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ORIGINAL ARTICLE

Laser ablation of fistula tract (LAFT) and complex fistula-in-ano: "the ideal indication" is becoming clearer…

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Abstract

Background An initial study enabled us to achieve 60% healing of high transsphincteric fistula-in-ano with laser ablation of fistula tract (LAFT) The purpose of this new study was to investigate other predictors of the success of this technique in the treatment of complex anoperineal fistulas.

Methods All patients treated with LAFT in our department between May 2017 and October 2018 were included prospectively. LAFT was used for patients with complex anoperineal fistulas who were at high risk of anal incontinence after fistulotomy. The fistula was considered healed when the internal and external openings were closed and the patient experienced no pain or leakage.

Results A total of 100 consecutive patients (65 males) with a median age of 43 years (range 22–88 years) were included in the study. Eight patients were lost to follow-up. The fistulas were low (8%) or high (79%) transsphincteric, and suprasphincteric (13%). After a median follow-up of 13.6 months (range 6–23 months), fistula healing was observed in 41 patients (44.6%). On univariate analysis, an anterior location, a narrow internal orifice and administration of less than 400 J of energy were significantly associated with healing. On multivariate analysis, a narrow internal orifice and low energy administration remained significant predictive factors of success [OR 5.08 (1.03–25.03), $p=0.046$; OR 2.59 (1.08–6.17), $p=0.032$]. No new cases of anal incontinence or any worsening of pre-existing anal incontinence was observed during follow up.

Conclusions This study indicates that complex anoperineal fistulas with a narrow internal orifice can be successfully treated with less than 400 J and are ideal for LAFT.

Keywords Anal fistula · Sphincter-saving technique · Laser · LAFT

Introduction

"Complex" anal fistulas are characterized by a tract that cannot be cured by a fistulotomy without taking a risk of significant incontinence due to the height of the tract and/or the patient's history (Crohn's disease, history of obstetric perineal tears, anterior fistula in women, chronic diarrhoea) [1]. Sphincteric-sparing techniques have been proposed to respond to this surgical challenge: heal the fistula while preserving anal continence. These techniques have the advantage of preserving sphincter function, but result in a higher rate of failure and recurrence of suppuration than after fistulotomy.

The main sphincter-saving techniques are insertion of a plug [2] and injection of biological glue [3], but also, and above all now, the advancement flap [4], ligation of the intersphincteric fistula tract (LIFT) [4] and, more recently, video-assisted anal fistula treatment (VAAFT) [5], radiofrequency [6] and laser ablation of fistula tract (LAFT), also known as fistula laser closure (FiLaC™) [7].

LAFT consists of closing the fistulous tract by burning it with laser energy. The first studies describing this technique were promising with a healing rate of 70–80%, but involved a small number of patients included retrospectively (Table 1). More recent studies have not confirmed the initial healing rates and struggle to find predictive factors for success that can help determine the ideal indication [7–14].

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Table 1 Literature review of published studies on LAFT

Author	*N*	Median age	Healing (%)	Median follow-up (months)	Internal orifice	Crohn's disease (*n*)	Predictors of success
Wilhelm (2011) [7]	11	51 (38–65)	81.80	7.4 (2–11)	Flap	0	NA
Giamundo (2014) [8]	35	48 (27–76)	71.40	20 (3–36)	No closure	2	NA
Öztürk (2014) [9]	50	41 (23–83)	82	12 (2–18)	No closure	0	NA
Giamundo (2015) [10]	45	46 (18–78)	71.10	30 (6–46)	No closure	0	Loose seton
Wilhelm (2017) [11]	117	46 (17–82)	64.10	25.4 (6–60)	Flap/suture	13	Intersphincteric fistulas
Cem Terzi (2018) [12]	103	43 (18–78)	40	28 (2.3–50)	No closure	0	NA
Marref (2018) [13]	69	42.3	45	6	No closure	6	High transsphincteric fistula
Lauretta (2018) [14]	30	52 (26–72)	33.30	11.3 (6–24)	No closure	0	Tract length < 30 mm
Present study (2019)	100	43 (22–88)	44.6	13.6 (6–23)	No closure	10	Narrow internal orifice Energy administered < 400 J

LAFT laser ablation of fistula tract

In our department, the technique has been used since 2012 and an initial study on 69 consecutive patients, carried out between May 2016 and April 2017, demonstrated a healing rate of 60% for high transsphincteric fistulas [13].

The purpose of the present study was to evaluate the healing rate of complex fistulas treated with LAFT in a larger new cohort of patients to identify other predictive factors of success.

