Innovative Bariatric Procedures and Ethics in Bariatric Surgery

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ORIGINAL CONTRIBUTIONS

Innovative Bariatric Procedures and Ethics in Bariatric Surgery: the IFSO Position Statement

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Abstract
With the rise in obesity and bariatric procedures worldwide, there has been a surge in new and innovative procedures that has been increasingly offered to patients. In this position statement, IFSO highlights the importance of surgical ethics in innovation and when offering new procedures. Furthermore, the task force reviewed the current literature to describe which procedures can be offered as mainstream outside research protocols versus those that are still investigational and need further data.

Keywords IFSO · Position statement · Innovative procedures · Alternative procedures · Ethics in surgery · Ethics in bariatric surgery · Institutional review board (IRB)

Introduction

Over the past several years, worldwide, there has been considerable rise in the number of bariatric procedures performed. Most of the procedures were performed surgically, while endoluminal approaches constituted less than 5% of cases. The laparoscopic sleeve gastrectomy (LSG) and the Roux-en-Y gastric bypass (RYGB) were the most commonly performed procedures [1]. Recently, several new bariatric procedures have been offered to patients. Some of them were reported in the literature early and were adopted while risks and long-term outcomes were still lacking.

The current position statement aims to delineate guidelines for acceptability in novel procedures in metabolic and bariatric surgery (MBS) and to caution against some "alternative bariatric procedures" that do not meet the guidelines.

Innovation and Surgical Progress

Like other types of surgery, MBS is based on technical capabilities, knowledge, and judgment capacity, with the surgeon–patient relationship placed at the core of surgical ethics [2].

Throughout history, the defining parameter of surgical progress has been the reduction of morbidity and mortality. However, in recent years, other factors such as cosmesis, improved technical feasibility, and economic efficacy, including the development of surgical tools, have emerged in the new procedures' evaluation process [3].

Because MBS is a relatively new field aiming at benefitting a particular patient group, the scientific committee of IFSO will focus on those aspects that may differ from the characteristics of other types of surgery.

1. A systematic review revealed that surgical innovation overall revolves around four major themes: oversight, informed consent, learning curve, and vulnerable patient groups (https://www.surgeons.org/en/become-a-surge

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on/about-specialist-surgeons). The latter aspect is of particular importance in MBS.

Innovation in MBS

The Duty of the Surgeon to the Patient

1. Surgeons should demonstrate objectivity and compassion, placing patients' interests first and always respecting a patient's dignity, individuality, and autonomy, as stated in Hippocrates' oath (https://www.surgeons.org/en/become-a-surgeon/about-specialist-surgeons).

Hippocrates' Oath

I pledge to always act in the best interests of my patients, respecting their autonomy and rights.
I undertake to improve my knowledge and skills, evaluate and reflect on my performance.
I agree to continue learning and teaching for the benefit of my patients, my trainees, and my community.
I will be respectful of my colleagues, and readily offer them my assistance and support.
I will never allow considerations of financial reward, career advancement, or reputation to compromise my judgment or the care I provide.

Ethics in Innovative Procedures: the Declaration of Helsinki

In 1964, the Declaration of Helsinki was developed by members of the World Medical Association. Levine stated that the Declaration "adapted the principles of the Nuremberg Code to the existential realities of medical research [4]." Like the Code, it was considered the cornerstone document on human research ethics. Also, like the Code, it is not legally binding under international law. The fundamental principles of the declaration are respect for the volunteer and his/her right to make informed decisions. The welfare of the research subject is more important than the interests of science or society [5]. The declaration focused primarily on physicians. It mandates the physician to uphold the following statement: "The health of my patient will be my first consideration." In addition, ethical behavior must also include any publications and the potential conflict of interest. As opposed to the Nuremberg Code, which addressed all types of research, the declaration was focused on medical research to understand the causes, development, and effects of diseases and improve interventions [5]. The declaration was unique because it incorporated that research protocols might include components expected to benefit individual subjects directly [6].

The basic principles of the declaration were to conform to moral and scientific principles. Research projects should be conducted only by scientifically qualified researchers and based on sound laboratory and animal experiments. The objectives should be weighed against the risks, and caution should always be exercised to protect the participant [7].

Since its inception in 1964, the Declaration of Helsinki has undergone several revisions (the most recent was in 2013). These revisions increased the size of the document from 11 paragraphs in 1964 to 37 paragraphs in 2013.

The Declaration addressed clinical research but stated that doctors were obligated to obtain consent when possible, but research could occur without the volunteer's consent if a proxy consent from a legal guardian was available [4] (Table 1).

Implementation of Ethics in Innovative Procedures: Role of the Institutional Review Board (IRB) & Research Ethics Committees (REC)

The institutional review board is also known as the research ethics committee, ethical review board, or research ethics board depending on the country and region. For the purpose of this position statement, we will refer to all of the above as Institutional Review Board & Research Ethics Committees (IRB/REC).

The IRB/REC is part of the research enterprise designated to protect human subjects. The primary purpose of the IRB is to provide an independent review of research proposals to determine whether they fulfill ethical standards [8]. This protects investigators from potential conflicts between the investigators' concerns about the pursuit of knowledge and the welfare of human subjects. IRB/REC approval of a proposal is not a one-time event but an ongoing process that involves continual IRB/REC

Table 1 The Helsinki Declaration—basic principles

1	Conform to accepted scientific principles
2	Design formulated in experimental protocol, reviewed by an independent ethics committee
3	Conducted by qualified and trained persons
4	Importance in proportion to the inherent risk
5	Assessment of risks vs. benefits
6	Safeguard subject's integrity (privacy)
7	Abstain unless hazards are predictable
8	Preserve accuracy when publishing
9	Adequately inform or right to withdraw
10	Obtain valid informed consent in writing
11	Reliance on the legal guardian
12	State compliance with the declaration

oversight. The IRB/REC can suspend or terminate previously approved research (e.g., a study found to cause severe unexpected harm to the subjects or not conducted per IRB/REC requirements). The IRB/REC reevaluates ongoing research at an interval appropriate to the degree of risk of the research project. Once the study is approved, the investigator must conduct the study as approved by the IRB/REC and meet the regulatory requirements related to modifications, reporting unanticipated events, and continuing review [9].

For a research proposal to be approved, it must meet specific minimum requirements. The risk to the subjects must be minimized by using strict scientific research principles.

The proposal must establish that the risks are reasonable concerning anticipated benefits to the subjects. When weighing risks and benefits, the IRB/REC does not consider the possible long-range effects of applying knowledge gained in the research. The selection of subjects should be equitable and should avoid undue emphasis, if possible, on vulnerable populations. If a vulnerable population is approached and there is any possibility of coercion, the protocol should establish how to maintain human-subject protections.

