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Clinical Evaluation of a Fully Synthetic Middle Meatal Stent for Safety and Tolerability

Peter J. Catalano, MD¹, Spencer Payne, MD², and Mark Thong, MD¹

Abstract
Objective. To evaluate the safety and tolerability of a novel, fully synthetic, poly-urethane middle meatal dressing after endoscopic sinus surgery (ESS).

Study Design. Case series with planned data collection.

Setting. Tertiary care medical facility.

Subjects and Methods. In total, 104 patients with medically refractory chronic rhinosinusitis were treated with patient-appropriate ESS and a poly-urethane sponge placed into their middle meatus at the end of operation, giving a total of 173 middle meatus stent placements. Patients were then assessed immediately postoperatively and 2, 6, 12, and 16 weeks after surgery for adverse systemic or local reaction to the stent and the incidence of postoperative infections.

Results. There was no pain or allergic reaction encountered with this new material. There were 11 middle meati (6.4%; 95% confidence interval, 3.2%-11.1%) with postoperative infection at 2 weeks follow-up. There were no other stent-related local reactions (ie, excessive bleeding, middle meatal synechia, or granulation) up to 16 weeks postoperatively. Residual middle meatal stent material was either absent or negligible at 2 weeks postoperatively.

Conclusions. This first fully synthetic poly-urethane middle meatal dressing used during ESS demonstrated excellent biocompatibility and safety. The incidence of localized postoperative infection was also low.

Keywords
middle meatal, dressing, stent, poly-urethane, synthetic, endoscopic sinus surgery

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Middle meatal (MM) dressings are commonly used during endoscopic sinus surgery (ESS) to potentially aid in local hemostasis, minimize MM synechia (Figure 1), and prevent middle turbinate lateralization. Debate over the need for and benefit of MM dressings/stents was prevalent in the 1990s because of conflicting reports of stent-induced increases in MM synechia in some series and reductions in others.¹² These inconsistent outcomes were likely multifactorial and, although initially attributed simply to the presence or absence of MM stents, probably reflected differences in surgical technique, the stent composition, and perioperative management regimens (ie, saline irrigations) as well.

Dressing composition has morphed over time from nonresorbable materials such as vaselinized gauze, Telfa pads, cotton-stuffed latex finger cots, silastic sheeting, and Merocel sponges to biodegradable products such as Gelfilm, MeroGel, hyaluronic acid gels, FloSeal, and cellulose gels.²⁻⁶ The transition from

Figure 1. Left middle meatus obstructed by postoperative synechia.
nonresorbable to resorbable materials was welcomed because of improved comfort afforded to patients and the ease of postoperative management and wound care for surgeons. Recent studies to evaluate the risk/benefit of biodegradable MM dressings have shown significant reductions in MM synechia with MeroGel and improved patient tolerance with a minimal increase in procedural costs.1

Several factors must be considered when selecting/designing effective MM dressings. These include material biocompatibility, retention time, size, shape, consistency, patient comfort, ease of placement, and cost. Although it is true that biocompatibility testing is required before Food and Drug Administration (FDA) clearance to market, many products are not clinically tested in patients with a specific disease state undergoing a procedure such as ESS. Therefore, we found it prudent to investigate the product in this setting.

Heretofore, there were no purely synthetic resorbable MM stents that provide the theoretic advantage of eliminating an immunogenic response to the animal or plant proteins typically found in currently available products. The polyurethane biomaterial therefore represents the first fully synthetic resorbable MM dressing. This product is available as a 1 (width) × 2 (height) × 4 cm (or 8 cm length) rectangular sponge of varied consistency (soft, medium, or firm; Figure 2).

In this study, we evaluate the safety profile of this polyether-ester-urethane sponge, and the incidence of postoperative bleeding, middle meatus granulation and synechia, and postoperative infection after placement of this product during ESS for chronic rhinosinusitis.

