Tack for Dissection Below-the-Knee

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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
Differences in Lesion Morphology: Above- and Below-the-Knee

Above-the-Knee

- Multiple plaque types
- Thrombus
- Medium to large vessels: 4 – 7 mm

Below-the-Knee

- More commonly calcified
- Tortuous anatomy
- Small vessels: 1.5 – 3.5 mm
- Long lesion lengths

Bishop Ann Vasc Surg 2008
Zeller Presentation LINC 2019
Challenges with Below-the-Knee Angiography

- Vessel size assessment:
  - Calcification and extent of disease alter the accuracy of quantitative angiography\(^1\)
  - Lumen size is particularly underestimated (≥34%) in BTK vessels\(^2,3\)
- Bone interference
- Small vessel caliber
- Vessel overlap

1. Kashyap J Endovasc Ther 2008
3. Shammas Vascular Disease Management 2018
Appropriate Balloon Sizing in Infrapopliteal Arteries

- More complete dilation = more durable result (particularly when associated by dissection)\(^1\)
- Naturally, larger balloon size leads to larger balloon diameter
  - Too much = dissection
  - BTK dissection is different: lesions tend to be inelastic and break, rather than stretch\(^2,3\)

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1. Geary Contemporary Cardiology 2007
2. Bakker Presentation LINC 2019 (top)
3. Shammas Vascular Disease Management 2019 (bottom)
Pathophysiology-Based Guidelines for BTK Angioplasty

• Aggressive dilation with balloon-vessel ratio >1:1
• Long inflations (≥3 minutes)
• Consider aggressive vessel prep (atherectomy, lithoplasty, etc.)
• Consider peri- and post-interventional vasodilation? Cilostazol?
• Don’t leave a focal dissection

1. Zeller Presentation LINC 2019
Dissection is the mechanism of action for all angioplasty...

Reported in up to 50% of BTK balloon angioplasty procedures.

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Dissection Rate (PTA, DCB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEBELLUM¹</td>
<td>15.0% PTA, 30.7% DCB</td>
</tr>
<tr>
<td>IN.PACT™ DEEP²</td>
<td>12.3% PTA, 19.2% DCB</td>
</tr>
<tr>
<td>IN.PACT™ BTK³</td>
<td>27.6% PTA, 54.2% DCB</td>
</tr>
</tbody>
</table>

1. Fanelli J Cardiovasc Surg 2014  
2. Zeller J Am Coll Cardiol 2014  
3. Liistro Presentation LINC 2021  
4. Razavi, J Vasc Interv Radiol 2014

In.Pact™ is a trademark of Medtronic.
Correlation Between Arterial Dissection and Restenosis

- 89 patients with BTK intervention
- 6-month follow up (clinical, Duplex)
- Residual stenosis > 50% in 40% patients
- Most residual stenosis due to dissection
- Dissection was the major predictor of restenosis

Index Procedure
3 Months
Limited Options for BTK Dissection Repair

Prolonged Inflation

• No data for infrapopliteal arteries

Stenting

• No approved BTK stents in US
  • Off-label use of coronary stents
• BTK arteries are susceptible to external crushing, especially the posterior tibial artery

1. Schneider Presentation LINC 2017
Tack purpose built for focal dissection repair

Multi-implant, minimal-metal designed for tapering vessels from SFA to ankle

Tack implants
- Multiple pre-loaded nitinol implants
  - ATK: 6 implants
  - BTK: 4 implants
- 6mm or 8mm deployed length
- Each implant selfsizes to tapering anatomy
  - ATK: 2.5 – 6.0mm and 4.0 – 8.0mm RVD
  - BTK: 1.5 – 4.5mm RVD

OTW Delivery System
- Accurate (≤1mm) deployment
  - ATK: 6F/.035
  - BTK: 4F/.014

INTENDED USE: The Tack Endovascular System (6F, 2.5-6.0mm) is intended for use in superficial femoral and proximal popliteal arteries, ranging in diameter from 2.5 mm to 6.0 mm, for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s). The Tack Endovascular System (4F, 1.5-4.5mm) is intended for use in mid/distal popliteal, tibial and peroneal arteries, ranging in diameter from 1.5 mm to 4.5 mm, for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

CONTRAINDICATIONS: The Tack Endovascular System is contraindicated for the following: 1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA. 2. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device. 3. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol). 4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy.
## Distinct vessel response and adaptive sizing

<table>
<thead>
<tr>
<th></th>
<th>Tack implant</th>
<th>Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Radial force</strong></td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td><strong>Inflammation</strong></td>
<td>Minimal</td>
<td>Chronic hyperplastic changes</td>
</tr>
<tr>
<td><strong>Pre-clinical study histology images</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td><img src="image1.png" alt="Proximal" /></td>
<td><img src="image2.png" alt="Proximal" /></td>
</tr>
<tr>
<td><strong>Metal burden</strong></td>
<td>6 mm or 8 mm length, open cell design</td>
<td>Significantly more metal to treat the same length dissection&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Sizing</strong></td>
<td><em>Adaptive sizing</em> from 1.5-4.5 mm, 3.5-6.0 mm or 4.0-8.0 mm</td>
<td>Requires more precise sizing</td>
</tr>
</tbody>
</table>

The Tack endovascular system’s low radial force and minimal metal compared to conventional stents causes less irritation to the vessel.

Preclinical studies have shown less inflammatory tissue response compared to stents.

Tack implant leaves behind >70% less metal than traditional stents<sup>4</sup> preserving vessel integrity and future treatment options.

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1. Schneider *J Amer Col Cardiol Intv* 2015  
Precision Dissection Repair with the Tack Endovascular System...

