# *Safety and efficacy of prophylactic resorbable biosynthetic mesh in loop-ileostomy reversal: a case–control study*

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ORIGINAL ARTICLE

# Safety and efficacy of prophylactic resorbable biosynthetic mesh in loop-ileostomy reversal: a case–control study

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## Abstract

Loop ileostomy (LI) is a widely used temporary stoma technique. Reversal of LI is generally considered a minor and safe procedure, with very low short-term postoperative mortality and morbidity rates. Complications include incisional hernia (IH), carrying a high probability of surgical repair. Clinical measures to reduce the IH rate warrant consideration. Recent researches suggest the use of a prophylactic non-absorbable mesh to reduce IH rate; however, surgeons are reluctant to implant a permanent foreign material in contaminated operative fields, because of a higher risk of mesh-related complications, infection, seroma, and pain. The aim of the present study is to assess feasibility, potential benefits, and safety of a prophylactic biosynthetic mesh placed during LI reversal. From January 2016 to December 2018, 26 consecutive patients underwent LI reversal positioning a resorbable biosynthetic mesh in an on-lay position [mesh group (MG)]. The mesh used was a GORE BIO-A tissue reinforcement, a biosynthetic mesh composed of a bioabsorbable polyglycolide—trimethylene carbonate copolymer. The MG was matched with 58 patients [control group (CG)], undergoing LI reversal without mesh placement from January 2013 to December 2018. To detect IH, abdominal wall was studied according to clinical and ultrasonographic criteria. Primary endpoint was IH rate on LI site, at 6 and 12 months after stomal reversal. Secondary endpoints included incidence of wound events. Thirty-day morbidity was classified according to Clavien–Dindo score; mortality and length of hospital stay were also collected. Mean follow-up was 15.4 ± 2.3 months (range 12.4–22.0) for MG vs 37.2 ± 26.9 (range 24.9–49.7) for. CG. At 1 year of follow-up, IH rate was lower in MG ($n = 1/26$ [3.8%]) vs CG ($n = 19/58$ [32.7%]; $P < 0.05$). A clinically evident IH was less frequent in MG ($n = 0$ [0%]) vs CG ($n = 13$ [68%]; $P < 0.05$). A radiologic IH was less frequent in MG ($n = 1$ [3%]) vs CG ($n = 6$ [31%]; $P < 0.05$). Stoma site hernia was repaired in 9/19 patients (47%) in CG; no patient of MG has hernia repaired. Incarcerated IH was observed in one patient of CG. No postoperative mortality was reported. Overall postoperative morbidity showed no difference comparing MG and MG ($n = 5$ [17%] vs $n = 15$ [19%], respectively; $P > 0.05$). Surgical site infections (SSI) were treated with antibiotic therapy, no debridement was necessary. Seroma occurred in two patients, one for each group. No statistically significant difference for surgical outcomes was found between the two groups at 30 days. Early results of the present study suggest that an on-lay prophylactic placement of GORE BIO-A tissue reinforcement might lower IH rate at LI site. The procedure seems to be safe and effective, even long-term results and further studies are needed.

**Keywords** Loop-ileostomy reversal · Incisional hernia · Resorbable mesh

## Introduction

Loop ileostomy (LI) is a widely used temporary stoma technique. Its use is indicated for de-functioning of distal bowel affected by severe disease, to cover anastomoses, to divert faeces in patients with anastomotic failure [1]. An increasing number of surgeons routinely perform a diverting stoma after sphincter-saving total mesorectal excision (TME), sigmoidectomy for diverticulitis to reduce the risk for symptomatic anastomotic leakage. If LI does not reduce

