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Schneiderian membrane perforation repair using a crosslinked collagen membrane: a retrospective cohort study

Daya Masri[1,2*], Ehud Jonas[1,2], Omar Ghanaiem[1,2] and Liat Chaushu[3]

Abstract

Objectives Perforation of the Schneiderian membrane (SM) is a common intraoperative complication of sinus augmentation. This study aimed to evaluate risk factors for SM perforation, and to compare clinical outcomes between patients with SM perforation repaired using crosslinked collagen membranes (CLM) compared to those with an intact SM.

Methods A retrospective cohort study was conducted at a single tertiary medical center. Data was collected on patients requiring sinus augmentation via lateral approach prior to implant placement. The collected data included demographics, surgical details, implant outcomes, radiographic analysis, and presence of SM perforation. In cases of perforation a CLM was used to repair the SM. Statistical analysis was performed to evaluate risk factors for perforation and whether SM perforation repair using CLM influenced early implant failure (EIF). A p-value < 0.05 was considered significant.

Results Data on 194 individuals who underwent 278 lateral approach sinus augmentation procedures was collected. SM perforation occurred in 66 (23.74%) sinuses. Treatment of SM perforation using CLM yielded similar results to sinuses without perforations: EIF and the augmented gained bone did not correlate with SM perforation. Younger patients, and thick SMs (> 3 mm) had significantly lower risk of perforation.

Conclusions Older age and thinner SMs are risk factors for sinus membrane perforations. No significant differences in bone gain and EIF were found between perforated and intact membranes.

Clinical relevance Schneiderian membrane perforation repair using crosslinked collagen membrane provides comparable results to sinus augmentations without perforations, demonstrating its effectiveness in preventing complications.

Keywords Crosslinked membrane, Schneiderian membrane, Sinus augmentation, Perforation, Collagen membrane, Implant

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Introduction

The Schneiderian membrane (SM) plays a crucial role in separating the sinus cavity from the oral environment. Composed of a delicate layer of ciliated pseudostratified columnar epithelium, it is responsible for producing mucus, filtering, and humidifying air entering the sinus cavities [1]. However, its proximity to the alveolar ridge and the oral cavity makes it vulnerable to injury during dental procedures, particularly sinus floor augmentation [2–5].

Sinus augmentation necessitates careful manipulation of the SM, especially during lateral approach procedures. Despite advances achieved in treatment planning, complication management, materials and the experience of operators, SM perforation remains a notable complication that could lead to sinusitis, oro-antral fistula, and failures in bone grafts and implants, potentially necessitating additionally and more complex surgical procedures [6]. SM perforation is not uncommon. Its incidence rate, ranging from 10 to 50%, underscores the operator's need to excel in managing such occurrences [5, 7].

Upon occurrence, repairing the perforation becomes paramount to prevent bone graft particles from migrating through the membrane and into the sinus cavity [8]. In response to this challenge, various techniques and materials have been suggested, ranging from sutures, collagen membranes, fibrin glue, and tissue engineering solutions [5, 7–10]. The selection of repair method is dictated by the size of the perforation, the surgeon's expertise, and the particular clinical scenario.

The use of crosslinked collagen membranes (CLM) in the repair of SM perforation has not been widely investigated. Engineered through a ribose crosslinking process, these membranes exhibit superior resistance to degradation [11]. It has been hypothesized that their use in SM repair might adversely influence the outcome of the augmentation, given their increased ability to inhibit the initial stages of bone augmentation such as epithelial cells and growth factors migration, angiogenesis and the delivery of nutrients to the newly augmented bone, particularly originating from the SM [3]. Several studies investigated the use of different types of collagen membranes in SM perforation repair. Some studies reported no differences in implant failure between repaired and intact SMs, while others reported more bone formation and implant survival in sinuses with intact membranes [12–25].

Therefore, the present study aimed to examine risk factors for SM perforation, and the effects of repairing it with a CLM versus having an intact membrane on the results of sinus augmentation.

Methods

This retrospective cohort study was executed at the Department of Oral and Maxillofacial Surgery, Beilinson Hospital, Petach Tikva, Israel. The study was conducted in accordance with the Helsinki Declaration and its subsequent amendments and was approved by the relevant ethics committee (0674-19-RMC). All participants signed an informed consent. Data was collected from patients who underwent lateral approach sinus augmentation during 2013–2021, focusing on evaluating the outcomes associated with the use of crosslinked collagen membranes (Ossix® Plus, Datum Dental Biotech, Lod, Israel) in cases of SM perforation.

Inclusion criteria

- Age > 18 years old.
- Consecutive individuals.
- Sinus augmentation via the lateral approach.
- Implants were eventually placed and were followed up until temporary or permanent implant rehabilitation.
- Use of CLM to treat SM perforations.

Exclusion criteria

- Incomplete documentation.

