Techniques in Coloproctology (2019) 23:893–897
https://doi.org/10.1007/s10151-019-02077-9

ORIGINAL ARTICLE

The optimal indication for FiLaC® is high trans-sphincteric fistula-in-ano: a prospective cohort of 69 consecutive patients

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Received: 25 February 2019 / Accepted: 5 September 2019 / Published online: 26 September 2019

Abstract

Background The aim of our study was to prospectively evaluate the effectiveness of the Fistula Laser Closure (FiLaC®) technique in patients at high risk of anal incontinence and to determine the predictors of success and the impact of the procedure on anal continence.

Methods A prospective study was conducted on all patients treated with FiLaC® in our department in May 2016–April 2017, because they were at high risk of anal incontinence after fistulotomy, The fistula was considered healed when the internal and external openings were closed and the patient experienced was no pain or leakage.

Results A total of 69 consecutive patients (34 males) with a median age of 40 years (33–53 years) were included in the study. One patient was lost to follow up. The fistulas were intersphincteric (3%), low (15%) or high (66%) trans-sphincteric, and suprasphincteric (16%). After a median follow-up period of 6.3 months (4.2–9.3), fistula healing was observed in 31 patients (45.6%). In univariate analysis, high trans-sphincteric fistulas ($p=0.007$) and age over 50 years ($p=0.034$) were significantly associated with healing. In multivariate analysis, only high trans-sphincteric fistulas were a predictive factor of significant success. No new cases of anal incontinence or any worsening in case of pre-existing anal incontinence were observed during follow-up.

Conclusions FiLaC® is particularly effective in cases of high trans-sphincteric fistulas (60% cure). This technique seems to be the most promising sphincter-saving technique available for this indication.

Keywords Anal fistula · Anal incontinence · Sphincter-sparing technique · Laser FiLaC

Introduction

The treatment of complex anal fistulas is a challenge. Fistulotomy provides excellent results, but can cause anal incontinence [1]. This is particularly the case for high fistulas, but also in case of a history of obstetric lesions, chronic diarrhea, and/or Crohn's disease [2, 3]. Several "sphincter-saving" techniques have been developed to cure fistula without compromising anal continence [4]. Examples include the advancement flap, biological glue, the plug, ligation of the intersphincteric fistula track (LIFT), and the over the scope (OVESCO®) clip. However, studies show that the rate of sustained healing obtained with these procedures usually remains below 50% [5]. Fistula Laser Closure (FiLaC®) is a new sphincter-saving technique, which consists of "burning" the fistulous tract using a radial laser probe to destroy the fistula walls and granulation tissue, and then shrink and seal the fistula tract. Early studies reported healing rates around 70–80%, but most of these were retrospective studies of small numbers of patients (Table 1) [6–12]. Moreover, the predictive factors of success are unknown. Patient selection is essential to offer each patient the most appropriate treatment and increase the chances of recovery.

The aim of our study was to evaluate the effectiveness of the FiLaC® technique. We also investigated predictors of success and the impact of the procedure on anal continence.

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Table 1 Main published results

First author (year) (Refs.)	Number of patients	Median follow-up period (months)	Healing rate (%)
Wihelm (2011) [6]	11	7.4 (2–11)	81.8
Giamundo (2013) [7]	35	20 (3–36)	71.4
Ôzturk (2014) [8]	50	12 (2–18)	82
Giamundo (2015) [9]	45	30 (6–46)	71.1
Wilhelm (2017) [10]	117	25 (6–60)	64
Terzi (2017) [11]	103	28 (2.3–49.9)	40
Lauretta (2018) [12]	30	11.3 (6–24)	33.3
Current study	69	6.3 (4.2–9.3)	45.6

Materials and methods

Patient selection/study design

The FiLaC® technique was proposed for patients who were considered to be at high risk of anal incontinence after fistulotomy. All adult patients treated with FiLaC® in our department between 2 May 2016 and 31 April 2017 were included, prospectively. Patients were seen at a first consultation to establish the indication for treatment, explain the procedure, and obtain the consent. Age, sex, comorbidities, fistula type according to the Parks classification [3], and prior treatments were also recorded. Ano-vaginal, tuberculous, or cancer-related fistulas were excluded.

