

Is FiLaC™ the Ideal Choice for Initial Treatment of Anal Fistula as a Minimally Invasive Treatment Option?

FiLaC™, Minimal İnvazif Tedavi Seçeneği Olarak Anal Fistülde Başlangıç Tedavisinde İdeal Tercih mi?

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Abstract

Background: The laser method (FiLaC™) has recently emerged as a minimally invasive treatment option in the treatment of anal fistula. Anal incontinence and fistula recurrence after anal fistula surgery are postoperative problems that complicate the treatment. In our study, we aimed to investigate the effectiveness of the film method in the treatment of anal fistula and in which cases it should be preferred in the treatment.

Materials and Methods: Twelve patients who underwent FiLaC™ diode laser at Derik State Hospital between July 2017 and August 2018 were included in the study. Patients were analyzed retrospectively in terms of age, gender, development of incontinence, recovery and return to work, fistula types, MRI findings, and complications.

Results: 11 of the patients included in the study were male and 1 female and the mean age was 46. Intraoperative complications were not observed in any of the patients. The mean follow-up period was 13.5 (7-19) months. Complete recovery was observed in 4 (33.3%) patients in the follow-ups of the patients, while no improvement was achieved in 8 (66.7%) patients.

Conclusions: The FiLaC™ procedure for the treatment of anal fistula is a safe, minimally invasive, sphincter-sparing treatment option with low efficacy. However, it can be preferred as an initial treatment in high-level fistulas and in patients who want minimally invasive intervention.

Key Words: FiLaC™, Anal fistula, Recurrence

Öz.

Amaç: Lazer yöntemi (FiLaC™), son zamanlarda anal fistül tedavisinde minimal invazif tedavi seçeneği olarak karşımıza çıkmaktadır. Anal fistül cerrahisi sonrası anal inkontinans ve fistül nüksü tedaviyi zorlaştıran postoperatif sorunlar olarak karşımıza çıkar. Çalışmamızda FiLaCTM yönteminin anal fistül tedavisinde etkinliğini ve tedavide hangi durumlarda tercih edilmesi gerektiğini araştırmayı amaçladık.

Materyal ve Metod: Temmuz 2017 ile Ağustos 2018 yılları arasında Derik Devlet Hastanesi'nde FiLaC™ diyet lazer uygulanan 12 hasta çalışmaya dâhil edildi. Hastalar retrospektif olarak yaş, cinsiyet, inkontinans gelişimi, iyileşme ve işe dönüş zamanı, fistül tipleri, MR bulguları ve komplikasyonlar açısından analiz edildi.

Bulgular: Çalışmaya alınan hastaların 11'ü erkek 1 kadın olup yaş ortalaması 46 idi. İntraoperatif komplikasyon hiçbir hastada görülmedi. Ortalama takip süresi 13,5 (7-19) ay idi. Hastaların takiplerinde 4 (%33,3) hastada tam iyileşme gözlenirken, 8 (%66,7) hastada ise iyileşme sağlanamadı.

Sonuç: Anal fistül tedavisi için FiLaC™ prosedürü, güvenli, minimal invaziv, sfinkter koruyucu bir tedavi seçeneği olup düşük etkinliğe sahiptir. Ancak yüksek seviyeli fistüllerde, minimal invazif girişim isteyen hastalarda başlangıç tedavisi olarak tercih edilebilir.

Anahtar kelimeler: FiLaC™, Anal fistül, Nüks

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Introduction

Anal fistula is a disease in which more than 90% of cases are of cryptoglandular origin and occurs after anorectal abscesses (1). According to the Parks classification, fistulas are divided into four main groups; intersphincteric, transsphincteric, suprasphincteric and extrasphincteric (2) (Figure 1). Although temporary relief is provided with antibiotics and analgesics in the acute period, the definitive treatment of the disease is surgery (3). In addition to seton application, fistulectomy and fistulotomy among surgical treatment methods, new methods such as intersphincteric fistula tract ligation (LIFT), video-assisted anal fistula treatment (VAAFT) and FiLaC™ diode laser have recently been used. The main purpose of fistula surgery; permanent recovery and preservation of anal continence.

