Treatment of fistula-in-ano with the Surgisis® AFP™ anal fistula plug

R.M. Lupinacci, C. Vallet, Y. Parc, N. Chafai, E. Tiret*

Summary
Objective. — Closure of the fistula tract with an anal fistula plug has been reported to provide success rates as high as 80%. The purpose of this study was to evaluate our results with this new method.
Method. — From June 2006 to September 2007, an anal fistula plug was used for the treatment of high transsphincteric fistulas. Success was defined as no residual leakage or abscess formation and closure of the external opening.
Results. — Fifteen patients (seven women), median age 46 years (range 32—58 years), were included in the study. Three had Crohn’s disease, three had an anovulvar fistula and seven had undergone previous surgical-repair attempts. Three patients expelled the prosthesis on postoperative day 2, 5 and 7, respectively, and a second plug placement was followed by expulsion again. One patient developed an abscess that was noted on postoperative day 4. The fistula tract healed in 6/15 patients (40%) after 3 months and in 8/15 (53.3%) after 7 months. The success rate in Crohn’s disease was 33%. No significant difference was found between patients with or without previous surgical repair.
Conclusion. — In our experience, this simple technique provided success rates of 40% at 3 months and 53% at 7 months.

Introduction
For patients with fistula-in-ano, the treatment objectives are to close the primary opening, heal the fistula tract, prevent recurrence and preserve continence. These objectives can generally be achieved with fistulotomy in those with intersphincteric and low transsphincteric fistulas that...
involve less than the lower half of the external sphincter [1]. For high transsphincteric and suprasphincteric fistulas, however, there is a risk of incontinence if the fistula tract is laid open. Several sphincter-sparing treatments have been proposed, including seton insertion, sealing the fistula tract with fibrin glue and more complex procedures, such as an endorectal advancement flap. Depending on the series, the risk of recurrence is around 30—40%, with a range of 0% to 100%.

Prosthetic devices designed to reinforce the intestinal wall can be fabricated from porcine intestinal submucosa. This material has natural resistance against infection, does not lead to a foreign-body or giant-cell reaction and serves as a matrix for host cell remodeling; during the 3 months following implantation [2,3]. Such good tolerance in a septic situation suggests that this type of prosthesis might be used in anal fistulas. For this reason, a conical device adapted to the fistula tract was designed, and the first results with this Surgisis® anal fistula plug (AFP™, Cook Ireland Ltd, Limerick, Ireland), have demonstrated better than 80% successful healing [4,5]. However, later studies have failed to confirm these results and, contrarily, have reported recurrence rates of up to 80% [6,7]. Indeed, the data reported in the literature are somewhat mixed.

The purpose of the present study was to report on our early experience with the Surgisis® anal fistula plug in a consecutive single-center series of patients treated for fistula-in-ano, all of whom had fistula tracts that could not be laid open because of the risk of incontinence.

Material and methods

Implantation of a Surgisis® anal fistula plug was performed, starting in June 2006, in all patients with either a high transsphincteric fistula involving more than half of the external sphincter or a suprasphincteric fistula. A prospective assessment of outcome was pursued through to September 2007. Fistulas without an intermediary tract, such as rectovaginal fistulas, were excluded from the study, as were fistulas with multiple tract pathways.

Demographic data (patients’ age and gender) and fistula characteristics (type and number of previous procedures) were noted for each patient (Table 1).

Implantation technique

Bowel preparation, using Fleet phospho-soda (E.C. De Witt & Co, Runcorn, Cheshire, UK), was the rule on the day before the procedure, which was performed under general anesthesia in the lithotomy position. A broad-spectrum antibiotic was also administered at the time of anesthesia induction. The fistula tract and the primary and secondary orifices were identified with a stylet. The tract was washed out with hydrogen peroxide or saline solution, but with no curettage to avoid tract enlargement. In compliance with the manufacturer’s instructions, the prosthesis was soaked in saline solution for 5 min before implantation. In cases where the fistula tract had not been drained with a seton, a guide thread was inserted to pull the plug into position. The plug was inserted via the primary internal orifice and pulled towards the external orifice until its large end effectively blocked the opening of the internal orifice. The plug was then cut flush with the anal mucosa, and its internal end anchored with two figure-of-eight sutures, using absorbable 00 thread, passed through the internal sphincter. The implant was then carefully covered with anal mucosa, while the external orifice was left open; the plug was then cut again and affixed to the skin.

