Novel Approaches to Femoropopliteal Disease: The PQ Bypass Technique

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Presenter Disclosure Information

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- ***PQ ByPass, Founder, Equity, Multiple Patents and Major Stock Holder;***

  Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure, Vascular Access Patents*

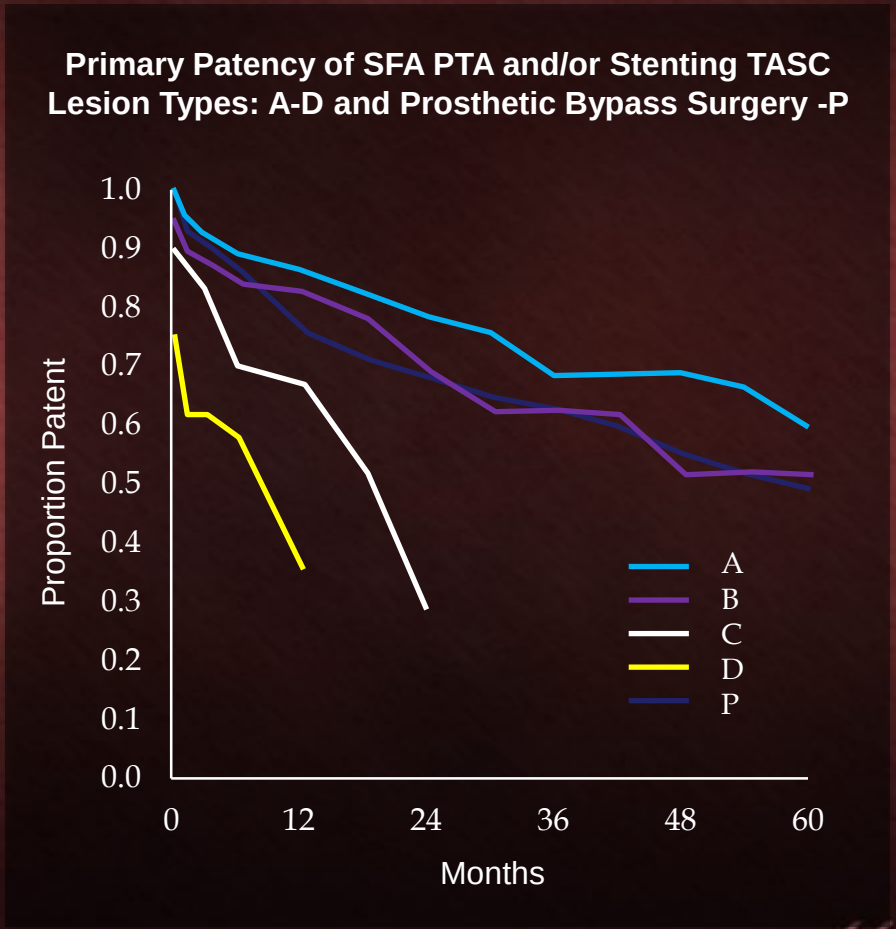
Not FDA cleared or approved.

Not available in the United States.

Background

Limitations in the Treatment of Long, Complex SFA Occlusions

- Revascularization of long, complex SFA occlusions has traditionally required open surgical bypass for **long-term success**
- Endovascular techniques and technologies have matured; however, **a durable solution for these severe lesions is still lacking**
- **Percutaneous bypass may provide the durability** associated with open surgery while reducing morbidity and mortality associated with more invasive interventions



Note: Srowiec SM, Davies MG, Eberly SW, et al. Percutaneous angioplasty and stenting of the superficial femoral artery. J Vasc Surg. 2005; 41:259-78.

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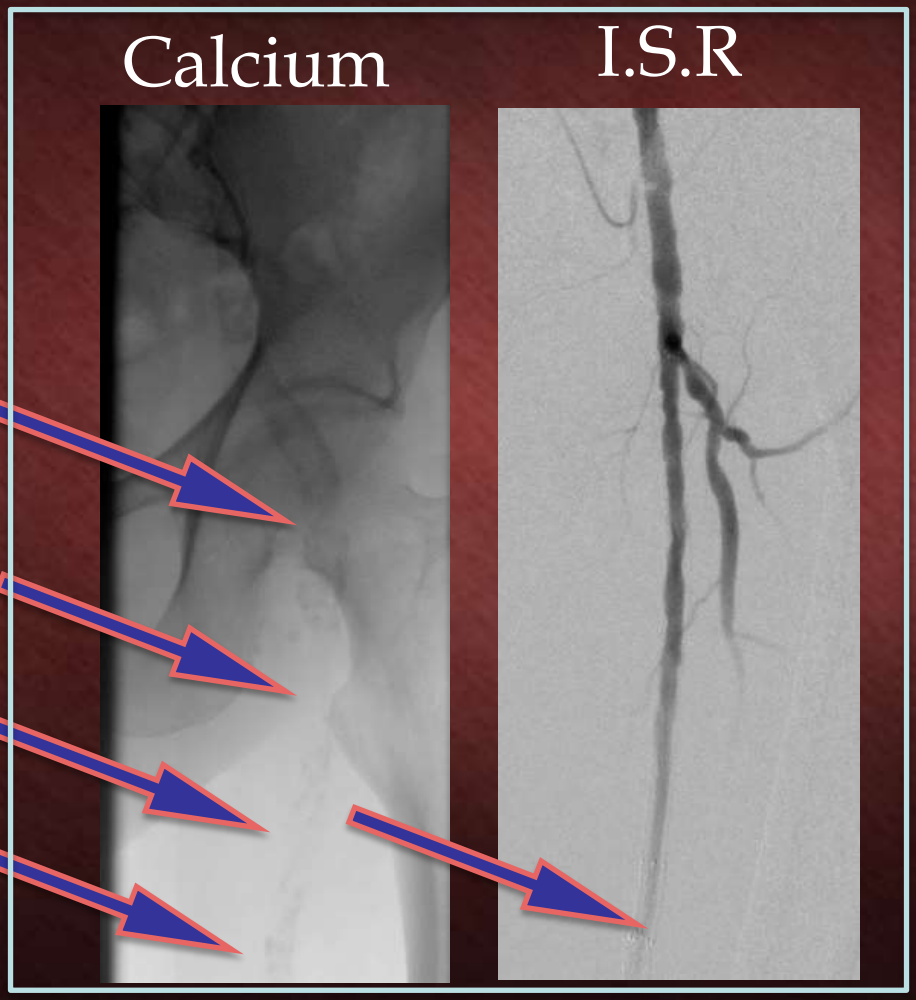
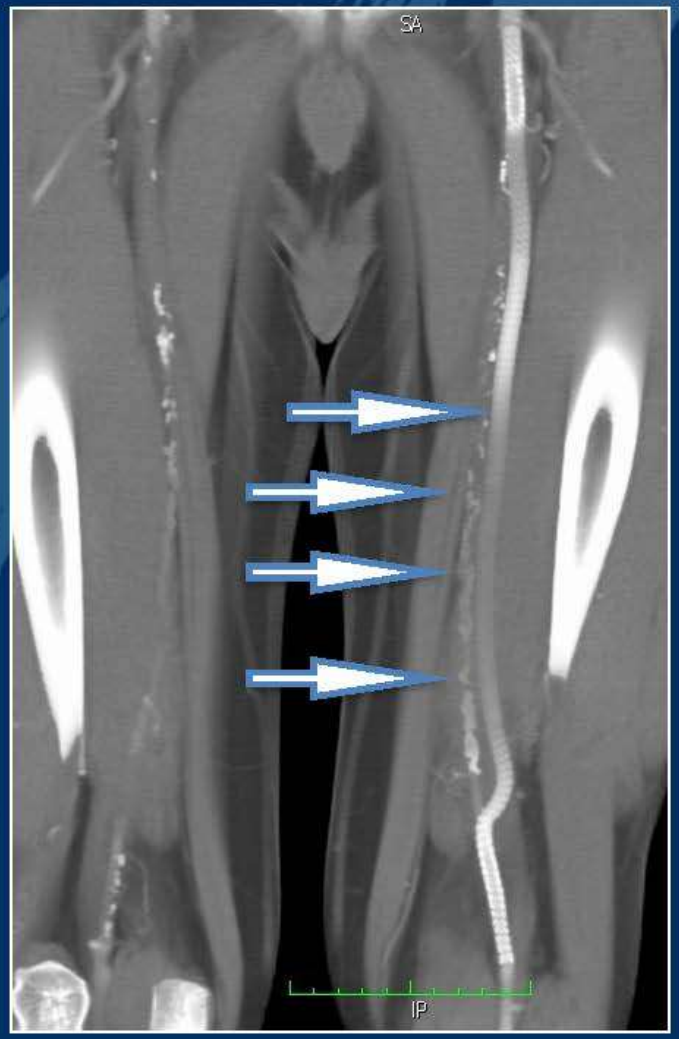
The Solution



The solution combine the best of both worlds:

- Patency of fem-pop bypass and
- Endovascular approach

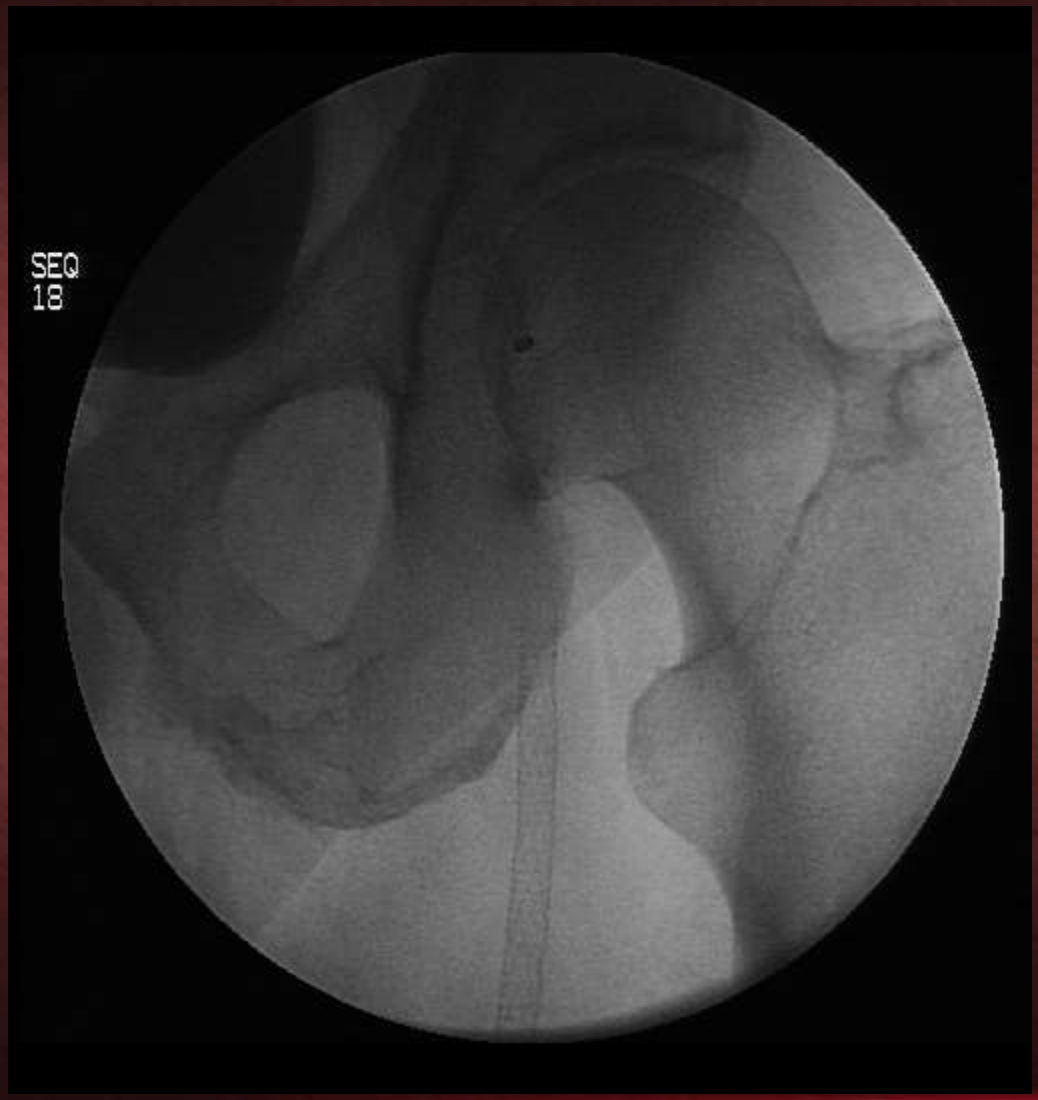
Who is it for?



The first frontier is still the last frontier?

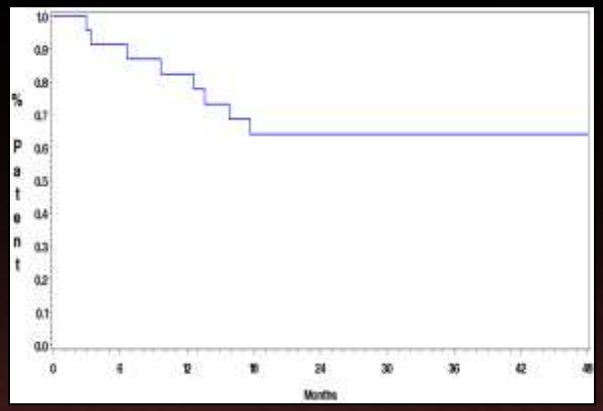
Bypassing calcium instead of crossing it?

Results of PQB at 5yrs



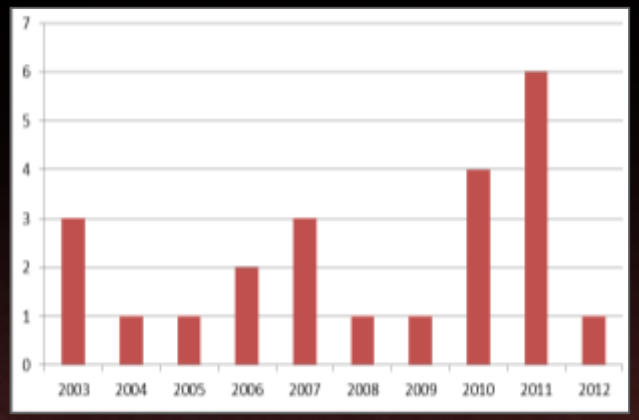
Proof of Concept

K/P Curve – Primary Patency



- El Camino Hospital, off-the shelf devices
- 25 limbs in 21 subjects treated
- Primary patency @ 1 year: **82%**
- Secondary patency @ 4 years: **91%**
- **No objective venous morbidity**
- **78%** discharged same or next day

Subject Enrollment



Lesion Characteristics

Lesion Length (cm)	31.2 ± 9.7
TASC D	88.0%
Rutherford 3 - Severe	42.9%
Rutherford 4 - Ischemic	28.6%
Rutherford 5 - Tissue loss	28.6%

Patency results reported using PSVR>2.0

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Intellectual Property

(12) **United States Patent**
Heuser

(10) **Patent No.: US 6,464,665 B1**
(45) **Date of Patent: Oct. 15, 2002**

(54) **CATHETER APPARATUS AND METHOD FOR ARTERIALIZING A VEIN**

(76) Inventor: **Richard R. Heuser**, 2626 E. Arizona Biltmore Cir., No. 5, Phoenix, AZ (US) 85016

(*) Notice: Subject to any disclaimer, the term of this

(12) **United States Patent**
Heuser et al.

(10) **Patent No.: US 8,062,321 B2**
(45) **Date of Patent: Nov. 22, 2011**

(54) **CATHETER SYSTEM FOR CONNECTING ADJACENT BLOOD VESSELS**

(75) Inventors: **Richard R. Heuser**, Phoenix, AZ (US); **James D. Joye**, Saratoga, CA (US)

(73) Assignees: **PQ Bypass, Inc.**; **Saratoga, Inc.**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 624 days.

(21) Appl. No.: **11/735,382**

(22) Filed: **Apr. 13, 2007**

(65) **Prior Publication Data**

US 2008/0065019 A1 Mar. 13, 2008

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/340,324, filed on Jan. 25, 2006, now Pat. No. 7,374,567.

(60) Provisional application No. 60/887,277, filed on Jan. 30, 2007.

(51) **Int. Cl.**
A61B 17/04 (2006.01)

(52) **U.S. Cl.** **606/185**

(58) **Field of Classification Search** 606/153, 606/170, 183, 167, 181, 185, 180, 194, 198, 606/219, 208, 213–215; 604/95.01, 104, 604/164.01; 623/1.1, 1.11–1.15, 1.2, 1.23, 623/1.35, 1.36

See application file for complete search history.

