ENDOVASCULAR INTERVENTION
M. Blair DeYoung, D.O.
McLaren Cardiovascular Institute


3x growth in endovascular interventions

- Total endovascular interventions: RR=3.3; 95% CI 2.9-3.8
- Major LE amputation: RR=0.71; 95% CI 0.7-0.8
- LE bypass surgery: RR=0.58; 95% CI 0.5-0.7


- Cardiologist: RR=2.5; 95% CI 2.2-2.8
- Vascular surgeon: RR=2.5; 95% CI 2.2-2.8
- Interventional radiologist: RR=2.5; 95% CI 2.2-2.8
Proportion of PAD Endovascular Intervention: 1996-2006

Complication Rates for Endovascular vs. Open Revascularization: 1998 vs. 2007

<table>
<thead>
<tr>
<th></th>
<th>1998</th>
<th>2007</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endovascular revascularization</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operative mortality</td>
<td>2.4%</td>
<td>1.1%</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Cardiac</td>
<td>1.6%</td>
<td>0.8%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.2%</td>
<td>0.1%</td>
<td>0.04</td>
</tr>
<tr>
<td>Bleeding</td>
<td>9.9%</td>
<td>6.7%</td>
<td>&lt;0.0001</td>
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<tr>
<td>Infection</td>
<td>1.7%</td>
<td>1.3%</td>
<td>0.02</td>
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<tr>
<td><strong>Open surgical revascularization</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Operative mortality</td>
<td>3.9%</td>
<td>2.7%</td>
<td>&lt;0.05</td>
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<tr>
<td>Cardiac</td>
<td>3.0%</td>
<td>2.2%</td>
<td>0.0006</td>
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<tr>
<td>Stroke</td>
<td>0.4%</td>
<td>0.3%</td>
<td>0.03</td>
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<tr>
<td>Bleeding</td>
<td>14.3%</td>
<td>10.8%</td>
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<tr>
<td>Infection</td>
<td>3.4%</td>
<td>3.8%</td>
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Lower Extremity Arterial Anatomy
Infrapopliteal Arterial Anatomy

Critical Limb Ischemia

Critical Limb Ischemia (CLI)

Primary Treatment

A Year Later

20% 25% 30% 25% 20%

Disease Categories

• Anatomic Lesion Classification
  — TASC II
  — Bolinger
  — Graziani

• Symptom Classification
  — Rutherford
  — Fontaine
  — WIfI (Wound, Ischemia, foot Infection)

TASC II

Lesion severity:
- 1 point: Occlusion of the lumen
- 2 points: Stenosis ≥50 percent of the luminal diameter
- 3 points: Stenosis >50 percent but <25 percent
- 4 points: Plaques impinging ≤25 percent of the diameter

Lesion extent:
- 1 point: Single lesion
- 2 points: Multiple lesions affecting less than half of the segment
- 3 points: Multiple lesions affecting more than half of the segment

Bolinger

Arterial segments:
- Profunda femoris artery
- Proximal (upper half) superficial femoral artery
- Distal (lower half) superficial femoral artery
- Above-knee popliteal artery
- Below-knee popliteal artery
- Tibioperoneal trunk
- Proximal (upper half) posterior tibial artery
- Distal (lower half) posterior tibial artery
- Proximal (upper half) anterior tibial artery
- Distal (lower half) anterior tibial artery
- Proximal (upper half) peroneal artery
- Distal (lower half) peroneal artery
- Plantar arch
Graziani Morphologic Classification

- Class 1 – Isolated, one vessel tibial or peroneal artery obstruction
- Class 2a – Isolated femoral/popliteal artery or two below-knee arteries obstructed but with patency of one of the two tibial arteries
- Class 2b – Isolated femoral/popliteal artery or two below-knee tibial arteries obstructed but with patency of the peroneal artery
- Class 3 – Isolated, one artery occluded and multiple stenoses of tibial/peroneal and/or femoral/popliteal arteries
- Class 4 – Two arteries occluded and multiple stenoses of tibial/peroneal and/or femoral/popliteal vessels
- Class 5 – Occlusion of all tibial and peroneal arteries (below-knee cross-sectional occlusion)
- Class 6 – Three arteries occluded and multiple stenoses of tibial/peroneal and/or femoral/popliteal arteries
- Class 7 – Multiple femoropopliteal obstructions with no visible below-the-knee arterial segments

