# Bariatric surgery and surgical devices in obesity management

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## Abstract
**Obesity levels worldwide are reaching epidemic proportions with resultant strain on healthcare systems and individual wellbeing. To date, bariatric surgery is the management option that produces the greatest degree of weight loss which can be maintained in the long term along with a reduction in obesity-associated comorbidities such as diabetes and fewer cardiovascular events. Roux-en-Y gastric bypass, laparascopic gastric band and sleeve gastrectomy are the most widely performed bariatric procedures but, despite low perioperative mortality and complication rates, these procedures may not be suitable for all patients due to other factors. Newer surgical techniques are being developed both laparoscopically and endoscopically, in addition to the use of less invasive non-surgical devices that can achieve weight loss, by (1) increasing satiety such as gastric pacing and vagal nerve inhibition and (2) reducing absorption through aspiration of gastric contents, duodenal sheaths and thermal ablation of the duodenal mucosa. This article reviews current and future bariatric surgical procedures and introduces non-surgical devices that may increasingly feature in the management of obesity.**

**Key words:** obesity, bariatric surgery, devices

## Background
Obesity is a chronic condition that is increasing in prevalence in all age groups, and is now considered to be a global epidemic.[1] The increase has been particularly high in England where prevalence has doubled over the last 25 years. In 2014 the WHO estimated that 1.9 billion adults worldwide were overweight and at

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least 600 million obese. By 2015 this is projected to rise to 2.3 billion and over 700 million, respectively.[2]

In most cases obesity results from an imbalance between energy input and expenditure. However, weight gain is multifactorial and may be due to identifiable and specific genetic defects (e.g. leptin deficiency, MC4 receptor mutations), damage to the hypothalamus (from trauma, tumours or surgery), drugs (e.g. antipsychotics) or life changing events (such as bereavement or separation). Short sleep duration, typically defined as having less than six hours of sleep, has also been associated with weight gain and obesity.[3] The likely mechanisms could involve leptin, ghrelin hormones and possibly glucagon-like peptide-1 (GLP-1) as they affect satiety, hunger and food intake.[4-6] Obesity is more prevalent in people with lower educational attainment, reduced employment prospects and lower socioeconomic status.[7]

Obesity is strongly associated with diabetes, the sex-specific prevalence increasing more than fivefold over the body mass index (BMI) range 15–50 kg/m$^2$ (from 2.8% to 11.4% for men; from 1.8% to 10.3% for women), most of this increase occurring above a BMI of 25 kg/m$^2$.[8] Estimates of the direct costs to the NHS for treating overweight and obese individuals, and related morbidity in England, have ranged from £479.3 million in 1998 to £4.2 billion in 2007.[9] Estimates of the indirect costs (those costs arising from the impact of obesity on the wider economy such as loss of productivity) over the same time period ranged between £2.6 billion[10] and £15.8 billion.[9]

Bariatric surgery, which is presently the most effective treatment for obesity in terms of producing significant and sustained weight reduction, has provided compelling evidence that weight loss can ameliorate many obesity-related conditions and improve life expectancy.[11-14] In 2007 a retrospective cohort study of obese subjects who were undergoing weight loss surgery showed a 40% reduction in all-cause mortality, a 92% reduction in diabetes deaths, a 56% reduction in coronary artery disease deaths and a 60% reduction in cancer deaths.[15]

## Current and future bariatric surgeries
Non-surgical weight management including calorie restriction, exercise and/or medication generally achieves no more than a 5–10% reduction in body weight. Recidivism after such weight loss exceeds 90% within 5 years. The disappointing results of these approaches have led to a burgeoning interest in bariatric surgery.[16]

