Soft Tissue Implants

Lecture #15
Minimal Requirements for Soft Tissue Replacements

- Reasonably close approximation of physical properties, especially flexibility and texture
- Should not deteriorate
- Should not cause severe tissue reaction
- Should not induce thick fiber encapsulation or ingrowth
- Noncarcinogenic, nontoxic, nonallergenic, and nonimmunogenic
Heart Valve Prostheses

- First successful implant in 1961
- First attempts were centrally occluding caged ball (Starr-Edwards) or caged disk
  - mitral and aortic valves on left side of heart
Caged Ball Prosthesis

- Successfully replaced mitral valve in 1961
- Cage
  - Polished Co-Cr alloy
- Ball
  - Silicone rubber
  - 2% barium sulfate for radiopacity
- Sewing ring
  - Silicone rubber insert under PPE-PTFE knitted fabric
- Large pressure drop
  - Turbulence
Tilting Disk Prosthesis

- Introduced in the late 1960s
- Initially polyacetal (Delrin®) disk and Teflon® sewing ring
- Polyacetals swell when in contact with humidity and blood contact
  - Delrin® replaced by pyrolytic carbon
- Struts and ring are usually Co-Cr or pure Ti
Another Design with UHMWPE Disk
Bi-leaflet Prostesis

- Developed in 1970s
- Improved blood flow characteristics
- Pyrolytic carbon leaflets and housing
- Polyester (Dacron®) knitted velour suture ring
  - Better tissue ingrowth
- W incorporated into leaflet layer for radiopacity
Tri-leaflet Prosthesis

- Better mimic actual heart valve
- True central flow characteristics
- Minimal backflow
Problems

- Thrombo-embolic complications significant
  - Thrombi form in “back water” regions near prosthesis due to stresses induced in blood cells as they flow across the valve
  - Patients under long-term anti-coagulant therapy
- Mechanical failure of struts
  - Leaflet “escapes”
- Pitting and erosion of valves/leaflets
- Cavitation
Cavitation (*in vitro*)
Cavitation Effects – Pitting
Biological Heart Valves

- First were *homografts* harvested from cadavers within 48 hours of death
  - Long-term durability
  - Availability

- *Xenografts* used beginning in the 1960s
  - Porcine
    - Harvested from 7-12 month old pigs
    - Stented and fixed with gluteraldehyde
  - Bovine
    - Pericardial tissue used to construct valves
Bioprostheses

Porcine

Bovine
# Biomaterials Used in Heart Valve Prostheses

<table>
<thead>
<tr>
<th>Prosthesis Type</th>
<th>Component</th>
<th>Biomaterial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caged ball</td>
<td>Ball/occluder</td>
<td>Silicone rubber</td>
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<tr>
<td></td>
<td>Cage</td>
<td>Co-Cr/Ti</td>
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<tr>
<td></td>
<td>Suture ring</td>
<td>Silicone rubber under knitted Teflon®/PPE</td>
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<tr>
<td>Tilting disk</td>
<td>Leaflet/disk</td>
<td>Delrin®/Pyrolytic carbon/UHMWPE</td>
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<tr>
<td></td>
<td>Housing/strut</td>
<td>Co-Cr/Ti</td>
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<tr>
<td></td>
<td>Suture ring</td>
<td>Teflon®/Dacron®</td>
</tr>
<tr>
<td>Bi-leaflet</td>
<td>Leaflets</td>
<td>Pyrolytic carbon</td>
</tr>
<tr>
<td></td>
<td>Housing</td>
<td>Pyrolytic carbon</td>
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<tr>
<td></td>
<td>Suture ring</td>
<td>Double velour Dacron® knit</td>
</tr>
<tr>
<td>Porcine bioprosthesis</td>
<td>Leaflets</td>
<td>Porcine aortic valve fixed with gluteraldehyde</td>
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<tr>
<td></td>
<td>Stents</td>
<td>Dacron®-covered PPE /knitted Teflon®-covered wire</td>
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<tr>
<td></td>
<td>Suture ring</td>
<td>Dacron®/soft rubber insert covered with Teflon® cloth</td>
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<tr>
<td>Pericardial bioprosthesis</td>
<td>Leaflets</td>
<td>Bovine pericardial tissue fixed with gluteraldehyde</td>
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<tr>
<td></td>
<td>Stents</td>
<td>Dacron®-covered PPE /knitted Teflon®-covered wire</td>
</tr>
<tr>
<td></td>
<td>Suture ring</td>
<td>Teflon® fabric over silicone rubber filter</td>
</tr>
</tbody>
</table>
Common Problems

I. Mechanical Valves
a) Thrombo-embolism
b) Structural failure
c) Red blood cell and platelet destruction
d) Tissue Overgrowth
e) Damage to endothelial lining
f) Leakage
g) Tearing of sutures
h) Infection

II. Bioprosthetic Valves
a) Tissue calcification
b) Leaflet rupture
c) Leakage
d) Infection
Total Artificial Hearts (TAHs)

- 1980s – attempts to permanently implant TAHs with pneumatically powered units
  - Neurological complications – indefinitely suspended
    - Thrombo-embolism
    - Infection
    - Blood and kidney complications
- Can be used temporarily until suitable donor heart is identified
Typical Pneumatic Artificial Heart

- Pneumatic line
- Ventricular chambers
- Inflow
- Outflow
Electrically Powered TAH
Dialysis
Artificial Skin

- Material that can adhere to a large, burned surface
- Polymeric materials and/or reconstituted collagen

The healing process of synthetic skin

- A patch of synthetic skin is placed on top of damaged tissue.
- The patch contains chemicals that trigger growth of new blood vessels and proteins for skin regeneration.
- The blood vessels restart blood flow to the area and the silicone membrane is removed.
- A small graft of the patient's own skin replaces the silicone membrane.
- The skin graft eventually creates a smooth surface of regenerated skin.

Source: Integra LifeSciences Corporation
Maxillofacial Implants

- **Extraoral**
  - Reconstructing defective regions in the maxilla (cheek), mandible (jaw), and face
    - Match of color and texture
    - Mechanical and chemical stability
    - Ease of fabrication

- **Intraoral**
  - Bone defects in same areas
Chin Implants
Ear Implants

- Hearing loss
  - Cochlear implants
- Cosmetic
  - Artificial ear
Breast Implants

- History
  - Date to the late 1880s
  - Implants
    - Ivory
    - Glass balls
    - Ground rubber
    - Ox cartilage
  - Injections
    - Parrafin
    - Petroleum jelly
    - Industrial silicone fluid/medical-grade silicones
- Reactions
  - Pain, discoloration, disfiguration, breast loss, liver problems, respiratory distress, pulmonary embolism, coma, death
Breast Implants II

- 1963 – Dow Corning introduced first silicone-gel implant
- 1968 – Heyer Schulte Corp. first domestic manufacturer of saline implants
  - Fragile
  - Slooshing
- 1992 – Federal moratorium on use of silicone-gel implants (no firm evidence that leakage caused problems)
  - Rigid qualifications