

# Fistula-tract Laser Closure (FiLaC<sup>TM</sup>): long-term results and new operative strategies

P. Giamundo · L. Esercizio · M. Geraci ·  
L. Tibaldi · M. Valente

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## Abstract

**Background** Fistula-tract Laser Closure (FiLaC<sup>TM</sup>) is a sphincter-saving technique for the treatment of anal fistulas that has been shown to be successful in the short and middle term. However, the long-term success rate is unknown. This study aimed to report long-term results in performing FiLaC<sup>TM</sup>.

**Methods** This study was performed as a retrospective observational study. Forty-five patients who underwent FiLaC<sup>TM</sup> between July 2010 and May 2014 were evaluated. In all cases, FiLaC<sup>TM</sup> was performed with a diode laser at a wavelength of 1470 nm by means of a radial fiber. Patients and fistula characteristics, previous treatments, healing rates, failures and postoperative incontinence were reviewed.

**Results** Median follow-up time was 30 months (range 6–46 months). Thirty-five patients (78 %) had a history of previous surgery for their fistulas. Primary healing was observed in 32 patients (71.1 %), and the median healing time was 5 weeks (range 3–8 weeks). Eleven of the 13 failures (85 %) were early failures (persistent symptoms). No patient reported postoperative incontinence. The best healing rate was observed in patients who had been previously treated with loose seton (19/24, 79 %).

**Conclusions** Long-term follow-up after FiLaC<sup>TM</sup> seems to confirm the favorable short-term success rates reported for this procedure. Although sealing of chronic anal fistulas may be obtained with FiLaC<sup>TM</sup> in a single treatment, our current strategy consists of placing a loose seton into the

fistula tract a few weeks prior to laser treatment. Seton treatment facilitates the following laser procedure and seems to have favorable effects on healing.

**Keywords** Anal fistula · Laser · Fistula closure · Sphincter saving · FiLaC<sup>TM</sup>

## Introduction

Fistula-tract Laser Closure (FiLaC<sup>TM</sup>) is a novel procedure for the treatment of anal fistulas. Primary closure of the fistula tract is obtained using a diode laser. Laser energy causes shrinkage of tissue and progressive sealing of fistulas. Being a sphincter-saving technique, it is mostly indicated in patients with high fistulas or in patients with weak sphincters and thus potential for fecal incontinence. This procedure has been already described by our group in the treatment of “complex” or recurrent fistulas [1].

Although the definition of ‘complex’ anal fistulas in the literature is not often clear, we believe the degree of “complexity” depends on the quantity of sphincter involved and the potential for fecal incontinence after treatment.

In the current study, we assessed our long-term experience with this novel procedure.

Critical review of failures helped us to define potential technical improvements in order to maximize healing.

## Materials and methods

Our study was a retrospective analysis of prospectively collected data. The analysis was performed on 45 patients (21 males and 24 females) who underwent the FiLaC<sup>TM</sup>

P. Giamundo (✉) · L. Esercizio · M. Geraci · L. Tibaldi ·  
M. Valente  
Department of General Surgery, S. Spirito Hospital,  
Bra, CN, Italy  
e-mail: pgiamundo@gmail.com

procedure in our institution between July 2010 and May 2014. All patients gave informed consent to undergo the laser procedure and to participate in regular follow-up. In all cases, preoperative assessment included clinical examination, proctoscopy and endorectal ultrasound (ERUS). Preoperative magnetic resonance imaging (MRI) was performed when fistulas had recurred repeatedly or when an abscess of the ischioanal or pelvirectal space or a horseshoe fistula was suspected. The procedure was performed with a diode laser platform emitting laser energy of 12 W at a wavelength of 1470 nm (Biolitec Biomedical Technology GmbH, Jena, Germany). We excluded from our analysis the first group of patients we had treated because we had used different laser energy (15 W) at a different wavelength (980 nm) or with a different laser radial fiber. Therefore, our current analysis was based on a more homogeneous group.