## Standard bariatric procedures
Traditionally, obesity surgery is considered appropriate for adult

patients with a BMI >40 kg/m$^2$ or a BMI of 35–40 kg/m$^2$ with an obesity-related comorbidity. These selection criteria were developed in March 1991 by the National Institutes of Health Consensus Development Panel and have subsequently been adopted by all major surgical and non-surgical societies.[17] Bariatric surgery is one of the fastest growing operative procedures performed worldwide, with an estimated >340,000 operations performed in 2011.[18] Bariatric surgical procedures affect weight loss through two fundamental mechanisms: restriction of food intake and malabsorption. Adjustable gastric bands (AGB) and sleeve gastrectomy (SG) are restrictive procedures with reductions in BMI of 11.4 kg/m$^2$ and 16.7 kg/m$^2$ at 3 years, respectively.[19] Gastric bypass (GB) surgery and biliopancreatic diversion/duodenal switch have both a restrictive and malabsorptive component generally resulting in greater weight loss with a reduction in BMI of 21.9 kg/m$^2$ at 3 years.[19] This observed weight loss following bariatric surgery is associated with increased rates of remission of diabetes compared with controls, achieving 67.7%, 85.5% and 92.8% following AGB, SG, and GB respectively. Reduced incidence of diabetes (96%, 84% and 78% at 2, 10 and 15 years), myocardial infarction and stroke (adjusted hazard ratios or 0.71 and 0.66) have also been demonstrated in the Swedish Obesity Study (SOS).[20]

In addition to restriction and malabsorption of food, there are a number of other mechanisms which contribute to weight loss including alteration of gut microbiota, action on signalling between gut and brain and impact on gut hormones such as reduced orexigenic hormones such as ghrelin and increased anorectic hormones such as GLP-1 and peptide YY postprandially, which also aid insulin secretion and glucose control.[21-30]

## Newer surgical techniques

Not all patients benefit from the above standard bariatric procedures and several newer surgical techniques have been developed, some of which are described below.

*Primary Obesity Surgery Endoluminal (POSE) procedure*: POSE is a minimally invasive incision-free endoscopic procedure wherein the stomach is folded in on itself. POSE is performed using a specialised endoscope inserted through the mouth. This procedure is performed under general anaesthesia and sutures are used to create new folds in the stomach, thereby reducing the capacity of the stomach. In a case series, 116 patients (79% of total) who were available for follow-up at 1 year had a mean 45% excess weight loss. POSE was reported to be an effective, safe and well tolerated procedure;[31] however, weight regain has limited its widespread use.

*Laparoscopic Greater Curvature Plication (LGCP)*: This technique evolved from the Laparoscopic Sleeve Gastrectomy (LSG). In this procedure the stomach is folded in on itself and stitched into position to create a small stomach pouch which results in reducing the capacity of the stomach. The natural outlet of the stomach is maintained. The pouch is thought to be similar in form and function to that of a LSG, without the increased risks associated with cutting and stapling the stomach.

A retrospective study found a reduction of 82.1% in excess BMI at 12 months.[32] However, in a meta-analysis comparing LGCP with LSG, LGCP was shown to result in significantly less weight loss than LSG and may in fact be associated with more adverse events over a 12-month period of follow-up.[33] LGCP is an emerging and reversible technique sparing gastric resection and intestinal bypass. Its effectiveness is satisfactory for patients with BMI<45 kg/m² and the complication rate is acceptable.[34]

*Band-on-Bypass (BoB)*: In patients who have started to regain weight after having gastric bypass surgery, BoB is an option if they cannot have a more complex surgery like biliopancreatic diversion or duodenal switch. It is adapted from the Fobi procedure whereby a silicon ring was placed around the gastric pouch at the same time as the primary bypass operation in an attempt to minimise weight regain and this is still performed by some centres. Adverse effects include increased reflux and vomiting leading to explantation of the ring.[35]

