



L I N 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

# Primary Patency Favors DES

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

CIRSE

CLINICAL INVESTIGATION

ARTERIAL INTERVENTIONS

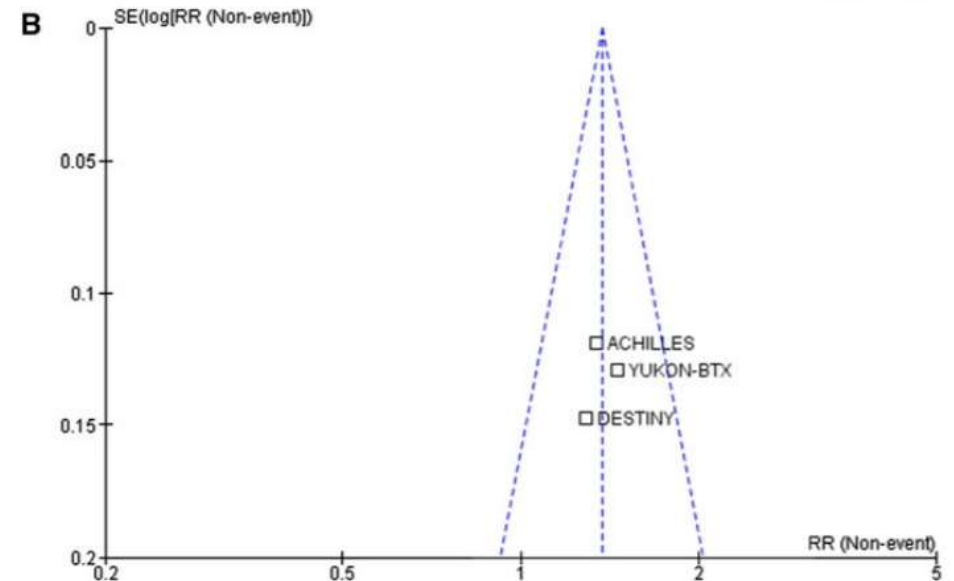
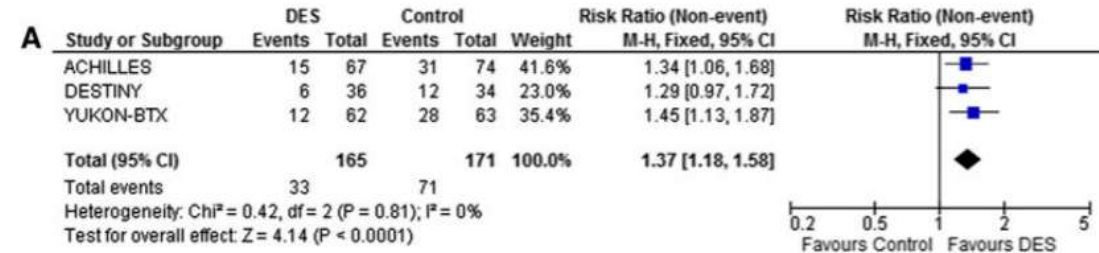
## Systematic Review of Intrapopliteal Drug-Eluting Stents: A Meta-Analysis of Randomized Controlled Trials

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

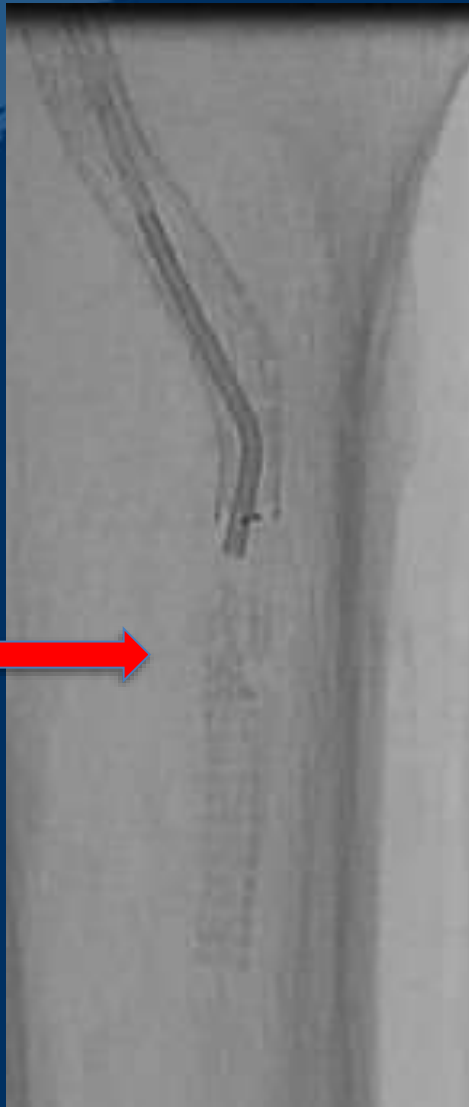
- Scaffold and reliable luminal gain
- Reliable drug delivery even in calcification
- Prolonged drug delivery
- No toxic effects (systemic and distal)

