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# Short term Outcomes of Fistula Laser Closure (FILAC) as a Sphincter Sparing Technique Versus Fistulotomy with Immediate Sphincter Reconstruction (FISR) in High Trans-Sphincteric Fistula–in-ano; a Prospective Cohort Study

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**Background:** The challenge of treating high trans-sphincteric fistula-in-ano lies in preserving anal sphincter integrity whilst achieving complete eradication of the fistula tract. FILAC has been recently introduced as a sphincter-saving technique in high fistulas, but its efficiency is still questionable regarding rates of recurrence and fecal incontinence. **Objectives:** To review short term results of FILAC as a sphincter preserving technique in comparison with lay open fistulotomy plus immediate sphincter reconstruction (FISR) during treating high trans-sphincteric anal fistula.

**Patients and methods:** This is a prospective cohort study which included 21 patients of FILAC and 22 patients of FISR in the period between April 2019 and April 2021 at Ain Shams University Hospitals. Both groups where compared to each other regarding several intra and post operative variants specially incidence of recurrence and fecal incontinence.

**Results:** The mean age of study population is  $42.05\pm6.91$  years for group 1, and  $40.18\pm7.28$  for group 2. Wound took remarkably shorter time to heal in FILAC group (mean  $13.67\pm2.20$  days) versus  $37.27\pm7.84$  days in FISR group, P= 0.001. Patients who underwent FILAC technique experienced significantly lower pain score than those in the comparing group (mean  $4.14\pm1.39$  vs  $6.50\pm1.06$  respectively, P= 0.001. None of FILAC patients versus 5 cases (22.7%) of FISR group reported symptoms suggestive of incontinence (P= 0.048). Although recurrence was higher in FILAC group compared to FISR group (7 cases (33.3%) vs 4 cases (18.2%) respectively), it failed to prove statistical significance, P= 0.255.

**Conclusion:** FILAC has proven superiority to FISR technique in terms of post-operative pain score, wound healing time and incidence of fecal incontinence in treating high trans-sphincteric anal fistula .However ,the incidence of recurrence was higher in FILAC group than FISR group without statistical significance. Further randomized clinical trials are encouraged to confirm our results.

Key words: FILAC, fistulotomy, immediate reconstruction, recurrence.

#### Introduction

High trans-sphincteric fistula-in-Ano treatment is quiet challenging anorectal disease, and there is no consensus on the ideal way to treat such fistula.<sup>1</sup> It is a matter of balance between achieving low recurrence rate and to maintain the sphincter function and integrity.<sup>2</sup>

So many sphincter sparing techniques emerged trying to achieve this delicate balance between recurrence and sphincter integrity as LIFT, FiLaC (fistula track laser closure), video assisted anal fistula treatment (VAAFT) and the use of advancement flaps and seton in treatment of high Tran-sphincteric fistula-in-Ano.<sup>3-5</sup>

Lay open of fistula and Primary sphincter repair is not a new concept but it was not studied thoroughly and always surgeons were skeptical towards the results.<sup>6</sup> and it was revisited few times over the last 30 years with preliminary encouraging results.<sup>7</sup>

The concept of diode laser source (FILAC) was

inspired by varicose vein laser treatment and was first reported by Wilhelm in 2011. The only difference is that the FILAC thermal energy is dissipated radially. As a result, unlike previous lasers used in coloproctolgy, such as the YAG laser<sup>6</sup> or the CO2 laser,<sup>7</sup> it can cause homogeneous obliteration of the fistula tract.<sup>8</sup> The notion of FILAC in the treatment of fistula-in-ano is based on a combination of granulation tissue demolition and fistulous tract obliteration as thermal energy disrupts cell protein and thus creates the sealing effect.<sup>9</sup>

The aim of our study is to review the short term results of FILAC as a sphincter sparing technique in comparison with lay-open fistulotomy with immediate sphincter reconstruction (FISR) regarding recurrence and anal incontinence.

