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CLINICAL GUIDELINES

Evaluation and management of perianal abscess and anal fistula: a consensus statement developed by the Italian Society of Colorectal Surgery (SICCR)

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Abstract Perianal sepsis is a common condition ranging from acute abscess to chronic fistula formation. In most cases, the source is considered to be a non-specific cryptoglandular infection starting from the intersphincteric space. The key to successful treatment is the eradication of the primary track. As surgery may lead to a disturbance of continence, several sphincter-preserving techniques have been developed. This consensus statement examines the pertinent literature and provides evidence-based recommendations to improve individualized management of patients.

Keywords Fistula-in-ano · Perianal abscess · Seton · Advancement flap · LIFT · Plug · Fibrin glue · Horseshoe extension · Transsphincteric fistula · VAAFT

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Introduction

Perianal sepsis is a common condition ranging from acute abscess to chronic fistula formation [1]. In most cases, the source is considered to be a non-specific cryptoglandular infection, but less frequently anorectal sepsis is associated with inflammatory bowel disease, infection such as actinomycosis, tuberculosis, lymphogranuloma venereum, human immunodeficiency virus, trauma, surgery, malignancy and irradiation [2–10]. An anal fistula is an abnormal communication between the anorectal tract and the perineal skin. Its incidence is about 2 cases per 10,000 population per year, and it affects men more than women [11–15]. A fistula may present de novo, but in about 30–50 % of patients, it follows a previous anorectal abscess which can cause the formation of a primary track and a secondary track in about 25 % of patients [16] presenting with anal fistula. Parks' classification identified four different types of anal fistula based on the relationship between the primary track and the sphincter [17]. A fistula can also be categorized as simple or complex. The former includes those with an intersphincteric or low transsphincteric track that involves less than 30 % of the sphincter complex. A fistula in the presence of inflammatory bowel disease, malignancy, incontinence, chronic diarrhea or previous irradiation should be considered complex as well as those with an anterior track in a female patient [18]. In some complex cases, a staged surgical procedure will be required.

Methodology

The consensus statement was commissioned by the Italian Society of Colorectal Surgery [Società Italiana di Chirurgia ColoRettale (SICCR)] with the aim of providing practice

parameters for appropriate diagnosis and management of cryptogenic anal abscess and fistula. It was based on evidence derived from an organized search of PubMed, Medline, EM-BASE and the Cochrane Database. Perianal Crohn's disease was excluded from this search. The review was performed up to October 2014 and was limited to articles in the English language. Keywords included anal, perianal, fistula, fistula-in-ano, abscess, seton, advancement flap, LIFT, plug, fibrin glue, implant, biomaterial, horseshoe extension, transsphincteric fistula and VAAFT. Additional papers were retrieved from the bibliography in the articles selected. All data were classified on the basis of the hierarchy of evidence, and recommendations were graded from A to C according to the report from the American College of Chest Physicians Task Force (Table 1) [19].

Preoperative evaluation

1. *Statement: the diagnosis is usually made on the basis of the patient's history and physical examination*
   Grade of recommendation: 1C
   It is important to distinguish anorectal abscess from other perianal suppurative processes such as hidradenitis suppurativa, a skin furuncle or other infections including herpes simplex, human immunodeficiency virus, tuberculosis, syphilis and actinomycosis [20–22]. *Data suggest that the predictive accuracy of Goodsall's rule is higher when the external opening is located behind a line drawn across the anal orifice from 9 o' clock to 3 o' clock, while its reliability decreases in the case of recurrent fistula* [23–25].
2. *Statement: imaging techniques may be considered in selected patients*
   Grade of recommendation: 1C
   Most abscesses and fistulas do not require any imaging. Instrumental investigation may be needed in complex cases to detect occult abscess and secondary tract formation or to assess the integrity and function of the sphincter muscles.
3. *Statement: fistulography is not recommended for the diagnosis of anal fistula*
   Grade of recommendation: 1B
   Fistulography has a low accuracy and may be poorly tolerated [26].
4. *Statement: endoanal ultrasound may be the first-line imaging in complex fistula*
   Grade of recommendation: 1B

