

Original Research

Received 20 May 2026

Revised 26 June 2026

Accepted 14 July 2026

Natural Resources for Human Health 2026, Vol. 6 (7s): 581–587

KEYWORDS:

Anal fistula; FiXcision device; Fistulectomy; Ligation of intersphincteric fistula tract; Sphincter-preserving surgery .

Comparative Study of the FiXcision Device and the Ligation of Intersphincteric Fistula Tract Procedure for the Management of Fistula in Ano

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ABSTRACT:

Introduction: Fistula-in-ano is an anorectal disorder that requires complete eradication of the fistulous tract while preserving anal sphincter function. Procedures like ligation of intersphincteric fistula tract have gained acceptance; while newer approaches like FiXcision device have been introduced to improve healing and reduce morbidity. Aim: To compare the clinical outcomes of fistulectomy using FiXcision device versus ligation of intersphincteric fistula tract in patients with intersphincteric and transsphincteric fistula-in-ano.

Methods: Study included 100 patients with fistula-in-ano. Group A underwent fistulectomy using the FiXcision device (n=50) and Group B underwent the ligation of intersphincteric fistula tract procedure (n=50). Operative findings, postoperative pain scores, wound healing, complications, hospital stay, time to return to normal activity, continence status, and histopathological findings were analysed. Statistical significance was set at $p < 0.05$.

Results: Mean operative time was shorter in Group A compared to Group B (28.4 SD5.1 versus 31.2 SD6.8 minutes; $p = 0.003$). Intraoperative blood loss was higher in Group A ($p < 0.001$). Postoperative pain, analgesic requirement, hospital stay, number of dressing changes, and time to return to work were lower in Group B ($p < 0.001$). Wound healing occurred earlier with Group B. Early complications were frequent in the Group A. Minor transient incontinence occurred in a few patients of Group A.

Conclusion: Both procedures achieved healing with preservation of continence. Group B demonstrated better early postoperative outcomes, faster recovery, fewer complications, and earlier wound healing, making it a favourable sphincter-preserving option in present study.

INTRODUCTION

Fistula-in-ano is a chronic inflammatory condition characterized by an abnormal communication between the anal canal and the perianal skin, most commonly resulting from cryptoglandular infection of the anal glands [1]. It is a common anorectal disorder with an estimated incidence of 1–2 cases per 10,000 population annually and shows a clear male predominance [2]. Persistent discharge, recurrent perianal abscesses, pain, and local discomfort significantly impair quality of life and often necessitate surgical intervention.

The cryptoglandular hypothesis explains the pathogenesis of fistula-in-ano as originating from infected anal glands located at the dentate line, with subsequent spread into the intersphincteric space and beyond [3,4]. Based on their anatomical relationship to the sphincter complex, fistulas are classified as intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric [5]. Among these, intersphincteric and transsphincteric fistulas are the most frequently encountered in clinical practice.

The primary objective of surgical management is complete eradication of the fistulous tract while preserving anal sphincter function and preventing recurrence [6]. Conventional procedures such as fistulotomy and fistulectomy are associated with high healing rates in low fistulas but carry a significant risk of sphincter damage and postoperative fecal incontinence when applied to higher or more complex fistulas [7,8]. This has led to the development of several sphincter-preserving techniques.

Ligation of the intersphincteric fistula tract, involves identification and ligation of the fistulous tract within the intersphincteric plane, thereby eliminating the source of infection without dividing the sphincter muscles [9]. The ligation of intersphincteric fistula tract procedure has gained widespread acceptance due to its technical simplicity, favourable healing rates, and low incidence of postoperative incontinence, particularly in transsphincteric fistulas [10–12]. However, failure rates have been reported, often attributed to difficulty in identifying the tract, fibrosis, residual infection, or incomplete ligation [13].

FiXcision device is a recently introduced, minimally invasive, device-assisted technique designed to excise the fistulous tract circumferentially using a standardized cylindrical cutting system [14]. The technique aims to achieve complete removal of the epithelialized tract while minimizing collateral damage to surrounding sphincter tissue. Early reports suggest that FiXcision device may offer acceptable healing rates with preserved continence and improved reproducibility due to its standardized approach [15–17]. However, evidence directly comparing FiXcision device with established sphincter-preserving techniques remains limited.

Given the ongoing need to balance fistula healing with sphincter preservation and the lack of robust comparative data, this study was undertaken to compare fistulectomy using the novel FiXcision device with the ligation of intersphincteric fistula tract procedure in patients with intersphincteric and transsphincteric fistula-in-ano, focusing on operative parameters, postoperative recovery, healing outcomes, complications, and continence.

PATIENTS AND METHODS

Study Design and Setting

This hospital-based prospective comparative study was conducted in the Department of General Surgery at a tertiary care teaching hospital over a period of two years. Institutional ethical committee approval was obtained prior to the commencement of the study, and written informed consent was taken from all participants.

