Reliable treatment of perianal fistulas using laser ablation.
Results in 67 patients

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BACKROUND: *We aim to show that fistula ablation with laser (FAL) is a reliable method to repair a perianal fistula, and we share the results of a 24-month follow-up on FAL treatments of different perianal fistula types.*
STUDY DESIGN: *The FAL procedure was performed using a ceramic diode laser platform (30-50 J/cm of energy at a wavelength of 1470 nm). All operations were performed under spinal anesthesia in the jackknife position.*
RESULTS: *Of the 67 patients, 48 (71.6%) were male and 19 (28.4%) were female. Of these, 40 (59.7%) had intersphincteric fistulas, 21 (31.3%) had transsphincteric fistulas, 3 (4.47%) had suprasphincteric fistulas, and 3 (4.47%) had extrasphincteric fistulas. Based on perianal fistula disease severity scores, 40 patients (59.70%) experienced complete healing, 10 (14.92%) had persistent symptomatic drainage, 14 (20.89%) had slight drainage with minimal symptoms, and 3 (4.47%) had painful, symptomatic drainage. No major complications were observed in any patient.*
CONCLUSIONS: *The FAL is a minimally invasive initiative with the lowest morbidity and highest curative recovery rate, especially for simple fistulas.*

KEY WORDS: Anal fistula, Fistula ablation with laser, Reliable surgery

Introduction

A perianal fistula is a frequently encountered benign conditionin general surgical practice. It is a chronic anorectal infection related to purulent drainage or abscessformation and is characterizedby spontaneous abscess drainage. Its frequency is approximately 0.01%, and it is seen 4 times more often in the male population [1]. A fistula is formed by an infected crypt and tract that enable drainage [2]. Even though perianal fistulas can be secondarily causedby Crohn's disease, cancer, HIV, actinomycosis, tuberculosis, and so one, most fistulas stem from cryptoglandular structures [2,3].

In 1976, Parks identified a classification system, which is commonly used in perianal fistula classification and is based on the internal and external sphincter. The classification comprises 4 groups: intersphincteric, suprasphincteric-supralevator, transsphincteric, and extrasphincteric [4]. The most frequent symptom of a perianal fistula is drainage [5].
The definitive treatment of perianal fistula is surgery.[6] The location of the internal os, it's position concerning the sphincter muscles, and the associated fistula and blind-ended abscess must be determined before the operation and must be cleaned to prevent relapse for a successful surgery without complications.
The most accepted treatment methods for perianal fistulas are fistulotomy, drainage, and marsupialization for simple fistulas anda drainage seton, cutting seton, mucosal advancement flaps, and intersphincteric fistula tract ligation (LIFT) for complex fistulas. Studies to prevent serious complications, such as incontinence and relapse have been conducted for more effective and easy-to-apply treatment options. For this purpose, studies have been

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conducted on the effectiveness of various methods, such as the fistula ablation with laser, bio-prosthetic mesh, and video-assisted anal fistula treatment (VAAFT) [7]. In recent years, the use of laser in perianal fistula surgery has been adopted in surgical practice. In this retrospective study, the purpose is to share the results of a 24-month follow-up on FAL treatments of perianal fistula types.

Materials and Methods

Patients

This study is a retrospective analysis of prospectively collected data. Informed consent forms were obtained from all patients. Between January 2016 and January 2019, 67 perianal fistula patients who agreed to the FAL procedure were included in the study. Only cryptoglandular fistulas were analyzed. Patients who had a chronic disease, such as diabetes mellitus or Crohn's disease, were not included in the study. In our experience we recommend FAL the patients who do not have anorectal disease other than perianal fistula, do not have incontinens, do not want radical surgery. All patients were evaluated preoperatively by clinical examination, flexible rectosigmoidoscopy, and contrast-enhanced pelvic MRI. The fistulas were classified according to the Parks classification system. Intersphincteric fistulas are defined as simple fistulas, and transsphincteric, suprasphincteric, and extrasphincteric fistulas are defined as complex fistulas.

