Laser Atherectomy

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## DISCLOSURES

### Consultant/Medical/Scientific Boards
- Abbott
- Boston Scientific
- Cardiva
- Cook Medical
- CR Bard
- Lake Regional Medical
- Medtronic
- Spectranetics

### PVD Training
- Abbott
- Bard
- Boston Scientific
- Spectranetics
- TriReme Medical

### Stockholders
- CardioProlific
- Cardiva
- Spectranetics
- Vasamed

### Speaker’s Bureau
- Abbott
- Bard
- Boehringer-Ingelheim
- Bristol-Myers-Squibb/Sanofi
- Cardiva
- Cook Medical
- Cordis
- DSI/Lilly
- Spectranetics
Photochemical

- UV light pulse hits tissue
- 125 nanosecond duration
- 100 microns penetration
- Billions of tissue bonds fracture per pulse

- 80 pulses per second x 100 u = 0.8 mm/sec
Absorption creates molecular vibration in tissue.
Vibration of molecules heats intracellular water.
Water vaporizes, rupturing cells.
Steam forms expanding vapor bubble.
Occurs in 100 millionths of a second.
+/- 50º C tissue temperature at catheter tip.

125 ns to 120 us
Photomechanical

- Expansion and collapse of vapor bubble breaks down tissue and sweeps debris away from tip
- Debris is water, gas, & small particles (90% < 10 microns)
- Ablation depth -10 microns per pulse
- Entire process time per pulse is 500 millionths of a second

120-500 us
LASER ATERECTOMY IN INFRAPOPLITEAL DISEASE
Critical Limb Ischemia (CLI):

LACI Phase 2 Results: (20 clinical sites, 169 patients)

• Procedural Success - 97%
• 6 month limb salvage – 93%
• Complications (minor) - 3%

7% Amputation Rate at 6 months!!
Posterior Tibial Artery
Coronary Wire
2.0 Coronary Balloon
Following Laser & PTA
Following Laser & PTA
Following Laser & PTA
Limb Salvage Laser and PTA

Pre

1 Mo Post
ELA – “LACI Equivalent” Study

Methods:

• October 2001 - March 2003 (15 months)
• 44 patients CLI for “true limb salvage”
  – Rutherford class 5-6 with established tissue loss
• Peri and postprocedural GP IIb/IIIa agents
  – 6-8 hrs infusion
Arteries Treated:

- 56 infrapopliteal including:
  - Tibioperoneal trunk - 18/56 (32%)
  - Peroneal - 14/56 (25%)
  - Posterior tibial - 18/56 (32%)
  - Anterior tibial - 6/56 (10.7%)
  - Multiple - 14/56 (27%)
Arteries Treated:

- SFA - 23/44 (52%)
- Popliteal - 12/44 (27%)

“Step-by-step” technique - 4/44 (9%)
ELA – “LACI Equivalent” Study

Results:

• 95.4% (42/44) immediate procedural success
• No periprocedural major complications
• 3/44 (6.8%) minor complications
  – (<3cm hematoma)
• Arteries stented
  – SFA 15/23 (65%)
  – Popliteal 4/12 (33%)
  – Infrapopliteal 7/56 (12.5%)
ELA – “LACI Equivalent” Study

Results

• 6 month limb salvage - 30/33 (90.9%)
• 12 month limb salvage - 18/21 (85.7%)
Turbo Booster

The view is such that you are looking directly down on the device with the catheter above the Turbo Booster.
CLiRpath® Excimer Laser System to Enlarge Lumen Opening

CELLO STUDY

12 MONTH RESULTS

Rajesh M. Dave, MD
Principal Investigator
TURBO-Booster™

Turbo-elite™

Ramp

Orientation Marker

Distal Marker

Pilot Channel

First Pass

Second Pass
• Prospective, 20 center, non-randomized study in the United States

• Objective - evaluate the safety and efficacy of the TURBO Booster, in combination with the available laser catheters ≤ 2.0 mm, to create larger lumens for treatment within the superficial femoral and popliteal arteries.
Primary Endpoint: % Stenosis Reduction (N=65)

Angiographic Core Lab Assessment

Visual Assessment
PATENCY (N=65)

**% Duplex Patency**
- 30 Day: 96.9%
- 6 Month: 59.3%
- 12 Month: 54.3%

**% Freedom From TLR**
- 30 Day: 100%
- 6 Month: 86.0%
- 12 Month: 77.0%
A reduction in the Rutherford category shows clinical improvement

P-value <0.0001

N=65

N=62

N=63
An increase in Walking Impairment Questionnaire (WIQ) shows clinical improvement.
Secondary Endpoints

ABI

An increase in ABI shows improvement

P-value <0.0001

N=63
N=62
N=62
# Adverse Events at 12 Months (N=65)

<table>
<thead>
<tr>
<th>Major Adverse Clinical Events</th>
<th>Percent</th>
<th>N</th>
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<td>Major Adverse Clinical Events</td>
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<td>Clinical Perforation</td>
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<td>Major Amputation</td>
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<td>Cerebral Vascular Accident</td>
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<td>Myocardial Infarction</td>
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<td>Death</td>
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<tr>
<td>Serious Adverse Events (Not Device Related)</td>
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<td>11†</td>
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<tr>
<td>Serious Adverse Events (Probably Device Related)</td>
<td>1.5</td>
<td>1†</td>
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</table>

- *CVA occurred at 12 months post procedure Adjudicated by CEC
CELLO Conclusions

• The TURBO Booster Laser System:
  • Demonstrated significant tissue removal measured by angiographic and IVUS core labs.
  • Was very safe with no MACE events out to 6 months.
  • Achieved high procedural success and significant improvement in Rutherford Class, WIQ, and ABI at 12 months.
  • Demonstrated good duplex patency with low TLR at 12 months.
4 Quadrant 360 degree TURBO- Booster Catheter (2.0 mm Laser) Pathway
Final Angio
After 4 Quad Pass
6.0 mm x 120 mm
PTA
3 min inflation
Final Angio
After 4 Quad Pass
& PTA
100-110 mm
SFA CTO
Pilot Channel
1 pass 2.0 mm Laser
Pilot Channel
1 pass 2.0 mm Laser
Final Angio
Ater 4 Quad Pass
Conclusions

• Excimer laser works
  – It has to be used correctly
• Understanding technique and new improvements have made laser more effective
• New designs have lead to directional control and larger lumens
• Future changes in energy modulation may allow more effective crossing and tissue removal
Closing Remarks