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ORIGINAL ARTICLE

Observational Study

Reinforced tissue matrix to strengthen the abdominal wall following reversal of temporary ostomies or to treat incisional hernias

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Abstract

BACKGROUND

Abdominal wall deficiencies or weakness are a common complication of temporary ostomies, and incisional hernias frequently develop after colostomy or ileostomy takedown. The use of synthetic meshes to reinforce the abdominal wall has reduced hernia occurrence. Biologic meshes have also been used to enhance healing, particularly in contaminated conditions. Reinforced tissue matrices (RTMs), which include a biologic scaffold of native extracellular matrix and a synthetic component for added strength/durability, are designed to take advantage of aspects of both synthetic and biologic materials. To date, RTMs have not been reported to reinforce the abdominal wall following stoma reversal.

AIM

To evaluate the effectiveness of using an RTM to reinforce the abdominal wall at stoma takedown sites.

METHODS

Twenty-eight patients were selected with a parastomal and/or incisional hernia who had received a temporary ileostomy or colostomy for fecal diversion after rectal cancer treatment or trauma. Following hernia repair and proximal stoma closure, RTM (OviTex® 1S permanent or OviTex® LPR) was placed to reinforce the abdominal wall using a laparoscopic, robotic, or open surgical approach. Postoperative follow-up was performed at 1 month and 1 year. Hernia recurrence was determined by physical examination and, when necessary, *via* computed tomography scan. Secondary endpoints included length of hospital stay, time to return to work, and hospital readmissions. Evaluated complications of the wound/repair

site included presence of surgical site infection, seroma, hematoma, wound dehiscence, or fistula formation.

RESULTS

The observational study cohort included 16 male and 12 female patients with average age of 58.5 years ± 16.3 years and average body mass index of 26.2 kg/m^2 ± 4.1 kg/m^2. Patients presented with a parastomal hernia (75.0%), incisional hernia (14.3%), or combined parastomal/incisional hernia (10.7%). Using a laparoscopic (53.6%), robotic (35.7%), or open (10.7%) technique, RTMs (OviTex® LPR: 82.1%, OviTex® 1S: 17.9%) were placed using sublay (82.1%) or intraperitoneal onlay (IPOM; 17.9%) mesh positioning. At 1-month and 1-year follow-ups, there were no hernia recurrences (0%). Average hospital stays were 2.1 d ± 1.2 d and return to work occurred at 8.3 post-operative days ± 3.0 post-operative days. Three patients (10.7%) were readmitted before the 1-month follow up due to mesh infection and/or gastrointestinal issues. Fistula and mesh infection were observed in two patients each (7.1%), leading to partial mesh removal in one patient (3.6%). There were no complications between 1 month and 1 year (0%).

CONCLUSION

RTMs were used successfully to treat parastomal and incisional hernias at ileostomy reversal, with no hernia recurrences and favorable outcomes after 1-month and 1-year.

Key Words: Reinforced tissue matrix; Reinforced forestomach matrix; Ileostomy; Colostomy; Ostomy takedown; Incisional hernia; Abdominal wall

Core Tip: Reinforced tissue matrices (RTMs), which include elements of both synthetic and biologic mesh materials, were shown to be effective in treating parastomal and incisional hernia following ileostomy or colostomy reversal. Twenty-eight patients received OviTex® RTM to reinforce the abdominal wall using a laparoscopic, robotic, or open surgical approach. Positive primary outcomes (*i.e.*, 0% hernia recurrence) and low rates of complications were observed at 1-month and 1-year follow-up.

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INTRODUCTION

Hernias commonly develop at locations in the abdominal wall that have been weakened or breached in some way. Parastomal hernias often occur at sites where stomas have been placed through the abdomen, with incidence of hernia reported to be as high as 28% and 48% for colostomies and ileostomies, respectively[1,2]. Some researchers/clinicians have suggested that development of a parastomal hernia is inevitable in patients with stomas and that the variability in reported occurrence rates is due primarily to differences in duration (*i.e.*, length of time post-stoma creation) and type (*i.e.*, clinical or radiological) of follow-up[3,4]. While these types of hernias can be asymptomatic, many patients experience complications that may include abdominal discomfort, pain, ill-fitting pouching systems (leading to leakage and skin breakdown), bowel obstruction caused by incarceration and strangulation of the intestine, and perforation[5-9]. A variety of approaches are used to surgically treat hernias arising from a stoma site, *via* open or laparoscopic techniques, including primary fascial repair and stoma relocation with direct closure of the original site[5,10].

