Comparing the efficacy of Silastic and gloved-Merocel middle meatal spacers for functional endoscopic sinus surgery: a randomized controlled trial

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Background: Spacers are inserted into the middle meatal space (MMS) following functional endoscopic sinus surgery (FESS) to prevent lateralization of the middle turbinate, scarring, and synechiae. Our objective was to determine if the incidence of postoperative synechiae, facial pain/discomfort, pain during spacer removal, scarring, and discharge differed between nasal cavities receiving Silastic or gloved-Merocel (GM) spacers following FESS.

Methods: A double-blind, randomized controlled trial (RCT) was conducted in adults requiring bilateral FESS for chronic rhinosinusitis (CRS) ± nasal polyposis. Participants served as their own controls, with each subject receiving both a Silastic and GM spacer. Spacers were inserted into the MMS during FESS and left in situ for 6 days. Participants were reviewed at 6 days, 5 weeks, and 12 weeks postoperatively. The presence of synechiae and scarring were evaluated endoscopically. Inflammation, discharge, and pain during spacer removal were assessed using a visual analogue scale (VAS).

Results: Forty-eight participants (96 nasal cavities) were recruited. Preoperatively, Lund-Mackay computed tomography (CT) scores were similar between Silastic-treated and GM-treated cavities (6.38 ± 2.35 vs 6.18 ± 2.17). The incidence of synechiae and scarring did not differ significantly between spacers up to 12 weeks postoperatively. Pain during spacer removal was significantly greater for Silastic than GM spacers (2.13 ± 1.34 vs 1.51 ± 1.23, $p = 0.020$). Facial pain prior to removal and extent of discharge did not differ significantly between spacers.

Conclusion: Following FESS, patients report less pain during removal of GM than Silastic spacers. However, the likelihood of synechiae and scarring did not differ between either of the spacers.

Key Words:
FESS; endoscopic sinus surgery; quality of life; chronic rhinosinusitis; sinusitis; postoperative

How to Cite this Article:
Manji J, Habib ARR, Macias-Valle L, et al. Comparing the efficacy of Silastic and gloved-Merocel middle meatal spacers for functional endoscopic sinus surgery: a randomized controlled trial. *Int Forum Allergy Rhinol.* 2018;8:948–954.

Functional endoscopic sinus surgery (FESS) is the gold standard surgical intervention for chronic rhinosinusitis (CRS) refractory to treatment with appropriate medical therapy.[1] Synechiae formation in the middle meatus is the most common complication of FESS (Fig. 1).[2] To prevent synechiae formation, spacers may be placed in the middle meatus for 1 to 2 weeks postoperatively.[3] A middle meatal spacer is meant to prevent early postoperative contact between potentially damaged opposing mucosal surfaces of the middle turbinate and the lateral nasal

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Potential conflict of interest: None provided.
Presented as a poster at the Annual ARS Meeting on September 16–17, 2016, in San Diego, CA.
Public clinical trial registration: http://clinicaltrials.gov/show/NCT02077322. Rates of Middle Meatal Synechia Formation Following Functional Endoscopic Sinus Surgery: A Double-Blind Randomized Controlled Trial Comparing Gloved Merocel and Silastic Middle Meatal Spacers.

Received: 9 January 2018; Revised: 11 February 2018; Accepted: 1 March 2018
DOI: 10.1002/alr.22119
View this article online at wileyonlinelibrary.com.

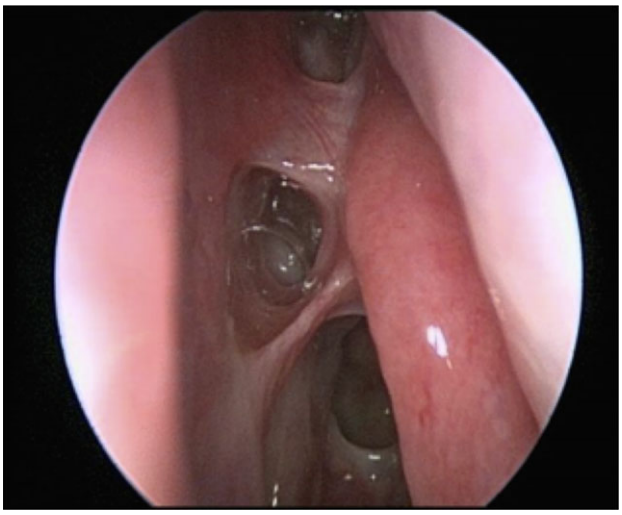

FIGURE 1. Synechiae formation between middle turbinate and lateral nasal wall in a post-FESS patient. FESS = functional endoscopic sinus surgery.

