

Prospective pilot study of anorectal fistula closure with the OTSC Proctology

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Abstract

Aim The OTSC Proctology is a surgical device for anorectal fistula closure. It consists of a super-elastic nitinol clip, which is placed (with the aid of a transanal applicator) on the internal fistula opening to achieve healing of the fistula track. A prospective, two-centre clinical pilot study was undertaken to assess the efficacy and safety of the OTSC Proctology in patients with a complex high anorectal fistula.

Method In patients with a complex anorectal fistula the primary track was debrided using a special brush and the clip was applied to the internal fistula opening. After 6 months the postoperative clinical course and fistula healing were assessed.

Results Twenty patients with a cryptoglandular anorectal fistula (14 with a transsphincteric fistula and six with a suprasphincteric fistula) were included in the study. There were no intra-operative technical or surgical complications. Postoperatively no patient reported intolerable discomfort or a sensation of a foreign body in

the anal region. At 6 months after surgery, 18 (90%) patients had no clinical signs or symptoms of fistula and were considered healed, whereas in two the fistula persisted. In 13 (72%) of these 18 patients, the clip was still in place without causing problems, whereas in three patients the clip had spontaneously detached. In the two remaining patients it was necessary to remove the clip due to discomfort and delayed wound healing.

Conclusion Anorectal fistula closure with the OTSC Proctology is an innovative, sphincter-preserving minimally invasive procedure with promising initial results and a high rate of patient satisfaction.

Keywords Anorectal, anal, fistula, OTSC, proctology, clip, nitinol

What does this paper add to the literature?

This is the first prospective clinical study on anorectal fistula closure using a new surgical clip device, the OTSC Proctology.

Introduction

Anorectal fistulas still represent a troublesome condition for both the surgeon and the patient. The surgical treatment of these fistulas is a delicate balance between their complete eradication and preservation of fecal continence. In general, anorectal fistulae may be divided into two categories: simple, superficial fistulae, which may be treated safely with fistulotomy which is extremely effective; and high anorectal or complex fistulae, in which fistulotomy is not an option because these fistulae

incorporate a significant amount of the anal sphincter, and excision would inevitably result in incontinence.

In an attempt to identify safe and effective therapeutic strategies for complex anal fistulae, various sphincter-preserving techniques have been evaluated, including advancement flaps, fistulotomy with primary sphincter reconstruction, fistula plugs or fibrin glue injection. Unfortunately, their results vary widely in terms of invasiveness, postoperative continence impairment, patient satisfaction and recurrence rates, with partly disappointing long-term outcomes [1].

The Over-The-Scope-Clip (OTSC) Proctology (Ovesco Endoscopy AG, Tuebingen, Germany) is an innovative surgical device for transanal anorectal fistula closure, which consists of a clip and a clip applicator (Fig. 1). The clip is made from a super-elastic shape-memory alloy (nitinol), and the opened clip resumes its

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Figure 1 The clip of the OTSC Proctology is 14 mm in diameter and is made of a super-elastic shape memory alloy (Nitinol). The OTSC Proctology system consists of the clip and the clip applicator. A special fistula brush and an anchor device are accessories of the OTSC Proctology.

original (closed) shape after release from the applicator. If applied on the internal fistula opening, the clip exerts constant compression on the tissue between the jaws of the clip and therefore closes the internal fistula opening.

We report on the results of a prospective two-centre clinical pilot study in which the OTSC Proctology was evaluated as a surgical treatment for complex cryptoglandular anal fistulae.

Method

To assess the efficacy and safety of the OTSC Proctology in patients with complex high anorectal fistulae, a prospective, two-centre, clinical pilot study was undertaken. The study, the study protocol and the follow-up protocol were approved by the Ethics Committee responsible for the two surgical centres.

Between October 2011 and April 2013, patients with a complex anorectal cryptoglandular fistula were enrolled into the study after giving written consent. Determina-

tion of the fistula type and location was achieved by pre- and intra-operative clinical examination. No specific diagnostics, such as transanal ultrasound or MRI, were regularly applied. Exclusion criteria were inflammatory bowel disease, acute inflammation or abscess, more than one internal fistula opening, anorectal–vaginal fistulae or more than one previous fistula surgery.

In all patients a seton was placed in the fistula tract at least 6 weeks before fistula closure (Fig. 2, left). Pre-operatively, per-oral gut lavage was performed. Perioperatively, one dose of cephalosporin+metronidazole was administered.