(56) **References Cited**

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3,788,318	A	1/1974	Kors et al.
3,828,779	A	8/1974	Kors et al.
3,828,782	A	8/1974	Polin
4,000,739	A	1/1977	Stevens
4,241,289	A	12/1980	Bowling
4,430,081	A	2/1984	Timmermans
4,650,466	A	3/1987	Luther

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Heuser, M.D., Richard R., et al. "The Use of a New Wire in a 6-Year-Old Coronary Artery Occlusion: The Jagwire Recanalization Guidewire." Catheterization and Cardiovascular Diagnosis. 1995. pp. 173-176. vol. 29.

(Continued)

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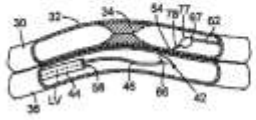
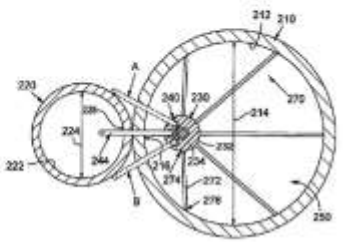
Assistant Examiner — Katherine M Shi
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

The catheter apparatus may be used to assist in creating a fistula between two adjacent blood vessels. The apparatus includes a catheter for inserting into a first blood vessel which lies adjacent to a second blood vessel, the catheter having a plurality of openings through which a physician may navigate a piercing tool. The physician maneuvers the tip of the catheter to a position within the first blood vessel adjacent to a portion of the first blood vessel wall in which the physician intends to create an opening. The physician may then rotate the piercing tool within the catheter and extend the piercing tool through one opening at a time, without rotating the catheter, until the physician chooses an opening that is properly aimed at the second blood vessel. Such a configuration allows for a wide arc of potential firing space.

24 Claims, 7 Drawing Sheets





(12) **United States Patent**
Heuser

(10) **Patent No.: US 6,858,038 B2**
(45) **Date of Patent: Feb. 22, 2005**

(54) **STENT SYSTEM**

(76) Inventor: **Richard R. Heuser**, 525 N. 18th St., Suite 506, Phoenix, AZ (US) 85006

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/177,816**

(22) Filed: **Jun. 21, 2002**

(65) **Prior Publication Data**

US 2003/0236560 A1 Dec. 25, 2003

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1.35**; 623/1.11

(58) **Field of Classification Search** 623/1.1, 1.11, 623/1.12, 1.15, 1.16, 1.18, 1.19, 1.2, 1.35

(56) **References Cited**

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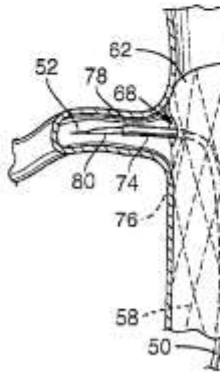

(12) **United States Patent**
Heuser

(10) **Patent No.: US 7,402,141 B2**
(45) **Date of Patent: Jul. 22, 2008**

(54) **CATHETER GUIDEWIRE SYSTEM USING CONCENTRIC WIRES**

(76) Inventor: **Richard R. Heuser**, 500 W. Thomas Rd., Suite 900, Phoenix, AZ (US) 85013

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/927,340**

(22) Filed: **Aug. 25, 2004**

(65) **Prior Publication Data**

US 2006/0047222 A1 Mar. 2, 2006

Related U.S. Application Data

(60) Provisional application No. 60/498,427, filed on Aug. 27, 2003.

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **600/585**

(58) **Field of Classification Search** 600/433, 600/434, 435, 585; 604/164.13

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,720,211	A	1/1956	Peter
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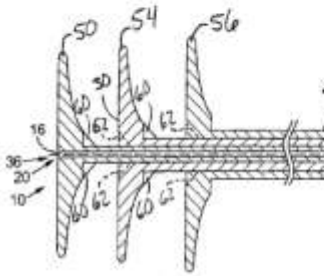
3,788,318	A	1/1974	Kors et al.
3,828,779	A	8/1974	Kors et al.
3,828,782	A	8/1974	Polin
4,000,739	A	1/1977	Stevens



(10) **Patent No.: US 7,374,567 B2**
(45) **Date of Patent: May 20, 2008**

(12) **United States Patent**
Heuser

(54) **CATHETER SYSTEM FOR CONNECTING ADJACENT BLOOD VESSELS**

(76) Inventor: **Richard R. Heuser**, 500 W. Thomas Rd., Suite 900, Phoenix, AZ (US) 85013

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **11/340,324**

(22) Filed: **Jan. 25, 2006**

(65) **Prior Publication Data**

US 2007/0173878 A1 Jul. 26, 2007

(51) **Int. Cl.**
A61B 17/04 (2006.01)
A61B 17/08 (2006.01)

(52) **U.S. Cl.** **606/185**; 606/153

(58) **Field of Classification Search** 606/153, 606/167, 170, 181, 184, 185; 219–220, 213–215; 623/1.11; 227/175.1, 182.1

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,720,211	A	1/1956	Peter
3,751,305	A	8/1973	Baebecher
3,788,318	A	1/1974	Kors et al.
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4,241,289	A	12/1980	Bowling
4,430,081	A	2/1984	Timmermans
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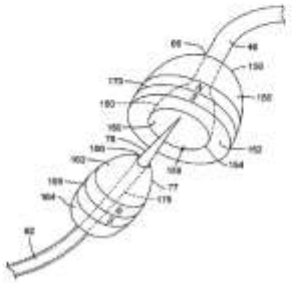
Primary Examiner — Michael J. Hayes
Assistant Examiner — Christine Gerbino
(74) *Attorney, Agent, or Firm* — Kilpatrick Stockwell, P.C.

(57) **ABSTRACT**

A catheter system is provided for creating a fistula between blood vessels, using a first catheter with a piercing tool adjacent its distal end, and a second catheter with a receptor adjacent its distal end. The receptor includes an opening and a channel providing a guide surface for receiving the piercing tool. The receptor and piercing tool include one or more magnets to draw the piercing tool into the channel of the receptor. The piercing tool and the receptor are provided with a complementary configuration, such as a mating conical shape. A filter catheter may be provided with a double balloon for use in sealing off the fistula site. The piercing tool may be provided on a metal guidewire that includes a lumen with a distal opening. The piercing tool may include a base and a needle coupled to the base at a nominal angle of at least about 20-degrees. The piercing tool may be selectively moved between an extended position wherein the needle is positioned outside the guidewire at the nominal angle and a retracted position wherein the needle is positioned substantially within the guidewire.

21 Claims, 4 Drawing Sheets



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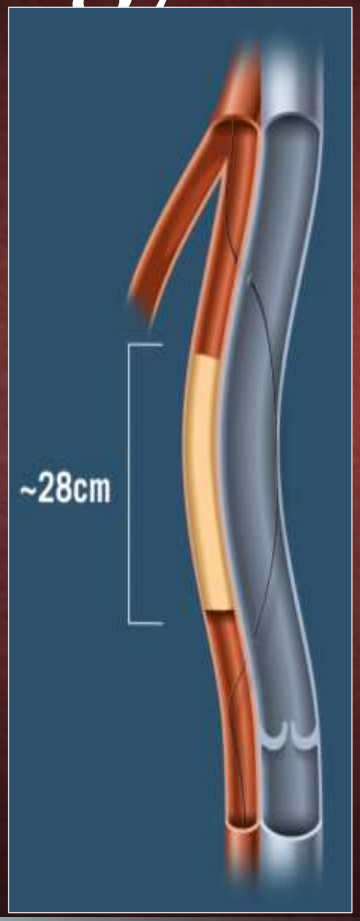
The PQ Detour (PQ Bypass, Inc) Technology

- Designed to achieve the same **end-result as open bypass surgery**
- Revascularization via modular stent graft bypass
- Utilizes the **femoral vein as a conduit**



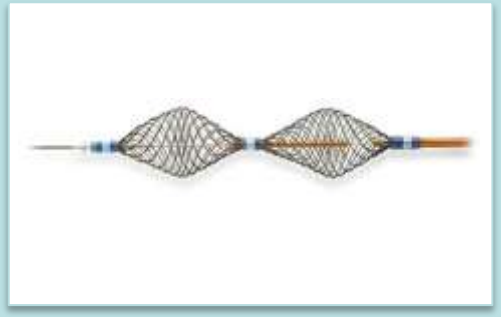
Addresses current SFA treatment limitations with a novel endovascular approach

The DETOUR Percutaneous Bypass Technology

Torus Stent Graft

- Self-expanding nitinol wire frame encapsulated in ePTFE
- High radial force
- Elongated, exposed end rings to prevent edge stenosis

PQ Snare



- Over-the-wire dual-caged scaffold
- Captures and extracts guidewires through the tibial vein

PQ Crossing Device

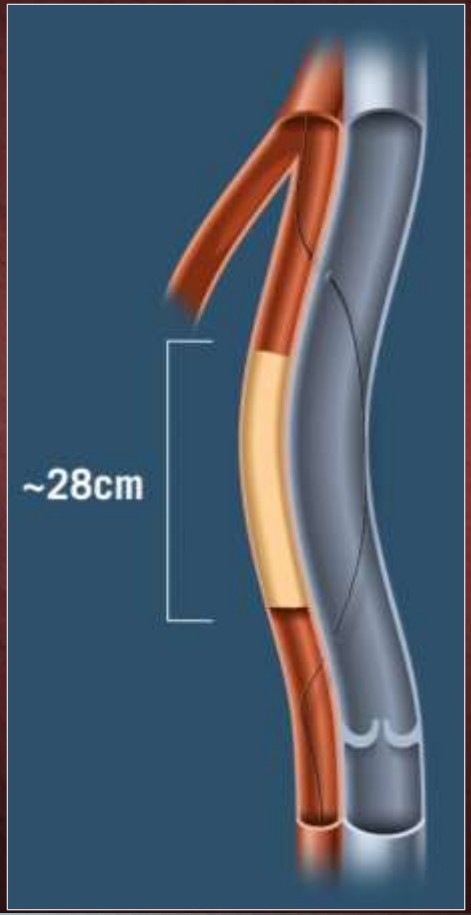
- Spring-loaded guidewire support and delivery system
- Creates initial artery-vein-artery communication

Who is eligible ?

- SFA occlusion up to 30 cm
- 1 cm proximal SFA stump
- SFA reconstitution 3 cm above patella

The DETOUR Percutaneous Bypass Procedure

- Designed to achieve the same **end-result as open bypass surgery**
- Revascularization via modular stent graft bypass
- Utilizes the **femoral vein as a conduit**



Addresses current SFA treatment limitations with a novel endovascular approach

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Background

- We report the results of a prospective, multi-center single-arm study of the DETOUR Technique for Percutaneous Femoral-Popliteal Bypass in patients with occlusive long-segment superficial femoral artery disease
  - Included is the one of the largest prospective series evaluating the percutaneous treatment of SFA occlusions ≥ 25cm

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The DETOUR I Trial

A Prospective, Multi-Center, Independently Reviewed Single-Arm Trial to Evaluate the Safety and Performance of the PQ Bypass DETOUR Technology and Technique for Percutaneous Femoral-Popliteal Bypass – 6-Month Outcomes

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Albert Kramer, MD
Grzegorz Oszkinis, MD
Dierk Scheinert, MD
Andrew Holden, MD

DETOUR I Trial Overview

OBJECTIVE

To assess the safety and performance of the PQ Bypass DETOUR technology and technique for the treatment of long-segment superficial femoral artery occlusions

60 patients treated at 7 international sites from Jan 2015 to May 2016

PRIMARY ENDPOINTS:
30D MAE
6M Patency
(OPG >70%)

Clinical, lab, and DUS follow-up at 1, 3, 6, 12, 18, and 24M

Venous Clinical Severity Score (VCCS) Villalta Scale 1, 3, 6, 12, 18, and 24M

MAE: Death, TVR (Target Vessel Revascularization), Target Limb Amputation

Key Endpoints

Primary Safety Endpoint	MAE at 30 days defined as Death, TVR (Target Vessel Revascularization), and Target Limb Amputation
Primary Efficacy Endpoint	Primary patency at 6 months, defined as: no evidence of clinically significant stenosis (≥50%) within, immediately above, or below the treated arterial segment based on duplex ultrasound (PSV>2.5)
Key Secondary Endpoints	• MAVE • Deep Vein Thrombosis (DVT) on ipsilateral limb • Venous Clinical Severity Score (VCSS) through 24 months • Villalta Scale through 24 months • RB improvement by ≥1

Investigational Centers

Stradins University Hospital, Riga, Latvia (n=24), Universidad Católica de, Santiago, Chile (n=7), Poznan University of Medical Sciences, Poznań, Poland (n=4), Institute of Hematology Medicine, Warsaw, Poland (n=7), University Leipzig Medical Centre, Leipzig, Germany (n=3), Gdańsk Medical University, Gdańsk, Poland (n=14), Auckland, New Zealand (n=1)

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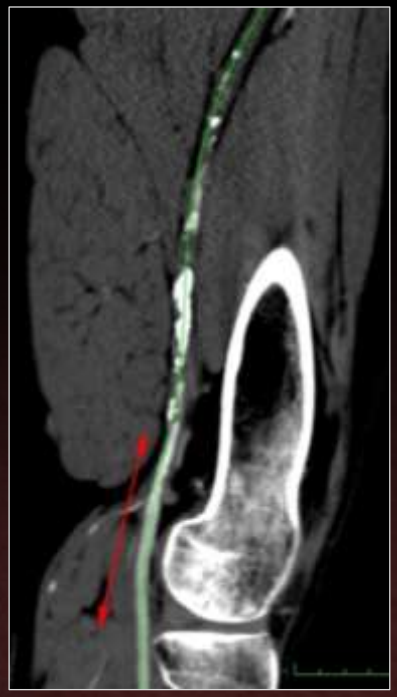
Key Inclusion Criteria

- Femoro-popliteal lesions ≥10 cm in length considered to be:
  - Chronic total occlusion (100% stenosis);
  - Diffuse stenosis (>50% stenosis) with moderate to heavy calcification;

  < OR >
  - In-stent restenosis (>50% stenosis)
- ≥1 patent tibial artery to the foot
- Patent femoral vein ≥10 mm in diameter or duplicate femoral vein

Long SFA occlusion

Proximal SFA stump



3 cm patent artery distal to planned graft, above *tibial plateau*

Key exclusion criteria: history of DVT, known hypersensitivities to nitinol, PTFE; aspirin, heparin, antiplatelet, anticoagulant or thrombolytic therapy; or anticoagulation or contrast media

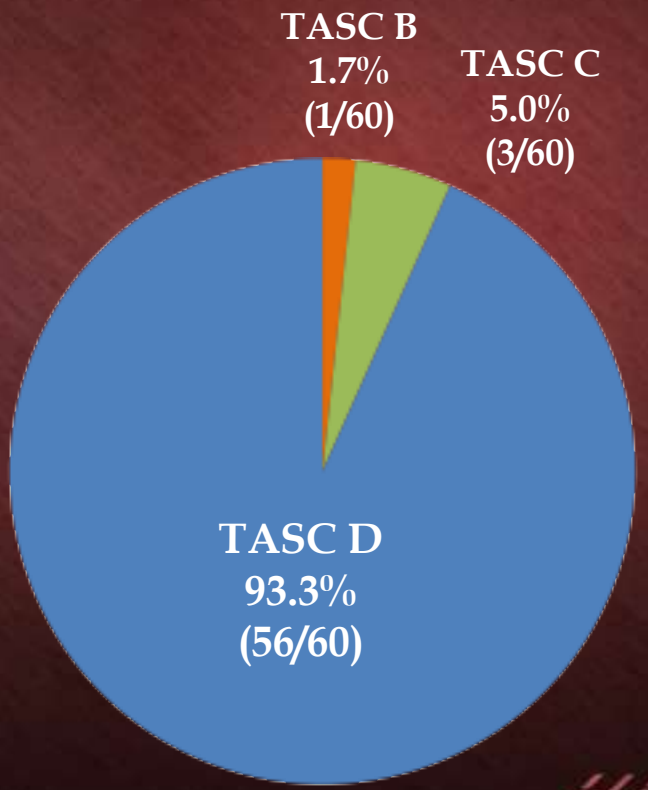
Baseline Clinical Characteristics

	n=60 Subjects
Age, Y ± SD	64 ± 9
Male, % (n)	83.3% (50/60)
Diabetes, % (n)	20% (12/60)
Smoking Hx, % (n)	92% (55/60)
Previous Peripheral Intervention, % (n)	33.3% (20/60)
Duplicate Femoral Vein, % (n)	20% (12/60)
Rutherford Class, % (n)	
3	96.6% (58/60)
4	1.7% (1/60)
5	1.7% (1/60)
ABI ± SD Range (n)	0.65 ± 0.19 0.34 – 1.50 (59)

Baseline Lesion Characteristics

	n=60 Lesions
Lesion length (cm ± SD)	**28.6 ± 5.1**
Range (cm)	**13.4 – 43.2**
Total Occlusions, % (n)	96.7% (58/60)
Calcification at Landing Zone, % (n)	
Mild	56.7 % (34/60)
Moderate to Severe	43.3% (26/60)
Run-off vessels, % (n)	
0	1.7% (1/60)
1	15.0% (9/60)
2	36.7% (22/60)
3	46.6% (28/60)

