2022 MID-ATLANTIC CONFERENCE

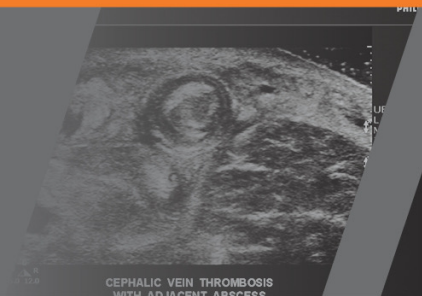
10th ANNUAL CURRENT CONCEPTS IN

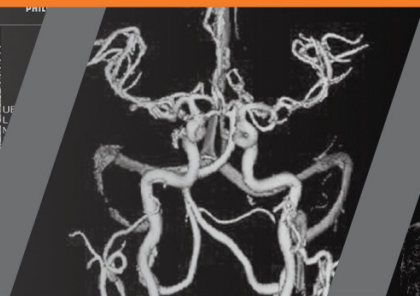
VASCULAR THERAPIES

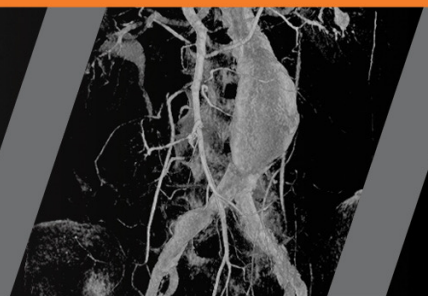
2022

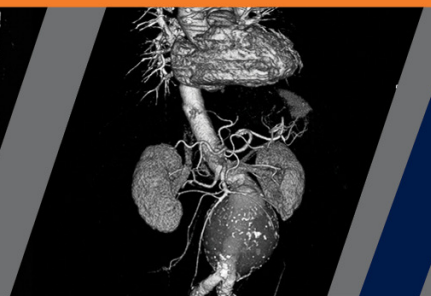
Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 28-30









Sentara Vascular Specialists

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2022

Alternative Endo Approach to Bypass

Samuel N. Steerman, MD, FACS, RPVI
EVMS Assistant Professor of Surgery
Sentara Vascular Specialists

Disclosures

- Becton Dickinson – consultant and speaker
- Medtronic – speaker

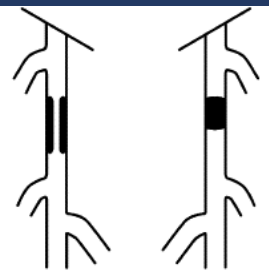
- This lecture involves an:
  - Investigational device. Limited by Federal (or United States) law to investigational use.

Outline

- Standard treatment for SFA disease
- Limitations of current treatment
- Introduction to the PQ Bypass
- Technique of PQ bypass
- Outcomes data
- Local experience

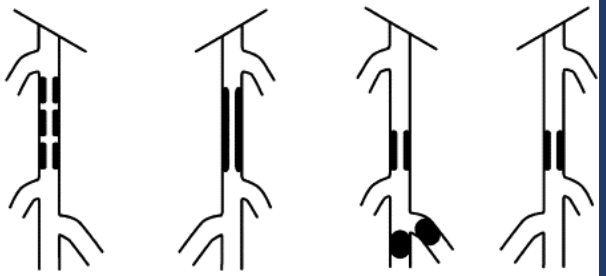
Type A lesions

- Single stenosis ≤10 cm in length
- Single occlusion ≤5 cm in length



Type B lesions:

- Multiple lesions (stenoses or occlusions), each ≤5 cm
- Single stenosis or occlusion ≤15 cm not involving the infrageniculate popliteal artery
- Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
- Heavily calcified occlusion ≤5 cm in length
- Single popliteal stenosis

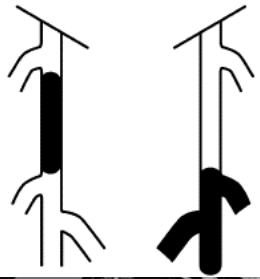


Type C lesions

- Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification
- Recurrent stenoses or occlusions that need treatment after two endovascular interventions

Type D lesions

- Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery)
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels



TASC II

A. Endovascular

B. Endovascular

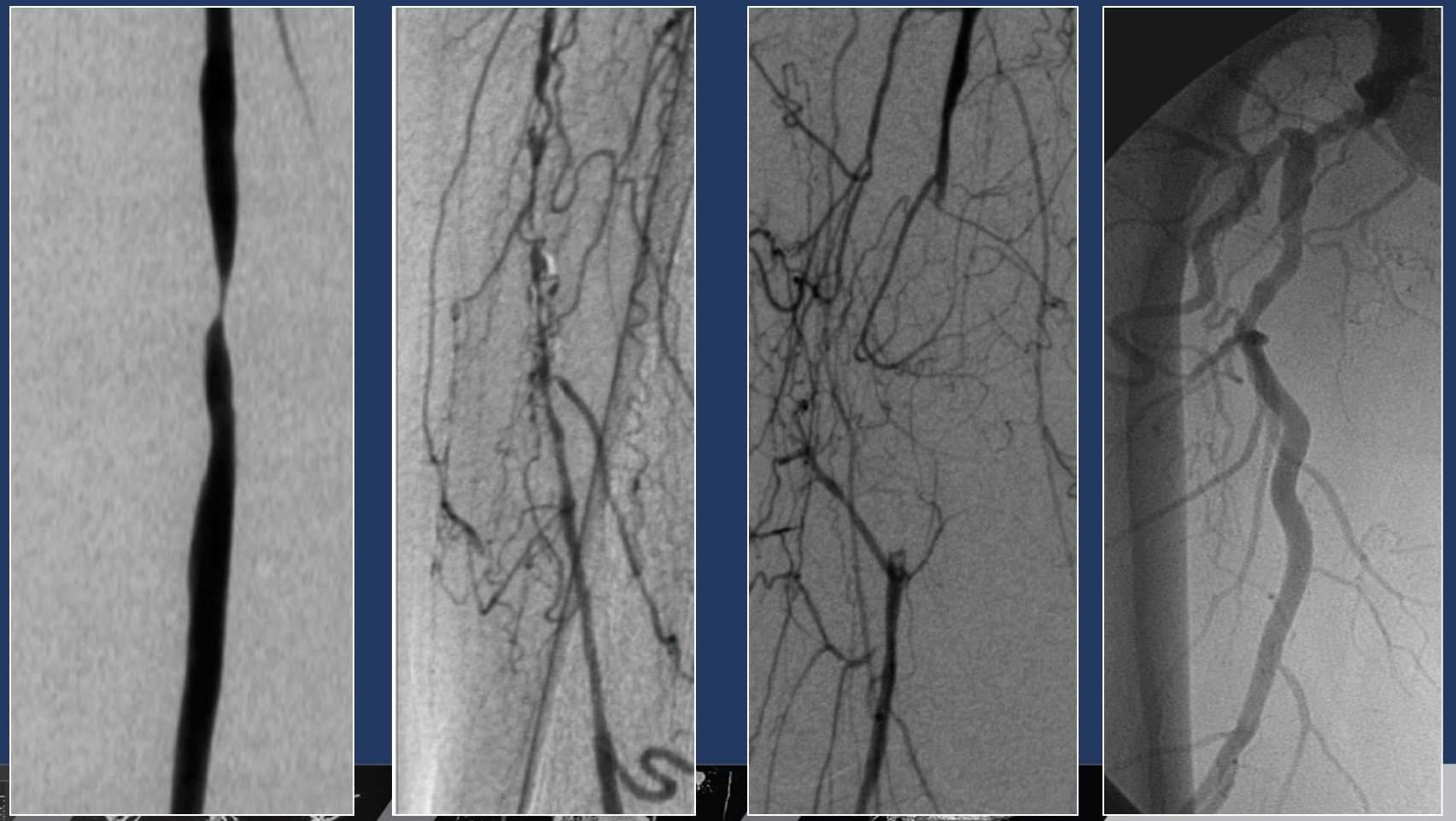
C. Open Surgery Preferred

D. Open Surgery

Journal of Vascular Surgery 2007 45, S5-S67DOI: (10.1016/j.jvs.2006.12.037)

