

# Acceptable results using plug for the treatment of complex anal fistulas

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## ABSTRACT

**INTRODUCTION:** The management of complex fistula-in-ano remains a surgical challenge. Previously published studies on the treatment of fistula-in-ano with the anal fistula plug have reported a success rate reaching 35-87%. The aim of this study was to assess the results of the anal fistula plug procedure in a group of Danish patients with complex fistulas, and to analyse if the results were compatible with previous international findings.

**MATERIAL AND METHODS:** A retrospective analysis of prospectively collected data was performed for 37 consecutive patients treated with the Surgisis AFP plug for complex fistula-in-ano at the Surgical Department of Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark, between June 2006 and April 2010. Surgery and evaluation were performed by one of two specially trained proctologists.

**RESULTS:** The success rate per patient was 45.9% (17/37) and the success rate per procedure was 44.7% (17/38). A total of 40 fistulas were treated with the AFP and the success rate per fistula was 47.5% (19/40). Plug dislodgement occurred after 28.9% of the procedures, thereby accounting for 52.4% of the failed AFP procedures (11/38). No patients experienced any change in continence after the procedure.

**CONCLUSION:** We found a patient cure rate of 45.9% which is in accordance with previously reported patient cure rates of 35-87%. Current knowledge suggests that the AFP is a good choice for first-line management of complex fistula-in-ano, but further evaluation is needed.

Fistula-in-ano occurs as sequelae in up to 30-50% of perianal abscesses and is the result of persistent anal sepsis and/or an epithelialized track [1, 2]. The prevalence rate is 8.6 cases per 100,000 with a male-to-female ratio of 1.8:1. The average age of the affected cases is 38.3 years [3].

Fistula-in-ano is categorized according to location relative to the anal sphincter muscles as either intersphincteric, transsphincteric, suprasphincteric or extrasphincteric. Furthermore, fistulas-in-ano is classified as simple or complex fistulas. The complex fistula is defined as one whose treatment poses a relatively high risk of continence impairment. A fistula-in-ano may be termed complex when the track crosses > 30-50% of the external sphincter, is anterior (in females), has multiple tracks

and is recurrent or if the patient has pre-existing incontinence, local irradiation or Crohn's disease [2, 4].

The main objective of fistula surgery is closure of the fistula's tract without a change in continence. No single treatment exists that is appropriate for treatment of all fistulas. Fistulotomy is an accepted treatment for simple fistulas with a recurrence rate between 2% and 9% and a change in continence ranging from 0% to 17% of patients [1, 5].

Complex fistula management remains a challenge and various types of closure techniques have been developed. Complex fistulas may be treated by use of a seton and/or staged fistulotomy which enjoys low recurrence rates (0-8%), but carries significant rates for minor (34-63%) and major (2-26%) incontinence [2]. The high rates of minor and major incontinence after sphincter cutting treatment has made it necessary to develop sphincter-sparing techniques for the treatment of complex fistulas. Endorectal advancement flaps for closure of fistula-in-ano have a reported success rate between 36.6% and 98.5% with a weighted average of 79.2% [6]. Although endorectal advancement flap is a sphincter-sparing technique, the incontinence rate ranges from 0% to 35% with a weighted average of 13.2% [6]. Fibrin glue treatment of anal fistulas has long-term closure rates of between 14% and 60%, and change in continence has not been reported [2, 7, 8].

The anal fistula plug (AFP) (**Figure 1**) was first described by Johnson et al in 2006. Several subsequent studies have reported variable results. A systematic review of the AFP by Garg et al shows a success rate of 35-87% in complex fistula-in-ano. Furthermore, the AFP appears to be a safe procedure associated with a low risk of incontinence [9].

The aim of this study was to assess the results of the AFP procedure in a group of Danish patients with complex fistulas, and to assess whether the results were compatible with previous international findings.

## MATERIAL AND METHODS

A retrospective analysis of prospectively collected data was performed on consecutive patients treated with the Surgisis AFP plug for complex fistula-in-ano at the Surgical Department of Bispebjerg Hospital, University of

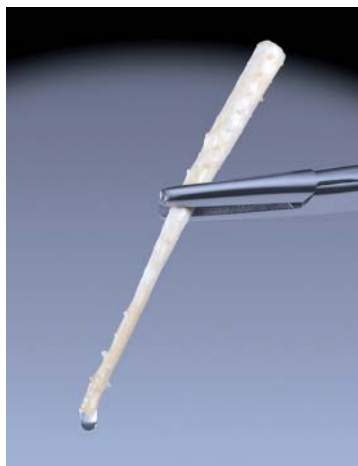
## ORIGINAL ARTICLE

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 FIGURE 1

The Surgisis  
AFP plug.



