

# Predictors of Long-Term Healing for Endorectal Advancement Flap for Anorectal Fistulas

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## Abstract

**Introduction** Anorectal fistulas are some of the commonest surgical proctologic disorders treated by surgeons. Despite the recent introduction of various sphincter preserving techniques, the search for the optimal operation continues. The purpose of this study was to determine the predictors of long-term healing for the endorectal advancement flap

**Methods** A retrospective review of a single surgeon experience with the endorectal advancement flap for anorectal fistulas over an 18-year period. The impact of various patient and fistula related factors were analyzed for their impact on the primary endpoint of long-term fistula healing

**Results** 87 patients underwent endorectal advancement flap (Male/Female 42.5/57.5%). Median age was 41 years. Sixty-nine patients (79.3%) had anal fistula while 18 patients had rectal fistula (20.7%). An anterior based fistula was noted in 45 patients (51.7%). The most common etiology was cryptoglandular disease (87.4%). The median operative time was 75 minutes (range 36-250). Postoperative septic complications were noted in 4 patients (4.6%). Fistula healing was documented in 80 patients (93%). During a median follow-up of 4 months (range 1-38, 1 patient lost to follow-up), recurrence was noted in 8 patients (9.3%), yielding an overall long-term success rate of 83.7%. The long-term healing rate was higher in patients with fistulas from cryptoglandular etiology (86.6%) compared to fistulas from other etiologies (63.6%) [ $p = 0.027$ ].

**Conclusions** The endorectal advancement is associated with a high healing rate, a low postoperative septic complication rate, and infrequent risk for recurrence. Long-term healing without recurrence is achieved more frequently in patients with cryptoglandular etiology of the fistula compared to patients with non-cryptoglandular etiology.

## Keywords

- ▶ anorectal fistula
- ▶ endorectal advancement flap
- ▶ healing
- ▶ predictor of outcome

## Introduction

Anorectal fistulas are some of the most common proctologic disorders surgically treated by general and colorectal surgeons. An anorectal fistula is an epithelial-lined connection between the anal canal or rectum and the perianal skin or

adjacent organs such as the vagina or urethra.<sup>1</sup> It is more common in men between the ages of 20 and 60 years. The prevalence of anal fistula is approximately 1.80 per 100,000 patients.<sup>2</sup>

The goals of anal fistula surgery are to eradicate or control the sepsis, minimize postoperative complications, and

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prevent recurrence. Although there is no “gold standard” treatment method for anorectal fistulas, numerous operations have been proposed over the last century. In general, the operations are divided into 2 main categories: sphincter preserving and non-sphincter preserving. In the last 2 decades, several sphincter preserving operations have been introduced to minimize the impact of intervention on anal sphincter function. Despite the addition of these new surgical techniques, the treatment of anorectal fistulas remains challenging for both patients and surgeons due to inconsistent results.<sup>3,4</sup> The choice of operation is based on several factors including etiology and anatomy of the fistula, prior surgical history, body habitus of the patient, baseline anorectal function, and familiarity of the surgeon with the various operations. While patients with superficial or low-lying fistulas can be often treated successfully with a single stage operation, patients with high or recurrent fistulas can pose significant challenges, with the surgeon balancing the success rate of the operation with the functional outcome.<sup>4-8</sup>

The endorectal advancement flap (ERF) procedure is a sphincter-sparing technique that aims to eradicate the internal focus of anal sepsis with a rectal flap coverage. Numerous articles have reported variable healing rates with this technique.<sup>7,9-12</sup> This variation in success rate can be attributed to various factors including patient selection heterogeneity, technical variations by surgeons, and length of postoperative follow-up. Due to this disparity in outcome, ERF has not been widely accepted and adopted by all surgeons. Furthermore, a paucity of data is available in the literature on the predictors of long-term outcome.

This aim of this study is to report the outcome of ERF and to analyze the impact of various patient and fistula related factors on long-term healing of the fistula.