The process for obtaining IRB/REC approval may seem intimidating. However, clinical investigators must research in a manner that protects human participants, and it is the mission of the IRB/REC to help them accomplish this task.

Implementation of Ethics in Innovative Procedure: Informed Consent

Background

The quality of care, safety, and patient outcomes during the process must be upheld at all costs. This means communicating effectively with patients or substitute decision-makers and being sensitive to different beliefs, backgrounds, values, and cultures that may influence a patient's understanding, decisions, or responses. No matter how minimal, any known risks must be disclosed to the patient. Healthcare providers have been urged to integrate patients more actively as partners in decisions. Such patient involvement is often considered to fall under a shared decision-making model where both patient and provider contribute to the decision [10, 11].

The surgeon must inform the patients of the new technique/procedure results from properly conducted trials from elsewhere and be upfront regarding any adverse outcomes that might occur. Ethically, the concept of informed consent arises from the right of individuals to decide what is or is not done to their bodies. Legally, the physician has two duties: to obtain consent and to provide evidence that the patient was sufficiently informed [12].

Patient Information

Before undergoing (innovative) bariatric/metabolic surgery, patients should be fully informed of the surgical risks, the surgeon's acquaintance with the innovative procedure as well as the short and long-term outcomes. Care should be taken to determine the appropriateness of the content and communication approaches to ensure patient understanding of the information.

Informed Consent

Although informed consent may be standard for all patients, under specific circumstances such as marginal indications or for procedures whose long-term outcomes may not be known, it is important to provide a more detailed discussion.

Risks vary by patient and provider characteristics. Therefore, informed consent should incorporate realistic projections of the short- and long-term risks, benefits, as well as consequences of surgery and alternatives to surgery, including the potential for weight regain and modest benefits. Patients need to be aware that not all pre-existing medical and psychosocial consequences of obesity will necessarily improve after surgery and should also recognize that good results require behavioral and dietary changes and that some consequences of weight loss surgery such as gastrointestinal symptoms, cosmetic effects, and nutritional restrictions that could affect their quality of life [13].

The education process should continue until the patient demonstrates comprehension of relevant material and concepts. Comprehension of surgery's risks, benefits, and consequences ensures realistic expectations, optimal decision-making, and good outcomes [14].

Vulnerable Population (Adolescents and Children)

There are several definitions available for the term "vulnerable population." It generally implies a disadvantaged sub-segment of the community requiring utmost care, specific ancillary considerations, and augmented protections in research [15]. Although the bariatric patient population should be regarded as a vulnerable population as a whole, the children and adolescents are a special subgroup of this population. What makes the bariatric patient population vulnerable is the fact that they have struggled with this chronic disease for several years and have tried various nonsurgical solutions with no success. The factors mentioned above make most patients willing to accept almost any offered surgical solution to their disease, even if the procedure they are undergoing is alternative or experimental.

Different country jurisdictions (and even states within the same country) allow adolescents to decide their medical treatments. However, most studies require parental or

guardian consent for children under the age of 18 (or 16 in some countries) before they may be included in the research study [16].

Although parental permission and child assent involve the same components of information sharing, comprehension, and voluntariness, how these components are understood and operationalized should differ depending on the developmental level of the child/adolescent. By understanding child assent and the essential protections of parental permission, child/adolescent assent does not need to be burdened with the same informational and process requirements. However, the researchers should not assume a lack of capacity, disregarding a child's/adolescent's wishes by failing to solicit meaningful assent or dissent [17].

In the field of MBS, surgeons have the moral obligation to ensure that the investigational procedure/technique/device has proven benefit and is appropriate for the patients. If proven beneficial, it is also incumbent upon the surgeon to acquire the appropriate knowledge and skills to apply the new procedures and/or technology [18].

In the application of investigational procedures/techniques, MB surgeons have the obligation to:

- Acknowledge the well-being of the individual patient as the paramount concern, regardless of the value of the research project.
- disclose any known risks to the patient and seek to minimize these risks.
- ensure that patients who participate in new/alternative procedures have given their written informed consent.

Conflict of Interest

All surgeons are responsible for maintaining their professional standards and performance, including their financial and commercial dealings regarding the quality of patient care, safety, and patient outcomes. Hence, surgeons must be aware of all related laws, regulations, and guidelines relevant to their field of practice in their hospital, university, institution, state, country, and college.

A conflict of interest in medical practice arises when a surgeon, entrusted with acting in the interests of a patient, also has financial, professional, or personal interests or relationships with third parties, which may affect their care of the patient [18].

A surgeon must not accept financial remuneration, either by way of money or goods or services, based solely or partly on the use or expectation of use, of medication, devices, or prostheses. This also refers to personal gain, be it in the form of status or academic position. The following overriding principles concerning new procedures, devices, or prostheses should be respected (adapted and modified from Australasian College of surgeons):

1. That the best interest of the patient(s) is paramount.
2. That surgeons conduct themselves with transparency and accountability.
3. Acknowledgement of perception of conflict of interest as an issue if any form of personal gain, whether financial, professional, or personal interests or relationships with third parties, may affect their care of the patient [18].

Surgical procedures will be considered investigational until the published medical evidence regarding their risks, benefits, and overall safety and efficacy are sufficient to regard them as established surgical practice. That evidence should derive from appropriately designed, peer-reviewed, published studies performed in different institutions to confirm their scientific validity and allow independent verification. IFSO will, in its publications at regular intervals, review the literature and decide if any of these procedures that are considered innovative or investigational has accumulated enough scientific evidence to be accepted as standard. Procedures considered investigational should be performed only with the specific review of a properly constituted Institutional Review Boards [19].

One of the recommendations of the IRB may be the incorporation of the patient qualifying for the investigational procedure into a clinical trial, preferably a randomized controlled trial (RCT) or into an "ad hoc" established registry, to help avoid the dissemination-first followed by the evidence-later approach [20].

A clinical trial is defined as a prospective scientific experiment involving human subjects in whom treatment is initiated to evaluate a therapeutic intervention. In an RCT, each patient is assigned to receive a specific treatment intervention by a chance mechanism.

