

Uses of FiLaC laser as a sphincter-preserving technique in closure of fistula tract in Upper Egypt

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Received: 7 December 2020

Revised: 21 December 2020

Accepted: 21 December 2020

Published: 18 May 2021

The Egyptian Journal of Surgery 2021, 40:380–386

Aim

Treatment of anal fistula as one of anorectal disease is difficult. Anal incontinence and recurrence of fistula are fearful morbidities of surgeons. Many techniques for sphincter preservation such as internal sphincter fistula tract attachment, anorectal flap application, and bioprosthesis plugs have been tried to overcome the complications. This article aimed to estimate the safety and efficacy of the FiLaC method in the management of fistulous tract.

Patients and methods

A total of 26 patients (22 males, four females) who underwent FiLaC diode laser treatment between October 2019 and October 2020 were admitted at the Surgical Department, Al Azhar University Hospital, Assiut, and Al-Rowad Hospital, Assiut. They were retrospectively analyzed for age and sex, BMI, American Society of Anesthesiologist score, duration of operation, fistula types, complications, and patient satisfaction.

FiLaC a 15-W laser probe with a wavelength of 1470 nm and a power of 100–120 J/cm was applied to the fistulous track under the spinal anesthesia.

Results

The number of male patients were 22 and female patients were four, and the mean age was 35.55 ± 10.32 years. The mean time of operation was 18.37 ± 5.27 min. Intraoperative complications were not recorded. The period of follow-up was 12 months. A total of 23 (88.46%) patients recovered. There were three (11.53%) failures. Satisfaction score of the patients was 4.62 ± 1.07 .

Conclusion

FiLaC laser for the use of closure of fistulous tract is an effective, safe, minimally invasive technique for preservation of the anal sphincter, with a high success rate.

Keywords:

anal fistula, anal incontinence, FiLaC, minimally invasive, sphincter saving

Egyptian J Surgery 40:380–386

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Introduction

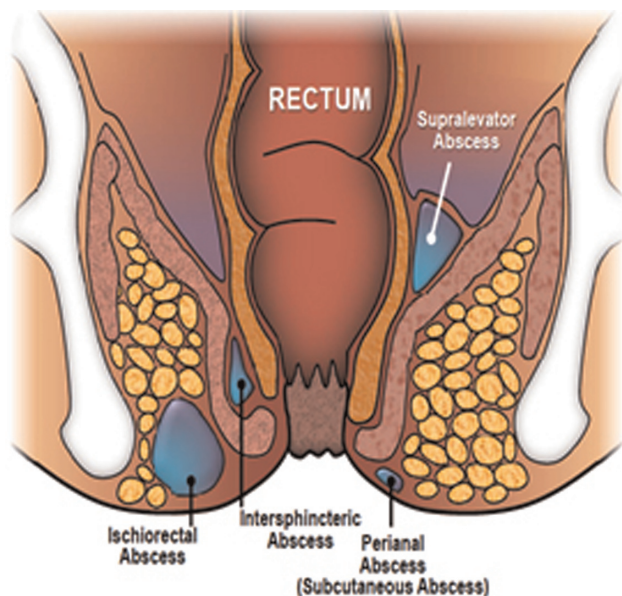
Anal fistula is an anorectal disease, with more than 90% of cases being cryptoglandular in origin and taking place after anorectal abscesses (Fig. 1) [1].

The most drastic complications occurred with treatment of anal fistulas are stool incontinence owing to damage to anal sphincter, and recurrence of the fistula [2,3]. According to the Parks classification, anal fistulas are classified into four main groups: suprasphincteric, transsphincteric, intersphincteric, and extrasphincteric (Fig. 2) [4]. Actually, even the simplest fistulas have a confined risk of incontinence. The estimated rate of incontinence overall varies up to 40% according to the fistula type and the surgical procedure performed. Even without damage of anal sphincter, in the early postoperative period, most cases complain of some sort of continence disorder [5]. Fistulotomy is the gold standard management of fistulous tract, but the recovery rate is more than 90% [6–8]. However, patients were treated with a fistulotomy had a risk of anal sphincter dysfunction postoperatively. Females and

