





ORIGINAL ARTICLE

Long-term outcome of the Surgisis[®] (Biodesign[®]) anal fistula plug for complex cryptoglandular and Crohn's fistulas

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Abstract

Aim: To evaluate the long-term success rate of treatment with the Surgisis[®] (Biodesign[®]) anal fistula plug for complex anal fistulas, assess fistula plug failure over time and compare success rates for fistula plug between a group of patients with cryptoglandular fistula and another group with Crohn's fistula.

Method: This is a single-centre study of consecutive patients treated with the Surgisis[®] (Biodesign[®]) anal fistula plug between May 2006 and October 2009. All patients had complex anal fistulas in need of surgical treatment. The patients were assessed preoperatively by physical examination and three-dimensional (3D) endoanal ultrasound, and treated with a loose seton. Postoperative assessment by clinical examination and 3D endoanal ultrasound was performed at 2 weeks, 3 months and 6–12 months. Long-term follow-up was carried out in 2017 using a questionnaire, and clinical examination combined with 3D endoanal ultrasound was performed if the questionnaire indicated any signs of fistula recurrence.

Results: A total of 95 patients were included; 30 had quiescent Crohn's disease. Overall, 151 plug procedures were performed. Long-term follow-up was undertaken in 90 (95%) patients; the results showed that after a median period of 110 months, the overall healing rate after one to five plug procedures was 38%. No statistically significant difference in success rate was found between the cryptoglandular fistula group and the Crohn's fistula group ($P = 0.37$). No further healing was observed after the use of three plugs.

Conclusion: Considering its low morbidity in a complex disease with high recurrence rates over time, the anal fistula plug may still be considered as one of the first-line treatments for patients with complex anal fistulas.

KEYWORDS

Complex anal fistula, anal fistula plug, Crohn's disease

Parts of the study were presented as a podium presentation at the meeting of the European Society of Colorectal Surgery, Nice, France, 26–28 September, 2018.

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INTRODUCTION

Treating complex anal fistulas with sphincter-preserving techniques remains a therapeutic challenge [1]. The Surgisis® (Biodesign®) anal fistula plug (Cook Medical, Bloomington, Indiana, USA) was introduced in 2005 to treat cryptoglandular fistulas and fistulizing anoperineal Crohn's disease. Earlier studies showed high early success rates, while more recent reports have demonstrated huge variations in the success rate, with an increase in plug failure rate with longer follow-up time. The success rates reported vary between 14% and 100%. Although many studies include follow-up during the first post-operative year, few include follow-up periods of up to 60 months [2-15]. A meta-analysis from 2012 concluded that the anal fistula plug was an effective treatment for complex anal fistulas [16]. However, a systematic review concluded that the anal fistula plug has not been adequately evaluated for treatment of Crohn's disease [17].

This study aimed to evaluate the long-term success rate of treatment for complex anal fistulas using an anal fistula plug. We assessed fistula plug failure over time, and compared success rates in two groups of patients – one with cryptoglandular fistula and the other with Crohn's fistula.

MATERIALS AND METHODS

Study design and patient selection

Between 2 May 2006 and 29 October 2009, consecutive patients with complex fistulas in need of surgical treatment at a referral centre were eligible for enrolment in this single-centre study. The fistula was defined as 'complex' if a simple lay-open was not the first treatment option (i.e., if the tract involved more than 30%–50% of the length of the anal sphincter (depending on fistula orientation), or if the patient had a history of incontinence, Crohn's disease or local irradiation). Anterior fistulas in female patients were also considered to be 'complex'. Patients with ano/rectovaginal fistulas were excluded.

Ethical considerations

The study protocol was approved by the regional Ethics Committee. All patients provided informed consent. All procedures performed were in accordance with the ethical standards of the Institutional and National Research Committees and with the 1964 Helsinki declaration and its later amendments. As no previous large studies were available, we aimed to include approximately 100 patients within a 3- to 4-year study period.

Surgical procedure

All patients meeting the inclusion criteria were assessed by clinical examination and three-dimensional (3D) endoanal ultrasound.

What does this paper add to the literature?

