“Choice of Mesh in Complex Abdominal Wall Hernia Repairs”

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With the Rapid Evolution of Implants the Goals of Hernia Repair Have **Not** Changed!

- Restore function and integrity
  - “flexible not rigid”
- Provide stable skin and soft tissue coverage
- Maintain abdominal wall dynamics
- Innervated and vascularized tissue
- Autologous and local tissue when possible
- Prevent incarceration and strangulation
“The use of artificial materials in the repair of hernias has created an interest and evoked a literature which probably exceeds the importance of this innovation. From [the] numerous materials and various techniques … promulgated, few factual conclusions can be drawn.”

Zimmerman 1968

Ouch!
Now I am really confused?
Recent areas of confusion in VHR and AWR

- Macroporous polypropylene is safe and effective even in contaminated VHR and AWR is an increasing belief amongst surgeons.
- Are the Dermal matrix materials really durable?
- Growing *belief* that all the “biologics” essentially the same and they dissolve?
- Why the increase in use of “bio-absorbables” or absorbable meshes—primarily Phasix®
  - Real data or marketing
### Choices of “Mesh” Options Continue to Expand in 2018

<table>
<thead>
<tr>
<th>Synthetics</th>
<th>Synthetic-Absorbable</th>
<th>Biologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymer based products</td>
<td>Polymer -polyglycolic acid +trimethylene carbonate(Bio-A)</td>
<td>Collagen-based</td>
</tr>
<tr>
<td>Strong, permanent</td>
<td>Poly-4-hydroxybutyrate (Phasix)</td>
<td>Infection “resistant / tolerant”</td>
</tr>
<tr>
<td>Multiple ; sizes, shapes,</td>
<td>Vicryl, Seri, other various polymers</td>
<td>Variable</td>
</tr>
<tr>
<td>porosity, weight, elasticity</td>
<td>good bio-compatibility</td>
<td>Lower risk of adhesion, fistula or encapsulation</td>
</tr>
<tr>
<td>Cost reasonable</td>
<td>Allows tissue ingrowth</td>
<td>non-crosslinked</td>
</tr>
<tr>
<td>Good long term data</td>
<td>Dissolves over 3-36 months</td>
<td>Incorporates and remolds</td>
</tr>
</tbody>
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**CONCERNS**
- Infections
- Adhesions
- Fistula to bowel
- Migration
- Contraction
- Need for explantation

**CONCERNS**
- No long term data
- Unknown characteristics of tissue which replaces mesh in humans

**CONCERNS**
- Processing procedures
- Market confusion
- Marketing vs data
- Long term stability
- Expense
What About Prosthesis Use?

- Use of mesh for incision hernia increasing

  Incidence of mesh use
  - 35% in 1987
  - 66% in 1999
  - Estimated over 80% in 2013

- Why the increase in mesh use
  - Marketing
  - Traditionally poor outcome with primary repair
  - Obesity
  - Evolution of techniques
    » vascular sparing, TARS, anterior CS etc.
  - Evolution of mesh: biologics, synthetics, biosynthetics

Hawn MT JACS 2010
Improving Outcomes: Mesh or Primary Repair

- Randomized Prospective Study: N=200 primary and first recurrence
  - Polypropylene mesh underlay 2 to 4 cm, continuous running suture, no anterior fascial closure. Prolene® suture
  - Hernia < 6 cm in length or width (~30 sq cm)
  - Relatively healthy patients, median follow-up 75 months
  - Long term complications 17% mesh group vs 8% in suture repair

- Data suggest a significant reduction in recurrence rates with the use of synthetic mesh

Ventral Hernia Management

Expert Consensus Guided by Systematic Review

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and David H. Berger, MD‡

Mesh Reinforcement

Consensus

- Mesh reinforcement is recommended for elective repair of ventral incisional hernias and primary VH ≥ 2 cm in width with no contamination. Grade A
- Mesh reinforcement should be evaluated on a case by case basis for emergency VHR, open repair of primary hernias < 2 cm width, and in the face of contamination. Grade D
Interpreting the Evidence: Different Perspectives May Result!

