


German S3 guidelines: anal abscess and fistula (second revised version)

Andreas Ommer¹  · Alexander Herold² · Eugen Berg³ · Alois Fürst⁴ · Stefan Post⁵ · Reinhard Ruppert⁶ · Thomas Schiedeck⁷ · Oliver Schwandner⁸ · Bernhard Strittmatter⁹

Received: 14 September 2016 / Accepted: 1 February 2017 / Published online: 1 March 2017
© Springer-Verlag Berlin Heidelberg 2017

Abstract

Background The incidence of anal abscess and fistula is relatively high, and the condition is most common in young men. **Methods** This is a revised version of the German S3 guidelines first published in 2011. It is based on a systematic review of pertinent literature.

Results Cryptoglandular abscesses and fistulas usually originate in the proctodeal glands of the intersphincteric space. Classification depends on their relation to the anal sphincter. Patient history and clinical examination are diagnostically sufficient in order to establish the indication for surgery. Further examinations (endosonography, MRI) should be considered in complex abscesses or fistulas. The goal of surgery for an abscess is thorough drainage of the focus of infection while preserving the sphincter muscles. The risk of abscess recurrence or secondary fistula formation is low overall. However, they may result from insufficient drainage. Primary fistulotomy should only be performed in case of superficial

fistulas. Moreover, it should be done by experienced surgeons. In case of unclear findings or high fistulas, repair should take place in a second procedure. Anal fistulas can be treated only by surgical intervention with one of the following operations: laying open, seton drainage, plastic surgical reconstruction with suturing of the sphincter (flap, sphincter repair, LIFT), and occlusion with biomaterials. Only superficial fistulas should be laid open. The risk of postoperative incontinence is directly related to the thickness of the sphincter muscle that is divided. All high anal fistulas should be treated with a sphincter-saving procedure. The various plastic surgical reconstructive procedures all yield roughly the same results. Occlusion with biomaterial results in lower cure rate.

Conclusion In this revision of the German S3 guidelines, instructions for diagnosis and treatment of anal abscess and fistula are described based on a review of current literature.

Keywords Fistula-in-ano · Anal abscess · Anal fistula · Diagnostic · Operative treatment · Fecal incontinence

✉ Andreas Ommer
aommer@online.de

¹ End- und Dickdarm-Zentrum Essen, Rüttenscheider Strasse 66, 45130 Essen, Germany

² Deutsches End- und Dickdarmzentrum, Mannheim, Germany

³ Prosper-Hospital Recklinghausen, Recklinghausen, Germany

⁴ Caritas-Krankenhaus Regensburg, Regensburg, Germany

⁵ Universitätsklinikum Mannheim, Mannheim, Germany

⁶ Klinikum Neuperlach, Munich, Germany

⁷ Klinikum Ludwigsburg, Ludwigsburg, Germany

⁸ Krankenhaus Barmherzige Brüder, Regensburg, Germany

⁹ Praxisklinik, 2000 Freiburg, Germany

Introduction

Anal fistula and its acute form of anal abscess are common diseases with an incidence of about 2 cases per 10,000 inhabitants per year. It is most likely to occur between the ages of 30 and 50 [76]. Men are more likely to be affected than women [60].

Methods

German guidelines for the treatment of anal abscess and fistula have been published in 2011 for the first time [43–46]. The content of the present guidelines is based on an extensive

actual review of literature, published after finishing the first version. The selection of new publications can be found in the German version of these guidelines [48, 49].

Definitions of strength of evidence, recommendation grade, and strength of consensus have been established (Tables 1 and 2) [28, 53, 61]. Due to a large difference between evidence level and clinical practice in some cases, the recommendation grade was defined as “point of clinical consensus.” The guidelines group (Table 3) produced this text in the context of a consensus conference on March 11, 2016, in Munich.

In this publication, statements are based primarily on new developments of treatment. Whereas in anal abscess new evidence for treatment options are missing, in anal fistulas some new surgical procedures have been introduced (LIFT procedure, laser, video-assisted fistula treatment (VAAFT), over-the-scope clip (OTSC), stem cells, new plug materials), which are mentioned in this version. For further information, see the first publications of these guidelines [45, 46].

Etiology and classification

Cryptoglandular anal abscesses and fistulas arise from an inflammation of the proctodeal glands, which are only rudimentary in humans. They are situated in the intersphincteric space (Fig. 1) [30].

A distinction is made between four different types of abscess based on its origin (Fig. 1). In clinical routine, classification of anal fistulas by their relationship to the sphincter has proved useful (Fig. 2). Types 4 and 5 are not cryptoglandular fistulas.

Some publications are discussing diabetes mellitus, obesity, alcohol, and smoking [1, 13] but also some lifestyle factors like spending too much time sitting, less movement, straining at defecation [72], and psychosocial stress [10] as risk factors for abscess or fistula formation.

Symptoms and diagnosis

Symptoms of anal abscess comprise painful swelling and possible reddening with acute onset in the anal region. Because of the pain involved, the rectal examination should be kept to a minimum. Discharge from a perianal opening is the typical symptom of anal fistula. Preoperative advanced diagnostics, particularly imaging, is not required in the majority of patients.

Further procedures are performed intraoperatively under anesthesia. They include inspection of the anal canal to confirm or exclude internal fistula opening. The area may be carefully probed using a curved probe, but extensive examination is not recommended. The abscess can be localized by endosonography, and the best surgical access route can be chosen accordingly, particularly in case of supralelevator abscesses.

In summary, anal abscess is diagnosed using clinical signs and symptoms, as well as inspection and palpation. Imaging diagnostics should only be considered in case of supralelevator abscess or recurrent abscess.