✓ Leaves **minimum metal** behind\(^1\)

✓ **Minimizes** vessel **inflammation**\(^2\)

✓ Maintains **normal** vessel biomechanics

✓ Preserves **future treatment options**
TOBA II BTK Study Design

**Infrapopliteal dissection repair with Tack Endovascular System (4F)**

<table>
<thead>
<tr>
<th>Prospective, multi-center, non-blinded, <strong>pivotal IDE study</strong> in US, Europe, New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>233 patients with post-PTA dissection following POBA</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Safety Endpoint</th>
<th>Freedom from MALE + POD at 30d</th>
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</thead>
<tbody>
<tr>
<td>Primary Efficacy Endpoint</td>
<td>Freedom from MALE at 6m + POD at 30d</td>
</tr>
</tbody>
</table>

MALE + POD: composite of all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s), defined as new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis

2. Geraghty J Endovasc Ther 2020
### Key baseline patient/lesion characteristics
(ITT population, core lab adjudicated)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD (N) or n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>74.4 ± 10.0 (233)</td>
</tr>
<tr>
<td>Male gender</td>
<td>157/233 (67.4%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>153/233 (65.7%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>218/233 (93.6%)</td>
</tr>
<tr>
<td>Chronic renal insufficiency</td>
<td>57/232 (24.6%)</td>
</tr>
<tr>
<td>TBI in treated leg</td>
<td>0.43 ± 0.23 (118)</td>
</tr>
<tr>
<td>Rutherford 3</td>
<td>38/233 (16.3%)</td>
</tr>
<tr>
<td>4</td>
<td>78/233 (33.5%)</td>
</tr>
<tr>
<td>5</td>
<td>153/233 (50.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD (N) or n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target vessel:</td>
<td></td>
</tr>
<tr>
<td>P2/P3</td>
<td>13/248 (5.2%)</td>
</tr>
<tr>
<td>TPT</td>
<td>25/248 (10.1%)</td>
</tr>
<tr>
<td>Ant. Tib</td>
<td>103/248 (41.5%)</td>
</tr>
<tr>
<td>Post. Tib</td>
<td>55/248 (22.2%)</td>
</tr>
<tr>
<td>Peroneal</td>
<td>53/248 (21.4%)</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>80 ± 49 (248)</td>
</tr>
<tr>
<td>PTA length (mm)</td>
<td>154 ± 110 (238)</td>
</tr>
<tr>
<td>RVD (mm):</td>
<td></td>
</tr>
<tr>
<td>Prox.</td>
<td>3.5 ± 1.0 (248)</td>
</tr>
<tr>
<td>Distal</td>
<td>2.6 ± 0.7 (248)</td>
</tr>
<tr>
<td>Total Occlusion</td>
<td>118/248 (47.6%)</td>
</tr>
<tr>
<td>Mod/Severe Calcium</td>
<td>125/211 (59.3%)</td>
</tr>
</tbody>
</table>

2. Geraghty J Endovasc Ther 2020
Post-PTA dissection severity and resolution (ITT population, core lab adjudicated)

**Post-PTA Dissection Severity (NHLBI)**

- **A, 21%**
- **B, 39%**
- **C, 12%**
- **D, 27%**
- **E, 1%**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Mean ± SD (N) or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissections per subject</td>
<td>1.4 ± 0.6 (229)</td>
</tr>
<tr>
<td>Tack implants per subject</td>
<td>4.0 ± 2.8 (230)</td>
</tr>
<tr>
<td>Dissection resolution</td>
<td>100%</td>
</tr>
<tr>
<td>Bail out stent to Tacked segment</td>
<td>0.4%</td>
</tr>
<tr>
<td>Freedom from fracture at 12m</td>
<td>100%</td>
</tr>
</tbody>
</table>

35% of implants were deployed in mid and distal tibials

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2. Geraghty J Endovasc Ther 2020
Tacked segment and target lesion patency

Tacked segment patency: DUS flow/no flow in Tacked segment (Tack implant + 5mm artery proximal and distal; Tacks within 1cm are considered same segment)

Target lesion patency: DUS flow/no flow in PTA treated length (mean 154mm)

81.3% @ 360d (Tacked segment)
78.6% @ 360d (target lesion)

2. Geraghty J Endovasc Ther 2020
# MALE, CD-TLR and limb salvage

*ITT population, core lab adjudicated*

<table>
<thead>
<tr>
<th></th>
<th>K-M Freedom from MALE + POD (all pts)</th>
<th>K-M Freedom from CD-TLR (all pts)</th>
<th>K-M Target Limb Salvage (CLI pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95.8%</td>
<td>92.0%</td>
<td>98.4%</td>
</tr>
<tr>
<td>6-Month Results¹</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>94.2%</td>
<td></td>
<td>83.1%</td>
<td>96.1%</td>
</tr>
<tr>
<td>12-Month Results²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>92.2%</td>
<td></td>
<td>73.6%</td>
<td>96.1%</td>
</tr>
<tr>
<td>24-Month Results³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>91.6%</td>
<td></td>
<td>69.6%</td>
<td>93.9%</td>
</tr>
<tr>
<td>36-Month Results⁴</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Geraghty J Endovasc Ther 2020  
3. Adams J Endovasc Ther 2022  
4. Data on file, Intact Vascular, a Philips company
Tack Endovascular System BTK

• **BTK angioplasty is different than ATK:**
  – Goals for treatment (limb salvage vs. patency)
  – Vessels (undersizing, etc)
  – Morphology (calcium vs. plaque)

• **Post-Infrapopliteal PTA Dissections:**
  – Occur often, yet frequently missed or underestimated
  – Can have substantial clinical impact, with limited tools for repair

• **Tack Endovascular System:**
  – With less metal, less force
  – Preserves future treatment options
  – TOBA II BTK has positive results through 36 months
Thank You!
Tack for Dissection Below-the-Knee

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