Table 1 Grading recommendations

Grade of recommendation/ description	Benefits versus risks and burdens	Methodological quality of supporting evidence	Implications
1A/strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B/strong recommendation, moderate-quality evidence	Benefits clearly outweigh risks and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C/strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risks and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher-quality evidence becomes available
2A/weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendations, best action may differ depending on circumstances or patients' or societal values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendations, best action may differ depending on circumstances or patients' or societal values
2C/weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks and burdens; benefits, risks, and burdens may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

RCTs Randomized controlled trials

Endoanal ultrasound (EU) is a cost-effective investigation able to detect abscesses or fistulas with an accuracy of 80–89 % [27, 28]. *There is agreement between the surgical findings and EU in 82 % of cases* [29]. *The injection of hydrogen peroxide through the external opening increases the diagnostic accuracy and the identification of the internal opening* [30–32]. *In patients with a complex fistula, peroxide-enhanced EU correlates better than clinical examination with the site of associated abscess or secondary track formation* [33]. *The use of high-frequency transducers and three-dimensional (3D) technology has increased the accuracy of EU* [31, 34]. *Peroxide enhancement and 3D technology can optimize the diagnostic accuracy up to 90 %, a value comparable with magnetic resonance imaging (MRI)* [35]. *The diagnostic reliability is, however, operator dependent. The compartmental field of view and the suboptimal identification of the levator plate are the main technical limitations of the accuracy of EU particularly when assessing secondary track formation* [36].

5. *Statement: computerized tomography (CT) may be useful in the imaging of acute complex anorectal sepsis*
   Grade of recommendation: 1C
   CT has restricted indications but is valuable for the differentiation of supralevator from infralevator abscess [37]. *As it does not expose the patients to ionizing radiation, EU can be the first choice when MRI is not feasible* [38].
6. *Statement: MRI is the gold standard imaging technique for anorectal sepsis. It is indicated to determine the pathological anatomy of complex fistula, recurrent fistula or where a secondary track is suspected on digital examination*
   Grade of recommendation: A
   MRI can achieve an accuracy of 90 % in establishing the pathological anatomy of almost all forms of anorectal sepsis [39]. *It demonstrates the levator plate on each side and therefore is indispensable in distinguishing between a supralevator and an infralevator abscess both of which cause non-specific supralevator induration on digital examination* [40].
   A meta-analysis comparing MRI with EU for the assessment of cryptoglandular and Crohn's anal fistula, found a similar sensitivity [0.87 (95 % confidence interval (CI) 0.63–0.96); 0.87 (95 % CI 0.07–0.95)] in both groups. The specificity was higher for MRI (0.69 vs. 0.43) although it was poor overall for both imaging modalities, whereas EU showed better detection of the internal opening [41, 42].
7. *Statement: Anal manometry can predict poor postoperative function after surgery in cases requiring sphincter division*
   Grade of recommendation: 1B
   A continence disturbance may occur after fistula surgery even in the case of adult males with a previously intact sphincter [43]. *Sanio et al.* [44] *found varying degrees of continence disturbance in 34 % of patients after fistulotomy. Pescatori et al.* [45] *reported better results in patients who underwent manometry before surgery with a lower recurrence rate compared with controls (3 vs. 13 %) and less postoperative soiling (14 vs. 31 %).*

Treatment anal abscess

8. *Statement: antibiotic therapy is unnecessary in uncomplicated anorectal abscess*
   Grade of recommendation: 1B
   Once an abscess is established, antibiotic therapy is futile and delays surgery, allowing the suppurative process to progress [46, 47]. *Limited data suggest that antibiotics should be considered in patients with extensive cellulitis, systemic disease, human immunodeficiency virus infection or infection by atypical microbes including tuberculosis* [47–49]. *According to the American Heart Association Guidelines, antibiotics are recommended before incision and drainage in patients with previous bacterial endocarditis, prosthetic valves, congenital heart disease and heart transplant recipients with valve pathology* [50].
9. *Statement: the treatment of anal abscess is surgical incision and drainage*
   Grade of recommendation: 1B
   For superficial abscesses, drainage is feasible under local anesthesia. It should be performed as close as possible to the anal verge providing adequate drainage and the breakdown of any loculations [47, 51]. *If the abscess is more complex, drainage should be performed in the operating room, under general anesthesia, sedation or local anesthesia* [52].
   A true supralevator abscess associated with an intersphincteric fistula should be drained transanally into the upper anal canal by limited division of the internal sphincter. In contrast, an infralevator abscess should be drained through the ischioanal fossa. In the case of the former, it is important not to drain through the ischioanal fossa, since this will result in a suprasphincteric fistula. A small Pezzer or Malecot catheter is left in the cavity for 3–4 days [48]. *In contrast an abscess in the ischiorectal fossa associated with a transsphincteric fistula must not be drained through the rectum; otherwise, a*

suprasphincteric fistula will be created [46, 52]. *MRI is highly sensitive in distinguishing between a supra- and infralevator abscess and should always be performed whenever supralevator induration is found on digital examination.*