Recommendation level: point of clinical consensus

Strength of consensus: strong consensus

In cases of complex recurring anal fistulas, the use of imaging techniques should be considered [8]. Endosonography is a simple and cheap technique, and its usefulness can be improved by contrast enhancement, e.g., using hydrogen peroxide. The correlation between intra-anal ultrasonography and intraoperative clinical examination is higher than 90% [8]. Endosonography is easy and cheap, but its results depend to a high degree on the examiner’s experience. Magnetic resonance imaging (MRI) can be employed either as an external investigation with or without contrast medium or using an intrarectal coil [59]. MRI is cost-intensive and not always available, and its diagnostic value depends on technical conditions; however, it should be preferred to endosonography in cases of lesions distant from the anus. Another advantage of

Table 1 Definition of evidence levels and recommendation grades [53, 61]

Strength of recommendation	Level of evidence	Types of treatment studies
A (“should”)	1a	Systematic review of randomized controlled studies (RCT)
	1b	A suitably planned RCT
	1c	All-or-nothing approach
B (“ought to”)	2a	Systematic review of good-quality cohort studies
	2b	A good-quality cohort study, including RCT with moderate follow-up (<80%)
0 (“may”)	3a	Systematic review of good-quality case control studies
	3b	A good-quality case-control study
0 (“may”)	4	Case series, including poor-quality cohort and case-control studies
0 (“may”)	5	Opinions without explicit critical assessment, physiological models, comparisons, or principles

Table 2 Classification of the strength of consensus [28]

Strong consensus	Agreement of >95% of participants
Consensus	Agreement of 75–95% of participants
Majority agreement	Agreement of 50–75% of participants
No consensus	Agreement of <50% of participants

MRI is a pain-free acquisition of images which can be evaluated independently of the examiner. A review by Siddiqui et al. [62] showed a sensitivity of 0.87 (95% CI 0.63–0.96) and a specificity of 0.69 (95% CI 0.51–0.82) regarding the MRI examination, and a sensitivity of 0.87 (95% CI 0.70–0.95) and a specificity of 0.43 (95% CI 0.21–0.59) for the studies on endosonography. There are complaints with regard

Table 3 The guidelines group

Members of the anal fistula guidelines group:

For the German Society of General and Visceral Surgery (DGAV), the Surgical Working Group for Coloproctology (CACP), the German Society of Coloproctology (DGK), and the Association of Coloproctologists in Germany (BCD)

Dr. A. Ommer, Essen, Germany
 Prof. Dr. A. Herold, Mannheim, Germany
 Dr. E. Berg, Recklinghausen, Germany
 Priv.-Doz. Dr. St. Farke, Halberstadt, Germany
 Prof. Dr. A. Fürst, Regensburg, Germany
 Priv.-Doz. Dr. F. Hetzer, Uznach, Switzerland
 Dr. A. Köhler, Duisburg, Germany
 Prof. Dr. S. Post, Mannheim, Germany
 Dr. R. Ruppert, Munich, Germany
 Prof. Dr. M. Sailer, Hamburg, Germany
 Prof. Dr. Th. Schiedeck, Ludwigsburg, Germany
 Prof. Dr. O. Schwandner, Regensburg, Germany
 Dr. B. Strittmatter, Freiburg, Germany

For the German Society of Dermatology (DDG)

Dr. B.H. Lenhard, Heidelberg, Germany

For the Working Group for Urogynecology and Plastic Pelvic Floor Reconstruction (AGUB) of the German Society for Gynecology and Obstetrics

Prof. Dr. W. Bader, Bielefeld, Germany

For the German Society of Urology (DGU)

Prof. Dr. S. Krege, Essen, Germany

For the German Society of Gastroenterology, Digestive and Metabolic Diseases (DGAV)

Prof. Dr. H. Krammer, Mannheim, Germany

Prof. Dr. E. Stange, Stuttgart, Germany

Annotation: The complete text of the guidelines (in German) has been published in the Journal “Coloproctology” and online at <http://www.awmf.org>. Anal abscess: Coloproctology 2016 (38), 378–398 [48], <http://www.awmf.org/leitlinien/detail/II/088-005.html>. Anal fistula: Coloproctology (39) 16–66 online first [49], <http://www.awmf.org/leitlinien/detail/II/088-003.html>

to the distinct heterogeneity between the various studies. As a result, both methods provide equal sensitivity whereas MRI renders a better result with regard to specificity.

Core statement

Patient history and clinical examination are diagnostically sufficient to establish the indication for surgery. Further examinations (endosonography, MRI) should be considered only in case of recurrent, complex abscesses and complex fistulas of difficult clinical classification.

Evidence level: 1a

Recommendation grade: A

Consensus strength: strong consensus

Treatment for anal abscess

An anal abscess is treated surgically, with clinical signs and symptoms determining the timing of the surgical intervention. The purpose of the treatment is decompression of the abscess cavity in order to prevent progressive inflammation with potentially life-threatening complications (e.g., pelvic sepsis or Fournier gangrene [75]).

While acute abscess is an emergency, surgical intervention is also recommended in case of spontaneous perforation, since insufficient drainage may cause abscess recurrence or fistula formation.

Conservative treatment options, particularly antibiotic treatment, are unlikely to be successful and are not considered appropriate. Currently, there are no publications providing new information on recommendations on treatment.

Core statement

The timing of the surgical intervention primarily depends on the patient’s signs and symptoms, with acute abscess always representing an indication for emergency surgery.

Recommendation grade:	Point of clinical consensus
Strength of consensus:	Strong consensus

Abscess drainage technique

Generally, abscess surgery is performed under general or regional anesthesia. The surgical technique depends on the type of abscess [40]. In subnodular and ischioanal abscesses, a perianal incision or an excision removing an oval-shaped section of tissue is made. The latter is preferable for easier placement of the drainage. The incision should run parallel to the

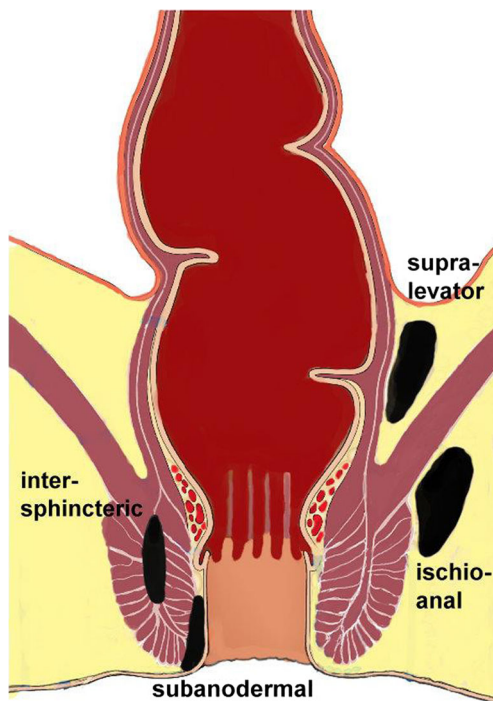


Fig. 1 Classification of anal abscesses

fibers of the sphincter ani externus muscle. Currently, there are no publications providing new information on recommendations on treatment.

