Clinical Case Reviews

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Disclosure

• Paid Consultant for
  • 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
Concept of Deep Venous Arteriolization (DVA)
Case Examples
LimFlow 5

60 Male, DM, Hyperlipidemia, Renal Impairment, Smoker x 40 years (recently quit),
IHD with Cath 2014 $\rightarrow$ diffuse disease,
EF 55% SWMA
## Clinical Course

<table>
<thead>
<tr>
<th>Indication</th>
<th>Procedure</th>
<th>Date</th>
<th>Clinical Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Forefoot Gangrene</td>
<td>Popliteal, ATA  PTA Peroneal POBA</td>
<td>24/3/2007</td>
<td>Wound Healed</td>
</tr>
<tr>
<td>Left Forefoot Stump Wound</td>
<td>Left SFA stent, TPT Peroneal DES</td>
<td>4/8/2010</td>
<td>Wound Healed</td>
</tr>
<tr>
<td>Left Forefoot Stump Wound</td>
<td>SFA Popliteal TPT Peroneal DEB (INPACT) for ISR</td>
<td>15/7/2011</td>
<td>Wound Healed</td>
</tr>
<tr>
<td>Rest Pain</td>
<td>Rotarex+Thrombolysis, SFA Peroneal POBA for ISR</td>
<td>11/4/2014</td>
<td>Rest Pain Resolved</td>
</tr>
<tr>
<td>Left Forefoot Stump Wound</td>
<td>SFA Popliteal TPT Peroneal DEB (Lutonix)</td>
<td>15/5/2014</td>
<td>Granulation Slow</td>
</tr>
<tr>
<td>Left Forefoot Stump Wound</td>
<td>Failed retrograde DP Angioplasty</td>
<td>29/9/2014</td>
<td>Granulation Slow</td>
</tr>
<tr>
<td>Left Forefoot Stump Wound</td>
<td>Limflow (crossover Popliteal Artery to TPT Vein/PT)</td>
<td>3/11/2014</td>
<td>SSG Taken on 30/11/14</td>
</tr>
</tbody>
</table>
Attempted Retrograde DP under USG and Fluoro failed

The “Desert” Foot
Antegrade 7F (CFA), Retrograde 5F (PTV) under US Guidance
The ‘A’ Catheter (Send)

Slider pushes needle out

Insertion Port for 0.014 Crossing Wire

Monorail Design
‘V’ Catheter (Receive)
Aligning the Catheters (Rotation + Depth)
Aligning the Catheters (Rotation + Depth)
Wire into sheath

Crossover point
Sending Spartacore across puncture site
3mm Pacific

Crossover point
Unable to disrupt Valve with POBA @ High Pressure

4 x 60 Pacific

20 ATM

5 x 20 REEF

26 ATM
5F Reverse Valvulotome over V18

5 mm finally effaced
Covered stent 5 x 38

Crossover point
5mm Self Expanding Covered Stent
Crossover point

Post Dil
Final Runs

Crossover point
Final Runs and iFlow
Simultaneous Debridement
Post op
• 73 yrs old Male
• Forefoot gangrene
• Rutherford 6
• Diabetic
• Hypertensive
Failed Tarsal Artery Intervention

AP Foot
LimFlow 11 July 2014

Pre-Dil ATA Venous Catheter in ATV

Crossing
Occluded graft 15 Sep 2014

6F Rotarex
Post Rotarex and INPACT DEB
4mm INPACT DEB 11 June 2015
**LimFlow 1** Follow-up: $\uparrow$ TcpO2

![Graph showing Patient #1's TcpO2 levels over time with a treatment intervention at 400 days.](image-url)
LimFlow 1 Follow-up: Wound Healing

Pre-Op

Day 12 – after forefoot Amp

Day 18

Day 31

Day 53
Clinical Case #3 Follow-up: Wound Healing

Day 70

Day 80

Day 91

Day 103 – Skin Graft
Clinical Case #3 Follow-up: Wound Healing

Day 108

Day 138

Day 164
LimFlow 1

Day 66

Day 545
LimFlow 4

Dr Steven Kum
Dr Tan Yih Kai
85 yrs old Female

**Severe Rest Pain & Toe Gangrene**

- Rutherford 5
- Diabetic
- Hypertensive
- Poor Perfusion
  - TcpO2: 3mmHg
LimFlow 4
LimFlow 4 Follow-up: Wound Healing

