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ORIGINAL ARTICLE

Results of the Gore Bio-A fistula plug implantation in the treatment of anal fistula: a multicentre study

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Abstract
Background The aim of this prospective study was to determine the efficiency of the Gore Bio-A synthetic plug in the treatment of anal fistulas.
Methods A synthetic bioabsorbable anal fistula plug was implanted in 60 patients. All fistulas were transsphincteric and cryptoglandular in origin.
Results The healing rate after 1 year of follow-up was 52 % (31 out of 60 patients). No patient was lost to follow-up. The treatment had no effect on the incontinence score. The plug dislodgement rate was 10 % (6 out of 60 patients). Thirty-four per cent of the patients (16 out of 47) required reoperation. The average operating time was 32 ± 10.2 min, and the average length of hospital stay was 3.3 ± 1.8 days.
Conclusions Synthetic plugs may be an alternative to bioprosthetic fistula plugs in the treatment of transsphincteric anal fistulas. This method might have better success rates than treatment with bioprosthetic fistula plugs.

Keywords Anal fistula · Anal fistula plug · Bioabsorbable plug

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Introduction

Anal fistula is a common disorder with an incidence of 8.6 per 100,000 patients/year [1]. In general, anal fistulas are divided into high (proximal) and low (distal) perianal fistulas. Fistulectomy is the treatment of choice for low fistulas and has a success rate above 90 % [2–4]. The optimal treatment algorithm for high fistulas, however, is still under debate. The more invasive procedures are more efficient but lead to higher incontinence rates. The most common surgical technique is mucosal advancement flap (MAF), with a success rate of 60–80 % [3, 5].

In 2004, the Cook Surgisis AFP (now Biodesign) anal fistula plug made of porcine intestinal submucosa was introduced for the treatment of high perianal fistulas. The success rate of the bioprosthetic AFP varies between 14 and 83 % [4, 6–15]. Dislodgement of the plug is reported to occur in 9–41 % of cases, and the abscess rate is 5–29 %.

In 2009, a new synthetic bioabsorbable plug (Gore Bio-A fistula plug) was developed by the W.L. Gore Corporation. It consists of 67 % polyglycolic acid (PGA) and

33 % trimethylene carbonate. The same material is used in sutures and meshes for several other different medical indications. The surgical experience with this kind of plug is currently limited, and no randomized trials are available. The design of this plug includes a head that is used to fixate the plug and prevent its dislodgement. Six arms are used to occlude the tract. These can be trimmed to an appropriate size and length (Fig. 1). Preliminary studies showed better dislodgement rates for the synthetic plug than those reported for plugs made from porcine submucosa.

The aim of our study was to determine the efficacy of the Gore Bio-A fistula plug in the treatment of transsphincteric anal fistulas. This is the first and largest prospective multicentre European study on this use of a synthetic bioabsorbable anal fistula plug.

Materials and methods

This trial was conducted as a prospective, multicentre, non-randomized, observational, open study in 11 centres in Germany, Austria and Switzerland.

In total, 60 synthetic bioabsorbable fistula plugs were implanted in patients with transsphincteric fistulas. Only patients with fistulas of cryptoglandular origin that were not appropriate for fistulectomy or fistulotomy were included.

Informed consent was obtained from all participants included in the study.

The plugs were supplied by Gore Corporation.

