

Anal Sphincter Preserving Fistula Laser Closure FiLaC™: First Study in Iraq

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ABSTRACT

Perianal fistulas, and specifically high perianal fistulas, remain a surgical treatment challenge. Many techniques have, and still are, being developed to improve outcome after surgery. The ideal surgical treatment for anal fistula should eradicate sepsis and promote healing of the tract, whilst preserving the sphincters and the mechanism of continence. This novel sphincter-saving technique uses an emitting laser probe [Fistula laser closure (FiLaC™), Biolitec, Germany], which destroys the fistula epithelium and simultaneously obliterates the remaining fistula tract. Since the main reason for surgical failure is a persistent fistula tract or remnants of fistula epithelium which were not excised, it was postulated that the benefit of this newly designed radial-emitting laser probe was to eliminate fistula epithelium or any granulation tissue in a circular manner and then, to obliterate the fistula tract by a shrinkage effect. This is the first pilot Iraqi study which presents the outcome of FiLaC™ in the management of high and recurrent anal fistulae. The study conducted in a single hospital, by a single trained general and GIT surgeon (NA). All patients were preoperatively assessed for history of presentation, clinical examination, ano-proctoscopy, and MRI of the perineum to assess the dimensions and relations of the fistulous tract to the anal sphincter complex and Levatorani muscle. All patient subjected to 2 staged operation: First stage is drainage, staining with methylene blue of fistula tract and probing under general or epidural anesthesia, and insertion of 2-mm latex vessel loop (Ethilooop®, Ethicon Products, Germany). Second stage started after 6 weeks when the tract length is little bit shorter and diameter of the fistula tract is 5mm and less, with no abscesses. The internal opening is closed with 2/0 vicryl®. The laser probe was inserted through the perineal fistula opening using a “Leonardo DUAL 45®”) diode laser (Biolitec AG, Germany), and the fistulae tracts subjected to laser energy millimeter by millimeter in the aim of elastin melting and ablation. Patients discharged same day with follow up schedule for 1-2 year.

All 72 patients were male, one female with ano-vaginal fistula has been excluded from the study. Median age 37 years; range 19-56 years. Follow-up period 3-24 months. FiLaC™ started for the first time in May 2018, and the patients are still under follow up. Forty seven patients 47 (65.2%) were previously subjected to anal surgery, either abscess drainage, fistulectomy, or fistulotomy, no one has been subjected to Laser, Flap, Plug or LIFT surgery. One patient came with first stage abscess drainage and seton placement. Majority, 52 patients (72.2%) were trans-sphincteric, 12 patients’ (16.6%) inter-sphincteric, 6 patient (8.3%) supra-sphincteric and 2 patients (2.7%) were extra-sphincteric. The median operation time was 18 (10-32) min. Primary healing observed after the first application of FiLaC™ In 43 patients (59.7%), from these; 39 patients (54.1%) of total patients has pass 12 months follow up and certified as permanently healed, still 4 cases waiting final healing announcement which represent 5.5% added success. We have 10 (13.8%) patients subjected to FiLaC™ in the last 3 months and under follow up 8 (11.1%) promises healing, this will make success rate cases to 51 (70.8%). Patient who are considered failed to heal and needs further application of laser or switch to other modality of treatment were 21(29.1%)

Up to 30% of fistulas persist after surgery despite many improvements in surgical skills and technique. One major reason for surgical failure is a persistent fistula track or remnants of the fistula epithelium which could not be removed during surgery, Wilhem A. The FiLaC™ procedure is performed in our study in 2 states with the aim of improving the healing and raising the success rate. Even we have a short experience with the FiLaC™ procedure; we found it to combines the ability to treat complicated and simple fistulae with high success rate, with no compromise to the anal sphincter continence. As a pilot study, the above conclusion looks acceptable but, a longer follow up and a larger cohort study needed in future.

Keywords: FiLaC™ procedure; Fistula-in-ano; Laser; minimally invasive; sphincter-saving.

