DES for SFA/Pop 12 Month Results of the DESAFINADO Registry

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Disclosure

Speaker name:

Steven Kum

I have the following potential conflicts of interest to report:

- ☑ Consulting *BSC*
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

DES works for short lesions..

MAJESTIC

Overall Efficacy & Safety

36-Month Safety Profile

- **85.3%** freedom from TLR rate (K-M estimate)
- No target limb major amputations
- 2 deaths at >365 days post-procedure, unrelated to study device or procedure

Stent Integrity

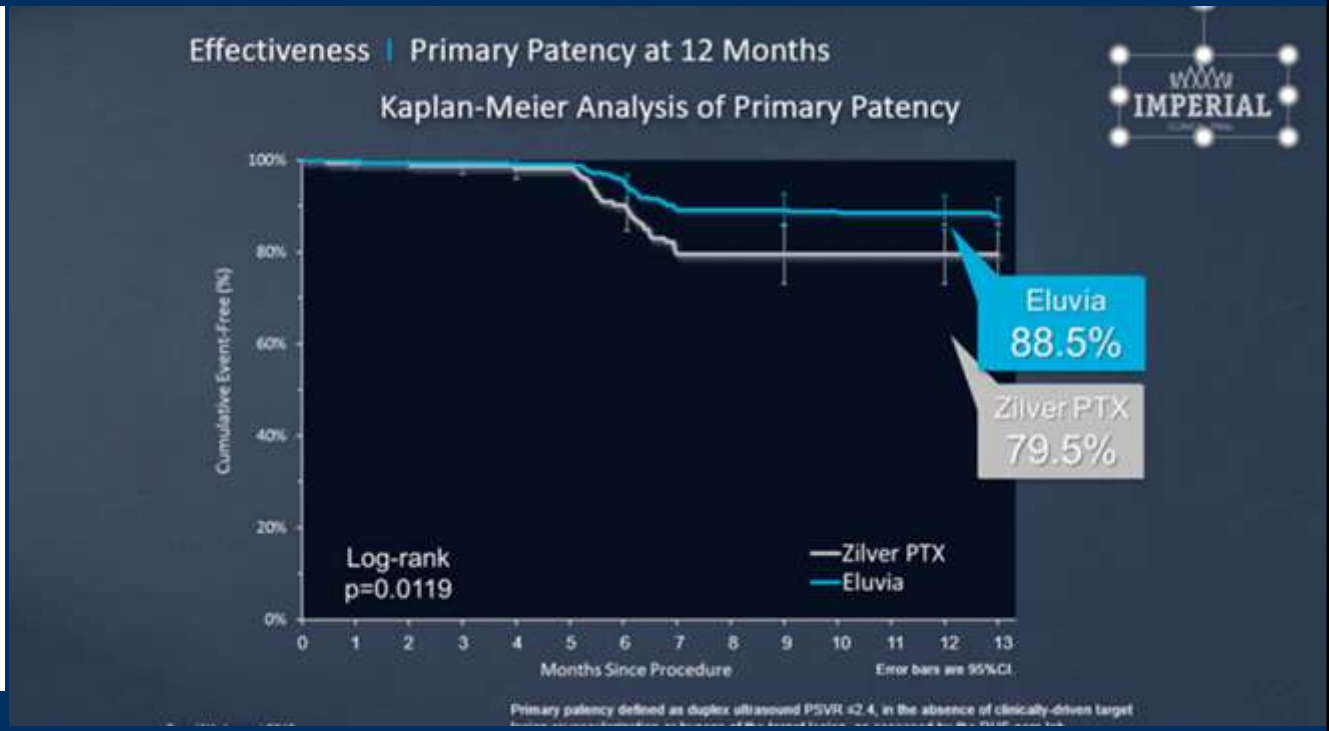
- No stent fractures[a]

	12 Months	24 Months
TLR	96.4%	92.8%
Primary Patency[b]	96.4%	83.5%
Assisted Primary Patency[c]	98.2%	88.9%

Note: Kaplan-Meier estimates.
[b]Duplex ultrasound peak systolic velocity ratio ≤2.5 and absence of TLR or bypass. [c]No TLR and those with TLR not for complete occlusion or bypass who were free of restenosis at 24 months.

[a]X-ray evaluation with angiographic verification were performed at 12 and 24 months. No fractures were reported in relation to adverse events through 3 year follow up.

IMPERIAL



DESAFINADO Registry

DES
for
Arteria **F**emoralis
IN
Asian
Diabetic
F**O**ot

AIM:
Investigate use of Eluvia DES in real world cases

Study Endpoints (@12 months)

1. **Primary Endpoint**
   - Primary patency by DUS (PSV < 2.4)
2. **Secondary Endpoints**
   - FF CD-TLR
   - AFS
   - Clinical Improvement (Complete wound healing/resolution rest pain/improvement in claudication)

Inclusion Critieria

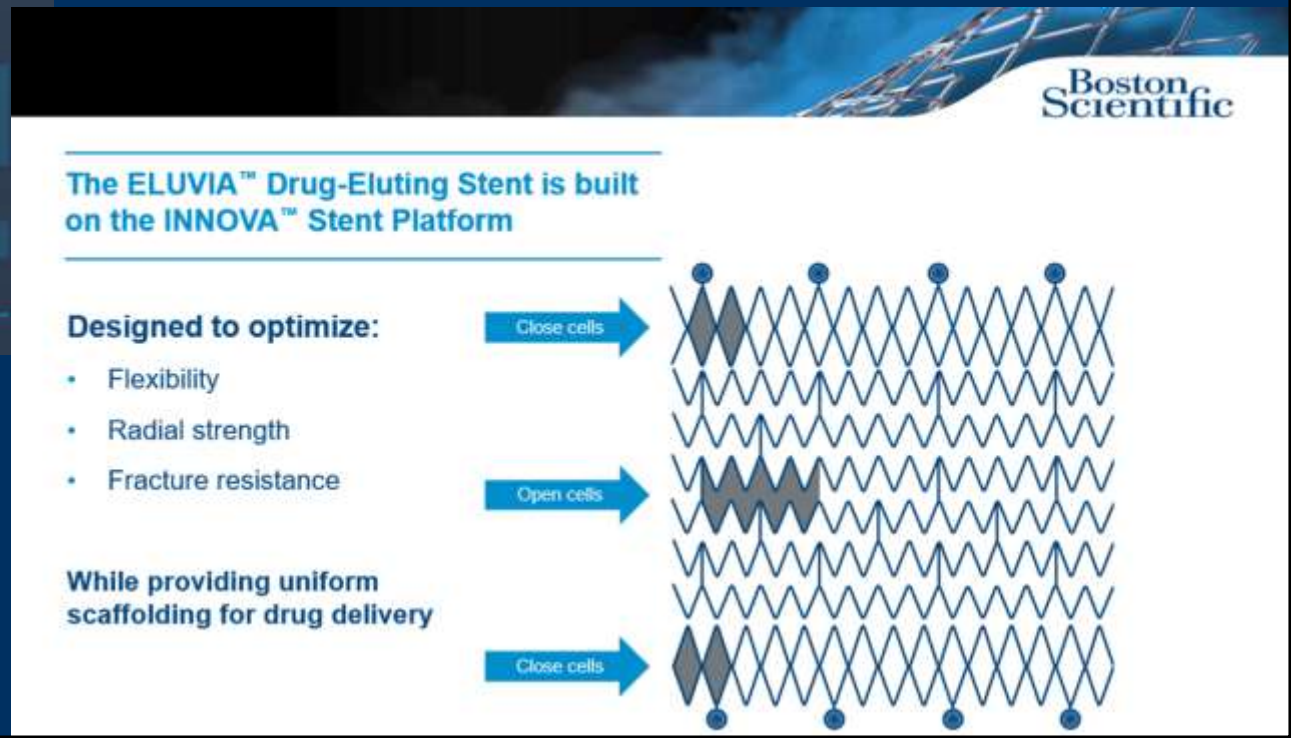
- Single-center, physician-initiated, retrospective study
- SingHealth institutional review board (IRB 2019/2493)
- All comers, CLI and Claudication (CLI predominant)
- Eluvia DES for SFA/Popliteal (including P3)between September 2016 and October 2018

