

FISTULA LASER ABLATION FOR ANAL FISTULAS (systematic review)

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AIM: to reveal fistula healing incidence after application of FiLaC™ technique and factors that can affect it.

PATIENTS AND METHODS: when searching electronic medical databases for publications that evaluated the results of the FiLaC™ technique in the treatment of anal fistula, 6 studies were selected, corresponding to the search queries. The search was carried out taking into account the principles of systematic literature reviews and meta-analyses (PRISMA). The time interval for searching publications was between 2011 and October 2018. In the publications included in the analysis, the following parameters were evaluated: general characteristics of the study groups, technical aspects of the FiLaC™ technique, the site of the fistula in relation to the anal sphincter, the option of closing the internal fistula, the incidence of healing and recurrence of fistula, the duration of the follow-up period after surgery, re-operated cases of fistula recurrences.

RESULTS: taking into account the data obtained in the analysis of the selected studies, the mean incidence of fistula healing was 64.5 (40.0–88.2)%. It was found that the only factors that can be used to assess their impact on the incidence of fistula healing were: the gender and the variant of the fistula site in relationship to the anal sphincter (transsphincteric/extrasphincteric). Statistical analysis and evaluation of the odds ratio revealed no effect on the treatment result of the above parameters.

CONCLUSION: the analysis of the data showed that FiLaC is mainly indicated for the treatment of patients with extrasphincter and transsphincteric anal fistulas. The method can be recommended as a sphincter-sparing treatment in patients with initially weakened anal sphincter function and, consequently, with a high risk of anal sphincter insufficiency in the application of traditional techniques. Further evaluation of the treatment results in the treated period and their comparison with the results after other variants of coagulation of the fistula walls is required to obtain a clearer understanding of the effectiveness of the FiLaC technique.

[Key words: fistula-in-ano, minimally invasive techniques, laser ablation]

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The problem of treatment of complex anal fistulas has been and remains relevant in coloanal surgery. The question of the choice of surgery technique is still debatable, especially in the treatment of fistulas that capture more than 1/3-1/2 of the external sphincter or located extrasphincterally, which is associated with a high risk of anal incontinence after surgery and recurrence of the disease.

When choosing a particular method of treatment, one should always take into account the relationship of the fistula to the elements of the anal sphincter, as well as the surgical anatomy of the fistula tract.

Traditional methods – excision of the fistula with suturing of the sphincter, seton method, the method of bringing down the flap of the anal wall, have the most radical and effective in the treatment of complex fistulas, but are associated with a significant risk of

postoperative anal incontinence.

Thus, according to the literature, anal incontinence after excision of the fistula with suturing of the sphincter develops in 6-21% of cases [1-4], and after the use of the cutting seton its incidence reaches 60% [5-9,22].

It is connected with this ongoing search for the most optimal method to eliminate fistula without disrupting the function of the anal sphincter.

Given the urgency of the problem, against the background of the development of new technologies and operative methods, approaches to the treatment of complex anal fistulas continue to be modernized.

So, in recent years were proposed a variety of sphincter-saving methods: application of bioplastic materials, different types of implants, liquid compositions for filling fistula tract, videoassisted anal fistula treatment

(VAAFT), ligation of intersphincteric fistula tract (LIFT), technology with the use of mesenchymal stem cells (Autologous Mesenchymal Stem Cells), etc. [10-14].

These methods have appeared for the last 10-13 years and now there is an accumulation of experience of their use in the treatment of fistulas.

One of the variants of modern sphincter-saving techniques is FiLaC™ (Fistula Laser Closure, Biolitec, Germany) – fistula laser thermoablation [15-19].

The method was first proposed by Wilhelm A. in 2010 and over time it was used to treat anal fistulas along with other sphincter-saving methods [18,20].

Describing the technical features of the technique, the following laser radiation parameters are most often given in publications: a light guide with radial laser radiation, a wave length of 1470 nm, a radiation power of 13W, a speed of advancement of the light guide through the fistula channel of 1 mm/sec. These parameters contribute to a uniform, circular coagulation of the fistula walls with a penetration depth of up to 2-3 mm, which leads to minimal tissue injury and provides an optimal curve of thermal energy absorption by the aqueous medium.

AIM

The purpose of this systematic review was to determine the average rate of fistula healing after the application of the FiLaC™ technique and to identify factors that can affect this parameter.

MATERIALS AND METHODS

To conduct the analysis, a search was made for published studies that evaluated the results of the FiLaC technique in the treatment of anal fistulas. The published papers were selected in accordance with the principles of systematic reviews and meta-analyses (PRISMA) [21]. To search were used the databases: PubMed / Medline, Google Scholar, eLibrary. The time interval for the search was between 2011 and October 2018 (Fig. 1).

