

# GORE VIABAHN® endoprosthesis with bioactive propaten surface versus bare nitinol stent in the treatment of TASC B, C and D lesions in superficial femoral artery occlusive disease

<b>Submission date</b> 18/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/10/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Johannes Lammer

**Contact details**  
Medical University of Vienna  
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Vienna  
Austria  
1090

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

GORE VIABAHN® endoprosthesis with bioactive propaten surface versus bare nitinol stent in the treatment of TASC B, C and D lesions in superficial femoral artery occlusive disease

**Acronym**

VIASTAR

**Study objectives**

In comparison to the use of bare nitinol stents in treating chronic long Superficial Femoral Artery (SFA) lesions, the use of the GORE VIABAHN® endoprosthesis with bioactive propaten surface will result in greater mid- and long-term patency of the treated arterial lesion.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of the Medical University of Vienna approved on the 26th September 2007 (ref: EK Nr 203/2007)

**Study design**

Randomised controlled multicentre trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Peripheral arterial occlusive disease

**Interventions**

Percutaneous transluminal stenting with GORE VIABAHN® endoprosthesis with Propaten bioactive surface vs bare nitinol stent"

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Efficacy: Primary patency based on color doppler ultrasonography (CDUS) and computed tomographic angiography (CTA) at 1 year post-procedure
2. Safety: Composite of major procedural (30-day) adverse events

**Key secondary outcome(s)**

1. Primary assisted patency. Timepoints: 12 and 24 months.
2. Secondary patency. Timepoints: 12 and 24 months.
3. Technical success. Timepoints: Immediately after intervention.

4. Target vessel revascularisation. Timepoints: 12 and 24 months.
5. Target lesion revascularisation. Timepoints: 12 and 24 months.
6. Clinical success. Timepoints: 1 month, 6, 12 and 24 months.
7. Primary composite safety and efficacy endpoint. Timepoints: 1 month and 12 months.
8. Change in ankle-brachial index (ABI). Timepoints: 1, 6, 12 and 24 months.
9. Alternate Peak Systolic Velocity Ratios (PSVR of 2.5 or less). Timepoints: 1, 6, 12 and 24 months.

**Completion date**

01/04/2012

## Eligibility

**Key inclusion criteria**

1. Lifestyle-limiting claudication or rest pain (meeting angiographic entry criteria) affecting a lower extremity (Fontaine stages II-IV)
2. Subject (or their legal guardian) has read, understood and provided written informed consent, which has been reviewed and approved by the Institutional Review Board
3. At least 18 years of age
4. Noninvasive lower extremity arterial studies within 45-days prior to study procedure demonstrating resting Ankle-Brachial Index (ABI)  $\geq$  0.8 in the study limb
5. If applicable, staged ipsilateral vascular procedure = 14 days prior to study procedure. ABIs must be completed prior to the study procedure a minimum of 14 days after the staged vascular procedure
6. If applicable, vascular treatment on non-study leg for bilateral claudication = 14 days prior to study procedure demonstrating Fontaine stage I in non-study leg at the time of study procedure. ABIs must be completed prior to the study procedure a minimum of 14-days after treatment on the non-study leg
7. Male, infertile female, or female of child bearing potential practicing an acceptable method of birth control with a negative pregnancy test within 7 days prior to study procedure
8. Projected life expectancy of greater than three years
9. The ability to comply with protocol follow-up requirements and required testing
10. Angiographic and Lesion Requirements (assessed intraoperatively):
  - a. Multiple stenoses or occlusions totalling  $>15$  cm with or without heavy calcification or recurrent stenoses or occlusions that need treatment after two endovascular interventions ( $>50\%$  by visual estimate) located in the region beginning 1 cm below origin of the profunda femoris artery and ending 5 cm above the radiographic knee joint. Prior angioplasty, if applicable on the target lesion, must have been performed = 6 months prior to the study procedure
  - b. Orifice and proximal 1 cm of SFA are patent
  - c. Popliteal artery is patent 5 cm proximal to the radiographic knee joint line
  - d. Reference diameter of 4.0-7.5 mm in proximal and distal treatment segments within the SFA
  - e. Angiographic evidence of a minimum of at least one tibial artery runoff to the ankle that does not require intervention
  - f. Guidewire has successfully traversed lesion and is within the true lumen of the distal vessel

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Untreated flow-limiting aortoiliac occlusive disease
2. Any previous stenting or surgery in the target vessel
3. Subjects with arterial lesions requiring treatment with device diameters other than 5, 6, 7, or 8 mm
4. Severe ipsilateral common femoral/profunda disease requiring surgical intervention
5. Femoral or popliteal aneurysm
6. Non-atherosclerotic disease resulting in occlusion (e.g., embolism, Buerger's disease, vasculitis)
7. Tibial artery disease requiring treatment
8. Prior ipsilateral femoral artery bypass
9. Severe medical comorbidities (untreated Coronary Artery Disease [CAD]/Congestive Heart Failure [CHF], severe Chronic Obstructive Pulmonary Disease [COPD], metastatic malignancy, dementia, etc.) or other medical condition that would preclude post-procedural ambulation
10. Popliteal artery vascular access at any time during procedure
11. Serum creatinine >2.5 mg/dL within 45 days prior to study procedure
12. Major distal amputation (above the transmetatarsal) in the study or non-study limb
13. Septicemia
14. Any previously known coagulation disorder, including hypercoagulability
15. Morbid obesity or operative scarring that precludes percutaneous approach (physician's discretion)
16. Contraindication to anticoagulation or antiplatelet therapy
17. Known allergies to stent/stent-graft components
18. History of prior life-threatening reaction to contrast agent
19. Currently participating in another clinical research trial

**Date of first enrolment**

01/04/2009

**Date of final enrolment**

01/04/2012

**Locations****Countries of recruitment**

Austria

Germany

**Study participating centre**

**Medical University of Vienna**  
Vienna  
Austria  
1090

## Sponsor information

### Organisation

Medical University of Vienna (Austria)

### ROR

<https://ror.org/05n3x4p02>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Medical University of Vienna (Austria)

### Funder Name

Vienna General Hospital (Austria)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/10/2013		Yes	No
<a href="#">Results article</a>	results	01/02/2015		Yes	No