

# Endoscopic Sleeve Gastroplasty (ESG) - A Recently Approved Procedure For The Treatment of Obesity

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## 1. Abstract

Endoscopic sleeve gastroplasty (ESG) has recently been recognized as a valid procedure in the management of obesity. A consensus of several societies has confirmed grade 1 and 2 obesity as indications, as well as grade 3 obesity in patients who are ineligible for or do not want surgery. The natural orifice transoral endoscopic (NOTES) approach is used to perform the procedure. A significant reduction in stomach volume is achieved by applying rows of full thickness sutures, usually in a U-shape, to retract the stomach wall along the greater curvature. This remodelling reduces the functional gastric capacity. As a result, earlier onset of satiety leads to reduced food and energy intake, which in turn promotes weight loss.

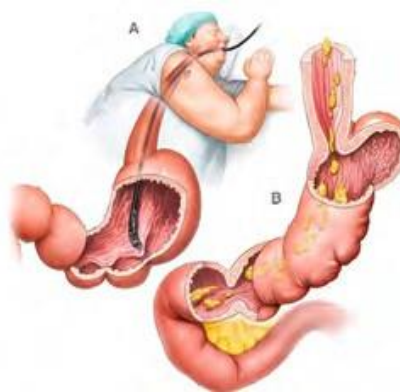
## 2. Background

The development of endoluminal suturing techniques, such as those used in endoscopic sleeve gastroplasty (ESG), has historically depended on relevant technological achievements, not least the time-consuming development of the endoscope itself. This long evolution has paved the way for endoluminal surgery. As such, these fundamental innovations need to be seen as an integral part of the broader narrative in the field [1,2]. It is worth noting that the first endoscope, attributed to the German physician Philipp Bozzini in 1806, was greatly improved in 1877 by the German urologist Max Nitze, who added magnifying lenses and an internal light source. He was the first to take endoscopic pictures and perform endoscopic

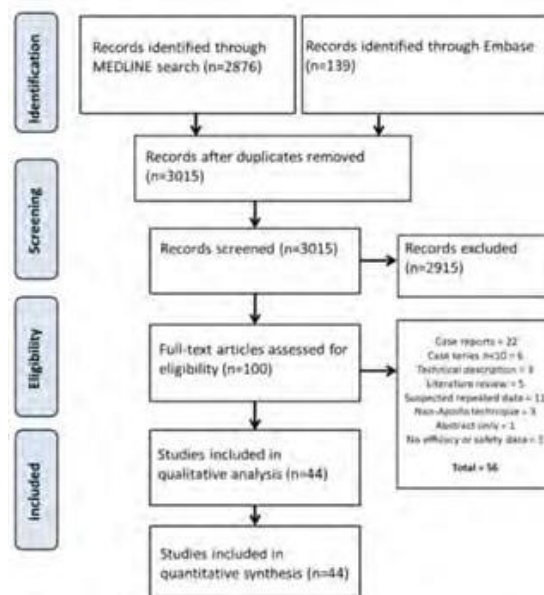
surgery using wire loops. Around the same time, Adolph Kussmaul, a German gastroenterologist (1867), and Johann v. Mikulicz, a German surgeon (1881), introduced upper endoscopy into clinical practice. It took almost another century before Harold Hopkins, a British physicist, significantly improved optical efficiency in 1960, while around the same time Basil Hirschowitz, an American gastroenterologist, developed a flexible endoscope using fibre optics. Brilliant visualisation, essential for precise endoluminal surgery, was revolutionised by Karl Storz, who in 1965 combined the Hopkins optical system with fibre optics to bring light to the tip of the endoscope. A new endoluminal era was dawning [1,2]. Now able to perform flexible endoscopy with adequate visibility, new interventional tools have been developed. Therapeutic endoscopic interventions are one of the most promising areas in today's modern minimally invasive era. Some years ago, this led to the development of NOTES (Natural Orifice Transluminal Endoscopic Surgery), the idea of performing even more minimally invasive surgery using natural orifices and an endoluminal platform [3]. Time and circumstances were not yet mature. Today, the introduction of endoscopic suturing devices represents another evolutionary goal for new interventional techniques and endoluminal procedures (4-6). They represent the latest achievement and milestone in the development of modern endoluminal surgery. In their own way, they provide an evolution of the former NOTES procedures. As always, innovative procedures must prove themselves to many critics, but one of several innovative endoscopic suturing techniques has already

