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BEGRAFT PERIPHERAL

First 6-month results of the BeGraft Peripheral PMCF trial

Marc Bosiers, MD

Disclosure slide

- ☐ I have the following potential conflicts of interest to report:
  - ☐ Consulting
  - ☐ Employment in industry
  - ☐ Stockholder of a healthcare company
  - ☐ Owner of a healthcare company
  - ☐ Other(s)
- ☑ I do not have any potential conflict of interest

BeGraft Peripheral PMCF study
Study design

- Prospective, non-randomized, multi-center study

- Study objective:

  To evaluate the long-term (up to 12 months) safety and effiacy of the BeGraft Peripheral Stent Graft System (Bentley Innomed®).

BeGraft Peripheral PMCF study

Device description

The Stent Compliance of the BeGraft Peripheral

Inflation Pressure [bar]	Stent Outer Diameter [mm]					
	Ø 5.0	Ø 6.0	Ø 7.0	Ø 8.0	Ø 9.0	Ø 10.0
8				8.0	9.0	10.0
9	5.0	6.0	7.0	8.3	9.2	10.2
10	5.2	6.2	7.2	8.5	9.4	10.4
11	5.3	6.4	7.3	8.7	9.6	10.6
12	5.4	6.5	7.5	8.8	9.7	10.7
13	5.5	6.6	7.6			

Bentley InnoMed

BeGraft Peripheral PMCF study
Participating centers

- **BELGIUM**
  - M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  - P. Peeters, J. Verbist - Imelda Hospital, Bonheiden
  - L. Maene, R. Beelen - OLV, Aalst
  - K. Keirse - RZ Heilig Hart, Tienen

BeGraft Peripheral PMCF study

Inclusion Criteria

- **Rutherford** classification from **2 to 5**
- **(Re)Stenotic (≥50%) or occlusive lesion at the iliac arteries**, suitable for stenting.
- A modified TASC-II class A, B, C or D lesion with one of the listed specifications:

  - Type A lesions
    - Unilateral or bilateral stenoses of the Common Iliac Artery
    - Unilateral or bilateral single short (≤3 cm) stenosis of the External Iliac Artery
  - Type B lesions
    - Unilateral Common Iliac Artery occlusion
    - Single or multiple stenosis totaling 3–10 cm involving the External Iliac Artery not extending into the Common Femoral Artery
    - Unilateral External Iliac Artery occlusion not involving the origins of Internal Iliac Artery or Common Iliac Artery
  - Type C lesions
    - Bilateral Common Iliac Artery occlusions
    - Bilateral External Iliac Artery stenoses 3–10 cm long not extending into the Common Femoral Artery
  - Type D lesions
    - Unilateral occlusions of both Common Iliac and External Iliac Artery
    - Diffuse disease involving the aorta and both iliac arteries requiring treatment
    - Bilateral occlusions of External Iliac Artery

BeGraft Peripheral PMCF study
Exclusion criteria

- **PTA** is technically **not possible**
- **Previously implanted stent** at study lesion site
- Target lesion is a modified TASC-II class B,C or D lesion with aortic or common femoral lesion involvement:

- Type B lesions
  - Short (≤3 cm) stenosis of infrarenal aorta
- Type C lesions
  - Unilateral External Iliac Artery stenosis extending into the Common Femoral Artery
  - Unilateral External Iliac Artery occlusion that involves the origins of the Internal Iliac and/or Common Femoral Artery
  - Heavily calcified unilateral External Iliac Artery occlusion with or without involvement of origins of the Internal Iliac and/or Common Femoral Artery
- Type D lesions
  - Infra-renal aortoiliac occlusion
  - Iliac stenoses in patients with an Abdominal Aortic Aneurysm (AAA) requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery
  - Diffuse multiple stenoses involving the unilateral Common Iliac, External Iliac and Common Femoral Artery

BeGraft Peripheral PMCF study
Primary Endpoint

- **Primary patency at 12 months,** defined as:

absence of restenosis (≥50% stenosis or systolic velocity ratio ≥2.4), and without Target Lesion Revascularization (TLR) within 12 months.