Exclusion

- Acute Limb Ischemia
- CFA disease
- DES for ISR
- DCB of same segment 1 month prior
- DCB with bail out stenting with DES (ie extensive “double drug”)

Study Device

	Eluvia™ DES Boston Scientific		Zilver® PTX® Cook Medical	
				
Stent Platform	Innova		Zilver Flex	
Material	Nitinol		Nitinol	
Polymer	Biostable Fluorinated Polymer Matrix (PROMUS polymer)		None	
Drug **Dose Density**	Paclitaxel 0.167µg/mm²		Paclitaxel 3 µg/mm²	
Deployment	Self-expanding		Self-expanding	
Sizes	Diameter 6-7 mm	Length 40-150 mm	Diameter 6-8 mm	Length 40-120 mm



Implantation technique

- Lesion assessment on 2 view angiography
- Pre-dil 1:1 → assess recoil and dissection
- Decision for DCB or DES or “Hybrid” DCB/DES combination
- Aggressive pre-dilatation 1:1 with NC Balloons (Mustang/Dorado) with ***High pressure*** (>20 atm) of segments intended for DES
- DES with Eluvia
- Post dilatation with same High Pressure balloon to reduce recoil

Results – Stenting Strategy

- Preferred technique is total lesion coverage with DES
- “Hybrid” lesion coverage with DES/DCB combination

Study Population (n = 64)

Age, mean±SD	70±12.5
Gender (male)	38(59)
Ischemic heart disease	26 (41)
Diabetes Mellitus	50 (78)
Hyperlipidemia	48 (75)
Hypertension	55 (86)
Dialysis dependent renal failure	11 (17)
Rutherford	
3	11 (16)
4	3 (5)
5	53 (79)
Runoff	
0	8 (12)
1	32 (48)
2	16 (24)
3	3 (11)

78% DM

84 % CLTI

Lesion Characteristics (n = 67)

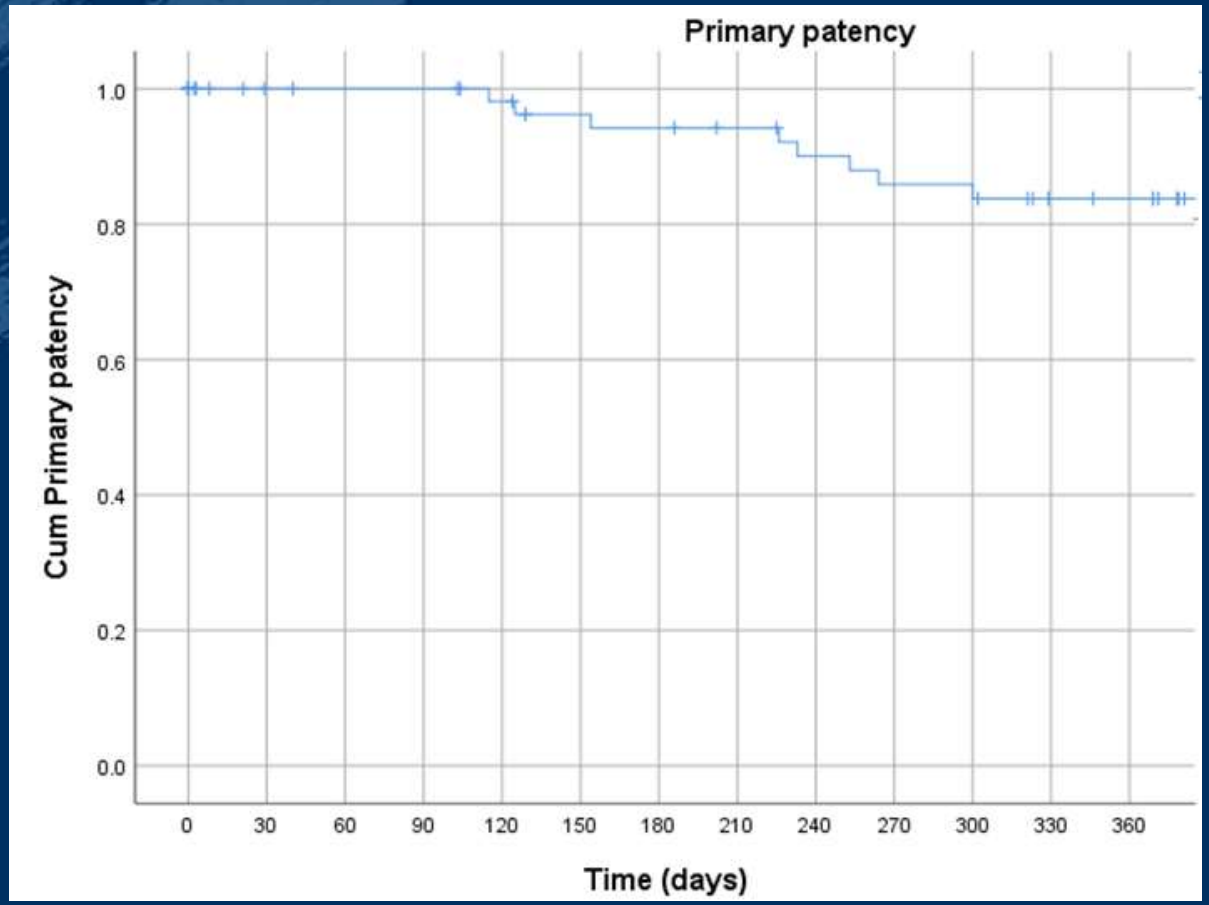
Total number of lesions treated with Eluvia	n (%)
Lesion length, mean (SD)	193 (±128)
Total number of Eluvia stents	146
Total lesion coverage with Eluvia	47 (70)
Occlusions	32 (48)
Lesion location	
Upper SFA	40 (60)
Mid SFA	48 (72)
Lower SFA	45 (67)
P1	35 (52)
P2	25 (37)
P3	20 (30)
PARC classification	
Severe	35 (52)
TASC classification	
A	14 (21)
B	14 (21)
C	17 (25)
D	22 (33)

