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REVIEW

Effectiveness of Laser-Based Fistula Therapies with and without Adjunctive Measures in Anal Fistulas Management: A Systematic Review and Single-Arm Meta-Analysis

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Abstract

Purpose Fistula Laser Closure (FiLaC®) is a sphincter-preserving technique for anal fistulas, but its efficacy and safety remain under discussion. Therefore, we aim to evaluate the efficacy and safety of FiLaC® in the management of patients with cryptoglandular fistulas.

Methods A systematic review was performed in MEDLINE, Embase, and Cochrane databases in January 2025, following PRISMA guidelines. We included randomized controlled trials (RCTs) and observational studies assessing FiLaC® for cryptoglandular fistulas, with or without surgical adjunctive measures. The main outcome was the primary healing rate. Secondary outcomes included fistula recurrence, incontinence, reoperation rates, and postoperative complications. Subgroup analyses explored variables related to the primary healing rate. Data are presented as percentages (95% confidence interval). Statistical analyses were performed using R (version 4.4.1 (2024–06-14 (ucrt)).

Results We included 24 studies with 1,503 patients. The pooled primary healing rate was 57.46% (49.40–65.33). Recurrence occurred in 18.48% of patients (10.14–28.47), while new-onset incontinence was rare (0.57%; 0.00–2.15). The reoperation rate was 36.49% (28.95–44.36), and anal abscesses or infections affected 6.54% (1.93–13.09) of patients. Subgroup analysis showed no statistically significant differences in the primary healing rate based on fistula type, adjunctive measures, or sex. Sensitivity analysis confirmed the robustness of our findings.

Conclusions FiLaC® seems to be a safe option with an intermediate healing rate in patients with cryptoglandular fistulas, although it is associated with a considerable recurrence rate. While its sphincter preservation advantage is evident, further RCTs standardizing the technique and adjunctive approaches are needed to optimize outcomes and refine its application in fistula management.

Keywords Cryptoglandular fistulas · Rectal fistula · FiLaC · Healing rate · Meta-analysis

Abbreviations

CI	Confidence interval
EAF	Endorectal advancement flap
FiLaC®	Fistula Laser Closure
IO	Internal Opening
KTP	Potassium titanyl phosphate

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LAFT	Laser Ablation of Fistula Tract
LIFT	Ligation of the Intersphincteric Fistula Tract
MRI	Magnetic resonance imaging
ND:YAG	Neodymium-doped yttrium aluminium garnet
PICOTT	Patients/population/; intervention; comparison; outcome; time; type
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized controlled trials
REML	Restricted maximum likelihood
RoB 2	Cochrane Risk of Bias 2
ROBINS-I	Risk Of Bias In Non-Randomized Studies
Suppl	Supplementary
VAAFT	Video-assisted anal fistula treatment

Introduction

Anal fistulas are a significant challenge in colorectal surgery, often caused by cryptoglandular infections secondary to anorectal abscesses [1, 2]. While simple fistulas can be effectively managed with fistulotomy, complex anal fistulas present a dilemma due to their higher recurrence rates and the risk of fecal incontinence [3–6]. Sphincter-preserving techniques, including ligation of the intersphincteric fistula tract (LIFT), advancement flaps, and biomaterial-based therapies, have sought to optimize healing while minimizing functional impairment [7–9]. These approaches have yielded promising results; however, limitations persist, particularly regarding recurrence and long-term continence preservation.

Laser-based therapies, particularly Fistula Laser Closure (FiLaC®), have emerged as an alternative sphincter-sparing technique, offering a minimally invasive approach to obliterating the fistula tract while preserving surrounding structures [10, 11]. FiLaC® utilizes a radially emitting diode laser probe to induce photothermal destruction of the fistula epithelium, promoting controlled fibrosis and closure [12]. Some studies have demonstrated healing rates and incontinence risks comparable to well-established techniques, placing FiLaC® as a promising option for complex anal fistulas [13, 14]. Nonetheless, reported efficacy across studies is highly heterogeneous, which can be explained by differences in laser power settings, withdrawal speeds, and the role of adjunctive measures such as internal opening (IO) closure or seton placement [15].

Two prior meta-analyses have evaluated FiLaC®, reporting primary healing rates of approximately 63–67% and minimal fecal incontinence rates [15, 16]. However, these encouraging findings are limited by the small sample size, absence of subgroup analysis, heterogeneity in techniques, and inclusion of papers until 2020. Additionally, they lack further analysis of the impact of adjunctive interventions (e.g., IO closure and seton placement), the long-term recurrence rates, and the influence of fistula complexity on outcomes. Therefore, we aimed to perform an uptaded systematic review and single-arm meta-analysis of FiLaC® for anal fistula treatment to evaluate the influence of adjunctive measures, identify predictive factors for success, and assess evidence for technique applicability and procedural refinement.

Methods

This systematic review and meta-analysis was conducted following the Cochrane Handbook for Systematic Reviews of Interventions and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. [17, 18] The protocol for this study was prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO) database under protocol number CRD42025642605.

Eligibility criteria

Eligibility criteria were defined using the PICOTT framework. We included cohort and RCTs studies that assessed FiLaC® or laser ablation of fistula tract (LAFT) as standalone treatments or combined with adjunctive measures, such as prior seton placement or IO closure via sutures or flaps, in patients with cryptoglandular anal fistulas, regardless of the age at the procedure time. Papers that enrolled up to 25% of patients with Crohn's disease in complete remission were also included. Exclusion criteria were studies that enrolled patients with ano-vaginal or malignant fistulas, radiation proctitis, and infectious diseases, as well as modification in the standard Diode laser at a wavelength of 1470 nm characteristics (e.g., photodynamic therapy, carbon dioxide laser, ND:YAG laser and KTP laser), and combinations with video-assisted anal fistula treatment (VAAFT) procedures. Case reports, narrative and systematic reviews, meta-analyses, abstracts, conference proceedings, protocols, and studies with population overlap were also excluded. Only papers published in English were considered.

Search strategy

A comprehensive literature search was conducted in MEDLINE, Embase, and the Cochrane CENTRAL Register of Controlled Trials from inception to January 18, 2025. The search strategy utilized keywords and medical subject headings (MeSH) such as “Rectal Fistula”, “anal fistula”, “perianal fistula”, “Fistula-in-ano”, “FiLaC”, “fistula laser closure”, “laser ablation”, and “Laser Therapy”. The full search strategy for each database can be found in the

Supplementary Material. Two independent reviewers (J.D. and B.N.) screened titles and abstracts, followed by full-text reviews, to identify studies meeting the inclusion criteria. Discrepancies were resolved by consensus.

