Boston Scientific
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IMPERIAL RCT SUMMARY

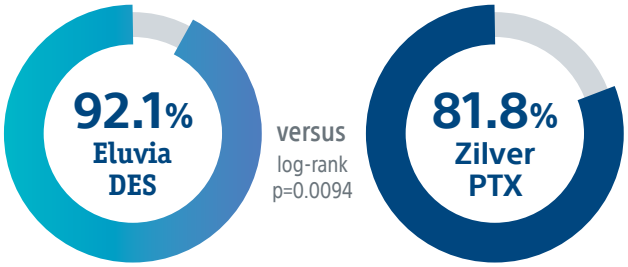
The world's first head-to-head DES SFA Trial, evaluating Boston Scientific Corporation's Eluvia™ Drug-Eluting Vascular Stent System and Cook Medical's Zilver™ PTX™ Stent

Sustaining strong results through five years

The results of the IMPERIAL RCT show that Eluvia Drug-Eluting Stent (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.

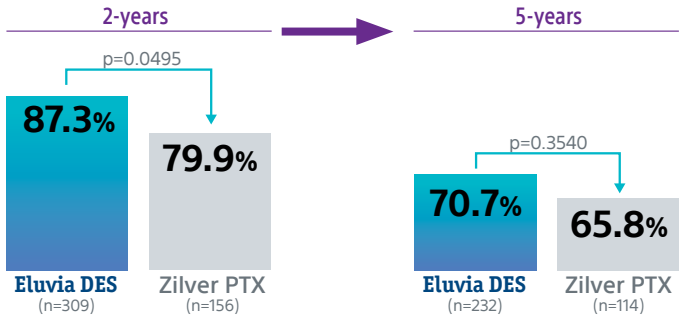
Eluvia DES demonstrated superiority over Zilver PTX[1] with a statistically significant primary patency through 1-Year

IMPERIAL RCT 1-YEAR RESULTS
K-M Primary Patency



Eluvia DES showed lower revascularization rates than Zilver PTX through 5 years[2] with statistical significance[3] at 2-Years

FREEDOM FROM CD-TLR RATES

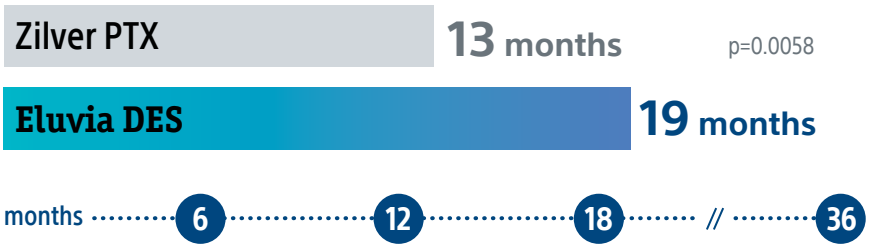


Durable, consistent outcomes in long and complex lesions

IMPERIAL TRIAL 2-YEAR CLINICAL RESULTS
Excellent Patient Follow-up at 24-Months (~90%)

	IMPERIAL RCT[4] (n = 309)	IMPERIAL Long Lesions[5,6] (n = 56)	Diabetic Subgroup[7,8] (n = 116)	Severe/ Moderate Calcium Subgroup[8] (n = 193)	CTO Subgroup[8] (n = 96)
Study Design	RCT, global multicenter	Single arm, global multicenter	RCT, global multicenter	RCT, global multicenter	RCT, global multicenter
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

Eluvia DES patients on average avoided reintervention 6 months longer than Zilver PTX patients at 3-Years[2†]



IMPERIAL TRIAL OBJECTIVE

Evaluate the safety and effectiveness of the Boston Scientific Corporation Eluvia™ Drug-Eluting Vascular Stent System for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 140mm in length.

IMPERIAL TRIAL DESIGN

Global multi-center, 2:1 randomization against Cook Medical's Zilver™ PTX™ Stent, controlled, single-blind, non-inferiority trial; core lab adjudicated.

- 465 (RCT) patients across 64 sites
- 5-year follow-up
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4mm and ≤ 6mm
- Total lesion length ≥ 30mm and ≤ 140mm

BASELINE CHARACTERISTICS

Patient Demographics	Eluvia (n=309)	Zilver PTX (n=156)
Age (Years)	68.5±9.5	67.8±9.4
Male Gender	66.0%	66.7%
Diabetes Mellitus	41.7%	43.6%
History of Smoking	86.1%	84.0%

Lesion Characteristics	Eluvia (n=309)	Zilver PTX (n=156)
Target Lesion Length (mm)	86.5±36.9	81.8±37.3
Severely Calcified	40.1%	32.3%
Total Occlusions	31.2%	30.3%
Extending into Distal SFA	66.3%	65.4%

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

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 WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1.
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.
8. Dr. Gray LINC presentation -2. Gray, W. 2 year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and ZilverPTX. LINC 2020.

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