patients with complex fistulas, history of preoperative incontinence, recurrence, or previous anorectal surgery are at high risk [8,9]. In addition, studies have shown that fistulotomy, even in cases of simple fistulas, may cause anal sphincter dysfunction [10–12]. Therefore, various ‘sphincter-sparing’ procedures including the use of fibrin glue, anal fistula plugs, anorectal advancement flap, and ligation of the intersphincteric fistula tract were used to decrease concerns about functional outcomes in the surgery of fistulas [13]. These previous approaches were initially promising, but the rate of success revealed conflicting results [13]. None has been universally accepted as the gold standard surgical approach for fistula treatment. In 2011, FiLaC was first used by Wilhelm [14] for closure of fistula tract. This maneuver involved removal of total length of the fistula tract using a laser diode source and a radial laser

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Figure 1



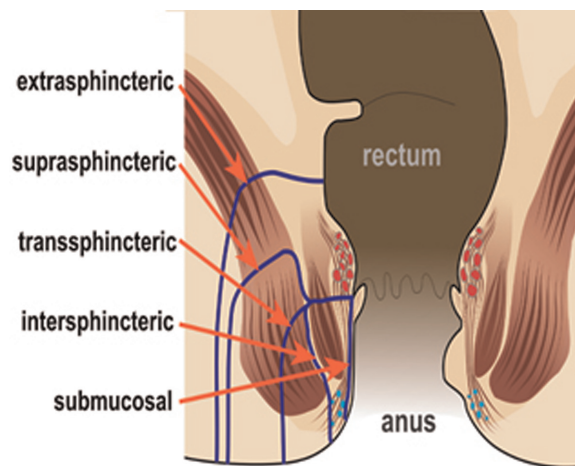
Origin of fistula.

probe for closure of the tract and closing the internal opening of the fistula. The most important feature of FiLaC is that the laser tip used does not do harm to the sphincters and other structures. The FiLaC maneuver was designed for elimination of both anal gland/crypt and the epithelial lining of the fistula via photo thermal effect, while also closing both the internal and external fistula openings. The main causes of fistula recurrence in other approaches such as bioprosthesis plugs and fibrin plugs include overlooked or improper treatment of internal openings, improper drainage of the intersphincteric space, overlooked side tracts, and/or residues of fistula epithelium and granulation tissue [15–17]. This retrospective study presents the results of an analysis of this technique with the FiLaC device in the treatment of patients with anal fistulas.

Patients and methods

This article is a retrospective clinical study. The local ethics committee approved the study done in the period between October 2019 and October 2020. Informed written consent was obtained from all patients who underwent the FiLaC procedure. A total of 26 patients who were admitted at the Surgical Department, Azhar University Hospital, Assiut, and Al-Rowad Hospital, Assiut, were analyzed and treated for anal fistulas. Evaluation of all patients was done preoperatively with clinical examination and proctosigmoidoscopy and were classified using contrast-enhanced pelvic MRI. Demographic data (sex, age, and BMI), the type of

Figure 2



Parks classification.

fistula, and previous surgical approaches were recorded. Postoperative complications, period of follow-up, and satisfaction of the patient were evaluated. Satisfaction of the patients was assessed according to the Likert scale: (a) very unsatisfied, (b) unsatisfied, (c) neutral, (d) satisfied, and (e) very satisfied. The questionnaire of patient satisfaction was conducted 1 year after surgery. A simple questionnaire was used to evaluate the status of postoperative anal continence. The preoperative preparation included mechanical bowel preparation and 1g cefotaxime and 500 mg metronidazole intravenously. The patient received two or more doses of intravenous 500 mg metronidazole postoperatively over 24 h. A FiLaC diode laser (Biolitec AG, Otto-Schott-str. 15, O7745 Jena, Germany) was used in this study (Fig. 3).

