EFFECTS OF SEALING THE PERFORATED SINUS MEMBRANE WITH A RESORBABLE COLLAGEN MEMBRANE: A PILOT STUDY IN HUMANS

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KEY WORDS

Resorbable collagen membrane
Sealing perforated sinus membrane

The effects of repairing the perforated sinus membrane with collagen membrane are unknown. The purpose of this pilot study was to clinically, histologically, and histomorphometrically evaluate the results of repairing the perforated sinus membrane with resorbable collagen membrane. A split-mouth design was followed in the current study. Five subjects requiring bilateral sinus grafting were included in the study, where one site was accidentally perforated during sinus augmentation procedures and the other site was not perforated. The perforated sites were repaired with a resorbable collagen membrane. Dental implants were placed at a second stage and biopsies were harvested from both sinuses. New bone formation was measured for all sites. Implant survival was recorded at second-stage surgery. Nonperforated sites demonstrated significantly more bone formation (34.40%) than perforated sites (12.80%) ($P = .016$). Implant survival at second-stage surgery was significantly inferior in perforated sites (54.5%) when compared with nonperforated sites (100%) ($P = .0146$). The study demonstrated that perforation and repair of the Schneiderian membrane can compromise new bone formation and implant survival rate.

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INTRODUCTION

Dental implants offer a predictable treatment modality for the totally or partially edentulous patient.[1,2] After the introduction of sinus-grafting techniques[3,4] implant placement and prosthetic rehabilitation of the resorbed posterior maxilla has become 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 (DFDBA) powder,[5,13–15] hydroxyapatite,[5,8,12,16–18] and combinations of these.[5,8,12,19–22] 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 at the space underneath the reflected membrane.[3] The most common complication during sinus graft surgery is tearing or perforating the sinus membrane (SM).[23] If membrane perforation occurs, the opening can be

Table 1
Subject distribution*

Subject	Age	Sex	Healing Period of Graft Material (Months)
1	64	F	8
2	56	M	8
3	65	F	9
4	58	F	7
5	78	F	14
Average	64.2	N/A	9.2
SD	4.3		1.6

*N/A indicates not applicable.

sealed with a piece of resorbable collagen membrane.[18,23–25]

Even though it has been clinically recommended, there is no study to evaluate the potential of sealing the perforated SM. A study was designed to clinically, histologically, and histomorphometrically evaluate the effects of sealing the perforated SM with a resorbable collagen membrane.

Materials and Methods

Five human subjects were included in this pilot study (Table 1). A split-mouth design was followed. Subjects who received bilateral sinus grafting procedure and had the SM accidentally perforated in 1 side only 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.

Inclusion criteria

The inclusion criteria were as follows:

1. Patients with bilateral atrophic posterior maxillary region with height of residual bone 0–4 mm (SA-4)[23] as measured through panoramic and tomographic radiographs.
2. Subjects who received bilateral sinus grafting and had the SM perforated in 1 side only.
3. Good oral hygiene.

Exclusion criteria

Exclusion criteria were as follows:

1. Smoking or alcohol consumption.
2. Acute or recurrent sinusitis at any of the 2 maxillary sinuses.
3. Uncontrolled systemic disease.

For all subjects, a healing period of 8–14 months was allowed before implant surgery. During implant surgery, the bone quality was recorded (Type I–IV) and a biopsy was taken from the grafted area.

Pre- and postoperative medication

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

Surgical procedure

The subjects were given the option to proceed with (a) local anesthesia alone, (b) local anesthesia in conjunction with oral sedation, and (c) local anesthesia in conjunction with IV sedation.

The sinus augmentation procedure followed the technique described by Tatum[4] and Smiler et al.[18] Briefly, a supracrestal incision was made from 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 #4 round bur (ACE Surgical Supply Inc, Brockton, Mass). 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 bovine bone mineral (Bio-Oss, Osteohealth Co, Shirley, NY).

