

# BARIATRIC SURGERY

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Table of Contents	Page
<a href="#">INSTRUCTIONS FOR USE</a> .....	1
<a href="#">CONDITIONS OF COVERAGE</a> .....	1
<a href="#">BENEFIT CONSIDERATIONS</a> .....	2
<a href="#">COVERAGE RATIONALE</a> .....	2
<a href="#">DEFINITIONS</a> .....	4
<a href="#">APPLICABLE CODES</a> .....	4
<a href="#">DESCRIPTION OF SERVICES</a> .....	6
<a href="#">CLINICAL EVIDENCE</a> .....	9
<a href="#">U.S. FOOD AND DRUG ADMINISTRATION</a> .....	38
<a href="#">REFERENCES</a> .....	39
<a href="#">POLICY HISTORY/REVISION INFORMATION</a> .....	47

## Related Policies

- [Minimally Invasive Procedures for Gastroesophageal Reflux Disease \(GERD\)](#)
- [Obstructive Sleep Apnea Treatment](#)
- [Robotic Assisted Surgery](#)

## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

## CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes <sup>2, 3</sup>
Precertification with Medical Director Review Required	No <sup>1, 2</sup>
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Inpatient, Outpatient, Office
Special Considerations	<p><sup>1</sup>Medical Director Review is required for CPT codes:, 43647-43648, 43659, 43881-43882, 43999, 64590, and 95980-95982 and HCPCS codes 0312T, 0313T, 0314T, 0315T, 0316T, and 0317T.</p> <p><sup>2</sup>All other procedure codes in this policy require precertification and review by a Medical Director or their</p>

Special Considerations  
(continued)

designee.

<sup>3</sup>Precertification is required for services covered under the Member's General Benefits package when performed in the office of a participating provider. For Commercial plans, precertification is not required, but is encouraged for out-of-network services performed in the office that are covered under the Member's General Benefits package. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.

## BENEFIT CONSIDERATIONS

Most Certificates of Coverage and many Summary Plan Descriptions explicitly exclude benefit coverage for bariatric surgery.

Some states may require coverage for bariatric surgery. Please refer to the member specific benefit plan document to determine availability of benefits for these procedures. As in all benefit adjudication, state legislated mandates must be followed. Therefore, the applicable state specific requirements and the member specific benefit plan document must be reviewed to determine what benefits, if any, exist for bariatric surgery.

### **Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

## COVERAGE RATIONALE

### **The following bariatric surgical procedures are proven and/or medically necessary in adults for treating Extreme Obesity:**

- Gastric bypass (Roux-en-Y; gastrojejunal anastomosis)
- Adjustable gastric banding (laparoscopic adjustable silicone gastric banding) – See the [U.S. Food and Drug Administration](#) section
- Gastric sleeve procedure (also known as laparoscopic vertical gastrectomy or laparoscopic sleeve gastrectomy)
- Vertical banded gastroplasty (gastric banding; gastric stapling)
- Biliopancreatic bypass (Scopinaro procedure)
- Biliopancreatic diversion with duodenal switch

### **Bariatric surgery using one of the procedures identified above (primary, secondary or revisions), for treating obesity is proven and/or medically necessary when all of the following criteria are met:**

- Class III obesity, (Extreme Obesity), [Body Mass Index (BMI) > 40 kg/m<sup>2</sup>]; **or**
  - Class II obesity (BMI 35-39.9 kg/m<sup>2</sup>) in the presence of one or more of the following co-morbidities:
    - Type 2 diabetes; **or**
    - Cardiovascular disease (e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy); **or**
    - History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; **or**
    - [Obstructive Sleep Apnea \(OSA\)](#) confirmed on polysomnography with an AHI or RDI of  $\geq 30$ ; **or**
    - History of cardiomyopathy
- and**
- The individual must also meet the following criteria:
    - Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; **and**
    - Psychosocial behavioral evaluation to provide screening and identification of risk factors or potential post-operative challenges that may contribute to a poor post-operative outcome.

**The bariatric surgical procedures identified above are proven and/or medically necessary in adolescents for treating Extreme Obesity and who have:**

- Achieved greater than 95% of estimated adult height based on documented individual growth pattern; **and**
  - A minimum Tanner stage of 4; **and**
  - Meet the following medical necessity criteria:
    - Class III obesity ([Extreme Obesity](#)) [Body Mass Index (BMI) > 40 kg/m<sup>2</sup>] with mild [Obstructive Sleep Apnea](#); or
    - Class II obesity (BMI 35-39.9 kg/m<sup>2</sup>) in the presence of one or more of the following co-morbidities:
      - Type 2 diabetes; or
      - Cardiovascular disease (e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy); or
      - History of coronary artery disease with a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty; or
      - BMI 35-39.9 kg/m<sup>2</sup> with moderate to severe [Obstructive Sleep Apnea](#); or
      - History of cardiomyopathy
- and**
- The individual must also meet the following criteria:
    - Documentation of a motivated attempt of weight loss through a structured diet program, prior to bariatric surgery, which includes physician or other health care provider notes and/or diet or weight loss logs from a structured weight loss program for a minimum of 6 months; and
    - Psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential post-operative challenges that may contribute to a poor post-operative outcome.

**Note:** See additional information in the Description of Services section for [growth and BMI charts](#).

**Bariatric surgical procedures in a person who has not attained an adult level of physical development and maturation are unproven and/or not medically necessary.**

Potential safety issues must be addressed in studies with sufficient sample size and adequate follow-up times necessary to demonstrate the impact of the surgery on physical, sexual and reproductive maturation and the long-term improvement of co-morbidities in this age group.

**Bariatric surgery as the primary treatment for gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence, gastroesophageal reflux (including for Barrett's esophagus or gastroparesis) or other obesity associated diseases that generally do not lead to life threatening consequences is unproven and/or not medically necessary.**

There is insufficient published clinical evidence to support bariatric surgery for the definitive treatment of gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as a treatment for gastroesophageal reflux and other obesity associated diseases. Bariatric surgery will frequently ameliorate symptoms of these co-morbidities; however, the primary purpose of bariatric surgery in obese persons is to achieve weight loss.

**Robotic assisted gastric bypass surgery is proven and/or medically necessary as equivalent but not superior to other types of minimally invasive bariatric surgery.**

**Surgical adjustment or alteration of a prior bariatric procedure is proven and/or medically necessary for complications of the original surgery, such as stricture, obstruction, pouch dilatation, erosion, band slippage when the complication causes abdominal pain, inability to eat or drink or causes vomiting of prescribed meals.**

**The following procedures are unproven and/or not medically necessary for treating obesity:**

- Transoral endoscopic surgery
- Mini-gastric bypass (MGB) or laparoscopic mini-gastric bypass (LMGBP)
- Gastric electrical stimulation with an implantable gastric stimulator (IGS)
- VBLOC<sup>®</sup> vagal blocking therapy
- Intra-gastric balloon
- Laparoscopic greater curvature plication, also known as total gastric vertical plication
- Stomach aspiration therapy (AspireAssist<sup>®</sup>)
- Bariatric artery embolization (BAE)

Further studies are needed to determine the safety and efficacy of these procedures as a treatment option for obesity.

**Gastrointestinal liners (EndoBarrier<sup>®</sup>) are investigational, unproven and/or not medically necessary for treating obesity.**

Gastrointestinal liners have not received FDA approval. Their long-term efficacy has not been demonstrated.

## DEFINITIONS

**Body Mass Index (BMI):** A person's weight in kilograms divided by the square of height in meters. BMI can be used as a screening tool but is not diagnostic of the body fatness or health of an individual (Centers for Disease Control and Prevention [CDC], 2015).

The National Heart, Lung and Blood Institute (NHLBI) (Jensen et al., 2013) classifies the ranges of BMI in adults as follows:

- <18.5 - Underweight
- 18.5 to 24.9 kg/m<sup>2</sup> - Normal Weight
- 25-29.9 kg/m<sup>2</sup> - Overweight
- 30-34.9 kg/m<sup>2</sup> - Obesity Class I
- 35-39.9 kg/m<sup>2</sup> - Obesity Class II
- > 40 kg/m<sup>2</sup> - Extreme Obesity Class III

**Extreme Obesity:** Having a Body Mass Index (BMI) of  $\geq 40$  kg/m<sup>2</sup>; also referred to as Class III obesity (NHLBI, 2016). **Note:** The term "morbid obesity" is equivalent to Extreme Obesity.

### **Obstructive Sleep Apnea (OSA):**

The American Academy of Sleep Medicine (AASM) defines Obstructive Sleep Apnea as a sleep related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe.

OSA severity is defined as:

- Mild for AHI or RDI  $\geq 5$  and  $< 15$
- Moderate for AHI or RDI  $\geq 15$  and  $\leq 30$
- Severe for AHI or RDI  $> 30$ /hr

For additional information see the medical policy titled "Obstructive Sleep Apnea Treatment."

## APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

**Coding Clarification:** Utilize CPT code 43775 to report laparoscopic sleeve gastrectomy rather than the unlisted CPT code 43659.

CPT Code	Description
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum

CPT Code	Description
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
43999	Unlisted procedure, stomach
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95980	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming

CPT Code	Description
95982	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

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## DESCRIPTION OF SERVICES

### **Obesity**

Obesity and weight are defined clinically using the [Body Mass Index](#) (BMI). Obesity is a significant health concern due to its high prevalence and associated health risks.

Health consequences associated with obesity include hypertension, Type II diabetes, hyperlipidemia, atherosclerosis, heart disease, stroke, diseases of the gallbladder, osteoarthritis, certain types of cancer, Obstructive Sleep Apnea and respiratory problems. In addition, certain cancers are more prevalent in obese individuals, including endometrial, ovarian, breast, prostate, colon cancer, renal cell carcinoma, and non-Hodgkin's lymphoma.

The U.S. Preventive Services Task Force (USPSTF) recommends screening all adults for obesity. Clinicians should offer or refer patients with a BMI of 30 kg/m<sup>2</sup> or higher to intensive, multicomponent behavioral interventions (USPSTF, 2012).

Results from the 2011–2012 National Center for Health Statistics' National Health and Nutrition Examination Survey (NHANES) indicate that an estimated 33.9% of U.S. adults aged 20 and over are overweight, 35.1% are obese, and 6.4% are extremely obese (Fryar et al., 2014).

The NHLBI Obesity Expert Panel (2013) estimates that 8.1% of women, and 4.4% of men in the U.S. population has a BMI over 40. The NHLBI clarified that the term Class III or Extreme Obesity has replaced the term "morbid obesity." The American Society for Metabolic and Bariatric Surgery (2016) estimates there were over 196,000 bariatric surgery procedures in 2015.

### **Bariatric Surgery in the Pediatric and Adolescent Population**

For adolescents, physical development and maturation may be determined utilizing the gender specific growth chart and BMI chart developed by the Centers for Disease Control and Prevention, National Center for Health Statistics (2000).



Male Growth Chart



Female Growth Chart



Male BMI Chart



Female BMI Chart

Estimated adult height may also be calculated utilizing the Mid-Parental height calculation (FP Notebook, 2015):

#### **Boy**

- In:  $(\text{Father's Height} + \text{Mother's Height} + 5) / 2$
- Cm:  $(\text{Father's Height} + \text{Mother's Height} + 13) / 2$

#### **Girl**

- In:  $(\text{Father's Height} - 5 + \text{Mother's Height}) / 2$
- Cm:  $(\text{Father's Height} - 13 + \text{Mother's Height}) / 2$

Tanner stages are as follows (CGF, 2010):

Tanner Stage	Male	Female	Pubic Hair (Male and Female)
I	Prepubertal	Prepubertal	Prepubertal (can see vellus hair similar to abdominal wall)
II	Enlargement of scrotum and testes; scrotum skin reddens and changes in texture	Breast bud stage with elevation of breast and papilla; enlargement of areola	Sparse growth of long, slightly pigmented hair, straight or curled, at base of penis or along labia

III	Enlargement of penis (length at first); further growth of testes	Further enlargement of breast and areola; no separation of their contour	Darker, coarser and more curled hair, spreading sparsely over junction of pubes
IV	Increased size of penis with growth in breadth and development of glans; testes and scrotum larger, scrotum skin darker	Areola and papilla form a secondary mound above level of breast	Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
V	Adult genitalia	Mature stage: projection of papilla only, related to recession of areola	Adult in type and quantity, with horizontal distribution ("feminine")

### **First-line Treatments for Obesity**

First-line treatments for obesity include dietary therapy, physical activity, behavior modification, and medication management; all of which have generally been unsuccessful in long-term weight management for obese individuals (Lannoo and Dillemans, 2014).

### **Bariatric Surgical Procedures**

Surgical treatment of obesity offers two main weight-loss approaches: restrictive and malabsorptive. Restrictive methods are intended to cause weight loss by restricting the amount of food that can be consumed by reducing the size of the stomach. Malabsorptive methods are intended to cause weight loss by limiting the amount of food that is absorbed from the intestines into the body. A procedure can have restrictive features, malabsorptive features, or both. The surgical approach can be open or laparoscopic. The clinical decision on which surgical procedure to use is made based on a medical assessment of the patient's unique situation. All of the referenced procedures may be performed by open or laparoscopic technique.

#### ***Roux-en-y Bypass (RYGB)/Gastric Bypass***

The most commonly performed restrictive approach is the Roux-en-Y bypass (RYGB), which combines gastric restrictive and malabsorptive features. Use of the term "gastric bypass" typically refers to RYGB.

The RYGB procedure involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, bypassing a large part of the stomach and duodenum.

#### ***Laparoscopic Adjustable Gastric Banding (LAGB)***

The laparoscopic adjustable gastric banding procedure involves placing an inflatable silicone band around the upper portion of the stomach. The silicone band contains a saline reservoir that can be filled or emptied under fluoroscopic guidance to change the caliber of the gastric opening.

#### ***Vertical Sleeve Gastrectomy (VSG)***

VSG can be performed as part of a two-staged approach to surgical weight loss or as a stand-alone procedure. A VSG involves the removal of 60-75% of the stomach, leaving a narrow gastric "tube" or "sleeve." This small remaining "tube" cannot hold as much food and produces less of the appetite-regulating hormone ghrelin, lessening a patient's desire to eat. VSG is not a purely malabsorptive procedure, so there is no requirement for lifetime nutritional supplementation (California Technology Assessment Forum, 2015).

#### ***Vertical Banded Gastroplasty (VBG)***

VBG restricts the size of the stomach using a stapling technique; there is no rearrangement of the intestinal anatomy. VBG has been abandoned by many due to a high failure rate, a high incidence of long-term complications, and the newer adjustable gastric band (AGB) and sleeve gastrectomy (van Wezenbeek et al., 2015).

#### ***Biliopancreatic Diversion with Duodenal Switch (BPD/DS) (also known as the Scopinaro procedure)***

BPD is primarily malabsorptive but has a temporary restrictive component. As in RYGB, three "limbs" of intestine are created: one through which food passes, one that permits emptying of fluids (e.g., bile) from digestive organs, and a common limb through which both food and digestive fluids pass. This procedure involves removal of the greater curvature of the stomach instead of the distal portion. The two limbs meet in a common channel measuring only 50 to 100 cm, thereby permitting relatively little absorption.

#### ***Robotic-Assisted Surgery***

Robotic surgery provides surgeons with three-dimensional vision, increased dexterity and precision by downscaling surgeon's movements enabling a fine tissue dissection and filtering out physiological tremor. It overcomes the

restraint of torque on ports from thick abdominal wall, and minimizes port site trauma by remote center technology (Bindal et al., 2015).

### ***Transoral Endoscopic Surgery***

Transoral endoscopic surgery for treatment of obesity is a form of natural orifice transluminal endoscopic surgery (NOTES) which is an alternative to conventional surgery. This procedure eliminates abdominal incisions and incision-related complications by combining endoscopic and laparoscopic techniques to diagnose and treat abdominal pathology (McGee et al., 2006).

The transoral gastropasty (TOGA<sup>®</sup>) system did not reach its clinical endpoints and further research has been halted (Hayes, 2011). StomaphyX was a revision procedure for individuals who had Roux-en-Y gastric bypass surgery and regained weight due to a stretched stomach pouch or enlarged stomach outlet. According to EndoGastric Solutions, Inc. (2017), StomaphyX is no longer being manufactured.

### ***Laparoscopic Mini Gastric Bypass (LMGBP)***

LMGBP involves the construction of a gastric tube by dividing the stomach vertically, down to the antrum. As in the RYGB, food does not enter the distal stomach. However, unlike gastric bypass surgery, digestive enzymes and bile are not diverted away from the stomach after LMGBP. This can lead to bile reflux gastritis which can cause pain that is difficult to treat.

### ***Implantable Gastric Stimulator (IGS)***

IGS is a small, battery-powered device similar to a cardiac pacemaker, in a small pocket, created beneath the skin of the abdomen using laparoscopy (hollow surgical tube and instruments inserted through an abdominal incision). Electrodes from the IGS are then implanted into the wall of the stomach and imaging or endoscopy is used to check that no perforations of the stomach wall have resulted. After a 1-month wait for healing at the surgical site, the device is turned on to intermittently stimulate the stomach wall. The IGS is programmed externally using a controller that sends radiofrequency signals to the device. Although the exact mechanism of action is not yet understood, gastric stimulation is thought to target ghrelin, an appetite-related peptide hormone (Gallas and Fetissov, 2011).

### ***Vagus Nerve Blocking Neurostimulation Therapy (VBLOC)***

VBLOC uses an implanted subcutaneous neurostimulator to deliver electrical pulses to the vagus nerve, which may suppress appetite (ECRI, 2016).

VBLOC therapy (such as via the Maestro<sup>®</sup> System; Enteromedics, Inc.) is designed to target the multiple digestive functions under control of the vagus nerves and to affect the perception of hunger and fullness.

### ***Intragastric Balloon (IGB)***

An IGB is a temporary aid for obese adults with a BMI of 30-40 kg/m<sup>2</sup> who have had unsatisfactory results in their treatment for obesity, and in super obese patients who often have a high risk for surgery (Fernandes et al., 2007). The balloon, placed endoscopically, is designed to float freely inside the stomach to reduce the volume of the stomach and leading to a premature feeling of satiety.

### ***Laparoscopic Greater Curvature Plication (LGCP) (also known as total gastric vertical plication [TGVP])***

LGCP is a restrictive procedure that involves folding and suturing the stomach onto itself to decrease the size of the stomach and requires no resection, bypass, or implantable device. This procedure is a modification of the gastric sleeve which requires surgical resection of stomach.

### ***Stomach Aspiration Therapy***

Stomach aspiration therapy, such as with the AspireAssist<sup>®</sup>, is a relatively new type of treatment for obesity which uses a surgically-placed tube to drain a portion of the stomach contents after every meal.

The AspireAssist is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Patients must be monitored regularly for weight loss progress, stoma site health, and metabolic and electrolyte balance.

### ***Bariatric Artery Embolization (BAE)***

Bariatric artery embolization (BAE) is a minimally invasive procedure which is the percutaneous, catheter-directed, trans-arterial embolization of the left gastric artery (LGA). The procedure is performed by an interventional radiologist and targets the fundus that produces the majority of the hunger-controlling hormone ghrelin. Beads placed inside the vessels purportedly help decrease blood flow and limit the secretion of ghrelin to minimize feelings of hunger to initiate weight loss.

## **Gastrointestinal Liners**

Gastrointestinal liners, such as the EndoBarrier™ system, utilize an endoscopically implanted sleeve into the stomach to reduce the stomach size. The sleeve is then removed after weight loss has been achieved. It is not approved for use by the U.S. Food and Drug Administration (FDA) in the United States; it is limited by federal law to investigational use only.

Once in place, the liner conforms to the shape and movement of the patient's intestine and begins to work immediately. It does so by creating a physical barrier between receptors in the intestinal wall and any food being digested releasing gut hormone signals (GI Dynamics website, 2017).

## **Revisional Surgery**

The primary indications for revisional surgery are treatment of severe side effects (persistent nausea and vomiting, intolerance to solid food, severe dumping syndrome) or complications from prior bariatric procedures (strictures, nonhealing ulcers); however, an increasing number of revisional surgeries are being performed due to inadequate weight loss from the primary procedure. A revisional procedure can be defined as a conversion, correction, or reversal (Ma and Madura, 2015).

Prior to revisional surgery, patients should undergo a thorough multidisciplinary assessment and consideration of their individual risks and benefits from revisional surgery (Brethauer et al., 2014). It is important to determine if the poor response to primary bariatric surgery is due to anatomic causes that led to inadequate weight loss or weight regain or to the patient's postoperative behavior, such as not following the prescribed diet and lifestyle changes (e.g., consuming large portions, high-calorie foods, and/or snacks between meals; not exercising).

## **CLINICAL EVIDENCE**

The criteria for patient selection for bariatric surgery are relatively uniform among clinical studies published in the peer-reviewed literature and broadly correspond to criteria recommended by the American Association of Clinical Endocrinologists (AACE), The Obesity Society, and American Society for Metabolic & Bariatric Surgery (ASMB) (Mechanick et al., 2013):

- Patients with a BMI  $\geq 40$  kg/m<sup>2</sup> without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk.
- Patients with a BMI  $\geq 35$  kg/m<sup>2</sup> and 1 or more severe obesity-related co-morbidities.
- Demonstration that a multidisciplinary approach with dietary, other lifestyle modifications (such as exercise and behavioral modification), and pharmacological therapy, if appropriate, have been unsuccessful.

Refer to the [Professional Societies](#) section of the policy for additional information.

The NHLBI Obesity Expert Panel (2013) considers that the evaluation of efficacy end points for weight loss and change in CVD risk factors and other health outcomes requires studies with a minimum post-surgical follow-up of 2 years and inclusion of a nonsurgical comparator group. Studies evaluating predictors of weight change or medical outcomes, including patient factors (e.g., presence vs. absence of diabetes) or surgical factors (e.g., RYGB vs. BPD), require direct comparison of these factors plus a minimum 2-year follow-up. Studies evaluating complications of bariatric surgery require at least a 30-day post-surgical follow-up. For observational studies with 10 or more years of follow-up or for studies on BPD or SG procedures, the work group agreed to require a sample size  $\geq 100$  and for all other observational studies to require a sample size  $> 500$ . This sample size requirement was instituted because the most important complications are infrequent (e.g., perioperative mortality rates are  $< 1$  percent) so that smaller studies could give inaccurate estimates of complication rates.

The National Institute for Health and Care Excellence (NICE) 2014 guideline on obesity identification, assessment and management offers bariatric surgery as a treatment option for people with obesity when they have: a BMI of 40 kg/m<sup>2</sup> or more, or between 35 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup> and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight; all appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss; have a multi-disciplinary team approach; the person is generally fit for surgery and anesthesia; and the person commits to the need for long-term follow-up.

