Percutaneous Deep Venous Arterialization - 1 year Results of the LimFlow Procedure

Steven Kum MD
Vascular & Endovascular Surgeon
Director of Vascular Services
Changi General Hospital
Singapore
Disclosure

• Workshop/Speaker Honourarium: Medtronic, Cook, Biotronik, Abbott, Straub Medical, Boston Scientific, Bard

• Consultancy: MdStart/Limflow, Acelity, Abbott, Boston Scientific

• The use of off label devices in this presentation should not be construed as an endorsement

• Minor equity for method and device patents related to LimFlow
Surgical DVA
Venous Arterialization for Salvage of Critically Ischaemic Limbs: a Systematic Review and Meta-Analysis

M. A. Schreve¹, C. G. Vos¹, A.C. Vahl², J.P.P.M. de Vries³, S. Kum⁴, G.J. de Borst⁵, Ç. Ünlü¹,

¹Department of Surgery, Noordwest Ziekenhuisgroep, Alkmaar, The Netherlands
²Department of Surgery, OUZ, Utrecht, The Netherlands
³Department of Surgery, St Elisabeth, Tilburg, The Netherlands
⁴Department of Surgery, CHUV, Lausanne, Switzerland
⁵Department fo Surgery, UNMC, Omaha, Nebraska

Pooled Limb Salvage 75% @ 1 year (7 studies)
Patency of the venous arterializations 59%-71% at one year (6 studies)
30 day Mortality 0 to 10% (12 studies)
Survival 54 to 100% with a mean follow-up ranging from 5 to 60 months (10 studies)
Concept of LimFlow

- ARTERY
- VEIN
- Venous collateral
- Valves
- CAPILLARY BED
Tibial CTO
Desert Foot
Post Intervention

22 JUNE

5 AUG
Day 150
Wound healed

Pre Procedure

Day 240
Graft Occluded
Day 240

2 years

LimFlow No. 4

Patient #4

TopO2 (mmHg)

Time (days)

0 100 200 300 400 500 600 700

0 10 20 30 40 50 60 70

Graph showing the progression of TopO2 over time.
LimFlow No. 3

7 months of primary patency

8 months for wound healing

28 July 2014

TCPO2 = 24

Symptom Free

Persistent AVF signal even with graft occlusion

7 Oct 2015

TCPO2 > 50
HYPOTHESIS

Pressurization of Venous Bed allows collaterals to reach CAPILLARY BED

Persistent collateral circulation after occlusion of PBDVA

Courtesy Pramook
Summary of Experience – Primary Endpoints

- Pilot study 7 patient, No Option CLI
- 100% DM, 100% R5/6(57% R6), 6/7 SVS WiFi High Risk
- Median follow-up 619 days (171-964 days)
- No 30 day Deaths
- No 30 day MALE, 2 x myocardial leaks treated medically
Complete Wound Healing
- 4/7 (57.1%) at 6 months
- 5/7 (71.4%) at 12 months
- Median healing time of 138 days (95% CI; 84-192 d)

Median Post-Procedural Peak TCPO2
- 61.5 mmHg compared to pre-procedure level of 8 mmHg (p=0.046)

Limb Salvage
- 85.7% at 6 months
- 68.6% at 12 months

Technical success = 100%
Summary of Experience - Angiographic

LimFlow No. 5

LimFlow No. 3
Summary of Experience –
Objective Measurement of Perfusion with TCPO2
Can we apply this to not so end stage patients?
Heel Gangrene non healing for 1 month despite HBOT

Small plantar arch vessels
28 MAY
10 JUNE
13 JULY
17 AUG

Healed

114 Days

19 SEP
Some of the European cases..
Hôpital Européen Georges-Pompidou (HEGP), Paris

Marc Saproval
Constantino Del Giudice
Tristan Mirault

Pre-procedure

5 Month

7 months Healed

LimFlow
Noordwest Ziekenhuisgroep, Alkmaar, The Netherlands

Michel Schreve
Cagdas

Pre Procedure

1 month

6 months
Humanitas Gavazzeni
Bergamo, Italy

Roberto Ferrerasi

LimFlow
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
• CE Mark achieved Oct 2016. FDA Feasibility study with Jihad Mustapha 1st quarter 2017
Thank you!

steven_kum@cgh.com.sg
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