DEEP VEIN ARTERIALIZATION EXPERIENCE WITH THE LIMFLOW PROCEDURE

Daniel Clair, MD
Chair, Department of Surgery

CLI Intervention & the “No Option” Segment

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. No Option Patients represent 14-20% of CLI population

Disrupting the March to Amputation

Mortality Rates Post-Amputation

- 6 out of 10 patients with a PAD/Diabetes combination will be dead one-year after amputation
- 5-year survival rate post amputation is similar to that of pancreatic cancer

No Diabetes/PAD
With Diabetes
With Diabetes & PAD

NO REVASCULARIZATION OPTIONS

- A small but significant minority of patients with vascular disease have no reasonable target distally
- This patient group is increasing as DM, ESRD, and elderly population are increasing
- For these individuals we seek an option to retain limbs
- Venous arterialization may fill this need

NEW REVASCULARIZATION OPTION

- DVA initially proposed by Halstead in 1921
- Primarily performed as a surgical reconstruction and not always accompanied by valvular destruction
- Leaves patients with significant swelling
- Not always successful patency
- Limb salvage rates in reports at 70-80%

The pDVA 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

Key Procedure Steps
Pedal Arch Reconstruction

Push Valvulotome:
Designed to maximize outflow by rendering vein valves incompetent

Key Procedure Steps
Percutaneous Bypass Creation

Covered Stents:
Conical and straight covered stents to maximize outflow to the foot

The pDVA quick overview
Safe, Reproducible, fully Percutaneous Foot Perfusion

LimFlow Clinical Example: Restored Perfusion*

PRE-LIMFLOW
34 WEEKS POST-LIMFLOW
400 DAYS post-LimFlow

LimFlow Clinical Example: Wound Healing*

PRE-LIMFLOW
34 WEEKS POST-LIMFLOW
400 DAYS post-LimFlow

Pilot Study – 7 “No-Option” CLI patients

Wound Healing – example 2*

PRE-LIMFLOW
2 Months post-LimFlow
3 Months post-LimFlow

PRE-LIMFLOW
2 Months post-LimFlow
3 Months post-LimFlow

Wound Healing – example 2*

PRE-LIMFLOW
2 Months post-LimFlow
3 Months post-LimFlow

PRE-LIMFLOW
2 Months post-LimFlow
3 Months post-LimFlow

Pilot Study – 7 “No-Option” CLI patients

<table>
<thead>
<tr>
<th>Procedure (Demographics)</th>
<th>Results - Primary Endpoints (at 30 Days)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Characteristics</td>
<td>100%</td>
</tr>
<tr>
<td>Survival</td>
<td>100%</td>
</tr>
<tr>
<td>Technical Success</td>
<td>100%</td>
</tr>
</tbody>
</table>

* Major complications: two non-ST, non-procedure-related elevated MIs; one patient developed spontaneous retroperitoneal bleeding 8 weeks post-procedure and was managed conservatively after cessation of anticoagulation.
# three procedure-unrelated deaths within 12 months: 2 patients died of pneumonia at 6 and 8 months, respectively; 1 patient had a fatal MI at 7 months following above-the-knee amputation.

† LimFlow Clinical Example: Restored Perfusion

LimFlow Clinical Example: Wound Healing

LimFlow Patient #5

* Videos courtesy of Dr. S. Kum, Changi Hospital, Singapore

* Pictures courtesy of Dr. M. Sapoval, HEGP, France

5 Months post-LimFlow

6.8 Months post-LimFlow

1 Month post-LimFlow
Pilot Study – 12 months Endpoints

- 57% Complete Wound Healing
- 86% Limb Salvage
- 71% Perfusion - TcPO2

12 Month Endpoints*

* Data Source: Journal of Endovascular Therapy website – July 2017

OUS Clinical Experience Patient Demographics

- 43 "No option" patients
- Mean age 68 y.o. (range 36-94 y.o.)
- Majority of male patients (61% male, 39% female)
- 81% of the patients were diabetic
- As of today 22% of patients were on dialysis

Rutherford classification

- Class 4
- Class 5
- Class 6

First 43 LimFlow Patients
Survival and Amputation Free
Kaplan-Meier

Clinical Summary – all patients to date

- 71% patients alive and amputation free 6 months after pDVA

LimFlow pDVA Clinical Program

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

A Case

73 y/o woman with gangrenous toes
Felt to have no revascularization options

Offered amputation

Diminutive calf vessels

No adequate vein
WHERE DO WE STAND?

- Feasibility trial ongoing
  - PI Jihad Mustapha
  - 7/10 patients in the US enrolled
  - 3 sites
- Increasing experience OUS
- Will clearly enhance what we can offer for patients with no revascularization options