ARTICLE

Prospective, Double-Blind, Randomized Trial Evaluating Patient Satisfaction, Bleeding, and Wound Healing Using Biodegradable Synthetic Polyurethane Foam (NasoPore) as a Middle Meatal Spacer in Functional Endoscopic Sinus Surgery

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ABSTRACT

Objective: **To compare NasoPore (Stryker Canada, Hamilton, ON, Canada) and a traditional middle meatal spacer (MMS) composed of Merocel ((Medtronic Xomed, Mississauga, ON, Canada) placed in a vinyl glove finger in functional endoscopic sinus surgery (FESS) with regard to postoperative bleeding, wound healing, and patient comfort.**

Design: **A prospective, double-blind, randomized trial of 30 consecutive adults (age > 16 years) with chronic or recurrent acute rhinosinusitis undergoing bilateral FESS, excluding patients with significant difference in their sinus disease bilaterally using preoperative computed tomographic scan assessment (Lund-McKay scores > 2).**

Setting: **Tertiary hospital, Vancouver, British Columbia.**

Methods: **Preoperatively, all patients were randomized and blinded to receive NasoPore (Stryker Canada) on one side and Merocel on the other. Patients completed a questionnaire during their first postoperative week relating to their subjective assessment of pain, pressure, nasal blockage, swelling, and bleeding. Patients were evaluated 1 week postoperatively for packing removal and debridement, and associated discomfort and bleeding with the removal, as well as overall preference for either pack. A clinician blinded to the randomization process objectively assessed the healing status of the nasal cavities at 4 and 12 weeks postoperatively.**

Main Outcome Measures: **Patient satisfaction, bleeding, and wound healing postoperatively.**

Results: **Thirty patients were enrolled. There was no significant difference between the Lund-Mackay scores in both groups preoperatively ($p = .80$). Postoperatively, there was no significant difference between both groups with regard to patients' pain, pressure, blockage, swelling, bleeding, or discomfort on packing removal ($p > .05$). There was no statistical difference in the amount of bleeding associated with packing removal ($p = .32$). Mucosal grading at 4 weeks was significantly better for the traditional MMS ($p = .03$), but this difference disappeared at the 12-week visit ($p = 1.00$).**

Conclusions: **The absorbable pack did not significantly reduce the risk of bleeding or patient discomfort compared with a traditional nonabsorbable MMS and was associated with significantly slower mucosal healing initially, an effect that disappeared after 3 months postoperatively. There was no significant patient preference for either pack.**

SOMMAIRE

But: **L'étude visait à comparer NasoPore avec un espaceur du méat moyen (EMM) ordinaire, composé de Merocel (Medtronic Xomed, Stryker Canada, 45 Innovation Drive, Hamilton [Ontario] L9H 7L8), placé dans un doigt d'un gant de vinyle dans la chirurgie endoscopique fonctionnelle des sinus (CEFS) au regard des saignements postopératoires, de la cicatrisation de la plaie et du bien-être des patients.**

Type d'étude: **Il s'agit d'un essai prospectif, à double insu et à répartition aléatoire, mené chez 30 adultes consécutifs (âge > 16 ans) souffrant d'une rhinosinusite chronique ou d'une rhinosinusite aiguë récidivante et devant subir une CEFS bilatérale, à**

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l'exclusion des patients ayant des différences importantes entre les deux côtés en ce qui concerne l'atteinte sinusale, d'après l'évaluation préopératoire par tomodensitométrie (échelle de Lund-McKay : > 2).

Milieu: **L'étude a été menée dans un hôpital de soins tertiaires, à Vancouver, en Colombie-Britannique.**

Méthode: **Avant l'opération, tous les patients ont été désignés pour recevoir au hasard et à l'insu NasoPore (Stryker) d'un côté et Merocel de l'autre. Les sujets ont rempli un questionnaire au cours de la première semaine postopératoire relativement à l'évaluation subjective de la douleur, de la pression, de l'obstruction nasale, de l'enflure et du saignement. Les patients ont été rencontrés 1 semaine après l'opération pour le retrait des tampons et le débridement et pour l'évaluation des malaises et du saignement associés au retrait, de même que pour l'évaluation de leur préférence générale à l'égard de l'un ou l'autre des tampons. Un clinicien ignorant du processus d'hasardisation a évalué objectivement l'état de la cicatrisation des cavités nasales au bout de 4 et 12 semaines postopératoires.**

