Update on Tack Optimized Balloon Angioplasty (TOBA) Below the Knee

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Critical Limb Ischemia

• Infrapopliteal arterial disease is a leading source of CLI\textsuperscript{1}

• CLI treatment aims to:
  • Relieve ischemic rest pain,
  • Promote wound healing, and
  • Preserve limbs by

\textbf{Restoring at least one straight line of blood flow to the foot}

• PTA is most common method of endovascular therapy for BTK arteries\textsuperscript{2}

• Long-term outcomes are limited by:
  • Recoil
  • Remodeling
  • \textbf{Dissection}

\textsuperscript{1}Van Overhagen, \textit{Cardiovasc Intervent Radiol} 2013
\textsuperscript{2}Razavi, \textit{J Vasc Interv Radiol} 2014
Dissection After BTK Angioplasty

Dissection is the mechanism of action for all angioplasty...

Rates of post-PTA dissection in BTK arteries are thought to be underestimated due to small vessel caliber and overlap of bony structures³

<table>
<thead>
<tr>
<th>Device</th>
<th>PTA Rate</th>
<th>DCB Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEBELLUM¹</td>
<td>15.0%</td>
<td>30.7%</td>
</tr>
<tr>
<td>IN.PACT™ DEEP²</td>
<td>12.3%</td>
<td>19.2%</td>
</tr>
</tbody>
</table>

¹Fanelli, J Cardiovasc Surg 2014
²Zeller, J Am Coll Cardiol 2014
³Razavi, J Vasc Interv Radiol 2014

Reported in up to 30.7% of BTK balloon angioplasty procedures

In.Pact™ is a trademark of Medtronic
Dissection Repair Below the Knee

• **Prolonged inflation**
  - No data for BTK arteries
  - Longer inflation times seem to lower the rate of SFA dissection\(^1\)
  - *Does not prevent 100% of SFA dissections*

• **Stenting**
  - BTK arteries are susceptible to external crushing force, especially the posterior tibial artery\(^2\)
  - Chronic inflammation from high metal burden
  - In-stent restenosis (difficult to treat)
  - Limited future treatment options

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\(^1\) Zorger, *J Vasc Interv Radiol* 2002
\(^2\) Schneider, *LINC* 2017
**Tack Endovascular System®**

**Novel Implant Design**

- **Four** self-expanding implants on one system
- **~6mm** deployed implant length
- Each implant treats vessel diameter range **1.5mm to 4.5mm**
- **Nitinol with gold RO markers** for visibility
- **Unique anchors** designed to minimize migration

**High-Precision Delivery System**

- **4Fr: 90, 150cm** working length
- **0.014”** over-the-wire delivery system
- **High accuracy** Tack implant deployment (within ~1mm)

**CAUTION: Investigational device.**
Tack Endovascular System is limited by Federal (United States) law to investigational use. Not approved for sale in the United States. Tack Endovascular System is CE Mark authorized under EC Directive 93/42/EEC. Tack Endovascular® System and Tack® are registered trademarks of Intact Vascular, Inc.
# TOBA BTK Study Design

## Prospective, single-arm, multi-center

| **Population** | • CLI (RCC 4-5) patients with de novo, stenotic or occluded lesions located between knee joint and ankle  
• Up to 2 tibial arteries with cumulative length of ≤ 15cm  
• Angiographic evidence of a dissection post-PTA |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sites</strong></td>
<td>6 sites in Europe and New Zealand</td>
</tr>
<tr>
<td><strong>Subjects</strong></td>
<td>35</td>
</tr>
</tbody>
</table>

## Primary Endpoints

<table>
<thead>
<tr>
<th><strong>Safety</strong></th>
<th>Composite of MALE and POD at 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Success</strong></td>
<td>Successful delivery and deployment of study device(s) at intended target site(s) and successful withdrawal of delivery catheter</td>
</tr>
<tr>
<td><strong>Procedure Success</strong></td>
<td>Ability of the Tack to demonstrate vessel patency as reported by the physician (visual estimate) without the occurrence of MALE + POD on the date of procedure</td>
</tr>
</tbody>
</table>
Challenging Patients; Complex Lesions