Surgery was standardized: the patient was positioned in the lithotomy position under general or spinal anaesthesia. Surgery started with the circumferential excision of anoderm around the internal opening of the fistula to obtain an area of exposed internal sphincter muscle measuring approximately 2 cm in diameter (Fig. 2, right). This was done to prevent application of the clip onto the very sensitive anoderm. A special fistula brush

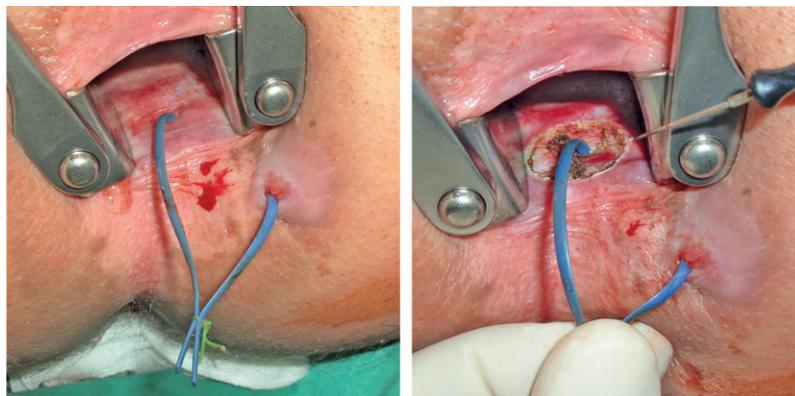


Figure 2 Left: preoperative situation with seton in place. Right: circumferential excision of anoderm around the internal fistula opening, of about 2 cm in diameter.

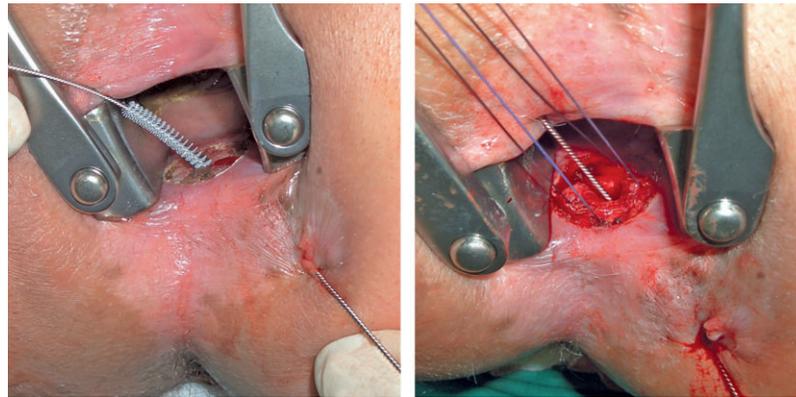


Figure 3 Left: debridement of the fistula tract of epithelium and granulation tissue using the fistula brush. Right: placement of two U-shaped sutures at 90° to each other, centring on the internal fistula opening.

was used to remove the granulation tissue and epithelium lining the fistula tract (Fig. 3, left), being introduced into the tract by attachment to the seton. The fistula tract was irrigated with saline and the brush was left in place to mark the internal opening. Two resorbable, U-shaped sutures were then placed at 90° to each other through the sphincter, centred on the internal opening (Fig. 3, right). They were tied at their distal ends and were pulled through the channel of the clip applicator using the integrated thread retriever (Fig. 4, left). Holding the sutures under slight tension, the preloaded clip applicator was advanced towards the internal opening (Fig. 4, right). The applicator was aligned along the axis of the anal canal to achieve an anatomical orientation of the curved clip within the anorectum. The applicator cap with the preloaded clip was pressed gently against the exposed sphincter muscle around the fistula opening whilst simultaneously elevating the tissue with the sutures (Fig. 5, left). After removal of the

safety-lock of the applicator, the clip was released by pulling the trigger on the handle of the clip applicator. The clip was then pushed from the applicator cap to achieve closure of the internal opening by compression of the sphincter muscle and the proximal fistula tract by the closed teeth of the clip (Fig. 5, right). As a control of the appropriate clip placement the U-shaped sutures through the sphincter muscle were seen in the center of the captured tissue within the clip. To evaluate the effectiveness of the clip closure they were cut off and removed rather than knotted. Effective closure was inferred when saline injected via the external opening did not come out of the internal opening (Fig. 6, left). The external opening of the fistula was widened by some coring out by diathermy to achieve adequate drainage (Fig. 6, right).

Postoperatively, a liquid diet was started on the first day, and by the third postoperative day oral intake was normal.

