

The logo for LIN C, featuring the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font. To the left of the letters is a stylized graphic consisting of three curved, overlapping bands in shades of red, orange, and yellow, resembling a flame or a dynamic shape.

LIN C

12 Month Results of the ***DISAPEAR Registry*** **BVS IN CLTI**

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Disclosure

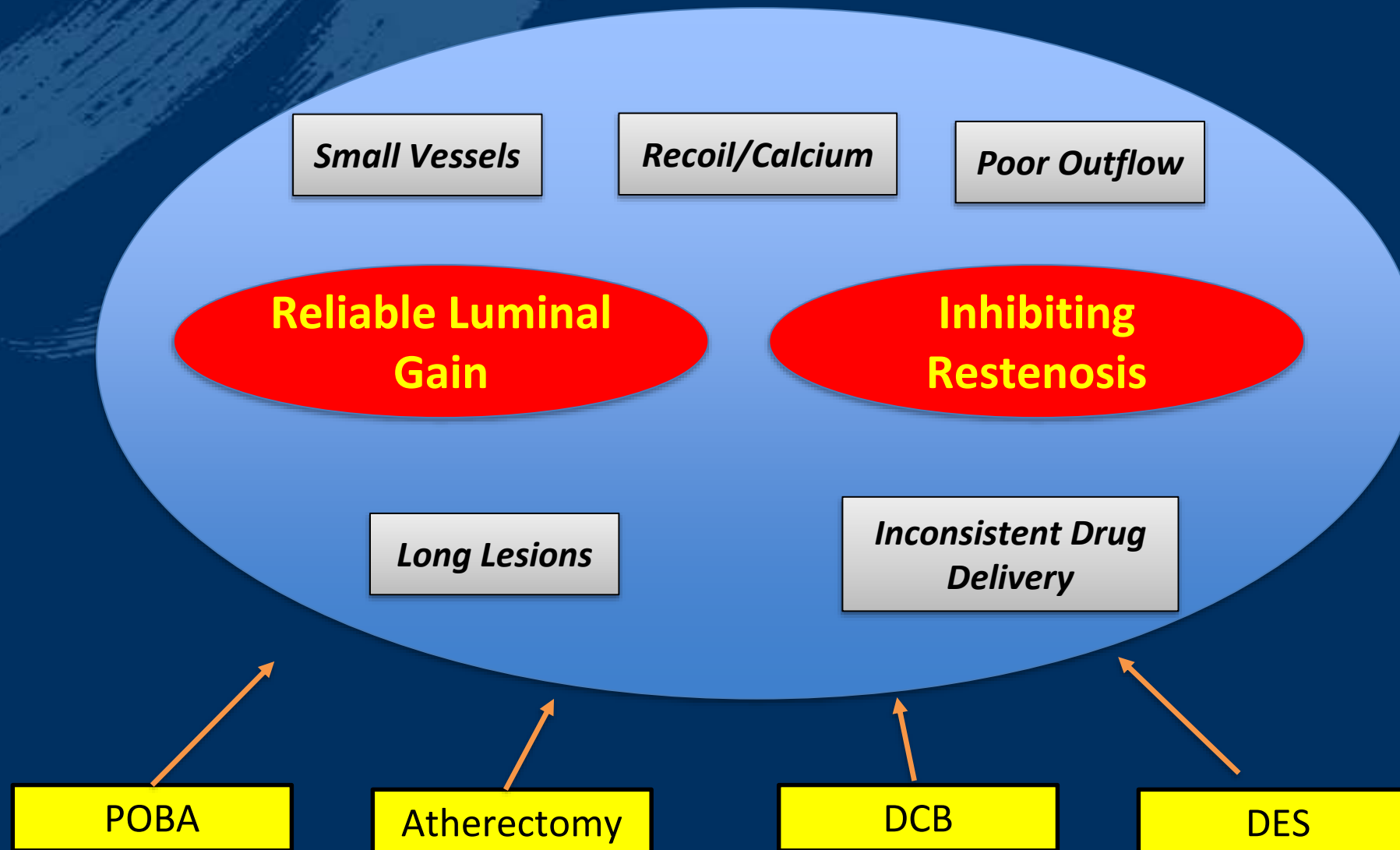
Speaker name:

Steven Kum

I have the following potential conflicts of interest to report:

- Consulting *Abbott Vascular*
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
-
- I do not have any potential conflict of interest

What are the Problems and Needs in BTK Therapies?



Primary Patency Favors DES

Cardiovasc Intervent Radiol (2013) 36:645–658
DOI 10.1007/s00270-013-0578-2

CIRSE

CLINICAL INVESTIGATION

ARTERIAL INTERVENTIONS

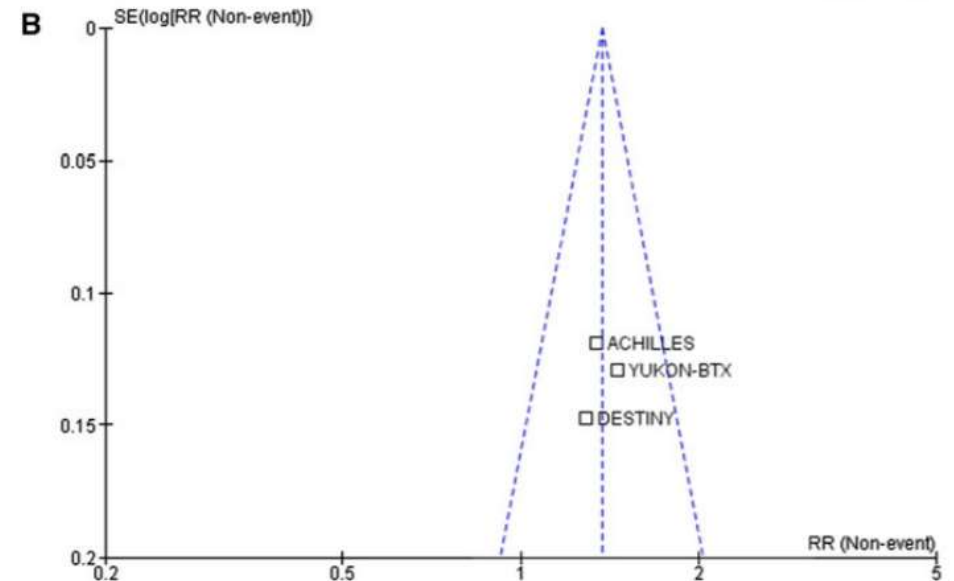
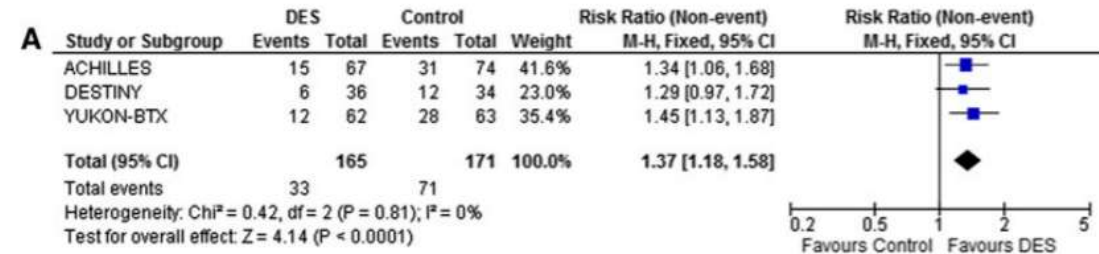
Systematic Review of Intrapopliteal Drug-Eluting Stents: A Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos · Stavros Spiliopoulos ·
Athanasios Diamantopoulos · Dimitris Karnabatidis ·
Tarun Sabharwal · Dimitris Siablis

