28th TCTAP

MAY 6-9, 2023
GRAND WALKERHILL SEOUL, KOREA

Eluvia : IMPERIAL Trial

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Disclosure

- Nothing to disclose regards to this presentation

PAD is Diverse than CAD ➔ Approach & Strategy also Diverse

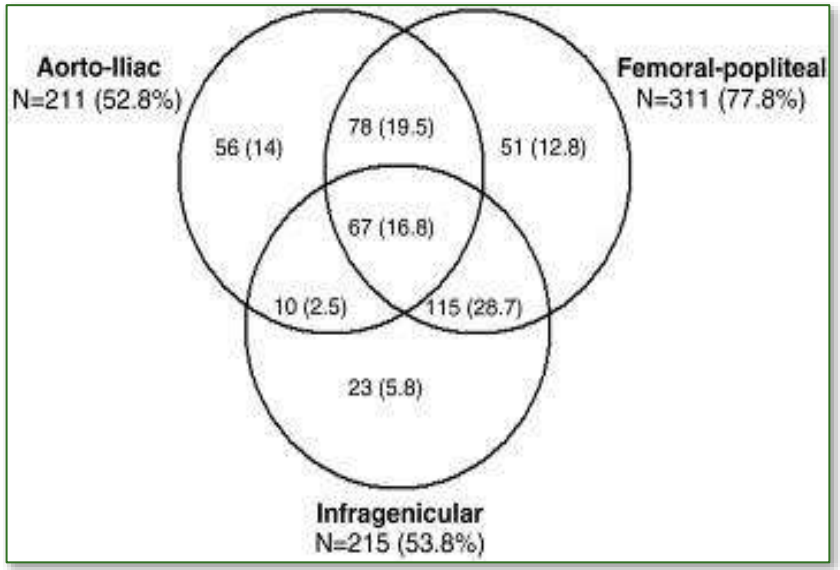
- *Patients with PAD display a wide range of clinical and lesion characteristics*
  - *Symptoms: intermittent claudication vs. critical limb ischemia*
  - *Comorbidities (e.g., diabetes, ESRD)*
  - *Anatomical location of lesions (Above vs. below the knee)*
  - *Degree of stenosis -CTO vs. stenosis*
  - *Lesion morphology (e.g., calcification, thrombus etc.)*

Initial Presentation	
Asymptomatic	20-50%
Claudication	10-35%
Critical Limb Ischemia	1-2%

Hirsch et al. Circulation, 2006;113:e463-654.

- *Patient and lesion characteristics influence:*
  - *Approach to and goals for treatment*
  - *Ability to access a lesion and deliver therapy*
  - *Susceptibility to restenosis*

Distribution of Arterial Lesions Among Patients with Peripheral Arterial Disease

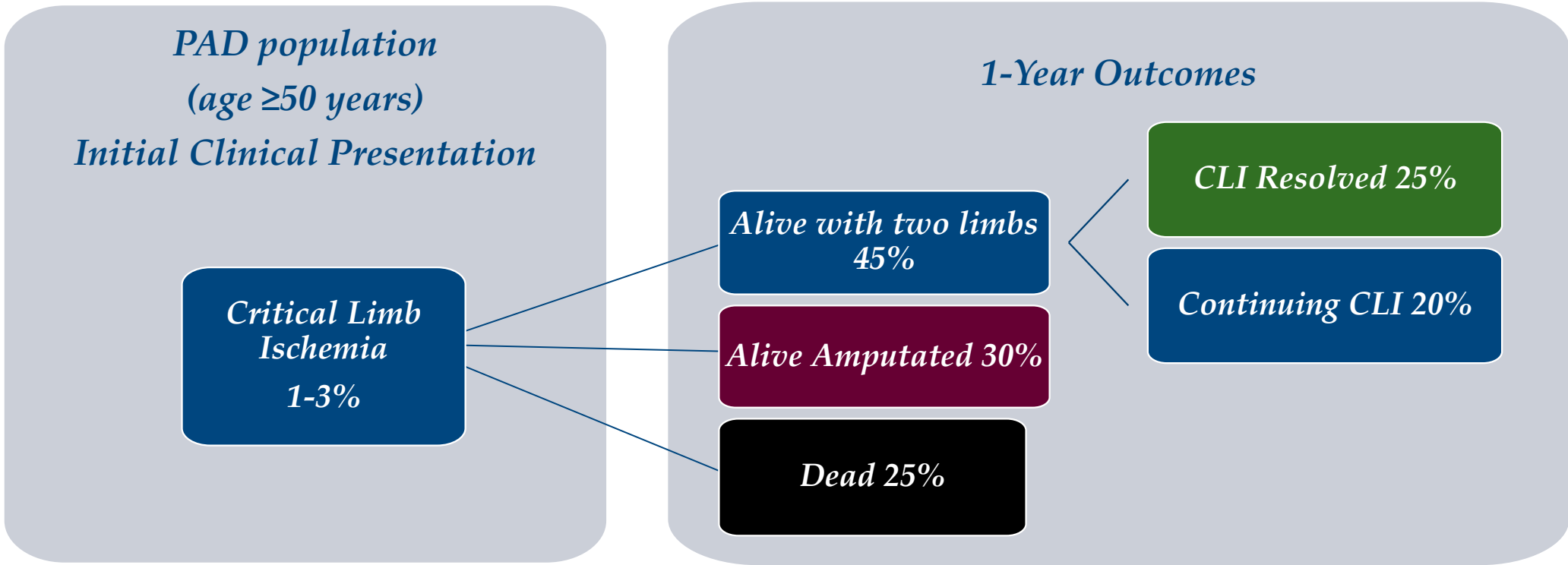


Aboyans V, et al. J Am Coll Cardiol. 2010;55(9):898-903.

Critical Limb Ischemia: Factors & Fate

Risk factors for CLI:

- *Age >65 years*
- *Lipid abnormalities*
- *ABI <0.7*
- *Smoker*
- *Diabetes*



Norgren et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007;45:S5A-S67A

Key Factors for Restenosis Risk

Patient

- *Diabetes[1-3]*
- *Smoking[2]*
- *Female sex[1,3]*
- *Renal failure/Dialysis[1-3]*

Lesion/vascular

- *Lesion length[1,2]*
- *Calcification[4]*
- *Occlusion[2,3]*
- *Critical limb ischemia[1,2]*
- *Poor runoff (0-1 below-the-knee vessels) [1-3]*

*"In general, the **outcomes of revascularization** depend upon **the extent of the disease** in the subjacent arterial tree (**inflow, outflow and the size and length of the diseased segment**), the **degree of systemic disease** (co-morbid conditions that may affect life expectancy and influence graft patency) and the **type of procedure performed**."[2]*

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1. Soga Y, et al. J Vasc Surg. 2011;54(4):1058-66. 2. TASC II- Norgren L, et al. Eur J Vasc Endovasc Surg. 2007;33 Suppl 1:S1-75.
3. Iida O, et al. JACC Cardiovasc Interv. 2014l;7(7):792-8. 4. Fujihara M, et al. J Endovasc Ther. 2019;26(3):322-330.

Factors that Affect Restenosis Risk in BMS

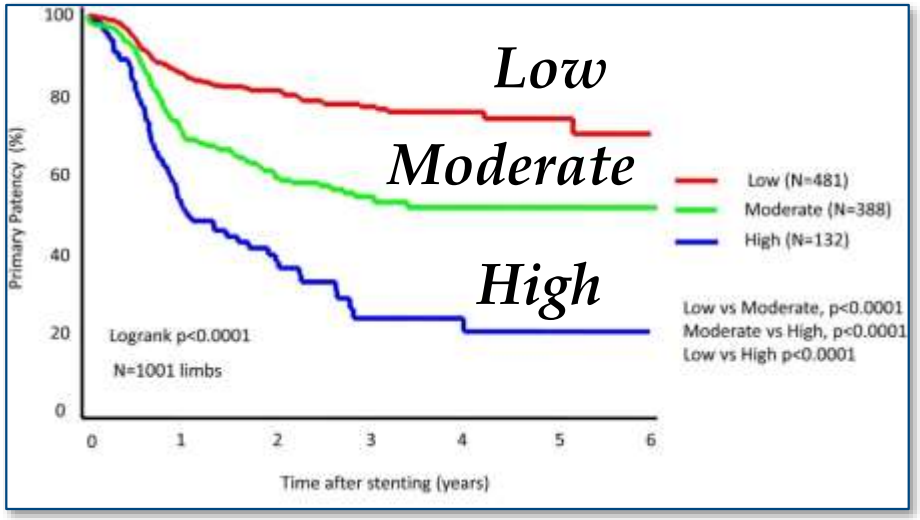
- Based on 807 patients (1,001 limbs) with nitinol stents in the SFA
- Multicenter, retrospective

FeDCLIP Score

Risk Factor	Points
Lesion length >150 mm	2
Female	1
Diabetes	1
Dialysis	1
CLI	1
Poor runoff (0-1 BTK vessel)	1
Total	**7**

More points, greater risk

Primary Patency by Risk Group



Score	Risk Category	1-Year Primary Patency
0-2	Low	85.7%
3-4	Moderate	71.5%
5-7	Severe	53.0%

Soga Y, et al. J Vasc Surg. 2011;54(4):1058-66.

SFA Treatment Landscape:

DCB vs DES Considerations

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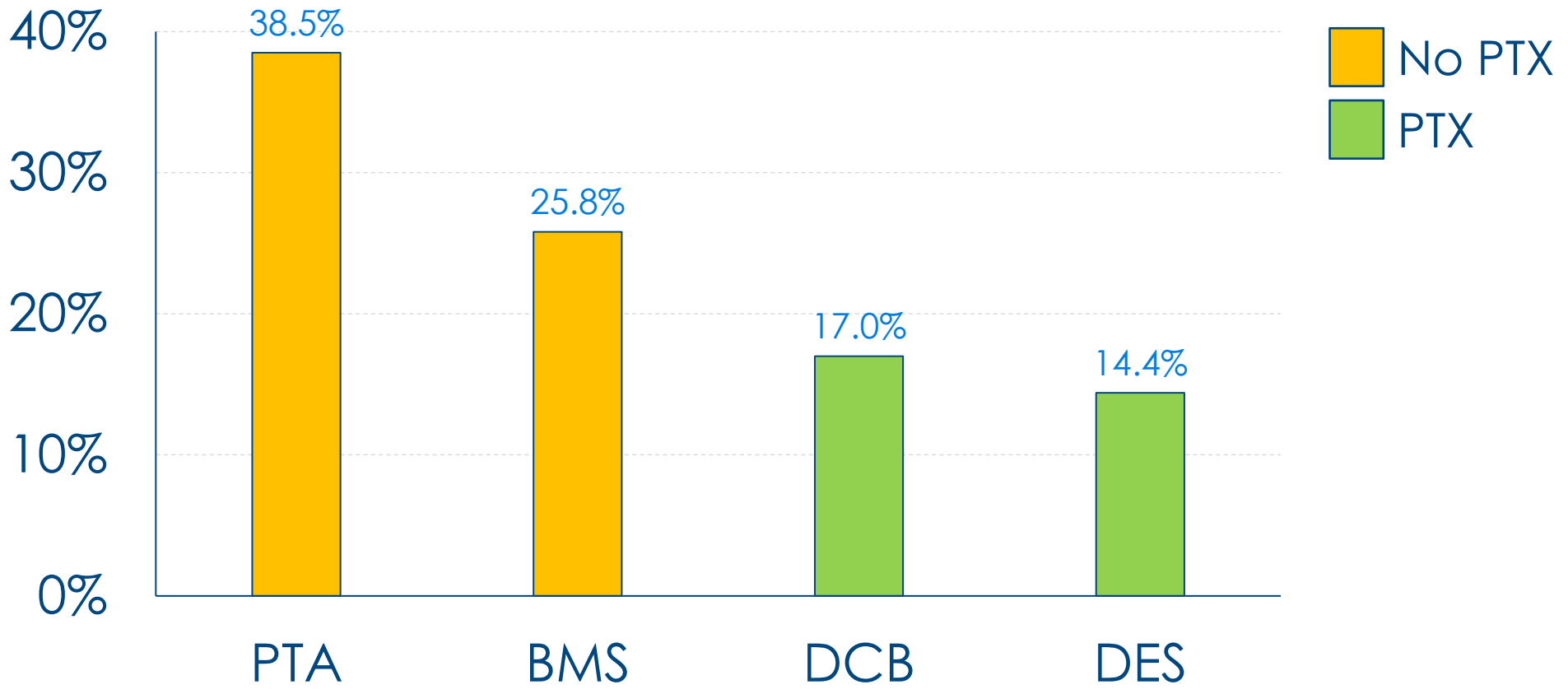
Paclitaxel Therapies Reduce Repeat Procedures Through 2 Years

2-Year Target Lesion Revascularization Rate



Sridharan ND, et al. J Vasc Surg. 2018;67(1):343-352. doi: 10.1016/j.jvs.2017.06.112.

BMS, bare metal stent; DCB, drug-coated balloon; DCS, drug-coated stent; PTA, percutaneous transluminal angioplasty

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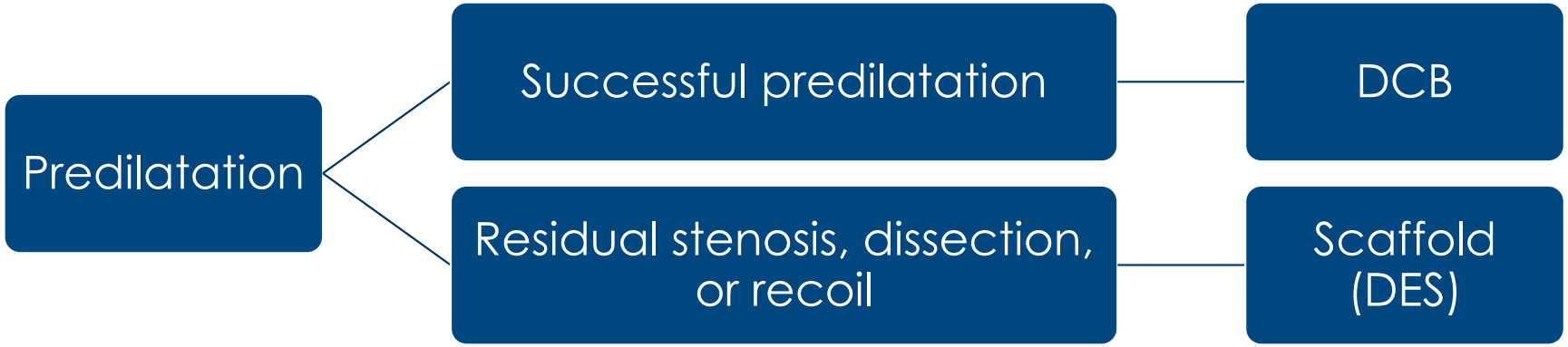
Considerations for DCB vs DES in PAD

- *Severe calcium → Consider adjunctive atherectomy*
- *Long lesion → Consider a scaffold*
- *Predilate to assess vessel response (uncoated balloon angioplasty)*



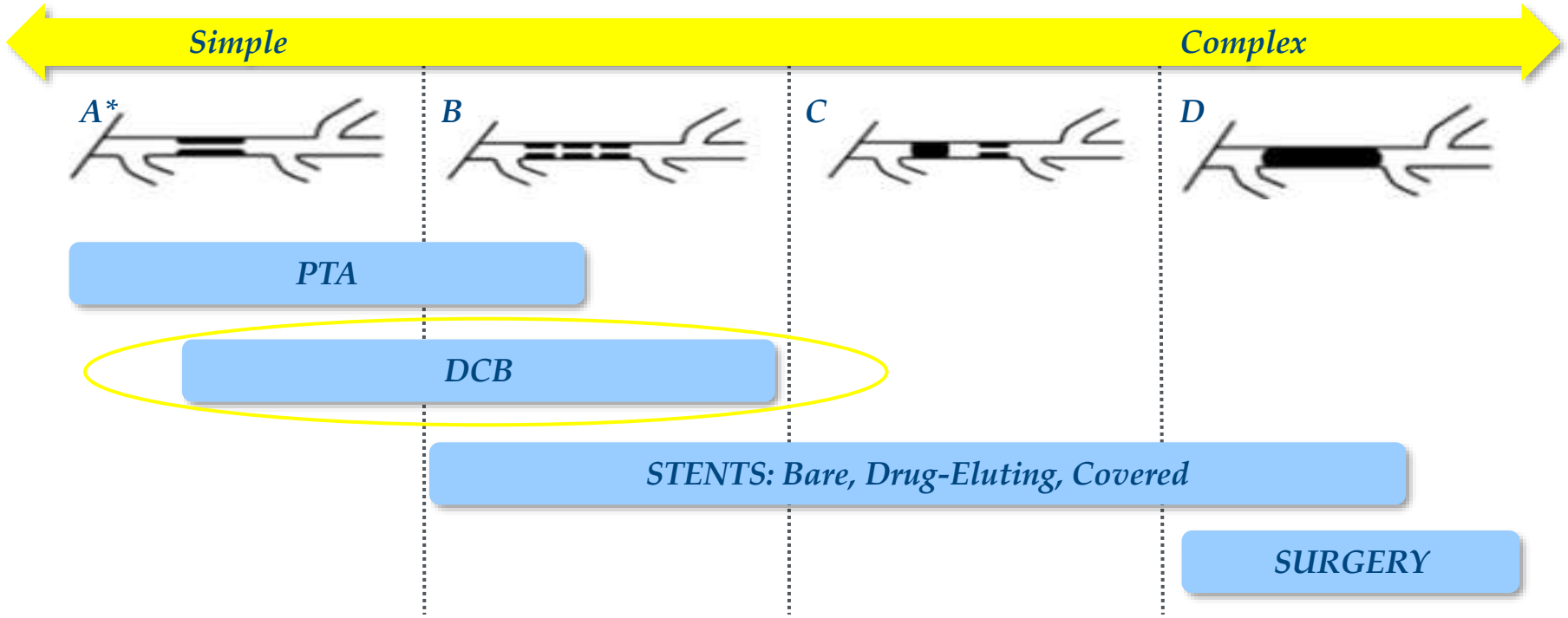
DCB, drug-coated balloon; DES drug-eluting stent.

Ansel G, Phillips JA. Drug elution, data, and decisions. Supplement to Endovascular Today. Nov 2014.

