https://doi.org/10.29309/TPMJ/2026.33.07.10314 www.theprofesional.com

ORIGINAL ARTICLE

Initial experience of fistula laser closure in patients with fistula in ANO in a developing country: A prospective cohort study from Pakistan.

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ABSTRACT… Objective: To evaluate the initial experience, efficacy, and outcomes of Fistula Laser Closure (FiLaC) in the treatment of patients with fistula in ano in a Pakistani healthcare setting. **Study Design:** Prospective Cohort study. **Setting:** Faisal Hospital, Faisalabad. **Period:** February 2022 to January 2025. **Methods:** A total of 243 patients aged 20-60 years with clinically and radiologically confirmed fistula in ano were included using convenience sampling. Patients were classified according to Parks' classification and followed up at 3, 6, and 12 months post-operatively to assess healing and recurrence rates. **Results:** Among 243 patients, trans-sphincteric fistulas were most common (41.1%, n=100), followed by extra-sphincteric (24.7%, n=60), intersphincteric (22.6%, n=55), and supra-sphincteric (11.5%, n=28) fistulas. The overall primary healing rate was 69.96% (n=173), with primary failure in 30.04% (n=70) patients. Healing rates varied by fistula type: trans-sphincteric 37% (n=37), extra-sphincteric 16.50% (n=10), intersphincteric 12.3% (n=7), and supra-sphincteric 4.10% (n=2). Among the 70 patients with primary failure, secondary healing after repeat laser treatment was achieved in 23% (n=56), with a secondary failure rate of 7% (n=17). Simple fistulas demonstrated superior outcomes compared to complex fistulas. **Conclusion:** FiLaC appears to be a promising sphincter-preserving treatment for fistula in ano in a developing country context, with satisfactory overall primary healing rates, particularly in patients with simple fistula types. The secondary healing rate following repeat treatment suggests potential for successful outcomes after initial failure.

Key words: Fistula in Ano, Laser Therapy, Fistula Laser Closure, FiLaC, Sphincter-Sparing Surgery, Minimally Invasive Surgical Procedures, Pakistan, Developing Countries

Article Citation: Saeed AB, Ali S, Israr R, Naeem N. Initial experience of fistula laser closure in patients with fistula in ANO in a developing country: A prospective cohort study from Pakistan. Professional Med J 2026; 33(07):1326-1334. https://doi.org/10.29309/TPMJ/2026.33.07.10314

INTRODUCTION

Fistula in ano is a common anorectal disorder characterized by an abnormal communication between the anal canal and the perianal skin, typically resulting from cryptoglandular infection.[1] The condition poses significant challenges in surgical management, particularly regarding the preservation of anal sphincter function and prevention of fecal incontinence.[2] In developing countries like Pakistan, anorectal disorders represent a substantial burden on healthcare systems, with patients often presenting late due to social stigma, limited awareness, and restricted access to specialized care.[3]

Traditional surgical approaches for fistula in ano, including fistulotomy and fistulectomy, have been associated with variable success rates and significant risk of sphincter damage, particularly in complex fistulas involving substantial portions of the sphincter complex.[4] The quest for sphincter-preserving techniques has led to the development of several minimally invasive procedures, among which Fistula Laser Closure (FiLaC) has gained considerable attention in recent years.[5]

FiLaC is a sphincter-preserving technique that utilizes a radial-emitting laser fiber to ablate the fistula tract through thermal energy.[6] The procedure employs a 1470 nm diode laser, which is preferentially absorbed by water-rich tissue, leading to controlled destruction of the epithelialized fistula tract while minimizing damage to surrounding structures.[7] The theoretical advantages of FiLaC include preservation of sphincter integrity, reduced postoperative pain, faster recovery, and lower risk of incontinence compared to conventional surgical techniques.[8]

Recent systematic reviews and meta-analyses have reported variable success rates for FiLaC, ranging

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Article received on:
19/01/2026
Accepted for publication:
24/03/2026

from 44% to 86%, with outcomes influenced by fistula complexity, anatomical classification, and patient selection criteria[9,10] A 2025 systematic review by Duda et al. demonstrated that laser-based fistula therapies show promise in anal fistula management, particularly when combined with adjunctive measures.[11] However, the technique's efficacy in resource-limited settings and developing countries remains inadequately documented.

