Superficial Femoral Artery Occlusion: Recanalization Techniques

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SFA: Prime target (and model) for CTO

- The Superficial Femoral Artery (SFA) is the most common site of peripheral arterial involvement
  - Leading cause of claudication (read: significant experience)
  - Disease tends to be “mirrored” in the contralateral limb

- Occlusions:
  - 3 times more common than stenoses in the SFA and they are frequently 20-30 cm long
  - ~50% of SFA disease is occlusive
  - Reliable collaterals via profunda femoris to the geniculate vessels to popliteal artery

- Plaque in the distal SFA (Adductor canal) becomes occluded, and the occlusion propagates retrograde to the next largest branch point, the profunda femoris
  - Plaque is bulky, calcified, and typically has a admixture of atheroma and organized thrombus
  - Adventitia represents 70%-80% of vessel strength
SFA CTO

- Profunda femoris
- SFA occlusion
- Geniculate collaterals
- Adductor canal
- Popliteal artery
Micro CT scan of a CTO

The challenge of the CTO
CTO Crossing
Definition of Success: a Proposal

- **Overall Crossing Success**
  - Overall crossing success measured by gaining wire access to the distal true lumen.

- **Secondary Success**
  - Bail-out technique, often using a re-entry tool to access the distal true lumen from a subintimal channel
  - Introduce: “Re-Entry Ratio”
    - Utilization rate of Re-Entry devices in CTO crossing cases
    - Ex. 1:5 – 1 Re-entry device used for every 5 CTO cases
Re-Entry Ratio Significance

- Re-entry catheters are important adjuncts to crossing devices
  - Secondary, bail-out devices should your initial CTO crossing effort take a “wrong turn”.
- A low Re-Entry ratio (1:30) means:
  - Low re-entry device utilization and high central lumen success
    - Re-entry devices are being used only 1 in 30 cases
- Central lumen navigation:
  - Maximizes subsequent therapeutic options
    - Atherectomy, balloon and stent utilization
• Success rates with wire and catheter vary widely (26%-100%), averaging 70%-80%
  ▪ However much of this literature is 10-20 years old and unlikely to represent the complexity of lesions being approached today (lack of nitinol stents, covered stents, re-entry devices, etc)
• Subintimal passage rates are not well described
SFA plaque volume=distal embolization?

Incidence and clinical significance of distal embolization during percutaneous interventions involving the superficial femoral artery

Russell C. Lam, MD, Syed Shah, MD, Peter L. Faries, MD, James F. McKinsey, MD, K. Craig Kent, MD, and Nicholas J. Morrissey, MD,

New York, NY

Conclusion: While ES were recorded at each step of SFA intervention, the frequency was greatest during stent deployment. Despite the frequency of these events, only one patient developed angiographically and clinically significant embolization. Thus, our findings do not support the routine use of protection devices during percutaneous SFA intervention. (J Vasc Surg 2007;46:1155-9.)
Assessment of true lumen re-entry devices

- 87 CTO: 58 iliac and 29 SFA
- Previous attempts failed
- 26% true lumen could not be re-entered
  - Iliac (34%) > SFA (13%)
- Re-entry ratio (devices successful in all cases)
  - Overall: 4:1
  - Iliac 3:1
  - SFA 8:1

Jacobs et al. JVS 2006 June;43(6):1291-6
Frontrunner use in endovascular CTO

- Prospective evaluation of the Frontrunner in 36 patients in aiding in recanalizing CTO’s
- Previous attempts at CTO had failed
- No determined effort or ability to maintain a central lumen passage

Achievement of primary endpoint: 91%

<table>
<thead>
<tr>
<th>Location of CTO</th>
<th>Successful recanalization</th>
<th>Failed recanalization</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac</td>
<td>21</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>CFA</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>SFA</td>
<td>14</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>Popliteal</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Terminal aorta</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>4</td>
<td>44</td>
</tr>
</tbody>
</table>

Length (cm): 9 ± 7 (Successful), 14 ± 6 (Failed), 9.5 ± 7 (Total)
Calcification grade: 1.8 ± 0.1 (Successful), 2.3 ± 0.5 (Failed), 1.9 ± 0.9 (Total)
Adjunctive therapy and adverse events

- **Adjunctive Rx:**
  - Re-entry catheter use: 35% (RER 3:1)
  - Stent implantation: 85%

