



# Feasibility of laparoscopic abdominal wall reconstruction in an outpatient community-hospital setting using cPTFE prosthetic mesh: a prospective, multicenter case series

Terry Unruh<sup>1</sup>, Joseph Adjei Boachie<sup>2</sup> and Eduardo Smith-Singares<sup>3</sup>

## Abstract

**Objective:** This study investigated the use of prosthetic condensed polytetrafluoroethylene (cPTFE) for laparoscopic ventral hernia repair (LVHR) in an outpatient community-hospital setting.

**Methods:** Patients underwent LVHR with cPTFE at one of three community hospitals. Primary endpoint was hernia recurrence at 1-year postoperatively. Secondary endpoints included pain, surgical site infection, medical/surgical complications, and patient-reported outcomes.

**Results:** This study included 65 females and 52 males, aged  $46.6 \pm 13.2$  years (mean  $\pm$  SD; range 18–84 years). Mean prosthetic size was  $413.8 \pm 336.11$  cm<sup>2</sup> (range 165–936 cm<sup>2</sup>). Mean follow-up was 30 months (range 12–46 months). Hernia recurrence rate was 4.3%. Rate of hospitalization in the first postoperative week was 2.6%. Early and late secondary endpoint complication rates were 24.8% and 27.4%, respectively; pain was the most common complication, followed by seroma (8.5%).

**Conclusions:** Outpatient LVHR using cPTFE is feasible in community hospitals. Complication rates were similar to previous reports, and the seroma rate was markedly lower.

## Keywords

cPTFE mesh, incisional hernia, outpatient laparoscopic hernia, ventral hernia

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<sup>1</sup>Department of Surgery, Medical Center Hospital & Odessa Regional Medical Center, Odessa, TX, USA

<sup>2</sup>College of Medicine, University of Illinois at Chicago, Chicago, IL, USA

<sup>3</sup>Department of Surgery, Division of Surgical Critical Care, University of Illinois at Chicago, Chicago, IL, USA

## Corresponding author:

Eduardo Smith-Singares, Department of Surgery, Division of Surgical Critical Care, University of Illinois at Chicago, Chicago, IL 60612, USA.

Email: singares@uic.edu



## Introduction

Surgeons today face numerous challenges in the current economic and regulatory climate. Maintaining a balance while meeting established benchmarks for performance in a private, community-based environment requires keen consideration of both revenue and expenses. The cost of providing surgical care must also be considered as a portion of the larger societal financial impact, which includes both the financial burden at the point-of-service and the loss of revenue arising from complications. With the sources of financing for a small business differing markedly from those available to larger University-based providers, initiatives that include efficient and cost-effective delivery of care are required to meet legislative demands.

One of the most frequent procedures performed in community-based general surgical practice is ventral hernia repair (incisional and non-incisional), which is a large component of the cost of healthcare.<sup>1</sup> While there is an ample body of literature addressing the procedure and its nuances, the body of evidence pertaining to the practice in small, community-based hospitals is limited. In particular, there is little research into whether it is feasible and safe to perform laparoscopic ventral hernia repair (LVHR) with a prosthetic mesh as a same-day procedure in a small community hospital.

Abdominal wall reconstruction can be achieved via many therapeutic alternatives and devices, but the clinical evidence to support some of these options is sparse. Effective comparisons between therapeutic alternatives and devices thus rely on anecdotal evidence and data from marketing literature that may be largely derived from animal studies. New Biocompatible technologies like condensed polytetrafluoroethylene (cPTFE) have the potential to bridge the gap between affordability and tissue repair quality due to its competitive pricing among the

synthetics currently on the market, and although studies are still forthcoming, data reported in the literature suggest that cPTFE is not inferior to other more expensive synthetic meshes that are currently available.<sup>2</sup>

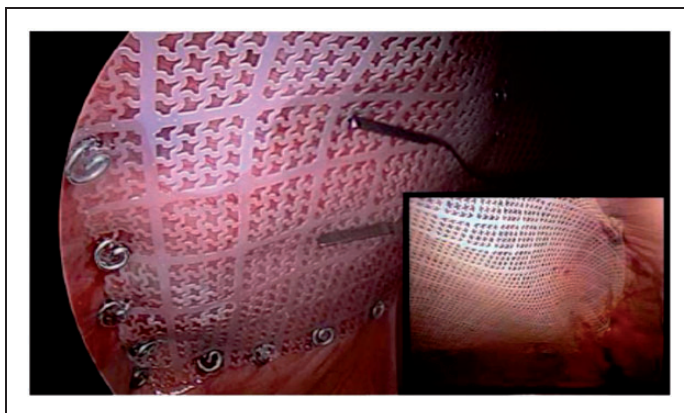
cPTFE has been promoted in the United States of America as a substrate for hernia repair since May 2005. It has been made available at marked savings, and continues to be adopted by surgeons and hospitals interested in cost-reduction. To date, clinical reports on cPTFE, its efficacy and potential complications are sparse. The current study aimed to evaluate the use of cPTFE for LVHR in the outpatient community-hospital setting.

