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Devices and techniques for bariatric and metabolic endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Technical and Technology Review

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ABSTRACT

Endoscopic bariatric and metabolic therapies (EBMTs) are increasingly recognized as valuable tools for managing obesity and related metabolic disorders. As the prevalence of obesity continues to rise globally, there is a growing demand for effective, safe, and less invasive treatment options. This review provides a comprehensive summary of the available EBMTs, including both stomach-targeted and small-bowel-targeted devices. The review details the various devices, outlines the techniques for their proper use, and discusses their indications. It also presents data on their efficacy and safety, and the management of adverse events and weight regain, as well as anticipated future developments. The paper emphasizes the necessity for additional high quality randomized controlled trials and long-term outcome data to better define the role of these therapies within obesity treatment protocols. Overall, this review

serves as an authoritative resource for endoscopists, bariatric specialists, and the wider healthcare community involved in obesity care, promoting best practices and guiding the appropriate implementation of EBMTs in clinical settings.

ABBREVIATIONS

AE	adverse event
ALT	alanine aminotransferase
APC	argon plasma coagulation
ASGE	American Society for Gastrointestinal Endoscopy
BMI	body mass index
CE	Conformité Européenne
DJBL	duodenal–jejunal bypass liner
DMR	duodenal mucosal resurfacing
EBMT	endoscopic bariatric and metabolic treatment
EGR	endoscopic gastric remodeling
ESG	endoscopic sleeve gastroplasty
ESGE	European Society of Gastrointestinal Endoscopy
EWL	excess weight loss
FDA	US Food and Drug Administration
GEJ	gastroesophageal junction
GI	gastrointestinal
GJA	gastrojejunal anastomosis
GLP-1RA	glucagon-like peptide-1 receptor agonist
IGB	intragastric balloon
IMAS	incisionless magnetic anastomosis system
IQR	interquartile range
POSE	primary obesity surgery endoluminal
RCT	randomized controlled trial
ReCET	recellularization via electroporation therapy
TBWL	total body weight loss
TORe	transoral outlet reduction
TPS	TransPyloric Shuttle

SOURCE AND SCOPE

This European Society of Gastrointestinal Endoscopy (ESGE) Technical and Technology Review addresses the technical aspects of bariatric and metabolic endoscopy, providing updated guidance on the available devices and techniques.

1 Introduction

1.1 Background

Obesity is a chronic relapsing medical condition resulting from a complex interplay of genetic and environmental factors, which include: high calorie Western diet, sedentary lifestyle, poor sleep habits, metabolic disorders, and gut microbiota [1, 2]. According to the World Health Organization (WHO), obesity refers to excessive or abnormal body adiposity. It is commonly defined by a body mass index (BMI) equal to or greater than 30 kg/m^2 [2].

Obesity carries a significant healthcare burden as it is a well-known risk factor for several diseases, including cardiovascular diseases, several types of cancer, type 2 diabetes, metabolic-associated steatotic liver disease and steatohepatitis (MASLD/MASH), and chronic respiratory diseases like obstructive sleep apnea [3–5]. Furthermore, it has reached the magnitude of a global pandemic. Recent estimates from the WHO indicate that the global prevalence of obesity among adults reached 13 % in 2016. The situation is even more concerning for children and adolescents aged 5–19 years, with the prevalence of overweight and obesity exceeding 18 % in 2016 [6]. These numbers are expected to grow more and more, making obesity one of the most significant public health issues of the 21st century. This epidemic calls for an expansion of treatment options for this chronic, incurable, and relapsing disease. Moreover, it will necessitate an increase in the number of available therapists familiar with the subject.

Behavioral and lifestyle modifications, such as low calorie diet and physical activity, are the cornerstone therapies for weight loss; however, they typically result in modest weight loss, and patients often experience weight regain in the long term [7, 8]. Bariatric surgery is currently the most effective and durable therapeutic option for obesity; however, only approximately 1 % of eligible patients undergo surgery, partly because of the high costs and partly because of the potential for serious adverse events (AEs) and mortality [9].

Recently, significant advancements in research have led to the approval of several antiobesity medications, such as glucagon-like peptide-1 receptor agonists (GLP-1RAs). These medications have been proven to induce significant weight loss and improve risk factors linked with the development of chronic diseases [10]; however, their use is limited by costs, insurance coverage, shortage of drugs, and intolerance [11]. Furthermore, their discontinuation may lead to weight regain, and there are limited data on their long-term efficacy and safety [11].

Endoscopy has always played a role in the management of complications of bariatric surgery. In recent years, primary endoscopic bariatric and metabolic treatments (EBMTs) have evolved and, although they are still struggling to gain recognition from surgical colleagues, endobariatrics has branched off as a specialized, minimally invasive, endoluminal discipline. The expansion of EBMTs in clinical practice stems from the necessity of bridging the therapeutic gap between surgery and lifestyle modifications, and the increasing demand for an alternative to long-term pharmacological therapy.

This review summarizes the recent and emerging evidence related to EBMTs regarding the technologies, their safety, and the efficacy outcomes to help guide clinical decision-making.

1.2 Methodology

For this review, we searched PubMed and the Cochrane Library to find relevant articles published up to November 2024, with the terms "bariatric endoscopy," "endoscopic bariatric treatments," "endoscopic gastroplasty," "endoscopic gastric plication," and "metabolic endoscopy." We restricted our search to articles written in the English language. Additional relevant articles were identified by searching the reference lists of the identified articles. Whenever possible, we prioritized evidence from systematic literature reviews, meta-analyses, and randomized controlled trials (RCTs). We aimed to include studies with a minimum duration of 1 year and with a control group wherever possible.

1.3 Devices and/or technologies covered in this review

EBMTs can be categorized into gastric and small-bowel devices and procedures, whose mechanisms are mainly based on restriction/delayed gastric emptying and malabsorption, respectively. The devices and technologies covered in this review are summarized in ▶ **Table 1**. Currently, restrictive procedures, namely intragastric balloons (IGBs) and endoscopic gastric remodeling (EGR)/endoscopic sleeve gastroplasty (ESG), are the most popular procedures and are routinely performed in clinical practice worldwide. Several devices and procedures that target the small bowel have been developed and investigated in multiple clinical trials, although none have currently been released for routine use. As such, these treatments are accessible only in the setting of clinical trials.

▶ **Table 1** Classification of endoscopic bariatric and metabolic treatments (EBMTs).

Stomach-targeted EBMTs (restrictive)	Small-bowel-targeted EBMTs (malabsorptive)
Space-occupying devices	**Liners**
Intragastric balloons: ▪ Orbera Apollo ▪ MedSil ▪ Allurion ▪ ReShape ▪ Obalon ▪ Spatz3	Duodenal–jejunal bypass liner
TransPyloric Shuttle	Gastroduodenal–jejunal bypass sleeve
Endoscopic gastric remodeling (EGR)/Endoscopic sleeve gastroplasty (ESG)	**Resurfacing**
OverStitch	Duodenal mucosal resurfacing (Revita)
Primary obesity surgery endoluminal (POSE) device	Duodenal recellularization via electroporation therapy (ReCET)
Endomina	
EndoZip	
Others	**Anastomosis**
Plenity	Incisionless magnetic anastomotic system
Aspiration therapy	

1.4 Indications

The American Society for Gastrointestinal Endoscopy (ASGE) and European Society of Gastrointestinal Endoscopy (ESGE) guideline published in 2024 suggests the use of EBMTs combined with lifestyle modifications in adults with obesity (BMI ≥ 30 kg/m^2) or with a BMI of 27–29.9 kg/m^2 with at least one obesity-related co-morbidity (conditional recommendation; very low quality of evidence) [12]. As most of the evidence covers IGBs and EGR, the guideline suggests using IGBs and devices for EGR in conjunction with lifestyle modification for this population (conditional recommendation; moderate quality of evidence) [12].

The International Federation for the Surgery of Obesity and Related Disorders (IFSO) consensus on definitions and clinical practice guidelines for the management of obesity published in 2023 included the approval of the indications for ESG, supported by evidence from the randomized controlled trial (RCT) of ESG versus lifestyle intervention (MERIT) [13, 14]. For IGBs and all other currently available EBMTs presented, there was no expert support in the guideline. The endorsed statements are:

- ESG combined with lifestyle intervention is preferable to lifestyle interventions alone, for the management of adults with class I obesity
- ESG combined with lifestyle intervention is preferable to lifestyle interventions alone, for the management of adults with class II obesity
- ESG combined with lifestyle interventions is an acceptable management option for adults with class III obesity who either do not qualify for (given medical or psychological co-morbidities) or do not wish to pursue metabolic bariatric surgery
- in individuals with class I obesity and co-morbidities, ESG is effective at inducing sustained weight loss that remains at 12–24 months follow-up
- ESG combined with lifestyle intervention is preferable to lifestyle interventions alone, for the management of adolescents with class II obesity.

In February 2024, an international team of experts – mainly bariatric surgeons – also voted on the indications for the treatment of class I (BMI 30–34.9 kg/m^2) and II obesity (35–39.9 kg/m^2) in adults using a Delphi technique. Following this, they endorsed three of the main statements on EBMTs that the IFSO had already endorsed. They also reached agreement on a cautious statement on IGB therapy [15].

With regard to small-bowel EBMTs, larger studies have only been conducted on the duodenal–jejunal bypass liner (DJBL), which has since been withdrawn from the market [16]. This

was a setback from which the small-bowel EBMTs have yet to fully recover, although some very interesting techniques are being developed to add to the endoscopic toolbox, as the duodenum appears to be the center of orchestrated metabolic control [17]. Sufficient evidence will however be needed before clear indications for interventions in the small bowel can be defined for clinical use.

Furthermore, the indications for combining endoscopic procedures with antiobesity medications have not been well established. Antiobesity medication can be used in two ways: as a neoadjuvant treatment or as an additional adjuvant treatment. Adjuvant use is most interesting for EBMTs, which mainly target class I and II obesity; however, clear thresholds for combination use must be defined to generate reliable and intelligible evidence. Once established, the resulting combination effect could open up new dimensions in treating obesity.

2 Description of the devices and/or technologies, and techniques for correct use

2.1 Intragastric balloons

IGBs induce satiety mainly by reducing gastric volume, similarly to an artificial bezoar, and by modifying stomach emptying [18]. The placement of an IGB is temporary and does not cause any permanent anatomical changes in the stomach.

Several types of balloon are currently available on the market. Each balloon differs in its indwelling time, modality of insertion/removal, filling medium, number of balloons, volume, or a combination of these factors (▶ **Table 2**).

The Orbera 365 (Boston Scientific, Marlborough, Massachusetts, USA), MedSil (Medispar, Genk, Belgium), ReShape (ReShape Lifesciences, Eden Prairie, Minnesota, USA), and Spatz 3 (Spatz Medical, Fort Lauderdale, Florida, USA) balloons are placed under endoscopic guidance. The procedure is performed with the patient under sedation in the left lateral position to minimize the risk of aspiration. If the procedure is performed with the patient under general anesthesia, they can be in the supine position. An upper gastrointestinal (GI) endoscopy is performed to detect any contraindications for IGB placement, including peptic ulcers, esophageal or gastric varices, a large hiatal hernia, and prior gastric surgery. Once a proper upper GI endoscopy examination has been performed, the gastroscope is slowly withdrawn.

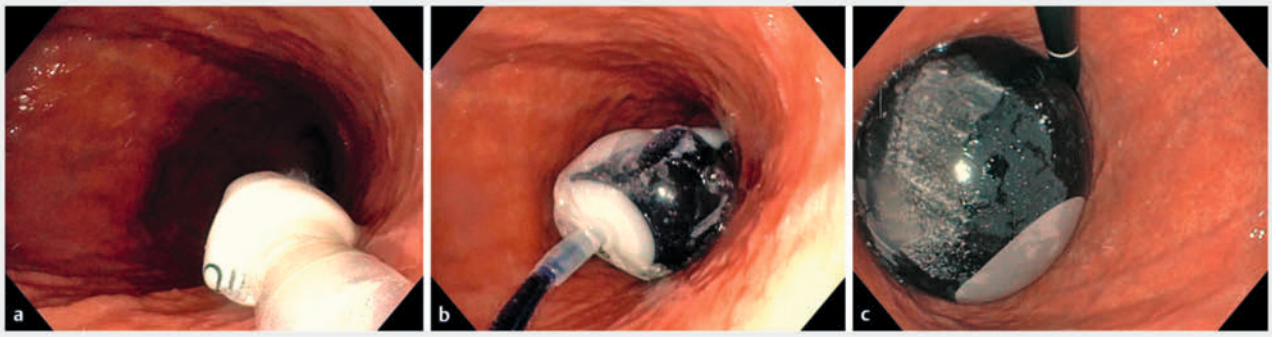
The introducer balloon catheter is then removed from the packaging, taking care not to remove the sheath that covers the balloon or the guidewire within the catheter, as this will impede introduction. The introducer balloon catheter is then lubricated and advanced into the esophagus. The gastroscope is reinserted into the esophagus and, under direct visualization and with gentle traction on the catheter, the introducer with the balloon is pushed into the gastric cavity (▶ **Fig. 1a**). The Spatz 3 introduction technique is different: the balloon with the adjustment tube connected to an intravenous extension tube is attached to the endoscope tip by a flexible sheath and then slowly advanced into the gastric cavity with the gastroscope.

