Insight in the German BEVAR approval study to get bridging stents approved for the indication

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:
☑ Consulting/Proctorship  Cook and Bentley
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest

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CMD- FEVAR/BEVAR:

Well-established for about 20 years.

Dedicated bridging stentgrafts are still missing!
Off-The-Shelf mBEVAR for TAAAs

Off the shelf:

T-BRANCH: Launched 9/2012

T-BRANCH (COOK)
- 34mm
- 202 mm
- 18 mm

Unibody
- 22 mm
- 81, 98, 115, 132 mm
SFH Münster results 2014

N = 150 pt
Mean FU 15 ±12.6 months

Freedom from occlusions
@3 years 85%

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<table>
<thead>
<tr>
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<th>N @ risks</th>
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<tbody>
<tr>
<td>CT</td>
<td></td>
<td>104</td>
<td>35</td>
<td>13</td>
<td>4</td>
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<tr>
<td>SMA</td>
<td></td>
<td>140</td>
<td>46</td>
<td>17</td>
<td>3</td>
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<tr>
<td>Renal Artery</td>
<td></td>
<td>275</td>
<td>94</td>
<td>35</td>
<td>5</td>
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</table>

Occlusions n=13 2.5%

CT 16%
SMA 15%
Renal artery 69%
Bench test of different BSG in a flat fenestrated model

Advanta V12™
Getinge

BeGraft™
Bentley

BeGraft+™
Bentley

V BX™
Gore

ePTFE outside

Kobaldchrom in between

Kobaltchrom inside

ePTFE inside

stainless steel (encapsulated)

ePTFE outside

Radial force
Kink-resistance

Flexibility

2015

2017

2017

Could all these Stentgrafts be used as Bridging stentgraft in FEVAR or BEVAR?
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BeGraft peripheral Plus - BEVAR Study

Branched Endocascular Aortic Repair (BEVAR)

Study Set-up:

*Prospective, single arm, multi-center, clinical trial investigating the BeGraft Peripheral Plus Stent Graft System as bridging stent in BEVAR for complex aortic aneurysms*

Primary Endpoints

*Technical success*

- successfully introduction and deployment of the BeGraft Plus (Bentley InnoMed) as bridging stent in BEVAR

  *Bridging stent patency at 12 months*, (24 month planned)

*Safety*

- Absence of procedure related complications and bridging stent related endoleaks at 12 months.
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BeGraft peripheral Plus - BEVAR Study

Secondary endpoints:
1. Bridging stent patency post-op and at 6-months
2. Freedom from bridging stent related endoleaks post-op and at 6 months
3. Freedom from bridging stent related secondary intervention
4. Freedom from type I & III endoleaks post procedure and at 6 and 12 months 30-day mortality
5. Freedom from stent graft migration, freedom of fracture or dislocation of bridging stent.
6. Freedom from AA diameter increase at 6 and 12 months as compared to post-op implantation
7. Freedom from aneurysm related secondary endovascular procedures
8. Freedom from aneurysm related secondary endovascular procedures
9. Freedom from conversion to open surgical repair post procedure and at 6 and 12 months
10. Freedom from aneurysm related mortality post procedure and at 6 and 12 months
11. Freedom from aneurysm rupture within 12 months post-implantation
12. Freedom from any major adverse events post procedural and at 6 and 12 months
13. Health Related Quality of Life scores at 12 months post implantation
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BeGraft peripheral Plus - BEVAR Study

Study Design:
Prospective, single arm, multi-center, clinical study
8 clinical centers
100 patients in total with appr. 250 BeGraft peripheral Plus implanted
Recruiting time: 12 month
12 month Follow-up
Additional 12 month follow-up planned

Status of Study:
• Clearance national authorities: August 2020
• First Patient In: 10.09.2020

➢ 100 patients
➢ 8 sites in Germany
  • Münster
  • Nuremberg
  • Leipzig
  • Hamburg
  • Munich
  • Regensburg
  • Aachen
  • Stuttgart
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**Procedure:**

The branched endograft should be positioned so that all target vessels can be reached using only 1 bridging stentgraft.

The BGP+ should cover at least the entire branch/cuff.

The balloon of the BGP+ should be inflated to reach at least the size of the target vessel.

Investigator should aim for a landing zone of 15mm (at least 10mm).

Renal arteries with >100° cranial orientation should be excluded.
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BeGraft Peripheral Plus

BeGraft Evolution

1. Generation BeGraft peripheral

2. Generation BeGraft peripheral

BeGraft peripheral Plus
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## Product Portfolio

<table>
<thead>
<tr>
<th>Expanded Stent Graft Diameter</th>
<th>Nominal Stent Graft Length (mm)</th>
<th>Introducer Sheath Compatibility</th>
<th>Catheter Lengths</th>
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<tbody>
<tr>
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<td>28, 38, 58</td>
<td>7F</td>
<td>120cm</td>
</tr>
<tr>
<td>6mm</td>
<td>28, 38, 58</td>
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<td>120cm</td>
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<tr>
<td>8mm</td>
<td>27, 37, 57</td>
<td>7F</td>
<td>120cm</td>
</tr>
<tr>
<td>9mm</td>
<td>27, 37, 57</td>
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<td>120cm</td>
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Performance Testing

Kink resistance – 90° bending

BeGraft peripheral Plus
Ø8 x 57mm
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Bench test of different BSG in a flat fenestrated model

Fatigue-Test:

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>After 10 Mio</th>
<th>After 50 Mio</th>
<th>After 100 Mio</th>
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Case: male, 68 Y. Pararenal aneurysm 62 mm
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Case: male, 68 Y. Pararenal aneurysm 62 mm
Take-home message:

Unique study to understand how the stentgraft BeGraft plus performs as a bridging stentgraft in BEVAR.

Chance to have an approved and dedicated bridging stentgraft in the future.

Hope that some more companies take care of this special indication for covered stentgrafts.
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Thank you for your attention!