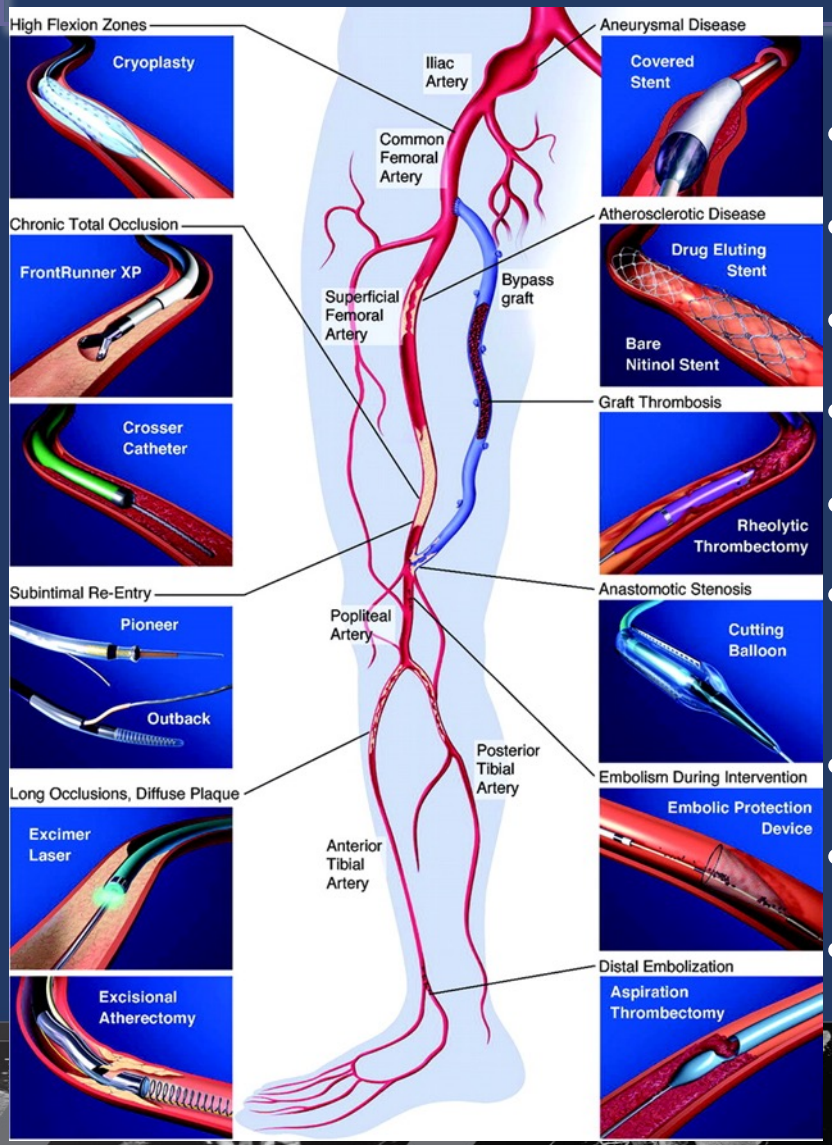
TASC Angiography

TASC A **TASC B** **TASC C** **TASC D**



•Management of PAD-TransAtlantic Inter-Society Consensus (TASC) JVS 2000 31(1;2)

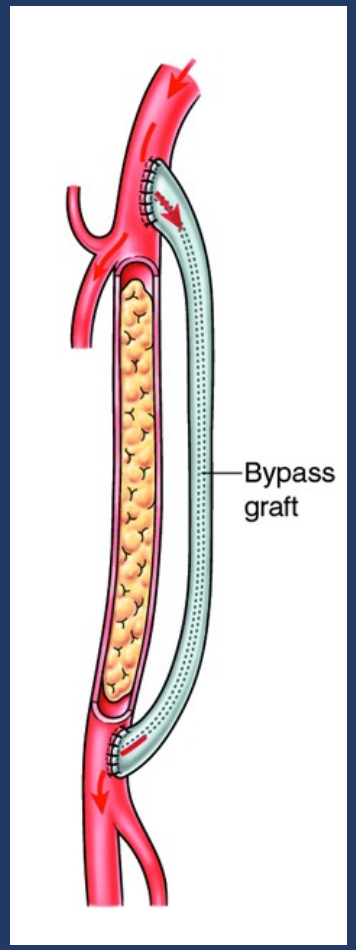
Endovascular SFA Treatment
Options are varied

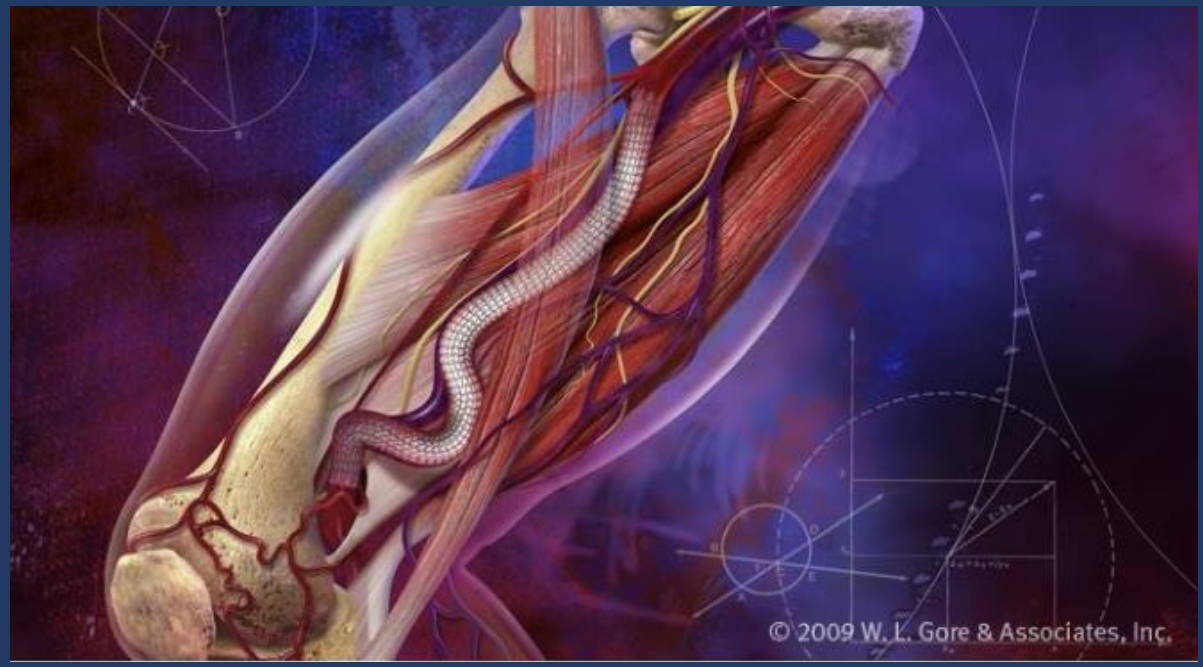


- PTA (transluminal/cutting)
- Cryoplasty
- Stenting (bare, covered, DES)
- Laser Atherectomy
- Mechanical Atherectomy
- Pharmacomechanical Thrombectomy
- Recanalization by CTO devices
- Subintimal angioplasty
- Hybrid Surgical/Endovascular

...ason H. Rogers, and John R. Laird
...Circulation. 2007;116:2072-2085

The “internal bypass”