During the search, the following keywords were used: «anal fistula», «fistula-in-ano», «FIA», «laser», «treatment», «Laser anal fistula treatment», «FiLaC», «minimally-invasive fistula treatment». As a result, were selected all studies in which the results of the application of the FiLaC method in the treatment of anal fistulas were evaluated.

The duration of follow-up of patients was not a criterion for selecting the publication for inclusion in the review, also, given the small world experience of using the FiLaC™ technique, the nature of the study did not matter – randomized (RCT), cohort, «case-control»

study, etc. Language restrictions were not applied.

The systematic review did not include papers that did not provide data on the incidence of fistula healing, disease recurrence and complications. Works in which own clinical material was not presented, and also publications of the same group of authors in various editions were excluded.

As a result, 6 of 15 selected papers were included in the study, including 1 article in Russian, 5 – published in English-language editions.

The following parameters were evaluated for data analysis in the research materials:

- Male / female ratio;
- Average age of patients;
- Type of fistula according to the Park's classification (intersphincteric / transsphincteric / suprasphincteric / extrasphincteric) [22].

In this situation it is necessary to recall that suprasphincteric fistulas, according to the Park's classification, correspond to the extrasphincteric fistulas, according to the Russian classification.

Additionally, when specified in the publications, was taken into account the division of the fistulas according to the classification of the American Gastroenterological Association (AGA) on simple (intersphincteric, low transsphincteric involving ≤30% of the external sphincter) and complex (high transsphincteric fistulas involving more than 30% of the external sphincter, suprasphincteric fistulas, extrasphincteric fistulas, anal fistulas during inflammatory bowel diseases).

- Technical details of the FiLaC™ technique (wavelength of laser radiation [nm], laser power [W],

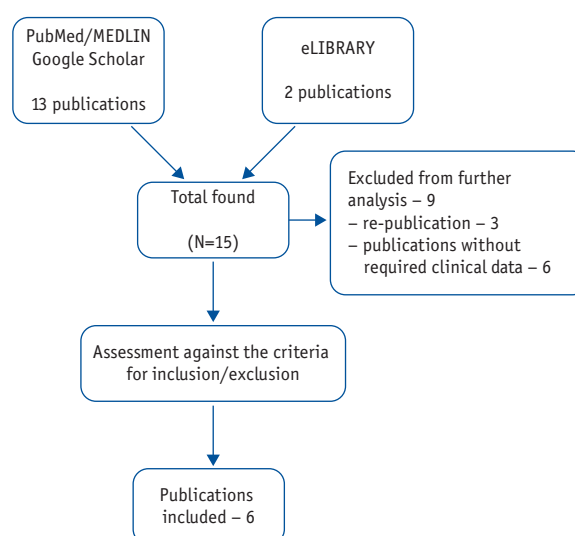


Figure 1. Diagram of selection of studies for systematic analysis

- speed of removal of the light guide from the fistula [mm/sec.]), used equipment;
- The presence or absence of a laser-mounted draining seton installed prior to the surgery, the timing of drainage of the fistula course (months);
 - The option of closing the internal fistula orifice (only fistula laser thermoablation, fistula laser thermoablation with suturing of internal fistula opening, fistula laser thermoablation with the closure of internal fistula opening using one of the variants of the flap);
 - Incidence of fistula healing and recurrence;
 - Incidence and type of postoperative complications;
 - Duration of follow-up of patients in the postoperative period;
 - Type of re-operations in cases of fistula recurrence.

In the presence of similar data in the analyzed works, which can be combined for statistical analysis, the assessment of their impact on the incidence of fistula healing was performed.

The GraphPad Prism v.6 software was used for statistical processing. The Fisher F-test was used to evaluate qualitative nonparametric data.

To assess the influence of the analyzed factors on the incidence of fistula healing, the odds ratio (OR) was evaluated using the software Review Manager, version 5.3. In the study of 6 papers, it was found that only two factors made it possible to perform a statistical analysis of the data with an assessment of their impact on the incidence of fistula healing after the application of the FiLAC™ technique – fistula site and its relationship to the anal sphincter and the gender of patients. Other factors were mentioned only in some works, which did not allow to include them in the systematic analysis.

RESULTS

The primary aim of this analysis was to assess the incidence of fistula healing after using the FiLAC™ technique.