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INTRODUCTION

Perianal fistulae, and specifically high perianal fistulae, remain a surgical treatment challenge. The classification system developed by Parks, Gordon, and Hardcastle (generally known as the Parks classification) is the one most commonly used for fistula-in-ano. This system (Figure 1) imagedefines four types of fistula-in-ano that result from cryptoglandular infections, as follows: Inter-sphincteric, Trans-sphincteric, Supra-sphincteric and Extra-sphincteric [1].

Many techniques have, and still are, being developed to improve outcome after surgery. Ligation of inter-sphincteric fistula tract [2], anal fistula plug [3] derived from porcine small intestinal submucosa and the new designed GORE BioA® plug, Fibrin glue [4], Fistula laser closure, Video-assisted anal fistula (VAAFT) treatment [5] and Adipose-derived stem cells [6,7]. Other literature mentioned over-the-scope clip (OTSC®) proctology system, are all novel sphincter-sparing techniques targeted at healing anal fistulae [8]. The ideal surgical treatment for anal fistula should eradicate sepsis and promote healing of the tract, whilst preserving the sphincters and the mechanism of continence [9]. The use of laser in the treatment of anal fistula was initially described in 2011 in a pilot study by Wilhelm [10]. This novel sphincter-saving technique uses an emitting laser probe [Fistula laser closure (FiLaC™) [11-13] (Figure 1), Biolitec, Germany], which destroys the fistula epithelium and simultaneously obliterates the remaining fistula tract. Since

the main reason for surgical failure is a persistent fistula tract or remnants of fistula epithelium which were not excised, it was postulated that the benefit of this newly designed radial-emitting laser probe was to eliminate fistula epithelium or any granulation tissue in a circular manner and then, to obliterate the fistula tract by a shrinkage effect. The procedure also includes the closure of the internal opening by means of an anorectal flap. When some scar tissue prevents that, either mucosa or ano-dermal flap is used for closure of the internal opening.

A modified laser procedure was adopted by Giamundo et al. [14]. It consists of sealing the fistula tract by laser with no need for endorectal flap. The closure of the internal opening is allowed by a laser shrinkage effect [15]. This is the first pilot Iraqi study which presents the outcome of FiLaC™ in the management of high and recurrent anal fistulae.

RESEARCH METHODOLOGY

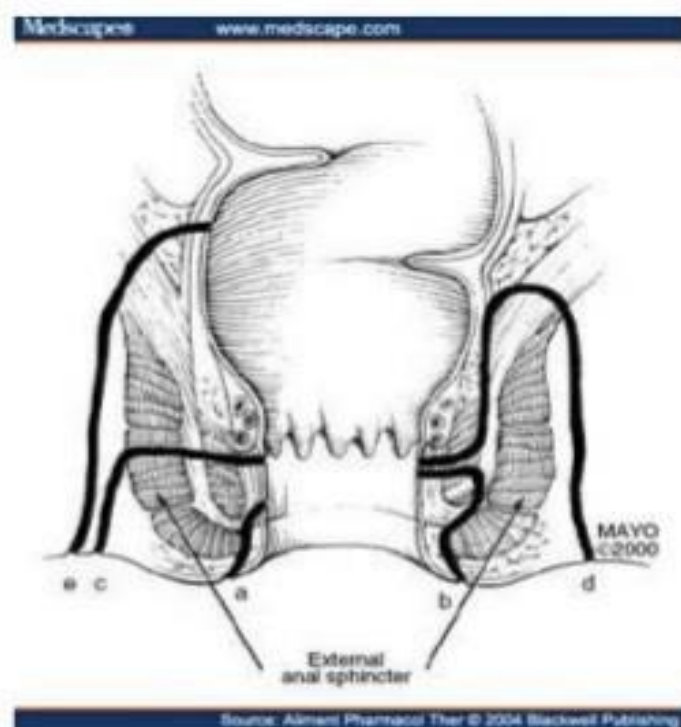
The study conducted in a single hospital, by a single trained general and GIT surgeon (NA). All patients were preoperatively assessed for history of presentation, clinical examination, ano-proctoscopy, and MRI of the perineum to assess the dimensions and relations of the fistulous tract to the anal sphincter complex and Levator ani muscle. Fistulae classified according to Park's classification. All patients were informed about the procedure in details; they

