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SPORTS Trial

Investigator-Sponsored[1], Core-lab Adjudicated, Randomised Controlled Trial Evaluating Drug-Eluting Stent or Primary Bare Nitinol Stent Application Versus Drug-Coated Balloons in Long SFA Lesions

OBJECTIVE

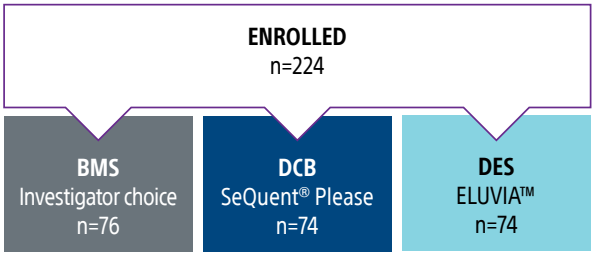
Compare angiographic and clinical outcomes of TASC C/D SFA lesions after treatment with BMS v. DCB v. DES

TRIAL DESIGN

Investigator-sponsored | Prospective | Core-lab adjudicated | Multi-center | Three-arm randomisation (1:1:1) of BMS v. DCB v. DES

KEY INCLUSION CRITERIA

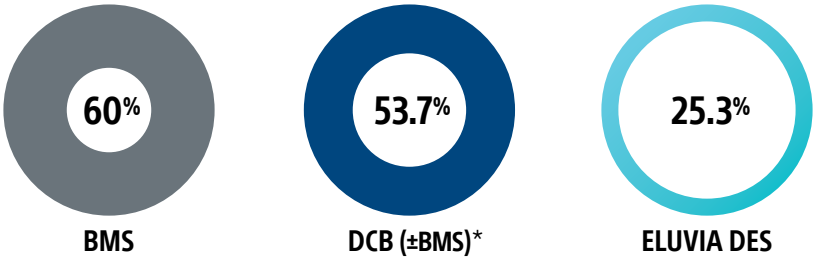
SFA/PPA lesion lengths at least 130mm (treatment length ≥ 150mm) | Rutherford classes 2–4 | Diameter stenosis ≥ 70%



Eluvia DES Proved Statistically Superior to BMS in Long, Complex Lesions.

- Eluvia vs BMS p for superiority <0.0001
- Percent diameter stenosis was 112% greater for DCB than Eluvia, but these groups were not compared statistically for the primary endpoint.
- DCB was non-inferior to BMS in terms of diameter stenosis at 1 year.

1-YEAR ANGIOGRAPHIC DIAMETER STENOSIS



BMS had **137% more** diameter stenosis than Eluvia DES at 1-year.

DCB had **112% more** diameter stenosis than Eluvia DES at 1-year.

High Rate of Bail-Out Stenting in DCB Arm

In long, complex lesions,

58%

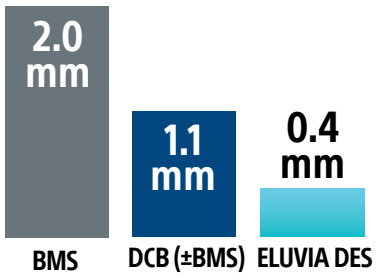
of lesions treated with a DCB required a bail-out BMS which provided no additional clinical benefit versus BMS alone.

* DCB in SPORTS trial was B. Braun SeQuent® Please Drug-Coated Balloon

1. Tepe, G. SPORTS Trial: Drug Eluting Stent or Primary Bare Nitinol Stent Application versus Drug Coated Balloons in Long SFA Lesions. Presented at TCT 24 Oct 2023.

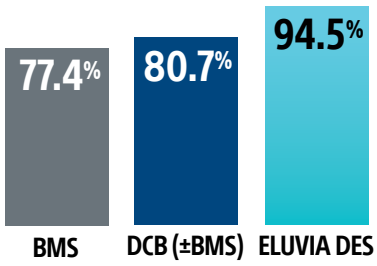
1-Year Late Lumen Loss and Freedom from CD-TLR Differed Statistically Across Groups, Favoring Eluvia DES

1-YEAR LATE LUMEN LOSS



p<0.0001

1-YEAR FREEDOM FROM CD-TLR



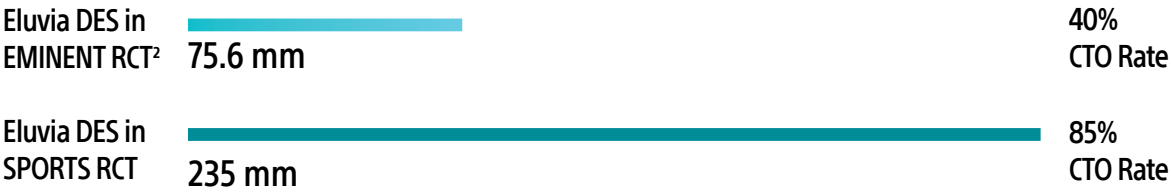
K-M, p=0.015

BASELINE CHARACTERISTICS

Patient Characteristics	BMS n=76	DCB n=74	DES n=74
Age (Years)	67	70	68
Male Gender (%)	72	66	60
Diabetes Mellitus (%)	26	30	23
Renal Disease (%)	3	12	8
Current Smoker (%)	58	60	55

Lesion Characteristics	BMS n=76	DCB n=74	DES n=74	p-value
Mean Lesion Length (mm)	**227**	**221**	**235**	**0.57**
Occlusion (%)	**74**	**70**	**85**	**0.08**
Occlusion length (mm)	151	175	179	0.18
RVD (mm)	5.2	5.0	5.3	0.01
MLD in lesion (mm)	0.3	0.4	0.2	0.18
Mod/Severe Calcification (%)**	67.1	71.7	58.1	0.36
Diameter stenosis in lesion (%)	94.2	92.6	96.8	0.10

AVERAGE LESION LENGTH & OCCLUSION PERCENTAGE IN PERSPECTIVE ACROSS ELUVIA V. BMS RCTs



** PACSS Grade 3/4 may be considered moderate to severe calcification

2. Gouëffic, Y, et al. Efficacy of a Drug-Eluting Stent Versus Bare Metal Stents for Symptomatic Femoropopliteal Peripheral Artery Disease: Primary Results of the EMINENT Randomised Trial.

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