

applications

Problems in bariatric surgery:

anastomotic leaks and bleeders – fistulae – pouch dilation/weight regain

Bariatric procedures, such as gastric bypass or sleeve gastrectomy have reached a high standard with good clinical outcomes and a favourable risk-benefit ratio. However, even in experienced hands there are several typical complications of considerable impact which are not infrequent. Among these are acute anastomotic leaks and bleeders and the development of chronic fistulae between different organs. Another common problem is weight regain, limiting the long-term efficacy of bariatric procedures.

Anastomotic leaks and bleeders

Gastrointestinal bleeding in the early postoperative period has an incidence of 1–4% (Dick A et al., 2010). Bleeding may be self-limiting but may also require immediate therapeutic action, especially in patients under anticoagulative or antithrombotic medication. The treatment options include endoscopic or surgical hemostasis.

Leaks of anastomotic lines are a known problem in both, gastric bypass and gastric sleeve procedures. The incidence specified by the literature varies between 2% and 9%, depending on procedure and technique used (Fullum TM et al., 2009; Spyropoulos C et al., 2011; Jurowich C et al., 2011). The available treatments comprise endoscopic techniques, clipping or stent placement and surgical repair, such as resection of the leaking staple line and re-anastomosis.

Fistula

Fistulas after bariatric procedures can be a complication with significant therapy resistance and require multiple treatments. A broad variety of fistulas are known, including gastrogastric fistula after gastric bypass surgery, gastrocolonic, gastrocutaneous, gastrobronchial and other locations. The incidence of fistulas in the literature varies between approx. 2 and 5% (Fuks D et al., 2009; Sabbagh C et al., 2010).

The treatment is often complicated and may require several attempts to be successful, endoscopic and surgical closure or covered stenting are standard options today.

Weight regain

In spite of the efficacy of gastric bypass surgery to produce significant excessive weight loss, the long-term effects can be compromised by secondary regain of body weight. Over a post-operative period of 4 years, significant weight regain may happen in more than half of the patients (Abu Dayyeh BK et al., 2011). The diameter of the gastrojejunal stoma shows a significant association with weight regain after gastric bypass surgery and hence is seen as an independent risk factor for weight increase.

Different endoscopic techniques for reduction of the gastrojejunal stoma have been described in the literature as possible treatment options.

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Educational scope:

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Other clinical bulletins

- OTSC® in GI hemostasis
- OTSC® in GI perforation closure
- OTSC® GI fistula closure
- OTSC® Proctology in anal fistula closure



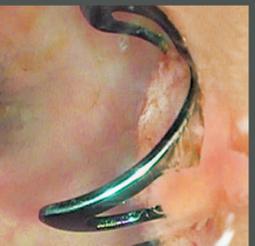
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OTSC® in the treatment of bariatric surgery complications



the OTSC® system

The OTSC® system is a new innovative closure system to be applied via flexible endoscopes. It offers the physician three particular advantages:

