7th MUNICH VASCULAR CONFERENCE 2017
... where doctors meet science
December 07–09 | Klinikum rechts der Isar | Munich | Germany

Endovascular femoro-popliteal bypass grafting via the femoral vein (PQ Bypass) - the DETOUR I study

Y. Bausback
Clinic for Angiology
University Hospital Leipzig
Germany

DISCLOSURE

Speaker name:

Yvonne Bausback

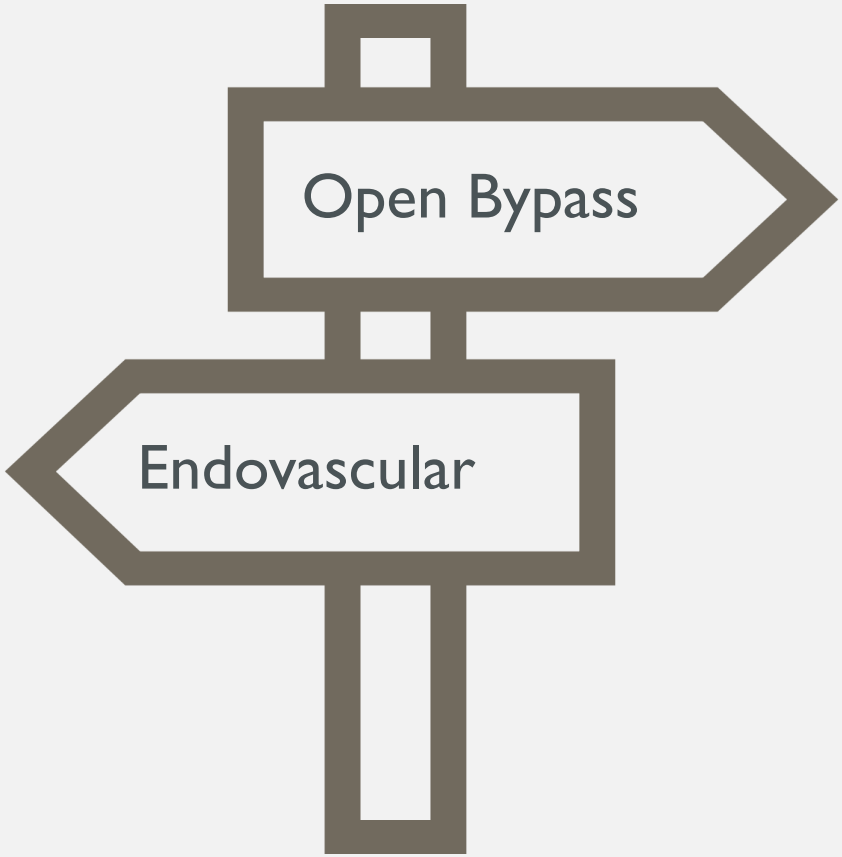
I do not have any potential conflict of interest concerning the content of this presentation

SFA - REVSCULARSATION CAN BE CHALLENGING

- Procedural CTO fail-to-cross very common
- Mechanical Restoring adequate blood flow through 20+ cm of disease
- Physiological Not possible to resuscitate an ischemic vessel

THE LONG SEGMENT SFA DISEASE TREATMENT OPTIONS

Unmet Need: Endovascular Approach with the Durability of Open Surgery



LESS INVASIVE

But…

- Durability
- Procedure time
- Devices per procedure ($$$)

