CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 25-27 2018

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Hybrid arterialization of the foot veins in no-option patients with CLI

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Disclosure

Roberto Ferraresi, MD

I have the following potential conflicts of interest to report:

Consultant: ABBOTT, Asahi, Cook, MEDTRONIC, Shire, Astra Zeneca

Stock shareholder: Limflow

Our experience

Inclusion criteria

Patients

1. left ventricular ejection fraction > 30%, no heart failure history, no aortic stenosis
2. acceptable life expectancy
3. acceptation of the procedure expressed by the patient

Foot

CLI with tissue lesion:
- RTF 5-6, WIfI W1-2-3
- Extended and irrecoverable foot gangrene excluded

WIfI Ischemia grade 3:
- TcPO2 < 30 mmHg

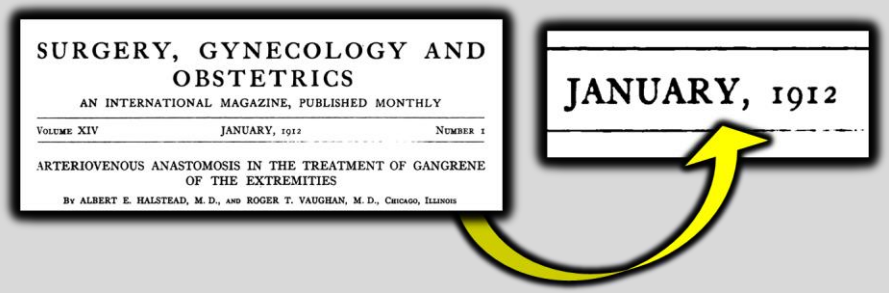
Absence of infection or infection completely removed by means of previous surgical and antibiotic treatment

Disease of the foot arteries considered not revascularizable by means of conventional angioplasty or distal bypass

Who is a no-option CLI patient?

Who is a no-option CLI patient?

The definition changes according to the available techniques in a certain era and place. 105 years ago every patient with supposed CLI was, by definition, a no-option patient. Due to this lack of effective treatments, many attempts of proximal surgical arteriovenous fistula were made, generally with poor results.


SURGERY, GYNECOLOGY AND OBSTETRICS

AN INTERNATIONAL MAGAZINE, PUBLISHED MONTHLY

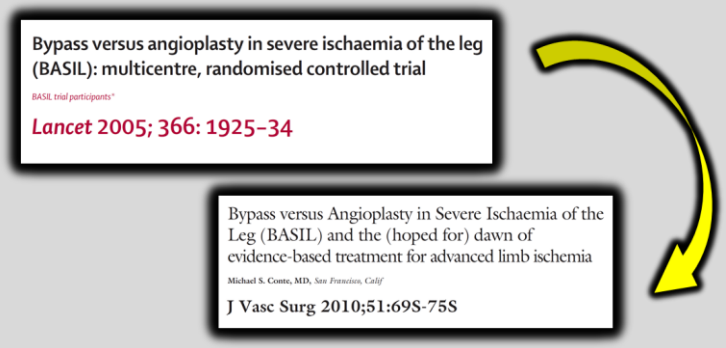
VOLUME XIV JANUARY, 1912 NUMBER 1

ARTERIOVENOUS ANASTOMOSIS IN THE TREATMENT OF GANGRENE OF THE EXTREMITIES

BY ALBERT E. HALSTEAD, M. D., AND ROGER T. VAUGHAN, M. D., CHICAGO, ILLINOIS

JANUARY, 1912

In 2005, in an audit of the BASIL trial sites, approximately 50% of all SLI patients were still considered not revascularizable by either surgery or angioplasty, and were treated conservatively


Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial

BASIL trial participants*

Lancet 2005; 366: 1925–34

Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) and the (hoped for) dawn of evidence-based treatment for advanced limb ischemia

Michael S. Conte, MD, *San Francisco, Calif*

J Vasc Surg 2010;51:69S-75S

We lack a consensus on the definition of no-option CLI patient!


