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Transanal OPening of the Intersphincteric Space (TROPIS) for Anal Fistula: High Overall Healing Rates but Divergence Between Simple and Complex disease — A Prospective Pilot Study

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Research Article

Keywords: Anal fistula, TROPIS, sphincter-preserving surgery, complex fistula; freedom from recurrence, continence preservation

Posted Date: June 16th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9677403/v1

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Additional Declarations: No competing interests reported.

Abstract

Background

The management of anal fistula requires a balance between eradication of sepsis and preservation of continence. Transanal opening of the intersphincteric space (TROPIS) is a sphincter-preserving technique with encouraging early results, although comparative outcomes between simple and complex fistulas remain limited.

Methods

This prospective pilot cohort study included 72 consecutive patients with cryptoglandular anal fistula treated using TROPIS between January 2023 and June 2025. All patients underwent preoperative magnetic resonance imaging. Fistulas were classified as simple (n = 27) or complex (n = 45). Primary outcomes were primary and overall healing. Secondary outcomes included healing time, continence using the Cleveland Clinic Incontinence Score (CCIS), and freedom from recurrence using Kaplan–Meier analysis.

Results

Primary healing (80.6% overall) was significantly higher in simple versus complex fistulas (96.3% vs 71.1%, p = 0.012). After reintervention, the overall healing rate reached 93.1%, with no significant between-group difference. Median healing time was shorter in simple fistulas (31 vs 45 days, p = 0.0006). Continence was preserved, with no major incontinence recorded. On multivariable analysis, fistula complexity was the only independent predictor of primary healing failure (OR 0.06, 95% CI 0.01–0.51, p = 0.010). Kaplan–Meier analysis demonstrated significantly worse freedom from recurrence in complex fistulas (log-rank p = 0.004).

Conclusion

TROPIS achieved high overall healing rates with excellent continence preservation. Complex fistulas demonstrated lower primary healing and worse freedom from recurrence, despite comparable overall healing after reintervention.

1. Introduction

Anal fistula is a chronic anorectal condition arising most commonly from cryptoglandular infection, characterized by a persistent epithelialized tract between the anal canal and perianal skin.[1,2] Despite being a benign disease, it poses significant clinical challenges due to its tendency for recurrence and its

potential impact on continence, particularly in complex cases.[3] The management of anal fistula therefore requires a careful balance between eradication of sepsis and preservation of sphincter function.

While fistulotomy remains the gold standard for simple fistulas, its application in high or complex fistulas is limited by the risk of sphincter injury and subsequent incontinence.[4] Consequently, sphincter-preserving procedures such as ligation of the intersphincteric fistula tract (LIFT), advancement flap, and other minimally invasive approaches have gained increasing attention.[5] However, outcomes remain variable and no single technique has demonstrated consistent superiority. A recent meta-analysis of LIFT involving 1,378 patients reported a pooled success rate of approximately 76.5%, with failure associated with horseshoe configuration, previous surgery, and Crohn's disease.[6] These findings highlight the persistent limitations of current approaches, particularly in complex fistulas.

The underlying reason for these suboptimal outcomes may relate to incomplete control of infection within the intersphincteric space. Emerging evidence suggests that persistent sepsis in this anatomical compartment plays a central role in fistula maintenance and recurrence.[1,2] In this context, newer techniques have shifted focus toward adequate drainage of the intersphincteric tract. The PERFACT (Proximal superficial cauterization, Emptying Regularly Fistula tracts And Curettage of Tracts) procedure represents one such approach, achieving an overall healing rate of approximately 80% without deterioration in continence in a prospective series.[7]

The transanal opening of the intersphincteric space (TROPIS) has been proposed as a modification of this concept, aiming to directly deroof the intersphincteric space and allow continuous drainage into the anal canal, thereby addressing the primary source of infection while preserving sphincter integrity.[8] Early clinical studies have reported encouraging results, particularly in complex fistulas, with high healing rates and minimal impact on continence.[9,10] A recent systematic review and meta-analysis further confirmed the efficacy and safety of TROPIS across a range of fistula types.[11,12] However, comparative evidence across varying degrees of fistula complexity — particularly using time-to-event analyses — remains limited.