Surgical Bypass

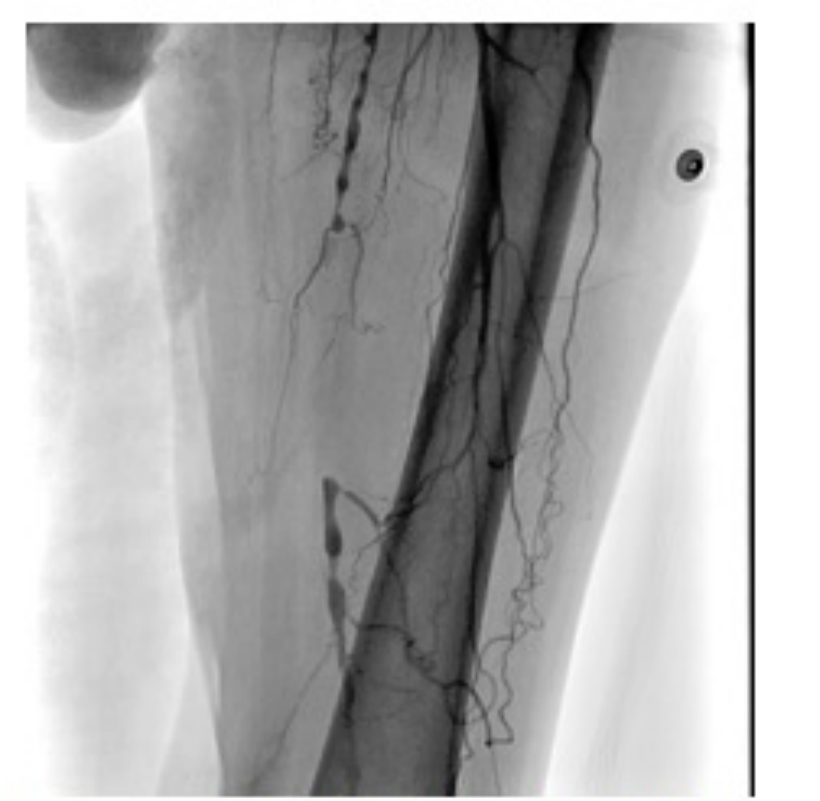
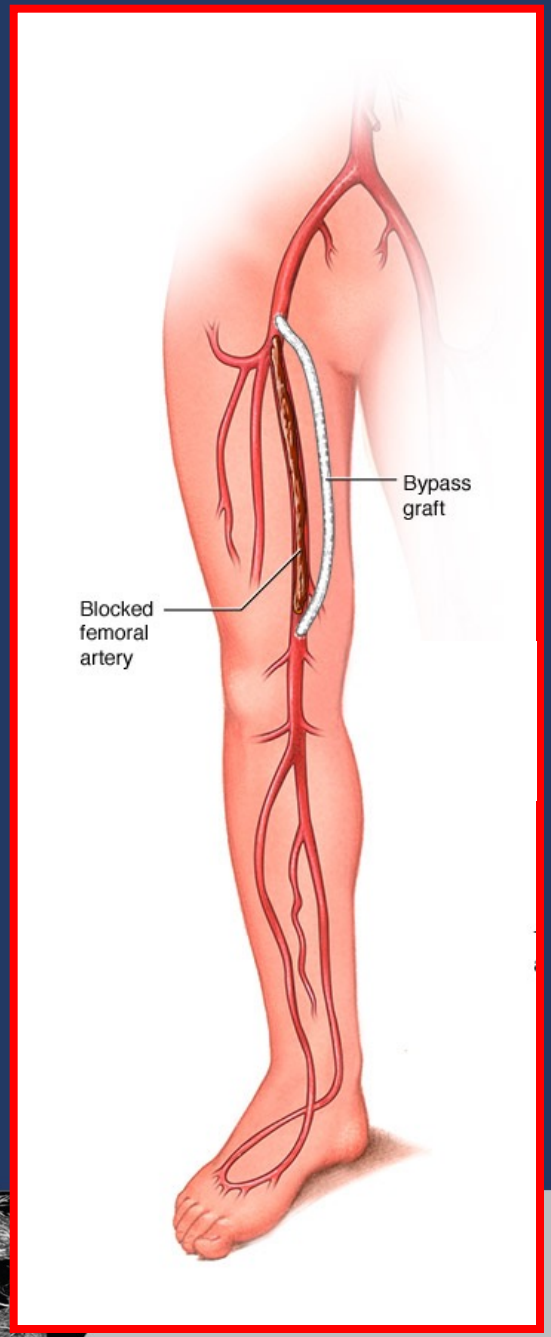
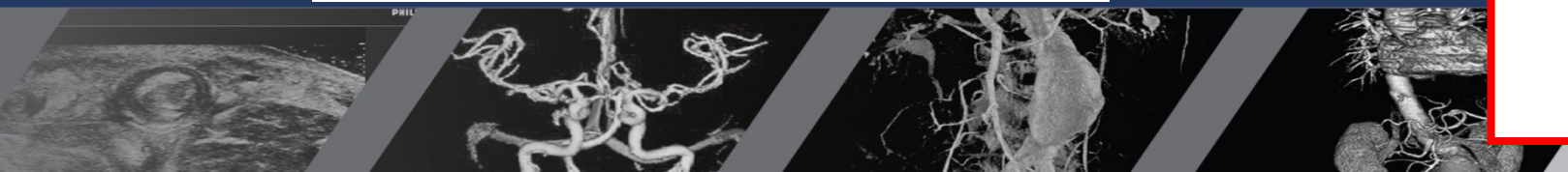
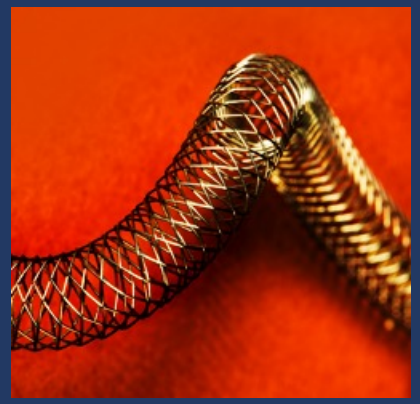


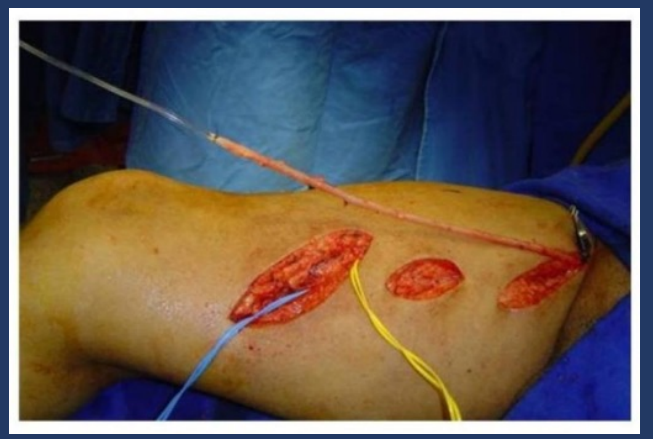
Figure 1. Occluded left superficial femoral artery







Comparison



Endovascular

- Local and sedation
- Outpatient
- Ambulate in 2 hrs
- Percutaneous
- Post-op wound care
  - Remove Band-Aid

Open Surgery

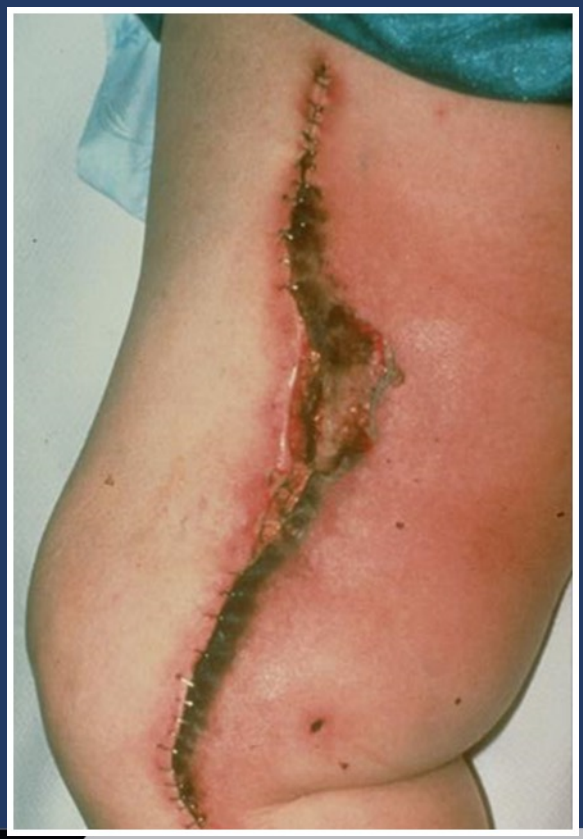
- General Anesthesia
- ICU + Med/Surg =3-6
- Ambulate with Physical Therapy

