Effect of Medical-Grade Polyurethane Sponges on Sinus Membrane Perforation With a Lateral Window Approach

Yusuke Hamada, DDS, MSD[1]*
Abudulaziz AlSakr, BDS, MDS[1]
Stephen Towns, DDS[1,2]
Steven B. Blanchard, DDS, MS[1]

The most commonly reported complication during the sinus elevation surgical procedure is the perforation of the Schneiderian membrane. The aim of this retrospective study was to compare the rate of sinus membrane perforation during lateral window augmentation using either conventional sinus curettes or medical-grade polyurethane sponges. This retrospective study included patients who received a lateral window approach for sinus floor elevation. The sinus elevation procedures using medical-grade polyurethane sponges (test) or conventional curettes (control) were recorded and analyzed. All subjects' demographic data and preexisting conditions were evaluated. A total of 38 procedures met inclusion criteria, and those data were evaluated for analysis. There were no statistically significant differences in demographic data or preexisting conditions including age, sex, treatment location, presence and absence of septum, Schneiderian membrane thickness, and residual bone height between test and control groups. The membrane perforation rate was 7% in the test group and 43% in the control group; however, this difference did not reach statistical significance ($P = .064$). Within the limitations of this study, although there was no statistically significant reduction of sinus membrane perforation with the use of medical-grade polyurethane sponges, the decreased incidence of perforation might be of clinical significance.

Key Words: sinus membrane perforation, dental implants, medical-grade polyurethane sponges, sinus pneumatization

INTRODUCTION

Implant-supported and -retained prostheses are commonly used to reconstruct the partial and complete edentulous ridge in daily practice. Following extraction, the alveolar ridge undergoes a change in both the vertical and horizontal dimensions as a result of alveolar bone remodeling.[1,2] In addition to these ridge dimensional changes, alveolar bone resorption after extraction of the maxillary posterior teeth often leads to pneumatization of the maxillary sinus. This may compromise the ability to place implants of optimal length. In these cases, vertical bone augmentation of the subantral area to raise the sinus floor is necessary to secure sufficient bone height, prior to or at the time of implant placement.[3]

Currently, there are 2 main methods used for sinus elevation: a transalveolar approach and a lateral window approach.[4] The transalveolar approach is usually used when the residual bone height is sufficient to achieve implant primary stability and the anticipated amount of additional sinus floor elevation needed is less than 5 mm.[5] However, when severe sinus pneumatization and atrophy of the alveolar ridge is present and the residual bone height is less than 5 mm, the lateral window sinus floor elevation procedure is recommended. Although the lateral approach is well documented and has demonstrated high predictability for successful implant placement, it is not without complications. These intraoperative complications include abnormal bleeding by injury to the posterior superior alveolar artery and damage to the adjacent teeth during the osteotomy procedure.[6] However, the most commonly reported complication is perforation of the Schneiderian membrane during the sinus elevation surgical procedure.[7] Sinus membrane perforation if often associated with the presence of septa, thickness of the lateral wall of bone, thickness of the sinus membrane, residual bone height, and pathological sinus changes.[8,9] With proper management, a sinus perforation does not negatively affect the implant survival rate after healing.[10] However, Nolan et al[11] reported that 70.8% of sinus graft failures were associated with perforated Schneiderian membrane sites. The overall implant failure rates were 11.3% with membrane perforations and 3.4% with nonperforation sites. Moreover, a higher incidence of additional antibiotics usage was needed when sinus perforations occurred.[11] Usually, sinus perforation occurs at the time of membrane reflection and osteotomy site preparation. Atieh et al[12] conducted a systematic review to compare piezoelectric surgery and rotary instruments for lateral window sinus osteotomy preparation. This review showed that the risk of sinus membrane perforation was not statistically different between piezoelectric surgery and rotary burs.[12] It was noted that sinus perforations occurred most commonly at the beginning of Schneiderian membrane reflection with conventional sinus curettes.