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anastomotic leakage incidence, it does decrease the magnitude of adverse effects once leakage occurs [2, 3]. Morbidity following LI includes: obstruction, retraction, prolapse, skin problems, and para-stomal hernia [4–6]. Moreover, reversal of LI is generally considered a minor and safe procedure: several studies showed very low rates of short-term postoperative mortality and morbidity [7]. Complications following reversal include anastomotic leaks, obstruction, wound infection, wound dehiscence, and the development of incisional hernias (IH) [7–10]. Some authors showed high rate of development of IH on side of reversal LI, with possible need for surgical repair. In a systematic review and meta-analysis by Bhangu et al. [1], one out of three patients were found developing a hernia after stoma closure, and about half of them required repair. The authors concluded that clinical measures to reduce the incidence of IH warrant consideration. In Literature, several risk factors for postoperative hernia have been identified, such as diabetes mellitus, obesity, smoking habit, chronic obstructive pulmonary disease, and surgical site infection [11, 12]. Several studies testing effectiveness and safety of placing a mesh for closure of vertical laparotomy to prevent incisional hernia have been published. These studies have been analysed in two different systemic reviews [13, 14]. Recent research suggests that addition of a prophylactic, non-absorbable mesh can reduce the rate of IH [15]. However, surgeons are reluctant to implant a permanent foreign material in a patient undergoing a contaminated ventral hernia repair for the high risk of postoperative infection, bowel adhesion, mesh extrusion, mesh erosion, fistula formation, seroma development, and pain [16].

On the other side, biosynthetic meshes can be used in grossly contaminated wounds, such as para-stomal hernia, with limited risk for infectious complications [17, 18]. The aim of this study was to assess the feasibility, potential benefits and safety of an IH prophylactic biosynthetic (BIOA Gore) mesh placed during stoma reversal. The GORE BIO-A tissue reinforcement is a biosynthetic mesh constituted of a bioabsorbable polyglycolide—trimethylene carbonate copolymer, which is gradually absorbed by the body.

## Methods

From January 2016 to December 2018, 26 prospective consecutive patients underwent a loop-ileostomy closure with use of BIO-A mesh in on-lay position (mesh group). Loop ileostomy was performed to cover anastomoses or to divert faeces in patients with anastomotic breakdown or fistulae in oncologic or inflammatory diseases. This "active" group was matched with 58 patients who underwent a loop-ileostomy reversal without mesh placement from January 2013 to December 2018 and served as control group (CTRL G). The two groups were well matched with regard to sex, age (± 10%), body mass index (BMI ± 10%), medically treated diabetes mellitus, indication for stoma, and neoadjuvant radiotherapy. The GORE BIO-A tissue reinforcement is a biosynthetic mesh comprised of a bioabsorbable polyglycolide—trimethylene carbonate copolymer, which is gradually absorbed by the body. The open three-dimensional (3D) matrix structure, with highly interconnected pores, facilitates tissue generation, and healing. The primary endpoint was incidence of IH on side of LI following closure at 6 and 12 months after stomal reversal. IH was clinically defined as any visible or palpable "blowout" in abdominal scar. The ultrasonic criteria of incisional hernia were a visible gap within the abdominal wall and/or "tissue moving through the abdominal wall by Valsalva manoeuvre" and/or a detectable "blowout". For the diagnosis of IH, either clinical criteria, or ultrasound criteria or both had to be fulfilled [19]. Ultrasound imaging was performed in all mesh patients at 12 months and it was used to examine the stoma site for any asymptomatic, clinically undetectable IH in control group. In both groups, in doubtful cases CT scan was performed. Secondary endpoints included incidence of wound events, morbidity, and mortality of loop-ileostomy closure and postoperative pain. Wound events were classified as surgical site infections based on CDC criteria into superficial, deep, or organ space [20]. Surgical site occurrences were reported based on the Ventral Hernia Working Group definitions [21, 22]. Interventions for wound events were categorized as: antibiotics only, bedside wound interventions, percutaneous interventions, or surgical debridement. 30-day morbidities were classified with Clavien–Dindo score [23], mortality, and length of hospital stay were also collected. The patients died or re-operated for disease unrelated to incisional hernia were excluded. Postoperative pain was recorded by visual analogue scale (VAS) from 0 to 10 [19]. VAS score was valuated at 1 and 12 months. Stomal reversal was performed at 6–8 weeks after its creation if colonoscopy and radiologic control with grafin did not show any evidence of anastomotic leakage. Stomal reversal was delayed in cases of anastomotic leakage.

