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Modified endoscopic gastroplasty for the treatment of obesity

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Abstract

Background Endoscopic sleeve gastroplasty is a safe and feasible treatment for obesity. This study is focused on our technique modification which suggests a different suturing pattern in order to distribute suture tension more evenly.

Methods A retrospective study of 148 patients (121 women) who underwent this procedure and were monitored for 12 months was conducted. The average age was 41.53 ± 10 years. The average BMI was 35.11 ± 5.5 kg/m^2 with the average initial weight being 98.7 ± 17 kg. A subgroup of the first 72 patients (60 women) were monitored for 18 months. A new running "Z" stitch pattern was used to provide gastric cavity reduction by means of 4 parallel suture rows. The stitch pattern was intended to provide a homogenous distribution of the disruptive force on the suture among all stitch points.

Results %TWL was 17.53 ± 7.57 in 12 months and 18.5 ± 9% in 18 months indicating durability of the procedure. Patients with a BMI < 35 benefited most from an endoscopic gastroplasty. Leptin did not predict a response to endoscopic gastroplasty and decreased in all patients. In just one case there was a mild bleeding (0.67%) at the insertion point of the helix, which was resolved by sclerotherapy.

Conclusions Endoscopic gastroplasty offers a real choice for obese patients. This single-center experience with a modified suturing pattern provides a successful technique for weight loss.

Keywords Gastroplasty · Z pattern · Overstitch · Sutures · Leptin

Obesity is a chronic disease with a worldwide prevalence that has doubled from 1980 to 2014. It is estimated that more than half of the European population is overweight (defined as a body mass index—BMI—between 25 and 30 kg/m^2) and that 25% suffer from obesity (BMI > 30 mg/m^2). The WHO estimated that in 2014 more than 1.9 billion adults were overweight, of which more than 600 million were obese. Thus, by 2014, about 13% of the world's adult population (11% of men and 15% of women) were obese [1].

Obesity has been associated with the development of comorbidities such as hypertension, insulin resistance, type 2 diabetes, dyslipidemia, gastroesophageal reflux disease, obstructive sleep apnea, gout, and de generative arthropathy [2].

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Bariatric surgery such as vertical gastrectomy or roux-en-Y bypass has been proven to be effective, but surgery is risky and poorly accepted by patients. In 2013, for the first time endoscopic gastroplasty was described as a safe and feasible treatment for patients to achieve significant and sustained weight loss [3]. This technique has been used in our center since 2013. We have focused on the modification of the endoscopic sleeve gastroplasty, implementing a different suturing pattern intended to distribute suture tension more evenly.

Patients and methods

Patients

This is a retrospective study of the patients treated by endoscopic gastroplasty from January 2015 to February 2016. All cases had been collected in a prospective data registry.

Patients undergoing this procedure had class I, II, and III obesity (BMI 30–35, 35–40, and over 40 kg/m^2,

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respectively). Before performing the endoscopic procedure a physical, nutritional, and psychological assessment was performed. In addition, all patients underwent upper GI endoscopy in order to screen for possible contraindications, i.e., potentially bleeding lesions, such as ulcers or erosive duodenitis, and preneoplastic or neoplastic findings. Patients were also assessed by anesthesia, to screen for contraindications such as severe cardiorespiratory pathologies, coagulopathy, and anti-thrombotic therapy. All patients underwent chest X-ray, electrocardiogram, and complete preoperative blood work.

Post-procedural data collection included weight in kg, body mass index (BMI), total weight loss in kg (TWL), % of excess weight lost (% EWL), and % of total weight loss (% TWL). Data were collected quarterly. BMI was calculated dividing the patient's weight in kilograms by the square of his/her height in meters. The % EWL was calculated dividing the excess weight times 100 by the initial excess weight; excess weight was calculated as the difference between the current weight and the ideal weight for the sex and height of the patient. The ideal weight was calculated using the Lemmens formula (22 × height in cm^2). The % TWL was calculated dividing the weight as recorded at the different evaluation points by the initial weight times 100.

All patients had signed an exhaustive consent form. All data were coded to maintain the anonymity of each patient, following the recommendations of good clinical practice and the Declaration of Helsinki. The study was approved by the IRB of our hospital.