The study was accepted by the Hospital Group Ethics Committee and all patients gave their consent after receiving information.

Surgical technique

All patients underwent preliminary surgical drainage of any abscess and drainage of their fistula by a loose seton. They were routinely given oral metronidazole (500 mg × 2) immediately before surgery. The procedure was performed in the lithotomy position under locoregional or general anaesthesia. The seton was removed, the track was cleaned mechanically using a curette, and then, the 1470-nm diameter laser fibre (Biolitec AG, Jena, Germany) delivered 12–15 W of power from the internal orifice to the external orifice. The internal orifice was not closed surgically. The device settings (power) as well as the number of joules delivered to the fistulous track were left to the discretion of the operator. Whether or not to give postoperative oral metronidazole treatment was also left to the discretion of the operator.

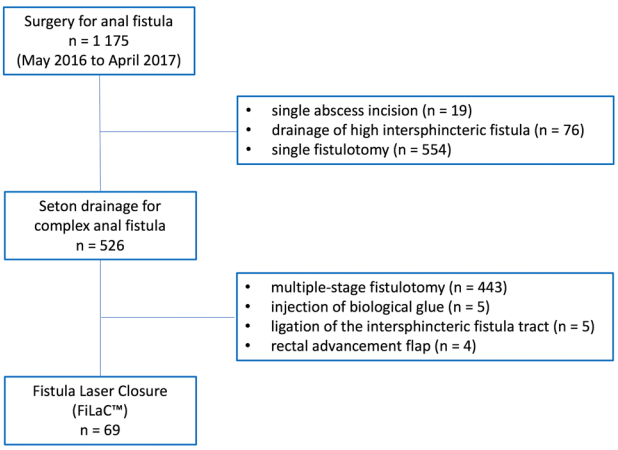

Fig. 1 Flow diagram of the study

Outcome measures

In postoperative consultations, the fistula was considered healed when the internal and external openings were closed and the patient experienced no pain or leakage. Otherwise, the treatment was considered a failure. Anal continence was assessed on the basis of a simple score distinguishing normal continence from incontinence to gas, to gas and liquid stool, and to gas and liquid and solid stools.

Statistical analysis

The results of the descriptive analysis of the study population were expressed as mean and standard deviations, median, and extreme for the quantitative variables and in proportions and 95% confidence intervals for the qualitative variables. Multivariate analysis was performed using a Cox model. Statistical analysis was performed using the STATA software (version 14).

Results

Patient cohort

During the 12 months of evaluation, 1175 surgical procedures for fistulas were performed in the department (Fig. 1) and 69 patients, including 34 males (49%), were included prospectively. One patient was lost to follow-up. A total of 68 patients were included in the analysis. Their median age was 40 years (range 33–53 years). Ten of the women had a history of vaginal delivery. Six patients had Crohn's disease (9%), 4 had human immunodeficiency virus (HIV) infection, and 2 had diabetes mellitus. Thirty-seven patients (54.4%)

had undergone prior surgery for their fistula. They had had seton drainage of fistula ($n=33$), simple or multiple-stage fistulotomy ($n=24$), abscess drainage ($n=21$), or injection of biological glue ($n=4$). The mean number of previous operations was 2.2 ± 1.4. Five patients had anal incontinence before treatment with FiLaC®, in one case incontinence to gas, and in four cases to gas and liquid stool.

The fistulas were high trans-sphincteric ($n=45$, 66%), suprasphincteric ($n=11$, 16%), low trans-sphincteric ($n=10$, 15%), intersphincteric ($n=2$, 3%), and both interphincteric fistulas were anterior, which explains why fistulotomy was not performed due to the risk of anal incontinence. The median length of the fistulas was 4 cm (range 3–5 cm). The internal orifice was located at the posterior pole of the anus in 36 cases (53%). There was secondary extension in 22 cases (32%), contralateral horseshoe ($n=17$), intramural ($n=4$), or supra levatorian ($n=1$).

Prior loose seton drainage of fistula tracts lasted for a median time period of 3.5 months (range 3–5) months. Laser treatment was carried out after removal of the seton. The average energy delivered by the laser was 488.1 ± 48.6 joules in total and 126.1 ± 85.5 joules per cm of fistulous track. The laser was delivered with a power of 13 W in 51% of cases.

