration of osteogenic cells.[10]

Due to numerous studies in the literature, it has come to our attention that the healing process following sinus augmentation surgery exhibits significant variability in terms of waiting times, based on the type of bone graft material utilized during the surgical procedure.[11] As a result, the recovery period can exhibit significant variability.[12]

It is important to note that there are relatively few comparative studies in the literature that focus on the histomorphometric results after sinus perforation repair using different techniques. In most cases, outcomes of new bone formation between grafting materials are compared.[13]

This retrospective study evaluated histomorphometrically the surgical management of sinus membrane perforations using two techniques: (1) the use of collagen membranes and resorbable sutures[14] and (2) a new method of graft management, the "Sinus Pack" technique,[15] and relate them to the size of the membrane perforation.

Materials and Methods

This pilot study was designed to retrospectively assess subjects who underwent sinus lift procedures using the lateral wall technique between September 2019 and October 2022. A group of subjects with sinus membrane perforation, managed with either the "Sinus Pack" technique or collagen membrane coverage, was specifically chosen for analysis.

The study adhered to the principles outlined in the 1975 Declaration of Helsinki, with subsequent revisions up to 2013. Informed consent was obtained from each patient following a detailed explanation of the clinical procedures.

Approval for the study was granted by the Ethics Committee/Institutional Review Board of the "Fondazione Policlinico Universitario A. Gemelli", (Protocol number 0009738/22).

Details of this study regarding the set-up, population, inclusion and exclusion criteria, and clinical and surgical procedures, are reported in Part 1 (1/3) of this study in this same American Journal of Dentistry Special issue.[16]

During the surgical procedure, when membrane perforation was detected, the maximum distance between clinically detectable perforation margins was measured with a periodontal probe.

Six months postoperatively, a CBCT scan (Pax-i3D Smart,[a] 50-99 kVp/ 4 - 16 mA) was performed to evaluate bone volume at the augmentation site, before planning implant placement.

Table 1. Univariate analysis of surgical outcomes and perforation size.

	Perforation size						
	< 5 mm (n = 9)	5-10 mm (n = 4)	> 10 mm (n = 6)	P	0-5 mm (n = 9)	≥ 5 mm (n = 10)	P
Vital bone, %	33.2 (27.0)	34.8 (24.0)	45.7 (11.9)	0.730	33.2 (27.0)	40.1 (16.7)	0.497
Soft tissue, %	25.6 (25.7)	16.0 (7.1)	27.2 (27.5)	0.983	25.6 (25.7)	22.7 (21.7)	0.905
Non-absorbable granules, %	12.1 (8.4)	7.8 (9.0)	8.2 (7.0)	0.551	12.1 (8.4)	8.1 (7.4)	0.356

Then, titanium dental implants (Neodent[b]) were inserted into the grafted areas, following the manufacturer's guidelines and a two-stage protocol.

At the same time as implant placement, a 10 mm-deep bone sample was taken crestally with a 3 mm inner diameter trephine drill[c] at the implant site and submitted for histological analysis. Each bone core biopsy was analyzed starting from at least 4 mm beyond the residual ridge height.

Histomorphometric analysis was performed by an independent examiner. Bone samples were fixed in 10% phosphate-buffered formalin, followed by decalcification in a hydrochloric acid/formic acid solution (4/5%). After decalcification, samples were dehydrated in a series of alcohol baths and then embedded in paraffin. Full-length 5 µm-thick histological sections were then prepared and stained with hematoxylin-eosin. Sections were digitally scanned at various magnifications, and images of each area were analyzed using image analysis software (ImageJ[d] public domain software) and LOCI-Laboratory for Optical and Computational Instrumentation.[e] The percentage of residual graft particles, newly formed bone, and other tissue components (bone marrow and/or connective tissue) in each sample was assessed (Figure).

Statistical analysis - Data were reported as mean ± standard deviation (SD), median and range (min-max) for quantitative variables, and relative frequencies and percentages for qualitative variables. Frequencies were compared through the univariate chi-square and Fisher's exact test, while comparisons on quantitative data were performed through the Kruskal-Wallis test with Dunn's procedure in case of more than two groups (i.e., sinus angle or perforation size) and the Mann-Whitney U test for comparisons between two groups. Statistical significance was set at 5% ($P < 0.05$). Analyses were performed through STATA17.[f]

Results

Nineteen subjects (7 males, 12 females, mean age 53.3± 10.5 years) who experienced a membrane perforation during lateral sinus lift procedures were included. The perforations were managed using the "Sinus Pack" technique (test, 11 subjects) or collagen membranes and absorbable sutures (control, eight subjects).

The histomorphometric results, derived from a univariate analysis of surgical outcomes and perforation size, revealed that for the nine perforations smaller than 5 mm, the percentage of vital bone reached 33.2%, soft tissue accounted for 26.5% and non-absorbable granules constituted 12.1%.

