EXCITE ISR

Complete 6-Month Results

Eric J Dippel, MD FACC

Principal Investigators
Eric J Dippel, MD
Craig M Walker, MD
Disclosure

Speaker name: Eric Dippel, MD

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I have the following potential conflicts of interest to report:

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

- [ ] I do not have any potential conflict of interest
Overview

Objective
• To evaluate safety and efficacy of Laser with adjunctive PTA (Laser+PTA) versus PTA alone for treating femoropopliteal in-stent restenosis (ISR)

Design
• Prospective, randomized controlled at 40 U.S. centers

Status
• Enrollment stopped at 250 patients
• Data on initial 250 patients submitted to FDA resulting in indication for atherectomy in ISR (Dippel et al. JACC:CI 2015)
• 6 month follow up completed; 12 month follow up continuing
Study Diagram

252 Randomized*

Laser + PTA
N=170

Primary Endpoints
30 day N= 167
6 month N= 156

6-Month Follow-up Complete
Death n=1
Lost to Follow Up n=3
Withdrew Consent n=10

PTA alone
N=82

Primary Endpoints
30 day N= 76
6 month N= 72

6-Month Follow-up Complete
Death n=2
Lost to Follow Up n=5
Withdrew Consent n=3

*two patients enrolled after study completion of 250 patients included in analysis; one patient in each group
Primary Endpoints

Primary Safety Endpoint

• Major Adverse Events through 37 days:
  – Death
  – Unplanned Major Amputation
  – Target Lesion Revascularization (TLR)

Primary Efficacy Endpoint

• Freedom from clinically driven TLR at 6 months (212 days)
  – DUS binary restenosis
  – Return of clinical symptoms
  – Deteriorated ABI or Rutherford Classification
Excimer Laser Atherectomy Catheters

- **Turbo Elite** → Initial debulking to create channel for Turbo Tandem
- **Turbo Tandem** → Biased laser catheter for large lumen ablation
“Real World” Patients

• Key Inclusion Criteria
  – ISR lesion ≥ 4 cm
  – Rutherford classification 1-4
  – RVD ≥ 5.0 mm and ≤ 7.0 mm
  – ≥ 1 patent tibial artery

• Key Exclusion Criteria
  – Target lesion extends >3 cm beyond stent margin
  – Untreated inflow lesion
  – Grade 4 or 5 stent fracture

• Follow-up
  – Discharge, 30 days, 6 months and 1 year post-procedure

• No lesion length limit
• Multiple stents allowed
• Common stent fractures (Grades 1-3)
• Popliteal stents included
## Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>Laser + PTA (N=169)*</th>
<th>PTA Alone (N=81)*</th>
<th>P- Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>68.5</td>
<td>67.8</td>
<td>0.60</td>
</tr>
<tr>
<td>Male</td>
<td>62.7 %</td>
<td>61.7 %</td>
<td>0.89</td>
</tr>
<tr>
<td>Hypertension</td>
<td>95.8 %</td>
<td>93.8 %</td>
<td>0.53</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>96.4 %</td>
<td>95.0 %</td>
<td>0.73</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>47.0 %</td>
<td>47.5 %</td>
<td>1.00</td>
</tr>
<tr>
<td>CAD</td>
<td>64.3 %</td>
<td>68.8 %</td>
<td>0.57</td>
</tr>
<tr>
<td>Previous ISR</td>
<td>32.7 %</td>
<td>30.0%</td>
<td>0.77</td>
</tr>
<tr>
<td>Smoking History</td>
<td>85%</td>
<td>91.3%</td>
<td>0.23</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td></td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>1</td>
<td>3.0%</td>
<td>3.7%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>18.9%</td>
<td>14.8%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>62.1%</td>
<td>69.1%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>15.4%</td>
<td>11.1%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0.6%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>0.0%</td>
<td>0.6%</td>
<td></td>
</tr>
</tbody>
</table>

