

Fistula Laser Assisted Closure (FiLaC) For Complex Fistula In Ano: Predictors Of Success, Risks And Options After Failure

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Citation

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Abstract

Introduction: FiLaC (fistula laser assisted closure) for fistula in ano is now an established treatment option. There are few studies which showed healing rate of more than 70%. We wanted to evaluate healing rates at our institute. We also tried to analyse the treatment options after failed.

Methods: We offered FiLaC procedure for patients who were not fit to have fistulotomy. All patient treated from March 2019 till March 2023 who underwent FiLaC procedure were included prospectively in the study. The fistula was considered healed, when the external opening was completely closed without pain or discharge.

Results: Out of 61 patients treated with FiLaC 4 patients were lost to follow up. There were no intra-op complications. The primary healing was observed in 38 (67%) patients. Two patients reported urgency, which settled at 3 months interval. Their ano-rectal Physiology tests were normal.

There were 17 failures and two recurrences at one year. Out of these 19 patients four were offered re-FiLaC and two of them healed without any further intervention. 9 patients were successfully treated with fistulotomy. Two patient settled with VAAFT procedure. Four patients decided to have long term seton.

Conclusions: The treatment of fistula ano with lasers has got acceptable healing rate and no risk of incontinence. We therefore conclude that FiLaC is a reasonable first line option for complex fistula in ano.

INTRODUCTION:

The best cure we can offer for fistula in ano is by fistulotomy. Fistulotomy is not a good option in case of anterior fistula in ano in women, Crohn's patients, patients with chronic diarrhoea and high anal fistulae. In these cases, the risk of incontinence is not acceptable to patients. Few patients with even simple low fistulae treated with fistulotomy can have functional disturbances (1,2).

The main sphincter saving procedures are ligation of the inter-sphincteric fistula tract (LIFT), video assisted anal fistula treatment (VAAFT), over the scope clip proctology system (OTSC), anorectal advancement flaps (ARAF), applications of fistula plug (AFP) or glue, Radiofrequency ablation of fistula tract (Fistura system) and Fistula laser assisted closure (FiLaC). Fistulectomy with repair of

sphincter muscle has an acceptable failure of sphincter repair rate of 20% (3).

Fistula laser assisted closure (FiLaC) is a relatively new approach to treat fistula in ano. There are few studies with more than 70 % success rate of curing fistula without affecting continence (4). The initial study of use of lasers for fistula was first reported by Wilhelm in 2011(5). In his study he combined anal advancement flap with FiLaC (6). In subsequent study by Giamundo published in 2014 has reported success without addressing internal opening (4).

We wanted to review our results of FiLaC at our institute. The purpose of was to evaluate the healing rate (cure rate) in our cohort of NHS patients. We also made an attempt identify predictors of success and options after failed FiLaC.

MATERIALS AND METHODS:

This is a single centre NHS study with analysis of prospectively collected data. The FiLaC was offered to patients where simple fistulotomy was not possible. The data of patients who underwent FiLaC from March 2019 till March 2023 was analysed. The data was collected regarding patient demographics, previous surgeries, smoking status, Crohn's disease, seton placement prior to FiLaC, intra-op use of laser energy, any complications, post op follow up and any pre-op MRI findings.

Primary end point of the study was fistula cure rate. All patients were examined by a qualified surgeon at 6-12 weeks interval. If required further appointments were given. Fistula was considered healed if there was closure of the external opening with absence of pain, discharge and induration.

All the patient had a thorough assessment of fistula in clinic. If it was not possible to classify fistula in clinic, they had an MRI scan. However, MRI scan was not routinely offered to all patients. All patients had surgery under general anaesthesia in Lloyd Dewis position. The patients were given Iv metronidazole intra-operatively and oral metronidazole for 5 days post op. They also received 40mls of 0.25% levobupivacaine as a pudendal and perianal block. If patients were found to have excessive sepsis or abscess, it was drained and planned surgery was abandoned.

We used betadine flush to identify internal opening as it does not stain the tissue. Majority of our patients had seton in place and this was useful. We used a FiLaC probe (Biolitec Germany) emitting 12 watts at 1470 wavelength.

Figure 1

Leonardo laser with radial laser fibre. Source: presented with the permission of Promed UK and Biolitec AG, Germany