A new novel approach has been developed that uses medical-grade polyurethane foam sponges for sinus floor

[1] Department of Periodontology, Indiana University School of Dentistry, Indianapolis, Ind.
[2] Private practice, Indianapolis, Ind.
* *Corresponding author,* e-mail: yuhamada@iupui.edu
https://doi.org/10.1563/aaid-joi-D-19-00137

membrane reflection. Shahi and coworkers[13] reported the use of the Safer-Simplified-Sinus-Surgery Technique (4ST) with these polyurethane sponges. This soft sponge allows the gradual application of slow pressure and expansion in a 360° manner onto the membrane to slowly reflect it off the bony walls of the maxillary sinus. This case report suggested a lower perforation rate of the Schneiderian membrane when the sponges were used for sinus floor elevation. The aim of this retrospective study was to compare the incidence of sinus membrane perforations between medical-grade polyurethane foam sponges and conventional sinus curettes used during the lateral window approach for sinus elevation.

Materials and Methods

The Institutional Review Board reviewed and approved the protocol as Exempt Category 4 prior to conducting this retrospective study (#1709215181). Exempt Category 4 is defined as secondary use of pre-existing data: research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if (1) these sources are publicly available or (2) the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This study included patients who received implant placement surgery. All patients who received a lateral window sinus floor elevation procedure between January 1, 2013, and September 13, 2017, were included. All data were gathered from the Axium (Deltek, Herndon, Va) electronic patient record database.

Inclusion/exclusion criteria

Subjects were included if they met the following criteria: (1) received a lateral window sinus floor elevation between January 1, 2013, and September 13, 2017, (2) at least 18 years old at the time of procedure, (3) had partial or full edentulism, and (4) had no absolute contraindications for implant therapy. The exclusion criteria were patients who (1) did not meet inclusion criteria or (2) had insufficient documentation recorded in the database.

Data correction and description of surgical procedures

Data extracted for analysis were age, sex, site (right or left), presence of septa, sinus membrane tissue thickness, residual bone height, type of instruments for osteotomy and membrane reflection (piezoelectric, rotary burs, polyurethane sponge, etc), and presence of sinus perforation during the surgical procedure. Data from patients treated using medical-grade polyurethane sponges (test) or conventional sinus curettes (control) for sinus membrane elevation were recorded and analyzed. All pretreatment cone-beam computerized tomography (CBCT) images were evaluated by one examiner (Y.H.). Before the evaluation, calibration sessions were performed. For the intra-examiner calibration, 10 CBCT scans were randomly selected, and 1 examiner evaluated those scans twice within 1 week at 2 separate time frames. For the interexaminer calibration, 2 examiners evaluated 10 randomly selected CBCT scans at different locations. These sessions were repeated until the interclass correlation coefficient reached >0.90.

All lateral window sinus floor elevations were performed under local anesthesia with or without moderate intravenous sedation by graduate periodontal residents. Following local anesthesia, a full-thickness flap was elevated beyond the mucogingival junction. A piezoelectric device and/or low-speed rotary diamond burs were used to initiate the osteotomy. After the creation of the lateral window, either conventional sinus elevation curettes (control) or medical-grade polyurethane foam sponges (test; 4ST Store, Chino, Calif) were used to reflect the Schneiderian membrane. For the control group, conventional sinusotomy curettes were used to reflect the sinus membrane of the surrounding bony walls. For the test group, a sponge was gently inserted into the sinus subantral area with a slow movement, and the surgeon allowed the sponge to expand a 360° manner to apply light pressure. Additional sponges were placed in the same manner as needed until sufficient sinus membrane elevation was achieved. After sufficient membrane reflection, all sponges were removed before placement of bone graft materials (Figure 1). Any noted sinus membrane perforations were recorded in the patient's chart. If a sinus membrane perforation occurred, either a bioabsorbable membrane or a platelet-rich fibrin membrane was placed over the perforation. Deproteinized bovine bone mineral (Bio-Oss, Geistlich Pharma, Princeton, NJ) or freeze-dried bone allograft (Straumann USA LLC, Andover, Mass) was placed in the subantral area. Following a periosteal releasing incision to allow primary closure, the flap was repositioned and sutured using materials of the surgeon's choice.

