



Immediate sphincter repair following fistulotomy for anal fistula: does it impact the healing rate and septic complications?

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Purpose: Fistulotomy is considered the most effective treatment for anal fistula; however, it carries a risk of incontinence. Sphincteroplasty in the setting of fistulotomy is not standard practice due to concerns regarding healing and potential infectious complications. We aimed to compare the outcomes of patients who underwent fistulotomy with primary sphincteroplasty to those who did not undergo repair.

Methods: This was a retrospective review of consecutive patients who underwent fistulotomy for cryptoglandular anal fistula. All operations were performed by one colorectal surgeon. Sphincteroplasty was performed for patients perceived to be at higher risk for continence disturbance. The main outcome measures were the healing rate and postoperative septic complications.

Results: In total, 152 patients were analyzed. Group A (fistulotomy with sphincteroplasty) consisted of 45 patients and group B (fistulotomy alone) included 107 patients. Both groups were similar in age ($P = 0.16$) and sex ($P = 0.20$). Group A had higher proportions of multiple fistulas (26.7% vs. 6.5%, $P < 0.01$) and complex fistulas (mid to high transsphincteric, 37.8% vs. 10.3%; $P < 0.01$) than group B. The median follow-up time was 8 weeks. The overall healing rate was similar in both groups (93.3% vs. 90.6%, $P = 0.76$). No significant difference between the 2 groups was noted in septic complications (6.7% vs. 3.7%, $P = 0.42$).

Conclusion: Fistulotomy with primary sphincter repair demonstrated a comparable healing rate to fistulotomy alone, without an increased risk of postoperative septic complications. Further prospective randomized studies are needed to confirm these findings and to explore the functional outcomes of patients who undergo sphincteroplasty.

Keywords: Rectal fistula; Fistulotomy; Sphincteroplasty; Healing rate; Septic complications

INTRODUCTION

Anal fistula remains one of the most common benign anorectal conditions treated by general and colorectal surgeons. Most patients with anal fistula require an operative intervention to heal. The goals of treatment are to eradicate the fistula, minimize post-

operative septic complications, prevent recurrence, and preserve continence. The outcome of anal fistula surgery is dependent on multiple factors, including the type of fistula, certain patient characteristics, and the surgeon's decision regarding which surgical procedure to perform [1, 2].

Anal fistulotomy, which involves unroofing the entire tract

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from the external to the internal opening, remains the most effective and simplest treatment for most patients with anal fistula [2, 3]. However, fistulotomy carries the risk of fecal incontinence due to the loss of sphincter function and a deformity of the anus resulting from the division of tissue encircled by the fistula [4, 5]. The rate of continence disturbance following fistulotomy has been reported to be as high as 58% and depends on factors such as fistula location, classification, baseline function, prior anal interventions, and obstetric history in women [1, 2, 4–8]. Due to the risk of incontinence, several sphincter-preserving operations have been advocated, including fibrin glue injection, anal fistula plug, the endorectal advancement flap, and more recently, the ligation intersphincteric fistula tract (LIFT) procedure [9–17]. Techniques such as fibrin glue and the fistula plug initially showed promise, but subsequent studies reported success rates between 14% and 24% [9–12]. In a recent review of modern studies, the endorectal advancement flap yielded an average success rate of 81% but was associated with an incontinence rate of 13% [14]. The LIFT procedure is the latest addition to the anal fistula surgical armamentarium, with early success rates ranging from 63% to 90% [16, 17].

The role of anal sphincter repair following obstetric trauma is well established [18, 19]. However, fistulotomy with immediate primary sphincteroplasty (FIPS) has not gained widespread acceptance as a standard treatment due to concerns regarding a potentially higher failure rate and increased risk of septic complications in the presence of an active fistula. Despite the relative paucity of prospective or randomized clinical trial studies, there has been a growing interest in this procedure recently [20, 21].

The aim of this study was to compare the fistula healing rate and postoperative infectious complications between patients who underwent FIPS and those who underwent fistulotomy without sphincter repair.

METHODS

Ethics statement

The study was approved by the Institutional Review Board of Kaiser Permanente Southern California (No. 5590). All patients were counseled about the surgical intervention, and written informed consent was obtained. The study was conducted in compliance with the ethical principles of the Declaration of Helsinki.

