#### **ORIGINAL ARTICLE**



# A Prospective Study of Combined Sphincter Preserving Procedure (LIFT + VAAFT + FiLAC) in Complex Anal Fistula

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#### Abstract

Successful treatment of complex perianal fistula continues to be a challenging problem. Various new techniques have evolved such as ligation of the intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment (VAAFT), fistula laser closure (FiLaC), fibrin glue, and fistula plug. However, the results of all these techniques are variable and far from being optimal. In this study, we have combined the LIFT procedure with VAAFT and FiLaC in the treatment of complex anal fistula. We hypothesize that the combined approach can improve the healing rate without causing any change in continence. Patients of complex anal fistula (high trans-sphincteric, supra-sphincteric, and horse-shoe fistula) were included in the study based on clinical examination and MRI. All the patients were operated using the combined approach by the same team of surgeons. Patients were followed for 1 year. The assessment of continence was done by Wexner scoring. The healing, recurrence, and continence status were noted. The study included forty five patients with complex anal fistula. Primary healing occurred in 91.11% patients and none of the patients reported any de-novo incontinence. The patients with minor pre-existing incontinence did not report any worsening of continence after the procedure. The preoperative and postoperative Wexner scores did not show any significant change. The average healing time was 43.53 days. This study concludes that the combined sphincter sparing approach (LIFT + VAAFT + FiLAC) is a safe and effective procedure for complex anal fistula. Combining the various techniques can improve the outcome without compromising the continence status of patient.

Keywords Fistula-in-ano · LIFT · VAAFT · FiLaC

## Introduction

The incidence of fistula-in-ano (perianal fistula) varies between 0.86 and 2.32 per 10,000/year. There is a male predominance with male to female ratio varying from 2:1 to 5:1 [1]. The most accepted etiologic factor for causation of fistula-in-ano is infection starting in the anal glands [2].

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<sup>1</sup> Department of Surgery, King George's Medical University, Lucknow, India Infection developing in an anal gland lying within the sub mucosa or the inter-sphincteric space of the anal canal is the direct cause of most fistula-in-ano; hence, the term "crypto-glandular fistula" is often used. Other rare causes include inflammatory bowel disease, tuberculosis, carcinoma, and trauma. The most widely used classification for perianal fistula is Park's classification which is based on the course of the fistula tract. As per this classification, there are four major groups of anal fistula: inter-sphincteric (70%), transsphincteric (25%), supra-sphincteric (5%), and extra-sphincteric (1%) [3]. The trans-sphincteric fistula may be low (lower 30% of external sphincter is involved) or high (more than 30% of the external sphincter violated [4].

Ideal surgical treatment for anal fistula should aim to eradicate sepsis and promote healing of the tract, while preserving the sphincters and the mechanism of continence [5]. The simple anal fistulae (minimal involvement of sphincter muscles) can be treated safely with conventional surgical procedures (fistulotomy/fistulectomy), without compromising continence. For the more complex fistulae, where a significant proportion of the anal sphincter is involved, great concern remains about damaging the sphincters and subsequent poor functional outcome, which is quite inevitable following conventional surgical treatment. For this reason, over the last two decades, many sphincterpreserving procedures for the treatment of anal fistula have been introduced with the common goal of minimizing the injury to the anal sphincters and preserving optimal function. These procedures include ligation of inter-sphincteric fistula tract (LIFT), video assisted anal fistula treatment (VAAFT), fistula laser closure (FiLaC), and the use of fibrin glue and collagen plug.

The LIFT procedure involves secure closure of internal opening as well as removal of the infected cryptoglandular tissue in the inter-sphincteric plane, yielding success rate ranging from 57 to 94% in various studies [2]. Videoassisted anal fistula treatment (VAAFT) is a minimally invasive, sphincter sparing procedure for treatment of complex anal fistula [6]. The success of VAAFT procedure ranges from 66.7 to 87.5% [7–11]. The VAAFT procedure includes two stages, diagnostic and therapeutic. The goal of the diagnostic part is direct visualization of the fistula tract and identification of the internal opening. The therapeutic part includes cleaning and de-epithelization of the fistula tract along with closure of internal opening. Recently, diode laser is used for the treatment of complex anal fistula in a procedure called FiLaC (fistula laser closure). The diode laser is used with a radial emission fiber with the wavelength of 1470 nm. The internal opening is closed by direct suture closure or by myomucosal flap and the fistula tract is fulgrated at the end of the procedure [12].