Statistical analysis

This research methodology was reviewed by an independent statistician, and the statistical analysis was performed by the same individual. Statistical software SAS version 9.4 (SAS institute Inc, Cary, NC) was used to analyze the data. Test and control groups were compared for differences in demographic and preoperative characteristics using 2-sample *t* tests and Fisher exact tests, as appropriate for continuous and categorical data, respectively. A propensity score analysis was used to compare the groups for differences in the proportion of patients with perforation. The propensity score is the probability of treatment using a sponge given demographic and preoperative characteristics and was calculated using logistic regression. A second logistic regression model was then used to compare the groups for differences in the proportion of patients with perforation, using the propensity score as a covariate. $P < .05$ was used for the statistically significant level.

Results

A total of 38 sites were included in this retrospective study (test: $n = 15$; control: $n = 23$). There were no statistically significant differences in any demographic data or preexisting conditions including age, sex, location of treatment, presence or absence of a septum, Schneiderian membrane thickness, and residual bone height in both the test and control groups. The prevalence of a sinus septum was 36.8% (14/38 cases), and

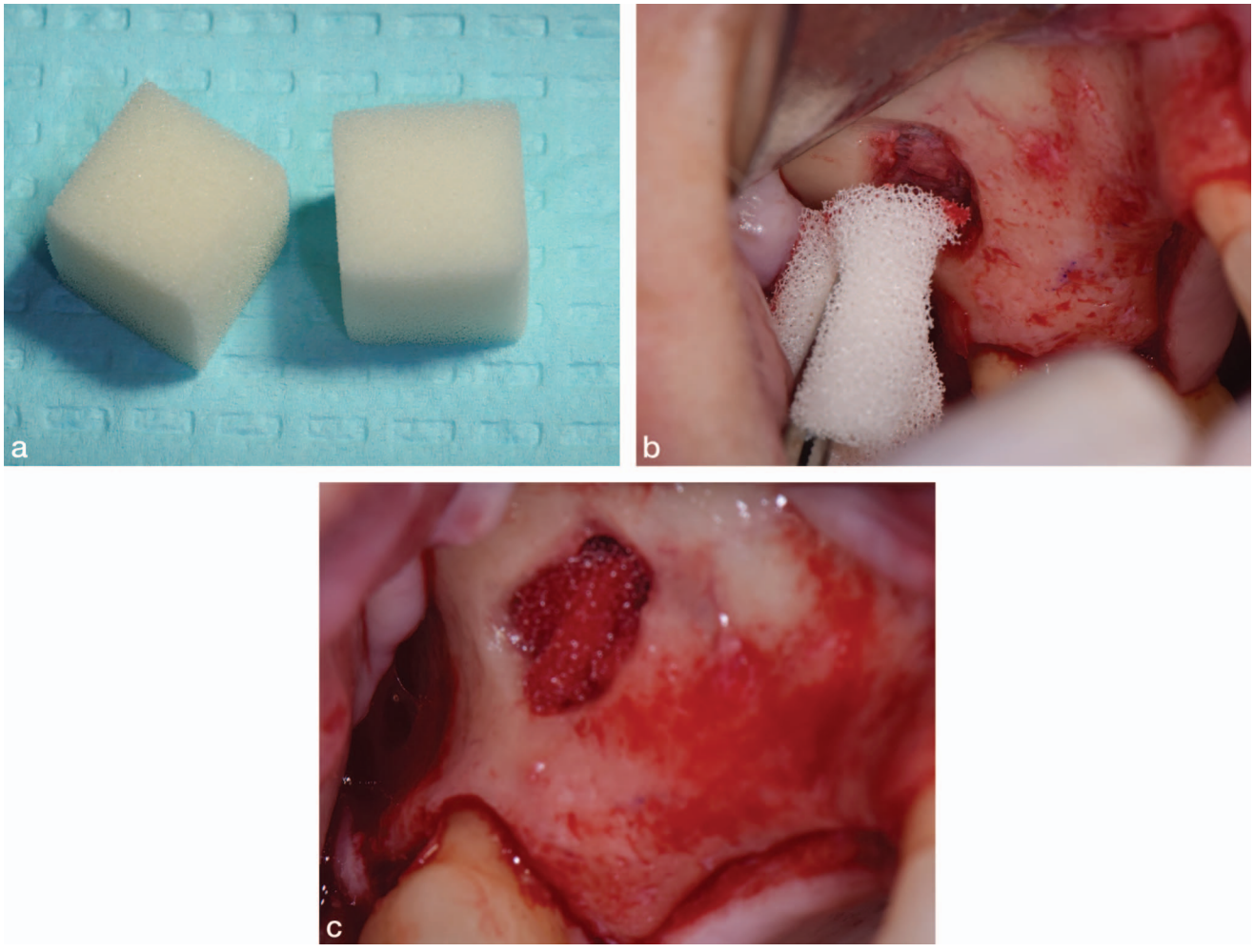

Figure 1. (a) Medical-grade polyurethane sponge. (b) Insertion of sponges into the nasal sinus. (c) Sinus membrane was elevated with sponges.

the membrane perforation rate when a septum was present was 7% (1/14 cases). One case of sinus membrane perforation with a preexisting sinus septum was associated with the conventional technique using sinus curettes.