wall that may have taken place during surgery. The major disadvantages attributed to middle meatal spacers are discomfort and mucosal injury upon removal.[4] Different spacers have been studied, including nonabsorbable, absorbable, and drug-eluting; however, their relative efficacy is still controversial.[5] A systematic review showed a nonsignificant trend favoring the use of middle meatal spacers to no spacers for the prevention of synechiae after FESS (relative risk [RR], 0.40; 95% confidence interval [CI], 0.14 to 1.12). A subgroup analysis within the same study suggested that nonabsorbable spacers could be more effective than absorbable spacers for preventing the formation of middle meatal synechiae compared to no spacers.[2] However, the sample of studies included had high heterogeneity, and a subsequent systematic review by Zhao et al.[6] did not show differences in the rate of adhesion formation between absorbable and nonabsorbable spacers.

Sinus surgeons commonly use nonabsorbable spacers because they are effective, easily manipulated, widely available, and economical.[7] What remains unknown is which, if any, of the nonabsorbable spacers is most effective at preventing formation of middle meatal synechiae. We sought to evaluate surgical outcomes and patient satisfaction with the use of 2 nonabsorbable spacers that are commonly used by otolaryngologists. Silastic® (Dow Corning Corporation, Auburn, MI) is a nonreactive, inert, flexible silicone elastomer that is widely available and can be easily tailored to the shape and size of the operated cavity (Fig. 2A).[8] Merocel® (Medtronic, Minneapolis, MN) is an inflatable polyvinyl acetate–based sponge material that was adapted for use as a middle meatal spacer (Fig. 2B). It has proven to be a versatile device that has been studied with various modifications, such as impregnated with topical medication or encased in a vinyl surgical glove-finger.[9,10]

The objective of this study was to determine if the postoperative incidence and severity of synechiae, scarring, discharge, facial pain, and pain upon spacer removal differed between sinonasal cavities receiving Silastic or gloved-Merocel (GM) middle meatal spacers. We hypothesized that there would be no significant difference in postoperative outcomes between the Silastic and GM middle meatal spacers.

Patients and methods

Conduct of study

This double-blind, randomized, controlled trial (RCT) was conducted under the auspices of the University of British

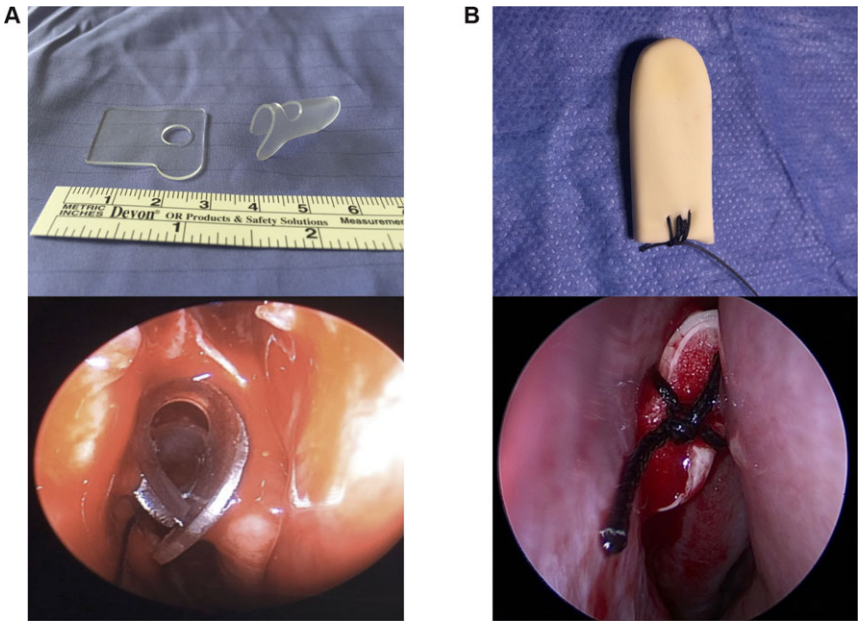

FIGURE 2. Nonabsorbable spacer conformations used in this trial. (A) Silastic spacer. (B) GM spacer. GM = gloved-Merocel.