Therefore, the present pilot study aimed to evaluate the clinical outcomes of TROPIS in a prospective cohort, with particular emphasis on comparing primary healing, overall healing, and freedom from recurrence between simple and complex fistulas.

2. Methods

Study design and setting

This prospective pilot cohort study was conducted at Viet Duc University Hospital, Hanoi, Vietnam (IRB approval No. 1275/QĐ-VĐ), and is reported in accordance with STROBE guidelines. Seventy-two consecutive patients with cryptoglandular anal fistula who underwent TROPIS between January 2023

and June 2025 were included. Written informed consent was obtained from all participants. As a pilot study, a formal a priori sample size calculation was not performed; findings are hypothesis-generating and intended to inform future comparative trials.

Patient selection

Patients aged ≥ 18 years with cryptoglandular anal fistula who underwent TROPIS as the primary surgical treatment were included. Exclusion criteria were fistula associated with Crohn's disease, tuberculosis, or malignancy, and incomplete follow-up data.

Fistula classification

Fistulas were classified according to the Parks system.[5] Transsphincteric fistulas (type II) were further subclassified by height of external sphincter involvement into types 2a (lower third), 2b (middle third), and 2c (upper third), following the approach of Garg et al.[13] Fistulas were categorized as simple (types I and 2a) or complex (types 2b, 2c, and III). All patients underwent preoperative MRI, with fistula anatomy graded using the St. James University Hospital classification.[14]

Surgical procedure

All procedures were performed under spinal anaesthesia with the patient in the lithotomy position. A Hill-Ferguson retractor was used to expose the anal canal. The internal opening was identified using probe exploration and hydrogen peroxide injection through the external opening, with localisation corroborated by preoperative MRI findings.

A curved artery forceps was inserted through the internal opening into the intersphincteric tract, and the overlying mucosa and internal anal sphincter were incised with monopolar electrocautery along the course of the tract. Wound edges were trimmed to create a saucer-shaped cavity, and a short vertical incision was made inferiorly to the anal verge to facilitate postoperative drainage. Secondary intersphincteric extensions were addressed at the same setting. The external anal sphincter was preserved throughout.

The extrasphincteric tract in the ischiorectal fossa was debrided from the external opening, and a soft silicone tube drain was placed up to the level of the external sphincter and secured to the perianal skin with a 2 – 0 nylon suture. Both wounds were left open to heal by secondary intention, with daily wound care from postoperative day one. The drain was removed upon confirmed healing of the intersphincteric wound.

Outcomes and follow-up

Patients were followed until complete wound healing (typically within 3 months) then reviewed if symptoms recurred. Follow-up data were collected until 30 April 2026. Primary healing was defined as complete epithelialization without reintervention after the initial procedure. Overall healing included

healing after one or more reinterventions. Reintervention was the composite Kaplan–Meier endpoint, encompassing both primary failure and true recurrence (re-emergence after confirmed healing). Continence was assessed using the Cleveland Clinic Incontinence Score (CCIS; 0–20) preoperatively and at last follow-up.

Statistical analysis

Continuous variables are reported as mean ± SD or median (interquartile range (IQR)) according to data distribution assessed using the Shapiro–Wilk test. Categorical variables are presented as frequencies and percentages. Between-group comparisons were performed using the independent t-test or Mann–Whitney U test for continuous variables, and Fisher's exact test for categorical variables. Multivariable logistic regression analysis was performed to identify factors associated with primary healing, adjusting for age and prior surgical history. Freedom from recurrence was estimated using Kaplan–Meier analysis and compared using the log-rank test. All analyses were performed using IBM SPSS v26.0 (IBM Corp., Armonk, NY, USA), with a two-sided p-value < 0.05 considered statistically significant

3. Results

Baseline characteristics

A total of 72 patients were included, comprising 27 with simple fistulas and 45 with complex fistulas. Median follow-up was 21.7 months (IQR 14.5–29.4 months; range 3.5–52.2 months). Baseline characteristics are presented in Table 1. Patients in the complex group were significantly older (42.8 ± 14.0 vs 35.2 ± 8.9 years, p = 0.034) and more likely to have had previous fistula surgery (33.3% vs 11.1%, p = 0.049). Operative time and hospital stay were significantly greater in the complex group. There were no significant differences in sex or BMI.

