Single Centre Long-Term Experience with the Boston Scientific Eluvia DES in Femoro-popliteal Artery Occlusive Disease

Andrew Holden MBCHB, FRANZCR, EBIR, ONZM

Director of Interventional Radiology

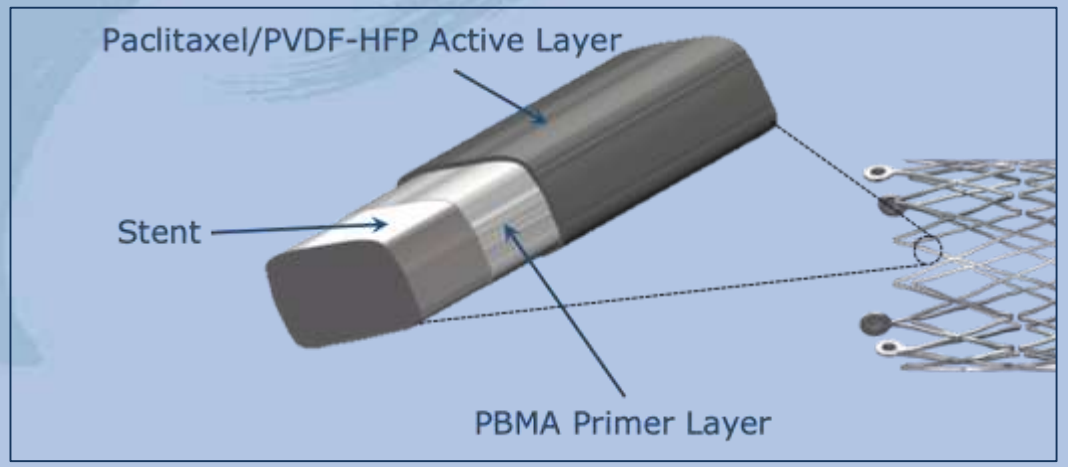
Auckland Hospital, Auckland, New Zealand

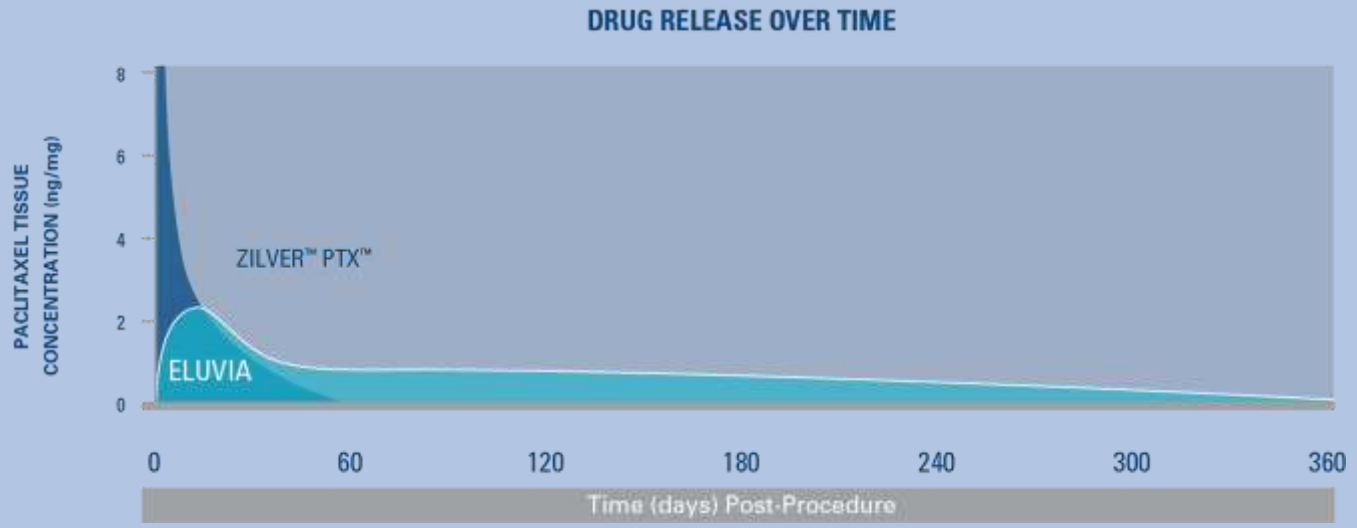
Disclosures: Dr. Andrew Holden

- Dr. Holden is a Medical Advisory Board Member for Medtronic, Boston Scientific, and Gore
- Dr. Holden is a Clinical Investigator for Medtronic, Boston Scientific, Gore, Abbott, Cagent, Endologix, Intact Vascular, Shockwave, Bard, Cook, Endospan, Intervene, Spectranetics, TriReme, Merit, Reflow, Terumo, Surmodics
- No other relevant disclosures

