Endovascular Treatment of Aortoiliac Occlusive Disease: What’s in My Toolbox in 2018

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Disclosures

• Research support and royalties, Cook Inc.
TASC A and B Aortoiliac Disease

- Endovascular therapy first line treatment
- One year primary patency rates > 95%

TASC C Aortoiliac Disease

- Surgery is preferred treatment for good-risk patient with type C lesion
- Need to consider patient’s co-morbidities and operator’s success rate when making treatment recommendations
TASC D Aortoiliac Disease

Type D lesions:
- Infrarenal aortoiliac occlusion
- Diffuse disease involving the aorta and both iliac arteries requiring treatment
- Diffuse multiple stenoses involving the unilateral CIA, EIA, or EFA
- Unilateral occlusions of both CIA and EIA
- Bilateral occlusions of EIA
- Iliac stenoses in patients with AAA requiring treatment and not amenable to endovascular placement or other lesions requiring open aortic or iliac surgery

- Surgery is treatment of choice for type D lesion

Endovascular First: TASC C/D Lesions

- High technical success rate with modest morbidity
  - Newer available technologies
  - Increased experience and skill set: results should get even better

- Re-interventions can be performed percutaneously
  - Secondary patency rates comparable to open surgery

- Still candidate for conventional surgical therapy
  - If outcome does not meet expectations, not much lost
Endovascular Treatment: TASC C/D Aortoiliac Disease

• Access:
  - Ipsilateral retrograde
  - Contralateral crossover
  - Bilateral femoral
  - Brachial access
  - Combined femoral/brachial approach
  - Hybrid approach: open femoral endarterectomy

• Crossing techniques:
  - Subintimal angioplasty
  - Re-entry devices
  - CTO devices

Endovascular Treatment of AIOD: Potential Complications

• Vessel wall perforation
• Dissection
• Avulsion of vessel from aorta
• Embolization
• Access site complications
State of the Art Imaging Equipment

Endovascular AIOD Toolbox

- Wide range of wires, catheters, and balloons
  - 0.014, 0.018, 0.035
- Re-entry devices
- CTO devices
- Stents
  - Uncovered and covered
  - Self-expanding and balloon expandable
- Stent-grafts
- Available vascular surgeon nearby
Re-entry Devices

- Outback LTD/Elite Catheter (Cordis)
- Pioneer Plus Catheter (Philips)
- Enteer Re-entry system (Medtronic)

Outback LTD
- 6 F sheath compatible
- Visible L and T markers to orient re-entry cannula
- 22-gauge nitinol re-entry cannula
- 0.014 wire compatibility
- 120 cm length

Outback Elite
- Enhanced control and precision from ergonomic handle
- Also available in 80 cm length
Outback Catheter

Make sure catheter is adjacent to vessel

Point "L" marker toward true lumen

- Position image intensifier so that "L" marker is >1cm beyond point of reconstitution
- Point L marker toward true lumen

Tune the "L" Marker

Confirm the "T" Marker is over the vessel and at least 1cm beyond the point of reconstitution

- Move the image intensifier to 90 degree view
- Ensure catheter is "in line" with true lumen
- Fine tune catheter to display full "T" marker

Tune the "T" Marker

Deploy the cannula in the "L" view

- Deployed cannula
- Advance 0.014 wire through the cannula tip
- Retract the cannula tip into the catheter

Deployed cannula
Chronic Left Common Iliac Artery Occlusion

- Ipsilateral retrograde and contralateral antegrade access
- Subintimal plane
- Multiple unsuccessful attempts to re-enter true lumen in aorta
Chronic Left Common Iliac Artery Occlusion

- Outback Re-entry device

Chronic Left Common Iliac Artery Occlusion

- Balloon-expandable kissing stents
- Additional self-expandable stent into L CIA
Pioneer Plus Re-entry Catheter

- IVUS-guided re-entry into true lumen
- 6French sheath, 120 cm working length, 0.014” wire
- Adjustable 24 gauge needle depth (3mm, 5mm, 7mm)

Pioneer Re-entry Catheter

1. Insert the Pioneer Plus catheter over the 0.014” suboptimal guidewire.
2. Use IVUS to precisely target reentry. IVUS is used in order to localize the true lumen by the presence of flow. The Pioneer Plus catheter should be rotated so the true lumen (identified by the ChromaFlo feature) is at the 12 o’clock position.
3. Deploy the rotolo needle to create a pathway to the true lumen.
4. Advance a non-hydrophilic 0.014” guidewire through the needle into the true lumen. This guidewire will be used to facilitate the placement of subsequent catheters after the Pioneer Plus catheter is removed.
5. Retract the needle and remove the Pioneer Plus catheter. The vessel is now ready for additional interventions.
Enteer Re-entry System

- 0.014 and 0.018 guidewire compatibility
- 2 balloon sizes, 3 guidewire options
- When inflated, flat shaped balloon orients toward true lumen in subintimal space
- 180° and offset exit ports allow guidewire to re-enter into true lumen