BeGraft Peripheral PMCF study

BeGraft Peripheral PMCF study: Patient demographics

	N=70
Male *(%)*	45 *(64.3%)*
Age *(min – max; ±SD)*	65.04 *(41– 91 ±10.01)*
Nicotine abuse *(%)*	41*(58.6%)*
Hypertension *(%)*	46 *(65.7%)*
Diabetes mellitus *(%)*	14 *(20.0%)*
Renal insufficiency *(%)*	7 *(10.0%)*
Hypercholesterolemia *(%)*	41 *(58.6%)*
Obesity *(%)*	14 *(20.0%)*

BeGraft Peripheral PMCF study:

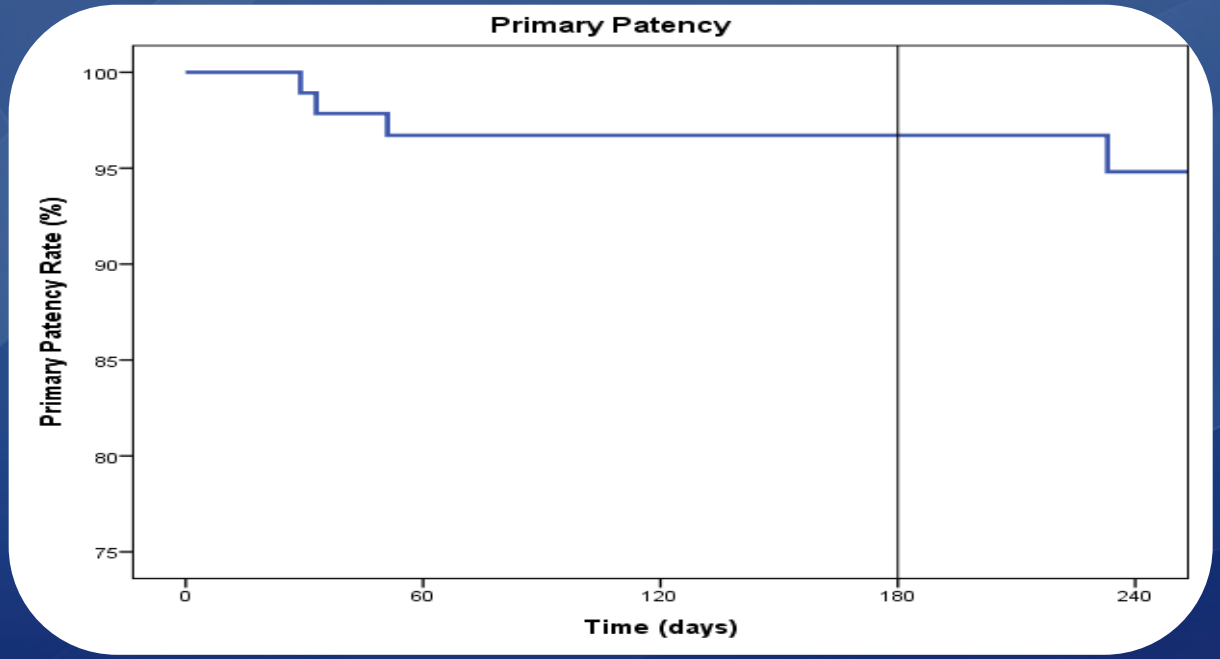
	N=70
TASC A *(%)*	54 *(77.1%)*
TASC B *(%)*	10 *(14.3%)*
TASC C *(%)*	4 *(5.7%)*
TASC D *(%)*	2 *(2.9%)*
Lesion Side	
Left *(%)*	26 (37.1%)
Right *(%)*	21 (30.0%)
Bilateral *(%)*	23 (32.9%)

23 patients treated bilateral
93 lesions for 70 patients

BeGraft Peripheral study: Lesion characteristics

	N=93
Lesion length *(min – max; ±SD)*	34.3 mm *(6.0 – 100.0; ±15.45)*
Reference vessel diameter	7.96 mm
Mean lumen diameter	1.34 mm
Occlusion *(%)*	13 *(14%)*
Calcified lesion *(%)*	53 *(57%)*