Rundback JH, et al. Curr Treat Options Cardiovasc Med. 2015 ;17(9):400.

Historical patient population for DCB studies

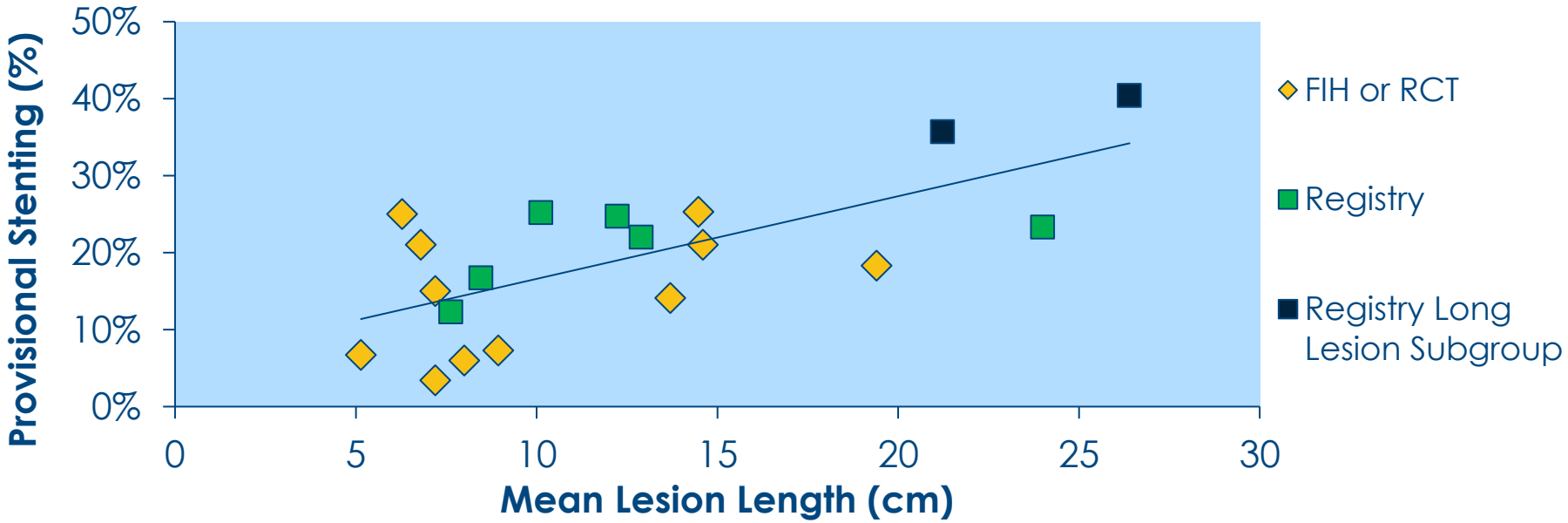
- *DCB trial/registry patients represent population with less complex lesions*
  - *Primarily TASC A/B, lesion length <10 cm*
  - *Less calcification*
  - *Fewer occlusions*



** TransAtlantic Inter-Society Consensus (TASC) II Lesion Classification (Type A, B, C, D) for peripheral arterial disease*

Stents used in DCB studies

- *Stents are utilized in studies intended to evaluate DCB efficacy*
- *Longer mean lesion length correlates with higher provisional stenting rate*



Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

Zeller T, et al. J Endovasc Ther. 2014;21(3):359-68.
BIOLUX P-I- Scheinert D, et al. J Endovasc Ther. 2015;22(1):14-21.
REAL PTX- Scheinert D, LINC 2018.
DRASTICO- Liistro F, et al. J Am Coll Cardiol. 2019;74(2):205-215.
BIOLUX PIII Registry- Tepe G, LINC 2018.
RANGER SFA Registry- Lichtenberg M, et al. J Cardiovasc Surg (Torino). 2018;59(1):45-50.
Micari A Et al. J Am Coll Cardiol Intv 2012
Schmidt A, et al. JACC Cardiovasc Interv. 2016;9(7):715-24.
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In.Pact Global Registry- Ansel G, TCT 2015.
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ILLUMENATE EU RCT - Schroeder H, et al. Circulation. 2017. pii: CIRCULATIONAHA.116.026493.
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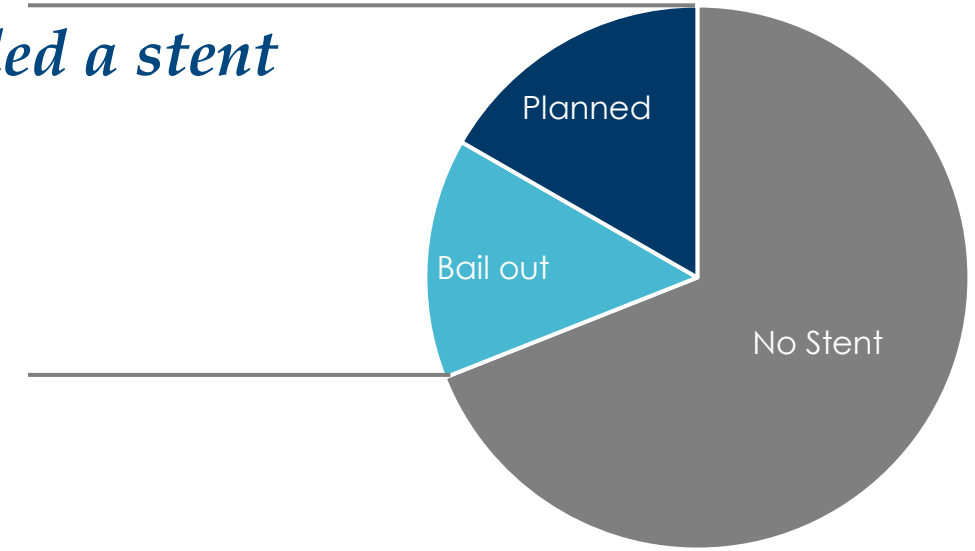
LEVANT 2- Rosenfield K, et al. N Engl J Med. 2015;373(2):145-53.
CONSEQUENT- Tepe G, et al. Cardiovasc Intervent Radiol. 2017 Oct;40(10):1535-1544.

Stents are Commonly Used in DCB Procedures

- *Analysis of 224 patients in the XLPAD Registry treated with a DCB in 2014-2016*
- *Lesions treated with adjunctive stents were longer (150 mm vs 100 mm; p<.001)*
- *66% of CTOs were treated with a stent*

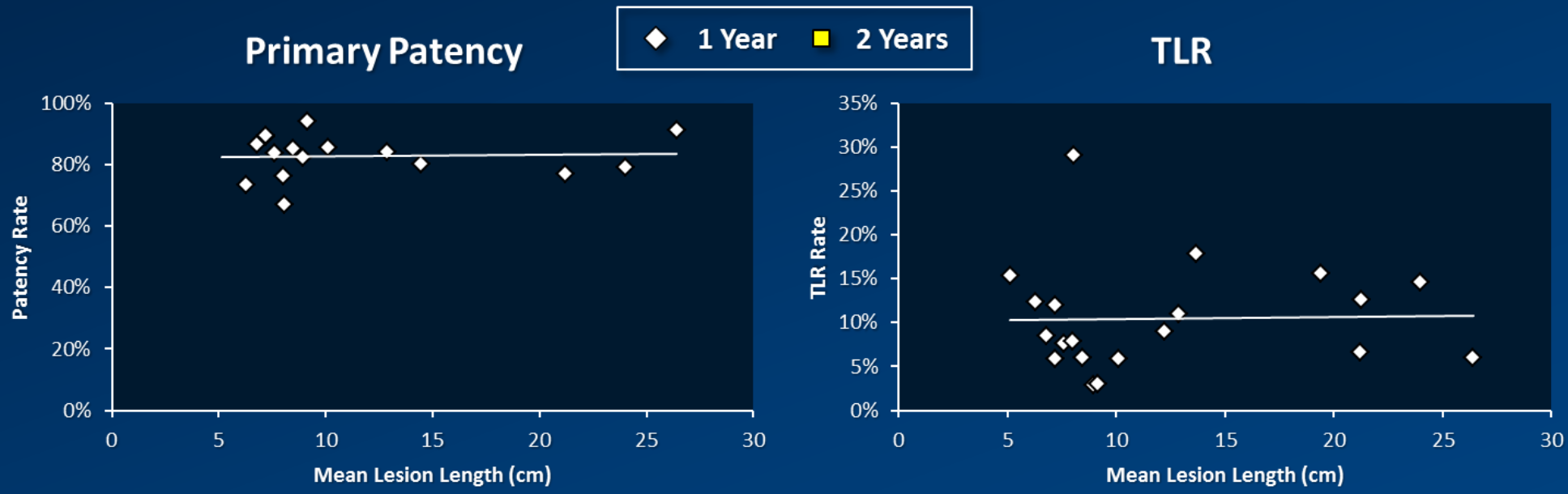
- *31% of interventions included a stent*
- *Of the implanted stents:*
  - *46% bail-out*
  - *54% planned*

Stents Used in DCB Interventions



Kokkinidis DG, et al. Vasc Med. 2018;23(4):358-364. doi: 10.1177/1358863X18775593.

Limits of DCB Treatment Durability / Lesion Length



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Micari A, et al. J Am Coll Cardiol Intv 2012; & Micari A, JACC Cardiovasc Interv. 2013;6(3):282-289.
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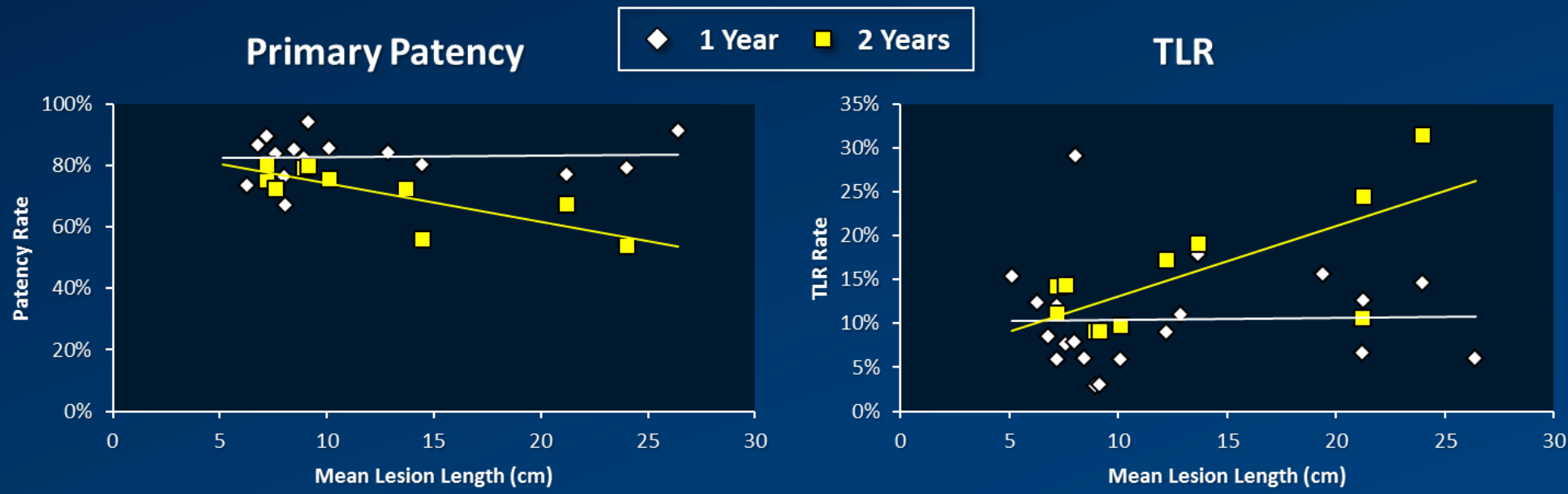

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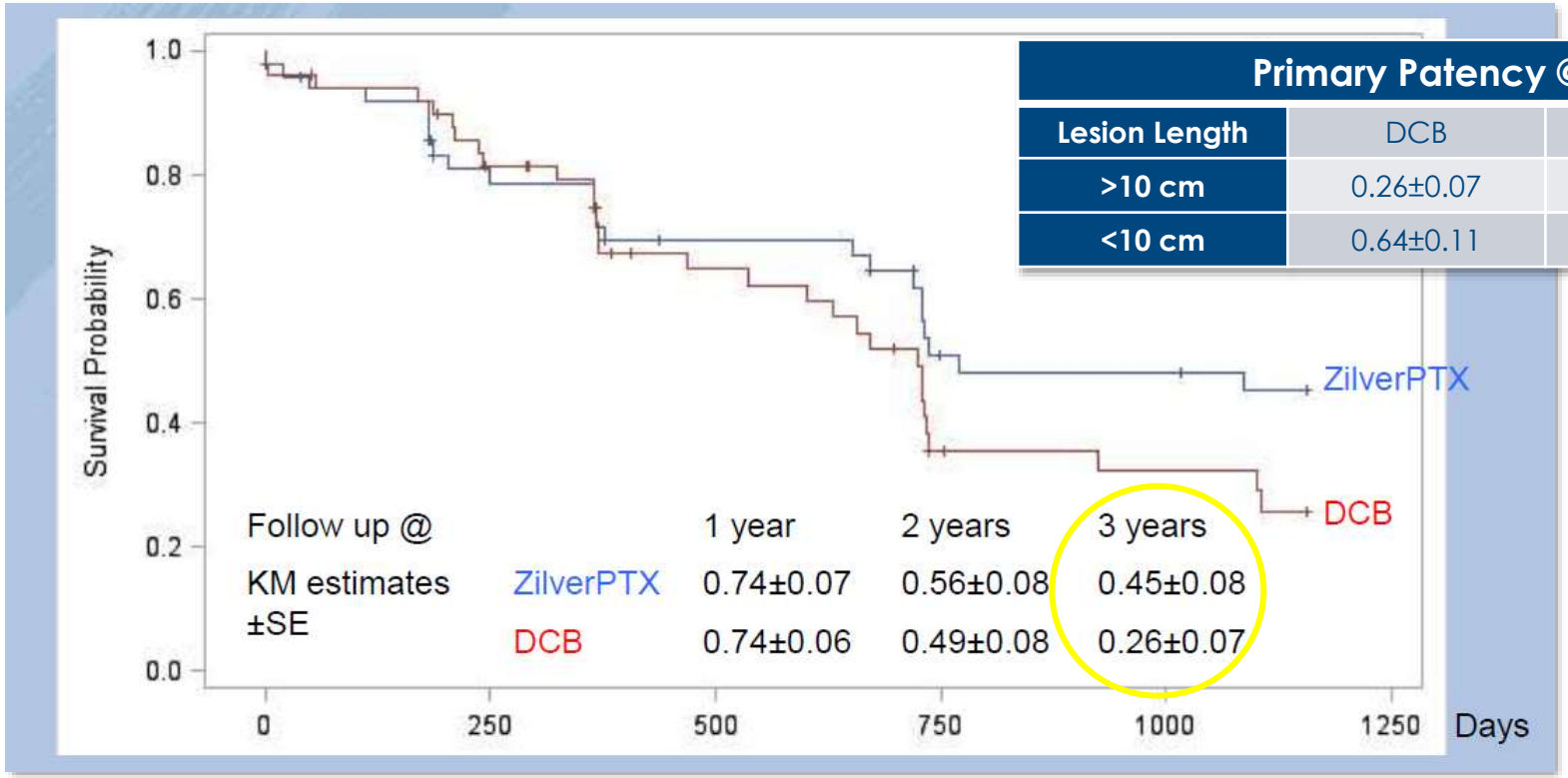
Lesion Length & Treatment Durability

- *REAL PTX- RCT DCB vs DES*
- *Pilot study results suggest increased benefit of DES (vs DCB) in lesions >10cm in length (greater separation between patency curves)*

Primary Patency @ 36 months in lesions >10cm



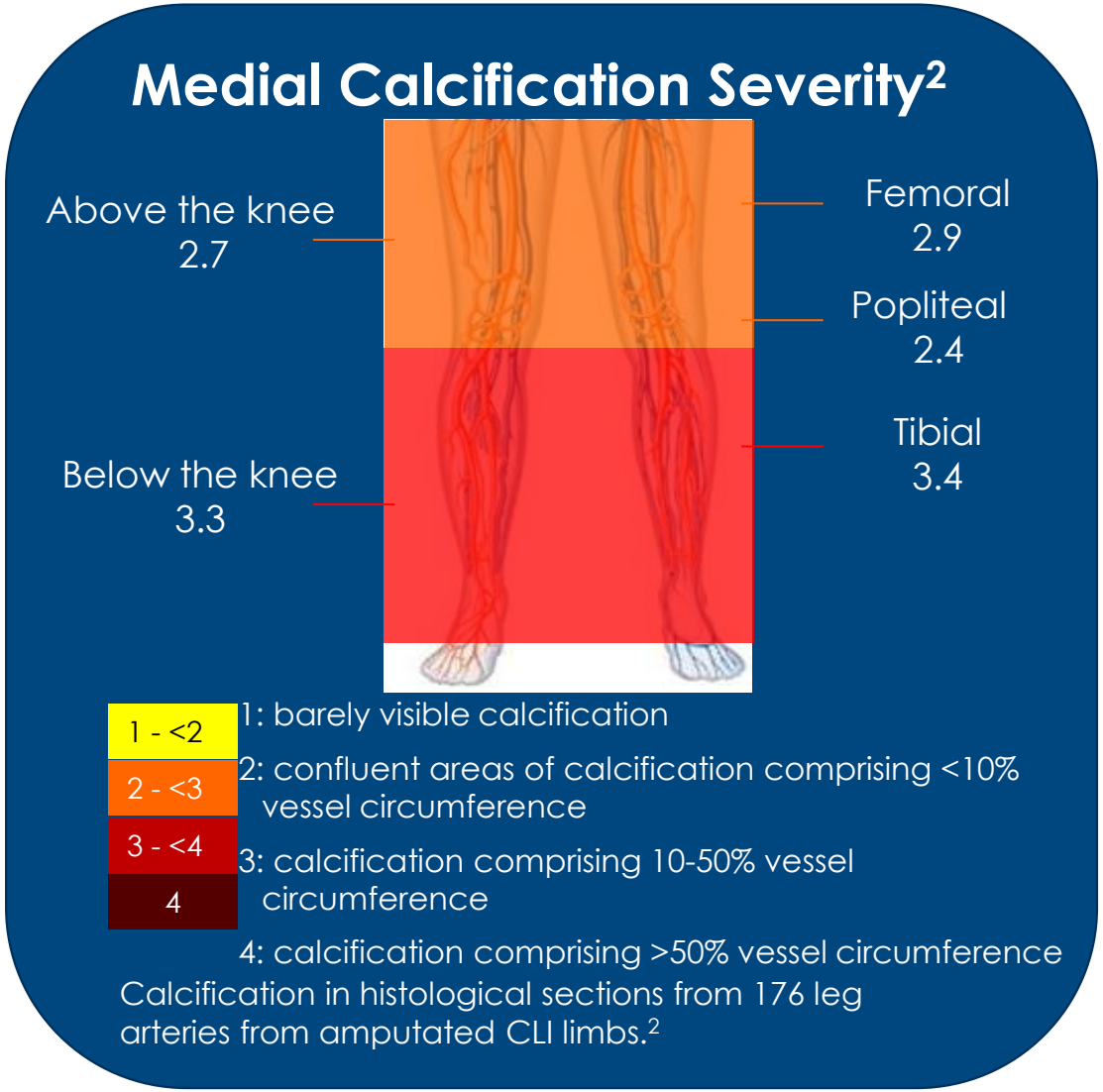
Primary Patency @ 36 months			
Lesion Length	DCB	Zilver™ PTX™	P
>10 cm	0.26±0.07	0.45±0.08	0.1892
<10 cm	0.64±0.11	0.77±0.09	0.4524

Intent-to-treat; DCB group includes patients who received bailout stents.