In addition, the NICE guideline notes that bariatric surgery is the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m<sup>2</sup> when other interventions have not been effective. Further, surgical intervention is not generally recommended in children or young people, however it may be considered only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity.

Maciejewski et al. (2016) examined 10-year weight changes in a large, multisite, clinical cohort of veterans who underwent Roux-en-Y gastric bypass (RYGB) compared with nonsurgical matches and the 4-year weight change in

veterans who underwent RYGB, adjustable gastric banding (AGB), or sleeve gastrectomy (SG). The 1787 patients undergoing RYGB had a mean (SD) age of 52.1 (8.5) years and 5305 nonsurgical matches had a mean (SD) age of 52.2 (8.4) years. Patients undergoing RYGB and nonsurgical matches had a mean body mass index of 47.7 and 47.1, respectively, and were predominantly male [1306 (73.1%) and 3911 (73.7%), respectively]. Patients undergoing RYGB lost 21% (95% CI, 11%-31%) more of their baseline weight at 10 years than nonsurgical matches. A total of 405 of 564 patients undergoing RYGB (71.8%) had more than 20% estimated weight loss, and 224 of 564 (39.7%) had more than 30% estimated weight loss at 10 years compared with 134 of 1247 (10.8%) and 48 of 1247 (3.9%), respectively, of nonsurgical matches. Only 19 of 564 patients undergoing RYGB (3.4%) regained weight back to within an estimated 5% of their baseline weight by 10 years. At 4 years, patients undergoing RYGB lost 27.5% (95% CI, 23.8%-31.2%) of their baseline weight, patients undergoing AGB lost 10.6% (95% CI, 0.6%-20.6%), and patients undergoing SG lost 17.8% (95% CI, 9.7%-25.9%). Patients undergoing RYGB lost 16.9% (95% CI, 6.2%-27.6%) more of their baseline weight than patients undergoing AGB and 9.7% (95% CI, 0.8%-18.6%) more than patients undergoing SG. The authors concluded that surgical patients lost substantially more weight than nonsurgical matches and sustained most of this weight loss in the long-term. Roux-en-Y gastric bypass induced significantly greater weight loss among veterans than SG or AGB at 4 years.

Arterburn et al. (2015) evaluated the association between bariatric surgery and long-term survival in a retrospective cohort study of obese patients treated at the Veterans Administration (VA) health system. A cohort of surgical patients [n=2500; mean age, 52 years; mean body mass index (BMI) of 47], undergoing any bariatric surgery procedure, were compared with control patients (n=7462). At the end of 14 years, there were a total of 263 deaths in the surgical cohort group (n=2500) and 1277 deaths in the matched controls (n=7462). Based on Kaplan-Meier estimates, mortality rates were 2.4% at 1 year, 6.4% at 5 years, and 13.8% at 10 years for surgical cohort patients. In the matched controls, mortality rates were 1.7% at 1 year, 10.4% at 5 years, and 23.9% at 10 years. Bariatric surgery was associated with reduced mortality compared controls after 1 to 5 years [hazard ratio (HR), 0.45; 95% CI, 0.36 to 0.56] and after 5 years (HR, 0.47; 95%CI, 0.39 to 0.58). Across different subgroups based on diabetes diagnosis, sex, and period of surgery, there were no significant differences between surgery and survival at the mid- and long-term evaluations.

Magallares et al. (2015) conducted a meta-analysis of 21 studies evaluating the mental and physical health-related quality of life (HR-QOL) measures with the Short Form-36 (SF-36) before and after bariatric surgery. Study authors reported that obese patients scored less in the mental health component of SF-36 prior to bariatric surgery (n=2680) compared with after surgery (n=2251). Similar results were observed in the physical health component of SF-36. Study authors concluded that obese patients experienced strong improvement in mental and physical QOL measures following surgery.

Sjostrom et al. (2004) published a prospective controlled study of patients that had gastric surgery (average BMI of 41) and matched them with conventionally treated obese control subjects. Two treatment groups were identified: those who had surgery two years prior (4,047 patients) and those who had it 10 years prior (1,703). After two years, the weight had increased by 0.1% in the control group and decreased by 23.4% in the surgery group. After ten years, the weight in the control group had increased by 1.6% and had decreased in the surgical group by 16.1%. In addition to total weight loss, they measured laboratory values and lifestyle changes. The authors concluded that bariatric surgery appears to be a viable option for the treatment of severe obesity and resulted in long-term weight loss, improved lifestyle and improvement in risk factors that were elevated at baseline.

A study by Lee et al. (2004) concluded that metabolic syndrome (MS) is prevalent in 52.2% of morbidly obese individuals and that significant weight reduction one year post surgery markedly improved all aspects of metabolic syndrome with a cure rate of 95.6%. They also note that obesity surgery performed by laparoscopic surgery is recommended for obese patients with MS.

A retrospective cohort study was conducted by Yska et al. (2015) within the Clinical Practice Research Datalink involving 2978 patients with a record of bariatric surgery, with a BMI of > 35. They identified 569 patients with type 2 diabetes (T2DM) and matched them to 1881 patients with diabetes without bariatric surgery. Data on the use of medication and laboratory results were evaluated. Among patients undergoing bariatric surgery, the authors found a prevalence of 19.1% for T2DM. Per 1000 person-years, 94.5 diabetes mellitus remissions were found in patients who underwent bariatric surgery compared with 4.9 diabetes mellitus remissions in matched control patients. Patients with diabetes who underwent bariatric surgery had an 18-fold increased chance for T2DM remission [adjusted relative rate (RR), 17.8; 95% CI, 11.2-28.4] compared with matched control patients. The authors conclude that bariatric surgery strongly increases the chance for remission of T2DM with gastric bypass and sleeve gastrectomy having a greater effect than gastric banding.

In a systematic analysis, Osland et al. (2017) evaluated the post-operative impact on type 2 diabetes resolution following laparoscopic vertical sleeve gastrectomy (LVSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB). Seven RCTs involving a total of 732 patients (LVSG n = 365, LRYGB n = 367) met inclusion criteria. Significant diabetes

resolution or improvement was reported with both procedures across all time points. Similarly, measures of glycemic control (HbA1C and fasting blood glucose levels) improved with both procedures, with earlier improvements noted in RYGB that stabilized and did not differ from LVSG at 12 months post-operatively. Early improvements in measures of insulin resistance in both procedures were also noted in the studies that investigated this. The authors suggest that both procedures are effective in resolving or improving pre-operative type 2 diabetes in obese patients during the reported 3-to -5 year follow-up periods. However, further studies are required before longer-term outcomes can be elucidated. Areas identified that need to be addressed for future studies on this topic include longer follow-up periods, standardized definitions and time point for reporting.

A 2014 Cochrane Systematic Database Review by Colquitt et al. found that surgery results in greater improvement in weight loss outcomes and weight associated comorbidities compared with non-surgical interventions, regardless of the type of procedures used. They noted the overall quality of evidence in this analysis to be moderate. When compared with each other, certain procedures resulted in greater weight loss and improvements in comorbidities than others. Outcomes were similar between RYGB and sleeve gastrectomy, and both of these procedures had better outcomes than adjustable gastric banding. For people with very high BMI, biliopancreatic diversion with duodenal switch resulted in greater weight loss than RYGB. Duodenojejunal bypass with sleeve gastrectomy and laparoscopic RYGB had similar outcomes; however this is based on one small trial. Isolated sleeve gastrectomy led to better weight-loss outcomes than adjustable gastric banding after three years follow-up. This was based on one trial only. Weight-related outcomes were similar between laparoscopic gastric imbrication and laparoscopic sleeve gastrectomy in one trial. Across all studies adverse event rates and reoperation rates were generally poorly reported. The authors also found that most trials followed participants for only one or two years, therefore the long-term effects of surgery remain unclear.

In a systematic review and meta-analysis, Chang et al. (2014) examined the effectiveness and risks of bariatric surgery using up-to-date, comprehensive data and appropriate meta-analytic techniques. A total of 164 studies were included (37 randomized clinical trials and 127 observational studies). Analyses included 161,756 patients with a mean age of 44.56 years and body mass index of 45.62. In randomized clinical trials, the mortality rate within 30 days was 0.08% (95% CI, 0.01%-0.24%); the mortality rate after 30 days was 0.31% (95% CI, 0.01%-0.75%). Body mass index loss at 5 years postsurgery was 12 to 17. The complication rate was 17% (95% CI, 11%-23%), and the reoperation rate was 7% (95% CI, 3%-12%). Based on this review, the authors found that gastric bypass was more effective in weight loss but associated with more complications, adjustable gastric banding had lower mortality and complication rates (yet, the reoperation rate was higher and weight loss was less substantial than gastric bypass), sleeve gastrectomy appeared to be more effective in weight loss than adjustable gastric banding and comparable with gastric bypass. The authors concluded that bariatric surgery provides substantial and sustained effects on weight loss and ameliorates obesity-attributable comorbidities in the majority of bariatric patients, although risks of complication, reoperation, and death exist. Death rates were lower than those reported in previous meta-analyses.

Batterham and Cummings (2016) observed that historically, the physiological and molecular mechanisms underlying the beneficial glycemic effects of bariatric surgery remained incompletely understood. These changes, acting through peripheral and/or central pathways, lead to reduced hepatic glucose production, increased tissue glucose uptake, improved insulin sensitivity, and enhanced  $\beta$ -cell function. A constellation of factors, rather than a single overarching mechanism, likely mediate post-operative glycemic improvement, with the contributing factors varying according to the surgical procedure.

Cohort studies show that bariatric surgery reduces all-cause mortality by 30% to 50% at seven to 15 years postsurgery compared with patients with obesity who did not have surgery. (Schroeder et al., 2016)

Adams et al. (2015) reviewed the association between bariatric surgery and long-term mortality. They concluded that the general consensus is that bariatric surgical patients have: 1) significantly reduced long-term all-cause mortality when compared to extremely obese non-bariatric surgical control groups; 2) greater mortality when compared to the general population, with the exception of one study; 3) reduced cardiovascular-, stroke-, and cancer-caused mortality when compared to extremely obese non-operated controls; and 4) increased risk for externally caused death such as suicide.

In a review of findings from retrospective or cohort studies on bariatric surgery and impact on nonalcoholic fatty liver disease (NAFLD), Aguilar-Olivos et al. (2016) remarked that bariatric surgery is the most effective treatment for morbid obesity and its associated metabolic comorbidities. There is evidence indicating that bariatric surgery improves histological and biochemical parameters of nonalcoholic fatty liver disease (NAFLD), but currently is not considered a treatment option for NAFLD. The aim of this work is to review the evidence for the effects of bariatric surgery on NAFLD and the metabolic syndrome (MetS). The authors found that insulin resistance, alterations in glucose metabolism, hypertension, plasma lipids, transaminases, liver steatosis, steatohepatitis and fibrosis improve after bariatric surgery. Weight loss and improvement of NAFLD are greater after RYGB than after other interventions. The

authors conclude that patients with indications for bariatric surgery will most likely benefit from the improvements in the MetS and NAFLD.

Xie et al. (2016) prospectively evaluated Apnea-Hypopnea Index (AHI) and Functional Outcomes of Sleep Questionnaires Scores (FOSQ) pre- and post-operatively in patients undergoing bariatric surgery. A total of 167 subjects were studied. The median age was 46 (14-75) years and BMI 49 (36-69) kg/m<sup>2</sup>. Ninety two (55.0%) patients were diagnosed with obstructive sleep apnea (OSA) pre-operatively. Fifty (54.0%) required positive airway pressure (PAP) therapy. The mean reduction in BMI post bariatric surgery was 12.2 ± 4.52 kg/m<sup>2</sup> at 6.56 ± 2.70 months. Eighty (87.9%) reported improved sleep quality reflected in improved scores in all domains of the FOSQ (p < 0.001, paired t-test). Improvement in FOSQ scores remained significant (p < 0.05) in those with and without OSA. Thirty-nine (90.7%) patients discontinued PAP due to resolution of daytime sleepiness. In conclusion, the authors identified that weight loss following bariatric surgery has a positive impact on sleep in patients with and without OSAS.

The NHLBI Obesity Expert Panel (2013) completed a systematic evidence review to evaluate critical questions regarding overweight and obesity management in adults. On the topic of bariatric surgical procedures, they concluded that in obese adults, bariatric surgery produces greater weight loss and maintenance of lost weight than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight. For patients with obesity who have obesity-related comorbid conditions or who are at high risk for their development, bariatric surgery offers the possibility of meaningful health benefits, albeit with significant risks.

Kuruba et al. (2007a) prospectively studied 201 obese patients (body mass index 48±7 kg/m<sup>2</sup>), of which 65 reported urinary incontinence, to evaluate the effects of bariatric surgery to resolve urinary incontinence. Of the 45 patients that underwent bariatric surgery, 38 reported mild (4%), moderate (47%), or severe (49%) urinary incontinence preoperatively. Nineteen of the 38 patients (50%) demonstrated resolution of urinary incontinence and the other 19 reported residual slight-moderate (36%) or severe (13%) urinary incontinence. The authors concluded that bariatric surgery in obese patients with urinary incontinence improves or eliminates symptoms. The study is limited by small sample size and fact that patients with urinary incontinence undergoing bariatric surgery already had a diagnosis of morbid obesity.

Kuruba et al. (2007b) also provided the following recommendations for evaluation in the preoperative period. In the perioperative period treatment of co-morbidities should be optimized. For patients with a history of type 2 diabetes mellitus, strict glycemic control should be instituted to maintain a blood glucose level <150 or a hemoglobin A1c<7. Patients with OSA should be using CPAP or BiPAP at least 4-6 weeks prior to surgery in an effort to decrease hypercarbia, hypoxemia and pulmonary artery vasoconstriction. Patients with NASH may benefit from calorie restriction for a several weeks preoperatively to reduce the size of the liver, making surgery easier. Beta blockers may decrease the risk of intra-operative ischemia, infarction or dysrhythmia in patients with coronary artery disease, however its role has not been defined in bariatric surgery.

Buchwald et al. (2004) found in their meta-analysis that substantial majority of patients with type 2 diabetes mellitus, hyperlipidemia, hypertension and obstructive sleep apnea experienced complete resolution or improvement after bariatric surgery. Post-operative mortality was 0.1%-1.1% depending on the surgery type with lowest mortality in the restrictive techniques and highest for biliopancreatic diversion method.

Dixon et al. (2008) conducted an unblinded randomized controlled trial to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control. A total of 60 patients were randomized into the 2 groups; 30 receiving surgical treatment and 30 receiving conventional treatment. Remission of type 2 diabetes, at 2 year follow-up, was reduced 73% in the surgical group and 13% in the conventional therapy group.

Christou et al. (2004) concluded that bariatric surgery not only decreased risk factors, but also decreased overall mortality. They performed a matched cohort study of 1,035 patients who had bariatric surgery with 5,746 obese patients who did not have surgery. Subjects with medical conditions other than morbid obesity were not included. The participants were followed for 5 years. The mortality rate in the treatment group was 0.68% compared with 6.17% of the controls which results in a reduction in the relative risk of death by 89%.

Pregnancy after bariatric surgery was examined by Sheiner et al. (2004) who concluded that previous bariatric surgery had a high correlation with Cesarean delivery. There was no correlation with other indicators of adverse perinatal outcomes such as dystocia, Apgar scores, perinatal complications or perinatal mortality.

In a review of the mechanisms, pathophysiology, and management of obesity, Heymsfield and Wadden (2017) noted that although weight loss is an effective, broad-acting therapeutic measure, not all risk factors and chronic disease states respond equally well. Severe obstructive sleep apnea is one example that may improve but rarely fully remits in

response to weight-loss treatments, including bariatric surgery. Mean losses of 16 to 32% of baseline weight produced by bariatric surgery in patients with severe obesity may lead to disease remission, including remission of type 2 diabetes in patients who undergo bariatric surgery, particularly Roux-en-Y gastric bypass. Significant reductions in all-cause mortality have also been shown in observational studies of surgically treated patients. The main treatment options with sufficient evidence-based support are lifestyle intervention, pharmacotherapy, and bariatric surgery. Pronounced clinical improvements are observed in most obesity-related health conditions, particularly type 2 diabetes, after Roux-en-Y gastric bypass, vertical-sleeve gastrectomy, and to a lesser extent, gastric banding. Limitations of current surgeries include high costs initially and at 1 year, risks of short- and long-term complications and weight regain in approximately 5 to 20% of patients. In the author's opinion, the Roux-en-Y gastric bypass and vertical-sleeve gastrectomy are by far the most effective long-term treatments for severe obesity.

Narayanan and Syed (2016) evaluated medical complications and management in pregnancy after bariatric surgery. They found that while rates of many adverse maternal and fetal outcomes in obese women are reduced after bariatric surgery, pregnancy is best avoided for 12-24 months to reduce the potential risk of intrauterine growth retardation. Dumping syndromes are common after bariatric surgery and can present diagnostic and therapeutic challenges in pregnancy.

Badreldin et al. (2016) commented that although bariatric surgery may have a beneficial effect on rates of fetal macrosomia, gestational diabetes, hypertension, and preeclampsia, conversely, studies have showed that bariatric surgery may increase the risk of small for gestational age infants and preterm birth. Given its rising incidence, they recommend that physicians be able to thoroughly and accurately counsel and treat patients who plan to, or do, become pregnant after bariatric surgery.

In a retrospective review of 670 women with singleton births who previously underwent bariatric surgery, Johansson et al. (2015) concluded that compared to the control group, bariatric surgery was associated with reduced risks of gestational diabetes and excessive fetal growth, shorter gestation, an increased risk of small-for-gestational-age infants, and possibly increased mortality.

Shen et al. (2004) studied the impact of patient follow-up on weight loss after bariatric surgery. They found that weight loss was correlated with the number of follow-up visits completed in the first year post surgery. They concluded that patient follow-up plays a significant role in the amount of weight loss after bariatric surgery and that patient motivation and surgeon commitment for long-term follow-up is critical for successful weight loss after bariatric surgery.

Spaniolas et al. (2016) found that patients with complete follow-up (3, 6, and 12 months) were compared to patients who had one or more prior missed visits. There were 51,081 patients with 12-month follow-up data available. After controlling for baseline characteristics, complete follow-up was independently associated with excess weight loss  $\geq 50\%$ , and total weight loss  $\geq 30\%$ . Adherence to post-operative follow-up is independently associated with improved 12-month weight loss after bariatric surgery. The authors urge that bariatric programs should strive to achieve complete follow-up for all patients.

Still et al. (2007) conducted a prospective, longitudinal assessment of characteristics and outcomes of gastric bypass patients to analyze whether modest, pre-operative weight loss improved perioperative outcomes among high-risk, morbidly obese patients undergoing Roux-en-Y gastric bypass. Patients (n=884) were required to participate in a standardized multidisciplinary pre-operative program that encompassed medical, psychological, nutritional, and surgical interventions and education. In addition, patients were encouraged to achieve a 10% loss of excess body weight prior to surgical intervention. A total of 425 (48%) lost more than 10% of their excess body weight prior to the operation. After surgery (mean follow-up, 12 months), this group was more likely to achieve 70% loss of excess body weight ( $P < .001$ ). Those who lost more than 5% of excess body weight prior to surgery were statistically less likely to have a length of stay of greater than 4 days ( $P = .03$ ). The authors noted that because of the older age, high disease burden, and high BMIs of this population, these results may not be applicable to all pre-operative candidates for bariatric surgery. Further studies to extend these results and to evaluate the effects on pre-operative weight loss of specific surgical outcomes as well as its correlation with long-term weight loss are ongoing.

In a systematic review and meta-analysis, Kadeli et al. (2012) evaluated whether pre-operative weight loss before gastric bypass correlates to weight loss up to 1 year post-surgery. Of the 186 studies screened, 12 were identified. A meta-analysis was performed to further classify studies (A class, B class, regression, and rejected). The authors conclude that losing weight leads to better outcomes because a patient entering surgery with a lower weight than someone entering surgery without weight loss will have more weight loss in total.

Blackledge et al., (2016) conducted a retrospective analysis of 300 patients who underwent laparoscopic Roux-en-Y bypass. There were no significant demographic differences among the quartiles however, there was an increased time to operation for patients who gained or lost  $\geq 5\%$  excess body weight ( $p < 0.001$ ). Although there was no statistical

significance in post-operative complications, there was a higher rate of complications in patients with  $\geq 5\%$  EWG compared to those with  $\geq 5\%$  EWL (12.5 vs. 4.8%, respectively;  $p = 0.29$ ). Unadjusted and adjusted generalized linear models showed no statistically significant association between pre-operative% excess weight change and weight loss outcomes at 24 months. This was a single-center study and may not be representative of all patient populations.

According to an NHLBI Obesity Expert Panel evidence report on managing overweight and obesity in adults (Jensen et al., 2013), the pattern of weight loss over time with dietary intervention shows the average weight loss is maximal at 6 months with smaller losses maintained for up to 2 years while treatment and follow-up tapers. Weight loss achieved by dietary techniques aimed at reducing daily energy intake ranges from 4 to 12 kg at a 6-month follow-up. Thereafter, slow weight regain is observed, with a total weight loss of 4 to 10 kg at 1 year and 3 to 4 kg at 2 years. The authors cited both psychological and biologic factors as responsible for weight regain, and recommend future studies to identify strategies that prevent or minimize weight regain after successful dieting.

Greenberg et al. (2005) found a high incidence of depression, negative body image, eating disorders, and low quality of life (QoL) in patients with severe obesity. Although their investigation showed there are no predictive relationships between pre-operative psychological evaluations and post-operative weight loss, they recommended that all bariatric surgery candidates be evaluated by a licensed mental health care provider experienced in the treatment of severely obese patients and working with a multidisciplinary team. In another study of clients followed for 1 year after weight loss surgery, perceived obesity-related health problems, motivation, and sense of coherence (SoC) predicted better weight loss. A history of sexual abuse correlated with poorer weight loss, whereas intrinsic motivational factors appeared to predict greater weight loss after surgery. (Ray et al., 2003) Although research supports the association of psychological problems such as depression and personality disorder with less successful obesity surgery outcomes, rarely are the psychological problems cited as contraindications for surgery. (Greenberg et al., 2005) Furthermore, the goal of psychological assessment should be the development of pre- and post-surgical treatment plans that address psychosocial barriers to post-operative success. Professional consensus is that bariatric surgery should be performed only in motivated, educated patients who have participated in a combined multidisciplinary assessment and only after behavior-based interventions have failed. (Bachman et al., 2005)

The American Diabetes Association (ADA) *Standards of Medical Care in Diabetes - 2017* states that to be consistent with other ADA position statements and to reinforce the role of surgery in the treatment of type 2 diabetes, they now refer to bariatric surgery as metabolic surgery. The ADA recommends metabolic surgery to treat type 2 diabetes in appropriate surgical candidates with BMI  $\geq 40$  kg/m<sup>2</sup> (BMI  $\geq 37.5$  kg/m<sup>2</sup> in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in adults with BMI 35.0–39.9 kg/m<sup>2</sup> (32.5–37.4 kg/m<sup>2</sup> in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy. (Level of evidence: A). Metabolic surgery should be considered for adults with type 2 diabetes and BMI 30.0–34.9 kg/m<sup>2</sup> (27.5–32.4 kg/m<sup>2</sup> in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin). (Level of evidence: B) The ADA supports long-term lifestyle support and routine monitoring of micronutrient and nutritional status.

