

Original Article

Single-surgeon Experience of Intersphincteric Fistula Tract Ligation for Anal Fistula

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Key Words

Ligation of intersphincteric fistula tract;
Anal fistula;
Healing rate

Purpose. Ligation of intersphincteric fistula tract is a newly developed surgery for complicated anal fistulas with the advantage of sphincter preservation. This study aimed to provide a single-surgeon experience of the ligation of intersphincteric fistula tract procedure in the management of anal fistulas.

Methods. All patients who underwent the ligation of intersphincteric fistula tract procedure between December 2018 and July 2020 at the institution were included in this study. A total of 59 patients were treated with elective ligation of intersphincteric fistula tract. In this retrospective study, patient characteristics, outcomes, and complications were collected and analyzed for possible risk factors for recurrence.

Results. A total of 59 patients was analyzed. The overall success rate was 70.6%, and the recurrence rate was 29.3% after a median follow-up time of 325.5 days. There was one case of postoperative hemorrhage and no clinically fecal incontinence. The risk factor for recurrence was the complexity of the anal fistula ($p < 0.005$). However, body mass index, sex, operation time, wound dehiscence, and fibrin sealant use were not associated with recurrence.

Conclusions. The ligation of intersphincteric fistula tract procedure is effective and safe for treating anal fistulas with acceptable healing rates and complications.

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Anal fistula is a chronic abnormal communication between the epithelialized surface of the anal canal and usually the perianal skin. An anal fistula was seen as a chronic manifestation of acute anorectal abscess. There are several subtypes of anal fistulas in terms of their relationship to the anal sphincter complex: intersphincteric, transsphincteric, suprasphincteric, extrasphincteric, and superficial (Fig. 1). Among these subtypes, the intersphincteric type is the most common. Surgical treatment of anal fistula aims to eradicate sepsis while preserving fecal continence. For simple anal fistulas, fistulotomy results in healing

in over 90% of patients.¹ For more complex anal fistulas, draining setons, advancement flaps, and modified Hanley procedures are applied. Recently, a number of new sphincter-preserving surgeries have been developed, including ligation of intersphincteric fistula tract (LIFT) and use of expanded adipose-derived stem cells, video-assisted anal fistula treatment, and radial-emitting laser probe (FiLaC™), with variable outcomes.² Among them, ligation of the intersphincteric fistula tract procedure appears to be safe and effective and may be routinely considered for complex anal fistulas.

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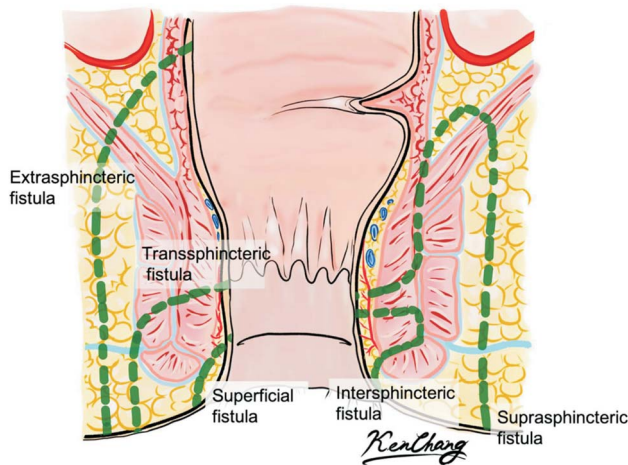


Fig. 1. Classifications of anal fistulas.

LIFT was first described in 2007 by Rojanasakul et al. with a 94.4% primary healing rate.³ Since then, this novel technique has gained popularity worldwide. Many studies report that the procedure has a 61%-90% success rate.⁴

LIFT was introduced in our hospital in December 2018 and performed by a single colorectal surgeon (YC Cheng). This study aimed to retrospectively review the LIFT procedure in the management of anal fistulas at our hospital.

Materials and Methods

All patients who underwent the LIFT procedure between December 2018 and July 2020 at Tri-Service General Hospital were included in this study. The inclusion criteria for this study were age 18 to 75 years and the presence of anal fistula after examination by a colorectal surgeon. Image evaluation, including computed tomography or magnetic resonance imaging, was not mandatory.

