

Leaving Nothing Behind but an Open Artery
-
**Advanced Limb Salvage for Tibial Disease
in a South Asian Population**

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Changi
General Hospital

THE **VERVE** SYMPOSIUM
Visionary Endovascular and Vascular Education

L I N C

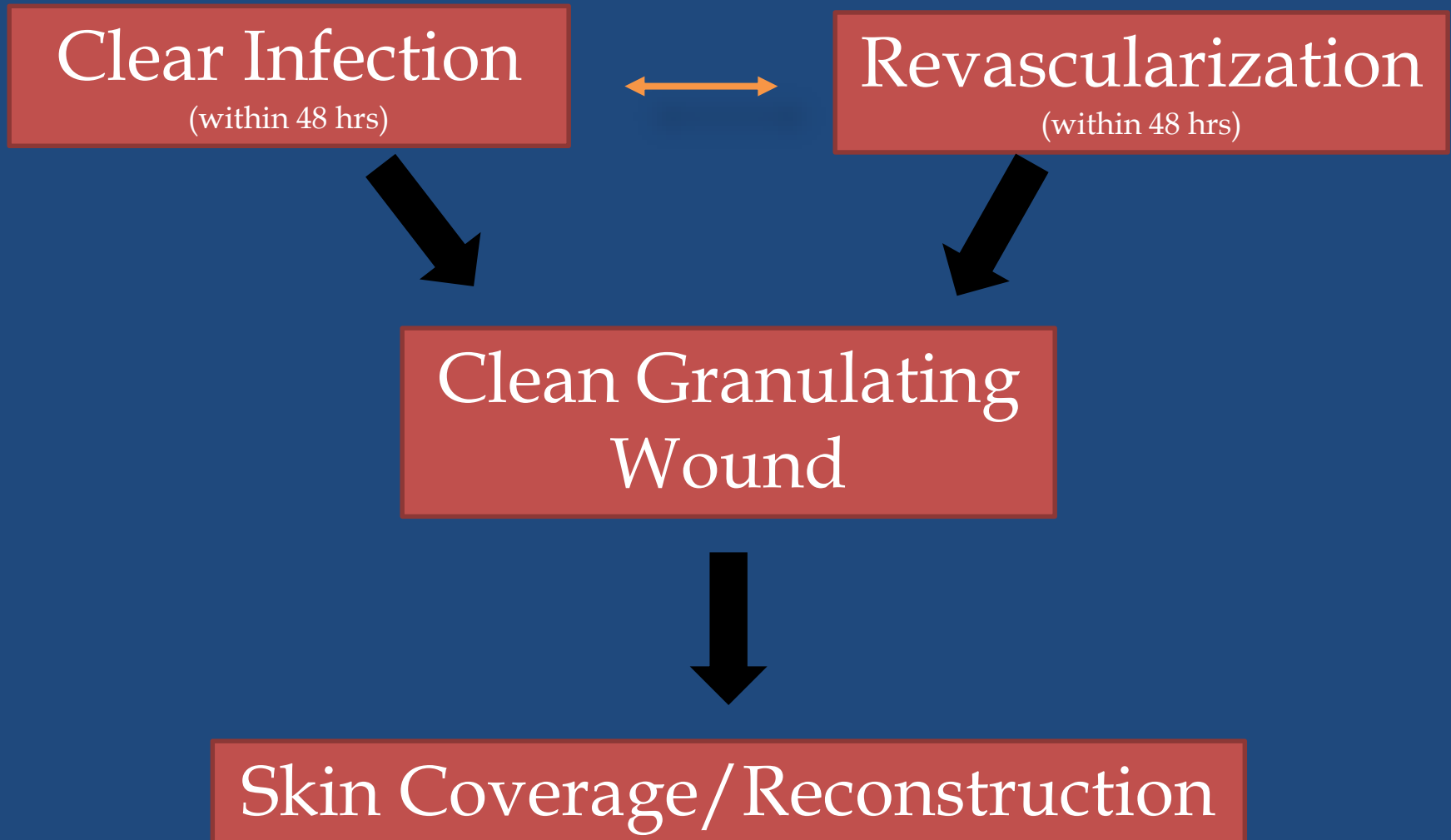


Changi
General Hospital

- 900 bed Tertiary Hospital
- 12.7 % of adults are diabetic
- On average of 1 CLI per day mostly due to Diabetes
- Vascular Team handles Revascularization and Wound Care/Reconstruction
- Simultaneous Revascularization and Soft Tissue work performed in Hybrid OR



All Diabetic Foot CLI are considered Emergencies



Challenges in S'pore

SMOKERS

DIABETICS

MIXED

Request ID: NRIC: S0113977J Date: 08 Jul 1950

Name Of Patient: ER PUAY HOON

US Doppler Arterial, Both Lower limbs

01-Jun-2012 Radiology BY CGH12229189701US01

RPID:

KEY: Soft plaque Calcification

RIGHT LEFT

Above the knee

Log arterial stenosis PSV ratio PSV (cm/s)

>50%	2:1	150-200
>70%	3:1	200-400
>90%	4:1	>400

COMMENTS: Technically difficult. The arteries are heavily calcified.

Changi General Hospital Department of Radiology

ARTERIAL ULTRASOUND - LOWER LIMB

Request ID: 001158499 Date: 08-Jul-2011

Name Of Patient: NAME: SUTAH BIE BIRAMAD

DOB: P1/01/1948

KEY: Soft plaque Calcification

RIGHT LEFT

Below the knee

Log arterial stenosis PSV ratio PSV (cm/s)

>50%	2:1	150-200
>70%	3:1	200-400
>90%	4:1	>400

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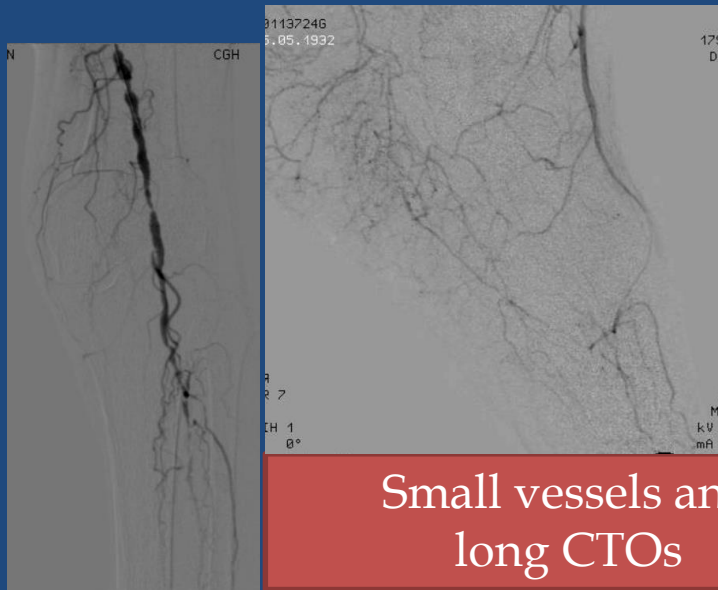
COMMENTS: Technically difficult. The arteries are heavily calcified.

Challenges Treating CLI in S'pore

Late presentation with severe tissue loss

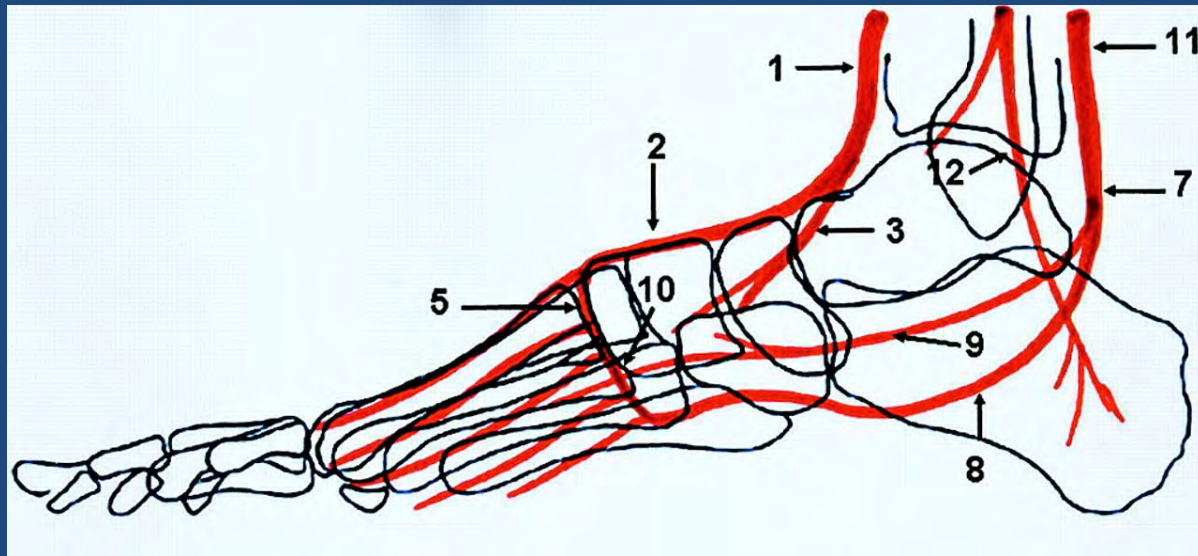


Wound spans multiple angiosomes



Small vessels and long CTOs

Plantar Arches are diseased in diabetics/renal failure



Angiosome Concept is even more important...

69
NR 6

LIH 1
R 0°
W 50 L 50
27.11.2012
15:53:27

180
DSA_E

HQ
DSA_E
MAG 1

kV 67
mA 10.8

cGy cm²
1424.30
min 43:31



Goals in Therapy for CLI

1°

Wound healing
before restenosis

2°

Early return to
meaningful walking
function with
freedom from
re-ulceration



**TAILORED
REVASCULARIZATION
ACCORDING TO
ANGIOSOME AND WOUND
BURDEN**

Endovascular CLI Strategy



R4
Rest pain



R5
Minor loss



R6
Major loss

Revasc ATK +/- BTK

Revasc ATK + BTK

Revasc ATK + BTK

Open **single**
Appropriate
Angiosome

Able to
open
Boundary
Angiosome
only

Open **multiple**
tibials especially if
high risk

- Wound across 2 angiosomes
- Renal failure
- Incomplete plantar arch
- Large wound burden eg TMA
- Non ambulatory status
- High surgical risk

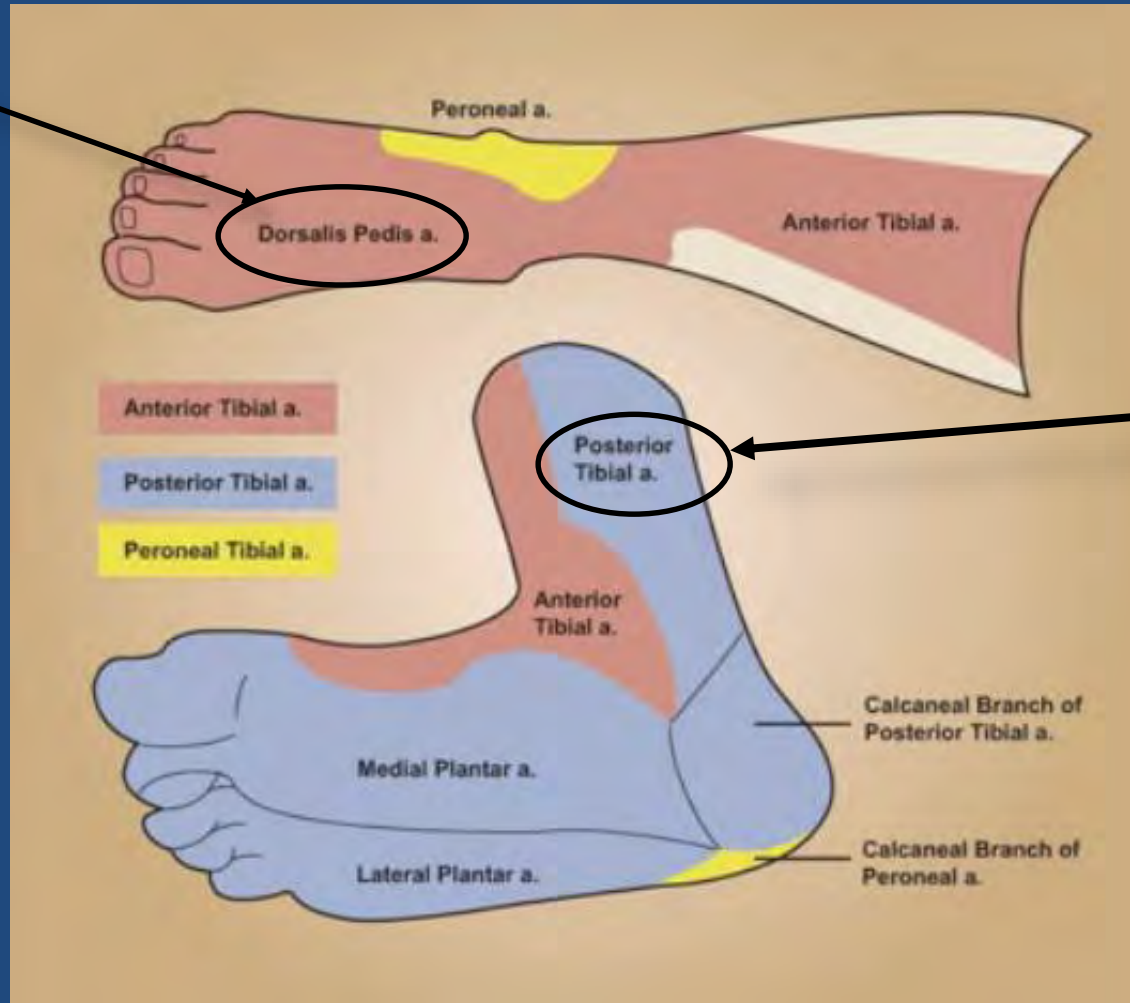
Early definitive
foot surgery
and skin
closure before
restenosis