~ 30% P2/P3

58% TASC C/D

RESULTS

12 Month Primary Patency – Total Cohort

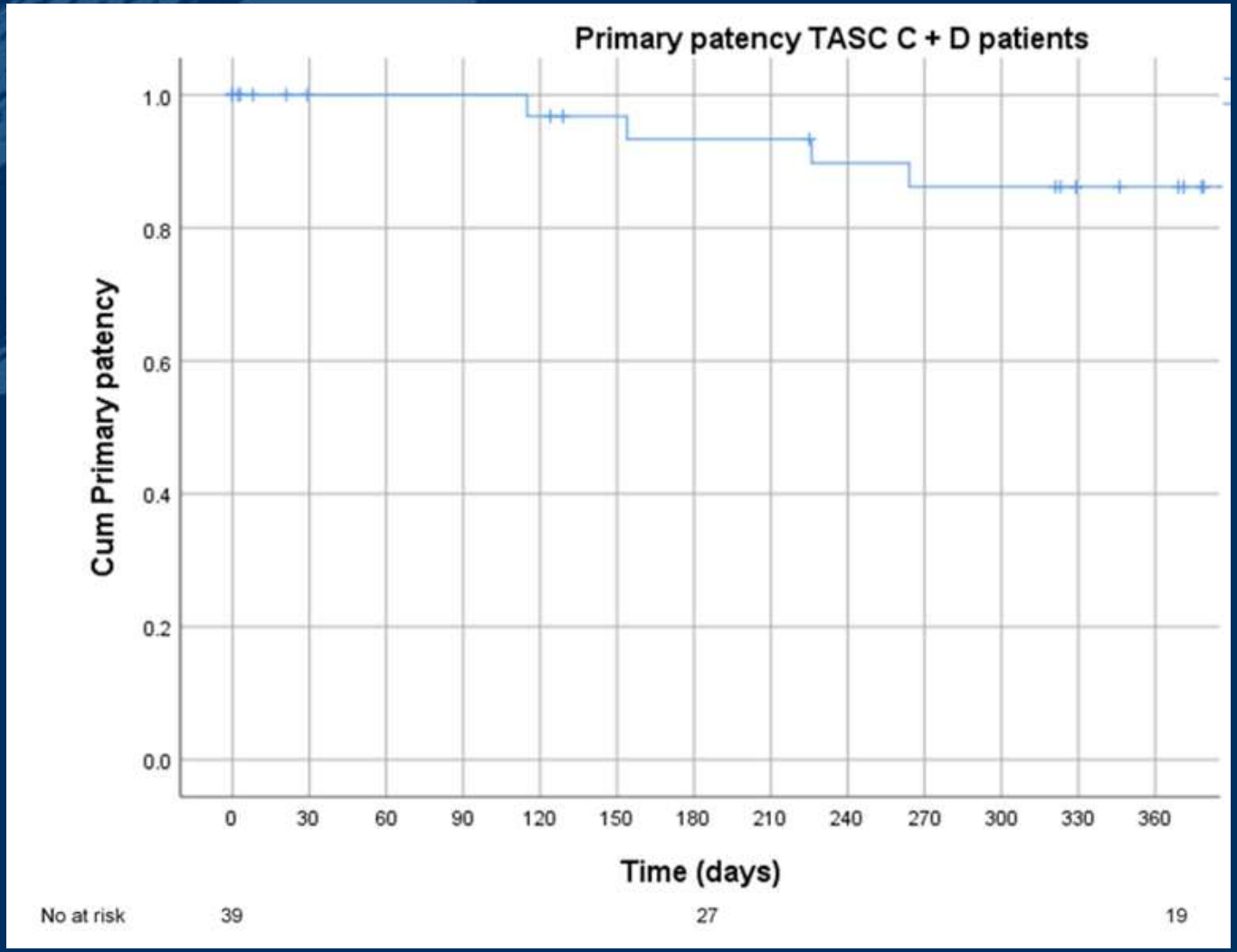


Total Cohort

PP = 84 %

PSVR < 2.4

12 Month Primary Patency – TASC C & D Cohort

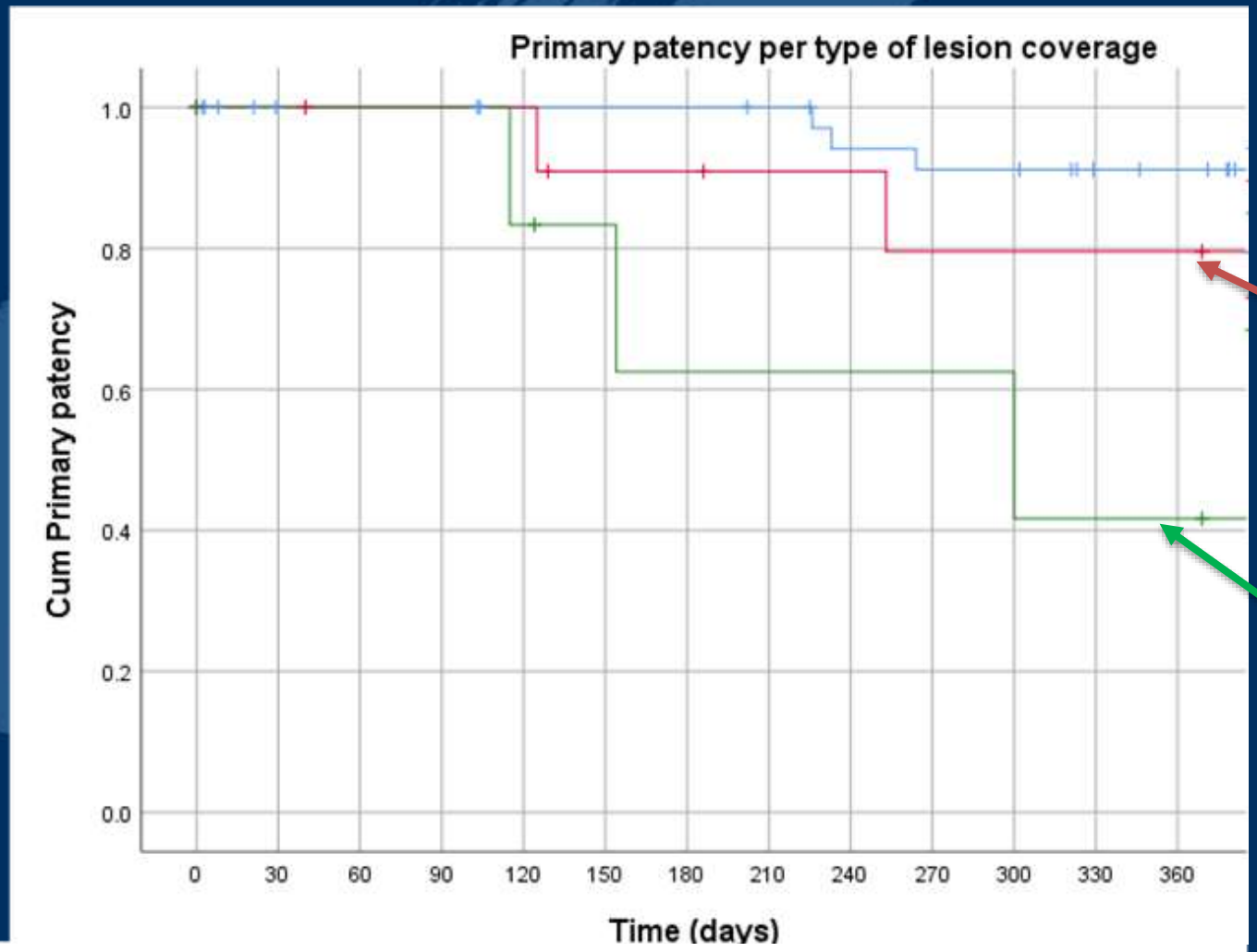


TASC C & D

PP = 86 %

PSVR < 2.4

12 Month Primary Patency – Coverage subtype



Total Lesion Coverage with DES

(mean LL = 201 ± 136)

PP = 91 %

"Hybrid" lesion coverage with DES/DCB

(mean LL = 153 ± 86)

