Global CERAB study: where are we standing?

Michel MPJ Reijnen, MD, PhD

Department of Vascular Surgery, Rijnstate Hospital Arnhem
Technical Medical Centre, University of Twente, Enschede
The Netherlands
Disclosures

Consultancy and/or Research Funding:

- Medtronic
- Bentley InnoMed GmbH
- Terumo Aortic
- Endologix Inc.
- W.L. Gore and associates
- Vascular Insights LLC
Kissing stent configuration

- 2-year primary patency; 81%
  - 84% intermittent claudication
  - 53% TASC A & B

Patency affected by:
- Radial mismatch
- Differences in stent conformation
- The protrusion length of the stents in the distal aorta
  - Re-circulation, turbulence and stasis
  - 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
Covered Endovascular Reconstruction of the Aortic Bifurcation - CERAB

- Comparison of CERAB patients with matched KS patients
- No difference in preoperative anatomy or indication for intervention
- Comparable D-ratio but significantly more mismatch in KS patients
- Data confirms the in-vitro data

<table>
<thead>
<tr>
<th>Method</th>
<th>Area (mm²)/volume (mm³)</th>
<th>CERAB mean (SD)</th>
<th>KS mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ellipse</td>
<td>Radial mismatch area</td>
<td>14.1 (4.2)</td>
<td>172.7 (70.0)*</td>
</tr>
<tr>
<td></td>
<td>Radial mismatch volume</td>
<td>307.7 (131.2)</td>
<td>7268 (3810.9)*</td>
</tr>
<tr>
<td>ROI</td>
<td>Radial mismatch area</td>
<td>11.0 (4.8)</td>
<td>165.8 (71.5)*</td>
</tr>
<tr>
<td></td>
<td>Radial mismatch volume</td>
<td>240(127.3)</td>
<td>7047.0 (3239.0)*</td>
</tr>
</tbody>
</table>

*denotes P <0.05

CERAB
Laser Particle Image Velocimetry

CERAB and BM kissing stents; Mostly laminar flow throughout the cardiac cycle

BM Kissing stents; turbulence and recirculation at phases B and C

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 %

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current smoking</td>
<td>100</td>
<td>78</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>46</td>
<td>35</td>
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<tr>
<td>Hypertension</td>
<td>96</td>
<td>74</td>
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<tr>
<td>Hyperlipidemia</td>
<td>121</td>
<td>93</td>
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<tr>
<td>Cardiac disease</td>
<td>61</td>
<td>47</td>
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<tr>
<td>Pulmonary disease</td>
<td>51</td>
<td>39</td>
</tr>
<tr>
<td>Carotid disease</td>
<td>26</td>
<td>20</td>
</tr>
<tr>
<td>Renal disease</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>ASA category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>73</td>
<td>57</td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td>39</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

*Taeymans K et al. J Vasc Surg 2018 May;67(5):1438-1447*
Clinical results of CERAB
Midterm outcome

<table>
<thead>
<tr>
<th>Rutherford classification:</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>n=1</td>
<td>0.8%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>n=0</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>n=84</td>
<td>66.1%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>n=22</td>
<td>17.3%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>n=18</td>
<td>14.2%</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>n=2</td>
<td>1.6%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TASC-II classification:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>n=7</td>
<td>(5.4%)</td>
</tr>
<tr>
<td>C</td>
<td>n=7</td>
<td>(5.4%)</td>
</tr>
<tr>
<td>D</td>
<td>n=116</td>
<td>(89.2%)</td>
</tr>
</tbody>
</table>

Taeymans K et al. J Vasc Surg 2018 May;67(5):1438-1447
Clinical results of CERAB

Major complications

- **Procedural**
  - Unintended dissection  n=6
  - Bleeding  n=4
  - Stent dislocation  n=1
  - Stent deformation  n=1
  - Thrombus formation  n=2

- **Post Procedural**
  - Pneumonia  n=3
  - Stent deformation  n=3
  - Thrombosis  n=2
  - CFA occlusion  n=1
  - MODS  n=1
  - Renal insufficiency  n=1

- **No 30-day mortality**
Clinical results of CERAB

Midterm outcome

- 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%

Taeymans K et al. J Vasc Surg 2018 May;67(5):1438-1447
Balloon expandable covered stents

- Issues with availability of large diameter Advanta V12
- Alternative BE covered stents are available

