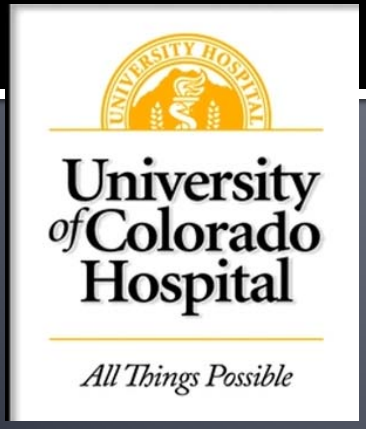
Mesh: Materials, Manufacture, and Marketing

University of Colorado
School of Medicine
Department of Surgery
Grand Rounds
Feb 13, 2012



Paul Montero, MD

Disclosures

- none

Acknowledgements

- B. Todd Heniford, Carolinas Medical Center

- Cook
- Gore
- Covidien
- Atrium
- Lifecell
- Novus Scientific
- Ethicon

- Todd Arcomano, MD
- Mike Schurr, MD
- Kent Kercher, MD
- Yuri Novitsky, MD
- Mike Rosen, MD
- Brent Matthews, MD

Overview

- Why Use Mesh?
- Limitations in Data
- Mesh Materials
  - Synthetics
  - Composites
  - Biologics
- Trends in Manufacturing

Fellowship

Fellowship

Carolinas Simulation Center

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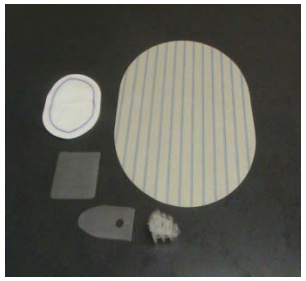
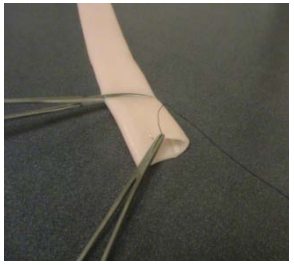
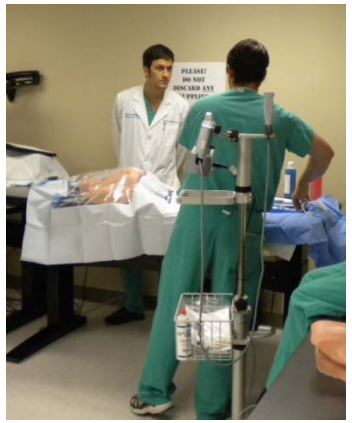
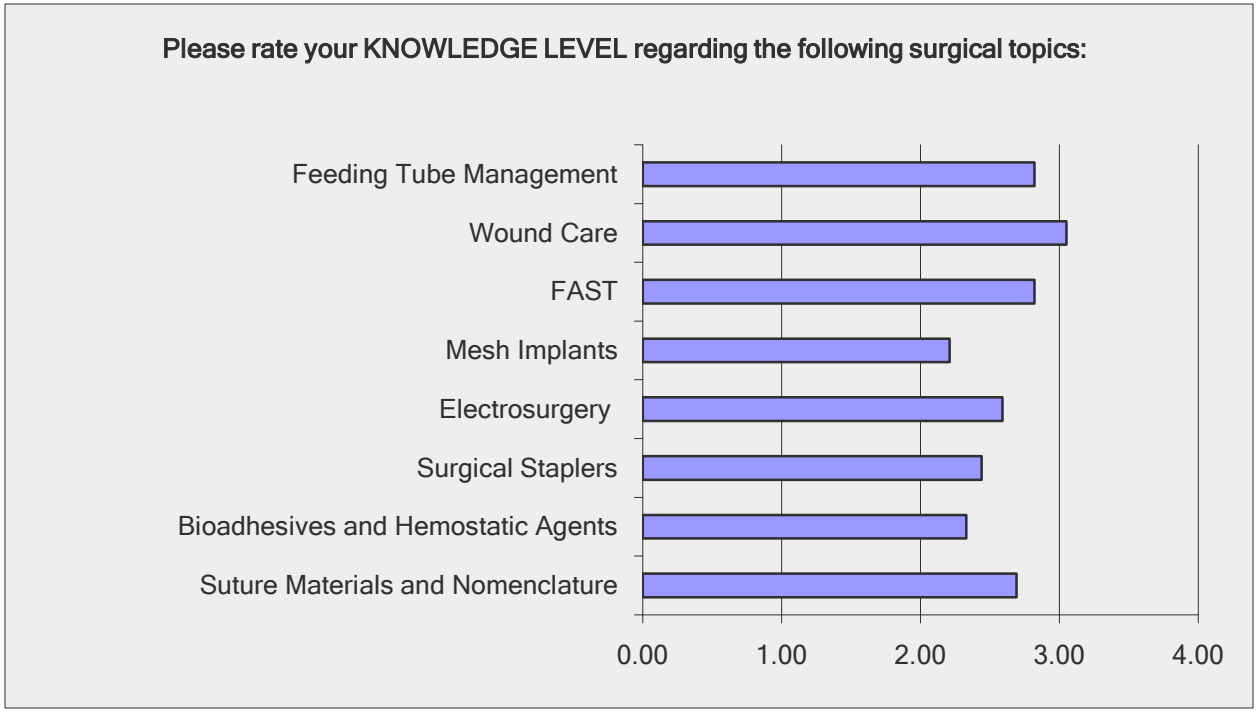






Why Discuss Mesh?

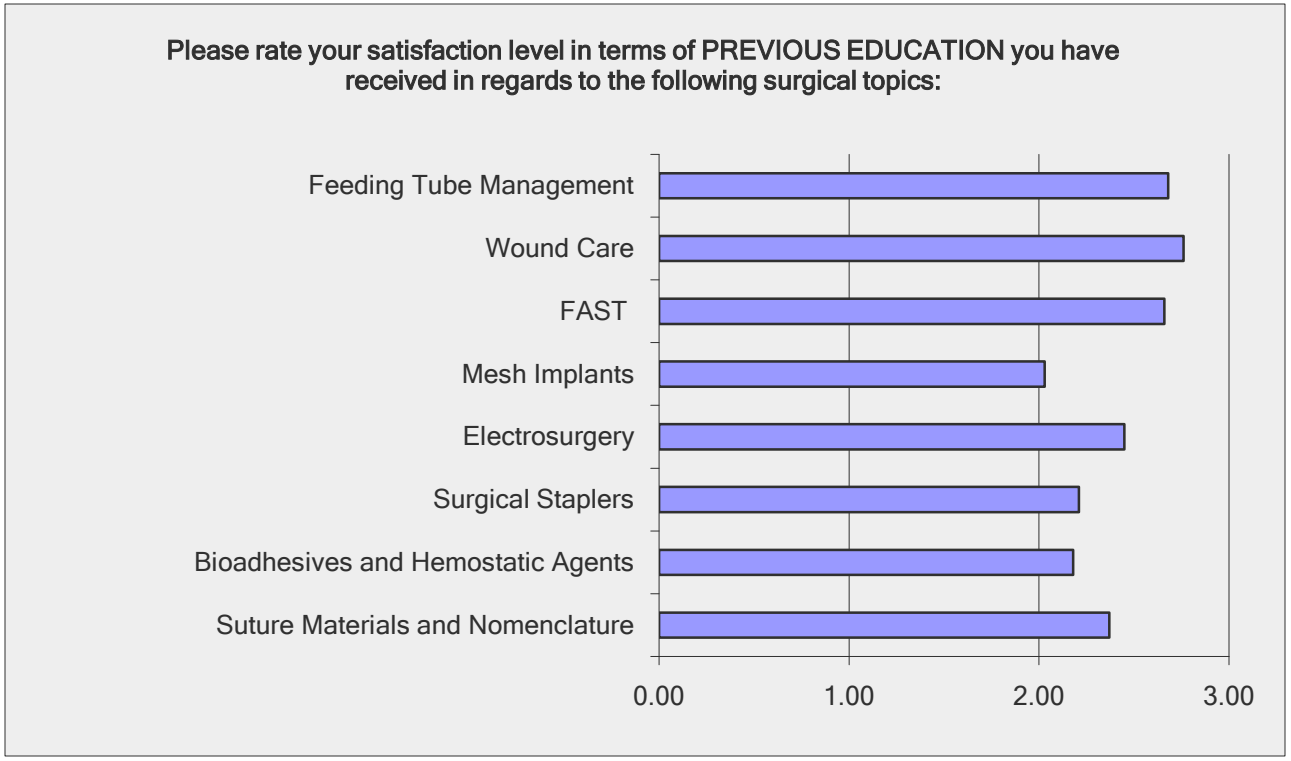


1 = No Knowledge
2 = Little Knowledge
3 = Adequate Knowledge
4 = Extensive Knowledge

Electronic Survey
4 Surgery Residencies
41 Responses

Surgical Education Research Fellowship 2010 - 2011

Why Discuss Mesh?



1 = Very Unsatisfied
2 = Unsatisfied
3 = Satisfied
4 = Very Satisfied

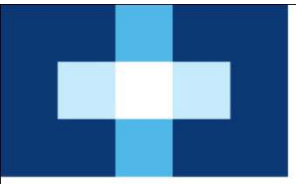
Surgical Education Research Fellowship 2010 - 2011

"Identify the main source of your education regarding these surgical topics"

- Most residents (76-97%) indicated their main source of information was provided 'on the job' rather than in a formal setting

- **Industry representatives** provided more education than formal lectures for bioadhesives and **mesh** topics

Mesh – the Industry



COVIDIEN

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ETHICON

a Johnson & Johnson company

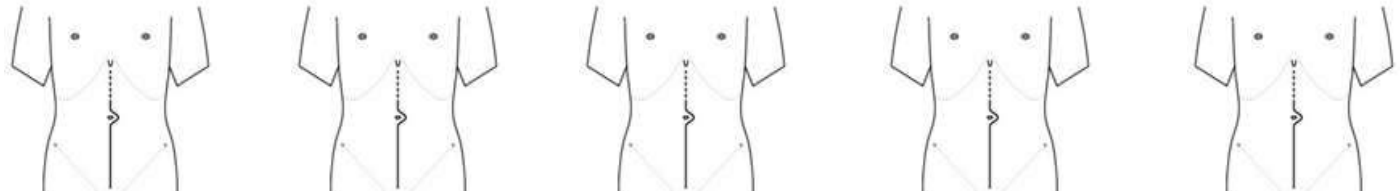
BARD

DAVOL INC.

Hernias

- 4-5 million laparotomies performed in the US each year
- Reported incidence of ventral hernia is 2 – 25%
- 150,000-500,000 hernias repaired annually in U.S.

- Hernia repair is the most commonly performed surgery worldwide



Choi et al. Annals of Surgery 2012
Breuing et al. Surgery 2010

Hernias

- **“A surgeon can do more for the community by operating on hernia cases and seeing that his recurrence rate is low than he can by operating on cases of malignant disease.”**

Sir Cecil Wakely - 1948
President, Royal College of Surgeons


M*E*S*H

Hernia Repair: Mesh

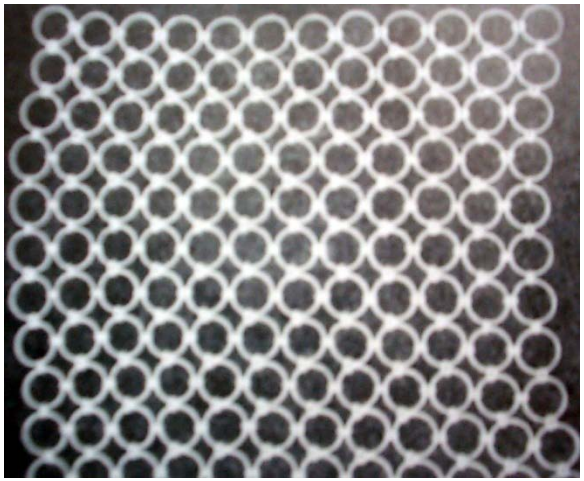
"If we could artificially produce tissue of the density and toughness of fascia and tendon, the secret of the radical cure of the hernia repair would be discovered."

Hernia Repair: Mesh

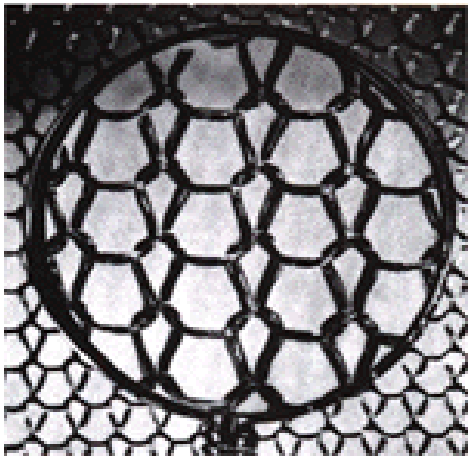
"If we could artificially produce tissue of the density and toughness of fascia and tendon, the secret of the radical cure of the hernia repair would be discovered."

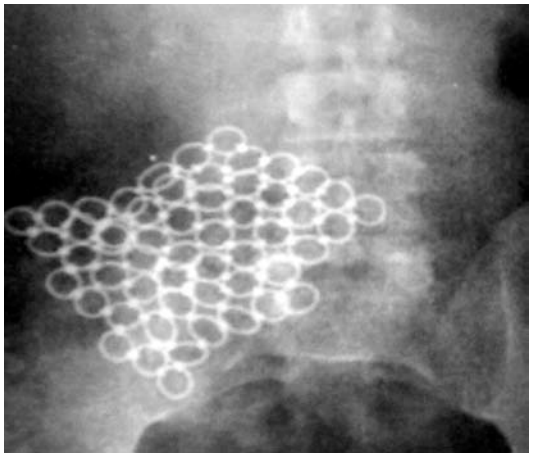
Theodore Bilroth 1857

Stainless Steel

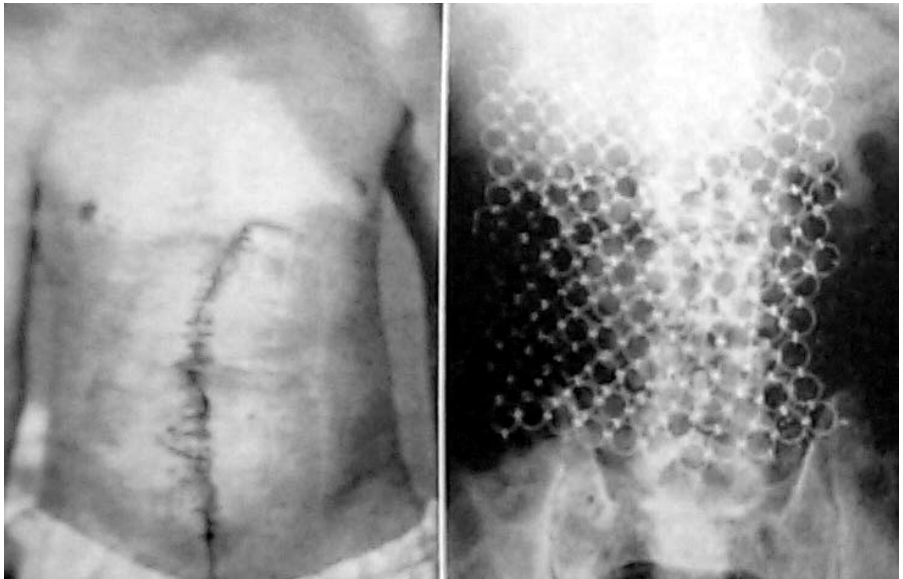


1941





1958

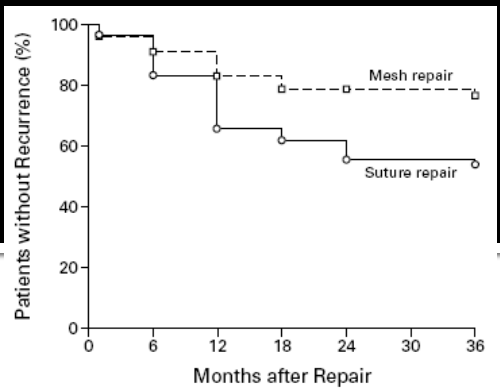


Polymers

- Polypropylene (Francis Usher 1958)
  - A high density plastic invented in the 1950s by two chemists and popularized by *Wham-O* with their construction of hula hoops

- Polyester (Mersilene 1956)
  - Popularized in Europe by Rives and Stoppa

Why use mesh?



The New England Journal of Medicine

A COMPARISON OF SUTURE REPAIR WITH MESH REPAIR FOR INCISIONAL HERNIA

ROLAND W. LUIJENDIJK, M.D., PH.D., WIM C.J. HOP, PH.D., M. PETROUSJKA VAN DEN TOL, M.D., DIEDERIK C.D. DE LANGE, M.D., MARIJEL M.J. BRAAKSMA, M.D., JAN N.M. IJZERMANS, M.D., PH.D., ROELOF U. BOELHOUWER, M.D., PH.D., BAS C. DE VRIES, M.D., PH.D., MARC K.M. SALU, M.D., PH.D., JACK C.J. WERELDSMA, M.D., PH.D., CORNELIS M.A. BRUIJNINCKX, M.D., PH.D., AND JOHANNES JEEKEL, M.D., PH.D.

- Prospective, Randomized
- N = 181
- Primary Hernia or 1st Recurrence
- Single Defect, No Previous Mesh
- 3 yr follow up (Physical Exam)

- Suture recurrence rate - 43%
- Mesh recurrence rate - 24%
- Defects < 10 cm^2: 44% vs 6%

Why use mesh?

Long-term Follow-up of a Randomized Controlled Trial of Suture Versus Mesh Repair of Incisional Hernia

Jacobus W. A. Burger, MD, Roland W. Luijendijk, PhD,† Wim C. J. Hop, PhD,‡ Jens A. Halm, MD,* Emiel G. G. Verdaasdonk, MD,* and Johannes Jeekel, PhD**

N = 126

10 year cumulative recurrence rate

- 32% recurrence rate with mesh repair
- 63% recurrence rate with suture repair

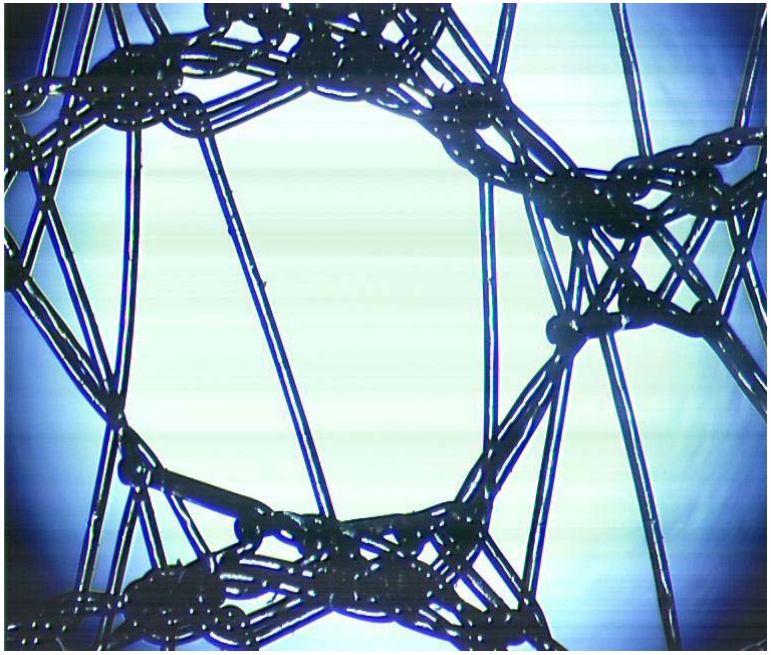
Recurrence rate with hernias < 10 cm^2

- 17% recurrence rate with mesh repair
- 67% recurrence rate with suture repair

Ann Surg 2004

Why use mesh?

