



Removing the magnetic sphincter augmentation device: operative management and outcomes

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Abstract

Background Recurrent or persistent symptoms of reflux, dysphagia, or device erosion can lead to removal of the magnetic sphincter augmentation (MSA aka Linx) device. Device removal has been previously reported, and outcomes of various surgical management strategies at the time of removal have not been well described.

Methods This is a retrospective review of patients undergoing MSA removal from March 2009 to September 2017 in a single institution. Reason for removal, operative management, and short-term outcomes are reported.

Results During the study, 435 MSA devices were implanted, 24 of which required removal (5.5%). Removal was due to refractory dysphagia in 1.8% (8/435), for recurrent or persistent GERD in 2.9% (13/435), and secondary to erosion in 0.5% (2/435). Mean time from implant to removal was 863 days (range 119–1762 days). The most common reasons for removal were recurrent GERD (54%), dysphagia (38%), or erosion (8%). Significant operative findings included recurrent or progressive hiatal hernia (38%), erosion (8%), and normal anatomy (46%). Hiatal hernia was found and repaired at the time of device removal in 38% of patients (9/24). The MSA device was removed through laparotomy (4%), laparoscopically (88%), or through a combination of endoscopy and laparoscopy (8%). After removal patients underwent repeat MSA (33%), fundoplication (21%), gastrectomy (4%), or no additional procedure (42%). Symptoms prompting removal of the MSA device had resolved in 52% of patients and improved in an additional 35% at last contact. Of the 10 patients having no anti-reflux procedure after removal, 9 were available for follow-up at a mean of 97 (106) days of whom 22.2% (2/9) had symptoms of GERD or required any anti-reflux medication. No major complications occurred after removal.

Conclusion MSA removal when necessary can be accomplished through minimally invasive means. Repeat Linx or fundoplication can be performed after removal, however may not be necessary in patients with removal for dysphagia.

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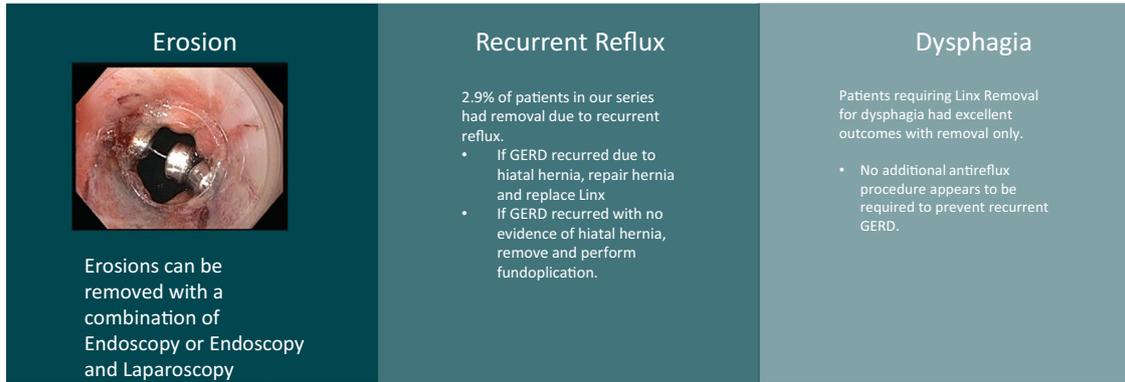
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Graphical abstract

Removing the Magnetic Sphincter Augmentation Device: Operative Management and Outcomes



Keywords GERD · LINX · MSA · Magnetic sphincter augmentation · Linx removal

The magnetic sphincter augmentation device (MSA) common known as the Linx has become an important tool in the surgical management of gastroesophageal reflux disease. The Linx demonstrates equal or superior outcomes to the traditional fundoplication surgery in patient without hiatal hernia and recent reports demonstrate that it is both safe and effective when used in patient with hiatal hernia [1–3]. Concerns of erosion of a foreign body placed at or near the gastroesophageal junction (GEJ) led to initial skepticism of the device from some. These concerns were reasonable given the history of devices placed at or the near GEJ, including the Angelchick device, synthetic mesh at the hiatus, and even the lap band bariatric device [4–6]. Initial and follow-up studies over the past decade demonstrate the rate of Linx removal after implant has remained low at around 1.1–6.7% [7–9]. Studies focusing on device failure, removal, and outcomes of various surgical strategies after removal remain important in this stage of the adoption of Linx into surgical practice. This is a single-center review that discusses intra-operative management and subsequent patient outcomes in attempt to determine how failure might be prevented and how subsequent outcomes might be optimized at the time of removal.