Surgical protocol

Experienced oral and maxillofacial surgeons executed the surgical interventions. The pre-surgical radiographic assessment involved either CBCT (Cone Beam Computed Tomography) or MDCT (Multi Detector Computed Tomography). Patients with less than 5 mm of residual alveolar bone underwent sinus augmentation using Boyne and James' lateral approach [26]. (See Fig. 1)

The surgical approach to the lateral wall of the maxillary sinus involved creating a mucoperiosteal flap with crestal and vertical releasing incisions. Flap mobility was enhanced by scoring the buccal periosteum. A round diamond bur was used to create a bony window to the maxillary sinus. Careful elevation of the SM was performed to avoid perforation. Upon perforation, it was covered with a crosslinked collagen membrane. Xenogeneic bone substitute (Bio-Oss, Geistlisch Pharmaceutical, Wolhusen, Switzerland) filled the void. Implants were placed following the manufacturer's protocol when primary stability was achieved. The antrostomy defect was covered in all cases using a CLM. The incisions were sutured to ensure hemostasis and primary tension-free closure. (See Fig. 2)

Prosthetic loading was performed after 9 months, in either simultaneous or delayed implant placement. In delayed implant placement, surgeries occurred after a

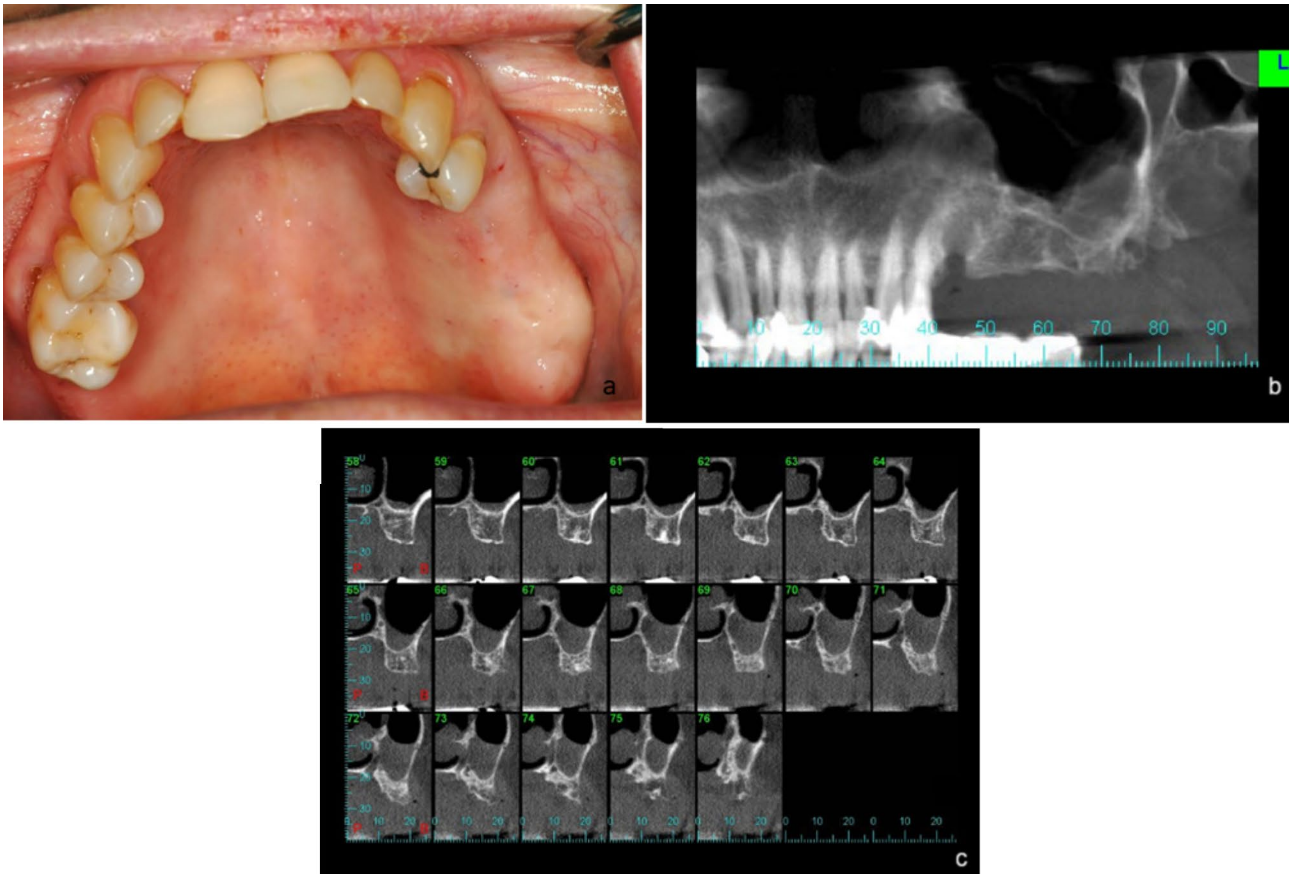

Fig. 1 Posterior maxilla rehabilitation through sinus augmentation. **a**: A preoperative photograph, **b**: Preoperative panoramic reconstruction from CBCT, and **c**: Preoperative CBCT paraxial slices highlighting the atrophic alveolar ridge in the maxillary premolars and molars area