Endoscopic technique

The technique consisted of using a flexible double-channel endoscope (Olympus GIF -2T180, Olympus Medical Systems, Japan) in which the endoscopic suture system (OverStitch, Apollo Endosurgery, Inc., Austin Texas, USA) was incorporated. The suturing device was approved by the European Medicines Agency in February 2013 and its use, in the primary treatment of obesity, was accepted in 2013 by the Ethical Committee of the hospital.

All procedures were performed by one of the two endoscopists, in the surgery room, with the patient in supine position under general anesthesia and endotracheal intubation. A third-generation cephalosporin was given intravenously at the beginning of the procedure. The anesthesiologist kept the patient under controlled hypotension to minimize bleeding, and to maximize visualization of the mucosa. An intravenous dose of spasmolytic (20 mg IV butylscopolamine) was given to improve stitch localization and avoid peristaltic waves. An overtube was used to facilitate the atraumatic passage of the instrument through the esophagus. Ambient air was used for insufflation.

A new running "Z"-shaped stitch pattern was used to produce gastric cavity reduction both concentrically and longitudinally by means of parallel suture rows. This provided a more homogenous and a better distribution of the disruptive force on the suture in all stitch. The suture pattern previously described followed a triangular or a layer distribution (Fig. 1).

A technique proposed by our group tried to substitute the two previous suture patterns. By using this technique, each suture line was distributed over 8–14 stitches, using 4 sutures proceeding from the gastric incisura to the fundus (Fig. 2) in a running "Z" pattern. The distance between stitches was 1.5–2 cm. A total of four rows of sutures with this stitch pattern were placed: two of each straddling the greater curve, one along the posterior wall and another one along the anterior wall of the gastric body.

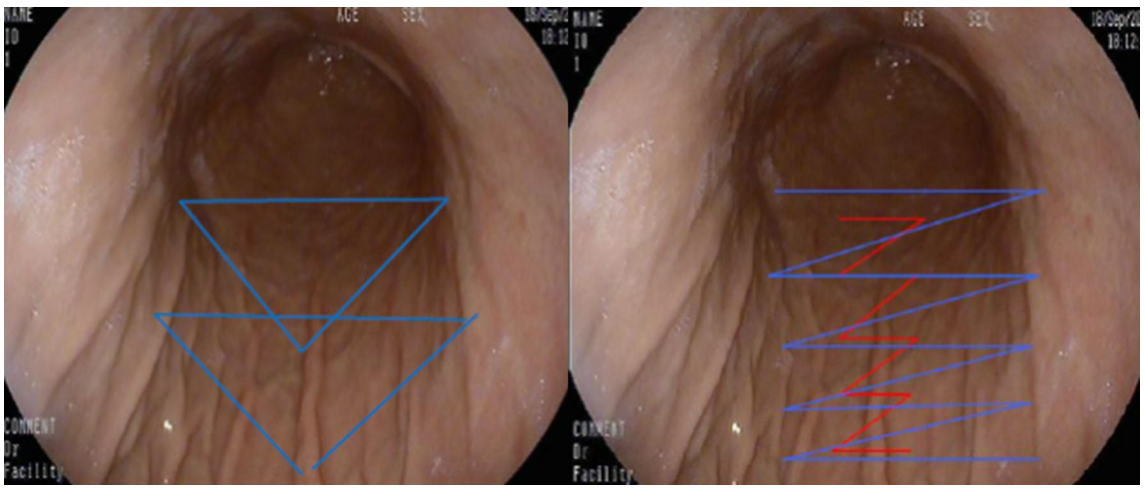


Fig. 1 Pattern of sutures distribution in previous versions of endoscopic gastroplasty. (Left—standard triangular 6 stitch plication. Right—overlapping greater curve running layers pattern)

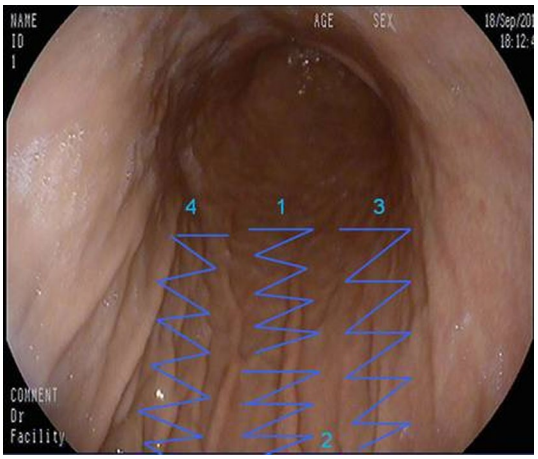


Fig. 2 New distribution of the points with longitudinal and parallel sutures

Fig. 3 Appearance after performing the procedure applying the new Z stitch pattern technique with a substantial reduction of gastric volume

Upon completion, a second look endoscopy was performed, to lavage and to insufflate the gastric cavity, in order to ascertain hemostasis and to confirm adequacy of the reduction of the gastric volume (Fig. 3). In case of suboptimal volume reduction, additional sutures were placed.