Scheinert D, LINC 2018

Calcification in PAD

- *Arterial calcification is frequently observed among patients with PAD, especially those with severe claudication or CLI*[1,2]
- *Arterial calcification severity increases in distal arteries*[2,3]



1. Zacharias SK, et al. Vasc Med. 2016;21(4):337-44.
2. O'Neill WC, et al. Arterioscler Thromb Vasc Biol. 2015;35(2):439-47.
3. Bishop PD, et al. Ann Vasc Surg. 2008;22(6):799-805.

CLI, critical limb ischemia; PAD, peripheral arterial disease

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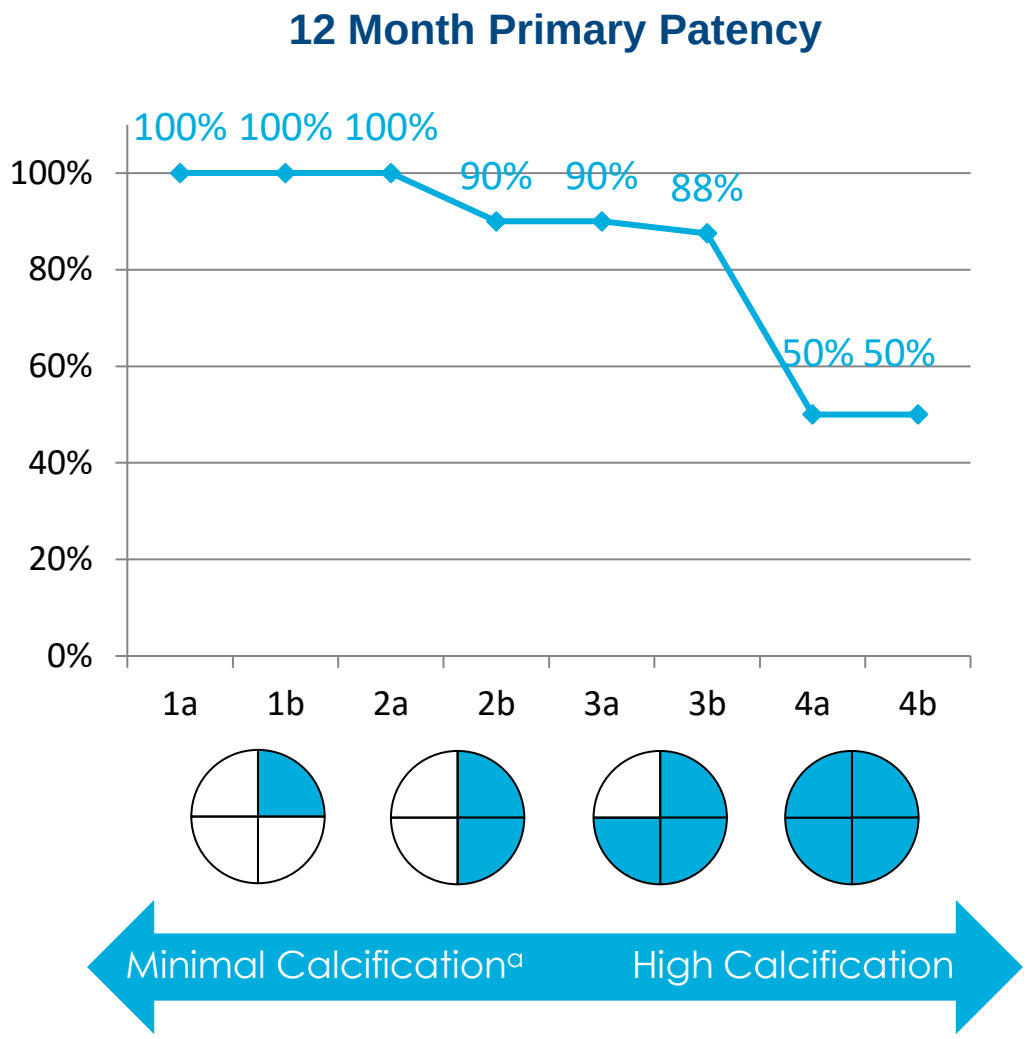
Lesion Calcification May Affect Drug-Coated Balloon Efficacy

- *60 patients with SFA stenosis or occlusion treated with DCB*
- *50% primary patency rates in heavily calcified SFA lesions, regardless of lesion length*
- *Greater calcification was associated with poorer outcomes at 1 year:*
  - *Greater TLR rate*
  - *Lower ankle-brachial index*
  - *Greater late lumen loss*



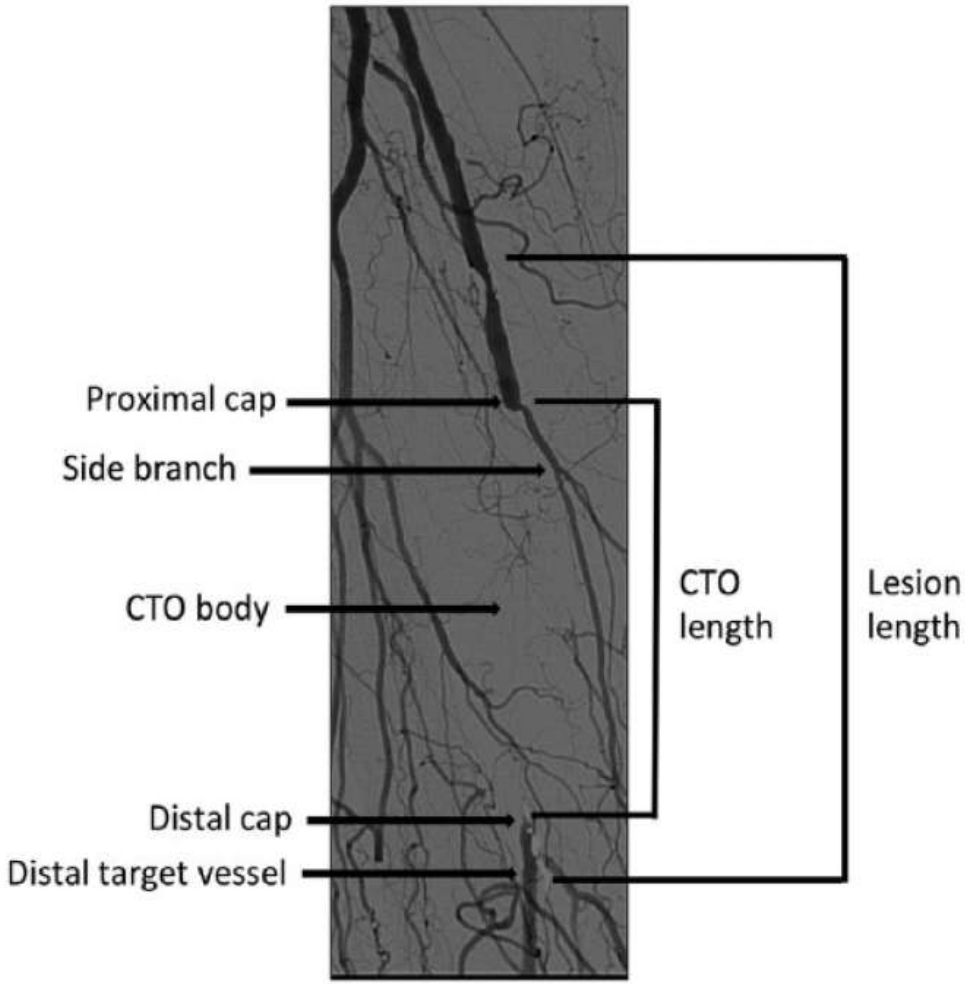
[a]Calcium burden quantified with computed tomography angiography (CTA), digital subtraction angiography (DSA), and intravascular ultrasound (IVUS).

DCB, drug-coated balloon; SFA, superficial femoral artery; TLR, target lesion revascularization.

Fanelli F, et al. Cardiovasc Intervent Radiol. 2014 ;37(4):898-907.

CTO Prevalence

- *Upto 42% of infrainguinal lesions are CTOs[1]*
- *CTO is common among patients with Critical Limb Ischemia[2,3], but is also observed in patients with claudication*
- *CTO increases risk of restenosis[4]*



Banerjee S, et al. J Endovasc Ther. 2015;22(4):525-34.

1. Banerjee S, et al. JACC Cardiovasc Interv. 2016;9(21):2243-2252.
2. Ortmann J, et al. J Vasc Surg. 2012 ;55(1):98-104.
3. Gallagher KA, et al. J Endovasc Ther. 2011;18(5):624-37.
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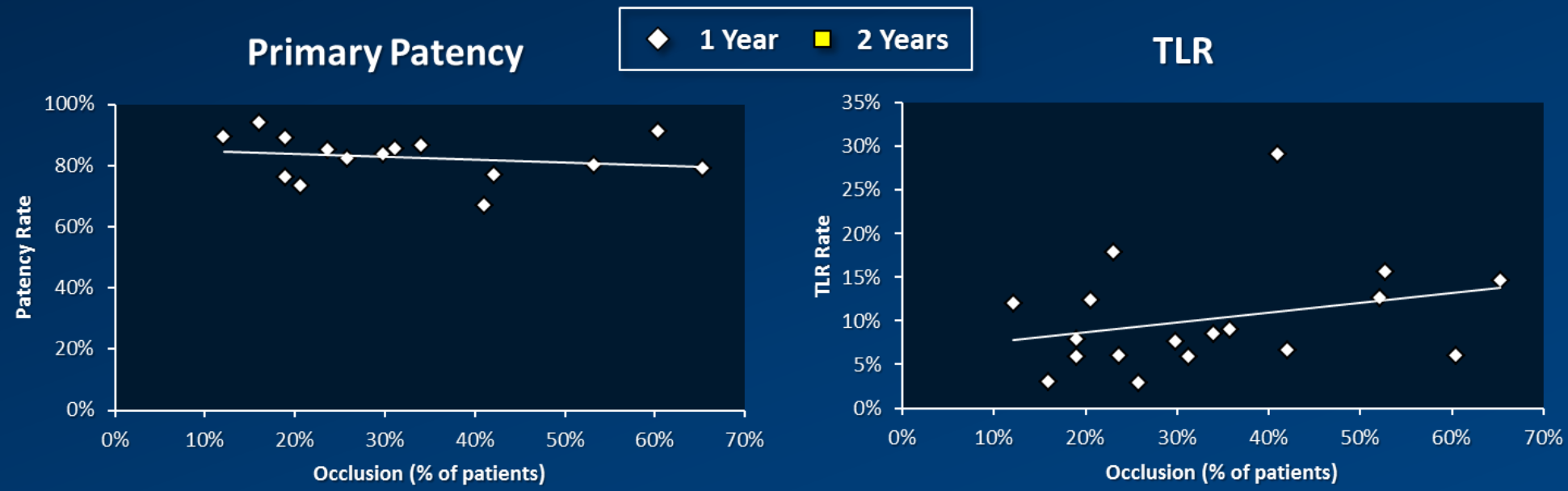
Limits of DCB Treatment Durability / Occlusions



- **1 year**: no association between occlusions and worsening primary patency or TLR rates
- **2 years**: patency and reintervention rates appear to be worse for cohorts with greater proportions of patients with occlusions

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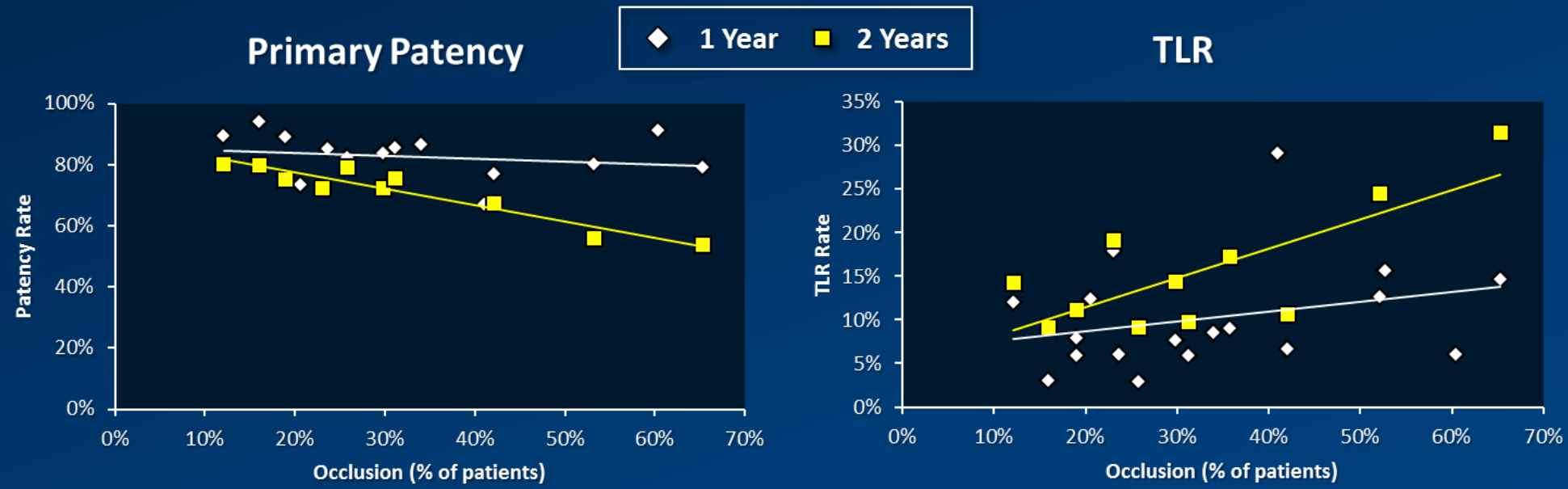

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Eluvia™ Drug-Eluting Vascular Stent System

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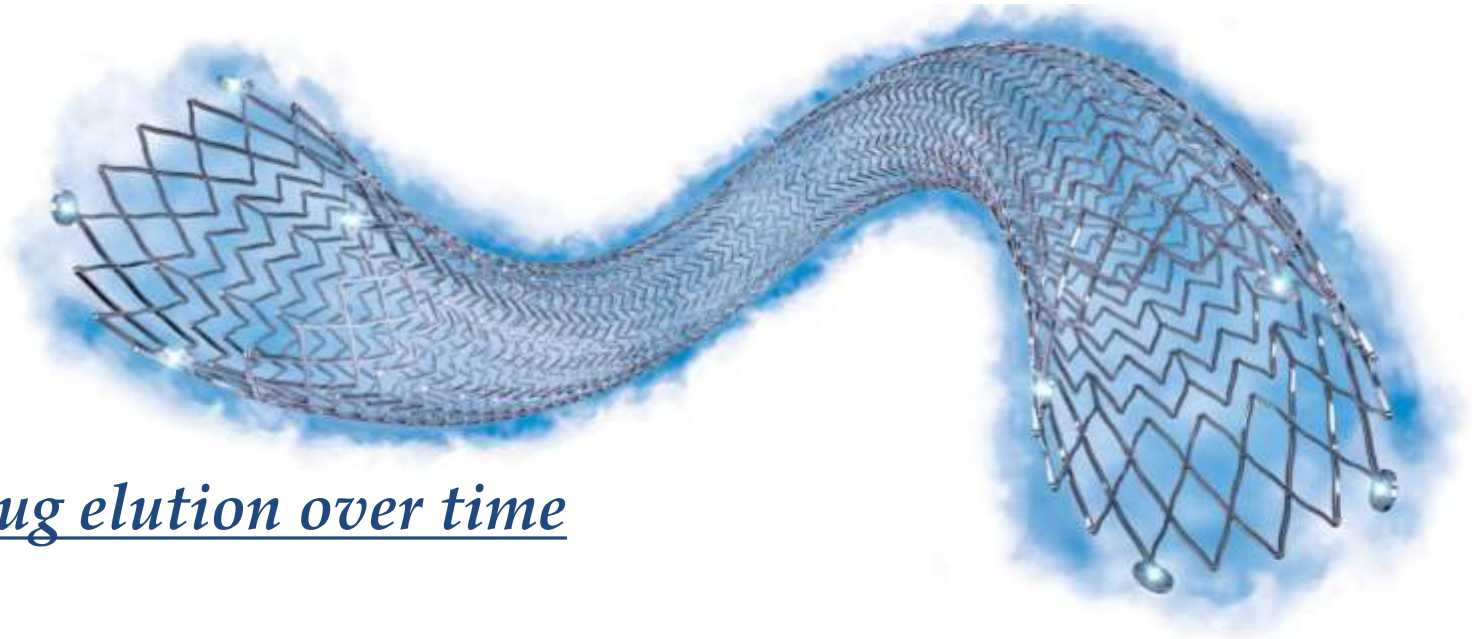
Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific

