



## 2 Trans-vaginal repair of recurrent rectovaginal fistula with interposition 3 of BIO-A Tissue Reinforcement

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### 7 Abstract

8 Rectovaginal fistulas (RVFs) represent the majority of all symptomatic leakages after anterior and low anterior resection in  
9 women. Conservative management is useful in paucisymptomatic patients with small fistulas but is usually unsuccessful in  
10 all other cases. The surgical strategies are various and heavily dependent on the type and extent of anatomic involvement. We  
11 present a case of a 51-year-old female with a multi-recurrent rectovaginal fistula that occurred since a laparoscopic sigmoidec-  
12 tomy was performed for a complicated diverticular disease in May 2015. An attempt to close the fistula was undertaken three  
13 times. In July 2019, a transvaginal repair was performed with interposition in the rectovaginal septum of GORE<sup>®</sup> BIO-A<sup>®</sup>  
14 Tissue Reinforcement. The postoperative course was uneventful. There was no recurrence and functional outcome was good  
15 at 24-months follow-up. Rectovaginal fistula can be successfully treated using the interposition of a GORE<sup>®</sup> BIO-A<sup>®</sup> Tissue  
16 Reinforcement with significant economic savings and good functional outcomes even through a transvaginal approach. It  
17 represents a therapeutic option for an otherwise difficult-to-treat complex fistula.

18 **Keywords** Rectovaginal fistula · Transvaginal repair · Biosynthetic reinforcement

### 19 Introduction

20 Rectovaginal fistula (RVF) is an abnormal passage between  
21 the anterior wall of the rectum and the posterior wall of the  
22 vagina. The common causes of acquired colorectal-vaginal  
23 fistula are obstetric injury, pelvic irradiation, pelvic malign-  
24 nancies, diverticular disease, inflammatory bowel disease  
25 and iatrogenic conditions [1]. Among the latter there are  
26 colorectal resection, ileal pouch–anal anastomosis, proce-  
27 dures involving the posterior vaginal wall, perineum, anus  
28 or rectum. RVFs cause significant and distressing symptoms  
29 including passage of faeces or flatus from the vagina, recur-  
30 rent urinary tract infections, vaginitis, vaginal bleeding and  
31 vaginal discharge. Currently, the preferable modalities of  
32 choice for pelvic fistula evaluation are magnetic resonance

(MRI) and multidetector computed tomography (CT) for  
patients unable to get an MRI [2].

Various surgical strategies have been described to repair  
RVFs and their associated anatomical defects.

We illustrate the technique of transvaginal repair with  
GORE<sup>®</sup> BIO-A<sup>®</sup> Tissue Reinforcement (W. L. Gore &  
Associates, Inc. Newark, DE, USA) interposition in a case  
of multi-recurrent RVF in a 51-year-old woman who first  
underwent laparoscopic sigmoidectomy for stenosing diver-  
ticulitis and then, from June 2015 to November 2018, was  
unsuccessfully treated by two further colorectal resections  
and one transvaginal repair with diverting ileostomy. At  
first a Hartmann's procedure was performed but a few days  
after laparoscopic Hartmann's reversal the RVF recurred. A  
resection of the colorectal anastomotic complex was then  
performed with a new double-stapled colorectal anastomo-  
sis protected by a diverting ileostomy. The RVF recurred  
18 months after ileostomy closure. Finally, a transvaginal  
repair was attempted, and a diverting ileostomy fashioned  
again (July 2017) but 9 months after ileostomy closure  
(October 2018), the patient was referred to our department  
for perineal pain and smelly discharge from vagina.

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55 **Surgical technique and technologies**

**AQ4** At first, a diverting loop colostomy was fashioned to prevent tissue contamination and patient was advised to do periodic enemas and vaginal douching. In July 2019 the transvaginal repair of the rectovaginal fistula was performed using GORE® BIO-A® Tissue Reinforcement.

