

A new technique for sphincter-preserving anal fistula repair using a novel radial emitting laser probe

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Abstract Anal fistula repair still remains challenging. Up to 30% of fistulas persist after surgery despite many improvements in surgical skills and technique. One major reason for surgical failure is a persistent fistula track or remnants of the fistula epithelium which could not be removed during surgery. To overcome this problem, a novel technique was developed using a newly invented radial emitting laser probe (“FiLaCTM”, Biolitec, Germany) to destroy the fistula epithelium and to simultaneously obliterate the remaining fistula track. In a pilot study, we operated on 11 patients with cryptoglandular anal fistula. All patients underwent previous surgery up to 6 times prior to definitive surgery. In the primary operation, the initial abscess was drained, the internal opening of the fistula identified and seton drainage placed. During fistula repair, we used the flap technique for conventional closure of the internal opening. The remaining fistula track was cleaned mechanically, the laser inserted into the track and energy applied homogeneously at a wavelength of 1,470 nm and 13 watt. While providing continuous retraction of the probe, the remaining epithelium was destroyed and the fistula track obliterated. The median follow-up was 7.4 months. Nine out of 11 fistulas showed primary healing (81.8%). Only one minor form of incontinence (limited soiling) was

observed and no complications occurred. The use of a novel diode laser source and a radial emitting laser probe in addition to conventional surgery is a very promising new technique in sphincter-preserving anal fistula repair. The observed healing rate is high. Due to minimized trauma to the sphincter muscle, there are good short-term functional results without observable procedure-related complications.

Keywords Anal fistula · Repair · Sphincter-preserving · Laser

Introduction

Anal fistula repair still remains challenging. Persistent fistulas occur in up to 30% of cases following definitive surgery despite many improvements in surgical skills and technique [1]. Even new inventions such as the anal fistula plug or fibrin glue have not proven successful in the long-term [2, 3]. The main reasons for surgical failure are a missed and untreated internal opening, insufficient drainage of the intersphincteric space, missed side tracks and a persistent primary fistula track with remnants of fistula epithelium or granulating tissue [1, 4, 5]. For these reasons, complete excision of the fistula with subsequent repair of the sphincter muscle only has resulted in acceptable healing outcomes [6]. The main disadvantage of this procedure is incontinence due to failure of the sphincter repair in up to 20% of cases [6]. Therefore, a novel technique for sphincter-preserving surgery was developed. In addition to conventional anal fistula repair using the flap technique, our technique destroys the epithelial layer of the fistula with a newly invented radial emitting laser probe (“FiLaCTM”, Biolitec, Germany), which simultaneously obliterates the remaining fistula track.

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Materials and methods

In a pilot study, we operated on 11 (8 men, 3 women) patients. The median age was 51 years (range, 38–65 years). **Only cryptoglandular fistulas were analyzed and cases of inflammatory bowel disease-related fistulas were excluded from analysis.** Informed consent was provided by all patients. We treated two type 4, three type 3, five type 2 and 1 type 1 fistulas (Table 1) in accordance with the Parks' fistula classification [7]. All patients had undergone previous surgery due to a perianal abscess and fistula with a maximum of 6 prior surgeries prior to referral to our unit (mean \pm SD of 3.1 ± 1.6). Three dimensional endorectal ultrasound was routinely performed in all patients (B–K Medical, Copenhagen, DK).