Classification of anal fistulas

All anal fistulas are classified using the Park systems because it is commonly used not only to accurately describe the anatomic track of the fistula but also to predict the complexity of the operation, the need for varying degrees of sphincterotomy, and the

potential for continence disturbance.^{5,6}

1. Intersphincteric type (type I): the tract ramifies only in the intersphincteric plane.
2. Transspincteric type (type II): the tract passes from the intersphincteric plane through the external sphincter complex at varying levels of the ischioanal fossa. Transspincteric fistulae are further classified as either high or low. A high transspincteric fistula passes through the upper or middle third of the external anal sphincter, whereas low transspincteric fistulae traverse the lower third of the external anal sphincter.⁷
3. Suprasphincteric type (type III): the tract passes through the intersphincteric plane over the top of the puborectalis and then downwards again through the levator plate to the ischioanal fossa and finally to the skin.
4. Extraspincteric type (type IV): the tract passes from the perineal skin through the ischioanal fat and levator muscles to the rectum.

Anal fistula may also be classified by their complexity into simple anal fistula and complex anal fistula. Simple anal fistula encompasses superficial, intersphincteric and low transspincteric fistula. Complex anal fistula includes high transspincteric, suprasphincteric, extraspincteric, semihorseshoe and horseshoe fistula.

Surgical technique

1. Identify the internal opening by injecting hydrogen peroxide into the external opening.
2. Make a 2 cm curvilinear incision at the intersphincteric groove.
3. Start meticulous dissection using an electrocautery pen until the anal fistula is exposed.
4. Skeletonize the anal fistula and hook the tract with a right-angled clamp.
5. Ligate the tract near the internal opening with 2-0 or 3-0 polyglactin sutures.
6. Inject hydrogen peroxide to ensure the fistula tract is ligated.
7. Ligate the other side of the tract and divide the tract using scissors.

8. Core out fistulectomy from external opening to remove the fistula remnant.
9. Inject TISSEEL into the intersphincteric space. (This step is optional).
10. Approximate the intersphincteric incision with a 2-0 polyglactin suture.

Post-operative care and follow-up

Patients who underwent the LIFT procedure were discharged on the day after surgery with stool softener, analgesic drugs, and oral ciprofloxacin plus metronidazole for 2 weeks. Sitz baths were prohibited, but cleaning with tap water was encouraged. All patients were followed up at the outpatient department 1 week after the surgery and 2 weeks interval subsequently until the wound healed. Complications such as wound dehiscence, clinically fecal incontinence, and recurrence were recorded. A healed wound was defined as the absence of symptoms and the presence of complete healing of both the intersphincteric incision wound and the external opening. Primary healing was defined as the healing of both the anal fistula and external opening during the first 12 weeks of clinical surveillance. However, a newly developed anal fistula can be noted 12 weeks later. An unhealed wound was defined as the early presence of persistent symptoms within 12 weeks.

Statistical analysis

Data were analyzed using SPSS version 22. Continuous variables were expressed as mean \pm standard deviation (SD) or median and normal range, whereas categorical variables were expressed as percentages. Mann-Whitney U tests were used to compare continuous variables, and chi-square or Fisher's exact tests were used for comparison of proportions. Univariate and multivariate Cox regression tests were used to determine the predictive factors for recurrence. Variables with univariate significance of 0.15 or less were included in the multivariate analysis to identify risk factors for recurrence. For all statistical tests, a 2-tailed *p*-value of less than 0.05 was considered significant.

Results

In this retrospective study from December 2018 to June 2020, 59 patients who underwent the LIFT procedure plus coring out of the external opening met the inclusion criteria. Of the 59 patients, 53 (89.8%) were male and 6 (10.2%) were female. The median age was 42 years (range, 19-62 years). Mean body mass index (BMI) was 26.6. The anal fistula was classified as intersphincteric-type in 2 cases (3.3%), low-transsphincteric type in 32 cases (54.2%), high-transsphincteric type in 8 cases (13.5%), semi-horseshoe type in 10 cases (16.9%), horseshoe type in 5 cases (8.4%), and extra-sphincteric type in 2 cases (3.3%). The operative time ranged from 26 to 113 min, with a median of 65 min. Two patients had hypertension (3.3%), 11 had diabetes mellitus (18.6%), and 2 patients had alcoholism (3.3%). The patient demographics are shown in Table 1.

