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CLINICAL EXPERIENCE OF APPLYING A MODIFIED FILAC PROCEDURE FOR TREATMENT OF COMPLEX ANAL FISTULAS

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ABSTRACT — Surgical treatment of complicated anal fistulas remains one of the most difficult issues of coloproctology. In this study we used a modification of Fistula Laser Closure procedure in complex treatment of patients with anal fistulas.
The purpose of our study was to assess the short-term and remote results of applying the modified FiLaC procedure in patients with complex anal fistulas and compare these results with conventional fistulectomy.
The patients with complex transsphincteric and extrasphincteric anal fistulas were prospectively divided into FiLaC and conventional fistulectomy groups.
The operative duration was longer, by 31% ($p<0.05$), in the FiLaC group compared to the control group. The healing of fistulas was faster by 42% ($p<0.05$)in the FiLaC group (7.3 ± 0.5 weeks versus 12.6 ± 0.7 weeks). The Wexner Incontinence scale scores were significantly lower ($p<0.05$) in the FiLaC group. The recurrence of rectal fistula after the surgery was observed in 37.2% in the control group versus 17.5% in the FiLaC group ($p<0.05$) (median follow up period — 13 months). The pressure parameters of the anal sphincter were significantly higher ($p<0.05$) in the long-term follow-up period in patients of the FiLaC group and continence was maintained in 92.5% of the FiLaC group.
Thus, the study has shown that the modified FiLaC procedure accelerates the healing time of the fistula by 42% ($p<0.05$), reduces the number of fistula recurrences from 37.2% to 17.5% ($p<0.05$), and has minimal negative effects on anal continence.

KEYWORDS — FiLaC, anal fistula, laser treatment.

INTRODUCTION

Surgical treatment of transsphincteric and extrasphincteric anal fistulas remains one of the most difficult issues of coloproctology. This problem is accompanied by a high level of the disease recurrence, severity of the pain syndrome in the early postoperative period, long disability, and a high incidence of anal incontinence in the distant postoperative period [1, 2, 3]. A promising development of minimally invasive surgery is the emergence of FiLaC technology (Fistula Laser Closure) [4, 5, 6].

The aim of the study was to compare the short term and long terms results of FiLaC with historical, standard fistulectomy, controls in the management of transsphincteric and extrasphincteric anal fistulas.

MATERIALS AND METHODS

Clinical charts of patients with transsphincteric and extrasphincteric anal fistulas were analyzed and then divided into two groups: the FiLaCgroup (n=40) and the control group (n=43). Modified FiLaC procedure was used for treatment of fistulas in the FiLaC group. Standard fistulectomy with excision of the fistula's inner opening into the lumen of the anal canal and excision of cicatricial and purulent-inflammatory perineal tissue was used in the control group. 43 patients of the control group were operated from 2008 till 2012 and 40 patients of the FiLaC group were operated from 2012 till 2016.

The preoperative examination methods included a digital rectal examination, colonoscopy, fistuloradiography, sphincteromanometry with Peritrondevice (Australia), endorectal ultrasound, pelvic MRI, and perineal examination in order to locate the external and internal openings of fistula and the area of cicatricial and inflammatory changes in the perirectal space and on the perineum.

In FiLaC group the operation was performed in lithotomy position with general anesthesia and muscle relaxants. The operation began with the injection of contrasting liquid into the fistulous tract (brilliant green solution), and then the external opening was ex-

cised by the fringing incision (incision that surrounds the external fistulous opening, O-shaped), the main fistula tract was detected in the operating wound and transected at a distance of 0,5 cm from the entrance to the anal sphincter mass. Additional fistulous tracts and purulent cavities were drained by separate point incisions through every 2 cm taking into account the data of endorectal ultrasound and MRI (Fig. 1). Latex drains were placed through the point incisions. The fistula was catheterized by the laser fiber FiLaC Fistula Probe (Fig. 2, 3). Then laser coagulation of the sphincter portion of the fistula by the laser with a wavelength of 1470 nm, 12 W power, in a continuous wave mode, with a total energy of 100 Jper cm was performed, achieving ablation and decontamination of the fistula, without damaging the anal sphincter and fibrous sheath of the fistula. The internal opening was sewn with interrupted stitches with Vicryl 2.0.

