Update on Optimal Bridging Stentgrafts for F/BEVAR: Advantages and Disadvantages of BeGraft, BeGraft PLUS and Advanta V12 (iCAST)

Experience with more than 2000 Target Vessels

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Disclosures

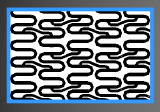
- William Cook Europe/Cook Inc.
  - Consultant & Research Grants
- Getinge
  - Consultant
- Bentley
  - Part of "Early Launch" Group of the BeGraft PLUS
  - PI of the on-label study BeGraft in FEVAR
  - Consultant

Advanta V12-ICAST (Getinge)

- For more than 15 years, the Advanta V12 balloon expandable covered stent has been trusted by physicians for its proven and reliable outcomes
- Available lengths: 22, 32, 38, 59mm
- Profile: 7F

Evolution Advanta V12-ICAST (Getinge)

New open cell stent design/Crimping Process on Balloon



Increased flexibility

Greater radial strength

Lower recoil
Lower crossing profile

Higher stent retention
Smooth inner surface

Nuremberg Experience with Advanta V12

(2010-2020)

- TAAA: N=426
  - Advanta V12: N=1202 (76.3%)
- Pararenal: N=582
  - Advanta V12: N= 1258 (92.3%)
- IBD: N= 130 (154 IBDs)
  - Advanta V12: N=123 (76.6%)

Total Advanta V12: 2583/3104 (83.2%)

Nuremberg Experience with Advanta V12

(Patients with FU in Nuremberg)

- TAAA: N= 231
- Pararenal: N= 405

Total Advanta V12: 1702

(1675 target vessels)


Long Term Outcomes of the Advanta V12 Covered Bridging Stent for Fenestrated and Branched Endovascular Aneurysm Repair in 1 675 Target Vessels

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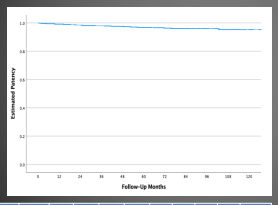
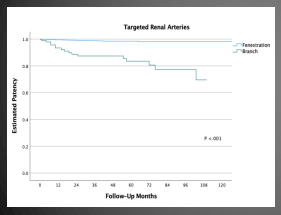
Target Vessel Patency
(N=1675)



Time (months)	12	24	36	48	60	72	84	96	108	120
Vessels at risk	1480	1257	1064	913	606	469	350	350	114	114

99.1 ± 0.2% at 1 year
96.9 ± 0.5% at 5 years
96.2 ± 0.7% at 8 years

Target Vessel Patency
Renal Arteries



- Fenestrations
  - 99.5 ± 0.2% at 1 year
  - 98.5 ± 0.4% at 5 years *
  - 98.2 ± 0.5% at 8 years *
- Branches
  - 93.4 ± 2.6% at 1 year
  - 83.5 ± 4.3% at 5 years *
  - 77.3 ± 5.9% at 8 years *

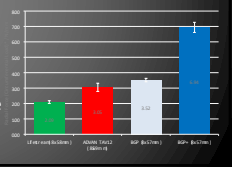
P<0.001*

BeGraft and BeGraft PLUS (Bentley)

- Clear interest in development of dedicated covered stents for Fenestrations and Branches
- Factory in Germany
- Reliable Logistics/Large Variety of Lengths

BeGraft and BeGraft PLUS (Bentley)

- BeGraft in Fenestrations
  - Available in all diameters and lengths
    - Lengths: 22/23, 27/28, 37, 57
  - 6F compatible
- BeGraft PLUS in Branches
  - High radial force, kink-resistant and flexible
  - 7F compatible



BeGraft & BeGraft PLUS
Nuremberg Experience (2017-2024): N=1548

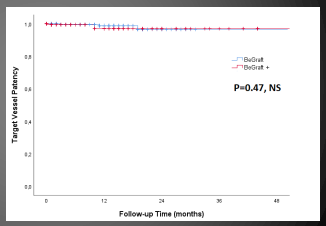
(Paper accepted by EJVES)

