

Comparison of the Efficacy of Laser and Hybrid Seton Methods in the Treatment of Perianal Fistula

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ABSTRACT

Objective: To compare the efficacy and postoperative complications of laser and hybrid seton methods in the treatment of perianal fistula (PF).

Study Design: A descriptive cross-sectional study.

Place and Duration of the Study: Department of General Surgery, University of Health Sciences, Bursa Yuksek Ihtisas Training and Research Hospital, Bursa, Turkiye, from January 2021 to April 2022.

Methodology: A total of 76 patients, with 46 in the hybrid seton group and 30 in the laser group, were included in the study. Perianal fistula classification was based on preoperative magnetic resonance imaging. The Likert satisfaction scale was assessed for patient satisfaction and the Cleveland Clinic Florida Faecal Incontinence (CCF-FI) scoring system was used for incontinence. Treatment outcome was determined based on success rate and postoperative faecal incontinence.

Results: The mean age of the patients was 43 ± 13 years and 59 (78%) of them were male. Forty-seven (62%) patients had simple fistula. Acute and late complications were significantly higher in the hybrid seton group than in the laser group ($p < 0.001$). According to the Likert satisfaction scale, the rate of unsatisfied patients was significantly higher in the laser group than in the hybrid seton group ($p = 0.02$). According to the CCF-FI scoring system, incontinence was significantly higher in the hybrid seton group than in the laser group ($p = 0.01$). Treatment failure was higher in the laser group ($p = 0.03$).

Conclusion: The laser method has lower intraoperative / postoperative complications, but higher treatment failure and lower patient satisfaction compared to the hybrid seton method.

Key Words: Anal fistula, Fecal incontinence, Laser therapy, Outcome, Loose seton method.

How to cite this article: Taskin AK, Akar M, Ozcetin B. Comparison of the Efficacy of Laser and Hybrid Seton Methods in the Treatment of Perianal Fistula. *J Coll Physicians Surg Pak* 2024; **34(09)**:1040-1045.

INTRODUCTION

Perianal fistula (PF) is a disease that usually causes chronic discharge and impairs quality of life. There is still no standard treatment for this disease and the treatment process is difficult.¹⁻³ Most patients with PF undergo more than one operation during their lifetime. Therefore, PF is extremely important in terms of morbidity.¹ It is usually seen in the individuals of age upto 30-50 years and 2-fold more in males than females. Diabetes mellitus, smoking, obesity, and hyperlipidaemia are accepted as risk factors.^{1,2} Inflammatory bowel disease, foreign body, radiation, trauma, tumours, and tuberculosis may also cause PF.³

The success of treatment in PF depends on the presence of abscess accompanying PF in the perineal region, the ability to reveal the sphincter tract during the treatment application phase, and not damaging the sphincter muscles.¹ In PF treatment, the fistulotomy / fistulectomy method is preferred only in simple (superficial and intersphincteric) fistulas to avoid damage to anal canal sphincters.⁴ In addition, loose seton is used in all (simple / complex) fistulas associated with abscess or Crohn's disease.^{1,4} The loose seton method does not pose a risk for anal incontinence in PF treatment, but it does not cure it either. The loose seton increases the disappearance of abscess in PF and fibrosis of the fistula tract.⁴ The cutting seton method is preferred for healing of the fistula tract in all (simple / complex) fistulas. However, this method has encouraged the surgeons to attempt new methods for reasons, such as the high rate of anal incontinence (gas, liquid, faeces), long postoperative pain duration, prolonged hospitalisation, and negative effects on the patient's quality of life.⁵ Therefore, methods such as hybrid seton, laser application, ligation of the intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment (VAAFT), and closure of the fistula tract with plugs (fibrin glue or collagen paste) have become more widely used in PF (simple / complex) in recent years.^{6,7}

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Received: May 13, 2024; Revised: July 23, 2024;

Accepted: August 23, 2024

DOI: <https://doi.org/10.29271/jcpsp.2024.09.1040>

The aim of this study was to compare the efficacy and postoperative complications of laser and hybrid seton methods used in the treatment of PF in recent years.