All these techniques have produced variable results and are not free of shortcomings. The healing rate of none of these procedures are comparable to the conventional surgical procedures (fistulotomy/fistulectomy). In this study, we have combined the LIFT procedure with VAAFT and FilaC for the treatment of complex anal fistula. The fistuloscope is used to visualize the tract, to identify any secondary tracts, and to localize internal opening. The debridement and cleaning of the fistula tract is also accomplished using the endo-brush through the fistuloscope. The LIFT procedure is performed to disconnect the fistula tract from the anal canal. The laser fiber is used for the fulgration of the remaining portion of tract at the end of the procedure. The results of this combined approach are compared with the results of the standard LIFT procedure. We hypothesized that the combined sphincter sparing procedure will improve the healing rates as compared to the standard LIFT procedure.

This prospective observational study was conducted at the Department of General Surgery, King George's Medical University, Lucknow, UP, India. Patients with complex perianal fistula were included in the study after obtaining written and informed consent. The anal fistulae were classified based on findings of physical examination and MRI. Patients with high trans-sphincteric fistula (external sphincter involvement > 30%), supra-sphincteric fistula, and horseshoe fistula were included in the study. Patients with anorectal abscess, simple fistula (low inter-sphincteric fistula, low trans-sphincteric fistula where external sphincter involvement < 30%), extra sphincteric fistula (internal opening was above pectinate line), and secondary fistula (evidence of tuberculosis, Crohn's disease, malignancy) were not included in the study. Preoperative assessment of continence was done in all the patients by Wexner scoring. The follow up period was 1 year. The study was approved by the institutional ethics committee.

All the patients were operated in regional anesthesia. Patients with posteriorly placed fistulas were operated in prone jack knife position and those with anteriorly placed fistulas were operated in lithotomy position. The internal opening was identified by injecting saline/water from the external opening. A diagnostic fistuloscopy was performed to identify any secondary tracts and internal opening. A 2-cm curvilinear incision was given at the inter-sphincteric groove corresponding to the internal opening. By careful dissection in the inter-sphincteric plane, the internal and external sphincter muscles were separated to expose the fistula tract. Care was taken not to divide any sphincter muscles. Once the tract was dissected free, it was divided and ligated on the side of the internal sphincter. On the external sphincter side, the sutures were placed but not tightened. The fistuloscope was used again to clean and debride the tract with endo-brush. The fistuloscope used is provided by Karl Storz GmbH (Tuttlingen, Germany), which comprises fistuloscope, obturator, unipolar electrode, fistula probe, endo-brush, forceps, and di-wing anoscope.

Following thorough debridement with fistuloscope, the tract is fulgurated with Diode laser fiber of 1470 nm (FiLaC fistula probe, Biolitec, Germany, The BIOLITEC LEONARDO). The fiber is gradually withdrawn 5 mm every 3 s, from the opening in the inter-sphincteric groove to the external orifice. This causes simultaneous destruction and sealing of paths with energy dispersion of 8 W and 100 J/cm. The transfixation sutures in the fistula tract toward the external sphincter are now tightened in the inter-sphincteric groove and the inter-sphincteric wound is closed. All patients received antibiotics for 1 week after the operation. The patients were followed up to 1 year and monitored for wound healing, recurrence, and any change in continence in the outpatient clinic. Recurrence was defined as a non-healing wound or reappearance of an external opening with persistent discharge or reappearance of a fistula after the initial wound has healed. The continence assessment of the patients was done at 6 weeks, 3 months, 6 months, and at 1 year by Wexner scoring.

All the numeric statistical data regarding healing, recurrence, and incontinence was collected and arranged in a master-chart and processed through various statistical test (independent *t*-test, chi-square test, one-way ANOVA test) and final results have been expressed in tabular form.