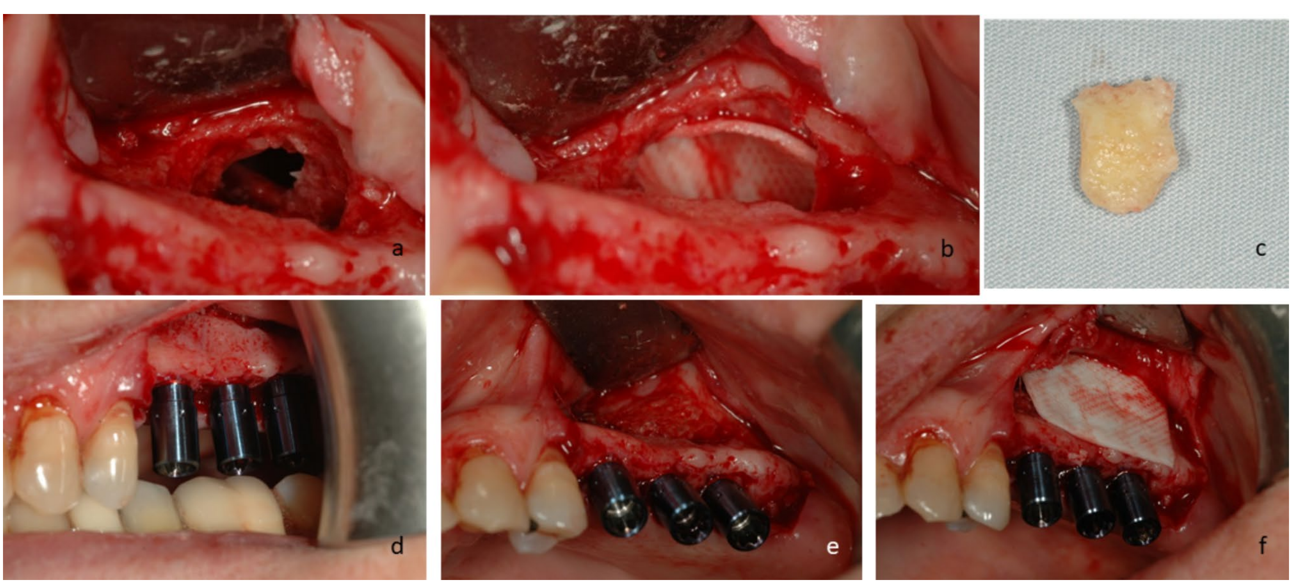

Fig. 2 Intraoperative photography. **a**: A significant perforation found while elevating the sinus membrane. **b**: Closure of the perforation with CLM. **c**: Bone graft. **d**-**e**: Simultaneous implant placement. **f**: Use of CLM to cover the lateral wall

