

Clinical Performance in Laparoscopic Ventral Hernia Repair

Literature Summary
(n=3756 patients)

Laparoscopic Ventral Hernia Repair: Clinical Performance Reported in Literature

Pooled Data from all Studies	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
GORE® DUALMESH® Biomaterial and GORE® DUALMESH® PLUS Biomaterial (n = 3756)*	4.0%	1.1%	0.0%	0.0%	4.7%	2.3%	4.0%



Performance, not just promises.

* Data based on an analysis of current literature: several Medline searches were performed to identify publications pertaining to ePTFE synthetic patches. Search criteria included (1) articles published from January 1998 through June 2009, (2) key words used were GORE-TEX®, DUALMESH®, hernia, ventral, laparoscopic, human, ePTFE, (3) articles in English language, (4) N equal to or greater than 10 hernia repairs, (5) clinical publications, (6) case reports were excluded, (7) studies which included multiple ePTFE patches were identified and percent use with GORE® DUALMESH® Biomaterial were reported in study details. Articles that did not meet the above criteria were not included in this analysis.

Materials and Performance in Laparoscopic Ventral Hernia Repair**

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Ventral incisional hernia remains one of the most common postoperative complications of abdominal surgery with rates as high as 20% after a midline laparotomy.¹ A recent prospective, randomized trial demonstrated a 50% reduction in hernia recurrence when open incisional hernia repair is performed with synthetic mesh using a retrorectus, preperitoneal technique.

Nevertheless, the 10-year cumulative rate of recurrence for mesh repair was 32%.² Due to frequent recurrences of incisional hernias after open mesh repair in long-term follow-up, patients are subjected to repeat operations, exposing themselves to significant morbidity and increasing health care expenditures to manage abdominal wall defects. As an alternative to open mesh repair of incisional hernias, laparoscopic ventral hernia repair was developed and first reported by LeBlanc in 1991.³

Laparoscopic ventral hernia repair is an intraperitoneal technique in which a prosthetic biomaterial is placed intra-abdominal against an intact peritoneum and anchored to the posterior abdominal wall with transabdominal sutures and titanium spiral tacks or stainless steel rings.

The repair avoids wide fascial dissection and flap creation, allows for an increased surface area ratio of mesh to hernia defect size and facilitates exposure and mesh coverage of the entire length of a previous abdominal incision and contiguous areas potentially at risk for herniation. A recent meta-analysis of laparoscopic versus open ventral hernia repair by Pierce et al reported fewer wound-related and overall complications and a lower rate of hernia recurrence for laparoscopic ventral hernia repair.⁴

In one of the largest published series to date, Heniford et al reported a recurrence rate of 4.7% after laparoscopic ventral hernia repair during a mean follow-up of 20 months in 744 patients available for postoperative evaluation.⁵ Laparoscopic ventral hernia repair is now being utilized increasingly in the management of patients with uncomplicated as well as more complex incisional hernias.

Despite the excellent results and low recurrence rates obtained with laparoscopic ventral hernia repair, the placement of prosthetic biomaterials into the peritoneal cavity has not been standard surgical practice since the widespread use of polypropylene and polyester mesh began over four decades ago. The development of intra-abdominal adhesions to the macroporous mesh and the potential complications of bowel obstruction and enterocutaneous fistula are among the many concerns related to the intraperitoneal placement of prosthetic biomaterials. Prosthetic biomaterials elicit inflammatory responses which are dependent on the unique properties (porosity, electrical charge, surface chemistry, texture) of each individual mesh.

The intraperitoneal host tissue response to the prosthetic biomaterial also determines its biocompatibility and a greater foreign body response. Macroporous (polypropylene and polyester) prosthetic biomaterials tend to promote more vigorous adhesion formation and tissue ingrowth compared to microporous prosthetic biomaterials such as expanded polytetrafluoroethylene (ePTFE) when placed in direct contact with the intestines. Macroporous prosthetic biomaterials have a propensity to potentiate biomaterial-related complications.

