Laser Atherectomy for Lower Extremity Occlusive Disease: Has the Technology Improved and are the Results Showing It?

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DISCLOSURE

John Laird, MD

• **Consultant / Advisory Board:** Boston Scientific, Bard Peripheral Vascular, Abbott Vascular, Medtronic

• **Stocks:** Syntervention, Eximo Medical, Schockwave Medical, PQ Bypass, Reflow Medical, NexGen.
Trade with North Korea
Light Spectrum

Ultraviolet vs. Infrared

- Excimer (CVX-300®)
- Excimer (ophthalmology)
- CO2
- Ho:YAG

Wave lengths:

- Ultraviolet: 308nm, 193nm
- Infrared: 2090nm, 10600nm
Excimer Laser

Pulsed XeCl- Laser (Spectranetics/Phillips CV300)

- Wavelength: 308 nm
- Pulse duration: 135 ns
- Fluence: 30-80 mJ/mm²
- Repetition Rate: 25-80 Hz
## Mechanisms of Action

<table>
<thead>
<tr>
<th></th>
<th>Photochemical</th>
<th>Photothermal</th>
<th>Photomechanical</th>
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<tbody>
<tr>
<td>1</td>
<td>Breaking molecular bonds</td>
<td>Producing thermal energy</td>
<td>Creating kinetic energy</td>
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</table>
Long SFA Occlusion
Following Laser and PTA
Limb Salvage Following Laser-Assisted Angioplasty for Critical Limb Ischemia: Results of the LACI Multicenter Trial

John R. Laird, MD; Thomas Zeller, MD; Bruce H. Gray, DO; Dierk Scheinert, MD; Mitar Vranic, DO; Christopher Reiser, PhD; and Giancarlo Biamino, MD
for the LACI Investigators

Washington Hospital Center, Washington, DC, USA. 2Herz-Zentrum Bad Krozingen, Germany. 3Greenville Memorial Hospital, Greenville, SC, USA. 4Herzzentrum, Universität Leipzig, Germany. 5Arizona Heart Hospital, Phoenix, AZ, USA. 6Spectranetics, Colorado Springs, CO, USA.

Purpose: To evaluate the effectiveness of laser-assisted angioplasty for patients with critical limb ischemia (CLI) who were poor candidates for surgical revascularization.

Methods: A prospective registry at 14 sites in the US and Germany enrolled 145 patients with 155 critically ischemic limbs; the patients were poor candidates for bypass surgery owing to inadequate target vessel or saphenous vein, prohibitive cardiac disease, or significant comorbidities (ASA class 4). Additional comorbid risk factors included diabetes in 66%, hypertension in 83%, previous stroke in 21%, and myocardial infarction in 23%. Endovascular treatment included guidewire traversal and excimer laser angioplasty followed by balloon angioplasty with optional stenting.

Results: Occlusions were present in 92% of limbs. A mean of 2.7 ± 1.4 lesions were treated per limb; the total median treatment length was 11 cm (mean 16.2, range 0.2–123). Stents were implanted in 45% of limbs. Procedural success, defined as <50% residual stenosis in all treated lesions, was seen in 86% of limbs. At 6-month follow-up, limb salvage was achieved in 110 (92%) of 119 surviving patients or 118 (93%) of 127 limbs.

Conclusion: Excimer laser-assisted angioplasty for CLI offers high technical success and limb salvage rates in patients unfit for traditional surgical revascularization.

Key words: critical limb ischemia, laser angioplasty, excimer laser, limb salvage

J Endovasc Ther 2006;13:1-11
LACI Trial

- 155 limbs in 145 patients
- 71% of patients with tissue loss (Rutherford 5 or 6)
- 2.7 lesions per patient
- Mean lesion length per patient 16.0 cm
- 6 month limb salvage rate: 93%
Excimer Laser

Technical Improvements:
Evolution of Catheter Designs

• Extreme
• Optimally Spaced
• Point 9
• Turbo
• Turbo Elite
• Turbo Booster/Tandem
• Turbo Power
2.3 mm and 2.5 mm peripheral catheters  FDA approved 2004
Standard vs. Optimally Spaced