The diode laser emits 100–120 J/cm of energy at a wavelength of 1470 nm. This configuration is believed to result in effective local tissue shrinkage and protein denaturation and provides the optimal absorption curve in water. When no water is retained in the tissue and the temperature exceeds 100°C, a vaporization effect is observed as white smoke. The application of a radial tip laser at this wavelength allows the destruction of epithelial and granulation tissues and causes it to affect a 2–3-mm region, resulting in more controlled tissue damage with less power (13 W) [14]. In suprasphincteric (Parks type 3) fistulas, the laser probe reaches the ‘turning point’ of the fistula tract via the internal opening, thereby obliterating the intersphincteric component. Closure of the fistula tract by coagulation is achieved by slowly withdrawing the laser probe through the fistula tract at a rate of ~3 s/cm. This maneuver is continued until the laser probe coagulates and closes the external opening

of the fistula. Caution must be taken during this approach to avoid excessive burns to the treated and surrounding tissue, and damage to adjacent tissues. Under spinal anesthesia all patients were treated. All patients were placed in the lithotomy position, and then sterilization was done. Examination was done under anesthesia, followed by identification of fistulous tract and the internal and external fistula

Figure 3



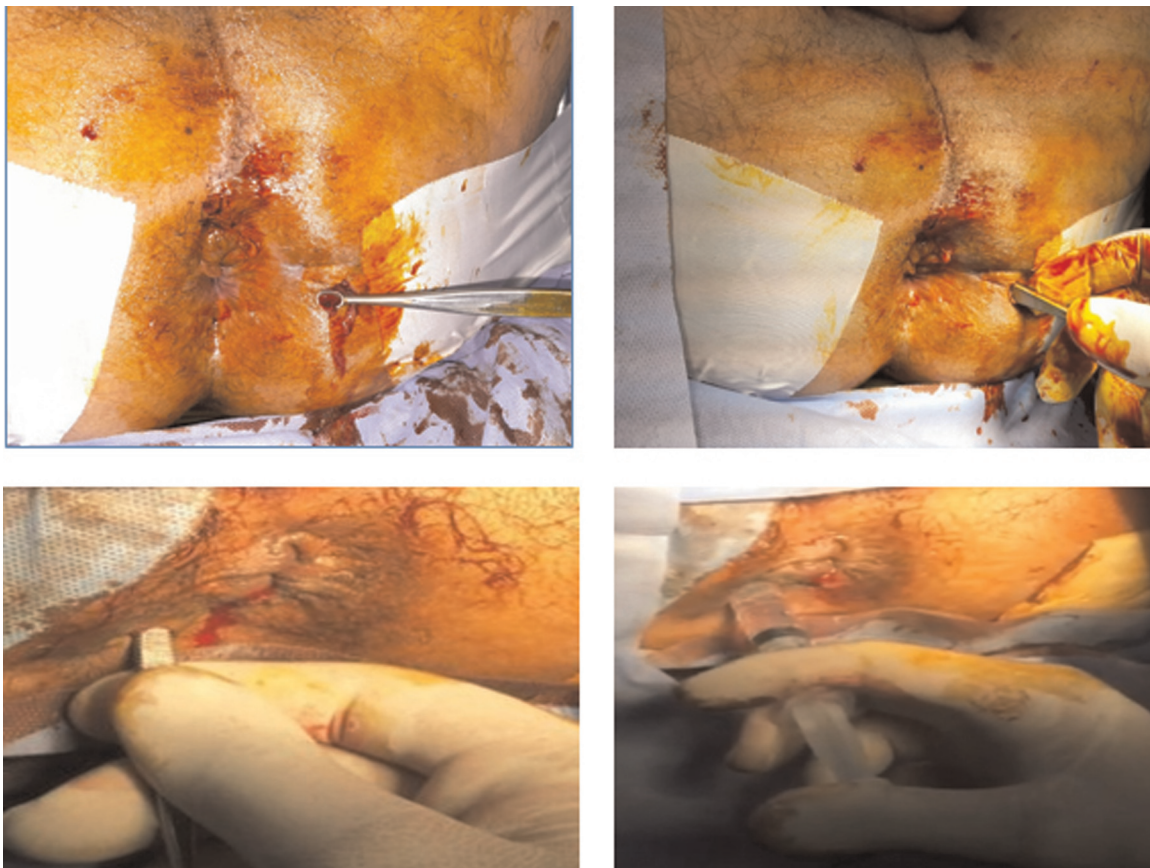
Biolitec AG, Germany.

openings. The fistula tract was mechanically cleaned using a curette and washed with hydrogen peroxide and saline (Fig. 4).