PP = 80 %

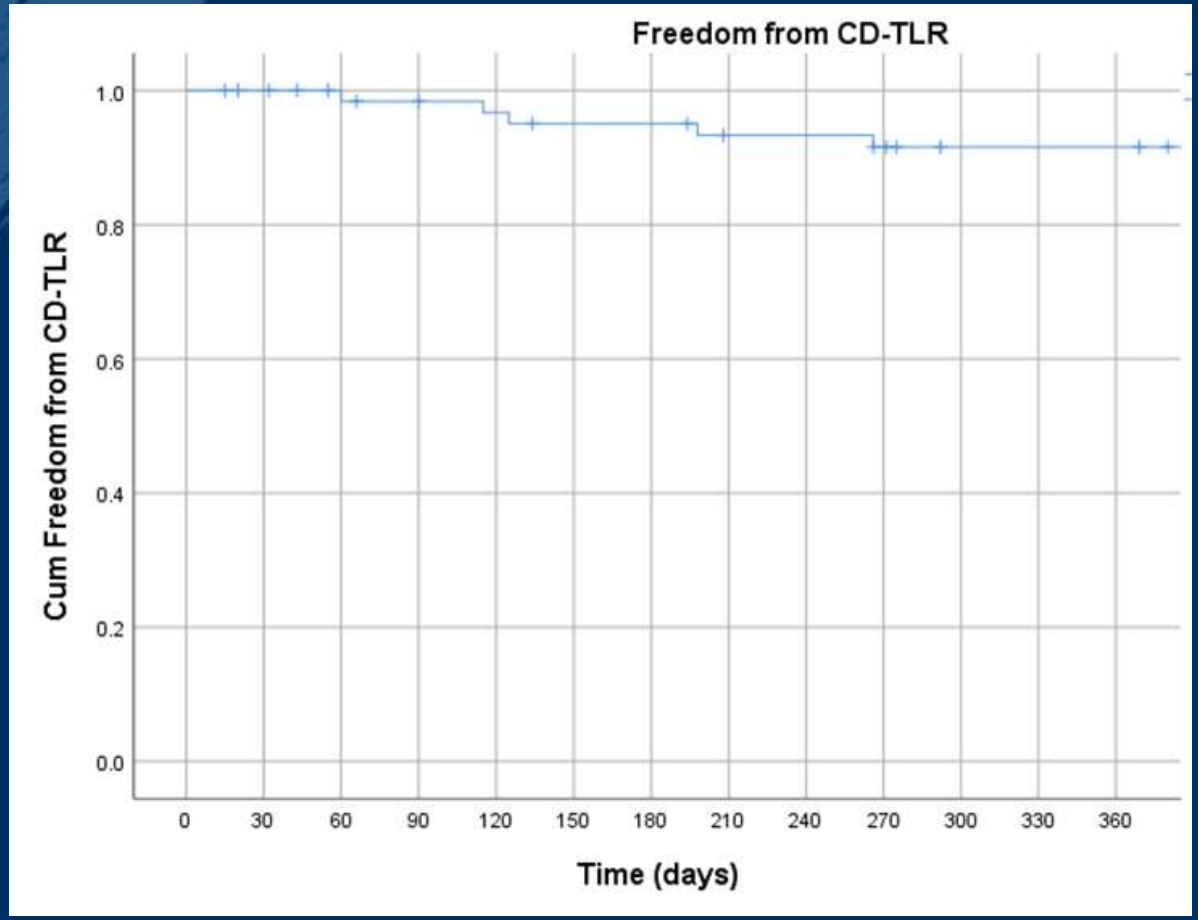
BMS/POBA + DES

(mean LL = 211 ± 143)

PP = 42 %

12 Month Freedom from CD-TLR

FF CD-TLR = 92 %



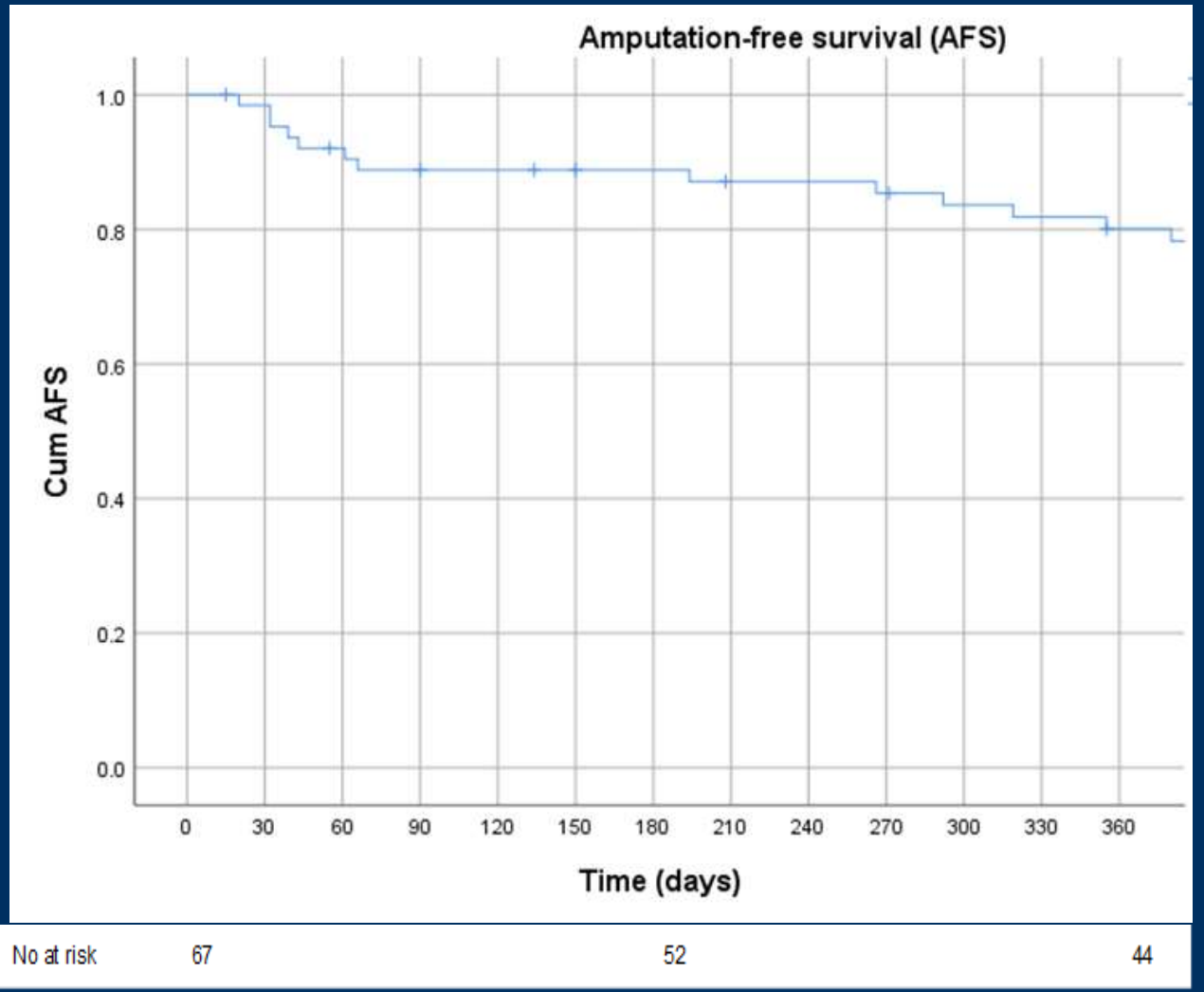
12 Month Clinical Outcome

AFS = 80%

Limb Salvage = 93%

Complete Wound Healing = 80%

Clinical Improvement*= 84%



**Clinical improvement = Complete wound healing, resolution of rest pan or improvement of claudication more than 1 Rutherford class*