April 2017
TcPO2 5 mmHg


SFA
DFA
5 cm
L: 1473
W: 2414

We considered no-option CLI patients only pts with SAD: small artery disease, the *"final failure of the foot artery distribution system"*.

No any artery was found in the foot able to be a target for distal angioplasty or bypass

Step-by-step technical strategy

1. Make a bypass on a distal vein
2. Destroy distal vein valves
3. Focalize blood to the wound
4. Make a “tension free” foot surgery
5. Wait for wound healing, fighting for patency, wound care & infection

1) Surgical bypass on medial marginal vein

In every case we have not any blood flow to the foot due to distal vein valves!

Step-by-step technical strategy

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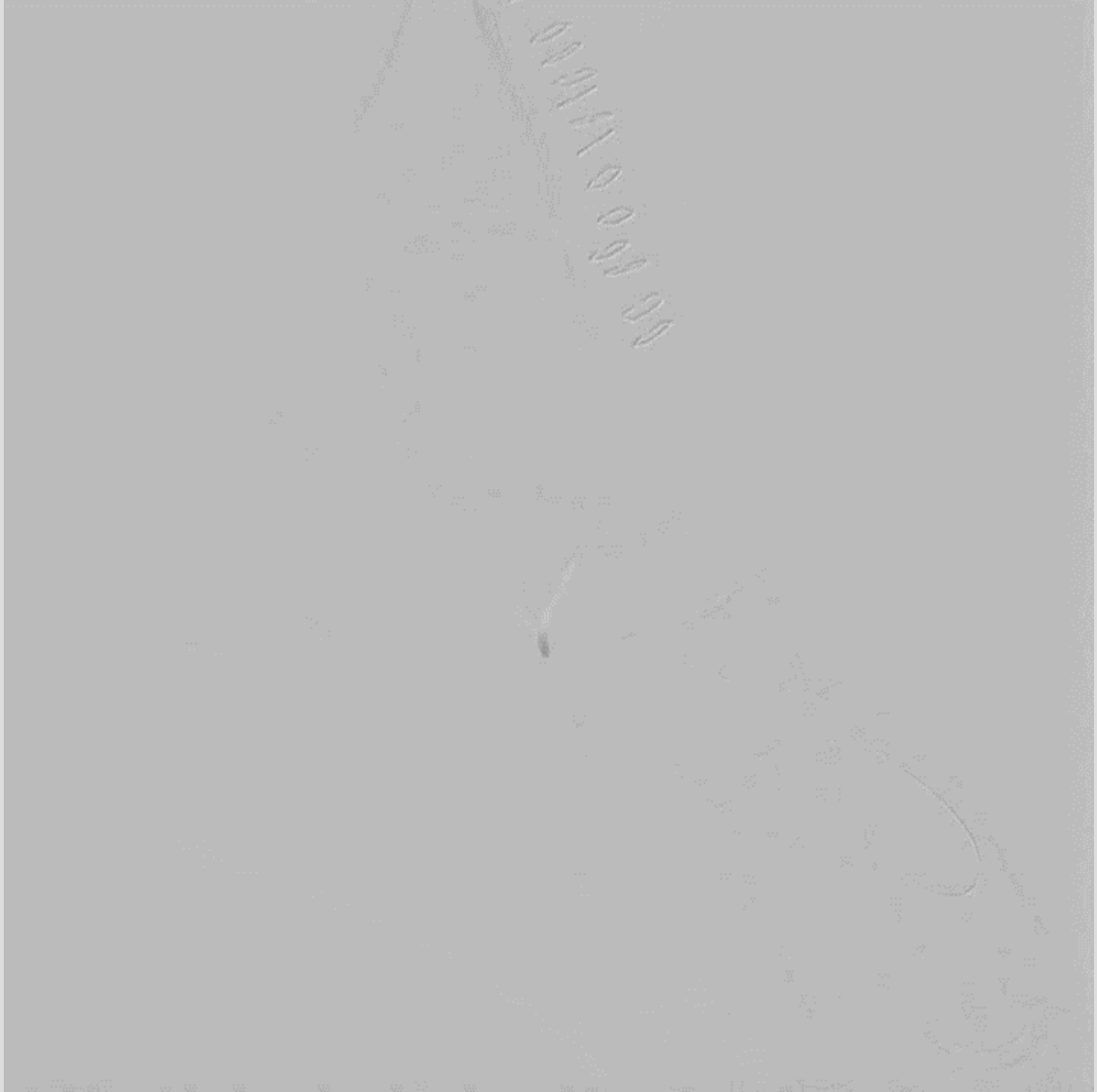
Dancing wire