US Perspective
Interpreting Medical Evidence: Different Perspectives May Result!

US Perspective

Canadian Perspective
Various perspectives: Surgeon

- Surgeons
  - Peri-op
    - # of post op visits, reoperations, patient/office expense (dressings, wound vac)
  - Readmissions
    - Durability
    - True recurrence comparisons
      - Show data comparing apples to apples
    - Potential for explantation if becomes infected
    - Resistance to contamination
    - Evidence of engraftment
      - Even in face of infection
    - Cost data
      - Not just up front cost of product
Various perspectives: the hospital accountant

• Administration / accountants
  – Cost
    • Not necessarily value
  – Purchased vs consignment
  – Ability to buy off contract or buying group
Various perspectives: the patient

- Patient
  - Quality of life
  - Days in hospital
  - Subsequent risk of development of complications
  - Time off of work
The Million Dollar Questions when using any prosthesis?

- Strength over time?
  - Predictability
  - If biologic or bioabsorbable what is strength of tissue which replaces the scaffold?

- Performance in the face of contamination / infection?

- Inflammatory response?
The Ideal Implanted Material

- Chemically inert
- Non-carcinogenic
- Not adversely modified by tissue fluids
- Non-inflammatory / foreign body reaction
- Non-allergenic / hypersensitivity reaction
- Resistant to mechanical strains
- Fabricated in the form required
- Easy to sterilize

- Resistant to infection
- Resistant to adhesion formation
- Rapid incorporation

Mesh Choice?
Factors to consider when choosing from the various mesh prosthetics

- Durability (in-vivo)
- Tensile strength, suture pull through
- Tissue incorporation
  - synthetics – absorbables – biologics
- Resistance to infection
  - Rate of tissue incorporation or revascularization
- Published experience ---- transparency of data collection
- Cost effectiveness (must consider downstream events)
  - 15% of hernias consume 50% of the $ spent on VH repair
- Not all “synthetics” are the same
  - PTFE ≠ Polyester ≠ polypropylene
- Not all “biologics” are the same
- Not all “bio-absorbables” are the same

Autologous Tissue: Fascia Lata Graft
Tantalum Fragmentation
We have come a long way!

- Silver Filigrees
- Tantalum Gauze
- Stainless Steel
Non-Metal Prostheses

- Fortisan Fabric
- Polyvinyl Sponge (Ivalon)
- Nylon
- Silastic
- Carbon Fiber
- Polyester / Dacron (Mersilene) Mesh
- Polypropylene (Marlex / Prolene / Trelex) Mesh
- Teflon (chemical similar to PTFE)
- Expanded Polytetrafluoroethylene (ePTFE/Gore-tex)
Fortisan Fabric

- 1952 (Narat)
- Regenerated cellulose
- Temporary trellis for connective tissue in-growth
- Easy to handle
- Well tolerated
- Poorly tolerant to infection (wadded up in tissue)
Nylon

- 1960’s - 1980’s
- Lose of 80% of tensile strength due to hydrolysis and denaturing in vivo

Polyester

1939 polymer discovered
1956 used for mesh in surgery (Wolstenholme)
First real popular non-metal mesh
Pliable, durable,
Disorganized collagen, extensive adhesions
highly inflammatory
Expanded Polytetrafluoroethylene (ePTFE)

- Stronger than other mesh available
- Variable pore size (3-25μ)
- Orderly orientation of collagen
- Tolerant to infection
- Decreased adhesions
ePTFE Dual Mesh
Composite Mesh (Composix)
Polypropylene Mesh