During the follow-up period, the median follow-up time was 325.5 days, and the median time of recurrence was 80 days. The healing rate of the anal fistula was 70.6% (41/58), and the recurrence rate was 29.3% (17/58). One patient was lost to follow-up after surgery.

The outcomes and management of unhealed or primary-healed anal fistulas are summarized in Fig. 2. We divided our patients into four subgroups based on

Table 1. Patient demographics

| | All patients (n = 59) |
|--------------------------|-----------------------|
| Age (years) | 42.9 \pm 11.7 |
| Male (%) | 53 (89.8) |
| BMI (kg/m ²) | 26.6 \pm 3.7 |
| Type of fistula | |
| Inter | 2 |
| Trans | 32 |
| High-trans | 8 |
| Semi-horseshoe | 10 |
| Horseshoe | 5 |
| Extra | 2 |
| Comorbidities | |
| Hypertension | 2 |
| Diabetes | 11 |
| Alcoholism | 2 |
| Complication | 1 (bleeding) |

BMI, body mass index.

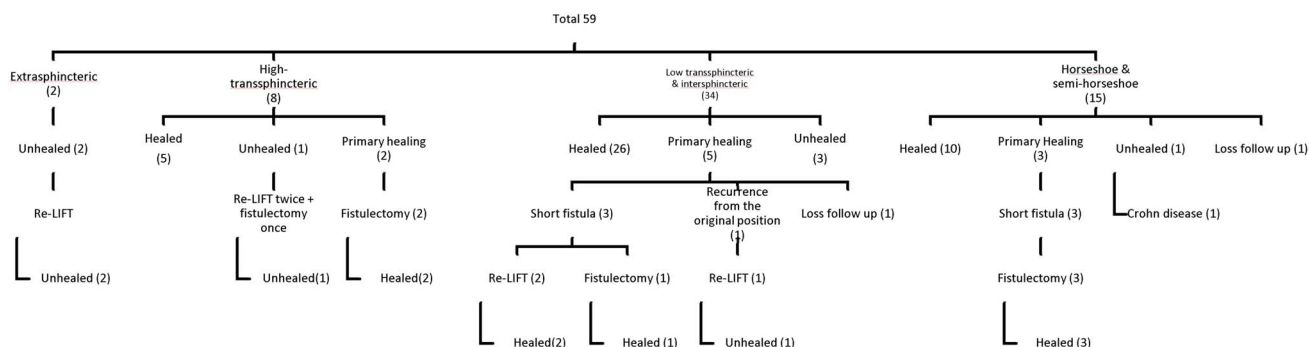


Fig. 2. Flow diagram showing outcome of all patients and subsequent management of recurrence.

the complexity of anal fistula and success rate as follows: low-transsphincteric and intersphincteric type, high-transsphincteric, semihorseshoe and horseshoe type, and extrasphincteric types. Low-transsphincteric and intersphincteric type were grouped together since they were classified as simple anal fistula and had closed healing rate in the literature.⁸ Of the 17 patients with recurrence (including unhealed and primary-healed patients), 2 patients in the extrasphincteric group underwent Re-LIFT surgery and remained unhealed. In the high-transsphincteric group, there were 3 recurrences, 2 of whom underwent fistulectomy for short fistula and 1 underwent Re-LIFT surgery. Among the 7 recurrences in the low-transsphincteric and intersphincteric groups, 2 underwent Re-LIFT and 2 underwent fistulectomy. In the horseshoe and semi-horseshoe groups, 3 recurrences had fistulectomy and 1 recurrence was diagnosed as Crohn’s disease. Ultimately, 4 of the original patients remained unhealed, 5 of whom were lost to follow-up at the clinic and another initiated biologic agent for Crohn’s disease with anal manifestation.

Further comparisons between the cured and recurrence groups are presented in Table 3. Age (41.4 ± 11.5 vs. 45.6 ± 11.3; *p* = 0.206), sex distribution (92.7% male vs. 82.4% male; *p* = 0.345), BMI (27.0 ± 3.8 vs. 26.0 ± 3.7; *p* = 0.645), mean operation time (61.2 ± 20.7 vs. 73.1 ± 21.5; *p* = 0.061), wound dehiscence (39.0% vs. 17.6%; *p* = 0.114), and follow-up times (323.0 ± 203.2 vs. 401.3 ± 199.6; *p* = 0.297) were not significantly different (Table 2).