Randomized controlled trials may not always be feasible to evaluate participative interventions. Moreover, randomization aims to ensure equal distribution of all factors, including motivational ones, among the two or more arms of a trial. This will not necessarily be achieved, mainly when the patient prefers one of the treatments. The pragmatic question of which treatment is more useful under what are judged to be optimal conditions of motivation should be considered a legitimate alternative to the explanatory, but a sometimes unrealistic, question of which is the best treatment per se. Investigators must be clear about which class of question each kind of trial can and cannot answer. Problems of interpretation are bound to arise when trials of participative treatments are hypothetically designed. Reactions to disappointment may introduce bias, leading the randomized groups to differ in ways other than the intended experimental contrast [21]. The lack of randomized trials in MBS may be attributable to the assumption that the invasive nature of the procedure precludes the design of methodologically sound and ethically appropriate trials [20]. Surgeons have defended the lack of randomized trials by "surgical exceptionalism," the view that the unique nature of the surgical discipline somehow allows for regulatory and ethical exceptions [22].

Investigational Versus Established Metabolic Bariatric Procedures

The history of Metabolic Bariatric Surgery (MBS), initially referred to as "Obesity Surgery," began in the 1950s with intestinal bypass procedures [23]. However, these operations were observed to result in significant long-term metabolic complications such as vitamin and mineral deficiencies, protein malnutrition, arthralgias, and liver cirrhosis.

The gastric bypass, introduced by Edward Mason in 1967, prevented most dangers of the intestinal bypass [24]. However, it was a formidable operative procedure that also carried a significant risk for developing life-threatening complications on its own [25]. Whereas the advent of laparoscopy improved the outcomes, other bariatric procedures emerged. Some have succeeded in becoming mainstay, such as the sleeve gastrectomy (LSG).

Roux-en-Y gastric bypass (RYGB) and the LSG are currently the most commonly performed MBS procedures globally, and both balance good safety profiles with excellent efficacy. Many novel procedures are currently under study. While it is prudent to respect the prerequisite of IRB acceptance for all procedure that diverges from widely accepted and practiced techniques, "divergence" from an existing technique must be defined. Divergence may pertain to the approach (endoscopic versus laparoscopic) or to the degree of anatomic variance.

Endoscopic Procedures

Multiple endoscopic bariatric procedures (EBPs) are currently being evaluated worldwide to fill an important gap in managing patients with obesity and metabolic diseases. A recent expert review based on a comprehensive search of several databases and a review of relevant publications on these therapies provides advice on how to incorporate them into clinical practice [26]. Below is an edited version of the recommendations:

a) EBPs should be considered in patients with obesity unsuccessful in losing or maintaining weight loss with lifestyle interventions.
b) EBPs can be used in patients with severe obesity as a bridge to traditional bariatric surgery or unrelated surgical interventions that cannot be performed due to weight limits, i.e., orthopedic surgery and organ transplantation.
c) Clinicians may utilize EBTs as part of a structured weight loss program that includes dietary intervention, exercise therapy, and behavior modification in the active weight loss phase and the long-term maintenance phase.
d) Clinicians should screen potential EBPs candidates with a comprehensive evaluation for medical conditions, comorbidities, and psychosocial or behavioral patterns that contribute to their condition.
e) Clinicians incorporating EBPs into their clinical practice should follow patients prospectively on weight loss, weight-related comorbidities, and related adverse outcomes.
f) Clinicians embarking on EBPs should have a comprehensive knowledge of the indications, contraindications, risks, benefits, and outcomes of the procedure and practical knowledge of the risks and benefits of alternative therapies for obesity.
g) Patients should be fully informed of the risks and benefits of the procedure, including real expectations on weight loss, control of comorbid conditions, and durability.

Single Anastomosis Duodeno-ileal Switch (SADI-S)

The SADI-S or one anastomosis duodenal switch was proposed in 2007 as a modification of the standard procedure. Theoretical benefits of the SADI-S over the DS include reducing the operative risk by eliminating one anastomosis while potentially achieving similar weight loss and health benefits. In an IFSO position paper published in 2020 [27], which included a review of 50 publications, the following conclusions were established:

a) SADI offers substantial weight loss that is maintained into the medium term.
b) The procedure provides improvements in metabolic health that are maintained into the medium term.
c) Nutritional deficiencies are emerging as long-term safety concerns, and patients undergoing this procedure need to be aware of this and counseled to stay in long-term multidisciplinary care.
d) Bariatric surgeons are encouraged to participate in national and international registries to facilitate the learning of the outcomes.
e) IFSO supports the SADI as a recognized bariatric and metabolic procedure but highly encourages Randomized Control Trials.

One Anastomosis Gastric Bypass (OAGB), Formerly Referred to as Mini Gastric Bypass (MGB)

The single-anastomosis gastric bypass (OAGB) has been proposed as a simpler but efficient weight loss surgery procedure like the RYGB. Controversies regarding the efficiency and risks of OAGB include an alleged critical malabsorptive component, a possible higher risk of nutritional complications, besides a higher incidence of bile reflux [28].

IFSO issued a position statement on OAGB in 2018 that was updated in 2020 [29, 30]. The 2020 task force undertook a new systematic review to provide up-to-date information to guide practice.

Abbreviated recommendations of the IFSO OAGB Taskforce [30]:

a) The outcomes from OAGB are promising in terms of short operative time, low perioperative complication rate, promising weight loss, and good comorbidities remission (T2DM, hypertension, obstructive sleep apnea, and dyslipidemia) and appear at least equivalent to other bariatric surgery procedures.
b) OAGB in the primary setting provides better weight loss, comorbidity reduction, and fewer complications compared to the outcomes when OAGB is performed as a revisional procedure. Patients should be aware of these differences if undertaking OAGB as a revisional procedure.
c) Due to the risk of underreporting of bile reflux and the time lag for carcinogenesis following OAGB, patients should remain under the care of their multidisciplinary bariatric team and have regular endoscopic examinations as per the IFSO position statement on endoscopy.
d) Bariatric surgery aims to produce long-term weight loss and control of associated comorbidities. OAGB has a relatively short operative time, low complication rate, promising weight loss, and comparative remission/improvement of obesity-related comorbidities, transforming the operation into an attractive option.
e) IFSO supports the OAGB as a recognized bariatric and metabolic procedure but highly encourages randomized control trials, preferably with long-term outcome assessment [31].

Sleeve Fundoplication Procedure

Since the first report of a laparoscopic Sleeve-Collis-Nissen gastroplasty in 2015 [32], multiple variations of the procedure aimed to produce a technique that would enable surgeons to offer LSG to patients with pre-existing reflux as an alternative to the "gold standard RYGB."