Close follow-
up KIV Bypass

Consider **early**
bypass if wound
deteriorates or
unable to open
angiosome

Direct and Boundary Angiosomes

Direct Angiosome

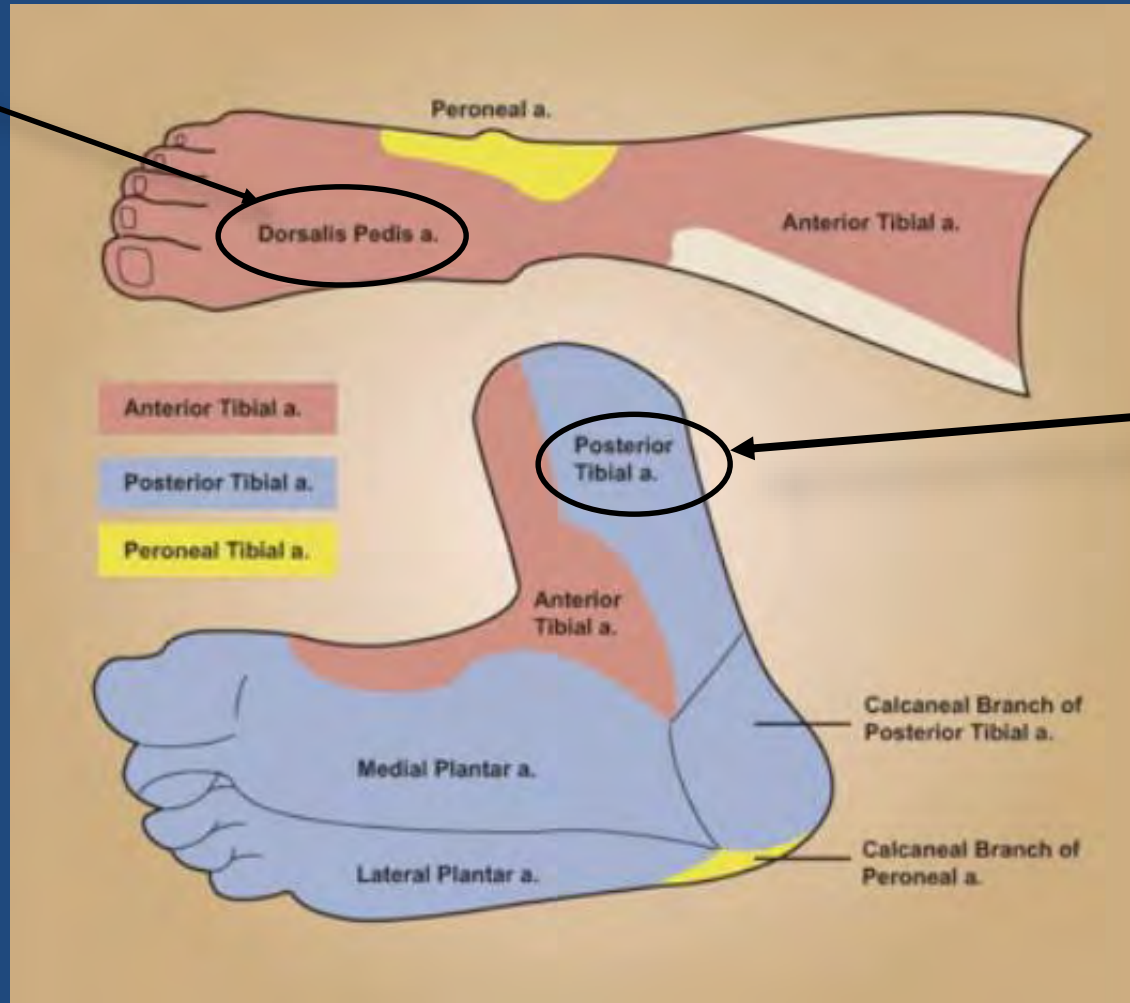


Boundary Angiosome



Direct and Boundary Angiosomes

Direct Angiosome



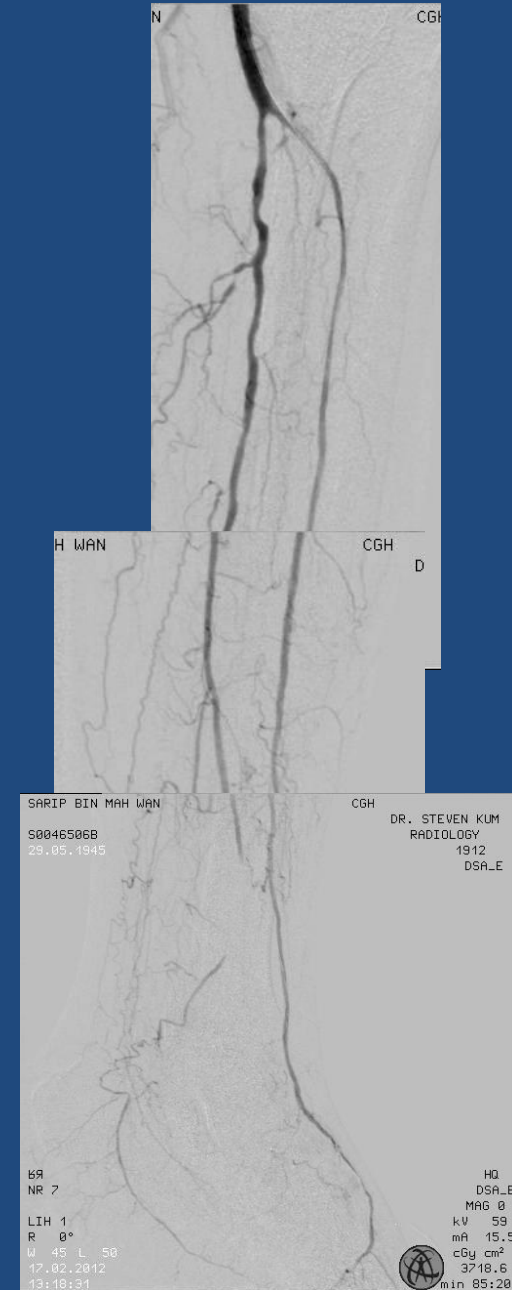
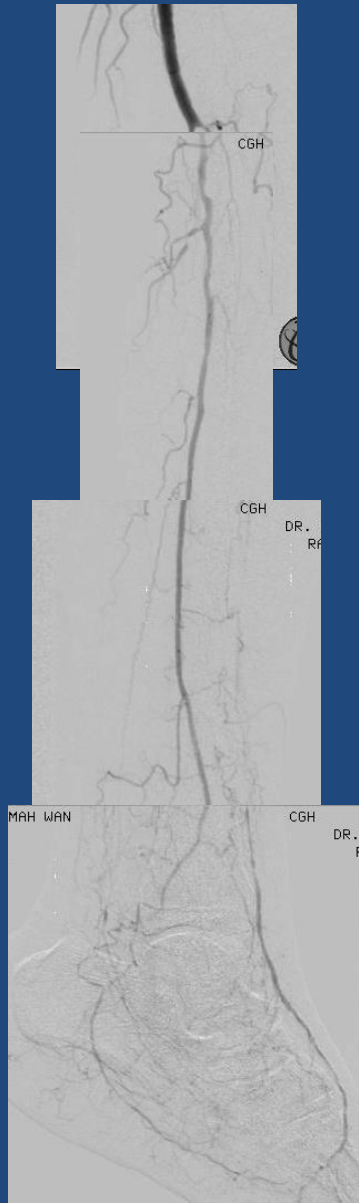
Direct Angiosome