Patient recovery after infrainguinal bypass grafting for limb salvage

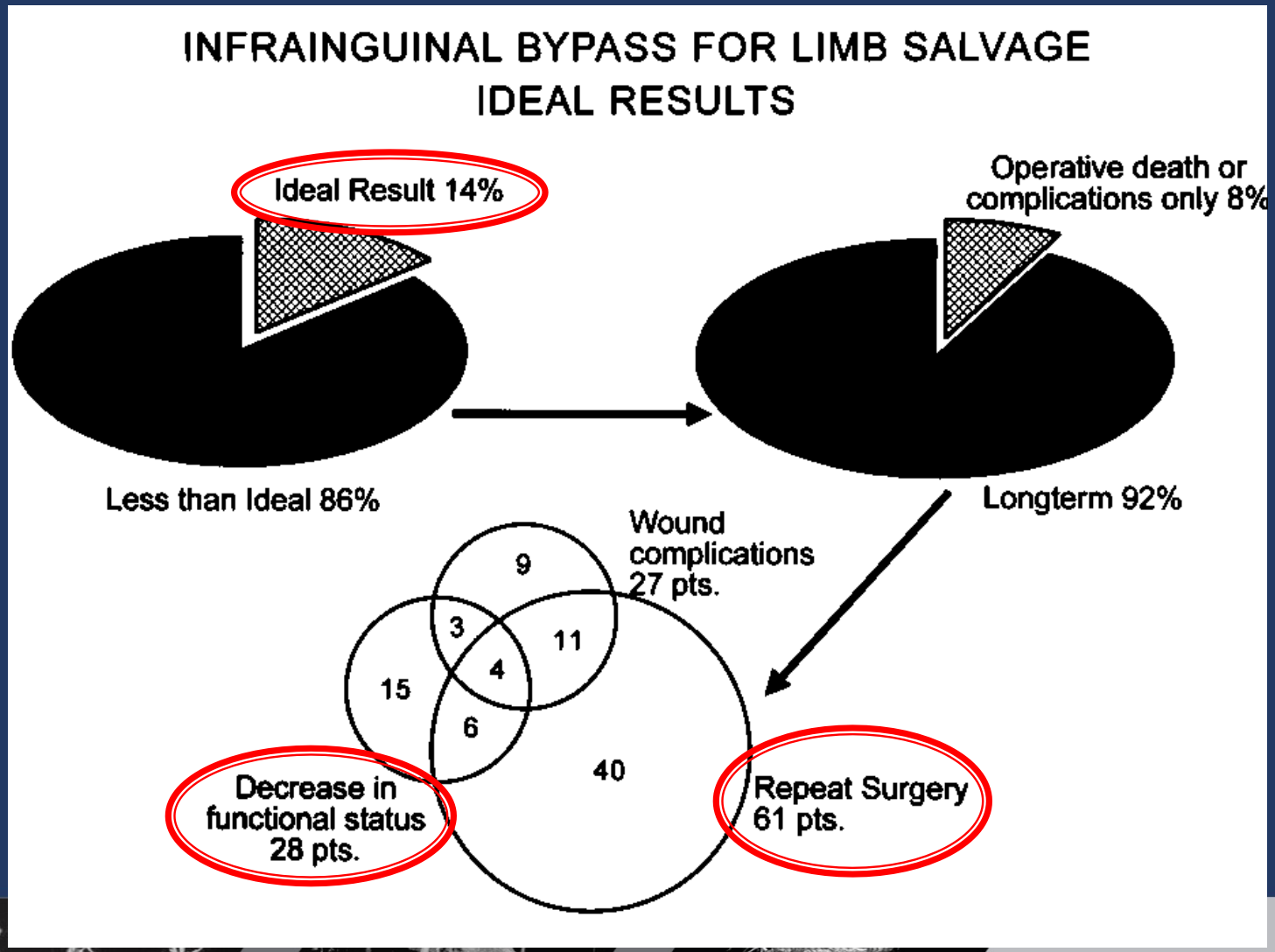
JOURNAL OF VASCULAR SURGERY
February 1998

Alexander D. Nicoloff, MD, Lloyd M. Taylor, Jr., MD, Robert B. McLafferty, MD, Gregory L. Moneta, MD, and John M. Porter, MD, *Portland, Ore.*

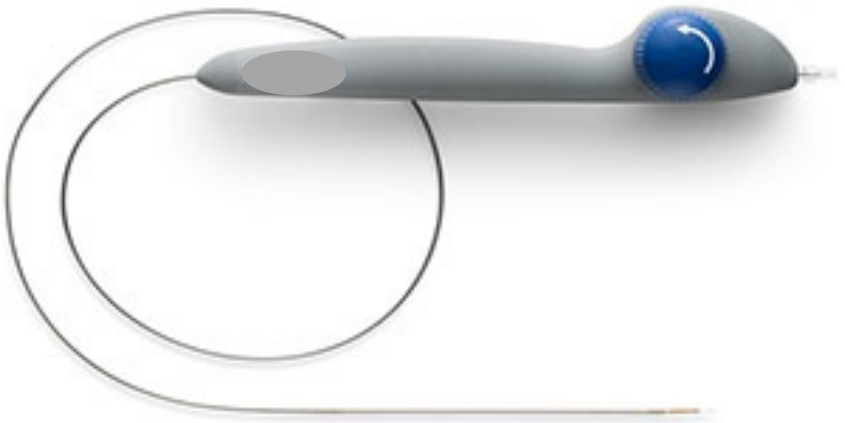
- **Retrospective review of 112 consecutive patients who underwent initial infra-inguinal bypass surgery for limb salvage**
- **<u>The ideal result</u>**
  - **uncomplicated operation**
  - **elimination of ischemia**
  - **prompt wound healing**
  - **rapid return to premorbid functional status without recurrence or repeat surgery.**



Ideal Results Following Bypass



PQ BYPASS SYSTEM



TORUS Stent Graft Delivery System

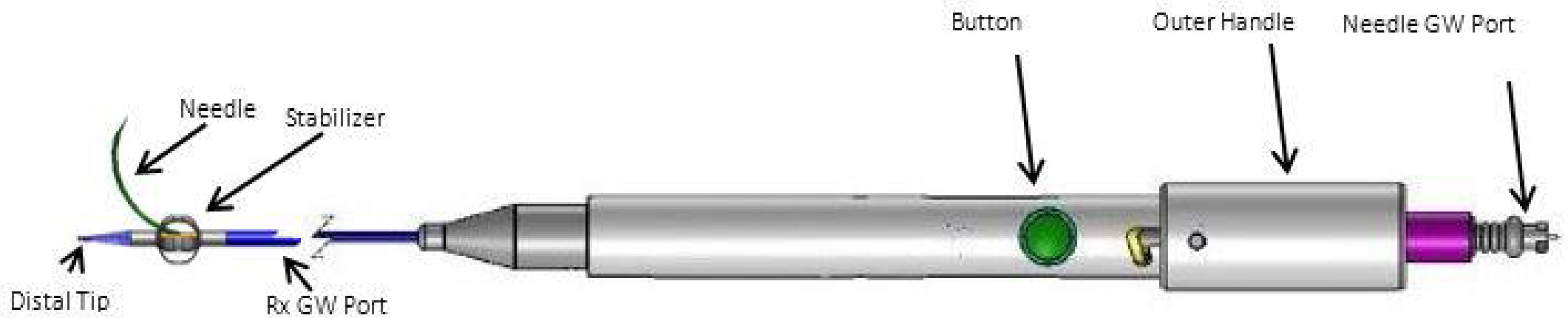
TORUS Stent Graft System

TORUS Stent Graft

PQ Crossing device

PQ CROSSING DEVICE

- Spring-loaded delivery tool
- 0.025″ Nitinol Needle with 15 mm throw
- 8Fr compatible device with 135 cm working length
- Dual 0.014″ guidewire ports
- Create anastomoses between artery and vein