Principaux critères d'évaluation: **Les principaux critères consistaient en l'évaluation de la satisfaction des patients, des saignements et de la cicatrisation de la plaie après l'opération.**

Résultats: **Trente patients ont participé à l'étude. Il n'y avait pas d'écart important quant aux résultats de Lund-MacKay entre les deux groupes, avant l'opération ($P = 0,80$). Après l'opération, il n'y avait pas d'écart important entre les deux groupes en ce qui concerne la douleur, la pression, l'obstruction, l'enflure, les saignements et les malaises liés au retrait des tampons ($P > 0,05$), pas plus qu'il n'y avait de différence significative relativement à la quantité de sang perdu au moment du retrait des tampons ($P = 0,32$). Le degré de cicatrisation de la muqueuse au bout de 4 semaines était significativement meilleure pour l'EMM ordinaire que pour l'autre espaceur ($P = 0,03$), mais la différence était disparue au bout de 12e semaines ($P = 1,00$).**

Conclusions: **Le tampon résorbable n'a pas diminué de façon significative le risque de saignement ou les malaises des patients comparativement à l'EMM ordinaire, non résorbable, et il a été associé à une cicatrisation initiale significativement plus lente de la muqueuse que l'autre espaceur, différence qui est toutefois disparue au bout de 3 mois postopératoires. Les patients n'ont pas manifesté de préférence marquée pour l'un ou l'autre des tampons.**

Key words: *absorbable packing, endoscopic sinus surgery, NasoPore, nasal packing, randomized trial, outcomes*

Functional endoscopic sinus surgery (FESS) has emerged as an effective management modality of acute recurrent rhinosinusitis (ARRS) and chronic rhinosinusitis (CRS). The surgical principles involve reestablishing ventilation and drainage via the natural ostia, with minimal damage to the sinonasal mucosa. Postoperative management, although varying considerably between surgeons, is regarded as an important determinant of the surgical outcome.[1–4] There is a lack of randomized prospective studies on the effectiveness of the various postoperative measures.

Nasal or middle meatal packing is often used at the end of endoscopic surgery to control bleeding for middle turbinate stabilization and to prevent synechiae formation or restenosis.[5] Endoscopic packing products can be classified as fibrin-based, nonfibrin biologic, and synthetic products. Bugten and colleagues demonstrated that a nonabsorbable packing (NAP) in the middle meatus for 5 days post-FESS significantly reduced the extent of adhesions compared with saline irrigation alone.[6] However, packing carries some inherent risks; it may cause some pain and bleeding, contribute to nasal mucosal damage, and increase the total costs.[7,8]

The ideal middle meatal pack should be easy to insert and remove, comfortable while in the nasal cavity, should prevent postoperative bleeding, but should not impede mucosal healing. The options include nonabsorbable middle meatal packs versus dissolvable packs. There are limited data regarding the use of dissolvable packs in sinus surgery. Jameson and colleagues conducted a recent randomized, double-blinded study comparing FloSeal (Baxter Canada, Mississauga, ON, Canada) (a bovine collagen–derived gelatine matrix) with saline-soaked neuropatties and demonstrated significantly less postoperative bleeding and less discomfort in the FloSeal group.[9]

NasoPore (Stryker Canada, Hamilton, ON, Canada) is a biodegradable synthetic polyurethane foam produced by a freeze-drying process. The polyurethane bonds provide strong initial compressive mechanical properties, whereas the hydrophilic component facilitates water uptake and rapid fragmentation. The material starts to dissolve within days and can be suctioned from the ethmoid cavity at day 7 postoperatively.

The purpose of this study was to compare the efficacy of a NasoPore middle meatal pack versus a traditional nonabsorbable middle meatal spacer (MMS) made by placing Merocel (Medtronic Xomed, Mississauga, ON, Canada) within a vinyl glove finger, as described by Kuhn and Javer.[10] The parameters measured included post-FESS bleeding, wound healing, and patient comfort.