- 1959/1963 knit (Usher)
- More pliable and tolerant of stress
- Good tissue ingrowth
- Newer PP “fairly” tolerant to contamination
  - Porous vs non-porous
  - Wide vs narrow weave
  - Light vs heavy weight
    - Light < 30 gm/m sq
    - Medium 30 to 80 gm/m sq
    - Heavy > 80 gm/m sq
- Adhesions / inflammation / infection
- Newer synthetic products with various coating
  - 50-50 with polygalactine
    » (50 to 70 day resorbtion)
  - Titanium coated
    » Less shrinkage
    » Less inflammation
  - Na-hyaluronate / carboxymethylcellulose
    » fewer adhesions
- Omega-3 Fatty acids
- Collagen hydrogel
- Oxygen regenerated cellulose
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.
In Vivo Evaluation of Bacterial Infection Involving Morphologically Different Surgical Meshes

Measures intensity and spread of bioluminescence

Engelsman AF Ann Surg 2010;251: 133–137
• Peri-fiber granulomas / fibrosis
• Bridging fibrosis where individual granulomas become confluent with each in microporous/hw mesh
Granulomas forming around individual mesh fibers and bridging where individual granulomas become confluent with each other and encapsulate the entire mesh.

Too Lightweight ?

Tick, Tock, Tick, Tock, Tick, Tock, Tick, etc...
To Lightweight?

Central failures of lightweight monofilament polyester mesh causing hernia recurrence: a cautionary note

C. C. Petro · E. H. Nahabet · C. N. Criss · S. B. Orenstein · H. A. von Recum · Y. W. Novitsky · M. J. Rosen

- 22% (8/36) recurrence with monofilament polyester (Parietex TCM)
  - Central mesh failure (CMF) in 7/8 (88% of recurrences)
- CMF seen once with lightweight polypropylene
- ?Due to plastisizing of polyester or lightweight nature?
- Zuvela et al (Hernia 2014) report 3 cases of CMF w Ultrapro, however all were bridged repairs

➢ If bridging required, use heavyweight mesh
➢ Use caution with monofilament polyester

3. *Pfili iidi dii*
Have we gone too far?

- The ultra-light weight meshes reported to “fracture”
Central Mesh Failure
Urgent: Medical Device Removal

Ethicon PhysioMESH™ Flexible Composite Mesh
(All Product Codes)

May XX, 2016

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Please distribute this information to all staff within your facility who use ETHICON PHYSIO MESH™ FLEXIBLE COMPOSITE MESH.

At Ethicon, Inc. ("Ethicon"), our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

We have initiated a worldwide medical device removal of ETHICON PHYSIO MESH™ Flexible Composite Mesh (for laparoscopic use) ("ETHICON PHYSIO MESH™ Composite Mesh"). We are removing the product following an analysis conducted at the request of the Ethicon Medical Safety Team of unpublished data from two (2) large independent hernia registries (Herniated German Registry and Danish Hernia Database-DHDB). The recurrence/reoperation rates (respectively) after laparoscopic ventral hernia repair using ETHICON PHYSIO MESH™ Composite Mesh were higher than the average rates of the comparator set of meshes among patients in these registries.

Based on the currently available data, we believe the higher rates to be a multifactorial issue (including possible product characteristics, operative and patient factors), but we have not been able to fully characterize these factors. Consequently, we have not been able at this time to issue further instructions to surgeons that might lead to a reduction in the recurrence rate and have decided to remove ETHICON PHYSIO MESH™ Composite Mesh from the global market.

Health care practitioners that have treated patients using ETHICON PHYSIO MESH™ Composite Mesh should continue to follow those patients in the usual manner.

This worldwide medical device removal has been communicated to the U.S. Food and Drug Administration (FDA).

This action involves only the ETHICON PHYSIO MESH™ Composite Mesh product line. It does not include the ETHICON PHYSIO MESH™ Open Flexible Composite Mesh Device, or other hernia mesh or device products manufactured or sold by Ethicon.