POBA with (oversized) balloons



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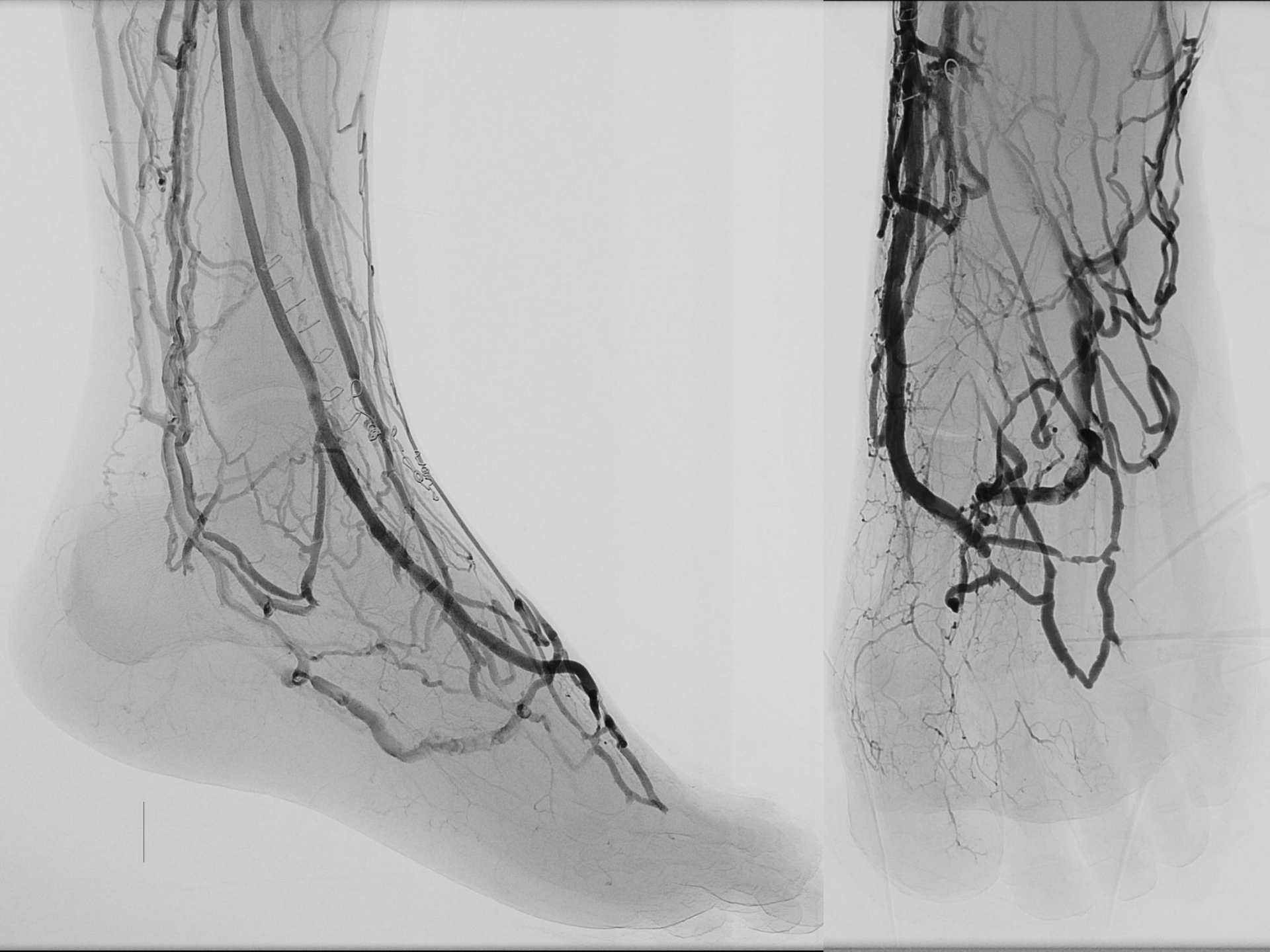