METHODOLOGY

This descriptive cross-sectional study included a total of 76 patients with PF treated with laser or hybrid seton in the General Surgery department of Bursa Yuksek Ihtisas Training and Research Hospital, Bursa, Turkiye between January 2021 and April 2022. The demographic and clinical data were recorded from the patient files. The preoperative pelvic magnetic resonance imaging (MRI) results of the patients were evaluated. The patients were classified as intersphincteric, transfincteric, and suprasphincteric according to the Park classification⁸ and as simple/low or complex/high according to the American Society of Colon and Rectal Surgeons Standards Committee-2 (ASCRS-2) criteria⁹ based on the MRI findings. All the patients underwent preoperative rectosigmoidoscopy or colonoscopy to exclude a possible inflammatory bowel disease or malignancy.

Pain severity scores were recorded using a visual analogue scale (VAS) at the 6th and 24th postoperative hours in all patients.¹⁰ Patient satisfaction was evaluated in outpatient clinic controls 1 year after the treatment with the 5-option measurement system used by Likert.¹¹ Faecal incontinence values of the patients were calculated with the Cleveland Clinic Florida Faecal Incontinence (CCF-FI) scoring system preoperatively and at 1 year postoperatively.¹² The treatment outcome of the patients was evaluated according to the PF severity score as complete recovery, mild drainage with minimal symptoms, permanent symptomatic drainage, and painful symptomatic drainage.¹³ Acute complication was defined as haemorrhage, haematoma, oedema, and urinary retention, while the late complication was defined as incontinence. In addition, treatment failure was defined as the presence of persistent symptomatic drainage or recurrence of the disease. The recurrence was defined as the reappearance of the fistula or the development of any new fistula. The duration of hospitalisation of each patient was also recorded.

This study included patients aged 18 years and older with no previous PF treatment and at least 12 months of regular postoperative follow-up after the laser or hybrid seton treatment. Patients with pelvic abscess, inflammatory bowel disease, anovaginal fistula, malignancy, perianal tuberculosis, diabetes mellitus, previous perianal fistula surgery, missing data in the file, and the patients who did not attend follow-up regularly were excluded. All treatment modalities were performed by a general surgeon specialised in colorectal surgery. All the patients underwent preoperative mechanical bowel preparation with 210ml sodium dihydrogen phosphate + disodium hydrogen phosphate enema. Prophylactic 1g cefuroxime and 500mg metronidazole were administered intravenously. All except one of the patients treated with hybrid seton or laser underwent spinal anaesthesia. One patient underwent general

anaesthesia at his request. The operation was started with all patients in the lithotomy position.

In the laser method, after the fistula tract was exposed with a stylet, the fistula tract was curetted with a Lempert 2.4mm surgical curette. The residual epithelium and granulation tissue were brushed with a brush-sized 2, 3, 4, or 5mm according to the diameter of the fistula tract. The fistula cavity was washed with 20ml of 0.9% saline. Subsequently the internal epithelium and granulation tissue of the fistula tract were homogeneously obliterated with a radial 1,470nm diode laser (Neo-laser) probe with an average of 100joules of energy (12 watts for 3 seconds for every 10mm, 100joules of energy for every 10mm in total). This procedure was started from the inner mouth of the fistula tract and the fistula tract was obliterated as far as the outer mouth. The inner mouth of the fistula was not sutured in any patient.

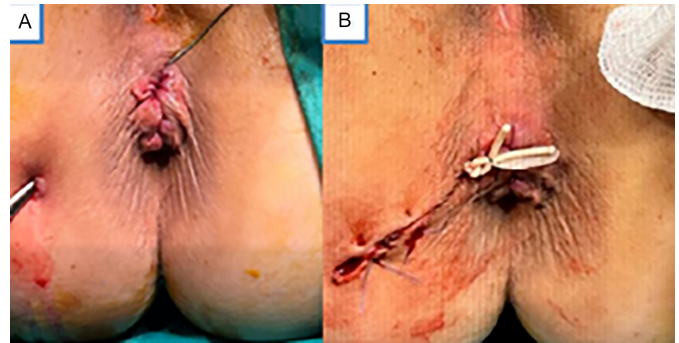


Figure 1: (A) Exposing the fistula pathway, (B) Hybrid seton treatment.