In the case of a horseshoe extension from an ischiorectal abscess derived from a transsphincteric fistula, a counter-incision is made in the perianal skin overlying the controlateral ischiorectal fossa to drain both sides adequately [46]. *Recurrence is likely to be due to inadequate drainage, failure to break up loculations in the abscess, failure to identify an abscess or failure to deal with the primary transsphincteric tract* [53].

10. *Statement: the placement of a seton should be considered when the internal opening is identifiable. Primary fistulotomy is still controversial and could be considered in selected patients*

Grade of recommendation: 1B

Insertion of a seton through the fistula track facilitates drainage and allows assessment some weeks later. A second-stage fistulotomy could be carried out after 8 weeks. Furthermore, seton can be used as a staged procedure in case of complex fistula formation [54].

Drainage of the abscess with a simultaneous fistulotomy may be done for a simple fistula when the internal opening is found by careful probing [55, 56]. *However, concomitant induration due to inflammation may obscure the internal opening and overzealous attempts with a fistula probe should be discouraged as they can cause iatrogenic damage* [57, 58].

Simple anal fistula

Simple fistulas include intersphincteric tracks or single transsphincteric tracks that cross less than 30 % of the external sphincter.

11. *Statement: simple anal fistula should be treated by immediate fistulotomy*

Grade of recommendation: 1B

Fistulotomy is associated with a high success rate ranging from 79 to 100 % [59–62]. *Some degree of impairment of continence has been reported in up to 44 % of patients after fistulotomy performed at the time of the drainage of an acute abscess* [56, 62]. *In females and in patients with preoperative impairment of continence, a high or recurrent fistula, previous fistula surgery or Crohn's disease, any division of the sphincter should be undertaken with caution and by an experienced surgeon* [63, 64]. *Even in the case of an intersphincteric fistula, fistulotomy is associated with a significant decrease in maximum and resting anal pressure with significantly poorer continence in women and in patients with a reduced preoperative anal resting pressure* [65]. *There is no agreement about the extent of muscle division that can be considered safe even though it has been demonstrated that a fistulotomy of more than 25 % of the external sphincter correlates significantly with the subsequent fecal incontinence severity index* [66]. *The location of the internal opening per se, whether high or low in the anal canal, should not be used as a guide to "safe fistulotomy". Preoperative MRI shows that half of transsphincteric fistulas track obliquely in a cranial direction from the internal opening through the anal sphincter into the ischioanal fossa at an acute angle and 30 % of patients have a track that passes acutely upwards from the internal orifice at an angle of less than 60°. A fistulotomy could therefore divide more sphincter than would be suggested by the level of the internal opening, threatening a disturbance of fecal continence* [67]. *In a prospective study, impaired continence followed fistulotomy in 44 % of patients with a low anal internal opening* [62].

12. *Statement: the energy source does not seem to influence the results of fistulotomy; radiofrequency is associated with less pain and a shorter time to healing*

Grade of recommendation: 2B

Fistulotomy can be performed either with a scalpel or by cutting diathermy. It has been suggested that the use of radiofrequency division may reduce the operating time, bleeding, postoperative pain and speed healing and recovery [68, 69]. *Two RCTs have been performed both showing no difference in continence but less pain, shorter time to healing, shorter operating time and less intraoperative bleeding with radiofrequency* [68, 70]. *The studies were not sufficiently powered and contained several sources of bias* [71]. *Diathermy is widely available while radiofrequency is not.*

13. *Statement: marsupialization of the wound edges following fistulotomy is associated with a shorter healing time*

Grade of recommendation: 1B

Following fistulotomy the anal wound is hardly ever closed, and in almost all cases it is left open to heal by secondary intention. Marsupialization resulted in less bleeding and a shorter healing time in two RCTs [72, 73]. *No significant differences with regard to continence and recurrence were found in either study.*

