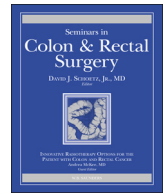




Contents lists available at ScienceDirect

## Seminars in Colon and Rectal Surgery

journal homepage: [www.elsevier.com/locate/yscrs](http://www.elsevier.com/locate/yscrs)

## Anal fistula plug: Where were we, where are we now?

Skandan Shanmugan, MD<sup>a,\*</sup>, Bradley J. Champagne, MD<sup>b</sup><sup>a</sup> Division of Colon and Rectal Surgery, Pennsylvania Hospital, Perelman School of Medicine, University of Pennsylvania, 800 Walnut St, 20th Floor, Philadelphia, PA 19107<sup>b</sup> Division of Colorectal Surgery, UH Case Medical Center, Cleveland, OH

## A B S T R A C T

The controversy associated with the treatment of complex fistula disease is rooted within the balance of the therapeutic index—highly efficacious techniques, such as fistulotomy, have unfavorably high rates in incontinence. Unfortunately, safer techniques, such as fibrin glue and anal fistula plugs sacrifice better cure rates for lower rates of post-operative incontinence. This article will discuss the use of the anal fistula plug (AFP) from its inception, evolution of technique, and its predictors of success, while summarizing the literature on the bioprosthetic anal fistula plugs in the management of anal fistulas.

© 2014 Elsevier Inc. All rights reserved.

The management of complex anal fistulas is a fine balance between eradicating the tract and preventing recurrence while preserving fecal incontinence. Traditionally, well-drained, low-lying simple inter-/trans-sphincteric fistulas are treated with simple fistulotomy.<sup>1</sup> Fistulotomy is the centuries-old “gold standard” that involves laying open the fistula tract in its entirety. Overall fistula recurrence following fistulotomy ranges from 0% to 21%, with high, although widely variable, rates of resultant incontinence (0–82%).<sup>2–4</sup> Complex fistulas require a different management approach. For example, high fistula tracts that incorporate a large portion of the internal (IAS) and external (EAS) anal sphincters are not amenable to traditional fistulotomy because of the significant risk of fecal incontinence. Additionally, women with anterior fistulas and patients with Crohn's disease are also at an increased risk for incontinence from a surgical fistulotomy.<sup>5,6</sup> Therefore, in the surgical era of “less is more,” a multitude of new sphincter-sparing techniques and synthetic biological materials have been introduced to treat anal fistula disease. While newer techniques like the LIFT procedure will be discussed elsewhere, this article will highlight the rise and fall of the anal fistula plug (AFP).

The AFP is an attractive option in the management of anal fistulas in patients where the risk of incontinence associated with fistulotomy is unacceptably high. While the high failure rates of fibrin glue injection has been attributed to the inability of the glue to remain in the tract,<sup>7–11</sup> the theoretical advantage of the AFP is that the plug is secured into the fistula tract, keeping the material

in place and allowing time for ingrowth. Furthermore, the insertion of an AFP may circumvent the risk of incontinence associated with fistulotomy, mucosal advancement flaps, and the LIFT procedures. However, in the spectrum of treating anal fistulas, the trade-off for minimizing incontinence is higher recurrence rates.

Currently, there are 2 commercially available fistula plugs. In 2005, the first biosynthetic plug was introduced by Cook Surgical (Bloomington, IN) for treatment of anorectal fistulas. The Cook Surgisis<sup>®</sup> AFP<sup>™</sup> plug is made from an extracellular matrix extracted from porcine small intestine submucosa, providing a scaffold for patient tissue incorporation. In 2006, Cook Surgical introduced the modified SIS Fistula Plug, made in a tapered configuration with a button to provide increased retention of the plug and improved blockage of the fistula (Fig. 1). In March 2009, W.L. Gore & Associates (Newark, DE) introduced the BIO-A<sup>®</sup> Fistula Plug that is comprised of a porous structure of synthetic bio-absorbable polyglycolic acid:trimethylene carbonate copolymer fiber (Fig. 2). The indications for use and performance of the GORE BIO-A<sup>®</sup> Fistula Plug are essentially equivalent to its predecessor, the Cook SIS Fistula Plug.