Study design and setting

A retrospective chart review was conducted of all consecutive patients with anal fistula of cryptoglandular origin who underwent FIPS or fistulotomy without primary sphincter repair over a 10-year period. All operations were performed by a single colon and

rectal surgeon (MAA) at Kaiser Permanente (Los Angeles, CA, USA). The choice of operation and selective addition of sphincter repair were based on the surgeon's judgment for patients perceived to be at higher risk for anal incontinence. This assessment took into account factors such as fistula complexity, including a high fistula tract, multiple fistulas, prior anal operations with some muscle loss (as in patients with a previous fistulotomy or sphincterotomy), and cases with borderline baseline sphincter tone from any cause, including prior obstetric injuries. Additionally, fistulotomy with sphincter reconstruction was performed when other sphincter-preserving techniques were not viable options based on individual case assessments. This included patients with prior failed fibrin glue, plug, or flap procedures; patients with anal scarring and some degree of stenosis; and patients with difficult body habitus and a posterior-based fistula who were not suitable candidates for a flap operation.

The exclusion criteria for this study were inflammatory bowel disease, prior radiation to the anorectal region, malignant fistulas, and the following fistula types: subcutaneous, horseshoe, rectovaginal, and rectourethral. The routine postoperative follow-up consisted of clinic visits at 1 week, 1 month, and 3 months, with additional visits as indicated by the clinical course. Patients with incomplete data or a follow-up period of less than 1 month were excluded from this study. Data were retrieved from electronic medical records and included the following parameters: demographics, fistula classification, number of fistula tracts, etiology of the fistula, and prior anal interventions. Fistula classification was based on preoperative 3-dimensional ultrasound findings in conjunction with intraoperative observations. Patients' baseline continence was documented as part of their clinical history without the use of standardized surveys. The primary outcome measures were fistula healing rate and postoperative septic complications. Fistula healing was defined by the absence of any symptoms reported by the patient (i.e., pain, drainage, swelling) and complete external skin healing without evidence of a skin opening or any manifestation of an active fistula. Postoperative septic complications were determined through a clinical evaluation based on patients' symptoms (i.e., increasing swelling with pain, fever, increasing drainage) and physical examination (i.e., cellulitis and/or abscess). Patients with abscesses were treated by local incision and drainage, and antibiotics were prescribed for both patients with abscesses and those with cellulitis. The length of follow-up for each patient was calculated from the day of the operation to the last recorded colorectal surgery clinic visit.

Surgical technique for fistulotomy with sphincter reconstruction

On the morning of the operation, preoperative rectal cleansing was performed using 2 rectal enemas. A single dose of intravenous cefazolin and metronidazole was administered preoperatively. Patients who underwent primary sphincter repair received an additional week of oral antibiotics postoperatively. All operations were conducted in the prone jackknife position under general or spinal anesthesia. If a draining seton was present, it was removed at the beginning of the operation. The anorectum was irrigated with betadine, and the Pratt bivalve speculum was used for exposure. A fistula probe was inserted from the external fistulous opening to the internal opening, and the fistula was gradually laid open with electrocautery. Granulation tissue was curetted, and the epithelialized fistula tract, including the edges of the mucosa surrounding the initial internal opening, was cauterized. At this stage of the operation, the degree of muscle involvement and fistula classification was confirmed through both palpation and visual inspection of the wound to assess the anatomy.

In cases of fistulotomy without sphincter repair in patients with long subcutaneous tracts, the edges of the wound were marsupialized using 3.0 Vicryl sutures in a running fashion. The anoderm

was tacked to the edge of the epithelialized fistula tract. For patients who underwent primary sphincter repair, the external sphincter and, in select cases, the internal sphincter muscle was approximated using 2.0 polydioxanone (PDS) sutures in a horizontal mattress fashion. Care was taken to completely obliterate the space behind the muscle repair to prevent the formation of another fistula. This was achieved by driving the needle with the suture through one cut end of the muscle, through the fistula tract bed, out of the other edge of the cut muscle, and going backward the same way to complete the horizontal mattress. In most patients, 2 to 4 horizontal mattress sutures were needed to perform the repair (Fig. 1). Upon completion of the muscle repair, a thin fistula probe was used to probe behind the muscle repair to ensure that the original area of the fistula tract had been completely obliterated. Finally, the edges of the wound were marsupialized by tacking the anoderm to the muscle repair using 3.0 Vicryl sutures in a running fashion (Fig. 2).

