Fistula-tract laser closure versus fistulotomy with primary sphincteroplasty for treatment of transsphincteric anal fistula: a prospective controlled study

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Background
Fistula surgery is challenging owing to high incidence of postoperative complications such as recurrence and incontinence. The best surgical option provides complete healing of the fistula and saving sphincter function.
Aim
To assess and compare fistula-tract laser closure (FiLaC) and fistulotomy with primary sphincteroplasty (FIPS) for management of transsphincteric anal fistula regarding their efficacy and postoperative complications.
Patients and methods
A total of 100 patients with transsphincteric anal fistula were divided into two groups: group A (*N*=50, FiLaC) and group B (*N*=50, FIPS). They were subjected to clinical assessment and MRI of the perianal region. Patients were followed up for 12 months to assess postoperative complications, recurrence, and continence.
Results
The patients' ages ranged from 18 to 65 years. Overall, 78% in group A were males versus 74% in B ($P>0.05$). Mean operative time and postoperative hospital stay were shorter in group A (24.7 ± 4.33 vs. 35.1 ± 7.65 min, and 1 ± 0 vs. 2.9 ± 1.2 days, respectively; $P<0.01$). Recurrence rates were higher in group A (26 vs. 8%, $P<0.05$) but with better continence scores. A strong negative correlation was found between good fitting of fistula tracts on the 1.5-mm metal probe and recurrence ($r=-0.628$, $P<0.01$) and a weak correlation between MRI fistula length and percentage of sphincter affection with recurrence ($r=-0.101$ and $r=0.147$, $P>0.05$).
Conclusion
FiLaC had great outcomes in treating transsphincteric anal fistula in patients with long fistula tracts and appropriate caliber in relation to laser probe, whereas FIPS remained a good option with low recurrence and minimal affection of the continence.

Keywords:
anal fistula, fistula-tract laser closure, fistulotomy with primary sphincteroplasty, fistulotomy, sphincteroplasty, transsphincteric

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Introduction

Fistulas are very common anorectal problems that result in considerable negative patient experiences [1]. Perianal fistula can be divided into simple and complex types: the complex types include transsphincteric involving more than 30% of the external sphincter, suprasphincteric, extrasphincteric, or horseshoe fistulas, and anal fistulas associated with radiation, malignancies, IBD, chronic diarrhea, or preexisting fecal incontinence. Simple fistulas have none of these complex features and include intersphincteric and low transsphincteric involving more than 30% of the sphincter complex [2,3].

Surgical management of anal fistulas has been documented in the literature for thousands of years. A simple or low fistula type is best treated with a primary fistulotomy giving excellent healing rates and functional outcomes. However, the approach to complex anal fistulas is more difficult, with higher rates of failure and functional disability [4]. Owing to the diverse causes and forms of complex anal fistula, surgical treatment is often accompanied by a high risk of recurrence and potential incontinence [5].

Definitive surgical management options include setons (temporary draining, cutting), fistulotomy or fistulectomy (primary or staged, with or without sphincteroplasty), endorectal advancement flap, anocutaneous advancement flap, fistula plug, fibrin glue,

electrocauterization or fistula-track laser closure (FiLaC), and ligation of intersphincteric fistula tract [4].

For the best choice of the surgical procedure, two major points should be taken into consideration, which are healing of the fistula and preservation of stool continence and sphincter function; however, none of the different currently used surgical procedures represent an ideal standard one [6,7].

Aim

The aim of this study was to prospectively assess and compare two techniques for management of transsphincteric anal fistula, which are FiLaC as a modern technique and conventional [fistulotomy with primary sphincteroplasty (FIPS)] in terms of their efficacy and superiority of one over the other regarding recurrence, incontinence, and other complications.

Patients and methods

This prospective randomized controlled study was conducted over a period of 3 years from July 2018 to June 2021 after approval by the local Medical Ethical Committee. A total of 115 patients with transsphincteric-type anal fistula accepted to participate in our study, and they were randomized into two groups using a computer program for randomization (random allocation software). Overall, 15 patients dropped out during the follow-up schedule, and 100 patients continued the study, who were divided into two groups: group A included 50 patients who underwent the FiLaC technique and group B included 50 patients who underwent the FIPS technique. Written informed consent was obtained from all patients before surgery after explanation of risks, complications, and alternative procedures.

Inclusion criteria: patients with transsphincteric type of anal fistula were included.