- Inguinal Hernia
  - Mesh: 50%-75% reduction in recurrence rates
- Umbilical Hernia
  - Suture recurrence rate - (11%)
  - Mesh (1%)



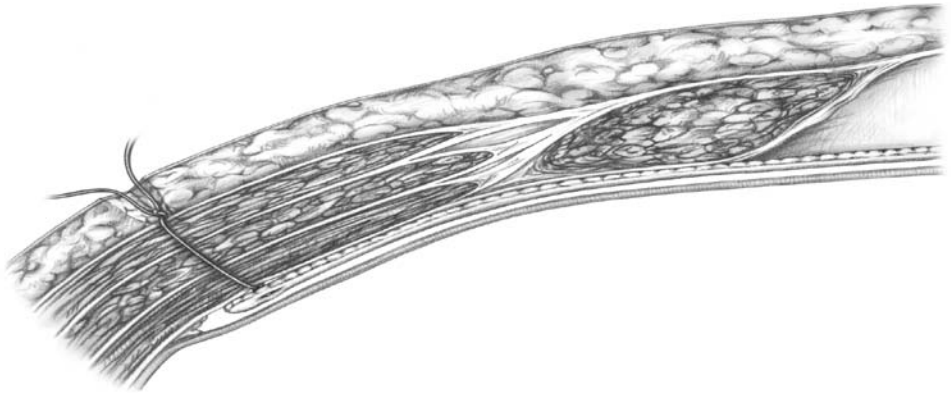
Grant AM, EU Hernia Trialists Collaboration, Hernia 2002
Arroyo A, Br J Surg 2001

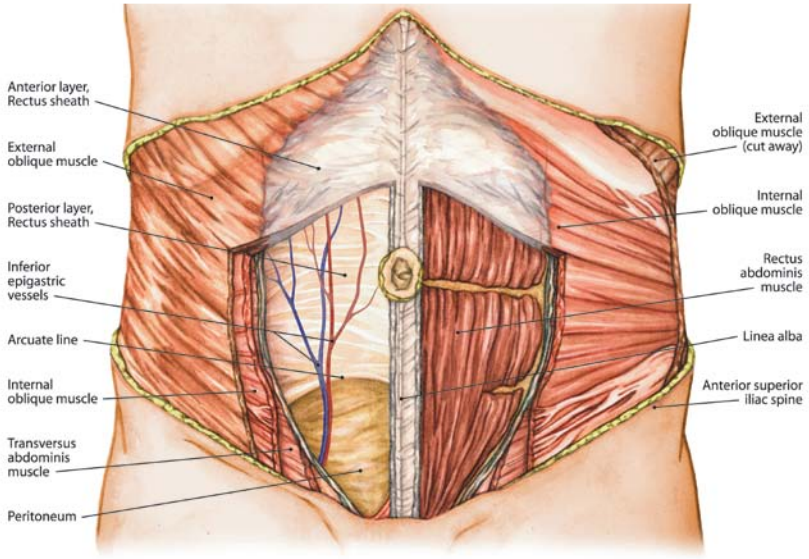
The Ideal Mesh

- Strong
- Biocompatible
  - Inert
  - Compliance similar to native fascia
- Tissue ingrowth
- Resists adhesions to viscera
- Resists infection
- Easy to use
- Minimizes inflammatory response
- Inexpensive
- Does not shrink, deform, or stiffen

The Ideal Mesh – Depends on Where You Put It!

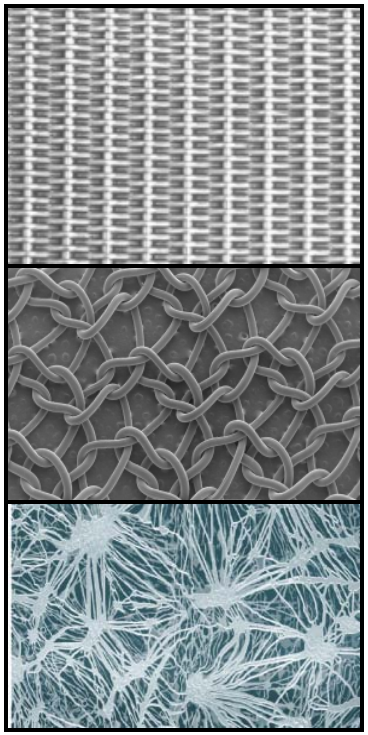
- Onlay
- Bridge
- Underlay
  - Retrorectus
  - Extraperitoneal
  - Intraperitoneal
- Contaminated Field

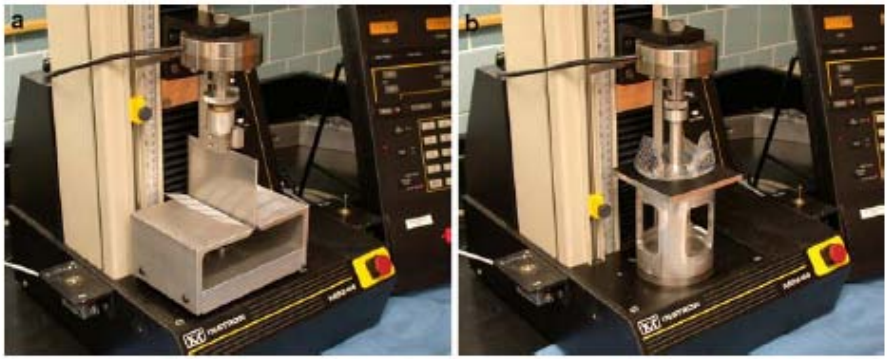




Mesh Characteristics

- Surface Area/Density/Weight
- Woven/Knitted/Expanded
- Hydrophobicity/Hydrophilicity
- Adhesiogenicity
- Strength
- Permanence
- Ease in Handling



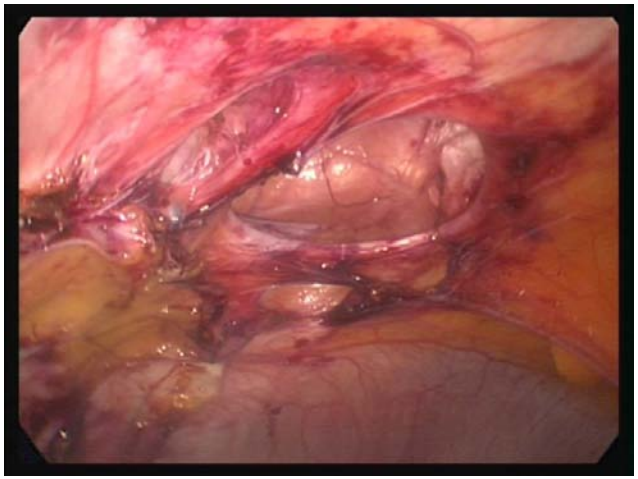


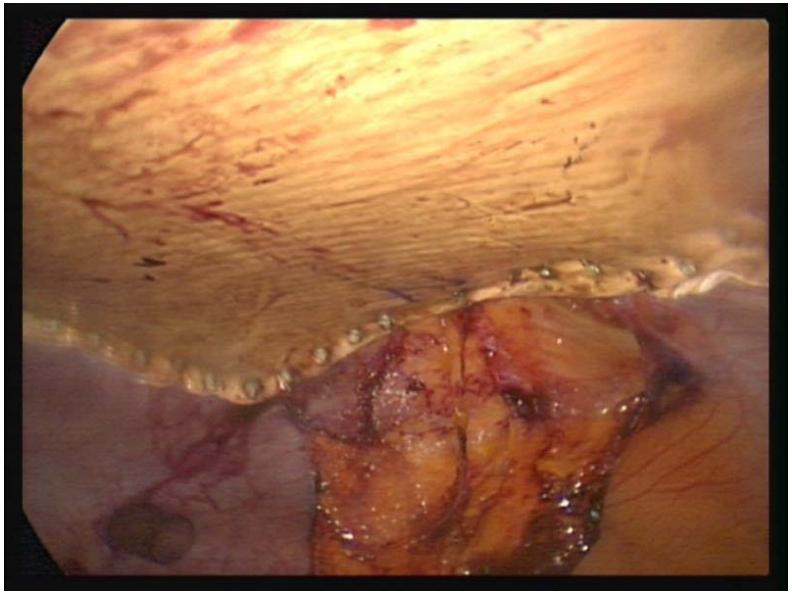
Mesh terminology 101

W. S. Cobb · R. M. Peindl · M. Zerey · A. M. Carbonell · B. T. Heniford

Limitations to Data Acquisition

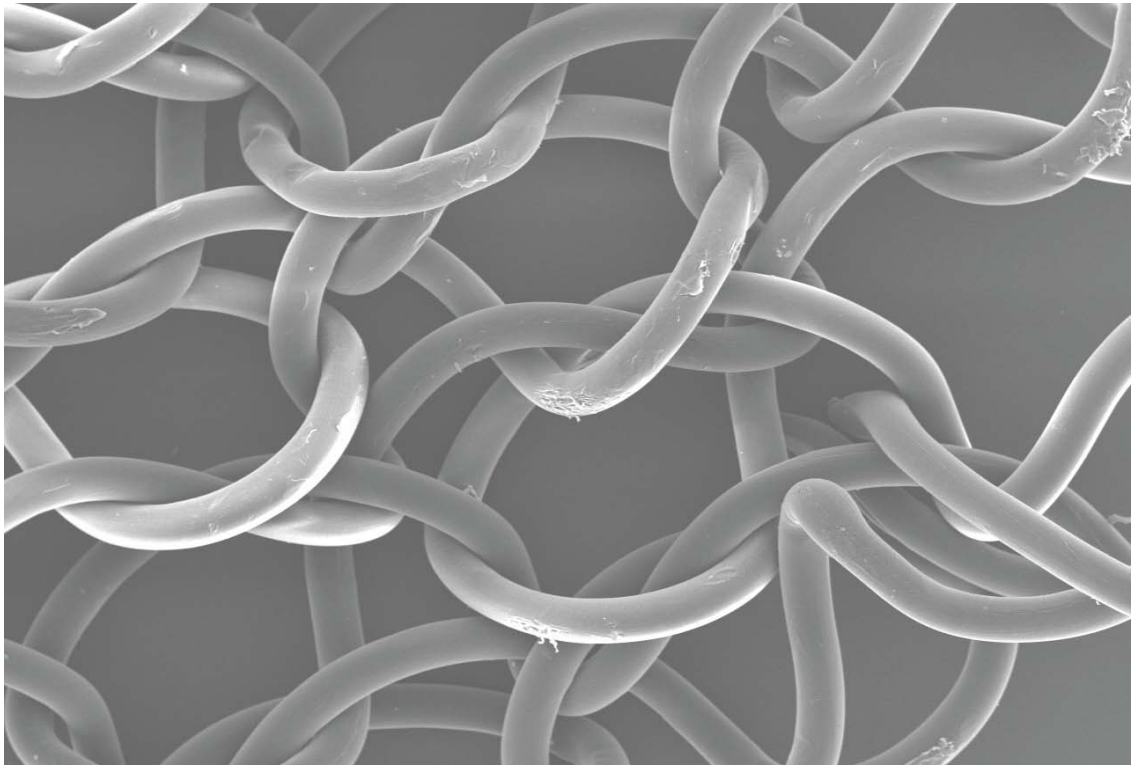
- Techniques
- Patient Factors
- Ability to Study
- Parameters/Outcomes
  - Recurrence
  - Infection
  - Adhesion
  - Cost





Mesh Materials

- Synthetic
  - Permanent
  - Absorbable
- Biologic
  - Allograft
  - Xenograft



Well over 80 different prosthetic materials are available on the market for hernia repair

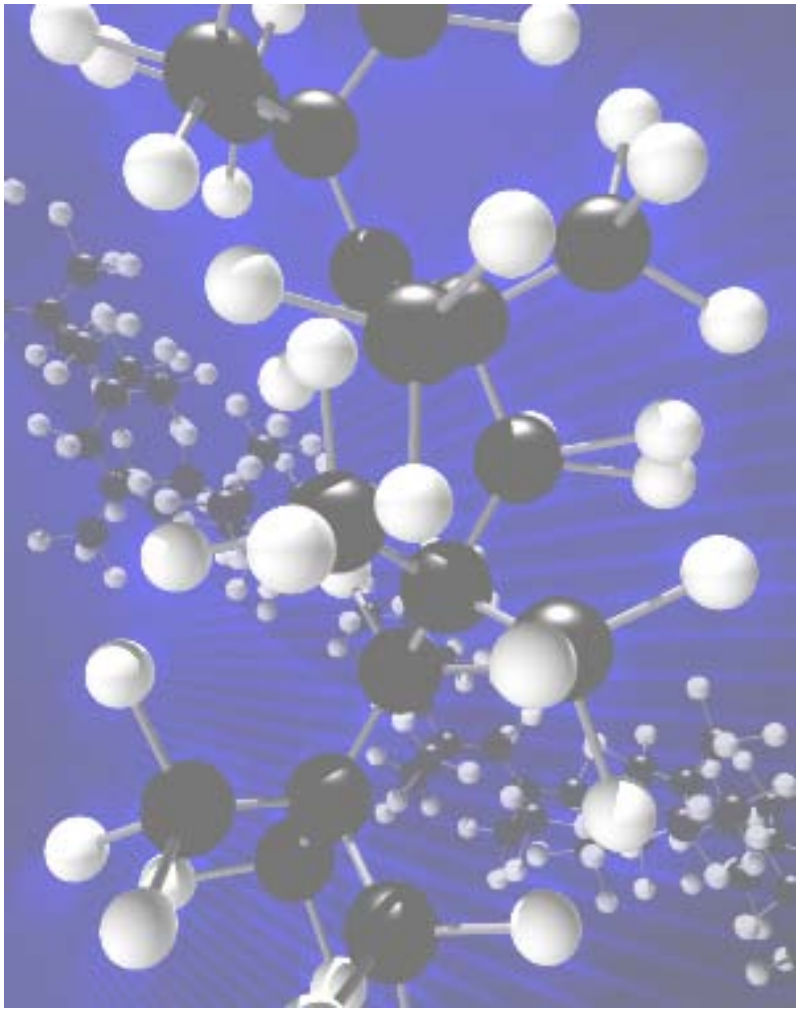
Definitions

- **Polymer -** a macromolecule composed of repeating structural units

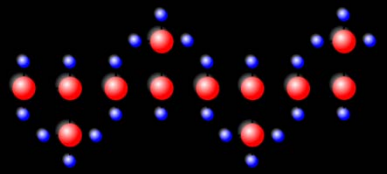
- **Composite** – engineered material composed of two or more constituent materials with significantly different physical or chemical properties

Synthetic - Permanent

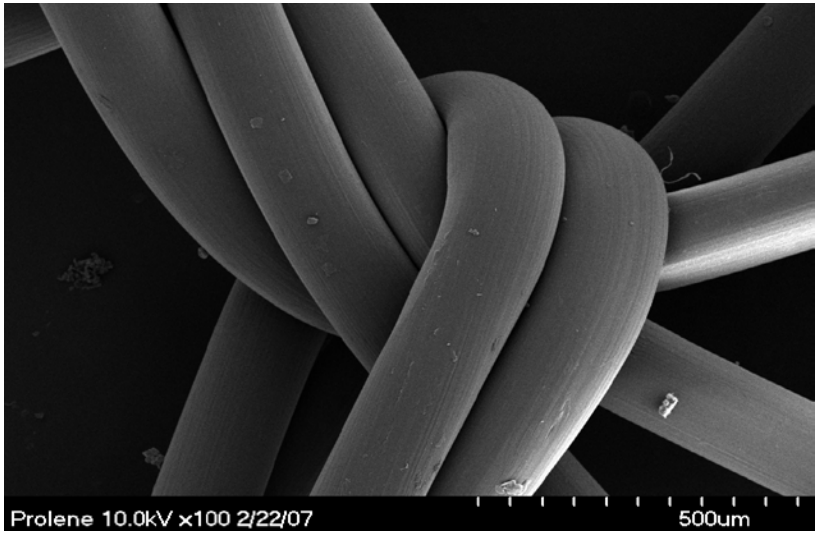
- Polypropylene
- Polyester
- PTFE



Polypropylene

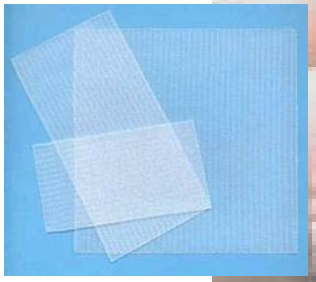


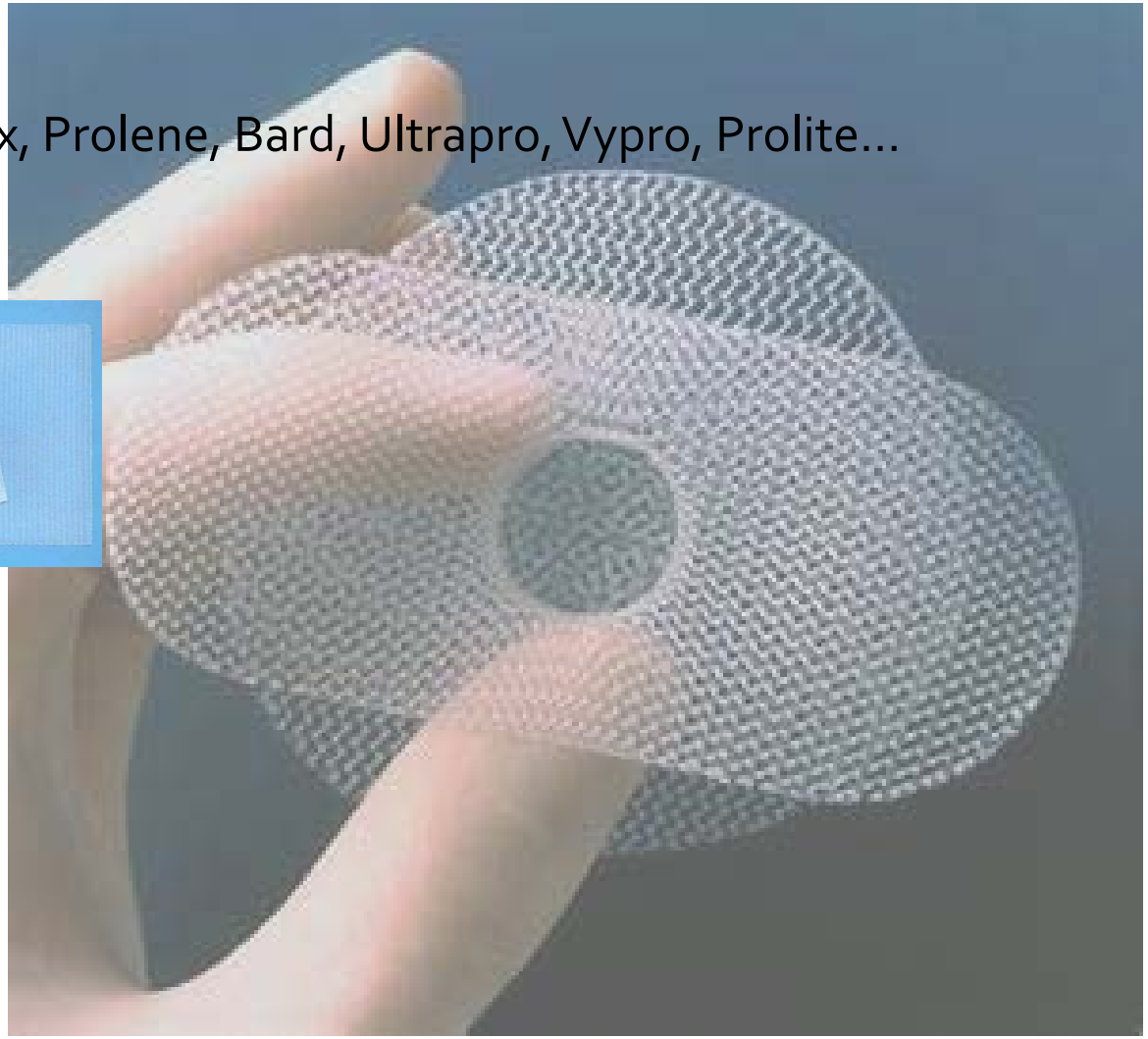
- Properties
  - Hydrophobic
  - Broken down by oxidation
- Advantages
  - Rapid ingrowth
  - Can be salvaged if infected
- Disadvantages
  - Can cause dense adhesions



Polypropylene

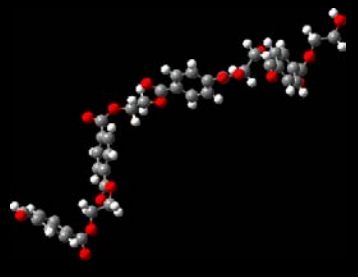
- Examples: Marlex, Prolene, Bard, Ultrapro, Vypro, Prolite…
- Forms
  - Sheets
  - Plug
  - 3-D (lap IHR)
  - Composites





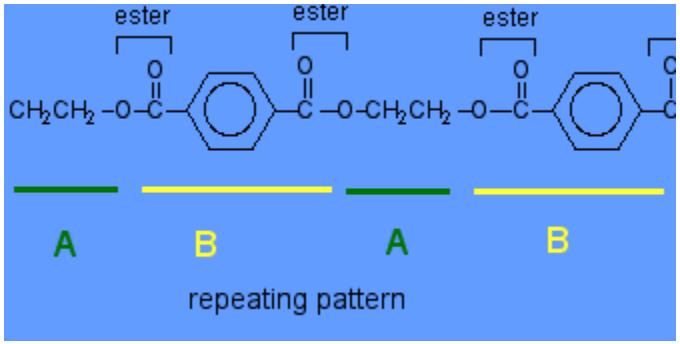
Polyester

aka Dacron
aka Polyethylene Terephthalate (PET)



- Properties
  - Hydrophilic
  - Multi-filamentous

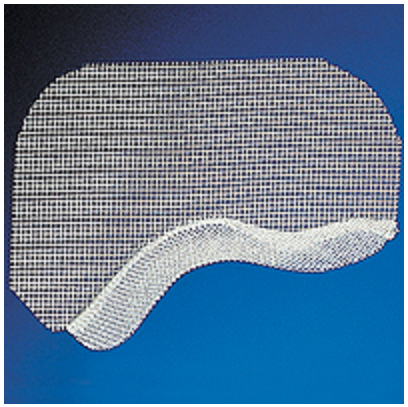
- Advantages
  - Better pliability/handling
  - Decreased seroma formation

