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Evaluation of Fistula Laser Closure (FiLaC) in Management of High Trans- sphincteric Fistula- in- ano

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ORIGINAL ARTICLE

Evaluation of Fistula Laser Closure in the Management of High Transsphincteric Fistula-in-Ano

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Abstract

Background: **As a revolutionary sphincter-preserving approach, Wilhelm proposed 'fistula laser closure' (FiLaC) in 2016. It uses a radial emitting laser probe and had an initial rate of success of 81.8% in 11 patients with a median follow-up of 7.4 months.**

Aim: **To analyze the efficacy of FiLaC technique in treating high transsphincteric fistula-in-ano, look at the procedure's effects on anal continence, and predictors of success.**

Patients and methods: **This prospective cohort research was conducted between April 2021 and November 2021 on 20 patients with high transsphincteric fistula-in-ano at the Department of Surgery at Al-Azhar University Hospitals, Cairo, Egypt. Patients received care using the FiLaC procedure, and they were monitored for at least 6 months after surgery.**

Results: **There was significant difference between simple and complicated fistulas regarding hospital stay, early incontinence, pain score, and patient satisfaction ($P < 0.001$).**

Conclusion: **Simple anal fistulas may be successfully treated with FiLaC, particularly in individuals with weak sphincters who run the risk of developing fecal incontinence.**

Keywords: Fistula laser closure, Fistula, Fistulectomy, Surgery

1. Introduction

While laying open fistulotomy may repair simple fistula-in-ano with healing rates up to 98%, treating complicated fistula-in-ano is more difficult as the condition may reoccur or the patient's continence status may be jeopardized.[1]

Fistulotomy yields fantastic outcomes but may result in anal incontinence.[2] This is especially true for high fistulas, but it is also true when there has previously been a history of obstetric lesions, persistent diarrhea, or Crohn's disease.[3,4]

A radial emitting laser probe was used by Wilhelm in 2011 to establish fistula laser closure (FiLaC), a new sphincter-preserving procedure with an initial success rate of 81.8% in 11 patients during a median follow-up of 7.4 months. By emitting energy in a radial pattern, this approach maximizes circumferential heating while limiting collateral harm to the nearby sphincter complex. The circumferential heating shrinks and obliterates the surrounding fistula track by denatured proteins, completing the track closure.[5]

The FiLaC method aims to concurrently obliterate the internal and external fistula orifices, the crypt gland, and the extra epithelial layer of the fistula track using a photothermal action.[5]

Early research indicated recovery rates between 70 and 80%; however, the majority of them were retrospective studies with few individuals. Moreover, it is unclear what criteria predict success.[5–11]

The key benefit of FiLaC is its excellent safety record, which includes extremely few mild problems and nearly no adverse effects on continence. These encouraging outcomes should add FiLaC to the surgical toolbox for fistula-in-ano therapy. To support the encouraging results reported in this analysis, well-designed randomized control studies contrasting the FiLaC with alternative procedures are necessary.[12]

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The study objectives were to assess the efficacy of FiLaC technique in treating high transsphincteric fistula-in-ano, look into success indicators, and assess how the treatment affected anal continence.

2. Patients and methods

Between April 2021 and November 2021, this prospective, randomized trial recruited participants from Al-Azhar University hospitals with a follow-up period of just 6 months postoperatively. The research was carried out after receiving approval from the Al-Azhar University's institutional ethics council. Every patient who was involved provided their informed consent.

Inclusion criteria were age above 20 years and high transsphincteric fistula-in-ano which was considered a high risk of anal incontinence after fistulotomy.

Exclusion criteria were patients younger than 20 years; patients with fistulae that are superficial or with low risk for incontinence; patients who were unfit for anesthesia; patients with ano-vaginal, tuberculous, or cancer-related fistulae; and patient refusal.

All patients were be subjected to the following:

Preoperative management included (a) full history taking and clinical examination, where surgical and family histories were considered with special concentration on patient comorbidities, proctosigmoidoscopy, the fistula type according to the Parks classification,[12] the degree of continence as evaluated by the Wexner scoring system, and prior treatments. (b) Investigations included routine laboratory investigations required for preoperative assessment; necessary imaging, ECG, and chest radiograph when required; and radiological studies (plain radiograph fistulogram, MRI fistulogram, and endoanal ultrasonography). (c) Preoperative management of the general condition included control of concomitant illness, for example, hypertension and diabetes mellitus, and cessation of smoking. (d) Antibiotic prophylaxis included the following: all patients received broad-spectrum antibiotic as third-generation cephalosporin cefotaxime (cefotaxime) 1 g by intravenous drip one dose preoperatively and another dose after 2 h postoperatively. (e) Optimum skin hygiene included showers with hexachlorophene soap and on-table shaving of the perineal hair.

