

Robotic endoscopic sleeve gastropasty

Vincenzo Bove,^{1,2} Maria Valeria Matteo,^{1,2} Valerio Pontecorvi,^{1,2} Martina De Siena,^{1,2} Guido Costamagna,^{1,2} Ivo Boskoski ^{1,2}

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¹Digestive Endoscopy Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Italy
²Center for Endoscopic Research Therapeutics and training (CERTT), Università Cattolica del Sacro Cuore, Roma, Italy

Correspondence to

Dr Ivo Boskoski, Digestive Endoscopy Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma 00168, Italy; ivo.boskoski@policlinicogemelli.it

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MESSAGE

Obesity is a pandemic with significant impact on the healthcare systems; endoscopic bariatric treatments may fill the therapeutic gap between medical and surgical approaches. As part of the rapid technological development in endoscopy, a novel robotic and completely automated suturing system has been developed (EndoZip) and is currently under investigation in a multicentric clinical trial. By using vacuum wall aspiration, strong and standardised full-thickness sutures with much less operator dependence may become possible. We present here in the technology and the technical and morphologic results of the first cases with initial body mass index (BMI) between 30 and 40 kg/m². Follow-up showed reduced gastric volume maintained at 6 months.

IN MORE DETAIL

Obesity is a global pandemic that affects over 650 million adults (13% of the world population).¹ Along with the rising prevalence of obesity, the frequency of obesity-related comorbidities such as type 2 diabetes mellitus, arterial hypertension, coronary heart disease, non-alcoholic fatty liver disease is steadily growing with a significant impact on the economy of healthcare system.² Lifestyle modifications and pharmacotherapy often fail to lead to a proper and sustained weight loss. Non-invasive approaches to obesity, including diet, physical exercise and drugs, often fail to induce an adequate and prolonged weight loss.³ In turn, bariatric surgery is currently the most effective treatment for morbid obesity but only about 1% of eligible patients actually undergo surgery.⁴ During the last two decades, the need for bridging the therapeutic gap between medical and surgical approaches to obesity led to the development of endoscopic bariatric procedures to provide minimally invasive, and more accessible and attractive therapeutic options for patients with obesity who fail non-interventional treatments.⁵

Among the endoscopic bariatric treatments, gastric remodelling or endoscopic sleeve gastropasty (ESG) is a restrictive bariatric procedure that recently gained popularity as a minimally invasive approach for patients with obesity who are not good candidates for bariatric surgery or have limited access to it.^{6,7}

ESG consists of placing full-thickness stitches through the wall of the gastric body thus obtaining a tubulisation and restriction of the stomach. This approach has proved to achieve significant weight loss and comorbidities improvement along with a favourable safety profile, with less than 5% of moderate to serious adverse events.⁶⁻⁹ To date,

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Obesity is rapidly rising around the globe. Bariatric endoscopy is evolving fast and is more and more requested by patients and physicians, mostly due to its efficacy and safety. Currently, there are several suturing devices for bariatric endoscopy but these suturing devices are all manual, and procedures are operator and highly skill-dependant.

WHAT THIS STUDY ADDS

⇒ The new robotic device for bariatric endoscopy democratises gastric suturing. All sutures are the same and replicable, the procedure is minimal-operator dependent, is fast and basic endoscopy skills are required to accomplish it.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This new robotic device will standardise the procedure for all patients and will flatten the learning curve. The device has the potential to directly improve weight loss. The robotic endoscopic sleeve gastropasty has the potential to directly impact the research in all fields of obesity and metabolic diseases.

several stapling devices with different technologies are used in clinical practice, including Apollo Overstitch, Endomina and Incisionless Operating Platform for Primary Obesity Surgery Endoluminal 2-0.⁶⁻¹¹

The rapid development of robotics in endoscopy has recently reached the field of gastric suturing for obesity.¹² We describe a novel endoluminal-sutured gastropasty system (EndoZip, NitiNotes based in Caesarea, Israel) based on robotic technology, CE and Food and Drug Administration (FDA) approval pending. This robotic and automated technology is designed to further improve the technical feasibility, usability, and reproducibility of the procedure.