Statistical analysis

Statistical analysis was performed with IBM SPSS ver. 27.0 (IBM Corp). To analyze the significance of associations between the variables and postoperative outcomes in both comparison groups, 2-tailed P-values were calculated using Fisher exact probability test. The unpaired t-test was used to calculate the statistical signif-

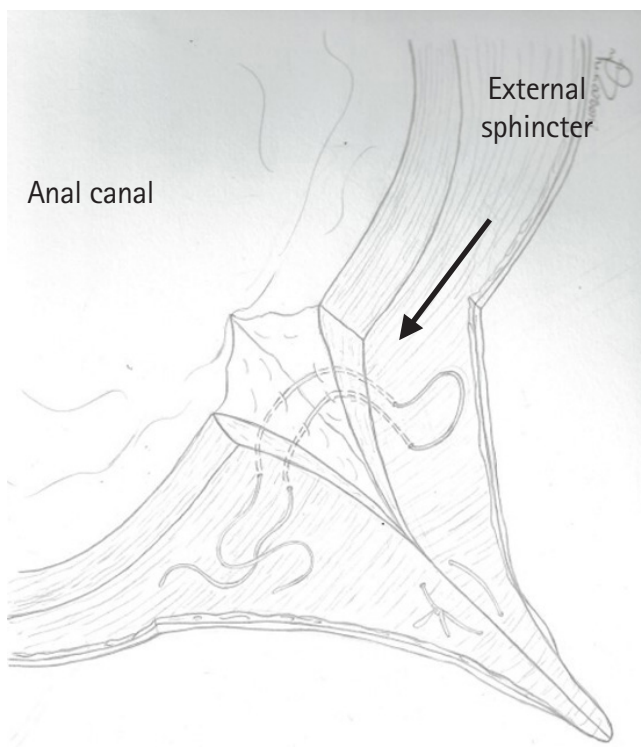


Fig. 1. External sphincter (arrow) repair with mattress sutures drawn by the authors.

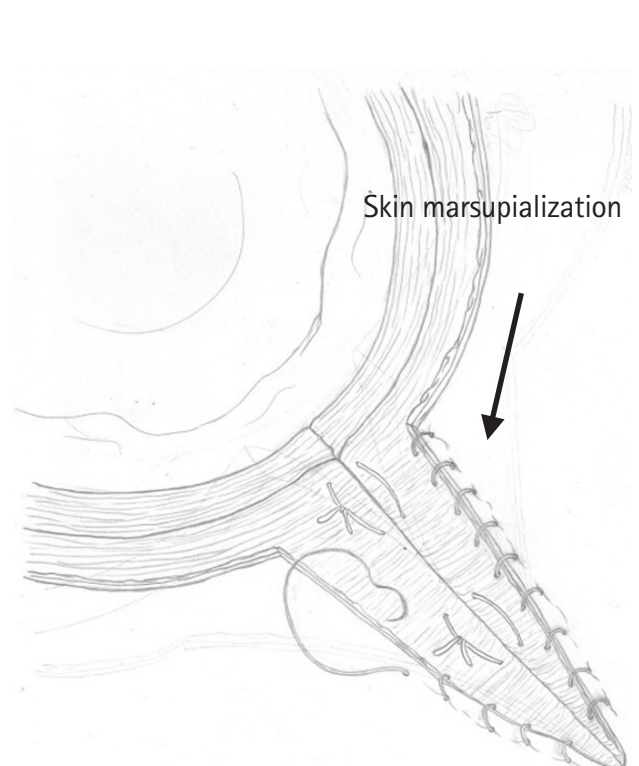


Fig. 2. Wound skin marsupialization (arrow) drawn by the authors.

incance of age and duration of follow-up for both groups. A P-value of <0.05 was the criterion for statistical significance.