Statistical Analysis

The software SPSS (v. 22, IBM Corp, Armonk, NY) was used for all statistical analyses. The chi-square test was used for disease severity comparison through the Parks classification system, and $p < .05$ is considered significant. Fisher's exact test has been used for comparison of the full recovery among fistula types, and $p < .05$ is considered significant.

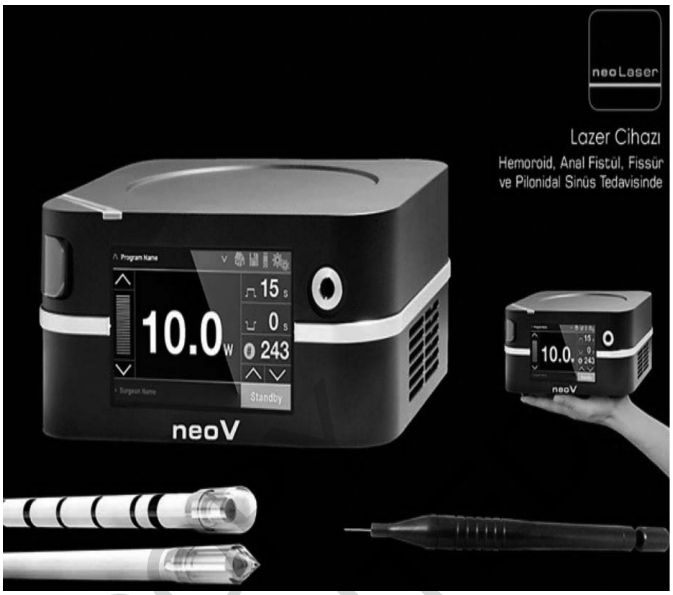

Fig. 1: An Alfadiode laser (NeoLaser, Israel).

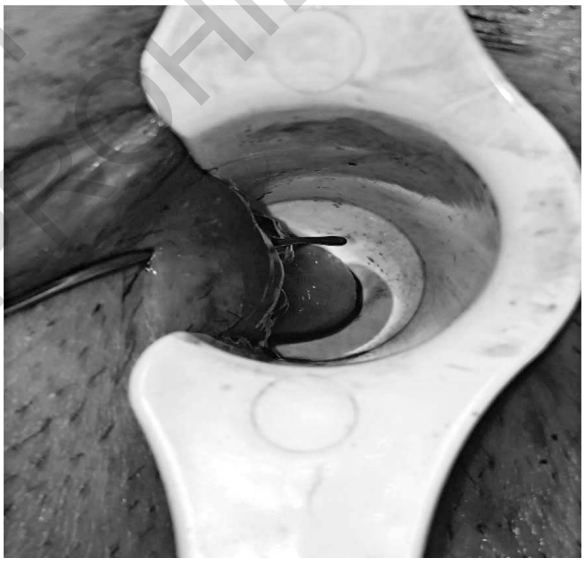

Fig. 2: Fistula tract identified using the Seldinger maneuver.

Surgical Technique

An Alfa diode laser (NeolLaser, Israel) was used in this study (Fig. 1). During a procedure using an Alfa laser,the energy was delivered via a radial emitting optical fiber into the anal fistula tract, and the laser was used to thermally ablate and close off the abnormal pathway. The laser energy inducedthe destruction of the fistula epithelium and the simultaneous obliteration of the remaining fistula tract through a shrinkage effect. The diode laser emitted 30-50 J/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 occurs and FAL procedure is not effective.

The fistula tract and the internal and external fistula openings were identified using the Seldinger maneuver (Fig. 2). Then, the fistula tract was mechanically cleaned using a flexible poliamid nylon brush and was washed with saline (Fig. 3). The laser probe was inserted into the external opening, was extended through the fistula tract, and was passed through the internal opening (Fig. 4). Then, the tip of the probe was withdrawn within a few millimeters of the internal opening. The laser

