A novel approach to manage Schneiderian membrane perforation in the maxillary sinus floor augmentation: The "Sinus Pack" technique. A retrospective case-control study. Part 1/3

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Abstract: Purpose: This retrospective study evaluated the effectiveness of a technique for the management of maxillary sinus floor augmentation. **Methods:** Nineteen subjects [7 males, 12 females, mean age 53.3±10.5 (standard deviation) years], who experienced membrane perforation during lateral sinus lift procedure, were included. Perforations were managed either using the "Sinus Pack" technique (test, 11 subjects) or collagen membranes and resorbable sutures (control, eight subjects). Clinical and radiological outcomes were assessed. **Results:** The mean follow-up was 18.3± 11.7 months (range 5-40 months). A significantly lower mean vertical gain was observed in the control group (7.8± 0.9 mm), compared to the sinus pack approach (8.8± 0.9 mm) (P= 0.04), but both were effective for implant-prosthetic rehabilitation. (*Am J Dent* 2024;37:13A-17A).

Clinical significance: The "Sinus Pack" technique was effective in managing perforations during sinus floor elevation surgery, allowing the completion of the surgical procedure even in cases of large perforations.

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Introduction

The most common intraoperative complication during the sinus lift procedure is accidental perforation of the Schneiderian membrane, with a reported incidence ranging from 10% to 56%.[1] The main causes of sinus membrane perforation can be iatrogenic, derived by improper surgical handling or individual anatomical factors, which can make the procedure challenging.[2]

The occurrence of a perforation can lead to sinusitis, infection, graft failure, and blockage of the ostium. Perforations smaller than 5 mm can be treated by detaching and folding the membrane itself.[3] When perforations are larger in size, the most recommended treatment is the use of a slow-resorbing collagen membrane, with the possible use of a suture. Also, fibrin sealants or platelet concentrates such as PRF (platelet-rich fibrin) can be used to prevent graft particles from leaking into the sinus.[3]

For even larger perforations, the use of wide, thick collagen membranes attached to the outside of the antrostomy with nails, or sutured near the antrostomy, is indicated. Other techniques include the use of bone blocks (autologous or heterologous), cortical laminae, and buccal fat pads.[3]

This retrospective study evaluated clinically and radiographically the surgical management of sinus membrane perforations using: (1) collagen membranes and resorbable sutures and (2) a recent method of graft management, the "Sinus Pack" technique.[4]

Materials and Methods

This is a retrospective case-control study of subjects who underwent lateral sinus lift between September 2019 and October 2022 with the Schneiderian membrane perforation. The study was conducted under the 1975 Declaration of Helsinki, revised in 2013. Each subject signed an informed consent after receiving explanations of clinical procedures. The study was authorized by the Ethics Committee/Institutional Review Board of the "Fondazione Policlinico Universitario A. Gemelli", (Protocol number 0009738/22).

Selection criteria - Residual crestal bone height < 4 mm below the sinus floor, preoperative diagnostic cone beam computed tomography (CBCT) documentation and well-documented follow-up reports after sinus lift surgery were required to be included in this study.

The clinical criteria for subjects' exclusion from surgical treatment were: otorhinolaryngological contraindications to a maxillary sinus lift, acute oral infections, ongoing bisphosphonate therapy, history of chemotherapy or radiation therapy in the head or neck region in the past 12 months, immunocompromised status, psychiatric illness, any uncontrolled systemic disease, alcohol or drug abuse, smoking more than 10 cigarettes per day (smoking subjects were asked to quit smoking 1 week before surgery and to refrain from smoking for the next 3 weeks).

Relevant information about the treated subjects, such as age, and gender, as well as that related to the surgical procedure, dental implant placement, and surgical treatment outcomes, was collected.

Surgery procedures - At the 1-week visit before undergoing surgery, all subjects had a full-mouth plaque score (FMPS) and full-mouth bleeding score (FMBS) values of less than 15%.

All subjects took oral nimesulide 100 mg (2 hours before surgery) and amoxicillin 875 mg + clavulanic acid 125 mg (2 g 1 hour before surgery) as antibiotic prophylaxis.

The subjects underwent local anesthesia using an infiltrative technique (mepivacaine[a] 20 mg/ml + adrenaline 1: 100,000. A crestal incision of a triangular, full-thickness flap was made to expose the alveolar ridge and lateral maxillary wall.

All surgeries were performed using piezo surgery combined with a "sinus lift kit" and "osteotomy kit" (OT7, OT8L+OT8R) piezoelectric tips (Mectron[b]). Trapezoidal osteotomy of trap

Fig. 1. The particulate was mixed with blood taken from the intervention site, placed in the center of the resorbable membrane (OsteoBiol Evolution), and then folded over the graft to create the package for insertion into the antrostomy.