The scope of this action includes all product codes of ETHICON PHYSIO MESH™ Composite Mesh.
Combination Meshes Vypro

- 50% resorbable polyglactine absorbed in 56-70 days
- 50% polypropylene
- Lightweight, macroporous
- Polyglactine may increase inflammation and fibrosis around mesh in rats
- No significant difference in adhesions in pig study compared to Polypropylene alone

Rosch Eur Surg Res 2003
Sepra-Mesh

Polypropylene

Na-hyaluronate / carboxymethylcellulose

Difficult to handle
Synthetic Mesh

**Advantages**

- Less expensive than biologics
- Wide range of products and sizes available
- Long term in-vivo data available
- Long shelf life

**Disadvantages**

- More adhesions when placed in the peritoneum
- Increased risk of infection in high risk populations
  - variable between polymers
- Explant commonly required if infection occurs
  - PTFE > Polyester > polypropylene
- Shrinkage with time
  - Widely variable 10 to 35%
- Increases risk in subsequent surgery for enterotomy and fistula (>10x)
- Higher risk of erosion into other structures
- Greater inflammatory response
Chronic Inflammation

- All meshes induce inflammation

Orenstein et al. 2010/2012
Foreign Body Reaction

- **Symbotex/Versatex/ProGrip** (Covidien) – Monofilament polyester
  - → Severe FBR w/ numerous FBGCs, Inflammation

Synthetic Mesh Summary

• **Polyester** creates a local “hostile” environment
  – Severe FBR, inflammation, fibrosis
  – Monofilament becomes brittle, woven increase risk of infection

• **ePTFE** is not “inert”
  – Fibrosis with encapsulation not incorporation, moderate FBR
  – Significant increase risk of infection

• **Polypropylene**
  – Weight/Density Reduction
    → Reduced FBR and fibrosis
    → Not necessarily reduced inflammation

• Preferred factors for biocompatibility:
  - Polypropylene (w/o adjuncts)
  - Medium weight
  - Macroporous
Alternatives to Synthetic Mesh in Contaminated Cases

- Primary closure
- Staged approach
  - absorbable mesh, STSG, second repair
- Autologous tissue transfer
  - TFL
  - Rectus femoris
  - Bilateral components separation
  - Tissue expanders
- Synthetic absorbable
- Biological tissue grafts
  - Homograft, Xenografts
- Combined approaches
Absorbable Mesh Choices

- **Vicryl**
  - 100% polyglactin
  - Strength
    - 77% lost in 2 weeks
  - Woven multifilament

- **Bio-A**
  - 67% PGA
  - 33% TMC (timethylene carbonate)
  - Multifiber sheet-like
  - COBRA Study (2 yrs)
    - 17% recurrence (40% if placed intra-ab)
    - 18% post-op infection

- **TIGR Mesh**
  - Synthetic resorbable
  - Resorbs of 4 to 36 months
  - Two fiber types
    - Fast: Glycolide, Lactide and Trimethylene carbonate (TMC)
    - Slow: Lactide, TMC
  - Metabolism: hydrolysis

- **Phasix**
  - Monofilament
  - Resorbs in 9 to 18 months
  - P4HB (poly-4-hydroxybuterate)
    - Fermentation product
    - CO₂ H₂O are end products

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Novus Brochure
Davol Brochure
Ethicon Brochure
Deekens, Matthews JSR 2013
Rosen MJ et al Ann Surg 2017
GORE BIO-A

• Biosynthetic mesh
  • Bioabsorbable mesh
  • Polyglycolide-trimethylene carbonate copolymer
    – 3D matrix “highly interconnected” pores
• Degradation
  – Hydrolysis (polyglycolide)
  – Enzymatic (macrophage mediated)
  – 6-7 months for absorption

• Theoretical benefits
  – Temporary support, strength and reinforcement while serving as scaffold for cellular in-growth
  – Uniformity in mechanical properties
Multicenter, Prospective, Longitudinal Study of the Recurrence, Surgical Site Infection, and Quality of Life After Contaminated Ventral Hernia Repair Using Biosynthetic Absorbable Mesh