Exclusion criteria: patients with other types of anal fistula, patients with inflammatory bowel disease or tuberculosis, patients with acute perianal abscess or any perianal collection, patients with recurrent or branching fistula, patients with fecal incontinence, patients with malignant fistulas, and patients with other chronic illnesses that affect healing were excluded.

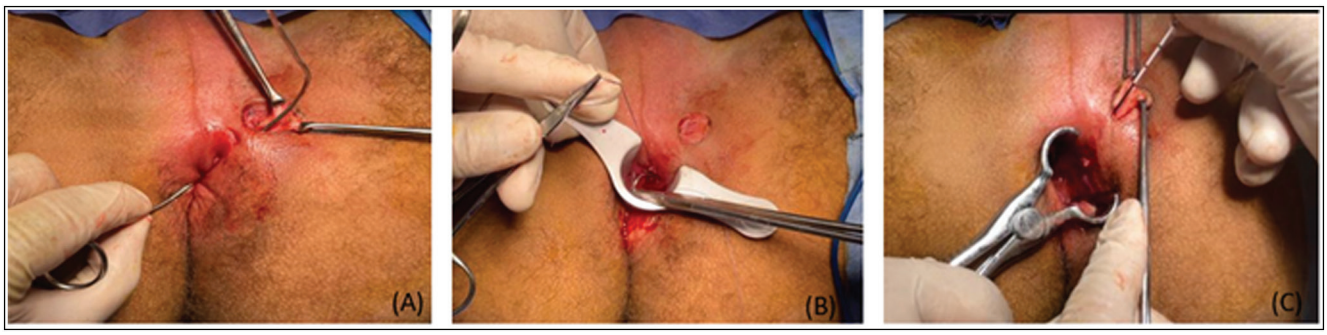
Preoperative data collection included patient demographics, comorbidities such as diabetes mellitus and hypertension, duration of the fistula, and history of previous perianal abscess in addition to the continence level using the Wexner score (WS).

Clinical assessment of the patients preoperatively was done by digital examination and proctoscopy. They were all referred for MRI of the pelvis and perianal region for identification of fistula type, length of fistula tract, and percentage of sphincter affection. Before surgery, all patients had a mechanical bowel preparation.

Surgical techniques:

Group A ('FiLaC;' Ceralas, Biolitec, Germany): our technique was quite similar to the one adopted by Wilhelm [7] in which the external opening of the fistula was firstly excised, whereas the internal opening was curetted after its identification, and then the fistula tract was mechanically cleaned with a very small-sized curette and washed with saline. Our added tip was that all fistula tracts were assessed for its caliber using two malleable metal fistula probes of 1.5- and 3-mm size. The internal opening within the internal sphincter muscle was then closed using a 2/0 Vicryl suture, and the laser probe was inserted from the perineal opening. By applying energy at 13 W at a wavelength of 1470 nm, the fistula tract was obliterated under continuous retraction of the laser, which was withdrawn at a rate of 1 cm/3 s, as shown in Fig. 1.

Figure 1



FiLaC technique: (a) probing of the fistula tract with identification of internal opening, (b) closure of internal opening and excision of the external one, and (c) insertion of the laser probe and obliteration of the tract. FiLaC, fistula-tract laser closure.

Group B (FIPS): the procedure was similar to the technique proposed by Ratto *etal.*[8]. We first identified the fistula tract by probing followed by complete lay open of the primary tract from the external to the internal opening, with section of both anal sphincters. The primary fistulous tract peripheral to the external sphincter was then excised and the one passing through the sphincters was curetted to remove any granulation tissue. The internal opening was removed at the mucosal surface. Then, an end-to-end primary sphincteroplasty was performed using a series of three to four interrupted 3-0 PDS (polydioxanone) stitches encompassing both sphincter stumps and entire wall of the fistula tract. Finally, anal mucosa and submucosa were closed with a 3-0 Vicryl interrupted sutures. The external part of the perianal wound was left open to permit drainage, as shown in Fig. 2.

Postoperatively, patients were instructed for clear oral fluids for days and then they were allowed to eat normally with no dietary restrictions starting on the third day postoperatively. They were all placed on stool softeners for 2 weeks after the operation. Follow-up of the patients was conducted on the first week and then on first, third, sixth, and 12th month for assessment of postoperative complications, recurrence rate, and continence level by the WS system.