- *FDA Approval September 2018*
- *CE Mark February 2016*



- *Innova stent platform*
- *Self-expanding nitinol*
- *Biostable polymer matrix for drug elution over time*
- *Low-dose paclitaxel*
- *0.167µg PTX/mm² stent surface area*

- *6F Tri-axial SDS, 0.035" guidewire compatible*

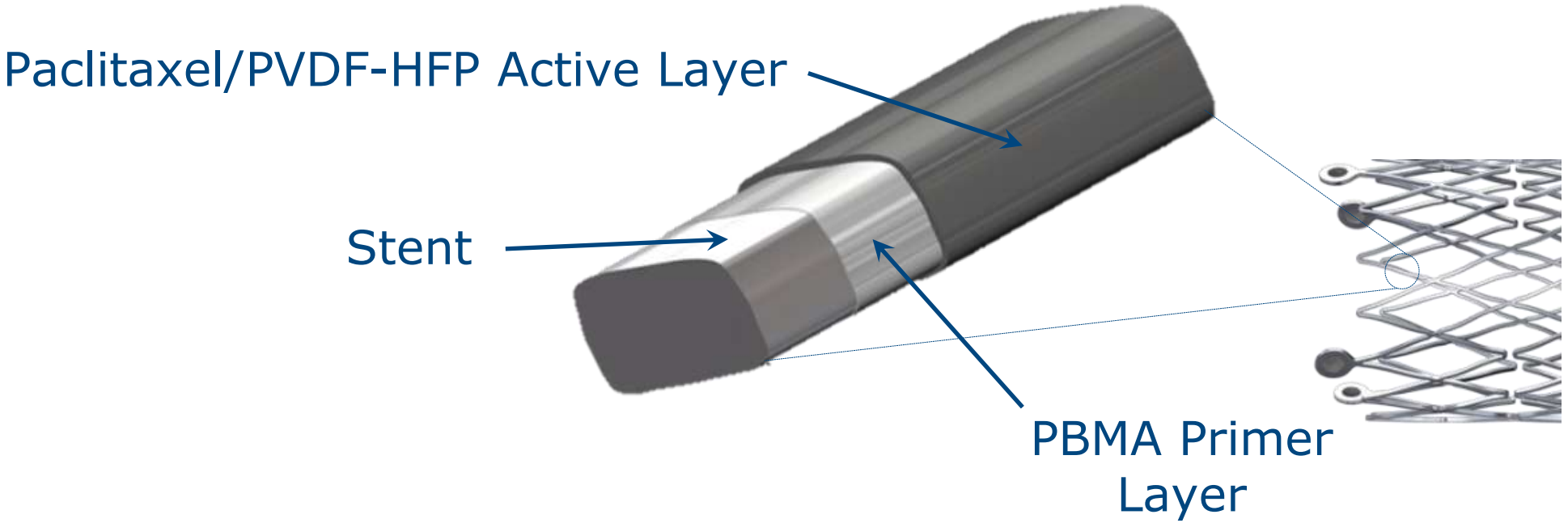
PI-979201-AE-BSC-DES_US&EU_M

CAUTION: The law restricts these devices to sale by or on the order of a physician. Rx Only.

Eluvia Dual-Layer Coating Design

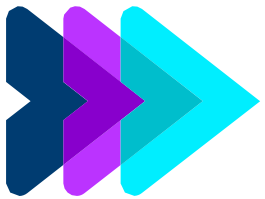
Boston Scientific

- *Active Polymer Layer (PTx, PVDF-HFP) controls release of paclitaxel*
  - *Diffusion-controlled low-dose elution over time*
- *0.167µg PTx/mm² stent surface area*
- *Primer Layer (PBMA) promotes adhesion of active layer to stent*
- *Conformal coating for both layers*



Boston Scientific

Advancing science for life™



EMINENT RCT

Eluvia DES vs. Bare Metal Stents

EMINENT Trial Design and Endpoint

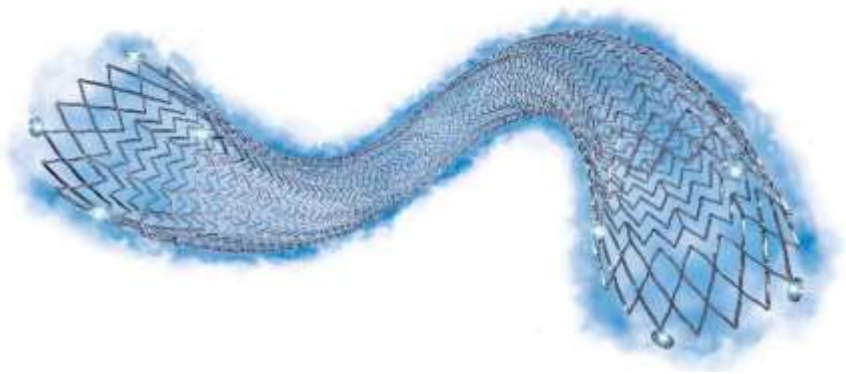
Primary Investigators	**Prof. Dr. Yann Gouëffic** Vascular Surgeon (Paris, France) **Prof. Dr. Giovanni Torsello** Vascular Surgeon (Münster, Germany)
Study Design	RCT (Eluvia DES vs Bare Metal Stent) • 2:1 randomized • Single-blind • Superiority trial
Patients	N=775 Eluvia N=508 vs BMS N=267
Primary Endpoint	12-Month Primary Patency
Investigational Centers	58 study centers in 10 European Countries

EMINENT Clinical Trial 12-Month results presented by Professor Yann Gouëffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

EMINENT Study Devices

ELUVIA Drug-Eluting Stent
N=508



VS

Bare Metal Stents (BMS)
N=267

Innova™ Vascular Self-Expanding Stent	(Boston Scientific)
Supera™ Peripheral Stent	(Abbott)
LifeStent™ Vascular Stent	(Bard)
EverFlex™ Self-Expanding Peripheral Stent	(Covidien/Medtronic)
S.M.A.R.T® Flex Vascular Stent and S.M.A.R.T. CONTROL® Vascular Stent	(Cordis/Cardinal)
Pulsar®-18	(Biotronik)
Compete® SE Vascular Stent	(Medtronic)

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Baseline Patient Characteristics

EMINENT Trial Details:

- 775 (RCT 2:1) patients across 58 centers in 10 European countries
- Rutherford category 2, 3, or 4
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 210 mm

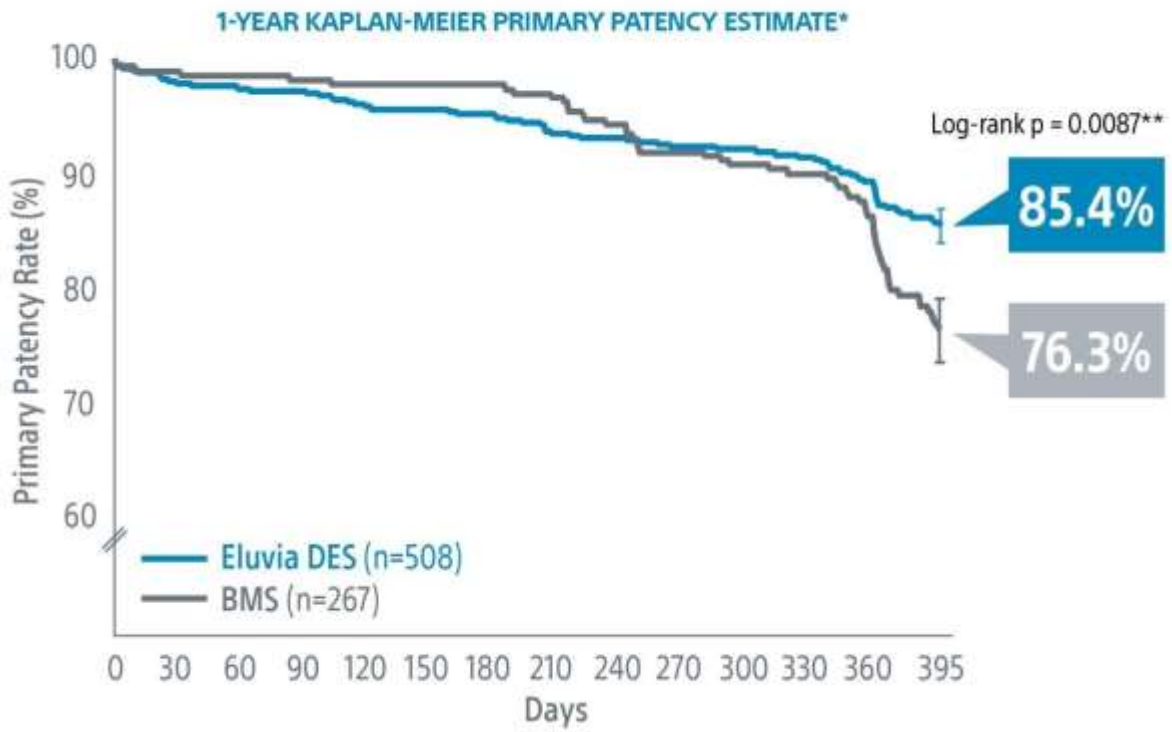
	Baseline Characteristics	ELUVIA DES (n=508)	CONTROL (n=267)	p-value
Demographics	Age (years)	68.9 ± 8.7	68.9 ± 9.1	0.9739
	Male Gender	71.5%	67.4%	0.2431
	Diabetes Mellitus (medically-treated)	31.9%	32.6%	0.8440
	History of Smoking (current/previous)	36.0%/39.6%	36.0%/41.6%	0.9849/0.5884
Lesio	Percent Stenosis (%)	86.6 ± 15.2	85.5 ± 15.3	0.3629
	Total Occlusions	42.3%	39.9%	0.5372
	Total Stented Length (mm)	105.8 ± 48.4	109.2 ± 49.8	0.3858
	Target Lesion Length (mm)	75.6 ± 50.3	72.2 ± 47.0	0.3815
	Moderately Calcified	21.6%	26.0%	0.1849
	Severely Calcified	30.3%	31.1%	0.8122

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Statistically Significant 1-Year Primary Patency with Eluvia DES

Eluvia DES demonstrated **superiority over BMS[1]** with a statistically significant primary patency through 1-Year



*Kaplan-Meier Estimate: Primary patency defined as core-lab assessed duplex ultrasound peak systolic velocity ratio (PSVR) ≤2.4 at 12 months in the absence of clinically-driven TLR or bypass of the target lesion.
**Log-rank p-value compares the entire K-M curves from time point zero to day 395 (full 1-year follow-up window)
1. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. Primary Endpoint: 1-Year Binary Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).
EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

PI-1141903-AC

Rutherford Score Improvement with Eluvia DES

Eluvia DES demonstrated a **statistically significant greater rate of primary sustained clinical improvement** without reintervention over BMS through 1-Year

***In EMINENT, primary sustained clinical improvement was defined as an improvement (decrease) by at least 1 Rutherford category, without TLR.
EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

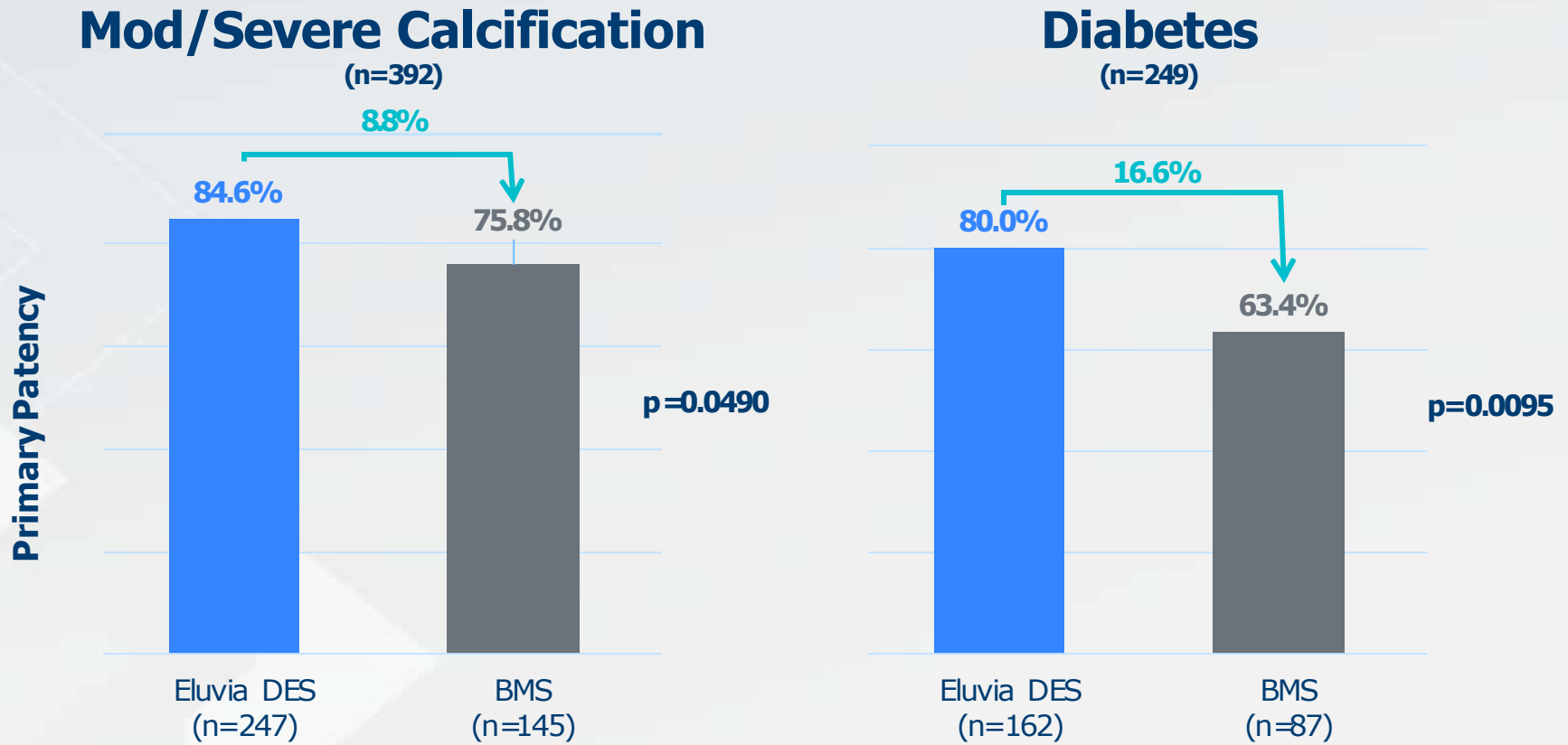
Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

PI-1141903-AC

Eluvia has superior patency even in the most challenging patients and lesions

Boston Scientific

Complex Lesion/Patient Subgroup Analysis



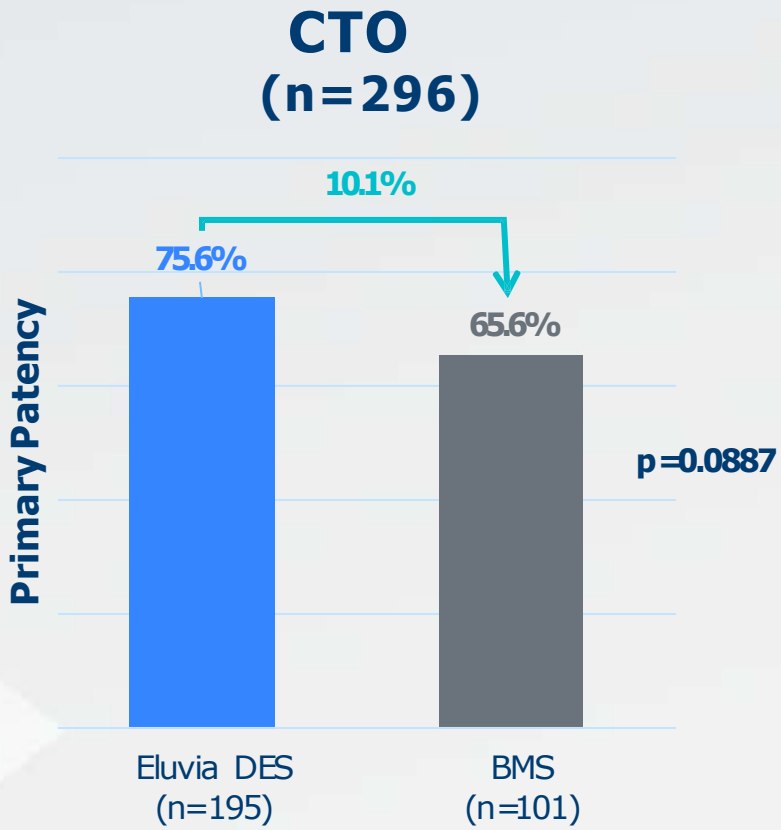
EMINENT Clinical Trial, 12-Month Effectiveness, Safety & Subgroup Analysis presented by Professor Yann Goueffic, MD. LINC 2022

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

PI-1141903-AC

Eluvia also outperformed BMS in CTO lesions

Complex Lesion Subgroup Analysis



EMINENT Clinical Trial, 12-Month Effectiveness, Safety & Subgroup Analysis presented by Professor Yann Goueffic, MD. LINC 2022

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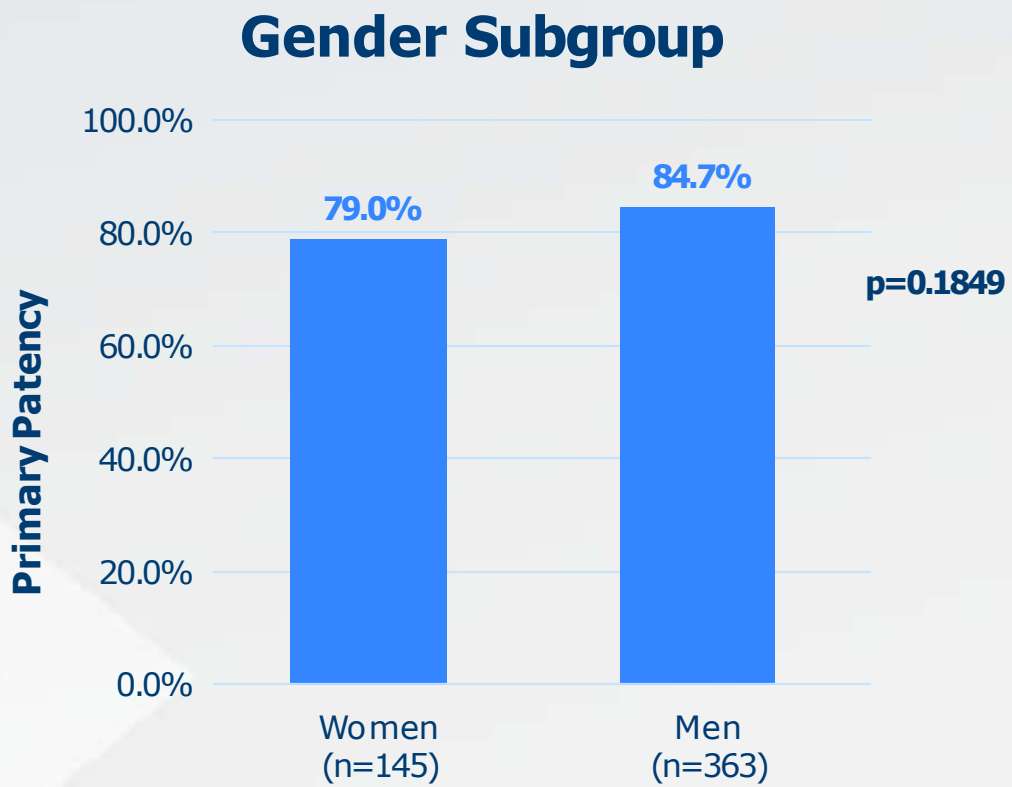
PI-1141903-AC

Eluvia maintained high primary patency rates regardless of gender.

