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Ventral Hernia Repair With a Hybrid Absorbable-permanent Preperitoneal Mesh

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Objective: To analyze device safety and clinical outcomes of ventral hernia repair with the GORE SYNECOR Preperitoneal Biomaterial (PRE device), a permanent high-strength mesh with bioabsorbable web scaffold technology.

Materials and Methods: This multicenter retrospective review analyzed device/procedure endpoints and patient-reported outcomes in patients treated for hernia repair ≥1 year from study enrollment.

Results: Included in this analysis were 148 patients with a mean age of 56 years; 66.2% met the Ventral Hernia Working Group grade 2 classification. Median hernia size was 30.0 cm^2 and 58.8% of patients had an incisional hernia. Repairs were primarily a robotic (53.4%) or open approach (41.9%). All meshes were placed extraperitoneal. Procedure-related adverse events within 30 days occurred in 13 (8.8%) patients and included 7 (4.8%) patients with surgical site infection, 2 (1.4%) with surgical site occurrence (SSO), 4 (2.7%) requiring readmission, and 3 (2.0%) who had reoperation. The rate of SSO events requiring procedural intervention was 2.7% (4 patients) through 30 days and 3.4% (5 patients) at 12 months. The rate of procedure-related surgical site infection remained at 4.8% through 12 months (no further reports after 30 d) and 3.4% for SSO (2 reports after 30 d). There were no site-reported clinically diagnosed hernia recurrences throughout the study. Median patient follow-up including in-person visit, physical examination, reported adverse event, explant, death, and questionnaire response was 28 months (n = 148). Median patient follow-up with patient questionnaire was 36 months (n = 88).

Conclusions: Use of the PRE device, which incorporates the proven advantages of both an absorbable synthetic mesh and the long-term durability of a permanent macroporous mesh, is safe and effective in complex ventral hernia repairs. When used in the retromuscular space, the combination of these 2 materials had lower wound complications and recurrence rates than either type of material alone.

Key Words: ventral hernia, extraperitoneal placement, hybrid absorbable permanent mesh

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Ventral and incisional hernias are some of the most common operations performed by surgeons, with 10% to 30% of laparotomies leading to an incisional hernia.[1–4] The advantages of using mesh for repair of ventral and incisional hernias have been well-established in meta-analyses and use of mesh for repair is recommended by consensus expert review.[5–10]

Intraperitoneal and extraperitoneal placement of mesh devices is the most common approaches for repairing ventral hernias due to the lower recurrence and seroma rates compared with onlay repairs.[11] For many surgeons, intraperitoneal mesh placement was reported as the most common approach for minimally invasive procedures, such as laparoscopic or robotic-assisted, which isolates the hernia and secures the mesh to the peritoneal surface of the abdominal wall.[12] Extraperitoneal placement utilizing open or robotic-assisted procedures is technically more difficult and more time-consuming as the mesh is placed within the layers of the abdominal wall.

The intraperitoneal onlay mesh (IPOM) and sublay repair data in patients with ventral or incisional hernia repair show both advantages and disadvantages. While sublay mesh placement documents superior outcomes for open procedures, laparoscopic IPOM has the advantages of fewer surgical site occurrences (SSOs) and faster recovery. However, IPOM is also associated with negative patient outcomes, such as adhesive bowel obstruction, mesh erosion, enterocutaneous fistula, and postoperative pain.[13–15] Mesh selection is an important factor in hernia repair outcomes. Recently, absorbable mesh was shown to have durable long-term outcomes that approach the recurrence rates reported with permanent mesh repair in