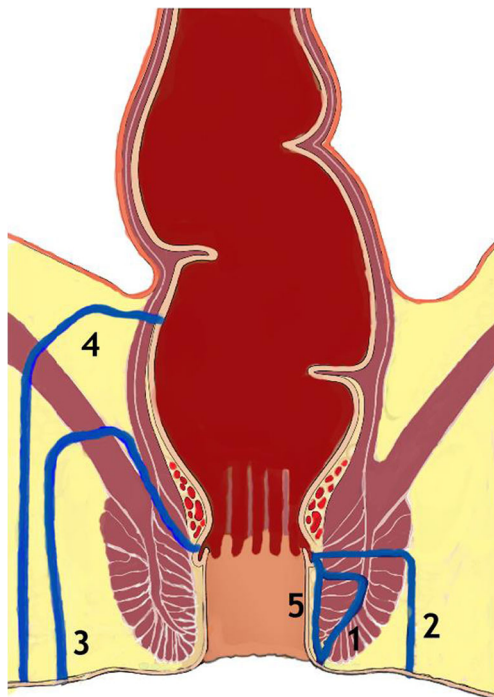


Fig. 2 Classification of anal fistulas (1 intersphincteric, 2 transsphincteric, 3 suprasphincteric, 4 extrasphincteric, 5 subnodermal)

Core statement

Anal abscesses are treated surgically. Access (transrectal or perianal) depends on the location of the abscess. The goal of surgery is thorough drainage of the infection focus while preserving the sphincter structures.

Recommendation grade:	Point of clinical consensus
Strength of consensus:	Strong consensus

Causes of abscess recurrence

Insufficient drainage [9, 50] and late drainage [74] can cause early recurrence.

Sufficient drainage of anal abscesses is therefore important to prevent recurrence and fistula formation. In case of extensive abscess, generous criteria should be applied when determining the indication for revision under anesthesia. Currently, there are no publications providing new information on recommendations on treatment.

Core statement

Overall, the risk of abscess recurrence or secondary fistula formation is low. They can be caused by insufficient drainage.

Evidence level:	4
Recommendation level:	B (Justification: For ethical reasons, this generally accepted statement cannot be tested using randomized studies.)
Strength of consensus:	Strong consensus

Indications for primary fistula surgery

Different publications indicate that fistulas identified in the context of abscess incision do not always require follow-up surgery. Moreover, the fistula may close spontaneously after thorough draining [25, 41, 57].

A current Greek paper [16] has shown a significantly higher recurrence rate in the follow-up at 12 months following simple excision and drainage compared to the results after excision and primary fistula treatment (44 vs. 6%). Treatment of the fistula consisted of dissection in case of intersphincteric fistulas and of seton drainage in case of high fistulas. At the same time, a significant number of continence disorders were to be observed in the group with primary fistula operations.

In summary, superficial fistulas, which perforate only small parts of the anal sphincter, should be treated with primary fistulotomy performed by experienced surgeons. An experienced surgeon is not really defined. In our opinion, an experienced surgeon should have done more than a minimum of 100 fistulas. Nevertheless, every division of parts of the anal sphincter bears the risk of fecal incontinence. In case of unclear findings or high fistulas, repair should be performed in a second procedure. High fistulas are defined as complex fistulas that enclosed large parts of the sphincter or are recurrent. A clear definition does not exist. Currently, there are no publications providing new information on recommendations on treatment.

Core statement

Intraoperative fistula exploration requires high caution. Excessive examination in order to confirm a fistula is not recommended. Primary fistulotomy should only be performed in superficial fistulas and by experienced surgeons. The risk of postoperative continence impairment increases with the amount of transected sphincter. In case of unclear findings or high fistulas on abscess surgery, repair should be performed in a second procedure.

Evidence level:	1a
Recommendation level:	A
Strength of consensus:	Strong consensus

Incidence of confirmed secondary fistula

In addition to abscess recurrence, development of an anal fistula requiring further intervention is the most common sequela associated with abscess surgery. According to literature, only some cases of abscesses are leading to development of chronic fistula [33, 57, 64]. One literature review reports chronic fistulas in 7 to 66% of cases (median 16%) and abscesses in 4 to 31% of cases (median 13%) [24]. Therefore, extensive fistula exploration is not recommended in the initial procedure. Currently, there are no publications providing new information on recommendations on treatment.

Evidence level:	3
Recommendation level:	B (Justification: For ethical reasons, this generally accepted statement cannot be tested using randomized studies.)
Strength of consensus:	Strong consensus

Surgical treatment: reviews

In 2011, guidelines of the American Society for Coloproctology [65] and in 2015 guidelines of the Italian Society for Colorectal Surgery have been published [3]. In 2016, the European Society for Coloproctology has published a review of the guidelines concerning treatment of anal abscess and fistula [12].

Therapeutic procedures

Diagnosis of anal fistula is usually an indication for surgery in order to prevent a recurring septic process. The operative technique is chosen according to the fistula tract and its relation to the anal sphincter. The surgical techniques are as follows:

Fistulotomy

The most common operative technique in use is fistulotomy, that is, division of the tissue between the fistula tract and the anal canal. Healing rates are between 74 and 100%. Rates of impaired continence vary between 0 and 45%. For low fistulas, a healing rate of almost 100% can be achieved. In literature, rates of postoperative incontinence were found to be relatively low. However, it is still a sequel to be taken seriously. In all cases, the incontinence rate rises with the amount of sphincter being divided. Extensive division should always be avoided. A current multicentric study on 537 patients [22] describes a primary healing rate of 84% (follow-up 60 months). The rate of continence disturbances (74%) was quite high (major incontinence 28%), but quality of life does not differ from the general population.

