

PROVEN CLINICAL RESULTS



120 Day Comparative Analysis of Adhesion Grade and Quantity, Mesh Contraction, and Tissue Response to a Novel Omega-3 Fatty Acid Bioresorbable Barrier Macroporous Mesh After Intra-abdominal Placement *Surgical Innovation March 2009: 16,1:46-54*

Richard A Pierce et al.

Objective: To evaluate adhesion formation, mesh contraction, and tissue response to an omega 3 fatty acid barrier-coated lightweight polypropylene mesh (C-Qur) after intra-abdominal placement, and compare the prosthesis to those of other commercially available meshes.

Study Design: After randomisation, 3 x 3 cm pieces of Atrium C-Qur Mesh, Pro-Lite Ultra, BARD® COMPOSIX™, Covidien Parietex Composite, Ethicon Proceed, BARD® SEPRAMESH™ IP Composite and Gore Dualmesh were sewn to the intact peritoneum on either side of a midline incision in 41 New Zealand white rabbits. Necropsy was performed at 120 days, and explants were evaluated for adhesion grade, adhesion amount, and mesh contraction. Histological evaluation included extent of capsule formation, abdominal wall tissue ingrowth, degrees of inflammation and vascularisation of the surrounding tissue, and the presence of mesothelialisation.

Key Findings:

Adhesion Coverage:

- SEPRAMESH™ IP Composite resulted in the lowest percentage of adhesion coverage of all mesh products studied. (Table 3).

Table 3 - Adhesion Properties and Mesh Contraction

Mesh Type	N	Adhesion grade (1-4)	Adhesion coverage (%)	Mesh Contraction (%)
ProLite Ultra	12	1.7 ± 1.1	10.7 ± 19.8	9.1 ± 8.3
C-Qor	6	1.2 ± 0.4	3.0 ± 7.3	3.3 ± 2.1
COMPOSIX™	10	1.3 ± 1.2	24.8 ± 37.0	7.2 ± 7.1
DualMesh	10	1.3 ± 0.9	1.4 ± 4.4	39.0 ± 6.0
Parietex	6	1.2 ± 0.4	0.8 ± 2.0	14.7 ± 5.0
Proceed	6	2.8 ± 1.0	28.8 ± 16.1	29.7 ± 12.5
SEPRAMESH™	6	1.0 ± 0.0	0.0 ± 0.0	6.4 ± 8.4

Mesh Contraction:

- SEPRAMESH™ IP Composite demonstrated the second lowest percentage mesh contraction compared to all other meshes studies. (Table 3).

Inflammatory Response:

- SEPRAMESH™ IP Composite resulted in a moderate inflammatory response, which was comparable to the parietal side of 5 out of the 7 mesh products studied.



Evaluation of New Prosthetic Meshes for Ventral Hernia Repair *Surgical Endoscopy 2006:20:1320-1325*

J.W.A. Burger, J.A. Halm, A.R. Wijsmuller, S. ten Raa, and J. Jeekel

Objective: In hernia repair direct contact between mesh and abdominal organs cannot always be avoided. Several mesh materials and composite meshes have been developed to decrease subsequent adhesion formation. Recently new materials have been introduced.

In an experimental rat study, their value was established and compared with that of meshes already available on the market.

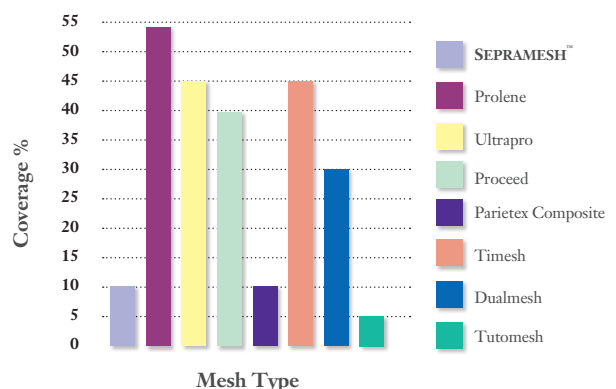
Study Design: In 200 rats, 8 different meshes were placed intraperitoneally and in direct contact with abdominal viscera. The following meshes were tested: polypropylene (Prolene, Ethicon), e-PTFE (Dualmesh, Gore) polypropylene-polyglycaprone composite (Ultrapro, Ethicon), titanium-polypropylene composite (Timesh, GfE Medizintechnik), polypropylene with carboxymethylcellulose-sodium hyaluronate coating (SEPRAMESH™), polyester with collagen-polyethylene glycol-glycerol coating (Parietex, Sofradim Composite), polypropylene-polydioxanone composite with oxidised cellulose coating (Proceed, Ethicon), and bovine pericardium (Tutomesht, Tutogen). At 7 and then at 30 days postoperatively, adhesion formation, mesh incorporation, tensile strength, shrinkage, and infection were scored by 2 independent observers.

