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RESEARCH ARTICLE

Closure of Fistula Tract with FiLaC™ Laser as a Sphincter-Preserving Method in Anal Fistula Treatment

Anal Fistül Tedavisinde Sfinkter Koruyucu Yöntem Olarak FiLaC™ Lazer Yöntemiyle Fistül Traktının Kapatılması

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ABSTRACT

Aim: Anal fistula is a difficult anorectal disease. Anal incontinence and fistula relapse after anal fistula surgery are morbidities feared by surgeons. Many techniques for sphincter preservation such as ligation of the intersphincteric fistula tract, anorectal flap application, and bioprosthetic plugs have been used in an effort to overcome these issues. We aimed to investigate the efficacy and safety of the FiLaC™ method in the treatment of anal fistula in our study.

Method: Twenty-seven patients (23 males, 4 females) who underwent FiLaC™ diode laser treatment between December 2013 and December 2014 were retrospectively analyzed for patient age, sex, body mass index, American Society of Anesthesiologists score, duration of operation, fistula types, complications, and patient satisfaction. FiLaC™, a 15-watt laser probe with a wavelength of 1470 nm and a power of 100-120 joules/cm, was applied to the anal fistula patients through the fistula under the spinal anesthesia.

Results: Twenty-three of the patients were male and 4 were female and the mean age was 35.55±10.32 years. The mean duration of the surgery was 18.37±5.27 minutes. Intraoperative complications were not reported. The mean follow-up period was 22 (17-26) months. Twenty-four (88.89%) patients fully recovered. The procedure failed in 3 patients (11.11%), at 4 months in 1 patient and at 6 months in another 2 patients. Patient satisfaction was 4.62±1.07.

Conclusion: The laser FiLaC™ procedure for anal fistula therapy is a safe, effective, minimally invasive, sphincter-preserving procedure with a high success rate.

Keywords: FiLaC™, anal fistula, anal incontinence

ÖZ

Amaç: Anal fistül tedavisi zor bir anorektal hastalıktır. Anal fistül cerrahisinin anal inkontinans ve fistül nüksü cerrahları korkutan morbiditeleridir. Bunun üstesinden gelmek için intersfinkterik fistül traktı ligasyonu, anorektal flep uygulaması, biyoprostetik tıkaçlar gibi sfinkter koruyucu birçok teknik denenmiştir. Çalışmamızda FiLaC™ yönteminin anal fistül tedavisinde etkinlik ve güvenilirliğini araştırmayı amaçladık.

Yöntem: Aralık 2013 ile Aralık 2014 yılları arasında FiLaC™ diyot lazer uygulanan 27 hasta (23 erkek, 4 kadın) retrospektif olarak hasta yaş, cinsiyet, vücut kitle indeksi, Amerikan Anestezistler Derneği skoru, operasyon süresi, fistül tipleri, komplikasyonlar ve hasta memnuniyeti açısından analiz edildi. FiLaC™ 1470 nm dalga boyunda ve 100-120 joule/cm enerji üreten 15-watt'lık bir lazer probu spinal anestezi altında anal fistül hastalarına fistül dış ağzından girilerek uygulandı.

Bulgular: Hastaların 23'ü erkek 4 kadın olup yaş ortalaması 35,55±10,32 idi. Ortalama ameliyat süresi 18,37±5,27 dakikaydı. İntraoperatif komplikasyonlar bildirilmedi. Ortalama takip süresi 22 (17-26) ay idi. Yirmi dört (%88,89) hastada iyileşme gözlendi. Bir hastada 4. ay diğer 2 hastada 6. ay olmak üzere 3 (%11,11) hastada başarısızlık vardı. Hasta memnuniyeti 4,62±1,07 idi.

Sonuç: Anal fistül tedavisi için lazer FiLaC™ prosedürü, güvenli, etkili, minimal invaziv, sfinkter koruyucu prosedürü olup yüksek başarı şansına sahiptir.