In clinical studies, the most reliable adhesion-resistant prosthetic biomaterial for intra-abdominal placement during laparoscopic ventral hernia repair has been 100% expanded polytetrafluoroethylene (GORE® DUALMESH® Biomaterial, W. L. Gore & Associates, Flagstaff, AZ). In fact, Koehler *et al.* reported minimal adhesions to ePTFE mesh after laparoscopic ventral hernia repair in 65 re-operative cases with a mean mesh implantation time of 420 days (range, 2-1739).⁶ Novel, adhesion-resistant composite biomaterials with absorbable and nonabsorbable barriers covering macroporous polypropylene and polyester mesh have been developed and are commercially available for clinical use.

But, an evidence-based approach to selecting a biomaterial for laparoscopic ventral hernia repair is crucial to minimize hernia recurrence and ensure long-term protection from mesh-related complications.

**This work was prepared with financial support from W. L. Gore & Associates, Inc.

Performance, not just promises.

▶ Laparoscopic Ventral Hernia Repair: Clinical Performance Reported in Literature

Repair Type	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
GORE® DUALMESH® Biomaterials and GORE® DUALMESH® PLUS Biomaterials (n = 3756)*	4.0%	1.1%	0.0%	0.0%	4.7%	2.3%	4.0%

As Compared To

Open Primary (no mesh)	Up to 51% [†]	N/R	N/R	N/R	N/R	N/R	N/R
Open with Mesh	10-24% [†]	5-10% ^{††}	N/R	N/R	N/R	N/R	N/R
Polyester Mesh [#]	34%	16%	16%	N/R	N/R	N/R	N/R
Polypropylene Mesh [#]	15%	5%	1.7%	N/R	N/R	N/R	N/R

N/R – Not reported in the literature

[†] LeBlanc KA. Incisional hernia repair: laparoscopic techniques. *World Journal of Surgery* 2005;29(8):1073-1079.

^{††} Fabian TC, Croce MA, Pritchard FE, et al. Planned ventral hernia. Staged management for acute abdominal wall defects. *Annals of Surgery* 1994;219(6):643-650.

[#] Leber GE, Garb JL, Alexander AI, Reed WP. Long-term complications associated with prosthetic repair of incisional hernias. *Archives of Surgery* 1998;133:378-382.

Recurrences after laparoscopic repair of ventral and incisional hernia: lessons learned from 505 repairs

Wassenaar, *et al.*, 2009⁷

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
N=505	1.8%	0.8%	N/R	N/R	8.6%	1.2%	2.2%

Study Details

- Retrospective study; January 2001 through December 2005
- Follow-up examinations at two, six, and 12 weeks and one year
- Mean follow-up 31.3 months
- GORE® DUALMESH® Biomaterial for all patients
- Mean BMI 29.8

Type of Hernia	Number of Repairs
Ventral	291
Umbilical	206
Epigastric	65
Spigelian	20
Incisional	214
Midline	94
Subcostal right	27
Transverse right or left	16
McBurney	11
Lumbar	1
Parastomal	2
Pfannestiel	6
Other*	57

Conclusion

“[GORE® DUALMESH® Biomaterial] The prosthesis used in our series can be visualized on CT scans, so imaging usually allows the clinician to determine whether the patient has a recurrence or bulging from a mesh protrusion.”

“The most common cause of hernia recurrence after laparoscopic repair of IS [incisional hernia] is disregard for a principle that is established in open hernia repair: that the whole incision — not just the hernia — must be addressed.”

* Recurrent umbilical, recurrent epigastric, trocar site

▶ Laparoscopic repair of incisional hernia: Outcomes of 100 consecutive cases comprising 25 wall defects larger than 15 cm

Ferrari, *et al.*, 2008⁸

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
N=100	3%	1%	N/R	N/R	2%	3%	3%

Study Details

- Retrospective study; April 2002 through April 2007
- Follow-up examinations at 10, 30, 60, 90, 180, and 360 days
- Mean follow-up 24 months
- GORE® DUALMESH® PLUS Biomaterial for all patients
- 25 patients with defects greater than 15 cm, six patients with greater than 20 cm

Dimensions of defects (diameter, area)

	n (Total n = 100)
Small (<5 cm)	5
Medium (5-10 cm)	41
Large (>10 cm)	52
Giant (>20 cm)	2

Conclusion

“Surgical repair by minimal access of fascial defects larger than 15 cm in diameter seems to be promising and should have the same outcomes as that of laparoscopic repair of smaller defects.”