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Centers for Disease Control (CDC) class I wounds.[16,17] While absorbable mesh alone has decent results, when permanent synthetic mesh is used it leaves a long-lasting scaffold for wound healing providing a durable repair.[18] With each type of mesh having unique properties, a hybridized combination of these materials might capitalize on the advantage of each one. The GORE SYNECOR Preperitoneal (PRE) Biomaterial (hereafter, PRE device; W.L. Gore & Associates, Inc.) is a tri-layer mesh comprised of a nonabsorbable macroporous knit constructed of monofilament polytetrafluoroethylene (PTFE) fibers between two layers of bioabsorbable material. The bioabsorbable layers are a synthetic porous fibrous structure comprised of polyglycolide:trimethylene carbonate copolymer (PGA:TMC). Degraded through a combination of hydrolytic and enzymatic pathways, the PGA:TMC copolymer has been found to be both biocompatible and nonimmunogenic. In vivo studies with this copolymer indicate the bioabsorption process should be complete in 6 to 7 months.[19,20] The PRE device is designed for extraperitoneal placement and should be placed between tissue layers where ingrowth is desired.[21]

The aim of this retrospective review was to evaluate the performance and safety of extraperitoneal placement of the PRE device for the repair of ventral or incisional hernias.

MATERIALS AND METHODS

Study Design

This multicenter, nonrandomized, retrospective study included adult patients treated with the PRE device to repair primary and incisional ventral hernias. Data were collected between March 2020 and November 2022 from patients at least 18 years of age who underwent hernia repair with the use of the mesh across seven hospitals in the United States. A record search was conducted on cases of patients treated at least 1 year before site initiation. Hernia repair procedures occurred between May 2017 and January 2021. The CDC Surgical Wound Classification class 1 wound and hernia types 1 and 2, as classified by the Ventral Hernia Working Group (VHWG), were included in this study. No vulnerable populations were included in the study. The technique for hernia repair was at the medical discretion of the implanting physician. The exclusion criteria included CDC wound class >1, procedures where mesh was placed intra-abdominally, and the inability to achieve sufficient overlap of the hernia defect, as determined by the implanting surgeon. Additional exclusion criteria included evidence of systemic infection, known wound-healing disorder, cirrhosis, current dialysis, immunosuppression, or surgical site infection (SSI) at the time of mesh placement.

Eligible patients were enrolled, and within 90 days of enrollment, demographics, medical history, physical examination, adverse event, and device use data were collected retrospectively from existing medical records. Patients completed the Ventral Hernia Recurrence Inventory (VHRI), an adapted patient-reported outcomes (PROs) questionnaire[22]; these data were collected prospectively. Patient surveillance and data collection were scheduled at the procedure and within follow-up windows of 1 month (1 to 30 d), 6 months (31 to 182 d), 12 months (183 to 365 d), 24 months (366 to 730 d), and 36 months (731 to 1095).

The study was funded by W. L. Gore & Associates, Inc., and conducted in accordance with the US Federal regulations and with Institutional Review Board approval.

Device

The PRE device is intended for use in the repair of hernias and abdominal wall soft tissue deficiencies that may require the addition of a nonabsorbable reinforcing or bridging material. Device size selection, and thus the extent of mesh overlap of the hernia, was left to the discretion of the implanting physician.

Endpoints

The 3 coprimary objectives were the procedural, device, and PRO-related events. Procedural events were defined as incidence through 30 days of SSI, SSO, ileus, readmission, reoperation, and death. Device events were defined as serious device incidence of mesh erosion, infection, excision/removal, exposure, migration, shrinkage, device-related bowel obstruction and fistula, and hernia recurrence through 12 months. The PRO included bulge, physical symptoms, and pain (Supplemental Table 1, Supplemental Digital Content 1, http://links.lww.com/SLE/A459, details the study endpoint definitions).

All procedural endpoints were captured as device or procedure-related, with the exception of death, which was captured for device-related events only. Severity was captured as serious or nonserious for the SSI, SSO, and ileus events, and as serious only for readmission, reoperation, and death. All device endpoints were captured for events that were device-related or serious in severity.

The VHRI is an adapted PRO patient questionnaire[22] and contains 3 "yes/no" questions regarding symptoms that may be associated with hernia recurrence. The responses were not considered adverse events. Though this is a retrospective review, the VHRI survey responses were collected prospectively to assess the 3 questions on the survey that are based on the perception of patients after their hernia mesh treatment.