The joint statement by international diabetes organizations on metabolic surgery in the treatment algorithm for type 2 diabetes (American Diabetes Association, International Diabetes Foundation, Diabetes UK, Chinese Diabetes Society, and Diabetes India) states that sufficient clinical and mechanistic evidence exists to support inclusion of metabolic surgery among antidiabetes interventions for people with type 2 diabetes and obesity. The organizations note that additional studies are needed to further demonstrate long-term benefits (Rubino et al., 2016).

### **Gastric Bypass (Roux-en-Y; Gastrojejunal Anastomosis)**

In a matched observational cohort study, Liakopoulos et al. (2017) evaluated 6132 patients with a baseline BMI of 42 kg/m<sup>2</sup> and type 2 diabetes who underwent RYGB. Over a 6 year follow-up period, beneficial changes in body mass index (BMI), hemoglobin A1C, blood lipids and blood pressure were seen compared with control persons. The authors concluded that improvements in risk factors might contribute to the reduction of mortality risk after RYGB in obese individuals with type 2 diabetes, but the main effect seems to be mediated through a decrease in BMI, which could serve as a proxy for several mechanisms.

In a retrospective cohort study conducted over 18 years by Adams et al. (2007), 9949 patients who had undergone gastric bypass surgery and 9628 severely obese persons who applied for driver's licenses were studied. From these subjects, 7925 surgical patients and 7925 severely obese control subjects were matched for age, sex, and body-mass index. The authors concluded that long-term total mortality after gastric bypass surgery, particularly deaths from diabetes, heart disease, and cancer, was significantly reduced. However, the rate of death from causes other than these diseases was higher in the surgery group than in the control group. Review of the data showed that a substantial number of severely obese persons have unrecognized presurgical mood disorders or post-traumatic stress disorder or have been victims of childhood sexual abuse. This is leading some bariatric surgery centers to recommend that all patients undergo psychological evaluation and, if necessary, treatment before surgery and psychologically related surveillance post-operatively. Despite an improved quality of life after gastric bypass surgery, certain

unrecognized presurgical conditions may reappear after surgery. Therefore, further research is needed to explore the optimal approach to evaluating candidates for surgery, including the possible need for psychological evaluation and psychiatric treatment before surgery, and aggressive follow-up after surgery.

Lager et al. (2017) retrospectively studied 30-day postoperative complications as well as changes in weight, blood pressure, cholesterol, hemoglobin, hemoglobin A1C, and creatinine from baseline to 2, 6, 12, and 24 months postoperatively in 383 patients undergoing RYGB and 336 patients undergoing sleeve gastrectomy (SG). Follow-up rates were 706/719 at 2 months, 566/719 at 6 months, 519/719 at 12 months, and 382/719 at 24 months. Baseline characteristics were similar in both groups except for higher weight and BMI in the SG group. The RYGB group experienced greater total body weight loss at 6, 12, and 24 months (41.9 vs. 34.6 kg at 24 months,  $p < 0.0001$ ). Excess weight loss was 69.7 and 51.7% following RYGB and SG respectively at 24 months ( $p < 0.0001$ ). Blood pressure improved significantly in both groups. Surgical complication rates were greater after RYGB (10.1 vs. 3.5%,  $p = 0.0007$ ) with no significant difference in life-threatening or potentially life-threatening complications. Weight loss was greater following RYGB compared to SG at 2 years. The risk for surgical complications was greater following RYGB. The authors recommend that surgical intervention be tailored to surgical risk, comorbidities, and desired weight loss.

In a systematic review, Jirapinyo et al., (2017) identified that despite initial successful weight loss, some patients may experience weight regain following RYGB, thus showing the importance of close follow-up, early recognition and intervention. There is a lack of established definition of weight regain in the current literature.

Cooper et al. (2015) assessed weight loss and occurrence of weight regain among patients ( $n=300$ ) at 1 year follow-up who underwent Roux-en-Y gastric bypass (RYGB) at a single institution. The mean weight regain for all patients was 23.4% of maximum weight loss. Using categorical analysis, mean weight regain in the <25, 25-30, 30-35, and >35% weight loss cohorts was 29.1, 21.9, 20.9, and 23.8%, respectively. Excessive weight regain, defined as  $\geq 25\%$  of total lost weight, occurred in 37% of patients. Despite the percentage of weight loss over the first year, all cohort patient groups regained on average between 21 and 29% of lost weight. Excessive weight gain was experienced by over one third of patients. Greater initial absolute weight loss leads to more successful long-term weight outcomes.

Giordano (2015) conducted retrospective comparative study of consecutive super-obese patients. Patients either underwent laparoscopic Roux-en-Y gastric bypass procedure ( $n=102$ ) or laparoscopic adjustable gastric banding ( $n=79$ ). Early complications and weight loss outcomes were comparable between the two groups in the short term. However, weight loss and excess weight loss percent at 6 and 12 months of follow-up was significantly higher in patients who underwent Roux-en-Y surgery than gastric banding.

A 2014 Cochrane Systematic Database Review by Colquitt, et al. found that in comparison with laparoscopic adjustable gastric banding (LAGB), the LRYGB procedure resulted in greater duration of hospitalization in two RCTs (4/3.1 versus 2/1.5 days) and a greater number of late major complications (26.1% versus 11.6%) in one RCT. In addition, open RYGB, LRYGB and laparoscopic sleeve gastrectomy (LSG) led to losses of weight and/or BMI but there was no consistent picture as to which procedure was better or worse in the seven included trials.

In a systematic review and meta-analysis, Yan et al. (2016) compared RYGB surgery versus medical treatment for type 2 diabetes mellitus (T2DM) in obese patients. Six RCTs with 410 total obese T2DM patients were included and follow-up ranged from 12 to 60 months. The pooled analysis of T2DM remission rates revealed a significantly higher remission rate after RYGB surgery than after medical treatment alone. The meta-analysis showed a significant lower BMI in individuals who underwent RYGB than those who received medical therapy alone. Based on the results, the authors conclude that RYGB surgery is superior to medical treatment for short- to medium-term remission of T2DM, improvement of metabolic condition, and cardiovascular risk factors. The authors recommend well-designed studies with consistent definition of adverse events, as well as a larger number of RCTs with long-term follow-up (>60 months) to evaluate the safety and long-term benefits of RYGB surgery on obese patients with T2DM.

Griffith et al. (2012) reviewed the major perioperative and late complications that can arise in patients who have undergone LRYGB. Post-operative complications following LRYGB can be broadly grouped into early and late complications. By definition, early complications occur within the immediate perioperative period — the first 2 weeks post-LRYGB. Early complications may include anastomotic or staple line leak (ASL), post-operative hemorrhage, bowel obstruction and incorrect Roux limb reconstructions. Anastomotic or staple line leaks are the most dreaded and potentially devastating early complication of this procedure, with a mortality rate of nearly 50%. Late complications arise after the second post-operative week. Aside from the formation of internal hernias, a range of other complications can develop over the long-term in patients who have undergone LRYGB. These complications include anastomotic stricture, marginal ulcer formation, fistula formation, weight gain and nutritional deficiencies.

### **Laparoscopic Adjustable Gastric Banding (LAGB)**

Vinzens et al. (2017) evaluated the long-term results of 405 patients (age  $41 \pm 10$  years, with a BMI of  $44.3 \pm 6$  kg/m<sup>2</sup>, who were treated with laparoscopic adjustable gastric banding (LAGB). Mean follow-up was  $13 \pm 3$  years, with a follow-

up rate of 85% (range 8-18 years), corresponding to 343 patients. One hundred patients exceeded 15-year follow-up. In 216 patients (63%), sleeve gastrectomy, gastric bypass, or biliopancreatic diversion with duodenal switch was performed as revisional surgery. Twenty-seven patients (8%) refused revisional surgery after band removal. Finally, 100 patients (29%) still had the band in place at the final follow-up, with a mean BMI of  $35 \pm 7$  kg/m<sup>2</sup>, corresponding to an excess BMI loss of  $48 \pm 27\%$ . According to the Bariatric Analysis and Reporting Outcome System (BAROS), the failure rate was 25%, and 50% had what was considered to be a good to excellent outcome. The authors concluded that more than 10 years after LAGB, 71% of patients lost their bands and only 15% of the 343 followed patients with the band in place had a good to excellent result.

In a retrospective review, Khoraki et al. (2017) reported long-term outcomes from a cohort of 208 patients who underwent LAGB. Complete follow-up was available for 90% at one year (186/207), 80% at five years (136/171), and 71% at ten years (10/14). Percentage of excess weight loss at one, five, and ten years was 29.9, 30, and 16.9, respectively. LAGB failure occurred in 118 (57%) and 48 patients (23.1%) required a reoperation. Higher baseline BMI was the only independently associated factor (OR 1.1; 95%CI 1.0-1.1;  $p = 0.016$ ).

Angrisani et al. (2013) retrospectively evaluated the efficacy and safety of laparoscopic adjustable gastric banding (LAGB) in moderately obese subjects with or without obesity-related co-morbidities. Thirty-four patients with BMI between 30 and 35 kg/m<sup>2</sup> and mean percentage excess weight  $48.7 \pm 9\%$  who underwent LAGB were included. Good response was defined as BMI <30 kg/m<sup>2</sup> or percentage estimated weight loss (%EWL) >50. Poor response was defined as BMI >30 kg/m<sup>2</sup> or %EWL less than 50 after a minimum of 1 year. Mean weight, BMI and %EWL were recorded at 1, 3, 5 and 7 years and were  $77.4 \pm 7.6$ ,  $69.9 \pm 10.8$ ,  $70.9 \pm 9.3$  and  $73.3 \pm 12.0$  kg;  $28.8 \pm 2.9$ ,  $26.4 \pm 3.2$ ,  $26.5 \pm 3.4$  and  $27.4 \pm 5.0$  kg/m<sup>2</sup>; and  $36 \pm 23$ ,  $46.1 \pm 33.8$ ,  $58.6 \pm 31.5$  and  $45 \pm 57$ , respectively ( $p < 0.01$ ). Co-morbidities were diagnosed in 17/34 (50%) patients at baseline and underwent remission or improvement in all cases after 1 year. The authors concluded that LAGB is a safe and effective procedure in patients with a BMI <35 kg/m<sup>2</sup>. Small sample size was a limitation to this study.

### **Biliopancreatic Diversion with Duodenal Switch (BPD/DS)**

Topart et al. (2017) reported weight loss and nutritional outcomes in a 10-year follow-up of 80 patients who underwent BPD/DS. A follow-up of  $141 \pm 16$  months was available for 87.7% of the patients at least 10 years from surgery. Preoperative BMI decreased from  $48.9 \pm 7.3$  to  $31.2 \pm 6.2$  kg/m<sup>2</sup> with an EWL of  $73.4 \pm 26.7\%$  and a TWL of  $35.9\% \pm 17.7\%$ . Despite weight regain  $\geq 10\%$  of the weight loss in 61% of the cases, 78% of the patients maintained a BMI <35. Fourteen percent of the patients had a revision. Normal vitamin D levels were found in 35.4%. The overall PTH level was  $91.9 \pm 79.5$  ng/mL, and 62% of the patients had hyperparathyroidism. Other deficiencies were less frequent but fat-soluble deficiencies as well as a PTH >100 ng/mL were significantly associated with the absence of vitamin supplementation.

Based on the results of their study, the authors conclude that although BPD/DS maintains a significant weight loss at 10 years, it is associated with side effects that in some cases led to revision and multiple vitamin deficiencies. The most severe deficiencies are related to the lack of supplementation compliance.

In a retrospective review, Sethi et al. (2016) evaluated the long-term weight loss, co-morbidity remission, complications, and quality of life in patients (n=100) after BPD (34%) and BPD/DS (64%). Outcomes included weight loss measures at 2, 5, and 10-15 years post-operatively; co-morbidity remission; long-term complications; nutritional deficiencies; and patient satisfaction. Mean pre-operative BMI was 50.2 kg/m<sup>2</sup>. Mean follow up was 8.2 years (range: 1-15 yrs.) with 72% of eligible patients in active follow up at 10-15 years post-operatively. Excess weight loss (EWL) was 65.1% at 2 years, 63.8% at 5 years, and 67.9% at 10-15 years. Approximately 10% higher %EWL was achieved for those with pre-operative BMI <50 kg/m<sup>2</sup> versus  $\geq 50$  kg/m<sup>2</sup> and patients who underwent BPD/DS versus BPD. Although co-morbidities improved, 37% of patients developed long-term complications requiring surgery. There were no 30-day mortalities; however, there was one mortality from severe malnutrition. Nutritional deficiencies in fat-soluble vitamins, anemia, and secondary hyperparathyroidism were common. The authors observed that higher levels of excess weight loss are achieved by patients with a lower pre-operative BMI and BPD/DS. Although nutritional deficiencies and post-operative complications are common, and according to the authors the patient satisfaction remains high.

Risstad et al. (2017) conducted a randomized clinical trial with 60 patients with body mass index 50-60 kg/m<sup>2</sup> to investigate bile acid profiles up to 5 years after Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion with duodenal switch. Total bile acid concentrations increased substantially over 5 years after both gastric bypass and duodenal switch, with greater increases in total and primary bile acids after duodenal switch. Higher levels of total bile acids at 5 years were associated with lower body mass index, greater weight loss, and lower total cholesterol.

Strain et al. (2017) reported nine-year outcomes of biliopancreatic diversion with duodenal switch (BPD/DS). Initially 284 patients received a BPD/DS; 275 patients (69.8% women) age 42.7 years, BMI 53.4 kg/m<sup>2</sup> qualified for baseline analysis. Two hundred seventy-five patients were available in year 1; 275 patients in year 3; 273 patients in year 5;

259 patients in year 7; and 228 patients in year 9. Gender distribution was not different. BMI was 30.1 at 1 year and 32.0 at 9 years. Body fat was reduced to 26% after 2 years. Nutritional problems developed in 29.8% of patients over the course of observation. There were significant positive changes in quality of life between baseline and year 1 for most patients. Data showed that after surgery, the resolution of comorbidities continued for the 9 year follow-up period. Weight loss during the first year was well maintained, resolving comorbidities and improving quality of life. According to the authors, rates of surgical complications resemble other bariatric procedures; however long-term nutritional deficiencies are of concern.

A single-center, nonblinded, randomized, controlled trial performed by Mingrone et al (2012), with 60 patients between the ages of 30 and 60 years with a body-mass index BMI of 35 or more, a history diabetes for at least 5 years, and a glycosylated hemoglobin level of 7.0% or more were randomly assigned to receive conventional medical therapy or undergo either gastric bypass or biliopancreatic diversion. The primary end point was the rate of diabetes remission at 2 years [defined as a fasting glucose level of <100 mg per deciliter (5.6 mmol per liter) and a glycosylated hemoglobin level of <6.5% in the absence of pharmacologic therapy]. In severely obese patients with type 2 diabetes, bariatric surgery resulted in better glucose control than did medical therapy. Pre-operative BMI and weight loss did not predict the improvement in hyperglycemia after these procedures.

### **Vertical Gastrectomy (Sleeve Gastrectomy)**

Coupave et al. (2017) conducted a prospective study on 47 patients who underwent sleeve gastrectomy (SG) to evaluate the evolution of gastroesophageal reflux disease (GERD) by ambulatory 24-h pH monitoring (APM) and to determine pre- and postoperative clinical and manometric factors associated with its evolution. One year after SG, esophageal acid exposure globally worsened, mostly because of de novo GERD, whereas 63% patients with preoperative GERD improved, without preoperative predictive clinical or manometric factor. No preoperative clinical or manometric parameters were predictive of postoperative GERD.

Noel et al. (2017) conducted a retrospective analysis of a prospective cohort of 168 patients who underwent laparoscopic sleeve gastrectomy (LSG) to present the 8-year outcome concerning weight loss, modification of comorbidities, and occurrence of revisional surgery. Follow-up was available for 116 patients (69%). Of the remainder, 23 patients underwent revisional surgery and 29 were lost to follow-up. For the entire cohort, the mean excess weight loss (EWL) was 76% (0-149) at 5 years and 67% (4-135) at 8 years, respectively. Of the 116 patients with 8 years of follow-up, 82 patients had >50% EWL at 8 years (70.7%). Percentages of comorbidities resolved were hypertension, 59.4%; type 2 diabetes, 43.4%; and obstructive sleep apnea, 72.4%. Twenty-three patients had revisional surgery for weight regain (n = 14) or for severe reflux (n = 9) at a mean period of 50 months (9-96). Twelve patients underwent repeat LSG, 6 patients underwent conversion to a bypass, and 5 patients to duodenal switch (1 single anastomosis duodeno-ileostomy). A total of 31% of patients reported GERD symptoms at 8 years.

Felsenreich et al. (2017) evaluated long-term outcomes and complications following SG. Besides weight regain, GERD is the most common reason for conversion to Roux-en-Y gastric bypass. Patients (53) did not have symptomatic reflux or hiatal hernia preoperatively. Of 43 patients available for follow-up, six patients (14.0%) were converted to RYGB due to intractable reflux over a period of 130 months. Ten out of the remaining non-converted patients (n = 26) also suffered from symptomatic reflux. Gastroscopies revealed de novo hiatal hernias in 45% of the patients and Barrett's metaplasia in 15%. SG patients suffering from symptomatic reflux scored significantly higher in the RSI (p = 0.04) and significantly lower in the GIQLI (p = 0.02) questionnaire. This study shows a high incidence of Barrett's esophagus and hiatal hernias at more than 10 years after SG. Its results therefore suggest maintaining pre-existing large hiatal hernia, GERD, and Barrett's esophagus as relative contraindications to SG. The limitations of this study include its small sample size as well as the fact that it was based on early experience with SG-make drawing any general conclusions about this procedure inconclusive.

Flølo et al. (2017) presented 5-year outcomes after vertical sleeve gastrectomy (VSG), including complications and revisions, weight change, obesity-related diseases and health-related quality of life (HRQOL). Of 168 operated patients (mean age, 40.3 ± 10.5 years; 71% females), 92% completed 2-year and 82% 5-year follow-up. Re-intervention for complications occurred in four patients, whereas revision surgery was performed in six patients for weight regain and in one patient for gastroesophageal reflux disease (GERD). Mean body mass index (BMI) decreased from 46.2 ± 6.4 kg/m<sup>2</sup> at baseline to 30.5 ± 5.8 kg/m<sup>2</sup> at 2 years and 32.9 ± 6.1 kg/m<sup>2</sup> at 5 years. Remission of type 2 diabetes mellitus (T2DM) and hypertension occurred in 79 and 62% at 2 years, and 63 and 60% at 5 years, respectively. The percentage of patients treated for GERD increased from 12% preoperatively to 29% at 2 years and 35% at 5 years. Preventing weight regain and GERD are important considerations with this procedure.

Nocca et al. (2017) reported 5-year outcomes from a cohort of 1050 patients who underwent SG (mean preoperative BMI was 44.58 kg/m<sup>2</sup>) either as the primary or revisional surgical procedure. The overall reoperative rate was 6.8%, and the most common late complication was GERD (39.1%). After 3, 4 and 5 years of LSG, the average of %EBL was, respectively, 75.95% (±29.16) (382 patients), 73.23% (±31.08) (222 patients) and 69.26% (±30.86) (144 patients). The success rate at 5 years was 65.97% (95 patients). The improvement or remission of comorbidities was found,

respectively, in 88.4 and 57.2% of diabetic patients; 76.9 and 19.2% for hypertensive patients and 98 and 85% for patients with sleep apnea syndrome. The authors conclude that five-year results are very convincing for SG, although GERD is the main long-term complication.

Genco et al. (2017) evaluated the incidence of GERD on the basis of clinical, endoscopic, and histologic data in 162 patients who underwent primary SG. A total of 110 patients were available for follow-up (69.1%). At a mean 58 months of follow-up, incidence of GERD symptoms, VAS mean score, and PPI intake significantly increased compared with preoperative values (68.1% versus 33.6%:  $P < .0001$ ; 3 versus 1.8:  $P = .018$ ; 57.2% versus 19.1%:  $P < .0001$ ) At EGD, an upward migration of the "Z" line and a biliary-like esophageal reflux was found in 73.6% and 74.5% of cases, respectively. A significant increase in the incidence and in the severity of erosive esophagitis (EE) was evidenced, whereas nondysplastic Barrett's esophagus (BE) was newly diagnosed in 19 patients (17.2%). No significant correlations were found between GERD symptoms and endoscopic findings.

Stenard and Iannelli (2017) conducted a systematic review to evaluate GERD in association with SG and other bariatric procedures. GERD is described as either de novo or as being caused by aggravation of preexisting symptoms. Some cases are caused by the large compliant stomach being transformed into a long and narrow tube. Other factors are related to dismantling of the anatomical antireflux mechanisms, including disruption to the Hiss angle and resection of the sling fibers in the distal part of the lower sphincter, which results in low esophageal-sphincter pressure. The final shape of the sleeve also plays a role as it may favor GERD and regurgitation when it is funnel-shaped. Technical mistakes include narrowing at the junction between the vertical and horizontal parts of the sleeve, twisting of the sleeve, anatomical stenosis, and persistence of the gastric fundus and/or a hiatal hernia that has not been diagnosed before surgery. The role of the gastric antrum has not been fully clarified but it is thought that extensive resection of the antrum may impair gastric emptying and favor GERD. The presence of other factors, such as a HH or an impaired LES, may lead to the appearance of de novo GERD or aggravate a preexisting GERD. Based on their review, the authors conclude that when patients develop GERD after a SG resistant to PPI, a RYGB remains the operation of choice, whereas some patients with residual fundus after a SG may be suitable candidates for a redo fundectomy or a redo SG.