Chronic Total Occlusion Devices (True Lumen Devices)

- Frontrunner (Cordis)
- Crosser (Bard)
- Wildcat (Avinger)
- TruePath (Boston Scientific)
- Viance (Medtronic)
**Frontrunner CTO Catheter**

- NOT an over the wire system
- Used with microcatheter (advancing and retracting allows variable support)
- Blunt microdissection to create a channel
- Open the jaws, push against the cap and break it, then push it forward in closed position
- Shapeable distal tip (0.039” crossing profile, jaws open to 2.3mm)
- May be helpful with calcific lesions
- 90 cm and 140 cm

**Crosser CTO Catheter**

- Utilizes high frequency mechanical vibration
- Available over the wire and rapid exchange
- Crosser catheter connected to the Crosser Generator through high frequency transducer
- Foot switch used to activate system (capital equipment)
Wildcat Catheter

- Rotation device
- Spinning distal tip
- Wedges guide through tougher plaque or can act as an anchor
- Juicebox attachment (optional power supply to facilitate catheter tip rotation)
- 2mm crossing profile
- 110 cm working length, 6 Fr sheath, 0.035" wire compatible

TruePath CTO Device

- Diamond-coated distal tip rotating at 13,000 rpm
- 0.018" diameter
- No capital equipment
Viance Crossing Catheter

- Multi-wired coiled shaft with atraumatic tip
- Catheter is rapidly spun using a torque device to facilitate advancement through lesion
- Flexible or standard catheters
- 5Fr sheath compatible
- Working length of 150 cm and tracks over 0.014” guidewire
- No capital equipment

Endovascular Rx of Extensive AIOD

- Stents
  - Balloon-expandable in common iliac artery
  - Self-expanded in external iliac artery
- “Kissing” stents
  - Balloon-expandable stents
  - Uncovered vs covered
- Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) technique
  - Balloon-expandable covered stents
- Stent-grafts
  - Endologix AFX
## Systematic Review

### Table III. Summary of data obtained from the included studies

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<th>First author</th>
<th>Year</th>
<th>N</th>
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NcAID: number of patients with extensive atherosclerotic occlusive disease (AOD); NR, data not retrievable for patients with extensive AOD; NS, not stated in the article.

- 19 nonrandomized studies with 1711 patients; 1329 with extensive AID
- Technical success reported in all studies: range 86% to 100%

Jongkind et al; JVS 2010

## Systematic Review

### Table IV. Primary and secondary patency rates

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C: results for patients with TASC type C lesions; D: results for patients with TASC type D lesions; PP: primary patency; SP: secondary patency.

- 1-year primary patency rates: 70%-97%
- 1-year secondary patency rates: 88%-100%
- 4- or 5-year primary patency rates: 60%-86%
- 4- or 5-year secondary patency rates: 80-98%

Jongkind et al; JVS 2010
**Systematic Review**

Table III. Summary of data obtained from the included studies

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N of ADOD: Number of patients with extensive aortic occlusive disease (ADOD). NR, data not retrieved for patients with extensive ADOD; NS, not stated in the article.

- No perioperative or 30-day mortality in 12 studies
- 7 studies reported mortality rate ranging from 1.2%-6.7%

**Meta-Analysis of Endovascular treatment of TASC C/D Lesions**

**Technical outcome**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Studies (n)</th>
<th>Patients (n)</th>
<th>Technical success (%)</th>
<th>Technical success 95% CI</th>
<th>Heterogeneity Q (P)</th>
<th>I² (%)</th>
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Ye et al; JVS 2011
Meta-Analysis of Endovascular Treatment of TASC C/D Lesions

Ye et al; JVS 2011

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Studies (n)</th>
<th>Patients (n)</th>
<th>12-month primary patency (%)</th>
<th>12-month primary patency 95% CI</th>
<th>Heterogeneity</th>
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<td>82.5-90.9</td>
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<td>$P = 0.01, I^2 = 70%$</td>
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</table>

Covered vs Bare Balloon Expandable Stents

- Benefit of covered stents:
  - Reduce intimal hyperplasia
  - Less thrombogenic than BMS?
- Numerous reports demonstrate promising results
- One randomized trial: Covered Versus Balloon Expandable Stent Trial (COBEST)
  - 168 iliac arteries in 125 patients with TASC B/C/D lesions
  - Randomly assigned to receive Advanta V12 covered stent (Atrium) or commercially available bare metal balloon expandable stents
  - Follow-up at 1, 6, 12, and 18 months
COBEST: Primary Outcomes