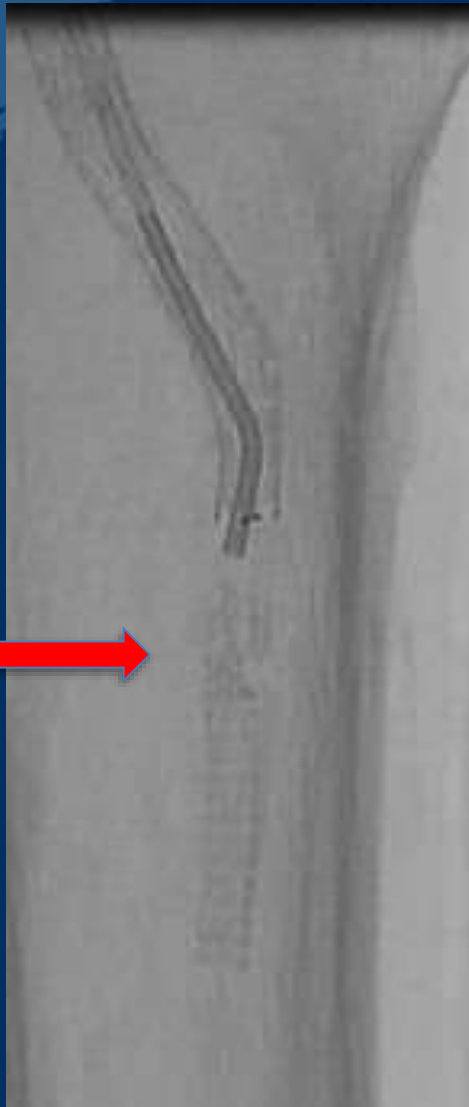
- Scaffold and reliable luminal gain
- Reliable drug delivery even in calcification
- Prolonged drug delivery
- No toxic effects (systemic and distal)

effects model (95 % CIs). The *blue squares* and *horizontal lines* indicate the RR value with the respective 95 % CI for each included RCT, and the size of each *square* is proportional to the statistical weight assigned to the trial by the software. The *black diamond* indicates the pooled effect estimate; the centre of the diamond indicates the exact pooled estimate; and the left and the right ends of the diamond correspond to the 95 % CI. Statistical heterogeneity with Cochran's Q (χ^2) test and the I^2 statistic are also provided. **B** *Funnel plot* of RCTs included in the meta-analysis. The SE of the log-RR was plotted against the RR value for each trial

Primary patency



Metallic implants may be problematic in reintervention



Abbott Vascular ABSORB

- Poly-L-Lactic Acid structure
- Poly-D,L-Lactic Acid polymer
- Everolimus (100 μ g/cm²)
- 80% (\pm 10%) elutes 28d



Not available commercially

DISAPEAR Registry in CLTI - Singapore

Drug
Impregnated Bioabsorbable
Stent in
Asian
Population
Extremity
Arterial
Revascularization

The screenshot displays the ClinicalTrials.gov website interface. At the top, the logo "ClinicalTrials.gov" is visible, along with the text "A service of the U.S. National Institutes of Health". A search bar is present with the example text "Heart attack AND Los Angeles". Below the search bar, a yellow banner reads "Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting". A navigation menu includes "Find Studies", "About Clinical Studies", "Submit Studies", "Resources", and "About This Site". The breadcrumb trail shows "Home > Find Studies > Search Results > Study Record Detail". The search results indicate "Trial record 1 of 1 for: disappear". The study title is "Drug Impregnated Bioabsorbable Stent in Asian Population Extremity Arterial Revascularization (DISAPEAR Study) (DISAPEAR)". Key details include: "This study is currently recruiting participants. (see Contacts and Locations)", "Verified February 2016 by Changi General Hospital", "Sponsor: Changi General Hospital", "Information provided by (Responsible Party): Steven Kum Wei Cheong, Changi General Hospital", "ClinicalTrials.gov Identifier: NCT02043795", "First received: October 29, 2013", "Last updated: February 16, 2016", "Last verified: February 2016", and "History of Changes".

DISAPEAR Registry

Inclusion criteria

- Chronic Infrapopliteal lesions
- Rutherford 4, 5 and 6
- De novo lesions - Stenosis >50% or Occlusion
- 8 cm above ankle joint

Exclusion criteria

- BVS across the ankle joint

Study Population

Characteristic	Total patients, n=41; Limbs, n=41
Age, median (IQR) (years)	64 (15)
Male	23 (56)
Comorbidities	
Ischemic heart disease	24 (59)
Diabetes mellitus	37 (90)
Hyperlipidemia	36 (88)
Hypertension	37 (90)
Dialysis-dependent renal failure	5 (12)
Smoking history	16 (48)
Rutherford category	
4	2 (4.87)
5	24 (58.5)
6	15 (36.5)

} 95% with Tissue Loss

Lesion/Scaffolds

Total patients = 41
Limbs = 41

Target lesion location	N (%)
Tibioperoneal trunk	17(33)
Anterior tibial artery	14(26)
Posterior tibial artery	11(21)
Peroneal artery	6(11)
Popliteal artery	5(9)
Target lesion length (mean±SD[range]) mm	22.7±17.2 (4-88)
Degree of stenosis (median [range]) (%)	80 (50–100)
Total occlusion	4 (8)
Target vessel diameter (median [range]) mm	3 (2.5–3.5)
PARC classification	
Non	1 (2)
Focal	19 (46)
Mild	4 (10)
Moderate	7 (17)
Severe	10 (24)
TASC classification	
A	25 (61)
B	14 (34)
C	0 (0)
D	2 (5)
No, of Lesions	53
Total number of scaffolds deployed	69



