Update on the Tack Optimized Balloon Angioplasty (TOBA) studies in the femoropopliteal arteries

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Disclosure

I have the following potential conflicts of interest to report:

☑ Consulting: Intact Vascular
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Dissections Occur Frequently...

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

Reported in up to 84% of femoropopliteal balloon angioplasty procedures\(^1\)

<table>
<thead>
<tr>
<th>Study</th>
<th>Dissection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACIFIER(^2)</td>
<td>47.4% POBA 73.5% DCB</td>
</tr>
<tr>
<td>THUNDER(^3)</td>
<td>56%</td>
</tr>
<tr>
<td>LEVANT 2(^4)</td>
<td>72.3% POBA 63.7% DCB</td>
</tr>
<tr>
<td>Fujihara(^1)</td>
<td>84% POBA</td>
</tr>
</tbody>
</table>

\(^1\) Fujihara, J Endovasc Ther 2017  
\(^2\) Werk, Circ Cardiovasc Interv 2012  
\(^3\) Tepe, N Engl J Med 2008  
TOBA: Baseline Dissection Grade

Major disparity between site-reported and core lab dissection grade

Which Dissections Matter?

NHLBI Dissection Grades

1. Minor radiolucent areas
2. Linear dissection
3. Contrast outside the lumen
4. Spiral dissection
5. Persistent filling defects
6. Total occlusion w/o distal antegrade flow

Dissection grades adjudicated by angiographic core laboratory
ALL Dissections Affect Long-Term Outcomes

**THUNDER Study\(^1\)**
Overall Dissection Rate = **31.1%** (48/154)

<table>
<thead>
<tr>
<th>Dissection Grade</th>
<th>TLR at 6m</th>
<th>TLR at 24m</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Post-PTA Dissection</td>
<td>10.5%</td>
<td>NR</td>
</tr>
<tr>
<td>Grade A-B (n=34)</td>
<td>33%</td>
<td>43%</td>
</tr>
<tr>
<td>Grade C-D-E (n=14)</td>
<td>43%</td>
<td>78%</td>
</tr>
</tbody>
</table>

**Fujihara et al\(^2\)**
Overall Dissection Rate = **84.0%** (628/748)

<table>
<thead>
<tr>
<th>Dissection Grade</th>
<th>TLR at 6m</th>
<th>TLR at 12m</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Post-PTA Dissection</td>
<td>14%</td>
<td>25%</td>
</tr>
<tr>
<td>Grade A-B (n=314)</td>
<td>34%</td>
<td>66%</td>
</tr>
</tbody>
</table>

Rates of TLR for A/B SFA dissections reported similar to C/D/E dissections at six months

Small diameter, long lesion and vessel occlusion were predictive of high risk for dissection in the SFA

\(^1\)Tepe J Endovasc Ther 2013
\(^2\)Fujihara J Endovasc Ther 2017
Dissection Repair

• **Prolonged inflation**
  • 16% dissection rate for inflations of 30 seconds vs. 6.8% of 180 seconds\(^1\) in SFA
  • *Does not prevent 100% of SFA dissections*

• **Stenting**
  • 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
Tack Endovascular System®

**Novel Implant Design**

- Six self-expanding implants on one system
- ~6mm deployed implant length
- Each implant treats vessel diameter range 2.5mm to 6.0mm

*Nitinol with gold RO markers* for visibility

*Unique anchors* designed to minimize migration

**High-Precision Delivery System**

- 6Fr: 80, 120, 135cm working length
- 0.035” over-the-wire delivery system
- High accuracy Tack implant deployment (within ~1mm)

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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.
### Design
Prospective, single-arm, multi-center confirmatory trial for optimization of tissue apposition in peripheral arteries with Reference Vessel Diameters (RVD) ranging in diameter from 2.5 mm to 5.5 mm.

### Objective
Collect confirmatory data in support of the safety and performance of the Intact Vascular Tack Endovascular System

### Intended Use
The Tack Endovascular System 1.0 is indicated for tissue apposition to optimize angioplasty in peripheral arteries 2.5 mm to 5.5 mm* in diameter. It is designed to treat dissection, tissue flaps or an irregular luminal surface.

### Primary Endpoints

<table>
<thead>
<tr>
<th>Safety</th>
<th>Composite of new-onset major device-related adverse event(s) including device embolization, need for emergency surgical revascularization, index limb amputation (above the ankle), or CD-TLR at 30 days.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Technical Success</td>
<td>The ability of the Tack to resolve post-PTA dissection, tissue flaps or irregular luminal surface which demonstrates that the artery at the Tack(s) location of the Tack implant remains patent at the end of the procedure (&lt;30% residual stenosis by completion angiogram).</td>
</tr>
</tbody>
</table>

*The current Tack Endovascular System 1.5 is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 2.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s) type(s) A through F.
The 24M population is a subset of the original population with no prior non-patency or TLRs as of 12M follow-up and who consented to be followed-up at 24M.
## Patient and Lesion Characteristics

