Percutaneous Femoropopliteal Bypass Using the Novel PQ Bypass DETOUR Procedure: From Concept to Clinical Reality

Grzegorz Halena MD, PhD
Department of Cardiovascular Surgery
Vascular Surgery Division
Medical University of Gdansk
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
The DETOUR Percutaneous Bypass Procedure

• Fully percutaneous stent graft bypass
• Originates in SFA, travels through the femoral vein, ends in popliteal artery
• Designed for long, complex lesions

CTO | ISR | DENSE CALCIFICATION
Percutaneous Fem-Pop Bypass Concept

1. Can a fem-pop bypass be performed via percutaneous, endovascular methods? ✓ YES

2. Can the femoral vein serve as “safe passage” for a stent graft bypass yet still maintain function and health? ✓ YES

3. Can a percutaneous bypass demonstrate better durability than current endovascular approaches? ✓ YES
Proof of Concept: A Critical Milestone

21 Patients / 25 Limbs with Very Long, Complex Lesions

- **Primary patency @ 1 year: 82%**
- **Secondary patency @ 4 years: 91%**
- **No objective venous morbidity**
- **78% discharged same or next day**

**Lesion Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (cm)</td>
<td>31.2 ± 9.7</td>
</tr>
<tr>
<td>TASC D</td>
<td>88.0%</td>
</tr>
<tr>
<td>Rutherford 3 - Severe</td>
<td>42.9%</td>
</tr>
<tr>
<td>Rutherford 4 - Ischemic</td>
<td>28.6%</td>
</tr>
<tr>
<td>Rutherford 5 - Tissue loss</td>
<td>28.6%</td>
</tr>
</tbody>
</table>

**K/P Curve Primary Patency**

% Patent

**Subject Enrollment**

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>21</td>
</tr>
<tr>
<td>2004</td>
<td>22</td>
</tr>
<tr>
<td>2005</td>
<td>23</td>
</tr>
<tr>
<td>2006</td>
<td>24</td>
</tr>
<tr>
<td>2007</td>
<td>25</td>
</tr>
<tr>
<td>2008</td>
<td>26</td>
</tr>
<tr>
<td>2009</td>
<td>27</td>
</tr>
<tr>
<td>2010</td>
<td>28</td>
</tr>
<tr>
<td>2011</td>
<td>29</td>
</tr>
<tr>
<td>2012</td>
<td>30</td>
</tr>
</tbody>
</table>

**Months**

0 6 12 18 24 30 36 42 48
PQ Bypass DETOUR™ System

*Designed Specifically for DETOUR Procedure*

-- Proprietary Stent Graft and Bypass Kit --

**Torus™ Stent Graft**

- 2 mm elongated exposed proximal rings designed to reduce edge stenosis
- Designed with increased radial force and resists compression at anastomoses
- Variable radial force at proximal and distal ends designed to gently conform to native vessel wall

**DETOUR Bypass Kit**

*Simplify Guidewire Placement*

- DETOUR Snare
- DETOUR Crossing Device

Pathway around blockage
The DETOUR Procedure

Gaining Access

Preop angiography

Preop venography
The DETOUR Procedure

Proximal Crossing and Wire Snare
The DETOUR Procedure

*Distal Crossing*
The DETOUR Procedure

*Distal Deployment of Torus Stent Graft*
The DETOUR Procedure

Proximal Deployment of Torus Stent Graft
The DETOUR Procedure

Completion Angiography

SFA

Distal SFA/Popliteal

Before

After

Before

After
The DETOUR Procedure

Completion Venography

10mm femoral vein
6

6-8mm duplicate veins
6
DETOUR Result vs. Conventional Endovascular Approach

- SFA with "Full Metal Jacket"
- Surgical Bypass with Failed "Full Metal Jacket"
- DETOUR at 1 Year
Conclusions

Percutaneous bypass has the potential to fill the gap in treatment options for long segment SFA Disease.

Early data from the DETOUR I Trial has demonstrated feasibility of the DETOUR procedure.

Initial experience with the DETOUR procedure was established in the longest and most complex lesions in an endovascular study.

DETOUR II IDE will leverage the initial experience of DETOUR I to expand the safety and effectiveness profile of the DETOUR procedure.
Percutaneous Femoropopliteal Bypass Using the Novel PQ Bypass DETOUR Procedure: From Concept to Clinical Reality

Grzegorz Halena MD, PhD
Department of Cardiovascular Surgery
Vascular Surgery Division
Medical University of Gdansk