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Endoscopic Full-Thickness Gastric Plication Using an Endoscopic Suturing Platform: A Case Report

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Abstract

Endoscopic tissue approximation enables natural-orifice closure of gastrointestinal (GI) defects, avoiding the morbidity associated with laparoscopic or open surgery. Adoption has been limited by platforms that require dedicated endoscopes, complex assembly, multiple accessory exchanges, and a steep learning curve. We report full-thickness gastric tissue approximation using a single-use, preloaded triangulation suturing platform (endomina EZFuse, Endo Tools Therapeutics, Gosselies, Belgium) that mounts on a standard gastroscope and features a bendable, independently moving therapeutic channel. In the United States, the system is FDA-cleared for endoscopic suture placement and soft-tissue approximation in the GI tract.

A 43-year-old man (BMI, 33) with prediabetes, hypertension, and obstructive sleep apnea (OSA) underwent physician-directed gastric tissue plication. Seven sutures were placed under direct visualization. The total procedure time was 45 minutes (mean, 6.5 minutes per suture), with two table-side operators. Sutures were tightened and cut in a single motion without instrument exchange. No intraprocedural adverse events occurred, and the patient was discharged on the same day. At three months, his BMI was 27, prediabetes had resolved (normal A1C), and OSA symptoms had improved. No delayed adverse events were observed.

This case demonstrates the technical feasibility of full-thickness gastric tissue approximation using the endomina EZFuse System with a standard gastroscope.

Categories: General Surgery, Endocrinology/Diabetes/Metabolism, Gastroenterology
Keywords: bariatric and metabolic surgery fbms, endoscopic advanced treatment, endoscopic sleeve gastroplasty, plication, surgical weight loss

Introduction

Therapeutic endoscopy increasingly requires the endoscopist to do more than diagnose and resect. Durable approximation of gastrointestinal (GI) tissue, whether to close a defect, secure a device, or reduce a lumen, has traditionally required a surgical approach or a specialized endoscopic platform [1]. The appeal of performing this approximation entirely through a natural orifice lies in the ability to approximate GI tissue endoscopically, without a surgical incision [2].

The Endomina EZFuse System (Endo Tools Therapeutics SA, Gosselies, Belgium) [3] is a novel endoscopic suturing platform that mounts onto a standard gastroscope. We report a case of full-thickness gastric tissue plication performed using this platform and describe the procedural sequence, peri-procedural course, and workflow characteristics observed by the operating team.

Case Presentation

Patient and indication

A 43-year-old man with a history of prediabetes, hypertension, and obstructive sleep apnea (OSA) presented with a height of 5'10" and a BMI of 33 (232 lb). Initial evaluation included laboratory testing, which showed a hemoglobin A1C level of 5.8% (prediabetes range, 5.7%-6.4%). Preoperative endoscopy demonstrated chronic superficial gastritis (Figure *1*). Prior management consisted of medication and dietary regulation.

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FIGURE 1: Endoscopic view of the gastric lumen demonstrating chronic superficial gastritis

After multidisciplinary discussion, the patient was offered gastric plication using endoscopic tissue approximation as part of the treating physician's clinical management. The rationale was to alleviate the patient's comorbid conditions with gastric plication, which would have a synergistic effect with diet regulation and medication. Written informed consent for the procedure was obtained.

Device

The endomina EZFuse Platform is a single-use, sterile, preloaded triangulation platform supplied ready for use. It mounts onto an adult-sized standard endoscope and is introduced transorally under direct endoscopic visualization, requiring no dedicated or double-channel endoscope. A therapeutic channel bends independently of the endoscope tip, allowing the suturing element to be positioned at an angle to the endoscopic view for tissue acquisition and approximation under direct observation.

The endomina EZFuse Suture (reference IA-EZFUSESUTURE-02) carries two anchors and a fuse element. Once both anchors are placed and the tag is captured, a single movement of the handle tightens the suture and releases it, completing the stitch without a separate cinching device or an accessory exchange through the working channel.

Procedure

The procedure was performed in an ambulatory surgery center (ASC), with the patient under general endotracheal anesthesia and monitored anesthesia care, in the left lateral decubitus position. Prophylactic antibiotics were administered.

An esophagogastroduodenoscopy (EGD) was performed using an adult-sized AMBU endoscope (Ambu A/S, Ballerup, Denmark), and a guidewire was placed into the stomach. The platform was then introduced into the stomach over the guidewire under direct vision. The target tissue was identified, and a standard grasper was used to pull the tissue 30 mm into the device to obtain full-thickness bites.

