



## Laser Management for Anal Fistulas: A Prospective study

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**Abstract: Introduction:** Laser treatment for fistula-in-ano, also known as FiLaC (fistula laser closure) or LAFT (laser ablation of fistula tract), has gained increasing attention in the last decade. The procedure consists of delivering laser energy at 360° within the lumen of fistulas by means of a radial fiber which is slowly withdrawn from the external orifice. **Material & Methods:** The study analysed 40 patients treated for anal fistulae in Saphthagiri Institute of Medical Sciences, Bangalore between November 2020 to June 2021. Fistulae were classified in accordance with the Parks' classification system, and all patients were preoperatively assessed by clinical examination and proctosigmoidoscopy and classified using three-dimensional (3D) endoanal ultrasonography performed by a sonographer experienced in endoanal ultrasound. **Results:** Of the 40 patients, 26 were female and 14 were male (overall median age 46 years; range 17–82 years). The median period of follow-up was 11 months, follow up was scheduled in the outpatient at 1 and 2 weeks and 1, 3, 6 and 11 months postoperatively. However, patients were instructed to return to the outpatient at any time should symptoms recur. In the cohort, 39 fistulae (97.5%) were cryptoglandular in origin and 1 (2.5%) were Crohn's related. 97.5% had previously undergone surgery including abscess drainage and prior fistula operations. The mean number of operations before FiLaC treatment was 2.4 (±1.7) with a range of 1–9 previous operations. **Discussion:** The use of FiLaC for the treatment of anorectal fistula has shown encouraging. The technique is easy to learn and fast to perform, allows exploration of curved paths and any size since the fiber is very flexible and long. The destruction of the epithelialized path and sealing is carried out by laser emission radially 360°, thereby allowing the application of energy across the path homogeneous in a controlled manner. **Conclusion:** The FiLaC, sphincter preservation minimally invasive surgery in the treatment of anal fistulas, looks promising although prospective and long-term follow-up studies should be conducted.

**Keywords:** Anal Fistula, Laser, Faecal Incontinence.

## INTRODUCTION

Laser treatment for fistula-in-ano, also known as FiLaC (fistula laser closure) or LAFT (laser ablation of fistula tract), has gained increasing attention in the last decade. The procedure consists of delivering laser energy at 360° within the lumen of fistulas by means of a radial fiber which is slowly withdrawn from the external orifice. Laser ablation is limited to the lumen of fistulas making the technique 'sphincter-saving'. Its main indication is the treatment of high fistulas and complex fistulas, in general, of all fistulas where more invasive treatments may impair anal continence.<sup>[1]</sup>

Since 2011, after a German group published the first pilot study, clinical results of this minimally invasive procedure were reported in a few papers, prompting growing interest in this novel technique in the scientific community. As for most procedures, the literature showed controversial results over the years. Following the first encouraging results, some studies reported a high percentage of failures. This raised some concerns and led to the consideration that the destiny of the procedure was similar to that of many others: the initial enthusiasm was followed by a high, yet unexpected, disappointing future at long-term follow ups. However, a few considerations need to be stressed.<sup>[2,3]</sup>

First of all, the results of a few studies showed a variable percentage of success but longer follow-ups were not necessarily associated with higher recurrence rate. Interestingly, in most series, the failures after FiLaC were in the form of 'non-healing' or persistence of the fistula tract rather than recurrence.<sup>[4]</sup>

Therefore, attention needs to be focused primarily on the efficacy of the procedure and not to failure in the long term like for other sphincter-saving treatments (fibrin glue, plugs).

The shrinkage of fistula tracts caused by laser depends on the wavelength and the amount of energy of the laser beam delivered within the tract. With the parameters used by most centers, the shrinking effect should successfully heal fistulas with a diameter of maximum 4–5 mm. [5]

The length of the fistula tract may also play a role in influencing the success rate. In this regard, results in the literature are rather controversial. While some authors consider the length of the fistula the ‘Achille’s heel’ of laser treatment [6,7], we have a different opinion based on our experience: the longer the fistula the better the shrinkage effect elicited by laser energy. This finding has been confirmed in a recent study. The concept is based on the assumption that the presence of a longer tract around the sphincters increases the chance of tract closure as opposed to a short tract crossing only small amounts of soft adipose tissue.

## METHODOLOGY

The study was approved by the local hospital ethics committee, and all patients undergoing the FiLaC procedure provided informed consent. The study analysed 40 patients treated for anal fistulae in a single tertiary referral centre by one experienced colorectal surgeon between November 2020 to June 2021. Fistulae were classified in accordance with the Parks’ classification system [8-9], and all patients were preoperatively assessed by clinical examination and proctosigmoidoscopy and classified using three-dimensional (3D) endoanal ultrasonography (Sapthagiri Institute of Medical Sciences, Bangalore) performed by a sonographer experienced in endoluminal anal ultrasound. Very superficial fistulae where fistulotomy could be performed without compromising sphincter function and malignant fistulae were excluded from analysis.

