Balloon-expandable bridging stent-grafts for F/BEVAR: Long-term Outcomes & Evolution

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Disclosures

- Cook Medical
  - Speaker & proctor fee
- W.L. Gore
  - Speaker fees
- Artivion
  - Speaker fees
- Bentley Innomed
  - Consultant

Cleveland Clinic Experience

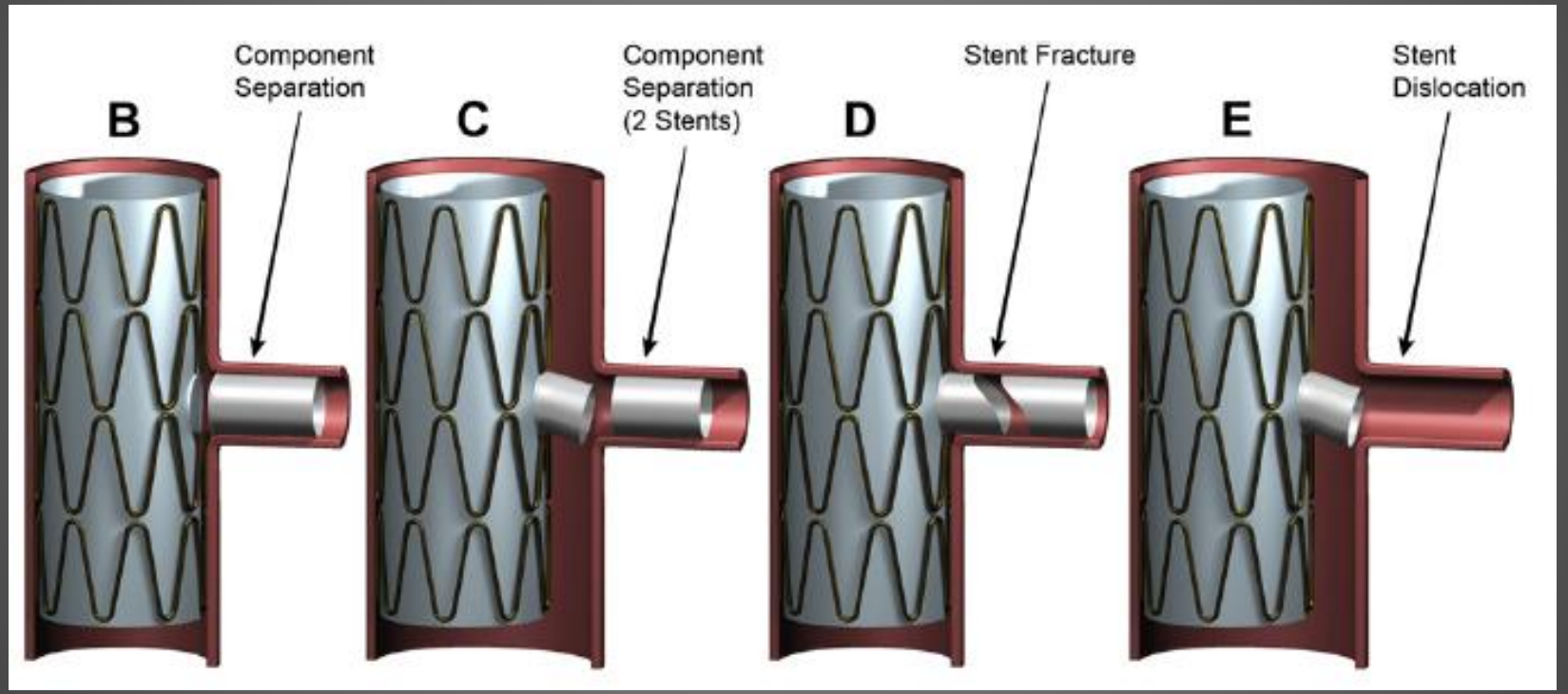
Durability of branches in branched and fenestrated endografts

Tara M. Mastracci, MD, Roy K. Greenberg, MD, Matthew J. Eagleton, MD, and Adrian V. Hernandez, PhD,
Cleveland, Ohio

(J Vasc Surg 2013;57:926-33.)

→ Bridging stents in F/BEVAR are durable are Rarely the Cause of Patient Death

Bridging stent Potential Problems



Mastracci et al. JVS 2013

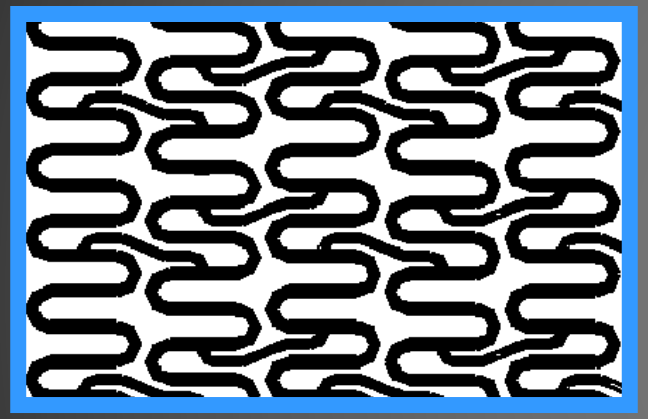
Balloon-Expandable Bridging Stents

Stent-type specific outcomes

Advanta V12

Evolution Advanta V12

New open cell stent design/Crimping Process on Balloon



Increased flexibility

Greater radial strength

Lower recoil

Higher stent retention

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

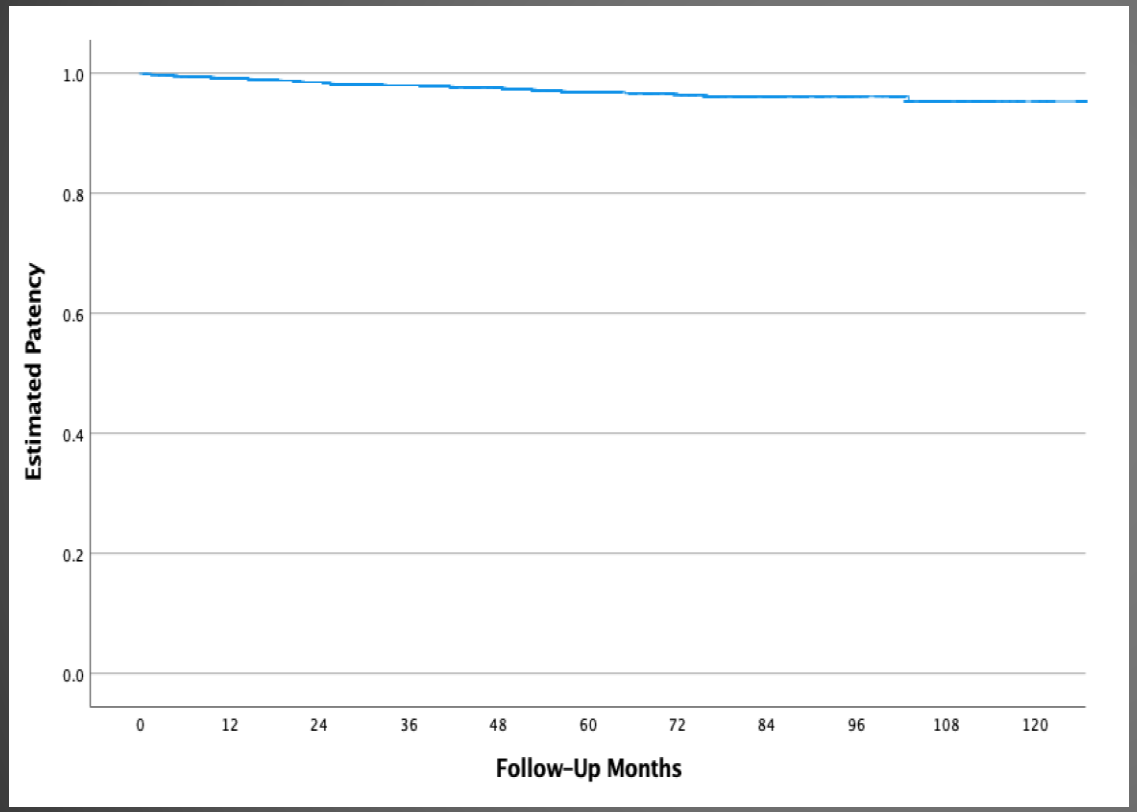
Athanasios Katsargyris *, Natasha Hasemaki, Pablo Marques de Marino, Melad Abu Jiries, Nargis Gafur, Eric L.G. Verhoeven

