



# Fistulotomy and primary sphincteroplasty for anal fistula: long-term data on continence and patient satisfaction

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## Abstract

**Background** The aim of this study was to evaluate the safety and long-term efficacy of fistulotomy and primary sphincteroplasty (FIPS). Secondary endpoints were its impact on postoperative continence status and patients' satisfaction.

**Methods** A retrospective study was conducted on patients with cryptoglandular anal fistula (AF) who had FIPS between June 2006 and May 2017. Patients were evaluated with standardized telephone interviews and clinical/instrumental assessment. Main outcome measures included fistula healing rate, continence status, and patient satisfaction. Incontinence was defined as an inability to hold either gas, liquid, or solid stools, as well as postdefecation soiling, and was measured by the Cleveland Clinic fecal incontinence score. Patient satisfaction was evaluated by an 11-point numeric rating scale.

**Results** There were 203 patients (139 males; mean age: 48.7 years) who had FIPS. The overall healing rate was 93% (188 patients) with a mean follow-up period of  $56 \pm 31$  months. Half of the total cohort (51%) had a complex fistula. Preoperatively, 8 (4%) patients complained of postdefecation soiling and 2 (1%) of gas incontinence. Postoperatively, 26 (13%) patients had continence impairment (de novo  $n = 24$ ), mainly consisting of postdefecation soiling (10%). In univariate analysis, patients with recurrent (RR 6.153 95% CI 2.097–18.048;  $p = 0.002$ ) or complex (RR 3.005 95% CI 1.203–7.506;  $p = 0.012$ ) AF and those with secondary tracts (RR 8.190 95% CI 2.188–30.654;  $p = 0.004$ ) or previous set on drainage (RR 5.286 95% CI 2.235–12.503;  $p = 0.0001$ ) were at higher risk of incontinence. In multivariate analysis, no significant predictors were found, although fistula complexity approached statistical significance (RR 5.464 95% CI 0.944–31.623;  $p = 0.050$ ). The mean patient satisfaction numeric rating scale was  $9.3 \pm 1.6$ . Lower satisfaction rates were found in patients with transsphincteric ( $p = 0.011$ ) or complex ( $p = 0.0001$ ) AF, with secondary tracts ( $p = 0.041$ ) or previous seton drainage ( $p = 0.008$ ), and in those with postoperative continence impairment ( $p = 0.0001$ ). Postoperative onset of incontinence was the only significant factor in multivariate analysis ( $p = 0.0001$ ).

**Conclusions** FIPS should be considered a valid therapeutic option for selected AF. However, the risk of postoperative minor fecal incontinence exists, and should be discussed during preoperative patient counselling.

**Keywords** Fistulotomy · Primary sphincteroplasty · Anal fistula · Fecal incontinence

## Introduction

Surgical anal fistula (AF) treatment remains challenging, mainly due to variability in success and reoccurrence rates as well as continence impairment risks [1]. So far, no procedure can be considered the “gold-standard” for surgical treatment. Yet, strong efforts to identify effective and “complication-free” surgical treatment options are ongoing [2]. For this reason, several minimally invasive procedures have been developed. However, after initial enthusiasm, many of these “new kids on the block” did not provide the expected results [3, 4]. There is some scepticism about new sphincter-sparing techniques, mainly due to uncertainty about the

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impact on pathophysiological mechanisms underlying AF [5, 6]. Anal fistulotomy can be considered the best AF treatment option, providing a perfect surgical field view, allowing direct access to the source of chronic inflammation (i.e., the intersphincteric space) and demonstrating high healing rates [1, 7]. Controversy exists concerning the risk of continence impairment associated with the approach. Several researchers consider the risk as acceptable [7, 8], but many others the risk as to high [9, 10].

Three decades ago, Parkash et al. proposed immediate sphincter reconstruction after fistulotomy, to reduce both the risk of postoperative fecal incontinence and to healing time [11]. Despite proved efficacy also in complex AF cases [12], fistulotomy/fistulectomy and primary sphincteroplasty (FIPS) is still regarded with scepticism.

