

GORE® BIO-A® Fistula Plug for Treatment of Anal Fistulas

*W. John B. Hodgson, MD, MSURG, FACS, FRCS, FACG
Professor of Surgery,
Albert Einstein College of Medicine,
Bronx, New York*



Treatment of Anal Fistulas

In the past, anal fistulas were treated by laying open the fistula tract (fistulotomy), a method that may have been used at least as long ago as the classical Roman era. Most practitioners preferred to open the tract widely enough so that the anal end of the fistula healed first. However, the more the anal sphincter is involved in the fistula, the greater the chance that surgical treatment will cause fecal incontinence. Because of this risk, surgeons began to use a silk ligature (seton), which was passed through the sphincter with the idea that the presence of the device would promote healing. There are two types of setons. A cutting seton is tied tightly and replaced with another tied seton when it loosens as the body extrudes it (a “slow fistulotomy”). A loose seton is placed only to facilitate drainage, thereby helping to control infection.¹ Seton-only therapy for anal fistulas is still used in some cases, but healing may take months and the treatment is associated with considerable pain, scarring of the perianal tissues, and fecal incontinence rates of up to 67%.²

Another alternative for treating anal fistulas is creation of an anal mucosal flap. Various types of flaps have been used, including tongue flaps, lip flaps, and tubular or sleeve flaps. The goal of all flap treatments is to cover the internal fistulous opening, blocking passage of fecal material into the fistula so that the tract can heal. Initially, secondary necrosis of flaps, with consequent reopening of the fistula, was common. To prevent necrosis, some surgeons cut into the internal sphincter, hoping that this would help maintain blood supply to the flap. However, the more the sphincter muscle is used as a flap, the higher the risk of fecal incontinence. Although healing rates in patients treated with a mucosal flap may be as high as 70%,³ fecal incontinence rates have exceeded 25% in several series.⁴⁻⁷

Recently, various sphincter-sparing techniques for treating anal fistulas have been developed with the aim of avoiding fecal incontinence. The first was instillation of fibrin glue, which was initially made at operation by the surgeon from the patient’s own blood but is now available commercially. Fibrin-glue treatment preserves continence, and the early experience with this method indicated that it was effective in achieving healing. However, as the procedure gained wide acceptance, success rates began to decrease, especially in patients with complex fistulas. Although success rates ranging from 14% to 74% have been reported,⁸ the average is about 30% to 50%.^{3,9,10}

The next sphincter-sparing method introduced was implantation of a collagen anal fistula plug (Surgisis® [now called Biodesign®]; Cook Medical, Bloomington, IN), a device composed of lyophilized, decellularized porcine small-intestinal submucosa. We began to use this plug in 2007 and gained a good deal of experience with it. We found that it had certain faults, however, with the most important being a tendency to fall out, sometimes on the day of implantation or a few weeks later. Indeed, collagen-plug extrusion rates of about 20% or higher have been observed in a number of studies,^{7,11-13} including at least one randomized trial.¹⁴ In another randomized trial, the fistula recurrence rate after implantation of a collagen plug was 71%.¹⁵

In our practice, we inserted plastic buttons in an attempt to keep collagen plugs from falling out, but the buttons had several disadvantages: patients found them very uncomfortable, they did not always prevent

plug extrusion, and some had to be removed surgically. Our success with the collagen plug was disappointing. We were able to achieve an overall success rate of 66%, but this was only by persistence in the face of failure; that is, when a fistula recurred, we put in another plug and, in some cases, healing then occurred. Use of a rubber draining seton or removal of granulation tissue from the fistula tract before placement of a collagen plug did not improve our results.

The next sphincter-sparing innovation was the GORE® BIO-A® Fistula Plug, which was introduced into the US market in 2009. This plug is a completely synthetic prosthesis composed of polymers (polyglycolic acid/trimethylene carbonate [PGA/TMC]) that are gradually absorbed by the body. The PGA/TMC material has a three-dimensional matrix of open, interconnected pores that serves as a scaffold for tissue regeneration. The plug device consists of a disk to which three pairs of tubes or “legs” (a total of six) are attached. By removing one or more of the legs, the surgeon can tailor the plug to fit and fill a specific fistula, thereby possibly decreasing the likelihood of plug dislodgement and treatment failure. In a nonrandomized comparative study, the synthetic plug had a success rate that was more than four times higher than that of the collagen plug.¹⁶ We have been using the GORE® BIO-A® Fistula Plug for 2 years and here describe our implantation technique and initial results with the device.