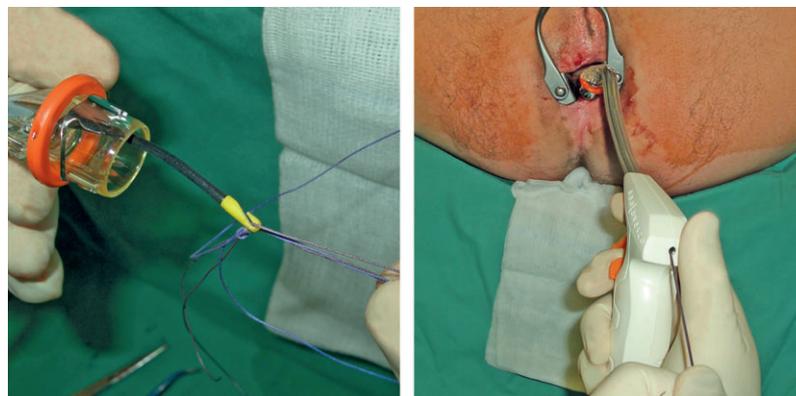


Figure 4 Left: the sutures are tied at their distal end and pulled through the working channel of the clip applicator using the thread retriever. Right: advancement of the clip applicator over the sutures towards the internal fistula opening.



Figure 5 Left: The applicator is pressed gently against the sphincter muscle around the internal opening. Right: application of the clip

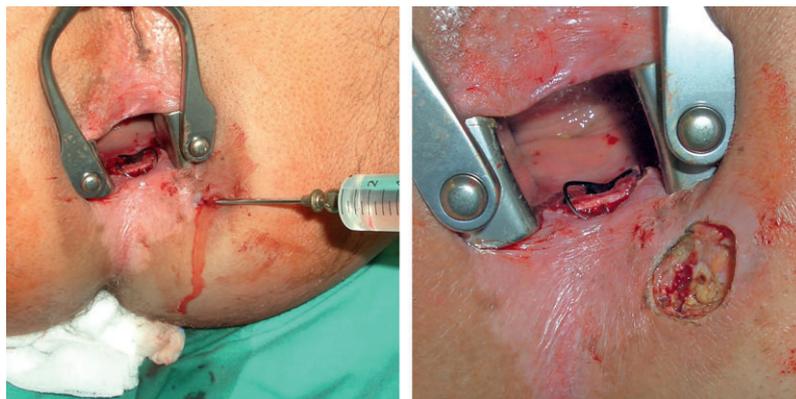


Figure 6 Left: testing for occlusion of the fistula tract by irrigation from the external opening. Right: excision of the external fistula to facilitate drainage of the tract.

Postoperative examination was performed at 1, 3 and 6 months. Patients without clinical signs and symptoms of a fistula, defined as complete closure of the internal and external opening with no sign of inflammation or secretion at the last follow-up 6 months after surgery, were considered to be cured. No specific diagnostic tests, such as transanal ultrasound or MRI, were performed.

Results

Twenty patients with a cryptoglandular anal fistula (14 trans-sphincteric and six suprasphincteric) were enrolled into the study. All operations were performed by five experienced colorectal surgeons. The median operation time was 32 (range: 17–66) minutes. There were no intra-operative technical problems. Only one clip was used per patient, and there was no intra-operative difficulty in its application. There were no major or minor intra-operative complications.

Postoperative pain and analgesia did not exceed levels comparable with 'normal' fistula surgery. Pain was

subjectively felt at the external wound rather than at the site of application of the clip. There were no specific early postoperative complications.

At 6 months after surgery, 18 patients had no clinical signs or symptoms of fistula and were considered as healed, giving an overall success rate of 90%. In 13 (72%) of the 18 patients the clip was still in place without causing any symptoms. There were no side effects related to the clip, such as necrosis, ischaemia or pressure ulceration. In three (17%) of the 18 patients, spontaneous detachment of the clip occurred between 10 days and 4 weeks after surgery. Two (11%) of the 18 patients required operative clip removal: in one patient (female, 25 years of age) the clip had to be removed in an outpatient procedure 5 weeks postoperatively owing to clip detachment and painful dislocation into the anal canal (Fig. 7, left). The other patient presented with recurrent wound-healing problems at the external drainage site, probably because of clip migration and mechanical skin irritation. The clip was removed through the external wound without re-opening the internal fistula site (Fig. 7, right).



Figure 7 Left: clip detachment and dislocation into the anal canal. Right: wound-healing problems at the external drainage site, probably as a result of clip migration. Clip removal through the external wound without re-opening the internal fistula site.

Persistence of the fistula occurred in two of the 20 patients. In one this was associated with early detachment of the clip on the third postoperative day. In the other patient fistula secretion persisted, so that the clip had to be removed and the fistula tract to be drained again with a seton.