#### **Patients and methods**

This is a prospective cohort study which enrolled 43 patients who were diagnosed with high linear transsphincteric perianal fistula, which is classified as a complex fistula as per the Standard Practice Task Force classification .The patients were diagnosed and operated upon in the colorectal unit at Ain Shams University Hospital (El-Demerdash Hospital) between April 2019 and April 2021.

# The study population were divided into two groups:

**Group 1:** 21 patients who underwent Fistula-tract Laser Closure (FILAC) with preservation of the anal sphincter.

**Group 2:** 22 patients who underwent layopen fistulotomy with immediate anal sphincter reconstruction (FISR).

In both groups, the patients are over 18 years old, able to possess the information and agree to the consent.

#### **Exclusion criteria**

- 1. Patient with recurrent fistula.
- 2. Patient who was previously diagnosed with inflammatory bowel disease.
- 3. Patients with anal cancer or who had previous irradiation.
- 4. Patients who had any degree of anal incontinence according to the Wexner score as shown in **Table 1.**

Assessment of all patents was preoperatively implemented with history taking, clinical examination, and local digital rectal examination in addition to anal canal Magnetic Resonance Imaging as shown in **(Figure 1).** A Wexner score was calculated for all patients.



Fig 1: Shows an MRI with high linear perianal fistula.

While the length of the fistulous tract is thought to promote fistula plug success, the width of the tract may be relevant in FiLaC as the laser fixed penetration power may be less effective in the centre of the track cavity. Thus, preoperative magnetic resonance imaging (MRI) assessment of tract diameter may be beneficial for future research. Patients consented to the procedure. All surgeries were done by the same surgical team under general or spinal anesthesia in a lithotomy position after bowl preparation with rectal enema the night before surgery. Intravenous (3<sup>rd</sup> generation) cephalosporin was given with the induction of anesthesia.

Patients were followed up for a year after surgery, with assessment windows at one week, one month, three months, six months, and one year. At each appointment, a digital rectal examination was performed, and the Wexnerscore was computed. Furthermore, magnetic resonance imaging was scheduled for any patient who experienced signs of recurrence.

# **Ethical considerations**

All patients signed a written formal consent describing the procedure and possible postoperative complications after patient counseling. The study was approved by the Institutional Review Board (IRB) at General Surgery Department, Ain Shams University.

# **Surgical techniques**

# Group 1 (FILAC)

21 patients were operated with a FILAC diode laser device (BIOLITEC AG, Germany) as shown in **(Figure 2)** with the use of a laser probe as shown in **(Figure 3)**.



Fig 2: Shows FILAC BIOLITIC device.



Fig 3: Shows the diode laser probe.

The procedure was started with identification of external opening, internal opening and fistulous

tract. The fistulous tract was mechanically cleaned by a Curette and was washed with hydrogen peroxide followed by normal saline. At a wavelength of 1470 nm, the laser probe was inserted into the fistulous tract and directed toward the internal opening (Figure 4a). The diode laser provides 100-120 J/cm of energy. This arrangement is believed to result in effective local tissue shrinkage and protein denaturation, as well as the best water absorption curve. When no water is maintained in the tissue and the temperature exceeds 100 °C, white smoke is produced as a result of evaporation. The use of a radial tip laser at this wavelength destroys epithelium and granulation tissues while affecting a 2-3-mm zone, resulting in more controlled tissue damage with less power (13 W). During application, the laser probe was gently withdrawn a few centimeters and was advanced forward to the internal opening to ensure proper coagulation of the fistulous tract. The tip of the laser probe was removed and cleaned after every three shots to avoid carbonization. Laser application was discontinued when the tip of the laser probe was a few millimetres from the external opening. Application of an ice pack for 2 minutes was done. Closure of the internal opening using Vicryle 3/0 was performed after proper debridement of its edges (Figure 4b).