Anahtar Kelimeler: FiLaC™, anal fistül, anal inkontinans

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Introduction

Anal fistula is an anorectal condition with over 90% of cases being cryptoglandular in origin and occurring after anorectal abscesses.[1] The most feared complications associated with treatment of anal fistulas are fecal incontinence due to anal sphincter damage, and recurrence of the fistula.[2,3] According to the Parks classification, fistulas are divided into four main groups; intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric (Figure 1).[4] Generally speaking, even the simplest fistulas pose a limited risk for continence disorders. The reported overall incontinence rates vary up to 40% depending on the type of fistula and the surgical treatment applied. Even without anal sphincter damage, most cases experience minor anal incontinence in the early postoperative period.[5] Fistulotomy is the gold standard in the treatment of anal fistulas, but the recovery rate is >90%.[6,7,8] However, patients treated with a fistulotomy are at risk of developing postoperative anal sphincter dysfunction. This risk is higher in women and patients with complex fistulas, preoperative incontinence, recurrence, or past anorectal surgery.[8,9] In addition, studies have shown that fistulotomy, even in cases of simple fistulas, may cause functional impairment (anal incontinence) in some patients, which adversely affects patients' quality of life.[10,11] Concern about the risk of continence disorder increases when using fistulotomy to treat "high" fistulas due to the anal sphincter damage that can occur during surgery.[12] For this reason, various "sphincter-sparing" techniques including the use of fibrin glue and anal fistula plugs, the anorectal advancement flap, and ligation of the intersphincteric fistula tract (LIFT) have been described to minimize concerns about functional outcomes in the surgical treatment of fistulas.[13] These approaches were initially promising, but the success rates reported in the literature revealed conflicting results.[13] None has been universally accepted as the gold standard surgical approach for fistula treatment.

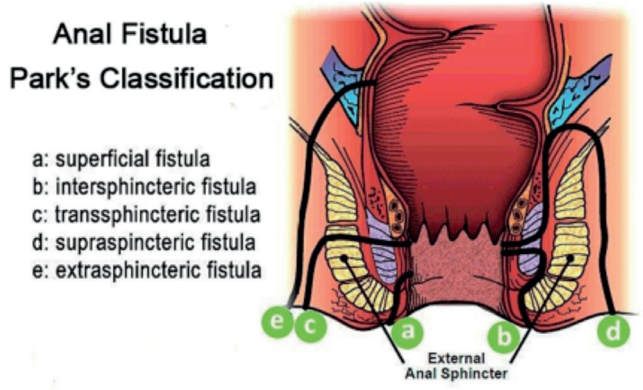

Figure 1. Park classification

FiLaC™ was first used by Wilhelm[14] in 2011 for the treatment of anal fistulas. This procedure involved completely removing the entire length of the fistula tract and closing the internal opening of the fistula using a laser diode 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 was designed to simultaneously eliminate both the anal gland/crypt and the epithelial layer of the fistula via photothermal effect, while also closing both the internal and external fistula openings. The main causes of fistula recurrence in other techniques such as bioprosthetic plugs and fibrin plugs include overlooked or untreated internal openings, insufficient drainage of the intersphincteric space, overlooked side tracts, and/or residues of fistula epithelium and granulation tissue.[15,16,17] This retrospective study presents the results of an analysis of our approach with the FiLaC™ device in the treatment of patients with anal fistulas.

Materials and Methods

Our study is a retrospective clinical study and informed consent was obtained from all patients who underwent the FiLaC™ procedure. Twenty-seven patients who were treated for anal fistulas at the İstanbul Lütfiye Nuri Burat State Hospital between December 2013 and December 2014 were analyzed in the study. The fistulas were classified according to the Parks classification system. All patients were evaluated preoperatively with clinical examination and proctosigmoidoscopy and were classified using contrast-enhanced pelvic magnetic resonance imaging (MRI).