Evidence level: 2b

Recommendation grade: B

Consensus strength: strong consensus

Seton drainage

Placement of a seton drain is another frequently employed technique in anal fistula surgery. The material used is either a strong braided non-resorbable suture or a plastic (vessel loop, etc.) suture thread. Three different techniques are in use:

Drainage seton (loose seton)

The aim of this technique is long-term drainage of the abscess cavity. This helps to prevent premature closure of the external fistula opening. Later, the thread is removed in order to allow spontaneous healing of the fistula. Healing rates in retrospective observational studies identified a variance between 33 and 100%. Impaired continence is reported in 0 to 62% of cases

[53]. These results are due to the fact that interventions undertaken in addition to placement of the seton are not always clearly defined. There are no randomized studies on this subject so far. Definitive healing of cryptoglandular anal fistulas, even in the long term, by leaving a loose seton in place may be seen as the objective only in extremely few cases. Usually, further intervention is required. Currently, there are no publications providing new information on recommendations on treatment.

Fibrosing seton

Placement of a fibrosing seton usually occurs either primarily or secondarily in the setting of an acute or persistent inflammation. The aim is to fibrose the fistula tract before further surgical interventions. Secondary lay open of the remaining fistula is most often described in the literature. The observational studies identified in the literature search report healing rates of nearly 100%. However, this is associated with a high rate of impaired continence. Overall, results in literature vary between 0 and 70%. In Germany, the fibrosing seton is used mainly in high fistulas before definitive reconstruction surgery. Whether the use of the seton promotes success of a reconstructive procedure is not clear.

Cutting seton

The aim of the cutting seton is successive division of those parts of the sphincter which are enclosed by the fistula tract once the inflamed area has been cored out. The seton can be stretchable (usually rubber) and will gradually cut through the tissue, or repeated tightening will be required. The principle of so-called chemical or medicated setons is loose placement of a thread (Kshara Sutra), as used in Ayurvedic therapy. This thread must be changed every week. Therapeutic goal is spontaneous loss of the thread after chemical division of the fistular tissue [38].

The healing rates of the cutting seton procedure have been reported between 80 and 100%. Rates of impaired continence varied between 0 and 92%. Recent reviews [56, 70] indicate an unacceptably high incontinence rate after use of the cutting seton. In view of the current literature, the recommendation for this method, as seen in other guidelines [65], should not be continued. In the authors' opinion, the most important function of the seton drainage is preparation for subsequent definitive treatment of high anal fistulas demonstrated during abscess drainage.

Evidence level: 2a

Recommendation grade: B

Consensus strength: strong consensus

Closure by surgical reconstruction

The aim of the various procedures is excision of both the fistula and the cryptoglandular focus of infection with closure of the inner fistula cavity. Five different techniques are used:

Direct suture without advancement flap

In some studies, the internal fistula cavity was not covered up after direct suturing of the sphincter muscle; reported healing rates varied between 56 and 100% [5].

Mucosal/submucosal advancement flap

Alternatively, the sphincter sutures can be protected by being covered with an advancement flap. This flap can consist of mucosa, submucosa, and superficial parts of the internal muscle (mucosal/submucosal flap). The identified studies showed healing rates between 12 and 100% [66].

A current review by Göttgens et al. [23] identified the mucosal flap as the best evaluated procedure. Although there are 14 published randomized studies, no "best surgical procedure" could be evaluated.

Rectal advancement flap

Alternatively, a rectal full thickness advancement flap may be used to cover the sutures. The results of the identified studies are largely similar to those using the mucosal/submucosal flap, with healing rates between 33 and 100% and incontinence rates between 0 and 71% [4, 51]. A randomized study of Hagen et al. [68] compared the results of mucosal flap and fibrin glue (15 patients each, follow-up 50 months). The healing rate was twice as high in the flap group than in the group using fibrin glue (mucosal flap 80%, fibrin 40%). Continence disorders have not been reported in both groups.

Khafagy et al. [29] have compared the results of mucosal and rectal advancement flap in a randomized study. In the full-thickness flap group, healing rates were clearly higher (85 vs. 30%), but at the same time the rate of continence disorders was higher after rectal wall flap.

In another randomized study, Madbouly et al. [34] have compared the LIFT procedure and the mucosal flap. Success rates in both groups were quite similar after 12 months (LIFT (74%)/mucosal flap (67%)). Only healing time was longer in the flap group (32 vs. 22 days).

Van Koperen et al. [69] have compared mucosal flap and fistula plug. With a recurrence rate of 52% (mucosal flap) and

72% (plug), respectively, the results were quite disappointing in both groups. However, functional results were similar.

Anodermal advancement flap

Another option for covering the inner fistula cavity is the use of anodermal flaps. Here, an advancement flap made of anodermal tissue is used. The anodermal flap can be especially advantageous in patients with a narrow anal canal (e.g., scar tissue from previous operations) that might prevent complete exploration and proximal flap formation. In the identified studies, healing rates vary between 46 and 95%, while impaired continence rates range from 0 to 30% [32]. New publications could not be evaluated.

Fistula excision with direct sphincter reconstruction

In fistula excision with primary reconstruction of the sphincter muscle following complete excision of the fistula and its associated inflammatory tissue, primary readaptation of the divided sphincter apparatus is carried out. Healing rates between 54 and 97% have been reported; rates of impaired continence of 4 to 32% have been noted. Especially in patients with high fistulas, wound dehiscence after division and reconstruction is associated with a high risk of incontinence. In summary, data concerning this technique are still relatively few. Moreover, the role of reconstruction of even small sphincter defects is unclear at present.

In a review from 2015, Ratto et al. [55] evaluated 14 studies of low quality. The general success rate of 93% has been reported. The rate of patients with continence disorders has been shown to be 12%. Quality of life was rising in all studies. As a conclusion, the authors stated a high success rate in combination with a risk of incontinence, which is lower than after simple fistulotomy. Further studies are demanded.

Evidence level: 1b

Recommendation grade: A

Consensus strength: strong consensus

LIFT method

In 2007, Rojanasakul et al. [58] introduced the ligation of the intersphincteric plane called the ligation of the intersphincteric fistula tract (LIFT) method. The principle of this operation is dissection of the fistula tract in the area of the intersphincteric plane. After ligation of both sides, the fistula tract is cut.