Methods

Study population

All patients who underwent MSA with the LINX® Reflux Management System (Torax® Medical, Inc. Shoreview, MN) at our two affiliated institutions, Keck Hospital of

the University of Southern California (Los Angeles, CA USA) and Hoag Memorial Presbyterian (Newport Beach, CA, USA) between December 2012 and November 2016 are included in this study with follow-up complete through November 2017. The institutional review board of the University of Southern California approved the study (HS-13-00300). Inclusion criteria were any patient undergoing removal of the MSA device whose initial implantation occurred in our practice. Criteria for initial implantation were age greater than 18, pH monitoring confirmation of acid reflux, and normal motility demonstrated by videoesophagram or manometry. All patients underwent 48-h esophageal pH testing and upper gastrointestinal endoscopy prior to operative intervention. A DeMeester score of > 14.72 diagnosed GERD. Screening for hiatal hernia or dysmotility pre-operatively was through review of videoesophagram and esophagogastroduodenoscopy findings, and high-resolution manometry was performed in cases with the video esophagram or symptoms suggested dysmotility. Detailed operative procedure can be reviewed in previous publications [3, 10]. All magnetic sphincter augmentation device implantation and hiatal hernia repairs were performed by authors JCL or NB.

Initial post-operative surveillance

Post-operatively patients were evaluated at routine visits at 1 week, 1 month, 3 months, and then yearly after the date of surgery. Post-operative visits included assessment of PPI use, dysphagia, and recurrence or resolution of symptoms at each visit. Patients with persistent dysphagia or reflux were seen more frequently on an as needed basis. Symptom

resolution or improvement was based on patient response to verbal inquiry.

Routine 1-year post-operative surveillance includes videoesophagram (VEG) and/or esophagogastroduodenoscopy (EGD) to assess for hiatal hernia recurrence, irrespective of patient symptoms and on an as needed basis to evaluate concerning symptoms. A recurrent or persistent hiatal hernia is defined as an excursion of the stomach above the level of the diaphragm equal to or greater than 2 cm by either EGD or VEG.

Criteria for removal or reoperation

Patient who exhibited persistent or recurrent reflux or dysphagia after device implantation were evaluated as needed with endoscopy, ambulatory pH monitoring, videoesophagography, manometry, or CT scans. Patient with persistent dysphagia or food impaction were treated with an escalating combination of oral or IV steroids, EGD with balloon dilatation, and anti-spasmodics in attempt at symptom resolution. Patients with food impaction were given additional counseling regarding food hygiene. Up to 4 balloon dilations were performed for patients with persistent dysphagia or impaction before surgery for revision/removal was considered.

Patient with persistent symptoms of reflux confirmed by ambulatory pH monitoring, recurrent/progressive hiatal hernia, or device location proximally on the stomach were offered surgery. Any patient with device erosion into the esophageal lumen had the device removed.

Surgical procedure

MSA device removal was accomplished through any of several approaches. One device was removed at the time of laparotomy to treat debilitating gastroparesis with a gastrectomy, the two erosions were both partially removed with endoscopy followed by laparoscopy, and the remainder were removed through primary laparoscopy. All patients underwent intraoperative endoscopy at the time of removal.

Endoscopic removal was performed in cases of erosion (Fig. 1). This was accomplished through division of the wire with endoscopic heavy sheers followed by removal per orum with rat-toothed endoscopic forceps. Laparoscopy was performed in one case to remove the remainder of the MSA device, and in one case to exclude transmural perforation.

