Original article

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Closure of fistula-in-ano with laser – FiLaC™: an effective novel sphincter-saving procedure for complex disease

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Abstract

Aim Fistula laser closure (FiLaC™) is a novel sphincter-saving procedure for the treatment of anal fistula. Primary closure of the track is achieved using laser energy emitted by a radial fibre connected to a diode laser. The energy causes shrinkage of the tissue around the radial fibre with the aim being to close the track. This pilot study was designed to investigate the safety and effectiveness of this new technique in the treatment of anal fistula.

Method Thirty-five patients with anal fistula underwent the FiLaC™ procedure. They had either a primary or a recurrent trans-sphincteric anal fistula, a previously placed seton or a fistula involving a significant portion of the sphincter with a potential risk of postoperative incontinence on fistulotomy. The surgical procedure consisted of 'sealing' the fistula by laser energy. The primary end-point was cure of the disease and evaluation of morbidity. The secondary end-point was an assessment of the degree of postoperative continence using the Cleveland Clinic Florida (CCF) Fecal Incontinence Score.

Results The median operation time was 20 (6–35) min. No intra-operative complications were reported. Median duration of follow up was 20 (3–36) months. Primary healing was observed in 25 (71.4%) patients. There were eight (23%) failures and two recurrences at 3 and 6 months after the operation. No patient reported incontinence postoperatively.

Conclusion The laser FiLaC™ procedure for fistula-in-ano is a safe, relatively simple, minimally invasive, sphincter-saving procedure with a high chance of success.

Keywords Fistula-in-ano, FiLaC™ procedure, laser, sphincter-saving, minimally invasive

What does this paper add to the literature?

A novel procedure to treat complex anal fistula using a diode laser is described. It differs from previous laser procedures by not requiring closure of the internal opening by a surgical procedure such as endorectal flap repair. Success was achieved in 71.4% of patients, without any defect in continence.

Introduction

The use of laser in the treatment of anal fistula has recently been described in a pilot study [1]. Laser energy, emitted by a radial fibre into the fistula track, causes shrinkage of tissue and thus progressive sealing. The procedure includes closure of the internal opening by means of an endorectal flap. In the current study, a modified laser procedure was adopted, which consists of sealing the fistula track by laser with no need for an endorectal flap. This technique allows closure of the internal opening by a laser shrinkage effect. The primary aim of this study was to evaluate the safety and effectiveness of this modified laser procedure in patients with anal fistulae. A secondary end-point was the evaluation of pre- and postoperative continence.

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Method

Thirty-five patients with anal fistula, who were treated using the laser technique from November 2009 to January 2013, were identified from a prospectively maintained database. The aetiology was cryptoglandular in 33 patients and Crohn's disease-related in two patients.

The selection criteria for the laser technique were as follows: a mid or a high trans-sphincteric fistula; an anterior intersphincteric or a low trans-sphincteric fistula in a woman with preoperative low sphincter anal

tone and/or some degree of faecal incontinence; a fistula previously treated by seton placement; and a Crohn's-related fistula. Exclusion criteria included a superficial fistula that could be treated by fistulotomy without compromising anal sphincter function and any fistula related to malignancy. All patients gave informed consent to undergo the modified laser procedure and agreed to participate in regular follow-up assessments.

Data prospectively entered into the database included patient demographics, past surgical treatments, fistula type, previous fistula drainage and/or seton placement, preoperative Cleveland Clinic Florida Fecal Incontinence (CCF-FI) score [of 0 (perfect continence) to 20 (severe incontinence)] [2], operative time and intra- and postoperative morbidity.

Patient assessment

All patients were assessed preoperatively by digital examination, proctoscopy and endoanal ultrasound (H19 H1 Vision; Hitachi-Medical Systems Europe, Zurich, Switzerland; BK Medical System, Herlev, Denmark). Patients were preoperatively referred for pelvic MRI if they had a recurrent fistula, potentially high secondary multiple tracks or abscess formation. Intraoperative endoanal ultrasound was performed in most cases to confirm closure of the fistula track at the completion of the laser treatment.