The laser probe was inserted into the external opening, extended through the fistulous tract, and passed through the internal opening (Fig. 5).

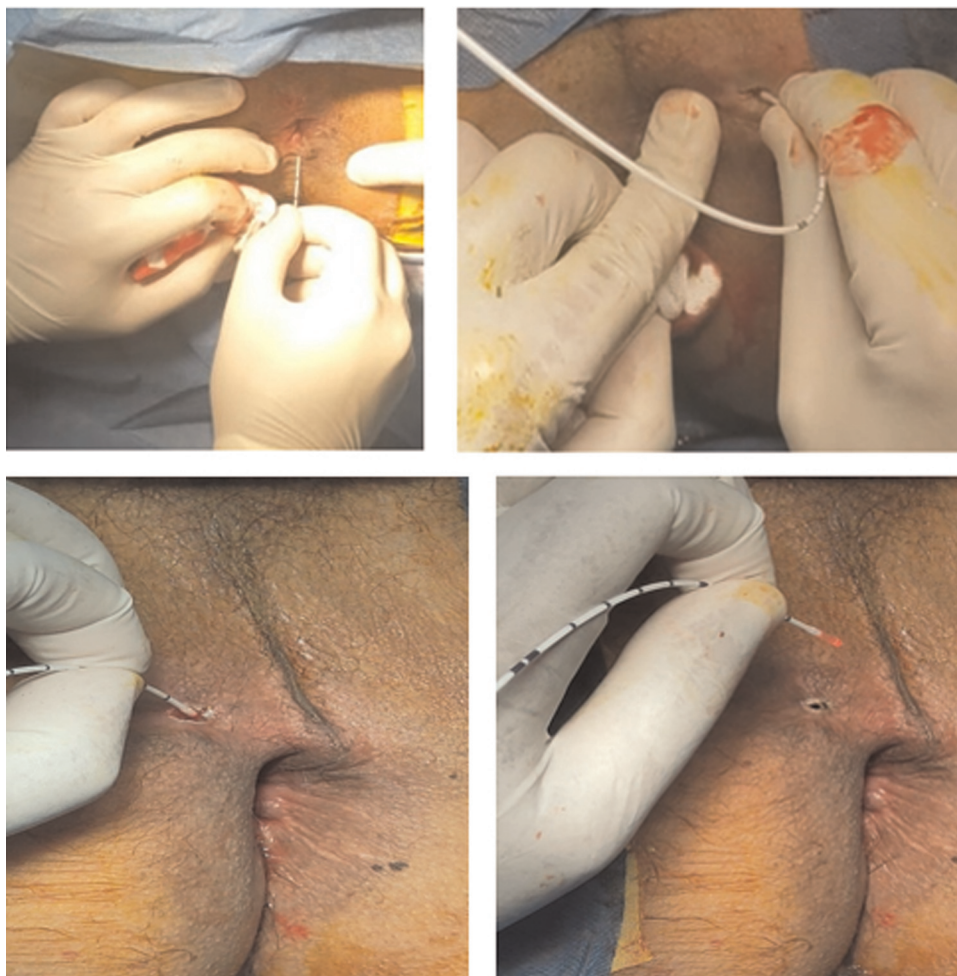
Then, the tip of the probe was withdrawn to within a few millimeters of the internal opening. The internal openings were sutured with vicryl 2/0. The laser was applied at an energy level of 100 J. During application, the laser probe was allowed to pass through the fistula tract by itself and was manually withdrawn when its path was obstructed. Gently withdrawing the probe a few centimeters and then advancing it back toward the internal opening was sufficient to eliminate any untreated sections of the fistula tract (Fig. 5). After every three shots, the laser probe was removed, and the tip of the probe was cleaned with gauze soaked in hydrogen peroxide to prevent carbonization. Laser application was discontinued when the tip of the probe was a few millimeters from the external opening. Ice pack was applied for 1–2 min (Fig. 6), and no ointments or topical medications were used.