BeGraft: N= 669		BeGraft Plus: N= 332	
– F/BEVAR:	624	– F/BEVAR:	248
– IBD:	2	– IBD:	58
– F/B Arch:	11	– F/B Arch:	9
– Other indications:	32	– Other indications:	17

Target Vessel Patency

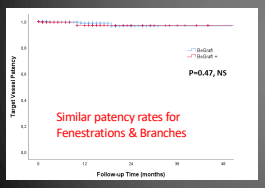
BeGraft Group
98.8 ± 0.9% at 1 year
96.5 ± 2.4% at 3 years

BeGraft PLUS Group
97 ± 1.8% at 1 year
97 ± 1.8% at 3 years

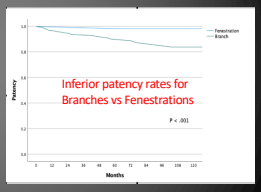


Comparison

BeGraft/BeGraft PLUS (N=872)

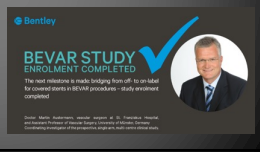


Advanta V12 (N=1675)



BeGraft PLUS: Preferred for Branches?

On the Way to on-label Bridging stent-grafts…



Trial Design

- Prospective, single arm, multi-center, clinical study
- 9 Clinical Centres in Germany
  Nürnberg (Verhoeven) / Münster (Austermann) / Munich (Tsilimparis) / Regensburg (Pfister) / Aachen (Kotelis) / Stuttgart (Geisbüsch) / Gießen (Kalder) / Freiburg (Czerny) / Hamburg (Kölbel)
- 100 Patients (expected: about 250 BeGrafts)

Objective

- To evaluate the safety and performance of the BeGraft balloon expandable covered stent Graft System (Bentley Innomed, Hechingen, Germany) implanted as bridging stent in FEVAR (fenestrated endovascular aortic repair) for complex aortic aneurysms

Primary Endpoints

- Efficacy endpoint
  a. Technical success, defined as successful introduction and deployment of the BeGraft
  b. Bridging stent patency at 12 months, defined as absence of restenosis (≥50% stenosis) or sole target vessel occlusion based on CT Angio at 12 months
- Safety endpoint
  – Absence of procedure related complications and bridging stent related endoleaks at 12 months.

Results

- Inclusion: Q1/2021-Q3/2023: N=103
- Patients: 90% male, mean age 72 (52-92)
- ASA III/IV: 82%
- Cook Fenestrated grafts: 86%
- 350 Vessels with BeGrafts (almost all 3x-4xFEVAR)
  – Deployment Issues: 1.14%

Patient Outcome

- Overall Mortality: N = 13 (13%)
  - Surgical Mortality: N = 1 (0.97%)
    - Died at day 25 due to MOF
- SAE: N = 75
  - Related to the device: N = 2
  - Related to the procedure: N = 25

Results at 12 months

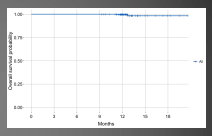
	Patients (n)	Occlusions per Patient
Patency at 12MFU	80	2 (2.44%)*

Patency at 1 Year per Vessel in 80 Patients: 274/276 (99.3%)

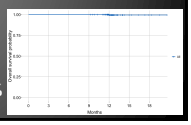
* 1 CT occlusion on DUS; 1 SMA Occlusion on CTA (both incidental findings – no clinical events)

1-Year Results: Primary Endpoints

- Efficacy endpoint
  a. Technical success: **97.4% (337/346)**
  b. Bridging stent patency: **99.3%**



- Safety endpoint
  - Absence of procedure related complications
    - SAE related to bridging procedure: N=13
    - SAE with relation to bridging stent: N=4
  - Absence of bridging stent related endoleaks: **99.6%**



Conclusions

- Fenestrations: BeGraft and Advanta V12 both EXCELLENT
- Branches: BeGraft PLUS seems superior to Advanta V12
- Overall, if compared, both have smaller advantages/disadvantages

- BeGraft now officially the first bridging stentgraft to achieve on-label indication in FEVAR.