#### Results

The study was started in October 2019 and the process of patient recruitment and operations was continued up to March 2020. The patients were followed for minimum up to 1 year and the study was completed in March 2021. The follow up period ranged from 12 to 16 months (median 14 months). The study included forty-five patients of which 41 were male and 4 were female. The mean age of patients was 42.13 years. The youngest patient was 20 years old and the oldest patient was 73 years old. MRI was performed in all the patients preoperatively. Out of the 45 patients of complex anal fistula, 38 patients had trans-sphincteric fistula, 2 patients had supra-sphincteric fistula, and 5 patients had horse-shoe fistula. All the horse-shoe fistulae were transsphincteric with single internal opening and bilateral tracts and external openings. The type and classification of the fistulae based on the three frequently used classification systems is described in Table 1.

The preoperative Wexner score was normal in thirty-three patients. There was recurrent disease in twelve patients and they had variable degree of incontinence (mean Wexner score 2.92). The overall Wexner score ranged from 0 to 5 (mean 0.80).

 Table 1
 The type and classification of the fistulae based on the three frequently used classification systems

Parks AG [3]		Garg P [13]		Morris J [14]		
Туре	Number of patients	Туре	Number of patients	Туре	Num- ber of patients	
Type 2a (high)	35	IIIA	26	Grade 3	35	
Type 2b	8	IIIB	4	Grade 4	8	
Type 3	2	IVB	8	Grade 5	2	
		IVC	5			
		VB	2			

Complete wound healing was observed in 41 patients (91.11%) at the end of 1 year follow up. In 4 patients there was discharge of pus and blood which continued at 6 weeks, 3 months, and at further follow up visits. These patients were designated as recurrence/failures. So, the primary healing rate of combined approach surgery in the study was found to be 91.11% and failure or recurrence rate was 8.89% (Table 2). Postoperative MRI was performed in the patients who had persistent disease or recurrence. Out of the four patients with recurrence/failure, two patients had tanssphincteric fistula and they were managed by fistulotomy, one patient had horse-shoe fistula who was managed by partial coring, and one patient had supra-sphincteric fistula who was managed by a repeat combined approach. The most likely cause of recurrence/failure in these patients was presence of occult abscess in the intersphincteric plane.

There was no de-novo incontinence in patients who had normal preoperative sphincter functions. There was no significant change in the over-all Wexner score of the patients as the change in mean pre-operative Wexner score (0.80 with 1.37 standard deviation) and the Wexner score at 1 year (post-operative mean Wexner score 0.77 with 1.31 standard deviation) was not significant (Table 3).

There was variable degree of incontinence preoperatively in twelve patients due to previous procedures. The preoperative mean Wexner score of the patients with recurrent disease was 2.92 with 0.79 standard deviation. The Wexner score of these patients increased in the immediate postoperative period to 3.42 with standard deviation of 1.00 at 6 weeks. At 3 months, the Wexner score of these patients was 3.00 with standard deviation 0.85. After 6 months, the

Table 2 Primary healing rate of combined approach surged	er	ry
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Healing	(n=45)		
	n	%	
At 6 weeks			
Healed	37	82.22	
Persistent discharge	8	17.78	
At 3, 6 months, and 1 year			
Healed	41	91.11	
Recurrence	4	8.89	

Tal	ble 3	Over-all	Wexner	score	of	the	patients
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Wexner score	Mean	Std. Deviation	<i>p</i> -Value	
Pre-operative	0.80	1.37	0.988	
6 weeks post-operative	0.93	1.62		
3 months post-operative	0.82	1.42		
6 months post-operative	0.77	1.33		
1 year post-operative	0.77	1.31		

Wexner score improved to 2.83 with 0.72 standard deviation. Hence, there was no worsening of incontinence in patients who had recurrent disease and variable degree of incontinence in the preoperative period (Table 4).

The mean hospital stay was 1.4 days with 0.62 standard deviation. The mean duration of wound healing was 43.53 days with 11.38 standard deviation while duration requires return to normal work is 20.42 days with 8.08 standard deviation.

