Repair of the Perforated Sinus Membrane with a Resorbable Collagen Membrane: A Human Study

Periklis Proussaefs, DDS, MS[1]/Jaime Lozada, DDS[2]/Jay Kim, PhD[3]/Michael D. Rohrer, DDS, MS[4]

Purpose: *The purpose of this study was to evaluate the results of the repair of perforated sinus membranes with resorbable collagen membrane.* ***Materials and Methods:*** *A split-mouth design was followed. Twelve subjects requiring bilateral sinus grafting were included in the study; one site had been accidentally perforated during sinus augmentation and the other site had not been perforated. The perforated sites were repaired with a resorbable collagen membrane. Dental implants were placed during a second surgery, and biopsy samples were harvested from both sinuses during implant placement. New bone formation was measured for all sites. Implant survival was recorded at second-stage surgery. Panoramic radiographs were taken before and after sinus grafting and after implant placement.* ***Results:*** *Nonperforated sites demonstrated significantly more bone formation (33.58% ± 7.45%) than perforated sites (14.17% ± 7.06%) (*$P < .0001$*). Perforated sites demonstrated significantly more soft tissue formation (63.58% ± 12.96%) than nonperforated sites (48.5% ± 12.57%) (*$P = .006$*). In nonperforated sites, residual graft particles had more of their surface in contact with bone (40.17% ± 14.92%) than perforated sites (14.5% ± 12.03%) (*$P < .0001$*). The implant survival rate at second-stage surgery was superior for nonperforated sites (100%) in comparison to perforated sites (69.56%) (*$P = .0028$*).* ***Discussion:*** *This study suggested that repairing the perforated site of the sinus membrane with a resorbable collagen membrane may result in reduced bone formation and implant survival rate. A different technique and/or materials than those used in the current study may offer better results for the repair of the perforated sinus membrane.* ***Conclusion:*** *The study demonstrated that perforation and repair of the sinus membrane may compromise new bone formation and implant survival.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:413–420

Key words: *artificial membranes, collagen, dental implants, maxillary sinus, sinus augmentation, sinus membrane*

Dental implants offer a predictable treatment modality for completely or partially edentulous patients.[1,2] After introduction of the sinus grafting technique,[3,4] implant placement and prosthetic rehabilitation of the resorbed posterior maxilla became a valid treatment option.[5–8]

Several grafting materials have been used to augment the antral space, including autografts,[3,4,9–12] demineralized freeze-dried bone powder,[5,13–15] hydroxyapatite,[5,8,12,16–18] and combinations of these materials.[5,7,8,12,19–21] Regardless of the type of graft that is used, the sinus augmentation procedure involves elevation of the schneiderian membrane and placement of the graft material in the space underneath the reflected membrane.[3] The most common complication during sinus graft surgery is tearing or perforating the sinus membrane (SM).[22] If membrane perforation occurs, the opening can be sealed with a piece of resorbable collagen membrane.[18,22–24]

Even though it has been clinically recommended, there has been no study to evaluate the results of sealing the perforated SM. This study was designed to evaluate the effects of sealing the perforated SM with a resorbable collagen membrane.

[1]Assistant Professor, Graduate Program in Implant Dentistry, Loma Linda University, Loma Linda, California; Private Practice, Santa Clarita, California.
[2]Professor and Director, Graduate Program in Implant Dentistry, Loma Linda University, Loma Linda, California.
[3]Professor of Biostatistics, Education Services, Loma Linda University, Loma Linda, California.
[4]Professor and Director, Division of Oral and Maxillofacial Pathology, University of Minnesota, Minneapolis, Minnesota.