What has changed our practice

1. Techniques in crossing lesions
2. Endovascular Adjuncts
3. Aggressive Wound Care

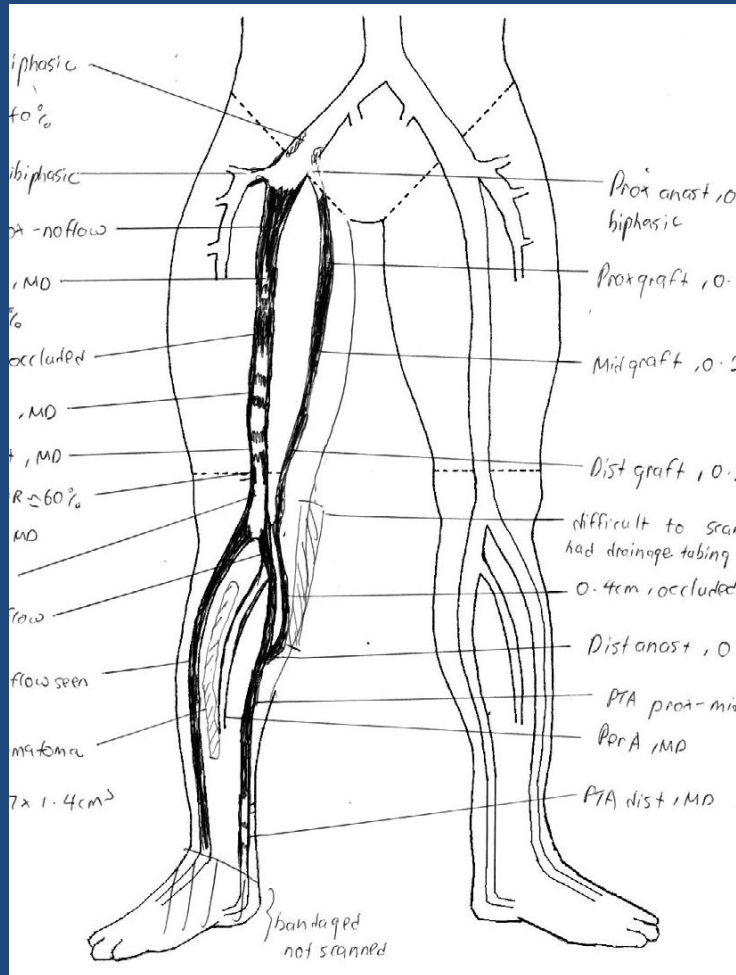
RETROGRADE TECHNIQUES TO CROSS LESIONS

Retrograde DP Puncture under Fluoro



Retrograde Techniques to cross lesions

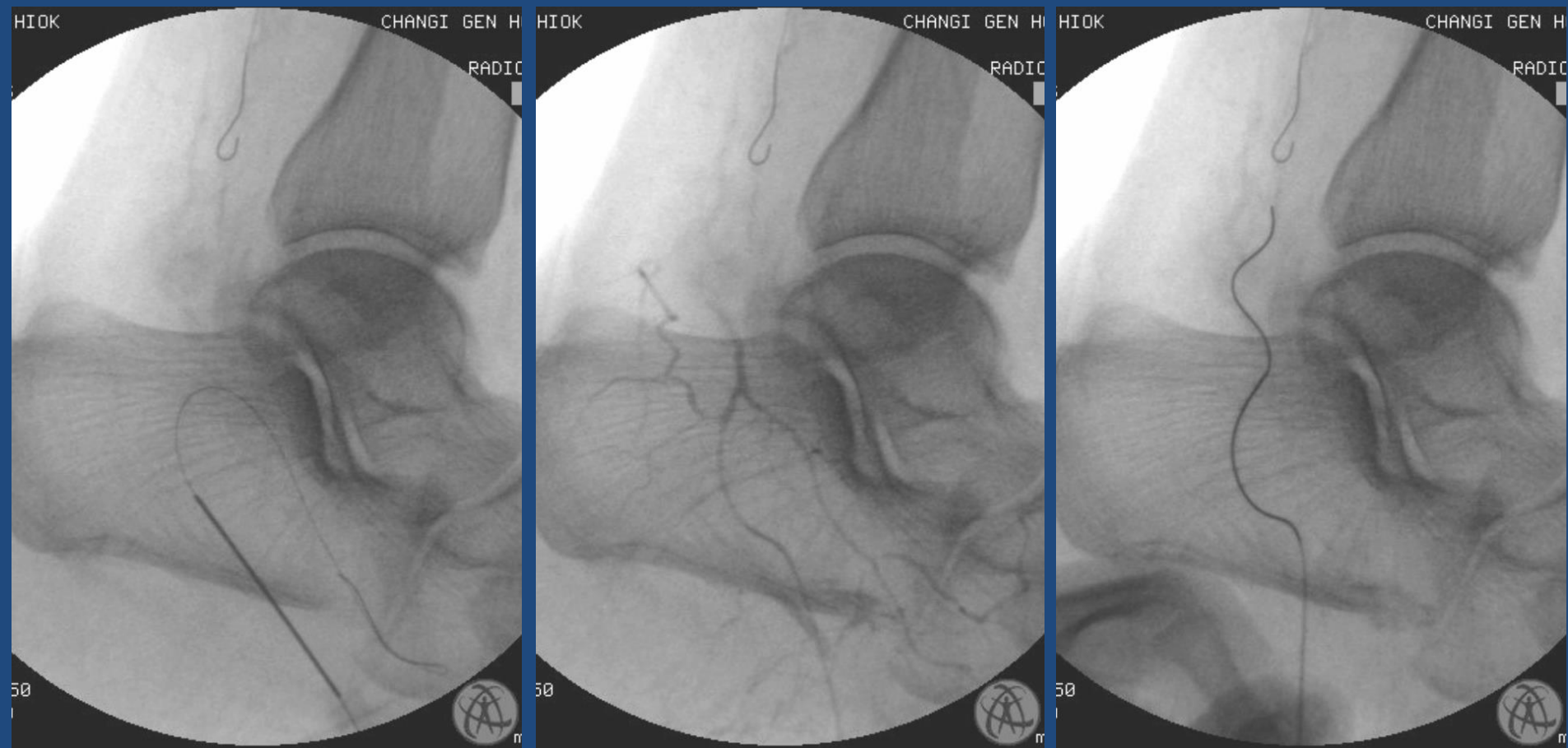
Renal Failure
 Occluded Fem-PT
 bypass



Retrograde PT



Retrograde Lateral Plantar

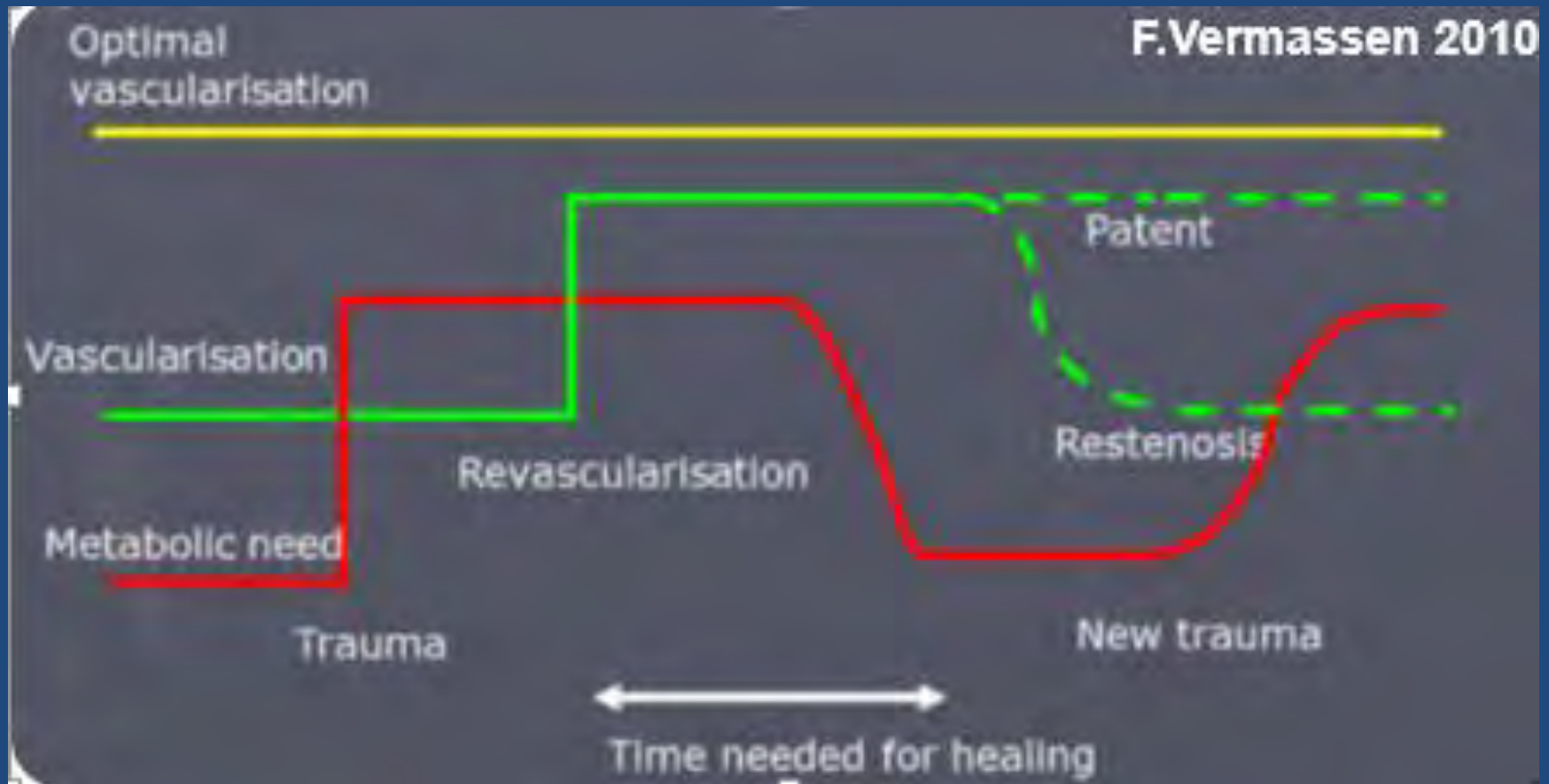


Retrograde Lateral Plantar



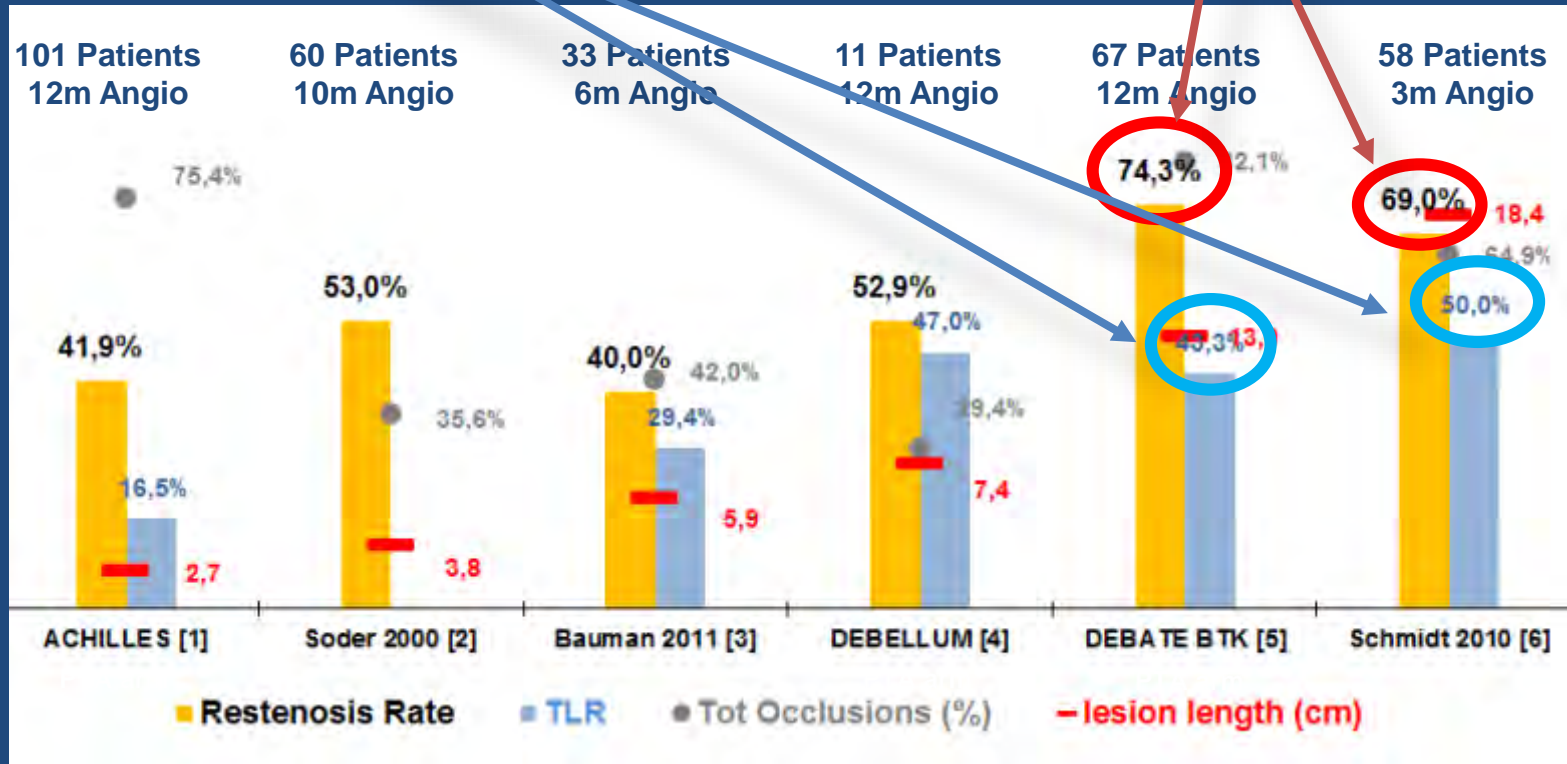
ENDOVASCULAR ADJUNCTS

The CLI Roller-Coaster



BTK TLR Rates

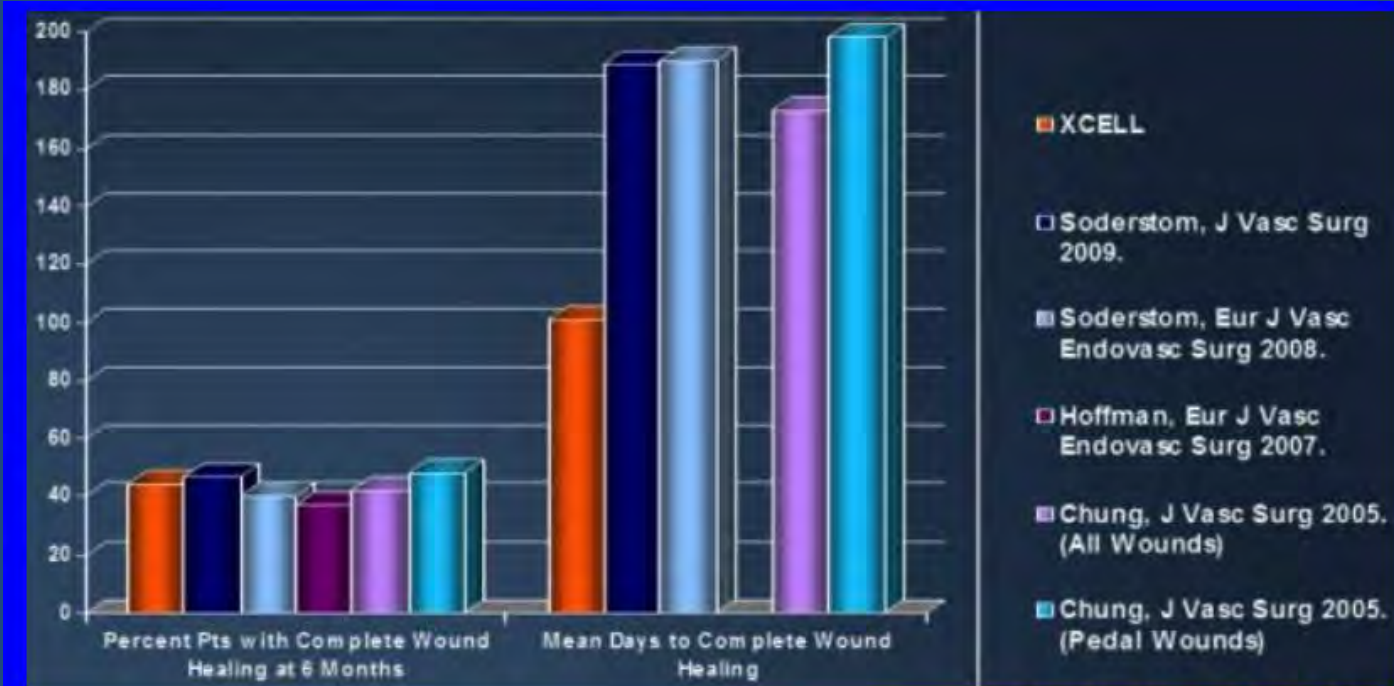
BTK Restenosis Rates



1. D.Scheinert, J Am Coll Cardiol 2012;60:2290-5)
2. H.K.Soder, J Vasc Interv Radiol 2000; 11:1021-1031
3. F. Baumann, J Vasc Interv Radiol 2011; 22:1665-1673
4. F.Fanelli, J Endovasc Ther. 2012;19:571-580
5. F.Liistro, TCT 2012 oral presentation
6. A.Schmidt, Catheter Cardiovasc Interv. 2010 Dec 1;76(7):1047-54

Wound Healing in CLI

Only 1/2 of the patients have complete healing at 6 months after bypass or PTA/stent for Rutherford 5/6 lesions.



Is Patency Important in CLI

Patency important for wound healing

- makes healing faster and healing rates higher
- Protects foot against recurrent ulcerations

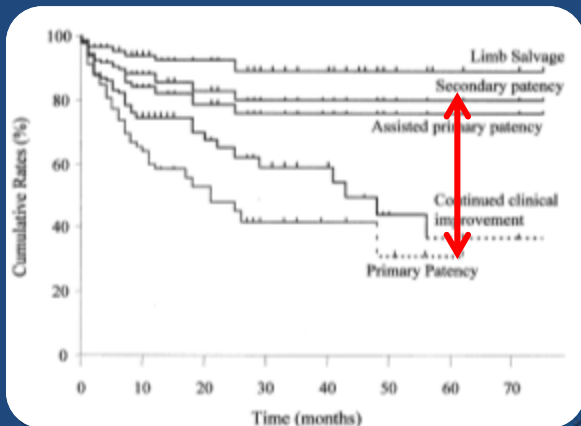
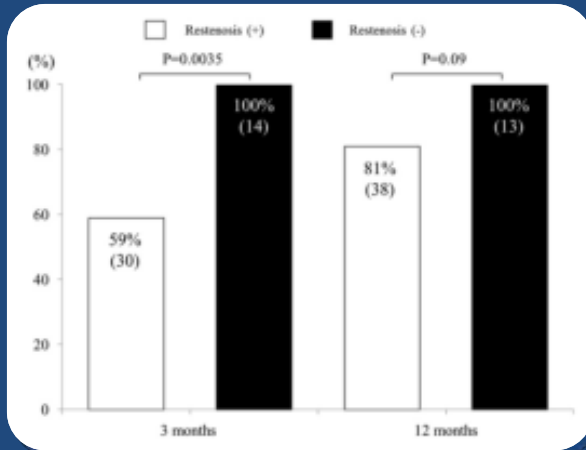
O.Iida et al. angiographic restenosis and its clinical impact after intrapopliteal angioplasty. *Europ J of Vasc and Endovasc Surgery* 2012

Primary Patency better than Secondary Patency

- reduces TLR and adds QoL

T.Kudo et al. The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: A 10-year experience. *J Vasc Surg* 2005;41:423-35.)