TASC II Lesion Type[1]



[1] As assessed by Independent Medical Review

Procedural and Clinical Success

		n=60 Subjects
Technical Success	Successful delivery of the investigational devices to the identified area and removal of delivery system	98.3% (59/60)
Procedural Success	Successful delivery of the investigational devices to the identified area and removal of delivery system in the absence of in-hospital MAEs	96.7% (58/60)
Clinical Success	≥1 Grade Improvement in Rutherford Class at 6 months	94.7% (54/57)

DETOUR Trial Met the Primary Safety and Efficacy Endpoints

Results

N = 59 patients[1]

30 Day MAE Rate	**3.4%**
6 Month Primary Patency Rate (PSVR > 2.5)	**84.7%**

[1]*One patient withdrew post-discharge fro the index procedure (no device implanted due to technical failure).*

Low 30D and 6M MAVE Rate

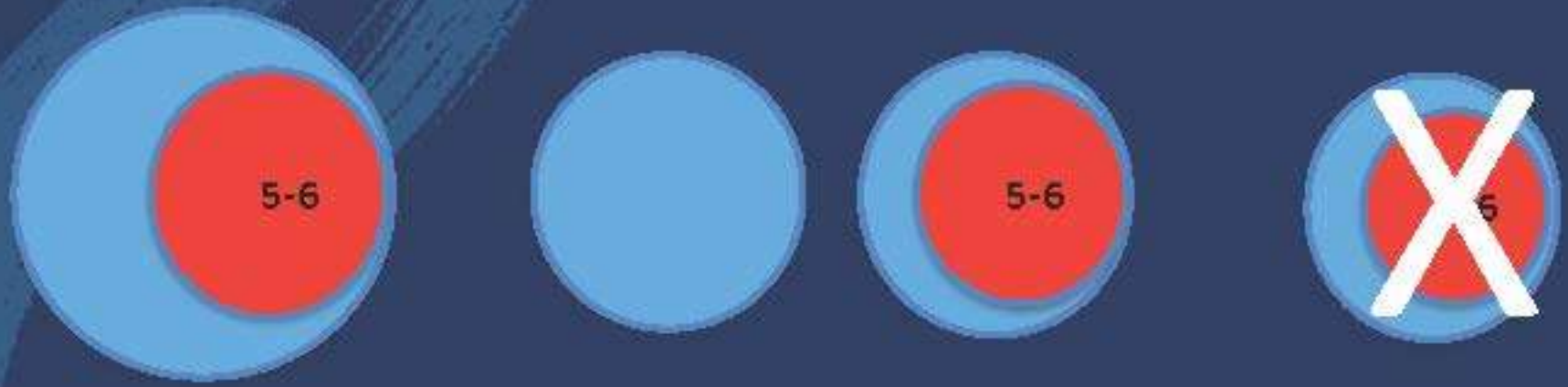
MAVE[1]	MAVE through 30 Days N = 59 Subjects	MAVE through 6 Months N = 59 Subjects
Major Amputation of Ipsilateral Target Limb	0% (0/59)	0% (0/59)
Clinically Apparent Distal Embolization	0% (0/59)	0% (0/59)
Procedure Related Arterial Rupture	0% (0/59)	0% (0/59)
Bleeding Event Requiring Transfusion >2 Units of Packed Red Blood Cells	0% (0/59)	0% (0/59)
Acute Limb Ischemia	1.7% (1/59)	1.7% (1/59)
Stent Thrombosis	3.4 % (2/59)	10.2% (6/59)
Total Patients with MAVE	**5.1% (3/59)**	**11.9% (6/59)**

[1]Includes stent thrombosis, target limb amputation, clinically apparent distal embolization, defined as causing end-organ damage (e.g. lower extremity ulceration, tissue necrosis, or gangrene), procedure related arterial rupture, acute limb ischemia or bleeding event requiring transfusion >2 units of packed red blood cells.

What happens to the vein?

- No Clinical DVTs at 30 Days
- Femoral veins ≥ 10mm in diameter retain at least 50% of their volume and remain patent
- Duplicate femoral veins are occupied
- No observed impact on venous health

Deep Femoral Vein as a Conduit

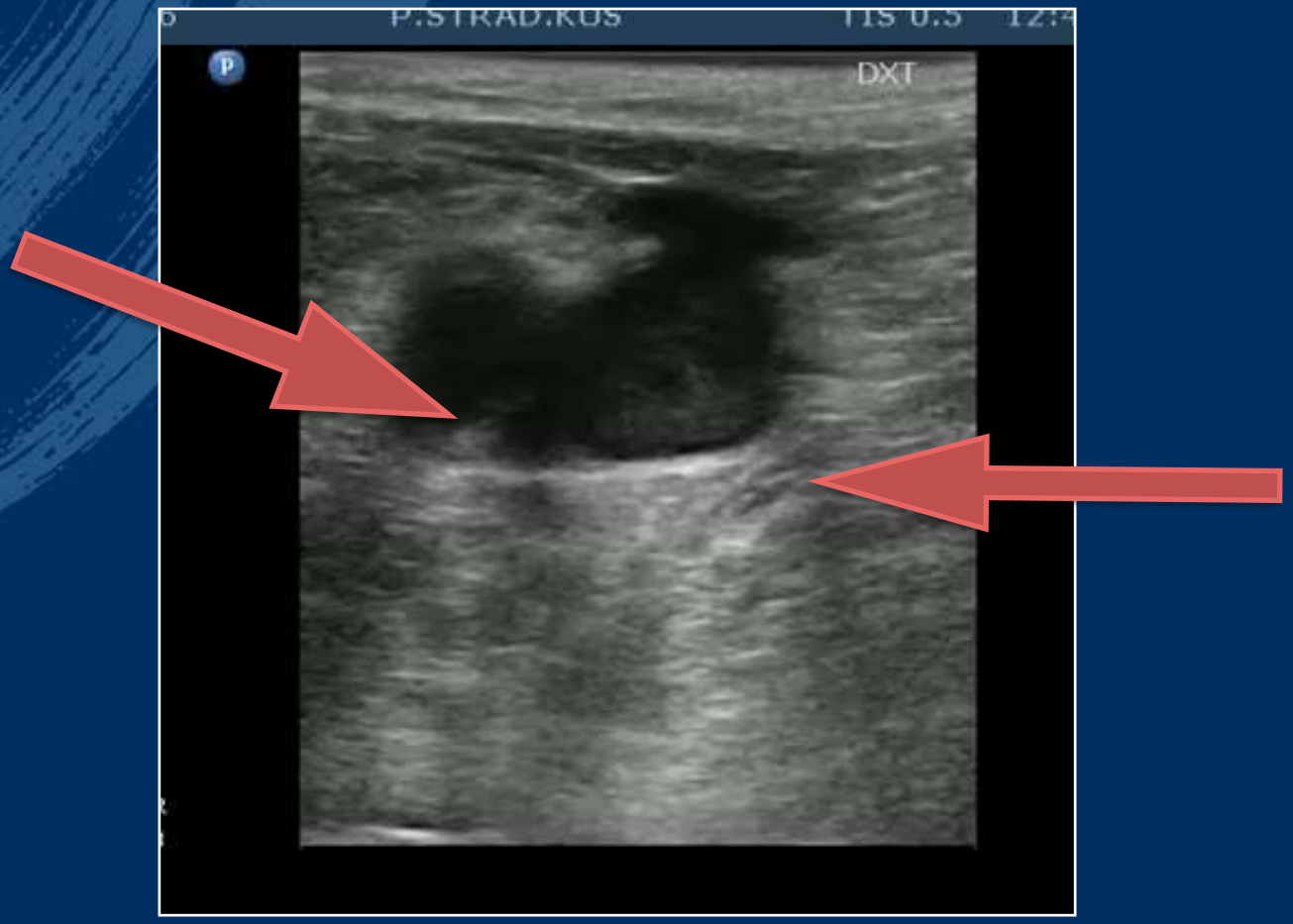


11 mm femoral vein

6-8 mm duplicate veins

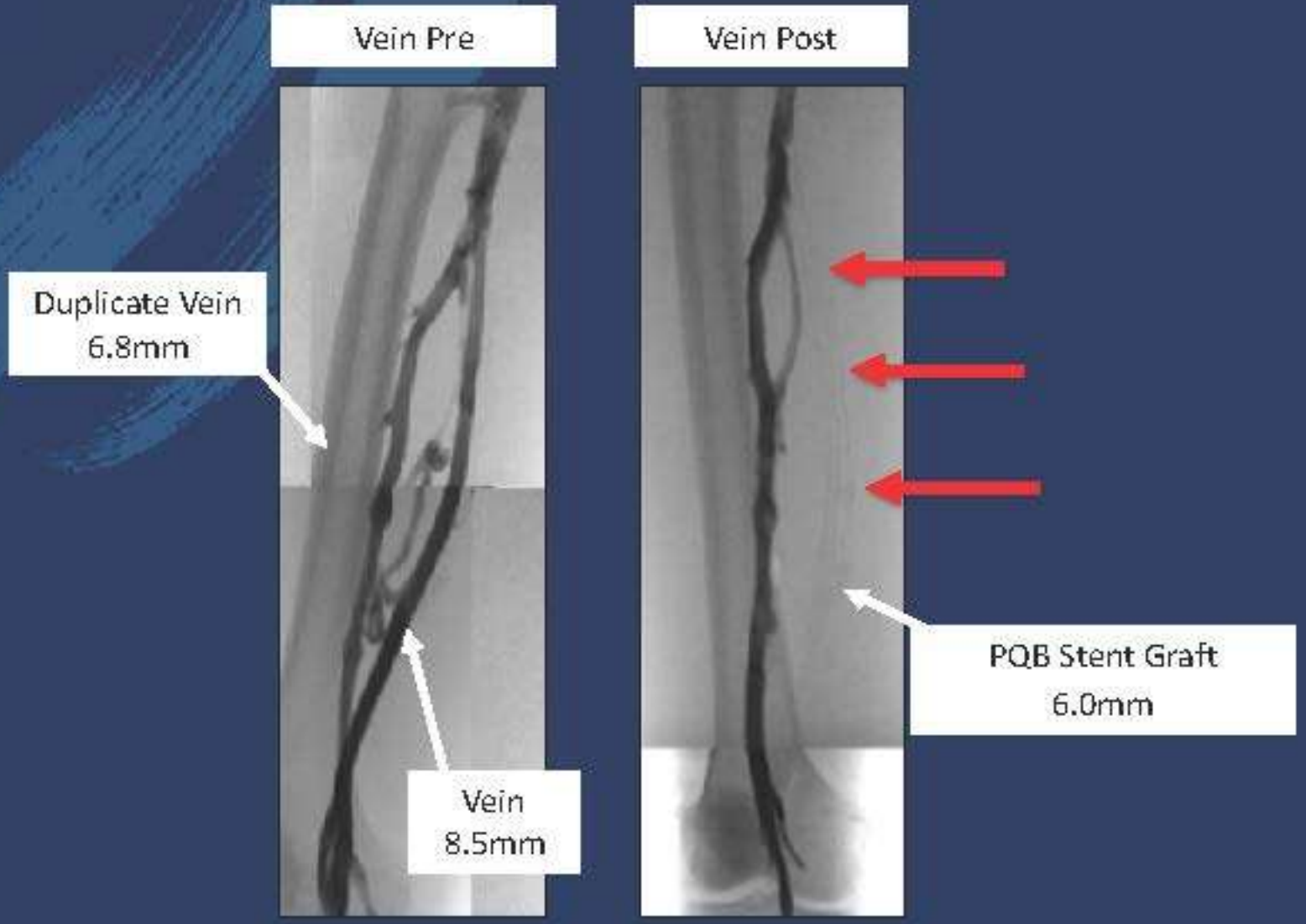
8 mm vein

Venous Compression with DUS



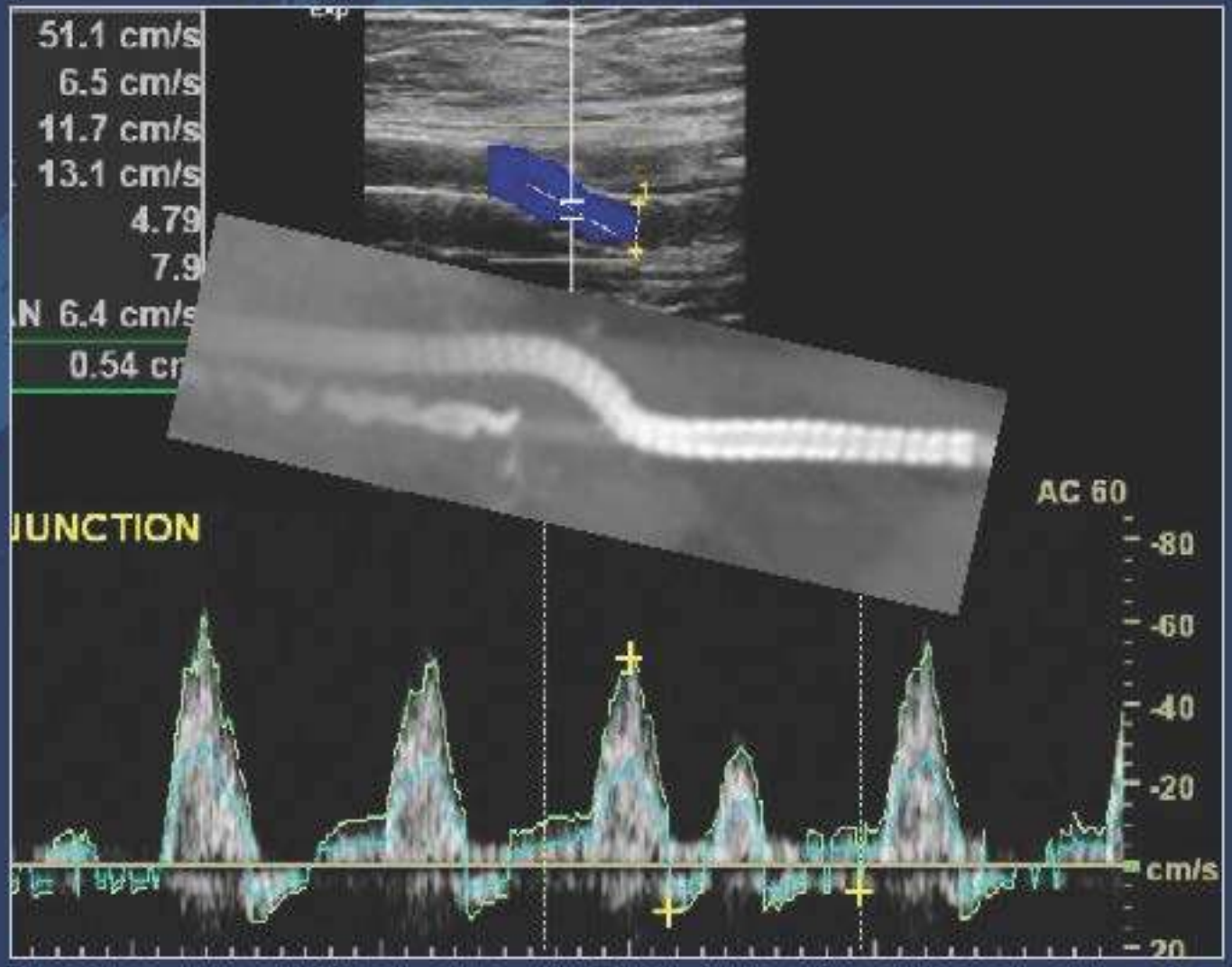
Cine: Vein remains patent around implanted Torus Stent Graft