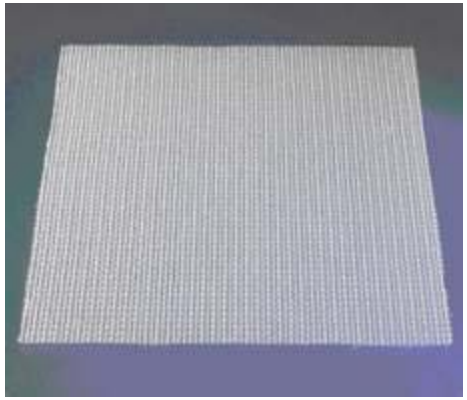


- Disadvantages
  - Increased infection rate
  - Loses burst strength over time

Polyester

- Examples: Mersilene, Parietex, Starester
- Forms
  - Sheet
  - Composite



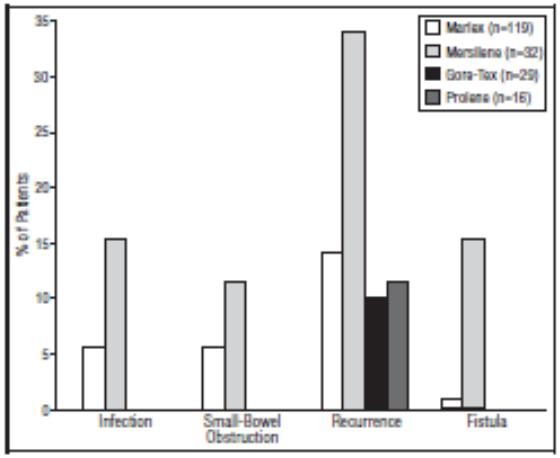


Polyester: Mersilene

Long-term Complications Associated With Prosthetic Repair of Incisional Hernias

Geoffrey E. Leber, MD; Jane L. Garb, MS; Albert I. Alexander, MD; William P. Reed, MD

Arch Surg 1998



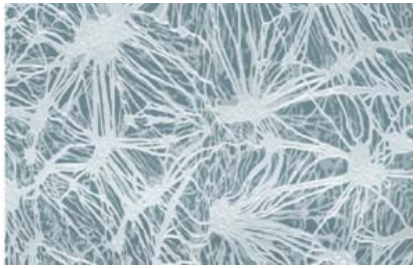
Conclusion: “Polyester mesh should no longer be used for incisional hernia repair”

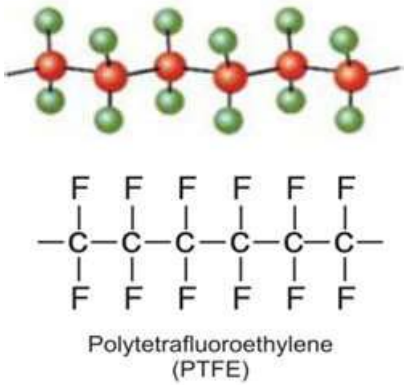
32 patient with unprotected PET mesh
80% had direct contact with abdominal viscera

Rosen et al. Am J Surg 2009
N = 109 PET meshes
F/U > 1 year
No fistulas, 4 infections, 1 SBO

PTFE - polytetrafluoroethylene

- 'polymer' (ePTFE = expanded)
  - aka Teflon
- Properties
  - Chemically Inert
  - Hydrophobic
- Advantages
  - No chemical cleavage/degradation
  - Effective anti-adhesion barrier
- Disadvantages
  - Very difficult to eradicate infection
  - Encapsulation, seroma formation
  - Increased FB giant cells

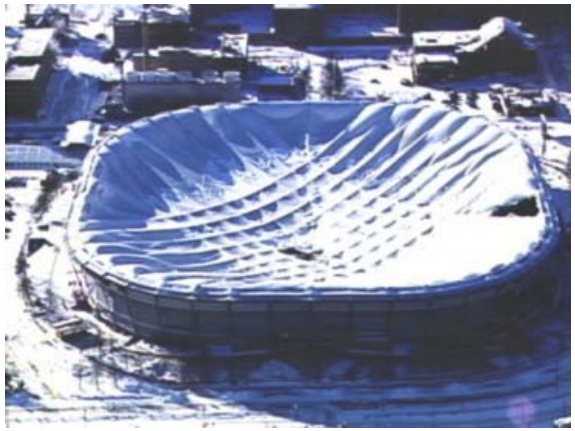




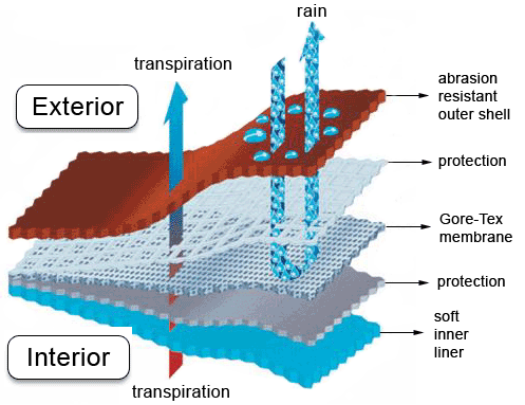
Orenstein et al. J Surg Research

PTFE

- History – Dupont, Gore (Not NASA!)
  - Strength Coating
  - Non-Stick Coating
- Vascular Grafts
- Winter Gear

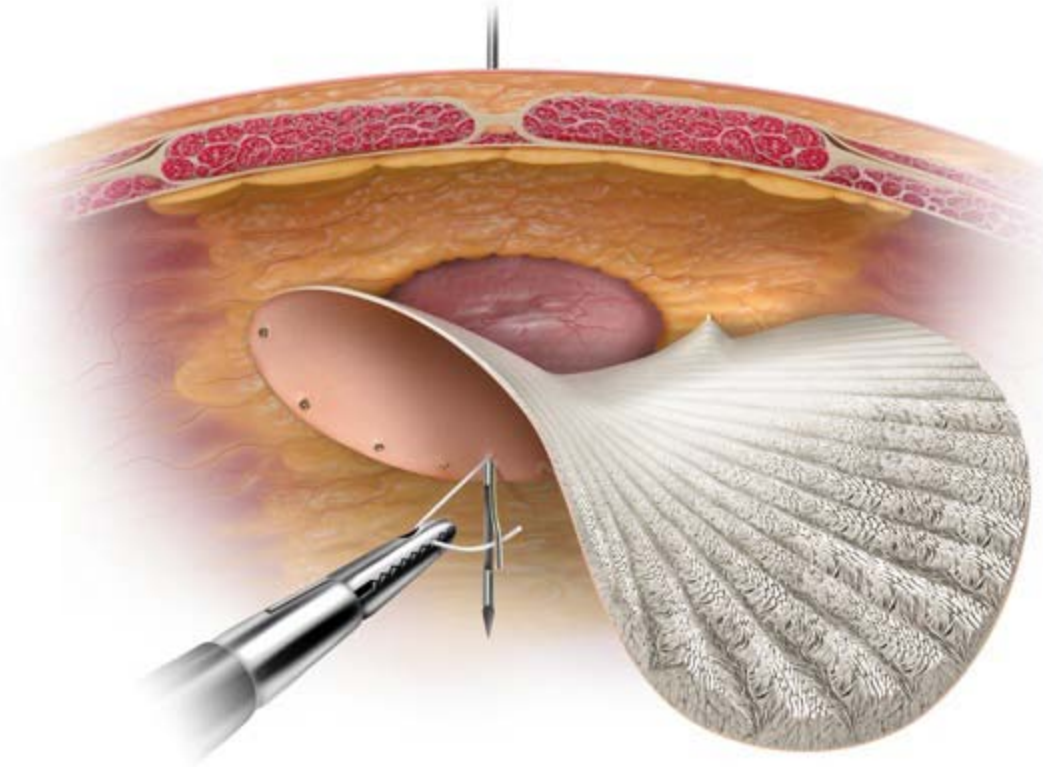


PTFE = Gore-Tex



PTFE

- Dualmesh
- Dulex
- Various Composite Meshes

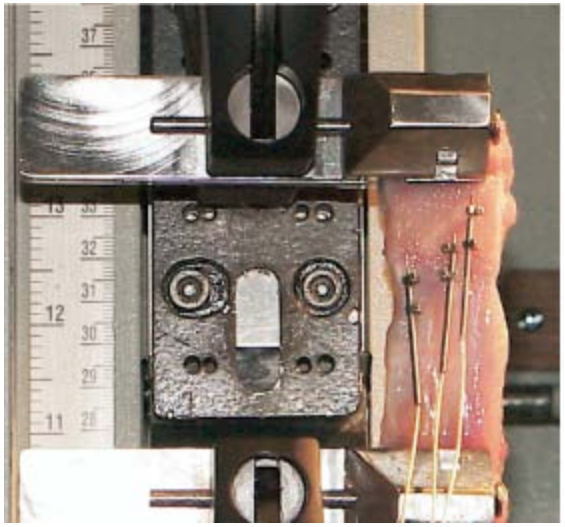


PTFE – not all PTFE is created equally!

Journal of Surgical Research **140,** 6–11 (2007)
doi:10.1016/j.jss.2006.09.015

Association for Academic Surgery, 2006

Comparative Evaluation of Adhesion Formation, Strength of Ingrowth, and Textile Properties of Prosthetic Meshes After Long-Term Intra-Abdominal Implantation in a Rabbit[1]



N = 4 mesh types, 40 implants

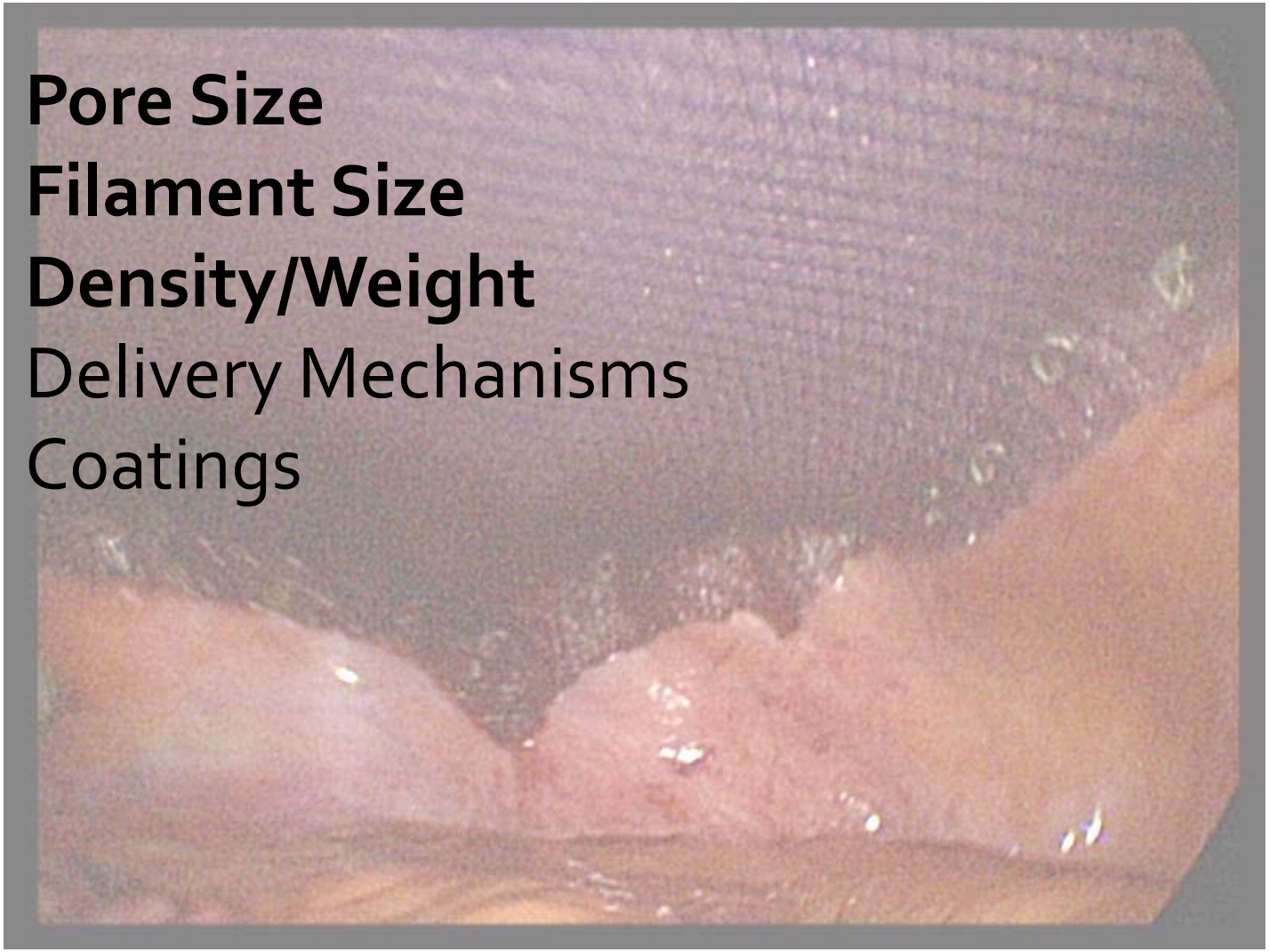
Explant at one year, analysis of adhesions, shrinkage, strength, and compliance

"Composix had significantly higher rates of adhesion formation than did Dualmesh"

Novitsky et al, J Surg Research 2007

Manufacturing: More than Materials…

- **Pore Size**
- **Filament Size**
- **Density/Weight**
- Delivery Mechanisms
- Coatings



Potential Downsides of Traditional Heavy-Weight Mesh

- Excessive foreign body reaction
- Chronic, severe inflammation

→ **Chronic Pain**

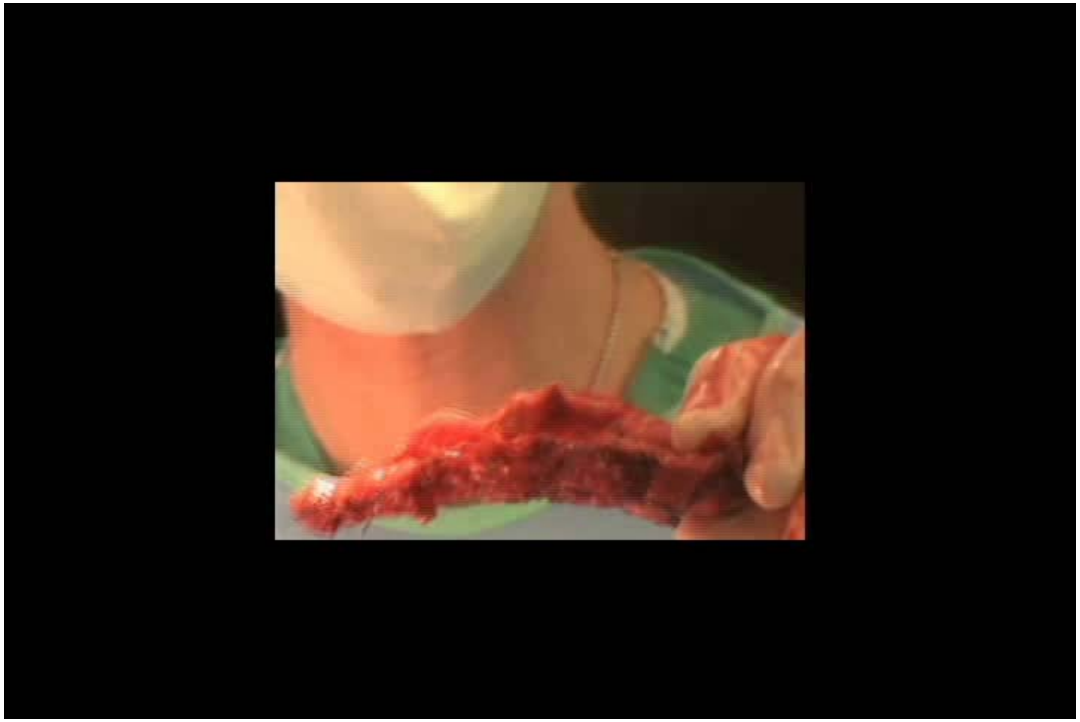
- Disorganized fibrocollagenous tissue ingrowth
- Scar plate formation
- Bridging fibrosis

→ **Shrinkage**
Recurrence

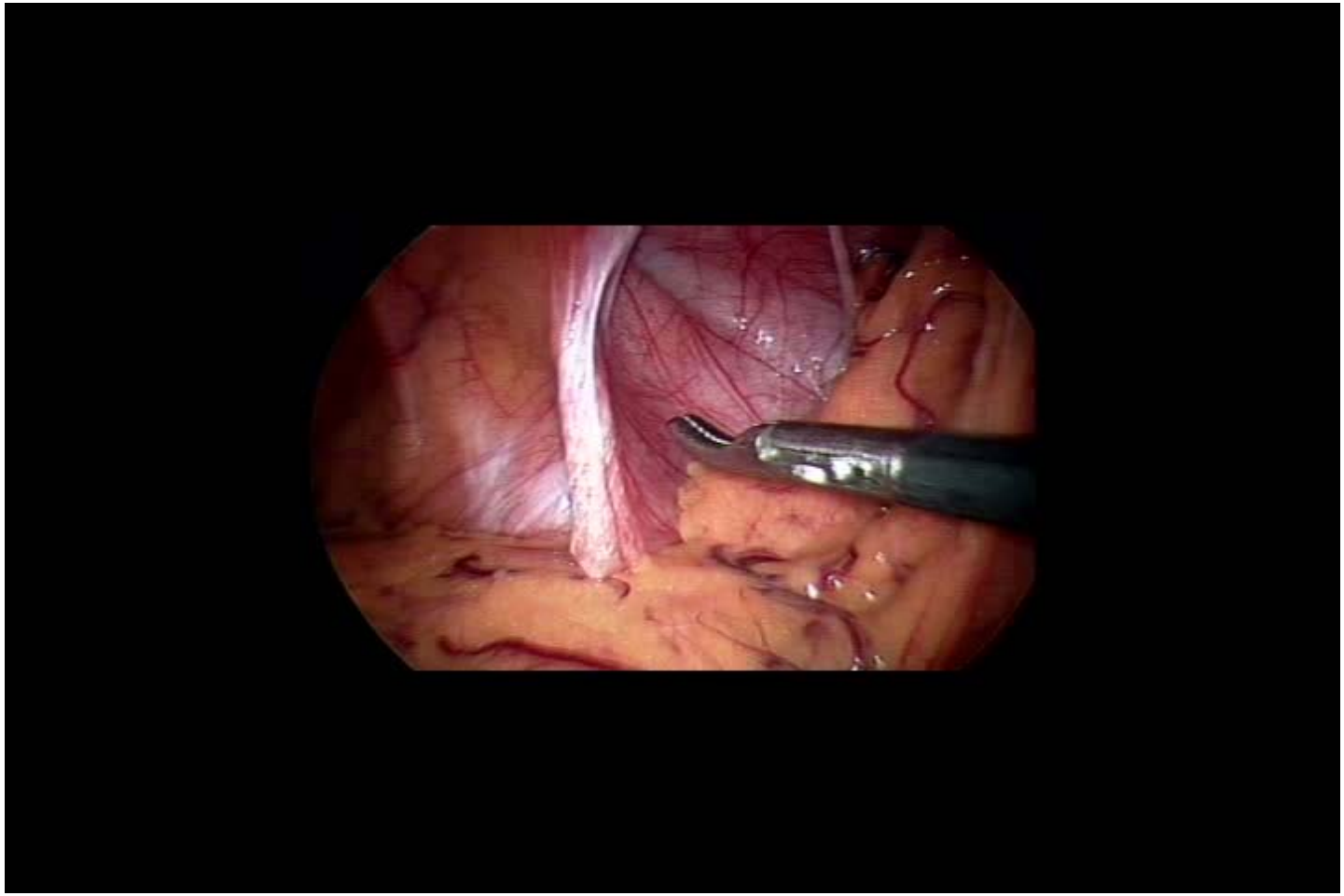
- Stiffness (↓ compliance) → **Abdominal Wall Restriction**

Klinge et al J Surg Res 2002
S.Post et al British J Surg 2004

Inflammation, Fibrosis



Pain, Decreased QOL, Recurrence



Pain, Decreased QOL, Recurrence

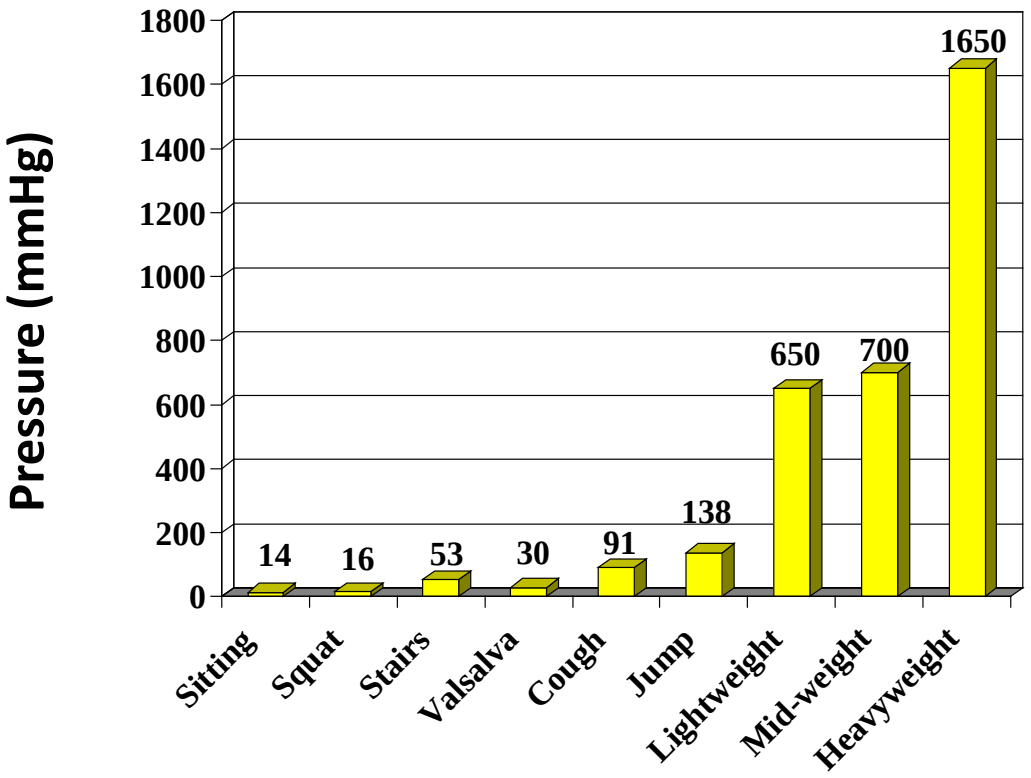
"Heavyweight" Mesh is Over-Engineered

Normal Intraabdominal Pressure in Healthy Adults

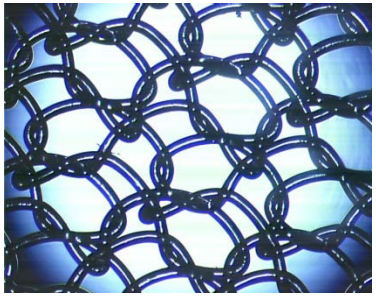
William S. Cobb, M.D.,[1] Justin M. Burns, M.D., Kent W. Kercher, M.D., Brent D. Matthews, M.D., H. James Norton, Ph.D., and B. Todd Heniford, M.D.