The findings of this study reveal that there is no statistically significant difference between success rates of the Surgisis® (Biodesign®) anal fistula plug for treatment of cryptoglandular or Crohn's fistulas at a follow-up more than 5 years after surgery.

Patients were treated with a draining loose seton for at least 6 weeks before the surgery. A 360° rotating 13 MHz transducer with a 3-D Pro Focus machine (BK Medical, Herlev, Denmark) was used for the ultrasound examinations.

Four surgeons with extensive experience in fistula surgery performed all procedures: two were present at each procedure. Preoperatively, patients were given a mini enema as bowel preparation. Oral or intravenous antibiotics (1.5 g metronidazole + 160/800 mg trimethoprim/sulfamethoxazole) were given in a single dose on the day of surgery. Surgery was performed with the patient under general anaesthesia and placed in the lithotomy position. Another 3D endoanal ultrasound was performed perioperatively to check that no further tracts or undrained abscesses were present. Clinical examination also ensured that in patients with Crohn's disease no active proctitis was present.

The anal fistula plug Surgisis® (Biodesign®) (Cook Medical, Bloomington, Indiana, USA) was placed in the fistula tract according to the instructions of the manufacturer, with one adjustment: two double-armed monofilament absorbable 2-0 sutures were placed as a cross through the plug and over the internal opening and the internal sphincter. Rather than using a figure-of-eight suture, the plug was fixed at the internal opening by tying the crossed sutures. Special attention was paid to ensure adequate fixation and that the plug was covered by mucosa when closing the internal opening.

Follow-up

The patients were assessed by a clinical examination and 3D endoanal ultrasound 2 weeks, 3 months and at some point between 6 and 12 months after surgery. Healing 6–12 months after surgery was defined clinically by the absence of discharge and a dry scar at the external opening. Failure was classified by the entire plug falling out (up to 2 weeks postoperatively), signs of surgical site inflammation and/or infection and discharge of faeces or gas through the external opening (at any time point). However, if the patient reported persistent, but decreasing, fluid discharge without any other clinical findings 3 months postoperatively, the procedure was not automatically classified as a failure. Within 1–3 weeks of failure, a new loose seton was inserted for drainage. Depending on the clinical situation, either a new plug was inserted after 6 weeks of drainage or another surgical procedure was performed. If a new plug was inserted, the clinical procedure, described above, was followed.

After the last clinical assessment, the patients were told to contact the clinic if any symptoms of plug failure occurred. The patients who contacted the clinic with new symptoms were re-assessed, as described above. If this follow-up assessment showed fistula recurrence, it was treated according to the best clinical practice and a new surgical procedure was performed, when necessary. Patients with clinical symptoms of late recurrence or a fistula in need of surgical intervention on the same side as the previously treated fistula were considered to have plug failure.

Long-term follow-up

The long-term follow-up was conducted between 21 August and 22 December 2017. Patients not known to have undergone any further fistula surgery received a questionnaire regarding any symptoms of recurrence. Healing of the fistula tract was defined by no additional fistula surgery, a closed external opening and the absence of discharge. A reminder was sent to the patients who did not answer the first questionnaire, and attempts were made to contact the patients by telephone if no answer was received. Patients reporting any symptoms of recurrence were assessed by clinical examination and 3D endoanal ultrasound. Patients who had already been assessed clinically in the outpatient department or at the Department of Gastroenterology during the previous year were considered to have no recurrence if no clinical signs of an active fistula had been noted.

Statistical analyses

Patient characteristics are expressed as frequency (percent) or median (range), as appropriate. Comparisons between categorical variables were made using the χ^2 test. Kaplan–Meier analysis with the log-rank test was used to determine differences between the study groups in the distribution of fistula recurrence. A value of $P < 0.05$ was considered statistically significant. All analyses were performed using IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, New York, USA).

RESULTS

Patient characteristics

In total, 95 patients (61 male, 34 female; median age: 44 years; age range: 10–80 years) were included in the study. Thirty patients (18 male, 12 female; median age: 34 years; age range: 10–66 years) had quiescent Crohn's disease, 19 (63%) of whom were treated with biological medication during the study. Sixty-five patients (43 male, 22 female; median age: 46 years; age range: 21–80 years) did not have any history of inflammatory bowel disease. Sixty-six (70%) patients had not undergone any fistula procedures other than the

preoperative drainage that was performed at the beginning of the present study. Posterior fistula tracts were present in 49 (50%) patients. The characteristics of the patients included in this study are summarized in Table 1.