Baseline Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Safety (n=35)</th>
<th>Performance (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Y)</td>
<td>76.1 ± 9.3</td>
<td>76.1 ± 9.5</td>
</tr>
<tr>
<td>Gender:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>48.6%</td>
<td>43.8%</td>
</tr>
<tr>
<td>Male</td>
<td>51.4%</td>
<td>56.3%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>77.1%</td>
<td>81.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>91.4%</td>
<td>90.6%</td>
</tr>
<tr>
<td>Smoking:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>5.9%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Former</td>
<td>29.4%</td>
<td>32.3%</td>
</tr>
<tr>
<td>Rutherford:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCC 4</td>
<td>11.4%</td>
<td>12.5%</td>
</tr>
<tr>
<td>RCC 5</td>
<td>88.6%</td>
<td>87.5%</td>
</tr>
</tbody>
</table>

Safety

- Lesion length (mm): 51.4 ± 28.0
- Total occlusion: 22.2%
- Dissection Grade: B (60.6%), C (18.2%)
- Lesion Location: Anterior tibial (38.9%), Peroneal (16.7%)
- Calcification: None/mild (36.1%), Moderate (61.1%), Severe (2.8%)

- Almost 80% of dissections were grade B or higher
- >60% of lesions were moderately/severely calcified
- Lesion lengths up to 8 cm
- 1/5 of patients had total occlusion
- Broad anatomic distribution
# Safety and Performance

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Safety Sample (n=35)</th>
<th>Perf. Sample (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Success(^1)</td>
<td>91.4% (32/3)</td>
<td>NA</td>
</tr>
<tr>
<td>Procedure Success(^2)</td>
<td>97.1% (34/35)</td>
<td>96.9% (31/32)</td>
</tr>
</tbody>
</table>

\(^1\)Successful delivery and deployment of the study device(s) at the intended target site(s) and successful withdrawal of the delivery catheter

\(^2\)Demonstrated vessel patency as reported by the physician (visual estimate) without the occurrence of MALE + POD on the date of procedure

## Primary Safety at 30 Days

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<thead>
<tr>
<th>Primary Safety at 30 Days</th>
<th>Safety Sample</th>
<th>Perf. Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite Primary Safety Endpoint</td>
<td>97.1% (34/35)</td>
<td>96.9% (31/32)</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>0% (0/35)</td>
<td>0% (0/32)</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>2.9% (1/35)</td>
<td>3.1% (1/32)</td>
</tr>
<tr>
<td>Death</td>
<td>0% (0/35)</td>
<td>0% (0/32)</td>
</tr>
</tbody>
</table>
TOBA BTK 12-Month Results

Primary Patency
78.4% at 12m

Primary Assisted Patency
89.2% at 12m

Observational Endpoint | 30 Days | 12 Months
--- | --- | ---
Amputation-free survival (above the ankle) | 100% | 84.5%
Freedom from CD-TVR | 100% | 93.5%
Freedom from CD-TLR | 100% | 93.5%
Update: TOBA II BTK

Pivotal IDE study of the Tack device in the treatment of patients with critical limb ischemia

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<tr>
<th>Study Design</th>
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<tbody>
<tr>
<td>Population</td>
<td>Subjects with CLI (RCC 4-5) and angiographic evidence of a dissection post-PTA requiring repair in the mid, distal popliteal, tibial and/or peroneal arteries</td>
</tr>
<tr>
<td>Subjects/Sites</td>
<td>232 subjects at up to 60 sites in US, Europe and New Zealand</td>
</tr>
</tbody>
</table>
| Primary Endpoints:   | **Safety:** MALE + POD at 30 days  
|                      | **Efficacy:** MALE at 6 months + POD at 30 days |
Update: TOBA II BTK

Enrollment rate is ahead of goal
TOBA Takeaways

• Importance of treating dissections is still underestimated

• Tack Endovascular System may offer a new paradigm in treating post-PTA dissections

• Adjunct to below the knee angioplasty

• Minimal metal footprint

• Preserves future treatment options
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