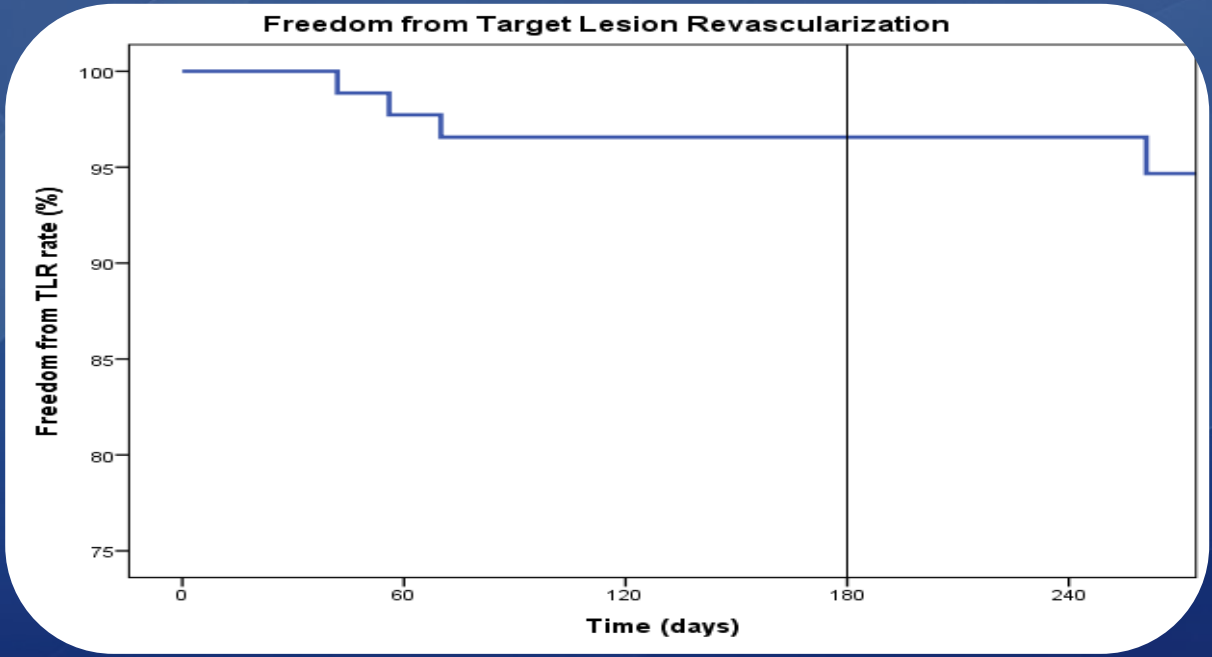
BeGraft Peripheral PMCF study:
6 Month Primary Patency



96.7 %

Time	baseline	1MFU	6MFU
at risk	93	92	76
%	100	98.9	96.7

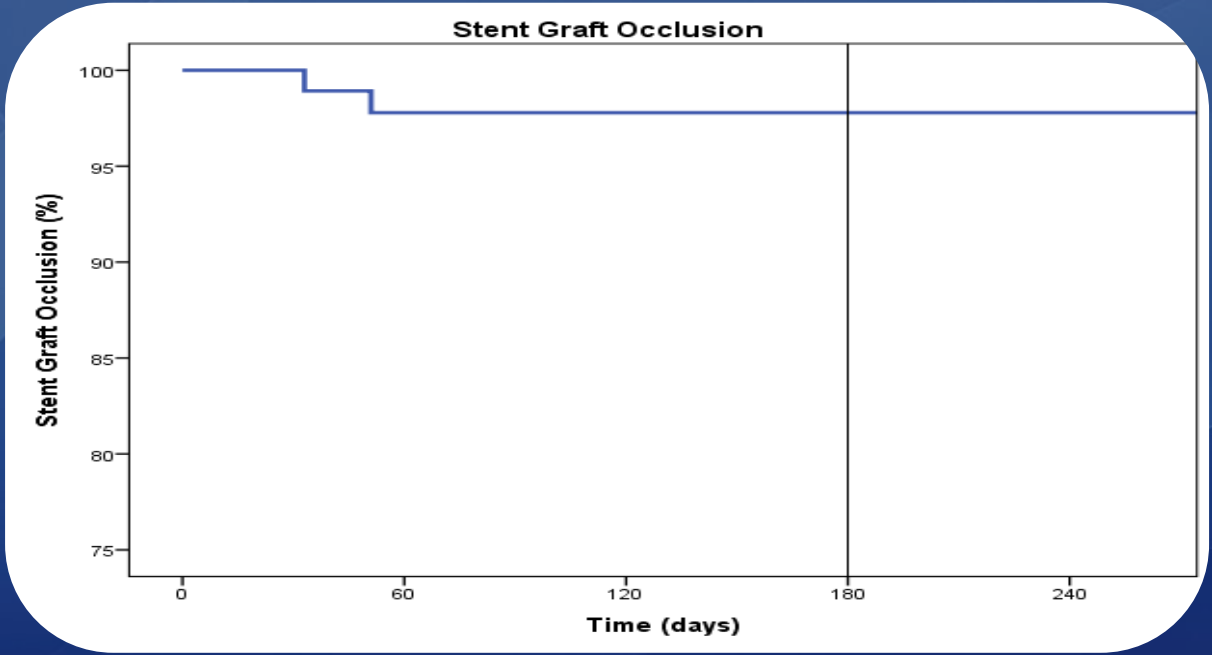
BeGraft Peripheral PMCF study: 6 Month Freedom from TLR