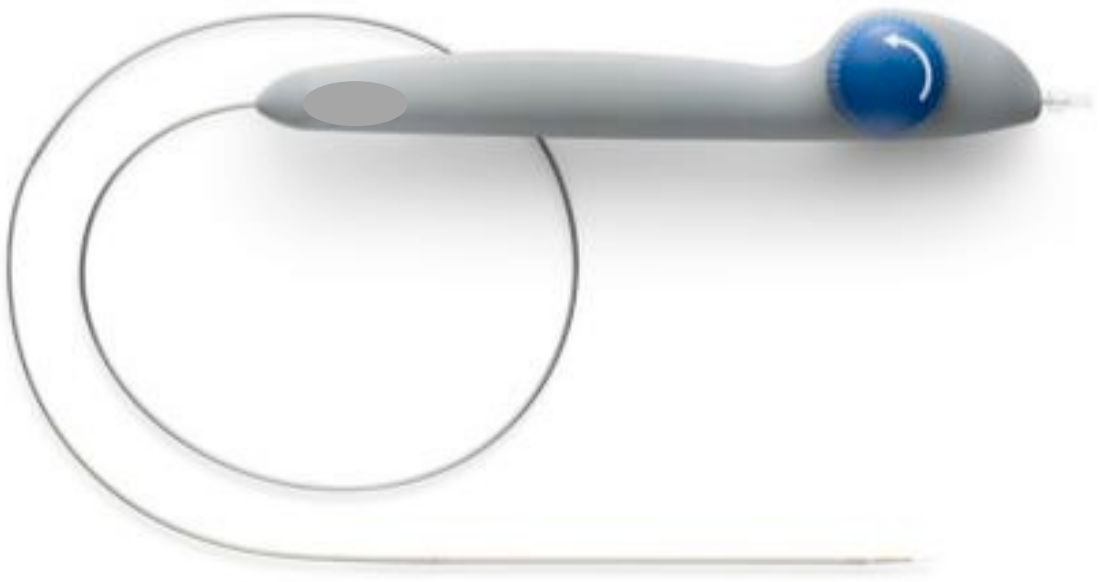
TORUS STENT GRAFT SYSTEM

TORUS Stent Graft

- Self-expanding, flexible, composite structure comprised of a NiTi-wire frame encapsulated in an ePTFE film
- Available in 5.5 – 6.7 mm diameters and working lengths from 100 – 200 mm
- Synthetic conduit used to create a fully-percutaneous bypass

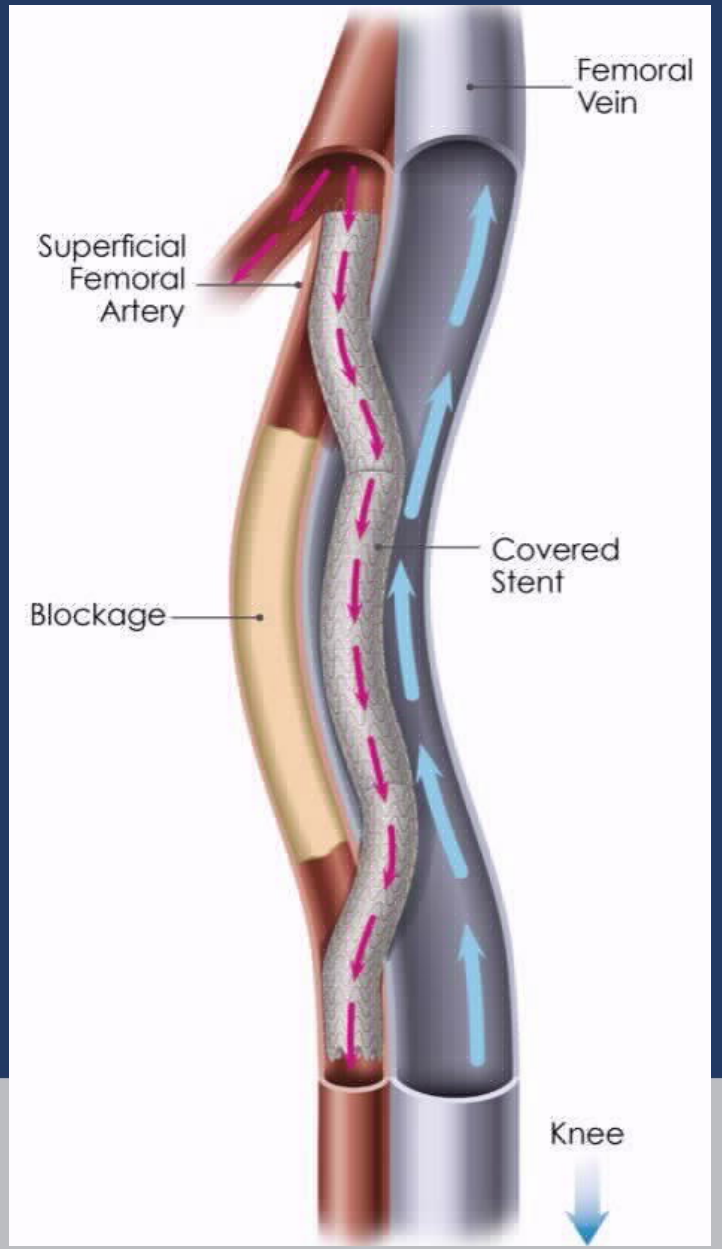
TORUS Stent Graft Delivery System

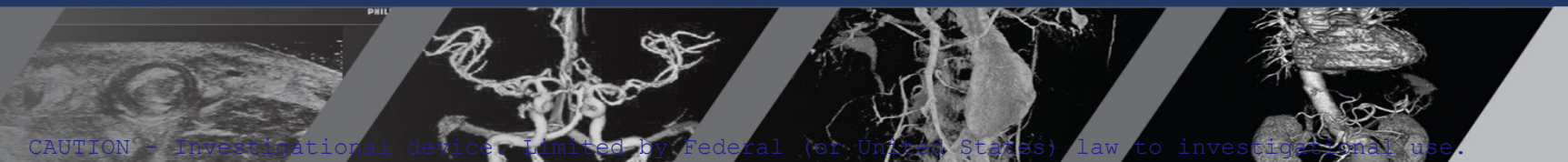
- 8Fr System
- Compatible with a 0.035″ guidewire
- 135 cm working length



