Anal Fistula Repair Without Sphincterotomy: The Anal Fistula Plug

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Introduction

Sphincter-sparing options have been sought to treat complex anal fistula, which include transsphincteric, multi-tract and horseshoe, and anterior fistula in women. Non-surgical approaches in complex fistula are attractive options to patients because of the considerable risk for incontinence if the sphincter muscle is divided. In complex fistula, anal fistula plugs are a viable alternative to fistulotomy, advancement flap, and other surgical procedures. Currently, there are 2 commercially produced plugs available: the COOK® BIODESIGN™ SURGISIS® Fistula Plug (COOK®, Cook Medical, Inc.) and the GORE® BIO-A® Fistula Plug (GORE®, W.L. Gore & Associates, Inc.). The advantages of the GORE® BIO-A® Fistula Plug, namely its synthetic bioabsorbable material and customizable design, allow for sphincter-preserving repair and reduces the likelihood of the plug becoming dislodged.

Risk for Incontinence Proves Challenging

For surgical treatments of complex fistulas such as fistulotomy, the risk for incontinence is so great that many surgeons consider the procedure inappropriate. The range of reported continence disturbance after fistulotomy is from 0 to 64%. Success with the endorectal advancement flap procedure has been variable, and incontinence rates range from 0 to 35%. Because sphincter-sparing treatments minimize the risk for incontinence, some experts advocate these modalities as the preferred initial method in complex fistula surgery.

After initial promise in small series, many sphincter-sparing treatments have produced disappointing results in rigorous and controlled trials. For example, incremental tightening of cutting setons, although in use for centuries, has produced incontinence rates as high as 67%. The use of fibrin sealant or glue to close the fistula, often after placement of a draining seton, has resulted in rates of recurrence approaching 70%. Other strategies used in small series at single centers, such as a recent report of injection of collagen matrix, have not proven long-term benefits.

GORE® BIO-A® Fistula Plug: Material Matters

The first-generation COOK® BIODESIGN™ SURGISIS® Fistula Plug appeared to be a significant advancement when it originally became available, according to Herand Abcarian, MD, professor of surgery, University of Illinois at Chicago. Although very high rates of healing were initially reported, overall long-term results appeared to be only slightly greater than that achieved with fibrin sealants, which also had been disappointing after an initial report of high rates of success. Still, efforts were made to use the plug in certain cases. Alexander Herold, MD, professor of surgery, End- und Dickdarmzentrum Mannheim, Germany, noted that COOK® BIODESIGN™ SURGISIS® Fistula Plug was effective in a limited proportion of patients, but the rates of failure were sufficient that Prof. Herold abandoned this device after his initial experience.

GORE® BIO-A® Fistula Plug has several unique features. Introduced in 2009, this plug employs a synthetic, bioabsorbable scaffold of polyglycolic acid and trimethylene carbonate copolymer to facilitate tissue...
Fistula Plug can be employed in situations where pre-

- Consider Repeat Plug or Another Sphincter-Sparing Approach
- Follow Up to Verify Sustained Healing

- Non-Closure
- Fistula Closure

- Repeat Sphincter-Sparing Approach or Consider Surgery
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- Non-Closure
- Fistula Closure

**Figure 2. Treatment algorithm.**
Adapted from reference 6.

BIODESIGN™ SURGISIS® Fistula Plug,” noted Prof. Herold. “There are a number of features that predict substantial advantages for fistula closure. The special head of the GORE® BIO-A® Fistula Plug is more likely to occlude the inner fistula opening and reduce the number of plugs that become dislodged. The multiple arms of the plug increase the proportion of fistulas which can be adequately filled with the scaffolding material.”

Patients who feel that incontinence is too great a risk often choose the plug, especially with the decreased risk for recurrence. “At our center, we are seeing long-term closure without recurrence of approximately 60%, but the current initiative to collect data prospectively will provide more definitive information about relative efficacy,” said Prof. Herold.

One of the advantages of using a fistula plug, like other sphincter-sparing treatments, is that it is possible to consider a second placement if the first is unsuccessful, explained Prof. Herold. Although this might provide an unacceptable delay to resolution of the fistula for some patients, others may choose to repeat the plug procedure to avoid risk for incontinence. By 6 months, the GORE® BIO-A® Fistula Plug is completely absorbed. If the fistula still persists, placement of a second plug can be considered, especially if improvement of the fistula tract has been achieved (Figure 2). “We have to await the results of further trials, whether we may see overall success rates rise if we include patients who achieve closure with a second (salvage) attempt,” said Prof. Herold. He noted that many patients with a complex fistula opt to retry a sphincter-sparing technique when concerned about complications from a more aggressive approach.

**Clinical Evidence**

In a treatment study presented at the 2011 annual meeting of the European Society of Coloproctology, results were presented for 25 patients who were treated for an anal fistula using a GORE® BIO-A® Fistula Plug and followed for a median of 281 days. At that time, 11 (44%) patients had complete healing of the fistula tract, 10 (40%) had partial healing with the remaining fistula being more superficial and amenable to treatment with fistulotomy without a risk for incontinence, and 2 (8%) had a persistent transphincteric fistula. In the remaining 2 patients, 1 had early loss of the fistula plug and 1 had persistent postoperative pain that led to removal of the plug even though there was no evidence of infection. The authors concluded that the GORE® BIO-A® Fistula Plug is a viable treatment option. It has a low complication rate, and may be especially useful for patients with former anal fistula surgery.

