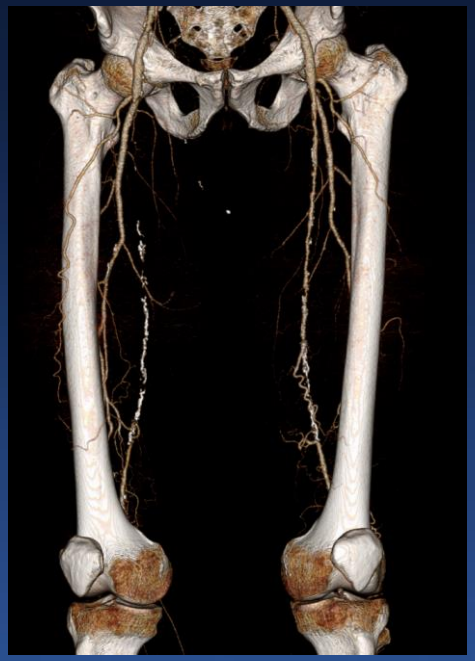
Percutaneous Bypass: Update on the DETOUR and DETOUR II Trials



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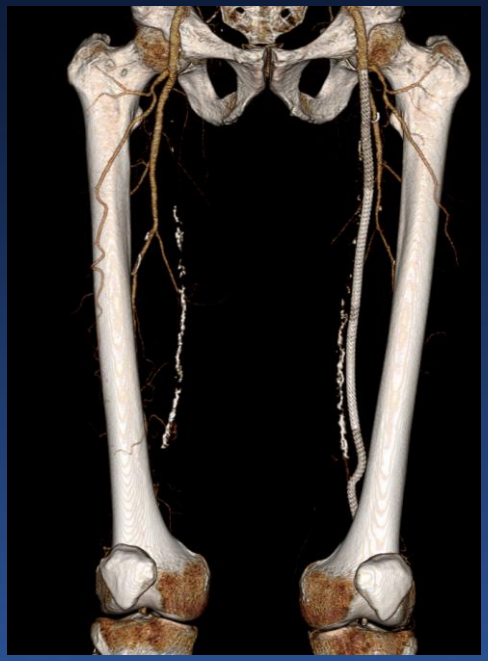


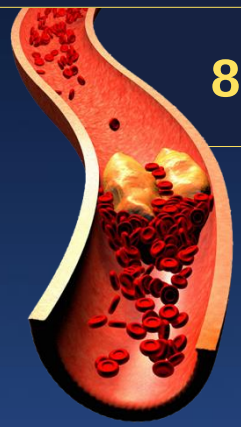
Disclosure Statement of Financial Interest

I, Ehrin Armstrong, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

The Inconvenient Truth About Femoropopliteal Revascularization

Despite numerous devices with "long lesion" indications, long, complex SFA lesions do not have an optimal endovascular treatment strategy