In contrast, for four perforations between 5 and 10 mm in size, the percentage of vital bone reached 34.8%, soft tissue rated for 16% and non-absorbable granules constituted 7.8%. Instead, for six perforations larger than 10 mm, the percentage of vital bone achieved 45.7%, soft tissue represented 27.2%, and non-resorbable granules made up 8.2% (Table 1).

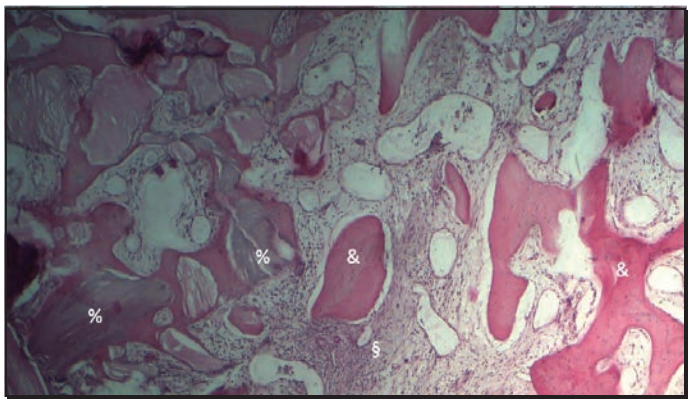

Figure. Histological sample. H&E staining. Legend: %: Xenograft particles, &: Vital bone, §: Soft tissue. 25×

Table 2. Comparison between surgical techniques on histomorphometric outcomes. Quantitative data are expressed as mean values (standard deviation).

	Sinus Pack (n = 11)	Covering+suture (n = 8)	P-value
Vital bone, %	44.5 (19.8)	26.3 (21.2)	0.045**
Soft tissue, %	19.8 (20.4)	30.1 (26.4)	0.395
Non-resorbable granules, %	9.7 (8.0)	10.3 (8.3)	0.840

** Statistically significant.

Analyzing the histomorphometric results obtained from the comparison of the two techniques employed for sinus membrane repair, the "Sinus Pack" technique, performed on 11 subjects, yielded a mean percentage of vital bone of 44.5%, a mean percentage of soft tissue of 19.8%, and a mean percentage of non-absorbable granules of 9.7%. In contrast, utilizing the covering + suture technique on eight subjects resulted in a mean percentage of vital bone of 26.3%, a mean percentage of soft tissue of 30.1%, and a mean percentage of non-absorbable granules of 10.3%. (Table 2)

Discussion

In this study, the percentage of vital bone in sinuses with perforated membranes repaired with "Sinus Pack" technique was almost double compared with those treated with collagen membranes and/or sutures (44.5 ± 19.8% vs. 26.3 ± 21.2%, respectively), with residual graft around 10% in both cases.

The results for porcine grafting agree with those of previous studies. Barone et al[17] found an average amount of newly formed bone of 43.9%

Correia et al[18] in a randomized clinical trial evaluated porcine cortico-cancellous collagenic bone mix (OsteoBiol mp3) in lateral maxillary sinus lift procedures and, based on histological, histomorphometric, clinical, and radiological results, concluded that it is a valid alternative to autologous bone grafts, due to its excellent osteoconductivity and biocompatibility, and to the absence of foreign body reactions or infections. They found a

percentage of total hard tissue volume of approximately 56%, including in this percentage the residual graft.[17]

Sinus perforations repaired with collagen membranes and sutures and grafted with bovine bone showed in the present study a percentage of vital bone similar to that previously reported by Testori et al[19] (22% to 26%) and Froum et al[8] (26%).

A possible explanation for the greater amount of bone present using porcine grafts in the Sinus Pack technique may be that the membrane was effective in containing and immobilizing the graft particles during the bone healing phase[8] and the (OsteoBiol GTO) porcine graft, thanks to the presence of copolymers that make it compact at body temperature and remains stable without undergoing micromovements. This is widely considered a determining factor for integration and revascularization.[20]

To facilitate vascularization of the biomaterial, it is important to use a resorbable membrane with a resorption time sufficient to give the Schneiderian membrane adequate time to heal. If the membrane will be resorbed fast, the space occupied by the collagen membrane could promote the deposition of bone cells derived from the periosteum and spongy bone, allowing the formation of new bone in this region. It has been demonstrated that new bone will form in the maxillary sinus lift even without the presence of biomaterial, replacing the space occupied by clotted blood.[21]

Only minor complications occurred in a small percentage of subjects and were all recovered without compromising graft healing. This agrees with Ding et al,[22] who reported that graft maturation is not affected by membrane perforation, and with the Froum et al[8] study in which no complications were reported after treatment of perforated membranes.

Conversely, in the study by Nolan et al[22] it was found that perforated sinuses had a three times higher risk of bone graft failure and six times higher incidence of infection or sinusitis than non-perforated sinuses. Different approaches to perforation management may lead to different results.

However, further studies involving a more extensive sample size are needed to bolster the results derived from histomorphometric analysis.

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