Carolinas Laparoscopic and Advanced Surgery Program, Carolinas Medical Center, Charlotte, North Carolina

J Surg Res 2005



New Mesh Concepts



- Reduction in synthetic content: thinner filaments
  - 80 – 95 gm / m ^{2} → 20 – 30 gm / m ^{2}
- Increased pore size
  - < 1 mm → 3-5 mm
  - Less granuloma formation and bridging fibrosis
  - Improved native tissue in-growth
  - Monofilament grafts associated with less contraction and reduced inflammatory responses
- Clinical implications
  - Mimic physiology of abdominal wall
  - Allow for increased flexibility and comfort
  - Enhanced incorporation into host tissue
  - Less long-term discomfort / neuralgia

Klosterhalfen B et al. Biomaterials 1998

Lightweight Mesh

Polypropylene content

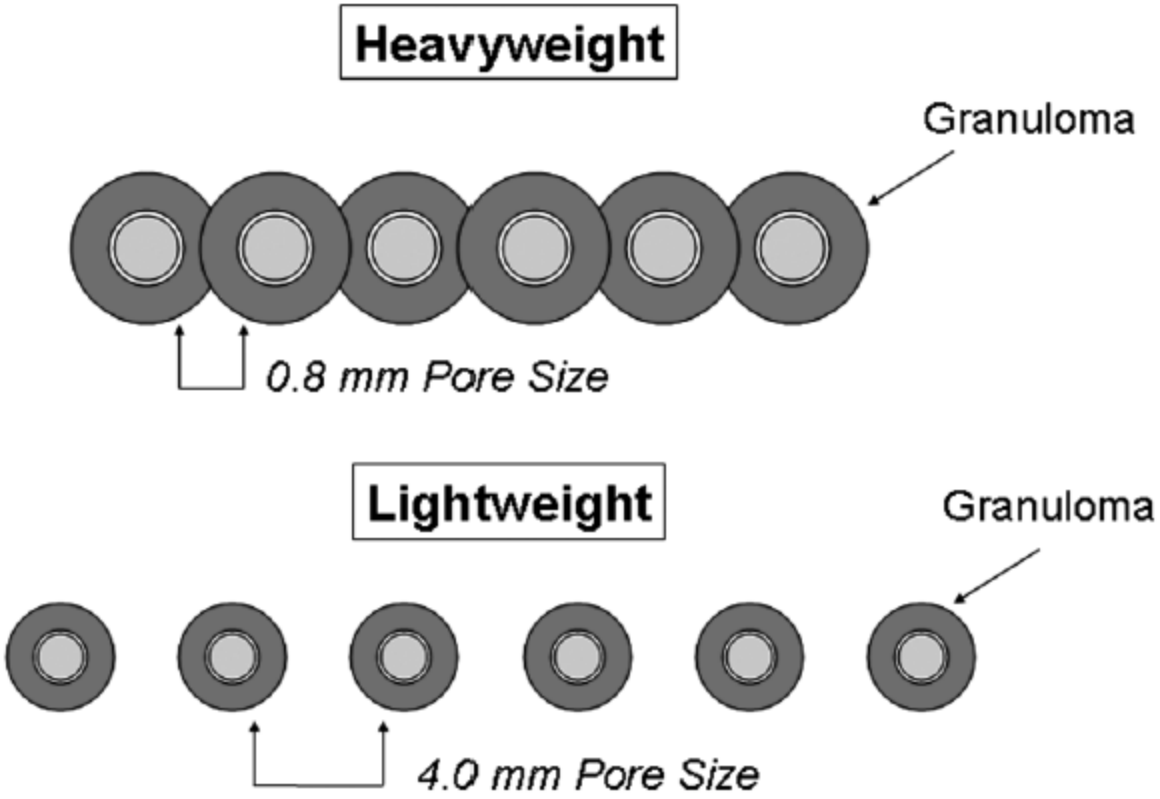
• Heavyweight	95 - 110 g/m²
• Mid weight	40 - 55 g/m²
• Lightweight	25 - 30 g/m²

Lightweight Mesh

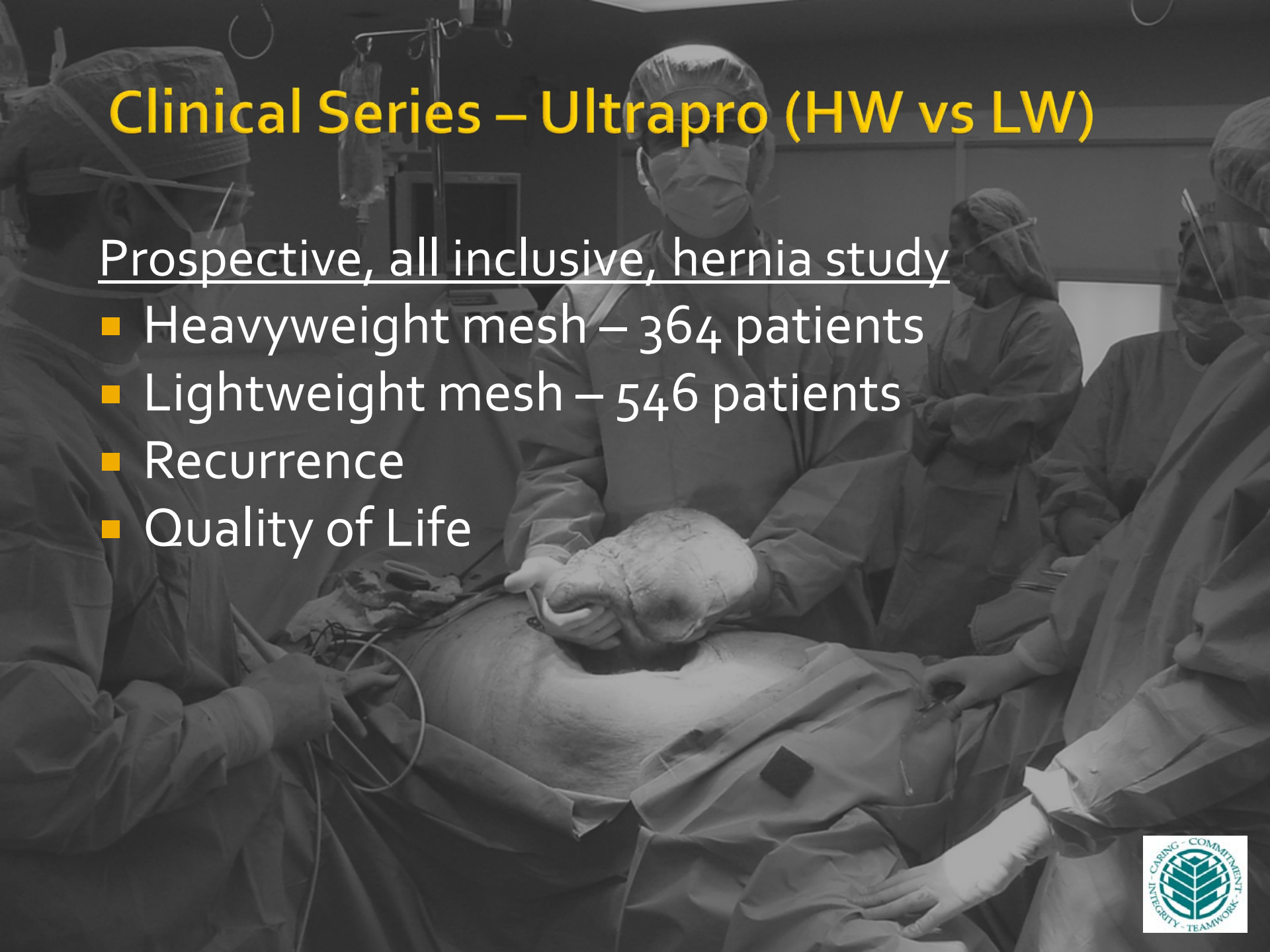
The Argument for Lightweight Polypropylene Mesh in Hernia Repair

William S. Cobb, MD, Kent W. Kercher, MD, and B. Todd Heniford, MD

Surg Innov 2005



Clinical Series – Ultrapro (HW vs LW)



Prospective, all inclusive, hernia study

- Heavyweight mesh – 364 patients
- Lightweight mesh – 546 patients
- Recurrence
- Quality of Life

Pre-operative SF-36 for Ventral/Incisional Hernia - LW vs HW Mesh

Category	Lightweight	Heavyweight	*p*
General Health	47.98	44.80	0.1816
Vitality	43.11	43.71	0.1968
Social Function	40.87	38.93	0.6187
Role Emotional	37.53	36.78	0.4054
Mental Health	46.28	44.76	0.1118
Physical Function	37.22	36.15	0.7066
Role Physical	35.65	33.59	0.3218
Bodily Pain	36.61	35.08	0.1993
PCS	37.78	36.41	0.3170
MCS	44.86	40.20	0.1902

Post-operative SF-36 for Ventral/Incisional Hernia - LW vs HW Mesh

Category	Lightweight	Heavyweight	*p*
General Health	46.31	36.70	0.02178*
Vitality	52.85	44.50	0.0491*
Social Function	45.81	42.44	0.5178
Role Emotional	45.33	34.65	0.0480*
Mental Health	49.18	39.15	0.0381*
Physical Function	46.25	37.78	0.0490*
Role Physical	45.55	39.59	0.2077
Bodily Pain	49.49	40.58	0.0290*
PCS	46.67	40.03	0.1175
MCS	48.08	40.69	0.2075

Post-operative Carolinas Comfort Scale for Ventral/Incisional Hernia - LW vs HW Mesh

Category	Lightweight	Heavyweight	*p*
Laying Down	1.93	2.50	0.2941
Bending Over	3.15	5.87	0.0158*
Sitting Up	2.51	5.13	0.0211*
ADL	2.48	5.75	0.0139*
Coughing or Deep Breathing	2.95	5.75	0.0314*
Walking	2.36	4.62	0.0427*
Stairs	2.77	4.31	0.1505
Exercising	3.19	6.14	0.0222*
Total Comfort Scale	17.62	40.23	0.0084*

Randomized Prospective Trials: Open Inguinal Hernia Repair

- Lichtenstein repair (n = 122)
- LW mesh (Vypro [25 gm/m^2 PP]) vs HW mesh (Surgipro [110 gm/m^2 PP])
- SF-36 and VAS
  - Preoperative, 2 days and 6 months post-op
- Primary outcomes measures
  - Foreign body sensation
  - Recurrence rate
  - Chronic pain

Post et al. BJS 2004

Randomized Prospective Trials: Open Inguinal Hernia Repair

- Early and late complications
  - No differences
- Pain on exercise at 6 months (VAS 0-5)
  - 0.79 HW vs 0.16 LW (p=0.042)
- Foreign body sensation
  - 44% HW vs 17% LW (p = 0.003)
- Recurrence
  - No difference (4.2% HW vs 3.4% LW)

Post et al. BJS 2004

Prospective double-blind randomized controlled study comparing heavy- and lightweight polypropylene mesh in totally extraperitoneal repair of inguinal hernia: early results

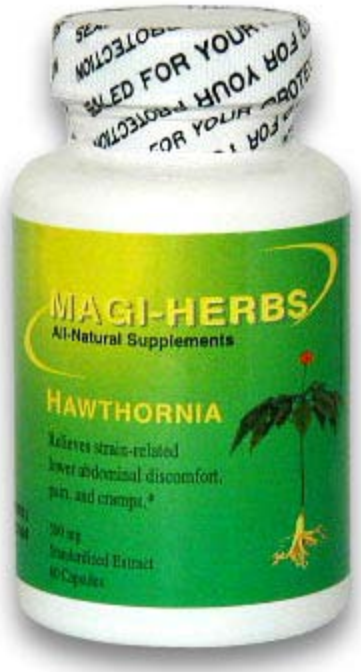
- TEP bilateral inguinal hernia repairs (n = 25)
- Lightweight on one side - Heavyweight on the other
- Glue for fixation
- Follow-up with quality of life measures
- Independent, blinded follow-up

- Lightweight mesh:
  - Reduced pain scores
  - Patient comfort with exertion
  - Reduced discomfort with sexual activity
  - All 25 patients correctly identified the side with LW mesh
  - No differences at 3 months, 12 months

Agarwal BB et al, Surg Endosc 2009

Lightweight Mesh

Mesh: Material and Density



Physicomechanical Evaluation of Polypropylene, Polyester, and Polytetrafluoroethylene Meshes for Inguinal Hernia Repair

Corey R Deeken, PhD, Michael S Abdo, Margaret M Frisella, RN, Brent D Matthews, MD, FACS

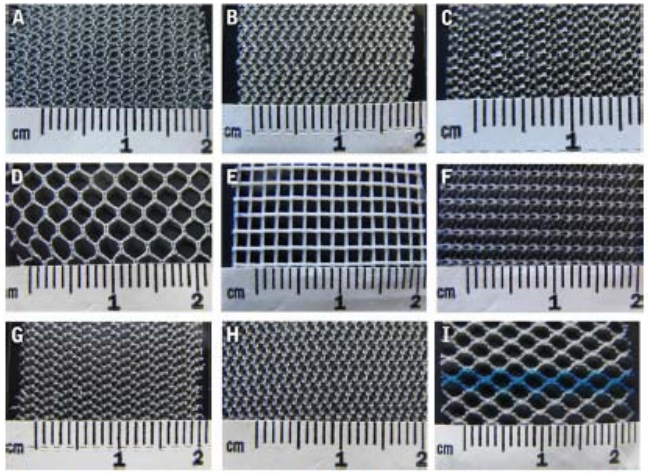


Figure 1. Photos of each mesh evaluated in this study: (A) BardMesh, (B) C-QUR Lite Large, (C) C-QUR Lite Small, (D) INFINIT Mesh, (E) Parietex Flat Sheet TEC, (F) PROLENE, (G) ProLite Ultra, (H) ProLite, (I) ULTRAPRO.

Table 3. Comparison of Physicomechanical Properties of Meshes Commonly Used for Inguinal Hernia Repair

Mesh type	Area of interstices	Filament diameter	Thickness	Density	Suture retention strength, N	Tear resistance, N	Ball burst strength, N/cm	Strain at 16N/cm, %
BardMesh	Medium	Large	Thin	Heavy-weight	>20	>20	>50	10–30
PROLENE	Medium	Small	Thin	Medium-weight	>20	>20	>50	<10
ProLite	Medium	Medium	Very thin	Medium-weight	>20	>20	>50	10–30
ProLite Ultra	Medium	Very small	Very thin	Light-weight	>20	<20	>50	10–30
Parietex Flat Sheet TEC	Large	Very large	Thin	Heavy-weight	>20	>20	>50	<10
INFINIT Mesh	Very large	Very small	Very thin	Medium-weight	>20	<20	<50	<10
C-QUR Lite "Small"	Medium	Very small	Very thin	Medium-weight (polypropylene = light-weight)	>20	<20	>50	10–30
C-QUR Lite "Large"	Medium	Medium	Very thin	Heavy-weight (polypropylene = medium-weight)	>20	>20	>50	10–30
ULTRAPRO	Very large	Very small	Thin	Medium-weight	<20	<20	<50	10–30

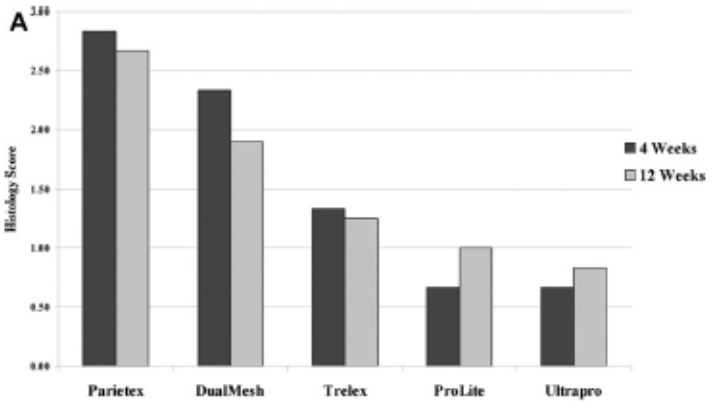
PP vs PET vs PTFE

Comparative Analysis of Histopathologic Effects of Synthetic Meshes Based on Material, Weight, and Pore Size in Mice

Sean B. Orenstein, M.D.,* Ean R. Saberski, B.S.,† Donald L. Kreutzer, Ph.D.,* and Yuri W. Novitsky, M.D.*†‡,[1]

*Department of Surgery, University of Connecticut Health Center, Farmington, Connecticut; †University of Connecticut School of Medicine, Farmington, Connecticut; and ‡Department of Surgery, University Hospitals Case Medical Center, Case Western Reserve University School of Medicine, Cleveland, Ohio

Foreign Body Giant Cells



Collagen Deposition

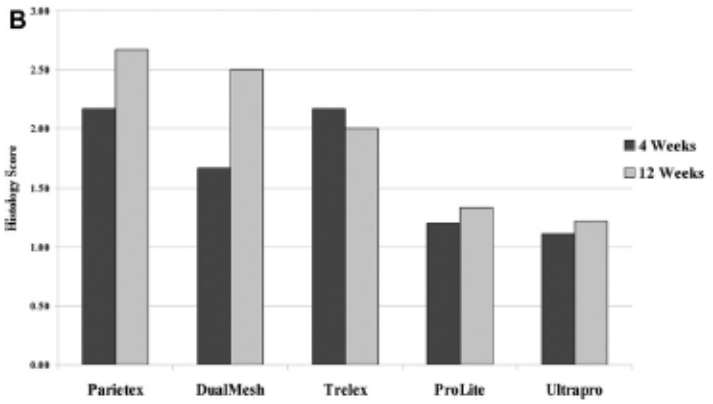


TABLE 2

Histologic Scoring Scale

Score	Inflammation	Foreign body reaction (FBGCs)	Fibrosis	Collagen organization	Vascularity
0	None	None	None	Disorganized	None
1	Minimal-mild	Minimal-mild	Minimal-mild	Slightly organized	Minimal
2	Moderate	Moderate	Moderate	Moderately organized	Moderate
3	Severe	Severe	Severe	Well organized	Abundant

FBGCs = foreign body giant cells.