- **Adverse events**
  - No deaths
  - No perforations
  - One stent thrombosis
Peripheral CTO Options

- Glidewire manipulation
  - Subintimal angioplasty and re-entry
- FrontRunner Catheter
- FlowCardia Crosser
- Subintimal Re-entry Devices
  - Lumend Outback and Medtronic Pioneer
- Step-By-Step Laser Technique
The CROSSER System

FlowCardia Generator

- Converts AC power into high frequency current
- Piezoelectric crystals within the Transducer convert high frequency current into vibrational energy
- Foot switch activates System
CROSSER Catheter Attributes

- **Front Line Therapy**
  - Use before guidewire attempt to avoid subintimal path

- **Enables Central Lumen Crossing of CTO’s**
  - Blunt, atraumatic CROSSER tip is 3x guidewire diameter
  - Short, 4 RBC (20µ) stroke depth with CROSSER
  - CROSSER takes path of most resistance
    - CROSSER most effective against in-elastic material

- **Central Lumen Navigation Maximizes Therapeutic Options**
  - Optimizes Atherectomy, PTA & stenting
PATRIOT: US Pivotal Study

85 Guidewire refractory, peripheral CTO Patients

- **84% CROSSER success rate** in guidewire resistant CTOs
- 0% CROSSER Clinical Perforations
- 94.1% Freedom from limb loss, clinical perforation & repeat revascularization through 30 days (80/85)

### CTO Specs
- 63.5% SFA & Above
- 20.0% Popliteal
- 16.5% Tibial/Peroneal
- **117.5mm Long**
- 16.0 Months Old
- 75.0% Mod/Severe Calcium

### Procedure Detail
- **2min 6sec Avg CROSSER Activation**
- 36 min Fluoro Time Avg
- 102 min Procedure Time Avg
Central Lumen IVUS Run
Post CROSSER Catheter CTO Recanalization

CROSSER/IVUS case courtesy of Tom Davis, MD, St. John’s Hospital, Detroit, MI
Frontrunner XP blunt dissection catheter

- FRONTRUNNER® XP CTO Catheter
  - .039” distal tip & crossing profile when jaws closed
  - 2.3 mm maximum diameter when jaws open
  - 90cm & 140cm lengths
  - Braided, hydrophilic shaft with shapeable distal tip
Outback re-entry catheter
Device Specifications

- Second generation device
- 5.9 F profile
- 6F sheath compatible
- .014” guidewire compatible
- 120 cm length
- 22 gauge re-entry cannula
Pioneer catheter for US guided re-entry
Dominant method

- Sub-intimal tracking and re-entry (STAR)
  - Glidewire (0.035” straight) as far as can be delivered
  - Glidewire (0.035” angled) is looped---tightly---and used to bluntly dissect the subintimal space
  - Re-entry distally is accomplished by “feathering” into the true lumen
  - Where re-entry is not possible (calcification), re-entry devices are useful (~5% of cases)
  - With this algorithm, ~95% of CTO’s are successful, usually in a matter of a few minutes
SFA CTO: Glidewire Method
SFA CTO: “Dead-end”
Re-entry Devices: Outback
SFA CTO: Outback Re-entry
SFA CTO: Frontrunner method
SFA CTO: Combined method
Laser Step-By-Step Approach
Sub-intimal tracking: US guidance
Sub-intimal tracking: US guidance
Sub-intimal stent deployment

Plaque

Prior stent
Relevance of central lumen passage

- Opens other therapeutic options:
  - Atherectomy
- Reduced stent usage
- Setting the stage for DEB availability?
Conclusions

As compared to coronary CTO, peripheral CTO:

- Has considerably greater:
  - Plaque volume
  - Length
  - Calcification
  - Thrombus

- Has less:
  - Tortuosity
  - Concern regarding dissection perforation
Conclusions

• The mechanistic causes of occlusion appears to be distal occlusion and proximal cap
• Greater tool selection reflects both the greater challenge, greater tolerance, and better “visibility” of procedure
  ▪ STAR the “rule”, re-entry tools enable success
• Accordingly, success rates in experienced hands are >95% with very limited complication
• The concept of central lumen passage appears to be a potentially important one if drug coated balloons prove effective vs. PTA
  ▪ ?DCB efficacy in stented segments
Thank you
Two 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
    - All adjunctive devices designed to operate in the arterial lumen