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MAJESTIC Clinical Trial
3-Year Follow-Up[1]

MAJESTIC Stenting of the Superficial Femoral and/or Proximal Popliteal Artery Project with Boston Scientific's (ELUVIA™) Drug-Eluting Stent

OBJECTIVE:

To evaluate the performance of the Eluvia Drug-Eluting Vascular Stent System in the treatment of superficial femoral (SFA) and/or proximal popliteal artery (PPA) lesions.

TRIAL DESIGN:

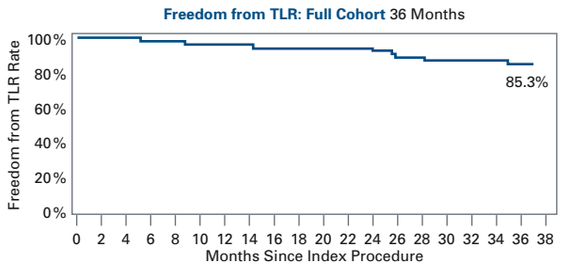
- Prospective, single-arm, non-randomized, multi-center, core lab adjudicated
- Primary patency, ankle-brachial index (ABI), Rutherford classification and stent fracture evaluated at 12 and 24 months
- Freedom from TLR evaluated at 12, 24 and 36 months
- Eligible patients with chronic, symptomatic (Rutherford categories 2, 3 or 4) lower limb ischemia and stenotic, restenotic or occlusive lesions in the native superficial femoral artery or proximal popliteal artery (n=57)
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 110 mm

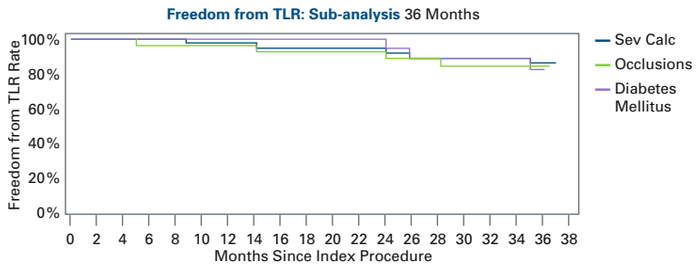
BASELINE CHARACTERISTICS:

Patient Demographics	n = 57 subjects	Lesion Characteristics (Core Lab)	n = 57 lesions
Age (Years)	69.3 ± 9.3	Reference Vessel Diameter	5.2 ± 0.8
Male Gender	82.5%	Target Lesion Length	70.8 ± 28.1
Diabetes Mellitus	35.1%	Severely Calcified	64.9%
History of Smoking	87.7%	Percent Diameter Stenosis	86.3% ± 16.2%
Hypertension	73.7%	Total Occlusions	46.2%
Hyperlipidemia	63.2%	% Extending into Distal SFA	77.2%
Coronary Artery Disease	38.6%	% Extending into PPA	8.8%

3-YEAR RESULTS:

The Eluvia Stent continues to demonstrate unprecedented clinical outcomes with an 85.3% freedom from TLR at 3 years, one of the highest reported in comparable SFA clinical trials.





	12 Months	24 Months
Primary Patency[a]	96.4%	83.5%
Assisted Primary Patency[b]	98.2%	88.9%

Note: Kaplan-Meier Estimates. Per study protocol, primary patency was not evaluated at 36 months.

[a] Duplex ultrasound peak systolic velocity ratio ≤2.5 and abscence of TLR or bypass.

[b] No TLR and those with TLR not for complete occlusion or bypass who were free of restenosis at 24 months.

[1] Müller-Hülsbeck S, et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3 Year Follow up. Cardiovasc Interv Radiol. 2017, in press.

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SAFETY RESULTS:

- 15.1% composite major adverse event rate at 36 months
- No deaths or amputations; 8 TLRs (8/53)

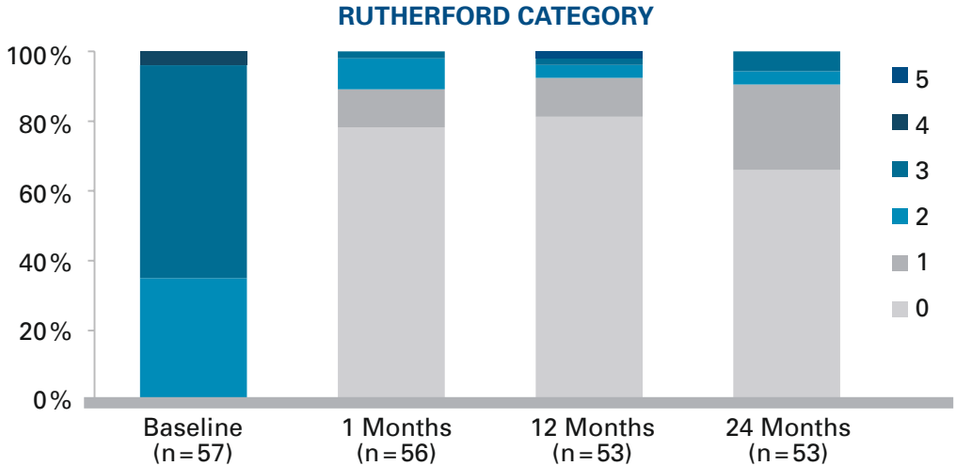
	Overall
36-Month MAE	**15.1%**
All-Cause Death at 1 Month	0.0%
Target Limb Major Amputation	0.0%
Target Lesion Revascularization (TLR)	15.1%

STENT INTEGRITY:

- No stent fractures at 24 months upon angiographic core lab analysis[2]

PATIENT OUTCOMES:

- 91% of patients presented with no or minimal claudication (Rutherford 0-1) at 24 months[2]
- 91% of patients sustained clinical improvement through 24 months
- Mean ABI improved from 0.73 ± 0.22 at baseline to 0.93 ± 0.26 at 24 months



CONCLUSIONS:

- Long-term results from the MAJESTIC study of the Eluvia stent continue to demonstrate good clinical outcomes (assessed through 2 years) and a low reintervention rate (through 3 years).
- Subgroup analysis suggests that the low TLR rate was representative of outcomes for patients with risk factors such as diabetes, severe calcification, and occlusion

1 Müller-Hülsbeck S, et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3 Year Follow up. Cardiovasc Interv Radiol. 2017, in press.

2 Per study protocol, duplex ultrasound (DUS), systematic x-ray fracture evaluation, ankle-brachial index (ABI), and Rutherford classification assessments were not evaluated at 3 years.

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