EDITORIAL

The Surgisis® AFP™ anal fistula plug: a new and reasonable alternative for the treatment of anal fistula

Le « plug »: une nouvelle alternative raisonnable dans le traitement des fistules anales

Introduction

Because of the morbidity associated with the performance of anal fistulotomy, especially that of impairment for bowel control, less invasive options have been advocated in recent years. Small intestinal submucosa has been found to gradually remodel into new tissue by the host without an immunologic reaction [1,2]. This biomaterial has since been developed into several medical products, one of which is the Surgisis® AFP™ fistula plug [3–16]. The material is of conical shape and has a biological configuration suitable for the treatment of fistula disease. When the plug is implanted, there is invasion of host tissue cells and blood vessels into it. The small intestinal submucosa essentially provides a scaffold to allow infiltration of the patient’s connective tissue. The material is supplied in a sterile, peel-open package and is intended for one-time use only.

The procedure is minimally invasive, does not affect the anal sphincter mechanism, and thus avoids the complication of incontinence. However, success rates with the AFP™ plug have been essentially anecdotal, and in the absence of a prospective, randomized, controlled clinical trial, there has been a need for the development of a consensus statement. In May 2007, surgeons experienced with this procedure convened to develop a consensus paper on the proper technique, patient selection criteria, and pre- and postoperative management in order to achieve the highest possible success rate with the AFP™ plug procedure [17]. The following is a synopsis of that meeting.

Patient selection

Indications

Primary indications include transsphincteric fistula, anovaginal fistula, intersphincteric and extrasphincteric fistula. However, a trans-sphincteric fistula is considered to be the ideal indication for use of the plug. With respect to anovaginal fistula, the shorter the tract, the less likely the plug implantation procedure will be successful. However, it is still felt to be a reasonable alternative to at least attempt. If conventional fistulotomy for intersphincteric fistula poses a significant risk of incontinence, the plug may still be considered. This includes patients with inflammatory bowel disease and those with prior radiation therapy.

Treatment of Crohn’s-related fistulas represent a challenge. Uncomplicated fistulas represent a minority of Crohn’s fistulas, and can often be safely treated with conventional fistulotomy. Advancement flaps for more complex fistulas are associated with a high failure rate and a prolonged healing time. While seton placement is a safe option for maintaining drainage and avoiding persistent infection, no cure can be effected without division. Recent reports have indicated an excellent fistula closure rate (up to 80%) with Crohn’s-related fistulas managed with the plug [18,19]. Extrasphincteric fistula is considered an uncommon indication for fistula surgery but is regarded as an indication for the
use of the plug. However, suturing the plug to the internal opening is considered to be potentially difficult.

Contraindications

With conventional, uncomplicated intersphincteric fistula, standard fistulotomy is virtually 100% successful with minimal morbidity. The cost/failure rate with the use of the plug cannot, therefore, be justified for this indication. In addition, the following conditions are felt to be inappropriate because of the extremely low probability of success:

- pouch-vaginal fistula;
- recto-vaginal fistula (because of the short tract length);
- fistula with a persistent abscess cavity;
- fistula with any suggestion of infection. Examples included those with associated anorectal abscess formation, persistent cavity, and anal fistula with induration or purulent drainage;
- allergy to porcine products;
- inability of the surgeon to identify both the internal and external openings. This is an absolute contraindication for doing the procedure.

Preoperative preparation

Bowel preparation and/or rectal enemas are left to the surgeon’s discretion. No data exists on this topic to make any recommendation. A single dose of systemic antibiotics is recommended before the procedure.

Intraoperative management

Anesthetic

The anesthesia can be conducted as per the surgeon’s preference in consultation with the patient and the anesthesiologist.

Positioning of the patient

The positioning is to be determined by the surgeon. It is, however, important that the internal opening be well visualized in order to facilitate the correct placement of the suture.

Surgical technique

If inflammation, purulence or excessive drainage is encountered, a temporary seton should be placed for the time required to clear the inflammatory process—usually from 6 to 12 weeks. If no inflammation is encountered and the decision is made to proceed with the plug operation, immersion of the AFP™ plug in sterile saline for 2 minutes will soften it. Excessive immersion for a longer period of time risks fragmentation. Conversely, a nonhydrated plug will be extremely painful when implanted.

Identifying the internal and external openings is an essential step. Once this has been accomplished, irrigation of the fistula tract with peroxide or saline should be performed. Gentle probing of the fistula to confirm the track should also be done. Debridement, curettage or brushing is not advised, since this may lead to a larger tract and risk expulsion of the plug.

The internal opening may have an epithelial recess or dimpling that may require limited mobilization, with debridement of the mucosal edges, to permit suture placement. A suture or ligature is placed at the narrow end of the plug and then pulled from the internal opening to the external opening until the plug is snug. Excess plug should be trimmed from the internal opening. A 2-0 long-term, braided, absorbable suture is then placed to anchor the larger end, making certain that it incorporates the underlying internal sphincter. The excess external plug is then excised flush with the skin without being sutured to it. The external opening may be somewhat widened to enhance drainage.

Postoperative care

There is no meaningful data for one to dictate a postoperative care regimen. No restriction in diet is recommended. It seems reasonable, however, to refrain from strenuous activity, sexual activity, and heavy lifting for 2 weeks, in order to avoid dislodgment of the plug. Constipation and diarrhea should be prevented or treated. The area should be kept clean with showering and gentle cleansing. Most important, during the follow-up visits the tract should not be probed.

Outcome

Defining failure

Plug extrusion is most likely due to a technical error and can occur in from 10 to 41% of patients [19—22]. This occurs primarily because of the tract being too wide, the plug being pulled too tightly, or to inadequate fixation. Persistent drainage with non-healing has been reported as 15% in one series [14]. There have been two reports of abscess formation requiring drainage in 11 and 23% of cases, respectively [23,24]. Importantly, a 3-month interval should be taken before assuming failure. Late failure can be encountered after the fistula has healed, however. Therefore a follow-up of up to 1 year is reasonable if one is to assess success [20,23].

Conclusions

Closure of anal fistula using the Surgisis® anal fistula plug is safe with a reasonable success rate of 50—60% in the hands of trained and experienced surgeons. The anal fistula plug is beneficial only for certain types of anal fistula, namely transphincteric, anovaginal, extrasphincteric fistulas, and some intersphincteric fistulas, Crohn’s fistulas. Adequate preoperative preparation and good postoperative care contribute to low failure rate. Careful patient selection, prevention of infection and proper surgical technique are critical to achieving success.
The use of suturable biologic anal fistula plug is an effective method of treating anorectal fistulas and has been shown to be more reliable than fibrin glue [16]. Although current evidence suggests that there are no major safety concerns associated with the closure of anal fistula using a suturable bioprosthetic plug, long-term studies are warranted to further validate the safety and efficacy of the procedure.

References


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