RESEARCH PAPER

Short-term clinical healing and postoperative outcomes after FiLaC versus conventional open surgery for cryptoglandular fistula-in-ano: A prospective non-randomized comparative study

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ABSTRACT

Background: Fistula-in-ano is a challenging condition where surgical management aims to eradicate sepsis and promote tract healing while preserving faecal continence. Fistula tract laser closure (FiLaC™) is a sphincter-preserving, minimally invasive technique designed to minimize tissue trauma. This study compared the clinical healing, postoperative pain, continence outcomes, and wound care requirements of FiLaC™ with conventional open surgery for cryptoglandular fistula-in-ano.

Methods: In this prospective, non-randomized comparative study conducted between August 2019 and August 2020 at a single tertiary hospital, 70 adult patients with confirmed cryptoglandular fistula-in-ano were allocated based on informed choice to either the FiLaC™ procedure (n = 35) or conventional surgery (fistulectomy/fistulotomy, n = 35). The primary outcome was clinical healing at 12 weeks. Secondary outcomes included healing at 2 weeks, Visual Analogue Scale (VAS) pain scores at 6, 12, and 24 hours, hospital dressing requirements, and faecal incontinence assessed by the Wexner score through 12 weeks.

Results: Operative time was significantly longer in the FiLaC™ group compared to the conventional group (66.0 ± 20.0 vs 57.8 ± 5.3 minutes; p = 0.023). Postoperative VAS pain scores were significantly lower in the FiLaC™ group at 12 hours (1.8 ± 1.0 vs 3.5 ± 1.1; p < 0.001) and 24 hours (1.4 ± 0.9 vs 2.1 ± 0.8; p < 0.001), although no difference was noted at 6 hours. FiLaC™ patients required significantly fewer hospital dressings (1.3 ± 0.7 vs 3.1 ± 0.9; p < 0.001). Clinical healing rates did not differ significantly at 2 weeks (88.6% vs 100.0%; p = 0.114) or at 12 weeks (80.0% vs 97.1%; p = 0.055). Minor early faecal incontinence was uncommon and resolved in all FiLaC™ patients by 2 weeks, with no statistically significant differences between groups across follow-up intervals.

Conclusion: FiLaC™ significantly reduces early postoperative pain and wound dressing needs compared with conventional surgery, with minimal risk to continence and acceptable short-term healing. While conventional surgery demonstrated a trend toward higher 12-week clinical healing, FiLaC™ represents a viable sphincter-sparing option when minimizing postoperative morbidity is prioritized.

Keywords: *Fistula-in-ano; FiLaC; Diode laser; Fistulectomy; Fistulotomy; Sphincter-preserving surgery; Faecal continence.*

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1. INTRODUCTION

Fistula-in-ano is a chronic condition that consists of abnormal epithelialized tract extending from the lumen of the anorectum and perianal skin. About 90% of anal fistulae are cryptoglandular in origin, which means that they are caused by infection of the anal glands and subsequent abscess formation.[1,2] Non-cryptoglandular causes include Crohn's disease, tuberculosis, malignancy, and other rare causes.[3]

Although surgical care has improved over the years, the management of fistula is still a challenge, and the main objectives are to eradicate sepsis, heal the tract, and preserve continence.[3,4] The estimated incidence is 8.6–10 cases per 100,000 population every year, is more common in men, and has a peak presentation age of between 20 and 50 years.

Although the traditional approach has a strong healing rate, the pain after surgery, possible disturbance of continence and need for a long time of wound treatment exist especially in the case of the complex disease.

To address these limitations, minimally invasive techniques have been developed (such as Fistula tract Laser Closure [FiLaC™], Video-Assisted Anal Fistula Treatment [VAAFT] and Ligation of the Intersphincteric Fistula Tract [LIFT]), which use a 1470 nm diode laser to deliver radial radiation to ablate the fistula tract epithelium and crypt glands, and simultaneously obliterate the internal and external openings to the fistulae, thereby theoretically minimizing recurrence from unrecognized tracts and/or remaining epithelium.[5]

There is still a lack of comparative data between FiLaC™ and conventional open surgery. The objective of this study

was to compare FiLaC™ with conventional fistulectomy/fistulotomy on clinical healing, postoperative pain, faecal continence and wound care needs.

2. MATERIALS AND METHODS

2.1 Study design and setting

This prospective, non-randomized comparative study was conducted in the Department of General and Minimal Access Surgery, Manipal Hospital, Bengaluru, India, from 10 August 2019 to 10 August 2020. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants.