In the hybrid seton method, the inner opening of the fistula was exposed with a stylet (Figure 1). If the inner mouth of the fistula could not be exposed, hydrogen peroxide was given through the outer mouth and the inner mouth was revealed with the help of an anal retractor. The fistula was excised from the external mouth to the anal sphincter muscle complex. The remaining fistula tract was curetted. A 1 / 0 silk suture was tied to the end of the stylet and placed in the fistula tract. An elastic seton was tied to the end of the silk suture (outer ring of latex surgical glove no.8 (2-3mm), Beybi® Istanbul). The stylet was retracted and the elastic seton was tied on itself without excessive tension (unlike the traditional cutter seton) by enclosing all or part of the sphincter complex (Figure 1). The possibility of serous discharge during the hybrid seton was explained to the patients. Patients were encouraged to contact the clinic if they suspected a relapse of the disease, if they noticed that the seton had fallen off, and if they noticed that the seton was too loose. All patients were given antibiotherapy for one week postoperatively. All patients were advised to clean with warm water after defaecation in the postoperative period.¹⁴ All patients were followed up on postoperative Day 7 and 30, and at 3rd and 12th months. In patients who underwent hybrid seton, the seton was slightly tightened when severe looseness of the seton was detected during the follow-up.

Data obtained in the study were analysed statistically using IBM SPSS Statistics 21.0 (IBM Corp., Armonk, NY, USA). The study population was checked for normal distribution with the

Kolmogorov-Smirnov test. Values were expressed as mean \pm standard deviation for normally distributed variables, median (25th-75th percentile) for non-normally distributed variables, and counts and percentages for categorical variables. In the comparison of the data between the two groups, the independent-samples t-test was used for the parametric data, and the Mann-Whitney U test was used for the non-parametric data. The Chi-square test was used to compare the categorical variables. For all analyses, a p-value less than 0.05 was considered to be statistically significant.

Approval for the study was obtained from the Ethics Committee of Training and Research Hospital. The study was conducted in accordance with the Declaration of Helsinki.

RESULTS

The mean age of the patients was 43 ± 13 (range: 20-77) years and 59 (78%) of the patients were male. Forty-six (60.5%) patients underwent hybrid seton treatment. According to the Park classification, 47 (62%) patients had intersphincteric fistula, while 47 (62%) patients had simple fistula according to the ASCRS-2 classification (Table I). The mean postoperative follow-up of the patients was 17 ± 4 (range: 12-24) months. The complete recovery was observed in 71 (93.4%) of the patients after 1 year postoperatively. According to the Likert satisfaction scale 1 year after the operation, 71 (93.4%) of the patients were satisfied or very satisfied with the treatment (Table II).

Table I: Distribution of demographic and clinical characteristics of the patients.

Variables	All patients (n = 76)	Hybrid seton (n = 46)	Laser (n = 30)	p-value
Age, years*	43 \pm 13	45 \pm 13	39 \pm 11	0.02
F/M, n (%)	17 (22) / 59 (78)	11 (24) / 35 (76)	6 (20) / 24 (80)	0.68
Smoking, n (%)	28 (37)	16 (35)	12 (40)	0.64
Park classification, n (%)				0.40
Intersphincteric	47 (62)	26 (57)	21 (70)	
Transsphincteric	20 (26)	13 (28)	7 (23)	
Suprasphincteric	9 (12)	7 (15)	2 (7)	
ASCRS-2 classification, n (%)				0.23
Simple / low	47 (62)	26 (57)	21 (70)	
Complex / high	29 (38)	20 (43)	9 (30)	

*Mean \pm standard deviation, F: Female, M: Male, ASCRS: American Association of Colon and Rectal Surgeons Standards Committee. Independent-samples t-test, Mann-Whitney U test, and Chi-square test.

Table II: Comparison of clinical characteristics of the patients in the treatment group.

