Revascularization Strategies for the Superficial Femoral Artery

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• Peripheral arterial disease (PAD) most commonly occurs in the superficial femoral artery (SFA)
  • ~30 cm long
  • 4-7 mm in diameter
  • Surrounded by two major flexion points (hip and knee)
  • A relatively high incidence of calcification and total occlusion
Forces Exerted on the SFA

1. Extension / Contraction
2. Torsion
3. Compression
4. Flexion
• Endovascular interventions have evolved quickly.
• Initial tools were large and bulky.
• The profiles of endovascular equipment have diminished dramatically.
• Technological advances have led to more frequent and assertive approaches to treating peripheral vascular disease endovascularly.
Obstructive Peripheral Disease Endovascular Therapies for the SFA

• PTA
• Drug-Coated Balloons (DCB)
• Atherectomy
• Stent
• Atherectomy + PTA
• PTA + Stent
• Atherectomy + PTA + Stent
• PTA + DCB
• Atherectomy + DCB
Angioplasty

• Initial endovascular treatment of SFA disease limited to angioplasty.
DRUG-COATED BALLOONS

BARD LUTONIX

MEDTRONIC IN.PACT ADMIRAL
BARD/LUTONIX LEVANT 2
PRIMARY PATENCY KAPLAN-MEIER

Free from Primary Patency Event (%)

Months from Randomization Date

<table>
<thead>
<tr>
<th>Time</th>
<th>Lutonix DCB</th>
<th>Standard PTA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>365 days</td>
<td>73.5%</td>
<td>56.8%</td>
<td>0.001</td>
</tr>
</tbody>
</table>
IN.PACT SFA ALL ITT, 12-MONTH PRIMARY PATENCY

Primary patency is defined as freedom from clinically-driven TLR and freedom from restenosis as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) ≤ 2.4

(p<0.001 by log-rank test)

<table>
<thead>
<tr>
<th></th>
<th>IN.PACT</th>
<th>PTA</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Month Clinically-driven TLR [^1]\</td>
<td>2.4%</td>
<td>20.6%</td>
<td>&lt;0.001 [^2]\</td>
</tr>
</tbody>
</table>

Laird JR. Randomized Controlled Trials I: New Insights from IN.PACT SFA I-II. TCT 2014.
Atherectomy

Plaque Debulking

• Laser Atherectomy
  • TurboElite Excimer Laser (Spectronetics)
  • TurboPower (Spectronetics)

• Orbital Atherectomy
  • Diamondback 360 (CSI)

• Directional Atherectomy
  • SilverHawk/TurboHawk/HawkOne (Medtronic)
  • Pantheris (Avinger)

• Rotational Atherectomy
  • Jetstream (Boston Sci)
  • Rotablator (Boston Sci)
  • Phoenix (Volcano)
The TALON Registry

End points:
• 6 and 12 month TLR

Registry population
• Consecutive SilverHawk patients; lower extremity peripheral vasculature
• Total Patients Enrolled: 728
  • Limbs: 906
  • Lesions: 1517
• Total Procedures: 1001
12-month Freedom From Target Lesion Revascularization

Percent Without Revascularization

Time (Months)

N=659 lesions

N=659 lesions
DEFINITIVE-LE

• 799 claudicants and critical limb ischemia patients for treatment with a SilverHawk atherectomy device.

• Primary patency rate of 78% in the claudicant cohort and 71% in the critical limb ischemia group at 1 year

• No statistical difference between the diabetic and non-diabetic patients.

• Associated with a 3.8% distal embolization rate and a 5.3% rate of vessel perforation.

• 3% of the patients received provisional stenting.
Directional Atherectomy

Histological Examination of vessel\textsuperscript{1}:

Indiscriminate Directional Cutter

Indiscriminate cutter may cause \textit{medial layer injury} which triggers a natural clotting response in the vessel
PANTHERIS: PRECISE. CONSISTENT. SAFE.