**Materials and Methods**

This single-center study involved consecutive patients with chronic rhinosinusitis (as defined by the American Academy of Otolaryngology expert panel clinical practice guideline on adult sinusitis)7 who were medically refractory and therefore indicated for ESS. Institutional review board approval was obtained for the study.

Surgery was performed as appropriate for patient and disease. The procedures performed generally included all or a combination of anterior/total ethmoidectomy, middle meatal antrostomy, resection of middle turbinate concha bullosa, and shaving of the lateral aspect of a hypertrophic middle turbinate.

At the end of the operation, under endoscopic visualization, one-half of a 1 × 2 × 4-cm “soft” poly-urethane sponge (ie, 1 × 2 × 2-cm piece) was placed into each MM (Figure 3). This was done so as not to occlude the majority of the sinus ostia and to minimize disposable costs. The sponge had been purchased from the company as per routine hospital procurement procedure and inserted by either 1 of 2 attending surgeons.

Per routine, each patient then received a single injection of methylprednisolone 20 mg intramuscularly (IM) prior to discharge from the recovery area and a 1-week course of postoperative oral antibiotics. All patients began isotonic nasal saline irrigations bid on postoperative day 1 and were instructed to continue them for the next 30 days.

Prior to discharge from the recovery area, patients were evaluated for any atypical localized pain or allergic reaction. At 2, 6, 12, and 16 weeks after surgery, patients returned to the office for evaluation and bilateral nasal endoscopy. Outcome metrics included postoperative epistaxis, presence of facial pain, purulent rhinorrhea/infection, MM granulation tissue, or synechia.

Any complications encountered (eg, infection) were treated accordingly and progress documented. All treatment provided (ie, antibiotics, MM debridement) and the corresponding patient response were documented. No “medium” or “firm” poly-urethane dressings were used in this study.

**Results**

In total, 104 consecutive patients were offered and accepted admission into this study; there were no refusals. Their ages not
ranged from 14 to 81 years. The MM dressing under investigation was subsequently placed into 173 sinonasal sides/MM.

All 104 patients returned for their scheduled 2- and 6-week postoperative reviews, 98 patients returned for their 12-week evaluation, and 93 patients returned for their 16-week reviews. However, only 2 patients defaulted on both the 12- and 16-week follow-up visits because of work out of state. Therefore, 102 of 104 patients were seen at postoperative visits 1, 2, and either 3 or 4. In the immediate postoperative evaluation in the recovery area, no patient reported any unusual localized pain or allergic reaction to the poly-urethane sponge.

Through all follow-up visits, no patient reported postoperative epistaxis or pain that was localized or could be attributed to the test product. Several patients reported headache within the first 2 weeks of surgery, but the pain was either diffuse or frontal in nature and consistent with the early postoperative course after ESS.

Unilateral purulent discharge was noted on endoscopy in 11 patients (6.4%; 95% confidence interval [CI], 3.2%-11.1%) at their 2-week postoperative visit. All patients were successfully treated with oral antibiotics for 10 days and told to continue their saline nasal irrigations until their 6-week visit. There were no further sinonasal infections seen in these 11 patients or the rest of the patients over the 4-month postoperative surveillance period.

There were no MM granulations or synechia seen in any patient throughout the 4-month follow-up period. No patient required oral steroids during this period.

Residual poly-urethane sponge in the MM was either absent or negligible by the 2-week follow-up visit in all patients. Postoperative debridement was not required in this study.

**Discussion**

MM dressings have been used in ESS to help reduce the incidence of postoperative complications and improve surgical outcome, namely by assisting in local hemostasis, reducing synechia formation, and preventing middle turbinate lateralization. Ideally, an MM stent should be (1) biocompatible, (2) resistant to infection, (3) of adequate bulk, (4) biodegradable and dissolve at an appropriate rate, (5) comfortable for patients, (6) easy to use by surgeons, and (7) cost-effective. Not all stents possess these qualities in equal measure, and it is their underlying composition that frequently determines most of their functional as well as biocompatibility characteristics. Issues with biocompatibility may present clinically in various ways, from local mucosal irritation (leading to localized pain, postoperative bleeding, granulation, or scar formation) to systemic allergic reactions.