Variables	All patients (n = 76)	Hybrid seton (n = 46)	Laser (n = 30)	p-value
Operation duration, sec*	(1104 \pm 244)	(1251 \pm 162)	(877 \pm 161)	<0.001
Length of hospital stay, day**	1 (1-1)	1 (1-1)	1 (1-1)	0.54
Follow-up duration, month*	(17 \pm 4)	(15 \pm 3.5)	(19 \pm 3.8)	<0.001
Duration of symptoms, month**	12 (7-18)	12.5 (8-16.5)	12 (6-24)	0.98
VAS**, h				
6 th	3 (2-4)	3 (2-4)	2 (1-3.2)	0.002
24 th	1 (0-2)	1 (1-2)	0 (0-2)	0.11
Likert satisfaction scale, n (%)				0.02
Absolutely agree	44 (57.9)	25 (54.3)	19 (63.3)	
Agree	27 (35.5)	20 (43.5)	7 (23.3)	
Undecided	1 (1.3)	1 (2.2)	0	
Absolutely disagree	4 (5.3)	0	4 (13.3)	
Intraoperative haemorrhage, n (%)	44 (58)	44 (95.7)	0	<0.001
Postoperative complication, n (%)				<0.001
Acute	26 (34)	24 (52)	2 (6.6)	
Late	14 (18.4)	14 (30.4)	0	
Postoperative CCF-FI score, n (%)				0.01
Perfect continence	61 (81.6)	32 (69.6)	30 (100)	
Mild incontinence	12 (15.8)	12 (26.1)	0	
Moderate incontinence	1 (1.3)	1 (2.2)	0	
Severe incontinence	1 (1.3)	1 (2.2)	0	
Complete incontinence	0	0	0	
Treatment outcome, n (%)				0.03
Complete recovery	71 (93.4)	45 (97.8)	26 (86.7)	
Slight drainage with minimal symptom	1 (1.3)	1 (2.2)	0	
Treatment failure	4 (5.3)	0	4 (13.3)	

* Mean \pm standard deviation, ** Median (25th -75th percentile), Sec: Second, h: Hour, VAS: Visual analogue scale, CCF-FI: Cleveland Clinic Florida Faecal Incontinence. Independent-samples t-test, Mann-Whitney U test, and Chi-square test.

According to the CCF-FI scoring system, no incontinence was observed in any patient in the laser group. In the hybrid seton group, only mild incontinence was found in 12 (26.1%) patients. Of those 12 patients, seven patients had fluid incontinence, and five patients had gas incontinence. The 6th median VAS score was significantly higher in the hybrid seton group ($p = 0.002$), whereas there was no significant difference between the groups in terms of the 24th median VAS score ($p = 0.11$, Table II).

DISCUSSION

Over the years, many different surgical techniques have been developed for sphincter-sparing PF repair. However, the treatment failure rate is still quite high at 7-50%. Patients mostly prefer non-invasive treatments that are effective and painless, require a short hospital stay, and do not cause incontinence.^{14,15} In recent years, hybrid seton and laser methods have been used as an alternative to classical surgical treatment methods in PF.^{16,17} To the best of the authors' knowledge, no previous study has compared these methods, so this is the first such study in the literature.

It has been reported in the literature that PF is more common in the middle-aged male population.^{13,17} In the present study, the majority of the patients were middle-aged male patients, consistent with the literature. In a previous study, the duration of hospitalisation varied between 1 and 2 days in the patients who underwent laser operation.¹⁴ Another study reported that PF patients treated with hybrid seton were hospitalised for 1-2 days.¹⁸ Similar to the literature, in this study, all of the patients stayed in the hospital for only 1 day, except for one patient in the hybrid seton group who was discharged after 2 days.

The first laser treatment in PF was performed in 2011.¹⁹ In the literature, it was reported that the rate of intraoperative haemorrhage was approximately 20%¹ and the rates of treatment failure varied from 11 to 80% in patients who underwent laser treatment.^{6,14} The high recurrence rates observed after laser surgery in a few studies were attributed to various reasons such as a history of fistula surgery, no imaging method having been used to determine abscess, the presence of complex PF, the presence of a secondary fistula tract, and variability of fistula tract diameter.^{1,13,14,20} In this study, although no intraoperative bleeding was observed in any patient in the laser group, the treatment failure rate was 13.3%. The lower rates of intraoperative bleeding and treatment failure in the laser group compared to the literature may be related to the fact that the present study consisted of patients without perianal abscesses, without previous fistula surgery, and predominantly with simple PF. However, it has been reported that the success rate in patients with PF treated with laser therapy is higher in patients with complex fistula than in the patients with simple fistula.²¹ In this study, all patients with simple fistula