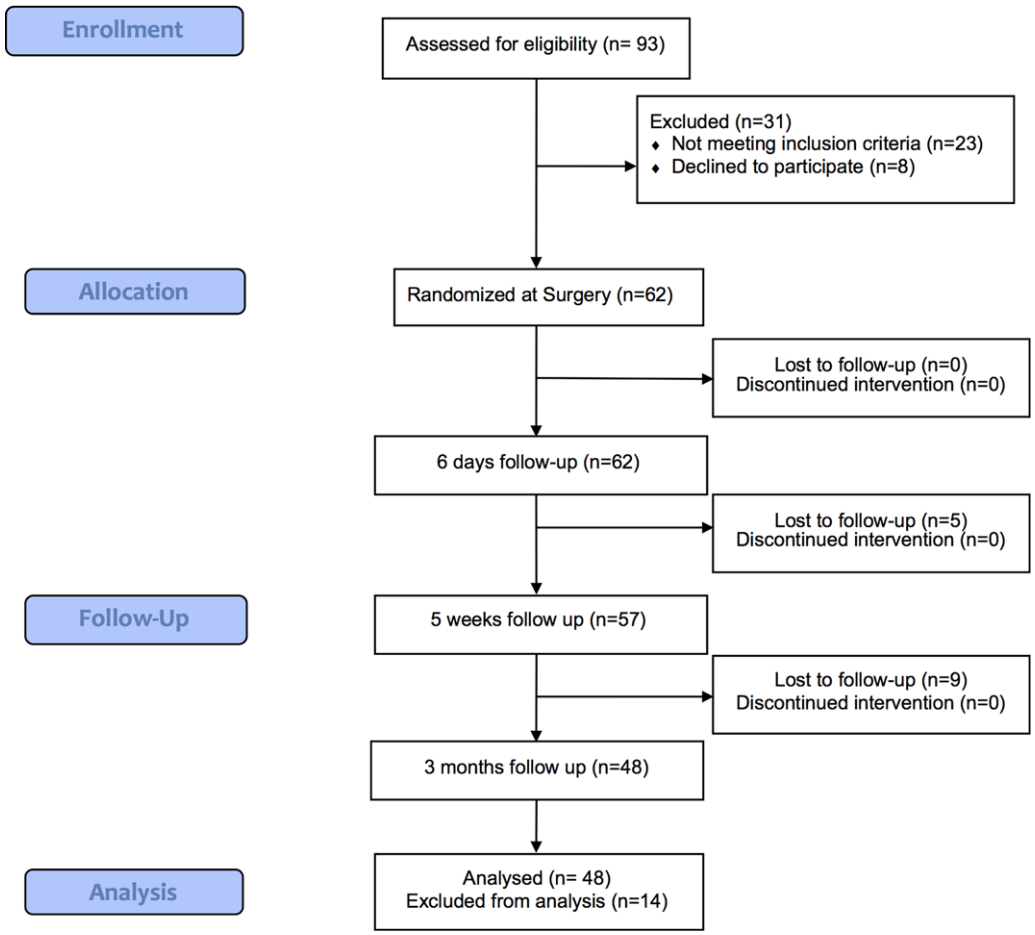

FIGURE 3. Study flowchart (CONSORT). CONSORT = Consolidated Standards of Reporting Trials.