Lopez-Nava et al. (2016) conducted a prospective single-center follow-up study of 25 patients (5 men, 20 women) who underwent flexible endoscopic suturing for endoluminal gastric volume reduction. All patients had failed lifestyle modification efforts. A multidisciplinary team provided post-procedure care. Patient outcomes were recorded at 1 year after the procedure. Linear regression analysis was done to evaluate the variables associated with best results at 1 year of follow-up. Mean body mass index (BMI) was  $38.5 \pm 4.6$  kg/m<sup>2</sup> (range 30–47) and mean age  $44.5 \pm 8.2$  years (range 29–60). At 1 year, 22 patients continued with the follow-up (2 dropped out at 6 months and 1 at 3 months). There were no major intra-procedural, early, or delayed adverse events. Mean BMI loss was  $7.3 \pm 4.2$  kg/m<sup>2</sup>, and mean percentage of total body weight loss was  $18.7 \pm 10.7$  at 1 year. In the linear regression analysis, adjusted by initial BMI, variables associated with %TBWL involved the frequency of nutritional ( $\beta = 0.563$ ,  $P = 0.014$ ) and psychological contacts ( $\beta = 0.727$ ,  $P = 0.025$ ). The number of nutritional and psychological contacts was predictive of good weight loss results. The authors concluded that endoscopic sleeve gastropasty is a feasible, reproducible, and effective procedure to treat obesity. Nutritional and psychological interactions are predictive of success.

El Chaar et al. (2016) evaluated the incidence, indications, and outcomes of revisional surgery following LSG in adult patients. Of the 630 LSGs performed, 481 patients were included in the analysis (mean age and BMI = 46.2 and 44.3, respectively; 79.5% female; 82.3% white). A total of 12/481 patients underwent conversion to a different bariatric procedure due to inadequate weight loss, GERD, or both. The 6/12 patients with GERD-related symptoms and failed medical management underwent conversion to Roux-en-Y gastric bypass (RYBG) following pre-operative wireless Bravo pH monitoring (Given Imaging) to confirm the diagnosis objectively. The other 6/12 patients with inadequate weight loss received either RYBG or bilio-pancreatic diversion with duodenal switch (BPD/DS) based on personal choice. Overall, 9/12 patients underwent conversion to RYBG, and 3/12 underwent conversion to BPD/DS. Median time from the initial surgery to conversion was 27 months (range 17–41). Median operating room time was 168 min (range 130–268). Median length of stay was 48 h (range 24–72). The follow-up rate at 3 months was 100% (12/12 patients). The authors conclude that conversion to RYBG or BPD/DS may be done safely and effectively in patients present following LSG with refractory GERD or inadequate weight loss. Longer term outcomes are needed.

In a retrospective study of prospectively collected data, Garofalo et al. (2016) assessed the safety and efficacy of laparoscopic sleeve gastrectomy (LSG) performed in older patients ( $\geq 65$  years old). A total of 27 (90%) primary LSG and 3 revisional LSG (10%) were performed. Thirty-day morbidity included 3 cases of self-limiting nausea and vomiting and 1 case of gastric sleeve stenosis necessitating conversion to gastric bypass. No mortality reported. The overall mean percentage of excess weight loss ( $\pm$ SD) and percentage of total weight loss ( $\pm$ SD) at 12 months were  $53.8 \pm 19.8$  and  $23.9 \pm 8.4$ ;  $52.9 \pm 21.8$  and  $24 \pm 9.9$  at 36 months, respectively. No patients were lost to follow-up but 5 were excluded because they underwent revisions. Age-adjusted mixed model analyses revealed that baseline BMI ( $P = .018$ ), BMI  $> 45$  kg/m<sup>2</sup> ( $P = .001$ ), and having diabetes ( $P = .030$ ) were associated with excess weight loss  $< 50\%$

across follow-up. Their conclusion is that LSG seems to be effective and safe for patients  $\geq 65$  years old and that obesity related co-morbidities have improved across follow-up.

Brethauer et al. (2009) performed a systematic review ( $n=36$  studies) of the evidence on sleeve gastrectomy (SG). Studies included a single nonrandomized matched cohort analysis, RCTs ( $n=2$  studies) and uncontrolled case series ( $n=33$  studies). The mean BMI in all 36 studies was  $51.2 \text{ kg/m}^2$ . The mean baseline BMI was  $46.9 \text{ kg/m}^2$  for the high-risk patients (range 49.1 - 69.0) and  $60.4 \text{ kg/m}^2$  for the primary SG patients (range 37.2 - 54.5). The follow-up period ranged from 3–60 months. The mean% of excess weight loss (EWL) after SG reported in 24 studies was 33–85%, with an overall mean%EWL of 55.4%. The mean post-operative BMI was reported in 26 studies and decreased from a baseline mean of  $51.2 \text{ kg/m}^2$  to  $37.1 \text{ kg/m}^2$  post-operatively. Improvement or remission of type 2 diabetes was found in more than 70% of patients. Significant improvements were also seen in hypertension and hyperlipidemia, as well as in sleep apnea and joint pain. The major post-operative complication rate ranged from 0% - 23.8%.

A randomized, nonblinded, single-center trial, Schauer, et al. (2012) evaluated the efficacy of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy in 150 obese patients with uncontrolled type 2 diabetes. The mean age of the patients was  $49 \pm 8$  years, and 66% were women. The average glycated hemoglobin level was  $9.2 \pm 1.5\%$ . The primary end point was the proportion of patients with a glycated hemoglobin level of 6.0% or less 12 months after treatment. In obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery achieved glycemic control in significantly more patients than medical therapy alone. Further study will be necessary to assess the durability of these results.

A prospective, randomized, double blind study by Karamanakos et al. (2008) evaluated 32 patients (16 LRYGBP; 16 LSG) to compare the effects of laparoscopic Roux-en-Y gastric bypass (LRYGBP) with LSG on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels. Patients were reevaluated on the 1<sup>st</sup>, 3<sup>rd</sup>, 6<sup>th</sup>, and 12<sup>th</sup> post-operative month. Blood samples were collected after an overnight fast and in 6 patients in each group after a standard 420 kcal mixed meal. Body weight and body mass index (BMI) decreased markedly ( $P < 0.0001$ ) and comparably after either procedure. After LRYGBP fasting ghrelin levels did not change significantly compared with baseline ( $P = 0.19$ ) and did not decrease significantly after the test meal. On the other hand, LSG was followed by a marked reduction in fasting ghrelin levels ( $P < 0.0001$ ) and a significant suppression after the meal. Fasting PYY levels increased after either surgical procedure ( $P \leq 0.001$ ). Appetite decreased in both groups but to a greater extent after LSG. In addition, patients in the LRYGBP group had an increase in appetite after 12 months whereas the LSG group maintained a reduced appetite during the same timeframe. The authors concluded that LSG has better outcomes than LRYGBP with regard to appetite suppression and excess weight loss due to reduced ghrelin levels and increased PYY levels after LSG. This study is limited by small sample size and short term follow-up; however the strengths are that this is a double blind, randomized study.

A prospective randomized by Himpens et al. (2006) compared the laparoscopic adjustable gastric band (GB) with sleeve gastrectomy (SG) in 80 patients (40 GB and 40 SG). Weight loss, feeling of hunger, sweet eating, gastroesophageal reflux disease (GERD), complications and re-operations were recorded post-operatively in both groups at 1 and 3 years. Loss of feeling of hunger after 1 year was registered in 42.5% of patients with GB and in 75% of patients with SG ( $P=0.003$ ); and after 3 years in 2.9% of patients with GB and 46.7% of patients with SG ( $P<0.0001$ ). Loss of craving for sweets after 1 year was achieved in 35% of patients with GB and 50% of patients with SG (NS); and after 3 years in 2.9% of patients with GB and 23% of patients with SG (NS). GERD appeared de novo after 1 year in 8.8% of patients with GB and 21.8% of patients with SG (NS); and after 3 years in 20.5% of patients with GB and 3.1% of patients with SG (NS). Post-operative complications requiring re-operation were necessary for 2 patients after SG. Late complications requiring re-operation after GB included 3 pouch dilations treated by band removal in 2 and 1 laparoscopic conversion to Roux-en-Y gastric bypass (RYGBP), 1 gastric erosion treated by conversion to RYGBP, and 3 disconnections of the system treated by reconnection. Inefficacy affected 2 patients after GB, treated by conversion to RYGBP and 2 patients after SG treated by conversion to duodenal switch. The authors concluded that patients with sleeve gastrectomy had better overall weight loss, loss of hunger and sweets than those who underwent gastric banding; however the number of re-operations is important in both groups, but the severity of complications appears higher in SG.

Rubin et al. (2008) conducted a prospective study of 120 consecutive morbidly obese patients to review the rate of post-operative complications and the lack of consensus as to surgical technique for laparoscopic sleeve gastrectomy (LSG). Patients underwent LSG using the following technique: (1) division of the vascular supply of the greater gastric curvature and application of the linear stapler-cutter device beginning at 6-7 cm from the pylorus so that part of the antrum remains; (2) inversion of the staple line by placement of a seroserosal continuous suture close to the staple line; (3) use of a 48 French bougie so as to avoid possible stricture; (4) firing of the stapler parallel to the bougie to make the sleeve as narrow as possible and prevent segmental dilatation. Mean follow-up was 11.7 months. Intraoperative difficulties were encountered in 4 patients. There were no post-operative complications, no hemorrhage from the staple line, no anastomotic leakage or stricture, and no mortality. The authors concluded that the procedure

evaluated was safe and effective; however, long-term results are still pending. This study is limited by lack of randomization, short follow-up, and lack of comparison to other bariatric surgical procedures.

In a non-randomized study of vertical gastrectomy by Lee et al. (2007), 846 patients undergoing primary laparoscopic bariatric procedures were compared. Of the 846 patients, 271 opted for the Band, 216 underwent vertical gastrectomy, 303 had Roux-en-Y, and 56 had duodenal switch operation. In the study, vertical gastrectomy patients experienced a similar rate of weight loss compared to Roux-en-Y and duodenal switch. There were also fewer complications with vertical gastrectomy (7.4%) than Roux-en-Y (22.8%) and duodenal switch (48.2%) with the Band procedure having the fewest complications (6.6%). The authors conclude that long-term efficacy of vertical gastrectomy is unclear but is promising. Further studies are needed to determine long-term results.

A retrospective review by Lalor et al. (2008) examined laparoscopic sleeve gastrectomy (LSG) as a primary or revision bariatric procedure in 148 patients with a mean body mass index (BMI) of 44. All but 3 cases were completed laparoscopically (98%). Major complications occurred in 4 patients (2.9%) and involved 1 leak (0.7%) and 1 case of hemorrhage (0.7%), each requiring reoperation; 1 case of post-operative abscess (0.7%), and 1 case of sleeve stricture that required endoscopic dilation (0.7%). One late complication of choledocholithiasis and bile duct stricture required a Whipple procedure. LSG was used as a revision surgery in 16 patients (9%); of these, 13 underwent LSG after complications related to laparoscopic adjustable gastric banding, 1 underwent LSG after aborted laparoscopic Roux-en-Y gastric bypass, and 2 underwent LSG after failed jejunoileal bypass. One of the revision patients developed a leak and an abscess (7.1%) requiring reoperation; 1 case was aborted, and 2 cases were converted to an open procedure secondary to dense adhesions. No deaths occurred in either group. Seven patients (4.9%) required readmission within 3 months after surgery. The authors concluded that LSG is a relatively safe surgical option for weight loss as a primary procedure and as a primary step before a secondary non-bariatric procedure in high-risk patients; however, additional studies are needed to evaluate the clinical evidence of post-operative reflux, gastric sleeve dilation, and long-term maintenance of weight loss. This study did not examine LSG in super-obese patients or those with multiple co-morbidities and is limited by lack of long-term follow-up. (Same population also reported by Tucker et al. 2008)

### **Vertical Banded Gastroplasty (VBG)**

van Wezenbeek et al. (2015) retrospectively evaluated a total of 392 patients (80% female) with a mean body mass index of  $44 \pm 5$  kg/m<sup>2</sup> who underwent primary VBG. Mean follow-up after VBG was  $66 \pm 50$  months and showed a mean excess weight loss (EWL) of  $53 \pm 27\%$  and comorbidity reduction of 54%. One hundred fifty-two patients (39%) out of 227 patients (58%) with long-term complaints underwent revisional surgery. Main reasons for revision were weight regain and vomiting/food intolerance. Analysis before revision showed an outlet dilatation (17%), pouch dilatation (16%), and outlet stenosis (10%). After revision, an additional EWL of 23% and 33% further reduction in comorbidities was seen. They concluded that primary VBG has an acceptable EWL of 53% and 55% of comorbidities were improved however, the high complication rate, often necessitating revision, underlines the limits of this procedure.

A Cochrane Database Systematic Review by Colquitt et al. (2009) found that while complication rates for vertical banded gastroplasty are relatively rare, revision rates requiring further surgical intervention are approximately 30%. Complication rates for VBG were not included in their updated 2014 Cochrane Database Systematic Review.

### **Robotic-Assisted Gastric Bypass Surgery**

Ayloo et al. (2016) retrospectively reviewed their experience with robotic approaches to RYGB using prospectively maintained data. Procedures were categorized into three groups: laparoscopic, hybrid robotic (HR), and total robotic (TR). The study included 192 RYGB consecutive patients who underwent laparoscopic, HR, or TR surgery. Mean patient age, pre-operative body mass index, and pre-operative weight were  $40.4 \pm 9.3$  years (range 22-64),  $46.2 \pm 5.9$  kg/m<sup>2</sup> (range 35-64), and  $130.3 \pm 22.1$  kg (range 76.7-193.4) respectively. Ninety-two patients (47.9%) had undergone previous abdominal surgery. Mean operative time, estimated blood loss, and length of stay were  $223.4 \pm 39.2$  min (range 130-338),  $21.9 \pm 18.8$  mL (range 5-10), and  $2.6 \pm 1.1$  days (range 2-15), respectively. There were 248 concomitant procedures such as upper endoscopy, cholecystectomy, etc., 7 revisional surgeries, and 2 conversions to open surgery. Intraoperative complications included one liver laceration and one bowel injury. There were two cases each of bowel obstruction, transfusions, and deep vein thrombosis/pulmonary embolus, but no deaths or anastomotic leaks. Although there were variables such as different concomitant procedures, the authors conclude that early experience with a total robotic approach for RYGB appears to be safe, with similar outcomes to the laparoscopic approach.

In a systematic review and meta-analysis, Bindal et al. (2015) evaluated the role of robotics in bariatric surgical procedures. Several studies showed a lower complication rate with the robotic platform including leaks, hemorrhage and stricture. Another advantage noted by the authors for the use of the robotic system is improved ergonomics and lesser operator fatigue. With the advent of newer technologies in robotics the authors conclude that it will provide an empowering tool to the surgeons, which can potentially change the way surgery is practiced. Large and well-designed

randomized clinical trials with long follow-up are needed to further define the role of digital platforms in bariatric surgery.

Economopoulos et al. (2015) conducted a systematic review and meta-analysis to evaluate the available literature on patients treated with robotic RYGB and compared the clinical outcomes of patients treated with robotic RYGB with those treated with the standard laparoscopic RYGB. Fourteen comparative and 11 non-comparative studies were included in this study, reporting data on 5145 patients. Based on their review they found robotic-assisted RYGB was associated with significantly less frequent anastomotic stricture events, reoperations, and a decreased length of hospital stay compared with the standard laparoscopic procedures; however, these findings should be interpreted with caution given the low number and poor quality of the studies currently available in the literature.

Mohr et al. (2005) conducted a retrospective case study comparing the first 10 patients who underwent a totally robotic laparoscopic Roux-en-Y gastric bypass to a retrospective sample of 10 patients who had undergone laparoscopic Roux-en-Y gastric bypass surgery. The median surgical times were significantly lower for the robotic procedures. Researchers from the same institution also conducted a RCT to compare a single surgeon's results using the da Vinci system (n=25) with those using traditional laparoscopic Roux-en-Y gastric bypass surgery (n=25) when the techniques were learned simultaneously. The mean operating time was again significantly shorter for the robotic procedures. The largest difference was in patients with a BMI >43 kg/m<sup>2</sup> (Sanchez, 2005). The authors concluded that these studies demonstrated the feasibility, safety, and potential superiority of robotic laparoscopic Roux-en-Y gastric bypass. In addition, the learning curve may be significantly shorter with the robotic procedure. Further experience is needed to understand the long-term advantages and disadvantages of the totally robotic approach.

Sudan et al. (2007) evaluated the safety, feasibility, and reproducibility of robotic-assisted biliopancreatic diversion with duodenal switch (BPD/DS) in 47 patients with a mean body mass index (BMI) of 45 kg/m<sup>2</sup>. The operating time decreased for the last 10 procedures. Three patients underwent conversion to open surgery, and four patients experienced post-operative leaks with no mortality. No control group was available in this study.

### **Revision Surgery**

Pinto-Bastos et al., (2017) conducted a systematic review of reoperative surgery following the failure of primary bariatric surgery. The etiology of reasons for undergoing a second surgery includes medical (e.g., fistula, ulcer disease) and behavioral aspects. Eating and lifestyle behaviors, difficulty in embracing the required lifestyle changes, and reappearance of depressive and anxious symptoms have been associated with failure of weight loss or weight regain after primary surgeries. The authors recommend that particular attention be paid to surgical candidates with a history of difficulties in engaging in healthy eating patterns.

In a retrospective review, Fulton et al. (2017) evaluated outcomes of revisional bariatric surgery in 2769 patients. The mean preoperative body mass index (BMI) was 44.7 ± 9.5 in revision patients compared with 45.7 ± 7.6 in primary bariatric surgery patients. Most revision patients had a prior vertical banded gastroplasty (VBG; 48%) or a laparoscopic adjustable gastric band (LAGB; 24%). Bands were removed in 36% of all LAGB patients presenting to clinic. Of the 134 procedures performed in the revision clinic, 83 were bariatric weight loss surgeries, and 51 were band removals. Revision clinic patients experienced a significant decrease in BMI (from 44.7 ± 9.5 to 33.8 ± 7.5, p < 0.001); their BMI at 12-month follow-up was similar to that of primary clinic patients (34.5 ± 7.0, p = 0.7). The authors identified that complications were significantly more frequent in revision patients than primary patients (41% v. 15%, p < 0.001).

Sharples et al. (2017) conducted a systematic review and meta-analysis of outcomes after revisional bariatric surgery. 2617 patients in 36 studies underwent either adjustable gastric band to Roux-en-Y gastric bypass (B-RYGB) or band to sleeve gastrectomy (B-SG). There was no difference between the B-RYGB and B-SG groups in morbidity, leak rate or return to surgery. Percentage excess weight loss (%EWL) following the revisional procedure for all patients combined at 6, 12 and 24 months was 44.5, 55.7 and 59.7%, respectively. There was no statistical difference in %EWL between B-RYGB and B-SG at any time point. The rates of remission of diabetes, hypertension and obstructive sleep apnea were 46.5, 35.9 and 80.8%, respectively. Available observational evidence does suggest that revisional bariatric surgery is associated with outcomes similar to those experienced after primary surgery. Further, high-quality research, particularly RCTs, is required to assess long-term weight loss, comorbidity and quality of life outcomes.

Tran et al., (2016) conducted a systematic review of 24 studies and 866 patients to evaluate outcomes and complications of different surgical methods of revision that were done after failed primary RYGB. All patients in the studies reported significant early initial weight loss after revisional surgery. However, of the five surgical revision options considered, biliopancreatic diversion/duodenal switch, distal RYGB, and gastric banding resulted in sustained weight loss, with what is considered by the authors as an acceptable complication rate.

Switzer et al. (2016) found that revisional bariatric procedures are increasingly common. With more primary procedures being performed to manage extreme obesity and its complications, 5% to 8% of these procedures will fail, requiring revisional operation. Reasons for revisional bariatric surgery are either primary inadequate weight loss, defined as less than 25% excess body weight loss, or weight recidivism, defined as a gain of more than 10 kg based on the nadir weight; however, each procedure also has inherent specific complications that can also be indications for revision. This article reviews the history of each primary bariatric procedure, indications for revision, surgical options, and subsequent outcomes.

Quezada et al. (2016) conducted a retrospective analysis of laparoscopic sleeve gastrectomy (SG) conversion to Roux-en-Y gastric bypass (n=50) due to the observation of increased complications of SG as the number of procedures increase. Revisions were done due to weight regain, GERD, or gastric stenosis. At follow-up (over a 3 year period), the authors reported median excess weight loss was 60.7 lbs., all gastric stenosis symptoms had resolved, and over 90% of GERD patients reported either a resolution or improvement in symptoms. Despite their findings, long-term follow-up on this patient population is needed.

Felsenreich et al. (2016) reviewed 10-year outcomes from patients (n=53) who underwent a laparoscopic sleeve gastrectomy. Nineteen of the 53 patients (36%) were converted to Roux-en-Y gastric bypass (n = 18) or duodenal switch (n = 1) due to significant weight regain (n = 11), reflux (n = 6), or acute revision (n = 2) at a median of 36 months. Within a long-term follow-up of 10 years or more after SG, a high incidence of both significant weight regain and intractable reflux was observed, leading to conversion, most commonly to Roux-en-Y gastric bypass.

In a retrospective review of 66 open revisions to RYGB, Roller and Provost (2006) found that patients who had undergone one or more previous revisions required longer operative times and hospital stays and also suffered greater blood loss than patients undergoing revision to RYGB for the first time. Patients with previous revisions were also more likely to have complications (16.7% patients versus 9.3%) and had slightly poorer weight loss outcomes (mean%EWL 54.3% versus 60.6%), but the authors considered the complication rate and outcomes in both groups to be acceptable.

### **Pediatric and Adolescent Bariatric Surgery**

The American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee (Michalsky et al., 2012) best practice guidelines state that there is a mounting body of evidence that supports the use of modern surgical weight loss procedures for carefully selected, extremely obese adolescents. All adolescent boys and most adolescent girls <18 years old with a BMI of 35 kg/m<sup>2</sup> are greater than the 99th BMI percentile, so the BMI thresholds used for adult selection criterion appear to be appropriate for adolescents, with some modification with regard to associated comorbid disease thresholds. Although current evidence is not sufficiently robust to allow a precise discrimination or recommendations among specific bariatric procedures, an increasing body of data demonstrating evidence of safety and efficacy exists for 2 of the more commonly performed bariatric procedures for this age group [i.e., Roux-en-Y gastric bypass (RYGB) and adjustable gastric band (AGB)]. (Refer to the [Professional Societies](#) section for additional ASMBS information on the pediatric and adolescent population.)