Duplicate Femoral Vein with the Bypass



Patient 10-014

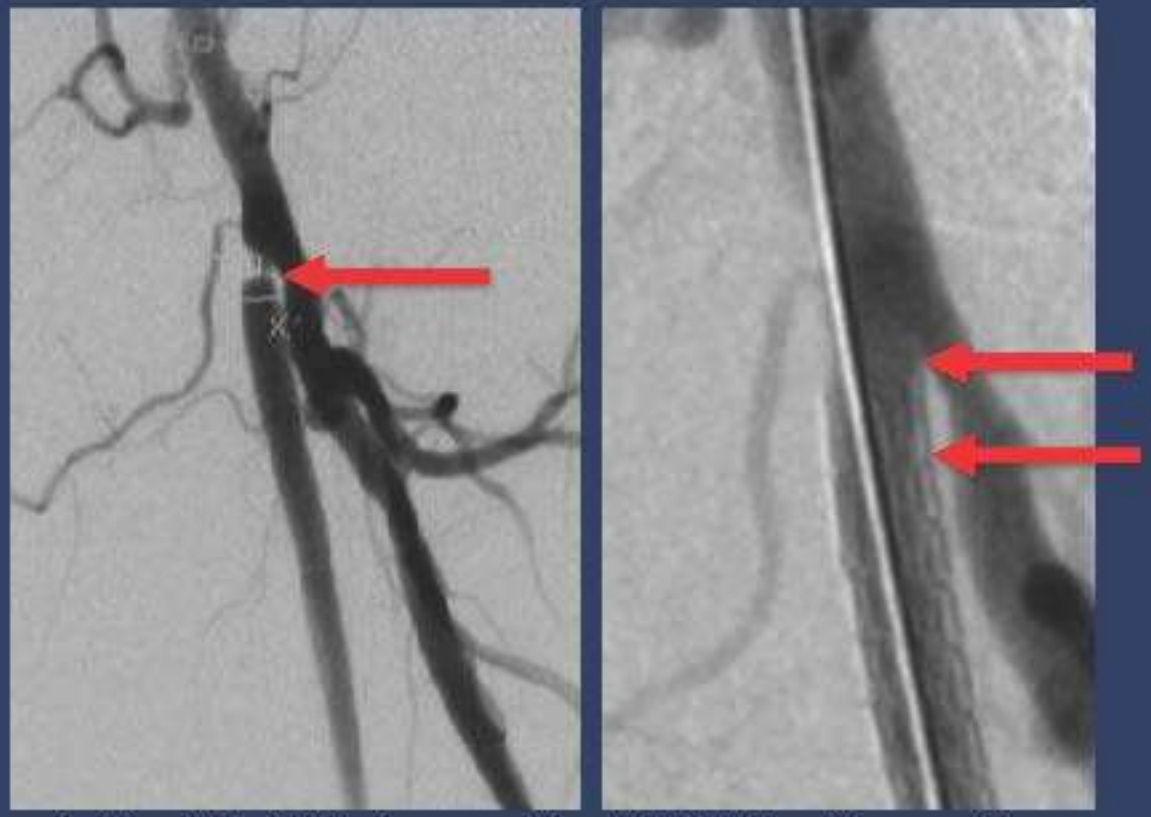
Flow Characteristics at Anastomoses



Anastomotic junctions demonstrate wide lumen with smooth transition and tri-phasic bloodflow

Post 6-Month Re-interventions

- **No occlusions**
- 2 stenoses post 6 months
- That stenoses could have been avoided !
- High placement of proximal edge of the graft is critical



Patient 10-029: Pre and Post DEB Re-intervention

Venous Function through 6 Months

Venous Clinical Severity Scale (VCSS) and Villalta Assessments

No Clinical DVTs at 30 Days

VCSS Scale	Baseline N = 60 Subjects[1]	6 Months N = 58 Subject[1]	6 Month Change from Baseline[2]	P-Value Baseline vs. 6 Months[3]
Overall				0.68
Mean ± SD (n)	0.81 ± 1.37 (59)	0.78 ± 1.30 (58)	-0.05 ± 0.96 (58)	

Villalta Score	Baseline N = 60 Subjects	6 Months N = 58 Subjects	6 Months Change fr om Baseline	P-Value Baseline vs. 6 Months
Overall				0.11
Mean ± SD (n)	0.81 ± 1.53 (59)	0.50 ± 1.01 (58)	-0.33 ± 1.53 (58)	

[1]Sample sizes less than 60 subjects at baseline, 59 subjects at 30 days/58 at 6 months reflect unknown data.
[2]Change from baseline calculated using matched pairs.
[3]P-values are calculated for absolute change using paired t-test for matched data.

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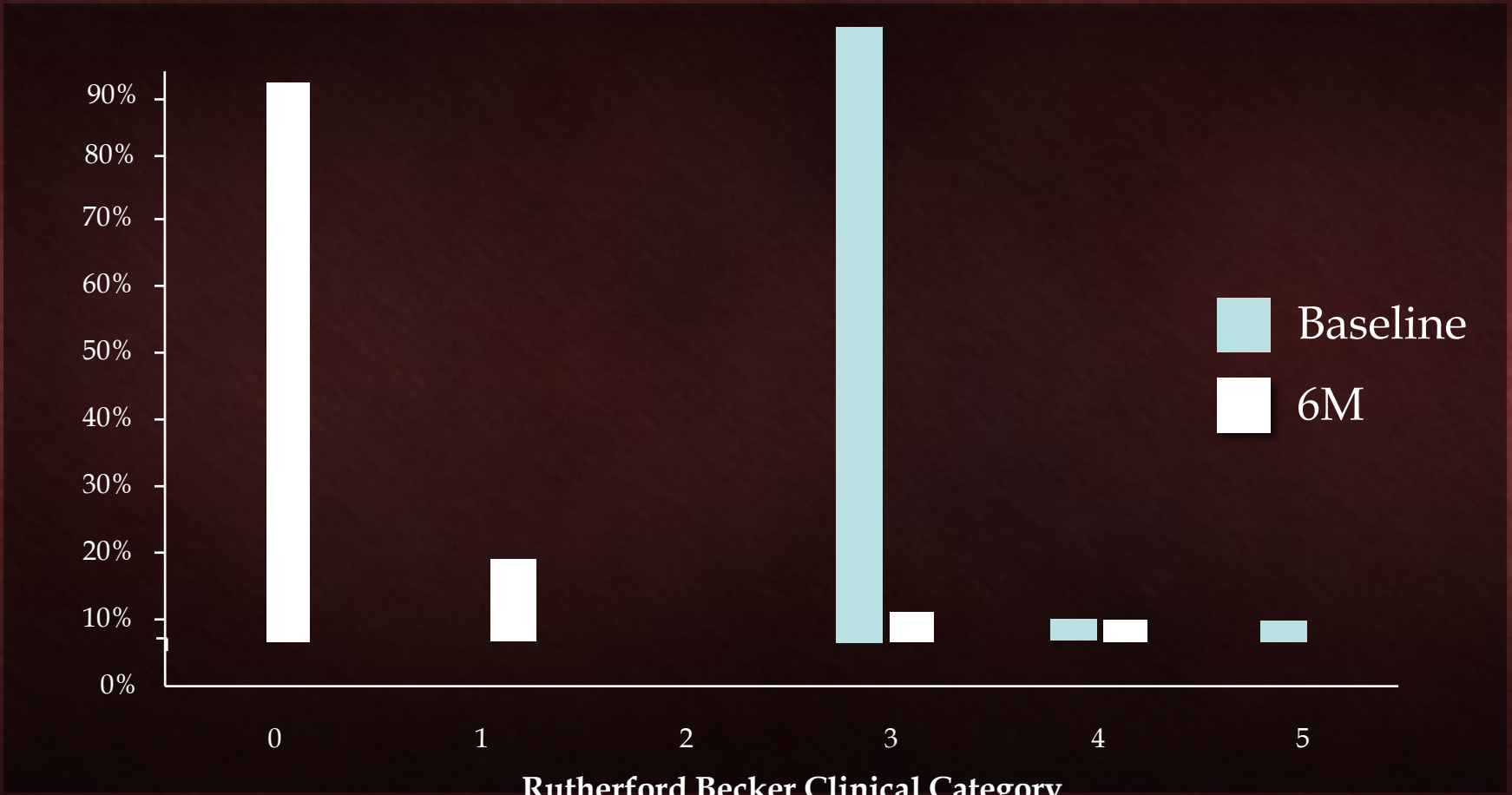
94% of Subjects Improved ≥1 RB Class at 6M as Compared to Baseline (p<0.0001)



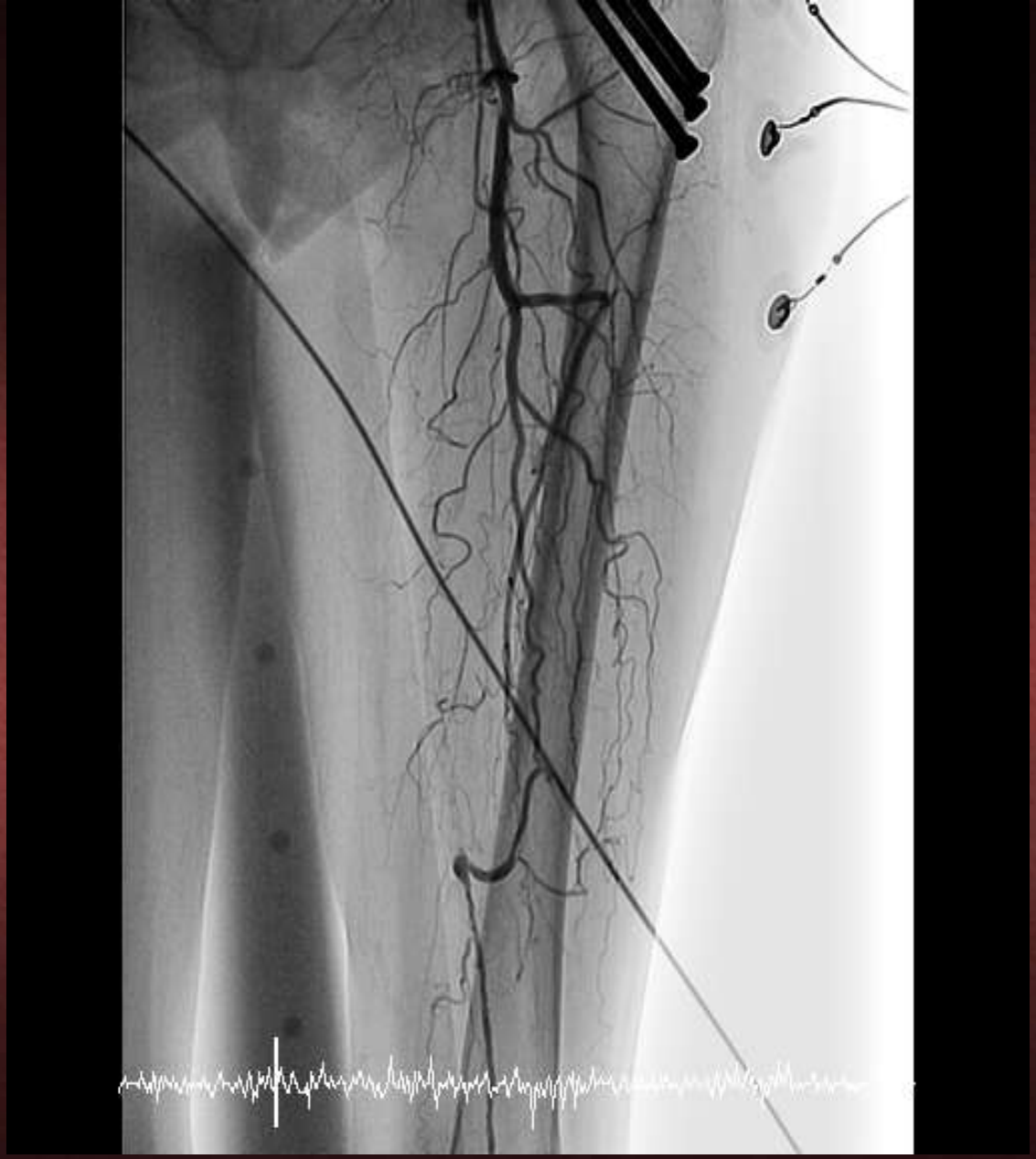
10.5% improved by 2 RB clinical categories | 80.7% improved by 3 categories | 3.5% improved by 4 categories
3.5% had no change in category | 1.8% worsened by 1 category

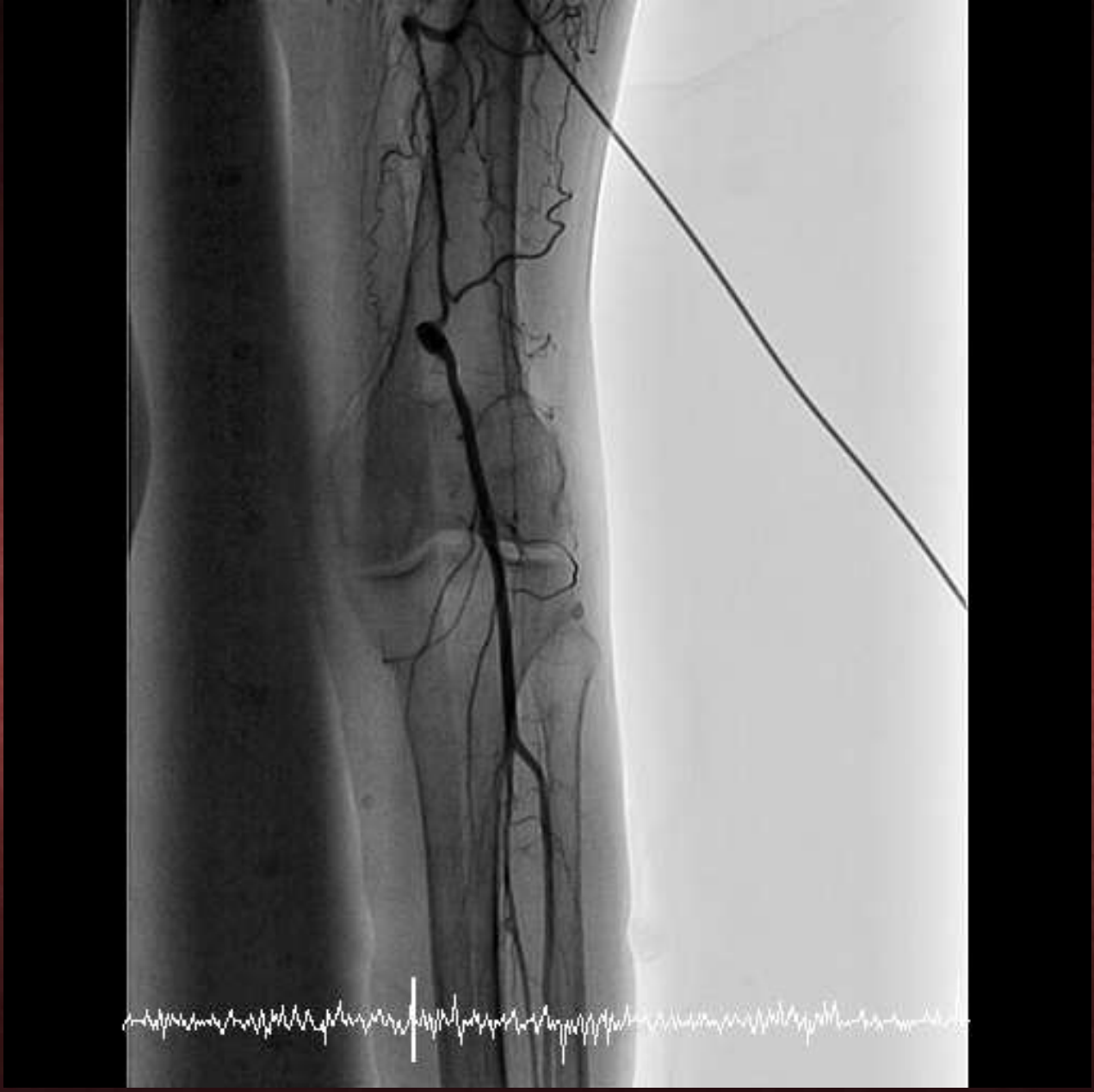
Conclusions

- Primary Patency: 84.7% at 6 Months in nearly 30cm TASC II D lesions
- Primary performance endpoint met
  No impact on venous health; low MAE rate
- High procedural and technical success rates of >95%
- Clinical performance in severe lesions (95% CTOs, 93% TASC II D, 28.6 cm mean length) demonstrates this novel therapy's potential for complex patients without a durable endovascular option

Percutaneous Bypass using the Femoral Vein as a Conduit may Prove to be An Important Step Forward in the Treatment of Long SFA Occlusions

48 y/o mother who has had recurrent non-healing ulcers of her left foot. She is 4 years status post femoral/popliteal bypass on her left leg





PQ Bypass Would Not Have Been Possible Without the Help of Jim Joye, Rich Ferrari and Tom Fogarty

R. Heuser

PQ Bypass Wins CE Mark for DETOUR Percutaneous Bypass Technologies

3/13/2017 7:50:13 AM

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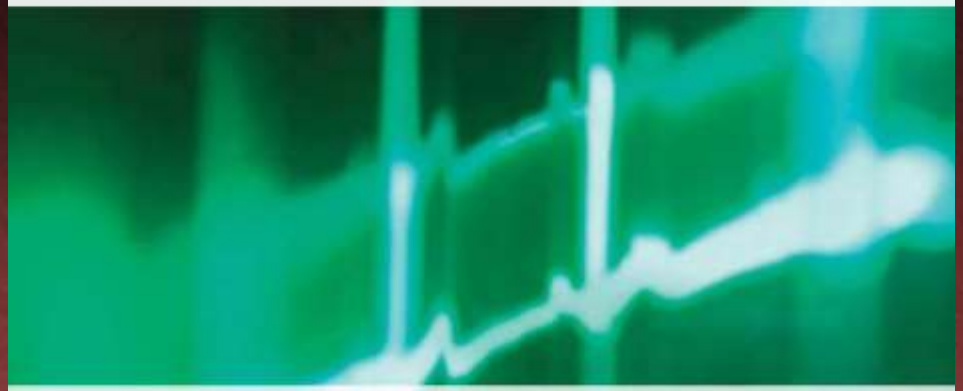
5th Annual Symposium