For areas where the SM was perforated during reflection (Figure 1), a resorbable collagen membrane was trimmed and placed at the site of the perforation prior to the insertion of the graft material (Figures 2 and 3). The mucoperiosteal flaps were repositioned and sutured with horizontal mattress and single interrupted sutures. Implants were placed after a period of 8 to 14 months. Bone quality (Type I–IV) was recorded during implant placement.[26] Second-stage surgery followed after a 6- to 9-month healing period.

Radiographic evaluation

In all cases, panoramic radiographs were taken before and after the sinus grafting procedure (Figures 4 and 5) and after placement of the implants.

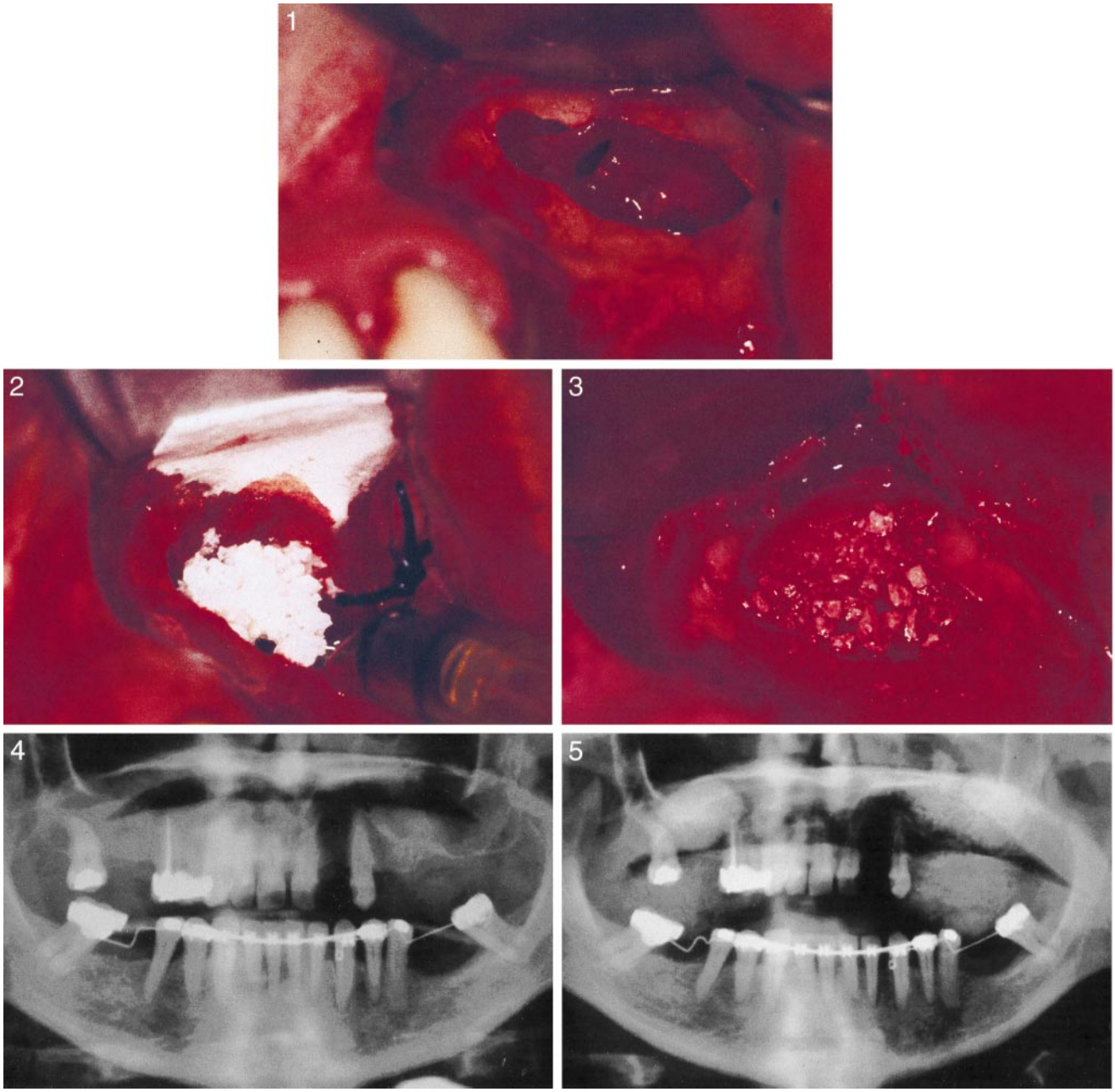
Implant survival

Implant survival was recorded at second-stage surgery (SSS). Implant mobility was evaluated by placing a healing abutment and bimanual use of 2 hand instruments. In addition, the Periotest Unit was used to assess implant mobility.[27] Mobility more than +1 dictated implant failure. Symptoms of pain or sensitivity to percussion as well as clinical signs of infection were recorded as implant failures.

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

Biopsy procedure

A healing time of 8 to 14 months was allowed before proceeding to implant surgery. The biopsy sample was harvested with a 2-mm internal-diameter trephine bur (ACE Surgical Supply Inc) 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 has the least



FIGURES 1–5. FIGURE 1. Perforation of the sinus membrane is observed. FIGURE 2. A resorbable collagen membrane is placed to repair the sinus membrane. Bio-Oss is subsequently added as graft material against the collagen membrane. FIGURE 3. The Bio-Oss particles are placed into the sinus. FIGURE 4. Panoramic radiograph before the sinus-graft procedure. FIGURE 5. Panoramic radiograph after performing bilateral sinus graft. The left sinus had been perforated. Some graft material appears to have escaped into the sinus area (black arrow). In the other side, a sharp line (white arrow) defines the upper margin of the graft material that now represents the floor of the sinus.

