



# Fistulectomy with primary sphincter reconstruction

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## Abstract

**Aim** Despite modern medical techniques, anatomically proximal (high) anal fistulas are still a challenge in colorectal surgery. In previous years, the standard of care was complete fistulectomy with a high rate of continence disorders. Over the past 20 to 30 years, sphincter-saving procedures have gained wide acceptance. They represent the technique used in these cases. Additionally, many patients received indefinite treatment, namely the placement of a seton to maintain surgical drainage. The main problem with all fistula surgical possibilities is the high recurrence rate of 30 to 50% in flap procedures and 100% persistence in seton treatments. In recent years, a direct repair (primary reconstruction) in distal fistulas was instigated and shows excellent results. It allowed our technique for proximal (high) anal fistulas to evolve.

**Method** All patients who underwent surgery at the University Medical Center Mannheim, Department of Colo-proctology (from 06/2003 to 11/2015), were retrospectively evaluated using a prospective database. Patients who underwent fistulectomy with primary sphincter reconstruction were all included.

**Results** The primary healing rate, after a mean follow-up of 11 months (7 to 200 months), was 88.2% (374 of 424). Taking into account revisionary surgeries with secondary sphincter repair, this rate reaches 95.8% (406 of 424). Factors such as gender and fistula location as related to the sphincter had significant influence on the study outcome, whereas variables such as the amount of reconstructed muscle (in mm), number of revisions, patient age, other anal operations, and concomitant medication did not. The incontinence of a subgroup of 148 patients was evaluated in detail by way of a questionnaire. Even at a preoperative baseline, 9.6% of those patients reported some minor degree of continence disorders. After the procedure, incontinence disorders were observed in 34 patients (23.0%), with 23 of these patients suffering from flatus incontinence (15.5%), 10 patients from liquid incontinence (6.8%), and 1 patient from solid fecal incontinence.

**Conclusion** Fistulectomy with primary sphincter reconstruction is a feasible procedure resulting in a low recurrence rate. No other procedure has shown better results in transsphincteric fistulas. Continence disorders seem to be of minor relevance/consequence for these patients.

**Keywords** Anal fistula · Fistulectomy · Primary reconstruction · Continence · Seton · Recurrence

## What does this paper add to the literature?

To our knowledge, this is the first publication wherein the amount of affected sphincter muscle is evaluated in such a

differentiated fashion. Our cohort included more patients than did other trials. Our results demonstrated that fistulectomy with primary sphincter reconstruction is a safe and feasible procedure for both distal and intermediate transsphincteric fistulas alike, showing higher rates of healing than other procedures. Even in proximal (high) transsphincteric fistulas, the procedure shows comparable healing rates as compared to other procedures.

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## Introduction

Even in this millennium, high anal fistulas are a challenge in colorectal surgery. In former years, the standard of care was a complete fistulectomy, bringing with it a high rate

of continence disorders [1]. Because of this, there was a shift towards sphincter-sparing procedures. Over the past 20 to 30 years, flap procedures have gained wide acceptance and were used in these cases. Alternatively, many patients were treated with a seton as a definite treatment, e.g., Crohn's fistulas. The main complication of all of these surgical possibilities is still a high rate of recurring and persisting fistulas, with a recurrence of 30 to 50% in flap procedures and 100% in seton placements [1]. Direct repairs in distal fistulas, via the use of primary reconstruction, began 10 years ago and produced excellent results [2]. This success allowed surgeons to expand such surgical techniques to incorporate intermediate and proximal (high) anal fistulas as well.

## Method

This study is a retrospective evaluation of prospectively acquired data from patients in a single-center setting. The study was approved by the local ethics committee (2017-819R-MA). All patients have given their informed consent to participate.

## Patients

All consecutive patients operated on by the principal surgeon were retrospectively evaluated by use of a prospective database. In this study, 439 patients, of which 171 were female and 268 were male, with a mean age of 47 years, underwent operations (Table 1). Finally, we could enroll 424 patients with a complete data set. In 17%, surgery was performed to treat persisting fistulas following prior fistula operations, 5% were