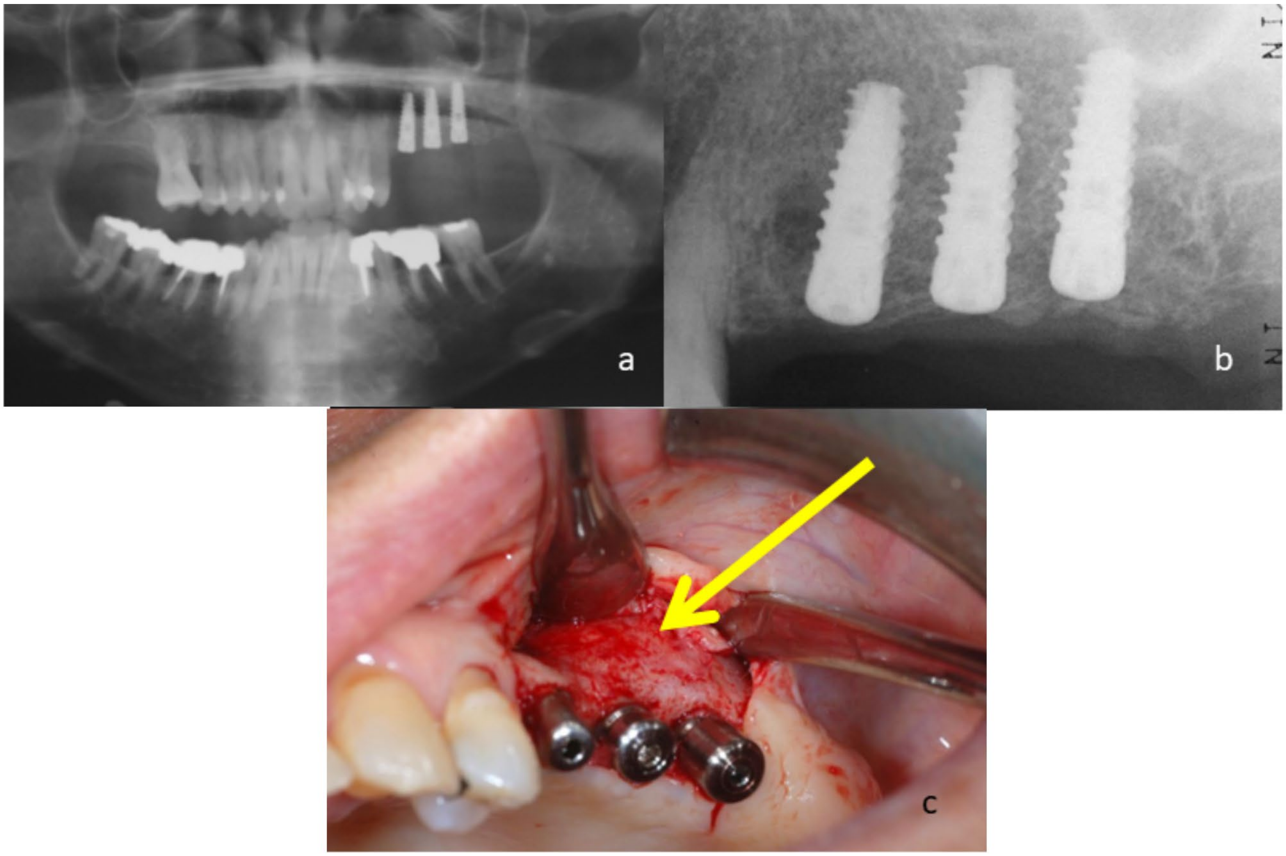

Fig. 3 **a**: Periapical radiograph showing three parallel implants immediately after the sinus augmentation. **b**: Panoramic X-ray six months after the augmentation and implantation. **c**: Uncovering the implants and fitting healing abutments, yellow arrow pointing the successful healing of the bone graft and absorption of the collagen membrane

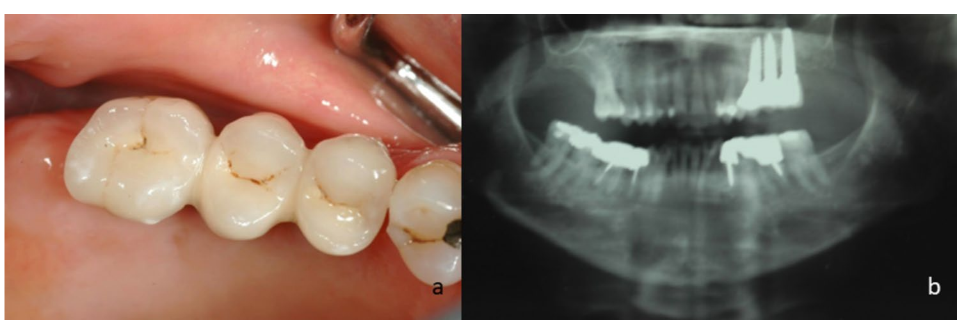

Fig. 4 Final rehabilitation **a**: Clinical photography **b**: Panoramic x-ray

4-month post-augmentation period and implant exposure after additional 5 months. (See Figs. 3 and 4)

Data collection

Data was extracted from the medical center's electronic medical records. Two experienced clinicians collected the data separately. In cases of differences in the data collected, the data was reanalyzed and reviewed by a third clinician. The data collected included:

- Age.
- Gender.
- ASA (American Society of Anesthesiology) classification.
- Smoking habits.
- Sinus augmentation approach (simultaneous or delayed).
- Number of implants.
- Early implant failure (failure up to temporary or permanent rehabilitation).

When available, additional radiographic measurements were taken such as (See Fig. 5):

- Sinus morphology (classified as triangular, round, or oval based on their coronal or paraxial shape).
- Alveolar residual bone height (mm).
- Bone gain (calculated as the difference between the alveolar residual bone height and the length of the implant placed).
- Presence of bony septa (Underwood's septa).
- Presence of blood vessels (Alveolar antral artery).
- Lateral wall width (mm).
- SM thickness- Categorized to four levels based on its radiographic thickness: 1 (0–1 mm), 2 (1–2 mm), 3 (2–3 mm), 4 (>3 mm).

Data analysis

Data analysis was conducted using Python version 3.12, with Pandas version 2.1.3 and Statsmodels 0.14.1 for statistical computations. Descriptive statistics calculated means and standard deviations for continuous variables and frequencies for discrete variables. Kolmogorov-Smirnov test was performed to assess the normal distribution of the variables. Univariable correlations were analyzed using general estimation equations (GEE) to account for within subject correlations (two sinus augmentations in the same patient) and clustering effects. The models were adjusted for clustering of subjects, binomial distribution, logit link function, and an exchangeable working correlation was assumed. This method handles potential errors associated with experimental unit of analysis. For variables with a p-value cutoff point of 0.1, multicollinearity was assessed using a matrix correlation and variance inflation factor. Variables attaining univariable significance under 0.1 and non-multicollinearity were forced to a multivariable GEE model. A p-value below 5% was considered statistically significant.

