Peripheral Arterial Stent Grafts: The Next Evolution in Stents

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Disclosures

• Founder and stock in PeriTec Biosciences
The Clinical Need for Peripheral Covered Stent Grafts
Trauma

• 18 year old male from OIF
  – IED with 52 fragments to body, 2 L of blood from chest tube.
  – Stabilized by FST, tx to Kuwait, tx to Lansdahl Airforce Base, Germany, then to Walter Reed Army Medical Center
  – Lower ext hyperemia
  – Expanding chest wall hematoma
Diagnostic Angiogram
Stiff wire
No Sheath
Bilateral Femoral Access

Viabahn stent graft
Completion Angiogram
Trauma

• 55 year old male with type I DM
  – 6 month hx of progressive rest pain.
  – ABI – non-compressible vessels.
Angiogram

Calcified sfa

High grade stenosis
Angioplasty

Perforated Vessel

Stent Graft (Viabahn)
• 75 year old female, with ischemic rest pain after failed ePTFE bypass
  – Redo fem anterior tibial bypass after failed ePTFE.
  – Multiple angioplasties for high grade stenosis from intimal hyperplasia.
  – Loss of graft pulse
High grade stenosis

Angiogram
Post Angioplasty w/ Cutting Balloon
3 Weeks Later – Pulsatile Thigh Mass

Pseudoaneurysm
ICAST – covered stent
Challenges of Currently Available Peripheral Stent Grafts

- Clinical Results
- Fatigue
- Neointimal hyperplasia/Inflammation
- Infection
Long Term Clinical Results
SFA Stent Grafts

  - Hemobahn in 54 patients with long segment occlusion (> 10 cm).
  - Cumulative primary patencies at 1, 6, and 12 months are 88%, 67%, and 58%
Peripheral Stent Graft Results

SFA

Viabahn
- ePTFE covered graft
- w/ exo-stent skeleton
- requires 8F or 9F sheath
- easy deployment
- PMA

Table 6. Summary of Effectiveness Outcome Measures

<table>
<thead>
<tr>
<th></th>
<th>PTA (N=100)</th>
<th>Viabahn All (N=144)</th>
<th>Viabahn Randomized (N=97)</th>
</tr>
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<tbody>
<tr>
<td>12-month</td>
<td>45%</td>
<td>51%</td>
<td>50%</td>
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</table>
• Coronary Saphenous Vein Grafts
Covered Stents

JOMED Stent Graft

BSC SYMBIOT®

Cardiovasc P-15
Clinical Trials

• 3 Trials:
  – Recover, STING, and Symbiot found less benefit of covered stent grafts vs bare metal stents in coronary saphenous vein grafts.
Other Common Covered Stent Uses

- AV Access
- TIPS
Durability/Fatigue
SFA Mechanics Are Unique

- The adductor canal has non laminar flow dynamics, especially with walking.
- The forces exerted on SFA include torsion, compression, extension and flexion.
- Challenge for endovascular devices (stents)
Stent Fractures
Inflammation/Neointimal Hyperplasia
Neointimal Hyperplasia
“In-Stent” Restenosis
ePTFE Healing Response
Research
Hypothesis

• The peritoneum will act as a clot resistant layer which improves patency, and limits neointimal hyperplasia.
Background
“Tube With in A Tube”

- Why peritoneum – what is it?
- Mesothelial layer derived from endoderm.
- 150µ in thickness
- Abdominal cavities equivalent to endothelium.
- Frictionless smooth surface.
Arterial Patch Summary

• Animal studies demonstrated superiority of bovine peritoneal fascia patch compared to bovine pericardium and dacron.
• FDA 510 K letter January 12, 2005
• Published JVS 2005
Outline of Technology

JEVT April, 2006
Experimental Design
Peritoneal Lined Stent Graft

• Bovine fixed peritoneal lined stent -
  ➢ balloon injury to dog iliac
  ➢ balloon expandable peritoneal lined stent
  ➢ wall graft as control
• 18 animals
  ➢ Sacrifice ½ at 30 days and ½ at 180 days
6 Month Results
Peritoneal Lined Stent

• All vessels open/patent.
• Minimal intimal hyperplasia.
  – 8/9 vessels patent in PLS
  – 6/9 vessels patent in DLS
## Histology

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>180 Days</th>
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<tbody>
<tr>
<td></td>
<td>PLS (mm²)</td>
<td>DLS (mm²)</td>
</tr>
<tr>
<td><strong>Neointima Area (mm²)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.6 ± 1.0</td>
<td>8.3 ± 1.8</td>
</tr>
<tr>
<td><strong>Media Area (mm²)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.4 ± 0.7</td>
<td>3.2 ± 0.7</td>
</tr>
<tr>
<td><strong>Intima/Media Ratio</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.4 ± 0.4</td>
<td>2.7 ± 0.8</td>
</tr>
</tbody>
</table>
Six Month Histology

PLS

DLS
Endothelium

Factor VIII and CD34 Heavily Stained
Smooth Muscle $\alpha$-Actin

PLS

DLS

A

B

* *
Challenge

• To make this a clinically viable stent graft, it must be self expanding, stored in liquid and easily crimped on the table.
• It must withstand the rigors of arterial flow.
• It must be easy to use.
Loading
Delivery
Stent Mechanical Testing – 10 Year Simulation

- Accelerated Pulsatile Fatigue (50 million cycles)
  - 400 million cycles no fracture
- Axial Torsion Fatigue
  - torsion - extension 100 million cycles
Torsion Test – Preliminary data suggests peritoneum may support the stent from fractures.
Multi-Center International Safety Trial
PeriTec Biosciences

• 50 patients initial feasibility trial for lesions < 10 cm
• 2 Sites - PIs:
  – Albrecht Kramer, MD - Catholic University Hospital, Santiago, Chile
  – Pierre Galvagni Silviera, MD, Florianopolis, Brazil
• CRO – ACTIVA
• US IDE
First in Man

• First patient 76 yo male and second 64 yo male, both with short distance lifestyle limiting claudication.

• Patient#1
  – Preop - ABI = 0.60
  – MRA –
    • high grade SFA stenosis with 1 vessel runoff
First in Man
Diagnostic Arteriogram

- 4 cm 90% SFA stenosis with irregular borders.
- Tandem lesions
First in Man

Device 7 x 60 mm

Post angioplasty & stent
Ruptured SFA Following Angioplasty  Successful Treatment with Peritoneal Lined Stent

Calcified SFA  Perforated SFA Post Dilatation
Total Occlusion Successfully Treated With a Peritoneal Lined Stent

Occluded SFA

Peritoneal Lined Stent
AFIRM Challenges

• Create a stent graft that:
  – Can be easily used in the field to arrest bleeding and maintain patency.
  – Is resistant to long term fatigue.
  – Is resistant to neointimal hyperplasia.
  – Is less susceptible to infection.
Proposal

• A bioabsorbable tissue lined stent graft.
  – Stent is strong enough to resist early fatigue, but dissolves to eliminate sequela of long term fastigue.
  – A tissue lined stent graft that the stent can be removed
  – Stent lining is resistant to intimal hyperplasia to prevent restenosis.
Current Bioabsorbable Stents

- Reva
- Abbott
- Medtronic
- Biotronik
Materials Testing

- Burst Strength after stored in anhydrous liquids
  - PLA
  - Vicryl
  - Cat gut
  - PDS
  - Magnesium
- Stent Construction – balloon vs self expanding stent
- Fatigue Testing
- Animal Studies
- Clinical Trials