Materials and methods

Patient selection/study design

This study was a retrospective evaluation of a single-centre cohort prospectively constituted in the medico-surgical proctology department of the Saint Joseph Hospital Group in Paris.

Consecutive patients with complex anal fistula treated with LAFT in our department between 3 May 2017 and 2 October 2018 were included in the study. Patients were followed up clinically in pre- and postoperative consultation as part of their usual treatment during which their age, sex, comorbidities and previous fistula treatments were recorded.

Surgical technique

All patients had an initial surgical procedure to detect the fistula tract with placement of a loose seton to drain any abscesses and/or to cure any diverticula. The type of fistula tract was determined by the surgeon during this first operation according to the Parks classification [15]. In case of doubt about the quality of drainage, multiple surgical interventions on the fistula, continence disorders and/or Crohn's disease, magnetic resonance imaging (MRI) and/or endoanal ultrasound could be performed preoperatively, but was not routinely required.

Antibiotic prophylaxis with 1 g oral metronidazole was administered preoperatively. The procedure was performed under general anaesthesia or locoregional anaesthesia. After removal of the seton, the tract was debrided with a specific brush. Treatment was performed using a 1470 nm wavelength laser probe (Biolitec AG, Jena, Germany) and standardized 13 W power in continuous mode. During the procedure, the internal orifice was not closed. The size of the internal orifice was estimated by the operator: it was considered to be narrow when its diameter was equal to that of the laser probe and wide when it was larger than the probe.

The fistula was considered healed when the internal and external openings were closed and the patient experienced no pain or leakage.

End points

The primary end point of our study was the fistula healing rate at the last recorded follow-up visit defined clinically by internal and external orifice closure, and absence of pain and leakage, as assessed by a proctologist in the department. Early failures were defined as occurring before the third postoperative month and recurrences after the third month.

Secondary end points were predictive factors of success of the technique (gender, age, body mass index, Crohn's disease, use of immunosuppressor, the duration of the fistula progression, the duration of the pre-LAFT fistula drainage, the localization (anterior or posterior) highness and length of the fistula tract, the amount of energy administered on fistula tract and internal orifice), comparison of pre- and postoperative Wexner scores to check that there was no impact of LAFT on sphincter continence and the incidence of other complications after surgery.

Statistical analysis

Univariate analysis was performed to check the prognostic role of the various potential risk factors on the healing rate. The Fisher and Chi^2 tests were carried out for qualitative variables. Continuous quantitative variables were transformed into qualitative variables for simplicity by separating them according to their median. Multivariate analysis was performed for factors associated with healing obtained by univariate analysis and a p value < 0.2. All of the tests were two sided. A p value of < 0.05 was considered statistically significant. These statistical analyses were performed using SPSS (version 23, IBM Corp, Armonk, NY, USA).

Ethics

The hospital's ethics committee approved the study.

Results

Study population

During the 17-month study period, 100 patients with complex fistulas had LAFT for anal fistulas (Fig. 1).

The main preoperative patient characteristics are presented in Table 2. The aetiology of the fistulas was cryptoglandular infection in 89 cases (89%). Ten patients (10%) were treated for Crohn's disease and were all treated with anti TNF-alpha, and in four cases in combotherapy with a thiopurine. One patient (1%) had a fistula due to a laser haemorrhoidoplasty.

Table 2 Patient and fistula characteristics

	$N = 100$
Demographics	
Median age, years (range)	43 (22–88)
Males, *n* (%)	65 (65)
Mean body mass index, kg/m^2 (± SD)	26.7 (5.37)
Diabetes, *n* (%)	8 (8)
Crohn's disease, *n* (%)	10 (10)
Human immunodeficiency virus, *n* (%)	3 (3)
Mean number of prior operations (± SD)	2.42 (1.63)
Fistula characteristics, *n* (%)	
Tract type	
Intersphincteric, *n* (%)	0
Low transsphincteric, *n* (%)	8 (8)
High transsphincteric, *n* (%)	79 (79)
Suprasphincteric, *n* (%)	13 (13)
Extrasphincteric, *n* (%)	0
Tract location	
Anterior, *n* (%)	43 (43)
Posterior, *n* (%)	57 (57)
Secondary tracts, *n* (%)	13 (13)
Horseshoe, *n* (%)	12 (92.3)
Intramural, *n* (%)	1 (7.7)
Drainage time/median LAFT, days	112 (42–1040)
Peroperative findings	
Mean main tract length, cm (± SD)	4.08 (1.73)
Wide internal orifice, *n* (%)	16 (16)
Narrow internal orifice, *n* (%)	84 (84)