Copenhagen, Copenhagen, Denmark, from June 2006 to April 2010. Patients were prospectively enrolled if they had a fistula that was complex and if they were considered suitable for treatment with the Surgisis AFP plug at the time of examination. All patients were examined and operated by one of two specially trained proctologists. Endoanal ultrasound or magnetic resonance imaging was used for most of the patients, but not systematically. Data recorded were age, gender, aetiology of the fistula, fistula anatomy, number of tracks, number of previous repairs, if they had drainage with a loose-seton prior to the procedure and length of follow-up. Patients were evaluated by the operating surgeon in the outpatient clinic and the primary endpoint was closure of the fistula. Outcome was defined as healed or non-healed fistula. Plug dislodgement was also noted.

**Operative procedure:** Prior to plug insertion, most patients were drained using a loose rubber seton for 6-12 weeks. Before insertion, a total mechanical bowel cleansing as used before colonoscopy was applied. The patient had antibiotic prophylaxis with one dose of metronidazole (1 g) and cefuroxime (1.5 g). The seton was removed and the fistula tract brushed with a fistula brush, the fistula tract was irrigated with hydrogen peroxide and metronidazole. The plug was drawn through the fistula tract from the inside opening with the broader end inside. The plug was fixed to the internal sphincter with 3-0 or 4-0 vicryl. The remaining plug inside was excised and the inner opening closed with a mucosal flap. In the first five fistulas, the outer opening was fixed to the skin. After no. 6 we left it free of fixation, and sometimes even opened the outer opening a bit. The patient was confined to bed for 24 hours and was prohibited to ride a bike or have intercourse for two weeks.

Continuous data are presented as median and range, and categorical data are presented as frequency or percentage unless otherwise specified. Fisher's exact test was used for categorical data and the Mann-Whitney U test was used for continuous data. SPSS was used for data analysis.

## RESULTS

A total of 37 patients were enrolled to receive the Surgisis AFP plug. One patient underwent the procedure twice, and on both occasions closure of the fistula failed, resulting in a total of 38 procedures. Three patients had two fistulas, and two of the three patients had two AFPs inserted during the same procedure. Both patients had successful closure of both their fistulas. The patient treated with only one AFP had a transsphincteric fistula in combination with a blind extrasphincteric fistula. One patient was treated unsuccessfully for an ano-vaginal fistula. Two patients with anterior superficial fistulas that only involved the lower part of the external sphincter were enrolled because they met the criteria of having a complex fistula. Both patients experienced unsuccessful closure of their fistula. The remaining patients had transsphincteric fistulas, except one who had an intersphincteric fistula. All fistulas were categorized as complex.

There was no significant difference in age, gender, aetiology of the fistula, fistula anatomy, number of tracks, number of previous repairs or loose seton drainage between the procedures that yielded a successful healing of the fistula and those that did not (**Table 1**). When the numbers of previous repairs were not grouped, there was still no significant difference between the two groups ( $p = 0.688$ ).

The success rate per patient was 45.9% (17/37) and the success rate per procedure was 44.7% (17/38). A total of 40 fistulas were treated with the AFP, and the success rate per fistula was 47.5% (19/40) (**Table 2**).

Plug dislodgement occurred after 28.9% of the procedures, thereby accounting for 52.4% of the failed AFP procedures (11/38).

The overall median follow-up time was 60.5 (7-1,248) days. There was a significant difference in follow-up time between the two groups ( $p = 0.008$ ). For the group that was successfully treated with the AFP, the median follow-up time was 125 (28-1,248) days, and for the group that was unsuccessfully treated, the median follow-up time was 35 (7-321) days.

Two patients had transsphincteric fistula after ileal pouch-anal anastomosis and both of these patients were unsuccessfully treated with the AFP. One patient had Crohn's disease and two patients had HIV. All three patients had successful closure of their fistula. The remaining 32 patients had cryptoglandular fistulas. All but eight

patients were treated with loose seton drainage prior to the AFP insertion. A total of 22 patients had undergone anal fistula surgery prior to enrolment. No patients experienced any change in continence after the procedure.

## DISCUSSION

We achieved a patient cure rate of 45.9% which is in accordance with previously reported patient cure rates of 35-87% for complex fistula-in-ano [9]. The reported patient cure rate of the AFP procedure ranges from 13.9% to 87%. The large variability in the reported patient cure rates could partially be explained by the fact that the published studies are heterogeneous and small [9, 10].

There was a significant difference in follow-up time between those who had closure of their fistula and those who did not. This is probably due to the fact that 52.4% of the failed AFP procedures had plug dislodgement, which frequently occurs within the first two weeks after the procedure. The total rate of plug dislodgement was 28.9%. The previously reported rates of plug dislodgement following AFP insertion range from 4% to 41% with an average of 19% [9]. Plug dislodgement is the most commonly reported cause of failure. If it is possible to reduce the rate of plug dislodgement by using a better technique or by better selection of patients, it should be possible to achieve a higher success rate. When plug dislodgement cases are excluded, the success rate per procedure increases to 63%. However, healing of the fistula has been reported despite plug dislodgement [11]. Ky et al showed that the success rate of the AFP declined over a period of one year [12]. Ellis et al showed that two out of eight patients with clinical healing after a minimum of one year after their latest treatment had residual fistula tract or fluid in the area where the fistula had previously been located [13]. We might have achieved a lower success rate if we had extended the follow-up period.

