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Fistula Laser Closure: Early outcomes and influencing factors

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Abstract

Background: Fistula laser closure is a surgical technique developed in accordance with the trend toward minimally invasive procedures that preserve the anal sphincter. Its mechanism involves destroying the fistula epithelium and inducing shrinkage of the surrounding tissues through laser energy, thereby sealing the fistula lumen. This approach causes minimal damage to anatomical structures and is associated with a low incidence of postoperative complications, particularly fecal incontinence.

Objective: The aim of this study was to determine the early outcomes and influencing factors of this technique.

Methods: The study size was determined by the number of consecutive patients who underwent FiLaC procedures at Hanoi Medical University Hospital between February 2024 and June 2024. This was a retrospective analysis of prospectively maintained database.

Results: A total of 30 patients underwent fistula laser closure. The mean operative time was 27.5 minutes, and the mean hospital stay was 1.27 days. The patients were followed for a mean duration of 10.6 months. The primary healing rate was 70%, and by the end of the study, 90% of patients had achieved complete healing. No serious postoperative complications were observed.

Conclusion: Fistula laser closure is a minimally invasive and safe treatment modality for anal fistula, offering a high fistula closure rate and low complication rates.

Keywords: Anal Fistula; Laser; Fistula Closure; Sphincter-Preserving; FiLaC

1. Introduction

The management of anal fistulas remains a challenge for surgeons, particularly in cases of complex fistulas. The treatment objectives are to resolve the infection and eliminate the fistula tract while preserving the anatomical structure and continence function of the anus[1–3]. Many methods for treating anal fistula have been investigated; however, no surgical procedure has been recognized as the gold standard. The rate of residual fistula tracts postoperatively remains high, reaching up to 30%[2–5]. Anal fistula treatment generally follows three approaches: fistulectomy, fistulotomy, and fistula closure. Fistulotomy and fistulectomy are associated with high success rates. However, they carry several disadvantages, including large surgical wounds, significant postoperative pain, and an increased risk of anal incontinence[2,6–9]. As a result, minimally invasive, sphincter-preserving surgical techniques are increasingly being utilized. Most patients prefer to maintain anal continence rather than achieve fistula healing at the

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expense of continence loss[10]. Numerous minimally invasive approaches have been studied and implemented[11–15]. Although these methods initially showed promising outcomes, long-term studies have reported inconsistent results[2,16–20].

Fistula laser closure (FiLaC) was first described by Wilhelm in 2011[4]. Since its introduction, numerous studies worldwide have examined FiLaC, yielding promising results[2,5,16,20–22]. In the present study, we aimed to evaluate the early outcomes and identify factors influencing the success rate of this technique.

Patients and methods

The study size was determined by the number of consecutive patients who underwent FiLaC procedures at Hanoi Medical University Hospital between February 2024 and June 2024. No formal sample size calculation was performed, as this was a retrospective analysis of prospectively collected data. This study was approved by the local ethics committee of our institution. Written informed consent was obtained from all participants, including consent to use anonymized clinical data and surgical images for publication.

1.1. Patient selection criteria

All patients in our study underwent sequential clinical examination, perineal ultrasound, proctoscopy and pelvic magnetic resonance imaging (MRI). All patients diagnosed with anal fistula, regardless of a prior history of fistula surgery, were included in the study. Patients with anal fistulas associated with abscesses were excluded, as this is a contraindication for the FiLaC technique[5]. In addition, cases with superficial fistulas amenable to fistulotomy without significant risk to the anal sphincter were also excluded from the study.

1.2. Surgical technique

We used a laser probe (Biolitec, Jena, Germany), which was set to continuous mode, with a power of 13 watts and a wavelength of 1470 nanometres (nm). In an optimal environment, laser energy destroys the epithelial lining, denatures protein structures and blood in the fistula tract, ultimately inducing shrinkage and closure of the tract[4,22].

The basic surgical steps are illustrated in Figure 1. During surgery, the fistula tract was first identified. It was sequentially cleansed using a brush, hydrogen peroxide, povidone-iodine, and normal saline. The laser probe was then inserted into the fistula tract via the external opening until the tip of the probe was located at 1 or 2 mm beyond the internal opening. Fistula closure was initiated from the internal opening outward, retracting the laser fiber at a rate of 1 mm/s. Every 3 mm, we gently advanced the fiber forward to assess whether the tract had sealed. Upon completion of fistula closure, we sutured the internal opening by absorbable sutures, and excised the fibrous tissue around the external opening to allow drainage and prevent premature wound healing. The excised tissue was submitted for pathological examination.