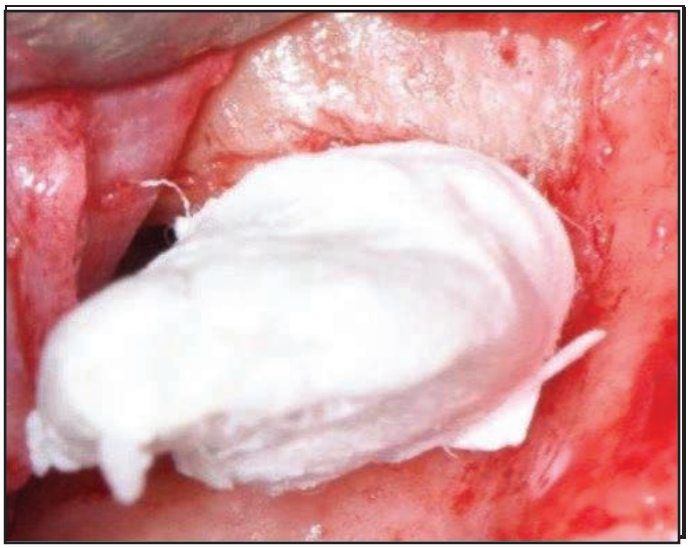

Fig. 2. Insertion of the "Sinus Pack" inside the antrostomy.

door was shaped keeping the tip angled at 45° to facilitate rehousing. When the sinus membrane became visible, the trap door was detached from the underlying soft tissue, and kept hydrated, to be repositioned at the end of surgery.

The sinus membrane was gently and completely reflected from the sinus floor and medial wall with the help of manual sinus lifting instruments[c] to create enough space for the grafting material and to improve vascularization of the graft.

When the membrane perforation was detected, the membrane that encircled the perforation was carefully detached with a blunt instrument to relieve tension in the perforated area, and then, the maximum distance between clinically detectable margins of perforation was measured with a periodontal probe.

Perforation handling - Subject treatment options depended on availability of materials in the clinic facility at time of surgery:

1. The "Sinus Pack" technique protocol was used for treating membrane perforations of any size. This technique involved a 0.22 mm-thick resorbable mesenchymal porcine collagen membrane (OsteoBiol Evolution[d]) that was hydrated with saline, and xenogeneic dual-phase bone substitute (OsteoBiol GTO[d]), consisting of a mixture of porcine bone granules, type I and III collagen, polyunsaturated fatty acids, and a biocompatible synthetic copolymer. The particulate was mixed with blood taken from the intervention site, and placed in the center of the resorbable membrane, which was folded over the graft (Fig. 1). This pack was finally inserted into the antrostomy (Fig. 2) in contact with the medial wall of the sinus, to cover the perforation, and then stabilized and covered with additional biomaterial. Then, the trap door was cautiously repositioned over the antrostomy. Due to the internal bevel design of the antrostomy, the trap door could be easily stabilized, and then covered with a thin layer of bone substitute to further stabilize it. At body temperature, the copolymer in the dual-phase biomaterial hardens and compacts the graft, making it unnecessary to cover the antrostomy with a resorbable membrane for protection. The flap was then sutured with a horizontal mattress and interrupted sutures (4-0 PTFE sutures – Perma Sharp Sutures[c]).[4]
2. The alternative repair technique consisted of a bioresorbable collagen bovine membrane (Bio-Gide[e]) trimmed and adapted to the size of perforation (for small perforations of 0-5 mm size). For medium size perforations (5-10 mm) and sinus membrane thickness ≥ 1.0 mm, the collagen membrane was fixed with resorbable sutures (5-0 PGA sutures - Perma Sharp Sutures). For larger perforations (10-15 mm), another collagen membrane extending from the inside to the outside of the antrostomy was stabilized with periosteal sutures. Then, the sub-entral space was filled with demineralized bovine bone particulate (spongiosa granules, 0.5-1 mm). The graft material (Bio-Oss[e]) as first packed onto the edges of the collagen tape to prevent displacement, and then at the level of the perforation. In this case, another resorbable membrane was placed onto the trap door to stabilize and protect the graft. Finally, the mucoperiosteal flap was sutured with a horizontal mattress and interrupted sutures (4-0 PTFE sutures - Perma Sharp Sutures).[28]

Postoperative care - Subjects were advised not to blow their nose, and to avoid open-mouth sneezing for 1 week after surgery. Subjects were also instructed not to wear prostheses for 2 weeks, to avoid mouthrinses on the day of surgery, to follow a soft, warm diet, and to avoid brushing in the region where stitches were present. Antibiotics (amoxicillin 875 mg + clavulanic acid 125 mg twice daily, or clarithromycin 500 mg for subjects allergic to penicillin) were prescribed for 7 days, and analgesics were taken if needed.