CLASSIFICATION

Park's Classification

(according to the relationship of primary tract to the anal sphincters)

- ⊙ **Intersphincteric (45%)**
 - Simple low tract
 - **High** tract
 - **High** tract with rectal opening
 - Extra rectal extention
- ⊙ **Trans-sphincteric (40%)**
 - Uncomplicated
 - **High** tract
- ⊙ **Suprasphincteric**
 - Uncomplicated
 - **High** tract
- ⊙ **Extrasphincteric**
 - Secondary to trauma
 - Secondary to anorectal disease
 - Secondary to pelvic inflammation



Ref: The ASCRS textbook of colon and rectal surgery
By Bruce G. Wolff, James W. Fleshman, David E. Beck

Figure 1: The classification system developed by Parks, Gordon, and Hardcastle (generally known as the Parks classification).

are willing because of previous failing procedures and provisional satisfaction by the results. Superficial low type fistulae, malignant and Crohns fistulae excluded from this study. Data sheet for demographic, morbidities; prior anal surgery and the continent status were recorded. All patients subjected to 2 staged operation: First stage is drainage and staining and probing of fistulae (Figures 2-7) under GA or epidural anesthesia, and insertion of 2-mm latex vessel loop (Ethiloop®, Ethicon Products, Germany) (Figure 8). Those patients should wait for 6 weeks with twice weekly wash of the periloop fistula tract with diluted povidone iodine and Hydrogen peroxide through the peri-loop tract (Figure 9). Second stage started when the tract length is little bit shorter and diameter of the fistula tract is 5 mm and less, with no abscesses. Before a definitive fistula repair with the FiLaC™ device, all patients underwent mechanical bowel preparation with 3 L Coloclean (a glycol) and received 2 g intravenous cefuroxime plus 500 mg metronidazole intravenously and two further doses of metronidazole over the first post-operative 24 h.

Procedure: At the commencement of each treatment, the external and internal orifices of the fistula track were excised using electrocautery and fine curate, the tract is brushed and irrigated with normal saline and hydrogen peroxide (Figures 2, 9, 10, and 11-17). The internal opening is closed with 2/0 vicryl© (Figures 18 and 19). The laser probe was inserted through the perineal fistula opening using a “Leonardo DUAL 45©”) diode laser (Biolitec AG,



Figure 2: Intersphincteric and Suprasphincteric fistulae.



Figure 3: Trans-sphincteric fistula-1.



Figure 4: Trans-sphincteric fistula-2.



Figure 5: Staining tract with methylene blue.



Figure 6: cannulation of fistula to introduce laser probe.

Germany) (Figures 12-16). This type of laser delivers energy at a wavelength of 1470 nm, providing an optimal absorption curve in



Figure 7: Probing fistula.



Figure 10: Passing latex vessel loop-1.



Figure 8: Irrigating fistula tract from debris and pus.



Figure 11: Passing multiple latex vessel loops-2.



Figure 9: Passing latex vessel loop.



Figure 12: Radial laser probe application-1.

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



Figure 13: Radial Laser probe application-2.



Figure 14: Laser application-1.



Figure 15: Laser application-2.

by the radial-tip laser fiber permits destruction of the granulation and epithelial tissue causing a 2 mm to 3 mm zone of controlled tissue damage with less power (13 W) and a diminished likelihood of perifistular collateral thermal damage (Figures 17-20). Post-operatively, there were no dietary restrictions, and all patients were placed on stool softeners for a 2-week period. 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. To define healing after FiLaC™ laser treatment patient should have no evidence of recurrence clinically and sonographically for at least 1 year (Figures 21 and 22).