height. The trephine bur was used as the first drill during the osteotomy preparation for implant placement. Subsequently, an hydroxyapatite-coated threaded root-form implant (Steri-Oss; Nobel Biocare, Yorba Linda, Calif) was placed according to the manufacturer's protocol. The 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 by means of the cutting-grinding system (Exact Medical Instruments, Oklahoma City, Okla). The sections were then ground to 40 to 50 μm and were stained with Stevenel's blue and Van

TABLE 2

Bone quality of grafted area and implant survival until second-stage surgery

	Perforated Side				Nonperforated Side			
Subject	Bone Quality	Implants Planned To Be Placed	Implants Placed	Failures at Second-Stage Surgery	Bone Quality	Implants Planned To Be Placed	Implants Placed	Failures at Second-Stage Surgery
1	IV	2	1	0	III	2	2	0
2	III	2	2	0	II	2	2	0
3	IV	2	2	0	III	1	1	0
4	IV	2	1	0	III	2	2	0
5	IV	3	3	3	II	3	3	0

Gieson' s picro-fuchsin for histomorphometric analysis and light fluorescent microscopy.[28,29]

Histomorphometric evaluation

Histomorphometric evaluation was performed by one investigator (P.P.) by using a computer-assisted linear analysis program, Ribbon, developed at Loma Linda University.[30] This program uses a series of systematically spaced horizontal lines (each 2 pixels wide), 1 by 1, on a vertically oriented image selected for analysis. 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 given 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 given by the ratio of the number of line intersections with bone-particle interfaces to the total number of graft xenograft surface intersections.

All histomorphometric analysis was performed by capturing an image under ×2 magnification (Olympus Microscope, Model BH-2; McBain Instruments, Chattworth, Calif).

Statistical analysis

The Mann-Whitney *U* test was used at significance level a = .05 to compare new bone formation, connective tissue, residual graft (Bio-Oss) particles, and bone to Bio-Oss contact between perforated sites (PS) and nonperforated sites (NPS).

A 2-sample test for binomial proportions was used to compare implant survival rate between PS and NPS.

RESULTS

Clinical evaluation

No immediate postoperative complication (infection, persistent pain, or bleeding) occurred in any of the sinus-graft procedures. During implant surgery, 2 patients (Table 2) that had perforation of the SM demonstrated inadequate consistency of the graft material in some areas, precluding primary stabilization of dental implant. PS had typically Type IV bone quality (4 patients) while NPS had Type II or III.