The aim of this retrospective study was to evaluate the safety and long-term efficacy of FIPS, and to assess its impact on patients' postoperative continence status and satisfaction.

## Materials and methods

All patients who had surgical treatment for cryptoglandular AF at our institution between June 2006 and May 2017 were identified from our patient database. All patients had full clinical and physical evaluation, and endoanal ultrasound (EAUS) performed with a three-dimensional (3D)-ultrasound (US) instrument (model 2202, BK Medical, Herlev, Denmark) equipped with a 360° rotating endoprobe (model 2052, BK Medical, Herlev, Denmark). The following AFs were defined as complex: high transsphincteric tract, crossing > 30% of the external anal sphincter; low transsphincteric tract, only when considered at risk for postoperative fecal incontinence (anterior fistula in women, recurrent fistula, or history of fecal incontinence); and supra-sphincteric or extra-sphincteric tracts. Patients' medical records were screened, and only patients who had FIPS were selected. Selection criteria for FIPS were patients with either primary or recurrent, simple or complex AF. Exclusion criteria were: extra- and supra-sphincteric AF, inflammatory bowel disease (IBD), traumatic-, cancer- or radiotherapy-related AF. Patients with acute perianal sepsis were first treated by incision and drainage ± seton placement and had definitive surgery only after acute sepsis had resolved. All patients provided written informed consent. Ethical approval was obtained from the local Ethics Committee.

Data collected included: patients' demographics, comorbidities, smoking status, fistula type, location of the internal and external openings, primary or recurrent AF, seton placement, previous anorectal surgery, type and number of surgical procedures performed in the same patient, and preoperative continence status.

All patients were regularly followed up with a clinical and physical examination (plus an EAUS if needed) at our institution, according to the following schedule: 1 week, 1–3–6–12 months, and then every 6 months. Specifically, for this study, the clinical condition of patients was updated by a standardized telephone interview. The following main outcome measures were collected: fistula healing, continence status (assessed by the Cleveland Clinic Fecal Incontinence score [CCFIS] [13]), onset of postdefecation soiling, morbidity rate, and patient's satisfaction (11-point numeric rating scale [NRS], ranging from 0 to 10). Incontinence was defined as an inability to control the passage of gas, liquid, and solid stools, and also as postdefecation soiling. Healing was defined as the absence of drainage or abscess formation, fistula closure, and complete wound healing. Patients reporting healing or continence status doubts during the telephone interview were invited to our institution for clinical and physical examination.

