Feasibility of a new endoscopic suturing device: a first Western experience (with video)

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Background and Aims: Endoscopic hand suturing (EHS) is a new technique for the closure of mucosal defects in the GI tract. Although this method was tested for wound closure after endoscopic submucosal dissection (ESD) in Japan, a feasibility test in a Western setting is lacking. In this study, we present our first experience with EHS for different indications and in different anatomic locations.

Methods: The technical success of EHS and suturing speed were retrospectively determined for all available EHS cases in our center. Technical success was defined as complete closure of the mucosal defect or visually tight fixation of the target.

Results: A total of 19 EHS procedures were performed in 17 patients (mean age, 54.9 years; standard error of the mean [SEM], 4.2 years; male, 53% [n = 9]). Technical success was achieved in 78.9% (n = 15). Total EHS operation time was 40.0 minutes (SEM, 3.1 minutes) with 3.3 minutes (SEM, 0.2 minutes) per single stitch. In a constant team of endoscopist and assistant, mean stitch times declined significantly from the first 4 to the second 4 of 8 cases (4.0 [SEM, 0.6] vs 2.3 [SEM, 0.2] minutes, $P = .02$).

Conclusions: EHS was technically feasible and applicable in different anatomic locations. Further studies may elucidate a possible effect on adverse event rates of endoscopic resections.

In recent years, endoscopic suturing has been developed and tested for various indications in the GI tract. Among these, the Overstitch endoscopic suturing system (Apollo Endosurgery, Austin, Tex, USA) was used for bariatric interventions like endoscopic sleeve gastroplasty for obese patients with high perioperative risk[1] or for endoluminal revision of a dilated gastroenterostomy in patients with late dumping syndrome after Roux-en-Y gastric bypass.[2] Furthermore, this technique is applicable for the treatment of GI fistulas[3] as well as the prevention of stent migration.[4,5] Other suturing techniques include the X-Tack HeliX tacking system (Apollo Endosurgery), which has been tested for the closure of polypectomy defects,[6] as well as the Zeosuture M double-arm-bar suturing system (Zeon Medical Co., Tokyo, Japan), which was used for the closure of the defect after gastric endoscopic submucosal dissection (ESD).[7]

The SutuArt (Olympus Medical Systems Corp, Tokyo, Japan) endoscopic hand suturing (EHS) system falls into the same category. Here, a through-the-scope needle holder is used to grasp a semicircle needle attached to a barbed dissolving string, thereby mimicking the process of hand suturing. A defect can be closed by continuous suturing and,

Abbreviations: EHS, endoscopic hand suturing; ESD, endoscopic submucosal dissection; G-POEM, gastric peroral endoscopic myotomy; SEM, standard error of the mean.

This video can be viewed directly from the *GIE* website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

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because of the barbed thread, tying a surgical knot is not required.[8] In Japan, this new method has been used for the closure of mucosal defects after ESD in the stomach[9-11] and the colon,[12] as well as for full-thickness perforations.[13] Because this new device has not been used in a Western setting, it remains unclear if the results of Japanese endoscopic experts can be reproduced. This study aims at evaluating the feasibility of the SutuArt system for different indications in a Western academic center.

PATIENTS AND METHODS

The main outcome parameter of this study was technical success of EHS) using the SutuArt system for various indications. This was defined as complete closure of the mucosal defect or visually tight fixation of the target tissue in the required position. Secondary outcomes included short-term adverse events, defined as adverse events during the hospital stay or within 3 days of the procedure, and required time for suturing. For this purpose, all EHS cases from the introduction of the technique in June 2023 until December 2023 were retrospectively included in the analysis.

Patients were selected for EHS according to clinical indications for closure of mucosal incisions or ESD resection sites as well as individual indications according to expert opinion (Table 1). For ESD cases, indications included an estimated high risk of secondary perforation caused by the location of resection or intraprocedural muscle injury, when closure by other methods was deemed inappropriate. All procedures were performed by gastroenterologists with training in interventional endoscopy and expertise in ESD (>100 procedures). Cases were performed using GIF-EZ1500 or GIF-1TH190 gastroscopes and EVIS X1 processors (Olympus Medical Systems Corp). Patients were under general anesthesia or conscious analgosedation according to standard operation procedures of the unit. Written informed consent for the entire procedure was obtained from all patients.