When analyzing the data of 6 selected publications, it was found that the incidence of fistula healing ranged from 40% to 83.5% (average healing rate – 64.5%). Given that the method of closing the internal fistula opening varied in different papers, it was not possible to estimate the effect of this factor on the fistula healing rate (Table 1).

In a total of 6 publications, 400 patients (288 men, 112 women) were included in the analysis. In one of the 6 papers (Wilhelm A. 2017), among the operated patients there were the ones with fistulas developed during Crohn's disease. In 9 (69.2%) of these patients, the authors noted healing of fistula [19].

When assessing the dependence of the fistula healing rate on the gender of the patients, 3 studies were included in the analysis, in which this parameter was indicated. As a result of the statistical analysis with an assessment of the odds ratio, the influence of gender on the incidence of healing was not revealed (Fig. 2).

In all publications, the authors used a diode laser with a wavelength of 1470 nm. However, the indicators of power were different, and most of the authors used the radiation power 12-13 W with the excretion rate of the lightguide of 1.0 mm per second. Instructions for pre- and postoperative antibiotic therapy were given in 2 studies (Giamundo P. 2015, Wilhelm A. 2017). Thus, in the work of Giamundo P. (2015) in the postoperative period, patients were prescribed oral taking of metronidazole at a dose of 250 mg 4 times a day, lasting 5 days. In the work of Wilhelm A. (2017) in the preoperative period, parenteral administration of 2000 mg of Cefazolin and 500 mg of metronidazole was used.

In the postoperative period (first 24 hours) metronidazole was administered parenterally at a dose of 1000 mg [16,19].

In the study of Giamundo R. (2015), the healing incidence was also assessed depending on whether the draining seton was inserted in the fistula tract or not. Thus, of the 24 patients in whom before radical stage the draining seton was used, healing occurred

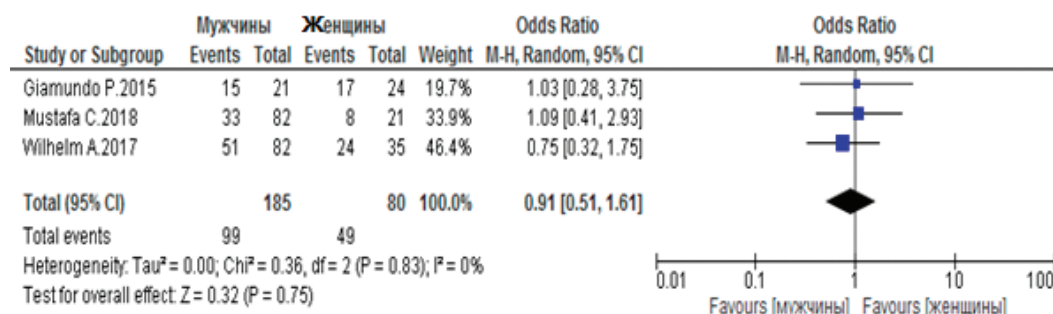


Figure 2. Evaluation of the odds ratio of fistula healing depending on the gender of patients

Males/Men / Females/Women

Table 1. Characteristics of studies on the duration of the observation period, the incidence of fistulas healing, options for closing the internal fistula opening after application of the FiLAC™ technique

Author	Follow-up (months)	Healing incidence (%)	The option of closing the internal fistula opening
Wilhelm A. (2017)	6-60	75 (64,1%)	– Mucosal-submucosal flap – Mucosal-muscle flap – Skin-anal flap – Suturing the internal fistula opening
Giamundo P. (2015)	30	32 (71,1%)	– Muco-muscle flap – Without suturing the internal fistula opening
Ozturk E. (2014)	12	41 (82%)	– Without suturing the internal fistula opening
Lemarchand N. (2015)	3	36 (80%)	No data available
Mustafa C. (2018)	No data available	41 (40%)	– Without suturing the internal fistula opening
Khitariyan A. (2016)	6-28	33 (83,5%)	– Mucosal-muscle flap

Note: No data available

in 19 (79%) patients, recurrence of the fistula in 5 (21%) cases. In patients who did not have seton previously, healing was detected in 13/21 (62%) cases, recurrence – in 8 (38%).

In the comparative analysis with the assessment of the odds ratio of fistula healing depending on the presence or absence of preliminary seton drainage of fistula, no statistically significant differences were found ($p=0.32$, Fischer test, $OR=2.33$ [CI 0.62-8.76]).

Based on the data of the 3 studies, the analysis of the incidence of fistula healing depending on the relationship of the fistula to the anal sphincter (transsphincteric fistula / extrasphincteric fistula) did not reveal statistically significant influence of this factor on the fistula healing rate ($OR=0.75$; 95% CI 0.36-1.59; $p=0.46$) (Fig. 3).