Eluvia DES – Clinical Results

	IMPERIAL RCT	MAJESTIC	IMPERIAL Long Lesions	Münster Registry	DESAFINADO Registry
12 Month Primary Patency*	88.5% Diabetic subgroup: 87.4% CTO subgroup: 83.9% Mod/Sev Ca subgroup: 89.2% Japan cohort: 91.1%	96.4%	87.9%	87%	84% Total lesion coverage cohort = 91% (mean LL = 201 ± 136)
Study design	RCT, multicenter, global	Single arm, multicenter	Single arm, multicenter, global	Single center registry	Single center registry
N (Eluvia)	309	57	50	62	67
Remarks			DM 40% PSVR 2.4	DM 37% CLTI 48% Dialysis 5% PSVR 2.0	DM 78% CLTI 84% Dialysis 17% PSVR 2.4
Lesion length (mm)	86.5 ± 36.9	70.8 ± 28.1	162.8 ± 34.7	200 ± 120	193 ±128
Follow-up duration	12 months complete, continue to 5 years	3 years	12 months complete, continue to 5 years	up to ~16 months	12 months

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Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2017;40(12):1832-1838.
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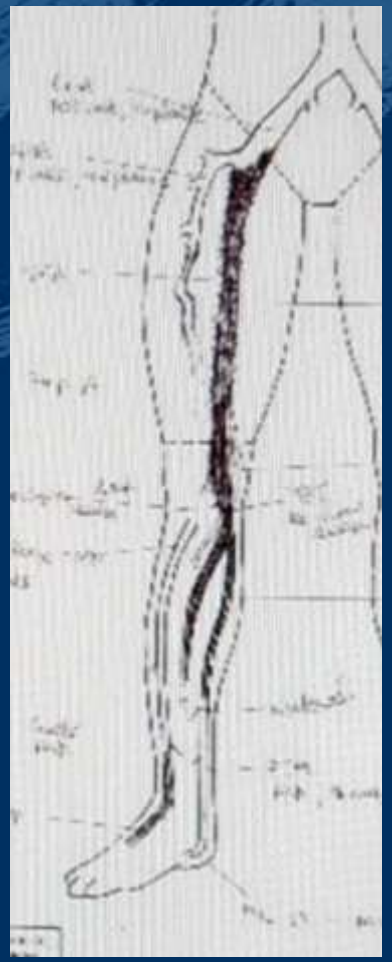
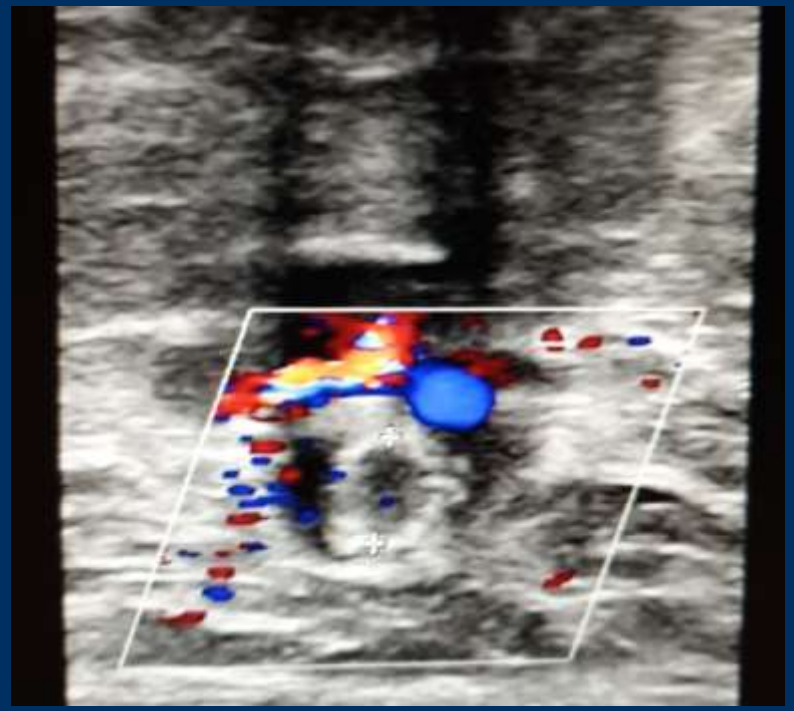
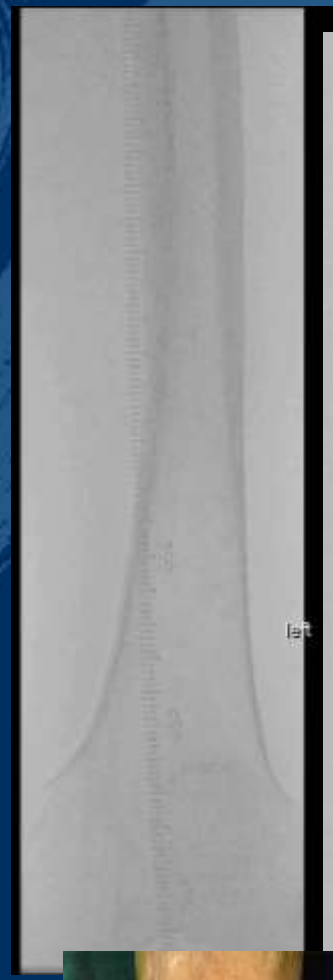
Aneurysmal change





CASE EG


Left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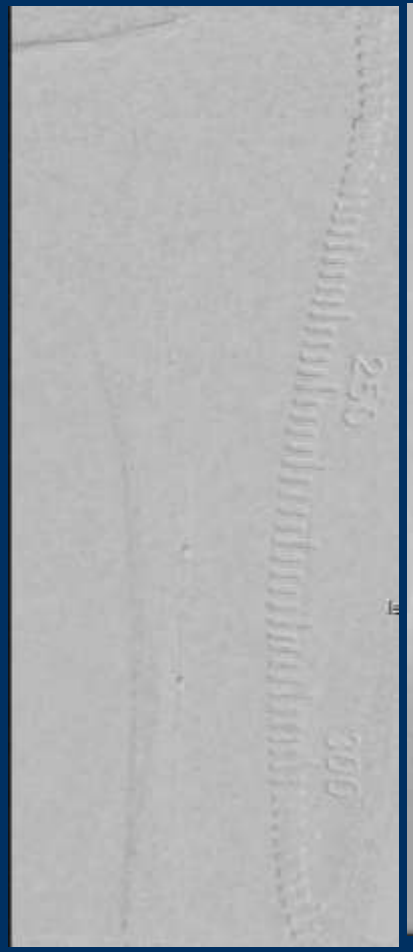
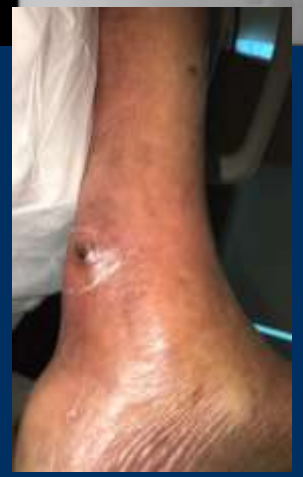
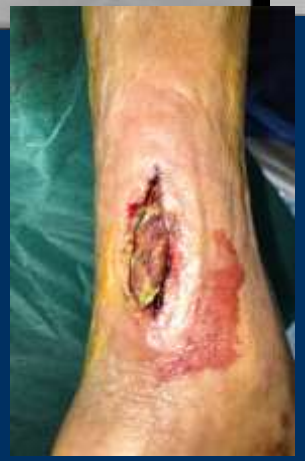
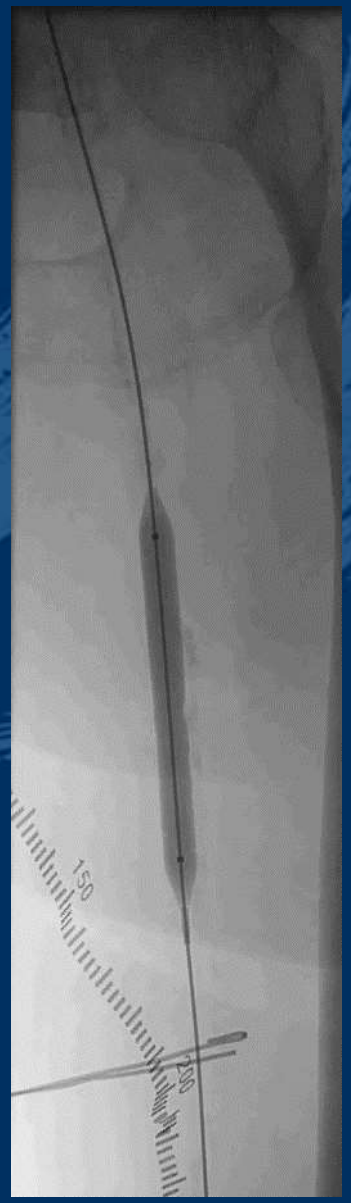
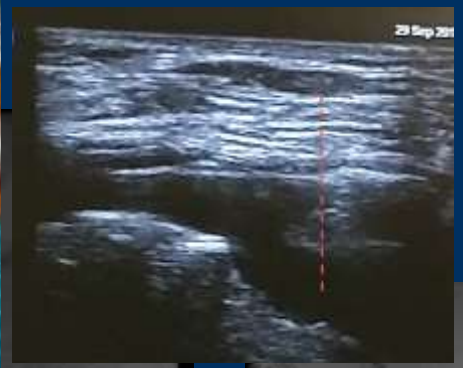


