Disease of the femoral and popliteal veins

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FP Disease

- Reflux
- Obstruction
- Reflux + Obstruction
Anatomic Considerations

**Iliac-CFV obstruction** significant contributor to PTS – Main venous outflow of the leg

**FP disease** may lead to severe PTS - Main outflow for the below knee limb
Hemodynamic Considerations

The role of venous outflow obstruction in patients with chronic venous dysfunction
PTS Risk Factors

- More central disease: > ambulatory venous pressures
- Higher ambulatory pressures > severity of PTS

That doesn’t mean **infra-inguinal** disease is benign

Indeed, **axialization of the profunda** is not always adequate
PTS: Prevalence with F-P DVT

• 950,000 VTE cases/yr in US
• 18% Iliac veins - 60% PTS: 100K
• 55% fem-pop segment – 30-40% PTS: 150-200K

### Effect of Venous Thrombus Location and Extent on Developing PTS

CEAP classification in patients with vein thrombosis in multiple segments

<table>
<thead>
<tr>
<th>Segment</th>
<th>Total</th>
<th>Class 0-1</th>
<th>Class 2-3</th>
<th>Class 4*</th>
<th>Class 5-6</th>
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</thead>
<tbody>
<tr>
<td>IF ± IVC</td>
<td>9</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>IF + fem-pop</td>
<td>10</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>IF + fem-pop + calf</td>
<td>13</td>
<td>0</td>
<td>6</td>
<td>5</td>
<td>2</td>
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<tr>
<td><strong>Fem-pop</strong></td>
<td>19</td>
<td>5</td>
<td>8</td>
<td>4</td>
<td>2</td>
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<tr>
<td><strong>Fem-pop + calf</strong></td>
<td>28</td>
<td>2</td>
<td>18</td>
<td>6</td>
<td>2</td>
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<tr>
<td><strong>Total</strong></td>
<td>79</td>
<td>10</td>
<td>40</td>
<td>21</td>
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</table>

30% Advanced CVI

F-P disease can be devastating
Standard Of Care of CVD due to F-P disease

AC, ECS, elevation & wound care = Not enough

Consider FP - intervention

GOAL OF INTERVENING ON CHRONIC FP disease:
- Restore flow
- Decrease venous pressures
- Subsequently the severity of PTS
Patients with F-P disease:

- Severe PTS
- Failed conservative Rx: AC + ECS
- QOL Limitations
- Candidates for Intervention

What are the options?
## Reflux - Valve Options 2018

<table>
<thead>
<tr>
<th>INDICATION: INSUFFICIENCY</th>
<th>VALVE TYPE</th>
<th>INSERTION</th>
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<tbody>
<tr>
<td>PRIMARY</td>
<td>BICUSP</td>
<td>OPEN</td>
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<tr>
<td>PRIMARY</td>
<td>BICUSP</td>
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<td>SECONDARY PRIMARY</td>
<td>BICUSP</td>
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</tr>
<tr>
<td>SECONDARY</td>
<td>MONOCUSP (BICUSPID)</td>
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<tr>
<td>SECONDARY PRIMARY</td>
<td>MONOCUSP (DIFFERENT)</td>
<td>PERC</td>
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<tr>
<td>SECONDARY</td>
<td>MONOCUSP</td>
<td>PERC</td>
</tr>
<tr>
<td>SECONDARY PRIMARY</td>
<td>MONOCUSP</td>
<td>OPEN</td>
</tr>
</tbody>
</table>
#1 - Sail Valve

- Percutaneous
- Monocusp – sort of
- PTFE
- Physiologic leak
Sail Valve Study

• Iliac veins – 10 pigs

• Femoral vein access – 6 Fr.