## Material and Methods

### Patients

A retrospective review was performed of all ERF procedures performed by a colorectal surgeon between 2003 and 2021. Institutional approval was obtained to perform the study. Written informed consent was obtained from all patients prior to surgical intervention. Data abstracted included patient's demographics, fistula characteristics, intra-operative data, and postoperative outcome. The anatomical location of the fistula was classified according to the Parks classification system.<sup>13</sup> In many patients, routine postoperative follow-up in the clinic was obtained at 1 week, 1 and 3 months, and beyond 3 months if clinically indicated. Patient who did not return at 3 months were usually contacted by phone to document healing and lack of symptoms. Healing was defined as complete resolution of the patient's symptoms and closure of the external opening of the fistula. Recurrence was defined as interval development of new symptoms at the original fistula site after complete healing has been documented. The long-term healing rate was calculated by subtracting the recurrence rate from the initial healing rate.

### Surgical Technique

The technical steps of the procedure have been previously described.<sup>14</sup> All patients underwent a bowel preparation with 2 enemas. Intravenous antibiotics were administered with a second or third-generation cephalosporin and metronidazole in absence of a penicillin allergy. The operation was performed in the prone jackknife position under either a spinal or general anesthetic. After antiseptic irrigation of the rectum, the rectal wall was infiltrated with 1:100,000 lidocaine with epinephrine solution. When seton was present, it was removed, and the external skin opening was excised and enlarged to ensure proper drainage of the tract postoperatively. The tract was debrided from an external to an internal approach using a curette. A partial thickness advancement flap was raised, usually encompassing about 40 to 50% of the rectal circumference including the mucosa, submucosa, and a portion of the internal sphincter muscle fibers. The dissection was started approximately 1 centimeter distal to the internal opening. The base of the flap was twice as wide as the distal aspect to ensure good blood perfusion distally. The intramuscular portion of the internal opening was closed with absorbable 2.0 polyglactin (Ethicon Endosurgery, Ohio, USA). The distal lip of the flap containing the initial mucosal portion of the internal opening was excised and the flap was matured on its base using absorbable 3.0 polyglactin. The sutures were spaced in a way to even out the advancement in order to avoid any tension. The distal lip of the flap was matured 1 cm beyond the internal opening in order to avoid overlap of the intramuscular suture line.

### Postoperative Care

In most of the patients, ERF was performed either on an outpatient basis or with a 23-hour admission for observation. All patients resumed a regular diet the day of surgery. Pain control was achieved with paracetamol (acetaminophen) and non-steroidal anti-inflammatory medications. Severe pain was treated with oxycodone. All patients were discharged with daily fiber supplementation and 1 week course of oral antibiotics (usually a 2<sup>nd</sup> generation cephalosporin with metronidazole or ciprofloxacin with metronidazole).

### Statistical Analysis

The impact of various patient related factors and fistula characteristics was evaluated on long-term healing. The differences between independent variables were evaluated using the chi-square test. P value <0.05 was considered statistically significant.

## Results

87 patients underwent ERF during the study period [► **Table 1**]. Female gender comprised 57.5% of all patients. Median age at operation was 41 years (range 17-86). Median body mass index (BMI) was 27.2 kg/m<sup>2</sup> (range 19.4-56.5). Baseline continence disturbance was documented in 4 out of 80 patients (5%) (data not collected in 4 patients with fecal diversion and 3 patients undocumented). ► **Table 2** represents the fistula characteristics. Anal fistula was present in 79.3% of

**Table 1** Characteristics of 87 patients who underwent ERF

Characteristics	Number of Cases (%)
Gender	
Male	37 (42.5)
Female	50 (57.5)
Age	
≤40 years	38 (43.7)
> 40 years	49 (56.3)
BMI*	
≤30 kg/m <sup>2</sup>	40 (67.8)
> 30 kg/m <sup>2</sup>	19 (32.2)
Smokers	17 (19.5)
Diabetic	13 (14.9)
Baseline continence disturbance**	4 (5%)

\*reported in 59 patients.

\*\*data documented in 80 patients.

patients while 20.7% of patients had a rectal fistula. A low to mid transsphincteric fistula was noted in 35.6% of patients. An anterior based fistula was noted in 51.7% of cases. The most common etiology was cryptoglandular