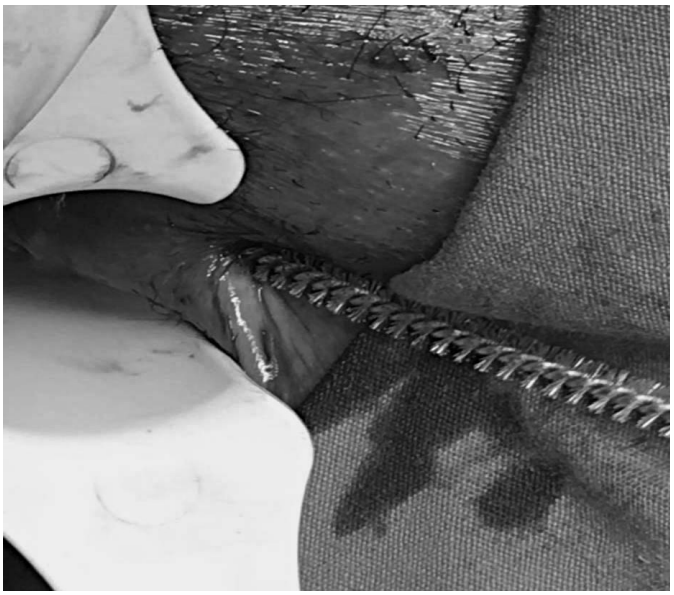

Fig. 3: Fistula tract mechanically cleaned using a brush.

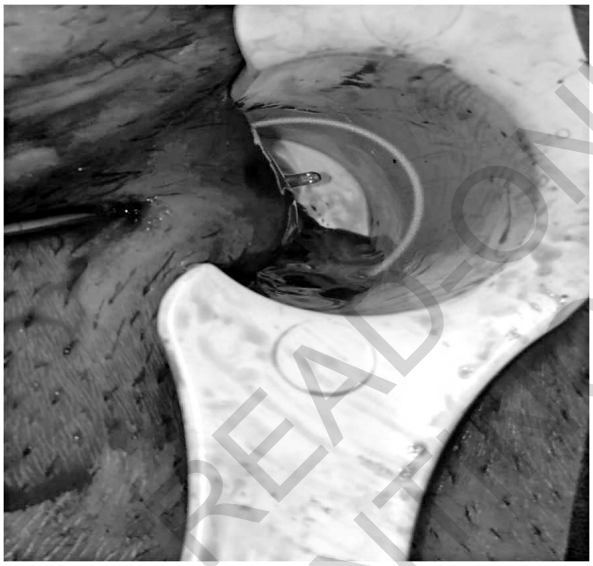

Fig. 4: Laser probe in the fistula tract.

was applied at an energy level of 50 J. During application, the laser probe passed through the fistula tract 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. Thus, we think that the possible intact epithelium structure is impaired by mechanical action.

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. Although there is no consensus in the number of shots, we think that three shots are sufficient for the closure of the fistula tract in our clinical practice. The laser application stopped 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. Additional surgical techniques, such as the closure of the internal orifice with a pursestring suture, seton procedure, or an advancement flap,were not used.

All operations were performed under spinal anesthesia in the jackknife position. We use jackknife position in anal surgery procedures as a clinical approach and in this position, we have more control over the surgical field. All patients had an enema just before surgery and received 1 g of ceftriaxone and 500 mg of metronidazole intravenously and two further doses of metronidazole over the first postoperative 24 h. A single dose of 500 mg of paracetamol was recommended to patients who required analgesics. All patients were discharged 12h after surgery.

Healing was evaluated using a perianal fistula disease severity score [8]:

Score 0: no active disease or complete healing;
Score 1: slight drainage with minimal symptoms;
Score 2: persistent symptomatic drainage;
Score 3: painful symptomatic drainage;
Score 4: severe perianal disease potentially requiring diversion.

In the first and last follow-up examinations, patients were asked whether they experienced any major incontinence symptoms (solid or liquid stool or gas incontinence) related to their FAL procedure. The first postoperative follow-up was performed on the 15th day. All patients adhered to our follow-up protocol, and the median follow-up period was 24 months (range 6–30 months). The follow-up program was performed as face-to-face controls at 1,6,12,18, and 24 months after FAL.

Results

Patient Characteristics

Out of the 67 patients included in the study, 48 (71.6%) were male and 19 (28.4%) were female. The median age of the patients was 42 years (range 17–64 years). In addition, 40 (59.7%) patients had intersphincteric fistulas, 21 (31.3%) had transsphincteric fistulas, 3 (4.47%) had suprasphincteric fistulas, and 3 (4.47%) had extrasphincteric fistulas. Nine (11.7%) patients had perianal fistula surgery, and all recurrent perianal fistulas were intersphincteric (Table I).

