

Short-term outcomes of a novel endoscopic clipping device for closure of the internal opening in 100 anorectal fistulas

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Abstract

Background One hundred consecutive applications of a new clipping device, the OTSC[®] Proctology (Ovesco Endoscopy AG), were analyzed to assess its efficacy for the treatment of complex anorectal fistulas.

Methods In patients with anorectal fistulas, minimally invasive surgery with the OTSC[®] Proctology system was performed according to a standardized technique: the fistula tract was debrided using a special fistula brush, and the clip was applied on the internal fistula opening. In some of the patients, postoperative pain was evaluated using a visual analog scale. After 6 months, the postoperative clinical course and the fistula healing were assessed.

Results A total of 100 OTSC[®] Proctology procedures were performed in 96 patients with 55 transsphincteric, 38 suprasphincteric, 2 extrasphincteric, and 5 rectovaginal fistulas. In all but 11 fistulas (8 Crohn's disease, 3 ulcerative colitis), the fistulas were of cryptoglandular origin. The median operation time was 32 min (range 17–66 min). There were no major intraoperative technical problems. All patients found the postoperative pain to be tolerable with standard pain medication. The short-term results of 99 clip applications were analyzed: the healing rate for first-line fistula therapy was 79 %, whereas in recurrent fistulas, the success rate was 26 %. OTSC[®] Proctology was successful in 45 % of fistulas associated with inflammatory bowel disease and in 20 % of rectovaginal fistulas.

Conclusions OTSC[®] Proctology provides convincing results as first-line treatment for complex cryptoglandular fistulas. It is a safe, effective, minimally invasive, and sphincter-sparing procedure with postoperative pain comparable to other types of fistula surgery.

Keywords Anorectal · Fistula · OTSC[®] Proctology · Clip · Nitinol

Introduction

Surgical treatment of complex anorectal fistulas is a difficult challenge, due to the high risk of recurrence and incontinence, depending on the type of fistula and the technique used. Over the last decade, various sphincter-preserving strategies have been developed, such as fistula plugs, fistula laser closure (FiLaC), and special endoscopic instruments (video-assisted anal fistula treatment (VAAFT)) [1–4]. However, there is no consensus as to what constitutes the best surgical treatment of anorectal fistulas. One of the latest surgical innovations, which has been clinically developed for transanal anorectal fistula closure, is the OTSC[®] Proctology (Ovesco Endoscopy AG, Tuebingen, Germany). It consists of a clip and a clip applicator (Fig. 1). The opened clip is made of a super-elastic shape memory alloy (nitinol) and returns to its originally closed shape after release from the applicator cap. If applied on the internal fistula opening, the clip exerts constant compression on the tissue between the jaws of the clip and closes the internal fistula opening. This facilitates healing of the fistula since stool and bacteria are prevented from entering the fistula tract. Initial clinical results and healing rates of OTSC[®] Proctology are very encouraging. In addition, it is a simple procedure with a

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

minimally invasive and sphincter-preserving approach [5]. We evaluated the first consecutive 100 OTSC[®] Proctology applications in two surgical centers, and to our knowledge, this is the largest series reported in the literature so far.

Materials and methods

To assess the short-term efficacy and safety of the OTSC[®] Proctology system in patients with complex anorectal fistulas, a retrospective analysis of surgical results of two high-volume fistula centers was performed. The procedures were performed by five experienced rectal surgeons who decided before and during surgery whether a patient was eligible for fistula clip closure. All types of fistulas (transsphincteric, suprasphincteric, extrasphincteric, and rectovaginal) of cryptoglandular origin or associated with CD/UC were treated, either as first-line therapy or due to fistula recurrence. All patients gave written informed consent to the surgical procedure and were treated with a standardized approach. Because of the retrospective analysis of data and the use of a CE-marked medical product, no study-specific requirements were necessary. Surgery and its evaluation were performed in accordance with ethical standards (Declaration of Helsinki).

In all patients, a seton was placed into the fistula tract at least 6 weeks before fistula closure. Any active inflammation or abscess was ruled out before surgery. Preoperatively oral bowel lavage was performed. In general, perioperative antibiotic single-shot prophylaxis was administered using a cephalosporin–metronidazole combination.

