ELUVIA™ Drug-Eluting Vascular Stent System

12-month 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

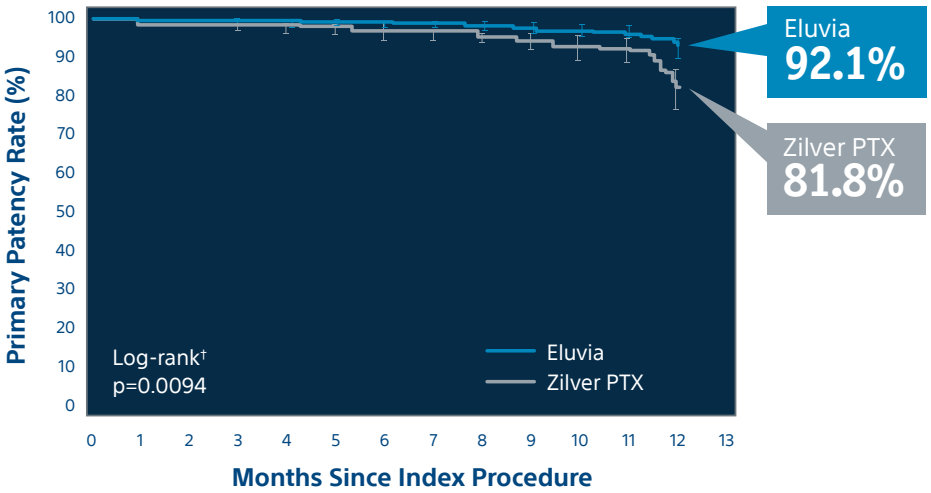
BASELINE CHARACTERISTICS:

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%

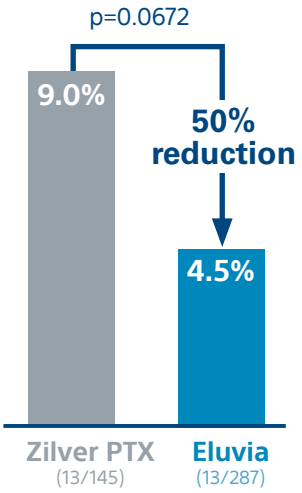
Lesion Characteristics	Eluvia (n=309)	Zilver PTX (n=156)
Target Lesion Length (mm)	86.5±36.9	81.8±37.3
Severely Calcified	40.1%	32.3%
Total Occlusions	31.2%	30.3%
Extending into Distal SFA	66.3%	65.4%

12-MONTH RESULTS: Eluvia demonstrated a **statistically significant difference in primary patency** and **half the TLR rate** vs. Zilver PTX at 12 months

PRIMARY PATENCY RATES K-M Estimate*



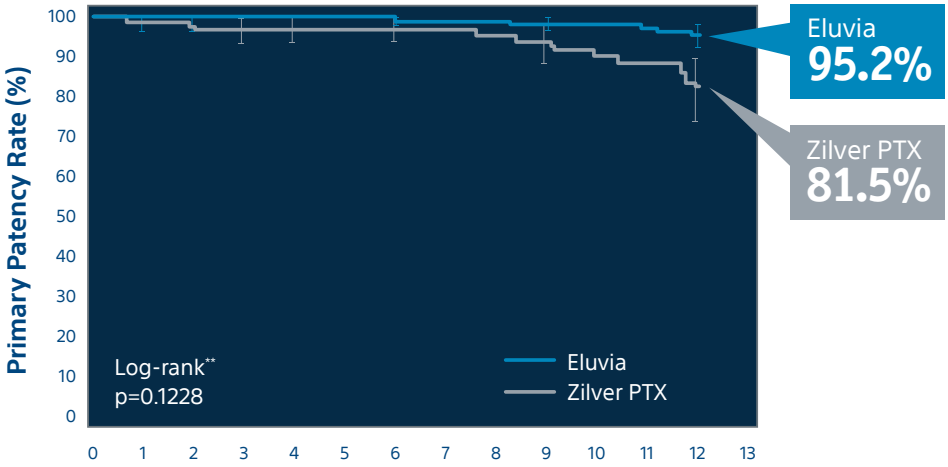
CLINICALLY-DRIVEN TLR RATE**



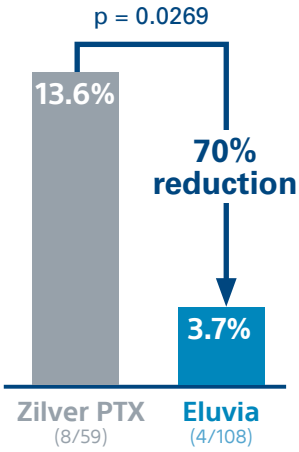
In IMPERIAL RCT and as reported in The Lancet, 1-year ITT, CEC adjudicated mortality rates were 2.1% (6/292) for Eluvia and 4.0% (6/150) for Zilver PTX (p=0.23).
*Kaplan Meier Estimate; Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤ 2.4 at the 12-month follow-up visit, in the absence of clinically-driven TLR or bypass of the target lesion.
** Gray, WA TCT 2018.
† Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.
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).

IMPERIAL Diabetic^ Subgroup 12-Month Results: Eluvia demonstrated a **higher primary patency** and a statistically significant **TLR reduction of greater than 70%** in diabetic patients vs. Zilver PTX

PRIMARY PATENCY RATES
K-M Estimate*



CLINICALLY-DRIVEN TLR RATE[1]



12-Month Remarkable and Consistent Results in Complex Lesions

	IMPERIAL RCT[2] (n = 309)	IMPERIAL Long Lesions (n = 50)	IMPERIAL Diabetic Subgroup Analysis[3] (n = 116)	IMPERIAL Severe / Moderate Calcium Subgroup Analysis (n = 193)	IMPERIAL CTO Subgroup Analysis (n = 96)	Münster Registry (n = 62)
Study Design	RCT, multicenter, global	Single arm multicenter, global	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, global	Single-center registry
12-month primary patency rate*	**92.1%**	**91.0%**	**95.2%**	**92.5%**	**86.4%**	**87.0%[4]**
Lesion length (mm)	86.5	162.8	87.0	89.9	94.4	200
Severe calcification	40%	28%	46%	n/a	n/a	42%[5]
Total occlusions	31%	32%	25%	n/a	100%	79%
	Statistically significantly **higher primary patency**	Remarkable primary patency in **long lesions**	Statistically significantly **lower TLR (3.7%) and stent thrombosis rate (0.9%)**	Remarkable primary patency and **2.8% TLR** in **heavy calcium**	Low TLR (7.9%) and **stent thrombosis rate** (2.2%)	**CLI in nearly half** of patients

^Diabetes = medically-treated diabetic patients.
*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.
1. Intention to treat. Müller-Hülsbeck S, LINC 2019.
2. In IMPERIAL RCT, Eluvia K-M Primary Patency was 92.1% vs. 81.8% for Zilver PTX at 12 months.
3. In IMPERIAL Diabetic Subgroup, Eluvia K-M Primary Patency was 95.2% vs. 81.5% for Zilver PTX at 12 months.
4. PSVR < 2.0.
5. Moderate and severely calcified.

Boston Scientific
Advancing science for life™

www.bostonscientific.eu

PI-567103-AE