PARIETEX™ COMPOSITE
10 YEAR ANNIVERSARY 1999-2009

10 YEARS OF CLINICAL EVIDENCE
THE CONCEPT

Polyester mesh takes on the challenge of hernia repair with material and manufacturing innovations to optimize healing and comfort through fast and intimate tissue in-growth. The new architecture of hernia repair features an enhanced hydrophilic, multi-filament construct and optimal porosity. Studies show that polyester is superior to other materials, such as polypropylene and ePTFE, in lack of shrinkage, advanced rate of healing and improved patient comfort.

**Optimized Material** - hydrophilic polyester enhances rapid tissue in-growth rapid and complete tissue integration is an important requirement for an optimal hernia repair mesh. To answer this need, our technology begins with a material difference — polyester. When this material is designed with optimum pore size it enhances fast and intimate tissue ingrowth. Polyester promotes the attraction, fixation and survival of young fibroblasts and mesothelial cells due to its hydrophilic nature. In contrast, polypropylene and ePTFE tend to repel all cells and avoid the fixation of all living cells to the material because of their hydrophobic characteristic. When a hydrophobic material like polypropylene, which do not promote the attraction of cells, is combined with a small-pore, size a common result is encapsulation of the mesh with scar tissue.

**Optimized Structure** – porosity promotes connective tissue differentiation. To allow fast and intimate tissue in-growth without any peripheral fibrous capsule (which can cause shrinkage, discomfort and chronic pain), a mesh must also have porosities that are as large as possible. Pore sizes below 1 mm trigger an intense inflammatory response. Inflammation and scar formation lead directly to encapsulation which in turn leads to contraction.

Parietex™ technology creates both micropores for optimized cellular in-growth between the fibers and large macropores for true connective tissue differentiation. Parietex™’s porosity allows the right amount of connective tissue in-growth with no fibrotic encapsulation or degradation.

**Preventing Visceral Attachments**
Intraperitoneal placement of the mesh represents a real advance in the ventral hernia repair; it facilitates laparoscopic treatment of small incisional hernia repair. The result is a reduction of operative time that benefits the patient by decreasing of surgical and anesthetic morbidity.

When placing a mesh intraperitoneally it must provide a permanent or temporary interface between normally separated structures.

The requirements for an ideal mesh are:

- To physically separate anatomical structures during the early healing phase
- To induce a minimized inflammatory response in order to reduce both encapsulation and adhesions to the barrier itself
- To restore normal cleavage plans

Parietex™ Composite (PCO) Mesh is composed of three-dimensional polyester structure on the parietal side and an absorbable collagen film on the visceral side.
A proprietary manufacturing process creates a strong link between the film and the threedimensional polyester structure (picture 1) which eliminates the risk of delamination that has been reported in other meshes.

The continuous, smooth, hydrophilic and resorbable collagen film is composed of a mixture of oxidized atelocollagen type I, polyethylene glycol and glycerol.

The hydrogel film’s physico-chemical properties: hydrophilicity, elasticity and transparency make it easy for surgeons to implant the mesh intraperitoneally. Moreover, the film extends 5 mm over the mesh edges providing additional protection.

Parietex™ Composite (PCO) Mesh provides a temporary barrier and the film’s hydrophilicity promotes the attraction of mesothelial cells. After absorption it leaves a neo-peritoneum composed by mesothelial cells that will prevent visceral attachments.
An optimal balance of properties backed the largest portfolio of clinical studies.

<table>
<thead>
<tr>
<th>Study #</th>
<th>Adhesion</th>
<th>Integration</th>
<th>Shrinkage</th>
<th>Degradation</th>
<th>Pain</th>
<th>Infection</th>
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### Study 1.

80 patients were included in this prospective multicenter clinical trial. The main objective was to evaluate the antiadhesive properties of Parietex™ Composite (PCO) Mesh. Ultrasound (US) specific examinations of intestinal movement was initially validated (pre-operative prediction vs. Preoperative findings) and then used during the follow-up.

#### Results

After 12 months, 86% of the patients were ultrasonically adhesion free.

- There was 0% occlusion and fistula.
- Late complications were: mesh sepsis (1%), new defects (4%) and recurrence (2.5%).
- At four years, 56 patients (75.7%) were clinically evaluated with a mean follow-up of 48±6 months.
- One direct recurrence was noted while six patients experienced new defect outside the mesh. No long-term severe complication such as occlusion or enterocutaneous fistula was observed.

### Study 2.

In this retrospective study, the author evaluated a minimally invasive surgical technique of moderate to large incisional and ventral hernia defects using Parietex™ Composite (PCO) Mesh. The midterm results for 400 patients are presented in terms of efficacy and safety.