Data Extraction

Two authors (J.D and L.F.) independently extracted data using a standardized form, capturing key study characteristics (design, sample size), type of fistula, patient demographics (sex, age, previous fistula surgery, body mass index), intervention details (previous seton placement, weeks of seton placement pre-FiLaC®/LAFT, fistula wavelength, and watts), time of follow-up, and data for the primary and secondary outcomes.

Outcomes

The main outcome was fistula healing rate (defined as complete fistula closure). Secondary outcomes included recurrence rate (reappearance of the fistula after initial healing), postoperative complications (e.g., infections, abscesses), time from FiLaC®/LAFT to fistula healing, duration of surgery, rates of fecal incontinence, reoperation by any other method, and reoperation using laser-based therapy. No restrictions were placed on the duration of follow-up.

Subgroup Analyses

Subgroup analyses were performed comparing outcomes according to the surgical technique: (1) FiLaC®/LAFT alone, (2) FiLaC®/LAFT + Seton Placement, (3) FiLaC®/LAFT + IO Suturing Closure, and (4) FiLaC®/LAFT + IO Flap Closure. Additionally, we performed subgroup analyses according to sex, location, IO closing by suture or flap, and Parks classification.

Statistical Analysis

We conducted a meta-analysis of proportions using the inverse variance method with the restricted maximum likelihood (REML) estimator. Heterogeneity was assessed using the Cochrane Q chi-square test and an I^2 statistic; $I^2 > 50\%$ and p values < 0.10 were considered significant for substantial heterogeneity. Proportions were transformed using the Freeman-Tukey double arcsine method, and confidence intervals for individual study estimates were calculated using the Clopper-Pearson method. All analyses were performed using the R software (version 4.4.1 (2024–06-14 (ucrt)) using the "meta" package and presented in forest plots [19]. Sensitivity analyses using the leave-one-out method were conducted to assess the robustness of our findings and determine if any single study was driving the overall result.

Risk of Bias Assessment

Two reviewers (J.D. and M.C.) independently performed a risk of bias assessment, using the Risk Of Bias In Non-Randomized Studies—of Interventions (ROBINS-I) tool for non-randomized studies and the Cochrane Risk of Bias 2 (RoB 2) tool for RCTs [20, 21]. Discrepancies were solved through consensus.

Publication bias was evaluated using contour-enhanced funnel plots for the outcomes of primary healing rate, recurrence, and analysis for new cases of incontinence, further confirmed by Egger's test [22].

Results

Study Selection and Baseline Characteristics

A total of 321 records were identified in January 2025. After removing 64 duplicates, 257 studies were screened based on their titles and abstracts, with 115 full-text articles assessed for eligibility (Fig. 1). We enrolled 1,503 patients from 24 studies, two of which were RCTs [11–14, 23–42]. The main reasons for exclusion were studies with population overlap and articles in languages other than English. Among the included patients, 6% (n = 23/382) had diabetes, 51.11% (n = 733/1434) underwent IO closure, and the energy used during FiLaC®/LAFT procedures ranged from 30 to 120 J. Magnetic resonance or transanal ultrasound before FiLaC®/LAFT was reported in 22 studies. The baseline characteristics of the included studies are summarized in Table 1. A summary of the outcomes is available in Table 2.

Abbreviations: IO: Internal Opening; [a] % of patients who had IO closed when not done routinely; [b] mean or median; NA: not available; RCT: randomized controlled trial; FiLaC™: Fistula Laser Closure; LAFT: Laser Ablation of Fistula Tract.

Abbreviations: CI: Confidence Interval; FiLaC®: Fistula Tract Laser Closure); LAFT: Laser Ablation of Fistula Tract; IO: Internal Opening.

Primary Healing Rate

The pooled primary healing rate after FiLaC®/LAFT was 57.38% (95%CI 49.33–65.24; $I^2 = 87.0\%$; Fig. 2).

Duration of Surgery and Days-to-Primary Healing

The mean duration of surgery was 25.70 min (95% CI 18.61–35.50; $I^2 = 97.3\%$; Supplementary Fig. 1), while