Follow-up

Only the intake of fluids was allowed for 48 h. Metronidazole was prescribed at 1.5 g/day. Patients were advised to avoid strenuous exercise, including straining, for 2 weeks following the operation. Patients were then reviewed after 1, 3 and 6 months and, after that, on an individual basis. Success was

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patients’ data.</th>
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<tr>
<td>Patients (gender, age in years)</td>
<td>Type of fistula</td>
</tr>
<tr>
<td>M, 36</td>
<td>Transsphincteric</td>
</tr>
<tr>
<td>M, 47</td>
<td>Transsphincteric</td>
</tr>
<tr>
<td>F, 39</td>
<td>Anovulvar</td>
</tr>
<tr>
<td>M, 50</td>
<td>Transsphincteric</td>
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<tr>
<td>M, 50</td>
<td>Transsphincteric</td>
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<tr>
<td>F, 33</td>
<td>Transsphincteric</td>
</tr>
<tr>
<td>M, 56</td>
<td>Transsphincteric</td>
</tr>
<tr>
<td>M, 32</td>
<td>Transsphincteric</td>
</tr>
<tr>
<td>F, 48</td>
<td>Anovulvar</td>
</tr>
<tr>
<td>M, 48</td>
<td>Transsphincteric</td>
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<tr>
<td>M, 40</td>
<td>Anovulvar</td>
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<tr>
<td>F, 44</td>
<td>Transsphincteric</td>
</tr>
<tr>
<td>M, 58</td>
<td>Transsphincteric</td>
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<tr>
<td>F, 35</td>
<td>Transsphincteric</td>
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<tr>
<td>F, 46</td>
<td>Transsphincteric</td>
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M: male; F: female.
defined as the absence of leakage or residual abscess and closure of the secondary orifice. A control magnetic reso-
ance imaging (MRI) scan was not performed systematically.
The quality of diurnal and nocturnal continence of flatus and stool (liquid, solid) was assessed by a simple questionnaire.

Results

Fifteen patients (seven women, eight men), median age 46 years (range 32–58 years), were included in the present study. Twelve had a cryptoglandular fistula and three had Crohn’s disease-related anoperineal fistula. Three patients presented with anovular fistulas. There were no multiple fistulas. Six patients (40%) had undergone one to four previ-
ous operations for fistula repair. Two patients had undergone colostomy prior to implantation of the fistula plug, and all patients but one (93.3%) had a seton, which had been inserted an average of 5.4 ± 4.3 months before implantation of the plug.

The plug was expelled in three patients (20%) at post-
operative days 2, 5 and 7, respectively. A second plug was inserted in these three cases. One patient under-
went the second implantation the day after plug expulsion, and the fistula healed 2 months later. For the two other patients, who both had complicated Crohn’s disease, the second attempt was performed a few months later, and the new plugs were expelled on postoperative days 5 and 7, respectively. A third attempt was made in one of these patients, but this was again unsuccessful, with expulsion occurring on postoperative day 7. One patient (6.6%) developed an abscess that was noted on day 4 and treated by drainage. In this case, the fistula closed 2 months later.

Median follow-up duration was 8.1 ± 3.4 months. The fis-
tula tract was closed in six patients at 3 months and in eight patients at 7 months. Thus, the success rate was 40% at 3 months and 53.3% at 7 months. The time to healing was long in one patient with a recurrent anovular fistula that required a discharge colostomy after four failed repair attempts. On postoperative day 7, debris from the prosthesis was expelled when the patient attempted to lift an object. Despite this partial expulsion, the fistula tract healed after 7 months, which enabled the subsequent closure of the colostomy with no recurrence of the fistula at 20 months.

The fistula tract healed in one of the three patients (33%) with Crohn’s disease. The plug was expelled after both the first and second implantation attempts.

Six patients (40%) had undergone previous surgical proce-
dures for the treatment of their fistula (average number of procedures: 2.33; range: 1–4, seton excluded). An endorec-
tal advancement flap was unsuccessful in five of the six patients. A Martius flap was unsuccessfully attempted in one Crohn’s patient with an anovular fistula. However, the suc-
cess rate for the anal fistula plug was 55.5% (5/9 patients) and 66.7% (6/9 patients) after 3 and 7 months in those who had not undergone prior treatment (seton excluded) com-
pared with 16.7% (1/6 patients) and 33.3% (2/6 patients) of those who had. These differences were, however, not signiﬁcant.

None of the patients in our series complained of inconti-
nence disorders postoperatively.

Discussion

The ideal treatment for fistula-in-ano aims to achieve per-
manent eradication of the fistula tract without affecting continence. The fistula tract can be laid open only if it is
unique, interspinchteric or low transspinchteric involving less than the lower half of the external sphincter. How-
ever, such fistulotomy is not recommended for complex fistulas involving more than half the sphincter or for ante-
rior fistulas in women. For such cases, sphincter-sparing techniques, such as endorectal advancement flaps or sealing
the tract with fibrin glue, have been developed [8]. These techniques leave the anal sphincter intact and, thus,
have less impact on postoperative continence. Neverthe-
less, they are associated with higher rates of recurrence.

Sealing the fistula tract with fibrin glue has good success rates, in the order of 31% to 62%, with no risk of incon-
tinence [9], and the chances of success are even higher in patients who have not been previously treated. A suc-
cess rate of 54% was reported in a series comparing fibrin
plug plus endorectal advancement flap vs fibrin glue alone (33%) [10], rectal advancement flap technique spares the integrity of the sphincter as well [11]. Yet, continence disorders may still be seen postoperatively, particularly in patients who have been previously treated. Never-
theless, for many authors, the endorectal advancement flap remains the gold standard for complex fistula-in-ano,
with success rates ranging from 50% to 100% that were inversely correlated with the number of previous proce-
dures.

