Percutaneous bypass with the DETOUR procedure
Using the femoral vein as a natural conduit...
In situ with a twist!

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Head Prof. J. Rogowski
Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Is fully endovascular bypass possible in TASC D lesions?

Multicenter EU trial

60 patients → 100 patients

Our site performed 22 procedures over 16 months

Bypassing Ca++ instead of crossing it?

lesions up to 28 cm
The DETOUR Percutaneous Bypass Procedure

- Designed to achieve the same end-result as open bypass surgery
- Revascularization via modular stent graft bypass
- Utilizes the femoral vein as a conduit

Addresses current SFA treatment limitations with a novel endovascular approach
The DETOUR Percutaneous Bypass Technology
Trio of proprietary devices designed specifically for the DETOUR procedure

Torus Stent Graft
- Self-expanding nitinol wire frame encapsulated in ePTFE
- High radial force
- Elongated, exposed end rings to prevent edge stenosis

PQ Snare
- Over-the-wire dual-caged scaffold
- Captures and extracts guidewires through the tibial vein

PQ Crossing Device
- Spring-loaded guidewire support and delivery system
- Creates initial artery-vein-artery communication
Deep Femoral Vein as a Conduit

- 11 mm femoral vein
- 6-8 mm duplicate veins
- 5-6 mm vein
- 8 mm vein (marked with an 'X')
Venous Compression with DUS

Vein remains patent around implanted Torus Stent Graft
Single Femoral Vein with the Bypass

Fig: Veins with a diameter $\geq 10$mm retain at least 50% of their volume
Duplicate Femoral Vein with the Bypass

Vein Pre

Vein 8.5mm

Duplicate Vein 6.8mm

Vein Post

PQB Stent Graft 6.0mm

Patient 10-014
Anastomotic junctions demonstrate wide lumen with smooth transition and tri-phasic bloodflow.
22 Patients over 16 months
Procedural Time = Learning Curve

- Learning Curve ~ 10 cases
- DETOUR procedure can be performed in 60-90 minutes
- Consistent enrollment is beneficial
## Patient Demographics and Lesion Type

### n=22 Subjects

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age, Y</td>
<td>64.5</td>
</tr>
<tr>
<td>Male, % (n)</td>
<td>77.3% (17/22)</td>
</tr>
<tr>
<td>Mean Lesion Length, cm</td>
<td>28.5</td>
</tr>
<tr>
<td>% TASC D Lesions</td>
<td>90.9% (20/22)</td>
</tr>
<tr>
<td><strong>Procedural and Clinical Success</strong></td>
<td>n=22 Subjects</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Technical Success</td>
<td>Successful delivery of the investigational devices to the identified area and removal of delivery system</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>Successful delivery of the investigational devices to the identified area and removal of delivery system in the absence of in-hospital MAEs</td>
</tr>
<tr>
<td>Clinical Success</td>
<td>≥1 Grade Improvement in Rutherford Class at 6 months</td>
</tr>
</tbody>
</table>
DETOUR Trial Results at Gdansk Medical University

Results

30 Day MAE Rate (N = 22) 0%
6 Month Primary Patency Rate (N = 14) (PSVR > 2.5) 100%
## Components of Primary Safety Endpoint

<table>
<thead>
<tr>
<th>MAE</th>
<th>MAE through 30 Days</th>
<th>MAE through 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 21 Subjects</td>
<td>N = 14 Subjects</td>
</tr>
<tr>
<td>Death</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
</tr>
<tr>
<td>TVR</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
</tr>
<tr>
<td>Major Amputation of Ipsilateral Target Limb</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
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<tr>
<td>Total Patients with MAE</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
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1 patient required transfusion of 2 blood units
## Low 30D and 6M MAVE Rate

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<td>0% (0/14)</td>
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<tr>
<td>Clinically Apparent Distal Embolization</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
</tr>
<tr>
<td>Procedure Related Arterial Rupture</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
</tr>
<tr>
<td>Bleeding Event Requiring Transfusion &gt;2 Units of Packed Red Blood Cells</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
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<tr>
<td>Acute Limb Ischemia</td>
<td>0% (0/21)</td>
<td>0% (0/14)</td>
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<tr>
<td>Stent Thrombosis</td>
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<td>0% (0/14)</td>
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<tr>
<td><strong>Total Patients with MAVE</strong></td>
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¹Includes stent thrombosis, target limb amputation, clinically apparent distal embolization, defined as causing end-organ damage (e.g. lower extremity ulceration, tissue necrosis, or gangrene), procedure related arterial rupture, acute limb ischemia or bleeding event requiring transfusion >2 units of packed red blood cells.
Venous Function through 6 Months
Venous Clinical Severity Scale (VCSS) and Villalta Assessments

**Villalta Score**

<table>
<thead>
<tr>
<th>Baseline</th>
<th>6 Months</th>
<th>Change from Baseline&lt;sup&gt;1&lt;/sup&gt;</th>
<th>P-Value Baseline vs. 6 Months&lt;sup&gt;2&lt;/sup&gt;</th>
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<tr>
<td>Overall</td>
<td>0.0 ± 0</td>
<td>0.07 ± 0.26</td>
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<sup>1</sup> Change from baseline calculated using matched pairs.
<sup>2</sup> P-values are calculated for absolute change using paired t-test for matched data.

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**Difference in ankle circumference between limbs was 0-1cm**

no femoral vein DVTs at 30 days
Post 6-Month Re-interventions

- No occlusions
- 2 stenoses post 6 months
- That stenoses could have been avoided!
- High placement of proximal edge of the graft is critical

Patient 10-029: Pre and Post DEB Re-intervention
Optimal position of the proximal Torus Stent Graft

Uncovered Proximal Edge of Torus Stent Graft

2mm of exposed frame at the proximal edge allow high landing into the CFA without encroaching on the profunda.

Optimal Graft Placement 2-3mm above SFA Ostium
Primary Patency: 100% at 6 Months in nearly 30cm TASC II D lesions

Primary performance endpoint met
No impact on venous health; low MAE rate

All procedures done under local anaesthesia without sedation

Performing fully endovascular fem-pop bypass is now possible
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