To analyze the risk factors for recurrence of anal fistula, we used univariate analysis, and the results are shown in Table 1. Between patients with and without

recurrence, several factors had a significance level of < 0.15, including fistula subtype (*p* = 0.005), operation time (*p* = 0.080), and wound dehiscence (*p* = 0.119). On the other hand, BMI, sex, previous surgery, and fibrin sealant use did not increase the risk of recurrence (Table 3).

Multivariate Cox regression analysis of the risk factors for recurrence that attained a significance level of < 0.15 in the univariate analysis demonstrated that fistula subtypes such as high-transsphincteric (*p* = 0.001, 95% confidence interval (CI) 0.003-0.241), semi-horseshoe/horseshoe (*p* = 0.019, 95% CI 0.010-0.664), and extra-sphincteric type (*p* = 0.010, 95% CI 0.009-0.523) were the most important predictors of

Table 2. Comparison of patients who were cured and those who had recurrence

| | Cure (n = 41) | Recurrence (n = 17) | <i>p</i> -value |
|----------------------|---------------|---------------------|-----------------|
| Age, year | 41.4 ± 11.5 | 45.6 ± 11.3 | 0.206 |
| Male (%) | 38 (92.7) | 14 (82.4) | 0.345 |
| BMI | 27.0 ± 3.8 | 26.0 ± 3.7 | 0.645 |
| Type of fistula | | | |
| Inter | 2 | 0 | |
| Trans | 24 | 7 | |
| High-trans | 5 | 3 | |
| Semi-horseshoe | 6 | 4 | |
| Horseshoe | 4 | 1 | |
| Extra | 0 | 2 | |
| Operation time, min | 61.2 ± 20.7 | 73.1 ± 21.5 | 0.061 |
| Healing time, day | 55.9 ± 26.1 | N/A | |
| Wound dehiscence (%) | 16 (39.0) | 3 (17.6) | 0.114 |
| TISSEEL (%) | 13 (31.7) | 3 (17.6) | 0.347 |
| Follow-up time, day | 323.0 ± 203.2 | 401.3 ± 199.6 | 0.297 |

* One patient was lost to follow-up. BMI, body mass index; N/A, not available.

Table 3. Univariate and multivariate analysis for risk factors of recurrence

| Variable | Univariate analysis | | Multivariate analysis | |
|--|---------------------|-----------------|-----------------------|-----------------|
| | 95% CI | <i>p</i> -value | 95% CI | <i>p</i> -value |
| BMI | 0.840-1.090 | 0.506 | | |
| Sex | 0.395-4.899 | 0.607 | | |
| Previous surgery | 0.238-4.623 | 0.949 | | |
| Fistula type | | 0.005 | | |
| Low-transsphincteric vs. intersphincteric | | 0.978 | | |
| High-transsphincteric vs. intersphincteric | 0.003-0.154 | 0.000 | 0.003-0.241 | 0.001 |
| Semihorseshoe and horseshoe vs. intersphincteric | 0.007-0.436 | 0.006 | 0.010-0.664 | 0.019 |
| Extrasphincteric vs. intersphincteric | 0.008-0.362 | 0.003 | 0.009-0.523 | 0.010 |
| Operation time | 0.997-1.047 | 0.080 | 0.977-1.030 | 0.806 |
| Wound dehiscence | 0.739-14.317 | 0.119 | 0.838-17.089 | 0.084 |
| Fibrin sealant | 0.558-6.879 | 0.294 | | |

CI, confidence interval; BMI, body mass index.

recurrence after the LIFT procedure.

Discussion

The goal of anal fistula surgery is to remove associated epithelialized tracks while maintaining anal sphincter function and preventing recurrence. Many modern treatments have been developed to treat anal fistulas and to ensure the integrity of the anal sphincter. Biosynthetic fistula plugs have healing rates between 15.8% and 72.7% and low healing rates (< 50%) when used for treating high anal fistula.^{9,10} Fibrin sealant is also not very effective, with a high re-

currence rate of approximately 23%.¹¹ Guidelines published by the American Society of Colon and Rectal Surgeons strongly recommend that ligation of the intersphincteric fistula is suitable for both simple and complex anal fistulas, resulting in a fistula healing rate of 61%-94%¹² (Table 4).