These variations include Sleeve-Collis-Nissen, Sleeve-anterior fundoplication, Sleeve Nissen, and Sleeve-Rossetti. We will refer to them as sleeve fundoplication (SF) procedures. Although SF has been shown to improve the lower esophageal sphincter's function and reduce acid exposure [33], SF procedures have been only reported in small series and need further evaluation [34] (Fig. 1).

Two major systematic reviews and meta-analyses examined the currently available evidence and reported outcomes of the SF procedure. Aiolfi et al. reviewed the outcomes of 6 studies published between 2015 and 2020. At 12 months of follow-up, the total reported data on 485 patients revealed an EBWL of 66.2%. There was a 9.8% complication rate, including a 2.9% perforation rate, 1% leak rate, and 4.1% reoperation rate. In terms of efficacy after 1 year, there was 8% esophagitis, 7.8% PPI use, and 11% GERD. They concluded that SF procedures have limited evidence and a high complication rate [35].

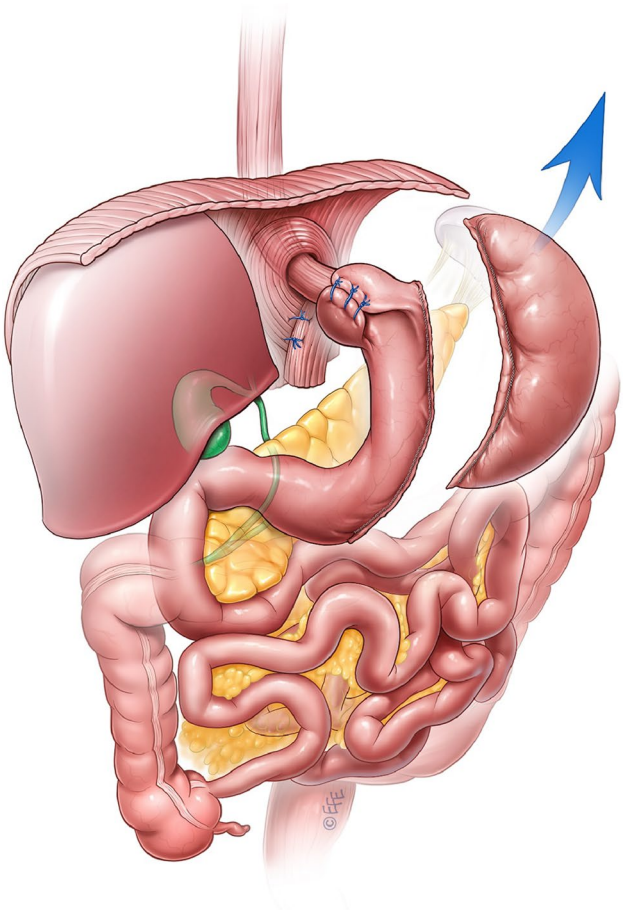

Fig. 1 Sleeve fundoplication namely the nissen sleeve

The second systematic review and meta-analysis by Carandina and colleagues examined the outcomes of 487 SF patients as reported in 7 studies. They also reported a 9.4% postoperative complication rate, with the most common complication being gastric perforation (3.1%). Interestingly, this meta-analysis reported the specific complication rate of each variation of the SF procedures. The complication rate was 5.7% for the Collis-Nissen, 11.2% for Nissen fundoplication, 3.2% for Dor, and 12.3% for the Nissen Rosetti [36].

All the available evidence regarding SF procedures comes from small series. The two meta-analyses and systematic reviews reported a high postoperative complication rate, lacking long-term weight loss outcomes. Furthermore, there are no randomized controlled trials to evaluate the efficacy and safety of SF procedures and their variations.

Nissen-P or Nissen Plication

A 2011 publication by Khazzaka et al. described the combination of laparoscopic fundoplication with gastric plication (LNP) in 16 patients concluded that this procedure provided reasonable control of GERD while offering a mean weight loss of 10 kgs at 1 year [37] (Fig. 2).

A publication by Lee et al. described the outcomes of 25 patients that underwent LNP at 6–18 months follow-up. Sixteen percent of patients had occasional regurgitation symptoms, and 17% still had evidence of erosive esophagitis. The percentage of excess body weight loss (%EBWL) was 18.1% at 12 months. These modest results came at the expense of 8% major postoperative complication rate [38]. Talha et al. reported 48.3% EBWL at 1 year in 18 patients at 17.7 months follow up [39].

Other authors attempted to document the efficacy of LNP by performing pre- and postoperative PH monitoring. Ospanove et al., in their 56 patients, reported that PH monitoring demonstrated that LNP is as effective as a Nissen fundoplication with more weight loss at 1 year [40]. Ivano et al. reported that LNP performed in 16 patients led to the decrease of DeMeester scores from 28.7 to 2.8. This study has 3 months of follow-up only [41].

Multiple concerns have been raised regarding this procedure. Firstly, the weight loss provided is slight and of questionable durability. Secondly, the mechanism of GERD resolution is unclear, and the efficacy of combining a fundoplication with a restrictive procedure is unknown. Thirdly, future revisions of LNP can be technically challenging [42].

The literature describing the LNP consists of a single-center, small series with very short follow-up. This procedure has several unanswered questions that raises caution.

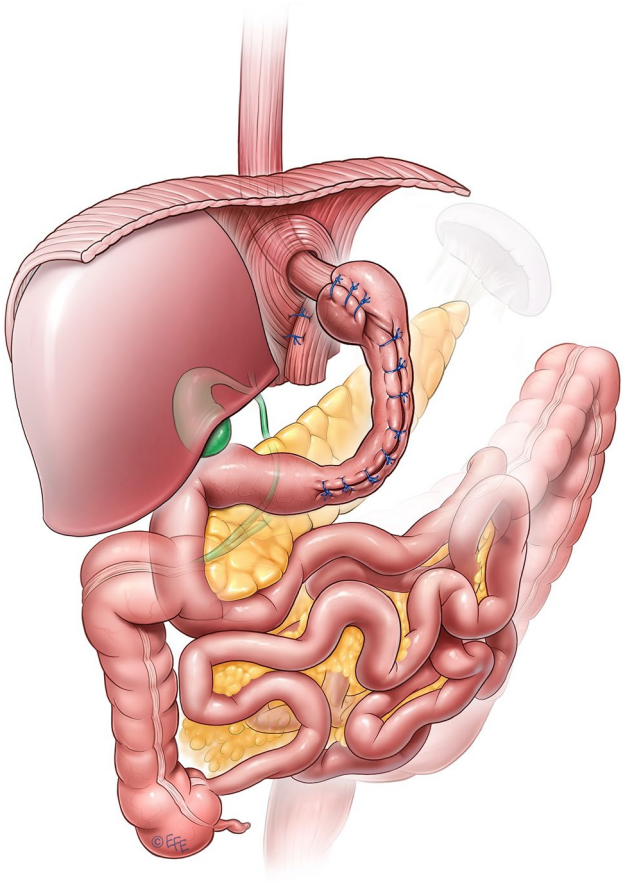

Fig. 2 Nissen plication or Nissen-P

Gastric Bipartition and Sleeve ileal Bypass (SASI)

Two of these new procedures are the standard gastric bipartition (GB) and a modification called the single anastomosis sleeve ileal bypass (SASI). These procedures are based on the theory that early diversion of some of the ingested food may alter gut hormones leading to improved weight loss and improvements in comorbid conditions.