96.6 %

Time	baseline	1MFU	6MFU
at risk	93	93	76
%	100	100	96.6

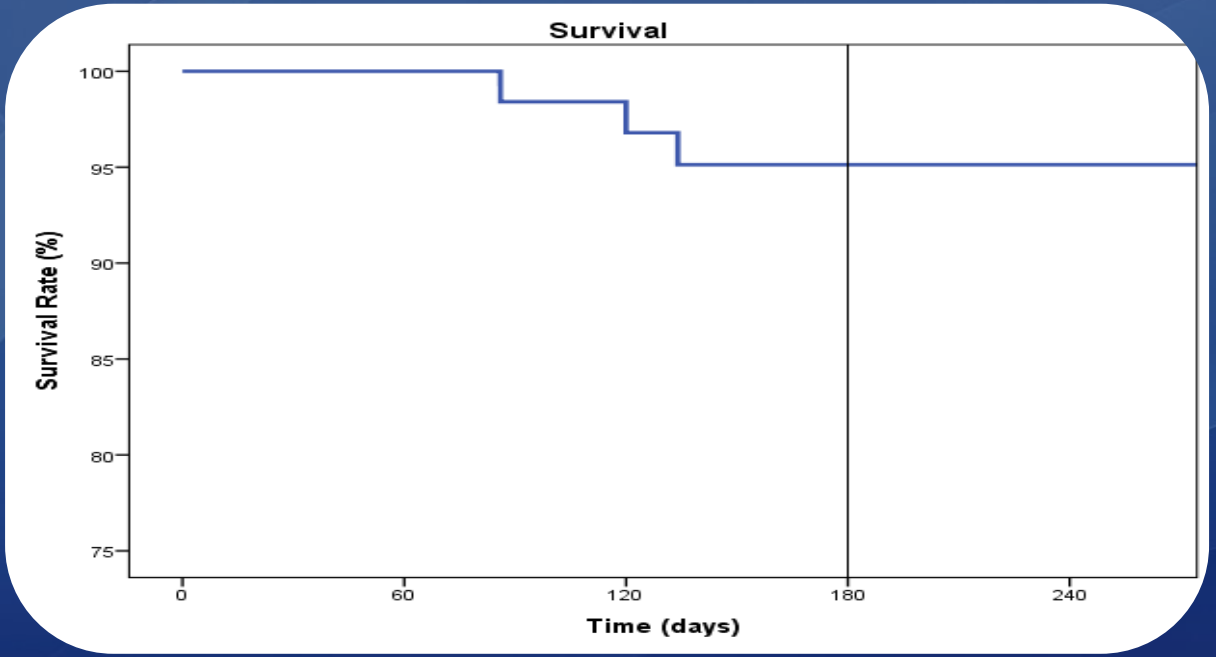
BeGraft Peripheral PMCF study:
6 Month Freedom from Stent Graft Occlusion