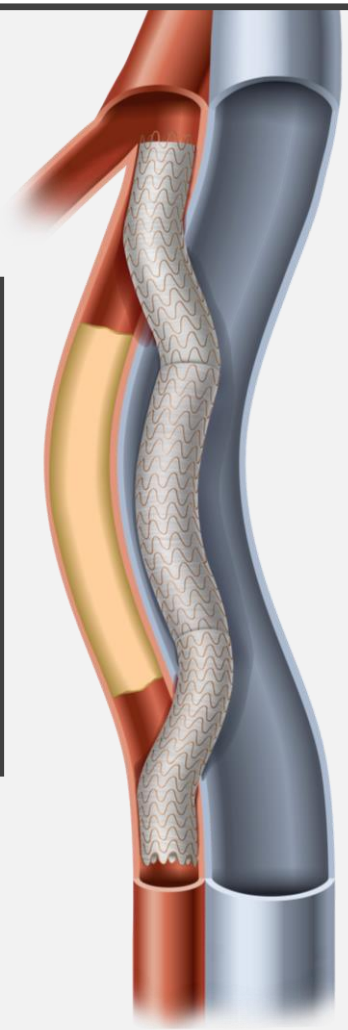
MORE DURABLE

But…

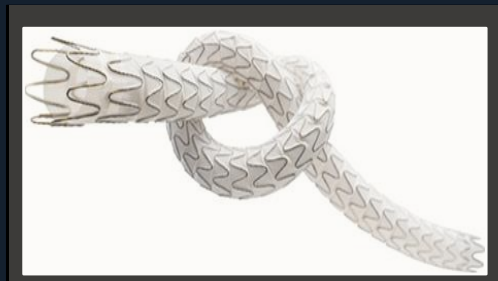
- Morbidity
- More invasive
- Length of stay

THE DETOUR PERCUTANEOUS BYPASS PROCEDURE

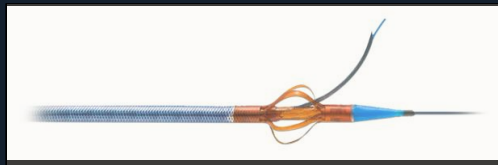
DESIGNED TO BE A FIRST-LINE TREATMENT FOR LONG SEGMENT SFA (TASC C & D) LESIONS



TORUS™ Stent Graft



DETOUR Crossing Kit



DETOUR I CLINICAL TRIAL (FIRST IN MAN)

No Exclusions for CTO, ISR, or Severe Calcification

Design

- DESIGN: Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and technique for percutaneous bypass
- ENDPOINTS: 30 day MAE and 6 month primary patency (Met primary endpoints)
- STATUS
  - CE Mark granted Feb 2017
  - Patients being followed to 24 months

78 patients/82 limbs enrolled at 8 global sites

77 patients/81 limbs with DETOUR™ implanted

First patients at 12 months with lesion length ≥ 30cm (core lab)

23 Patients / 25 Lesions

Extreme Lesion Analysis

12 Month Results of Long Lesion Sub-Analysis Presented

DETOUR I EXTREME LESION ANALYSIS

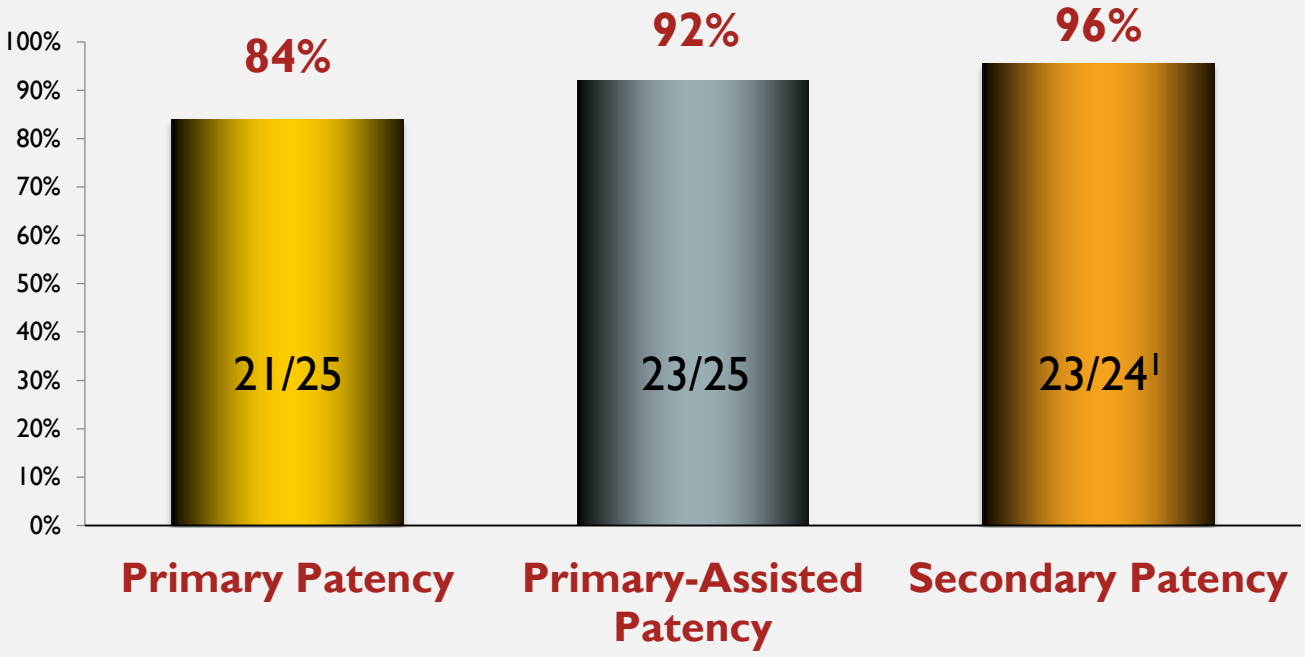
12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions