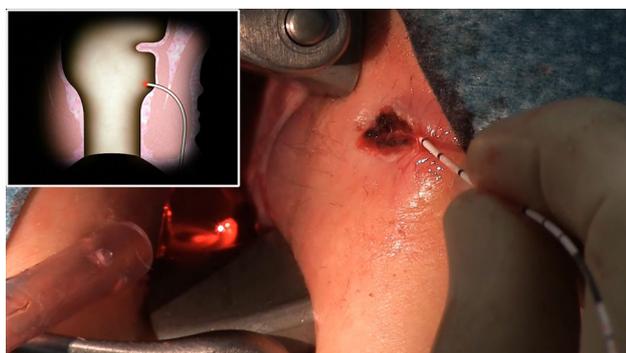
Fistula-tract Laser Closure (FiLaC™) was performed as described in our previous paper [1]. The laser fiber was introduced into the fistula tract through the external orifice with a Seldinger maneuver till it reached the internal orifice in the anal canal. The fiber delivered laser energy homogeneously at 360° causing shrinkage of the tract around the fiber, while it was withdrawn at the speed of 1 mm/sec (Fig. 1).

The majority of patients (35/45, 78 %) had a history of previous surgery for their fistulas.

Twenty-four patients (53 %) had a loose seton placed for a median period of 10 weeks (range 4–28 weeks) before the laser procedure. In 50 % of these patients (12/24), the seton had been placed while draining an abscess of the ischioanal space.

A repeat ERUS was performed before the laser procedure in those patients who had a seton in place in order to exclude the presence of a persistent undrained abscess or previously undetected secondary tracts.

In three patients in our series, the laser procedure had to be postponed as the presence of a new abscess with one secondary tract required a repeat surgical drainage.



**Fig. 1** Intraoperative view of the laser fiber being introduced into the fistula tract *inset*

All laser procedures took place in a “one-day surgery” setting under general or epidural anesthesia except in one case where the patient chose local anesthesia.

Patients were discharged with the prescription of oral antibiotics (metronidazole 250 mg × 4) for 5 days, high-fiber diet, sitz baths and analgesics if needed.

Follow-up was scheduled at 1 week, 3 months and 12 months after surgery. Telephone interviews were used to assess for any recurrence of symptoms at follow-ups longer than 12 months.

Patients were considered healed when symptoms completely disappeared without additional interventions. In cases of postoperative long-lasting discomfort and/or sporadic anal discharge, patients were assessed by MRI and/or ERUS to exclude recurrences.

## Results

Forty-five patients who underwent the FiLaC™ procedure in our institution were followed for a median of 30 months (range 6–46 months; Table 1). Median age was 46 years (range 18–78 years). Thirty-eight patients (84 %) had follow-up exceeding 12 months.

Surgery previous to FiLaC™, beside drainage and seton placement, included: mucosal advancement flaps ( $n = 3$ ), fistulectomy ( $n = 2$ ), fistulotomy ( $n = 3$ ) and fibrin glue/fistula plug ( $n = 3$ ).

One patient had two external orifices heading to a common internal opening.

The median fistula tract length, measured during the procedure by means of the laser fiber, was 4.5 cm (range 2.5–9 cm).

No intraoperative complications occurred. Median operative time was 20 min (range 6–35 min).