Methods

All patients with clinical evidence of a fistula undergo an endoanal ultrasound evaluation using hydrogen peroxide to confirm the diagnosis and detect tracts not observable clinically. A draining seton is placed until drainage stops and perineal pain has become minimal; this may take a few weeks to several months. Patients are given cefazolin (500 mg) and metronidazole (500 mg) before plug placement.

Synthetic-plug implantation is performed with the patient under spinal anesthesia and in the prone jackknife position with the buttocks taped apart. A 2-0 silk ligature is tied to the seton, which is then removed. The ligature is pulled through the fistula as the seton emerges. A piece of wet gauze (4 x 4 cm) is unrolled and the ligature is tied to it. The gauze is then pulled back and forth through the tract to remove granulation tissue.

To treat single fistulas (Figures 1-4), we customarily use two legs of the synthetic plug (always from the same pair) and cut off the other four. Although hydration of the plug is not



Figure 1. The fistula tract is debrided of granulation tissue by pulling wet gauze back and forth within the tract.

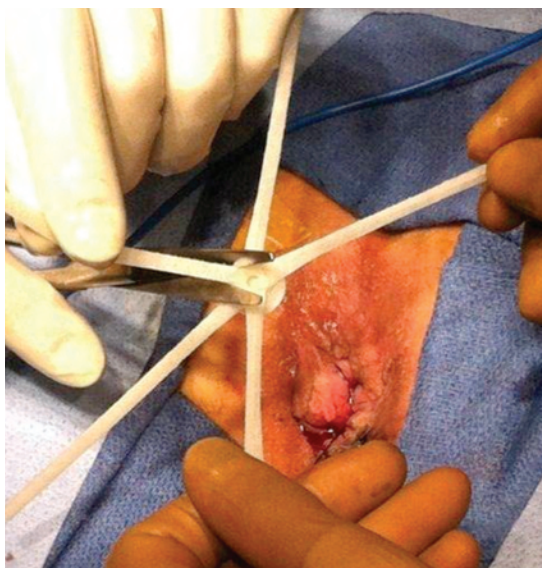


Figure 2. The fistula plug is tailored to conform to the fistula. Six “legs” (tubes) are available for filling the tract. Individual tubes can be removed to make the size of the device appropriate for the diameter of the tract.

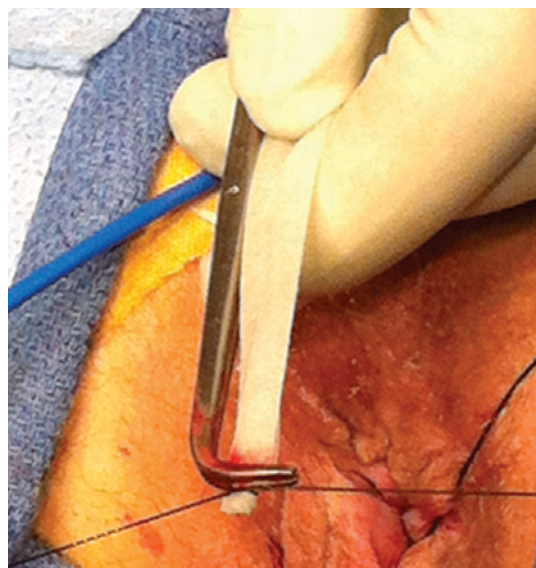


Figure 3. A suture tied to the end of the fistula plug is used to pull the entire device into the fistula tract.

required, soaking it in saline for a few minutes after removal from its packaging will facilitate insertion because the device slides better when wet. The legs to be used are tied together with the silk ligature already in the fistula, and the entire plug device is pushed into the anal canal. Gentle traction is then employed to pull the ligature from the external orifice so that the legs pass through the tract. The disk part of the device ends up flush against the internal fistulous opening.

Our plug-fixation technique involves burying the disk in a pocket created in the submucosa. The disk is pulled back from the fistula, and 1% lidocaine with epinephrine is pumped under the mucosa to create a space between the sphincter and mucosa to facilitate dissection. An incision slightly larger than the diameter of the disk is made, and a wide pocket is formed. The disk is slipped into the pocket, which is then closed by using 3-0 sutures placed at least 5 mm from the incision and with a 5-mm interval between them.