Correspondence to: Dr Periklis Proussaefs, Loma Linda University, School of Dentistry, Graduate Program in Implant Dentistry, Loma Linda, CA 92350. Fax: +909-558-4803. E-mail: pProussaef@hotmail.com

Table 1 Distribution of Subjects

Subject	Age (y)	Gender	Graft healing period (mo)
1	64	F	8
2	56	M	8
3	65	F	9
4	58	F	7
5	78	F	14
6	56	M	8
7	75	M	11
8	70	F	10
9	75	F	16
10	67	F	15
11	67	M	7
12	75	F	6
Mean	67.17		9.92
SD	7.73		3.57

MATERIALS AND METHODS

Twelve human subjects were included in this study (Table 1). A split-mouth protocol was followed. Subjects who were treated with a bilateral sinus grafting procedure and accidentally had the SM perforated on 1 side during the sinus grafting procedure were included in the study. All subjects were asked to respond to the corresponding informed consent approved by the Institutional Review Board for Human studies at Loma Linda University.

Patients were included in the study if they met the following requirements:

1. Bilateral atrophy of the posterior maxillary region, with height of the residual bone at 0 to 4 mm (SA-4),[22] as measured through panoramic and tomographic radiographs
2. Received bilateral sinus grafting and had the SM perforated on one side only
3. Perforation size greater than 2 mm
4. Good oral hygiene

Patients were excluded if they smoked or consumed alcohol, if they suffered acute or recurrent sinusitis in either of the 2 maxillary sinuses, or if they had any uncontrolled systemic disease.

Surgical Procedures

Before surgery, subjects received 500 mg of amoxicillin (Novopharm, Toronto, Canada). Following surgery, subjects were prescribed amoxicillin (500 mg 3 times a day for 10 days) and ibuprofen (800 mg 3 times a day for at least 3 days).

The subjects were given the option to proceed with: *(1)* local anesthesia alone, *(2)* local anesthesia in conjunction with oral sedation, or *(3)* local anesthesia in conjunction with intravenous sedation.

The sinus augmentation procedure followed the technique described by Tatum[4] and Smiler and coworkers.[18] Briefly, a supracrestal incision was made from the canine or first premolar area to the ipsilateral maxillary tuberosity region. Full-thickness mucoperiosteal flaps were raised and the lateral wall of the sinus was exposed. A rectangular osteotomy was made with a no. 4 round bur (ACE Surgical Supply, Brockton, MA). The inferior osteotomy was 5 mm above the sinus floor. The superior osteotomy was left intact to allow infracture of the lateral sinus wall. The SM was carefully elevated. A portion of the antral space was filled with inorganic bovine bone mineral (IBM) (Bio-Oss; Osteohealth, Shirley, NY) alone or mixed with demineralized freeze-dried bone allograft (Processed human allograft, Skeletal Transplant Foundation, Edison, NJ).

The same type of graft material was used in both sites for each patient. The amount of graft material used at each site varied according to the extent of maxillary bone resorption and sinus anatomy.

For areas where the SM was perforated during reflection (Fig 1a), a resorbable collagen membrane was trimmed and placed at the site of the perforation prior to insertion of the graft material (Figs 1b and 1c). No membrane barrier was placed against the graft material. The mucoperiosteal flaps were repositioned and sutured with horizontal mattress and single interrupted sutures.

Implants were placed after a period of 6 to 16 months. During implant placement surgery, the bone quality was recorded (types 1 to 4 according to Lekholm and Zarb[25]) and a sample was taken from the grafted area for biopsy.

Radiographic Evaluation

In all cases, panoramic radiographs were obtained before and after the sinus grafting procedure and after placement of the implants.

Implant Survival

Implant survival was recorded at second-stage surgery. Implant mobility was evaluated following placement of a healing abutment by the bimanual use of 2 hand instruments. In addition, the Periotest unit (Siemens, Bensheim, Germany) was used to assess implant mobility.[26] Mobility of more than +1 Periotest value was considered to indicate implant failure. Implants with symptoms of pain or sensitivity to percussion as well as clinical signs of infection

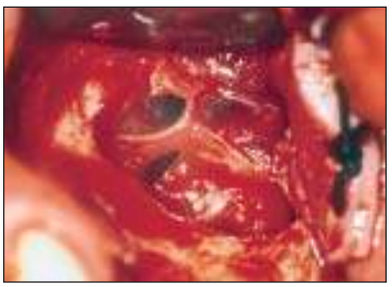

Fig 1a Perforation of the sinus membrane is observed.