In the last years, a multitude of case studies have been published indicating healing rates of 40–95%. Thus, this method represents a valuable alternative to the flap techniques, with a comparable success rate. One advantage seems to be a new access route to the fistula, especially in case of recurrent fistulas.

In an already mentioned randomized study, Madbouly et al. [34] compared the LIFT procedure and the mucosal flap. Success rates in both groups were quite similar after 12 months (LIFT (74%)/mucosal flap (67%)). Only healing time was longer in the flap group (32 vs. 22 days).

A further advancement is the BioLIFT procedure described by Ellis [14]. After para-anal incision, a biological membrane (Surgisis Biodesign©), size 4 × 7 cm, is placed following dissection of the intersphincteric area. A primary healing rate of 94% has been described in 31 patients. The LIFT procedure has been evaluated in several reviews. The most current review of von Sirany et al. [63] evaluated 26 studies, which described healing rates between 47 and 95%. The operative technique varied in the different studies.

In conclusion, the LIFT procedure offers a new surgical option in patients with complex fistulas. Healing and continence rates do not differ significantly from those of the flap procedures.

Evidence level: 1b

Recommendation grade: A

Consensus strength: strong consensus

New technical developments

Laser application

Coagulation of fistula by a laser probe (FiLaC®, Biolitec), partly combined with a flap technique, has been introduced as a new method. Current studies showed success rates of 71–82% without noteworthy impact on continence [20, 73]. Further conclusions cannot be drawn due to the current data.

VAAFT method

Another new technique is the video-assisted fistula treatment (VAAFT) according to Meinero [36, 37]. Here, the fistula tract is probed using videoendoscopic assistance, rinsed, curetted, and filled with fibrin glue. The internal ostium of the fistula is then closed using a stapler (Contour™, Ethicon Endo-Surgery) or by direct suture. Costs are high for the special instruments and the stapler. The inventor observed healing rates between 58 and 87%, which have been partly confirmed by other authors [31, 71].

Evidence level: 5

Recommendation grade: 0

Consensus strength: strong consensus

OTSC clip

Over-the-scope clip (OTSC) has been used endoscopically for closure of the bowel wall after traumatic lesions or incisions. A modified technique for anal fistulas has been first used in

2011. [54]. Current studies showed diverging data of healing rates between 12 and 90%. Therefore, conclusive evaluation is not possible.

In conclusion, the new technical developments could not yet demonstrate a clear advantage compared to established methods.

Evidence level: 4

Recommendation grade: 0

Consensus strength: strong consensus

Biomaterials

Fibrin glue

After curettage of the fistula tract, the tract is filled with fibrin glue. Results in the literature showed healing rates that varied widely between 0 and 100%. Only eight studies contained information about continence and reported having observed no impairment. The majority of these studies are personal case series involving inhomogeneous patients with a wide variety of fistula types [2].

The review articles identified in the literature search [11] confirmed the great heterogeneity of the studies, especially since good results reported in earlier studies could not be reproduced in the more recent ones. Therefore, the guideline working group agreed that fibrin glue should only be used in special cases.

Evidence level: 1b

Recommendation grade: B

Consensus strength: strong consensus

Collagen injection

This new technique is occluding the fistula tract with collagen in combination with or without fibrin glue (Permacol®) [26].

Giordano et al. [21] reported a success rate of 54% after 12 months in a multicenter study of 10 clinics with 28 patients. The healing rate has been 67% for intersphincteric and 44% for transsphincteric fistulas. One patient with deterioration of continence has been reported. In this context, the low number of patients is a critical factor (28 patients from 10 clinics). The current range of trials on the application of collagen for anal fistulas does not allow definite conclusions.

Evidence level: 4

Recommendation grade: C

Consensus strength: strong consensus

Injection of autologous stem cells

Injection of autologous stem cells has been reported in seven studies especially from Spain [18, 27, 67]. All in all, there have been healing rates between 35 and 90%. High costs

represent a limiting factor for the application in Germany. The current range of trials on the application of autologous stem cells for anal fistulas does not allow definite conclusions.

Evidence level: 1b

Recommendation grade: A

Consensus strength: strong consensus

Surgisis® AFP™ anal fistula plug

The anal fistula plug is a biomedical product made of porcine small-intestinal submucosa. Unlike in “conventional” procedures, the inflammatory tissue is not excised, but merely occluded with the cone-shaped plug, which acts as a matrix for the body’s own tissue to grow into. Some authors combined plugging with closing of the internal fistula cavity using an advancement flap. The published observational studies showed healing rates between 14 and 93%. Most of them did not investigate impairment of continence. Only three studies reported unchanged continence [35, 51]. The two randomized studies that compared plugging with surgical closure have found markedly lower healing rates using plugging. It appears to be important that the fistula tract is long enough [35].

Von der Hagen et al. [68] have compared the results for mucosa flap and fibrin glue for 15 patients respectively and a follow-up of about 50 months. The healing rate was twice as high in the flap group as in the group with fibrin glue (mucosa flap 80%, fibrin 40%). No impairment of continence has been reported in both groups.

One review [19] described success rates varying between 24 and 92%. The rate of recurrent abscess after fistula plugging was 4 to 29%, and the frequency of plug loss was 4 to 41%. A notable feature is the low morbidity of the procedure. Any effect of plugging on continence is expected to be negligible. To sum up, plugging has added a new option for the treatment of high anal fistula, but the healing rates are quite low.

Evidence level: 1b

Recommendation grade: B

Consensus strength: strong consensus

Gore Bio-A Fistula Plug®

Another plug of resorbable synthetic material has been introduced recently (Gore Bio-A Fistula Plug®). One possible advantage compared to the conventional plug is better feasibility of fixation due to the head and the greater volume of the plug. Studies observed healing rates between 16 and 73%. Therefore, currently there is no noteworthy advantage compared to the Surgisis plug [7, 47].

In the review by Narang et al. [39], evidence has been rated as insufficient. Nevertheless, it seems to be a secure and

simple method resulting in low complication rates and minor disturbance of continence.

Evidence level: 4

Recommendation grade: C

Consensus strength: strong consensus

Core statement

In all high anal fistulas, a sphincter-sparing procedure (flap technique, sphincter reconstruction, LIFT, biomaterials) should be carried out. The results of the various techniques for a surgical reconstruction are largely identical. In general, occlusion using biomaterials result in lower healing rates and also lower incontinence rates.