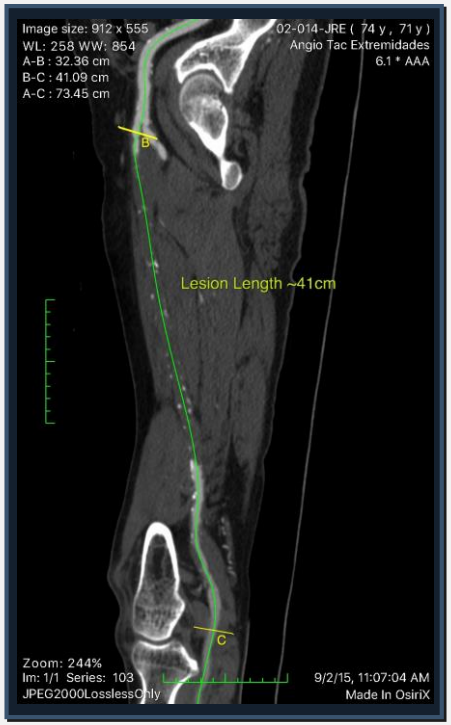
Baseline Lesion and Clinical Characteristics

Lesion Length, cm (mean ± SD)	**35.9 ± 4.1**
Total Occlusions, % (n/N)	92.0% (23/25)
De novo Lesions, % (n/N)	64.0% (16/25)
Age, years (mean ± SD)	67 ± 7.4
Male Gender, % (n/N)	73.9% (17/23)
History of Smoking, % (n/N)	91.3% (21/23)
R-B Classification, (mean ± SD)	3.0 ± 0.2

DETOUR I EXTREME LESION ANALYSIS: PATENCY

12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions



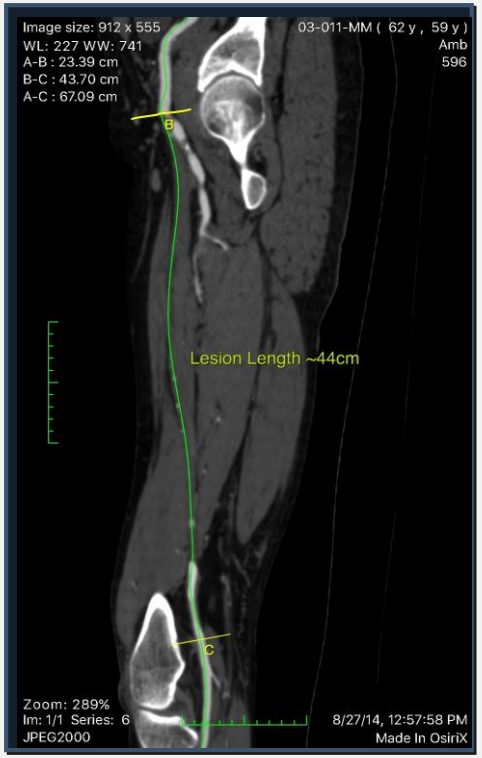


[1]Patient 03-011 was exited from the study following surgical treatment for thrombosis post 1-month follow-up.