Postoperative morbidity included: temporary pain and animus in eight cases (18 %) and moderate bleeding in

**Table 1** Patient and fistula characteristics

Number of patients	45
Gender (M, F)	21:24
Age (years)	46 (18–78)
Previous fistula surgery	35 (78)
Previous loose seton	24 (53)
Type of fistula	
Intersphincteric	7 (15)
Low transsphincteric	7 (15)
Mid transsphincteric	19 (42)
High transsphincteric	10 (22)
Suprasphincteric	2 (4)

Values are given as  $n$ ,  $n$  (%) or median (range)

F female, M male

**Table 2** Results of the FiLaC™ at a median follow-up of 30 (range 6–46) months

Results	n (%)
Cured	32 (71.1)
Failed	11 (24.4)
Recurrence	2 (4.4)

**Table 3** Univariate analysis of possible predictive factors (45 patients)

Factor	Success (n = 32)	Failure (n = 13)	p
Sex			0.6 <sup>a</sup>
Males (n = 21)	15 (71.4 %)	10 (28.6 %)	
Females (n = 24)	17 (70.8 %)	7 (29.2 %)	
Age (years)			
Median (range)	45 (18–76)	47 (27–78)	0.45 <sup>b</sup>
Previous surgery for fistula			0.6 <sup>b</sup>
Yes (n = 35)	25 (71.4 %)	10 (28.6 %)	
No (n = 10)	7 (70 %)	3 (30 %)	
Seton use prior to FiLaC™			0.20 <sup>c</sup>
Yes (n = 24)	19 (79 %)	5 (21 %)	
No (n = 21)	13 (62 %)	8 (38 %)	

<sup>a</sup> Mann–Whitney *U* test<sup>b</sup> Fisher's exact test<sup>c</sup> Chi-square test

three (6 %). The median intensity of postoperative pain was 3.0 (on a scale of 1–10, with 10 = worst pain) during the first week.

Successful closure of fistula tracts with the absence of symptoms was observed in 32 patients (71.1 %), and the median healing time was 5 weeks (range 3–8 weeks; Table 2).

In the 27 patients followed for more than 12 months, the success rate was 71 %.

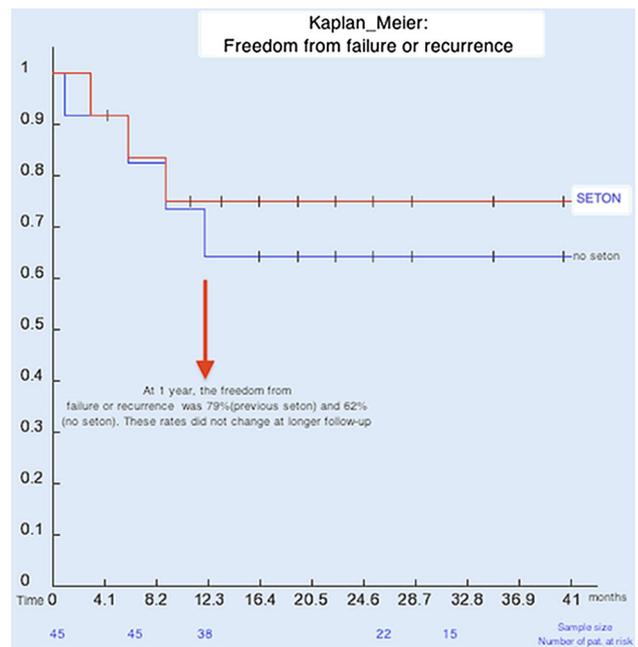
Eleven of the 13 patients in whom FiLaC™ failed continued to report discomfort and discharge from the external orifice postoperatively which never resolved. The other two patients reported temporary healing of the external orifice followed by a recurrence at 6 and 9 months after the operation.

The probability of failure or recurrence was estimated according to the Kaplan–Meier method (Fig. 2). All recurrences were reported within the first 12 months.

Healing rates for patients with or without previous seton treatment were 79 % (19/24) and 62 % (13/21), respectively (Table 3).

No significant changes in continence were reported by patients postoperatively.

Of the 13 patients with recurrent or persisting fistulas, two were treated with a repeat FiLaC™ (one with success),

**Fig. 2** Kaplan–Meier analysis of freedom from failure/recurrence

three with fistulotomy, five with internal mucosal flap + curettage of the external orifice and three with extrasphincteric fistulectomy + curettage.