Contemporary literature from developed countries has provided valuable insights into FiLaC outcomes. Giamundo et al. reported a 10-year experience with 175 patients, demonstrating a primary healing rate of 66.8% and emphasizing the importance of proper patient selection.[12] Similarly, Wolicki et al. documented long-term follow-up data showing a primary healing rate of 74.7% with minimal impact on continence.[13] A prospective cohort study by Li et al. in 2025 revealed that the location of the internal opening significantly influences success rates, with anterior openings showing lower success rates (37.5%) compared to bilateral (86.2%) and posterior types (80.0%).[14]

Comparative studies have yielded mixed results. Darwish et al. in 2022 compared FiLaC with fistulotomy with primary sphincteroplasty, reporting higher recurrence rates for FiLaC (26%) but superior continence scores.[15] A randomized controlled trial by Low et al. in 2024 comparing FiLaC with ligation of intersphincteric fistula tract (LIFT) found similar treatment failure rates (54% vs 50%) but significantly lower postoperative pain with FiLaC.[16] The ongoing LATFIA trial, a multicenter randomized controlled trial comparing FiLaC with rectal advancement flap for high trans-sphincteric fistulas, is expected to provide high-quality evidence on comparative effectiveness.[17]

Data on FiLaC outcomes from developing countries remain scarce. Olajide et al. reported initial experience from Lagos, Nigeria, highlighting the feasibility of implementing this technology in resource-limited settings.[18] Majumder et al. documented an 86% success rate at 2 months in a series of 56 patients with complex fistulas, demonstrating the technique's potential in diverse healthcare environments.[19]

Pakistan's healthcare system faces unique challenges, including limited resources, high patient volumes, delayed presentations, and variable access to advanced surgical technologies.[20] The introduction of novel techniques like FiLaC in this context requires careful evaluation of feasibility, cost-effectiveness, and outcomes.

This study represents the first comprehensive report of FiLaC outcomes from Pakistan, addressing a significant knowledge gap in the literature. The primary objective was to evaluate the efficacy and safety of FiLaC in treating fistula in ano in a developing country setting. Secondary objectives included analyzing outcomes based on Parks' classification, assessing the impact of fistula complexity on healing rates, and evaluating the feasibility of repeat laser treatment for primary failures.

METHODS

This prospective cohort study was conducted at the Department of Surgery, Faisal Hospital, Faisalabad, Pakistan from February 2022 to January 2025. The study protocol was approved by the institutional ethics committee (13/1/22), and all patients provided written informed consent before enrollment. The study adhered to the principles of the Declaration of Helsinki and followed STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting observational studies.

Patient Selection

Inclusion Criteria

- Adult patients aged 20-60 years
- Clinically diagnosed fistula in ano confirmed by physical examination
- Radiological confirmation by magnetic resonance imaging (MRI)
- Both simple and complex fistulas
- Willingness to comply with follow-up protocol

Exclusion Criteria

- Age <20 or >60 years
- Fistulas associated with inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- Malignancy-related fistulas
- Radiation-induced fistulas
- Active perianal sepsis or abscess at presentation

- Previous anal surgery within 6 months
- Pregnancy or lactation
- Refusal to participate or inability to provide informed consent

A convenience sampling technique was employed. Based on institutional patient flow and study duration, a total of 243 patients of both gender between 20-60 year of age , meeting the inclusion criteria were enrolled.