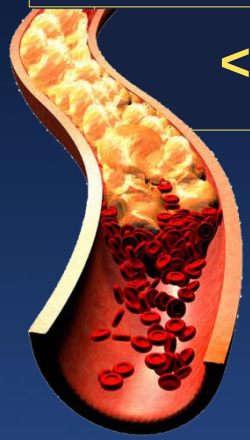
Simple Lesions



80% patency at 12M

Endovascular = usually first choice for shorter or less complex lesions

Long, Complex Lesions

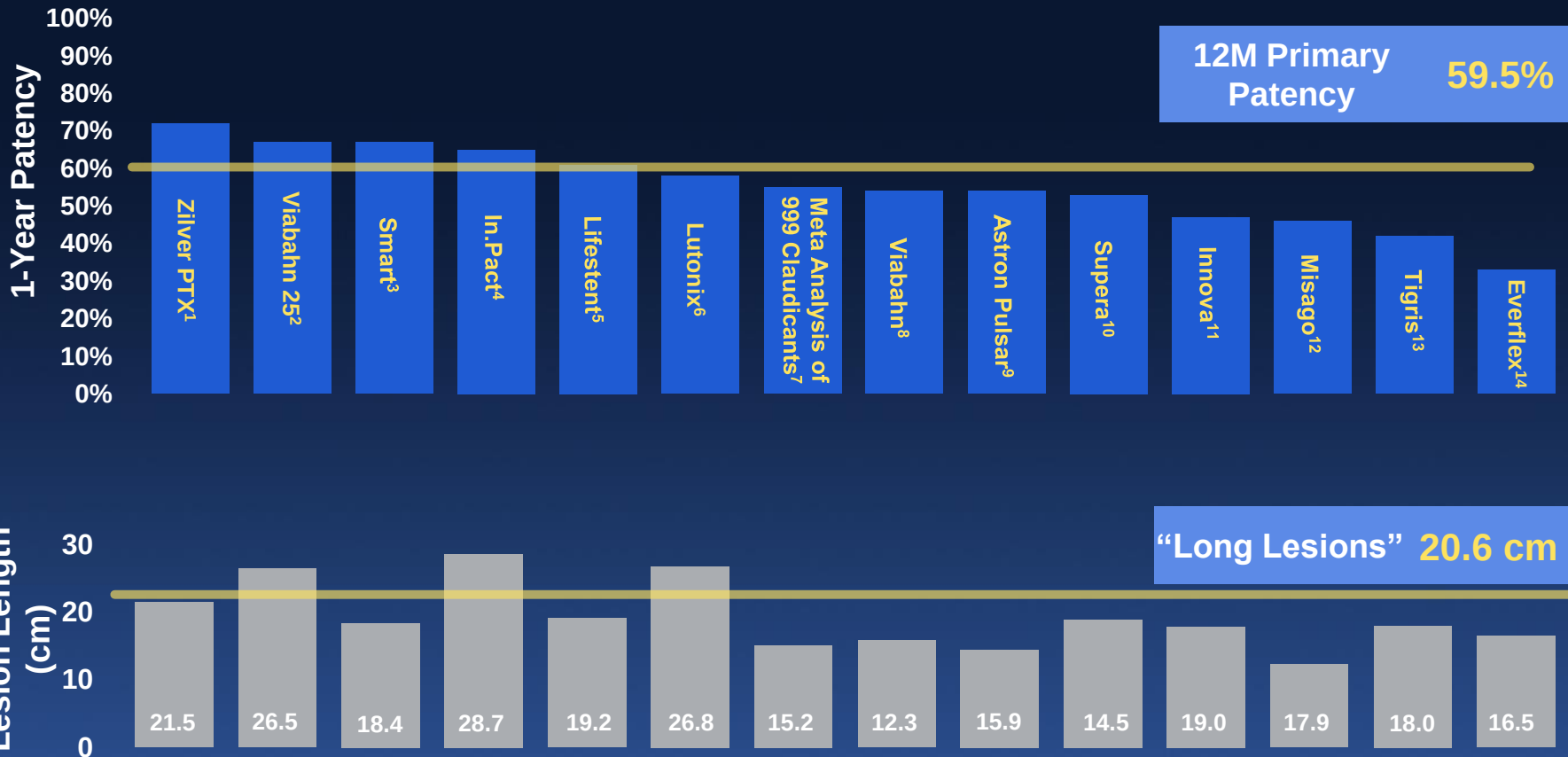


<60% patency at 12M*

Endovascular = consistently less durable than open bypass though 12 months

* Composite of the following sources: [1] P100022/S020; [2] P040037/S060; [3] P120002 ; [4] P140010/S037; [5] P070014/S010; [6] P130024; [7] Rocha-Singh, Krishna J., et al. "Patient-level Meta-analysis Of 999 Claudicants Undergoing Primary Femoropopliteal Nitinol Stent Implantation." Catheterization and Cardiovascular Interventions 89.7 (2017): 1250-1256.; [8] P040037; [9] P160025; [10] P120020; [11] P140028; [12] P140002; [13] P160004; [14] P110023

SFA Devices Consistently Demonstrate an Inverse Relationship Between Lesion Length and Durability

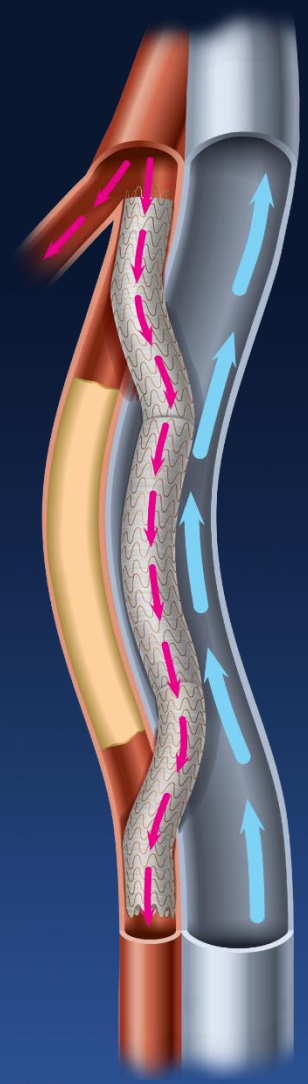


tct2017

[1] P100022/S020; [2] P040037/S060; [3] P120002 ; [4] P140010/S037; [5] P070014/S010; [6] P130024; [7] Rocha-Singh, Krishna J., et al. "Patient-level Meta-analysis Of 999 Claudicants Undergoing Primary Femoropopliteal Nitinol Stent Implantation." Catheterization and Cardiovascular Interventions 89.7 (2017): 1250-1256.; [8] P040037; [9] P160025; [10] P120020; [11] P140028; [12] P140002; [13] P160004; [14] P110023 [15] Interpolated avg. assuming normal distribution.

Cardiovascular Research Foundation

The DETOUR Procedure



Percutaneous femoropopliteal bypass

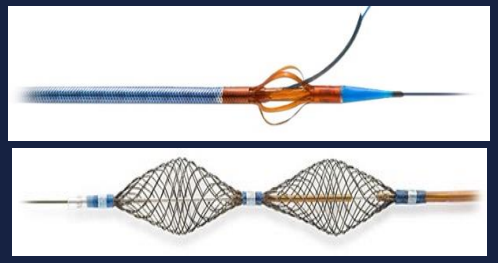
Surgical principles using an endovascular approach

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

Femoral vein becomes pathway for stent graft bypass

TORUS™ Stent Graft

DETOUR Crossing Kit

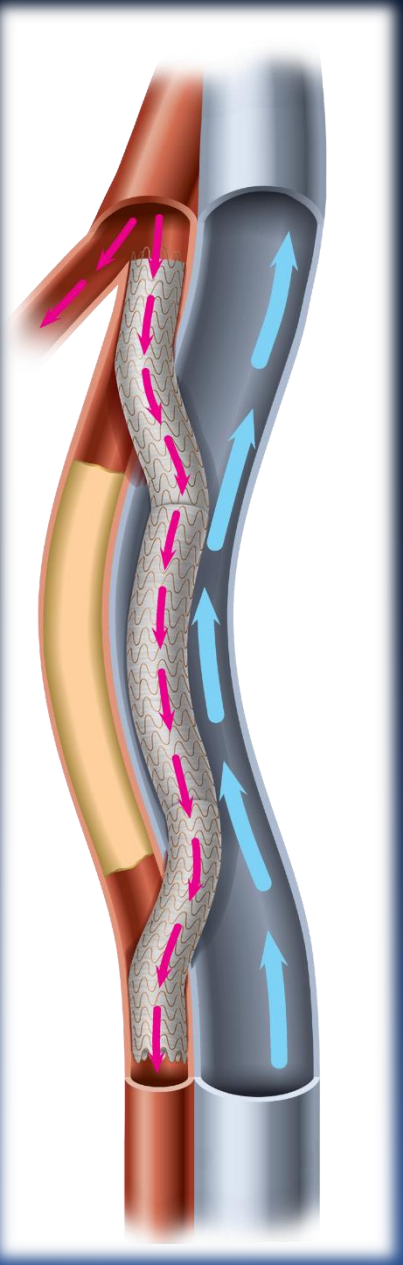


Step 1: Proximal Anastomosis

Specialized crossing device and snare create arteriovenous connection above proximal margin of the lesion