For EHS, the V-LOC absorbable wound closure device (Covidien/Medtronic, Dublin, Ireland) was used. This system consists of a monofilament absorbable thread with unidirectional barbs with a tapered-pointed-tip semicircle needle. The tail of the thread holds a small loop. For endoscopic suturing, only 3-0 V-LOC 180 threads (tear strength, 21 days; absorption profile, 180 days) with 26-mm needles in gastric and 17-mm needles in esophageal, duodenal, rectal, and colonic applications were used. For suturing, the SutuArt needle holder was used, which allows grasping of the needle by a special forceps and locks the needle in a plane perpendicular to the endoscope tip. Suturing is achieved by a combination of twisting the instrument and manipulating the endoscope tip as well as the insertion depth of the instrument.

The procedure was performed according to the specifications of and after specialized training by the manufacturer (Fig. 1 and Video 1, available online at www.giejournal.org). First, the needle was introduced to the suturing site. Safe insertion was ensured by introducing the needle inside a disposable distal attachment (Model D-206-05, Olympus Medical Systems Corp). After deposition of the needle, the cap was exchanged for a shorter disposable distal attachment (Model D-201-11804, Olympus Medical Systems Corp). All endoscopes had their working channels in the 7 o'clock position, so single sutures were always executed from left to right. For gastric cases, the first stitch was made on the aboral side of the mucosal defect. This stitch was anchored by pulling the needle through a preformed loop of the thread. Afterward, the defect was closed by continuous suturing. A selective mucosal plication—verified by the mobility of the stitched mucosal layer compared to the GI wall—was attempted in all cases; however, in esophagotracheal and esophagobronchial fistulas, full-thickness plication had to be performed because of severe tissue fibrosis. Sutures were set as tight as possible without ripping the thread or the mucosa. After tightening of the sutures, the remaining thread was cut using a loop cutter (Model FS-410U, Olympus Medical Systems Corp). The needle was then extracted via the introduction cap. For colonic cases, the first stitch was placed at the left side of the mucosal defect and anchored in the same way as in gastric cases. Then, the defects were closed by continuous sutures from left to right, alternating between the oral and aboral side of the defects. Stitches were always placed in 5-mm intervals. For gastric cases, sutures were placed 5 mm from the border of the mucosal defect in such a way that either entry or exit of the stitch was inside the mucosal defect. For colonic cases, both entry and exit of the needle were placed outside the mucosal defect with a margin of 5 mm.

All cases were recorded, and durations of procedural steps were determined from the corresponding video sequences. For time measurements, the start of the EHS procedure was defined as the moment when the endoscope equipped with the needle was introduced in the mouth or anus. Each stitch was defined from the point in time when the needle touched the mucosa to perform a suture. Loop cutting started when the loop cutter appeared in the visual field and ended when the thread was visibly cut. Extraction started immediately after loop cutting and ended when the endoscope together with the needle was extracted from the mouth or anus.

All patients were admitted to a hospital ward overnight after the procedure. Follow-up was performed according to national guidelines for the respective underlying conditions.

Values are given as mean plus or minus standard error of the mean (SEM), where appropriate. The Mann-Whitney U test was used for statistical testing. A linear regression model was used for trend analysis. A P value of $<.05$ was considered statistically significant. This study was approved by the ethics committee of Regensburg University, Regensburg, Germany (project no.: 24-3627-104).

TABLE 1. Patient characteristics

Case number	Sex	Age, y	Underlying illness	Procedure
1	Male	59	Rectal SMT	Rectal ESD
2	Female	52	Colonic polyp	Colonic ESD
3	Female	27	Gastroparesis	G-POEM
4*	Male	66	Bronchoesophageal fistula	Bronchoesophageal fistula closure
5*	Male	66	Tracheoesophageal fistula	Tracheoesophageal fistula closure
6	Male	66	Rectal SMT	Rectal ESD
7	Male	67	Rectal polyp	Rectal ESD
8	Male	38	Duodenal SMT	Duodenal ESD
9	Female	77	Gastroparesis	G-POEM
10	Female	42	Rectal polyp	Rectal ESD
11	Female	53	Early gastric cancer	Gastric ESD
12	Male	41	Early gastric cancer	Gastric ESD
13	Male	62	Gastroparesis	G-POEM
14	Male	89	Gastric adenocarcinoma	NEWS
15	Female	38	Gastroparesis	G-POEM
16	Female	24	Gastroparesis	G-POEM
17	Male	63	Colonic polyp	Colonic ESD
18	Female	69	Gastric adenoma	Gastric ESD
19*	Male	66	Recurrent esophageal stent dislocation	Esophageal stent fixation

ESD, Endoscopic submucosal dissection; *G-POEM*, gastric peroral endoscopic myotomy; *NEWS*, nonexposure endoscopic wall-inversion surgery; *SMT*, submucosal tumor.
*Cases 4, 5 and 19 were performed in the same patient.