Surgery followed a standardized operative pathway [5]. It started with a circumferential excision of anoderm around the internal opening of the fistula to obtain a small area of exposed internal sphincter muscle. This was done to

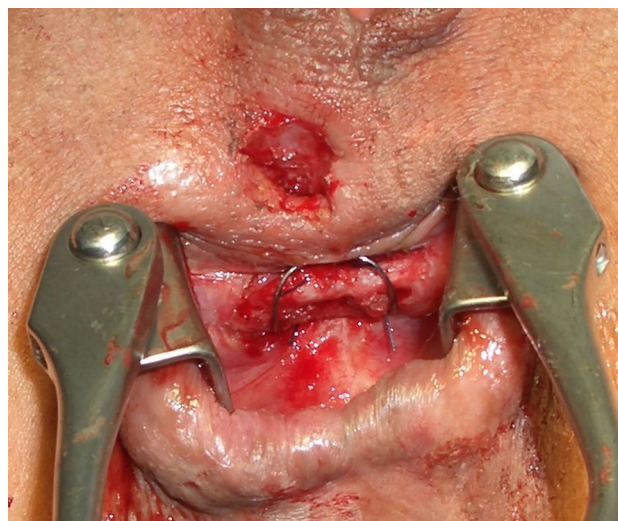


Fig. 2 Intraoperative view after clip application on the internal fistula opening. The external fistula opening has been excised to ensure adequate drainage

prevent pain due to application of the clip to the very sensitive anoderm. A special fistula brush was used to remove the granulation tissue and epithelium lining the fistula tract. The fistula was then intensively rinsed. With the aid of sutures, which were placed in a crosswise fashion through the internal fistula opening, the preloaded clip applicator was introduced transanally. The clip was then released from the applicator tip to achieve closure of the internal fistula opening. Finally, the external opening of the fistula was excised to ensure adequate drainage (Fig. 2).

In general, postoperative nutrition started with liquid diet the first day, which was followed by light and regular solid food on postoperative days 2 and 3, respectively. In some patients, postoperative pain was evaluated using a visual analog scale (VAS).

Postoperatively, regular clinical follow-ups were performed to verify fistula healing and clip position. Wounds and external and internal fistula openings were inspected. Secretion, swelling, and local inflammation were assessed, and pain was recorded.

Patients without clinical signs and symptoms of a fistula (including complete closure of the internal and external opening, no sign of any inflammation, no secretion) at follow-up 6 months after surgery were considered to be healed. There was no routine use of specific imaging diagnostics such as transanal ultrasound or magnetic resonance imaging.

Results

A total of 100 OTSC[®] Proctology procedures were performed in 96 patients: In 4 patients, the clip was applied twice. There were 64 male and 32 female patients with a

mean age of 50 years (range 20–80 years). Fifty-five transsphincteric, 38 suprasphincteric, 2 extrasphincteric, and 5 rectovaginal fistulas were treated. In all but 11 fistulas (8 CD, 3 UC), the fistulas were of cryptoglandular origin. In 73 cases, the clip was used as first-line therapy, whereas in 27 cases, OTSC[®] Proctology was applied in recurrent fistulas.

All operations were performed by five experienced colorectal surgeons over a period of almost 5 years (2011–2015) using the same surgical technique. The median operation time was 32 min (range 17–66 min). There were no major intraoperative technical problems regarding clip application. In 7 operations, clip application did not achieve adequate closure of the internal fistula opening. Therefore, the clip had to be removed by cutting the lateral hinges of the clip with a special OTSC[®] clip cutter allowing for atraumatic removal of the halved clip from the anorectum. Then, a new clip was applied.