0.018 compatible 61 micron fibers

0.014 compatible 61 micron fibers

Beam Profile

22% larger lumen

62% greater ablation area
Turbo Booster

- Guidewire
- Distal Marker
- Orientation Band
- Laser Catheter
- Turbo Booster
Turbo Booster
Turbo-Power™
Laser Atherectomy Catheter

Remote automatic rotation offers
PRECISE DIRECTIONAL CONTROL

TREATS AT THE TIP creating a pilot channel
and debulking the lesion IN ONE STEP

VAPORIZES RESTENOTIC TISSUE
with the only technology backed
by Level 1 clinical evidence

NEW DESIGN features eccentric vaporizing technology for
maximal luminal gain

Specifications

<table>
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<tr>
<th></th>
<th>2.3mm</th>
<th>2.0mm</th>
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<tbody>
<tr>
<td>Catheter Diameter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model Number</td>
<td>423-050</td>
<td>420-050</td>
</tr>
<tr>
<td>Vessel Diameter</td>
<td>≥3.5mm</td>
<td>≥3.0mm</td>
</tr>
<tr>
<td>Max Guidewire Compatibility</td>
<td>0.018&quot;</td>
<td>0.018&quot;</td>
</tr>
<tr>
<td>Sheath Compatibility</td>
<td>7F</td>
<td>6F</td>
</tr>
<tr>
<td>Max Tip Outer Diameter</td>
<td>0.091&quot;</td>
<td>0.080&quot;</td>
</tr>
<tr>
<td>Max Shaft Outer Diameter</td>
<td>0.091&quot;</td>
<td>0.081&quot;</td>
</tr>
<tr>
<td>Working Length</td>
<td>120cm</td>
<td>150cm</td>
</tr>
<tr>
<td>Fluence (mJ/mm²)</td>
<td>30-60</td>
<td>30-60</td>
</tr>
<tr>
<td>Repetition Rate (Hz)</td>
<td>25-80</td>
<td>25-80</td>
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</table>
The CELLO Trial
The ClirPath Excimer Laser System to Enlarge Lumen Openings
CELLO Study Design

- Prospective, multicenter, non-randomized study
- 70 patients to be enrolled at 15 US sites (up to 85 patients with roll ins)
- Rutherford class 1-3 with denovo or restenotic (non-stented) lesion in SFA or popliteal artery ≥2cm and ≤15 cm in length
- Follow up at 30 days, 6 months, and 12 months
IVUS Post 2 mm Pilot channel

Angio Post 2 mm Pilot channel
60 Fl/40 Hz
IVUS Post TURBO-Booster

Angio Post 8 Fr TURBO-Booster with 2 mm catheter at 60 Fl/40 Hz
4 passes/11,114 pulses
Angio Post PTA using 5 mm x 8 cm and 6 mm x 2 cm balloons @ 2 atm
EXCITE ISR
Excimer Laser Randomized Controlled Study for Treatment of Femoropopliteal In-Stent Restenosis

Randomized trial of Excimer laser with Turbo Tandem device plus PTA compared to PTA alone for FP-ISR
EXCITE ISR Trial

Design

- **DESIGN**: Prospective, randomized, multi-center clinical evaluation of excimer laser atherectomy (ELA)

- **OBJECTIVE**: To evaluate safety and efficacy of ELA with adjunctive PTA (ELA+PTA) versus PTA alone for treating femoropopliteal in-stent restenosis

- **PRINCIPAL INVESTIGATORS**
  - Eric J Dippel, MD
  - Craig Walker, MD

250 patients enrolled between June 2011 and February 2014 in 40 clinical sites in United States

250 lesions crossable by guidewire

7 lesions uncrossable

169 ELA + PTA

Primary Safety endpoint at 37 days (n=155)

Primary Efficacy endpoint (n=117)

81 PTA

Primary Safety endpoint at 37 days (n=73)

Primary Efficacy endpoint (n=56)
EXCITE Trial – Left SFA ISR
Survival Probability