Conte M.S Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. *JVS* 2009;50:1462-1473



Registry experience - INPACT

First Experience with DEB in BTK: the Leipzig Registry vs historical PTA cohort (A.Schmidt et al. CCI 2010)

	IN.PACT (angio subgroup)	PTA* (histor. group)	3m Angiographic FU	
# patients / limbs	74 / 79	58 / 62		
Male gender	51 (68.9%)	38 (65.5%)	Restenosis (>50%)	27.4% vs 69%
mean age (y)	73.5 ± 9.3	70.5 ± 8.08	Full-segm. Resten.	10% vs 56%
diabetics	54 (73%)	52 (89.7%)	Restenosis Length	64 mm vs 155 mm
Renal insuff.	34 (45.9%)	30 (51.7%)	Clinical FU	
RC 3	16 (20.3%)	0 (0%)	12-month	15-month
RC 4	14 (17.7%)	16 (25.8%)	Deaths	16.3% vs 10.5%
RC 5	49 (62%)	46 (74.2%)	Limb Salvage	95.6% vs 100%
RC 6	0 (0%)	0 (0%)	Clinical Improv. ⁽¹⁾	91.2% vs 76.5%
avg lesion length	173 ± 87 mm	183 ± 75 mm	Compl. wound heal.	74.2% vs 78.6%
Tot occlusions	61.9%	64.9%	TLR	17.3% vs 50%

RCT INPACT DEB for CLI

Circulation. 2013 Aug 6;128(6):615-21.

Drug-eluting balloon in peripheral intervention for below the knee angioplasty evaluation (DEBATE-BTK): a randomized trial in diabetic patients with critical limb ischemia.

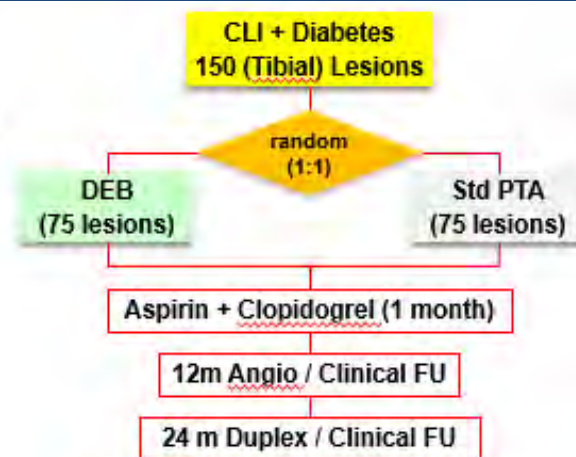
Liistro F, Porto I, Anqioli P, Grotti S, Ricci L, Ducci K, Falsini G, Ventoruzzo G, Turini F, Bellandi G, Bolognese L.

Cardiovascular and Neurological Department, San Donato Hospital, Via Pietro Nenni 20, 52100, Arezzo, Italy. francescoliiastro@hotmail.com

DEBATE BTK

F.Liistro LINC 2013

- Single Center Randomized (1:1)
- CLI, Diabetic patients
- IN.PACT Amphirion vs. std PTA
- Primary Endpoint: 12-month (>50%) Angiographic RR



• Key Inclusions

- RC 4-5-6 and Diabetes
- Stenosis / occlusions >40 mm in at least 1 tibial vessel with distal run-off

• Key Exclusions

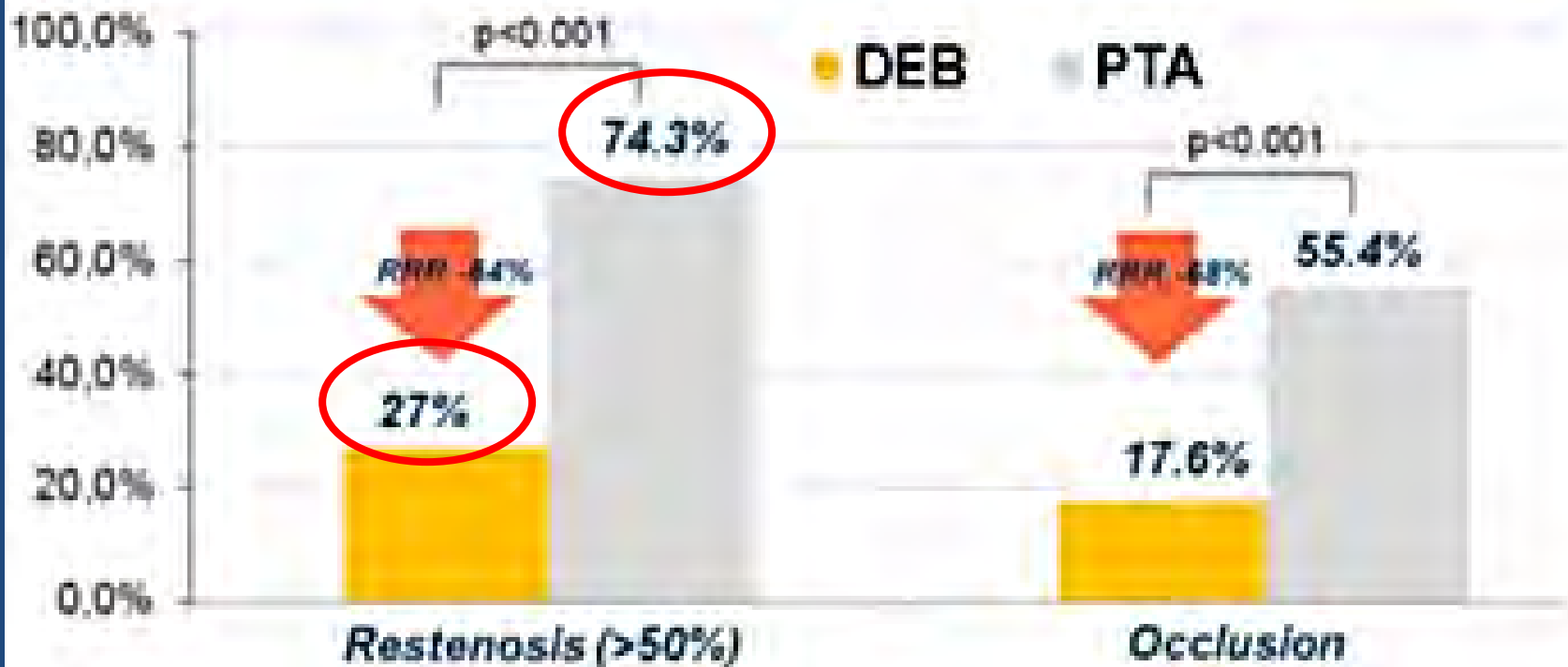
- Allergy to Paclitaxel
- Contraindication for DAPT
- Life expectancy <1 year

DEBATE- BTK 1 Year Restenosis

Angio: 81% (DEB) / 89% (PTA)
Duplex: 18% (DEB) / 11% (PTA)

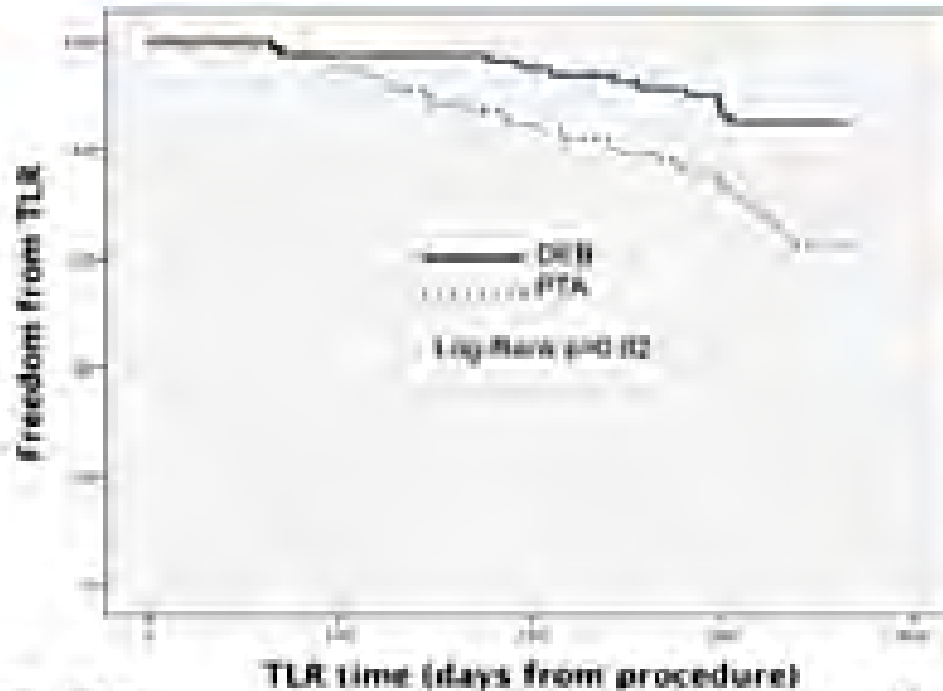
Lesion length = 12 cm
Occlusions = 80%

Restenosis and Occlusion Rates



DEBATE - BTK 1 Year TLR

TLR



12-month TLR
DEB vs. PTA:
18.5% vs. 43.3%
(p=0.003)

RESULTS – **BTK** TREATED US PATENCY AT 6 MONTHS

- 63.3% occlusions
- 60% Restenosis or ISR
- Lesion length > 12 cm
- 86.7% moderate or severe calcification
- 100% R5/R6 CLI

30 legs available
for analysis

No restenosis	<50% stenosis	>50% stenosis	Occluded
(n = 20)	(n = 3)	(n = 5)	(n = 2)
66.7%	10.0%	16.7%	6.6%