achieved this goal. – the endoscopic sleeve gastroplasty (ESG). ESG is performed using the Overstitch (Boston Scientific, Marlborough, MA, USA), a device mounted on a flexible endoscope that allows full-thickness suturing as both single and continuous sutures (Figure 1). Endoscopists of all backgrounds involved in bariatric therapy have developed and refined endoluminal sleeve gastroplasty as a primary intervention for the treatment of obesity. ESG significantly reduces the capacity of the stomach by applying rows of full thickness running sutures to quantitatively retract the stomach wall along the greater curvature. The applied pattern is usually a U-shaped suture running from the anterior wall across the greater curvature to the posterior wall and back, with 8 to 10 stitches, but the use of a Z-line pattern has also been reported. This procedure spares the fundus, creates a pouch-like reservoir and, unlike laparoscopic bariatric surgery, preserves the angle of the HIS. In addition to shortening and

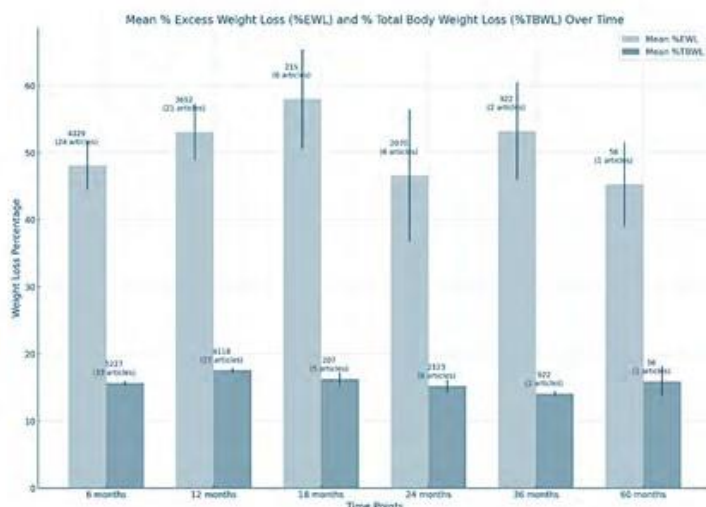
tightening the stomach, ESG also prolongs gastric accommodation, both of which significantly differentiate ESG from laparoscopic sleeve gastrectomy. In addition, unlike laparoscopic bariatric surgery as well, ESG is not associated with long-term metabolic complications such as malnutrition, dumping syndrome or reflux [7]. In addition, as demonstrated by the Multicentre ESG Randomised Interventional Trial (MERIT), it is repeatable and safe [8]. This procedure has been developed at a time when obesity is reaching epidemic proportions worldwide [9,10]. The necessity to treat patients in need is likely to accelerate its use. Successfully performing such an endoluminal procedure requires not only a comprehensive understanding of the physiology of obesity, but also advanced endoscopic skills, including precise orientation within the stomach, even under interventional conditions. If these preconditions are met, it shows that it is an effective and low-risk treatment for obesity.



**Figure 1:** Endoscopic sleeve gastroplasty (ESG), © Dr Levent Efe, courtesy of IFSO.



**Figure 2:** PRISMA flowchart of the source meta-analysis (16).



**Figure 3:** Excess Weight Loss (%EWL) and Total Body Weight Loss (%TBWL) by time points. For context, the number of individuals and articles at each time point are included above the bars (16).

