ORIGINAL ARTICLE

The OTSC® Proctology clip system for anal fistula closure: First prospective clinical data

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Abstract

Introduction: Anorectal fistulas represent a troublesome condition for both patient and surgeon. The OTSC® Proctology clip system is a new device for transanal anorectal fistula closure. Material and methods: The OTSC® Proctology system was evaluated in a prospective clinical study undertaken in two surgical proctological centers. Ten patients (three women, seven men; median age 55 years, range 25-73 years) with nine transsphincteric and one suprasphincteric fistulas were enrolled into the study. Results: The median operation time was 30 minutes (range 20-45 minutes). There were no intraoperative technical or surgical complications. Postoperatively, no patient reported intolerable discomfort, immoderate pain or foreign body sensation in the anal region. At follow-up examination six months after surgery, nine out of ten patients had no clinical signs or symptoms of their previous fistula and were considered as healed (success rate 90%). In one patient persistency of the fistula was noted due to spontaneous early clip detachment on the third postoperative day. Discussion: These first data demonstrate the efficacy of the OTSC® Proctology system in the treatment of anal fistulas. Currently, more patients were enrolled into this prospective study to allow further evaluation of this new device and to assess its future role in relation to established surgical strategies for anorectal fistulas.

Key words: Anal fistula, OTSC, proctology, clip, Nitinol

Introduction

Anal fistulas remain an ongoing challenge to colorectal surgeons still leading to the development of new techniques and devices. Fistulas can be classified as simple or complex. Simple, superficial fistulas may be operated on safely with fistulotomy. However, in complex, high anal fistulas, fistulotomy is not an option because it will inevitably result in destruction of major parts of the sphincter with possible consecutive incontinence. In an attempt to identify safe and effective therapeutic strategies for complex anal fistulas, various sphincter-preserving techniques have been evaluated, including advancement flaps, fistulotomy with primary sphincter reconstruction, fistula plugs or fibrin glue injection. Unfortunately, some of these techniques result in significant morbidity, such as fecal incontinence or severe patient discomfort, whereas others have shown relatively high recurrence rates and partly disappointing long-term outcomes.

The OTSC® Proctology system (Ovesco Endoscopy AG, Tuebingen, Germany) is a new device for transanal anorectal fistula closure, which consists of a clip (Figure 1) and a clip applicator (Figure 2). The opened clip, which is made of a super-elastic shape memory alloy (Nitinol), re-takes its originally closed shape after release and thus exerts a constant compression on the tissue between the jaws of the clip. The system is a modification of the endoscopic OTSC® clip, which is widely used in flexible endoscopy. A special fistula brush can be used for debridement of the fistula tract and a tissue anchor device is an optional application aid for the OTSC® Proctology system (Figure 2).

The OTSC® Proctology system has been successfully applied clinically and in a pre-clinical trial (1,2). We report on the first data of a prospective study in which the OTSC® Proctology system was used as first-line surgical treatment for complex cryptoglandular anal fistulas.
Material and methods

This is a prospective, non-randomized and non-blinded clinical study undertaken in two surgical centers specialized in anorectal operations. The main goal of the study was to assess the feasibility and safety of the OTSC®/C210 proctology. Patients requiring surgery with the diagnosis of complex anal fistulas were evaluated for OTSC® proctology fistula closure. All patients eligible for participating in the study were fully informed about the study, which had been approved for a total of 20 patients by the ethics committee responsible for the two surgical centers.

All patients without exclusion criteria (inflammatory bowel disease, acute inflammation or abscess, more than one internal fistula opening, anorectal-vaginal fistula, or more than one previous fistula surgery) were entered into the study after written consent had been given.

In all patients a seton was placed into the fistula tract at least six weeks before fistula closure (Figure 3A). Preoperatively per-oral gut lavage was performed. Perioperative antibiotic single-shot prophylaxis was administered using a cephalosporin-metronidazole combination.

Surgery followed a standardized operative pathway: The patient was positioned in supine position under general or spinal anesthesia. 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 (Figures 3B and 4A). This was done to avoid that the clip would be applied on the very sensitive anoderm rather than on the stable sphincter. For fistula preparation the special fistula brush was used to remove all of the granulation tissue and epithelium lining the fistula tract (Figure 3C). Therefore the seton for drainage was attached to the lug of the brush for simplified insertion of the brush. After debridement of the fistula tract, it was rinsed with saline. The shaft of the brush was left in place to indicate the internal opening of the fistula. Two resorbable U-shaped sutures were placed through the sphincter muscle centering the internal opening of the fistula in a cross-like fashion (Figure 3D). The sutures were knotted at their distal end and pulled through the working channel of the clip applicator using the integrated thread retriever (Figure 3E). By holding the sutures under slight tension the preloaded clip applicator was advanced towards the internal opening of the fistula (Figure 3F). The applicator was aligned in parallel to the axis of the anal canal to achieve an anatomical orientation of the curved shaped clip within the captured tissue. The applicator cap with the preloaded clip was slightly pressed against the exposed sphincter muscle around the opening of the fistula while lifting the tissue with the sutures. 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 pushed from the applicator cap to close the internal opening of the fistula by the clip’s teeth penetrating the sphincter muscle and compressing the proximal fistula tract (Figure 4B). 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. Finally, the external opening of the fistula was slightly cored out by diathermy to accomplish sufficient drainage.

Postoperative nutrition started with liquid diet on the first day, which was followed by light and regular solid food on the second, respectively the third postoperative day.

Regular clinical follow-ups were performed at least one month, three months and six months after clip closure of the fistula. Patients without clinical signs and symptoms of a fistula (e.g. fistula opening, secretion, etc.) at the last follow-up six months after surgery were considered to be healed.

