SFA Spot Stenting

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Disclosure

• Nothing to disclose
SFA Revascularization
“The Challenges”

Variables That Effect Patency and Clinical Outcome

- **Variables**
  - 15-20 cm breaking point?
  - Ostial
  - Popliteal
  - Moderate to severe or more
  - Maximized MLD
  - Coagulation issues
  - Technically Issues
  - Stent vs no stents
  - Focal vs Diffuse vs Occlusion
Biomechanical Forces in the SFA

Elongation/Compression
Torsion
Bending
Crush

Courtesy: Alexandra J. Lansky, Director, Interventional Cardiology Research, Yale University
Lesion Lengths & Stent Fractures

Repetitive compression, creep deformation due to axial and radial stresses, kinking and shear stresses during movement in patients may also cause metal fatigue and subsequent fracture.
Evidence - SFA Specific Stents

Nitinol Stent Implantation Versus Balloon Angioplasty for Lesions in the Superficial Femoral Artery and Proximal Popliteal Artery Clinical Perspective – The RESILIENT Trial

by John R. Laird, Barry T. Katzen, Dierk Scheinert, Johannes Lammer, Jeffrey Carpenter, Maurice Buchbinder, Rajesh Dave, Gary Ansel, Alexandra Lansky, Ecaterina Cristea, Tyrone J. Collins, Jeffrey Goldstein, Michael R. Jaff, and

Circ Cardiovasc Interv
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RESILIENT: Stent Fractures Rates low but not absent

<table>
<thead>
<tr>
<th>Fracture Type</th>
<th>Total 0-18 Months</th>
<th>≥ 2 Overlapping Stents</th>
<th>Stent Elongation at Deployment</th>
<th>Locations*</th>
<th>Lesion Moderate - Severe Calcification</th>
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</thead>
<tbody>
<tr>
<td>Type I</td>
<td>6</td>
<td>1 of 6</td>
<td>1 of 6</td>
<td>MMMMD</td>
<td>3 of 6</td>
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<tr>
<td>Type II</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Type III</td>
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<tr>
<td>Type IV</td>
<td>6</td>
<td>4 of 6</td>
<td>6 of 6</td>
<td>MMMMP</td>
<td>4 of 6</td>
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</tbody>
</table>

Fractured Stents: 1, 9, 12
Fracture Rate: 0.3%, 3.1%, 4.1%

* Fractures / 291 Stents evaluated by the Angiographic Core Lab
* Per Core Lab Analysis at 6, 12, & 18 Months; M=Mid SFA, D=Distal SFA, P=Popliteal

RESILIENT: Study Device

LIFEStent® Vascular Stent

Helically-Designed, Nitinol Self-Expanding Stent

Device Sizes Use in the Trial:
• 6 & 7 mm Diameters; 40, 60, 80 mm Lengths
Approved lengths today include:
• 100, 120, 150, 170, & 200 mm
Ever since I started learning Angiology one thing I have learned for sure is that “Paradigms in SFA treatment keeps on Changing“
For Example:
Long CTO
Option No 1

This is what most of us may land up doing

Long Stenting
Option No 2

SPOT Stenting
Do We Have Some Comparison?
Outcomes of spot stenting versus long stenting after intentional subintimal approach for long chronic total occlusions of the femoropopliteal artery.

196 limbs in 163 patients, implanted with BMS after subintimal in long femoropopliteal occlusions (lesion length 25 ± 8 cm)

- Spot stenting (n = 129) and long stenting (n = 67)
- Primary patency at 2 years: 77% vs 47% (p < 0.001)
- Freedom from TLR at 2 years: 84% vs 52% (p < 0.001)
- Long stenting was an independent predictor of restenosis (HR: 2.0)
- Long stenting involving the P2 or P3 segment of the popliteal artery was associated with 7.5-fold increases in restenosis risk (p < 0.001)
Result

2 Year Follow up

Spot Stenting

Long Stenting

PP

TLR

77% ± 47%

84% ± 52%
So Spot Stenting does work?
Option No 2

SPOT Stenting

Not Full Proof
Only Spot Stenting
or
Spot Stenting with some Adjuvant
Adjuvants?