## Discussion

Management of anal fistulas continues to be a difficult problem due to the high incidence of recurrences and failures reported with most current surgical procedures.

Deciding what procedure to use can be a challenge since the potential for sphincter damage must be taken into consideration.

Unfortunately, several traditional procedures that are most effective in healing anal fistulas are also likely to cause sphincter lesions with consequent fecal incontinence. Cutting setons are often associated with rather high success rates but also unacceptably high incontinence rates [2].

Fistulotomy is usually associated with high healing rates but may cause severe fecal incontinence especially in high fistulas. In addition, the alteration of anatomy due to postoperative scars and fibrosis must not be underestimated [3–5].

Therefore, sphincter-preserving fistula management is very often the first choice for most surgeons.

This interest in a minimally invasive approach also reflects patient preference.

Ellis [6] indicated that for the majority of patients, minimizing the risk of diminished continence is of greater importance than a highly successful treatment for their fistula.

The surgeon's goal should be curing patients while keeping alterations of anatomy to a minimum.

Unfortunately, many sphincter-preserving procedures, after encouraging initial results, often had disappointing success rates at longer follow-up [7–9].

Ligation of the intersphincteric tract (LIFT) [10] seems a promising sphincter-saving technique with some favorable long-term results [11]. However, more prospective randomized trials are needed to better define the role of this procedure, especially for longer and more complex fistulas.

Fistula-tract Laser Closure (FiLaC™) is one of the newest procedures described in the literature to treat complex anal fistulas. It consists of sealing the fistula lumen by means of diode laser energy. The shrinkage and the denaturing effect elicited by the laser energy are confined to the lumen of the fistula; therefore, no impairment of sphincter function has been reported with this procedure.

It is mainly indicated in transsphincteric or high fistulas. However, as a result of its sphincter-saving nature and subsequent preservation of anal continence, it may also be indicated in inter-sphincteric and/or lower fistulas in patients with weak sphincters preoperatively who may potentially develop incontinence. Due to the shrinkage effect elicited by the laser, the best results are obtained in longer fistulas (ca. 4 cm). Fistula tracts shorter than 2 cm should not be treated with FiLaC™. Crohn's disease is not a contraindication. In our overall experience, we had two cases that were successfully treated.

What we have described above is our modification of the FiLaC™ procedure previously described by Wilhelm in which the closure of the internal orifice was performed with an advancement flap before laser treatment of the fistula tract [12]. Our modification was based on the assumption that the internal anal orifice can be completely sealed by laser energy obviating the need for the advancement flap.

With a median follow-up of 30 months and 84 % of the patients followed for more than 1 year, our current study includes, to the best of our knowledge, the longest follow-up to date of FiLaC™ patients. In addition, all procedures were performed by the same surgeon who avoids the risk of one potential confounding factor: the variation of surgical technique.

In the current study, 71.1 % of patients had successful closure of fistula tracts. This figure is comparable to the 71.4 % success rate we reported [1] in our previous study with a shorter follow-up.

Our previous series included clinical results of two different groups of patients treated with laser at two different wavelengths (980 and 1470 nm) with different laser energy (15 and 12 W, respectively). The current study reports only our experience with a diode laser at 1470 nm which showed an advantage in terms of better performance at lower energy and less postoperative pain [1].

The vast majority of failures in our experience occurred within the first 3 months and resulted from reopening of the fistula tract before the denaturing effect of the laser succeeded in completely sealing the fistula lumen. This could be attributed to the presence of small, undetected secondary tracts.

In fact, FiLaC, like most of the currently used procedures for treating anal fistula, is essentially a “blind” procedure which may miss the presence of secondary tracts at the time of surgery. However, in our series, endoanal ultrasound is routinely performed at preoperative staging and repeated 2 weeks before the operation in order to exclude the presence of newly formed abscesses or previously undetected tracts.

Another cause of failure may be a variation in the caliber of the fistula tracts. This may create some “skip” areas within the lumen of the fistula where laser energy may not be sufficient to adequately seal the tract.