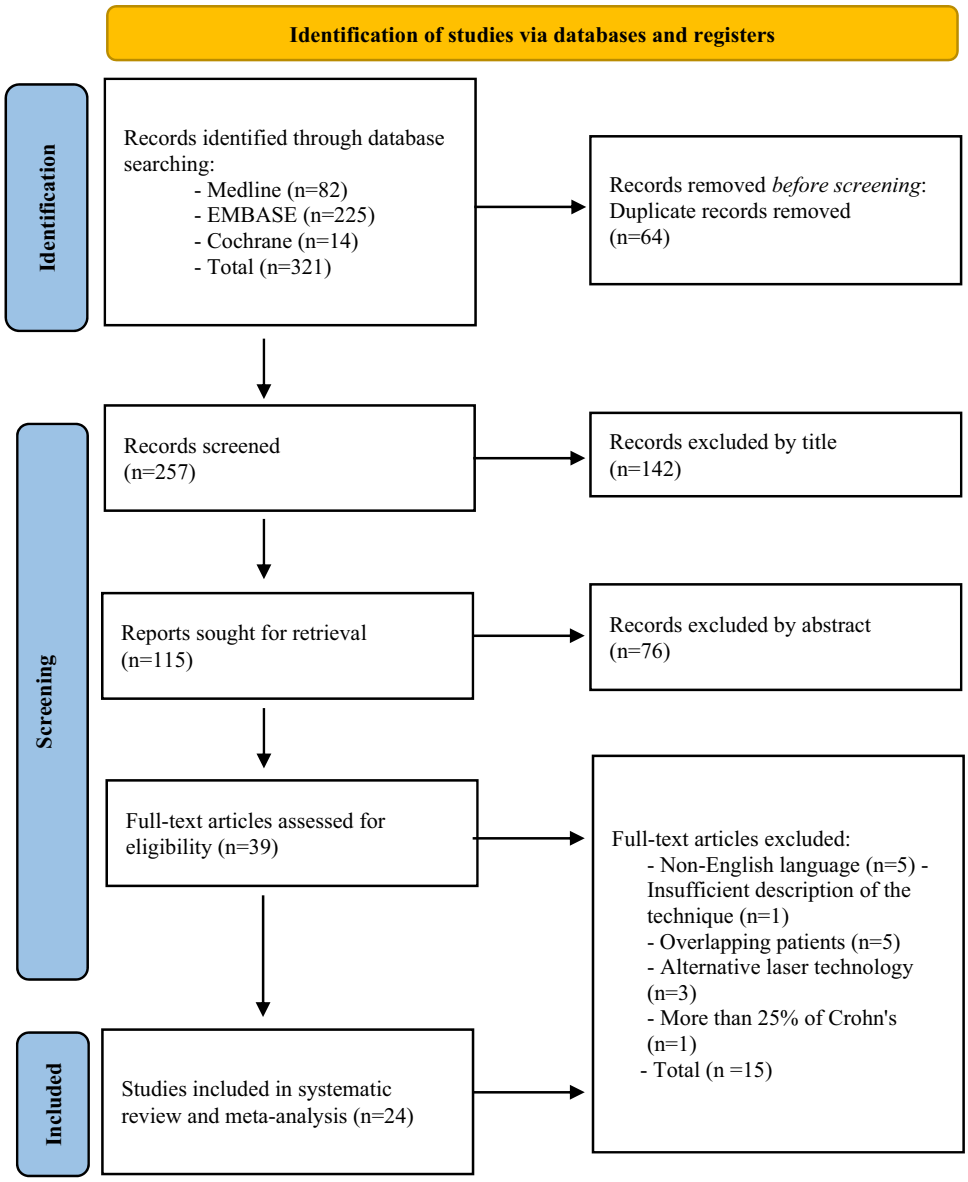

Fig. 1 PRISMA flowchart of study screening and selection

the average time for clinical healing was 53.39 days (95% CI 12.30–94.48; $I^2 = 99.2\%$; Supplementary Fig. 2).

New Cases of Anal Incontinence, Primary Failure, and Recurrence Rates

The new-onset incontinence had a pooled incidence of 0.57% (95%CI 0.00–2.14; $I^2 = 67.3\%$; Fig. 3). Additionally, the pooled incidence of primary failure of FiLaC®/LAFT was 44.43% (95%CI 36.10–52.92; $I^2 = 84.8\%$; Supplementary Fig. 3), and the pooled recurrence rate was 18.78% (95%CI 10.91–28.06, $I^2 = 89.9\%$; Fig. 4), with the latter defined as the reappearance of a fistula after initial wound healing.

Healing Rate After Previous Surgery, Seton Placement, and IO Closure

Patients who previously underwent fistula surgery demonstrated a healing rate of 49.04% (95%CI 37.97–60.16; $I^2 = 72.8\%$; Supplementary Fig. 4), while healing following seton placement was reported at 60.38% (95%CI 44.10–75.62; $I^2 = 90.3\%$; Supplementary Fig. 5). Among patients with fistulas whose IOs were closed using sutures and/or flaps, the overall healing rate was 62.03% (95%CI 50.37–73.06; $I^2 = 87.2\%$; Supplementary Fig. 6).

Table 1 Baseline characteristics of included studies

Study	Design	Patients	Intervention (%[a])	Female (n, %)	Age (y)[b]	Crypto-glandular (n, %)	Wavelength (nm)/ watts(W)	Previous fistula surgery (n, %)	Previous Seton Placement (n, %)	Time from Seton placement to FiLaC (weeks)	Probe withdrawn velocity (mm/s)	Follow-up (months)
Wolicki 2021	Retrospective	83	FiLaC + IO suturing (78)	19 (22.9)	50	81 (97,6)	1470/12	28 (33.7)	65 (78.3)	6.9	NA	42
Nordholm-Carstensen 2021	Retrospective	66	FiLaC + IO suturing	38 (58)	40	57 (83.8)	1470/13	22 (32)	68 (100)	78	1.6	19
Giamundo 2021	Retrospective	175	FiLaC + IO suturing (12.6)/Flap (2.9)	60 (34.3)	49	175 (100)	1470/12	150 (85.7)	142 (81.1)	14	1	60
Serin 2020	Retrospective	35	FiLaC + IO suturing	11 (32)	43	35 (100)	1470/12	22 (73)	10 (28.5)	NA	NA	13
Brabender 2020	Retrospective	18	FiLaC + IO suturing	8 (44)	41	14 (78)	1470/10–14	15 (83)	16 (89)	NA	NA	29
Sluckin 2022	Retrospective	99	FiLaC + IO suturing	36 (37)	46	99 (100)	1470/13	44 (43)	79 (80)	7	NA	7
Low 2024	RCT	28	FiLaC + IO suturing	5 (18)	37	28 (100)	1470/10	8 (28)	12 (43)	NA	1	6
Wilhelm 2017	Retrospective	117	FiLaC + IO suturing (10.2)/Flap (89.8)	35 (30)	46	110 (94)	1470/13	16(13)	99 (84)	16	NA	25
Lauretta 2018	Retrospective	30	FiLaC	14 (46)	52	30 (100)	1470/12	22(73)	26 (86)	22	1	11
Marref 2019	Prospective	68	FiLaC	35 (51)	40	62 (91)	1470/10–15	24(35)	68 (100)	15	NA	12
Akgül 2021	Retrospective	67	LAFT	19 (28)	42	67 (100)	1470/NA	9(13)	0	NA	NA	24
Terzi 2018	Retrospective	103	FiLaC	21 (20)	43	103 (100)	1470/12	53(52)	0	NA	NA	28
Bonnechose 2020	Prospective	100	LAFT	35 (35)	43	89 (89)	1470/13	NA	100 (100)	16	NA	13
Tang 2022	Retrospective	63	LAFT	19 (30)	NA	63 (100)	1470/10–12	NA	0	NA	NA	10
Stijns 2019	Prospective	20	LAFT	16 (80)	45	20 (100)	1470/10	NA	15 (75)	2	NA	10
Amr 2022	Prospective	28	FiLaC	4 (14)	40	28 (100)	1470/12	NA	0	NA	1	6
Taskin 2024	Cross-sectional	30	FiLaC	6 (20)	39	30 (100)	1470/10–12	NA	0	NA	NA	19

Table 1 (continued)

