Introduction

- General surgeons perform approximately 800,000 inguinal & 100,000 ventral hernia repairs per year in the United States
- There are a multitude of options for surgical technique and prosthetics
- FDA approval does not mean new prosthetics are tested in terms of long term outcomes or relative performance
- Patients and surgeons are effectively engaging in poorly designed, uncontrolled, inadequately monitored, and haphazardly analyzed clinical research trials
- Familiarity with the history of hernia prosthetics can inform contemporary decision making

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 in the necessary form
- Can be sterilized

Hernia Prosthetics Timeline

1887 Bassini ushers in the modern age of anatomic hernia surgery
1894 Silver coils (Phelps) used to induce wound fibrosis
1900 Silver wire filigree (Witzel & Goepel) used handmade devices
- Despite impressive results (recurrence rates <0.5%), use gradually stopped by the late 1950s due to patient discomfort, “work hardening,” seroma, and sinus tract formation & the arrival of new prosthetic materials
Silver Filigrees

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1948 Tantalum gauze popularized after 4 clinical reports published
- the best available synthetic prosthesis for hernia repair
- several year follow up yielded work hardening, mesh fractures, seroma formation and dense adhesions to exposed viscera
1952 Stainless steel mesh or screens introduced
- reports on >2,000 cases noted no work hardening, mesh fatigue, good patient acceptance
- prejudice against metal prostheses, especially in the era of synthetic biomaterials, limited adoption
1954 Fortisan, a regenerated cellulose fabric, introduced
- easy to handle, excellent host incorporation, but in the presence of infection rolls up and provides a foreign body reaction

Hernia Prosthetics Timeline

Foreign-body giant cell reaction
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1954 Fortisan, a regenerated cellulose fabric, introduced
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1956 Polyester (Dacron) mesh: a polymer of ethylene glycol & terephthalic acid developed in 1939
- hydrophilic, soft mechanical feel, reduced scar tissue contraction
- knitted into a fabric mesh (Mersilene), has an extensive clinical experience over five decades, and represents the first non-metallic mesh to stand the test of time. Remains a popular hernia prosthetic in current practice.
1957 Polyvinyl sponge: a polymer of polyvinyl alcohol & formaldehyde, acid, white material whose properties were altered in vivo and was poorly tolerated in the presence of infection
1958 Polypropylene mesh: a plastic material
- popularized by its pliability, tensile strength, resists fragmentation & infection, and no size limits, available in different densities, weave and pore sizes
- formulation dictates degree of fibrogenesis
- enormous impact on surgery, justifiably the most popular prosthetic mesh for hernia repair
### Hernia Prosthetics Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Material</th>
<th>Description</th>
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<tbody>
<tr>
<td>1957</td>
<td>Polyvinyl sponge</td>
<td>A polymer of polyvinyl alcohol &amp; formaldehyde. Solid, white odorless material whose properties were altered in vivo and was poorly tolerated in the presence of infection.</td>
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<td>1958</td>
<td>Polypropylene mesh</td>
<td>A plastic material. Popularized by its pliability, tensile strength, resists fragmentation &amp; infection, and no size limits.available in different densities, weaves and pore sizes. Formulation dictates degree of fibrogenesis. Enormous impact on surgery. Justifiably the most popular prosthetic mesh for hernia repair.</td>
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<td>1959</td>
<td>Teflon (polytetrafluoroethylene, PTFE)</td>
<td>Used following its accidental discovery in 1938 by a du Pont chemist. Famous as a non-stick cooking surface, cannot be wet by water, nothing will adhere. Not incorporated into tissues, does not tolerate infection &amp; high rate of wound complications.</td>
</tr>
<tr>
<td>1959</td>
<td>Goretex mesh</td>
<td>Expanded Polytetrafluoroethylene (ePTFE) mesh.</td>
</tr>
<tr>
<td>1961</td>
<td>Nylon nets and mesh</td>
<td>Popularized. Excellent tissue incorporation and strength. Unreliable in infected wounds &amp; loses tensile strength in vivo due to hydrolysis &amp; chemical denaturing.</td>
</tr>
<tr>
<td>1967</td>
<td>Silastic (polymers of alternating silicone &amp; oxygen)</td>
<td>Introduced by pediatric surgeons to treat omphalocele &amp; gastroschisis. Silastic sheeting generates organized fibrosis responses with linear arrays of fibroblasts. Limited use of dacron-reinforced silastic sheets for large vents were promising as the silastic served as a “fibrogenetic template.”</td>
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<tr>
<td>1980</td>
<td>Carbon fiber (flexible filaments)</td>
<td>Considered given their use in orthopedic surgery. Despite many appealing characteristics, concern over possible carcinogenesis likely contributed to limited clinical experience with this prosthetic material.</td>
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Hernia Prosthetics Timeline