**Table 2** Fistula characteristics in 87 patients with ERF

Characteristics	Number of Cases (%)
Type of Fistula	
Anal	69 (79.3)
Low to mid transsphincteric	31 (35.6)
High or suprasphincteric	25 (28.7)
Horseshoe	10 (11.5)
Anoperineal	3 (3.4)
Rectal	18 (20.7)
Rectovaginal	14 (16.1)
Rectourethral	4 (4.6)
Location of Fistula	
Anterior	45 (51.7)
Posterior	28 (32.2)
Not reported	14 (16.1)
Etiology	
Cryptoglandular disease	76 (87.4)
Inflammatory bowel disease	6 (6.9)
Radiation	2 (2.3)
Others	3 (3.4)
Previous Operations	
Abscess drainage	9 (10.3)
Draining seton	68 (78.2)
Definitive fistula surgery	18 (20.7)

disease 87.4%. Other etiologies are listed in ► **Table 2**. Draining seton placement prior to ERF was noted in 68 patients (78.2%) with a median duration of 12 weeks (range 4-68). Eighteen patients (20.7%) had prior definitive anal fistula surgery.

Seventy-six patients (87.4%) underwent ERF alone. ERF was combined with another procedure in 11 patients (12.6%) [► **Table 3**]. A second fistula was treated in 3 patients (3.4%); fistulotomy in 2 patients and the LIFT procedure in 1 patient. The addition of sphincteroplasty was done in 2 patients. In 5 patients (5.7%), a biologic mesh interposition was combined with ERF. Median operative time was 75 minutes (range 36-250). Median estimated blood loss was 5 milliliters (range 1-200). Fifty-three patients (60.9%) were admitted to inpatient setting with the majority staying for 23-hour observation (median length of stay 1 day, range 1-5). Four patients (4.6%) experienced septic postoperative complications requiring readmission with incision and drainage and/or antibiotics. Postoperative continence disturbance was documented in 9 out of 80 patients (11.25%) (data not collected in 2 patients with fecal diversion and in 5 patients was not documented).

Median follow-up time was 4 months (range 1-38) with only 1 patient lost to follow-up. Eighty patients (93%) had initial healing of the fistula. Recurrence of the fistula after initial healing was noted in 8 patients (9.3%) (► **Table 3**).

**Table 3** Intraoperative and postoperative outcome of 87 patients with ERF

Parameters	Number of Cases (%)
Type of surgery	
ERF only	76 (87.4)
ERF + biological mesh augmentation	5 (5.7)
ERF + sphincteroplasty	2 (2.3)
ERF + fistulotomy	2 (2.3)
ERF + LIFT	1 (1.1)
ERF + wart removal	1 (1.1)
Intraoperative time in minutes (range)	75 (36-250)
Estimated blood loss in milliliters (range)	5 (1-200)
Short-term outcomes	
Outpatient stay	34 (39.1)
Inpatient hospitalization	53 (60.9)
Postoperative septic complications	4 (4.6)
Long-term Outcome*	
Primary healing rate	80 (93.0)
Non-healing	6 (6.9)
Recurrence	8 (9.3)
Long-term healing	72 (83.7)
Postoperative continence disturbance**	9 (11.25%)

\*1 patient lost to follow-up.

\*\*documented in 80 patients.

**Table 4** Impact of various factors on long-term healing rate without recurrence

Parameters	Healed N = 72	Non-healed N = 14	P value
Gender			
Male	31 (83.8)	6 (16.2)	0.779
Female	41 (83.7)	8 (16.3)	
Age			
≤40 years	39 (81.3)	9 (18.7)	0.485
> 40 years	33 (86.8)	5 (13.2)	
BMI (N = 60)			
≤30 kg/m <sup>2</sup>	15 (83.3)	3 (16.7)	0.827
> 30 kg/m <sup>2</sup>	34 (80.9)	8 (19.1)	
Smoker	13 (76.5)	4 (23.5)	0.366
Non-Smoker	59 (85.5)	10 (14.5)	
Diabetic	11 (73.3)	4 (26.7)	0.230
Non-Diabetic	61 (85.9)	10 (14.1)	
Anal Fistula	55 (84.6)	10 (15.4)	0.692
Other Type of Fistula	17 (81.0)	4 (19.0)	
Low to mid transsphincteric Fistula	27 (87.1)	4 (12.9)	0.524
Other Type of Fistula	45 (81.8)	10 (18.2)	
Anterior Location (N = 45)	38 (84.4)	7 (15.6)	0.883
Posterior Location (N = 28)	24 (85.7)	4 (14.3)	
Cryptoglandular Etiology	65 (86.6)	10 (13.4)	0.027
Other Etiology	7 (63.6)	4 (36.4)	
Previous Fistula Surgery	52 (86.6)	8 (13.4)	0.261
Seton Insertion	58 (85.3)	10 (14.7)	0.442

\*1 patient lost to follow-up.