Adolescent severe obesity is associated with numerous comorbidities, and persists into adulthood. Bariatric surgery is the most effective treatment available, resulting in major weight loss and resolution of important comorbid conditions. (Desai et al., 2016) Clinical practice guidelines for pediatric obesity treatment recommend consideration of surgery after failure of behavioral approaches. Careful screening and post-operative management of patients by a multidisciplinary team is required. Long-term studies are needed to assess the impact of adolescent bariatric surgery. Adolescent obesity is associated with preventable chronic health conditions such as type two diabetes mellitus (T2DM), hypertension, obstructive sleep apnea syndrome (OSAS), dyslipidemia, nonalcoholic steatohepatitis, polycystic ovary syndrome, and various musculoskeletal diseases. Obese adolescents are likely to suffer from psychological morbidity, loss of self-esteem, and social exclusion which has the potential for life-long effects. The risk of dying from any obesity-related cause increases by 6–7% for every 2 years lived with obesity. Presently, adolescent obesity is mostly managed by combined lifestyle interventions focusing on behavioral and dietary modifications. These treatments are typically initiated and evaluated by a multidisciplinary team including a pediatrician, dietician, psychologist, and a physiotherapist. While often effective in short term, long-term effects are relatively disappointing. Potential adverse effects on growth and development in prepubertal patients who have not reached full maturity raise concerns. However, bariatric surgery relatively early in life intervenes before comorbidities become irreversible and reduces the risk of surgical complications. (Paulus, et al., 2015)

Ryder et al. (2017) evaluated factors associated with long-term weight-loss maintenance following bariatric surgery in adolescents (n=50) with severe obesity who underwent Roux-en-Y gastric bypass surgery. Follow-up visits at 1 year and at a visit between 5 and 12 years following surgery (follow-up of Adolescent Bariatric Surgery at 5 Plus years (FABS-5+) visit. A non-surgical comparison group (n=30; mean±s.d. age and BMI=15.3±1.7 years and BMI=52±8 kg m<sup>-2</sup>) was recruited to compare weight trajectories over time. The BMI of the surgical group declined from baseline to 1 year (-38.5±6.9%), which, despite some regain, was largely maintained until FABS-5+ (-

29.6±13.9% change). The BMI of the comparison group increased from baseline to the FABS-5+ visit (+10.3±20.6%). When the surgical group was split into maintainers and re-gainers, no differences in weight-related and eating behaviors, health responsibility, physical activity/inactivity, or dietary habits were observed between groups. However, at FABS-5+, maintainers had greater overall QOL scores than re-gainers (87.5±10.5 vs 65.4±20.2, P<0.001) and in each QOL sub-domain (P<0.01 all).

Jaramillo et al. (2017) conducted a retrospective study on 38 adolescents who underwent laparoscopic sleeve gastrectomy (LSG). Mean age was 16.8 years, mean weight was 132.0 kg and mean BMI was 46.7. There were no reported surgical complications. Mean%EWL was 19.4%, 27.9%, 37.4%, 44.9%, and 47.7% at 1.5, 3, 6, 9, and 12 month follow up visits, respectively. Comorbidity resolution rates were 100% for hypertension and nonalcoholic fatty liver disease, 91% for diabetes, 44% for prediabetes, 82% for dyslipidemia and 89% for OSA. The authors concluded that based on their current data, LSG is an effective and safe method of treatment of morbid obesity in adolescents as it can significantly decrease excess body weight and resolve comorbid conditions. Further studies are needed to investigate the long-term effects of LSG in adolescents.

In a retrospective study of prospectively collected data, Vilallonga et al. (2016) evaluated long-term outcomes after laparoscopic Roux-en-Y gastric bypass (LRYGB) in patients <18 years. This group of patients (ChG) was matched with an adult control group (AdG) of randomly chosen patients with similar characteristics who underwent LRYGB during the same period. Nineteen of the original 28 patients (67.9%) were available for follow-up. Pre-operatively, 3 had type 2 diabetes mellitus (T2DM), 1 arterial hypertension, 5 dyslipidemia and 1 sleep apnea. In the ChG, average BMI after 7 years dropped from 38.9 kg/m<sup>2</sup> pre-operatively to 27.5 kg/m<sup>2</sup>. In the AdG, average BMI decreased from 39.4 to 27.1 kg/m<sup>2</sup> in the same time period (nonsignificant between groups). One patient in the ChG needed a reoperation (internal hernia) versus 3 patients in the AdG (1 leak, 2 obstructions). All patients resolved their initial comorbidities. The authors concluded that LRYGB seems to be safe, provide good weight loss, and cure comorbidities in an adolescent population. Small patient population was a limitation to this study.

In a systematic review and meta-analysis, Paulus et al. (2015) evaluated the efficacy, safety, and psychosocial health benefits of various bariatric surgical techniques (RYGB, LAGB, LSG) as a treatment for morbid obesity in adolescents. A total of 37 peer-reviewed articles were included, although the studies were mainly observational and varied in quality. Authors of 9 studies were contacted for additional information. All three procedures lead to significant weight loss in morbidly obese adolescents, and weight loss is most pronounced after RYGB. This seems to persist after both RYGB and LAGB. For LSG studies, long-term follow-up were not yet available. While adverse events are relatively mild and long-term complication rates are acceptable, they are more frequent and more serious after RYGB than after LAGB. In the currently available follow-up after LSG, the rate of adverse events appears to be similar to that after LAGB. Although a healthy nutritional status in adolescents is important to prevent developmental and growth deficiencies, standard post-operative vitamin supplementation regimens and the occurrence of deficiencies are not reported in most studies (not at all in LSG studies). However, more and more severe deficiencies occur after RYGB than after LAGB. Reduction of comorbidity, which is pivotal for health gain, is impressive in all techniques, and QOL consistently showed improvement, although follow-up up to 24 months may not be enough to capture negative long-term effects in life after bariatric surgery. A limitation of this review is the lack of high-quality, prospective randomized controlled trials, which increases the risk of bias and therefore introduces heterogeneity.

Zitsman et al. (2015) studied a population of morbidly obese teenagers (n=137) who underwent LAGB to evaluate its safety and effectiveness. The mean weight gain between enrollment and LAGB was 4.7 kg. Mean pre-operative weight, body mass index (BMI), and excess BMI were 136.1 kg, 48.3 kg/m<sup>2</sup>, and 23.6 kg/m<sup>2</sup>, respectively. Mean BMI at 6, 12, 18, 24, and 36 months was 43.8, 41.6, 41.5, 40.5, and 39.3. Excess BMI loss was 28.4%, 35.9%, and 41.1% at 1, 2, and 3 years postop. Co-morbid conditions improved or resolved with weight loss after LAGB. Thirty patients (22%) underwent one or more additional operations for complications. Twenty-seven patients (20%) converted to other weight loss procedures or had their bands removed. The authors concluded that morbidly obese adolescents can lose weight successfully and experience health improvement following LAGB, but the role of LAGB in the younger population requires long-term evaluation.

Brissman et al. (2017) evaluated 2-year outcomes in cardiorespiratory fitness, body composition, and functional capacity in a subset of adolescents (n=41) from the Adolescence Morbid Obesity Surgery (AMOS) study who had Roux-en-Y gastric bypass. In addition to anthropometric measurements, participants performed a submaximal bicycle test, 6-min walk test, dual-energy X-ray absorptiometry, and a short interview at baseline, 1 and 2 years after surgery. Relative improvements in maximal oxygen consumption (VO<sub>2</sub>max) per kilogram body mass (+62%) and per kilogram fat-free mass (+21%), as well as walking distance (+13%) were observed after 1 year, and persisted 2 years after surgery. Despite a reduction of fat-free mass (-15%), absolute VO<sub>2</sub>max was maintained across the full group (+8%, p = ns) and significantly increased in non-smokers. Body mass and fat mass were significantly decreased (-45.4 and -33.3 kg, respectively). Self-reported physical activity was significantly increased, and pain associated with movement was reduced. In adolescents with obesity, Roux-en-Y gastric bypass improved VO<sub>2</sub>max more than could be explained by fat mass loss alone. In combination with improved functional capacity and body

composition, these results suggest that surgery in adolescence might add specific benefits of importance for future health. However, longer term outcomes are needed.

Beamish et al. (2016) studied bone health and body composition in 72 adolescents who underwent RYGB. Inclusion criteria included the following: age 13-18 years and body mass index (BMI) > 35 kg/m<sup>2</sup>. Patients underwent dual-energy X-ray absorptiometry and serum bone marker analyses pre-operatively and annually for 2 years. Differences in body fat and lean mass proportions were observed according to sex following RYGB. Mean BMI reduction at 2 years was 15.1 kg/m<sup>2</sup>. Body composition changes included a reduction in fat mass (51.8% to 39.6%,  $p < 0.001$ ) and relative increase in lean mass (47.0% to 58.1%,  $p < 0.001$ ). In contrast to previous studies in adults, adolescent boys lost a greater percentage of their body fat than girls (-17.3% vs. -9.5%,  $p < 0.001$ ). Individual bone mineral density Z-scores (BMD-Z) at baseline were within or above the normal range. The mean (SD) BMD-Z was 2.02 (1.2) at baseline, decreasing to 0.52 (1.19) at 2 years. Higher concentrations of serum CTX ( $p < 0.001$ ) and osteocalcin ( $p < 0.001$ ) were observed in boys throughout the study period. Levels rose in the first year, before decreasing modestly in the second. Levels of serum markers of bone synthesis and resorption were higher in boys, whose skeletal maturity occurs later than girls'. Bone turnover increased, and BMD decreased to levels approaching a norm for age. Long-term outcome will determine the clinical relevance.

Mirensky (2016) found that bariatric surgery provides a clinically effective and cost-effective means of achieving sustained weight reduction and management of associated comorbidities and has been met with increasing enthusiasm for application in obese youth. Following trends seen among obese adults, carefully selected obese youth are now undergoing bariatric surgical procedures with excellent short-term and intermediate-term outcomes. Although long-term data are not yet available, the author comments that the results thus far hold great promise in the management of this population.

The Teen-Longitudinal Assessment of Bariatric Surgery (LABS) Study was a prospective, multicenter, observational study, which enrolled 242 adolescents ( $\leq 19$  years of age) who were undergoing bariatric surgery from March 2007 through February 2012 at 5 US adolescent bariatric surgery centers. The patients underwent Roux-en-Y gastric bypass ( $n=161$ ), sleeve gastrectomy ( $n=67$ ), or laparoscopic adjustable gastric band ( $n=14$ ). Ryder et al. (2016) evaluated 2-year outcomes to determine the impact of bariatric surgery on functional mobility and musculoskeletal pain. Participants completed a 400-m walk test prior to bariatric surgery ( $n=206$ ) and at 6 months ( $n=195$ ), 12 months ( $n=176$ ), and 24 months ( $n=149$ ) after surgery. Time to completion, resting heart rate (HR), immediate posttest HR, and HR difference (resting HR minus posttest HR) were measured and musculoskeletal pain concerns, during and after the test, were documented. Data were adjusted for age, sex, race/ethnicity, baseline body mass index (calculated as weight in kilograms divided by height in meters squared), and surgical center (posttest HR and HR difference were further adjusted for changes in time to completion). Compared with the baseline, the post-surgery data showed an improvement in all measurements at all times measured. The authors conclude that bariatric surgery in adolescents with extreme obesity is associated with significant improvement in functional mobility and in the reduction of walking-related musculoskeletal pain up to 2 years after surgery.

In a prospective, non-randomized controlled study of 81 adolescents (aged 13–18 years) with severe obesity who underwent Roux-en-Y bypass, Olbers et al. (2017) compared clinical outcomes with those of matched adolescent controls undergoing conservative treatment and of adult controls undergoing Roux-en-Y gastric bypass. The primary outcome measure was change in BMI over 5 years. The change in bodyweight in adolescent surgical patients over 5 years was -36.8 kg (95% CI -40.9 to -32.8), resulting in a reduction in BMI of -13.1 kg/m<sup>2</sup> (95% CI -14.5 to -11.8). Mean BMI rose in adolescent controls (3.3 kg/m<sup>2</sup>, 95% CI 1.1–4.8) over the 5-year study period, whereas the BMI change in adult controls was similar to that in adolescent surgical patients. Comorbidities and cardiovascular risk factors in adolescent surgical patients showed improvement over 5 years and compared favorably with those in adolescent controls. 20 (25%) of 81 adolescent surgical patients underwent additional abdominal surgery for complications of surgery or rapid weight loss and 58 (72%) showed some type of nutritional deficiency; health-care consumption (hospital visits and admissions) was higher in adolescent surgical patients compared with adolescent controls. 20 (25%) of 81 adolescent controls underwent bariatric surgery during the 5-year follow-up. The authors' interpretation was that although the adolescents who underwent Roux-en-Y gastric bypass had substantial weight loss over 5 years alongside improvements in comorbidities and risk factors, gastric bypass was associated with additional surgical interventions and nutritional deficiencies. Conventional non-surgical treatment was associated with weight gain and a quarter of patients had bariatric surgery within 5 years.

Inge et al. (2017) conducted a prospective follow-up analysis of long-term (>5 years) outcomes of Roux-en-Y gastric bypass in a cohort of young adults 13-21 years of age ( $n=58$ ) who underwent the procedure during adolescence, in the Follow-up of Adolescent Bariatric Surgery at 5 Plus Years (FABS-5+) extension study. Outcomes assessed included BMI, comorbidities, micronutrient status, safety, and other risks. At baseline, the mean age of the cohort was 17.1 years (SD 1.7) and mean BMI was 58.5 kg/m<sup>2</sup> (10.5). At mean follow-up of 8.0 years (SD 1.6; range 5.4–12.5), the mean age of the cohort was 25.1 years (2.4) and mean BMI was 41.7 kg/m<sup>2</sup> [12.0; mean change in BMI -29.2% (13.7)]. From baseline to long-term follow-up, significant declines were recorded in the prevalence of elevated blood

pressure [27/57 (47%) vs 9/55 (16%);  $p=0.001$ ], dyslipidemia [48/56 (86%) vs 21/55 (38%);  $p<0.0001$ ], and type 2 diabetes [9/56 (16%) vs 1/55 (2%);  $p=0.03$ ]. At follow-up, 25 (46%) of 58 patients had mild anemia (not requiring intervention), 22 (45%) had hyperparathyroidism, and eight (16%) had low amounts of vitamin B12 (below the normal cutpoint). The authors conclude that Roux-en-Y gastric bypass surgery resulted in substantial and durable bodyweight reduction and cardiometabolic benefits for young adults. In addition, they recommend that long-term health maintenance after Roux-en-Y gastric bypass should focus on adherence to dietary supplements and screening and management of micronutrient deficiencies.

Inge et al. (2016) reported 3-year outcomes from the TEEN-LABS study of adolescents ( $n=242$ ) undergoing Roux-en-Y gastric bypass (161 participants) or sleeve gastrectomy. Changes in body weight, coexisting conditions, cardiometabolic risk factors, and weight-related quality of life and post-operative complications were evaluated. The mean weight had decreased by 27% [95% confidence interval (CI), 25 to 29] in the total cohort, by 28% (95% CI, 25 to 30) among participants who underwent gastric bypass, and by 26% (95% CI, 22 to 30) among those who underwent sleeve gastrectomy. By 3 years after the procedure, remission of type 2 diabetes occurred in 95% (95% CI, 85 to 100) of participants who had had the condition at baseline, remission of abnormal kidney function occurred in 86% (95% CI, 72 to 100), remission of prediabetes in 76% (95% CI, 56 to 97), remission of elevated blood pressure in 74% (95% CI, 64 to 84), and remission of dyslipidemia in 66% (95% CI, 57 to 74). Weight-related quality of life also improved significantly. However, at 3 years after the bariatric procedure, hypoferritinemia was found in 57% (95% CI, 50 to 65) of the participants, and 13% (95% CI, 9 to 18) of the participants had undergone one or more additional intraabdominal procedures. The authors found significant improvements in weight, cardiometabolic health, and weight-related quality of life at 3 years after the procedure. Risks associated with surgery included specific micronutrient deficiencies and the need for additional abdominal procedures.

Ejaz, et al. (2016) reported outcomes following laparoscopic sleeve gastrectomy (LSG) as a first-line bariatric procedure among adolescents under 21 years of age ( $n=18$ ). BMI among all patients was  $48.6\pm 7.2\text{kg/m}^2$  and did not differ by gender ( $P=0.68$ ). One patient (5.6%) experienced a 30-day perioperative complication (pulmonary embolism). Median LOS following LSG was 3 days (IQR: 2, 3). 2 patients (11.1%) were readmitted within 30-days because of feeding intolerance that resolved without invasive intervention. At a median follow-up of 10.6 (range: 0-38) months, percent excess weight loss (%EWL) among all patients was 35.6%. Among patients with at least 2 years follow-up ( $n=3$ ), %EWL was 50.2%. The authors conclude that laparoscopic sleeve gastrectomy in morbidly obese adolescents is a safe and feasible option. Short- and long-term weight loss appears to be successful following LSG.

Hervieux et al. (2016) commented that due to disappointing results obtained with dietary and medical programs, bariatric surgery has been offered to adolescents, although in their opinion this practice remains controversial. In a prospective study, they compared 2-year results between adolescent patients and young adult controls that underwent LAGB. Follow-up program were similar, weight loss and comorbid disease were analyzed. During this period, insulin resistance and dyslipidemia decreased similarly in both groups, although there was no difference between overall weight loss and BMI. The authors' overall assessment is that provided there is careful selection of patients and a supportive multidisciplinary team, satisfying results can be obtained after LAGB in adolescents, comparable to those obtained in young adults at 2-year follow-up.

Serrano et al. (2016) evaluated patients  $\leq 21$  years old to determine the safety and efficacy of bariatric surgery in this population. The primary end point was excess weight loss (EWL). Secondary end points included surgical morbidity, improvement in obesity-related metabolic parameters, and subjective obesity-related symptoms at 1 year. Fifty-four patients were identified who had a laparoscopic Roux-en-Y gastric bypass (LGBP) or laparoscopic sleeve gastrectomy (LSG). Fourteen patients were male (25.9%), and 40 patients were female (74.1%). Thirty-seven patients (68.5%) underwent LGBP, and 17 patients (31.5%) underwent LSG. Median follow-up was 13.3 months. The baseline BMI was  $51.7\text{ kg/m}^2$  for the LGBP group and  $51.0\text{ kg/m}^2$  for the LSG group. EWL was 35.2, 47.6, 62.4, 58.1, and 61.8% for the LGBP group; 29.7, 44.7, 57.4, 60.3, and 59.0% for the LSG group at 3, 6, 12, 24, and 36 months, respectively. They reported complications which included 1 anastomotic bleed, 1 post-operative stricture, and 1 patient who developed vitamin deficiency that manifested as a peripheral neuropathy in the LGBP group. LGBP was more successful than LSG in improving lipid panel parameters and HbA1c at 1 year, and it also seemed to offer better subjective improvement in obesity-related symptoms. Overall, they observed that LGBP and LSG seem to confer comparable weight loss benefit in patients  $\leq 21$  years old with acceptable surgical morbidity.

In a retrospective analysis of Roux-en-Y gastric bypass versus sleeve gastrectomy in adolescents, Maffazioli et al. (2016) found 1–6 months and 7-18 months reductions in BMI following both RYGB and SG, and no difference between the groups for changes in BMI and weight regain following surgery, indicating that in their opinion, both RYGB and SG are effective options for weight loss in adolescents. However, weight reduction at 7–18 months following RYGB trended higher than that following SG. Although surgical time and length of stay at the hospital were greater in the RYGB group, the rate of post-operative complications did not significantly differ between groups. This is in accordance with prior studies (23) and supports the safety profile of both procedures. The authors cite limitations in their study to be the retrospective analysis in which data elements were not uniformly collected; patients were not matched for

some baseline measures, such as creatinine and LDL, which may have influenced some results of comparisons of post-surgical changes; relatively small sample size, and a limited time frame for evaluation of post-operative changes. Longer studies with larger sample sizes will be needed to confirm the present findings. However, in evaluating patients with pre-existing diabetes, the authors found that at least 67% of subjects had achieved remission and 22% had improved glycemic levels following surgery. This is consistent with previous studies showing remission of type 2 diabetes following bariatric procedures.

Hsia et al. (2012) reviewed the epidemiology of pediatric obesity, indications for operative therapy in adolescents, surgical outcomes, and multidisciplinary management. The authors comment that the use of BMI as a marker of obesity in children is more complicated than it is in adults because age, sex, and growth patterns in children change the proportion of height to weight. Children have the additional factors of reliance on parents and psychosocial impact of family dynamics. Given the unknown long-term risks of surgery in the still-developing adolescent, more stringent criteria have been proposed for this population. In the authors' opinion, the unknown long-term risks of bariatric surgery in adolescents are counterbalanced by the potential benefits of improved quality and length of life. The review outlines the International Pediatric Endosurgery Group (IPEG) 2009 guidelines for bariatric procedures in adolescents. The criteria include a BMI >35 with severe comorbidities: Type 2 diabetes, moderate to severe sleep apnea, pseudotumor cerebri. BMI >40 with mild comorbidities: hypertension, dyslipidemia, mild obstructive sleep apnea, venous stasis disease, panniculitis, urinary incontinence, impairment in activities of daily living, steatohepatitis, GERD, severe psychosocial distress, weight-related arthropathies. Additional criteria include a Tanner stage of 4 or greater, 95% skeletal maturity, a demonstrated commitment to lifestyle change, and a stable psychosocial environment. Contraindications listed by IPEG include a medically correctable cause of obesity, documented substance abuse problem, disability that would impair adherence to post-operative treatment, current or planned pregnancy or breastfeeding, and unwillingness to understand and acknowledge the consequences of the procedure, particularly the nutritional concerns.

A systematic review by Pratt et al. (2009) evaluated best practice guidelines for pediatric and adolescent weight loss surgery and recommended modifications to the previously defined patient selection criteria. Bariatric surgery may be considered for adolescents with a BMI  $\geq$  35 and specific obesity-related co-morbidities for which there is clear evidence of important short-term morbidity (i.e., type 2 diabetes, severe steatohepatitis, pseudotumor cerebri, and moderate-to-severe obstructive sleep apnea). In addition, bariatric surgery should be considered for adolescents with extreme obesity (BMI  $\geq$  40) and other co-morbidities (mild obstructive sleep apnea, hypertension, insulin resistance, glucose intolerance, dyslipidemia, impaired quality of life or activities of daily living) associated with long-term risks.

O'Brien et al. (2010) conducted a prospective, randomized controlled study of 42 adolescents to compare the outcomes of gastric banding (n=24) with an optimal lifestyle program (n=18) for adolescent obesity. Patients in the gastric banding group had an estimated weight loss of 78.8% compared to 13.2% in the optimal lifestyle program. Body mass index scores decreased from 42.3 to 29.6 in the gastric banding group compared with 40.4 to 39.1 in the optimal lifestyle program group. Prior to the study, 9 gastric banding patients and 10 lifestyle patients had metabolic syndrome. At 24 month follow-up, none of the patients in the gastric banding group had the metabolic syndrome compared with 4 in the lifestyle group. Eight reoperations were required in 7 patients due to proximal pouch dilatation or tubing injury during follow-up. The authors concluded that use of gastric banding compared with lifestyle intervention resulted in a greater percentage of excess weight loss. Study limitations include small number of study participants as well as a third of the gastric banding patients' required surgical revision due to complications.