Oral metronidazole for 7 days was prescribed for 20 patients (29%).

Outcomes

The postoperative course of our patients was uneventful without significant complications or major pain [visual analog scale (VAS) score < 3].

After a median follow-up period of 6.3 months (range 4.2–9.3 months), fistula healing was observed in 31 patients (45.6%).

In univariate analysis, high trans-sphincteric fistulas ($p=0.007$) and age over 50 ($p=0.034$) were significantly associated with healing (Table 2). In multivariate analysis, only high trans-sphincteric fistulas remained a significant predictor of success after adjusting for sex, age, fistula etiology, and presence of secondary extension (Table 3). The healing rate for high trans-sphincteric fistulas was 60%.

No new cases of anal incontinence or any worsening in case of pre-existing anal incontinence were observed during follow-up.

The 37 failures were recorded within a median time of 1 month (range 0.3–3.3 months). They presented as persistent leakage in 25 cases (67.6%) and abscess in 12 cases (32.4%). They were treated as follows:

- A new treatment with FiLaC® ($n=3$), including 1 cure and 2 failures; one patient was cured after a fistulotomy and the other is waiting for treatment.
- An injection of biological glue ($n=2$) with 2 failures; the patients are waiting for treatment.
- A single fistulotomy ($n=3$), which cured all patients.

Table 2 Descriptive analysis of the population by healing

Variables	Healing (%)	Failure (%)	p*
Sex ($n=68$)			
Males	17 (52)	16 (48)	0.341
Females	14 (40)	21 (60)	
Age ($n=68$)			
< 35 years	10 (45)	12 (55)	0.034
35–50 years	7 (28)	18 (72)	
> 50 years	14 (67)	7 (33)	
Fistula etiology ($n=68$)			0.417
Cryptoglandular	28 (47)	32 (53)	
Crohn's disease	3 (50)	3 (50)	
Other	0 (0)	2 (100)	
Types of fistula ($n=68$)			
Intersphincteric	0 (0)	2 (100)	0.007
Low trans-sphincteric	2 (20)	8 (80)	
High trans-sphincteric	27 (60)	18 (40)	
Suprasphincteric	2 (18)	9 (82)	
Median track length ($n=60$)			
≤ 4 cm	15 (42)	21 (58)	0.431
> 4 cm	13 (54)	11 (46)	
Internal orifice site ($n=68$)			
Anterior	13 (41)	19 (59)	0.438
Posterior	18 (50)	18 (50)	
Secondary extension ($n=68$)			
Yes	14 (64)	8 (36)	0.067
No	17 (37)	29 (63)	
Secondary track type ($n=22$)			
Horseshoe	9 (53)	8 (47)	0.176
Intra wall	4 (100)	0 (0)	
Supra levator	1 (100)	0 (0)	
Power ($n=68$)			
12 Watts	4 (36)	7 (64)	0.804
13 Watts	17 (49)	18 (51)	
15 Watts	10 (45)	12 (55)	
Average energy/cm of track ($n=60$)			
≤ 126 joules	18 (47)	20 (53)	0.886
> 126 joules	10 (45)	12 (55)	
Average total energy ($n=68$)			
≤ 488 joules	20 (44)	25 (56)	0.791
> 488 joules	11 (48)	12 (52)	
Postoperative antibiotic therapy ($n=68$)			
No	21 (44)	27 (56)	0.790
Yes	10 (50)	10 (50)	

*p from the Chi-squared test considering the variable in its entirety

Table 3 Multivariate analysis according to the Cox model

Variables	HR (IC 95%)	*p*
Sex (68)		
Male		
Female	1.13 (0.54–2.34)	0.744
Age (68)		
< 35 years		
35–50 years	0.86 (0.31–2.44)	0.783
> 50 years	0.60 (0.21–1.74)	0.350
Type of fistula (68)		
Intersphincteric	5.48 (1.09–27.66)	0.039
Low trans-sphincteric	1.59 (0.56–4.51)	0.387
High trans-sphincteric		
Suprasphincteric	2.99 (1.18–7.61)	0.021
Fistula etiology (68)		
Cryptoglandular		
Crohn's disease	0.82 (0.22–3.12)	0.773
Other	4.38 (0.81–23.68)	0.086
Secondary track (68)		
No		
Yes	0.50 (0.21–1.20)	0.158

- A multiple-stage fistulotomy ($n=9$), which cured all patients.
- Progressive elastic tightening fistulotomy ($n=5$), which cured all patients.
- A loose drainage seton while waiting for treatment ($n=11$).

and 4 patients were lost to follow-up.