Open and Laparoscopic Approach in Incisional Hernia Repair with ePTFE Prosthesis

Zografos, *et al.*, 2007⁹

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
Open (n = 73) [†]	2.6%	3.9%	0.0%	0.0%	0.0%	0.0%	N/R
Laparoscopic (n = 30)	3.3%	0.0%	0.0%	0.0%	0.0%	0.0%	N/R

Study Details

- Retrospective study; July 1997 through December 2004
- Mean follow-up was 52 months (range 15-107)
- GORE® DUALMESH® Biomaterial for 103 patients had
 - 3 patients removed from summary above had polypropylene mesh
 - 9 patients underwent open repair for recurrent hernias
 - A patient treated with polypropylene mesh developed a colocutaneous fistula

Conclusion

“The expanded polytetrafluoroethylene (ePTFE) prosthesis has advantage over the polypropylene mesh, regarding adhesion formation with the bowel, and facilitates mesh removal, if required.”

“It is widely acknowledged that the ePTFE mesh has the fewest bowel complications associated with its use.”

“We have abandoned the use of polypropylene mesh, and we are currently using the ePTFE mesh.”

[†] These 73 patients are not included in the overall summary since they were an open ventral hernia repair. They are only included in the above table as reference and summary of the complete paper.

Laparoscopic Mesh Repair of Incisional Hernia: An Alternative to the Conventional Open Repair

Stickel, *et al.*, 2006¹⁰

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 62	5.2%*	1.6%	0.0%	0.0%	N/R	N/R	See study details

N/R – Not reported in the literature *Based on 57 patients available to follow up

Study Details

- Retrospective study; January 2000 through June 2005
- Median follow-up was 13 months; 62 patients analyzed, 5 lost during follow-up
- GORE® DUALMESH® Biomaterial in all patients
- Postoperative pain evaluated in the style of the McGill pain questionnaire
- 49% reported no or little postoperative pain, 35% reported mild to moderate postoperative pain
- Overall patient contentment was reported as good, 63% were very content
- 85% of patients indicated they would choose a laparoscopic approach for hernia repair

Conclusion

“In general, complications following laparoscopic hernia repair appear to be rare and are observed more frequently in the early phase of the learning curve.”

“The laparoscopic approach results in lower wound complication rates, including haematoma, infections and wound dehiscence.”

“Patient contentment was high in our study with little postoperative pain and fast return to normal activity was noted.”

▶ Laparoscopic Ventral Hernia Repair: A Single Center Experience

Cobb, *et al.*, 2006¹¹

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 270	4.7%	0.7%	0.0%	0.0%	0.7%	0.7%	3.2%

Study Details

- Retrospective study; July 1998 through December 2003
- Prospective data collection with follow-up times extending greater than 6 years
- GORE® DUALMESH® Biomaterial used in all cases
- Mean defect size of 143.3 cm²
- Majority were obese with average BMI of 33 kg/m²
- 97% had prior abdominal surgery, 50% had prior failed repair
- 270 of 277 had successful LVHR procedures

Conclusion

“The results of these studies point to LVHR as having reduced perioperative morbidity and reduced rates of hernia recurrence during follow-up.”

“Our choice of mesh is also partially based on its ability to reduce the incidence of infection. W. L. Gore & Associates have impregnated their ePTFE mesh with silver/chlorhexidine. In both in vitro and in vivo experiments, we demonstrated the ability of [GORE® DUALMESH® PLUS Biomaterial] to kill bacteria and resist infection.”