Study	Design	Patients	Intervention (%[a])	Female (n, %)	Age (y)[b]	Crypto-glandular (n, %)	Wavelength (nm)/ watts(W)	Previous fistula surgery (n, %)	Previous Seton Placement (n, %)	Time from Seton placement to FiLaC (weeks)	Probe withdrawn velocity (mm/s)	Follow-up (months)
Isik 2020	Retrospective	100	LAFT	28 (28)	42	100 (100)	1470/15	NA	NA	NA	1.6	48
Olajide 2023	Retrospective	11	FiLaC	0	39	11 (100)	1470/10	3(27)	11 (100)	6	NA	12
Yashaswini 2024	RCT	34	LAFT + IO suturing (14)/Flap (73)	3 (8.8)	40	34 (100)	1470/12	20(58)	NA	NA	NA	6
Kelley 2024	Prospective	46	FiLaC + IO suturing	18 (39)	48	46 (100)	1470/10	24(52)	46 (100)	8	NA	12
Tümer 2023	Retrospective	104	LAFT + IO suturing	12 (11)	35	104 (100)	1470/10	0	NA	NA	NA	9
Lalhruaizela 2021	Prospective	31	LAFT + IO Flap	12 (38)	38	31 (100)	1470/NA	13 (42)	NA	NA	3.3	24
Uzun group **1** 2024	Retrospective	25	FiLaC + IO suturing	4 (16)	39	25 (100)	1470/15	0	25 (100)	13	NA	10
Uzun group **2** 2024	Retrospective	22	FilLaC + IO Flap	2 (9)	41	22 (100)	1470/15	0	22 (100)	13	NA	8

Abbreviations: IO: Internal Opening;[a]% of patients who had IO closed when not done routinely;[b]mean or median; NA: not available; RCT: randomized controlled trial; FiLaC™: Fistula Laser Closure; LAFT: Laser Ablation of Fistula Tract.

Table 2 Summary of the outcomes of the included studies

Outcomes	Number of Studies	Participants	Pooled Estimate (%, 95% CI)	I^2 (%)	p-value
Primary Healing Rate	24	1497	57.46 (49.40–65.33)	87	—
IO Closure Primary Healing Rate	12	703	62.03 (50.37–73.06)	87.2	—
Seton Placement Healing Rate	8	472	60.38 (44.10–75.62)	90.3	—
Healing Rate after Previous Surgery	9	333	49.04 (37.97–60.16)	72.8	—
Re-FiLaC®/LAFT healing	12	98	49.11 (31.79–66.50)	47.2	—
Healing by Sex					
Female Sex	12	327	54.32 (43.25–64.99)	63.5	0.8750
Male Sex	12	617	53.46 (42.85–63.76)	76.6	
Healing by Location					
Anterior Location	6	188	50.52 (42.68–58.35)	0.0	0.8911
Posterior Location	6	186	49.07 (25.26–73.30)	81.8	
Fistula Classification					
Intersphincteric	8	174	53.61 (30.48–76.07)	80.4	0.3611
Trans-sphincteric	12	666	52.63 (44.77–60.43)	72.4	
Suprasphincteric	8	59	35.01 (17.83–53.83	32.9	
Extrasphincteric	2	9	30.33 (0.00–98.49)	75.5	
Healing by Etiology					
Crohn's	5	40	60.76 (43.16–77.31)	0.0	0.8520
Cryptoglandular	20	1300	57.74 (49.37–65.90)	86.1	
Seton Placement					
Non-Seton Placement	3	205	47.47 (34.80–60.30)	69.9	0.4505
Seton Placement	6	332	56.16 (37.73–73.80)	86.6	
Adjunctive Measures					
FiLaC®/LAFT Alone	5	328	60.87 (45.43–75.31)	84.8	0.1882
Seton Placement + IO Closure	3	161	61.35 (29.22–89.00)	93	
Seton Placement Only	3	171	46.09 (38.44–53.83)	0.0	
IO Closure					
IO Closure with Suture and/or Flap	10	630	61.14 (46.68–74.72)	90.7	0.2949
Non-IO Closure	10	549	51.32 (39.85–62.73)	80.1	
IO Flap vs. Suture					
IO Closure with Flap	3	158	76.97 (55.06–93.39)	81	0.0955
IO Closure with Suture	9	472	54.65 (39.36–69.54)	91.4	
Recurrence	14	849	18.48 (10.14–28.47)	90.6	—
Incontinence	18	1152	0.57 (0.00–2.15)	67.2	—
FiLaC®/LAFT Primary Failure	21	1268	44.65 (35.86–53.61)	85.4	—
Reoperations	16	1111	36.49 (28.95–44.36)	80.6	—
Re-FiLaC®/LAFT	15	1119	10.04 (5.37–15.81)	84.4	—
Abscess/Infection	13	812	6.54 (1.93–13.09)	87.2	—
Time to Primary Healing (days)	2	127	39.37 (−5.51–84.26)	99.6	—
Major Complications	9	534	0.00 (0.00–0.23)	0.0	—
Surgery Duration (min.)	10	573	24.85 (18.57–33.34)	97.3	—

Abbreviations: CI: Confidence Interval; FiLaC®: Fistula Tract Laser Closure); LAFT: Laser Ablation of Fistula Tract; IO: Internal Opening

Reoperation Rate and Re-Filac/LAFT Healing Rate

Reoperation by any technique was required in 36.49% of cases (95%CI 28.95–44.36; $I^2 = 80.6\%$; Suppl Fig. 7), and the proportion of patients who underwent a repeat laser procedure (Re-FiLaC®/LAFT) was 9.96% (95%CI 5.32–15.71; $I^2 = 84.4\%$; Suppl Fig. 8). Among patients with a Re-FiLaC®/LAFT procedure, the healing rate was 49.11% (95%CI 31.79–66.50; $I^2 = 47.2\%$; Supplementary Fig. 9).