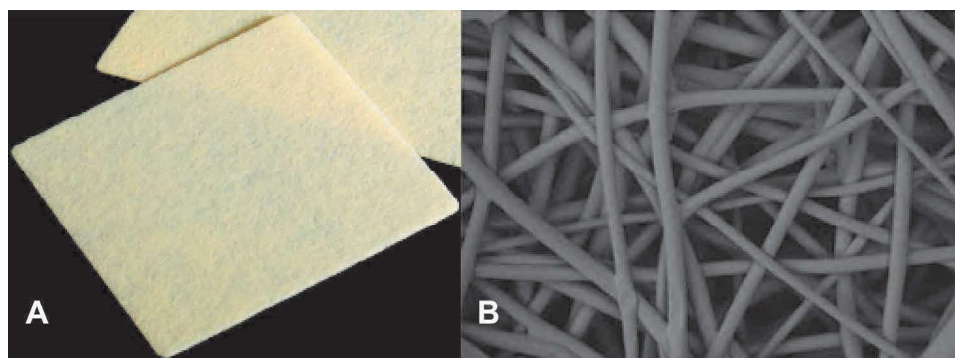
GORE® BIO-A® Tissue Reinforcement is a biosynthetic web scaffold designed for soft tissue reinforcement. It features a 3D matrix of open, highly interconnected pores that facilitates cell infiltration and tissue generation, leaving no permanent material behind (Fig. 1).

Through a transvaginal approach, with the vaginal lumen kept open wide with vaginal retractors, the fistulous tract was visualized on the posterior wall right below the posterior fornix at about 7 cm from the vulvar ostium. The orifice of the fistula was opened wide, achieving suitable exposure of the rectovaginal septum with transfixed suture traction on the rim of the vaginal wound.

The rectovaginal septum was markedly thin and weak. It was first extensively dissected, then curetted and irrigated with a povidone-iodine solution and saline solution. Three residual staples in the rectovaginal septum were removed. This allowed us to have a clear view of the colorectal anastomosis and assess its integrity.

An 8 × 8 cm GORE® BIO-A® Tissue Reinforcement was trimmed tailoring its dimension down to 8 × 6 cm intraoperatively. The patch was interposed between the anterior colorectal wall including the colorectal anastomosis and the posterior vaginal wall with at least 3 cm overlap above and below the anastomosis. It was then fixed with fibrin glue (Tisseel—Baxter Healthcare Corp. Deerfield, IL, USA) to minimise displacements, thus reinforcing the RV septum. The posterior wall of vagina was finally closed with several 2-0 Polyglycolic Acid interrupted suture (Fig. 2a–c). Drainage was not required.

**Fig. 1** **A** GORE® BIO-A® Tissue Reinforcement, especially designed for rectovaginal repair. **B** Electronic microscopic appearance of the polymers, polyglycolic acid and trimethylene carbonate mesh scaffold (Mag × 100)

**Postoperative course**

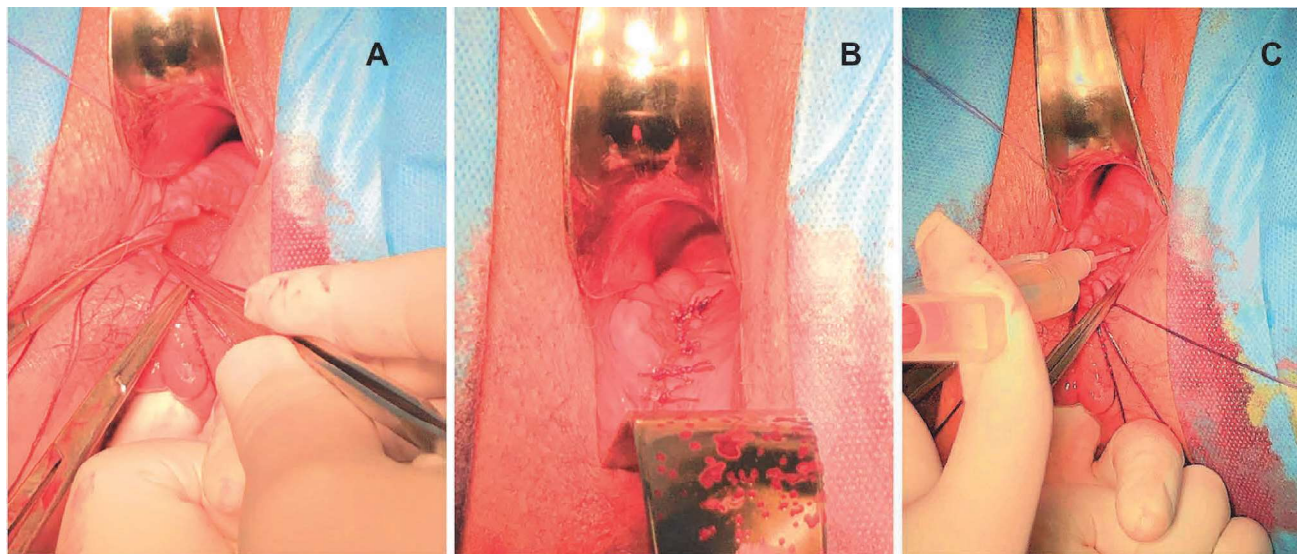
The stoma was reversed 3 months later. Postoperative course was uneventful. There was no recurrence and functional outcomes were good at 24-month follow-up. The patient reported substantial wellbeing with good anal function. The pelvic floor muscle function and strength was evaluated clinically but no instrumental examination was performed. Presence of postoperative subclinical leaks has been evaluated by pelvic MRI at 6-month follow-up. This is the time the tissue reinforcement is almost completely absorbed and presumably with the highest risk of fistula recurrence. Control MRI showed scar tissue thickening of the rectovaginal septum and no fluid collection (Fig. 3b).