Operative management: the patient was placed in lithotomy position and administered spinal anesthesia. At the start of operation, 500 mg of metronidazole and 1.5 g of cefuroxime were administered intravenously. The surgical site was treated antiseptically. Proctoscopy and a digital rectal examination were performed after inspection. To determine the internal entrance, the exterior opening location was probed. If required, identification was facilitated by injecting diluted hydrogen peroxide via the exterior hole. The track was mechanically cleansed with a curette, and the fistula's length and location were assessed by palpation and the delicate use of a probe that was preserved as a guide for dissection. The skin around the external opening was elliptically incised, and the track was dissected as high as possible. The fistulous track was 'cored-out' up to and through the external sphincter, which were clearly exposed during the operation. LASER machine setting was set up to the level at which coagulation is activated, and the LASER probe was connected. The laser probe is introduced into the fistulous tract along the whole tract. LASER ablation of the tract was started from inside to outside gradually while withdrawing of the LASER probe. After ablation, the whole tract was guided by power and quantity was limited not to induce sphincteric injury nor the epithelial layer of anal canal.

Follow-up: the outpatient clinic set up follow-up appointments for 1, 2, and 6 months after surgery. In the event that symptoms returned, patients were advised to see the outpatient clinic as soon as possible. An interview over the phone was done for follow-up, which lasted more than a year. Physical examination and proctoscopy were included in the postoperative clinical assessment. At each visit, the CCF-FI score and the visual analog scale (VAS) score (used to measure pain) were recorded. To rule out recurrence, patients who had pain and/or occasional anal discharge despite the exterior opening seeming to be closed were additionally evaluated using endorectal ultrasonography and/or MRI.

2.1. Statistical analysis

SPSS, v27 (IBM, Chicago, Illinois, USA), was used for statistical analysis. Histograms and Shapiro–Wilk test were used to assess the normality of the data distribution. Mean and SD were used to show quantitative parametric data, and an analysis of variance (F) test with a post-hoc test was used to analyze them (Tukey). To compare each group, quantitative nonparametric data were provided as median and interquartile range and were then analyzed using the Kruskal–Wallis test and Mann–Whitney test. χ^2 test was used to analyze qualitative variables, which were provided as frequency and proportion (percent). Statistical significance was defined as a two-tailed P value less than 0.05.

3. Results

Patients' demographics are illustrated in Table 1.

Table 2 shows that the mean operative time was 1.30 ± 0.47 h, 100% had complete tract ablation, the mean hospital stay was 1.45 ± 0.51 days, the mean early incontinence (Wexner score) was 1.15 ± 1.18, and the mean VAS score was 1.10 ± 0.85. Overall, 20% had hematoma and/or infection, 50% experienced postoperative discharge, and the mean patient satisfaction was 3.85 ± 0.93.

Table 3 shows that 30% had early recurrence and the mean healing time (weeks) was 9.90 ± 1.52.

Table 4 shows that there was a significant difference between simple and complex fistulas regarding blood loss (ml) (55.0 ± 15.81 vs. 105.0 ± 28.38, $P < 0.001$).

Table 5 shows that there was a significant difference between simple and complex fistulas regarding postoperative discharge and early recurrence ($P < 0.001$).

Table 6 shows that there were significant differences between simple and complex fistulas regarding hospital stay, early incontinence, pain score, and patient satisfaction ($P < 0.001$).