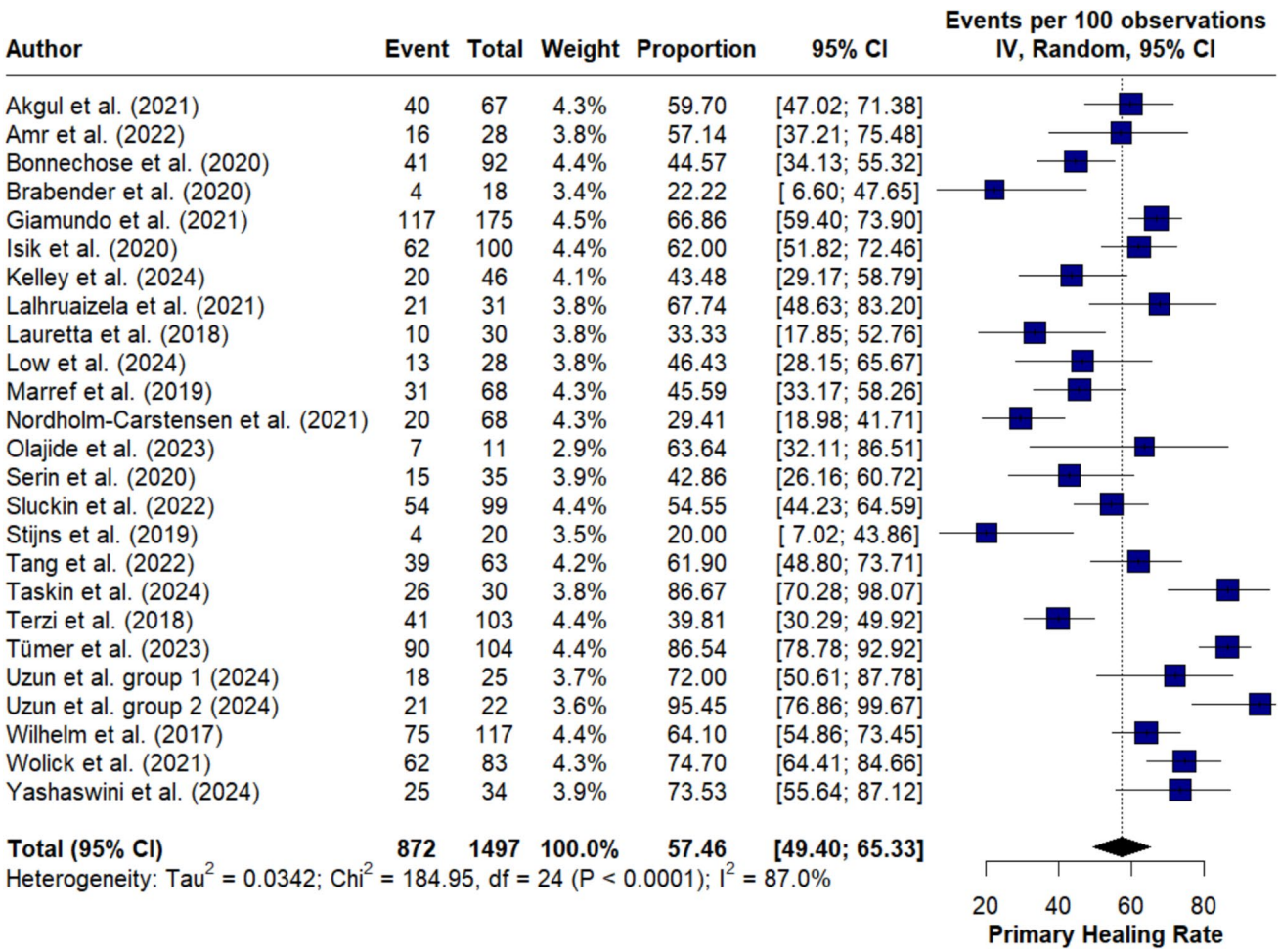

Fig. 2 FiLaC®/LAFT was associated with a 57.46% primary healing rate in patients with anal fistulas

Postoperative Complications

The incidence of perianal abscesses or infections following surgery was 6.54% (95%CI 1.93–13.09; $I^2 = 87.2\%$; Supplementary Fig. 10). Major complications, such as severe bleeding, were nearly absent (0.00%; 95%CI 0.00–0.23; $I^2 = 0.0\%$; Supplementary Fig. 11). One study reported a patient with migration of the fistula from the base of the labia to the introitus of the vagina, and a transperineal primary repair with gracilis flap and protective loop ileostomy was performed. Another patient from the same study experienced a recurrence and worsening of the disease process, leading to subsequent involvement of the coccyx. Fistulectomy with primary closure, coccygectomy, bilateral flaps, and protective ileostomy were also undertaken [11].

Subgroup analyses

Surgical adjunctive measures

Additional analyses showed no statistically significant difference in the primary healing rate when comparing (1) the presence or absence of seton placement before FiLaC®/LAFT ($p = 0.4505$, Supplementary Fig. 12), (2) seton placement combined with IO closure versus seton placement alone versus FiLaC®/LAFT alone ($p = 0.1882$, Supplementary Fig. 13), and also (3) IO Closure (Suture and/or Flap) vs. Non-IO Closure ($p = 0.2949$, Fig. 5). When comparing studies with patients who had the IO Closed with Flap versus IO Closed with Suture, no significant difference was found between groups (76.97% vs. 54.65%, $p = 0.0955$, Supplementary Fig. 14).

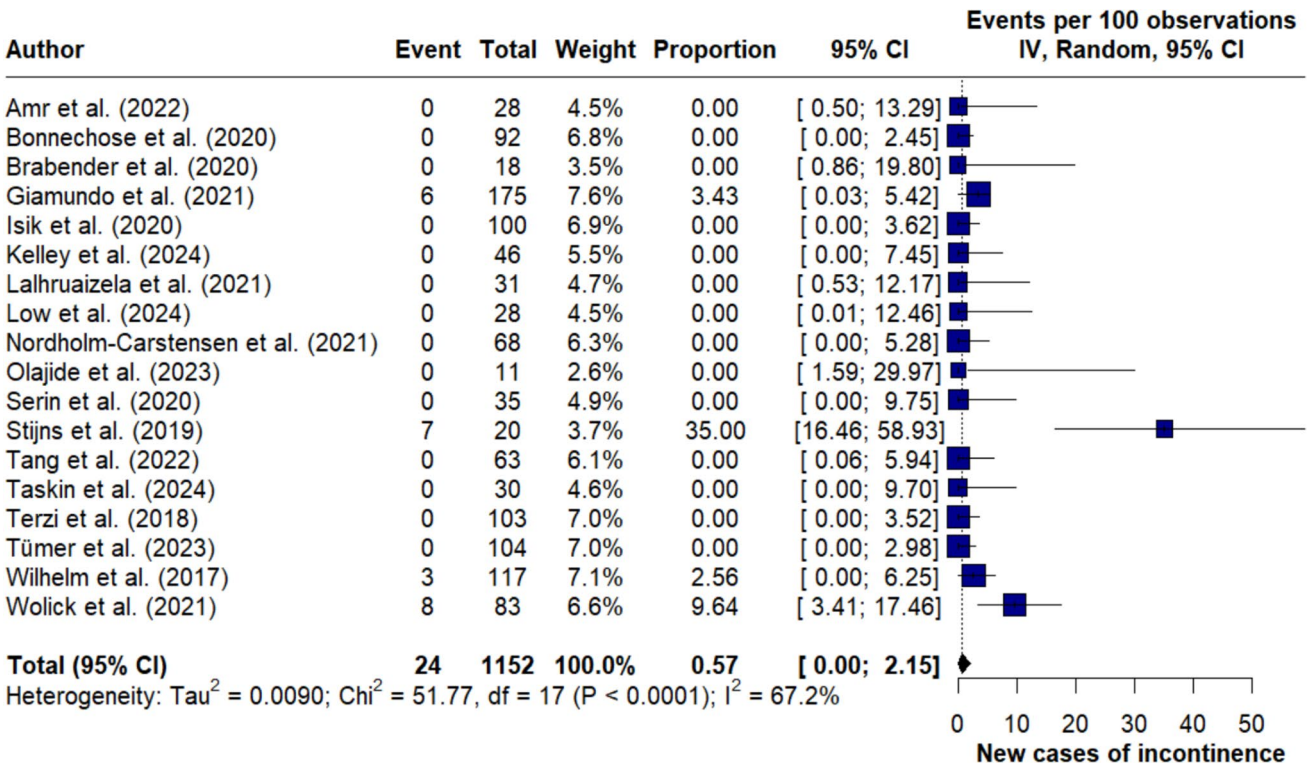

Fig. 3 FiLaC.®/LAFT was associated with a low rate of new cases of incontinence (0.57%)