Subjects returned after 12 days for suture removal, and information regarding postoperative care was collected. Subjects returned for control visits at 2 and 3 weeks, and at 1, 3, and 6 months after surgery.

Six months postoperatively, a CBCT scan (Pax-i3D Smart,[f] 50-99 kVp / 4 - 16 mA) was done to evaluate bone volume at the augmentation site, before planning implant placement. Then, titanium dental implants (Straumann[g]) were inserted into the grafted areas, following the manufacturer's guidelines and a two-stage protocol. Bone biopsy specimens were taken at the time of implant surgery. Implants were prosthetically loaded after at least 3 months of their placement.

Outcome measures - Primary outcome was bone augmentation, calculated by measuring the difference between the post-surgical ridge height (measured at the 6 months post-op CBCT) and the initial (residual) ridge height on the same coronal

section of CBCTs.

Secondary outcome measures were:

1. The occurrence of adverse events (e.g., wound infection, exposure of the graft and wound dehiscence, swelling, bleeding, acute or chronic sinus infection, bacterial invasion, loss of the graft material, and dysfunction of normal sinus physiology) recorded at weeks 1, 2, and 3, and followed up to 6 months after surgery.
2. Implant survival at the longest follow-up after placement: in situ, implants had to be nonmobile, functional, without evidence of peri-implant soft tissue disease, and spontaneous or evoked symptoms.[5] The cause of any implant loss was recorded.
3. Implant-associated complications, such as mucositis, peri-implantitis, component fracture or prosthetic problems were reported during follow-up. The diagnosis of peri-implant mucositis or peri-implantitis was based on the criteria established by the 2017 Consensus Report on peri-implant diseases.[6]
4. Subjects' overall post-op discomfort was appraised after sinus lift with membrane perforation for the first 7 days, using a Visual Analogue Scale (VAS) (NPRS: numeric pain rating scale). After 1 week, the subject indicated the intensity of pain by ticking the appropriate number on a 0 to 10 scale, with 0 corresponding to "no pain" and 10 to "worst possible pain".

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 quantitative data were compared using the Mann-Whitney U test for comparisons between two groups. Variables were compared at baseline and 6 months. Given the non-normal distribution (Shapiro-Wilk test) and reduced sample size. Wilcoxon's paired-sample signed ranks test was utilized for within-group comparison (baseline vs 6 months).

Statistical significance was set at 5% ($P < 0.05$). Analyses were performed through STATA17.[h]

Results

Of the 30 subjects initially selected that fulfilled the inclusion criteria, 11 had to be excluded for the following reasons: five did not continue the treatment, three were treated with different procedures, in two cases it was not possible to collect sufficient clinical and radiological information, and in one case it was decided to interrupt and postpone the intervention. This resulted in a final sample of 19 cases (12 females, 7 males, mean age 53.3 ± 10.5 years), accounting for a total of 31 implants. The mean follow-up was 18.3 ± 11.7 months (range 5 to 40 months). Two implants failed (one per each treatment group). The overall implant survival rate was 94.7% on a patient basis, and 96.8% on an implant basis. A total of eight peri-operative complications were detected 1 week post-intervention in six subjects. Specifically, nasal bleeding occurred in two subjects, sinusitis in two subjects, swelling in three subjects, and wound dehiscence in one subject. Sinusitis required additional therapy with antibiotics and corticosteroids, while wound dehiscence required revision with a new suture. There was no statistically significant between-group difference in the incidence of complications, which resolved within 3 weeks, without graft failure. Biological complications at the implant level were observed in 5/31 implants (four mucositis and one peri-implantitis).

No statistically significant differences were recorded in terms of NPRS, for the two techniques compared. The results are summarized in Tables 1 and 2.

Table 1, Subjects' characteristics and surgery outcomes.

Age, years	Mean (SD)	53.3 (10.5)
	Median (range)	54 (36-75)
Gender	Females	12 (63.2%)
	Males	7 (36.8%)
Perforation size	< 5 mm	9 (47.4%)
	5 - 10 mm	4 (21.1%)
	> 10 mm	6 (31.6%)
Surgical technique	"Sinus Pack"	11 (57.9%)
	Collagen membrane covering	8 (42.1%)
No. of implants/subject	1 implant	8 (42.1%)
	2 implants	10 (52.6%)
	3 implants	1 (5.3%)
Vertical gain, mm	Mean (SD)	8.4 (1.1)
	Median (range)	8.3 (6.5-10.3)
Vertical residual bone before surgery, mm	Mean (SD)	3.2 (0.8)
	Median (range)	3.2 (2.0-4.4)
Vertical residual bone after 6 months, mm	Mean (SD)	11.6 (1.2)
	Median (range)	11.4 (9.0-13.6)
NPRS (VAS) Scale	Mean (SD)	3.5 (1.9)
	Median (range)	3 (1-8)
Perioperative complications	No. of subjects (%)	6 (31.6%)
	Nasal bleeding	2 (10.5%)
	Sinusitis	2 (10.5%)
	Swelling	3 (15.8%)
	Wound dehiscence	1 (5.3%)
Implant survival	Per subject	18/19 (94.7%)
	Per implants	30/31 (96.8%)
Follow-up	Mean (SD)	18.3 (11.7)
	Median (range)	18 (5-40)
Loading time	Mean (SD)	14.4 (11.2)
	Median (range)	14 (1-34)
Implant complications	Periimplantitis	1 (5.3%)
	Mucositis	4 (21.1%)