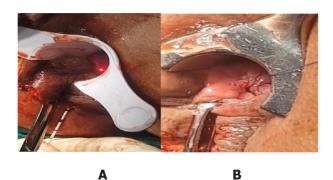


Fig 4: (A) shows the diode laser probe inserted through the fistulous tract. (B) Closure of the internal opening by vicryl 3/0.

# Group 2 (FISR)

22 Patients were operated on with a lay-open with primary sphincter repair. The procedure was started with proper localization of the internal opening by injection of hydrogen peroxide through the external opening. Fistulectomy of the tract till the lateral edge of the external sphincter was done as shown in **(Figure 5)** and then laying open all the layers. The track was curetted thoroughly and was excised, taking into consideration the need to be as superficial as possible. The muscle was repaired end to end using PDS 2/0 interrupted sutures **(Figure 6)** and the mucosa was repaired using vicryl 2/0 interrupted sutures to recreate the mucosa and the Ano-Derm.



Fig 5: Preliminary fistulectomy till the lateral edge of the external sphincter.



Fig 6: The 2 ends were stitched using PDS.

# Outcomes

# **Primary outcome: Recurrence**

Anal fistula surgery Success is frequently defined as full epithelization of the anal wound with no residual tract, external or internal apertures, or perianal discharge. The persistence of fistula surgery is divided into three categories: Recurrence, de-novo fistula, and permanent fistula. Persistence of anal fistula is defined as the failure of the anal fistula to heal completely for more than six months after surgery. Recurrence is defined as the clinical return of the fistula within one year of the procedure after complete healing of the surgical incision. On the other hand, a de-novo fistula is the clinical manifestation of a fistula after complete healing of the surgical site that occurs more than one year following the treatment.<sup>29,30</sup>

#### Secondary outcomes

#### **Fecal incontinence**

The faecal incontinence scoring system (Wexner score) was postoperatively calculated for both groups. The Wexner score, known colloquially as the Cleveland Clinic Fecal Incontinence Severity Scoring System (CCIS), is a faecal incontinence severity score ranging from 0 to 20, with 0 reflecting perfect continence and 20 indicating full incontinence.

#### Pain score

The international pain score is a numeric rating scale from 0 to 10 that was calculated for both

groups. A score of 0 represents no pain, 1-3 equals mild pain that mildly affects daily living activities, and 4-6 equals moderate pain that significantly interferes with daily living activities. A score of 7–10 indicates severe disabling pain that prevents people from performing daily living activities.

**Statistical analysis:** The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) Shapiro wilk's test was used to evaluate normal distribution of continuous data. Student t test was used to compare a Quantitative variable between two study groups. Chi square and Fisher's exact test were used to examine the relationship between Categorical variables. A P-value< 0.05 was considered statistically significant.

# Results

The mean age of study population is  $42.05\pm6.91$  years for group 1, and  $40.18\pm7.28$  for group 2. BMI was around the figure of 28. Male gender represented the majority of the study; 32 cases (74.42%). Only 7 cases of the whole study are diabetic and classified as ASA grade 2 **(Table 2)**.

Wound took remarkably shorter time to heal in FILAC group (Mean  $13.67\pm2.20$  days) versus  $37.27\pm7.84$  days in FISR group, P= 0.001. Patients who underwent FILAC technique experienced significantly lower pain score than those in the comparing group (mean  $4.14\pm1.39$  vs  $6.50\pm1.06$  respectively, P= 0.001. None of FILAC patients versus 5 cases (22.7%) of FISR group reported symptoms suggestive of incontinence (P= 0.048). Operative duration and hospital stay length did not demonstrate significant difference amongst the two groups. Although recurrence was higher in FILAC group compared to FISR group (7 cases (33.3%) vs 4 cases (18.2%) respectively), it failed to prove statistical significance, P= 0.255 **(Table 3).** 

#### Table 1: Wexner Score

Type of incontenece	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Never: 0, rarely <1/month, sometimes <1/week or >1 /month, usually <1/day or <1/week, always >1/day. 0: Perfect, 20: Complete continence.

