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REVIEW

Short-term efficacy and safety of three novel sphincter-sparing techniques for anal fistulae: a systematic review

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Abstract

Background The surgical treatment of complex anal fistulae, particularly those involving a significant portion of the anal sphincter in which fistulotomy would compromise continence, is challenging. Video-assisted anal fistula treatment (VAAFT), fistula tract laser closure (FiLaC™) and over-the-scope clip (OTSC®) proctology system are all novel sphincter-sparing techniques targeted at healing anal fistulae. In this study, all published articles on these techniques were reviewed to determine efficacy, feasibility and safety.

Methods A systematic search of major databases was performed using defined terms. All studies reporting on experience of these techniques were included and outcomes (fistula healing and safety) evaluated.

Results Eighteen studies (VAAFT—12, FiLaC™—3, OTSC®—3) including 1245 patients were analysed. All were case series, and outcomes were heterogeneous with follow-up ranging from 6 to 69 months and short-term (< 1 year) healing rates of 64–100%. Morbidity was low with only minor complications reported. There was one report of minor incontinence following the first reported study of FiLaC™, and this was treated successfully at 6 months with rubber band ligation of hypertrophied prolapsed mucosa. There are inconsistencies in the technique in studies of VAAFT and FiLaC™.

Conclusions All three techniques appear to be safe and feasible options in the management of anal fistulae, and short-term healing rates are acceptable with no sustained effect on continence. There is, however, a paucity of robust data with long-term outcomes. These techniques are thus welcome additions; however, their long-term place in the colorectal surgeon's armamentarium, whether diagnostic or therapeutic, remains uncertain.

Keywords Anal fistula · VAAFT · Video-assisted anal fistula treatment · Over-the-scope clip · Fistula tract laser closure

Introduction

Anal fistulae have a long-standing place in the history of challenging surgical pathologies [1]. Broadly speaking, most simple fistulae can be laid open with a limited risk of minor continence disturbances.

Whilst fistulotomy will cure a "high" fistula [2], the increasing concern is the risk of impairment of continence the higher the fistula. Furthermore, it is noteworthy that even for simple fistulae, fistulotomy may cause functional disturbance in some patients, which they find unacceptable [1, 3]. Thus, to minimize the functional dilemma in fistula surgery with curative intent, several "sphincter-preserving" techniques have been described which include fibrin glue, anal fistula plug (AFP), anorectal advancement flap (ARAF) and ligation of the intersphincteric tract (LIFT) procedure. These have had initially promising but variable success rates in the published literature. None has been universally accepted as the gold-standard surgical approach, i.e. one which can offer the success of fistulotomy without the risk of functional deficit.

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More recently, video-assisted anal fistula treatment (VAAFT) [4], over-the-scope (OTSC®) [5] proctology clip system and fistula tract laser closure, FiLaC™ (using a radial emitting laser probe) [6], have been added to the surgical armamentarium as new sphincter-preserving techniques.

VAAFT (Fig. 1) was first developed by Meinero in 2006 [4]. The main features of this technique include the ability to view the fistula from the inside and locate the internal fistula opening and possible secondary tracts or abscess cavities (i.e. diagnostic phase), and the operative phase which includes destruction of the fistula from the inside using diathermy, cleansing of the fistula tract with irrigation and finally closure of the internal opening.

FiLaC™ (Fig. 2) was initially described by Wilhelm in 2011 [6], using a novel diode laser source and radial emitting laser probe to obliterate the fistula tract throughout its length from within, whilst using an advancement flap procedure to close the internal opening. Subsequent studies have reported successes without addressing the internal/external opening.

OTSC was initially described in 2012 by Prosst and Ehni [5]. The technique adopts the OTSC® clip (made from elastic shape memory alloy—Nitinol), which upon application to the internal fistula opening exerts constant compression and theoretical closure.

The aim of this study was to review the efficacy and safety of these novel surgical techniques and to identify their role in anal fistula surgery.