Discussion

In this study, which evaluated FiLaC® prospectively in anoperineal fistulas, the healing rate was 45.6%. This rate is lower than that of the first published data (70–80%), even though our cohort seemed comparable, notably in terms of patient profile and type of fistulas treated [6–10]. However, the healing rates for the 3 most recently published studies of FiLaC® were lower at 64.1% [10], 40% [11], and 33.3% [12]. As in several studies on sphincter-saving techniques, our study does not confirm the excellent results of the initial studies [13].

Our results confirmed that FiLaC® is a sphincter-saving technique in the true sense of the term, since no new case of anal incontinence or aggravation of pre-existing anal incontinence was observed. Other studies report similar results [6, 7, 9, 11, 12].

Interestingly, our results suggest that FiLaC® is significantly more effective in case of high trans-sphincteric fistula (60% cure). This is an important point, because these fistulas are precisely those which are treated by a sphincter-saving technique. We do not have a clear explanation for this result, but it relates to long fistulous tracks and such tracks have been shown to be easier to close by other saving techniques, such as glue injection [14, 15] or a plug procedure [16]. However, this is inconsistent with the recent results of Lauretta et al. study in which shorter fistulas had better outcomes [12].

FiLaC® proved to be ineffective in suprasphincteric fistulas (18% healing), even though this type of track is often long. The explanation is perhaps related to poor drainage of the intersphincteric space, specific to this type of fistula [17], which would have gone unnoticed in this study, since we rarely use imaging in our center in case of cryptoglandular fistula. We believe that systematic use of imaging, endoanal ultrasound, or magnetic resonance imaging should make FiLaC® more effective in this indication.

There are certainly ways to improve the technique. One concerns the closure of the internal orifice. We did not carry out any other procedure in this study, but Arne Wihelm, the German surgeon who pioneered FiLaC®, almost routinely uses an advancement flap [6, 10]. In a randomized controlled trial that recently evaluated mesenchymal stem-cell injections in complex Crohn's disease fistulas, simply closing the internal orifice with resorbable wire achieved sustainable healing in 36% of patients in the placebo group [18]. We, therefore, believe that it is now preferable to combine FiLaC® with a closure procedure at the internal orifice. Another potential area for improvement is the amount of laser energy delivered. Little attention has been paid to this topic, but we think that it may be important. The average energy delivered by the laser was not significantly associated with healing in this study. It is difficult to harmonize the amount of energy delivered, because it also depends on the speed of probe withdrawal, which can vary from one operator to another. However, we found in our center a tendency to deliver less energy over time: the amount was on average 640 ± 280 joules in a study of 45 patients in 2015 (unpublished data), but it was only 488.1 ± 403.5 joules in the current series. This is due to the "overburning" phenomenon, which may widen the internal orifice and/or the track, thus making it more difficult to heal. However, the healing rate was 80% in 2015 versus 45.6% in the current series. In addition, in the study by Öztürk et al., the median amount of energy delivered was 1.176 joules (320–6.843) with a healing rate of 82% [8]. We, therefore, believe that more energy may need to be provided.

This study has three main limitations. The laser technique was not standardized, because it was a real-life evaluation and it was certainly a bias in analysis of outcomes. The small number of patients limited the scope of the statistical analysis. Because the follow-up was short, there may have been

unreported late failures, since in the literature, some have been reported between 9 and 12 months after completing FiLaC® [9].

Conclusions

FiLaC appears to be a simple, safe, and effective, sphincter-saving technique. Further studies are needed, especially to evaluate the suitability of combining the technique with an internal orifice closure procedure and the optimal amount of laser energy to be delivered.

Compliance with ethical standards

Conflict of interest M. Aubert and N. Lemarchand were invited by Biolitec company to attend a demonstration of the FiLaC® technique in Germany. Others authors declare that they have no conflicts of interest.

Ethical approval The study was accepted by the Hospital Group Ethics Committee.

Informed consent All patients gave their consent after receiving information.

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