With regard to the lateral window osteotomy, a piezoelectric device was used for 17 sites, a combination of piezoelectric device and rotary burs was used for 15 sites, rotary burs alone were used for 5 sites, and an end-cutting bur was used for 1 site (Table). Overall, the Schneiderian membrane perforation rate associated with a lateral window approach (test and control) was 28.9% (11/38 sites). The rate of membrane perforation was 7% (1/15 sites) in the test group and 43% (10/23 sites) in the control group. Following the logistic regression model analysis, including demographic data and methods of osteotomy procedures, the rate of Schneiderian membrane perforation was not statistically different between the test and control groups ($P = .064$; Figure 2).

Discussion

Following the loss of maxillary posterior teeth, alveolar bone resorption and maxillary sinus pneumatization negatively affect restorative driven implant placements. Sinus floor elevation procedures that include osteotome sinus lift and the lateral window approach are considered as predictable treatment options to augment bone prior to and during simultaneous implant placement. However, these procedures are not free of complications, and membrane perforation is the most common intrasurgical complication with sinus augmentation. The incidence of perforation has been reported to be vary widely,

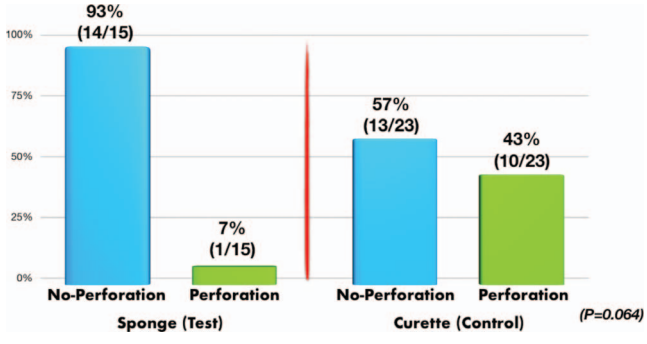

Figure 2. Schneiderian perforation rate with test and control groups.

TABLE

Subjects' demographic data and preexisting conditions*

		Sponge (n = 15)	Curette (n = 23)	*P* Value
Age	Mean (SD)	57.1 (8.1)	59.1 (10.3)	.517
Sex	F	7 (47%)	14 (61%)	.509
	M	8 (53%)	9 (39%)	
Side	L	11 (73%)	13 (57%)	.329
	R	4 (27%)	10 (43%)	
CT, septa	N	9 (60%)	15 (65%)	1.000
	Y	6 (40%)	8 (35%)	
CT, membrane thickness, mm	Mean (SD)	1.9 (2.9)	3.2 (5.7)	.363
CT, residual bone height, mm	Mean (SD)	3.9 (1.4)	3.9 (1.5)	.923
Piezo	N	2 (13%)	4 (17%)	1.000
	Y	13 (87%)	19 (83%)	
Bur	N	5 (33%)	13 (57%)	.198
	Y	10 (67%)	10 (43%)	
Perforation	N	14 (93%)	13 (57%)	.064
	Y	1 (7%)	10 (43%)	

*CT indicates computerized tomography.