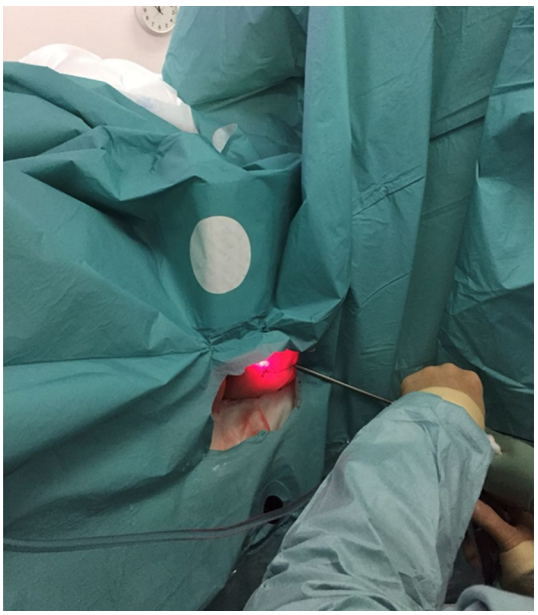

Fig. 1 Video-assisted anal fistula treatment (VAAFT) procedure—fistula demonstrating fistuloscope in situ with optical view showing seton as well as electrocautery probe. Modified preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram showing selection of articles for review

Fig. 2 Fistula with fistula tract laser closure (FiLaC™) probe in situ

Materials and methods

Search strategy

A systematic search using MEDLINE and Embase databases was performed from 2006 through to 31 April 2017 according to preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement. We used the following keywords/terms and Medical Subject Headings (MeSH): “fistula”, “fistuloscope”, “video assisted anal fistula treatment”, “Over-the-scope clip”, “over-the-scope proctology clip”, “fistula tract laser closure” “VAAFT”, “OTSC”, “FiLaC”, “laser”, “surgery”.

The studies were supplemented with searches of reference lists and bibliographies of selected articles to ensure that no relevant articles were missed. Two assessors (SA and KS) undertook independent systematic searches and evaluated the abstracts to select the studies for the review.

Inclusion/exclusion criteria

All available studies published in the English language, on the above techniques, were screened for inclusion in this review. Original studies describing a patient population undergoing any of the above three techniques were included. Case reports, conference abstract and review articles were excluded. Data were limited to those for idiopathic/Crohn’s related fistula. Rectovaginal fistulae were excluded from the analysis.

Endpoints

Primary	Efficacy of the procedure
Secondary	(1) Complications (safety)
	(2) Inter-procedure inconsistency/variations of techniques
	(3) Sub-analysis of patients with Crohn's disease (CD)

Data extraction and statistical analysis

Collected data were expressed in spreadsheet format (using Microsoft Excel, Microsoft, Redmond, WA, USA) and analysed to ascertain any possible conclusions from their collective information. Data collected for each study included: year/country of publication, the number of patients, sex distribution, pre-existing CD, operating time, operative success (i.e. healing of fistula), duration of follow-up, success/healing rates and complications. These were expressed as total (percentage) and in descriptive terms as applicable.

Results

The literature search revealed 198 citations, from which 21 full-text articles were selected and assessed for eligibility. From these, 3 studies were excluded, as they were updated by the relevant authors reporting larger series including the initial reported cohort. A total of 18 studies including 1245 patients (VAAFT $n = 917$, OTSC $n = 116$, FiLaC $n = 212$), were identified and included. All studies were prospective case series (Fig. 3).

Tables 1 and 2 summarize the findings.

Primary endpoint

Efficacy

VAAFT Twelve studies reported on VAAFT [7–18]. In the study by Schwandner [7], the diagnostic phase of VAAFT was used as an adjunctive therapy to advancement flap repair of complex fistulae in patients with CD. Grolich et al. [12] similarly utilized VAAFT solely for its diagnostic potential in 30 patients, reporting feasibility of fistuloscope assessment in 93% of patients. The internal opening was identified in 67% of patients. It was not specified whether additional findings such as secondary tracts were identified with VAAFT when compared with baseline fistula assessment investigations (fistulography, endosonography, magnetic resonance imaging (MRI)) [12].

Operating time varied from 18 to 135 min. Success rates (i.e. clinical healing) varied from 67% (12/18 patients after an average of 10-month follow-up) [11] to 100% (40/40 at 3-month follow-up) [18]. Notably, the largest study by Chowbey et al. [16] (involving 416 patients) reported a success rate of 74% (in 99 of 134 patients followed up at 1 year). Meinero et al. [9] (2nd largest study involving 203 patients) reported a 6-month cumulative probability of freedom from fistula estimated at 70% (according to a Kaplan–Meier analysis; 95% CI 64–76%).