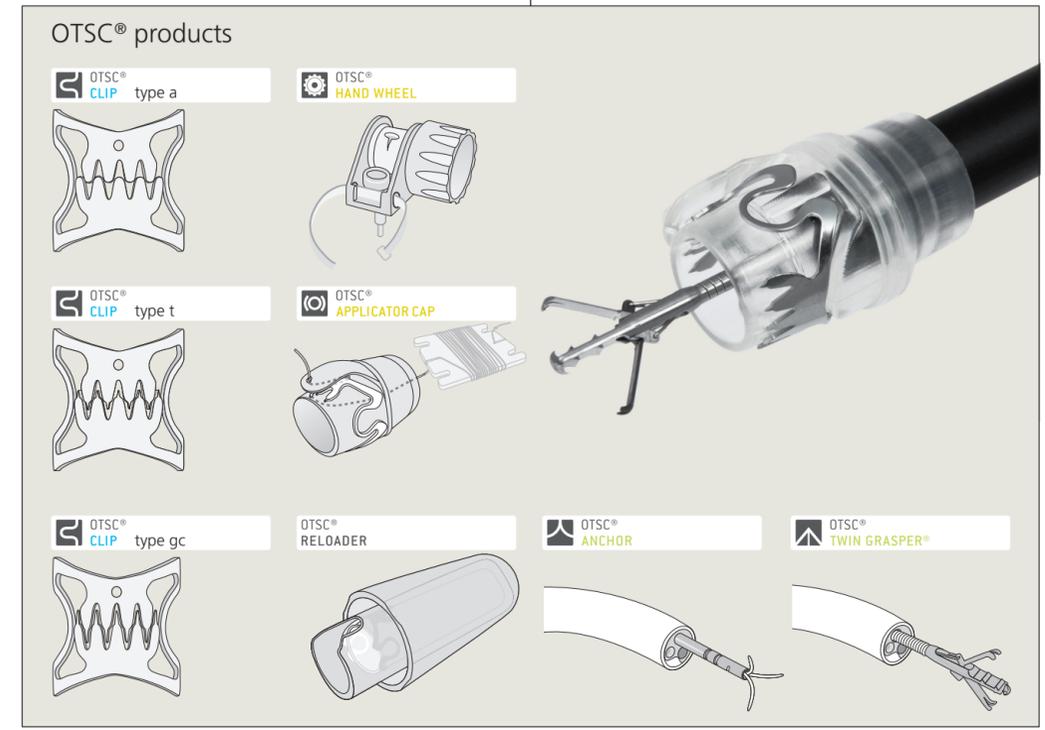
- Large volume of tissue secured
- High stability at the region of interest and constant dynamic tissue compression (constant force at lesion)
- Minimal strain on surrounding tissue

These features and therapeutic functions of the system are based on material selection and design: the superelastic Nitinol® is biocompatible and, if needed, even suited and approved to be applied as a long-term implant. The dynamic tissue compression enabled by the superelastic material adapts to thickness and texture of the tissue grasped and readjusts depending to the actual requirements of the situation/tissue. This avoids overcompression and at the same time ensures constant pressure delivery to the tissue which makes it also most suitable for the treatment of chronic defects like fistulas and anastomotic leakages as well as chronic ulcers.

The use of the OTSC® system is based on a transparent applicator cap and is available in a variety of different sizes and types.

In addition, for precise and easy closure of even larger lesions several application aids are available: the OTSC® Anchor and the OTSC® Twin Grasper® assist you in approximating tissue in treating acute and chronic lesions (perforations, fistulae etc.)

The range of application of the OTSC® system includes hemostasis, closure of lesions such as leaks, perforations and fistulae as well as the endoscopic compression and approximation of tissue.



modes of application

Treatment of anastomotic leakage and chronic fistula

Due to the postoperative impairment of the blood supply in the stomach and the usually impaired wound healing in obese patients anastomotic leakage, gastric band erosion, and fistula formation represent frequent and serious complications in bariatric surgery. The surgical treatment of these long-term complications is dangerous and burdened with a high morbidity and failure rate. The conventional endoscopic options are manifold but have their shortcomings too. The innovative OTSC® system offers a completely new quality of treatment which adds to the degree of freedom for the interventionist even and especially in complicated cases.

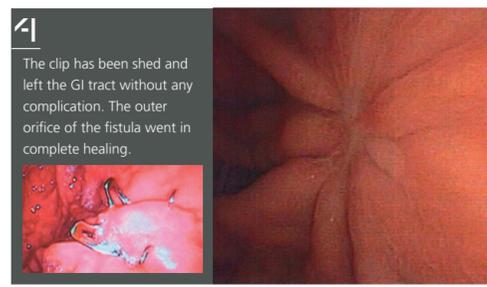
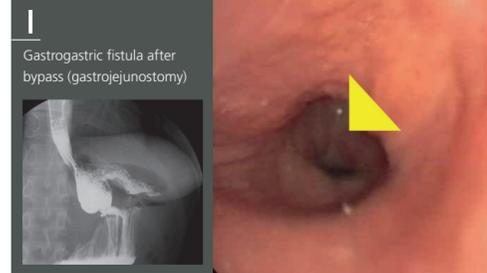
I In contrast to fresh perforations the edges of an anastomotic leak and the orifice of a fistula are fibrotic due to inflammation. This causes typical problems in positioning the scope correctly at the lesion, center it right and deploy the clip. The OTSC® Anchor has been developed especially for this purpose allowing for a firm grip even on complete fibrotic tissue where all other tools may fail.