**Table 1** Patient characteristics preoperative

|                           |        |         |
|---------------------------|--------|---------|
| Number                    | 439    |         |
| Sex                       |        |         |
| Men                       | 268    | 61.05%  |
| Women                     | 171    | 38.95%  |
| Age (years)               | 47     | (19–79) |
| Incontinence <sup>a</sup> | 13/148 | 9.60%   |
| Gas                       | 10     | 7.40%   |
| Liquid                    | 9      | 6.60%   |
| Solid                     | 3      | 2.20%   |
| Crohn's disease           | 24     | 5.47%   |
| Medication                |        |         |
| Anticoagulation           | 18     | 4.10%   |
| Immunomodulation          | 6      | 1.30%   |

<sup>a</sup>Data from 148 patients with special evaluation of incontinence

**Table 2** Information about the surgeries

|   |            |
|---|------------|
| Number  | 424        |
| Length of surgery (min)                               | 21 (12–62) |
| Type of fistula (% involved sphincter)                |            |
| Supra/high transsphincteric (> 70%)                   | 36 8.5%    |
| Intermed transsphincteric (> 40–> 70%)                | 243 57.3%  |
| Distal transsphincteric (< 40%)                       | 145 34.2%  |
| Postop hospital stay (days)                           | 3 (1–17)   |
| Time between seton placement and fistulectomy (month) | 9 (7–38)   |

suprasphincteric fistulas, and 95% were transsphincteric fistulas. Intersphincteric, subcutaneous, anovaginal, and rectovaginal fistulas were excluded. Patients with Crohn's disease were also included. Initially, most patients presented with a primary abscess or with chronic inflammation of a residual fistula tract. Therefore, it was necessary to reduce inflammation by way of wide abscess excisions or partial fistulectomies and to place a seton for 7 to 36 weeks (Table 2). After complete resolution of the local inflammation, patients were scheduled for a fistulectomy with primary sphincter reconstruction.

## Surgical technique

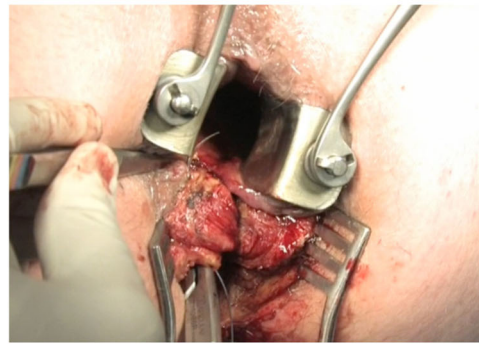
All patients received an enema or laxative suppository but no further bowel preparation. First, the fistula situation is examined again to check its operative suitability. This entails the tract being probed with a fine fistula probe (Fig. 1a). Via palpation, the amount of involved muscle can be estimated. In the vast majority of patients, the inner opening lies at the dentate line. The length of the fistula differs from case to case and depends on whether the course of the tract is straight or curved. Comparable internal and external openings might involve different amounts of sphincter muscle.

Directly distal of the inner opening is where the incision should begin, from the anoderm to the anocutaneous line. From there, the external opening is excised in an elliptical form. After the dissection of all of the subcutaneous tissue, the fistula tract is gently excised as far to the outer border of the external sphincter as possible. Now, all tissue is excised, same for the muscle. At this stage of the procedure, it is still feasible to alter techniques, if the planned operation seems unsuitable (Fig. 1b). If the procedure seems suitable, the patient received single-shot

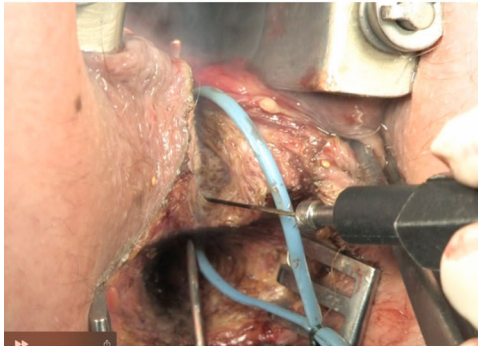
**Fig. 1** a Proximal transsphincteric dorsal fistula with a seton and probe. **b** Complete excision of fat and scar to the external sphincter and superficial incision of the sphincter. **c** Complete sphincter dissection until the fistula; direct vision of the dorsal fistula aspect. **d** Excision of granulation; epithelial tissue and scar around the fistula. **e** Starting the reconstruction on the right side of the sphincter. **f** Approximation of the muscle with single sutures. **g** Final aspect with complete reconstruction