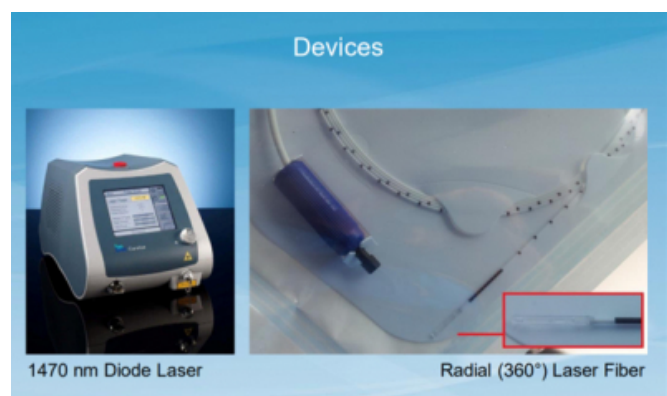
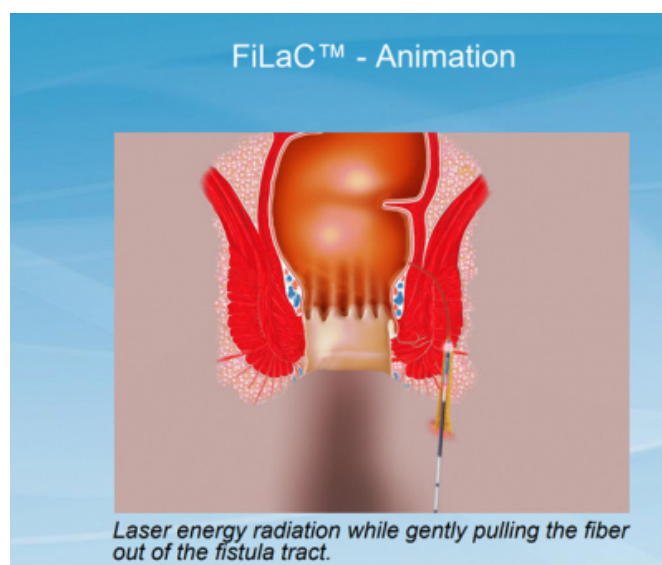


Figure 2

FiLaC animation. Source: presented with the permission of Promed UK and Biolitec AG, Germany



The laser was applied in two phases. First phase was preparatory phase in which laser fibre was passed through the external opening till internal opening. While firing laser energy fibre was slowly withdrawn at the rate on 1 mm/sec. The burnt epithelium was curetted out taking care not to enlarge the diameter of the tract. In the treatment phase the laser energy was applied in the similar manner and withdrawn at the same rate.

Figure 3

Intra -op photograph. Source: presented with the permission of Promed UK and Biolitec AG, Germany



Initially, we did not attempt to close the internal opening but from 2021 onwards we closed the internal opening with a 30 PDS "Z" stitch or interrupted stitches.

All patients were followed up in clinic at 6-12 weeks interval. If patient had some residual symptoms, they had

MRI scan or further follow up appointments. If fistula was still discharging at 3 months or second follow up appointment, they were considered failed FiLaC procedure. If fistula had re appeared after initial promising healing it was classified as recurrence after FiLaC.

RESULTS:

All the patients were discharged on the same day. None of the patients suffered immediate post op complications like reactionary bleeding or severe pain. They were asked to return to hospital in case of any complications including severe pain.

Out of 61 patients we lost 4 patients to follow up. So, we included only 57 patients in the analysis.

Table 1

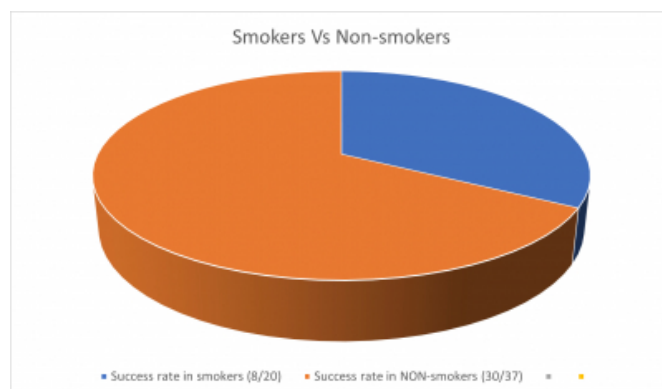
Demography and results

Variable	Results
Male/Female	40/17
Median age in years (range)	38 (21-73)
Smokers % (numbers)	35 (20/57)
Crohn's disease % (numbers)	10% (6/57)
Type-Inter-sphincteric	8/57
Type- low trans-sphincteric	45/57
Type- high trans-sphincteric	4/57
Median energy used in joules	368 (142-785)
Success rate	67% (38/57)

The majority (70%) of our patients were male. Most of our fistulas were trans-sphincteric. We used median 368 joules of energy. Low energy (less than 400 joules) use was associated with good healing. In low energy group 30/36 (83%) healed and high energy group 8/21 (38%). The energy used varied depending on type and length of the fistula.

We had 19 failures out of which two were recurrences at 6 months and 1 year after initial healing. Out of 19 patients were 12 were smokers. The success rate in smokers was 40% (8/20) compared to that success rate in non-smokers was 81% (30/37).

Picture 4



Results with closure of internal opening were slightly better. 50 of 57 patients had closure of internal opening and the healing rate was 72 % (36/50). As oppose to that only 2 of the 7 patients (28.5%) without the closure of internal opening healed.