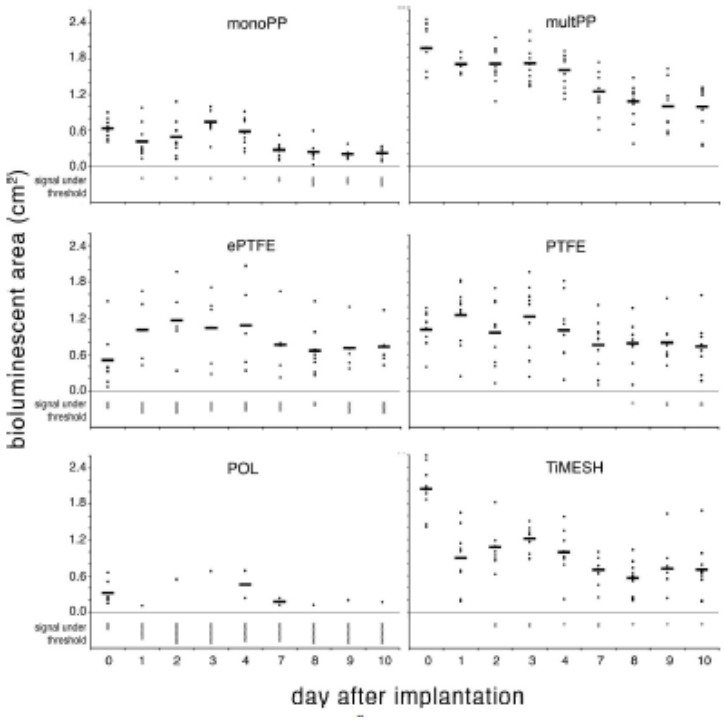
- PET induced greatest foreign body response
- Marked fibrosis and encapsulation seen with ePTFE
- Heavyweight PP displays greater early and persistent fibrosis

J Surg Research 2011

PP vs PET vs PTFE

In Vivo Evaluation of Bacterial Infection Involving Morphologically Different Surgical Meshes

Anton F. Engelsman, MD, Gooitzen M. van Dam, MD, PhD,†‡ Henny C. van der Mei, PhD,* Henk J. Busscher, PhD,* and Rutger J. Ploeg, MD, PhD†*



Conclusions: multifilament and hydrophobic meshes significantly increase bacterial persistence

Ann Surg 2010

Major mesh-related complications following hernia repair

Events reported to the Food and Drug Administration

T. N. Robinson, J. H. Clarke, J. Schoen, M. D. Walsh

Department of Surgery, University of Colorado Health Sciences Center, Box C311, 4200 East Ninth Avenue, Denver, CO 80262, USA

Table 1. Major complications related to mesh material types

	All mesh (%)	PP (%)	COMP (%)	Sepra (%)	PTFE (%)	BIO (%)
Infection	42 (107)	43	42	13	75†	29
Mechanical failure	18 (46)	17	12	80*	0	0
Pain	9 (23)	10	11	0	13	0
Reaction	8 (20)	10	0	0	0	57
Intestinal	7 (18)	4	14*	7	13	0

All mesh, combination of all mesh types reported; PP, polypropylene; COMP, composix mesh, SEPRA, Seprafilm/polypropylene mesh; PTFE, expanded polytetrafluoroethylene; BIO, combination of all mesh created from human or animal collagens; Reaction, foreign body reaction; Intestinal, intestinal complications including fistula and bowel obstruction

*$p < 0.05$

†$p = 0.07$

PP vs PTFE

Prospective Evaluation of Adhesion Formation and Shrinkage of Intra-Abdominal Prosthetics in a Rabbit Model

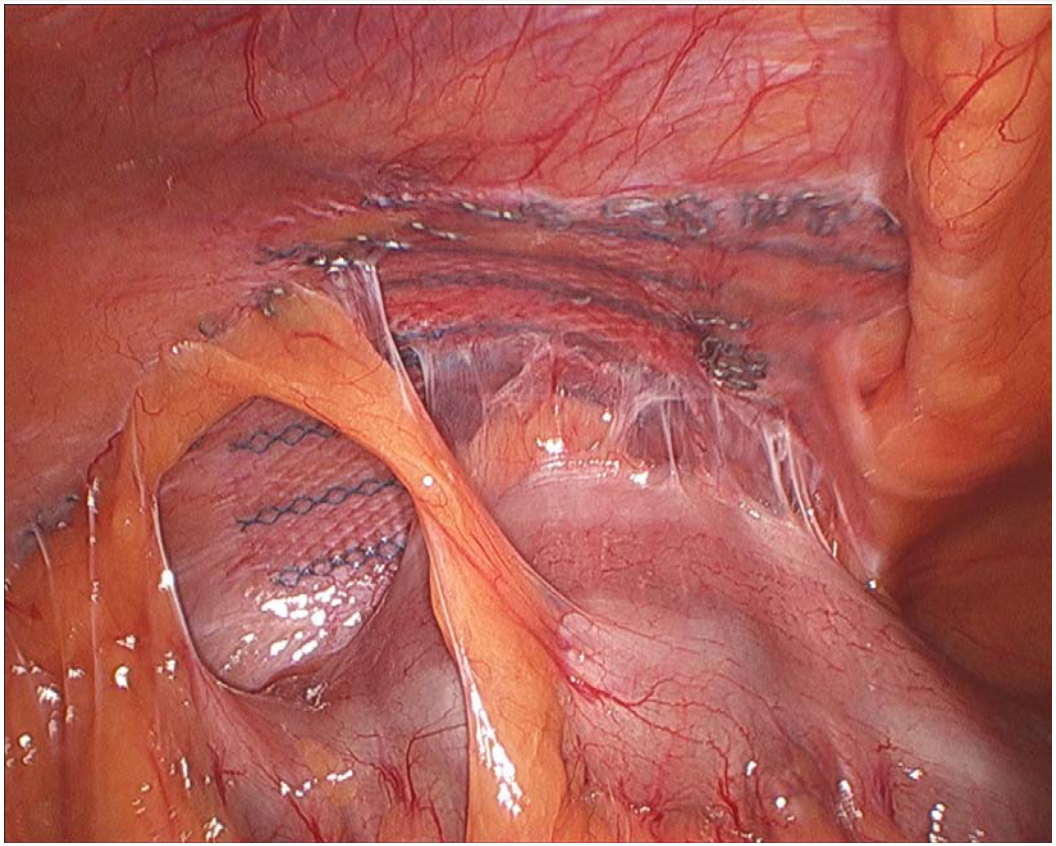
ANDREW G. HARRELL, M.D., YURI W. NOVITSKY, M.D., RICHARD D. PEINDL, PH.D., WILLIAM S. COBB, M.D., CATHERINE E. AUSTIN, B.S., JOSEPH A. CRISTIANO, B.S., JAMES H. NORTON, PH.D., KENT W. KERCHER, M.D., B. TODD HENIFORD, M.D.

- 4 mesh types, 15 implants each, explanted and analyzed after 16 weeks, mini-laparoscopy performed at 1, 4, 8, and 16 weeks
- Adhesions (Area)
  - Marlex (22%) >> Proceed (4.6%) = Composix (0.7%) > DualMesh (0.2%)
- Compliance similar between groups
- Shrinkage
  - Greater for DualMesh (35%) than for any other mesh

    Proceed 10.9%, Composix 10.2%, Marlex 3.6%

American Surgeon 2006

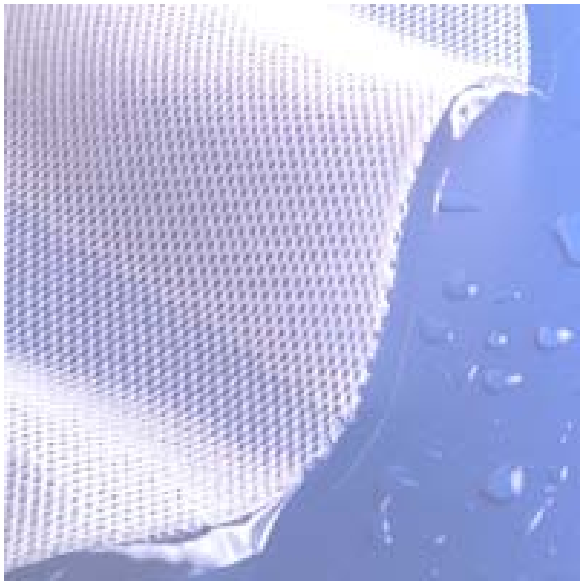
Adhesions…



…Can lead to fistulas, bowel obstructions…

Adhesion Barriers aka Tissue Separating Meshes

- Absorbable Barrier Coatings
  - Parietex
  - Proceed
  - C-Qur
  - Sepramesh
  - Physiomesh
- Permanent Barrier (microporous ePTFE)
  - Gore DualMesh
  - Bard Composix



Absorbable Barrier Meshes

Mesh	Maker	Material	Barrier	Longevity (days)	Weight (g/m^2)
Parietex Composite	Covidien	PET	**PEG, glycerol, collagen**	20	75
C-Qur	Atrium	PP (LW)	**Ω-3 fatty acid**	90-180	50
Proceed	Ethicon	PP (LW)	**oxygenated regenerated cellulose**	<30	45
Sepra-mesh	Davol	PP (LW)	**Seprafilm (hyaluronate)**	<30	102
Physiomesh	Ethicon	PP (LW)	**Poliglecapr one 25**	90-120	<40

Comparison of Barrier Meshes

- Animal Data- Pierce et al. Surg Innov 2009
  - C-Qur adhesion grade and amount significantly less than Composix and Proceed
  - C-Qur contracted less than all meshes, most notably DualMesh and Proceed
  - DualMesh had most amount of capsule formation and inflammation on parietal side
- Reviews- Deeken et al. Surg Endosc 2012
  - Parietex and Dualmesh cited most frequently for favorable adhesion characteristics
  - Sepramesh and C-Qur followed closely
  - Composix, Proceed, and uncoated polypropylene cited most frequently for having tenacious and extensive adhesions

Comparison of Barrier Meshes

- Human Data- Jenkins et al. Surg Endosc 2010
  - Prospective laparoscopic evaluation for subsequent surgeries
  - N = 69 (recurrent hernia, chronic pain, GB, parastomal hernia, SBO, nephrectomy, nissen)
    - Dualmesh least tenacious
    - Adhesion surface area similar among Dualmesh and barrier coated meshes, more for Composix and uncoated mesh
    - Adhesiolysis time to surface area ratio:

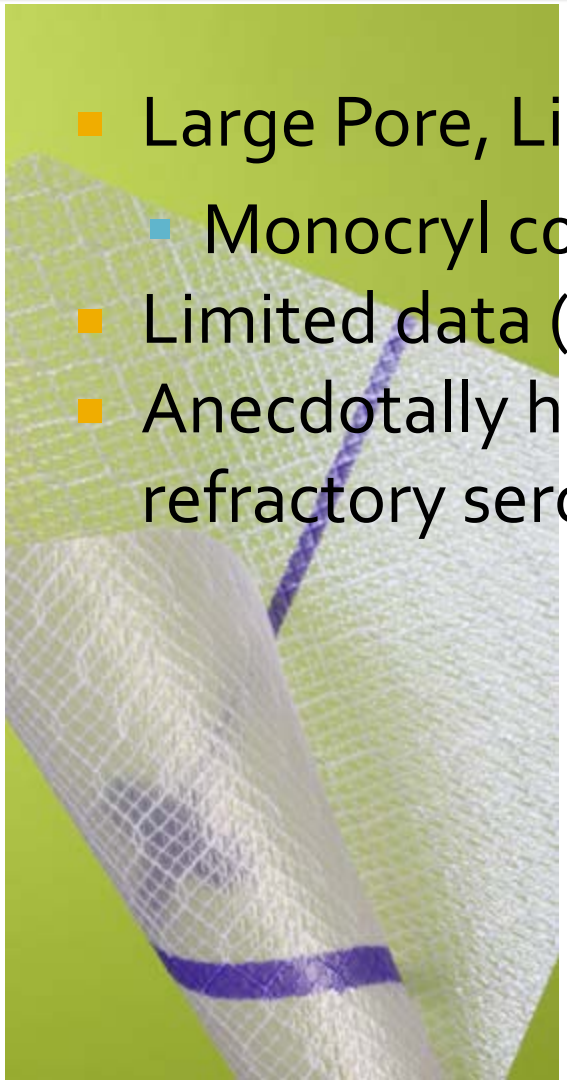
      Dualmesh << Composix, uncoated PP, biologic mesh

      Dualmesh ≈ barrier meshes

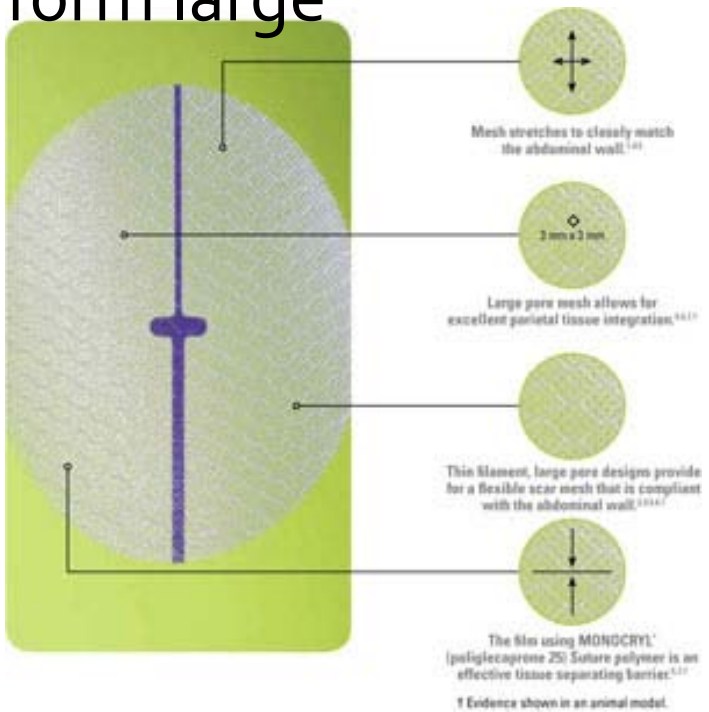
Table 6 Adhesion characteristics of absorbable-barrier-coated mesh defined by tenacity, surface area, and ratio of adhesiolysis time to mesh surface area

Intraperitoneal mesh	Adhesion tenacity	Adhesion surface area (0–10)	Adhesiolysis time/mesh surface area (min/cm^2)
PROCEED™ ($n = 8$)	3.4 ± 0.5	8.1 ± 1.5	0.28 ± 0.1
C-Qur ($n = 5$)	2.8 ± 0.4	4.8 ± 1.8	0.14 ± 0.1
Sepramesh ($n = 4$)	3.3 ± 0.5	7.5 ± 1.3	0.16 ± 0.1
Parietex™ Composite ($n = 1$)	3.0	6.0	0.25

Barrier Meshes - Physiomesh



- Large Pore, Lightweight
  - Monocryl coating on both sides
- Limited data (new on market)
- Anecdotally has tendency to form large refractory seromas



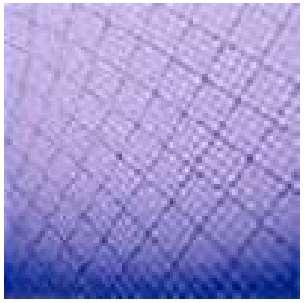
HERNIAS

Start the reactor!

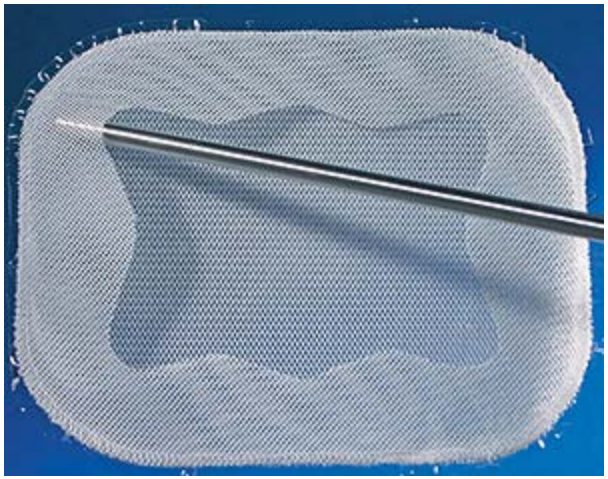
Delivery Mechanisms

- Interwoven absorbable materials
- Skirts for fixation
- Pre-peritoneal inguinal hernia devices
- V-Patch (umbo/trocar hernias)
- Balloon Delivery System (ECHO)
- 3 dimensional (Lap IHR – 3D Max, Anatomic)
- Strength Ring ***

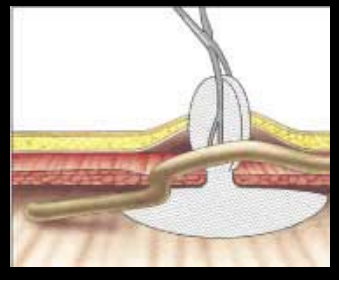
Interwoven Absorbable Materials



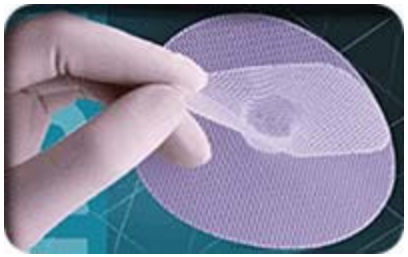
Skirts/Pockets for Fixation



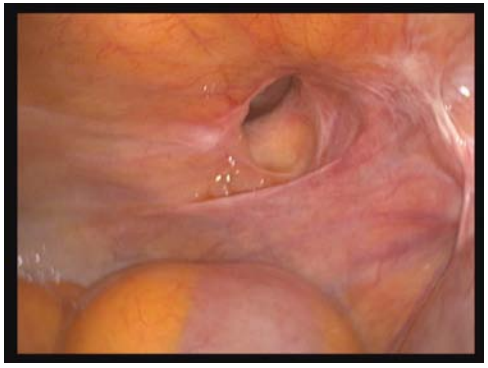
Inguinal Hernia Systems

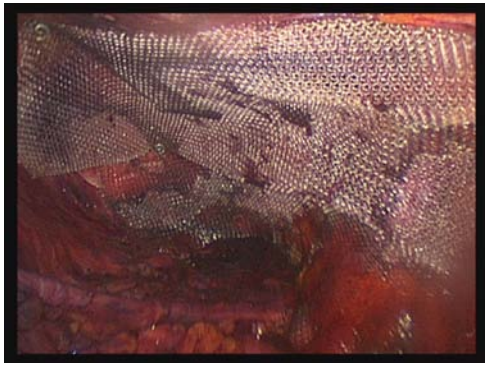


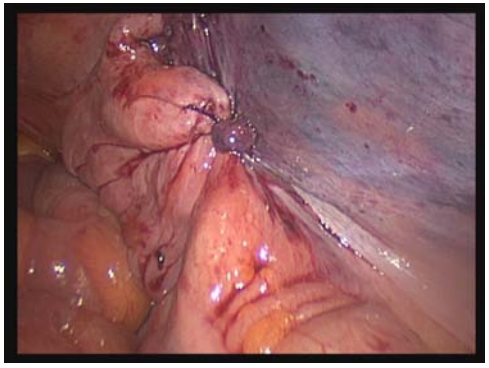
- Prolene Hernia System (PHS)



RIHR Op Report: “indirect rather than a direct hernia…inferior epigastric vessels lie medial to the connector of the PHS…the floor of the canal was more substantial on this side, and a single suture [Vicryl] was used to tack the inferior edge of the mesh to the shelving edge…and a single suture used over the pubic tubercle”





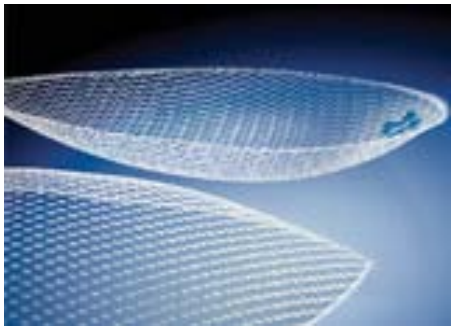


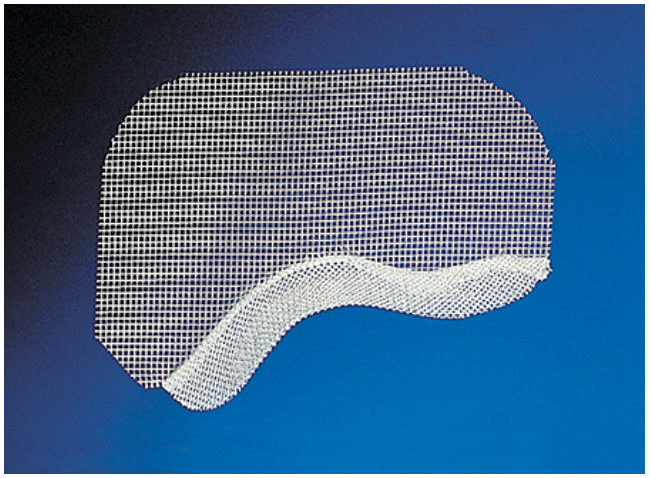
Ventral Patches

Balloon Delivery System

http://www.davol.com/products/soft-tissue-reconstruction/hernia-repair/ventral-hernia-repair/laparoscopic-repair-options/echo-ps/