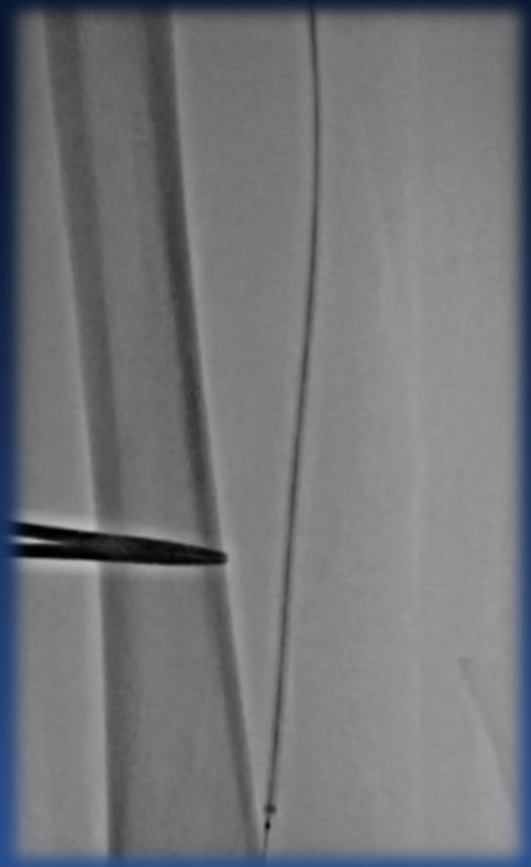
Step 2: Distal Anastomosis

Specialized crossing device and snare create arteriovenous connection below distal margin of the lesion



Step 3: Graft Deployment

Stent graft bypass exits artery, travels within femoral vein, adjacent to occlusion and reenters artery at the site of reconstitution

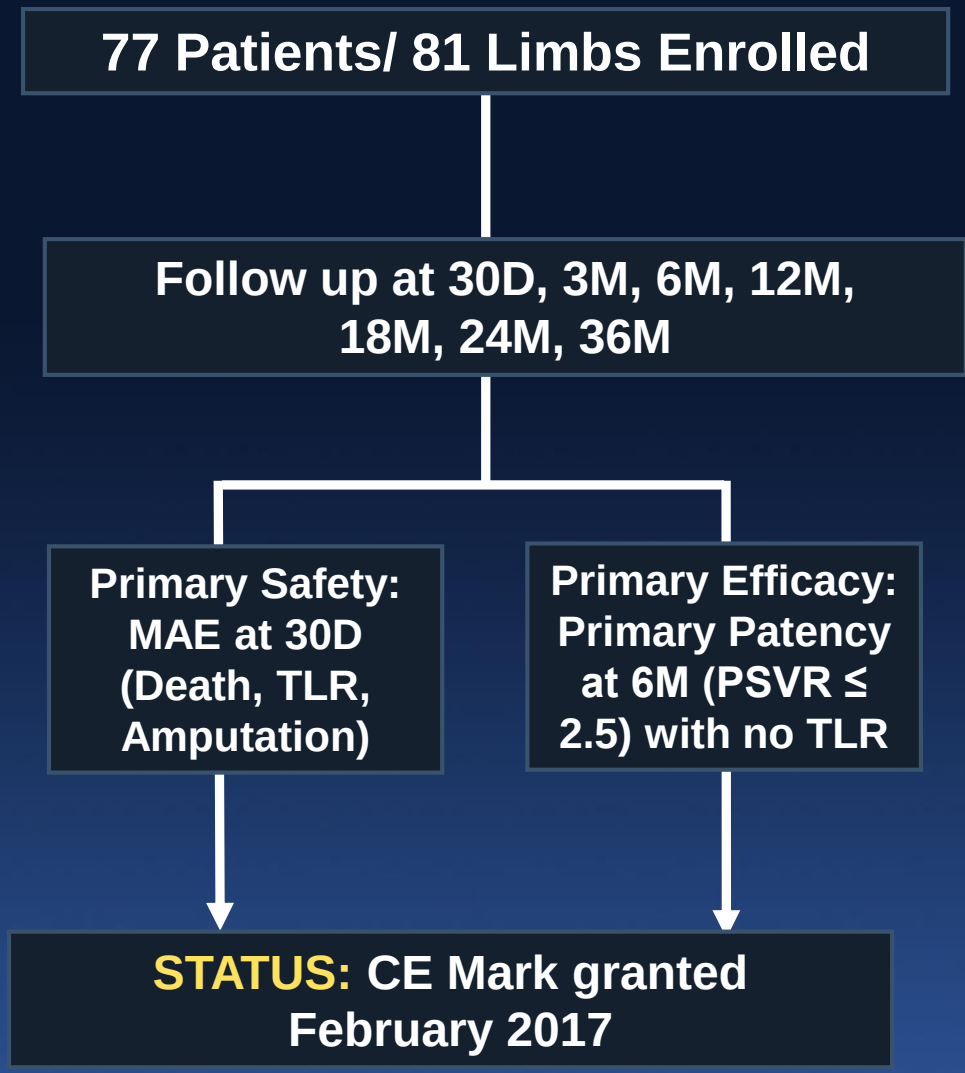


PQ Bypass Clinical Program

	Proof of Concept	CE Mark (DETOUR I)	US Pivotal (DETOUR II)
# Subjects	23	81	292
# Centers	1	8	40
Study Design	IRB-approved, observational	Prospective, single-arm	Prospective, single-arm safety and efficacy
Follow Up	10 Years	3 Years	3 Years
Enrollment	LPI	LPI Jul ‘17	Ongoing