Eluvia DES Design Features

- Familial Innova stent platform, paclitaxel eluting
- 6F Tri-axial SDS, 0.035” guidewire compatible
- Dual layer polymer coating provides controlled drug release

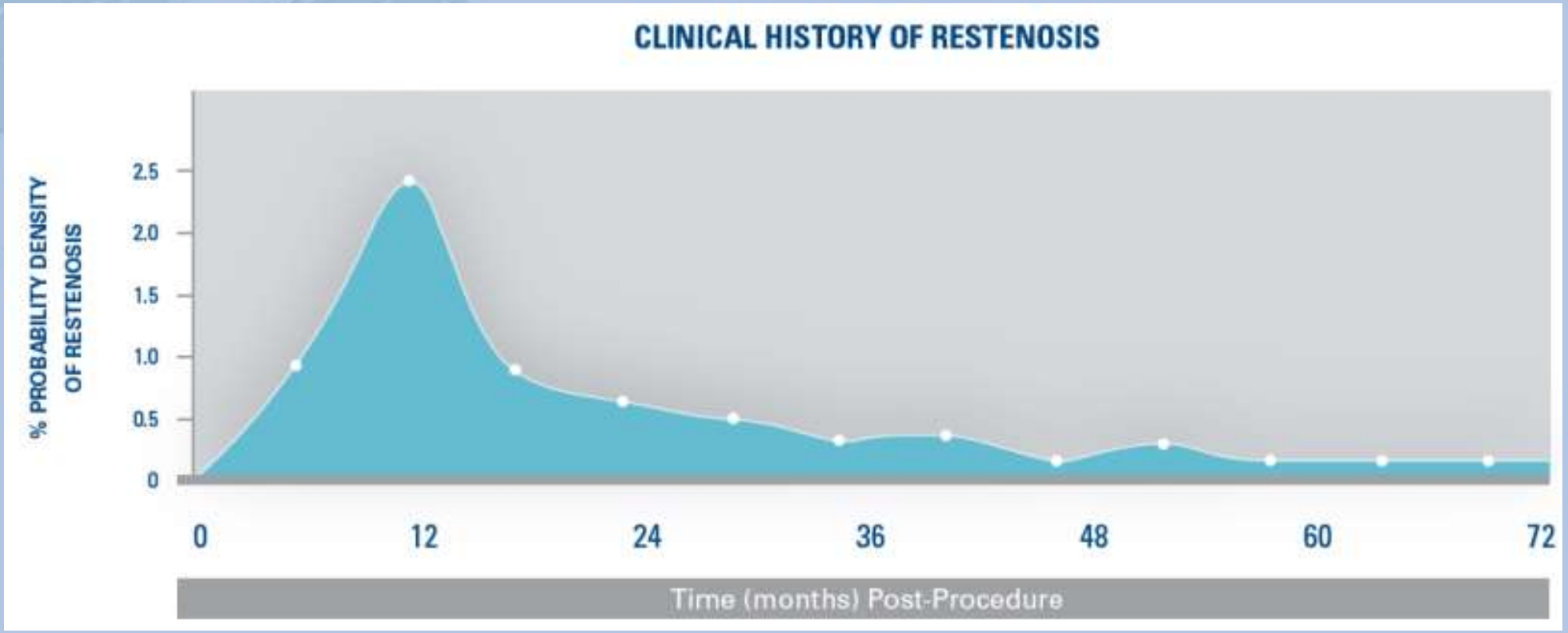




Boston Scientific Data on File. * PVDF-HFP on PBMA = poly-vinylidene fluoride - hexafluoropropylene on poly *n*-butyl methacrylate

Clinical Probability of Restenosis Following SFA Stenting

Restenosis following nitinol stenting in the SFA peaks at ~12 months

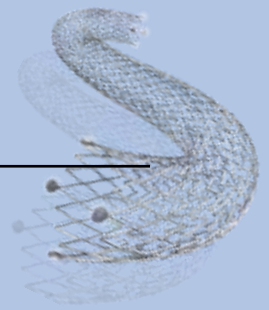


Iida, O. et al. Cath and Cardiov Intv. 2011; 78:611–617.

