Detour 2 3-Year Results with PTAB using Detour Procedure with the Torus 2

Sean P. Lyden, MD, FACS
Professor & Chairman
Vascular Surgery

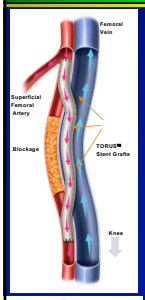
Disclosures

- Consultant: BD, Boston Scientific, Contego Medical, Cordis, Endologix, Inspire MD, Medtronic, Rapid Medical, Shockwave, Penumbra, Vivasure, Nectero, Reflow
- Stock options: Inspire MD and Centerline Biomedical, Reflow
- VIVA Physicians, Board Member
- Research Studies: Abbott, Endologix, Surmodics, W.L. Gore, Terumo Aortic, NIH, Boston Scientific, Merit, Contego Medical, Inspire MD, Reva Medical, Penumbra, Medalliance, Nectero

Complex Femoral Popliteal Disease

- Bypass and EndoRx are current strategies for long complex (≥ 200mm) femoropopliteal lesions.
- Bypass is complicated by high morbidity, lengthy hospitalization, and high readmission rates.
- EndoRx common but long-term efficacy is limited
- PTAB with DETOUR = Bypass through 2 years.
- We present the 3-year results of the DETOUR2 Study.

DETOUR Procedure for Percutaneous Fem-Pop Bypass



Originates in SFA, travels within the femoral vein, and returns to the popliteal artery

Surgical principles using an endovascular approach

Femoral vein becomes pathway for stent graft bypass

TORUS™ Stent Graft

Endocross Device

DETOUR 2 IDE

Objective: Prospective, single-arm, multi-center clinical evaluation of the DETOUR System and Procedure for a percutaneous Fem-Pop bypass	
Patients (n)	202
Sites (n)	36
Regions	US and Europe
Enrollment Period	Dec 13, 2017 -Oct. 5, 2020
Follow Up	30 Days, 6M, 12M, 24M, 36M
Duplex Core Lab	✓
Angiographic Core Lab	✓
Clinical Events Committee	✓
Data Safety Monitoring Board	✓
Primary Safety Endpoint	MAE at 30D (Death, CDTLR, Amputation, DVT, PE, Major Bleeding)
Primary Efficacy Endpoint	Patency at 12M (defined as the absence of CD-TLR and PSVR of >2.5 within the stent

DETOUR2 Inclusion Criteria

- Rutherford 3-5
- Symptomatic femoropopliteal lesions ≥ 20 cm:
  - Chronic total occlusion (100% stenosis)
  - Diffuse stenosis (> 50% stenosis)
  - In-stent restenosis
- Reference vessel diameter (RVD) ≥ 4.5 mm and ≤ 6.7 mm
- Accessible SFA at origin
- Patent popliteal artery (< 50% stenosis) distal to the landing zone
- At least 1 patent tibial artery extending to the foot
- Patent femoral vein ≥ 10 mm in diameter or duplicate

DETOUR2 Baseline Demographics and Lesion Characteristics

Demographics	All Subjects N=202
Age	68.9 ± 9.4 (range: 47-88)
Gender (Male)	73.8%
Rutherford Classification Category	
3	77.7%
4	17.8%
5	4.5%
Hypertension	87.6%
Hyperlipidemia	69.3%
Diabetes	34.7%
CAD	46.0%
Prior History of Smoking	91.1%
Renal Insufficiency	10.9%
Previous PAD Intervention	60.5%
Previous PAD Surgery	16.8%
History of Venous Disease	0%

Lesion Characteristics	All Subjects* N=202
Total Occlusion (100% stenosis)	96.9% (194/202)
Diffuse Stenosis (> 70% stenosis)	97.0% (196/202)
In-stent Restenosis	17.3% (35/202)
Lesion Length (Normal to Normal, mm)	327 ± 67.4 (180) 328 [195, 520]
Calcified Length (mm)	64 ± 77.5 (178) 41 [0, 416]
CTO length (mm)	217 ± 86.0 (191) 232.5 [0, 436]
Definitive Ca++	
None/Mild	29.1% (52/179)
Moderate	0.6% (1/179)
Severe	70.4% (126/179)
Pre-DETOUR PTA performed	76.1% (153/201)