Gender Subgroup Analysis



EMINENT Clinical Trial, 12-Month Effectiveness, Safety & Subgroup Analysis presented by Professor Yann Goueffic, MD. LINC 2022

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PI-1141903-AC

Similar Major Adverse Events Among Eluvia and BMS

No significant differences in CEC-adjudicated major adverse event rates.
No significant difference in all-cause death through 1-Year.

1-Year Major Adverse Event Rates	ELUVIA DES (n=492)	BMS (n=273)	p-value
All Death, Major Amputation, TLR	11.8% (56/474)	11.8% (31/263)	0.9912
All-Cause Death at 12 Months	2.7% (13/474)	1.1% (3/263)	0.1528
Target Limb Major Amputation	0.2% (1/474)	0.0% (0/263)	1.0000
Clinically-Driven Target Lesion Revascularization	8.4% (40/474)	10.6% (28/263)	0.3212

As-treated. Major adverse events adjudicated by the Clinical Events Committee. P values from Chi-square test or two-sided Fisher's exact test.

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

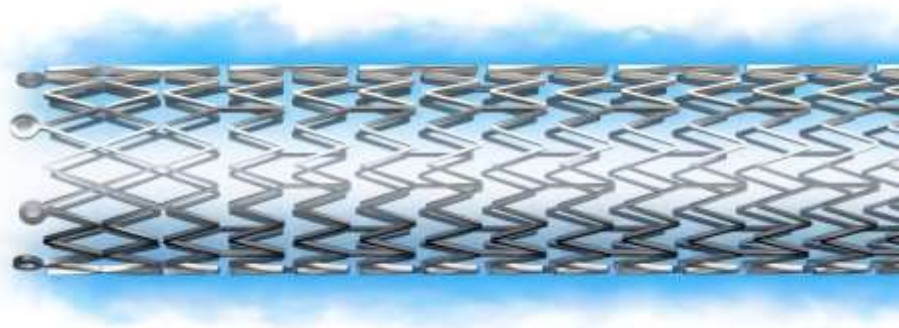
PI-1141903-AC

EMINENT RCT 1year Results

EMINENT is the largest randomized controlled trial (2:1) comparing Eluvia™ Drug-Eluting Vascular Stent System to self-expanding bare metal stents (BMS) for SFA/PPA

At 1-Year, Eluvia DES demonstrated:

- **Superior effectiveness** over BMS[1] and
- **A statistically significant** greater rate of primary sustained clinical improvement without reintervention



1. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. Primary Endpoint: 1-Year Binary Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).

EMINENT Clinical Trial 12-Month results presented by Professor Yann Goueffic, MD. VIVA 2021

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PI-1141903-AC

Boston Scientific

Advancing science for life™

IMPERIAL RCT

Eluvia DES vs. Zilver®PTX®

IMPERIAL Clinical Study Overview

Boston Scientific

Primary Investigators	*Global: William A. Gray, MD* *European: Stefan Müller-Hülsbeck, MD*		
Study Design	*Head to Head RCT (Eluvia DES vs Zilver™PTX™)*	*Long Lesion Sub-study (Eluvia)*	*Pharmacokinetic Sub-study (Eluvia)*
	• *2:1 randomized* • *Single-blind* • *Non-inferiority trial*	• *Single arm* • *Lesion length 140 mm-190 mm*	• *Single-arm*
Patients	*N=465* *Eluvia N=309 vs* *Zilver PTX N=156*	*N=50*	*N=13*
Investigational Centers	*65 study centers: US, Canada, New Zealand, Belgium, Germany, Austria, Japan*		

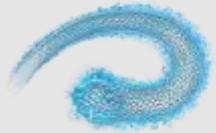
IMPERIAL CLINICAL TRIAL

PI-979201-AE-BSC-DES_US&EU_March2021-FINAL

Gray WA, et al. Lancet. 2018;392(10157):1541-1551.

IMPERIAL Study Devices

Boston Scientific

	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	Length	Diameter	Length
	6-7 mm	40-150 mm	6-8 mm	40-120 mm

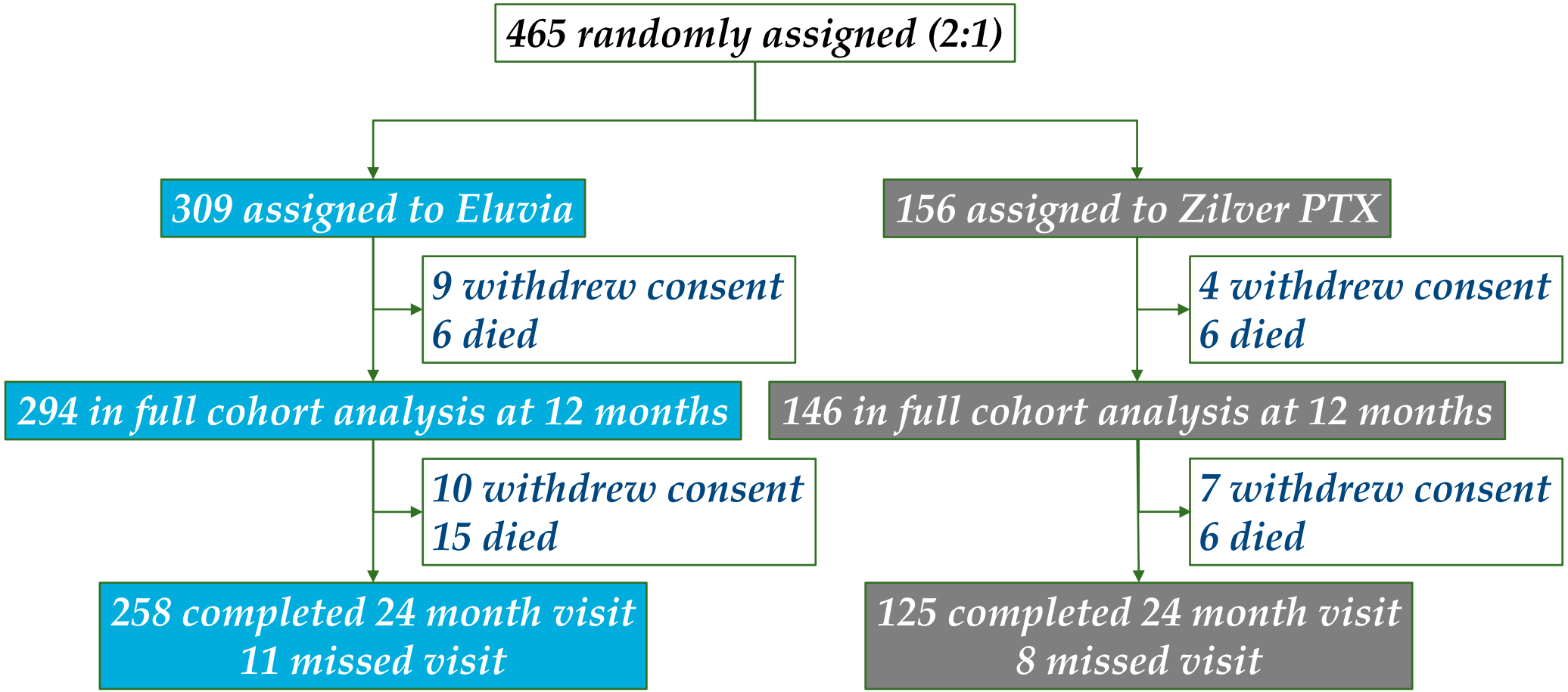
BSC Data on file. Cook Medical (2014). Zilver PTX Drug-Eluting Peripheral Stent Instructions for Use.

IMPERIAL CLINICAL TRIAL

PI-979201-AE-BSC-DES_US&EU_March2021-FINAL

IMPERIAL RCT I Patient Flow

24 Months



Iida O, VIVA 2019

IMPERIAL RCT: the first Head-to-Head DES SFA Trial

Enabling direct objective comparison of Eluvia DES and Zilver® PTX®

Trial Design

All other drug-eluting pivotal trials were randomized vs. PTA or BMS

465 subjects at 64 sites worldwide

Lesion Characteristics

40% severely calcified

(4x higher than IN.PACT and Lutonix FDA-approval trials)

31% total occlusions

42% diabetics

IMPERIAL Trial[1]:

- A global randomized controlled multi-center trial with 2:1 randomizat ion of the Eluvia™ Drug-Eluting St ent against Cook Medical's Zilver® PTX® Stent
- Single-blind, non-inferiority design; independent core lab adjudication.
- Superior efficacy determined in a post hoc analysis that was specified prior to unblinding.
- 1-Year Primary Patency rate of **86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm** (p-value = 0.0144).
- Trial data published in the Lancet. (Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1).

1. IMPERIAL Trial: A global randomized controlled multi-center t rial w ith 2:1 randomization of the Eluvia™ Drug-Eluting Stent against Co ok Medical's Zilver™ PTX™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that w as specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX ar m (p-value = 0.0144).
Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1.

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Eluvia DES has Strong, Consistent Primary Patency through 5-years

IMPERIAL RCT

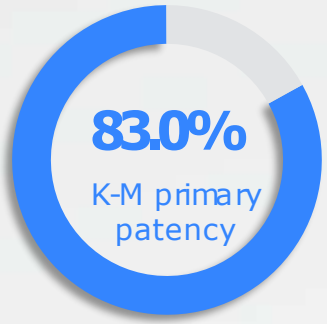
1-year results[1]

At 1 yr, Eluvia DES **demonstrated superiority over Zilver PTX with a statistically significant primary patency through 1-Year**

(log-rank p=0.0094)

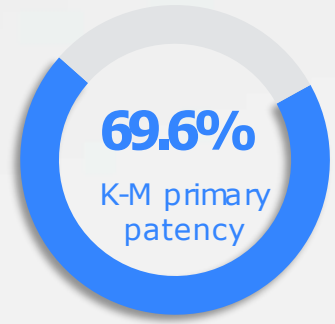
2-year results[2-7]

Highest 2-yr K-M primary patency ever reported of any SFA stent



5-year results[8]

Sustaining Strong Results through 5- years with near 70% primary patency



1. IMPERIAL Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value =0.0144). Gray W A, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1. 2. Gray W. 2-year Outcomes from the IMPERIAL Randomized Head-to-Head Study of Eluvia DES and Zilver PTX; LINC 2020, Leipzig Jan 28,2020. 3. Rocha-Singh et al (2015). Catheterization and Cardiovascular Interventions 86: 164-170; Severe Calcification: EveFlex Instruction for Use (Oct 2014). 4. Garcia et al (2017) Catheterization and Cardiovascular Interventions 89: 1259-1267 (2017). 5. Laird JR, Zeller T, Loewe C, Chamberlin J, Begg R, Schneider PA, Nanjundappa A, Bunch F, Schultz S, Harlin S, Lansky A, Jaff M R. Novel Nitinol Stent for Lesions up to 24 cm in the Superficial Femoral and Proximal Popliteal Arteries: 24-Month Results From the TIGRIS Randomized Trial. J Endovasc Ther. 2018 Feb;25(1):68-78. doi: 10.1177/1526602817749242. Epub 2017 Dec 29. PM ID: 29285955. 6. de Boer, Sanne et al (2019). Drug coated balloon supported Supera stent versus Supera stent in intermediate and long-segment lesions of the superficial femoral artery: 2-year results of the RAPID Trial. The Journal of cardiovascular surgery. 60. 10.23736/S0021-9509.19.11109-3. 7. Osamu Iida (2019). 2-Year Outcomes From the IMPERIAL Randomized Study of Eluvia and Zilver PTX. VIVA 2019, Las Vegas, NV. 8. Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Durable, Consistent Results in Long and Complex Lesions at 2-years

IMPERIAL TRIAL 2-YEAR CLINICAL RESULTS Excellent Patient Follow-up at 24-Months (~90%)	IMPERIAL RCT[1]	IMPERIAL Long Lesions[2,3]	Diabetic Subgroup[4,5]	Severe / Moderate Calcium Subgroup	CTO Subgroup
	(n = 309)	(n = 56)	(n = 116)	(n = 193)	(n = 96)
Study Design	RCT, multicenter, global	Single arm, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global
24-month primary patency rate**	**83.0%**	**77.2%**	**85.7%**	**85.0%**	**76.4%**
Lesion length (mm)	86.5	162.8	87.0	89.9	94.4
Severe calcification	40%	28%	46%	n/a	n/a
Total occlusions	31%	32%	25%	n/a	100%
	Highest primary patency ever reported at 2 years*	**Highly durable outcomes in ~16cm lesions at 2 years**	TLR (12%) in line with overall cohort and **low stent thrombosis rate** (0.9%)	Remarkable primary patency and **<10% TLR** in **heavy calcium**	**Highly durable outcomes in CTOs at 2 years**

*Highest-two-year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.
**Intention to treat. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 730 days and Duplex Ultrasound data at 24 months. Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or by pass of the target lesion, as assessed by the DUS core lab.

1. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.
2. Golzaar, J. et al, Journal of Endovascular Therapy, Jan 2020. https://doi.org/10.1177/1526602820901723.
3. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020.
4. In IMPERIAL Diabetic Subgroup, Eluvia K-M Primary Patency was 95.2% vs. 81.5% for Zilver PTX at 12 months. Diabetic = Medically Treated Diabetes
5. Gray, W. 2 year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX. LINC 2020.

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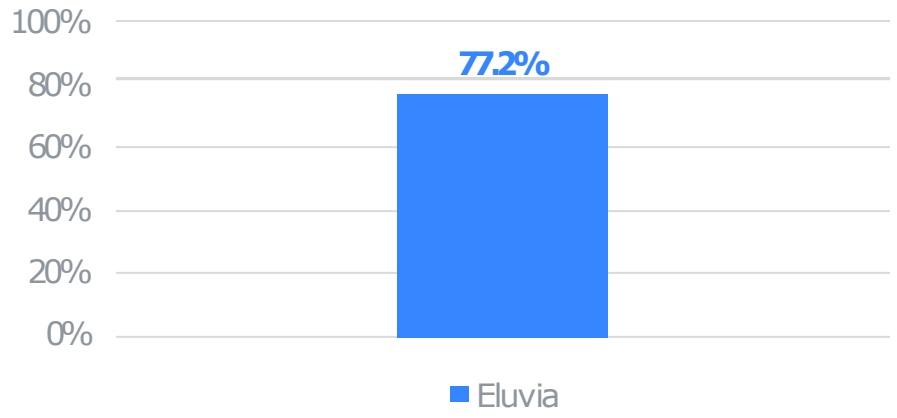
Long Lesion Sub-Study 2-Year Patency in Perspective

LONG LESION SUB-STUDY 24-MONTH OUTCOMES[1] with Eluvia

Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: Outcomes of the Single-Arm IMPERIAL Long Lesion Sub-study of the Eluvia Drug-Eluting Stent

Lesion Characteristics	IMPERIAL Long Lesion
Lesion Length	16.2 cm
Mod/Sev Calcium	70%
Chronic Total Occlusion (CTO)	32%
Diabetics	40%

2-yr KM Primary Patency

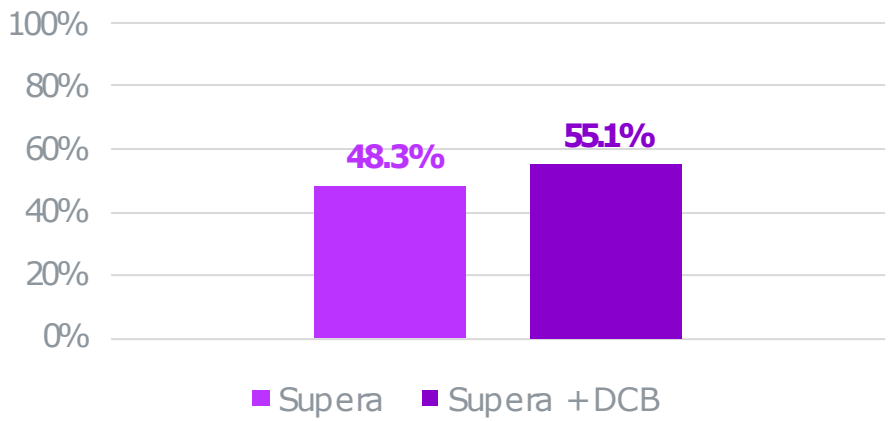


RAPID TRIAL 24-MONTH OUTCOMES[2] with Supera and DCB

Drug coated balloon supported Supera stent versus Supera stent in intermediate and long-segment lesions of the superf icial femoral artery: 2-year results of the RAPID Trial

Lesion Characteristics	RAPID
Lesion Length	15.8 cm
Mod/Sev Calcium	Not Reported
Chronic Total Occlusion (CTO)	>70%
Diabetics	~30%