In 10 of the last patients included in the analysis, postoperative pain was assessed using a visual analog scale (VAS) (0 = worst pain, 10 = least pain). The mean VAS score was 3 (range 0–4) on the evening of surgery, 2 (range 0–6) on postoperative day 1, 2 (range 0–8) on postoperative day 2, and 1 (range 0–2) on postoperative day 3. All patients, including the remaining 90 patients without VAS evaluation, found the postoperative pain was well controlled with standard pain medication (ibuprofen, paracetamol, or metamizole). Patients were discharged home on the third ($n = 7$) and fourth ($n = 3$) postoperative days.

After 18 procedures, the clip spontaneously detached too early between 3 days and 4 weeks postoperatively, leading to fistula persistence in 12 (67 %) of these cases. Recurrent fistulas were associated with a higher likelihood of early clip loss, since in 8 of these 18 procedures (44 %), recurrent fistulas were treated (vs. 27 % overall rate of recurrent fistulas in the analysis).

The results of 99 clip applications were analyzed, since 1 patient was lost to follow-up. On examination 6 months after surgery, 65 % of patients had no clinical signs or symptoms of their previous fistula and were considered healed. When the clip was used as first-line therapy, the healing rate was 79 %, whereas in recurrent fistulas the success rate was 26 %. The healing rates of transsphincteric, suprasphincteric, extrasphincteric, and rectovaginal fistulas were 61, 74, 100, and 20 %, respectively. In CD and UC, use of OTSC[®] Proctology was successful in 45 % of cases.

At follow-up 6 months after surgery, we attempted to assess whether the clip was still in place. The clip was clearly detectable in only 15 patients, as it was partly visible or palpable. However, these findings did not exclude spontaneous clip loss in all other cases, as scar

tissue covering the clip and its flat design may hinder its identification.

In 6 cases, the clip had to be removed due to failed fistula healing requiring further surgical treatment. In another 8 cases, the clip was explanted under short-acting general anesthesia despite fistula healing: in 1 case due to pain, in 2 cases because of clip dislocation into the anal canal, in 2 cases because of secretion and wound-healing problems, in 1 patient due to slight discomfort, and in another 2 cases at the patient's request without subjective and clinical problems. For this purpose, the clip was carefully freed from the covering mucosa and granulation tissue. The lateral hinges of the clip were cut with the special OTSC[®] clip cutter to allow removal of the clip.

Discussion

Anal fistulas usually develop as a result of chronic anorectal suppuration. In general, they are associated with secretion, hygienic problems, and pain, leading to impaired quality of life and work incapacity. The therapeutic management of fistulas is always surgical and has a twofold objective: eliminating suppuration while preserving sphincter function. Superficial fistulas, such as submucosal or intersphincteric fistulas, can be cured by simple excision of the fistula tract, a fistulectomy. High transsphincteric, extrasphincteric, or suprasphincteric are not suitable for removal as cutting would destroy the sphincter muscle, leading to fecal incontinence. To minimize the risk of intraoperative sphincter damage, new minimally invasive techniques have been developed in recent years, including the OTSC[®] Proctology clip device. It is derived from the endoscopic OTSC[®] system, which has proven to be a valuable tool in endoscopic interventions for hemostasis, for the closure of leaks, fistulas, and the transgastric access in natural orifice transluminal endoscopic surgery (NOTES) procedures [6–10]. The current literature reveals a mean success rate of clip treatment for leaks and fistulas of 76–84 % [7, 9, 10]. The principle of OTSC[®] Proctology for the treatment of anorectal fistula is the effective and durable closure of the internal fistula opening, while sufficient drainage via the external fistula opening allows healing of the fistula tract. In that respect, the principle of action is much like that of advancement flaps [11]. However, conventional sutures placed at the internal fistula opening allow a possible reopening of the fistula tract if the captured tissue changes after surgery, for example due to fibrotic shrinking. The super-elastic nitinol clip adapts to changes in the tissue and maintains constant compression on the internal fistula opening to achieve permanent closure.