Once placed in the stomach, the balloon is inflated by injecting 50 mL aliquots of saline plus methylene blue through a closed infusion circuit (▶ **Fig. 1b**). The entire procedure is performed under direct endoscopic view. When the inflation is completed, the infusion circuit is closed, and gentle backward traction is applied to the filling catheter, which is withdrawn while leaving the inflated balloon in the stomach (▶ **Fig. 1c**).

▶ **Table 2** Details of the available intragastric balloons.

	Description	Filling volume and medium	Insertion	Indwelling time, months	FDA/EC approval
Orbera/ Orbera 365	Single silicone balloon	400–700 mL; Saline	Endoscopy	6–12	FDA/EC approved
MedSil	Single silicone balloon	400–700 mL; Saline	Endoscopy	6	EC approved
ReShape	Two independent silicone balloons linked by a silicone shaft	450 mL each (900 mL); Saline	Endoscopy	8	FDA/EC approved
Spatz 3	Single silicone balloon connected to filling catheter with a valve at the end	300–850 mL (adjustable); Saline	Endoscopy	8	FDA/EC approved
Obalon	Plastic (up to three independent balloons)	250 mL each (750 mL overall); Nitrogen gas	Swallowed (radiographic control, no endoscopy or sedation needed)	6	FDA/EC approved
Allurion	Vegan polyurethane	550 mL; Liquid	Swallowed (radiographic control, no endoscopy or sedation needed)	4	EC approved

EC, European Conformity; FDA, US Food and Drug Administration.



▶ **Fig. 1** Endoscopic views of intragastric balloon insertion for the Orbera balloon showing: **a** the introducer with the deflated balloon inserted into the gastric cavity; **b** the balloon inflated with saline plus methylene blue; **c** the inflated balloon in the stomach.

The Spatz 3 comes with a filling catheter equipped with a valve at the end. This allows saline to be added or removed while the balloon is in place, adjusting the volume to match the patient's tolerance/sense of satiety and the desired weight loss. Volume adjustments require the patient to undergo an endoscopy in order to bring the catheter, which is caught with a snare, out of the oral cavity to allow saline to be added or removed. Once the volume adjustment is completed, the catheter is pushed back into the gastric cavity.

The insertion of the Obalon (ReShape Lifesciences) and Allurion (Allurion Technologies, Natick, Massachusetts, USA) balloons does not require endoscopy or sedation. The Obalon is collapsed and enveloped in a soluble gelatin capsule that is swallowed under fluoroscopic guidance to ensure it reaches the stomach. The balloon is connected to a thin catheter that extends outside the mouth and is used to inflate the balloon with a gas mixture, up to a maximum volume of 250 mL. After the balloon has been inflated, the catheter is disconnected and removed with gentle traction, allowing the balloon valve to seal itself safely. Three independent balloons can be placed, with each balloon being placed 1 month apart. Similarly, the Allurion balloon is compressed and enclosed in a vegetarian capsule linked to a thin catheter. The capsule is swallowed, and the correct position is verified radiographically. The balloon is then filled with fluid up to 550 mL, and the catheter is removed by gently pulling it back.

Once the treatment period is completed, the balloons, except for the Allurion, must be removed through an endoscopic procedure. The procedure is performed with the patient under sedation in the left lateral position. If the procedure is performed with the patient under general anesthesia, they can be in the supine position. The endoscope is introduced into the stomach, and the balloon is visualized. The balloon is then punctured using a large-bore needle, and its contents are aspirated until completely deflated. Subsequently, a grasper or forceps is used to catch and remove the balloons, pulling them gently through the esophagus and out of the mouth. The Allurion balloon is designed to automatically deflate, thanks to the spontaneous opening of its valve, and pass through the GI tract after 4 months.

With a focus on correct use and patient safety, the following factors are absolute contraindications for the placement of an IGB: active gastric, duodenal, or esophageal ulcers; history of gastric surgeries; hiatal hernias measuring ≥ 5 cm in size; gastric and esophageal varices; coagulation disorders or use of anticoagulants; pregnancy or the desire to become pregnant during the balloon placement period; breastfeeding; alcoholism; and drug addiction [19, 20]. Relative contraindications include: a large hiatal hernia measuring ≥ 3 cm in size; inflammatory bowel disease; previous abdominal surgeries; esophagitis; chronic nonsteroidal anti-inflammatory drug usage; and uncontrolled psychiatric disorders [19, 20].

2.2 Endoscopic gastric remodeling

EGR consists of full-thickness suturing of the gastric body, resulting in volume restriction and delayed gastric emptying [21–24]. These events lead to an alteration in the appetite pathway and, eventually, to weight loss. EGR can be performed with several devices, which are described in the following sections. The choice of device depends on the clinical context, patient values, availability, and operator experience [12, 25], as current evidence is insufficient to make a specific recommendation for one device over another.

The procedure is performed with the patient under general anesthesia using CO_2 insufflation; however, deep sedation for EGR has been described and can be used [26]. Patients should be placed in a partial left lateral or supine position to move abdominal organs away from the gastric cavity (liver, spleen, abdominal wall).

Before suturing is begun, an initial upper GI endoscopy should be performed with a standard gastroscope to rule out contraindications. Periprocedural antibiotics are recommended to reduce the complication rate, as no concrete evidence exists to state otherwise. Patients are typically given periprocedural nausea control with ondansetron 4 mg intravenously and pain control with nonopioid pain medications.

Once the suturing process is complete, an upper GI endoscopy is required to check the result and to exclude any AEs. Patients can be discharged the same day after a 2–3-hour post-

operative recovery; however, hospitalization is recommended in accordance with national reimbursement practices.

EGR is contraindicated for patients who have gastric or esophageal varices, active peptic ulcers, congestive gastropathy, gastric polyposis (except for hyperplastic polyps), and uncontrolled/untreated psychiatric disorders [26].

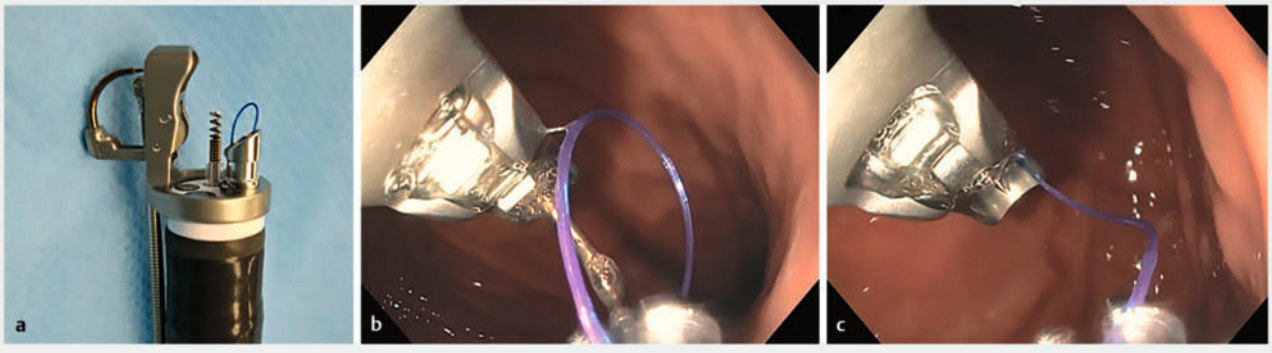
2.2.1 OverStitch suturing system

The OverStitch platform (Boston Scientific) used to perform ESG is the most commonly used device for EGR/ESG globally. Currently, there are two different versions: the first version, the OverStitch (▶ **Fig. 2**), is designed for use with a double-channel endoscope, while the OverStitch Sx (▶ **Fig. 3**) can be mounted on a single-channel gastroscope and is provided with two independent channels [27].

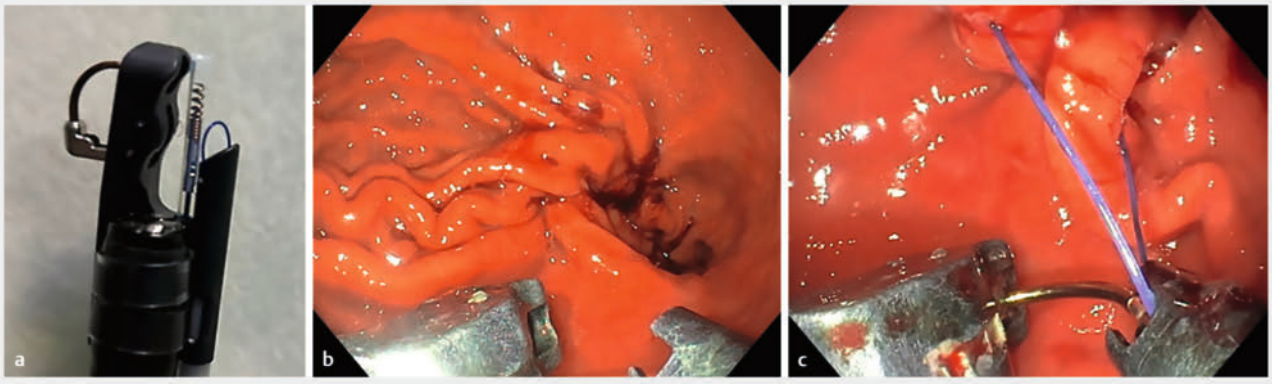
Both types operate on the same principle to create full-thickness stitches during the creation of the endoscopic sleeve. The components of the device include a handle that enables manipulation of the needle driver at the endoscope's tip, the anchor exchange, a catheter-based device that carries the needle and thread, the tissue helix that allows grasping of the gastric wall, and the cinch that allows tightening and locking of the suture. The anchor exchange is inserted into the right channel of the scope for the original version and of the device itself for the Sx version, while the helix is inserted into the left channel.

Recently, the next-generation OverStitch NXT Endoscopic Suturing System has been released [28]. This device, compatible with a single-channel gastroscope, features a physician-controlled helical retractor that aligns with the suturing component to enable larger full-thickness plications. In addition, the suturing arm is provided with advanced rotational and bending capabilities, ensuring precise articulation in challenging anatomical regions. Finally, the system includes an auxiliary channel that enhances suction and irrigation, maintaining clear visibility and a clean operative field.

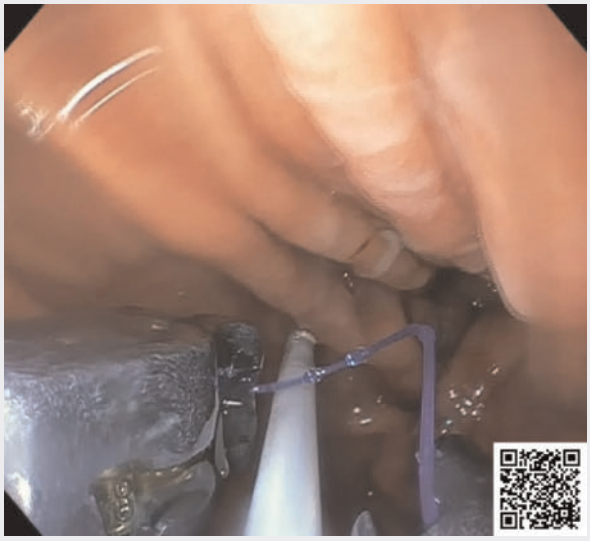
An esophageal overtube can be placed to prevent oropharyngeal and esophageal trauma; however, this step is optional according to the endoscopist's preference, as the device must be introduced with the needle driver closed, which should prevent any damage [29]. The use of argon plasma coagulation (APC) for marking sites is also optional according to the endoscopist's preference.



▶ **Fig. 2** The OverStitch device, which is designed for use with a double-channel device, is shown: **a** photographically; **b,c** in use on endoscopic view.



▶ **Fig. 3** The OverStitch Sx, which is designed to be mounted on a single-channel gastroscope, is shown: **a** photographically; **b**, **c** on endoscopic view.



Video 1 Endoscopic gastroplasty with the OverStitch Sx device.
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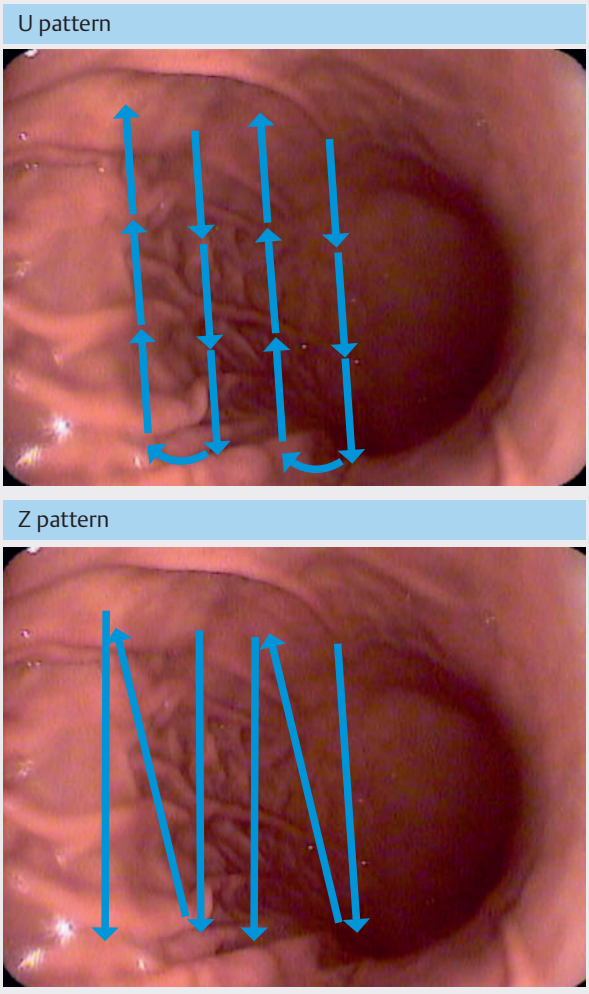


▶ **Fig. 4** Illustration of the two suture patterns for endoscopic sleeve gastroplasty.