Anal manometry was used in patients with preoperative symptoms of a continence disturbance or with low anal tone on digital examination. In cases of postoperative discomfort and/or sporadic anal discharge despite apparent successful closure of the external opening, patients were assessed by endorectal ultrasound and/or MRI to exclude recurrence.

Surgical technique

All patients were administered preoperative short-term antibiotic prophylaxis (1 g of Cefazolin and 500 mg of metronidazole intravenously). Epidural anaesthesia was used in 32 patients, general anaesthesia in two and local anaesthesia in one. The patient was placed in the lithotomy position. Anal examination was performed and a Parks' anal retractor was inserted. The external opening was injected with methylene blue or hydrogen peroxide to visualize and locate the internal opening. A guide-wire was inserted into the fistula track. The fistula track was either gently rubbed using the guide wire or debrided with a curette. Particular care was taken to avoid widening the fistula track during debridement. It was then gently irrigated with saline. A plastic hollow 14F catheter was inserted into the fistula track using the guide-wire. A 400-μm radial-emitting disposable laser fibre was then inserted into the 14F catheter with its tip emerging at the internal orifice, ready to be activated (Figs. 1 and 2). The fibre delivered laser energy homogeneously at 360°, and, by applying continuous laser energy, the fistula track was closed whilst withdrawing the fibre at a speed of 1 mm/s. Patients who had a loose seton inserted had a more expeditious procedure as the seton facilitated localization of the fistula and introduction of the laser fibre into the track.

For the first eight patients of our series, a diode laser (biolitec AG, Jena, Germany), delivering energy at 980 nm, was employed as it was readily available in our institution for use in another, unrelated, procedure. At this wavelength, a power of 13 W was necessary to seal the fistula track. In the remaining 27 patients, a diode laser at 1470 nm (biolitec AG) was used. In this case, laser energy of 10 W was sufficient to seal the fistula track. Diode laser energy at both wavelengths causes coagulation and shrinkage of the fistula track around the radial emitting laser fibre by interacting with water and blood. In addition, complete sterilization of the fistula track is achieved. A wavelength of 1470 nm allows the fistula to shrink with the use of less power, thus reducing the potential for thermal damage of the tissue around the fistula track (Fig. 3a,b). A wavelength of 980 nm has a better coagulating effect.

The external fistula opening was dissected off the external sphincter muscle in only five patients in our series. In the remaining patients no dissection was deemed necessary. All patients were admitted

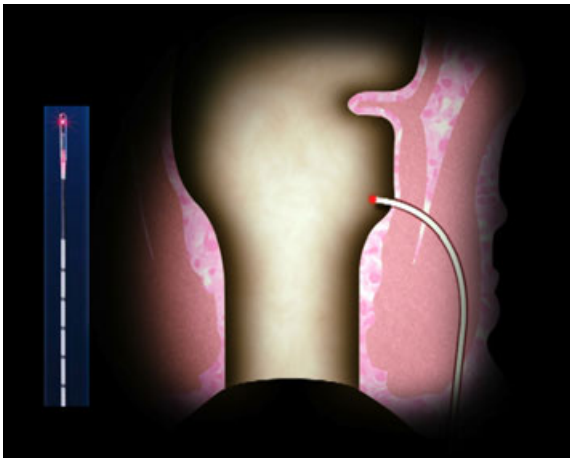

Figure 1 The radial-tip laser fibre and a diagram showing its tip emerging at the internal orifice.

Figure 2 Entry of the laser fibre into the fistula track and emergence at the internal orifice in the anal canal.

overnight and were discharged the day after the operation.