### Operative technique

The reversal procedure was performed according to a standardized technique in all patients. Peristomal circular incision was always performed. Careful dissection into the peritoneal cavity and mobilization of the bowel segments were then performed. A short bowel resection was performed when necessary. The small bowel was joined with a side to side stapled anastomosis with an DST SERIES™ GIA™ 80 reloadable staplers (Medtronic, Mansfield, Massachusetts, USA), and the resulting entero-enterotomy was over stapled with a staple reload, allowing resection of the ileostomy

peripheral to the staple line. An overrun with vicryl 2:0 was performed. The patients who required a midline incision or a manual anastomosis during stomal reversal were excluded from study. In all patients, the abdominal wall was closed in two layers using continuous sutures of polyglactin 0 (vicryl; Ethicon) on the posterior and anterior layers of the rectus sheath. In the mesh group(MG), a 9X10 cm BIO-A was placed in on-lay position and fixed with two or four 2–0 vicryl stitches. Skin was sutured with a purse-string approximation technique using a 4.0 poliglecaprone suture (monocryl, Ethicon) in all patients i9. No wound drains were inserted. At induction, all patients received a single dose of intravenous antibiotics: cefazolin 2gr and metronidazole 500 mg. Antibiotic therapy was administered for 3 days.

### Statistical analysis

Quantitative variables were expressed as mean ± standard deviation, and categorical variables as absolute numbers and percentages. Comparison analyses of quantitative variables were performed with the Student t test test or the nonparametric Mann–Whitney *U* test in case of normal or non-normal distribution, respectively. The incidence of IH during follow-up was analysed with the Kaplan–Meier curve and the log-rank test. Statistical significance was set at $P < 0.05$. The description of variables and the statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) program (version 18.0 for Windows).

## Results

Characteristics of the patients are presented in Table 1. The 26 patients from the mesh group were matched with 58 patients who constituted the control group. The two groups did not present any difference regarding main clinic or demographic variables. All meshes were placed in on-lay position. Mean operative time, from skin incision to skin closure, was 56 ± 29 min (range 30–100) in MG and 50 ± 27 min (range 30–130) in the CG. The mean operative time devoted to placement of the mesh was 9 ± 1 min (range 5–11). All patients in the MG underwent ultrasound study at 12.1 ± 0.7 months to detect cases of IH. In 13 out of 19 control patients with of IH it was clinically evident; ultrasound examination was necessary for 6/19 IH diagnoses; TC scan was necessary in 1/26 (3%) in MG to exclude the diagnosis of IH, no TC scan was performed among CTRL G. Primary end points: at 1 year, the incidence of IH was lower in the MG ($n = 1/26$ [3.8%] vs $n = 19/58$ [32.7%]; $P < 0.05$). On this 1 year, the presence of a clinically evident IH was also less frequent in the mesh group ($n = 0$ [0%] vs $n = 13$ [68%]; $P < 0.05$). During a mean follow-up of 15.4 ± 2.3 months (range 12.4–22.0) in the MG vs 37.2 ± 26.9 (range 24.9–49.7) in the CTRL G, a radiologic IH was diagnosed less frequently in the mesh group ($n = 1$ [3%] vs $n = 6$ [31%]; $P < 0.05$). Operative repair of the stoma site hernia was performed in 9/19 patients (47%) in the control group and in no patients of mesh group. One case of incarcerated IH was observed in the control group. The median time to hernia detection was available for the mesh group and was 9 months. Short-term (30 days) outcomes of the two groups are shown in Table 2. There was no postoperative mortality. Overall postoperative morbidity showed no difference comparing mesh and control groups ($n = 3$ [11.5%] vs $n = 7$ [12%], respectively; $P > 0.05$). Surgical site infections (SSI) at ileostomy site closure were treated with antibiotic therapy (cefazoline two group) for 7 days, no debridement was necessary. One seroma was observed during follow-up in both groups. Postoperative outcomes after loop-ileostomy closure are shown in Table 2. No statistically