Figure 4



Curettage of fistulous tract and washed with hydrogen peroxide (H₂O₂) and saline.

Figure 5



The laser probe was inserted into the external opening.

Table 1 Characteristics of the patient group

Characteristics	Mean±SD or n (%)
Age (years)	36.55±10.32
Sex (male/female)	22/4
Height (cm)	74.11±10.33
Weight (kg)	176.81±6.65
BMI	23.72±3.48
ASA I/II/III	22/4/0
Diabetes mellitus	7 (27)
Smoking	19 (73)

ASA, American Society of Anesthesiologist.

Results

A total of 26 patients were included in the study. Demographic data pertaining to the patients are presented in Table 1.

The number of male patients was 22, and the number of female patients was four. The average age of the patients was 36.55±10.32 years. The average BMI was 23.72±3.48. Seven of the patients had diabetes mellitus; four patients were classified as American

Society of Anesthesiologist II and 22 patients as American Society of Anesthesiologist I. Overall, 19 patients were smokers, but no pathology was found in the patient's chest radiographs and pulmonary function tests. The average period of follow-up was 1 year (range, 10–12 months). Patients completed a patient satisfaction questionnaire at postoperative 1 year. After 1 year, follow-ups were done at 3-month intervals. All patients were discharged after being uneventfully hospitalized for one day. There were no cases that needed postoperative opioid analgesia. The ability of all cases to drive or walk the day after the operation was reported. Data regarding the patients' anal fistulas and surgeries are presented in Table 2. There were three cases from 26 cases in which failure of closure of fistula tract was reported.

These cases were categorized as failed procedures. Of the patients with failed FiLaC procedures, one had an extrasphincteric fistula and two had suprasphincteric fistulas. The success rate with FiLaC was 88.46. The patient with the extrasphincteric fistula had a

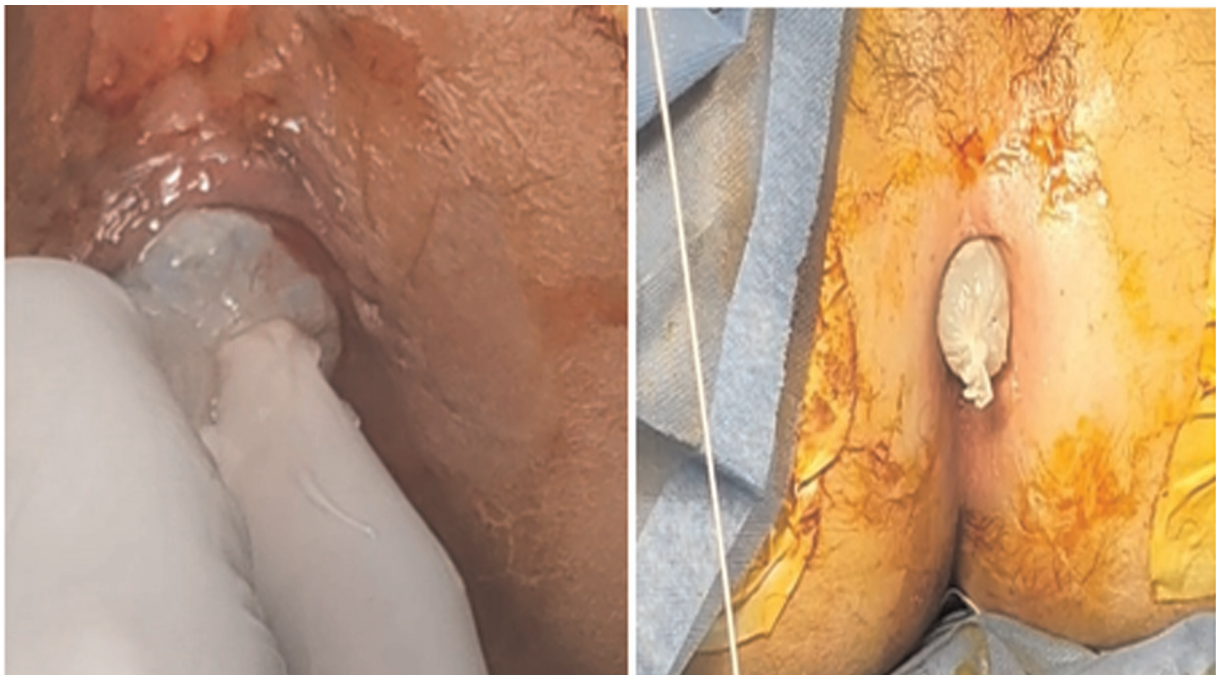
horseshoe fistula. After the first session, the fistula transformed into a transsphincteric fistula. The patient underwent a second session of laser. At 12-month follow-up, the fistula appeared to have healed. The other two patients had suprasphincteric fistulas and did not consent to a second session of laser application. A loose seton stitch was used for these patients. Follow-up and treatment of these two patients are ongoing. At postoperative 1 year, the mean patient satisfaction level was 4.62 ± 1.07 .