A US Food and Drug Administration (FDA) approved clinical trial by Nadler et al. (2009) evaluated the impact on metabolic health following laparoscopic adjustable banding in 45 morbidly obese adolescents. Thirty-nine of the 45 patients had 85 identified co-morbidities. All patients completed a 1 year follow-up with 41 patients completing 2 year follow-up. Mean age was  $16.1 \pm 1.2$  years, pre-operative weight was  $299 \pm 57$  lb, and BMI was  $48 \pm 6.4$  kg/m<sup>2</sup>. The estimated weight loss at 6 months was  $31 \pm 16$ ; at 1 year  $46 \pm 21$ ; and 2 years  $47 \pm 22$ . At 1-year follow-up, patients had a significant decrease in their total and android fat mass. At follow-up, 47 of the 85 identified co-morbidities (55%) were completely resolved and 25 (29%) were improved in comparison with baseline. Improvements in alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, hemoglobin A1c, fasting insulin, triglycerides, and high density lipoprotein, were also seen. The authors concluded that based on these results, laparoscopic adjustable banding is an appropriate surgical option for morbidly obese adolescents.

A retrospective study by Lawson et al. (2006) reported one-year outcomes of Roux-en-Y gastric bypass for morbidly obese adolescents (n=39) aged 13 to 21 years of age. Weight loss of the surgical group was compared to a non-surgical group (n=12). Other outcomes were metabolic changes and complications. Mean BMI in the surgical group decreased from 56.5kg/m<sup>2</sup> to 35.8kg/m<sup>2</sup> at 12 months post-operatively compared to the nonsurgical group at 47.2kg/m<sup>2</sup> to 46.0kg/m<sup>2</sup>. Surgical patients showed significant improvements in triglycerides (-65 mg/dL), total cholesterol (-28 mg/dL), fasting blood glucose (-12 mg/dL), and fasting insulin (-21 microM/mL]). Fifteen patients experienced complications. Nine had minor complications with no long-term consequences (food obstruction, wound infection, nausea, diarrhea, hypokalemia, or deep vein thrombosis), 4 had at least 1 moderate complication

(persistent iron deficiency anemia, peripheral neuropathy secondary to vitamin deficiency, reoperation due to staple line leak, obstruction, or gastrostomy revision, shock or internal hernia) for at least 1 month, and 2 had at least 1 severe medical complication with long-term consequences (including beriberi and death). The authors concluded that post-operatively, adolescents lose significant weight and realize major metabolic improvements. Complication rates and types are similar to those of adults; however, the small sample size of this precludes calculation of complication rates.

### **Transoral Endoscopic Surgery**

Eid et al. (2014) conducted a prospective, single-center, randomized, single-blinded study from July 2009 through February 2011, to investigate the safety and effectiveness of endoscopic gastric plication with the StomaphyX device vs a sham procedure for revisional surgery in RYGB patients to reduce regained weight. Enrollment was closed prematurely because preliminary results indicated failure to achieve the primary efficacy end point in at least 50% of StomaphyX-treated patients. One-year follow-up was completed by 45 patients treated with StomaphyX and 29 patients in the sham treatment group. Primary efficacy outcome was achieved by 22.2% (10) with StomaphyX vs 3.4% (1) with the sham procedure ( $P < .01$ ). Patients undergoing StomaphyX treatment experienced significantly greater reduction in weight and BMI at 3, 6, and 12 months ( $P \leq .05$ ). There was one causally related adverse event with StomaphyX, that required laparoscopic exploration and repair.

A case series by Mullady et al. (2009) evaluated 20 patients who underwent restorative obesity surgery, endoluminal (ROSE) procedure due to weight regain post gastric bypass, with a confirmed dilated pouch and gastrojejunal anastomosis (GJA) on endoscopy. Seventeen of 20 (85%) patients had an average reduction in stoma diameter of 16 mm (65% reduction) and an average reduction in pouch length of 2.5 cm (36% reduction). The mean weight loss in successful cases was 8.8 kg at 3 months. The authors concluded that the ROSE procedure is effective in reducing not only the size of the gastrojejunal anastomosis but also the gastric pouch and may provide an endoscopic alternative for weight regain in gastric bypass patients. This study is limited by small sample size and short term follow-up.

### **Laparoscopic Mini-Gastric Bypass (One Anastomosis Gastric Bypass)**

In a prospective, observational and descriptive study of 150 morbidly obese patients who underwent laparoscopic one anastomosis gastric bypass, lipid profiles were evaluated preoperatively and at different intervals during a 2-year follow-up. The authors (Carbajo et al., 2017) reported a mean weight loss of  $48.85 \text{ kg} \pm 15.64$  and mean%excess weight loss of  $71.87 \pm 13.41$ . kg. Total cholesterol and low density lipoprotein (LDL) levels significantly decreased, and high density lipoprotein (HDL) levels significantly increased which the authors believe translate into theoretical relevant cardiovascular risk benefits. Long-term randomized studies are needed to fully evaluate the impact of this procedure.

Lessing et al. (2017) conducted a retrospective analysis of all patients ( $n=407$ ) who underwent one anastomosis gastric bypass (OAGB), reporting an average excess weight loss 1 year following surgery as  $88.9 \pm 27.3$  and  $72.8 \pm 43.5\%$  in patients that underwent primary and revision OAGB, respectively. Study limitations include single center data analysis and non-randomization.

Musella et al. (2017) retrospectively evaluated complications of 2678 patients who underwent a mini/one anastomosis gastric bypass (MGB/OAGB). Follow-up at 5 years was 62.6%. Intraoperative and early complication rates were 0.5 and 3.1%, respectively. The late complication rate was 10.1%. A statistical correlation was found for postoperative duodenal-gastro-esophageal reflux (GERD) in patients with pre-existing GERD or with a gastric pouch shorter than 9 cm. The authors conclude that MGB/OAGB is a reliable bariatric procedure in comparison with more mainstream procedures (Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy). Additional long-term outcomes are needed to evaluate this procedure.

Long-term outcomes (up to 11 years) in a cohort of 156 patients undergoing silastic ring mini gastric bypass were evaluated by Sheikh et al. (2017). Computer-based hospital information was available on a total of 139 patients; 92 patients responded to the follow-up questionnaires. The authors concluded that the data supports the mini gastric bypass to be durable, with favorable excess weight loss at up to 11 years post-surgery (84.3%). Seven patients had alterations of the original silastic ring and 9.4% of the original cohort required conversion to a Roux-en-Y gastric bypass. The number of patients on anti-reflux medications increased from 5.1% to 44.6% at 11 years. In the authors' opinion, patients who are poorly controlled medically will require conversion to a different bariatric procedure.

Kansou et al. (2016) retrospectively evaluated one year outcomes for patients who underwent either a sleeve gastrectomy ( $n=261$ ) or LMGBP ( $n=161$ ) as an alternative to a Roux-en-Y gastric bypass. At one year, rate of follow-up was 88.4%. Main outcome was% of Total Weight Loss (%TWL) at one year. Propensity score matching and multivariable analyses were used to compensate for differences in some baseline characteristics. After matching sleeve gastrectomy ( $N = 136$ ) and LMGBP ( $N = 136$ ) groups did not differ for initial BMI,% of female patients, age (years) and diabetes. At one year,%TWL, change in BMI and rate of stenosis were higher for the LMGBP group, respectively:  $38.2 \pm 8.4$  vs.  $34.3 \pm 8.4$  ( $P < 0.0001$ );  $-16.5 \pm 4.6$  vs.  $-14.9 \pm 4.4$  ( $P = 0.005$ ) and  $16.9\%$  vs.  $0\%$  ( $P$

< 0.0001). In multivariate analyses ( $\beta$  coefficient), LMGBP was a positive independent factor of %TWL (2.8;  $P = 0.008$ ). The authors concluded that LMGBP appears to have better weight loss at one year compared to sleeve gastrectomy, with higher gastric complications.

Obese patients who underwent either a LMGBP ( $n=169$ ) or SG ( $n=118$ ) were retrospectively analyzed by Plamper et al. (2017) for short-term for perioperative and early post-operative outcomes. Both groups were comparable for BMI at baseline (MGB = 54.1 kg/m<sup>2</sup> vs. SG = 54.6 kg/m<sup>2</sup>,  $p = 0.657$ ). Mean operation time (81.7 vs. 112.1 min,  $p < 0.0001$ ) as well as hospital stay was lower in the MGB-group (4.5 vs. 7.2 days,  $p < 0.0001$ ). Perioperative (30 days) mortality was 0% in MGB versus 0.8% in SG (one patient). Perioperative complication rate was also lower in the MGB-group (3.0 vs. 9.3%,  $p = 0.449$ ). %EWL was significantly better after 1 year in MGB: 66.2% ( $\pm 13.9\%$ ) versus 57.3% ( $\pm 19.0\%$ ) in SG ( $p < 0.0001$ ), as well as BMI which was 34.9 kg/m<sup>2</sup> ( $\pm 4.8$  kg/m<sup>2</sup>) in MGB versus 38.5 kg/m<sup>2</sup> ( $\pm 8.6$  kg/m<sup>2</sup>) in SG ( $p = 0.001$ ). The authors concluded that MGB achieved superior weight loss at 1 year and had a lower 30-day complication rate in comparison with SG for super-obese patients.

Piazza et al. (2015) reported their experience with laparoscopic mini-gastric bypass (LMGB) as a revisional procedure for failed primary laparoscopic adjustable gastric banding (LAGB). From June 2007 to November 2012, 48 patients, who had undergone LAGB, underwent revisional surgery to LMGB. The revisions to a mini-gastric bypass (MGB) were completed laparoscopically in all cases except in four, when the MGB was deferred because of gastric tube damage. Mean age was 38 years (range 20-59) and BMI was 43.4  $\pm$  4.2 kg/m<sup>2</sup>; 82% of patients were females. Revision was performed after a mean of 28.6 months. The mean hospital stay was 3.25 days. Within 60 days of the MGB, mortality and morbidity were nil. They observed a significant difference in mean BMI after 6 months' follow-up ( $P < 0.001$ ). Diabetes remission was observed in 88% of patients, apnea remission in 66%, and hypertension remission in 66% after LMGB ( $p < 0.001$ ). Moreover, four patients with GERD reported symptom resolution. All LAGB patients had positive outcomes after the conversion to MGB, with a mean gain of 1.7 points in the bariatric analysis and reporting outcome system questionnaire. The authors suggest that based on their results, LMGB is a safe, feasible, effective and easy-to-perform revisional procedure for failed LAGB.

### **Gastric Electrical Stimulator**

Lebovitz (2016) reviewed interventional treatment of obesity and type 2 diabetes with gastric electrical stimulation. Gastric electrical stimulation for effectively treating moderate (class 1 and class 2) obesity has remained elusive in part due to the constellation of causes of obesity which may differ among obese individuals. Combining lifestyle modification with gastric electrical stimulation frequently complicates the interpretation of the results and requires that the studies be double blind and inactive implanted device controlled. The relationship between the metabolic benefits of gastric electrical stimulation in improving glycemic control and lowering systolic blood pressure needs further analysis through randomized controlled studies.

The Screened Health Assessment and Pacer Evaluation (SHAPE) trial by Shikora et al. (2009) compared gastric stimulation therapy to a standard diet and behavioral therapy regimen in a group of obese patients. The difference in excess weight loss between the control group and the treatment group was not found to be statistically significant at 12 months of follow-up. These results suggest that this technology is not effective in achieving significant weight loss in severely obese individuals.

Shikora (2004a) reported an update of the two U.S. clinical trials for gastric stimulation in obesity. The first was an RCT in 2000 that included patient's age 18–50 who had a BMI of 40–55. No statistical difference in the weight loss between study and control groups was found at six-month follow-up. The second trial, the Dual-Lead Implantable Gastric Electrical Stimulation Trial (DIGEST), was a non-randomized, open-label study of patients with a BMI 40–55 kg/m<sup>2</sup> or 35–39 kg/m<sup>2</sup> and one or more significant comorbidities. At the 12-month follow-up point, 71% of participants lost weight (54% lost > 10% of excess, and 29% lost > 20% excess). At the 16-month follow-up, mean EWL was 23%.

In a systematic review, Cha et al. (2014) evaluated the current state regarding implantable gastric stimulators. Thirty-one studies consisting of a total of 33 different trials were included in the systematic review for data analysis. Weight loss was achieved in most studies, especially during the first 12 mo, but only very few studies had a follow-up period longer than 1 year. Among those that had a longer follow-up period, many were from the Transcend<sup>®</sup> (Implantable Gastric Stimulation) device group and maintained significant weight loss. Other significant results included changes in appetite/satiety, gastric emptying rate, blood pressure and neurohormone levels or biochemical markers such as ghrelin or HbA1c respectively. The authors conclude that although GES holds great promise, stronger evidence is required through more studies with a standardized way of carrying out trials and reporting outcomes, to determine the long-term effect of GES on obesity.

### **Vagus Nerve Blocking**

The ReCharge pivotal study sponsored by the manufacturer (Ikramuddin et al., 2014), was a prospective, randomized, double-blind, sham-controlled, multi-center trial to evaluate the safety and effectiveness of the Maestro system in

treating obesity. The trial enrolled subjects who had a BMI 40–45 kg/m<sup>2</sup> or a BMI 35–39.9 kg/m<sup>2</sup> with at least one obesity-related co-morbid condition, and who had failed a more conservative weight reduction alternative. A total of 239 subjects were enrolled at 10 investigational sites; 162 subjects were randomized to the device group, and 77 were randomized to the sham control group. Subjects randomized to the sham control group underwent a surgical procedure consisting of anesthesia, implantation of a non-functional neuroregulator, and the same number of incisions an investigator would use during the laparoscopic placement of the leads. The study authors noted that the trial met its primary safety endpoint and helped more than half of patients lose at least 20% of their excess weight. The use of vagal nerve block therapy compared with a sham control device did not meet either of the prespecified co-primary efficacy objectives which were to determine whether the vagal nerve block was superior in mean percentage excess weight loss to sham by a 10-point margin with at least 55% of patients in the vagal block group achieving a 20% loss and 45% achieving a 25% loss.

Apovian et al. (2017) reported the two-year outcomes from the ReCharge study. At 24 months, 123 (76%) vBloc participants remained in the trial. Participants who presented at 24 months (n = 103) had a mean excess weight loss (EWL) of 21% [8% total weight loss (TWL)]; 58% of participants had ≥5% TWL and 34% had ≥10% TWL. Among the subset of participants with abnormal pre-operative values, significant improvements were observed in mean LDL (-16 mg/dL) and HDL cholesterol (+4 mg/dL), triglycerides (-46 mg/dL), HbA1c (-0.3%), and systolic (-11 mmHg) and diastolic blood pressures (-10 mmHg). QOL measures were significantly improved. Heartburn/dyspepsia and implant site pain were the most frequently reported adverse events. The primary related serious adverse event rate was 4.3%.

Sarr et al. (2012) conducted a randomized, prospective, double-blind multicenter trial to evaluate use of intraabdominal vagal blockade (VBLOCTherapy). Five hundred three subjects were enrolled at 15 centers. After informed consent, 294 subjects were implanted with the vagal blocking system and randomized to the treated or control group. Main outcome measures were percent excess weight loss (percent EWL) at 12 months and serious adverse events. Subjects controlled duration of therapy using an external power source; therapy involved a programmed algorithm of electrical energy delivered to the subdiaphragmatic vagal nerves to inhibit afferent/efferent vagal transmission. Devices in both groups performed regular, low-energy safety checks. Study subjects consisted of 90% females, body mass index of 41 ± 1 kg/m<sup>2</sup>, and age of 46 ± 1 years. There was no mortality. 12-month percent EWL was 17 ± 2% for the treated and 16 ± 2% for the control group. Weight loss was related linearly to hours of device use; treated and controls with ≥ 12 h/day use achieved 30 ± 4 and 22 ± 8% EWL, respectively. The authors concluded that VBLOC<sup>®</sup> therapy to treat morbid obesity was safe, but weight loss was not greater in treated compared to controls; clinically important weight loss, however, was related to hours of device use. Post-study analysis suggested that the system electrical safety checks (low charge delivered via the system for electrical impedance, safety, and diagnostic checks) may have contributed to weight loss in the control group.

In an open-label study, Camilleri and associates (2008) evaluated the effects of vagal blocking by means of a new medical device that uses high-frequency electrical algorithms to create intermittent vagal blocking (VBLOC therapy) on EWL. Electrodes were implanted laparoscopically on both vagi near the esophago-gastric junction to provide electrical block. Patients [obese subjects with body mass index (BMI) of 35 to 50 kg/m<sup>2</sup>] were followed for 6 months. The authors concluded that VBLOC therapy is associated with significant EWL and a desirable safety profile. They noted that these findings have resulted in the design and implementation of a randomized, double-blind, prospective, multi-center trial in an obese subject population.

Hwang et al. (2016) summarized current surgical options in weight loss reporting that initial studies in the use of the Maestro Rechargeable System show that although the VBLOC device is not as effective for weight loss as the laparoscopic vertical sleeve gastrectomy or laparoscopic Roux-en-Y gastric bypass, it appears to be a viable option for weight loss in obese patients desiring a “less invasive” procedure for weight loss, or who would not be able to tolerate a more invasive procedure. Well-designed studies are needed to determine the best usage of the Maestro Rechargeable System.

### **Intragastric Balloon (IGB)**

The REDUCE pivotal trial, (Ponce et al., 2015) was a prospective, randomized controlled pivotal trial of a dual intragastric balloon to evaluate the safety and effectiveness of a dual balloon system plus diet and exercise in the treatment of obesity compared to diet and exercise alone. Participants (n = 326) with body mass index (BMI) 30–40 kg/m<sup>2</sup> were randomized to endoscopic dual balloon system (DBS) treatment plus diet and exercise (DUO, n = 187) or sham endoscopy plus diet and exercise alone (DIET, n = 139). Co-primary endpoints were a between-group comparison of percent excess weight loss (%EWL) and DUO subject responder rate, both at 24 weeks. Thereafter DUO patients had the DBS retrieved followed by 24 additional weeks of counseling; DIET patients were offered DBS treatment. Mean BMI was 35.4. Both primary endpoints were met. DUO weight loss was over twice that of DIET. DUO patients had significantly greater %EWL at 24 weeks (25.1% intent-to-treat (ITT), 27.9% completed cases (CC, n = 167) compared with DIET patients (11.3% ITT, P = .004, 12.3% CC, n = 126). DUO patients significantly exceeded a 35% response rate (49.1% ITT, P < .001, 54.5% CC) for weight loss dichotomized at 25% EWL. Accommodative symptoms abated rapidly with support and medication. Balloon deflation occurred in 6% without migrations. Early

retrieval for nonulcer intolerance occurred in 9%. Gastric ulcers were observed; a minor device change led to significantly reduced ulcer size and frequency (10%). The authors concluded that the dual balloon system was significantly more effective than diet and exercise in causing weight loss with a low adverse event profile. Additional randomized controlled studies are needed.

In a Cochrane review by Fernandes et al. (2007), nine randomized controlled trials involving 395 patients comparing intragastric balloon with conventional weight loss management. Six out of 9 studies had a follow-up of less than one year with the longest study duration was 24 months. Compared with conventional management, IGB did not show convincing evidence of a greater weight loss. On the other hand, complications of intragastric balloon placement occurred, however few of a serious nature. The relative risks for minor complications like gastric ulcers and erosions were significantly raised.

Melissas et al. (2006) studied 140 morbidly obese patients who underwent intragastric balloon placement. These patients refused bariatric surgery because of fear of complications and mortality and were followed over a 6- to 30-month period (mean 18.3 months) after balloon extraction. Of the 140 patients in the study, 100 patients lost  $\geq 25\%$  of their excess weight on balloon extraction and were categorized as successes, while 40 patients did not achieve that weight loss and were categorized as failures. During the follow-up period, 44 of the originally successful patients (31.4%) regained weight and were categorized as recurrences, while the remaining 56 patients (40%) maintained their EWL of  $\geq 25\%$  and were considered long-term successes. In addition, during follow-up, 45 patients (32.1%) requested and underwent bariatric surgery for their morbid obesity (21 adjustable gastric band, 11 laparoscopic sleeve gastrectomy, 13 laparoscopic gastric bypass). Of these, 13 (32.5%) were from the group of 40 patients categorized as failures upon intragastric balloon removal, 28 (63.6%) were from the group of 44 patients whose obesity recurred, and 4 (7.1%) were from the 56 patients who although they maintained successful weight loss requested further weight reduction. The authors concluded that use of the intragastric balloon served as a first step and a smooth introduction to bariatric surgery for morbidly obese patients who initially refused surgical intervention; however, the incidence of surgical intervention was double in patients who initially experienced the benefits of weight loss and then had obesity recurrence, compared with patients in whom the method failed.

Nunes et al. (2017) conducted a retrospective review of 2002 patients who underwent an intragastric balloon (IGB) procedure to determine its effectiveness with different degrees of obesity. A total of 946 patients were lost to follow-up. Overall, 40 (3.78%) had device removal due to intolerance, and 1016 patients completed the 6-month treatment. The mean weight loss was 18.9%, excess weight loss 60.1% and a BMI reduction of 6.76 points. Six months after removal of the balloon 842 patients had continued follow-up (82.8%). At this time, weight loss was 19.84%, excess weight loss was 59.49%, and BMI reduction of 7.06 points. In all groups there was statistical difference between the times T0 and T1 and between T1 and T2 ( $P < 0.001$ ). There was no statistical difference between T2 and T3, in any group. The authors concluded that IGB provided sustained weight loss in patients who remained in dietary follow-up for 1 year. Longer term outcomes with well-designed randomized clinical controlled trials are needed to further evaluate the IGB.

Saber et al. (2017) conducted a systematic review and meta-analysis to evaluate the efficacy and safety of intragastric balloon (IGB) treatment. A total of 20 RCTs involving 1195 patients were identified. Weight loss results before and after 3 months were analyzed separately. The weight loss results of patients with and without IGB treatment were compared. A significant effect size was calculated that favored fluid-filled IGBs over air-filled IGBs. Flatulence, abdominal fullness, abdominal pain, abdominal discomfort, and gastric ulcer were significantly more prevalent among IGB patients than among non-IGB control patients. No mortality was reported from IGB treatment. In the authors' opinion, IGB treatment, in addition to lifestyle modification, is an effective short-term modality for weight loss. However, there is not sufficient evidence confirming its safety or long-term efficacy.