Incisional hernias can develop at temporary stoma locations after takedown of colostomies or ileostomies. Studies tracking hernia development following stoma closure have reported rates ranging between 15%-35%[11-13]. Significant risk factors include high body mass index (BMI), previous history of hernia, longer reversal time, open resection, hypertension, and lower age group[11,14]. In order to reduce the frequency of incisional hernia development at stoma sites, some surgeons have begun using prosthetic mesh to reinforce the abdominal wall at the time of stoma reversal; one randomized controlled trial found that mesh placement significantly reduced hernia formation from 20% down to 12% [13], providing an encouraging outcome of 40% hernia reduction.

Synthetic meshes have been used for many years to aid the repair of all types of hernia (*e.g.*, ventral, incisional, parastomal, *etc.*) and have generally been successful in augmenting the strength of native abdominal tissues. Synthetic meshes are relatively inexpensive and durable, with low failure rates compared to other implant options[8]. In recent years, biologic meshes have been introduced to overcome some limitations of synthetic materials and to provide unique advantages in promoting healing of host tissues. Specifically, biologic meshes have been recommended with the possibility of offering better tissue compatibility, less adhesion formation, less erosion into the bowel or skin, and less susceptibility to infection, particularly in contaminated fields[2,4,5,7]. To date, a wide variety of biological meshes have

been used to repair the abdominal wall after ileostomy or colostomy procedures, including biomaterials derived from dermis (human, porcine, bovine), small intestine submucosa (porcine), and pericardium (bovine)[4]. Results of parastomal hernia repair using biologic mesh have generally been positive, with several studies concluding that this approach is safe and effective, beneficial in cases of elevated risk of contamination, and with acceptable recurrence rates[3,5-7,9].

Biologic mesh has been used at the time of stomal closure to reinforce the abdominal wall. Several studies of patients that received biological mesh during stoma takedown demonstrated high feasibility, safe short-term results, and positive overall outcomes (*e.g.*, low rates of incisional hernia and no surgical site infection)[12,15]. Results have compared favorably to synthetic mesh repairs[16] and direct tissue repair[17]. A large randomized controlled trial of 790 patients undergoing elective ileostomy or colostomy closure were assigned to receive suture alone or biologic mesh augmented stoma takedown. After 2 years, patients receiving biologic mesh had reduced formation of incisional hernia compared to the suture repair group[13]. Thus, placement of biologic mesh at the time of stoma removal has shown promising results for decreasing the incidence/impact of hernia formation.

In an effort to take advantage of beneficial aspects of both synthetic and biologic materials for hernia repair, reinforced tissue matrices (RTMs) have been introduced and implemented clinically. RTMs contain a biologic scaffold composed of ovine forestomach matrix as the base material, which contains many natural components of native extracellular matrix and basement membrane, with a synthetic component (*i.e.*, permanent or resorbable stitching throughout the scaffold) to provide additional strength and durability. Clinical outcomes using RTM materials in ventral hernia repair have been positive[18-21], suggesting that these materials can leverage advantages and limit disadvantages of both synthetic and biologic hernia meshes. In addition, favorable outcomes have been reported for the use of RTMs in treating inguinal and hiatal hernias[22,23]. To date, RTMs have not been reported in the published literature to reinforce the abdominal wall following stoma reversal. Given the positive results using RTMs in other hernia types, and the desire to reduce risk of hernia formation for high-risk patients following stomal removal, the objective of this study was to evaluate outcomes after implantation of RTMs to reinforce the abdominal wall at the time of stoma takedown to prevent hernia development and/or recurrence.

MATERIALS AND METHODS

Patient enrollment

Patients were selected based on having previously received chemotherapy and/or radiation for rectal cancer with a temporary ileostomy or prior placement of a temporary ileostomy/colostomy after trauma. Exclusion criteria included any patient on Avastin, receiving palliative chemotherapy or radiation, classified as American Society of Anesthesiologists Grade 4, or otherwise unable to undergo surgery. This study was approved by the UT Health Houston Institutional Review Board. All patients provided consent to participate in the study.