RESULTS

A total of 152 patients met the eligibility criteria for inclusion in this retrospective review. Group A consisted of 45 patients who underwent FIPS, while group B comprised 107 patients who underwent fistulotomy without sphincteroplasty. **Table 1** summarizes the general characteristics of the groups. There was no significant difference between groups A and B in terms of median age (46 vs. 45 years, $P=0.16$) or male sex (80.0% vs. 88.7%, $P=0.20$). Group A had a higher proportion of multiple fistulas than group B (26.7% vs. 6.5%, $P<0.01$). Likewise, group A had a higher percentage of deeper fistulas (mid to high transsphincteric, 37.8% vs. 10.3%; $P<0.01$). No significant difference was observed between

the groups regarding prior surgical interventions to drain abscesses or treat fistulas. The baseline rate of continence disturbance was similar in both groups.

Table 2 presents the postoperative outcomes. The fistula healing rate at the last follow-up (with an overall median follow-up of 8 weeks) was comparable between both groups (93.3% vs. 90.6%, $P=0.76$). Likewise, there was no significant difference in postoperative septic complications ($P=0.42$). No dehiscence of the muscle repair was observed in group A. The development of new continence disturbances was also similar in both groups (17.8% vs. 14.0%, $P=0.62$).

DISCUSSION

Predictors of the outcomes of anal fistula surgery include patient-related features, fistula characteristics, and surgeon factors,

Table 1. Patient characteristics (n = 152)

Characteristic	Group A (n = 45)	Group B (n = 107)	P-value
Age (yr)	46 (26–76)	45 (22–72)	0.16
Sex			0.20
Male	36 (80.0)	95 (88.8)	
Female	9 (20.0)	12 (11.2)	
Type of fistula			<0.01
Single	33 (73.3)	100 (93.5)	
Multiple	12 (26.7)	7 (6.5)	
Fistula classification			
Intersphincteric	2 (4.4)	21 (19.6)	0.02
Low to mid transsphincteric	20 (44.4)	71 (66.4)	0.02
Mid to high transsphincteric	17 (37.8)	11 (10.3)	<0.01
Suprasphincteric	5 (11.1)	4 (3.7)	0.13
Extrasphincteric	1 (2.2)	0 (0)	0.29
Prior incision and drainage	28 (62.2)	55 (51.4)	0.28
Prior fistula surgery	21 (46.7)	62 (57.9)	0.22
Baseline incontinence	4 (8.9)	7 (6.5)	0.73
Gas	2 (50.0)	4 (57.1)	
Liquid and/or solid stool	2 (50.0)	3 (42.9)	

Values are presented as median (range) or number (%). Group A, patients who underwent fistulotomy with immediate primary sphincteroplasty. Group B, patients who underwent fistulotomy without sphincteroplasty.

Table 2. Postoperative outcome (n = 152)

Outcome	Group A (n = 45)	Group B (n = 107)	P-value
Healing rate	42 (93.3)	97 (90.6)	0.76
Postoperative sepsis	3 (6.7)	4 (3.7)	0.42
New postoperative incontinence	8 (17.8)	15 (14.0)	0.62
Gas	4 (50.0)	6 (40.0)	
Liquid and/or solid stool	4 (50.0)	9 (60.0)	
Follow-up (wk)	8 (1–77)	8 (1–170)	0.89

Values are presented as number (%) or median (range). Group A, patients who underwent fistulotomy with immediate primary sphincteroplasty. Group B, patients who underwent fistulotomy without sphincteroplasty.

