

ProceedTM Mesh for Laparoscopic Ventral Hernia Repair

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ABSTRACT

Background and Objectives: Laparoscopic technique to repair ventral hernia offers advantages over conventional open surgery such as shorter recovery time, decreased pain, and lower recurrence rates. There are a myriad of meshes available for laparoscopic repair of ventral hernias. This study evaluated the outcomes of laparoscopic repair of ventral hernias with Proceed mesh (Ethicon, Somerville, NJ, USA) in a single academic institution.

Methods: An institutional review board-approved retrospective review was performed for 100 consecutive patients with ventral hernia who underwent a laparoscopic approach at our institution from August 2006 to February 2009. All patients were operated on by a single surgeon using a standard technique with transabdominal suture fixation and tacks.

Results: The study included 100 consecutive patients (57 female and 43 male patients). The mean age was 55 years (range, 16-78 years), and the mean body mass index was 33.3 kg/m^2 (range, $19.6-68.9 \text{ kg/m}^2$). Of the repairs, 27%were performed for a recurrent hernia. The mean and median size of the defect were 128 cm² and 119.5 cm² (range, 4–500 cm²), respectively. To ensure appropriate mesh overlap, the mean size of mesh was 253 cm² (range, 36–700 cm²). There were 4 conversions. The mean operative time was 117 minutes (range, 35-286 minutes). The mean length of stay was 1.9 days. There were no major abdominal complications. With a mean follow-up period of 50 months (range, 38-68 months), we have not re-

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corded any recurrences. No mesh-related complications have been documented.

Conclusions: The laparoscopic approach to ventral hernia repairs using Proceed mesh is associated with a low conversion rate and no major complications. At 50 months of follow-up, the recurrence rate is 0%. There were no mesh-related complications.

Key Words: Hernia, Laparoscopic, Ventral Hernia, Proceed, Mesh.

INTRODUCTION

Ventral hernias continue to be one of the most prevalent complications after abdominal surgery, with an incidence of 15%. 1-3 Primary suture repair has met with dismal outcomes, with recurrence rates >50%.4 Different techniques of herniorrhaphy have been developed, but the use of synthetic mesh has been a major contributor to decreased recurrence rates, ranging from 10% to 23%.5-7 In addition to the advent of synthetic mesh, the adaptation of laparoscopy to ventral hernia repairs has led to shortened hospital stays, decreased pain, faster recovery times, decreased wound morbidity, and lower recurrence rates.8-12

Laparoscopic ventral hernia repair (LVHR) involves the placement of synthetic mesh in the intraperitoneal location, which allows direct contact of the mesh with viscera. The development of several different mesh types in recent years has been primarily done to decrease complication rates associated with adhesions without compromising tissue incorporation. The 3 most common prosthetic scaffolds are polypropylene (PP), polyester, and expanded polytetrafluoroethylene (ePTFE).¹³ Proceed mesh (Ethicon, Somerville, NJ, USA) is composed of an inner nonabsorbable PP layer surrounded by polydioxanone on each side. One side of the mesh is covered with a bioreabsorbable oxidized regenerated cellulose layer that theoretically helps to minimize bowel adhesions, thus preventing many of the complications associated with traditional synthetic mesh.14-17 Our study used the composite mesh Proceed to examine its utility in patients undergoing LVHR.

METHODS

Patient Selection

A retrospective, institutional review board–approved analysis of patients undergoing attempted LVHR with Proceed mesh by the senior author (P.B.) from August 2006 to February 2009 was performed (**Table 1**). Patient chart review was used to determine preoperative patient characteristics and postoperative outcomes.

Repair Technique

One surgeon performed all cases using a standard technique, securing the Proceed mesh in an intraperitoneal location with transabdominal suture fixation and nonabsorbable tacks, ensuring at least 3 cm of overlap. Conversion to an open technique was performed if the laparoscopic repair was unable to be completed because of either technical issues or patient safety.

All patients received prophylactic antibiotics before the first incision based on individual drug allergy information. The patient was positioned supine on the operating table. Compression boots were used for deep venous thrombosis prevention. A Foley catheter was frequently inserted depending on hernia location and size. Gastric decompression was accomplished with an oral gastric tube in all patients.

A Veress needle was used to access the peritoneal cavity, with the location dependent on the location of the hernia

 Table 1.

