Reconstruction Of The Aortic Bifurcation For Occlusive Disease The CERAB Procedure 3-Year Good Results; Advantages; Best Available Stent Grafts
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Aorto-iliac occlusive disease

• Open surgery still often still the preferred treatment modality for extensive disease
• Broad range in patency of kissing stents but mostly inferior compared to isolated stents
• Patency affected by geometrical factors:
  > Re-circulation, turbulence and stasis of blood
  > Mesenchymal tissue, thrombus and intimal hyperplasia


Covered Endovascular Reconstruction of the Aortic Bifurcation - CERAB

Goal: to provide a more anatomical and physiological endovascular reconstruction of the aortic bifurcation

Clinical results of CERAB

**Midterm outcome**

- February 2009 – July 2016
- 130 elective patients, two centers
- Age 61 (36-81) years, 69 male
- Chimney procedures excluded
- Previous aorto-iliac intervention in 41%

**Rutherford classification:**
- 1: n=1 (0.8%)
- 2: n=0 (0.0%)
- 3: n=86 (66.1%)
- 4: n=22 (17.3%)
- 5: n=18 (14.2%)
- 6: n=2 (1.6%)

**TASC-II classification:**
- B: n=7 (5.4%)
- C: n=7 (5.4%)
- D: n=116 (89.2%)

**Procedural complications:**
- Unintended dissection: n=6
- Bleeding: n=6
- Stent dislocation: n=5
- Stent deformation: n=3
- Thrombus formation: n=2

**Post-Procedural complications:**
- Pneumonia: n=3
- Stent deformation: n=3
- Stent thrombosis: n=2
- CVA occlusion: n=2
- MODS: n=2
- Renal insufficiency: n=1
- No 30-day mortality

**Median follow-up:** 24 months

**Total primary patency:**
- 12 months: 91%
- 24 months: 89%
- 36 months: 87%

**Secondary patency:**
- 12 months: 97%
- 24 months: 97%
- 36 months: 97%

**Clinical improvement at 36 months:** 96%

**Limb salvage rate at 36 months:** 97%

**Previous treatment of AIOD:**
- Surgical reconstruction of the aortoiliac segment (n=7);
- Endovascular intervention (N=46, 35%)
  - 46% PBA of the common iliac artery (17% kissing balloons)
  - 37% Stenting of the common iliac artery (31% kissing stents)

**Graft Material**
- ePTFE sleeve
- ePTFE film

**Stent Material**
- CoCr (L605) Stainless Steel

**Stent Graft Design**
- Single Stent
  - ePTFE sleeve clamped at stent ends
- Film-Cast Encapsulation (Stent encapsulated in ePTFE)

**Sheath Compatibility**
- 6F up to 8x57mm
- 7F for remaining sizes

**Guide Wire**
- 0.035" (6.5F (10mm + 12mm) 8F up to 11x79mm)

**Nominal Pressure**
- 9 bar (Ø5 - 7 mm)
- 8 bar (Ø8 - 10mm)

**Rated Burst Pressure**
- 13 bar (Ø5 - 7 mm)
- 12 bar (Ø8 - 10mm)

**Crimped Profile**
- 2.0 – 2.4mm

**Balloon expandable covered stents**
- BeGraft
- ePTFE sleeve
- LifeStream
- Viabahn BX

<table>
<thead>
<tr>
<th>Product</th>
<th>Diameter</th>
<th>Length</th>
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<tbody>
<tr>
<td>BeGraft</td>
<td>14 mm</td>
<td>60 cm</td>
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<tr>
<td>ePTFE sleeve</td>
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<td>60 cm</td>
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<tr>
<td>LifeStream</td>
<td>14 mm</td>
<td>60 cm</td>
</tr>
<tr>
<td>Viabahn BX</td>
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</table>
CERAB with different aortic stents

CERAB trial

• Prospective observational trial
• Sample size 145 patients
• 15 international sites
• CERAB using exclusively Bentley BeGraft stents
• Primary endpoints: technical success and primary patency at 12 months
• Secondary endpoints: patency, CD-TVR, re-interventions, clinical improvement, and QOL
• First enrollment anticipated in December 2018

Summary

• CERAB is related to the best geometry and most optimal flow patterns
• Clinical outcome is good up to three years using the Atrium V12 stents, but there are issues with availability of the LD Atrium V12 stent
• Alternatives are available and the choice now will mainly depend on availability, personal preference and costs
• Further studies are indicated to assess the outcome of alternative balloon-expandable covered stents

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