<table>
<thead>
<tr>
<th></th>
<th>Atrium Maquet V12</th>
<th>Bard Lifestream</th>
<th>Bentley BeGraft</th>
<th>Gore Viabahn BX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent material</td>
<td>316L Stainless steel</td>
<td>316L Stainless steel</td>
<td>CoCr (L605)</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>Graft material</td>
<td>ePTFE</td>
<td>ePTFE</td>
<td>ePTFE</td>
<td>ePTFE with Heparin surface</td>
</tr>
<tr>
<td>Porosity</td>
<td>≈55µm</td>
<td>10-40 µm</td>
<td>102±25 µm</td>
<td>N/A</td>
</tr>
<tr>
<td>Graft design</td>
<td>Completely encapsulated</td>
<td>2 Layers, sandwich</td>
<td>Single stent, external cover</td>
<td>Internal cover</td>
</tr>
<tr>
<td>Stent diameters (mm)</td>
<td>OTW: 5, 6, 7, 8, 9, 10 LD: 12, 14, 16</td>
<td>5, 6, 7, 8, 9, 10, 12</td>
<td>SV: 5, 6 MV: 7, 8 LV: 9, 10</td>
<td>5, 6, 7, 8, 9, 10</td>
</tr>
<tr>
<td>Stent lengths (mm)</td>
<td>OTW: 16, 22, 38, 59 LD: 29, 41, 61</td>
<td>5-8 Ø: 16, 26, 37, 58 9-12 Ø: 38, 58</td>
<td>SV: 18, 22, 28, 38, 58 MV: 18, 23, 27, 37, 57 LV: 27, 37, 57</td>
<td>5-7 Ø: 15, 19, 39, 59 8-10 Ø: 39, 59</td>
</tr>
<tr>
<td>Strut Dimensions (Strut Width x Strut thickness)</td>
<td>N/A</td>
<td>N/A</td>
<td>0.135 x 0.145 mm (SV) 0.145 x 0.145 mm (MV) 0.165 x 0.145 mm (LV)</td>
<td>N/A</td>
</tr>
<tr>
<td>Catheter length (cm)</td>
<td>80 and 140</td>
<td>80 and 135</td>
<td>75 and 120</td>
<td>80 and 135</td>
</tr>
</tbody>
</table>
CERAB with different aortic stents

- AdvantaV12™
- Lifestream™
- CP Stent™
- BeGraft™
CERAB global Registry

- International prospective multicenter trial
- 145 patients in 15 international sites
- CERAB using Bentley BE covered stents
- First enrollment Q1 2019

**Comparison of BeGraft and Advanta V12**

**BeGraft**
- Small cramped profile
- High stent retention force
- High flexibility without kinking
- Potential interaction with wire/sheath when re-entering

**Advanta V12**
- Larger cramped profile
- Lower stent retention force
- Reduced flexibility, prone to kinking
- No interaction with wire/sheath when re-entering
Primary endpoints:

• Technical success
• Primary patency at 12 months

Secondary endpoints:

• Technical: Patency, TLR, Conversion to open surgery
• Clinical: Freedom from Re-interventions, morbidity, SAE’s, Overall and reintervention-free survival, clinical improvement, health status (WIQ and EQ-5D)
Inclusion criteria

- Age 18 years or older
- Provided written informed consent
- Clinical necessity for treatment
- Eligible anatomy for CERAB without the need for chimney’s

Exclusion criteria

- Participating in another conflicting clinical study
- Life expectancy <2 years
- Psychiatric or other condition that may interfere with the study
- Known allergy to any device component
- Patients with a systemic infection who may be at increased risk of endovascular graft infection
- Coagulopathy or uncontrolled bleeding disorder
- CVA or an MI within the prior three months
- Pregnancy
CERAB global Registry

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Discharge</th>
<th>1 month (±15 days)</th>
<th>6 months (±30 days)</th>
<th>1 year (±60 days)</th>
<th>2,3,4 years (±90 days)</th>
<th>5-years (±90 days)</th>
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<tbody>
<tr>
<td>Physical exam</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X*</td>
<td>X</td>
<td>X*</td>
</tr>
<tr>
<td>Routine labs</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
<td>X*</td>
</tr>
<tr>
<td>CTA with contrast</td>
<td>X</td>
<td></td>
<td>X**</td>
<td>X*</td>
<td>X**</td>
<td>X*</td>
<td>X**</td>
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<tr>
<td>Duplex ultrasound</td>
<td>X</td>
<td>X*</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X*</td>
<td>X</td>
</tr>
<tr>
<td>ABI measurements</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pregnancy test (if appl.)</td>
<td>X</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Questionnaires</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Items marked with * are not mandatory, but preferred. These would be performed according to the local protocols of the institutions, items marked with ** at these time points either a duplex or a CTA should be performed. In case duplex US is not available in a participating site, CTA will be used for follow-up.
Summary

- CERAB is related to the best geometry and optimal flow patterns
- Clinical outcome is good up to 3 years using the Atrium V12 stents, but there are issues with availability of the LD Atrium V12 stent
- Alternatives are available and the choice will mainly depend on availability, personal preference and costs
- The prospective CERAB trial will provide robust evidence on the performance of the Bentley BE covered stent for this particular indication
Global CERAB study: where are we standing?

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