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 ( $\chi^2$ ) 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 $\mu$ g/cm<sup>2</sup>)
- 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 "Example: '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 % 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	<b>22.7±17.2 (4-88)</b>
Degree of stenosis (median [range]) (%)	80 (50–100)
Total occlusion	4 (8)
Target vessel diameter (median [range]) mm	3 (2.5–3.5)
<b>PARC classification</b>	
Non	1 (2)
Focal	19 (46)
Mild	4 (10)
Moderate	7 (17)
Severe	<b>10 (24)</b>
<b>TASC classification</b>	
A	25 (61)
B	14 (34)
C	0 (0)
D	2 (5)
No, of Lesions	<b>53</b>
Total number of scaffolds deployed	<b>69</b>



# RESULTS

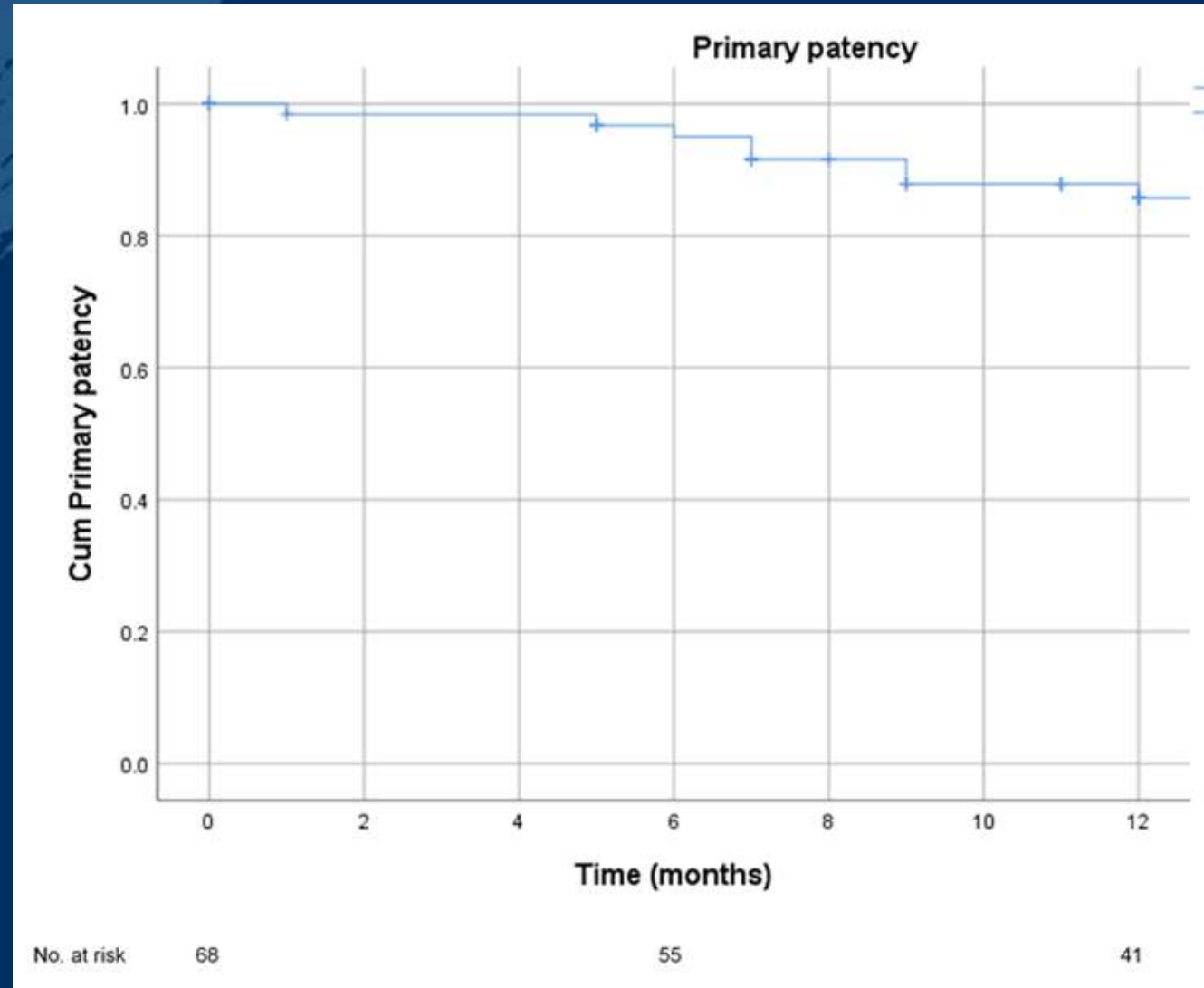
# Primary Patency

## Primary Patency

6 month = 95%

12 months = 86%

DUS PSVR<2.0

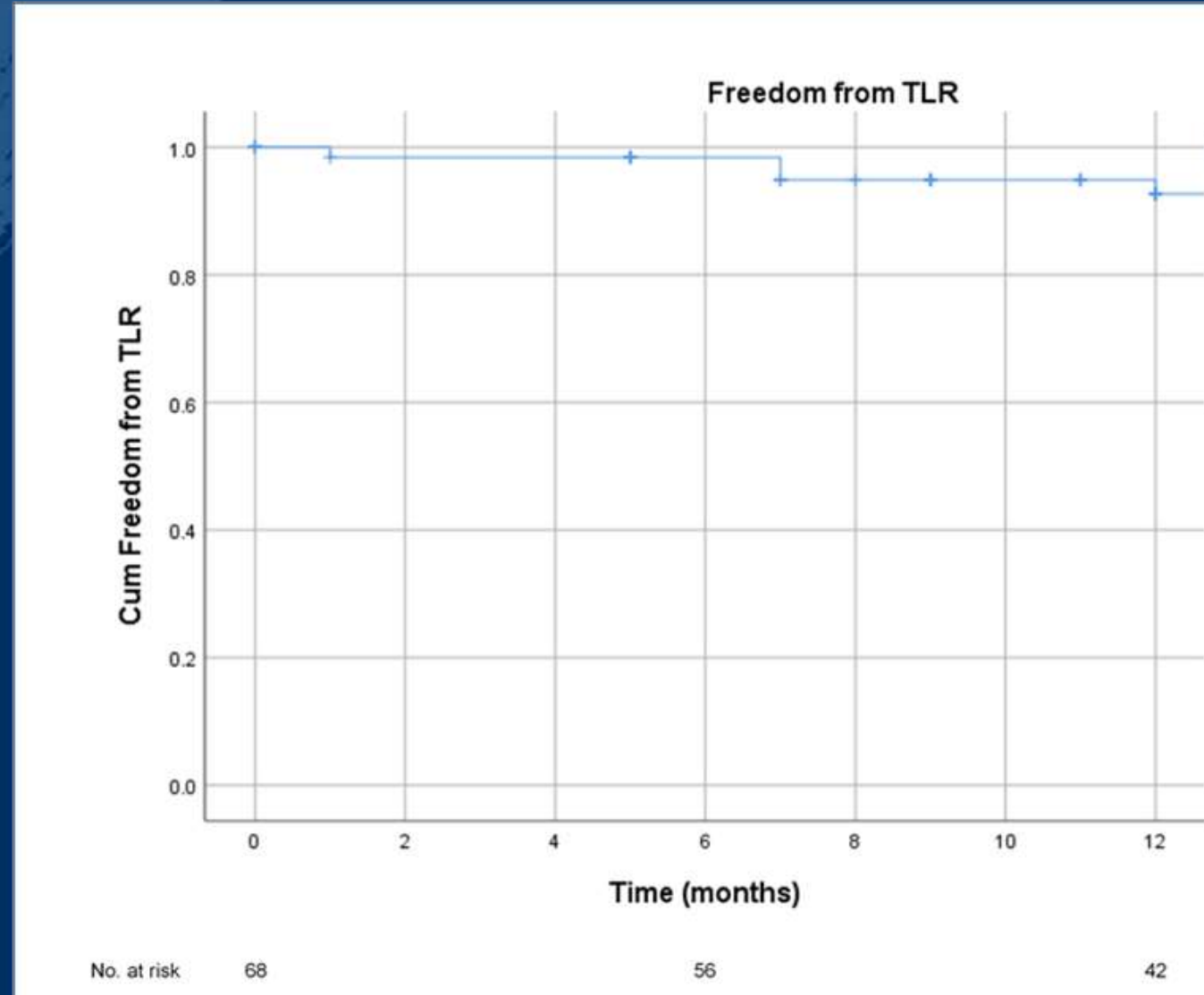


# Freedom from CD-TLR

## FF CD-TLR

6 month = 98%

12 month = 93%

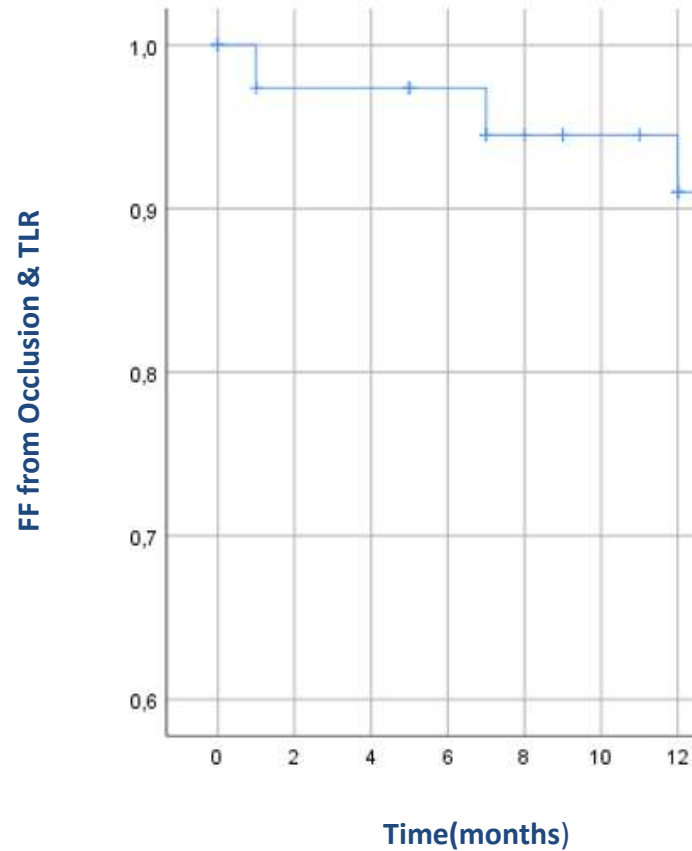


# Freedom from TLR & US Occlusion

## FF TLR & Occlusion

6 month = 98%