Rutherford

The Rutherford classification has seven stages:
1. Stage 0 – Asymptomatic
2. Stage 1 – Mild claudication
3. Stage 2 – Moderate claudication
4. Stage 3 – Severe claudication
5. Stage 4 – Rest pain
6. Stage 5 – Ischemic ulceration not exceeding ulcer of the digits of the foot
7. Stage 6 – Severe ischemic ulcers or frank gangrene

The distance that delineates mild, moderate and severe claudication is not specified in the Rutherford classification, but is mentioned in the Fontaine classification at 200 meters.

Fontaine

The Fontaine classification is not usually used in everyday clinical practice. On the other hand, it is useful for research purposes. There are five Fontaine stages (actually there are four, and one subtype):

- Stage I – Asymptomatic.
- Stage II – Intermittent claudication. This stage takes into account the fact that patients usually have a very constant distance at which they have pain:
  - Stage IIa – Intermittent claudication after more than 200 meters of pain free walking.
  - Stage IIb – Intermittent claudication after less than 200 meters of walking
- Stage III – Rest pain.
- Stage IV – Ischemic ulcers or gangrene (which may be dry or humid).
Wound: Ischemia, foot Infection

**Grade 0:** mild, shallow ulcer (≤ 1 cm) on distal leg or foot with exposed bone limited to distal phalanx (ie, major tissue loss: salvagesome with simple digital amputations or standard transmetatarsal amputation [TMA] plus skin coverage).

**Grade 1:** deeper ulcer on distal leg or foot with exposed bone, joint, or tendon, or shallow heel ulcer without involvement of the calcaneus (ie, major tissue loss: salvageable with ≤ 3 digital amputations or standard transmetatarsal amputation [TMA] plus skin coverage).

**Grade 2:** extensive deep ulcer on the foot, below ankle or wrist, or full thickness heel ulcer involving > 60% of the calcaneus (ie, minor tissue loss: salvageable with foot reconstruction or nontraditional TMA [eg, Chopart or Lisfranc amputation]).

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**Iliac Intervention**

**Right iliac stenting for iliac artery occlusion**

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<table>
<thead>
<tr>
<th>Author</th>
<th>Type of intervention</th>
<th>Number of patients</th>
<th>Type of lesion</th>
<th>Binary result</th>
<th>Primary patency rate at 1 year</th>
<th>Primary patency rate at 3 years</th>
<th>Primary patency rate at 5 years</th>
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<td>Chung et al.</td>
<td>2006</td>
<td>48</td>
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**Femoropopliteal Intervention**

Therapies:
- Angioplasty
- Self-expanding stents
- Drug coated balloons
- Drug coated stents
- Atherectomy
Peripheral Drug Coated Balloons

Medtronic
IN.PACT Admiral Drug-Coated Balloon

Bard
Lutonix® 035 Drug Coated Balloon PTA Catheter

Spectranetics
Stellarex™

Drug Coated Balloons

<table>
<thead>
<tr>
<th></th>
<th>1-Year</th>
<th>2-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>IN.PACT DCB</td>
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<tr>
<td><strong>Primary Patency</strong></td>
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<tr>
<td>1-Year</td>
<td>87.5%</td>
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<td>2-Year</td>
<td>73.0%</td>
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<tr>
<td>CD-TLR</td>
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<tr>
<td>1-Year</td>
<td>2.4%</td>
<td>9.1%</td>
</tr>
<tr>
<td>2-Year</td>
<td>12.3%</td>
<td>18.0%</td>
</tr>
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</table>

IN.PACT Admiral Drug-Coated Balloon Overview

Proven balloon platform utilizing Medtronic’s proprietary coating technology, offering rapid drug transfer and consistent quality.

Indication for Use
The IN.PACT Admiral Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of non-acute restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
The DCB mechanism of action facilitates the transfer of PTX deep into vessel tissue.