The suture is loaded on the anchor exchange and passed through the right channel of the endoscope/device. The needle is then passed from the anchor exchange to the needle driver, and the anchor exchange is pulled back into the channel. The helix is introduced through the left channel and is used to grasp the gastric wall by turning the catheter clockwise two to three times. The grasped tissue is then pulled back into the device tip, the needle driver is closed, allowing the needle and the suture to pass through the tissue, the anchor exchange is advanced to catch the needle from the needle driver, the handle is opened, and the tissue is released by turning the helix counterclockwise. The same sequence is repeated for each bite of the suture line. Once the running line has been completed, the needle is released into the gastric cavity by pushing the blue button on the anchor exchange. The anchor exchange is then withdrawn, the thread is passed through the cinch distal hole, the cinch is introduced until the tip reaches the site of the first bite, and the suture is tightened and cut (▶ **Video 1**). The suturing device can be reloaded with another suture.

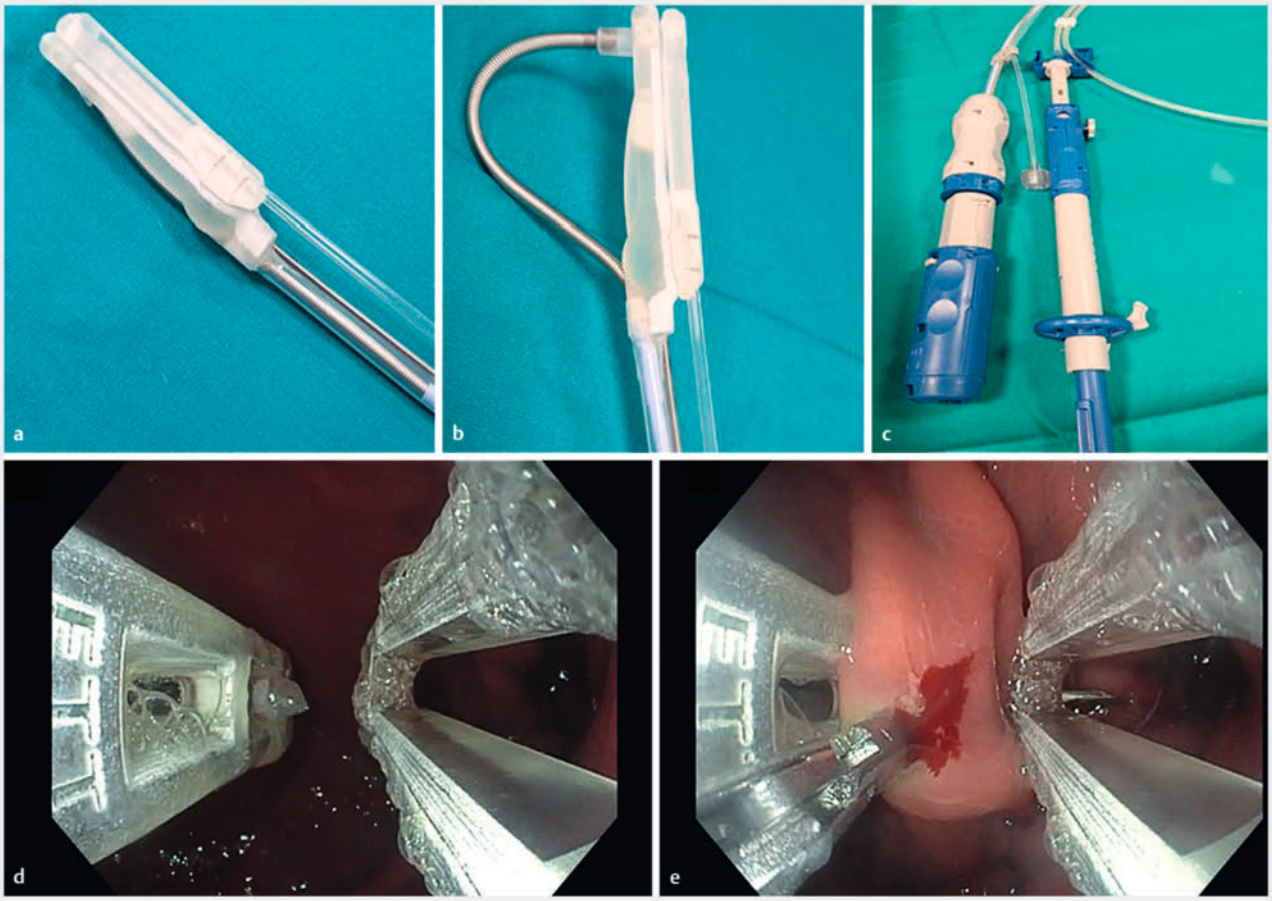
Multiple types of suture patterns (Z and U patterns) can be used (▶ **Fig. 4**), but no data supporting one pattern over another are available [30]. The suturing process begins at the proximal antrum/incisura and continues toward the body–fundus junction. The result of the procedure is a tubular reconfiguration of the gastric lumen.

A new suture pattern with the OverStitch NXT, named the "interlocking ESG," has recently been described, consisting of staggered sutures, creating interlocking peaks and valleys that maximize surface contact between the approximated gastric walls allowing more consistent tubulization and shortening of the stomach [28].

The OverStitch is approved by the US Food and Drug Administration (FDA) and has Conformité Européenne (CE) marking for ESG.

2.2.2 Endomina triangulation platform

The Endomina v2 (Endo Tools Therapeutics S.A., Gosselies, Belgium) is a disposable, sterile triangular platform with two lateral channels, one of which is flexible and can be bent at a 90° angle from the line of sight [31]. The device is inserted blindly into the stomach using two rigid guidewires previously positioned in the duodenum by endoscopy. Once the tip of the Endomina is within the stomach (a marked ring indicates 60 cm from the distal tip of the device at the patient's mouth level), a standard gastroscope is introduced to provide visualization. The Endomina is then opened from the user interface, the endoscope is inserted, and the device is tightened around the endoscope. The platform can be attached to or detached from



▶ **Fig. 5** Images of the Endomina showing: **a** the tip of the Endomina with the channel neutral; **b** the tip of the device with the channel bent at 90°; **c** the handles of the Endomina (left) and the TAPES (right); **d,e** endoscopic views of the Endomina assembled over the endoscope.

the endoscope within the stomach at any point during the procedure (▶ **Fig. 5**).

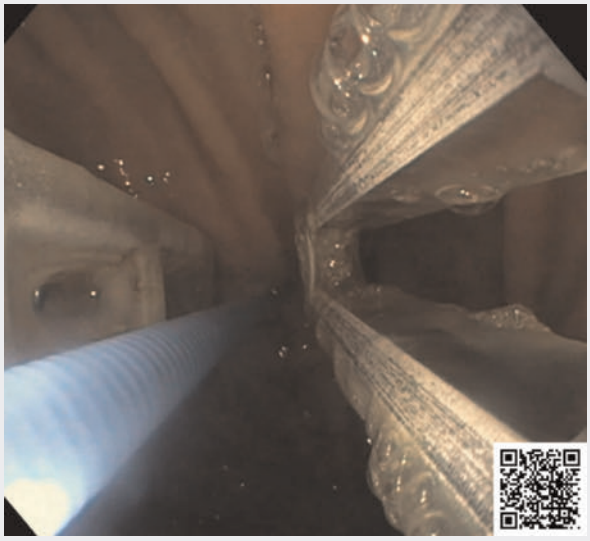
TAPES is a suturing device consisting of a single-use 5-Fr needle preloaded with sutures. It is designed to pierce and connect two tissues (specifically serosa to serosa) together. The TAPES is inserted and maneuvered through the angulated channel of Endomina v2.

Starting at the incisura, the junction of the anterior gastric wall and the greater curvature is grasped with forceps and pulled a few centimeters back inside the triangulation platform. The 5-Fr needle preloaded with suture (bent at 90°) is pushed through the wall, and a first tag with a knot is released. A second plication is made with the same needle at the opposite wall, with the release of a second tag. The knot is then grasped with a snare and pulled to tighten the suture (▶ **Video 2**). This sequence is repeated several times along the gastric body up to the body–fundus junction. The result is a continuous line of double plications of the greater curvature of the gastric body through interrupted sutures that run transmurally anterior to posterior. Like the OverStitch, various suture patterns can be used with no differences in efficacy outcomes [32]. The number of sutures required varies according to the stomach dimensions, generally being between four and eight. Both the Endomina and TAPES are provided with the CE mark for ESG.

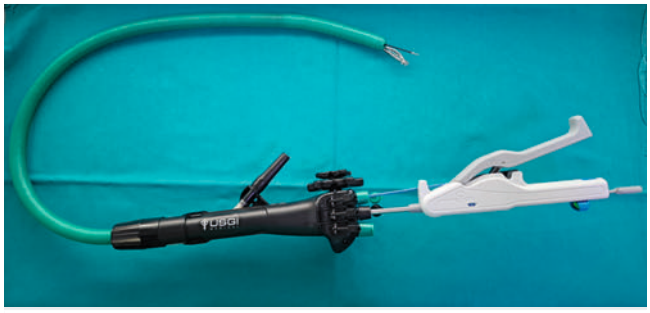
2.2.3 POSE procedure

The primary obesity surgery endoluminal (POSE) procedure employs the Incisionless Operating Platform (USGI Medical, San Clemente, California, USA) [23]. The system includes a 54-Fr four-lumen tube called the "TransPort," which comes with a control handle that allows movement in four directions. There are four channels in the tube, which can be used to insert an ultraslim scope (diameter 5.4–5.9 mm) for intraprocedural vision, as well as specialized devices, such as "g-Lix" and "g-Prox EZ," for grasping gastric tissue, releasing tissue anchors, and cinching the sutures with another dedicated tool named the "g-Cath EZ." This technology allows for full-thickness plications and serosa-to-serosa contact (▶ **Fig. 6**).

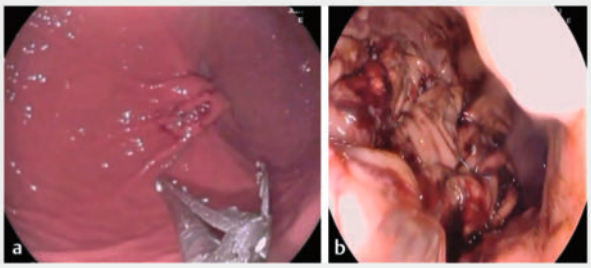
Two clinicians or a clinician and a nurse are necessary to perform the procedure, with one of them responsible for visualizing and maneuvering the ultraslim gastroscope. With gentle traction, the Flexible TransPort is passed into the esophagus and advanced to the gastroesophageal junction (GEJ). From the GEJ, ideal visualization of the greater curvature is achieved.



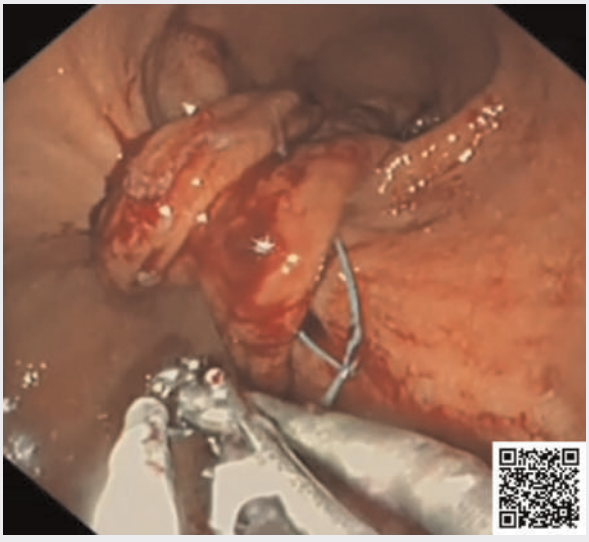
Video 2 Endoscopic gastroplasty with the Endomina device.
Online content viewable at:
https://doi.org/10.1055/a-2630-2062



▶ **Fig. 6** Illustration of the primary obesity surgery endoluminal (POSE) device.



▶ **Fig. 7** Endoscopic images showing the primary obesity surgery endoluminal (POSE) procedure.



Video 3 Endoscopic gastroplasty with the POSE 2.0 procedure.
Online content viewable at:
https://doi.org/10.1055/a-2630-2062

Throughout the procedure, controlled pressure insufflation is provided using a laparoscopic insufflator.

The procedure begins by advancing the g-Lix into the tissue of the greater curvature, the tissue is grasped by clockwise rotation and slowly, with the help of suction, drawn into the apex of the g-Prox allowing for maximal approximation. The g-Prox is closed, entrapping the approximated tissue. The needle is passed across the approximated tissue, and the first basket is deployed. The g-Lix is removed by counterclockwise rotation until the tissue is freed. The needle is withdrawn, and the distal basket is deployed. The plication is tightened using the g-Prox by pulling the thread with countertension applied to the distal basket; this allows for tightening and locks the plication in place. The slack of the plication is then cut using the g-Prox. The g-Cath is reloaded, and the steps are repeated (▶ **Fig. 7**; ▶ **Video 3**).