Table 1. Distribution of the examined instances based on several criteria (N = 20).

	n (%)
Age (years)	
20–	2 (10.0)
30–	5 (25.0)
40–	6 (30.0)
50–	7 (35.0)
Minimum–maximum	28.0–57.0
Mean ± SD	43.55 ± 9.13
Median (IQR)	43.0 (36.0–51.50)
Family history	
No	18 (90.0)
Yes	2 (10.0)
Comorbidities	
No	15 (75.0)
Yes	5 (25.0)
Diabetic	2 (40.0)
HTN	2 (40.0)
Psychiatric disorder	1 (20.0)
Type of fistula	
Simple high transsphincteric	10 (50.0)
Complex high transsphincteric	10 (50.0)
Seton	
No	16 (80.0)
Yes	4 (20.0)
Blood loss (ml)	
Minimum–maximum	50.0–150.0
Mean ± SD	80.0 ± 34.03
Median (IQR)	75.0 (50.0–100.0)

HTN, hypertension; IQR, interquartile range.

Table 2. Distribution of the examined instances based on various criteria (N = 20).

	n (%)
Intraoperative finding	
Operation time (h)	
1	14 (70.0)
2	6 (30.0)
Minimum–maximum	1.0–2.0
Mean ± SD	1.30 ± 0.47
Median (IQR)	1.0 (1.0–2.0)
Complete tract ablation	
No	0
Yes	20 (100.0)
Hospital stay (days)	
Minimum–maximum	1.0–2.0
Mean ± SD	1.45 ± 0.51
Median (IQR)	1.0 (1.0–2.0)
Early incontinence (Wexner score)	
Minimum–maximum	0.0–3.0
Mean ± SD	1.15 ± 1.18
Median (IQR)	1.0 (0.0–2.0)
Pain (VAS score)	
0	6 (30.0)
1	6 (30.0)
2	8 (40.0)
Minimum–maximum	0.0–2.0
Mean ± SD	1.10 ± 0.85
Median (IQR)	1.0 (0.0–2.0)
Development of hematoma and\ or infection	
No	16 (80.0)
Yes	4 (20.0)
Postoperative discharge	
No	10 (50.0)
Yes	10 (50.0)
Patient satisfaction (1–5)	
Minimum–maximum	3.0–5.0
Mean ± SD	3.85 ± 0.93
Median (IQR)	3.50 (3.0–5.0)

IQR, interquartile range; VAS, visual analog scale.

4. Discussion

One of the newest treatments for complex anal fistulas described in the literature is called FiLaC. It entails using diode laser radiation to close the fistula lumen. No known sphincter function impairment has been linked to this therapy as the shrinking and denaturing effect produced by the laser light are limited to the fistula's lumen.[13]

Table 3. Distribution of the examined cases based on duration to healing and early recurrence (N = 20).

	n (%)
Early recurrence	
No	14 (70.0)
Yes	6 (30.0)
Healing time (weeks)	
Minimum–maximum	8.0–12.0
Mean ± SD	9.90 ± 1.52
Median (IQR)	10.0 (8.0–11.0)

IQR, interquartile range.

Table 4. Relation between type of fistula and different parameters (N = 20).

	Type of fistula [*n* (%)]		Test of significance	*P*
	Simple (*N* = 10)	Complex (*N* = 10)		
Age (years)				
20	2 (20.0)	0	$\chi^2 = 3.744$	$^{MC}P = 0.297$
30	2 (20.0)	3 (30.0)		
40	4 (40.0)	2 (20.0)		
50	2 (20.0)	5 (50.0)		
Minimum–maximum	28.0–54.0	33.0–57.0	$t = 1.548$	0.139
Mean ± SD	40.50 ± 8.51	46.60 ± 9.09		
Median	41.0	48.0		
Family history				
No	9 (90.0)	9 (90.0)	$\chi^2 = 0.000$	$^{FE}P = 1.000$
Yes	1 (10.0)	1 (10.0)		
Comorbidities				
No	9 (90.0)	6 (60.0)	$\chi^2 = 2.400$	$^{FE}P = 0.303$
Yes	1 (10.0)	4 (40.0)		
Diabetic	0	2 (50.0)	$\chi^2 = 3.431$	$^{MC}P = 0.195$
HTN	0	2 (50.0)		
Psychiatric disorder	1 (100.0)	0)		
Seton				
No	9 (90.0)	7 (70.0)	$\chi^2 = 1.250$	$^{FE}P = 0.582$
Yes	1 (10.0)	3 (30.0)		
Blood loss (ml)				
Minimum–maximum	50.0–100.0	50.0–150.0	$U = 9.000$[a]	0.001[a]
Mean ± SD	55.0 ± 15.81	105.0 ± 28.38		
Median	50.0	100.0		

χ^2, χ^2 test; FE, Fisher exact; MC, Monte-Carlo; *U*, Mann–Whitney test.
[a] Statistically substantial at *P* value less than or equal to 0.05.