Basic patient demographic data (age, sex) along with fistula type and information (where available) concerning prior surgical treatments were collected. A simple questionnaire was used to assess post-operative continence status. All forty patients with fistula underwent laser fistula treatment. [10-11]

We also defined superficial and intersphincteric fistulas as low/ simple fistulas and transsphincteric, suprasphincteric, and extrasphincteric fistulas as high/complex fistulas. Most of the fistulas are transsphincteric and intersphincteric.

The selection criteria for the laser technique were as follows: a mid or a high trans-sphincteric fistula; an anterior intersphincteric or a low trans-sphincteric fistula in a woman with preoperative low sphincter anal tone and/or some degree of faecal incontinence; a fistula previously treated by seton placement; and a Crohn’s-related fistula. Exclusion criteria included a

superficial fistula that could be treated by fistulotomy without compromising anal sphincter function and any fistula related to malignancy. All patients gave informed consent to undergo the modified laser procedure and agreed to participate in regular follow-up assessments.

The fistula track was cleaned mechanically using a curette and irrigated with saline. The internal opening within the internal sphincter muscle was closed by means of a 2/0 Vicryl suture, and the laser probe was inserted from the external opening. For suprasphincteric type 3 fistulas, the probe was inserted primarily from the internal orifice to reach the “turning point” of the fistula track in order to close the transmuscular fistula component. Then, the internal opening was closed using 2/0 Vicryl, and the subcutaneous part of the fistula track was treated with the laser from the outer opening as described above.

The laser probe was inserted through the external opening using 1470 nm diode laser. This type of laser delivers energy at a wavelength of 1470 nm providing an optimal absorption curve in water which is considered to result in a more efficient local tissue shrinkage and protein denaturation. When there is no longer any water in the tissue and the temperature exceeds 100 C, a white smoke vaporization effect is observed. The use of this wavelength by the radial-tip laser fibre permits destruction of the granulation and epithelial tissue causing a 2- to 3-mm zone of controlled tissue damage with less power (10 W) and a diminished likelihood of peri fistular collateral thermal damage. [12] In those suprasphincteric (Parks’ Type 3) fistulae, the laser probe is introduced via the internal fistula opening reaching the “turning point” of the fistula track so as to obliterate the intersphincteric component. For obliteration, the fistula track is treated with a continuous slow retraction of the laser fibre withdrawn at a rate of approximately 1mm/seci. Clearly, overburning or protein denaturation of the treated and surrounding tissue should be avoided. The internal opening was closed with SLOFT or LIFT or a mucosal advancement flap depending upon the local tissue circumstances. [13]

Post-operatively, there were no dietary restrictions, and all patients were placed on stool softeners for a 2-week period, antibiotic for 2 weeks and analgesic as needed. Patients were discharged on either the 2nd or the 3rd post-operative day. Follow-up was conducted on the 4th and 10th post-operative days and at 6 weeks, 3 months, 6 months and 1 year thereafter. follow-up was done and patients were instructed to return to the clinic in the interim if symptoms recurred. [14] Healing after the first FiLaC laser treatment was defined as primary success, and healing following a repeat operative therapy after initial laser treatment failure was defined as secondary success (Table 1).

In the event of treatment failure, there was selective management at the discretion of the surgeon which included repeat laser treatment, fistula excision with partial sphincter reconstruction (if 30% of the sphincter complex was involved) or complete fistula excision with major sphincter reconstruction (if 30% of the sphincter complex was involved), and shows a lay-open fistulotomy (Table 2).

### Statistical Analysis

Statistical analysis was performed with SPSS 25<sup>th</sup> Version. Differences in treatment success between

patient subgroups were quantified as healing rate ratios (HRRs) with 95% confidence intervals (95% CI) and assessed for statistical significance using Fisher's exact test. The largest subgroup was consistently chosen as the reference group. Age distributions were characterized by their median and interquartile range. A Kruskal–Wallis rank test was used to assess age differences between patient subgroups for statistical significance. Two-sided p values < 0.05 were considered significant.

## RESULTS

Out of the 40 patients, 26 were female and 14 were male (overall median age 46 years; range 17–82 years). The median period of follow-up was 11 months, follow up was scheduled in the outpatient clinic at 1 and 2 weeks and 1, 3, 6 and 11 months postoperatively. However, patients were instructed to return to the outpatient clinic at any time should symptoms recur. In the cohort, 39 fistulae (97.5%) were cryptoglandular in origin and 1 (2.5%) were Crohn's related. Thirty-Eight patient (95.0%) had previously undergone surgery including abscess drainage and prior fistula operations. The mean number of operations before FiLaC treatment was 2.4 ( $\pm 1.7$ ) with a range of 1–9 previous operations. Primary operations had been performed elsewhere in 20

cases (50.0%). Four patients (10.0%) underwent immediate definitive laser treatment without prior abscess drainage and 5 (12.5%) underwent FiLaC treatment without deployment of a seton following abscess drainage performed elsewhere. A seton was placed in 8 patients (20%) with a mean period between seton insertion and definitive fistula treatment of 16.1 ( $\pm 29.2$ ) weeks. Six patients (15%) had a persistent fistula following previous outside fistula repair before laser treatment was performed. Out of this group, 19 (47.5%) had two previous attempts to repair the fistula. The overall results of the study with primary and secondary success rate in relation to the different variables are listed in Table 1.