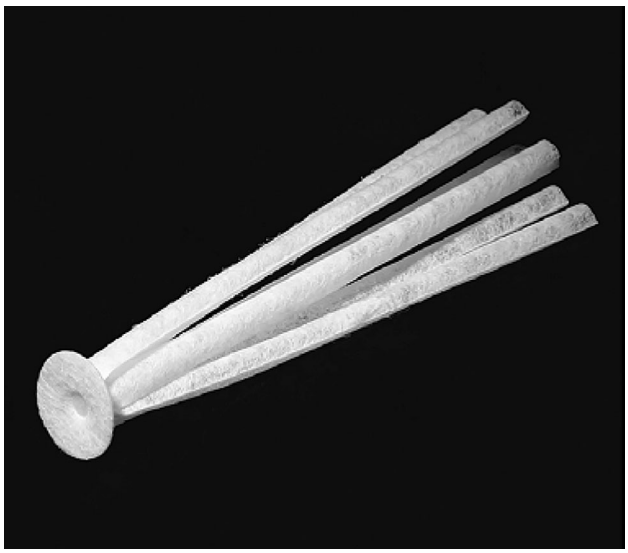

Fig. 1 Gore Bio-A fistula plug. Image of plug with fixating plate and six tubes. The fixating plate can be fixed in place using sutures. Polydioxanone or Vicryl sutures are usually used. Upon placement the tubes can be shortened or completely removed to adjust the length and width of the plug to the size of the fistula

The following exclusion criteria were used:

- Any type of fistula other than transsphincteric.
- Inflammatory bowel disease.
- Length of fistula shorter than 2 cm.
- Anovaginal, rectovaginal, rectourinary fistulas.
- Multiple-tract fistulas.
- Two or more previous operations for fistula healing.

Single-shot broad-spectrum antibiotics were administered at the start of the operation. After identifying and probing of the fistula, its whole length was flushed, brushed and/or curetted depending on the surgeon's preference. The synthetic bioabsorbable plug was implanted after excising the tissue (anoderm/mucosa) around the internal opening. Before insertion, the plug was trimmed in order to adjust its width to the size of the fistula. With the help of a suture or a grasper, the plug was pulled through the fistula from the inner to the outer opening under gentle traction. Afterwards, the fixating plate was sutured to the surrounding tissue and the underlying internal sphincter. In some cases, a proximal mucosal flap was raised and then pulled distally to cover the fixation plate. Finally, the distal ends of the plug were cut at the cutaneous level.

Postoperatively, oral analgesics (e.g. non-steroidal anti-inflammatory drugs) were administered on demand. Patients were advised to refrain from physical labour and sports for 4 weeks following the operation. No bowel regimen was recommended.

Follow-up visits in the outpatient department were planned 4 weeks, 3, 6 and 12 months after the operation with an optional endoanal ultrasound or magnetic resonance imaging at the last visit. During the visit, a clinical examination involving plug assessment was conducted.

The treatment was considered successful if complete healing of the anal fistula was achieved within 6 months after surgery (complete closure of the internal and external opening without any signs of inflammation and the cessation of any secretions). Persistent symptoms, or persistence or recurrence of the fistula after 6 months were considered a failure.

The primary endpoint of the study was the healing rate.

Secondary endpoints included the length of the surgical procedure, intra- and postoperative complications, plug dislodgement rates and the length of hospital stay. We also evaluated incontinence (Cleveland Clinic Incontinence score) postoperatively in some cases.

The clinical outcome was assessed by the operating surgeon.

The statistical analyses were performed using the Fisher, Chi-square and Mann–Whitney U tests.

Results

From October 2010 to February 2013, 60 patients in 11 colorectal centres in Germany, Austria and Switzerland underwent implantation of a synthetic bioabsorbable fistula plug. The number of patients at each centre was 1–15. Ten patients were operated on in 2010, 45 in 2011, 4 in 2012 and 1 in 2013. All patients fulfilled the inclusion and exclusion criteria. The patient demographics are presented in Table 1. Twenty-three patients were operated on for recurrent fistulas.

Most of the patients had had previous surgical treatment; 36 patients had had seton drainage, 7 patients had had partial fistulotomy, 13 had had MAF, and 2 had had a previous anal plug attempt.

The follow-up time was 12 months, and none of the patients was lost to follow-up or withdrew from the study (Table 2). Not all of the 60 patients included in the study attended the follow-up visit at 4 weeks, 3 or 6 months. However, the results for all 60 patients were documented 12 months after the operation.

The mean operating time was 32 ± 10.2 min. No intraoperative complications were observed in any of the patients. Postoperatively, 4 patients developed an abscess only one of which healed long-term. The abscesses were routinely drained and the rest of the plug removed in the clinical setting. In one patient, the plug dislodged within the first 4 weeks and was directly replaced by a new plug. This fistula healed uneventfully during follow-up. The length of hospital stay ranged from 0 to 6 days, averaging 3.3 ± 10.2 days.