## Patients and methods

The study design was evaluated by the respective local regulatory bodies and approved before the beginning of data collection. During the recruitment phase, all patients referred for evaluation with clinical signs and symptoms of ventral, umbilical or incisional abdominal wall hernias were screened for inclusion in the study. Eligibility criteria included physical examination confirming the diagnosis of abdominal wall hernia and the presence of signs and symptoms such as cosmetic deformity, pain or evidence of incarceration. Exclusion criteria included contraindications for general anaesthesia (made on a case-by-case basis), contraindications for laparoscopic repair, and patient preference. Eligible individuals were scheduled for surgical intervention, and informed consent was obtained.

## Surgical procedure

All surgical procedures were performed in one of the following community hospitals: Odessa Regional Hospital and Medical Center Hospital, both in Odessa, TX and Saint Anthony Hospital in Chicago, IL. The procedures were performed in a



**Figure 1.** Laparoscopic view of cPTFE mesh affixed to the abdominal wall with evenly spaced polypropylene sutures and laparoscopic fixation devices.

standardized fashion, following the same surgical principles. After induction of general anaesthesia, a pneumoperitoneum was established using a Veress needle, followed by the placement of laparoscopic trocars. The surgeon determined the number (between two and five) and position of the trocars intraoperatively, depending on the location and type of hernia, and the presence and quality of adhesions. Adhesiolysis was performed as needed until the entire antero-lateral abdominal wall was fully exposed. The diagnosis was then confirmed laparoscopically. The size of the cPTFE prosthetic mesh (MotifMesh; Proxy Biomedical, Galway, Ireland) was selected based on the size of the abdominal wall defect, to achieve an overlap of 3 to 5 cm from the hernia limit. The mesh was then affixed to the abdominal wall (Figure 1) with evenly placed transcutaneous, horizontal mattress sutures of polypropylene (Prolene; Ethicon, Somerville, NJ). The free borders of the prosthesis were then treated with evenly placed laparoscopic fixation devices (ProTack<sup>TM</sup>; Covidien, Dublin, Ireland). cPTFE implants were not available at the time of surgery for seven patients; those patients received a different mesh, and were thus excluded from the data. Postoperatively, all patients

were observed in the recovery unit and evaluated for discharge for outpatient management.

### Follow-up

During the follow-up period, all patients were seen at 1 and 5 weeks postoperatively, and additional clinic visits were scheduled as needed. Follow-up consisted mostly of clinic visits; because of discomfort generated by this type of repair, follow-up was frequently long-term, and was for more than 1 year in most patients. Besides scheduled clinic visits, follow-up information was obtained from referral physicians and occasionally from the hospital portal. Outside of these sources, long-term follow-up was performed via the telephone, and additional visits were scheduled as needed. During follow-up visits, patients were questioned about symptoms of hernia recurrence and other complications, and pain level was measured using the visual analog pain scale.

Complications were recorded and grouped into early and late, primary and secondary endpoints. The primary endpoint was hernia recurrence; early hernia recurrence was defined as recurrence within 1 year postoperatively. Recurrences were

scheduled for re-intervention when detected. The secondary endpoints were any other complications; early secondary endpoint complications were defined as those that occurred in the period from the end of the operation to the first follow-up appointment at 1 week postoperatively, and late complications were those that occurred any time thereafter. Pain at the transfixion suture sites was treated with injections of 2 ml of triamcinolone (Kenalog-40; Bristol-Myers Squibb, Princeton, NJ) and 10 ml of bupivacaine (Marcaine; AstraZeneca, London, England) at the points of greatest discomfort. Once the follow-up period was completed, patients were returned to their referring care provider for long-term care. Patients who did not complete the follow-up period were excluded from the study. After a recurrence was detected and repaired, the study subjects were treated as new cases and their initial postoperative time was treated separately from the secondary follow-up.