Study Population and Eligibility Criteria

A total of 100 adult patients diagnosed with fistula-in-ano were enrolled in the study. The study was conducted over a fixed period of two years. All consecutive eligible patients fulfilling the inclusion criteria during the study period were enrolled.

Inclusion criteria were patients aged ≥ 18 years with intersphincteric or transsphincteric fistula-in-ano who were fit for surgery and willing to participate.

Exclusion criteria included patients below 18 years of age, pregnant women, patients unfit for surgery, those with complex fistulas, recurrent fistulas, Crohn's disease, malignancy-associated fistulas, or those unwilling to comply with follow-up.

Patient allocation and Surgical Procedures

This was a prospective comparative observational study, and treatment allocation was determined by the operating surgeon based on clinical judgement and patient preference. A total of 100 patients were included, with 50 patients in each study group.

- **Group A (FiXcision device group):** Patients underwent fistulectomy using the FiXcision device. The fistulous tract was

identified, and the FiXcision device was used to excise the tract circumferentially along its entire length and sent for histopathological examination. The internal opening was closed primarily using absorbable sutures at the surgeon's discretion, while the external opening was left open for drainage and healing by secondary intention.

- **Group B (Ligation of Intersphincteric Fistula Tract group):** Patients underwent the ligation of intersphincteric fistula tract procedure. The intersphincteric plane was accessed through a curvilinear incision, the fistulous tract was identified, ligated close to the internal sphincter, and divided. The intervening intersphincteric segment of the fistulous tract was excised and sent for histopathological examination. The external opening was left open to heal by secondary intention.

All surgeries were performed under appropriate anesthesia following standard aseptic protocols.

Postoperative Care and Follow-up

Postoperatively, patients received standard analgesics and antibiotics as per institutional protocol. They were followed up at regular intervals to assess postoperative pain using the Visual Analogue Scale (VAS), wound healing status, complications, duration of hospital stay, time to return to normal activities. Anal continence was assessed using the Cleveland Clinic Incontinence Score (Wexner score). Histopathological examination of excised tissue was performed when applicable.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) software. Continuous variables were expressed as mean standard deviations (SD), and categorical variables were expressed as frequencies and percentages. Intergroup comparisons were performed using student's *t*-test or Mann–Whitney U test for continuous variables and the Chi-square test or Fisher exact test for categorical variables. A *p*-value <0.05 was considered statistically significant.

RESULTS

A total of **100 patients** with fistula-in-ano were included in the study, with **50 patients each** undergoing fistulectomy using FiXcision device (Group A) and ligation of intersphincteric fistula tract (LIFT) (Group B). Both groups were comparable with respect to baseline demographic, clinical, and fistula-related characteristics.

The mean age of the study population was **41.0 SD12.8 years**, with male predominance (74%). Transsphincteric fistula was the most common type (78%). Baseline demographic, clinical presentation, and fistula characteristics were statistically comparable between the two groups (Table 1).

Table 1: Baseline Demographic, Clinical, and Fistula Characteristics

Parameter	Group A (FiXcision device) n=50	Group B (LIFT) n=50	p-value
Mean age (years)	40.2 SD12.5	41.8 SD13.2	0.524
Male gender	38 (76%)	36 (72%)	0.642
Mean BMI (kg/m ²)	24.3 SD3.2	24.7 SD3.5	0.562
Duration of symptoms ≥3 months	42 (84%)	43 (86%)	0.892
History of perianal abscess	38 (76%)	36 (72%)	0.644
Parks classification			
• Intersphincteric	12 (24%)	10 (20%)	0.758
• Transsphincteric	38 (76%)	40 (80%)	
Simple fistula	46 (92%)	45 (90%)	0.723
Posterior internal opening	25 (50%)	27 (54%)	0.682
Single external opening	48 (96%)	47 (94%)	0.645

FiXcision device was associated with **significantly shorter operative time**, whereas **blood loss was significantly higher** compared to LIFT. Intraoperative complications were infrequent and comparable between groups (Table 2).