All were focal

All were focal

No or low grade stenosis: 76.7%

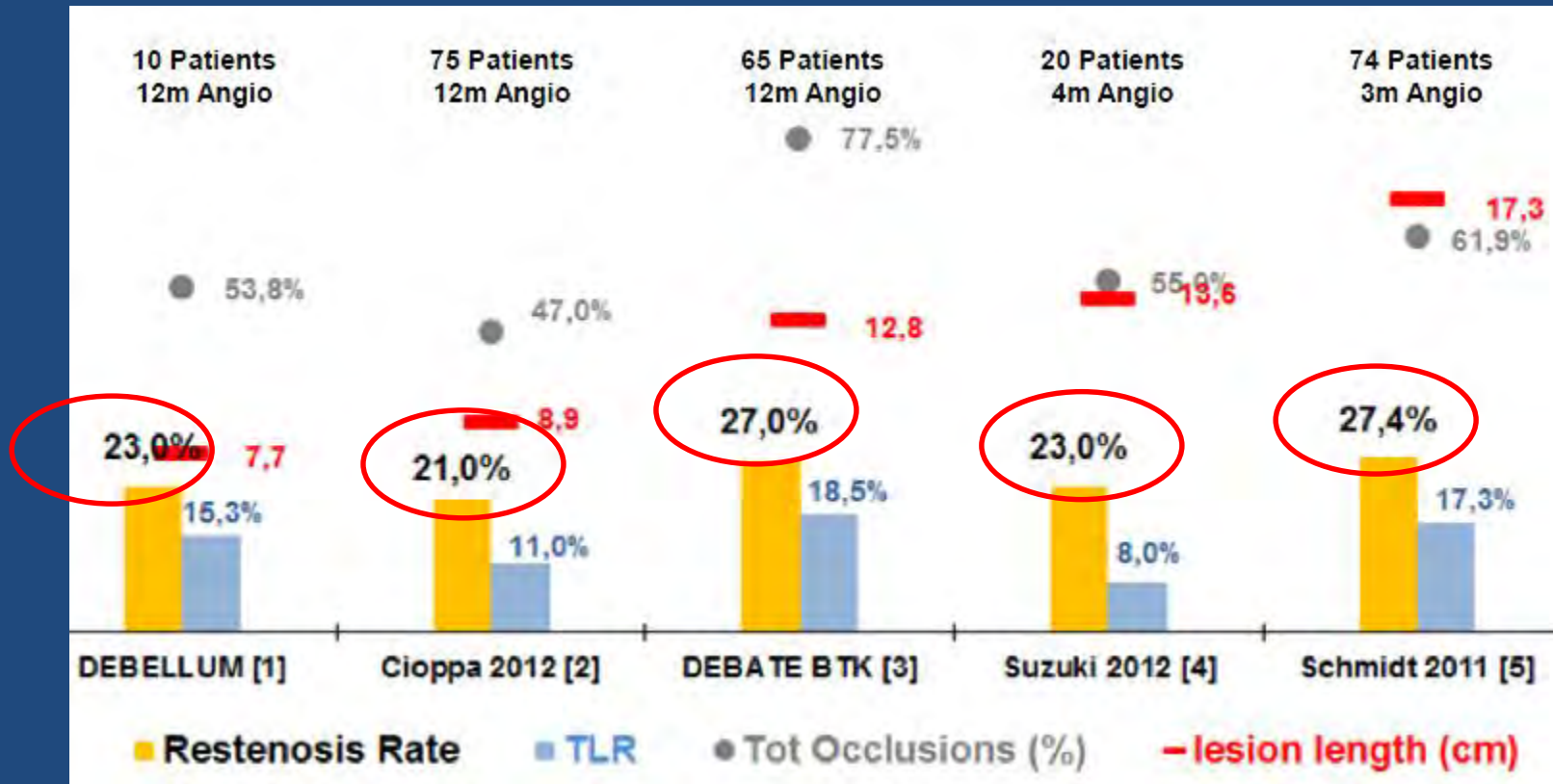
Re-stenosis rate: 23.3%

Clinical Distal Pulse felt in 83.3 % of patients

Clinically driven TLR was 10 % at 6 months

> 50% stenosis defined by PSV ratio > 2

Restenosis and TLR rates in INPACT DEB



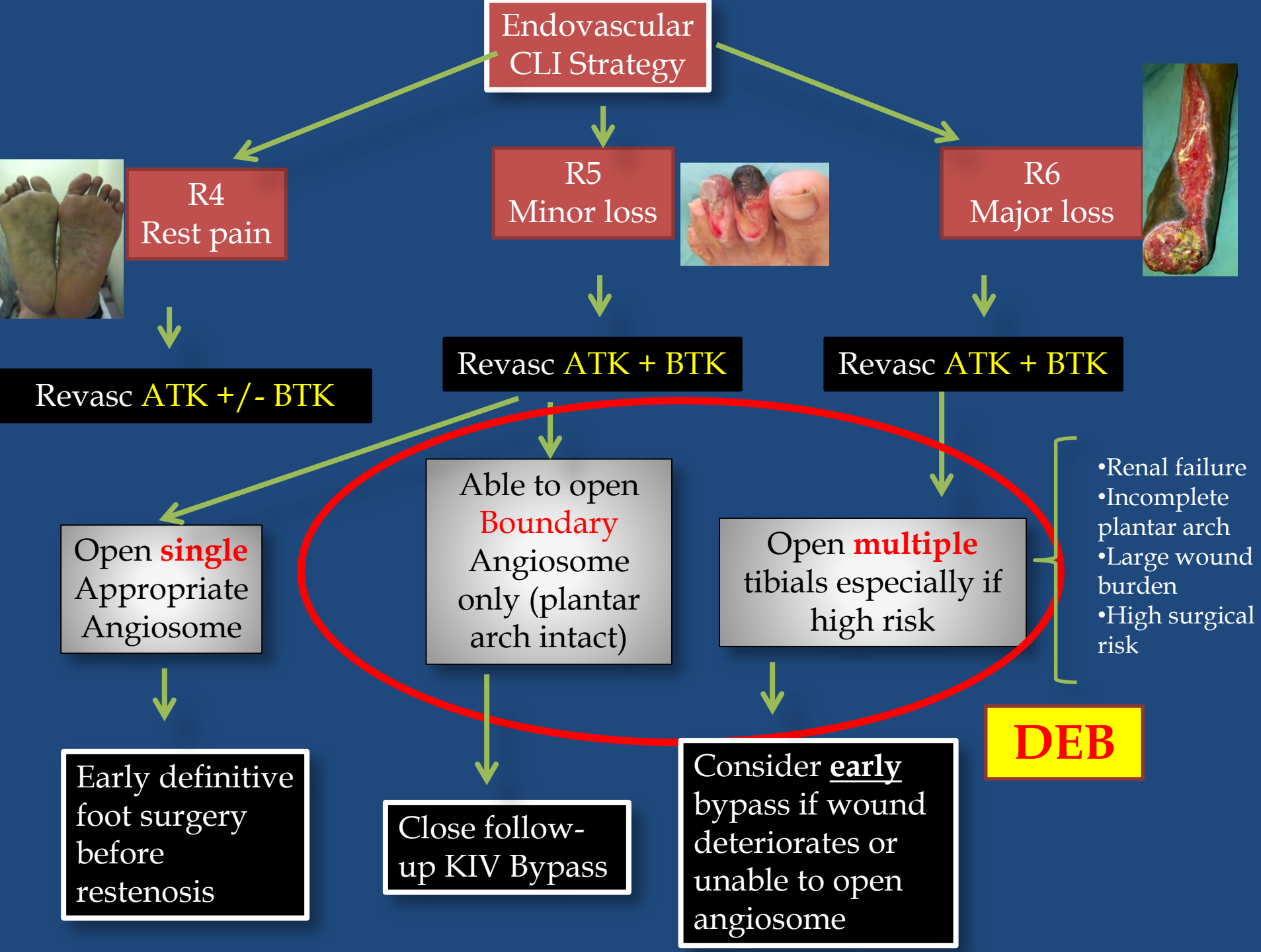
1. F. Fanelli et al. J EVT 2012; 19: 571–580

2. A. Cioppa – EuroPCR 2012

3. F. Liistro – TCT 2012 2011

4. K. Suzuki – LINC Asia Pacific 2012

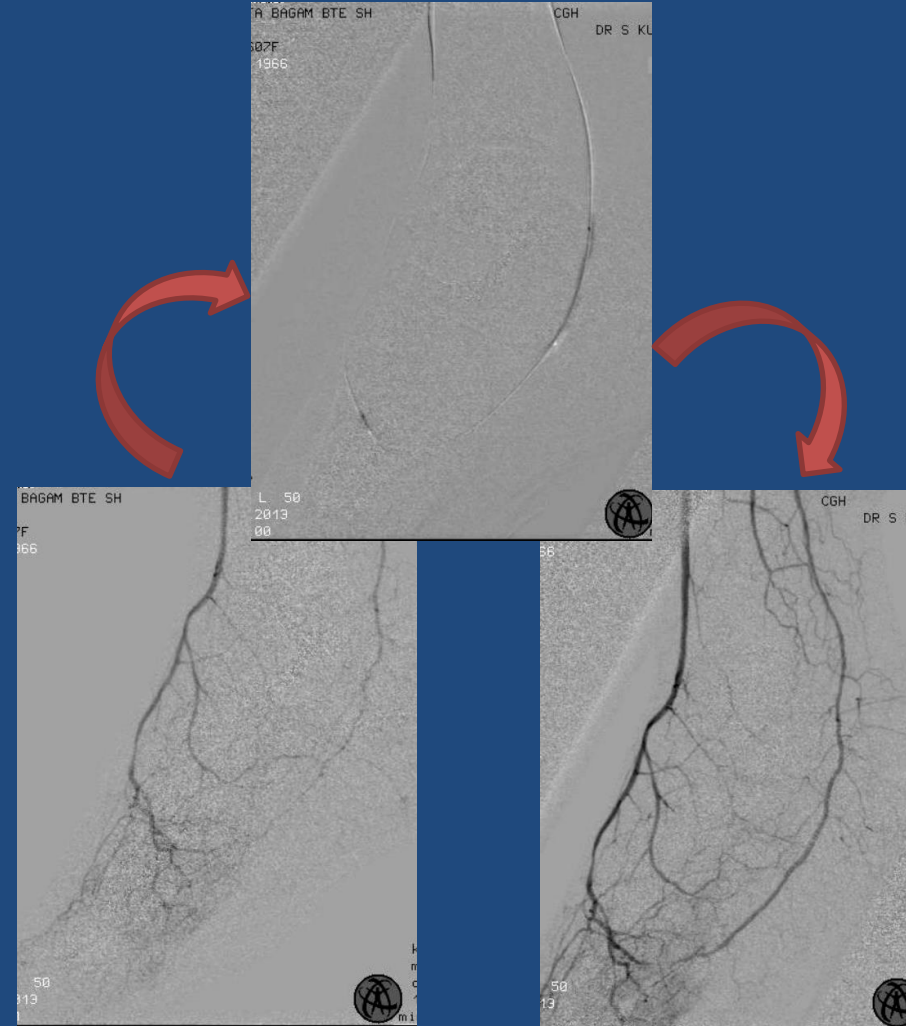
5. A. Schmidt et al. J Am Coll Cardiol 2011; 58: 1105–9



Rutherford 6 - DEB in Direct Angiosome

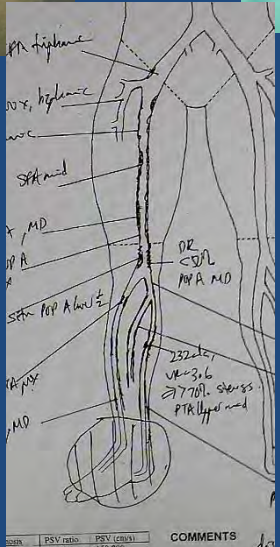


DEB to P3

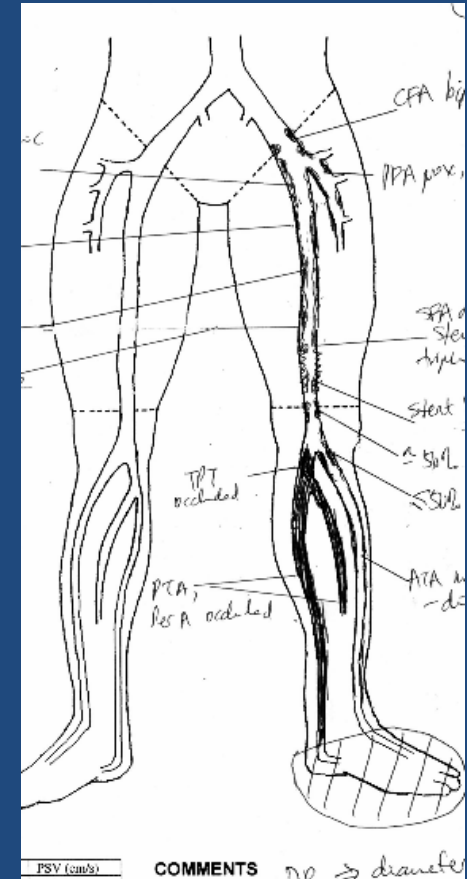


DEB to Lateral Plantar Artery

4 months for wound healing

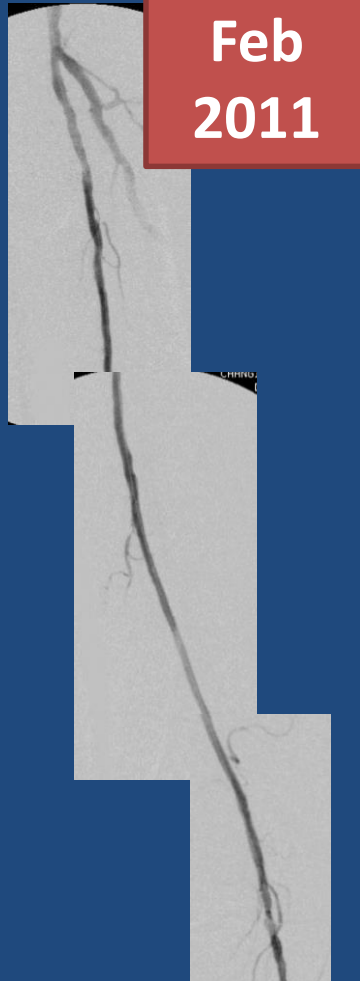
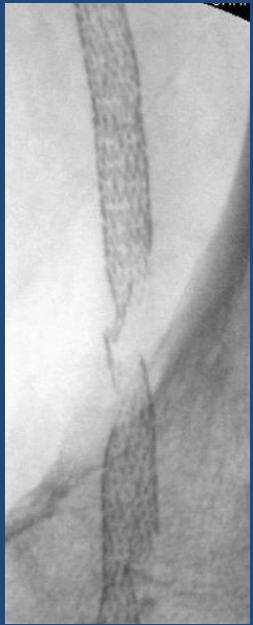