Cardiovascular Disease Management:
A Case-Based Approach



Richard R. Heuser, MD, FACC
Program Director

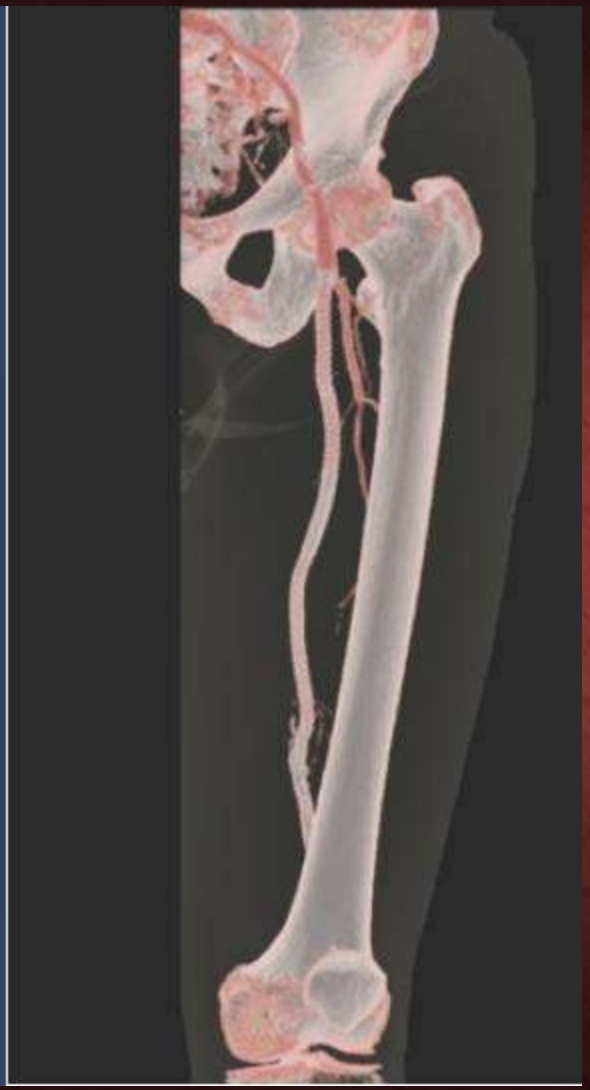
October 5-6, 2017
Arizona Biltmore, Phoenix, Arizona

Nursing Symposium will take place
October 4, 2017 from 12:00 – 5:00 pm

SAVE THE DATE
For more information, please visit www.promedicacme.com

California | American College of Cardiology Arizona Chapter

Thank You for Your Attention

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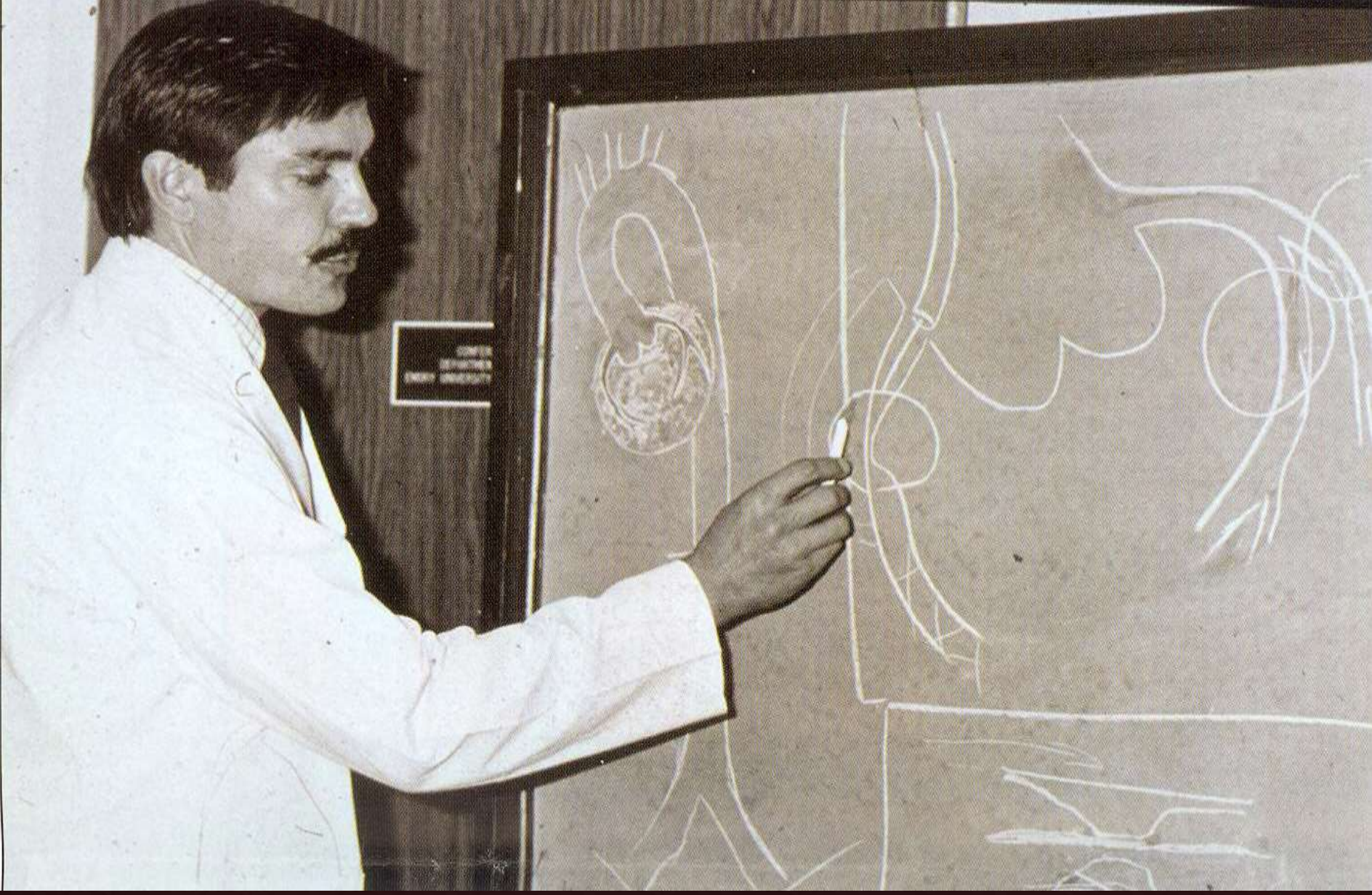

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California

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PERCUTANEOUS TREATMENTS FOR MITRAL REGURGITATION

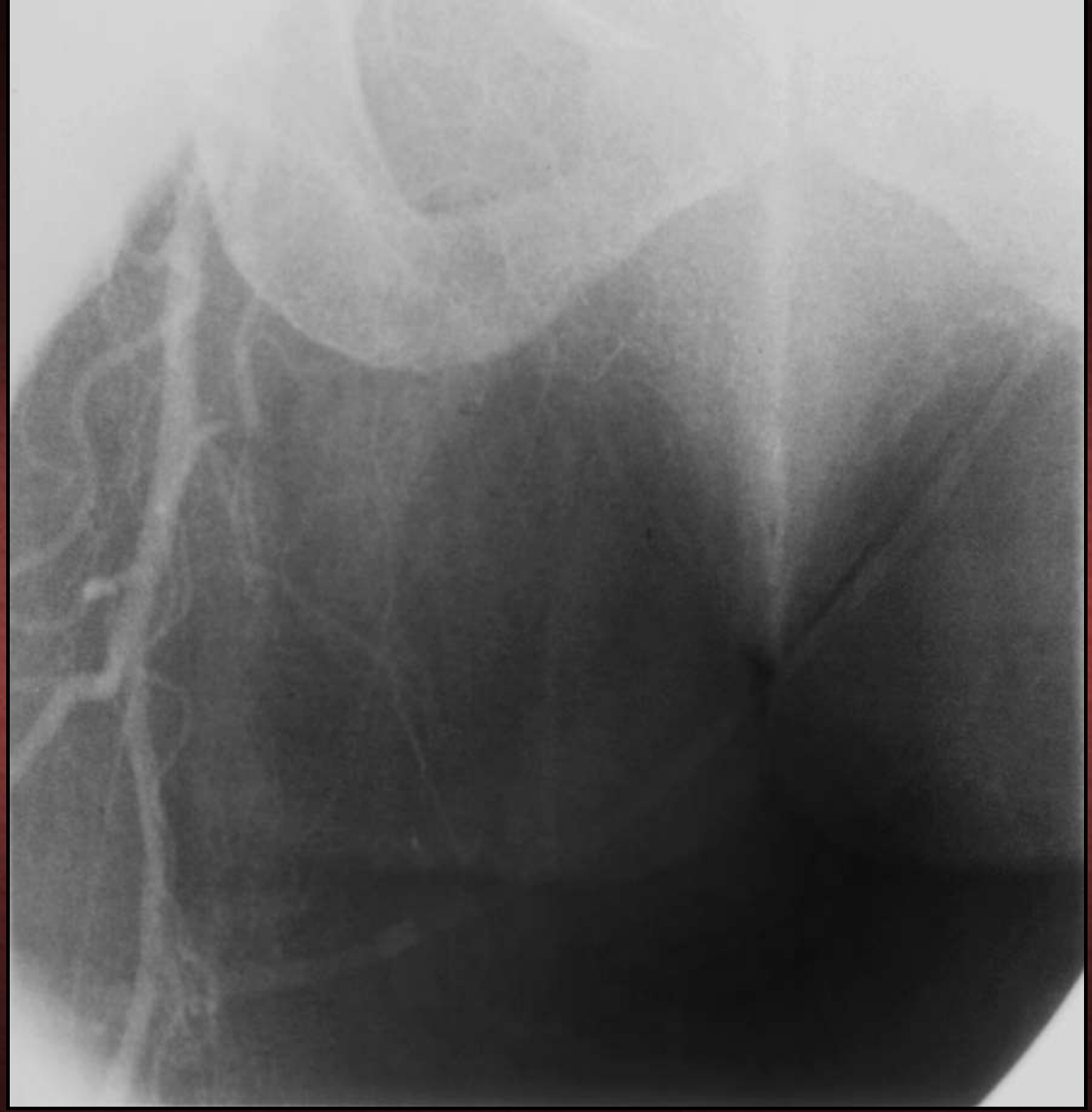
Percutaneous Treatment for Ischemic Mitral Regurgitation is not new…….

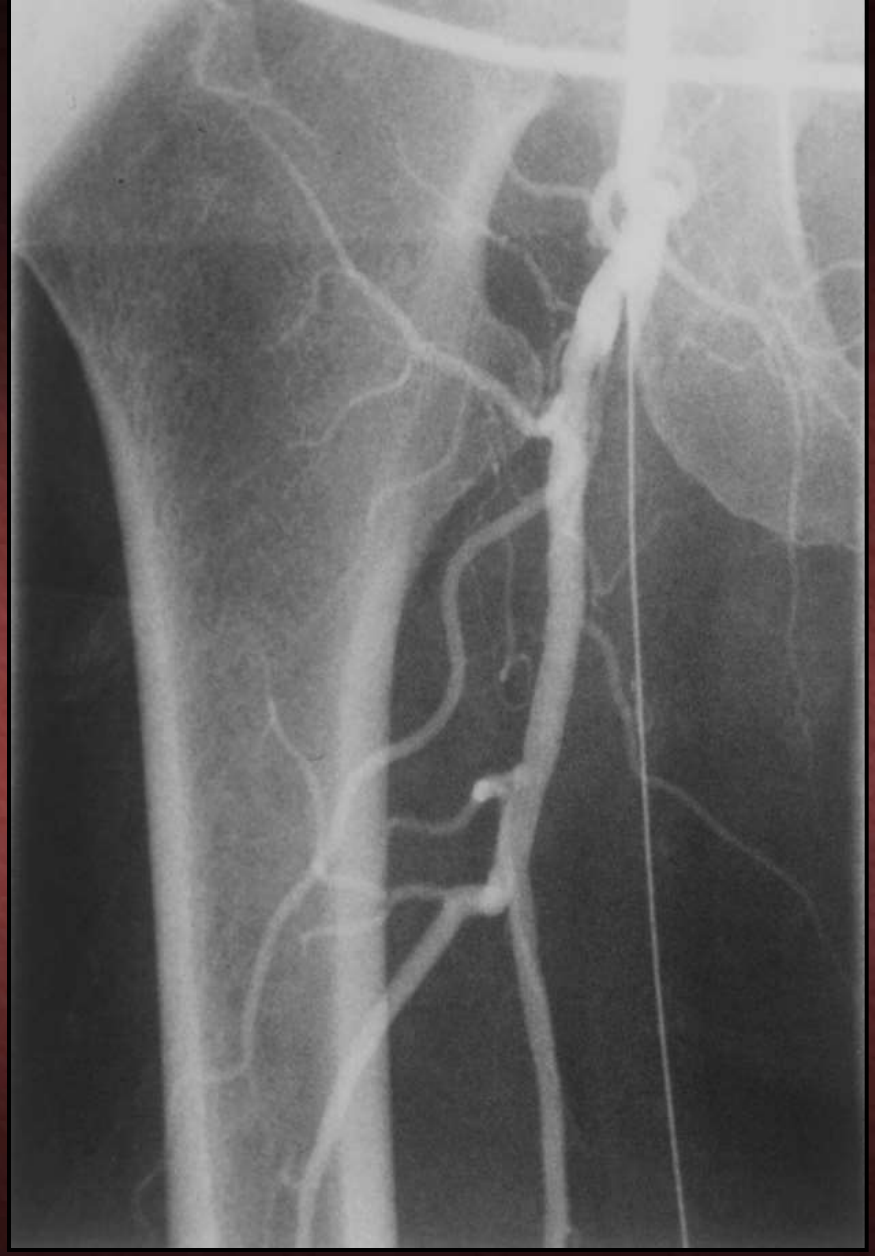
Coronary Angioplasty for Acute Mitral Regurgitation Due to Myocardial Infarction

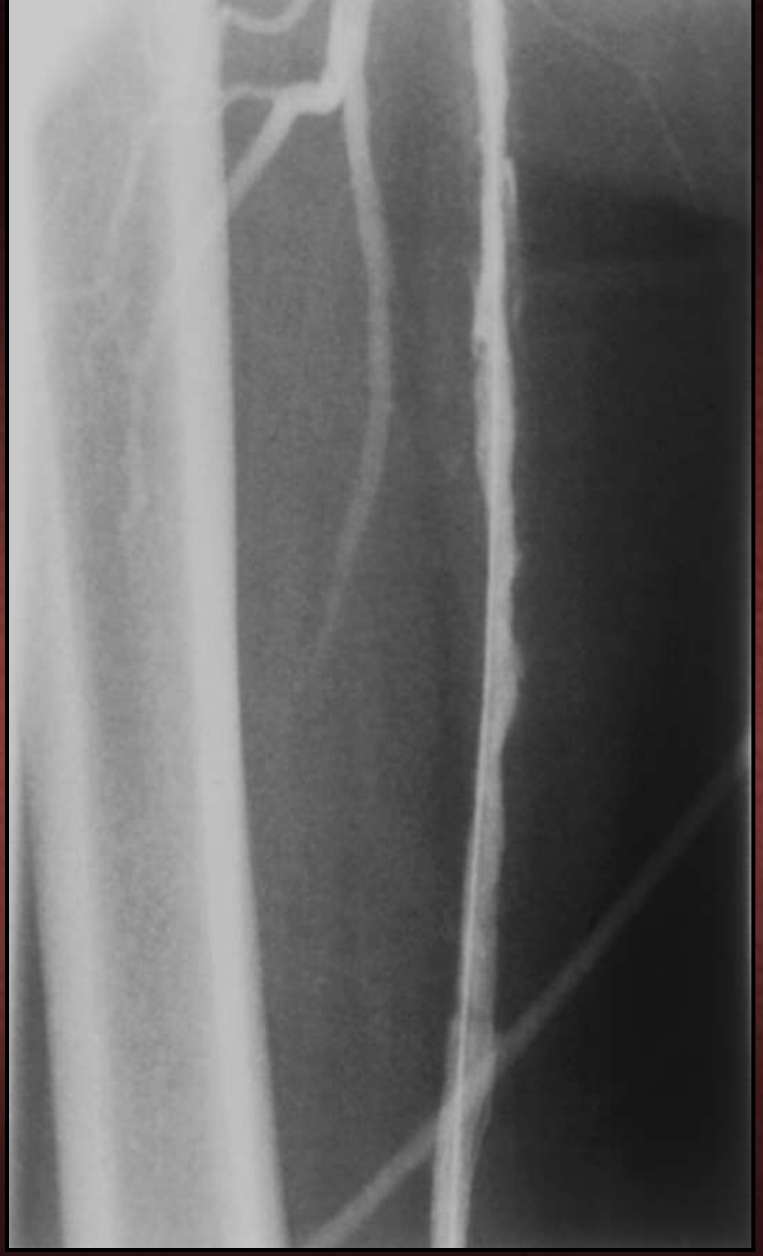
A Nonsurgical Treatment Preserving Mitral Valve Integrity

RICHARD R. HEUSER, M.D.; GERRY L. MADDOUX, M.D.; JEROME E. GOSS, M.D.; BARRY W. RAMO, M.D.; GILBERT L. RAFF, M.D.; and NEAL SHADOFF, M.D.; Albuquerque, New Mexico

Annals of Internal Medicine. 1987;107:852-855.