Product-Limit Survival Estimates

With number of subjects at risk

p < 0.005

EXCITE Trial
Primary Patency

Days from Index Procedure
Laser Atherectomy for Treatment of Femoropopliteal In-Stent Restenosis

For patients with Class III ISR treated with laser atherectomy:

- **Lower rate of recurrent restenosis at two years (69% vs. 100%)**
- **Lower rate of recurrent instent occlusion at 2 years (33% vs. 71%)**
Excimer Laser Limitations

- Clunky, expensive capital equipment
- Expensive catheters
- 5 minute warm up time
- Need for saline flush
- Time consuming
- Not effective for heavily calcified lesions
- Risk of distal embolization (especially with more aggressive debulking techniques)
- Limited (good quality) data supporting use
Eximo B-Laser™ Hybrid Atherectomy System
B-Laser™ Hybrid Atherectomy System

- Small and light solid-state Nd:YAG laser
- 355 nm wavelength, short pulses (~10 ns)
- No calibration and no warm up time for laser system
- Indifferent to contrast media presence
- Aspiration capability (for the 2mm and 2.35 mm)
- “Off-center” capability for large lumen creation and for non concentric lesions (2.35mm)
Effective for Calcified Lesions
Baseline lesion characteristics

<table>
<thead>
<tr>
<th>Lesion characteristics</th>
<th>(N=54)</th>
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<tbody>
<tr>
<td>Lesions/subject ± SD</td>
<td>1.1 ± 0.3</td>
</tr>
<tr>
<td>SFA, % (n)</td>
<td>83 (45/54)</td>
</tr>
<tr>
<td>Femoro-popliteal, % (n)</td>
<td>4 (2/54)</td>
</tr>
<tr>
<td>Popliteal, % (n)</td>
<td>9 (5/54)</td>
</tr>
<tr>
<td>Tibial, % (n)</td>
<td>4 (2/54)</td>
</tr>
<tr>
<td>Length, cm ± SD</td>
<td>8.7 ± 6.4</td>
</tr>
<tr>
<td>Calcification, any, % (n)</td>
<td>87 (47/54)</td>
</tr>
<tr>
<td>Moderate-severe calcification, % (n)</td>
<td>59 (32/54)</td>
</tr>
<tr>
<td>Total occlusion, % (n)</td>
<td>78 (42/54)</td>
</tr>
<tr>
<td>Stenosis type</td>
<td></td>
</tr>
<tr>
<td>stenosis, de novo, % (n)</td>
<td>93 (50/54)</td>
</tr>
<tr>
<td>In stent restenosis, % (n)</td>
<td>7 (4/54)</td>
</tr>
<tr>
<td>Stenosis (visual estimation), % ± SD</td>
<td>93.7 ± 14.7</td>
</tr>
</tbody>
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# Efficacy Endpoint results of the B-Laser™

<table>
<thead>
<tr>
<th>Efficacy measurements</th>
<th>(N=49)</th>
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<tbody>
<tr>
<td>Device/procedure success, % (n)</td>
<td>100 (49/49)</td>
</tr>
<tr>
<td>Device failure, % (n)</td>
<td>0 (0/49)</td>
</tr>
<tr>
<td>Freedom from TLR (30 days), % (n)</td>
<td>100 (49/49)</td>
</tr>
<tr>
<td>Freedom from TLR (6 months), % (n)</td>
<td>100 (39/39)</td>
</tr>
<tr>
<td>Freedom from TLR (1 year), % (n)</td>
<td>96 (24/25)</td>
</tr>
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</table>
Stenosis (%) pre and post the atherectomy procedure and post adjunctive therapy

93.7% before
58.7% post atherectomy
12.2% post adjunctive therapy

35.0% reduction post B-Laser™
B-Laser™ Interim Clinical Experience
25 cm Moderate Calcified CTO (2mm Catheter)

Before

After B-Laser™

After B-Laser™ + Balloon

Severe Calcific.
Summary

Has the Technology Improved? Yes

Are the Results Showing it? ????