Laparoscopic removal was accomplished with the use of monopolar cautery on scissors to dissect free the adhesive capsule of each bead, with upward retraction used to sequentially deliver the beads into the free intraperitoneal

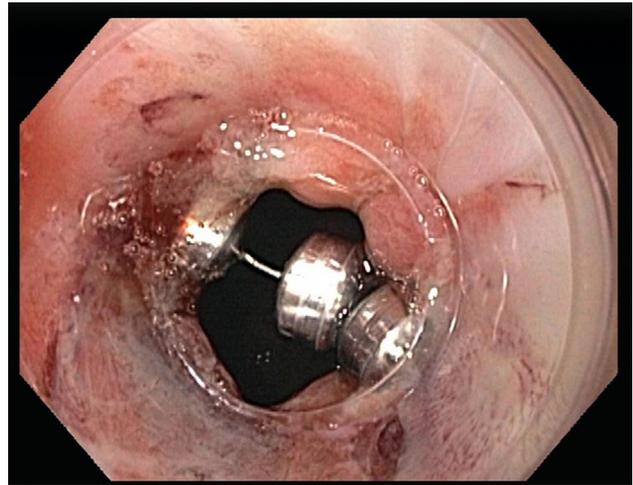


Fig. 1 Endoscopic view of full-thickness MSA erosion

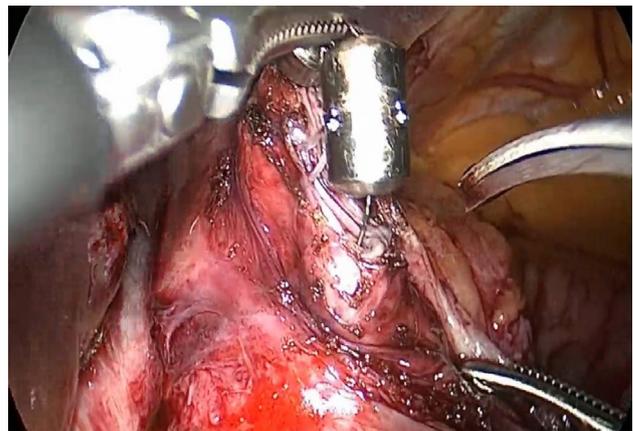


Fig. 2 Dissection of MSA from adhesive capsule

cavity (Fig. 2). Once the majority of the MSA device had been dissected free in both the clockwise and counterclockwise direction, the wire was severed with laparoscopic sheers or the claps was undone, and the device removed through an abdominal port.

After device removal, surgical repair was tailored to specific patients and included hiatal hernia repair when indicated with or without fundoplication, graham patch, MSA reimplantation, or no additional procedure at the time of removal. Factors leading to operative management included the predominant reason for removal—recurrent GERD as confirmed or excluded by pH monitoring or predominantly symptoms of dysphagia without reflux. Perforations were treated with a graham patch only if there was a positive leak test and no additional anti-reflux procedure at the time of removal.

Post-removal management and follow-up

Patients were routinely evaluated with videoesophagram on post-operative day 1 after removal and started on an appropriate diet. Patients were followed post-operatively after removal at 1 week, 3 weeks, 3 months and 6 months. Patients symptoms were assessed and endoscopy and/or videoesophagram were performed as needed.

Statistical analysis

Demographic data, perioperative characteristics, and post-operative outcomes were recorded into a centralized database and summarized. Statistical analyses were performed using SPSS® Statistics v. 25 (IBM®).

Results

During the study period, 435 MSA devices were implanted, all of which were accomplished through uncomplicated laparoscopic surgery. Device removal subsequently occurred in 24 patients (5.5%), patient characteristics are found in Table 1. The MSA device was removed due to refractory dysphagia in 1.8% (9/435), for recurrent or persistent GERD in 2.9% (13/435), and secondary to erosion in 0.5% (2/435). Mean age at implant was 54 (SD: 16); 50% (12/24) were female. Mean time from implant to removal was 863 days (Range 119–1762 days). The most common symptoms resulting in removal were persistent or recurrent GERD (54%), persistent dysphagia (38%), or device erosion into the esophagus (8%). Significant operative findings included location on the proximal stomach (8%), erosion (8%), and

normal anatomy (46%). Hiatal hernia was found and repaired at the time of device removal in 38% of patients (9/24), and this was the most common pathology found at the time of removal. The MSA device was removed through laparotomy (4%), laparoscopically (88%), or through a combination of endoscopy and laparoscopy (8%). After removal, patients underwent repeat MSA placement (33%), fundoplication (21%), gastrectomy (4%), or no additional procedure (42%). Mean operative time for removal was 107 (73) minutes; mean length of stay was 1.0 (0–10) days. Mean follow-up time after removal is 130 (159) days. Symptoms prompting removal of the MSA device had resolved in 52% of patients and improved in an additional 35% of patients.

