Open Bypass for Limb Salvage: What are the Options when there is no Saphenous Vein

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Florida State University Medical School
Mote Vascular Foundation, Inc
Sarasota Vascular Specialists

Disclosure

Consultant for W.L. Gore®
We all know single segment autogenous saphenous vein is the best conduit for infra-inguinal bypasses

- Too large
- Too small
- Calcified
- Superficial phlebitis
- CABG
- Varicose vein stripping
- Laser and radiofrequency ablation
Options

- Spliced vein including small saphenous, cephalic and basilic veins
- Cadaveric vein
- Umbilical vein
- Bovine graft
- Prosthetic polyester (Dacron)
- Prosthetic ePTFE
- Prosthetic ePTFE heparin bonded
- Gore® Hybrid graft

Multiple site harvests

- Poor wound healing
- Chronic limb swelling
- Prolonged operation
- Prolonged recovery period
Saphenous vein vs standard ePTFE

Above Knee

Below Knee

Role of Spliced Vein

Spliced vein requires more secondary revisions than ePTFE
Cadaveric (Cryopreserved) Vein

- Patency: 23%
- Limb Salvage: 62.3%

Good for infections

Polyester (Dacron) vs ePTFE

<table>
<thead>
<tr>
<th></th>
<th>Polyester (Dacron)</th>
<th>ePTFE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events in %</td>
<td>127 (41%)</td>
<td>127 (29%)</td>
</tr>
<tr>
<td>Censored in %</td>
<td>532 (59%)</td>
<td>532 (20%)</td>
</tr>
<tr>
<td>Median survival (months)</td>
<td>54</td>
<td>48</td>
</tr>
</tbody>
</table>

Source: BMC Surgery © 1996-2008 BioMed Central Ltd
**Carmeda BioActive Surface® -CBAS®**

**SEA BASS**

**Heparin-Bonded PTFE (Gore - Propaten®)**

*Inside the microstructure*

- Heparin molecule
- Bioactive heparin site
Mechanism of Action

- Heparin molecules are bonded to the graft’s luminal surface
- Bioactive site of the heparin molecule binds to antithrombin (AT)
- Antithrombin binds to thrombin (T) – a neutral AT-T complex is formed
- Thrombin loses its ability to catalyze the conversion of fibrinogen to fibrin
- Neutral AT-T complex detaches from the heparin molecule
- Heparin bioactive site becomes available to again bind antithrombin

How long does heparin last? (Human explant)

- Explant after ~ 3 years
  - Below-knee femoral to tibioperoneal trunk bypass
  - PROPATEN was patent; outflow vessel (peroneal) occluded
- Substantial heparin bioactivity detected

Widely patent lumen of GORE® PROPATEN® Vascular Graft
One Year data comparing Propaten to Standard ePTFE

The Scandinavian Propaten™ Trial — 1-Year Patency of PTFE Vascular Prostheses with Heparin-Bonded Luminal Surfaces Compared to Ordinary Pure PTFE Vascular Prostheses — A Randomised Clinical Controlled Multi-centre Trial


1 Basic Research Unit, Department of Vascular Surgery, Nyhamnshospital, Box 700, 650 08 Växjö, Sweden
2 Department of Vascular Surgery, Sahlgrenska University Hospital, Sahlgrenska Academy, University of Gothenburg, Göteborg, Sweden
3 Department of Vascular Surgery, Academic Hospital, University of Gothenburg, Göteborg, Sweden
4 Department of Vascular Surgery, St. Erik Hospital, Stockholm, Sweden
5 Department of Vascular Surgery, University Hospital, Herlev, Denmark
6 Department of Vascular Surgery, Aarhus University Hospital, Aarhus, Denmark

Two year Data

Gore papers


Method

- From 2003 to 2007 93 Standard wall ePTFE femoral-popliteal bypasses
- Since August 2007 108 Gore Propaten® femoral-popliteal bypasses