14. *Statement: loose inert setons and chemical setons should not be used since they are associated with longer healing times and more postoperative pain*
Grade of recommendation: 1B
An inert seton is usually inserted through the primary track of the fistula to promote drainage of sepsis, thereby preventing an acute exacerbation of abscess formation and to allow healing of any secondary tracts. The results of a long-term indwelling loose seton for low transsphincteric and intersphincteric fistulas were reported in 108 patients [74]. *The seton was kept in the fistula track for an average of 13.7 months. It cut through the tissues in 17.6 % of patients, and a fistulotomy of the residual track was needed in 80 patients.*
In an ayurvedic medicine technique known as Kshara Sutra, the seton is soaked in a caustic chemical derived from the plant Kshara and has antibacterial and anti-inflammatory properties. It was compared with conventional fistulotomy in two RCTs [75, 76]. *The multicenter trial by the Indian Council of Medical Research enrolled 502 patients with low and high anal fistulas* [76]. *The chemical group had a significantly longer median time to healing (8 vs. 4 weeks) but a lower recurrence rate (4 vs. 11 %) at 1 year. There was a high drop out rate of patients in this trial which considerably reduced its power. In another study, Ho et al.* [75] *recruited 100 patients with a low fistula. At a two-month follow-up, there was no difference in the duration of hospital stay, wound healing time and anal resting and squeeze pressures. Significantly more pain was reported in the chemical seton group on the day of operation and on postoperative days 1, 2 and 4, which was thought likely to be due to the chemical trauma to the tissues. There was no significant difference in the continence score of the chemical seton and conventional fistulotomy groups in either trial, but 13 patients in the chemical seton group complained of impaired continence, even though no muscle was divided. Chemical injury to the sphincter could not be ruled out.*
15. *Statement: fistulectomy should not be undertaken for simple anal fistula. The fistula track should be laid open rather than excised*
Grade of recommendation: 1B
Fistulectomy has been widely performed for anal fistula often in addition to an advancement flap. Only one early RCT compared fistulectomy with fistulotomy for superficial, intersphincteric and low transsphincteric fistulas showing no significant difference in outcome [77]. *Conversely, comparing radiofrequency fistulectomy with diathermy fistulotomy, Filingeri et al.* [70] *found less immediate postoperative pain and faster wound healing in the former, but these results could reflect the effect of radiofrequency rather than fistulectomy per se. Using anal ultrasound, larger defects in the sphincter were seen following fistulectomy* [78].
16. *Statement: simple anal fistula may be treated with novel techniques*
Grade of recommendation: 2C
Several innovative surgical techniques for the treatment of anal fistula have been described including fibrin glue, cyanoacrylate glue, the anal fistula plug, ligation of the intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment (VAAFT) and fistula laser closure (FiLaC). All the series published have included patients with a simple anal fistula and reported a high rate of successful closure and no change in continence [79–81]. *It is possible that these techniques are not suitable for fistulas with secondary track formation. Their cost needs to be justified, considering that a simple anal fistula is successfully managed by a fistulotomy. These techniques may only play a role in patients at high risk of continence.*

Complex anal fistula

Complex fistulas include high transsphincteric, suprasphincteric, extrasphincteric, recurrent and horseshoe fistulas, multiple tracks, anteriorly lying tracks in female patients, and those associated with inflammatory bowel disease, radiation, preexisting incontinence, or chronic diarrhea.

17. *Statement: an endorectal advancement flap can be used to treat complex anal fistula with a mean success rate of around 70 % at medium term follow-up*
Grade of recommendation: 1B
The advancement flap technique results in no division of the external sphincter muscle.
Certain technical points are crucial to promote a successful outcome. The dissection should start distally in the submucosa and the thickness of the flap should be increased as it proceeds proximally. The sphincter remains intact and the wide base of the flap ensures that it is well perfused and mobile. Alternatively, a curvilinear flap can be used to avoid ischemia at the edges [82]. *Whatever its shape, the incision should be made well away from the anoderm to avoid ectropion.*
Healing ranges from 57 % to over 90 % over an acceptable period of follow-up. In a retrospective