The secondary endpoints included SSO, SSI, bowel perforation, unexplained or chronic pain, seroma, fistula, or adhesion formation. Only device-related and serious severity events were captured, with exception of the SSO and SSI, which were also captured for procedure-related and nonserious events. In addition, the tertiary endpoint of SSO requiring procedural intervention (SSOPI) was also evaluated. Patients could experience multiple occurrences of SSOPI. These events included abdominal wound dehiscence, open abdominal wall wound, abdominal wound, abdominal wound with subcutaneous abscess, wound infection, abdominal wall abscess, intra-abdominal hypertension, and acute respiratory failure.

Adverse events were defined as serious or nonserious. A serious adverse event (SAE) may include an event that led to death, led to a serious deterioration in the health of the subject that either resulted in a life-threatening illness or injury, or permanent impairment of a body structure or a body function, or in-patient or prolonged hospitalization, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.

Statistical Method

The 95% 2-sided CI was calculated using the exact binomial test for each estimate for the procedural, device,

and PRO endpoints and included the all-enrolled patient population. Missing data were not included.

RESULTS

Patient Population

A total of 148 patients were included in this analysis. Table 1 details the demographics and medical history and hernia characteristics at baseline for the device placement population. Patients were a mean age of 56 years, 60.8% were males, 84.5% were white, and 84.5% were non-Hispanic. Associated comorbidities included obesity (53.4%), hypertension (40.5%), hypercholesterolemia (16.9%), current smoker (16.9%), and diabetes mellitus (15.5%). One patient reported a previous abdominal aortic surgery. The mean hernia surface area was 88.2 cm^2. Hernias were incisional (58.8%) or umbilical (39.2%) and were located primarily in the midline (87.8%). All hernias were CDC Wound class I, and by VHWG classification, 66.2% were grade 2 (high risk, comorbid); one was classified as grade 3 potentially contaminated due to the presence of a stoma, but determined to be CDC Wound class I. Mesh was placed in the underlay position (anterior to the peritoneum and posterior to the rectus sheath) in 52% or in the retromuscular/sublay position (posterior to the rectus muscles and anterior to the posterior rectus sheath) in 43.9% (Table 1). The remaining cases included 3 noted as onlay, 1 case noted as inlay, and 2 noted as "other." The 3 cases noted as onlay had a PRE device used as an onlay for component separation, as well as a GORE SYNECOR Intraperitoneal Biomaterial device as a lap IPOM. The procedures denoted as "other" had a retrorectus placement, as well as an onlay over component separations. Finally, the case denoted as inlay positioned a PRE device as an underlay, an inlay PRE device to bridge the fascia of the hernia, as well as a third non-Gore device overlay; this patient was ultimately explanted on day 1 postprocedure. Most patients had robotic (53.4%) or open (41.9%) repair. The majority (85.8%) of patients had one PRE device, 19 (12.8%) patients had 2 PRE devices, and 2 (1.4%) patients had 3 or more devices due to the size of the hernias and the sizes of the mesh available at the time. All patients received a form of device fixation. Patients primarily received absorbable sutures for fixation, 121 (81.8%). This was followed by fibrin glue in 35 (23.7%) patients, permanent

TABLE 1. Patient Demographics and Hernia Characteristics

No. patients (hernias)	N = 148
Demographics	
Male, n (%)	90 (60.8)
Race, n (%)	
White or Caucasian	125 (84.5)
Black or African American	9 (6.1)
Other	11 (7.4)
Age (y), mean (±SD)	56 (15)
Range (minimum to maximum)	25, 88
Weight (lbs), mean (±SD)	209 (51)
BMI (kg/m^2), mean (±SD)	32 (7)
Range	21, 56
Medical history	
Tobacco use, n (%)	
Current	25 (16.9)
Former	47 (31.8)
Never	76 (51.4)
Hypercholesterolemia	25 (16.9)
Hypertension	60 (40.5)
Diabetes mellitus	23 (15.5)
Chronic obstructive pulmonary disease	11 (7.4)
Cancer	11 (7.4)
Cardiovascular disease	19 (12.8)
Obese	79 (53.4)
Hernia characteristics	
Hernia size (cm^2), mean (±SD)	88.2 (130.5)
Median	30.0
Range	(1.0, 900.0)
Hernia length (cm), mean (±SD)	9.2 (8.1)
Hernia width (cm), mean (±SD)	6.8 (5.0)
Repair type, n (%)	
Laparoscopic	2 (1.4)
Robotic	79 (53.4)
Open	62 (41.9)
Open conversion	5 (3.4)
VHWG classification, n (%)	
Grade 1: low risk	49 (33.1)
Grade 2: comorbid	98 (66.2)
Grade 3: potentially contaminated	1 (0.7)
Grade 4: infected	0
Device placement (extraperitoneal)	
Onlay	3 (2.0)
Inlay	1 (0.7)
Retromuscular/sublay	65 (43.9)
Underlay	77 (52.0)
Other	2 (1.4)