RESULTS

In a 7-month study period, 19 EHS procedures were performed in 17 patients (Table 2). Nine men and 8 women with a mean age of 54.9 ± 4.2 years were included. One male patient underwent 3 EHS procedures. Indications for EHS were the closure of ESD resection sites (n = 3 gastric, n = 1 duodenal, n = 4 rectal, and n = 2 colonic), closure of the submucosal tunnel after gastric peroral endoscopic myotomy (G-POEM) (n = 5), closure of spontaneous tracheoesophageal and bronchoesophageal fistulas, and closure of the mucosal defect after nonexposure endoscopic wall inversion surgery. In 1 case, EHS was used for esophageal stent fixation. Procedures were performed with the patient under analgosedation (n = 11) or general anesthesia (n = 8).

Technical success was achieved in 15 of 19 cases (78.9%). One colonic ESD resection site could not be completely closed because of its size of 55 × 40 mm (case 2). In 2 gastric ESDs in close proximity to the pylorus, suturing was aborted and completed sutures reopened because of an estimated high risk of subsequent gastric outlet obstruction (cases 12 and 18).

One patient presented with locally advanced gastric cancer (case 14). Because of comorbidities, the patient refused gastrectomy. Thus, a nonexposure endoscopic wall-inversion surgery was performed.[14,15] The mucosal defect after removal of the target lesion was successfully closed by EHS.

Another patient presented with tracheoesophageal and bronchoesophageal fistulas after palliative chemoradiation for squamous cell carcinoma of the tubular esophagus (cases 4, 5, and 19). After failure of esophageal stenting because of repeated stent dislocations despite conventional fixation measures, closure of the fistulas by EHS was attempted. Although closure of the tracheoesophageal fistula was successful, the larger bronchoesophageal fistula could not be closed by EHS because of tissue stiffness. The procedure was aborted, and the remaining fistula was again treated by esophageal stenting. The patient later developed a second tracheoesophageal fistula, which was deemed unsuitable for EHS and was also treated by esophageal stenting. Because of repeated dislocations of this stent despite conventional stent fixation measures, this stent was successfully fixed in a third EHS procedure.

Short-term adverse events included 1 suspected covered perforation after colonic ESD when complete closure by EHS had not been possible (case 2); the lesion was managed endoscopically by placement of 1 over-the-scope clip. Two patients presented with postprocedural elevated body temperature, which resolved with intravenous antibiotics (cases 6 and 11). One patient developed aspiration pneumonia and recovered with antibiotic treatment (case 13). In 2 cases