In a primary operation, all patients underwent drainage of their perianal abscess, removal of possible side tracks, identification of the internal opening and seton drainage of the principal fistula track using a 2 mm silicone vessel loop. Prior to definitive fistula repair all patients had a mechanical bowel preparation (3 liters Oralav[®], B. Braun Melsungen AG, Germany). Patients received antibiotics (1 \times 2 g Cefuroxime, 3 \times 500 mg Metronidazole IV) for 5 days. Primarily, the outer and internal opening of the fistula was excised. Following this, an advancement flap was prepared where possible. If scarring prevented this, either a mucosal or an anodermal flap was used for closure of the internal opening (Table 1). Following this, the remaining fistula track was cleaned mechanically with a curette and washed with saline. The internal opening within the internal sphincter muscle was closed using a 2/0 Vicryl[®] suture, and the laser probe was inserted from the perineal opening (Fig. 1). By applying energy at 13 Watts, the fistula track was obliterated under continuous retraction of the laser which was withdrawn at a rate of 1 cm/3 s. Finally, a flap was constructed to cover the former site of the internal opening. Patients were allowed to eat and drink

liquids from day 1 to day 3. From that day on they were placed on a normal diet and were discharged by day 5 after clinical and proctoscopic examination.

Results

The median follow-up was 7.4 months (range, 2–11 months). Nine of the 11 fistula patients healed primarily (81.8%). One fistula persisted in a patient with a type 4 extrasphincteric fistula and in a second patient with a transsphincteric fistula following complicated drainage of a horseshoe abscess. Only one minor form of type 1–2 incontinence (soiling) was observed. This lasted for 6 months and was successfully treated by rubber band ligation of hypertrophic prolapsed mucosa. No major or minor complications were noted during follow-up.

Discussion

Over the years, many different surgical techniques have been devised for sphincter-preserving anal fistula repair. Many of these novel techniques do not result in sustainably successful long term outcome [1–3]. There are different reasons for fistula recurrence. Firstly, the internal opening is often cited as a principal cause for persistent/recurrent disease [6]. Secondly, the intersphincteric space is often not adequately drained and side tracks are frequently missed [1]. As a result, appropriate primary surgery has to be performed when patients present with perianal abscesses or persistent fistulas. Abscesses need to be completely evacuated, side tracks require excision, the intersphincteric space should be adequately drained, the internal opening identified and seton drainage placed. At our unit, we believe that seton drainage is a crucial part of the procedure if subsequent advancement anoplasty is planned, enabling

Table 1 Summary of all patients treated by the new procedure

Patient	Fistula type	Flap type	Healing	Follow up/months	Incontinence
1	2	Advancement	Yes	6	N
2	2	Advancement	Yes	8	N
3	1	Mucosa	Yes	8	N
4	3	Advancement	Yes	9	Soiling
5	2	Advancement	Yes	9	N
6	3	Anodermal	Yes	11	N
7	4	Advancement	Yes	11	N
8	4	Mucosa	No	11	N
9	2	Advancement	Yes	4	N
10	2	Anodermal	No	3	N
11	3	Anodermal	Yes	2	N