Table 2: Intraoperative Parameters

Parameter	Group A (FiXcision device)	Group B (LIFT)	p-value
Mean operating time (minutes)	28.4 SD5.1	31.2 SD6.8	0.003
Mean blood loss (mL)	45.6 SD12.3	28.4 SD8.6	<0.001
Intraoperative bleeding	4 (8%)	1 (2%)	0.362
Sphincter injury	2 (4%)	0 (0%)	0.495
No complications	44 (88%)	49 (98%)	0.31

Mean VAS pain scores in Group A versus Group B were 4.2 SD1.3 versus 2.8 SD1.2 on Day 1, 3.4 SD1.1 versus 1.8 SD0.9 on Day 3, 2.1 SD0.8 versus 0.8 SD0.6 at 1 week, 1.2 SD0.6 versus 0.3 SD0.4 at 2 weeks, and 0.4 SD0.3 versus 0.1 SD0.2 at 4 weeks, with mean differences between 0.3 and 1.6 and p-values <0.001 except at 4 weeks where p = 0.008. At 8 and 12 weeks, VAS scores were 0 in both groups. (figure 1)

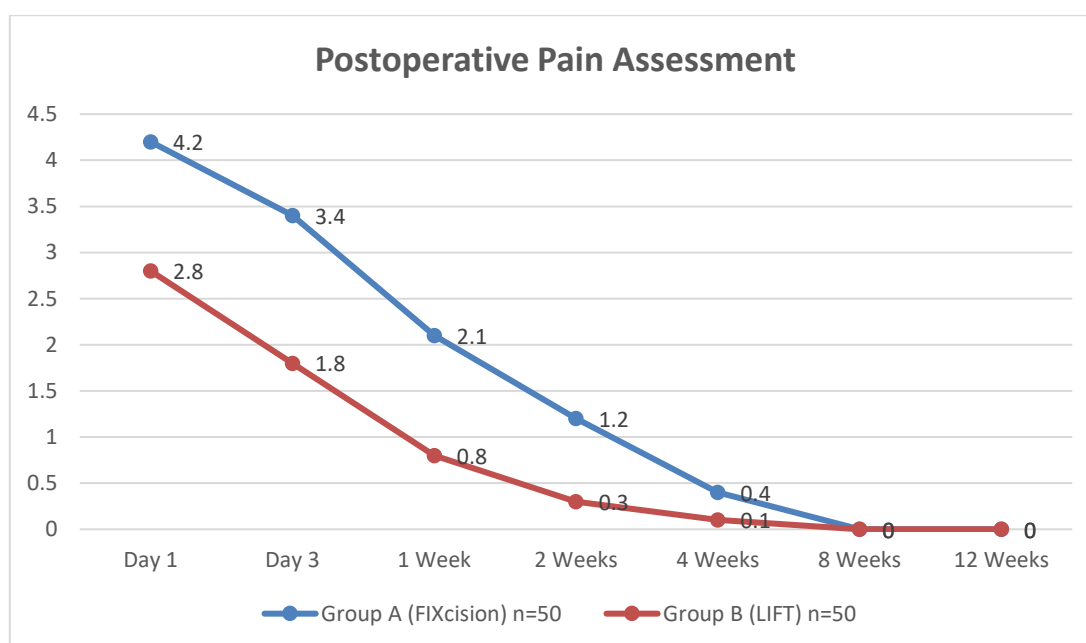


Figure 1: VAS score comparison between both groups at different intervals

Patients undergoing **LIFT** experienced **significantly less postoperative pain**, shorter hospital stay, fewer dressing requirements, earlier return to routine activities, and **faster wound healing** compared to FiXcision device (Table 3)

Table 3: Postoperative Recovery and Wound Healing

Parameter	Group A (FiXcision device)	Group B (LIFT)	p-value
Hospital stay (days)	2.8 SD0.9	1.8 SD0.7	<0.001
Analgesic requirement (days)	5.2 SD1.8	2.9 SD1.3	<0.001
Dressing changes (number)	8.4 SD2.3	4.2 SD1.6	<0.001
Return to normal activity (days)	12.6 SD3.4	7.8 SD2.1	<0.001
Mean healing time (weeks)	6.8 SD1.5	5.2 SD1.2	<0.001
Complete healing at 8 weeks	38 (76%)	47 (94%)	0.014

Early postoperative complications were significantly more frequent in the FiXcision device group. Transient minor incontinence was observed only in FiXcision device patients and resolved completely by 12 months. Histopathological examination showed significantly higher presence of muscle fibres in FiXcision device specimens. (Table 4)

Table 4: Complications, Continence, and Histopathology

Outcome	Group A (FiXcision device)	Group B (LIFT)	p-value
Any early complication	18 (36%)	8 (16%)	0.025
Delayed wound healing	6 (12%)	2 (4%)	0.269
Mean CCIS at 1 month	0.8 SD1.2	0.2 SD0.6	0.003
Transient incontinence (3 months)	4 (8%)	0 (0%)	0.117
Persistent incontinence (12 months)	0	0	—
Muscle fibres on histopathology	28 (56%)	12 (24%)	0.001

DISCUSSION

The management of fistula-in-ano continues to pose a therapeutic challenge, as the ideal procedure must achieve complete eradication of the fistulous tract while preserving anal sphincter function and minimizing recurrence. In recent years, sphincter-preserving techniques have gained prominence, particularly for intersphincteric and transsphincteric fistulas. This study compared a device-based fistulectomy technique (FiXcision device) with the LIFT procedure and demonstrated that although both techniques were effective, LIFT offered superior early postoperative outcomes.