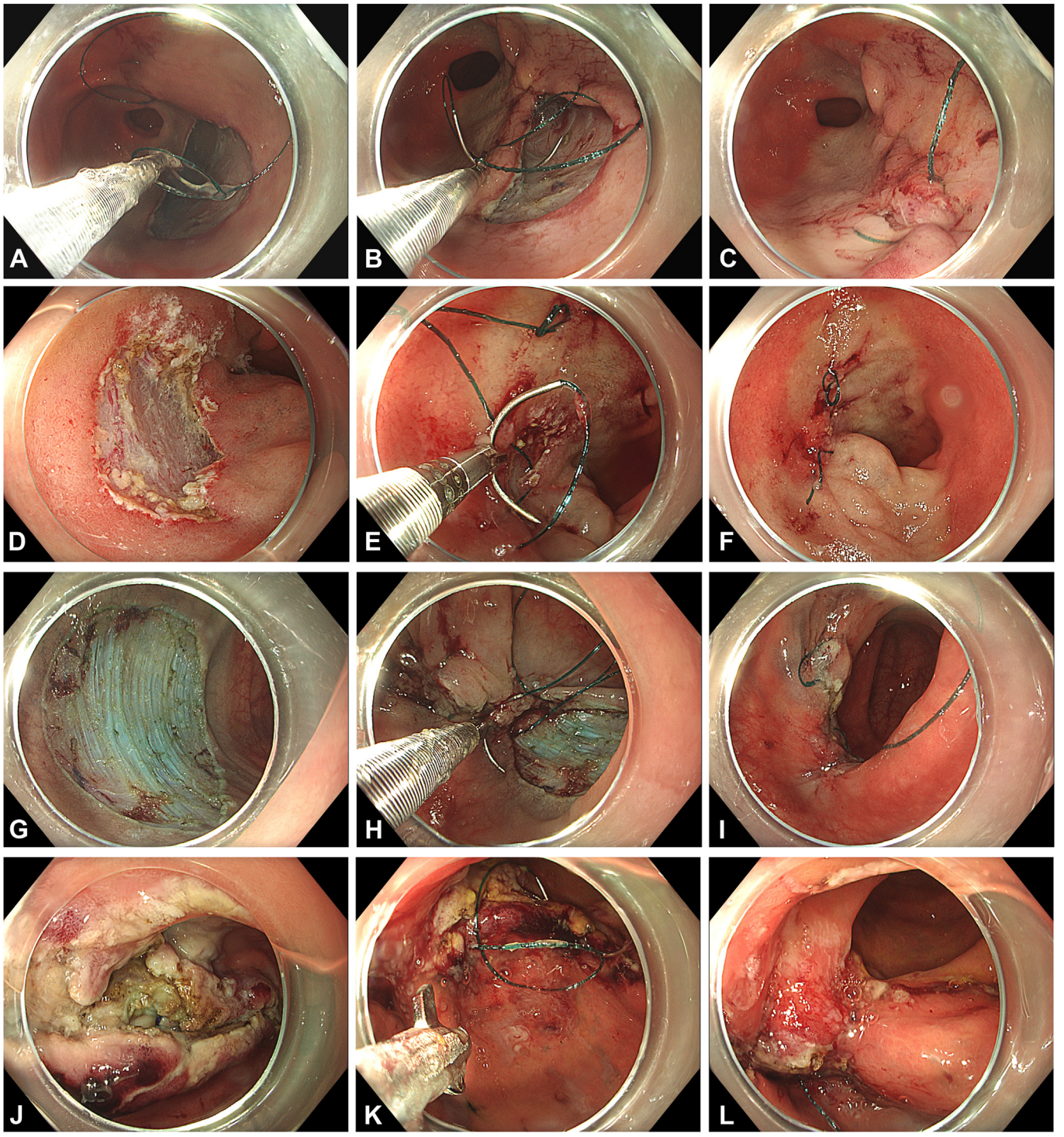

Figure 1. Four examples of endoscopic hand suturing. **A,** Gastric endoscopic submucosal dissection (ESD) resection site with preparation of the anchor stitch by threading the needle holder through the preformed anchor loop. **B,** Sequential continuous suturing of the resection site after 7 stitches performed. **C,** Complete closure of the target defect after 16 stitches. **D,** Resection site after duodenal ESD of a submucosal tumor. **E,** Consecutive closure of the resection defect after 4 stitches. **F,** Closure completed after 6 stitches. **G,** Resection site after colonic ESD. **H,** Intermediate stage of closure via endoscopic hand suturing after 7 stitches. **I,** Complete closure after 14 stitches. **J,** Resection site after nonexposure endoscopic wall-inversion surgery with the serosal sutures visible inside the wound. **K,** Intermediate stage of closing the mucosal defect after 7 stitches. **L,** Complete closure of the mucosal defect after nonexposure endoscopic wall-inversion surgery after placement of 11 stitches.

TABLE 2. Suturing procedure characteristics

Case number	Defect size,* mm	Stitch number	Procedure time,† min	Single stitch time, min	Adverse events
1	20	5	39.0	5.7	None
2‡	55	8	–	5.9	Secondary covered perforation
3	20	9	43.1	3.9	Transient chest pain
4	30	9	38.2	3.7	None
5	15	8	17.1	1.9	None
6	25	10	22.1	1.7	Elevated body temperature
7	30	14	43.7	2.8	None
8	15	6	18.7	2.3	None
9	20	10	55.1	4.0	Mucosal tear in lower esophagus
10	45	22	49.7	2.1	None
11	35	16	37.4	2.0	Elevated body temperature
12	50	12	45.4	3.1	None
13	20	7	34.0	3.3	Aspiration pneumonia
14	45	11	45.2	3.3	Mucosal tear in lower esophagus
15	20	10	34.1	2.1	None
16	20	11	64.7	4.7	None
17	35	13	51.5	3.7	None
18	40	5	24.4	3.2	None
19#	Not applicable	5	56.1	9.2	None

*Defect size measured as the longest defect diameter.
†Procedure time defined as the suturing time including insertion and extraction of the material.
‡In case 2, because of technical failure, measurement of the whole procedure time was not possible, but all single stitches were recorded.
#In case 19, an esophageal stent was fixed, so there was no defect sutured.

of gastric EHS, introduction of the needle inside the protective cap caused superficial mucosal tears in the lower esophagus, which were managed conservatively (cases 9 and 14). One patient developed transient chest pain after G-POEM and EHS (case 3).