Location of ePTFE grafts

- AK: 76
- BK: 17
### Variables

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>PROPATEN</th>
<th>STANDARD PTFE</th>
<th>P-value</th>
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<tbody>
<tr>
<td>AK</td>
<td>65.7%</td>
<td>82.8%</td>
<td>0.017</td>
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<tr>
<td>Isolated popliteal</td>
<td>1.4%</td>
<td>7.1%</td>
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<tr>
<td>One runoff artery</td>
<td>37.1%</td>
<td>32.3%</td>
<td></td>
</tr>
<tr>
<td>Two runoff arteries</td>
<td>37.1%</td>
<td>27.3%</td>
<td></td>
</tr>
<tr>
<td>Three runoff arteries</td>
<td>18.6%</td>
<td>27.3%</td>
<td></td>
</tr>
<tr>
<td>Preop ABI</td>
<td>0.56</td>
<td>0.59</td>
<td></td>
</tr>
<tr>
<td>Postop ABI</td>
<td>0.95</td>
<td>0.97</td>
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<tr>
<td>Gangrene</td>
<td>21.4%</td>
<td>18.2%</td>
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<tr>
<td>Ulceration</td>
<td>35.7%</td>
<td>19.2%</td>
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<tr>
<td>Rest pain</td>
<td>27.1%</td>
<td>26.3%</td>
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<tr>
<td>Claudication</td>
<td>34.3%</td>
<td>41.4%</td>
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*Note: p<0.05*
### Variables

<table>
<thead>
<tr>
<th>VARIABLE</th>
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<tr>
<td>Smoking</td>
<td>34.3%</td>
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<tr>
<td>Hypertension</td>
<td>81.4%</td>
<td>80.8%</td>
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<tr>
<td>Diabetes</td>
<td>48.5%</td>
<td>38.4%</td>
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<tr>
<td>Prior Stroke</td>
<td>22.9%</td>
<td>15.2%</td>
<td></td>
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<tr>
<td>CAD</td>
<td>47.1%</td>
<td>61.6%</td>
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<tr>
<td>Hyperlipidemia</td>
<td>72.9%</td>
<td>60.6%</td>
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<tr>
<td>Statins</td>
<td>57.1%</td>
<td>44.4%</td>
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<tr>
<td>Beta- blockers</td>
<td>51.4%</td>
<td>44.4%</td>
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<tr>
<td>Aspirin</td>
<td>68.6%</td>
<td>50.5%</td>
<td>0.02</td>
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<tr>
<td>Flavix®</td>
<td>30.0%</td>
<td>17.2%</td>
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<tr>
<td>Coumadin</td>
<td>21.4%</td>
<td>26.3%</td>
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</tbody>
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### Above knee femoropopliteal grafts

- **Propaten ePTFE**
- **92%**
- **85%**
- **51%**
Below knee femoropopliteal grafts

A comparison of tibial artery bypass performed with heparin-bonded expanded polytetrafluoroethylene and great saphenous vein to treat critical limb ischemia

Richard F. Neville, MD, Avery Capone, BS, Richard Amdur, PhD, Michael Lidsky, MD, Joseph Babrowicz, MD, Anton N. Sidawy, MD, MPH

Journal of Vascular Surgery
Volume 56, Issue 4, Pages 1008-1014 (October 2012)
DOI: 10.1016/j.jvs.2012.03.020
• Propaten® is as good as vein for AK fempops
• Propaten® is a valid first line graft material for AK fempops
• Propaten® may not be as good as "good vein" below the knee but it is probably better than "bad vein."

What are the results showing us?

• Early failures seem to occur at similar rates with Heparin bonded ePTFE vs. Standard ePTFE
• Late failures are less frequent so some antithrombotic activity seems to persist for years
• Plavix adds to patency of both standard and heparin bonded ePTFE
What’s going on here?
What is actually so unique about this Propaten Graft?
And will other heparin grafts have the same results?

FUSION Bioline heparin bonded graft

Lumsden, Alan B., MD; Morrissey, Nicholas J., MD.
Gore® Hybrid

Unmatched graft adapting characteristics
Nitro-reinforced section allows consistent vessel insertion

Edward Woo MD

Computational Fluid Dynamics (CFD)*

Conventional End-to-side Anastomosis

Endoluminal Anastomosis with the GORE® Hybrid Vascular Graft

Edward Woo MD
Other Benefits to Hybrid

- Sutureless anastomosis
  - Diseased target vessel
  - Less vessel exposure needed for anastomosis
  - No narrowing of anastomosis
  - Less ischemic time

A few provisos

- Can exclude important distal collateral
- Can prevent important retrograde flow
- Can cause distal flap or embolization
No Saphenous vein

Above knee
- Propaten

Below knee
- Hybrid
- Spliced vein
- No vein
  - Propaten