No case of faecal incontinence was observed during the follow-up. In addition, there was no obvious clip-related damage to the sphincter, even in the two patients in whom the procedure failed.

Discussion

Over the last decade the endoscopic OTSC clip system has shown convincing results for the treatment of bleeding, perforation, anastomotic leakage and fistula formation in the gastrointestinal tract. Most recently, it has been used to close the gastric defect when transgastric access is used in performing natural orifice transluminal endoscopic surgery (NOTES). A meta-analysis of OTSC closure of gastrointestinal fistulae showed early success rates of 84.6% and 69.0% in the long term [2]. The clip is therefore an established and useful tool in interventional endoscopy.

The good clinical results of the endoscopic clip system led to its adaption for transanal closure of anal fistula: the OTSC Proctology. Current procedures for complex anorectal fistula, such as advancement flaps or fistulectomy with primary sphincter reconstruction, achieve healing rates of 70–80% at best and may be associated with disordered postoperative continence in up to 20–30% of patients [1].

To overcome the risk of incontinence, new, minimally invasive techniques have been developed with the aim of avoiding sphincter damage. Different approaches are used to close the fistula tract, including electro- or laser coagulation, as in video-assisted anal fistula therapy

(VAAFT) and fistula laser closure (FiLaC) [3,4], or surgical ligation, as in the ligation of intersphincteric fistula tract (LIFT) technique [5]. OTSC Proctology is a completely different approach in that it relies on dynamic compression and closure of the internal fistula opening after debridement of the tract. Sutures, as used in advancement flap techniques, may become loose or tear out, whereas the superelastic nitinol clip maintains permanent compression on the internal fistula opening.

The present study is the first to assess prospectively the efficacy of the OTSC Proctology system for anal fistula. The 6-month follow-up results in the 20 patients of the present study confirm those in our preliminary analysis of 10 patients, in which 90% were cured [6]. At 6 months the clip was still *in situ* in 13 patients and it produced no symptoms, with the clip usually becoming covered with a thin layer of fibrous tissue. As nitinol is biocompatible, the clip can be left in place as long as it remains problem-free, but if it becomes loose or painful, as it did in one patient, it can easily be removed. Even when it detached spontaneously there was no negative effect on healing of the fistula. It seems that clip compression of the internal opening for about one week is sufficient for healing.

Possible pain is obviously a cause for concern and for this reason a circular area of anoderm was removed around the internal fistula opening, so that the clip was placed directly on the internal sphincter muscle rather than on the sensitive skin. In addition, the curve of the clip was aligned to the contour of the anorectum to avoid putting pressure on the anorectal wall. As observed, these measures were sufficient to avoid severe pain after surgery.

Use of the OTSC Proctology is still ‘real’ fistula surgery and the basic rules of surgery apply. Although it is difficult to be certain, seton drainage and excision of the external opening to promote drainage may well be

important elements of the procedure. Similarly, oral bowel preparation, perioperative antibiotics and gradual introduction of a normal diet postoperatively may also be important, even though their role has not been assessed. The surgeon should be experienced in fistula surgery, so that if the clip is found intra-operatively not to be applicable, a suitable alternative procedure can be carried out.

There is a discussion of whether clinical criteria of healing are, on their own, sufficient to declare cure. Imaging can be valuable in demonstrating secondary tract formation, which is the cause of recurrence in 20–25% of cases [7]. It may also show any residual primary tract after surgery. In the present study, it was not possible to exclude secondary tract formation.

As the OTSC Proctology is still quite a new device on the market, a comprehensive assessment of this innovative surgical technique is not yet possible. Information on healing rates, for example, in Crohn's fistulae or in complicated recurrent fistulae are so far not available in a statistically relevant number of patients. Future studies with more patients, and with all types of anorectal fistula, are mandatory for further evaluation of the OTSC Proctology.

In conclusion, initial data of anorectal fistula closure using the OTSC Proctology is promising. It is a minimally invasive surgical technique without major intra- or postoperative complications. There is no significant trauma to the sphincter muscle, thereby avoiding postoperative incontinence. Clip closure does not lead to a negative affection on any further therapy even if the fistula closure fails. According to the experience gained so far, the clip procedure is associated with high patient satisfaction.

Conflicts of interest

Ruediger L. Prosst has advised Ovesco Endoscopy AG in regulatory affairs and product development.

The OTSC Proctology and its accessories in this clinical study were supplied courtesy of Ovesco Endoscopy AG. The authors did not receive any direct payments or gratifications.

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