*Analysis performed on initial 250 patients*
## Baseline Lesion Characteristics

### Angiographic Core Lab Assessment

<table>
<thead>
<tr>
<th></th>
<th>Laser + PTA (N=169)*</th>
<th>PTA Alone (N=81)*</th>
<th>P- Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Lesion Length (cm)</td>
<td>19.6</td>
<td>19.3</td>
<td>0.85</td>
</tr>
<tr>
<td>Diameter Stenosis (%)</td>
<td>81.7%</td>
<td>83.5%</td>
<td>0.42</td>
</tr>
<tr>
<td>Popliteal Lesion</td>
<td>21.3%</td>
<td>23.4%</td>
<td>0.93</td>
</tr>
<tr>
<td>Total Occlusion</td>
<td>30.5%</td>
<td>36.8%</td>
<td>0.37</td>
</tr>
<tr>
<td>Calcium (Mod/Sev)</td>
<td>27.1%</td>
<td>9.1%</td>
<td>0.002</td>
</tr>
<tr>
<td>Stent Fracture</td>
<td></td>
<td></td>
<td>0.16</td>
</tr>
<tr>
<td>0</td>
<td>85.8%</td>
<td>95.8%</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>5.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6.4%</td>
<td>4.2%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2.1%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0.7%</td>
<td>0.0%</td>
<td></td>
</tr>
</tbody>
</table>

- **20% of lesions > 30 cm**

*Analysis performed on initial 250 patients*
Procedural Success

<table>
<thead>
<tr>
<th></th>
<th>Laser+PTA n = 169*</th>
<th>PTA n = 81*</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turbo Elite use</td>
<td>79.9</td>
<td>30.9</td>
<td>na</td>
</tr>
<tr>
<td>Distal protection</td>
<td>40.2</td>
<td>30.9</td>
<td>0.16</td>
</tr>
<tr>
<td>% Diameter Stenosis</td>
<td>23.9±9.3</td>
<td>25.1±10.9</td>
<td>0.24</td>
</tr>
<tr>
<td>Residual Stenosis &gt;30%</td>
<td>4.7</td>
<td>13.6</td>
<td>0.02</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>93.5</td>
<td>82.7</td>
<td>0.03</td>
</tr>
</tbody>
</table>

*Analysis performed on initial 250 patients
Procedural Complications
All events adjudicated by CEC*

*Analysis performed on initial 250 patients
Primary Safety Endpoint
Freedom from MAE thru 37 days

Initial Results (TCT 2014)
- Laser + PTA: 94.2%
- PTA: 79.2%

6 Month Complete Follow Up
- Laser + PTA: 94.6%
- PTA: 80.3%

statistical significance: P<0.001
Primary Efficacy Endpoint
Freedom from TLR thru 6 months

Initial Results (TCT 2014)
- Laser + PTA: 73.5% (n=117)
- PTA: 51.8% (n=56)

6 Month Complete Follow Up
- Laser + PTA: 78.2% (n=156)
- PTA: 59.7% (n=72)

P<0.005
# 6 Month Clinical Status

<table>
<thead>
<tr>
<th></th>
<th>Laser + PTA (N=156)</th>
<th>PTA Alone (N=72)</th>
<th>P- Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency (%)</td>
<td>75.0</td>
<td>59.8</td>
<td>0.02</td>
</tr>
<tr>
<td>Freedom from MAE (%)</td>
<td>81.7</td>
<td>64.8</td>
<td>0.007</td>
</tr>
<tr>
<td>Survival (%)</td>
<td>99.3</td>
<td>97.1</td>
<td>0.30</td>
</tr>
<tr>
<td>Freedom from Amputation (%)</td>
<td>100</td>
<td>98.5</td>
<td>NA</td>
</tr>
<tr>
<td>Rutherford Class (RC)</td>
<td>1.3 ± 1.2</td>
<td>1.4 ± 1.5</td>
<td>0.48</td>
</tr>
<tr>
<td>Improved (%)</td>
<td>75</td>
<td>69.4</td>
<td></td>
</tr>
<tr>
<td>Same (%)</td>
<td>22.7</td>
<td>16.3</td>
<td>0.01</td>
</tr>
<tr>
<td>Worsened (%)</td>
<td>2.3</td>
<td>14.3</td>
<td></td>
</tr>
<tr>
<td>Increase in Stent Fracture Grade (%)</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
</tbody>
</table>

Analysis at 180 days post-procedure
Conclusions
EXCITE ISR

• Complete 6 month results confirm Laser with adjuncive PTA is superior to PTA alone for the treatment of femoropopliteal ISR:
  – Difficult to treat lesions averaging 20 cm and 30% total occlusion
  – Significantly higher safety rate (freedom from MAE: Laser+PTA 94.6% vs. PTA alone 80.3%, P<0.001)
  – Significantly higher freedom from TLR through 6 month follow up (Laser+PTA 78.2% vs. 59.7%, P<0.005)

• 12 month follow up ongoing
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