2-yr KM Primary Patency



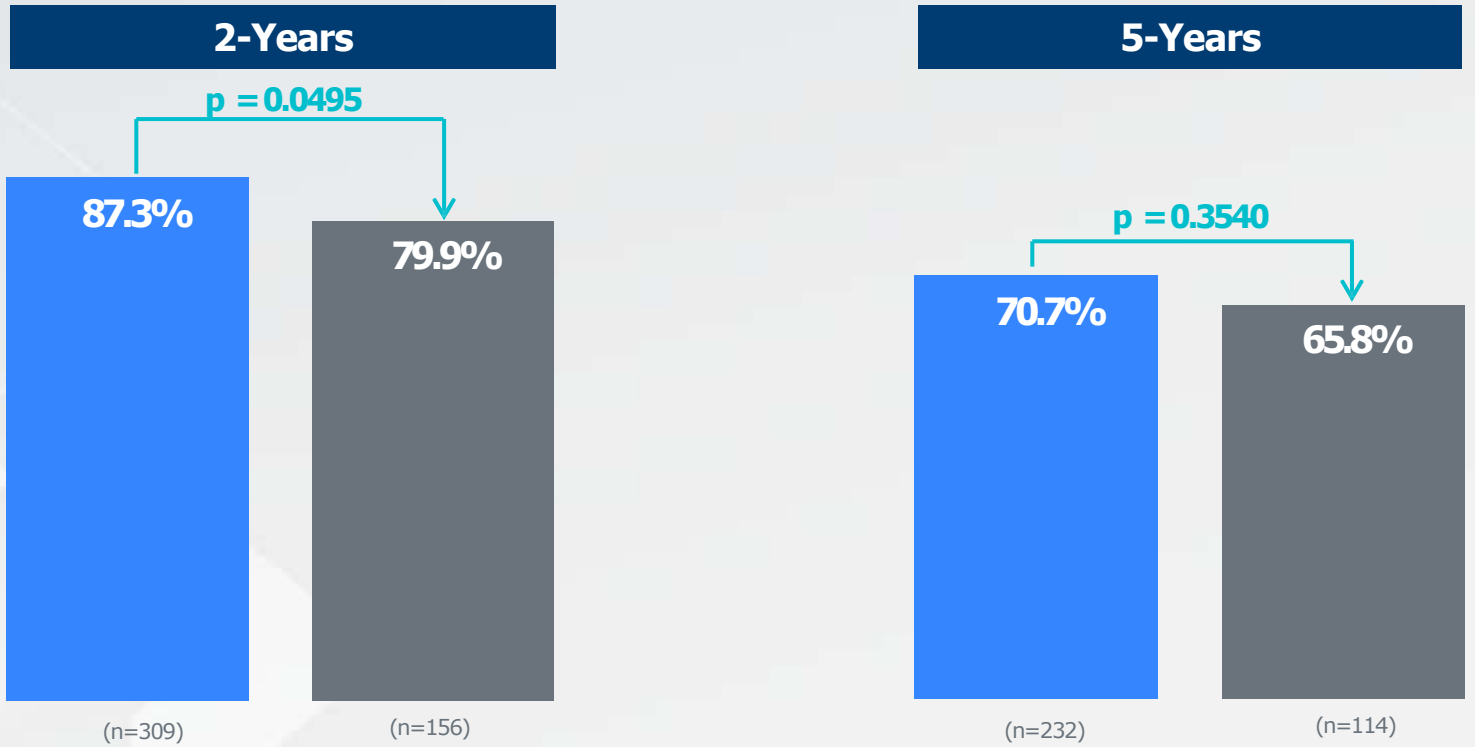
*Results from different clinical investigations are not directly comparable. Information provided for educational purposes only

1. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020
2. de Boer, Sanne et al (2019). Drug coated balloon supported Supera stent versus Supera stent in intermediate and long-segment lesions of the superficial femoral artery :2-y ear results of the RAPID Tr ial. The Journal of cardiovascular surgery. 60. 10.23736/S0021-9509.19.11109-3.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Eluvia DES has Lower Revascularization Rates than Zilver PTX through 5-years

Freedom from CD-TLR Rates



ELUVIA had **significantly greater freedom from reinterventions with Eluvia DES compared with ZILVER PTX**[1] at 2-Years

1. Intention to treat. Iida O, VIVA 2019. RCT, randomized controlled trial; TLR, target lesion revascularization.
2. Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023.

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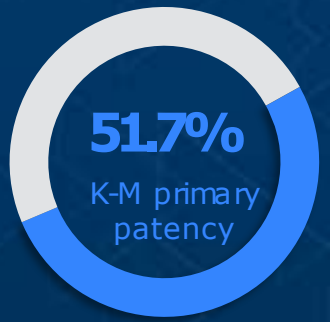
Durable Results in Long Lesions through 5 years

IMPERIAL- Long Lesion Sub-Study Patient and Lesion Characteristics

	Eluvia DES (N=50)
Age (years)	68.2 ± 8.9
Male	64.0%
Diabetes Mellitus	40.0%
Lesion Length (mm)	162.8 ± 34.7
Occlusion	32.0%
Calcification	
Moderate	42.0%
Severe	28.0%

Durable Patency in Long, Complex Lesions through 5-years[1]



ELUVIA
(n=35)

Consistent Freedom from CD-TLR through 5-years[1]

57.1%

ELUVIA
(n=20/35)

Nearly **6 out of 10 patients** with a long lesion (>140mm) did not require a reintervention within 5 years

The IMPERIAL Long Lesion Sub-Study is the only 5-year global DES data studying long, challenging lesions

Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023.

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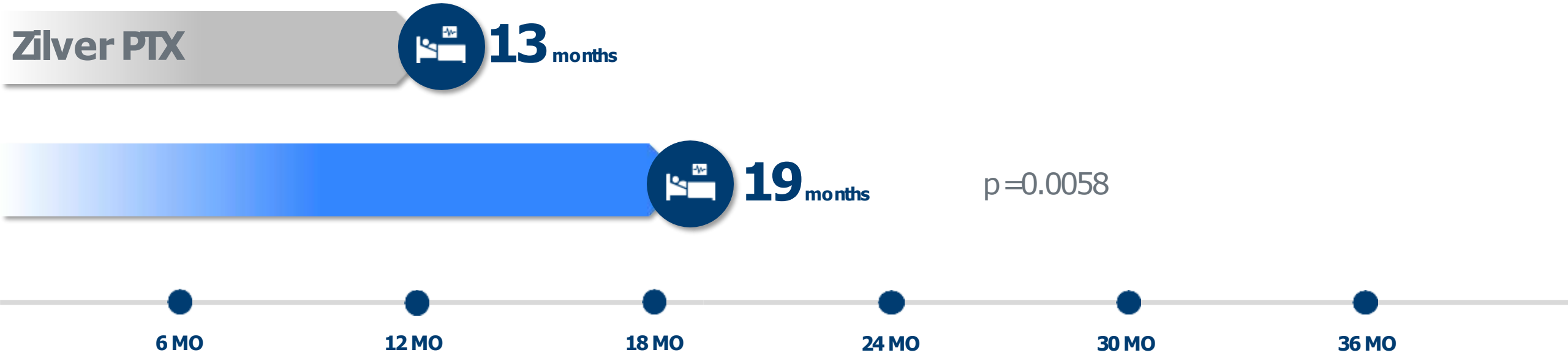
Eluvia DES patients avoided reintervention 6 months longer than Zilver PTX patients[1,]*

IMPERIAL RCT 3-year Analysis



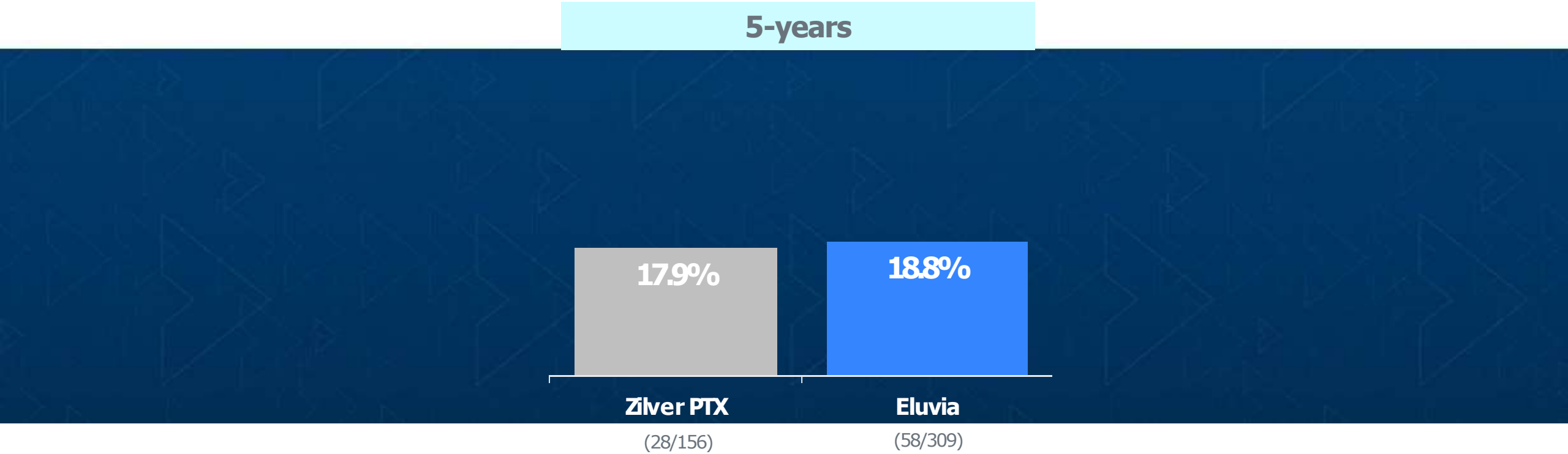
When revascularization was required at later time points, IMPERIAL showed **these procedures occurred later for patients initially treated with Eluvia DES**

1. Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023.

*Among patients who underwent a CD-TLR within 3 years of the index procedure

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Both Devices Demonstrate Low All-Cause Mortality through 5-years



All-cause mortality was within range expected for symptomatic PAD and no differences were observed between both therapies**

Intention to t reat. Adapted from I ida, O, VIVA 2019 Presentation
* Crude rate including all vital status assessments regardless of CEC adjudication.
**Amputation Rates, Mortality , and Pre-operative Comorbidities in Patients Revascularised for Intermittent Claudication or Critical Limb I schaemia: A Population Based Study Baubeta Fridh, E. et al. European Journal of Vascular and Endovascular Surgery , Volume 54 , I ssue 4 , 480 – 486

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ELUVIA™ Drug-Eluting Vascular Stent System

A New Standard of Care in SFA Stenting

Eluvia demonstrated a statistically significant superior primary patency at 1-Year over BMS[3] and Zilver PTX.[4]

No SFA stent has performed better at 2-Years. No matter the lesion complexity. No matter the patient.[1,2]

Eluvia demonstrated statistically significant fewer repeat procedures compared to Zilver PTX at 2-Years.[5]

1. Highest-two year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT. Intention to treat. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 730 days and Duplex Ultrasound data at 24 months. Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion, as assessed by the DUS core lab.
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p =0.1008. Diabetic Subgroup Analysis =Medically Treated Diabetes
3. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. Primary Endpoint: 1-Year Binary Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).
4. IMPERIAL Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144).
5. Intention to treat. IMPERIAL Head-to-Head RCT. 2-Year results presented by Osamu Iida, M D. VIVA 2019

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PI-1141903-AC

Eluvia Shows Durable and Consistent Results Across Real-World Studies

Boston Scientific

First-in-Human Trials and Real-World Data

		Independent Studies				
		MAJESTIC[1] (n=57)	**Munster Registry**[2] (n=130)	**Auckland All-comers Registry**[3] (n=51)	**DESAFINADO**[4] (n=64)	**CAPSICUM**[5] (n=1,097)
Primary Patency (K-M Estimate)**	12 months	**96.4%**	**90%**	**94.0%***	**84%**	**87.1%†**
	24 months	**83.5%**	**71%**	**93.8%***	**NA**	**NA**
Study Design		Single arm, multicenter trial	Single center retrospective registry	Single center registry	Single center retrospective registry	Multicenter prospective registry
Lesion length (mm)		70.8 ± 28.1	194	105.4	193 ± 128	186 ± 99
Occlusion (%)		46%	74%	53%	48%	53.2%

*Observed Rate
†Freedom from Restenosis Rate

First ever FIM data for TLR or Eluvia demonstrating polymeric PTX yields exceptional primary patency rates

CLI in nearly 1/3 of patients

Consistent and reproducible primary patency results at 1 and 2 years in real world lesions

Over 75% of patients with Diabetes and CLI

>66% of patients had chronic kidney disease and >28% had end-stage renal disease

**Kaplan Meier Estimate; Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤2.4 at the 12-month follow-up visit, in the absence of clinically-driven bypass of the target lesion.

1. Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2017;40(12):1832-1838.
2. Stavroulakis, JACC Cardiovasc Interv. https://doi.org/10.1016/j.jcin.2021.01.026
3. Holden, A. Single Center Long-Term Experience with the Boston Scientific Eluvia DES in Femoropopliteal Artery Occlusive Disease. LINC 2020.
4. Kum, S. DES for SFA/Pop 12 Month Results of the DESAFINADO Registry. LINC 2020.
5. Iida, O. M.D., et al. JACC Cardiovasc Interv. 2022 Mar 28;15(6):630-638. doi: 10.1016/j.jcin.2022.01.019. PMID: 35331454

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Eluvia Clinical Trial Amputation & Mortality Rates

Eluvia DES				
	MAJESTIC Trial[1] 3-Year Results	IMPERIAL[2] 2-Year Results	IMPERIAL[3] 1-Year Results	IMPERIAL[4] 5-Year Results
All Cause Mortality	3.6% (2/55)	7.1% (21/295)	2.1% (6/292)	18.8% (58/309)
Major Amputation	0.0%	1.5% (4/275)	0.3% (1/287)	3.4% (8/232)

PAD Data: *Amputation* Rates in CLI & Intermittent Claudication[5]	3-Year	2-Year	1-Year
Intermittent Claudication (n=6,272)	1.2%	0.9%	0.5%
CLI (n=10,617)	18.6%	17.2%	14.8%

PAD Data: *Mortality* Rates in CLI & Intermittent Claudication[5]	3-Year	2-Year	1-Year
Intermittent Claudication (n=6,272)	12.0%	7.5%	3.4%
CLI (n=10,617)	41.4%	31.7%	20.5%

Müller-Hülsbeck S, et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up. Cardiovasc Intervent Radiol. 2017 Dec;40(12):1832-1838. doi: 10.1007/s00270-017-1771-5. Epub 2017 Sep 25. PMID: 28948322. 2. Müller-Hülsbeck S, et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021 Mar;44(3):368-375. doi: 10.1007/s00270-020-02693-1. Epub 2020 Nov 22. PMID: 33225377. 3. Gray W A, et al. IMPERIAL investigators. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018 Oct 27;392(10157):1541-1551. doi: 10.1016/S0140-6736(18)32262-1. Epub 2018 Sep 24. PMID: 30262332. 4. Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023. 5. Baubeta Fridh E, et al. J. Amputation Rates, Mortality, and Pre-operative Comorbidities in Patients Revascularised for Intermittent Claudication or Critical Limb Ischaemia: A Population Based Study. Eur J Vasc Endovasc Surg. 2017 Oct;54(4):480-486. doi: 10.1016/j.ejvs.2017.07.005. Epub 2017 Aug 7. PMID: 28797662.