LAFT laser ablation of fistula tract

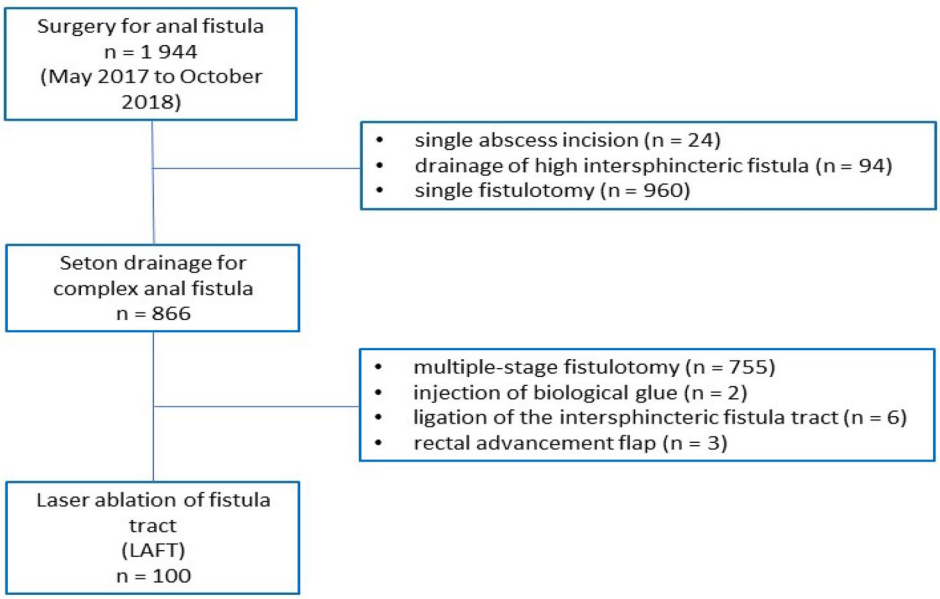

Fig. 1 Flow diagram of the study

The fistula characteristics are shown in Table 2. There were eight low transsphincteric tracts treated with LAFT because of the high risk of anal incontinence after fistulotomy [Crohn's disease ($n=1$), anal incontinence established preoperatively ($n=2$), anterior tract in women ($n=4$), and high number of pre-LAFT interventions ($n=1$)]. There was no supralevatorial secondary diverticulum.

The procedure was performed in the outpatient department and the 21 patients (21%) who had conventional hospitalization was mainly due to precautions around the use of anticoagulants ($n=7$) or the absence of an accompanying person ($n=14$) allowing them to be discharged on the day of the procedure. A mean energy of 552 J (±443) was administered. The mean period of sick leave was 4.98 days (±5.82).

Outcomes

Eight patients were lost to follow-up. After a median follow-up of 13.6 months (range 6–23 months), 41 of the 92 patients followed (44.6%) were considered clinically healed. Early failures and recurrences as well as treatments are reported in Table 3.

On univariate analysis, anterior tract location, a narrow internal orifice and the amount of energy administered during LAFT of less than 400 J were statistically associated with success. On multivariate analysis, only a narrow internal orifice and a low level of energy were associated with procedural success [OR 5.08 (1.03–25.03), $p=0.046$; OR 2.59 (1.08–6.17), $p=0.032$]. Results for all the potential prognostic factors investigated are reported in Table 4. For the analysis of the impact of fistula tract location, we analysed low and high transsphincteric fistulas in a single block due to the low number of low fistulas and the lack of statistical significance due to the low number of patients.

Table 3 LAFT results

Healing, *n* (%)	41 (44.6)
Low transsphincteric, *n* (%)	5/8 (62.5)
High transsphincteric, *n* (%)	33/79 (41.8)
Suprasphincteric, *n* (%)	3/13 (23.1)
Failure, *n* (%)	51 (55.4)
Early failure with persistent leakage, *n* (%)	35/51 (68.6)
Recurrence of leakage, *n* (%)	8/51 (15.7)
Recurrence with abscess occurrence, *n* (%)	8/51 (15.7)
Mean time to abscess onset, days (±SD)	244 (130)
Treatment failure	*N*=51
Abscess drainage, *n* (%)	17 (33.3)
Immediate fistulotomy, *n* (%)	15 (27.4)
Repeat LAFT, *n* (%)	3 (5.9)
Awaiting treatment, *n* (%)	16 (31.4)

LAFT laser ablation of fistula tract

In addition, the length of the fistulous tract can be linked to the amount of energy used during surgery. We assessed the amount of energy related to the length of the fistulas treated (in J/cm of fistula). A persistent trend in favour of lower energy/cm was associated with healing (58.5% in the low-energy group versus 41.5% in the higher-energy group), but without reaching significance. ($p=0.098$).