#### Table 2: Demographic characteristics of study population

		Group 1 (FILAC)		Group 2 (FISR)		Р	Sig
		Mean	±SD	Mean	±SD	_	
Age (Years)		42.05	6.91	40.18	7.28	0.394	NS
BMI		28.05	2.09	28.45	2.50	0.566	NS
Gender	Male	15	71.4%	17	77.3%	0.661*	NC
	Female	6	28.6%	5	22.7%	— 0.661*	NS
DM	No	18	85.7%	18	81.8%	- 1.0**	NC
	DM	3	14.3%	4	18.2%	- 1.0	NS
ASA grade	Grade 1	18	85.7%	18	81.8%	- 1.0**	NS
	Grade 2	3	14.3%	4	18.2%		115

‡Student t test.

\*Chi-Square Tests.

\*\*Fisher's Exact Test.

	Group 1 (FILAC)		Group 2 (FISR)		Р	Sig
	Mean	±SD	Mean	±SD	_	
	31.62	3.29	31.68	3.23	0.950	NS
Days)	13.67	2.20	37.27	7.84	0.001	HS
	4.14	1.39	6.50	1.06	0.001	HS
1 Day	21	100.0%	18	81.8%	- 0.108**	NS
2 Days	0	0.0%	4	18.2%		
No	14	66.7%	18	81.8%	- 0.255*	NS
Yes	7	33.3%	4	18.2%		
No	21	100.0%	17	77.3%	- 0.048**	S
Yes	0	0.0%	5	22.7%		
	1 Day 2 Days No Yes No	Mean   31.62   Days) 13.67   4.14   1 Day 21   2 Days 0   No 14   Yes 7   No 21	Group 1 (FILAC)   Mean ±SD   31.62 3.29   Days) 13.67 2.20   4.14 1.39   1 Day 21 100.0%   2 Days 0 0.0%   No 14 66.7%   Yes 7 33.3%   No 21 100.0%	Mean ±SD Mean   31.62 3.29 31.68   Days) 13.67 2.20 37.27   4.14 1.39 6.50   1 Day 21 100.0% 18   2 Days 0 0.0% 4   No 14 66.7% 18   Yes 7 33.3% 4   No 21 100.0% 17	Group 1 (FILAC) Group 2 (FISR)   Mean ±SD Mean ±SD   31.62 3.29 31.68 3.23   Days) 13.67 2.20 37.27 7.84   4.14 1.39 6.50 1.06   1 Day 21 100.0% 18 81.8%   2 Days 0 0.0% 4 18.2%   No 14 66.7% 18 81.8%   Yes 7 33.3% 4 18.2%   No 21 100.0% 17 77.3%	Group I (FILAC) Group Z (FISR) P   Mean $\pm$ SD Mean $\pm$ SD   31.62 3.29 31.68 3.23 0.950   Days) 13.67 2.20 37.27 7.84 0.001   4.14 1.39 6.50 1.06 0.001   1 Day 21 100.0% 18 81.8% 0.108**   2 Days 0 0.0% 4 18.2% 0.255*   No 14 66.7% 18 81.8% 0.255*   No 21 100.0% 17 77.3% 0.048**

#### Table 3: Operative and post-operative variants in FILAC and FISR groups

Student t test.

\*Chi-Square Tests.

\*\*Fisher's Exact Test.

# Discussion

Preservation of anal sphincter integrity and continence has been the utmost concern of anal surgeons who are treating complex fistula-in-ano. Albeit fistulotomy is considered effective in treating high anal fistulae, fear of continence disruption limits its use and patient selection is crucial.<sup>10</sup> This urges anal surgeons to find out newer methods with similar efficacy and lower complication rates especially incontinence. FILAC has emerged and been accepted as a sphincter-preserving technique. However, FILAC efficacy and drawbacks have not been proven yet. This retrospective study attempts to compare both methods regarding recurrence and incontinence rates.

