Advances in Anal Fistula Repair: Minimizing Risk for Incontinence

The pathophysiology of an anal fistula and the reason for a peak incidence in young to middle-aged adults remains controversial, but infection in cryptoglandular spaces of the anal canal is a frequently cited hypothesis for the initiating event. The theory is that an abscess formed by infection in glands surrounding the anal canal progresses into formation of the fistulae that connect the muscular wall of the sphincter to the perianal skin. Although it is believed that all fistulae originate as abscesses, only a proportion of abscesses progress to fistulae.

In the Parks Classification system, anal fistulae, defined by their position in relation to the anal sphincter, are described as trans sphincteric, intersphincteric, suprasphincteric, or extrasphincteric. The most common presentation is intersphincteric, followed by trans sphincteric. The remaining 2 types are relatively uncommon. The position of the anal fistula has critical importance to the choice of therapy. High trans sphincteric fistulae, which are defined by involvement of at least one-third of the external anal sphincter muscle as assessed by clinical examination or radiologic imaging, are regarded as the most challenging.

While fistulotomy is effective in 80% to 90% of primary fistulae, it poses a risk for complications and does not preclude recurrences. For high transphincteric or other complex fistulae, the risk that incontinence will follow fistulotomy is so great that most surgeons consider the procedure inappropriate. The range of reported continence disturbance after fistulotomy varies from 0 to 64%. A cutting seton may also be used to perform a staged fistulotomy; however, incontinence resulting from this approach can be significant (2% to 63%).

Alternative treatments have been pursued in high trans sphincteric fistulae or complex fistulae, such as those with multiple channels.

The design of the GORE® BIO-A™ Fistula Plug features bundled hollow tubes attached to a circular disk. The disk helps the plug stay in place, reducing the chance for extrusion of the plug. It also facilitates reproducible anchoring for dependable performance.

In patients with high trans sphincteric or complex fistulae, fistulotomy is less attractive because of a need for significant injury of the sphincter muscle that can lead to incontinence, making more conservative measures a reasonable choice for preserving options. Although success rates may be no greater with conservative measures, there are numerous advantages when healing is achieved, including less risk for morbidity, the potential for lower cost, and faster recovery.

The disadvantages of several conservative therapies include a high rate of failure. Some techniques, such as fibrin glue, that have produced fistula closure rates of less than 20% in some series are no longer widely used. Success with endorectal advancement flap has been variable: a review of the literature from 1978 to 2008 shows efficacy rates from 36.6% to 98.5%, with reported incontinence ranging from 0 to 35%. The LIFT procedure is promising but relatively new and has not been well studied outside of centers that pioneered the technique. As a result, the efficacy in trans sphincteric and complex fistulae, compared with other conservative techniques or fistulotomy, remains poorly defined.

Anal fistula plugs also have been associated with variable success rates, but there are differences between the 2 available devices. The first commercially available anal plug in the United States was developed from lyophilized porcine intestinal submucosa (COOK® BIODISIGN™ SURGISIS® Fistula Plug, Cook Medical Inc., Bloomington, IN), which was created into a conical shape for insertion to the fistula tract. Although this plug, which was licensed by the FDA in 2005, was superior to fibrin glue for closure of high trans sphincteric fistulae in a 25-patient, nonrandomized study, the limitations of fibrin glue made this efficacy difficult to interpret. Subsequent studies suggested that this device yields relatively low success rates in the complex and challenging fistulae for which it is most needed, falling as low as 13.9% in some series.

The newer of the 2 anal fistula plugs, licensed by the FDA in 2009 (GORE® BIO-A™ Fistula Plug, W. L. Gore & Associates, Inc., Flagstaff, AZ), is a 100% bioabsorbable, synthetic construction (polyglycolic acid:trimethylene carbonate) that employs a tube-like structure intended to provide a greater barrier to dislodgement (Figure 1). The scaffolding of the synthetic material allows cells to migrate into the matrix and tissue formation begins as the body gradually absorbs the material. As it is absorbed, the material is replaced with native tissue, predominantly type 1 collagen, in an approximately 1:3 ratio over time (Figure 2). In addition, the plug is engineered to conform to the tract and reduce the likelihood of plug dislodgement. Initial healing rates reported by 2 experts experienced with this device have been encouraging and suggest this is a useful tool when used selectively.