Fig 1b A resorbable collagen membrane is placed against the perforated site to repair the sinus membrane.

Fig 1c Inorganic bovine bone mineral is subsequently added as graft material against the collagen membrane.

were considered failures. There were instances where the bone graft appeared soft and inadequate to provide primary stability during implant placement. During the statistical analysis, these cases were also recorded as failures.

Biopsy Procedure

A healing time of 6 to 16 months was allowed before proceeding with implant placement surgery. During surgery, a biopsy sample was harvested with a 2-mm (internal diameter) trephine bur (ACE Surgical Supply) starting from the alveolar crest and ending at the most superior part of the graft. The site of biopsy was the area where the original bone had the least height. The trephine bur was used as the first drill during the osteotomy preparation for implant placement. Subsequently, a hydroxyapatite-coated, threaded, root-form implant (Steri-Oss; Nobel Biocare, Yorba Linda, CA) was placed according to the manufacturer's protocol. The biopsy specimens were fixed in 10% buffered formalin.

Histologic Processing

The specimens were dehydrated in alcohol, and embedded in specialized resin (Technovit 7200 VLC; Kulzer, Wehrheim, Germany). Initial midaxial sections of 200 µm were made with a cutting-grinding system (Exact Medical Instruments, Oklahoma City, OK). The sections were then ground to 40 to 50 µm and stained with Stevenel's blue and van Gieson's picro-fuchsin for histomorphometric analysis and fluorescent microscopy.[27,28]

Histomorphometric Evaluation

Histomorphometric evaluation was performed by one investigator using a computer-assisted linear analysis program developed at Loma Linda University.[29] This program uses a series of systematically spaced horizontal lines (each 2 pixels wide) on a vertically oriented image selected for analysis.[30] In this study, the lines were spaced 50 pixels apart in the object plane, and the first line was placed randomly within 50 pixels of the top of the image. Keyboard entries and cursor clicks recorded the lengths of the line segments that crossed the various types of tissue (bone, soft tissue, or residual bone graft particles). Intersections of lines with residual bone graft particles were recorded as contacting bone or soft tissue, depending on the type of tissue at the interface. For each histologic specimen, 1 to 3 images were analyzed (depending on the size of the specimen).

Percent composition of the specimen was represented by the ratio of the sum of the lengths of line segments falling on a given component (bone, soft tissue, graft particles) to the total length of lines analyzed. The percent of residual xenograft surface occupied by bone was represented by the ratio of the number of line intersections with bone/particle interfaces to the total number of graft/xenograft surface intersections.

All histomorphometric analyses were performed by capturing an image under 2× magnification (Olympus Microscope, Model BH-2; McBain Instruments, Chatsworth, CA).

Statistical Analysis

The Mann-Whitney *U* test was used at a significance level of .05 to compare new bone formation, presence of connective tissue, residual IBM particles, and bone/IBM particle contact between perforated sites (PS) and nonperforated sites (NPS).

Using normal approximation of the binomial distribution, the authors compared the survival rate of implants in PS and NPS at second-stage surgery.

RESULTS

Clinical Evaluation

No immediate postoperative complication (infection, persistent pain, or bleeding) occurred in any of the sinus graft procedures. During implant surgery,

Table 2 Bone Quality* of Grafted Areas and Implant Survival at Second-Stage Surgery

	Perforated side				Nonperforated side			
Patient	Bone quality	Implants planned	Implants placed	Failures	Bone quality	Implants planned	Implants placed	Failures
1	4	2	1†	0	3	2	2	0
2	3	2	2	0	2	2	2	0
3	4	2	2	0	3	1	1	0
4	4	2	1†	0	3	2	2	0
5	4	3	3	3	2	3	3	0
6	3	1	1	0	2	1	1	0
7	3	2	2	0	2	2	2	0
8	3	2	2	0	2	2	2	0
9	4	1	1	0	2	1	1	0
10	4	2	2	0	2	2	2	0
11	3	2	2	0	3	2	2	0
12	4	2	2	2	2	2	2	0

*According to Lekholm and Zarb.[25]
†In these patients, bone quality was inadequate to provide primary stability for a second implant; 1 implant was placed instead of 2, as was originally planned.