Laparoscopic Ventral Hernia Repair in Obese Patients

Novitsky, *et al.*, 2006¹²

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 163	5.5%	1.2%	0.0%	N/R	See details	N/R	3.7%

N/R – Not reported in the literature

Study Details

- Retrospective study; July 1, 1998 through December 31, 2003
- Mean follow-up of 25 months
- GORE® DUALMESH® Biomaterial used
- Mean defect size of 148 cm²
- BMI ≥ 30 kg/m²
- 67% of patients BMI ≥ 35 kg/m²
- 54.6% had prior failed open hernia repair
- Seromas were formed in almost all patients and resolved without intervention

Hernia Details

Location	n =
Center or Periumbilical	60
Upper Midline	56
Lower Midline	44
Right Upper Quadrant	20
Right Lower Quadrant	18
Left Upper Quadrant	7
Left Lower Quadrant	14
Other	2

Conclusion

“ . . . the placement of an adequate prosthesis that allows for an extensive overlap of the abdominal wall defects is mandatory.”

“Such seromas are common and rarely require intervention . . . given their common occurrence, self-limiting nature, and the fact that seromas were essentially never reported in the literature describing open ventral hernia repair, we no longer consider seromas as complications unless they require an intervention.”

“ . . . we believe that in experienced hands LVHR may be the approach of choice for most patients with a BMI of 30 or higher.”

Laparoscopic Ventral Hernia Repair with the Goretex Dualmesh: Long-term Results and Review of the Literature

Ph. Topart, *et al.*, 2005¹³

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=151 [*]	5.4%	1.3%	0.0%	0.0%	2.6%	N/R	2.6%

N/R – Not reported in the literature ^{*}146 patients with 151 repairs

Study Details

- Retrospective study; March 1997 through March 2003
- Mean follow-up 26.6 months
- GORE® DUALMESH® PLUS Biomaterial
- Mean defect size was 6.5 cm
- Mean BMI was 28.5 kg/m², 10% of the patients had BMI ≥ 30 kg/m²
- Mean age 57.4 years
- 73% of patients underwent incisional hernia repair
- 22% of patients had a failure of a previous ventral hernia repair
- 31 patients complained of pain in the mesh fixation areas

Conclusion

“Laparoscopic ventral hernia repair using the [GORE® DUALMESH® Biomaterial] is a reliable operation with a low rate of conversion to open.”

“Most of the published series of laparoscopic ventral hernia repair use ePTFE graft.”

“Intraoperative mesh placement has been made possible with the use of ePTFE while avoiding the risk of bowel fistula and with a reduction in adhesion formation.”

Laparoscopic Ventral Hernia Repair without Sutures – Double Crown Technique: Our Experience After 140 Cases with a Mean Follow-up of 40 Months

Morales-Conde S, *et al.*, 2005¹⁴

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=140	2.1%	0.0%	0.0%	0.0%	2.1%	1.4%	N/R

N/R – Not reported in the literature

Study Details

- November 1998 through September 2003
- GORE® DUALMESH® PLUS Biomaterial with Holes used in all cases
- Mean defect size 115.87 cm²
- Mean age 57.61 years
- 140 hernia repairs in 135 patients

Type of Hernia	Number of Repairs
Incisional	122
Primary	18
Umbilical	9
Epigastric	7
Spigelian	2

Conclusion

“ . . . the mesh infection rate was 0%, in keeping with results reported by other authors who do not use these [transmural] sutures.”

Minimally Invasive Incisional Herniorrhaphy: A Review of 208 Cases

Frantzides CT, *et al.*, 2004¹⁵

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 208	1.4%	0.0%	0.0%	0.0%	*	1.4%	N/R

*seromas formed but not associated with morbidities and were excluded, N/R – not reported

Study Details

- Retrospective review; January 1995 through December 2002
- Median follow-up of 24 months (6 to 72 months)
- GORE® DUALMESH® Biomaterial
- Mean defect size 173 cm²
- Postoperative routine visits at one week, one month, and six months followed by yearly appointments

Conclusion

“The real risk of placing polypropylene mesh on the intestines has been described, but it seems that PTFE does not carry the same risk.”