Michael J. Stamos, MD: Current Application of Anal Fistula Plugs

In the treatment of complex anal fistulae, therapy must always be individualized. Although the success rate with fistulotomy in uncomplicated fistulae may exceed 95%, neither surgery nor conservative measures achieve this type of success in fistulae that are complex (as defined by a high trans sphincteric location, prior treatment failure, or the presence of multiple tracts). Once complex fistulae are drained—typically with seton placement—and infection has been controlled, it is reasonable to provide patients with treatment options that may include advancement flap surgery, anal plug placement or, in some cases, the LIFT procedure (Figure 3). The advantage of the anal fistula plug is that it preserves all other treatment options. In particular, flap surgery remains viable in the event success is not achieved. Although flap surgery has the potential for definitive repair, the risk for incontinence is substantial in difficult cases. This encourages many patients to select a fistula plug, which has become an attractive option since the Gore device was...


a) The device is pulled into the tract until the disk lies flat and is well apposed to the anorectal mucosa.

b) The Gore® Bio-Advantage Fistula Plug can be securely seated at the internal opening by covering it or by suturing the disk to the anorectal mucosa and muscularis, as shown in this case.

introduced, as an initial procedure. The previous plug, the COOK BIODESIGN® SURGISIS® Fistula Plug was not effective in well-designed studies. In a prospective study of consecutive patients published 2 years after the plug was made available, the success rate was only 41%. Dislodgement has been a particularly common problem, and my success rates were sufficiently disappointing that I abandoned this procedure, said Dr. Stamos.

The design features of the Gore® Bio-Advantage Fistula Plug, particularly a structure that permits a tighter fit into the fistula, has revived the interest in the anorectal mucosa and muscularis, as shown in this case.

Patient selection and education are critical. Although the newer plug can be employed effectively to reduce the need for more invasive surgery and the risk for incontinence in many complex fistulae, surgeons need to prepare patients for potential unresolved fistula, as is known to occur with complex anal fistulae. When effective, the anal fistula plug is a relatively simple procedure with very low risk for complications and without eliminating other treatment options if success is not achieved, said Dr. McConnell.

Conclusion

Complex anal fistulae pose a significant clinical challenge because not all of the variables that influence treatment success are fully understood. Although surgery may offer one effective option, it is not without risks. In my experience success rates have been approximately 50%, which compares favorably to alternatives even though it is among the least invasive approaches, said Dr. Stamos.

Elizabeth McConnell, MD: Current Application of Anal Fistula Plugs

For complex fistulae, the anal fistula plug can be an effective treatment once the fistula has matured, usually following a period in which a drainage seton has permitted the fistula to stabilize. At this point, it becomes clearer which approach might be most suitable. In cases when minimal division of the sphincter is involved, fistulotomy is effective with an acceptable risk for incontinence. In patients with a complex fistula for whom a conservative approach may be more attractive to circumvent the risks associated with surgery, the fistula plug often is an attractive choice.

Due to a low rate of success, mainly resulting from dislodgement, Dr. McConnell discontinued use of the COOK BIODESIGN® SURGISIS® Fistula Plug after an initial patient series. However, based on changes in design and reports of improved outcomes with the Gore® Bio-Advantage Fistula Plug, she reintroduced this device into her treatment modality 18 months ago. Since that time, Dr. McConnell has treated a total of 20 fistulae in 12 patients, with a fistula placement success rate of 75% (15 of 20 fistulae) and a patient success rate of 67% (8 of 12 patients) for patients followed at least 12 months. These rates are equivalent to her experience with the LIFT procedure, but the fistula plug better preserves options. In the event of failure, in many cases, it is appropriate to make a second attempt with the fistula plug. Although a plug on second attempts has been lower, at approximately 50% (2 successful fistulae in 4 repeat attempts), this rate of success remains substantial for a relatively noninvasive approach to a challenging problem.

“In my experience with the fistula plug by Gore, patients are uncomfortable during the initial 3 days after the procedure, which may be the result of an inflammatory reaction, but patients warned of this phenomenon usually are tolerant, and the pain typically resolves completely after this period,” said Dr. McConnell. In successful treatment, healing may be achieved within 6 to 8 weeks, although longer healing may be required and failure should not be declared until at least 4 months of follow-up. Dietary counseling, particularly an emphasis on high-fiber diets, is an essential part of efforts to increase healing and prevent recurrence.

Not all patients with complex fistulae are candidates for anal fistula plugs even if they are not well suited for surgery. Dr. McConnell does not employ anal fistula plugs in women with anterior fistulae or in patients with diabetes with posterior fistulae, but her experience has provided much confidence for the use of the Gore® Bio-Advantage Fistula Plug in routine care when employed selectively. “When these are effective, they allow patients to undergo a relatively simple procedure with a very low risk for complications and without eliminating other treatment options if success is not achieved,” said Dr. McConnell.

References


Supported and approved by