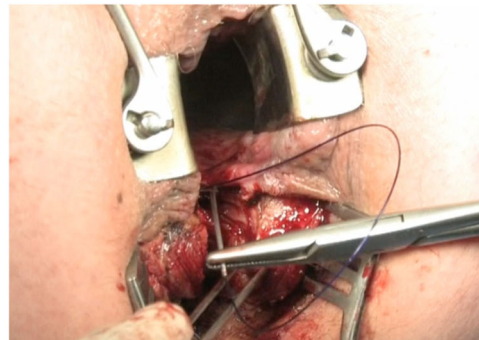
a) Proximal transsphincteric dorsal fistula with a seton and probe



e) Starting the reconstruction on the right side of the sphincter



b) Complete excision of fat and scar to the external sphincter and superficial incision of the sphincter



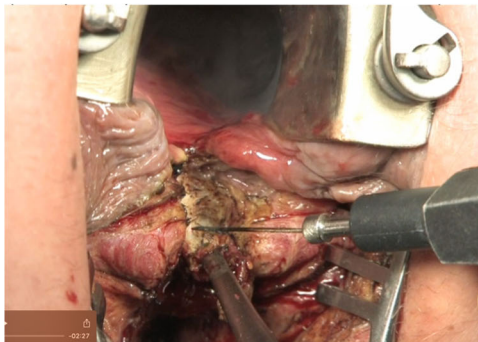
f) Approximation of the muscle with single sutures



c) Complete sphincter dissection until the fistula, direct vision of the dorsal fistula aspect



g) Final aspect with complete reconstruction



d) Excision of granulation, epithelial tissue and scar around the fistula

antibiotic prophylaxis (ceftriaxone 2 g and metronidazole 500 mg). The sphincter muscle is then incised vertically until the fistula tract is reached (Fig. 1c). This lay-open allows an ideal view to the tract and all surrounding tissue. No other technique allows for better exposure. In many cases, not a single tract will be found, but instead, residual cavities and holes, especially in the proximal portion of the sphincter. This technique allows these to be visualized, so that excision can be performed accurately (Fig. 1d). Practically, one starts from the distal external side. The dorsal aspect of the granulous tract is completely excised, including all cavities, and leaving only healthy tissue behind (Fig. 1e). This gives the surgeon a perfect view of the fistula, enabling a complete excision of all granulation and scar tissue. Due to the inflammation and chronic sclerosis in most cases, the separation of the internal and external sphincter is not possible, but for reconstruction, such a separation is not necessary. To achieve sufficient mobility, the sphincter muscle is mobilized from the anoderm and the external ischioanal fat. Generally, only a few millimeters of excision suffice. Reconstruction starts at the proximal-most part of the dissection; the first stiches are placed at a 45° angle to the fistula axis, so as to adapt the uppermost tissue (Fig. 1e, f). With every muscle stitch, you take a deep bite to both sides and adapt the muscle by suturing a firm knot. The knots are placed on the outside of the sphincter, so as not to interfere with the healing on the inside. After two to three stiches in the muscle, the upper part of the anoderm, or distal part of the rectal mucosa around or above the dentate line, is approximated, so that the anoderm can also be reconstructed (Fig. 1g). The retractor is then carefully closed, so that the next part of the muscle can be sutured, followed by the anoderm of this section. Polydioxanone sutures (PDS), size 0 or 2 × 0, were used for muscles, and vicryl, size 0, was used for the anoderm. Finally, the entire sphincter complex is anatomically reconstructed, and the distal wound of the ischioanal space is left open to allow for lateral drainage

**Table 3** The three groups of patients

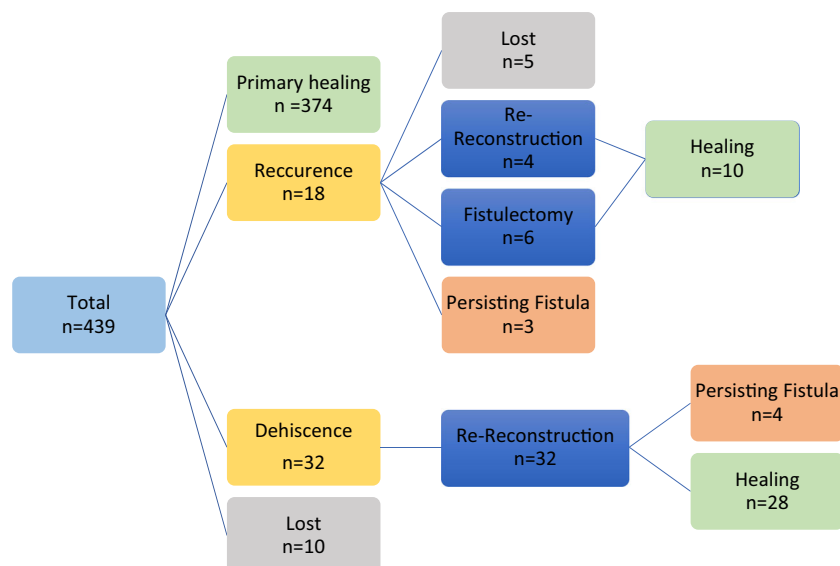
|  | Persisting fistula (%) | Dehiscence (%) |
|--|------------------------|----------------|
| Distal fistulas ( <i>n</i> = 145)      | 3.4                    | 1.4            |
| Intermediate fistula ( <i>n</i> = 243) | 3.7                    | 6.2            |
| Proximal fistula ( <i>n</i> = 36)      | 11.1                   | 41             |