Gastric Bipartition

The GB was introduced by Sanet al. et al. in 2012 [43]. It is also referred to as a sleeve gastrectomy with transit bipartition (LSG + TB). It is essentially a sleeve gastrectomy with an ileal Roux limb anastomosed to the gastric antrum. It is believed that while the majority of the food consumed will exit the sleeve through the pylorus (like all sleeves), some of the food will leave the sleeve via the gastroileostomy. The bipartition concept was initially developed as a metabolic procedure to treat diabetes mellitus (Fig. 3).

The theory behind these procedures is that patients with severe obesity may have an imbalance in the absorption of food, with more being absorbed proximally than distally, resulting in enterohormonal disturbances [43]. The bipartition would correct this imbalance. However, currently, there is no published evidence to confirm a gut hormonal imbalance in patients with severe obesity and that the bipartition corrects this imbalance.

In his study involving 1020 patients, Santoro et al. [43] reported a mean excess BMI lost at 5 years of 74%, and 86% of patients with diabetes were in remission. There were 2 deaths and a 6% surgical complication rate. However, follow-up was only 59% at 5 years.

Bilecik performed this procedure on 35 females with type 2 diabetes and severe obesity (mean BMI = 42.0 ± 1.3 kg/m2). Mean follow-up was 14.3 ± 2.8 months. They reported that the mean BMI decreased to 24.8 ± 1.6 kg/m^2. 88.6% of patients achieved diabetes remission. Additionally, 50% of patients were off of their statins [44].

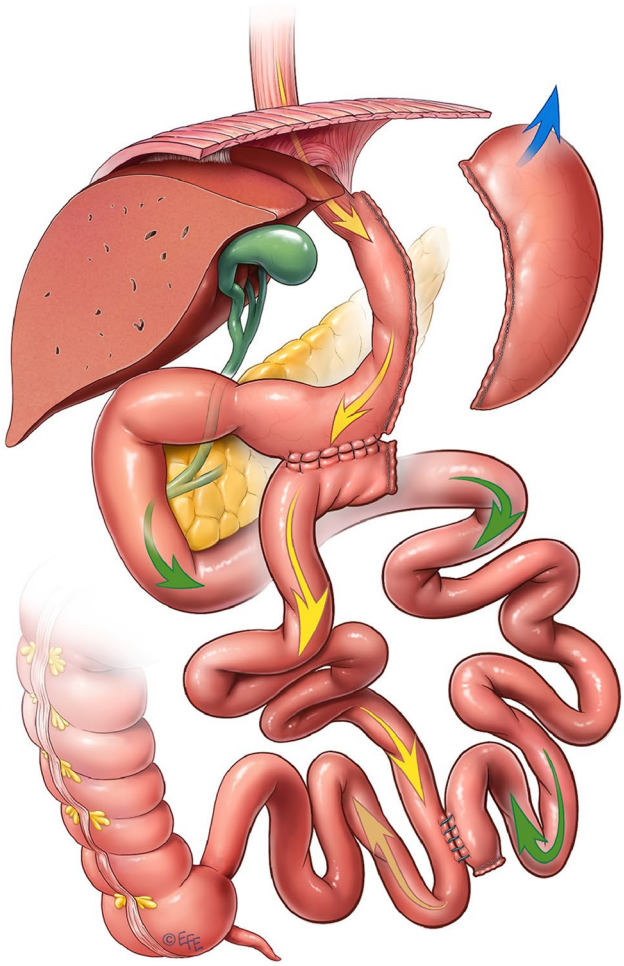

Fig. 3 Gastric bipartition

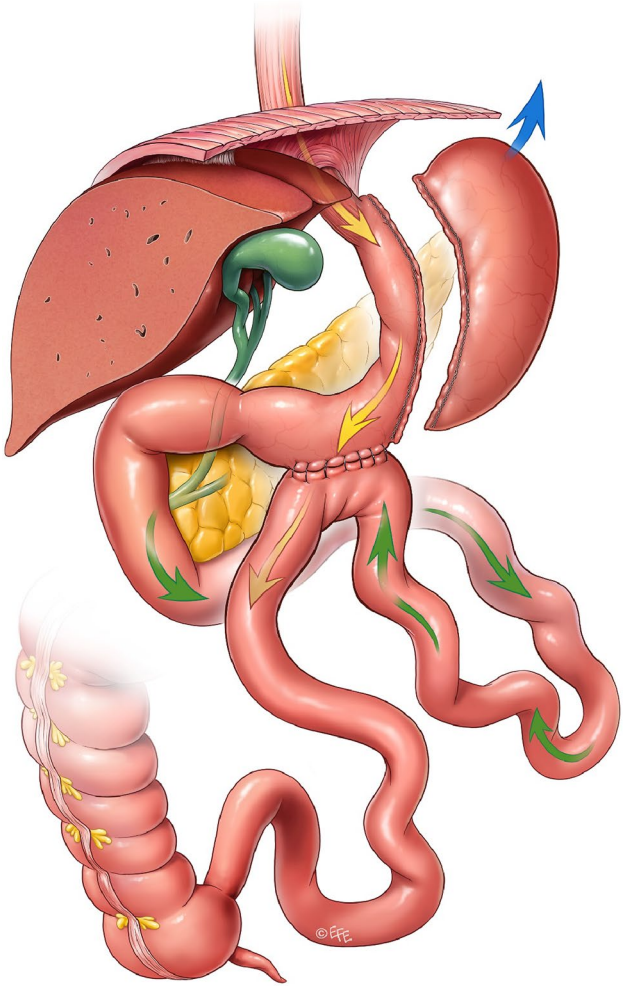

Fig. 4 Single anastomosis sleeve ileal bypass (SASI)

Single Anastomosis Sleeve Ileal Bypass (SASI)

In 2014, Mui et al. reported a modification of the procedure replacing the ileal roux limb for a loop but still constructing a gastroileostomy at the antrum. The ileum was run, and a 250-cm proximal to the ileal-cecal valve was chosen for the gastroileostomy [45]. Like the duodenal switch and the gastric bypass, replacing the roux limb with a loop is an attractive consideration as it eliminates the second anastomosis resulting in shorter operating time and a reduction in complications. The modified procedure was referred to as a sleeve gastrectomy with loop bipartition (LSG + LB) (Fig. 4).