2 patients (patients 1 and 4; Table 2) demonstrated inadequate consistency of the graft material in some areas (in PS), which precluded primary stabilization of the dental implant. PS had typically type 4 bone (7 of 12 patients), while most of the NPS had type 2 bone quality (8 of 12 patients).

Radiographic Evaluation

NPS demonstrated sharp definition between the grafted and nongrafted areas of the maxillary sinus (Fig 2a). PS appeared to have graft particles beyond the borders of the SM and lacked definition between the grafted and nongrafted sinus areas. In areas where the graft material had been dislodged beyond the boundaries of the sinus membrane, resorption of the graft material was observed (Figs 2b and 2c). In addition, there were instances where the grafted area at the PS appeared to be more radiolucent in comparison to NPS (Fig 3).

Implant Survival

NPS had a 100% implant survival rate up to the second-stage surgery, while PS showed a 69.56% survival rate. Statistical analysis (normal approximation to the binomial distribution) showed a significantly higher survival rate at NPS compared to PS ($P = .0028$).

Histologic Observations

NPS appeared to have enhanced bone formation (Fig 4a). Residual IBM particles were in tight contact with newly formed bone (Figs 4b and 4c). PS had abundant connective tissue formation (Fig 5a), and the residual IBM particles were surrounded mostly by connective tissue (Fig 5b).

Histomorphometric Analysis

NPS had 33.58% ± 7.45% bone formation, 48.50% ± 12.57% soft tissue, and 18.17% ± 9.07% residual graft material; 40.17% ± 14.92% of the surfaces of the IBM particles were surrounded by bone (Fig 6, Table 3). PS had 14.17% ± 7.06% bone formation, 63.58% ± 12.96% soft tissue, and 22.25% ± 10.46% residual IBM particles; and the IBM particle/bone contact was 14.50% ± 12.03%. Bone formation was significantly greater in the NPS ($P < .0001$) compared to the PS, while PS had more soft tissue formation ($P = .006$) (Fig 6, Table 4). Significantly more IBM particle/bone contact was seen in NPS than in PS ($P < .0001$).

DISCUSSION

The current study demonstrated that SM perforation can result in reduced bone formation and a compromised implant survival rate. It can be hypothesized that bacterial penetration through the torn membrane and mucus invasion into the grafted area[22] may contribute to this compromised result. In addition, repair of the SM with a collagen membrane does not preclude release of graft particles within the sinus space through the torn site. During graft placement and packing, the clinician is unable to observe whether or not membrane repair is adequate to resist pressure during graft placement. Haas and associates,[31] in a study performed in sheep, observed that there were inflammatory cells and slight inflammation with less bone formation close to perforated areas of the SM.

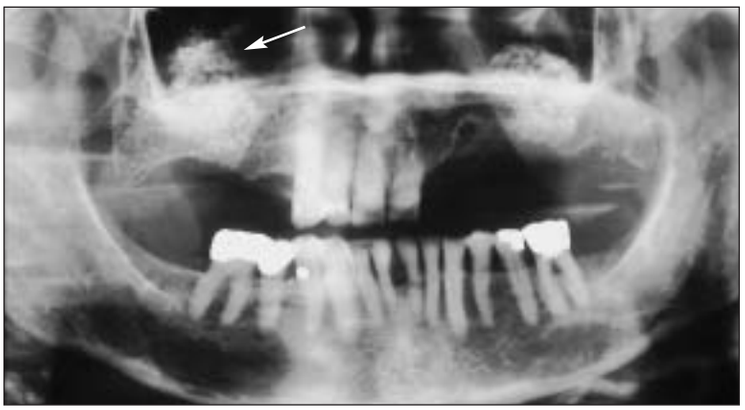

Fig 2a Panoramic radiograph after bilateral sinus grafting procedure. The right side had been perforated. In the perforated site, the graft material lacks sharp definition *(arrow)* as compared to the nonperforated site.