12 month = 93%

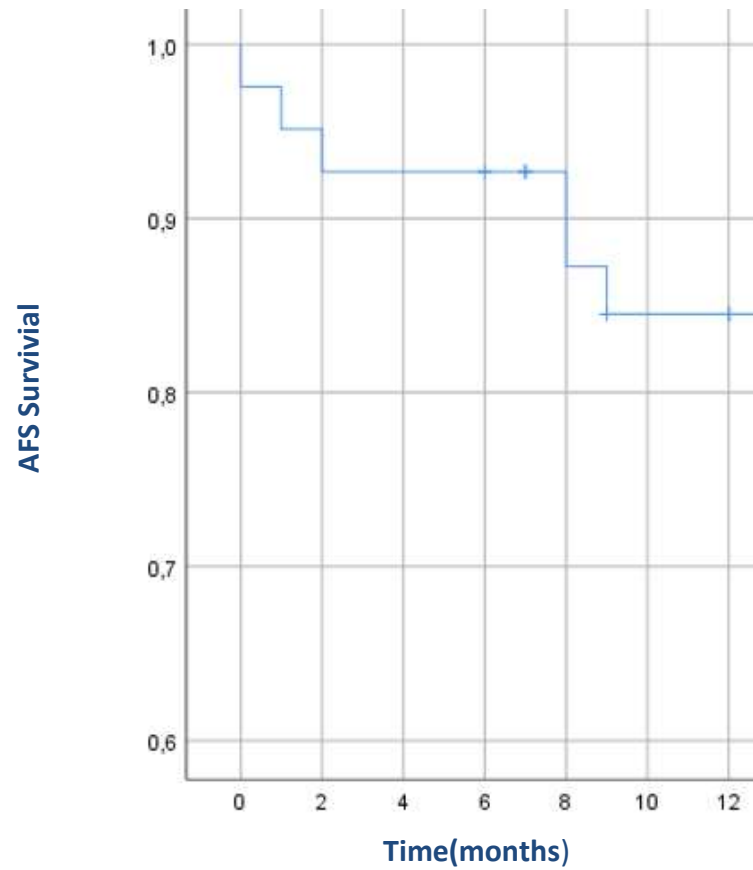


# AFS

## 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



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

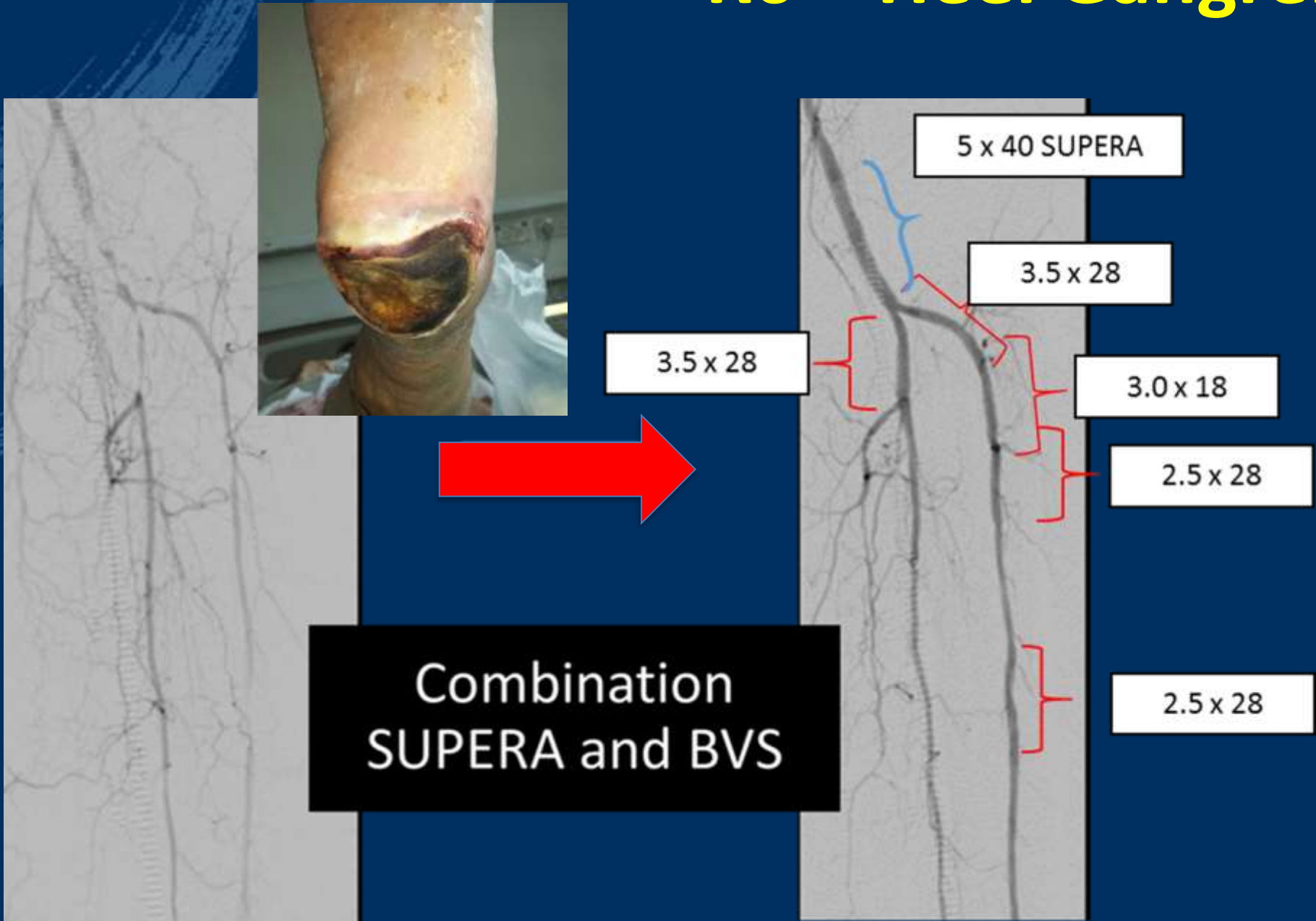


4 months

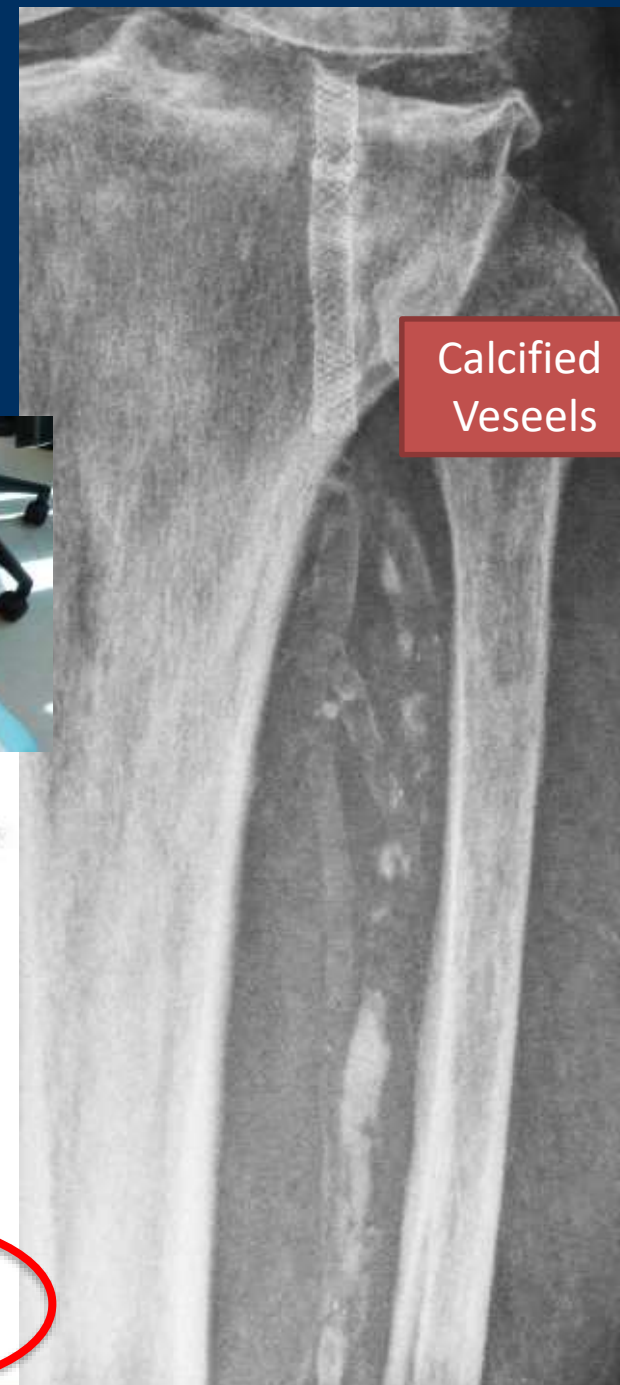
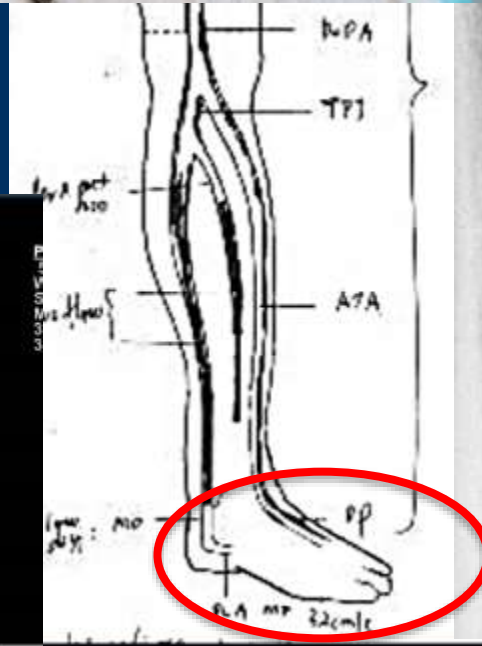