Statistical analysis

Data were collected, revised, coded, tabulated, and entered to the Statistical Package for Social Science (SPSS), version 21. The following were done: qualitative data were presented as number and percentages, whereas quantitative data were presented as range, mean, and SDs. The comparisons between two groups with qualitative data were done by using χ^2 test and/or Fisher exact test, which was used instead of χ^2 test when the expected count in any cell was found to be less than 5. Correlation analysis included Pearson's method (r) for the strength of association between two quantitative parametric variables. P value more than 0.05 represents nonsignificant, less than 0.05 for significant ones, and less than 0.01 for highly significant results.

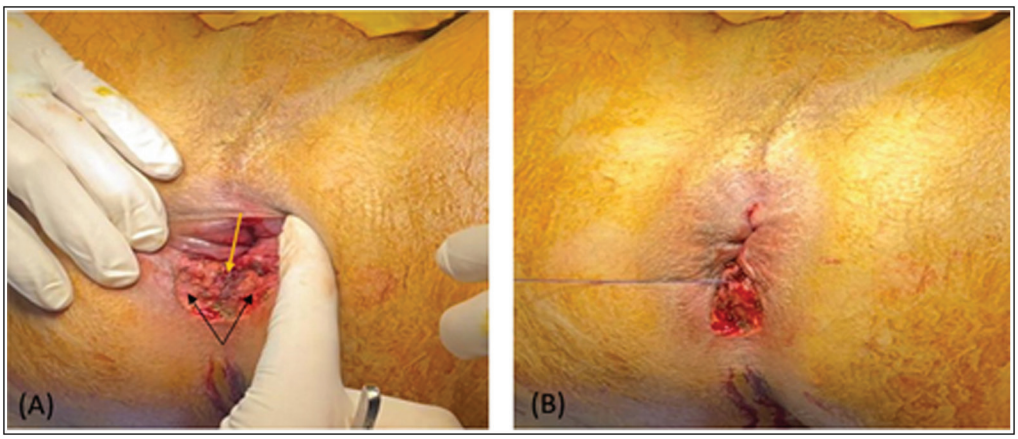
Results

This study was completed on 100 patients with transsphincteric anal fistula who were divided into two groups: group A (N=50, FiLaC) and group B (N=50, FIPS). The age of the patients ranged from 18 to 65 years, with mean±SD of 35.64±10.39 years in group A and 39.30±11.06 in group B. Of 50 patients, 39 (78%) in group A were males compared with 37 (74%) patients in group B, with no statistically significant difference between patients in the two groups regarding their age and sex (P>0.05).

Past history of diabetes mellitus was reported by 11 (22%) patients in group A and 10 (20%) patients in group B, whereas hypertension was found in 13 (26%) and 14 (28%) patients, respectively. A total of 38 (76%) patients in group A had a positive history of previous perianal abscess compared with 37 (74%) patients in group B (P>0.05). In group A, 11 (22%) patients reported that they had the fistula for less than a year and 15 (30%) had it for more than a year, whereas 24 (48%) patients were not able to accurately identify the actual duration of fistula compared with 13 (26%), 17 (34%), and 20 (40%) patients in group B, respectively (P>0.05), as described in Table 1.

Preoperative MRI of the pelvis and perianal region revealed that the mean length of the fistulas was 5.42±1.9 cm in group A and 5.7±1.75 cm in group B, whereas the mean percentage of sphincter involvement was 33.2±16.71% in group A and 34.8±17.02% in group B.

Figure 2



FIPS technique: (a) lay open of the fistula tract (yellow arrow) with exposure of the cut ends of sphincter muscles (black arrows) and (b) end-to-end sphincter repair. FIPS, fistulotomy with primary sphincteroplasty.

Comparing the operative time between both groups, there was significantly shorter operative time in group A compared with group B (24.7 ± 4.33 vs. 35.1 ± 7.65 min, $P<0.01$), and intraoperative assessment of fistula caliber among patients in group A revealed that 38 (76%) fistulas were well fit on the 1.5-mm probe, whereas 12 (24%) were wide enough to fit better on the 3-mm probe size. Postoperatively, the mean length of hospital stay was 1 day for patients in group A, which was significantly shorter than that seen in patients in group B (2.9 ± 1.2 days, $P<0.01$) (Table 2).

Following up the patients at first week postoperatively showed that only one patient in group A had bleeding compared with two patients in group B; however, patients in group A reported significant lower rates of wound infection compared with those in group B (0 vs. 6, $P<0.05$), and assessment of pain using visual analog scale (VAS) showed highly significant lower scores of pain among patients in group A compared with group B (3.54 ± 0.813 vs. 6.50 ± 1.389, $P<0.01$).