Demographic data (age, sex, body mass index), details regarding fistula type, and previous surgical treatments were recorded. Postoperative complications, follow up periods, and patient satisfaction were assessed. Patient satisfaction was assessed according to the Likert scale (1: very unsatisfied, 2: unsatisfied, 3: neutral, 4: satisfied, 5: very satisfied). The patient satisfaction questionnaire was conducted 1 year after surgery. A simple questionnaire was used to assess postoperative anal continence status. Preoperatively, all patients underwent mechanical bowel preparation with fleet oral soda and fleet enema and received 1 g cefuroxime and 500 mg metronidazole intravenously. They received two more doses of intravenous 500 mg metronidazole postoperatively over 24 hours.

A FiLaC™ diode laser (Biolitec AG, Germany) was used in this study. The diode laser emits 100-120 joules/cm of energy at a wavelength of 1470 nm. This configuration is believed to result in more efficient local tissue shrinkage and protein denaturation, and provides the optimal absorption curve in water. When no water remains in the tissue and the temperature exceeds 100 °C, a vaporization effect is

observed as white smoke. The use of a radial tip laser at this wavelength allows the destruction of granulation and epithelial tissue and causes it to affects 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 about 3 seconds per cm. This procedure is continued until the laser probe coagulates and closes the external opening of the fistula. Care must be taken during the procedure to avoid excessive burns to the treated and surrounding tissue, and damage to adjacent tissues.

Our patients were treated under spinal anesthesia. Following spinal anesthesia, the patients were placed in the lithotomy position, then stained and covered. The surgery was then initiated. The fistula tract and the internal and external fistula openings were identified. The fistula tract was mechanically cleaned using a curette and washed with saline. The laser probe was inserted into the external opening, extended through the fistula tract, and passed through the internal opening (Picture 1). Then, the tip of the probe was withdrawn to within a few millimeters of the internal opening. The laser was applied at an energy level of 100 joule. 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 fistula tract (Picture 2). After every 3 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. The internal and external openings were not sutured and no ointments or topical medications were used.

Picture 1. FiLaC™ diode laser probe being advanced from the external opening to the fistula tract

Results

Twenty-seven patients were included in the study. Demographic data pertaining to the patients are presented in Table 1. Twenty-three of the patients were male and 4 were female. The average age of the patients was 35.55±10.32 years. The average body mass index was 23.72±3.48.

Seven of the patients had diabetes mellitus; 5 patients were classified as the American Society of Anesthesiologists (ASA) 2 and 22 patients as ASA 1. Twenty patients were smokers, but no pathology was found in the patients' posteroanterior chest radiographs and pulmonary function tests.

The average follow-up period was 22 months (range, 17-26 months). Patients completed a patient satisfaction

Picture 2. FiLaC™ diode laser probe in the fistula tract

questionnaire at postoperative 1 year. After 1 year, follow-ups were done over the phone at 3-month intervals.

All patients were discharged after being uneventfully hospitalized for one or two days. None of the patients required opioid drugs. All patients were able to drive or walk the day after the procedure. The patients were given oral antibiotics for one week.

Data regarding the patients' anal fistulas and surgeries are presented in Table 2.

FiLaC™ failed to close the fistula tract in 3 of the 27 patients. These cases were categorized as failed procedures.

Table 1. Characteristics of the patient group

Characteristic	Patient n (%)
Age (years)	35.55±10.32
Sex (male/female)	23/4
Height (cm)	75.11±10.33
Weight (kg)	176.81±6.65
Body mass index	23.72±3.48
ASA 1/2/3	22/5/0
Diabetes mellitus	7 (26)
Smoking	20 (74)

ASA: American Society of Anesthesiologists

Table 2. Perianal fistula features and surgical data

Characteristic	Patient number, n (%)
Park classification	
Intersphincteric	14 (51.8)
Transsphincteric	7 (26)
Suprasphincteric	5 (18.5)
Extrasphincteric	1 (3.70)
Symptom duration (months)	82 (48-134)
Preoperative seton stitch	5 (18.5)
Tract length (cm)	5 (3-10)
Site of IO	
Distal to the dentate line	9 (33.33)
On the dentate line	5 (18.5)
Proximal to the dentate line	13 (48.17)
Surgery duration (min)	18.37±5.27
Recurrence	3 (11.11)
Follow-up period (months)	22 (17-26)
Patient satisfaction	4.62±1.07

Data were reported as median (range) or n (%)

IO: Internal orifice

Of the patients with failed FiLaC™ procedures, one had an extrasphincteric fistula and two had suprasphincteric fistulas. The success rate with FiLaC™ was 88.89%. 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 14-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 is ongoing.