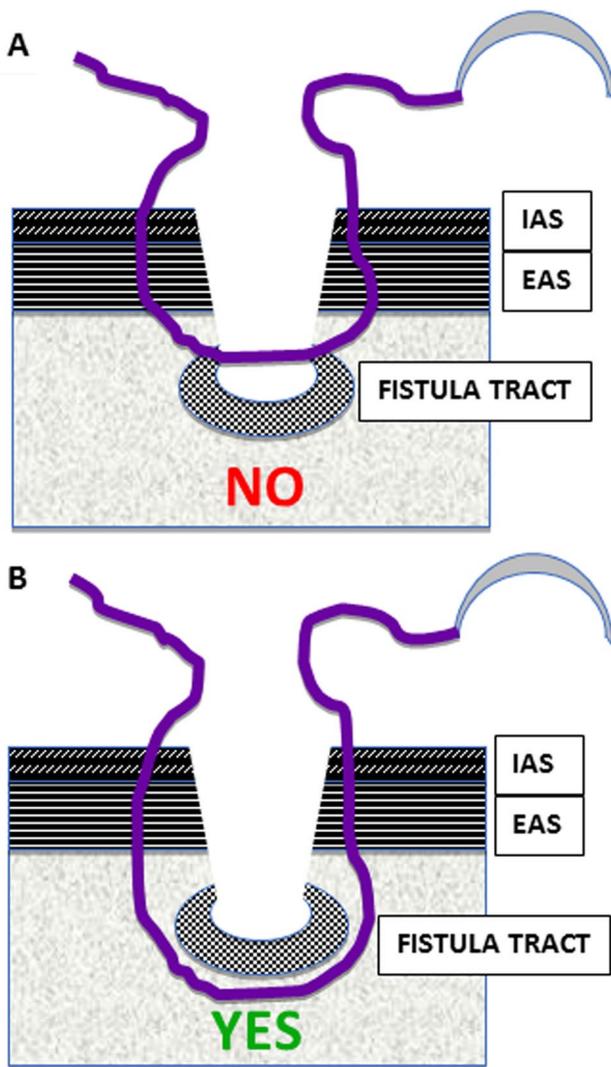
## Surgical procedure

All patients had FIPS as described in the literature [14]. The procedures were performed by the senior colorectal surgeon (CR). Briefly, two enemas were administered for bowel preparation; no prophylactic or postoperative antibiotic treatment was given, and all procedures were conducted under general anaesthesia in lithotomy position. Setons, if present, were removed, the internal fistula opening and fistula tract were identified. A complete fistulotomy of the primary tract was carried out and the primary tract was curetted in order to remove any granulation tissue. An end-to-end primary sphincteroplasty was then fashioned using a series of interrupted 2-0 Vicryl™ stitches (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA). In case of intersphincteric fistulas, each stitch encompassed the internal anal sphincter and fistula tract; in case of transsphincteric fistulas, both sphincters and fistula tract were encompassed by the suture (Figures 1 and 2). Anal mucosa and submucosa were continuously sutured with 3-0 Vicryl™ (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA), while keeping an external wound drain.

During the first 2 postoperative weeks, stool softeners and analgesics were prescribed, and it was recommended to avoid intense physical activities.

## Statistical analysis

Continuous data were reported as mean ± SD (range), and compared using the paired sample *T* test; categorical data were presented as frequencies and percentages, and compared using the Chi-squared test, Fisher's exact test, or McNemar test if applicable. To assess potential predictive factors of success, postoperative continence impairment, and satisfaction rate, the following data were



**Fig. 1** Schema of end-to-end primary sphincteroplasty **a** incorrect suture not including the entire fistula tract, with a “dead space” behind the suture, at risk of persistence of fistula tract; **b** correct suture including IAS, EAS, and the entire fistula tract. *IAS* internal anal sphincter, *EAS* external anal sphincter

considered: sex, smoking status, previous abscess drainage, prior seton drainage, complex fistula, secondary tract fistula, recurrent fistula, anterior fistula, and pre-existent continence disturbances. In the assessment of potential predictive factors, postoperative continence impairment, and satisfaction rate, the risk estimate of the potential factors’ associations was provided. Binomial or linear logistic regression models were performed.  $P < 0.05$  was considered statistically significant. Analyses were carried out using SPSS software version 17.0 for Windows (SPSS, Chicago, IL, USA).