RESULTS

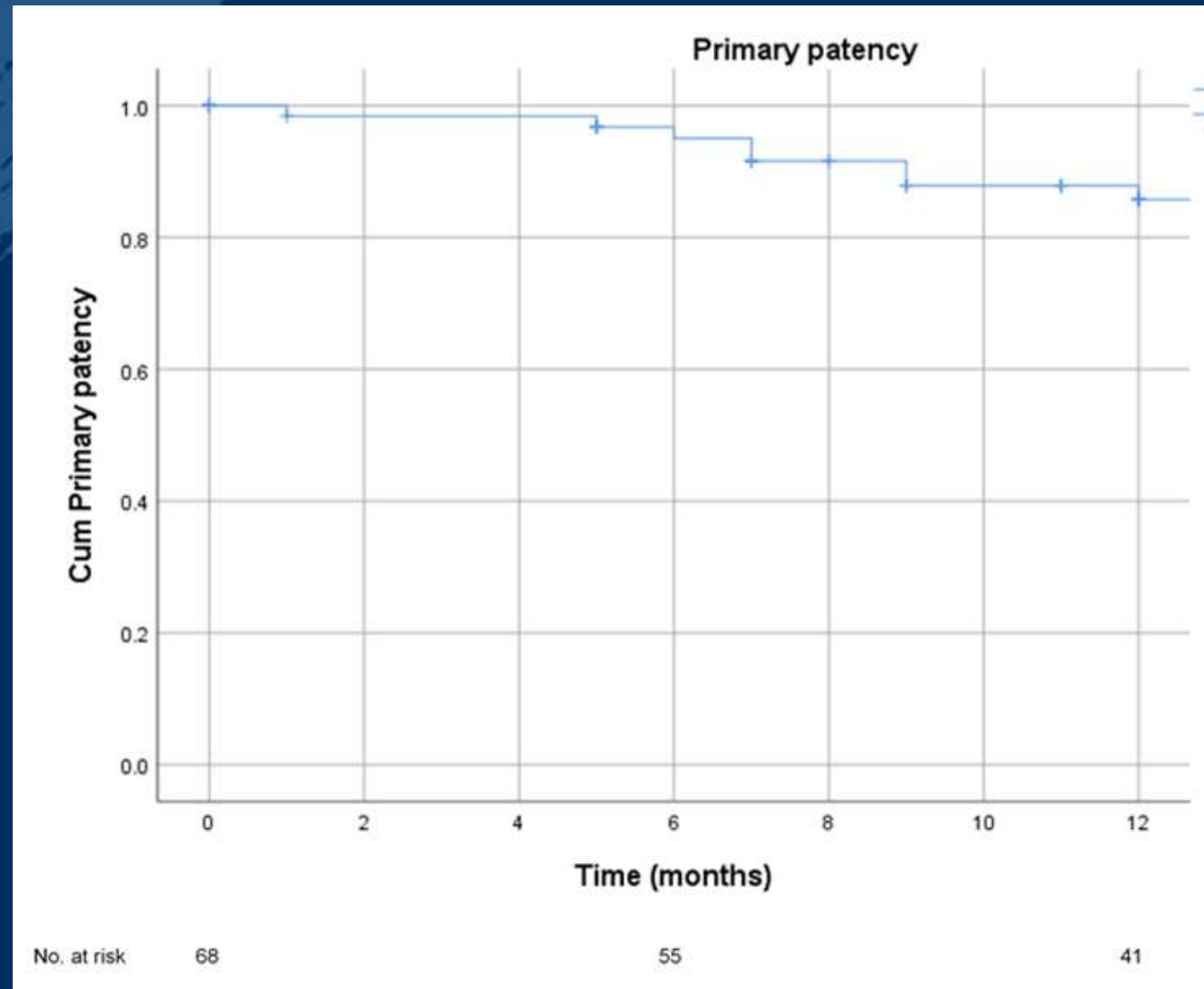
Primary Patency

Primary Patency

6 month = 95%

12 months = 86%

DUS PSVR<2.0

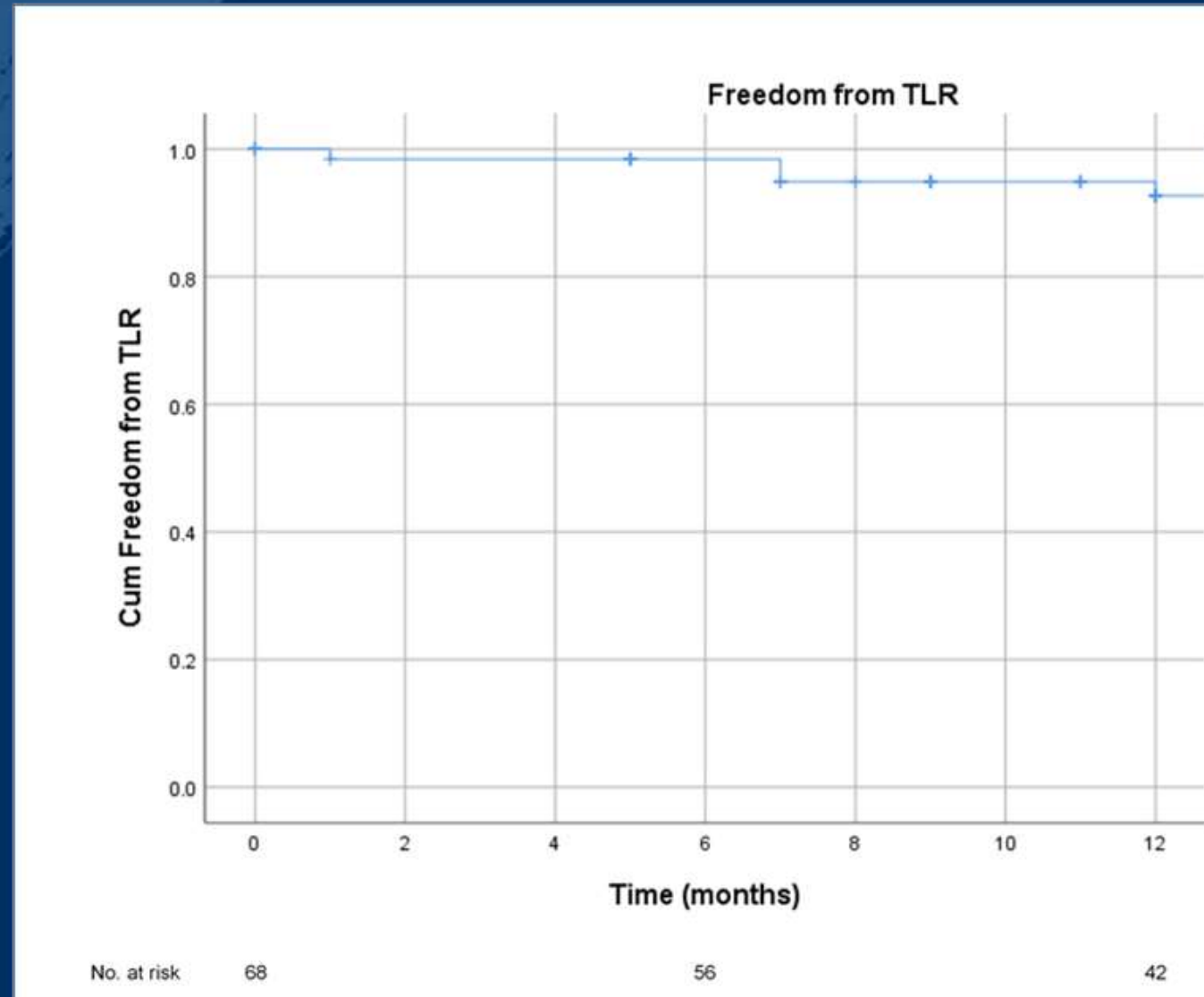


Freedom from CD-TLR

FF CD-TLR

6 month = 98%

12 month = 93%

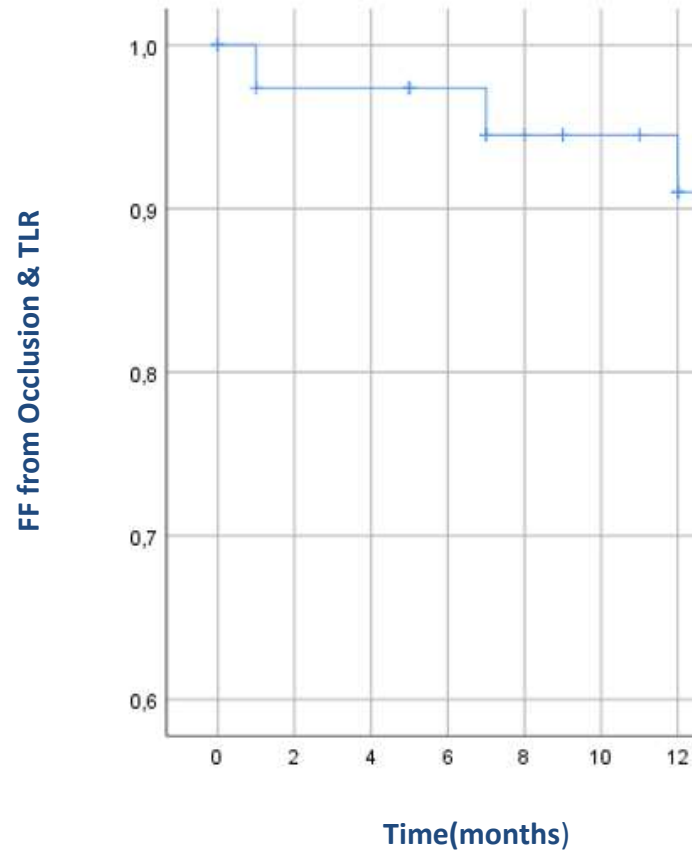


Freedom from TLR & US Occlusion

FF TLR & Occlusion

6 month = 98%

12 month = 93%

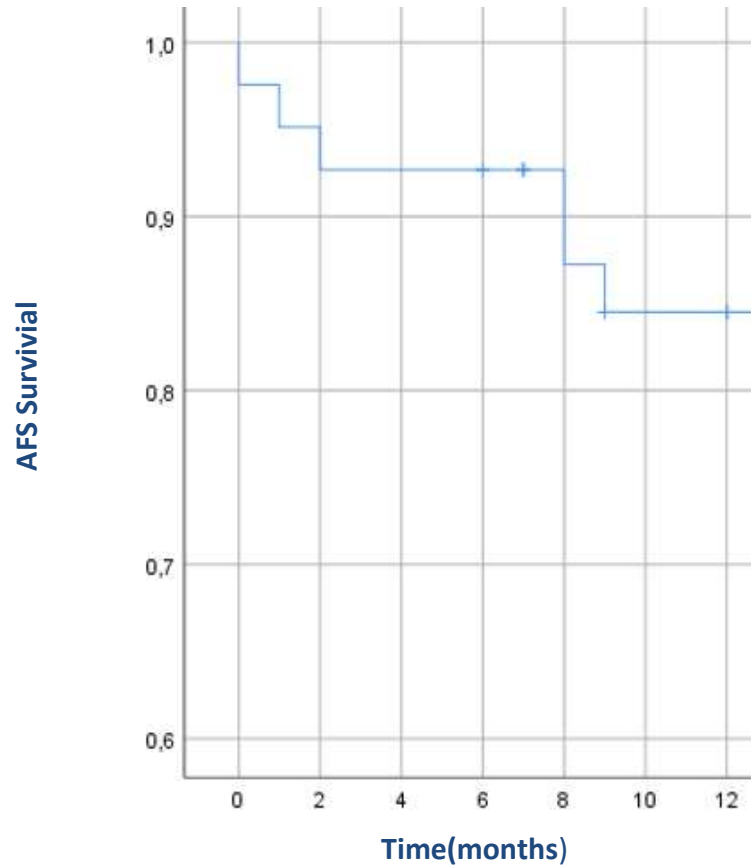