The technique for inserting an AFP is highly variable. Over the years, surgeons have taken liberties to modify the prescribed manufacturer's instructions to increase the overall success. Some reported modifications have actually been detrimental to the success of the AFP. For example, during the early introductory phase, surgeons occasionally sutured the plug to the external opening to prevent external migration. This actually led to increased rates of abscess at the secondary opening and an increased rate of “fall outs.”<sup>12</sup> The procedure is not technically demanding, yet several critical details are essential to optimize outcomes. Irrespective of the surgeon's modifications, the

\* Corresponding author.

E-mail address: [skandan.shanmugan@uphs.upenn.edu](mailto:skandan.shanmugan@uphs.upenn.edu) (S. Shanmugan).

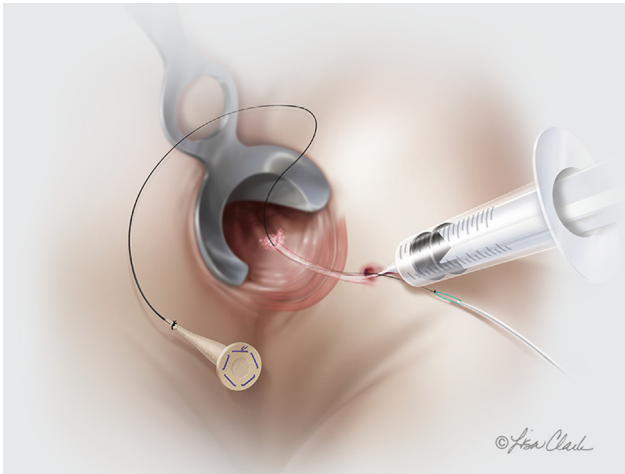


Fig. 1. SIS Fistula Plug, Cook Surgical.

following steps are consistently included: (1) the identification of the internal and external openings, (2) drawing the plug through the internal opening and through the tract until resistance is felt, (3) trimming away excess plug material flush to the anal mucosa of the internal opening, (4) suturing the internal end of the plug in place with resorbable suture, (5) creation of mucosal flaps and coverage of the internal opening, and (6) trimming of excess plug at the external opening flush with the skin and leaving the external tract open to facilitate drainage.

Initial reports of the anal fistula plug were favorable. Johnson et al.<sup>13</sup> prospectively enrolled 25 patients with high trans-sphincteric fistulas to either treatment with fibrin glue ( $n = 10$ ) or with the Cook Surgisis<sup>®</sup> AFP<sup>™</sup> ( $n = 15$ ). Following a short 3-month follow-up, failure rates were 60% in the fibrin glue group compared to only 13% in the AFP group. In a larger cohort study ( $n = 45$ ) with a longer median follow-up time of 12 months, a success rate of 83% with the Cook Surgisis<sup>®</sup> AFP<sup>™</sup> in patients with high cryptoglandular anorectal fistulas was reported.<sup>14</sup> Similarly, the early Saudi experience in 2007 after an 18-month follow-up reported an 86% success rate in their initial population of 22 patients.<sup>15</sup> In 2007, van Koperen et al.<sup>16</sup> reported on 17 patients with “difficult” high perianal fistulas, defined as those traversing the upper two-thirds of the external anal sphincter complex. In this complicated re-operative cohort, 41% (7 of 17) of fistulas were healed at a mean follow-up of 7 months (range: 3–9 months). Ellis<sup>17</sup> retrospectively reported their fistula plug experience ( $n = 19$ ) compared to a historical group receiving either mucosal or anodermal advancement flap ( $n = 95$ ). At a median follow-up of 10 months, fistula plug success rate was 88%, while the advancement flap success rate was 67.4% ( $p > 0.05$ ). By 2008, the early results for AFP appeared promising, yet the studies were

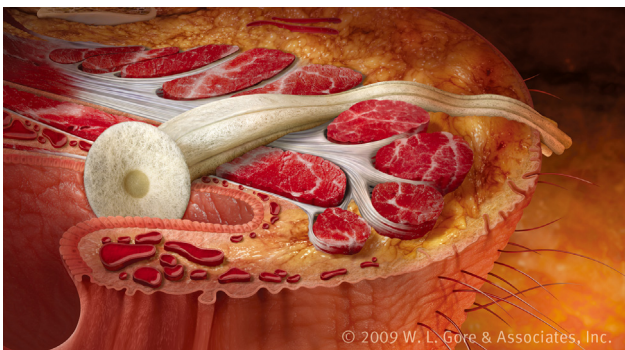


Fig. 2. BIO-A<sup>®</sup> Fistula Plug, W.L. Gore & Associates.

underpowered and also hindered by their retrospective nature, dissimilarity between groups, and short-term follow-up.

