

## The Value Of High-Pressure PTA Balloons And Long-Term Results Of pDVA

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### Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

<p><b>Affiliation/Financial Relationship</b></p> <ul style="list-style-type: none"> <li>• <b>Research Support</b></li> <li>• <b>Consulting Fees/Honoraria</b></li> <li>• <b>Advisory Board</b></li> <li>• <b>Equity</b></li> </ul>	<p><b>Company</b></p> <ul style="list-style-type: none"> <li>• Boston Scientific, LimFlow/Inari</li> <li>• LimFlow/Inari, Acelity, Abbott Vascular, Boston Scientific, Orbus Neich, Bypass Solutions, PEDRA, Xeltis</li> <li>• Abbott, Boston Scientific, Xeltis, LimFlow/Inari, Fastwave, Corflow, VCD, Bypass Solutions, Protexa</li> <li>• LimFlow/Inari, Mercator, Cagent, PEDRA, Xeltis, Fastwave, Corflow, VCD, Bypass Solutions, Protexa, R3</li> </ul>
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### The Problem caused by Calcium

**Transmission Failure**  
Big Artery Disease (BAD)  
(eg Iliac to DP, Lat Plantar)

- Balloon passage
- Recoil
- Dissection

**Distribution Failure**  
Small Artery Disease (SAD)  
(eg Plantar arch, metatarsal, digital)

- No Outflow is "Desert foot"



Ferrero R, Mauri G, Losordo D, Tardif N, Brancaccio D, Carramegli C, Neri L. J Cardiovasc Surg (Torino). 2018 Oct;59(5):655-664. doi: 10.23736/S0021-9559-18-10572-6. Epub 2018 May 22.

### Transmission - Vessel Radius/Diameter affects Flow/Perfusion


**Volume flow in Arterial Segments – Healthy subjects**

- 60 patients
- Doppler Volume flow analysis (ml/min) of flow in separate arterial segments

Segment	Flow (ml/min)
CFA	434
SFA	172
Pop Artery	92
Dorsalis Pedis	12
Plantar Artery	12

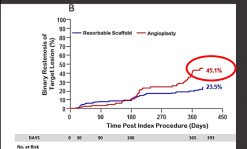
$$F = \frac{\Delta P \pi r^4}{8L\eta}$$

flow (F), pressure gradient (ΔP), tube radius (r), tube length (L), fluid viscosity (η)



Liang H. Doppler Flow Measurement of Lower Extremity Arteries Adjusted by Pulsatility Index. Adv Anesth. 2021; 2021:1024512. doi: 10.2147/AA.S217062.

### Acute results in POBA arm of Life BTK are poor



Time Post Index Procedure (Days)	Resectable Scaffold	Angioplasty
0	0	0
30	~10	~10
100	~20	~20
270	~30	~30
360	~40	~30
400	~45	~30

	Total (N=28) (n=27)	Resectable Scaffold (N=17) (n=17)	Angioplasty (N=11) (n=10)	Difference (95% CI)
<b>Final Diameter stenosis &lt;30%</b>	22/25 (81.2)	16/17 (94.1)	6/10 (60.0)	23.3 (19.1, 27.4)

**POBA Arm (Angio and DUS Core Lab)**

- Lesion length 44.8 ± 29.1mm
- Only 73% had < 30% stenosis after POBA ie **27% had residual stenosis ≥ 30%**
- Patency at 12 months was only 55% (PSVR 2.0)

### Angiographic Patency for conventional POBA is poor

- 58 CLI patients, 77 infra-popliteal arteries
- R5 = 74%
- Mean LL = 180 mm, Occlusions = 65%
- **3 month Angiographic Patency = 31.2%** (Restenosis >50% = 68.8%)
- **Reintervention = 50% @ 3 months**
- Clinical improvement<sup>1</sup> = 76% @ 3 months

PERIPHERAL VASCULAR DISEASE

Original Studies

Angiographic Patency and Clinical Outcome After Balloon-Angioplasty for Extensive Infrapopliteal Arterial Disease

Angelo Di Biase<sup>1,2</sup>, et al. JACC Cardiovasc Interv. 2018;11(12):2115-2124.