Patients are generally scheduled to return for follow-up clinical evaluations 1, 2, and 6 weeks postoperatively and monthly thereafter until the fistula has healed or additional intervention is necessary. For nonhealing fistulas, the tract is injected with 3% hydrogen peroxide at each visit, with a blunt plastic cannula (usually size 18) used to access the persistent tract. Whether healing has occurred is determined by examining the perianal skin for fistula closure. The presence of even a small amount of drainage indicates that the fistula has not healed.

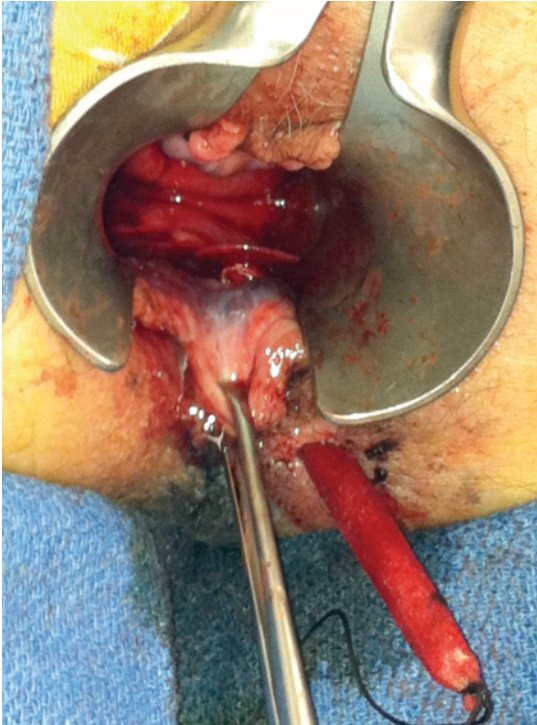


Figure 4. The fistula plug is pulled into the fistula tract from the internal to the external opening by using a suture attached to the end of the tubes. The device is fixed in place by burying the disk in a pocket created in the submucosa. Any tube segments protruding from the external opening are trimmed flush with the perianal skin.



Figure 5. A multitract fistula is treated by dividing tubes from a single GORE® BIO-A® Fistula Plug between the tracts and pulling the device into place with a silk ligature. The tubes are then trimmed flush with the perianal skin.

Results

We have placed a GORE® BIO-A® Fistula Plug in 25 patients with an overall success rate of 76.9% (32 anal fistula tracts): 19 men and 6 women (mean age, 46 years [range, 31-77 years]). Eighteen of these patients (23 fistula tracts) have been followed for at least 6 months. Twelve of the 18 patients had healing, yielding a 66.6% patient success rate. Most of the healed patients were free of pain within 3 weeks of treatment. The per-fistula success rate in the series was 43.5%, reflecting the fact that multiple fistulas are more difficult to manage than one fistula. So far, no fistula recurrence has developed in the eight patients with a follow-up duration of less than 6 months. No plug in the series has migrated or fallen out.

Some of the fistulas healed quite rapidly. For example, the patient shown in Figure 5 had bilateral fistula tracts and was treated with one plug (two pairs of legs). His pain resolved within a week, and both tracts healed within 2 weeks.

“Our results with the relatively simple technique of implanting a synthetic fistula plug have been promising.”

Discussion

Management of anal fistulas is multifactorial, but the most simple technique should be used initially because, if it works, complications associated with more complex procedures can be avoided. Unfortunately, many patients who are referred to us with unhealed fistulas have extensively incised perianal areas and hard subcutaneous scar tissue. Healing in the presence of scarring and fibrosis is always difficult to achieve, regardless of treatment method. Nevertheless, our results with the relatively simple technique of implanting a synthetic fistula plug have been promising.

There has recently been an increase in interest in using ligation of the intersphincteric fistula tract (LIFT) to treat anal fistulas. The LIFT procedure, however, is far more invasive than insertion of a fistula plug because it involves a deep dissection in the posterior anal space that extends at least 1.5 cm from the internal fistulous orifice on all sides. Posteriorly, this deep space leads to the rectum, which, theoretically, could be injured during the dissection. Moreover, in women, in whom the upper end of the vagina is immediately anterior to the anus, there is a risk of injury that could result in a high rectovaginal fistula.

