

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

A. Heydari, MD, G. M. Attinà, MD, E. Merolla, MD, M. Piccoli, MD, G. Melotti, MD FACS

Department of General Surgery, Sant' Agostino-Estense General Hospital (NOCSAE), Modena, Italy

OBJECTIVES AND STUDY

The management of anal fistula continues to present a challenge to the colorectal surgeon and is a balance between eradicating the fistula and maintaining anal continence. Traditional surgical techniques such as fistulotomy and seton technique, sever the internal anal sphincters and may damage the external sphincter. The use of a seton has a recurrence rate of ~8% and minor and major incontinence is 34-64% and 2%-26% respectively. An alternative approach is the application of a fistula plug.

The GORE® BIO-A® Fistula Plug is a bioabsorbable device which provides a scaffold for soft tissue repair and facilitates closure of the anal fistula. A single plug configuration can be adapted to different shapes and sizes of fistula. This plug is a porous fibrous structure composed solely of synthetic bioabsorbable poly(glycolide-trimethylene-carbonate) copolymer. The copolymer has been found to be both biocompatible, nonantigenic, able to facilitate tissue generation and healing throughout a combination of hydrolytic and enzymatic pathways. The plug's fibers form a non-woven scaffold with highly interconnected pores. Cells migrate into the scaffold and the tissue is generated as the body gradually absorbs the material, leaving no permanent material in the body, without dividing the sphincter muscles, thereby reducing the risk of incontinence. This study was designed to analyze the efficacy of the GORE® BIO-A® Fistula Plug for the management of trans-sphincteric anal fistulas.

METHODS

We examined the outcome of 37 patients with trans-sphincteric fistulas who underwent a total of 39 anal plug insertions (2 patients had a second plug inserted for not healing) from November 2009 to May 2011. 34 of the 37 fistulas were of criptoglandular origin, and 1 was because of Crohn's disease. All patients were evaluated preoperatively and postoperatively with a physical examination and transanal sonography. Plugs were only inserted into "clean" fistula tracts with no sign of ongoing sepsis. The tract was curetted. The plug was inserted through the internal opening to reach the external opening. The internal opening was fixed and secured to mucosa with a 2/0 VICRYL® or PDS suture.

RESULTS

Thirty-seven patients (25 men and 12 women) with mean age 48 (range 23-76) years underwent plug insertion. All operations were performed in day surgery; all under spinal anesthesia except 3 cases performed under general anesthesia. The mean operative time was 20 min (range 18-32). The mean follow up was 6 months. Patients were divided in two groups: one with a follow up less than or equal to 6 months (8) and the other with a follow up more than 6 months (29). The healing rate was 71,4% in second group (20/28). There was no change of the continence status in any patients, no major postoperative complications.

CONCLUSIONS

This method, in contrast to traditional techniques as fistulectomy, is a good surgical option: it respects the integrity of the sphincter reducing the risk of incontinence and shows a good performance and effectiveness with less postoperative pain and shortened healing.



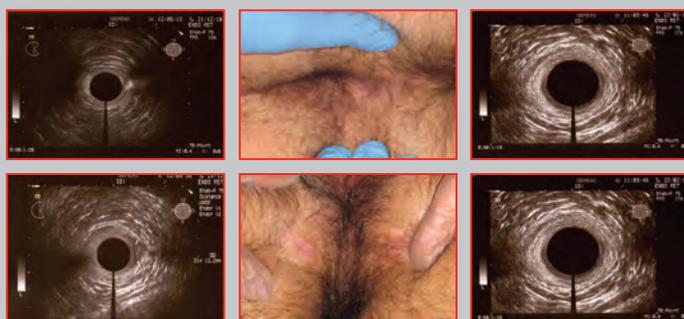
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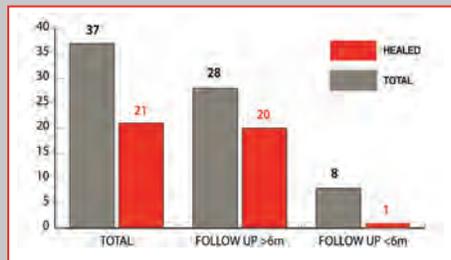
PLUG ACTION



RESULTS



CASES



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