## Discussion

The treatment of simple anal fistula (involvement of lower part of sphincter complex) is straight forward and a conventional fistulotomy offers satisfactory cure rate without compromising continence [15–17]. Treatment of complex anal fistula continues to be challenging and its treatment options range from sphincter cutting procedures (fistulectomy with primary sphincter reconstruction) to sphincter sparing procedures (LIFT, VAAFT, FiLaC etc.).

When fistulotomy/fistulectomy is performed for complex perianal fistula (involvement of more than 30% of external sphincter), the cure rate is still good; however, it can cause significant disturbances with continence. Therefore, fistulectomy may be combined with a primary sphincter reconstruction in patients of complex anal fistula [18]. Alternatively, the complex fistula may be treated by the sphincter sparing procedures. The sphincter sparing procedures offer preservation of continence but the recurrence rate is higher than the fistulotomy/fistulectomy. Many sphincter sparing procedures have been proposed, however, none of them has produced results comparable to fistulotomy/fistulectomy.

In this study we combined the standard LIFT procedure with VAAFT and FiLaC with the intent to improve the healing rate. The overall healing rate was 91.11% and 8.89% patients had recurrence at 1 year follow up in our study. In a previous study done at our center (2017), the standard LIFT procedure was performed in trans-sphincteric and

Table 4 Wexner score of the patients with pre-existing incontinence

Wexner score	Patients with $(n=12)$	<sup>1</sup> <i>p</i> -value	
	Mean	±SD	
Pre-operative	2.92	0.79	0.241
Post-operative			
6 weeks	3.42	1.00	
3 months	3.00	0.85	
6 months	2.83	0.72	
1 year	2.75	0.75	

SD, standard deviation;  $^{1} = ANOVA$ 

supra-sphincteric anal fistulas in 110 patients. The over-all healing was 83.3% at 1 year follow up [19]. The addition of VAAFT and FiLaC has improved the results of the standard LIFT procedure at our institution.

Samira Zirak-Schmidt and Sharafkarim Pederwood conducted a systemic review of 19 original articles on management of anal fistula by LIFT procedure. The primary healing rate was 70.6% (healing shown in 432 out of 612) with follow up duration of 8 months [20]. In a recent systematic review (26 studies, 1378 patients of anal fistula), undergoing LIFT procedure demonstrated the success rate of 76.5% with 1.4% anal incontinence rate [21].

A multi-center randomized study (235 patients) was carried out to compare LIFT procedure with LIFT combined with fistula plug application. There were 118 patients in the LIFT group and 117 patients were treated by LIFT-Plug. The LIFT-plug group showed higher healing rate of 94% in comparison to LIFT group where healing was 83.9% with a follow up period of 6 months [22]. A comparative study conducted by Sirikurnpiboon on 41 patients of complex anal fistula to compare healing rates between LIFT and LIFT plus partial fistulectomy procedures showed overall healing rate of 83%. While in LIFT group healing rate was 81% and in LIFT plus group it was 85%. None of the group showed incontinence [23]. Ellis conducted Bio-LIFT procedure (bioprosthetic was placed in the inter-sphincteric plane to reinforce the closure of the fistula tract) on 31 patients; all with trans-sphincteric fistula achieved 94% success rate after follow up period of 12 months. No sphincter function variation was noted in post-operative follow up period. Bio-LIFT procedure has been used for management of recto-vaginal fistula [24].

In a single-centered, non-randomized, prospective study on VAAFT for management of perianal fistula conducted by Michal Romaniszyn, primary healing rate was 54.41%, and success rate for simple fistula was 73.3% but for complex fistula it was just 39.47%. The mean follow up period time was 31 months [25]. In a proportional meta-analysis of 786 patients (8 studies), who underwent VAAFT from 2010 to 2016, the net pooled success rate was 76.01% (95% *CI* 1/4 68.1–83.9). The net complication rate was 16.2% (95% *CI* 1/4 12.1–20.2) [26]. In most of the studies the internal opening was closed by endo GI stapler although other methods (mattress suture, an advancement flap, mucosal flap, usage of fibrin glue) of closure of internal opening were also used in many studies.

