RECOIL study: Core-lab adjudicated study to assess recoil after scoring PTA vs POBA

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Disclosure

Speaker name: Michael Lichtenberg

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
• Recoil is real and compromises the intervention’s objective: Lumen Gain

• An increase in arterial recoil increases the likelihood for reintervention

• Recoil: Defined by Baumann, MD et. al. as acute lumen compromise of >10% at 15min after balloon angioplasty

• Data on elastic recoil is limited

1 Mustapha et al, One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12m TLR, LINC 2017

2 Bauman et al, Early Recoil after balloon Angioplasty of tibial artery Obstruction in patients with critical limb ischemia, JEndovascTher 2014; 21:44-51
One Month Duplex Ultrasound Evaluation of Vessel Recoil after Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12 Month Target Lesion Revascularization

Authors: Michael Sumners, DO; Osama Hallak, MS-4; Fadi Saab, MD; Larry Diaz-Sandoval, MD; Theresa McGoff, BSN, RN; Jihad Mustapha, MD

Introduction

Tibial vessel recoil was determined by verifying the maximum inflation size of the treating balloon for the lesion site on index PVI compared to average luminal diameter at the same site (via 3 measurements) by 30 day DUS.

Methods, Cont’d

Pre Intervention

Results, Cont’d

Target Lesion Revascularization Group
- Average intervention inflation diameter was 2.99mm
- Mean 1 month DUS lesion lumen diameter 2.05mm

Control Group: No re-intervention to 12 months
- Average interventional inflation diameter was 2.79mm
- Average 1 month DUS lesion lumen diameter 2.60mm

Average balloon inflation sizes:
- Proximal 3.1mm. Mid 3.0mm. Dista 2.9mm

Average balloon inflation time:
- 116 seconds TLR group
- 109 seconds Control group

Average inflation atmospheric pressure:
- 6 ATM

Recoil % Re-intervention (%) Re-intervention (n/N)
- 0.10% 14.80% 4/27
- 11.20% 32.30% 10/31
- 31.00% 66.70% 8/12
- 31.40% 87.50% 14/16
- 41.50% 53.30% 14/15

Conclusions

Vessel recoil after tibial PVI evaluated at one month duplex ultrasound may predict target lesion revascularization in advanced PAD and CLI patients over a 12 month follow-up. Multi-center analysis with a larger sample size is warranted to further validate findings.

Acknowledgements

Special thanks to Larry Miller, PhD of Miller Scientific Consulting, Inc. for statistical support.

Subjects with >10% lumen compromise at 15 minutes (as per Baumann definition) | POBA** (n=30) |
---|---|
29/30 (97%) |
Average recoil across all lesions at 15 minutes | 29% |

** No Angiographic Core lab
Indication for Use:
The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, popliteal, and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neurovasculature.

Available Sizes

<table>
<thead>
<tr>
<th>Balloon Diameter (mm)</th>
<th>Balloon Length (mm)</th>
<th>Guidewire Compatibility</th>
<th>Sheath Size (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5, 3.0, 3.5</td>
<td>40</td>
<td>0.014&quot;</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>120</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0, 5.0, 6.0</td>
<td>40</td>
<td>0.018&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>120</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Catheter Length: 150cm

1,000X point force of POBA
Serration Angioplasty Achieves Lumen Gain

Mechanism of Action

**Point Force**
Applies 1,000x the force compared to POBA

**Linear Serrated Strips**
Effective in all lesion morphologies with arterial expansion along the serrated line

**Low & Slow Inflation**
4 ATM for 60 seconds
6 ATM for 60 seconds
## Study Objectives:
To assess the ability to define and measure post treatment recoil in infrapopliteal arteries.

Preliminary evidence as to the differences between serration angioplasty and standard balloon angioplasty as defined by post treatment recoil, lumen gain, and dissection.