2.2 Study population

The criteria for inclusion of adult patients (age 18–80) were clinically diagnosed and radiologically confirmed (TRUS or MRI) cryptoglandular fistula-in-ano, normal preoperative continence, and scheduled for elective surgery. Fistulae associated with Crohn's disease, tuberculosis, lymphogranuloma venereum, actinomycosis, rectal duplication, foreign bodies or malignancy were excluded. Uncontrolled diabetes mellitus and patients who could not or were not willing to be followed up were also excluded.

2.3 Allocation

If eligible for inclusion, patients were recruited consecutively. Patients underwent counselling regarding both the risks, benefits and costs of FiLaC™ versus conventional surgery and then opted for the procedure of their choice. Randomization was not conducted because FiLaC™ is a newer, more expensive method which was not universally accepted.

Patients were randomized into:

Group A (FiLaC): FiLaC™ procedure.

Group B (Conventional): Fistulectomy and/or fistulotomy.

2.4 Preoperative preparation

Overnight fasting, antibiotic prophylaxis (ornidazole 500 mg and ofloxacin 200 mg intravenously) and a proctoclysis enema were provided to all the patients. The routine intraoperative monitoring was applied. Procedures were performed under spinal or general anaesthesia in the lithotomy position.

2.5 Surgical techniques

FiLaC™

After identifying the external and internal openings, a fistula probe was passed through the tract. Hydrogen peroxide was instilled if the internal opening was unclear. A radial-emitting 1470-nm diode laser probe (Biolitec®) was introduced via a guide tube. The tract was ablated at 12 watts in continuous mode (1 mm/sec; slower initially for crypt glands). The internal opening was closed with a 3-0 polyglactin purse-string suture; the external opening was curetted.

Conventional surgery Fistulotomy involved laying open the tract along the probe and curetting the base. Fistulectomy involved circumferential excision of the tract. Individual procedure types within the conventional group were not consistently recorded and were analysed as a heterogeneous group.

2.6 Postoperative care

Surgical duration was recorded. Pain was assessed at 6, 12, and 24 hours using VAS. Intravenous antibiotics were continued postoperatively. Patients were discharged with instructions for sitz baths, stool softeners, and topical lignocaine. Faecal incontinence was assessed using the Wexner score at 24 hours, 2 weeks, and 12 weeks.

2.7 Outcome measures

Primary outcome: Clinical healing at 12 weeks (cessation of discharge, absence of fistula-related pain, and closure of external opening).

Secondary outcomes: Clinical healing at 2 weeks; postoperative pain scores (6, 12, 24 hours); faecal incontinence (24 hours, 2 weeks, 12 weeks); number of hospital dressings.

2.8 Statistical analysis

Data were analysed using R version 3.2.3. Continuous variables were expressed as mean ± SD; categorical variables as counts and percentages. Independent t-tests were used for continuous variables and chi-square or Fisher's exact tests were used for categorical variables. Statistically significant results were considered to be a two-sided p value of <0.05.

3. OBSERVATIONS AND RESULTS

Seventy patients meeting the inclusion criteria were enrolled: 35 in the FiLaC group and 35 in the conventional surgery group (Figure 1). Baseline characteristics, operative details, and postoperative outcomes are summarized in Tables 1–5.

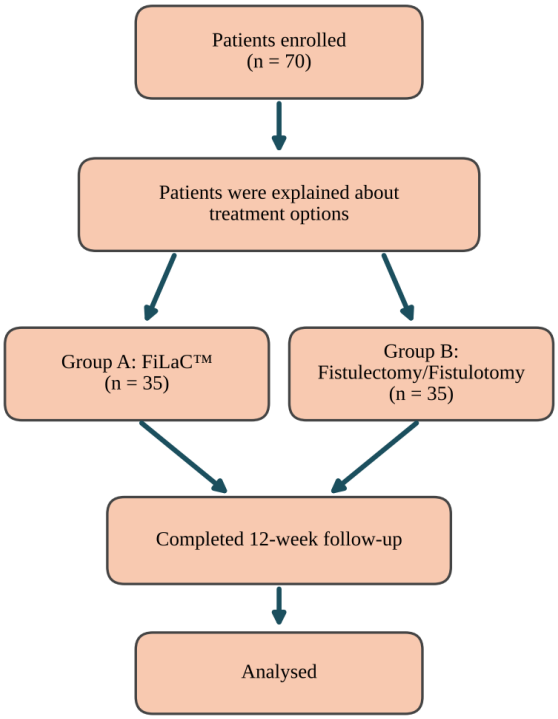


Figure 1. CONSORT-style flow diagram of patient enrollment, allocation, and follow-up.

