

Laser fistula surgery [FiLaC]: When and how?

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ABSTRACT

Anorectal fistula repair is still one of the most challenging conditions treated by surgeons. Despite modern advances in surgical care, failure rate of surgical treatment exceeds 30%. One of the challenges that surgery cannot properly address is the obliteration of the fistula tract epithelium. Another challenge is the treatment of high fistulas which involve significant portion of the anal sphincter muscles. Unfortunately, surgical treatment of these fistulas may cause long term anal incontinence in some of the patients. Fistula-tract Laser Closure (FiLaC™, Biolitec AG, Jena, Germany) was developed to overcome these issues, by using a radially energy emitting laser probe that obliterate the epithelial tract while closing the defect without causing any damage to the sphincters. Up to date, 11 studies have been published with promising results. In this review, we will be evaluating the indications, the technical steps, short and long-term results of laser fistula surgery.

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Introduction

The description and the first treatment of anorectal fistula can be traced back to Ancient Greece.¹ Although thousands of years of experience have introduced various treatment options, the management of complex or recurrent fistulas remains very challenging. Superficial tracts that do not compromise anal sphincters can be treated with fistulotomy or fistulectomy reserving draining setons for specific patients such as those with inflammatory bowel disease. However, non-sphincter preserving options that involve division of the anal musculature may not be appropriate for high fistulas due to the risk of fecal incontinence.² To overcome the risks and avoid the complications of sphincter division, sphincter preserving techniques such as anal fistula plug, fibrin glue injection, the intersphincteric fistula tract ligation (LIFT), and the video-assisted anal fistula treatment (VAAFT) have been developed and advocated for anal fistula treatment.^{3–5} One of these new sphincter preserving techniques is the Fistula-tract Laser Closure (FiLaC™, Biolitec AG, Jena, Germany).⁶ The procedure uses laser technology to obliterate the epithelial layer of the fistula tract by using a radially emitting laser without damaging the sphincter. Although laser technology has been previously described for the treatment of fistulas, the probes used emitted only linear energy which could not be effectively used in anal fistula tracts that are circumferential in nature.^{3,4}

Indications for laser fistula surgery

Laser surgery can be utilized in the treatment of superficial, recurrent, branching, or multiple fistulas (Fig. 1). Although there is not enough evidence for favoring this procedure in certain subtypes of fistulas according to the Park's Classification, high transsphincteric and suprasphincteric subtypes would theoretically benefit the most from laser surgery therapy compared to conventional therapies due to the advantage sphincter preservation.⁹ Patients with abscesses that are associated with fistulas should be refrained from this therapy and require drainage and curettage of abscess with placement of a draining seton first to allow for gradual healing of the abscess and conversion to a tract without cavity. Fistulas associated with inflammatory bowel diseases (IBD) and previously treated with surgery are not a contraindication to laser surgery. Although data is very limited, similar primary healing rates can be achieved in both patient groups especially in patients with IBD whose disease activity is controlled with medical therapy.

Equipment and methods

The FiLaC™ Fistula kit (Biolitec AG, Jena, Germany) contains a disposable laser probe which receives a laser beam from an energy generator (Fig. 2). The treatment is delivered with the 15-watt laser emitting diode (1470 nm wavelength) at a 100–120 J/cm energy level (Fig. 3). All patients are preoperatively assessed with physical examination and in select cases imaging evaluation with 3-D endoanal ultrasound or magnetic resonance imaging. The operation is performed under general anesthesia. Evacuation of the rectal content is achieved with 1 or 2 enemas performed the evening prior to or the