Table 1 Patient demographics

Patient characteristics		%
Sex ratio (M:F)	48:12	
Age (years)	48.9 ± 12.5 (mean ± SD)	
Fistula		
Distal transsphincteric	9	15.00
Intermediate transsphincteric	19	31.67
Proximal transsphincteric	32	53.33
Smoking	46	76.67
Wexner Score preoperatively	2.4 ± 3.9 (mean ± SD)	
Previous treatment		out of 60
Partial fistulotomy	7	11.67
Seton	36	60.00
Plug	2	3.33
MAF	13	21.67
No treatment	10	16.67
Localization		
Dorsal (5–7 h in lithotomy position)	41	68.33
Ventral (11–12 h in lithotomy position)	9	15.00
Other	10	16.67
Recurrent fistula	23	38.33

MAF mucosal advancement flap, *SD* standard deviation

The healing rates and plug dislodgment rates are presented in Table 2.

Plug dislodgment was documented in 6 out of 60 patients (10 %) in the first 6 months after the operation.

The healing rate after 4 weeks was 6 % (3 out of 54 patients), and after 3 months it was 42 % (18 out of 46 patients). The healing rate after 6 months of follow-up did not change and stayed just above 50 %: Data were collected from 53 patients, and 27 of them showed complete healing of the fistula (51 %). Twelve months after the operation, 31 out of 60 patients showed complete healing (52 %) (Table 2).

After the procedure, 16 out of 47 patients (34 %) required reoperation due to recurrent fistula or postoperative complications. For 13 patients, there was no information on further treatment. This was not mandatory according to the study design. Within 6 months of primary plug placement, 9 out of 46 (20 %) of the patients needed a reoperation.

The Wexner score was only documented in 21 patients preoperatively and 6 months after the operation. There was no significant difference between the score pre- and postoperatively (Table 3). Difference within the groups with healed and non-healed anal fistulas was not significant p values, respectively ($p = 0.375$ and $p = 1.0$).

No data concerning continence were collected from the other 39 patients.

In 50 out of 60 patients, in addition to the plug, a mucosal flap was used to cover the fixating plate in a similar fashion to the MAF procedure. The healing rate in this group was 56 % (28 out of 50). The healing rate in patients without the mucosal flap was 30 % (3 out of 10). However, due to the small sample size the difference was not significant ($p = 0.1747$) (Table 4).

We found no evidence of a positive effect of set on drainage before the operation on the healing rate ($p = 0.83$). Twenty-four patients had no drainage, and in 12 of them (50 %) the fistula healed successfully. Various other factors that might have influenced the operative outcome were also analysed. Based on this analysis, the sample size was too small for conclusive recommendations and the results should be interpreted with caution. Only curetting of the fistula as well as trimming the fixating plate had a significant effect. On the other hand, the number of previous treatments, bowel regime and the number of stitches had no significant effect (Table 4).

Discussion

There are currently two fistula plugs available on the market: the bioprosthetic AFP from Cook Biodesign and the synthetic bioabsorbable AFP from Gore Corporation.

Table 2 Healing and dislodgement rates of Gore Bio-A fistula plug

	4 weeks	3 months	6 months	12 months
Number of patients	54	46	53	60
Healed	3 (6 %)	18 (42 %)	27 (51 %)	31 (52 %)
Plug dislodged	4 (6.7 %)	1 (1.7 %)	1 (1.7 %)	–

Table 3 Incontinence score before and 6 months after the operation

Wexner score	Number	Median	Min	Max	*p* value
Preoperative	21	2	0	20	0.5859
6 Months	21	0	0	12	

Table 4 Significance of effect of different factors on healing rate

Factors	*p* value
Anaesthesia	0.6545
Sex	0.7856
Fistula type	0.5285
Age	0.5427
Smoking	0.6396
Incontinence	1.0000
Wexner score preoperatively	0.5189
Number of previous operations	0.8455
Seton drain preoperatively	0.8329
Previous MAF	0.8590
Previous plug operation	1.0000
Localization	0.6908
Bowel preparation	0.2472
Curettage	0.0156
Downsizing of fixating plate	0.0392
Number of tubes	0.7077
Length of tubes	0.2841
Fixation of the plate	1.0000
Number of stitches	0.3937
Mucosal flap	0.1747
PDS stitches	0.3393
Vicryl stitches	0.8542
Length of the operation	0.7590

