Ultrasound Guided Distal AV Fistula Creations For Segmental Foot Arterialization

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Speaker name:

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I have the following potential conflicts of interest to report:

- [x] 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
Heal to Toe Lateral Plantar Vein Evaluation
Pre-Procedure Ultrasound

Pedal Dorsal Veins
- Assess patency GSV and MMV
- Map access points

Pedal Plantar Veins
- Confirm Lateral Plantar Vein (LPV)
- Mark location for potential LPV access points as distal as on the foot as possible (ideal size for access >0.3cm)

“If you can’t see it, they can’t stick it”
LimFlow - Permanently Bypass Unreconstructible Arteries
LimFlow pDVA Procedure Overview

1. Crossing is done.
2. Valvulotome renders valves incompetent.
3. Limflow Self-Expanding Covered Extension Stents
4. Tapered Covered Crossing Stent
5. Forward flow is achieved.
LimFlow System Purpose-built for pDVA

- **Straight Stent Grafts**
- **Conical Stent Graft**
- **Ultrasound AV Positioning Kit**
- **Push Valvulotome**
LimFlow Stent Graft Overview

• Unique purpose-built stent graft for pDVA
• Tapered crossing stent is specifically designed to optimize sizing for both the artery and vein
• Self-expanding Nitinol/PTFE stent graft designed to conform to the vessel and focus flow distally to the foot
• 7Fr delivery system maximizes applicability
LimFlow Ultrasound Arterial and Venous Catheters

- LimFlow is the only purpose built system for safe and effective AV crossing
- Arterial ultrasound send catheter
  - 7Fr Outer Diameter enhances trackability
  - 10mm nitinol crossing needle is ideally shaped for AV crossing
- Venous ultrasound receive catheter
  - 4Fr Outer Diameter with a 360° ultrasound receiver for repeatable crossing
LimFlow Valvulotome

- LimFlow’s unique push (antegrade) valvulotome is specifically designed to atraumatically cut venous valves reaching from the tibial to the distal pedal veins
- Self-expanding laser cut nitinol basket maximizes valve engagement
- 4Fr Outer Diameter optimizes deliverability

CAUTION: Investigational device. Limited by Federal law to investigational use.
PROMISE I: Amputation Free Survival

AFS Kaplan–Meier, Breakout

74% AFS @ 6 months

Survival Freedom from Amputation Composite AFS

Days Post LimFlow Index Procedure

# at risk 32 28 22 22 18 17 13 10 9 8

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PROMISE I: Wound Area Reduction

*Two patients experienced TMA of their treated foot between 3 and 6 months.

Average Wound Area- Core Lab Results

<table>
<thead>
<tr>
<th>Time</th>
<th>Wound Area cm²</th>
<th>Patients (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>10.01</td>
<td>28</td>
</tr>
<tr>
<td>1M</td>
<td>16.19</td>
<td>25</td>
</tr>
<tr>
<td>3M</td>
<td>3.96</td>
<td>18</td>
</tr>
<tr>
<td>6M</td>
<td>6.86*</td>
<td>19</td>
</tr>
<tr>
<td>9M</td>
<td>2.12</td>
<td>13</td>
</tr>
</tbody>
</table>

*Two patients experienced TMA of their treated foot between 3 and 6 months.

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PROMISE I: Wound Healing Status

Wound Status Over Time – Core Lab Results

- **Healed + Healing**
- **Healed**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Healed + Healing (%)</th>
<th>Healed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Month (N=26)</td>
<td>0%</td>
<td>31%</td>
</tr>
<tr>
<td>3 Month (N=20)</td>
<td>15%</td>
<td>29%</td>
</tr>
<tr>
<td>6 Months (N=21)</td>
<td>67%</td>
<td></td>
</tr>
<tr>
<td>9 Month (N=13)</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

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PROMISE I Case Example: Patient Overview

- 80 y/o, R5 male
- Type II diabetes
- Hx of smoking and MI
- Hyperlipidemia
- 2 failed prior interventions
- Nonhealing hallux gangrene

Courtesy of Dr. Henao, New Mexico Heart Institute
PROMISE I Case Example: Wound Healing

Wound Healing Over Time

Wound Area cm²

Follow-up Timepoint

BL 1M 3M 6M 9M 1Y

Courtesy of Dr. Henao, New Mexico Heart Institute, LimFlow data on file
Conclusions

• The LimFlow System is a novel, safe, and reproduceable approach for treating patients with no-option CLTI

• It may improve wound healing rates and reduce amputation rates in a population for whom amputation would otherwise be considered inevitable

• Amputation free survival and wound healing rates are very promising and additional study is warranted

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