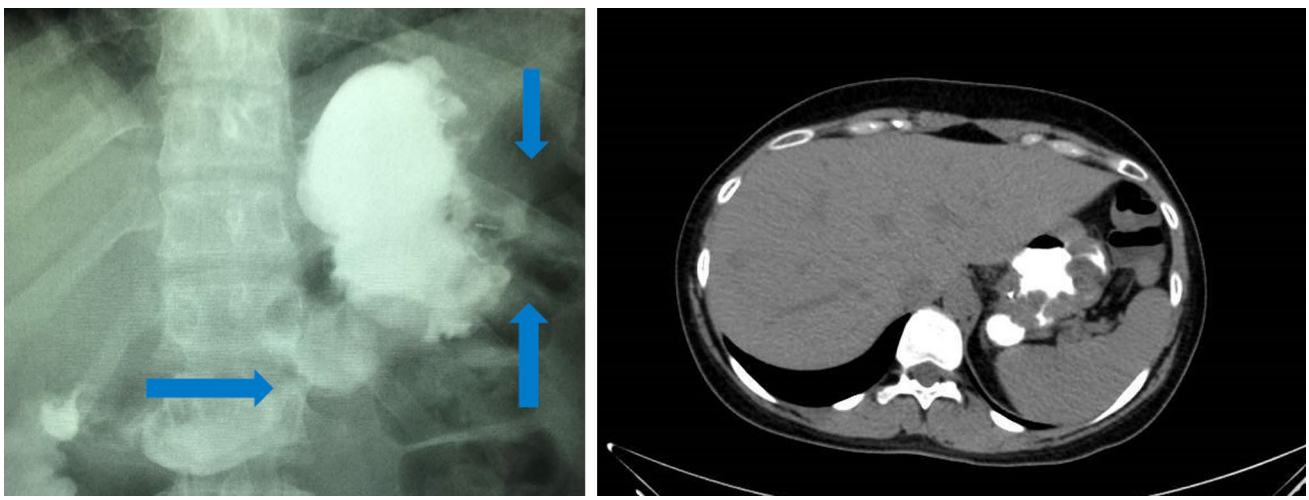
Patients were hospitalized until the following morning with no activity restrictions. Analgesics, usually metamizole, anti-emetics or spasmolytics, and low-dose of butylscopolamine were provided. At 24–48 h, patients were encouraged to continue with their daily routine and to perform mild physical exercises such as walking or swimming. Endoscopic or radiological follow-up were not performed unless a problem warranted these studies. In some cases, the patients were assessed voluntarily after the procedure to check the magnitude of gastric volume reduction.

Every patient received ondansetron on the first day and omeprazole for the next 2 months.

Figures 4 and 5 show an evident reduction of gastric volume on barium swallow and CT, especially a shortening of the gastric body and a greater curvature elevation.

Patients were placed on a low-calorie diet and were monitored by experienced nutritionists weekly at the beginning and monthly thereafter. During each visit, patients were weighed with the same scale. Leptin was measured every 3 months.

The progressive diet guideline was done for approximately 4 weeks, i.e., 2 weeks of liquid diet, followed by 2 weeks of semiliquid diet. Eventually the participants were allowed to have a regular diet, designed to provide 1000–1200 cal/day which included 70 g of proteins.



Figs. 4 and 5 Radiological image by barium and CT scan performed after the procedure, in which a marked reduction of gastric volume is observed especially shortening of the gastric body

Statistical analysis

The study objectives were to calculate TWL, %EWL, and %TWL at 3, 9, 12, and 18 months. The data averages were compared by *T* student test with 2 tails in excel program.