In a systematic review, Tate and Geliebter (2017) evaluated 8 randomized controlled trials comparing percentage total body weight loss (%TBWL) between intragastric balloon (IGB) and control groups. Five of the eight studies had balloon treatment duration of 6 months. IGB showed lower efficacy than bariatric surgery (median weight loss of 27% for RYGB). The weighted mean reported incidence of serious adverse events (SAEs) in the IGB group across all eight studies was 10.5%. Only 6 of the 8 reviewed studies reported adverse events (AEs) in the IGB group, with a pooled reported incidence of 28.2%. Based on the available evidence, the authors conclude that it is unlikely that IGB use will supplant other forms of obesity treatment. Collectively, a relatively small control-subtracted %TBWL and the potential for serious complications make the IGB unlikely to become widely adopted.

Neylan et al. (2016) reviewed the literature on endoscopic treatments for obesity. The authors' evaluation is that intragastric balloons are the best-studied of all the treatments and although they show 30%-50% excess weight loss after device removal, there is a lack of significant long-term follow-up.

Adverse effects associated with the intragastric balloon include gastric erosion, reflux, and obstruction (Fernandes et al., 2007). Additional adverse outcomes reported in the first three days have included nausea vomiting,

gastroesophageal reflux disease (GERD), eructation, and dyspepsia lasting more than 30 days. More severe, albeit rare, events have occurred included gastric outlet or intestinal obstruction caused by underinflated or leaking balloon, dehydration, gastric perforation with sepsis, aspiration pneumonia, abdominal cramping, and infection (fluid inside balloon positive for *Candida albicans*) (Hayes, 2015).

### **Gastrointestinal Liner**

Quezada et al. (2017) conducted a single-arm, open-label, prospective trial to evaluate the safety and efficacy of endoscopically placed duodenal-jejunal bypass liner (DJBL) over a 3-year period. Of 80 patients enrolled in the study, (age: 35±10 years; 69% female; weight: 109±17 kg; BMI: 42±5.4 kg/m<sup>2</sup>), 72 severe adverse events (AEs) were observed in 55 patients (68%). Nine subjects required a prolonged hospital stay and three subjects required major interventions. At 52 weeks (71 patients), 104 weeks (40 patients), and 156 weeks (11 patients), the mean%EWL were 44 ± 16, 40 ± 22, and 39 ± 20, respectively (p < 0.001). This study shows significant and sustained weight loss after 3 years of treatment with the new DJBL. However, the high frequency and severity of AEs preclude the use of this prototype for periods longer than 1 year.

Schouten et al. (2010) conducted a randomized controlled trial of an endoscopically placed duodenal-jejunal bypass sleeve or EndoBarrier Gastrointestinal Liner in 30 patients. An additional 11 patients served as a diet control group with all patients following the same low-calorie diet during the study period. Twenty-six devices were successfully implanted. In 4 patients, implantation could not be achieved and the devices were explanted prior to the initial protocol end point because of migration (1), dislocation of the anchor (1), sleeve obstruction (1), and continuous epigastric pain (1). The remaining patients all completed the study. Mean excess weight loss after 3 months was 19.0% for device patients versus 6.9% for control patients. Of 8 patients with diabetes, 7 patients showed improvement at follow-up. The authors concluded that the EndoBarrier Gastrointestinal Liner was a safe noninvasive device with excellent short-term weight loss results; however, long-term randomized studies are necessary to determine the role of the device in the treatment of morbid obesity.

A prospective, randomized trial by Gersin et al. (2010) compared 21 patients receiving the duodenojejunal bypass liner (DJBL) with 26 patients undergoing a sham procedure. Primary outcomes measured the difference in the percentage of EWL at week 12 between the 2 groups. Thirteen duodenojejunal bypass liner subjects and 24 sham subjects completed the 12-week study. The duodenojejunal bypass liner group had a EWL of 11.9% compared to 2.7% in the sham group. Eight patients in the duodenojejunal bypass liner group dropped out of the study early because of GI bleeding (n = 3), abdominal pain (n = 2), nausea and vomiting (n = 2), and an unrelated preexisting illness (n = 1). The authors concluded that duodenojejunal bypass liner promotes a more significant weight loss beyond a minimal sham effect in candidates for bariatric surgery. This study is limited by small patient sample, short term follow-up and relatively high complication rates.

In a retrospective review, Betzel et al. (2017) evaluated the efficacy and safety profile of the DJBL. Inclusion criteria for treatment with a DJBL were: age 18-70 years, BMI 28-45 kg/m<sup>2</sup>, and T2DM with a HbA1c > 48 mmol/mol. Primary outcomes were changes in HbA1c and body weight. Secondary outcomes included changes in blood pressure, lipids, and anti-diabetic medication. Predictive factors for success of treatment with the DJBL were determined. The authors reported that 185 out of 198 patients successfully underwent a DJBL implantation procedure, with an intended implantation time of 12 months. In these 185 patients, body weight decreased by 12.8 ± 8.0 kg (total body weight loss of 11.9 ± 6.9%, p < 0.001), HbA1c decreased from 67 to 61 mmol/mol (p < 0.001) despite a reduction in anti-diabetic medication, and blood pressure and serum lipid levels all decreased. In total, 57 (31%) DJBLs were explanted early after a median duration of 33 weeks. Adverse events occurred in 17% of patients. C-peptide ≥1.0 nmol/L and body weight ≥107 kg at screening were independent predictive factors for success. The authors concluded that treatment with the DJBL in T2DM patients with (morbid) obesity resulted in improvement in glucose control, a reduction in anti-diabetic medication, and significant weight loss. The largest changes are observed within the first 3-6 months. Initial C-peptide levels and body weight may help to select patients with the greatest chance of success.

Vilarrasa et al. (2017) evaluated the efficacy and safety of Endobarrier® in grade 1 obese T2DM patients with poor metabolic control and the role of gastro-intestinal hormone changes on the metabolic outcomes. Twenty-one patients aged 54.1 ± 9.5 years, diabetes duration 14.8 ± 8.5 years, BMI 33.4 ± 1.9 kg/m<sup>2</sup>, and HbA1c 9.1 ± 1.3%, under insulin therapy, were implanted with Endobarrier®. Fasting concentrations of PYY, ghrelin and glucagon, and AUC for GLP-1 after a standard meal test were determined prior to and at months 1 and 12 after implantation. They found that the Endobarrier® in this subset of patients is associated with significant weight decrease and moderate reduction in HbA1c at month 12. Longer term outcome data is needed.

In a systematic review and meta-analysis, Rohde et al. (2016) evaluated the efficacy and safety of the DJBS. Five randomized controlled trials (RCTs; 235 subjects) and 10 observational studies (211 subjects) were included. The risk of bias was evaluated as high in all studies. The mean body mass index ranged from 30 to 49.2 kg/m<sup>2</sup> and 10-100% of the subjects had T2D. Meta-analysis showed that the DJBS was associated with significant mean differences in body weight and excess weight loss of -5.1 kg [95% confidence interval (CI) -7.3, -3.0; four trials; n=151;

I(2)=37%] and 12.6% [95% CI 9.0, 16.2; four trials; n=166; I(2)=24%], respectively, compared with diet modification. The mean differences in glycated hemoglobin (-0.9%; 95% CI -1.8, 0.0) and fasting plasma glucose (-3.7 mM; 95% CI -8.2, 0.8) among subjects with T2D did not reach statistical significance. Adverse events consisted mainly of abdominal pain, nausea and vomiting. No deaths occurred. Future high-quality long-term RCTs are needed to further assess efficacy and safety of the DJBS for obesity.

A 2015 National Institute of Health and Care Excellence (NICE) interventional procedure guidance on managing type 2 diabetes states that current evidence on the safety and efficacy of implantation of a duodenal-jejunal bypass liner for managing type 2 diabetes is limited in quality and quantity. Therefore the procedure should only be used in the context of research. Further research should give details of patient selection, including information about use of the procedure in patients with different levels of BMI. The research should provide information on complications; reasons for early removal of the device; medication used for treating type 2 diabetes, both when the device is in place and after its removal; and control of type 2 diabetes after device removal.

### **Laparoscopic Greater Curvature Plication (LGCP)**

Doležalova-Kormanova et al. (2017) reported outcomes in a cohort of LGCP patients at 5-year follow-up. Patients with complete weight data through 5-year follow-up was 86.9%, (212/244). The ANOVA database indicated a significant BMI reduction out to 2 years ( $p < 0.001$ ), a plateau at 3 and 4 years, and a moderate but significant BMI increase at 5 years ( $p < 0.01$ ). EBMI at 1, 2, 3, 4, and 5 years was as follows:  $50.7 \pm 9.1\%$ ,  $61.5 \pm 8.1\%$ ,  $60.2 \pm 7.0\%$ ,  $58.5 \pm 7.0\%$ , and  $56.8 \pm 6.3\%$ . At 5 years, 79.2% (168/212) of patients were successful; 20.8% (44/212) experienced a suboptimal weight outcome; mean weight regain, 9.2%. Cluster analysis identified four distinct LGCP patient profiles. Diabetes improvement rate was 65.5%. There were 12 reoperations (4.9%): 4 emergency (1.6%) and 8 (3.3%) elective. There was no mortality. The authors concluded that based on their original cohort and a 56.8% EBMI and low rate of complications, LGCP proved to be safe and effective. Additional long-term outcomes are needed to evaluate LGCP in comparison to other bariatric procedures.

In an 18-month prospective, observational, open-label study, Bužga et al. (2017) reported outcomes of 127 patients; 84 underwent laparoscopic sleeve gastrectomy (LSG) and 43, LGCP. LSG and LGCP were then compared during long-term follow-ups in terms of glycemic control, hormone and lipid secretion, and changes in body composition. Significant weight-loss and a reduced body composition resulted from either procedure vs. baseline (i.e., pre-surgery), with levels of fasting glucose and glycated hemoglobin also showing statistically significant reductions (at 3 and 18 months for either surgery). Intergroup comparisons for glycemic parameters yielded no statistically significant differences. However, a dramatic reduction in ghrelin was detected following LSG, falling from pre-surgery levels of 140.7 to 69.6 ng/L by 6 months ( $P < 0.001$ ). Subsequently, ghrelin levels increased, reaching 107.8 ng/L by month 12. Conversely, after LGCP, a statistically significant increase in ghrelin was seen, rising from 130.0 ng/L before surgery to 169.0 ng/L by month 12, followed by a slow decline. The authors concluded that although the data showed good metabolic outcomes following LGCP, this method was less effective than LSG, possibly due to its preservation of the entire stomach, including secretory regions.

Grubnik et al. (2016) compared two-year outcomes in a European prospective randomized controlled trial comparing laparoscopic greater curvature plication (LGCP) versus laparoscopic sleeve gastrectomy. A total of 54 patients with morbid obesity were allocated either to LGCP group ( $n = 25$ ) or LSG group ( $n = 27$ ). Main exclusion criteria were: ASA  $> III$ , age  $> 75$  and BMI  $> 65$  kg/m<sup>2</sup>. There were 40 women and 12 men, and the mean age was  $42.6 \pm 6.8$  years (range 35-62). Data on the operation time, complications, hospital stay, body mass index loss, percentage of excess weight loss (%EWL), loss of appetite and improvement in comorbidities were collected during the follow-up examinations. One year after surgery, the mean%EWL was  $59.5 \pm 15.4\%$  in LSG group and  $45.8 \pm 17\%$  in LGCP group ( $p > 0.05$ ). After 2 years, mean%EWL was  $78.9 \pm 20\%$  in the LSG group and  $42.4 \pm 18\%$  in the LGCP group ( $p < 0.01$ ). After 3 years, mean%EWL was  $72.8 \pm 22$  in the LSG group and only  $20.5 \pm 23.9$  in the LGCP group ( $p < 0.01$ ). Loss of feeling of hunger after 2 years was 25% in LGCP group and 76.9% in the LSG group ( $p < 0.05$ ). The comorbidities including diabetes, sleep apnea and hypertension were markedly improved in the both groups after surgery. The authors concluded that the short-term outcomes demonstrated equal effectiveness of the both procedures, but 2-year follow-up showed that LGCP is not as effective as LSG as a restrictive procedure for weight loss.

Additional evidence evaluating the safety and effectiveness of laparoscopic greater curvature plication consists primarily of case series with patient populations ranging from 26-244. (Niazi, et al., 2013; Fried, et al., 2012; Taha, 2012; Talebpour, et. al., 2012; Skrekas, et al., 2011; Ramos, et al., 2010) Limitations in these studies include lack of a randomized controlled study design and short-term follow-up.

Tang et al. (2015) conducted a meta-analysis to compare laparoscopic greater curvature plication (LGCP) with laparoscopic sleeve gastrectomy (LSG) in terms of efficacy and safety. Eligible studies included one randomized controlled trial and three non-randomized controlled trials involving 299 patients. The meta-analysis demonstrated a significantly greater% excess weight loss after LSG than LGCP at the follow-up time points of 3 months ( $Z=2.26$ ,

p=0.02), 6 months (Z=4.49, p<0.00001), and 12 months (Z=6.99, p<0.00001). The difference in the resolution of diabetes mellitus between these two approaches did not reach statistical significance (p=0.66). According to the pooled data, LGCP was associated with more adverse events than was LSG (p=0.01). The operation time (p=0.54) and post-operative hospital stay (p=0.44) were comparable between the two groups. LGCP is inferior to LSG not only in terms of providing effective weight loss but also in terms of safety.

### **Stomach Aspiration Therapy**

In the pivotal PATHWAY study, Thompson et al. (2016) conducted a 52-week randomized controlled trial at 10 leading institutions across the United States. 207 participants with a body-mass index (BMI) of 35.0–55.0 kg/m<sup>2</sup> were randomly assigned in a 2:1 ratio to treatment with AspireAssist plus Lifestyle Counseling (n =137; mean BMI was 42.2±5.1 kg/m<sup>2</sup>) or Lifestyle Counseling alone (n =70; mean BMI was 40.9±3.9 kg/m<sup>2</sup>). The co-primary end points were mean percent excess weight loss and the proportion of participants who achieved at least a 25% excess weight loss. At 52 weeks, participants in the AspireAssist group, on a modified intent-to-treat basis, had lost a mean (±s.d.) of 31.5±26.7% of their excess body weight (12.1±9.6% total body weight), whereas those in the Lifestyle Counseling group had lost a mean of 9.8±15.5% of their excess body weight (3.5±6.0% total body weight) (P <0.001). A total of 58.6% of participants in the AspireAssist group and 15.3% of participants in the Lifestyle Counseling group lost at least 25% of their excess body weight (P <0.001). The most frequently reported adverse events were abdominal pain and discomfort in the perioperative period and peristomal granulation tissue and peristomal irritation. A total of 46 subjects are available for the extended follow-up study. Outcomes of the post-approval study may provide more solid evidence regarding the longer term efficacy of the AspireAssist.

Sullivan et al. (2013) conducted a pilot study of 18 obese subjects who were randomly assigned (2:1) to groups that underwent aspiration therapy for 1 year plus lifestyle therapy (n = 11; mean body mass index, 42.6 ± 1.4 kg/m<sup>2</sup>) or lifestyle therapy only (n = 7; mean body mass index, 43.4 ± 2.0 kg/m<sup>2</sup>). Lifestyle intervention comprised a 15-session diet and behavioral education program. Ten of the 11 subjects who underwent aspiration therapy and 4 of the 7 subjects who underwent lifestyle therapy completed the first year of the study. After 1 year, subjects in the aspiration therapy group lost 18.6% ± 2.3% of their body weight [49.0% ± 7.7% of excess weight loss (EWL)] and those in the lifestyle therapy group lost 5.9% ± 5.0% (14.9% ± 12.2% of EWL) (P < .04). Seven of the 10 subjects in the aspiration therapy group completed an additional year of therapy and maintained a 20.1% ± 3.5% body weight loss (54.6% ± 12.0% of EWL). The authors reported that there were no adverse effects of aspiration therapy on eating behavior (including binge eating) and no evidence of compensation for aspirated calories with increased food intake. The small sample size does not allow a conclusion to be made as to whether the outcomes can be generalized to a larger population. Lack of long-term follow-up data is another study limitation.

Norén and Forsell (2017) reported 1 and 2-year outcomes from their prospective observational study of 25 obese subjects to evaluate weight reduction and safety of aspiration therapy with AspireAssist™. Twenty of the original 25 subjects completed the initial 1 year treatment. These 20 subjects lost mean 54% of their excess weight. At 2 years, 15 subjects had lost mean 61% of their excess weight. This weight loss surpassed our expectation and is nearly at the level of gastric bypass procedure and other major abdominal surgery for obesity. The subjects reported improved quality of life during treatment. There was neither mortality nor any event more severe than grade III-a according to Clavien-Dindo grading system. Limitation of this study is the combination of aspiration therapy and cognitive behavioral therapy (CBT) without any control group. Long term patency is still unknown.

Forsell and Norén (2015) conducted an observational study of 25 obese patients [BMI 39.8±0.9kg/m<sup>2</sup>] who after following a very low calorie diet for 4 weeks had the AspireAssist gastrostomy tube placed. A low-profile valve was installed 14 days later and aspiration of gastric contents was performed approximately 20 minutes after meals three times per day. Cognitive behavioral therapy was also started. At 6 months, mean weight lost was 16.5±7.8 kg in the 22 subjects who completed 26 weeks of therapy (P=0.001). The mean percentage excess weight lost was 40.8 ± 19.8% (P=0.001). Two subjects were hospitalized for complications: one subject for pain after gastrostomy tube placement, which was treated with analgesics, and another because of an aseptic intra-abdominal fluid collection 1 day after gastrostomy tube placement. No clinically significant changes in serum potassium or other electrolytes occurred. The authors concluded that the results suggest the potential of the AspireAssist as an attractive therapeutic device for obese patients. Further research with randomized controlled trials is needed to validate these findings.

### **Bariatric Artery Embolization (BAE)**

Research on BAE has primarily occurred on animal models and is in the early phases of human clinical trials. Despite promising pre-clinical and early clinical data, there are many unanswered questions that require investigation before BAE can be routinely offered to bariatric patients. For example, the complicated vascular anatomy of the stomach and its rich supply of collateral vessels creates a technical challenge to administer either small particle or liquid embolics without non-target embolization and resultant tissue damage in a population of patients without a terminal illness. Therefore, the development of methodologies and devices that allow for more accurate catheter placement or prevent the distribution of embolic material to non-target areas would have the effect of increasing the safety profile of BAE. (Weiss, et al. 2015)

The BEAT Obesity Trial, a U.S. Food and Drug Administration (FDA)-approved prospective investigational device exemption study, is being conducted to evaluate the feasibility, safety, and short-term efficacy of bariatric artery embolization (BAE) (Weiss et al., 2017). In the initial phase of the study, 5 severely obese patients (four women, one man) who were 31-49 years of age and who had a mean body mass index of  $43.8 \text{ kg/m}^2 \pm 2.9$  with no clinically significant comorbidities were enrolled in this study and received BAE. There were no major adverse events (AEs), 2 minor AEs healed prior to the time of the 3-month endoscopy. Mean change in serum ghrelin was  $8.7\% \pm 34.7$  and  $-17.5\% \pm 29$  at 1 month and 3 months, respectively. Mean changes in serum glucagon-like peptide 1 and peptide YY were  $106.6\% \pm 208.5$  and  $17.8\% \pm 54.8$  at 1 month. There was a trend toward improvement in QOL parameters. Hunger/appetite scores decreased in the first 2 weeks after the procedure and then rose without reaching preprocedure levels. The authors concluded that in this initial phase of the study, BAE is feasible and appears to be well tolerated in severely obese patients. In this small patient cohort, it appears to induce appetite suppression and may induce weight loss. Further expansion of this study will provide more insight into the long-term safety and efficacy of bariatric embolization.

ECRI (2016) reported outcomes from a Johns Hopkins Medicine study of 7 patients who were severely obese (body mass index 40 to  $50 \text{ kg/m}^2$ ) who received BAE. Patients had an average excess weight loss of 5.9% at one month, 9.5% at three months, and 13.3% at six months. Patients had an average 17.5% decrease in ghrelin levels at three months. No major adverse events were reported.

## **Professional Societies**

### ***American Society for Gastrointestinal Endoscopy (ASGE)***

The ASGE Technology Committee conducted a systematic review and meta-analysis to evaluate whether endoscopic technologies have met appropriate thresholds outlined by ASGE by the Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) document. (Abu Dayyeh et al., 2015a) The study authors evaluated Orbera intragastric balloon (IGB) (Apollo Endosurgery) and the EndoBarrier duodenal-jejunal bypass sleeve (DJBS) (GI Dynamics). Results of the meta-analysis (17 studies,  $n=1683$ ) indicate that the Orbera IGB satisfies the PIVI thresholds for therapy for primary and non-primary bridge obesity. The percentage of EWL (%EWL) associated with the Orbera IGB at 12 months was 25.44% (95% CI, 21.45 to 29.41%) with a mean difference over controls of 26.9% (%EWL) (95% CI, 15.66% to 38.24%;  $P \leq 0.01$ ) in a total of 3 RCTs. The pooled %TWL after use of Orbera IGW was 13% at 6 months (95% CI, 12.37% to 13.95%) and 11.27% (95% CI, 8.17% to 14.36%), both which exceed the PIVI threshold of 5% TBWL for nonprimary bridge obesity therapy.

The ASGE Bariatric Endoscopy Task Force and the ASGE Technology Committee reviewed endoscopic bariatric therapies (EBT) and summarized that EBTs hold the promise of providing the next major breakthrough in the management of obesity. They commented that the development of a variety of new endoscopic therapies that replicate the physiological benefits of bariatric surgery in a safe, cost-effective, and minimally invasive fashion may potentially offer the best path to making a meaningful impact on the obesity epidemic, as less than 1% of qualified patients actually undergo bariatric surgery. Currently investigated devices have established promising outcomes in short-term weight loss and in control of the metabolic and other medical adverse events of obesity. Further studies will help define their optimal role in the comprehensive management of obesity. (Abu Dayyeh et al., 2015b)

In its position statement on EBTs in clinical practice, the ASGE states that EBTs that have been approved by the FDA and meet thresholds of efficacy and safety as defined in the ASGE/ASMBS Preservation and Incorporation of Valuable Endoscopic Innovations should be included in the obesity treatment algorithm as adjunctive therapies to a lifestyle intervention program as outlined in the 2013 American Heart Association(AHA)/American College of Cardiology(ACC)/The Obesity Society (TOS) guidelines for the management of overweight and obesity in adults. ASGE advises that endoscopists performing EBT have a mechanism to enroll patients in long-term follow-up care for weight loss maintenance. (Sullivan et al., 2015)

### ***American Association of Clinical Endocrinologists (AACE), the Obesity Society, and American Society for Metabolic & Bariatric Surgery (ASMBS)***

In an updated clinical practice guideline for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient, the AACE, the Obesity Society, and the ASMBS (Mechanick, et al., 2013) cite selection criteria to be the following:

- Patients with a  $\text{BMI} \geq 40 \text{ kg/m}^2$  without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible.
- Patients with a  $\text{BMI} \geq 35 \text{ kg/m}^2$  and 1 or more severe obesity-related co-morbidities, including T2D, hypertension, hyperlipidemia, obstructive sleep apnea (OSA), obesity-hypoventilation syndrome (OHS), Pickwickian syndrome (a combination of OSA and OHS), nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH), pseudotumor cerebri, gastroesophageal reflux disease (GERD), asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life, may also be offered a bariatric procedure.