“To date, the collective world experience with intraperitoneal placement of PTFE for elective incisional hernia repair suggests that this procedure does not pose a significant risk to the patient.”

Complications of Laparoscopic Incisional – Ventral Hernia Repair

Bower CE, *et al.*, 2004¹⁶

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 100	2.0%	2.0%	0.0%	0.0%	1.0%	2.0%	3.0%

Study Details

- Retrospective review; August 1999 through January 2003
- Follow-up consisted of three week and six week visits
- GORE® DUALMESH® Biomaterial and GORE® DUALMESH® PLUS Biomaterial used in all cases
- Mean defect size 124.4 cm²
- Mean BMI of 33.9 kg/cm²
- 32% had previous incisional repairs

Conclusion

“[GORE® DUALMESH® Biomaterial] has a smooth side and a textured side. The smooth side of the polytetrafluoroethylene has demonstrated a unique property of providing a surface that causes low incidence of postoperative complications involving the viscera.”

“Polypropylene was not used because it was previously reported to have several potential complications including fistulization.”

“The LIVH procedure may be performed safely with low complication and recurrence rates.”

Laparoscopic Incisional and Ventral Hernioplasty: Lessons Learned from 200 Patients

KA LeBlanc, *et al.*, 2003¹⁷

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
Group I, n=100	9.0%	2.0%	0.0%	0.0%	8.0%	7.0%	7.0%
Group II, n=100	4.0%	2.0%	0.0%	0.0%	7.0%	9.0%	2.0%
Total, n=200	6.5%	2.0%	0.0%	0.0%	7.5%	8.0%	4.5%

Study Details

- Group I represents early experience with laparoscopic approach GORE® DUALMESH® Biomaterial and GORE® DUALMESH® PLUS Biomaterial used in 176 patients, GORE-TEX® Soft Tissue Patch used in 29 patients from the early Group I study
- Median age 57.8 years
- Defect size 2.25-600 cm²
- 21% were recurrent hernias
- 43 “Swiss-cheese” multiple defects

Type of Hernia	Number of Repairs
Incisional	181
Midline	167
Postcolostomy	3
Right subcostal	4
Pfannenstiel	2
Appendectomy	2
Flank incisional	2
Renal transplant	1
Primary	18
Midline	8
Umbilical	3
Spigelian	1
Other	6
Unknown	1

Conclusion

“The current state of the art should include judicious use of any energy source to dissect adhesions, the placement of ePTFE as the prosthesis of choice, a minimum of a 3-cm overlap, and dual methods of fixation by transfacial sutures and tacks or Salute constructs.”

Laparoscopic Repair of Ventral Hernias Nine Years' Experience with 850 Consecutive Hernias

BT Heniford, *et al.*, 2003⁵

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=850	4.7%*	0.7%*	0.0%*	0.0%*	2.6%*	3.0%*	1.6%*

Seroma is defined as persistent if ≥ 8 weeks; pain is defined as prolonged if ≥ 6 months

*744 patients available for follow up on recurrences, 819 patients for others

Study Details

- Multicenter study (4 clinical centers); November 1992 through February 2003
- Mean follow-up time 20 months (range 1 to 96 months)
- GORE[®] DUALMESH[®] Biomaterial used in 97% cases
- Mean defect size 118 cm²
- Mean BMI 32.1 kg/m²
- 850 patients; 85% prospectively collected
- Yearly follow-ups
- 34% cases had prior open hernia repairs

Conclusion

"The most commonly used mesh in laparoscopic ventral hernia repair has been an expanded polytetrafluoroethylene material with a smooth, microporous (3 μ m pores) surface on one side and a corrugated (rough) surface on the other [(GORE[®] DUALMESH[®] Biomaterial)]."

"The products combined with polypropylene had significantly more intestinal adhesions and no greater abdominal wall ingrowth than the pure e-PTFE product. These findings along with the lack of reported bowel obstruction or fistula formation have dictated our prosthetic choices."