Results

One hundred and forty-eight patients, of whom 121 were women, were treated by this new endoscopic technique. The average age was 41.53 ± 10 years. The average BMI was 35.11 ± 5.5 kg/m^2 with the average initial weight being 98.7 ± 17 kg. The majority of the procedures were completed in 45–60 min. The participants were monitored for 12 months. A subgroup of the first 72 patients, 12 men and 60 women, aged 41.3 ± 9 years, with an initial weight of 98.42 ± 17.65 kg were monitored for 18 months.

Follow-up was available for all patients, but the follow-up for some patients was longer (18 months), because their treatment was carried out at the beginning of the study.

There was no mortality in the present study.

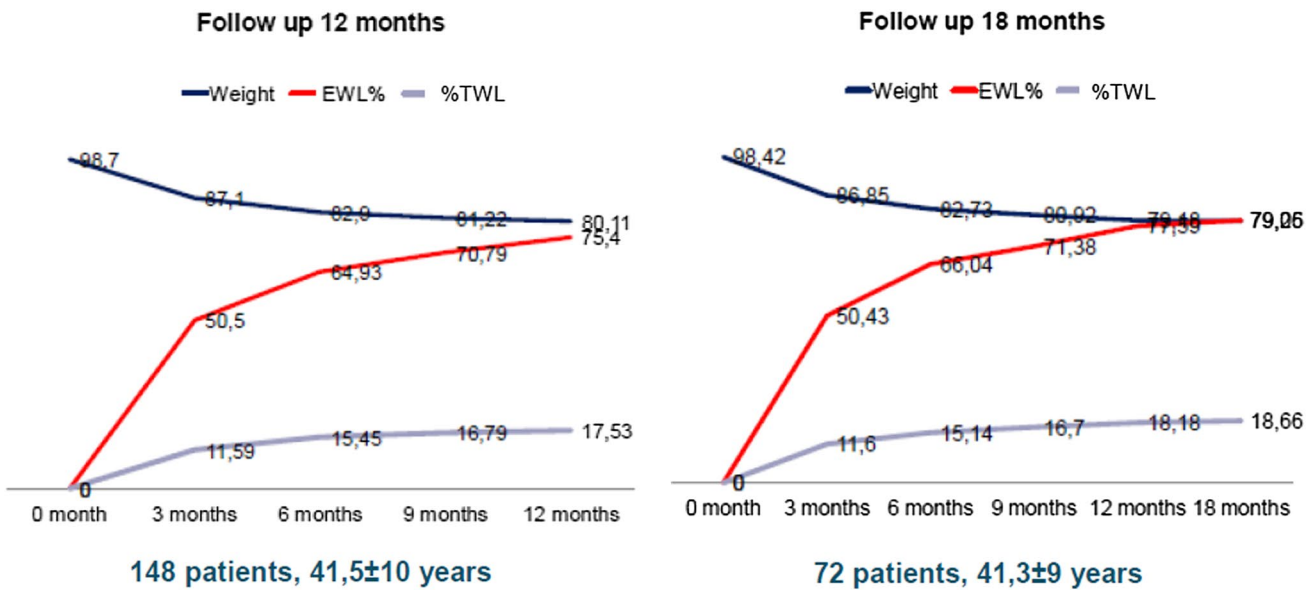
Tables 1 and 2 summarize the results of both groups at 12 and 18 months, respectively. Figures 6 and 7 show TWL, %TWL, and %EWL in the group monitored for 12 months and in the group monitored for 18 months.

Table 1 Results at 12 months

148 cases	Start	3 months	6 months	9 months	12 months
Weight (kg)	98.7 ± 17.49	87.1 ± 15.52	82.9 ± 14.7	81.22 ± 15	80.11 ± 15
BMI (Kg/m^2)	33.39	31.23	29.72	29.11	28.72
Weight loss (kg)		11.53 ± 4.7	15.5 ± 7.41	16.89 ± 8.63	17.62 ± 9.22
Weight loss %		11.59 ± 3.82	15.45 ± 5.9	16.79 ± 7.01	17.53 ± 7.57
Excess weight loss (%)		50.5 ± 56	64.93 ± 51	70.79 ± 68	75.4 ± 85