BMI indicates body mass index; VHWG, Ventral Hernia Working Group.

TABLE 2. Procedure-related Endpoints Through 30 Days

Procedure-related through 30 d primary endpoints	n/N (%)
Procedural events, patients with any events through 30 d*, n/N (%)	13/148 (8.8)
95% CI	4.8, 14.6
SSI	7/147 (4.8)
SSO	2/148 (1.4)
Ileus	4/147 (2.7)
Readmission	4/148 (2.7)
Reoperation	3/148 (2.0)
Death	0/147

*Procedural events were site-reported as device or procedure-related. Patients with multiple types of events only count once for the composite endpoint in this row but may appear in multiple rows below.

SSI indicates surgical site infection; SSO, surgical site occurrence.

TABLE 3. Device-related Primary Endpoints Through 12-Months

Device-related through 12 mo primary endpoints*	n/N (%)
Patients with any device-related event through 12 mo†, n/N (%)	1/147 (0.7)
95% CI	0.02, 3.7
Device-related bowel obstruction	0/146
Device-related fistula	1/147 (0.7)
Mesh erosion	0/146
Mesh infection	1/147 (0.7)
Mesh excision/removal	1/147 (0.7)
Mesh exposure	0/146
Mesh migration	0/146
Mesh shrinkage	0/146
Hernia recurrence	0/146

*All device events were site-reported as device-related and serious.

†Patients with multiple types of events only count once for the composite endpoint in this row but may appear in multiple rows below.

TABLE 4. Secondary Endpoints

Procedure endpoints*	n/N (%)
Patients with any secondary endpoint event through 12 mo	10/148 (6.8)
Seroma†	0/146
Fistula†	1/147 (0.7)
SSI‡	7/147 (4.8)
SSO‡	5/148 (3.4)
Adhesion formation†	0/146
Bowel perforation†	0/146
Unexplained or chronic pain†	0/146
Hernia recurrence (all cause)§	0/146

*Patients with multiple types of events only count once for the composite endpoint in this row but would appear in multiple rows below.
†Site-reported as device-related and serious.
‡Site-reported as device or procedure-related and serious.
§Clinically diagnosed hernia recurrence reported as adverse event.
SSI indicates surgical site infection; SSO, surgical site occurrence.

sutures in 30 (20.3%) patients, absorbable tacks in 17 (11.5%) patients, and permanent tacks in 4 (2.7) patients. Drains were placed in 62 (41.9%) patients; of these patients, 79% of the drains were adjacent to the mesh. Twenty-one patients (14.2%) underwent repair of a recurrent hernia and of those, 15 of the previously placed devices were explanted before the placement of the PRE device.

The median patient follow-up of all patients (n = 148) was 28 months, and the mean follow-up was 24 months. This follow-up was calculated based on the latest contact data derived from follow-up visits, physical examinations, reported adverse events, explant, death, and date of last patient questionnaire response.

Procedure and Device-related Events

Tables 2 and 3 detail the procedure and device-related endpoints of the study. Overall, no deaths were reported through 12 months.