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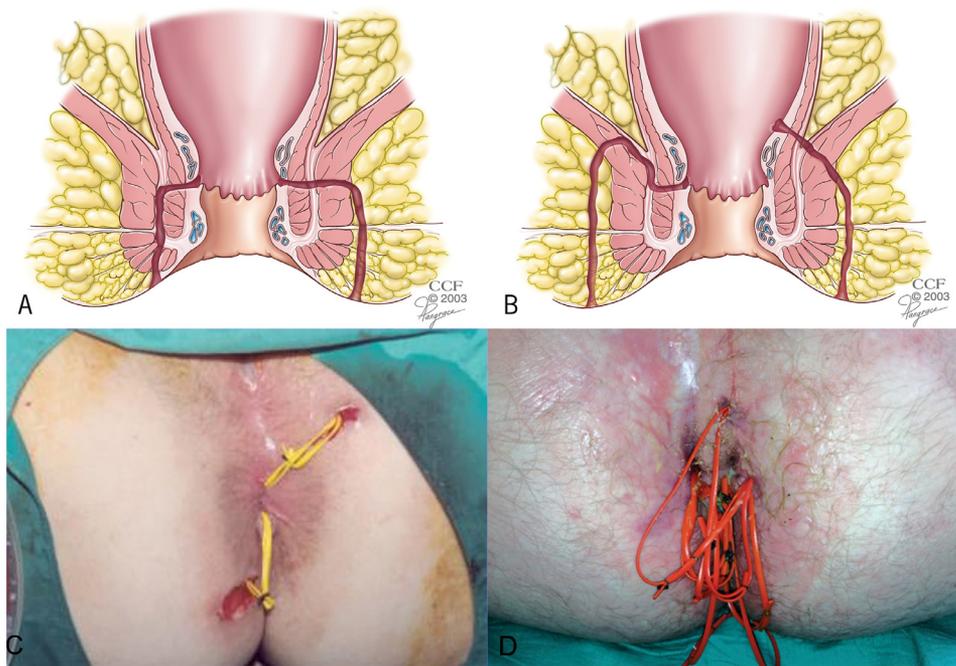


Fig. 1. (A) Intersphincteric and transsphincteric fistulas. (B) Suprasphincteric and extrasphincteric fistulas. (C) Anterior and posterior fistulas. (D) Complex multiple fistulas.

morning of surgery. After the identification and exploration of the fistula tract through the external opening, it is curetted with a cytologic brush. The probe is advanced from the external opening towards the internal opening until visualized inside the anal canal. The probe's tip is positioned 1–2 mm beyond the internal opening. The energy source is activated, and the probe is slowly pulled back at the speed of 10 mm / 5 s (Fig. 4). The probe can be pushed forward periodically to retreat the tract in order to ensure adequate tract sealing. Because of the probe radial energy emitting capabilities, penetration and over-burning of deeper tissues can be avoided. The internal opening can be left open or closed transanally with a figure of 8 Vicryl suture. The external fistula opening is left open to drain. Patients are sent home on the day of the operation, prescribed stool softeners for 2 weeks and typically follow-up at 3-week intervals.

Current short and long-term results

A search of the existing English literature was performed using PubMed, Cochrane, Embase, and Ovid databases. The keywords used for this search included anal fistula, sphincter preserving, laser, FiLaC™. The first laser perianal fistula treatment attempt was described in dogs by Ellison and colleagues who reported 80% primary success rate.³ The use of CO₂ laser ablation in the treatment of patients with complex fistulas was reported in 1988.⁴ Four out of seven patients (57.1%) experienced healing. Later on, the same group published their results of 27 patients with Crohn's Disease.⁵ These patients underwent multiple operations. At the first post-operative visit, complete healing rate was 15% and at their final visit the rate was 41%. The mean follow-up was 19.1 ± 18.1 months. According to their findings, healing rate was not

affected by presence of abscess at the time of surgery, number of openings or other demographic variables.⁵ These initial studies were performed using the older generation of laser probes which delivered the laser energy in a linear fashion. The first use of a radial energy emitting fistula probe, FiLaC™ (Biolitec AG, Jena, Germany) was reported by Wilhelm et al. in 2011.⁶ Although, FiLaC™ was the first commercially available radial energy emitting laser product for the treatment of anorectal fistulas, similar line of products has been introduced by other companies (neoVLaser™ and CORONA™ Fistula Probe, Caesarea, Israel; LASEmaR 1500™, HF Ring Fibers™, Eufoton, Italy).

In addition to the described technique above, Wilhelm et al's procedure also included closure of internal opening with an anorectal flap. In this study, eleven patients with cryptoglandular lesions were treated with an overall primary healing rate of 81.8% and median follow-up of 7.4 months.⁶

The laser procedure for anal fistula was modified by Giamundo et al. as they only used coagulation power of laser device to seal to internal opening instead of using flaps as performed by Wilhelm et al.^{6,7} In their first study, Giamundo et al. performed FiLaC™ in 35 patients with the



Fig. 2. Laser Probe (Biolitec™, reprinted with permission from the manufacturer).