<sup>1</sup> clinical improvement = marked reduction of ulcer-size or rest pain

Schmidt A, Ulrich M, Wenzel B, Kneifing C, Baumbach Y, Baurigk S, Bortone S, Krasniqi M, Verroca RL, Kum S, Schmitt D. Angiographic patency and clinical outcome after balloon-angioplasty for extensive infrapopliteal arterial disease. Catheter Cardiovasc Interv. 2010 Dec 1;73(7):1047-54. doi: 10.1002/ccd.22658. PMID: 20518006.

### Semi Compliant vs NC Balloons

**Vessel Recoil**  
→ Poor lumen gain

**Excessive Vessel Stretch**  
→ Dissections  
→ Unwanted vessel injury

With an increase in pressure, a semi-compliant balloon will undergo a greater amount of stretch than a non-compliant balloon. Semi-compliant balloons will undergo a greater amount of stretch than non-compliant balloons.

• Semi-Compliant = 10-15% growth within the working range when inflated  
• Non-Compliant = 0-5% growth within the working range when inflated

**Semi-Compliant Angioplasty**  
Hemoglobin severed lesion  
Less dilating force at lesion

**Non-Compliant Angioplasty**  
Shape retention  
Greater dilating force at lesion

### CGH JADE Registry

- 20 consecutive patients 23 lesions 21 limbs, Diabetes 95%, Dialysis 20%
- R5 = 85.7%, R6 = 14.3%
- Mean LL = 374mm (>90% TASC C/D), Below the ankle = 52.2%
- Occlusions = 56.5%, Severe Calcification (PARC) = 78.3%
- Mean balloon diameter 2.9 mm, Bail out stent = 0%
- 6 months:**
  - AFS = 85.7%
  - FF-TLR = 94.7%
  - Limb Salvage = 90%
  - Complete wound healing = 66.7%
- 12 months:**
  - AFS = 85.7%
  - FF-TLR = 89.2%
  - Limb Salvage = 90%
  - Complete wound healing = 71.4%

High-pressure, non-compliant balloon angioplasty for long and calcified infrapopliteal and inframalleolar lesions is feasible.

Huizing E, Kum S, Adams G, Ferraresi R, de Vries JP, Unlü C. High-pressure, non-compliant balloon angioplasty for long and calcified infrapopliteal and inframalleolar lesions is feasible. *Int Angiol.* 2020 May 13. doi: 10.23736/0392-9590-20-04375-8. Epub ahead of print. PMID: 32401473.

### SGH JADE Registry

- 86 patients DM (94%) and Dialysis (38%)
- R5 = 91% and R6 = 9%
- 84% had moderate/severe vessel wall calcification.
- 90% had > = 1 TASC D tibial lesion
- 6-month tibial patency was 73%. (PSVR 2.5) FF-TLR was 91% @ 1 year, One-year AFS was 67%.**
- 47/66 (71%) patients had a clinical improvement of at least one Rutherford class at 6 months and 52/59 (88%) experienced complete wound healing at 12 months.

Tang TY, Lee SQW, Chan SL, Yap CJQ, Soon SKY, Chong TT, Choke ETC, Yan BPV. Utility of a novel high-pressure non-compliant balloon for tibial atherosclerotic lesions in Asian patients with chronic limb-threatening ischaemia. *Vasc.* 2020 Oct-6(6):475-482. doi: 10.1024/0301-1526/a000888. Epub 2020 Jul 22. PMID: 32693707.