Based on the perianal fistula disease severity scores, 40 patients (59.70%) experienced complete healing, 10 (14.92%) had persistent symptomatic drainage, 14 (20.89%) had slight drainage with minimal symptoms, and 3 (4.47%) had painful, symptomatic drainage. No

TABLE I - *Patient and fistula characteristics of patients undergoing the FAL procedure.*

Characteristics	Data
Number of patients	67
Sex,men/women, n (%)	48 (71.6) / 19(28.4)
Age, median (range), years	42 (17-64)
Previous anal fistula surgery, n(%)	9 (13.4)
Intersphincteric fistula,n(%)	40 (59.7)
Transsphincteric fistula,n(%)	21 (31.3)
Suprasphincteric/extrasphincteric fistula,n(%)	6 (8.9)

TABLE II - *Evaluation of FAL based on the Park classification (p = .013).*

Perianal fistula disease score	Total	Intersphincteric	Transsphincteric	Suprasphincteric	Extrasphincteric
Complete healing,n (%)	40 (59.7)	29 (43.3) P	11 (16.4)	0	0
Slight drainage with minimal symptoms,n (%)	14 (20.89)	6 (8.95)	7 (10.44)	1 (1.5)	0
Persistent symptomatic drainage,n(%)	10(14.92)	3 (4.47)	3 (4.47)	2 (2.98)	2 (2.98)
Painful symptomatic drainage,n (%)	3 (4.47)	1(1.49)	0	1(1.49)	1(1.49)

TABLE III - *Evaluation of FAL based on the perianal fistula disease severity score and previous fistula surgery (p =.043).*

Perianal fistula disease score	Total	Simple perianal fistula	Complex perianal fistula	Previous anal fistula surgery No	Previous anal fistula surgery Yes
Complete healing, n (%)	40 (59.7)	30 (44.8)	10 (14.9)	34 (50.74)	6 (8.95)
Slight drainage with minimal symptoms, n (%)	14 (20.89)	9 (13.43)	5(7.46)	12(17.91)	2(2.98)
Persistent symptomatic drainage, n(%)	10(14.92)	2(2.98)	8(11.94)	10 (14.92)	0
Painful symptomatic drainage, n (%)	3 (4.47)	1(1.49)	2(2.98)	2(2.98)	1(1.49)

TABLE IV - *Complete healing and slight drainage with minimal symptomsaccepted as healingand comparison by fistula type (p =.028).*

	Total	Complete healing and slight drainage with minimal symptoms, n (%)	Persistent and painful symptomatic drainage, n(%)
Simple perianal fistula	42 (62.7)	39 (92.85) p	3 (7.14)
Complex perianal fistula	25 (37.3)	15 (60)	10 (40)
Total	67	54 (80.60)	13 (19.40)

serious cases of perianal disease and morbidity, potentially misleading us, were observed in patient groups. The effectiveness of the FAL procedure was evaluated separately according to the Park classification and disease severity. When the disease severity was compared through Park classification, the recovery rate was higher for intersphincteric fistulas (chi-square test,p = .013). Full recovery occurred in 29 out of 40 intersphincteric fistulas (72.5%). Six patients with supra/extrasphincteric fistulas have not fully recovered. Conventional perianal fistula surgery was performed on 13 patients with persistent and painful symptomatic drainage (Tables II and III). Fistulotomy was due to 4 (30.76%) patients from 13 patients fistula tract shorted. Seton procedure is applied to other patients.

When a simple fistula was compared with a complex fistula, full recovery was substantive in the simple fistula (Fisher's exact test p = .043). A substantive difference in terms of recovery was not detected in patients with perianal fistula surgical history.

When a second surgery was recommended to patients with slight drainage with minimal symptoms during patient follow-ups, they did not accept. They stated that occasional minimal painless drainage did not affect them and their social lives, and the preoperative symptoms had almost completely reduced. When patients with slight drainage with minimal symptoms are considered to be recovered along with those with complete healing, the success rate reaches 80.59%, and this rate is statistically significant (chi-square test p = .028; Table IV).

