

Study Protocol

Version 1

25 June 2025

Title:

The Modified Clipped Ligation of Intersphincteric Fistula Tract (Clipped-LIFT) for High Transsphincteric or Suprasphincteric Fistula: a Proof-of-concept Study.

Design:

A retrospective study.

Settings:

The Sixth Affiliated Hospital of Sun Yat-sen University.

Patients:

Patients who underwent modified LIFT procedures to treat transsphincteric or suprasphincteric fistulas.

Intervention:

Suturing-LIFT Group: This group received conventional ligation with absorbable sutures.

Clipped-LIFT Group: This group was treated with absorbable clips commonly used for vascular or biliary duct occlusion.

Primary Outcome Measure:

the one-stage healing rate: Complete wound healing without discharge more than 6 months after the modified LIFT procedure

Secondary Outcome Measures:

1. Safety (including incidence of postoperative adverse events and serious adverse events): Adverse events and serious adverse events occurring within 8 weeks after operation were assessed.

2. Overall healing rate: complete wound healing observed for more than 6 months following either the initial LIFT procedure or subsequent salvage surgery.

Study Participants:

Patients with perianal fistulas who consecutively underwent surgery performed by the same colorectal surgeon (Heng Zhang) at The Sixth Affiliated Hospital of Sun Yat-sen University between January 2020 and September 2024 were included in this study.

Inclusion Criteria:

1. Diagnosed with anal fistula and preoperative pelvic MRI confirming Parks classification;
2. all patients undergoing a modified LIFT procedure, either with suture ligation (suturing-LIFT group) or clip ligation (clipped-LIFT group)

Exclusion Criteria:

1. presence of secondary rectal or anal openings identified as unsuitable for LIFT during postoperative evaluation;
2. lack of clinical outcomes following initial modified LIFT procedure.

Study Intervention:

Suturing-LIFT Group: This group received conventional ligation with absorbable sutures.

Clipped-LIFT Group: This group was treated with absorbable clips commonly used for vascular or biliary duct occlusion.

Sample Size Justification:

Patients with perianal fistulas who consecutively underwent surgery performed by the same colorectal surgeon (Heng Zhang) at The Sixth Affiliated Hospital of Sun Yat-sen University between January 2020 and September 2024 were included in this study.

Statistical Analysis:

Data processing and graphical displays were accomplished using R statistical software

(v4.4.0, available at <http://www.r-project.org>). The Shapiro-Wilk procedure was utilized to determine continuous variable distribution patterns. Parametric data were summarized as mean (SD), while nonparametric data were reported as median (IQR). Group comparisons for continuous measures were conducted with either independent t-tests or Mann-Whitney tests based on distribution characteristics. Categorical variable analyses employed Pearson's χ^2 or Fisher's exact tests as warranted. Multivariable logistic regression models included variables demonstrating $P < 0.2$ or clinical relevance in univariate screening, applying the "enter" methodology. All hypothesis testing was two-sided with statistical significance established at the 0.05 threshold.