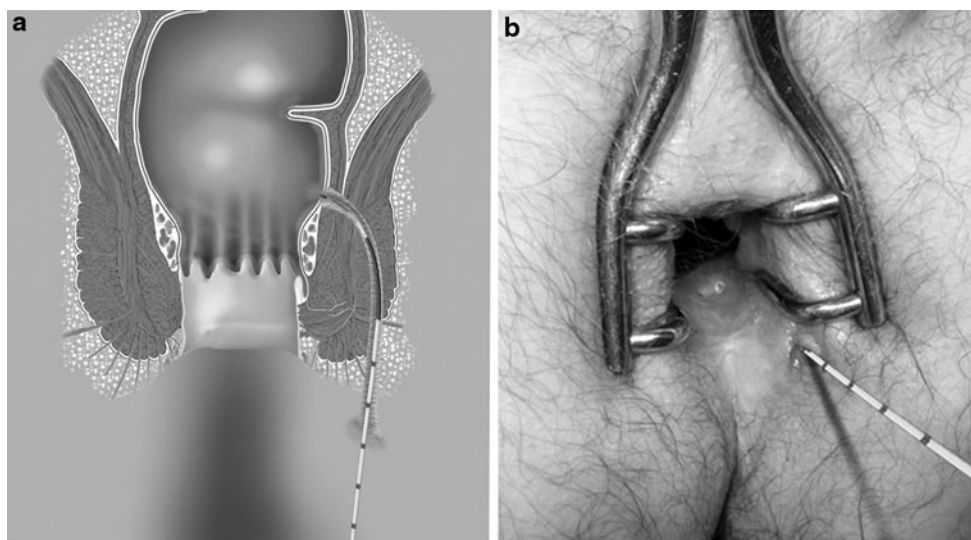


Fig. 1 **a** Schematic of the laser probe within a trans-sphincteric fistula track (Source: **a** presented with the permission of Biolitec AG, Germany). **b** Intra-operative picture of the laser probe in a trans-sphincteric fistula

continuous drainage of the fistula track to reduce local infection. If primary surgery is performed appropriately, the principal reason for recurrence or persistence of the fistula is the presence of epithelial remnants or granulation tissue [1, 5], and this is the main reason for the use of laser ablation reported in this study.

Until now, persistent residual epithelium has been removed either mechanically or destroyed chemically (most commonly with hydrogen peroxide) [2, 6]. The main disadvantage of these methods is a lack of control of their efficiency. To eliminate this problem, complete excision of the fistula track with subsequent repair of the sphincter muscle was performed where laser use results in minimal trauma to the sphincter muscle resulting in minimal trauma to the sphincter muscle with a reduced risk of developing

troublesome fecal incontinence [8]. In order to destroy the fistula epithelium and to minimize the trauma to the anal sphincter, we performed sphincter-preserving anal fistula repair using a newly invented radial emitting laser probe.

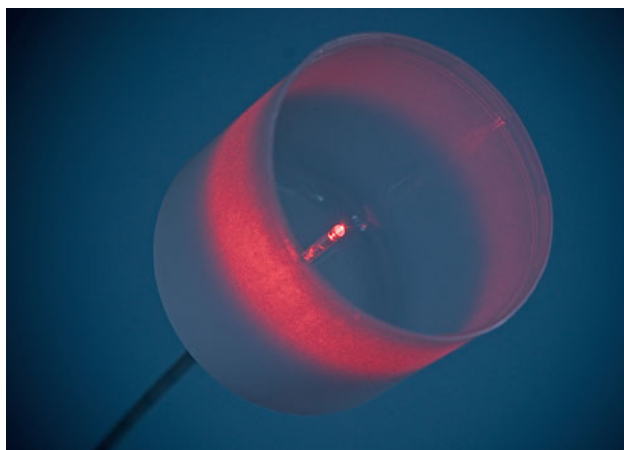
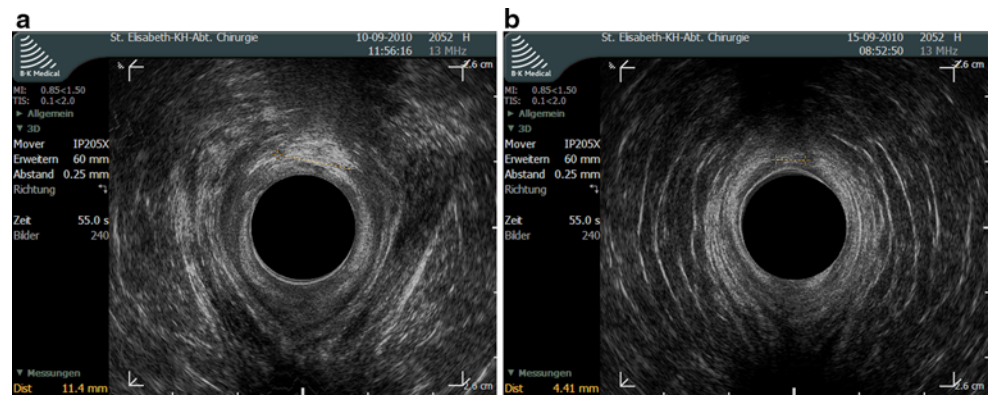