Our aim has always been to keep surgical treatment of anal fistulas as minimally invasive as possible. We thus avoid use of the LIFT procedure and believe that success can be achieved with the following protocol: accurate pretreatment identification of the anatomical position and number of fistulas and fistula tracts by using endoanal ultrasonography or anal magnetic resonance imaging, keeping in mind that double tracts can be missed clinically, especially if they have the same entry and exit point; and implantation of a GORE® BIO-A® Fistula Plug, with care taken to place the disk portion of the device in a very large pocket. We think that completely covering the disk contributed to the dramatically accelerated healing and quick resolution of pain in our most recent cases.

References

1. Malik AI, Nelson RL. Surgical management of anal fistulae: a systematic review. *Colorectal Dis.* 2008;10(5):420-430.
2. Dudukgian H, Abcarian G. Why do we have so much trouble treating anal fistula? *World J Gastroenterol.* 2011;17(28):3292-3296.
3. de Parades V, Zeitoun J-D, Atienza P. Cryptoglandular anal fistula. *J Visc Surg.* 2010;147(4):e203-e215.
4. Roig JV, Jordán J, García-Armengol J, Esclapez P, Solana A. Changes in anorectal morphologic and functional parameters after fistula-in-ano surgery. *Dis Colon Rectum.* 2009;52(8):1462-1469.
5. van der Hagen SJ, Baeten CG, Soeters PB, van Gemert WG. Long-term outcome following mucosal advancement flap for high perianal fistulas and fistulotomy for low perianal fistulas: recurrent perianal fistulas: failure of treatment or recurrent patient disease? *Int J Colorectal Dis.* 2006;21(8):784-790.
6. van Koperen PJ, Wind J, Bemelman WA, Bakx R, Reitsma JB, Slors JF. Long-term functional outcome and risk factors for recurrence after surgical treatment for low and high perianal fistulas of cryptoglandular origin. *Dis Colon Rectum.* 2008;51(10):1475-1481.
7. Christoforidis D, Pieh MC, Madoff RD, Mellgren AF. Treatment of transsphincteric anal fistulas by endorectal advancement flap or collagen fistula plug: a comparative study. *Dis Colon Rectum.* 2009;52(1):18-22.
8. Deeba S, Aziz O, Sains PS, Darzi A. Fistula-in-ano: advances in treatment. *Am J Surg.* 2008;196(1):95-99.
9. Shawkí S, Wexner SD. Idiopathic fistula-in-ano. *World J Gastroenterol.* 2011;17(28):3277-3285.
10. Rizzo JA, Naig AL, Johnson EK. Anorectal abscess and fistula-in-ano: evidence-based management. *Surg Clin North Am.* 2010;90(1):45-68.
11. Garg P. To determine the efficacy of anal fistula plug in the treatment of high fistula-in-ano: an initial experience. *Colorectal Dis.* 2009;11(6):588-591.
12. El-Gazzaz G, Zutshi M, Hull T. A retrospective review of chronic anal fistulae treated by anal fistulae plug. *Colorectal Dis.* 2010;12(5):442-447.
13. Kleif H, Hagen K, Wille-Jørgensen P. Acceptable results using plug for the treatment of complex anal fistulas. *Dan Med Bull.* 2011;58(3):A4254.
14. Ortiz H, Marzo J, Ciga MA, Oteiza F, Armendáriz P, de Miguel M. Randomized clinical trial of anal fistula plug versus endorectal advancement flap for the treatment of high cryptoglandular fistula in ano. *Br J Surg.* 2009;96(6):608-612.
15. van Koperen PJ, Bemelman WA, Gerhards MF, Janssen LW, van Tets WF, van Dalsen AD, Slors JF. The anal fistula plug treatment compared with the mucosal advancement flap for cryptoglandular high transsphincteric perianal fistula: a double-blinded multicenter randomized trial. *Dis Colon Rectum.* 2011;54(4):387-393.
16. Buchberg B, Masoomi H, Choi J, Bergman H, Mills S, Stamos MJ. A tale of two (anal fistula) plugs: is there a difference in short-term outcomes? *Am Surg.* 2010;76(10):1150-1153.



W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific) 800.437.8181 (United States)
00800.6334.4673 (Europe) 928.779.2771 (United States)

goremedical.com

Products listed may not be available in all markets.
GORE®, BIO-A®, and designs are trademarks of W. L. Gore & Associates.
Biodesign® and Surgisis® are registered trademarks of Cook Medical.
© 2012 W. L. Gore & Associates, Inc. AR2422-EN1 FEBRUARY 2012