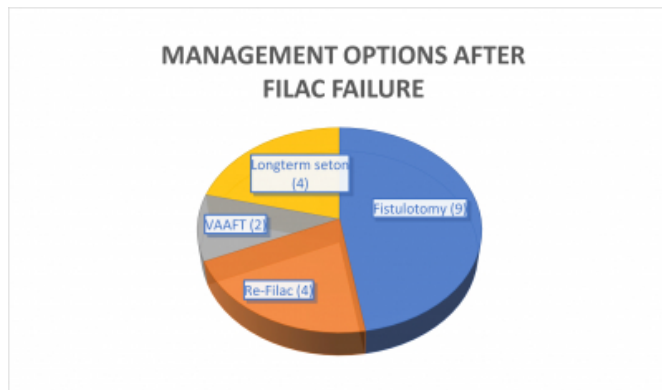
7 of 8 (87%) patients with inter-sphincteric fistula healed successfully. 31 of 49 (63%) patients with trans-sphincteric fistulae healed. We did not have patients with supra-sphincteric fistulas.

32 of the 38 patients who healed had pre-op seton in place. The success rate with pre-op seton was 80% (32/40) and success rate without seton was 35% (6/17).

17 of the 19 patients with failures reported failures within 2 weeks of surgery. Although patients reported failure, they also told us that discharge was considerably less than original condition. Only 2 of the 6 patients of Crohn's disease healed. Both of these patients had their disease well under control and had preop seton in place.

We had two patients reporting urgency after surgery. They both had anorectal physiology tests. Their anal pressures were with in normal limit and the symptoms of urgency disappeared after 3 months follow up.

Picture 5



9 out of 19 patients had fistulotomy and healed with this procedure. Out of 19 patients 4 had re-FiLaC and 2 of these patients healed. Two had VAAFT procedure with advancement flap and healed. Four (2 patients of Crohn's disease) patients decided to have long term seton.

DISCUSSIONS:

The treatment of fistula in ano has been an "Achilles heel" to a surgeon. There are various options but not a single best option. In surgery, if there is one single best procedure which can cure patients with minimal side effects then that option is adapted and rest of the options fade out. Ideal operation is the one which cures fistula without damaging continence.

The laser surgery is more appealing as it is easy to use and has almost flat learning curve. In recent time there has been an explosion of published studies about use of laser in proctology. It is the radial emitting laser fibre which has caused this increase in the interest. As fistula tract is cylindrical tissue radial fibre causes adequate ablation of the tract. Another important aspect of laser is depth of penetration. In general lasers cause more precise burn than other electrocautery or radiofrequency methods. As protein/blood in the tract de-natures and solidifies it results in sealing of the tract. Most of the studies about use of lasers in fistula treatment are observational or retrospective studies. There is no long-term data available.

We believe the preparation of tract is very important prior to application of lasers. It is probably not that important as what you use for preparing the tract it can be a cytology (10) brush or ophthalmic curette.

Pre-Op seton application can also be crucial for healing. We don't think it is a prerequisite for success. It helps to settle

the sepsis and tract matures. It also saves time during surgery as you will not be struggling with tract and identification of internal opening. As in a study by Giamundo (8), our series also showed higher cure rates with prior seton (80% vs 35%). A word of caution though is surgeon should be very carefully not to create false passage. If there is any abscess that needs adequate drainage prior to any laser treatment. Ultimately if the tract is re-epithelised it certainly leads to failure (7).

In our series, the overall success rate of fistula healing was a modest 67%. The primary reason we think for this is few patients from simple inter-sphincteric fistula. Most of our patients were referred and complex fistulae (Trans-sphincteric). We preferred fistulotomy for inter-sphincteric simple fistulae. When FiLaC was used for inter-sphincteric fistulae only in 1 of the 8 patients it failed. We did not want to select patient to guarantee the success rate.

We also noticed that FiLaC has poorer results in smokers. We don't know exactly how smoking interferes with healing. In future we probably be cautious in offering FiLaC in smokers and immunocompromised patients.

When we started FiLaC in our hospital initially we did not close the internal opening. We later on changed our practice and we now close the internal opening with either a "Z" stitch or interrupted 30 PDS stitches. In our series healing rate was better 71 % Vs 28.5% in closure of the internal opening group. However, we had only 7 patients in without the closure of int opening group. These 7 patients were from the initial cohort. It might be part of our learning curve which played a role.

We don't think use of the amount of laser energy has any effect on success rate. It is the length of fistula tract which determines the energy use. However, we should be cautious not to use too much of laser energy as it can damage the sphincter muscles and cause incontinence. It is very much unlikely to cause damage to sphincter muscle if the rate of withdrawal of laser fibre is 1mm/sec.

CONCLUSION:

FiLaC is simple easy to learn technique. It has acceptable rates of cure. FiLaC is a less invasive sphincter-preserving procedure for the treatment of fistula-in-ano. It does not cause incontinence. It can be offered as a first line of treatment for fistula in ano. There are no major complications from the procedure. The success rate is more

in patients with previous seton in place and in non-smokers.

When it does not work there are various other options still available including reuse of FiLaC. We recommend multicentric randomised trials with laser steering groups to standardise the technique. We will need further refinements of the technique.

Conflict of interest: The authors declare that they have no conflict of interest

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