New Modalities and Advanced Techniques: The Role of Crossing Devices and Atherectomy

Satish Gadi, MD FACC FSCAI
Interventional Cardiologist, Cardiovascular Institute of the South (CIS) Baton Rouge
Clinical Assistant Professor, Tulane University School of Medicine
Disclosures

• None
TASC II Classification of Femoro-Popliteal Occlusions

- **Type A Lesions** - single occlusions < 5 cm
- **Type B Lesions** – single occlusions < 15 cm not involving infra-geniculate Popliteal a.
- **Type C Lesions** – multiple stenoses or occlusions > 15 cm +/− calcification
- **Type D Lesions** – CTO of SFA > 20 cm involving the Popliteal artery
  - CTO of Popliteal artery and proximal trifurcation
The prevalence of PAD increases with age for both men and women.\textsuperscript{1}
12 Million U.S. PAD Patients

2.3 Million Diagnosed

1.0 Million Procedural Interventions

- 600,000 Endo Tx
- 243,000 Bypass
- 160,000 Amputation

1.3 Million
Medical Treatment Lifestyle Change

American Heart Association. Heart Disease and Stroke Statistics—2007 Update, Michael Weinstein, Market estimates
Challenges of CTOs...

- Flush ostial SFA occlusion
- Severe calcification
- Long (> 15 cm) occlusions
- Instent restenosis
- Popliteal artery occlusions with collaterals
What’s in a CTO?
- Proximal cap
- Body
- Distal cap
The simple wire and support catheter...

Benefits of the Glidewire Advantage may include:
- Reduced risk of complications
- Shorter procedure time
- Decreased fluoroscopy time
- Greater efficiency for clinical staff
- Fewer product codes on shelves

Unique DuoCore™ Technology
Fuses Glidewire construction with stiffer nitinol proximal end

Terumo Glide Technology™
hydrophilic coating

Polyurethane jacket with tungsten

Nitinol core

Angled tip with 5 cm taper

Stiffer nitinol core with spiral PTFE coating

Gladewire construction on distal 25 cm
**Quick-Cross® Support Catheter**

**Wire support for crossing occlusions.**

**Translucent Shaft**
- Easy visualization of blood within the catheter confirms luminal access

**Three, Evenly Spaced Radiopaque Markers**
- Assists in the assessment of lesion geometry
- Enables confirmation of catheter positioning

**Hydrophilic Coating**
- For smooth tracking

**Low Profile Tapered Tip**
- Seamless catheter-to-guidewire transition facilitates crossing of challenging lesions
- Allows for tracking through tortuous anatomy and diffuse disease

TrailBlazer™ Support Catheter
Crossing Devices

- Wild Cat – Avinger
- Crosser – Bard
- Powerwire – Bayliss
- Truepath – BSC
- Frontrunner – Cordis
- Viance – Cordis
- Ocelot - Avinger
• High-frequency mechanical vibrations
• Microbubble cavitation – microbubbles erode into the CTO
**CROSSER® Catheter System**

**CROSSER 14S (OTW & RX)**
- Workhorse
- .014” GW compatible
- ATK & BTK CTOs
- Large, tortuous vessels
- Small, straight distal anatomy

**CROSSER 14P (OTW & RX)**
- Flexible
- .014” GW compatible
- BTK CTOs
- Small, tortuous distal anatomy

**Images:**
- Advance CROSSER® over wire
- CROSSER Catheter Activation
- CROSSER through, Wire Advanced
Crosser – PATRIOT TRIAL

• 85 pts with guidewire “failure” were enrolled
• Avg. CTO length was 11.7 cm
• 63.5 % SFA, 20% Popliteal, 16% crural
• 75% moderate calcification
• Avg. Crosser activation time = 2 min.
• 83% procedural success with intraluminal recanalization
• No perforations
• 94% limb salvage
Crosser - Case

- 85 y/o/m
- Severe claudication left limb
- Ulcer on toe
- Options: Bypass surgery Vs Endovascular tx.
Ocelot – Avinger Inc.

- Real-time intravascular cross-sectional imaging
- Optical Coherence Tomography
OCELOT FEATURES

MIDDLE MARKER
Opposite the deflection of catheter tip

LAYERED STRUCTURES
Indicates intravascular arterial structures

NON-LAYERED STRUCTURES
Indicates intravascular atherosclerosis

OCT IMAGES
CHRONIC TOTAL OCCLUSION

MIDDLE MARKER

LAYERED STRUCTURES

NON-LAYERED STRUCTURES

CAT EARS
Ocelot – CONNECT II TRIAL
(VIVA 2012)

- 100 pts
- Mean lesion length 16.6 cm
- SFA and Popliteal CTOs
- 97% Crossing Success
- 98% Freedom from MAEs
OCELOT - Case

• 59 year-old female with lifestyle-limiting claudication
• Fontiane class 2b
• Flush Right SFA occlusion, h/o prior SFA stent
Re-Entry Devices

- BSC – Offroad
- Cordis – Outback
- Covidien – Enteer
- Medtronic - Pioneer
PIONEER - Medtronic

• 6F
• Premounted needle
• IVUS-guided (Volcano)
Atherectomy

- Atherectomy is a minimally invasive surgical method of removing, mainly, atherosclerosis from a large blood vessel.

Why Atherectomy?