Follow-up

Follow-up was complete for 90 (95%) patients. Five patients (one with Crohn's disease) were lost to follow-up. The duration of follow-up for the five patients lost to follow-up ranged from 4 to 30 months. The median duration of follow-up for all patients who healed was 110 (range: 93–138) months. The median durations of follow-up for the cryptoglandular and Crohn's fistula groups were 111 (range: 93–138) months and 109 (range: 97–133) months, respectively.

Complications

No serious complications, such as sepsis or death, were recorded for any patient.

Fistula healing

Figure 1 shows the treatment and result algorithm for the study. Fistula healing was reported in 28 (31%) patients, while failure occurred in 62 (69%) following insertion of the first fistula plug. Thirty-seven patients received a second plug after failure of the first, and fistula healing was noted in five (14%) of these patients. Eleven patients received a fistula plug more than twice; healing was noted in one patient after the third plug. No fistulas healed in patients who underwent four (two patients) or five (three patients) plug procedures.

Figure 2 shows the treatment and result algorithm for the patients with cryptoglandular fistulas. Fistula healing was noted in 25 (41%) patients after one to two plug procedures. No healing occurred in patients after three, four or five plug procedures.

Figure 3 shows the treatment and result algorithm for the patients with Crohn's disease. Nine (31%) patients showed signs of complete fistula healing after one to three plug procedures.

Overall healing rate

After a median follow-up of 110 (range: 93–138) months, the overall healing rate was 38% (34/90), as shown in Figure 1.

Failure rate per plug

A total of 151 plug procedures were performed in this study. As five patients with incomplete follow-up were excluded, 146 plug

TABLE 1 Characteristics of participants in the cryptoglandular and the Crohn's fistula groups

Characteristic	Total (N = 95)	Crohn's group (n = 30)	Cryptoglandular group (n = 65)
Age (y)	44 (10–80)	34 (10–66)	46 (21–80)
Gender			
Female	34 (36)	12 (40)	22 (34)
Male	61 (64)	18 (60)	43 (66)
Earlier procedure			
None	66 (70)	19 (63)	47 (72)
Fistulectomy	12 (13)	5 (17)	7 (11)
Advancement flap	3 (3)	-	3 (5)
Other	13 (14)	5 (17)	8 (13)
Unknown	1 (1)	1 (3)	-
Internal opening			
Anterior	30 (32)	7 (23)	23 (35)
Lateral	15 (16)	8 (27)	7 (11)
Posterior	49 (50)	15 (50)	34 (52)
Unknown	1 (1)	-	1 (2)

Values are given as median (range) or n (%).