DETOUR I EXTREME LESION ANALYSIS: PERFORMANCE AND SAFETY

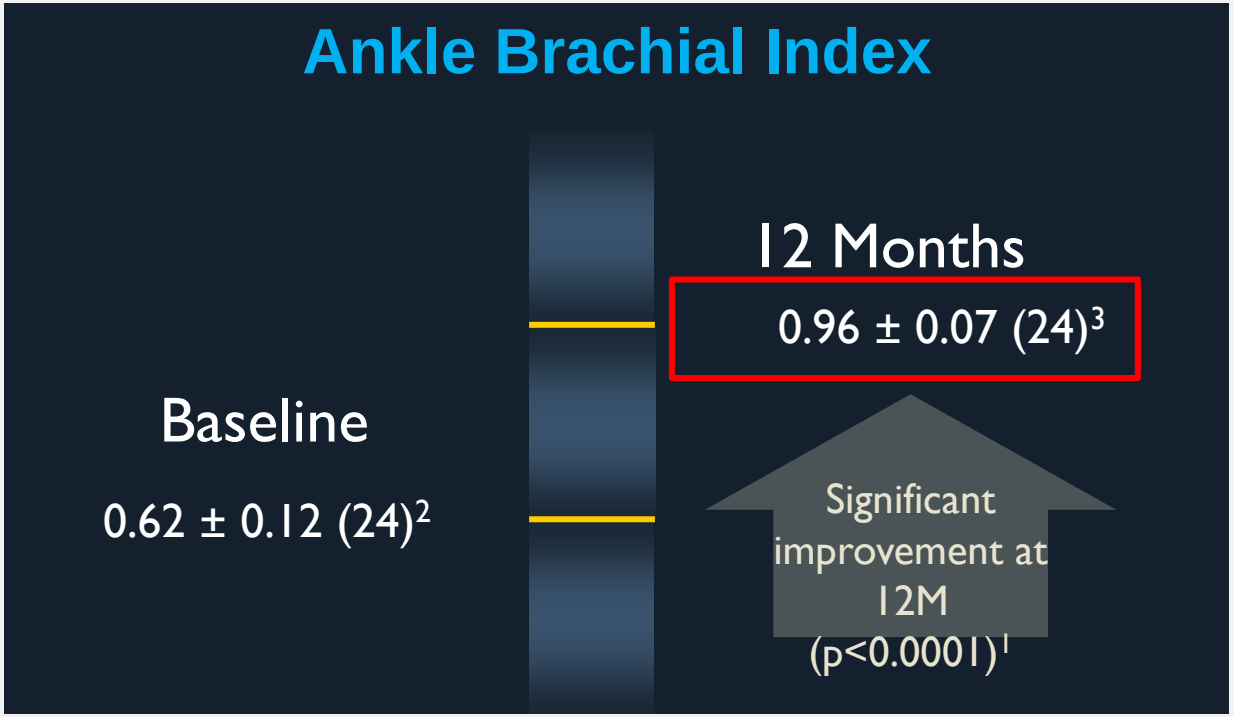
12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions

Key Secondary Performance Endpoints	
Technical Success	100% (25/25)
Procedural Success	96% (24/25)
Key Secondary Safety Endpoints at 30 Days	
Freedom from Deep Vein Thrombosis	100% (25/25)
Freedom from Death	100% (23/23)
Freedom from Amputation	100% (25/25)
Freedom from Acute Limb Ischemia	96% (24/25)
Freedom from TVR	96% (24/25)