Radiographic evaluation

Nonperforated sites demonstrated a sharp definition between grafted and nongrafted areas of the maxillary sinus (Figure 5). Perforated sinuses appear to have graft particles beyond the borders of the SM, lacking definition between the grafted and nongrafted sinus area.

Implant survival

The NPS had 100% implant survival rate until SSS, while PS had 54.5% survival. The NPS had a significantly better implant survival rate ($P = .0146$).

Histologic observations

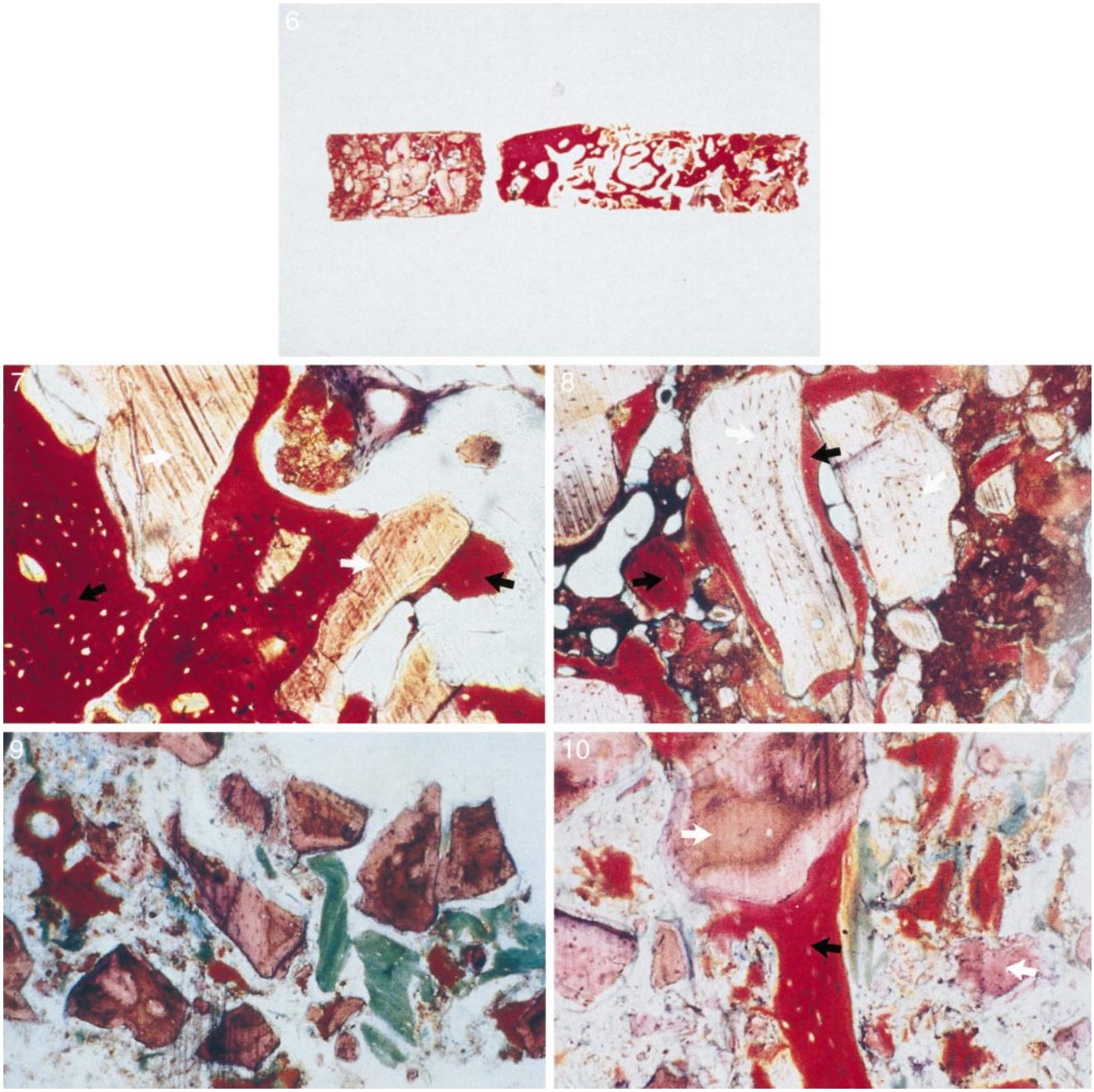
The NPS appeared to have enhanced bone formation (Figure 6). Residual Bio-Oss particles appeared in tight contact with newly formed bone (Figures 7 and 8). The PS had abundant connective-tissue formation (Figure 9). Few areas with bone formation appeared not to be connected between them. Even though there were areas where tight Bio-Oss to bone contact could be seen (Figure 10), in the majority of the cases, Bio-Oss particles were surrounded by connective tissue.