Table 2 Perianal fistula features and surgical data

Characteristics	n (%) or median (range)
Park classification	
Intersphincteric	13 (50)
Transsphincteric	7 (27)
Suprasphincteric	5 (19)
Extrasphincteric	1 (3.8)
Symptom duration (months)	82 (48–134)
Preoperative seton stitch	5 (19)
Tract length (cm)	5 (3–10)
Site of internal opening (IO)	
Distal to the dentate line	9 (35)
On the dentate line	5 (19)
Proximal to the dentate line	12 (46)
Surgery duration (min)	18.37 \pm 5.27
Recurrence	3 (11.5)
Follow-up period (months)	22 (17–26)
Patient satisfaction	4.62 \pm 1.07

IO, Internal orifice.

Figure 6



Ice pack were applied to anal canal.

Discussion

The goal of fistula surgery is to permanently eliminate the suppuration process without compromising fecal continence. Fistulotomy is accepted as the gold standard procedure in the surgery of anal fistula. However, this treatment is more successful in the treatment of intersphincteric fistulas and low transsphincteric fistulas. Higher level fistulas can result in undesirable results such as recurrence and anal incontinence. The identification of associated risk factors may contribute to decrease in the appearance of this drastic complications. The anal incontinence and recurrence of fistula which occur following fistulotomy in high fistulas have led surgeons to convert to other treatment modalities. The main goal is the avoidances of anal incontinence and recurrence. The conventional treatment for complex anal fistulas is seton placement [18]. In this procedure, the treatment process continues with cutting and tightening of the seton. For this reason, this maneuver is recommended for reducing postoperative fecal incontinence [18,19].

Ligation of the intersphincteric fistula tract was first described in 2007 as a sphincter-sparing technique for management of fistulas [3]. In subsequent studies, this technique has been recommended for the treatment of primary and recurrent anal fistulas. In a retrospective clinical trial by Malakorn *et al.* [20] including 251 cases, the technique was found to have a high success rate in low transsphincteric and semihorseshoe fistulas, but a low