Department of Vascular and Endovascular Surgery, General Hospital & Paracelsus Medical University, Nuremberg, Germany

Eur J Vasc Endovasc Surg (2023) 66, 313–321

- 636 Patients (pts with F/U in Nuremberg)
  - 1675 Target Vessels

Target Vessel Patency



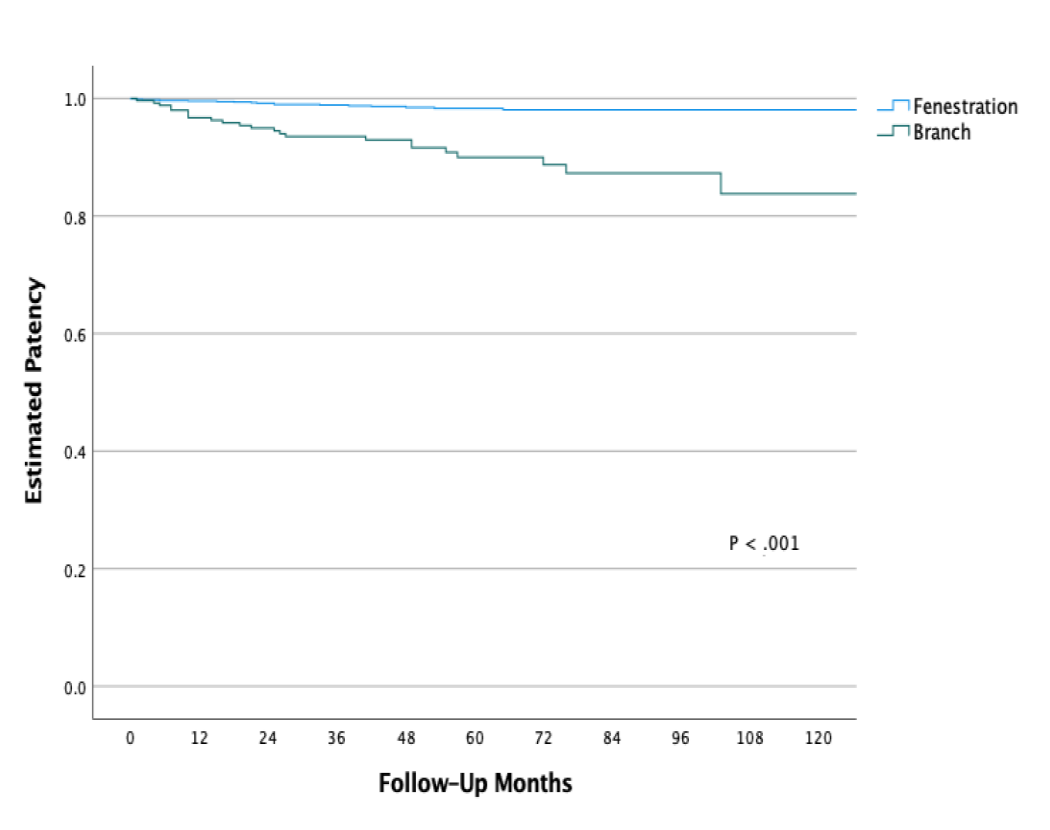
99.1 ± 0.2% at 1 year

96.9 ± 0.5% at 5 years

96.2 ± 0.7% at 8 years

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

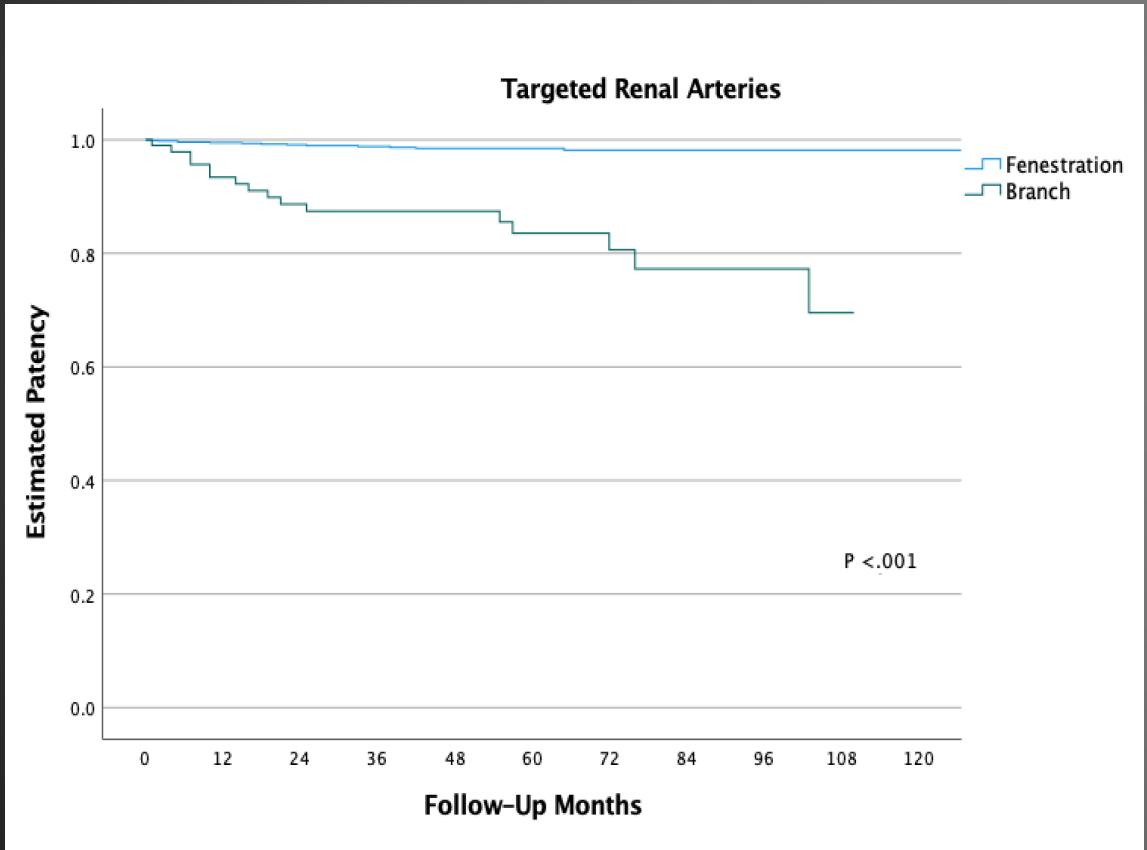
Target Vessel Patency



- Fenestrations
  - 98.3 ± 0.4% at 5 years
  - 98.1 ± 0.5% at 8 years
- Branches
  - 90.0 ± 2.2% at 5 years
  - 87.3 ± 2.9% at 8 years

