The use of ePTFE for Intra-Abdominal Placement

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PROVEN CLINICAL RESULTS

Technique and Outcomes of Abdominal Incisional Hernia Repair Using a Synthetic Composite Mesh: A Report of 455 cases

Journal of the American College of Surgeons, vol 206, no.1, Jan 2008

David A Iannitti, MD, FACS et al.

Background: Abdominal wall hernias are a frequent and formidable challenge for general surgeons. Several different surgical techniques and types of mesh prosthetics are available for repair. We evaluated outcomes of an open ventral hernia repair using a synthetic composite mesh.

Study Design: We prospectively collected data on consecutive patients undergoing open ventral hernia repair using a synthetic composite mesh from January 1, 2000 to December 31, 2005, at 4 large medical centres. Four surgeons used a standardised surgical procedure for all patients.

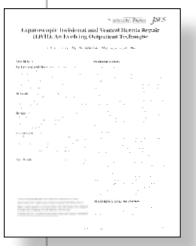
Key Findings:

455 patients presented with an average age of 56 years; 56% were men. 69% of the patients underwent repairs for recurrent hernias.

Mean defect size was 44cm^2, and mean mesh size was 213cm^2. Average length of hospital stay was 1.1 days. 31 patients had 33 early complications (7%), and 3 patients (0.7%) required reoperation (one each for seroma, bowel injury and wound breakdown.)

Early infection occurred in 4 patients (0.9%) and 1 patient required reoperation and graft removal. Late complication occurred in 9 patients (0.4%), with 2 patients requiring reoperation. Late infections occurred in 2 patients (0.4%); both required antibiotic treatment. Recurrent hernias were observed in 6 patients (1%) at a mean follow up of 29.3 months.

Conclusion: "In this large multicentre series, open ventral hernia repair using a composite mesh resulted in short hospital stay, moderate complication rate, low infection rate and low recurrence rate."



Laparoscopic Incisional and Ventral Hernia Repair (LIVR): An Evolving Outpatient Technique

Journal of the Society of Laparoendoscopic Surgeons: 2002 6:315-322

G. Kevin Gillian, MD, W. Peter Geis, MD, Gary Grover, MD

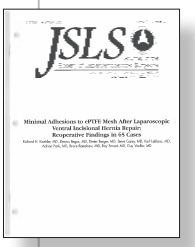
Objective: The contemporary results of open incisional and ventral hernia repair are unsatisfactory because of high recurrence rates and morbidity levels. Laparoscopic repair of ventral and incisional hernias (LIVH) can be accomplished in a simple, reproducible manner while dramatically lowering recurrence rates and morbidity.

Study Design: 100 consecutive patients underwent laparoscopic repair of their ventral and incisional hernias over a 27-month period. BARD® COMPOSIX™ mesh and COMPOSIX™ E/X mesh were utilised for the repairs. Transfixion sutures were not used.

Key Findings:

All repairs were completed laparoscopically. No conversions to open techniques were necessary. No postoperative infections have been observed. 1 recurrent hernia was identified and subsequently repaired with the same technique.

Conclusion: "LIVH can be accomplished with a dramatic reduction in recurrence rates and morbidity. The technique for this repair is still in a state of evolution. The construction and handling characteristics of this particular type of mesh (BARD® COMPOSIX™ and COMPOSIX™ E/X) have allowed us to eliminate transfixion sutures and to simplify the repair technique while maintaining a very low recurrence rate."



Minimal Adhesions to ePTFE Mesh after Laparoscopic Ventral Incisional Hernia Repair

Journal of the Society of Laparo-endoscopic Surgeons. Volume 7, number 4, Oct-Dec 2003

Richard H. Koehler, MD et al.

Objective: Laparoscopic ventral incisional hernia repair involves intraabdominal placement of a synthetic mesh, and the possibility of formation of severe visceral adhesions to the prosthesis is a principal concern. Little clinical information based on reoperative findings is available about adhesions to biomaterials placed intra-abdominally. We conducted a multi-institutional study of adhesions to implanted expanded polytetrafluoroethylene (ePTFE) mesh at reoperation in patients who had previously undergone laparoscopic incisional hernia repair done with the same mesh implantation technique.