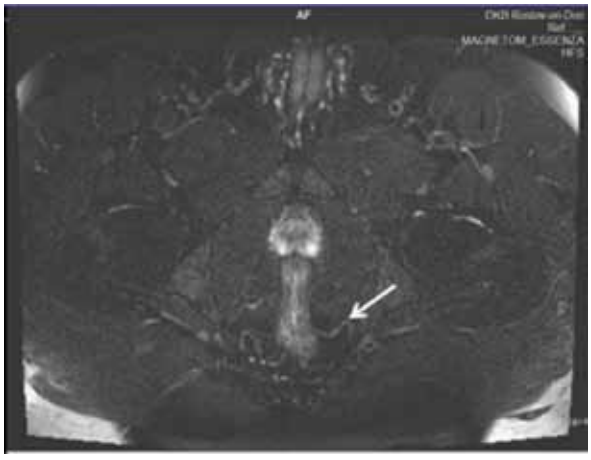

Fig.1. *MRI of the fistula tract*

Fig. 2. *Catheterization of fistula by FiLaC Fistula Probe*

In the control group, the operation was performed in lithotomy position with general anesthesia. Then the external opening was excised by the fringing incision, continuing the access perianally along the entire extent of the cicatricial-inflammatory tissues of the perineum using mono- and bipolar coagulation, then removing all additional fistula tracts and excising the internal aperture of the fistula tract into the lumen of the anal canal. The internal opening was closed by Z-shaped absorbable suture.

When the fistula was spread through the puborectal muscle, a silicon filament loop Ethicon 1.1 was additionally inserted through the fistulous tract to the internal opening and tightened after dissecting its mucosa below the inner fistula opening saving a deep portion of the anal sphincter and the puborectal muscle. The cutaneous edges of the perineal wound were sewn to the underlying tissues by Vicryl 1.0 filament, leaving the wound open for the secondary healing in a form of a triangle or trapezium facing the perineum. Tamponing of the wound was not used, as we preferred frequent baths, irrigation with antiseptics, ultrasonic cavitation of the wound.

Fig. 3. *Catheterization of fistula by FiLaC Fistula Probe*

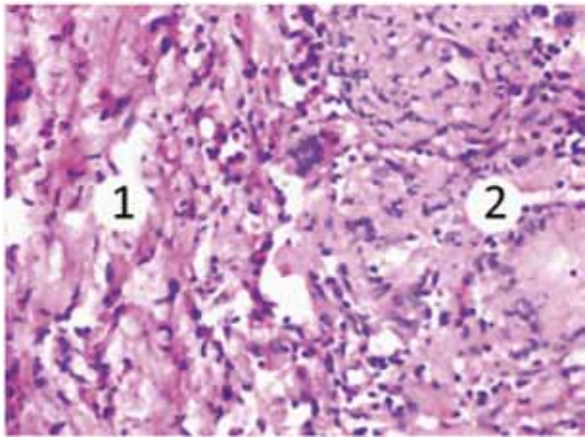

Fig. 4. *Fibrous capsule of the fistula after the exposure of laser with a 12 W power, 100 J/cm energy. X400. Hematoxylin-eosin.*
1 — coagulation edema and defibration of structures of the internal part of the fistulous tract
2 — the external part of the fistulous tract remains intact

Table 1. *Initial characteristic of patients in both clinical groups.*

Index	FiLaC group (n=40)	Control group (n=43)
Men, abs. (%)	31 (77.5%)	30 (70%)
Women, abs. (%)	9 (22.5%)	13 (30%)
Age, years (M ± m)	44.5±1.8	47.6±2.1
Type of fistula: – complextranssphincteric – extrasphincteric III grade of complexity – extrasphincteric IV grade of complexity	 9 (22.5%) 26 (65%) 5 (12.5%)	 11 (25.6%) 28 (65.1%) 4 (9.3%)
Number of previously operated patients, abs. (%)	25 (62.5%)	22 (51.2%)
Diabetes mellitus, abs. (%)	7 (17.5%)	6 (14%)
Obesity, abs. (%)	9 (22.5%)	10 (23.3%)
Initial results of sphincterotonometry, mmwg. • at rest – operated previously – non-operated previously – summary • when straining – operated previously – non-operated previously – summary	 49.3±1.6 65.2±2.3 57.6±2.0 77.5±1.9 109.4±1.5 83.6±1.1	 48.2±1.8 63.1±2.7 59.4±2.2 76.2±2.4 104.7±1.3 89.5±1.4
ScoresontheWexnerscale: – operated previously – non-operated previously – summary	 7.3±0.3 2.1±0.6 5.2±0.5	 8.1±0.4 2.0±0.2 5.4±0.4
Fecal incontinence (operated previously patients) 1 stage, abs. (%) 2 stage, abs. (%)	 2 (5%) 1 (2.5%)	 2 (4.7%) -

The general characteristics of patients in clinical groups are presented in Table 1.