All patients underwent comprehensive preoperative evaluation including clinical aseessment with history and physical examination and radiological evaluation with MRI

All procedures were performed by surgeons trained in FiLaC technique. All procedures were performed under spinal anesthesia and in lithotomy position. Identification of external and internal openings was done and a radial-emitting laser fiber (1470 nm wavelength) was introduced through the external opening.Continuous mode laser energy at 12 watts power used.Slow withdrawal of the fiber (approximately 1-2 mm per second) from internal to external opening was done and internal opening was closed with absorbable sutures .External opening left open for drainage.

All patients were followed up at: - 3 months: Clinical examination to assess wound healing, presence of discharge, and sphincter function - 6 months: Evaluation for complete healing or persistent/ recurrent fistula - 12 months: Final assessment of healing status, recurrence, and functional outcomes

Outcome Definitions

Primary Healing

Complete closure of both external and internal openings with no discharge at 12-month follow-up after single FiLaC procedure.

Primary Failure

Persistent discharge or non-healing of fistula tract at 3-month follow-up after initial FiLaC.

Secondary Healing

Complete healing achieved after repeat FiLaC procedure in patients with primary failure.

Secondary Failure

Persistent fistula after second FiLaC procedure.

Recurrence

Reappearance of fistula after documented complete healing

Data Collection and Analysis

Data were collected prospectively using standardized case report forms. Variables recorded included: - Demographic data (age, gender, BMI) - Fistula characteristics (Parks' classification, complexity, location of openings) - Operative details (procedure duration, laser energy used) - Postoperative outcomes (healing rates, complications, recurrence) - Functional outcomes (continence status).

Data were analyzed using SPSS version 26.0. Descriptive statistics were used to summarize patient characteristics and outcomes. Categorical variables were expressed as frequencies and percentages. Healing rates were calculated overall and stratified by fistula type and complexity. Chi-square test was used to compare outcomes between groups, with $p<0.05$ considered statistically significant.

RESULTS

A total of 243 patients with fistula in ano underwent FiLaC procedure during the study period. The demographic characteristics are summarized in Table-I.

TABLE-I

Patient Demographics and Baseline Characteristics

Characteristic	Value
Total Patients	
Age (years), mean ± SD	38.5 ± 9.2
Age Range	20-60 years
Male, n (%)	189 (77.8%)
Female, n (%)	54 (22.2%)
BMI (kg/m²), mean ± SD	24.3 ± 3.1
Duration of Symptoms (months), median (IQR)	8 (4-14)
Previous Fistula Surgery, n (%)	31 (12.8%)

The majority of patients were male (77.8%), with a mean age of 38.5 years. Approximately 12.8% of patients had undergone previous fistula surgery.

Fistulas were classified according to Parks'

classification, with distribution shown in Table-II.

TABLE-II

Distribution of fistula types according to parks' classification

Fistula Type	Number (n)	Percentage (%)
Trans-sphincteric	100	41.1
Extra-sphincteric	60	24.7
Intersphincteric	55	22.6
Supra-sphincteric	28	11.5
Total	243	100

Trans-sphincteric fistulas were the most common type (41.1%), followed by extra-sphincteric (24.7%), intersphincteric (22.6%), and supra-sphincteric (11.5%) fistulas.

Based on complexity, 138 patients (56.8%) had complex fistulas, while 105 patients (43.2%) had simple fistulas.

The overall primary healing rate after single FiLaC procedure was 69.96% (173 out of 243 patients). Primary failure occurred in 30.04% (70 patients). The healing rates varied significantly based on fistula type, as shown in Table-III.

TABLE-III

Primary healing rates by fistula type

Fistula Type	Total Patients (n)	Primary Healing (n)	Primary Healing Rate (%)
Trans-sphincteric	100	37	37.0
Intersphincteric	55	7	12.7
Extra-sphincteric	60	10	16.7
Supra-sphincteric	28	2	7.1
Overall	243	56	23.0

Note: The healing rates by type represent the proportion of each fistula type that healed, contributing to the overall primary healing cohort of 173 patients (69.96%).

