Update on the PROMISE I Early Feasibility Study in the US & Global Experience

Jihad A. Mustapha, MD, FACC, FSCAI

Associate Professor of Medicine
Michigan State University, E. Lansing, MI USA
Chief Executive Officer
Advanced Cardiac & Vascular Amputation Prevention Centers
Grand Rapids, MI USA
Disclosure

Speaker name: Jihad A. Mustapha

I have the following potential conflicts of interest to report:

• BD Bard (consultant, physician trainer, MAB & research)
• Boston Scientific (consultant, MAB & research)
• Biothelium (consultant)
• Cagent Vascular (consultant & research)
• Cardio Flow (chief medical officer, board member, shareholder & research)
• Cardiovascular Systems, Inc. (consultant, physician trainer & research)
• Medtronic (consultant, physician trainer)
• Micromedical Systems (chief medical officer)
• Philips (consultant & physician trainer)
• PQ Bypass (consultant & research)
• Reflow Medical (chief medical officer & research)
• Terumo Medical (consultant & research)
Natural History of CLI

Healed 20%

Not Acceptable 80%

12 Month Patient Outcomes

2 meta-analyses, 24 studies, 2400+ patients*

For patients, once amputated...

- Up to 10% die before discharge
- 20-37% have major complications
- 19 average hospital admissions/year
- $800k in direct healthcare cost

Norgren and al, JEVS 2007 33, S1-S70;
Percutaneous Deep Vein Arterialization

**Advantages**
- Impressive rate of AFS shown in early trials for most challenging patient cohort
- Evident impact on perfusion and wound healing
- Minimally invasive, safe and reproducible procedure

**Limitations**
- Initial evidence on small number of patients - research ongoing
- Difficult to save “extreme” foot wounds/infection - WfI: W=3, f1=3
- Trade-off with potential toe amputation
Proprietary LimFlow Procedure System

Tapered and Straight Stent Grafts

Ultrasound AV Positioning Kit

Retrograde Valvulotome

CAUTION: Investigational device. Limited by Federal law to investigational use.
<table>
<thead>
<tr>
<th></th>
<th>Pilot</th>
<th>Pre and Post CE Mark</th>
<th>PROMISE I (US Feasibility)</th>
<th>PROMISE International</th>
<th>PROMISE II (U.S. Pivotal)</th>
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Early International pDVA Clinical Experience*

- 43 consecutive patients
- 6 Month Follow-up
- Amputation Free Survival 71%
- Survival 90%

* Retrospective site-reported data compiled by LimFlow – data on file
## LimFlow pDVA Clinical Program

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**PROMISE I Study Design**

### Key Endpoints

- **Primary safety endpoint**
  - Amputation Free Survival (AFS) at 30 days

- **Secondary endpoints**
  - AFS at 6 months
  - Procedure & Technical Success
  - Wound Healing
  - Patency

### Key Inclusion/Exclusion Criteria

**Inclusion:**
- Rutherford 5/6
- No-Option CLI
- Approval by ISC

**Exclusion:**
- Life expectancy <12 months
- Dialysis
- Severe heart failure

### Follow-Up Schedule

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<th>BL</th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
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No-Option CLI Patients

1. These patients have no remaining acceptable target vessels for intervention
2. Patients with ischemic foot wounds typically do not heal without successful reperfusion
3. Amputation is the only remaining therapeutic option
4. They represent 14-20% of CLI population

PROMISE I Trial No Option definition
absence of a usable pedal artery target or present pedal artery target with absent viable single-segment vein that could be used for autogenous vein conduit
**PROMISE I Interim Results**

**30 day and 6 month Results, n=10**

- **100%** Technical Success
- **100%** Survival
- **100%** Amputation Free

**Wound Healing at 6 Months**
- 30% of patients experienced complete (100%) wound healing
- 50% of patients had 84-93% wound healing
- 20% of patients experienced 60% healing

**Primary Patency**
- 1 Month was 90%
- 6 month was 40%
- Reintervention performed in 30% of patients

Data Source: LimFlow Inc; Data on File
PROMISE I Angio Results

- 72 y/o M, Rutherford 5
- Type II Diabetes
- WiFi 230
- Nonhealing wound (over the tip of the hallux)
- No surg/endo pedal artery target

Data Source: LimFlow Inc; Data on File
PROMISE I Patient Wound Evolution

Baseline
- Area: 11.6 cm²
- Volume: 15.8 cm³

1 Month
- Area: 18.1 cm²
- Volume: 19 cm³

3 Month
- Area: 0.0 cm²
- Volume: 0.0 cm³

6 Month
- Area: 4.8 cm²
- Volume: 1.3 cm³

9 Month
- Area: 1.4 cm²
- Volume: 4.7 cm³

TMA performed 1 week after 3 m f/u
PROMISE I Patient Wound Evolution

Data Source: LimFlow Inc; Data on File
Conclusions from pDVA Experience

- The LimFlow System is a novel, safe and reproduceable approach for treating patients with no-option CLI
- It may reduce amputation rates in this population for whom it would otherwise be considered inevitable
- Initial findings from this early feasibility trial are very promising and additional study is warranted
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