**Table 1** Demographic characteristics of 84 patients who underwent ileostomy, with or without biosynthetic mesh placement

| Patients | Mesh group ($n = 26$) | Control group ($n = 58$) | $P$ |
|---|---|---|---|
| Age | 69 ± 6 (29–81) | 70 ± 11 (28–85) | > 0.05 |
| Male | 11 | 21 | |
| Female | 15 | 37 | |
| BMI | 24 ± 2 (20–38) | 23 ± 3 (19–37) | > 0.05 |
| ASA (I–II) (%) | 22 (85%) | 50 (85%) | > 0.05 |
| ASA (III–IV) (%) | 4 (15%) | 8 (15%) | > 0.05 |
| Diabetes mellitus (%) | 5 (19%) | 12 (20%) | > 0.05 |
| Chronic obstructive pulmonary disease (%) | 3 (11%) | 6 (10%) | > 0.05 |
| Heart ischemia | 4 (15%) | 9 | > 0.05 |
| Oncologic disease | 4 (15%) | 8 (15%) | > 0.05 |
| Inflammatory disease | 22 (85%) | 50 (85%) | > 0.05 |
| Neoadjuvant therapy | 3 (11%) | 8 (15%) | > 0.05 |
| Time of operation | 56 ± 29 (60–130) | 50 ± 27 (60–130) | > 0.05 |
| Delay first intervention stoma reversal | 8 ± 5 (5–27) | 8 ± 7 (5–21) | > 0.05 |

**Table 2** Outcomes of 84 patients who underwent diverting ileostomy reversal

| Outcomes | Mesh group ($n=26$) | Control group ($n=58$) | $P$ |
|---|---|---|---|
| Mortality | 0 | 0 | $>0.05$ |
| Anastomotic leakage | 0 | 1 (1.7%) | $>0.05$ |
| Small bowel obstruction | 0 | 1 (1.7%) | $>0.05$ |
| Wound hematoma | 1 (3.8%) | 2 (3.4%) | $>0.05$ |
| Seroma | 1 (3.8%) | 1 (1.7%) | $>0.05$ |
| Wound infection (SSI) | 1 (3.8%) | 2 (3.4%) | $>0.05$ |
| Duration of postoperative hospital stay (days) | $5.1 \pm 0.7$ (5–11) | $6.6 \pm 0.7$ (5–19) | $>0.05$ |
| Morbidity (grades I–V), *n* (%) | 3 (11.5%) | 7 (12%) | $>0.05$ |

significant differences for surgical outcomes were found between two group at 30 days. VAS scores were evaluated in all patients from mesh group and 21 controls at 6 weeks (VAS 1.1 vs 1.2, respectively; $P>0.05$ and at 1 year (VAS 0.22 vs. 0.24; $P>0.05$).