Materials and Methods

Institutional Clinical Research Ethics Board approval was obtained for the study. Informed consent was also obtained from all study subjects.

Thirty consecutive patients undergoing FESS at St Paul's Sinus Centre in Vancouver, British Columbia, were enrolled in the study. Patient inclusion criteria included age greater than 18 years, bilateral CRS or ARRS, and a Lund-MacKay computed tomographic (CT) scan score difference of 2 or less between the left and right sides. Exclusion criteria included unilateral disease, underlying bleeding disorder, and significant difference in disease status between the nasal cavities based on CT scan (Lund-MacKay score difference > 2).

Preoperatively, patients had their nasal cavities randomized by a coin toss to determine which side was to receive a NasoPore packing intraoperatively. In all cases, the other nasal cavity had a vinyl gloved Merocel packing placed within the osteomeatal complex. Patients were therefore able to act as their own controls. Patients were under anesthesia when the middle meatal packs were placed and therefore blinded to the type of pack on each side. One surgeon (A.J.), not blinded to the preoperative randomization, placed the packings in the assigned sinus cavities. A surgeon, blinded to the randomization process (H.G.), left the operating room prior to the insertion of the nasal packing, unaware of the type of nasal packing placed in each side.

Patients were asked to complete a nonvalidated questionnaire during their first postoperative week relating to their subjective assessment of five criteria: pain, pressure sensation, nasal blockage, swelling, and bleeding. For each of these criteria, and for each side, they were asked to give a score from 0 (no symptom or bleeding) to 10 (maximal symptom or bleeding). They were then seen in follow-up on day 7 postoperatively, at which point, the Merocel packing was removed and NasoPore packing was suctioned by the primary surgeon (A.J.). The nonblinded surgeon objectively graded the degree of bleeding during packing removal from 0 to 3 (Table 2). Immediately thereafter, patients were asked to complete two more items on the questionnaire; the first was a 0 to 10 subjective score of the level of pain or discomfort involved in the packing removal process for each side (0 denoting no pain and 10 maximal pain), and the second was a question on the overall preference of the nasal packing between the two sides.

Patients were rescheduled for follow-up visits at 4 and 12 weeks postoperatively. During these visits, the blinded surgeon (H.G.) performed nasal endoscopic examinations and assessed for the presence of synechia or infection, as well as objectively graded the degree of mucosal edema (Table 1).

Statistical analysis of all data reported in this study was performed using *SPSS* 16.0 (SPSS Inc., Chicago, IL). The parameters were compared using the Wilcoxon signed rank test and chi-square test. A value of $p \leq .05$ was considered statistically significant.

Table 1. Grading of the Degree of Sinonasal Mucosa

Grade	*Degree of Sinonasal Mucosa*
0	No edema or polypoid changes
1	Mucosal edema
2	Polypoid edema
3	Polyps

Results

Demographics

Thirty patients were randomized with 60 sinus cavities included in this study. Twenty of the 30 patients (66.6%) were males. The mean age was 54 years (range 29–76 years). The NasoPore packing was randomly assigned for use in the left sinus cavity in 18 patients (60.0%).

Lund-Mackay Scoring

The sinus cavities that received the traditional Merocel MMS had a mean preoperative Lund-Mackay CT score of 7.80, and those that received the NasoPore packing had a mean score of 7.83. Of the 30 subjects involved, 21 patients (70.0%) had identical Lund-Mackay scores on both sides, with the remaining subjects having a score difference of $\pm$ 2 between each side. Overall, there was no statistical significance between the Lund-Mackay scores of the Merocel MMS and the NasoPore groups ($p = .80$).

Questionnaire Results

All 30 patients completed the postoperative symptomatology and preference questionnaire. The NasoPore packing had slightly lower (better) scores with respect to postoperative pain (mean 3.3 vs 3.7) and pressure (mean 3.3 vs 3.7) (Table 3). The traditional MMS had slightly lower (better) scores with respect to blockage sensation (mean 3.87 vs 4.07) and bleeding (mean 3.4 vs 3.67). The patients' perceived degree of swelling postoperatively was similar between the two groups (mean 2.78). The pain score during the removal process was also similar between the two groups (mean 4.0). There was no statistical significance between the mean scores in any of these criteria ($p > .05$).