from 3.6% to 41% among studies.[10,11,14,15] Nolan and colleagues[11] reported an incidence of sinus membrane perforation of 41% using a Hall drill with a carbide round bur. Monje et al[15] conducted a prospective study to assess the incidence of sinus membrane perforation with a reamer drilling sequence. This particular reamer allowed the created space to be filled with bone particles while drilling, theoretically reducing the risk of membrane tear. The authors reported that the rate of sinus membrane perforation was 12.5% with this drilling sequence. In addition, another 2.5% of membrane tearing was noted during membrane reflection.[15] Toscano and coworkers[14] used a piezoelectric device and reported a zero perforation rate at the time of lateral antrostomy preparation but noted that 2 of 56 sites (3.6%) developed membrane perforations during membrane elevation with hand instruments. Both of these perforations were associated with the presence of septum.[14] According to these studies, piezoelectric devices and specially designed drills, such as a reamer-shaped drill, can reduce the risk of sinus membrane perforation during the osteotomy creation. The perforation may still occur at the time of actual membrane elevation from the bony sinus walls. In this study, the piezoelectric device itself or a combination of a piezoelectric device and rotary burs was used for most of the lateral window osteotomies in the test and control groups. There were no statistically significant differences between control and test groups in terms of method of antrostomy preparation. Conventional curettes were used to elevate the membrane in the control group, and the membrane perforation rate was 43% (10/23). The test group showed only a 7% (1/15) perforation rate using the polyurethane sponges. Although this difference did not achieve statistical significance, possibly because of the sample size, the difference was judged to be clinically significant. The use of the 4ST sponges appeared to clinically reduce the rate of membrane perforations when compared with conventional sinusotomy curettes for membrane elevation from the internal bony walls. These medical-grade polyurethane sponges are compressed prior to insertion into the subantral sinus area. The gradual expansion force gently applies pressure between the sinus walls and Schneiderian membrane. Shahi et al[13] described this effect as a "cushioned" force application, as these sponges have been shown to produce approximately 40–60 g of force upon expansion. Membrane thickness at sites with sinus membrane perforation was 0.42 mm in the test group, as measured from pretreatment CBCT images. However, the minimum amount of membrane thickness needed to resist the gradual force from the 4ST sponge expansion without tearing remains unclear. Additional controlled studies are needed to confirm the relationship between membrane resistance and sponge expansion forces. Medical-grade polyurethane sponges offer the advantage of being relatively inexpensive materials and are relatively easy to use with minimal additional training.

There are several limitations to this retrospective study. First, because of the inherent nature of this retrospective study, there is the risk of convenience sampling, even though all included data met the inclusion criteria. Since some uncontrolled subjects were included, there is a risk of some sort of bias in answering the specific the aim of the study. As a matter of fact, some of the patient records did not specify the specific timing when the sinus membrane perforation occurred. In the retrospective chart review study by Nolan et al,[11] the authors reported a 41% sinus membrane perforation rate during surgical procedures. However, the timing of when the perforation occurred was not clear.[11] These issues can be avoided using prospective studies that can be more specific with regard to the specific etiology and timing of perforations relative to antrostomy creation, membrane reflection, or placement of bone graft materials.[15] Therefore, the outcome of this retrospective study cannot be conclusive because of the limitations of the accuracy of records, other confounding factors, and possibly biased sample selections. Needless to say, the other major limitation was the relatively small sample size. However, these medical-grade sponges are relatively new materials to be used for membrane elevation. Thus, one of the strengths of this study is that this is the first report to compare the rate of sinus membrane perforation using a conventional technique and this technique. The other strength of this study was that 4ST sponges were tested with relatively

inexperienced surgeons. This is because the lateral window procedures were performed by multiple residents.

In the future, more controlled prospective clinical trials will be needed to confirm the benefit of using 4ST sponges for reducing sinus membrane perforation during the reflection of the sinus membrane in the lateral window approach. To overcome the limitations of our study, additional controlled prospective studies need to be conducted to verify the usefulness of the sponges in reducing sinus membrane perforations. To reduce confounding factors, a single surgeon should perform all procedures using a single method of window creation in a prospective study to analyze the efficacy of this medical-grade sponge technique.