**Discussion and conclusion**

At present, the main therapeutic methods include conservative therapy, surgical treatment and interposition of biomaterials. Although conservative management has been utilized in some cases, majority of patients are treated surgically [3]. Diversion stoma helps symptoms control most times. Surgical treatment includes abdominal repair with resection of colorectal anastomosis, closure of the vaginal fistula and creation of a new anastomosis. To reduce local recurrence it is important to interpose healthy tissue like omentum between the vaginal repair and the new anastomosis. Transposition of the gracilis muscle seems to be an effective procedure especially for recurrent rectovaginal fistula when conventional surgery fails [4].

Direct closure is not considered to be effective for rectovaginal fistula repair and fistula size may be a contraindication. Furthermore, a direct closure was already attempted unsuccessfully.

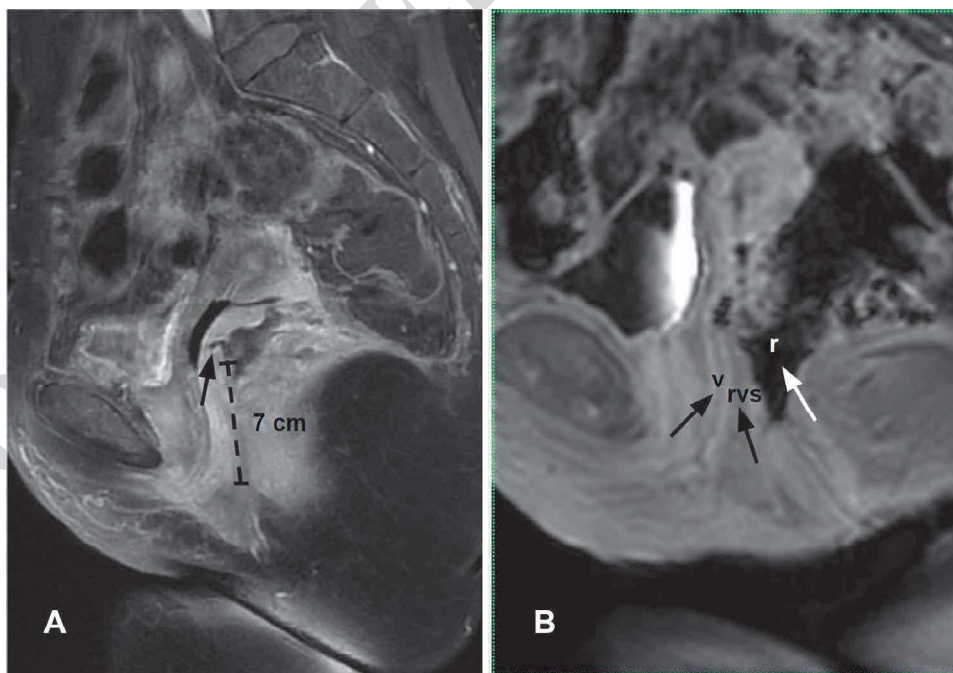
The bioabsorbable GORE BIO-A® Tissue Reinforcement provides a scaffold for ingrowth of native tissue. Consequently, the eventual absorption of exogenous material after healing aims to avoid the long-term complications of