Table 2. Endoscopic Grading of Bleeding at the One-Week Postoperative Visit

Grade	*Bleeding on Packing Removal*
0	No bleeding
1	Minimal (mild bleeding confined to nasal cavity)
2	Moderate (bleeding out of nasal cavity; repacking not required)
3	Severe (bleeding requires repacking)

Of the 30 subjects involved in this study, 27 (90.0%) expressed a preference for one nasal packing method. Sixteen of 27 (59.3%) patients favoured the NasoPore packing; however, this was not statistically significant ($p = .34$).

Mucosal Healing Results

All 30 subjects returned for follow-up at the 1-week postoperative visit. Assessment of bleeding on packing removal demonstrated slightly less bleeding with the traditional MMS (mean 0.8) compared with NasoPore (mean 0.9) (see Table 3). This difference, however, was not statistically significant ($p = .32$).

All 30 subjects returned for assessment of mucosal healing at the 1-month postoperative visit. Mucosal grading at this time was better for the traditional MMS (mean 0.77) compared with NasoPore (mean 1.17) (see Table 3). This difference was statistically significant ($p = .03$).

Mucosal healing was reassessed at the 3-month postoperative visit. At this time, 28 patients (93.3%) returned for evaluation. Mucosal grading at this visit showed comparable scores (NasoPore, mean 0.67, MMS, mean 0.68), with no statistical significance between the two scores ($p = 1.00$) (Table 4).

Table 3. Results of Patient Questionnaire Assessing Symptoms during the First Postoperative Week and Pain on Packing Removal

Symptom	*Minimum*	*Maximum*	*Mean*	*SD*	p *Value*
Pain					
MMS	0	8	3.70	2.98	
NasoPore	0	8	3.33	2.50	.23
Pressure					
MMS	0	8	3.72	2.96	
NasoPore	0	8	3.34	2.69	.46
Blockage					
MMS	0	8	3.87	2.69	
NasoPore	0	10	4.07	2.70	.69
Swelling					
MMS	0	8	2.78	2.36	
NasoPore	0	8	2.78	2.52	.80
Bleeding					
MMS	0	8	3.44	2.01	
NasoPore	0	10	3.67	2.450	.74
Removal pain					
MMS	0	9	3.97	2.72	
NasoPore	0	9	4.03	2.80	.93

MMS = middle meatal spacer.

Discussion

Modern FESS emphasizes a minimalist approach with mucosal sparing to optimize healing. The postoperative treatment is regarded by many as an important determinant of the surgical outcome. There is a paucity of well-randomized prospective trials assessing the efficacy of the various postoperative treatment regimens. The intent of this study was to conduct a randomized, placebo-controlled, double-blinded trial to assess the efficacy of a biodegradable nasal packing (NasoPore) with a traditional nondissolvable MMS. Postoperative patient comfort, degree of bleeding and discomfort associated with packing removal, and the effect on sinus mucosal healing was measured and compared between the two sides.

The use of middle meatal packing post-FESS is common among sinus surgeons. A middle meatal pack is felt to help promote hemostasis and behave as a stent to maintain middle turbinate lateralization and as a spacer to prevent blood or mucus accumulation in the ethmoid cavity postoperatively. Packing may also prevent synechia development and reduce the risk of restenosis.[6,11] The widespread practice of FESS has promoted the development of biodegradable nasal packing materials. In addition to the functions served by a traditional

Table 4. Grading of Bleeding during Packing Removal and Mucosal Healing Alone and 3 Months Postoperatively

	Minimum	*Maximum*	*Mean*	*SD*	p *Value*
Bleeding					
MMS	0	2	0.83	0.53	
NasoPore	0	3	0.90	0.55	.32
MH 1					
MMS	0	2	0.77	0.77	
NasoPore	0	2	1.17	0.83	.03
MH 3					
MMS	0	2	0.68	0.72	
Nasopore	0	2	0.67	0.73	1.00

MH 1 = mucosal healing at the 1-month postoperative visit; MH 3 = mucosal healing at the 3-month postoperative visit; MMS = middle meatal spacer.