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Tension-free surgery

The foot is still ischemic: avoid any tension that could precipitate local necrosis

Step-by-step technical strategy

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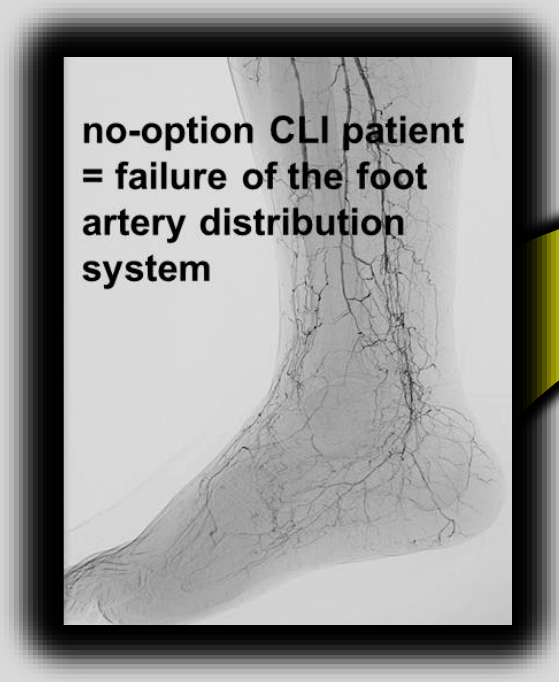
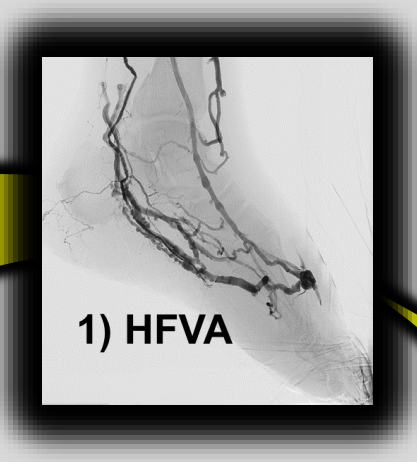




We have arterialized veins and a big wound, now we need the true hero of the drama: the remodeling of the vascular distribution system of the foot


TcPO2 5 mmHg
April 2017


Nov 2017


TcPO2 55 mmHg

Our experience

Population: 36 pts

Patients

	n	%
Age	69 ± 12 years	
Male sex	29	80%
Hypertension	33	91%
Diabetes mellitus	29	80%
Smoke	27	75%
CAD	19	52
COPD	2	5
CKD	12	33
ESRD (HD)	2	5
Neuropathy	18	50
Mean Follow up	10 ± 2 months	

Feet

	n	%
WIfI-Wound 1	4	11
WIfI-Wound 2	4	11
WIfI-Wound 3	28	77
WIfI-Ischemia 3	36	100
Rutherford 5	4	11
Rutherford 6	32	89
TcPO2 (mean ± DS)	6 ± 5.2 mmHg	