(Fig. 1g) (for complete procedure, see Fig. 1a–g). The operation is completed with a soft gauze dressing. No intraanal plug is necessary. No special wound care is employed, and the wound can be rinsed out in the shower starting on the first day after the operation. The patient is allowed to walk, but physical exercises should be restrained for 4 to 6 weeks.

## Endpoints and study visits

The main indicator used in this trial was the healing rate. This was defined as the complete healing of all tracts, of external and internal opening, and no further induration evaluated by clinical examination. All patients were evaluated 2 to 4 weeks, 4 to 6 weeks, 3 months, and 6 months after the operation, as well as after 12 months, if possible. Dehiscence could be easily detected 2 to 4 weeks after the operation via inspection and palpation, because at this point, the external wound is still open. The latter examination is mandatory and is performed by the operating surgeon, who is aware of the patient's intraoperative status and the postoperative situation.

A failure to heal resulted in persisting fistulas. Primary healing with a subsequent recurrence was also observed. Both of these situations were summarized under the term recurrence in this trial.

**Fig. 2** Flowchart of all patients

**Table 4** Results depending on millimeters of affected sphincter

| Amount affected sphincter (mm)           | < 10        | 10         | 15         | 20         | 25           | 30          | 35          | 40          | 50          | 60          |
|--|-------------|------------|------------|------------|--------------|-------------|-------------|-------------|-------------|-------------|
| Total number per group ( <i>n</i> = 424) | 3           | 104        | 134        | 84         | 49           | 32          | 2           | 8           | 5           | 3           |
| Recurrence %<br>( <i>n</i> = 18)         | 0.0<br>(0)  | 4.8<br>(5) | 1.5<br>(2) | 3.4<br>(3) | 4.2<br>(2)   | 15.6<br>(5) | 0.0<br>(0)  | 0.0<br>(1)  | 0.0<br>(0)  | 0.0<br>(0)  |
| Dehiscence %<br>( <i>n</i> = 32)         | 0.0<br>(0)  | 2.9<br>(3) | 3.7<br>(5) | 6.7<br>(6) | 12.5<br>(6)  | 12.5<br>(4) | 50.0<br>(1) | 37.5<br>(3) | 60.0<br>(3) | 33.3<br>(1) |
|  | 0 – 20      |            |            |            | >20 – <40    |             |             | ≥40         |             |             |
|  | 325         |            |            |            | 83           |             |             | 16          |             |             |
|  | 3.1<br>(10) |            |            |            | 8.4<br>(7)   |             |             | 6.3<br>(1)  |             |             |
|  | 4.3<br>(14) |            |            |            | 13.3<br>(11) |             |             | 37.5<br>(6) |             |             |

Because of the large cohort, subgroups were established: distal fistulas, where the tract crosses the distal third of the sphincter; intermediate fistulas, where the tract crosses the middle third of the sphincter; and proximal fistulas, where the tract crosses the proximal third of the sphincter. The sphincter length and the amount of sphincter that was surrounded by the fistula tract were measured in millimeters (mm). These were always rounded up or down per 5 mm part. This range of two measurements was then compared, resulting in the percentage of involved sphincter, e.g., 20 mm of included sphincter out of a total length of 50 mm, which results in 40% of engaged muscle. To our knowledge, this is the first study evaluating these details.