As can be seen in figure 3, of the 227 patients with transsphincteric fistulas, healing was observed in 127 (55.9%) cases and in patients with extrasphincteric site of the fistulas, it was 23/36 (63.9%).

Among the complications, cases of bleeding were described in the studies of Khitariyan A.G. (2016) and Giamundo, P. (2015). Thus, in 1 patient in the study of Khitariyan A.G. and 3 patients in the work of Giamundo P. moderate bleeding was noted, which did not require surgical hemostasis.

One of the most important criteria for evaluating the

results after any surgery for anal fistula is the rate of anal incontinence (AI). Analysis of publications to assess the incidence of development of this complication after FiLAC™ technique showed that in 2 works cases of Grade I of AI were described [5.24]. Wilhelm, A. in his study, recorded the development of AI after surgery in only one patient, the manifestations of which were independently stopped in 7 days after the surgery.

With the development of the disease recurrence after the FiLAC™ technique application, the authors carried out various options of new surgeries (Table 2).

As can be seen from the table, in 3 out of 4 studies that indicated the nature of re-surgeries with fistula recurrence after fistula laser thermoablation, the technique was re-used. The greatest experience of re-surgeries using the FiLAC technique is presented in the work of its founder Wilhelm, A. (2017), however, the outcomes of these surgeries are not indicated by the author.

CONCLUSION

Recently, it is difficult to imagine progress in medicine without laser technologies, which have opened up new opportunities in solving numerous medical problems

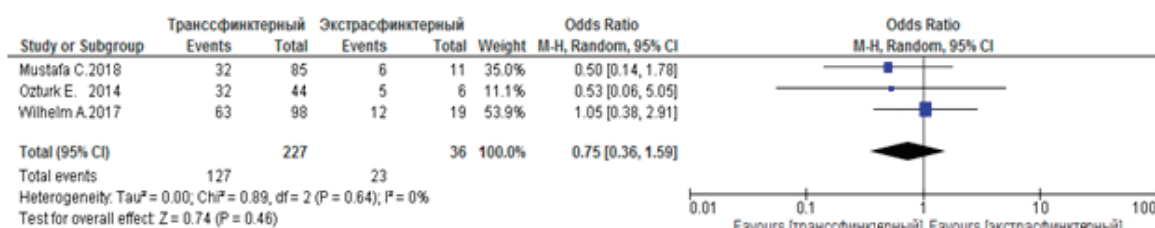
**Figure 3.** Analysis of the effect on the fistula healing incidence by the level of their site in relationship to the anal sphincter Transsphincteric / Extrasphincteric

Table 2. The type of re-surgeries for the fistula preservation after FiLAC™ technique application

Authors	Mucosal-muscle flap	Mucosal-submucosal flap	Excision of a fistula	Other types of surgeries	Re-surgery FiLAC
Giamundo P., 2015	5	–	6	–	2
Ozutruk E., 2014	–	1	8	–	–
Wilhelm A., 2017	–	–	–	11	31
Mustafa C., 2018	–	–	–	21	7

[4,14]. The study of the mechanisms of exposure to biological tissues of laser radiation with different wavelengths and energy levels allowed to create medical laser devices, the range of application of which in clinical practice has become quite wide. Among the diseases, in the treatment of which laser technologies can be successfully used, are anal fistulas.

The results of the conducted literature review showed that the incidence of fistula healing after the use of fistula laser thermoablation was, on average, 64.5% (40–83.5%).

The conducted statistical analysis with the evaluation of the odds ratio showed that the gender of patients, the type of fistula (transsphincteric/extrasphincteric), do not significantly affect the healing incidence after the use of FiLAC technology. Complications after fistula laser thermoablation were either completely absent or represented by a minor hemorrhage (4.7%) which did not require special arrangements for their stopping.

The results of the systematic review allow us to conclude that the technique of fistula elimination using a diodelaser is mainly applicable and used for the treatment of patients with trans – and extrasphincteral fistulas, and can also be recommended for patients in whom traditional fistula excision is accompanied by a high risk of anal incontinence.

As for further research aimed at determining advantages and features of the effect of laser radiation on tissue, comparing the results of fistula laser thermoablation technique with other electrothermal effects on the fistulous walls (monopolar coagulation) may be interesting.

This study will answer the question of how much exposure to the laser can improve the fistula healing incidence compared with the treatment of fistula walls using a standard electrocoagulating action.

The authors declare no conflicts of interest.

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