#### Results

- On 400 patients, no major complications were observed, 0 small bowel obstruction, 0 entero-cutaneous fistula and 0 infections.
- A second look study (for other indications) was performed on 35 patients (8.75%) 3 to 13 months postoperatively that confirms the global results.
- The majority (23 patients, 65.71%) were adhesion free.
- Some had loose adhesions of the omentum (grade 1 of Mueller’s classification; n = 10), and the remainder had easily cleavable serosal adhesions (grade 2 of Mueller’s classification; n = 2)
- There were no cases of chronic infection, small bowel obstruction, fistula, or hernia fistula, and no conversions occurred in this study.
Study 3

In an experimental rat study, the authors wanted to evaluate adhesion formation with different types of currently available composite meshes. Eight different meshes were placed intraperitoneally and in direct contact with abdominal viscera in 200 rats.

The following meshes were tested: polypropylene (Ethicon’s Prolene®), ePTFE (Gore’s Dualmesh®), polypropylene–polyglecaprone composite (Ethicon’s Ultrapro®), titanium–polypropylene composite (GfE’s Timesh®), polypropylene with carboxymethylcellulose–sodium hyaluronate coating (Bard* Sepramesh®), polyester with collagen-polyethylene glycol–glycerol coating (Parietex™ Composite), polypropylene–polydioxanone composite with oxidized cellulose coating (Ethicon’s Proceed™), and bovine pericardium (Tutogen Medical’s Tutomesh®).

Adhesion formation, mesh incorporation, tensile strength, shrinkage, and infection were evaluated at 7 days and 30 days.

Results

• At 7 days and 30 days, Parietex™ Composite resulted in significantly less adhesions (3.9% and 11.2% respectively) than observed with other meshes except Tutogen Medical’s Tutomesh® and Bard* Sepramesh®

Study 4.

This prospective, randomized animal study compared shrinkage, adhesions and tissue ingrowth between Parietex™ Composite (PCO) Mesh, Ethicon’s Proceed™ and uncoated polypropylene. 3 different 10x15 meshes were implanted in 10 pigs and then evaluated after 28 days.

• The mean area of adhesions to Parietex™ Composite (PCO) Mesh (11%) was significantly less than for Ethicon’s Proceed™ (48%; p< 0.008) or PPM (46%; p < 0.008)

Study 5.

In this prospective animal study Parietex™ Composite (PCO) Mesh and Bard’s Composix® E/X (Bard) were implanted in female Yorkshire swine and evaluated in terms of adhesion and tissue integration. The meshes were analyzed at 28 days post implantation by a veterinary pathologist who was blinded to the data.

Results

• At 28 days, PCO induced fewer adhesions than ePTFE mesh (14.5% vs 53.4%, P=0.007).
• On an adhesion scale (0–5), we had 1.75 for PCO (P<0.03) vs 3.6 for ePTFE Bard’s Composix® E/X

Study 6.

3 types of meshes polypropylene (PPM), expanded polytetrafluoroethylene (ePTFE), and polyester with antiadhesive collagen layer (PCO) were implanted laparoscopically in eight pigs using sutures and tacks for fixation.

Adhesion formation, fibrous ingrowth and shrinkage were evaluated after 28-day survival.

Results

• Mean area of adhesions to PCO (8.25%) was less than that to ePTFE (57.14%, p < 0.001) or PPM (79.38%, p < 0.001).
• Adhesion peel strength was less for PCO (2.3N) than for PPM (16.1 N, p < 0.001) or ePTFE (8.8 N, p = 0.02).

Study 11

The purpose of this prospective animal study was to compare the effectiveness of five meshes which had been developed to resist adhesion formation to that of an untreated mesh after 21 days following surgery.

5 composite mesh products (Parietex™ Composite, Parietene™ Composite, Bard Bard’s Composix® E/X, Bard’ Sepramesh’, and Gore-Tex Gore’s DualMesh®) and one untreated mesh (Parietene”) were implanted in 80 rats.
**Study 12**

This study examined the ability of different coated and uncoated meshes to attenuate adhesion formation.

6 meshes were placed intraperitoneally in rats: Ethicon’s Prolene® (polypropylene), GfE’s Timesh® (polypropylene with titanium), Ethicon’s Ultrapro (polypropylene composites with polyglecaprone), Ethicon’s Proceed™ (polypropylene mesh coated with a layer of cellulose) and Parietene™ Composite and Atrium’s C-QUR™ (polypropylene mesh coated with a layer of omega-3 fatty acids).

Adhesions and incorporation were evaluated macroscopically and microscopically after 7 and 30 days.
TISSUE INTEGRATION

**Study 3**
- Parietex™ Composite (PCO) showed at 7 days and 30 days the highest tissue incorporation.
- Parietex™ Composite (PCO) showed the highest tensile strength (14.2 N)

**Study 4**
- Peak peel strength from the abdominal wall was significantly higher for PCO (17.2 N) than for Ethicon’s Proceed™ (10.7 N) or PPM (10 N; p < 0.002)

**Study 5**
- Good tissue ingrowth and neovascularisation had been observed in both meshes, although PCO showed a more complete neoperitoneum.