Evidence level:	1a
Recommendation level:	A
Strength of consensus:	Strong consensus

Preoperative and intraoperative management

In case of excision of the fistula or placement of a seton, no special bowel preparation is necessary. Whether preoperative cleaning of the bowel or postoperative delay or prevention of bowel movements improve the healing rates is at time unclear.

Evidence level:	1a
Recommendation level:	A
Strength of consensus:	Strong consensus

Postoperative management

Postoperative care following anal surgery is unproblematic. The external wound heals by secondary intention and should be rinsed regularly. Clear water is best for this purpose, particularly since antiseptic solutions are associated with a risk of cytotoxicity. However, the external opening of the drainage may not close prematurely. Regular wound packing is not required [52]. The value of accompanying antibiotic treatment has not yet been sufficiently clarified. In general, however, antibiotic treatment seems to be indicated only in special cases (immune deficiency, serious phlegmonous inflammation).

Core statement

The anal area should be rinsed regularly (using tap water). The use of local antiseptics is associated with a risk of cytotoxicity. Antibiotic treatment is required only in exceptional cases.

Evidence level	4
Recommendation level	B (Justification: For ethical reasons, this generally accepted statement cannot be tested using randomized studies.)
Strength of consensus	Strong consensus

Complications

Impaired continence after anal fistula operations

Impairment of continence is a frequent complication after anal fistula surgery. The causes are usually multifactorial, with sphincter lesions to the fore. The risk of postoperative continence impairment rises with the amount of sphincter that has been divided [17]. Garcia-Aguilar [17] observed in patients with previous surgery for fistula-in-ano after division of less than 25% of the external muscle continence disorders within 44% of the patients, which increased to 75% after division of more than 76%. The degree of impairment varies greatly and depends to a large extent on preexisting injury. Its effect on the patient also relates to subjective experience. In the literature, impaired continence rates of 10% in low fistulas and of 50% in high fistulas have been reported [42]. A study by Blumetti et al. [6] showed clear reduction of the rate of cutting procedures over time favoring sphincter-saving procedures. [15]. Therefore, it is important to give the patient comprehensive information. The sphincter apparatus must be spared as much as possible.

Core statement

Every treatment for anal fistula is associated with the risk of reduced continence, and this risk rises with the extent of transected sphincter. In addition to intentional transection of parts of the sphincter muscle, contributing causes comprise preexisting injury, previous operations, and other factors (age, sex, and others).

Evidence level: 1c

Recommendation grade: A

Consensus strength: strong consensus

Acknowledgements Thanks are due to Dr. C. Muche-Borowski from AWMF for support on methodical correctness of these guidelines. We thank Mr. Markus Noll for his support in translating the manuscript.

Compliance with ethical standards

Funding This study was not funded.

Conflicts of interest The authors declare that they have no conflict of interest.

Human and Animal Rights This article does not contain any studies with animals performed by any of the authors.