3.1 Baseline characteristics

The overall mean age was approximately 43 years; the majority were male (91.4%) and ASA grade I (62.9%). Mean age was significantly higher in the FiLaC group (46.7 ± 14.7 vs 39.7 ± 11.5 years; $p = 0.030$), and the FiLaC group had a higher ASA grade distribution ($p < 0.001$). Gender, comorbidities (diabetes and hypertension), Park's classification, duration of symptoms, and history of previous perianal surgery were comparable between groups (Table 1).

Intersphincteric fistulae (Park's type A) were most common (65.7%), followed by transsphincteric (17.1%) and

suprasphincteric (17.1%) types, with no significant difference between groups (p = 0.416) (Table 1).

Variable	FiLaC (n = 35)	Conventional (n = 35)	p value
Age, mean ± SD (years)	46.7 ± 14.7	39.7 ± 11.5	0.030
Male sex, n (%)	31 (88.6)	33 (94.3)	0.670
ASA grade, n (%)			< 0.001
– Grade I	13 (37.1)	31 (88.6)	
– Grade II	20 (57.1)	4 (11.4)	
– Grade III	2 (5.7)	0	
Diabetes mellitus, n (%)	6 (17.1)	5 (14.3)	0.742
Hypertension, n (%)	8 (22.9)	3 (8.6)	0.101
Park's classification, n (%)			0.416
– Intersphincteric (A)	22 (62.9)	24 (68.6)	
– Transsphincteric (B)	5 (14.9)	7 (20.0)	
– Suprasphincteric (C)	8 (22.9)	4 (11.4)	
Duration of symptoms, mean ± SD (months)	5.1 ± 4.1	4.8 ± 3.2	0.218
Previous perianal surgery, n (%)	9 (25.7)	6 (17.1)	0.906

Table 1. Baseline characteristics of study population

Data are mean ± SD or n (%). p values from independent t-test (age, duration), chi-square or Fisher's exact test (categorical variables).

3.2 Operative details and postoperative course

All patients in Group A underwent FiLaC™. In Group B, 31 patients (88.6%) underwent fistulectomy and 4 (11.4%) fistulotomy; however, procedure types within the conventional group were not consistently recorded and were analysed as a heterogeneous group.

Mean operative time was longer in the FiLaC group (66.0 ± 20.0 vs 57.8 ± 5.3 minutes; p = 0.023) (Table 2). All patients were discharged 24–36 hours after surgery (on postoperative day 1).

Variable	FiLaC (n = 35)	Conventional (n = 35)	p value
Procedure type, n (%)			–
– FiLaC	35 (100)	–	
– Fistulectomy	–	31 (88.6)	
– Fistulotomy	–	4 (11.4)	
Operative time, mean ± SD (minutes)	66.0 ± 20.0	57.8 ± 5.3	0.023

Table 2. Operative details

Individual procedure types within the conventional group were not consistently recorded and were analysed as a heterogeneous group.

3.3 Postoperative pain

There were no differences in mean pain scores at 6 hours between the groups. At 12 and 24 hours, pain scores were significantly lower in the FiLaC group (12 h: 1.8 ± 1.0 vs 3.5 ± 1.1, p < 0.001; 24 h: 1.4 ± 0.9 vs 2.1 ± 0.8, p = 0.001) (Table 3).

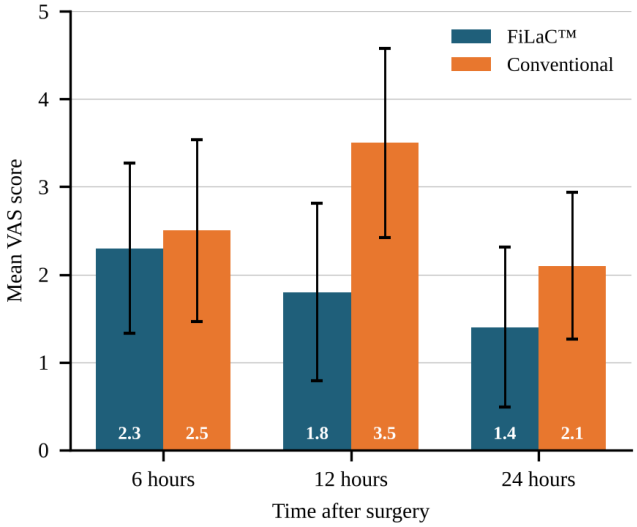


Figure 2. Mean postoperative pain scores (Visual Analogue Scale) at 6, 12, and 24 hours after FiLaC versus conventional open surgery.