History of PQ Bypass

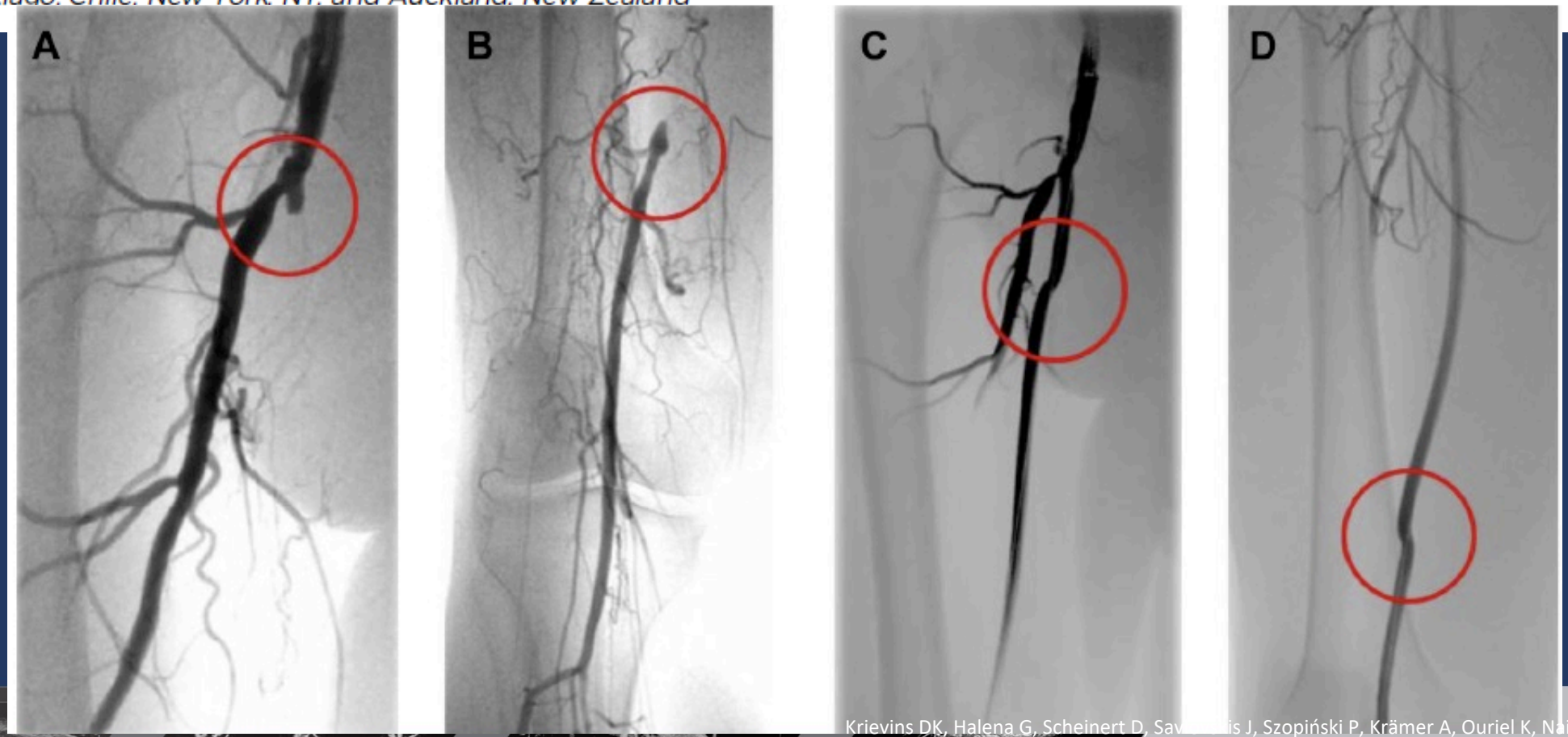
- Founders: J. Joye DO & R. Heuser MD
- Founded in 2009- Fogarty Institute for Innovation
- Percutaneous Bypass Proof of Concept Study: 2003-2012
- Pre-clinical Studies: 2012-2015
- N.Z. First in Man Study: 2014
- DETOUR1 CE Mark Study: 2015-2016- **82 pts.**
- TORUS 1 SFA study: Enrollment Complete- **61pts.**
- Breakthrough Device Designation- Sept. 2020
- DETOUR 2 IDE Study: 2020- Enrollment Complete- **220 pts.**
- **Acquisition by Endologix - 2021**
- TORUS2 IDE Study: 2021- Enrollment Complete- **188 pts.**





One-year results from the DETOUR I trial of the PQ Bypass DETOUR System for percutaneous femoropopliteal bypass

Dainis K. Krievins, MD, PhD,[a] Grzegorz Halena, MD,[b] Dierk Scheinert, MD,[c] Janis Savlovskis, MD, PhD,[d] Piotr Szopiński, MD, PhD,[e] Albrecht Krämer, MD,[f] Kenneth Ouriel, MD,[g] Kasthuri Nair, BS,[g] Andrew Holden, MBChB,[h] *and* Andrej Schmidt, MD,[c] *Riga, Latvia; Gdansk and Warsaw, Poland; Leipzig, Germany; Santiago, Chile; New York, NY; and Auckland, New Zealand*



Krievins DK, Halena G, Scheinert D, Sav[illegible]is J, Szopiński P, Krämer A, Ouriel K, Nair K, Holden A, Schmidt A. One-year results from the DETOUR I trial of the PQ Bypass DETOUR System for percutaneous femoropopliteal bypass. J Vasc Surg. 2020 Nov;72(5):1648-1658.e2. doi: 10.1016/j.jvs.2020.02.043. Epub 2020 Apr 8. PMID: 32276015.

Data – DETOUR 1

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY
A SAGE Publication
ISEVS

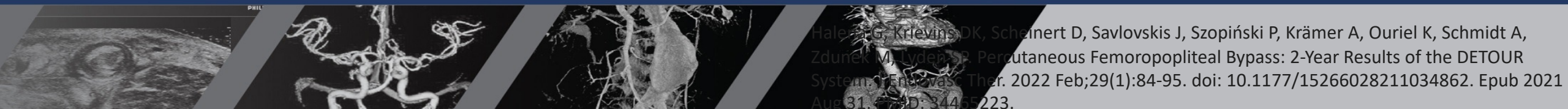
Journal of Endovascular Therapy
1–12

DOI: 10.1177/15266028211034862
www.jevt.org
SAGE

Percutaneous Femoropopliteal Bypass: 2-Year Results of the DETOUR System

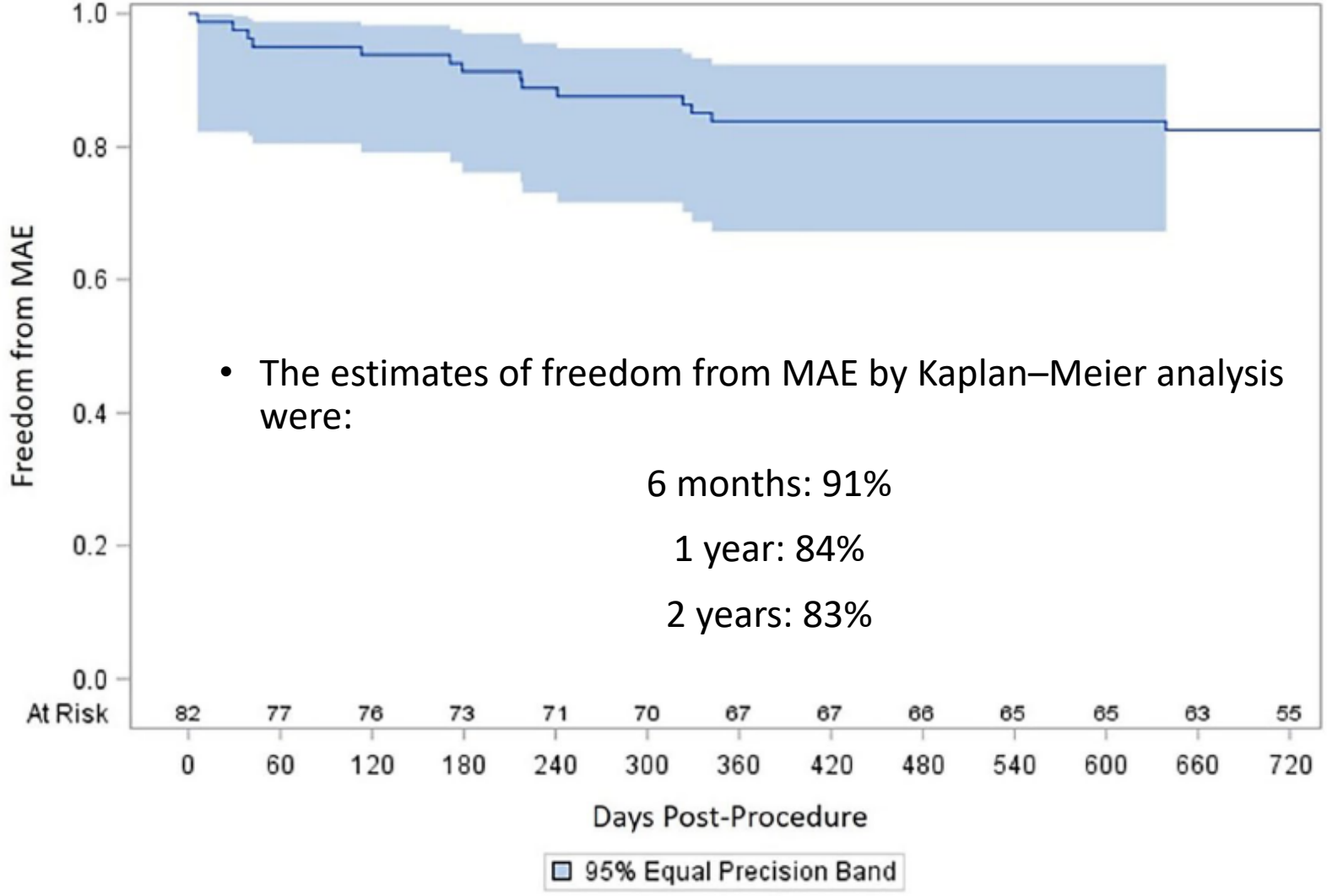
Grzegorz Halena, MD, PhD[1], Dainis K. Krievins, MD, PhD[2], Dierk Scheinert, MD[3], Janis Savlovskis, MD, PhD[1], Piotr Szopiński, MD, PhD[4], Albrecht Krämer, MD[5], Kenneth Ouriel, MD, MBA[6], Andrej Schmidt, MD[3], Michal Zdunek, MD[1], and Sean P. Lyden, MD[7]