At postoperative 1 year, the mean patient satisfaction level was 4.62±1.07.

Discussion

Anal fistulas are treated surgically. The goal of fistula surgery is to permanently eliminate the suppurative process without compromising stool continence. Fistulotomy is accepted as the gold standard in anal fistula surgery. However, this treatment is more successful in the treatment of intersphincteric fistulas and low transsphincteric fistulas. Higher level fistulas can result in undesirable outcomes such as anal incontinence and recurrence. Although evidence indicates that this condition has been known and treated for thousands of years, there are very few studies in the literature offering a critical and thorough discussion of factors associated with recurrence and incontinence. However, the identification of associated risk factors may contribute to the reduction of such complications.

Complications such as anal incontinence and fistula recurrence which occur following fistulotomy to treat high fistulas have led surgeons to turn to other treatments. Their goal is to prevent anal incontinence and recurrence. The conventional treatment for complex anal fistulas is seton placement.[18] Theoretically, placing a seton, is an alternative to a one-stage fistulotomy in which the internal and external openings of the fistula are joined with a stylet and knotted with nonabsorbable suture (silk, polypropylene, polyester), and can be applied in one of two ways, either loose seton or tight seton. In this technique, the treatment process continues with cutting and tightening of the seton. For this reason, this technique is recommended for reducing postoperative fecal incontinence.[18,19] Vial et al.[19] systematically reviewed and scrutinized studies in which the seton procedure was utilized and determined a fecal incontinence rate of 5.6-25.2% and a recurrence rate between 3-5% in 19 case series and 448 patients.

LIFT was first described in 2007 as a sphincter-sparing method for the treatment of fistulas.[3] In subsequent studies, the 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 semi-horseshoe fistulas, but a low success rate in high transsphincteric and horseshoe fistulas. There were no cases of anal incontinence in that study. In a retrospective clinical study of complex anal fistulas conducted by Xu and Tang[21] in 2017, there was a 40% recurrence rate and 1 of the 55 patients developed fecal incontinence.

Fibrin glue is one of the minimally invasive techniques (no resection of the muscle tissue) that can be used in the treatment of complex anal fistulas. Fibrin glue is the first biologic material to be used in anal fistula treatment.[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 other methods have attempted to reduce recurrence and anal incontinence in the treatment of complex anal fistulas. Some of these methods include bioprosthetic plugs and anorectal tissue flaps.[24,25,26] However, these methods failed to yield the desired results in terms of 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 our 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 our 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 2-30 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 one month, patients were followed at 3-months 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 our 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. At the time of writing this report, the patient is at postoperative 13 months and the fistula appears to have closed. 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 our 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 our 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[29]. We achieved a success rate of 88.89% 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 to other studies.

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 institution, thus reducing the overall costs. It is also worth noting that disposable diode radial lasers are moderately expensive, but still cheaper than most fistula plugs.

In light of the results of our study, FiLaC™ is a safe treatment method for anal fistulas and does not require additional surgical closure of the internal orifice. This procedure has a high success rate and low morbidity. Because it is sphincter-sparing and preserves 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. Placing a loose seton on the fistula tract can facilitate the FiLaC™ procedure and facilitate healing. Despite the favorable findings of this study, much larger series and multicenter randomized trials are needed to confirm these results.

Ethics

Ethics Committee Approval: Ethics committee approval was not obtained because our study is a retrospective clinical study.

Informed Consent: Consent form was filled out by all participants.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: T.D., Concept: T.D., Design: T.D., E.H., Data Collection or Processing: T.D., Analysis or Interpretation: T.D., E.H., Literature Search: E.H., Writing: T.D.

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