1982 **Bovine pericardium**
- Chemically cross-linked via glutaraldehyde fixation to resist degradation
- Limited use for a variety of hernia repairs, including diaphragmatic and parastomal
- A current application as laparoscopic staple line reinforcement

1982 **Polyglycolic acid (Dexon) mesh; weave of braided dexon fibers**
- Biodegradable over ~90 days
- Useful in infected surgical fields or for temporary barriers
- Soft, pliable and elastic

1983 **Polyglactin 910 (Vicryl) mesh; synthetic fiber first used as suture**
- Similar to Dexon mesh, biodegradable, but a more tightly woven broadcloth that is less elastic than Dexon

1983 **Intestinal submucosa**; product derived from porcine intestine
- Excellent tissue incorporation and strength
- Unreliable in infected wounds & loses tensile strength in vivo due to hydrolysis & chemical denaturing

1995 **Acellular dermal matrix**; human, porcine or bovine in origin
- Dermal collagen matrix that promotes tissue ingrowth and re-vascularization
- Actively remodels to "resemble adjacent connective tissue"
- Chemical cross-linking of collagen proteins reduces susceptibility to infection

2003 **Coatings**; various substances used to coat inert mesh
- Materials range from omega-3 fatty acids to titanium
- A real paucity of available clinical data
So, what product should I use? 
What's the best for the patient?
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<tr>
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<td>XXX</td>
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<td>XXX</td>
</tr>
<tr>
<td>Inert</td>
<td>XX</td>
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<td>Organized fibrogenesis</td>
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<td>No visceral adhesions</td>
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<td>Resists infection</td>
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So, what product should I use to fix ventral hernias?

**Ventral Hernias: National Experience**
- Approximately 100,000 ventral hernia repairs/year in the U.S. with an estimated $800 Mil market value by 2013;
- Average patient in their 5th decade of life;
- Risk factors include obesity, diabetes, lung disease, smoking, wound infection, and steroids;
- No universally accepted classification system or evidence-based management guidelines;
- Wide variation in surgical techniques and strategies for repair.

**Complex Ventral Hernias**
- Involve a compromised surgical field where gastrointestinal, biliary or genitourinary procedures are performed
- Significant patient co-morbidities
  - obesity
  - diabetes
  - COPD
  - smoking history
- Prior hernia repairs
- Gross infection or compromise of the skin or soft tissues
- Large fascial defects (>100 cm²)
- Large volume hernia sacs ("the acquired omphalocele")

**Ventral Hernias: UCSF Experience**
- 508 open ventral hernia repairs over the past 5 years and volume is increasing;
- 25% of patients had previous attempts at repair;
- 16% had a previous solid organ transplant;
- 38% post-operative complications with 0.01% mortality;
- 19% recurrence rate (33% transplant v. 17% non-transplant);
- >95% of repairs involve use of prosthetic material.
UCSF Experience: Case Presentations

• 52 year old man presents 10 months after surgery for perforated diverticulitis with fecal peritonitis, abdominal sepsis, diverting colostomy and an open abdomen;

• Massive ventral hernia, skin graft and colostomy:
49 year old man presents with a massive ventral hernia s/p five failed repairs and a chief complaint of increasing abdominal pain for the past four days after hearing something go "pop";

- Found on CT scan to have a strangulated ventral hernia containing an intestinal perforation;
Ventral Hernias

- Multiple options for surgical repair:
  - primary repair
  - synthetic prosthesis (absorbable v. permanent)
  - biomaterial prosthesis (porcine v. human)
  - composite prosthesis

- All hernia repair prosthetics are considered *medical devices*, not pharmaceuticals.
Summary

- Inadequate data regarding the relative merits and effectiveness of the various products available;

- Real concern that acellular dermal matrices are “expensive hernia sacs”;

- The surgeon must combine clinical judgment, prior experience with a patient-driven therapeutic strategy when determining how to repair complex ventral hernias;
  - risk of infection or wound breakdown
  - risk of visceral adhesions or fistula formation
  - risk of recurrence