97.8 %

Time	baseline	1MFU	6MFU
at risk	93	93	76
%	100	100	97.8

BeGraft Peripheral PMCF study:
6 Month Survival Rate



95.1 %

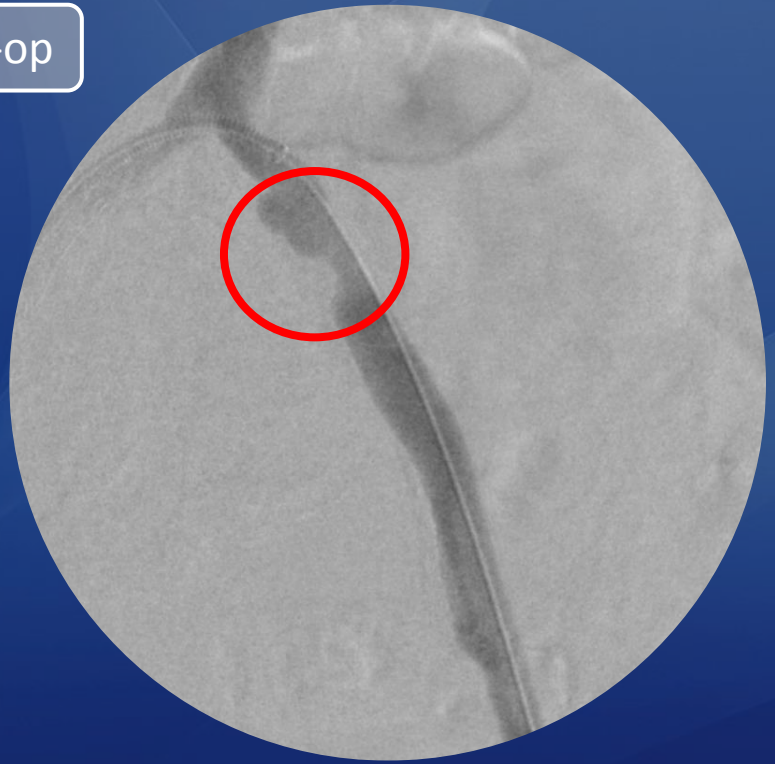
Time	baseline	1MFU	6MFU
at risk	70	69	57
%	100	100	95.1

BeGraft Peripheral PMCF study: 6 Month Limb Salvage Rate

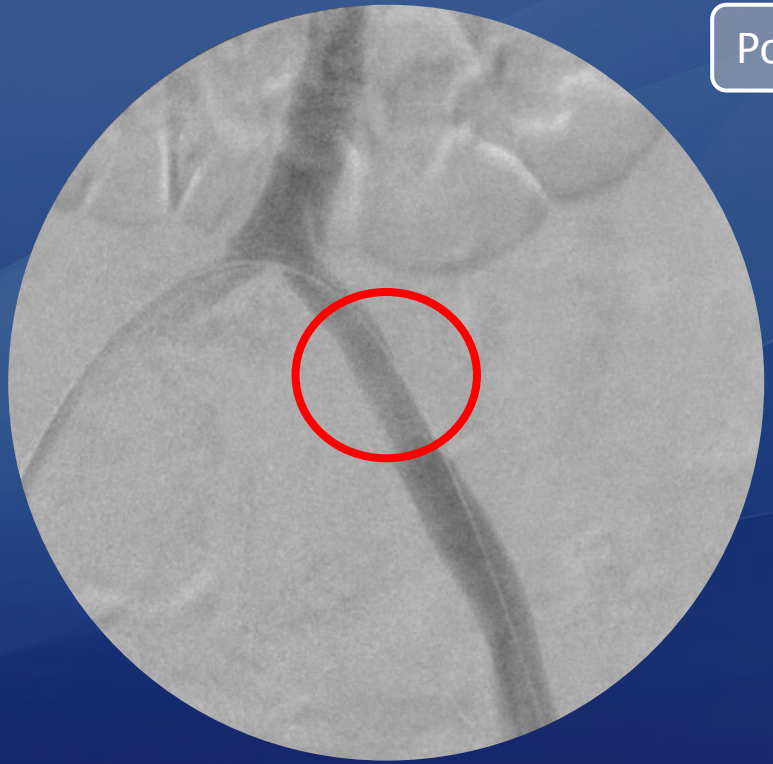
- No major amputations have been reported between baseline and 6MFU visit.
- 6 Month Limb Salvage Rate is **100%**