Key Findings:

Parietex Composite, SEPRAMESH™ and Tutomesht resulted in decreased surface coverage with adhesions, whereas Prolene, Dualmesh, Ultrapro, Timesh and Proceed resulted in increased adhesion coverage.

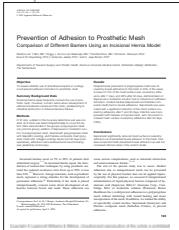
Parietex Composite, Prolene, Ultrapro and SEPRAMESH™ resulted in the most mesh incorporation.

Dualmesh and Tutomesht resulted in significantly increased shrinkage.



Conclusion: "Parietex Composite and SEPRAMESH™ combine minimal adhesion formation with maximum mesh incorporation and tensile strength."

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Prevention of Adhesion to Prosthetic Mesh – Comparison of Different Barriers Using an Incisional Hernia Model

Annals of surgery January 2003: 237: 123-128

Martijne van't Reit et al.

Objective: To assess whether use of anti-adhesive liquids or coatings could prevent adhesion formation to prosthetic mesh.

Study Design: In 91 rats, mesh was placed intraperitoneally to cover a defect made in the muscular abdominal wall and divided into 5 mesh groups. The meshes placed were polypropylene mesh only (control group), addition of Genzyme Sepracoat or Baxter Healthcare Icodextrin solution to polypropylene mesh, Bard SEPRAMESH™ polypropylene mesh with carboxymethylcellulose-sodium hyaluronate coating (SEPRAMESH™), and polyester mesh with collagen-polyethylene glycol-glycerol coating (Sofradim Parietex composite). At 7 and 30 days postoperative adhesions and incorporation were assessed and wound healing was studied by microscopy.

Key Findings:

Adhesion Coverage:

“When SEPRAMESH™ was used, a significant reduction in the mean percentage of mesh surface covered by adhesions was found after 7 days (55% vs 74%, $P = .01$), as well as after 30 days (25% vs 48%, $P = .03$), compared to the control group.”

“In addition, none of the animals with SEPRAMESH™ developed adhesions between bowel and the mesh compared to 57% of the animals with polypropylene mesh ($P = .04$).

With Parietex Composite mesh, there was no bowel adhesions to the mesh either ($P = .04$), however, the percentage of mesh surface covered by adhesions was higher in the Parietex Composite group (78%) than in the control group (48%, $P = .03$).”

Inflammatory Response:

SEPRAMESH™ resulted in inflammation response comparable to all groups (grade 2) on the inflammation grading scale. However, in the Parietex composite group a more severe inflammatory response was found (grade 3) on the inflammation grading scale.

Conclusion: “SEPRAMESH™ significantly reduced mesh surface covered by adhesions and prevented bowel adhesion to the mesh. Parietex composite mesh prevented bowel adhesions as well but increased infection rates in the current model.”



Effect of Prosthetic Material on Adhesion Formation After Laparoscopic Ventral Hernia Repair in a Porcine Model

Hernia 2004:8:108-112

E.C.Borrazzo, M.F. Belmont, D. Boffa, D.L. Fowler

Objective: To evaluate the efficacy of PPM/HA/CMC when placed laparoscopically in the porcine model and to compare adhesion formation after the placement of three types of mesh.

Study Design: 21 pigs were randomised to receive laparoscopic placement of plain polypropylene mesh (PPM), expanded polytetrafluoroethylene (ePTFE, Dualmesh, Gore), or polypropylene coated on one side with a bioresorbable adhesion barrier (PPM,HA,CMC, SEPRAMESH™ Biosurgical Composite). The animals were sacrificed after 28 days and evaluated for adhesion formation. In addition, portions of the mesh, both with and without adhesions were reviewed by a veterinary pathologist who was blinded as to the type of mesh used at the time of surgery.

Key Findings:

Adhesion Coverage:

- The SEPRAMESH™ group resulted in the lowest mean area of adhesions covering the mesh than the other groups studied
- “There were relatively fewer adhesions to the tacks on the periphery of the mesh in the SEPRAMESH™ group than there were to the tacks in the two other groups.”

Inflammatory Response:

- Histology of the abdominal wall with attached mesh revealed the least number of pigs showing a marked inflammatory response in the SEPRAMESH™ group
- Additional histological examination revealed a layer of cells overlying the mesh (similar to a mesothelial layer) present in all pigs in the SEPRAMESH™ group.

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