In this case report, patient lost 97% of his excess weight in 12 months. He was off all of his medications by 2 months after surgery. However, gut hormones were not checked to validate the proposed mechanism of action.

In 2016, Mahdy et al. reported on a series of 50 patients with type 2 diabetes and severe obesity who underwent the LSG + LB procedure (now referred to as single anastomosis sleeve ileal bypass or SASI procedure) [46]. The preoperative mean BMI was 48.7 ± 7.6 kg/m^2. At 12-month follow-up, the mean %EBWL was 90%. By month three, all patients had normal blood glucose levels. There was an 86% remission of HTN, 100% remission of hypercholesterolemia, and 97% remission of hypertriglyceridemia. There were six postoperative complications (pulmonary embolus, hemorrhage, leak, SBO, marginal ulcer, and one patient requested a reversal). There were no significant vitamin, mineral, or protein deficiencies.

In a follow-up study, Mahdy et al. compared SASI results with the LSG and the one anastomosis gastric bypass (OAGB) [47]. The study enrolled 264 patients with diabetes and severe obesity. Ninety- nine patients had sleeves, 91 patients had OAGB, and 74 underwent SASI. The study was not a randomized controlled study. At 12 months follow-up, the SASI resulted in better weight loss. The mean %EBWL for the sleeve = 72.5 ± 33.9, OAGB = 65.9 ± 25.1, SASI = 79.5 ± 15.6, ($p < 0.0001$) and a significantly higher

rate of improvement in type 2 diabetes (97.7% for SASI vs. 71.4% for SG and 86.7% for OAGB, $p = 0.04$).

However, the SASI procedure had the highest short-term and long-term complication rates (i.e., long-term complications = sleeve 2%, OAGB 9.8%, SASI 14.9%). Lastly, The SASI also had the highest rate of hypoproteinemia, 9 patients.

Recently, Emile et al. performed a systematic review of the published literature on the SASI procedure [48]. The review evaluated 10 studies, including 941 patients. However, over 600 of the patients came from one program. The medium preoperative BMI was 45.6 (43.2–58.3) kg/m^2. The investigators found that at 12 months, the median excess weight loss was 90.1%. However, there was significant variation with the 12-month weight loss ranging from 65 to 94% of excess body weight. There also was improvement noted in several comorbid conditions. 98.1% of the diabetic patients experienced complete or partial improvement. The complication rate was 12.3%.

The SASI procedure is an interesting BMS operation that has achieved good weight loss and resolution of the obesity-related comorbid conditions, possibly better than the sleeve or gastric bypass. However, it currently lacks validation. The published data is scarce, and most of it comes from a single BMS program and surgeon. In addition, there is no long-term data as most studies only report 12-month follow-ups. There are currently no randomized controlled trials, so patient selection introduces significant bias. Lastly, there is no proof that an enterohormonal imbalance is related to obesity or that the bipartition corrects any imbalance. This procedure may achieve excellent results solely on the basics that it is a malabsorptive procedure.

Sleeve Gastrectomy Associated Duodeno-Jejunal Bypass (LSG-DJB)

The LSG-DJB was introduced by Kasama et al. in 2009 to treat obesity and metabolic disorders as an alternative to RYGB [49]. The procedure was adopted for its restrictive and malabsorptive effects and to negate having an excluded stomach for countries with a high incidence of gastric cancers, such as Japan. Pylorus preservation in LSG-DJB reduces the incidence of gastro-jejunostomy stenosis and the dumping syndrome compared to the RYGB [50]. In the LSG-DJB procedures, the small bowel is counted from the ligament of Treitz rather than the ileocecal valve; thus, it is more proximal and less intestine is bypassed compared to the duodenal switch procedures (Fig. 5).

The 5-year (medium-term) results by Seki and Kasama [51] reported a mean percent of total body weight loss (%TWL) 30.7% and remission of T2DM at 63.6%. In a randomized trial in 2012 by Praveen et al. [52] with 58 patients randomized either to LSG-DJB or RYGB, weight loss at the end of 12 months between the groups was not statistically significant. The operating times were higher in the SG-DJB group. The rate of resolutions of diabetes, hypertension, and dyslipidaemias was also similar with no statistical significance. In another study conducted in 2014 on 1-year outcomes on 1-year outcomes, Lee et al. found that adding DJB to LSG raised EBWL by up to 20% (to 87.2% EWL) [53].

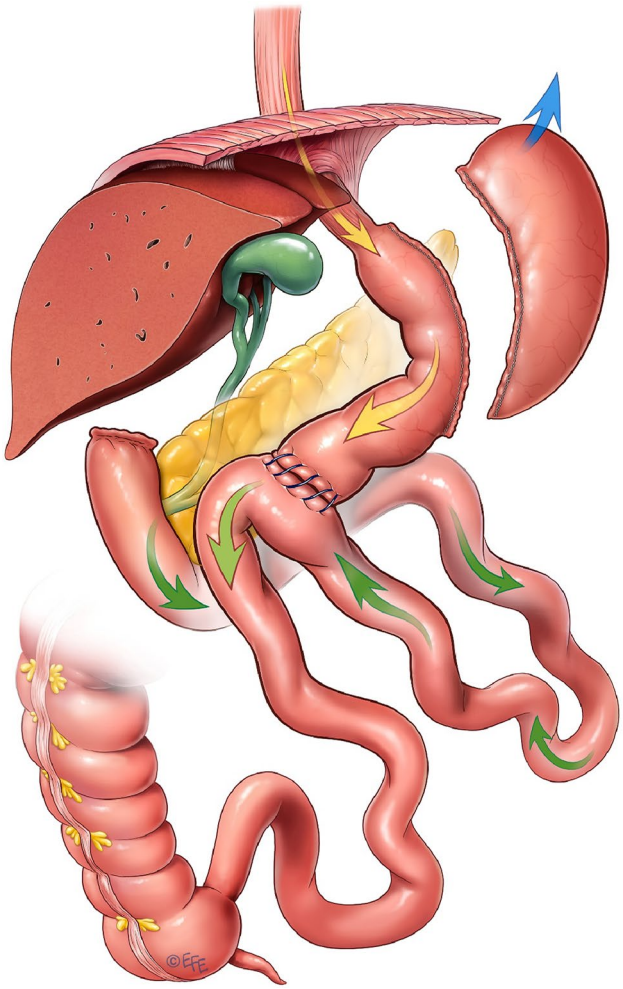

Fig. 5 Sleeve gastrectomy associated duodeno-jejunal bypass (LSG-DJB)

Most recently, a 2018 multicenter comparison study by Naitoh and Kasama reported that LSG-DJB ($n = 121$) resulted in significant weight loss 67% EWL when compared to LSG ($n = 177$) 59.4% at 1 year in patients with obesity and diabetes. Diabetes remission rate at 12 months after surgery was 80.8% for LSG and 86.0% for SG-DJB. In addition, SG-DJB is more effective in reducing T2DM in patients with lower BMI [54].