This study was conducted in a retrospective, single-institution manner, reporting on the experience of a single surgeon. The overall healing rate was 70.6%, and the recurrence rate was 29.3% at a median follow-up of approximately one year, and the results were similar to those reported in the literature. Worldwide experiences regarding the LIFT procedure with different designs and follow-up periods are presented

Table 4. Worldwide experiences of LIFT

| Study | Design | Year | Patient number | Healing rate | Wound dehiscence | Follow-up (mon) |
|-------------------------------------|---------------------------|------|----------------|--------------|------------------|-----------------|
| Sun et al. ²³ | Retrospective | 2019 | 70 | 81.7% | 24.3% | 16.5 |
| Alhaddad et al. ²⁴ | Retrospective comparative | 2018 | 33 | 81.1% | - | 23.9 |
| Wen et al. ²⁵ | Retrospective | 2018 | 62 | 83.9% | 11.2 | 24.5 |
| Galan et al. ²⁶ | Retrospective | 2017 | 55 | 71% | - | 32 |
| Chen et al. ²⁷ | Retrospective | 2017 | 43 | 83.7 | 18.6 | 26.2 |
| Parthasarathi et al. ²⁸ | Prospective | 2015 | 167 | 94.1 | 0 | 12.8 |
| Malakorn et al. ⁸ | Retrospective | 2017 | 251 | 94.4 | - | 71 |
| Madbouly et al. ²⁹ | Randomized trial | 2014 | 35 | 74.3% | - | 12 |
| Sileri et al. ³⁰ | Prospective | 2013 | 26 | 73% | - | 16 |
| Tsunoda et al. ³¹ | Prospective | 2013 | 20 | 95% | - | 18 |
| Sirikurnpiboon et al. ³² | Retrospective | 2013 | 41 | 83% | - | 24 wk |
| Bleier et al. ³³ | Retrospective | 2010 | 39 | 57% | - | 20 wk |
| Wallin et al. ³⁴ | Retrospective | 2012 | 93 | 57% | - | 19 |
| Rojanasakul et al. ³ | Retrospective | 2007 | 18 | 94% | - | 4 wk |

in Table 2. A recent meta-analysis published by Emile et al. included 26 studies comprising 1,378 patients (73.3% male) and yielded a mean success rate of 76.8% after a median follow-up of 16.5 months.¹³ Another meta-analysis conducted earlier in 2014 yielded 24 studies with 1,110 patients and a follow-up of 10.3 months; this study also demonstrated that the LIFT procedure could reach a successful treatment rate of 76.4%.¹⁴ Compared to previous studies, our study included more patients with complex anal fistulas, including 67.8% transsphincteric fistulas and 25.4% horseshoe and semihorseshoe anal fistulas. Our results demonstrated that the average healing time was 55.9 ± 26.1 days, which is comparable to a previous study conducted by Alasari et al.¹⁵ Besides recurrence, only one case of post-operative bleeding was reported, and no clinically fecal incontinence was noted. Based on these findings, we conclude that the LIFT procedure is effective and safe for treating anal fistulas.

Many previous studies have aimed to clarify the risk factors for LIFT failure. Factors affecting healing include complexity of fistula, horseshoe extension, lack of identification or lateral location of the internal fistulous opening, previous fistula surgery, obesity, smoking, and the length of the fistula tract.^{13,16-18} However, in most studies, different surgical techniques have been used. A recent systemic review published by Emile et al. in 2020 focused solely on the LIFT procedure. The study demonstrated that statistically associated factors were horseshoe fistulas, fistulas associated with Crohn's disease, and a history of previous fistula surgery. A meta-analysis published in 2019 by Mei et al. revealed that anal fistula recurrence is associated with high transsphincteric tract and horseshoe extensions and multiple tracts. The low-transsphincteric type had a recurrence rate of 10.7%, 37.8% for high transsphincteric tracts, and 44.4% for tracts with horseshoe extensions. Sex, age, and obesity were not associated with anal fistula recurrence.¹⁹ This was compatible with our study results showing that the possible risk factor affecting surgical failure was the complexity of anal fistula and not BMI and sex. Previous surgery is a well-known risk factor for recurrence,^{13,19} but it appeared to not be statistically significant in our study.