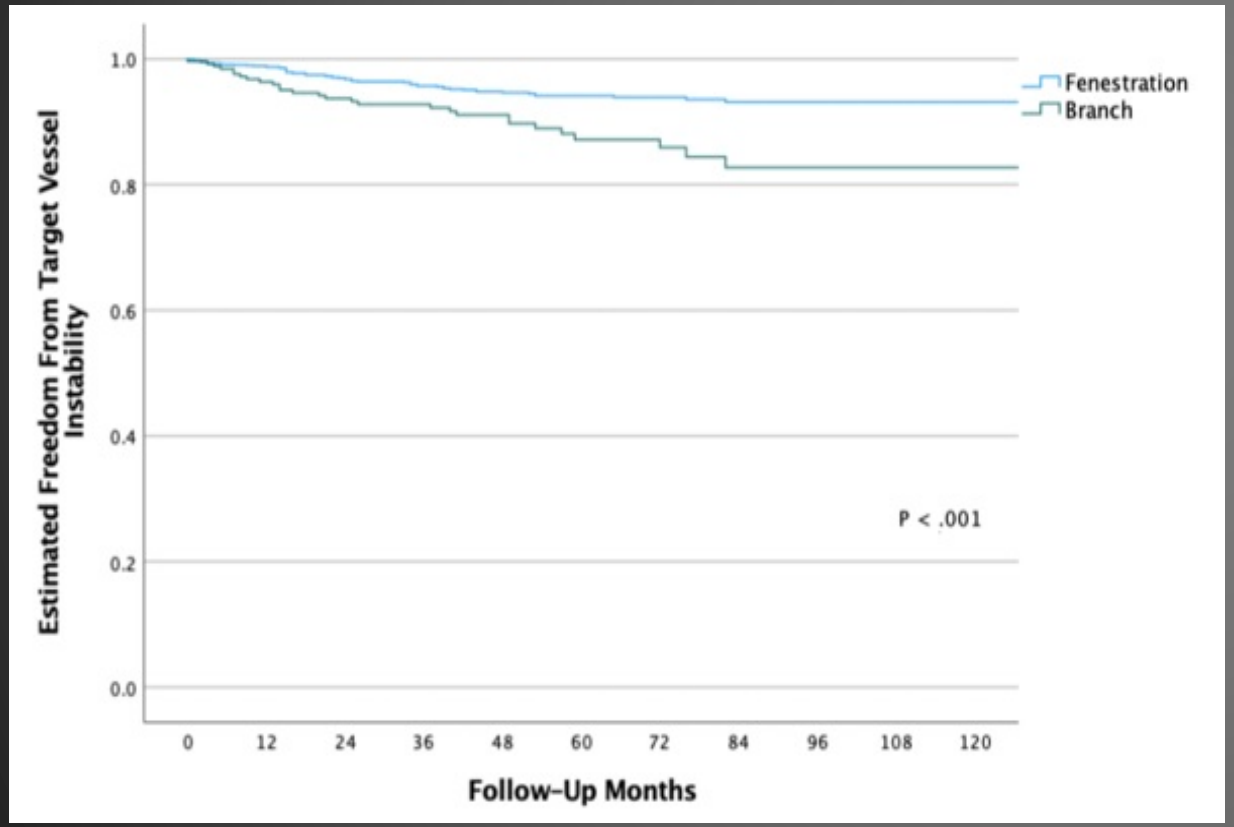
Target Vessel Patency

Renal Arteries



- Fenestrations
  - 98.5 ± 0.4% at 5 years
  - 98.2 ± 0.5% at 8 years
- Branches
  - 83.5 ± 4.3% at 5 years
  - 77.3 ± 5.9% at 8 years

Freedom from Target Vessel Instability



- Fenestrations
  - 94.1 ± 0.8% at 5 years
  - 93.2 ± 0.9% at 8 years
- Branches
  - 87.2 ± 2.5% at 5 years
  - 82.7 ± 3.5% at 8 years

Editor's Choice – 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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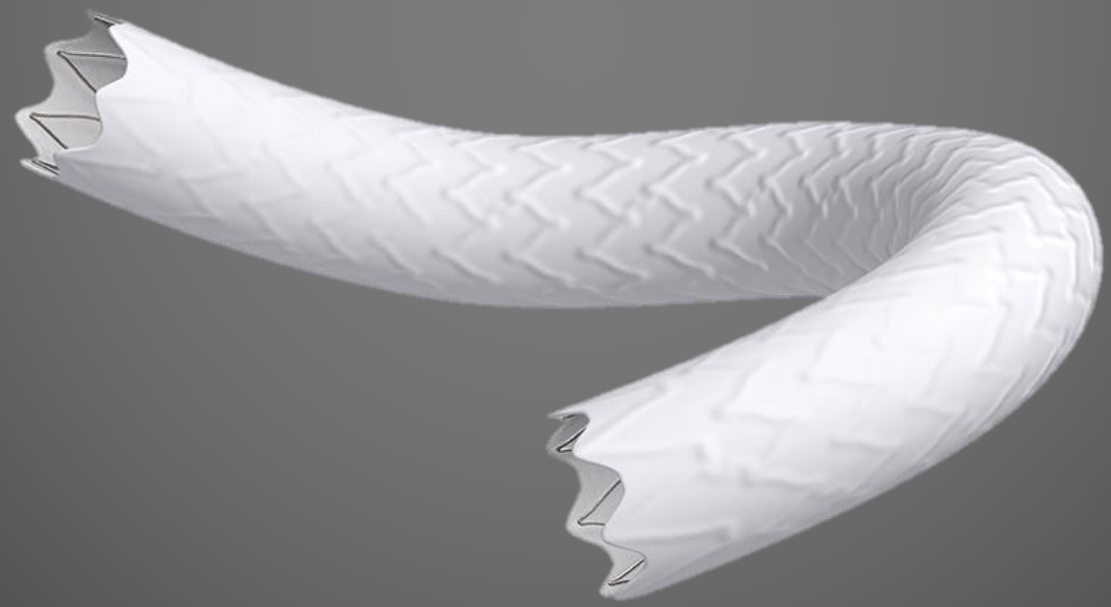
Eur J Vasc Endovasc Surg (2023) 66, 313—321

Conclusion: The Advanta V12 shows excellent technical success rates as a covered bridging stent in F/BEVAR. Late outcomes remain good with low rates of TV occlusion, endoleak, and re-intervention. Renal arteries targeted with branches demonstrated a higher risk of occlusion and instability compared with those targeted with fenestrations.

BeGraft & BeGraft Plus



BeGraft Evolution

BeGraft peripheral

2013

Launch BeGraft peripheral

BeGraft peripheral

2014

2015

Launch BeGraft peripheral
- modified design -

BeGraft Evolution

BeGraft peripheral

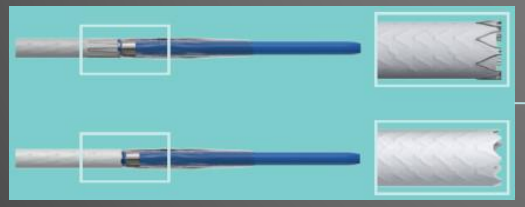
BeGraft peripheral

2013 — Launch BeGraft peripheral

2014

2015 — Launch BeGraft peripheral - modified design -

PTFE fixed at both stent ends



BeGraft Evolution

BeGraft peripheral

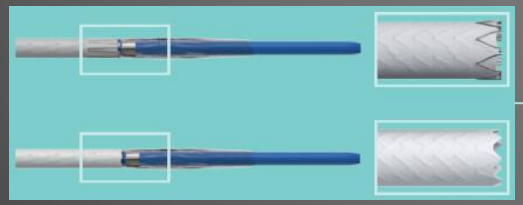
BeGraft peripheral

2013 — Launch BeGraft peripheral

2014

2015 — Launch BeGraft peripheral - modified design -

PTFE fixed at both stent ends



Increased PTFE thickness

BeGraft Evolution

BeGraft peripheral

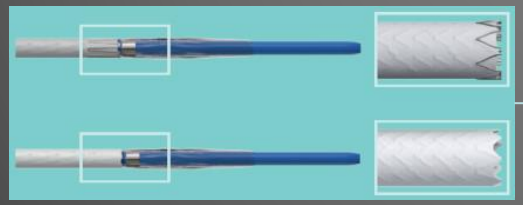
BeGraft peripheral

2013 — Launch BeGraft peripheral

2014

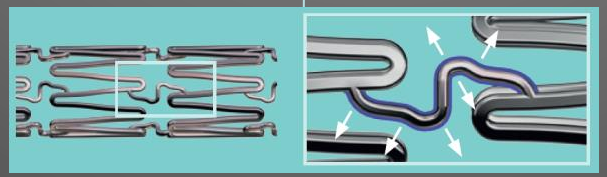
2015 — Launch BeGraft peripheral - modified design -

