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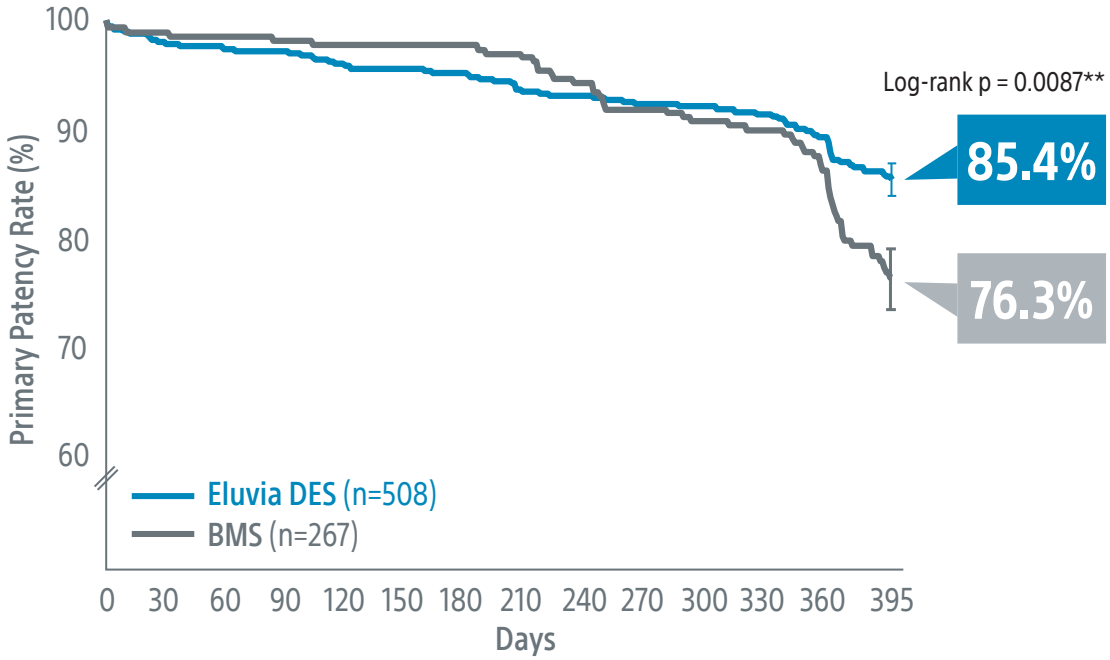
EMINENT CLINICAL TRIAL[1]

EMINENT is the largest randomised controlled trial (2:1) comparing Eluvia™ Drug-Eluting Vascular Stent System to self-expanding bare metal stents (BMS) for SFA/PPA
EU multi-centre; superiority trial; core lab adjudicated

SUPERIOR EFFECTIVENESS:

Eluvia demonstrated **superiority over BMS[2]** with a **statistically significant primary patency** of **85.4% versus 76.3%** through 1-Year

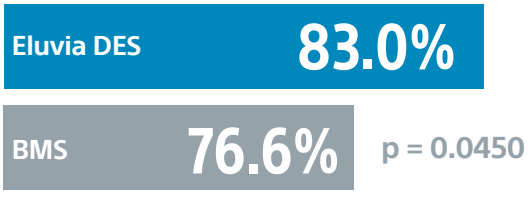
1-YEAR KAPLAN-MEIER PRIMARY PATENCY ESTIMATE*



SUSTAINED CLINICAL IMPROVEMENT:

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

1-YEAR PRIMARY SUSTAINED CLINICAL IMPROVEMENT***



*Kaplan-Meier Estimate: Primary patency defined as core-lab assessed duplex ultrasound peak systolic velocity ratio (PSVR) ≤ 2.4 at 1-year 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)
***In EMINENT, primary sustained clinical improvement was defined as an improvement (decrease) by at least 1 Rutherford category, without TLR.

1. EMINENT RCT 1-Year results presented by Yann Gouëffic, MD. VIVA 2021
2. 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. 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 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
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
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

CONTROL STENT USAGE (n=294)

- **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)
- **Complete® SE** Vascular Stent (Medtronic)

1-YEAR SAFETY RESULTS

No significant differences in Major Adverse Event (MAE) rates or All-Cause Death between **patients treated with Eluvia DES vs. BMS** through 1-Year.

	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

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ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM
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