MMS, an ideal biodegradable material would improve patient comfort, promote mucosal healing, and reduce the incidence of complications associated with nonabsorbable packing. Potential complications include mucosal injury with or without septal perforation, pack dislodgment and aspiration, obstructive sleep apnea secondary to nasal obstruction, and infection.[8] As well, patients who are unable to return within a week for the packing removal would benefit from the luxury of having a biodegrable MMS. Although many studies have evaluated the effect of absorbable nasal packs on hemostasis, patient comfort, and/or mucosal healing, there is a relative paucity of literature comparing these agents with traditional forms of MMS.

Recent studies have demonstrated that NAP does not significantly reduce the risk of post-FESS bleeding.[11–13] Frenkiel and colleagues assessed the efficacy of Sepragel (Genzyme Canada, Mississauga, ON, Canada), a hyaluronic acid–based biodegradable product, in hemostasis.[14] The study design involved placing Sepragel in one cavity while leaving the contralateral side unpacked to serve as a control. There was no statistically significant difference between the Sepragel and control sides with respect to volume of bleeding. These findings suggest that nasal packing is unnecessary to control bleeding following standard FESS. The literature directly comparing dissolvable packs with traditional NAP with regard to hemostasis is lacking. In the current study, most patients experienced mild bleeding that resolved within 48 hours. Subjectively, there was no statistically significant difference in the amount of bleeding between the NasoPore and control sides.

Two major drawbacks to conventional packing are potential damage to the ciliated sinonasal mucosa from the pressure of the pack or from trauma of packing removal and the discomfort associated with the packing and during its removal. Studies have demonstrated that patients undergoing FESS often consider packing removal to be the most uncomfortable part of the perioperative experience.[15,16] To reduce the discomfort, surgeons have tried several different packing methods, including the use of petroleum gauze impregnated with 5% lidocaine ointment, encasing the MMS tampon in Silastic,[17] or removing the pack after 2 hours postoperatively.[18] Kimmelman and colleagues assessed the efficacy of Sepragel as a dissolvable nasal pack.[19] In comparison with the unpacked control side, pain was significantly less on the Sepragel side during the first 2 postoperative weeks. In our study, the patient's subjective assessment of pain during the first postoperative week and during the packing removal process was generally regarded as mild, although the range of scores was variable (0–8). There was no statistically significant difference in patients' perception of pain between suctioning of the NasoPore pack and removal of the Merocel MMS. This may be attributable to two reasons. First, we place the Merocel pack inside a vinyl glove finger, which may lessen the discomfort and mucosal damage during its removal. Second, we perform a thorough endoscopic debridement of clots and crusts following removal of the MMS. On the NasoPore side, this would include thorough suctioning of the dissolvable pack and debridement of the rest of the cavity. As the majority of this first postoperative follow-up visit is dedicated to debridement of the cavities, any discomfort experienced in removal of the MMS may be overshadowed by the subsequent debridement on both sides. The debridement was typically lengthier on the NasoPore side since it usually took longer to suction the material.

The effect of traditional nasal packing on the mucosal surface has been studied in both human and animal models. Klinger and Siegert demonstrated that balloon tamponade results in decreased perfusion as measured by laser Doppler flow,[20] an effect that Weber and colleagues believe is unlikely to occur with expandable foam–type packs.[5] Studies performed on the sheep model showed that ribbon and neuropattie packing resulted in a significant loss of ciliated mucosal surface, 68% and 50%, respectively.[21] Subsequent animal studies attempting to evaluate the effect of biodegradable materials on mucosal healing have been conflicting.[22] McIntosh and colleagues evaluated the effects of MeroGel (Medtronic Xomed) (hyaluronic acid–based product) on mucosal surface healing in a sheep model by examining mucosal biopsies at 4, 8, 12, and 16 weeks following injury and comparing them with an unpacked control.[23] The results showed that MeroGel was associated with significant increases in epithelial height at 4 weeks and reepithelialization at 12 weeks, with no electron microscopic differences with regard to cilia regeneration between the two. This study suggests that hyaluronic acid products may increase the rate of mucosal healing. On the contrary, Maccabee and colleagues performed a study in the rabbit model in which mucosa was stripped from the maxillary sinus bilaterally in 12 animals.[24] One sinus in six rabbits was filled with FloSeal, and one sinus in the other six rabbits was filled with MeroGel. In all 12 rabbits, one maxillary sinus was left unpacked. Histologic evaluation of the sacrificed animals at 2 weeks revealed that sinuses with either of the foreign materials showed an increased degree of fibrosis, lymphocytic infiltration, and incorporation of the material into the regenerating mucosa compared with unpacked controls. Likewise, Jacob and colleagues demonstrated osteogenesis associated with MeroGel in a mouse model.[25]