3.4 Wound dressings

The mean number of hospital dressings was lower in the FiLaC group (1.3 ± 0.7 vs 3.1 ± 0.9; p < 0.001). In the FiLaC group, 77.1% required only one dressing, compared with none in the conventional group (Table 3).

Variable	FiLaC (n = 35)	Conventional (n = 35)	p value
Pain score (VAS), mean ± SD			
– 6 hours	2.3 ± 1.0	2.5 ± 1.0	0.478
– 12 hours	1.8 ± 1.0	3.5 ± 1.1	**< 0.001**
– 24 hours	1.4 ± 0.9	2.1 ± 0.8	**<0.001**
Hospital dressings, mean ± SD	1.3 ± 0.7	3.1 ± 0.9	**< 0.001**

Table 3. Postoperative pain and wound dressings

Footnote:

VAS, Visual Analogue Scale (0 = no pain, 10 = worst imaginable pain). p values from independent t-test.

3.5 Clinical healing at 2 and 12 weeks

At 2 weeks, clinical healing was observed in 31/35 (88.6%) FiLaC patients and 35/35 (100%) conventional surgery patients (p = 0.114). At 12 weeks, healing was observed in 28/35 (80.0%) FiLaC patients and 34/35 (97.1%) conventional surgery patients (p = 0.055) (Table 4).

Time point	Group	Healed, n (%)	Not healed, n (%)	p value
2 weeks	FiLaC	31 (88.6)	4 (11.4)	0.114
	Conventional	35 (100)	0	
12 weeks	FiLaC	28 (80.0)	7 (20.0)	**0.055**
	Conventional	34 (97.1)	1 (2.9)	

Table 4. Clinical healing at 2 and 12 weeks

Footnote:
Clinical healing defined as cessation of discharge, absence of fistula-related pain, and closure of the external opening on examination. p values from chi-square or Fisher's exact test.

3.6 Faecal incontinence

Minor incontinence for gases and/or liquids at 24 hours occurred in 8.6% of FiLaC patients and 11.4% of conventional surgery patients (p = 0.999). At 2 weeks, incontinence was reported in 11.4% of the conventional group and none in the FiLaC group (p = 0.114). At 12 weeks, one patient (2.9%) in the conventional group and none in the FiLaC group reported minor incontinence (p = 0.999) (Table 5).

Time point	Group	Incontinence, n (%)	No incontinence, n (%)	p value
24 hours	FiLaC	3 (8.6)	32 (91.4)	0.999
	Conventional	4 (11.4)	31 (88.6)	
2 weeks	FiLaC	0	35 (100)	0.114
	Conventional	4 (11.4)	31 (88.6)	
12 weeks	FiLaC	0	35 (100)	0.999
	Conventional	1 (2.9)	34 (97.1)	

Table 5. Faecal incontinence

Footnote:
Incontinence assessed using the Wexner Faecal Incontinence Score; any score > 0 considered as incontinence. p values from Fisher's exact test.

4. DISCUSSION

In this prospective, non-randomized comparative study of 70 patients with cryptoglandular fistula-in-ano, FiLaC™ was associated with significantly lower postoperative pain and fewer hospital dressings than conventional open surgery (fistulectomy/fistulotomy). Conventional surgery showed a higher observed clinical healing rate at 12 weeks (97.1% vs 80.0%), although this difference did not reach conventional statistical significance (p = 0.055). Short-term faecal incontinence was infrequent and did not differ significantly between groups.

Baseline differences in age and ASA grade favouring the conventional group, the non-randomized design, small sample size, and 12-week follow-up limit causal inference. Nonetheless, the findings support FiLaC™ as a feasible sphincter-preserving alternative in selected patients, particularly when reduced postoperative morbidity is prioritized, but do not establish equivalence or superiority over conventional surgery. Previous systematic reviews similarly describe FiLaC™ as a potentially effective sphincter-saving treatment while emphasizing the predominantly observational nature of the evidence and the need for randomized comparative trials.[6]

4.1 Comparison with existing literature

Our cohort reflected the typical demographic profile reported in the fistula literature: mean age around 40–50 years and a marked male preponderance. [7-10] The predominance of intersphincteric fistulae is consistent with the anatomical classification described by Parks et al.; however, several FiLaC™ series have reported transsphincteric fistulas as the most frequent subtype.[11-13]