Under direct endoscopic visualization, gastric tissue was acquired, and sutures were placed using the device's anchor-based approximation mechanism (Figure *2*). Following placement of the paired anchors, the

sutures were tightened and released using the device's integrated mechanism. This sequence was repeated to place a total of seven sutures in an interrupted configuration. Full-thickness bites were achieved by grasping the gastric mucosa with standard graspers and pulling the tissue into the shoulders of the device, as shown in Figure *2*. The tissue was pulled 30 mm into the device before the needle was traversed through it.

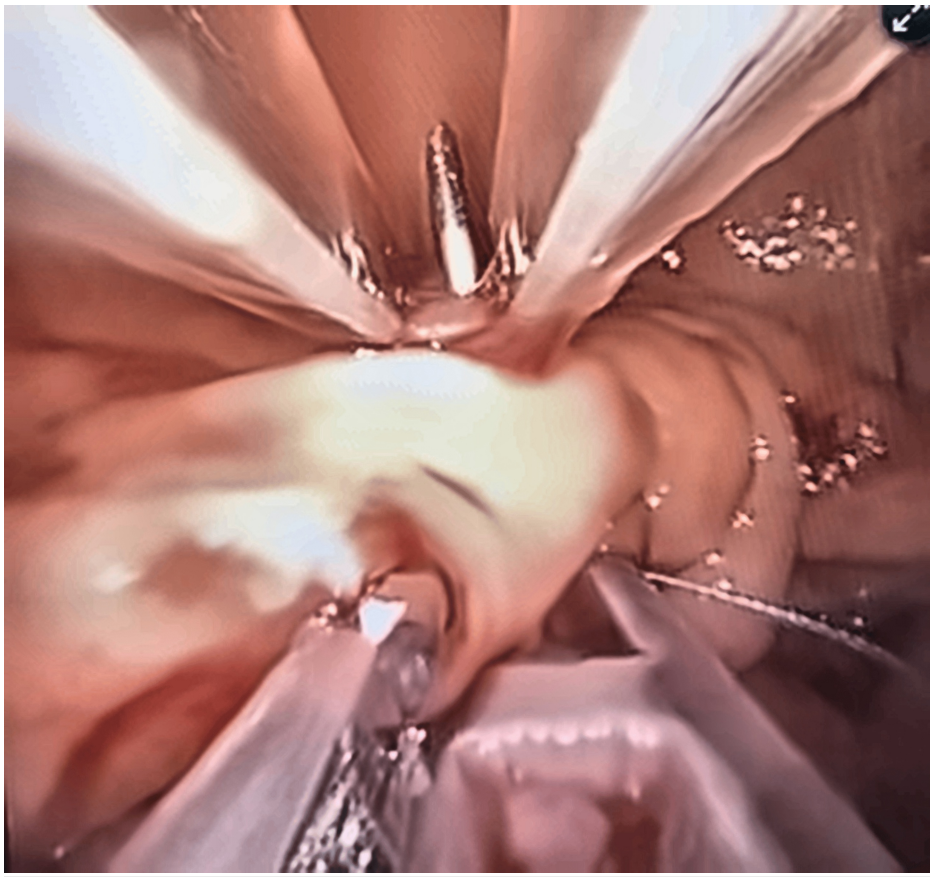


FIGURE 2: Endoscopic view of suturing

Endoscopic view of the gastric lumen following suture placement with the endomina EZFuse system. Mucosal folds are drawn toward the approximated tissue at the center of the field. The device is visible in the lower-right corner of the image.

We considered this to be full-thickness based on animal studies in which the same technique was performed on porcine gastric tissue, which is thicker than human gastric tissue, and the stitches traversed all layers, from the mucosa to the serosa, as observed during extraperitoneal examination. The plications were distributed from the prepyloric antrum, 2 cm from the pylorus, to the gastric body, 2 cm distal to the gastroesophageal junction, and the gastric fundus. Approximation was confirmed endoscopically at the conclusion of suturing. Complete apposition of the tissue, with no residual gap, was observed. Hemostasis was confirmed, and there was no stenosis or obstruction. The device and endoscope were withdrawn without difficulty.

Throughout the case, the device was managed at the table by two operators. No exchange of accessories through the working channel was required for suture tightening or cutting. These are observations from this individual case and are not intended to establish general staffing or procedural-performance requirements. Procedural parameters are summarized in Table *1*.

Parameter	Observed value
Gastroscope used	AMBU
Total procedure time	45 minutes
Sutures placed	7
Mean time per suture	6.5 minutes
Personnel managing the device at the table	2
Accessory exchanges required	Accessory exchanges for suture tightening/cutting - 0
Estimated blood loss	5 mL
Intraprocedural adverse events	None
Technical success	Successful tissue approximation observed - Yes
Length of stay	Same-day discharge
Follow-up interval	2 weeks, 1 month, 3 months

TABLE 1: Procedural parameters

The values represent observations from this single procedure and should not be interpreted as established performance, efficiency, staffing, or comparative claims.