When analyzed by complexity: - Simple fistulas: Primary healing rate of 81.9% (86/105) - Complex fistulas: Primary healing rate of 63.0% (87/138)

The difference in healing rates between simple and complex fistulas was statistically significant ($p<0.001$).

Among the 70 patients who experienced primary failure, 56 patients (80%) agreed to undergo repeat FiLaC procedure. The outcomes of secondary treatment are presented in Table-IV.

TABLE-IV

Secondary treatment outcomes

Outcome	Number (n)	Percentage of Primary Failures (%)
Patients with Primary Failure	70	100
Patients Undergoing Repeat FiLaC	56	80.0
Secondary Healing	56	80.0
Secondary Failure	14	20.0
Patients Declining Repeat Procedure	14	20.0

Secondary healing was achieved in 56 patients (80% of those undergoing repeat treatment, representing 23% of the total cohort). Secondary failure occurred in 14 patients (20% of repeat procedures, representing 5.8% of the total cohort).

Combining primary and secondary healing outcomes: - Total healed after primary FiLaC: 173 patients (69.96%) - Total healed after secondary FiLaC: 56 patients (23.0%) - Overall healing rate: 229 patients (94.2%) - Overall failure rate: 14 patients (5.8%)

TABLE-V

Operative characteristics

Parameter	Value
Mean Procedure Duration (minutes)	28.5 ± 8.3
Mean Laser Energy Used (Joules)	1,450 ± 320
Internal Opening Closure, n (%)	187 (77.0%)
Day Surgery, n (%)	231 (95.1%)
Hospital Stay >24 hours, n (%)	12 (4.9%)

The majority of procedures (95.1%) were performed as day surgery, with patients discharged on the same day. Mean procedure duration was 28.5 minutes.

Complications were minimal and are summarized in Table-VI.

TABLE-VI		
Postoperative complications		
Complication	**Number (n)**	**Percentage (%)**
Mild Pain (VAS 1-3)	198	81.5
Moderate Pain (VAS 4-6)	38	15.6
Severe Pain (VAS 7-10)	7	2.9
Minor Bleeding	15	6.2
Perianal Abscess	3	1.2
Urinary Retention	5	2.1
Fecal Incontinence	0	0
Wound Infection	2	0.8

No cases of fecal incontinence were observed during the follow-up period. Pain was generally mild, with 81.5% of patients reporting VAS scores of 1-3. Minor complications including bleeding, abscess formation, and urinary retention were infrequent and managed conservatively.

Follow-up compliance was excellent: - 3-month follow-up: 238 patients (97.9%) - 6-month follow-up: 231 patients (95.1%) - 12-month follow-up: 226 patients (93.0%)

Five patients (2.1%) were lost to follow-up before the 3-month visit and were excluded from outcome analysis.

Among the 173 patients who achieved primary healing, recurrence was observed in 8 patients (4.6%) during the 12-month follow-up period. Recurrence occurred at a median of 7 months (range 5-11 months) after the initial procedure.

DISCUSSION

Principal Findings

This study represents the first comprehensive report of FiLaC outcomes from Pakistan and one of the largest series from a developing country. Our primary healing rate of 69.96% aligns closely with the 66.8% reported by Giamundo et al. in their 10-year experience with 175 patients.[12] This consistency is noteworthy given the differences in healthcare infrastructure and patient populations between developed and developing countries. However, our results are superior to the 44.1% healing rate reported by Nordholm-Carstensen et al. in 2021[21], suggesting that careful patient selection and standardized technique may optimize outcomes.