Total EHS operation time was 40.0 ± 3.1 minutes. Introduction and extraction of the needle accounted for 7.2 ± 0.8 minutes, the plain suturing procedure consumed 32.9 ± 2.7 minutes, and the cutting of the thread took 0.4 ± 0.1 minutes. On average, 3.3 ± 0.2 minutes were measured per single stitch. For complete ESD closure, a mean of 2.4 stitches were performed per centimeter of the longest diameter of the resection specimen. In total, 191 stitches were performed, with a range of 5 to 22 stitches per procedure. Grouping of ESD and G-POEM cases of the team of endoscopist and assistant with the highest case load showed a steep learning curve, with mean single stitch times declining from 4.0 minutes (first 4 cases: SEM, 0.6 minutes) to 2.3 minutes (last 4 cases: SEM, 0.2 minutes; $P = .02$) within 8 procedures. In these cases, the team performed 90 stitches in total. Linear regression for single stitch times revealed a regression coefficient of –0.037 ($P < .001$) with an R^2 value of 0.162.

Clinical follow-up was available for 16 of 17 patients after a mean period of 160 days (SEM, 15 days). None of the patients developed symptoms associated with EHS in the follow-up period or received additional treatment because of suture-related adverse events like stenosis, secondary dehiscence and perforation, or infection. Endoscopic follow-up was performed in 10 of 17 patients on average 102 days after the procedure (SEM, 15 days). All endoscopies showed no sign of suture-related adverse event, dehiscence of previously completed sutures, or stenosis. In 2 patients, endoscopic follow-up after 32 and 39 days showed the suture in place without signs of adverse event, whereas in all other cases, no suture material was detected (n = 6). This is in accordance with the data from the manufacturer, which states dissolution of the material after up to 180 days. One patient was lost to follow-up.

DISCUSSION

Endoscopic interventionalists are about to adapt the surgical technique of wound closure for endoluminal application. Several systems are already on the market that are not entirely satisfactory; they either require a cumbersome sewing apparatus or, in the case of through-the-scope applications, exhibit a low tearing strength.[16,17] EHS (eg, SutuArt) may be a valuable addition because it combines high tensile strength with versatility of application in the esophagus, stomach, duodenum, colon, and rectum.

The technology of SutuArt requires basic training and, subsequently, frequent application in the clinical setting. Best results are obtained with the coordinated teamwork of the interventionalist and assistant, whose role is more active than usual. The evaluation of single stitch times, however, suggests that the stitching time can be lowered substantially during fewer than 10 applications.

In this first Western feasibility study, a technical success rate of 78.9% was calculated. It would have been even higher if 2 cases of gastric ESD closure were excluded: prepyloric suturing was aborted because of a risk of gastric outlet obstruction but not because of a technical failure. Real technical failures were a large colonic ESD resection defect and inflammation/scarring of an irradiated wound in the case of a bronchoesophageal fistula. It will have to be shown in further studies which indications are most suitable for EHS.

Adverse events after combined endoscopic interventions (resection and suturing) are usually attributable to the resection part and not to EHS. Unwanted effects specifically attributable to EHS are, theoretically, lesions by unfortunate handling of the semicircle needle or inadvertent narrowing/closing of the intestinal lumen. Both could be avoided in the present case series.

The objective of this study was to determine the technical feasibility of EHS in a Western setting. The overall technical success rate was deemed satisfactory. Furthermore, the applicability of SutuArt in various locations of the GI tract could be shown. However, there were several limitations. The number of cases was small, and the acquisition of data was retrospective. Different indications were included in the analysis, and the follow-up period was short. Because this study was designed to show technical feasibility, definitive conclusions concerning a potential clinical benefit cannot be drawn based on the presented data. Thus, the role of EHS under various clinical circumstances will have to be evaluated further.

DISCLOSURE

This author disclosed financial relationships: H. Messmann is a consultant for the following: Relationship with Apollo Endosurgery, Biogen, Boston Scientific, CDx Diagnostic, Cook Medical, CSL Behring, Dr. Falk Pharma, Endo Tools Therapeutics, Erbe, Fujifilm, Hitachi, Jannsen-Cilag, Medwork, Norgine, Nutricia, Olympus, Ovesco Endoscopy, Servier Deutschland, and US Endoscopy; grant recipient from Amgen, Bayer, Dr. Falk Pharma, MSD, Novartis, Olympus, and Roche; paid speaker for Covidien, Dr. Falk Pharma, and Olympus; and consultation fees from Boston Scientific, CDx Diagnostics, Covidien, Erbe, Lumendi, Norgine, and Olympus. All other authors disclosed no financial relationships.

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