## Results

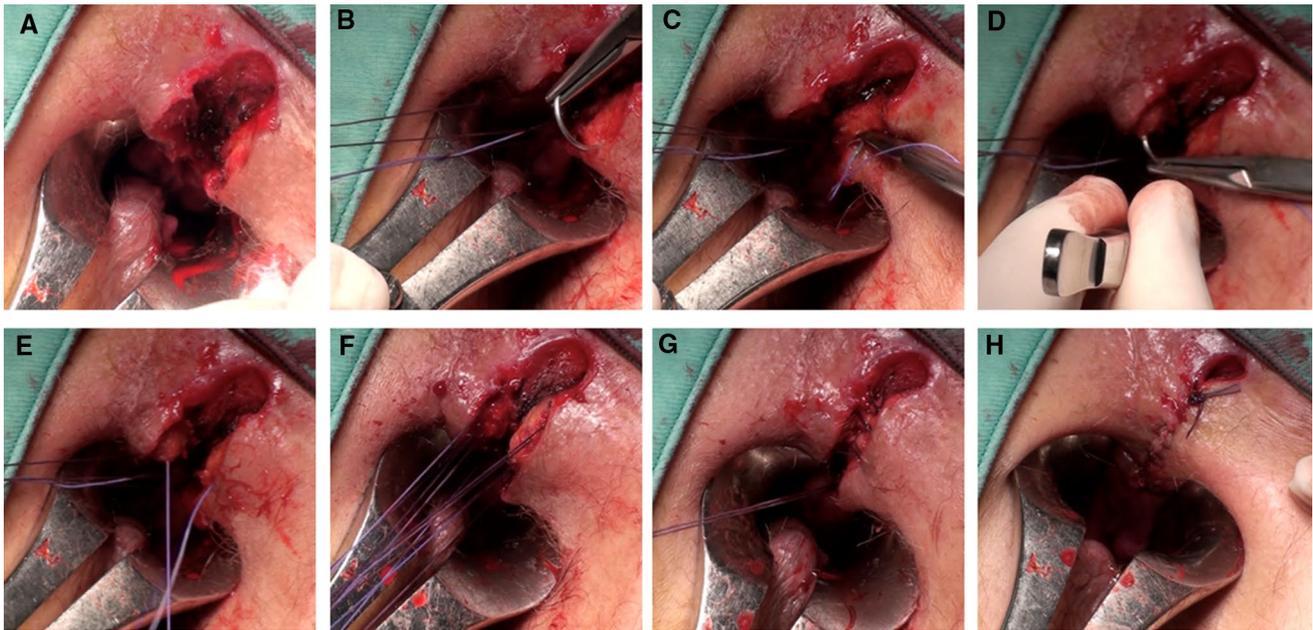
Between June 2006 and May 2017, 704 patients with AF were surgically treated at our institution, and 218 of them underwent FIPS. Among these, 203 patients (139 males; mean age:  $48.7 \pm 14.3$  years, range: 18–85 years) with a follow-up (FU) of at least 1 year were included in this study. The remaining 15 patients were excluded, either because they could not be reached or because they refused to participate. All 203 patients were regularly followed up with a clinical and physical examination at our institution, according to the following schedule: 1 week, 1–3–6–12 months, and then every 6 months. Thirty-five patients underwent clinical and physical examination again after being interviewed.

Table 1 summarises patients’ clinical features at baseline. AF were intersphincteric in 58 patients (29%) and transsphincteric in 145 (71%) patients. Among these, 60 (41%) transsphincteric fistulas were considered low, and 85 (59%) high according to EAUS findings. In 17 (8%) patients, the fistula was recurrent, and in 10 (5%) patients, a secondary tract was identified. Overall, 103 (51%) AF were complex. The internal fistula opening was located in the anterior or posterior quadrants of the anal canal in 61 (30%) and 142 (70%) cases, respectively. Prior to definitive surgery, 56 (28%) patients underwent incision and perianal abscess drainage, and 46 (23%) seton placement (Table 1) for a mean of  $4.1 \pm 1.9$  (range, 1–8) months. Eighty-seven (43%) patients were active or former smokers; other comorbidities are detailed in Table 2.

The mean duration of the surgical procedure was  $23.8 \pm 3.9$  (range 12–28) min, and mean length of postoperative stay was  $1.2 \pm 0.7$  (range 0–4) days. No patients developed postoperative perianal sepsis, bleeding, or intractable pain. Three (1.4%) patients had sphincter dehiscence (detected in all cases at the 1-week FU visit), requiring a redo sphincteroplasty, which was performed 1 month after the first procedure. No patients had a diverting stoma.

## Healing rate

After a mean FU of  $55.9 \pm 30.9$  (range, 12–143) months, the overall healing rate was 93% (188/203 patients). Fifteen (7%) patients experienced fistula recurrence, which was treated by redo FIPS in 5 (3%) patients. All of them achieved complete healing, resulting in an overall success rate of 95%. The other ten recurrences were managed as follows: endorectal advancement flap ( $n = 2$ ), video-assisted anal fistula treatment (VAAFT) ( $n = 1$ ), and lay-open fistulotomy ( $n = 1$ ), with subsequent healing in all



