Update on the DEEPER LIMUS trial: the Bare Temporary Spur Stent System in conjunction with a Sirolimus coated balloon

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Disclosures

Speaker name: Marianne Brodmann

I have the following potential conflicts of interest to report:

✘ Consulting:
☐ Employment in industry: None
☐ Stockholder of a healthcare company:
☐ Owner of a healthcare company: None
☐ Other(s): None

☐ I do not have any potential conflict of interest
Challenges to treatment of BTK arteries and the use of drug-coated technology

**Infrapopliteal disease**
- Vessel Recoil
- Calcification
- Lesion length/tortuosity
- Dissection

**Drug Coated Technology**
- Drug uptake
  - Diameter mismatch
  - Luminal surface contact
  - Uptake
  - Penetration

1. Baumann, 2014
2. Loss of drug to circulation

\[1 \text{ Vessel Recoil Peroneal} \]
\[2 \text{ Loss of drug to circulation} \]
Bare Temporary Spur Stent System*

- Self-Expanding nitinol stent designed with radial spikes integrated onto a 6F balloon delivery system
  - Simple and familiar delivery system
  - Creation of channels may optimize greater drug uptake when followed by a commercially available DCB
- Temporary mechanical scaffolding may:
  - Minimize vessel recoil and dissections
  - Increase acute luminal gain
- Intended to deliver stent-like results while leaving nothing behind

* For clinical investigational use only
## Clinical Validation Spur* + DCB

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Status</th>
<th>Endpoints</th>
</tr>
</thead>
</table>
| DEEPER (completed 2019) | Completed [N=23 (ITT)] [N=17 (PP)] | Primary Efficacy: Primary patency at 6 months (DUS): 88.9% (PP)  
Primary Safety:  
Freedom from device and procedure-related death through 30 days: 100% (PP)  
Freedom from target limb major amputation and CD-TLR through 6 months: 94.1% (PP) |
| DEEPER OUS (ongoing, initiated 2019) | ENROLLMENT COMPLETE APRIL 2022 N = 107  
Follow up to 5 years | Primary Efficacy: Primary patency at 6 months (DUS)  
Final results: 72/84 (85.7%)  
Vessel Recoil Sub-study: Vessel recoil post Spur treatment (N=38)  
Rate of Recoil: 42.5% Recoil Spur vs. 97%¹  
Full sub-study cohort presented at LINC 2023  
Primary Safety: Freedom from 30-day perioperative mortality  
Final results: 102/102 (100%) |
| DEEPER LIMUS (ongoing, initiated 2020) | ENROLLMENT COMPLETE JUNE 2022 Current N: 26 | Primary Safety Endpoint:  
6-month composite of All-Cause Mortality, Major Amputation and CD-TLR  
Important Secondary Endpoints:  
1. LLL at 6 months by QVA  
2. Primary patency at 6 months by QVA  
3. Freedom from MALE and POD at 30 days  
4. Freedom from MALE at 6 and 12 months  
5. Improvement in Rutherford at 3, 6, 12 months  
6. Wound healing/WIfI at 6 and 12 months |

¹ Baumann, et al, 2014
## DEEPER LIMUS RESULTS TO DATE

### PRIMARY ENDPOINT

<table>
<thead>
<tr>
<th>Description</th>
<th>Result</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-month composite of All-Cause Mortality, Major Amputation and Clinically Driven-Target Lesion Revascularization (N=22)</td>
<td>11.5% (3/26)</td>
<td>1 patient died of COVID-19, 1 patient had major amputation due to infection, 1 patient with CD-TLR</td>
</tr>
</tbody>
</table>

### SECONDARY ENDPOINTS

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Result</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency at 6 months by QVA (N=18)*</td>
<td>83% (15/18)</td>
<td>3 patients declined angiography at 6 month follow up</td>
</tr>
<tr>
<td>*Patients with available corelab-adjudicated data (Syntropic, Columbus, OH)</td>
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</tr>
<tr>
<td>Primary patency at 6 months by DUS (N=21)*</td>
<td>85.7% (18/21)</td>
<td>One DUS nondiagnostic</td>
</tr>
<tr>
<td>*Patients with available corelab-adjudicated data (Vascore, Boston, MA)</td>
<td></td>
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<tr>
<td>Subsegmental Late Lumen loss at 6 months by angiography (N=21 lesions)*</td>
<td>0.40mm (+ .66 mm)</td>
<td></td>
</tr>
<tr>
<td>Freedom from Major Adverse Limb Event (MALE)** and POD at 30 days (N=26)</td>
<td>96.2% (25/26)</td>
<td></td>
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<tr>
<td>Freedom from MALE** at 6 and 12 months</td>
<td>6 Months: 24/25 (96%), 12 Months: Pending 12 month follow up</td>
<td></td>
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<tr>
<td>**MALE defined as major amputation above the ankle</td>
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1. As of May, 2023  
2. As of November, 2022 (final data review pending 1 year follow up)
Trial Rationale: LIMUS Challenges addressed

- Concerns for long-term impact of Paclitaxel (Katsanos, et. al., 2018, 2020)
- Limus-based drug coating historically challenging to deliver in absence of stent
- Bare Temporary Spur Stent System* → Platform for DRUG DELIVERY into diseased artery, may allow for improved tissue absorption and deposit further into arterial wall