3D for Laparoscopic Inguinal Hernia





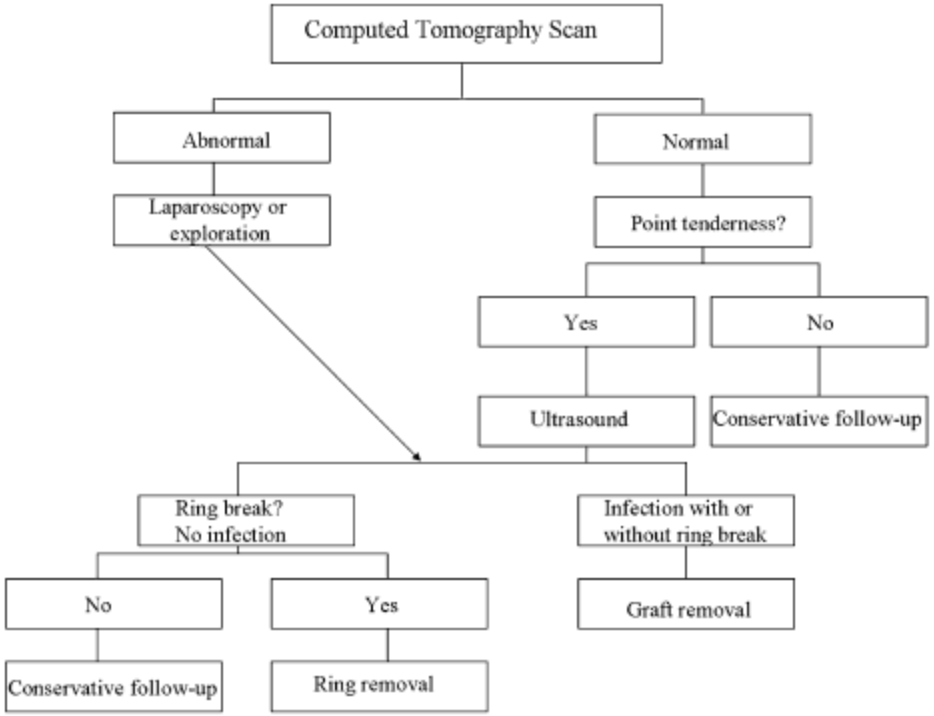
Memory Recoil Ring: the Infamous Kugel

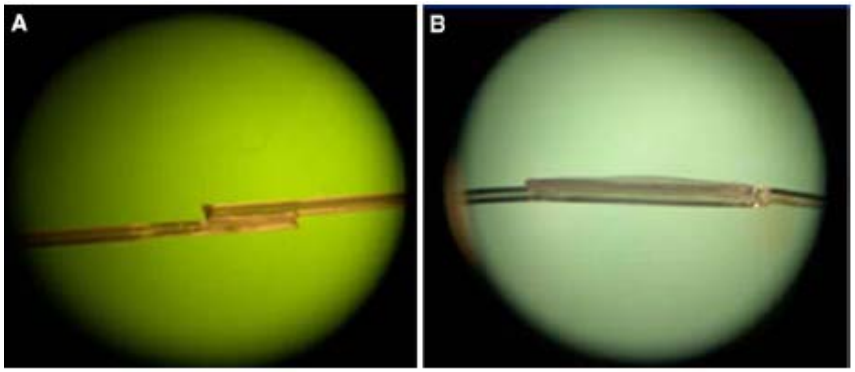
- Design
  - Flaw – defective memory recoil ring
  - History – FDA approved in 1996; estimated 350,000 meshes implanted
  - Recall – voluntary recall in 2005 after 31 reports of ring breakage (0.009%)
  - AEs – deaths, fistulas, re-operations

Kugel Mesh Recall

An algorithm for managing patients who have Composix® Kugel® ventral hernia mesh

Hernia 2009





Ring weld design
A) Initial
B) Modified

Marketing – What's in a name?

- Composix
- Ventrio with Sorbaflex
- Ventrio ST
- Ventralex
- Ventralex ST
- Ventralight
- Sepramesh IP
- Dulex
- Echo PS
- Composix L/P
- Composix EX

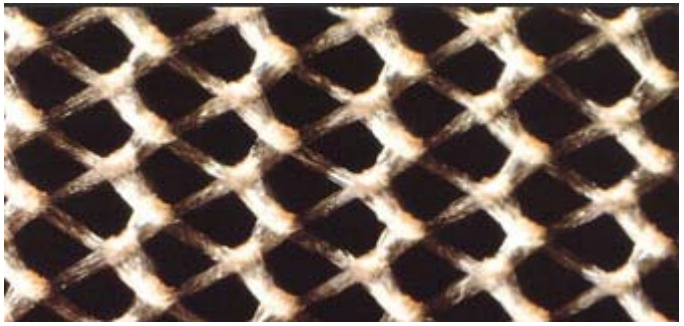
- Parietex PCOx
- Parietex PCO
- Parietex PCO OS
- Parietex PCO 2H
- Parietex Anatomical

- Proceed
- UltraPro
- PVP
- Prolene

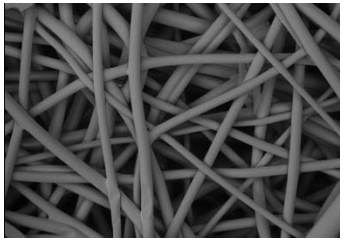
- Surgisis
- Surgisis Gold
- BioDesign

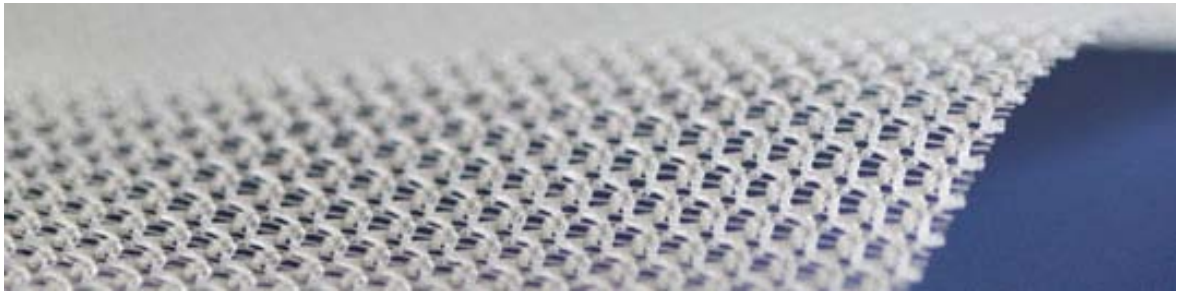
Synthetic – Absorbable Meshes

- Fast
  - Dexon
  - Vicryl



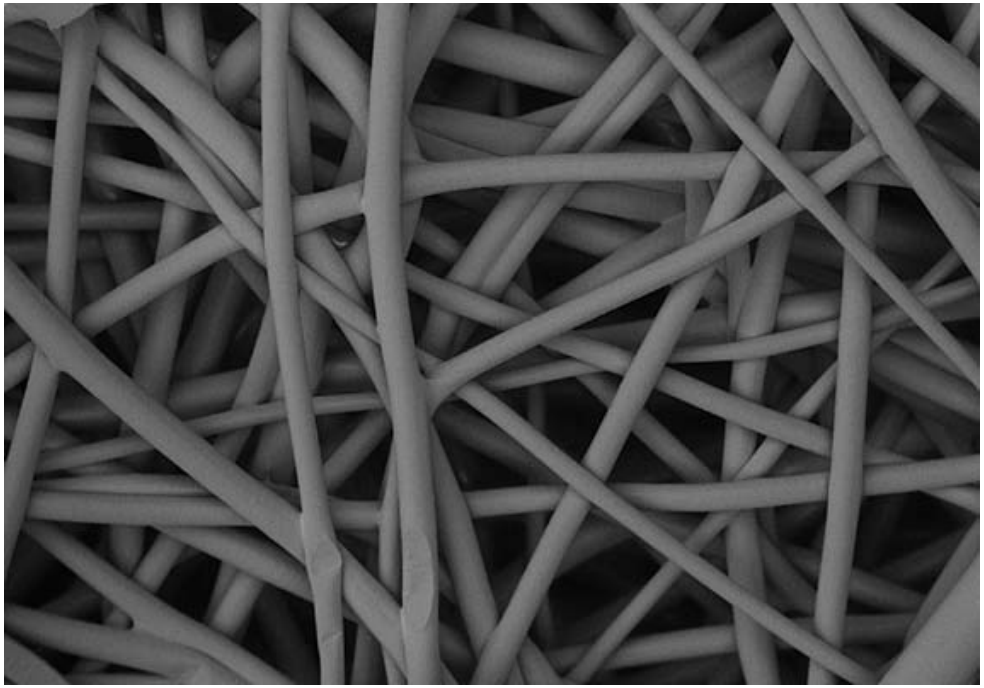
- Slow
  - Bio-A
  - TIGR Matrix





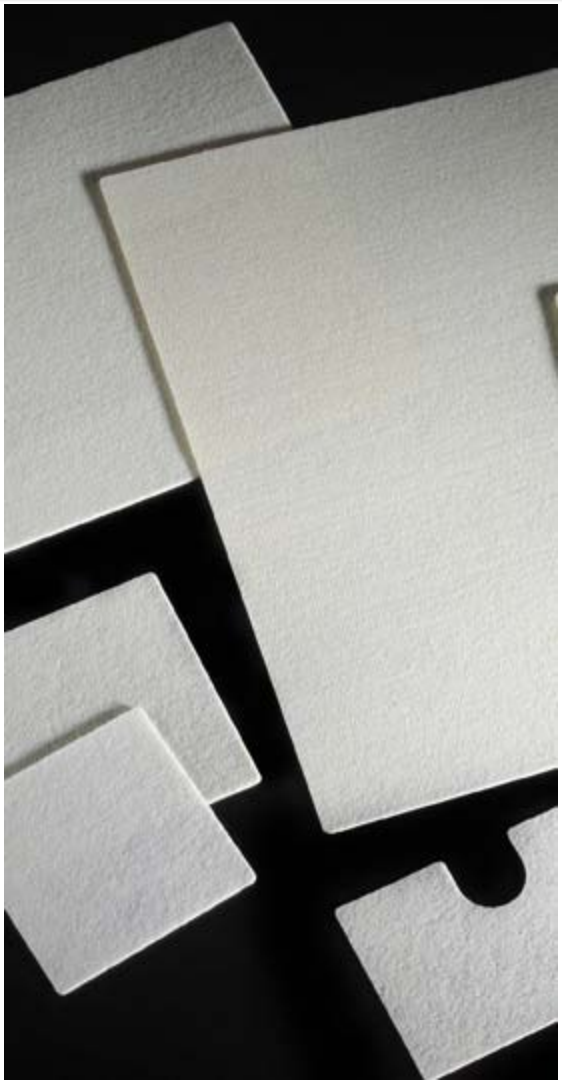
Bio-A

- Non-woven network of polyglycolic acid – trimethylene carbonate
  - Polymer discovered in 1954
  - Derived from Chitin (exoskeleton component)
  - Maxon suture
  - 3-D Scaffold
- Forms
  - Sheet
  - Hiatus
  - Plug



Bio-A

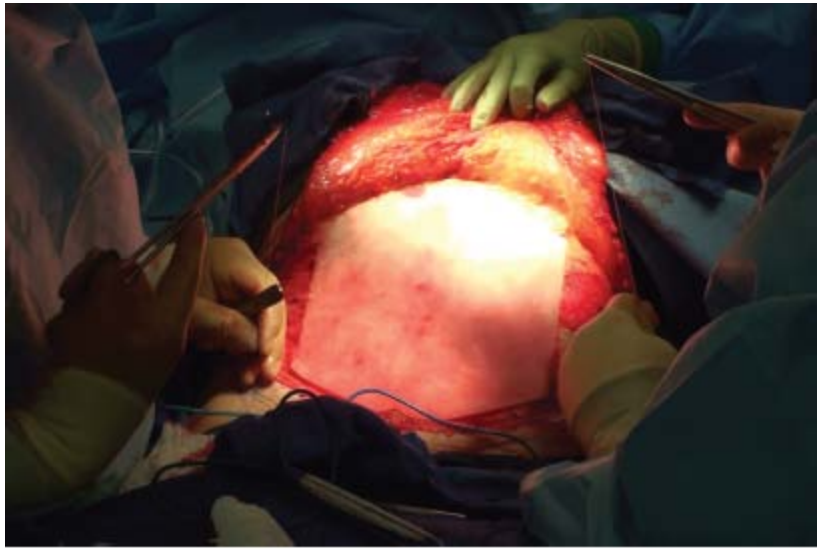
- Advantages
  - Fully absorbable; breakdown products are exhaled/excreted
  - Promotes 1:1 collagen replacement
- Disadvantages
  - Hydrolyzed at 6 months
  - Limited Data



Bio-A: Human Data

Jacobsen et al. "Clinical Use of GORE BIO-A Tissue Reinforcement in Ventral Hernia Repair Using the Components Separation Technique"

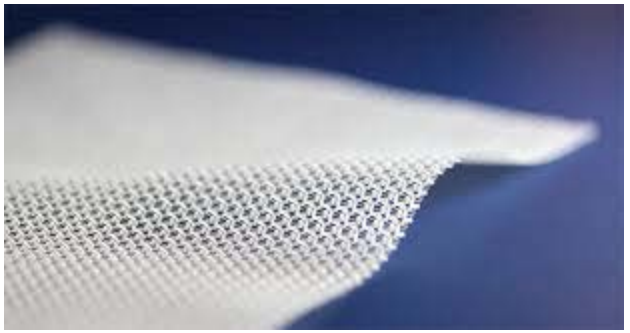
Prepared and funded at the request of WL Gore and Associates



Case Series Summary	
Number of patients	33
Hernia defect size	Mean, 145 cm^2
Age	Mean, 55 years (range, 26-78)
BMI	Mean, 28.5
Patient factors	48% had recurrent hernia (mean, 2.4 previous repairs) 20% diabetic 15% smokers 11% undergoing chemotherapy
Placement	55% onlay 34% rectorectus 11% other
Operative field	79% clean 21% clean-contaminated or contaminated
Results	
Follow-up	Range, 6-687 days Mean, 120 days
Complications	3 seromas
Recurrences	0

TIGR Matrix Mesh

- Materials
  - Lactide, glycolide, and trimethylene carbonate copolymer (fast-resorbing)
  - Lactide and trimethylene carbonate (slow-resorbing)
- Advantages
  - Maintains strength longer than BIO-A
- Disadvantages
  - Not indicated in setting of intestinal surgery
  - Cannot touch bowel
  - Limited Data
- Indications
  - For reinforcement (no bridge)
  - Concern for mesh related pain



TIGR Matrix Mesh: Human Data

- Case Reports
  - Open Ventral Hernia Repair and Cholecystectomy
  - Open Ventral Hernia Repair after Necrotizing Pancreatitis

Biologic Mesh

- $400,000,000 spent on biologic grafts in 2007 in the United States
- Predicted to be $500,000,000 by 2013

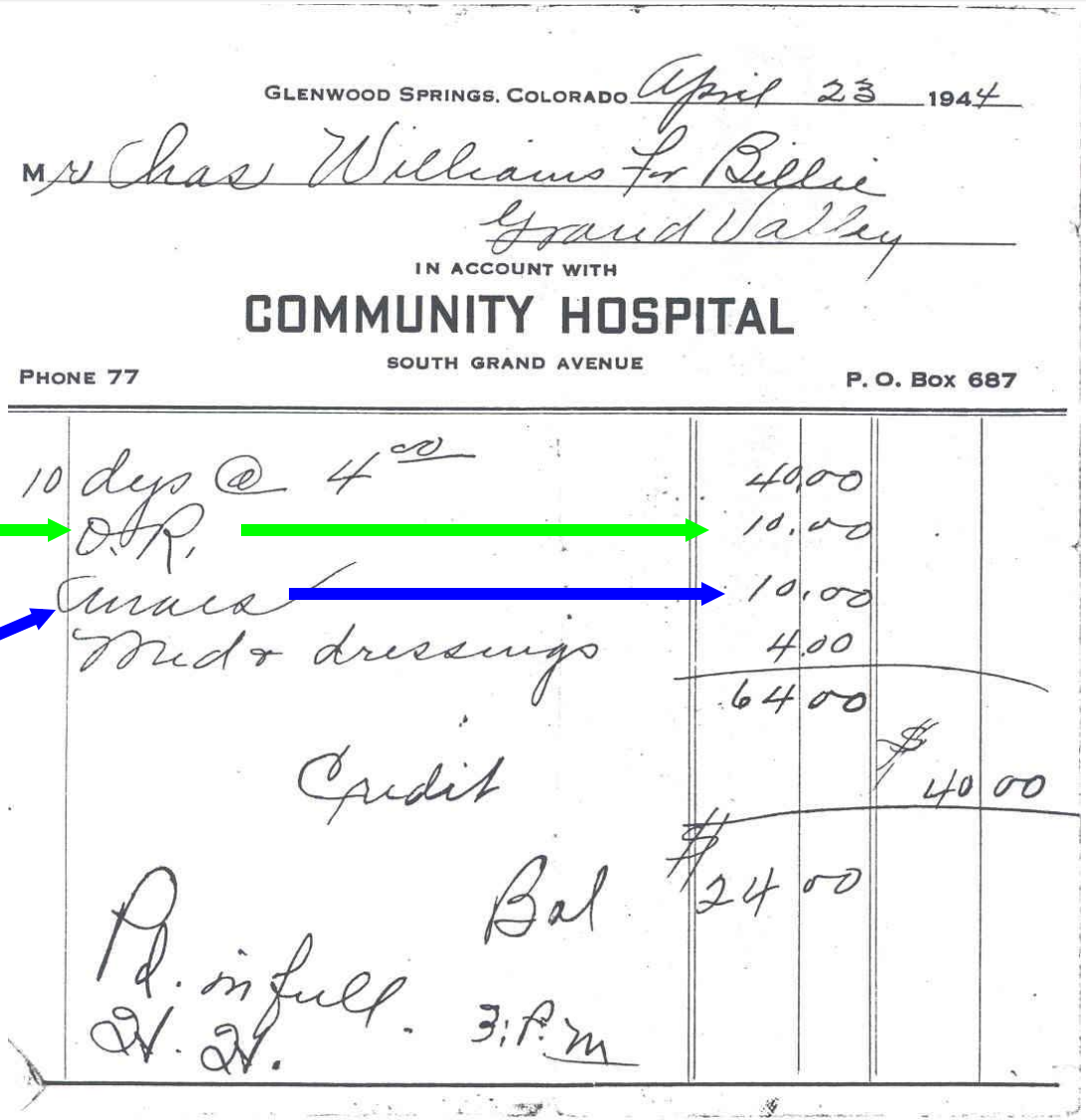
Harth et al. Surg Innov 2009

Advances?

Incisional Hernia Repair in Colorado, 1944:

OR charges

Anesthesia charges



GLENWOOD SPRINGS, COLORADO April 23 1944

Mrs Chas Williams for Billie
Grand Valley

IN ACCOUNT WITH

COMMUNITY HOSPITAL

SOUTH GRAND AVENUE

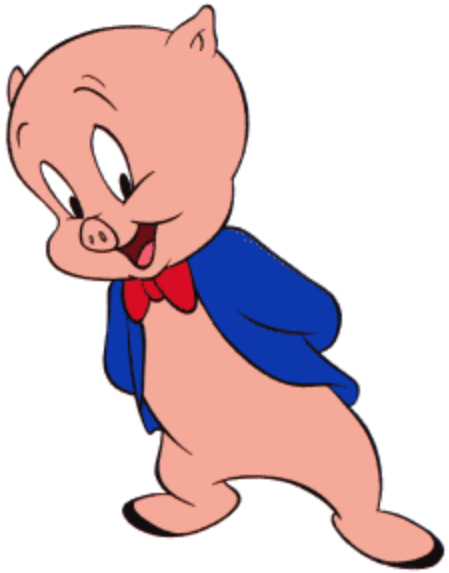
PHONE 77 P. O. Box 687

10 days @ 4.00	40.00	
O.R.	10.00	
Anes	10.00	
Med & dressings	4.00	
	64.00	
Credit		40.00
Bal		24.00

Pd. in full. 3:P.M.
W. W.