**Fig. 2** Surgical steps of (FIPS) in a transphincteric anal fistula: **a** fistula tract following fistulotomy and accurate curettage; **b** starting the primary sphincteroplasty, the suture needle is introduced through the anal canal submucosa covering the internal anal sphincter; **c** the needle is penetrated within both internal and external anal sphincter, above the fistula tract; **d** following the needle has encompassed the

fistula tract, it is recovered on the opposite side; **e** the suture placed all around the fistula tract is shown; **f** the row of interrupted stitches already placed is shown and ready for ligation; **g** the primary sphincteroplasty has been completed by ligation of the interrupted stitches; **h** the muco-cutaneous running suture has been completed, leaving a small cutaneous drainage

cases. Five patients refused further surgical treatment given a low symptom severity related to the recurrence (i.e., rare episodes of small perianal swelling and serum secretions). One patient was treated at another hospital and refused outcome disclosure of the surgery.

FIPS was equally effective in primary compared to recurrent, simple compared to complex fistulas, intersphincteric compared to transphincteric (low or high) fistulas, and in patients with or without a previous seton placement (Table 3). Therefore, none of the potential predictive factors of healing was statistically significant in univariate analysis (Table 4).

### Continence status

At baseline, 8 (4%) patients complained of postdefecation soiling, and additionally, 2 (1.0%) reported flatus incontinence. Postoperatively, 26 (13%) patients sustained some minor form of continence impairment, consisting of postdefecation soiling (20 [10%] patients) and flatus incontinence (19 [10%] patients); 12 (6%) patients developed major fecal incontinence (to liquid and/or solid stools) (Table 5). The overall CCFIS did not significantly change at last FU (from  $0.04 \pm 0.4$  to  $0.5 \pm 1.8$ ) compared to baseline. However, the CCFIS increased from  $0.5 \pm 1.2$  to  $3.7 \pm 3.6$  ( $p=0.005$ ) in patients with postoperative continence impairment. Changes

in the CCFIS were detected after 3 months of FU, with no significant change of its value afterwards. Six (3%) patients complaining postdefecation soiling at baseline were fully continent at the last FU. Finally, de novo continence impairment (minor and/or major) occurred in 24 (12%) patients reporting full continence prior to surgery.

Univariate analysis results of fecal continence factors showed that patients with recurrent ( $p=0.002$ ) or complex ( $p=0.012$ ) AF, and those with secondary tracts ( $p=0.004$ ) or history of seton drainage ( $p=0.0001$ ) were at a higher continence impairment risks; however, fistula complexity was the only almost significant factor in multivariate analysis ( $p=0.050$ ) (Tables 3 and 6).

### Patient satisfaction

The mean NRS was  $9.3 \pm 1.6$ . Lower satisfaction rates were found in patients with transphincteric ( $p=0.011$ ) or complex ( $p=0.0001$ ) AF, secondary tracts ( $p=0.041$ ), history of previous abscess drainage ( $p=0.0001$ ), seton placement ( $p=0.008$ ), and patients with postoperative continence impairment ( $p=0.0001$ ) assessed with univariate analysis of factors influencing this outcome.

De novo postoperative continence impairment was the only factor associated with a lower satisfaction rate in multivariate analysis ( $p=0.0001$ ) (Table 7).

**Table 1** Baseline clinical features

	Patients <i>n</i> <sup>o</sup> (%)
Sex	
Male	139 (69)
Female	64 (32)
Age (years, SD, range)	48.7 (14.3) (18–85)
Smoking	
Yes	87 (43)
No	116 (57)
Fistula type	
Simple	100 (49)
Complex	103 (51)
Fistula anatomy:	
Intersphincteric	58 (29)
Transsphincteric	145 (71)
Low	60 (41)
High	85 (59)
Anterior	61 (30)
Posterior	142 (70)
Secondary tracts	10 (5)
Recurrent fistula	
Yes	17 (8)
No	186 (92)
Previous abscess drainage	
Yes	56 (28)
No	147 (72)
Seton drainage	
Yes	46 (23)
No	157 (77)
Cleveland Clinic fecal incontinence score (mean, SD, range)	0.04 (0.4) (0–4)
Postdefecation soiling	
Yes	8 (4)
No	195 (96)