## Results

There were 130 patients screened for inclusion between March 2006 and January 2009. Nine patients were excluded because they either met the established exclusion criteria or did not receive the cPTFE implant intraoperatively. One patient who had no hernia visualized during diagnostic laparoscopy was also excluded. Four individuals (3%) were lost to follow-up during the study period, and were excluded from the study. The remaining 117 patients underwent 122 laparoscopic abdominal wall hernia repairs using cPTFE prosthetic mesh. Patient demographic characteristics and diagnostic data are recorded in Table 1. The average prosthetic size used was  $413.8 \pm 336.11 \text{ cm}^2$  (range 165–936  $\text{cm}^2$ ). No intraoperative injuries were detected during the study period. A right inguinal hernia was incidentally discovered during a low incisional ventral hernia repair procedure in one

**Table 1.** Characteristics of abdominal hernia patients treated as outpatients at one of three small community hospitals ( $n = 117$ ).

Mean age (range) in years	46.6 (18–84)
Males	52 (44%)
Females	65 (56%)
<b>Hernia types</b>	
Incisional	60
Recurrent	11
Trocar site	11
Incarcerated	4
Umbilical	48
Incarcerated	5
Tenderness/pain	22
Epigastric	10
Spigelian	3
Concurrent umbilical and epigastric	1

patient, and was included in the repair. Mean follow-up period was 30 months (range 12–46 months).

There were five late primary endpoint complications, four of which were repaired laparoscopically and the secondary follow-up was completed. The remaining recurrence was repaired via the open approach and was excluded from the secondary analysis. No new recurrences were observed. Mesh shrinkage and insufficient mesh overlap were not issues related to recurrence; more often the recurrence was due to inherently poor tissue factor or pull through of the transfixion sutures or a combination of these factors.

There were 29 early secondary endpoint complications (Table 2). One patient developed an acute abdomen after an incarcerated hernia repair and required a laparotomy; no injuries were detected during exploration, and the mesh was not explanted. Another patient developed necrosis of part of the hernia sac and the mesh became exposed; this was treated with a vacuum-assisted closure device and the repair was saved in 14 days. A third patient

**Table 2.** Secondary endpoint complications in 117 patients who underwent laparoscopic ventral hernia repair with cPTFE as outpatients at one of three community hospitals.

Early complications <sup>a</sup>	No. of patients	Percentage
Simple ecchymosis	8	6.8
Hematoma	1	0.9
Mild to moderate abdominal pain (including trocar site and transfixion suture pain) NOT requiring readmission	12	10.2
Severe abdominal pain (requiring readmission)	2	1.7
Purulent drainage/mesh exposure	1	0.9
Cellulitis – trocar wound disruption and drainage	4	3.4
Hematuria – testicular pain	1	0.9
<b>TOTAL</b>	<b>29</b>	<b>24.8</b>
<b>Late complications<sup>b</sup></b>		
Seroma requiring aspiration	10	8.5
Pain with exercise	3	2.6
Pain at the mesh site/trocar site	13	11.1
Pain in the transfixion suture site	5	4.3
Erectile dysfunction	1	0.9
<b>TOTAL</b>	<b>32</b>	<b>27.4</b>

<sup>a</sup>Early complications were defined as complications that occurred in the first postoperative week.

<sup>b</sup>Late complications were defined as complications that occurred any time after postoperative day 7.

required admission for 23 hours for post-operative nausea, vomiting and uncontrolled pain. These three patients failed the outpatient management strategy.

There were 32 late secondary endpoint complications (Table 2). One patient died during follow-up due to an unrelated advanced malignancy. Another patient developed acute appendicitis during follow-up, and was treated via laparoscopic appendectomy. A third patient presented 1 month postoperatively with a new mass in the right flank, which CT revealed as a previously undiagnosed Spigelian hernia. The epigastric hernia repair appeared adequate and no recurrence in the area was noted. The patient underwent laparoscopic repair of the new hernia with a different mesh, and this particular procedure with the different mesh was excluded from the study.

The most common complication during follow-up was pain; either at the mesh site or at the transfascial suture sites. All patients with pain responded to one or more injections of triamcinolone and bupivacaine at the site of maximum tenderness. The injections were started at around 3 months postoperatively, and a short series of less than six injections usually led to marked improvement. In some patients, the pain simply stopped for unknown reasons at 6 months postoperatively.