### 3. Indications

In 2023, all available evidence was presented to a multidisciplinary expert committee on behalf of the International Federation for the Surgery of Obesity and Related Diseases (IFSO). Using the Delphi method, recommendations on the usefulness of ESG for the treatment of obesity were evaluated according to the resulting expert opinion. In its consensus on practice guidelines, the IFSO Committee supports the use of the procedure for obesity grades 1 and 2, as well as for those with obesity grade 3 who are ineligible for or refuse surgery. This minimally invasive procedure achieves significant short and medium term % Excess Weight Loss (EWL) and % Total Body Weight Loss (TBWL), while maintaining a reasonable risk profile. It was a first that the ESG was also approved for use in adolescents suffering from obesity in the second degree, when conservative treatment has failed (Table. 1) [11].

Apart from the unique adolescent indication, many other associations have published homonymous indications for the ESG, recognizing its role in the treatment of obesity. ESG is FDA-cleared (U.S. Food and Drug Administration) and has recently received a HCPCS procedural code. It is considered a primary procedure for the treatment of obesity in Italy and as such is included in Italian guidelines – equivalent to other laparoscopic bariatric procedures -, and there is an evidence-based interventional procedure guideline from the National Institute for Health and Care Excellence (NICE) in the UK, to name but a few recognitions of this endoluminal procedure [12-15]. In general, the endoscopic procedure should be complemented by a multidisciplinary obesity program [11]. Following these indication definitions, a meta-analysis recently published as a position statement by the IFSO Endoscopy Committee endorsed ESG as a procedure that has its established role in the treatment algorithm of interventional obesity treatment worldwide. This meta-analysis is summa-

rized below [16]. IFSO Position Statement on Endoscopic Sleeve Gastroplasty for the Treatment of Obesity [16]. ESG has been the subject of more than 200 publications, including the Multicenter ESG. Randomized Interventional Trial (MERIT), demonstrating the consolidation of evidence for its efficacy and safety. The procedure is currently used worldwide, with more than 40,000 clinical procedures reported to date. In line with other societies, the Endoscopy Committee of the International Federation of the Surgery of Obesity and Related Diseases (IFSO) has published a comprehensive systematic review and meta-analysis as its position statement on ESG to officially endorse this procedure.

### 4. Methodology

Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Cochrane guidelines, the review primarily examined weight loss outcomes and safety data of ESG performed with the Overstitch™ platform (Boston Scientific, Marlborough, MA, USA). The underlying original paper describes the state-of-the-art methodology in a comprehensive and excellent way. The review included full-text articles in any language on ESG performed with the Overstitch™ device, but did not stipulate a specific suture pattern. Regardless of the study design, the sample size had to include at least 10 individuals. Finally, 44 articles, consisting of 29 case series, 14 cohort studies and one randomized controlled trial (RCT), were included (Figure 2). ESG results were extracted for inclusion in the non-comparative meta-analysis from cohort studies that compared ESG with either sleeve gastrectomy, lifestyle intervention, or ESG in combination with anti-obesity medication, to allow for above mentioned outcomes at specific time points (6, 12, 18, 24, 36, and 60 months) (Table 2, Figure 3). Using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach, the pooled evidence was graded into 4 categories, including very low, low, moderate and high.

## 5. Non-Comparative Results

Finally, the non-comparative analysis included 49,848 patients, of whom 15,714 underwent ESG compared to 34,134 control subjects. The majority were female (83.2%) The average baseline age and BMI were 44.24 years (SE 1.405, 95% CI 41.48-46.99; 41 articles, n=13,562) and 37.56 (SE 0.45, 95% CI 36.66-38.46; 42 articles, n=13,876), respectively. Serious adverse events occurred at a pooled rate of 1.25% (194 out of 15,398 procedures). Table 1 summarizes the weight loss results by time point after ESG. The maximum reported follow-up was five years (56 patients, 1 article) resulting in an excess weight loss (EWL) of 45% (standard deviation 47.32), corresponding to a total body weight loss (TBWL) of 16% (standard deviation 16.79).