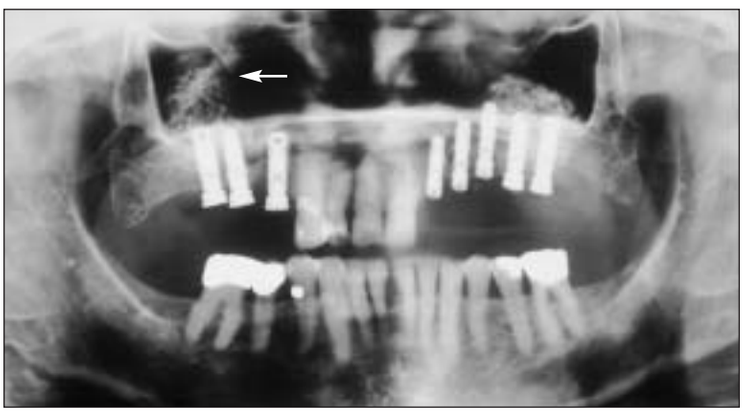

Fig 2b Implants were placed. The panoramic radiograph suggests that graft particles were located beyond the boundaries of the sinus membrane *(arrow)*. The perforated site appears to be more radiolucent compared to the initial stage (Fig 2a).

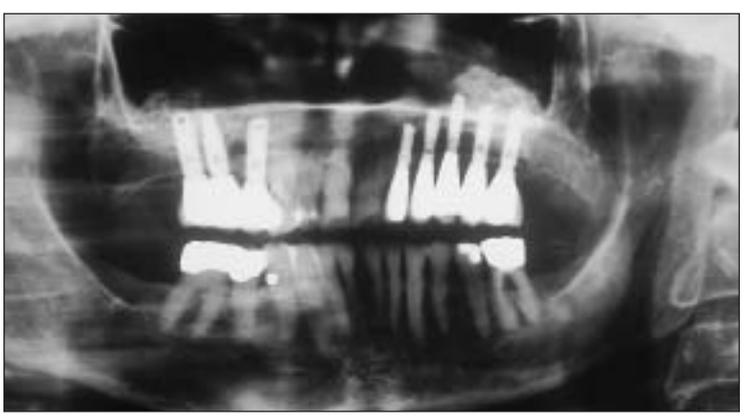

Fig 2c Six months after loading. The graft material at the perforated site appears to have resorbed completely. The nonperforated site appears to have minimal or no resorption.

Fig 3 Panoramic radiograph after bilateral sinus graft was performed. The right sinus membrane had been perforated. The perforated site appears more radiolucent than the nonperforated site.

Fig 4a Histologic overview of a core harvested from a nonperforated site (original magnification ×4).

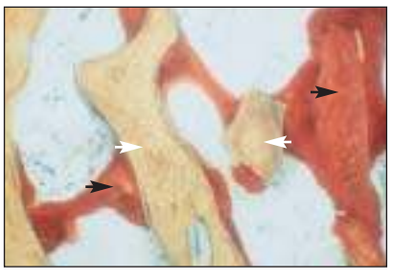

Fig 4b Newly formed bone *(black arrows)* appeared to be in contact with residual IBM particles *(white arrows)* (original magnification ×10).

Fig 4c Polarized microscopy emphasizes active remodeling of newly formed bone (original magnification ×10).

Fig 5a Histologic overview of a core harvested from a perforated site (original magnification ×4).

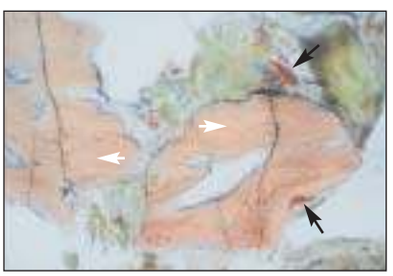

Fig 5b Minimal bone formation *(black arrows)* is observed, while residual IBM particles *(white arrows)* are mostly in contact with connective tissue (original magnification ×10).