Using the OTSC® Anchor (like any other grasping tool in combination with the OTSC® system) one has to make sure that the shaft of the instrument is well within the cap or at least level with the edge of the cap when the clip is released. Otherwise the endoscope might get immobilised within the patient. On the other hand, the OTSC® Anchor allows for a closure of the OTSC® clip over the three Anchor needles which afterwards can be pulled back through the clip after release.

II Once an OTSC® clip is successfully deployed it will stay in situ for several weeks to several months, always depending on the amount and texture of the tissue secured. According to the nature of fibrotic tissue the clip will remain here rather shorter a period. Unlike other techniques the OTSC® system is dynamic and will always follow the tissue exerting the same force at all times. This is a key feature, especially for the treatment of fistulas. In most cases a surgical suture is unable to provide the same adaptability and will fail eventually. Because of its geometry the OTSC® system will not impair the perfusion of the tissue and thus support better wound healing.

III Clinical reports have shown promising results in the treatment of fistulas with the OTSC® system (Kirschniak A et al., 2011, Iacopini F et al., 2010, Manta R et al., 2011). The average success rate is about 80%. Recently, Barthet performed a prospective trial on patients with fistulas in the GI tract. He concluded that the OTSC® system is very suitable in fistulas after sleeve resection of the stomach where he could achieve a 90% success rate (Mercky P et al., 2011). In some cases permanent closure could be achieved in a second or third OTSC® session.

IV The OTSC® clip will leave the GI tract in the grand majority of cases. Occasionally, it may be overgrown by mucosa and stay as permanent implant which is no problem because of excellent safety and tolerability features.



Treatment of weight regain due to dilation of the gastrojejunostomy after bypass surgery

Bariatric surgery is an undisputed option for morbid obesity. However, the long-term failure rate after gastric bypass surgery is 20–35%, and even higher in super-obese patients (Buchwald H et al., 2004). A number of studies suggest that a weight gain may be due to the gradual enlargement of the stomach pouch or due to the dilatation of the gastrojejunal anastomosis because of overeating. Reoperation with reducing the pouch volume or shortening the common loop is one option (Mullady DK et al., 2009). Given the high morbidity (15%) and even mortality (1%) of any surgical intervention in these patients, alternative endoscopic methods have been proposed (Heylen AM et al., 2010). The OTSC system proved safe and efficacious here.

I Recently Heylen et al. reported of the successful treatment of weight regain due to a progressive dilation of the gastrojejunal stoma in 94 bariatric patients (over 3/4 were female) following Fobi banded TVCB (Heylen AM et al., 2010). Two years after surgery they gained weight by around 10% or more again, faced reappearing comorbidities and an increased volume per meal or an increased frequency of meals. At this stage they were treated with the OTSC® system.

II Heylen achieved best results by narrowing the pouch outlet with two OTSC® clips positioned at both angles reducing the gastric outlet by about 80%. Obviously it is recommended to approximate mucosa and muscularis layer. For this purpose OTSC® Twin Grasper® or OTSC® Anchor often are useful in order to get better control over the tissue. Heylen used the spiked version of clips which provide better grip on fibrotic tissue. Due to the anatomy of the upper GI tract the preferred clip size was 11 (outer diameter diagnostic scope) and 12 (therapeutic scope). This translates into the following product specifications: OTSC 11/6 t or 12/6 t. Location of clips and gastrointestinal patency were controlled by contrast swallow and by gastroscopy if clinically needed. Patients were on a liquid diet immediately, followed by readjusted speed of eating and drinking.

III Starting from a BMI of 45.8 (±3.6) patients had responded properly to the gastric bypass operation regarding weight loss. Two years after surgery they regained weight and were at a BMI of 32.8 (±1.9) when their dilated gastrojejunostomy was treated with the OTSC® system. At first follow-up about three months (mean 118 days, ±46 days) after OTSC® clip application the mean BMI was down to 29.7 (±1.8). At the second follow-up after one year (mean 352 days, ±66 days) the mean BMI was 27.4 (±3.8). The average weight loss over the first 6 weeks was 4.5 kg (±2.4 kg), thereafter patients still lost 3 kg (±1.7 kg) monthly. Mean follow-up time was 12 months. No major complications occurred. A longer follow-up than described here may be needed to answer the question whether or not these patients will need a further intervention.