Figure 16: Leonardo DUAL 45© diode laser from Biolitec AG, Germany. Wavelength 980-1470 nm. Maximum energy 15 Watts.



Figure 17 : Final results after laser application.



Figure 18: Vicryl suture closure for internal opening of fistula.



Figure 19: Final result after laser application and internal opening closure.



Figure 20: Final result after laser application in two fistulae.

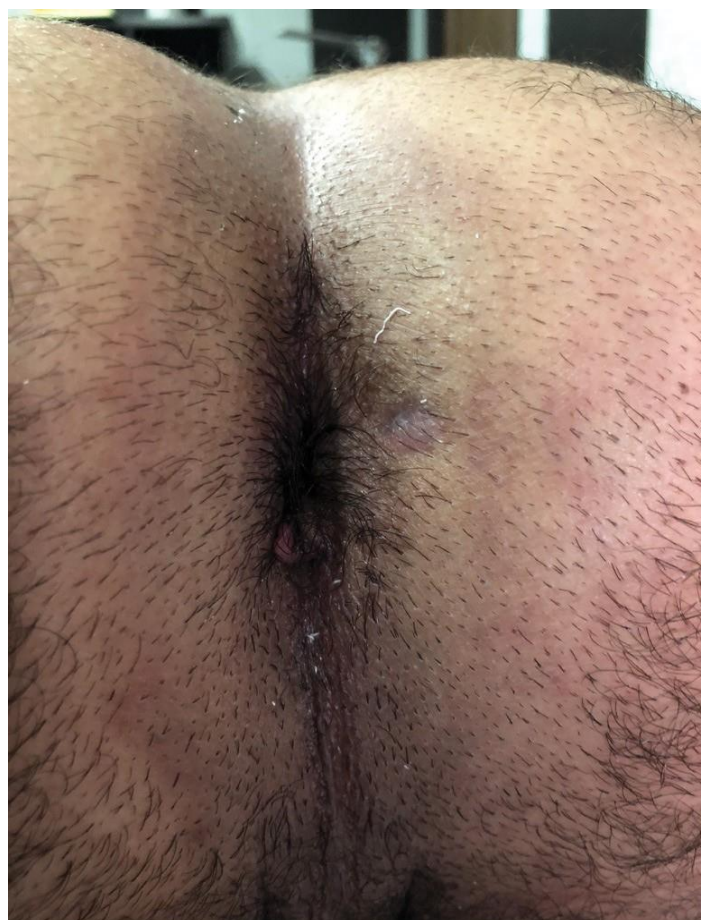


Figure 21: Fistula healed after 3 months.

RESULTS

All 72 patients were male, median age 37 years; range 19-56 years. Follow-up period 3-24 months. FiLaC™ started for the first time in May 2018, and the patients are still under follow up. Forty seven patients 47 (65.2%) were previously subjected to anal surgery, either abscess drainage, fistulectomy, or fistulotomy, no one has been subjected to Laser, Flap, Plug or LIFT surgery. Majority, 52 patients (72.2%) were trans-sphincteric, 12 patients' (16.6%) inter-sphincteric, 6 patient (8.3%) supra-sphincteric and 2 patients (2.7%) were extra-sphincteric. The median operation time was 18 (10-32) min. Primary healing observed after the first