Procedure-related events through 30 days were reported in 8.8% (95% CI: 4.8, 14.6) of patients. The rate of patients requiring reoperation was 2.0% (n = 3), and readmission was 2.7% (n = 4). Through 30 days, SSIs were reported in 7 (4.8%) patients, and SSOs were reported in 2 (1.4%) patients, of which one required both readmission and reoperation. One patient developed acute hypoxemic respiratory failure (day 1 postoperative) requiring emergent intubation with concern for intra-abdominal hypertension with end-organ damage. This patient underwent an exploratory laparotomy, and the device was explanted (day 1).

There were no device-related events reported through 30 days. Through 12 months endpoint, 1 (0.7%) patient had device-related events of fistula, mesh infection, and mesh excision (day 175; device explanted day 287). This patient did not receive antibiotic treatment and ultimately had their device explanted. There were no device-related events of: device-related bowel obstruction, mesh erosion, mesh exposure, mesh migration, mesh shrinkage, or hernia recurrence at the original treatment location.

Secondary Endpoints Through 12 Months

Through 12 months, secondary endpoint events were reported in 10 (6.8%) patients (Table 4). There were no reports of device-related or serious events of seroma, known adhesion formation, bowel perforation, or unexplained or chronic pain. Further, there were no in-person clinically diagnosed hernia recurrences. One device was removed due to an abscess in the retrorectus space at 32 months (999 d) after implantation, and the patient recovered without further sequelae after removal. The percentage of patients with SSI remained at 4.8% as no further reports occurred after 30 days, 86% (6/7) of the patients that experienced an SSI had an open surgery. Only one patient who had an open repair had their mesh removed due to infection on day 287. The total percentage of patients with SSO was 3.4% of which 2 reports occurred within 30 days, 100% (5/5) of the patients that experienced an SSO had open surgery.

Tertiary Endpoints

SSOs requiring procedural intervention (SSOPI) were reported in 4 (2.7%; 95% CI: 0.7, 6.8) patients through 30 days. One patient experienced a wound infection and was treated with antibiotics and recovered without sequelae. Through 12 months, one additional SSOPI was reported bringing the total to 5 (3.4%; 95% CI: 1.1, 7.7) patients. The additional patient experienced seroma, granulation tissue, dehiscence of midline incision, and mesh infection. This patient did not undergo antibiotic treatment and ultimately had the device explanted.

Safety and Patient-reported Outcomes

Through 12 months, there were a total of 75 adverse events experienced by 49 patients. Of these, 46 SAEs were reported in 36 patients and are inclusive of SAEs captured as part of the primary and secondary endpoints. Device and procedure-related serious and non-SAEs through 12 months are detailed in Table 5.

Recurrence and Patient-reported Outcomes

There were no in-person clinically diagnosed hernia recurrences through 28 months (median) follow-up. The VHRI PRO questionnaire was completed by 59.5% (88/148) of patients. The median number of years to completion of the PRO was 36 months (range: 15 to 60 mo). At any time, a "yes" response was reported by 11 (12.5%) patients for the question "Do you feel or see a bulge at the treatment site?" For the question "Do you feel your hernia has come back?", 6 (6.8%) patients responded "yes" and for "Do you feel physical symptoms of pain at the site?", 12 (13.6%) patients responded "yes." None of these patients chose to follow-up in-person to determine whether or not they had a recurrence.

Mesh Explant

In this study, 3/148 (2.0%) patients had the PRE device removed during the study. Of the 3 devices that were explanted, 2 were explanted due to infections, whereas the third device was explanted due to a subsequent procedure on postimplantation day 1. Postoperatively, the patient developed acute hypoxemic respiratory failure requiring emergent intubation with concern for intra-abdominal hypertension with end-organ damage, which was noted as procedure-related. One of the 2 devices, removed due to infection, was explanted 287 days postimplantation. This patient had an SSI and seroma at the incision site shortly after surgery. Multiple attempts were made to treat the wound infection, including a topical antimicrobial agent; systemic antibiotics were not administered. A mesh infection was observed 5 months later; no additional treatment of the infection was attempted before the device explant. The