*Results are presented as percentage (events/evaluable subjects), or mean ± SD (evaluable), median [min, max]

DETOUR Procedural Characteristics

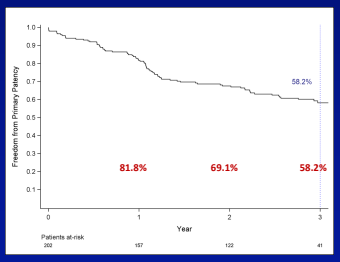
Variable	All Subjects N=202
Procedural Complications/AEs	5.0% (10/202)
Estimated blood loss (ml)	50 ± 57.5 (201) 30.0 (0, 400)
Contrast volume used (ml)	208 ± 111.7 (199) 180 (50, 900)
Fluoroscopy time (min)	46.4 ± 19.5 (199) 42.0 (12, 122)
Total procedure time (min)	181.4 ± 90. 6 (202) 163.0 (55, 495)
Length of Stay (Through Discharge)	1.1 ± 1.8 days
Major Procedure-Related Infections within 30 Days	0.5% (1/199)
Technical Success (Through Procedure)	100.0% (200/200)
Procedural Success (Through Discharge)	98.5% (197/200)

DETOUR Procedural Outcomes

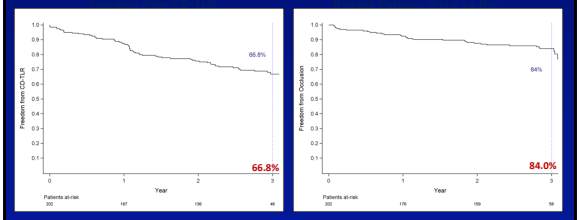
	30 Days	6 Months	12 Months	24 Months	36 Months
Clinical Success	92.9% (182/196)	94.3% (182/192)	96.0% (173/178)	95.3% (142/148)	96.7% (145/150)

Clinical Success defined as limb ischemia improvement as assessed by Rutherford Clinical Classification (improvement in scale by ≥1) at 30 days and 6, 12, 24 and 36 months
Data presented as % (n/N) [95% CI] where N is the number of subjects with available data.

Primary Patency (ITT) through 3 years



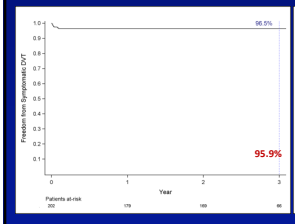
Other Efficacy Outcomes through 3 years (ITT)



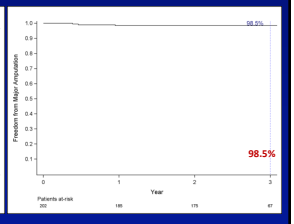
At-risk denominators include patients with informative data and have not yet experienced an event

Safety through 3 years

Freedom from Symptomatic DVT



Freedom from Major Amputation



At-risk denominators include patients with informative data and have not yet experienced an event
Major amputation: 2 subjects were RCC 3 and 1 subject was RCC 5 on presentation

Primary Patency through 3 years in contemporary practice

OUTCOMES	DETOUR2 STUDY	ENDOVASCULAR APPROACH[1]	OPEN BYPASS (NON-AUTOLOGOUS GRAFT) REPAIR[2]
3 YR PRIMARY PATENCY	58.2%	43%	46% (PTFE)

1. Endovascular Intervention for the Treatment of Trans-Atlantic Inter-Society Consensus (TASC) D Femoropopliteal Lesions: A Systematic Review and Meta-Analysis. Cardiovasc Revasc Med. 2021 Jan;22:52-65
2. A meta-analysis to compare Dacron versus polytetrafluroethylene grafts for above-knee femoropopliteal artery bypass. J Vasc Surg. 2014 Aug;60(2):506-15.

Conclusions

- PTAB with DETOUR provides new EndoRx for long complex femoropopliteal lesions
- DETOUR2 demonstrates durable efficacy through 3 years with 58.2% primary patency and 66.8% freedom-from CD-TLR
- When looking at open or not 84% PTAB open at 3 years
- PTAB has no late venous issues or added DVT risk at 3 years
- 3 year DETOUR results equal Bypass and surpass those of EndoRx
- PTAB with DETOUR is a novel endovascular technique to perform endovascular surgical bypass and fills a unique role in our armamentarium