AFS

AFS

6 month = 93%

12 month = 85%



Limb Salvage & Wound Healing

- Limb salvage = 98% @ 6 and 12 months
- Complete wound healing (R5/6) = 79.5% @ 12 months
- Median time to wound healing = 4 months



CASE EXAMPLES



Preliminary Results

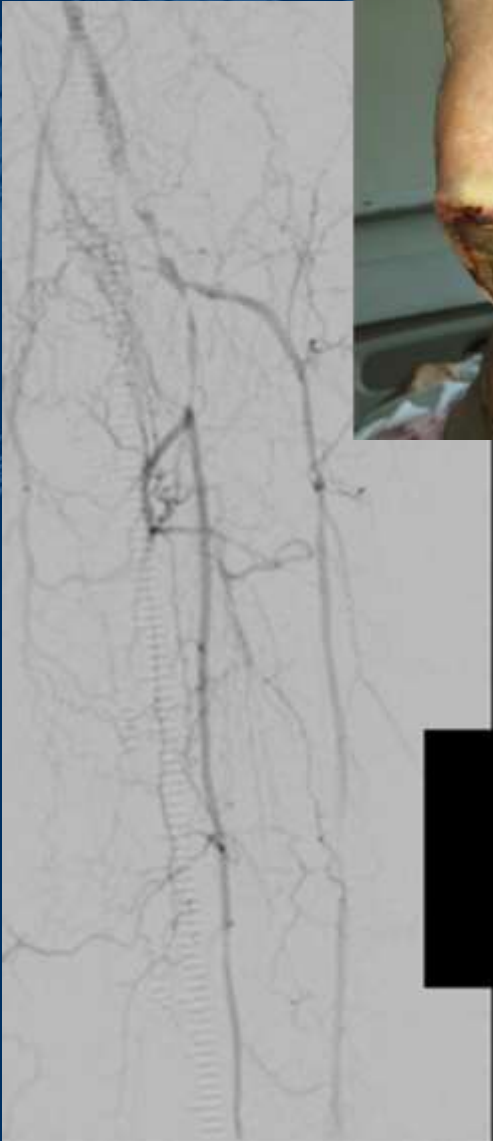
MLD	1.49 mm
Ref D.	2.61 mm
% MLD	43 %
% MLA	68 %
Length	10.33 mm
CF	0.1106 mm/pix