The COBRA Study

Michael J. Rosen, MD,* Joel J. Bauer, MD,† Marco Harary, MD,↑ Alfredo M. Carbonell, DO,‡ William S. Cobb, MD,‡ Brent Matthews, MD,§ Matthew I. Goldblatt, MD,¶ Don J. Seizer, MD, MS,|| Benjamin K. Poulous, MD, MPH,** Bibi M. E. Hansson, MD, PhD,†† Camiel Rosman, MD,↑↑ James J. Chao, MD,↑↑ and Garth R. Jacobsen, MD§§

COBRA = Complex Open Bioabsorbable Reconstruction of the Abdominal Wall
Methods/Results

- Prospective, multicenter, observational study
- 9 centers in US and Netherlands (2011-2014)
- Grade 2 and 3 hernia (contaminated and clean contaminated)
- Hernia: determined intraoperative with ruler
  - Defect size, 137 cm² (10 to 513)
  - Defect width 9 cm (3-25)
- Placed as underlay
  - Intraperitoneal
  - retrorectus

- Results
  - 84 completed trial
  - Recurrence 17% (n=16) at 2 years
AHSQC data review:
- elective hernia repairs, Jan 2013-Oct 2016
- Clean with co-morbidities, CC or contaminated
- 1:3 propensity matched
- Biosyn used in 8.5% of 2051 elective open VHR
  - 57% of those in low risk or co-morbid clean cases

Results:
- No difference in 30 day SSI (21 v 17%)
- No difference in unplanned readmissions 13.8 v 9.9%
- Significant difference in
  - SSI 22.4 vs 10.9 (p<0.03)
  - SSI required intervention 24.1 v 13.3 (p<0.049)
  - Reoperations 13.8 v 4.0 (p<0.009)
Poly-4-Hydroxybutyrate (P4HB) material: PHASIX™ Structure

• P4HB produced via fermentation by E.coli K12
  • Eliminated via Krebs Cycle (CO₂ + H₂O)
• A knitted monofilament mesh
  • Pore size: .3074 mm²
  • Implant weight: 164 g/m²
• Predictably and gradually degrades via hydrolysis
  • Not enzymatic – key in susceptibility to bacterial degradation
• Handles like mid to heavy wt polypropylene
• Contributes mechanical strength up to 9-12 months (<10% over 12m)
• Provides a scaffold that enables “remodeling” to host tissue over time
• Retrospective review – Phasix (n=31) vs Porcine dermis (n=42)
• Onlay repair with fascial closure +/- comp separation (anterior)
• Phasix vs Strattice: Single surgeon
  – → Decreased drain time (10 vs 14 days, p<0.05)
  – → Decreased complications (23 vs 41 %, p<0.05)
  – → Decreased recurrence rate (6.5% vs 23.8%, p<0.05) ?
  – Concerns:
    • Onlay ?
    • No data on CDC wound class
    • No data on length of follow-up
      – Biologic was first cohort (what changed over 5 yrs)
    • No data on peri-umbilical sparing anterior component separation
    • Not randomized or no propensity scoring
Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up

John Scott Roth¹ · Gary J. Anthone² · Don J. Selzer³ · Benjamin K. Poulse⁴ · James G. Bittner⁵ · William W. Hope⁶ · Raymond M. Dunn⁷ · Robert G. Martindale⁸ · Matthew I. Goldblatt⁹ · David R. Earle¹⁰ · John R. Romanelli¹⁰ · Gregory J. Mancini¹¹ · Jacob A. Greenberg¹² · John G. Linn¹³ · Eduardo Parra-Davila¹⁴ · Bryan J. Sandler¹⁵ · Corey R. Deeken¹⁶ · Guy R. Voeller¹⁷

• N=121 subjects. CDC Class 1
  • > 1 high risk criteria
    • BMI between 30-40
    • Smoking
    • DM
    • Others
  • 18 month follow-up
    • Primarily retro-rectus +/- components separation (anterior or posterior)

• Results
  • 9% infection
  • 6% seroma
  • 9% recurrence

• A knitted monofilament mesh
  • Pore size: .3074 mm²
  • Implant weight: 164 g/m²
  • Handles like HW PP

OHSU: study site
2 yr: N=13
Recurrence 4/12
Seroma 3/13
infection 2/13
How does macrophage class or phenotype relate to surgical scaffold and host response?