review of 91 patients who underwent an advancement flap repair for complex fistula, Ortiz et al. [83] *reported recurrence in 19 % of patients after a median follow-up of 42 months. The median interval to relapse was 5 months with no recurrence after 1 year. In a retrospective chart review, an advancement endorectal flap procedure was performed on 94 patients including 28 with Crohn's disease. At a mean follow-up of 40.3 months, the procedure was successful in 59.6 % of patients* [84]. *At long-term follow-up, Abbas et al.* [85] *reported success in 83 % of 36 patients with a complex anorectal fistula. Others have found that previous fistula-related operations increase the risk of recurrence and that partial rather than full thickness flaps are more prone to failure (35.5 vs. 5 %)* [86]. *Smoking and obesity adversely affect the outcome but their role is still unclear as these findings have not been confirmed by other investigators. Van Okelen et al. assessed 17 patient- and fistula-related variables in a retrospective series of 252 patients with a high transsphincteric cryptoglandular fistula. After flap repair, the 3-year failure rate was 41 %. The only predictor of a poor outcome was a horseshoe extension* [87]. *In a randomized trial comparing flap alone and flap plus fibrin glue injection in 58 patients with a transsphincteric fistula, glue did not reduce recurrence (20 vs. 46.4 %)* [88].

18. *Statement: endorectal advancement flap had mild or moderate effect on continence*
Grade of recommendation: 1B
Although endorectal advancement flap repair does not require any sphincter division, a mild or moderate continence disturbance has been reported in 7–38 % of patients after the procedure, with worse postoperative manometry [89–93]. *Several papers have reported transient and minor postoperative continence-related problems, a more common finding in patients who had undergone a previous surgical repair* [84, 89, 94–97]. *Dubsky et al. retrospectively compared full thickness (n = 20) with a partial thickness (mucosal) flap (n = 34). Although incontinence was found in five (11.1 %) patients, full thickness mobilization of the rectal wall for flap creation did not improve continence as only one of them belonged to the full thickness group* [86].
19. *Statement: complex anal fistula can be treated by LIFT*
Grade of recommendation: 1B
This new easy-to-learn inexpensive sphincter-sparing technique was described by Rojanasakul et al. in 2007 [98]. *LIFT requires a small incision in the intersphincteric groove to enter the intersphincteric space which allows an approach to the fistula tract as it passes from the internal to the external sphincter. Dissection is carried out until the tract is clearly identified; it is then ligated and divided.*
The initial report showed healing in 17 out of 18 patients at a mean follow-up of 4 weeks [98]. *Bleier et al.* [99] *reported success in 57 % of 35 of a series of 39 patients who were followed for 20 weeks with no subjective impairment of continence. The median time to recurrence was 10 (2–38) weeks. Shanwani et al.* [100] *reported a primary healing rate of 82 % in 45 patients at a median follow-up of 9 months*
Recent systematic reviews have shown a primary healing rate ranging from 71 to 81.7 % at a mean follow-up of 34 to 84 weeks with only 1.8 to 5.5 % of patients having a postoperative complication [101–104]. *Yassin et al.* [104] *collected data on 183 of 498 patients who were formally investigated for continence. Among these, 6 % experienced a minor continence disturbance. In other reports, all patients remained continent postoperatively* [101, 102]. *Obesity, smoking, multiple previous operations and the length of the fistula tract were identified as predictive of surgical failure while no association was found between the insertion of a seton before the LIFT procedure and a successful repair* [101–103].

New techniques for treating complex anal fistula

The aim of treatment of anal fistulas is to eliminate the track while preserving continence [105, 106]. Unfortunately many surgical procedures inevitably lead to a deterioration of continence. For example Lunniss et al. [107] reported a disturbance of continence in up to 53 % of patients following laying open of an intersphincteric or transsphincteric fistula, incidentally demonstrating the important contribution of the internal sphincter to maintaining continence. Subsequently several publications focused on the importance of the internal sphincter, the division of which has long-term effects which are largely unknown [108, 109].

Owing to these considerations, a growing number of innovative procedures and therapeutic strategies have been introduced. Unfortunately, in many cases subsequent studies have not replicated the promising results of the initial publications, and long-term follow-up has often shown declining success.

20. *Statement: debridement of fistula tract followed by fibrin glue injection may be used in the treatment of complex anal fistula*
Grade of recommendation: 2B
The procedure consists of injecting thrombin and

fibrinogen from a two-chambered syringe into the fistula track via a cannula inserted into the external opening. Lindsey et al. reported the results of a randomized prospective trial of 42 patients with a complex (n = 29) and a simple (n = 13) fistula treated either with fibrin glue injection or "conventional methods" (fistulotomy or seton + flap repair). In this trial, fibrin glue healed 50 % of patients with a simple fistula and 46 % of patients with a complex fistula. There were no differences in incontinence scores and anal pressures between the 2 groups, but patient satisfaction was higher with fibrin glue treatment than with conventional methods for complex fistulas [110].