**Table 1: Table 1 Primary and secondary success rates after FiLaC**

Patient characteristics	n	Primary healing Yes (%)	No (%)	p\$	Secondary healing <sup>#</sup>		
					Yes (%)	No (%)	p\$
n	40	16 (40)	24 (60)		35 (87.5)	5 (13)	
Age <sup>&amp;</sup>		47 (19)	45.5 (19)	0.281	46 (17)	42.5 (20)	0.982
Sex							
Male	14	9 (64.3)	5 (35.7)		12 (85.8)	2 (24.2)	
Female	26	19 (73.1)	7 (26.9)	0.540	22 (91.7)	4 (8.3)	0.553
Aetiology							
Cryptoglandular	39	24 (64.9)	13 (36.6)		34 (87.2)	5 (12.8)	
Crohn	1	1 (100.0)	0 (0.0)	0.771	1 (100.0)	0 (00.0)	0.971
Park classification							
I	4	4 (100.0)	0 (0.0)	0.045	4 (100.0)	0 (0.0)	0.923
II	31	19 (61.3)	12 (38.7)	0.923	28 (90.4)	9 (9.6)	
III	5	3 (60.0)	2 (30.0)	0.923	4 (80)	1 (20)	0.213
IV	1	1 (100.0)	0 (0.0)		1 (100.0)	0 (0.0)	0.531
Closure technique							
MSAF	6	4 (66.7)	2 (33.3)	0.947	5 (83.4)	1 (16.6)	0.763
Anodermal flap	5	3 (60.0)	2 (40.0)	0.931	3 (60.0)	2 (40.0)	
Mucosal flap	2	2 (100.0)	0 (00.0)	0.343	2 (100.0)	0 (00.0)	0.280
Suture closure	12	6 (50.0)	6 (50.0)		8 (66.7)	4 (33.3)	0.914
LIFT	15	9 (60.0)	6 (40.0)	0.931	10 (66.7)	5 (33.3)	0.947

p value from Fisher's exact test except for age, where the p value is from a Kruskal–Wallis test

<sup>#</sup> Defined as healing at the end of study

<sup>&</sup> Median (interquartile range)

**Table 2: Secondary success rates after reoperation for an initial failed FiLaC procedure**

Reoperation	Secondary healing	Secondary success rate (%)
Repeat FiLaC procedure	1/3	60
Excision and partial sphincter reconstruction	5/5	100
Excision and major sphincter reconstruction	2/2	100
Gore-Plug	0/1	0
Lay-open fistulotomy	1/1	100

No major forms of incontinence (solid, liquid stool or gas) were reported, with minor soiling noted in two patients (5.9%) (three patients after primary FiLaC procedure and four patients after a repeated second fistula surgery). Three of whom had an additional advancement flap to cover the internal opening. Another five of the seven patients responded to rubber band ligation for coincident mucosal prolapse/ectropion. There was one patient (2.5%) who

developed a late abscess and one patient (2.5%) who died of an unrelated cancer during the follow-up period. In those patients where there was initial failure of the FiLaC procedure, distalization of the primary track (conversion from a high to a low fistula) was observed in half of the cases. At the time of follow-up, 4 patients (9.4%) still have their fistula and have declined a second operative attempt at cure.

**Table 3: Previous fistula repair before FiLaC treatment**

	First operation	Second operation
Flap repair	4	1
Plug	2	1
LIFT	0	1

## DISCUSSION

The use of FILAC for the treatment of anorectal fistula has shown encouraging. The technique is easy to learn and fast to perform, allows exploration of curved paths and any size since the fiber is very flexible and long. The destruction of the epithelialized path and sealing is carried out by laser emission radially 360°, thereby allowing the application of energy across the path homogeneous in a controlled manner. This procedure can be combined with other techniques that close the internal orifice as Mio mucosal flap advancement.<sup>[15]</sup> The sealing of the path may be accompanied by endorectal ultrasound, if necessary, with good visibility of the fiber. FILAC success in healing anorectal fistulas in different studies in the literature is 71–82%, 4–7 with a mean of 12 months in the study with longer observation time. Among the adverse events reported, pain, tenesmus and soiling are the most common. There was no change in continence in anorectal manometry. No serious complications were reported in the studies. The need for prior use of setons and the optimal treatment of the internal orifice, either miomucosal advancement flap, simple stitches or leaves it open, is not well defined in the literature. Giamundo et al. recommends the use of setons preoperatively, bearing in mind that the healing rate in the subgroup of one of his works was higher in patients who used the Seton compared to those who did not use the Seton (81% × 63%, respectively). This observation should be viewed with caution due to the small number of patients and the characteristics inherent in the study.<sup>[16]</sup> A major

disadvantage of this method is the cost of laser fiber, which is still quite high in our country.

## CONCLUSIONS

The FILAC, sphincter preservation minimally invasive surgery in the treatment of anal fistulas, looks promising although prospective and long-term follow-up studies should be conducted.

**Conflict of Interest: None**

**Financial disclosure: None**

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