PAD Etiology

	n	%
Atherosclerosis	29	80
Buerger	5	14
Embolic	1	3
Popliteal entrapment	1	3

Our experience

Bypass

Prox anastomosis

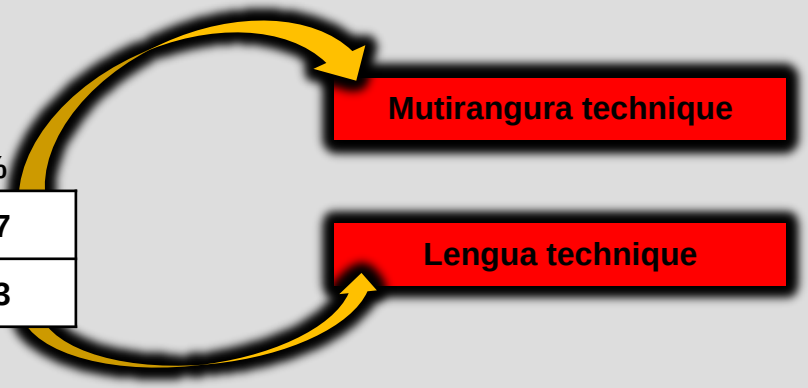
	n	%
CFA	4	11%
POP-P1	2	6%
POP-P3	30	83%

Type of graft

	n	%
GSV	26	72
Hep PTFE	7	20
Composite	3	8

Distal anastomosis

	n	%
Posterior tibial vein	17	47
Medial Marginal Vein	19	53



Our experience

Results: FU 10 ± 2 months

1° Limb salvage + wound healing

55% (20/36)

Minor amputations	n	%
No	1	3
Rays	5	14
TMT	9	25
Lisfranc	1	3
Chopart	4	10
Death	0	0

2° Limb salvage + not healing

14% (5/36)

Minor amputations	n	%
TMT	5	14
Death	1	3

3° Major amputation

31% (11/36)

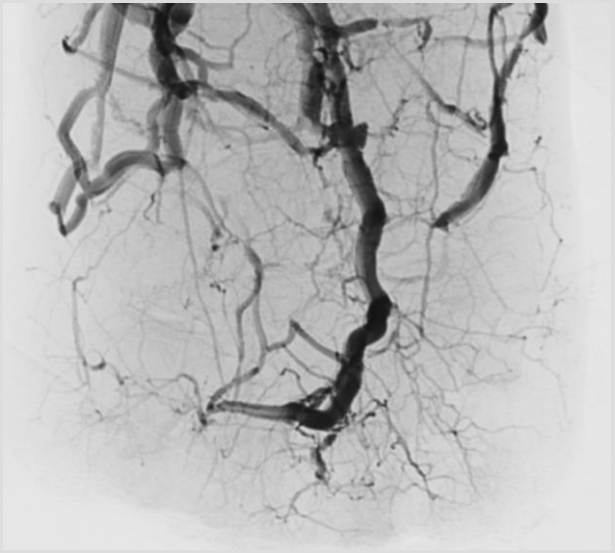
Major amputations	n	%
Above-the-knee	9	25
Below-the-knee	2	5
Infection-related	2	25
Death	0	0