## Statistical analysis

In order to compare two groups (i.e., healing “yes” or “no”), the following tests were used wherever appropriate:  $\chi^2$  test, Fisher’s exact test, Cochran-Armitage trend test, two-sample *t* test, or Mann-Whitney *U* test. Furthermore, a logistic regression analysis with a binary outcome was performed in order to

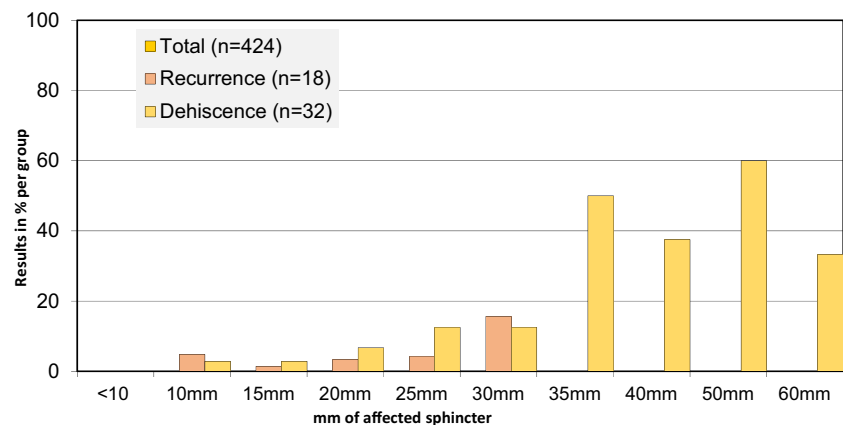
analyze several factors simultaneously. A test result with a *p* value less than 0.05 has been considered as significant.

All statistical calculations have been done with SAS, release 9.3 (SAS Institute Inc., Cary, NC, USA).

## Results

Our experience with complete fistulectomy, including primary sphincter reconstruction, started in 2003. The primary healing rate after a mean follow-up of 11 months (7 to 200 months) was 88.2% (374 out of 424). When adding a revisionary surgery with a second sphincter repair, this percentage reaches 95.8% (406 out of 424). The procedure was done in a median time of 21 min (12 to 62). The median postoperative hospitalization in these patients was 3 days (1 to 17) (Table 2).

If any dehiscence of the sutures was detected at the time of the first follow-up visit, a re-operation was indicated. During this procedure, the muscle was again sutured and approximated as in the first operation. Of the 32 patients who experienced wound dehiscence, 28 of those patients healed without further complications upon

**Fig. 3** Results depending on millimeters of affected sphincter

**Table 5** Results depending on percentage of affected sphincter

| Amount affected sphincter (%)        | 10          | 20         | 30         | 40         | 50          | 60          | 70          | 80          | 90          | 100         |
|--------------------------------------|-------------|------------|------------|------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Total number per group ( $n = 424$ ) | 5           | 29         | 111        | 87         | 95          | 61          | 11          | 11          | 7           | 7           |
| Recurrence %<br>( $n = 18$ )         | 0.0<br>(0)  | 6.8<br>(2) | 2.7<br>(3) | 1.2<br>(1) | 3.2<br>(3)  | 8.2<br>(5)  | 0.0<br>(0)  | 9.1<br>(1)  | 0.0<br>(0)  | 42.9<br>(3) |
| Dehiscence %<br>( $n = 32$ )         | 20.0<br>(1) | 0.0<br>(0) | 0.9<br>(1) | 4.6<br>(4) | 4.2<br>(4)  | 11.5<br>(7) | 36.4<br>(4) | 45.5<br>(5) | 42.9<br>(3) | 42.9<br>(3) |
|                                      | 0–20        |            | 30–<50     |            | 50–70       |             |             | >70–100     |             |             |
|                                      | 34          |            | 198        |            | 167         |             |             | 25          |             |             |
|                                      | 5.9<br>(2)  |            | 2<br>(4)   |            | 4.8<br>(8)  |             |             | 16<br>(4)   |             |             |
|                                      | 2.9<br>(1)  |            | 2.5<br>(5) |            | 8.9<br>(15) |             |             | 44<br>(11)  |             |             |

a second reconstruction. In four patients, the muscle could be sutured again and healed, but the fistula proximal of the reconstructed sphincter persisted. The flow chart of the whole group is presented in Fig. 2.

All recurrences ( $n = 18$ ) were persisting fistulas, where in no real recurrence after primary healing occurred. In all patients, where an extensive follow-up was possible, no recurrence developed.