Initial experience with the POSE procedure involved the placement of plications at the gastric fundus, to limit gastric accommodation; however, the inadequate outcomes reported by a blinded RCT, showing a percentage total body weight loss (%TBWL) of 5.0% at 1 year compared with 1.4% in the sham cohort, led to changes in the procedure (POSE 2.0) with the plications targeted from the fundus to the gastric body, as for the other existing gastroplasty techniques [33].

The plication pattern for the POSE 2.0 procedure consists of two vertical lines of repeated plications in the distal greater curvature and proximal greater curvature; these allow for a reduction of the volume of the gastric cavity. Two lines of horizontal plications are then performed to foreshorten the gastric cavity. These steps are repeated for each of the two vertical and horizontal lines, for a total of 16–18 plications per procedure [23, 34].

A recent improvement to the POSE 2.0 procedure is the use of two g-Lix to grasp more gastric tissue, thereby significantly reducing the gastric volume, the number of needed plications, and the overall cost of the procedure [35].

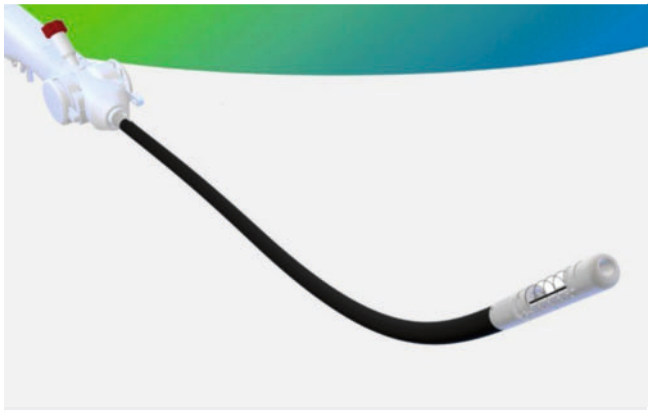
2.2.4 EndoZip

The EndoZip system (Nitinotes, Caesarea, Israel) is an automated disposable suturing system consisting of a bougie with a distal suturing end, an insertion tube, and a proximal control handle connected to a reusable motor unit (▶ **Fig. 8**). The system is designed to allow for the creation of multiple internal gastric segmentation in the stomach. The system enables the formation of wall-to-wall longitudinal attachments of the anterior and posterior stomach walls, creating multiple full-thickness plications within the stomach. The guidance for the proper use and approach to this technology and procedure stems from a single pilot trial and expert experience [36].

The device does not contain inherent fiberoptic guidance. On the handle, there is an aperture that allows the passage of an ultrathin gastroscope (5.4 mm). The EndoZip handle is connected to a standard off-the-shelf vacuum pump. First, a standard long overtube (Guardus Overtube – Gastric; length 50 cm, internal diameter 16.7 mm) is placed endoscopically so that the tip of the overtube is lined up with the GEJ. The device is then inserted into the stomach, and the bougie is positioned under endoscopic view. The position can be adjusted using distal and proximal articulating levers, which allow the bougie to bend at different joints. Once the desired site for suturing has been identified, the distal articulating handle is placed into a suturing position, straightening the distal aspect of the bougie, and a vacuum is applied to approximate the opposing gastric walls. The vacuum draws the tissue segments into the bougie and narrows the segmentation of the stomach. Following this approximation process, the operation button located on the EndoZip handle is activated to begin the suturing process. Once pressed, a custom-designed needle is driven through the bougie, passing the attached suture through the approximated tissue segments and creating continuous plication within the stomach. Then, upon a second button press, the device tightens and cinches the approximated tissue segment with an integrated, dedicated clip.

The system gives the physician a suturing stage indication through an LED bar on the handle. The system automatically performs the suturing actions when the physician presses the operation button, taking approximately 2 minutes to complete the suture. The unit has a sensing mechanism to ensure that the stages after stitching depend on the needle reaching its designated area. The procedure is finished by releasing the corset, retracting the device from the deployment site, and obtaining visual confirmation using a gastroscope (▶ **Video 4**).

The procedure should start by placing the distal end of the device at the base of the greater curvature below the incisura. As stated above, the device procedure is carried out, and the suture is examined for any trauma. The subsequent device and suture are placed superior to the first line in the same position in the gastric cavity. This allows for a "stacking" effect, which then allows for better apposition of the anterior and posterior walls of the gastric body. After three stacked sutures, there is a funneling effect from the gastric body to the antrum and significant restriction. The following line of sutures can be performed by placing the tip of the next device at the proximal end of the first plication created. This will maximize the distance between the GEJ and the suture line, and allows for a second line of stacked sutures; however, this time, there are typically one or two stacked sutures. The number of devices and plications varies based on patient size, ranging from three to six sutures per procedure.

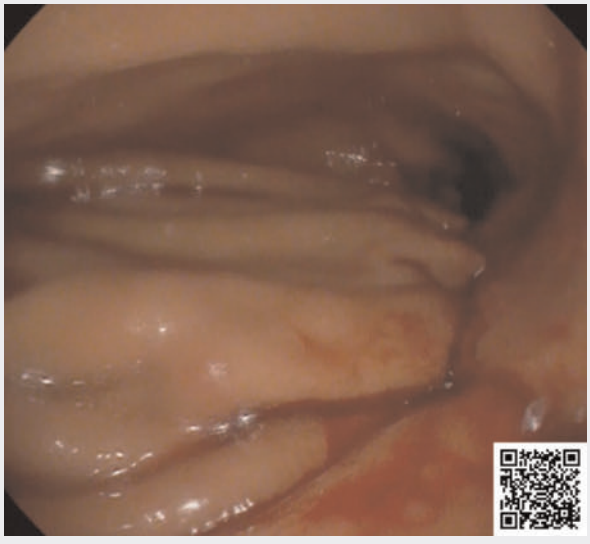


▶ **Fig. 8** Illustration of the EndoZip device. Source: Nitinotes Ltd.

2.3 Other devices

2.3.1 TransPyloric Shuttle

The TransPyloric Shuttle (TPS) system (BARONova, San Carlos, California, USA) consists of a large and a small bulb connected by a silicone tether and delivered using a preloaded endoscopic delivery device [37]. The procedure is performed with the patient under general anesthesia, and a preliminary gastroscopy is performed to place a standard gastric overtube (Guardus Overtube – Gastric) for esophageal protection. The TPS is pre-



▶ **Video 4** Automatic endoscopic gastroplasty with the EndoZip system.
Online content viewable at:
https://doi.org/10.1055/a-2630-2062

loaded in its delivery system in a coiled configuration and inserted through the overtube into the stomach, the coil is deployed and secured in the correct shape. As peristalsis moves the small bulb into the small intestine and the large bulb toward the pylorus, it causes delayed gastric emptying. Fluoroscopy is used to monitor device deployment.

The TPS device can remain in the stomach for up to 12 months before it is removed endoscopically. Removal steps include standard overtube placement, use of rat-tooth graspers to unlock the release mechanism and deconstruct the device, and use of a standard polypectomy snare to retrieve the device through the overtube.

The device is FDA approved for class I obesity with comorbidities, and class II obesity. Despite FDA approval, the device is currently not available on the market.

2.3.2 Plenity

Plenity (Gelesis, Boston, Massachusetts, USA) is a space-occupying device that consists of an orally administered capsule containing superabsorbent hydrogel particles [38]. These particles expand in the stomach after absorbing water, leading to feelings of satiety, slower emptying of the stomach, and delayed absorption of glucose. The hydrogel maintains its shape and properties as it passes through the small intestine. Once it reaches the large intestine, enzymes partially break down the hydrogel, causing it to lose its shape and most of its absorptive capacity [38]. Endoscopy is not required for placement or removal.

Plenity is FDA approved for use by patients with a BMI of 25–40 kg/m² in combination with dietary interventions.

2.3.3 Aspiration therapy

The AspireAssist system (Aspire Bariatrics, King of Prussia, Pennsylvania, USA) consists of a percutaneous endoscopic gastrostomy A-tube combined with a SkinPort and an aspiration system [39]. The A-tube is placed using a standard pull percutaneous endoscopic gastrostomy tube technique. The A-tube also includes a 15-cm intragastric portion lined with openings to facilitate the flow of gastric contents. The A-tube is connected to a SkinPort, an external disk that contains a valve that can be opened to allow gastric contents to flow out. Approximately 20–30 minutes after a meal, the patient attaches the SkinPort to the external connector and tubing, draining about 30 % of their ingested calories.

The FDA approved the AspireAssist in 2016 for patients aged 22 years and older with a BMI of 35–55 kg/m² after the failure of nonsurgical strategies [40]. However, despite the promising results of the AspireAssist, financial reasons led to the device's withdrawal from the market in February 2022 [41].

2.4 Small-bowel devices

As mentioned above, none of these devices are currently available for routine use; however, we will provide an overview of them and their usage techniques.

2.4.1 Duodenal–jejunal bypass liner

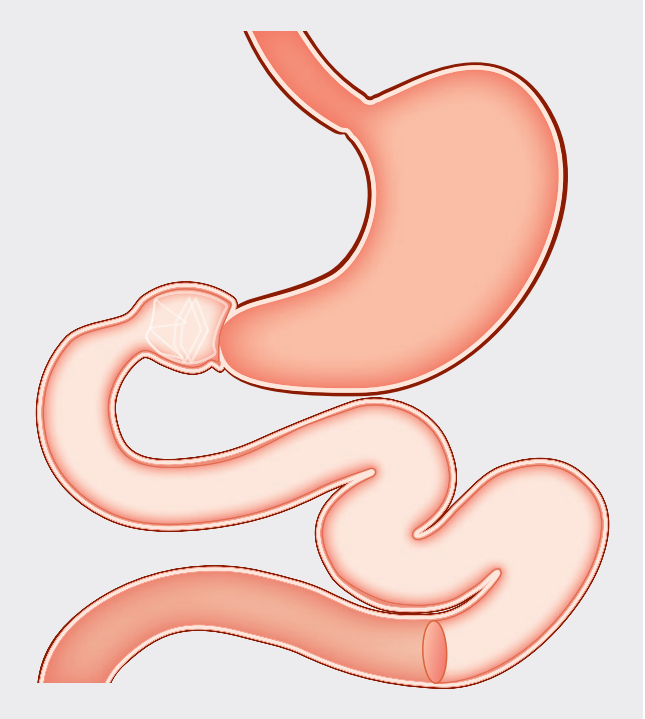
The DJBL (RESET, Morphic Medical, Boston, Massachusetts, USA; previously EndoBarrier, GI Dynamics, Lexington, Massachusetts, USA) is a 60-cm long, self-expandable fluoropolymer impermeable liner, with a proximal 5.5-cm nitinol self-expandable stent with nitinol spikes to secure the device within the duodenal bulb [42] (▶ **Fig. 9**). The TONGEE DJBL (Tangji Medical, Hangzhou, China) is similar to the RESET and was developed to improve the materials, anchoring, and delivery systems [43].

The liner is placed under combined endoscopic and fluoroscopic guidance. A catheter-based delivery system is inserted over a guidewire into the duodenal bulb, and the liner is then released, reaching the proximal jejunum with its distal end. The liner is impermeable and, once deployed, contact between nutrients and the mucosal surface of the proximal small bowel is precluded, thereby mimicking a surgical bypass. The device is retrieved endoscopically after an implantation period of up to 12 months. Both placement and removal procedures are performed with the patient under general anesthesia in the supine position.

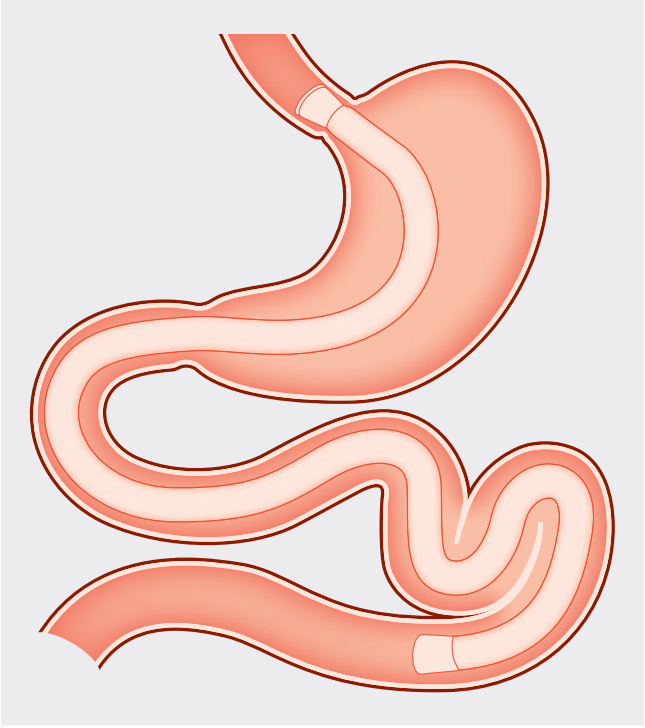
The device has been heavily investigated in multiple trials. It did not however obtain FDA approval, and its CE mark was revoked because of the high incidence of liver abscesses (3.5 %) in a randomized, sham-controlled pivotal trial that was prematurely suspended [16].