Patient 2

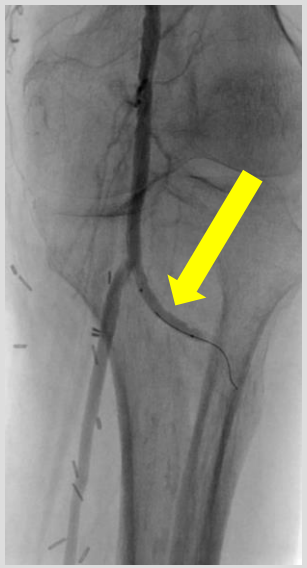
Baseline SAD patient

Immediately after HFVA

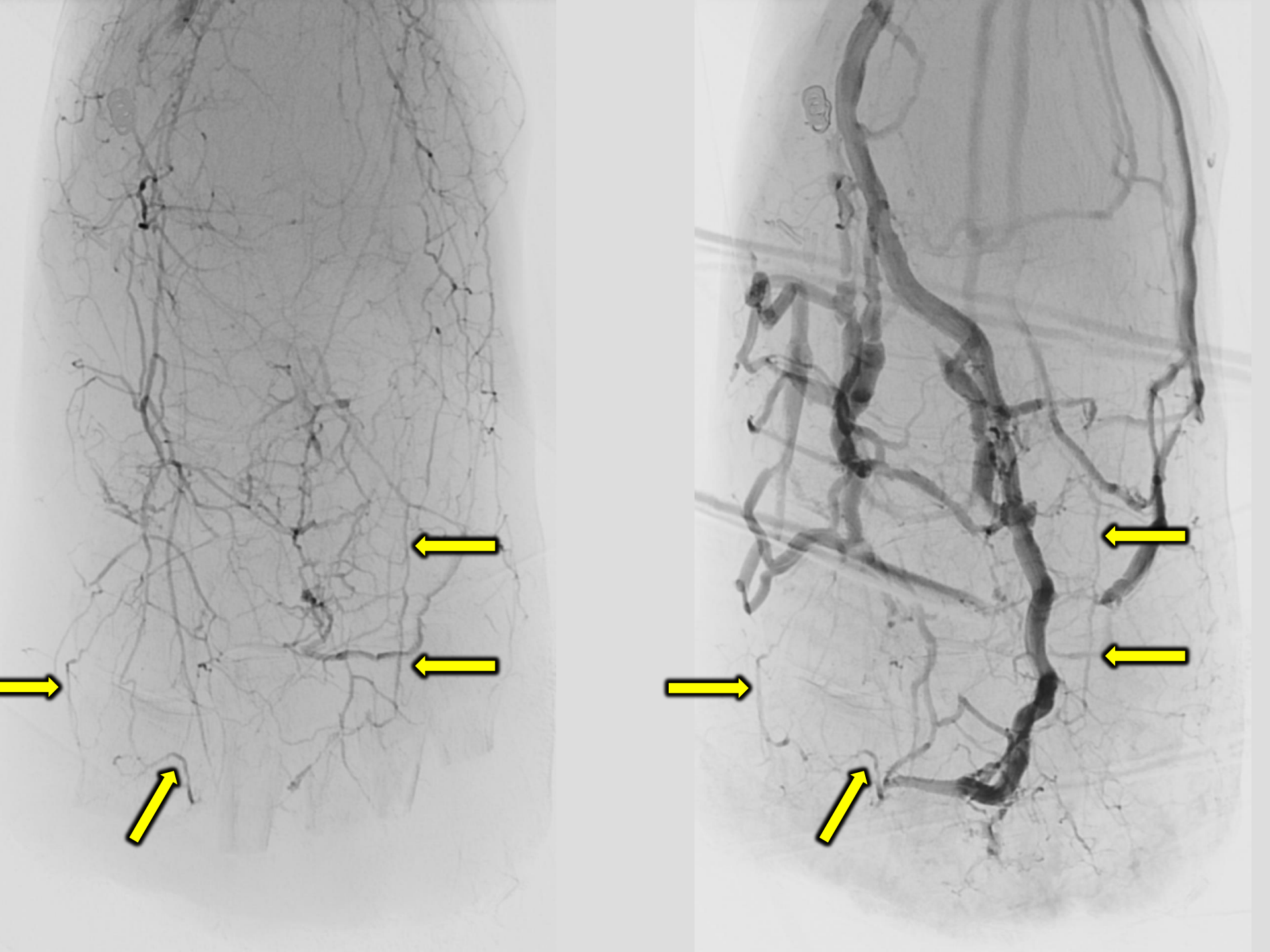
2 months after TMA



Occluded venous bypass: blood flow only in the old diseased artery system!



Occluded distal POP artery: blood flow only in the new venous bypass!



Is the arterialization of the venous system the last hope in "no option" patients with final failure of the arterial system?

Our experience

Results: FU 10 ± 2 months

1° Limb salvage + wound healing 55% (20/36)

Minor amputations	n	%
No	1	3
Rays	5	14
TMT	9	25
Lisfranc	1	3
Chopart	4	10
Death	0	0

2° Limb salvage + not healing 14% (5/36)

Minor amputations	n	%
TMT	5	14
Death	1	3

3° Major amputation 31% (11/36)

Major amputations	n	%
Above-the-knee	9	25
Below-the-knee	2	5
Infection-related	2	25
Death	0	3

I don't know!

We have seen very promising results in some patients, however we must clarify:

1. **Proper criteria of pts selection**
2. **Proper timing of the procedures**
3. **Standardization of a repeatable procedure**
4. **The true pathophysiology of the vascular system remodeling**