FiLaC™ Four studies reported on fistula tract laser closure (FiLaC™) [6, 19–21]. Two of these were by the same author describing an initial case series of 11 [6] followed by a later report of 5-year experience of 117 patients [21]. The latter study was used in this review of outcomes in FiLaC™ (see Table 2).

One study reported on operating times, with a range of 6–35 min.

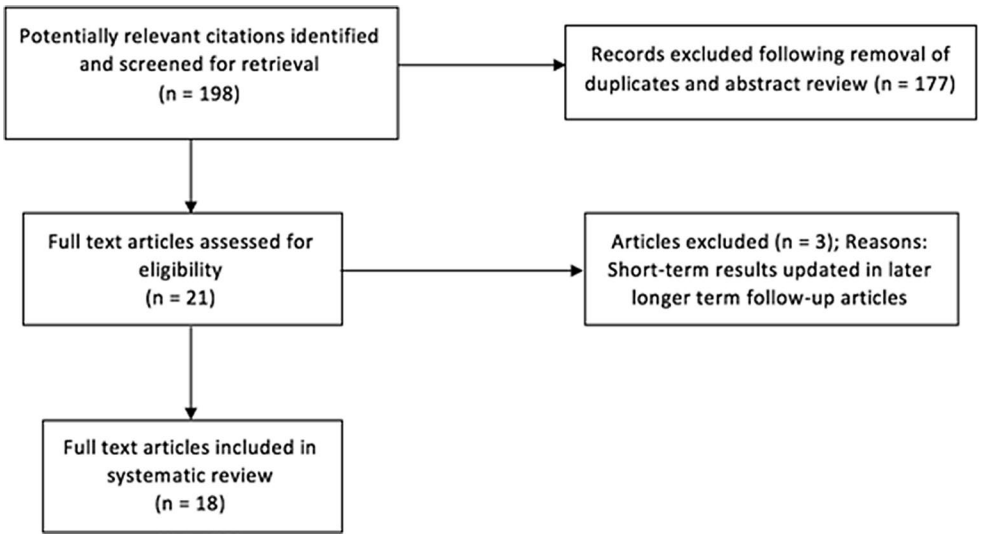

Fig. 3 Modified preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram showing selection of articles for review

Table 1 Outcomes for video-assisted anal fistula treatment (VAAFT)

References	Country	Patients	Age (years)	Follow-up (mos)	Closure of internal opening	Crohn's disease	Operation time (mins)	Success
Schwandner [7]	Germany	10	34 (21–51)	8.5 (6–9)	Advancement flap	10 (100)	22 (18–42)	9 (81%)
Kochhar [8]	India	82	35	6	Sutures or staples	0 (0)	45 (30–90)	69 (84%)
Meinero [9]	Italy	203	42 (21–77)	15 (6–69)	Staplers (linear or semicircular) or advancement flaps	0 (0)	90 (60–120)	74%[a]
Mendes [10]	Brazil	8	43 (29–66)	5	Sutures	0 (0)	31.7 (18–45)	7 (88%)
Wałęga [11]	Poland	18	47	10	Mattress sutures/ advancement flaps	NR	67 (45 –135)	12 (67%)
Grolich [12]	Czech Republic	30	NR	4 (< 1–30)	NA	9 (30)	NR	NA
Zarin [18]	Pakistan	40	NR	6	Sutures	0	NR	40 (100%)[b]
Selvarajan [15]	Malaysia	8	42.5	NR	Sutures	NR	NR	NR
Chowbey [16]	India	416	NR	NR	Linear or semicircular staplers	NR	50 (22–94)	99[c] (73.8)
Pini Prato [17]	Italy	9	9.6 (0.6–15.9)	10 (14–24)	Mucosal advancement flap	1 (11)	38 (25–60)	6 (67)
Seow-En [13]	Singapore	41	44 (18–69)	34 (12–44)	Staplers	0 (0)	NS	29 (71)
Jiang [14]	China	52	48 (19–71)	9	Sutures or staples	1 (0.01)	55 (35–90)	44 (85)
Total		917				21(2)		

Results are *n* (%) or median (range)

mos months, *mins* minutes, *NA* not available, *NR* not reported

[a]Cumulative probability of ultimate freedom from fistula at 1 year

[b]100% reported healed at 12 weeks (mode of outcome measurement not specified)