Results

194 patients underwent 278 lateral approach sinus augmentations. 628 implants were placed in the augmented sinuses. 66 (23.74%) of sinuses had an SM perforation that was repaired with a crosslinked collagen membrane. 172 of the sinus augmentation procedures were in females, and the mean age was 62.38 ± 12.08 years old. 22 sinuses (7.91%) were augmented in smokers, and 51.8% of sinuses were augmented simultaneously with implant placement.

Regarding the anatomical morphology of the sinuses, 55.35% were round shaped, 24.53% were oval, and the rest were triangular. In 33% and 44.65% of sinuses, a septa or blood vessel were detected in the radiographic examination respectively. The mean lateral wall width was 1.56 ± 0.95 mm, and the mean alveolar ridge height was 4.53 ± 1.46 mm. 36 sinuses had at least one EIF (12.95%). See Table 1.

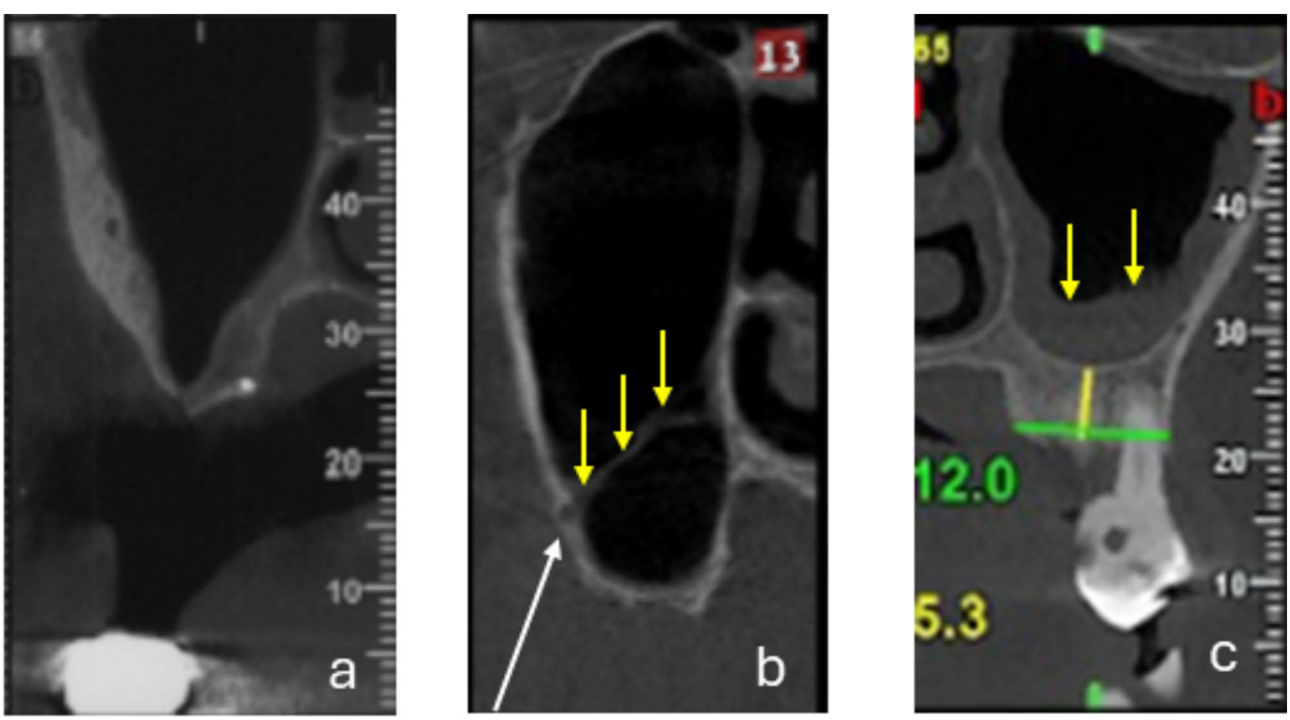

Fig. 5 Paraxial CBCT radiographic examinations: **a**: Triangular shape sinus. **b**: Oval shape sinus demonstrating a septa (yellow arrows) and a blood vessels (white arrow). **c**: Round sinus demonstrating a thick SM (yellow arrows)