In another study presented at the same scientific meeting, 37 patients with transphincteric fistulas were evaluated both preoperatively and postoperatively with a physical examination and transanal sonography for outcome of anal plug insertions. Except for a single patient with Crohn’s disease, the fistulas also were all of cryptoglandular origin. After fistula tracts were cleared of sepsis and curedt, the GORE® BIO-A® Fistula Plug was inserted through the internal opening and fixed by suturing the disk to the mucosa. The mean time for placement was 20 minutes. Of the 29 patients followed for more than 6 months, the healing rate was 71.4%. There were no postoperative complications and no change in the status of continence.
Case Study: Horseshoe or Multi-Tract Anal Fistula

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A 50-year-old college professor who was successfully treated with surgery for a noncomplex anal fistula returned with a new lesion on the opposite side that involved more than 50% of the anal sphincter muscle and was determined to have a horseshoe configuration with 2 interconnected channels. The fistula was drained and a seton was placed while awaiting resolution of the inflammation. Due to the substantial involvement of the sphincter, the patient wished to avoid surgery and attempt healing with sphincter-sparing therapy. When the lesion was fully drained and aseptic, 2 COOK® BIODESIGN™ SURGISIS® Fistula Plugs were placed in each of the channels. However, neither channel had closed once the plug had dissolved. After a second seton had been placed for draining and resolution of inflammation, the patient agreed to a second, similar insertion of fistula plugs but the outcome was jeopardized by dislodgement.

More than 1 year after presenting, the failure of the fistula to resolve was a substantial source of discomfort and diminished quality of life. Yet, the patient was unwilling to tolerate any risk for incontinence and continued to insist on a sphincter-sparing approach. The GORE® BIO-A® Fistula Plug, which had become available in the interval between the initial presentation and the failure of the second plug placement, was offered. The preparation for the GORE® BIO-A® Fistula Plug placement, including drainage and verification of clean channels, was similar to that of the COOK® BIODESIGN™ SURGISIS® Fistula Plug. With the GORE® BIO-A® Fistula Plug, only 1 device was needed where 3 of the 6 tubes were placed in the larger of the 2 channels, 2 placed in the smaller channel, and the final tube was cut off. The head of the plug was fixed with bioabsorbable sutures.

Results
In the acute healing period, the patient reported mild discomfort controlled with analgesics, but there was very little drainage, and all symptoms resolved within the first week. When re-examined 3 months after the procedure, the fistula appeared closed. There was no visible evidence of plug material. In follow-up, now out to 18 months, there has been no recurrence of symptoms, and the fistula appears to be resolved. The patient has had no change in bowel function and remains continent.

Comment
Due to the unpredictable nature of anal fistulas, it is impossible to determine whether the same result might have been achieved with the COOK® BIODESIGN™ SURGISIS® Fistula Plug, but the resolution of this lesion with the GORE® BIO-A® Fistula Plug is consistent with its design, which is better suited for a horseshoe configuration.

Healing Rates
Dr. Abcarian suggested that success rates of 50% or greater will compare favorably with current options. We need effective sphincter-sparing treatments for complex fistulas because of the risk for incontinence associated with surgery. Due to the unpredictable nature of anal fistula, there may be no perfect treatment, but it may be possible to repeat a sphincter-sparing approach after an initial failure before resorting to radical surgery, Dr. Abcarian reported. Although encouraged by his initial success with the GORE® BIO-A® Fistula Plug, Dr. Abcarian reported that long-term efficacy data provided by multiple participating centers, which is now being collected, is needed.

Given the highly unpredictable course of anal fistulas, which can recur years after a successful procedure according to Prof. Herold, the precise efficacy of the GORE® BIO-A® Fistula Plug requires longer follow-up, but Prof. Herold is encouraged by the initial rates of success and suggested that there is an urgent need for better sphincter-sparing approaches not only for their role in reducing risk for incontinence, but for their ability to reduce recovery time.

Acceptable healing rates combined with a minimized risk for incontinence make sphincter-sparing treatments attractive. When faced with a measurable risk for lifetime incontinence, many patients are likely to opt for several attempts to resolve the fistula without sphincterotomy before moving to a more aggressive surgical procedure.

Continued improvements in the success of sphincter-sparing therapy likely are to be viewed as a substantial advance by both patients and physicians.

Treating complex anal fistulas is a challenging problem due to variability in the healing rates and high risk for incontinence with traditional surgical techniques. Sphincter-sparing treatments are desirable for their minimized risk for incontinence, but several have been unable to produce healing rates that are acceptable to the surgical community. The design features of the GORE® BIO-A® Fistula Plug are engineered to overcome limitations of previous techniques, resulting in a sphincter-sparing treatment that continues to yield reports of successful applications and encouraging rates of healing.

References