Conclusion

Within the limitations of this study, there was no statistically significant difference in sinus membrane perforation during sinus floor elevation with medical-grade polyurethane sponges as compared with sinusotomy curettes. However, the difference in the perforation rate between the 2 techniques (43% vs 7%) was felt to be clinically significant. Because of the nature of this retrospective study and the relatively small sample size, a future prospective study is necessary to confirm these results.

Abbreviations

4ST: Safer-Simplified-Sinus-Surgery Technique
CBCT: cone-beam computerized topography
CT: computerized tomography

Note

The authors do not have any financial interests in any of the products mentioned in this article.

Acknowledgment

This study was partially funded by the Department of Periodontology fund at Indiana University School of Dentistry. The authors would like to thank to Mr George J. Eckert, MAS, biostatistician supervisor, Department of Biostatistics, Indiana University School of Medicine, for the statistical analysis.

References

1. Araujo MG, Lindhe J. Dimensional ridge alterations following tooth extraction: an experimental study in the dog. *J Clin Periodontol*. 2005;32:212–218.

2. Tan WL, Wong TL, Wong MC, Lang NP. A systematic review of post-extractional alveolar hard and soft tissue dimensional changes in humans. *Clin Oral Implants Res*. 2012;23(suppl 5):1–21.

3. Wallace SS, Tarnow DP, Froum SJ, et al. Maxillary sinus elevation by lateral window approach: evolution of technology and technique. *J Evid Based Dent Pract*. 2012;12(3 suppl):161–171.

4. Fugazzotto PA. Augmentation of the posterior maxilla: a proposed hierarchy of treatment selection. *J Periodontol*. 2003;74:1682–1691.

5. Lundgren S, Cricchio G, Hallman M, Jungner M, Rasmusson L, Sennerby L. Sinus floor elevation procedures to enable implant placement and integration: techniques, biological aspects and clinical outcomes. *Periodontol 2000*. 2017;73:103–120.

6. Bergh J, Bruggenkate CM, Disch FJ, Tuinzing DB. Anatomical aspects of sinus floor elevations. *Clin Oral Implants Res*. 2000;11:256–265.

7. Al-Dajani M. Recent trends in sinus lift surgery and their clinical implications. *Clin Implant Dent Relat Res*. 2016;18:204–212.

8. von Arx T, Fodich I, Bornstein MM, Jensen SS. Perforation of the sinus membrane during sinus floor elevation: a retrospective study of frequency and possible risk factors. *Int J Oral Maxillofac Implants*. 2014;29:718–726.

9. Lum AG, Ogata Y, Pagni SE, Hur Y. Association between sinus membrane thickness and membrane perforation in lateral window sinus augmentation: a retrospective study. *J Periodontol*. 2017;88:543–549.

10. Becker ST, Terheyden H, Steinriede A, Behrens E, Springer I, Wiltfang J. Prospective observation of 41 perforations of the Schneiderian membrane during sinus floor elevation. *Clin Oral Implants Res*. 2008;19:1285–1289.

11. Nolan PJ, Freeman K, Kraut RA. Correlation between Schneiderian membrane perforation and sinus lift graft outcome: a retrospective evaluation of 359 augmented sinus. *J Oral Maxillofacial Surg*. 2014;72:47–52.

12. Atieh MA, Alsabeeha NH, Tawse-Smith A, Faggion CM Jr, Duncan WJ. Piezoelectric surgery vs rotary instruments for lateral maxillary sinus floor elevation: a systematic review and meta-analysis of intra- and postoperative complications. *Int J Oral Maxillofac Implants*. 2015;30:1262–1271.

13. Shahi RG, Tanaka T, Towns S, Forrest A, Blanchard SB. Novel approach for lateral window sinus membrane elevation using medical grade polyurethane sponges: case report. *Clin Adv Periodontics*. 2017:1–18.

14. Toscano NJ, Holtzclaw D, Rosen PS. The effect of piezoelectric use on open sinus lift perforation: a retrospective evaluation of 56 consecutively treated cases from private practices. *J Periodontol*. 2010;81:167–171.

15. Monje A, Monje-Gil F, Burgueño M, et al. Incidence of and factors associated with sinus membrane perforation during maxillary sinus augmentation using the reamer drilling approach: a double-center case series. *Int J Periodontics Restorative Dent*. 2016;36:549–556.