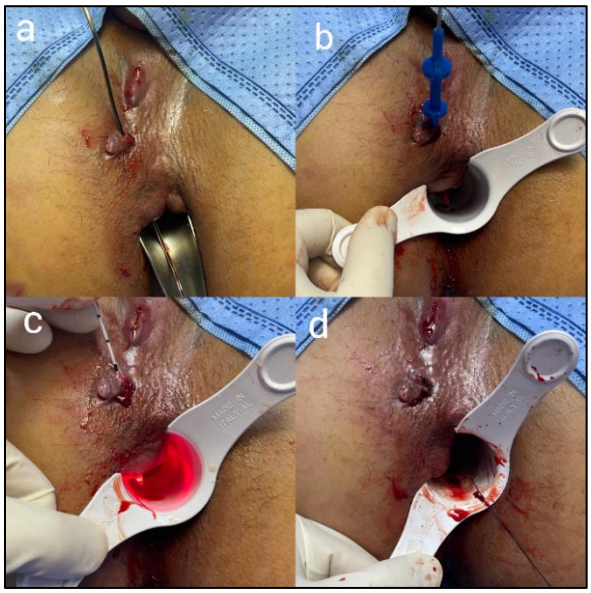

Figure 1 (a) Locating the fistula tract with a fistula probe. (b) Mechanically cleansing the tract with a brush. (c) Laser closure of the fistula. (d) Suturing the internal opening

1.3. Follow-up data

The patient was scheduled for follow-up visits at 2 weeks, 1 month, 3 months, 6 months, 1 year or earlier if any abnormalities occurred. For longer follow-up periods, the patient's condition was assessed through direct phone calls.

Cases with no discharge, no pain, and complete wound healing following the initial FiLaC procedure were defined as primary healing. All other cases were classified as failures. At the end of the study period, patients who remained asymptomatic with complete wound healing were defined as having achieved overall complete healing. We obtained all variables from prospectively maintained medical records, clinical examinations, and pelvic MRI. Measurements and assessments were standardized across all patients. Categorical variables were presented as frequencies and percentages, including gender (male or female), history of anal fistula surgery, Parks' classification (type 1: intersphincteric fistula, type 2: transsphincteric fistula, type 3: suprasphincteric fistula, type 4: extrasphincteric fistula)[23], placement of a loose seton prior to surgery, degree of anal incontinence (Table 1)[24], homogeneity of the fistula tract diameter (assessed by MRI), and complications (type of complication and how it was managed). Two means were compared using either the Student's t-test or the Mann-Whitney U test. Continuous variables were presented as mean ± standard deviation (SD) and range, including age (years), length of the fistula tract (centimetres, measured intraoperatively using the laser fiber), operative time (minutes), length of hospital stay (days), and duration of follow-up (months). Proportions were compared using the Chi-square or Fisher's exact test.

Table 1 Browning-Parks scale for assessing anal incontinence[24]

Grade	Description
1	No incontinence
2	Incontinence of flatus
3	Incontinence of liquid stool
4	Incontinence of solid stool

To minimize potential sources of bias, data in our study were collected using standardized case report forms. Patients were diagnosed according to a uniform protocol, and imaging findings were assessed objectively. All surgical procedures were performed by the same operating surgeon. Inclusion and exclusion criteria were applied consistently throughout the study.

2. Results

From February 2024 to June 2024, we performed FiLaC on 30 patients. All patients completed the planned follow-up and were included in the final analysis.

Table 2 Characteristics of the study sample

Characteristic	Result (n = 30)
Age, years, mean ± SD (range)	38.7 ± 11.4 (15 - 76)
Gender, n (%)	
Male	26 (86.7)
Female	4 (13.3)
History of anal fistula surgery, n (%)	11 (36.7)
Loose seton, n (%)	4 (13.3)
Seton placement time before FiLaC, weeks, mean ± SD (range)	16.8 ± 10.4 (7 - 30)
Parks' classification	
Type 1, n (%)	9 (30)
Type 2, n (%)	21 (70)