Table 2 Results at 18 months

72 cases	Start	3 months	6 months	9 months	12 months	18 months
Weight (kg)	98 ± 17	86.5 ± 15	82.73 ± 14	80.9 ± 14	79.18 ± 14	79.6 ± 14
BMI (kg/m^2)	34.72	30.65	29.30	28.66	28.05	28.01
Weight loss (kg)		11.34 ± 4	14.9 ± 5.7	16.5 ± 7.1	18.0 ± 8.5	18.5 ± 9
Weight loss (%)		11.60 ± 3.5	15.14 ± 4.85	16.70 ± 5.99	18.18 ± 6.78	18.66 ± 7.3
Excess weight loss (%)		50.43 ± 29	66.04 ± 39	71.38 ± 41	77.59 ± 42	79.25 ± 43



Figs. 6 and 7 Weight loss in kg and percentage and excess weight lost in % in the group followed up for 12 months and in the group followed up for 18 months. (Color figure online)

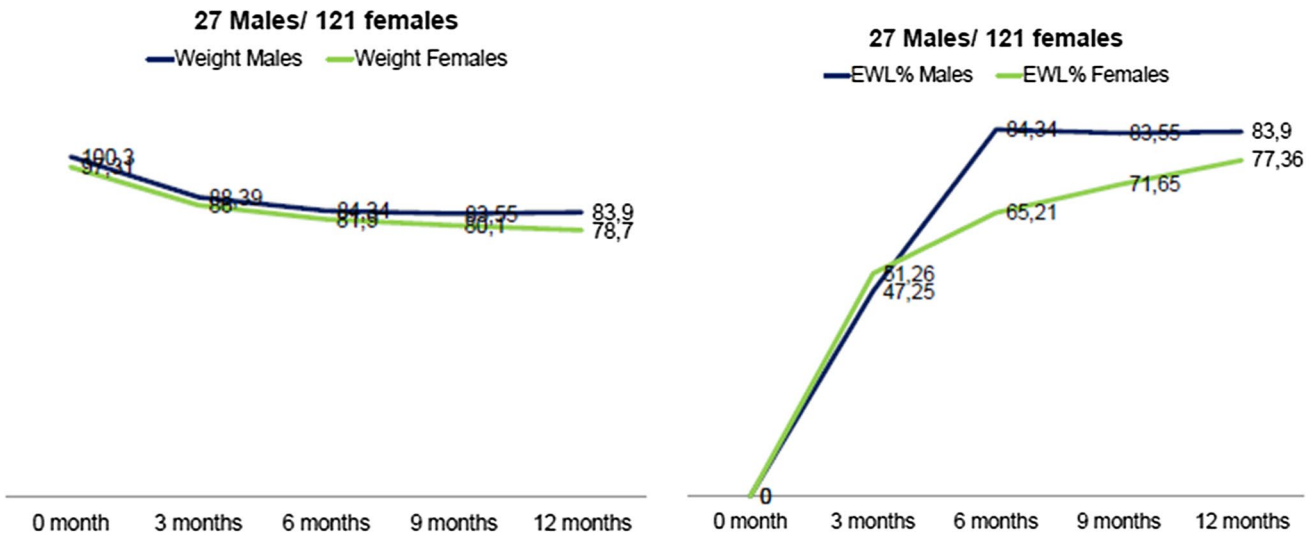


Fig. 8 Evolution of percentage excess weight loss (%EWL) in male and female participants. (Color figure online)

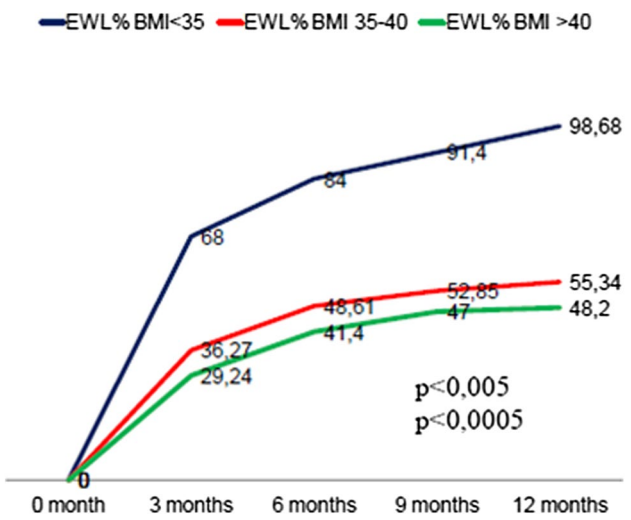


Fig. 9 Progression of excess weight loss (EWL) in patients as a function of BMI at baseline. (Color figure online)