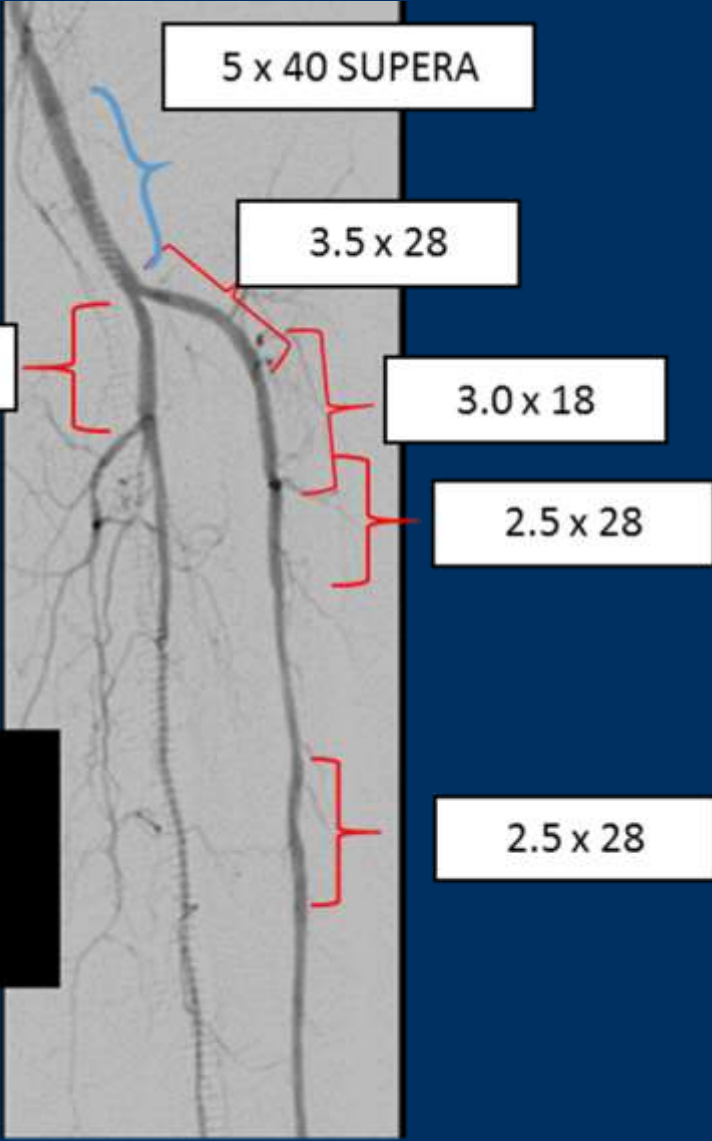
4 months



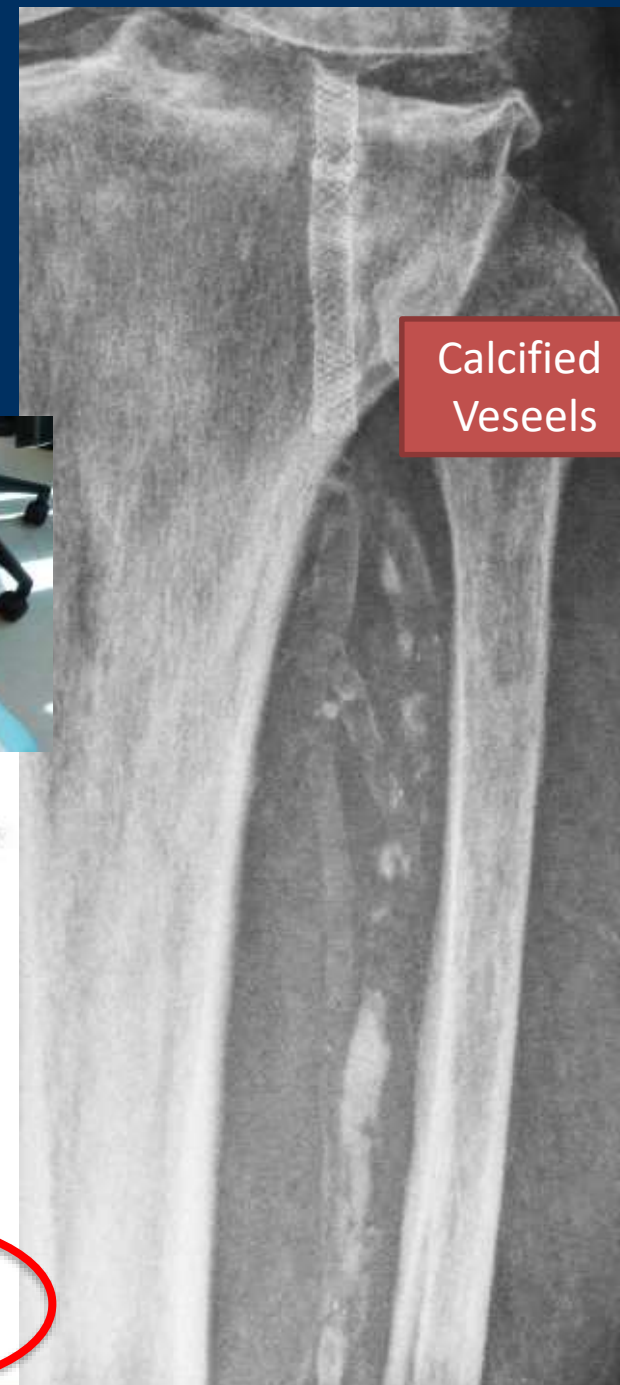
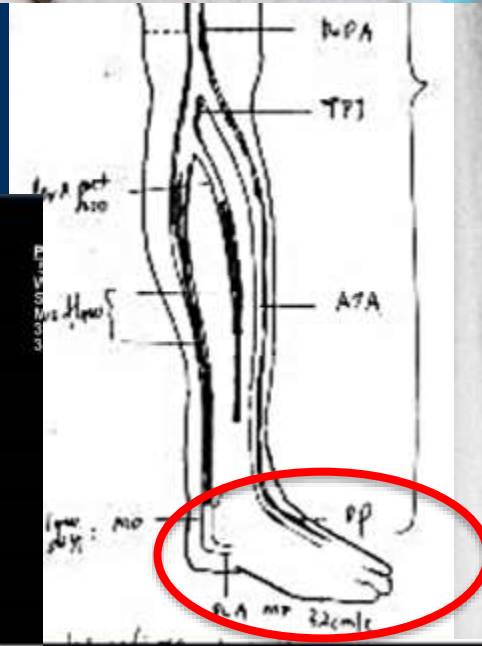
R6 – Heel Gangrene