DESCRIPTION OF THE TECHNOLOGY

This robotic system is designed to create multiple longitudinal wall-to-wall attachments of the anterior and posterior stomach. The previous generation of the system was cumbersome and with manual suturing and stapling control, while the current version is completely robotised with automatic suturing and cinching, also is more user friendly.¹³

In detail, the system consists of a disposable device that controls the procedure that is connected to a dedicated reusable electrical power supply. The



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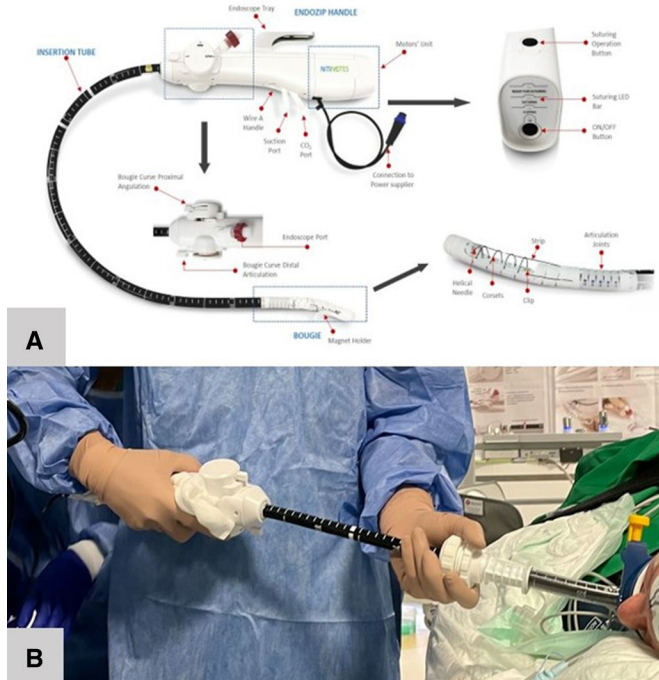


Figure 1 (A) A detailed description of the EndoZip disposable device. (B) Placement of the EndoZip disposable device through a long overtube (Steris Guardus, Mentor, Ohio, USA).

EndoZip disposable device consists of three main components: Bougie, Insertion Tube and Handle (figure 1A). The Bougie is the distal end of the device that contains a chamber that captures the tissue using a vacuum, to support full-thickness sutures and

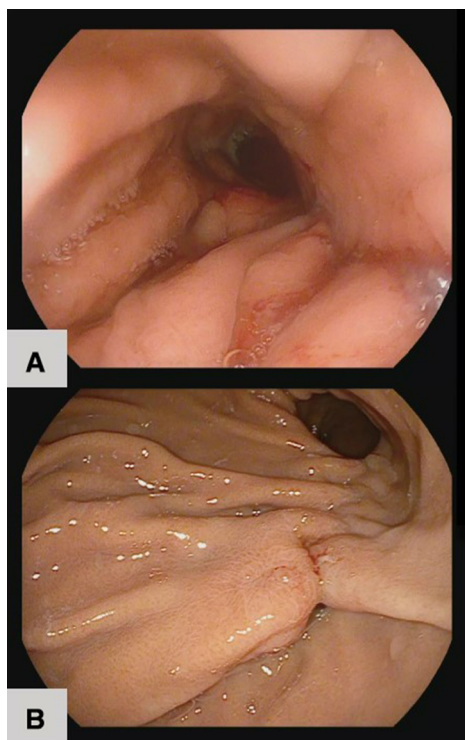


Figure 2 (A) Endoscopic appearance after robotic endoscopic sleeve gastroplasty immediately after four suturings with the EndoZip disposable device. (B) Endoscopic appearance after robotic endoscopic sleeve gastroplasty at 6 months after the index procedure.