*Laparoscopic one anastomotic gastric bypass (mini gastric bypass)*: First described at the turn of this century, the so called mini gastric bypass is gaining in popularity in established bariatric centres around the world. It was devised to be a quicker and safer alternative to conventional gastric bypass by having a single anastomotic site between a loop of jejunum and a lesser curvature-based tube of stomach. It has attracted controversy, however, with concerns regarding increased biliary reflux, upper gastrointestinal cancers and increased complication rates.[36] Weight loss appears to be similar to Roux-en-Y gastric bypass at around 38% at 12 months, which is maintained at 30% after 9 years with similar rates of resolution of diabetes, sleep apnoea and hypertension also reported.[36,37] In experienced hands, operative time is reduced with no increased complication rates or ulceration.[38]

*Single anastomosis duodeno-ileostomy (SADI)*: Similar to the mini gastric bypass, this procedure has been developed as a quicker and safer version of the biliopancreatic diversion or duodenal switch through the formation of a single anastomotic site between the duodenum and the ileum following a sleeve gastrectomy. Mean excess weight loss has been reported at around 100% at 3 years in a series of 50 patients, with improvements in metabolic parameters. Complication rates were low with two gastric leaks described and mild anaemia, hypoalbuminaemia and hypovitaminosis D noted in 10%, 25% and 40% of cases respectively at 3 years.[39] The SADI may be an option when weight regain occurs following sleeve gastrectomy or in the super-obese due to its weight loss and potential for fewer complications, but long-term nutritional monitoring is still clearly required. Longer term follow-up and trials alongside established bariatric procedures are required to determine its true clinical utility.

## Devices

The bariatric surgeries described above are associated with complications including anaesthetic risk during the procedure. Not

**Table 1** Summary of new therapeutic devices for the management of obesity

| Device (mode of action) | Trial type | Baseline BMI | Weight loss | Adverse events |
|---|---|---|---|---|
| VBLOC (increases satiety through vagal nerve stimulation) | Multi-centre RCT[40] (n=239) | 41 kg/m² intervention and sham group | Mean EWL 24.4% (intervention) vs. 15.9% (sham) 12 months | Dyspepsia, abdominal pain |
| Gastric pacemaker (increases satiety) | Single-centre observational[41] (n=91) | 41 kg/m² | Mean EWL 20% at 1 year, 25% at 2 years | Gastric penetration, lead dislodgment |
| Aspire Assist A-tube (allows aspiration of gastric contents) | Single-centre RCT[43] (n=18) | 42 kg/m² intervention group 39 kg/m² control | Mean EWL 49% (intervention) vs. 14.2% (control) | Abdominal discomfort, peristomal bleeding, irritation, infection, nausea |
| Duodeno-jejunal bypass liner (reduces duodenal absorption by minimising exposure of food to duodenal mucosa) | Single-centre observational[48] (n=165) | 53.5 kg/m² (12 week group) 35.6 kg/m² (6 month group) 35.1 kg/² (12 month group) | Mean 7% (12 week group) 10% (6, 12 month group) | GI bleeding, pancreatitis, hepatic abscess |
| Duodenal mucosal resurfacing (thermal ablation reduces absorptive capacity of duodenum) | Observational (n=39) | Not reported | 2.3 kg reduction | Duodenal stenosis |

BMI, body mass index; EWL, excess weight loss; GI, gastrointestinal; RCT, randomised controlled trial; VBLOC, vagal nerve block.

everyone will be suitable to undergo one of these surgical interventions for weight loss. In these patients a surgical device may be more appropriate, which is usually not associated with malabsorption and most of these procedures are reversible. Here we describe some of the devices currently being trialled (summarised in Table 1).

*Vagal Nerve Block (VBLOC)*: The vagus nerve is involved in gastric acid and digestive enzyme secretion, gastric capacity, satiety and energy metabolism. The VBLOC procedure involves delivering high frequency electrical pulses intermittently to the vagus nerve using two laparoscopically implanted electrodes to lie adjacent to the vagus nerve at the lower portion of the oesophagus. A subcutaneous rechargeable neuroregulator device delivers a signal to the two electrodes. Given the intermittent nature of the block, it is thought that the nervous and digestive systems will not adapt and appetite will remain supressed. VBLOC therapy is a reversible procedure and does not alter the digestive anatomy.