Patients of the FiLaCand control groups by age, sex, severity of the underlying disease, type and complexity of rectal fistulas, concomitant pathology, and previous surgical interventions did not differsignificantly ($p > 0.05$).

The duration of follow-up of patients was 6–28 months (mean 14.3 ± 2.6 months)in theFiLaCgroup, 10–36 months (an average of 14.3 ± 2.6 months)in the control group.Short- and long-term results of treatment in the FiLaC and control group were compared to each other using the Mann-Whitney test whileassessing the quantitative indices and the Pearson criterion with the Yates correction for continuity while comparing qualitative parameters with the Statistica 10.0 program.

RESULTS AND DISCUSSION

Characteristics of the intraoperative and early postoperative period in patients of both clinical groups are presented in Table 2. Fig. 5, 6, and 7 demonstrate the appearance of postoperative wound at 1, 2 and 6 months after the surgery, respectively.

The Wexner Incontinence scale scores were significantly lower ($p < 0.05$) in the Fi-LaCgroup (Table 3). This fact evidences that the usage of the FiLaC technique allows keeping anal sphincter muscles intact, avoiding incontinence. The parameters of anometry had recovered up to the initial value in the patients of the FiLaC group in the long-term period. At the same time, in the control group these parameters decreased in comparison with the initial values (Fig. 8). In 92.5%, continence was preserved in the FiLaC group. In the control group 6 previously operated patients noticed deterioration of the anal continence.

As witnessed by recent publications minimally invasive methods of anal fistula treatment have been rapidly adopted by proctologists. However, long-term results have showed a high incidence of fistula recurrence, up to 40–50%. Due to the convoluted fistulous tract, the need to remove additional fistulous tracts and cicatrical-inflammatory changes of perineal tissues, minimally invasive methods of treatment are limitedly used in grade III–IV anal fistulas.

Despite of advanced multiple methods of surgical treatment for rectal fistulas as fistulotomy, fistulectomy, cutting seton, advanced flap, minimally invasive methods with the use of fibrin glue, collagen implant ("Fistula plug"), isolating biomaterials, VAAFT and so on, not a single treatment has been found satisfactory. Minimally invasive methods are expensive and do not exclude relapses in the long-term postoperative period [7, 8].

Currently, endorectal advanced mucosal-submucosal flap continues to be a method of choice for the treatment of complex (transsphincteric, extrasphincteric and suprasphincteric) fistulas, supplemented in some cases by setons. Necrosis of the flap, anal incontinence, and fistula recurrence of 30–40% are risks of the flap repair [9, 10, 11].

In our series, the FiLaCoperation duration was greater than the control by 31%($p<0.05$), the patients took non-opioid analgesics less time on average ,the healing of fistulas was faster in the FiLaC group compared with the control group. The frequency of bleeding

Table 2. *Characteristics of intraoperative and early postoperative period in patients of both clinical groups*

Index	Statistic value	FiLaC group (n=40)	Control group (n=43)	p
Operation duration, min	M±m	42.9±2.4	32.7±2.9	<0.05
	[Min-Max]	25-65	20-80	
Duration of analgesics course in the postoperative period, days	M±m	2.3±0.4	7.2±0.5	<0.001
	[Min-Max]	0-10	3-30	
Duration of fistula healing, weeks	M±m	7.3±0.5	12.6±0.7	<0.001
	[Min-Max]	4-15	8-20	
Bleeding in early postoperative period (0-5 days)	Total number	1	2	>0.05
	%	2.5	4.7	
Bleeding in the remoteperiod (6-30 days)	Total number	-	3	-
	%	-	7.0	
Total number of bleedings	Total number	1	5	>0.05
	%	2.5	11.7	
Septic complications	Total number	5	7	>0.05
	%	12.5	16.3	

Fig. 5. *The appearance of postoperative wound in a month after the operative intervention*

Fig. 7. *The appearance of postoperative wound in 6 months after the operation*

Fig. 6. *The appearance of postoperative wound in 2 months after the operation*

and septic conditions did not differ in the two groups at the postoperative stage. The relapse of rectal fistula after the surgery was observed in 37.2% in the control group versus 17.5% in the Fi-LaC group. The pressure parameters of the anal sphincter were significantly higher in the long-term follow-up period in patients of the FiLaC group than in the control group, both in previously operated and non-operated patients, at rest and under straining.