Erosion

Two patients had removal for erosion. One device was removed completely via endoscopy and then had laparoscopy with leak test (air insufflation via endoscopy) revealing small bubbles after which a Graham patch was fashioned. The second patient with erosion had 6 beads of MSA removed endoscopically and 6 days later had the remaining 7 beads of the 13-bead device removed with laparoscopy; this patient had a negative leak test and no further intervention after completion of device removal during laparoscopy. Operative times for the two cases of erosion were 65 min and 163 min. One of the two patients developed mild dysphagia at 6 months after removal and required EGD balloon dilatation of stricture at the prior erosion site. Both patients had resolution or improvement of symptoms at last follow-up of 342 and 76 days, respectively, and neither was taking proton pump inhibitors.

Recurrent or persistent reflux symptoms

Recurrent GERD was the reason for removal in 13 patients (Table 2). Mean age was 55 (13), and mean time from implantation was 1057 (433) days. Minimal hiatal dissection (placement of the device without crural dissection or closure) was undertaken during implantation of 77% (10/13). At the time of operation, 70% had a recurrent/expanding hiatal hernia and 14% had the MSA placed too distally and it was found below the GEJ. 62% of patients underwent hiatal hernia repair with Linx device removal and replacement (with a new device); 23% (3/13) underwent MSA removal and fundoplication and two of these also had hiatal hernia repair. One patient had no removal beyond intervention, and one had a gastrectomy for treatment of concurrent gastroparesis.

Among patients who underwent MSA reimplantation and hiatal hernia repair, the mean follow-up time post-operatively is 96 (83) days: 75% of patients had resolution of reflux symptoms and 88% were off of PPI at last follow-up. Among patients who underwent MSA removal and

Table 1 Patient characteristics

<i>n</i> = 24	
Patient characteristics	
Age, mean (SD)	54 (16)
Gender male, %	50
Days from initial implantation, mean (SD)	863 (540)
Minimal hiatal dissection at implantation, <i>n</i> (%)	13 (54.2)
Reason for device removal	
Recurrent or persistent GERD, <i>n</i> (%)	13 (54.2)
Dysphagia, <i>n</i> (%)	9 (37.5)
Esophageal erosion, <i>n</i> (%)	2 (8.3)
Operative findings	
Recurrent/expanding hiatal hernia, <i>n</i> (%)	9 (38%)
Proximal location on stomach, <i>n</i> (%)	2 (8.4%)
Esophageal erosion, <i>n</i> (%)	2 (8.4%)
Normal anatomy, <i>n</i> (%)	11 (45.8%)

SD standard deviation, GERD gastroesophageal reflux disease

Table 2 Patient having MSA removal for reflux symptoms

	All <i>n</i> = 13 ^a	MSA re-implant and hiatal hernia repair <i>n</i> = 8	Fundoplication <i>n</i> = 3
Patient characteristics			
Age, mean (SD)	55 (13)	58 (11)	58 (4.9)
Gender male, %	46	50	2 (67)
Days from initial implantation, mean (SD)	1057 (433)	997 (413)	1500 (288)
Minimal hiatal dissection at implantation, <i>n</i> (%)	10 (76.9)	6 (75)	2 (67)
MSA size, mean (SD)	14 (1.4)	14 (1.5)	14 (1.5)
Operative findings			
Recurrent/expanding hiatal hernia, <i>n</i> (%)	9 (69.2)	8 (100)	2 (67)
Proximal location on stomach, <i>n</i> (%)	2 (15.4)	2 (25)	0 (0)
Post-operative outcomes			
Follow-up time, mean (SD)	127 (170)	96 (83)	61 (47)
Resolution of reflux symptoms	7 (53.8)	6 (75)	1 (33)
Improvement of reflux symptoms	3 (23.0)	0 (0)	2 (67)
Proton pump inhibitor use	1 (7.8)	1 (12.5)	0 (0)

SD standard deviation

^a1/13 patients had MSA removed at the time of gastrectomy for severe gastroparesis and reflux; 1/13 had no further intervention after MSA removal

