Long Segment SFA ISR is Best Treated Endovascularly: What Are The Best Current Endovascular Tools?

Craig M. Walker, MD, FACC, FACP
Chairman, New Cardiovascular Horizons
Clinical Professor of Medicine
Tulane University School of Medicine
New Orleans, LA
Clinical Professor of Medicine
LSU School of Medicine
New Orleans, LA
Founder, President, and Medical Director
Cardiovascular Institute of the South
Houma, LA
Clinical Editor
Vascular Disease Management
Global Vascular Digest

What is In-Stent Restenosis (ISR)?
- Restenosis is usually secondary to intimal in-growth in a fully expanded stent and reocclusion usually has superimposed thrombus. (Several investigators have noted increased incidence when stent fractures are present.)
- Infrequently ISR is secondary to an under-expanded stent
- Historically treatment of long diffuse disease and occlusions with PTA resulted in very poor patency.

Rationale of ISR Therapy
- Suboptimal results with balloon angioplasty are common
- Dilatation of intimal hyperplasia compresses water from the aqueous extra-cellular matrix, however rehydration ensues typically within one hour.
- Thrombotic material may embolize.
- Elastic recoil (NO POSITIVE REMODELING as the fully expanded stent won't enlarge)
- Suboptimal results occur with repeat bare metal stenting within ISR
- Embolization
- No barrier to intimal ingrowth/ won’t seal pseudo aneurysms
- Lumen compromised by at least the stent strut thickness
- Mechanical stabilization of fractured stents with either covered stents or Nitinol stents is probably crucial. Full stent expansion is mandatory.
- There are three FDA approved therapies for ISR that may be utilized alone or in conjunction (308 nm Excimer Laser/Gore Viabahn Device/ DCB).

Disclosures
- Consultant
  - Philips
- PVD Training
  - Philips
- Stockholders
  - Cardiva
  - Medtronic
  - Boston Scientific
- Medical/Scientific Boards
  - Spectranetics
  - Boston Scientific
  - Abbott
- Speaker’s Bureau
  - Abbott
  - Cardiva
  - DSILity
  - Amgen
  - Spectranetics

Treating FemPop In-Stent Restenosis
- Factors to consider before attempting FemPop, in-stent restenosis intervention.
  - Length of lesion
  - Location of lesion (in-stent or edge stenosis)
  - Stenosis versus occlusion
  - Acuity of symptoms (old vs. new thrombus)
  - Is the stent fully expanded or compressed
  - Type of stent (covered vs. bare metal)
  - Stent fractures
  - Runoff vessel status
  - Location in the artery
  - Vessel Diameter

EXCITE ISR
(308 nm excimer laser atherectomy to treat ISR)
Principal Investigators
Eric Dippel, MD
Craig Walker MD
Laser atherectomy is superior to PTA alone for treatment of Femoropopliteal ISR

<table>
<thead>
<tr>
<th>Primary Endpoints</th>
<th>ELA</th>
<th>PTA</th>
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<tbody>
<tr>
<td>Freedom from TLR</td>
<td>90.8%</td>
<td>85.6%</td>
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<tr>
<td>Freedom from TLR</td>
<td>78.1%</td>
<td>73.8%</td>
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Lesion Length and TLR

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<tr>
<th>Lesion Length (cm)</th>
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<tr>
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<td>0.96</td>
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In-Stent Restenosis

- 2.0 Turbo Elite Pilot Channel
- 8 Fr Turbo Booster
- 6.0x300 VascuTrak balloon

Before Laser Atherectomy

After Laser Atherectomy

GORE VIABAHN Endoprostheses for In-Stent Restenosis — RELINE Clinical Study

Prospective, randomized trial conducted at seven centers in Europe

GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface® versus PTA for treatment of in-stent restenosis of the SFA.

**Primary Patency**

Superior primary patency with GORE VIABAHN Endoprostheses in the pre-protocol analysis (shown below), intent-to-treat analysis, and in comparison to optimal PTA cohort.

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Primary Patency

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Randomized comparison of Viabahn vs. PTFE femoral-popliteal bypass (McQuade, JVS, 2010)

<table>
<thead>
<tr>
<th>GORE VIABAHN Endoprosthesis (n = 50)</th>
<th>ePTFE or Dacron Bypass (n = 50)</th>
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<tbody>
<tr>
<td>Diameter 5.7 mm</td>
<td>7.4 mm</td>
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<tr>
<td>Length 25.6 cm</td>
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<tr>
<td>TASC II A and B</td>
<td>TASC II C and D</td>
</tr>
<tr>
<td>n = 39</td>
<td>n = 35</td>
</tr>
<tr>
<td>TASC II C and D</td>
<td>n = 11 (22%)</td>
</tr>
<tr>
<td>TASC II D</td>
<td>n = 15 (30%)</td>
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<tr>
<td>Patency 1 Year</td>
<td>Patency 2 Year</td>
</tr>
<tr>
<td>72%</td>
<td>63%</td>
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<td>83%</td>
<td>74%</td>
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<td>80%</td>
<td>60%</td>
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<td>82%</td>
<td>70%</td>
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- One-year outcomes from the IN.PACT Global ISR Imaging Cohort were presented at last year’s VIVA meeting: the primary patency rate was 68.7% the clinically-driven target revascularization (CD-TLR) rate was 7.3%, outcomes that begin to approach what has been seen in the coronaries.

- Based on this data DCB’s were approved for treating ISR

**Medtronic’s IN.PACT Drug-Coated Balloon**

- RCT laser+DCB (n=24) vs. DCB n=24
- All diabetic CLI and total occlusions
- Treated stent length and lesion length >20cm
- 100% crossing success
- Complications:
  - Distal embolizations: 3:
    - Laser+DCB: 1 (4%), DCB: 2 (8%)
  - Zero perforations
  - Zero dissections

**Combination Therapy (Laser + DCB) vs. DCB Alone**

- 12 months result: Laser + DCB had much better outcomes

**12 months result:**
- Laser + DCB vs. DCB
- Patency Freedom from TLR
  - Laser + DCB: 66.7% vs. DCB: 50.0%
  - P ≤ 0.01
- Limb salvage Freedom from amputation
  - Laser + DCB: 91.3% vs. DCB: 92.0%
  - P = 0.03

**THERE IS A NEW PARADIGM FOR ISR INTERVENTION**

- PTA has been shown to be inferior to DCB/Viabahn/Laser
- Patency rates with each of these new therapies is better than with PTA alone.
- Combination therapy seems to be promising (first clean out the stent then either reline or treat with DCB).
- Patency rates approach those reported with PTFE bypass.
- Sparing vein for future BTK bypass if needed is probably prudent.
- Intervention is less invasive and can be repeated
- THESE NEW INTERVENTIONS ARE THE BEST TREATMENT FOR FEMORAL-POPLITEAL ISR.