# **Study Variants**

Study population characteristics like age, gender, BMI, presence of DM and ASA grade did not demonstrate statistical significance. This reflects that DM did not have negative effects on wound healing, and hence can be precluded as an important confounder of wound healing time, hospital stay and recurrence. Because all study candidates were either ASA I or ASA II, they are presumed to have favorable general condition without significant systemic diseases that might influence the study outcomes.

Wound healing time was highly significantly lower in group 1 (FILAC) compared to group 2 (FISR). This can be explained by the fact that a generous fistulotomy wound is created in group 2, and it is left open in a potentially contaminated area (Anal region). Those factors are well recognized to oppose healing process prolonging healing time. In contrast, in group 1, laser probe is just passed in the already-formed fistulous track without creating extra cuts. That is why FILAC group wounds healed remarkably faster than wounds in FISR group. In parallel, pain scores in laser arm were significantly lower than in lay open arm. This can be attributed to that the incision cuts through the sensitive perianal skin in FISR group, while in FILAC group laser causes coagulation within the granulation tissue inside the fistulous pathway which is considered relatively insensitive.

FILAC laser did not show any superiority over FISR technique in terms of operative duration and hospital stay length. Although recurrence rate was higher in FILAC cohort, it did not reach statistical significance in our series. This could be secondary to the relatively small sample size. The underlying theory of recurrence in FILAC usage is that the fistulous tract is still present, and therefore liable for reopening under the effect of crypto-glandular infection reactivation. In FISR method, in spite of track removal, recurrence is hypothesized to take place due to failure of sphincter repair and reformation of the fistulous pathway.

# Fecal Incontinence

None of the FILAC patients versus 22.7% of the FISR group experienced fecal incontinence along the whole follow up period achieving statistical significance. A plausible explanation is that FISR technique entails division of anal sphincter complex. Despite immediate surgical repair, anal sphincter muscles remain weak and this repair is highly susceptible to failure due to the following reasons: 1. Sutures may be too loose causing gapping or too tight causing tissue strangulation. 2. The dynamic nature of anal sphincter may disrupt the relatively static sutures. 3. Continuous fecal soiling and local bacterial flora may increase infection rates and cause suture failure. 4. The resulting fibrosis is

considered a weak point affecting the integrity of the whole sphincter complex. This is supported by the conclusion made by Barbosa et al who stated that full continence following sphincter repair of obstetric injury is rarely achieved. On the other hand, FILAC laser does not basically injure anal sphincters, as it focuses its energy on the granulation tissue inside the fistula triggering fibrosis without inducing collateral damage. Igbal et al reported that the overall incontinence rate was 11% and substantially higher than that demonstrated by SPTs such as video assisted anal fistula treatment (VAAFT) and ligation of the intersphincteric fistula tract (LIFT).<sup>10-12</sup> Sphincter defects can be missed in 70% of patients after surgery, and can be detected only endoanal ultrasound (EAUS) which is not routinely done in the vast majority of studies.<sup>14,15</sup>

# **Recurrence in FISR**

Aguilar and co-workers conducted a large prospective study comprising 107 patients with FIPS with the longest follow up period (Range 84 to 204 months, median 96 months). Recurrence rates ranged between 0% to 14%. They advised to avoid FIPS in pre-operatively continent patients, high tracts and women due to higher risk of recurrence and incontinence based on their logistic regression analysis.<sup>21</sup> Moreover, they emphasized on the necessity of long follow up periods as 47% of recurrences (8 of 17 patients) occurred after 12 months. A study by Christiansen and Rønholt.<sup>16</sup> involved only 14 complex fistulas, and some of these had only 12 months of follow-up, with a recurrence rate of 14.3%. Similarly, a study by Lewis and Phillips,<sup>17</sup> reported a recurrence rate of 9.4% among 32 complex fistula cases and an unclear follow-up duration. Roig et al,<sup>18</sup> reported a 9.7% recurrence rate but included simple and low-tract fistulas, with most patients followed up for 12 months.