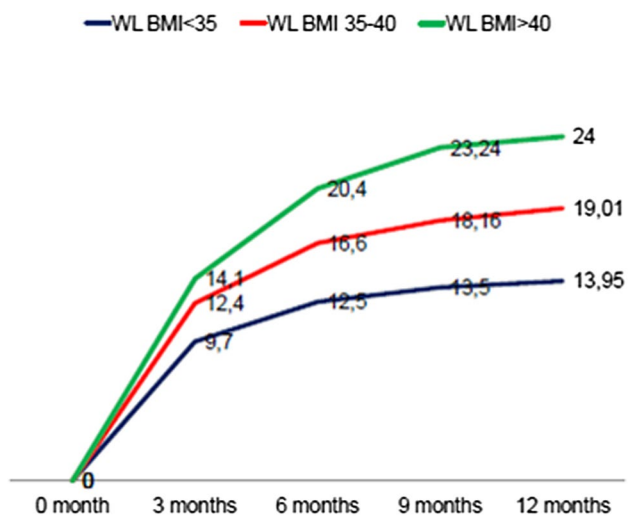


Fig. 10 Progression of weight loss (WL) in kg in patients as a function of BMI at baseline. (Color figure online)

In both cohorts, weight loss and % excess weight loss are more pronounced in the first 3 months post procedure (50% of the excess weight). In the following 12 months it continued to 75%, and the result remained unchanged between the 12th month and the 18th month (79% loss of excess weight).

In a comparative study between both the sexes in 1 year, greater weight loss and a greater %EWL was observed in males, although this difference did not gain a statistical value at any of the follow-up moments.

In Fig. 8, weight loss, %EWL and %TWL are shown in graph form in both groups.

In Figs. 9 and 10, % EWL and TWL are shown as a function of the pre-procedural BMI of the patients by grouping 72 cases (12 men and 60 women) with BMI less than 35 kg/m^2, 57 cases (11 men) with BMI between 35 and 40, and 25 cases (5 men) with BMI greater than 40. The subgroup with BMI below 35 reached almost the ideal weight at 12 months of follow-up. The difference in %EWL at 12 months between the BMI group of less than 35 and the BMI group between 35 and 40 was significant with $p < 0.005$. The difference in %EWL between the BMI group < 35 and the group with BMI > 40 was also significant ($p < 0.005$).

The majority of patients experienced a mild epigastric pain and self-limiting vomit after the procedure. In one single case, the patient needed to prolong her hospital stay more than 24 h because of sustained pain. In another case, a mild

bleeding (0.67%) at the insertion point of the helix happened which was solved by sclerotherapy. There was no perforation or delayed bleeding or other major surgical or anesthetic complications. In one case, two suture lines opened up, and in another, the sutures broke when regular diet was resumed. These two aforementioned individuals did not benefit from the technique.

The post-procedural leptin levels decreased in all patients compared to the baseline values (Table 3). Leptin levels were significantly higher in women at baseline ($p < 0.05$) and showed a significant decrease during the follow-ups in both men ($p < 0.0001$) and women ($p < 0.0001$). There were no differences between both the sexes 12 months after the intervention. There were also no significant differences ($p = 0.3$) between the baseline leptin in patients who lost more than 50% of excess weight at 12 months, and in those with EWL% < 33. There was no significant difference in the degree of leptin decline at 12 months between the patients who lost more than 50% of excess weight, and the less responders ($p = 0.03$), despite the fact that in the former group the difference in leptin levels at 12 months versus the baseline was highly significant ($p < 0.001$).

Of note, the 22 patients with less weight loss also showed a significant decrease in leptin from 28.9 ± 8 to 21.6 ± 6 ng/ml ($p < 0.005$).

Discussion

Despite the demonstrated efficacy of bariatric surgery, many patients are not willing to go through it [1–3]. For this reason, the development of endoscopic techniques for the treatment of obesity is extremely promising. The Mayo Clinic in 2013 published about the first four patients which were treated with endoscopic gastroplasty, demonstrating that this was a feasible and safe technique to induce anatomical changes similar to those achieved by surgical interventions [4]. López Nava et al. reported the case of a series of 25 patients treated with this technique and followed up for a year, demonstrating that nutritional and psychological support is directly related to the success of the procedure [5]. This group presented a series of 50 patients treated with endoscopic gastroplasty with safe and good weight loss results [6]. A larger single-center experience of 91 patients followed up for 2 years, subsequently reported significant reduction in body mass index and metabolic complications [7].