The demographic profile of patients in the present study was comparable between the two groups, with a mean age of approximately 41 years and a clear male predominance. This is consistent with previously published literature, which reports fistula-in-ano to be more common in males in the fourth and fifth decades of life [1–3]. Transsphincteric fistulas constituted most cases, like observations by Parks et al. and subsequent studies from the Indian subcontinent [4,5]. The comparable baseline characteristics between the groups support the validity of the observed outcome differences; however, the possibility of residual confounding cannot be excluded.

Intraoperatively, FiXcision device was associated with a significantly shorter operative time compared to the LIFT procedure. This may be attributed to the standardized, device-assisted excision of the tract, which reduces the need for extensive dissection. However, blood loss was significantly higher in the FiXcision device group. The higher incidence of muscle fibres identified on histopathological examination in the FiXcision group may suggest greater involvement of adjacent sphincter tissue during tract excision. In contrast, LIFT involves targeted ligation within the intersphincteric plane, thereby minimizing tissue disruption [6–8].

Postoperative recovery parameters clearly favoured the LIFT procedure. Patients undergoing LIFT experienced significantly less postoperative pain, required fewer days of analgesics, had shorter hospital stays, and returned to normal activities earlier than those undergoing FiXcision device. These findings are in line with previous studies reporting minimal postoperative morbidity and faster recovery with LIFT due to limited wound size and preservation of sphincter anatomy [9–11]. The higher pain scores and increased dressing requirements observed in the FiXcision device group can be explained by the larger raw area created after circumferential excision of the fistulous tract.

Wound healing outcomes further highlighted the advantages of LIFT. Complete healing at 8 weeks was significantly higher in the LIFT group, and the mean time to complete healing was shorter. Although both procedures ultimately achieved high healing rates at 12 weeks, delayed healing was more frequent in the FiXcision device group. Similar healing patterns have been reported in studies evaluating conventional fistulectomy, where larger wounds are associated with prolonged granulation and epithelialization phases [12–14].

Early postoperative complications were significantly more common in the FiXcision device group. Delayed wound healing was observed more frequently following FiXcision device, although this difference did not reach statistical significance. Transient minor incontinence occurred only in the FiXcision device group and resolved completely during follow-up. The lower complication rate

with LIFT has been consistently reported in the literature and is one of the primary reasons for its growing acceptance as a sphincter-preserving technique [15,16].

Preservation of continence is a critical outcome measure in fistula surgery. In the present study, transient minor incontinence was observed only in the FiXcision device group, with no cases of persistent incontinence at 12 months in either group. The higher early Wexner scores in the FiXcision device group correlate with the histopathological finding of increased sphincter muscle fibres in excised specimens. LIFT, by avoiding sphincter division, demonstrated superior continence outcomes, consistent with previously published data [17].

Overall, the findings of this study suggest that while FiXcision device is an effective technique for fistula tract excision, it is associated with greater tissue trauma, higher postoperative morbidity, and delayed recovery when compared to LIFT. The LIFT procedure, on the other hand, offers a favourable balance between fistula healing and sphincter preservation, making it a more suitable option for intersphincteric and transsphincteric fistula-in-ano.

LIMITATIONS

The present study has certain limitations. It was conducted at a single tertiary care center, which may limit the generalizability of the findings. The relatively modest sample size and non-randomized allocation of patients may have introduced selection bias. In addition, long-term recurrence outcomes were not evaluated beyond the study follow-up period. Further multicenter randomized controlled trials with larger sample sizes and extended follow-up are required to validate these findings.

CONCLUSION

Both FiXcision device and ligation of intersphincteric fistula tract procedures are effective sphincter-preserving techniques for the management of intersphincteric and transsphincteric fistula-in-ano, with high overall healing rates and preservation of long-term continence. However, the ligation of intersphincteric fistula tract procedure demonstrated superior early postoperative outcomes, including less pain, faster wound healing, shorter hospital stays, fewer complications, and earlier return to normal activities. FiXcision device, although associated with shorter operative time, resulted in greater tissue trauma and higher early morbidity. Based on the findings of this study, ligation of intersphincteric fistula tract appears to be a more favourable surgical option for selected patients with intersphincteric and transsphincteric fistula-in-ano.

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Declarations

Methods: Study included 100

Conflict of interest: The authors declare no conflict of interest and no financial disclosure.

Ethics Approval: The study was approved by the Ethics Committee of the Santosh Deemed to be University, Ghaziabad, Delhi NCR, India.

Consent: The informed and written consent were obtained from the patients participating in the study.

Data Availability: Data sets are available through the corresponding author upon reasonable request.

Author Contribution: All authors contributed towards the study and completion of manuscript.