Columbia Clinical Research Ethics Board (H13-03467) and was registered as an institutionally funded clinical trial (NCT02077322). All patients provided informed consent for their participation in the study, and for its dissemination through publication. Patients diagnosed with CRS, based on the Canadian clinical practice guidelines,[11] and undergoing primary bilateral FESS (± nasal septal reconstruction [NSR]) were included in the study. Patients with cystic fibrosis, or those who were immunocompromised, undergoing surgery for sinonasal tumors, or undergoing unilateral sinus surgery were excluded. All patients received a 14-day course of oral antibiotics, starting 7 days before surgery, and a 14-day course of oral prednisone (20 mg per day 7 days before and 10 mg per day 7 days after surgery), according to the standard of care at this center.

Recruited subjects were treated as their own controls, such that each participant would receive both a Silastic and GM spacer at completion of FESS. Randomization of the Silastic and GM spacer to the left or right side of the nose was performed using a computer-generated randomization sequence. The randomization groups were placed in sealed envelopes that were opened by the sinus fellow on the day of surgery. Spacers were inserted by the sinus fellow at the completion of the case so that the senior surgeon could remain blinded to treatment allocation. The middle meatal spacers remained in situ for 1 week before being removed in clinic. To maintaining blinding of the senior surgeon and patient participants, the spacers were removed without the senior surgeon in the room, as well as concealing spacers in gauze as they were being removed. Using a visual analogue scale (VAS; 0 to 10), participants reported their level of facial pain/discomfort with the spacer in situ and their level of pain during spacer removal at this visit. After spacers were removed, meticulous bilateral debridement of the cavities was performed by the senior surgeon (A.R.J.). Participants were seen in clinic again at 5 and 12 weeks postoperatively. The primary outcome, middle meatal synechiae, was assessed using rigid nasal endoscopy at the 5-week and 12-week postoperative visits. Synechiae were resected upon first presentation in clinic as per normal standard of care. Sinus mucosal inflammation (using the Modified Lund-Kennedy [MLK] staging system)[12] and discharge (VAS) were also assessed as secondary outcomes at these visits.

Nonabsorbable middle meatal spacers

The Silastic spacer employed in this study has the benefit of being mucosal sparing with an ability to allow the sinuses

TABLE 1. Baseline characteristics of study cohort

	Total cohort (n = 48)	Missing data n (%)
Demographics		
Age (years), mean (SD)	50.46 (14.05)	0 (0)
Males, n (%)	34 (70.8)	0 (0)
Females, n (%)	14 (29.2)	0 (0)
Smoker-never, n (%)	34 (70.8)	0 (0)
Smoker-former, n (%)	8 (16.7)	0 (0)
Smoker-current, n (%)	6 (12.5)	0 (0)
Diagnosis, n (%)		
CRSwNP	19 (39.6)	0 (0)
CRSsNP	29 (60.4)	0 (0)
Asthma	11 (22.9)	0 (0)
Preoperative treatment, n (%)		
Antibiotics	45 (93.8)	0 (0)
Steroids	44 (91.7)	0 (0)
Surgical characteristics		
Total LM score (0–24), mean (SD)	12.43 (4.28)	0 (0)
Total SNOT-22 score (0–110), mean (SD)	44.70 (21.77)	11 (22.9)
Total operative blood loss (mL), mean (SD)	281.56 (131.26)	0 (0)
Total operating time (minutes), mean (SD)	145.42 (33.657)	0 (0)
Primary surgery, n (%)	46 (95.8)	0 (0)
Concha bullosa right, n (%)	11 (22.9)	0 (0)
Concha bullosa left, n (%)	8 (16.7)	0 (0)
Paradoxical middle turbinate right, n (%)	5 (10.4)	0 (0)
Paradoxical middle turbinate left, n (%)	9 (18.8)	2 (4.2)
Septal deviation right, n (%)	28 (58.3)	0 (0)
Septal deviation left, n (%)	15 (31.3)	0 (0)
BICASS, n (%)	48 (100)	0 (0)
Nasal septal reconstruction, n (%)	39 (81.3)	0 (0)
SMRIT, n (%)	36 (75.0)	0 (0)
Anterior ethmoidectomy, n (%)	37 (77.1)	1 (2.1)
Posterior ethmoidectomy, n (%)	36 (75.0)	1 (2.1)
Frontal sinusotomy, n (%)	46 (95.8)	0 (0)
Sphenoidotomy, n (%)	46 (95.8)	0 (0)
Intraoperative pus, n (%)	15 (31.4)	0 (0)
Intraoperative mucin, n (%)	6 (12.5)	0 (0)
Intraoperative culture, n (%)	9 (18.8)	0 (0)