The Seton method is a surgical method that preserves the function of the sphincter muscle and reduces urinary incontinence compared to other methods. Fistulotomy is reported to be the most effective method in the treatment of anal fistulas and the cure rate is >90% (4-6). However, patients treated with fistulotomy are at risk of developing anal sphincter dysfunction after surgery. This risk is higher in women, those with complex fistula, those with preoperative incontinence problems, and those with recurrence or previous anorectal surgery (6,7). When the fistulotomy method is used to treat high-level fistulas, there is increased concern about the risk of continence impairment due to anal sphincter damage that may occur during surgery (8). Therefore, various "sphincter sparing" techniques such as fibrin glue, use of anal fistula plugs, anorectal advancement flap, and ligation of the intersphincteric fistula tract (LIFT) have been described to minimize concerns regarding functional outcomes in the surgical treatment of fistulas. These approaches were initially promising, but the success rates reported in the literature showed conflicting results (9). None of these treatments has been universally accepted as the gold standard surgical approach for fistula treatment. One of the new methods, FiLaC™, was first used by Wilhelm (10) in 2011 for the treatment of anal fistulas. This procedure involved complete removal of the entire length of the fistula tract, closure of the fistula's internal opening using a diode laser source and a radial laser probe. The most important feature of FiLaC™ is that the laser tip used does not damage the sphincters and other structures. The FiLaC™ approach is designed to simultaneously eliminate both the anal gland/crypt and the epithelial layer of the fistula via photothermal effect while closing both internal and external fistula openings. Major causes of fistula recurrence in other techniques such as bioprosthetic plugs and fibrin plugs include missed or untreated internal openings, inadequate drainage of the intersphincteric space, missed sideways and/or fistula epithelial remnants, and granulation tissue (11-13).

In our study; We aimed to present the results of patients for whom we used the FiLaC™ method in the treatment of anal fistula.

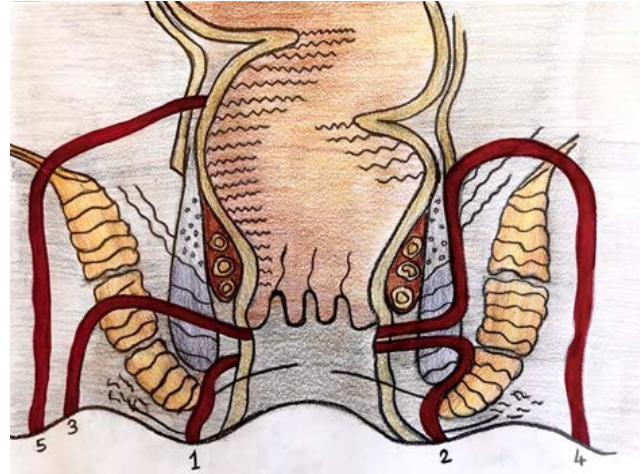


Figure 1. Park's Classification

1:superficial fistula, 2:intersphincteric fistula, 3:transsphincteric fistula, 4:suprasphincteric fistula, 5:extrasphincteric fistula

Materials and Methods

Twelve patients who underwent FiLaC™ diode laser at Derik State Hospital between July 2017 and August 2018 were included in the study. Our study is a retrospective clinical study and informed consent was obtained from all patients who underwent the FiLaC™ procedure. The study was approved by the Ethics Committee of Harran University (Date: 21/03/2022 - HRÜ.22/06/13). Fistulas were classified according to the Parks classification system (Figure 1). All patients were evaluated by preoperative clinical examination and classified using contrast-enhanced pelvic magnetic resonance imaging (MRI). Demographic data (age, gender), details of fistula type, and previous surgical treatments were recorded. Postoperative complications and follow-up times were evaluated. Preoperatively, mechanical bowel preparation with an emptying enema was performed in all patients, and 1 g of cefuroxime and 500 mg of metronidazole were administered intravenously. They received two more doses of 500 mg intravenous metronidazole within 24 hours of surgery.

FiLaC™ diode laser method

The FiLaC™ diode laser emits energy of 100-120 joules/cm at a wavelength of 1470 nm. This composition is believed to result in more effective local tissue resorption and protein denaturation. It is also thought to provide the most ideal absorption curve in water. When the temperature exceeds 100°C, the evaporation effect is seen in the form of white smoke. Using a radial tip laser destroys granulation and epithelial tissue. The procedure affects an area of 2-3 mm and causes more controlled tissue damage using less force (10). Closure of the fistula channel by coagulation is achieved by slowly pulling the laser probe out of the fistula channel at a rate of about 3 seconds per cm. This process should continue until it coagulates and the external opening of the fistula is closed.