 Patient Demographic and Hernia Characteristics

Characteristic	Results		
Total (N)	100		
Male (n)	43		
Female (n)	57		
Age [mean (range)] (y)	55 (16–78)		
BMI [mean (range)] (kg/m²)	$33.3 \pm 9.6 (19.6 - 68.9)$		
ASA ^a score [mean (range)]	2.3 (1–3)		
Recurrent ^b (n)	26 (27%)		
Location ^b	90 midline (94%)		
Mean defect size ^b [mean (range)] (cm ²)	$128 \pm 104 (4-500)$		
Median defect size (range) (cm ²)	119.5 (4–500)		
Mesh size ^b [mean (range)] (cm ²)	253 ± 139 (36–700)		

^aASA = American Society of Anesthesiologists.

and patient's surgical history. Pneumoperitoneum was established to 15 mm Hg. After placement of the first 5-mm trocar, two additional 5-mm blunt-tip trocars and one 12-mm blunt-tip trocar were inserted under direct visualization. A 5-mm 30° laparoscope was used to fully explore the abdomen and to perform adhesiolysis. This was performed mainly with laparoscopic shears without an energy source to prevent possible thermal injury to the bowel. For an incisional hernia, a complete lysis of adhesions was performed to evaluate the entire length of the incision. The hernia sac contents were reduced, leaving the sac in situ. The defect was sized with a spinal needle, and the margins were marked on the abdominal wall.

Proceed mesh was tailored to overlap the fascial defect by at least 3 cm. A minimum of 4 No. 0 Prolene sutures (Ethicon) were placed on the mesh. The mesh was then introduced through the 12-mm trocar. After proper positioning of the mesh, a suture passer was used to pull the transfascial sutures through separate incisions and tied down. Additional sutures were placed for larger mesh sizes. The circumference of the mesh was then tacked to the posterior fascia at 1- to 2-cm intervals.

At the completion of mesh placement, the bowel was examined for possible iatrogenic injury. The omentum was observed for hemostasis if involved in the hernia sac. Then the pneumoperitoneum was released. None of the trocar fascial defects were closed. The skin incisions were closed with absorbable sutures. No drains were placed.

Follow-up

Patients were seen in the clinic after LVHR at appropriate intervals. At each clinic visit, a full examination was performed to look for complications or signs of recurrence. Data from each visit were documented in the hospital's electronic medical record.

RESULTS

During the study period, we identified 100 patients who met the inclusion criteria. Patient demographic characteristics are shown in **Table 1**. The mean patient age was 55 years (range, 16-78 years) at the time of the operation, with a mean body mass index (BMI) of 33.3 ± 9.6 kg/m² (range, 19.6-68.9 kg/m²). The mean American Society of Anesthesiologists score was 2.3 (range, 1-3), with 28 patients (28%) having a history of herniorrhaphy. Among those repairs completed laparoscopically, 90 hernias (94%) were midline with a mean fascial defect size of 128 ± 104 cm² (range, 4-500 cm²) and median fascial

^bCompleted laparoscopically.

defect size of 119.5 cm², requiring a mean mesh size of 253 ± 139 cm² (range, 36-700 cm²).

Perioperative Outcomes

There were no major intraoperative morbidities or deaths. Of the 100 total patients, 96 had their repairs completed laparoscopically; 4 patients underwent successful open repair. The reasons for conversion to open repair included dense adhesions with incarcerated bowel (2), active mesh infection with abscess (1), and respiratory compromise with persistent high end-tidal carbon dioxide (CO2) level (1) (Table 2). The mean operative time and hospital length of stay were longer for open procedures, 117 ± 54 minutes (range, 35–286 minutes) versus 261 ± 62 minutes (range, 170–311 minutes) and 1.9 days (range, 0–12 days) versus 5.1 days (range, 4-6 days), respectively. When we examined only LVHR (Table 3), there was no difference in operative time for those patients without and with previous repair, 115 ± 58 minutes (range, 35-286 minutes) versus 122 ± 68 minutes (range, 46-223 minutes) (P = not significant), nor was there a difference in conversion to open repair, 1 (1%) versus 3 (11%) (P = notsignificant). There was no difference in rates of conversion to open repair or operative time with respect to BMI (Table 4).

There were no major complications in our cohort. Minor complications included chronic pain (2) and urinary retention (1). One of the patients with chronic pain required infiltration of a local anesthetic at a suture fixation site, which resulted in the complete resolution of pain. Twenty-one patients were identified as having small seromas in the early postoperative period based on clinical examination. All of the seromas were managed expectantly without requiring aspiration.

Long-Term Outcomes

The mean follow-up period for the patient population was 50 months (range, 38–68 months). There were no recur-

Table 2. Operative and Postoperative Data				
Variable	Laparoscopic	Open		
Operative time (min)	117 ± 54 (35–286)	261 ± 62 (170–311)		
Conversions (n)	4	not applicable		
LOS ^a (d)	1.9 (0-12)	5.0 (4-6)		
Complications	3 (3%)	0 (0%)		
^a LOS = length of stay	·.			

rences documented in any patients at their follow-up visits during this period. No mesh-related complications, including infection, have been documented, and no patients have required reoperation.