The ReCharge randomised clinical trial is a randomised multicentre double-blind sham-controlled clinical trial involving 239 participants; 162 patients received an active vagal nerve block device and 77 received a sham device. All participants received weight management education. The 12-month blinded portion demonstrated that vagal nerve block resulted in a mean 24.4% excess weight loss compared with 15.9% in the sham group, which failed to achieve statistical significance (p=0.71). The adverse events, which were more frequent in the vagal nerve block group, were dyspepsia and abdominal pain. VBLOC therapy was reported to be well tolerated, having met the primary safety objective.[40]

*Implantable gastric pacing*: This involves surgically implanting electric pacers into the stomach wall and then attaching the pacing wires to a generator placed in the subcutaneous tissue of the abdominal wall.[41] Detection of food or drink entering the stomach results in delivery of a series of low-energy electrical impulses to the stomach, providing gastric stimulation that creates an early sensation of satiety. This feeling of fullness experienced by the patient reduces the desire to overeat or to eat between meals. The increased stimulation is thought to increase gastric motility, but it may also change fundal tone and alter gut hormone secretion.[41]

The level of gastric stimulation can be customised for patients based upon their individual needs. In the future this pacemaker may even have the ability to capture apnoeic episodes. Patients having a pacemaker will need support with behavioural changes. This is a minimally invasive and reversible procedure. As this procedure does not significantly alter the gastrointestinal tract anatomy, nutritional deficiency is not encountered, unlike other malabsorptive bariatric surgeries. The European LOSS (Laparoscopic Obesity Stimulation Survey) trial showed it to be a safe treatment with an approximate excess weight loss of 20% at 1 year.[41] A review of gastric electrical pacing in 2014 found that, of 33 trials, significant results were found in appetite/satiety, gastric emptying rate, blood pressure and neurohormone levels or biochemical markers such as ghrelin or $HbA_{1c}$, respectively, and most studies observed significant weight loss at 12 months. Those with long-term follow-up such as the Transcend device group maintained significant weight loss.[42]

*Aspire Assist A-Tube*: The Aspire Assist Aspiration Therapy System consists of an endoscopically placed gastrostomy tube (percuta-

neous endoscopic gastrostomy), A-tube and a siphon assembly. The Aspire Assist A-tube is during a gastroscopy performed under conscious sedation. After approximately 2 weeks of insertion, aspiration therapy is commenced. Patients are instructed to thoroughly chew food to aid aspiration and aspirate gastric contents 20 min after a meal, removing around 30% of calories consumed.

In a pilot study conducted by Sullivan *et al* this procedure was deemed to be safe and well tolerated. Patients in the intervention arm of the study lost about 50% of the excess weight loss compared with 15% excess weight loss in the control arm.[43] In another study at 6 months 88% of the participants had a mean 41% of excess weight loss.[44] Reported adverse events include abdominal discomfort and bloating, peristomal irritation, bleeding and infection and nausea.

This is a minimally invasive procedure and does not alter gastrointestinal tract anatomy, making it an alternative for obese patients who are reluctant to undergo bariatric surgery. The results of a European super-obese study (BMI >55 kg/m$^2$) involving three centres and including 30 patients with an average BMI of 63 kg/m$^2$ are awaited. Although this procedure has been viewed with a lot of scepticism, there is a place for this procedure in the super-obese individual. Aspire Assist could be used either as a definitive therapy or as a bridge to standard bariatric surgery with the caveat that complication rates are likely to be greater.

*Endoscopic gastrointestinal bypass devices*: The EndoBarrier duodenal-jejunal bypass liner (DJBL) is a flexible collapsible 60 cm tube-like liner with a large proximal opening that is delivered endoscopically using a preloaded single-use device. Made from a durable polymer, the device is anchored in place with attached nitinol (alloy of nickel and titanium) points that adhere and secure the liner to the wall of the duodenum. The device is delivered endoscopically under general anaesthesia or moderate sedation during a procedure that takes on average about 30 min.