Elfeki et al.[12] found that depending on the procedure, it might take 35–40 min. This indicates that the procedure's operating time is brief and appropriate. In a meta-analysis evaluating the security and effectiveness of laser fistula closure, Elfeki et al.[12] found that the average operation lasted 18.33 min (range, 6–35 min). In three investigations, FiLaC was carried out as a day-case surgery, but the patients in the other trials were admitted for 1–2 days.

The current findings agree with those of Yöntem and Kapatõlmasõ[14] where they reported that the main complication of surgical treatment of the perianal fistula was the occurrence of incontinence. Yöntem and Kapatõlmasõ[14] found that patients' postoperative experiences were uncomplicated, with no severe problems or painful symptoms (a VAS score of <3).

In this study, we demonstrated that 20% had hematoma and/or infection, 50% suffered from postoperative discharge, and the mean patient satisfaction was 3.85 ± 0.93.

Giamundo et al.[6] found that 11 of the 13 patients in whom FiLaC failed reported persistent

Table 5. Relation between type of fistula and different parameters (N = 20).

	Type of fistula [*n* (%)]		χ^2	*P*
	Simple (*N* = 10)	Complex (*N* = 10)		
Complete tract ablation				
Yes	10 (100.0)	10 (100.0)	–	–
No	0	0		
Development of hematoma				
Yes	0	4 (40.0)	5.000	$^{FE}P = 0.087$
No	10 (100.0)	6 (60.0)		
Postoperative discharge				
Yes	1 (10.0)	9 (90.0)	12.800[a]	<0.001[a]
No	9 (90.0)	1 (10.0)		
Early recurrence				
Yes	0	6 (60.0)	8.571[a]	0.011[a]
No	10 (100.0)	4 (40.0)		

χ^2, χ^2 test; FE, Fisher exact.
[a] Statistically substantial at P value less than or equal to 0.05.

Table 6. Relation between type of fistula and different parameters (N = 20).

	Type of fistula [*n* (%)]		Test of significance	*P*
	Simple (*N* = 10)	Complex (*N* = 10)		
Operation time hour				
1	9 (90.0)	5 (50.0)	$\chi^2 = 3.810$	$^{MC}P = 0.141$
2	1 (10.0)	5 (50.0)		
Minimum–maximum	1.0–2.0	1.0–2.0	$U = 30.000$	0.143
Mean ± SD	1.10 ± 0.32	1.50 ± 0.53		
Median (IQR)	1.0	1.50		
Hospital stay days				
1	9 (90.0)	2 (20.0)	$\chi^2 = 9.899$[a]	0.005[a]
2	1 (10.0)	8 (80.0)		
Minimum–maximum	1.0–2.0	1.0–2.0	$U = 15.000$[a]	0.007[a]
Mean ± SD	1.10 ± 0.32	1.80 ± 0.42		
Median (IQR)	1.0	2.0		
Early incontinence				
0	9 (90.0)	0	$\chi^2 = 18.728$[a]	<0.001[a]
1	1 (10.0)	1 (10.0)		
2	0	6 (60.0)		
3	0	3 (30.0)		
Minimum–maximum	0.0–1.0	1.0–3.0	$U = 0.500$[a]	<0.001[a]
Mean ± SD	0.10 ± 0.32	2.20 ± 0.63		
Median (IQR)	0.0	2.0		
Pain VAS				
0	6 (60.0)	0	$\chi^2 = 15.267$[a]	<0.001[a]
1	4 (40.0)	2 (20.0)		
2	0	8 (80.0)		
Minimum–maximum	0.0–1.0	1.0–2.0	$U = 4.000$[a]	<0.001[a]
Mean ± SD	0.40 ± 0.52	1.80 ± 0.42		
Median (IQR)	0.0	2.0		
Patient satisfaction 1.5				
3	0	10 (100.0)	$\chi^2 = 20.999$[a]	<0.001[a]
4	3 (30.0)	0		
5	7 (70.0)	0		
Minimum–maximum	4.0–5.0	3.0–3.0	$U = 0.000$[a]	<0.001[a]
Mean ± SD	4.70 ± 0.48	3.0 ± 0.0		
Median (IQR)	5.0	3.0		
Healing time weeks				
8	5 (50.0)	1 (10.0)	$\chi^2 = 4.273$	0.136
10	4 (40.0)	5 (50.0)		
12	1 (10.0)	4 (40.0)		
Minimum–maximum	8.0–12.0	8.0–12.0	$U = 24.500$	0.052
Mean ± SD	9.20 ± 1.40	10.60 ± 1.35		
Median (IQR)	9.0	10.0		