Surgical methods

Patients were placed in the supine position. Sequential compression devices were placed on extremities bilaterally, and general endotracheal anesthesia was administered. Pre-operative antibiotics were administered, namely 1 g cefazolin (Ancef; GlaxoSmithKline, Philadelphia, PA, United States) and 500 mg metronidazole (Flagyl; Pfizer, New York, NY, United States). The chest and abdomen were then prepped in the standard sterile manner. The proximal limb to the stoma was closed with 2-0 Vicryl® suture (Ethicon; Somerville, NJ, United States). Each patient was subjected to either a laparoscopic, robotic, or open surgical approach (described below).

Laparoscopic approach: A 5-mm stab incision was made in the left upper quadrant and the abdomen entered using a trocar with Optiview® technology (Ethicon). After insufflating the abdomen to 12 mmHg using carbon dioxide gas, the small bowel was reduced and any observed adhesions lysed. The underside of the stoma was completely mobilized from the hernia sac using a LigaSure™ hook (Medtronic; Minneapolis, MN, United States). The skin surrounding the stoma was incised with cautery approximately 2 mm away from the mucocutaneous interface. Subcutaneous tissues were dissected from the stoma with a combination of cautery and sharp dissection, while fascia and rectus were dissected sharply. Once the stoma was completely mobilized, the mesentery leading to the stoma was ligated and divided. The proximal and distal limb were divided and a side-to-side functional end-to-end anastomosis created with a single firing of a 60-mm Endo GIA™ stapler (Medtronic). The common channel enterotomy was closed with a running 3-0 V-Loc™ suture (Medtronic) and imbricated with seromuscular sutures. After placing a 3-0 Vicryl crotch stitch, 5 mL of indocyanine green was administered followed by a 10-mL flush of normal saline. Using the PINPOINT system (Stryker; Kalamazoo, MI, United States), the anastomosis was visualized. Tisseel fibrin sealant (Baxter; Deerfield, IL, United States) was placed over the anastomosis, which was then placed into the abdomen. A sheet of Seprafilm® (Baxter) was placed in the subfascial location, the abdominal wall fascia cleared circumferentially, and hernia sac removed. Retrorectus space was created on both sides by incising the medial border of the rectus sheath. Myocutaneous flaps were created, as needed. Ileostomy defects in the posterior rectus sheath were closed with 2-0 Vicryl. RTM (OviTex® 1S permanent or OviTex® LPR; TELA Bio, Malvern, PA, United States) was cut to size and secured in the retrorectus space with transfascial sutures (Figure 1). After closing the anterior fascia, the ileostomy site was thoroughly irrigated and re-approximated with a 2-0 Monocryl® purse-string (Ethicon). The abdomen was re-insufflated and the hernia repair checked. All ports were removed, pneumoperitoneum evacuated, and trocar sites thoroughly irrigated and closed with 4-0 Monocryl® and Dermabond™ (Ethicon). Most patients received a subcutaneous drain.

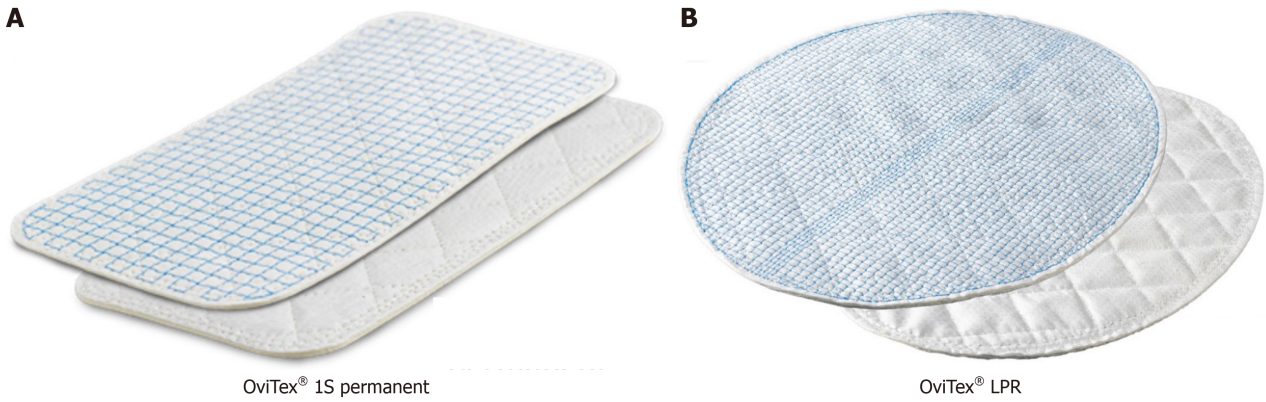

Figure 1 Reinforced tissue matrix products used in this study. A: OviTex® 1S permanent; B: OviTex® LPR.