such as the choice of operation and its technical conduct [1]. The first 2 factors are not modifiable, but the surgeon's choice of operation and its technical conduct can significantly impact the outcome. Failure of surgical intervention and/or the development of postoperative complications negatively affect the patient physically and emotionally, often resulting in additional interventions to treat complications and/or address persistent fistula. To date, fistulotomy remains the most effective and widely practiced operation for anal fistula [4, 22]. However, fistulotomy involves the division of the sphincter muscle for cure, and it has been associated with a risk of continence disturbance [3–8]. van Koperen et al. [5] reported the outcome of 179 patients who underwent fistulotomy or endorectal advancement flap. Postoperative soiling was noted in 40% of patients. Continence disturbance with either fistulotomy or the flap has prompted surgeons to explore less invasive operations that aim at muscle preservation. The last 2 decades have seen the introduction of several of these procedures, which involve injecting, filling, plugging, or obliterating the fistula tract [23]. Despite the early enthusiasm associated with the introduction of each new technique, the long-term results have been inferior to fistulotomy, and some of these options have been deemed ineffective. As we continue to pursue newer technologies to treat anal fistula, fistulotomy and fistulectomy remain common practices. A continued area of interest has been the impact of immediate sphincter reconstruction at the time of fistula removal [20, 21, 24–43]. Parkash et al. [24] reported the first modern series on FIPS in 1985. However, despite their initial report nearly 4 decades ago, FIPS has not gained wide acceptance due to concerns regarding both short- and long-term outcomes in terms of fistula healing and postoperative septic complications. Furthermore, the benefit of adding sphincteroplasty in the setting of anal fistula surgery has yielded mixed results [24–43]. Moreover, the practice of sphincteroplasty following obstetric trauma has been recently scrutinized due to its loss of effectiveness over the long run [18, 19, 44].

The current study aimed to answer 2 clinical questions: (1) Does the addition of sphincter repair at the time of fistulotomy impact the fistula healing rate? (2) Are there any adverse septic complications associated with muscle repair in a chronically infected field?

Despite a higher complexity of fistulas in the group that underwent FIPS, the healing rate was excellent and comparable to fistulotomy alone without sphincter reconstruction. Thus, in this study, fistula healing did not seem to be affected by the addition of sphincter repair. It is important to note that the technical steps of muscle reconstruction are simple but need to be carried out in a consistent manner, as described in the Methods section, to en-

sure complete obliteration of any potential tract.

Furthermore, despite muscle reconstruction in a chronically infected field, the rate of septic complications was low and similar to leaving the muscle divided without repair. Avoidance of postoperative sepsis is likely related to several factors: (1) adequate debridement of the fistulous tract and removal of all chronically infected granulating tissue to a clean tissue plane; (2) not mobilizing any muscle for an overlap; and (3) perioperative use of antibiotics. The edges of the divided muscle were opposed but not overlapped to avoid dissection of an additional portion of the sphincter muscle not involved in the fistula. All these factors contributed to a favorable postoperative outcome in patients who underwent FIPS.

However, the major limitation of this study was the lack of any meaningful conclusion related to the functional outcomes of FIPS. The retrospective nature of this study, the absence of detailed preoperative or postoperative surveys about anal continence, the length of follow-up, and the patient selection bias do not provide us with a definitive answer regarding the added functional benefits of muscle reconstruction at the time of fistulotomy. In this study, the surgeon determined whether sphincteroplasty should be added selectively based on the perceived increased risks of incontinence in a subgroup of patients, as described in the Methods section. It is conceivable that the continence disturbance in that higher-risk group could have been much higher if sphincter repair had not been undertaken at the time of fistulotomy. However, this assumption cannot be accepted without a randomized prospective clinical trial.

Table 3 [24–43] provides a summary of the majority of studies published thus far on FIPS. Notably, there is a scarcity of data, even though this procedure was introduced several decades ago. Moreover, most of the published studies are retrospective, with only a few prospective or randomized clinical trials. The cumulative findings of these studies have been previously summarized in 2 systematic reviews published in 2015 [20] and 2021 [21]. Fistula healing rates have been consistently high, ranging from 83.3% to 96.6%. The reported postoperative septic complications rate has been generally low, falling between 0% and 16.7%. Fewer than half of studies have reported on the integrity of sphincter repair. While most studies reported on superficial wound skin separation, the rate of muscle repair disruption has ranged between 0% and 25%. The published continence disturbance rate has ranged from 0% to 24%, but the data are limited due to several factors: (1) subjective reporting; (2) lack of questionnaires or incontinence surveys at baseline and postoperatively in most studies; (3) scarcity of physiologic testing data preoperatively and postoperatively; (4) baseline versus *de novo* incontinence; (5) inaccurate classification of patients with pseudoincontinence (i.e., drainage from fis-