• Deployment 100% - expands to 10mm

Sail Valve – Results 4 weeks

- Ascending venogram – all patent
- Descending venogram 8 valves
  - 5 competent
  - 1 partial
  - 2 incompetent malposition/tilt
- Histology – no macroscopic thrombus on valve
# 2 Endovenous Valve Formation System: EVFS

- Percutaneous
- Monocusp
Surgical Predicate – The Maleti Neovalve

Maleti, Lugli, Perrin
Techniques chirurgicales - Chirurgie vasculaire 2009
BlueLeaf™ Endovenous Valve Formation System
Autologous Leaflet Creation in 3 Steps

1. Identify Valve Site (IVUS)
2. Sub-intimal Access (Hydrodissection)
3. Leaflet Creation (Custom Tools)
History and Current Status: 4 Human

- **Gen 1 Development:** 5 acute animals, 40+ cadaveric studies

- **First In Human Clinical Trial:**
  - 2 cases (Holden/Hill, New Zealand)
  - Technical success in 2 of 2 cases
  - Follow-up data was informative as to iterations required on product design, clinical protocol and post-procedural management

- **Gen 2 Development and Validation Testing:**
  - 50+ cadaveric tissue studies for design iteration
  - 3 GLP chronic animal studies complete for IDE
  - Pre-clinical testing for extended feasibility study in process
#3 - VenoValve

- Porcine derived - from heart valve

- **monocusp/open** – 8-10mm

- Hancock-Jaffe Labs – 20 yrs heart valves

- Can tailor inflow/outflow size mismatch*

Valve implant and insertion: sheep EJV
Venotomy closure and implant
Ascending/Descending Venogram EJV: PATENCY
Animal Studies - Status

• 8 valves implanted – 30 day assessment

• External jugular sheep – 8mm (2), 10mm (2)

• Common iliac dogs – 8mm (2), 10mm (2)

• Anticoagulation – enoxaparin (sheep), ASA/Plavix (dogs)
Follow Up

• At 5 days and 30 days:
  - Sheep evaluated for patency with duplex ultrasound of the devices
  - Dogs evaluated with IVUS and ascending venography to evaluate patency and any evidence of migration.
  - Feasibility trial in United States – 2019 C5/C6
    Elias/Gasparis: Principal Investigators
Obstruction

“Chronic” DVT – post-thrombotic changes

**Misnomer:** “Chronic DVT” is not thrombus but rather organized, dense fibrotic tissue comprised of type I & III collagen

*Comerota, A et al. JVS 2010 52, 243-247*
F-P Obstruction

Potential Options in the management of F-P obstruction

• Venous bypass
• Venous stenting
• Venous angioplasty
• Open endovenectomy

Comerota, A et al. JVS 2010 52, 243-247
The ACCESS PTS Trial:
**ACCElerated Thrombolysis** for **Post-Thrombotic Syndrome**
**Using the EKOS System**

**Patients**
- Iliofemoral DVT diagnosed ≥ 6 months
- PTS with a Villalta Score ≥ 8
- Failure of 3 months of conservative therapy

**Protocol**
- Balloon Dilatation of the occlusive DVT segments
- Infusion ≥ 12h Acoustic Pulse Thrombolysis™ (0.5 - 1.0 mg tPA/hr)
- Enoxaparin (1 mg/kg BID) for 48h prior to and up to 90d post treatment
ACCESS PTS

Primary endpoint
(reduction in Villalta Score ≥ 4 at 30d)

• met in 67% of patients
• 34% improvement in the signs and symptoms of PTS
• One major bleed occurred within 72h and one PE within 30d of the procedure

n = 73 patients, 77 limbs; 18 centers

Limitations: Included FP disease and IFP disease
12-Year-Old DVT
A 60 year-old male with non-healing ulcerations of the left ankle. Previous fem-pop DVT. Underwent EIV stenting, UGS, compression and local wound care with no significant improvement.

DU – post-thrombotic luminal changes in the fem-pop veins
Venogram Pre-intervention
Summary

• Fem-pop disease plays a significant role in venous hypertension and development of PTS in some patients
• Patients with Severe PTS and failed conservative treatment may be candidates for intervention
• Currently PTA/lysis is a minimally invasive option with the need in new technology to address some of the challenges in treating these patients
• New technology is coming to address reflux