BACKGROUND: Ligation of the intersphincteric fistula tract is a well-accepted and often used surgical procedure for perianal fistulas.

OBJECTIVE: This study aims to confirm results of the ligation of the intersphincteric fistula tract in a specialized colorectal center.

DESIGN: This is a retrospective cohort study.

SETTING: This study took place in a large colorectal surgical department with a tertiary referral center for perianal fistulas.

PATIENTS: Consecutive patients were operated on with ligation of the intersphincteric fistula tract for a transsphincteric perianal fistula between 2012 and December 2018.

INTERVENTIONS: Patients underwent ligation of the intersphincteric fistula tract.

MAIN OUTCOME MEASURES: The primary outcome measured was the healing rate. The secondary outcomes measured were conversion into an intersphincteric perianal fistula, risk of recurrence, complications, and postoperative continence status.

RESULTS: Forty-six patients were treated with a ligation of the intersphincteric fistula tract procedure. All patients (100%) had preoperative imaging in their workup. Forty patients (87%) had a high transsphincteric fistula. The primary healing rate was a disappointing 17 of 46 patients (37%). The median time until failure was 4.2 months (interquartile range, 3.5–6.5). Of the failures, 16 converted to an intersphincteric fistula (55% of failures and 35% of all patients). The mean duration of follow-up in patients without a recurrence was 9.5 months (SD 11.9). Four patients (9%) were lost to follow-up. The mean Fecal Incontinence Severity Index postoperatively was only 2.35 (SD 5.7; range, 0–30). This resulted in 9 patients (20%) having a newly impaired continence status postoperatively. Continence impairment was mild in all these patients. The risk of developing a recurrence 1 year after surgery is 64.2% (95% CI, 49%–80%).

LIMITATIONS: This study was limited by its retrospective design and the small numbers with possible selection bias.

CONCLUSIONS: Results with the ligation of intersphincteric fistula tract procedure were not as good as hoped. The effect on fecal continence, however, was minimal. The procedure might be more suitable for low transsphincteric fistulas. See Video Abstract at http://links.lww.com/DCR/A992.

LA LIGADURA DEL TRACTO DE LA FÍSTULA INTERESFINTÉRICA PARA UNA FÍSTULA TRANSESFINTÉRICA ALTA, PRODUCE RESULTADOS MODERADOS EN EL MEJOR DE LOS CASOS: ¿ESTÁ CAMBIANDO LA MAREA?

ANTECEDENTES: La ligadura del tracto de la fistula interesfintérica es un procedimiento quirúrgico bien aceptado y de uso frecuente para las fistulas perianales.

OBJETIVO: Confirmar los resultados de la ligadura del tracto de la fistula interesfintérica en un centro colorrectal especializado.

DISEÑO: Estudio de cohorte retrospectivo.

AJUSTE: Gran departamento de cirugía colorrectal y con centro de referencia terciaria para fistulas perianales.
PACIENTES: Pacientes consecutivos operados con ligadura del tracto de la fístula interesfintérica para una fístula perianal transesfintérica, entre 2012 y diciembre de 2018.

INTERVENCIONES: Ligadura del tracto de fístula interesfintérica.

PRINCIPALES MEDIDAS DE RESULTADO: Tasa de cicatrización, resultados secundarios: conversión a una fístula perianal interesfintérica, riesgo de recurrencia, complicaciones y estado de continencia postoperatoria.