- Most synthetic permanent meshes produce an M1 macrophage response
- Non-crosslinked biologic matrix produce an M2 response
- P4HB yields a M2 response much like the non-crosslinked biologics matrix

Tan J et al. Advances in Immunology 2014
Butyrate

• Anti-inflammatory
• Enhance WBCs, macrophage
• ↓ Adhesion molecules
  (↓ microvascular thrombosis)

Ganapathy V et al J GI Surg 2011
Iraporda C et al Immunobiology 2015
Bernard H et al J Infectious Dis 2015
Polypropylene

Type 1 Macrophage stains red
Type 2 Macrophage stains blue

Note: rodent study – courtesy of Badylak Laboratory
Rabbit Model MRSA Inoculation
7 days post-inoculation with MRSA (1x10^8 CFU/ml)

P4HB Mesh demonstrated a greater than 4-log reduction of MRSA bacteria

Total MRSA CFU on Explanted Devices
Inoculum dose 10^8 MRSA

Preclinical data on file at C.R. Bard, Inc. Results may not correlate to performance in humans.
There is no perfect bioscaffold to date!
Butyrate based scaffold may have potential

Degradable/resorbable with no permanent residue
  – Anti-infective local environment produced with resorption

• Provides excellent mechanical properties for AWR
• Gradually over 12 to 18 months transfers mechanical load
• Macrophage polarization from pro-inflammatory (M1) host response to anti-inflammatory (M2) response
• Butyrate – alters blood flow, enhances wound healing, nutrient absorption by cell, and wound closure rates

Li et al 2016
Ji et al 2016
Allografts

• Cadaveric allografts
  – Acellular Human Dermis
    • AlloDerm® Regenerative Tissue Matrix
    • FlexHD®
    • Allomax ®

• Use is decreasing for abdominal wall
  • Excellent in infected and contaminated fields
  • Elasticity “diastasis” becomes a problem
Xenografts

– Porcine:
  • GI submucosa
    – Surgisis™
  • Dermis
    – Permacol™
    – Collamend®
    – Xenmatrix®
    – Strattice™

– Bovine
  • Pericardium
    – Veritas®
    – Tutopatch
  • Fetal calf dermis
    – SurgiMend™
The extracellular matrix contains complex three dimensional information

- Native collagen and key matrix components
- Matrix capable of supporting cell migration and capillary invasion (no abnormal cross-links)
- Rich in proteoglycans
- Initial biomechanics that supports suture retention and high load
- Results in:
  - rapid revascularization
  - minimal to no adhesions to underlying bowel
Regeneration and repair involve very focused and distinct mechanisms.

**Fetal Healing**
- Connective tissue formation
- Stem cells localize and divide
- Local signals instruct stem cells to replace missing tissue
- Normal structure/function/physiology
- **Regeneration**

**Adult Healing**
- Fibrin scaffold
- Inflammation and proliferation
- Fibrosis and remodeling to scar
- **Repair**
**Biological mesh**

**Advantages**

- Greater resistance to bacterial contamination
  - Variable
- Lower risk of adhesions when placed in peritoneal cavity
- Incorporate and remodel
  - Variable
- Readily available
- Strength equivalent to synthetics initially
- When contaminated or infected usually do not require explant
  - Variable
- Type 2 Macrophage response

**Disadvantages**

- Market confusion
- No level 1 long term data
- Expensive
- Encapsulation common
  - If crosslinked
- Processing makes end products consistency quite variable
  - Variable
- Shelf life significantly less than synthetics
- Animal products may result in refusal by patients for social and religious reasons
  - Extremely rare
Biologics?

The evolution continues

• “Resistance” to infection
  - Rate of revascularization

• Newer biologics decrease in +/- X-linking of collagen
  - Resistance to infection vs foreign body reaction
  - Resistance to collagenase
  - In-vivo “stiffness” and flexibility
  - Suture pull through

• What happens to the biologics ???
  - Scar --- scaffold---- regenerate --- replacement ??
  - Regeneration requires :scaffold, cells, signals !!!