## Study Design:
Multi-center, feasibility study treating up to 40 atherosclerotic lesions in the infrapopliteal arteries. The study will capture angiographic imaging (pre, during, post, and post 15 mins) for all lesions, and a subset (up to 10) of IVUS imaging data (pre, post, and post 15 mins), to compare serration angioplasty vs standard angioplasty and its effects on vessel recoil and final diameter stenosis.

## Primary Objective:
Obtain preliminary data on post treatment recoil in infrapopliteal arteries utilizing angiographic and IVUS data following serration angioplasty and standard angioplasty.

## Primary Endpoint:
The feasibility of using Angiography or IVUS to assess the presence of recoil.

If recoil occurs, assess the degree of recoil after serration angioplasty versus standard angioplasty treatment.

## Enrollment:
Up to 40 lesions

## Investigators:
- Stefan Stahlhoff, MD Klinikum Hochsauerland GmbH Arnsberg, Germany
- Venita Chandra, MD Stanford University School of Medicine Stanford, California

## Study Population:
The study population will consist of subjects with claudication or CLI, with de novo stenoses, non-stented restenotic, or total occlusion lesions in infrapopliteal arteries having lesion length up to and including 22 cm in length and reference vessel diameter from 2.5 mm to 3.5 mm inclusive

## Study Enrollment:
First enrolled subject: November 2021
Last anticipated subject: Q1 2023
## Inclusion/Exclusion Criteria

### Inclusion

**Inclusion Criteria:**

- Male or female of ≥18 years old.
- Women of childbearing potential must have a negative urine pregnancy test within 7 days of index procedure.
- Subject or subject’s legal representative has been informed of the nature of the study, agrees to participate, and comply, and has signed the consent form.
- Subject has Rutherford Clinical Category 3, 4, 5, or 6.

**Angiographic Inclusion Criteria:**

- Target lesion(s) has stenosis >70% by visual assessment;
- De-novo, or non-stented re-stenotic lesions;
- Reference vessel diameter is between 2.5 mm and 3.5 mm, inclusive;
- Target lesions involve infrapopliteal tibial arteries including pedal;
- A target lesion may consist of one long or multiple serial lesions that are up to and including 12 cm in length;
- If a second lesion is identified in another vessel, the second lesion can also be treated and if treated will be treated with the alternate treatment.

### Exclusion

**Exclusion Criteria:**

- Acute Total Occlusions; evidence of acute thrombus formation by angiography.
- In-stent restenotic lesions.
- Inability to cross the lesion with the assigned study device.
- Treatment of target lesion with atherectomy

**Angiographic Exclusion Criteria:**

- Evidence of aneurysm or acute thrombus in the target vessel.
- Subject has an allergy to contrast medium that cannot be pretreated.
- Subject is pregnant or breastfeeding.
Serranator vs POBA Demographics
36 Subjects Enrolled (40 lesions)

<table>
<thead>
<tr>
<th>Subjects with Applicable Medical History (n=36)</th>
<th>Serranator Arm (n=20)</th>
<th>POBA Arm (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of Diabetes Mellitus:</td>
<td>16 (80%)</td>
<td>15 (75%)</td>
</tr>
<tr>
<td>History of Smoking:</td>
<td>3 (15%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>History of Hypertension:</td>
<td>19 (95%)</td>
<td>19 (95%)</td>
</tr>
<tr>
<td>History of Hyperlipidemia:</td>
<td>18 (90%)</td>
<td>18 (90%)</td>
</tr>
<tr>
<td>History of Renal Insufficiency:</td>
<td>11 (55%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>History of Prior Amputation:</td>
<td>7 (35%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Rutherford Classification:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3 (15%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>4</td>
<td>2 (10%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>5</td>
<td>11 (55%)</td>
<td>13 (65%)</td>
</tr>
<tr>
<td>6</td>
<td>4 (20%)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>

*Four patients had two lesions treated and received one Serranator and one POBA per Recoil Trial Design*
## Results: Lesion Characteristics*