2.4.2 Gastroduodenal–jejunal bypass sleeve

The gastroduodenal–jejunal bypass sleeve (formerly marketed by ValenTx, Inc., Carpinteria, California, USA) is a 120-cm long, fluoropolymer sleeve; the proximal end is anchored at the



▶ **Fig. 9** Schema showing the duodenal–jejunal bypass liner.



▶ **Fig. 10** Schema showing the gastroduodenal–jejunal bypass sleeve.

esophagogastric junction and the distal end is deployed in the proximal jejunum [44]. Device placement requires endoscopic and fluoroscopic control to ensure proper release along the small intestine and correct attachment at the GEJ using full-thickness suture anchors. The device remains in place for 12 weeks and is then removed endoscopically. Both placement and removal procedures are performed with the patient under general anesthesia in the supine position (▶ **Fig. 10**).

The device is not FDA approved and is currently not in use.

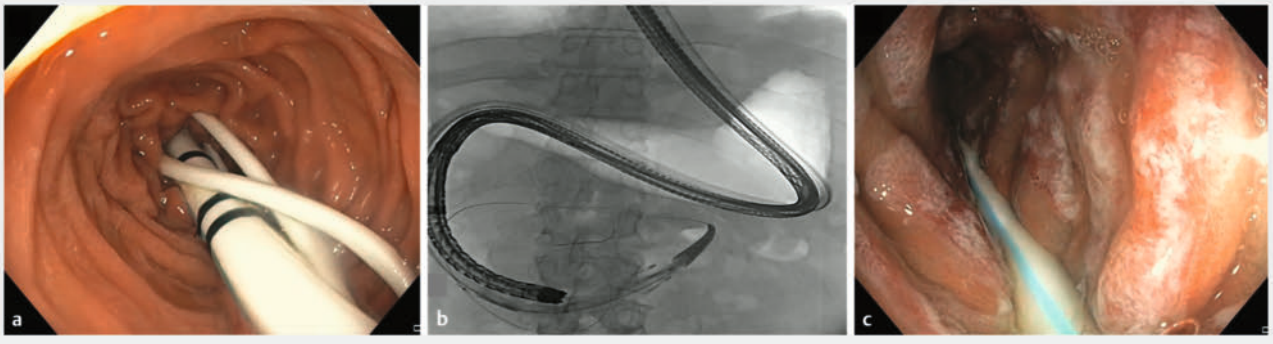
2.4.3 Duodenal mucosal resurfacing

Duodenal mucosal resurfacing (DMR) consists of hydrothermal ablation of the duodenal mucosa, aimed at inducing mucosal regeneration and reducing the aberrant signals from the duodenum typical of metabolic diseases [45, 46]. The procedure employs the Revita (Fractyl Laboratories, Lexington, Massachusetts, USA), which consists of a single-use balloon catheter that allows saline solution injection into the submucosa and burning of the duodenal mucosa. Currently, the device is CE-marked.

The procedure can be performed with the patient under general anesthesia in the supine position, or under deep sedation, as per local guidelines and the endoscopist's preference. The entire DMR process is carried out under dual guidance, using both endoscopic and fluoroscopic imaging.

First, a standard esophagogastroduodenoscopy is conducted with a pediatric colonoscope to exclude contraindications and to detect the location of the papilla of Vater, which is marked by applying a hemostatic clip on the opposite wall, serving as a reference to prevent thermal damage to the papilla itself. Next, a 0.035-inch guidewire is inserted under fluoroscopic control beyond the ligament of Treitz to facilitate the placement of the DMR balloon catheter distal to the papilla. After this, circumferential submucosal injection of saline solution and methylene blue is administered using three balloon-integrated needle injectors spaced 120° apart around the balloon circumference to create a thermal barrier and a uniform ablation surface. After submucosal elevation, mucosal ablation is performed by inflating the balloon with hot water (80–90 °C) for approximately 10 seconds. The balloon is then deflated and advanced to treat the downstream duodenal segment, and the sequence is repeated. Typically, 9–10 cm of duodenal mucosa, starting 1 cm distal to the papilla of Vater, is treated with at least five consecutive ablations (▶ **Fig. 11**).

An electronic device automatically controls all stages of the procedure, from submucosal injection to hot water circulation and subsequent balloon cooling. Initially, the injection and the ablation were performed separately, but the device has since been improved to integrate both functions into a single catheter, reducing the procedure time and ensuring precise ablation within the injection segment to prevent damage to



▶ **Fig. 11** Images of duodenal mucosa resurfacing with the Revita device showing: **a** on endoscopy, device insertion into the duodenum; **b** on fluoroscopy, the device inserted over a guidewire; **c** the final endoscopic appearance.

adjacent noninjected mucosa [47]. The average duration of the DMR procedure is now approximately 60–70 minutes.

2.4.4 Duodenal recellularization via electroporation therapy

Duodenal recellularization via electroporation therapy (ReCET; Endogenex Inc., Plymouth, Minnesota, USA) is a novel endoscopic technique that uses pulsed electric fields to stimulate duodenal mucosal regeneration [48]. The ReCET technology involves using a specialized catheter that is positioned within the duodenum under endoscopic control. Once in place, a small coil is deployed from the device, and intermittent bursts of electric current are delivered to the duodenal mucosa. This targeted electric current triggers cell apoptosis and regeneration, improving cellular signaling for glucose homeostasis. The entire procedure typically lasts around 60 minutes.

2.4.5 Incisionless magnetic anastomosis system

The incisionless magnetic anastomosis system (IMAS; GI Windows, Westwood, Massachusetts, USA) is a technique that enables the creation of a jejunal–ileal anastomosis through the use of self-assembling octagonal magnets [49]. These magnets are delivered endoscopically into the proximal jejunum and the terminal ileum via enteroscopy and colonoscopy, respectively, resulting in a partial jejunal diversion that allows a portion of the nutrients present to bypass most of the small bowel, while still maintaining the open native path. The IMAS device consists of a nitinol exoskeleton that allows for insertion in a linear configuration through the scope's working channel (diameter 3.7 mm) [50]. Once fully deployed in the small-bowel lumen, it takes the shape of an octagonal ring. Once the anastomosis is formed through tissue necrosis, the magnets naturally pass through the bowel in the stools. The procedure is performed with the patient under general anesthesia and requires laparoscopic assistance to assess the correct connection site and aid in the assembly process of the magnets.

3 Effectiveness and comparative data

3.1 Intragastric balloons

Over the past 30 years, multiple observational and randomized studies on the use of IGBs have been published. Most studies have reported results with the Orbera (previously known as Bioenterics IGB [Inamed Corporation, Santa Barbara, California, USA]), which was the first to be launched on the market, and is the most studied and the most used in routine clinical practice. The most significant evidence from large meta-analyses and RCTs is summarized in **Table 1 s**, see online-only Supplementary material [51–59].

One of the major shortcomings of the present research on IGBs is that the available data only cover short- and medium-term follow-up. Although long-term outcomes of IGBs are scarce, the trend observed indicates a tendency toward weight regain over time [60, 61]. This limited duration of treatment may be viewed as a disadvantage, given that obesity is a chronic relapsing condition.

3.2 Endoscopic gastric remodeling

Several observational studies and two RCTs have been published on EGR. Most studies report the results of ESG with the OverStitch, which is currently the most used device in clinical practice. **Table 2 s** summarizes the most significant evidence for EGR techniques [14, 31, 34, 62–67]. Most current evidence on ESG involves patients with class I and II obesity. Both of the RCTs included patients with class I and II obesity [14, 64]; however, a few observational studies have investigated ESG in class III obesity. In a retrospective study of 396 patients, ESG resulted in %TBWL of 20.5 %, 18.2 %, and 16.5 % in those with class I, II, and III obesity, respectively, at 1 year after the procedure (P< 0.001) [68]. Similarly, in another retrospective study of 1506 ESG procedures, subjects with class III obesity showed a %TBWL of 20.4 %, compared with 13.3 % and 13.6 % in those with class I and II obesity, respectively [69].

Evidence from nonrandomized studies suggests that EGR can be performed in adolescents and elderly patients with obesity. In a study by Alqahtani et al. [70], 109 patients (age range, 10–21 years; average BMI, 33.0 [SD 4.7] kg/m^2) demonstrated a %TBWL of 16.2 % (SD 8.3 %) 12 months after ESG and 13.7 % (SD 8.0 %) 24 months after, with no reported significant morbidity. A small retrospective study of 18 patients over 65 years with obesity (mean BMI, 41.7 kg/m^2) treated with ESG showed a median %TBWL of 15.5 % (interquartile range [IQR], 10.5 %–19.6 %) at 12 months and 15.5 % (IQR, 9.6 %–21.6 %) at 24 months, along with significant improvement in obesity-related co-morbidities and no serious AEs [71]. These results should however be further investigated in larger prospective studies.

To date, long-term data from RCTs are not available. A prospective cohort study of 68 patients by Sharaiha et al. [72] reported a mean %TBWL of 15.9 % (95 %CI 11.7 %–20.5 %) at 5 years from ESG, with 90 % and 61 % of patients having a %TBWL over 5 % and 10 %, respectively.

In terms of obesity-related co-morbidities, the MERIT trial reported significant improvements in one or more metabolic co-morbidities (i. e. diabetes, hypertension, dyslipidemia, metabolic syndrome) and quality of life was achieved in the ESG group, compared with the lifestyle modifications alone group [14]. Finally, a recent meta-analysis reported a 55.4 % (95 %CI 46 %–64 %) resolution of diabetes, 62.8 % (95 %CI 43 %–82 %) resolution of hypertension, 56.3 % (95 %CI 49 %–63 %) resolution of dyslipidemia, and 51.7 % (95 %CI 16 %–87 %) resolution of obstructive sleep apnea following ESG [73].

In a multicenter single-arm prospective trial, gastroplasty performed with the fully automated EndoZip device resulted in a mean %TBWL of 13.2 % (95 %CI 10.1 %–16.3 %), with 76.6 % of patients achieving >5 % %TBWL at 12 months. Furthermore, a significant reduction in waist circumference, glycated hemoglobin (HbA1c), and alanine aminotransferase (ALT) levels at 12 months was observed (P=0.001) [67, 74]. A multicenter study evaluating the impact of the EndoZip procedure on obesity-related co-morbidities is currently ongoing (NCT05623163).

A case report of "interlocking ESG" performed with the OverStitch NXT showed a %TBWL of 23.4% at 6 months in a patient with class II obesity [28]; however, no data from clinical trials are currently available.

3.3 Other devices

3.3.1 Aspiration therapy

An RCT including 207 subjects with BMIs of 35.0–55.0 kg/m^2 showed a significantly higher weight loss in the aspiration therapy group compared with the lifestyle modifications alone group, with a %TBWL of 12.1% versus 3.5% at 52 weeks (P< 0.001) [39]. A subsequent publication evaluating the long-term results of aspiration therapy in 58 patients reported a %TBWL and a percentage excess weight loss (%EWL) of 18.7% and 50.8% at 4 years, respectively [75].

A systematic review and metanalysis of five studies (three RCTs, one comparative, and one observational) showed significant improvements in systolic blood pressure (−7.8 mmHg), diastolic blood pressure (−5.1 mmHg), triglycerides (−15.8 mg/dL), high density lipoprotein (3.6 mg/dL), HbA1c (−1.3 percentage points), aspartate aminotransferase (AST; −2.7 U/L), and ALT (−7.5 U/L) at 1 year [76]. A subgroup analysis of two RCTs (n = 225) showed that subjects undergoing aspiration therapy experienced higher weight loss than controls (25.6% for %EWL and 11.6% for %TBWL), as well as greater improvements in HbA1c and ALT by 1.3 percentage points and 9.0 U/L, respectively [76].

3.3.2 TransPyloric Shuttle

An RCT reported a %TBWL of 9.5% and %EWL of 30.9% at 12 months in the TPS group, with a mean difference of 6.7 percentage points in %TBWL between the TPS group and the controls. This study led to the FDA approval [77].

3.3.3 Plenity

In a randomized, double-blind, placebo-controlled study, Plenity treatment resulted in a significantly greater weight loss than placebo (6.4% vs. 4.4%; P<0.001) at 6 months [38].

3.4 Small-bowel devices and technologies

3.4.1 Duodenal–jejunal bypass liner

A meta-analysis of 14 studies (five RCTs) with 412 patients with type 2 diabetes and obesity who underwent DJBL implantation with the RESET device for an average of 8.4 (SD 4.0) months reported a reduction in HbA1c of 1.3 percentage points (95% CI 1.0–1.6 percentage points) and homeostatic model assessment for insulin resistance (HOMA-IR) of 4.6 (95%CI 2.9–6.3) [78]. Furthermore, HbA1c was still below the baseline by 0.9 percentage points (95%CI 0.6–1.2 percentage points) 6 months after removal. The mean %TBWL and %EWL were 18.9% and 36.9%, respectively, at explantation; 1 year post-removal, considerable weight loss persisted, with an average %TBWL of 7% and %EWL of 27.7%.