treated using laser method were completely recovered. No data could be found in the literature related to intraoperative haemorrhage rates in the hybrid seton treatment method. The treatment failure rates at 1 year after hybrid seton treatment in PF have been reported to be 1.5-5.1%. Some of these patients had previously undergone fistula surgery. In this study, no treatment failure was observed in any of the patients who underwent hybrid seton, except for mild drainage with minimal symptoms in only one patient (2.2%), while intraoperative bleeding was observed in 95.7%. This result was consistent with the literature.

In previous studies, the median postoperative VAS value of patients receiving laser treatment for PF has been found to be between 0-2.^{1,22} In another study, the median VAS value was found to be 3.23 at 24th hour in the patients who underwent hybrid seton.⁷ In the current study, the median 6th - 24th hour VAS values in the laser and hybrid seton group were 2 - 0 and 3 - 1, respectively. The median VAS values in both groups were similar to the literature. None of the patients in the current study required analgesia after discharge. In the literature, incontinence has been reported at the rate of 0-1% in patients treated with laser. The low rate of incontinence after laser treatment is due to the minimal thermal damage of the laser. The majority of these incontinences observed after laser treatment have been reported as mild incontinence.^{1,20} In the current study, the median CCF-FI score was 0 in the patients treated with laser. In previous studies, anal incontinence in patients treated with hybrid seton has been reported to vary between 0% and 20%. No statistically significant difference was found between preoperative and postoperative CCF-FI values.^{17,23} In this study, mild, moderate, and severe incontinence in the hybrid seton group was 26.1%, 2.2%, and 2.2%, respectively. The total incontinence rate in the present study was 30.5%. Considering that no patient had incontinence preoperatively, these postoperative incontinence rates in the hybrid seton group are quite remarkable. The reason for this difference between the current study and the literature may be the demographic and clinical differences of the patients. Unlike previous studies, this study found a statistically significant difference between the postoperative CCF-FI values of the hybrid seton and laser groups, favouring the laser group.¹⁷ In patients with PF treated using laser, the rate of patient dissatisfaction after 1 year postoperatively according to the Likert satisfaction scale has been reported between 4.6% and 19%. To date, the Likert satisfaction scale has never been used in patients with PF treated with a hybrid seton. However, postoperative quality-of-life evaluation was performed.^{7,17} In this study, according to the Likert satisfaction scale, 13.3% of the patients in the laser group reported dissatisfaction, similar to the literature. In this study, all patients in the hybrid seton group were either very satisfied or satisfied according to the Likert satisfaction scale, except for one patient who was undecided. The negative contribution of smoking to the postoperative healing rate in PF has been

demonstrated.²⁴ Smoking was observed at the rate of 83% of patients treated with laser in a previous study.²⁵ No information about smoking was given in the studies of patients treated with hybrid seton. In the current study, the smoking rates were similar in both treatment groups, with no statistically significant difference determined.

The limitations of this study were the retrospective, single-centred design, and a small limited number of patients.

CONCLUSION

Although the laser treatment used in patients with PF has the advantages of shorter surgery duration, lower intraoperative bleeding, and lower postoperative complications compared to the hybrid seton method, it has a higher treatment failure rate and lower patient satisfaction rate. It is thought that prospective studies with large patient groups are needed to clarify the advantages and disadvantages of both methods.

ETHICAL APPROVAL:

Approval for the study was obtained from the Ethics Committee of Bursa Yuksek Ihtisas Training and Research Hospital (Approval Code: 2011-KAEK-25 2022/06-14) The study was conducted in accordance with the Declaration of Helsinki.

PATIENTS' CONSENT:

Informed consent was obtained from the patients.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

AKT: Designed the study, conducted the analysis, drafted the manuscript, and revised it for important intellectual content.

MA: Conceived, designed, and supervised the manuscript.

BO: Conducted the analysis and drafted the manuscript.

All authors approved the final version of the manuscript to be published.

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