Kimura T, et al. N Engl J Med 1996;334:561–567.

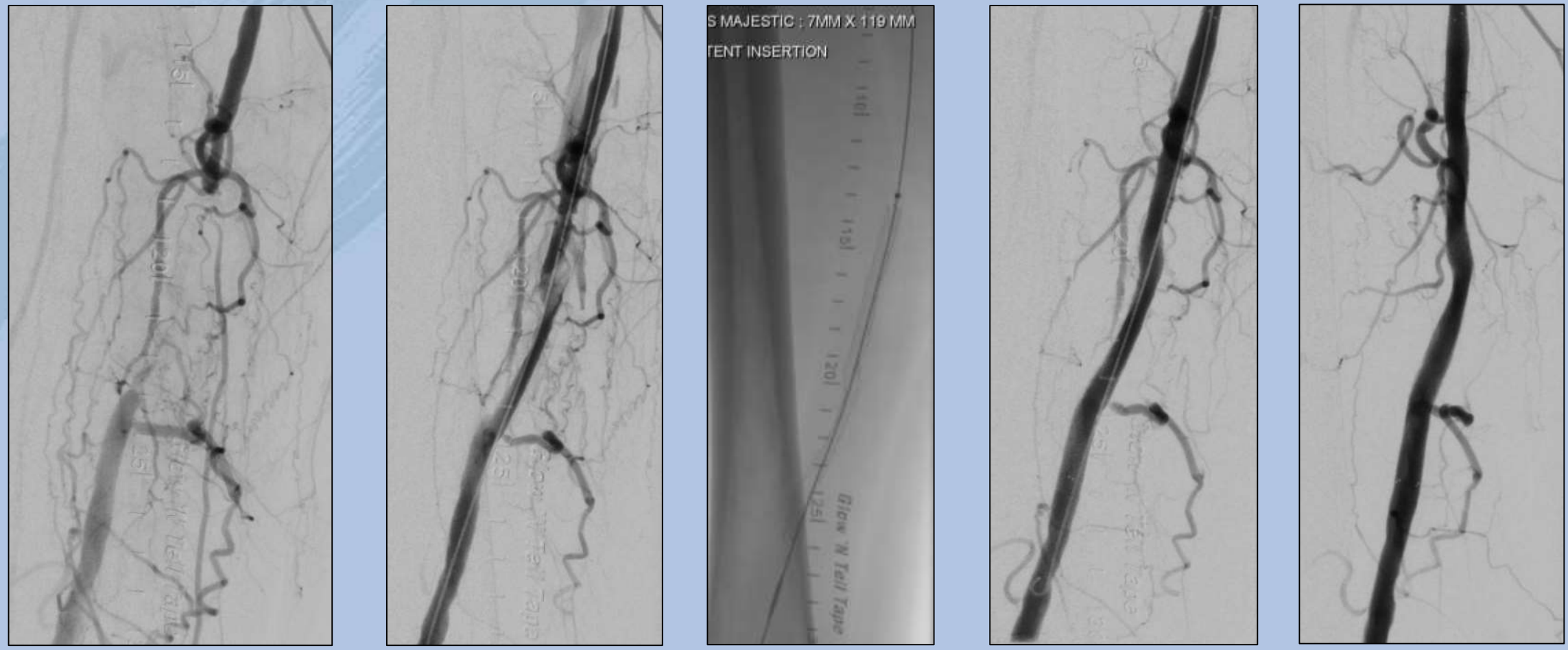
BSC PI Drug-Eluting Stent Clinical Program