**Fig. 2** Operative steps of BIO-A<sup>®</sup> Tissue Reinforcement placement for treatment of high RVF. A 8×8 cm e GORE<sup>®</sup> BIO-A<sup>®</sup> Tissue Reinforcement cut and tailored intraoperatively was interposed between the anterior colorectal wall including the colorectal anasto-

mosis and the posterior vaginal wall (A) and fixed with fibrin glue (Tisseal) in order to minimise displacements (B). The posterior wall of vagina was finally closed with 2-0 Polyglycolic Acid suture (C)

**Fig. 3** Preoperative and post-operative (18-month follow-up) imaging. **A** Preoperative MRI: Sagittal T2-weighted image showing the high rectovaginal fluid-filled fistula (arrow): the fistulous tract was visualized on the posterior wall right below the posterior fornix at about 7 cm from the vulvar ostium. **B** Postoperative MRI: coronal T1-weighted image showing scar tissue thickening of the rectovaginal septum (rvf) and no abnormal passage between rectum (r) and vagina (v) (arrows)



125 an indwelling foreign body. Its resorption starts at the 6th  
 126 week and is completed after 6–7 months. Diverting stoma  
 127 and the use of the bioabsorbable GORE<sup>®</sup> BIO-A<sup>®</sup> consent  
 128 to control postoperative infection. BIO-A<sup>®</sup> Tissue has good  
 129 handling and could be tailored intraoperatively for optimal  
 130 adaptation. Efthimiou and Negro showed satisfactory out-  
 131 comes in inguinal hernia repair. Burgess has also reported its  
 132 use in a case of Amyand hernia. Sutton et al. demonstrated

its effectiveness for the closure of an open abdomen. Ommer  
 et al. described the benefits of Gore Bio-A Fistula Plug<sup>®</sup> in  
 the treatment of high anal fistulas [5]. Recently it has been  
 used for paraesophageal hiatal hernia repair and repair of  
 other diaphragmatic defects [6].

To our knowledge, this is the first report in which BIO-A<sup>®</sup>, an absorbable Tissue Reinforcement, is used for the treatment of RVF with a trans-vaginal placement.

142 Very few cases of rectovaginal fistula repairs with Perma-  
 143 col™ (Medtronic—Minneapolis, MN, USA) are reported in  
 144 literature [7, 8]. Permacol is a cross-linked biological mesh  
 145 with high tensile strength, not absorbable and only partially  
 146 incorporated, and with high up-front costs. Furthermore,  
 147 interposition of Permacol meshes is reported only after redo  
 148 colorectal resection through the abdominal route and has  
 149 never been implanted through the vagina. The transvaginal  
 150 approach makes our procedure different from the others. The  
 151 costs are significantly higher for biologic mesh with a range  
 152 in price up to ~\$30/cm<sup>2</sup> compared to \$10/cm<sup>2</sup> for BIO-A®. It  
 153 has been developed to provide clinical results at considerable  
 154 economic value over biologic meshes, making it a preferable  
 choice for soft tissue reconstruction.

155 We preferred to have an as much clean as possible operat-  
 156 ing field before tissue reinforcement implant. This explains  
 157 the 8-month time lapse with close hygienic prescriptions  
 158 after colostomy construction. During the 24-month fol-  
 159 low-up the patient never reported functional impairment  
 160 thus, we did not consider necessary any further functional  
 161 investigation.

162 RVF can be successfully treated using the interposition of  
 163 a GORE® BIO-A® Tissue Reinforcement in selected cases,  
 164 with significant economic savings and good outcomes.  
 165

## 166 Declarations

167 **Conflict of interest** None.

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