Update on the DETOUR I study: Extreme (>30cm) lesion analysis 12-month data

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Disclosure

Dierk Scheinert, MD

Advisory Board /Consultant:
Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies
SFA Environment is Challenging
Long-Segment Disease Adds Even More Obstacles

- **Mechanical** Restoring adequate blood flow through 20+ cm of disease
- **Physiological** Not possible to resuscitate an ischemic vessel
- **Procedural** CTO fail-to-cross very common
Current Endovascular Options

Short Lesions = Durability Comparable to Open Bypass
Long Lesions = Treat…Repeat…Repeat…

Primary Patency

SFA PTA/Stenting TASC A-D and Prosthetic Bypass Surgery

Poor patency for TASC C & D lesions

Treatment for Extremely Long SFA Lesions
Is it possible to combine the best of both options?

Open Bypass
(more durable)

Endovascular
(less invasive)

But...

Durability
<60% patency at 12M

Procedure Complexity
# of devices, fail-to-cross

Procedure Cost
$$$, repeat at 6 months, $$$

But...

Morbidity
37% at 30 Days

Re-admissions
18% at 30 Days

Major Complications
20% at 30 Days
The DETOUR Percutaneous Bypass Procedure

Designed to be a First-Line Treatment for Long Segment SFA (TASC C & D) Lesions
PQ Bypass Clinical Program

Percutaneous Fem-Pop Bypass >>> The DETOUR Procedure

<table>
<thead>
<tr>
<th>Phase</th>
<th>Patients</th>
<th>Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proof Of Concept</td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td>DETOUR I (CE Mark)</td>
<td>77</td>
<td>8</td>
</tr>
<tr>
<td>DETOUR II IDE</td>
<td>212</td>
<td>40</td>
</tr>
</tbody>
</table>

10YR FU
LPI Jul/2017
FPI Dec/2017
DETOUR I Clinical Trial (First In Man)
No Exclusions for CTO, ISR, or Severe Calcification

**Design**

- **DESIGN:** Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and technique for percutaneous bypass

- **ENDPOINTS:** 30 day MAE and 6 month primary patency (Met primary endpoints)

- **STATUS**
  - CE Mark granted Feb 2017
  - Patients followed to 24 months

77 patients/81 limbs with DETOUR™ implanted

First patients at 12 months with lesion length ≥ 30cm
23 Patients / 25 Lesions

Extreme Lesion Analysis
12 Month Results of Long Lesion Sub-Analysis Presented
DETOUR I Extreme Lesion Analysis
12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions

<table>
<thead>
<tr>
<th>Baseline Lesion and Clinical Characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length, cm (mean ± SD)</td>
<td>35.9 ± 4.1</td>
</tr>
<tr>
<td>Total Occlusions, % (n/N)</td>
<td>100% (25/25)</td>
</tr>
<tr>
<td>Age, years (mean ± SD)</td>
<td>67 ± 7.4</td>
</tr>
<tr>
<td>Male Gender, % (n/N)</td>
<td>73.9% (17/23)</td>
</tr>
<tr>
<td>History of Smoking, % (n/N)</td>
<td>91.3% (21/23)</td>
</tr>
<tr>
<td>R-B Classification, (mean ± SD)</td>
<td>3.0 ± 0.2</td>
</tr>
</tbody>
</table>
DETOUR I Extreme Lesion Analysis: Patency

12 Month Analysis of Initial Patients with Lesions > 30 cm
N=23 Patients / 25 Lesions

Primary Patency: 84% (21/25)
Primary-Assisted Patency: 92% (23/25)
Secondary Patency: 96% (23/24)

1Patient 03-011 was exited from the study following surgical bypass conversion.
### DETOUR I Extreme Lesion Analysis: Performance and Safety

12 Month Analysis of Initial Patients with Lesions $\geq$ 30 cm  
N=23 Patients / 25 Lesions

#### Key Secondary Safety Endpoints at 30 Days

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Deep Vein Thrombosis</td>
<td>100% (25/25)</td>
</tr>
<tr>
<td>Freedom from Death</td>
<td>100% (23/23)</td>
</tr>
<tr>
<td>Freedom from Amputation</td>
<td>100% (25/25)</td>
</tr>
<tr>
<td>Freedom from Acute Limb Ischemia</td>
<td>96% (24/25)</td>
</tr>
<tr>
<td>Freedom from TVR</td>
<td>96% (24/25)</td>
</tr>
</tbody>
</table>

#### Key Secondary Performance Endpoints

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>100% (25/25)</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>96% (24/25)</td>
</tr>
</tbody>
</table>
DETOUR I Extreme Lesion Analysis: 
Goal = No Change in Venous Health 
Measured by VCSS and Villalta

**Venous Clinical Severity Score (VCSS)**

<table>
<thead>
<tr>
<th>Scale</th>
<th>Baseline</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>0</td>
<td>0.8±1.2</td>
</tr>
<tr>
<td>Severe</td>
<td>30</td>
<td>0.8±1.2</td>
</tr>
</tbody>
</table>

**Villalta Scale**

<table>
<thead>
<tr>
<th>Scale</th>
<th>Baseline</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>0</td>
<td>0.7±1.2</td>
</tr>
<tr>
<td>Severe</td>
<td>48</td>
<td>0.6±1.3</td>
</tr>
</tbody>
</table>

No change from baseline to 12M

No DVTs in the PQ Bypass Segment Through 12 Months
DETOUR I Extreme Lesion Analysis: Hemodynamic Improvement
12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions

Ankle Brachial Index

Baseline
0.62 ± 0.12 (24)

12 Months
0.96 ± 0.08 (24)

Significant improvement at 12M (p<0.0001)

1 p-values are calculated using paired t-test for matched data
2 1 subject missing ABI/ Rutherford at Baseline
3 Patient 03-011 was exited from the study following surgical treatment for thrombosis post 1-month follow-up
DETOUR I Extreme Lesion Analysis: Functional Status
12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions

Significant improvement at 12M (p<0.0001)
Conclusions

DETOUR is the first endovascular technology to demonstrate the durability of open surgery via a percutaneous approach in the treatment of lesions >35cm.

No impact on venous health.

DETOUR I demonstrated improvements in anatomic, hemodynamic, and functional outcomes in patients with the longest, most complex of lesions.

DETOUR II IDE will leverage the initial experience of DETOUR I to expand the safety and effectiveness profile of the DETOUR procedure.
DETOUR II IDE Study

**Design**

**DESIGN:** Prospective, single-arm, multi-center, international, non-randomized, pre-market, safety and effectiveness clinical investigation.

**ENDPOINTS:**

*Primary Safety:* 30-Day MAE
Deaths / TVR / Target Limb Amputation

*Primary Efficacy:* 12-Month Primary Patency Freedom from re-stenosis (PSVR>2.5) or CD-TLR

**STATUS**

FDA IDE approval granted Dec 2017

**Objective:**

To assess the safety and performance of the PQ Bypass DETOUR System for the treatment of long-segment superficial femoral artery occlusions

- Up to 212 Patients Enrolled at 30 Global Sites
- Patients Followed to 36 Months
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