Laparoscopic Approach to Incisional Hernia: Lessons Learned from 270 Patients Over 8 Years

Carbajo MA, et al., 2003¹⁸

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=270	4.4%	0.0%	0.0%	0.0%	11.8%	N/R	7.4%

N/R – not reported

Study Details

- Prospective study; January 1994 through November 2000
- Mean follow-up 44 months
- GORE® DUALMESH® PLUS Biomaterial
- Mean defect size 145 cm²
- 61% of patients had BMI ≥ 30 kg/m²
- 27% had prior hernia repair
- Postoperative follow-up every 3 months in yr 1, every 6 months year 2, annually after 2 years
- 96% follow-up in year 1, 88% follow-up year 2, 74% in remaining years
- 1 patient developed a small bowel fistula 2 months postoperatively unrelated to the mesh.

Conclusion

“We use the [GORE® DUALMESH® PLUS Biomaterial] because of its well proven integration conditions, resistance, limited inflammatory tissue reaction, and low degree of peritoneal adherence.”

“We do not advise the use of Marlex or polypropylene meshes described in some series because of their high risk of fixing, tissue breakthrough, and long-term complications.”

“Meshes of composite . . . are alternatives, but large series are needed with long-term results to determine their effectiveness.”

Medium-term Follow-up Confirms the Safety and Durability of Laparoscopic Ventral Hernia Repair with PTFE

Eid GM, *et al.*, 2003¹⁹

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=79	5.0%	0.0%	0.0%	0.0%	3.8%	1.3%	3.8%

Seroma is defined as persistent ≥ 8 weeks; pain is defined as prolonged ≥ 8 weeks

Study Details

- Retrospective data analysis; March 1996 through December 2001
- 1 year follow-up
- GORE® DUALMESH® PLUS Biomaterial (96% of patients)
- Mean defect size 103 cm²
- 24% of patients had BMI ≥ 35 kg/m²
- Prior abdominal surgeries average 2
- 17 patients being treated for recurrent hernias
- 20 had “Swiss-cheese” multiple defects
- 101 patients underwent LVHR with 79 patients followed greater than 1 year

Conclusion

“We used ePTFE mesh in 97% of the repairs with no evidence of fistula formation in our series. With a limited inflammatory response, a pliable nature, and a nonabrasive character, we find the ePTFE mesh to be particularly well suited for the repair of large ventral hernias.”

▶ The Experience with a Modified Technique or Laparoscopic Ventral Hernia Repair

Mizrahi, *et al.*, 2003²⁰

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 231	3.4%	3.0%	0.0%	0.0%	4.3%	N/R	N/R

N/R – not reported

Study Details

- Prospective study; January 1997 to December 2001
- Follow-up between 12 to 18 months
- GORE® DUALMESH® Biomaterial
- 8.6% of the patients had seromas that spontaneously resolved

Conclusion

“We observed that when the operation is performed in a patient with a large ventral hernia, a reactive seroma may develop that will be resorbed spontaneously most of the time.”

“We also found that meticulous surgical manipulation of the mesh reduces the rate of infected hematoma, and that appropriate placement of the spiral pins onto the healthy rim of the fascia (not snuggling it into the fatty parietal peritoneum) reduces the rate of recurrence.”

Postoperative Complications After Laparoscopic Incisional Hernia Repair

Berger, *et al.*, 2002²¹

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 150	2.7%	0.0%	0.0%	0.0%	See study details	1.3%	N/R

N/R – not reported

Study Details

- Prospective study; September 1999 through September 2001
- Follow-ups after 4 weeks, 3, 6, 12, and 24 months
- GORE® DUALMESH® Biomaterial
- Primary hernia mean size 96 cm², recurrent hernia size 83 cm²
- Primary hernia mean BMI 29 kg/m², recurrent hernia mean BMI 32 kg/m²
- IPOM technique
- 130 primary hernia and 20 recurrent repairs
- Seroma/hematoma determined by ultrasound, 5 treated with puncture, 1 with drainage

Conclusion

“The laparoscopic repair of incisional hernia is a surgically challenging but safe procedure.”