- 82 limbs
- 8 investigational sites in Poland, Germany, Latvia, Italy, Chile, and New Zealand
- 96% technical success rate of the procedure



Halena G, Krievins DK, Scheinert D, Savlovskis J, Szopiński P, Krämer A, Ouriel K, Schmidt A, Zdunek M, Lyden SP. Percutaneous Femoropopliteal Bypass: 2-Year Results of the DETOUR System. J Endovasc Ther. 2022 Feb;29(1):84-95. doi: 10.1177/15266028211034862. Epub 2021 Aug 31. PMID: 34465223.

DETOUR 1: results



- The estimates of freedom from MAE by Kaplan–Meier analysis were:

6 months: 91%

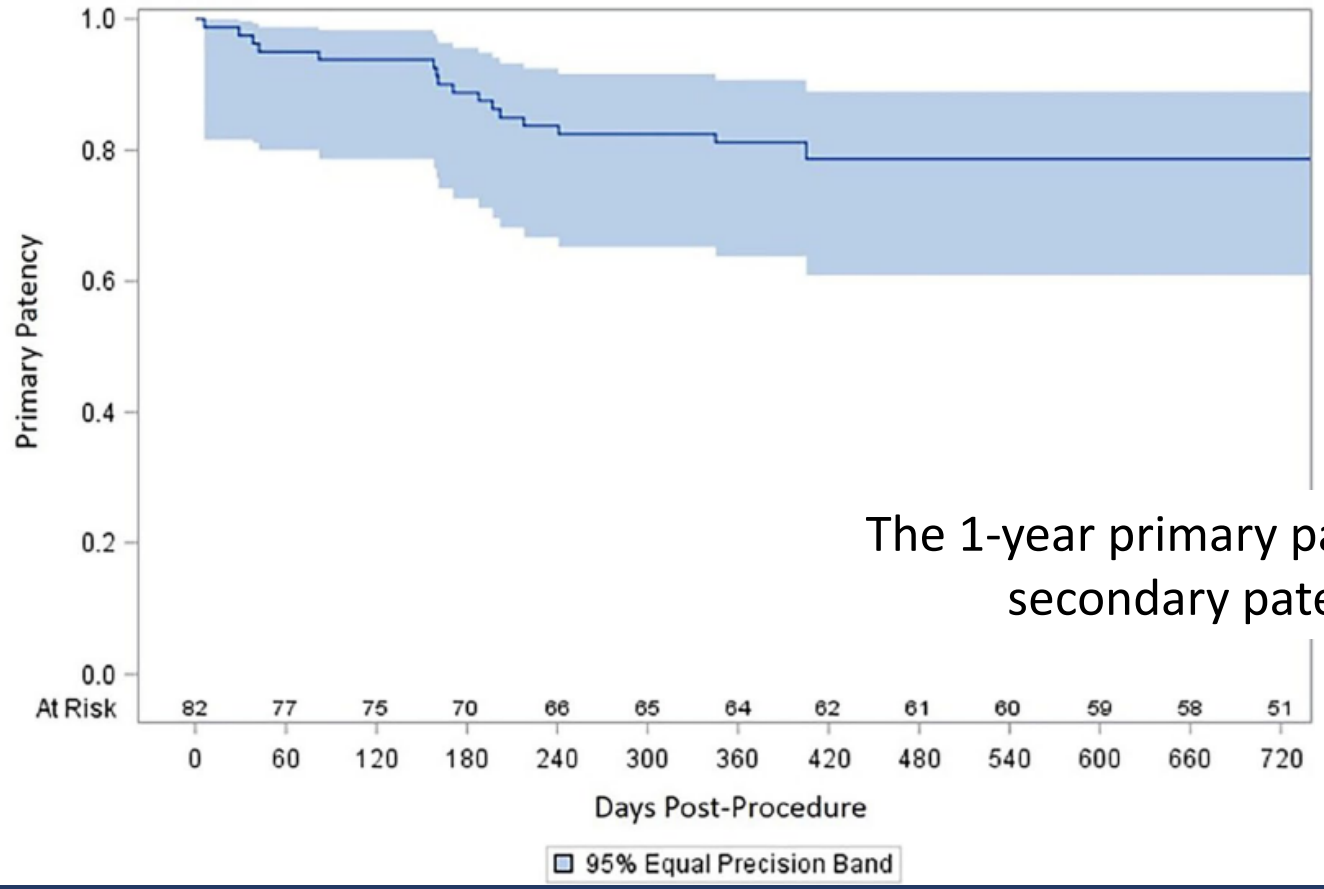
1 year: 84%

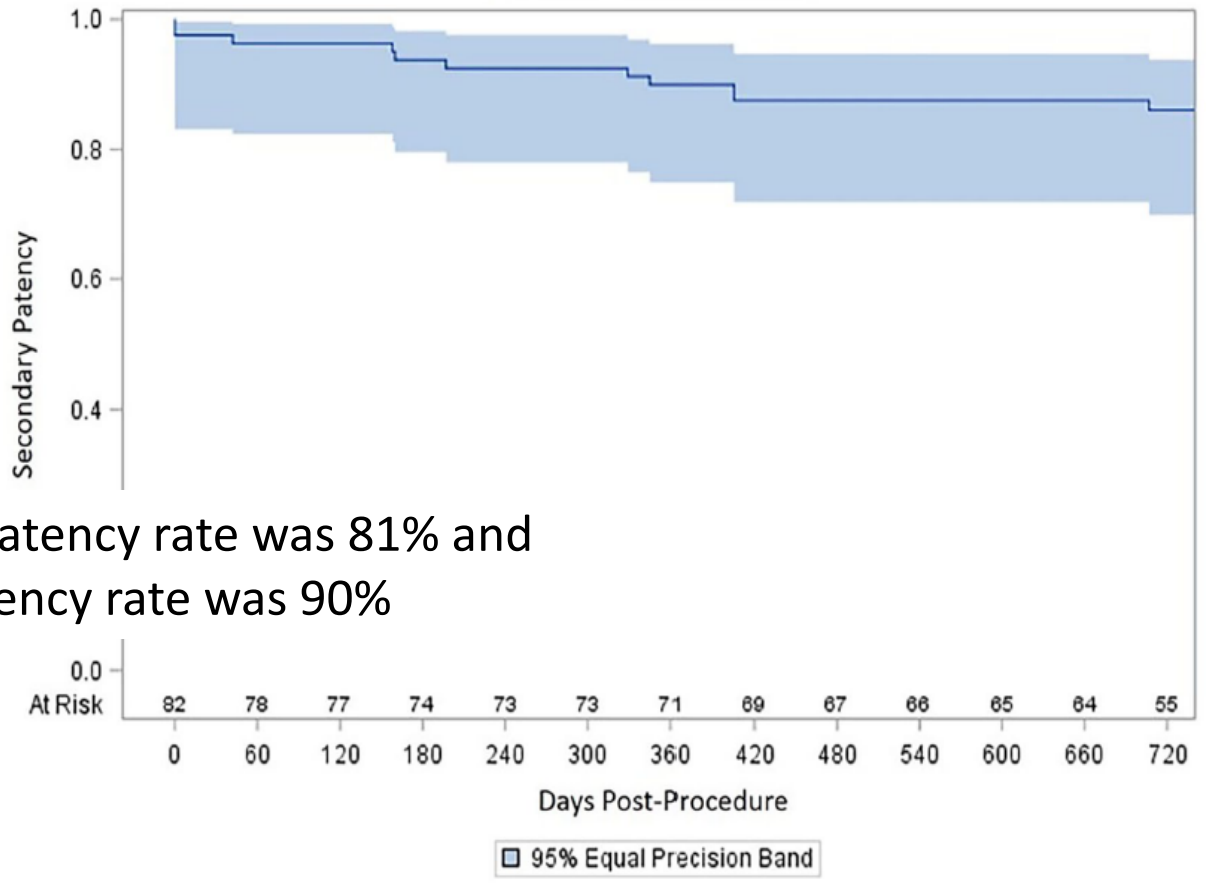
2 years: 83%

Table 2. Safety Outcomes.