Robotic approach: Patients were placed in a slight reverse Trendelenburg position. Using an Optiview® trocar port, the abdomen was entered in the left upper quadrant and insufflated to 15 mmHg using carbon dioxide gas. An 8-mm port was placed in the left mid-lateral abdomen and another port placed in the left lower quadrant. After docking the robot, the peritoneum was dissected off the fascia superiorly and inferiorly. The hernia sac was reduced completely into the abdomen, and further dissection prepared the space for matrix placement. RTM (OviTex® 1S permanent or OviTex® LPR; Figure 1) was secured into the center of the abdominal cavity with 0 V-Loc™ absorbable sutures, with attachments at the anterior abdominal wall, suture lines running superiorly and anteriorly, and sutures extending from the inferior and superior aspects cut at opposite ends. After desufflating the abdomen, ports were removed. Port incisions were irrigated and closed using 4-0 Monocryl® subcuticular closure. Dermabond™ was used to cover the skin incisions, and most patients received a subcutaneous drain.

Open approach: Retrorectus space was created by incising the medial border of the rectus sheath and extending bilateral myocutaneous flaps. The posterior sheath was closed with running 0 Vicryl® suture. RTM (OviTex® 1S permanent; Figure 1A) was cut to size and secured in the retrorectus space from xiphoid to pubis with four PDS™ transfascial sutures (Ethicon). The hernia sac was resected and the anterior rectus fascia closed with PDS™ sutures. A 19Fr Jackson-Pratt® wound drain (Cardinal Health; Dublin, OH, United States) was placed in the subfascial retromuscular location, above the mesh, and secured to the skin with suture. The midline fascia was closed with PDS™. Dermabond™ was used to cover the skin incisions, and an abdominal binder was placed for 4 wk. In most patients, a subcutaneous drain was placed.

Follow-up

Post-operative follow-up was performed *via* in-person visits at 1 month and 1 year. The primary endpoint, hernia recurrence, was determined by physical examination; in cases of uncertainty, an anterior/posterior computed tomography (CT) scan was acquired and evaluated for evidence of hernia recurrence. Secondary endpoints included length of hospital stay, time to return to work, and details regarding any hospital readmissions. In addition, evaluated features of the wound/repair site included presence of surgical site infection, seroma, hematoma, wound dehiscence, or fistula formation. Finally, mechanical obstruction and mesh infection were considered, and any cases of necessary mesh removal were documented. All results were computed as mean value and percent of study population.

RESULTS

Patient demographics

A total of 28 patients were enrolled (16 male; 12 female), with average age of 58.5 years ± 16.3 years and average BMI of 26.2 kg/m^2 ± 4.1 kg/m^2 (Table 1). Patients presented with a hernia at a former site of a temporary stoma (75%), incisional hernia (14.3%), or combined stoma-site/incisional hernia (10.7%). For this patient cohort, CDC wound classifications were class I (clean; 10.7%), class II (clean/contaminated; 7.1%), and class III (contaminated; 82.1%). Stomas were present in 78.6% of patients, and the most common co-morbidities were immunosuppression/steroid use (67.9%) and cancer (60.7%). Other details on patient conditions and co-morbidities are summarized in Table 1.