PTFE fixed at both stent ends



Increased PTFE thickness

Increased connector width to improve longitudinal stiffness



BeGraft Evolution

BeGraft peripheral

BeGraft peripheral

BeGraft+ peripheral

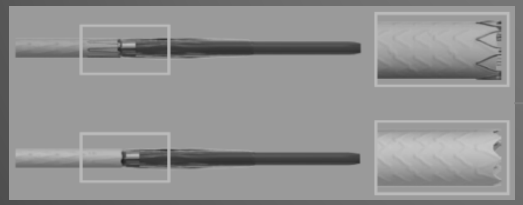
2013 2014 2015 2016 2017

Launch BeGraft peripheral

Launch BeGraft peripheral - modified design -

Launch BeGraft peripheral PLUS

PTFE fixed at both stent ends



Increased PTFE thickness

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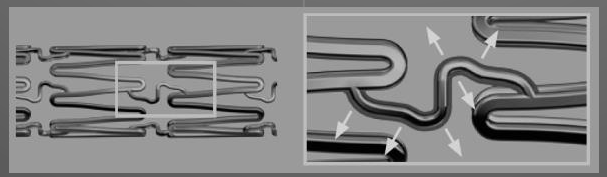
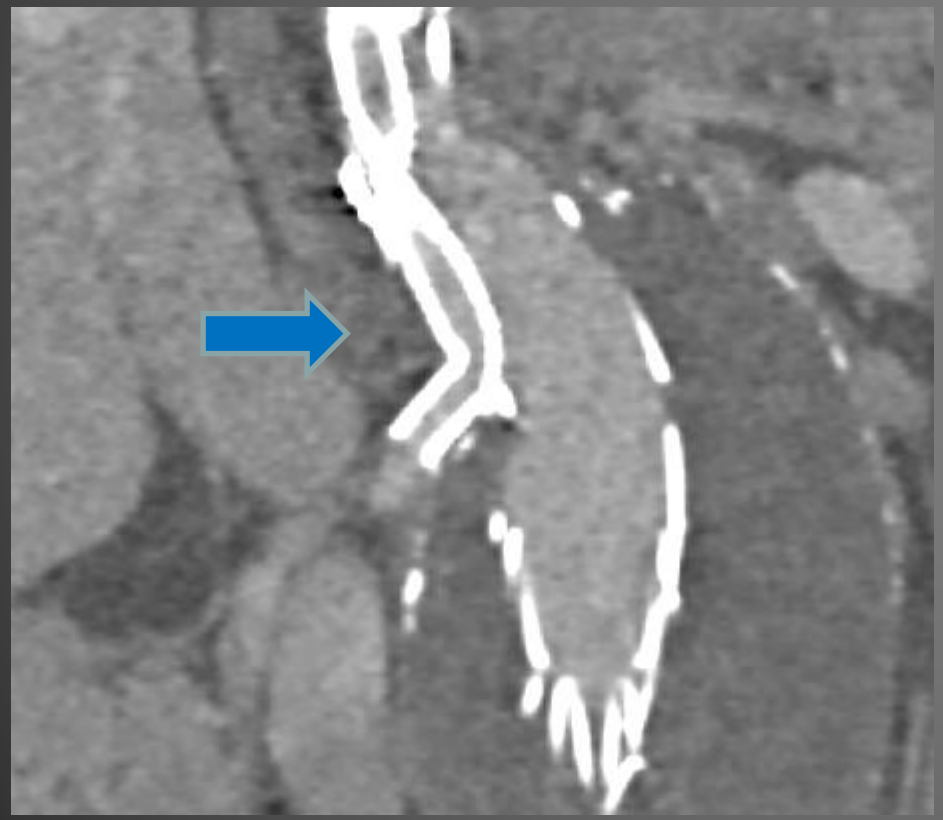


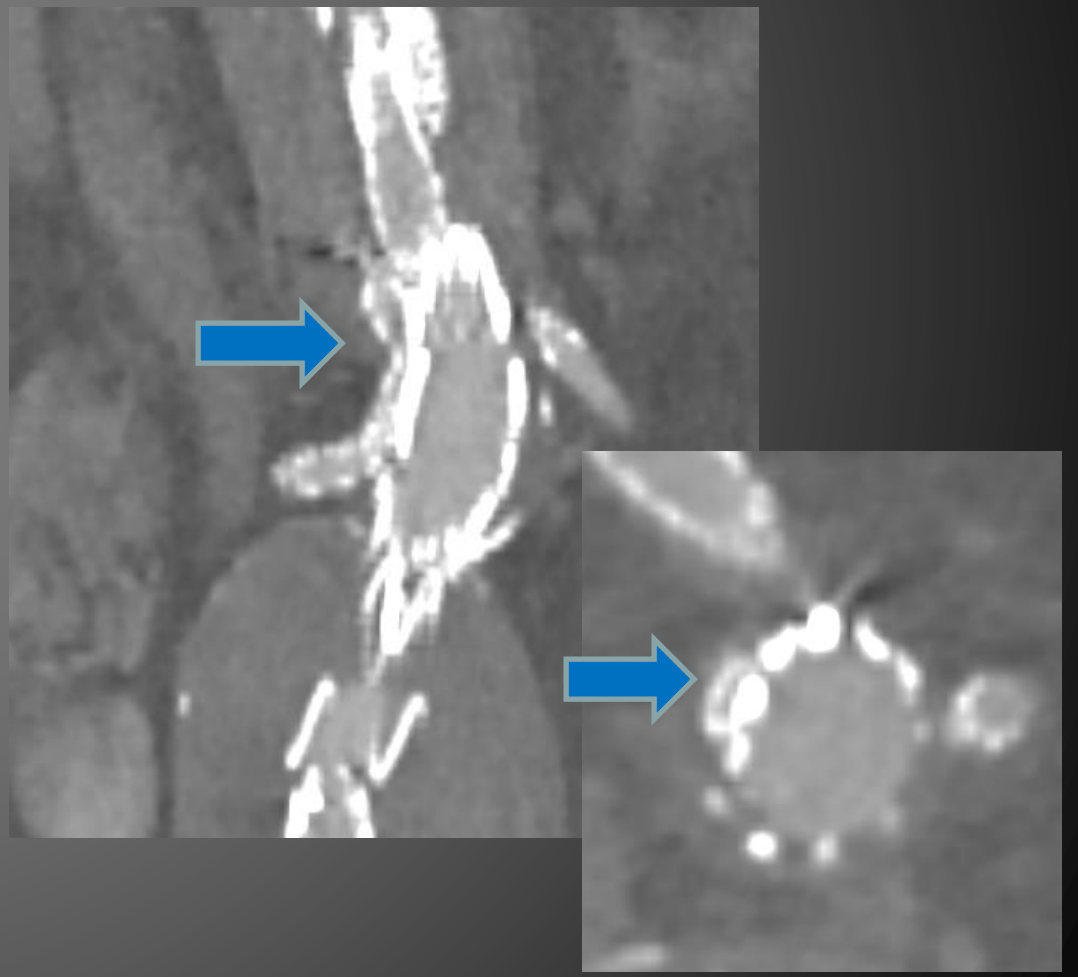
BeGraft PLUS

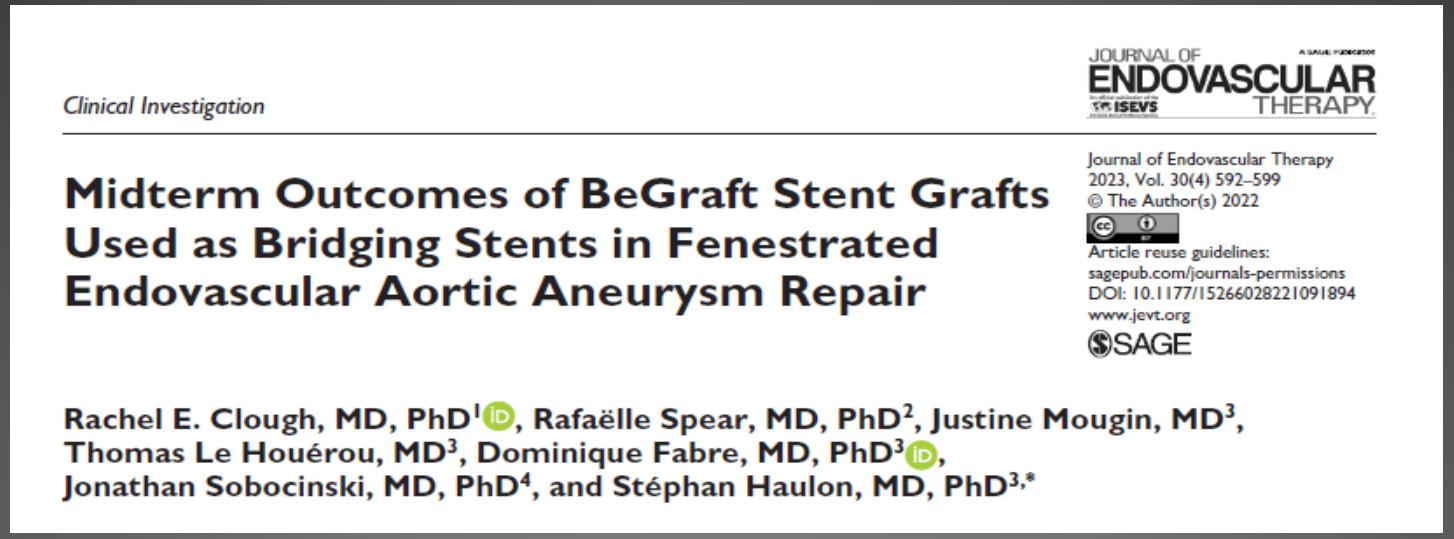
- Increased Radial Force and Kink Resistance

BeGraft Plus



Other BE Stent





Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Midterm Outcomes of BeGraft Stent Grafts Used as Bridging Stents in Fenestrated Endovascular Aortic Aneurysm Repair