IMPERIAL	**Multicenter, Head to Head RCT 2:1** (Eluvia : Zilver™PTX™)	N = 465		2Y follow up complete
MAJESTIC	**Multicenter, single-arm** (Eluvia)	N = 57		3Y follow up complete
EMINENT	**Multicenter, RCT 2:1** (Eluvia : BMS)	N = 750		Enrolling
REGAL	**Multicenter registry** (Eluvia)	N = 500		Enrolling
SPORTS*	**Multicenter, RCT 1:1:1** (Eluvia:DCB:BMS)	N = 222		Enrolling
SAVAL	**Multicenter, RCT 2:1** (SAVAL : PTA) & single-arm	N = 201 & N = 100		Enrolling



*These investigator-sponsored studies are supported by grant funding from Boston Scientific. Boston Scientific is not responsible for the collection, analysis or reporting of these studies which remain the sole responsibility of the investigators. Information for the use in countries with applicable product registrations.
SAVAL is an investigational device and not available for sale in the US. CAUTION: The law restricts these devices to sale by or on the order of a physician. Rx Only.

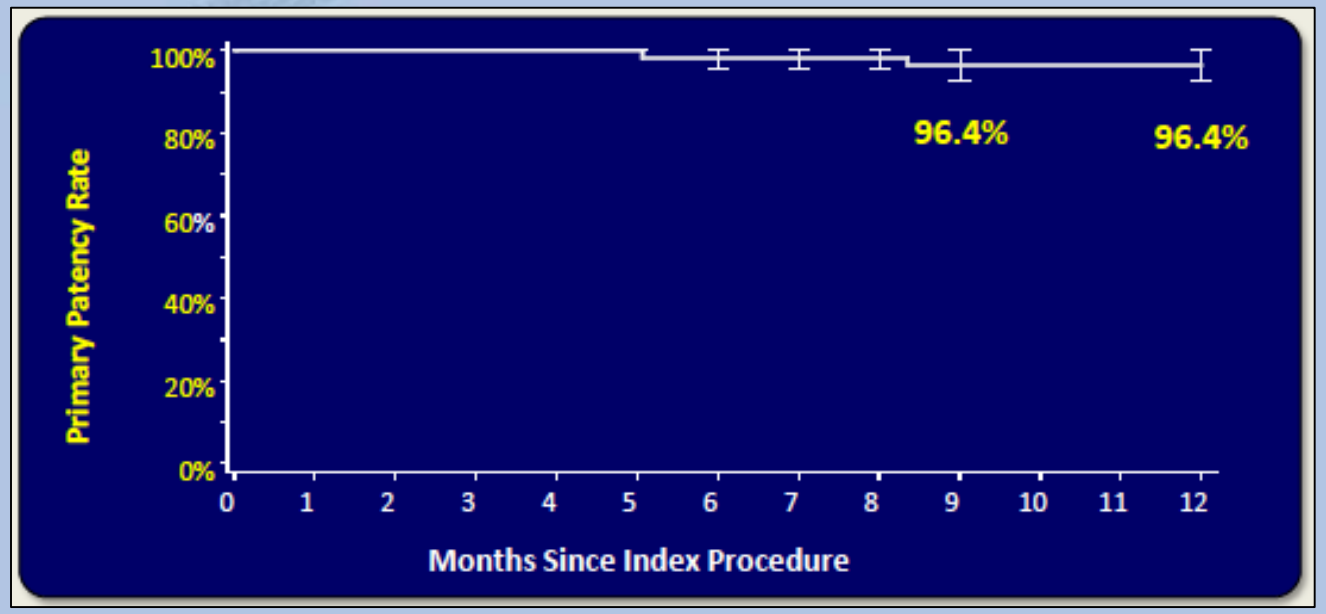
Majestic Clinical Trial: World First Eluvia Case