References

- Adamo K, Sandblom G, Brannstrom F, Strigard K (2016) Prevalence and recurrence rate of perianal abscess—a population-based study, Sweden 1997–2009. *Int J Color Dis* 31:669–673
- Altomare DF, Greco VJ, Tricomi N, Arcana F et al (2010) Seton or glue for trans-sphincteric anal fistulae: a prospective randomized crossover clinical trial. *Color Dis* 13:82–86
- Amato A, Bottini C, De Nardi P, Giamundo P et al (2015) Evaluation and management of perianal abscess and anal fistula: a consensus statement developed by the Italian Society of Colorectal Surgery (SICCR). *Tech Coloproctol* 19:595–606
- Athanasiadis S, Nafe M, Köhler A (1995) Transanaler rektaler Verschiebelappen (rectal advancement flap) versus Mucosaflap mit Internusnaht im Management komplizierter Fisteln des Anorectums. *Langenbecks Arch Chir* 380:31–36
- Athanasiadis S, Helmes C, Yazigi R, Köhler A (2004) The direct closure of the internal fistula opening without advancement flap for transsphincteric fistulas-in-ano. *Dis Colon rectum* 47:1174–1180
- Blumetti J, Abcarian A, Quinteros F, Chaudhry V, et al (2012) Evolution of treatment of fistula in ano. *World J Surg* 36:1162–1167
- Buchberg B, Masoomi H, Choi J, Bergman H et al (2010) A tale of two (anal fistula) plugs: is there a difference in short-term outcomes? *Am Surg* 76:1150–1153
- Bussen D, Sailer M, Wening S, Fuchs KH et al (2004) Wertigkeit der analen Endosonographie in der Diagnostik anorektaler Fisteln. *Zentralbl Chir* 129:404–407
- Chrabot CM, Prasad ML, Abcarian H (1983) Recurrent anorectal abscesses. *Dis Colon rectum* 26:105–108
- Cioli VM, Gagliardi G, Pescatori M (2015) Psychological stress in patients with anal fistula. *Int J Color Dis* 30:1123–1129
- Cirocchi R, Santoro A, Trastulli S, Farinella E et al (2011) Meta-analysis of fibrin glue versus surgery for treatment of fistula-in-ano. *Ann Ital Chir* 81:349–356
- de Groof EJ, Cabral VN, Buskens CJ, Morton DG, et al (2016) Systematic review of evidence and consensus on perianal fistula: an analysis of national and international guidelines. *Colorectal Dis* 18:O119–O134
- Devaraj B, Khabassi S, Cosman BC (2011) Recent smoking is a risk factor for anal abscess and fistula. *Dis Colon rectum* 54:681–685
- Ellis CN (2010a) Outcomes with the use of bioprosthetic grafts to reinforce the ligation of the intersphincteric fistula tract (BioLIFT procedure) for the management of complex anal fistulas. *Dis Colon rectum* 53:1361–1364
- Ellis CN (2010b) Sphincter-preserving fistula management: what patients want. *Dis Colon rectum* 53:1652–1655
- Galanis I, Chatzimavroudis G, Christopoulos P, Makris J (2016) Prospective randomized trial of simple drainage vs. drainage and initial fistula management for perianal abscess. *J Gastrointest & Dig System* 6:1
- Garcia-Aguilar J, Belmonte C, Wong WD, Goldberg SM et al (1996) Anal fistula surgery. Factors associated with recurrence and incontinence. *Dis Colon rectum* 39:723–729
- Garcia-Olmo D, Herreros D, Pascual I, Pascual JA et al (2009) Expanded adipose-derived stem cells for the treatment of complex perianal fistula: a phase II clinical trial. *Dis Colon rectum* 52:79–86
- Garg P, Song J, Bhatia A, Kalia H et al (2010) The efficacy of anal fistula plug in fistula-in-ano: a systematic review. *Color Dis* 12: 965–970
- Giamundo P, Esercizio L, Geraci M, Tibaldi L et al (2015) Fistula-tract Laser Closure (FiLaC): long-term results and new operative strategies. *Tech Coloproctol* 19:449–453
- Giordano P, Sileri P, Buntzen S, Stuto A, et al. (2016) A prospective, multicentre observational study of Permacol collagen paste for anorectal fistula: preliminary results. *Colorectal Dis*
- Göttgens KW, Janssen PT, Heemskerk J, van Dielen FM et al (2015a) Long-term outcome of low perianal fistulas treated by fistulotomy: a multicenter study. *Int J Color Dis* 30:213–219
- Göttgens KW, Smeets RR, Stassen LP, Beets G et al (2015b) Systematic review and meta-analysis of surgical interventions for high cryptoglandular perianal fistula. *Int J Color Dis* 30:583–593
- Hamadani A, Haigh PI, Liu IL, Abbas MA (2009) Who is at risk for developing chronic anal fistula or recurrent anal sepsis after initial perianal abscess? *Dis Colon rectum* 52:217–221
- Hämäläinen KP, Sainio AP (1998) Incidence of fistulas after drainage of acute anorectal abscesses. *Dis Colon rectum* 41:1357–1361 discussion 1361–2
- Hammond TM, Porrett TR, Scott M, Williams NS et al (2010) Management of idiopathic anal fistula using cross-linked collagen: a prospective phase I study. *Color Dis* 13:94–104
- Herreros MD, Garcia-Arranz M, Guadalajara H, De-La-Quintana P et al (2012) Autologous expanded adipose-derived stem cells for the treatment of complex cryptoglandular perianal fistulas: a phase III randomized clinical trial (FATT 1: fistula Advanced Therapy Trial 1) and long-term evaluation. *Dis Colon rectum* 55:762–772
- Hoffmann JC, Fischer I, Hohne W, Zeitz M et al (2004) Methodological basis for the development of consensus recommendations. *Z Gastroenterol* 42:984–986
- Khafagy W, Omar W, El Nakeeb A, Fouda E et al (2010) Treatment of anal fistulas by partial rectal wall advancement flap or mucosal advancement flap: a prospective randomized study. *Int J Surg* 8: 321–325
- Klosterhalfen B, Offner F, Vogel P, Kirkpatrick CJ (1991) Anatomic nature and surgical significance of anal sinus and anal intramuscular glands. *Dis Colon rectum* 34:156–160
- Kochhar G, Saha S, Andley M, Kumar A, et al. (2014) Video-assisted anal fistula treatment. *Jsls* 18
- Köhler A, Athanasiadis S (1996) Die anodermale Verschiebelappenplastik als alternative Behandlungsmethode zu den endorektalen Verschlusstechniken bei der Therapie hoher Analfisteln. Eine prospektive Studie bei 31 Patienten. *Chirurg* 67:1244–1250
- Lohsiriwat V, Yodying H, Lohsiriwat D (2011) Incidence and factors influencing the development of fistula-in-ano after incision and drainage of perianal abscesses. *J Med Assoc Thai* 93:61–65
- Madbouly KM, El Shazly W, Abbas KS, Hussein AM (2014) Ligation of intersphincteric fistula tract versus mucosal advancement flap in patients with high transsphincteric fistula-in-ano: a prospective randomized trial. *Dis Colon rectum* 57:1202–1208
- McGee MF, Champagne BJ, Stulberg JJ, Reynolds H et al (2010) Tract length predicts successful closure with anal fistula plug in cryptoglandular fistulas. *Dis Colon rectum* 53:1116–1120