DETOUR I

- **DESIGN:** Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and Procedure for Percutaneous Bypass
- **INCLUSION CRITERIA:** De novo, CTO, or ISR femoropopliteal Lesion ≥10 cm; femoral vein diameter ≥10mm or duplicate
- **Independent Review:** Core Lab (DUS, CT, Angio) by Cleveland Clinic; Clinical Events Committee by Syntactx



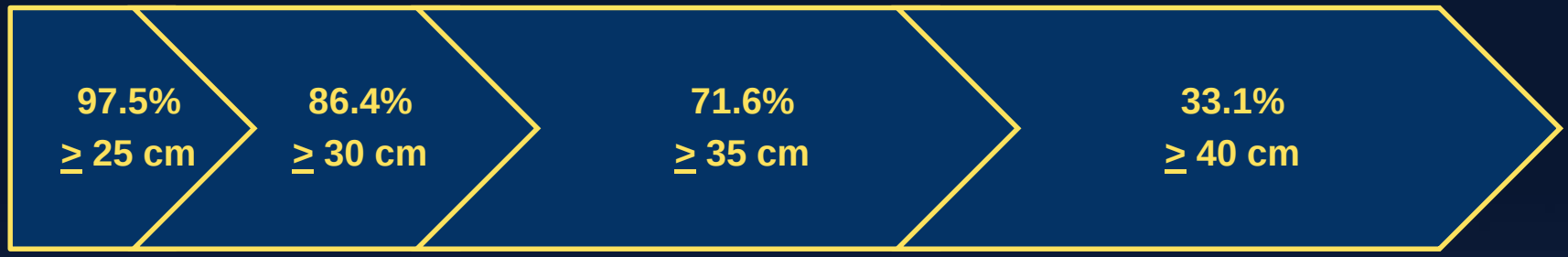
Baseline Characteristics

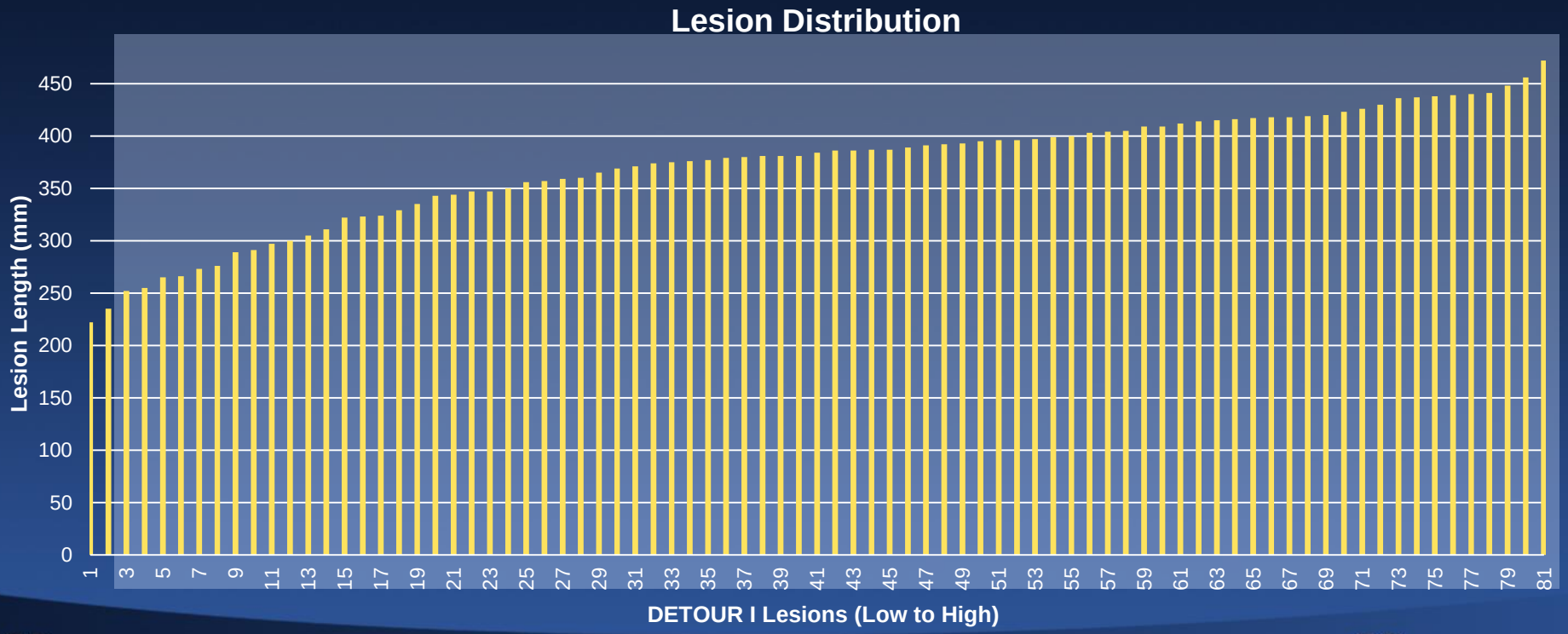
Clinical Characteristics	N=77 Patients
Male Gender	83.1% (64/77)
Age, Years	64.1± 7.2
Diabetes Mellitus	24.7% (19/77)
Hypertension	83.1% (64/77)
Hypercholesterolemia	39.0% (30/77)
History of CAD or MI	42.9% (33/77)
History of Smoking	87.0% (67/77)
Previous Peripheral Intervention	29.9% (23/77)
ABI	0.64 ± 0.17
Rutherford 3	92.2% (71/77)
Rutherford 4-5	7.8% (6/77)

Lesion Characteristics		N=81 lesions/ 77 patients
Lesion Length		**37.1 cm ± 5.5 cm**
Range		22.2 cm – 47.2 cm
% CTO		96% (78/81)
Calcification		
Severe		67.5% (54/80)
Moderate		13.8% (11/80)
Mild		18.8% (15/80)
TASC II Lesion Type		
	C	56% (45/81)
	D	44% (36/81)
Vessel Run-off		
	1	8% (6/77)
	2	29% (22/77)
	3	64% (49/77)