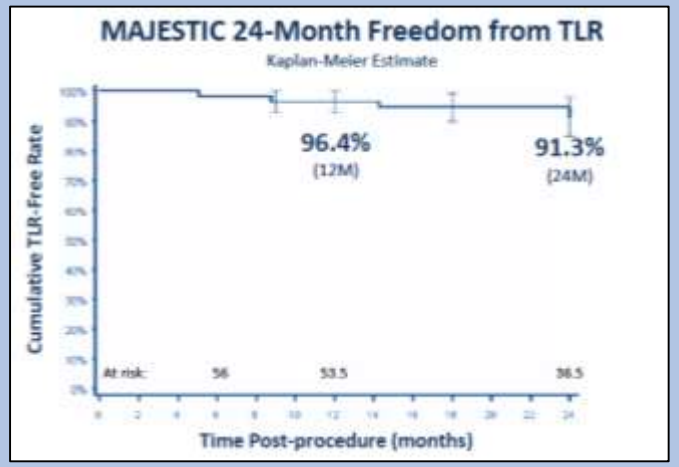


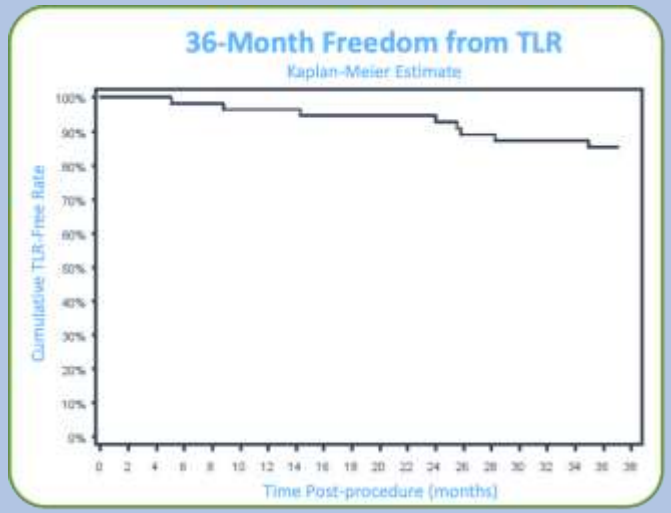
August 2013 – 72 year old male, right leg Rutherford 3 claudicant

Majestic FIH Eluvia DES Trial Results

- 12-month primary patency 96.4% (49/51)
- 24-month freedom from CD-TLR 91.3%
- 36-month freedom from CD-TLR 85.3%