Type 3, n (%)	Not present
Type 4, n (%)	Not present
Fistula tract length, centimetres (cm), mean ± SD (range)	2.9 ± 1.4 (1.5 – 5.7)
Presence of side tract, n (%)	1 (3.3)
Homogeneity of the fistula tract diameter, n (%)	17 (56.7)
Operative time, minutes, mean ± SD (range)	27.5 ± 10.0 (15 - 50)
Complications, n (%)	No complications observed
Hospital stay, days, mean ± SD (range)	1.3 ± 0.7 (1 - 4)
Follow-up duration, months, mean ± SD (range)	10.6 ± 1.5 (7 - 13)
Primary healing, n (%)	21 (70)

SD: Standard Deviation

The demographic characteristics of the study sample are presented in Table 2. The patients in our study had an average age of 38.7 years. Most of the cases in our study were male, accounting for 86.7%. 11 patients (36.7%) had a history of anal fistula surgery, of whom 4 (13.3%) had a loose seton placed prior to surgery with an average duration of 16.8 weeks. The average fistula tract length was 2.9 ± 1.4 cm (range: 1.5 - 5.7 cm). A secondary tract was identified in one case (3.3%) following the failure of the initial FiLaC procedure. Seventeen patients (56.7%) had a fistula tract of homogeneous diameter on MRI.

The mean operative time was 27.5 ± 10.0 minutes (range: 15 – 50 minutes). None of the patients experienced intraoperative or postoperative complications. The average length of hospital stay was 1.3 ± 0.7 days (range: 1 – 4 days), with 25 patients (83.3%) discharged after one day. The mean follow-up duration was 10.6 ± 1.5 months (range: 7 - 13 months). During the follow-up period, 21 patients (70%) achieved initial fistula closure (Figure 2).

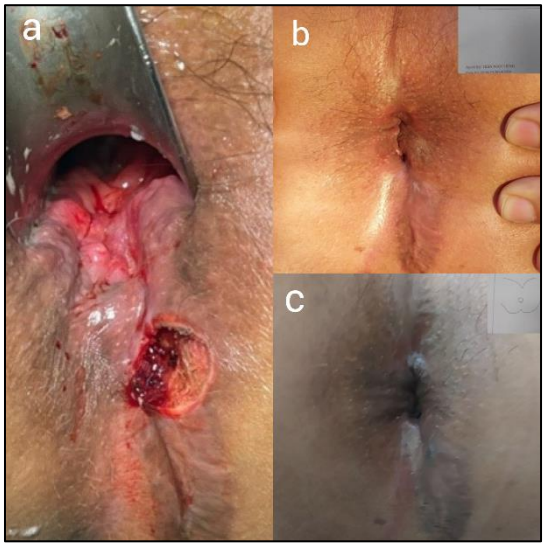

Figure 2 One successful case from the research group: (a) Intraoperative image. (b) Postoperative image at 10 weeks. (c) Postoperative image at 3 months

Among the nine cases that failed the initial surgery, one patient did not agree to undergo reoperation, while the remaining eight patients underwent reoperation by the research team. Two patients received a second FiLaC procedure, three underwent fistulectomy, two underwent seton placement for high transsphincteric fistula and drainage for a side track or an abscess, one underwent drainage for a horseshoe anal abscess. By the end of the study period, three patients had not achieved healing. The overall complete healing rate was 27 out of 30 patients (90%). There were no cases of anal continence disorders before or after surgery.

Differences in age, gender, history of anal fistula surgery, loose seton placement, Parks' classification and fistula tract length between the groups with primary healing and failure were not statistically significant (Table 3). The group with homogeneous fistula tracts achieved a primary success rate of 88.2%, whereas the group with heterogeneous tracts had a rate of 46.2%. Thus, the homogeneous tract group demonstrated a 42% higher primary success rate compared to the heterogeneous group (p = 0.02; RR = 1.91; 95% CI 1.04, 3.53).