- Drug-coated Balloons (DCB) with spot stenting for long femoropopliteal CTOs after subintimal recanalization.
- A DCB with or without atherectomy for the distal segment of the femoropopliteal artery.
- A new self expanding interwoven nitinol stent (Supera) for the treatment of popliteal lesions.
### 12-month Effectiveness Outcomes (Primary Patency)
**INPACT SFA vs. Levant 2**

<table>
<thead>
<tr>
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<th>IN.PACT DCB</th>
<th>PTA</th>
<th>p</th>
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<tbody>
<tr>
<td>Primary Patency (PSVR ≤ 2.4)</td>
<td>82.2%</td>
<td>52.4%</td>
<td>&lt;0.001</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th>Lutonix DCB</th>
<th>Standard PTA</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Primary Patency (PSVR ≤ 2.4) @365 days</td>
<td>73.5%</td>
<td>56.8%</td>
<td>0.001</td>
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</table>

### Meta-Analysis of Drug-Eluting Balloon Angioplasty and Drug-Eluting Stent Placement for Intrainguinal Peripheral Arterial Disease

**Mark Otto Baerlocher, MD, FRCPC, Sean Alexander Kennedy, BSc, Mohammad Reza Rajebi, MD, Felix J. Baerlocher, PhD, Sanjay Misra, MD, David Liu, MD, FRCPC, and Boris Nikolic, MD**

**Abstract**

**Purpose:** To perform a meta-analysis of randomized controlled trials (RCTs) of drug-eluting balloon (DEB) angioplasty and drug-eluting stents (DESs) for infrainguinal peripheral arterial disease.

**Materials and Methods:** Systematic searches were performed for all relevant RCTs.

**Results:** Eight RCTs for DEB angioplasty and 12 RCTs for a DES in peripheral arterial disease were identified. Meta-analysis demonstrated statistically significant superiority of DEB over plain balloon angioplasty of femoral-popliteal disease for late lumen loss, restenosis, and target lesion revascularization, with no benefit in major amputation or mortality. Statistically significant superiority of DEB over percutaneous transluminal angioplasty (PTA) was demonstrated for infrainguinal disease for restenosis and target lesion revascularization. Drug-eluting stents showed statistically significant superiority over bare metal stents (BMSs) of femoral-popliteal disease for late lumen loss and restenosis, with no benefit in mortality or amputation. Drug-eluting stents showed statistically significant superiority over BMSs of infrainguinal disease restenosis and target lesion revascularization, with no benefit in amputation or mortality.

**Conclusions:** Drug-eluting balloon angioplasty and DESs demonstrated superior outcomes compared to PTA and BMS, with no difference in amputation or mortality.
For Example

Lutonix® Drug Coated Balloon Catheter
Mechanism of Action

1. **30 second** minimum inflation transfers drug to endoluminal surface delivering a therapeutic dose.

2. PTX diffuses into the arterial wall from an endoluminal reservoir.

3. Over time, therapeutic drug levels are sustained in deep cell layers after endothelial drug levels become sub-therapeutic.

4. **Drug continues to inhibit restenosis** in arterial wall while allowing the lumen to restore and re-endothelialize.
Adding Atherectomy to DCB

• Calcium is the Achilles heel of endovascular therapy.
• Vessel prep is helpful for Better drug uptake
• Hence one of the cause of failure of DCBs is attributed to Calcium
• Huge study DCB + Atherectomy is awaited
SUPERB Trial: Evaluated the safety and effectiveness of Vasculomimetic Supera stent system for the treatment SFA & proximal PopA.

RESULT: Primary patency at 12 months (360 ± 30 days) was achieved in 78.9% (180/228) of the population (P < 0.001). Primary patency by Kaplan-Meier analysis at 12 months (360 days) was 86.3%. No stent fracture was observed by independent core laboratory analysis in the 243 stents (228 patients) evaluated at 12 months. Clinical assessment at 12 months demonstrated improvement by at least 1 Rutherford-Becker category in 88.7% of patients.
Our Institutional Algorithm

- **Severe Ca++**
  - Woven stent
  - Ather + DEB
- **None or Mod Ca++**
  - POBA
    - successful
      - DEB
    - Unsuccessful
      - If long: Woven
        - If Short: BMS
For Example:
Post Spot stenting of focal stenosis and DEB of Popliteal lesion
CONCLUSION

✓ Nailing a SFA lesion is a “Challenge”
✓ There is no “one-size-fits-all” approach
✓ Advantage of Spot stenting and use of adjuvants such as DCB may provide better results in challenging SFA lesions-Results from prospective studies are awaited e.g PARADE Trial?

PARADE Trial

Comparison of PrimAry Long Full Coverage Stenting vs Primary Short Spot Stenting for Long Femoropopliteal Artery Disease

Principal Investigator: Donghoon Choi

- Multicenter, Randomized, Controlled Trial
- Hypothesis:
  Primary long full coverage stenting is superior to primary short spot stenting in the treatment of long (≥8 cm) femoropopliteal artery lesions
THANK YOU FOR PATIENT LISTENING
SFA Spot Stenting

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