[c]99/134 patients followed up healed at 1 year

Table 2 Outcomes for fistula tract laser closure (FiLaC™) and over-the-scope clip (OTSC®) proctology system

References	Country	Patients	Age, years	Follow-up (mos)	Crohn's disease	Operation time (mins)	Success
OTSC®							
Prosst [24]	Germany	96	50 (20–80)	6	NS	32 (17–66)	72 (79%)
Mennigen [23]	Germany	10	41 (26–69)	7 (5–17)	6	41 (24–64)	7 (70%)
Gautier [22]	France	10[a]	43 (24–86)	5 (1–13)	4 (40)	25 (15–35)	2 (20%)
Total		116			10 (9)		
FILAC™							
Giamundo [28]	Italy	45	46 (18–78)	30 (6–46)	2 (4)	20 (6–35)	32 (71)
Ozturk [19]	Turkey	50	41 (23–83)	12 (2–18)	0 (0)	NR	41 (82)
Wilhelm [21]	Germany	117	46 (17–82)	25.4 (6–60)	13 (11.1)	NR	75 (64)
Total		212			15 (7)		

Results are *n* (%) or median (range)

NS not specified (study included 11 fistulas—8 Crohn's disease, 3 ulcerative colitis; however, unclear whether multiple fistulas in same patient were counted as separate), *mos* months, *mins* minutes, *NR* not reported

[a]Excluding rectovaginal fistulas

Success rates varied between 64% (median follow-up of 25 months) and 82% (median follow-up of 12 months). Healing was defined clinically (no symptoms/signs of recurrence/persistence) and radiologically (no evidence of fistula on endoanal ultrasound).

OTSC Three studies described the use of the over-the-scope proctology clip system in the treatment of anal fistulae (Table 2) [22–24]. Operating time varied from 17 to 66 min. Short-term (< 1 year) success rates varied between 20% (2/10) and 79% (72/96).

Secondary endpoints

Complications

VAAFT One study used a validated stool incontinence questionnaire (Cleveland clinic incontinence score) to assess continence [7], and Kochhar et al. used pre- and post-operative anal manometry as an objective measure of sphincteric function (with no significant difference in mean resting anal/squeeze pressures). There were, however, no reports of deterioration on follow-up questioning of patients across the studies, where mentioned. Across the studies, 52/917 patients (5%) were reported to have suffered complications. Jiang and co-workers report 3 cases of post-operative perianal sepsis that were subsequently treated with cutting setons. They also reported 3 cases of post-operative bleeding (secondary to laceration of rectal mucosa around the internal opening). Meinero et al. [9] reported 1 case of scrotal oedema, and Chowbey et al. [16] reported 29 cases of perineal oedema (caused by infiltration of irrigation solution after rupture of the fistula wall). Walega et al. [11] reported 1 patient with an anaesthetic complication (delayed discharge due to post-puncture syndrome after spinal anaesthesia). Other complications were: 5 cases of post-operative urinary retention, 2 cases of allergy to synthetic cyanoacrylate and 1 patient with delayed discharge (6 days post-operatively) because of a headache related to spinal anaesthesia [9]. Seven patients were readmitted: 5 due to rectal bleeding and 2 due to bloody discharge from the fistula tract [16].

FiLaC™ There were few complications reported secondary to this procedure. Wilhelm et al. [6] in the initial case series ($n = 11$) describe 1 case of minor incontinence which was temporary and successfully treated 6 months post-operatively with rubber band ligation of hypertrophied prolapsed mucosa. In the larger series ($n = 117$) published in 2017, there were no forms of incontinence (solid, liquid stool or gas) reported [21]. Other reported complications of the procedure included temporary pain and anismus in 8 cases (7.5%) and moderate bleeding in 3 cases (2.8%) across the 3 studies.

OTSC No formal assessment or reporting of post-operative continence was done across the 3 studies. One of the studies [23], however, reported 3 patients with complications (30%): slight anal discomfort (2/10) and soiling (1/10). The soiling was reported to be related to the OTSC clip, which was removed after approximately 6 months with successful fistula closure. The largest study, incorporating 96 patients, reported on pain scores in 10 of these patients, concluding that this was well controlled with simple analgesia.