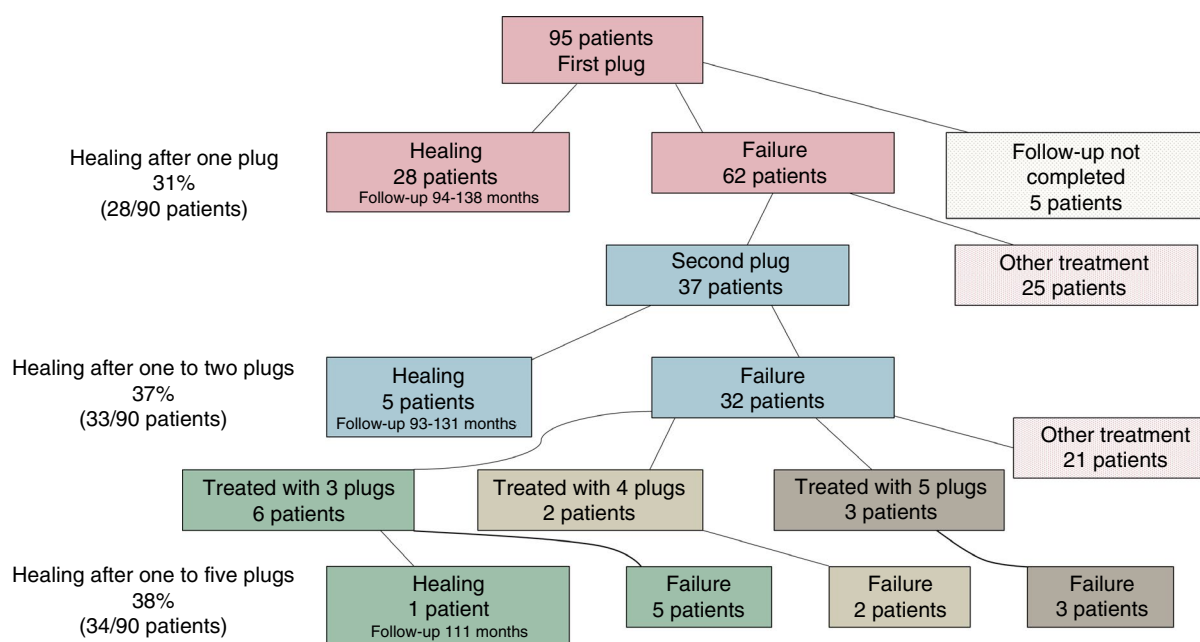


FIGURE 1 Treatment and result algorithm for the study

procedures were analysed. Of these, 112 (77%) showed plug failure during the study period.

Forty-three plugs (representing 38% of failed plugs) failed within 3 months of surgery, 14 (13%) as a result of spontaneous expulsion of the plug during the first few postoperative days. Twenty-five (22%) plugs failed at 3–6 months, while 21 (19%) plugs showed signs of failure 6–12 months after surgery. Twenty-three (21%) plugs failed later than 1 year after surgery. Thirty-seven (33%) plugs failed even after complete closure of the external opening.

Success rate over time: Cryptoglandular vs Crohn's fistulas

Figure 4 shows the Kaplan–Meier analysis for success rate over time for the 146 plugs included in the study. In the cryptoglandular fistula group (103 plug procedures), the success rate per plug was 24% (25 plugs with success, 78 plugs with failure). In the Crohn's fistula group (43 plug procedures), the success rate per plug was 21% (9 success, 34 failure). No statistically significant difference between the groups was found ($P = 0.37$).