DETOUR I EXTREME LESION ANALYSIS: HEMODYNAMIC IMPROVEMENT

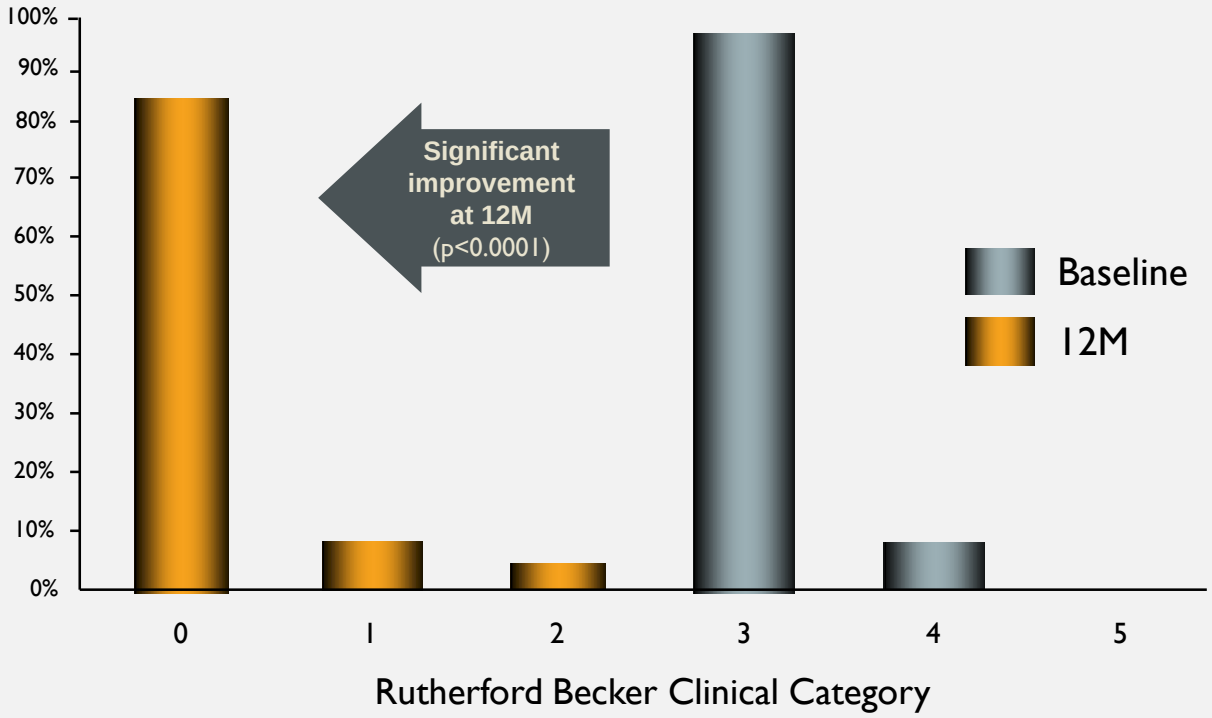
12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions



[1]p-values are calculated using paired t-test for matched data
[2]1 subject missing ABI/ Rutherford at Baseline
[3]Patient 03-011 was exited from the study following surgical treatment for thrombosis post 1-month follow-up

DETOUR I EXTREME LESION ANALYSIS: FUNCTIONAL STATUS

12 Month Analysis of Initial Patients with Lesions ≥ 30 cm
N=23 Patients / 25 Lesions



DETOUR I EXTREME LESION ANALYSIS: CONCLUSIONS

12 Month Analysis of Initial Patients with Lesions ≥ 30 cm

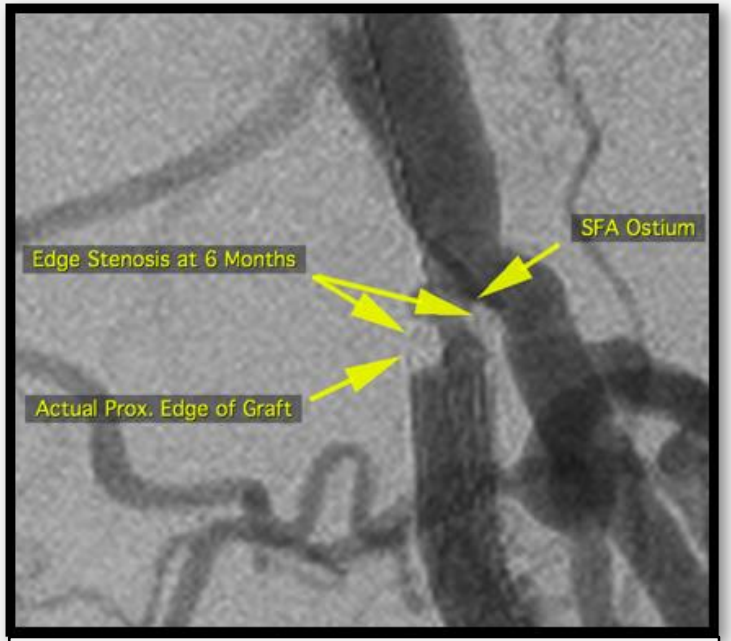
- Initial experience with the DETOUR System and procedure demonstrates durability without compromising venous health
- DETOUR I demonstrated improved outcomes in patients with the longest, most complex of lesions

Next step: DETOUR II IDE to expand the safety and effectiveness profile of the DETOUR procedure and continue to build the body of clinical evidence

KEY LESSON FROM DETOUR I TRIAL

Don't fear the Profunda

- Landing level-to or slightly proximal to the Profunda / SFA bifurcation is optimal
- Optimal placement can minimize edge stenosis



Proximal stent graft placed ~ 5.2 mm distal to the optimal landing position; edge stenosis at 6 months