Journal of Endovascular Therapy
2023, Vol. 30(4) 592–599

DOI: 10.1177/15266028221091894
www.jevt.org
SAGE

Rachel E. Clough, MD, PhD[1], Rafaëlle Spear, MD, PhD[2], Justine Mougin, MD[3], Thomas Le Houérou, MD[3], Dominique Fabre, MD, PhD[3], Jonathan Sobocinski, MD, PhD[4], and Stéphan Haulon, MD, PhD[3,*]

- 38 pts, 101 BeGrafts (2nd Generation) in FEVAR
- Mid-term report
  - Patency: 97% at 2 years
  - Freedom from reintervention: 96% at 2 years

Outcome of the Be Graft Bridging Stent in Fenestrated Endovascular Aortic Repair in a High-Volume Single Center and an Overview of Current Evidence

Journal of Endovascular Therapy
1–12

DOI: 10.1177/15266028241231882
www.jevt.org
Sage

Daniel Becker, MD[1], Carlota Fernandez Prendes, MD[1], Jan Stana, MD[1], Kostas Stavroulakis, MD[1], Nikolaos Konstantinou, MD[1], Ahmed Ali, MD[1], Barbara Rantner, MD[1], and Nikolaos Tsilimparis, MD[1]

- 113 pts, 361 BeGrafts
  - Technical Success: 99.4%
  - Freedom from TV Instability: 98.8% at 3 years

BeGraft & BeGraft Plus in F/BEVAR

Nuremberg & Athens Experience 2018-2023 (Total: N=816)*

- BeGraft: N= 532
  - For Fenestration

- BeGraft Plus: N= 284
  - For Branches/inner branches

**Pts with F/U in Nuremberg or Athens*

Freedom from TV Instability

BeGraft Group

(Fenestrations)

98.9 ± 0.5% at 1 year

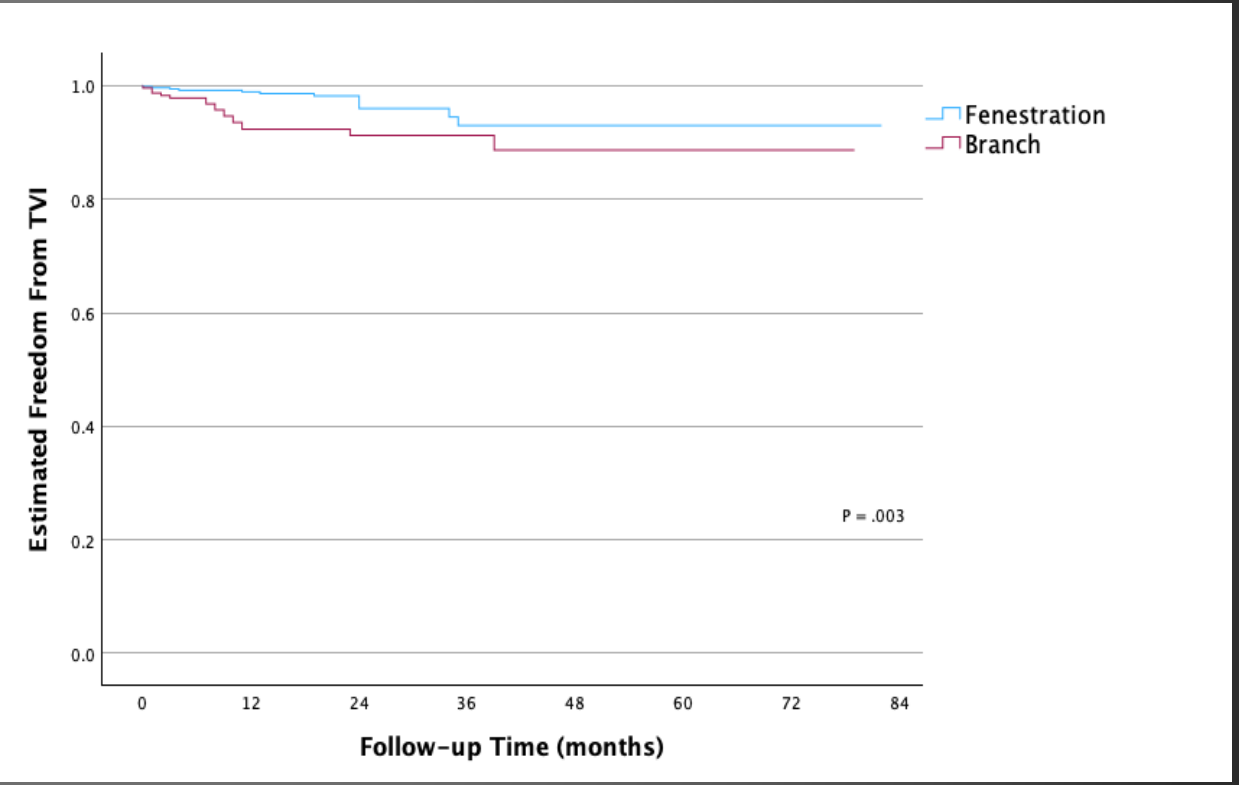
96.0 ± 1.3% at 2 years

BeGraft Plus Group

(Branches)

92.3 ± 1.9% at 1 year

91.2 ± 2.2% at 2 years



Target Vessel Patency

BeGraft Group

(Fenestrations)

99.1 ± 0.4% at 1 year

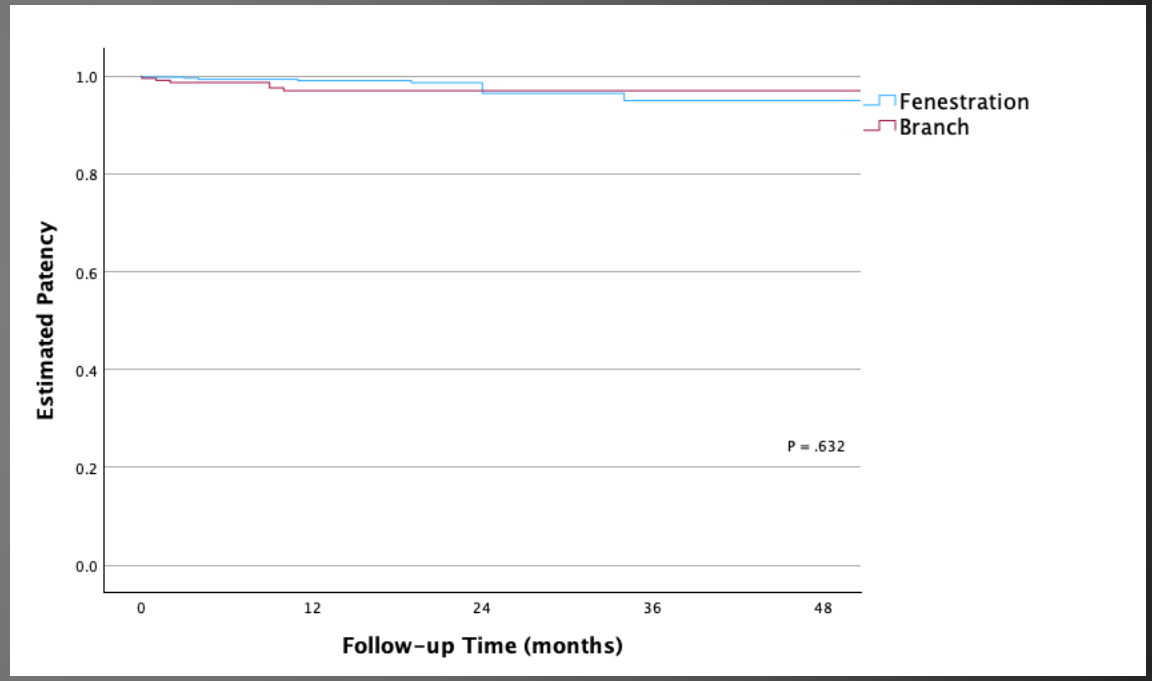
96.5 ± 1.5% at 2 years

BeGraft Plus Group

(Branches)