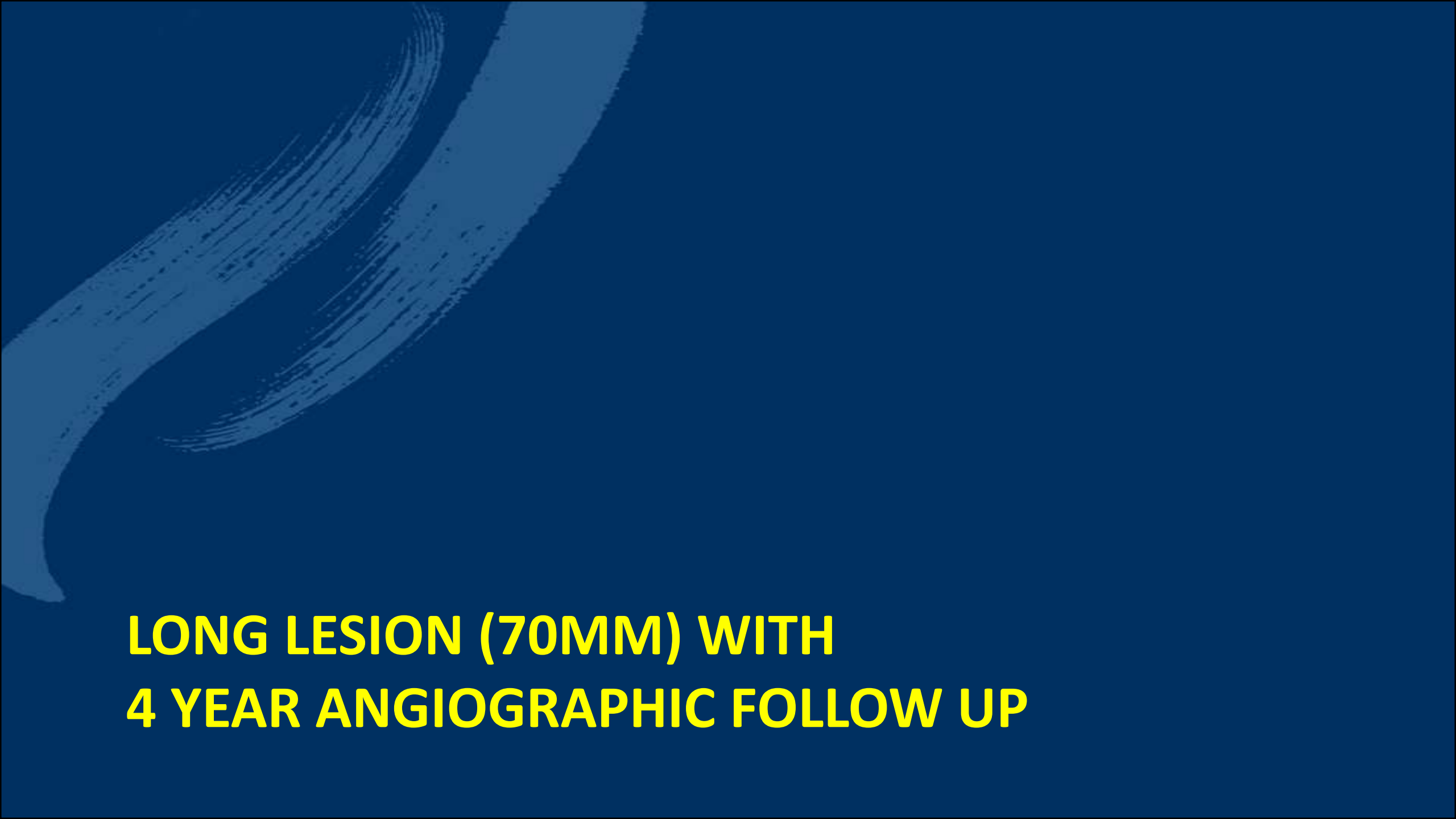
Combination
SUPERA and BVS



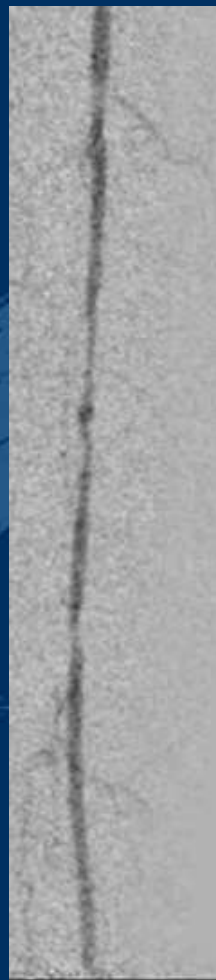
5.5 years – all stented vessels patent, no repeat interventions



