Focal Scaffolding: The New Concept for Optimized BTK Angioplasty?
Prof. Marianne Brodmann, MD
Medical University of Graz

Dissection: The Primary Mechanism of Angioplasty

Lesions with dissections have a TLR rate 3.5 times higher than lesions without dissection

Current tools for dissection repair (stents) have limitations

Insufficient Options for BTK Dissection Repair

Dissection Repair Should:
- Leave minimal metal behind
- Minimize vessel wall inflammation
- Maintain normal vessel biomechanics
- Preserve future treatment options

TOBA BTK Study Design

Prospective, Single-arm, Multi-center Study

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 ≤15 cm
- Angiographic evidence of a dissection post-PTA

Sites
6 sites in Europe and New Zealand

Subjects 35

Primary Endpoints
Safety
- Composite of MALE and POD at 30 days

Device Success
- Successful delivery and deployment of study device(s) at intended target site(s) and successful withdrawal of delivery catheter

Procedure Success
- 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

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Challenging Patients, Complex Lesions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Safety Sample (n=35)</th>
<th>Perf. Sample (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>76.4 ± 9.5</td>
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</tr>
<tr>
<td>Male</td>
<td>56.3%</td>
<td>56.3%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>81.3%</td>
<td>81.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>90.6%</td>
<td>90.6%</td>
</tr>
<tr>
<td>Smoking:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>6.5%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Former</td>
<td>32.3%</td>
<td>32.3%</td>
</tr>
<tr>
<td>Rutherford:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCC 4</td>
<td>12.5%</td>
<td>12.5%</td>
</tr>
<tr>
<td>ACC 5</td>
<td>87.5%</td>
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</tbody>
</table>

Core Lab Baseline Lesion Characteristics (Safety Sample, n=35)

- Lesion Length (mm): 51.4 ± 28.0
- Total Occlusion: 22.2%
- Dissection grade: A 31.2%, B 80.6%, C 18.2%
- Lesion Location: Anterior Tibial 38.9%, Tibioperoneal 27.8%, Peroneal 16.7%, Posterior Tibial 10.7%
- Calcification: None/mild 36.1%, Moderate 61.1%, Severe 2.8%

Lesion lengths up to 8cm: 1/5 of subjects had a total occlusion
~80% of dissections ≥ Grade B
Broad anatomic distribution
Real-world calcium

TOBA BTK: Safety and Performance

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<th>Perf. Sample (n=32)</th>
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<tbody>
<tr>
<td>Device Success†</td>
<td>93.4% (33/35)</td>
<td>NA</td>
</tr>
<tr>
<td>Procedure Success†</td>
<td>96.9% (31/32)</td>
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Primary Safety at 30 Days

<table>
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<th>Safety Sample (n=35)</th>
<th>Perf. Sample (n=32)</th>
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</thead>
<tbody>
<tr>
<td>Major Amputation</td>
<td>0% (0/35)</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>2.9% (1/35)</td>
</tr>
<tr>
<td>Death</td>
<td>0% (0/35)</td>
</tr>
</tbody>
</table>

TOBA II BTK Update

Pivotal IDE study of the Tack Endovascular System in the treatment of patients with CLI

Prospective, single-arm, multi-center study

Population: 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

Subjects/Sites: 233 subjects at up to 60 sites in US, Europe, and New Zealand

Primary Endpoints:
- Safety: MALE + POD at 30 days
- Efficacy: MALE at 6 months + POD at 30 days

Case Study:

Patient History and Clinical Presentation

- 72 yr male
- History:
  - Hypertension
  - Hyperlipidemia
  - CVA 2yrs ago
- No prior peripheral intervention
- ABI:
  - L: 0.75
  - R: 0.78
- TBI:
  - L: 0.37; TP: 55mmHg
  - R: 0.26; TP: 38mmHg
- WIfI: 0-3-0
- Rutherford: 4

Baseline

- 6F LFA antegrade access
- On daily ASA, clopidogrel
- IV heparin for procedure
**Baseline**

- Tibial lesion
- Small vessel
- Poor runoff

**Target Lesion PTA**

- 2.5/120 balloon inflation
  - 90 sec @ 8 atm

- 2.5/80 balloon inflation
  - 90 sec @ 9 atm

**Post-PTA Dissection**

- Use of magnification, multiple angles critical for dissection identification

**Repaired with 3 Tacks**
Tack: A New Therapy for Dissection Repair

• First trials to enroll 100% dissected vessels

• Precision dissection repair with the Tack Endovascular System:
  - Leaves minimal metal behind
  - Minimizes vessel inflammation
  - Maintains normal vessel biomechanics
  - Preserves future treatment options