Preoperative incontinence was reported in 15 patients (15%), primarily concerning gas with a median Wexner score of 4 (range 2–10). There were no new reports of postoperative anal incontinence or worsening of preoperative anal incontinence with an unchanged median Wexner score postoperatively.

No significant complications were noted postoperatively.

Discussion

Our study showed an overall healing rate of 44.6% of treated fistulas after a median follow-up of 13.6 months (range 6–23 months). This confirms the 45.6% rate obtained by our team in our previous study, and suggests that the high failure rate did not depend on the learning curve [13].

This 44.6% healing rate is lower than that obtained in the initial studies on this technique (Table 1). In 2011, in the pilot study by Wilhelm et al., healing was achieved in 81.8% of the 11 patients treated after a median follow-up time of 7.4 months (range 2–11 months) [7]. However, our results cannot be directly compared with these results because all patients treated by Wilhelm's team also had a mucosal advancement flap closing the internal orifice, whereas none of our patients did [4]. Similarly, Giamundo et al. reported in 2014 a healing rate of 71.4% in 35 patients after a median follow-up of 20 months (range 2–36 months) [8], and in 2015 a rate of 71.10% in 45 patients after a median follow-up of 30 months (range 6–46 months) [10]. However, their patients are not exactly comparable to ours, because the proportion of intersphincteric and low transsphincteric fistulas was higher than that in our population, reaching 56% of treated fistulas in the first study (8 low transsphincteric fistulas and 8 intersphincteric fistulas) and 30% in the second study (14 patients). Moreover, low fistulas accounted for only 8% of the fistulas in our study, because they can most often be treated with fistulotomy with good results. The same observation can be made regarding the study by Öztürk et al. reporting a healing rate of 82% with 88% low fistulas [9]. The success rates of the three most recently published studies were lower, closer to the rate we achieved [11, 12, 14]. In all three studies, the majority of treated fistulas were high transsphincteric and the profiles of the study populations were similar to that of our series. With many sphincter-sparing treatments, good initial results are often not confirmed by subsequent studies [16].

Table 4 Univariate and multivariate analysis of factors associated with healing

Variables	Failure ($n=51$)	Healed ($n=41$)	p	OR (IC)	p
Patient					
Males, *n* (%)	31 (51.7)	29 (48.3)	0.319		
Age at time of LAFT (years), mean (%)	45.5 (13.5)	43.9 (15.7)	0.609		
Age < 45 years mean (%)	28 (56)	22 (44)	0.905		
Age > 45 years mean (%)	23 (54.8)	19 (42.5)			
Mean BMI kg/m^2 (± SD)	27.1 (5.56)	27.1 (5.06)	1		
BMI < 27, *n* (%)	27 (52.9)	24 (47.1)	0.591		
BMI > 27, *n* (%)	24 (58.5)	17 (41.5)			
Use of antiaggregants, *n* (%)	1 (2)	3 (7.5)	0.201		
Use of anticoagulants, *n* (%)	4 (7.8)	1 (2.5)	0.267		
Crohn's disease, *n* (%)	3 (37.5)	5 (62.5)	0.285		
Diabetes, *n* (%)	3 (50)	3 (50)	0.782		
Immunosuppression, *n* (%)	3 (33.3)	6 (66.7)	0.168		
Fistula					
Duration of progression < 2 years, *n* (%)	37 (56.9)	28 (43.1)	0.656		
Duration of progression > 2 years, *n* (%)	14 (51.9)	13 (48.1)			
Duration of pre-LAFT seton drainage < 100 days, *n* (%)	21 (52.5)	19 (47.5)	0.619		
Duration of pre-LAFT seton drainage > 100 days, *n* (%)	30 (57.7)	22 (42.3)			
Anterior main tract, *n* (%)	17 (41.5)	24 (58.5)	**0.016**		**0.229**
Posterior main tract, *n* (%)	34 (66.7)	17 (33.3)			
Secondary diverticula, *n* (%)	7 (14)	3 (7.5)	0.346		
Transsphincteric tract, *n* (%)	41 (51.9)	38 (48.1)	**0.093**		**0.406**
Suprasphincteric tract, *n* (%)	10 (76.9)	3 (23.1)			
Mean main tract length, *n* (%)	4.32 (± 1.92)	3.78 (± 1.57)	0.14		
Mean main tract length (cm) < 3.5 cm, *n* (%)	22 (53.7)	19 (46.3)	0.759		
Mean main tract length (cm) > 3.5 cm, *n* (%)	29 (56.9)	22 (43.1)			
Narrow internal orifice, *n* (%)	40 (50.6)	39 (49.4)	**0.033**	**5.08 (1.03–25.03)**	**0.046**
Wide internal orifice, *n* (%)	11 (84.6)	2 (15.4)			
LAFT					
Average total energy ($n=68$) (± SD)	654 (525)	458 (337)	**0.043**		
Total energy < 400 J, *n* (%)	20 (39.2)	26 (65)	**0.021**	**2.59 (1.08–6.17)**	**0.032**
Total energy > 400 J, *n* (%)	31 (67.4)	15 (32.6)			
Average energy at the internal orifice (J), *n* (%)	92.8 (55.7)	87.0 (50.3)	0.6		
Outpatient treatment, *n* (%)	38 (52.8)	34 (47.2)	0.331		
Conventional hospitalisation, *n* (%)	13 (65)	7 (35)			