**Study 6**
- Peel strength of mesh from the abdominal wall was greater for PCO (2.8 N/cm, p = 0.001) or PPM (2.1 N/cm, p = 0.05) than for ePTFE (1.3N/cm of mesh width).
SHRINKAGE

Study 2

- Based on the 2nd look study (35 patients) the author noted the absence of prosthesis shrinking and wrinkling in all these cases confirming its total peritonization on the anterior abdominal wall.

Study 3

- Parietex™ Composite (PCO) showed 15.3% at 30 days with no significant difference with other mesh but Tutogen Medical’s Tutomesh® (44.3%)

Study 4

The area of each mesh at the time of insertion was 150 cm².

- PCO (105.8 cm², 29.5%) had less shrinkage than Ethicon’s Proceed™ (99.6 cm², 33.6%) but with no statistically significant difference.

Study 6

The area of each mesh at the time of insertion was 150 cm².

- ePTFE (94.4 cm², 63% of original area)
- PCO (118.6 cm², 79% of original area, p = 0.001)
- PPM (140.7 cm², 94% of original area, p = 0.002).

Study 13

Parietene™ Composite and FEG’s Dynamesh® IPOM had a similar value of 14% of shrinkage while Ethicon’s Proceed™ showed a 25% reduction in its surface area.

Study 14

- Parietene™ Composite (PCO) and FEG’s Dynamesh® IPOM had a similar value of 19% of shrinkage while Dual mesh showed a 52% reduction in its surface area.
Study 10

The study showed that at a strain of 16N new ideal meshes should show an elasticity of at least 25% in vertical stretching and 15% in horizontal stretching to achieve almost physiological properties.

The graphs below show the physiologic elasticity band and the elasticity of several meshes. Parietex™ and Parietene™ Composite are above the minimum requirement and don't impair the physiological abdominal wall elasticity.
Study 7

The objective of the study was to compare the state of alteration of different meshes commonly used in Pelvic Floor Disorder surgery.

Multicentric retrospective and comparative study of 100 explanted samples of different meshes: Low Density polypropylene mesh (LDPPMF), High Density polypropylene (HDPPMF), Polypropylene Multifilament, Non-Knotting Non-Woven Polypropylene (NKNW), Polypropylene-polyglactin acid (Composite), Polyethylene Terephtalate (PET).

Scanning Electron Microscopy (SEM) analysis was performed on each explanted meshes. SEM analysis has shown 39% of impaired meshes. All Polypropylene meshes 44.5%:

<table>
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<tr>
<th>Mesh Type</th>
<th>Percentage</th>
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<td>LDPPMF</td>
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<td>Composite</td>
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<td>NKNW</td>
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<tr>
<td>PET</td>
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</table>

Study 8

SEM analysis was performed on 25 explanted meshes after primary abdominal wall hernia repair.

The average period of implant was 32.5 months (range 2–180)

Results

- 100% of PP meshes (2 to 52 months of implantation) showed alterations
- 0% of PET meshes (36 to 180 months of implantation) showed alteration.
Study 9
14 Polypropylene meshes were removed from patients requiring revision surgery due to chronic pain, recurrence, infection, adhesions, or other complications.

Results
• 85% of the explanted meshes showed alterations of their surface (cracks, fissures, and increased surface roughness).
• Moreover, nearly all meshes showed a decrease of the compliance (from 4 to 30 times more force to fold the mesh than the pristine mesh).

PAIN

Study 1
• Pain was reduced to a very low level: 0.2±0.8/10 in the open group and 0.8±1.6/10 in the laparoscopic group.
• 69% of the patients were totally pain free (VAS= 0) in the open group and 67% in the laparoscopic group.

Study 2
• Transient pain was experienced by 10 patients (2.5%), and resolved over time with analgesic treatment.
• After 28 months, 97.5% of our patients were pain free, residual chronic parietal pain was reported for 10 patients (2.5%)

INFECTION

Study 1
• 1 mesh sepsis (1%) occurred at 8 months after a series of events on the incision, but it was not related directly to the mesh.

Study 2
• 1 mesh sepsis after day 3 requiring mesh explantation (0.25%).
• No chronic infection reported.

Study 15
This retrospective human study was designed to assess postoperative infections, fistulas, small-bowel obstructions and recurrence rates using Parietex™ Composite (PCO) Mesh in a complex group of patients. 109 patients had ventral hernias repaired and were tracked for a year. Forty-two (42%) of the patients were being treated for a recurrent hernia and twenty-six (26%) had prior intraperitoneal mesh placement.

Results
• In the laparoscopic group, there were no delayed mesh infections, fistulas or hernia recurrences during the 14 month follow-up period.
• In the open group, there were no long term bowel obstructions, fistulas or delayed infections related to the mesh during the 11 month follow up period.
• Dr Rosen concluded based on his experience with a follow up of approximately 1 year, there does not seem to be an increased risk of mesh infection, bowel obstructions, or enterocutaneous fistulas. Polyester mesh seems to be safe for ventral hernia repair.
References


2. Chelala E et al. The suturing concept for laparoscopic mesh fixation in ventral and incisional hernia repair: a mid term analysis of 400 cases. Surgical Endoscopy, 2006