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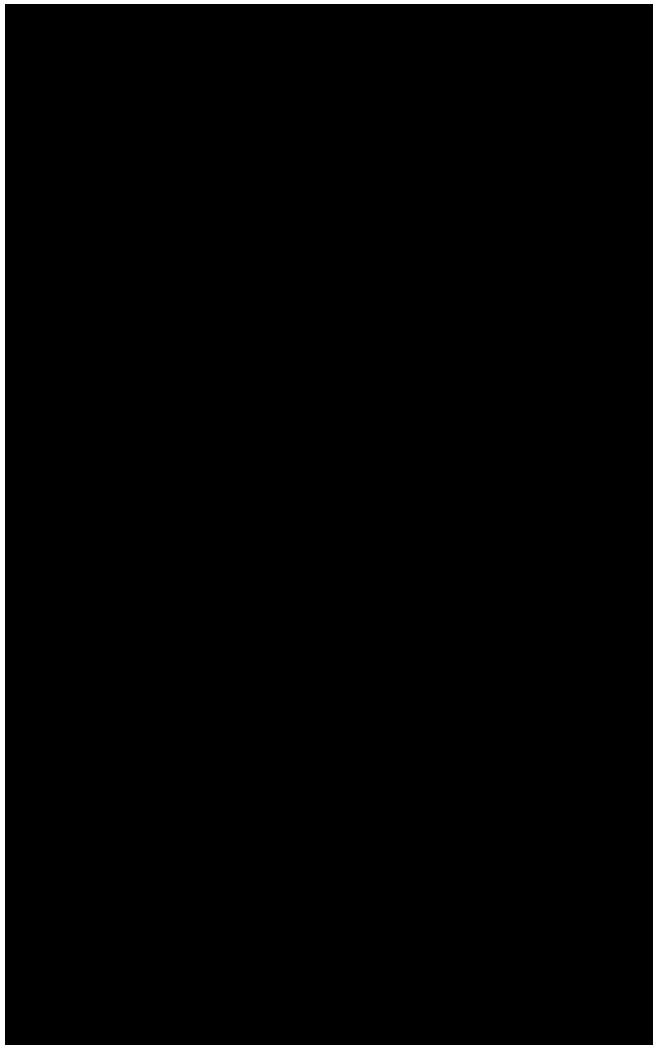
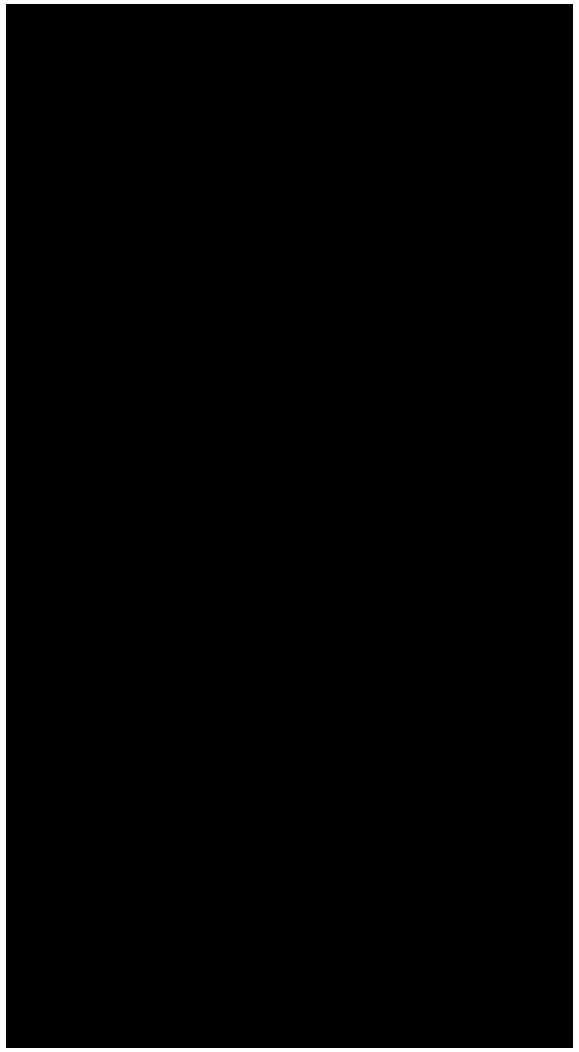
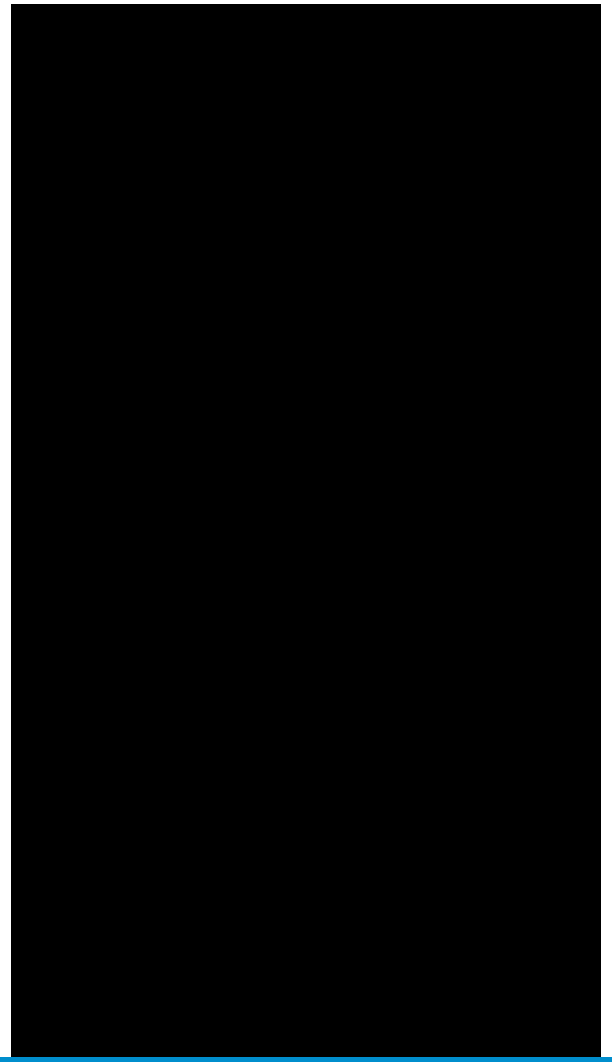
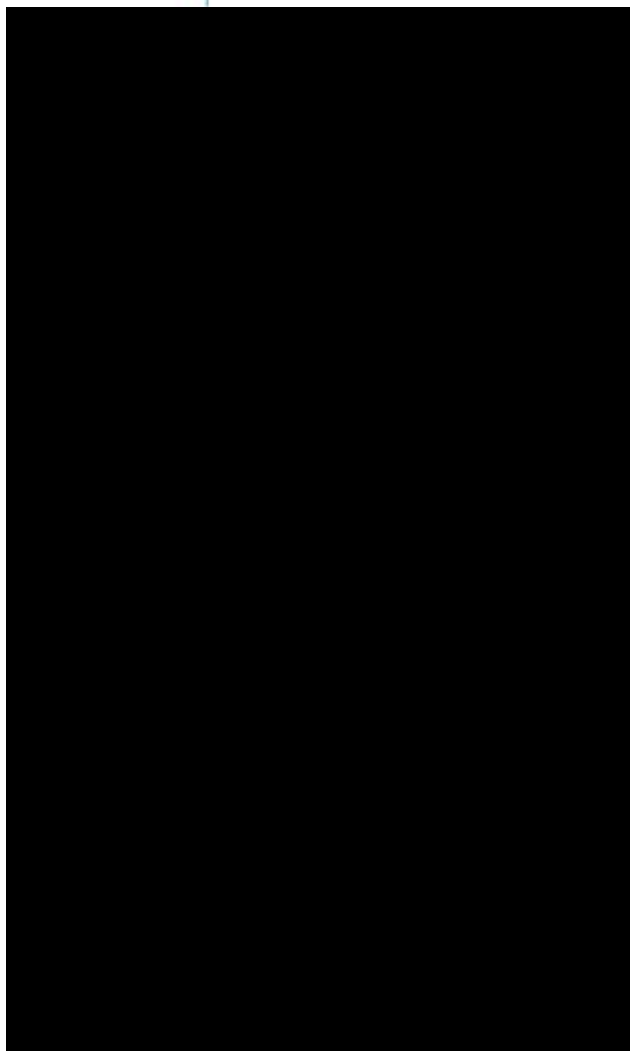
Severe calcifed long f-p lesion –Eluvia case

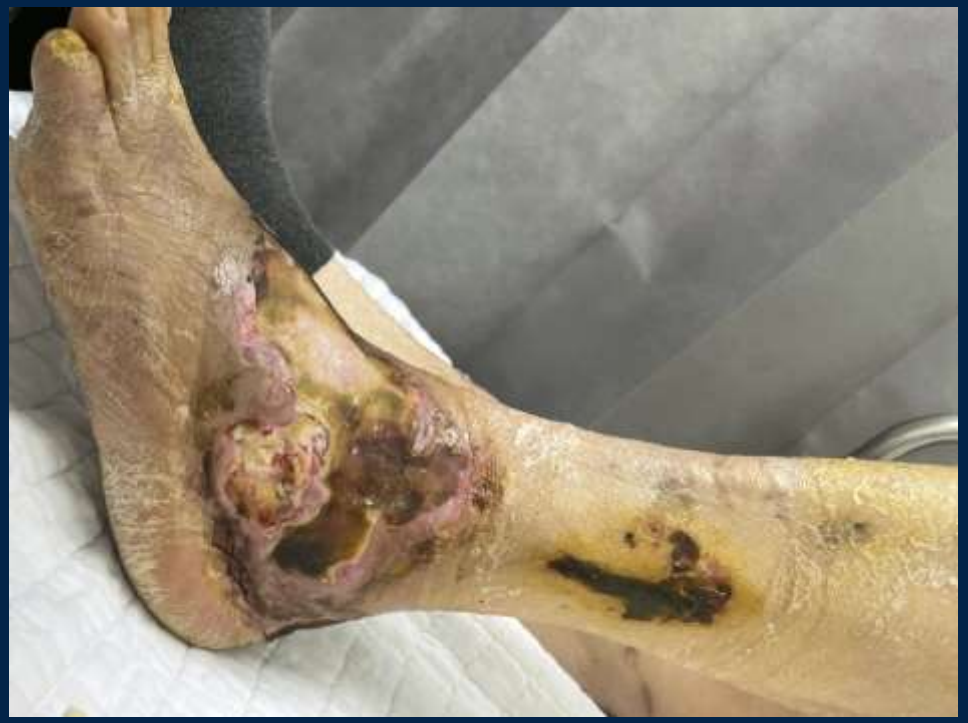
Boston Scientific

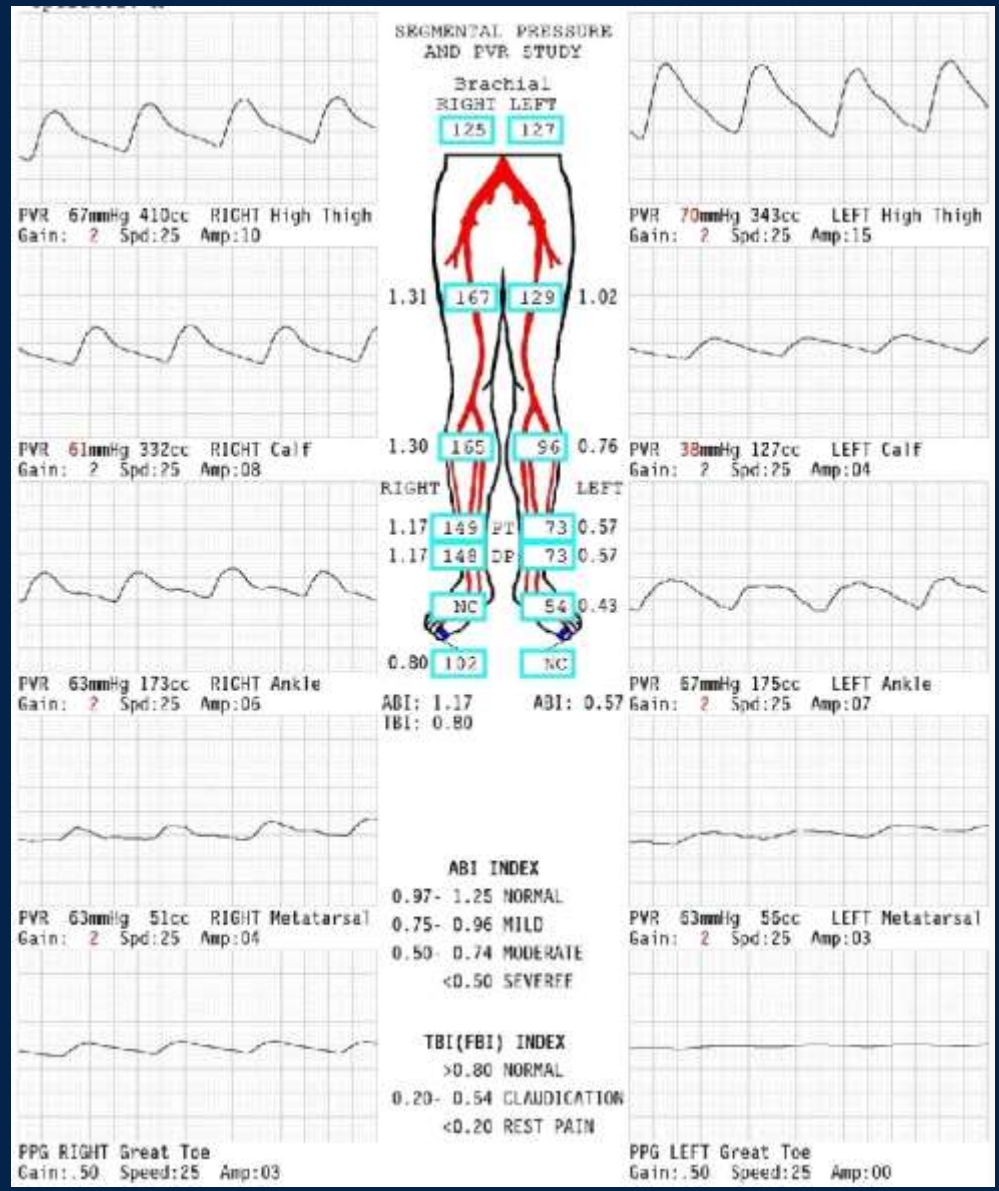





True lumen wiring – bidirectional ➔ Preballoon ➔ severe dissection/flow limitation

M/65

- *C.C: Poor wound recovery and soft tissue defect after recent trauma & multiple fracture s/p open reduction & internal fixation*