DETOUR I Lesion Distribution by Length

Independently adjudicated by Cleveland Clinic Core Laboratory

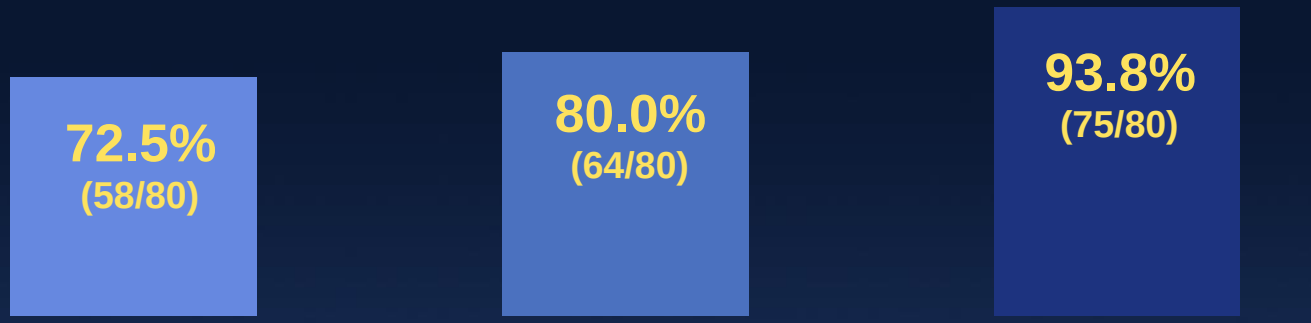




DETOUR I: Efficacy and Safety Through 12 Months

Independently adjudicated by Cleveland Clinic Core Laboratory and Syntactx CEC

Efficacy Through 12 Months



Primary Patency
PSVR < 2.5 without TLR

Primary Asst. Patency
Revasc of 50%-99% stenoses

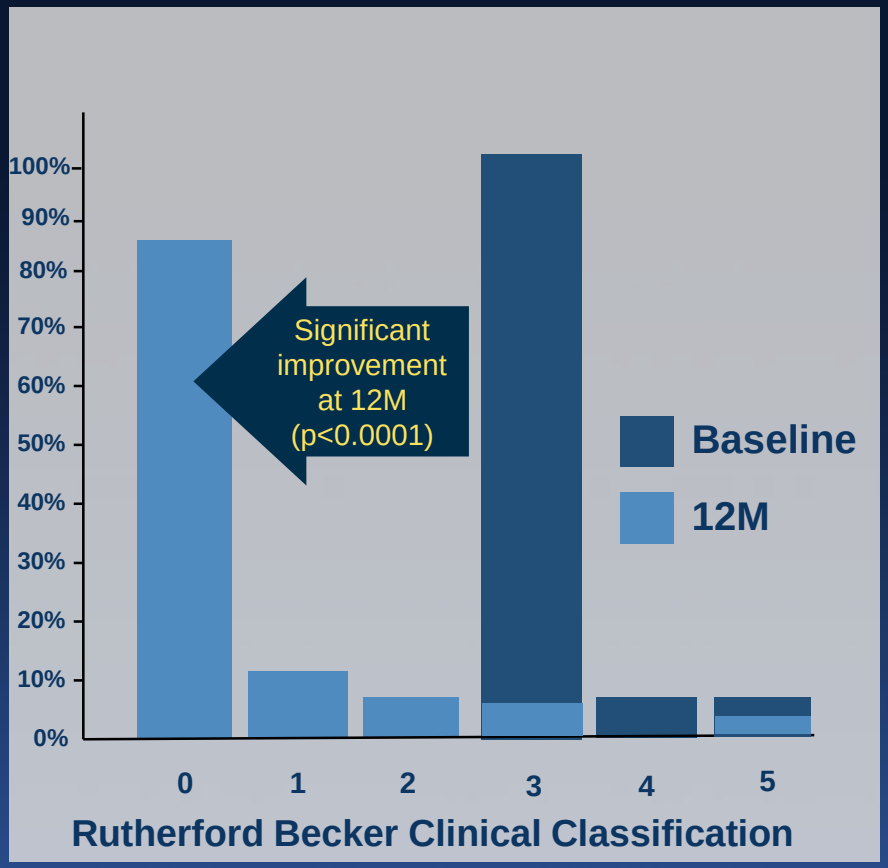
Secondary Patency
Revasc of 100% occlusion