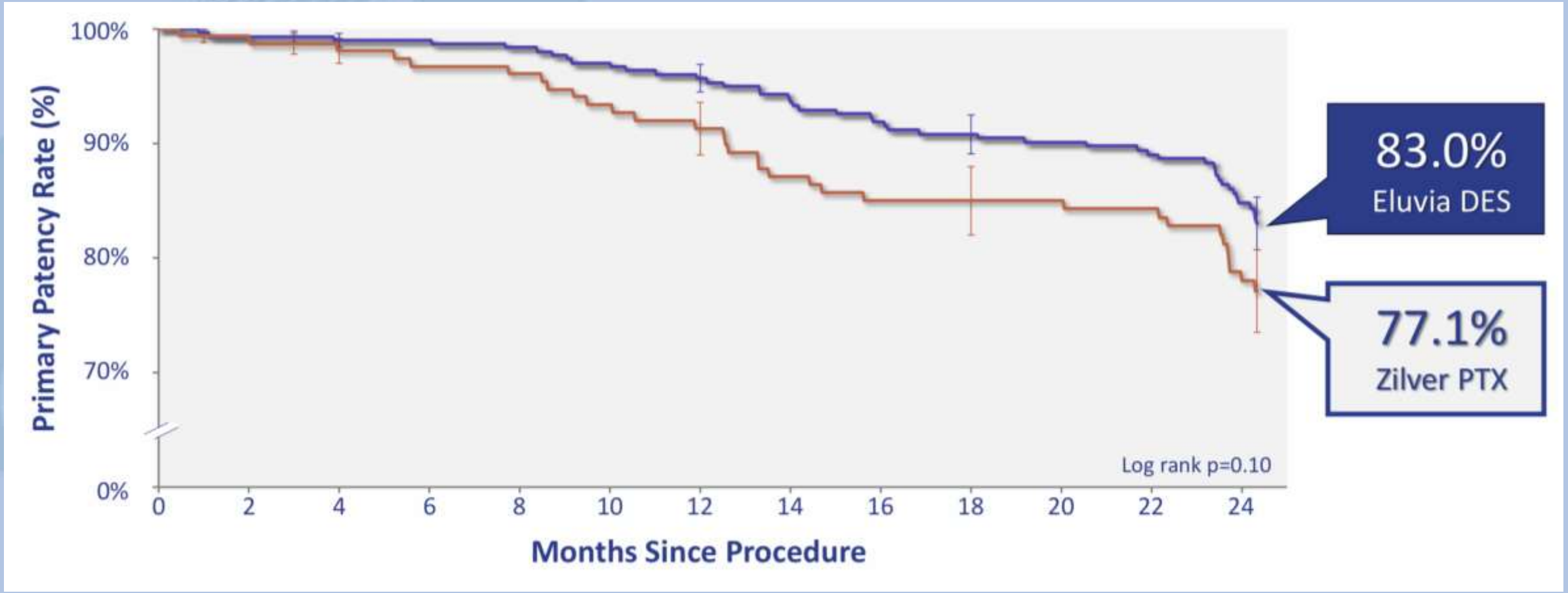


IMPERIAL Clinical Study Overview

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		

Gray WA, Lancet 2018.

Imperial Trial: 24-Month Primary Patency



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.

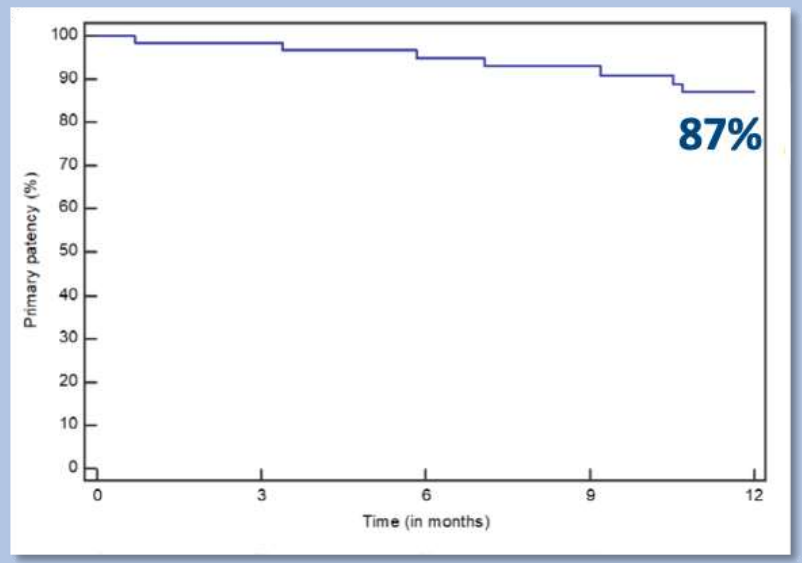
Real World Registries: Munster All-Comers Registry

- 62 patients, 49% CLI
- **12-month results**
- Mean lesion length 200mm
- Moderate – severe calcification in 42%; CTOs 79%

	12 Months
Primary Patency[a]	**87%**
Freedom from TLR	**87%**
Amputation-free Survival (Major)	
Claudicants	**100%**
CLI	**87%**
Stent Fracture Rate[b]	**0%**

Note: Kaplan-Meier Estimates. [a] Duplex ultrasound peak systolic velocity ratio ≤2.0 [b] 6-month results

12-month Primary Patency



Bisdas T, et al. JACC Cardiovasc Interv

Real World Registries: Auckland All-Comers Registry

- Single center audit of “real world” experience with Eluvia in femoro-popliteal intervention
- All patients had at least 2 years follow-up (treated March 2016 – October 2017)
- 51 patients (47 males, 4 females)
- 27 patients (52.9%) presented with critical limb ischemia
- Mean lesion length 105.4mm (25-270mm)
- 27 cases (52.9%) with CTOs
- Mean CTO length 90.1mm
- 26 cases (50.9%) with significant calcification (PACSS ≥ 3)

Real World Registries: Auckland All-Comers Registry

- Mean stent length 130mm (40 – 380mm)
- Concomitant ipsilateral limb intervention – 20 cases (39.2%), 17 cases tibial
- Technical success 98% (one early stent thrombosis)
- No stent fractures on follow up