IN.PACT balloon matrix coating:
- Paclitaxel
- Urea - excipient that controls drug release

DCB inflation:
- Matrix coating contact with the blood
- Urea hydrates causing the release of paclitaxel
- Paclitaxel binds to the wall due to its hydrophobic and lipophilic properties

Paclitaxel penetration:
- Through vessel wall deep into the media and adventitia
- Interferes with the causes of restenosis
- Can remain in the vessel wall for over 180 days at therapeutic levels

Drug Coated Balloons

IN.PACT SFA Trial
Primary Patency

IN.PACT SFA Trial
Freedom from CD-TLR through 3 Years
Peripheral Drug Coated Stent
Zilver PTX (Paclitaxel)

Cook
Zilver PTX Drug-Eluting Peripheral Stent

Atherectomy

<table>
<thead>
<tr>
<th>Phoenix</th>
<th>Hawkone</th>
<th>Diamondback</th>
<th>Laser Spectranetics</th>
<th>Turbo-Tandem and Turbo-Elite</th>
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<tr>
<td>Mechanism of Action</td>
<td>Rotational / front-cutting</td>
<td>Rotational, active aspiration</td>
<td>Laser pulses</td>
<td></td>
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<tr>
<td>Capital Cost</td>
<td>No</td>
<td>No</td>
<td>Tableside pump</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Competitive Analysis

Pros
1. Versatile in many tissue morphologies
2. 5 French profile
3. Front-cutting
4. 1% rate of symptomatic distal emboli in the EASE trial

Pros
1. Cuts to large diameters
2. Directable
3. Simple form factor

Cons
1. Risk of distal embolization
2. Must pass nosecone
3. Must remove catheter to clean out debris
4. Contraindicated for in-stent
5. IFU suggests use of embolic protection during use

Pros
1. Leader in treating calcium

Cons
1. If patient has angiographic evidence of thrombus; thrombolytic therapy must be instituted prior to atherectomy
2. Contraindicated in bypass graft stent
3. Has to be used with their wire and use of ViperSlide
4. Requires rest periods between runs and a total run time less than 8 min

Pros
1. Thrombectomy indication
2. Luminal gain ATK with blades-up

Cons
1. Profile
2. Risk of distal embolization
3. Can be cumbersome system to master
Definition of Photoablation

Photoablation is the use of light to vaporize and remove matter.

Spectranetics CVX-300™ Excimer Laser facilitates photoablation via the Turbo-Elite™ Laser Catheter and other SPNC catheters to remove arterial plaque.

THREE MECHANISMS OF ACTION

Laser atherectomy safely and reliably leverages THREE UNIQUE mechanisms of action.

Photochemical
- Breaking molecular bonds.
- UV light VAPORIZES plaque directly in front of the catheter tip.

Photothermal
- Producing thermal energy.
- Thermal energy SOFTENS collagen and protein fibers, and creates vapor bubble.

Photomechanical
- Creating kinetic energy.
- Repeated expansion & contraction of vapor bubble HAMMERS through hard plaque.

Treating ISR is a Significant Issue as Lower Limb Stenting Continues to Increase

"Restenosis occurs in 80 to 60 percent of treated segments after one year. The use of angioplasty to treat extensive disease of the superficial femoral artery has particularly poor results: at one year, the rates of restenosis exceed 70 percent for lesions longer than 100 mm."

—Professor Martin Schillinger
SFA with Diffuse Disease, Including Circumferential Calcium

Overview
- Patient: 76-year-old female
- Coronary disease, hypertension
- Presents with angina
- Single vessel disease of the proximal 150 mm diffuse disease with three areas of stenosis (90%)
- IVUS showed circumferential calcium

Treatment & Outcome
- Hawlik® 16 Senior treated with three insertions, resulting in 20% residual stenosis
- Post-dilation with 3 x 300 Overcoax™ PES at low
ATM
- Post-case IVUS showed minimum lumen diameter (MMLD) increased from 1.5 mm to 3 mm

CSI Diamondback 360 Atherectomy System

Volcano Phoenix Atherectomy System

Boston Scientific Jetstream Atherectomy System

Avenger Pantheris Atherectomy System
Endovascular revascularization & supervised exercise for Claudication (ERASE Trial)

Endovascular revascularization plus supervised exercise therapy is associated with greater improvement in functional performance in patients with PAD

Fakhry et al. AHA 2013 Late-breaking trial