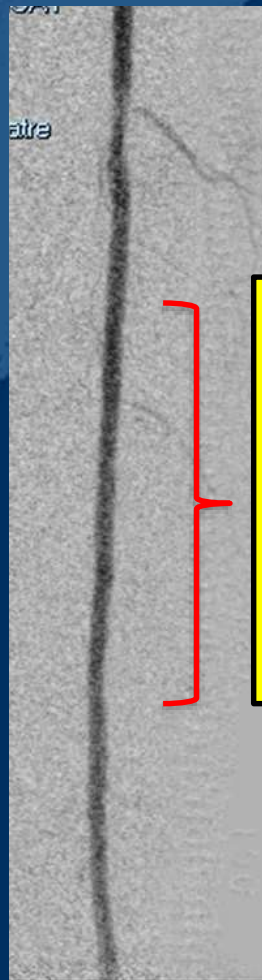
Calcified Vessels



**LONG LESION (70MM) WITH
4 YEAR ANGIOGRAPHIC FOLLOW UP**

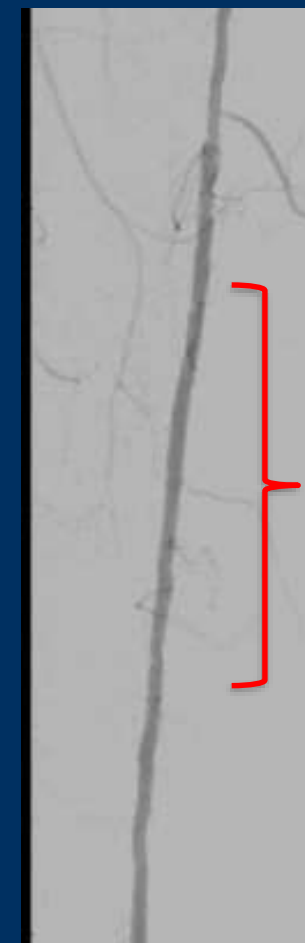


Aug 2012
pre implantation



Aug 2012
post implantation

BVS
3 x 28
3 x 28
3 x 18
Total Stented Length
= 70mm



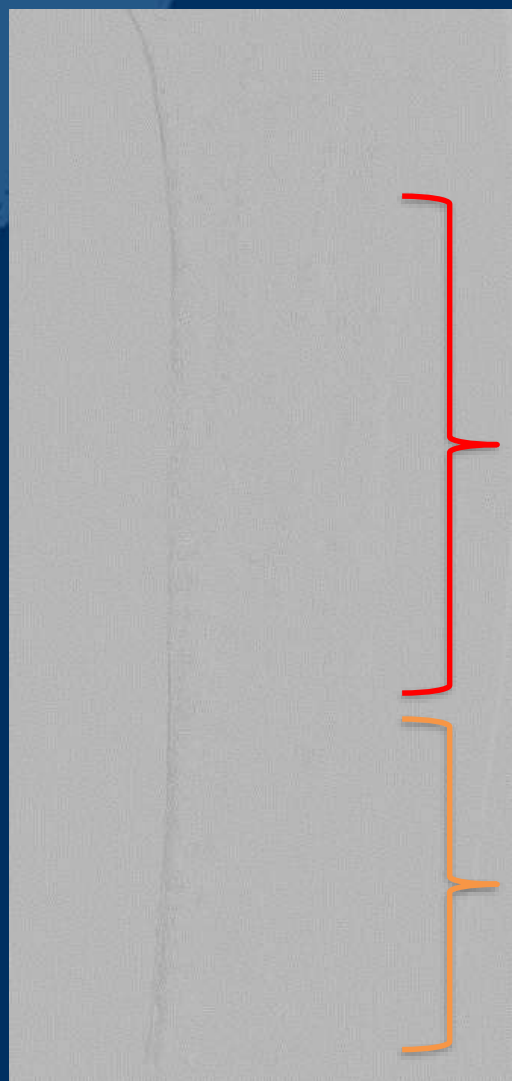
Oct 2016
Control Angiogram

Progression of disease in non stented vessel



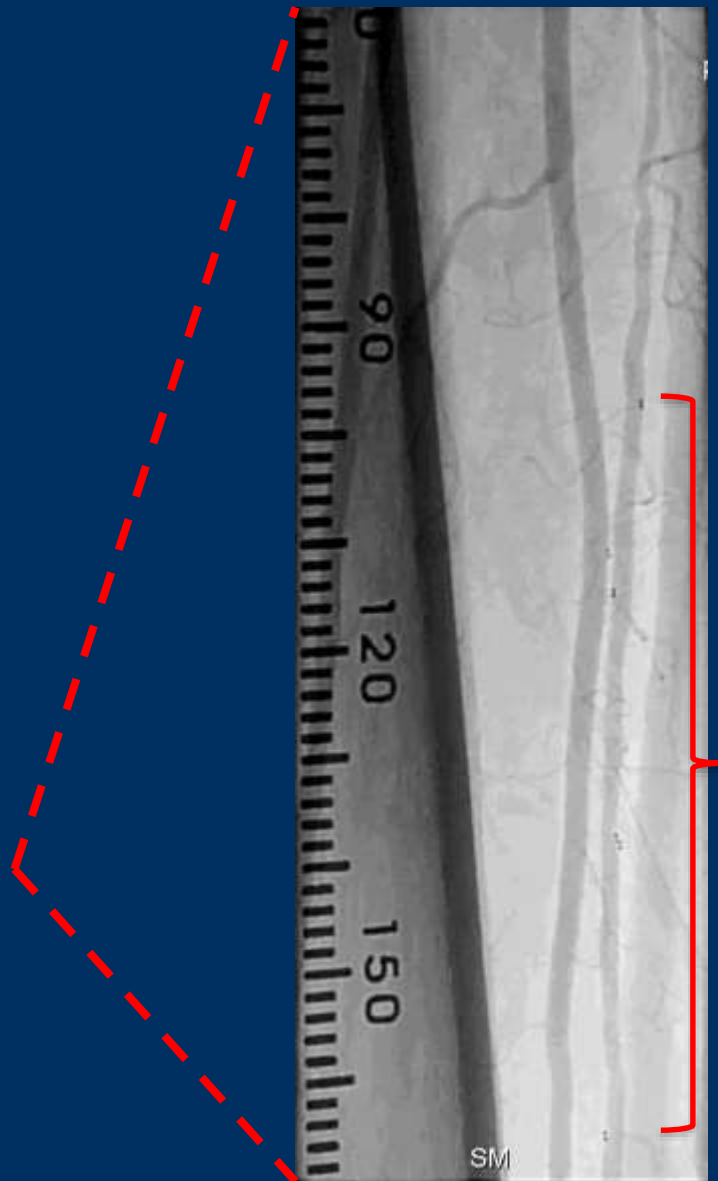
Upper ATA was normal

Disease segment



Progression of disease in the segment of ATA

BVS segment is disease free



Index Angio 2012 (before BVS)