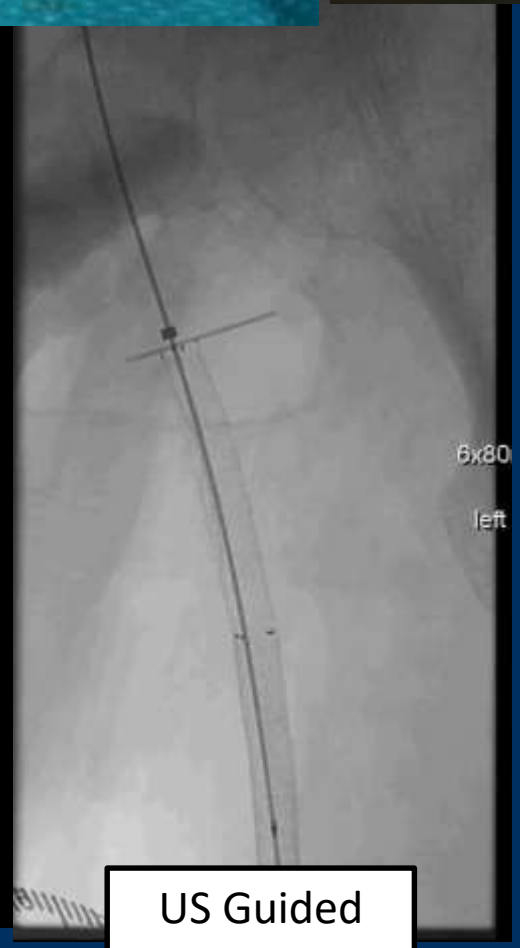






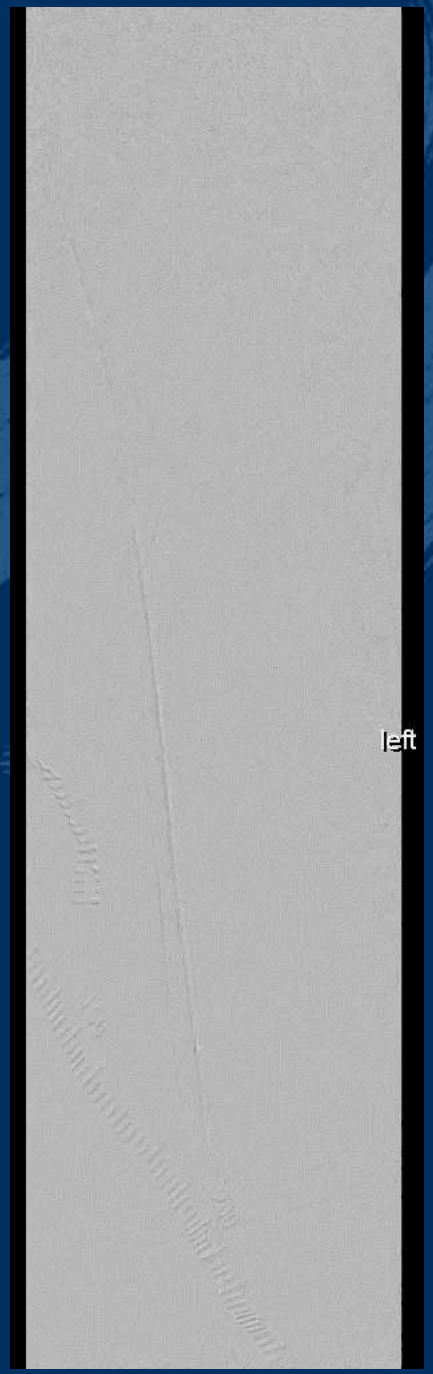
6/7mm mustang

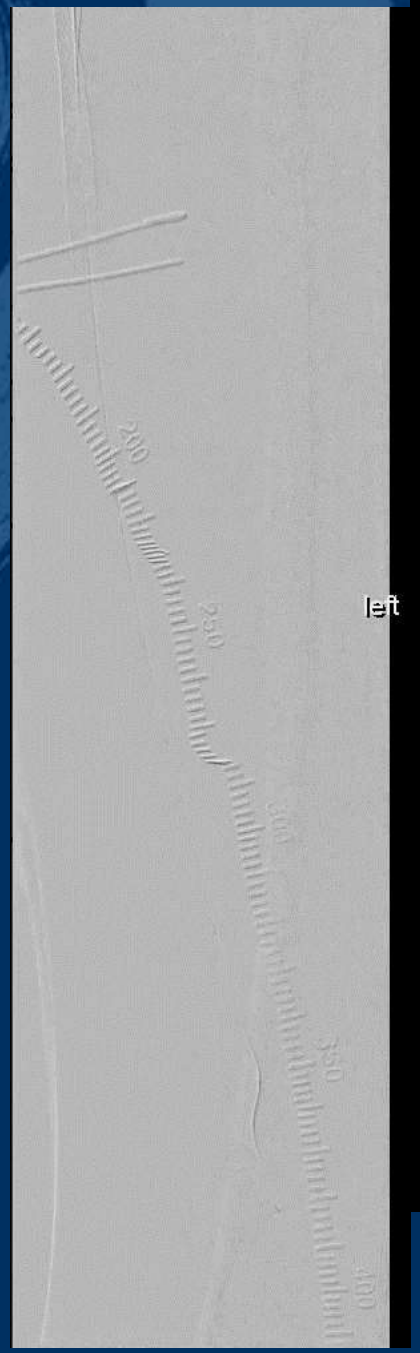


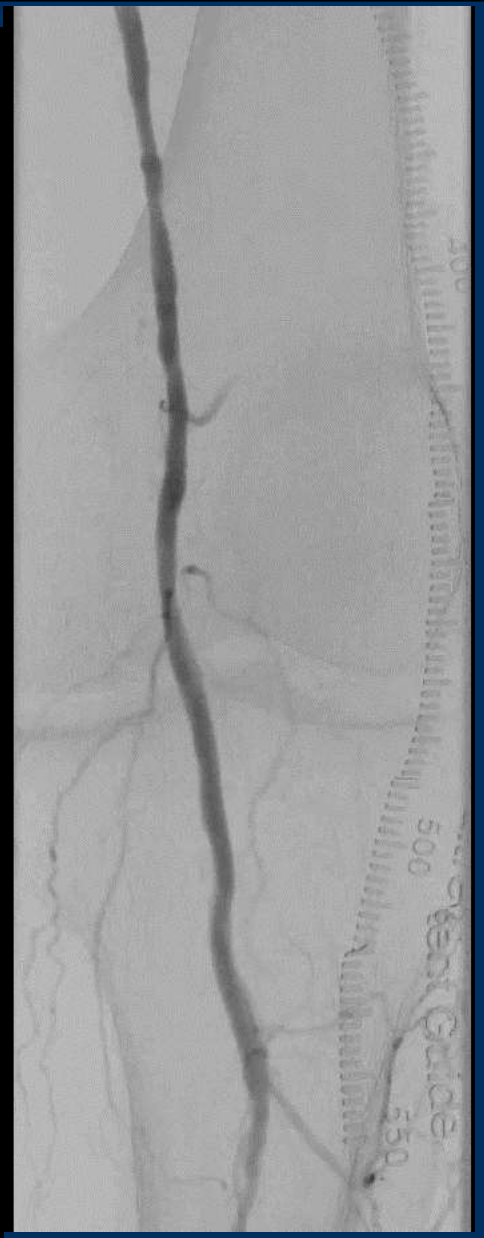


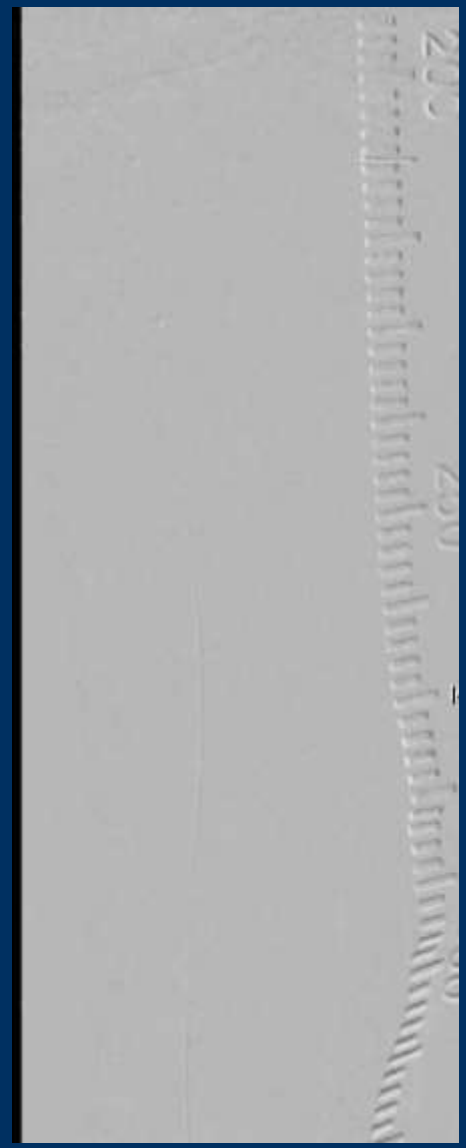
US Guided Stent Implantation

Ranger DCB





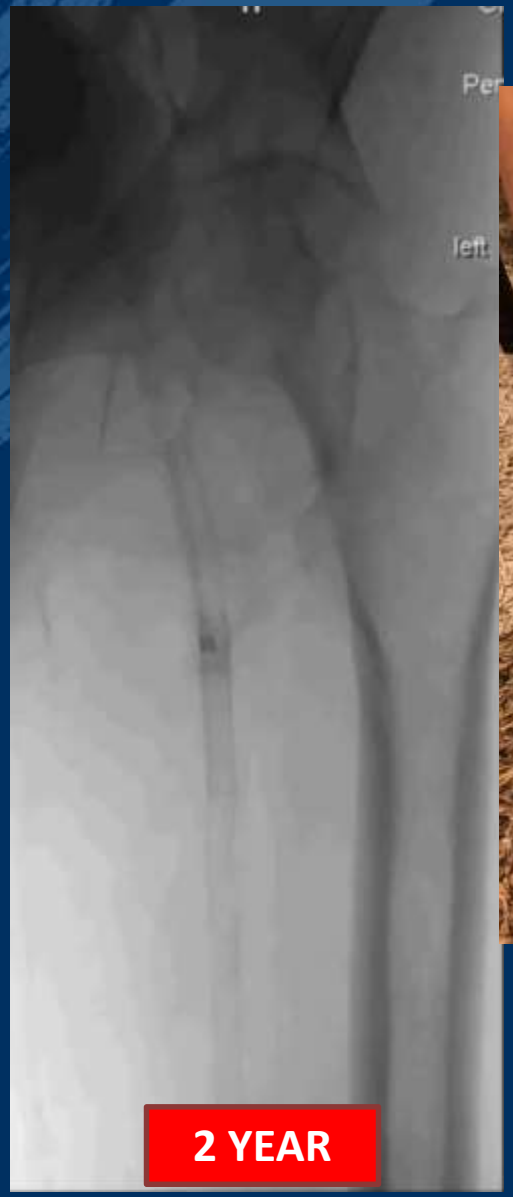




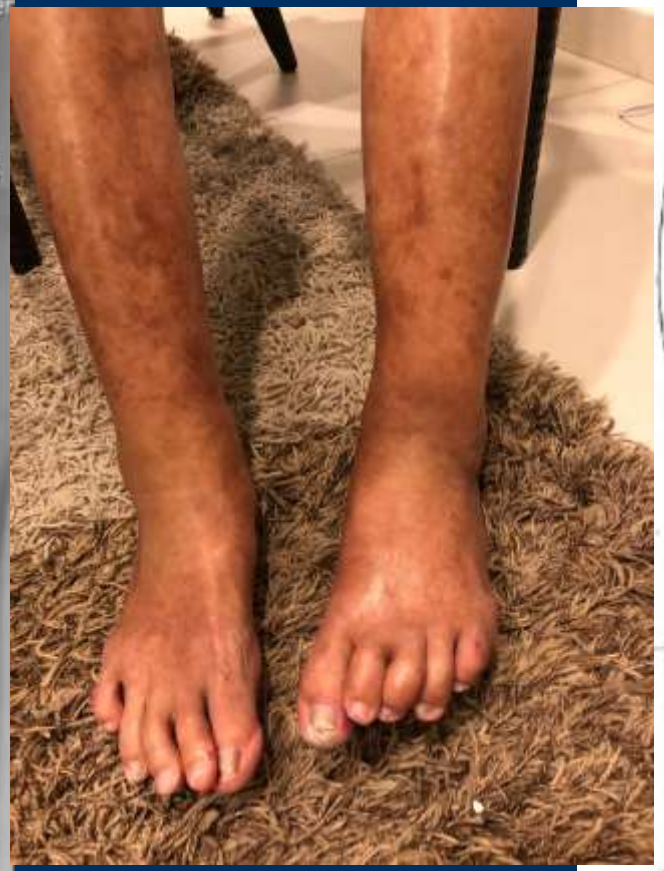
BVS TO TPT

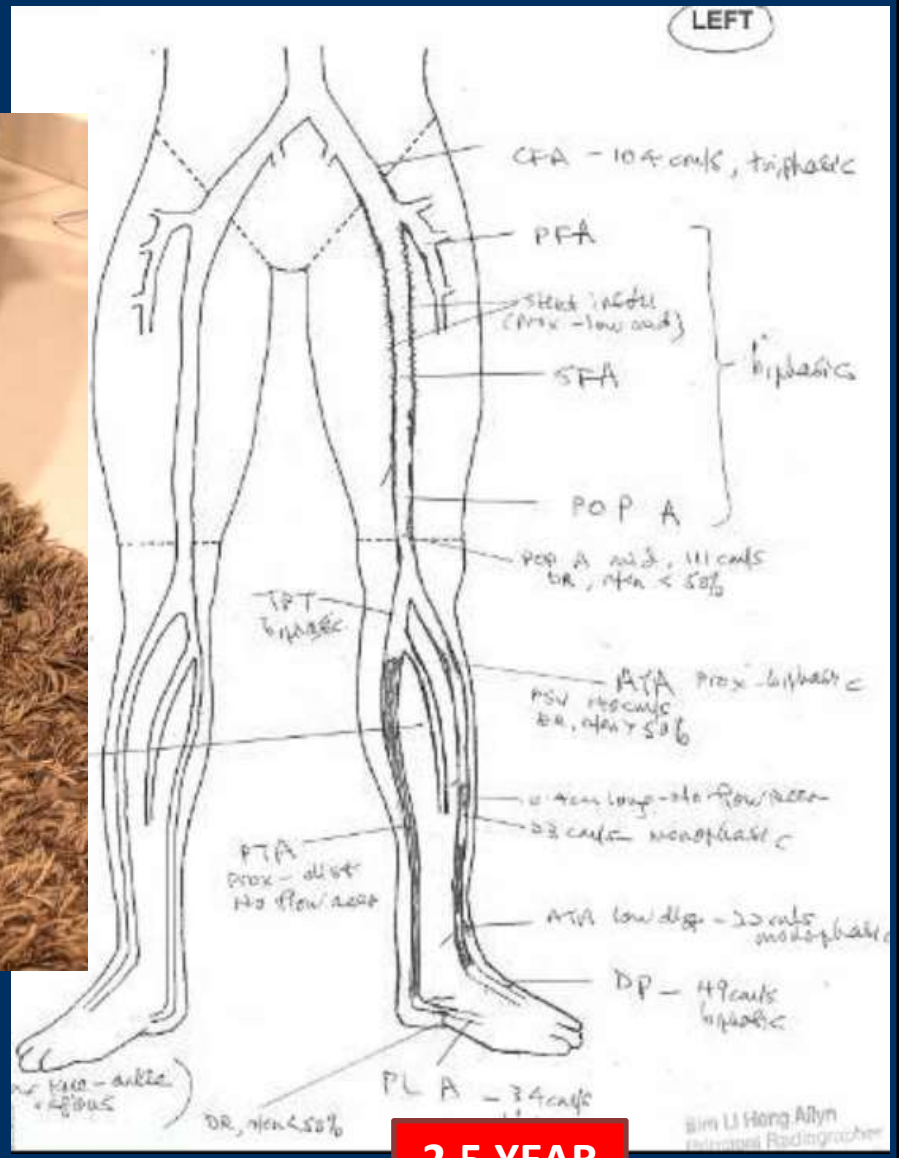