RESULTADOS: Cuarenta y seis pacientes fueron tratados con una ligadura del tracto de la fístula interesfintérica. Todos los pacientes (100 por ciento) tenían imagenología en su preparación preoperatoria. Cuarenta pacientes (87 por ciento) tenían una fístula transesfintérica alta. La tasa de cicatrización primaria fue decepcionante en 17 de 46 pacientes (37 por ciento). El tiempo medio hasta el fracaso fue de 4.2 meses (rango intercuartil 3.5–6.5). De los fracasos, 16 se convirtieron en una fístula interesfintérica (55 por ciento de los fracasos y 35 por ciento de todos los pacientes). La duración media del seguimiento en pacientes sin recurrencia fue de 9.5 meses (desviación estándar de 11.9). Se perdieron durante el seguimiento a cuatro pacientes (9 por ciento). Después de la operación, el promedio del índice de severidad de incontinencia fecal fue de solo 2.35 (desviación estándar de 5.7, rango 0–30). Esto resultó en que 9 pacientes (20 por ciento) tuvieron una continencia deteriorada postoperatoria. El deterioro de la continencia fue leve en todos estos pacientes. El riesgo de desarrollar una recurrencia a un año después de la cirugía es del 64.2 por ciento (intervalo de confianza del 95 por ciento: 49–80 por ciento).

LIMITACIONES: Diseño retrospectivo, números pequeños con posible sesgo de selección.


KEY WORDS: Fistula-in-ano; Ligation of intersphincteric fistula tract; Perianal fistula; Surgical treatment.

La ligadura del interesfintérica (LIFT) es now a well-documented and accepted treatment option for high transsphincteric perianal fistulas, which was first described in 2007 by Rojanaskul et al.1 Ever since, it has been modified,2,3 combined with biomaterials,4–6 used for low fistulas,7 and combined with other procedures.8 Some surgeons may even consider it a “classic” treatment option, even though it has only been around for about a decade.9

Only 2 randomized trials are available that compare the LIFT to the transanal advancement flap repair (TAFR), and results seem comparable between the 2 techniques with accepted healing rates of 65% to 75%.10,11 Besides these randomized trials, many prospective and retrospective results have been published with predominantly good results. The inventor of the LIFT recently published his 10-year results, showing a very high healing rate of 87.7% in a series of 251 patients.12

Our hospital is a national referral site for complex and recurrent perianal fistulas, and more than 150 patients are operated on annually for their fistulas (including simple as well as complex fistulas). We implemented many different techniques over the years, and while examining our own results, we found that the LIFT showed an unexpected outcome. Even though many results have been published discussing LIFT, we believe our results add interesting information. Our objective was to confirm the published healing rates of LIFT in our own patients.

MATERIALS AND METHODS

Patient Selection and Outcome

We used our institutional database for patients with peri- anal fistulas and selected all consecutive patients that were treated with LIFT. It was a chart-review-only study. This study is therefore defined as a retrospective cohort study. Both primary and recurrent fistulas were included. Patients with Crohn’s disease were excluded from the present study. In general, we do not offer patients with Crohn’s disease complex treatments like LIFT or TAFR because of the low healing rates. Data were prospectively collected in this database and kept up to date. Patients eligible for treatment with LIFT had a high transsphincteric fistula, with a straight or only slightly deviating fistula tract, and without septic criteria/abscesses. Other operative techniques are offered to patients with this kind of fistula, and definitive treatment is based on patient preference after extensive information and shared decision making. A high transsphincteric fistula was defined as a fistula tract running through the middle and/or upper third parts of the external anal sphincter. Standard workup included an MRI scan.

Primary outcome was defined as the healing rate after the LIFT procedure. A fistula was considered healed if the external opening was completely closed, without signs of septic criteria/signs of abscesses. Unhealed was defined as recurrence of the external opening after healing, or recurrence of previous signs (drainage and inflammation signs), or persistence of the fistula after 12 weeks.12
Secondary outcome measures were conversion into an intersphincteric perianal fistula, risk of recurrence using survival curves, and pre- and postoperative (post-LIFT) continence status, using the Fecal Incontinence Severity Index (FISI) that is used in all our patients with perianal fistula.13

Follow-up after a LIFT includes a first postoperative visit after 6 weeks, a visit after 12 weeks, and a visit after 6 months. Further visits are planned on an individual basis.