Table 1 Studies on anal fistula closure using the OTSC[®] Proctology system

Authors	Number of patients and types of fistulas treated	Healing rate (follow-up)	Intraoperative technical problems	Postoperative pain	Major complications
Prosst et al. [5]	<i>n</i> = 20 cryptoglandular fistulas (no Crohn's disease, no rectovaginal, and no recurrent fistulas)	90 % (FU 6 months)	None	90 % none, 10 % slight anal discomfort	None
Mennigen et al. [11]	<i>n</i> = 10 cryptoglandular (40 %), Crohn's disease (60 %) (all recurrent fistulas, no rectovaginal fistulas)	70 % (median FU 230.5 days; range 156–523 days)	None	70 % none, 30 % slight anal discomfort and soiling	None
Gautier et al. [13]	<i>n</i> = 17 cryptoglandular (35 %), Crohn's disease (35 %), rectovaginal fistulas (41 %)	12 % (median FU 4 months; range 2–7 months)	None	35 % no or minimal pain, 29 % moderate pain, 35 % intense pain	76 % primary technical failure, 65 % clip migration, 53 % abscesses

FU follow-up

OTSC[®] Proctology was validated initially in a porcine model, ensuring efficacy and safety of this new device [12]. Thereafter, it was evaluated in a prospective, non-randomized, bicenter pilot study on 20 patients with transsphincteric and suprasphincteric fistulas [5] (Table 1). There were no intraoperative 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 2 the fistula persisted. In 13 (72 %) of these 18 patients, the clip was still in place without causing problems, whereas in 3 patients, the clip had spontaneously detached. In the 2 remaining patients, it was necessary to remove the clip due to discomfort and delayed wound healing.

A retrospective single-center study assessed 10 patients with refractory fistulas treated with OTSC[®] Proctology [11] (Table 1). The etiology of the fistulas was cryptoglandular in 4 patients and CD in 6 patients. The surgical procedure was successful in all patients. Reported postoperative pain was comparable to that experienced after other types of fistula surgery. Seven patients did not sense the presence of the clip, and 3 patients (30 %) had symptoms that were easy to tolerate, such as slight anal discomfort and soiling. Permanent fistula closure was achieved in 6 patients (70 %) within a median time of 72 days. There were 3 failures (30 %) due to spontaneous clip loss in 2 cryptoglandular and 1 fistula associated with CD.

In a French retrospective study on 17 patients, a very low healing rate of 12 % after clip surgery was found [13] (Table 1). Numerous postoperative complications were reported, such as early clip detachment in 65 % of the patients, primary technical failure with persistent discharge after surgery in 76 %, postoperative pain in 65 %, and abscesses in 53 %. However, the study suffers from a

number of relevant shortcomings [14]. The heterogeneous population of patients with 41 % rectovaginal fistulas and 35 % CD associated was not ideal to study the initial experience with this new device. Only 35 % of the patients suffered from typical cryptoglandular anal fistula, which should be the main indication for OTSC[®] Proctology. In addition, the high complication rate indicates that the clip was apparently not been properly placed during surgery or that the orifice may have been too large or anatomically unsuitable to be closed by clips. If primary closure is not achieved, infectious and inflammatory complications of the fistula are unavoidable. The study demonstrates that patient selection and experience are of major importance. Although clip surgery appears to be simple and fast, it should be restricted to experienced rectal surgeons who are familiar with all aspects of fistula surgery.

These new data on 100 clip procedures are, as far as we know, the largest collection of patients consecutively treated with OTSC[®] Proctology.

The transanal clip procedure was fast and easy to perform in experienced hands. In 93 % of procedures, the clip reliably closed the internal fistula opening already after the first application. Clip malplacement with inadequate fistula closure requiring clip removal and application of a new clip occurred in only 7 procedures.

With an overall healing rate of 65 % and a success rate of 79 % for first-line fistula treatment, the clip achieves results at least as good as established surgical techniques like the advancement flap procedure and the fistulectomy with primary sphincter reconstruction. Moreover, this is done without traumatizing the sphincter muscle and without the risk of fecal incontinence, even if surgery fails. When compared to another sphincter-preserving minimally invasive technique, the fistula plug, which renders a maximal healing rate of 50–60 %, OTSC[®] Proctology obviously achieves better results [1].

Our success rate of 26 % for recurrent fistulas was significantly lower than that reported in the previously mentioned study by Mennigen et al. [11], presumably due to the use of the clip as final salvage therapy in extremely complicated cases in which various prior procedures had failed.

