Rethinking Stent Designs and Techniques for Use in the SFA: What does the future hold?

Brian G. DeRubertis, M.D., F.A.C.S
Associate Professor of Surgery
Division of Vascular Surgery
David Geffen School of Medicine at UCLA

Disclosures
In the last 12 month I have served as a consultant, speaker, proctor or served on an advisory board for the following companies:
- Abbott Vascular
- Boston Scientific
- Cook Medical
- Medtronic

Balloon Angioplasty
- 12m Primary Patency of 30-50%

Self Expanding Laser Cut Nitinol Stents
- 12m Primary Patency of 60-70%

Problems with Nitinol Stents:
- Not designed for the SFA or vascular beds
- Most are laser cut from cylindrical nitinol tubes
  - Limited flexibility or tolerance for torsion
  - Minimal kink resistance
- Stent properties may contribute to late failures
- Stent failures can have implications to re-treatment

Stent fractures occur in most series of nitinol stent use in the SFA and are associated with loss of patency

Excisional Atherectomy
- 800 pts (CLI and Claudicants)
- Prospective Registry design
- Core lab adjudication, lesion length
- 12mo Primary Patency of 79%
- Bailout stent rate 3%

Drug-coated Balloons
- 331 patients (Claudicants)
- RCT compared to PTA alone
- Core lab adjudication, lesion length
- 12mo Primary Patency of 89.9%
- Bailout stent rate 7.3% (in DCB arm)
Rethinking Stent Design & Techniques

Leaving Nothing Behind Approach

**Inflation Time**

<table>
<thead>
<tr>
<th></th>
<th>30sec</th>
<th>180sec</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major dissection</td>
<td>16</td>
<td>5</td>
<td>.019</td>
</tr>
<tr>
<td>Minor or no dissection</td>
<td>21</td>
<td>32</td>
<td>.010</td>
</tr>
<tr>
<td>Further interventions</td>
<td>20</td>
<td>9</td>
<td>.017</td>
</tr>
<tr>
<td>Stent</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Repeat balloon dilation</td>
<td>16</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>12</td>
<td>5</td>
<td>.097</td>
</tr>
</tbody>
</table>

Decreased rate of major and minor dissections, and decreased need for repeat angioplasty/stenting with longer inflation times (3min vs 30sec)

**Scaffolds still needed, likely at rates proportional to lesion complexity**

- **Stent %**
- **Lesion Length (cm)**

**Rethinking Stent Design & Techniques**

When stenting, Which Scaffold to Use?

- Mechanical scaffolding remains necessary in complex “real-world” lesions
- “Full metal jackets” of the SFA is now recognized as a less than ideal treatment paradigm in most patients
- Stents should provide the mechanical characteristics we desire without serving as a source of chronic inflammation / irritation to the vessel

**Contemporary Laser Cut Stent Design**

- Spacing of interconnecting bars and position of strut angles are designed for optimizing radial force and flexibility
- Paclitaxel and polymer coating
- MAJESTIC Trial: 0% stent fractures, 96% primary patency (mean lesion 7cm, 65% severe calcification)

**Common to all of these new stent designs, however, is the fact that they are laser cut from cylindrical nitinol tubes**
Rethinking Stent Design & Techniques
New Concept in Stent Design

- Improved flexibility
- Increased kink resistance
- Tolerance for longitudinal loading w/o displacement

Tigris Stent (WL Gore)

GORE Tigris Stent – Leipzig Experience
- Retrospective analysis in 32 patients
- Mean stented length 6.3 cm
- Primary patency
  - 6mo: 91.7%
  - 12mo: 85.5%

Rethinking Stent Design & Techniques
New Concept in Stent Design

Amount of intimal hyperplasia correlated to stent oversizing

Chronic outward radial force from stent oversizing may be an important contributor to vessel irritation and intimal hyperplastic response

Rethinking Stent Design & Techniques
New Concept in Stent Design

Supera Stent (Abbott Vascular)

Optimal
1.1 - 1.3 : 1

Medium
1.3 - 1.6 : 1

High
1.6 - 1.9 : 1

Chronic Outward Force Compression Resistance

Supera vs standard laser cut nitinol stents

Supera performance in severe calcification and long lesions

% of Lesions with Severe Calcification (SUPERB Trial)
45% (n=118)

Primary Patency (VIVA 12 months)
99%

91% Primary Patency and 97% freedom from TLR when nominally deployed (12mo)

Superb Study Overview:
- 264 subjects (ITT), 34 sites
- Prospective single-arm vs PTA OPG
- Core laboratory adjudicated
- 72% moderate / severe calcification
- Lesion length 7.8 cm, 66% mid/distal SFA
- Zero stent fractures at one year
- 12m Primary Patency: 86.3%
Rethinking Stent Design & Techniques

**Final Frontier in Stent Design**

- **Restenosis**
  - Biologic Factors
  - Mechanical Factors
  - Chronic Vessel Inflammation

- Ideal Platform: *drug delivery in a temporary scaffold*
- Would allow anti-restenotic therapy and scaffolding for mechanical sources of failure
- Resorption of the scaffold would prevent chronic vessel irritation and promote vascular remodelling

BioResorbable Vascular Scaffolds

- **ESPRIT** (Abbott Vascular)
- **ABSORB** (Abbott Vascular)
- Combination of bioresorbable PLLA scaffold and drug elution with everolimus
- Not commercially available currently
- Have been studied in SFA (ESPRIT Trial) and BTK (Ramon Varcoe, MD)

Conclusions

- Paradigm shift away from “full metal jacket” of the SFA by use of new techniques (long PTA inflation) and devices (atherectomy, DCB)
- Need for scaffolding continues in long and complex lesions
- Next generation stents offer improved results over last decade’s laser cut nitinol stents
- Bioresorbable technology with drug elution may be the next frontier both above and below the knee

Division of Vascular Surgery
University of California, Los Angeles
UCLA Ronald Reagan Medical Center
Los Angeles, California