- Patients with BMI of 30–34.9 kg/m<sup>2</sup> with diabetes or metabolic syndrome - current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.
- Interventions should first include a multidisciplinary approach, including dietary change, physical activity, behavioral modification with frequent follow up; and then if appropriate, pharmacologic therapy and/or surgical revision.

They further comment that:

- There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.
- The best choice for any bariatric procedure (type of procedure and type of approach) depends on the individualized goals of therapy [e.g., weight loss and/or metabolic (glycemic) control], available local-regional expertise (surgeon and institution), patient preferences, and personalized risk stratification.

In addition, they recommend that all patients seeking bariatric surgery have a comprehensive preoperative evaluation. This assessment is to include an obesity-focused history, physical examination, and pertinent laboratory and diagnostic testing. A detailed weight history should be documented, including a description of the onset and duration of obesity, the severity, and recent trends in weight. Causative factors to note include a family history of obesity, use of weight-gaining medications, and dietary and physical activity patterns.

A brief summary of personal weight loss attempts, commercial plans, and physician-supervised programs should be reviewed and documented, along with the greatest duration of weight loss and maintenance. This information is useful in substantiating that the patient has made reasonable attempts to control weight before considering obesity surgery. The guidelines state that preoperative weight loss should be considered for patients in whom reduced liver volume can improve the technical aspects of surgery.

#### ***American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE)***

The AACE and the ACE developed comprehensive clinical practice guidelines for the medical care of patients with obesity (Garvey, et al., 2016) based on diligent review of clinical evidence with “transparent incorporation of subjective factors.” The final recommendations recognize that obesity is a complex, adiposity-based chronic disease, where management targets both weight-related complications and adiposity to improve overall health and quality of life. The detailed evidence-based recommendations allow for nuanced clinical decision-making that addresses real-world medical care of patients with obesity, including screening, diagnosis, evaluation, selection of therapy, treatment goals, and individualization of care. The goal is to facilitate high-quality care of patients with obesity and provide a rational, scientific approach to management that optimizes health outcomes and safety.

The AACE and the ACE define obesity as a chronic disease caused by an interaction between biological factors, environmental factors, and behavior. (Garvey et al., 2014)

The AACE/ACE diagnostic algorithm for obesity has the following 2 main components

- Screening with body mass index (BMI) with adjustments for ethnic differences to better identify people with increased adipose tissue.
- Clinical evaluation for the presence and severity of obesity-related complications such as metabolic syndrome, type 2 diabetes mellitus (T2DM), dyslipidemia, hypertension, nonalcoholic fatty liver disease, polycystic ovary syndrome, obstructive sleep apnea, osteoarthritis, urinary stress incontinence, gastroesophageal reflux disease (GERD), disability and immobility, psychological disorder, and stigmatization.

#### ***American Heart Association/American College of Cardiology (AHA/ACC)/The Obesity Society***

The AHA/ACC and the Obesity Society published an updated 2013 Practice Guideline and Management of Overweight and Obesity in Adults. (Jensen et al., 2014) The updated guidelines reflect such consensus and offer update regarding treatment for patients who are overweight or obese. While the focus remains on sustained weight loss and decreased waist circumference, the authors also recommend use of bariatric surgery for patients with BMI >40 or 35 with comorbidities.

#### ***American Society for Metabolic & Bariatric Surgery (ASMBS)***

The ASMBS published recommendations for the presurgical psychosocial evaluation of bariatric surgery patients. (Sogg et al., 2016) They recommend that bariatric behavioral health clinicians with specialized knowledge and experience be involved in the evaluation and care of patients both before and after surgery. Given the importance of long-term follow up after WLS, the pre-operative psychosocial assessment provides a valuable opportunity for patients to establish a trusted connection to a behavioral health provider as an additional resource and integral participant in their post-operative care. The need to ensure that post-operative psychosocial care is available has been noted in established practice guidelines and evidence suggests that such care is associated with better outcomes after surgery.

In an updated guideline on the integrated health nutritional guidelines for surgical weight loss, the ASMBS (Parrott et al., 2016) states that optimizing postoperative patient outcomes and nutritional status begins preoperatively. Patients should be educated before and after weight loss surgery (WLS) on the expected nutrient deficiencies associated with alterations in physiology. Although surgery can exacerbate preexisting nutrient deficiencies, preoperative screening for vitamin deficiencies has not been the norm in the majority of WLS practices. Screening is important because it is common for patients who present for WLS to have at least 1 vitamin or mineral deficiency preoperatively.

Data continue to suggest that the prevalence of micronutrient deficiencies is increasing, while monitoring of patients at follow-up is decreasing. The ASMBS recommends that their guideline be considered a reasonable approach to patient nutritional care based on the most recent research, scientific evidence, resources, and information available. It is the responsibility of the registered dietitian nutritionist and WLS program to determine individual variations as they relate to patient nutritional care.

In 2012, the ASMBS updated its previously published 2007 and 2009 position statements on sleeve gastrectomy. Substantial comparative and long-term data were published in peer-reviewed studies which the ASMBS states demonstrates durable weight loss, improved medical co-morbidities, long-term patient satisfaction, and improved quality of life after SG. The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first-stage procedure in high-risk patients as a part of a planned staged approach.

In a 2016 position statement on pre-operative supervised weight loss requirements, the ASMBS noted that there is no data from any randomized controlled trial, large prospective study or meta-analysis to support the practice of mandated pre-operative weight loss. Further, there is no Level I data in the surgical literature, or consensus in the medical literature (based on over 40 published RCTs) that has clearly identified any one dietary regimen, duration or type of weight loss program that is optimal for patients with clinically severe obesity. Finally, they recommend that patients seeking surgical treatment for clinically severe obesity should be evaluated based on their initial BMI and co-morbid conditions.

The ASMBS, in their 2015 position statement on vagal blocking therapy for obesity (Papasavas et al., 2015), conclude that the quantity of the data available at this time (6 published studies; approximately 600 implanted devices) and the length of follow-up indicate adequate safety and efficacy in the short term. More prospective studies with longer follow-up are required to establish the clinically significant efficacy and patient tolerance of this device.

In a 2015 position statement on intragastric balloon therapy endorsed by SAGES, the ASMBS acknowledges that although utilization of intragastric balloons results in notable weight loss, separating the effect of the balloon alone from those of supervised diet and lifestyle changes may be challenging. (Ali et al., 2015)

The ASMBS Pediatric Committee (Michalsky et al., 2012) best practice guidelines state that there is a mounting body of evidence that supports the use of modern surgical weight loss procedures for carefully selected, extremely obese adolescents.

- All adolescent boys and most adolescent girls <18 years old with a BMI of 35 kg/m<sup>2</sup> are greater than the 99th BMI percentile, so the BMI thresholds used for adult selection criterion appear to be appropriate for adolescents, with some modification with regard to associated co-morbid disease thresholds. As recently recommended, the selection criteria for adolescents being considered for a bariatric procedure should include a BMI of  $\geq 35$  kg/m<sup>2</sup> with major co-morbidities [i.e., type 2 diabetes mellitus, moderate to severe sleep apnea (apnea-hypopnea index >15)], pseudotumor cerebri, or severe NASH) or a BMI of  $\geq 40$  kg/m<sup>2</sup> with other co-morbidities (e.g., hypertension, insulin resistance, glucose intolerance, substantially impaired quality of life or activities of daily living, dyslipidemia, sleep apnea with apnea-hypopnea index >5). The associated risk/benefit analysis should also include the consideration of the potential long-term health risks of untreated or inadequately treated obesity for the individual candidate.
- Bariatric surgery can result in improvement of the metabolic and inflammatory parameters of the metabolic syndrome, including hyperinsulinemia, insulin resistance, and abnormal lipid metabolism. Although evidence suggests that certain parameters associated with childhood obesity are linked to the development of the metabolic syndrome in adulthood, the diagnosis of the metabolic syndrome in this age group is ill-defined and not well standardized. Therefore, a diagnosis of the metabolic syndrome in obese adolescents is a relative indication for bariatric surgery.
- The associated risk/benefit analysis should also include the consideration of the potential long-term health risks of untreated or inadequately treated obesity for the individual candidate.
- Patients with a greater BMI and more serious medical illness are at increased risk of complications after bariatric surgery. Providing access to bariatric surgery earlier in life when the disease burden and severity is lower might decrease the operative risk, morbidity, and mortality. Additionally, earlier surgical intervention alters the natural course of many obesity-related co-morbidities that otherwise would put the patient at risk of long-term complications and early mortality.

- The psychosocial outcomes after bariatric surgery have not been adequately studied, particularly in adolescents. Although current short-term data show improvement in depression, eating disturbances, and quality of life after weight loss induced by bariatric surgery, the long-term results have not been well studied.
- Binge eating and self-induced purging occur in 5–30% of obese adolescents seeking bariatric surgery. The presence of such eating disturbances before bariatric surgery does not appear to affect weight loss outcome after bariatric surgery in adult cohorts, at least in the short term. Therefore, although not studied specifically in adolescents seeking bariatric surgery, the presence of eating disturbances is not an exclusion criterion. If an eating disorder is identified, treatment should be initiated and the patient should be considered stable before bariatric surgery.

In a systematic review of reoperative bariatric surgery, the ASMBS (Brethauer et al., 2014) states that the indications and outcomes for reoperative bariatric surgery are procedure-specific, but the current evidence does support additional treatment for persistent obesity, co-morbid disease, and complications. Additional surgical therapy may benefit patients who present with insufficient weight loss, continued co-morbid disease, or weight gain after bariatric surgery. A thorough evaluation should be conducted by a multi-disciplinary program to determine the potential causes for their poor responses.

As the risks of reoperative bariatric surgery are higher than with the primary procedure, evidence suggests the need for careful patient selection. In addition, the specific type of reoperative procedure performed should be based on the patient's primary procedure, the patient's anatomy, the patient's weight and co-morbidities, and the experience of the surgeon.

An ASMBS Task Force (Sudan et al., 2015) on reoperative surgery provided the updated definitions for reoperative surgery as follows:

Any operation after the first bariatric operation which qualified toward center of excellence volume requirements is considered a reoperation. Reoperations were further divided into corrective operations or conversions.

- An operation is considered corrective when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed.
- Conversions involve changing an index bariatric operation (first operation) to a different type of bariatric operation, and reversal restored original anatomy.

The Task Force also conducted a systematic review to evaluate morbidity, mortality, and weight loss outcomes after reoperative bariatric surgery. Data on reoperations was compared to that from patients who had initial bariatric operations but did not undergo reoperations. Reoperations were subdivided into corrective operations and conversions.

- Out of 449,753 bariatric operations, 28,720 (6.3%) underwent reoperations of which 19,970 (69.5%) were corrective and 8,750 (30.5%) were conversions.
- The mean% EBWL after conversion to a different bariatric operation was 39.3% and was 35.9% after a corrective operation. Although this% EBWL was lower than that after a primary operation (43.5%), it is still considered by the Task Force to be substantial and excellent weight loss. However, not all reoperations will result in further weight loss or resolution of comorbidity.
  - Restorative operations necessitated by intolerable side effects or complications of the index procedure such as removal of the laparoscopic adjustable gastric band for band intolerance or dilated esophagus, or reversing a duodenal switch or a gastric bypass for severe malabsorption, may in fact result in weight gain and return of comorbidities.
- Elderly patients (>60 years of age) comprised 11% of the primary and 12% of the reoperative group of patients. The data suggests an overall improvement in the rates of morbidity and mortality after bariatric operations in recent years, even for higher risk populations.

The Task Force concluded that although most patients do not require reoperative surgery, among those who do, the complication rate is low and outcomes are clinically comparable to primary procedures.

### **Endocrine Society**

In its 2016 guideline for the prevention and treatment of pediatric obesity (August et al., 2016), the Endocrine Society recommends that:

- Overweight be defined as having a body mass index (BMI)  $\geq$  85<sup>th</sup> percentile by  $\leq$  95<sup>th</sup> percentile, and obesity as BMI  $\geq$  95<sup>th</sup> percentile.
- Prescribing and supporting intensive lifestyle (dietary, physical activity, and behavioral) modification as the prerequisite for any treatment.
- An evaluation for obesity-associated co-morbidities in children with BMI  $\geq$  85<sup>th</sup> percentile.
- Pharmacotherapy (in combination with lifestyle modification) be considered in 1) obese children only after failure of a formal program of intensive lifestyle modification and in 2) overweight children only if severe co-morbidities persist despite intensive lifestyle modification.

- Pharmacotherapy should be provided only by clinicians who are experienced in the use of anti-obesity agents and aware of the potential for adverse reactions.
- Bariatric surgery should be pursued for adolescents with BMI > 50, or > 40 with severe co-morbidities in whom lifestyle modification and/or pharmacotherapy have failed.

### **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)**

A 2010 guideline by SAGES states that due to concerns for higher failure rates after fundoplication in the morbidly obese patient (BMI >35 kg/m<sup>2</sup>) and the inability of fundoplication to address the underlying problem (obesity) and its associated co-morbidities, gastric bypass should be the procedure of choice when treating GERD in this patient group. The benefits in patients with BMI>30 is less clear and needs further study (Stefanidis et al., 2010).

In its 2008 *Guidelines for Clinical Application of Laparoscopic Bariatric Surgery*, endorsed by the ASMBS, SAGES confirms that bariatric surgery is medically indicated for morbidly obese patients who fail to respond to dietary, behavioral, nutritional, and medical therapies, with clear evidence of efficacy and safety. BMI and age-based candidacy guidelines should not limit access for patients suffering with progressive or poorly controlled obesity-related comorbidities if the risk-versus-benefit analysis favors surgery. Laparoscopic RGB, AGB, and BPD have all been proven effective. They do not make a definitive recommendation for one procedure over another and note that at the present time, decisions are driven by patient and surgeon preferences, as well as considerations regarding the degree and timing of necessary outcomes versus tolerance of risk and lifestyle change.

Further, the 2008 guidelines state that there are no absolute contraindications to bariatric surgery. Relative contraindications to surgery may include severe heart failure, unstable coronary artery disease, end-stage lung disease, active cancer diagnosis/treatment, cirrhosis with portal hypertension, uncontrolled drug or alcohol dependency, and severely impaired intellectual capacity. Crohn's disease may be a relative contraindication to Roux-en-Y gastric bypass and biliopancreatic diversion.

### **American Academy of Sleep Medicine (AASM)**

In its 2009 *Clinical Guideline for the Evaluation, Management, and Long-Term Care of Obstructive Sleep Apnea in Adults*, the AASM Adult Obstructive Sleep Apnea Task Force (Epstein, et al., 2009) states that bariatric surgery may be adjunctive in the treatment of obstructive sleep apnea (OSA) in obese patients. There is a consensus that bariatric surgery should be considered as an adjunct to less invasive and rapidly active first-line therapies such as PAP for patients who have OSA and meet the currently published guidelines for bariatric surgery. The remission rate for OSA two years after bariatric surgery, related to the amount of weight lost, is 40%, emphasizing the need for ongoing clinical follow-up of these patients.

## **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Bariatric surgical procedures are not subject to FDA regulation. FDA approval information for several devices related to bariatric surgery is described below.

The FDA approved the ORBERA™ Intragastric Balloon System (Apollo Endosurgery, Inc.) on August 5, 2015. The ORBERA System is indicated for use as an adjunct to weight reduction in obese adults with BMI ≥30 and ≤40 kg/m<sup>2</sup>. It is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the likelihood of significant long-term weight loss and weight loss maintenance. It is indicated for adults who have failed conservative weight reduction strategies, such as supervised diet, exercise and behavior modification program. ORBERA has a maximum placement period of 6 months. For more information, please see: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p140008> (Accessed February 27, 2018)

The FDA approved the implantable EnteroMedics Maestro Rechargeable System to be marketed on January 4, 2015. The Maestro Rechargeable System is an implantable pacemaker-like device for patients who are morbidly obese or who are obese with one or more obesity-related conditions. For more information, please see: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130019>. (Accessed February 27, 2018)

Gastric banding, involves the use of an adjustable or nonadjustable gastric band, which is subject to FDA marketing approval. In 2001, the BioEnterics® LAP-BAND System was approved by FDA for marketing under the premarket approval process. According to the FDA labeling, this is approved for surgical treatment for severely obese adults for whom more conservative treatments (e.g., diet, exercise, behavioral modification) have failed. The LAP-BAND System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe co-morbid conditions, or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.

In February 2011, the FDA approved the Lap-Band Adjustable Gastric Banding System, by Allergan, for weight reduction in obese patients, with a Body Mass Index (BMI) of at least 40 kg/m<sup>2</sup> or less obese patients who have at least a body mass index (BMI) of 30 kg/m<sup>2</sup> and one or more additional obesity-related co-morbid condition, such as diabetes or hypertension. Additional information is available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/p000008s017a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/p000008s017a.pdf). (Accessed October 30, 2017)

On September 28, 2007, the FDA approved the REALIZE™ Adjustable Gastric Band (REALIZE Band) manufactured by Ethicon Endo-Surgery, Inc. The REALIZE Band also consists of a silicone band, tubing, and an injection port. Additional information is available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/P070009b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/P070009b.pdf). (Accessed October 30, 2017)

In October, 2010, the manufacturer voluntarily recalled the REALIZE Band due to the potential for a small ancillary component called the Strain Relief to move out of its intended position. The device was changed to add a silicone adhesive to bond the strain relief sleeve and the locking connector components of the injection port. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=8137>. (Accessed October 30, 2017)

Adjustable gastric bands are contraindicated in patients younger than 18 years of age.

Surgical stapling devices are used in all bariatric surgical procedures except gastric banding. These devices have been approved by FDA for use in various general surgical procedures. One device is the Endo Gia Universal Auto Suture, which inserts six parallel rows of staples into tissue. Other surgical staplers are manufactured by Ethicon Endo-Surgery. Additional information, product code GDW and GAG, is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm>. (Accessed October 30, 2017)

StomaphyX was granted 510(k) marketing approval on March 9, 2007. EndoGastric Solutions StomaphyX™ endoluminal fastener and delivery system is substantially equivalent in intended use and method of operation to a combination of the LSI Solutions Flexible Suture Placement Device and the Bard Endoscope Suturing System/Bard Endocinch. According to the FDA, the StomaphyX system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract. Additional information is available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf6/K062875.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062875.pdf). (Accessed October 30, 2017)  
According to EndoGastric Solutions, StomaphyX is no longer being manufactured.

The AspireAssist received FDA pre-market approval on June 14, 2016 for adults who are at least 22 years old and are obese, with a BMI of 35.0-55.0 kg/m<sup>2</sup> who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Additional information is available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P150024>. (Accessed February 27, 2018)

Transoral gastroplasty (TOGA) is not currently FDA approved.

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0362AA]

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#### POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
05/01/2018	<ul style="list-style-type: none"> <li>Corrected formatting error in coverage rationale/criteria (no content changes)</li> </ul>
03/01/2018	<ul style="list-style-type: none"> <li>Updated benefit considerations; removed instruction to check the member specific benefit plan document and any federal or state mandates, if applicable, before using this policy</li> <li>Revised coverage rationale: <ul style="list-style-type: none"> <li>Modified language pertaining to proven/medically necessary indications; replaced language indicating: <ul style="list-style-type: none"> <li>"The surgical procedures [listed in the policy] are proven <i>and</i> medically necessary in adults for treating Extreme Obesity" with "the surgical procedures [listed in the policy] are proven <i>and/or</i> medically necessary in adults for treating Extreme Obesity"</li> <li>"Bariatric surgery using one of the procedures identified [within the policy] (primary, secondary or revisions) for treating <i>weight loss</i> is medically necessary when all of the [listed] criteria are met" with "bariatric surgery using one of the procedures identified [within the</li> </ul> </li> </ul> </li> </ul>

Date	Action/Description
	<p>policy] (primary, secondary or revisions) for treating <i>obesity</i> is <i>proven and/or</i> medically necessary when all of the [listed] criteria are met”</p> <ul style="list-style-type: none"> <li>▪ “Bariatric surgical procedures identified [in the policy] are medically necessary in adolescents for treating Extreme Obesity” with “bariatric surgical procedures identified [in the policy] are <i>proven and/or</i> medically necessary in adolescents for treating Extreme Obesity”</li> <li>▪ “Robotic-assisted gastric bypass surgery is <i>proven and</i> medically necessary as equivalent but not superior to other types of minimally invasive bariatric surgery” with “robotic-assisted gastric bypass surgery is <i>proven and/or</i> medically necessary as equivalent but not superior to other types of minimally invasive bariatric surgery”</li> <li>▪ “Surgical adjustment or alteration of a prior bariatric procedure is <i>proven and</i> medically necessary for complications of the original surgery when the complication causes abdominal pain, inability to eat or drink or causes vomiting of prescribed meals” with “surgical adjustment or alteration of a prior bariatric procedure is <i>proven and/or</i> medically necessary for complications of the original surgery when the complication causes abdominal pain, inability to eat or drink or causes vomiting of prescribed meals”</li> </ul> <ul style="list-style-type: none"> <li>○ Modified language pertaining to unproven/not medically necessary indications; replaced language indicating: <ul style="list-style-type: none"> <li>▪ “[The listed services] are unproven <i>and</i> not medically necessary” with “[the listed services] are unproven <i>and/or</i> not medically necessary”</li> </ul> </li> <li>○ Updated list of qualifying co-morbidities for bariatric surgical treatment of Class II obesity; replaced language indicating “<i>cardiopulmonary problems as a result of another disease process, including but not limited to documented obstructive (OSA) confirmed on polysomnography with an AHI or RDI of &gt;30</i>” with “<i>Obstructive Sleep Apnea (OSA) confirmed on polysomnography with an AHI or RDI of &gt;30</i>”</li> </ul> <ul style="list-style-type: none"> <li>• Updated definitions: <ul style="list-style-type: none"> <li>○ Added definition of “Body Mass Index (BMI)”</li> <li>○ Modified definition of: <ul style="list-style-type: none"> <li>▪ Extreme Obesity</li> <li>▪ Obstructive Sleep Apnea (OSA)</li> </ul> </li> </ul> </li> <li>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references</li> <li>• Archived previous policy version SURGERY 029.35 T2</li> </ul>