## 6. Meta-Analysis

Eligible for quantitative synthesis and qualitative analysis were two studies comparing ESG with lifestyle interventions. A case-matched cohort study (2020) included patients with all degrees of obesity and compared ESG combined with low-intensity diet and lifestyle therapy (LIDLTL) with ESG and high-intensity diet and lifestyle therapy (HIDLTL). A total of 386 patients (105 ESG, 281 controls) with comparable baseline characteristics were enrolled, with final follow-up at one year. The cost of the interventions was borne by the patients. The other, a multi-center, FDA-regulated, open RCT included only patients with obesity grades I and II, comparing ESG plus lifestyle measures (85 patients) with lifestyle measures only (124 controls) (MERIT, 2022) [8]. As per the Cochrane Handbook, data from different study designs should not be combined when only a few eligible studies are available. Consequently, the data of both studies were analyzed separately. At 12 months, the case-matched cohort study showed a mean difference in %TBWL of 6.30 [95%CI 3.12-9.48] between the two groups. At the same time point, the RCT showed a mean difference in %EWL of 46.00 [95%CI 38.05-53.95] and a mean difference in %TBWL of 13.10 [95%CI 11.08-15.12]. The serious adverse event rate was 2%, with no associated mortality, need for intensive care or need for surgery.

## 7. Future Direction and Conclusion

The subsequent various approvals of the procedure were driven by the maturity of the technology and the regulatory approvals already achieved. Other endoluminal gastric remodelling techniques such as Primary Obesity Surgery Endoluminal (POSE) 2.0 (USGI Medical, San Clemente, CA), Endomina™ gastric plication (Endo Tools, Gosselies, Belgium) and the Endozip™ automated suturing device (Caesarea, Israel) are in various stages of clinical trials and evidence. All of these endoluminal suture devices have similar safety and efficacy profiles and will continue to evolve (17). As new clinical evidence emerges for these procedures, the IFSO Bariatric Endoscopy Committee will consider it in future revisions of its statement.

Recent advances in anti-obesity medication (AOM) suggest effective options for certain patients with obesity. Innovative therapies such as enteroendocrine-based agonists are rapidly emerging, although their long-term effects are not yet fully understood. The comparative efficacy of ESG versus MBS, particularly in combination with these pharmacotherapies, is an ongoing and promising area of research, as early observational studies have highlighted the benefits of combining or sequencing ESG with AOM. The initial results reported are particularly encouraging, specifically in terms of improving durability of response in the treatment of this chronic and relapsing disease [18]. To emphasize the importance of this procedure in its indication spectrum, an RCT comparing the effects of ESG with pharmacotherapy in adolescents - currently a unique indication, but with highly significant potential for the future - has recently begun recruiting patients under the leadership of the IRCAD (Institut de Recherche contre les Cancers de l'Appareil Digestif) in India [11,19]. In conclusion, however, the current literature, which typically includes follow-up data for five years or less, is not yet robust enough to understand all the long-term effects of ESG. As mentioned, any new methodology will have to stand the test of time and win over its critics before becoming widely accepted. The IFSO Bariatric Endoscopy Position Statement endorsing the procedure was an important step in this direction [16]. While these results suggest a promising future for future minimally invasive and much more personalized obesity therapies, there is still a long way to go. Improving durability of response is key to long-term treatment success, and personalized strategies based on a better understanding of the disease seem to be the winning approach of the future. It is also important to remember that endoscopy, including bariatric endoluminal therapy, is an interdisciplinary development by both surgeons and gastroenterologists. Given the breadth of knowledge required to treat obesity, non-competitive collaboration is ultimately the best way to advance the field of endoluminal therapies.

## 8. Acknowledgement

CS serves as chair of the IFSO (International Federation for the Surgery of Obesity and Related Diseases) Bariatric Endoscopy Committee and as president of BEWA (Bariatric Endoscopy World Association). She is writing on behalf of both, IFSO and BEWA. CS was also one author of the source meta-analysis. The comprehensive literature search is included in the original manuscript and consists of 76 articles.

## 9. Disclosure

CS has served as a consultant for Boston Scientific, USGI Medical, NovoNordisc, Johnson & Johnson, Lohmann & Rauscher, Morphic Medical, Trans.Duodenal.Concepts, and Cranax Medical Digestive. PT, the other author declared no conflict of interest.

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