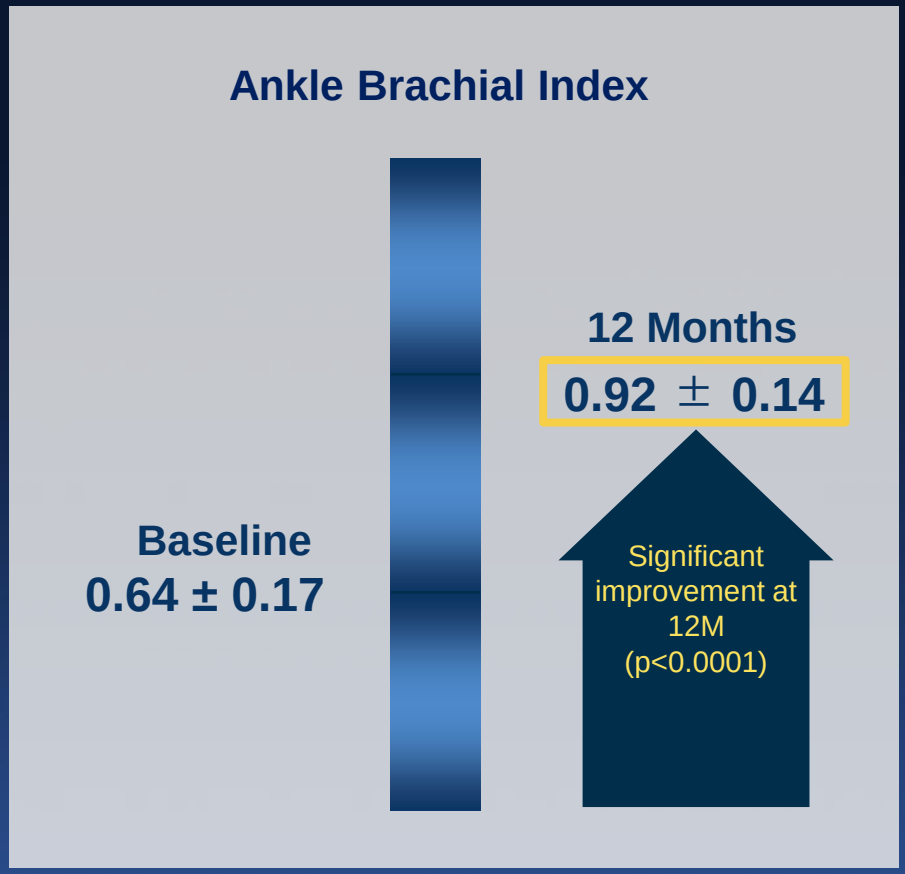
Safety Through 12 Months

N=77 Patients/81 Lesions	30D	12M
Freedom from DVT	100% (81/81)	97.5% (78/80)
Freedom From Death	100% (77/77)	98.7% (76/77)
Freedom from Amputation	100% (81/81)	100% (80/80)
Freedom from ALI	98.8% (80/81)	98.8% (79/80)
Freedom from TLR	97.6% (79/81)	78.8% (63/80)