### Trick : Popliteal Nerve block – Pain free HP NC POBA

JADE

### When does it not work? Subintimal crossing in calcified vessels, u need stents...

Recoil dissection despite 3 mm HP NC POBA → Bail out DES

11-March-2023 09:47:00:04  
ANGIOPLASTY EX08  
Fluoroscopy  
11-March-2023 16:38:10

LAD: 15.18 (RA: 0.95)  
RA: 0.95  
JPG2000(compressOnly)  
Images: 54/802  
Series: 54  
6 Feb 2023 16:38:10  
W: 37.00, H: 25.5

### What do we do about Distribution Failure?

Wound progressed to Gangrene + Cellulitis Over 6 months and referred for TADV

- June 2018 P/Lat Planter → Failed
- Aug 2018 DP/Planter → Failed
- Dec 2018 Retro Med Planter → Failed

### Arterialization of Arch via Medial Planter Vein

Conventional TADV LPV to ATV

Medial Planter TADV

POBA Medial Planter Vein

- 1 Month: TCPO2 19/33
- 2 Month
- 3 Month: TCPO2 69/53
- 5 Month
- 6 Month: TCPO2 92/74
- 18 Month: TCPO2 81/73

### Pilot Program with Long Term 5 year data (Interim results)

- Pilot program on LimFlow from a single centre
- We retrospectively analysed data from our centre on 25 patients between 2014 and 2024 with NOP CLTI performed with LimFlow device
  - Standardized procedure
  - Standardized wound care
  - 5 operators including 1 lead operator
- AFS, LS, Survival, Wound Healing (complete) data collected up to 5 years
- Perfusion data (more than 230 TCPO2 measurements) and wound healing data

### Healing rate

0-1 = no MAC  
2-3 = moderate MAC  
4-5 = severe MAC

Characteristic	Number (%)
Patients	25
Limbs	25
Men	11 (44.0)
Age, years	70.6 ± 11.4
Left limb	13 (52.0%)
Comorbidities	
Body mass index (kg/m <sup>2</sup> )	27.7 ± 4.6
Hypertension	24 (96.0)
Diabetes	22 (88.0)
Hyperlipidemia	25 (100.0)
Coronary artery disease	16 (64.0)
LVF	60 (65.6%)
Chronic kidney disease	11 (44.0)
Chronic liver disease	1 (4.0)
Stroke	1 (4.0)
Cerebrovascular accident	5 (20.0)
Smoking history*	8 (32.0)
Medication use	
Immunosuppressive	2 (8.0)
Statins	
A	1 (4.0)
B	17 (68.0)
C	6 (24.0)
NSAID risk rating	
High risk	21 (84.0)
Moderate risk	3 (12.0)
Low risk	1 (4.0)
SADM-MAC score*	
No MAC	2 (8.0)
Mild to MAC	6 (24.0)
Severe MAC	17 (68.0)

MAC = Medial artery calcification; NSAD = small artery disease

\*Continuous data are presented as mean ± SD or median (IQR)

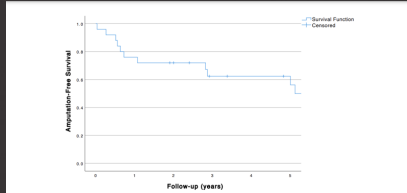
\*Categorical data are presented as number (%)

\*Items do not match because of missing values

Ferraresi R, Licci A, Ruzulio A, Lazzaroli F, Caminiti M, Minnello D, Casati A, Clerici G, Montero-Baker M, Mills J. A Novel scoring system for distal artery disease and Medial Arterial Calcification is strongly associated with Major Adverse Limb Events in Patients With Chronic Limb-Threatening Ischemia. J Endovasc Ther. 2021 Apr;28(2):194-207. doi: 10.1177/1526602820966308. Epub 2020 Oct 15. PMID: 33054496.