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

	"Sinus Pack" (n = 11)	Covering+suture (n = 8)	P-value
Vertical gain, mm	8.8 (1.1)	7.8 (0.9)	0.038**
NPRS (VAS)	3.2 (1.9)	4.0 (1.9)	0.355
Complications	3 (27.3%)	3 (37.5%)	1.000
Implant survival #	18/18 (100%)	12/13 (92.3%)	0.868

On an implant basis; **= Statistically significant.

Discussion

All surgeries performed were successfully completed, and subjects were subsequently implant-prosthetically rehabilitated. Only minor complications occurred in a small percentage of subjects and were all addressed without compromising graft

healing. The size of the perforation may play a key role in repair, as perforations smaller than 5 mm are more easily managed than larger ones.[5] Some authors[2] indicated that coverage is not necessary for such perforations. When perforations larger than 10 mm are managed properly, the surgery can be completed successfully.[3]

In the present study, vertical gain was significantly greater using the "Sinus Pack" approach with porcine collagenic graft (OsteoBiol GTO) as compared to using collagen membrane coverage and/or sutures, by about 1 mm. In addition, augmentation techniques using free granules require greater caution in filling the sub-entral space, as compared to the "Sinus Pack" technique, to avoid granule dispersion into the surrounding tissues.

The stability given by the pack with the membrane and the thermoset copolymer present in the grafted material (OsteoBiol GTO) might play a role in the capacity for graft integration and neoangiogenesis.[7,8]

Sinus lift complications - Only minor complications occurred in a small percentage of subjects and were all addressed without compromising graft healing. This agrees with Ding et al,[9] who reported that graft maturation is not affected by membrane perforation,[9] and with Froum's[7] study in which no complications were reported after treatment of perforated membranes.

Conversely, in the study by Nolan et al[10] 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.[10] Such different results may also depend on different approaches adopted for perforation management.

Implant survival rate - In all cases, the amount of bone gain assessed on CBCT allowed the clinician to place implants of standard length. Implants showed a high survival rate with only one implant lost for peri-implantitis with marked symptoms after 36 months.

Diaz-Olivares et al[11] reported a similar mean survival rate between implants placed in the sinus with repaired perforated membranes (97.7%), and those placed with intact membranes (98.9%). Conversely, others[12,13] reported that implant survival is negatively affected by the occurrence of sinus membrane perforation.

Advantages of this technique - The main advantage of the "Sinus Pack" technique is that the mesenchymal collagen membrane protects the biomaterial and prevents any dispersion of the granules into the sinus cavity. In addition, any complication resulting from small undetected perforations or damages to the Schneiderian membrane that may occur during filling with free granules is avoided. It was shown that such undetected perforations may pose a risk if left untreated.[14]

Furthermore, since the graft forms a rigid block, if the flap is not damaged, it is not necessary to cover the antrostomy with other membranes, avoiding the risk of soft tissue ingrowth from the alveolar mucosa. The compactness of the graft also prevents the loss of graft material through the window, in the event of increased intra-sinus pressure, which can be caused by postoperative inflammation or intra-sinus bleeding.[3]

The "Sinus Pack" approach can be used as a general sinus filling technique because it is simple and fast, since bone granules are added in a single step, and safe because it reduces the risk of granule dispersion and sinus membrane damage.[15]

If graft fragments pass through mucosal tears in the maxillary sinus, they may obstruct the natural ostium, especially if they are > 5 mm.[16] Maintenance of sinus drainage is important for Schneiderian membrane recovery, especially if damaged.[9] In a study[17] that used standard diagnostic ENT (ear, nose, and throat) criteria, subacute maxillary sinusitis occurred in 4.5% of the patients undergoing maxillary sinus elevation, and post-elevation chronic maxillary sinusitis developed in 1.3%.

Some limitations should be acknowledged, including the low sample size, and the retrospective nature of the study, which did not allow definitive conclusions to be drawn. The present findings should be confirmed in larger and long-term prospective studies possibly randomized, to control most confounding factors.

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