Because of the large number of patients, it was possible to separate subgroups and evaluate those in detail (Table 3).

Also, these three groups were large enough to differentiate still further subgroups: from < 10 to 60 mm of reconstructed sphincter, separate groups were created (Table 4, Fig. 3). In cases with up to 3 cm of reconstructed sphincter, the recurrence and dehiscence rate was below 15%, but in cases where more than 3.5 cm were affected, the dehiscence rate only rose to 50%, with surprisingly no recurrences. But this group of high transsphincteric and suprasphincteric fistulas represents only 18 out of the 424 patients, or, 4.2% of all operated patients. A logistic regression analysis showed no significant correlation between healing rates and the amount of reconstruction in millimeters ( $p = 0.1941$ ) (Table 6).

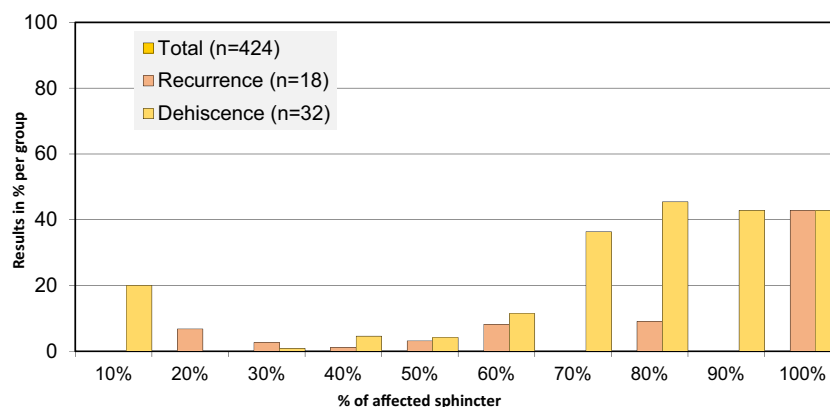
A comparable evaluation was done using the percentage of affected sphincter. This is much more precise in relation to each individual patient, e.g., 1 cm of dorsal sphincter in a man is

20%, or less, of his sphincter complex, but 1 cm of ventral sphincter is half of the whole muscle in a woman. The results are shown in Table 5 and Fig. 4: if up to 70% of the muscle was affected—this means two thirds of the sphincter complex—then the dehiscence rate was below 12%, and recurrences occurred in less than 10%. Furthermore, the logistic regression analysis for the percentage of affected muscle showed a high significant correlation concerning healing rates ( $p = 0.0114$ ). As demonstrated above, only when over 70% of the sphincter is affected, dehiscence and recurrence rate rises to around 40%. This group of 36 patients represents 8% of the total cohort. Conversely in 92% of our patients, low recurrence rates could be achieved.

This also demonstrates that the amount of affected muscle in millimeters is not as precise as the percentage of affected muscle in percent.

With multivariable evaluation, gender and location of the fistula as related to the sphincter had significant influence on the outcome, whereas the number of revisions, patient age, prior anal operations, and concomitant medication did not (Table 6).

Because of the retrospective analysis, it was not possible to rule out the results concerning the continence of all patients. Therefore, a subgroup of 148 patients, operated on from 2004 to 2007, was evaluated by using a

**Fig. 4** Results depending on percentage of affected sphincter

**Table 6** Results of multivariable analysis

| Parameter                               | Statistical test   | <i>p</i> value |
|---|--------------------|----------------|
| Gender                                  | Chi                | 0.0465         |
| CED                                     | Fisher             | 0.6127         |
| Type of fistula                         | Trend              | 0.0190         |
| Age                                     | <i>t</i> test      | 0.9191         |
| OR time                                 | <i>U</i> test      | 0.0016         |
| Amount of muscle (in mm)                | Logistic procedure | 0.1941         |
| Amount of muscle (% involved sphincter) | Logistic procedure | 0.0114         |

questionnaire to evaluate their degree of continence (not validated). Even at baseline, before the operation, 9.6% reported some minor degree of continence disorders (Table 1). After the procedure, those patients' incontinence disorders were observed in 34 of those patients (23.0%), with 23 (15.5%) of those patients suffering from flatus incontinence, 10 (6.7%) from liquid incontinence, and 1 patient from solid stool incontinence (Table 7).