Table 3 Analysis of factors influencing primary healing rate

Factors	**Primary healing group (n=21)**	**Failure group (n=9)**	**p-value**	**RR or MD (95% CI)**
Age, years, mean ± SD	38.0 ± 12.7	40.2 ± 8.3	0,63[a]	MD = -2.2 (-11.7, 7.2)
Gender, n (%)				
Male	17 (65.4)	9 (34.6)	0.29[b]	RR = 0.65 (0.49, 0.87)
Female	4 (100)	0 (0)		
History of anal fistula surgery, n (%)				
Yes	7 (63.6)	4 (36.4)	0.69[b]	RR = 0.86 (0.51, 1.46)
No	14 (73.7)	5 (26.3)		
Loose seton, n (%)				
Yes	1 (25)	3 (75)	0.07[b]	RR = 0.33 (0.06, 1.80)
No	20 (76.9)	6 (23.1)		
Parks' classification, n (%)				
Type 1	8 (88.9)	1 (11.1)	0.21[b]	RR = 1.44 (0.96, 2.16)
Type 2	13 (61.9)	8 (38.1)		
Fistula tract length, centimetres, mean ± SD	3.0 ± 1.4	2.7 ± 1.4	0.61[a]	MD = 0.3 (-0.9,1.4)
Homogeneous fistula diameter, n (%)				
Yes	15 (88.2)	2 (11.8)	0.02[b]	RR = 1.91 (1.04, 3.53)
No	6 (46.2)	7 (53.8)		

[a]Student's t-test. [b]Fisher's exact test. 95% CI: 95% confidence interval. MD: Mean difference. RR: Relative risk. SD: Standard Deviation

3. Discussion

In our study, 36.7% of the patients had a history of anal fistula surgery; this proportion varies among studies, ranging from 32% in Nordholm's study to 100% in De Hous's study[18,25]. This discrepancy may be attributed to differences in sample selection criteria among authors[7,16–18,20,22,25–27]. In our view, a history of anal fistula surgery is not a contraindication to FiLaC. On the contrary, patients who have undergone multiple surgeries and have perianal fibrotic scarring should preferentially be selected for FiLaC due to its advantage in preserving the anal sphincter. We consider drainage procedures, along with loose seton placement, as initial preparatory steps to facilitate subsequent FiLaC surgery[20]. Wilhelm's study reported 84.6% of cases with loose seton placement, Giamundo's study had 81.8%, and De Bonnechose reported 83%[16,20,28]. The rationale for using a loose seton is primarily to resolve the infection by draining the abscesses in the fistula tract, while also promoting the healing of side tracts. Additionally, it stimulates granulation tissue formation and promotes faster maturation of the fistula. This stabilizes the diameter of the main fistula tract[20]. In 2021, Giamundo's research, involving 175 cases, concluded that the placement of a loose seton significantly increases the primary healing rate of fistula[20]. However, our study has not yet demonstrated this effect. This may be due to our sample size not being large enough, particularly since there were only four cases where a seton was placed prior to FiLaC procedure.

Regarding the Parks' classification, our research team identified two types: intersphincteric fistula (type 1) and transsphincteric fistula (type 2), with transsphincteric fistula accounting for 21 cases (70%). Other studies also report that most cases are transsphincteric fistulas[5,16,18,20,21,27,28]. Some authors, such as Lauretta, only included transsphincteric fistulas in their study, which increased the homogeneity of the study group[17]. The impact of Parks' classification on the success rate remains controversial. Wilhelm's study indicated that intersphincteric fistulas have a higher success rate[16]. In contrast, Isik suggested that intersphincteric fistulas have a lower success rate, while Marref found that high transsphincteric fistulas have a higher success rate[21,27]. However, we found that intersphincteric fistulas represent a small percentage in their studies; Wilhelm's study was 8/117 (6.8%), Isik's study was 10/100 (10%), and Marref's study was 2/68 (2.9%)[16,21,27]. The results may differ if the sample size and proportion of intersphincteric fistulas increase. Our study did not show a significant difference in the success rate of fistula closure between the type 1 and type 2 groups ($p = 0.21$).

The patients in our study had an average fistula tract length of 2.9 cm, which is shorter than the study by Giamundo (4.2 cm) and Donmez (5 cm)[2,20]. This can be easily explained by the small sample size in our study, and the Parks' classification only included types 1 and 2. According to Giamundo, the appropriate fistula tract length for laser closure is 4 cm or more, as this allows for maximum tissue denaturation and shrinkage. Fistulas less than 2 cm are typically treated with fistulotomy or fistulectomy, provided there is no risk of causing anal incontinence[29]. However, Lauretta's study showed the opposite result, with patients having fistula tracts shorter than 3 cm achieving a higher success rate of closure compared to those with tracts longer than 3 cm. Lauretta explained that longer fistulas tend to have a greater variability in diameter, with more secondary tracks[17]. In our study, the average fistula tract length for the primary healing and failure groups was 3.0 ± 1.4 cm and 2.7 ± 1.4 cm, respectively, and the difference was not statistically significant.