Various materials have been used to manufacture biodegradable MM stents. Unfortunately, several studies demonstrate intense tissue reactivity to many of these materials. In each of these reports, however, the material was placed or used in a manner inconsistent with its clinical indication (ie, it was not placed in the middle meatus). Placing sheets of hyaluronic acid/collagen into a subcutaneous pocket is not how a nasal dressing was intended to be used. This is akin to using an oral antibiotic intravenously or vice versa. Others reported submucosal trapping of hyaluronic acid products in animal models where all sinus mucosa was removed—an unlikely scenario in the middle meatus after ESS. We would not expect the side effect profile to be the same if used according to its indications for use. Furthermore, when used properly, the relatively quick dissolution rate of these dressings makes them unlikely to cause the degree of fibrosis and tissue reaction reported when they are implanted in a subcutaneous pocket or used to completely fill the volume of the maxillary sinus.

However, even when resorbable material is used appropriately in the MM, there have also been reports of adverse outcomes. FloSeal is one such resorbable substance studied for use as an MM dressing as it is also a very effective hemostatic...
agent. However, when placed into the MM after ESS, it was subsequently shown to cause an increase in adhesion formation\(^1\)\(^\text{12-14}\) because it becomes integrated within sinonasal mucosa and as a result forms local granulomas.\(^9\)\(^,\)\(^13\) It appears that its particulate nature and material composition are responsible for this finding.

The poly-urethane sponge is a new, fully synthetic, biodegradable material for use in the sinonasal cavity that is also reported to be biologically inert. In this study, this product appears safe and biocompatible with no local granulations or synechia seen within the first 16 weeks of surgery and no adverse systemic or local effects such as allergy, pain, or excessive postoperative bleeding. This may be explained, in part, by the fact that it is fully synthetic and lacks animal or plant proteins typically found in other dissolvable dressings. These animal and plant products can, at least theoretically, behave as foreign antigens to the human immune system and thus produce more local tissue reactivity. In addition, the poly-urethane sponge dissolves quickly into \(\text{CO}_2\), reducing the likelihood of a foreign body reaction or sinus obstruction. It has been previously suggested that 5 to 8 days is the optimum retention time for an MM dressing.\(^1\)

One other key consideration with regard to MM nasal packings or dressings is the risk of infection. These dressings, especially if used as packing material, may predispose a patient to sinusitis by serving as a medium for pathogen colonization and multiplication and/or by obstructing sinus ostia. Different strategies have been followed to attenuate this problem, including removing packs after a few days, performing MM debridements, placing only the minimum amount of material required to meet the clinical need, and placing patients on prophylactic postoperative antibiotics. With the use of this new MM dressing and our standard postoperative regimen consisting of 1 week of oral antibiotics and 4 weeks of nasal saline irrigation, the incidence of postoperative sinusitis was low at 11 of 173 MM (6.4%; 95% CI, 3.2%\(^\pm\)11.1%). All the episodes of postoperative sinusitis were easily resolved with a 10-day course of oral antibiotics and continued nasal irrigation.

As this study was essentially designed to first evaluate the clinical safety and tolerability of this new MM dressing, there was no control group. In other words, it was designed to reveal some important in vivo behavioral characteristics about this product before we move forward and compare it to others. Although this study design prevents a direct comparison between different types of nasal dressings and thus prohibits any statements on product efficacy, it is clear from the study results that the material is extremely biocompatible, well tolerated by patients, safe, and not associated with postoperative problems such as bleeding, MM synechia, or granulations. To address efficacy, we have subsequently embarked on a prospective randomized controlled trial to study this new material further. The value of MM dressings is an important question for further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further. The value of MM dressings is an important question for perspective randomized controlled trial to study this new material further.