Ratto et al,<sup>15</sup> reported recurrence rates <10%, with a longer median follow-up, but some patients were only followed up for 6 months, highlighting the importance of publishing a minimum followup duration for a given series rather than simply a median. Recently, Litta et al,<sup>19</sup> published a study of 203 patients. Again, this series had only 51% complex tract cases and a mean follow-up period of 56 months. The recurrence rate was 7% but included simple and low fistulas. The incontinence rate was 19%. Ratto et al,<sup>20</sup> published a systematic review of 17 studies and 501 patients who underwent FIPS. The mean follow up period was 28.9 months, and they reported a recurrence rate of 6.8%. Nevertheless, many studies were of low quality, with heterogeneity in fistula types and short follow-up durations.

# FILAC Results

Frountzas and his colleagues conducted a meta-

analysis of 8 published articles and 476 patients. They reported only 50% success rate with almost 0% of incontinence, low complication rate and high quality of life (QoL). In addition, it was stated that increased laser energy and increased probe withdrawal speed were associated with lower complication rates.<sup>22</sup> In a narrative review of 14 articles, FiLaC is supposed to be feasible, safe, and easy to learn and is associated with minimal impairment of continence.25 Those merits were confirmed in another study in condition that internal opening is closed and external opening is excised.<sup>28</sup> Despite carrying promising results, FiLaC has still some limitations in the form of difficulty of the probe to access side tracks or extensions, which has a negative impact on recurrence rates.<sup>25</sup> Success rates (Primary healing, mostly assessed clinically), varied from 20% (4/20 patients),<sup>23</sup> at a median follow- up of 10 months to 89% (24/27 patients) reported by Donmez et al at a median follow-up of 22 months.<sup>24</sup> In a recent retrospective study by Wolicki et al, healing rate of 74.70% after an observation period of 41.99 (± 21.59) months on average. Postoperatively, 66.27% of the patients had no complaints and there were no major complications at all. Continence did not change significantly after the operation.<sup>28</sup> Technical variations of FiLaC in literature include the laser energy watts that was applied, closure of internal opening as well as the probe withdrawal speed (1-3 mm/ second).<sup>22,25</sup>

# Literature dilemma

During digging into published literature, remarkable data heterogeneity was noticed due to inconsistencies of reporting quality across all studies, lack of universal definitions of high anal fistula/ fistula length and healing time, lack of randomized controlled trials (RCTs) assessing the outcomes of FISR against other methods of treatment, and variable non-uniform tools to detect incontinence.<sup>10</sup> Indeed this variability in fistula type, length and size of the fistulas has been proposed to potentially contribute to the different outcomes.<sup>26</sup> Further work should be sought to highlight the heterogeneity of outcome reporting and develop a consensus in this context.27

#### Study strengths and limitations

This study compares FILAC to FIPS, not just a case series of one operation, increasing its credibility and scientific evidence. Only high fistulas were included rather than a mixed cohort of low and high fistulas. This enhances patient stratification, results homogeneity, and data interpretation. All cases were done in specialized referral colorectal center Study limitations include small sample size, retrospective design, single center and lack of randomization. Wexner score was not calculated before surgery leasing to missing some cases with continence impairment. Therefore, it is recommended to design large-sample multi-centric randomized controlled trials (RCTs) to consolidate our results and to compare FILAC to other treatments such as ligation of intersphincteric fistula tract, anal advancement flaps, fibrin glue, collagen paste, autologous adipose tissue, fistula plug and video-assisted anal fistula treatment.

# Conclusion

In the context of surgical treatment of high transsphincteric anal fistula, FILAC demonstrates superiority to FISR technique in terms of postoperative pain score, wound healing time and incidence of fecal incontinence. However, the recurrence rate was higher in the FILAC group than the FISR group. Hospital stay and operative time are comparable in both methods. Further randomized clinical trials are warranted to consolidate our data.

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