# R6 – Heel Gangrene



# 5.5 years – all stented vessels patent, no repeat interventions

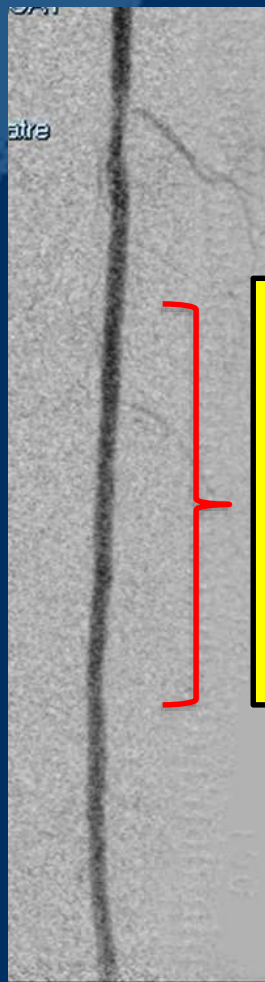


Calcified Vessels

# 4 year Angiographic Follow up

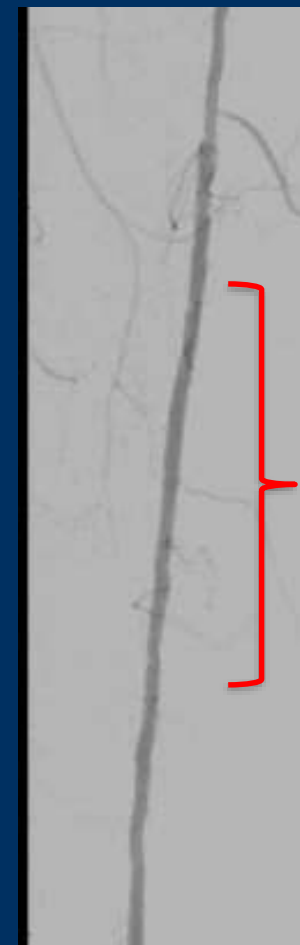


Aug 2012  
pre implantation



Aug 2012  
post implantation

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



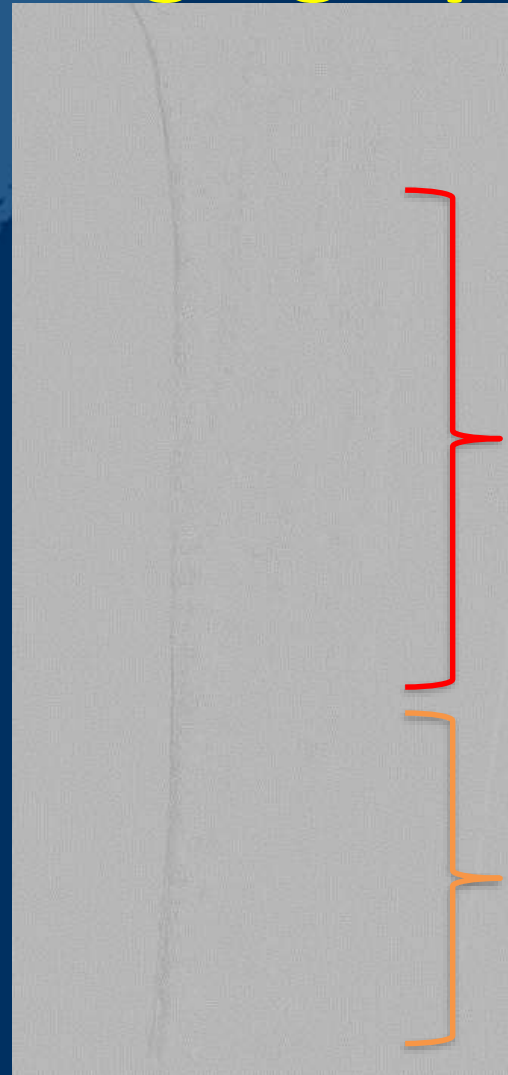
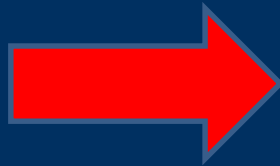
Oct 2016  
Control Angiogram