**Table 2** Comorbidities and concomitant pathology

	Patients <i>n</i> <sup>o</sup> (%)
Hemorrhoidal disease	40 (20)
Diabetes	14 (7)
Dyslipidemia	16 (8)
Dermatosis	10 (5)
Human immunodeficiency virus infection	2 (1)

## Discussion

The risk of postoperative continence impairment after a lay-open fistulotomy ranges from 0 to 60%, depending on the type of fistula and patient treated [15]. Several other

techniques (including advancement flap, fistula plug insertion, glue or paste injection, VAAFT, etc.) have been developed, even if for all of them high failure rates in long-term FU have been reported [3, 6]. For these reasons, in a group of patients (according to the criteria described above), we have attempted the primary sphincter reconstruction after fistulotomy and evaluated its results. This surgical procedure has been proposed about 3 decades ago [11], and further studies have shown a universally high success rate together with a relative low continence impairment rate [12].

To our knowledge, this is one of the largest single-center studies, with the longest FU period, to assess the outcome of the FIPS technique [12, 16]. A long FU period is of crucial importance to evaluate the outcomes of any fistula surgery. Indeed, a fistula may be inappropriately considered as “healed” even if it when it is just “silent” in the short term. This has been clearly demonstrated by van der Hagen et al., where the fistulotomy or endorectal flap recurrence rate significantly increased over time [17]. For this reason, in our study, analyses were restricted to patients with a minimum FU of 12 months. In our cohort, the primary healing rate was 93% with a mean FU of 56 months, reaching 95% after redo FIPS was performed to treat recurrences. These data became more relevant focusing on fistula complexity, which was diagnosed in half of our patients.

A recent study by Seyfried et al. showed that sex and high fistula tract were associated with a worse outcome [16]; on the contrary, we were unable to identify any risk factors for recurrence. In fact, in our experience the procedure was effective regardless of fistula type (i.e., primary or recurrent), gender, or complexity of the disease (Table 3). We think that this result is very important, because it demonstrates the efficacy of the technique in all patients, regardless of their specific characteristics. These data differ from other published studies on several techniques where the healing rate varied between subgroups of patients [18, 19]. The morbidity rate was low, with only 3 (2%) patients having a sphincter dehiscence (the most feared complication after FIPS) requiring a redo sphincteroplasty. In a previously published systematic review, this risk ranged from 0 to 8% [12], increasing with the amount of sectioned sphincter [16].

The impact of the procedure on the continence status was one of the endpoints of this study. Special care was taken to record the presence of continence impairment prior to surgery. Indeed, it was not surprising to observe resolution of pre-existent postdefecation soiling in 6 (3%) out of 8 patients. Unfortunately, continence deterioration (minor and/or major) occurred in 24 (12%) patients reporting full continence prior to surgery (Table 5). However, only 12 (6%) patients developed major fecal incontinence (to liquid and/or solid stools).

**Table 3** Healing rate and postoperative continence impairment in different type of fistulas

Factor (patients <i>n</i> <sup>o</sup> )	Healing <i>n</i> <sup>o</sup> (%)	<i>p</i> value	Postoperative continence impairment <i>n</i> <sup>o</sup> (%)	<i>p</i> value
Simple (100)	92 (92.0)	0.476	7 (7.0)	0.012
Complex (103)	96 (93.2)		19 (18.4)	
Intersphincteric (58)	53 (91.4)	0.435	5 (8.6)	0.186
Transsphincteric (145)	135 (93.1)		21 (14.5)	
Low transsphincteric (60)	55 (91.7)	0.399	7 (11.7)	0.287
High transsphincteric (85)	80 (94.1)		14 (16.5)	
Primary (186)	173 (93.0)	0.364	19 (10.2)	0.002
Recurrent (17)	15 (88.2)		7 (41.2)	

**Table 4** Healing rate: univariate analysis

Factor	Univariate analysis relative risk (95% CI)	<i>p</i> value
Male sex	1.921 (0.523–7.060)	0.245
Age > 45 years	1.446 (0.504–4.150)	0.336
Smoking	0.991 (0.917–1.071)	0.520
Recurrent disease	1.054 (0.882–1.259)	0.364
Previous abscess drainage	0.996 (0.914–1.086)	0.600
Seton drainage	0.998 (0.904–1.080)	0.546
Complex fistula	0.987 (0.913–1.067)	0.476
Fistula with secondary tracts	1.031 (0.835–1.272)	0.544