Outcome and follow-up

The immediate postprocedural course was uneventful. The patient was observed for four hours and discharged on the same day with a diet advancement plan (24 hours of clear liquids, two weeks of full liquids, and two weeks of soft foods) and anti-nausea medications. No postprocedural imaging was performed.

At the one-month follow-up, the patient reported symptom improvement. At three months, the patient's BMI had decreased to 27 (191 lb) from 33 (232 lb). Prediabetes improved, with the preprocedural HbA1c decreasing from 5.8% to 5.5% (prediabetes range, 5.7%-6.4%). The patient reported improved sleep, with less snoring and fewer waking episodes, as well as increased daytime energy, which allowed him to be more active. An objective sleep study is planned for the six-month follow-up. No additional lifestyle modifications, exercise programs, or weight-loss medications were administered during the postprocedural period. No delayed adverse events were observed during the three-month follow-up period.

Discussion

This case illustrates full-thickness endoscopic tissue approximation performed through a natural orifice using a standard gastroscope. Several workflow characteristics observed during the case are worth describing.

The fuse element allowed each suture to be tightened and released in a single movement of the handle, so no separate accessory exchange was needed for the tightening and cutting step. More broadly, suture placement, tightening, and cutting were all completed without exchanging instruments through the working channel. The platform also mounted onto the standard endoscope already in routine use in our unit. In this case, the device was managed at the table by two operators; we note this as an observation from a single procedure rather than as a general staffing claim, since formal assessment would require a comparative time-and-motion study. The anchor release sequence also contributed to the workflow. Because the anchor to be captured is the last one released, the tag was positioned for direct retrieval. Tag capture can be one of the more variable steps of endoscopic suturing, and the operating team found this sequence straightforward to follow.

Two further features of the platform bear on the technique itself rather than on workflow. First, the independently bending therapeutic channel provides an additional axis for positioning the suturing element relative to the target tissue. Second, the bites taken in this case were full thickness, which is the relevant depth for durable approximation, since mucosa-only apposition is prone to early failure [4]. Full-thickness tissue acquisition has been investigated as a factor potentially relevant to the durability of tissue approximation. Studies have demonstrated a correlation between suture appearance (i.e., how intact the sutures were) at 6 and 12 months and intervention effectiveness [5]. In a porcine model, endoscopic closures

relying on everted mucosal apposition had loosened by one week, whereas full-thickness inverted serosal apposition remained intact in every animal [4]. Human studies have also demonstrated the safety of endoscopic suturing techniques and clinical improvement, lasting from 12 to 36 months [6]. The relevance of these findings to durability with the EZFuse System has not yet been established.

Limitations

This report describes a single patient treated by a single operator at one institution, and no control or comparator group was studied. The operating team had prior experience with the first-generation endomina platform. No structured assessment of the learning curve or operator proficiency was performed in this case, so no conclusions regarding ease of use, learning curve, or time to proficiency can be drawn. Procedural times were recorded from the clinical record rather than through a structured time-and-motion protocol, and the workflow observations reported here are the impressions of the operating team. Follow-up extends to three months, which is insufficient to characterize the long-term durability of the approximation. None of the observations in this report should be interpreted as a comparative claim against other endoscopic suturing platforms; such conclusions require prospective, ideally randomized, comparisons. These findings are promising, but further studies involving a larger patient cohort and longer follow-up periods are needed to draw conclusions about long-term clinical efficacy. The procedure described was undertaken for a therapeutic purpose not specifically included in the device's U.S. FDA-cleared indication. This report was not designed to establish the safety, effectiveness, procedural efficiency, staffing requirements, learning curve, or comparative performance of the device.

Conclusions

Full-thickness endoscopic tissue approximation using the endomina EZFuse system, performed through a natural orifice with a standard endoscope, was technically successful in this single case. The integrated tightening/cutting mechanism and the absence of accessory exchange for that step were observed workflow characteristics of the procedure. These observations support further prospective evaluation of the platform, including assessment of clinical outcomes, procedural characteristics, and the durability of approximation. No conclusions regarding safety, effectiveness, procedural efficiency, learning curve, or comparative performance can be drawn from this single case.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Aziz Merchant, Aram E. Jawed

Acquisition, analysis, or interpretation of data: Aziz Merchant, Aram E. Jawed

Drafting of the manuscript: Aziz Merchant, Aram E. Jawed

Critical review of the manuscript for important intellectual content: Aziz Merchant, Aram E. Jawed

Supervision: Aziz Merchant

Disclosures

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