Perioperative data

For the 28 patients enrolled in this study, average defect dimensions were 7.5 cm ± 3.9 cm in length by 6.9 cm ± 3.4 cm in width, with average area of 63.8 cm^2 ± 77.2 cm^2 (Table 2). The most common surgical approach was laparoscopic (53.6%), followed by robotic (35.7%), and open (10.7%). When implanting the RTM (OviTex® LPR in 82.1% of cases, OviTex®1S in 17.9% of cases), the most common placement was sublay (82.1%), with an intraperitoneal onlay (IPOM; 17.9%) approach used less frequently. Matrices of various dimensions were used: 9 cm × 9 cm (71.4%), 10 cm × 12 cm (7.1%), 16 cm × 20 cm (14.3%), and 20 cm × 20 cm (7.1%). Component separation was achieved using a right myocutaneous flap in most cases

Table 1 Preoperative data: Patient demographics and hernia type, *n* (%)

Number of patients	*n* = 28
Sex	
Male	16 (57.1)
Female	12 (42.9)
Age, yr	58.5 ± 16.3
BMI, kg/m^2	26.2 ± 4.1
Patient type	
Stoma-site reinforcement	21 (75.0)
Incisional	4 (14.3)
Stoma-site/incisional	3 (10.7)
CDC wound class	
Class I: Clean	3 (10.7)
Class II: Clean/contaminated	2 (7.1)
Class III: Contaminated	23 (82.1)
Recurrent	5 (17.9)
Prior hernia repairs	5 (17.9)
Prior wound infection	6 (21.4)
Transplant patient	0 (0)
Stoma present	22 (78.6)
Cancer	17 (60.7)
Immunosuppression/steroid use	19 (67.9)
Hypoalbuminemia (albumin < 3.7 g/dL)	12 (42.9)
Diabetes	10 (35.7)
COPD/chronic cough	8 (28.6)
Smoking	8 (28.6)
MRSA	0 (0)

BMI: Body mass index; COPD: Chronic obstructive pulmonary disease; MRSA: Methicillin-resistant *Staphylococcus aureus*.

(64.3%), with fewer cases using left myocutaneous flap (7.1%), bilateral flaps (7.1%), unspecified separation (3.6%), or no component separation (17.9%). Bowel anastomosis was present in 82.1% of patients. Drains were placed in subcutaneous (82.1%) and retromuscular (10.7%) positions in a total of 24 of 28 (85.7%) of patients. Across all patients, the average duration of surgery was 85.7 min ± 40.9 min.

Postoperative data

All enrolled patients (*n* = 28) were evaluated at 1-month and 1-year follow-ups (Table 3). For the primary outcome, there were no hernia recurrences (0%) at either time point. The average hospital length of stay was 2.1 d ± 1.2 d and return to work occurred at 8.3 post-operative days ± 3.0 post-operative days. Three patients (10.7%) were readmitted before the 1-month follow-up due to mesh infection and/or gastrointestinal issues. There were no hospital readmissions between 1 month and 1 year. Of the measured secondary surgical outcomes (Table 3), fistula and mesh infection were observed in two patients each (7.1% of total group; one patient had both complications), leading to partial mesh removal in one patient (3.6% of total study population). The patient who received a partial mesh removal, which area was likely granulated in, still had an intact repair without recurrence at the 1-year follow-up. The second infection resolved with four weeks of antibiotics and bowel rest, while total parenteral nutrition led to fistula resolution in both patients. No other adverse outcomes were observed at 1 month, and no adverse events at all were reported between the 1-month and 1-year follow-up visits.

Table 2 Perioperative data: Mesh/defect dimensions and operative technique, *n* (%)

	Value
Surgical approach	
Open	3 (10.7)
Laparoscopic	15 (53.6)
Robotic	10 (35.7)
Implant location	
Sublay	23 (82.1)
IPOM	5 (17.9)
Matrix	
OviTex 1S®	5 (17.9)
OviTex LPR®	23 (82.1)
Duration of surgery	85.7 min ± 40.9 min
Defect dimensions	
Length	7.5 cm ± 3.9 cm
Width	6.9 cm ± 3.4 cm
Mesh dimensions (cm × cm)	
9 × 9	20 (71.4)
10 × 12	2 (7.1)
16 × 20	4 (14.3)
20 × 20	2 (7.1)
Component separation	
Left myocutaneous flap	2 (7.1)
Right myocutaneous flap	18 (64.3)
Bilateral	2 (7.1)
Unspecified	1 (3.6)
None	5 (17.9)
Bowel anastomosis	23 (82.1)
Intraoperative blood transfusion	0 (0)
Concomitant procedure(s)	0 (0)
Drains placed	
At least one	24 (85.7)
None	4 (14.3)
Drain locations	
Abdominal wall	0 (0)
Subcutaneous	23 (82.1)
Retromuscular	3 (10.7)
Skin closure	3 (10.7)
Vacuum-assisted closure device	0 (0)