(*Continued*)

TABLE 1. *Continued*

	Total cohort (n = 48)	Missing data n (%)
Postoperative treatment, n (%)		
Doyle splint	31 (64.6)	0 (0)
GM spacer right	23 (47.9)	0 (0)
GM spacer left	25 (52.1)	0 (0)
Silastic spacer right	25 (52.1)	0 (0)
Silastic spacer left	23 (47.9)	0 (0)
Premature spacer removal	1 (2.1)	0 (0)

BICASS = bilateral computer assisted sinus surgery; CRSsNP = chronic rhinosinusitis without nasal polyposis; CRSwNP = chronic rhinosinusitis with nasal polyposis; GM spacer = gloved-Merocel spacer; LM score = Lund-Mackay score; SD = standard deviation; SMRIT = submucous resection of inferior turbinate; SNOT-22 = 22-item Sino-Nasal Outcome Test.

TABLE 2. Comparison of baseline surgical characteristics between participants randomly allocated to receive GM and Silastic nasal spacers

	GM (n = 48)		Silastic (n = 48)	
Surgical characteristics	n (%)	Missing n (%)	n (%)	Missing n (%)
Concha bullosa	10 (20.8)	0 (0)	9 (18.7)	0 (0)
Paradoxical middle turbinate	7 (14.5)	0 (0)	7 (14.5)	0 (0)
Septum deviation	20 (41.6)	0 (0)	23 (47.9)	0 (0)
	Mean ± SD	Missing n (%)	Mean ± SD	Missing n (%)
Lund-Mackay score (0-12)	6.16 ± 2.12	0 (0)	6.27 ± 2.31	0 (0)

GM = gloved-Merocel spacer; SD = standard deviation.

TABLE 3. Comparison of postoperative visit 2 (5 weeks) and visit 3 (12 weeks) outcomes between participants randomly allocated to receive GM and Silastic nasal spacers in left or right nasal cavity

Visit	GM (n = 48)	Silastic (n = 48)			
Visit-2 (5 weeks)	Mean ± SD	Mean ± SD	Mean difference	95% CI	*p*
Endoscopic score (MLK)	3.50 ± 3.97	2.91 ± 3.92	0.58	−1.04 to 2.21	0.477
	Present n (%)	Present n (%)	Risk ratio[a]	95% CI	*p*
Synechiae	5 (10.6)	7 (14.9)	1.19	0.71 to 2.02	0.382
Frontal recess	0 (0)	2 (28.5)			
Lateral wall to MT	5 (100.0)	3 (42.9)			
MT to IT	0 (0)	1 (14.3)			
Posterior ethmoid to MT	0 (0)	1 (14.3)			
Visit-3 (12 weeks)	Mean ± SD	Mean ± SD	Mean difference	95% CI	*p*
Endoscopic score	2.26 ± 4.09	2.21 ± 4.04	0.05	−1.74 to 1.83	0.957
	Present n (%)	Present n (%)	Risk ratio[a]	95% CI	*p*
Synechiae	3 (6.5)	2 (4.3)	0.79	0.26 to 2.36	0.500
Maxillary Os (antrostomy)	0 (0)	1 (50.0)			
Lateral wall to MT	3 (100.0)	1 (50.0)			

[a]Risk ratio represents the risk of developing synechiae in nasal cavities with Silastic spacers compared to GM spacers.
CI = confidence interval; GM = gloved-Merocel spacer; IT = inferior turbinate; MLK = Modified Lund-Kennedy Endoscopic Scoring System; MT = middle turbinate; Os = ostium; SD = standard deviation.