Pre-Op

Day 7

Day 25

Day 63
LimFlow 4 Follow-up: Wound Healing

Day 112

Day 150

Day 388

Wound healed
Graft Occluded Day 240

TcpO2 values remaining high despite graft occlusion

Day 423
TcpO2 = 75
Abscess Forefoot

Occluded Fem-Pop Bypass with Peroneal Runoff
Previous DEB to Peroneal x 2

Rest Pain, bordering Acute Limb Ischaemia
IVUS within Covered Stent showing full expansion till 5mm

5mm self expanding covered stent
Wound Bleeding
There is perfusion after the graft occludes...
July 2014

Symptom Free
Persistent AVF signal even with graft occlusion

7 months of primary patency
8 months for wound healing

28 July 2014
TCPO2 = 24

7 Oct 2015
TCPO2 > 50
3 months of primary patency
8 months of secondary patency
5 months for wound healing

Symptom Free
Persistent AVF signal even with graft occlusion

TCPO2 = 75
22 Oct 2015

TCPO2 = 19
28 Aug 2014
1.5 months of primary patency

5+ months of secondary patency

Wound granulating
Persistent AVF signal even with graft occlusion
HYPOTHESIS

Pressurization of Venous Bed allows collaterals to reach CAPILLARY BED.

Persistent collateral circulation after occlusion of PBDVA

Courtesy Pramook
How can we further apply this???
Potentially Applicable to Any Angiosome?

Before

Post Tibial Artery is occluded

No lateral plantar target

Flow to Lateral Plantar Artery can only be achieved through plantar loop technique
Potentially Applicable to Any Angiosome?

Post Tibial Artery is recanalised Subintimally with rentry into Posterior tibial Vein. 4mm INPACT DEB

Wound Healed with skin graft

Flow from Post.Tibial Artery to Post.Tibial Vein
Surveillance?
Impending Occlusion
3rd Nov 2014

Flow rate
90 mls/min

Graft Occlusion and re-intervention
2nd Dec 2014

Graft Patent
12th Mar 2015
DEB Assisted Patency

564 Days of Patency from procedure date

15/09/14  07/01/16
Restenosis after DEB

18/05/15

207 Days

10/12/15

30% ISR
<table>
<thead>
<tr>
<th>6 Month Clinical Endpoint</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
<table>
<thead>
<tr>
<th>12 Month Clinical Endpoint Singapore</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>1/3</td>
<td>33%</td>
</tr>
<tr>
<td>Persistent Doppler signal despite graft occlusion</td>
<td>3/3</td>
<td>100%</td>
</tr>
</tbody>
</table>
Summary of Experience – Objective Measurement of Perfusion with TCPO2

Patient #1

Patient #2

Patient #3

Patient #4

Patient #5

Patient #6
Next Generation Improvements

- Balloon Mounted Venous Catheter for Ultrasound Guided Crossing
- Low Profile 4F OTW Forward Cutting Valvulotome
- Tapered Balloon Mounted Covered Stent
- Self Expanding Covered Extension Stents
Lessons Learnt

• Case Selection
  • Preserved Heart Function
  • No severe foot infection

• Case Procedure
  • Not your standard angioplasty. Must be patient. Next generation devices on the way
  • Venous access is crucial. Use Fluoro Guided or US Guided
  • Wires in the foot veins can be challenging especially with the presence of valves. Loop 14” or 18” with support catheter to cross valves

• Post Op Care
  • Wound healing takes longer than usual but it will happen
  • Nurse patient with elevated legs for 2 weeks to reduce swelling
  • Beware of heel pressure sores
  • DAPT and daily Clexane
Summary

- Percutaneous DVA (LimFlow) is an emerging way to treat “End Stage CLI”
- Safe, effective but there is a learning curve
- Potentially applicable to any Angiosome that cannot be opened via Conventional Techniques
- Sustained elevation of TCPO2 after graft occluded is surprising and has possible benefits
- Evidence is emerging
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