success rate in high transsphincteric and horseshoe fistulas. In this study, there were no cases of anal incontinence. In a retrospective clinical study of complex anal fistulas conducted by Xu and Tang [21] in 2017, there was a 40% recurrence rate, and one of the 55 patients developed fecal incontinence. Fibrin glue is one of the minimally invasive techniques that can be used in the treatment of complex anal fistulas [22]. Fibrin, enriched with platelet-derived growth factors or platelet-rich fibrin, has been shown to accelerate tissue growth and enable closure of the fistula tract when used to treat perianal fistulas [5]. In 2015, Lara *et al.* [23] reported in their prospective multicenter study of 60 patients that 40 (66%) showed anal fistula closing in an average follow-up period of 24 months, and none of the patients developed anal incontinence. Their success rate was 87.5% ($n=8$) for intersphincteric fistulas, 61.54% ($n=13$) for low transsphincteric fistulas, 64.52% ($n=31$) for middle transsphincteric fistulas, 57.14% ($n=7$) for high transsphincteric fistulas, and 100% ($n=1$) for suprasphincteric fistulas [23]. Limitations of that study were the small number of suprasphincteric fistulas, and that the procedure was not applied in cases with horseshoe fistula. Several methods have attempted to decrease recurrence and anal incontinence in the treatment of complex anal fistulas. Some of these methods include bioprosthetic plugs and anorectal tissue flaps [24–26]. However, these methods failed to obtain the desired results regarding tissue healing and fistula closure and did not prevent recurrence. The laser energy delivered to the fistula tract by the FiLaC laser radial tip fiber used in this study destroys endoluminal granulation tissue and the epithelial wall of the fistula tract. Simple diathermy cannot achieve the same results because it does not create the tissue shrinkage effect that regulates thermal damage in the normal sphincter muscle and cannot be controlled as easily as laser. In this study, the FiLaC procedure was used on patients with intersphincteric fistulas, low and high transsphincteric fistulas, suprasphincteric fistulas, and extrasphincteric and recurrent fistulas. The optimal shrinkage effect obtained by heat radiated by a radial tip fiber is limited by the fistula lumen to a radial penetration depth of 2–3 mm of the fistula tract. A 1470-nm wavelength is believed to be more effective at creating shrinkage and denaturation and to have the optimal absorption curve in water. Surgical trauma is very low, and the hyperthermic effect is considered minimal and reversible [27]. The patients were called for weekly follow-up for the first month after discharge. After 1 month, patients were followed at 3-month intervals for the first year. After the first year, the patients were followed by contacting them by phone and asking them if they had any complaints. Telephone

interviews were done after 12 months. The median follow-up period in my patients was 24 months. Three cases were considered unsuccessful at postoperative 12 weeks. One of these patients had an extrasphincteric fistula and was determined to have partially improved due to the procedure. MRI showed that the fistula had turned into a transsphincteric fistula. A second session of FiLaC was performed on this patient after 6 months. The other two patients had suprasphincteric fistulas and did not consent to a second session of the FiLaC procedure. Because FiLaC is a ‘blind’ procedure, small secondary tracts may be difficult to detect during surgery. This can be considered as a disadvantage of the procedure, as it may lead to recurrence. Intraoperative endoanal ultrasound shows the newly formed hyperechoic tissue closing the fistula track, and thus continues to be the best method for confirming fistula closure. Previous studies have reported severe anal pain in a significant proportion of patients treated with high-energy laser (980 nm diode laser). This can occur as a result of the use of higher laser energy volumes for successful adhesion of fistula fragments with a higher hyperthermic effect on the normal sphincter surrounding the fragments. In this study, we routinely used a 1470-nm diode laser instead of a 980-nm diode laser for FiLaC. There were no complaints of postoperative pain in any of the patients. In a retrospective clinical study including 50 patients, Oztürk and Gülcü [28] reported an 82% success rate with the FiLaC with an average follow-up period of 12 months. In a similar study, Giamundo *et al.* [27] achieved a success rate of 71.4% in a prospective clinical trial including 35 cases with an average follow-up period of 20 months. In their study including 117 cases and representing 5 years of experience with FiLaC, Wilhelm *et al.* [29] determined a 64.1% recovery rate after one application and average follow-up period of 25.4 months. The success rate in recurrent cases was 88% after the second session of treatment. We achieved a success rate of 88.46% in our study, which is slightly higher than that reported in similar studies. We attribute this difference to the lower number of complex fistula (suprasphincteric and extrasphincteric) cases in this study compared with other studies. FiLaC is a costly equipment in comparison with other sphincter-sparing techniques; however, the diode laser platform is a portable equipment and has many other surgical uses, such as the managements of varicose veins, hemorrhoidectomy, and in pilonidal sinus surgery. Therefore, for reduction of the cost, the equipment can be shared by different specialists in an institution. It is also worth noting that disposable diode radial lasers are moderately expensive but still cheaper than most fistula plugs.

Conclusion

FiLaC is a safe method for management of anal fistulas. The rate of success is high in this procedure and morbidity is low. It should be promoted as one of favorable technique for the management of complex anal fistulas, especially in anal fistula associated with weak sphincters. Despite the favorable findings of this study, much larger studies and multicentric randomized trials are needed for conformation of these results.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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