More recently, it has been proposed that the Surgisis®
bioabsorbable plug be used to seal the fistula tract, and
the preliminary results have been encouraging. The team
that described the technique in a comparative, but non-
randomized, study of cryptoglandular fistulas reported a healing rate of 87% vs 40% with glue [4]. The same team also
reported longer-term fistula healing in 83% of patients at a
median follow-up duration of 1 year [5]. These excellent
results—confirmed by Ellis [12], who reported 88% heal-
ing after a 6-month follow-up—have incited much interest
in the technique, which has already become popular in
North America. Reproducibility is, however, a problem, with
some authors finding healing rates at the other end of spec-
trum in the 20% range [6,7]. The present study achieved a
success rate of 40% at 3 months and 53% at 7 months, which
is in line with other series in which the healing rate was
about 40% [13,14].

Two randomized trials have compared advancement flaps
with Surgisis® plugs. In one, a single-center series included
31 patients [7]. After a median 6-month follow-up, 12 of the
15 patients in the Surgisis® group had a recurrence vs two
of the 16 patients in the flap group (P = 0.001). Thus, the
relative risk of recurrence was six times higher in the plug
group (RR = 6.4, 95% CI: 1.7–24). It must be noted, how-
ever, that the success rate with the Surgisis® plug was 20%
in this series, considerably lower than the rates found in
most of the other reports in the literature; likewise, the
87.5% success rate with the advancement flap was higher
than is usually reported. The other study was a multicen-
ter series from the Netherlands and included 60 patients
(oral communication, presented by van Loperen PJ, Bemel-
mam WA, Gerhards MF, Janssen LWM, van Tets WF, van Dalsen AD et al. at the 20th International Colorectal Disease Symposium, 12–14 February 2009, Fort Lauderdale, FL, USA).

Unlike the other study, here the results were disappointing for both techniques in both groups of patients. After a median 11 months of follow-up, the recurrence rate was 71% in the plug group vs 52% in the flap group. The difference was not significant ($P = 0.126$).

The disappointing results of some of the earlier published reports were generally attributed to a learning curve that, given the simplicity of the procedure, appears to be a weak argument. Christoforidis et al. [14] recently published the experience of a Minneapolis, MN, team involving 47 patients. After a median 6.5 months of follow-up, the success rate per procedure was 31%, with tract healing achieved in 43% of patients. Having a greater amount of external sphincter involvement was associated with failure. The authors also noted that failure was as common in the first half as in the second half of the series, despite several meetings to discuss procedural technique during the course of the study. This argument tends to go against any learning-curve effect. In our present series, no differences were found between the earlier and later patients.

In addition, our success rate was higher in patients who had not undergone any previous treatment other than seton insertion; in such patients, the success rate was 66.7% at 7 months. In contrast, only two of the seven patients (46.7%) who had undergone previous treatment achieved fistula healing after plug implantation. The difference, however, did not reach statistical significance. Indeed, other studies have shown that prior treatment is not a factor of failure [13,14].

Implantation of a second plug after failure of the first failed to lead to healing of the fistula tract, which is also in line with earlier, negative experience [13,15]. Also, given the cost of the prosthesis ($700), a second implantation is not advisable.

In our present series, only three patients had Crohn’s disease, and healing of the fistula tract was achieved in only one of them. In a series of 20 Crohn’s-related anorectal fistulas treated with a Surgisis® plug, O’Connor et al. [16] reported a success rate of 80%, and the rate was also better for simple fistulas than for complex or multiple fistulas.

Guidelines for plug implantation were established by a consensus workshop in 2007 [17]. As in our present study, high transsphincteric fistulas were considered the best indication for the procedure. Contraindications included rectovaginal fistulas, fistulas with persistent abscess or infection, inability to identify the internal and external orifices and, finally, allergic responses to products derived from porcine tissue. Evidence is lacking for the indication of resection for only 2 min, despite the manufacturer’s instructions calling for 5 min, the time used in our protocol and in most of the series reported in the literature. The shorter soaking time would avoid the early degradation of the prosthesis that would render it less solid for fixation and, thus, increase the risk of early expulsion, as was observed in three of our patients. Also, an acceptable success rate is considered to be around 50–60%.

**Conclusion**

Sealing a fistula-in-ano with a Surgisis® anal fistula plug is a simple procedure for the treatment of high transsphincteric and suprasphincteric fistulas with a long tract. Although success rates have been varied, this prosthesis can be recommended as a first-intention treatment, as it does not compromise any subsequent options. The main limitation is its high cost. Also, outcomes need to be further assessed in randomized trials with long-term follow-up.

**Conflict of interest statement**

None.

**References**