DEB to Boundary Angiosome - ATA and DP



**12 months of
patency wound
healing in 8 months**

DEB for In Stent Occlusion and Stent Fractures in Rest Pain



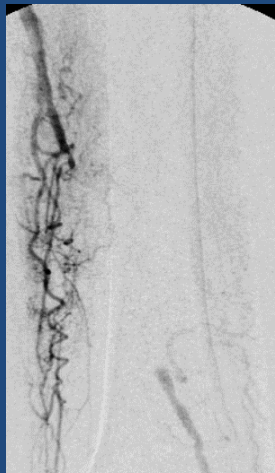
Feb
2011



2 1/2
years



Aug
2013



Prev Full Metal Jacket for
CLI now rest pain

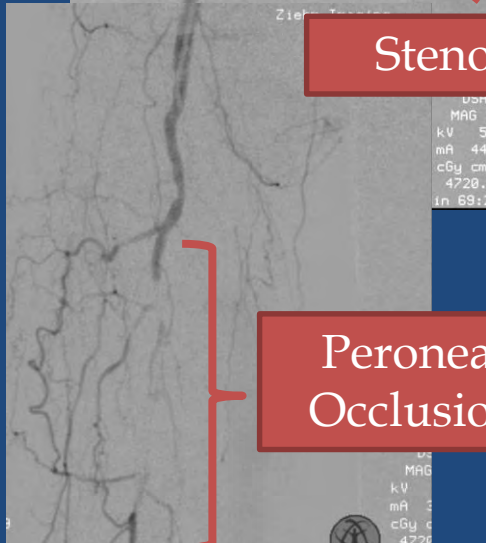
DEB from
P3 to SFA

No restenosis
seen

DEB to Preserve Bypass Runoff



Stenosis

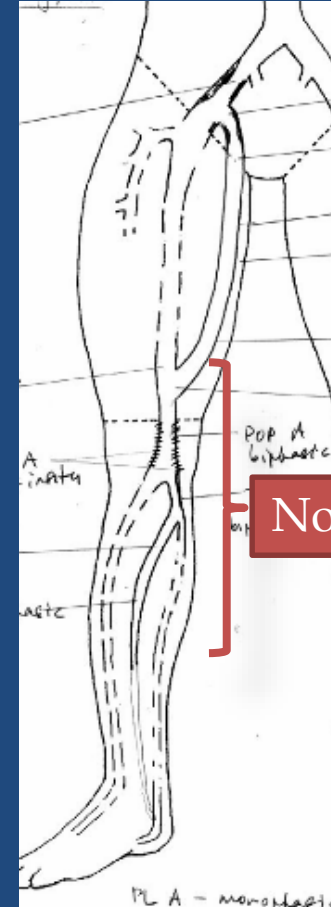


Peroneal Occlusion

Femoral -AK Pop bypass with Acute Limb Ischaemia - Post Thrombolysis



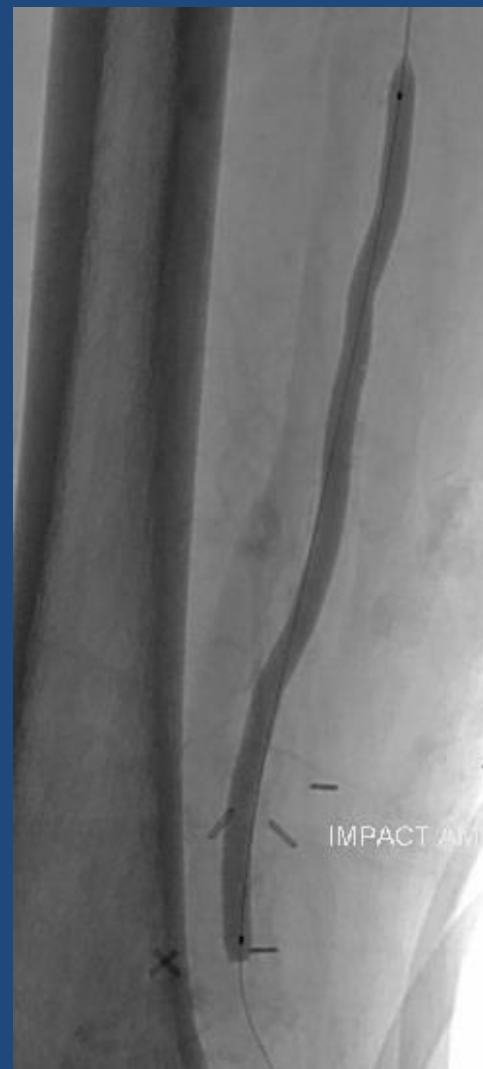
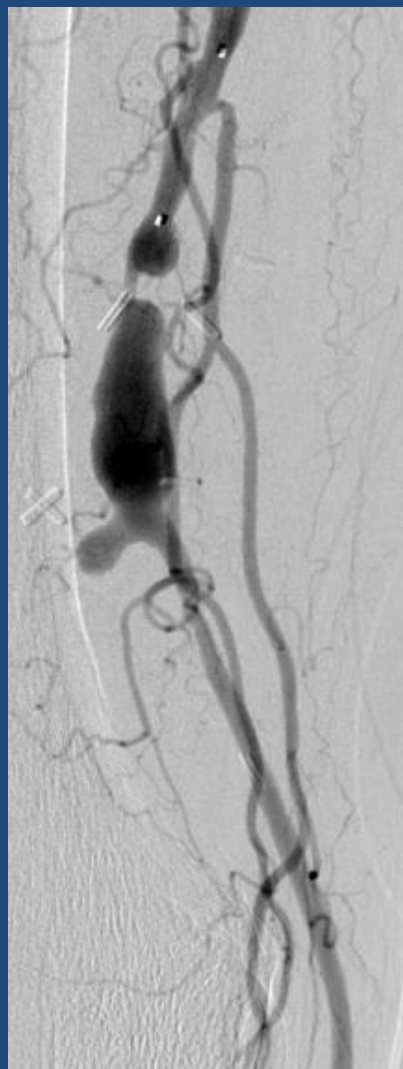
DEB to distal anastomosis, Popliteal and Peroneal



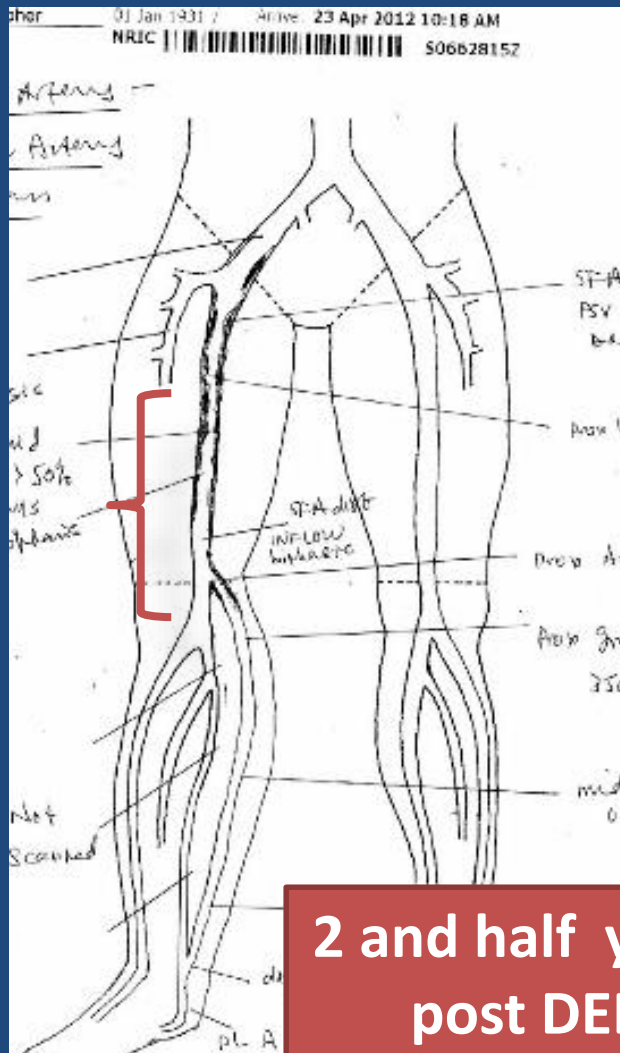
No restenosis

2 years post DEB

DEB for Bypass Anastomosis



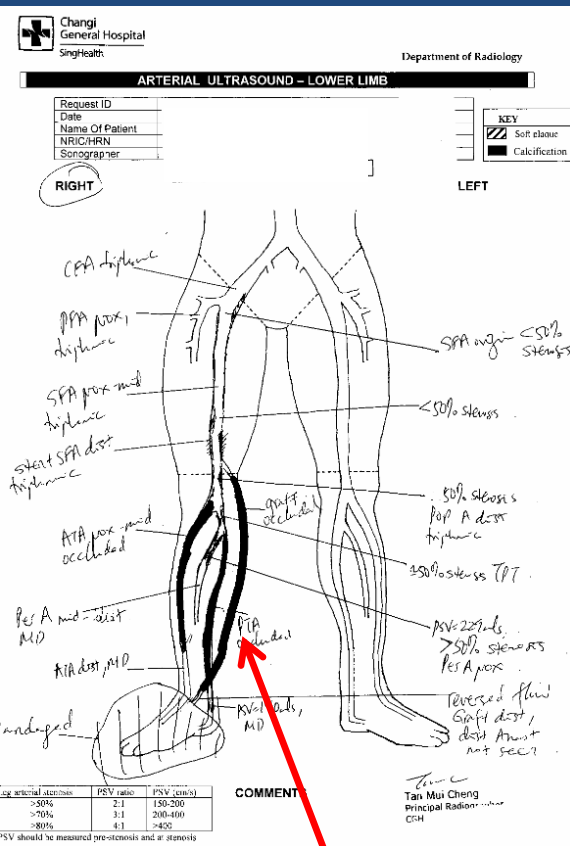
DEB for Bypass Anastamosis



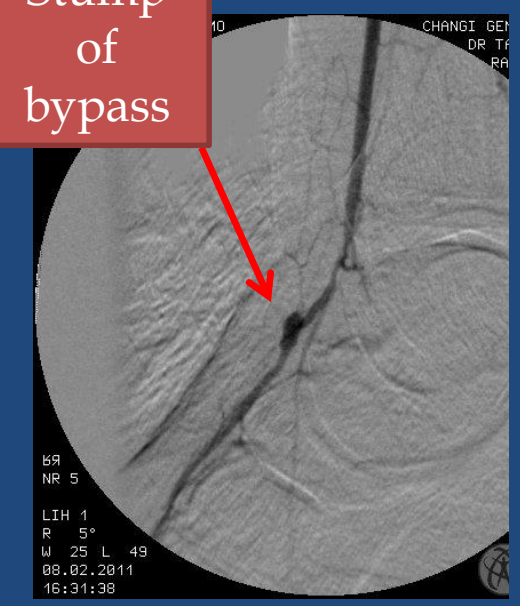
2 and half years
post DEB



Endovascular Salvage of Failed Bypass in Dialysis patients



Stump of bypass

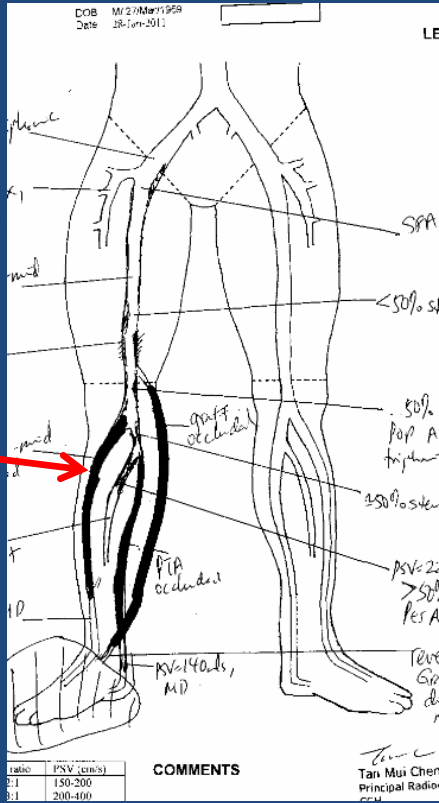


Occluded Pop-DP bypass

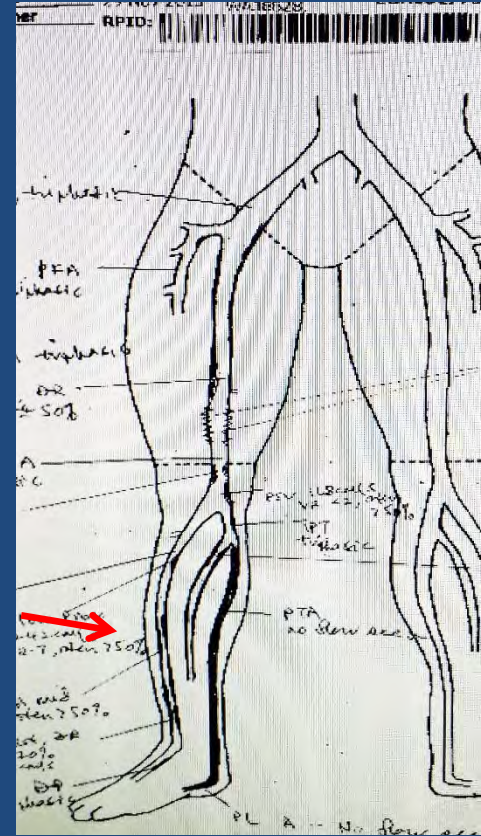
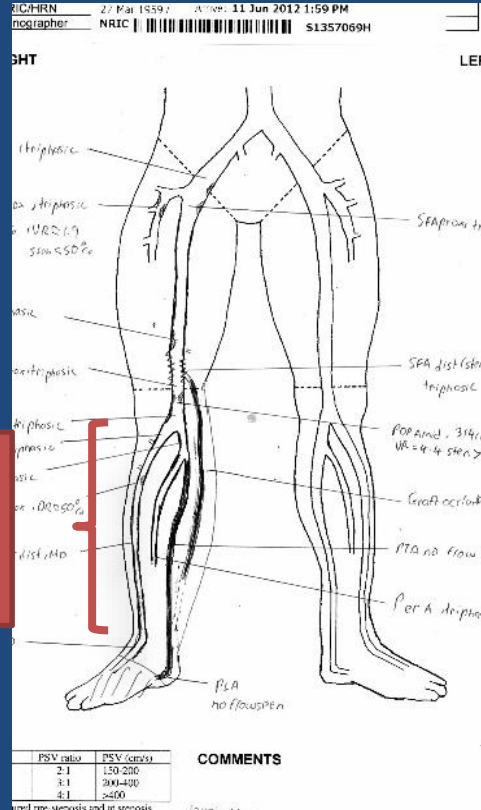
Retrograde Double balloon



Endovascular Salvage of Failed Bypass in Dialysis patients



DEB
ATA
and DP



Feb 2011

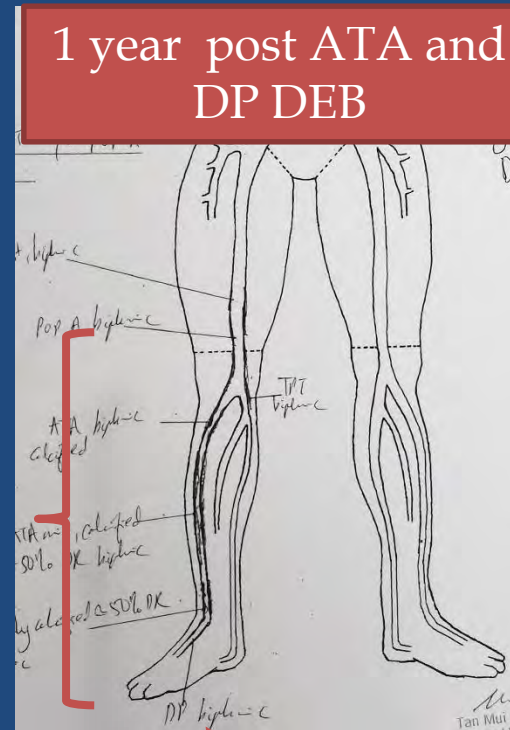
Nov 2013

33 months

DEB in Renal Failure

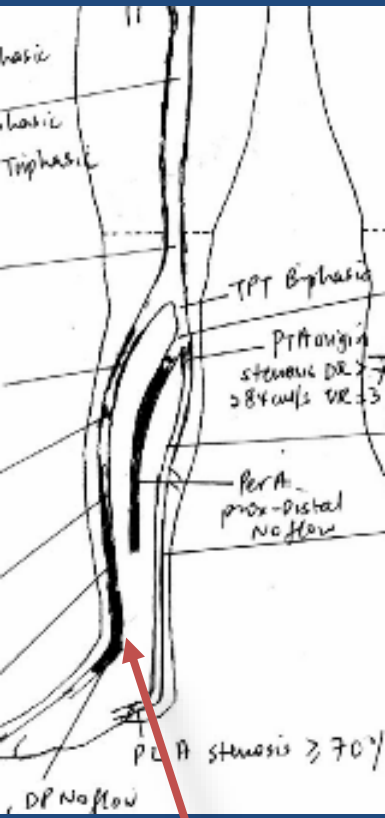
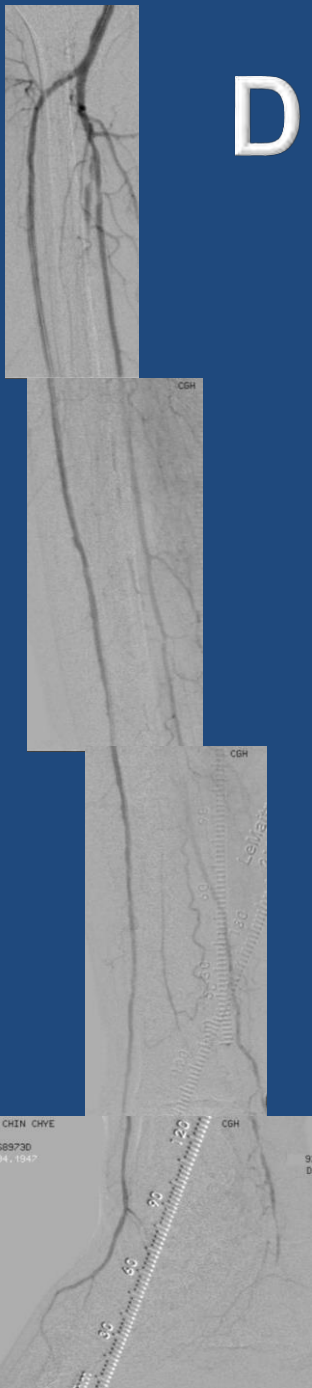
Hyallomatrix and SSG