Table 1
Baseline characteristics

Variable	Simple (n = 27)	Complex (n = 45)	p-value
Age (years), mean ± SD	35.2 ± 8.9	42.8 ± 14.0	**0.034**
Male sex, n (%)	26 (96.3%)	39 (86.7%)	0.244
BMI (kg/m²), median (IQR)	23.9 (22.1–25.7)	23.3 (22.0–24.0)	0.246
Previous surgery, n (%)	3 (11.1%)	15 (33.3%)	**0.049**
Operative time (min), median (IQR)	25 (15–30)	30 (25–35)	**0.008**
Hospital stay (days), median (IQR)	4 (3–5)	5 (5–7)	**0.003**

BMI: body mass index; IQR: interquartile range. Bold p-values indicate p < 0.05.

Fistula classification

Fistula types are summarized in Tables 2 and 3. The majority were transsphincteric fistulas (Parks types 2a–2c, 80.5%). On St. James grading, most patients had grade 3 (33.3%) or grade 4 (51.4%) disease.

Table 2
Fistula classification (Parks)

Type	n	%
Type 1 (intersphincteric) — Simple	5	6.9
Type 2a (low transsphincteric) — Simple	21	29.2
Type 2b (mid transsphincteric) — Complex	23	31.9
Type 2c (high transsphincteric) — Complex	14	19.4
Type 3 (suprasphincteric) — Complex	8	11.1
Other	1	1.4
Total	**72**	**100.0**

Table 3
Fistula classification (St. James University Hospital)

Grade	n	%
Grade 1	3	4.2
Grade 2	2	2.8
Grade 3	24	33.3
Grade 4	37	51.4
Grade 5	6	8.3
Total	**72**	**100.0**

Treatment outcomes

Primary healing was achieved in 58 patients (80.6%). Primary healing was significantly higher in simple fistulas (96.3% vs 71.1%, p = 0.012). After reintervention, overall healing was achieved in 67 patients (93.1%), with no significant difference between groups (100% vs 88.9%, p = 0.150

Table 4).

Table 4
Treatment outcomes by fistula complexity

Outcome	Simple (n = 27)	Complex (n = 45)	p-value
Primary healing, n (%)	26 (96.3%)	32 (71.1%)	**0.012**
Overall healing, n (%)	27 (100%)	40 (88.9%)	0.150

Multivariable analysis

On multivariable logistic regression, complex fistula was the only independent predictor of primary healing failure (OR 0.06, 95% CI 0.01–0.51, p = 0.010; Table 5). Neither age (OR 1.04, 95% CI 0.99–1.09, p = 0.136) nor previous surgery (OR 2.53, 95% CI 0.56–11.45, p = 0.228) reached significance after adjustment, indicating that group differences in primary healing reflect fistula complexity rather than patient-level confounding.

Table 5
Multivariable logistic regression — predictors of primary healing

Variable	OR	95% CI	p-value
Age (per year)	1.04	0.99–1.09	0.136
Previous surgery	2.53	0.56–11.45	0.228
Complex fistula	**0.06**	**0.01–0.51**	**0.010**

OR: odds ratio; CI: confidence interval. OR < 1 indicates lower odds of primary healing.

Management of primary failure

Among 14 patients with primary failure, six underwent repeat TROPIS (5 healed, 1 recurrence), five were managed with abscess drainage alone (all healed), two underwent surgery at other institutions (counted as failures), one had cutting seton placement, and one had persistent non-healing (Table 6). Notably, resolution with abscess drainage alone suggests that some failures represent residual localized infection rather than a persistent fistula tract.

Table 6
Management of primary failure (n = 14)

Strategy	n	Outcome
Repeat TROPIS	6	5 healed; 1 recurrence
Abscess drainage only	5	All healed
Surgery at other institutions	2	Considered failure
Cutting seton	1	Healed (considered failure of TROPIS)
No reoperation	1	Persistent non-healing

Healing time

Among patients who achieved healing (n = 68), median healing time was significantly shorter in simple fistulas (31 days, IQR 26–41) compared with complex fistulas (45 days, IQR 39–55; p = 0.0006; Table 7). Patients with persistent non-healing (n = 4, all complex) were excluded.