\*\*Data on 59 patients.

The overall long-term success rate of ERF (short-term healing without long-term recurrence) was 83.7%.

► **Table 4** reports the impact of various patient related factors and fistula characteristics on overall long-term healing rate. Fistulas from cryptoglandular etiology had a higher success rate compared to fistulas from other etiologies (86.6% vs. 63.6%,  $p=0.027$ ). Gender, age, obesity, smoking, diabetes, anal vs. rectal involvement, fistula classification and location, prior anal fistula surgery, or previous seton placement did not appear to impact long-term healing rate.

## Discussion

This study reported a single surgeon's experience with ERF. Healing without long-term recurrence was achieved in most patients. Patients with fistulas related to cryptoglandular disease had a higher healing rate compared to patients with fistulas from other etiologies. Postoperative septic complications were uncommon and long-term recurrence was low. Unlike most previously published studies on ERF, one of the strengths of this study is the standardized technical steps of

this operation performed by one surgeon without technical variability. Furthermore, standardization of the postoperative follow-up timing was achieved with complete data available in all patients except for 1.

ERF has been extensively studied and reported by various authors from around the world. Over a century ago, Elting reported an initial series of 96 patients with perianal fistula who were treated with a transanal advancement flap repair (TAFR) surgery. The surgery was successful in all cases and fecal incontinence was reported in only 4 cases (4.2%).<sup>15</sup> The 20th century saw several modifications of ERF technique for anal fistula.<sup>16,17</sup> However due to variable reported healing rate, ERF has not been widely adopted or accepted by most surgeons. Success rate of ERF varies widely in the literature and ranges from 30 to 100% with most studies reported a healing rate of over 60%.<sup>5</sup> In a review of 35 studies summarizing the outcome of over 2000 patients, Soltani and Kaiser presented a mean healing rate of 80.8% for cryptoglandular fistulas.<sup>5</sup> This is consistent with the results of our study which found a long-term success rate of 83.7%. However, Balciscueta and colleagues reported a rate of recurrence of 21% among several large-scale studies.<sup>18</sup>

It is important to note that while many studies have reported over the years the outcome of the endorectal advancement flap, to date a paucity of data exists on the factors that impact outcome. In this study, fistulas from cryptoglandular origin were associated with the highest long-term healing rate. Mizrahi and colleagues from the Cleveland Clinic Florida found that patients who underwent the advancement flap for Crohn's disease related fistulas had a higher recurrence rate compared to patients without Crohn's disease (57.1% vs. 33.3%,  $p=0.04$ ).<sup>7</sup> In our study, all other analyzed patient related factors and fistula characteristics did not seem to impact healing. Contrary to our findings, Schwandner reported a higher recurrence rate in obese patients.<sup>19</sup> In his review of 220 patients who underwent the endorectal advancement flap, patients with a BMI  $\geq 30$  kg/m<sup>2</sup> had a recurrence rate of 28% compared to 14% in patients with a BMI  $< 30$  kg/m<sup>2</sup> ( $p < 0.01$ ). Furthermore, the likelihood for reoperation in the setting of recurrence was higher in obese compared to non-obese patients (73% vs. 52%,  $p < 0.01$ ).<sup>19</sup> In our study, smoking was not associated with a lower healing rate. However, Zimmerman and colleagues found a lower healing rate in smokers compared to non-smokers (60% vs. 79%,  $p=0.037$ ).<sup>20</sup> In addition, they found that the number of cigarettes smoked per day inversely impacted the healing rate. Similarly, Ellis and Clark previously reported that tobacco smoking increased the risks for recurrence.<sup>21</sup> There is a paucity of data on the impact of prior anal fistula repair on successful healing. Ellis and Clark found that a prior history of anal fistula repair increased the rate of long-term failure. Abbas and colleagues reported a higher failure rate of the endorectal advancement flap in patients who had previously undergone repair of recurrent rectovaginal fistula.<sup>22</sup> In the current study, the location and classification of the fistula did not appear to influence the long-term healing rate. Interestingly, van Onkelen and colleagues found significantly less failures of the flap in patients with horseshoe extension, which is conventionally considered the most complex form of fistula.<sup>23</sup> Furthermore, most horseshoe fistulas are posteriorly based, a finding that add to the technical difficulty and complexity of raising a flap due to the limited proximal exposure related to the sharp angulation of the anorectal junction.