Table 3 Patient having MSA removal for dysphagia

<i>n</i> = 9	
Patient characteristics	
Age, mean (SD)	55 (20)
Gender male, %	5 (56)
Days from initial implantation, mean (SD)	441 (426)
Minimal hiatal dissection at implantation, <i>n</i> (%)	3 (33)
MSA size, mean (SD)	14 (0.88)
Operative findings/procedures	
Recurrent/expanding hiatal hernia, <i>n</i> (%)	0 (0)
Proximal location on stomach, <i>n</i> (%)	0 (0)
MSA removal only, <i>n</i> (%)	7 (78)
MSA removal and Toupet fundoplication, <i>n</i> (%)	2 (22)
Post-operative outcomes <i>n</i> = 8*	
Follow-up time, mean (SD)	119 (152)
Resolution of dysphagia, <i>n</i> (%)	4 (50)
Improvement of dysphagia, <i>n</i> (%)	4 (50)
Symptoms of reflux, <i>n</i> (%)	1 (13)
Proton pump inhibitor use, <i>n</i> (%)	1 (13)

^a1/9 lost to follow-up

fundoplication, the mean follow-up time is 61 (47) days: 33% had resolution and 67% improvement in reflux symptoms and all are off PPI at last follow-up.

Dysphagia

The MSA was removed for persistent dysphagia in 9 patients (Table 3). Mean age was 55 (20) years, mean time

from implant to removal was 441 (226) days, and mean MSA size at implantation was 14 (0.88) beads. None of these patients had a hiatal hernia and the MSA was in the appropriate position relative to the GEJ in all patients. The MSA was removed and no further intervention was needed in 78% (7/9), was removed and partial fundoplication was performed in 22% (2/9). Mean follow-up time after reoperation is 119 (152) days and 8 patients were available for post-operative follow-up. Symptoms had improved in 50% (4/8) and resolved in 50% (4/8). Only 13% (1/8) had symptoms or reflux or was on PPI.

Removal without additional anti-reflux procedure

The MSA device was removed from 10 patients without any additional anti-reflux procedure performed. This occurred in 2 patients who had removal for erosion, 7 with dysphagia, and 1 with recurrent reflux (Table 4). Mean follow-up time after removal was 97 (106) days. Mean time from implant to removal was 590 (560) days. Minimal hiatal dissection occurred at the time of implantation in 33% (3/9). Mean MSA size was 13 (0.74) beads. No hiatal hernia was found at return to the operating room. The patient who had removal for persistent reflux had improvement of symptoms (declined fundoplication) but continued on PPI therapy. Neither patient with removal for erosion had recurrent reflux symptoms. Of the 7 patients undergoing removal for dysphagia, 1 (14%) had recurrent reflux symptoms and required PPI.

Table 4 Patients having no additional anti-reflux procedure after MSA removal

Patient	Reason for removal	Size	Minimal dissection	Days to removal	Findings at OR	Operative management at removal	Complications	Follow-up time	GERD symptoms at last follow-up	Dysphagia at last follow-up	PPI use at last follow-up
1	Dysphagia	13	No	294	Normal anatomy	Lap removal	None	40 days	None	Improved	No
2	Dysphagia	15	No	211	Normal anatomy	Lap removal	None	66 days	None	Resolved	No
3	Dysphagia	13	No	1437	Normal anatomy	Lap removal	None	73 days	None	Improved	No
4	Dysphagia	13	Yes	307	Normal anatomy	Lap removal	None	195 days	None	Resolved	No
5	Erosion	13	Yes	1545	Erosion	EGD + Lap removal	Stricture	342 days	None	Resolved	No
6	Dysphagia	13	Yes	468	Normal anatomy	Lap removal	None	2 days	None	Resolved	--
7	Reflux	13	Yes	730	Normal anatomy	Lap removal	None	56 days	Improved	Improved	Yes
8	Dysphagia	14	No	119	Normal anatomy	Lap removal	None	15 days	None	Resolved	No
9	Dysphagia	13	No	145	Normal anatomy	Lap removal	None	11 days	Recurrent	Resolved	Yes
10	Erosion	17	Yes	1457	Erosion	EGD + Lap removal	None	76 days	None	Resolved	No

PPI proton pump inhibitor

Discussion

In this study, we document a low incidence of the need for MSA removal in our practice, and detail operative findings and management at the time of removal. We also describe the outcomes of patients who did not have any further therapy to prevent reflux after the MSA device was removed.