97 ± 1.2% at 1 year

97 ± 1.2% at 2 years



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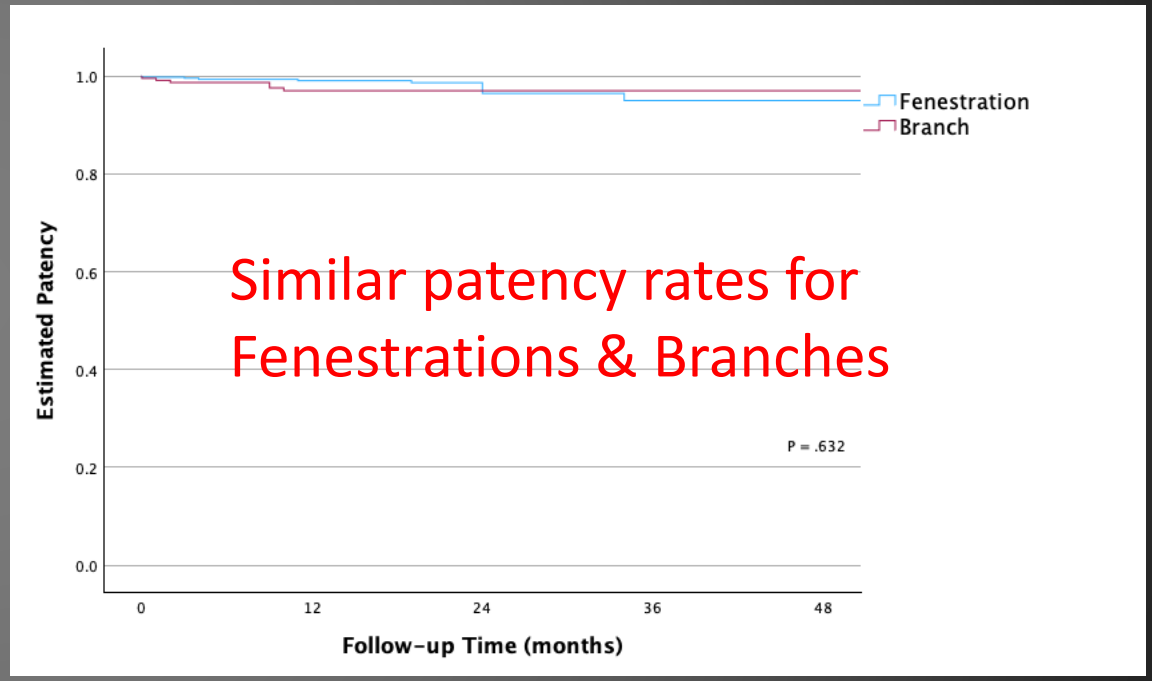

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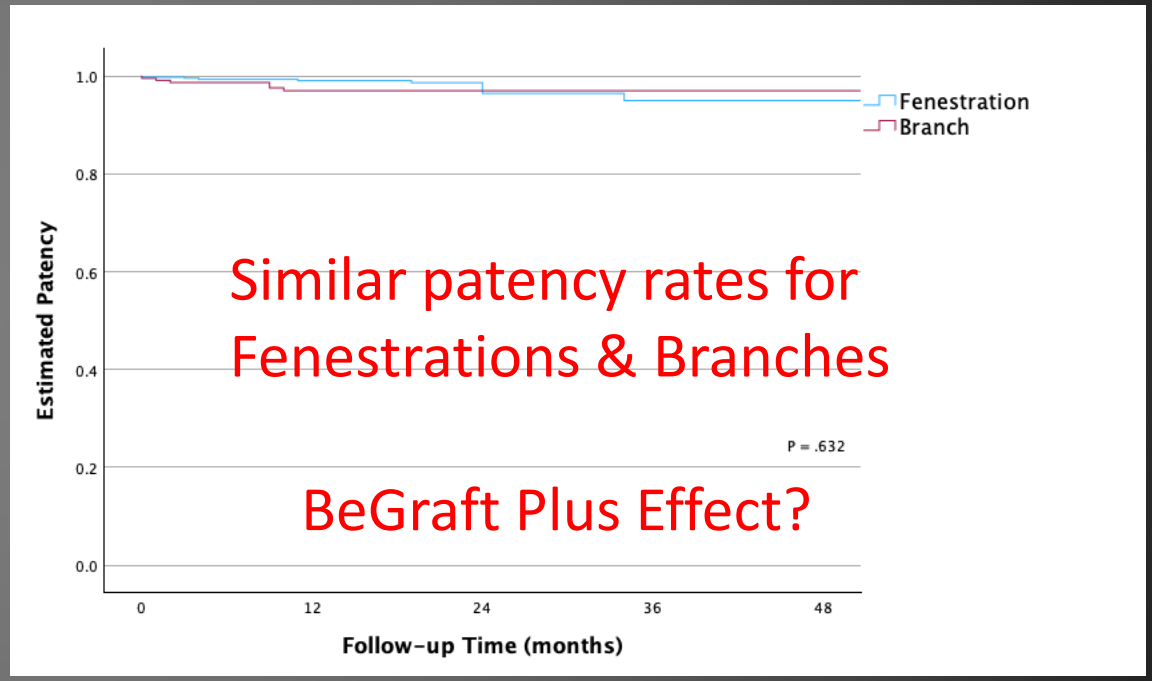
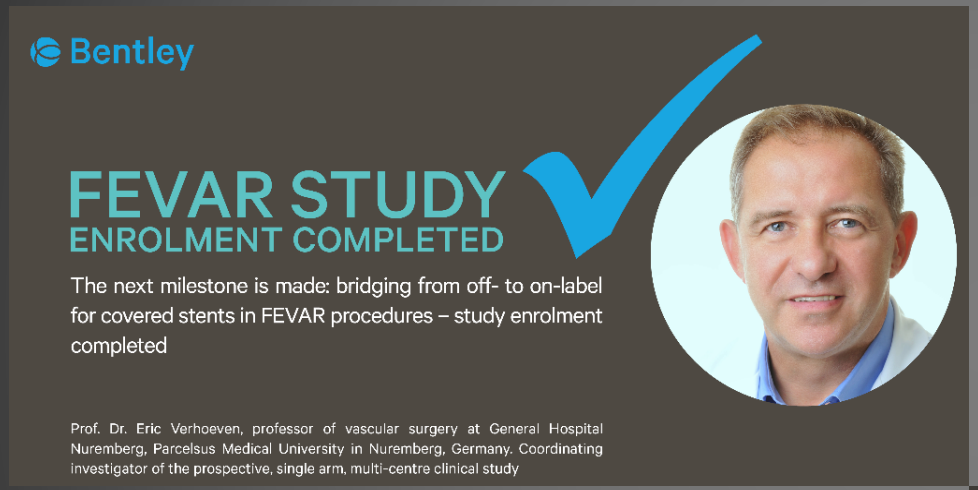


On the Way to on-label Bridging stent-grafts…



Gore VBX

- Non-supported stent-segments
  - ↑ Flexibility & conformability
- Can be flared up to 16mm
- Lengths up to 79mm

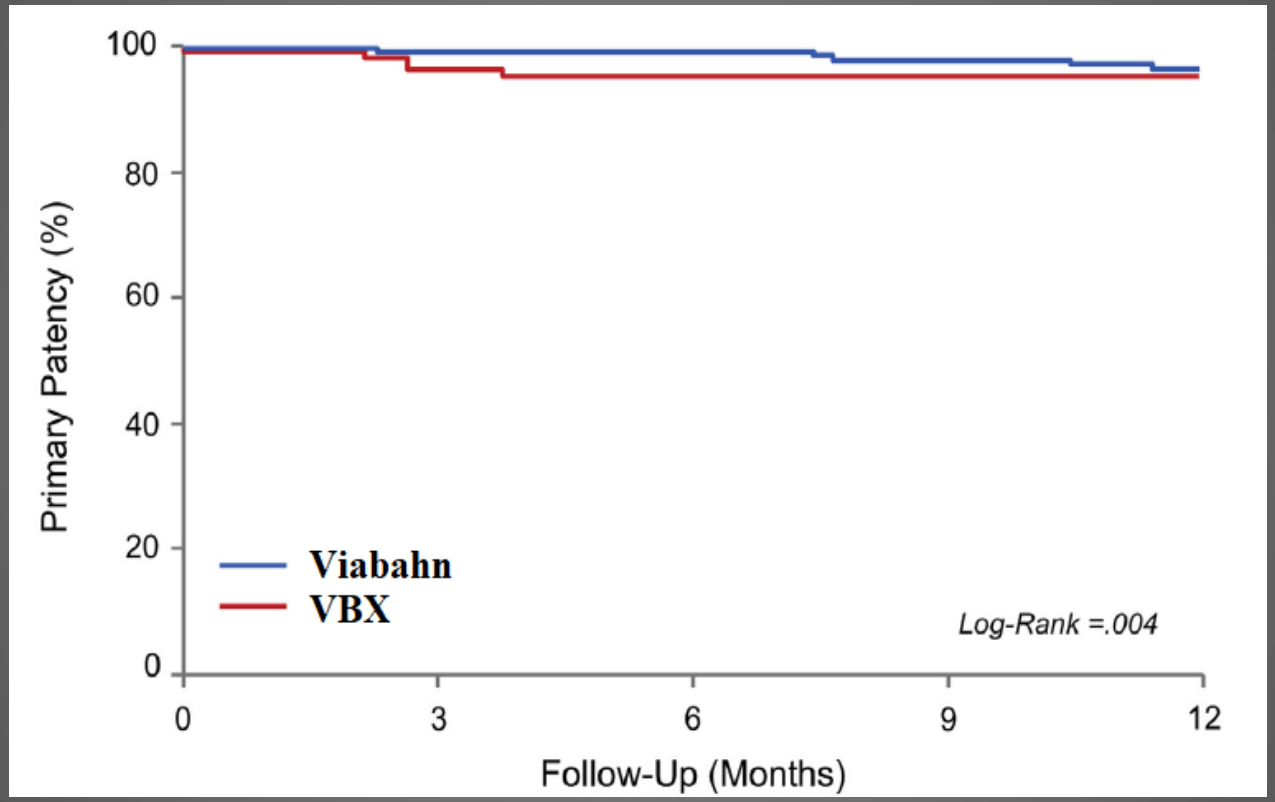
Outcomes of directional branches using self-expandable or balloon-expandable stent grafts during endovascular repair of thoracoabdominal aortic aneurysms