1 year post ATA and DP DEB



DP
Biphasic

Calcified
lesion

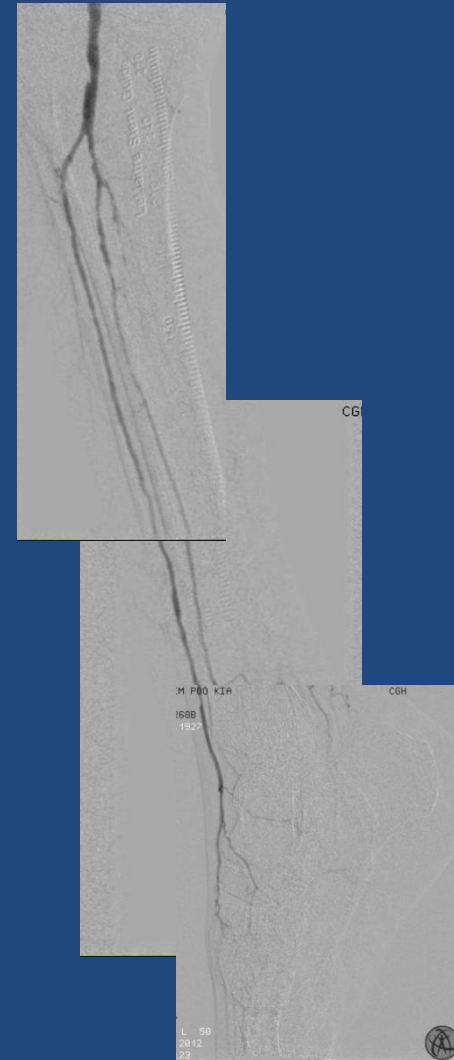


DEB ATA for CLI



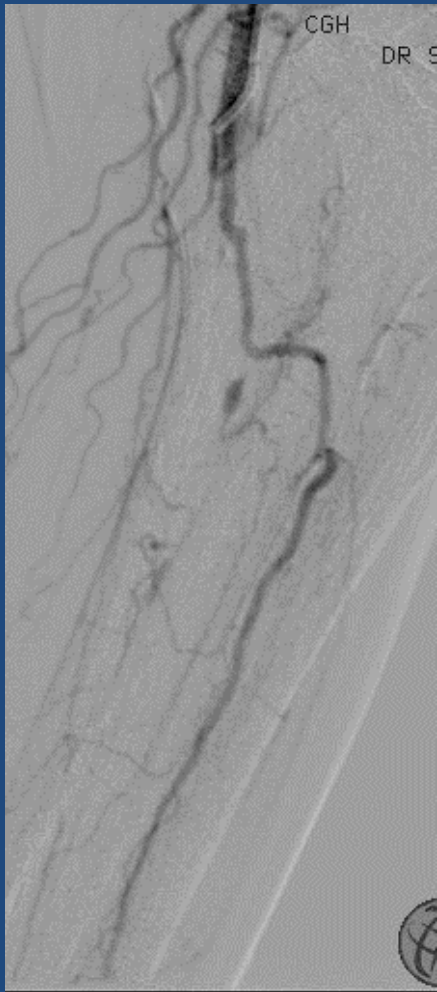
Initial angio
showing long ATA
Occlusion

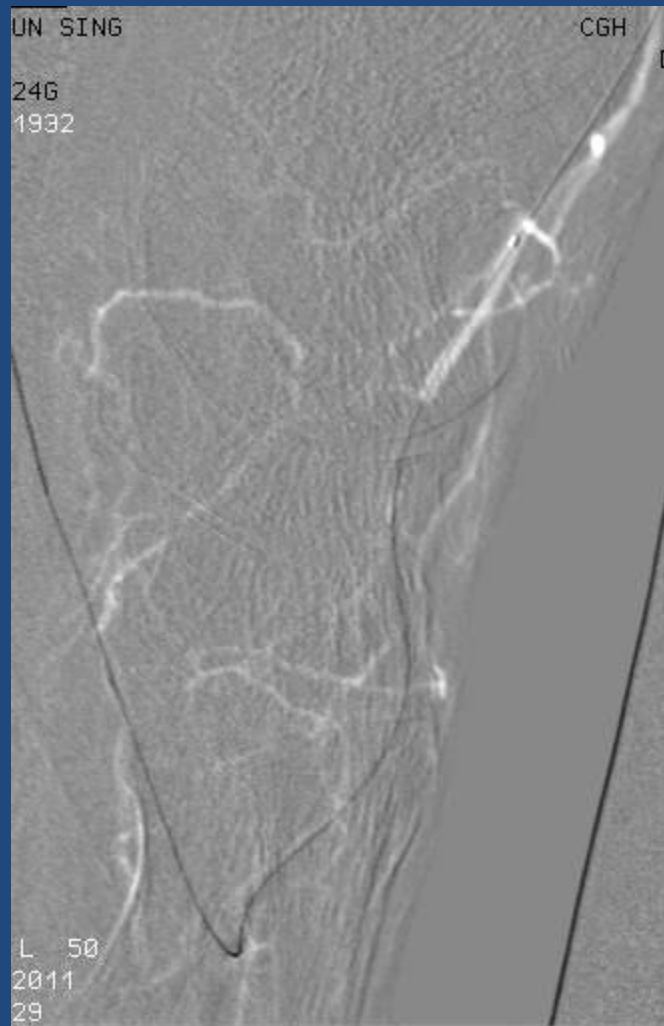
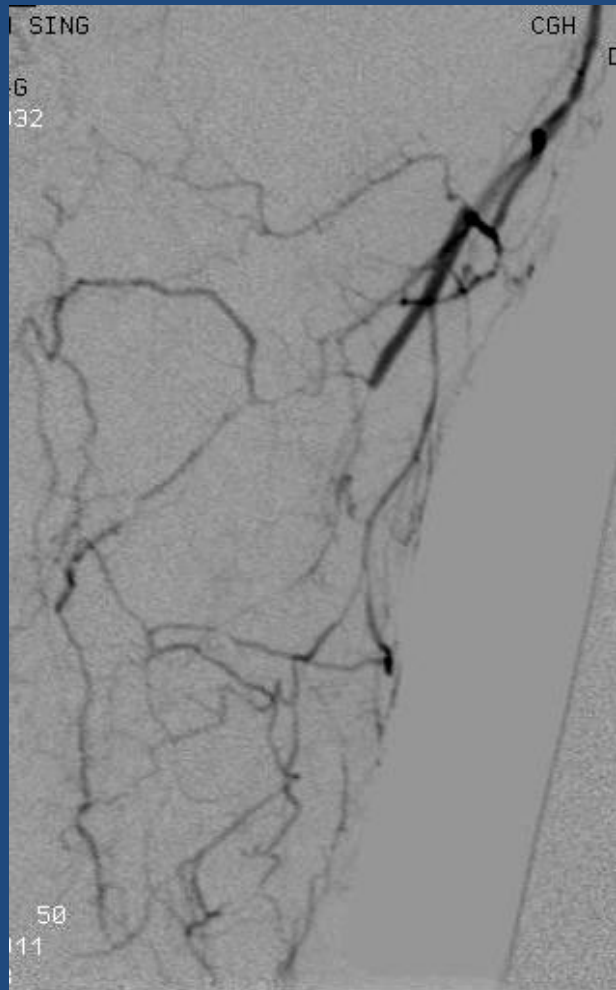
2 years