Surgical Technique

Our patients were operated on under spinal anesthesia. Following anesthesia, patients were placed in the lithotomy position, with sterile drapes. The internal and external mouths of the fistula were determined. The laser probe was inserted into the external opening, extended along the fistula tract, and passed through the internal opening (Figure 2). The tip of the probe was then pulled a few millimeters into the inner opening. The laser was applied at an energy level of 100 joules. The procedure was continued by gradually pulling out the probe at 5mm intervals. After every 3 shots, the laser probe was removed and the tip of the probe was cleaned with gauze dipped in hydrogen peroxide to prevent charring. The process continued until the probe tip came out of the outer opening. The internal opening was closed with 3/0 vicryl sutures, the external opening was not sutured.



Figure 2. Laser probe inside the fistula tract

Results

Of the 12 patients included in the study, 11 were male and 1 was female, and the mean age was 46 years. The distribution of patients according to fistula types is given in Table 1. Mean follow-up was 13.5 months (range, 7-19 months). After 1 year, the patients were followed up at 3-month intervals by telephone. All patients were discharged after one or two days of uneventful hospital stay. None of the patients needed opioids or iv analgesics. All patients were able to work, drive or walk the day after the procedure. FiLaC™ failed to close the fistula tract in 8 of 12 patients. These cases were categorized as failed procedures. Patients with failed FiLaC™ procedures had one extrasphincteric, five transsphincteric, and two intersphincteric fistulas. The success rate with FiLaC™ is 33.33%. In the patient with extrasphincteric fistula, our next choice was the loose seton technique. The other seven patients had transsphincteric and intersphincteric fistulas and did not consent to a se-

cond laser application session. Our next choice for these patients was the tight seton technique.

Table 1. Classification and data

Characteristics	Number of patients n (%)
Park's classification	
intersphincteric	4 (33)
transsphincteric	7 (58)
extrasphincteric	1 (9)
preoperative seton use	3
recurrence	8
follow-up time	15 (7-19)
incontinence	0 (0)
Time to return to work	5 (3-8)

Discussion

Anal fistulas are treated surgically. The aim of fistula surgery is to permanently remove the inflammatory process without compromising stool continence. Fistulotomy is considered the gold standard in anal fistula surgery. However, this treatment is more successful in treating intersphincteric fistulas and lower transsphincteric fistulas and superficial fistulas. Higher level fistulas can cause undesirable consequences such as anal incontinence and recurrence. Although evidence suggests that this condition has been known and treated for thousands of years, few studies in the literature offer a critical and comprehensive discussion of the factors associated with relapse and incontinence. However, identifying associated risk factors may contribute to reducing such complications. Complications such as anal incontinence and fistula recurrence following fistulotomy to treat high fistulas have prompted surgeons to seek other treatments. Their goal is to prevent anal incontinence and recurrence. The traditional treatment for complex anal fistulas is seton placement (14). Basically, seton placement is based on the principle that the inner and outer openings of the fistula are combined with a stylet and tied using a non-absorbable suture (silk, polypropylene, polyester). Technically, it can be applied in two ways as loose or tight seton. With this method, the treatment process continues by squeezing the seton and gradually cutting the tissue. Therefore, this technique is recommended to reduce the risk of postoperative fecal incontinence (14,15). Vial et al. (15), the fecal incontinence rate determined in a systematically reviewed study using the seton procedure was between 5.6-25.2%, and the recurrence rate was between 3-5% in 19 case series and 448 patients. The LIFT method, on the other hand, was first defined as a sphincter-sparing method for the treatment of fistulas in 2007 (16). In subsequent studies, the technique has been proposed for the treatment of primary and recurrent anal fistulas. Malakorn et al. (17) in a retrospective clinical study involving 251

cases found that this technique had a high success rate in low transsphincteric and half horseshoe fistulas, and a low success rate in high transsphincteric and horseshoe fistulas. There was no case of anal incontinence in this study.