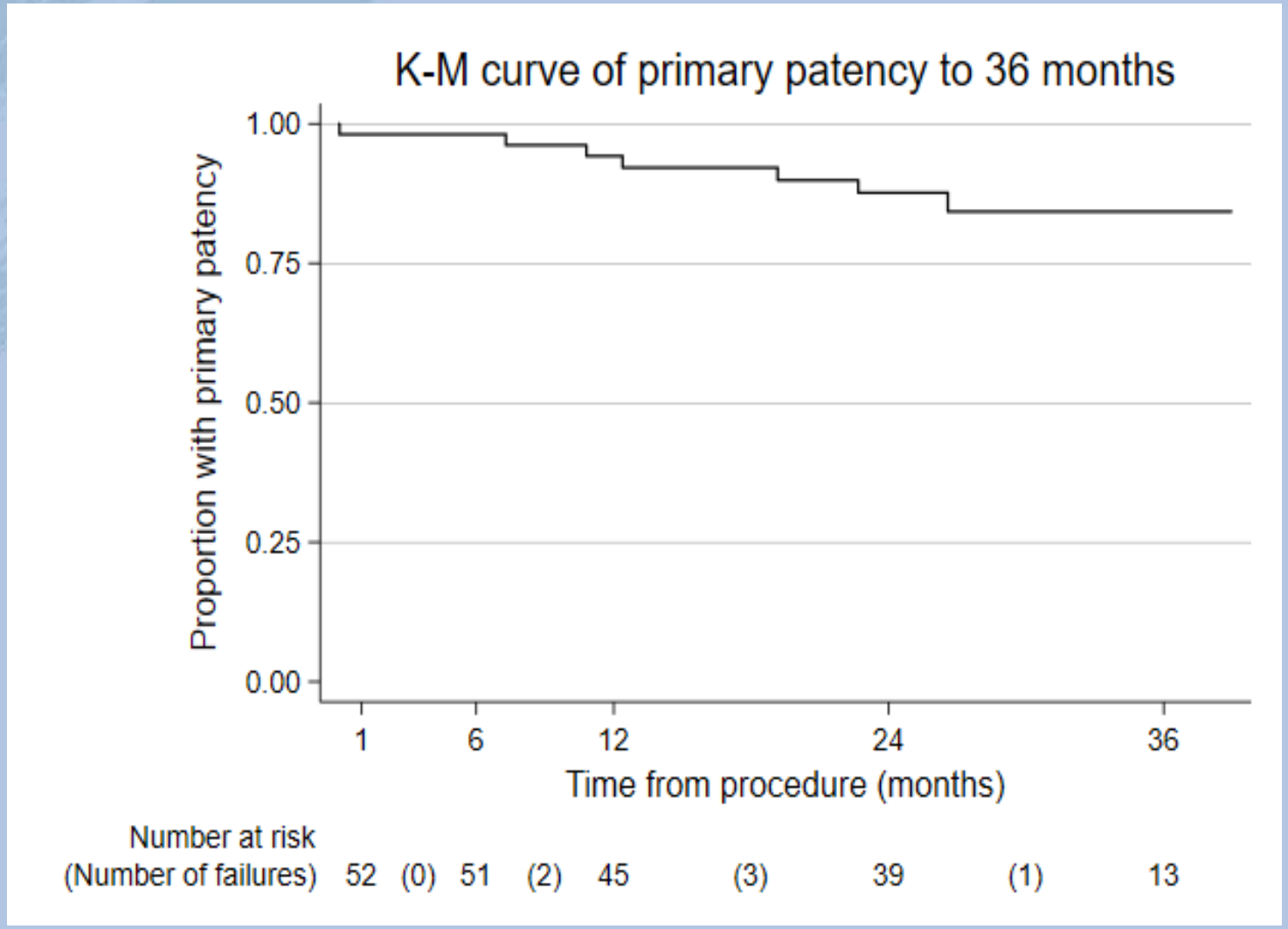
Primary Patency

	1 Month	6 Months	1 Year	2 Years
Primary Patency	98.0% (50/51)	98.0% (49/50)	94.0% (47/50)	93.8% (45/48)

Freedom from Target Lesion Revascularization

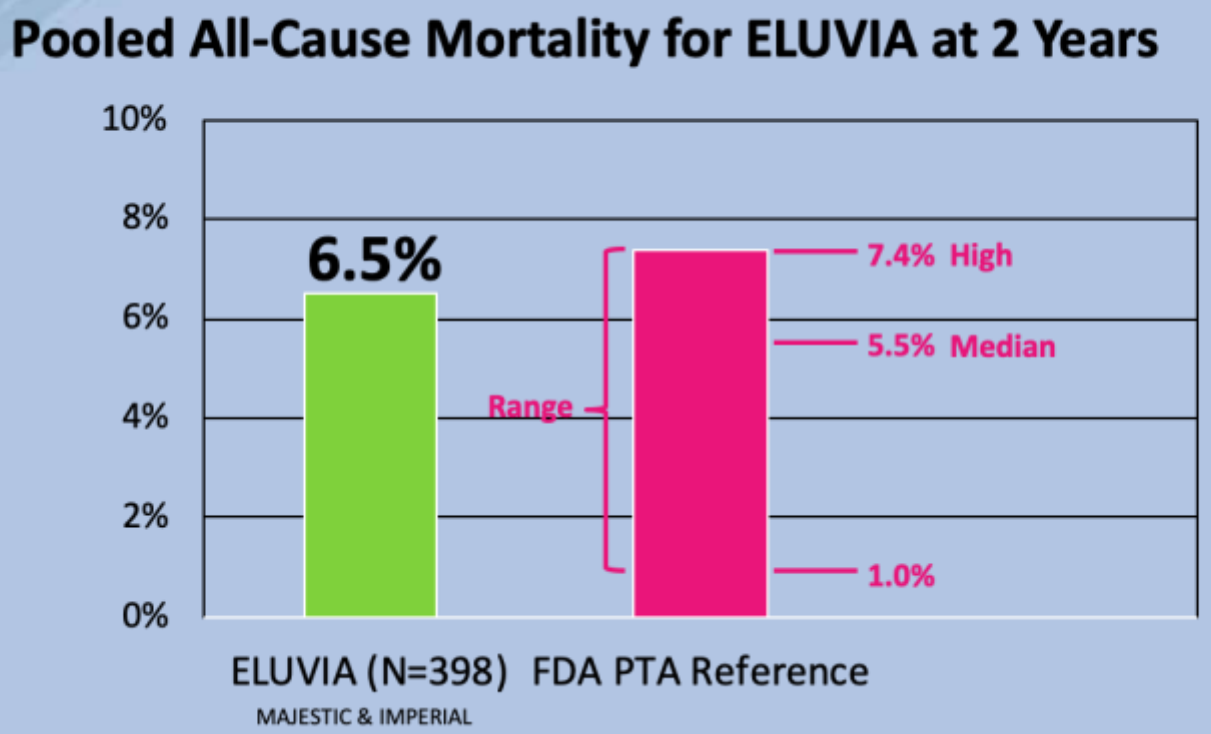
	1 Month	6 Months	1 Year	2 Years
Freedom CD-TLR	98.0% (50/51)	98.0% (49/50)	98.0% (49/50)	93.8% (45/48)

Real World Registries: Auckland All-Comers Registry



Real World Registries: Auckland All-Comers Registry

- No aneurysmal degeneration on Duplex US to 2 years and beyond
- 2-year all cause mortality 3/51 (5.8%) – suicide, heart failure, sepsis



BSC Data on File. MAJESTIC follow-up is final at 3 years. IMPERIAL follow-up is complete through 2 years and ongoing through 5 years. As-treated ELUVIA patients. PTA reference based on Pivotal Trials summarized in the FDA Advisory Panel Executive Summary. Abbreviations: DES, drug-eluting stent; PTA, percutaneous transluminal angioplasty.

Real World Registries: Comparisons

Auckland All-Comers Registry :

- Similar case numbers, longer follow-up
- Similar incidence CLI (Munster 49%, Auckland 53%)
- Shorter lesions but similar complexity
- No cases used after previous atherectomy or DCB angioplasty

	Case Numbers	Miniumum F/Up	Lesion length (mm)	CTOs	Mod-severe Ca^{2+}	12-month PP	24-month PP	Aneurysmal Degeneration
Munster Registry	62	12-months	200	42%	79%	87%	-	8.1%
Auckland Registry	51	24-months	105	53%	51%	94%	94%	0%

Conclusions

- Eluvia DES has demonstrated excellent patency to 12-months and longer term freedom from CD-TLR in the Majestic and Imperial Trials
- Both the Munster and Auckland All-Comers Registries have demonstrated excellent 12-month patency in ”real world’ lesions
- The Auckland Registry found 2-year patency sustained at 93.8% with no cases of aneurysmal degeneration

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