Table 3. Summary of studies reporting the results of FIPS

Study	Study type	No. of patients	Mean follow-up (mo)	Healing rate (%)	Sphincter repair dehiscence (%)	Septic complication (%)	Postoperative continence disturbance (%)
Parkash et al. [24] (1985)	Retrospective	120	6–60 ^a	96.6	11.7	-	0
Christiansen and Rønholt [25] (1995)	Prospective	14	12–48 ^a	85.7	-	-	21.4
Gemsenjäger [26] (1996)	Retrospective	21	2–9 ^a	95.2	4.8	-	4.8
Toccali et al. [27] (1997)	Retrospective	36	12	-	8.2	-	0
Roig et al. [28] (1999)	Retrospective	31	24 ^b	90.3	3.2	3.2	24.0
Perez et al. [29] (2005)	Prospective	35	32	94.3	0	0	12.5
Perez et al. [30] (2006)	RCT	28	36	92.9	0	0	17.4
Jivapaisarnpong [31] (2009)	Prospective	33	14	87.9	-	6.1	0
Roig et al. [32] (2010)	Retrospective	75	13	89.4	1.3	-	21.3
Kraemer and Picke [33] (2011)	Retrospective	38	-	97.4	2.6	-	5.3
Arroyo et al. [34] (2012)	Retrospective	70	81	91.5	0	1.4	16.6
Ratto et al. [35] (2013)	Retrospective	72	29.4	95.8	1.4	0	11.6
Hirschburger et al. [36] (2014)	Retrospective	50	22	88.0	-	-	6.0
Seyfried et al. [37] (2018)	Retrospective	424	11	88.2	7.5	-	23.0
Litta et al. [38] (2019)	Retrospective	203	56	93.0	1.4	0	13.0
Farag et al. [39] (2019)	Retrospective	175	12	90.9	-	-	2.3
De Hous et al. [40] (2021)	Retrospective	24	6 ^b	95.8	25.0	-	20.8
Aguilar-Martínez et al. [41] (2021)	Retrospective	107	96 ^b	84.1	-	-	14.9
Orban et al. [42] (2021)	Retrospective	24	6	83.3	8.3	16.7	12.5
Jain et al. [43] (2022)	Prospective	35	6	88.6	-	20	5.7
This study (2023)	Retrospective	45	2 ^b	93.3	0	6.7	17.8

FIPS, fistulotomy with immediate primary sphincteroplasty; RCT, randomized controlled trial.

^aRange. ^bMedian.

tula interpreted as incontinence) versus true incontinence; (6) the heterogeneity of patients and fistulas (classification and prior intervention); and (7) subjective definitions of minor versus major incontinence by some authors. All these issues pose significant challenges in interpreting the data on functional outcomes. Furthermore, most studies have reported the results of FIPS without comparison to fistulotomy alone or an alternative technique such as the endorectal flap [24–43].

Despite these limitations, there is growing interest in FIPS. In 2011, FIPS was included in the German clinical practice guideline [45] as an option for patients with cryptoglandular-related fistula, with evidence level 1b and recommendation grade A based on strong consensus. However, it is important to note that in the recently published clinical parameters guidelines of the American Society of Colon and Rectal Surgeons (ASCRS) in 2022 [23], there is no mention of FIPS, and sphincteroplasty is solely described for female patients with rectovaginal fistula with sphincter defect or patients undergoing episiotomy for obstetric or cryptoglandular-related fistula. The omission of FIPS from the recently published guideline underscores the fact that this technique has not been widely accepted, practiced, or taught in residency or fellowship training programs in North America and

most other countries.

Fistulotomy remains the most effective method for eradicating anal fistulas, but it carries a risk of continence disturbance. This study demonstrates that performing immediate sphincter repair during fistulotomy appears to be safe, with a similar healing rate and no difference in septic complications. However, the impact of sphincter repair on long-term anal sphincter function could not be determined by this study due to its selection bias and retrospective nature. Although our personal belief and current practice involve routinely performing sphincter repair at the time of fistulotomy, a large multicenter randomized study is necessary to assess the immediate short-term outcomes of FIPS, as well as a comprehensive evaluation of preoperative and long-term functional results, in order to further evaluate the benefits of sphincter reconstruction.

ARTICLE INFORMATION

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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Author contributions

Conceptualization: all authors; Formal analysis: ATT, MA; Investigation: ATT, MA; Methodology: all authors; Resources: ATT, MA; Writing–original draft: MAA; Writing–review & editing: all authors. All authors read and approved the final manuscript.

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