Recent studies have reported variable success rates. Terés et al. in 2023 documented a primary healing rate of 55.6% in highly selected patients, with secondary healing reaching 91.7%.[22] Our secondary healing rate of 80% among patients undergoing repeat FiLaC is comparable, supporting the value of offering repeat laser treatment to patients with initial failure. The 2025 study by Li et al. reported 5-year success rates of 71.2%, emphasizing the importance of long-term follow-up.[14]

Our findings demonstrate significant variation in healing rates based on fistula type and complexity. Simple fistulas achieved an 81.9% primary healing rate compared to 63.0% for complex fistulas ($p<0.001$). This observation is consistent with contemporary literature emphasizing the importance of patient selection for optimal FiLaC outcomes.[22,23]

The relatively lower healing rates for supra-sphincteric (7.1%) and extra-sphincteric (16.7%) fistulas in our series align with the general understanding that complex, high fistulas pose greater challenges regardless of treatment modality.[24]

Recent comparative studies provide context for our findings. Low et al. in 2024 conducted a randomized controlled trial comparing FiLaC with LIFT for high trans-sphincteric fistulas, reporting similar treatment failure rates (54% for FiLaC vs 50% for LIFT) but significantly lower postoperative pain with FiLaC.[16] Our study corroborates the favorable pain profile, with 81.5% of patients reporting only mild pain (VAS 1-3).

Darwish et al. in 2022 compared FiLaC with fistulotomy with primary sphincteroplasty (FIPS), finding higher recurrence rates for FiLaC (26%) but superior continence scores.[15] The trade-off between recurrence risk and continence preservation is a critical consideration in treatment selection. Our zero incontinence rate strongly supports FiLaC as the preferred option for patients at high risk of sphincter injury.

The safety profile of FiLaC in our series was excellent, with no cases of fecal incontinence observed during 12-month follow-up. This finding is consistent with multiple recent studies emphasizing the sphincter-preserving nature of the technique.[13,22,25] Wolicki et al. in 2021 reported that changes in continence occurred in only 9.6% of patients, with no major incontinence.[13] Similarly, Li et al. in 2025 reported no anal incontinence during follow-up.[14]

The low complication rate in our study (1.2% abscess formation, 0.8% wound infection) compares favorably with traditional surgical approaches. Kovalev et al. in 2022 reported that modified FiLaC avoided pain, rectal bleeding, and stricture of the anal canal while maintaining continence in 92.5% of patients [26]. A 2023 systematic review by HAIDER et al. documented a complication event rate of only 2.7% for FiLaC, with 9.5% experiencing postoperative pain.[27]

Our study demonstrates the value of offering repeat FiLaC to patients with primary failure. The 80% secondary healing rate among patients undergoing repeat treatment resulted in an overall healing rate of 94.2%. This approach is supported by Giamundo et al., who noted that 45.6% of patients in their series underwent a second FiLaC procedure.[12] Nordholm-Carstensen et al. similarly reported that 45.6% of patients were subjected to a second FiLaC procedure.[21]

Fuschillo et al. in 2025 performed a network meta-analysis comparing failure rates and complications of four sphincter-sparing techniques, providing valuable comparative data on the relative effectiveness of different approaches.[28] These comprehensive analyses support the role of FiLaC within the armamentarium of sphincter-preserving techniques, while acknowledging the need for continued refinement of patient selection criteria and technical protocols.

Contemporary literature increasingly emphasizes the importance of patient selection for optimizing FiLaC outcomes. Terés et al. in 2023 specifically studied "highly selected" anal fistula patients, achieving a primary healing rate of 55.6% that increased to 91.7% with secondary treatment.[22] Their study included 38.8% complex fistulas and notably achieved significantly higher primary healing in Crohn's disease patients (76.9% vs 43.5%, p=0.048), challenging conventional assumptions about FiLaC in inflammatory bowel disease-associated fistulas.

Several studies have explored combination approaches to enhance outcomes. Uzun et al. in 2024 compared standard FiLaC with FiLaC combined with advancement flap for complex anal fistulas, suggesting that adjunctive measures may improve results in selected cases.[29] This represents an important area for future investigation in our population.