*For clinical investigational use only
Key Eligibility Criteria: DEEPER LIMUS

**Inclusion**
- Rutherford category 3, 4, or 5
- Heel wounds permitted if no evidence of osteomyelitis
- De novo or restenotic infrapopliteal lesion (popliteal excluded)
- Target lesion
  - Reconstitutes at or above ankle
  - TV between 2.0 to 4.5 mm in dm
  - Lesion length **up to 220 mm**

**Exclusion**
- Osteomyelitis proximal to phalanges (permitted in digits of target foot)
- Rutherford category 0, 1, 2, 6
- Planned target limb major amputation
- Target lesion
  - Stents within target vessel/lesion
  - Extremely severe calcification not amenable to PTA
  - Angiographic evidence of thrombus in the target limb
# DEEPER LIMUS Demographic/Lesion Characteristics

## DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [mean (range)]</td>
<td>73 (56, 90)</td>
</tr>
<tr>
<td>Female sex [mean (n/N)]</td>
<td>38% (10/26)</td>
</tr>
<tr>
<td>Type 2 Diabetes [mean (n/N)]</td>
<td>77% (20/26)</td>
</tr>
<tr>
<td>Hypertension [mean (n/N)]</td>
<td>88% (23/26)</td>
</tr>
<tr>
<td>Tobacco abuse [mean (n/N)]</td>
<td>62% (16/26)</td>
</tr>
<tr>
<td>Chronic Kidney Disease [mean (n/N)]</td>
<td>27% (7/26)</td>
</tr>
<tr>
<td>Hyperlipidemia [mean (n/N)]</td>
<td>77% (20/26)</td>
</tr>
<tr>
<td>Atherosclerotic arterial disease (coronary and cerebral)</td>
<td>35% (9/26)</td>
</tr>
</tbody>
</table>

## LESION CHARACTERISTICS

<table>
<thead>
<tr>
<th>Target artery [mean (n/N)]</th>
<th>N= 30 lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior tibial</td>
<td>40% (12/30)</td>
</tr>
<tr>
<td>Posterior tibial</td>
<td>17% (5/30)</td>
</tr>
<tr>
<td>Tibioperoneal trunk</td>
<td>27% (8/30)</td>
</tr>
<tr>
<td>Peroneal</td>
<td>17% (5/30)</td>
</tr>
<tr>
<td>Diameter stenosis, % [mean (range)]</td>
<td>70-90% 56% (17/30)</td>
</tr>
<tr>
<td></td>
<td>91-99% 7% (2/30)</td>
</tr>
<tr>
<td></td>
<td>100% 37% (11/30)</td>
</tr>
</tbody>
</table>

| Spur-treated length mm [mean (range)] | 97 mm (60-210) |

## TASC

- TASC A: 17%
- TASC B: 0%
- TASC C: 35%
- TASC D: 48%
19 subjects with wound data had 6 month follow up data. Wlfi Risk scores were “High” in about 50% of patients at baseline, and improved to be “Very low” in about 60% of patients at 6 months. Rutherford score average decreased by 3 classes at 6 months.

* As of November, 2022 (final data review pending 1 year follow up)
73 year-old female, Rutherford class 5

• Pertinent history:
  • Type II Diabetes
  • Chronic kidney disease
  • Heel and toe wounds
  • Baseline ABI/TBI: .66; .3

• High-risk WIfI:
  • Wound: 3
  • Ischemia: 1
  • Infection: 0
DEEPER LIMUS Case Presentation

Image of 3.0x60 mm Spur* inflated

Post-Spur*

Post-DCB

* For clinical investigational use only
6-month angiogram Late Lumen Loss (LLL)

**Subsegmental LLL**
Difference in average diameter of treated segment at each time point

<table>
<thead>
<tr>
<th>Analysis Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsegmental LLL</td>
<td>.32 mm*</td>
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</table>

*Corelab adjudicated (Syntropic)
6 month Clinical follow up

<table>
<thead>
<tr>
<th>Baseline ABI/TBI</th>
<th>6 Month ABI/TBI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI: .66/TBI: .3</td>
<td>ABI: 1.41/TBI: .75</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline WIfI (high risk)</th>
<th>6 Month WIfI (low risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Wound: 3</td>
<td>• Wound: 0</td>
</tr>
<tr>
<td>• Ischemia: 1</td>
<td>• Ischemia: 0</td>
</tr>
<tr>
<td>• Infection: 0</td>
<td>• Infection: 0</td>
</tr>
</tbody>
</table>

Baseline Wound | 6 Month Wound

- Wound: 3
- Ischemia: 1
- Infection: 0

- Wound: 0
- Ischemia: 0
- Infection: 0
Reflow Medical’s Bare Temporary SPUR Stent System*

- Mechanical scaffolding: familiar design → consistent results, addressing current treatment hurdles
  - May reduce vessel recoil
  - May increase acute luminal gain
  - May reduce dissections
  - Allows continuous flow during treatment when balloon deflated
- Preserves future treatment options and reduces need for adjunctive therapies
- Drug agnostic device designed to create channels for drug delivery into the artery wall when used with DCB
- Promising clinical data (**DEEPER LIMUS**, **DEEPER OUS**)
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