Functional Improvement Through 12 Months

90% of patients experienced Rutherford improvement ≥ 2 classes

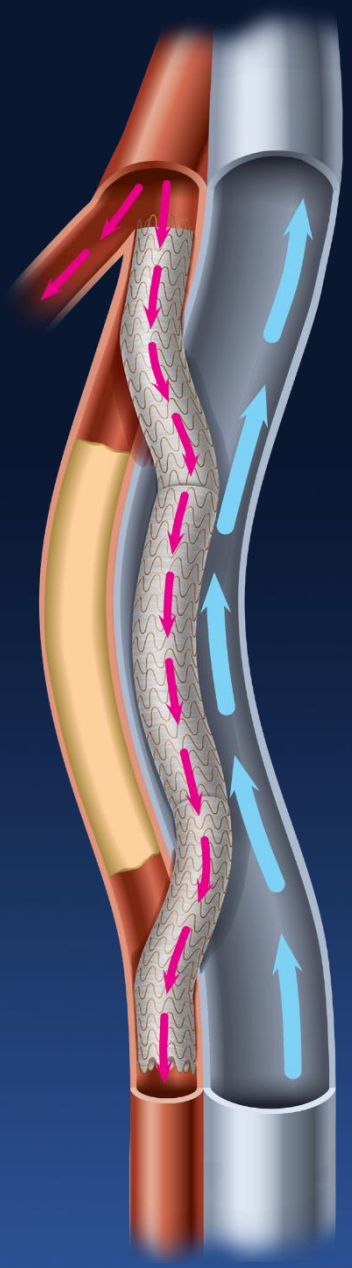




[1] 8 patients were missing Rutherford- Becker scores at 12M

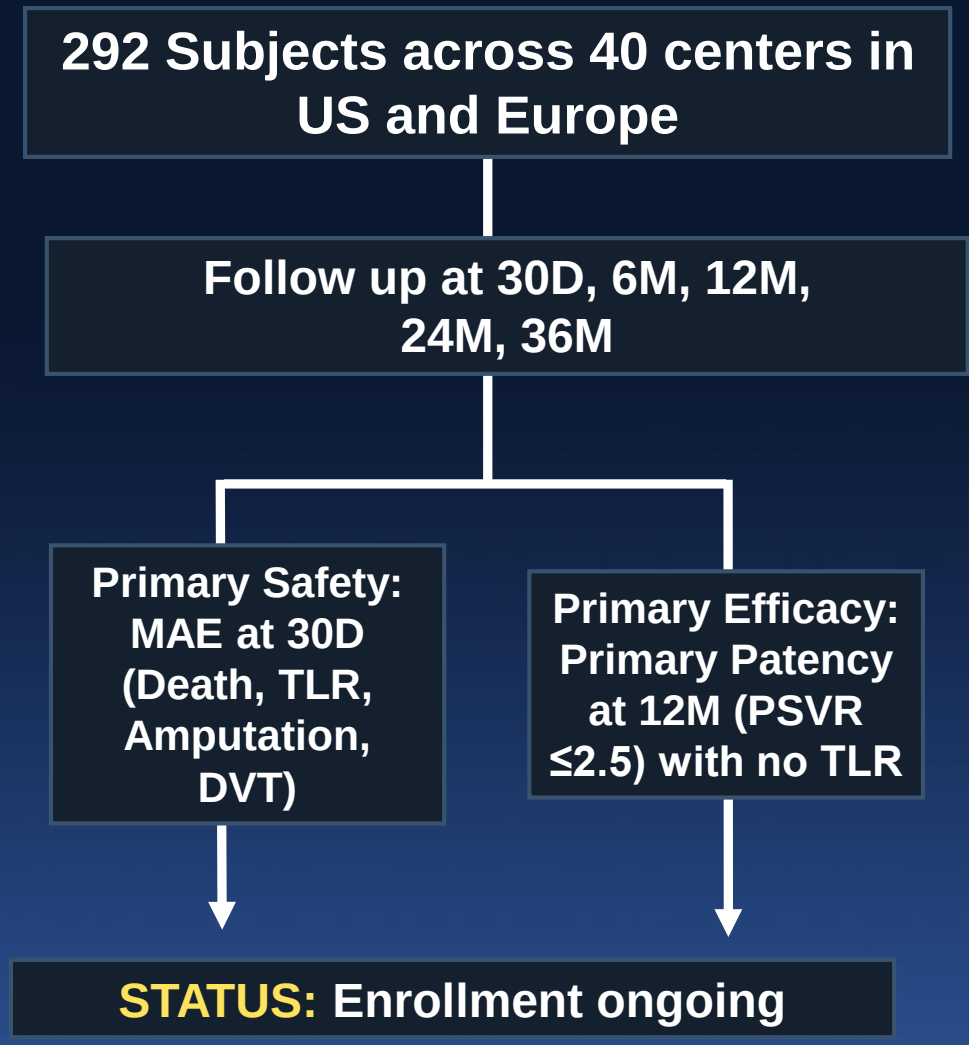
DETOUR II

Trial Update



DETOUR II

- **DESIGN:** Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and Procedure for Percutaneous Bypass
- **INCLUSION CRITERIA:** De novo, CTO, or ISR femoropopliteal Lesion ≥15 cm; femoral vein diameter ≥10mm or duplicate
- **Independent Review:** Core Lab (DUS, CT, Angio) by Cleveland Clinic; Clinical Events Committee by Syntactx



Case Review: Rocky Mountain VA

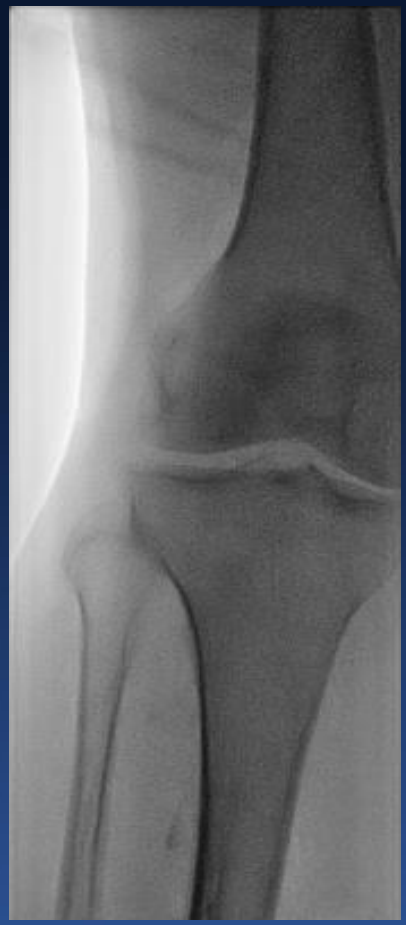
- 72 year-old male
- 35 cm TASC D lesion
- Rutherford 3
- History of smoking
- BMI of 30

Case Review: Pre Procedural Imaging

SFA

Popliteal

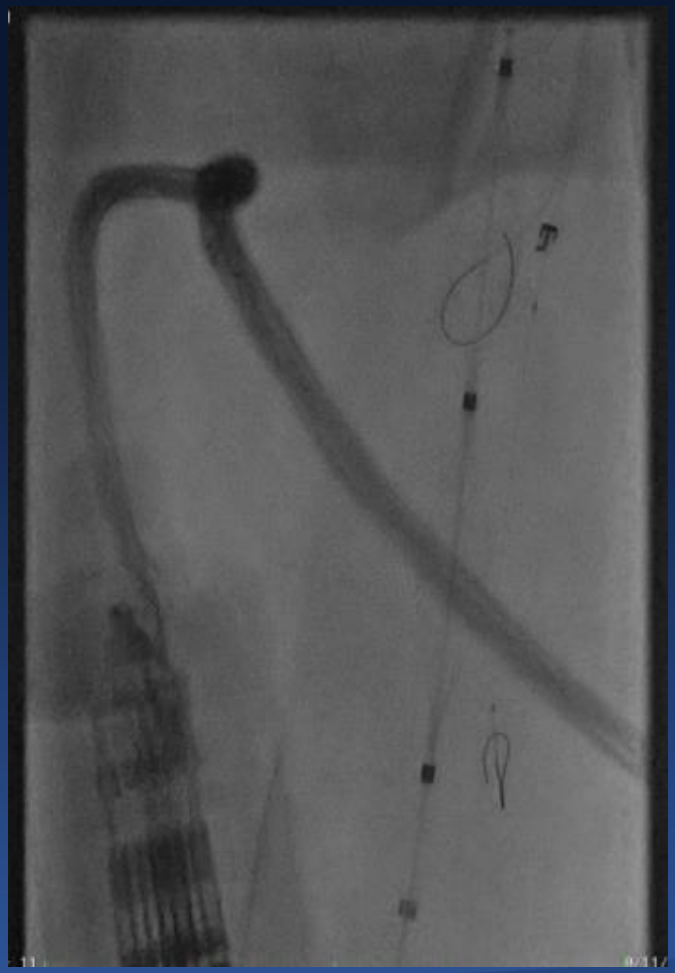
Venogram



Case Review: Proximal Crossing

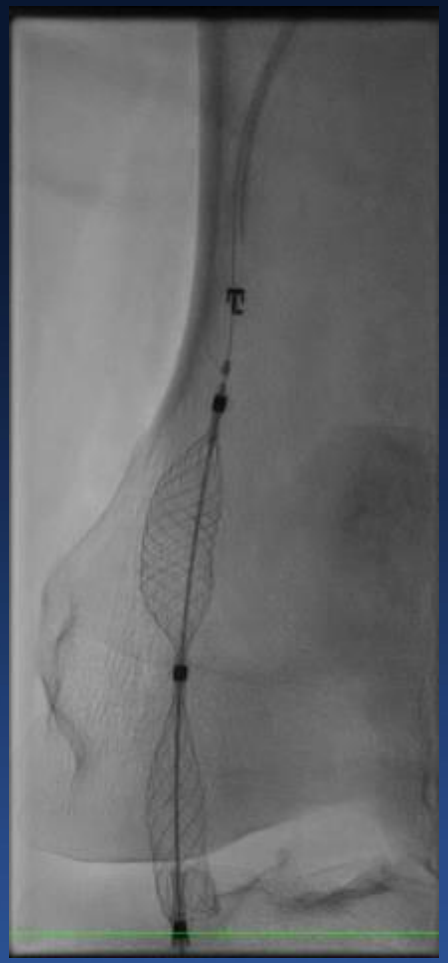
Alignment of Crossing Device Marker Band in SFA; Snare Expanded in FV