In a prospective study including 71 subjects with obesity, diabetes, and nonalcoholic fatty liver disease (NAFLD) treated with DJBL, the Fatty Liver Index dropped from 98.2 at baseline to 93.4 at explantation, and to 90.4 at 6-month follow-up (P< 0.001). Furthermore, the procedure resulted in a decrease in the NAFLD fibrosis score from 0.19 (SD 1.31) at baseline to −0.83 (SD 1.4) at withdrawal (P<0.001), along with a reduction of ALT levels (29.0 vs. 42.3 U/L; P<0.001), sustained at 6 months follow-up [79].

An RCT including 82 patients (2 : 1 ratio, DJBL : control) showed remission of metabolic syndrome in 12% of DJBL patients and 10% of controls (P=0.72) [16]. Patients in the DJBL group experienced greater reductions in BMI (mean adjusted difference −3.1 kg/m^2; P<0.001) and HbA1c (−0.5 percentage points, 95%CI −0.9 to −0.2; P<0.001) than controls; however, no differences remained statistically significant at 12 months after DJBL removal. The trial was prematurely stopped owing to a 39% incidence of at least one serious device-related AE, including liver abscesses. The development of liver abscesses during DJBL therapy has recently been linked to proton pump inhibitor therapy [80]. The new System Pivotal Trial (STEP-1) on the RESET device, limiting the use of proton pump inhibitors, to further explore the safety and efficacy of this device is ongoing (NCT04101669).

3.4.2 Gastroduodenal–jejunal bypass sleeve

A prospective multicenter clinical trial including 32 patients with obesity (mean BMI 42.3 kg/m^2) treated with the gastroduodenal–jejunal bypass sleeve (ValenTx) reported an %EWL of 44.8% and a %TBWL of 17.6% at 12 months [81]. Furthermore, HbA1c and fasting glucose levels decreased by 1.1 percentage points and 29 mg/dL in patients with type 2 diabetes, respectively.

3.4.3 Duodenal mucosal resurfacing

The main therapeutic target in the studies evaluating DMR is type 2 diabetes. **Table 3 s** summarizes the most relevant evidence on DMR with the Revita device [82–86]. Despite the small number of studies and the brief follow-up period, the data indicate that a single session of DMR can result in a significant decrease in glycemic values that can be sustained for up to 6–12 months in patients with poorly controlled type 2 diabetes (HbA1c>7.5%) who have been taking one or more oral antidiabetic medications for at least 3 months. It appears that a single-shot procedure is comparable with taking multiple oral antidiabetic medications for 6 months, without the need to ensure adherence to therapy. As a result, DMR may offer a synergistic approach to managing type 2 diabetes, with the potential to reduce the need for oral therapy and possibly insulin, thereby improving patient compliance and quality of life.

3.4.4 Duodenal recellularization via electroporation therapy

The ReCET procedure is currently under investigation to assess its efficacy and safety for treating type 2 diabetes. Preliminary results from a first-in-human multicenter, open-label study including subjects with poorly controlled type 2 diabetes on

noninsulin glucose-lowering medications showed a clinically significant reduction in Hb1Ac at 24 weeks (7.5 % [SD 1.1 %] vs. 8.4 % [SD 1.0 %] at baseline; $P < 0.05$) [48].

A single-center study evaluating the combination of the ReCET procedure combined with a GLP-1RA medication in 14 insulin-treated type 2 diabetic patients reported a significant improvement in glycemic control and metabolic parameters, with 12 patients (86 %) being able to withdraw insulin therapy at 12 months [87]. Over a 12-month period, HbA1c levels dropped from an initial median of 55 mmol/mol (IQR 53–57) to 47 mmol/mol (IQR 43–53), HOMA-IR decreased from 5.8 (IQR 3.9–7.5) to 1.8 (IQR 1.1–2.7), and a %TBWL of 18.4 % was recorded.

3.4.5 Incisionless magnetic anastomosis system

The IMAS has been investigated in a single-arm study including 10 patients who experienced a %TBWL of 14.6 % and a %EWL of 40.2 % at 1 year, along with a significant drop in Hb1Ac in all diabetic patients (−1.9 percentage points) and prediabetic patients (−1.0 percentage points) [49].

4 Safety

4.1 Intragastric balloons

Clinical trials and observational studies have provided valuable insights into the safety of IGBs [88]. While generally considered safe, these devices are not without risks. Common AEs include nausea, vomiting, abdominal pain, and gastroesophageal reflux. In rare cases, serious complications such as balloon migration, early deflation, bowel obstruction, and perforation may occur, necessitating prompt medical intervention [88, 89]. Very rarely, serious AEs have been reported, such as acute pancreatitis or IGB migration to the jejunal site requiring surgical removal [88]. Advancements in balloon design and insertion techniques have however somewhat helped mitigate these risks [88, 89].

Several factors influence the safety of IGBs, including patient selection, balloon type, and insertion procedure [88, 89]. Proper patient selection is crucial to minimize the risk of complications, carefully considering factors such as BMI, co-morbidities, and previous weight loss attempts [88]. Additionally, the choice of balloon type (fluid-filled vs. gas-filled) and the healthcare provider's expertise in performing the insertion play significant roles in ensuring safe placement and optimal outcomes [88–92].

4.2 Endoscopic gastric remodeling

4.2.1 ESG with the OverStitch

Clinical studies have demonstrated that ESG with the OverStitch is generally safe and well tolerated by patients. Common AEs associated with the procedure include transient nausea, vomiting, and abdominal pain, which typically resolve within a few days post-procedure [14]. Serious complications, such as gastric perforation, post-procedure bleeding needing blood transfusion, stricture formation (malnutrition requiring endoscopic reversal of the ESG), abdominal abscesses, usually perigastric (managed endoscopically or conservatively) [93], pulmonary embolism, or pneumoperitoneum and pneumothorax (requiring chest tube placement) are rare (up to 2.2 %), but can occur, emphasizing the importance of proper patient selection and procedural expertise to minimize these risks [94]. There have been no reported AEs that have required patients to undergo conversion to surgery for their management [95].

Various procedural factors influence the safety of ESG, including patient selection, technique, and post-procedure management. Additionally, adherence to standardized procedural protocols and ongoing endoscopist training are essential to optimize safety outcomes and minimize the risk of AEs [62].

4.2.2 POSE procedure

The most common AEs (pain, nausea, and vomiting) tend to present immediately and resolve quickly on their own or with only supportive therapy [33]. Serious AEs are rare (0.4 %) and comprise extragastric bleeding (treated surgically), hepatic abscess (drained radiologically), gastric perforation, and gastric bleeding (usually conservatively managed) [34].

4.2.3 Endomina triangulation platform

No serious procedure-related AEs have been reported with the Endomina triangulation platform [22, 31, 64]. A phase 3 multicenter trial comparing a control group to treatment with the Endomina is ongoing (enrollment completed; NCT03255005). In a recently published post-market registry, only mild-to-moderate procedure-related AEs have been reported, including abdominal pain and heartburn that were easily managed with symptomatic drugs [31].

4.2.4 EndoZip

Only minor transient AEs (abdominal pain and nausea) have been described for the EndoZip [96]. Preliminary results of a multicenter single-arm study showed two serious AEs (bleeding and gastric perforation) [67, 74]. The bleeding was stopped with endoscopic clipping, and the gastric perforation required surgical closure; these did not recur in other procedures after software updates had been performed.

4.3 Other devices

4.3.1 Aspiration therapy

Serious AEs have been reported in up to 4.1 % of patients, including periprocedural (severe abdominal pain, perioperative peritonitis) and post-procedural AEs (prepyloric ulceration, fungal growth affecting the tube) [39]. Buried bumper (2.3 %), peritonitis treated with intravenous antibiotics (0.6 %), severe abdominal pain treated with pain medication (0.6 %), abdominal pain secondary to prepyloric ulcer (0.3 %), and product malfunction requiring A-tube replacement (0.3 %) have been reported [76]. At 1, 2, 3, and 4 years, reported rates of persistent fistula were 2.2 % (1/45), 1.6 % (1/63), 39.3 % (11/28), and 33.3 % (3/9), respectively. Two patients required surgical intervention to close a persistent fistula, representing 1.4 % of all of the removed gastrostomy tubes.

4.4 Small-bowel devices and technologies

4.4.1 Duodenal–jejunal bypass liner

Most AEs are classified as mild, and have included post-procedural nausea and vomiting, general GI events during implantation, ulceration surrounding the DJBL anchor, and several laboratory measure-related AEs, such as hypoglycemia and anemia. Early device removal has been reported to be up to 24 % [97]. GI bleeding (6.5 %), DJBL migration (5.6 %), device obstruction (4.5 %), and liver abscesses (2.0 %) have been described; esophageal perforation is rare (0.3 %). Most serious AEs (88 %) occurred during implantation; the remaining were procedure-related.

AEs attributed to the design of the DJBL including perforation of the esophagus, GI bleeding, DJBL anchor tissue overgrowth, and perforation of the duodenal bulb had a causal relation with the anchor (42.5 %), while hepatic abscess and acute pancreatitis were likely caused by the anchor (42.5 %) [97]. In addition, 2.8 % of mild and moderate AEs were likely related to the liner of the DJBL, including obstruction and eversion of the liner.

4.4.2 Gastroduodenal–jejunal bypass sleeve

In the first human trial of endoluminal bypass using the gastroduodenal–jejunal bypass sleeve (ValenTx), no procedure-related complications were reported, and there was no need for operative conversion during device implantation or for operative assistance during endoscopic removal [98]. Only two early explantations have been described [81].

4.4.3 Duodenal mucosal resurfacing

In the first international, multicenter, prospective, open-label study of DMR with the Revita device, 13 % of serious AEs were reported during follow-up, of which one was procedure related. This concerned a patient with general malaise, mild fever (38°C), and an increased C-reactive protein (CRP) level on the first day after DMR. The mild fever resolved within 24 hours, and the CRP level normalized within 3 days [82]. Most AEs were mild and transient; the most common were abdominal pain, diarrhea, hyperglycemia, hypoglycemia, nasopharyngitis, and headache [83]. The most serious AE was duodenal stricture, which was successfully treated with a single dilation session [46].

These AEs were reported in the early experience and were thought to be caused by either the overlap of ablation or the ablation of noninjected mucosa. The use of a single catheter, a larger submucosal injection, and the refinement of the technique (ablation from proximal to distal instead of distal to proximal) has significantly enhanced intraprocedural mucosal visualization, thereby reducing the likelihood of incorrect ablation. One jejunal perforation caused by manipulation of the endoscope during the performance of an upper GI endoscopy required surgical repair with no further sequelae [83].

4.4.4 Duodenal recellularization via electroporation therapy

No serious procedure-related AEs or unanticipated adverse device effects have been reported with the ReCET procedure [87].

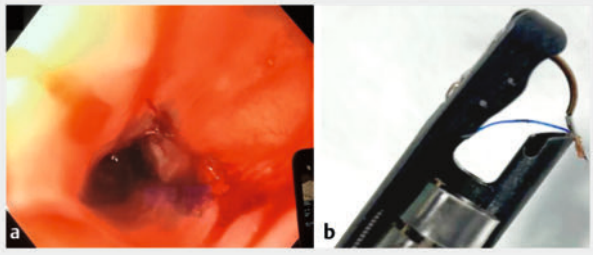
4.4.5 Incisionless magnetic anastomosis system

In the first pilot study of the IMAS, there were no serious AEs. All patients experienced short-term diarrhea after the procedure [49]. Recurrent diarrhea occurred in four patients (40 %), which appeared to be primarily related to dietary composition.

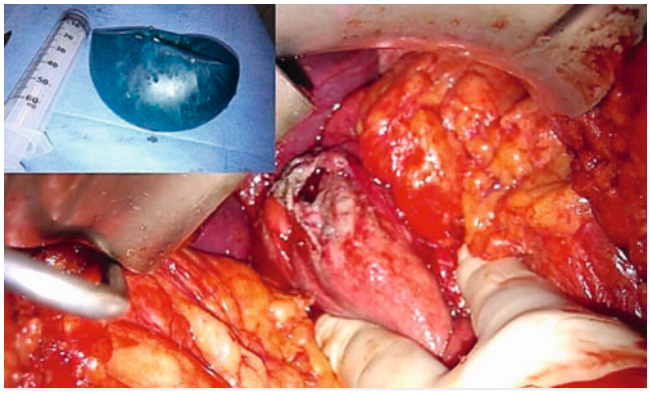
5 Management of adverse events

Pain and nausea prevention and management should always be used and standardized in primary bariatric endoscopy. Otherwise, bariatric endoscopic procedures can lead to all the known complications of endoluminal invasive therapy. Antibiotic therapy may be required for extraluminal fluid collections. Bleeding is of course part of the equation, but hemostasis can be achieved by all known means and does not require special attention; if bleeding from a stitch occurs during suturing, it can often be stopped simply by closing the suture.

To prevent complications, adequate pain and nausea management is crucial in primary bariatric endoscopy. While bleeding can be managed with standard hemostatic techniques, more severe injuries, such as esophageal or gastric perforations, often require surgical intervention, especially if treatment is delayed (▶ **Fig. 12** and ▶ **Fig. 13**). The classification of injuries based on their pattern and the timing of treatment initiation is essential for determining the appropriate response. Endoscopic solutions are viable for less severe injuries, but the accessibility and feasibility of these techniques can be limited by the injury's location. We provide a suggested flowchart to guide the decision-making process in managing AEs following EBMTs (▶ **Fig. 14**).