The insertion of a loose seton in the fistula lumen for 8–12 weeks before the laser treatment (53 % of patients in our current series) can ensure effective drainage, adequate control of sepsis (with consequent potential closure of secondary tracts) and maturation of the fistula tract around the seton. The seton can also stimulate the production of granulation tissue that reshapes the lumen around it making the tract also more homogeneous and fibrotic.

The presence of setons was found to influence success rates in our series (79 vs. 62 %) although this figures did not reach statistical significance ( $p = 0.20$ , Chi-square test). In addition, the insertion of the laser fiber into the fistula lumen is technically easier as the presence of the seton obviates the need to locate the internal opening and the seton itself is used to pull the guide-wire into the fistula in the first part of the procedure [1]. For these reasons, our operative strategy recently moved from a “one-stage” to a “two-stage” procedure. In the first stage, an examination of the anal canal under anesthesia is performed, abscesses are drained if present, and a seton is placed in the fistula tract. In the second stage, the seton is removed and the fistula is sealed using the laser.

Median healing time was 5 weeks (range 3–8 weeks). In some cases, a delay in healing may have been caused by inadequate “supporting” tissue around the most superficial part of the fistula tracts (extrasphincteric or subcutaneous part of the fistulas). This would suggest that FiLaC™ is indicated in deeper and longer rather than shorter fistula tracts. The scar tissue around the external orifice may be dissected off in selected cases.

It is noteworthy that FiLaC™ is easily repeatable. In our series, two patients underwent a repeat procedure. In three patients, the recurrent fistulas became more superficial, thus allowing fistulotomy to be successfully

performed with no further impairment of sphincter function. In another three cases of failure, only persistence of a blind tract lateral to the external sphincter was found. In these cases, a resection of the blind tract was successfully performed leaving the wound open for drainage purposes. In these particular cases, our experience can be considered similar to that of Shafik [13] who reported good clinical and functional outcome after excision of the distal part of the fistula tract down to the external sphincter following the closure of intersphincteric tract.

Ozturk et al. [14] reported an 82 % success rate in 50 patients treated with a similar laser technique. This study did not include the use of seton treatment as a “first stage.” In the second part of their series, patients with current draining abscesses were excluded. During the laser treatment, the laser probe was pushed back and forth in an attempt to increase the sealing effect. We believe this maneuver should be avoided as it may hamper the healing effect of the laser. In fact, the newly forming tissue in the lumen of the fistula is still incomplete and vulnerable during the procedure and can be easily perforated by the laser probe if it is pushed back into the treated tract.

To the best of our knowledge, our study reports the longest follow-up to date in a homogeneous group of patients treated with the FiLaC™ procedure for anal fistula, with a median follow-up of 30 months and 84 % of patients followed for more than 1 year.

All recurrences were reported within the first 12 months in our series.

The primary strength of the current study is the long follow-up. Its primary limitation is the retrospective single-institution nature and the small number of patients.

The small sample size does not give adequate power to statistically detect any potential effect on healing due to patient characteristics, the use of preoperative seton, length of fistula tracts and so on.

Another limitation consists of telephone interviews for follow-ups longer than 12 months and the lack of MRI in most cases.

## Conclusions

Our long-term results in this study confirm the encouraging short- and middle-term results of our previous study on FiLaC™.

Based on our results, we recommend the use of setons to drain anal fistulas for 8–12 weeks before laser treatment.

Fistula-tract Laser Closure (FiLaC™) can be considered a viable option in the treatment of complex anal fistulas, especially in patients with weak sphincters who may potentially develop fecal incontinence. Prospective randomized trials are needed in order to compare this procedure to other techniques used in the treatment of anal fistulas.

**Conflict of interest** P. Giamundo is “surgical trainer” for Biolitec Biomedical Technology GmbH. There is no conflict of interest for the remaining authors.

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