Example case

Pre-op

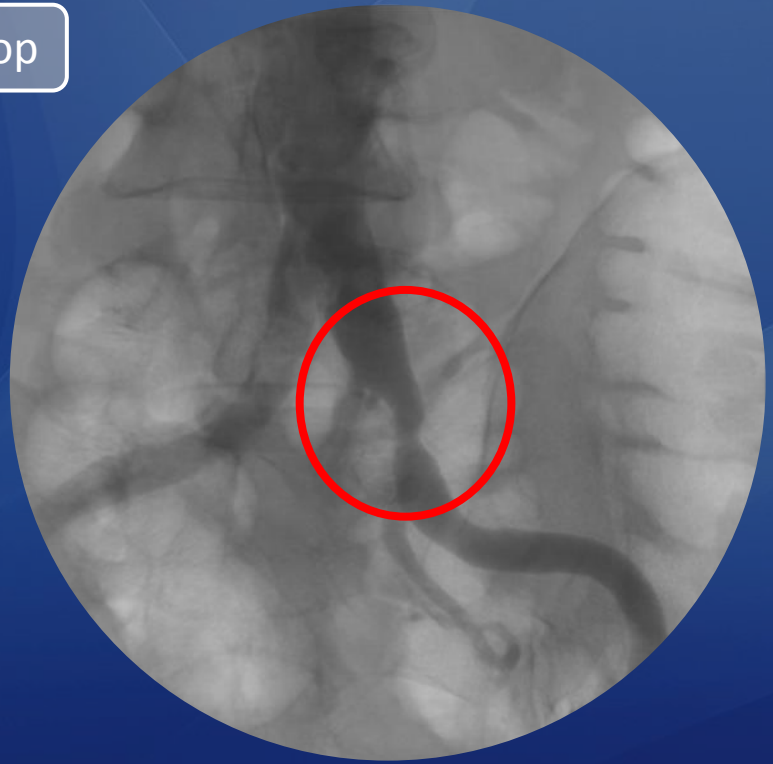


Post-op

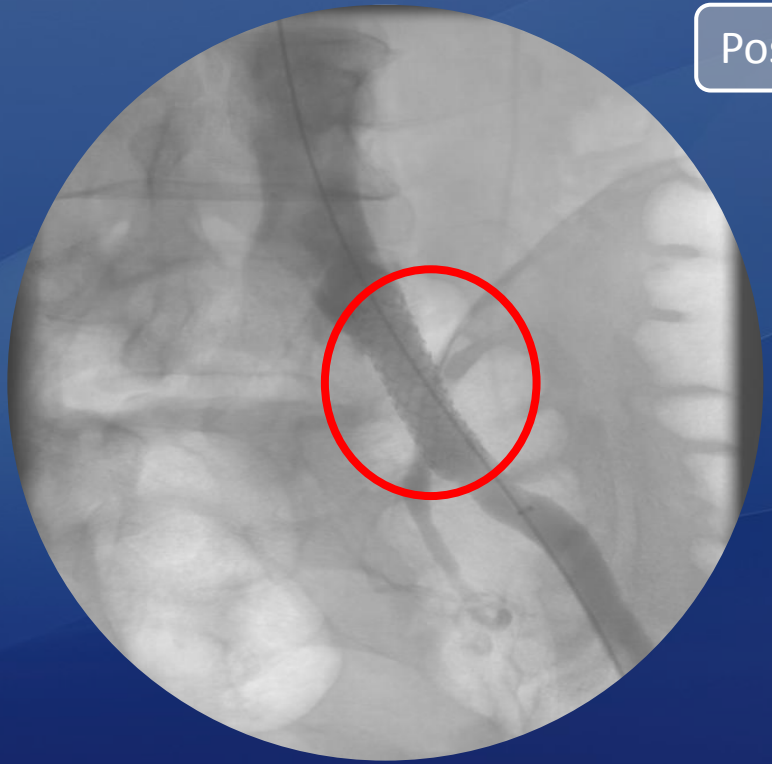


Example Case

Pre-op



Post-op



BeGraft Peripheral PMCF study

Conclusion

- The **BeGraft Peripheral Stent Graft System** seems to be a valid, safe and effective treatment option to treat **Iliac lesions**.

- Special benefit in **highly calcified lesions**