Fig. 2 The radial-emitting laser probe “FILAC™”. Source: presented with the permission of Biolitec AG, Germany



Fig. 3 Ex vivo studies demonstrate the limited penetration depth of the 1,470 nm diode laser within muscle tissue. Source: presented with the permission of Biolitec AG, Germany

Fig. 4 **a** Postoperative endorectal ultrasound of a laser-treated trans-sphincteric fistula. The hyperechogenic bands between the *cross-markers* show tissue alteration due to the applied energy. **b** The same patient as in **a** on day 5 postoperatively. The initial postoperative hyperechogenic area is hardly visible (*cross-hair markers*)



The “FiLaCTM” laser has only been designed recently. The fiber has a maximum diameter of 1.8 mm. In the past, diode lasers of 810, 940 and 980 nm were used linked to a bare end-firing fiber. Those lasers were mainly used in endovenous surgery. The main complications when used for varicose veins include vascular abrasion, vessel perforations and paresthesiae [8]. As a technical improvement, **a 1,470 nm diode laser was invented and combined with an innovative radial-tip fiber** [9]. The 1,470 nm wavelength has an optimal adsorption curve in water with a defined penetration depth limited to 2–3 mm. The homogeneous radial-emitted laser energy results in an improvement in the control of tissue radiation particularly when used intraluminally or in hollow organs (Fig. 2). With this novel laser technology, the complications seen in endovenous surgery as mentioned above have been essentially eliminated [9].

This new laser technology was approved for various surgical and endoscopic procedures including endovenous and hemorrhoidal treatment by German authorities and the Food and Drug Administration (FDA) (Declaration of Conformity at Ceram Optic GmbH, Bonn, Germany). **In preliminary ex vivo studies, we were able to verify the limited penetration depth in muscle and liver tissue and to define the appropriate energy for treatment (Fig. 3).** There are several advantages to using this new laser technology in anal fistula repair. **Firstly, the radial application of energy destroys remnants of fistula epithelium or granulation tissue in a predictable, reliable, circular manner. Secondly, the laser power shrinks surrounding tissue to obliterate the fistula track as occurs in blood vessels [8, 9]. These activities occur simultaneously. Thirdly, surgical trauma to the anal sphincter is diminished due to the low infiltration depth of laser energy. This effect on the sphincter muscle is reversible as shown by endorectal ultrasound (Fig. 4).** As a result, the incidence of persistent fistula appears to be low, and postoperative incontinence is likely to be diminished although larger and longer term studies are required. The relative lack of direct visualization of the fistula track is, however, a disadvantage necessitating this preliminary

study utilizing intraoperative ultrasound. A rather more sophisticated alternative would be to integrate a video camera into the laser probe. Intraoperative visualization of the fistula and possible side tracks was first achieved by Meinero [10] in his use of a fistula-scope (Karl Storz GmbH, Tuttlingen, Germany). In this technique of anal fistula repair, Meinero closed the inner opening of the fistula with a stapler and destroyed the fistula track with its remaining epithelium by electrocautery in what was described as a video-assisted anal fistula treatment (VA-AFT). This method along with our new minimally invasive technique of laser-assisted fistula surgery demonstrates that the basic prerequisite for anal fistula repair is similar.

In conclusion, anal fistula repair using a newly designed radial-emitting laser probe (FiLaCTM) in addition to conventional surgery with the flap technique is a very promising original procedure in sphincter-preserving anal fistula repair. The observed healing rates along with the results for postoperative continence are initially good without significant complications. In the future, as a result of our preliminary findings in this pilot study, it is our intention to incorporate other institutions into a multicentre study with standardized pre- and postoperative continence scoring for these complex recurrent anal fistulas.

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Conflict of interest The author does not have a financial relationship to Biolitec, Germany. He does have full control of all primary data and he agrees to allow the journal to review the data if requested.

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