Follow Up

1 YEAR



2 YEAR





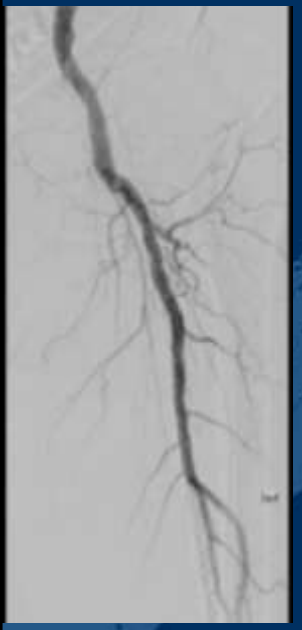
2.5 YEAR

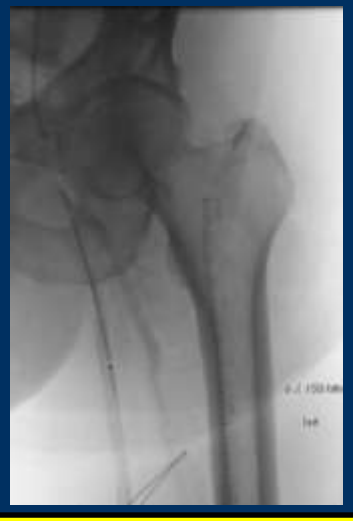
Summary

- New generation DES with prolonged elution provides a promising solution in complex long SFA/Popliteal lesions especially in a predominant diabetic + CLI population
- Total lesion coverage with DES seems to give better results
