The REGAL Study:
An Evaluation of Real-World Use of a Drug-Eluting Stent for Superficial Femoral Artery and Proximal Popliteal Artery Lesions Among European Patients

Wouter Lansink, MD, Ziekenhuis Oost-Limburg
on behalf of the REGAL Investigators
Disclosures (Wouter Lansink)

• This study was funded by Boston Scientific Corporation.
# Methods

A European, prospective, multi-center Post-Market Clinical Follow-up (PMCF) trial of the ELUVIA™ drug-eluting stent

## Inclusion Criteria

- Subjects age 18 and older
- De novo, restenotic or (re)occluded lesions in the native femoropopliteal arteries, with reference vessel diameter (RVD) ranging from 4.0-6.0 mm, suitable for endovascular treatment

## Data Collection

- Patient, lesion, disease, and procedure data collected at index procedure
- Follow-up recommended at 1-, 6-, 12-, and 24-months post-procedure, per local standard of care
  - Included evaluation of clinical and hemodynamic improvement
- Duplex ultrasound data were core-lab adjudicated
- Adverse events were CEC adjudicated
- All other data are site-reported
Study Device

Eluvia™ Drug-Eluting Stent

- **Platform:** Innova™ stent (self-expanding nitinol)
- **Polymer:** PROMUS polymer (Biostable fluorinated polymer matrix)
- **Paclitaxel** dose density $0.167\mu g/mm^2$

*Self-expanding bare nitinol stents simultaneously commercially available in Europe and the US, indicated for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries. All cited trademarks are the property of their respective owners.*
REGAL Enrollment

291 subjects enrolled across 22 centers

- Belgium 94 (32%)
- Spain 93 (32%)
- Italy 90 (31%)
- France 14 (5%)
## Baseline Demographics, Clinical Characteristics, and Medical History

<table>
<thead>
<tr>
<th>REGAL (N=291)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (SD)</td>
<td>69.7 (9.6)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>50 (17.2%)</td>
</tr>
<tr>
<td>Male</td>
<td>241 (82.8%)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>7 (2.4%)</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>275 (94.5%)</td>
</tr>
<tr>
<td>Smoking Status</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>98 (33.7%)</td>
</tr>
<tr>
<td>Previous</td>
<td>139 (47.8%)</td>
</tr>
<tr>
<td>Never</td>
<td>38 (13.1%)</td>
</tr>
<tr>
<td>Current Diabetes Mellitus</td>
<td>141 (48.5%)</td>
</tr>
</tbody>
</table>

### History of

<table>
<thead>
<tr>
<th>REGAL (N=291)</th>
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<tbody>
<tr>
<td>Hyperlipidemia requiring medication</td>
</tr>
<tr>
<td>Hypertension requiring medication</td>
</tr>
<tr>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>Renal insufficiency</td>
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### Rutherford-Becker Class

<table>
<thead>
<tr>
<th>REGAL (N=291)</th>
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<tbody>
<tr>
<td>≤3</td>
</tr>
<tr>
<td>≥4</td>
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</tbody>
</table>
Target Lesion Characteristics and Index Procedure Assessment

Mean Target Lesion Length: **98.4mm (SD\(^a\) = 73.6)**

Chronic Total Occlusion: **49.8\% (145/291)**

Procedural Success: **99.0\% (288/291)**

<table>
<thead>
<tr>
<th>History of endovascular interventions in target vessel(^b)</th>
<th>REGAL (N=291) N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atherectomy</td>
<td>4/43 (9.3%)</td>
</tr>
<tr>
<td>Drug-Coated Balloon (DCB)</td>
<td>13/43 (30.2%)</td>
</tr>
<tr>
<td>Percutaneous Transluminal Angioplasty (PTA)</td>
<td>26/43 (60.5%)</td>
</tr>
<tr>
<td>Stenting</td>
<td>8/43 (18.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>1/43 (2.3%)</td>
</tr>
<tr>
<td><strong>Pre-dilation performed(^c)</strong></td>
<td>277 (93.9%)</td>
</tr>
</tbody>
</table>

\(^a\)SD: Standard Deviation

\(^b\)Defined as treatment prior to the index procedure; data are site reported.

\(^c\)N = 295 lesions
Primary Patency Through 12 Months

*Calculated primary patency estimate at 12 months: 79.2% (114/144); KM estimate at 12 months: 92.2%*  
Subjects event-free at 456 days or later are censored at greater than 456 days.  
Intervals are end inclusive, e.g. interval 182 is defined as 120-182 days, inclusive.  
Bars represent +/- 1.5 times the standard error.  
Event rate and standard error estimates are for interval end. Standard errors are by Greenwood formula.  