*Core lab Adjudicated Syntropic CoreLab*

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Serranator (n=20)</th>
<th>POBA (n=19)**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Artery Treated</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TP Trunk</td>
<td>3 (15%)</td>
<td>4 (21%)</td>
</tr>
<tr>
<td>Tibial arteries</td>
<td>17 (85%)</td>
<td>15 (79%)</td>
</tr>
<tr>
<td><strong>Mean Lesion Length (mm)</strong></td>
<td>85.5mm (20-220)</td>
<td>83.7 (10-170)</td>
</tr>
<tr>
<td><strong>Degree of Calcification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non/mild</td>
<td>10 (50%)</td>
<td>10 (53%)</td>
</tr>
<tr>
<td>Moderate/Severe</td>
<td>10 (50%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td><strong>% Pre-Diameter Stenosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70%</td>
<td>8 (40%)</td>
<td>8 (42%)</td>
</tr>
<tr>
<td>&gt;70%</td>
<td>12 (60%)</td>
<td>11 (58%)</td>
</tr>
<tr>
<td><strong>Reference Vessel Diameter (RVD)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2.5</td>
<td>12 (60%)</td>
<td>13 (68%)</td>
</tr>
<tr>
<td>2.5-3.0</td>
<td>5 (25%)</td>
<td>5 (26%)</td>
</tr>
<tr>
<td>&gt;3.0</td>
<td>3 (15%)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>

**one angiographic image missing**
Left AT: POBA (Core lab Adjudication)

**Pre-Procedural Imaging**
- Average Minimum Lumen Diameter (MLD): 1.35 mm QVA
- Stenosis: 73%
- Lesion Length: 21.83 cm
- Calcification: None/Mild

**Post-Inflation (t0)**
- Residual Stenosis: 32%
- Lumen Diameter: 2mm

**Post-Inflation (t15)**
- Elastic Recoil: 100%
- Residual Stenosis: 77%
- Dissection: None
Left TP Trunk: **Serranator** *(Core lab Adjudication)*

**Pre-Procedure**

- Avg MLD: 1.38 mm
- Stenosis: 74%
- Lesion Length: 4 cm
- Calcification: None/Mild

**Post-Inflation (t0)**

- Residual Stenosis: 31%
- Lumen Diameter: 3.3 mm

**Post-Inflation (t15)**

- Elastic Recoil: 4%
- Residual Stenosis: 3%
- Dissection: None
## Results

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Serranator* (n=20)</th>
<th>POBA* (n=19)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean recoil across all lesions at 15min (+/- SD)</td>
<td>6% (+/- 26)</td>
<td>55% (+/- 69)</td>
<td>p = 0.009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Serranator* (n=20)</th>
<th>POBA* (n=19)</th>
<th>POBA/ Baumann** (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of lesions with recoil defined as: &gt;10% lumen compromise at 15 min</td>
<td>25% (5/20)</td>
<td>63% (12/19)</td>
<td>97% (29/30)</td>
</tr>
</tbody>
</table>

*Angiographic Core lab
** No Angiographic Core lab
# Results

## Dissection analysis

<table>
<thead>
<tr>
<th>Grade of Dissections</th>
<th>Serranator (n=20)</th>
<th>POBA (n=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>19</td>
<td>18</td>
</tr>
<tr>
<td>A</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>C/D</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Conclusions

- Research on recoil is limited, but the phenomenon is widely recognized in clinical practice of BTK revascularization.

- Recoil is associated with early occlusion or re-intervention is associated with early occlusion.

- The Mechanism of Action of the Serranator reduces recoil.

- In this head-to-head comparison Serranator decreased the mean recoil by 49%, the number of patients that met the < 10% threshold was substantially diminished.

- Recoil classification needs more study.
RECOIL study: Core-lab adjudicated study to assess recoil after scoring PTA vs POBA

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