The EndoBarrier liner creates a physical barrier between ingested food and the proximal intestine, mimicking the duodenal-jejunal exclusion of Roux-en-Y gastric bypass. Clinical data suggest that the EndoBarrier works by affecting key hormones involved in insulin sensitivity, glucose metabolism, satiety and food intake.[45] It is a relatively safe procedure, but the reported early removal rate due to patient intolerance or side effects is 10–20% in clinical trials outside the USA.[46]

Two recent studies have reported that the duodeno-jejunal bypass liner has a reasonable safety and tolerability profile and was associated with 10–20% reduction in body weight, depending on duration of implantation of the device (12 weeks, 6 months and 12 months), along with some improvements in metabolic parameters.[47,48] Post-procedure, many patients experience abdominal discomfort, mild to moderate pain and/or nausea, with more serious complications including device migration, gastrointestinal bleeding, perforation, obstruction, hepatic abscess, pancreatitis and cholecystitis.[46-48] Patient selection, expert use of the device at placement and removal, and the supportive care of an experienced multidisciplinary clinical team are key for safe and effective use of the DJBL.

## Key messages

- Bariatric surgery remains the most effective intervention in the management of obesity
- Current surgical techniques are not without their risks, complications and susceptibility to weight regain
- Physicians should be aware of the newer surgical techniques and devices now being used for weight management

In July 2015 a US study comparing the EndoBarrier with a sham procedure, the ENDO trial, was terminated early having recruited 325 of 500 patients due to concerns regarding the rate of hepatic abscess (n=7, incidence rate 3.2%), exceeding the safety threshold of 2%. The reason for the increased incidence of hepatic abscess in the trial compared with global figures (0.73% from 3,000 patients) is unclear, but a reduction in HbA$_{1c}$ of 1.1% at 12 months illustrates the potential clinical utility of the EndoBarrier if its safety profile can be improved.[49]

**Intragastric balloon:** The endoscopic placement of a balloon into the stomach to achieve weight loss by increasing satiety and reducing food intake has been recognised for several decades. A meta-analysis in 2013 reported 8.9 kg greater weight loss following 6 months of balloon placement compared with controls, with around 10% weight loss maintained at 1 year (6 months following balloon removal) in some studies and 50% remission of metabolic syndrome.[46,50,51] Adverse events such as nausea, vomiting and abdominal pain occurred much more frequently in the intervention group, along with gastric erosions and ulceration. Intragastric balloons are capable of producing clinically meaningful weight loss in the short term, but concerns exist regarding weight regain in the long term and therefore may be better placed as a bridge to bariatric surgery in high-risk individuals.[46]

**Duodenal Mucosal Resurfacing (DMR):** This novel minimally invasive technique is predominantly aimed at improving glycaemic control and is currently entering phase I clinical trials.[52] Promising results from a proof of concept study were reported at the 3rd World Congress on Interventional Therapies for Type 2 Diabetes in September 2015. Thermal ablation is employed to alter the duodenal mucosal surface with an improvement noted in HbA$_{1c}$ from 8.5% to 7.1% at 6 months in patients who received treatment on a long segment (>9 cm) and was associated with a modest 2.3 kg reduction in body weight. Complications included duodenal stenosis (7–8%, n=3) and thus the results of larger clinical trials are awaited with interest.

## Conclusion

Bariatric surgery remains the most effective intervention in the management of obesity in terms of weight reduction, resolution of co-

morbidities and improved mortality. Current surgical techniques are not without their risks, complications and susceptibility to weight regain, so it is important that they continue to be refined and challenged as our understanding of their underlying physiological effects improves. Surgery, however, is not the panacea of treatment, and the development of less invasive non-surgical techniques is important to assist physicians in the struggle against the relentless tsunami of obesity and diabetes. Further research is required to determine the efficacy and safety of these procedures before widespread implementation.

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