Despite the favorable initial reports, studies published after the early experiences in 2006 did not demonstrate the same success. Over the next several years, multiple studies were performed comparing the AFP to other treatment modalities and the early success was not substantiated. Christoforidis et al.<sup>18</sup> compared the Surgisis plug to the endorectal advancement flap and reported a 32% success rate in the plug group. In one of the few randomized control trials, Ortiz et al.<sup>19</sup> compared the Surgisis<sup>®</sup> AFP<sup>™</sup> to an endorectal anal flap (ERAF) in 32 patients with high anal fistulas. After 1-year follow-up, fistula recurrence was seen in 12 of 15 patients treated with an AFP vs. only 2 of 16 patients who underwent the flap procedure [relative risk (RR): 6.40; 95% confidence interval (CI): 1.70–23.97;  $p < 0.001$ ]. A large number of recurrences in the fistula plug group led to the premature closure of the trial. Additionally, van Koperen et al.<sup>16</sup> reported on a double-blinded, multicenter, randomized trial comparing AFP with mucosal advancement flap in 60 patients with high perianal fistulas. At 11-month follow-up, the authors reported fistula recurrence in 22 patients (71%) in the AFP group and 15 patients (52%) in the advancement flap group; due to the sample size, these rates were not significantly different ( $p = 0.126$ ), though they were certainly suggestive of the plug's inferiority. Adamina et al.<sup>20</sup> reported a success rate of 50% in 12 AFP with a median recurrence in 17 weeks, although the AFP was still more cost-effective than an advancement flap. Another retrospective review of 29 patients undergoing anal fistula plug repair showed a fistula closure rate of 34% compared to 62% in the control group who underwent transanal mucosal advancement flap repair ( $p = 0.045$ ).<sup>21</sup> Ultimately, by 2013, the reported success rates for AFP varied considerably from as high as 86% to as low as 20% (Table). In a comprehensive systematic review, O'Riordan et al.<sup>22</sup> used strict inclusion and exclusion criteria to obtain the most accurate estimate of the probability of success or failure for the AFP in a patient with a trans-sphincteric anal fistula. They reviewed 20 articles (530 patients) from 1999 to 2011 and found a success rate of 54.3%.

There are several reasons for the variability of the results quoted in the literature. First, the early reports with use of AFP were so encouraging that the inclusion criteria may have initially broadened to include all comers, thereby saturating the study population while decreasing its efficacy. Second, the follow-up periods documented in these studies are highly variable, but we

Table  
AFP studies and results.

Study	Follow-up, months (mean/median)	Success rate
Champagne et al. <sup>14</sup>	12	83% (38/46)
van Koperen et al. <sup>16</sup>	7	41% (7/17)
Echenique et al. <sup>28</sup>	10	60% (14/23)
El-Gazzaz et al. <sup>29</sup>	7.1	26.7% (8/30)
Garg et al. <sup>30</sup>	9.4	71% (15/21)
Starck et al. <sup>31</sup>	12	63% (26/41)
Lawes et al. <sup>32</sup>	7.4	24% (4/17)
Christoforidis et al. <sup>26</sup>	14	32% (12/37)
Chung et al. <sup>33</sup>	6	70% (19/27)
Wang et al. <sup>21</sup>	9	34% (10/29)
Ortiz et al. <sup>19</sup>	12	20% (3/15)
Schwandner et al. <sup>25</sup>	12	62% (37/60)
Zubaidi and Al-Obeed <sup>15</sup>	12	86% (19/22)
Anyadike et al. <sup>34</sup>	14.2	72% (26/36)
Adamina et al. <sup>20</sup>	7	50% (6/12)
McGee et al. <sup>23</sup>	24.5	44% (18/41)
Lupinacci et al. <sup>35</sup>	8	58% (7/12)
van Koperen et al. <sup>36</sup>	11	29% (9/31)

Download English Version:

<https://daneshyari.com/en/article/3319234>

Download Persian Version:

<https://daneshyari.com/article/3319234>

[Daneshyari.com](https://daneshyari.com)