- May be a preferred choice for “in flow” revascularization in a CLI patient with multi-level, multi-vessel disease rather than DCB, avoiding “slow flow” drug embolization phenomenum

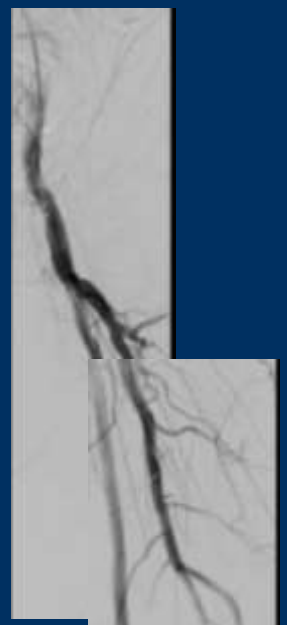
Video on slides: 5

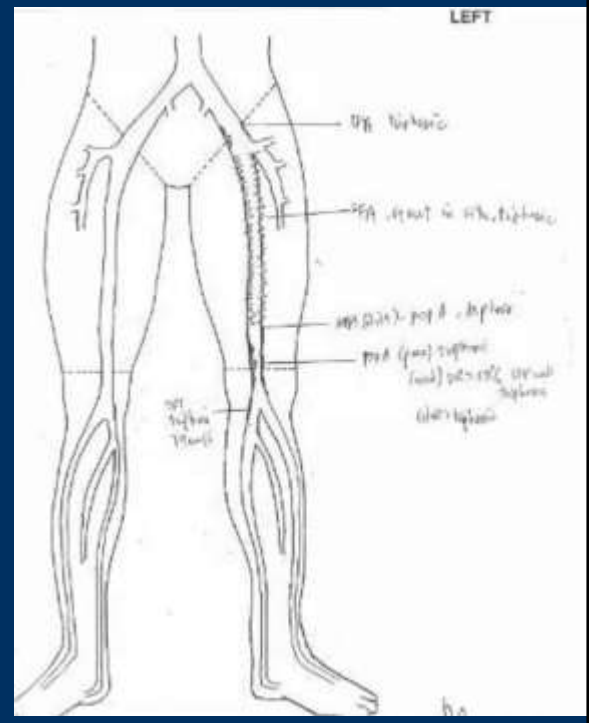
Sep 2016 – Claudication, Diabetic





Lesion length 220 mm
Stented length 270 mm





Patent at 2 years

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