Fig. 3. Laser LEONARDO® DUAL 45 with fiber (Biolitec™, reprinted with permission from the manufacturer).

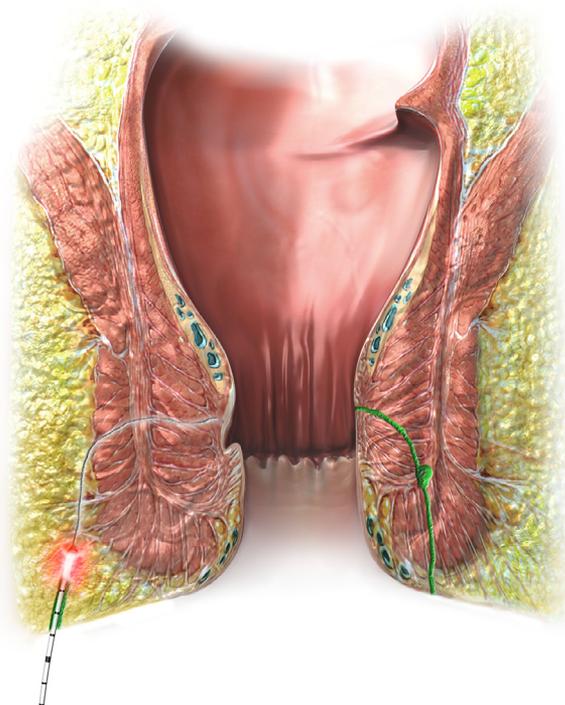


Fig. 4. FiLaC™ illustration (reprinted with permission from the manufacturer).

majority of their fistula related to cryptoglandular disease. During a median follow-up of 20 months, the success rate was 71.4%. For the first 8 patients they used a laser with a wavelength of 980 nm which required 13 W power to seal the tract. For the rest of the patients, they used a laser with a wavelength of 1470 nm with 10 W power. Although no major complication was reported in their study, 8 patients treated with the 980 nm wavelength laser experienced postoperative pain and anismus. They postulated that the use of higher wave length laser with lower power (10 W) settings can provide better post-operative results compared to 980 nm laser with 13 W power.⁷

A subsequent report from the same group included 45 patients with longer follow-up (median of 30 months) and demonstrated similar primary healing rate (71.1%).⁸ Their technical modification of the procedure challenged the belief that closure of internal opening with an anodermal/mucosal flap or mucosal advancement flap, was a

critical step to achieving success in the treatment of anal fistula. Ozturk et al. utilized a thin sterile plastic brush to curette the interior of the fistula tract before inserting the probe.⁹ With the addition of tract curettage, they achieved a primary healing rate of 82% with 12 months of median follow-up, in 50 patients with mostly trans-sphincteric fistulas.

The most important issue that should be addressed in the management of anorectal fistula is the obliteration of the tract. Although various attempts have been tried to promote spontaneous healing by filling the tract with fibrin or collagen glue,^{10,11} a collagen matrix plug, and adipocyte derived mesenchymal stem cells, the results of such options have been inconsistent with a wide variation in short-term healing rate ranging from 40 to 70%.^{14–16} To date there has been no comparison studies between these techniques and the FiLaC™ which histopathologic effect consists of tissue repair by recruiting fibroblasts and macrophages to the inflamed eschar zone formed by radial laser emitting probe.⁶

Out of 11 original publications, only 2 studies reported more than 100 patients. Wilhelm et al. studied 104 patients with anal fistula secondary to cryptoglandular disease and 13 patients with Crohn's disease.¹² (Table 1) In Wilhelm et al's study, the majority of the patients had undergone abscess drainage and prior fistula operations (mean 2.4 ± 1.7). The primary overall healing rate was 64.1%. The breakdown of primary healing rates according to the Park Classification are 100% in group I ($n=8$), 61.1% in group II ($n=90$), 61.5% in group III ($n=13$), and 66.7% in group IV ($n=6$).¹³ Patients with Crohn's disease had a healing rate of 69.2% compared to 63.5% in patients without Crohn's disease. Patients with non-healing of the fistula tract underwent a second FiLaC™ treatment. The secondary healing rate was reported as 88.0% without a significant difference between the cryptoglandular and Crohn's disease groups.

