Novel Endovascular Method for Percutaneous FemPop Bypass via the Venous System

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Background

- Revascularization of long-segment SFA occlusions has traditionally required open surgical bypass for long-term success

- While endovascular procedures have matured, a durable solution for these advanced lesions is still lacking

Primary Patency of SFA Stent Grafting

Financial Disclosures

- None

Percutaneous FemPop Bypass

- Minimally invasive, percutaneous approach
- Intended for long segment femoro-popliteal disease
- Achieves revascularization with modular stent graft bypass
- Takes advantage of adjacent femoral vein as a conduit

PQ Bypass System

Stent Graft Delivery System
- 8 Fr compatible
- 0.035" wire compatible
- 135 cm working length
- Tri-axial shaft design
- Ergonomic handle

Stent Graft
- 5.5, 6, 6.7mm OD
- 100, 150 and 200 mm length
- Graft – ePTFE film
- Frame – single NiTi wire

Guidewire Delivery System
- Proximal anastomosis device (crossing device)
- Venous Locator (snare)
**ECH Feasibility Study 2003-2012**

- El Camino Hospital (ECH) 2003 – 2013
- 21 Patients (25 limbs)
- 88% TASC D Lesions
- Average Lesion Length > 24 cm
- Endovascular Artery / Vein / Artery Bypass
- Utilizing Off-the-Shelf Devices

**Primary Patency**
- 82% @ 1 year
- 64% @ 4 years

**Study Design**
- Prospective, single-arm, multi-center, international, non-randomized
- Sample Size / # of Sites: 60 evaluable subjects from up to 16 sites
- Follow-Up Schedule: 30 days, 90 days, 6 months, 12 months, 18 months, 24 months
- Core Lab and CEC: Independent core laboratory to review DUS
- CEC/DSMB: to adjudicate MAEs

**Primary Safety Endpoint**
- Freedom from a major adverse event (MAE) at 30 days post-procedure, defined as death, target limb amputation, target vessel revascularization (TVR), major bleeding (transfusion of >2 units packed red blood cells (PRBC)), or deep vein thrombosis on ipsilateral limb.

**Primary Effectiveness Endpoint**
- Stent patency at 6 months as evidenced of clinically significant stenosis (≥50%) within the stent graft or immediately above or below the treated arterial segment based on duplex ultrasound (PSVR >2.5).

**Indication for Use**
- indicated for improving blood flow utilizing a percutaneous artery-vein-artery bypass in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions.
Clinical Sites (16)

Patient Summary - Chile

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Treated</td>
<td>5</td>
</tr>
<tr>
<td>Male</td>
<td>80%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>64.4 ± 3.2</td>
</tr>
<tr>
<td>Lesion Length (cm)</td>
<td>27.0 ± 4.4</td>
</tr>
<tr>
<td>Runoff vessels (0-3)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>2</td>
<td>60%</td>
</tr>
<tr>
<td>3</td>
<td>40%</td>
</tr>
<tr>
<td>PQ Time (min)</td>
<td>91 ± 30</td>
</tr>
<tr>
<td>Procedure Time (min)</td>
<td>148 ± 27 (105-177)</td>
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<tr>
<td>Fluoro Time (min)</td>
<td>38 ± 11 (20-56)</td>
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<tr>
<td>Proximal Attempts</td>
<td>2 ± 1.34 (1-4)</td>
</tr>
<tr>
<td>Distal Attempts</td>
<td>6 ± 7.63</td>
</tr>
<tr>
<td>Vein Diameter (mm)</td>
<td>10.6 ± 1.7</td>
</tr>
</tbody>
</table>

Patient 02-008-ABB

- 70 y/o female
- Lesion Length (A-B) 26.3 cm
- TASC D
- Total Procedure Time: 159 min
- PQ Procedure Time: 90 min
- Crossing Attempts:
  - Proximal: 1 / Distal: 2
- SG Devices:
  - 6 x 200mm distal 5.7mm artery
  - 6 x 200mm proximal 5.4mm artery
  - 6 cm overlap
- Venous Diameter: 9.4 mm

Patient 02-008-ABB

Lesion Length

Proximal Preop
Distal Preop

Proximal Postop
Distal Postop
SF vein

Patient 02-008-ABB

(6 months DUS)
Results Through 6 Month - Chile

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>N=5</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Procedural Success</td>
<td>100%</td>
<td>Successful delivery, access and placement of the investigational devices in the absence of in-hospital MACE.</td>
</tr>
<tr>
<td>Technical Success</td>
<td>100%</td>
<td>Successful delivery, access and placement of the investigational devices</td>
</tr>
</tbody>
</table>

**Primary Patency**
- 80% no evidence of clinically significant stenosis (≥50%) within the stent graft or immediately above or below the treated arterial segment based on duplex ultrasound (systolic velocity ratio of >2.5) at 6 months post procedure.

**30 Day MACE**
- 0% death, target limb amputation, target vessel revascularization (TVR), major bleeding (transfusion of >2 units packed red blood cells (PRBC)), or deep vein thrombosis on ipsilateral limb.

**Patient 02-001-FFD (August 3, 2015 – LL)**

- Procedure Date: Feb 12, 2015
- Lesion Length: 28 cm
- TASC: D
- Total Procedure Time: 105 min
- 30 Day MACE: 0%
- Crossing Attempts: Proximal: 1, Distal: 1
- Venous Diameter: 11 mm
- Proximal edge of SG: 2 mm below SFA ostium

**Conclusions**

- Percutaneous fem-pop bypass of long-segment SFA disease is feasible
- 6 months primary patency of 80% for avg lesion length of 27.6 cm
- 33 cases performed worldwide
- Patency data are accumulating and will be presented at future meetings