Biologic Prosthetics & Beyond

UCSF Postgraduate Course in General Surgery
San Francisco, CA
May 18, 2013

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Introduction

- General surgeons perform approximately 400,000 ventral hernia repairs per year in the United States
- There are a multitude of options for surgical technique and prosthetics
- FDA clearance for medical devices does not mean new prosthetics are tested in terms of long term outcomes or relative performance – different than FDA approval
The Ideal Implantable Biomaterial

• Not physically modified by tissue fluids
• Chemically inert
• Does not excite an inflammatory or foreign body reaction
• Non-carcinogenic
• Non-allergenic (no hypersensitivity)
• Resist mechanical strains
• Easily fabricated into the necessary form
• Can be sterilized
• Resists infection
• Does not form adhesions on visceral side
• Responds like autologous tissue

Hernia Prosthetics

<table>
<thead>
<tr>
<th>Prosthetic Class</th>
<th>Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetics</td>
<td>polypropylene, polyester, ePTFE, vicryl*, dexon*</td>
</tr>
<tr>
<td>Composites</td>
<td>two-sided</td>
</tr>
<tr>
<td>Biologics</td>
<td>human, porcine, bovine</td>
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</tbody>
</table>

*absorbable

Biologic Prosthetics Timeline

1992 Human acellular dermal matrix (HADM):
-- first introduced for the treatment of full-thickness burn wounds.
-- use extended to intraoral resurfacing, facial augmentation, breast reconstruction, and bladder sling reconstruction.

1995 Intestinal submucosa:
-- product derived from porcine intestine with excellent tissue incorporation and strength
-- a layered product containing a mixture of growth factors & ECM proteins
-- unreliable in infected wounds & loses tensile strength in vivo due to hydrolysis & chemical denaturing

2003 Guy et al first described the use of HADM for a novel method of one-stage closure following decompressive laparotomy for abdominal compartment syndrome...and the race was on!
## Biologic Prosthetics

<table>
<thead>
<tr>
<th>Source</th>
<th>Material</th>
<th>Name</th>
<th>Manufacturer</th>
<th>Capillary ingrowth (days)</th>
<th>Tensile Strength (N)</th>
<th>Cost ($/cm)</th>
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<td>AlloDerm</td>
<td>LifeCell</td>
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ADM: acellular dermal matrix  
ADM-X: cross-linked ACMD  
SIS: small intestine submucosa

**Notes:**
- ADM: Acellular dermal matrix
- ADM-X: Cross-linked ADM
- SIS: Small intestine submucosa

**Images:**
- AlloDerm: Human “regenerative” human matrix
- Strattice: Porcine dermal matrix
Biologic Prosthetics

What does the available data tell us?


Poor quality primary data:

- Studies included in analyses are either case series or case reports, all of which are a low level of evidence;
- These data are reported inconsistently, with different inclusion and exclusion criteria, outcome variables and follow-up periods;
- Ultimately, the shortcomings of poor-quality primary data cannot be overcome, no matter how rigorous and robust the analytic methods.

Allografts dominate the hernia repair literature:

- Over 70% of procedures reported in the literature involve the use of human acellular dermal matrix (AlloDerm);
- Many surgeons and the industry have become disillusioned with allografts for incisional hernia repair.
What does the available data tell us?

> **High rate of wound complications:**
> - all types of biologic mesh are associated with significant wound complication rates, ranging from 50-80%.
> - approximately half of the wound complications are infections, but also include seromas, hematomas, fistulas and skin necrosis.

> **High rate of hernia recurrences at one-year follow-up:**
> - recurrence rates of 15-25% are frequently reported as compared to one-year rates for synthetic mesh of ~5%.
> - solid clinical data (level 1b) indicates that using biologic mesh to bridge a fascial defect is associated with a 38% failure rate at 1 year.

**Greater experience in non-contaminated wounds:**
- use of a “natural, tissue-derived” biomaterial that develops neovascularity and thus can resist infection is the central indication that separates biologic versus synthetic prosthetics.
- But, less than 25% of incisional hernia repairs using a biologic mesh were performed under clearly contaminated conditions, with generally poor results.

**Cost analyses:**
- biologic mesh are 20-30 times more expensive than synthetic alternatives.
- the limited available data indicate that the use of biologic mesh can more than double to direct costs of incisional hernia repair.
• The cumulative data regarding biologic meshes use on ventral hernias under contaminated conditions does not support the claim that they are better than synthetic mesh used under the same conditions;

• The highly promoted and frequently discussed practice of placing biologic mesh in contaminated surgical fields is being done outside of the products’ original intended use, and in some instances, equates to off-label use of a medical device; and

• Biologic mesh use, even in non-contaminated conditions is questionable when the reported results are viewed in light of the high costs.

So, what prosthetic should I use to fix incisional hernias?

Hernia Prosthetic Choice

FASCIA CLOSED?

YES

YES

REINFORCE?

YES

NO

WOUND CONTAMINATION?

YES

NO

NO

NO

1. BIOLGIC

2. SYNTHETIC

3. ABSORBABLE SYNTHETIC or BIOLOGIC?

4. COMPOSITE