Biologic Mesh: Advantages

- More resistant to infection
- Reduced risk of fistulae
- Accelerated vascularization
- Better potential in hostile or potentially infectious environment



Biologic Mesh: Disadvantages

- **Cost**
- **Laxity**
  - Some advocate stretching it upon placement, violating the tension-free goal of repair with mesh
  - Newer human acellular dermis designed to minimize laxity (FlexHD, AlloMax)
- **Limited Data**

Biologic Mesh

- 12 FDA approved
  - 2 with no peer-reviewed publications
  - 3 with small rodent, single publications
  - 3 with one human series with short-term f/u
  - 4 with animal and human data

Bellow et al. Expert Rev Med Devices 2006 Sep 3(5) 657-675

Since 2006: 2 additional biologic meshes

XenMatrix – recalled Jan 2011 due to elevated endotoxin levels

SurgiMend approved 2009

Biologic Mesh

- Categories
  - Allograft vs Xenograft
  - Cross-linked vs Non-crosslinked

- Properties
  - Storage/Hydration
  - Collagen/Elastin
  - Sterilization

Biologic Mesh

Mesh	Manufacturer	Tissue Origin	Est. Cost ($/cm^2)
Surgisis®	Cook	Porcine Small Intestine	15.00
Permacol™	Covidien	Porcine Dermis	18.00
AlloDerm®	LifeCell	Human Dermis	32.00
SurgiMend®	TEI Bioscience, INC	Fetal Calf Dermis	14.00
Veritas®	Synovis Surgical	Bovine Pericardium	21.00
Strattice®	LifeCell	Porcine Dermis	27.00
Collamend™	Bard	Porcine Dermis	16.00
Allomax™	Bard	Human Dermis	27.00
FlexHD™	MTF (Ethicon)	Human Dermis	30.00
XenMatrix™	Bard	Porcine Dermis	23.00
Periguard®	Synovis	Bovine Pericardium	1.90
Tutopatch®	Tutogen	Bovine Pericardium	No data

Allografts

- Allomax™
  - Requires hydration, limited data available
- Alloderm®
  - Requires hydration, many sizes available, long-term data available, stretches significantly

Abdominal hernia repair with bridging acellular dermal matrix—an expensive hernia sac

Jeffrey Blatnik, B.A.[a,b], Judy Jin, M.D.[a,b], Michael Rosen, M.D.[a,b,*]

[a]*Department of Surgery, University Hospitals Case Medical Center and* [b]*Case Comprehensive Hernia Center, Case School of Medicine, Cleveland, OH, USA*

- Flex HD™
  - No hydration or refrigeration required, many available sizes, limited data available, 18 month shelf life

Xenografts

- Porcine
  - Dermis
  - Intestinal Submucosa
- Bovine
  - Pericardium
  - Fetal Calf Dermis

Xeno – alien, guest, stranger, foreigner
(Greek, *xenos*)

Porcine

- Strattice® – non cross-linked, large sizes available, human data available
- Permacol ™ – cross-linked, large sizes available, no refrigeration or hydration required, human data available
- BioDesign ® – non-cross-linked, no refrigeration, requires hydration, human data available
- Collamend™ – cross-linked, requires hydration, limited data available

Strattice®

Prospective Multicenter Clinical Study of Single-Stage Repair of Infected or Contaminated Abdominal Incisional Hernias Using Strattice™ Reconstructive Tissue Matrix

Investigators: Sanit Awad MD, Donald Baumann MD, Charles Bellows MD, George DeMeo MD, Michael Fiore MD, Steve Holzer MD, Scott Hultman MD, Kamal Itani MD, Stephen Kavic MD, Michael Rosen MD, Glen Steele MD, David Varga MD

Completed data as presented at: American College of Surgeons Clinical Congress, October 3–7, 2010, Washington, DC, USA; Posterior Nitzano-ppiti European Hernia Society, October 6–9, 2010, Istanbul, Turkey; OP 58.

LifeCell

Background

Single-stage synthetic mesh repair of infected or contaminated hernias carries considerable risk of infection, which may ultimately require removal of the mesh and result in further loss of abdominal-wall tissue. Biological meshes have been advocated as an alternative to synthetic meshes for single-stage repair of ventral incisional hernias in the presence of contamination. In this prospective observational study (NCT01617357) we evaluated Strattice™ Reconstructive Tissue Matrix (TM) in the repair of contaminated/infected ventral incisional hernias (The Strattice™ RICH Study).

Objectives

The primary objective of this study was to assess wound events following repair of contaminated or infected ventral incisional hernias using Strattice™ TM. Secondary objectives included: ability to manage infection in vitro; postoperative resumption of activities of daily living (ADL); pain assessment; resource utilization; and hernia recurrence at 24 months.

Methods

Patient inclusion/exclusion criteria and recruitment

- Adult patients with open repair of infected or contaminated ventral hernia ≥ 9 cm² in size and who provided informed consent were included.
- Those due to undergo laparoscopic hernia repair, with systemic infection or chronic conditions, with a body mass index (BMI) ≥ 40 kg/m², or with a life expectancy of < 24 months were excluded.
- Patients were recruited from 12 sites and prospectively followed from the time of repair.

Study intervention and follow-up

- All enrolled patients underwent repair with Strattice™ TM.
- Reconstruction required restoration of the midline, where possible, with primary closure of fascia and/or component separation techniques (CST).

Outcomes

- Endpoints were evaluated in an interim analysis at Day 30, Month 6, and Month 12.
- Primary endpoint: incidence of wound events, including significant local erythema or edema, seroma, skin necrosis, wound dehiscence, infection, incidence of re-operations, bedside debridement or removal of Strattice™ TM.
- Secondary endpoints: resumption of ADL using the Activities Assessment Survey at postoperative Day 30 and Months 3, 6, and 12; narcotic/analgesic usage and antibiotic use; length of hospital stay and resource utilization (e.g. operating room time, diet); and possible cost/hernia recurrence.
- We report herein the interim 12-month data for the primary endpoint.

Figure 1. Study population

ITT, intent-to-treat

Results

Patient characteristics

- A total of 85 patients consented to participate, of whom 80 were treated (intent-to-treat [ITT] population; Figure 1).
- Baseline patient demographics are reported in Table 1.
- Patient risk factors and comorbidities are shown in Table 2.
- Intraoperative challenges at the initial time of hernia repair are shown in Table 3.
- Hernia defects and place of Strattice™ TM placement are described in Table 4:
  - hernia defects (mean area: 236 ± 159 cm²) were clean-contaminated (n = 39; 49%), contaminated (n = 39; 49%), or dirty (n = 2; 2%)
  - defects can be classified as Grade 3 (n = 65) or 4 (n = 20) according to the Ventral Hernia Working Group system[1]
  - the midline was restored and primary closure achieved in 64 patients (80%), and Strattice™ TM reinforced the repair in the retro-rectus (n = 29; 36%) or intraperitoneal/underlay (n = 48; 60%) or onlay (n = 3; 4%) positions.
- 69 patients had at least 1 drain placed prior to closure of the hernia repair site. Patients had 3 ± 1 drains placed at the time of hernia repair, and these remained in place for 12 ± 12 days (median/median: 11 days; range 1–155).
- 71 patients were available for evaluation at or near follow-up of 1 year (362 ± 48 days; range 327–449).

Table 1. Baseline patient demographics (N = 80)

Characteristic	
Age, years	
Mean ± SD	57 ± 14
Median (range)	60 (23–84)
Male, n (%)	47 (58.8)
Ethnicity, n (%)	
Caucasian	71 (88.8)
African American	9 (11.3)

SD, standard deviation

Table 2. Patient risk factors and comorbidities

Risk factor/comorbidity	n (%)
Current or within past 2 weeks* smoker	14 (17.5)
Obese (BMI 35–40)	18 (22.5)
Diabetic	17 (21.3)
Chronic pulmonary conditions	13 (16.3)
Past aneurysm	7 (8.8)
Prior hernia repair (range 1–9)	51 (63.8)
Fistula present	7 (8.8)
Previous abdominal wound infection	27 (33.8)

BMI, body mass index

Table 3. Intraoperative challenges

Challenge	n (%)
Stoma present	31 (38.8)
Planned violation of gastrointestinal tract	27 (33.8)
Contamination present at or in operative site	42 (52.5)
Infection present at or in operative site	4 (5.0)
Infected mesh removed during procedure	15 (18.8)

Table 4. Operative repair (N = 80)

Parameter	
Hernia defects area, cm²	
Mean ± SD	236 ± 159
Position of mesh, n (%)	
Retro-rectus	29 (36.3)
Intraperitoneal/underlay	48 (60.0)
Onlay*	3 (3.8)
Fascial closure achieved, n (%)	64 (80.0)

*This combined a series of devices.

Table 5. Cumulative wound events up to 12 months

Repair site event	30 days n (%)	6 months n (%)	12 months n (%)
Seroma	17 (21.3)	17 (21.3)	22 (27.5)
Requiring intervention	5 (6.3)	5 (6.3)	5 (6.3)
Hematoma	6 (7.5)	6 (7.5)	7 (8.8)
Dehiscence (superficial only)	11 (13.8)	11 (13.8)	15 (18.8)
Infection	17 (21.3)	21 (26.3)	23 (28.8)
Medically managed	6 (7.5)	9 (11.3)	10 (12.5)
Surgically managed	11 (13.8)	12 (15.0)	13 (16.3)
Abscess			
Abdominal-wall abscess	3 (3.8)	3 (3.8)	4 (5.0)
Stitch abscess	0	2 (2.5)	3 (3.8)
Fistula*	1 (1.3)	2 (2.5)	2 (2.5)
Mesh removals	0	0	0

*Two fistulae were identified at 6 months, one of which was resected and the other was found to be a chronic fistula at 12 months.

Table 6. Hernia recurrence

Type of repair	Incidence of recurrence, % (n)
Fascial closure without CST (N = 13)	0 (0)
Fascial closure with CST (N = 52)	1.7 (1)
Fascial closure with & without CST, N = 64* (defect area: 203 ± 150 cm²)	14.1 (9)
No fascial closure with & without CST, N = 16* (defect area: 355 ± 141 cm²)	37.5 (6)
All ITT subjects (N = 80)	18.8 (15†)

*P = 0.05, compared to primary fascial closure
CST, component separation technique

Wound events

- 76 events are described, occurring in 51 patients (Table 5).
- No surgical site events required Strattice™ TM removal.

Seromas

- Most seromas were transient and resolved spontaneously.
- 5 interventions were performed: 3 seromas were aspirated (1 twice) and 1 was aspirated and a drain placed. All interventions were performed within the first 30 postoperative days (POD).
- All but 3 seromas resolved within the first 30 POD. Of the seromas that persisted:
  - 1 developed on POD 14 and persisted through Month 3
  - 1 developed on POD 30 and persisted through Month 12
  - 1 developed in Month 6 and persisted through Month 12.

Infection-related events

- Most (16/23; 69.6%) occurred and resolved within the first 30 POD.
- The remaining events occurred after the early postoperative period with:
  - 4 in Month 3
  - 1 in Month 6
  - 2 in Month 12.
- 10 of the events were "drainage only" and did not require any specific surgical intervention.
- 10 others required "incision and drainage":
  - small pieces of Strattice™ TM were debrided in 3 patients requiring "incision and drainage" procedures but no Strattice™ TM was explanted.
- The remaining 3 events were characterized as "cellulitis requiring antibiotics only."

Hernia recurrences

- 15 recurrences (18.8%) were reported (Table 6).
- Patients who experienced a recurrence had a significantly larger defect size at initial repair vs those who did not experience a recurrence (307 ± 138 cm² vs 213 ± 159 cm²; P = 0.03 [Student's t-test]).

Safety

- The type, frequency, and severity of adverse events are comparable to what has been reported in the literature regarding infected or contaminated hernias.[2]
- There were 3 deaths (3.8%) from causes reported as unrelated to Strattice™ TM:
  - 2 deaths were related to postoperative infection and subsequent systemic sepsis
  - 1 death occurred 21 days after the repair of a ruptured aortic aneurysm.

Discussion

- There are very few alternatives for hernia repair in such a complicated population. Patients are often closed in a 2-stage "planned hernia", for which synthetic mesh is inappropriate due to the high risk of postoperative infection, bowel erosion, and fistula formation when placed in a contaminated field.
- In this study, wound-related events in this complex patient population occurred at a rate similar to that reported in the literature[2] in ventral incisional hernia repair in general.
- This is the only published, large, prospective multicenter study of the repair of infected and contaminated ventral incisional hernias at the time of this interim 12-month analysis. This uniqueness creates difficulty in comparing these results to other studies that have one or all of the following characteristics: retrospective, single-center, small sample size, mixed surgical techniques, mixed patient populations, wide range of follow-up periods and variable follow-up methodologies.
- These 12-month interim results of this ongoing study with Strattice™ TM reinforcement of the repair of infected or contaminated hernias demonstrate that, with appropriate pre- and intraoperative bioburden reduction and despite the occurrence of expected surgical site events, no Strattice™ TM required explanting.

Conclusions

- This is the largest prospective, multicenter, observational study in a complex hernia patient population to date.
- No Strattice™ TM explants have been required in this study.
- The use of Strattice™ TM has allowed for safe, single-stage reconstruction that is definitive in 80% of patients in this study at one year.

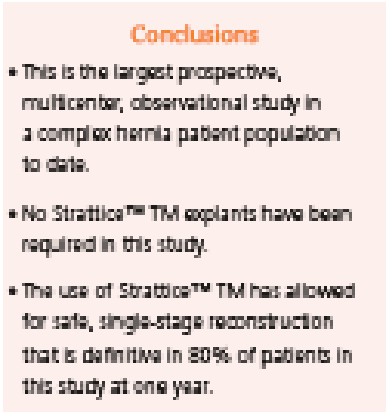
References

1. Ventral Hernia Working Group. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. Surgery. 2010;148(3):544–558.
2. Karthikesalingam, et al. Predictors of surgical site infection in laparoscopic and open ventral incisional hernia repair. J Surg Res. 2010;163(1):130–134.

Strattice®- Repair of Infected or Contaminated Hernia (RICH) Study

- Prospective, multicenter (12 sites) co-sponsored study
- Single-stage open repair n = 80
  - 49% clean contaminated
  - 49% contaminated
  - 2% dirty
- One year f/u

- No explanted xenografts
- Definitive repair in 80%
- 15 recurrences
- Wound complications similar to those in reported literature (seromas, infections, recurrences)



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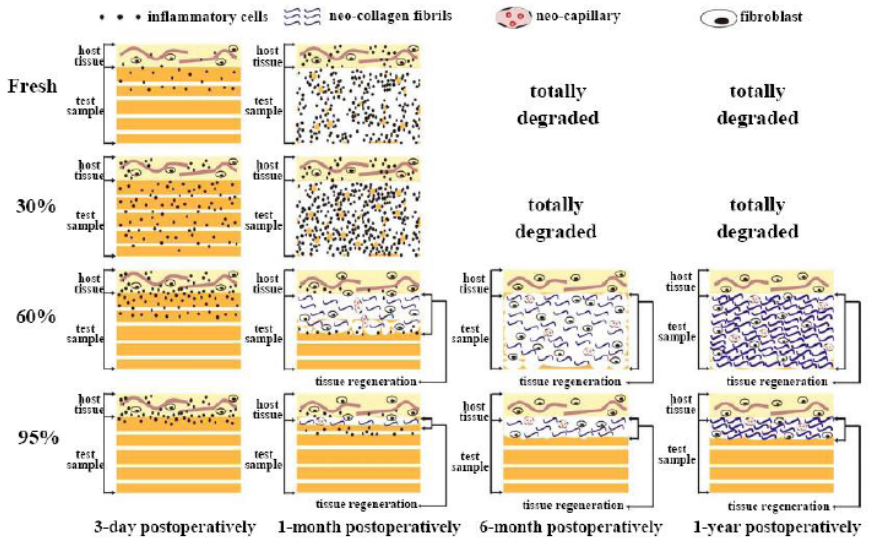
Cross-linking: Permacol™ and Collamend™

- Bonds between collagen chains
- Can be chemically induced or naturally occurring
- Slows remodeling
- Stronger → Longer
- Decreased ingrowth
- Increased burst strength
- May cause encapsulation



Liang et al. Biomaterials 2004

Permacol™ and Collamend™

Major Complications Associated With Xenograft Biologic Mesh Implantation in Abdominal Wall Reconstruction

Surg Innov 2009

Karem C. Harth, MD, MHS,[1] and Michael J. Rosen, MD, FACS[1]

Table 3. Three Commonly Reported Adverse Events for Xenograft Biologic Meshes in the FDA MAUDE Database Between 1997 and 2008[a]

Mesh Type	Acute Mechanical Failure/Evisceration (n = 63)	Mesh Disintegration (n = 48)	Poor Mesh Integration (n = 20)
Permacol	37/63 (59%)	34/48 (71%)	7/20 (35%)
Collamend	10/63 (16%)	2/48 (4%)	10/20 (50%)
SurgiMend	6/63 (10%)	7/48 (15%)	1/20 (5%)
Surgisis	2/63 (3%)	2/48 (4%)	2/20 (10%)
Veritas	7/63 (11%)	3/48 (6%)	0/20 (—)
Strattice	1/63 (1%)	0/48 (—)	0/20 (—)

[a]Data on postoperative infection, fistula formation, and other adverse events are given in the Results section.

Permacol and Collamend
Comprised 75% of all reported AEs

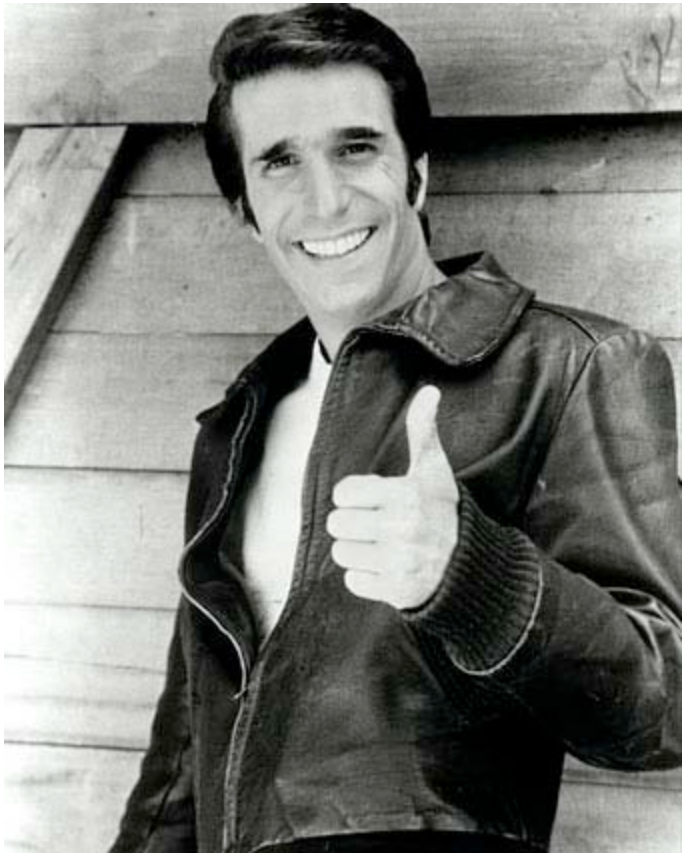
Cross-linking Fun Fact

- What do you get when you terminally cross-link xenograft dermis?

Cross-linking Fun Fact

- What do you get when you terminally cross-link xenograft dermis?

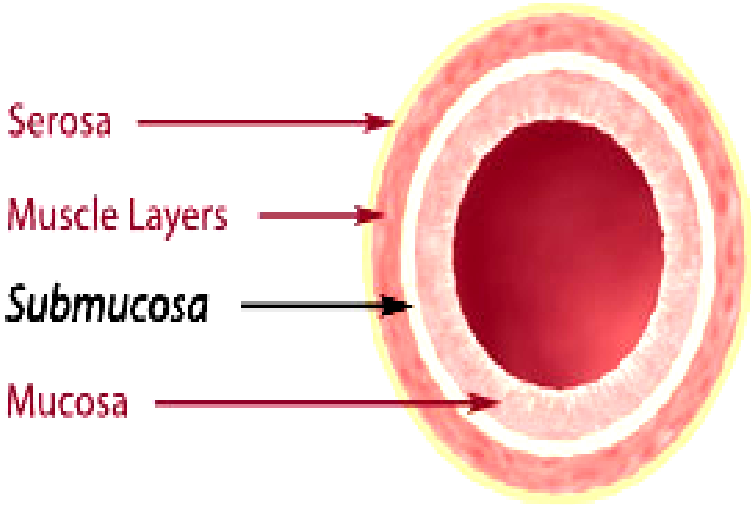
- Answer: LEATHER!



Surgisis®

- Porcine Small Intestine Submucosa
- Surgisis® → Surgisis Gold ® → BioDesign ®
  - Vacuum-Pressed → Lyophilized (Freeze-Dried)
  - Pores/Perforations
  - Removal of Lipids*

*Previously, a Th2 inflammatory cytokine response was elicited by Surgisis ®, causing local and systemic immune suppression.