Operative Technique

In all patients, a loose seton drainage was first applied for at least 2 to 3 months before the LIFT was planned. Patients are either treated under general or spinal anesthesia and positioned in the lithotomy position. Per local protocol, no preoperative antibiotics are administered. The seton is removed, and a metal probe is inserted through the fistula tract. A circular incision is made in the intersphincteric groove and a self-retaining retractor (Lone Star, Cooper Surgical, Trumbull, CT) is installed for traction. With diathermia, the intersphincteric plane is developed until the intersphincteric fistula tract appears. The fistula is circled with a clamp until there is enough space to ligate it. The probe is removed and the external and internal sides of the fistula are transfixed (suture material passed through the stump, tied off on one side, and then tied off around the entire stump) with absorbable (slow-absorbing) polyglactin sutures (Coated Vicryl, 2-0, Ethicon Inc, Cornelia, GA). A NaCl 0.9% solution is used to test the tract for leakage. In case of leakage, extra sutures are used to close the defect from within the intersphincteric plane. The wound is then approximated with fast resorbable sutures, but not closed completely. No antibiotics are used postoperatively. Patients are generally discharged at the day of operation and treated with oral analgesics.

Statistical Analysis

IBM SPSS 25 was used for analyzing our results. When a mean is cited, the SD is mentioned. In case a median value is given, the interquartile range is added. A Kaplan-Meier analysis was used to calculate the risk of recurrence and 95% CIs are reported as needed. A χ² test or Fisher Exact test was used to compare the results between surgeons and between types of fistulas. The study was conducted according to the STROBE statement and according to the national Dutch medical-ethical guidelines.

RESULTS

About 150 patients per year are treated for a perianal fistula; most are noncomplex fistulas for which a fistulotomy can be performed. We perform about 20 TAFRs per year. Between November 2011 and December 2018, 46 patients were treated with a LIFT procedure in our clinic.

A little more than half the patients were male (27 [59%]). Mean age at the time of the operation was 42.5 years (SD 14.3). All patients (100%) had preoperative imaging in their workup. Only one of these patients (2%) had an endoanal ultrasound due to contraindications for an MRI. All fistulas were transsphincteric, of which 40 (86.9%) were classified as high.

Only 6 patients (13%) had a recurrent fistula before we treated them with a LIFT. Four of these patients (9%) had one previous attempt at closure, of which all 4 (9%) were treated with laser ablation. One patient (2%) was treated twice with fistulectomy for a recurrent perianal sinus. In this case, the internal opening could not be found (in the referring center), until our seton placement. One (2%) patient was previously treated with TAFT and a fistula plug.

The primary healing rate was 17 of 46 patients (37%). The median time until failure was 4.2 months (interquartile range, 3.5–6.5). Of the 29 failures, 16 converted to an intersphincteric fistula (55% of failures and 35% of all patients). No keyhole defects were seen postoperatively in our series. Of the unhealed fistulas, 3 (10%) had a persisting fistula; the others were recurrences. A flow chart is shown in Figure 1. Twenty-four patients (52%) had an anterior fistula, of which 18 (75%) had a failure, compared to 11 of 22 (50%) for posterior fistulas. Failure rate was not significantly different between anterior and posterior fistulas, p = 0.08, but a tendency toward more failures was seen in the anterior fistulas.

No difference was seen in the failure rate between the first and second half of the series, p = 0.36 (69.6% and 56.5%). Of the 6 patients previously treated for their perianal fistula, 4 (67%) had treatment failure. Secondary treatments are shown in Figure 2.

Four patients (9%) were lost to follow-up. They did not have a recurrence at the end of their follow-up and
were therefore included in the healed group. Definitive healing could unfortunately not be confirmed in these 4 patients. Mean duration of follow-up in patients without a recurrence was 9.5 months (SD 11.9).

We did not see significant differences in outcome between both surgeons; however, a difference in the number of patients operated on was seen. D.Z. operated on 31 (67%) patients, and D.W. operated on 15 (33%). Failure rate was not significantly different with a \( p \) value of 0.11.