**Results**

Ten patients (three women and seven men of median age 55 years, range 25-73 years) with nine transsphincteric and one suprasphincteric fistulas were enrolled into the study so far. All operations were performed by three experienced rectal surgeons. The median operation time was 30 minutes (range 20-45 minutes). Intraoperative fistula preparation and clip application were achieved without surgical or technical problems. Only one clip was used per patient without inadvertent intraoperative malplacement of a clip. There were no major or minor intraoperative complications.

Postoperative pain and pain medication did not exceed levels comparable to ‘normal’ fistula surgery. Pain was subjectively localized to the external drainage wound rather than to the clip location at the

Figure 4. (A) Intraoperative situation with removed anoderm around the internal fistula opening which is marked by the seton; (B) final situation with the applied clip on the internal fistula opening.
sphincter muscle. Complaints could be handled with intravenous and oral analgesics for a few days. No patient reported an intolerable discomfort or foreign body sensation in the anal region. In one patient (female, 27 years old) the clip spontaneously detached at the third postoperative day for unknown reasons with subsequent persistency of the fistula. In all other patients the postoperative hospital stay remained uneventful without early clip detachment, bleeding or urinary retention.

At the last clinical follow-up six months after surgery nine out of ten patients had no clinical signs or symptoms of their previous fistula and were considered as healed (success rate 90%). In four patients (40%) the clip was still in situ without causing any problems. No unexpected side effects related to the clip, such as necrosis, ischemia or pressure ulcers, were noticed around its application site or at the opposite anorectal wall. In five patients (50%) the clip detached spontaneously ten days to four weeks after surgery. In one patient (female, 25 years-old) the clip had to be removed in an outpatient procedure five weeks postoperatively due to a clip detachment and painful dislocation into the anal canal.

No case of fecal incontinence was observed during the follow-up.

Discussion

The OTSC® clip system has become a valuable tool in interventional endoscopy for the treatment of bleedings, wall lesions, perforations, postoperative anastomotic leaks and fistulas in the gastrointestinal tract (3–7). A meta-analysis of clinical data about the OTSC® closure of GI fistulas revealed a high procedural success rate of 84.6% and a durable long-term clinical success rate of 69.0% (8).

Anorectal fistulas have represented a troublesome condition for both patient and surgeon throughout surgical history. The management of anorectal fistulas is a delicate balance between eradication of the fistula and preservation of fecal continence. On the one hand, technically demanding fistula techniques, such as the advancement flap or the fistulotomy with primary sphincter reconstruction demonstrate healing rates of up to 70-80%, but can be affected with incontinence rates of up to 20-30% (9). On the other hand, sphincter-sparing and simple techniques, such as the anal fistula plug, are associated with a low morbidity and a negligible incontinence rate, but with a low healing rate of about 30-55% (9). The exact reason for the overall unsatisfying healing rates of all established fistula techniques remains unknown so far. It can be hypothesized that the insufficient or incomplete closure of the internal fistula opening leads to the persistence of the fistula by continuous feeding of the tract with stool and fecal organisms. Sutures, which are meant for tight closure of the internal fistula opening e.g. during the flap procedure, may become loose as soon as the tissue shrinks or they tear out. As there is no re-tightening of knotted sutures, this static and therefore insufficient closure may contribute to the persistency of the fistula.

With a healing rate of 90%, our prospective study may justify further clinical application of the OTSC® clip for anorectal fistulas: In contrast to knotted threads, the Nitinol clip maintains a permanent compression on the internal fistula opening independently of the thickness of the captured tissue. Hence, the clip performs a dynamic closure of the internal fistula opening rather than a static and therefore potentially insufficient closure such as sutures.

During the development of the OTSC® Proctology system, one of the greatest concerns was the potential pain caused by the clip when applied at respectively close to the highly sensible anoderm in the narrow anorectum. Two precautions were taken to minimize this risk:

- A circular area of anoderm was removed around the internal fistula opening, so that the clip was placed directly on the sphincter muscle rather than getting into direct contact with the anoderm.
- The applied clip was aligned to the rounding of the anorectum, so that the curved shaped clip lay within the mucosal surface without protrusion and therefore without causing pressure or damage to the opposite anorectal wall.

These measures were sufficient to avoid intolerable pain and discomfort for all patients directly postoperatively and during the further healing process.

In our study half of the clips detached spontaneously ten days to four weeks after surgery. Obviously, clip compression of the internal opening for about one week seems to be sufficient for a definitive fistula healing. Early detachment of the clip, as seen in one case on the third postoperative day, leads inevitably to the persistency of the fistula. At the follow-up six months after surgery, four patients still had the clip in situ without complaining of symptoms. The clips were covered with a thin layer of scar tissue and hardly palpable. As Nitinol is a biocompatible material, the clips were left in place as long as they lay flat into the tissue. However, if the clip becomes loose and dislocates into the narrow anal canal, the twisted clip can cause sudden pain, which led to the immediate removal of the clip in one patient.
Conclusions

In conclusion, these data of the first prospective study using the OTSC® Proctology system for anal fistula closure confirm the minimally invasive and sphincter-sparing aspect of this surgical technique. The applied clip permanently closed the internal fistula opening allowing the fistula to heal in 90% of cases. Currently more patients were enrolled into this prospective study to allow further evaluation of OTSC® Proctology system and to assess its future role in relation to established surgical strategies for anorectal fistulas.

Declaration of interest: Rüdiger L. Prost is senior medical consultant of novineon CRO & Consulting Ltd. which advises Ovesco Endoscopy AG in regulatory affairs and product development. The OTSC® Proctology system 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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