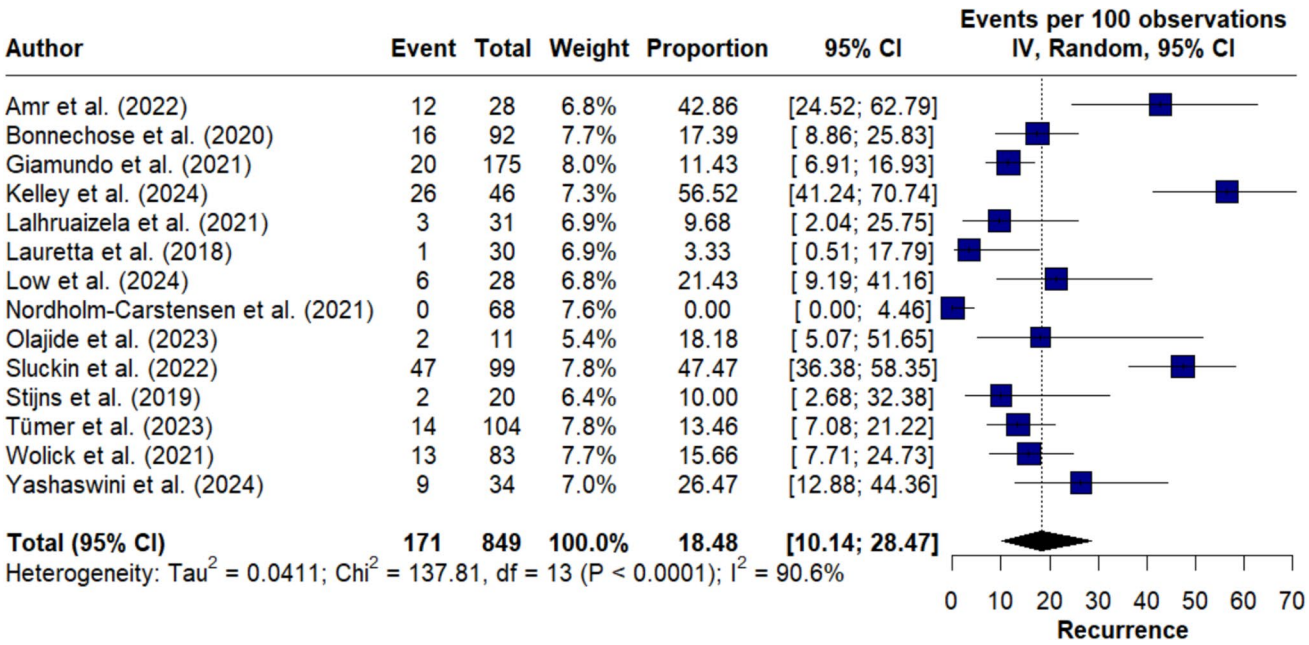

Fig. 4 Approximately one-fifth of patients had a recurrence of anal fistula after FiLaC®/LAFT