The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 4, 2006 VOL. 354 NO. 18

Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

Martin Schillinger, M.D., Schila Sabeti, M.D., Christian Loewe, M.D., Petra Dick, M.D., Jasmin Amighi, M.D., Wolfgang Mlekusch, M.D., Oliver Schlager, M.D., Manfred Cejna, M.D., Johannes Lammer, M.D., and Erich Minar, M.D.

ABSTRACT

BACKGROUND

Because stent implantation for disease of the superficial femoral artery has been associated with high rates of late clinical failure, percutaneous transluminal angioplasty is preferred for endovascular treatment, and stenting is recommended only in the event of suboptimal technical results. We evaluated whether primary implantation of a self-expanding nitinol (nickel–titanium) stent yielded anatomical and clinical benefits superior to those afforded by percutaneous transluminal angioplasty with optional secondary stenting.

METHODS

We randomly assigned 104 patients who had severe claudication or chronic limb ischemia due to stenosis or occlusion of the superficial femoral artery to undergo primary stent implantation (51 patients) or angioplasty (53 patients). Restenosis and clinical outcomes were assessed at 6 and 12 months.

RESULTS

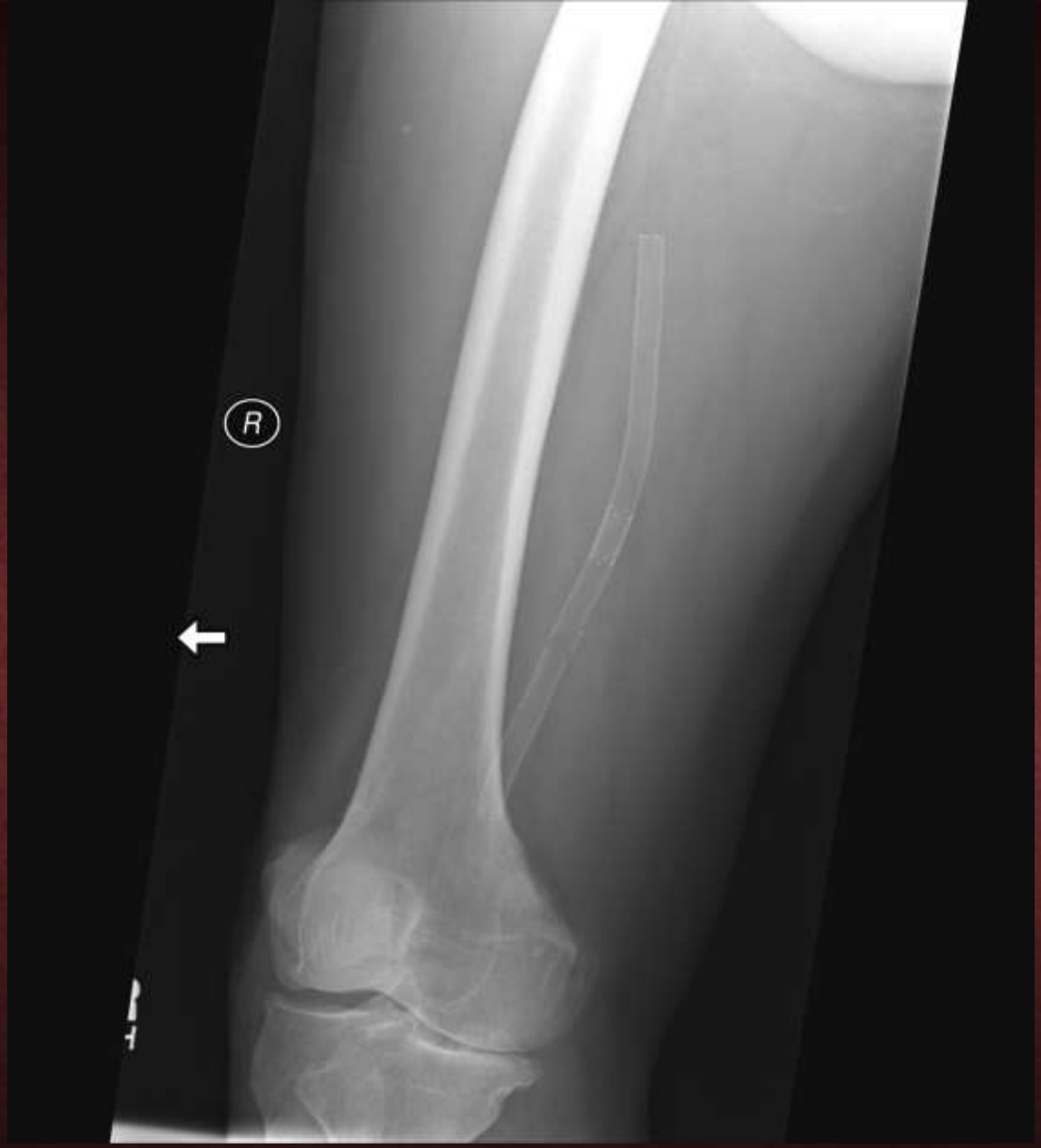
The mean (±SD) length of the treated segment was 132±71 mm in the stent group and 127±55 mm in the angioplasty group. Secondary stenting was performed in 17 of 53 patients (32 percent) in the angioplasty group, in most cases because of a suboptimal result after angioplasty. At 6 months, the rate of restenosis on angiography was 24 percent in the stent group and 43 percent in the angioplasty group ($P=0.05$); at 12 months the rates on duplex ultrasonography were 37 percent and 63 percent, respectively ($P=0.01$). Patients in the stent group were able to walk significantly farther on a treadmill at 6 and 12 months than those in the angioplasty group.

CONCLUSIONS

In the intermediate term, treatment of superficial-femoral-artery disease by primary implantation of a self-expanding nitinol stent yielded results that were superior to those with the currently recommended approach of balloon angioplasty with optional secondary stenting.

From the Departments of Angiology (M.S., S.S., P.D., J.A., W.M., O.S., E.M.) and Angiography and Interventional Radiology (C.L., M.C., J.L.), Medical University of Vienna, Vienna. Address reprint requests to Dr. Schillinger at the Department of Internal Medicine II, Division of Angiology, Vienna General Hospital, Medical University, Waehringer Guertel 18-20, Vienna A-1090, Austria, or at martin.schillinger@meduniwien.ac.at.

N Engl J Med 2006;354:1879-88.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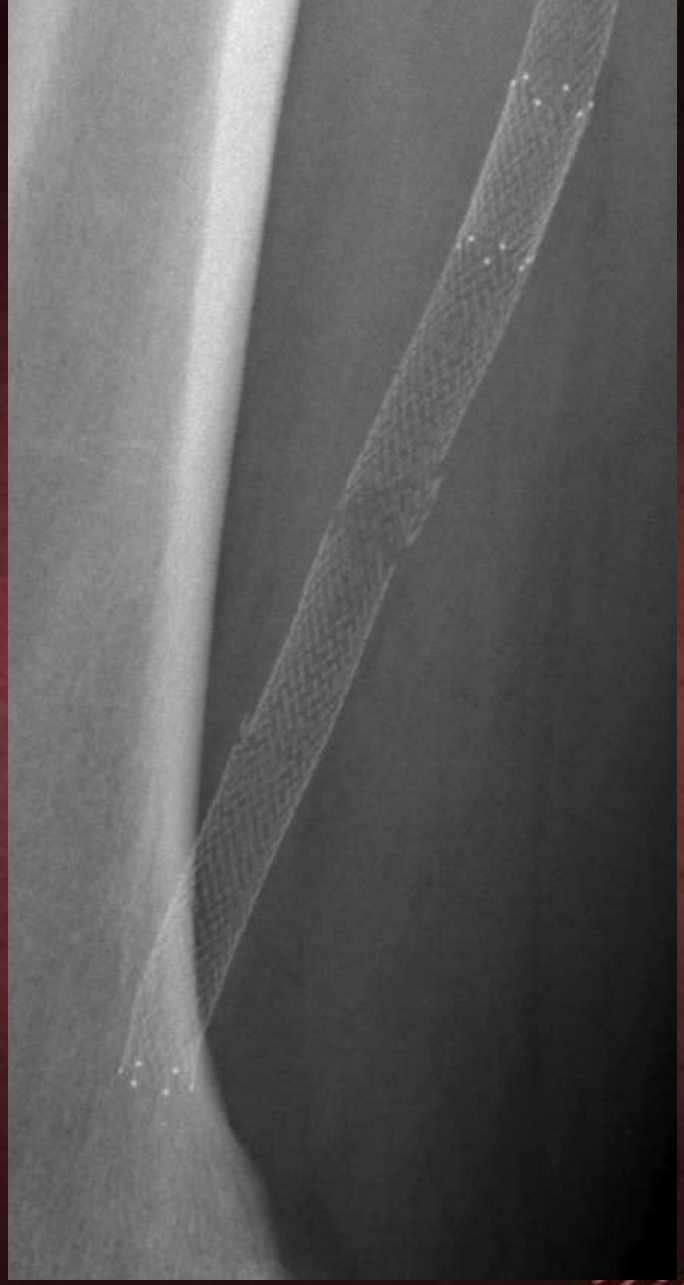