The selection of treatment of anal fistula should be made according to the patient related factors, the fistula characteristics, prior operations, and baseline continence level. While the primary goal of anal fistula surgery is to eradicate the fistula and control the sepsis, it has to be balanced with the long-term functional outcome and preservation of continence to the extent possible. Due to the complexity of anal fistula, heterogeneity of outcome for the various surgical options, no standardized algorithm for the treatment of anal fistula has gained broad consensus. While many studies have previously reported on the healing rate following ERF, functional outcome data has not been routinely documented using standardized fecal incontinence questionnaires. Schouten and Zimmerman reported a negative impact on function with impaired continence in 35% of the patients who underwent ERF for trans-sphincteric fistulas.<sup>16</sup> A recent report by Chaveli Diaz

examined the long-term recurrence and anal continence of patients with anal fistula treated by fistulectomy and ERF repair.<sup>1</sup> Anal continence was reported in 63.8% at 1-year follow-up, 71.5% at the end of follow-up of 10 years, and with worsening of continence postoperatively in 16.9% of cases. The authors claimed that neither recurrence nor continence was significantly correlated with previous anal or fistula surgical procedures or complexity of the fistula.<sup>1</sup> In our study, no formal questionnaire was used to evaluate the patient continence level at baseline or postoperatively. Part of obtaining the patients' initial history and assessing their postoperative recovery, they were asked about any urge or passive incontinence to gas, liquid, and/or solid stool. This cursory data was available in 80 patients and revealed slight deterioration in continence level postoperatively. Mizrahi and colleagues reported postoperative deterioration of continence in 9% of their patients and noted this finding more commonly in patients with prior surgical repair ( $p < 0.02$ ).<sup>7</sup> Their findings were similarly observed in our study.

One of the challenges in interpreting the literature on continence function following anal fistula treatment is the lack of routine use of standardized fecal incontinence questionnaire in most of the studies. This is compounded by the inability to obtain accurate baseline physiologic studies such as anorectal manometry and rectal compliance in patients with active anal fistula due to the discomfort associated with testing. Furthermore, the heterogeneity of patient population and fistula characteristics in the studies limits the accuracy of comparison between studies. Incontinence is a complex phenomenon involving anal sphincter function, pelvic floor dynamics, and large bowel function. Moreover, the variability in patient's follow-up can lead to suboptimal evaluation of functional outcome. In addition, the reluctance of patients to inform their physicians about continence disturbance due to embarrassment cannot be discounted.<sup>24,25</sup>

The limitations of most studies published on ERF include 1 or more factors such small sample size, heterogeneity of the patients' fistula characteristics, lack of technique standardization, the participation of several surgeons with various experience, the lack of objective assessment of continence, and inadequate postoperative follow-up.<sup>20</sup> While the majority of anorectal fistulas are caused by cryptoglandular infections, other conditions include atypical infections, inflammatory bowel disease (Crohn's disease), trauma, childbirth, radiation, and malignancy. While some studies report on the etiology of the fistula and classifications, a comprehensive set of data is frequently absent. These limitations of past and the current study can only be overcome by a large scale multicenter prospective clinical trial that can explore the impact of the various patients and fistula related characteristics on long-term outcome. Such trial should include baseline and postoperative evaluation of anal continence by questionnaire and physiologic testing.

## Conclusions

In this retrospective review of a single surgeon's experience over nearly 2 decades, the surgical outcome of ERF was very

favorable with a high healing rate, low postoperative complication rates, infrequent recurrence, and low risk for continence disturbance. Patients with fistula from cryptoglandular origin carried a higher success rate. Due to the limitations of this study and the existing scientific literature on the endorectal advancement flap, a multicenter prospective clinical trial is advisable to further delineate factors that impact long-term outcome in terms of healing and function. Such trial can identify the ideal candidates for the endorectal advancement flap and define the role of this operation within an algorithmic based treatment decision for patients with anal fistula in view of the growing number of operations advocated in the modern surgical era.

#### Conflict of Interest

None declared.

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