DISCUSSION

In this study of 28 patients, the use of an RTM to treat incisional hernias and/or reinforce the abdominal wall following ileostomy or colostomy reversal led to successful results in terms of the primary endpoint of hernia recurrence, with no recurrences at 1 month or 1 year follow-up. In addition, although some secondary complications were observed at 1

Table 3 Postoperative data: Primary and secondary study endpoints

Item	1 month	1 yr
Number of patients	28	28
Primary endpoint		
Hernia recurrence	0 (0)	0 (0)
Secondary endpoints		
Length of stay	2.1 d ± 1.2 d	NA
Return to work	8.3 d ± 3.0 d	NA
Readmission	3 (10.7)	0 (0)
Wound	0 (0)	0 (0)
Mesh infection	2 (7.1)	0 (0)
Gastrointestinal	2 (7.1)	0 (0)
Surgical site infection		
Superficial	0 (0)	NA
Deep	0 (0)	NA
Seroma	0 (0)	0 (0)
Hematoma	0 (0)	NA
Wound dehiscence	0 (0)	NA
Fistula	2 (7.1)	0 (0)
Mechanical obstruction	0 (0)	0 (0)
Mesh infection	2 (7.1)	0 (0)
Mesh removal	1 (3.6)	0 (0)

NA: Not available.

month (*e.g.*, fistula, mesh infection), all had resolved by the 1-year follow-up timepoint. Thus, overall outcomes were positive in augmenting parastomal and/or incisional hernia repair with RTM. Due to heterogeneity of the patient population, a range of surgical approaches, mesh types/sizes, implant locations, and component separation techniques were employed. Additionally, most of the repair procedures were in contaminated fields (82.1% CDC Class III) and many of the study participants were immunocompromised (67.9%) and/or had been diagnosed with cancer (60.7%), such that many of the procedures represented challenging clinical cases. Still, positive clinical results were achieved for all patients enrolled in this study by the study endpoint.

The primary novelty of this study was the use of RTM to repair incisional hernias and/or reinforce the abdominal wall after removal of temporary ostomies. The composite RTM materials used in the current study represent an approach that leverages the advantages of both biologic (*e.g.*, better biocompatibility, reduced infection) and synthetic (*e.g.*, enhanced mechanical strength) materials, which likely contributed to observed successful outcomes. The OviTex RTMs contain layers of ovine forestomach matrix scaffolds stitched together with permanent or resorbable polymer fibers (such as polypropylene or polyglycolic acid). For this study, OviTex® 1S permanent (6 layers) or OviTex® LPR scaffolds (4 layers) were used for repairs, with mesh selection being based more on defect size than on other differences between these two meshes (*e.g.*, number of layers, stitching pattern, *etc.*). OviTex® LPR was used more following ostomy closure while OviTex® 1S was used more for IPOM hernia repairs. Results indicate that both four- and six-layer RTM materials yield favorable outcomes.

In addition to repairing hernias that are already present, previous studies have shown positive outcomes when using biologic mesh to reinforce the abdominal wall during stoma takedown[12,15], leading to reduced rates of subsequent incisional hernia formation compared to direct suture repair alone[13]. Many of the cases in the current study (78.6%) included stoma reversal in addition to incisional hernia repair; the reinforcement of the repaired abdominal tissues following stoma closure with RTM implantation resulted in zero recurrences at 1-month and 1-year follow-up. Thus, the use of RTM in treating high-risk patients with few other available alternative materials yielded minimal complications and no hernia recurrence.

This study is not without limitations. A total of 28 individuals were evaluated in this study, which is a larger patient population than many case studies, but still a relatively small sample size. In addition, the patient population was relatively heterogeneous in terms of demographic data and clinical comorbidities. Similar results with a larger and more uniform cohort of patients would strengthen the results/conclusions presented in this study; still, positive results ob-

served in this observational, single-surgeon study suggest that the use of RTM meshes in stoma reversal may represent a promising surgical approach. In addition, while no hernia recurrences were observed at the final timepoint in this study (1 year), longer follow-up evaluation is necessary to demonstrate long-term efficacy of this treatment approach.