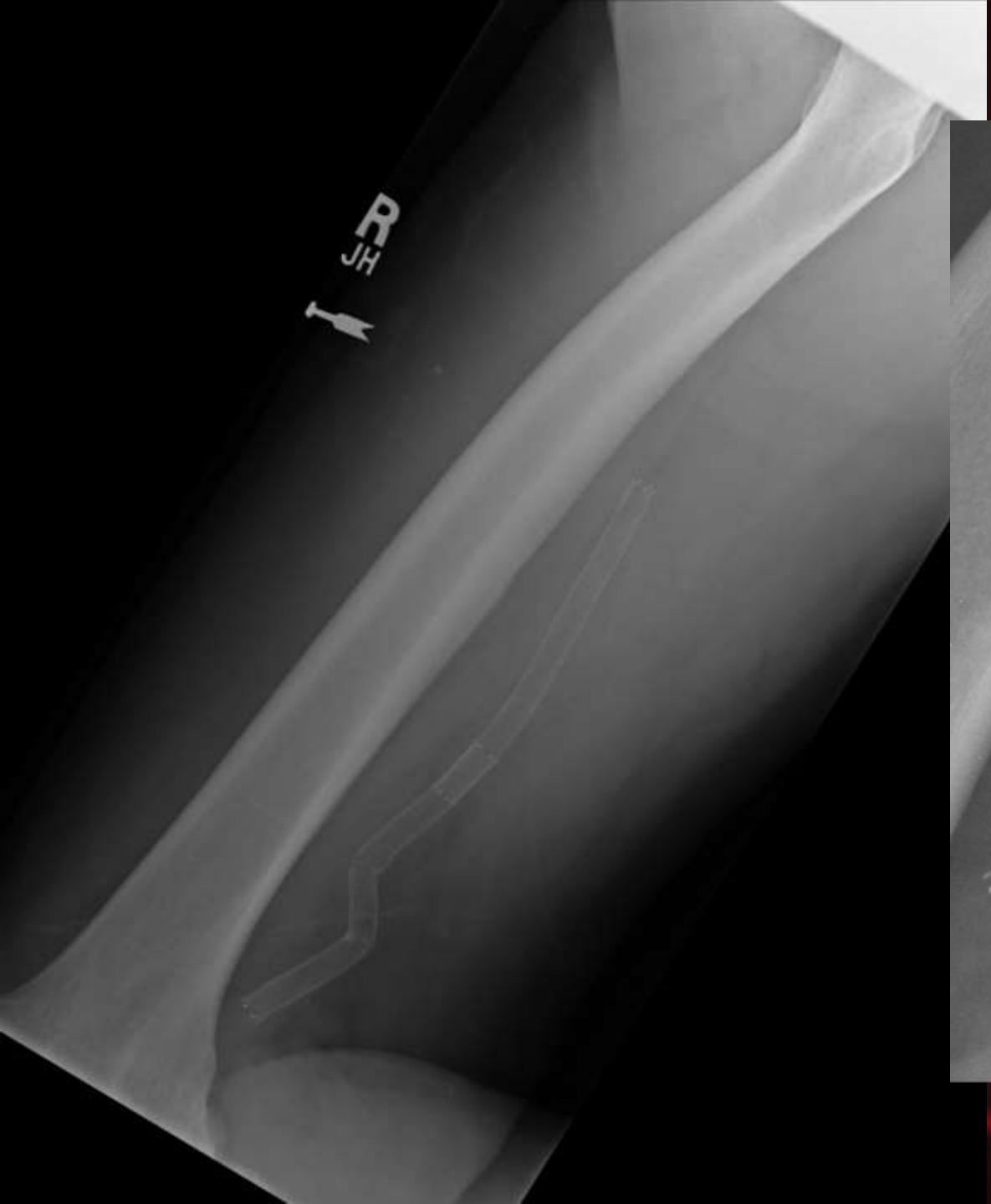

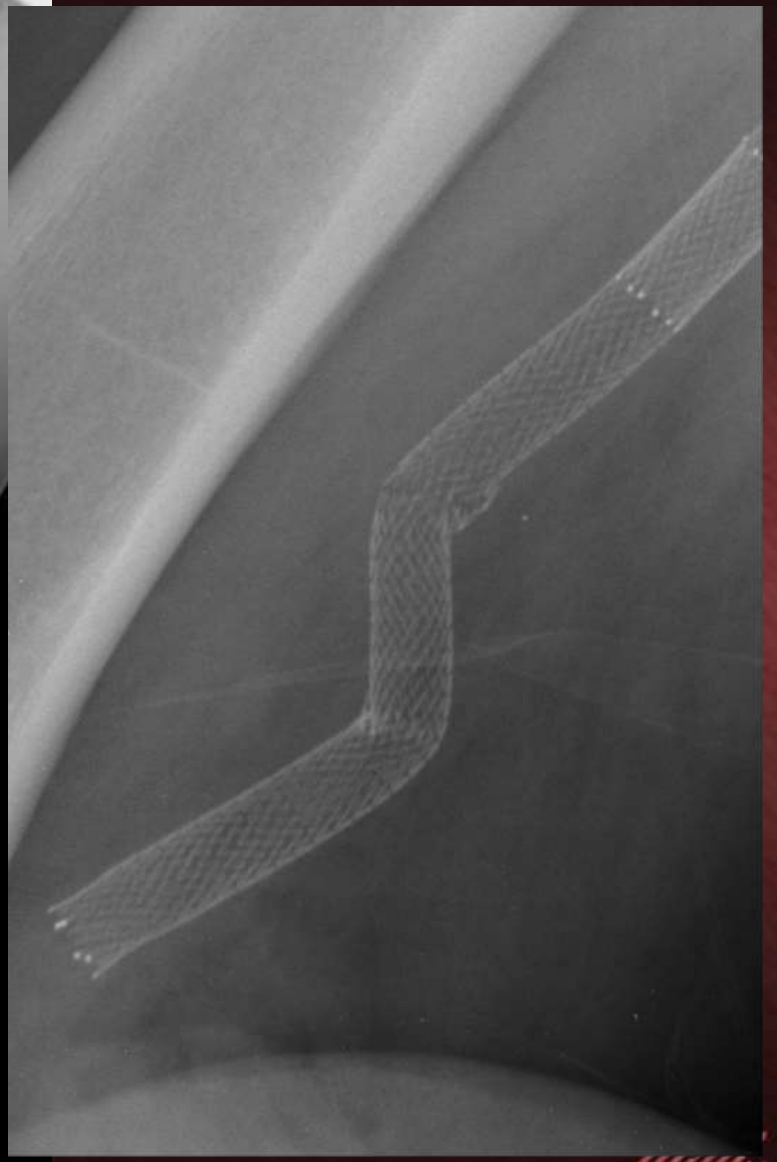

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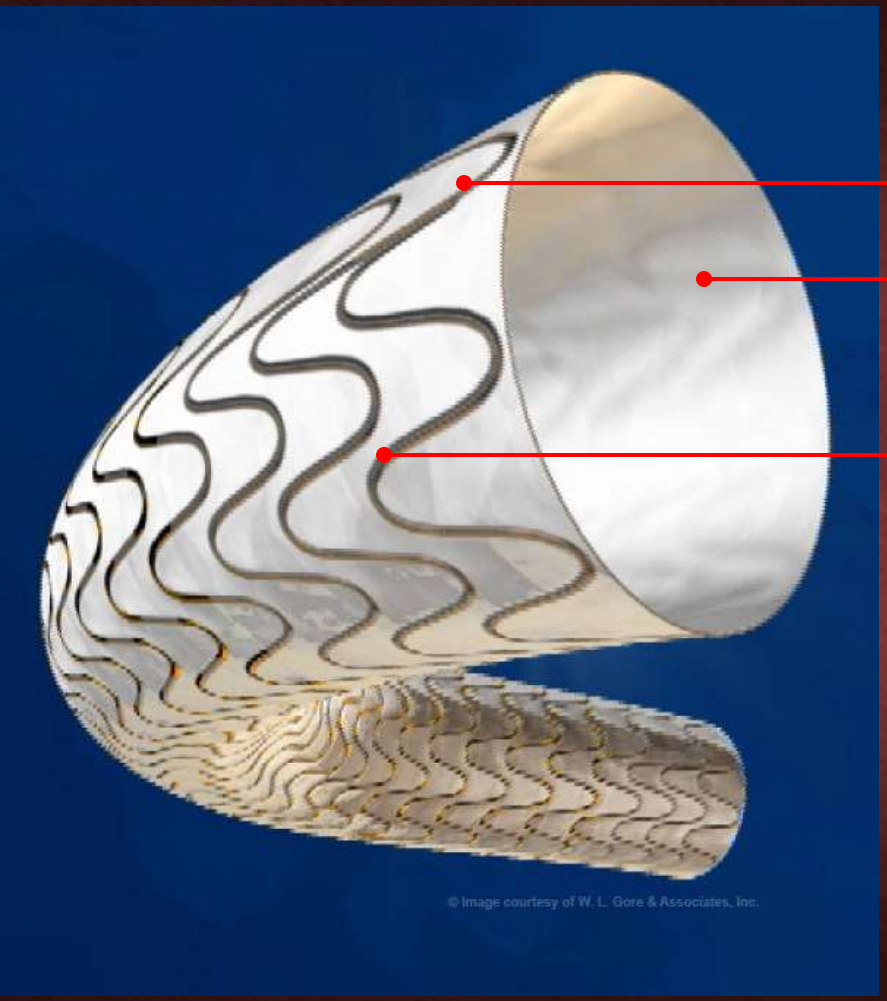
Description

New
HEPARIN-BONDED
Surface



- Polished nitinol support
- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Heparin Bioactive Surface
- Lengths: 2.5, 5, 10, and 15 cm
- Diameters: 5 – 8 mm

The DETOUR Percutaneous Bypass Technology

Trio of proprietary devices designed specifically for the DETOUR procedure

Torus Stent Graft

- Self-expanding nitinol wire frame encapsulated in ePTFE
- **High radial force**
- Elongated, exposed end rings to prevent edge stenosis

PQ Snare

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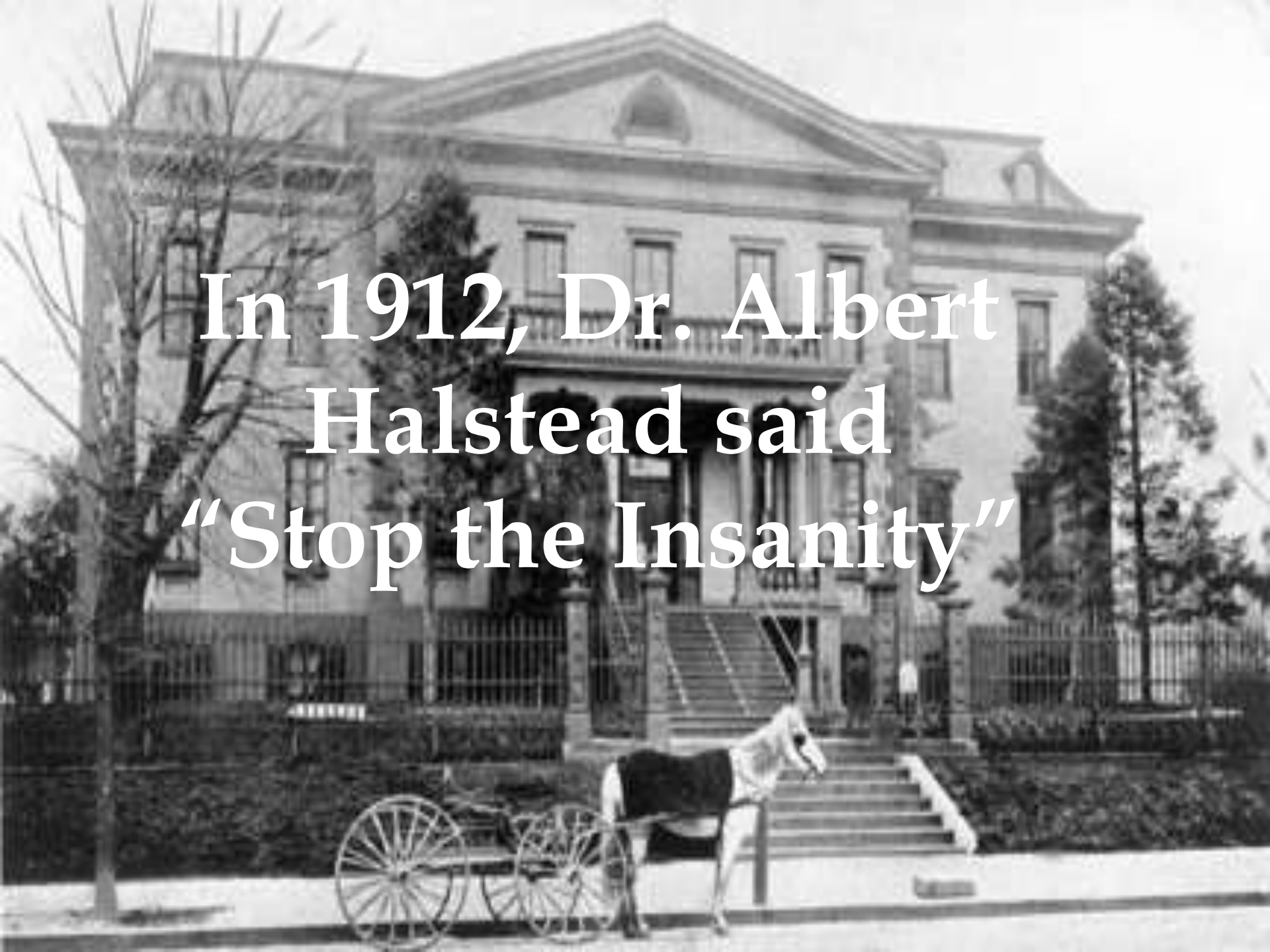
- Captures and extracts guidewires through the tibial vein

PQ Crossing Device

- Spring-loaded guidewire support and delivery system
- Creates initial artery-vein-artery communication


In 1912, Dr. Albert
Halstead said
“Stop the Insanity”

Halstead, MD, Albert. Arteriovenous Anastomosis in the Treatment of Gangrene in the Extremities. Surgery, Gynecology and Obstetrics. 1912. pp. 1-19. Vol. 2.

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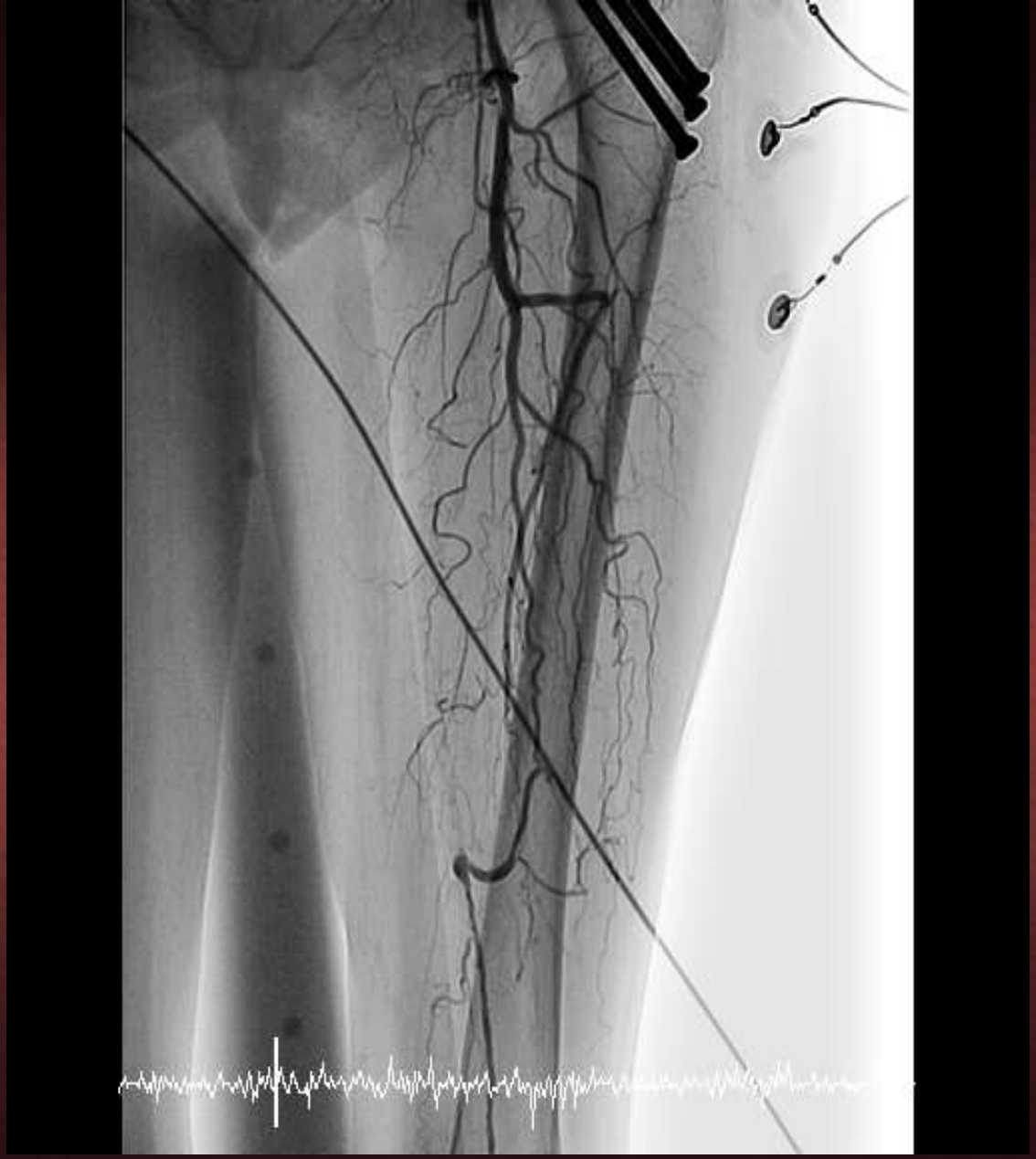
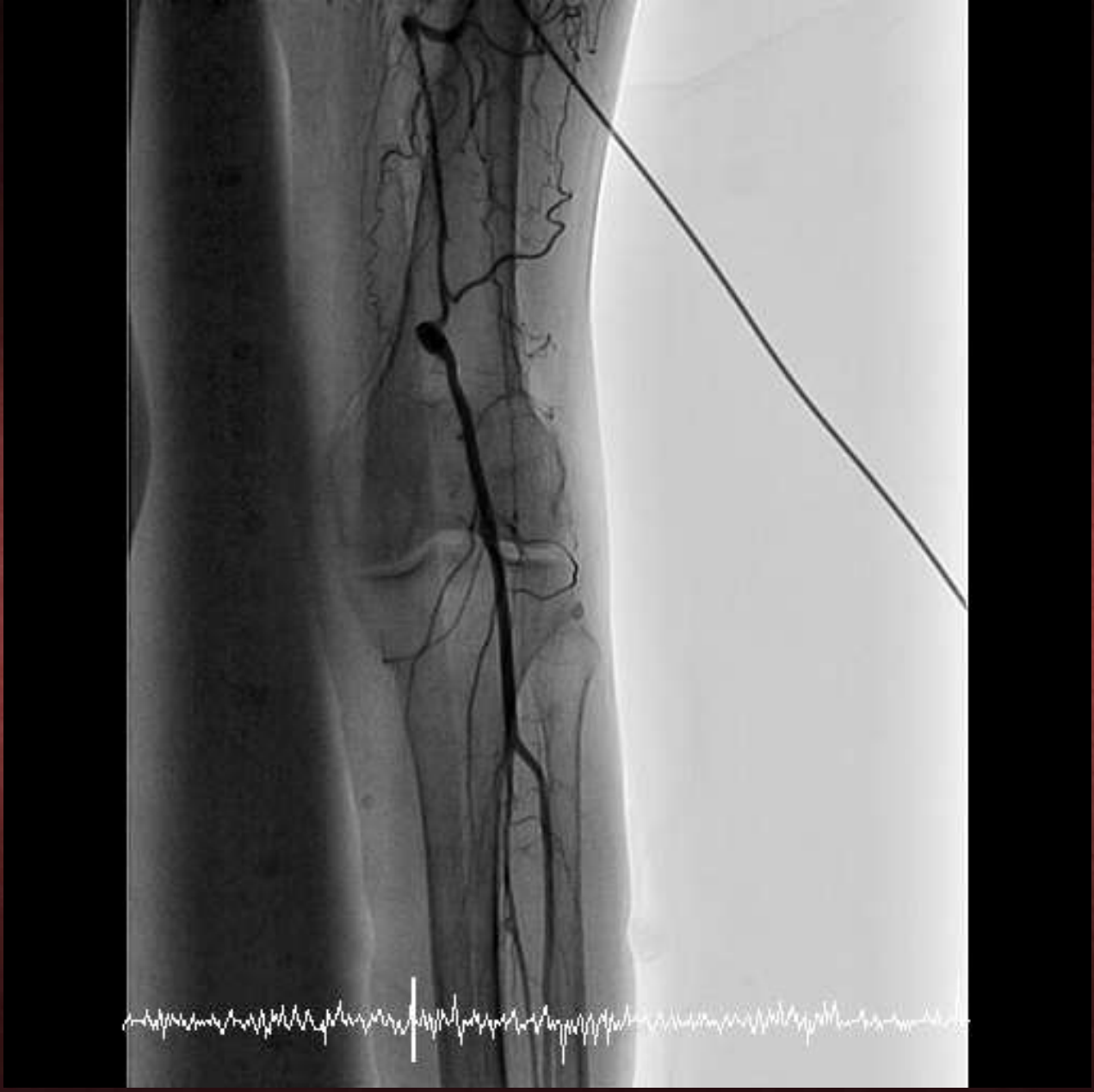
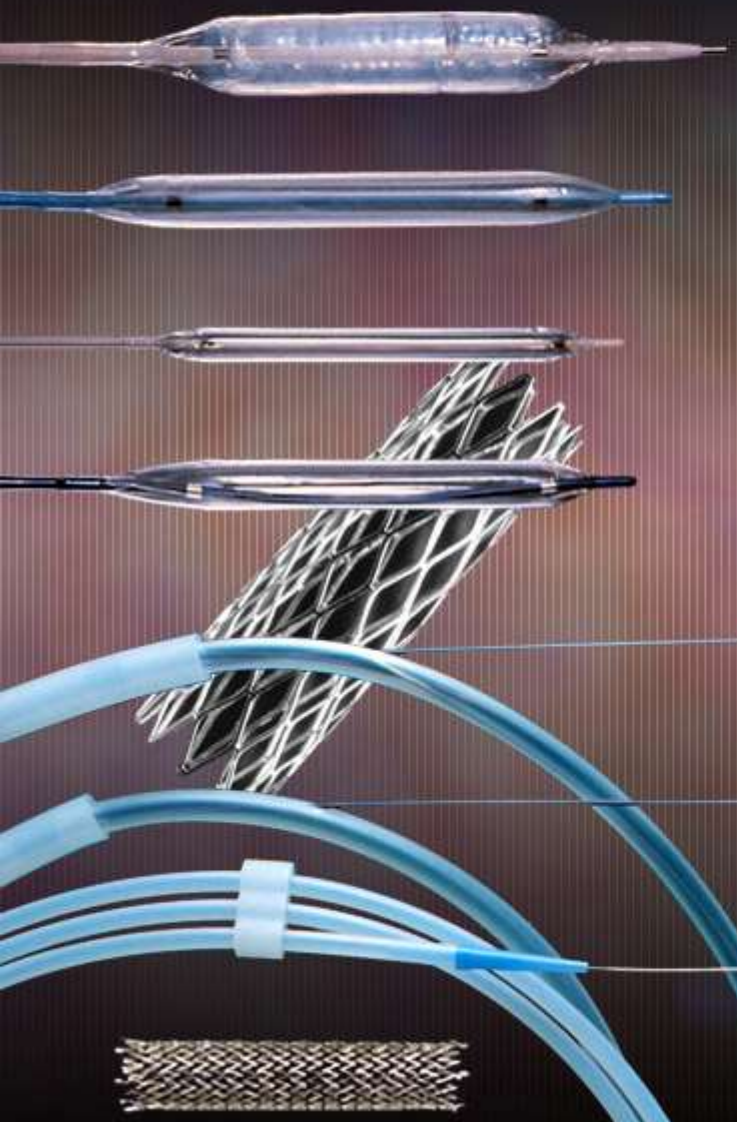
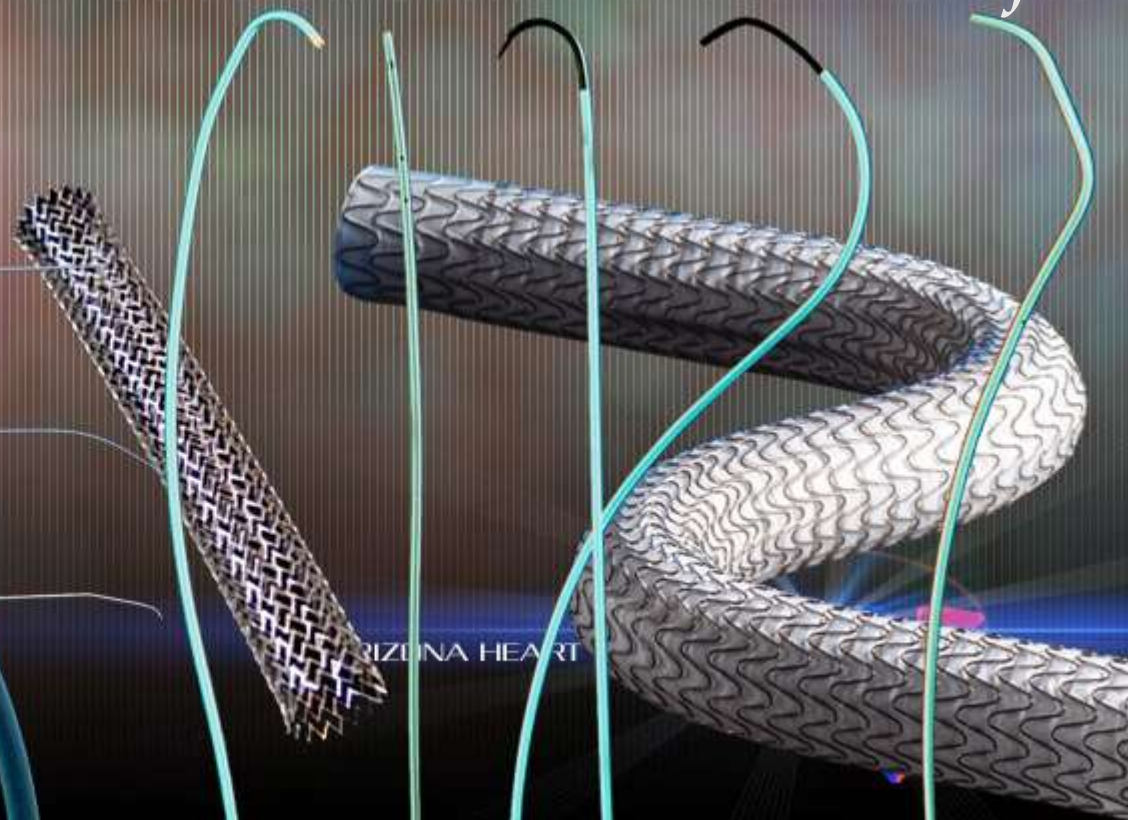