Subsequent studies have attempted to compare the effects of different topical packing methods on mucosal healing in human subjects, once again with variable results. Wormald and colleagues conducted a randomized, controlled, blinded study on 42 patients with chronic sinusitis undergoing FESS.[26] They compared MeroGel on one side to no packing on the other side. Patients were assessed at 2, 4, and 6 to 8 weeks after surgery. There was no statistical difference between the two sides with regard to synechia, edema, or infection. Catalano and Roffman compared postoperative synechia rates between two self-absorbing stents (Gelfilm and MeroGel) in 100 patients undergoing bilateral minimally invasive sinus techniques.[27] Follow-up consisted of three postoperative visits between weeks 1 and 12. Compared with Gelfilm (Pfizer Canada, Kirkland, QC, Canada), MeroGel stents produced significantly less synechia. Franklin and Wright compared MeroGel with NAP in 35 consecutive patients undergoing FESS, and the endoscopic appearance of the nasal cavities at 2 weeks postoperatively showed a trend toward improvement in the MeroGel group, which persisted over the 6-month follow-up period.[28] Miller and colleagues randomized either MeroGel or Merocel NAP to an ethmoid cavity in patients undergoing bilateral FESS.[29] Each cavity was graded endoscopically for the presence and severity of synechiae, edema, and infection at 2, 4, 6, and 8 weeks postoperatively. Overall, there were no statistically significant differences between the groups at any of the time points with respect to any of the variables. Some of these conflicting results may be attributable to variation in surgical technique, as well as different postoperative management regimens. In the present study, nasal cavities with the Merocel MMS had significantly better healing scores at the 1-month follow-up visit ($p = .035$) compared with those with the NasoPore. This difference, however, disappeared by the 3-month follow-up visit, with comparable scores ($p = 1.00$). It is difficult to speculate on these results, but the preceding literature review suggests that some absorbable hemostatic agents have been associated with synechiae formation, incorporation into regenerating mucosa, and possibly osteogenesis. Regular and meticulous postoperative debridement may have contributed to comparable healing at 3 months, and until further studies shed more light on the effect of these materials on healing mucosa, NAP is a safer and equally effective alternative.

Given the significant impact of postoperative care on the surgical outcome, one operator (A.J.) in this study was consistently responsible for surgery as well as all scheduled postoperative debridement. The validated Lund-Mackay staging system was used, and objective measures were used for assessment of mucosal healing throughout the follow-up period. Patients were asked to complete the questionnaires during the first postoperative week and bring the completed forms along with them on their first follow-up visit. The complementary questions of discomfort level during removal and preference to either side were answered during this first visit before patients left the clinic. This reduces recall bias and may aid patients in better qualifying their symptoms from side to side.

Conclusion

In patients undergoing endoscopic sinus surgery, a biodegradable synthetic polyurethane foam pack does not significantly reduce the risk of bleeding, patient discomfort (pain, pressure, congestion or swelling), or discomfort associated with packing removal compared with a traditional nonabsorbable MMS (foam polymer of hydroxylated polyvinyl acetate in a vinyl glove finger). Furthermore, the results of this study suggest significantly slower mucosal healing with the biodegradable pack in the initial postoperative period, an effect that disappeared and became comparable to that of a nonabsorbable pack after 3 months postoperatively. Overall, there was no statistically significant patient preference demonstrated for either type of nasal packing.

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