GUESS WHEN TO STOP

With precision OCT guidance - one single pass dramatically improves angiographic flow at target lesion.

KNOW WHEN TO STOP

Final Results:
1) One large smooth trough
2) Only plaque removed (confirmed via both OCT and histology)
3) No disruption of medial/adventitial borders during therapy
4) Laminar blood flow

FORMER CLEAVAGE PLANE REMOVED FOLLOWING OCT GUIDED ATERECTOMY
Atherectomy Tissue Gross + Histology

Plaque = 94.43%
Medial Tissue = 5.7%
Adventitial Tissue = 0%
What is their best use?

- **Laser**
  - Thrombus (small)
  - Soft or firm plaque
  - In-Stent Restenosis
  - Below the knee
  - CTO

- **Directional**
  - Soft or firm plaque
  - Eccentric lesions
  - Arteries with motion

- **Orbital**
  - Severely Calcified
  - Arteries with motion

- **Rotational**
  - Thrombus (large)
  - Soft, firm and calcified
  - Long areas
SFA Stents

- Life Stent (Bard)
- Zilver PTX (Cook)
- Supera (Abbott)
- Protégé (Covidien)
Data based on the RESILIENT Trial

These rates are estimated by Kaplan-Meier analysis. The p-values are based on the comparison of controls vs. test of the randomized patients (sient group, n=154 and FTR control group, n=72). Target Lesion Revascularization (TLR) occurred in subjects who underwent revascularization (surgical or endovascular) of the segment treated by the stent (test) or FTR (control).
# 2-Year Clinical Data Summary: Zilver PTX

## Patient Information

<table>
<thead>
<tr>
<th></th>
<th>Randomized Controlled Trial</th>
<th>Single-Arm Trial</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>479</td>
<td>787</td>
<td>Over 1,000 patients in 2 trials, including the largest SFA randomized controlled trial.</td>
</tr>
<tr>
<td>Average Lesion Length (ZPTX)</td>
<td>66 mm (up to 14 cm)</td>
<td>100 mm (up to 28 cm)</td>
<td>Moderate and long lesions treated.</td>
</tr>
<tr>
<td>Total Occlusions</td>
<td>30%</td>
<td>38%</td>
<td>High percentage of challenging lesions included in both trials.</td>
</tr>
<tr>
<td>Diabetics</td>
<td>49%</td>
<td>36%</td>
<td>Challenging patient subset represented in both trials.</td>
</tr>
<tr>
<td>Rutherford Classification</td>
<td>2-6</td>
<td>2-6</td>
<td>Real-world patients included in both trials.</td>
</tr>
<tr>
<td>1-Year Fracture Rate</td>
<td>0.9%</td>
<td>1.5%</td>
<td>Core-lab adjudicated.</td>
</tr>
</tbody>
</table>

## Proven Drug Effect at 2 Years

<table>
<thead>
<tr>
<th></th>
<th>Zilver PTX vs. PTA</th>
<th>Provisional Zilver PTX vs. BMS</th>
<th>Provisional Zilver PTX vs. BMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>PSVR &lt; 2.0</td>
<td>PSVR &lt; 2.0</td>
<td>Freedom from TLR²</td>
</tr>
<tr>
<td>0</td>
<td>Zilver PTX</td>
<td>(Provisional Zilver PTX)</td>
<td>(Provisional Zilver PTX)</td>
</tr>
<tr>
<td>1</td>
<td>82.7%</td>
<td>90.3%</td>
<td>54.7%</td>
</tr>
<tr>
<td>2</td>
<td>74.8%</td>
<td>83.4%</td>
<td>34.7%</td>
</tr>
</tbody>
</table>

*COOK®
DRUG-ELUTING PERIPHERAL STENT
Zilver PTX
definitions
Supera

Freedom from Clinically Driven TLR at 24 Months (SUPERB)

89% at 12 mos.
84% at 24 mos.