Follow up

Follow up was scheduled in the outpatient clinic at 1 and 2 weeks and 1, 3, 6 and 12 months postoperatively. However, patients were instructed to return to the outpatient clinic at any time should symptoms recur. Follow up of longer than 12 months was conducted by telephone interview. Postoperative clinical evaluation included physical examination and proctoscopy. The CCF-FI score and the visual analogue scale (VAS) score (to assess pain) were recorded at each visit. Patients with discomfort and/or sporadic anal discharge, despite the apparent closure of the external opening, were also assessed using endorectal ultrasound and/or MRI in order to exclude recurrence. The patient was considered as cured on closure of the external opening in the absence of drainage, pain or perianal swelling. Patients were deemed to have failed treatment if there was no evidence of closure of the external opening at the 3-month follow up. During evaluation of the results, specific focus was given to patients with a follow up of at least 12 months ($n = 25$; 71%). The overall median duration of follow up was 20 (3–36) months.

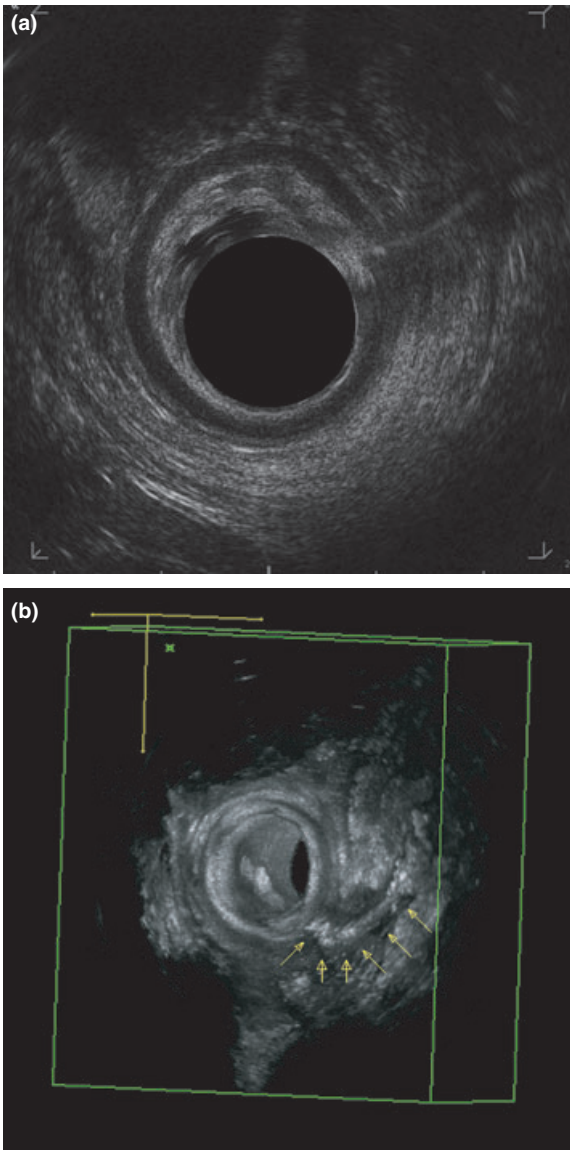

Figure 3 (a) Intra-operative endoanal ultrasound showing a transphincteric fistula (with guide wire) before laser treatment. (b) Intra-operative three-dimensional endoanal ultrasound at completion of laser treatment, showing the newly formed hyperechoic tissue in the former fistula track.

Statistical analysis

The Student's *t*-test was used for statistical analysis of pre- and postoperative CCF-FI scores.

Results

Thirty-five patients were treated with the modified FiLaC™ procedure (Table 1). Fistula tracks were primarily sealed by laser energy with no additional procedures. The median time from the onset of symptoms to

Table 1 Patient and fistula characteristics of patients undergoing the FiLaC™ procedure.

