The LimFlow procedure – technical details and current clinical experience in Europe

Michael K.W. Lichtenberg, MD
Conflict of Interest - Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Verryan</td>
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<td>2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Verryan, Boston Scientific</td>
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<td>3. Participation in clinical trials: Biotronik, CR Bard, Verryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow</td>
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<td>4. Research funding: Biotronik, Boston Scientific, Verryan, Veniti, AB Medica</td>
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pDVA Procedure quick overview
Safe, Reproducible, fully Percutaneous Foot Perfusion

**Key Procedure Steps**  Artery to Vein Crossing

**Ultrasound AV Positioning Kit:**
Intended to determine optimal Crossing point safely and reproducibly
pDVA Procedure quick overview
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**Key Procedure Steps**  Pedal Arch Reconstruction

Push Valvulotome:
- Designed to maximize outflow by rendering vein valves incompetent
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Key Procedure Steps  Percutaneous Bypass Creation

Covered Stents
Conical and straight Covered Stents to maximize outflow to the foot
First 43 treated “No option” patients

Mean age 68 y.o. (range 31-89 y.o.)

Majority of male patients (61% male, 39% female)

80% of the patients were diabetic and 2 had vasculitis

Over 20% of patients are on dialysis

Rutherford classification

- Class 4: 37%
- Class 5: 58%
- Class 6: 9%

Patient Demographics

Clinical Experience

Confidential and Proprietary
Distribution of arteries and veins used for crossing

Crossed Veins
- Peroneal: 8%
- AT: 16%
- PT: 76%

Crossing Arteries
- PT: 48%
- TP Trunk: 24%
- AT: 20%
- Peroneal: 8%

n=25
Clinical Summary
First 43 LimFlow Treated Patients

First 43 LimFlow Patients
Survival and Amputation Free Kaplan-Meier

Reproducible Therapy
Strong Safety Profile
Survival in line with patients co-morbidities
Evident Impact on Wound Healing & Amputation Risk

71% patients alive and amputation free 6 months after pDVA
## LimFlow pDVA Clinical Program

<table>
<thead>
<tr>
<th></th>
<th>Pilot</th>
<th>Pre and Post CE Mark</th>
<th>U.S. Feasibility</th>
<th>OUS Post-Market</th>
<th>U.S. Pivotal</th>
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<tr>
<td><strong># Patients</strong></td>
<td>7</td>
<td>36</td>
<td>25</td>
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<td>60 – 120</td>
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<td><strong># Centers</strong></td>
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<td>U.S.</td>
<td>EU, Singapore</td>
<td>U.S., TBD</td>
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Overview of International Clinical Study

- Single arm
- Open-label
- Prospective
- Post-market
- Multi-centric
- One-year follow-up
- Up to 50 patients

Leverages US FDA IDE Trial
- Eligibility criteria
- Study endpoints
- Visits & Exams
- Common independent committee (Syntactx)
  - Patient screening process
  - Endpoints adjudication
  - Electronic study tool support (ClinFlows, eKare)
Study Endpoints

**Primary endpoint**
- Amputation-free survival (AFS)

**Secondary endpoints**
- Complete wound healing
- Primary and secondary patency as assessed by duplex ultrasonography
- Limb salvage
- No Renal function deterioration
- Technical and procedural success
## Visits and exams

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<tr>
<th>Exams</th>
<th>Baseline</th>
<th>Treatment</th>
<th>M 01</th>
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☐  Follows standard of care in each site
72 y, male, diabetic, CKD
Pre/Post Angio
Post DI amputation and 8 weeks FU
Summary

- Percutaneous DVA (LimFlow) is an emerging way to treat “End Stage CLI” for absolute no option patients
- Safe, effective but there is a complex learning curve
- Potentially applicable to any Angiosome that cannot be opened via Conventional Techniques
- Evidence is emerging
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