With the use of the FiLaC technique, patients can be treated in an outpatient setting. Due to the absence of damage of the anal mucosa, the technique does not cause pain, rectal bleeding and stricture of the anal canal in the postoperative period. The lack of an individual approach to the choice of the laser energy densities can lead not to ablation of the fistulous tract only, but also to the destruction of its fibrous capsule, which can hinder the formation of a reliable scar in the area of the internal fistula outlet, and cause a relapse of the disease [12].

The use of the described technique does not make performing the operation more complicated. But at

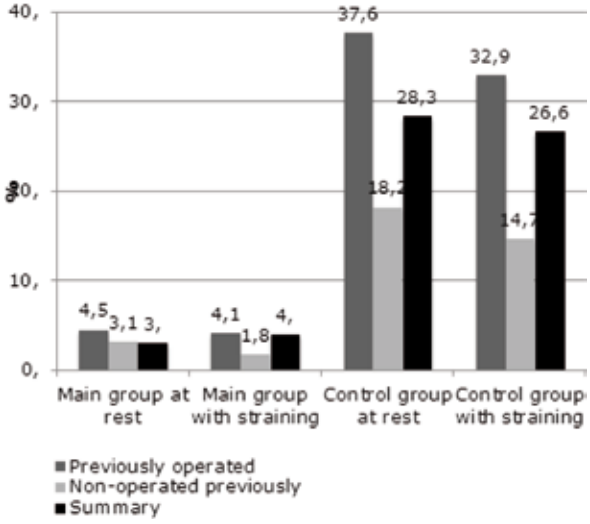

Fig. 8. Changes in the parameters of sphincterometry of the rectum in the remote postoperative period in comparison with the baseline values before surgery in patients of the FiLaC and control groups at rest and with straining effort.
** — significant differences in comparison with the initial values for p <0.05*

method enables to avoid postoperative rectal bleeding, does not affect the function of anal sphincter and accelerates the fistula healing time by 42% compared to the control group with the traditional operating technique. A reduced frequency of relapses in the FiLaC group — 17.5% versus 37.2% in the control group evidences the relevance of the technique.

In some cases, the main technical difficulties arise in case of a narrow fistulous tract when searching for the main tract at the site of perforation of the anal sphincter, as well as its catheterization with a laser light guide. We encountered such a situation in 6 cases, relapses of fistula were observed in 5 patients.

CONCLUSION

This study of short-term and long-term results of treatment of III–IV complexity grade transsphincteric and extrasphincteric fistulas using modified FiLaC technology suggests it may have advantages over standard fistulectomy.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

***Table 3.** Characteristics of the remote postoperative period in patients of both clinical groups*

Index	Statistic value	FiLaC group (n=40)	Control group (n=43)	p
The Wexner scale scores: – operated previously – non-operated previously – summary	M±m	 7.5±0.4 2.2±0.3 5.3±0.6	 10.6±0.5 5.4±0.1 8.9±0.4	 <0,05 >0.05 <0,05
Relapse of rectal fistula (6–36 months after surgery)	Total number	7	16	<0,05
	%	17.5	37.2	
Initial results of sphincterotonometry, mmwg. • at rest – operated previously – non-operated previously – summary • when straining – operated previously – non-operated previously – summary	M±m	 47.1±1.6 63.2±2.5 55.9±1.8 74.3±2.3 107.4±2.7 80.2±2.1	 30,1±1.5 51,6±2.8 42,6±2.0 51.1±1.9 89.3±2.2 65.7±2.6	 <0,05 <0,05 <0,05 <0,05 <0,05 <0,05
Absence of fecal incontinence	Total number	37	35	>0.05
	%	92.5	81.3	
Fecal incontinencestage 1	Total number	2	6	>0.05
	%	5.0	14.0	
Fecal incontinence stage 2	Total number	1	2	>0.05
	%	2.5	4.7	

the same time, it prolongs the operation time and requires the expensive laser equipment and radial laser fibers. The analysis of the short-term and long-term treatment re-sults in the FiLaC group shows that the

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