Comparing Outcomes of Treatments for Femoropopliteal Arterial Disease

- Katsanos et al performed a network meta-analysis of RCTs of endovascular treatment
- Compared plain balloon angioplasty, paclitaxel-coated balloons, drug-eluting stents, bare nitinol stents, and covered nitinol stents
  - Vascular restenosis lowest with paclitaxel-eluting stent and paclitaxel-coated balloon
  - TLR lowest with paclitaxel-coated balloon and paclitaxel-eluting stent

BNS, bare nitinol stent; CNS, covered nitinol stent; CrI, credible interval; PCB, paclitaxel-coated balloon; PES, paclitaxel-eluting stent; RCT, randomized controlled trial; RR, rate ratio; SES, sirolimus-eluting stent.


12-Month Primary Patency for SFA Endovascular Therapies

WHAT IS THE EXPLANATION FOR THE BETTER PERFORMANCE OF DES TECHNOLOGY?

Eluvia™ Drug-Eluting Vascular Stent System

- Self-expanding nitinol
- Innova stent platform
- Dual layer coating
  - Primer Layer to promote adhesion of active layer to stent
  - Active Layer (paclitaxel, PVDF-HFP) controls release of paclitaxel and provides sustained release over time
  - Dose: 0.167µg PTx/mm² stent surface area

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

Clinical Probability of Restenosis Following SFA stenting

- Restenosis following nitinol stenting in the SFA peaks at around 12 months
  - In Coronary stenting, restenosis predominantly occurs within 6 months after stenting
The Eluvia Stent system is an investigational device. Limited by US law to investigational use only. Not available for sale.


Based on pre-clinical PK analysis. Data on file at Boston Scientific.

12-Month MAE 3.8% [0.5%, 13.0%]

Peripheral Vascular History
Cardiac History
General Medical History
Demographics

History of Claudication
Other Peripheral Endovascular
Peripheral Vascular Surgery
Congestive Heart Failure
Myocardial Infarction
Coronary Artery Disease
Hypertension
Hyperlipidemia
Current Diabetes Mellitus
Smoking

Race/Ethnicity
Male Gender
Age (Years)

Target Lesion Revascularization (TLR) 3.8% [0.5%, 13.0%]
Target Limb Major Amputation 0.0% [0.0%, 6.7%]
All-Cause Death at 1Month 0.0% [0.0%, 6.7%]

Stent Integrity
No stent fractures observed upon angiographic core lab analysis

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

Baseline Characteristics (N=57)

Patients
Lesions

Demographics
Age (Years) 69.5±9.3
Male Gender 92.5%
Race/Ethnicity
Caucasian 94.7%
Asian 1.8%
Other 3.5%

Initial Lesion Adjudication
Reference Vessel Diameter (mm) 6.4±1.8
Minimum Lumen Diameter (mm) 5.2±0.8
Occlusions 46%
Severe 22.8%
Moderate 31.6%
None/Mild 28.1%

Calcification
None/Mild 35.1%
Moderate 87.7%
Severe 86.3%±16.2%

Lesion Site
Ostial 8.8%
Proximal Popliteal 77.2%
Mid 64.9%
Proximal 14.0%
Distal 21.1%

Lesion Length
0-10 38.6%
11-20 22.8%
21-40 28.1%
41-100 5.3%
101-150 5.3%
151-200 5.2%

Endpoint
Primary Patency Rate 12 Months: DES vs BMS
Primary patency of target lesion at 9 months

Kaplan-Meier estimate for Eluvia DES: 96.4%
Paclitaxel effect suggested by divergence from bare metal platform

Primary endpoint: Primary patency of target lesion at 9 months

94% of patients classified as Rutherford Category 0-1 at 12 months
ABI improvement sustained through 12 months

Patient Outcomes

Rutherford Category

Patient Outcomes

Baseline ABI, ankle-brachial index

0 1 2 3 4 5 6 7 8 9 10 11 12

Months Since Index Procedure

Primary Patency Rate

0% 20% 40% 60% 80% 100%

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 110mm in length

Study Design
Prospective, multicentre, single-arm, open label

Subjects
57 patients with femoropopliteal artery lesions

Investigation Centers
14 sites (Europe, Australia, New Zealand)

No center to enroll > 20% (11 subjects) of the total study population

Follow-up
Baseline, Procedure, 1 month, 9 months, 1 year, 2 years, 3 years

Primary Endpoint
Primary patency of target lesion at 9 months

Safety Profile

MAE
• 12-month composite MAE rate was 3.8% (2 TLR events)
• No new TLR events were observed between 9 and 12 months

12-Month MAE

<table>
<thead>
<tr>
<th>Overall</th>
<th>95% CI</th>
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<td>3.8%</td>
<td>[0.5%, 13.0%]</td>
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All-Cause Death at 1 Month 0.0% [0.0%, 6.7%]
Target Limb Major Amputation 0.0% [0.0%, 6.7%]
Target Lesion Revascularization (TLR) 3.8% [0.5%, 13.0%]

Stent Integrity
No stent fractures observed upon angiographic core lab analysis
KM curves for SFA DES studies

- Historically, SFA DES studies have demonstrated a pronounced decline in primary patency between 6 and 12M.
- The MAJESTIC study does not show the pronounced loss of patency during this time period.

Conclusion

- The ELUVIA dual layer coating design allows for a sustained drug release that coincides with the restenotic cascade.
- Primary patency at 12 months was 96.1%, accompanied by a TLR rate of 3.8%, and zero stent fractures observed through 12 months.
- Patients exhibited symptomatic and hemodynamic improvement through 12 months.
- Eluvia’s paclitaxel/polymer combination may provide a long-term benefit over the bare metal platform.
- The decline in primary patency between 6 and 12 months seen in similar SFA DES studies, was not seen in the MAJESTIC study.
- In Femoropopliteal Stenting Drug Elution Does Make a Difference vs. Uncoated Stents!