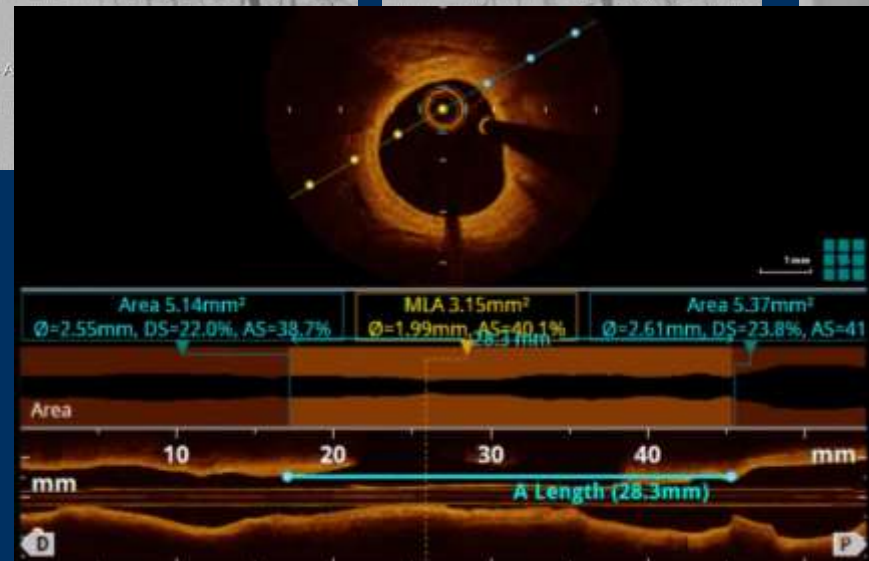
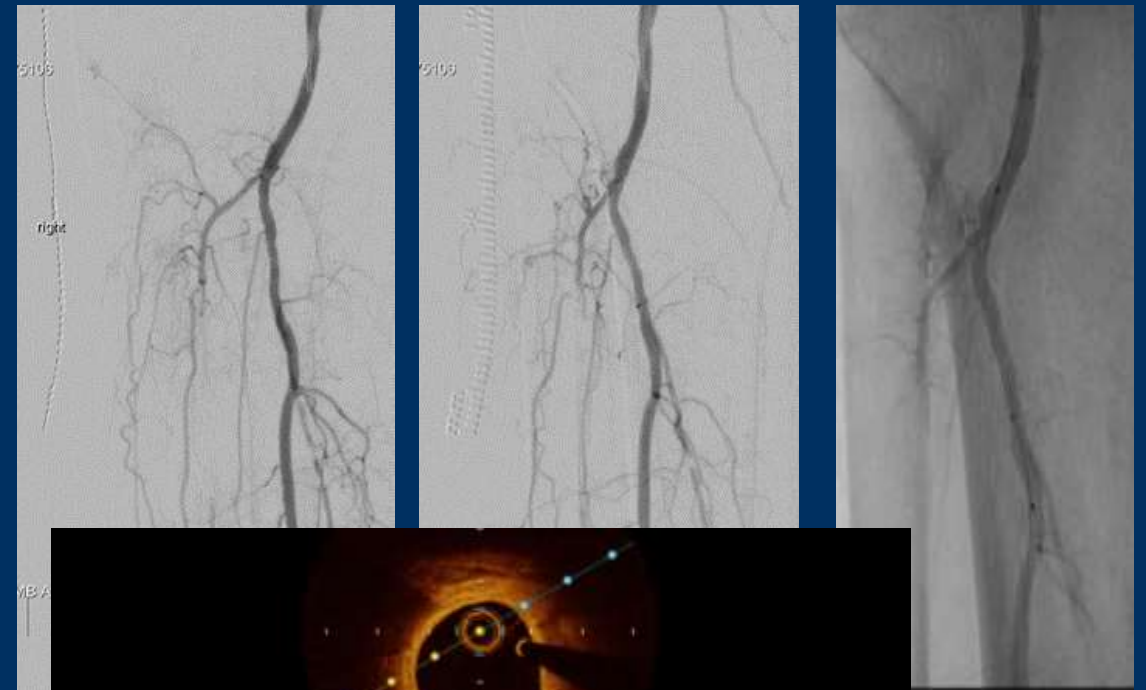
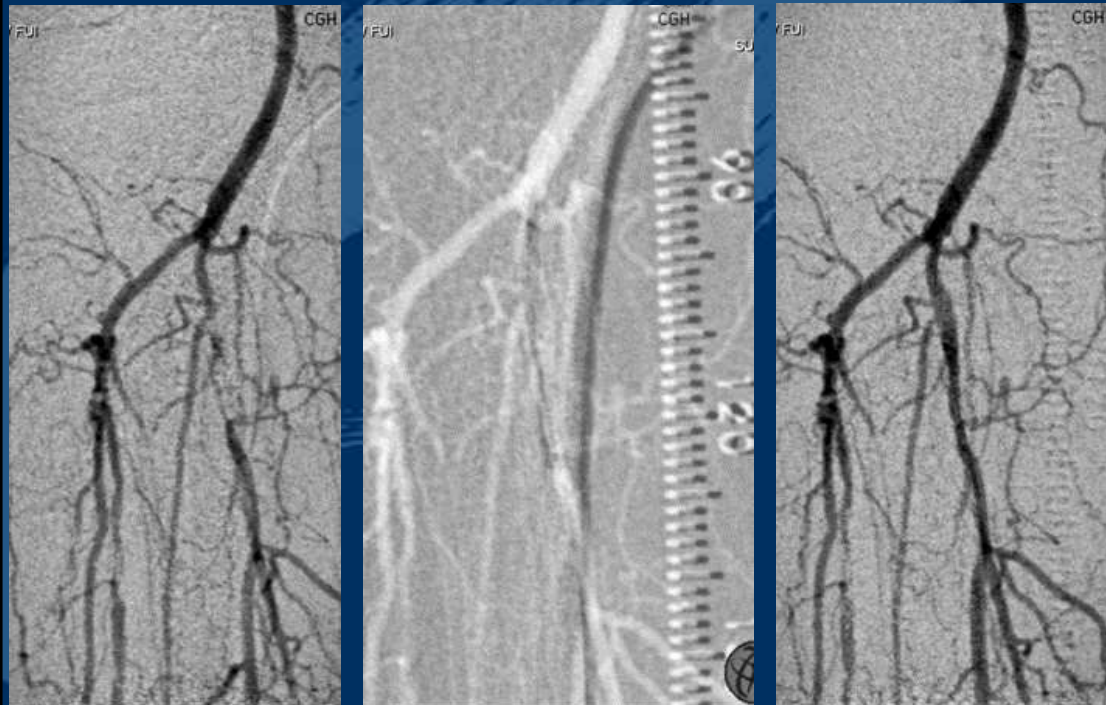
2016

SM



7 YEAR ANGIOGRAPHIC AND OCT FOLLOW-UP

7 Year BVS 3 x 28



Summary

- BTK lesions are associated with recoil, high restenosis and high reintervention when treated with standard POBA
- There may be a role for *Scaffold* and *Drug elution* for reliable lumen gain and consistent drug elution
- Our experience in the *DISAPEAR registry* is encouraging with good patency , low TLRs, and high limb salvage / wound healing rates
- We eagerly await the commencement of LIFE BTK Study

12 Month Results of the DISAPEAR Registry (ABSORB BVS in CLTI)

- Single centre retrospective analysis of BVS implanted in Rutherford 4/5/6 CLTI Aug 2012 to June 2017
- 90% DM, 12% Dialysis dependent, 93% R5/6 (tissue loss)
- 53 lesions treated with 69 scaffolds in 41 patients, Rutherford 5 = 56%, Rutherford 6 = 37%
- Lesion length = 22.7 ± 17.2 mm (Range 4-88), Median stenosis = 80%
- Lesion location: TPT 11 (33%), ATA 14 (26%), PTA 11 (21%), Peroneal 6 (11%), Popliteal 5 (9%)
- PARC Classification of calcification: Focal = 50%, Severe = 24%
- **Results**
 - Technical success 100%
 - Primary patency (DUS PSVR < 2.0) = 95% at 6 months, 86% at 12 months
 - FF CD-TLR = 98% at 6 months, 93% at 12 months
 - FF TLR & US Occlusion = 98% at 6 months, 93% at 12 months
 - AFS = 93% at 6 months, 85% at 12 months
 - Limb Salvage = 98% at 6 and 12 months
 - Complete wound healing = 79.5% at 12 months
 - Median time to wound healing = 4 months

The LINIC logo is located in the top left corner. It features the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font, arranged horizontally. To the left of the letters is a stylized graphic consisting of three overlapping, curved bands in shades of blue, red, and orange, resembling a flame or a dynamic shape.

LINIC

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