DISCUSSION

The repair of abdominal wall hernias has changed considerably with advancements in laparoscopy and the use of synthetic mesh. Both are credited with reducing the long-term recurrence rates. However, placement of mesh introduces additional morbidity with wound-related complications when an open approach is chosen. LVHR has shown excellent results while minimizing these complications. Our results are consistent with the literature, which reports minimal complications and low recurrence rates in all patient populations. 8–11,17

There are numerous mesh products available, with the most commonly used being polyester, PP, or ePTFE. The different meshes are unique in their tensile strength, pore size (allowing for tissue ingrowth), ability to minimize adhesions, and complication rates.¹³ Because mesh comes into direct contact with the abdominal viscera in LVHR, there has been a recent trend toward using composite grafts. Animal studies have shown that both ePTFE and composite grafts are associated with fewer adhesions when compared with controls of PP. 18-20 We used Proceed mesh in all of our patients not just for the theoretical benefit of decreased adhesions but also because Prolene-based mesh results in good long-term outcomes in patients undergoing LVHR. No patients in our series underwent reoperation; therefore we were unable to assess for adhesive disease.

To our knowledge, this is the fourth human study to use Proceed mesh for LVHR. We encountered 3 minor complications. Twenty-one patients did have seromas in the early postoperative period. None of these seromas were symptomatic (pain and/or infection), and they did not require aspiration; thus they were not included as complications. A study regarding seroma formation after LVHR found a 100% incidence with the use of ultrasonography, 35% of which were evident on clinical examination.²¹ The development of a seroma is multifactorial and is likely related to the introduction of a foreign body eliciting an inflammatory response, as well as leaving the hernia sac intact.²²

The recurrence rate using Proceed in previous studies was 0%, 0%, and 3.5% with mean follow-up periods of 8, 17,

Table 3. Comparison of Patients With and Without Previous Herniorrhaphy				
Variable	No Previous Repair $(n = 72)$	With Previous Repair (n = 28)	P Value	
Operative time (min)	115 ± 58 (35–286)	122 ± 68 (46–223)	$P = NS^a$	
Conversions (n)	1	3	P = NS	
Complication rate	2.8%	3.6%	P = NS	
Recurrences (n)	0	0		
^a NS = not significant.				

Table 4. Comparison of Patients with Increasing Obesity					
Variable	BMI $<30 \text{ kg/m}^2 \text{ (n = 44)}$	BMI of $30-40 \text{ kg/m}^2$ (n = 39)	BMI $>$ 40 kg/m ² (n = 17)	P Value	
Operative time (min)	122 ± 61 (35–311)	124 ± 68 (44–287)	121 ± 47 (38–180)	$P = NS^a$	
Conversions (n)	1	2	1	P = NS	
Complications (n)	1	2	0	P = NS	
Recurrences (n)	0	0	0		
^a NS = not significant.					

Table 5. Previous Studies Using Proceed Mesh				
Study	No. of Patients	All Complications (%)	Recurrence (%)	Mean Follow-Up (mo)
Moreno-Egea et al. ¹⁴	50	2	0	8
Rosenberg and Burcharth ¹⁵	49	12	0	17
Berrevoet et al. ²³	114	12	3.5	27

and 27 months, respectively (**Table 5**).^{14,15,23} Compared with previous Proceed mesh studies, our study has the longest follow-up period to date with no recurrences during a mean follow-up time of 50 months (range, 38–68 months).

Conversion to open repair was performed in 4 cases (4%). Two patients underwent conversion to open repair because of dense adhesions, with one of them also having an incarcerated hernia. The third case had laparoscopic findings of an intra-abdominal wall abscess with mesh infection that required conversion for debridement and drainage. The fourth patient could not tolerate the CO₂ insufflation, resulting in respiratory compromise exhibited by a high end-tidal CO₂ level. In one of the larger cohorts, Heniford et al.¹⁰ analyzed 850 consecutive LVHR cases and found that 3.6% required conversion, with severe adhesions representing nearly half of the cases. These

data, though representing a larger cross section of patients, coincide with our rate of conversion. Though not statistically significant, our incidence of conversion was higher in those patients with a history of herniorrhaphy: 3 of 28 cases versus 1 of 72 cases. There was no difference in the rates of conversion or complications in patients with higher BMIs.

CONCLUSION

Our data from 100 consecutive patients for LVHR show that the technique along with the use of Proceed mesh is safe and effective. The results showed no mesh-related complications and no recurrences with a mean follow-up period of 50 months. There was a low conversion rate. There is an associated short hospital stay, with some patients having same-day surgery. LVHR with Proceed mesh is a safe and effective operation.

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