Cross-section diagram of porcine small intestine

Surgisis ® : Human Data

The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up

Morris E. Franklin Jr · Jorge M. Treviño · Guillermo Portillo · Itzel Vela · Jeffrey L. Glass · John J. González

Surg Endosc 2008

- n = 116 – incisional, umbilical, inguinal, femoral, spigelian, or parastomal hernias
  - 7 recurrences
  - 11 seromas
  - 12 infections requiring mesh removal

Franklin: “If you can’t get tissue approximation, then Surgisis ® will work but not very well.”
General Surgery News 2008 35:03

Surgisis ® : Human Data

Short-term Outcomes With Small Intestinal Submucosa for Ventral Abdominal Hernia

Arch Surg 2005

W. Scott Helton, MD; Piero M. Fisichella, MD; Robert Berger, MD; Santiago Horgan, MD; Nocif Joseph Espat, MD; Herand Abcarian, MD

- n = 53 VHR (13 lap, 40 open) underlay, onlay, inlay (much heterogeneity)
  - 58% with bacterial contamination
  - F/U 14 months (median)

- 22 complications (41%)
- 12 early re-operations (32%)
- 13 partial dehiscences (21%)
- 6 mesh reactions (11%) – no long-term sequelae
- 9 recurrences (17%)
- Infections anterior to underlay Surgisis ® were problematic (closed-space), with delaminated mesh and gross purulence→ "layers of the mesh were partially liquefied and of a slimy, mucous consistency"
- Conclusion: 8 ply Surgisis Gold ® good in clean cases, bad in critically ill patients with dirty wounds

Surgisis ® : Human Data

Surgisis® in the management of the complex abdominal wall in trauma: A case series and review of the literature

Nadra Ginting [a], Lorraine Tremblay [b,c], J.B. Kortbeek [a,d,*]

Injury 2010

Table 2
Studies of Surgisis® use in contaminated fields.

Author	Population	n	Outcome	Follow up (mean, range)
Baillie et al.[1]	Contaminated	1	Uncomplicated	5 months
Franklin et al.[4]	Contaminated	116	6% recurrence 9% seroma 10% infection	52 months (1–78)
Gupta et al.[6]	Contaminated clean	41	41% seroma	29 months (3–39)
Helton et al.[7]	Contaminated clean	53	17% recurrence 24% dehiscence	14 months (2–29)
Johnson and Paquette[9]	Contaminated post-trauma	4	25% infection 25% death	6–90 days
Ueno et al.[12]	Contaminated	20	30% recurrence 10% seroma 40% infection	16 months

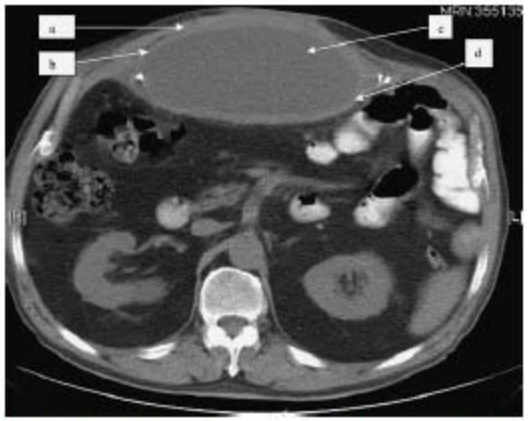
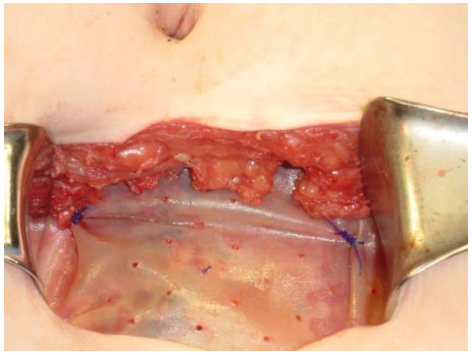


Fig. 2 Sub facial placement of Surgisis Gold perforated mesh. This computed tomography (CT) scan clearly demonstrated the incorporation of the outer layers of the mesh. The un-incorporated inner layers of the mesh result in the seroma formation. *a* Fascia. *b* Superficial layer of Surgisis mesh in contact with peritoneum. *c* Inner layers of the fascia seroma. *d* Deep layer of the Surgisis mesh in contact with omentum



Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm

A. Gupta · K. Zahriya · P. L. Mullens · S. Salmassi · A. Keshishian

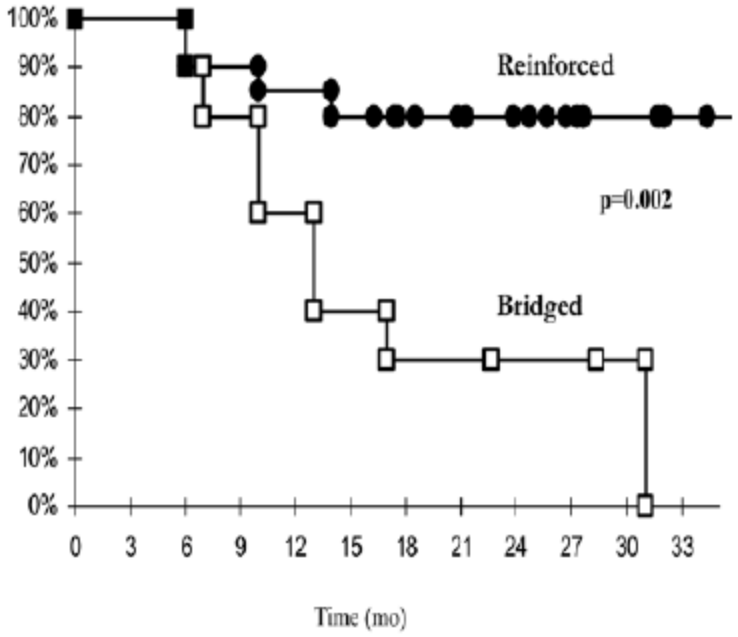
Hernia 2006

Fig. 3 Photograph of explanted Surgisis mesh material (back lit)

Avoid Biologic Bridging

Use of Acellular Dermal Matrix for Complicated Ventral Hernia Repair: Does Technique Affect Outcomes?

Judy Jin, MD, Michael J Rosen, MD, Jeffrey Blatnik, BA, Michael F McGee, MD, Christina P Williams, MD, Jeffrey Marks, MD, FACS, Jeffrey Ponsky, MD, FACS



N = 37 acellular human dermis hernia repair
11 bridged
26 reinforced

JACS 2007

Informed Consent: Cultural and Religious Issues Associated with the Use of Allogeneic and Xenogeneic Mesh Products

Eric D Jenkins, MD, Michael Yip, BS, Lora Melman, MD, Margaret M Frisella, RN, Brent D Matthews, MD, FACS

JACS 2010

- Discussion with leaders of Judaism, Islam, Buddhism, Hinduism, Scientology, Christianity, Vegans, and PETA
  - Dietary restrictions among Jews and Muslims do not translate to tissue implantation restrictions
  - Buddhists and Seventh-Day Adventists often practice vegetarianism, with may translate into refusal to use xenogeneic tissue
  - Hindus may vary in acceptance of human or animal products
  - PETA opposes all animal based products but do not oppose human acellular grafts or organ transplant
  - Some vegans prefer allogeneic to xenogeneic tissue implants
  - Methodists, Jehovah's Witnesses, and The Church of Jesus Christ of Latter-Day Saints leave decisions up to individuals

Coatings on Synthetic Mesh

- **Sirolimus** – anti-adhesive
- **Gold nano-particles** – improved biocompatibility
- **Airbrushed PCL ofloxacin-eluting coating** – antimicrobial
- **Vancomycin loaded polymer coating** – antimicrobial
- **Gentamycin polyvinyl fluoride** – antimicrobial, decreased inflammation
- **Nitric Oxide releasing mesh** – antimicrobial
- **Triclosan** – antimicrobial
- **Silver** – antimicrobial
- **Lysostaphin** - antimicrobial

Antimicrobial Coatings

- Challenges
  - FDA – device and drug approval
  - Allergic reactions
  - Other obstacles

Intra-Abdominal Placement of Antimicrobial-Impregnated Mesh is Associated with Noninfectious Fever

WILLIAM S. COBB, M.D., B. LAUREN PATON, M.D., YURI W. NOVITSKY, M.D., MICHAEL J. ROSEN, M.D., KENT W. KERCHER, M.D., TIMOTHY S. KUWADA, M.D., B. TODD HENIFORD, M.D.

From the Division of Gastrointestinal and Minimally Invasive Surgery, Carolinas Hernia Center, Carolinas Medical Center, Department of Surgery, Charlotte, North Carolina

Hazard/Risk Assessment

AN ECOLOGICAL RISK ASSESSMENT FOR TRICLOSAN IN THE TERRESTRIAL ENVIRONMENT

RICHARD REISS,*† GAVIN LEWIS,‡ and JOHN GRIFFIN†
†Exponent, King Street Station, 1800 Diagonal Road, Suite 300, Alexandria, Virginia 22314, USA
‡JSC International, Simpson House, Windsor Court, Clarence Drive, Harrogate, North Yorkshire HG1 2PE, United Kingdom

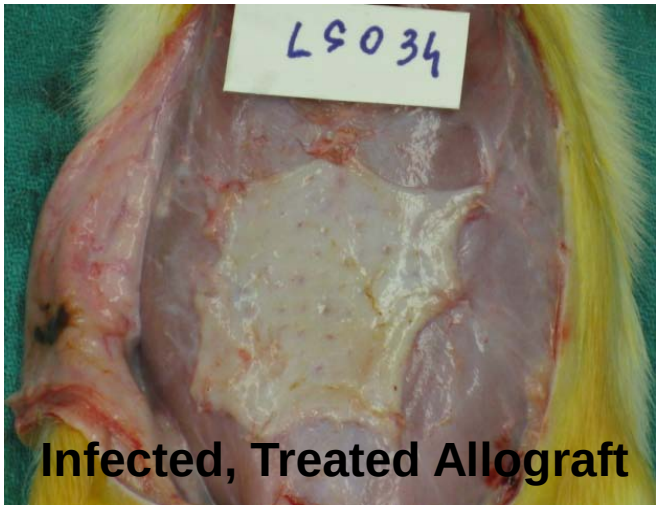
Antimicrobial Coatings: Lysostaphin

Lysostaphin-Coated Mesh Prevents Staphylococcal Infection and Significantly Improves Survival in a Contaminated Surgical Field

IGOR BELYANSKY, M.D., VICTOR B. TSIRLINE, M.D., PAUL N. MONTERO, M.D., ROHAN SATISHKUMAR, M.D., TERRY R. MARTIN, M.D., AMY E. LINCOURT, M.D., JOHN I. SHIPP, PH.D., ALEXEY VERTEGEL, PH.D., B. TODD HENIFORD, M.D.

From the Carolinas Laparoscopic and Advanced Surgery Program, Carolinas Medical Center, Charlotte, North Carolina

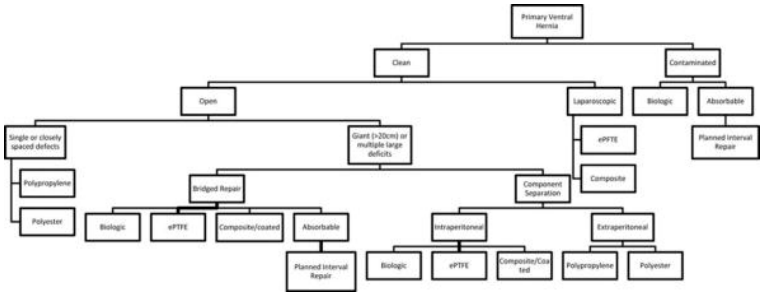
60 day allograft explants:

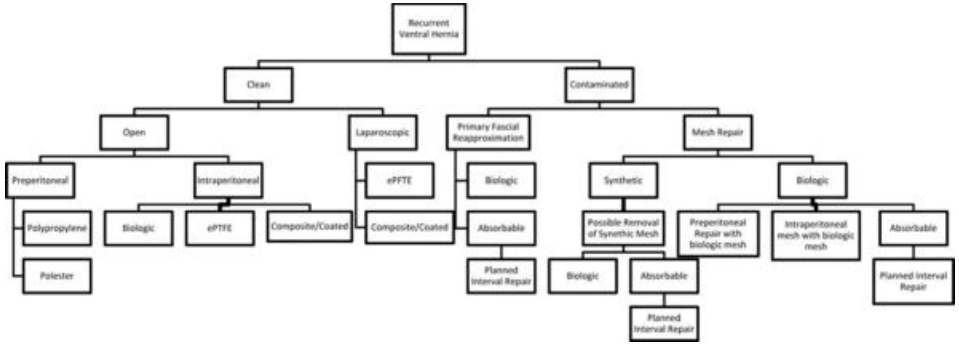


Which Mesh Do I Use?

A Review of Available Prosthetics for Ventral Hernia Repair.
Shankaran, Vidya; Weber, Daniel; Reed, R; Luchette, Fred; MD, MS

Annals of Surgery. 253(1):16-26, January 2011.





Which Mesh Do I Use?

Incisional ventral hernias: Review of the literature and recommendations regarding the grading and technique of repair

Breuning et al. Surgery 2010

Grade	Definition	Recommendation	Evidence
1	Low risk of complications, no history of wound infection	Surgeon Choice	1-C (low quality evidence)
2	Co-morbidities: smoking, obesity, DM, COPD, immunosuppression	Increased risk with permanent synthetic; Potential advantage of biologic	1-B (moderate quality evidence)
3	Potentially Contaminated: previous wound infection, stoma present, violation of GI tract	Permanent synthetic generally not recommended; potential advantage of biologic	1-B (moderate quality evidence)
4	Infected: infected mesh, septic dehiscence	Permanent synthetic not recommended; biologic should be considered	1-A (high quality evidence)

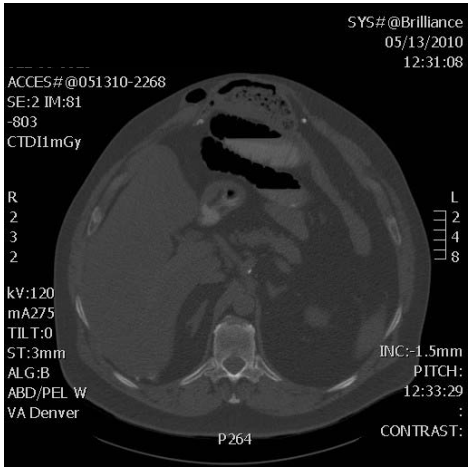
Which Mesh Do I Use?

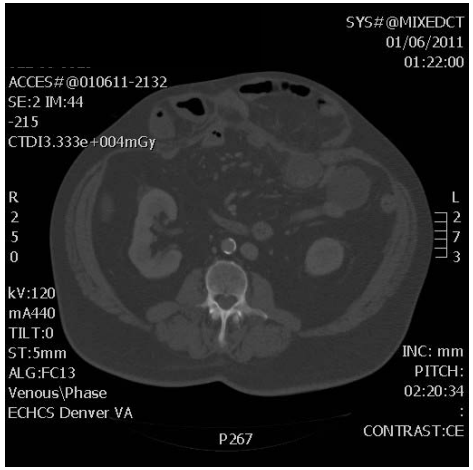
- Intraperitoneal – need a barrier (consider infection risk factors)
- Parastomal – PTFE (permanent barrier, ingrowth side generally will not erode into the intestine)
- Extraperitoneal – macroporous synthetic mesh (LW vs HW depending on size/tension)
- Contamination – absorbable/biologic
- Grossly Contaminated – staged repair

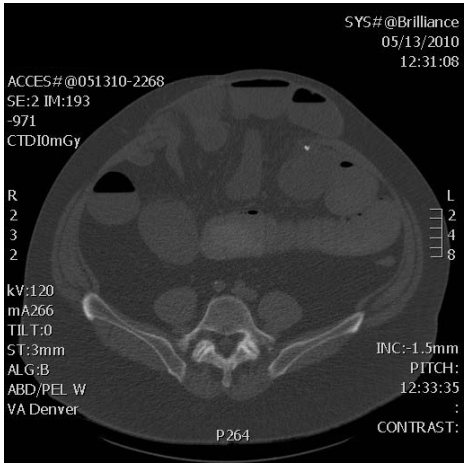
Case Example JR (at VA)

- Past SHx
  - Synthetic mesh
  - Biologic Mesh
  - Chronic Mesh infection (>9 months)

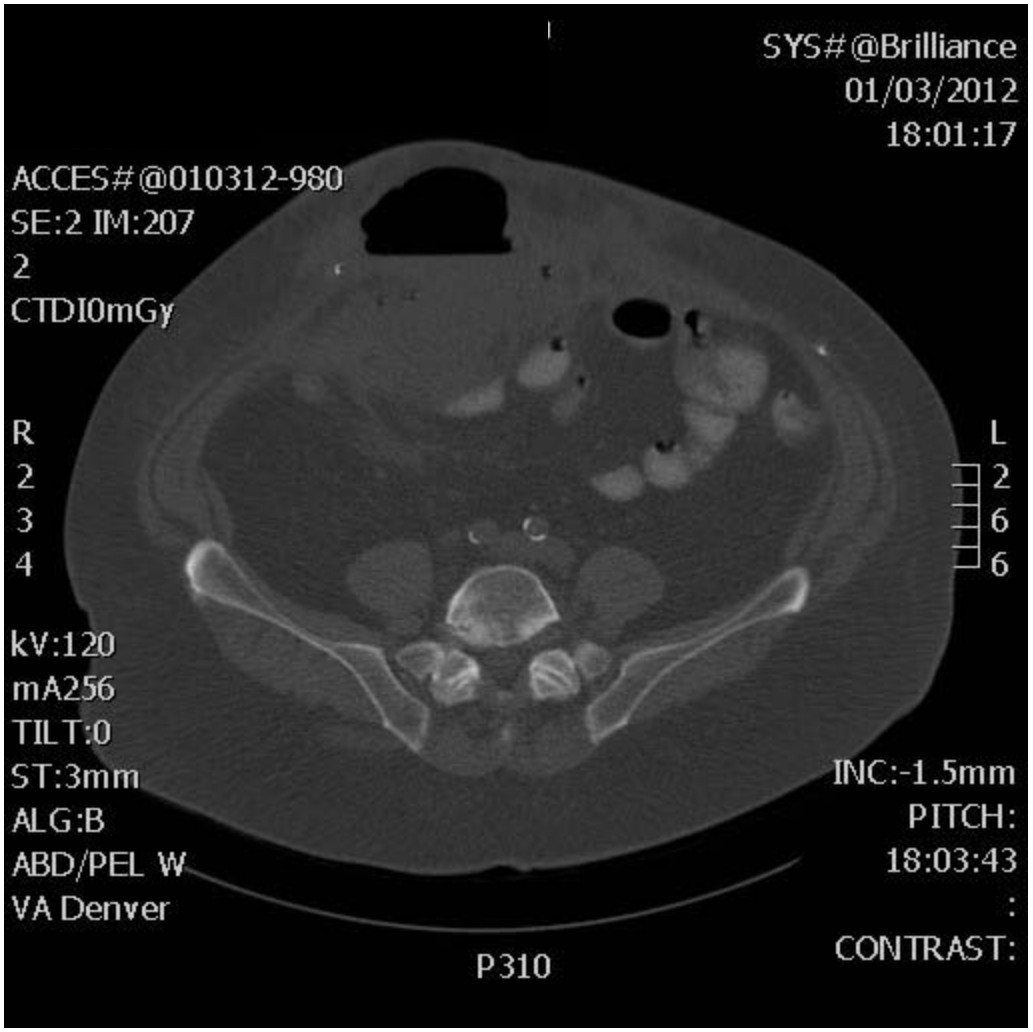
- Procedure: OVHR, mesh excision, SOC, underlay Strattice®



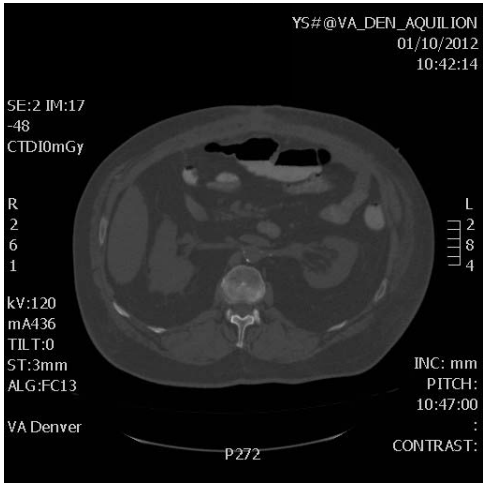


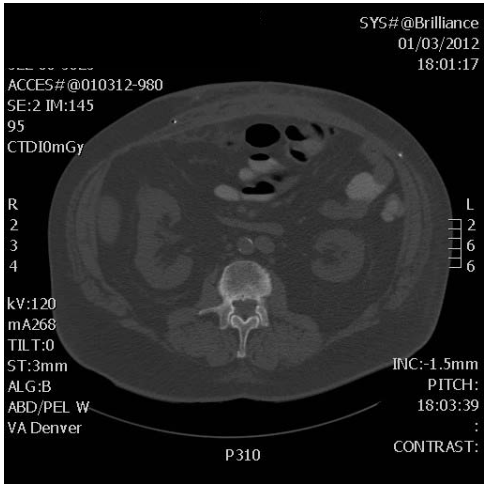


POD 12: Tachycardic and Febrile



POD 19: after I+D





Future Considerations

- Randomized Controlled Trials
  - Contaminated / Infected Ventral Hernia Repair Trial
    - Feb 2011
    - N = 100
    - Biologics vs LW PP vs Absorbable

Summary – Mesh

- Many ideal properties; no single mesh will attain them
- Mesh selection must be individualized to technique, patient factors, surgeon experience, and cost considerations
- Little data exist, overwhelming marketing strategies and claims exist