In addition to closing the fistula with laser energy, we sutured the internal opening in all cases using absorbable sutures. In our opinion, this is a simple procedure that does not significantly increase operative time or complication rates, while providing protection of the fistula tract from fecal contents and secretions. However, internal opening closure complicates the assessment of the isolated efficacy of the FiLaC technique[19]. Some studies have reported high primary success rates without closure of the internal opening[2,21,29], whereas others that incorporated internal closure have still demonstrated low primary success rates[18]. In 2018, Terzi reported 103 cases of FiLaC alone with a primary healing rate of 39.8%. Later, in 2020, Serin (along with Terzi's research group) reported 35 cases of FiLaC combined with internal opening suturing, with a primary healing rate of 42.9%, concluding that suturing the internal opening did not offer additional benefit[7,26]. De Bonnechose and Giamundo suggested that closure of the internal opening is only necessary when its size is excessively large, in order to prevent fecal matter from entering the fistula tract. Furthermore, the surrounding tissue must be viable and well vascularized[20,28]. For the external opening, we chose the method of excising the fibrous tissue around the external opening to drain any residual fluid in the fistula tract, preventing the external opening from healing too quickly. Since soft tissue and adipose tissue are less sensitive to the shrinkage effect of laser energy, the portion of the fistula tract outside the sphincter is also less responsive to the laser[20].

The primary healing rate in our study was 70%. This rate varies considerably across other studies, ranging from 20% (Stijns' study) to 89% (Donmez's study)[2,19]. The largest studies (including more than 100 patients) reported primary healing rates of 66.8% (Giamundo), 64.1% (Wilhelm), 62% (Isik), 44.6% (De Bonnechose), and 39.8% (Terzi)[7,16,20,21,28]. Our initial success rate of 70% is moderate, and considering that it is a minimally invasive procedure that preserves the sphincter, it remains a preferred method that allows for multiple surgeries if necessary[3]. Regarding postoperative complications, the meta analysis studies by Samuel and Elfeki both showed that the severity of complications was mild and did not require surgical or procedural intervention. Notably, Samuel did not report any cases of fecal incontinence[3,8]. Giamundo's research group, with 45 patients published in 2015, reported 8 cases of pain or anismus and 3 cases of postoperative bleeding, all of which responded to conservative treatment[29]. Other studies, such as those by Lauretta and Wolicki, also reported mild complications, including pain and bleeding, which did not require surgical intervention[17,22]. In 2021, a study by Giamundo involving 175 patients reported one case of bleeding that required reoperation[20]. Our research group also did not observe any postoperative complications, and no patients experienced anal incontinence after surgery. The patients in our study had short hospital stays and were able to return to daily activities quickly. 83% of patients were discharged after one day, which is consistent with studies by authors such as Wilhelm, Donmez, Ozturk, and Isik[2,5,16,21]. All these factors indicate that FiLaC is indeed a safe method with few and mild complications.

We observed nine cases of failure following the initial FiLaC procedure. One of the main causes of treatment failure was the presence of a secondary tract, which was identified in one case following the initial failure of the FiLaC procedure (Figure 3). Secondary tracts have also been reported by several authors as a contributing factor to treatment failure[2,16,17,29]. Another cause of failure is the heterogeneity of the fistula tract diameter (Figure 4), as seven cases

in our failure group shared this characteristic, including the case with secondary tract. We hypothesize that heterogeneous fistula tracts have gaps with excessively wide diameters, which reduce the effectiveness of the laser-induced shrinkage effect. Giamundo and Nordholm also suggested that excessively large fistula diameters reduce the sealing effect of the laser energy[18,20].