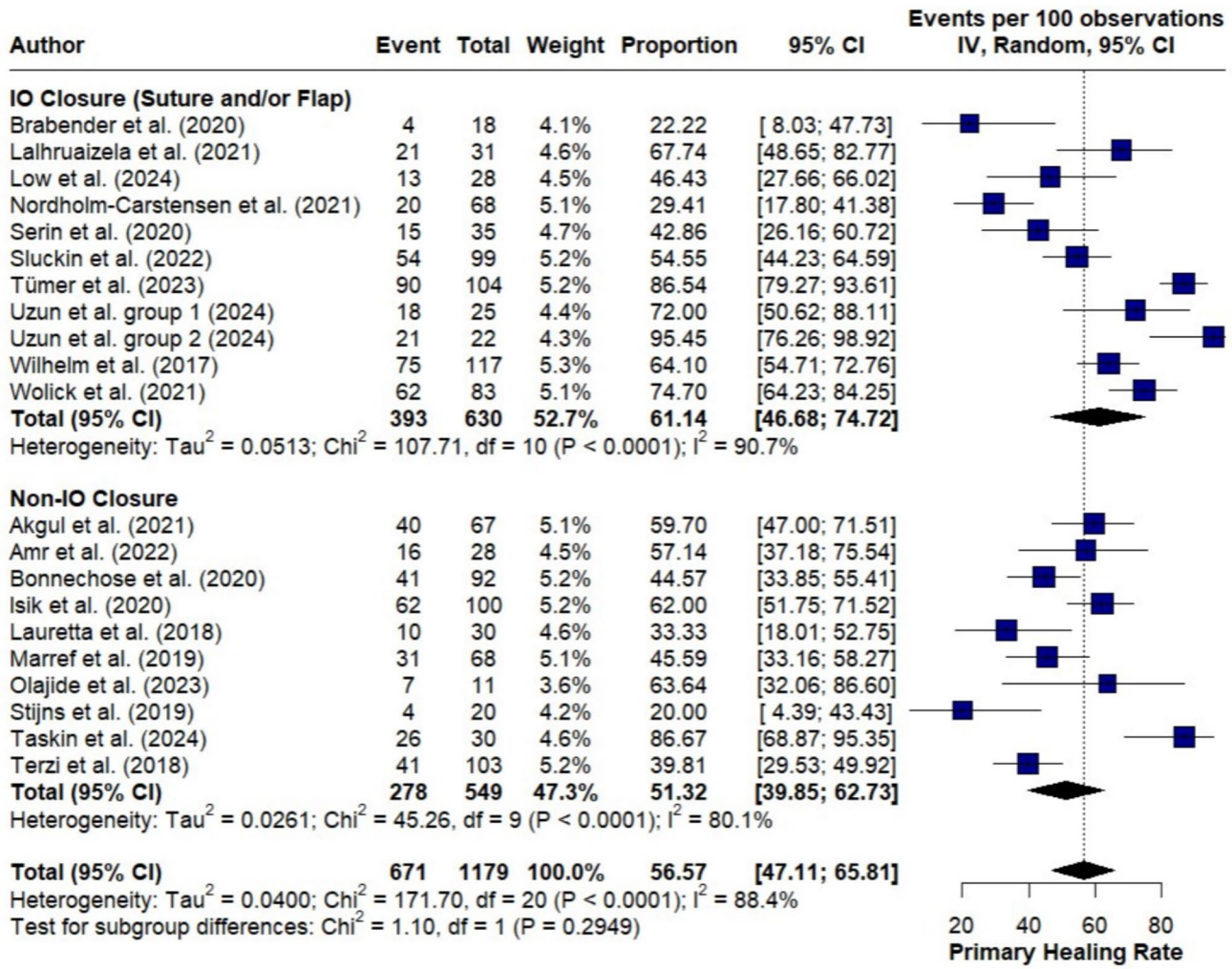

Fig. 5 Subgroups of primary healing rates based on internal opening (IO) management. There was no statistically significant difference between studies that closed the IO and those that left it open. The IO closure subgroup included both suture and flap techniques

Etiology

When stratified by etiology, the primary healing rate in cryptoglandular fistulas was 57.74% (95%CI 49.37–65.90; $I^2 = 86.1\%$; Supplementary Fig. 15), whereas Crohn's-related fistulas exhibited a healing rate of 60.76% (95%CI 43.16–77.31; $I^2 = 0.0\%$; $p = 0.8520$; Supplementary Fig. 15).

Fistula Location

An analysis based on fistula location showed that 50.52% (95%CI 42.68–58.35; $I^2 = 0\%$; Supplementary Fig. 16) of primary healing occurred in anterior fistulas, while 49.07% (95%CI 25.26–73.30; $I^2 = 81.8\%$; Supplementary Fig. 16) was observed for fistulas located posteriorly ($p = 0.8911$; Supplementary Fig. 16).

Type of Fistula (Parks Classification)

The pooled primary healing rate did not differ significantly across different types of fistulas according to the Parks classification ($p = 0.3611$; Supplementary Fig. 17): (1) intersphincteric (53.61%; 95%CI 30.48–76.07; $I^2 = 80.4\%$), (2) trans-sphincteric (52.63%; 95%CI 44.77–60.43; $I^2 = 72.4\%$), (3) suprasphincteric (35.01%; 95%CI 17.83–53.83; $I^2 = 32.9\%$), and (4) extrasphincteric (30.33%; 95%CI 0.00–98.49; $I^2 = 75.5\%$).

Sex

A sex-based analysis revealed a primary healing rate of 54.32% (95%CI 43.25–64.99, $I^2 = 62.4\%$) in females and 53.46% (95%CI 42.85–63.76, $I^2 = 74.7\%$) in males ($p = 0.8750$; Supplementary Fig. 18).

Laser power

Subgroup analysis of laser power (in watts) was conducted on data from 19 studies, stratified by levels of 10 W, 12 W, 13 W, and 15 W (Supplementary Fig. 19). Pooled primary healing rates were 53.32% (95% CI 29.05–76.84%; $I^2 = 92.9\%$) for 10 W, 56.23% (95% CI 43.29–68.77%; $I^2 = 86.2\%$) for 12 W, 48.4% (95% CI 34–63%; $I^2 = 87.1\%$) for 13 W, and 77.2% (95% CI 53–94%; $I^2 = 83.9\%$) for 15W. The test for subgroup differences was not significant ($p = 0.23$).

Quality Assessment

The RoB 2 tool for RCTs revealed some concerns in the Low et al. (2024) study and indicated a high risk of bias in the Yashaswini et al. (2024) study (Supplementary Fig. 20). [30, 42] The high risk in the latter was primarily due to issues in outcome measurement, likely resulting from inconsistent definitions. Among the observational studies assessed using ROBINS-I, most exhibited a serious risk of bias due to confounding (Supplementary Fig. 21) [20, 21]. The funnel plot for the outcomes of primary healing, recurrence rates, and new cases of incontinence showed no significant publication bias (Supplementary Figs. 22 to 24), which was further confirmed by Egger's test ($p = 0.4827$, $p = 0.6941$, and $p = 0.7320$, respectively).

Sensitivity Analyses

The leave-one-out analyses showed that, although heterogeneous, our results are robust since no single study had a dominant effect on the pooled prevalence of primary healing rate, recurrence, new cases of incontinence, Re-FiLaC®/LAFT healing rate, FiLaC®/LAFT primary failure, healing rate after previous fistula surgery, proportion of reoperations, proportion of Re-FiLaC/LAFT, post-FiLaC®/LAFT perianal abscess or infection, time to primary healing, major complications, surgery duration and FiLaC®/LAFT primary failure (Supplementary Figs. 25–36).

Discussion

In this systematic review and meta-analysis of 22 cohort and 2 RCTs, including 1,503 patients, we evaluated the efficacy and safety of laser-based therapies for anal fistulas. Almost 60% of patients presented with satisfactory healing after the procedure, while new-onset incontinence was rare. However, recurrence, primary failure, and reoperation rates were substantial, highlighting the importance of optimizing patient selection and refining the technique.

Since 1981, laser therapy has been utilized to treat benign proctological conditions [43]. In 2011, Wilhelm introduced FiLaC®/LAFT, an innovative technique designed to preserve the sphincter. This method employs a radial-emitting laser to deliver energy circumferentially, effectively denaturing proteins in the fistula tract. This process leads to shrinkage and closure while minimizing damage to the surrounding sphincter complex [10]. Notably, established techniques such as fistulotomy and LIFT demonstrate high healing rates, sometimes exceeding 80%. For instance, fistulotomy, the gold standard for simple fistulas, showed an 83.6–87% primary success in two significant studies, while LIFT presented with 76.5–79%, and the endorectal advancement flap (EAF) achieved 66%–87% [6–8, 44–47]. The same techniques showed recurrence rates of 6.8%, 12.4–21.9%, and 23%, respectively, compared to the 19% for FiLaC demonstrated in this meta-analysis [8, 48–50]. Yashaswini et al. conducted an RCT that showed a higher fistula recurrence with FiLaC®/LAFT compared to fistulectomy at three months (9% vs 0%), although they were comparable at six months (26% vs 26%) [42]. In contrast, fistulotomy, LIFT, and EAF resulted in incontinence rates of 12%, 1.6%, and 9–20%, respectively, all significantly higher than the 0.57% observed in patients who underwent FiLaC®/LAFT [49, 51, 52]. This suggests that FiLaC®/LAFT may be more appropriate for patients prioritizing continence preservation and acknowledging the possibility of reoperation.