Seventy-five patients had undergone fistula operations for recurrence. In this subgroup, the primary healing rate was 74.6% (56 out of 75). The rate of postoperative dehiscence was elevated to 13 out of 75 (17.3%). Adding the results of the re-reconstruction to the healing rate, this reaches 88.0% (66 out of 75).

## Discussion

In this large cohort of patients, it was possible to demonstrate the practicability of an until-now, rarely used procedure and to achieve very promising initial results, superior to those reported in advancement flaps, fibrin glue, or anal fistula plugs [1]. By using this technique, one normally fears the rupture of the muscle sutures, but this occurred only in 0 to 8% in the various studies—much less than expected [3–6]. In our experience, all of these insufficiencies could be repaired in a secondary operation, if performed in the first 2 to 4 postoperative weeks. So, this concern and fear—not present in other procedures, e.g., flap procedures—is altogether not neglectable but must be weighed against the benefit of a low recurrence rate, and it can be solved in a second operation. A rupture of the mucosal or anodermal sutures occurred in 30 to 40% without

**Table 7** New onset of incontinence

|                                     |                |
|-------------------------------------|----------------|
| Incontinence disorder, <i>n</i> (%) | 34/148 (22.97) |
| Gases                               | 23 (15.54)     |
| Liquid                              | 10 (6.75)      |
| Solid                               | 1 (0.67)       |

negative influence on the outcome, especially the healing of the sphincter muscle. Hull et al. were able to demonstrate that even the complete sphincter can be reconstructed with adequate results [7].

Today, the recurrence rate in transsphincteric anal fistulas is still quite high, but this problem is not yet solved by new procedures like plug operations or LIFT procedures. Fistulectomies with primary sphincter reconstruction have a lower recurrence rate compared to the aforementioned techniques [1, 5, 8–11]. In our study, the recurrence rate with fistulectomy and primary reconstruction was in the range of the results published by Roig et al. [3] and Arroyo et al. [4] (9.7 and 8.5%, respectively). Perez et al. [9, 12] and Lux et al. [11] observed an even lower recurrence rate of 6.0, 7.1, and 0.0%, respectively. However, the low recurrence rates may be attributed to the type of fistulas included in their studies. So far, the only randomized study [12] comparing fistulotomy and sphincter reconstruction with advancement flaps reported a similar recurrence rate (7.1 versus 7.4%) in both groups after 36 months. This demonstrated very impressive results especially when considering that only high transsphincteric and suprasphincteric fistulas were included. As described before, this technique can also be used after other procedures have failed [8].

To our knowledge, this is the first publication wherein the amount of affected sphincter muscle is evaluated in such a differentiated fashion. It was clearly demonstrated that the terms “transsphincteric” and “transsphincteric” cannot always be compared: a transsphincteric fistula with 70% (e.g., 3 cm) muscle involvement has a different outcome than a transsphincteric fistula with 30% (e.g., 1 cm) muscle involvement. Such an evaluation is only possible if you have access to a large cohort of patients who need treatment. But in all publications up until now, these are all incorporated into one group of transsphincteric fistulas. For further trials and publications, this differentiation must be taken into account when talking about results in fistula surgery. As mentioned above, a more precise description of transsphincteric fistulas is necessary to evaluate which procedure is suitable for which kind of fistula.

For those patients who had already undergone several past operations, and who were seeking a cure for a persisting fistula, a minor continence disturbance was considered to be acceptable. No patient in our group claimed a continence disorder on their own accord. Only after targeted questioning did the patients mention their issues with continence. So, in our daily practice, a patient's primary concern is fistula recurrence, and not incontinence. In the only randomized study comparing fistulotomy and sphincter reconstruction with advancement flaps, and postoperative incontinence [12], the result of the Wexner score (0.64 versus 0.48) was comparable—primary reconstructions did not show deteriorated sphincter functions as expected. Perez et al. were able to show that continence was improved after this reconstructive operation in

patients with preoperative continence disorders, without compromising fully continent patients [9].

## Summary

Fistulectomy with primary sphincter reconstruction is a feasible procedure resulting in a low recurrence rate. Direct repairs in distal and intermediate fistulas showed excellent results. Regarding proximal (high) anal fistulas, the risk of recurrence is higher but still comparable to other techniques used in these cases.

No other procedure has shown better results in transsphincteric fistulas. It seems that continence disorders are of minor concern for these patients. But further structured investigation is necessary.

## Compliance with ethical standards

The study was approved by the local ethics committee (2017-819R-MA). All patients have given their informed consent to participate.

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