includes a steerable segment that facilitates device maneuvering. The Handle allows the endoscopists to manoeuvre and position the device in the desired gastric area and controls all suturing activity. The handle comprises of a motor unit and a mechanic control unit. The motor unit includes motors and controllers to perform stitching, tightening, clipping and cutting of suture wire, and is provided with a sensing mechanism that ensures that the stages after stitching are contingent on the needle reaching the target area. Suturing activities are powered via electrical motors that are controlled by the micro control unit in the main board which receives feedback from five sensors. A safety mechanism triggers the system to start the suturing stage only after it verifies that the endoscope is absent, the distal tip of the device is in an optimal position, and the vacuum level is reached at the minimum required. All of this facilitates also a smooth passage of the needle through its predefined route. A second safety mechanism includes tracking the needle passage while stitching. Completion of this stage is verified and confirmed by the detection of the needle in the designated parking area. Clipping and cutting of the suture thread are performed after the needle has been fully passed to ensure the safe removal of the device. The mechanical control unit helps the physician to manoeuvre and position the device. The Insertion Tube connects the Handle and Bougie parts, supporting insertion and evacuation of air and CO₂, and contains a channel for the endoscope passthrough. This robotic system allows the creation of robust full-thickness sutures to ensure durable and successful modifications of the gastric cavity.

VIDEO OF THE PROCEDURE

The first part of the video demonstrates the robotic ESG with the EndoZip system (online supplemental video 1). The device is inserted into the stomach through a 50 cm long and 16 mm in diameter overtube (Steris Guardus, Mentor, Ohio, USA) and is visually positioned by a small-diameter endoscope (5.4 mm) passed through a dedicated channel of the robotic system. The system is connected to an external vacuum pump that generates a near-vacuum state within the distal end of the device by extracting the air from the chosen deployment site thus inducing the tissue segments drawing into the Bougie. At this stage, the endoscope is retrieved and from this point on a small black button is pressed and the procedure becomes completely automated. During the robotised step, a custom-designed needle is driven through the distal end towards its proximal end, creating continuous full-thickness suturing, tightening and cinching of the approximated tissue segments with an integrated clip. This stage is indicated by an LED bar located on the device handle. The suturing is repeated two to five times and every time a new device is introduced until a complete ESG is performed (figures 1B and 2A). The second part of the video shows the endoscopic appearance of the stomach 6 months after the index procedure (figure 2B). The gastric lumen is restricted with intact and well-tightened suture lines.

FIRST RESULTS

Seventeen patients were treated so far with the EndoZip robotic suturing system (Digestive Endoscopy Unit, Fondazione Policlinico Universitario Agoatino Gemelli IRCCS, Rome, Italy), as part of a multicentric clinical trial. By protocol, the baseline BMI was between 30 and 40 kg/m² and all patients were selected to this procedure by a multidisciplinary team. In particular, the patient of the video case that we presented here was the first one that had a complete 6 months follow-up. This was a 30-year-old

female patient with BMI 35.8 kg/m² at the index procedure. Her BMI dropped down to 25.9 kg/m² at 6 months when her satiety sense was persistent, and her quality of life was excellent. As shown on figure 2B, the stomach of this patient maintained the endoscopically altered anatomy at 6 months. Similar morphological results at upper endoscopy were seen in the subsequent consecutive five patients. Further results of this multicentre clinical trial are pending especially regarding weight loss.

COMMENT

The robotic ESG with the EndoZip system is a novel automatic, operator-friendly procedure aimed at simplifying gastric suturing by reducing operator dependence. The robotic and automatised technology and the use of vacuum, allow strong, potentially durable and standardised full-thickness sutures. As such, this procedure may further improve obesity treatment by standardising the procedure, thus expanding the access and acceptability to a broader population. Basic skills of overtube placement and upper endoscopy are required to perform the robotic ESG and this could mean much in further simplifying bariatric endoscopy. First experience in patients suggests durable results. However, the spectrum of possible complications is not fully known, and the data to support effective outcomes will be available at the end of 12 months follow-up period for all the patients. Further systematic studies are required to define the potential position of this new device in obesity endotherapy.

Twitter Ivo Boskoski @ivoboskoski

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ORCID iD

Ivo Boskoski <http://orcid.org/0000-0001-8194-2670>

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