

# Prospective Multicenter Study of a Synthetic Bioabsorbable Anal Fistula Plug to Treat Cryptoglandular Transsphincteric Anal Fistulas

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# Disclosures

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## ***BACKGROUND:***

Although interest in sphincter-sparing treatments for anal fistulas is increasing, few large prospective studies of these approaches have been conducted

## ***OBJECTIVE:***

To assess outcomes after implantation of a synthetic bioabsorbable anal fistula plug

## ***DESIGN:***

A prospective, multicenter investigation was performed

## ***SETTING:***

The study was conducted at 11 centers

# Investigators

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## ***PATIENTS:***

Ninety-three patients (71 men; mean age, 47 years) with complex cryptoglandular transsphincteric anal fistulas were enrolled.

## ***INTERVENTION:***

***Draining*** setons were used at the surgeon's discretion. Patients had follow-up evaluations at 1, 3, 6, and 12 months postoperatively

## ***MAIN OUTCOME MEASURES:***

The primary endpoint was healing of the fistula, defined as drainage cessation and closure of the external opening, at 6 and 12 months. Secondary endpoints were fecal continence **preoperatively and at 6 months (Wexner score)**, duration of drainage from the fistula, pain, and adverse events during follow-up

# METHODS

## *PATIENTS*

- Approved by the institutional review board at each of the 11 centers
- All enrolled patients provided written informed consent
- Patients presenting with a single-tract, transsphincteric anal fistula of probable cryptoglandular origin between March 2011 and September 2013 were considered for enrollment in the study
- Exclusion criteria included the presence of Crohn's disease, an active local infection, a wound-healing or autoimmune disorder, a current condition or treatment producing immunocompromise or immunosuppression, a history of more than 2 previous failed fistula repairs, a superficial fistula, and a history of pelvic radiation therapy

# METHODS

- Fistula tract was debrided
- At plug insertion, as many tubes as necessary were cut off, although an effort was made to retain the maximum number possible to ensure that the fistula tract was snugly filled. The disk portion of the device was not trimmed.
- The disk was sutured to the anorectal wall using at least 3 sutures (1 placed cranially and 1 placed on each side). Disks were neither covered with tissue nor buried in a tissue pocket. The ends of the retained tubes were trimmed flush with the skin. No sutures were placed in the external opening, which was left sufficiently open to allow drainage
- Follow-up visits were scheduled for 1, 3, 6, and 12 months

# Anal Fistula Plug and Surgical Technique

- The fistula plug used in the study consists of a PGA:TMC disk to which six tubes are attached. At the time of insertion, the surgeon can tailor the plug to fit and fill the specific fistula tract by removing one or more of the tubes.
- The material constituting the plug has a 3-dimensional matrix of interconnected pores designed to serve as a scaffold for tissue generation and healing.
- After implantation, PGA:TMC undergoes hydrolytic and enzymatic degradation. Studies in several species indicated that the bioabsorption process is complete within 6 or 7 months <sup>1</sup>