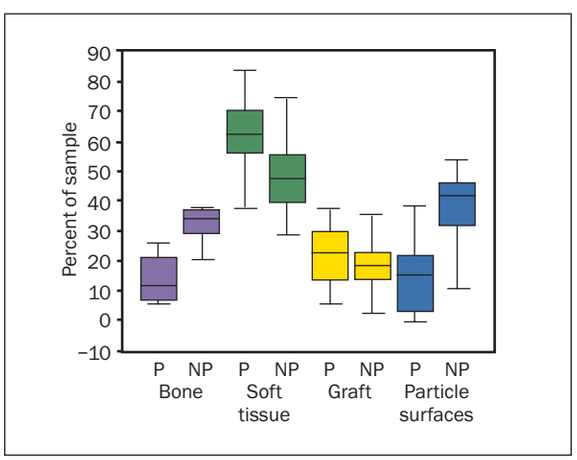

Fig 6 Histomorphometric analysis. NP = nonperforated sites; P = perforated sites; bone = percentage of newly formed bone; graft = percentage of residual IBM particles; particle surfaces = percentage of IBM particle/bone contact; soft tissue = percentage of newly formed connective tissue.

Reiser and coworkers[32] introduced a classification for the perforated SM. In that article, the authors correlated the extent of SM perforation to prognosis of the sinus grafting procedure. According to their classification, a class 1 perforation is a slight (< 2 mm) lateral or apical perforation. In this type of perforation, the resulting elevated dome-shaped membrane space retains its shape once the implant is placed; these perforations were considered to have a good prognosis. Class 2 described a perforation larger than 2 mm; this resulted in an implant exposed to the sinus cavity as well as loss of space and dome shape. The clinical outcome of these perforations was considered guarded.

Boyne[33] reported that minor membrane perforations may not play a significant role in the clinical outcome. However, it appears that the size of the SM perforation plays an important role in sinus augmentation procedures. The current study included perforations larger than 2 mm. It is unknown if the compromised results in PS would have been observed in cases with perforations that were smaller than 2 mm.

The described technique for repairing the perforated SM resulted in compromised bone formation. Even though several clinicians have recommended the use of a resorbable collagen membrane to repair a perforated SM,[18,22–24] no report has described the technique that needs to be followed when using collagen membrane for these cases. The compromised clinical outcome in the current study was the result of the inadequacy of the technique used in these cases. Perhaps application of a different technique or material than those used in this study would have

Table 3 Histomorphometric Analysis

	Perforated side (%)				Nonperforated side (%)			
Subject	Bone	CT	Graft	Contact	Bone	CT	Graft	Contact
1	13	57	30	15	37	47	18	54
2	26	38	36	39	49	48	3	70
3	6	75	19	0	21	75	4	11
4	11	83	6	26	27	61	13	27
5	8	62	30	0	38	38	24	42
6	6	84	10	8	23	62	15	25
7	21	52	27	22	35	29	36	48
8	19	66	15	18	32	49	19	37
9	21	63	16	17	34	45	21	43
10	21	66	13	22	33	50	17	42
11	11	62	27	7	37	41	22	45
12	7	55	38	0	37	37	26	38
Mean	14.17	63.58	22.25	14.50	33.58	48.50	18.17	40.17
SD	7.06	12.96	10.46	12.03	7.45	12.57	9.07	14.92

Bone = new bone formation; CT = connective tissue; graft = residual IBM particles; contact = bone/IBM particle contact.

produced different results in the PS. Proussaefs and Lozada[34] have introduced a technique (the "Loma Linda pouch") to repair the perforated SM. According to this technique, the collagen membrane forms a pouch around the sinus graft material. The collagen membrane surrounds the graft material and seals the lateral access window. A clinical study is needed to evaluate the results of this technique.

Table 4 Results of the Mann-Whitney *U* Test

Parameter	PS versus NPS	*P*
Bone	PS < NPS	< .0001
Soft tissue	PS > NPS	.006
Residual IBM particles	Statistically insignificant	.3780
Bone/IBM particle contact	PS < NPS	< .0001

CONCLUSIONS

The results of this study population demonstrated that even though there was an attempt to repair the perforated SM during sinus grafting, reduced bone formation and a less than desirable implant survival rate occurred.

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