In a retrospective clinical study of complicated anal fistulas conducted by Xu and Tang (18) in 2017, there was a 40% recurrence rate and 1 in 55 patients developed fecal incontinence. Fibrin glue was the first biological material used in the treatment of anal fistula (19). It has been shown that platelet-derived growth factors or material enriched with platelet-rich fibrin, when used to treat perianal fistulas, accelerate tissue growth and provide closure of the fistula tract (20). In 2015, Lara et al. (21) reported that 40 (66%) of them showed anal fistula closure in a mean follow-up period of 24 months in a prospective multicenter study involving 60 patients, and anal incontinence did not develop in any of the patients. The success rate for intersphincteric fistulas is 87.5% (n = 8), 61.54% (n = 13) for low transsphincteric fistulas, 64.52% (n = 31) for medium transsphincteric fistulas, 57.14% for high transsphincteric fistulas (n = 7) and 100% for suprasphincteric fistulas (n = 1). In this study, it was observed that there were few suprasphincteric fistulas and the procedure was not applied in cases with horseshoe fistula. Several other methods have been tried to reduce recurrence and anal incontinence in the treatment of complicated anal fistulas. Some of these methods include bioprosthetic plugs and anorectal tissue flaps (22-24). However, these methods failed to produce the desired results in terms of tissue healing and fistula closure and did not prevent recurrence. The laser energy transmitted to the fistula channel by the diode laser radial tipped fiber used in our study destroys the endoluminal granulation tissue and the epithelial wall of the fistula tract. Simple diathermy cannot achieve the same results as it does not produce the tissue reduction effect that regulates thermal damage in the normal sphincter muscle and cannot be controlled as easily as the laser. In our study, the FiLaC™ procedure was used in patients with intersphincteric fistulas, low and high transsphincteric fistulas, and extrasphincteric fistulas. The optimum shrinkage effect achieved by the heat dissipated by the radial tip fiber is limited by radial penetration by the fistula lumen. 2-30 mm depth of the fistula channel. It is believed that a wavelength of 1470 nm is more effective in creating shrinkage and denaturation and has an optimal absorption curve in water. Surgical trauma is very low, and the hyperthermic effect is considered minimal and reversible (25). The patients were called for weekly control in the first month after discharge. One month later, patients were followed up at 3-month intervals for the first year. After the first year, the patients were called by phone and asked if they had any complaints. After 12 months, phone calls were made. The median follow-up period of our patients was 15 months. Eight cases were considered unsuccessful at 12 weeks postoperatively. One of these patients had an extrasphincteric fistula. Of the other patients, four had high transsphincteric fistulas, two had intersphincteric fistulas,

and one had low transsphincteric fistulas. Not all relapsed patients accepted a second FiLaC™ session and requested further treatment procedures. Because FiLaC™ is a "blind" procedure, small secondary pathways can be difficult to detect during surgery. This can be considered a disadvantage of the procedure, as it can lead to relapse. Previous studies have reported severe anal pain in a significant proportion of patients treated with a high-energy laser (980 nm diode laser). This can occur as a result of using higher volumes of laser energy to be successful. In our study, we routinely used 1470 nm diode laser instead of 980 nm diode laser for FiLaC™. None of our patients needed postoperative IV analgesic administration. In a study on the FiLaC™ procedure, Terzi et al. (26) reported that they achieved complete recovery in 40% of the patients when they published their long-term results, which included 103 patients. In yet another prospective cohort study, Marref et al. (27) presented their results in 69 consecutive patients. According to these results, 45.6% improvement was observed in the median follow-up period of 6.3 months. Nordholm-Carstensen et al. (28) They published the results of 68 patients in another original article they published. Although there were patients who had repeated laser application, the success rate remained at 44.1%. The median follow-up was 19 months. In our study, we achieved a 33.3% success rate, which is slightly lower than those reported in similar studies. We attribute this difference to the lower number of patients in our study compared to other studies and to poor postoperative self-care conditions in our patients. At the same time, a second laser session was not applied to any of our patients in our study. FiLaC™ requires more costly equipment compared to other sphincter sparing procedures; however, the diode laser platform is easily portable and has many other surgical applications, such as the treatment of varicose veins. Therefore, the machine can be shared by different specialists in an organization, thus reducing overall costs. It should be noted that disposable diode radial laser probes are moderately expensive, but still less expensive than most fistula plugs. In the light of the results of our study, FiLaC™ is a safe and low morbidity treatment method for anal fistulas. Because it preserves the sphincter complex and anal continence, this procedure should be promoted as one of the options for the treatment of complex anal fistulas, especially in patients with weak sphincters. However, this procedure has a low success rate. Therefore, it can be preferred in the initial treatment in patients who demand minimally invasive treatment. Larger series and multicenter randomized studies are needed to confirm the results of this study.

Ethical Approval: The study was approved by the Ethics Committee of Harran University (Date: 21/03/2022 - HRÜ.22/06/13)

Author Contributions:

Concept: H.Y.

Literature Review: H.Y.

Design: H.Y.

Data acquisition: H.Y.

Analysis and interpretation: H.Y., F.T.

Writing manuscript: H.Y., F.T.

Critical revision of manuscript: H.Y., F.T.

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