“No primary mesh infection was observed in our series in contrast to about 1% in other reports...”

Laparoscopic Incisional/Ventral Herniorrhaphy: A Five Year Experience

Roth JS, *et al.*, 1999²²

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 150	2.7%	0.0%	0.0%	0.0%	4.0%	1.3%	N/R

N/R – not reported

Study Details

- Prospective data collection; December 1993 through January 1999
- Mean follow-up 17 months
- GORE® DUALMESH® Biomaterial for 84% of patients
- Mean defect size 101.1 cm²
- Mean BMI of 33.8 g/m²
- Postoperative care at 1, 6, and 12 months, annually thereafter

Conclusion

“Since the patch is thus in direct contact with the abdominal viscera, ePTFE is the biomaterial of choice.”

Recurrences in Laparoscopic Incisional Hernia Repairs: A personal Series and Review of the Literature

Koehler and Voeller, 1999²³

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=34	9.0%	5.9%	0.0%	0.0%	5.9%	N/R	N/R

N/R – not reported

Study Details

- Retrospective study; January 1996 through January 1999
- Median follow-up 20 months
- GORE® DUALMESH® Biomaterial used in all cases
- 38% previous repair
- 15% had previous mesh placement

Type of Hernia	Number of Repairs
Upper Midline	9
Midline	3
Lower Midline	5
Epigastric	4
Umbilical	3
Subcostal	6
Paramedian	3
Lower Transverse	1

Conclusion

“In our series, three patients with [GORE® DUALMESH® Biomaterial] were reoperated upon at 2 weeks, 6 months and 15 months. Adhesions of bowel to the [GORE® DUALMESH® Biomaterial] were seen but were relatively tenuous and easily lysed.”

“Due to the extreme adhesions between PP[polypropylene] mesh and intra-abdominal contents that we and others have experienced in LIVH surgery. . .we feel that PP is not an acceptable material for LIVH repair – given the advantages of ePTFE with regards to adhesion formation.”

Laparoscopic Repair of Postoperation Ventral Hernia

Kyzer S, et al., 1999²⁴

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n=53	1.9%	1.9%	0.0%	0.0%	N/R	N/R	N/R

N/R – not reported

Study Details

- All patients in 1996
- Median follow-up of 12 months (range 10 – 22 months)
- GORE® DUALMESH® Biomaterial used in all cases
- Median defect 117 cm²
- 55% previous repair
- 33% had multiple defects

Conclusion

“The intraperitoneal use of the ePTFE prosthesis is safe. Its use does not result in serious complications as reported with the use of Marlex mesh, such as bowel obstruction, bowel fistulization, and mesh migration.”

“[GORE® DUALMESH® Biomaterial] offers the unique advantage of two functionally distinct surfaces . . . These two distinctly different surfaces promote minimal tissue attachment to the peritoneal surface of the mesh while allowing characteristic infiltration to the other surface.”

► Prospective, Multicenter Study of Laparoscopic Ventral Hernioplasty: Preliminary Results

Toy FK, *et al.*, 1998²⁵

Total	Recurrence Rate	Infection	Fistula	Erosion	Seroma	Ileus	Pain
n = 144	4.2%	3.5%	0.0%	0.0%	16.0%	2.1%	N/R

N/R – not reported

Study Details

- Prospective, multi-center study; 2 year results
- Mean follow-up 222 days (range 7-731 days)
- GORE® DUALMESH® Biomaterial used in 88% cases (remainder used GORE-TEX® Soft Tissue Patch)
- Mean defect size 98.3 cm²
- 26% of the patients with recurrent ventral hernia
- 15 seromas resolved uneventfully within 30 days, 2 resolved after 30 days, 6 required aspiration (n = 23)

Type of Hernia	Number of Repairs
Incisional	92
Epigastric	11
Umbilical	23
Spigelian	2
Combination (≥ 1 type)	16

Conclusion

“ . . . We believe that ePTFE mesh is the most appropriate material for this procedure because it evokes minimal inflammation and little foreign-body response and adhesion formation while allowing good tissue ingrowth.”

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