Table 7
Healing time by fistula complexity

Group	n	Median (IQR), days	Mean ± SD, days	p-value
Simple	27	31 (26–41)	37.0 ± 16.0	
Complex	41	45 (39–55)	46.2 ± 10.8	**0.0006**

IQR: interquartile range. Patients with persistent non-healing excluded (n = 4, all complex). Mann–Whitney U test.

Continence outcomes

All 72 patients had a preoperative CCIS of 0. The mean postoperative CCIS was 0.09 (range 0–1); only 3 patients (4.2%) reported minor incontinence (CCIS = 1), all in the complex group. No cases of major incontinence were recorded.

Freedom from recurrence

Fourteen reintervention events were recorded: 1 in the simple group (3.7%) and 13 in the complex group (28.9%). Kaplan–Meier analysis demonstrated significantly worse freedom from recurrence in complex fistulas (log-rank p = 0.004; Fig. 1). Estimated freedom from recurrence for the overall cohort was 87.4% at 12 months and 71.9% at 24 months.

4. Discussion

The present pilot study demonstrates that TROPIS is an effective and safe sphincter-preserving technique for anal fistula management, achieving an overall healing rate of 93.1% without a significant deterioration in continence. These findings are consistent with the recent systematic review by Cui et al.,[12] which reported pooled healing rates of 80–88% for TROPIS, and support its reproducibility in a tertiary center setting.

A key observation is the divergence between primary and overall healing outcomes. Primary healing was significantly higher in simple fistulas (96.3% vs 71.1%, p = 0.012), indicating that fistula complexity influences early treatment success. However, after reintervention, overall healing rates became comparable (100% vs 88.9%, p = 0.150), consistent with results reported by Garg et al. in a large single-center series[9] and by Pehlevan-Özel et al. in a long-term follow-up study.[10] This pattern suggests that while TROPIS achieves high final healing rates across all fistula types, complex fistulas are more likely to require additional procedures, with implications for patient counseling.

Multivariable logistic regression confirmed that fistula complexity was the only independent predictor of primary healing failure (OR 0.06, 95% CI 0.01–0.51, p = 0.010) after adjustment for age and prior surgical history. Neither covariate was independently associated with healing failure, suggesting that the observed group differences were primarily related to anatomical complexity rather than patient-level confounding. Previous studies have identified prior surgery and complex anatomy as risk factors for failure across multiple techniques,[3,6] and our multivariable analysis clarifies their independent contributions in the specific context of TROPIS.

Kaplan–Meier analysis revealed a significant difference in freedom from recurrence between simple and complex fistulas, with 13/45 reintervention events in the complex group versus 1/27 in the simple group. The estimated freedom from recurrence was 87.4% at 12 months and 71.9% at 24 months. This time-to-event analysis demonstrates that crude healing rates alone underestimate the true differences between groups, and highlights the importance of Kaplan–Meier methodology in fistula outcome reporting — an approach that remains underutilized in many published series.

When compared with other sphincter-preserving techniques, TROPIS demonstrates at least comparable outcomes. LIFT has reported pooled success rates of approximately 76.5%,[6] while PERFACT achieved approximately 80% healing in prospective series.[7] The meta-analyses by Wang et al.[11] and Cui et al.[12] confirm that TROPIS achieves favorable continence outcomes relative to these alternatives, as it avoids sphincter division entirely. By deroofing the intersphincteric space, TROPIS converts a closed infected cavity into an open, well-drained tract, addressing the primary source of persistent intersphincteric sepsis[1,2] — a mechanism that may be more robust in complex fistulas with irregular or branching tract anatomy.