Postoperatively 28 patients (61%) had an MRI scan to confirm or exclude a recurrence. Most of the scans were made to confirm a recurrence and to confirm the fistula converted to an intersphincteric fistula. Only 5 patients (29%) without a recurrence, and 23 of 29 failures (79%) had an MRI scan.

Preoperative continence status was reported in all patients (100%). Only 1 patient (2%) had a preoperatively abnormal FISI score, which was 30. She reported major incontinence for solid stool. Her continence score was unchanged postoperatively. Six patients (13%) reported soiling postoperatively, and 3 reported incontinence for flatus (7%). The mean FISI score postoperatively was only 2.35 (SD 5.7; range, 0–30). This resulted in 9 patients (20%) having a newly impaired continence status postoperatively. Continence impairment was mild in all these patients.

A Kaplan-Meier curve (survival) for the fistula-free survival is shown in Figure 3. The risk of developing a recurrence 1 year after surgery is 64.2% (95% CI, 49%–80%). Two years after surgery the risk is 73.2% (95% CI, 57%–87%).

**DISCUSSION**

The LIFT is considered by many surgeons to be a robust technique to treat high transphincteric perianal fistulas. Two randomized controlled trials show good results comparing it to the TAFR.\(^{10,11}\) Malakorn et al\(^{12}\) reported that the 10-year results in the center that developed the LIFT were as high as 87.7%. In contrast to these extremely high healing rates, we only managed to heal 37% of our patients with a LIFT procedure.

We are a high-volume clinic for the treatment of fistulas, and all surgeons are well experienced in the techniques used to treat patients and no intersurgeon differences were seen. Therefore, we are unsure why our healing rate is low in comparison with other published results. The fact that the results of newer techniques decline over time when more data are available may be part of the reason. The TAFR is the preferred technique in our clinic, and has been used considerably more often than the LIFT. This is mostly because of the select group of patients to which we offer a LIFT. Also, when offered a choice, in our experience, many patients will choose the well-established healing rate of TAFR, which is consistently reported to be around 80%.\(^{14,15}\) This concurs with our own results that we show our patients.

The present moderate healing rate may be influenced by the learning curve in our center. Both surgeons were trained in the LIFT technique in certified training programs. A uniform operating protocol was ascertained by operating together frequently. All patients with a LIFT were included, which therefore includes patients in our learning curve. However, we did not see a difference between the first half or second half of the series. Besides, series published by other authors with an equally low number of patients show higher healing rates,\(^{16–18}\) although some also show results under 50%.\(^{19}\) From a technical point of view, we are unsure why we found these contrasting results, except that, in the first few patients, leakage of the tract after ligation was not confirmed. Going back to the previously

![Figure 2](image-url)
mentioned 10-year results from Thailand, their healing for high transsphincteric fistulas is considerably lower (60%) compared to intersphincteric or low transsphincteric fistulas (92% and 85%). Looking at our own results, 85% was classified as high transsphincteric. Although we did not find any significant difference in healing compared to low fistulas, this might, in part, explain why our results are not as good as hoped. Still, our primary healing rate is only 37% compared to 60% in Malakorn’s series for high transsphincteric fistulas, with similar healing criteria. Another point of influence might be that we do not administer antibiotics pre- or postoperatively in comparison with Malakorn, because of antibiotic stewardship that is becoming more and more important, and because we do not completely close the skin to allow for drainage. However, other studies with good results also do not administer antibiotics, which makes it less likely to be of influence.

When taking a closer look at the recurrences, we found quite a high number of conversions toward an intersphincteric fistula (55% of recurrences). This “downstaging” of the fistula opens the possibility for other techniques like a “simple” fistulotomy. We might consider this outcome to be true ”secondary healing.” Results in this group after secondary treatment are excellent. Many surgeons advocate that LIFT may be performed, as a means to modify the complexity of the fistula toward an intersphincteric fistula to facilitate secondary healing. This is of course a very welcome side effect. It does, however, result in another surgical intervention for the patient. It could be advocated to choose LIFT not as a means to cure the fistula, but as an attempt to simplify or “reroute” the fistula. In our opinion, the morbidity, as well as the difference in morbidity between LIFT and TAFR, does not warrant this approach.