## Discussion

Incisional hernias can occur after any type of abdominal wall incision: midline, paramedian, subcostal, McBurney, Pfannenstiel, or flank incision. They develop in approximately 10%–15% of abdominal incisions,<sup>3</sup> necessitating 90,000–245,000 ventral hernia operations per year in the United States.<sup>4</sup>

The laparoscopic approach to abdominal wall reconstruction was first described by LeBlanc and Booth in 1993.<sup>5</sup> Since its introduction, LVHR has undergone a number of improvements, both in technique and in the type of materials used. These improvements have resulted in outcomes that consistently surpass those reported for open ventral hernia repair.<sup>6–8</sup> However, this has not translated into a broader use of the technique. A retrospective analysis of the ACS-NSQIP database from 2005 to 2012 reported that only 26.6% of ventral hernia repairs were done via the laparoscopic approach.<sup>4,9,10</sup> Earlier studies reported use of the laparoscopic approach in less than 10% of ventral hernia repairs.<sup>11,12</sup>

The reasons for the lack of widespread use of LVHR are not clear. What is evident, however, is the benefit of the laparoscopic approach compared to its open counterpart, both clinically and economically. LVHR is associated with shorter operative time, decreased pain, shorter duration of hospitalization, faster return to work and lower incidence of wound infections and major complications compared with open repair.<sup>2,6,7,13</sup> When used for recurrent ventral hernia after failed open repair, LVHR showed significantly improved quality-of-life scores in follow-up.<sup>14</sup> It seems clear that, in the evolution from suture repair to mesh repair, LVHR represents the next logical step in the quest for improving outcomes.

The decrease in average duration of hospitalization associated with the laparoscopic approach has also been observed in other fields, notably in cholecystectomy. The decreased duration of hospitalization after laparoscopic compared with open cholecystectomy has been associated with cost reductions of about 45% at ambulatory surgical centers.<sup>7,15</sup> As the average duration of hospitalization for LVHR in most reported series is 1 day,<sup>7</sup> it makes sense to attempt a same-day approach, given its inherent advantages in cost reduction and patient

satisfaction.<sup>15</sup> This has already been done in University hospitals in the United States<sup>1</sup> and Europe;<sup>16</sup> however, reports on same-day LVHR in community-based hospitals and surgery centers are very sparse. The current study adds valuable data and experience to this particular body of knowledge. The current outcomes, especially the failure for outpatient management rate, match those reported by larger University hospitals.

One of the major costs associated with both laparoscopic and open hernia repair is the choice of prosthesis. Initially, LVHR was conducted using expanded polytetrafluoroethylene (ePTFE); ePTFE alone or in combination with polypropylene is still currently the prosthesis of choice for the majority of procedures.<sup>5</sup> Research has led to the development of cPTFE, where the material technology involves not the expansion (as in ePTFE), but rather the condensation of PTFE. The current study is one of the few to document human experiences with cPTFE mesh for abdominal wall reconstruction, and is the first to document its efficacy and safety during laparoscopic surgery. Previous animal and human reports have stressed the advantages of cPTFE over other materials, including ePTFE, polyester and polypropylene.<sup>2,17,18</sup> These advantages include better tissue integration, decreased adhesion formation and decreased mesh contraction, which should be considered during prosthesis selection, along with other factors such as the possibility of infection and cost.

The hernia recurrence rate in the current study on cPTFE for outpatient LVHR was 4.3%, which is well within the previously reported range of 2%–6%.<sup>11,19</sup> The complication rate in the current series does not exceed that reported elsewhere, and the rate of postoperative seroma formation was actually lower than that reported in previous studies of 10%–15%.<sup>20</sup> This lesser incidence of seroma is potentially due to the way that cPTFE is manufactured. Given its large mesh openings, there are more opportunities



for the collected fluid in the hernia sac after intraperitoneal mesh placement to exit and mix with peritoneal contents. This characteristic could also be responsible for the lower adhesiogenic properties of the implant, as the potential for adhesion formation is not only dependent on the polymer used, but also on the pore size, filament structure and surface area of the implanted mesh.<sup>2</sup>

## Conclusion

In this initial report, cPTFE appears to be a suitable material for LVHR in an outpatient, small community-hospital setting. The use of cPTFE matched reported outcomes for all procedures performed. Further clinical studies are required to confirm the current findings, and to compare this mesh with other established alternatives.

The current cohort of patients is thought to represent the typical general surgical population of a community-based surgeon in North America. Outpatient LVHR is a feasible and a safe choice, and should be considered whenever possible. The economic advantages are obvious, but formal cost analysis must be obtained prior to general adoption. Laparoscopic expertise continues to accumulate in this regard.