An important methodological feature of this study is the subclassification of transsphincteric fistulas into types 2a, 2b, and 2c based on sphincter height, following the framework of Garg et al.[13] This refined classification provides additional prognostic information beyond the traditional Parks system, as higher

fistulas involve a greater proportion of the sphincter and are anatomically more challenging. This may partly explain the longer healing time and higher reintervention rate in complex fistulas. Routine preoperative MRI, performed in all patients, further facilitated accurate anatomical characterization and surgical planning, consistent with established evidence supporting its role in fistula assessment.[14,15]

The heterogeneous management of primary failure reflects real-world practice. Notably, five patients achieved resolution with abscess drainage alone, suggesting that some failures represent residual localized infection rather than a persistent fistula tract. All patients had a preoperative CCIS of 0; the mean postoperative score was 0.09, with only three patients (4.2%) reporting minor incontinence (CCIS = 1), all in the complex group. These continence outcomes compare favorably with fistulotomy,[4] which carries incontinence risks of up to 30–40% in high fistulas, and support TROPIS as the preferred approach when sphincter preservation is a priority.

Limitations

This study has several limitations. It was conducted at a single center without a control group, limiting direct comparison with alternative techniques. As a pilot study without a priori sample size calculation, findings are hypothesis-generating and should be validated in larger comparative trials. The timing of recurrence was approximated by date of reoperation, introducing potential inaccuracy in Kaplan–Meier estimates. Management of primary failure was not standardized, and patient-reported quality-of-life outcomes were not assessed. Finally, residual confounding cannot be excluded given the observational design, and formal correlation of St. James MRI grading with outcomes was beyond the scope of this analysis.

5. Conclusion

In this prospective pilot cohort, TROPIS achieved a high overall healing rate of 93.1% with excellent continence preservation across both simple and complex anal fistula. Although primary healing was significantly higher in simple fistulas, overall healing rates became comparable after reintervention. Multivariable analysis identified fistula complexity as the sole independent predictor of primary healing failure (OR 0.06, 95% CI 0.01–0.51, p = 0.010), independent of age and prior surgical history.

Despite comparable overall healing, Kaplan–Meier analysis demonstrated significantly worse freedom from recurrence in complex fistulas (log-rank p = 0.004), with earlier and more frequent reintervention events. These time-to-event data highlight that crude healing rates alone underestimate the clinical burden of complex disease, and that close postoperative surveillance is warranted in this group.

These findings support TROPIS as an effective and safe sphincter-preserving option across the spectrum of anal fistula complexity. Further prospective comparative studies with larger sample sizes, standardized reintervention protocols, and patient-reported outcome measures are needed to confirm these results and to define the optimal role of TROPIS relative to other sphincter-preserving techniques.

Declarations

Author Contribution

(Contributor Roles Taxonomy)Author contributions are reported according to the CRediT taxonomy:• Conceptualization: Phuc Khanh Pham, • Data curation: Phuc Khanh Pham, Tat Thanh Do, Dac Thao Nguyen• Formal analysis: Phuc Khanh Pham, Nhat Huy Le, Dac Thao Nguyen• Investigation: Phuc Khanh Pham, Thi Thanh Huyen Pham• Methodology: Phuc Khanh Pham, Thi Thanh Huyen Pham, Thi Ly Nguyen• Project administration: Tat Thanh Do, Nhat Huy Le• Resources: Tat Thanh Do, Nhat Huy Le• Software: Tat Thanh Do, Nhat Huy Le• Supervision: Phuc Khanh Pham, Mathew Rickard• Validation: Phuc Khanh Pham, Mathew Rickard• Visualization: Phuc Khanh Pham, Dac Thao Nguyen• Writing – original draft: Phuc Khanh Pham, Thi Ly Nguyen, Mathew Rickard• Writing – review & editing: Phuc Khanh Pham, Mathew RickardAll authors have read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Data Availability

Data availability statementThe data that support the findings of this study are available from the corresponding author upon reasonable request. Anonymized data will be shared in compliance with applicable data protection regulations.