At 1-month postoperative follow-up, 34 (68%) patients in group A showed complete wound healing compared with 30 (60%) patients in group B ($P>0.05$). Assessment of continence level using the WS revealed that it was affected in two (4%) patients in group A (WS=1) and in four (8%) patients in group B (WS=2 in two patients and 3 in two patients). VAS for pain also showed highly significant lower pain scores among patients in group A compared with group B (0.74 ± 0.751 vs. 2.94 ± 0.86, $P<0.01$).

Follow-up at 3 months postoperatively showed that the recurrence rate was significantly higher in group A (10 patients, 20%) compared with group B (two patients, 4%, $P<0.01$). WS completely improved for the two previously affected patients in group A, whereas there was only mild improvement among patients in group B ($N=4$ and WS=1 in two patients, and two and 3 in another two patients). VAS for pain showed lower pain scores among patients in both groups, with no statistically significant difference between them (0.40 ± 0.08 and 0.67 ± 0.09, $P>0.05$).

Table 1 Characteristics of the patients in the study

	Group A (FiLaC) [*n* (%)]	Group B (FIPS) [*n* (%)]	Test of significance	
			Test value	*P* value
Age (years)	35.64 ± 10.398	39.30 ± 11.061	$t=-1.705$	0.091
Sex				
Male	39 (78)	37 (74)	$\chi^2=0.219$	0.640
Female	11 (22)	13 (26)		
DM				
No	39 (78)	40 (80)	$\chi^2=0.060$	0.806
Yes	11 (22)	10 (20)		
HTN				
No	37 (74)	36 (72)	$\chi^2=0.051$	0.822
Yes	13 (26)	14 (28)		
Previous abscess				
No	12 (24)	13 (26)	$\chi^2=0.053$	0.817
Yes	38 (76)	37 (74)		
Fistula duration				
<1 year	11 (22)	13 (26)		
>1 year	15 (30)	17 (34)	$\chi^2=0.655$	0.721
Unknown	24 (48)	20 (40)		
MRI				
Length (cm)	5.428 ± 1.993	5.724 ± 1.755	$t=-0.788$	0.433
Sphin. affection (%)	33.20 ± 16.714	34.80 ± 17.022	$t=-0.474$	0.636

DM, diabetes mellitus; FiLaC, fistula-tract laser closure; FIPS, fistulotomy with primary sphincteroplasty; HTN, hypertension.

Table 2 Operative data

	Group A (FiLaC) [*n* (%)]	Group B (FIPS) [*n* (%)]	Test of significance	
			Test value	*P* value
Operative time (minutes)	24.70 (4.334)	35.10 (7.659)	$t=-8.356$	0.000
Probe fitting				
1.5 mm	38 (76)			
3 mm	12 (24)			
Hospital stay (days)	1 ± 0	2.94 ± 1.202	$t=-11.411$	0.000

FiLaC, fistula-tract laser closure; FIPS, fistulotomy with primary sphincteroplasty.

After 6 months, three more patients in group A developed recurrence of their previous symptoms (total 13) compared with only one more case in group B (total three). WS did not show any change among patients in group A, with improvement in group B (*N*=3 and WS=1 in two patients and 2 in one patient).

Follow-up after a year since surgery showed no more recurrences within group A, whereas only one more patient (total 4) had recurrence in group B, with no change in the continence level of patients in both groups, as shown in Table 3.

Of the 13 patients in group A who developed recurrence upon follow-up, six underwent successful redo of FiLaC procedure (re-FiLaC), whereas it failed in another three patients, who were eventually treated with FIPS, in addition to four patients who refused to undergo re-FiLaC.