TABLE 4. Comparison of postoperative visit 1 outcomes between participants randomly allocated to receive GM and Silastic nasal spacers in left or right nasal cavity

	GM (n = 48)	Silastic (n = 48)			
	n (%)	n (%)			
Spacer in right nasal cavity	23 (47.9)	25 (52.1)			
Spacer in left nasal cavity	25 (52.1)	23 (47.9)			
Visit 1 (6 days)	Mean ± SD	Mean ± SD	Mean difference	95% CI	*p*[a]
Pain (VAS)	1.81 ± 1.28	1.71 ± 1.31	0.09	−0.43 to 0.62	0.725
Discharge (VAS)	2.22 ± 1.24	2.13 ± 1.22	0.08	−0.42 to 0.60	0.733
Removal pain (VAS)	1.51 ± 1.23	2.13 ± 1.34	−0.62	−1.15 to −0.09	**0.020**

[a]Bold values indicate statistical significance (alpha < 0.05).
CI = confidence interval; GM = gloved-Merocel spacer; SD = standard deviation; VAS = visual analogue scale.

to drain around it and through it while in situ (Fig. 2A). The design was similar to those reported in the literature, with modifications to tailor it to each respective sinonasal cavity.[13] A silastic sheet with a thickness of 1.02 mm was designed as shown in Figure 2A with a circular fenestration and then folded in half. A suture is placed in the proximal end and tied to the contralateral one anterior to the columella to prevent aspiration. A 2-0 silk suture was tied to the anterosuperior fenestration before placing the folded silastic sheet into the middle meatus. The superior fenestration was made to allow for drainage of frontal secretions.

The Merocel spacer is trimmed to fit the postoperative middle meatal cavity and encased in a surgical glove-finger. A single 2-0 silk suture is tied to the spacer in order to ensure the glove casing is adherent (Fig. 2B). Both spacers had elongated loose suture ends that were brought out of each nasal cavity and tied together around the columella as a safety feature in case of dislodgment into the nasopharynx during the postoperative period.

Sample size and statistical analysis

Based on previously published literature, we assumed a 20% difference in mean endoscopic scores to be clinically significant.[14] Miller et al.[14] performed an RCT evaluating the relationship between postoperative synechiae and nonabsorbable middle meatal nasal spacers and reported a synechiae incidence of 24%. We hypothesized that the use of Silastic spacers would reduce the incidence of postoperative synechiae to 9%. Using the 2-proportion sample size calculation, Type 1 error of 5% and effect size of 15%, we calculated a target sample size of 96 nasal cavities (48 patients) to achieve 80% statistical power.

The primary outcome in this study was the incidence of synechiae occurring in sinonasal cavities receiving either the Silastic or GM middle meatal spacers. A univariable, 2-sample proportions test was used to determine if differences in incidence rates are statistically significant. Values of p <5% ($\alpha = 0.05$) were considered significant. The secondary outcomes were considered as continuous, numerical variables. Mean, median, standard deviation, and interquartile range were reported.

Results

A total of 48 participants (96 nasal cavities) were enrolled and each received the control (GM middle meatal spacer, n = 48) and experimental (Silastic middle meatal spacer, n = 48) treatment (Fig. 3). Participant baseline sociodemographic and clinical characteristics are summarized in Table 1. This patient sample included 39.6% of individuals with CRS with nasal polyposis (CRSwNP) and 60.4% of CRS without nasal polyposis (CRSsNP), with a total Lund-Mackay score of 12.43 ± 4.23 and 22-item Sino-Nasal Outcome Test (SNOT-22) of 44.70 ± 21.77. All 48 participants (96 nasal cavities) had bilateral FESS consisting of a maxillary antrostomy (100%), anterior ethmoidectomy (77.1%), posterior ethmoidectomy (75%), frontal sinusotomy (96%), and sphenoidotomy (96%). The extent of the surgery was typically symmetrical between both sides, as well as the frequency of concha bullosa, paradoxical middle turbinates, and ipsilateral septal deviation (Table 2). Preoperatively, Lund-Mackay CT scores were similar between Silastic-treated and GM-treated cavities (6.27 ± 2.31 vs 6.16 ± 2.12).

