BeGraft Study for Fenestrated Grafting

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Disclosures

- Bentley
  - Part of “Early Launch” Group of the BeGraft PLUS
  - Consultant
- William Cook Europe/Cook Inc.
  - Consultant & Research Grants
- Getinge
  - Consultant

Timelines BeGraft peripheral

BeGraft peripheral

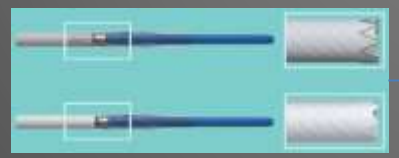
2013

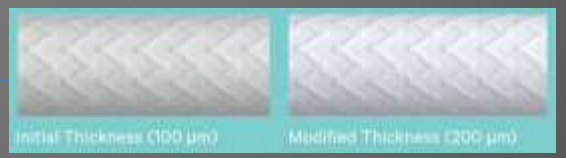
Launch BeGraft peripheral

BeGraft peripheral

2015

Launch BeGraft peripheral
- modified design -





BeGraft peripheral +

2017

Launch BeGraft peripheral PLUS

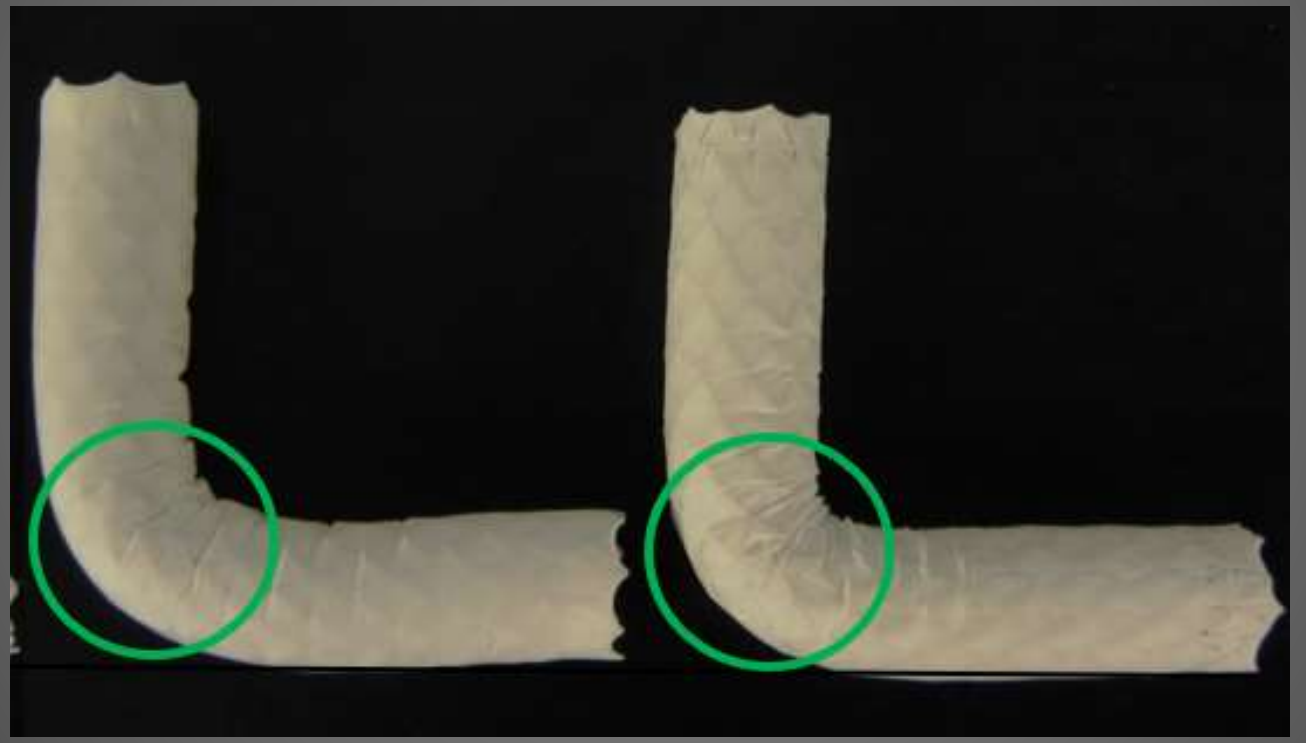
2014

2016

Lay-Out

- Why BeGraft?
  - First Impression (tactile)
  - Testing by the Company
  - First Clinical Experience & Logistics