The value of the "*p*" considered statistically significant or close to be (in bold)

LAFT laser ablation of fistula tract

The present study confirmed our previous results regarding the difficulty of treating suprasphincteric fistulas with LAFT. Only 23% of these fistulas healed which is close to the 18% healing rate obtained in our previous study [13]. This can be explained by the tortuous portion of the tract of this type of fistula within the interpshincteric space, making it more difficult to drain and therefore to treat with the laser probe [17]. Due to the lack of routinely performed preoperative imaging in our study, we may have overlooked this type of prolongation in some cases. In the case of a suprasphincteric fistula, routine preoperative imaging may allow better results to be obtained.

In this series, 16 patients relapsed more than 3 months after treatment and some of them up to 1 year later. This result reopens the debate on the time point after treatment when a fistula can be considered as healed.

Our study demonstrated that treatment with LAFT did not effectively treat fistulas with a wide internal orifice, as the healing rate in this group was 15.4%. This result reopens the debate on the closure of the internal orifice. Our results

suggest that a procedure to close a wide internal orifice may increases the chances of healing.

Our results also indicate that the amount of energy used during the procedure affects the healing rate. In our study, a lower amount of energy was significantly associated with fistula healing. This result was confirmed on multivariate analysis with a higher healing rate (65%) in the group of fistulas in which less than 400 J of energy was administered. This result could be explained by the fact that larger diameter fistulas, perhaps more difficult to heal, required more energy to be closed. It may also be explained by an "overburning" effect of too much energy, which could contribute to necrosis or enlargement of the fistula tract, leading to potential failure of the technique. Enlarging the internal tract or orifice, in addition to causing immediate failure, could also be harmful for subsequent treatments, as in our study a wide internal orifice was associated with failure of the technique. However, when calculating the amount of energy delivered per centimetre of fistula and not the total amount administered per fistula, there was just a statistical trend towards significance, indicating that more data is likely needed to draw firm conclusions.

Finally, our study confirmed that LAFT was a sphincter-sparing technique. As expected and reported in previous studies [7–14], there were no new cases of anal incontinence or worsening of pre-existing anal incontinence.

The strengths of our work are the homogeneity of the population with a majority of high fistulas and the high number of patients treated that made the analysis of predictive factors more relevant.

The limitations of our study are its single-centre nature, which limits the external validity and reproducibility of the results we obtained, the retrospective collection of data, and the patients lost to follow-up. In addition, healing was confirmed clinically, which can be criticized even though no study, to our knowledge, has proven the need to demonstrate healing of cryptoglandular fistulas by imaging.

Conclusions

Our results showed that administration of less than 400 J and a narrow internal orifice were significantly associated with healing and that LAFT is effective as first-line sphincter-saving therapy for complex anal fistulas. Prospective randomized controlled trials comparing LAFT with other sphincteric-sparing techniques are needed to better define its role in the management of anal fistulas.

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Compliance with ethical standards

Conflict of interest M. Aubert and N. Lemarchand were invited by Biolitec Company to attend a demonstration of the FiLaC® technique in Germany. The others authors declare that they have no conflicts of interest.

Ethical approval The cohort protocol has been approved by the institutional ethics committee (IRB number IRB00012157, n°initial agreement 331 and registered on national institute of health data platform INDS n°3614070219).

Informed consent Informed consent was obtained from all individual participants included in the study.

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