Discussion

A perianal fistula is a frequently encountered disease in general surgical practice. The definitive treatment of a perianal fistula is surgery. The purpose of the surgery is to provide full recovery without causing major complications, such as anal incontinence. A fistulotomy is successful, especially in the treatment of intersphincteric and lower transsphincteric fistulas. However, it might lead to serious complications in complex fistulas, such as relapse and incontinence [9].

Researchers have used different techniques and materials to prevent these complications, especially in the treatment of complex fistulas. The success rates of these various techniques are also different. The method with the highest success rate is the cutting seton at 82% to 100%. There were no major incontinence episodes in a study conducted by Hammond et al. but they suggest that 34% of patients have experienced minor continence disturbance [10]. Although the authors have reported that seton use has the highest success rate, we believe that fistulotomy is the most successful method when technically possible without causing serious impairment of sphincter function. The success of the seton has been determined to be 87.5% in a study conducted by Tatlı et al. In this sudy 12.5% recurrence determined [11]. The success rate of tissue adhesive fibrin glue ranges between 14% and 69%, which is a large gap [12,13]. A mucosal advancement flap has provided recovery with varying rates in previous studies (1%-75%) [14]. In addition, the LIFT treatment has been described as a protectivesphincter method in perianal fistula treatment. However, in another study conducted by Xu and Tang in 2017, the LIFT method was applied for the treatment of complex fistulas, and a relapse rate of 40% was observed.Moreover,fecal incontinence was observedin 1 patient out of 55 [15]. A few methods, such as bioprosthesis plugs and anorectal tissue flaps, failed to prevent relapse and close the fistulas [9]. The success rate in our study is 59.70%, independent of the fistula type. However, complete healing in simple fistulas is 44.8%, while in complex fistulas 14.9%.

The FAL removes endoluminal granulation tissue and the epithelial wall of the fistula channel and is a noninvasive method. Wilhelm used it for the treatment of anal fistulas in 2011 for the first time. This procedure involves the full removal of the total length of the fistula tract and the closure of the internal opening of the fistula using a laser diode source and a radial laser probe. The most important advantage of FAL is that it does not harm the sphincter and other structures. Besides closing both the interior and exterior fistula openings, FAL has been designed to shrinkage the fistula crypt and epithelial layer together and disrupts the structure of the fistula tract. The main reasons for a fistula relapse are unnoticed or untreated internal openings, insufficient drainage of the intersphincteric opening, and unnoticed secondary tracts and/or residual fistula epithelial and granulation tissue [16]. Fistula relapse rate of 19% was observed in our study.

In the study involving 11 patients published by Wilhelm in 2011, the full recovery rate was 81.8%. In the study,a fistula continued in 1 patient, and another patient developed a horseshoe abscess. A minor form of incontinence was observed in 1 patient, who recovered within 6 months. The number of patients was low, and the follow-up period was short in this first study [17]. In the study published by Wilhelm et al. [18] in 2017, involving 117 patients, all patients were treated using FiLaC, and 113 of these patients were already operated on due to abscess drainage or the fistula. This study, in addition to using FiLaC, also involved other surgical procedures, such as the mucosal flap and anodermal flap. Whereas 13 of these patients developed a fistula due to Crohn's disease, others developed cryptoglandular fistulas. The primary recovery rate for cryptoglandular fistulas was 63.5%. Minor incontinence was observed in two patients, and one patient developed a late-term abscess. The primary recovery rate in fistulas developed due to Crohn's disease was 69.2%. No difference between the secondary recovery rates of these two groups could be found. The secondary recovery rate in cryptoglandular fistulas was 85.5%, whereas this rate in fistulas due to Crohn's disease was 92.3%. In the present study,the secondary recovery rate is unrelated to the number of previous fistula surgeries or the period between these surgeries. The factors affecting the success of the treatment arethe level and severity of the fistula. In our study, fistulas formed due to causes such as crohn's disease were excluded from this study. In this study, mostly patients who had undergone simple fistula and previous anal surgery were preferred.