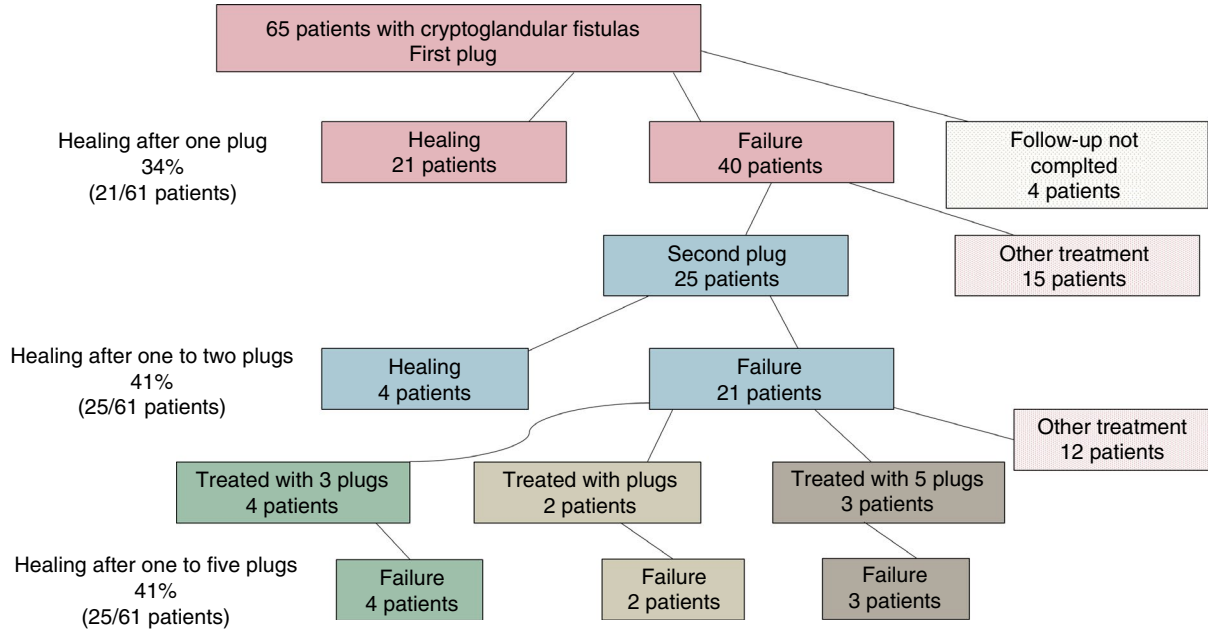


FIGURE 2 Treatment and result algorithm for patients with cryptoglandular fistulas

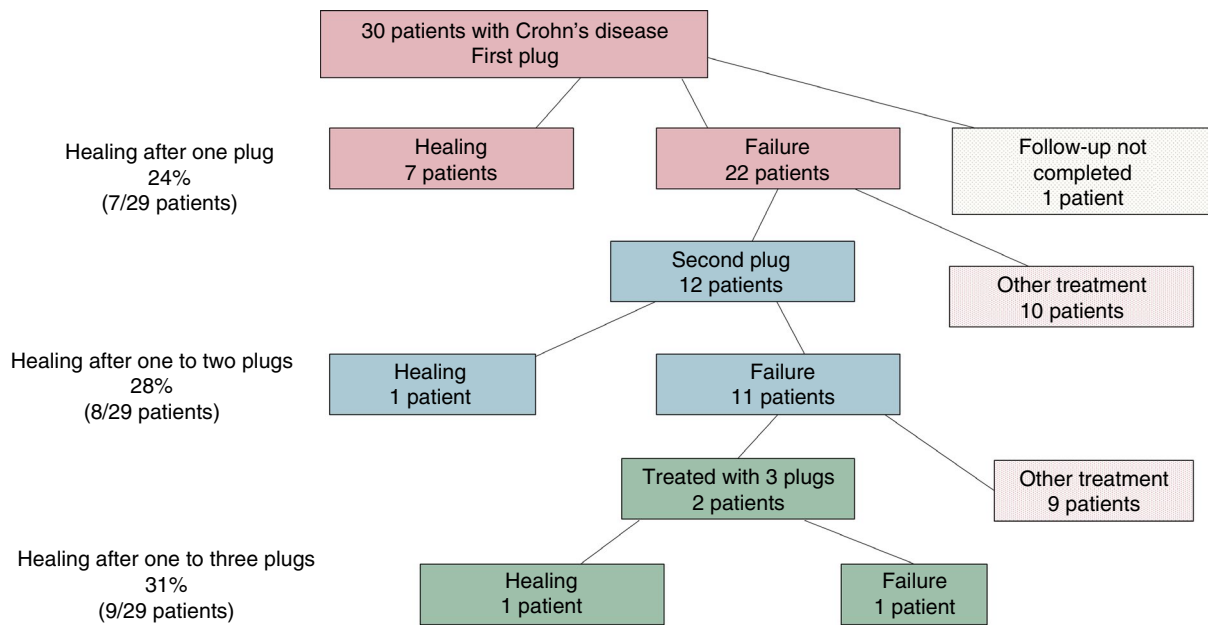


FIGURE 3 Treatment and result algorithm for patients with known Crohn's disease

Success rate per plug: Plug as the first definitive treatment

Sixty-two of the 146 plug procedures analysed in the study were performed as the first attempt at definitive fistula treatment. Success rate per plug in this group was 37% (23 success, 39 failure). Eighty-four plug procedures were performed for recurrence after any type of fistula surgery. In these, the success rate per plug was

13% (11 success, 73 failure). These results, implying greater success when a plug was used as first-line treatment, were statistically significant: $\chi^2(1, n = 146) = 11.50, P < 0.001$.