# 4 year Angiographic Follow up



Upper ATA  
was normal

Disease  
segment

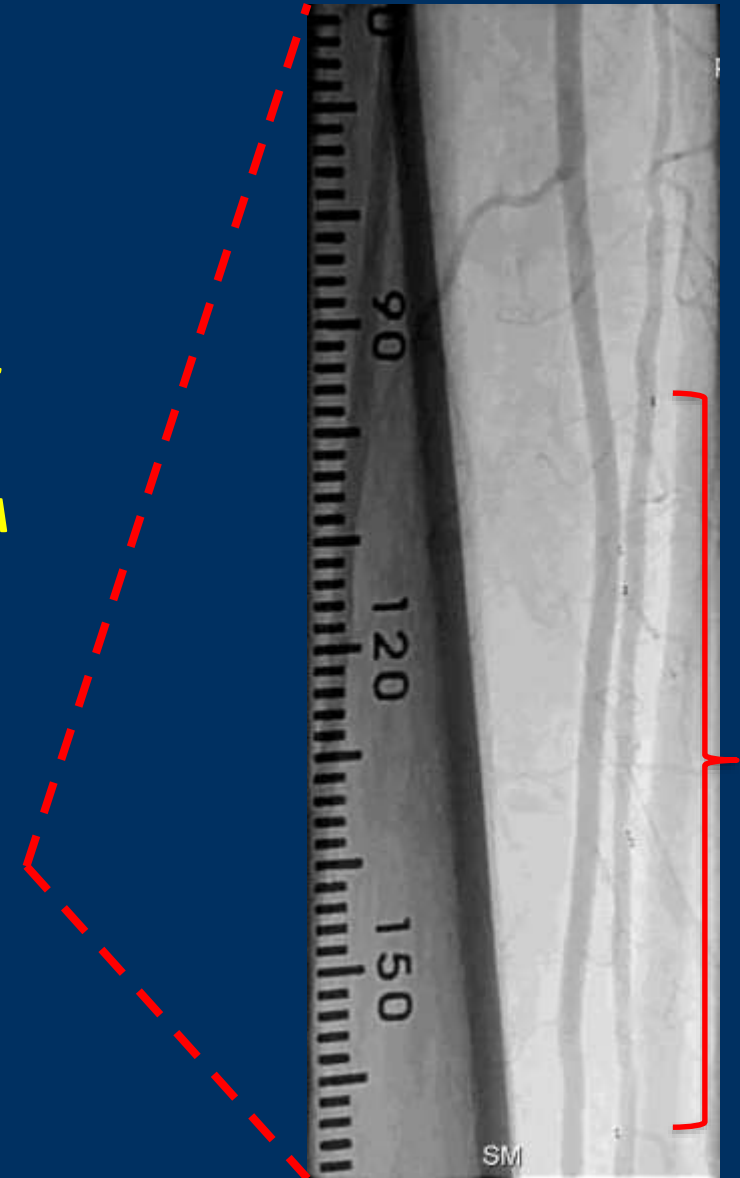


*Progression of  
disease in the  
segment of ATA*

*BVS segment is  
disease free*

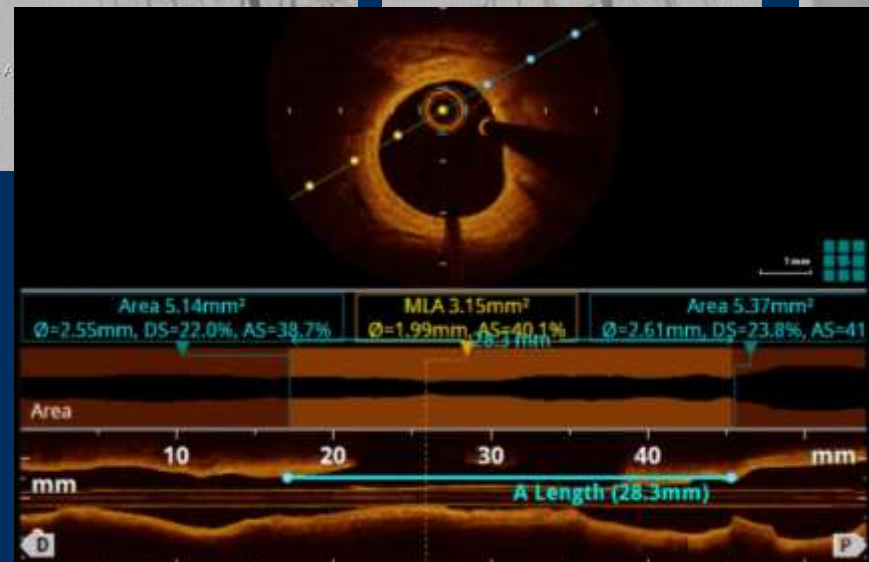
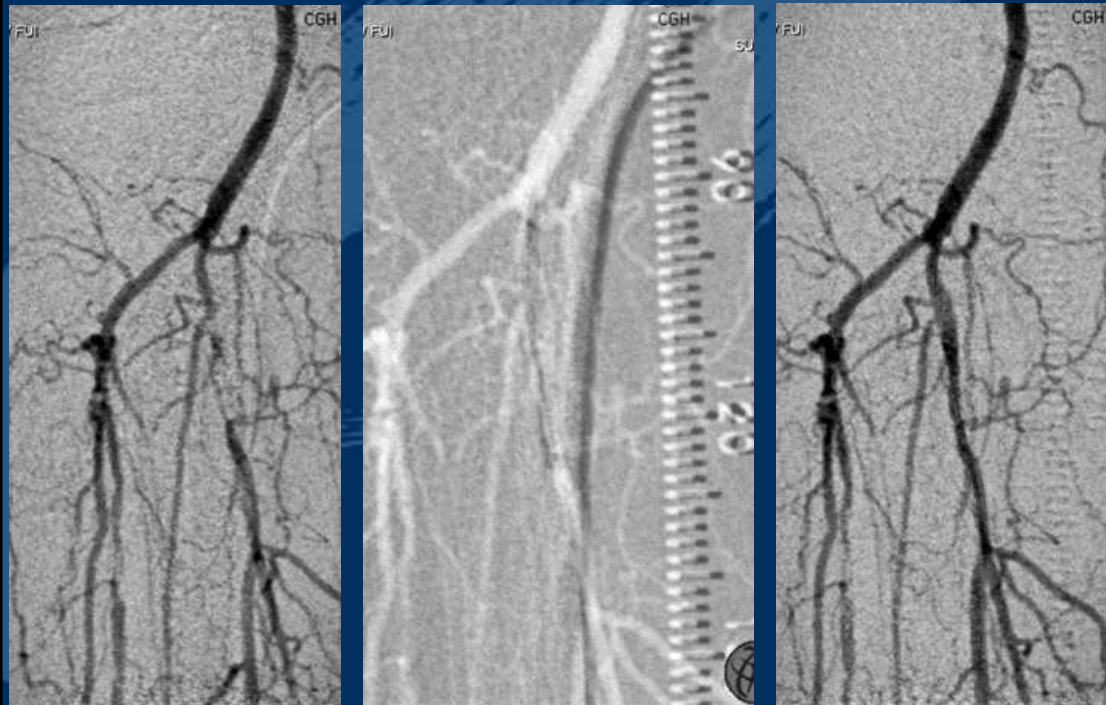
Index Angio 2012  
(before BVS)