Technique variations between studies

The diagnostic phase of VAAFT was consistently used in all patients, adopting the principles as first described by Meinero and Mori in 2006 [4]. However, there were differences between the studies regarding the operative phase of the procedure, particularly the treatment of the internal opening (IO), as highlighted in Table 1.

Concerning FiLaC, all studies used laser energy for ablation of the fistula tract, adopting similar wavelengths (1470 nm), with emitted energy ranging from 12 to 15 W. Probe withdrawal speed was different between studies, ranging from approximately 1 to 3 mm/s. The first study on FiLaC by Wilhelm [6] used advancement flaps (both initially and in larger case series) to close the internal opening, whereas subsequent studies had no specific treatment (i.e. other than laser ablation of the tract) for the internal/external openings.

The OTSC technique did not differ between studies.

Crohn's disease

In the study by Schwandner [7], the diagnostic phase of VAAFT was used as an adjunct to advancement flaps for repair of complex fistulae in patients with CD. In this study, only Crohn's fistulae were assessed.

Overall, a very small minority of patients [46/1245 (4%)] treated had CD-related perianal fistulae. Just under half of these patients (21/46) underwent VAAFT (9 purely diagnostic; 11 in combination with advancement flap), 10/46 had OTSC placement (7 of these 10 had successful fistula closure), and 15 had FiLaC (with primary success rate of 11/15).

Discussion

The surgical treatment of complex anorectal fistulae remains a problem [1]. Fistulotomy remains the best option when solely addressing the chance of cure. Furthermore, it can even be offered as a treatment modality for high fistulae, albeit in selected cases [2], although a third to a quarter of patients will experience mild leakage of flatus and mucus [2,

25]. However, for many patients this remains unacceptable and for some the functional impairment which would follow fistulotomy would be far worse. The goal of curing the disease whilst minimizing the risk of functional impairment has fuelled the development of sphincter-preserving techniques.

The novel therapies assessed in this study promise function-preserving curative surgical therapies for fistula-in-ano. VAAFT provides a minimally invasive technique with the ability to view the fistula from the inside so that all extensions can be identified and eradicated under direct vision using a fistuloscope. A presumed advantage of VAAFT lies in its diagnostic potential with the ability to identify secondary extensions and abscess cavities [7]. Meinero et al. [9] report the ability to characterize true fistulae (where tissue is characteristically red and floating) from the false passages (where the tissue is whitish and not floating), suggesting that fistuloscopy might be more accurate than endosonography and MRI. This diagnostic potential was reported by Schwandner [7] in CD, where additional side tracts not detected preoperatively (clinically or with endosonography) were identified in 64% (7/11) of patients. However, MRI is often considered the gold standard, for imaging the fistula tracts, and perhaps a comparison with MRI would offer a more interesting study.

The operative phase of VAAFT includes fistula destruction (with electrocoagulation), cleansing and closure of the internal opening. This closure is performed by various techniques including suturing, stapling (linear/semicircular) and advancement flaps. There is currently limited evidence to suggest which closure technique is favourable, with only one, non-randomized study comparing outcomes with stapled versus sutured closure of the internal opening [9]. A statistically significant difference between the two methods in favour of staple closure was found (log-rank test, 6.5; $p = 0.011$).

Our review demonstrates variable success rates with short-term (< 1 year) healing rates ranging from 67% [11] to 100% [18]. However, healing was assessed on a clinical basis without radiological assessment and without long-term follow-up in most cases. Zarin et al. [18] reported 100% success rate at 3-month follow-up, despite stating a mean follow-up period of 6 months. Furthermore, 3/40 patients required re-do surgery, at an unspecified time point, despite the quoted rate of 100% success, suggesting this result should be interpreted with caution. The largest study by Chowbey et al. [16] ($n = 416$) reported a success rate of 74% in 99 of 134 patients followed up at 1 year. Meinero et al. [9] ($n = 203$) reported a 6-month cumulative probability of freedom from fistula estimated at 70% (according to a Kaplan–Meier analysis, 95% CI 64–76%).

There were no deaths, and morbidity was low, with no significant surgical complications. In particular, there were no reports of incontinence, although only 1 study utilized anal manometry in providing the objective evidence of sphincteric function [8], finding no significant difference in resting tone or squeeze increments pre- and post-surgery.