Discharge as a prognostic factor

Three months postoperatively, clinical symptoms (namely the presence or absence of fluid discharge through the external opening),

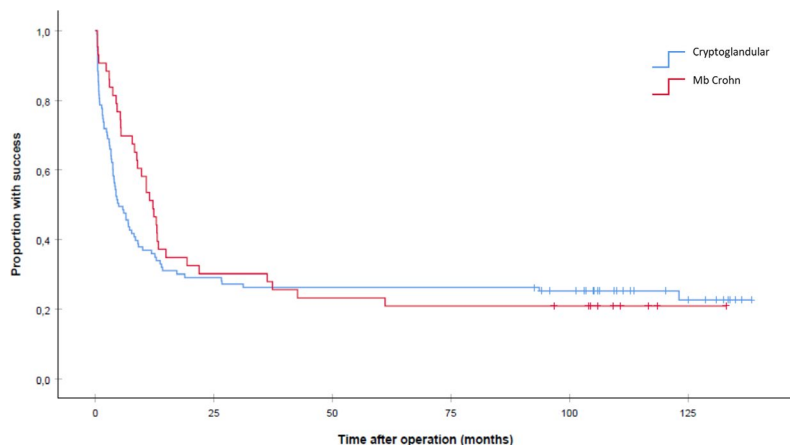


FIGURE 4 Kaplan–Meier analysis for success rate over time for the 146 plugs included in the study: 103 in the cryptoglandular fistula group and 43 in the Crohn's fistula group. A log rank test showed no statistically significant difference between success rate distributions ($P = 0.37$). Mb Crohn, Crohn's group

associated with the fistula plug treatment, were investigated for 113 plugs. This information was missing for one patient with plug success. In the group of patients reporting discharge at 3 months postoperatively (68 plug procedures), the subsequent success rate per plug was 10% (7 success, 61 failure). In the group of patients reporting no discharge at 3 months postoperatively (45 plug procedures), the success rate per plug was 58% (26 success, 19 failure). The relationship between these variables was statistically significant: χ^2 (1, $n = 113$) = 29.53, $P < 0.001$.

The presence of discharge 3 months after the plug procedure had 76% sensitivity and 77% specificity for plug failure. The positive predictive value for plug failure was 90%, while the negative predictive value was 58%.

DISCUSSION AND CONCLUSION

A systematic review has highlighted the need for studies with defined fistula types, homogeneity in the study groups and long-term follow-up [1]. To the best of our knowledge, our study is the first to include a long-term follow-up (>5 years) after treatment of complex fistulas with an anal fistula plug. In this single-centre study, treatment was carried out by four colorectal surgeons with extensive experience in fistula surgery. All postoperative follow-up was conducted in a standardized manner.

All patients included in this study were systematically assessed preoperatively, using 3D endoanal ultrasound, to define the fistula type; another ultrasound was performed perioperatively, immediately before the plug procedure, to confirm that no abscesses or further tracts were present. This could explain why no difference in plug success was found between patients with cryptoglandular fistula and patients with fistulizing ano-perineal Crohn's disease. After an earlier report of 80% closure rate in 20 patients with Crohn's disease [11], Ellis et al. concluded that a history of Crohn's disease is associated with a risk of plug failure [18]. A multicentre study of 126 patients (including 13 patients with Crohn's fistula) reported

an overall fistula healing rate of 24% after a median follow-up of 13 months [2]. However, the results were not stratified for patients with Crohn's disease. Another multicentre study treated 73 patients (11% with Crohn's fistula) with anal fistula plugs; that study reported a Crohn's fistula healing rate of 50% (4/8), with a mean follow-up of 15 months [19]. A randomized controlled trial treated 106 patients with Crohn's disease using either a plug procedure or seton removal after drainage for more than 1 month; no differences between the groups were found, and 12-week closure rates of 32% and 23%, respectively, were reported [13]. Many of the patients with Crohn's disease included in the current study presented with fistulas, and the proportion of patients on biological treatment was relatively low (63%). The number of patients with Crohn's fistulas in our study was too low to make any valid conclusions about the effects of biological medications on plug healing. We believe that Crohn's fistulas can be successfully treated with an anal fistula plug after sufficient drainage and no sign of active proctitis. However, further studies are needed to investigate factors affecting the healing process in Crohn's fistulas.