# Demographics & Operative Characteristics

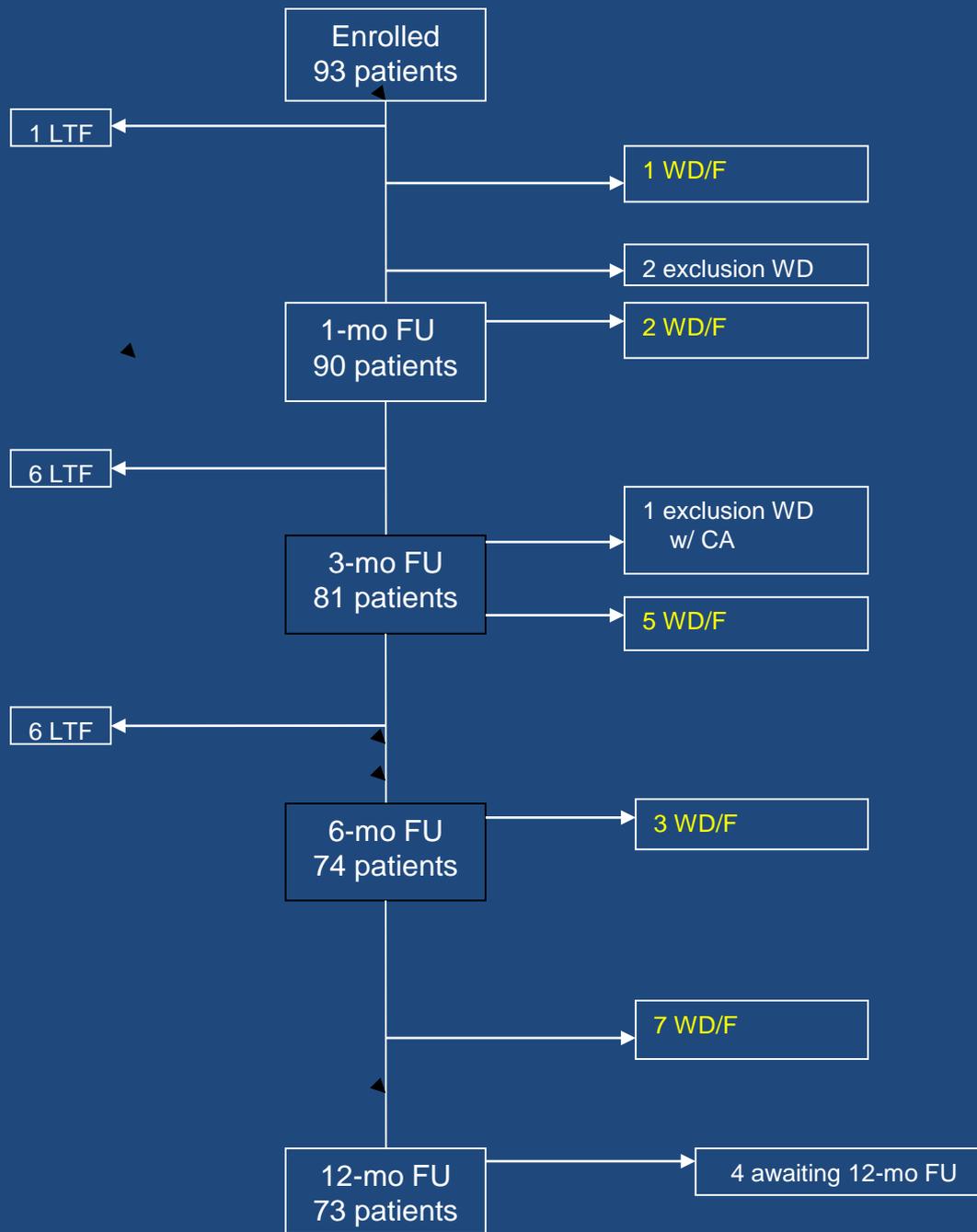
Characteristic	Value <sup>a</sup>
Mean age, y (range)	47 (19-82)
Sex: male/female	71(76)/22(24)
Mean BMI, kg/m <sup>2</sup> (range)	29.4 (18.6-48.4)
Recurrent fistula	26 (27.9)
Previous fistula treatment	
Fistulotomy	7 (7.5)
Advancement flap	5 (5.4)
Cutting seton	4 (4.3)
Fistula plug	4 (4.3)
LIFT procedure	2 (2.2)
Fistulectomy	1 (1)
Fibrin glue	1 (1)
Unknown	2 (2.2)



# Demographics & Operative Characteristics

Characteristic	Value <sup>a</sup>
Seton therapy before plug implantation	73 (78.4)
Mean duration of seton therapy, wk (range)	15 (3-50)
Fistula location: high/low <sup>b</sup>	34 (37)/58 (62)
Mean fistula tract length, cm (range)	4.2 (1.5-8)
Number of fistula plug tubes implanted	
1	5 (5)
2	20 (22)
3	21 (23)
4	27 (29)
5	4 (4)
6	16 (17)





# RESULTS

- Thirteen patients were lost to follow-up. Their data is included in the analysis up until the time they were lost to follow-up. 21 were withdrawn, 18 of whom opted to undergo an alternative treatment. Those 18 patients are recorded as a failed fistula repair in the analysis.
- The fistula healing rates at 6 and 12 months were **41%** (95% confidence interval [CI], 30%-52%; total n = 66) and **49%** (95% CI, 38%-61%; total n = 55), respectively; **9 patients healed between the 6 and 12 month follow up visits.**
- Half the patients in whom a previous treatment failed had healing.

# RESULTS

- By 6 months, the mean Wexner score had improved significantly ( $p = 0.0003$ ). Pre -op mean score – 5.3; 6 month mean score – 2.6.
- Adverse events included 11 infections/abscesses, 2 new fistulas, and 8 total and 5 partial plug extrusions. The fistula healed in 3 patients with a partial extrusion.

# RESULTS

- Analysis of factors possibly related to fistula healing found that recurrent fistula compared with first fistula, sex, BMI, number of plug tubes implanted, and fistula tract length were not significantly associated with healing.
- Patients in whom a draining seton was not used before plug implantation had a significantly higher healing rate (73% [11 of 15 patients] vs. 43% [24 of 56 patients];  $p = 0.045$ ).
- Fistula healing rate was also significantly higher in patients with a high transsphincteric fistula compared with those who had a low transsphincteric fistula (66% [19 of 29 patients] vs. 38% [16 of 42 patients];  $p = 0.03$ ).

# CONCLUSIONS

- Our findings indicate that implantation of the synthetic bioabsorbable fistula plug is a reasonably efficacious treatment for complex transsphincteric anal fistulas, especially given the simplicity and low morbidity of the procedure. The importance of long-term follow-up (and patience) in patients treated with the plug is indicated by the occurrence of healing more than 6 months after plug implantation in about 10% of patients originally enrolled in the study (20% of those who healed).
- Our data should help surgeons obtain fully informed consent from patients considered good candidates for treatment with the synthetic plug.