Ethics statement. *This study was reviewed and approved by the Institutional Review Board of Viet Duc University Hospital, Hanoi, Vietnam (Approval No. 1275/QĐ-VĐ). All procedures involving human participants were performed in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. Written informed consent was obtained from all individual participants included in the study prior to their enrolment.*

Consent to Participate: *Written informed consent was obtained from all individual participants included in this study prior to their enrolment. Participants were informed of the study objectives, procedures, potential risks and benefits, and their right to withdraw at any time without consequence to their clinical care.*

External Funding*: This study received no external funding*

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Figures

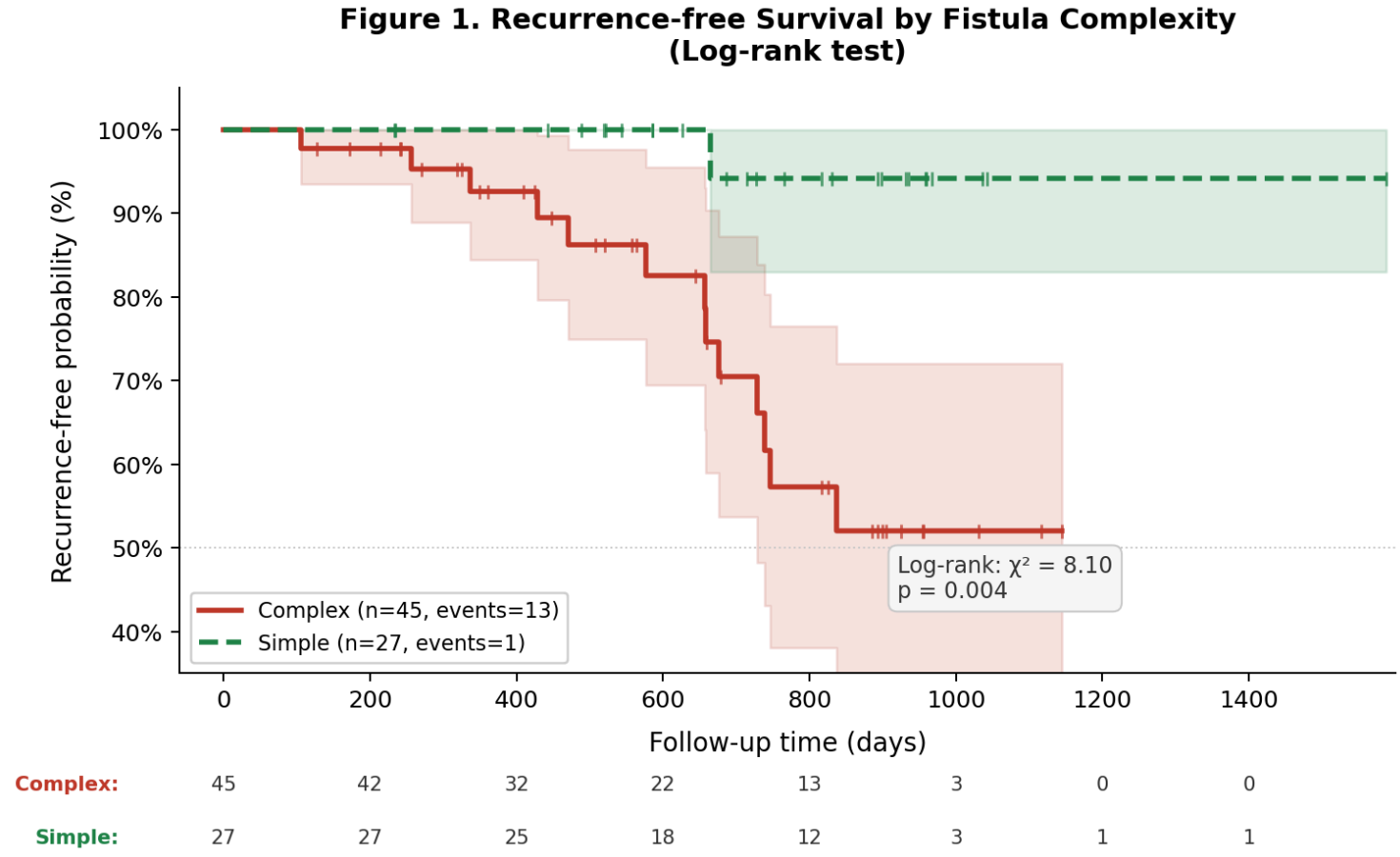


Figure 1

Kaplan–Meier freedom from recurrence curves by fistula complexity (log-rank p = 0.004)