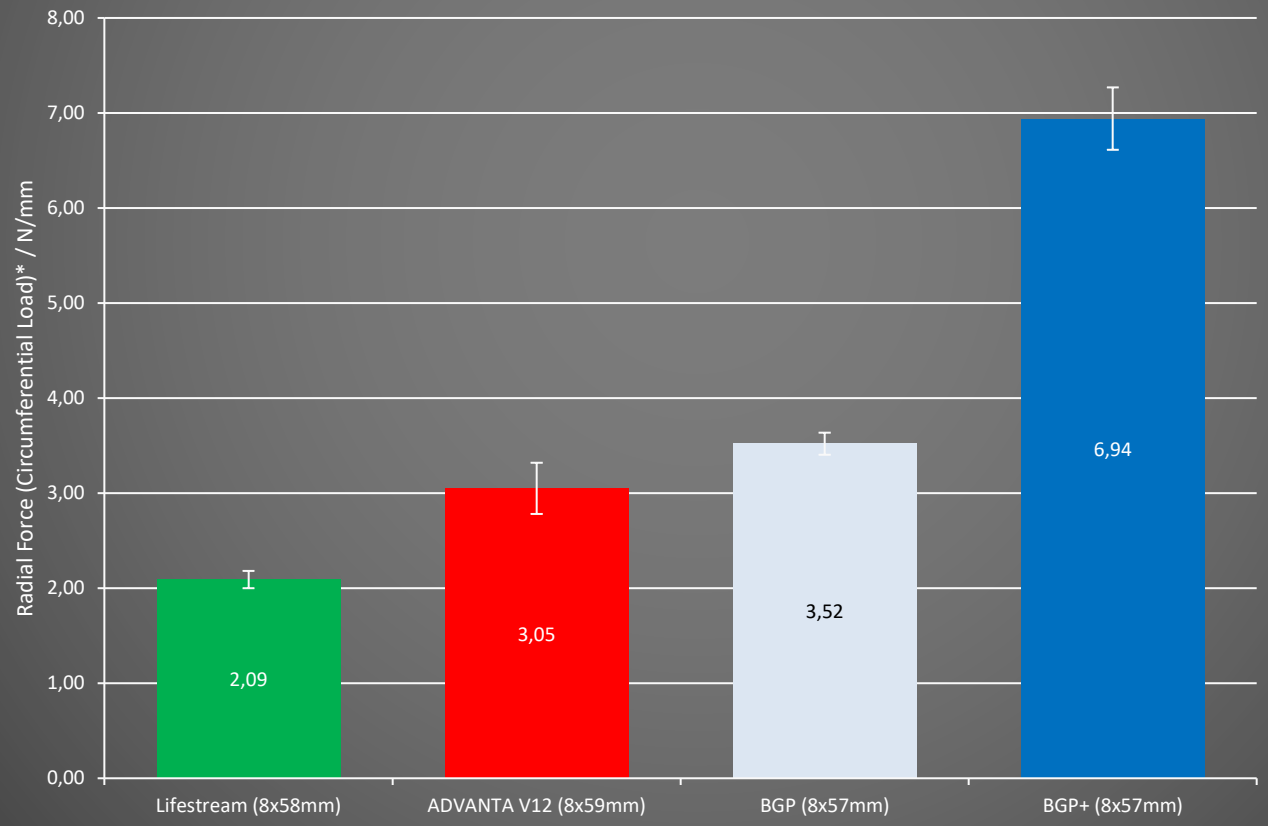
Performance: Kink Resistance



BeGraft
(8x57mm)

BeGraft PLUS
(8x57mm)

Performance: Radial Force
(Circumferential Load)



Clinical Experience & Logistics

- BeGraft in Fenestrations
  - Visibility++
  - Available in all diameters and lengths
    - Lengths: 22/23, 27/28, 37, 57

Problem

- All Bridging Stentgrafts in FEVAR are OFF-LABEL

Study

- Purpose: provide an on-label indication for use of the BeGraft in fenestrations

- Physician-Initiated Trial Investigating the BeGraft Stent Graft System as bridging stent in FEVAR for complex aortic aneurysms

Trial Design

- Prospective, single arm, multi-center, clinical study
- 8 Clinical Centres in Germany

  Nürnberg (Verhoeven) / Münster (Austermann) / Munich (Tsilimparis) / Regensburg (Pfister) / Aachen (Kotelis) / Stuttgart (Geisbüsch) / Gießen (Kalder) / Tübingen (Lescan)
- 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.

Secundary 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
5. 30-day mortality
6. Freedom from stent graft migration, freedom of fracture or dislocation of bridging stent.
7. Freedom from AAA diameter increase at 6 and 12 months as compared to post-op implantation
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

Conclusions

- Bentley is the first Medical Company to support a physician-initiated trial to finally achieve on-label indication for a covered stent in FEVAR

- Studies:
  - BeGraft Study in BEVAR has already started
  - Begraft Study in FEVAR is about to start