Results concerning continence status are relatively good with only 1 in 5 patients noticing a minimal decline in continence status. Compared to what we know of continence status after fistulotomy, for instance, these results are very good, but we need to take into account that the majority of patients will need an additional operation that will often include division of the internal sphincter. In a large series of fistulotomies for low perianal fistulas, major incontinence was reported in 28.0% and only 26.3% had a perfect continence status. These data confirm our hesitation in advocating LIFT merely as a modifier of complexity. Many authors state that fecal continence after LIFT is unimpaired. It has to be stated that very few robust data are available on fecal continence after LIFT. Validated scoring systems including preoperative data are seldom used. Our experience confirms that impairment of fecal continence is rare and, when present, mild. However, it seems
fully comparable to the functional results of TAFR as reported previously.\textsuperscript{22}

In general, it is very difficult to compare results of all available surgical techniques for closure of high perianal fistulas. It is even more difficult to compare these results in patients with Crohn’s disease, in part, because of the many variations in the techniques and different uses and duration of setons. Although we did not find a contrasting difference in our technique compared with centers we have visited, literature shows many different variations of the LIFT. The LIFT has been combined with several types of biomaterials like a Plug,\textsuperscript{4} the insertion of a bio-graft,\textsuperscript{23} combination of the technique with a TAFR,\textsuperscript{6} and variants with lateral approach of the intersphincteric plane.\textsuperscript{5} It is very doubtful it will be possible to compare all these variations to the “standard” LIFT procedure in a methodologically good fashion. The influence of these variations may therefore not be very noticeable. We concede our study is limited by its retrospective design, and our numbers are not that large. Besides that, selection bias will have influenced our results because of the type of fistula for which we offer the procedure, and the shared decision making with our patients. However, the present results show the outcomes of a high-volume fistula center with experienced colorectal surgeons. This should raise concern about the efficacy of LIFT. We wonder whether or not LIFT, like many other techniques that were initially reported to be very efficacious, will show more and more unfavorable results? Or might the LIFT just not be the right treatment for high transsphincteric fistulas as mentioned previously. The advent of many modifications to the technique may be a clue that several other authors have also been disappointed by the outcome of LIFT, otherwise, why would modifications be reported on a near-perfect technique?\textsuperscript{2,3,6,8,23}

Studies do not often show the difference in results for low and high transsphincteric fistulas, which might explain some of the difference with our results.\textsuperscript{18} Going back to the basics of the technique, the rationale of the LIFT is in contrast to most techniques for high perianal fistulas. Most other techniques aim at closure of the internal opening to allow the fistula tract to heal. The concept of LIFT is to divide the fistula tract, then for both ends to heal. The actual internal opening is not closed, but the internal side of the tract is ligated only in the intersphincteric plane. The reason why the fistulas may still heal after the LIFT is, in our opinion, still unclear. The mechanical part of the intervention might therefore not be the reason for healing. Many authors have, in recent years, tried to decipher the pathophysiology of fistula development and inflammation in surrounding tissue, but none have managed to completely explain the pathway.\textsuperscript{24,25} The old cryptoglandular theory by Parks is now being questioned.\textsuperscript{26} Aiming our research at this “basic” part of fistulas might be a far better way to invest our efforts than developing more and more other surgical procedures for fistula treatment.

**CONCLUSION**

In conclusion, our results with the LIFT procedure were not as good as hoped. The effect on fecal continence was minimal, however, but not negligible. In select cases, probably low transsphincteric fistulas, we will most likely still consider the LIFT as a viable treatment option, but due to the presented results it is likely we will revert to the TAFR more often, as a technique that has proven itself for far longer than the LIFT. Many authors have advocated that a comparative study should be performed to assess the true efficacy of LIFT in comparison with other sphinctersaving techniques; however, in our hands, there does not seem to be equipoise to justify a randomized study.

**REFERENCES**