The LSG-DJB seems to offer the benefits of the RYGB while not leaving an excluded stomach. It was based on the same physiological hypothesis of RYGB rather than new unfounded data.

Sleeve Gastrectomy with Jejunoileal Bypass

In 2012, Melissas et al. reported a novel procedure that combined LSG with side-to-side jejunoileal bypass. The procedure was performed by forming a looped anastomosis between the jejunum (100 cm distal the ligament of Treitz) and the terminal ileum (100 cm proximal to the ileocecal valve) [55].

The authors reported the outcomes of 32 patients that were followed for 6–24 months post-operatively. Although this procedure offered better %EBWL and diabetes resolution than LSG, it was associated with long-term complications requiring surgical revision such as intestinal obstruction, nausea, vomiting, and hypoalbuminemia [55]. This procedure was based on the theoretical belief that it will increase the transit time, thus increasing satiety and the postprandial incretin response [55].

In 2016, Hassn et al. modified the technique by performing a LSG and dividing the small bowel 75 cm from the ligament of Treitz and anastomosing it 75 cm proximal to the ileocecal valve. They reported that in 168 patients, an EBWL of 77% was achieved at a median of 4 years follow-up. On follow-up, although no patients developed hypoproteinemia, 2.4% of patients developed intussusception of the blind loop, 20.8% had hypocalcemia, and bowel movements averaged at 1 to 2 per day [56] (Fig. 6).

These procedures seem to replicate the outcomes of jejunoileal bypass of the 1960s and 1970s, which provided excellent weight loss results by creating surgical short bowel syndrome. However, it was abandoned due to severe complications of this procedure, starting from renal stones, gall stones, malnutrition, fatigue, renal failure, liver failure, and even death [57].

Ileal Interposition with Sleeve Gastrectomy

Multiple animal studies demonstrated the effectiveness of ileal interposition through different mechanisms. As a result, different techniques emerged. Mainly, ileal interposition with sleeve (LSG-II) gastrectomy, and ileal interposition with sleeve gastrectomy and duodenal exclusion or diverted sleeve gastrectomy (DSG-II) [58] (Fig. 7).

DePaula et al. reported the outcome of DSG-II for the treatment of T2DM in 69 non-obese patients. With a mean follow-up of 21.7 months, 62.5% achieved HbA1C < 6%. This publication reported short-term efficacy despite a 7.3% major postoperative complication rate [59].

Celik et al. also reported the outcomes of 360 of DSG-II with a mean of 12.4 months of follow-up. A postoperative complication rate of 6.1% was reported (leak and bleeding

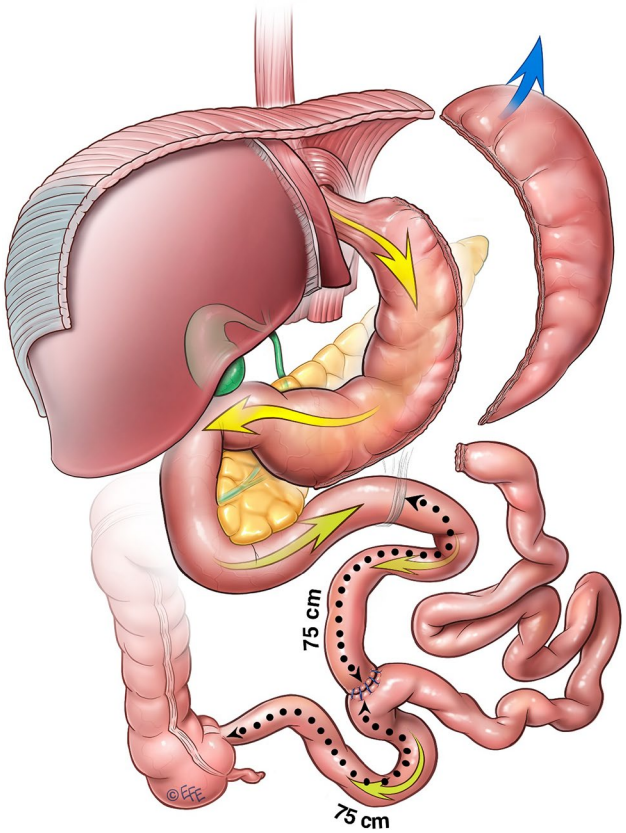

Fig. 6 Sleeve gastrectomy with jejunoileal bypass

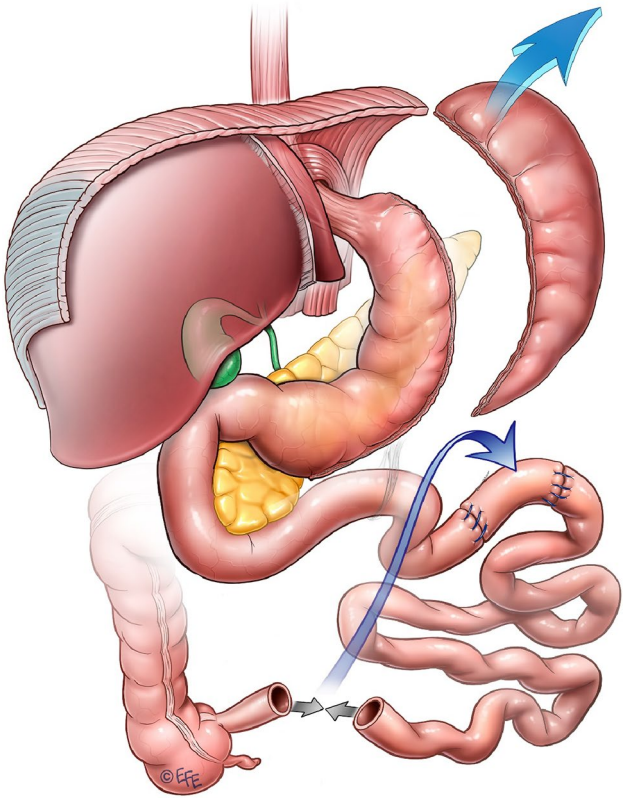

Fig. 7 Ileal interposition with sleeve gastrectomy

being the most common), including a 3.05% neurological complication rate [60].