Number of patients	35
Gender (M:F)	20:15
Age (years)	48 (27–76)
Type of fistula	
Intersphincteric	8 (23)
Low trans-sphincteric	8 (23)
Mid	12 (34)
High	6 (17)
Suprasphincteric	1 (3)
Multiple fistulous tracks	3
Previous fistula surgery	25
Previous draining (loose) seton	16
Operative time (min)	20 (6–35)

Values are given as *n*, *n* (%) or median (range).
F, female; M, male.

surgery was 13 (6–96) months. Twenty-five (71%) patients were treated for a recurrent fistula. In the 16 patients with a previously placed loose (draining) seton, the median time between seton placement and the FiLaC™ was 12.5 (6–28) weeks. The median fistula track length was 3.5 (1.5–6) cm. Three patients had secondary tracks: two were treated by lay open and the third was treated by a fistulectomy.

There were no intra-operative complications. Eight patients experienced postoperative discomfort and pain (mainly because of anismus and temporary constipation), which were treated with minor analgesics.

No patient was lost to follow up. Table 2 shows the morbidity reported during the 12-month follow-up period. No stenosis was observed. Higher pain scores and anismus were reported by a significant proportion of the patients treated with the 980-nm diode laser.

The mean ± SD preoperative CCF-FI score was 2.9 ± 2.5 and the mean ± SD postoperative CCF-FI score was 3.1 ± 2.8; no patient reported any relevant subjective change in continence ($P = 0.86$; Student's *t*-test).

Twenty-five (71%) of the 35 patients completed the 12-month follow-up. Of these, 18 (72%) were considered to be cured. The overall success rate at a median follow-up of 20 (3–36) months was 71.4% (25/35) patients (Table 3). Two recurrences were reported at 3 and 6 months after the operation, both of which were successfully treated by a lay-open procedure. In the eight patients whose procedure was considered to have failed, discomfort and discharge from the original external orifice did not resolve postoperatively. Five patients were treated with an endoanal mucosal flap and three are currently waiting for another laser therapy procedure after having a new seton inserted.

Table 2 Morbidity among 35 patients treated using the FiLaC™ procedure.

Symptom	*n* (%)
Urinary retention	2 (5.8)
Bleeding	1 (2.8)
Pain (VAS score of < 5 for more than 7 days)	4 (11.4)
Pain (VAS score of > 5 for more than 7 days)	4 (11.4)*
Anismus (7 days)	6 (17.1)†

*Three patients were treated with a 980-nm diode laser.
†Five patients were treated with a 980-nm diode laser.
VAS, visual analogue scale.

Discussion

The FiLaC™ method is a modification of the laser procedure previously described by Wilhelm in a small case series of 11 patients [1]. In Wilhelm's procedure, closure of the internal orifice was performed with an advancement flap before laser treatment of the fistula track. Our modification is based on the assumption that the internal anal opening can be completely and safely sealed by laser energy, obviating the need for the advancement flap, which prolongs operative time, may increase overall morbidity (including impaired continence) and may affect the final success rates. The FiLaC™ operation has been used in patients with a high trans-sphincteric fistula, in patients with a preoperative low sphincter tone and in those who are at high risk of faecal incontinence. Its indications also include recurrent fistulae previously treated by other procedures.

The optimal shrinkage effect obtained with a radial-tip fibre is confined to the lumen of the fistula, with a radial penetration depth of 2–3 mm beyond the fistula track. The 1470-nm wavelength is considered to be more efficient in eliciting the shrinkage and denaturing effect and has an optimal absorption curve in water. The laser energy emitted by the radial-tip fibre into the fistula track destroys the endoluminal granulation tissue and the epithelial wall of the fistula track. Simple diathermy cannot achieve the same goal because it

Table 3 Results of the FiLaC™ procedure at a median follow up of 20 (range, 3–36) months.

Results	*n* (%)
Cured	25 (71.4)
Failed	8 (22.8)
Recurrence	2 (5.8)

would not elicit the shrinkage effect on tissue and is less easily to control than a laser, especially in regulating the thermal damage on normal sphincter muscle. The shrinkage effect of a laser on the lumen of the track and on a small portion of the surrounding tissue is similar to that described in the treatment of varicose veins [3,4]. The surgical trauma is very low and the hyperthermic effect is considered minimal and reversible.