Table 1 Descriptive statistics at sinus level

Variable	Sub-group	Number	%	Mean	Std
Total		278	100.00%		
Gender					
	Male	106	38.13%		
	Female	172	61.87%		
Age (years)				62.38	12.08
ASA classification					
	1	37	13.31%		
	2	124	44.60%		
	3	117	42.09%		
Tobacco smoking		22	7.91%		
Procedure					
	Unilateral	110	39.57%		
	Bilateral	168	60.43%		
Surgical approach					
	Simultaneous	144	51.80%		
	Delayed	134	48.20%		
Coverage of antrostomy defect		235	84.53%		
Perforation		66	23.74%		
Septa		53	33.33%		
Blood vessel		71	44.65%		
Sinus morphology					
	Round	88	55.35%		
	Oval	39	24.53%		
	Triangular	32	20.12%		
Membrane thickness	Category			3.1	2.34
Alveolar ridge height (mm)				4.53	1.46
Bone gain (mm)				8.82	2.45
Lateral wall width (mm)				1.56	0.95
Implants[1]		628	100.00%	2.26	0.68
EIF		36	12.95%		

[1]Mean accounts for the average number of implants placed in each sinus

The univariate statistical analysis revealed that EIF, and the gained bone did not significantly correlate with SM perforation. Similarly, other factors including tobacco smoking, sinus morphology, and the dimensions of the sinus were not significant risk factors for SM perforation. However, the patients' age (older patients) was significantly correlated with SM perforation (O.$R = 1.04$, $p = 0.04$), and thick SMs (> 3 mm) was significantly associated with less perforations (O.$R = 0.5$, $p = 0.049$). See Table 2.

The multivariable GEE model to predict SM perforation estimated a within-patient correlation of 0.38, indicating a moderate positive association for perforating the contralateral sinus in the same patient. The model has also shown that none of the variables included reached significance as risk factors for SM perforation ($p < 0.05$). See Table 3.

Discussion

Sinus augmentation has been widely recognized as an effective and reliable method for restoring bone volume in the posterior maxilla [13–32]. However, a notable intraoperative challenge associated with this procedure is the perforation of the SM [5, 7, 9]. Previous studies have documented various techniques for repairing intraoperative perforations, each with varying success rates and levels of complexity. These techniques include resorbable sutures, clot formation, resorbable membranes, and platelet-rich fibrin (PRF) for small perforations (typically up to 5–10 mm) [4, 5, 7, 9, 10, 15, 29, 30]. Larger perforations often necessitate more extensive measures, such as larger resorbable membranes, resorbable sutures, PRF, sticky bone substitutes, bone blocks, a combination of these methods. If a perforation repair is unsuccessful, the procedure may be discontinued, with a two-month interval to facilitate SM regeneration prior to subsequent intervention [3, 5–9, 15, 29, 30]. In the present study, CLM was utilized to repair all perforation cases regardless of the perforation size. Our study revealed

Table 2 Univariate GEE statistical analysis at the sinus level

Binary variables						
Variable	**Subgroup**		**O.*R***		**CI**	***p-Value***
Total						
Gender						
	Male		1			
	Female		0.63		0.34–1.17	0.14
ASA classification						
	1		1			
	2		0.95		0.36–2.5	0.92
	3		1.22		0.47–3.21	0.67
Tobacco smoking						
	No		1			
	Yes		1.8		0.64–5.03	0.26
Surgical approach						
	Simultaneous		1			
	Delayed		1.22		0.69–2.2	0.49
Septa						
	No		1			
	Yes		0.67		0.3–1.55	0.35
Sinus morphology						
	Round		1			
	Oval		1.89		0.72–4.98	0.19
	Triangular		2.09		0.79–5.51	0.14
Blood vessel						
	No		1			
	Yes		1.34		0.62–2.9	0.45
EIF						
	Success		1			
	Fail		1.1		0.53–2.29	0.78
SM thickness						
	0–1 mm		1			
	1–2 mm		0.77		0.37–1.61	0.77
	2–3 mm		0.8		0.33–1.97	0.8
	3 < mm		0.5		0.25-1	0.049**

Continuous Variables							
	Perforation		**Intact**				
	Mean	**SD**	**Mean**	**SD**	**O.R**	**CI**	**p-Value**
Age (Years)	65.8	12.22	61.32	11.86	1.04	1-1.08	0.04**
Implants per sinus	2.21	0.67	2.27	0.68	0.96	0.64–1.46	0.86
Residual bone (mm)	4.3	1.35	4.59	1.49	0.85	0.7–1.03	0.09*
Bone gain (mm)	8.69	2.4	8.87	2.53	0.98	0.88–1.1	0.82
Lateral wall thickness (mm)	1.37	0.66	1.6	0.99	0.76	0.52–1.13	0.17

Statistical significance: *<0.1, **<0.05

Table 3 Multivariable GEE statistical analysis at the sinus level

Variable		**O.*R***	**CI**	***p*-vlaue**
Membrane thickness				
	1–2 mm	0.8	0.4–1.82	0.68
	2–3 mm	0.97	0.39–2.41	0.94
	> 3 mm	0.54	0.28–1.07	0.08*
Age		1.03	1-0.07	0.07*
Residual bone		0.86	0.72–1.05	0.14

Statistical significance: *<0.1, **<0.05. Variables were included following multicollinearity test and univariable significance < 0.1

that 23.74% of the augmented sinuses experienced SM perforation. None of the patients experienced complications such as sinusitis, bone graft migration, or implant migration during the follow-up period. These findings contribute valuable insights into the implications of SM perforation on the outcomes of the lateral wall approach in sinus augmentation.