Histomorphometric analysis

The NPS had 34.40% bone formation, 53.80% soft tissue, 12.40% residual graft material, while 40.80% of the surface of the Bio-Oss particles was surrounded by bone (Table 3). The PS had 12.80% bone formation, 63.00% soft tissue, 24.20% residual Bio-Oss particles, while Bio-Oss to bone contact was 16.00%. Bone formation was significantly more in NPS ($P = .016$) (Table 4). Bio-Oss to bone contact was increased in NPS as compared with PS (40.80 vs 16.00%) but the difference was not statistically significant ($P = .095$).

DISCUSSION

The current study demonstrated that SM perforation may result in reduced bone formation and compromised implant survival. It can be hypothesized that bacterial penetration through the torn membrane and mucous invasion



FIGURES 6–10. FIGURE 6. Histologic overview, core harvested from the nonperforated side of subject 1 (original magnification ×2). FIGURE 7. Newly formed bone appeared to cover the majority of the specimen (black arrows). Residual Bio-Oss particles (white arrows) appeared in tight contact with bone (original magnification ×4). FIGURE 8. At a higher magnification level, intimate bone (black arrows)-Bio-Oss (white arrows) contact can be observed (original magnification ×10). FIGURE 9. Histologic overview, core harvested from the perforated side of subject 2 (original magnification ×4). FIGURE 10. The residual Bio-Oss particles (white arrows) appeared to be surrounded by connective tissue. Little or no bone formation (black arrow) is observed (original magnification ×10).

into the grafted area[23] may be the reasons for 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 if membrane repair is adequate to resist pressure during graft placement.

No clinical study has evaluated the potential and results when regrafting the maxillary sinus. To the author's experience, once a sinus grafting procedure has failed, a regrafting procedure offers compromised results. Reflection of the SM is difficult because of the presence of irregular and sharp resid-

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
Average	12.80	63.00	24.20	16.00	34.40	53.80	12.40	40.80
SD	7.85	17.36	11.88	16.90	10.81	14.41	9.02	22.95

TABLE 4

Mann-Whitney *U*-test*

Parameter Evaluated	PS vs NPS	*P* Value
Bone	Statistically significant, nonperforated > perforated	.016
Soft tissue	Statistically nonsignificant	.421
Residual Bio-Oss particles	Statistically nonsignificant	.095
Bone to Bio-Oss contact	Statistically nonsignificant	.095

*PS indicates perforated site; NPS, nonperforated site.

ual graft particles. Extensive perforations of the SM occur in these cases.

Proussaefs and Lozada[31] have described a technique to repair the perforated SM. Briefly, collagen membrane is placed internally into the sinus to surround the entire internal surface of the maxillary sinus. The collagen membrane is then folded externally at the area of the window osteotomy to form a pouch (Loma Linda pouch) that isolates and protects the graft material. A clinical study is needed to validate the use of this technique.

However, it needs to be acknowledged that the number of subjects of this pilot study was limited. Even though the differences between PS and NPS offered statistically significant results regarding new bone formation and implant survival rate, a larger sample size is needed before definitive conclusions can be made.

CONCLUSIONS

In summary, the preliminary results of this pilot study demonstrated that perforation and repair of the SM during sinus grafting offers reduced bone formation and implant survival rate. An increased sample size is needed to validate the results of this preliminary report.

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