Higher pain scores and anismus were reported by a significant proportion of the patients treated with the 980-nm diode laser in the first part of our experience. This may be a result of the use of higher laser-energy volumes to elicit successful sealing of fistulae tracks with a consequently higher hyperthermic effect on normal sphincter surrounding the tracks. For this reason we consider that the routine use of a 1470-nm diode laser for FiLaC™ is preferable to the use of a 980-nm diode laser. As the FiLaC™ is a 'blind' procedure, small secondary tracks may be difficult to detect intra-operatively. This can be considered a disadvantage of the procedure as it may cause recurrence.

The use of a draining seton may stimulate growth of a new epithelial 'lining' of the fistula track. It may also help to create a more homogeneous calibre of fistula along its entire length. This seems to be very helpful as the shrinkage effect caused by laser energy can be more uniformly distributed along the fistula track. In addition, it may contribute to closure of secondary tracks before laser surgery. This might be the reason why complete and successful shrinkage of the fistula track seems to be more easily achieved in patients who were previously treated with a seton (13/16; 81%) than in those undergoing FiLaC™ as primary treatment (12/19; 63%). Although this observation is promising, the small number of patients in our study do not allow for any meaningful conclusions in this respect.

Follow up after 12 months was conducted by telephone interview. This may be considered a weakness of the study. However, patients were re-evaluated if any symptom suspicious of recurrence was reported. The vast majority of patients considered as cured showed no sign of discharge from the external orifice within 6 weeks following the procedure.

Eight patients were considered to have failed. We were not able to pinpoint any reasons for this. FiLaC™ may therefore have a further disadvantage of not allowing modification of the technique or better patient selection, to avoid further failure. Intra-operative endoanal ultrasound remains the best method to confirm closure of the fistula by showing the newly formed hyperechoic tissue sealing the fistula track. Postoperative injection of liquid into the external orifice is discouraged as it may destroy the newly formed semisolid tissue in the fistula track.

Randomized trials comparing FiLaC™ with other sphincter-saving procedures available to manage complex fistulae, such as ligation of intersphincteric fistula track (LIFT) [5–9], fistula plugs [10] or advancement flaps [11], are clearly needed as there is still no consensus on the correct approach to treat complex anal fistula. A treatment suitable for one patient may not be so for another [12,13]. Theoretically, FiLaC™ should have a shorter learning curve, a shorter operative time and less postoperative discharge compared with LIFT or endorectal flap formation.

In terms of cost, FiLaC™ requires more expensive equipment compared with other sphincter-saving procedures, but the diode laser platform, despite its high cost, is easily transportable and has several other applications in surgery, such as the treatment of varicose veins. The machine can therefore be shared by different specialists in one institution, thus reducing overall costs. It is noteworthy that although disposable radial laser fibres are moderately costly, they are less expensive than most fistula plugs.

The modified FiLaC™ procedure is a safe treatment for anal fistula and does not require additional surgical closure of the internal orifice. We report an acceptable success rate and low morbidity. As a result of its sphincter-sparing nature and subsequent preservation of continence, this procedure should be encouraged as part of the treatment options for anal complex fistulae, especially in patients with weak sphincters who may potentially develop faecal incontinence. Preplacement of a loose seton into the fistula track facilitates the FiLaC™ procedure and may have favourable effects on healing. Despite the favourable findings in our pilot study, larger series and multicentre randomized trials are needed to confirm these results.

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Author contributions

Paolo Giamundo: study conception and design of the study, writing the paper, patient recruitment, analysis of data. Maria Geraci and Livio Tibaldi: patient recruitment and follow-up, acquisition of data, critical review of the paper and approval of the final version. Marco

Valente: patient recruitment, critical review of the paper and approval of the final version.

Conflict of interests

Paolo Giamundo: surgical trainer for BIOLITEC-Italia, Maria Geraci, MD: no disclosures, Livio Tibaldi: no disclosures, Marco Valente: no disclosures.

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