Altomare et al. randomized 64 patients with a transsphincteric fistula to receive fibrin glue (Tissucol) injection (n = 39) or a cutting or loose latex seton (n = 25) inserted under spinal anesthesia. At 1 year, healing had occurred in 21 out of 24 patients in the seton group compared with 15 out of 38 patients in the fibrin glue group. The patients in the latter group had a shorter hospital stay and reported less postoperative pain, and less impairment of continence [111]. *Singer et al. randomized 75 patients to fibrin glue plus antibiotics or fibrin glue with closure of the internal opening or fibrin glue with antibiotics and closure. The healing rates at 1 year were 25, 44 and 35 % in the three groups, but the differences between the rates were not statistically significant. There were also some patients who received a repeated fibrin glue injection after the first procedure failed* [112]. *Ellis et al. reported the results of a prospective trial in which 58 patients with a transsphincteric fistula were randomized to have an advancement flap repair only or an advancement flap and fibrin glue injection. The recurrence rate was 20 % for advancement flap alone and 46.4 % for the flap plus fibrin glue* [88]. *De Parades et al. reported the results of fibrin glue injection following an 8-week period of seton drainage in 30 patients with a complex anal fistula followed for a mean of 11.7 months, at which point 50 % were healed* [113].

Two trials reported the long-term results of fibrin glue treatment. In the first, De Oca et al. [114] *reported a success rate of 70 % in 28 patients after a mean follow-up of 20 months. In the second, 26 % had recurred at a mean follow-up of 4.1 years from initial surgery. The authors found that a quarter of patients who had initially healed developed recurrence in the intermediate term* [115]. *In a prospective study in which 22 patients were followed by MRI after injection of fibrin glue, only three (14 %) showed no sign of persisting sepsis at a median follow-up of 14 months* [116].

In conclusion, fibrin glue is a well-tolerated, low-morbidity procedure. Reported recurrence rates differ widely. In two major RCT, healing rates were between 40 and 50 %. In a carefully performed prospective observational study, the absence of continuing sepsis was demonstrated in only 14 % of patients. Studies with longer follow-up showed an increasing incidence of recurrence. Persisting sepsis may be common as has been demonstrated by MRI.

21. *Statement: autologous expanded adipose-derived stem cells plus fibrin glue or acellular dermal matrix injections may be used to treat complex anal fistula*
Grade of recommendation: 2B
Garcia-Olmo et al. [117] *reported the results of a trial in which 49 patients were randomized to surgical closure of the internal opening plus injection of fibrin glue or with fibrin glue plus adipose-derived stem cells (20 million). Healing of the fistula was observed in 16 and 71 % of patients in the two groups, a result which was highly statistically significant. However, a multicenter randomized trial of 200 patients from 19 centers randomized to adipose-derived stem cells ± plus fibrin glue versus fibrin glue alone did not show statistically significant differences in healing between the three groups (39.1, 43.3 and 37.3 %) at 6 months* [118]. *A-ba-baike-re et al. analyzed a group of 90 patients randomized to advancement flap surgery or an acellular dermal matrix bioprosthetic material injection. Healing was reported in 82.2 % in the acellular dermal matrix group and in 64.4 % of the surgical group with no continence disturbance in either group* [119].
The long-term effectiveness of such procedures is currently unknown [120]. *In conclusion, the use of biologically derived products has no statistically significant advantage over traditional surgical treatment.*

22. *Statement: Permacol injection may be used to treat complex anal fistula*
Grade of recommendation: 2B
Permacol *is a porcine-derived isocyanate cross-linked acellular dermal sheet. It is predominantly composed of type I collagen (93–95 %) with additional type III collagen and a small amount of elastin.*
In a prospective randomized trial including 28 evaluable patients, 13 received a collagen implant and 16 collagen–fibrin glue. At 29 months, the respective healing rates were 53.8 % (7/13) and 80 % (12/15) [121]. *Permacol suspension was also*

used to augment rectal mucosal advancement flap repair in 11 patients with a fistula healing rate of 91 % at a median 8-month follow-up [122].