36. Meinero P, Mori L (2011) Video-assisted anal fistula treatment (VAAFT): a novel sphincter-saving procedure for treating complex anal fistulas. *Tech Coloproctol* 15:417–422
37. Meinero P, Mori L (2012) Video-assisted anal fistula treatment (VAAFT): a novel sphincter-saving procedure to repair complex anal fistulas. *Tech Coloproctol* 16:469–470
38. Mohite JD, Gawai RS, Rohondia OS, Bapat RD (1997) Ksharsootra (medicated seton) treatment for fistula-in-ano. *Indian J Gastroenterol* 16:96–97
39. Narang SK, Jones C, Alam NN, Daniels IR et al (2015) Delayed absorbable synthetic plug (GORE(R) BIO-A(R)) for the treatment of fistula-in-ano: a systematic review. *Color Dis* 18:37–44
40. Nomikos IN (1997) Anorectal abscesses: need for accurate anatomical localization of the disease. *Clin Anat* 10:239–244
41. Ommer A, Athanasiadis S, Happel M, Köhler A et al (1999) Die chirurgische Behandlung des anorektalen Abszesses. Sinn und Unsinn der primären Fistelsuche coloproctology 21:161–169
42. Ommer A, Wenger FA, Rolfes T, Walz MK (2008) Continence disorders after anal surgery—a relevant problem? *Int J Color Dis* 23:1023–1031
43. Ommer A, Herold A, Berg E, Farke S et al (2011a) S3-Leitlinie Analabszess. *Coloproctology* 33:378–392
44. Ommer A, Herold A, Berg E, Farke S et al (2011b) S3-Leitlinie Kryptoglanduläre Analfistel. *Coloproctology* 33:295–324
45. Ommer A, Herold A, Berg E, Fürst A et al (2011c) Clinical practice guideline: cryptoglandular anal fistula. *Dtsch Arztebl Int* 108:707–713
46. Ommer A, Herold A, Berg E, Fürst A et al (2012a) German S3 guideline: anal abscess. *Int J Color Dis* 27:831–837
47. Ommer A, Herold A, Joos AK, Schmidt C, et al. (2012b) Gore BioA Fistula Plug in the treatment of high anal fistulas—initial results from a German multicenter-study. *GMS German Medical Science* 10: Doc13
48. Ommer A, Herold A, Berg E, Farke S et al (2016a) S3-Leitlinie Analabszess - 2.revidierte Fassung. *Coloproctology* 38:378–398
49. Ommer A, Herold A, Berg E, Farke S et al (2016b) S3-Leitlinie Kryptoglanduläre Analfistel - 2. revidierte Fassung. *Coloproctology* 39:16–66
50. Onaca N, Hirshberg A, Adar R (2001) Early reoperation for perirectal abscess: a preventable complication. *Dis Colon rectum* 44:1469–1473
51. Ortiz H, Marzo J, Ciga MA, Oteiza F et al (2009) Randomized clinical trial of anal fistula plug versus endorectal advancement flap for the treatment of high cryptoglandular fistula in ano. *Br J Surg* 96:608–612
52. Perera AP, Howell AM, Sodergren MH, Fame H et al (2015) A pilot randomised controlled trial evaluating postoperative packing of the perianal abscess. *Langenbeck's Arch Surg* 400:267–271
53. Phillips B, Ball C (2009) Oxford Centre for evidence-based medicine—levels of evidence <http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>
54. Prosst RL, Herold A, Joos AK, Bussen D et al (2011) The anal fistula claw: the OTSC clip for anal fistula closure. *Color Dis* 14:1112–1117
55. Ratto C, Litta F, Donisi L, Parello A (2015) Fistulotomy or fistulectomy and primary sphincteroplasty for anal fistula (FIPS): a systematic review. *Tech Coloproctol* 19:391–400
56. Ritchie RD, Sackier JM, Hodde JP (2009) Incontinence rates after cutting seton treatment for anal fistula. *Color Dis* 11:564–571
57. Rizzo JA, Naig AL, Johnson EK (2010) Anorectal abscess and fistula-in-ano: evidence-based management. *Surg Clin North Am* 90:45–68 Table of Contents
58. Rojanasakul A, Pattanaarun J, Sahakitrungruang C, Tantiphlachiva K (2007) Total anal sphincter saving technique for fistula-in-ano; the ligation of intersphincteric fistula tract. *J Med Assoc Thai* 90:581–586
59. Sahni VA, Ahmad R, Burling D (2008) Which method is best for imaging of perianal fistula? *Abdom Imaging* 33:26–30
60. Sainio P (1984) Fistula-in-ano in a defined population. Incidence and epidemiological aspects. *Ann Chir Gynaecol* 73:219–224
61. Schmiegel W, Pox C, Reinacher-Schick A, Adler G et al (2008) S3-Leitlinie Kolorektales Karzinom. *Z Gastroenterol* 46:1–73
62. Siddiqui MR, Ashrafian H, Tozer P, Daulatzai N et al (2012) A diagnostic accuracy meta-analysis of endoanal ultrasound and MRI for perianal fistula assessment. *Dis Colon rectum* 55:576–585
63. Sirany AM, Nygaard RM, Morken JJ (2015) The ligation of the intersphincteric fistula tract procedure for anal fistula: a mixed bag of results. *Dis Colon rectum* 58:604–612
64. Sözener U, Gedik E, Kessaf Aslar A, Ergun H et al (2011) Does adjuvant antibiotic treatment after drainage of anorectal abscess prevent development of anal fistulas? A randomized, placebo-controlled, double-blind, multicenter study. *Dis Colon rectum* 54:923–929
65. Steele SR, Kumar R, Feingold DL, Rafferty JL et al (2011) Practice parameters for the management of perianal abscess and fistula-in-ano. *Dis Colon rectum* 54:1465–1474
66. van der Hagen SJ, Baeten CG, Soeters PB, van Gemert WG (2006) Long-term outcome following mucosal advancement flap for high perianal fistulas and fistulotomy for low perianal fistulas: recurrent perianal fistulas: failure of treatment or recurrent patient disease? *Int J Color Dis* 21:784–790
67. van der Hagen SJ, Baeten CG, Soeters PB, van Gemert WG (2011a) Autologous platelet-derived growth factors (platelet-rich plasma) as an adjunct to mucosal advancement flap in high cryptoglandular perianal fistulae: a pilot study. *Color Dis* 13:215–218
68. van der Hagen SJ, Baeten CG, Soeters PB, van Gemert WG (2011b) Staged mucosal advancement flap versus staged fibrin sealant in the treatment of complex perianal fistulas. *Gastroenterol Res Pract* 2011:186350
69. van Koperen PJ, Bemelman WA, Gerhards MF, Janssen LW et al (2011) The anal fistula plug treatment compared with the mucosal advancement flap for cryptoglandular high transsphincteric perianal fistula: a double-blinded multicenter randomized trial. *Dis Colon rectum* 54:387–393
70. Vial M, Pares D, Pera M, Grande L (2010) Faecal incontinence after seton treatment for anal fistulae with and without surgical division of internal anal sphincter: a systematic review. *Color Dis* 12:172–178
71. Walega P, Romaniszyn M, Nowak W (2014) VAAFT: a new minimally invasive method in the diagnostics and treatment of anal fistulas—initial results. *Pol Przegl Chir* 86:7–10
72. Wang D, Yang G, Qiu J, Song Y et al (2014) Risk factors for anal fistula: a case-control study. *Tech Coloproctol* 18:635–639
73. Wilhelm A (2011) A new technique for sphincter-preserving anal fistula repair using a novel radial emitting laser probe. *Tech Coloproctol* 15:445–449
74. Yano T, Asano M, Matsuda Y, Kawakami K et al (2010) Prognostic factors for recurrence following the initial drainage of an anorectal abscess. *Int J Color Dis* 25:1495–1498
75. Yilmazlar T, Ozturk E, Ozguc H, Ercan I et al (2010) Fournier's gangrene: an analysis of 80 patients and a novel scoring system. *Tech Coloproctol* 14:217–223
76. Zanotti C, Martinez-Puente C, Pascual I, Pascual M et al (2007) An assessment of the incidence of fistula-in-ano in four countries of the European Union. *Int J Color Dis* 22:1459–1462