In our study, healing of the fistula tract was defined as no further fistula surgery, a closed external opening and the absence of discharge after long-term follow-up. According to our results, fistula recurrence can occur several years after the plug procedure. Differentiation between recurring and new fistulas should be considered, but this is of minimal relevance to the patient as, to them, the fistula has recurred and is located in the same position as the previous one. Our study revealed that 21% of plugs showed clinical signs of failure later than 1 year after the plug procedure, indicating that studies with relatively high success rates, but short follow-up, are likely to have decreasing plug success rates over time. Our study findings are aligned with those of an earlier study, which reported that plug failure can occur even after complete closure of the external opening [18].

In our study, technical failure, defined as expulsion of the plug during the first 2 weeks after the procedure, occurred in nine (10%) patients. Three patients had two plugs that spontaneously

discharged within days following surgery, while one patient had three technical failures, one after the other. Four of these nine patients were women with anterior anal fistulas for whom failure can be the result of a short fistula tract, which results in difficulty with fixation of the plug. As the clinical consequences for these patients are the same as for patients who experienced plug failure because of other factors, we did not exclude the technical failures from the overall data. A systematic review reported early failure rates ranging from 4% to 41% [1].

One factor that may contribute to the early failures discussed above is the fact that fistula length was not measured in this study. In 2010, McGee et al. published a study that included 41 patients and a mean follow-up time of 2 years; they reported an overall closure rate of 43% and concluded that plug repair failed in nearly 80% of fistula tracts shorter than 4 cm [20].

Most (79%) plug failures occurred during the first year after surgery. One study concluded that the plug procedure is considered to have failed if there is no evidence of fistula closure 3 months postoperatively [19]. Interestingly, 10% of patients in our study who reported discharge through the external fistula opening 3 months after the procedure went on to demonstrate fistula healing later during the study period.

The long follow-up period and large study population are the main strengths of the current study. The patients were treated, operated on and followed up in a systematic manner, which can be difficult to manage in a multicentre study. To the best of our knowledge, no other studies have used perioperative 3D endoanal ultrasound to ensure adequate drainage of the fistula tract.

This study has some limitations that should be addressed. First, the study began when the plug procedure was new. Therefore, the methodology and limitations were not fully understood. Furthermore, some of the patients included would not have been considered as suitable candidates for the plug procedure today. Even experienced surgeons, such as those in this study, have a learning curve and this may have affected the results. Second, our study was not a randomized controlled clinical trial. A recently published randomized prospective multicentre study, which included a median follow-up of 12 (range: 9–24) months reported a significantly lower success rate of 34% (14/41 patients) in the plug group compared with 62% (25/40 patients) in the advancement flap group. The same study also showed that neither of the treatment methods had any significant effect on the St Mark's incontinence score, used to measure anal incontinence [3]. Finally, another limitation of our study is the risk of recall bias as four patients were followed up entirely by the gastroenterology department. All involved, however, were aware and were informed that they should report any signs of failure to our unit.

This study demonstrates that the anal fistula plug still has an acceptable success rate when used as a treatment for complex anal fistulas. An interesting finding is that plug procedures performed as the first attempt at definitive fistula treatment had a significantly higher success rate per plug compared with plug procedures performed after recurrence of fistula following any type of fistula surgery. We

believe that the results of collagen plug treatment may be improved by combining treatment with anal fistula plug with more novel treatment methods.

We demonstrated that repeated use of plugs had diminishing returns, with no patients healing after the insertion of a fourth or fifth plug and only one after a third. We therefore conclude that there is no value in inserting more than two plugs in succession.

In conclusion, this long-term (7–11 year) follow-up study for the treatment of complex anal fistulas with the Surgisis® (Biodesign®) anal fistula plug demonstrated an acceptable overall success rate of 38%. There was no statistically significant difference in success rates between the cryptoglandular fistula group and the Crohn's fistula group. Considering its low morbidity in a complex disease with high recurrence rates over time, the anal fistula plug may still be considered as one of the first-line treatments for patients with complex anal fistulas.

CONFLICT OF INTEREST

The authors declare no conflict of interests. No grant support or financial relationship.

DATA AVAILABILITY STATEMENT

Data are available on request because of to privacy/ethical restrictions.

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