• Not a “final” therapy – leaves future options open
• Suitable for complex/calcified lesions
• Collaterals and side branches are preserved
• Can be combined with other therapies (ex. Drug-elution, intravascular imaging, etc.)
Types of Atherectomy

- Rotational
- Orbital
- Laser
- Directional
CSI Orbital Atherectomy System

- The burr is located on a coil consisting of 3 helically-wound wires
- Orbital path of the device around the periphery of the lumen
- Orbital motion allows for more blood flow and cooling – minimizes thermal trauma and ischemia.
Diamondback - OASIS

OASIS was a multi-center IDE study completed in 2007 to establish safety and acute procedural efficacy.

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Study Overview</th>
<th>Objectives</th>
<th>Key Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>OASIS</td>
<td>Prospective</td>
<td>Primary endpoints:</td>
<td>Primary endpoints met:</td>
</tr>
<tr>
<td>124 Patients</td>
<td>Single-arm: OAS</td>
<td>- Efficacy: Acute reduction in % diameter stenosis of target lesions - Safety: Major Adverse Events (MAEs) at 30 days</td>
<td>- 68.9% plaque removal - 3.2% of MAE at 30 days - 100% target limb salvage at 30 days</td>
</tr>
<tr>
<td>201 Lesions</td>
<td>Multi-center</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Major adverse events include death, myocardial infarction, amputation or target vessel revascularization.

Diamondback - Case

• 59 year-old female
• Lifestyle-limiting claudication
• Fontaine class IIb
Laser Atherectomy

**Photoablation** – use of light to vaporize, breakdown, and remove matter.
Science of Laser Photoablation

• Atherectomy is performed by direct contact with and absorption of the laser energy by the plaque.

• **Photochemical effects** – billions of molecular bonds are fractured per UV light pulse

• **Photothermal effects** – vibration of bonds produces thermal energy with expanding vapor bubble

• **Photomechanical effects** – expansion and collapse of the vapor bubble breaks down tissue
Laser - Evidence


• 145 pts treated with Excimer Laser; total of 423 lesions were treated – SFA, Popliteal, and InfraPopliteal.

• Mean lesion length > 16 cm.

• Poor surgical candidates.

• Limb salvage rate of 93% at 6 months.
**Laser – Case**

- 65 year-old male
- Lifestyle-limiting claudication
- Rt. Popliteal CTO
- Prior distal SFA – Infrapopliteal bypass
Directional Atherectomy

- Silverhawk / Turbohawk – Covidien/ev3
- Plaque excision
- Ability to treat a broad spectrum of lesions incl. calcified plaque

TurboHawk Micro Efficient Compression (MEC) And Super Cutter 4-angled cutter blades
Right Pre-Intervention

Right Post-Intervention

Left Pre-Intervention

Left Post-Intervention
DEFINITIVE LE Study


- Prospective, nonrandomized, global study
- 800 subjects at 47 centers (CLI = 201)
- Lesion length up to 20 cm
- **Periprocedural Outcomes:**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Claudication (RCC 1-3)</th>
<th>CLI (RCC 4-6)</th>
<th>All Subjects (RCC 1-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Success (≤30% stenosis after plaque excision)</td>
<td>76%</td>
<td>72%</td>
<td>75%</td>
</tr>
<tr>
<td>Procedure Success (≤30% stenosis at end of procedure)</td>
<td>91%</td>
<td>83%</td>
<td>89%</td>
</tr>
</tbody>
</table>
# Key Study Endpoints

<table>
<thead>
<tr>
<th>Claudicants</th>
<th>Primary Endpoint: Primary Patency at 12 Months (PSVR ≤ 3.5)</th>
<th>Secondary Endpoint: Primary Patency at 12 Months (PSVR ≤ 2.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patency</td>
<td>LL (cm)</td>
</tr>
<tr>
<td>All (n=743)</td>
<td>82%</td>
<td>7.5</td>
</tr>
<tr>
<td>Diabetic (n=345)</td>
<td>80%</td>
<td>7.6</td>
</tr>
<tr>
<td>Non-Diabetic (n=398)</td>
<td>83%</td>
<td>7.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CLI</th>
<th>Primary Endpoint: Freedom from Major Unplanned Amputation of the Target Limb at 12 Months</th>
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<tbody>
<tr>
<td>All (n=201)</td>
<td>95%</td>
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### Periprocedural Complications

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Incidence (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal Embolization</td>
<td>3.8% (30)</td>
</tr>
<tr>
<td>No Intervention</td>
<td>2.1% (17)</td>
</tr>
<tr>
<td>Surgical Intervention</td>
<td>0.1% (1)</td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>1.5% (12)</td>
</tr>
<tr>
<td>Dissection (flow-limiting)</td>
<td>2.3% (18)</td>
</tr>
<tr>
<td>No Intervention</td>
<td>0.8% (6)</td>
</tr>
<tr>
<td>Surgical Intervention</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>1.5% (12)</td>
</tr>
<tr>
<td>Perforation</td>
<td>5.3% (42)</td>
</tr>
<tr>
<td>No Intervention</td>
<td>1.1% (9)</td>
</tr>
<tr>
<td>Surgical Intervention</td>
<td>0.1% (1)</td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>4.0% (32)</td>
</tr>
<tr>
<td><strong>OVERALL intervention rate</strong></td>
<td><strong>7.6% (61)</strong></td>
</tr>
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Disrupting the black line, promotes smooth muscle cell migration, proliferation and accelerated restenosis
Pantheris
(Lumivascular Directional Atherectomy)