2016



SM

# 7 year Angiographic + OCT



# Combined 3 centre BVS experience - *Interim*

3 Centre Experience  
(Varcoe, Kum, Shah)

189 scaffolds in 125 patients

## Primary Patency

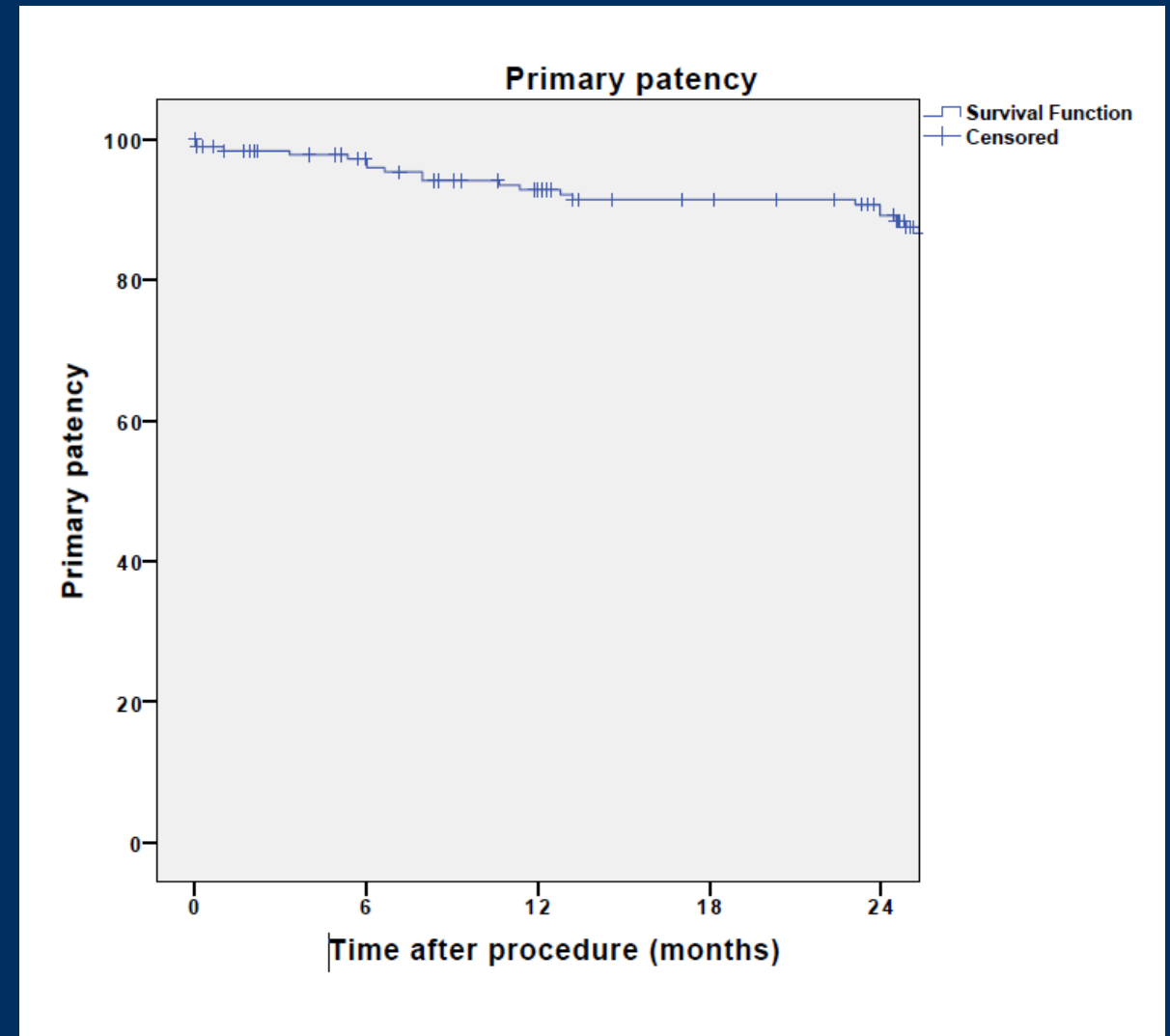
12 months 91.1%

24 months 88.6%

## TLR

12 months 96.6%

24 months 94.5%



# 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 next generation BVS dedicated for BTK interventions



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