Table 3 Follow-up data

Follow-up	Group A (FiLaC) [*n* (%)]	Group B (FIPS) [*n* (%)]	Test of significance	
			Test value	*P* value
1st week				
Bleeding				
No	49 (98)	48 (96)	Fisher exact test[a]	1.00
Yes	1 (2)	2 (4)		
Infection				
No	50 (100)	44 (88)	Fisher exact test[b]	0.027
Yes	0	6 (12)		
VAS	3.54±0.813	6.50±1.389	*t*=−13.005	0.000
1st month				
Healing				
No	16 (32)	20 (40)	χ^2=0.694	0.405
Yes	34 (68)	30 (60)		
WS				
0	48 (96)	46 (92)		
1	2 (4)	–		
2	–	2 (4)		
3	–	2 (4)		
VAS	0.74±0.751	2.94±0.867	*t*=−13.565	0.000
3rd month				
Recurrence				
No	40 (80)	48 (96)	χ^2=6.061	0.014
Yes	10 (20)	2 (4)		
WS				
0	50 (100)	46 (92)		
1	–	2 (4)		
2	–	1 (2)		
3	–	1 (2)		
VAS	0.40±0.086	0.673±0.095	*t*=−1.406	0.163
6th month				
Recurrence				
No	37 (74)	47 (94)	χ^2=7.440	0.006
Yes	13 (26)	3 (6)		
WS				
0	50 (100)	47 (94)		
1	–	2 (4)		
2	–	1 (2)		
12th month				
Recurrence				
No	37 (74)	46 (92)	χ^2=5.741	0.017
Yes	13 (26)	4 (8)		
WS				
0	46 (92)	47 (94)		
1	3 (6)	2 (4)		
2	1 (2)	1 (2)		

FiLaC, fistula-tract laser closure; FIPS, fistulotomy with primary sphincteroplasty; VAS, visual analog scale; WS, Wexner score.

Regarding patients in group A, a Pearson product-moment correlation was run to determine the relationship between MRI fistula length and recurrence up to 12 months. We noticed a statistically insignificant weak negative correlation between them (r=–0.101, P>0.05) and a weak positive one between percentage of sphincter affection and recurrence up to 12 months (r=0.147, P>0.05). However, studying the relationship between intraoperative fistula caliber and recurrence up to 12 months, it was noticed that there was a highly significant strong negative correlation between good fitting of fistula tracts on the 1.5-mm malleable metal probe and recurrence (r=–0.628, P<0.01).

Discussion

Treating different types of anal fistulas continues to be a surgical challenge owing to the high incidence of postoperative complications such as recurrences and sphincteric function affection reported with many procedures [9].

FIPS is an available technique for treating complex anal fistulas aiming at eradication of infection and anatomical reconstruction of the muscular defect [8,10]. It is usually associated with high healing rates but may have serious postoperative complications such as fecal incontinence, especially in high fistulas [11,12].

FiLaC is a recent minimally invasive sphincter-preserving technique described in the literature for the treatment of complex anal fistulas. The denaturation effect of the laser energy is confined to the lumen of the fistula, with no impairment of sphincter function [9].

To the best of our knowledge, this is the first study to compare the outcomes to these two techniques for the management of transsphincteric anal fistulas. The age and sex distribution of the patients in our study were approximately to that in the literature, which describe that the mean age for presentation of perianal abscess and fistula disease is 40 years (range, 20–60) and adult males have twice chance to develop them compared with women [13,14].

Comparison between both groups regarding the mean operative time and hospital stay was in great favor for the FiLaC procedure. This was in accordance with Giamundo *etal.* [15] who reported that the mean operative time for FiLaC procedure in their study was about 20 min (range, 6–30 min); this is slightly lower time compared with our study, which may be owing to that they did not perform internal opening closure and relied on its closure by the laser shrinkage effect and owing to different type of fistulas included in their study. In a recent study by Almahfooz [16], the median operative time for FiLaC was 18 min (range, 10–32 min), and patients were discharged on the same day of the operation. On the contrary, our results for FIPS procedure were slightly different from the results of the study by Ratto *etal.* [8], which stated that the mean duration of fistulotomy with end-to-end primary sphincteroplasty for anal fistula was 20.9 min (range, 12–26 min) and the mean length of postoperative stay was 1.3 days (range, 0–4).

Following up the patients one week after surgery showed that FiLaC procedure had great outcomes and very low rate of early complications with low mean VAS score for pain compared with FIPS; however, VAS score for pain continued to decrease with time and ended with very low, with insignificant scores for both groups by the third month of follow-up. This was in accordance with Giamundo *etal.* [9], who reported that postoperative morbidity after FiLaC in their study included temporary pain and animus in eight (18%) of 45 cases and bleeding in three (6%) cases, whereas the median VAS for postoperative pain was 3.0 during the first week. Marref *etal.* [17] also reported that the postoperative course of their patients was uneventful with no significant complications or major pain (VAS<3). Ratto *etal.* [8] documented in their study that none of the patients experienced any degree of local or systemic sepsis or fever after FIPS. In one (1.4%) male patient, a sphincter dehiscence occurred 5 days after the surgery, and he underwent a second FIPS procedure 1 month after that.