When a perforation occurs during sinus augmentation, it is critical to cover the perforated area. This precaution helps preventing bone graft particles from migrating into the sinus cavity, potentially increasing the risk of sinus infection. Two critical outcomes in bone augmentation and dental implantology are the EIF and the volume of bone gained. Consequently, assessing the impact of SM perforation and its subsequent repair on these outcomes is important.

The findings from our study indicate that perforations, when properly managed, do not have a significant adverse effect on EIF following the augmentation. Park et al. (2019) retrospectively analyzed the influence SM perforation and implant failure. They reported that perforation was not correlated with implant failure in non-repaired sinuses. However, perforated sinuses were significantly correlated with postoperative complications [8]. Díaz-Olivares and colleagues' (2021) meta-analysis aimed to investigate whether a perforated membrane was a risk factor for implant survival. Their analysis concluded that SM perforation was not a significant risk factor for implant failure [7]. Other studies resulted in similar conclusions [4, 27, 28]. On the contrary, Al-Moraissi et al. (2018) conducted a meta-analysis aiming to investigate the relationship between SM perforation and EIF. Their analysis resulted in a significant increase in EIF in perforated sinuses. However, their analysis did not differentiate between repaired and non-repaired SM, which could potentially increase the augmentation's failure rate as noted above [29]. Hernandez-Alfaro et al. (2008) conducted a retrospective analysis to evaluate the risk of complications associated with sinus augmentation. They concluded that SM perforation was significantly correlated with increased implant failure [9]. The variability in outcomes correlating EIF and SM perforation may also result from inadequate membrane elevation [33–36]. Inadequate elevation can prevent proper separation of the periosteum from the underlying bone, potentially leading to graft material placement within the connective tissue or above the SM, instead of the desired subperiosteal location. This misplacement can consequently impair bone regeneration and osteointegration [33–36].

The impact of SM perforation on the quantity of bone gained following augmentation has not been extensively explored. It could be hypothesized that perforating the SM and its subsequent repair might lead to a reduction in bone gain, as the SM serves to contain and stabilize the bone graft material. A compromised membrane might allow for the displacement or contamination of the graft material, potentially decreasing the amount of bone available for implant placement. However, the findings of this study did not reveal any significant differences in bone volume between perforated and intact sinuses. Similarly, Park et al. (2019) [8], Beck-Broichsitter et al. (2018) [30], Shlomi et al. (2004) [5], and others (10] reported no significant difference in bone graft height between perforated and intact SMs.

The varying reported observations regarding EIF and bone gained highlight the uncertainty surrounding the precise bone-to-implant contact (BIC) necessary for successful osseointegration. The fact that successful implants can exhibit such a wide range of BIC values, despite varying levels of EIF and bone gain observed in different studies, underscores the complex interplay of factors contributing to osseointegration. While complete BIC is unlikely, reported values associated with osteointegrated implants range widely (2.82–100%) [37–39]. The minimum BIC threshold for success remains undetermined. Boline et al. (2005) observed BIC values in successful implants ranging from 60 to 99%, with no correlation between higher BIC and increased success [40].

The employment of crosslinked or slow-absorbing collagen membranes for repairing SM perforations has prompted a debate within the scientific community. Critics argue that the utilization of crosslinked membranes could introduce complications that may impede the healing process, including foreign body reactions, delayed vascularization, and inhibited epithelial migration [31, 32]. Moreover, while the intention behind crosslinking is to decelerate the degradation of collagen membranes, this characteristic could paradoxically slow the healing process and result in reduced tissue integration [3]. Despite these concerns, the results of this study indicate that the use of crosslinked collagen membranes does not affect bone gain or EIF.

To the best of our knowledge, no previous study has directly compared the effects of crosslinked and non-crosslinked collagen membranes on the outcomes of sinus augmentation. While Jiménez Garcia et al. (2017) conducted a systematic review on the effects of these membranes on bone regeneration, their conclusion that both types were suitable for such procedures was tempered by the observation of higher postoperative complication associated with CLM [32]. Chandra et al. (2020) compared non-crosslinked and crosslinked collagen membranes in a rat model of SM perforation repair. They found that non-crosslinked membranes exhibited faster SM regeneration, without any significant advantage in bone regeneration or membrane degradation compared to CLM [3]. Bresaola et al. (2016) evaluated the effects of slow and rapid resorption collagen membranes on bone formation and remodeling in a rabbit model of sinus augmentation. Their histopathological analysis revealed that neither membrane type negatively impacted bone formation and remodeling, and both induced a similar effect of the focal inflammatory response [13].