TABLE 5. Device and Procedure-related Events Through 12 Months

Patient	Event	Study day of onset	SAE (Yes/No)	Study device or procedure relationship
1	Device-related infection	175	Yes	Device
2	Abdominal pain	78	Yes	Procedure
3	Abdominal wound dehiscence	22	Yes	Procedure
	Open wound of abdominal wall	36	Yes	Procedure
	Abdominal wall wound	50	Yes	Procedure
	Wound abscess	74	Yes	Procedure
4	Suture granuloma	168	No	Procedure
5	Wound infection	28	Yes	Procedure
6	Abdominal seroma	21	No	Procedure
7	Postoperative pain	0	Yes	Procedure
	Scar pain	158	No	Procedure
8	Postoperative pain	0	Yes	Procedure
9	Postoperative pain	0	Yes	Procedure
	Pulmonary embolus	7	Yes	Procedure
10	Postoperative bleeding	0	Yes	Procedure
	Postoperative pain	0	Yes	Procedure
11	Postoperative pain	0	Yes	Procedure
	Wound necrosis	2	Yes	Procedure
	Thrombosis venous deep	15	Yes	Procedure
12	Postoperative pain	0	Yes	Procedure
	Abdominal pain	4	Yes	Procedure
	Ileus	4	Yes	Procedure
13	Postoperative pain	0	Yes	Procedure
	Wound necrosis	44	Yes	Procedure
	Seroma	83	Yes	Procedure
	Implant site seroma	83	No	Procedure
14	Postoperative pain	0	Yes	Procedure
	Postoperative ileus	2	Yes	Procedure
	Postoperative pain	86	Yes	Procedure
15	Postoperative pain	0	Yes	Procedure
	Cellulitis	15	No	Procedure
16	Ileus	0	Yes	Procedure
17	Cellulitis	18	Yes	Procedure
	Cellulitis of abdominal wall	41	Yes	Procedure
	Fever	8	Yes	Procedure
18	Acute kidney injury	0	No	Procedure
19	Abdominal wall abscess	29	Yes	Procedure
20	Intra-abdominal hypertension	1	Yes	Procedure
	Acute hypoxic respiratory failure	1	Yes	Procedure
21	Postoperative pain	0	No	Procedure
	Incision site erythema	27	No	Procedure
	Seroma	35	No	Procedure
22	Incision site discharge	16	Yes	Procedure
	Seroma	35	Yes	Procedure
	Granulation tissue	35	No	Procedure
	Wound dehiscence	77	Yes	Procedure
23	Purulent discharge	23	No	Procedure
24	Drain site complication	21	Yes	Procedure
25	Seroma	29	No	Procedure

SAE indicates serious adverse event.

second explant due to infection occurred on day 999 postimplantation. This patient presented with an abscess, and as a result, treatment of the infection before the device explant was not attempted. This explant was also determined to be device-related but was beyond the 12-month device endpoint window.

DISCUSSION

This review of 148 patients with ventral hernias treated with the PRE device provides further evidence supporting the extraperitoneal placement and use of a hybrid biomaterial for ventral and incisional hernia repair in complex, high-risk patients. Over half of the study population had a VHWG grade 2 classification. Through 30 days, the primary endpoint of the rate of procedure-related SSI was 4.8%. Rates of SSO, SSOPI, ileus, readmission, and reoperation were $<3\%$. Only one patient had device-related events through 12 months and had to have the device explanted. There were no in-person clinically diagnosed hernia recurrences during the study.

The use of a hybrid absorbable and permanent component mesh is based on previous research. The PGA: TMC polymer-based absorbable mesh, GORE BIO-A Tissue Reinforcement (W. L. Gore & Associates, Inc.), has been shown to stimulate tissue ingrowth in animal models.[23] A retrospective review of 81 patients who underwent open complex ventral and incisional hernia