Other studies have also documented the complications or intolerance of the MSA device that lead to removal. The incidence in the literature remains low at 1.1–6.7% [7–9]. Our removal rate of 5.5% is consistent with the removal rate reported by other groups. A metaanalysis of the first 1000 MSA patients reports a removal rate of 3.4%, most commonly for dysphagia [8]. A more recent safety review by Lipham et al. examines 3283 patients at a mean follow-up of 1.4 years and documents a removal rate of 2.7%, 0.6% for GERD, 1.6% for dysphagia, and 0.15% for erosion [9]. A recent paper by Asti et al. reports a removal rate of 6.7%, also most commonly for reflux and dysphagia with 1.2% of removal for erosions [7]. The most common symptom leading to removal in this study is reflux (54%) followed by dysphagia in 38%. Erosion led to removal in two patients, 0.5%, consistent with rates of erosion reported by other groups [7, 9]. Patient with gastroparesis are no longer considered for MSA implantation out of concern that gastroparesis may only be the hallmark of developing global dysmotility.

Unique to this study is the assessment of outcomes after MSA removal in patients where no additional anti-reflux procedure is performed. In patients who are undergoing removal for recurrent or persistent reflux, it is important to determine if it a failure of the MSA device or a failure of the placement of the MSA device. In this series, 15% of devices were found to have been placed below the GEJ and 70% were found to have herniated into the mediastinum through an expanding or previously small and unaddressed hiatal hernia. Over the course of our experience with the MSA, we have anecdotally noted that our initial surgical strategy of minimal dissection at the esophageal hiatus may have led to missed small hiatal hernia that leads to subsequent failure. Due to this concern, all MSA device implantations are now accompanied by a complete circumferential dissection of the diaphragmatic hiatus and posterior cruroplasty. We believe that this obligatory dissection, even when pre-operative studies do not show evidence of a hiatal hernia, will prevent some instances of failure. Even in cases where the operative findings indicate that failure is due to hiatal hernia we dissect and remove the device completely before placing a new one. Our experience repairing large hiatal hernia in conjunction with the MSA device leads us to believe that the inflammatory response prompted by introduction of the foreign body

may explain why hernia recurrence has remained low, even in the absence of fundoplication to serve a physical barrier to re-herniation of the stomach through the hiatus [10–12]. In three patients we removed the MSA and performed fundoplication, two of these patients also had hiatal hernia repair. Given the small numbers of patients having received these two operative interventions, it is not possible to assess superiority of one. While we accurately describe our practice here, we emphasize that this is small study with limited follow-up. The most common operative findings in patients with persistent severe dysphagia is normal anatomy. In patients with predominant dysphagia but also reflux symptoms, we removed the MSA device and performed a partial fundoplication. In the absence of reflux symptoms or a + pH study, the MSA was simply removed. The incidence of reflux in the small group of patients after removal has proven low at 14% (1/7). This may be due to the anti-reflux properties of the elastic adhesive capsule that persists circumferentially around the GEJ, even after device removal. The persistence of acid control in these patients is an area for further study and would benefit from manometric evaluation of the properties of the adhesive capsule over time after device removal.

The device was removed without further intervention in 10 of the 24 patients in this series. Dysphagia was the reason for removal in 7, in 2 it was removed for erosion, and in 1 for reflux. Overall, the rate of recurrent reflux symptoms among these patients is low at 22% (2/9) among patients available for follow-up. Removal without additional intervention in the absence of an anatomic problem (malposition or hiatal hernia) seems a reasonable option after MSA removal from erosion or dysphagia. Others have described both the partial erosions of the MSA device into the esophageal lumen as well as the combined endoscopic/delayed laparoscopic removal technique we describe here with good results [13, 14]. We continue to recommend MSA replacement without or without hiatal hernia repair as indicated among patients with removal for recurrent or persistent reflux after the initial device implantation.

Limitations

This study is limited by its retrospective nature. Not all patients are available for follow-up after removal.

Compliance with ethical standards

Disclosures John C. Lipham and Nikolai Bildzukewicz are paid consultants for Torax Medical Corporation. James M. Tatum, Evan Alicu-

ben, Kamran Samakar, and Caitlyn Houghton have no conflict conflicts of interest or financial ties to disclose.

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