Endovascular femoro-popliteal bypass grafting via the femoral vein (PQ Bypass) - the DETOUR I study

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I do not have any potential conflict of interest concerning the content of this presentation
SFA - REVSCULARSATION CAN BE CHALLENGING

- **Procedural** CTO fail-to-cross very common
- **Mechanical** Restoring adequate blood flow through 20+ cm of disease
- **Physiological** Not possible to resuscitate an ischemic vessel
THE LONG SEGMENT SFA DISEASE TREATMENT OPTIONS

Unmet Need: Endovascular Approach with the Durability of Open Surgery

Open Bypass

LESS INVASIVE
But...
- Durability
- Procedure time
- Devices per procedure ($$$)

MORE DURABLE
But...
- Morbidity
- More invasive
- Length of stay
THE DETOUR PERCUTANEOUS BYPASS PROCEDURE

DESIGNED TO BE A FIRST-LINE TREATMENT FOR LONG SEGMENT SFA (TASC C & D) LESIONS
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 being followed to 24 months

Extreme Lesion Analysis

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

Baseline Lesion and Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</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>92.0% (23/25)</td>
</tr>
<tr>
<td>De novo Lesions, % (n/N)</td>
<td>64.0% (16/25)</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 1 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 treatment for thrombosis post 1-month follow-up.
### 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>

**12 Month Analysis of Initial Patients with Lesions ≥ 30 cm**

N=23 Patients / 25 Lesions

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**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: 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 ± 0.07 (24)

Significant improvement at 12M (p<0.0001)

1p-values are calculated using paired t-test for matched data
21 subject missing ABI/ Rutherford at Baseline
3Patient 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)

Rutherford Becker Clinical Category

Baseline
12M
DETOUR I EXTREME LESION ANALYSIS: CONCLUSIONS

12 Month Analysis of Initial Patients with Lesions ≥ 30 cm

Initial experience with the DETOUR System and procedure demonstrates durability without compromising venous health

DETOUR I demonstrated improved outcomes in patients with the longest, most complex of lesions

Next step: DETOUR II IDE to expand the safety and effectiveness profile of the DETOUR procedure and continue to build the body of clinical evidence
Don’t fear the Profunda

- Landing level-to or slightly proximal to the Profunda / SFA bifurcation is optimal
- Optimal placement can minimize edge stenosis

Proximal stent graft placed ~ 5.2 mm distal to the optimal landing position; edge stenosis at 6 months