Van Onkelen et al. reported that the LIFT procedure was sufficient on the side of the external anal sphincter but not always on the side of the internal anal sphincter.²⁰ Therefore, we assumed that if inflammation and infection are still occurring in the intersphincteric groove, there will be wound dehiscence or even persistent discharge. Wound dehiscence may be an early sign of recurrence. Hence, we compared the wound dehiscence rates between the cured and recurrence groups, but the results were not statistically significant (39.0% vs. 17.6%).

Although the LIFT procedure has gained popularity in recent years, failures are still observed. Tan et al. further classified the patterns of failure into three groups: I. Localized failure with discharge at the intersphincteric wound and absence of an internal opening; II. Partial failure, a tract from the internal opening to the intersphincteric wound; and III. Complete failure, a tract from the internal opening to the external opening with or without involvement of the intersphincteric wound.²¹ In our study, the recurrences were all group II and group III. Once the anal fistula was converted to a relatively simple intersphincteric fistula, fistulectomy was performed with excellent outcomes (Fig. 2).

Since the first description of the LIFT procedure by Rojanasukul in 2007, this procedure was modified to BioLIFT by Ellis. BioLIFT uses a bioprosthetic graft to reinforce the intersphincteric plane and shows primary healing rates from 47% to 94%.²² In our study, instead of the bioprosthetic graft, we used fibrin sealant (TISSEEL, Baxter) to fill the intersphincteric space as an alternative. The results also showed no statistically significant difference in whether commercial fibrin sealant could prevent failure of LIFT. However, due to the high cost, only 27.1% of patients used fibrin sealant in this study. Thus, the efficacy of fibrin sealant requires further large-scale study.

The limitations of this study were that it was retrospective in nature, had a small sample size, and had all procedures performed by only a single surgeon. It lacked adequate power to detect if a history of previous fistula procedures and preoperative characteristics of patients had any potential effect on healing. Another limitation was the lack of an objective scale

to evaluate fecal incontinence, such as anorectal manometry, to yield more accurate results. Lastly, as regards the use of fibrin sealant to prevent recurrence, the results showed no effect in terms of decreasing recurrence. The number of patients using fibrin sealants was also small. Therefore, a larger, long-term prospective randomized controlled study is needed to validate the true comparison between adding fibrin sealant to the LIFT procedure or standard LIFT procedure only.

Conclusions

The LIFT procedure for anal fistula is an inexpensive and safe procedure that led to healing in 41 out of 59 patients (70.6%) in this retrospective study. No clinically fecal incontinence was reported. This procedure is easy to learn and results in very few complications. The complexity of anal fistulas is the risk factor associated with failure. BMI, sex, and wound dehiscence were not associated with recurrence in our study. Further large-scale randomized controlled studies are required to determine the effectiveness of using fibrin sealant to prevent recurrence.

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原 著

括約肌間瘻管結紮術治療肛門瘻管 – 單一醫師經驗分享

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目的 括約肌間瘻管結紮術為一可以保留肛門括約肌手術，多用於治療複雜性瘻管，本研究提供此術式在單一醫師治療肛門瘻管的早期經驗及成果。

方法 自民國 107 年 12 月至 109 年 5 月，我們對 59 個接受括約肌間瘻管結紮術的病患接受回顧性研究，探討該術式的成功率及復發率，並針對性別、身體質量指數、手術時間等因素進行分析是否會影響瘻管復發。

結果 在追蹤近一年後，成功率為 70.6%，而整體復發率為 29.3%，術後併發症為出血 (1.7%)，所有病人沒有失禁的併發症產生。影響瘻管的風險因子為瘻管的複雜度，其他如性別、身體質量指數、手術時間、傷口崩裂，使用組織修復凝合劑對瘻管復發並無關連性。

結論 約肌間瘻管結紮術用來治療肛門瘻管是有效且安全的，手術成功率及併發症都在合理範圍內。

關鍵詞 括約肌間瘻管結紮、肛門瘻管、癒合率。