Emanuel R. Tenorio, MD, PhD, Jussi M. Kärkkäinen, MD, PhD, Bernardo C. Mendes, MD, Randall R. DeMartino, MD, Thanila A. Macedo, MD, Alisa Diderrich, RN, Jan Hofer, RN, *and* Gustavo S. Oderich, MD, *Rochester, Minn*

(J Vasc Surg 2020;71:1489-502.)

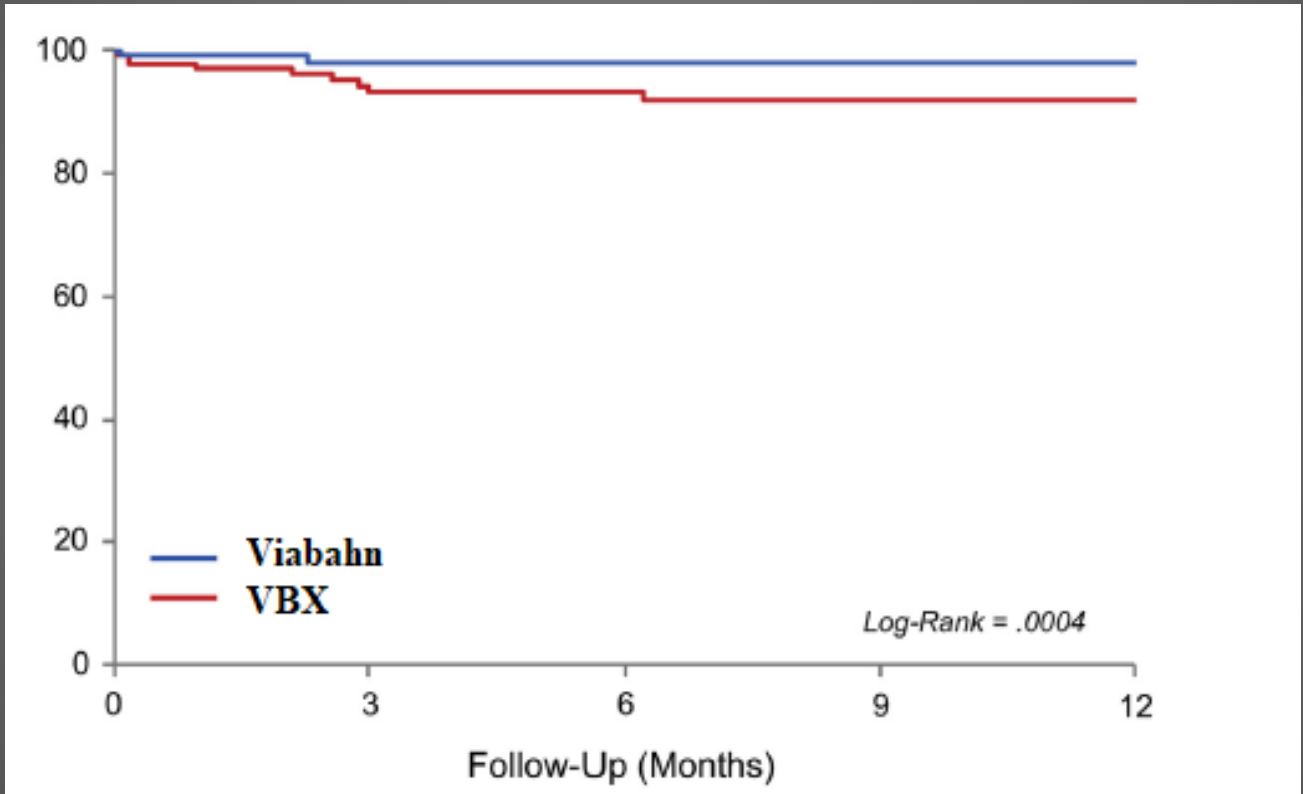
- 126 pts
  - 335 branches with Gore Viabahn
  - 176 branches with Gore VBX

Target Vessel Patency



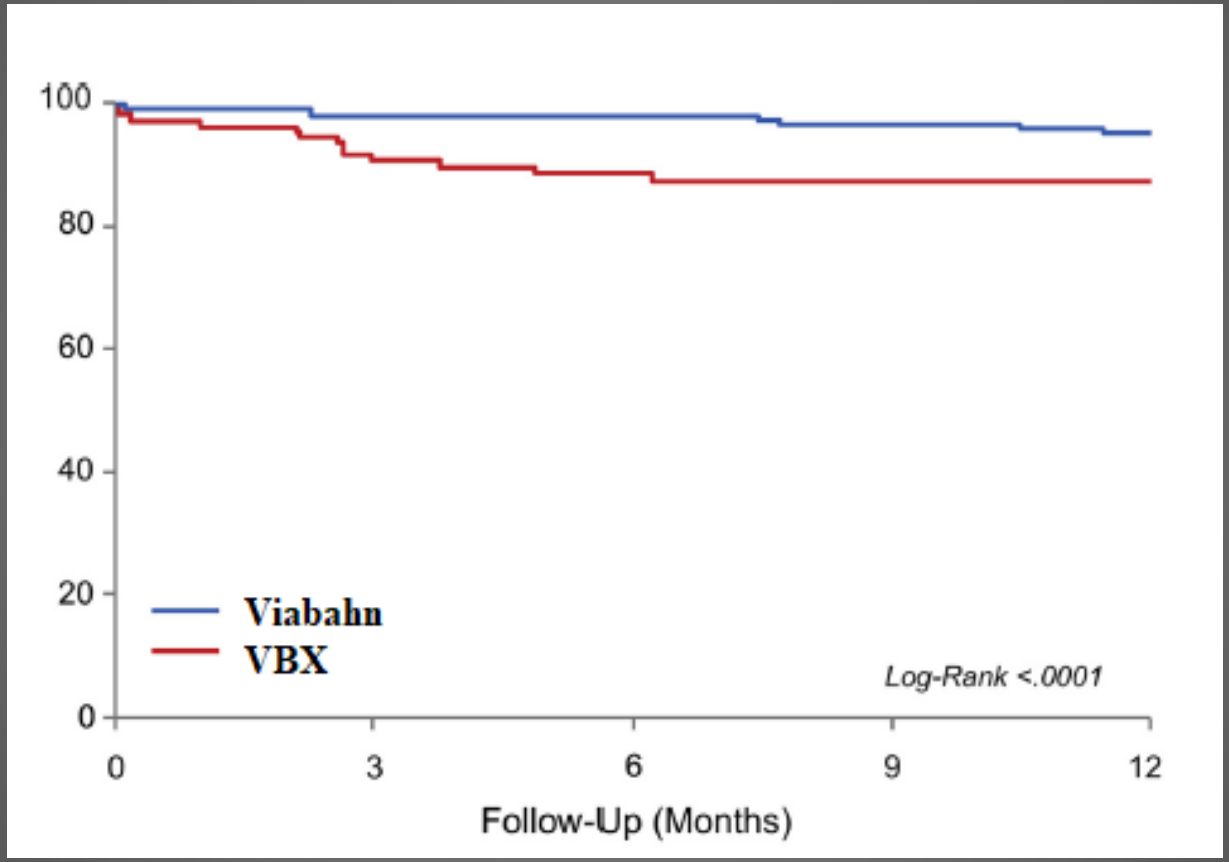
→ VBX lower patency rates vs Viabahn

Freedom from Endoleak



→ VBX higher endoleak rates vs Viabahn

Freedom from Instability



→ VBX higher instability rates vs Viabahn

Comparison of self- and balloon-expandable bridging stent-grafts in branched endovascular aortic repair (COVIBRI study)