### Interim results

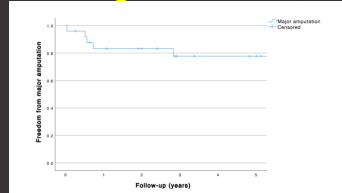
### AFS



**AFS**  
 1 year 76%  
 3 year 62%  
 5 year 56%

Amputation-free survival	0	1	2	3	4	5
Years	0	19	17	12	11	10
No. at risk	25	19	17	12	11	10
%	100	76.0	72.0	62.4	62.4	56.2

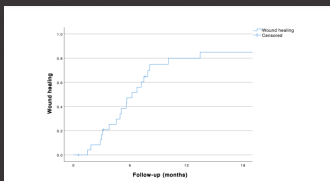
### Limb Salvage



**Limb Salvage**  
 1 year 83%  
 3 year 83%  
 5 year 78%

Freedom from major amputation	0	1	2	3	4	5
Years	0	19	17	12	11	10
No. at risk	25	19	17	12	11	10
%	100	83.3	83.3	77.7	77.7	77.7

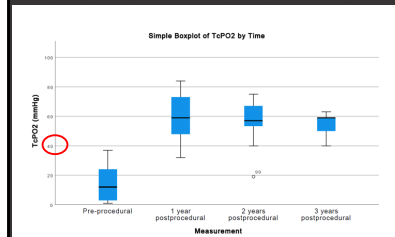
### Wound Healing (Complete)



**Complete Wound Healing**  
 0.5 year 47%  
 1 year 80%  
 1.5 year 85%

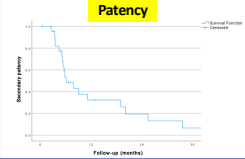
Wound healing	0	6	12	18
Months	0	12	4	3
No. at risk	25	12	4	3
%	0	47.2	79.9	84.8

### Perfusion – TCPO2

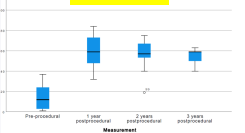


**TCPO2**  
 Pre 14mmHg  
 1 year 59mmHg  
 2 year 57mmHg  
 3 year 59mmHg  
 P = 0.01

### Patency

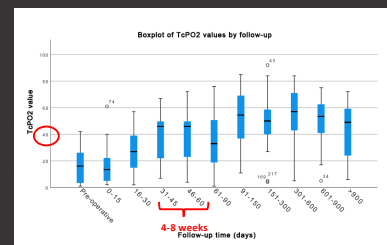


### TCPO2



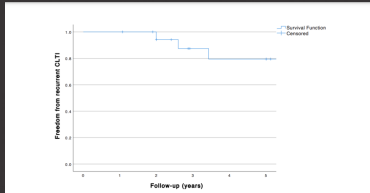
**TCPO2 stays elevated despite a drop in patency**

### Perfusion – TCPO2 with time



**4-8 weeks Follow-up time (days)**

### Freedom from Recurrent CLTI

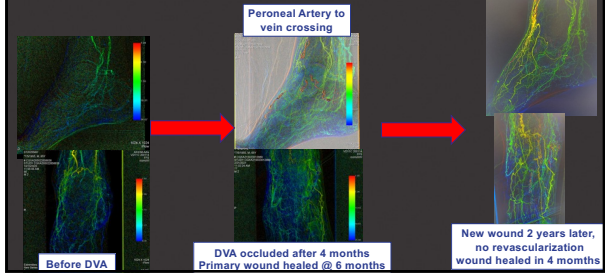


**FF – Recurent CLTI**  
 2 year 94%  
 3 year 84%  
 5 year 79%

Figure X. Freedom from recurrent CLTI

Years	0	1	2	3	4	5
No. at risk	25	18	16	11	10	8
%	100	100	94.1	84.4	79.4	79.4

### Persistent/Improved Perfusion



### Summary

- **Solutions for Transmission Failure**
  - Better balloon tech to achieve lumen gain
- **Solutions for Distribution Failure**
  - DVA
- Long term DVA with LimFlow show promising results and may prevent recurrent CLTI