• The “biologics” are not “all the same”
Wide variety of Biologic sources & Products
Foreign Body Reaction (FBGCs)

Orenstein et al. Presented at AHS National Meeting 2010
Cytokine response to biologic meshes


Data generated in a preclinical model. Data may not correlate to performance in humans.
Tolerance to infection

- 34 yo f with DM, class 3 obesity (BMI 63), smoking history.
- Presents with SBO from large incarcerated R subcostal hernia (pt was on the “watchful waiting” list)
- Repaired without “problem” using acellular non-crosslinked biologic mesh secondary to high risk of infection
- 10 x 12 cm area was partially “bridged”
- Now returns on POD 18 with pain, erythema, fever, nausea and emesis with 19 k WBC
Risk Factors:

- Obesity (BMI 63)
- DM
- Smoking
- SBO
- Prior repair
36 hours after initial washout
21 days from original hernia repair
Bridged portion 4 weeks after opening wound. NPWT (wound vac) for 12 days followed by moist saline BID
Biological mesh “melting” in face of infection

Bovine Fetal Collagen
Biological mesh “melting” in face of infection
Seen in clinic 2 weeks post op and inferior portion of wound opened with minimal drainage, returns one week later to clinic with this!

Bovine Fetal Collagen
in ability of tissue to incorporate!

- **Decellularization**
  - Detergents
- **Tissue processing**
  - Separating epidermis or isolating protein matrix
  - ? Cross-linking
- **Sterilization**
  - Chemical
  - Ethylene oxide
  - Radiation / e-Beam (? → x-linking)
- **Antigen reduction**
  - Xenogenic response

The professional opinion and views of Dr. Orenstein.
Indications for Biologics

“most would agree”

1) Contaminated
2) Clean contaminated
3) Expected need to return to the OR
   - Crohn’s (IBD)
   - Cesarean section

“some would agree”

1) Dirty – starting to change to staging
2) Multiple co-morbidities and high risk of complications
3) Unable to get coverage of the viscera
4) Previous MRSA / other infections (Biofilms, persister)
Indications for Biologic/Resorbable mesh

- **High-risk for infection***
  - Hx prior MRSA infection
  - Hx infected mesh
  - Chronic skin ulceration
  - Concurrent/recent bowel surgery w/ spillage
  - Ostomy (+/-)
  - Immunosuppressed (+/-)

(*Not actively infected)

Biofilms
Permanently colonized?

Dr. Orenstein’s professional opinion

**No mesh is indicated for use in a contaminated or infected field**
Other new meshes

- **Zenapro hybrid mesh**
  - Small Intestine Submucosa (SIS) + Polypropylene
  - Laminated, fenestrated mesh
  - SIS “protects” polypropylene during integration

- **XenMatrix AB (antibacterial)**
  - Bound Rifampin & Minocycline lasts ~14 days
  - Reduces bacterial colonization
  - No inhibition of tissue integration
Summary and Conclusion

- > 87 synthetic meshes available on market today and 24 biologic meshes (USA 2016)
- Optimal utilization comes from having some understanding of the principles of wound healing foreign bodies in tissue
- Trends are for increasing use of polypropylene of mid-weight (50-100 gm/m²) macroporous
- With biological trends toward non-crosslinked and processing of tissue which yield an in-vivo response which is “human-like” allowing less inflammation, rapid neovascularization and ingrowth
Is the jury in or out on the use of biologic mesh?
“If we could artificially produce tissue of the density and toughness of fascia and tendon the secret of the radical cure of hernia would be discovered.”

Dr. Theodor Billroth in Beitrage zur Chirurgie (1878)

The future will be personalized hernia repair

Dr. Theodor Billroth (1829-1894)
Conclusion

Keep an open mind

But insist on data and clinical experience to make conclusions and choice of mesh!
Thank You