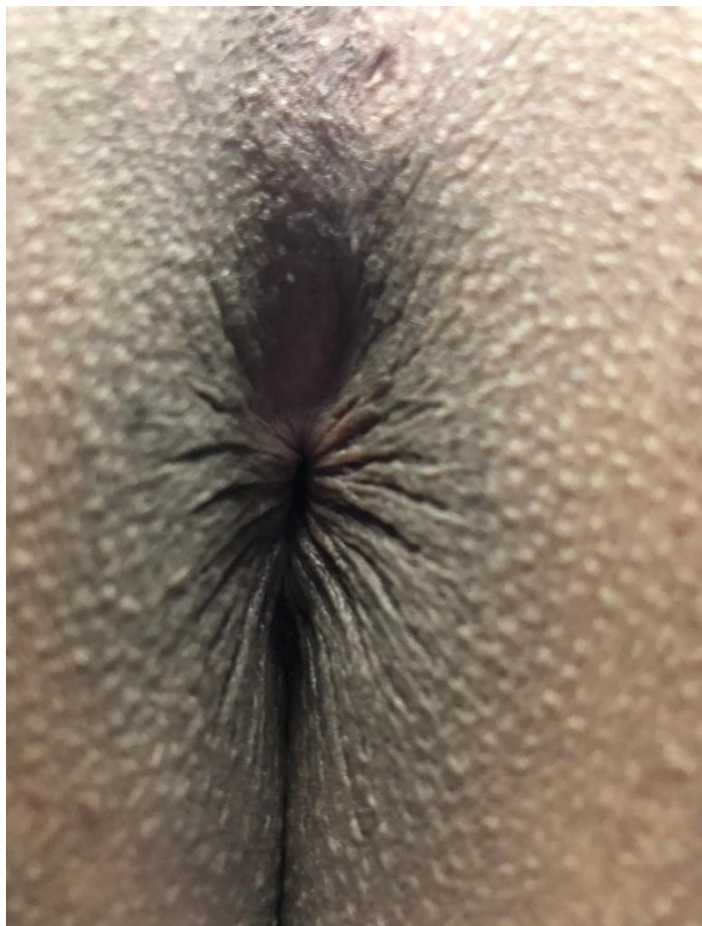


Figure 22: Healed fistula after 1 year.

application of FiLaC™ In 43 patients (59.7%), from these; 39 patient (54.1%)of total patients has pass 12 months follow up and certified as permanently healed, still 4 cases waiting final healing announcement which represent 5.5% added success. One patient that came with seton outside, delayed a little bit and healed in 5 months. We have 10 (13.8%) patients subjected to FiLaC™ in the last 3 months and under follow up 8 (11.1%) promises healing, this will make success rate cases to 51 (70.8%). Patients who are considered failed to heal and needs further application of laser or switch to other modality of treatment were 21(29.1%). No significant complications recorded locally as incontinence or systemically in all patients.

DISCUSSION

Minimally invasive fistula management, which balances clinical effectiveness with an absence of post-operative functional disturbance, has been the “holy grail” of anal fistula treatment since Tasci first presented a novel “fistulectome” device in 2003, designed to mechanically core out the primary fistula track [16]. Up to 30% of fistulas persist after surgery despite many improvements in surgical skills and technique. One major reason for surgical failure is a persistent fistula track or remnants of the fistula epithelium which could not be removed during surgery, Wilhem A. The FiLaC™ procedure is performed in our study in 2 stages with the aim of improving the healing and raising the success rate. Many studies agree with that, but some do the procedure in one stage with good results and some accept a lower success rate [17]. The period between the 2 applications of laser is nearly similar in most studies [14]. In the steps of fistulous tract management; in our study we use to close the internal opening using 2/0 Vicryl

suture after refreshing edges. Some studies use local flap closure of internal fistula opening, with an overall success of 81% at 7, 4 months of follow-up [13]. Most of our patients were subjected to previous anal fistula procedures once or twice and failed; this percent is higher than other studies. The use of latex vessel loop for 6 weeks prior to LASER application is aimed to ensure drainage and increase the fibrine production in the tract with homogeneous smaller diameter than initial situation, while some studies uses septon suture. Overall final healing success rate of 70.8% is nearly comparable to other studies with a range of 71-81%. We think that success rate can be better if patients agree for second application of LASER after first attempt, unfortunately this was not applicable in our cases because of economic reasons.

CONCLUSION

Even we have a short experience with the FiLaC™ procedure; we found it combines the ability to treat complicated and simple fistulae, with no compromise to the anal sphincter continence. The success rates unaffected by the nature and number of prior procedures. The minimally invasive FiLaC™ approach may therefore represent a sensible first-line treatment option for anal fistula repair. As a pilot study, the above conclusion looks acceptable but, a longer follow up and a larger cohort study needed in future.