CONCLUSION

In conclusion, RTMs were used to successfully treat abdominal wall deficiencies or weakness and/or incisional hernias at the time of ileostomy or colostomy reversal, with positive primary outcomes (*i.e.*, 0% recurrences) and low rates of complications (*e.g.*, SSI, mesh infection, seroma, *etc.*) at 1-month and 1-year follow-up. Results concur with previous studies that have demonstrated successful outcomes using RTM materials to repair other types of hernias[18-23]. Future examination of larger and more heterogeneous patient populations, more standardized surgical techniques, and longer evaluation endpoints could further demonstrate the utility of this approach in limiting the negative impacts of hernias for patients with abdominal stomas.

ARTICLE HIGHLIGHTS

Research background

Abdominal wall deficiencies are a common complication of temporary ostomies, and incisional hernias frequently develop after colostomy or ileostomy takedown. Synthetic and biologic meshes have been successfully leveraged to reinforce the abdominal wall and treat incisional hernias. Reinforced tissue matrices (RTMs) combine advantages of both biologic and synthetic scaffolds, but have not yet been used to strengthen the abdominal wall following stoma reversal.

Research motivation

To determine if RTMs could be successfully used to strengthen the abdominal wall after removal of temporary colostomies/ileostomies and treat incisional hernias that develop in previous stoma sites.

Research objectives

To determine rates of primary (*i.e.*, hernia recurrence) and secondary (*i.e.*, length of hospital stay, time to return to work, hospital readmissions) outcomes after using RTM to reinforce the abdominal wall or repair an incisional hernia after removal of a temporary stoma.

Research methods

Twenty-eight patients were selected with a parastomal and/or incisional hernia who had received a temporary ileostomy or colostomy. RTM was placed using a laparoscopic, robotic, or open surgical approach. Post-operative follow-up was performed at 1 month and 1 year.

Research results

At 1-month and 1-year follow-ups, there were no hernia recurrences (0%). Average hospital stays were 2.1 d ± 1.2 d and return to work occurred at 8.3 post-operative days ± 3.0 post-operative days. Three patients (10.7%) were readmitted before the 1-month follow up due to mesh infection and/or gastrointestinal issues. Fistula and mesh infection were observed in two patients each (7.1%), leading to partial mesh removal in one patient (3.6%). There were no complications between 1 month and 1 year (0%).

Research conclusions

RTMs were used successfully to treat parastomal and incisional hernias at ileostomy reversal, with no hernia recurrences and favorable outcomes after 1-month and 1-year.

Research perspectives

Future examination of larger and more heterogeneous patient populations, more standardized surgical techniques, and longer evaluation endpoints could further demonstrate the utility of this approach in limiting the negative impacts of hernias for patients with abdominal stomas.

FOOTNOTES

Author contributions: Agarwal AK designed the study; Agarwal AK performed the research; Agarwal AK, Lake SP, and Deeken CR analyzed the data and wrote the manuscript; and all authors have read and approve the final manuscript.

Institutional review board statement: This study was reviewed and approved by the UT Health Houston Institutional Review Board (approval No. HSC-MS-23-0471).

Informed consent statement: All study participants, or their legal guardian, provided consent prior to study enrollment.

Conflict-of-interest statement: This project was sponsored by TELA Bio of Malvern, PA (USA). Dr. Deeken is the owner of Covalent Bio, LLC, which received consulting fees from TELA Bio for this project, as well as other unrelated projects. Dr. Deeken also reports consulting fees from C.R. Bard, Inc./Davol/Becton, Dickinson and Company, Johnson & Johnson, Medtronic, SurgiMatrix, Tissium, Surgical Innovation Associates, Americas Hernia Society Quality Collaborative, Colorado Therapeutics, TELA Bio, Osteogenics, Polynovo, MedSkin Solutions, and Aran Biomedical outside the submitted work. In addition, Dr. Deeken holds the following issued patents: 2009293001, 2334257, 2,334,257UK, 602009046407.8, 2,334,257FR, 16/043,849 and 2,737,542. Dr. Lake is a consultant for Covalent Bio LLC and has received consulting fees from TELA Bio for the conduct of this study, as well as outside of the current work. Dr. Agarwal is a paid consultant for TELA Bio.

Data sharing statement: Dataset available from the corresponding author.

STROBE statement: The authors have read the STROBE Statement—checklist of items, and the manuscript was prepared and revised according to the STROBE Statement—checklist of items.

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