In conclusion, there is insufficient information on this treatment. Further RCTs are needed to justify the use of Permacol in the treatment of complex anal fistula.

23. *Statement: an anal fistula plug may be used for the treatment of complex anal fistula*

Grade of recommendation: 1C

The anal fistula plug consists of bioprosthetic materials inserted in the primary track with fixation by sutures to the smooth muscle of the internal anal sphincter at the internal opening to keep the plug in place to allow time for ingrowth of fibrous tissue leading to obliteration of the track.

There is a wide variation in the reported rate of healing. A good initial result was often followed by delayed failure. In a recent systematic review, 20 studies including 530 patients were evaluated. The plug extrusion rate was 8.7 %. The healing rate ranged from 24 to 83 % with an average of 54 % at a follow-up ranging from 3 to 40 months [123]. *In a previous systematic review, 12 studies including 317 patients reported a success rate ranging from 24 to 92 %. In prospective studies of complex fistula-in-ano, there was a success rate of 35–87 %* [124].

There are several different plugs available, but the porcine small intestinal submucosa bioprosthetic plug (Biodesign Surgisis, Cook Medical) has been the most studied. In a prospective multicenter study of 73 patients [125], *the overall success rate was 38 % at 12 months. In a retrospective trial, another form of bioabsorbable synthetic fistula plug (GORE BIO-A, Gore Medical) was used in 48 patients with an overall healing rate of 69.3 % at 12 months* [126]. *In a prospective pilot study, this fistula plug made of bioabsorbable polymer (67 % polyglycolide, 33 % trimethylene carbonate) was used in 19 patients, with successful closure in only 15.8 % at 12 months* [127].

In conclusion, there is a wide range of reported success of the fistula plug used for complex fistula. Despite the initial high rates of healing reported in the literature, the long-term results have been less promising. Considering the low morbidity, however, the anal fistula plug should still be regarded as a part of the treatment algorithm for patients with a complex anal fistula.

24. *Statement: debridement and cauterization under video-endoscopic control with closure of the internal opening may be used to treat complex fistula-in-ano*

Grade of recommendation: 2C

VAAFT is a new procedure based on the use of a specially designed fiber-optic fistuloscope to assess the internal configuration of a fistula including any secondary tracks or abscesses and enabling treatment by debridement and irrigation. Once the anatomy of the fistula is defined, the track is sterilized with diathermy coagulation, cleaned with a brush and irrigated. At the end of the procedure, the internal opening is closed with sutures, staples or an endorectal flap [128]. *Therefore, this technique essentially involves closure of the internal opening in common with other techniques. It is not certain whether debridement of the track adds to the beneficial effect of the treatment.*

In a retrospective observational study, 203 patients with a complex fistula were treated with VAAFT. No major complications occurred. No incontinence was reported. Healing at 6 months with the cumulative probability of freedom from the fistula was approximately 70 % [129].

The new element of this procedure is the fiber-optic video assistance to define the pathological anatomy of the fistula including the secondary tracks. It should be remembered, however, that closure of the internal opening is part of the procedure and that this may be the effective component. Despite the promising initial results, RCTs are needed to define the role of VAAFT in the treatment of complex anal fistula.

25. *Statement: laser ablation of the fistulous track with and without closure of the internal opening may be used for treatment of high fistulas*

Grade of recommendation: 2C

FiLaC is also a new procedure which uses a laser diode (LD) to treat the track at a wavelength of 1470 nm and a radial fiber which is passed along the track. The laser beam causes progressive shrinkage of the track around the fiber [130]. *An endorectal advancement flap may be added to close the internal opening* [131].

In the first prospective study of FiLaC, primary healing was reported in 71.4 % of 35 patients at 12-month follow-up [130]. *A success rate of 82 % was reported in a retrospective study of 50 patients at 12 months* [132]. *After laser ablation and obliteration of the track in addition to a conventional flap technique, 9 out of 11 patients showed primary healing at a median follow-up of 7.4 months* [131].

FiLaC is a promising sphincter-saving procedure for anal fistula. The procedure appears to have a high success rate and low morbidity. It is repeatable and easy to perform. RCTs and longer follow-up are needed to define its true effectiveness.

Compliance with ethical standards

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

Ethical approval This paper does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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