## Declaration of conflicting interest

The Authors declare that there is no conflict of interest.

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## References

- Gillian GK, Geis WP and Grover G. Laparoscopic incisional and ventral hernia repair (LIVH): an evolving outpatient technique. *JSLs* 2002; 6: 315–322.
- Cheesborough JE, Liu J, Hsu D, et al. Prospective repair of ventral hernia working group type 3 and 4 abdominal wall defects with condensed polytetrafluoroethylene (MotiMESH) mesh. *Am J Surg* 2016; 211: 1–10.
- Brooks DC and Cone J. Incisional hernia. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on May 8, 2016.).
- Savitch SL and Shah PC. Closing the gap between the laparoscopic and open approaches to abdominal wall hernia repair: a trend and outcome analysis of the ACS-NSQIP database. *Surg Endosc*. 2015 [Epub ahead of print]. doi: 10.1007/s00464-015-4650-7.
- LeBlanc KA and Booth WV. Laparoscopic repair of incisional abdominal hernias using expanded polytetrafluoroethylene: preliminary findings. *Surg Laparosc Endosc* 1993; 3: 39–41.
- Bingener J, Buck L, Richards M, et al. Long-term outcomes in laparoscopic vs open ventral hernia repair. *Arch Surg* 2007; 142: 562–567.
- Olmi S, Scaini A, Cesana GC, et al. Laparoscopic versus open incisional hernia repair: an open randomized controlled study. *Surg Endosc* 2007; 21: 555–559.
- Pierce RA, Spittler JA, Frisella MM, et al. Pooled data analysis of laparoscopic vs. open ventral hernia repair: 14 years of patient data accrual. *Surg Endosc* 2007; 21: 378–386.
- Funk LM, Perry KA, Narula VK, et al. Current national practice pattern for inpatient management of ventral abdominal wall hernia in the United States. *Surg Endosc* 2013; 27: 4104–4112.
- Mason RJ, Moazzez A, Sohn HJ, et al. Laparoscopic versus open anterior abdominal wall hernia repair: 30-day morbidity and mortality using the ACS-NSQIP database. *Ann Surg* 2011; 254: 641–625.
- Hawn MT, Snyder CW, Graham LA, et al. Long-term follow up of technical outcomes for incisional hernia repair. *J Am Coll Surg* 2010; 210: 648–655.
- Alder AC, Alder SC, Livingston EH, et al. Current opinions about laparoscopic incisional hernia repair: a survey of practicing surgeons. *Am J Surg* 2007; 194: 659–662.

13. Colavita PD, Tsirlime VB, Walters AL, et al. Laparoscopic versus open hernia repair: outcomes and sociodemographic utilization results from nationwide inpatient sample. *Surg Endosc* 2013; 27: 109–117.
14. Uranues S, Salehi B and Bergamaschi R. Adverse events, quality of life, and recurrence rates after laparoscopic adhesiolysis and recurrent incisional hernia mesh repair in patients with previous failed repairs. *J Am Coll Surg* 2008; 207: 663–669.
15. Paquette IM, Smink D and Finlayson SR. Outpatient cholecystectomy at hospitals versus freestanding ambulatory surgical centers. *J Am Coll Surg* 2008; 206: 301–305.
16. Moreno-Egea A, Cartagena J, Vicente JP, et al. Laparoscopic incisional hernia repair as a day surgery procedure: audit of 127 consecutive cases in a university hospital. *Surg Laparosc Endosc Percutan Tech* 2008; 18: 267–271.
17. Voskerician G, Jin J, White MF, et al. Effect of biomaterial design criteria on the performance of surgical meshes for abdominal hernia repair: a pre-clinical evaluation in a chronic rat model. *J Mater Sci Mater Med* 2010; 21: 1989–1995.
18. Raptis DA, Vichova B, Breza J, et al. A Comparison of woven versus nonwoven polypropylene (PP) and expanded versus condensed polytetrafluoroethylene (PTFE) on their intraperitoneal incorporation and adhesion formation. *J Surg Res* 2011; 169: 1–6.
19. Itani KM, Hur K, Kim LT, et al. Comparison of laparoscopic and open repair with mesh for the treatment of ventral incisional hernia: a randomized trial. *Arch Surg* 2010; 145: 322–328.
20. Sodergren MH and Swift I. Seroma formation and method of mesh fixation in laparoscopic ventral hernia repair—highlights of a case series. *Scand J Surg* 2010; 99: 24–27.