These findings raise a question regarding the clinical significance of the osteogenic capacity of the SM. Srouji et al. (2009) and Graziano et al. (2012) successfully isolated and cultured osteoprogenitor cells from the human SM [41, 42]. Furthermore, Srouji et al. (2010)

demonstrated that transplanting the SM beneath the skin of nude mice effectively simulates the elevation of the sinus floor, leading to new bone formation and thereby confirming the SM's capability for bone generation [43]. Within the scenario of SM perforation and its subsequent repair using a collagen membrane, it would be presumed that the osteogenic potential would be reduced due to the collagen membrane's ability to hinder the migration of mesenchymal stem cells from the SM, leading to a diminished results of the entire procedure. However, the results of this study did not indicate a significant impact on osteointegration suggesting that the osteogenic ability of the SM does not have a major influence on sinus augmentation.

Rong et al. (2015) conducted an experimental study using canine subjects, employing a titanium membrane to isolate the SM from the sinus' bony walls to investigate its role in bone formation after sinus augmentation. This approach was compared with a conventional sinus floor elevation in a control group and another group where the membrane shielded the bony walls of the sinus. Their findings demonstrated significant bone formation around the implanted materials near the inferior bony wall in the control group. In contrast, new bone formation was weak and slow near the SM, indicating that osteoprogenitor cells originating from the bony wall likely serve as the primary source of osteoblasts, whereas those from the SM may contribute minimally to osteoblast population [2].

The thickness of the SM was classified to four levels based on its radiographic measurements (0–1 mm, 1–2 mm, 2–3 mm and >3 mm). The univariate model revealed that membranes thicker than 3 mm had significantly lower odds of perforation than others, with a borderline significant result in the multivariable analysis ($p = 0.049$ and $p = 0.07$ respectively). This result aligns with several other studies that reported higher incidence of perforation in thinner membranes [6, 44, 45]. It is noteworthy that Lin et al. (2015) reported that in addition to thin (<1 mm) membranes, thick membranes (>2 mm) were also correlated with perforation [10]. Thinner membranes may be more delicate and harder to manipulate, which may cause a perforation during the lateral wall antrostomy or the process of separating the SM from the sinus' bony walls. One might assume that while a thick membrane is correlated with sinus pathologies it would result in higher odds of complications. Studies that radiographically analyzed the thickness of the SM reported that healthy SM is considered up to 3–4 mm [46–48]. Ritter et al. (2020) conducted a retrospective study to examine the association between preoperative maxillary sinus radiographic findings and the outcomes of the procedure. They concluded that incidental sinus imaging such as mucosal thickening (>2 mm) should not be addressed in asymptomatic patients unless a complete sinus obstruction is present [48].

We noticed a trend where older individuals appeared to have a higher likelihood of encountering perforations. This observation could potentially be linked to the broader and more complex health profiles typically associated with aging. Older patients often have a range of comorbidities that, while not directly related to the procedure at hand, might contribute to an increased vulnerability of membrane to damage. Therefore, it suggests an area for further research, where future studies could further study how these underlying health factors might influence the SM. This direction could unveil important considerations for managing and preparing for procedures in populations with significant comorbid conditions.

The limitations of this study primarily stem from its retrospective design and the involvement of multiple operators, which could introduce a variability in the perforation rate of the SM. The retrospective nature may limit our ability to control for all potential confounding variables or to capture the procedural nuances in real-time. Additionally, the presence of multiple surgeons, each with their individual levels of experience, might contribute to inconsistencies in the outcomes observed.

Conclusions

In conclusion, this research revealed that older individuals and thinner membranes (0–1 mm, compared with >3 mm) are risk factors for SM perforations. This study also showed insignificant differences in EIF and the gained bone between perforated membranes and intact controls. It emphasizes the efficacy and safety of utilizing a CLM for the management of SM perforation repair. Employing this type of membrane can negate the likelihood of complications arising.

Author contributions

All authors have significantly contributed to the study's idea and design. E.J, O.G and D.M were involved in the data collection. E.J, D.M, and L.C were involved in the data analysis, and data interpretation. All authors were involved in drafting the manuscript and revising it critically and have given final approval of the version to be published.

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Data availability

Raw data were generated at Rabin Medical Center. Derived data supporting the findings of this study are available from the corresponding author D.M on request.

Declarations

Ethical approval

The study was conducted in accordance with the Helsinki Declaration and its subsequent amendments and was approved by the relevant ethics committee (0674-19-RMC). All participants signed an informed consent.

Consent for publication
All study participants provided written informed consent for their anonymized data to be used in this research and its subsequent publication. The study protocol was approved by the Institutional Review Board of Rabin Medical Center, and adhered to the ethical standards outlined in the Helsinki Declaration.

Competing interests
The authors declare no competing interests.

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