MAF mucosal advancement flap, *PDS* polydioxanone suture

The initial report on bioprosthetic AFP by O'Connor et al. [14] showed a success rate of 83 %. Further multicentre prospective trials reported healing rates ranging from 24 to 44 %. However, the latest randomized trials showed healing rates ranging from 20 to 28 %, and these were significantly lower than those of the flap procedures with which they were compared [15, 16].

A recent study by Fisher et al. [17] showed AFP to be as effective as MAF but more cost efficient.

Buchberg et al. [18] compared both of these plugs and showed a much higher healing rate for synthetic bioabsorbable AFP (54.5 vs. 12 %). It is worth mentioning though that this study had a small sample size (16 vs.11).

Our study included 60 patients and showed a healing rate of 52 % after 12 months of follow-up.

A recent prospective multicentre study on the synthetic bioabsorbable plug conducted by Stamos et al. [19] reported a healing rate of 41 % after 6 months of follow-up and 49 % after 12 months. Our data showed no further improvement in the healing rate after 6 months of follow-up (51 and 52 %).

No changes in the incontinence rate were observed. This result was to be expected, as during the operation, except for curettage, no other damage was done to the sphincter muscle. Moreover, the fistula was likely to be the cause of incontinence, so healing may have resolved some cases of incontinence. Stamos et al. [19], for example, showed a significant improvement in the Cleveland Clinic Incontinence score after operation.

The other major result of this study was the low plug dislodgement rate. Due to design improvements and precise placing of the fixation plate, dislodgement of the plug was observed in only 6 patients (10 %). The plate could be cut to precisely cover the inner opening and further trimmed to fit the fistula. Previous studies on the Gore Bio-A fistula plug showed dislodgement rates of 5–18 %. A summary of previous relevant publications is presented in Table 5.

Favreu-Weltzer and de la Portilla reported much lower success rates for the Gore Bio-A fistula plug [20–22]. One probable explanation is the careful preselection of patients undergoing the procedure. Furthermore, Ommer et al. reported differences in success rates between surgeons, ranging from 0 to 75 % [23]. Thus, a standardized technique in performing the operation might also play a role. Whether suturing of the fixating plate to the inner opening led to improvement in the healing rate is unclear. The fixating plate was not sutured in 3 of our patients, and the fistula healed in 2 of them.

The limitations of this study are its non-randomized design. All 60 patients had a clinical examination after 12 months. Not all patients were examined at 4 weeks and 3 and 6 months. Furthermore, not all patients were assessed for a continence score. The bowel regime was not uniform.

Based on the literature, the healing rates for synthetic bioabsorbable plugs seem to be slightly better than those for bioprosthetic plugs.

Table 5 Healing and dislodgment rates for the Gore Bio-A fistula plug in the literature

References	Number of patients	Follow-up	Healing rate (%)	Dislodgement rate (%)
Buchberg et al. [18]	11	61 days	54	18
Ratto et al. [21]	11	5 months	73	0
Favreau-Weltzer et al. [21]	9	–	11	11
de la Portilla [20]	19	12 months	16	–
Ommer et al. [23]	40	12 months	57.5	5
Stamos et al. [19]	93	12 months	49	8.6
Present study 2015	60	12 months	52	10%

Because current results regarding the use of anal plugs for the treatment of fistulas show only moderate success, there is a need for therapies with better success rates (e.g. ligation of the intersphincteric fistula tract, MAF, over-the-scope clip).

Conclusions

Anal fistula plug implantation is an alternative in the treatment of transsphincteric fistulas. Prospective randomized studies with a larger sample size comparing synthetic bioabsorbable plugs to bioprosthetic plugs are needed to determine their efficiency.

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Compliance with ethical standards

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

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all participants included in the study.

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