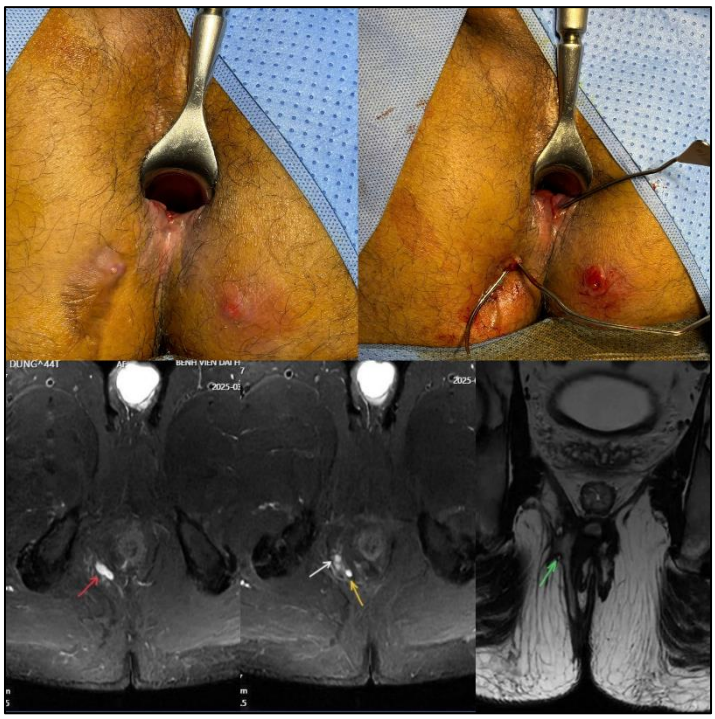

Figure 3 One failed case from the research group: (red arrow) The anal fistula begins to branch (red arrow). (yellow arrow) The primary tract. (white arrow) The secondary tract. (green arrow) The secondary tract ascends toward the levator ani muscle

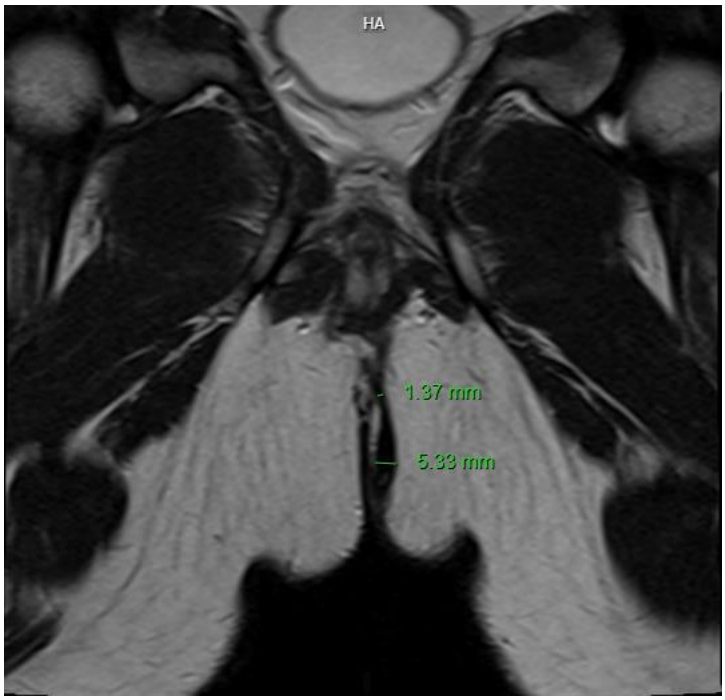

Figure 4 One case of a heterogeneous fistula tract on MRI

When studying the group of patients who failed, we observed one case where the patient initially had a high transsphincteric anal fistula, but by the second surgery, the fistula had only become an intersphincteric anal fistula, and we decided to perform fistulectomy. Some studies also report cases where the fistula tract lowered after the first FiLaC surgery, such as the studies by Giamundo, Wilhelm, and Donmez[2,16,29]. This further reinforces the advantage of FiLaC: the failure of the laser procedure does not hinder other surgical treatments for anal fistula and does not exacerbate the symptoms of the fistula[5].

The limitations of our study are: retrospective study, single-center, small sample size, and short follow-up duration.

4. Conclusion

FiLaC is a minimally invasive and safe treatment for anal fistula. The initial success rate is promising, with a low complication rate, particularly in terms of fecal incontinence. As a method that approaches the fistula from within and preserves the anal sphincter, FiLaC should be the preferred option for anal fistula surgery when indicated and can be performed multiple times. Fistulas with high homogeneity in diameter have a higher success rate of closure. Even in cases of failure, FiLaC does not hinder other surgical approaches and does not exacerbate symptoms.'

Compliance with ethical standards

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Disclosure of Conflict of interests

The authors declare no conflicts of interest related to this research.

Statement of ethical approval

This study was a retrospective analysis of prospectively collected data and was conducted in accordance with the ethical standards of the institutional and national research committee. Ethical approval was obtained from the Institutional Review Board of Hanoi Medical University.

Statement of informed consent

Written informed consent was obtained from all participants, including consent to use anonymized clinical data and surgical images for publication.

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