It is well known that the results of both primary and delayed sphincteroplasty after an obstetric trauma are good in the short and medium term, but deteriorate over time [20]. For this reason, scepticism exists about the long-term results of FIPS. In this study, the overall pre- and postoperative CCFIS did not change, although it was significantly higher in the group of patients with postoperative continence impairment. Furthermore, changes in the score were recorded up to the third postoperative month, with no change afterwards: this indicates that the effectiveness of the sphincter reconstruction tends to remain stable over time. This difference can be explained by some technical and pathophysiological

**Table 5** Preoperative and postoperative continence status

	Preoperative patients <i>n</i> <sup>o</sup> (%)	Postoperative patients <i>n</i> <sup>o</sup> (%)
Overall continence impairment:	8 (4)	26 (13)
Soiling	8 (4)	20 (10)
Gas incontinence	2 (1)	19 (10)
Liquid stool incontinence	0	12 (6)
Solid stool incontinence	0	4 (2)
Need to wear pads	0	3 (2)
Lifestyle alteration	0	11 (5)
Overall CCFI score (mean, SD, range)	0.04 (0.4) (0–4)	0.49 (1.8) (0–11)

CCFI cleveland clinic fecal incontinence score, SD standard deviation

**Table 6** Postoperative continence worsening: univariate and multivariate analysis

Factor	Univariate analysis relative risk (95% CI)	<i>p</i> value	Multivariate analysis relative risk (95% CI)	<i>p</i> value
Female gender	1.049 (0.929–1.184)	0.274		
Age > 45 years	1.630 (0.690–3.854)	0.182		
Smoking	0.643 (0.313–1.320)	0.159		
Recurrent disease	6.153 (2.097–18.048)	0.002	5.555 (0.625–49.363)	0.124
Previous abscess drainage	2.151 (0.921–5.025)	0.062		
Seton drainage	5.286 (2.235–12.503)	0.0001	5.011 (0.728–34.509)	0.102
Complex fistula	3.005 (1.203–7.506)	0.012	5.464 (0.944–31.623)	0.050
Fistula with secondary tracts	8.190 (2.188–30.654)	0.004	2.780 (0.285–27.145)	0.379
Anterior fistula	1.373 (0.662–2.848)	0.263		
Preoperative postdefecation soiling	3.879 (0.698–21.547)	0.149		

**Table 7** Patient satisfaction rate (NRS scale): univariate and multivariate analysis

Factor	Univariate analysis (mean value)	<i>p</i> value	Multivariate analysis <i>p</i> value
<b>Sex</b>			
Male	9.24	0.675	
Female	9.31		
<b>Age</b>			
< 45 years	9.35	0.622	
> 45 years	9.20		
<b>Recurrent disease</b>			
Yes	8.41	0.148	
Not	9.34		
<b>Previous abscess drainage</b>			
Yes	8.89	0.0001	0.182
Not	9.41		
<b>Seton drainage</b>			
Yes	8.80	0.008	0.524
Not	9.40		
<b>Complex fistula</b>			
Yes	8.96	0.0001	0.185
Not	9.57		
<b>Fistula with secondary tracts</b>			
Yes	7.70	0.041	0.124
Not	9.35		
<b>Location of fistula</b>			
Anterior	9.21	0.636	
Posterior	9.26		
<b>Postoperative continence impairment</b>			
Yes	7.50	0.0001	0.0001
Not	9.53		

aspects that are different between obstetric trauma and AF [21, 22].

An important limitation of this study is the absence of a physiological assessment of preoperative and postoperative anorectal function (e.g., using anorectal manometry). However, other published studies have shown that anal pressure was not significantly affected by this procedure [12]. Furthermore, results of a randomised-controlled trial comparing two groups of patients treated with flap and FIPS showed that neither maximum resting nor squeeze pressure differed significantly between the two groups [23].