The patient's gender did not have any effect on the primary and secondary healing rates. No major complication occurred during a median follow-up period of 25.4 months. Seven patients (5.9%) reported minor soiling, 5 patients had additional advancement flap surgery due to incomplete closure of internal opening. Five patients required band ligation for coincidental mucosal prolapse. Only 1 patient developed late abscess (0.8%). In patients who had a failed first attempt of FiLaC™ (42 patients), half of them had distalization of primary tract from high to low fistula (21/42). It is interesting to note that all of their patients underwent FiLaC™ with closure of the internal opening by either mucosal or anodermal flaps, mucosal advancement flaps or suture closure on case-by-case basis.

Table 1
Original Studies Involving Laser Surgery Treatment of Fistula (FiLaC™).

Reference	Number of Patients	Gender (women/men)	Fistula types*	Etiology	Primary Healing Rate	Median follow-up (in months)	Major Complications	Type of study
Wilhelm et al., 2017 ¹²	117	35/82	I-8; II-90; III-13; IV-6	Cryptoglandular-104 IBD-13	64.1%	25.4	1-late abscess	Retrospective Cohort Study
Terzi et al., 2018 ¹⁴	103	21/82	I-56; II-29; III, IV-11; s-7	Cryptoglandular	40%	28.3	0	Retrospective Cohort Study
Ozturk et al., 2014 ⁹	50	13/37	I-10; II-40	Cryptoglandular	82%	12	0	Retrospective Cohort Study
Giamundo et al., 2015 ⁸	45	24/21	I-7; II-36; III-2	Cryptoglandular-43 IBD-2	71.1%	30	0	Retrospective Cohort Study
Giamundo et al., 2014 ⁷	35	15/20	I-8; II-26; III-1	Cryptoglandular-33 IBD-2	71.4%	20	0	Retrospective Cohort Study
Lauretta et al., 2018 ¹⁵	30	14/16	II-30	NR	33.3%	11.3	0	Retrospective Cohort Study
Wilhelm et al., 2011 ⁶	11	3/8	I-1; II-5; III-3; IV-2	Cryptoglandular	81.8%	7.4	0	Retrospective Case Series
Arroyo et al., 2016 ¹⁶	10	4/6	II-9; III-1	Cryptoglandular	80%	14.9	0	Retrospective Case Series

* Park's Classification¹³: I-Intersphincteric, II-Transsphincteric, III-Suprasphincteric, IV-Extrasphincteric, s-Superficial Fistula; NR: Not reported; Major Complications: Major solid, liquid stool incontinence, late abscess.

Another issue that is frequently raised by surgeons is the necessity of inserting a draining seton first and delaying definitive fistula repair with FiLaC™ to a later date. In the Wilhelm et al. study all patients underwent the placement of a draining seton first while Ozturk et al. were able to achieve a high success rate without the routine use of a draining seton.^{9,12} Wilhelm et al. advocated that the indwelling seton can provide tract guidance for the laser probe similar to the Seldinger maneuver. It is however unclear whether a draining seton in patients without a chronic abscess cavity provides any additional advantages. Further research is needed to investigate the impact of seton placement on healing rates.

Currently there is a paucity of data on the outcome of FiLaC™ in patients with IBD. In 1 study reporting 13 patients with IBD treated with laser fistula surgery, the primary healing rate was 69.2%.¹² While such outcome appears promising, more data is needed to understand the impact of FiLaC™ on anal fistula healing in patients with IBD. Another challenging group of patients are those previously treated for anal fistula. A history of previous surgery does not seem to significantly affect the healing rates.^{8,12}

FiLaC™ is a minimally invasive technique with a low complication rate. The majority of reported studies have not encountered significant complications. (Table 1). Due to the sphincter preserving nature of the procedure, there is a minimal risk of long-term anal incontinence. However, it is important to note that most of the available data is retrospective in nature. To date, no prospective controlled studies has been published but Skåne University Hospital has an ongoing prospective trial that is expected to be concluded in May 2020. (NCT03017898)

Conclusions

FiLaC™ is a great addition to the treatment armamentarium of anal fistula. It is a minimally invasive technique with a good safety profile, and it can achieve healing in a significant number of patients while preserving anal continence. A review of the existing scientific literature is favorable. However further studies are needed including comparison studies with other existing treatment modalities with larger number of patients and longer follow-up periods are needed to determine the future role it will play in patients with anal fistula disease.

Declaration of Competing Interest

None.

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