<table>
<thead>
<tr>
<th>Interval</th>
<th>[0, 90)</th>
<th>[90, 180)</th>
<th>[180, 270)</th>
<th>[270, 360)</th>
<th>[360, 390)</th>
<th>[390, 720)</th>
<th>[720, 750)</th>
</tr>
</thead>
<tbody>
<tr>
<td># At Risk</td>
<td>264</td>
<td>242</td>
<td>237</td>
<td>217</td>
<td>201</td>
<td>197</td>
<td>149</td>
</tr>
<tr>
<td># Events</td>
<td>1</td>
<td>2</td>
<td>15</td>
<td>7</td>
<td>1</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td># Censored</td>
<td>21</td>
<td>3</td>
<td>5</td>
<td>9</td>
<td>3</td>
<td>38</td>
<td>43</td>
</tr>
<tr>
<td>Survival Rate*</td>
<td>1.000</td>
<td>0.996</td>
<td>0.988</td>
<td>0.925</td>
<td>0.894</td>
<td>0.890</td>
<td>0.840</td>
</tr>
<tr>
<td>Standard Error</td>
<td>0.000</td>
<td>0.004</td>
<td>0.007</td>
<td>0.017</td>
<td>0.020</td>
<td>0.020</td>
<td>0.025</td>
</tr>
</tbody>
</table>

Data on file at Abbott Vascular - Supera IFU  * Survival rate at beginning of time period
In a single center study evaluating stent fracture in 93 patients, Scheinert et al. found that stent fracture was associated with reduced patency with the following stents: S.M.A.R.T.®, SelfX and Luminexx™.
CTO - Crossing

• Support catheter and wire technique
  • 0.14, 0.18, 0.35 Support catheters
    • Quickcross, Seeker, Navicross, Trailblazer, Rubicon
  • Specialty CTO wires
    • ASAHI – Regalia, Treasure 12, Treasure Floppy, Astato 20, Astato 30
• CTO Crossing Devices
  • Crosser
  • Frontrunner
  • Truepath
  • Viance
  • Wildcat
  • Ocelot
• Re-entry Devices – Outback; Pioneer; Stingray
2 Strategies for CROSSING CTOs

• Subintimal Navigation
  – Well characterized, historical technique
  – Often as bail-out with re-entry devices necessary
  – Limits choices for adjunctive devices

• Central Lumen Navigation
  – Clinically preferred strategy
  – Maximizes therapeutic options
    • Adjunctive devices designed to operate in the arterial lumen
Competetive Landscape of CTO Devices

<table>
<thead>
<tr>
<th>DEVICE</th>
<th>MANUFACTURER</th>
<th>EFFECTIVENESS</th>
<th>CLINICAL STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCELOT¹</td>
<td>AVINERG</td>
<td>97%</td>
<td>CONNECT II</td>
</tr>
<tr>
<td>WILDCAT²</td>
<td>AVINERG</td>
<td>89%</td>
<td>CONNECT</td>
</tr>
<tr>
<td>CROSSE³</td>
<td>BARD</td>
<td>84%</td>
<td>PATRIOT</td>
</tr>
<tr>
<td>VIANCE⁴</td>
<td>COVIDIEN</td>
<td>77%</td>
<td>P-FAST</td>
</tr>
<tr>
<td>TRUE PATH⁵</td>
<td>BOSTON SCIENTIFIC</td>
<td>76%</td>
<td>REOPEN</td>
</tr>
<tr>
<td>FRONTRUNNER⁶</td>
<td>CORDIS</td>
<td>61%</td>
<td>post-market registry</td>
</tr>
</tbody>
</table>
• There are many tools to use for the treatment of obstructive peripheral arterial disease in the superficial femoral artery.

• Treatment algorithms should be individualized.

• Growing technology is providing an increasing number of options to overcome nearly every obstacle encountered.