In CD and UC fistula closure procedures, success rates are generally lower than in procedures treating cryptoglandular fistulas. Therefore, the healing rate of 45 % with OTSC[®] Proctology is meeting expectations. The healing rate of 20 % for rectovaginal fistulas suggests that the clip may not be the ideal treatment for these types of fistula. However, given the low number of cases treated ($n = 5$), further data are required to make recommendations.

One relevant risk factor for persistence of the fistula is early clip detachment. As seen in our analysis, clip loss within the first 4 weeks was associated with a persistence rate of 67 %. The earlier clip loss occurred, the more likely fistula healing was to fail. Surgery of recurrent fistulas was related to a higher likelihood of spontaneous clip detachment than operations on previously untreated fistulas.

Postoperative clip removal is a rare event; however, when required, a short procedure under anesthesia is needed. In our evaluation, clip removal was performed in 6 of 14 cases due to failed fistula healing during revisional surgery. In 6 of the remaining 8 cases, clip removal was necessary because of procedural problems, such as slight discomfort, secretion, wound-healing problems, clip dislocation, and pain despite fistula healing. Two patients requested clip removal although they did not have subjective or clinical problems.

It is not yet clear how to deal with the clip after successful healing of the fistula, as long-term data are limited. On the one hand, one might speculate that the clip could impair the anal sphincter in the long run and lead to foreign body problems. On the other hand, the clip is often buried under mucosa or scar tissue, and its removal might be traumatic or even reopen the fistula [11]. As nitinol is biocompatible material, the clips can be left in place as long as they remain flat in the surrounding tissue. In our opinion, there is no general need to remove the clip after a certain period of time. Only when the clip induces problems or if it is the patient's request, we explant the clip.

The compression maintained by the OTSC[®] Proctology clip raises critical questions and concerns about potential pain in the narrow anorectum with its highly sensitive anoderm. In our analysis, postoperative pain and pain medication did not exceed levels recorded after other fistula surgery. This can be explained by the design of the clip: The curved shape of the clip allows its alignment to the anorectum, and it lies flat within the mucosal surface without causing pressure on or damage to the opposite anorectal wall. Additionally, one step in the procedure is the excision of a circular area of anoderm

around the internal fistula opening to avoid placing the clip on the anoderm rather than on the internal sphincter muscle [5]. As assessed by the VAS in some patients, these measures are sufficient to avoid intolerable pain and discomfort after surgery. Complaints can be handled with intravenous and oral analgesics for a few days, allowing hospital discharge normally 3–4 days after surgery without appreciable pain.

The necessity of oral bowel preparation, perioperative antibiotics, and gradual introduction of a normal diet postoperatively after the clip procedure has not been assessed so far. Although there is no fundamental proof of a benefit, we routinely applied these precautions in order to minimize any procedure-related risk. Further experience with the clip technique will reveal whether these measures can be abandoned.

Conclusions

Analysis of these first consecutive 100 cases of anorectal fistula closure using the OTSC[®] Proctology system showed that the technique provides good short-term results as first-line treatment for complicated cryptoglandular fistulas. As it is a sphincter-sparing approach, it may even be superior to established but more invasive procedures. Due to the small number of patients with rectovaginal and IBD-associated fistulas, the potential of OTSC Proctology for these indications still has to be determined. Recurrent fistulas represent a challenge for the OTSC[®] Proctology procedure. OTSC[®] Proctology is a safe, effective, sphincter-sparing, and minimally invasive procedure with postoperative pain comparable to other types of fistula surgery.

Compliance with ethical standards

Conflict of interest Ruediger L. Prosst has advised Ovesco Endoscopy AG in regulatory affairs and product development. The author did not receive any direct payments or gratifications. Andreas K. Joos has no conflict of interest to declare.

Ethical approval Surgery and its evaluation were performed in accordance with ethical standards and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Because of the retrospective analysis of data and the use of a CE-marked medical product, no study-specific requirements (formal consent) were necessary.

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