The operative time was significantly longer with FiLaC™ than with conventional surgery. This contrasts with early FiLaC™ series, in which reported operative times were approximately 18–20 minutes. Giamundo et al. reported a median operative time of 20 minutes, with a range of 6–35 minutes, in an early series.Longer operative time in our study may reflect fistula complexity, the time required to identify and cannulate the tract, guide-tube placement, and the institutional learning curve associated with adoption of the technology.[9]

The minimally invasive nature of this procedure and previous reports of decreased early pain after laser ablation may have been responsible for the improvement seen in the FiLaC™ group at 12 and 24 hours postoperatively.[14]

The number of hospital dressings was also significantly reduced after FiLaC™, aligning with the smaller wound surface and reduced tissue trauma compared with open excision or laying open of the tract.[15]

Clinical healing at 12 weeks was higher after conventional surgery than after FiLaC™ (97.1% vs 80.0%; p = 0.055). The healing rate in the conventional group is consistent with the high early healing rates reported after appropriately selected fistulotomy. Hyman et al. reported healing in 87% of patients at 3 months after fistulotomy, while Tozer et al. reported an overall cure rate of 93% in a tertiary-care fistulotomy cohort.[16,17]

Reported FiLaC™ healing rates vary substantially according to fistula complexity, previous surgery, case mix, surgeon experience, outcome definition, and follow-up duration. Early FiLaC™ studies reported primary healing rates of approximately 64–71%, while systematic review data have reported a weighted mean primary healing rate of 67.3% at a median follow-up of 23.7 months. Our 80% healing rate therefore lies toward the higher end of previously reported short- to intermediate-term results. However, the 12-week follow-up in the present study precludes firm conclusions regarding durability or late recurrence, because recurrence may become apparent only after longer follow-up[6,7,18]

Short-term incontinence rates were low in both groups and did not differ significantly at 12 weeks. This is consistent with FiLaC™ studies reporting minimal or no postoperative incontinence and with systematic review evidence showing a very low pooled rate of continence impairment.[8-10]

Early postoperative continence symptoms may be related to pain, altered stool consistency, local inflammation, or transient anorectal dysfunction rather than permanent sphincter injury; however, the present study was not designed to distinguish these mechanisms. Therefore, this explanation should be regarded as a possible interpretation rather than a demonstrated mechanism.

When placed in the context of existing FiLaC™ series, our findings show comparable or higher short-term healing, very low incontinence, and the expected advantages of reduced early pain and wound-care requirements.[7-10,17,19]

However, the shorter follow-up, small sample size, baseline group differences, and non-randomized design preclude direct comparison of effectiveness or conclusions regarding equivalence or superiority between FiLaC™ and conventional surgery.

4.2 Strengths and limitations

This study has its merits: It was prospective; Perioperative protocols were standardized; Head to head comparison of FiLaC™ with conventional open surgery in one centre. It is the first study from this region to directly compare these approaches for cryptoglandular fistula in ano, as far as we know.

There are some important limitations to be recognized. Treatment allocation was by choice not by chance, and there was significant imbalance with respect to age and ASA grade. There was a small number of patients (n=100) which meant that the power to detect differences in less common outcomes like incontinence or persistent disease was limited. The follow-up was limited to 12 weeks, which is enough for early healing, but not for making a conclusion on the long-term recurrence. The conventional surgery group included a wide variety of fistulectomy and fistulotomy surgeries that were not clearly documented, with some surgeries not being consistently documented, so procedure specific conclusions could not be made. Lastly, clinical assessment of healing was used, not routine radiological confirmation.

The limitations indicate that the findings need to be viewed with caution, especially their findings about healing. Randomized trials of longer follow up duration with objective continent assessment (e.g. endoanal manometry) and cost effectiveness analysis is needed to further help determine the role of FiLaC™ versus traditional surgery.

5. CONCLUSIONS

In this prospective, non randomized study, postoperative pain and the number of hospital dressing were significantly reduced in patients undergoing for fistula in ano that had FiLaC™ as part of their treatment. Observed clinical healing rate was higher at 12 weeks in conventional surgery, but the difference was not statistically significant. Both groups had very few short term faecal incontinence cases.

FiLaC™ may be seen as a sphincter preserving alternative in carefully selected patients, especially if a preference for reduced postoperative morbidity is the top priority, but not as a replacement for conventional surgery in all patients.

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