### Patient Characteristics

**All Subjects (N = 130)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Subjects</th>
<th>WKK (N = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Y)</td>
<td>68.1 ± 9.7</td>
<td>71.9 ± 8.3</td>
</tr>
<tr>
<td>Male Gender</td>
<td>66.9%</td>
<td>56.2%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28.5%</td>
<td>25%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>77.7%</td>
<td>75%</td>
</tr>
<tr>
<td>Smoking:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>43.0%</td>
<td>53.8%</td>
</tr>
<tr>
<td>Remote</td>
<td>72.3%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Rutherford:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>21%</td>
<td>31%</td>
</tr>
<tr>
<td>3</td>
<td>74%</td>
<td>50%</td>
</tr>
<tr>
<td>4</td>
<td>5%</td>
<td>25%</td>
</tr>
<tr>
<td>Target Limb ABI</td>
<td>0.68 ± 0.2</td>
<td>NA</td>
</tr>
</tbody>
</table>

### Key Inclusion Criteria

- Rutherford 2 – 4
- ABI ≤ 0.90
- RVD 2.5 - 5.5 mm
- Target lesion ≤ 10 cm

### Key Exclusion Criteria

- Previous stent
- Severe calcium
- Untreated inflow

### Core Lab Baseline Lesion Characteristics

(All Subjects)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Subjects</th>
<th>WKK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (mm)</td>
<td>52.7 ± 30.5</td>
<td>52.9 ± 26.4</td>
</tr>
<tr>
<td>Total Occlusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissection Grade C and Higher</td>
<td>74.0%</td>
<td>62.3%</td>
</tr>
<tr>
<td>Lesion Location:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal SFA</td>
<td>14.6%</td>
<td>12.5%</td>
</tr>
<tr>
<td>Mid SFA</td>
<td>44.6%</td>
<td>31.3%</td>
</tr>
<tr>
<td>Distal SFA</td>
<td>31.5%</td>
<td>37.5%</td>
</tr>
<tr>
<td>Proximal Popliteal</td>
<td>7.7%</td>
<td>18.8%</td>
</tr>
<tr>
<td>Mid Popliteal</td>
<td>0.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Calcification:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/mild</td>
<td>34.1%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Moderate</td>
<td>60.5%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Severe</td>
<td>5.4%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

*Bosiers, J Vasc Surg 2016*
Improvement in ABI and Rutherford

**Improvement in Ankle-Brachial Index**

(P <0.001)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>12M</th>
<th>Δ</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>123</td>
<td>116</td>
<td>110</td>
</tr>
<tr>
<td>ABI</td>
<td>0.68 ± 0.18</td>
<td>0.94 ± 0.15</td>
<td>0.27 ± 0.21</td>
</tr>
<tr>
<td>% Change</td>
<td></td>
<td></td>
<td>38%</td>
</tr>
</tbody>
</table>

**Improvement in Rutherford Clinical Category**

Significant Improvement

TOBA Safety and Performance

30-Day Safety Profile
- 0.0% MAEs
- 98.5% Technical Success Rate

K-M Patency Across ALL Sites

6-Month Patency = 79.3%
12-Month Patency = 76.4%

Reported Range for 12-Month Patency for POBA Alone

12-Month Freedom from TLR = 89.5%
Single-Center 24-Month Patency
Westküstenkliniken, Heide, Germany

NO loss of patency between 12 and 24 months

6M Patency 93.8%
12M Patency 87.5%
24M Patency 87.5%
TOBA Case Study

Baseline

Post-PTA Dissection (Grade C*)

Final

Procedure: 48 min
Fluoro Time: 15 min
Contrast: 100 ml

*Dissection grades adjudicated by core laboratory
**Update: TOBA II/TOBA III**

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Prospective, single-arm, multi-center</th>
</tr>
</thead>
</table>
| **Population**        | • Subjects with de novo or restenotic or occluded lesions located in the SFA and P1 arteries with RVD of 2.5 to 6.0 mm  
                        • Subjects with <30% residual stenosis and evidence of dissection post-PTA |
| **Sites/Subjects**    | ≤40 sites in US and Europe  
                        213 subjects  
                        ≤15 sites in Europe  
                        200 subjects  
                        170 with lesions ≤ 150mm  
                        30 with lesions ≤250mm |
| **PTA Balloon**       | POBA or Lutonix® DCB  
                        IN.PACT™ Admiral™ DCB |
| **Enrollment Status** | ENROLLMENT COMPLETE  
                        LONG LESION ENROLLMENT COMPLETE  
                        Enrollment completion projected mid 2018 |

Lutonix® is a registered trademark of Bard  
IN.PACT™ and Admiral™ are trademarks of Medtronic
TOBA Takeaways

• Importance of treating dissections is still underestimated
• Tack Endovascular System may offer a **new paradigm** in treating post-PTA dissections
• Adjunct to above the knee angioplasty
• **Minimal metal** footprint
• **Preserves** future treatment options
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