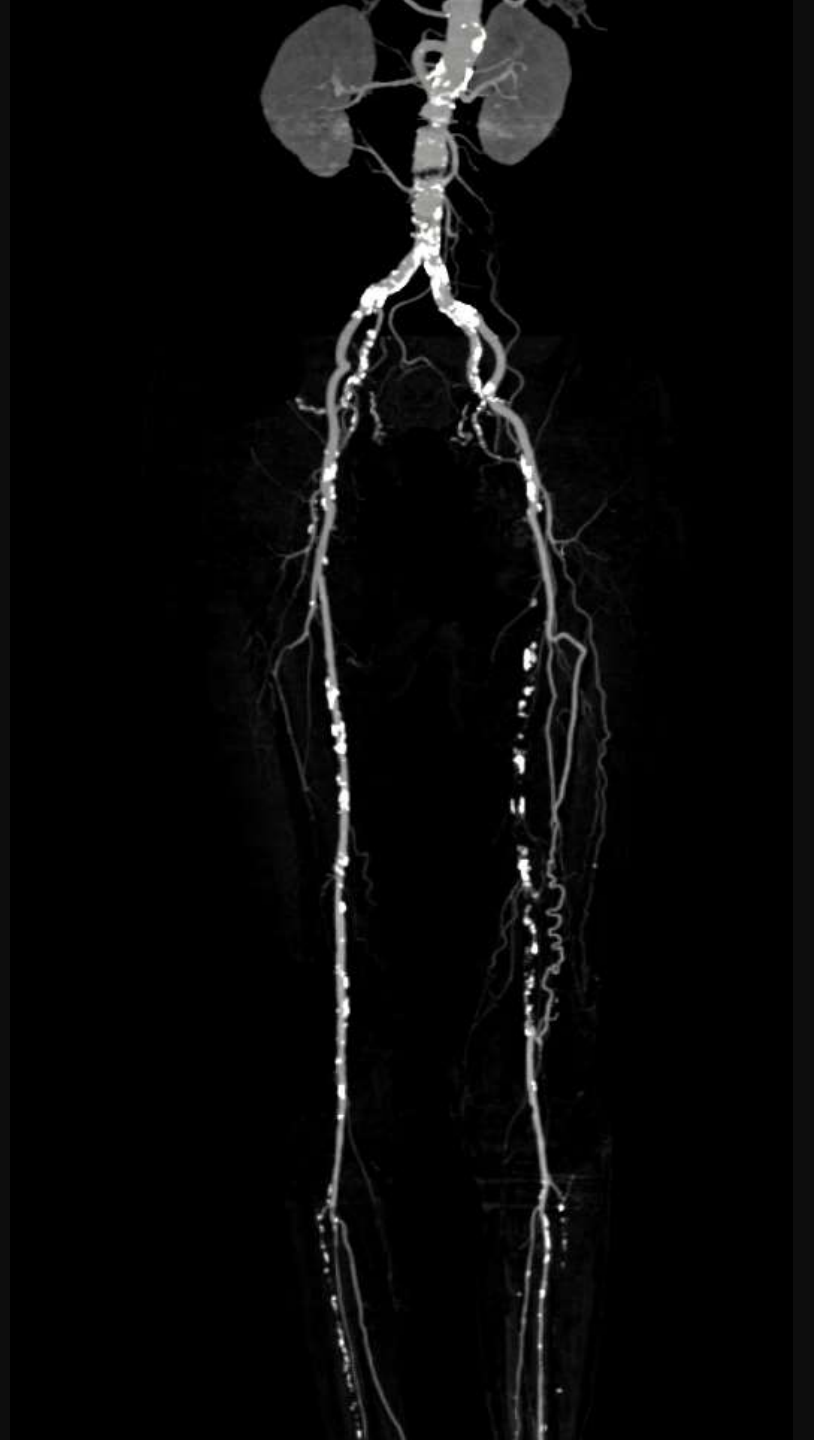




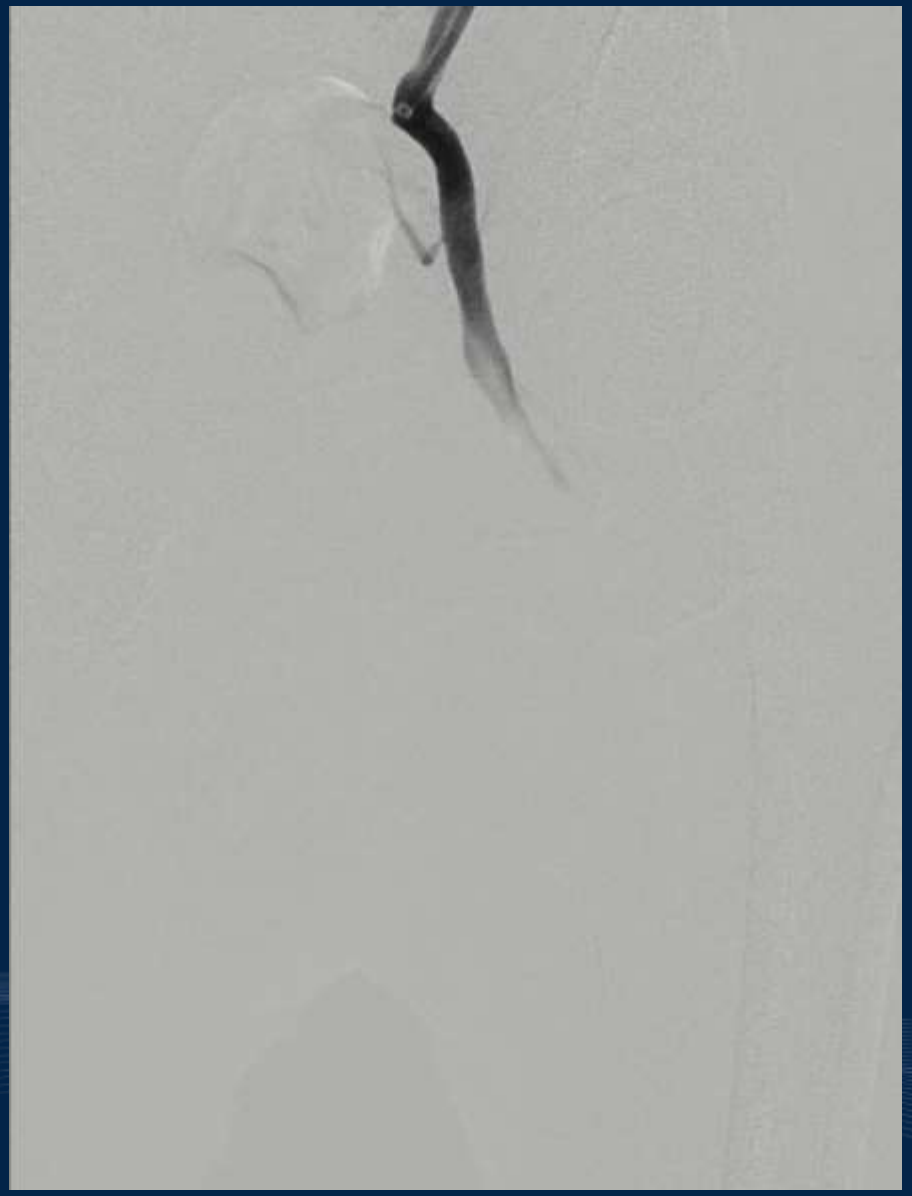
ABI- Rt: 1.17/ Lt: 0.57

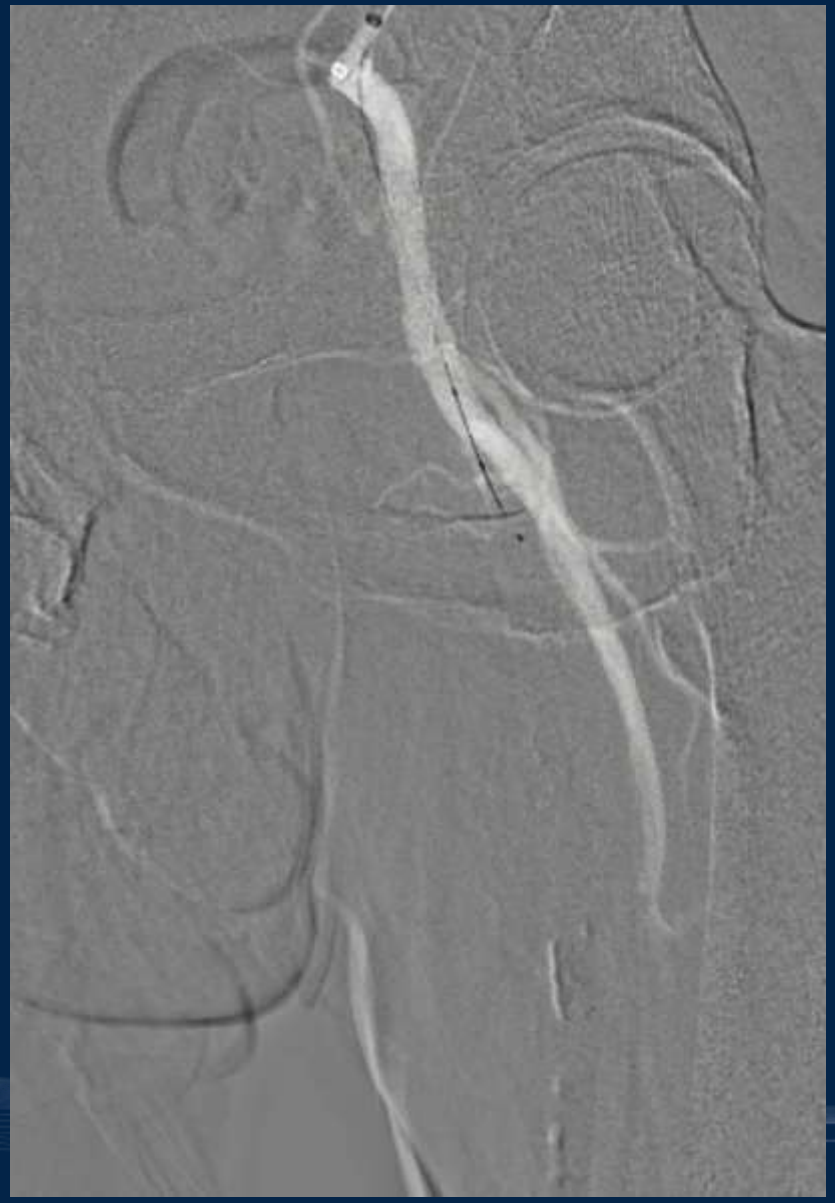
CT angiogram

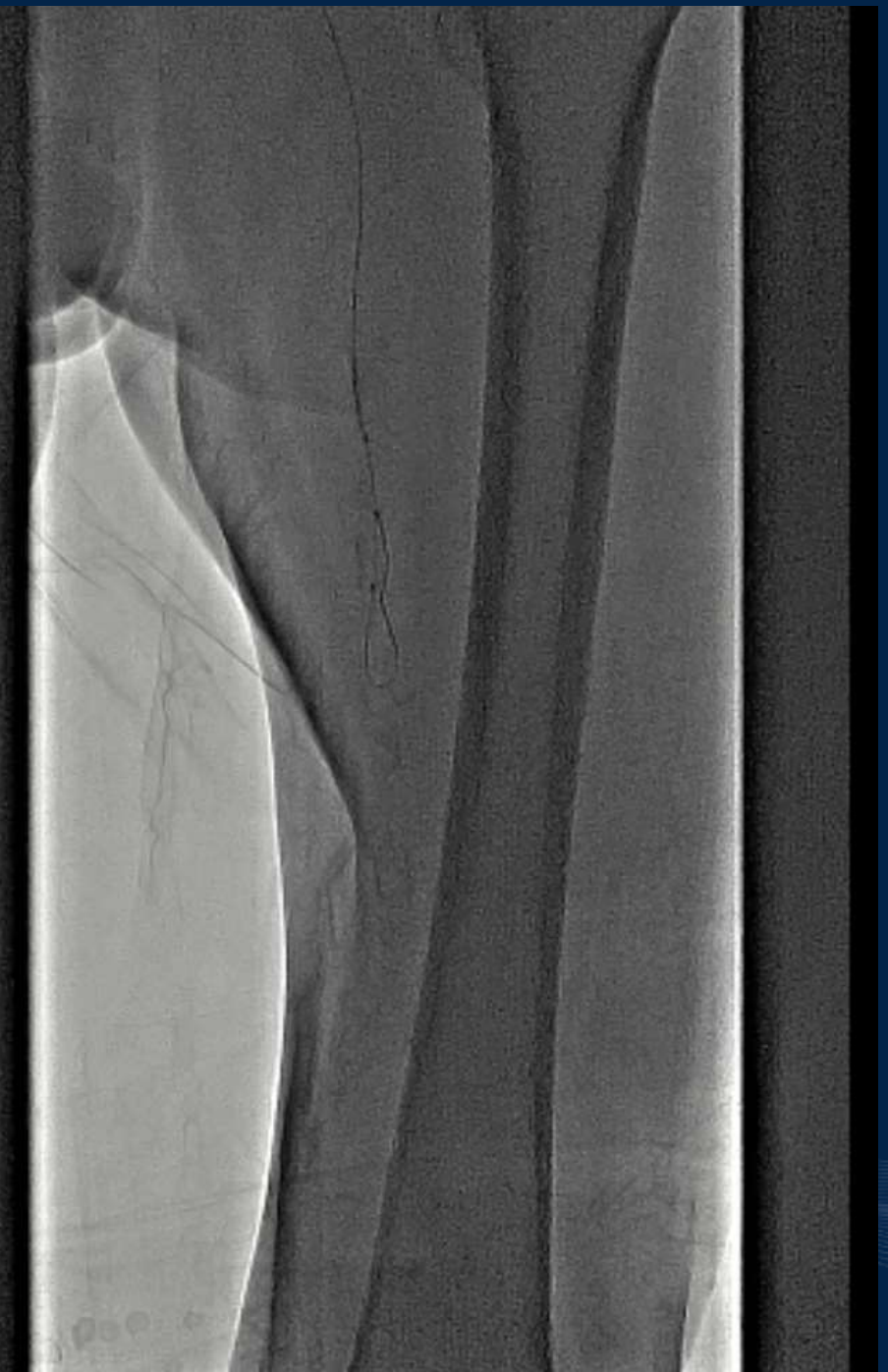
- Long SFA CTO
- Proximal short stump
- Scattered heavy calcium
- Short distal SFA to pop. Artery

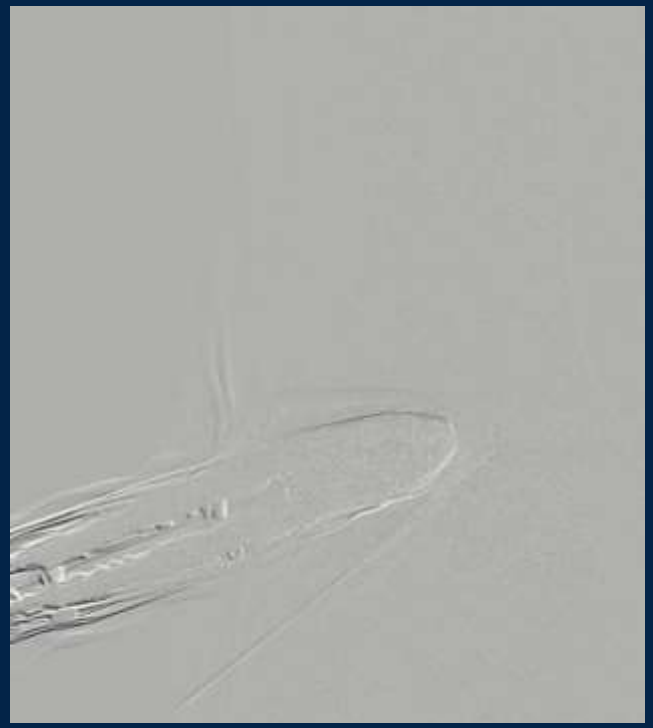


Proximal Stump +/Poor distal puncture site/ antegrade wiring first

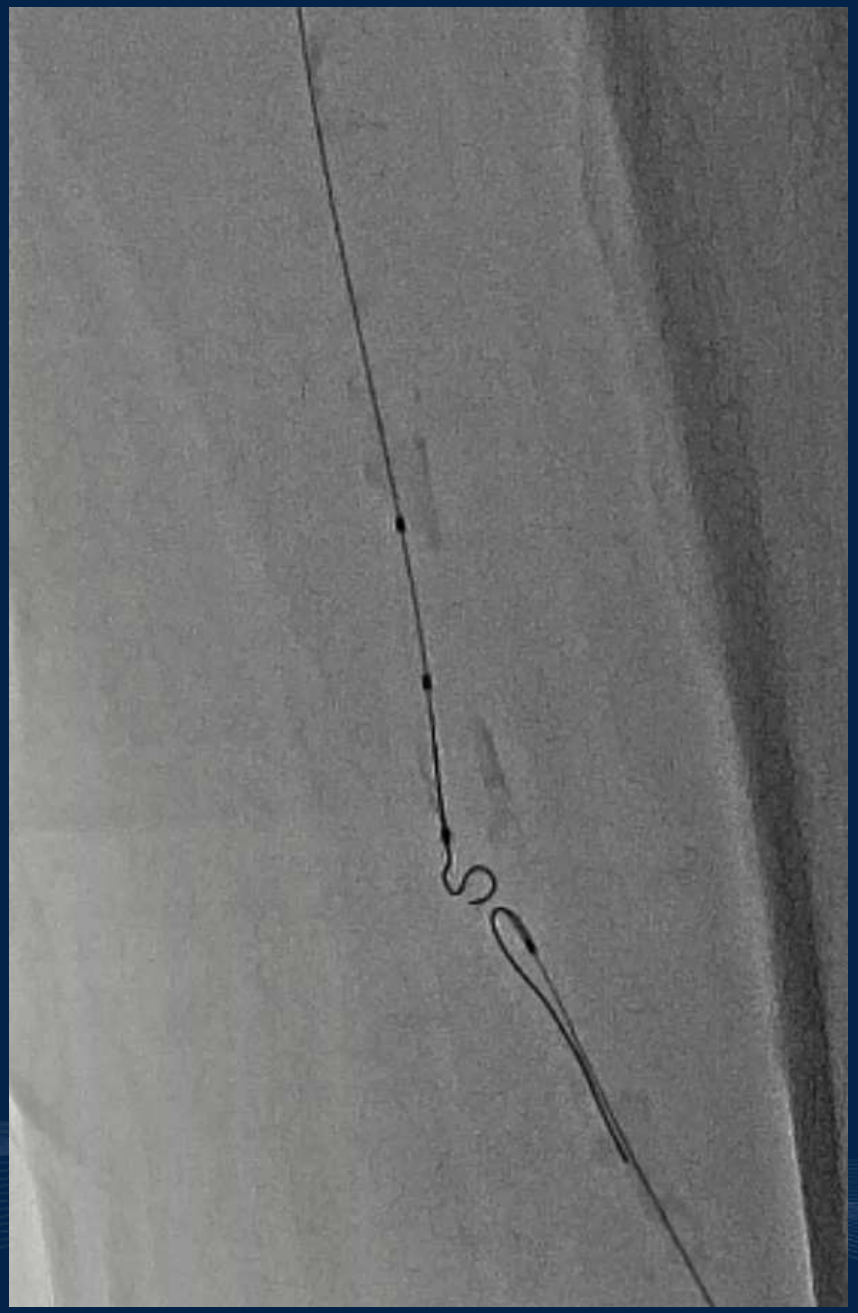


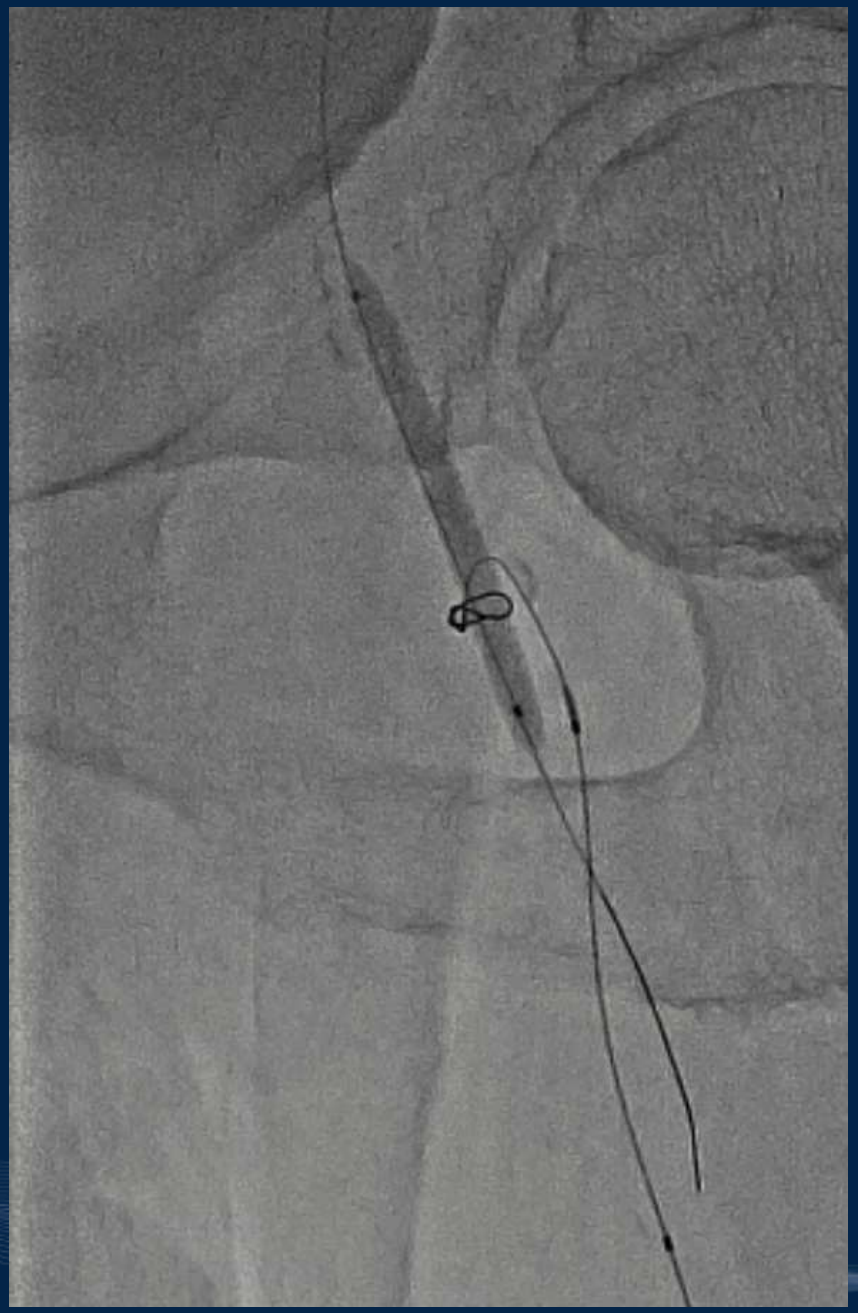






Poor penetration with subintimally → Frog leg and popliteal puncture (018 CXI with command 018)





Bidirectional wiring
➔ reverse CART distal to proximal SFA
➔ long NC balloon
➔ DES at p~m SFA

Eluvia 6X120/7X120mm
➔ DCB at dSFA to pop.

IMPERIAL RCT – 5 Yrs - Conclusions

The results of the IMPERIAL RCT show that Eluvia DES is clinically effective and safe in treating patients with symptomatic SFA disease both in the short-term during the height of restenosis risk, and long-term out to five years.

- **Superiority over Zilver PTX** with a **statistically significant primary patency** through 1-Year[1]
- **Lower revascularization rates than Zilver PTX** through 5 years[2] with **statistical significance over ZILVER PTX**[3] at 2-Years
- **Durable, Consistent Outcomes in Long and Complex Lesions**[1,2,4-7] through 5-Years

1. IMPERIAL Trial: A global randomized controlled multi-center trial with 1:1 randomization of the Eluvia™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™ Stent; single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 12-Month Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144). Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1.
Gray W. 2-year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX; LINC 2020, Leipzig Jan 28,2020.
*Kaplan Meier Estimate; Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤2.4 at the 12-month follow-up visit, in the absence of clinically-driven TLR or bypass of the target lesion.
**Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.
2. Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease. CRT 2023, Washington DC, Feb 27, 2023.
3. Intention to treat. Iida O, VIVA 2019. RCT, randomized controlled trial; TLR, target lesion revascularization.
4. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.
5. Golzaar, J. et al, Journal of Endovascular Therapy, Jan 2020. https://doi.org/10.1177/1526602820901723.
6. Vermassen, F. VIVA Late-Breaking Clinical Trials June 2020.
7. In IMPERIAL Diabetic Subgroup, Eluvia K-M Primary Patency was 95.2% vs. 81.5% for Zilver PTX at 12 months. Diabetic = Medically Treated Diabetes

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.