repairs with the PGA:TMC polymer used in the retrorectus position showed favorable outcomes at 22 months with a recurrence rate of 8%.[24] Further, long-term follow-up of these patients demonstrated continued durable repairs with a recurrence rate of 18% at 6 years, approaching rates reported for permanent mesh.[16,25,26] Despite the initial success of absorbable PGA:TMC alone, long-term recurrences in hernia repair can be related to continued weakening of the reinforcing material, patient factors, SSIs, need for additional operations, and undetectable early recurrences enlarging to become detectable.[27,28] Therefore, despite the initial success of absorbable material alone, additional long-term strength might improve the recurrence rate compared with absorbable mesh alone. Therefore, a hybrid mesh utilizing both the tissue ingrowth stimulation from absorbable web scaffold material and a macroporous durable permanent polymer might combine the best properties of each material. Unlike previous meshes that utilized expanded PTFE, the material in this study uses full-density PTFE which is macroporous and monofilament. The weight of the permanent component of this mesh is 101 g/m^2. The permanent and absorbable components of the mesh are essentially equal in weight in the product at implantation. This study shows that the hybrid material had no recurrences reported at a median of 28-months for all follow-up methods.

The retrorectus mesh position continues to demonstrate an ideal placement for mesh reinforcement of ventral hernias.[24,29–31] It has been postulated that the robust blood supply of the rectus muscles allows rapid tissue ingrowth with host immune cells at first and later fibroblasts. For this reason, over 95% of the patients in this study had their mesh placed in the retrorectus plane. At the same time, the mesh is sandwiched into a tight space between the rectus muscle and the posterior rectus sheath which limits the forces on the mesh that contribute to its movement and possible failure. In addition, all of the mesh was secured to the patient with fixation. The authors feel that fixation not only keeps the mesh from shifting during the ingrowth process, but it also helps take tension off of the fascial closure to allow a more durable union. Despite the success of retrorectus ventral hernia repairs, there is a real incidence of hernia recurrences when using macroporous mesh alone in the retrorectus position. Cobb et al[26] reported that light-weight polypropylene mesh yielded the highest rate of recurrence, 22.9% with a mean time to recurrence of 19.2 months. This likely means that despite the initial approximation of the abdominal wall, the formation of durable healing between the two fascial edges can break down and fail when the mesh fractures from repetitive stress. This recurrence rate is higher than when using absorbable PGA:TMC mesh alone.[24] Since the absorbable mesh is completely resorbed within 6 to 7 months,[19,20] one possible explanation for the success of the absorbable mesh is the absorbable material may create a more durable fusion of the abdominal wall than permanent material. Therefore, the combination of a permanent durable macroporous mesh with the absorbable PGA:TMC mesh in the PRE device may have been what led to the favorable results seen in this study.

Limitations

Though the results of this study are encouraging, the results are limited namely by the retrospective nature of the study. In addition, this is a single-arm study without a control group. The inclusion criteria for patients in this study does not incorporate all of the patients that each of the contributing surgeons operated on. While it might have been possible to retrospectively case-match study patients with other patients within the practices of the authors, there would be significant heterogeneity between the surgical approaches, type of mesh used, and patient characteristics and increasing the likelihood of selection bias. In addition, the average follow-up for all patients in this study was 2 years. Since hernia recurrences traditionally continue to accumulate over time, 2 years is relatively short in the life of these patients. Possible directions for future work include additional follow-up with these patients at 5 or 10 years.

Finally, an argument could be made that the surgeons in the study were experienced with the material, and, therefore, might have better outcomes. While this may be true, the biggest learning curve is in the dissection of the retrorectus space and the decision process of when to perform a component separation to get adequate mobilization of the rectus complex. The use of the mesh itself was straight forward and did not require any significant training.

CONCLUSIONS

This retrospective study was designed to collect device-relevant information to assess the performance and safety of the PRE device for the repair of ventral or incisional hernias in a real-world commercial application. The study represents a heterogenous population with diverse demographics, including patients that are predominantly comorbid (VHWG grade 2), undergoing complex ventral hernia repair utilizing various surgical approaches and mesh fixation techniques. The clinical data document the safe and effective use of this novel hybrid mesh that incorporates the proven advantages of both an absorbable biosynthetic web scaffold and the long-term durability of a permanent macroporous mesh in such applications. When used in the extraperitoneal (retrorectus) position, the combination of these 2 materials leads to favorable wound complication and hernia recurrence results.

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