Adding the step of sphincter reconstruction to the simple lay-open fistulotomy does not significantly increase surgery time, while positively affecting wound healing and avoiding (in the vast majority of cases) a deep scar at the anal verge that may lead to deformity and fecal soiling/seepage [12, 14]. We think that FIPS is a good option also for simple fistulas (intersphincteric and low transphincteric), because the suture of low sphincter(s) could reduce the risk of anal

deformity (“key-hole” look) as seen frequently after simple fistulotomy, where the risk of continence impairment (mostly soiling and seepage) is not negligible [9, 10]. Based on these considerations, FIPS seems suitable in patients with either middle-low transphincteric or intersphincteric fistulas. However, additional patients’ characteristics should be carefully considered such as risk of incontinence and presence of sepsis. The results of this and previously published studies show that FIPS provides significant improvement of patients’ continence status in the long term compared to that observed after simple fistulotomy, given that fistula complexity negatively affects functional outcomes of FIPS. Special attention should be paid when proposing this approach to patients with very complex AF (Table 3). Moreover, our study has shown that the risk of continence impairment was higher in patients with recurrent AF (Table 3). These results are similar to other published studies, where recurrent and more complex AFs were associated with a greater risk of postoperative incontinence [10, 25]. In this study, only 8% of the treated patients had a recurrent fistula: this rate is lower than that of other series published on the topic, although we think that there is no specific reason for this discrepancy.

Indeed, the impact of surgery on patient satisfaction and quality of life after surgery is crucial. In some studies, it is argued that the risk of fecal incontinence is of utmost importance, but also that a high recurrence rate (with the consequent need of numerous surgical procedures) will even be more detrimental for the patient [8, 16]. In this regard, a recent prospective multicentre study showed that patient satisfaction was high, both in patients undergoing fistulotomy for simple AF and in staged fistulotomy for complex AF, with an improved quality of life in both groups [24]. Our results confirmed that patient satisfaction rate after FIPS was high, but negatively correlated to postoperative onset of continence impairment. Similarly, a retrospective study with 7.8 FU years showed that fistulotomy was the strongest risk factor for postoperative continence impairment, and that the severity of incontinence correlated to AF complexity, with a negative impact on patients’ quality of life [10]. The retrospective nature of our study precluded the assessment of quality of life using a validated questionnaire. Therefore, the predisposition and opinion of the patient concerning this procedure should be better evaluated in future studies.

One of the limitations of this study is that it is a retrospective noncomparative study with a risk of selection bias; Another possible limitation is the different modality of last FU: all patients were evaluated by a clinical examination over the years in a regular FU program; however, the last evaluation of patients was carried out through a standardized telephone interview in patients reporting perfect clinical condition and absence of continence impairment; In case of any positive finding at telephone interview, they were invited to our institution for a complete exam. Finally, as discussed,

absence of a physiological assessment of preoperative and postoperative anorectal function by anorectal manometry is another limitation of the study.

## Conclusions

FIPS is associated with good healing rates and high patient satisfaction, with a low risk of continence impairment as compared to simple lay-open fistulotomy/fistulectomy, and should be considered as a valid treatment option for selected AF. Data from this study seem to suggest that patients suitable for FIPS could be those with either middle-low transphincteric or intersphincteric fistulas. However, the risk of developing postoperative (mainly minor) fecal incontinence exists and should be discussed during counselling. Indications for FIPS should be better evaluated in future trials to establish its role in an ideal treatment algorithm for the management of AF.

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**Author contributions** FL and CR contributed substantially to the conception and design of the study. FL, AP, VDS, UG, and RO provided data collection and contributed to literature review. FL conducted statistical analysis and wrote the manuscript. All authors contributed in the processes discussing findings, drawing conclusions, as well as the completion of the manuscript. All authors read and approved the final manuscript.

## Compliance with ethical standards

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

**Ethical approval** The study was conducted in accordance with the Declaration of Helsinki. It received approval from our local Ethics Committee.

**Informed consent** All patients signed a written consent.

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