Recurrence rates upon follow-up of the patients in our study up to 12 months after the operation showed better results within the FIPS group. In the first original article describing FiLaC using the same laser technique by Wilhelm [7], nine of the 11 (81.8%) fistula patients healed primarily upon mean follow-up of 7.4 months (range, 2–11 months), whereas Giamundo *etal.* [15] found that 25 of 35 patients were cured from their symptoms giving a healing rate of 71.4%, and on extension of their study in 2015 [9] to include 45 patients for longer duration of follow up, no serious changes were reported. A healing rate of 82% was also reported by Ozturk and Gulcu [18] who utilized a plastic brush to curette the interior of the fistula tract before inserting the laser probe. In 2017, Wilhelm *etal.* [19] studied the long-term outcome of FiLaC in a large cohort of patients with anal fistula (104 cryptoglandular and 13 Crohn's disease) and found that the primary overall healing rate was 64.1%. The secondary healing rate in their study was about 88.0%, without a significant difference between the cryptoglandular and Crohn's groups. Moreover, Marref

etal. [17] concluded from their study on 69 patients that FiLaC is particularly effective in cases of high transsphincteric fistulas (60% healing rate).

The recurrence rate described in the literature for the FIPS procedure varied largely since 1985 till 2021, ranging from 0 to 16% according to the type and complexity of the fistulas [8,20–23]. Our results were in best agreement with the study by Arroyo *etal.* [21], who reported a recurrence rate of 8.6% of patients (*N*=70) with complex anal fistula upon a mean follow-up time of 81 months. Recently, Litta *etal.* [22] published a study of 203 patients with anal fistula and reported a recurrence rate of 7%, with a mean follow-up period of 56 months. In a more recent large study on 107 patients by Aguilar-Martínez *etal.* [23], the overall recurrence rate after 90 days was about 16%, with slightly more affection in high fistulas more than nonhigh ones (16.2 vs. 15.7%).

Assessment of the continence level upon follow-up of the patients in our study showed very good outcomes with very minimal affection in both groups, especially within the FiLaC group. This goes well with a previous study by Wilhelm [7], who reported that only a minor form of type 1–2 incontinence (soiling) was observed after FiLaC in his study and lasted for 6 months till was successfully managed, whereas Giamundo *etal.* [15] and Marref *etal.* [17] reported that no new cases of anal incontinence or aggravation of preexisting anal incontinence were observed upon follow-up of the patients in their studies.Incontinence rates after FIPS procedure in the literature are variable, ranging from 3.6 to 21.7% [8–24] again according to the type and complexity of the fistulas included in the studies. In two consecutive studies done by Ratto *etal.* [8,25] on a large cohort of patients, they reported nearly close incontinence rates of 11.6 and 12.4%. In the recent study of Aguilar-Martínez *etal.* [23], 11.2% of the patients showed deterioration in continence at the end of follow-up, 36.5% improved, and 52.3% had no change in their WS taking into consideration that almost 37% of the patients in this study had some degree of fecal incontinence before the operation.

It was noticed from correlation studies that decreasing the length of the fistula tract and/or increasing the percentage of the sphincter involvement by MRI causes increase in the recurrence rate up to 12 months within the FiLaC group. This was supported by the study of Marref *etal.* [17], who suggested that FiLaC was significantly more effective in case of high transsphincteric fistula, and they explained that because of the long fistulous tracts, which were easier to close. However, this was inconsistent with the unexplained results of the study by Lauretta *etal.* [26], who reported very low healing rate (33.3%) and surprisingly found that only the fistula length had a significant positive correlation with healing, as tracts shorter than 3 cm were associated with a primary healing rate of 58.3%, whereas tracts longer than 3 cm were healed in only 16.6% of patients.

Studying the relationship between intraoperative fistula caliber and recurrence rate up to 12 months revealed that good fitting of fistula tracts on the 1.5-mm malleable metal probe decreases the recurrence rates markedly. This probe size was the closest one to the size of the used laser probe in our study, which gives a good indicator for better results and less recurrence.

Conclusion

FiLaC had great outcomes in treating transsphincteric anal fistula in patients with long fistula tracts and appropriate caliber in relation to laser probe, whereas FIPS remained a good option with low recurrence and minimal affection of the continence.

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Nil.

Conflicts of interest

No conflict of interest.

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