Short- to midterm outcomes of LSG-II in T2DM in 30 patients revealed significantly reduced HbA1C and fasting glucose levels at 6–18 months of follow-up. The remission rate was 80% over the follow-up period [61].

These operations are offered to patients based on the hypothesis that these operations work by applying the "ileal brake" concept. It is also hypothesized that the stimulation of this ileal segment eliminates the need for the cognitive control of eating behavior while also eliminating the risk of malabsorption or the need for vitamin supplementation [62]. Despite this methodology of thinking, nutritional deficiencies such as foot drop due to B1 deficiency and chronic diarrhea have been reported [63].

It is important to highlight that the risk–benefit ratio of these procedures is not known. They are complex and include a long staple line and anything between three to five small bowel anastomosis, duodenal stump, and multiple mesenteric defects [64]. Furthermore, the most comprehensive follow-up data is shorter than 2 years. Thus, it would be difficult to recommend this procedure as a standard bariatric procedure.

Conclusions and Recommendations

- Surgical ethics should be the cornerstone of every metabolic-bariatric surgeon's practice and, consequently, every IFSO member. Surgeons should not aim only to reduce morbidity and mortality, but it is their duty to ensure that the procedures they offer are safe, scientifically valid, and have proven long-term efficacy.
- The metabolic-bariatric surgeon must act in the patient's best interest while providing clinical care consistent with the prevailing standard of metabolic-bariatric surgery.
- Research is a vital part of bariatric surgery. Although new procedures and emerging technologies are constantly made available to the surgical community, the patient's well-being should remain the ultimate goal of procedural changes.
- The Declaration of Helsinki should be the standard followed by all surgeons offering investigational bariatric procedures to their patients. The surgeon has to make sure that IRB approval is obtained, and patients are well informed, consented, and retain their right to withdraw from any trial.
- IRB/REC should oversee such trials and procedures, and their role must be of continuous evaluation throughout the study period.
- While assessing their assent and dissent, special care must be given to vulnerable patient populations (children/adolescents).
- The difficulty in conducting randomized controlled trials in surgery and "surgical exceptionalism" should not give a free pass to surgeons to design and apply new and alternative bariatric procedures to patients without the proper approvals, animal studies, and primary science evidence. Registries, whether nationwide or worldwide, are key in studying the effects of surgical procedures.
- Surgeons are responsible for keeping their professional standards and performance, including their financial and commercial dealings. A conflict of interest can be financial, professional, or personal interests or relationships with third parties. This includes popularizing a new procedure or device to gain academic status (networking, advancing one's own name, presentations, and publications).
- New or alternative bariatric procedures will be considered innovative or investigational until the published medical evidence regarding their risks, benefits, and overall safety and efficacy are sufficient to regard them as established surgical practice.
- During emergency or revisional procedures, aiming the best outcomes for individual patients, the anatomy might be constructed in an unusual manner due to intraoperative limitations. Thus, this should not be considered innovative or investigational.
- Long-term nutritional consequences of investigational BMS procedures must be carefully investigated and reported once more efficacy and safety data are available for each specific procedure.
- IFSO will, in its publications at regular intervals, review the literature and decide if any of these procedures that are considered experimental or investigational has accumulated enough scientific evidence to be accepted as standard. Procedures considered innovative or investigational should be performed only with the specific review of a properly constituted IRB.

Alternative bariatric procedures recommendations

1. EBPs can be offered to patients that are suitable candidates. Counseling regarding risks and benefits regarding realistic weight loss expectations should be thoroughly provided. Long-term efficacy data are currently lacking. It is highly recommended to use RCTs and participation in registries to provide long-term data.
2. SF procedures have a high postoperative complication rate, and long-term weight loss outcomes are lacking. No RCTs are addressing their efficacy. It is recommended that SF procedures are only offered under IRB

and research protocol until further efficacy and safety data are available.

3. LNP data consists of a single-center, small series with very short follow-up. Its efficacy is unknown whether in controlling GERD or providing weight loss. Future revisions are technique challenging. If this procedure is to be offered, it should be done under IRB and research protocol until further efficacy and safety data are available.

4. Gastric bipartition and SASI currently have no RCTs, and there is no proof that an enterohormonal imbalance related to obesity is corrected by those procedures. It is recommended that they should be only offered under IRB and research protocols until further efficacy and safety data are available.

5. The LSG-DJB seems to offer the benefits of the RYGB while not leaving an excluded stomach. It was based on the same physiological hypothesis of RYGB rather than new unfounded data. It eventually can be offered to patients at a high risk of leaving an excluded stomach. Long-term efficacy data is pending.

6. The sleeve gastrectomy with jejunoileal bypass was based on the unproven hypothesis that it will increase the transit time, thus increasing satiety and incretin response postprandially. These procedures seem to set the patient up for the same complications of jejunoileal bypass of the 1960s and 1970s. It is recommended that this procedure can only be offered under IRB and research protocols until further efficacy and safety data are available.

7. As per the SADI position statement, IFSO supports the SADI as a recognized bariatric and metabolic procedure but highly encourages RCTs and participation in registries to provide long-term data.

8. As per the OAGB position statement, IFSO supports the OAGB as a recognized bariatric and metabolic procedure but highly encourages RCTs and participation in registries to provide long-term data.

9. The LSG-II has no documented risk–benefit data or long-term outcome data. It is based on the hypothetical unproven concept that the "ileal brake" controls cognitive eating behavior. It is recommended that this procedure can only be offered under IRB and research protocols until further efficacy and safety data are available.

Declarations

Informed Consent For this type of study, formal consent is not required.

Conflict of Interest Miguel Herrera and Lilian Kow do not have any conflict of interests. Ashraf Haddad is a speaker for Medtronic and EZsurg medical. Ricardo V Cohen reports Research Grant, Johnson&Johnson, Research Grant Medtronic, Research Grant, GI Dynamics. Speaker Johnson&Johnson, Medtronic, GI Dynamics, Jansen. SAB: GI Dynamics, NovoNordisk, Bariatek. Scott Shikora is the Editor-in-Chief of Obesity Surgery Journal.

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