Crossing Device Needle from Artery into Vein – Wire Advanced into Snare

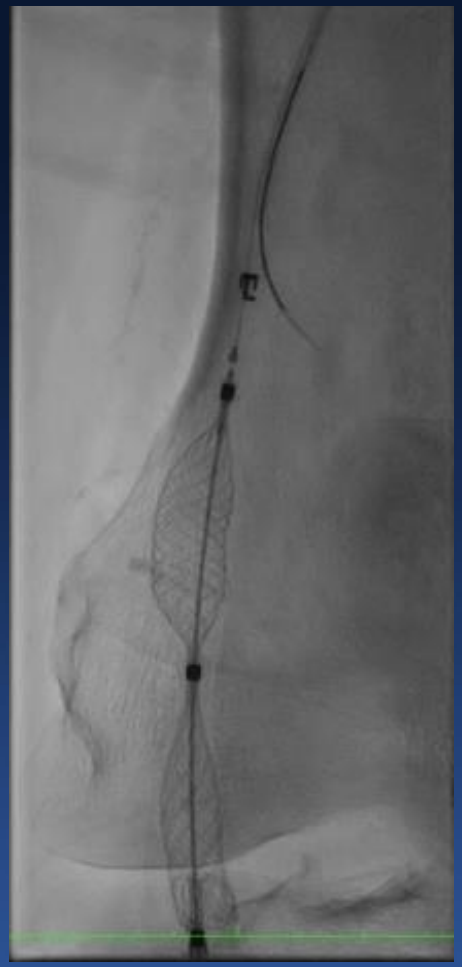


Case Review: Distal Crossing

Crossing Device Docked with Snare in Vein; Needle firing in orthogonal view



Wire advancement into popliteal artery



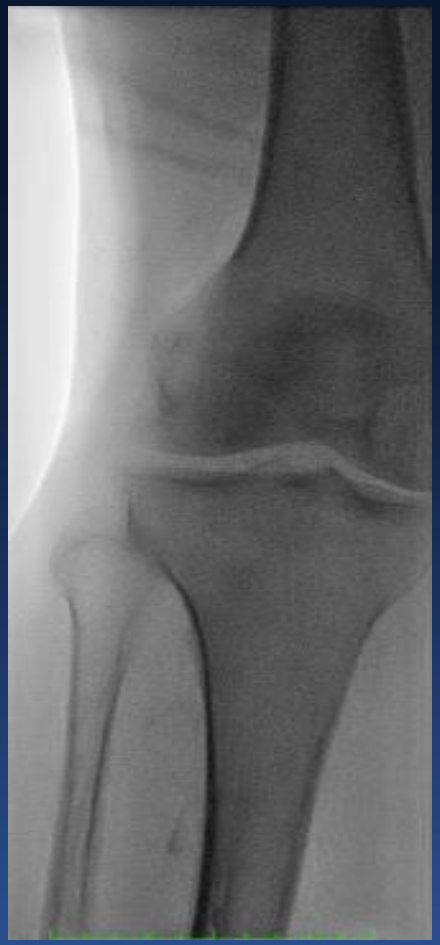
Case Review: Pre and Post Angiogram

Pre

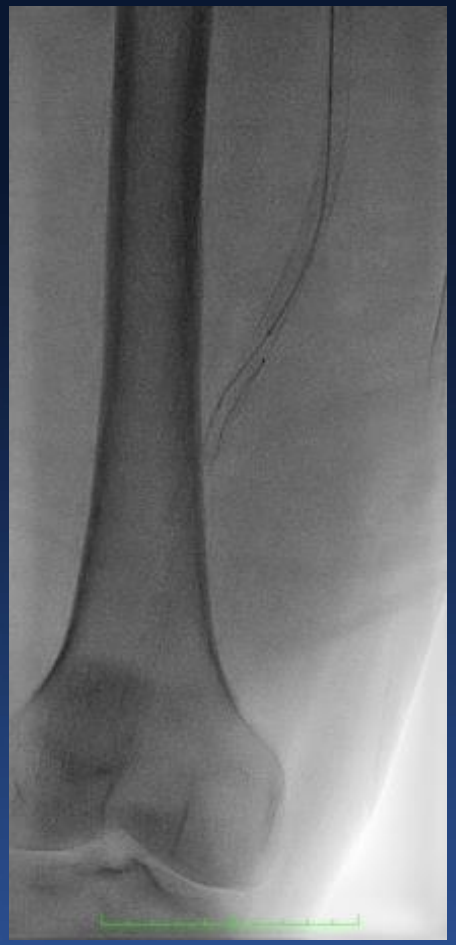
Post

Case Review: Pre and Post Venogram

Pre



Post



Conclusions

- Safety outcomes from DETOUR I demonstrate percutaneous bypass has a promising safety profile with 100% freedom from amputation, 98.8% freedom from acute limb ischemia and 98.7% freedom from death at 12 months
- Excellent durability in long, challenging, occlusive lesions (Cleveland Clinic Core Lab Adjudicated Patency)
- 72.5% Primary Patency, 78% Primary Assisted Patency, 93.8% Secondary Patency
- 12-Month safety and durability outcomes in DETOUR I demonstrate fully-percutaneous bypass is a promising endovascular alternative for complex femoropopliteal disease

DETOUR II IDE designed to build upon extant body of clinical evidence in even longer, more challenging lesions