Mattia Migliari, MD,[a] Nicola Leone, MD,[a] Gian Franco Veraldi, MD,[b] Gioele Simonte, MD, PhD,[c] Roberto Silingardi, MD,[a] Timothy Resch, MD, PhD,[d] *and* Stefano Gennai, MD,[a] Study collaborators, *Modena, Verona, and Perugia, Italy; and Copenhagen, Denmark*

- 106 pts
  - 220 branches with Covera
  - 125 branches with Gore VBX

Comparison of self- and balloon-expandable bridging stent-grafts in branched endovascular aortic repair (COVIBRI study)

Mattia Migliari, MD,[a] Nicola Leone, MD,[a] Gian Franco Veraldi, MD,[b] Gioele Simonte, MD, PhD,[c] Roberto Silingardi, MD,[a] Timothy Resch, MD, PhD,[d] *and* Stefano Gennai, MD,[a] Study collaborators, *Modena, Verona, and Perugia, Italy; and Copenhagen, Denmark*

- Median F/U: 13.9 months
  - Similar patency rates
  - VBX higher TV Instability mainly due to Type Ic endoleaks

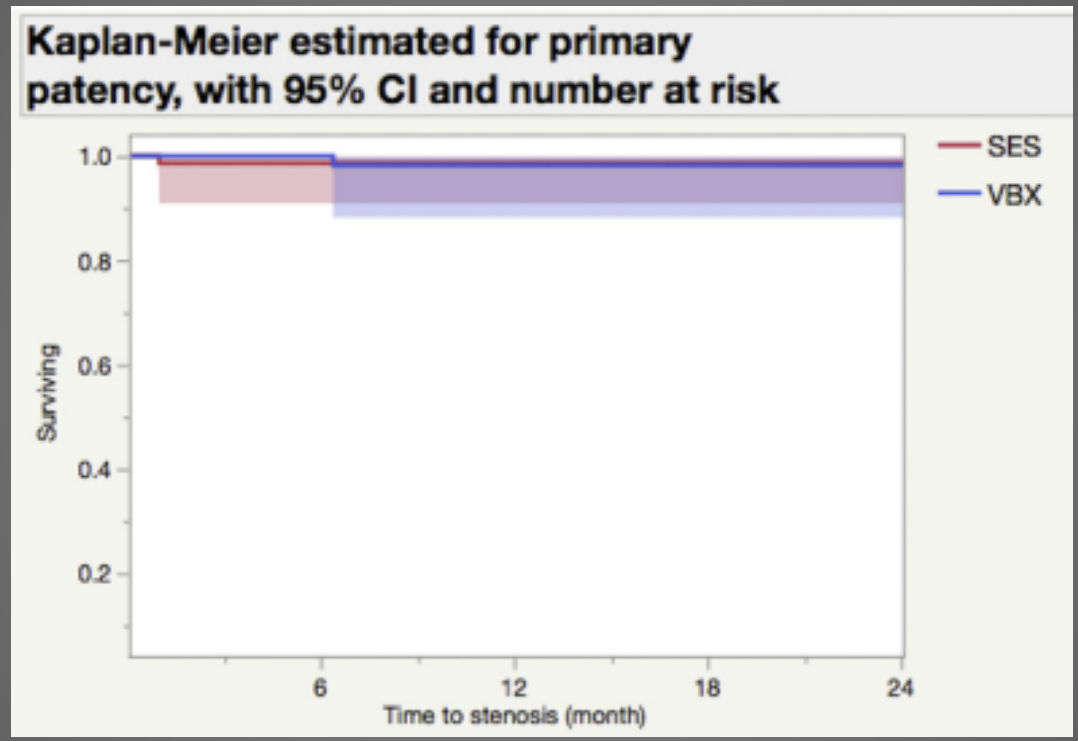
Performance of Viabahn balloon-expandable stent compared with self-expandable covered stents for branched endovascular aortic repair

Fernando Motta, MD, F. Ezequiel Parodi, MD, Martyn Knowles, MD, MBA, Jason R. Crowner, MD, Luigi Pascarella, MD, Katharine L. McGinigle, MD, MPH, William A. Marston, MD, Melina R. Kibbe, MD, Elad Ohana, RT(R)(CI)(VI), *and* Mark A. Farber, MD, *Chapel Hill, NC*

(J Vasc Surg 2021;73:410-6.)

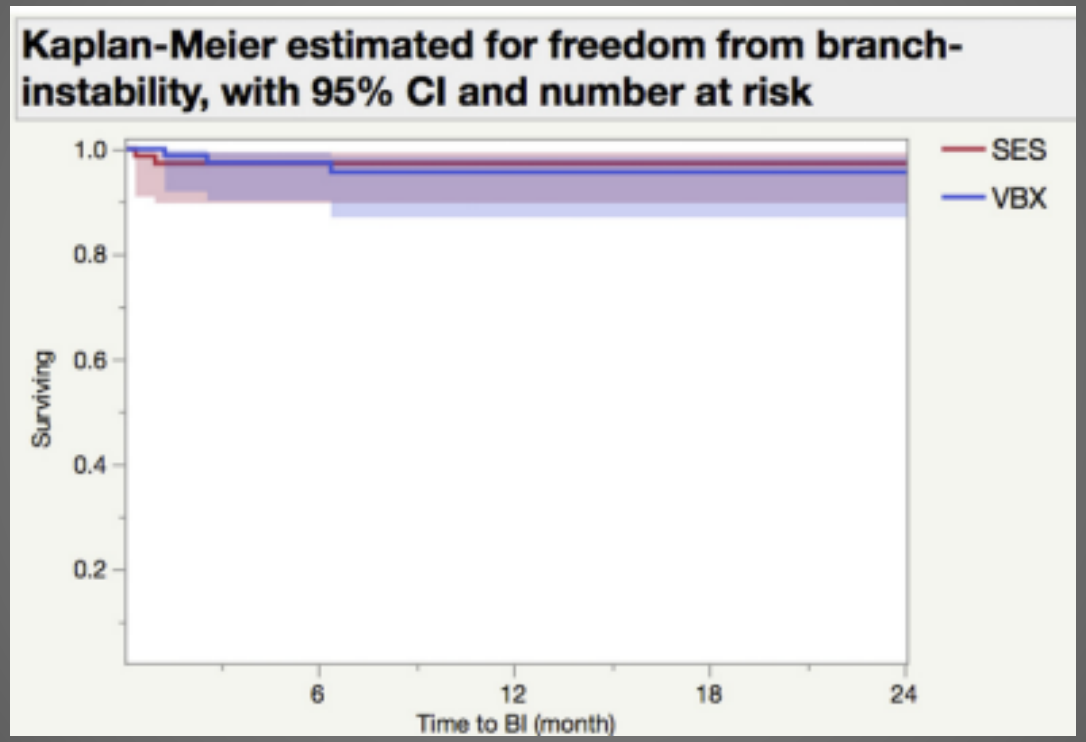
- 263 pts
  - 96 VBX vs 81 Self-expanding stents (Fluency & Viabahn)

Target Vessel Patency



→ Similar patency rates for VBX & Self-expanding stents

Target Vessel Instability



→ Similar instability rates for VBX & Self-expanding stents

Conclusions

- BE bridging stent-grafts in F/BEVAR
  - Perform generally well
  - Still common reason for reintervention...
    - Room for Improvement!

Conclusions

- Advanta V12
  - Proven long-term patency rates
    - Fenestrations: Higher patency rates compared to branches

Conclusions

- Advanta V12
  - Proven long-term patency rates
    - Fenestrations: Higher patency rates compared to branches
- BeGraft & BeGraft Plus
  - Very good early & mid-term outcomes
  - BeGraft Plus may improve patency rates in Branches

Conclusions

- Advanta V12
  - Proven long-term patency rates
    - Fenestrations: Higher patency rates compared to branches
- BeGraft & BeGraft Plus
  - Very good early & mid-term outcomes
  - BeGraft Plus may improve patency rates in Branches
- VBX
  - Good Flexibility & Conformability
  - Type Ic Endoleaks…improving with increasing experience


ROME WAS NOT
BUILT IN A DAY.
--MOTIVATION HUB--