Neither our study nor previously published studies [14, 15] have found a significant change in closure rates for patients treated with loose seton drainage prior to AFP insertion. The role of loose seton drainage remains unclear and further evaluation is needed.

Continence prior to and after the AFP procedure was not recorded, but a retrospective examination of the patients' medical charts showed no reports of change in continence. Schwander et al [16] found no significant change in continence level after AFP insertion. Lenisa et al [17] reported a decline in the Cleveland Clinic Florida incontinence score after AFP insertion, but knowledge of AFP insertion on continence level is otherwise poor. Nonetheless, it seems as if the AFP procedure is safe and carries only a very limited risk of incontinence. Further evaluation is needed to confirm this.



TABLE 1

Patient characteristics.

	Overall	Fistula not healed	Fistula healed	p
Age, years, mean $\pm$ SD	44 $\pm$ 14	41 $\pm$ 12	48 $\pm$ 16	0.176
Gender, n (%)				
Male	22 (57.9)	11 (28.9)	11 (28.9)	0.521
Female	16 (42.1)	10 (26.3)	6 (15.8)	
Total	38 (100)	21 (55.3)	17 (44.7)	
Fistulas, n (%)				
1	35 (92.1)	20 (52.6)	15 (39.5)	0.577
2	3 (7.9)	1 (2.6)	2 (5.3)	
Aetiology, n (%)				
Cryptoglandular	33 (86.8)	19 (50)	14 (36.8)	0.089
Crohn's disease	1 (2.6)	0 (0)	1 (2.6)	
HIV	2 (5.3)	0 (0)	2 (5.3)	
Pouch	2 (5.3)	2 (5.3)	0 (0)	
Fistula anatomy, n (%)				
Superficial	2 (5.3)	2 (5.3)	0 (0)	0.411
Intersphincteric	1 (2.6)	0 (0)	1 (2.6)	
Transsphincteric	34 (89.5)	18 (47.4)	16 (42.1)	
Ano-vaginal	1 (2.6)	1 (2.6)	0 (0)	
Seton, n (%)				
Yes	30 (78.9)	16 (42.1)	14 (36.8)	0.709
No	8 (21.1)	5 (13.2)	3 (7.9)	
Previous fistula surgery, n (%)				
Yes	23 (60.5)	15 (39.5)	8 (21.1)	0.185
No	15 (39.5)	6 (15.8)	9 (23.7)	
Previous repairs, n (%)				
0	15 (40.5)	6 (16.2)	9 (24.3)	0.578
1	12 (32.4)	8 (21.6)	4 (10.8)	
2	3 (8.1)	2 (5.4)	1 (2.7)	
$\geq 3$	7 (18.9)	4 (10.8)	3 (8.1)	
Follow-up time, days, mean (range)	60.5 (7-1,248)	35 (7-321)	125 (28-1,248)	0.008

n = number of patients; SD = standard deviation.



TABLE 2

Success rate.

	Total, n	Failure, n (%)	Success, n (%)
Patients	37	20 (54.1)	17 (45.9)
Procedures	38	21 (55.3)	17 (44.7)
Fistulas	40	21 (52.5)	19 (47.5)

In a retrospective study, Chung et al [18] compared the AFP, anal advancement flap fibrin glue and seton drainage in the treatment of high transsphincteric fistulas. They reported a closure rate of 59.3%, 60.4%, 39.1% and 32.6% for the AFP, anal advancement flap, fibrin glue and seton drainage, respectively. Johnson et al [19] reported higher closure rates for the AFP than for fibrin glue in a prospective, non-randomized study. A comparative study by Christoforidis et al [20] found a 63% success rate for endorectal advancement flap versus

a 32% success rate for the AFP in the treatment of trans-sphincteric fistulas. Furthermore, they found no change in continence level among patients who were successfully treated with the AFP, although this finding should be seen in the light of the small number of patients treated. Ortiz et al published a randomized clinical trial of the AFP versus endorectal advancement flap for the treatment of high cryptoglandular fistula-in-ano, but the study was terminated prematurely due to poor results in the AFP group [10]. They found fistula recurrence in 12 of 15 patients treated with the AFP versus two of the 16 patients treated with an endorectal advancement flap. It seems that the AFP is superior to fibrin glue, but inferior to the advancement flap in regards to closure of complex fistula-in-ano. Conversely, it seems that there is no or little risk of change in continence associated with AFP use.

## CONCLUSION

We found a patient cure rate of 45.9% which is in accordance with previously reported patient cure rates of 35-87% [9]. Current knowledge suggests that the AFP is a good first-line management of complex fistula-in-ano. Randomized controlled trials are needed to compare the AFP with conventional treatment in regard to fistula closure rates, complications and change in continence level.

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