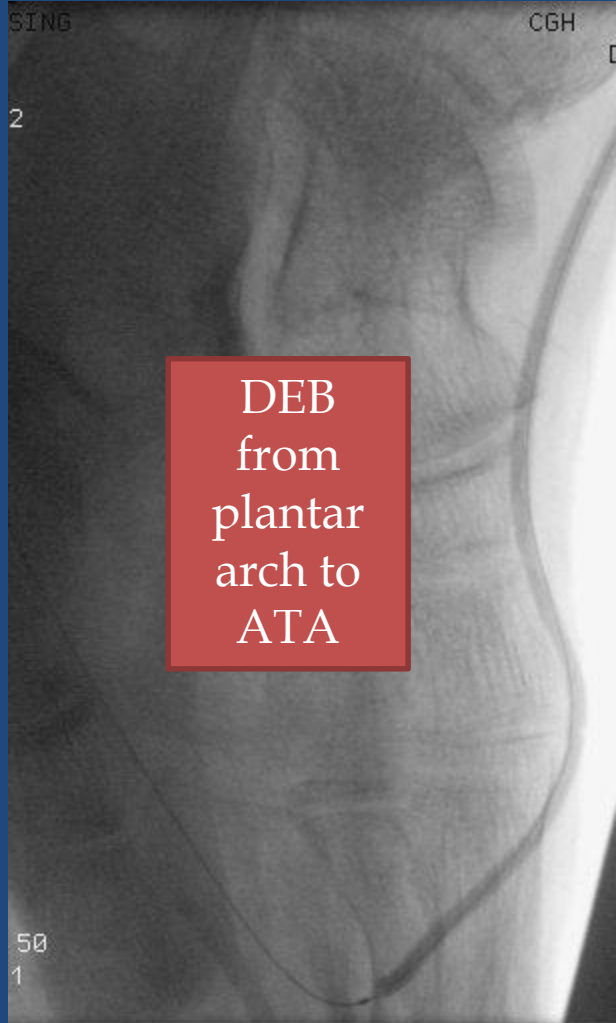


ATA no significant
stenosis 2 years post DEB

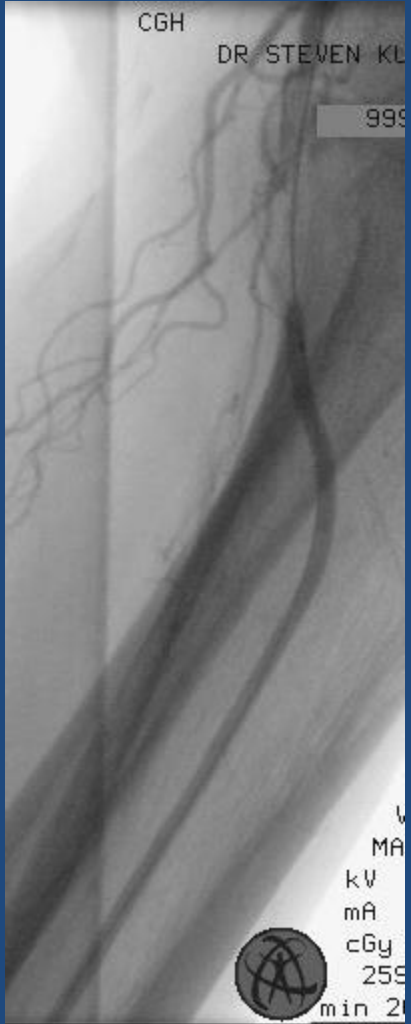
DEB for CLI



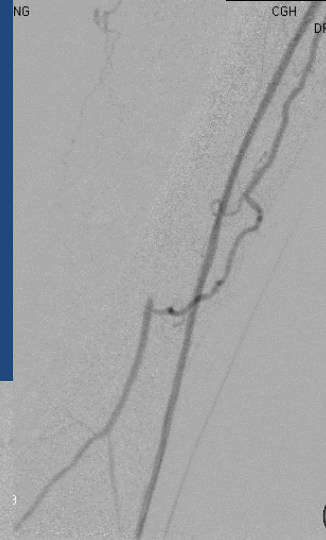




DEB
from
plantar
arch to
ATA



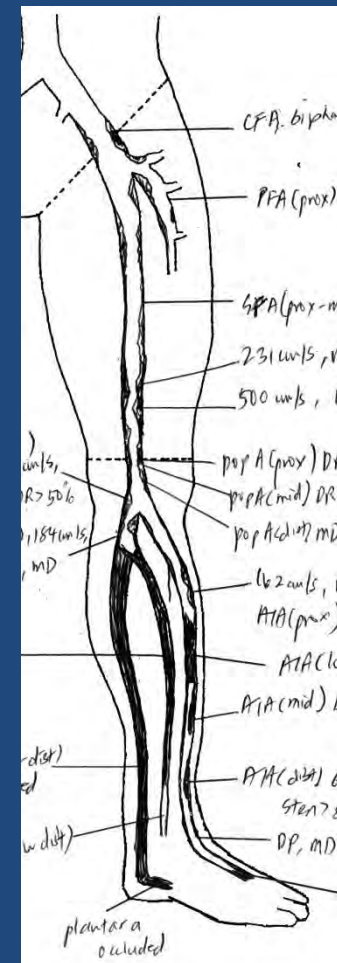
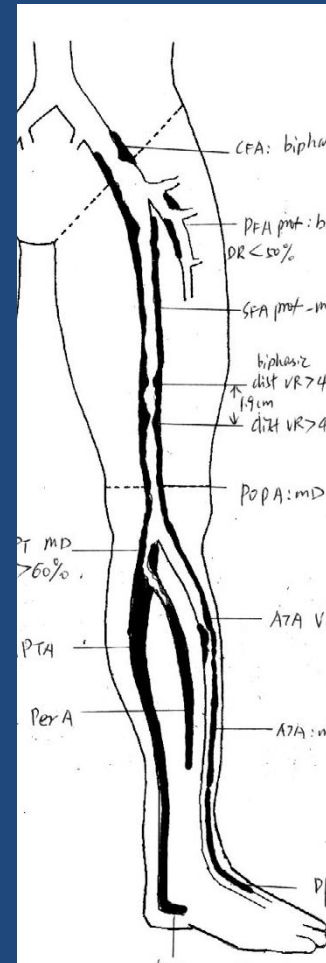
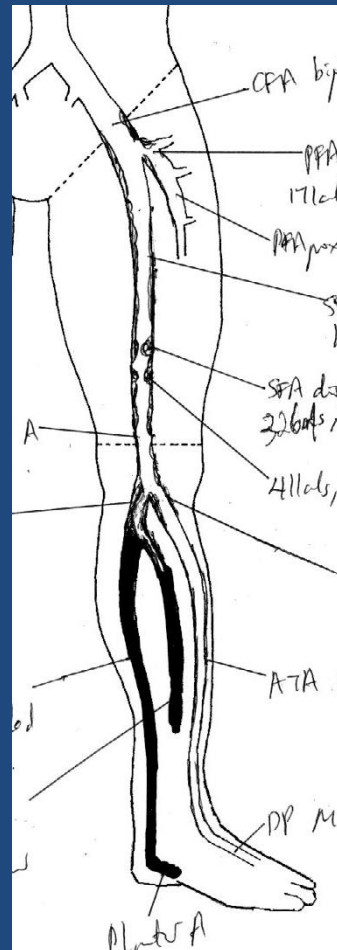
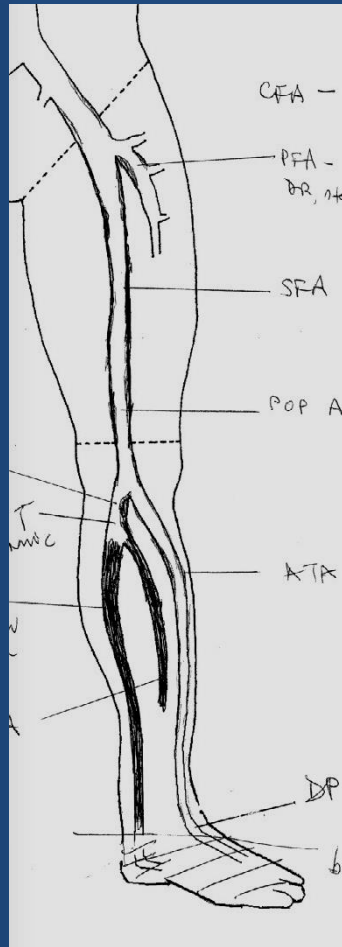
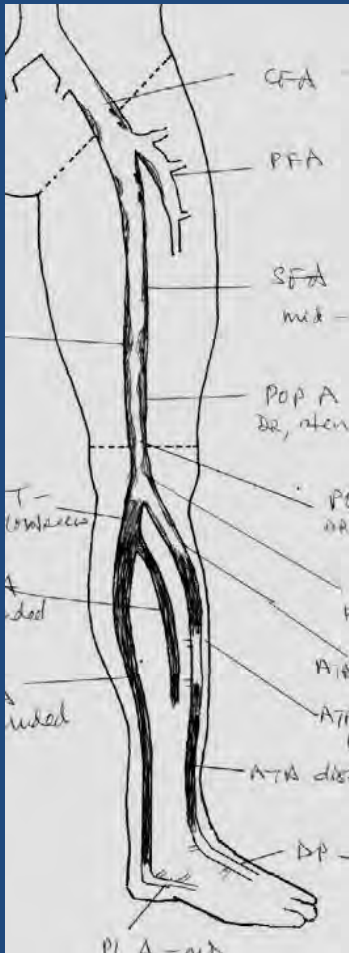
DEB with Total Lesion Coverage for CLI



DEB
from
plantar
arch to
ATA

Pre
Interention

Post
Interention



Oct 2011

Oct 2011

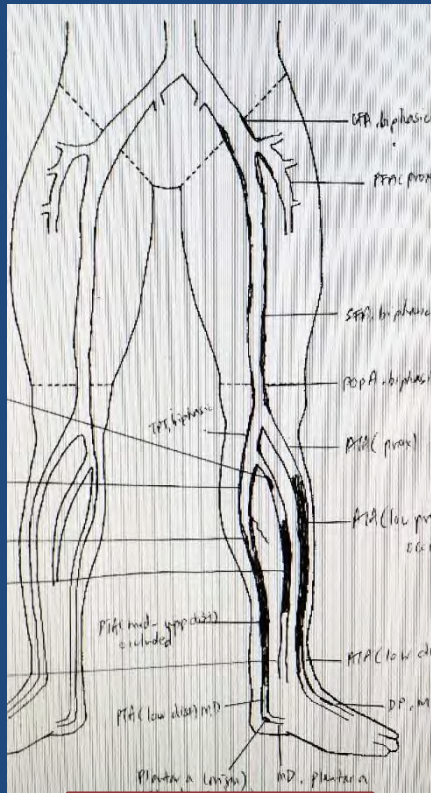
Jan 2012

Aug 2012

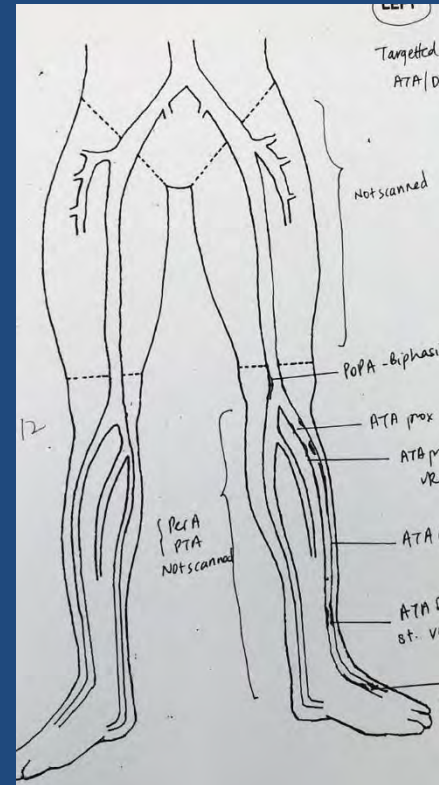
Nov 2012

Wound Healed

DEB for ATA

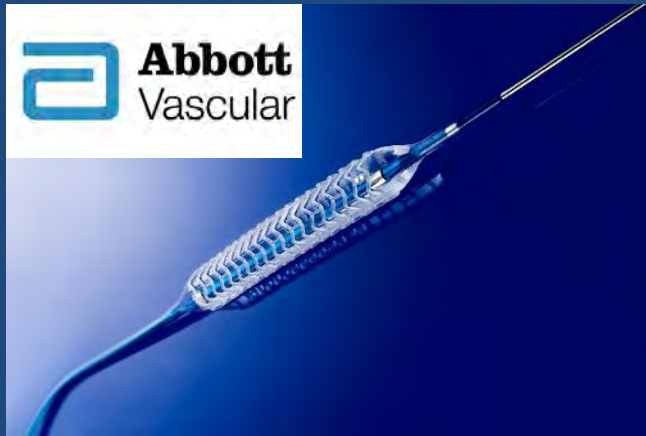


Dec 2012

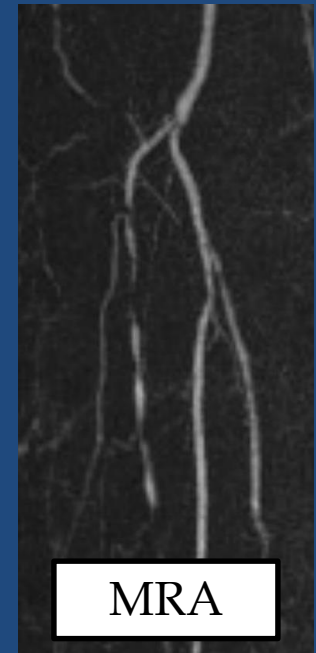
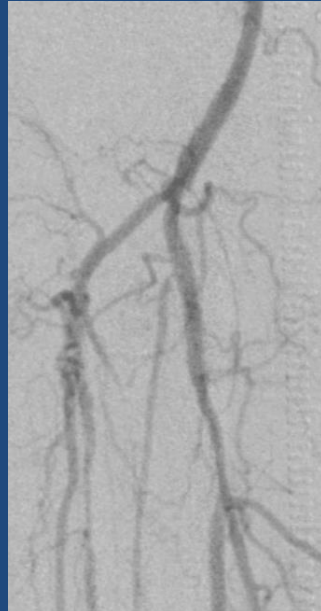
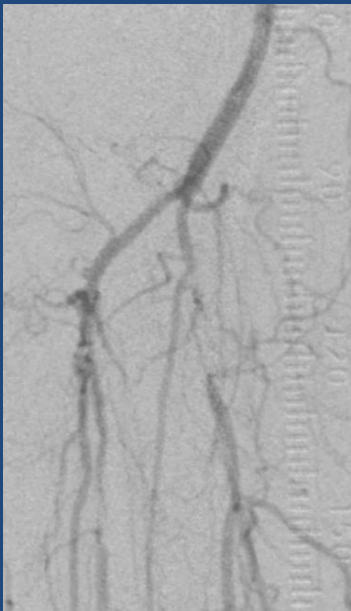


Nov 2013

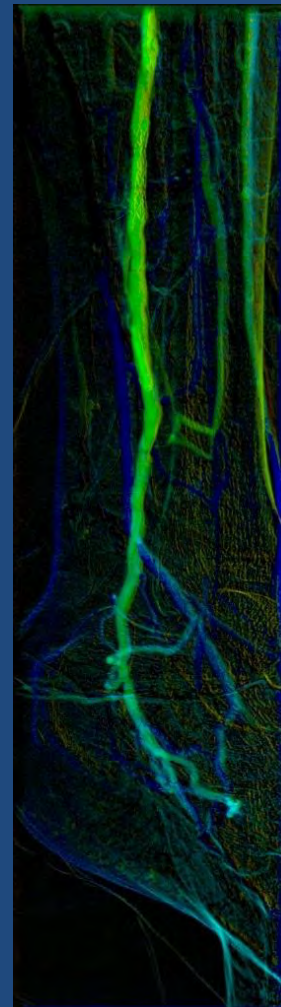
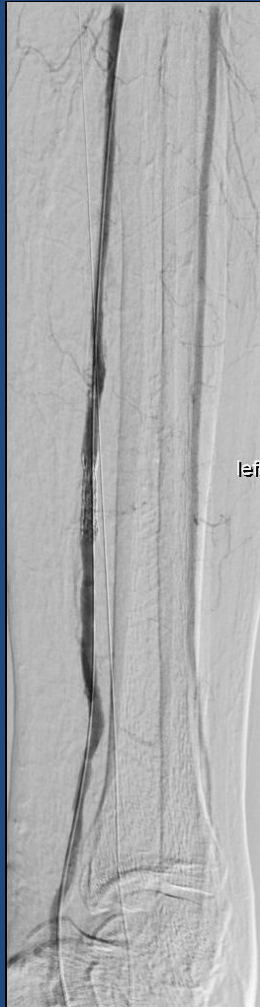
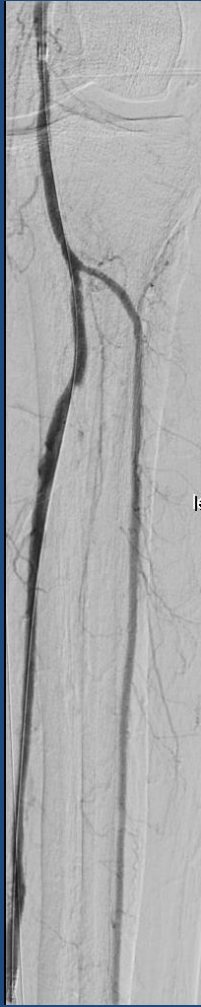
Bio-absorbable Stents



Drug Impregnated
Bioabsorbable Stents in Asian
Population Extremity Arterial
Revascularization
– **DISAPEAR BTK Study**



Percutaneous Deep Venous Arteriolization



Too Much 'High Tech' ?



Multidisciplinary Approach

Vascular
Interventionalist
and Surgeon

Endocrinology
DM Centre

Family Physicians

Team based approach

Wound Care Team

Anaesthesia

Orthopaedics
Foot & Ankle

Podiatry

Aggressive Early Skin Cover



Necrotising Fasciitis







Summary

- ▣ Rutherford Status and extent of tissue loss determines which BTK vessels need to be treated
- ▣ Utilization of Adjuncts seems to answer the challenges of restenosis, re-intervention for long lesions with large wounds in the ATK and BTK segments
- ▣ Extravascular care is important to “close the loop” and ensures a good angiographic result translates to a good clinical result



Thank you!



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