▶ **Fig. 12** A longitudinal esophageal injury that is not completely transmural but involves the muscle layer (nontransmural) is shown: **a** endoscopically, having been caused by: **b** a jammed needle tip in the device, with repair being performed endoscopically by clipping the 9 cm of injured esophageal wall, similarly to a regular peroral endoscopic myotomy closure.



▶ **Fig. 13** Endoscopic image showing a late gastric perforation caused by an intragastric balloon placed in a patient who had undergone previous gastric surgery and was admitted from home with systemic sepsis, with surgical repair required.

6 Management of weight regain and dumping syndrome after bariatric surgery

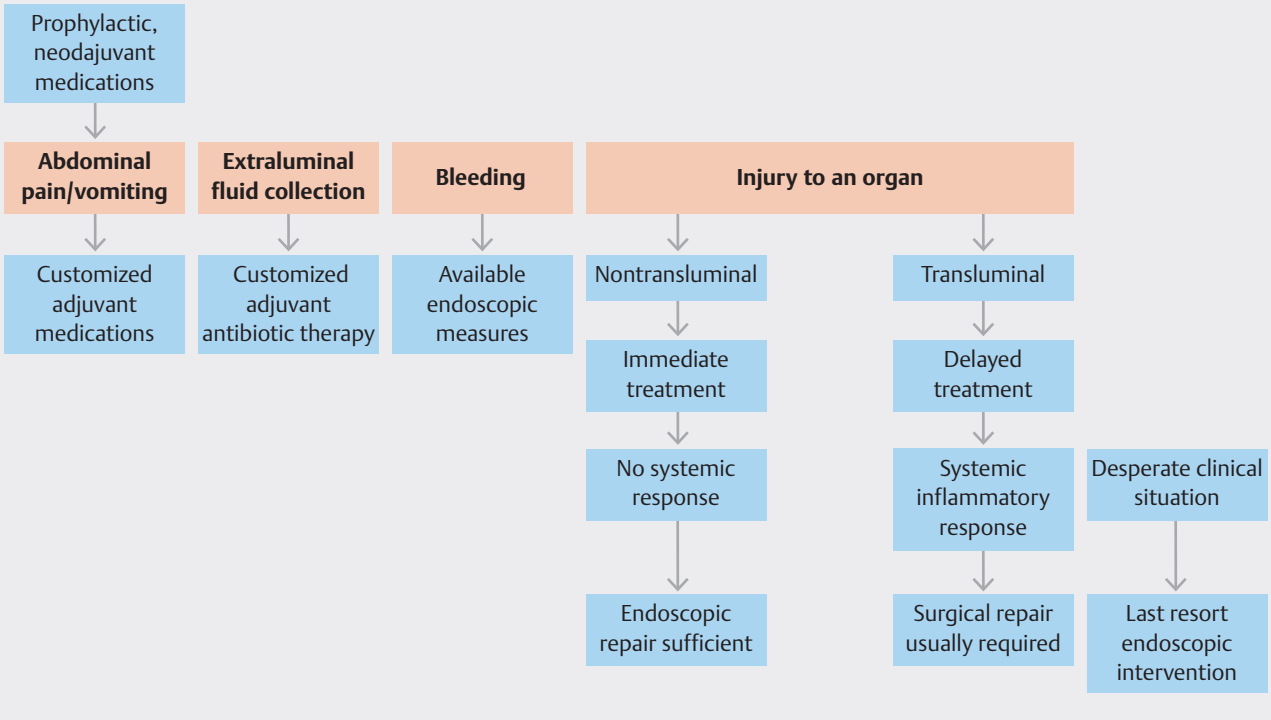
Weight regain following metabolic and bariatric surgery is a common long-term complication, with one-third of patients regaining almost all their lost weight in 10 years post-surgery [99–101]. This event has been associated with medical, behavioral, dietary, psychological, and anatomical factors, and requires multidisciplinary management [102]. Dilatation of the gastrojejunal anastomosis (GJA) and/or gastric pouch after Roux-en-Y gastric bypass, and sleeve dilatation following sleeve gastrectomy have been related to weight regain [103, 104].

Furthermore, GJA dilatation is associated with dumping syndrome, which consists of a cluster of post-prandial symptoms, including the desire to lie or sit down, drowsiness, palpitations, restlessness, dizziness, headaches, and sweating, induced by the rapid transit of undigested food into the small bowel [101, 102].

As revisional surgeries are technically complex and associated with high morbidity and mortality, endoscopic procedures have recently emerged as minimally invasive treatments in patients with weight regain after metabolic bariatric surgery to correct these anatomical changes [102, 105].

Transoral outlet reduction (TORe) is an endoscopic procedure aimed at reducing the size of the GJA to 8–10 mm. The procedure involves cauterizing the anastomotic rim with APC (40–70 W, 0.8 L/min), followed by endoscopic full-thickness suturing [106, 107]. The use of APC strengthens the attachment of the mucosa to ensure a stronger reduction of the anastomotic rim [107, 108]. It has been shown that performing APC around the GJA before suturing leads to more significant weight loss than suturing alone [108]. Two previously described endoscopic full-thickness devices, the OverStitch and the Incisionless Operating Platform, are currently used for TORe [106]. Suturing may be extended to the gastric pouch if there is pouch dilatation.

A systematic review and meta-analysis, including 30 studies, investigating TORe with the OverStitch showed a %TBWL of 11.3 % and 8.6 % at 6 and 12 months, respectively [109]. Similarly, TORe performed with the Incisionless Operating Platform



▶ **Fig. 14** Proposed treatment algorithm for complications caused by bariatric endoscopy.

resulted in a mean %TBWL of 9.5% at 12 months [110]. TORe has also proved to be effective in the treatment of dumping syndrome nonresponsive to medical therapy, with a significant reduction of symptoms up to 24 months post-procedure [107, 111].

In terms of safety, the overall incidence of AEs for TORe is approximately 11.4%–12.9%, with transient mild abdominal pain being the most common [109, 110]. Less frequent AEs include bleeding, anastomotic stenosis, and perforation [109–111].

A modified TORe technique that combines endoscopic submucosal dissection (ESD) around the GJA with full-thickness suturing has recently been described [112]. The rationale for replacing APC with ESD was to improve the durability of the anastomotic restriction. A retrospective study comparing modified ESD-TORe (19 patients) with traditional APC-TORe (57 patients) showed a greater %TBWL at 12 months in the ESD-TORe group (12.1% [SD 9.3%] vs. 7.5% [SD 3.3%]; $P=0.04$) [112]. No severe AEs occurred.

A novel technique for treating weight regain after gastric bypass uses a newly CE-marked flexible endoscopic system called the Bariatric Anastomotic Reduction System (BARS; Ovesco Endoscopy, Tübingen, Germany), which is derived from the endoscopic over-the-scope clipping system [113, 114]. The BARS device is attached to a single-channel gastroscope and is equipped with external working channels. Tissue manipulation and the process of pulling tissue into the cap with the mounted clip are accomplished using two anchors. The BARS device captures both limbs of the anastomosis, thereby reducing its size. Current data on this technique are limited. A case series of six patients showed a mean weight loss 6 kg (range 4–9 kg) at 3-month follow-up [113], while a pilot study of nine patients reported an absolute weight loss of 11 kg (range 6–14 kg) at 12 months [115].

EGR techniques can be employed to reduce the width and length of a dilated sleeve gastrectomy using a technique similar to that of the primary endoscopic procedure [106]. During the procedure, it is crucial however to avoid suturing along the scar lines of the surgical intervention, pulling too tightly, and excessive insufflation to minimize the risk of complications, such as perforation and bleeding. A multicenter study including 82 patients undergoing endoscopic revision of sleeve gastrectomy using the OverStitch showed %TBWL of 13.2% and 15.7% at 6 and 12 months, respectively. One moderate AE occurred, specifically GEJ stenosis, which was successfully treated with endoscopic dilation [116].

7 Financial aspects and comparison with alternative devices and/or technologies

Financial considerations for EBMTs are complex and should consider several factors, including the costs of disposable devices, anesthesia, and hospitalization [117]. These costs should be compared with those resulting from the impact of obesity and related diseases on the individual's health and the healthcare system. Because of the complexity of these matters, precise evaluations are currently not feasible; however, initial evidence of the cost-effectiveness of EGR is already available. A recent analysis reported that ESG is cost-effective in class I obesity (US$4105/QALY), while sleeve gastrectomy was cost-effective for class II and III obesity [118]. Interestingly, semaglutide was not cost-effective in any of the obesity classes owing to its current high costs. Furthermore, an analysis from the UK showed ESG to be cost-effective for class II obesity compared with lifestyle intervention, with an incremental cost-effectiveness ratio (ICER) of £2453/QALY [119]. Further large-scale analyses are needed to clarify the financial aspects related to EBMTs.

8 Future directions

Minimally invasive endoscopic procedures for treating obesity and related metabolic issues are of significant interest and are rapidly advancing.

Researchers have, for instance, explored the possibility of performing a fully endoscopic bypass using the Natural Orifice Transluminal Endoscopic Surgery (NOTES) technique in animal models. The NOTES technique is an endoscopic approach that accesses the peritoneal cavity through natural orifices, without the need for a percutaneous puncture through the abdominal wall. In a pilot feasibility study involving six growing pigs, a dedicated light beacon inserted into the jejunal region was used to measure the length of the bypassed limb (150 cm) [120]. A double-channel gastroscope was used to perform an endoscopic gastrostomy using a needle-knife, and a dedicated grasper was used to catch the jejunal loop and pull it back toward the gastrostomy [120]. A 20-mm lumen-apposing metal stent (LAMS) was then inserted between the stomach and the targeted jejunum, resulting in a GJA. Finally, a duodenal exclusion device was used to occlude the pylorus after 2 weeks. The technical success rate of the procedure was 100% [120] and a significant reduction in weight gain was reported; however, half of the treated animals experienced prosthesis migration of the gastrojejunal LAMS and other AEs, including diarrhea and stenosis [120]. While there are still technical challenges and a high rate of AEs to overcome, this minimally invasive technique holds great potential for further development in future.

Another promising novel device is the ForePass, which consists of a gastric balloon with a central channel connected to an impermeable sleeve that extends through the duodenum and proximal jejunum, preventing nutrient absorption [121], meaning the device combines both restriction and malabsorptive mechanisms. In an animal study, ForePass significantly reduced blood glucose and increased insulin sensitivity. Furthermore, the weight gain was 79% lower in treated pigs than sham-operated pigs. ForePass was associated with improved fecal microbiota composition [121].

New suturing devices that have the potential to simplify EGR procedures may also be on the horizon. For instance, a device has been developed for full-thickness suturing that fits through a 3.2-mm diagnostic gastroscope channel and requires no additional over-the-scope devices. It has been documented in animal trials that it performs well and has full-thickness suturing capabilities [122]. Further human trials are upcoming for this

promising technology that will allow the use of suturing to become more widespread, with a faster learning curve.

Given the high level of interest in bariatric and metabolic endoscopy, the development of devices is rapidly growing, as are the number of clinical trials. In parallel, novel and potentially more effective antiobesity medications, such as multireceptor agonists, are under investigation. Furthermore, as alterations in the gut microbiota have been related to the pathogenesis of obesity and its metabolic co-morbidities, microbiota manipulation may offer a promising approach to treat obesity, and this will be evaluated in future studies. Considering this dynamic scenario, there will soon be the opportunity of combined treatments to fight an extremely complex multifactorial disease.

9 Green endoscopy

The ESGE, in collaboration with the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA), has issued a comprehensive Position Statement dedicated to minimizing the environmental footprint associated with GI endoscopy [123]. There are still limited data in the literature regarding the environmental impact of GI endoscopy, with the data available regarding bariatric endoscopy even more scarce.

The Position Statement recommends performing most elective endoscopic procedures on an outpatient basis to avoid overnight hospitalization and reduce the overall environmental impact [123]. Most endobariatric procedures can be performed in accordance with this, as they are minimally invasive and allow for same-day discharge in most settings. We recommend, in line with ASGE and ESGE guidelines, adequate hydration in the preoperative and perioperative periods, as well as an antiemetic and acid-suppressive therapy in the postoperative period, which will aid in same-day discharge, thereby reducing resource expenditure. While we recognize that hospitalizations are often linked to national reimbursement plans, we recommend early discharge where possible to reduce the use of resources.

The most popular devices currently are undoubtedly those for EGR. All are single-use and non-reusable, despite being reloadable for single-patient use, with almost all of the accessories used for the procedure also being single use. While it is acknowledged that many accessories used during the procedure may penetrate the gastric mucosa and become contaminated with blood and other fluids, it is important to note that certain endoscopic devices marketed as reusable also face similar challenges, with examples including sphincterotomes, biopsy forceps, and reloadable clip applicators. Medical companies should strive toward incorporating reusable alternatives in the field of bariatric endoscopy, along with minimizing packaging waste.

Disclaimer

This ESGE Technical Review represents a comprehensive literature review of best practices based on the available evidence at the time of preparation. This is NOT a guideline, but a practical tool based on the available data on bariatric endoscopy, the effectiveness of procedures, AEs, and costs. The recommendations may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability. Further studies may be needed to clarify aspects of this document, and revision may be necessary as new data appear. This ESGE Technical Review is intended to be an educational device to provide information that may assist bariatric endoscopists in providing care to patients. It does not provide rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. The legal disclaimer for ESGE guidelines applies to the present position statement.