Duplex ultrasounds were adjudicated by an independent core lab.
Primary Patency Through 24 Months

*Calculated primary patency estimate at 24 months: 65.5% (72/110); KM estimate at 24 months: 82.9%.

Subjects event-free at 760 days or later are censored at greater than 760.

Intervals are end inclusive, e.g. interval 182 is defined as 120-182 days, inclusive.

Bars represent +/- 1.5 times the standard error.

Event rate and standard error estimates are for interval end. Standard errors are by Greenwood formula.

Duplex ultrasounds were adjudicated by an independent core lab.
Freedom from CD-TLR Through 24 Months

12 Months: 93.0%
24 Months: 88.8%

CD-TLR: Clinically-Driven Target Lesion Revascularization;
Subjects event-free at 760 days or later are censored at greater than 760.
Intervals are end inclusive. e.g. interval 182 is defined as 120-182 days, inclusive.
Calculated freedom from CD-TLR rates at 12 and 24 months were 91.4% and 89.1%, respectively.
Bars represent +/- 1.5 times the standard error.
Event rate and standard error estimates are for interval end. Standard errors are by Greenwood formula.
Rutherford-Becker Clinical Classification

Months Post-Procedure

Baseline N=288
1 Month N=266
6 Months N=247
12 Months N=224
24 Months N=202

Percentage

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4-6: 37.2%
≤3: 62.8%
Primary Sustained Clinical Improvement*

*Primary Sustained Clinical Improvement = improvement in Rutherford classification of one or more categories as compared to baseline without the need for TLR.

TLR: target lesion revascularization
Hemodynamic Improvement* = An ABI ≥ 0.90 or an ABI ≥ 0.10 as compared to baseline without the need for TLR.

*Hemodynamic Improvement = An ABI ≥ 0.90 or an ABI ≥ 0.10 as compared to baseline without the need for TLR.

ABI: ankle-brachial index; TLR: target lesion revascularization
Walking Impairment Questionnaire (WIQ)
Mean Percent Improvement As Compared to Baseline

Distance Speed Stair Climbing

Mean Percent Improvement from Baseline

WIQ Domain

1 Month (N = 269)
6 Months (N = 251)
12 Months (N = 225)
24 Months (N = 212)
CEC Adjudicated Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>1 Month (N=290)</th>
<th>6 Months (N=289)</th>
<th>12 Months (N=280)</th>
<th>24 Months (N=267)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Deaths</td>
<td>8 (2.8%)</td>
<td>18 (6.2%)</td>
<td>23 (8.2%)</td>
<td>28 (10.5%)</td>
</tr>
<tr>
<td>Major Amputation*</td>
<td>3 (1.0%)</td>
<td>5 (1.7%)</td>
<td>6 (2.1%)</td>
<td>6 (2.2%)</td>
</tr>
<tr>
<td>Clinically-Driven Target Lesion Revascularization</td>
<td>3 (1.0%)</td>
<td>15 (5.2%)</td>
<td>24 (8.6%)</td>
<td>29 (10.9%)</td>
</tr>
</tbody>
</table>

*Major amputation: amputation of the lower limb at the ankle level or above.
Note: Denominators for the cumulative rate is based on 1) subjects with events and 2) subjects with no events but their follow-up time reaches on or beyond the earliest visit window.
Conclusions

• In this study of real-world data with patients with long, complex lesions, high rates of CTO, and high rates of diabetes, REGAL demonstrated:
  • 12- and 24- month Kaplan-Meier primary patency event-free estimates of 92.2% and 82.9%
  • 12- and 24- month freedom from CD-TLR of 93% and 88.8%
  • 12- and 24- month sustained clinical improvement of 83.5% and 81.7%
  • Low rates of major amputation over 12- and 24- months (2.1% and 2.2%, respectively)

• Collectively, these data demonstrate the safety and efficacy of the ELUVIA stent in SFA and PPA lesions, even in a population with more advanced peripheral artery disease and a higher burden of comorbidities.

SFA: superficial femoral artery; PPA: proximal popliteal artery; CD-TLR: Clinically-Driven Target Lesion Revascularization
Acknowledgements

• All patients, sites, and participating investigators
• Boston Scientific for funding