In the study by Terzi et al. [19] involving only the laser protocol as the treatment procedure, the long-term results of 103 patients were shared. Fifty-three (52%) patients had already undergone a fistula surgery. According to the perianal fistula severity score, full recovery was 39.8%. Full recovery in simple and complex fistulas was 40% no difference in terms of a full recovery was detected between the patients that had already undergone a fistula surgery and the patients who had not. The rate was 40% in both groups. 28 of 103 patients underwent an additional operation during follow-up. Laser treatment was applied to 7 of 28 patients and symptoms regressed in 2 of the laser patients.

In a retrospective study conducted by Dönmez et al. [9], the results of 27 patients with fistulas, who were treated using FiLaC, were shared. The success rate in this study was 88.89%. In conclusion, Dönmez et al. stated that FiLaC is dependable for anal fistula treatment and that there is no need to close the internal opening using an additional method. The satisfaction level of the patients was 4.62±1.07. The laser could not close the fistula tract in three patients. In a patient with extras-

phincteric localization, the condition transformed into a transsphincteric fistula with the first FiLaC application, and the fistula was closed with another FiLaC application. The loose seton procedure was applied to two patients with suprasphincteric fistulas.

In a study conducted by Öztürk et al. [20], the success rate was 82% related to the LAFT treatment of 50 patients with perianal fistulas. Conventional surgical methods were applied to the patients, for whom the LAFT treatment was unsuccessful. The patients returned to their standard dailylives after a period of approximately 7 days.

The first article describing FiLaC without additional surgery for internal opening was published by Giamundo et al. [21] treated 35 patients using FiLaC and followed-up for 25 months. They provided curative treatment for 25 (71,4%) patients. The treatment failed for 7 (22.8%) patients, and the fistula relapsed in 2 patients (5.8%). Two years after this study, Giamundo et al. [22] stated in the second edition they conducted that the recovery rate was 79% for patients to whom a loose seton was applied before FiLaC. They stated that the loose seton was more successful with FiLaC because it provides effective drainage, although no statistically significant difference exists between this rate and the success rate for patients solely receiving FiLaC treatment.

Pellino et al. [23] used perineal packing for fistulas with diffuse perineal involvement. At least, one large perineal fistulotomy was performed in all patients, gauze swabs were placed in the fistula bed and sutured with several non-absorbable stitches. Then, gauze were removed within 2 days after surgery. It has been stated that the recovery time is 21.5 days on average. They reported that only one patient had bleeding It was also reported that there was no recurrence on MRI scan during a mean follow-up of 16.4 ± 2.1 months. These rates are compatible with our study. However, we did not need large incisions. In a study by Pasta et al. [24], patients with non-complex linear, intersphincteric or transsphincteric fistulas were examined. Using the two-stage technique, they used the same catheters to insert the branch tube in the first stage and position the seton in the second stage. We think that there may be a disadvantage compared to our study, since the procedure is two-stage and the recovery period is long.

Kaya et al. [25] used silver nitrat for perianal fistulas. It was stated that after the first procedure, silver nitrate was applied to the patients for 6 more sessions. It was determined that the rate of complete recovery in intersphincteric fistulas was 30.3%. In our study, this rate was 43.3%. In addition, while there were repetitive processes in this study, a single-step process was applied in our study. Using a different technique, Topal et al. [26] used stem cells derived from adipose tissue in the treatment of complex perianal fistulae. While the complete recovery rate after 9 months was 70% in their study, the rate of complete recovery of complex perianal fistulas after 24 months was found to be 60% in our study. We think that the rate of complete recovery of complex perianal fistulas was slightly affected, since the time followed in their study was shorter than our study. So, we consider that statistically more significant results will be obtained with long-term follow-up data.

Conclusions

FAL is a minimally invasive procedure with the low morbidity and high curative recovery rate, especially for simple fistulas. It can be used safely in anal fistula treatment, due to its protectiveness of the sphincter. Despite these positive findings, multi-center and prospective randomized studies are needed to further assess this method. The data collected within this study agree with the literature. However, the data are retrospective and no comparative data exist, which could be deemed shortcomings of our study.

Although the authors have reported that seton use has the highest success rate, we believe that fistulotomy is the most successful method when technically possible without causing serious impairment of sphincter function.

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