In the largest study of anal fistulas treated with the FiLaC technique, Wilhelm et al., reported primary healing rate of 64.1% (75 out of 117 patients over a 12-month period of follow-up). The secondary success rate (that is after a second application of the FiLaC technique) was reported to be 88%. It is interesting to note that the above-mentioned success rates refer to all types of fistula combined (according to

Parks classification). Internal opening was closed either by a mucosal or an anodermal flap [27]. P. Giamundo operated 35 patients of peri-anal fistulas (primary or recurrent transsphincteric anal fistulas) with FiLaC procedure. After the mean follow up period of 20 months, study showed 71.4% of healing rate. There were eight (23%) failures and two recurrences at 3 and 6 months after the operation. Internal opening was not closed and it was fulgrated and shrinked due to the effect of laser energy [28]. A systematic review and meta-analysis on FiLaC procedure (2020) showed 67.3% overall healing rate and mean rate of complication was 4% with 1% minor incontinence. It included 454 patients in which 35% were of recurrent disease with mean follow up period of 23.7 months [29].

In a recent study, video-assisted LIFT (VA-LIFT) was performed as a newer sphincter-preserving approach to anal fistulas in 103 patients with complex anal fistula, including 16 patients (15.5%) with recurrent fistula, and complex anal fistulas were completely healed in 87 patients after an index VA-LIFT, thus accounting for the primary healing rate of 84.5%. Based on fistula type, the success rate of VA-LIFT was 88% for anterior high transsphincteric fistula (44 of 50 cases), 77% for semi-horseshoe fistula (30 of 39 cases), and 93% for horseshoe fistula (13 of 14 cases) [30].

In our study, no de-novo incontinence was observed in patients with normal sphincter function. The patients who presented with recurrent disease and had varying degree of incontinence attributed to previous procedures, did not report any worsening of their incontinence. The results are suggesting that this combined sphincter sparing approach is safe and does not cause any incontinence.

Samira Zirak-Schmidt and Sharafkarim Pederwood conducted a systemic review of 19 original articles on management of anal fistula by LIFT procedure showed no sphincter function impairment. Similarly, Wilhelm et al. carried out a study on 117 patients of complex fistula by FiLaC procedure documented no change in continence status in post-op follow up period. In a study by P. Giamundo on 35 patients of perianal fistula (primary or recurrent trans-sphincteric anal fistulas) with FiLaC procedure, no change in sphincter function was found after the mean follow up period of 20 months.

The mean wound healing duration in our study was  $43.53 \pm 11.38$  days. The mean hospital stay (days) in our study was  $1.40 \pm 0.62$  days. The range of stay in hospital after surgery is from maximum 4 days to minimum 1 day. The mean return to normal work in our study was  $20.42 \pm 8.08$  days. The maximum time taken to go back to normal routine work is very subjective for each individual that is why there is a wide range in time taken to go back to normal routine work with minimum duration of 10 days to maximum of 60 days. Overall duration to return to normal work is  $20.42 \pm 8.08$  days. The maximum function of 8.08. The mean duration of surgery (min) in our study was

 $36.27 \pm 7.75$  min and mean duration of requirement of analgesia was  $7.09 \pm 2.48$  days.

## Conclusion

LIFT procedure has now become standard procedure for trans-sphincteric anal fistula. VAAFT procedure has also evolved as a sphincter sparing technique for all type of anal fistulae. FiLAC (fistula-in-ano laser closure) is a new procedure and becoming popular in sphincter saving category. We have performed the LIFT procedure along with fistuloscope and application of laser to deal with the remaining tract. The study has shown that the combined sphincter sparing approach (LIFT + VAAFT + FiLaC) is a safe and effective procedure for complex anal fistula and can improve the overall results. There is no de-novo incontinence after the procedure and no worsening of previously existing incontinence.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12262-021-03222-1.

#### Declarations

Conflict of Interest The author declares no competing interests.

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