We present the first study of endoscopic gastroplasty with a new suture pattern, the advantages of which are great in durability, demonstrated efficacy, and easy to be learned. This pattern does not present any disadvantage in comparison to the previous ones.

Our group has been performing more than 700 endoscopic gastroplasty since 2013 up to date. We have had a high rate of revisions, as high as 47%, with a technique which is used most commonly. This technique involves a triangular six-stitch large plication. It encouraged us to come up with a new distribution of stitches that would guarantee a greater durability of the gastroplasty and therefore a greater weight loss.

In our opinion, an endoscopic gastroplasty should fulfill the following assumptions: A high number of stitches, not fewer than 40, should be used with a homogenous distribution of force among all of them. This, decreases the suture tension at each stitch point. We believe that using parallel running "Z" sutures, when each stitch is placed very closely to the other, with a distance not more than 2 cm, distribute the tension much more evenly. In addition, we feel this new distribution of sutures is technically easier and, therefore, easier to learn.

Regarding weight loss, the new suturing pattern in gastroplasty, described here, is beneficial to those individuals with a BMI < 35. Even with BMI above 35, the technique is proved to be effective in both type II and type III obese patients with 48–55% of excess weight loss, respectively. We have thus shown that endoscopic gastroplasty techniques can also be applied to patients with grade III obesity who refuse surgical treatment, and it could even serve as a bridge in extreme cases for a patient in order to lose weight before facing a definitive surgical procedure [8].

Men lost more weight both in absolute form and in percentage of excess weight, although the difference was not significant. Endoscopic gastroplasty, in addition to reducing gastric volume, causes a greater sensation of satiety, alterations the motility which induces a slower gastric emptying, and decreases leptin levels [9]. A significant decrease in

Table 3 Leptin levels

	Leptin all (ng/ml)	Leptin women (ng/ml)	Leptin men (ng/ml)	EWL < 50% (ng/ml)	EWL > 50% (ng/ml)
Baseline	27.47 ± 9.2	27.72 ± 9.3	26.9 ± 8.7	27.7 ± 9.2	26.79 ± 0.2
Month 3	22.74 ± 7.5	25.5 ± 7.6	21.47 ± 6.9	22.74 ± 7.5	22.12 ± 7.5
Month 6	20.99 ± 7.13	24.5 ± 7.09	19.45 ± 6.4	20.99 ± 7.13	20.19 ± 6.9
Month 9	19.87 ± 6.6	23 ± 6.6	18.07 ± 5.6	19.87 ± 6.69	19.01 ± 6.4
Month 12	18.78 ± 6.5	22 ± 6.4	16.62 ± 5.15	18.78 ± 6.5	17.83 ± 6.17

leptin was observed after the procedure in all the analyzed groups. Probably the changes in the value of leptin were related to the weight loss. Intergroup analysis (EWL > and < 50%, men versus women) failed to record significant differences at 12 months. No other markers such as ghrelin or GLP1 were checked .

This new pattern of sutures does not increase the difficulty of performing a revision surgery in case it is needed.

An important shortcoming in our study is the retrospective design and the absence of a control group, i.e., a group of individuals without endoscopic treatment but with nutritional support. Having such a control group in our practice was not possible due to the fact that all are patients were charged for their treatment. A second shortcoming is that we did not do an endoscopic or radiographic surveillance on every patient.

We may conclude that our new method of endoscopic suturing may have technical and long-term advantages in the emerging technique of endoscopic gastroplasty, despite the fact that we do not have long-term (years after) follow-ups.

Compliance with ethical standards

Disclosures Dr. Javier Graus has an equity interest as consultant of Apollo Endosurgery, Inc. Dr. Jacques Himpens has an equity interest as consultant of Ethicon US, LLC and Medtronic, PLC. Drs. Laura Crespo, Andrea Marques, Belén Marín, Rubén Bravo, Estefanía Ramo, Carmen Escalada, and Carmen Arribas have no conflicts of interest or financial ties to disclose.

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