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Competing Interest

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CORRECTION

Correction: Devices and techniques for bariatric and metabolic endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Technical and Technology Review

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In the above-mentioned article the values for "Spatz 3" in Table 2 have been corrected. This was corrected in the online version on November 6, 2025.

Supplementary Material

Devices and techniques for bariatric and metabolic endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Technical and Technology Review

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Contents

Table 1s. Intragastric balloons – main evidence.

Study	Design	IGB model	N. pts	WL	Δ%WL (IGB Vs controls)	Metabolic/liver parameters
Abu Dayyeh et al.[51]	Metanalysis (17 studies: 14 observational, 3 RCTs*)	Orbera	1638	%TBWL 11.27% (95% CI; 8.17, 14.36) at 12 months %EWL 25.44% (95% CI; 21.47, 29.4) at 12 months	Δ%EWL*: 26.9% (95% CI, 15.6–38.2), p < 0.001	NA
Kumar et al.[52]	Metanalysis (44 studies)	Orbera	5549	%TBWL 13.2% (95% CI; 12.3, 14.0) at 6 months	NA	NA
Popov et al.[53]	Metanalysis (10# RCTs*, 30# observation studies)	Orbera (29#) ReShape (1 RCT#)	5668	NA	Δ%EWL*: 22.3% (95% CI; 8.9, 35.8) Δ%TBWL*: 5.9% (95% CI; 3.7, 8.1)	ΔFBG*: -12.7 mg/dl (95% CI; -21.5, -4), p<0.001 ΔHbA1C*: -1.1% (95% CI; -1.6, -0.6) p<0.001 ΔWC* -4.1 cm (95%CI; -6.9, -1.4) ΔSBP* -3.4 mmHg (95%CI; -8.5, 1.7), p=0.2 ΔDBP* −2.9 mmHg (95%C; -4.1, -1.8), p=0.001
Abu Dayyeh et al.[54]	RCT (Spatz Vs LSM)	Spatz	187 Vs 101	%TBWL 15.0% (95%; CI 13.9, 16.1) Vs 3.0% at 32 weeks (95%, CI 2.0–4.6)	Δ%TBWL 20.0%, p < 0.0001	NA
Sullivan et al.[55]	RCT (Obalon Vs Sham)	Obalon	174 Vs 176	%TBWL 6.6% ± 5.1 Vs 3.4% ± 5.1 at 6 months	Δ%TBWL 3.5% (95% CI; 2.5, 4.6), 0.0085	ΔFBG: -5 mg/dl (95% CI; -7,-2), p=0.0008

				%EWL 26.0% ± 19.0 Vs 13.0 ± 19.0 at 6 months	Δ%EWL 13.0% (95% CI; 9.1, 16.9), <0.0001	ΔHbA1C: 0% (95% CI; -0.1, 0.1), p=0.778 ΔSBP: -4 mmHg (95% CI; -7,-2) p=0.002 ΔDBP: -1 mmHg (95% CI; -3, -1), p=0.3383
Ponce et al.[56]	RCT (ReShape Vs LSM)	Reshape	187 Vs 139	%EWL 25.1% ± 1.6 Vs 11.3% ± 1.9 at 6 months	Δ%EWL 13.9%, 0.0041	Hb1AC: -0.2 mg/dl at 6 months, p<0.05 SBP -8.3 mmHg at 6 months, p<0.05 DBP -4.3 mmHg at 6 months, p<0.05 WC -7.4 cm at 6 months, p<0.05
Vantanasiri et al.[57]	Metanalysis: 6 prospective cohort studies	Allurion	2013	%TBWL 10.9% (95% CI; 5.0, 16.9%; I^2 83%) at 12 months	NA	NA
Aoko et al.[58]	Metanalysis: 19# (14 observational non-comparative, 4 observational comparative, 1 RCT)	Orbera (17#) Spatz (1#) Allurion (1#)	911	%TBWL 15.26% (95% CI; 12.78, 17.74), p< 0.01	NA	Hb1AC, -0.25 (95% CI; -0.09, --0.41), p< 0.01 HOMA-IR: -1.73 (95% CI; -0.97, -2.50), p< 0.01

						NAS: -3 (95% CI; 02.59, -3.43) ALT: -10.40 U/L (95% CI; -7.31,-13.49) AST: -10.68 U/L (95% CI; 5.03,-16.32) CAP score for hepatic steatosis: -38.74 dB/m (95% CI; -21.59, -53.92) LS: -4.43 (95% CI; -1.23, -10.09), p= 0.12
Silva et al.[59]	Metanalysis: 11 obeservational studies	Allurion	2107	%TBWL 12.47% (95% CI; -13.77, 11.17) at 4 mo %EWL 48.04% (95% CI; 50.61, 45.48) at 4 mo	NA	FBG: - 8.54 (95% CI; -12.12, -4.97), p< 00001 Triglycerides: -39.03 (95% CI; -47.7,-30.58), p<00001

Abbreviations: Δ: difference between IGB and controls; %EWL: percentage of excess weight loss; %TBWL: percentage of total body weight loss; LSM: lifestyle modifications; RCT: randomized controlled trial; CI: confidence interval; NA: not applicable; WC: waist circumference; FBG: fasting blood glucose; SBP: systolic blood pressure; DBP: diastolic blood pressure; NAS: NAFLD activity score; CAP: control attenuated parameter via Fibroscan; LS: liver stiffness measurement via Fibroscan; HOMA-IR: Homeostatic Model Assessment for Insulin Resistance.

* metanalysis of selected RCTs

Table 2s. Endoscopic Gastric Remodeling – main evidence.

Study	Design	Suturing device	N. pts	WL	Δ%WL	Metabolic/liver parameters
Hedjoudje et al.[62]	Metanalysis (4 prospective, 4 retrospective observational studies)	OverStitch	1772	%TBWL: 15.1% (95%CI; 14.3, 6.0) at 6months %TBWL: 16.5%(95%CI;15.2, 17.8) at 12 months %TBWL: 17.2%(95%CI,14.6–19.7) at 18-24 months	NA	NA
Abu Dayyeh et al[14]	RCT (ESG Vs LSM)	OverStitch	77 Vs 110	%EWL 49.2% ± 32 (ESG) at 12 mo %EWL 3.2% ± 0.8 (LSM) at 12 mo %TBWL 13.8% ± 8.0 (ESG) at 12 mo %TBWL 0.8% ± 0.5 (LSM) at 12 mo	Δ%EWL: 44.7% (95%CI; 37.5, 51.9), p<0.0001 Δ%TBWL: 12.6% (95%CI; 10.7, 14.5), p<0.0001	Hypertension improvement: 60% ESG Vs 40% LSM Hypertension worsening: 9% ESG Vs 23% LSM Met Syndrome improvement: 83% ESG Vs 35% LSM Met Syndrome worsening: 5% ESG Vs 38% LSM
Nunes et al.[63]	Metanalysis (4 observational studies)	OverStitch	175	%TBWL 17.28% (95% CI; 18.24, 16.31) I^2=41%; p<0.01 at 12 mo	NA	NFS: -0.5 (95% CI; -0.80, -0.19), I^2=12%, p<0.01 at 12 mo HSI: −4.85 (95% CI; −6.02, −3.67), I^2=41, p<0.01 at 12 mo ALT: −6.32 U/l (95% CI; −9.52, −3.11), I^2=8%, p<0.01 at 12 mo Hb1AC - 0.51% (95% CI; −0.90,-0.12), I^2=70%, p=0.01 at 12 mo

Huberty et al.[64]	RCT (ESG Vs LSM)	Endomina	49 Vs 22	%EWL 38.6% (95%CI; (31.11, 45.98) (ESG) at 6 mo %EWL 13.4% (95%CI; 0.74, 27.51) (LSM) at 6 mo %TBWL 11.8% at 12 mo (ESG)	Δ%EWL: 25.2% (95% CI; 11,39.4), p<0.001	NA
Matteo et al.[31]	Prospective observational post-market	Endomina	67	%TBWL 15.3% ± 10.6 at 12 mo %EWL 48.5% ± 38.6 at 12 mo	NA	NA
Lopez Nava et al.[34]	Observational prospective	POSE 2.0	44	% TBWL: 15.7% ± 6.8 at 12 mo % TBWL: 12.2% ± 9.6 at 24 mo	NA	Total cholesterol (from 198.8 ± 35.6 mg/dL at baseline to 187.8 43.1 mg/dL at 6 mo), p = 0.03 HDL (49 ± 12.5 mg/dL to 54.3 ± 12.7 mg/dL), p = 0.003 Triglycerides (131.5 ± 66 mg/dL to vs 83.6 ± 31.6 mg/dl), p < 0.001 ALT (32.4 ± 29 u/L to 18.5 5.3 u/L) P =0.005 HbA1C 6.5% ± 1.4% to 5.7% ± 0.8%), p=0.04 FBG (109.6 ± 25.2 mg/dL to 94.5 ± 16.7 mg/dL), p=0 .07)
AlKhatry et al.[65]	Comparative non randomized	POSE 2.0	22 POSE, 20 LM	%TBWL 18.0% (95 %CI; 15.1%, 20.9%) at 6 mo %TBWL 17.5% (95 %CI; 12.2%, 23.0%) at 12 mo	NA	CAP score -88.8 dB/m (95 %CI; -110.2, -67.3), p<0.001 at 12 mo* AST –7.81 (–13.15,–2.47), p=0.001* HIS –11.16 (–17.03, –5.29), p<0.001*

						APRI score –0.09 (–0.14,–0.04), p<0.001* *all changes significantly higher than controls
Jense et al.[66]	Observational retrospective	POSE 2.0	49	%TBWL 13.2% ± 6.7 at 6 mo %TBWL 14.8% ± 8.4 at 12 mo %EWL 50.9% ± 28.5 at 6 mo %EWL 54.3% ± 35.4 at 12 mo	NA	NA
Boskoski et al.[67]	Single arm prospective	Endozip	45	%TBWL 14.32% ± 1.33 at 6 mo %TBWL 13.21% ± 1.58 at 12 mo %EWL 55% ± 5.4 at 6 mo %EWL 51.4% ± 6.8% at 6 mo	NA	WC - 12.3% (95% CI; -9.7%, -14.9%; p < 0.0001) at 12 mo Hb1AC - 0.28 ± 0.51% at 12 mo ALT - 7.28 ± 18.7 IU/L at 12 mo

Abbreviations: Δ: difference between EGR and controls; %EWL: percentage of excess weight loss; %TBWL: percentage of total body weight loss; LSM: lifestyle modifications; RCT: randomized controlled trial; CI: confidence interval; NA: not applicable; WC: waist circumference NFS: NAFLD fibrosis score; CAP: control attenuated parameter via Fibroscan; LS: liver stiffness measurement via Fibroscan; HIS: hepatic steatosis index; WC: waist circumference

Table 3s. Duodenal Mucosal Resurfacing – main evidence

Study	Study design	N. patients	Indication	Baseline Hb1AC	Main Efficacy outcomes
REVITA-1[82]	Prospective, open-label, single-arm	46	T2DM on oral glucose-lowering mediations	70 (9) mmol/mol	Hb1Ac: -10±2mmol/mol at 24 weeks WL: −2.5±0.6kg at 24 weeks
REVITA-2[83]	Double-blind RCT	108 (56 Revita Vs 52 sham)	T2DM on oral glucose-lowering mediations	• DMR: 65.6 (8.7) mmol/mol • Sham: 66.1 (10.4) mmol/mol	DMR: Hb1Ac −10.4 (18.6) mmol/mol WL: −2.5 kg (4.5) Sham: Hb1Ac −7.1 (16.4) mmol/mol WL −1.5 kg (3.3)
de Oliveira et al.[84]	Metanalysis (1 RCT, 3 prospective)	127	T2DM on oral glucose-lowering mediations	NA	Hb1Ac -1.72% (95% CI; 0.25, 3.19); I^2 =95%, p=0.020 at 6 mo Hb1Ac -0.94% (95% CI; 0.68, 1.21), I^2 =0%, p<0.001] ALT -10.82 U/l (95% CI; -4.80, -16.84), I^2 = 50%, p<0.001] MRI-PDFF -6.59 (95% CI; 5.05,8.12); I^2 =18%, p<0.001 No significant weight loss

Van Baar et al.[85]	Pilot, prospective, single-arm (Revita + GLP1RA)	16	T2DM on insulin therapy	7.5% (7.1-7.9)	Hb1Ac: 7.5 (7.1-7.9) at baseline Vs 6.7 (6.6-7.0) at 6 mo (p=0.009) % Insulin withdrawal (Hb1Ac < 7.5): 69% at 6 mo 56% at 12 mo 53% at 18 mo WL: 87.8 kg (80.2-99.7) at baseline Vs 80.6 (77.7-92.7) at 6 mo(p=0.004)
Hadefi et al.[86]	Pilot, prospective, single-arm	11	NASH	6.5% (6.4–6.8)	No resolution of NASH at 12 months No significant weight loss, no changes in marker of liver fibrosis
BMI: body mass index; DMR: duodenal mucosal resurfacing; GLP1RA: glucagon-like peptide 1 receptor agonist; T2DM: type 2 diabetes mellitus; WL: weight loss NA: not applicable; MRI-PDFF: magnetic resonance imaging derived proton-density-fat-fraction.					

