Percutaneous Deep Vein Arterialization (LimFlow) for CLI
- Results Of First Clinical Experience & 1 Year Follow-Up

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Disclosure
• Consultancy work for
  • Medtronic/Covidien
  • Abbott
  • Biotronik
  • Boston Scientific
  • Cook
  • Bard
  • MdStart/Limflow
• The LimFlow device is not approved for use in the US
• The use of off label devices in this presentation should not be construed as an endorsement

What is end stage tibial disease?
• Clinical presentation
  • Advanced age
  • Multiple comorbid conditions eg ESRD, IHD with poor control of risk factors
  • Multiple prior interventions/bypass surgeries,
  • Multiple toes lost/soft tissue work done
  • Poor venous conduits
• Angiographic appearance
  • Small foot target vessels or "Desert Foot"
  • Severe calcification/recoil
  • Rapid restenosis after previous intervention or early bypass graft failure

Desert Foot – LimFlow No. 6

Concept of Deep Venous Arterialization (DVA)

DVA vs Distal Bypass?

Results: In 40 patients with CLI, 21 venous arterialisations and 19 pedal bypasses were performed. In the venous arterialisation group, early occlusion was 16%, primary patency was 74%, and limb salvage was 88%. In the PB group, early occlusion was 25%, primary patency was 78% and limb salvage was 48%. The only independent risk factor for limb salvage in multivariate analysis was bypass occlusion (p < 0.01).

Conclusions: Limb salvage after venous arterialisation was equal to limb salvage after pedal bypass surgery in this clinical comparative study.

Questions?
Hybrid DVA

• Rise in TCPO2 was impressive

Percutaneous DVA - LimFlow

• Prospective Single Centre, Changi General Hospital, Singapore (Investigators: Steven Kum MD, Tan Yih Kai MD, Tjun Tang MD)
• Ethics Review Board Approved
• Rutherford 4, 5 and 6, **No option CLI**
• 7 Patients, Clinical Follow-up
• Objective and Subjective measures of Perfusion + Wound outcomes

LimFlow: Review of Procedure

• Ultrasound Receive catheter
• Insertion of send catheter into target vein
• Insertion of send catheter into artery and orientation
• Crossover and insertion of GW
• Predil and insertion of covered stent

LimFlow No. 5

• 60 Male
• DM
• Hyperlipidemia
• Renal Impairment
• Smoker x 40 years
• IHD with Cath 2014 diffuse disease EF 55% SWMA

The “Desert” Foot

LimFlow Reversed OTW Valvulotome

• OTW Valvulotome with forward facing blades

The “Desert” Foot
Antegrade 7F sheath in CFA
Retrograde 5F sheath in
Posterior Tibial Vein under
US guidance

Double injection

The ‘A’ Catheter (Send)

Slider pushes inside out
Insertion Port for 0.014 Crossing Wire

‘V’ Catheter (Receive)

Aligning the Catheters
(Rotation + Depth)

Unable to disrupt Valve with POBA @ High Pressure

4 x 60 Pacific
5 x 20 REEF

5F Reverse Valvulotome over V18

5 mm balloon finally effaced

20 ATM
Balloon Mounted Covered stent

5mm Self Expanding Covered Stent

Crossover point

Final Runs

Crossover point

Final Runs and iFlow

Simultaneous Debridement

DAY 20 SPLIT SKIN GRAFT

Summary of Experience - Angiographic

Summary of Experience – Objective Measurement of Perfusion with TCPO2
Summary of Experience – Wound Bleeding

There is perfusion even after the graft occludes...

Summary of Experience – Wound Healing

HYPOTHESIS

Symptom Free Persistent AVF signal even with graft occlusion

Percutaneous DVA : 6 Month Results

<table>
<thead>
<tr>
<th>6 Month Clinical Endpoint Singapore</th>
<th>Results</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from 30 Day MALE</td>
<td>9/9</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from 30 Day MACE</td>
<td>7/9</td>
<td>78%</td>
</tr>
<tr>
<td>Survival</td>
<td>6/7</td>
<td>86%</td>
</tr>
<tr>
<td>Limb Salvage</td>
<td>6/7</td>
<td>86%</td>
</tr>
<tr>
<td>Resolution of Rest Pain</td>
<td>2/2</td>
<td>100%</td>
</tr>
<tr>
<td>Wound Healed</td>
<td>4/5</td>
<td>80%</td>
</tr>
<tr>
<td>Secondary Graft Patency</td>
<td>5/6</td>
<td>83%</td>
</tr>
</tbody>
</table>

- Mean time to graft occlusion was 109 days (42 to 205 days)
- Mean time to wound healing was 145 days
11/21/2015

**Percutaneous DVA: 12 Month Results**

<table>
<thead>
<tr>
<th>12 Month Clinical Endpoint</th>
<th>Results</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td>4/7</td>
<td>57%</td>
</tr>
<tr>
<td>Limb Salvage</td>
<td>3/4</td>
<td>75%</td>
</tr>
<tr>
<td>Resolution of Rest Pain</td>
<td>1/1</td>
<td>100%</td>
</tr>
<tr>
<td>Wound Healed</td>
<td>5/5</td>
<td>100%</td>
</tr>
<tr>
<td>Secondary Graft Patency</td>
<td>1/9</td>
<td>10%</td>
</tr>
<tr>
<td>Persistent Doppler signal despite graft occlusion</td>
<td>3/3</td>
<td>100%</td>
</tr>
</tbody>
</table>

**LimFlow: Future Steps – CE and FDA**

- CE mark: Study underway
  - Leipzig & Singapore approved
    - Andrej Schmidt & Dierk Scheinert
    - Steven Kum & Tan Yih Kai
  - 2 additional German centers will join the study
    - Prof. Holger Reinecke (Munster)
    - Prof. Giovanni Tosello/Dr. Arne Schwindt (Munster)
- CE Mark of Full System in Early 2016
- FDA: Pre-IDE submitted & accepted into "Early Feasibility Study" program in the US
- FDA: Plan to enrol patients in the US in Early 2016
  - Jihad Mustapha

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  - Tang Tjun Yip
  - Andrej Schmidt
  - Dierk Scheinert
  - Roberto Ferraresi
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- Vlad Alexandrescu, Jihad Mustapha, Pramook

**Thank You**

**VEITH Symposium**

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