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ELUVIA™ Drug-Eluting Vascular Stent System

2-year results from IMPERIAL, the world's first head-to-head DES SFA Trial[1]

Presented at LINC 2020

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 140 mm 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 ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 140 mm

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%

2-Year Results: Eluvia demonstrated the **highest primary patency** ever reported in an SFA US Pivotal Trial for DES or DCB*

2-Year Durable and Consistent Results in Complex Lesions

	IMPERIAL RCT[2] (n = 309)	IMPERIAL Diabetic Subgroup Analysis (n = 116)	IMPERIAL Severe / Moderate Calcium Subgroup Analysis (n = 193)	IMPERIAL CTO Subgroup Analysis (n = 96)
Study Design	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global
24-month primary patency rate**	**83.0%**	**85.7%**	**85.0%**	**76.4%**
Lesion length (mm)	86.5	87.0	89.9	94.4
Severe calcification	40%	46%	n/a	n/a
Total occlusions	31%	25%	n/a	100%
	Highest primary patency ever reported 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.

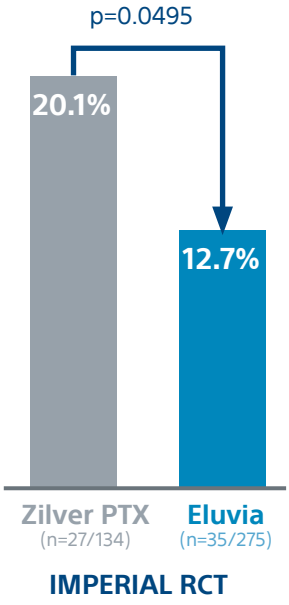
** Intention to treat. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 730 days and Duplex Ultrasound data at 24 months. Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion, as assessed by the DUS core lab.

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).

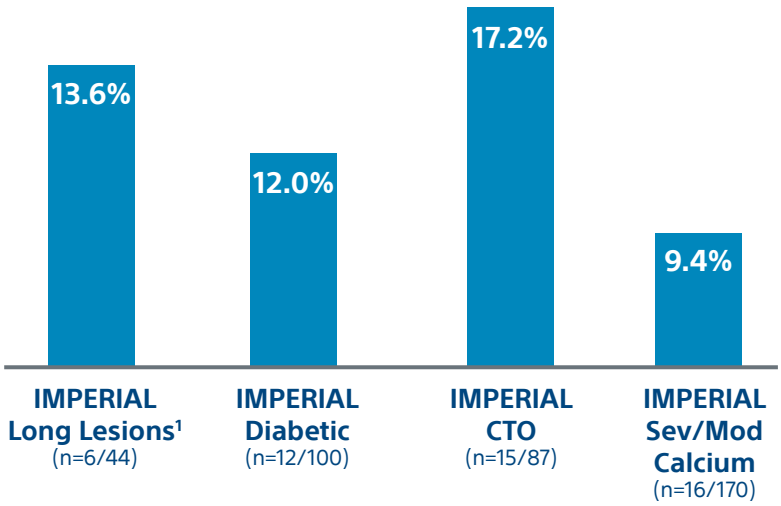
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 83% vs. 77.1% for Zilver PTX at 24 months, p=0.1008.

2-Year Results: In IMPERIAL RCT, Eluvia demonstrated a **statistically significant reduction in TLR** vs. Zilver PTX at 24 months

CLINICALLY-DRIVEN TLR RATE



CONSISTENTLY LOW 2-YEAR CD-TLR IN CHALLENGING SFA DISEASE



24-MONTH SAFETY RESULTS*:

- 85.8% of Eluvia patients were free from Major Adverse Events at 24 months (vs. 79.9% of Zilver PTX patients)
- All-cause mortality for Eluvia was 7.1% (21/295) vs. 8.3% (12/145) for Zilver PTX (p=0.6649)

	Eluvia	Zilver PTX	p-value
24-month MAE	14.2%	20.1%	0.1236
All-Cause of Deaths at 1 Month	0.0%	0.0%	Undefined
Clinically-driven TLR	12.7%	20.1%	0.0495

*Intention to treat. Clinical Events Committee-adjudicated adverse events included major adverse events (MAE), all deaths, and stent thrombosis. MAEs defined as all causes of death through 1 month, target limb major amputation through 24 months, and target lesion revascularization through 24 months.

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1. Long Lesion TLR is as-treated as presented at FDA Panel 2019. All other TLR data sets adapted from Gray, W. LINC 2020 Presentation, are intention to treat.

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