Postoperatively, the incidence of synechiae did not differ significantly between cavities receiving each spacer (Table 3). At the 5-week visit, the incidence of synechiae was 10.6% (n = 5) and 14.9% (n = 7) in the GM and Silastic groups, respectively. Synechiae presenting at 5 weeks were resected in-office. At 3-months postoperatively, the incidence of synechiae was 6.5% (n = 3) and 4.3% (n = 2) in the GM and Silastic groups, respectively.

At the first postoperative visit (day-6), pain reported during spacer removal was significantly more severe for Silastic spacers compared to GM spacers (2.13 ± 1.34 vs 1.51 ± 1.23, $p = 0.02$) (Table 4). The severity of facial pain and nasal discharge did not significantly differ between GM and Silastic groups (Table 4). At 5 weeks and 12 weeks

postoperatively, no significant difference was detected in endoscopic MLK scores (mean difference: 0.58, $p = 0.477$; and mean difference: 0.05, $p = 0.957$; respectively) or the likelihood of synechiae (risk ratio: 1.19, $p = 0.382$; and risk ratio: 0.79, $p = 0.500$; respectively) between GM and Silastic groups (Table 3).

Discussion

Prevention of synechiae formation post-FESS is of significant interest for the sinus surgeon. Outcomes obtained in the present study at 5 and 12 weeks postoperatively showed no difference between GM-treated and Silastic-treated sides in terms of the incidence of synechiae and endoscopic MLK scores. The overall incidence of synechiae in this study was comparable to rates reported in the literature.[6]

To our knowledge, this is the first RCT comparing post-FESS outcomes between GM and Silastic middle meatal spacers. Bagueley et al.[8] demonstrated that while Silastic spacers left in the middle meatus were effective in reducing adhesions after FESS, they did not yield any significant improvement in symptoms or ethmoid cavity endoscopic scores 12 weeks postoperatively when compared to the contralateral middle meatus that received no spacer.[13] Their patients also reported much greater discomfort and nasal obstruction on the side receiving the Silastic spacer. In a separate investigation by Bugten et al.,[15] patients were randomized to receive Merocel middle meatal spacers after FESS were compared to those receiving no spacers. There was no significant improvement in postoperative symptoms or endoscopic scores for participants that received a Merocel spacer when compared to controls, although those in the Merocel group benefited from a significant reduction in adhesions. However, patients receiving a Merocel spacer reported no additional symptoms of facial pain, headaches, or discomfort compared to those who received no spacer after FESS.[15]

In the present study, patient satisfaction was the only significantly distinguishing feature between Silastic and GM middle meatal spacers. Facial pain and discomfort with the spacer in situ was 1.81 ± 1.28 with the GM, compared to 1.71 ± 1.31 with the Silastic middle meatal spacer. This difference was not statistically significant (Table 3). There was also no significant difference in the nasal discharge VAS score between GM and Silastic spacers, which corresponded to 2.22 ± 1.24 and 2.13 ± 1.22, respectively. Most notably, pain reported during spacer removal was significantly more severe for Silastic compared to GM spacers (2.13 ± 1.34 vs 1.51 ± 1.23, $p = 0.020$) (Table 4). This may be because the anterosuperior edge of the Silastic spacer occasionally got caught in the axilla of the middle turbinate, something that might be avoided by carefully lowering the anterior aspect of the spacer upon removal. However, previous studies from this tertiary center have also shown that encasing the Merocel within a vinyl glove finger significantly improved patient comfort (when compared to a bare Merocel spacer).[10] In light of these findings, vinyl glove material may confer benefit over Silastic and plain Merocel by potentially reducing friction/abrasion between the spacer and adjacent sinonasal mucosa.

Overall, these findings demonstrate that post-FESS outcomes between GM and Silastic middle meatal spacers were comparable, with the exception of pain upon removal. By using patients as their own controls, this study design reduces the potential for confounding by factors such as differing postoperative debridement and pharmacotherapy.

Conclusion

The GM spacer does not yield any advantage over the Silastic spacer in terms of postoperative healing and the incidence of synechiae formation. However, patients report significantly less pain during the removal of GM spacers compared to Silastic spacers. Given that the postoperative outcomes associated with these nonabsorbable spacers is comparable, it would be reasonable to favor the use of a GM spacer with the expectation that it might yield higher patient satisfaction.

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