χ^2, χ^2 test; FE, Fisher exact; MC, Monte-Carlo; *U*, Mann–Whitney test; VAS, visual analog scale.
[a] Statistically substantial at P value less than or equal to 0.05.

postoperative pain and drainage from the external orifice that never went away. The external orifice temporarily healed in the other two patients, but at 6 and 9 months after the procedure, there was a recurrence. Similarly, Lauretta and colleagues found that four patients had mild postoperative problems that spontaneously disappeared, including two cases of fever, one case of acute discomfort, and one case of significant bleeding.

Yöntem and Kapatõlmasõ[14] found that at postoperative 1 year, the mean patient satisfaction level was 4.62 ± 1.07. In the study in our hands, we found that 30% had early recurrence and the mean healing time (weeks) was 9.90 ± 1.52. Wilhelm and colleagues found that the FiLaC procedure's first rate of success was 64.1% (75/117).

Giamundo et al.[8] found that 18 (72%) were deemed to be in remission. At a median follow-up of 20 (3–36) months, the overall success rate was 71.4% (25/35). At 3 and 6 months after the surgery, there were two reported recurrences. A lay-open approach was used to effectively treat both of them. Discomfort and drainage from the initial external orifice did not went away postoperatively in the eight individuals whose treatment was deemed to have failed. Three patients are awaiting another

laser therapy operation after having a new seton placed, whereas five patients had treatment with an endoanal mucosal flap.

Wolicki et al.[15] found that relapses occurred in 21 (25.3%) of the cases. The majority of patients (n = 62–74.4%) did not have any difficulties throughout the healing process. However, seven individuals experienced bleeding, whereas 11 patients claimed discomfort. The blood that was reportedly present was related to mending wounds. None of the patients required blood transfusions or further surgeries. Patients who experienced pain cited limitations on everyday activities, particularly sitting, as the source of their discomfort. The average duration of this discomfort was three weeks, and metamizole or nonsteroidal anti-inflammatory medications were used as analgesics.

In this trial, we revealed that there was a significant difference between simple and complex fistulas regarding blood loss (ml) (55.0 ± 15.81 vs. 105.0 ± 28.38, $P < 0.001$). Frountzas et al.[16] found that blood loss was substantially greater in complex fistula compared with simple fistula, with P value of 0.001. Nordholm-Carstensen et al.[17] found that there was a significant difference between simple and complex fistula regarding blood loss (ml).

Our results illustrated that there was a significant difference between simple and complicated fistulas regarding postoperative discharge and early recurrence ($P < 0.001$). Lauretta *et* al[11] found that simple fistula tracts were connected with a recurrence rate of 16.3%, whereas complex fistulas were connected with a recurrence rate of 58.6% ($P < 0.02$). Frountzas et al.[16] found that simple fistula is connected with better outcomes with laser fistula closure technique compared with complex fistula regarding postoperative discharge and early recurrence ($P < 0.001$).

In this research, we demonstrated that there was a significant difference between simple and complex fistulas regarding hospital stay, early incontinence, pain score, and patient satisfaction ($P < 0.001$). Alkhawaga et al.[18] found that complex fistulae undergoing laser closure had a higher rate of major incontinence (13%) than simple fistula (5%) ($P = 0.03$). After a week, postoperative pain was measured using the VAS. The median pain score was substantially greater in the complicated group (5.05) than in the simple group (3.95).

4.1. Conclusion

Based on the results of our research, FiLaC may be recommended as a therapeutic option for uncomplicated anal fistulas, particularly in patients with weak sphincters who run the risk of developing fecal incontinence but with a lower success rate in complicated anal fistulas, where our study's success rate was 60%.

Conflict of interest

The authors declared that there were no conflicts of interest.

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