	1-Month (%)	6-Month (%)	1-Year (%)	2-Year (%)
Major adverse events	2/81 (2.5)	7/81 (8.6)	13/80 (16.3)	14/78 (17.9)
Death	0/81 (0.0)	1/80 (1.3)	1/79 (1.3)	3/72 (4.2)
CD-TVR	2/81 (2.5)	6/80 (7.5)	12/79 (15.2)	12/76 (15.8)
Target limb amputation	0/81 (0.0)	0/80 (0.0)	0/79 (0.0)	1/73 (1.4)
Major adverse vascular events	4/81 (4.9)	9/80 (11.3)	14/79 (17.7)	15/76 (19.7)
Stent thrombosis	3/81 (3.7)	8/80 (10.0)	13/79 (16.5)	14/76 (18.4)
Clinically apparent distal embolization	0/81 (0.0)	0/80 (0.0)	0/79 (0.0)	1/73 (1.4)
Procedure related arterial rupture	0/81 (0.0)	0/80 (0.0)	0/79 (0.0)	0/72 (0.0)
Acute limb ischemia	0/81 (0.0)	0/80 (0.0)	0/79 (0.0)	0/72 (0.0)
Bleeding event requiring transfusion	1/81 (1.2)	1/80 (1.3)	1/79 (1.3)	1/72 (1.4)
Deep vein thrombosis in target limb	1/81 (1.2)	2/80 (2.5)	2/79 (2.5)	2/72 (2.8)
Venous clinical severity score	1.1±1.6	0.8±1.2	0.8±1.4	0.7±1.0
Villalta scale	0.4±0.9	0.5±1.0	0.5±1.1	0.4±0.9
Stent fracture	0/81 (0.0)	0/80 (0.0)	0/79 (0.0)	0/72 (0.0)

DETOUR 1: patency





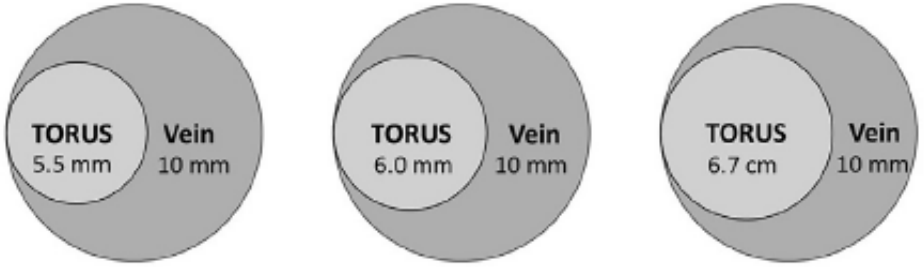
The 1-year primary patency rate was 81% and secondary patency rate was 90%

From the Society for Vascular Surgery

Check for updates

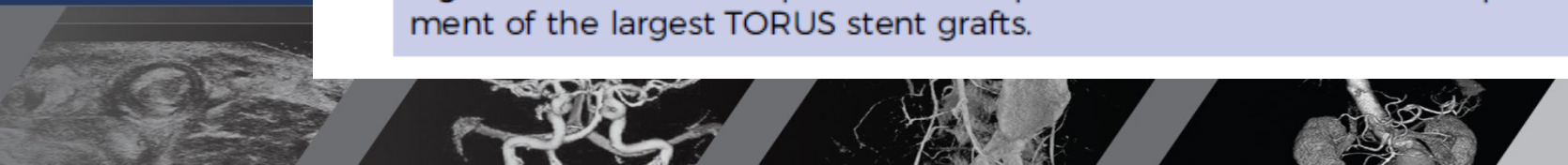
Venous outcomes at 1 year after using the femoral vein as a conduit for passage of percutaneous femoropopliteal bypass

Peter A. Schneider, MD,[a] Dainis K. Krievins, MD, PhD,[b] Grzegorz Halena, MD,[c] Andrej Schmidt, MD,[d] Sean Lyden, MD,[e] Victoria Lee, MD,[f] Minyi Hu, PhD,[f] *and* Mark Adelman, MD,[f] *San Francisco, Calif; Riga, Latvia; Gdansk, Poland; Leipzig, Germany; Cleveland, Ohio; and New York, NY*



Cross-sectional area of device	23.76 mm^2	28.27 mm^2	35.26 mm^2
Cross-sectional area of vessel	78.54 mm^2	78.54 mm^2	78.54 mm^2
Femoral vein luminal area preservation	69.75%	64.00%	55.11%

Fig 1. Calculation example of luminal preservation. Venous luminal preservation remained even with the placement of the largest TORUS stent grafts.

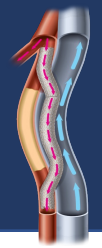


DETOUR 1 – venous outcomes

- 2 patients (2.4%) developed ipsilateral symptomatic deep vein thrombosis) through 1 year of follow-up
- A duplicate femoral vein was present in 20.7% of cases. The majority of patients (86.8%) had a femoral vein luminal area preservation of 55%
- Thirty-two patients experienced an increase in the vein diameter over time after the procedure, but this pattern of venous remodeling was not uniform
- The overall VCSS and Villata scores did not change during follow-up

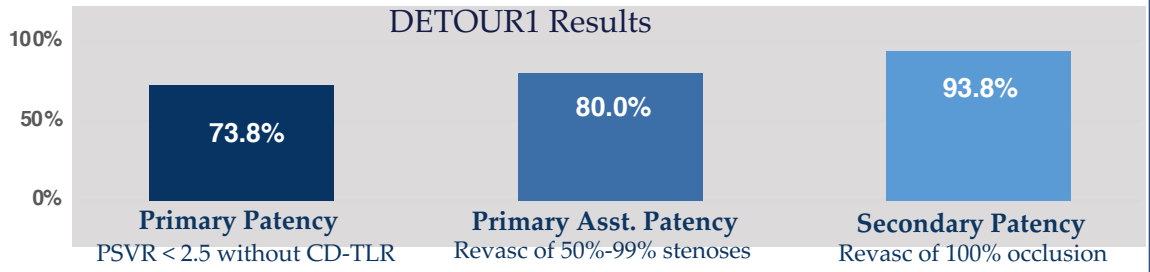
The Detour Endovascular Technique for Long OcclUsive Fem-pop Revascularization - 2 DETOUR II Clinical trial

- Prospective, single-arm, multi-center, international, non-randomized, safety and effectiveness clinical investigation of the PQ Bypass system
- symptomatic femoropopliteal chronic total occlusions ≥ 20 cm (TASC D)
- 202 participants at 36 sites in USA and Europe
- Enrollment completed Oct 2020



DETOUR® System
Building the Body of Clinical Evidence

Torus 2 Clinical Trial	3 YR F/U	188 Patients	40 Sites
Detour1 Clinical Trial	5 YR F/U	81 Patients	8 Sites
Detour2 Clinical Trial	12M F/U	202 Patients	40 Sites
Detour2CA	ENROLLING	8 Patients	8 Sites



Conclusions

- PQ bypass has been safety performed with acceptable outcomes in early trials
- More data is needed for wider adoption
- PQ bypass adds an additional tool for lower extremity revascularization in the comprehensive care of patients with peripheral artery disease