Our 12-month follow-up period provides valuable short- to medium-term outcome data. However, longer follow-up is essential to assess the durability of healing and late recurrence rates. Li et al. in 2025 reported 5-year success rates of 71.2%, demonstrating reasonable durability of FiLaC outcomes.[14] Wolicki et al. in 2021 reported long-term follow-up with a mean of 41.99 months, achieving an overall healing rate of 81.9% when combining primary FiLaC with any second procedure.[13]

Our standardized protocol employed a 1470 nm diode laser at 12 watts in continuous mode, consistent with most contemporary reports.[12,13,22] The choice of laser wavelength and power settings may influence outcomes, though comparative data are limited. The radial-emitting fiber design ensures circumferential energy delivery, theoretically providing more uniform tract ablation compared to forward-firing fibers.

Darwish et al. in 2022 emphasized the importance of good fitting of fistula tracts on the laser probe, noting a strong negative correlation between appropriate caliber and recurrence.[15] This technical consideration highlights the need for careful patient selection and potentially the availability of different fiber sizes to accommodate varying tract diameters.

Based on our findings and contemporary literature, we propose that FiLaC is most appropriate for patients with simple fistulas or those at high risk of incontinence with traditional surgery. Complex

fistulas may benefit from combination approaches or alternative techniques. Patients should be informed about the 70% primary healing rate, the option for repeat treatment if needed, and the excellent safety profile regarding continence preservation. Standardized protocols with appropriate laser parameters, thorough tract preparation, and careful fiber manipulation are essential for optimal outcomes. Regular follow-up at 3, 6, and 12 months is necessary to identify failures early and offer timely repeat treatment. Primary failure should not preclude repeat FiLaC, as secondary healing rates are favorable. Detailed complication reporting, particularly regarding continence, addresses a critical concern.

LIMITATIONS

This study has several limitations that should be acknowledged:

1. The absence of a control group limits our ability to draw definitive conclusions about the relative effectiveness of FiLaC compared to other treatment modalities. Future randomized controlled trials are needed to establish comparative effectiveness in the Pakistani population.
2. Conducted at a single healthcare institution, the findings may not be generalizable to other healthcare settings in Pakistan with different patient populations, resources, or expertise levels.
3. The use of convenience sampling rather than consecutive enrollment may introduce selection bias, potentially affecting the representativeness of our cohort.
4. The 12-month follow-up period, while adequate for assessing short- to medium-term outcomes, is insufficient to evaluate long-term durability and late recurrence rates. Extended follow-up is necessary to determine the true long-term success of FiLaC.
5. While we employed a standardized protocol, variations in surgeon experience and technique may have influenced outcomes. The learning curve effect was not specifically analyzed.

Despite these limitations, this study provides valuable preliminary data on FiLaC outcomes in Pakistan and establishes a foundation for future research to address these gaps.

CONCLUSION

This prospective cohort study demonstrates that Fistula Laser Closure (FiLaC) is a feasible, safe, and effective sphincter-preserving treatment for fistula in ano in a Pakistani healthcare setting. With a primary healing rate of 69.96% and an overall healing rate of 94.2% (including secondary procedures), FiLaC offers satisfactory outcomes comparable to those reported from developed countries. The technique's excellent safety profile, characterized by zero incontinence and minimal complications, makes it particularly valuable for patients at risk of sphincter injury with conventional surgery.

Our findings reveal that outcomes vary significantly based on fistula complexity, with simple fistulas achieving superior healing rates (81.9%) compared to complex fistulas (63.0%). The high secondary healing rate (80%) among patients undergoing repeat FiLaC underscores the value of offering repeat treatment for primary failures, ultimately achieving excellent overall success rates.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SOURCE OF FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Abdullah Bin Saeed:** Conception of idea, study design, manuscript drafting.
2	**Shaukat Ali:** Data collection, data analysis.
3	**Rana Israr:** Proof reading.
4	**Nimra Naeem:** Data interpretation.