Study Design: 9 surgeons retrospectively assessed the severity of adhesions to ePTFE mesh at reoperation in 65 patients. For each case, adhesions were assigned a score of 0 to 3, with 0 indicating no adhesions and 3 severe adhesions.

Key Findings:

The mean time from mesh implantation to reoperation was 420 days (range 2 to 1739 days.) No adhesions were observed in 15 cases. 44 cases received an adhesion score of 1, and 6 cases a score of 2, no scores of 3 were assigned.

59 patients (91%) had either no or filmy, avascular adhesions. No enterotomies occurred during adhesiolysis.

Conclusion: "In this large series of reoperations after laparoscopic incisional hernia repair, no or minimal formation of adhesions to implanted ePTFE mesh was observed in 91% of cases and no severe cohesive adhesions were found"

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Intraperitoneal Underlay Ventral Hernia Repair Utilizing Bilayer Expanded Polytetrafluoroethylene and Polypropylene Mesh

The American Surgeon 2003; 69:287-292

Keith W. Millikan, MD, Michael Baptista, MD, Beejal Amin, Daniel J Deziel, MD, Alexander Doolas, MD

Objective: A prospective study of patients with ventral hernias was undertaken to study the experience with an open intraperitoneal underlay technique utilising a bilayer prosthetic mesh.

Study Design: From September 1998 to March 2001, 102 patients underwent repair with a bilayer expanded polytetrafluoroethylene (ePTFE) and polypropylene mesh placed intraperitoneally and fixed into place with full thickness abdominal wall muscle sutures, to achieve a 5cm underlay of the fascial defect circumferentially

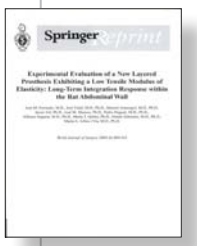
Key Findings:

There were 67 females and 35 males ranging in age from 29 to 76 years (mean 53 years). Average patient weight was 207 lb with 64 patients in the obese category. 40 patients presented with recurrent hernias. Mean operative time was 103 minutes with an average diameter hernia defect size of 15cm. Median hospital stay was 3 days,

There was no surgical mortality, and major morbidity occurred in 6 patients (2 wound infections, 1 deep vein thrombosis, 1 myocardial infarction, 1 pneumonia, and 1 pulmonary embolus.) Mean follow up is 28 months (rang 12-42 months.

No recurrence has been found with 100% follow up to date. No bowel obstruction of enteric fistulas have occurred during the follow up period.

Conclusion: "The open intraperitoneal underlay mesh technique can be performed with a 0% early recurrence rate. Bilayer prosthetic mesh composed of ePTFE and polypropylene can be safely placed intraperitoneally without causing intestinal obstruction or enteric fistula."



Experimental Evaluation of a New Layered Prosthesis Exhibiting a Low Tensile Modulus of Elasticity: Long Term Response within the Rat Abdominal Wall

World Journal of Surgery 2002:26:409-415

Jose M. Ferrando et al.

Background: BARD® COMPOSIX™ (BC) could provide a good solution for hernia repair when both minimal adhesions and maximum collagenous infiltration are necessary. We experimentally evaluated the long-term stability of this composite.

Study Design: In 15 Sprague-Dawley rats, a full thickness abdominal wall defect was created and repaired with BC. Studies were performed at 2,4 and 6 month in strips obtained from the prosthesis-host tissue interfaces. Light microscopy, environmental scanning and electron microscopy (ESEM), immunohistochemistry, and tensiometry were used.

Key Findings:

Overall findings provide evidence that PP and ePTFE association renders the alloy well suited for hernia repair, promoting a robust and durable alloplast-soft tissue union.

At all points studied the patch was well tolerated and meshes did not shrink, come loose or migrate. Neovascularisation continued 6 months after implantation.

After implantation, adequate tensile strength and a low modulus of elasticity were detected, conferring great adaptability to the abdominal wall.

Conclusion: "BARD® COMPOSIX™ layered prosthesis proved suitable for implantation in abdominal wall defects, exhibiting favourable biocompatibility and integration with minimal side effects."

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