## Discussion

The aim of this study is to evaluate the safe and effective use of prophylactic bioabsorbable (BIO-A) mesh at the time of stoma closure to prevention of IH. Overall, the presented, early results can be considered encouraging: a remarkable reduction in the risk of developing of IH (3.8% vs 32.7%) was detected in the MG at 12-month follow-up. At long-term postoperative follow-up, an important complication of LI reversal is IH, with rate reported up to 48% in some systematic reviews [1]. Some authors remark that the rate of IH after LI closure is influenced by risk factors related to kind of surgery (trans muscular incision, wound class contaminated) and related to the patient's characteristics [24]. Several studies identified categories at hjgh risk for IH: obesity, vascular, and diabetics. In these categories, several reports demonstrated that prophylactic mesh reinforcement of the abdominal wall significantly decreased the incidence of IH [24, 25]. The results of the "PRIMA"-trial [26] confirmed that the use of permanent mesh reinforcement led to a significant reduction in the incidence of IH. However, there are insufficient data regarding the rate of complications to recommend the routine use of prophylactic meshes. On the other hand, use of permanent mesh has been limited by the fear of bacterial contamination at the stomal site. Carbonell et al. [27] reported outcomes of surgical site infection, surgical site occurrence, need for mesh removal, and hernia recurrence in 100 patients with CDC class II–III wounds undergoing ventral hernia repair with retro-rectus mesh placement. The overall incidence of surgical site occurrence was 31%, higher in the contaminated than in the clean-contaminated cases. The 30-day surgical site infection rate was 14%. Mesh removal was required in four patients. There are some evidence that the implantation of foreign materials, such as prosthetic mesh, may lead to a decreased threshold for infection, thus representing the major obstacle to mesh reinforcement after clean-contaminated and contaminated surgery, potentially resulting in readmissions, reoperations, mesh explantation, and eventual hernia recurrence [27]. Data from the National Surgical Quality Improvement Program (NSQIP) regarding 33,832 patients with ventral hernia repair using mesh in clean-contaminated and contaminated surgical fields compared to clean cases showed a significantly higher odd ratio (OR) of having one or more postoperative occurrences with OR 3.56 (3.25–3.89) and 5.05 (1.78–12.41), respectively [28]. There was a significantly higher risk for superficial SSI (OR 2.53), deep SSI (OR 3.09), and wound disruption (OR 4.41) for clean-contaminated cases compared to clean cases [28]. As such, biologic mesh is often recommended in the setting of contamination. However, the use of biologic mesh has not been proven superior to permanent synthetic mesh in resisting infection [29–31]. In long-term analysis, recurrence rates after biologic mesh repair are significantly greater than in most series using synthetic mesh [32, 33] though reported results are highly variable. Moreover, the biologic meshes are more expensive. The systematic review by Atema et al. [34] showed no benefit of biologic over synthetic mesh for repair of potentially contaminated hernias with comparable surgical site complication rates. Overall surgical complication rate was 50% and mesh removal rate was 1% [34]. An alternative to biologic mesh for the repair or clean-contaminated and contaminated ventral hernia repairs is absorbable synthetic mesh. In this study, we used BIO-A (GORE). Constructive remodelling, a balance between scaffold degradation and collagen deposition with biomechanical integrity and resistance without evidence of biomaterial "footprint" long term, is a potential benefit of absorbable materials, whether biologic or synthetic. BIO-A mesh has the prospective advantages of a reduced cost vs biological mesh, informed consent in certain religious or cultural groups, and ability to be iterative in generational improvements in mesh constructs based on outcome studies compared allogeneic or xenogeneic mesh [35]. The location of the mesh is another matter of discussion. Whereas some authors promote the use of the mesh in pre-fascial situation (on-lay), others support the retro-muscular

preperitoneal space or even intraperitoneal space [19]. We chose the on-lay position because the surgical technique is common and much simpler to do and less time consuming. The mechanical rigidity of mesh need only one or two stich of bioabsorbable material to anchor. The mesh placement did not require dissection of the retro-muscular space, without differences with the control group regard the shits closure. There are concerns that mesh may adhere to bowel and precipitate fistula formation. The use of on-lay placement eliminates this risk. Although preperitoneal or intraperitoneal placement technically offers better protection against incisional hernias [26], the on-lay technique requires less dissection and disruption of underlying tissue planes, which minimizes the risk of breaching the peritoneum, bowel contact, and subsequent adherences or fistulisations. The rate of wound infection in the mesh group (3.4%) is comparable to routine non-mesh ileostomy closure [36-39]. No debridement was necessary. Infection resolved without mesh removal. Seroma and hematoma formation rates were comparable in two groups, probably for less dissection. A trend towards increased chronic pain after mesh implantation has been reported in the past [40, 41] However, in the present study, no difference in postoperative pain emerged between the two groups in the short or long term. Several study's limitations should be highlighted. First, patients in the mesh group were consecutive. To perform a case-matched study, we had to select patients from a longer time period in our prospective database. Follow-ups in the two groups were different, because patients from the control group were operated before patients from the mesh group. In the present study, the median time to hernia detection in MG was 9 months, unfortunately this data cannot be evaluated in the CTRL group. Besides, operations were not performed by a single surgeon and no randomization was created; however, all closures were performed by well-qualified senior surgeons.

## Conclusion

Early results of the present case-matched study suggested that prophylactic biosynthetic BIO-A (Gore) mesh placement onlay during stomal LI reversal is safe and may significantly reduce IH rate on LI stoma site.

### Compliance with ethical standards

**Conflict of interest** Francesco Pizza, Dario D'Antonio, Michele Arcopinto, Chiara Dell'Isola, and Alberto Marvaso declare that they have no conflict of interest.

**Ethical approval** Research involving human participants registered in Mendeley Data https://www.doi.org/10.17632/w3ybn7bh22.2.

**Informed consent** Informed consent was given to all patients.

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