Subgroup analysis did not reveal any statistically significant differences in the impact on primary healing rates based on sex, adjunctive measures, fistula location, laser power, or type (Parks' classification). However, trends suggested potentially higher healing rates with IO closure using flaps compared to sutures, although no statistical significance was found [40]. De Bonnechose et al. (2020) and Giamundo et al. (2021) suggested closing the IO that exceeds the size of the laser probe [26, 27]. Meanwhile, Kelley et al. (2024) found that internal sutures cause pain without benefits, as they either tear through tissue or break during defecation. Following their trial, they discontinued using sutures to close the IO [11].

It appears that higher power may improve healing rates by enhancing thermal ablation and tract shrinkage, but overlapping confidence intervals and variability suggest it isn't the sole factor. Laser therapy benefits, like better fistula closure, must be balanced against risks such as thermal damage at higher power or incomplete obliteration at lower power, which could cause recurrence. On the other hand, only six studies provided data on energy in Joules per centimeter (Wolicki et al., Giamundo et al., Akgül et al., Yashaswini et al., Taskin et al., and Isik et al.). [12, 13, 23, 27, 41, 42] Of these, five studies used energy levels between 100 and 120 J/cm, [12, 13, 27, 41, 42] while only one [23] employed energy levels between 30 and 50 J/cm. A formal statistical analysis was not possible due to the lack of granularity. Nonetheless, the primary healing rates for studies using

100–120 J/cm ranged from 62.0% to 86.67%, compared to 59.7% in the Akgül et al. study, which used 30–50 J/cm.

Previous studies indicated that longer fistulas tend to have lower success rates [29]. In our findings, suprasphincteric and extrasphincteric fistulas had a healing rate of 40.51% and 33.3%, respectively, both lower than intersphincteric (53.61%) and transsphincteric (52.63%) fistulas. However, due to inconsistencies in How fistula length was measured across a few studies, no data were suitable for statistical analysis. Additionally, some authors would suggest that tracts exceeding 4–8 mm in diameter have reduced healing rates [27, 41]. Nevertheless, there is a significant lack of direct data from other studies that link healing rates to fistula length or diameter. Notably, patients with prior fistula surgery experienced a lower healing rate (49.04%) compared to the overall healing rate (57.38%). This, alongside the previous discussion, suggests that anatomical complexity may influence healing outcomes.

High heterogeneity was observed across most analyses, reflecting variations in patient selection criteria, fistula complexity, prior interventions, and procedural modifications. Follow-up durations ranged from 6 to 60 months, and some studies included patients with Crohn's disease, previous fistula surgeries, or variable imaging protocols, contributing to inconsistencies. These inconsistencies reflect what has been observed in other fistula treatment studies [53]. No small-study effects were detected in the funnel plot analysis or Egger's test, further supporting the reliability of the results.

Future research should prioritize multicenter RCTs with standardized protocols for FiLaC®/LAFT, including consistent wavelengths (e.g., 1470 nm), fixed energy settings (e.g., 100–120 J/cm), withdrawal speed (e.g., 1–3 mm/s), and adjunctive measures (e.g., seton placement or IO closure). Additionally, integrating preoperative transanal ultrasound/magnetic resonance imaging for consistent anatomical assessments is crucial, as the imaging methods used across studies varied significantly. Long-term follow-up, exploration of adjunctive techniques outcomes, and direct comparisons with sphincter-sparing alternatives will be essential to clarify FiLaC®/LAFT's role in managing cryptoglandular fistulas and to diminish the uncertainties reflected in our heterogeneous outcomes.

This study has limitations. First, the heavy reliance on predominantly observational studies raises concerns about potential confounding and selection bias. This is reflected in the significant risk of bias in most ROBINS-I assessments, even though sensitivity analyses indicate stability. Second, high heterogeneity among studies highlights variability in patient populations (e.g., inclusion of patients with prior failed fistula surgeries and patients with Crohn's disease in remission), fistula characteristics, procedural techniques (the laser energy applied varied widely from 30 to 120 J/cm; probe withdrawal velocity was inconsistently reported (Table 1); lack of a universal protocol for using adjunctive measures; operator expertise and institutional preferences, which can influence the efficsacy in different directions), and follow-up durations (ranging from 6 to 60 months). This variability limits the precision of pooled estimates, as shown by the wide confidence intervals. Subgroup analyses for some of these variables, nevertheless, did not show a statistically significant impact on the overall healing rate (Supplementary Figs. 9, 12, 13, 14, 15, 16 and 19). Third, in the Nordholm et al. study, two patients exhibited two cryptoglandular fistulas. The data was, therefore, presented using fistulas as the unit of analysis, contrasting with the approach taken in the other studies included (one patient, one fistula). Although this could raise concerns about unit-of-analysis issues, the leave-one-out analysis indicated that this choice did not affect the overall results (Suppl Fig. 24,25,26,27,28,29,30,31,34,35). Fourth, Tang et al. grouped outcomes for LAFT-naïve and reoperated patients (seven patients who underwent Re-LAFT). When possible, we differentiated between these groups and included their data separately in our analyses. In instances where this distinction was not feasible, their data were excluded from consideration. Fifth, the single-arm design restricts our ability to directly compare with established techniques, such as fistulotomy or LIFT, thereby limiting our understanding of FiLaC.®/LAFT's relative efficacy compared to existing literature benchmarks. [6]

Conclusion

Based on this systematic review and single-arm meta-analysis, FiLaC®/LAFT seemed to be a safe and repeatable option for anorectal cryptoglandular fistulas, showing a primary healing rate of approximately 60%. Due to the high rates of recurrence and failure, FiLaC®/LAFT may primarily be used where preserving the sphincter is crucial, since the new-onset incontinence rate was Lower than 1%.

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Author's contributions J.R.D: Conceptualization, Methodology, Formal analysis and investigation, Writing - original draft preparation, Writing - review and editing, Supervision. B.C.R.N., L.F.F and M.C.N.C.: Methodology L.G.A.M.O.: Formal analysis and investigation D.B.D., M.C.F, M.C.P.C. and S.B.: Writing - review and editing S.B.: Supervision

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Declarations

Competing interests The authors declare no competing interests.

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