3-Year Results Of The Eluvia DES Shows Maintained Safety And Efficacy In The MAJESTIC RCT With Fem-Pop Lesions

Advantages Of This DES And Why It Is A Better Option Than DCBs For These Lesions

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Disclosure

I have the following potential conflicts of interest to report:

- Consulting – Boston Scientific, Terumo

MAJESTIC Clinical Study Overview

Device

Eluvia™ Drug-Eluting Vascular Stent System (Boston Scientific)

Objective

Evaluate the performance of Eluvia DES System when treating Superficial Femoral (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 110 mm in length

Study Design

Prospective, multicentre, single-arm, open label

Subjects

57 patients with femoropopliteal artery lesions

Investigational Centers

14 sites (Europe, Australia, New Zealand)

Follow-up

Baseline, Procedure, 1 month, 9 months, 1 year, 2 years, 3 years

Outcome Measures

Efficacy/Safety

Clinical Outcomes

Key Eligibility Criteria

- Chronic lower limb ischemia defined as Rutherford categories 2, 3, or 4
- De novo or restenotic lesions (≥70% stenosis) in the native SFA or proximal popliteal artery
- Reference vessel diameter 4-6 mm
- Total lesion length ≥30 mm and ≤110 mm

Baseline Patient Characteristics (N=57)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>69.2±9.3</td>
</tr>
<tr>
<td>Male Gender</td>
<td>82.5%</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>94.7%</td>
</tr>
<tr>
<td>Asian</td>
<td>1.8%</td>
</tr>
<tr>
<td>Other</td>
<td>3.5%</td>
</tr>
<tr>
<td>General Medical History</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>87.7%</td>
</tr>
<tr>
<td>Current Diabetes Mellitus</td>
<td>35.1%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>63.2%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>73.7%</td>
</tr>
<tr>
<td>Cardiac History</td>
<td></td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>28.6%</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>16.9%</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>5.3%</td>
</tr>
<tr>
<td>Peripheral Vascular History</td>
<td></td>
</tr>
<tr>
<td>Peripheral Vascular Surgery</td>
<td>2.1%</td>
</tr>
<tr>
<td>Other Peripheral Embolization</td>
<td>24.6%</td>
</tr>
<tr>
<td>History of Claudication</td>
<td>89.0%</td>
</tr>
</tbody>
</table>

Baseline Lesion Characteristics (core lab)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial Segments</td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>0.0%</td>
</tr>
<tr>
<td>Proximal</td>
<td>1.8%</td>
</tr>
<tr>
<td>Mid</td>
<td>59.6%</td>
</tr>
<tr>
<td>Distal Popliteal</td>
<td>67.3%</td>
</tr>
<tr>
<td>Length (mm)</td>
<td>70.8±28.1</td>
</tr>
<tr>
<td>Calcification</td>
<td></td>
</tr>
<tr>
<td>None/ Mild</td>
<td>21.1%</td>
</tr>
<tr>
<td>Moderate</td>
<td>14.0%</td>
</tr>
<tr>
<td>Severe</td>
<td>64.9%</td>
</tr>
<tr>
<td>Percent Diameter Stenosis</td>
<td></td>
</tr>
<tr>
<td>Occlusions</td>
<td>65%</td>
</tr>
<tr>
<td>Reference Vessel Diameter (mm)</td>
<td>5.2±1.0</td>
</tr>
<tr>
<td>Patency to Foot</td>
<td></td>
</tr>
<tr>
<td>No Infrapopliteal Vessel Patent</td>
<td>5.3%</td>
</tr>
<tr>
<td>1 Vessel Patent</td>
<td>28.1%</td>
</tr>
<tr>
<td>2 Vessel Patent</td>
<td>31.0%</td>
</tr>
<tr>
<td>3 Vessel Patent</td>
<td>22.8%</td>
</tr>
</tbody>
</table>
Overall Efficacy & Safety

36-Month Freedom from TLR

- **85.3%** freedom from TLR rate (K-M estimate)
- No target limb major amputations
- 2 deaths at >365 days post-procedure, unrelated to study device or procedure

Stent Integrity
- No stent fractures*

Primary Patency
- 96.4% at 12 months
- 83.5% at 24 months

Assisted Primary Patency
- 98.2% at 12 months
- 88.9% at 24 months

Note: Kaplan-Meier estimates.

* Duplex ultrasound peak systolic velocity ratio ≤2.5 and absence of TLR or bypass.

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

Patient Outcomes – 24 Months

- 91% of patients with no or minimal symptoms (Rutherford Category 0-1) at 24 months
- ABI improvement sustained through 24 months

Clinical Probability of Restenosis Following SFA Stenting

Restenosis following nitinol stenting in the SFA peaks at around 12 months

- Timing of SFA restenosis is longer compared to coronary stenting, which predominantly occurs within 6 months after stenting
- Factors for restenosis in the SFA include the number of runoff vessels, severity of lower limb ischemia, and length of diseased segments

Sustained Drug Release

- Drug release from the Eluvia system is sustained over time
  - >90% of drug is released at 1 year
  - Drug release coincides with the restenotic cascade

Eluvia™ Drug-Eluting Vascular Stent System

- CE Mark February 2016
- Innova stent platform
  - Self-expanding nitinol
  - Biostable polymer matrix
  - Paclitaxel

- 6F Tri-axial SIDS, 0.035” guidewire compatible
- Blue Tri-Ax shaft fixed as the clear middle shaft is retracted releasing stent during deployment

Eluvia Coating Design

- Dual Layer System
- Conformal Coating for Both Layers
- Primer Layer (PBMA): Promotes Adhesion of Active Layer to Stent
- Active Layer (PTx, PVDF-HFP): Controls Release of Paclitaxel
  - 0.167µg PTx/mm² stent surface area

Eluvia is an investigational device, limited under U.S. law for investigational use only. Not available for sale.
**Historical patient population for DCB studies**

- DCB trial/registry patients represent population with less-complex lesions
- Primarily TASC A/B, lesion length <10 cm
- Less calcification
- Fewer occlusions

**Severe calcification DCB and Stent studies**

- Severe calcification was more prevalent in stenting studies
- Severe calcification did not have a negative effect on TLR rate in the MAJESTIC study

**DCB Trial Outcomes: Treatment Durability in Perspective – 12M**

- Marked loss in primary patency and rise in TLR between 12 and 24 months

**Stents used in DCB studies**

- Longer mean lesion length correlates with higher provisional stenting rate

**Conclusions**

- Patients treated with the Eluvia paclitaxel-eluting stent had an excellent safety profile and low reintervention rate through 3 years
  - TLR-free rate of 85.3% at 36 months
  - Primary patency rate of 83.5% at 24 months
- The patients/lesions typically represented in studies of DCBs differ from those in studies of DESs
- DES use may overcome negative long-term effects of challenging baseline characteristics
- Patient selection for DES needs further evaluated
- Further trials on Eluvia such as IMPERIAL, Eminent and others will provide further insights, when to offer DES technology