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DISCLOSURE STATEMENT

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REFERENCES

1. Parks AG, Gordon PH, Hardcastle JD. A classification of fistula-in-ano. *Br J Surg.* 1976; 63(1):1-12 (ISSN: 0007-1323)
2. Cianci P, Tartaglia N, Fersini A, Giambavichio LL, Neri LV, Ambrosi A. The ligation of intersphincteric fistula tract technique: A preliminary experience. *Ann Coloproctol.* 2019; 35(5): 238–241. Published online 2019 Oct 31.
3. Lin H, Jin Z, Zhu Y, Diao M, Hu W. Anal fistula plug vs rectal advancement flap for the treatment of complex cryptoglandular anal fistulas: A systematic review and meta-analysis of studies with long-term follow-up. 2019; 21(5):502-515.
4. Cirocchi R, Farinella E, La Mura F, Cattorini L, Rossetti B, Milani D. Fibrin glue in the treatment of anal fistula: A systematic review. 2009 Nov 14; 3:12.
5. Garg P, Singh P. Video-Assisted Anal Fistula Treatment (VAAFT) in Cryptoglandular fistula-in-ano: A systematic review and proportional meta-analysis. 2017 Oct;46:85-91. 2017 Sep 4.
6. Qin X, Wang P, Huang Y, Li Y, Chao M, Wang W. Adipose-derived stem cells are an efficient treatment for fistula-in-ano of Japanese Rabbit. 2019 Oct 22; 2019:6918090.

7. Göttgens KW, Smeets RR, Stassen LP, Beets G, Breukink SO. Systematic review and meta-analysis of surgical interventions for high cryptoglandular perianal fistula. *Int J Colorect Dis.* 2015; 30:583–593.
8. Adegbola SO, Sahnan K, Pellino G, Tozer PJ, Hart A, Phillips RK. Short-term efficacy and safety of three novel sphincter-sparing techniques for anal fistulae: A systematic review. *Tech Coloproctol.* 2017; 21(10):775-782.
9. Limura E, Giordano P. Modern management of anal fistula. *World J Gastroenterol.* 2015; 21(1): 12–20.
10. Wilhelm A. A new technique for sphincter-preserving anal fistula repair using a novel radial emitting laser probe. *Tech Coloproctol.* 2011;15:445–449.
11. Elfeki H, Shalaby M, Emile SH, Sakr A, Mikael M, Lundby L. A systematic review and meta-analysis of the safety and efficacy of fistula laser closure. 2020;24(4):265-274.
12. Wolicki A, Jäger P, Deska T, Senkal M. Sphincter-saving therapy for fistula-in-ano: Long-term follow-up after FiLaC ®. 2020
13. Marref I, Spindler L, Aubert M, Lemarchand N, Fathallah N, Pommaret E. The optimal indication for FiLaC ® is high trans-sphincteric fistula-in-ano: A prospective cohort of 69 consecutive patients. 2019;23(9):893-897.
14. Giamundo P, Geraci M, Tibaldi L, Valente M. Closure of fistula-in-ano with laser-FiLaC™: An effective novel sphincter-saving procedure for complex disease. *Colorectal Dis.* 2014;16:110-115.
15. Tasci I. The fistulectome: A new device for treatment of complex anal fistulas by “Core-Out” fistulectomy. *Dis Colon Rectum.* 2003; 46:1566–1571.
16. Terzi MC, Agalar C, Habip S, Canda AE, Arslan NC, Obuz F. Closing perianal fistulas using a laser: Long-term results in 103 patients. *Dis Colon Rectum.* 2018;61(5):599-603.
17. Oztürk E, Gülcü B. Laser ablation of fistula tract: A sphincter-preserving method for treating fistula-in-ano. *Dis Colon Rectum.* 2014; 57:360–364.