Freedom from binary restenosis

Mwipatayi et al; JVS 2011

COBEST: Freedom From Binary Restenosis*

TASC C/D group

*More TASC D lesions in covered stent group

Mwipatayi et al; JVS 2011

TASC B group
Covered Ballon-Expandable Stents

- iCast stent (Atrium) – U.S. version of the Advanta V12
- Viabahn VBX stent (Gore)
  - First FDA-approved balloon-expandable covered stent for use in the iliac artery
- Lifestream stent (Bard)
  - FDA-approved for use in iliac artery

Systematic Review of Kissing Stents to Treat AIOD

- 1,390 patients in 21 studies
- 48% of TASC C/D lesions
- Significant heterogeneity in types of stents
  - Self-expanding, balloon-expandable, uncovered, covered
- 98.7% technical success rate
- 10.8% complication rate (mostly minor)
- 89% 1-year, 79% 2-year primary patency

Jebbink et al; Ann Vasc Surg 2017
Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB)

- Balloon expandable stents in distal aorta and common iliac arteries to rebuild the aortic bifurcation
- Rationale:
  - Positioning of kissing stents results in discrepancy between stented lumen and aortic lumen
  - This causes flow perturbations and thrombus formation, which may decrease stent patency
  - CERAB minimizes this discrepancy, and is less invasive than bifurcated stent-graft

Jebbink et al; J Vasc Surg 2015

Still Photos

Angiography

Kissing stents  CERAB

Bronchoscopy

Kissing stents  CERAB

Jebbink et al; J Vasc Surg 2015

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Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) Technique

- 9Fr and 7 Fr sheaths into common femoral arteries
- Recanalization of occlusive lesion(s)
- 12mm V12 balloon-expandable covered stent (Atrium) in distal aorta 20 mm above bifurcation
- Proximal 2/3 of aortic stent flared with 16 mm balloon
  - Creates funnel shaped covered stent
- Two covered stents (usually 8 mm) placed into the distal 1/3 of aortic stent and into the common iliac arteries
- Distal extensions added as necessary

Grimme et al; Eur J Endovasc Surg 2015
CERAB: Clinical Outcomes

- 130 patients from 2 centers in Europe, 89% with TASC D lesions
- 97% technical success
- 30-day mortality: 0%
- Median follow up: 24 months
- 30 day minor and major complication rate was 33% and 8%
  - 3 cases: stent collapse in one of the limbs
  - 2 cases: early thrombosis of CERAB
  - 1 case: femoral artery occlusion
  - 1 case: renal failure
- 86% primary patency at one year; 82% primary patency at 3 years

Taeymans et al; J Vasc Surg 2017

Stent-grafts to Treat Extensive AIOD

- Narrow distal aorta limits use of many stent grafts
  - May be overcome by unibody stent-graft concept
  - Preserves anatomical bifurcation
- Endologix AFX is bifurcated unibody graft with short, integrated iliac limbs
  - Avoids need to cannulate contralateral gate
Endologix AFX To Treat Extensive AIOD

- Total distal aortic occlusion
- Recanalization from one iliac artery to the other
- Cross femoral wire
- Recanalization of aorta from one of the iliac arteries
- Kissing balloons to fully expand iliac limbs and AFX main body
- Adjunctive iliac stenting often required

Maldonado et al; Eu J Vasc Endovasvc Surg 2016

Pros:
- Preserves native aortic bifurcation
- May be better than kissing stents in heavily calcified aortic bifurcations or those with thrombus
- Protective in cases of rupture
- Sits on aortic bifurcation – future “up and over” interventions may be less technically challenging
Endologix AFX To Treat Extensive AIOD

- **Cons:**
  - Larger sheath profile than kissing stents or CERAB (17 Fr ipsilateral sheath, 9Fr contralateral; AFX2 now with 7Fr contralateral)
  - Coverage of collateral vessels
  - Requires high level of endovascular technical skill
  - Cobalt chromium component of graft lacks sufficient radial force - high rate of adjunctive stenting
  - More expensive than kissing stents or CERAB
  - Outside of device IFU
  - 22 mm is smallest graft
  - PTFE on outside of stent; material moves independently of stent; guidewire can inadvertently get caught between graft and stent

Endologix AFX To Treat Extensive AIOD

- Multicenter retrospective review of 91 patients with AIOD using the AFX device
- 74/91 (81%) with TASC D lesions
- 100% technical success
- 1% 30-day mortality from extensive pelvic thromboembolism
- 22% complication rate
  - 6 groin infections, 4 hematomas, 4 vessel ruptures, 4 dissections, 3 thromboembolic events
- 9 patients required 16 secondary interventions
- 1 year primary patency: 91%

Maldonado et al; Eu J Vasc Endovasc Surg 2016
Endovascular Treatment of Extensive AIOD: What Should be in Your Toolbox?

- Depends on how aggressive you want to be...
- Access to advanced imaging equipment
- Wide variety of wires, catheters, balloons
- Wide range of stents
  - Uncovered and covered
  - Self-expanding and balloon-expandable
- Re-entry device(s)
- CTO device(s)
- Aortoiliac stent-grafts
  - Endologix AFX