Important considerations for VAAFT include the cost of the equipment and long operating times, although the latter may decrease with increased familiarity with the procedure. Technical aspects also need further evaluation such as progression of the fistuloscope through the fistula tract, which may be hampered by its own rigidity, or by the presence of other tracts with difficult trajectories arising from the primary path [10, 26]. There are also concerns regarding iatrogenic false passages (caused by over-aggressive irrigation) and collateral thermal damage by the electrode during ablation, with the possibility of this being a risk for delayed healing and recurrence [27].

FiLaC™ has shown benefit for both simple and complex fistulae (mostly transsphincteric). Closure of the internal opening has been described as an adjunct, but 2 of the 3 studies reporting on FiLaC™ have shown success without this extra step [19, 28], with the suggestion that it may be unnecessary [29, 30]. All 3 studies [6, 19, 28] used mechanical curettage, followed by introduction of the laser fibre into the fistula tract via the external opening. Curettage cleanses the tract and results in bleeding. These are thought to allow the laser to have maximum effect on tissue, with red blood cells hypothesised to add to sealing of the tract [31]. The optimum wavelength appears to be 1470 nm as this achieves the optimum wattage needed for sealing whist minimizing anismus post-operatively. The speed at which the laser emitting fibre is removed was variable between the institutions (1–3 mm/s). At the slowest speed, there was no reported anismus [28]. Success rates after primary treatment were over 64% in our review, and Wilhelm and co-workers [21] uniquely reported on secondary success rates following initial FiLaC™ with 28/42 patients achieving healing after repeat treatment. Repeat treatment consisted of a variety of procedures, including repeat FiLaC, sphincter reconstruction, plug treatment and fistulotomy.

Three studies reporting the use of OTSC were included [22, 23, 32]. The technique was initially developed for haemostasis and perforation closure in the gastrointestinal tract following flexible endoscopy [33, 34]. Modification of this offers a minimally invasive surgical technique, with no significant damage to the sphincter muscle. The fate of the OTSC is unclear, however, with some patients having the clip left in situ, spontaneous discharge (with associated fistula persistence [23]) and some patients undergoing operative removal. The data available are conflicting, with Gautier et al. reporting a disappointing experience in comparison with Prosst et al., albeit the former included fewer patients in their study. The included numbers make it difficult to accurately compare outcomes such as fistula healing.

It is not possible to comment on the role of these procedures for fistulating perianal CD, but their minimal morbidity and minimal effect on continence with reports of successful treatment suggest this is an area which should be explored in the future, at least for palliation of symptoms.

The present review has several limitations.

Firstly, there is significant heterogeneity in the population studied, fistula morphology and aetiology, with no standardized population. The majority of studies are uncontrolled case series, and follow-up times are widely variable and relatively short; high initial success rates (many lacking radiological assessment) may be misleading, and recurrences may develop more than a year after surgery [35]. These are common problems in studies of fistula treatment [36], often making comparison and pooling of data between studies difficult. Adherence to guidelines developed in 2016 for surgical case series reporting [37], as well as the development of a core outcome data set for perianal CD fistulae, would ultimately improve reporting in this field and facilitate meaningful analysis.

The cost of the procedures is an important consideration. All three involve the use of novel medical devices with an associated cost which is not a consideration when performing procedures like fistulotomy, advancement flap or LIFT. No studies assessed cost-effectiveness. This needs to be further investigated.

However, our study has some strengths. We highlighted the discrepancies between techniques with which each of the procedures is performed, with specific emphasis on facets that need to be standardized when planning prospective trials. Most of the series were performed by the same authors or groups, and there is a need to assess the reproducibility and generalisability of the procedures.

Notwithstanding the need of further research, the limited evidence available suggests that VAAFT is safe and feasible with acceptable early healing rates and no reported deterioration in continence. The paucity of studies on FiLaC and OTSC makes it difficult to comment accurately on success rates, but early reports are promising.

Notable advantages of these techniques are their avoidance of sphincter injury, minimal morbidity and the ability to repeat them or perform other surgical techniques following failure. They are a welcome addition to the surgical armamentarium. However, long-term data will need to be appraised to fully understand their role in fistula surgery. Our findings need to be carefully considered when planning prospective studies on larger samples of patients.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The present paper as a review of the literature was exempt from approval.

Informed consent For this review of the literature, informed consent was not required.

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