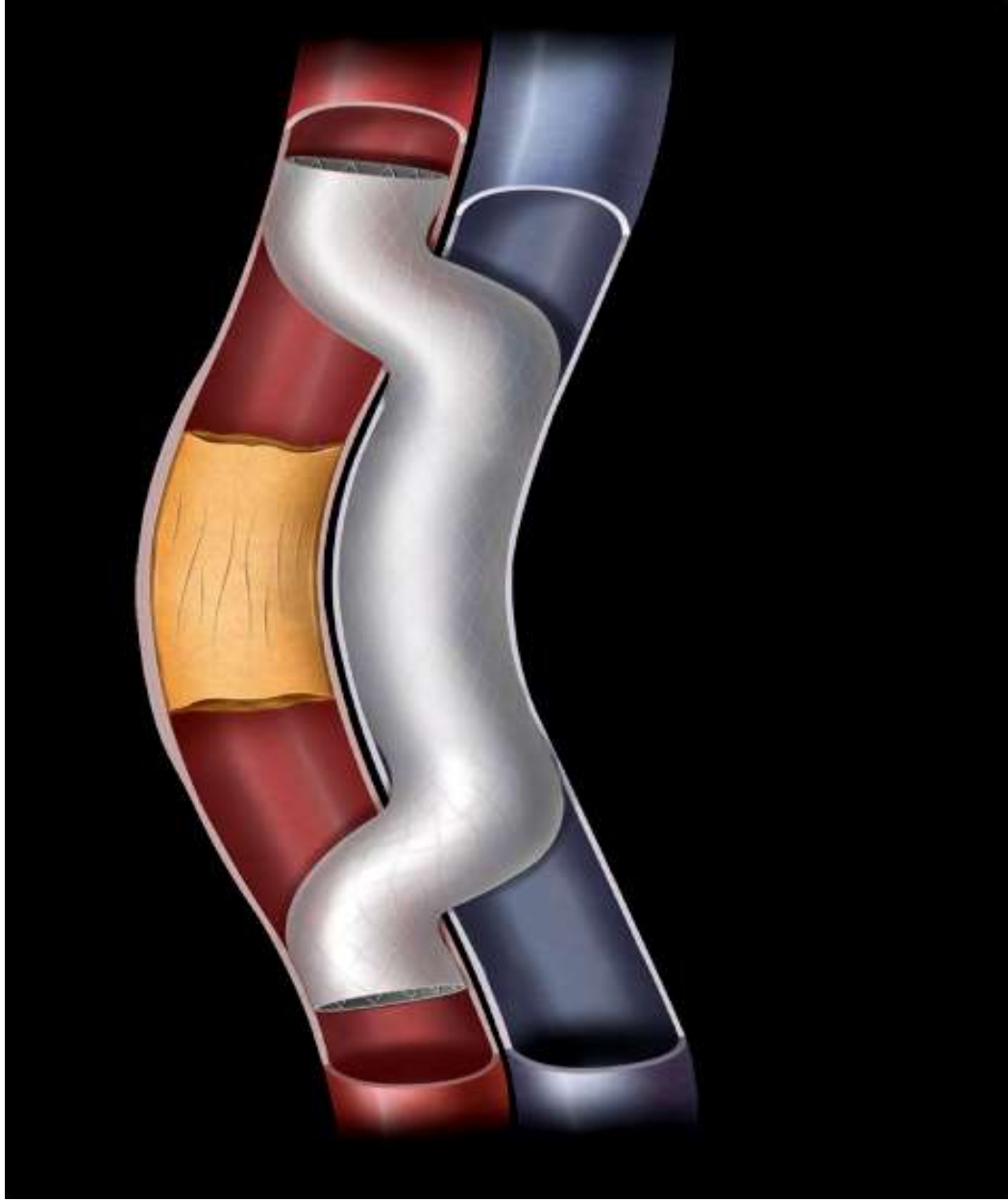
Emergence of Equipment

- *Wires*
- *Catheters*
- *Balloons*
- *Stents*
- *Covered Stents & Stent Grafts*





Introducing Percutaneous Bypass



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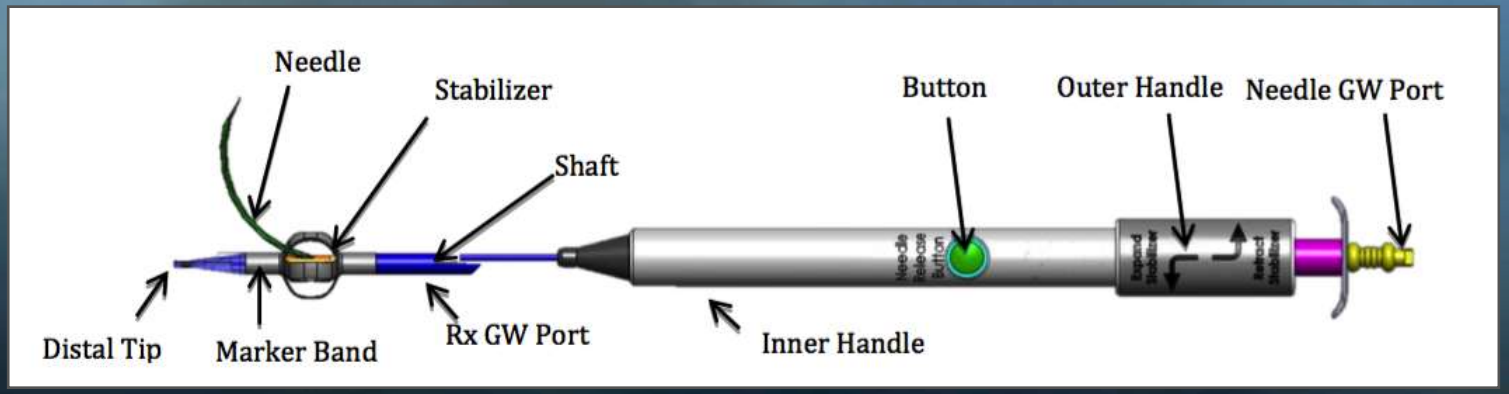
R. Heuser

PQ Bypass System

5.5, 6, 6.7mm OD
100, 150 and 200 mm length

VL (cage, snare)



Percutaneous Anastomosis Device

R. Heuser

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Percutaneous Bypass of Extra Long, Complex SFA Occlusions

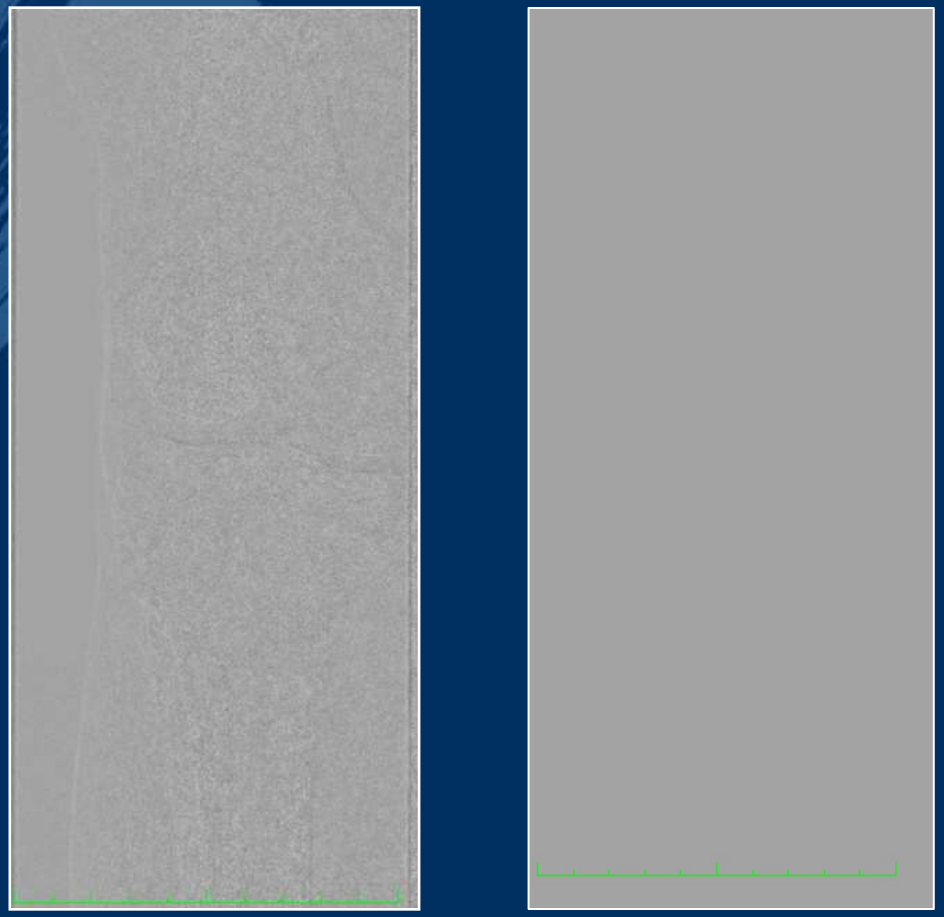
10 Steps to DETOUR

Grzegorz Halena, MD, PhD
Michał Zdunek, MD
Department of Cardiac and Vascular Surgery
Division of Vascular Surgery
Medical University of Gdańsk, Poland
Head Prof. J. Rogowski

01a. Venous access - introducing 7F sheath in the ipsilateral tibial vein

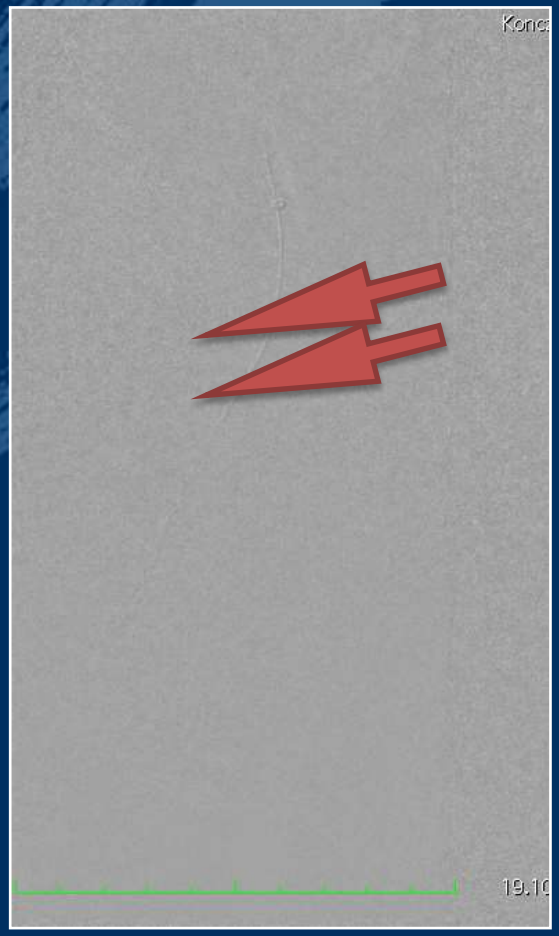
Tibial and Femoral Venograms

01a. Venous access - introducing 7F sheath in the ipsilateral tibial vein



Cine: Tibial and Femoral Venograms

01b. Arterial access - crossover Balkin 8F sheath



Cine: Femoral Angiogram

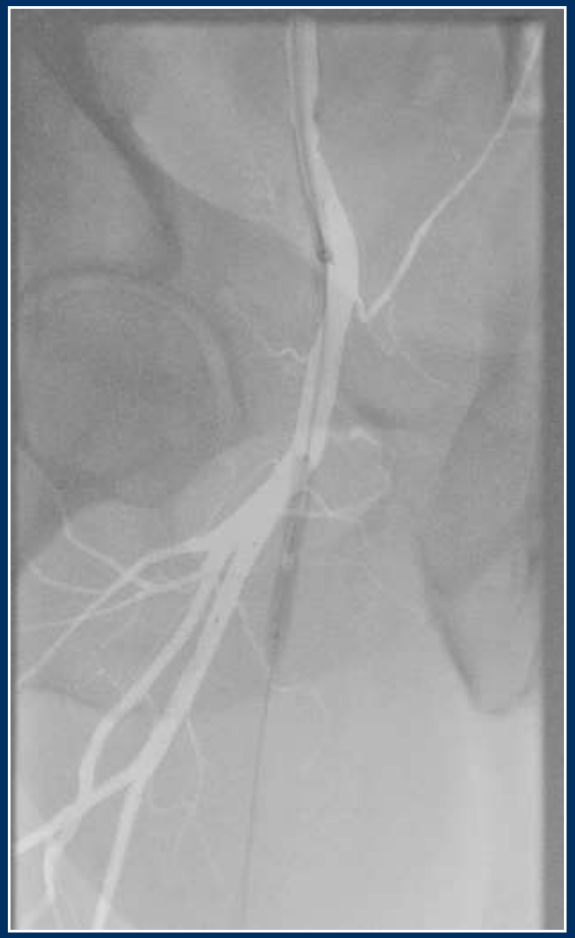
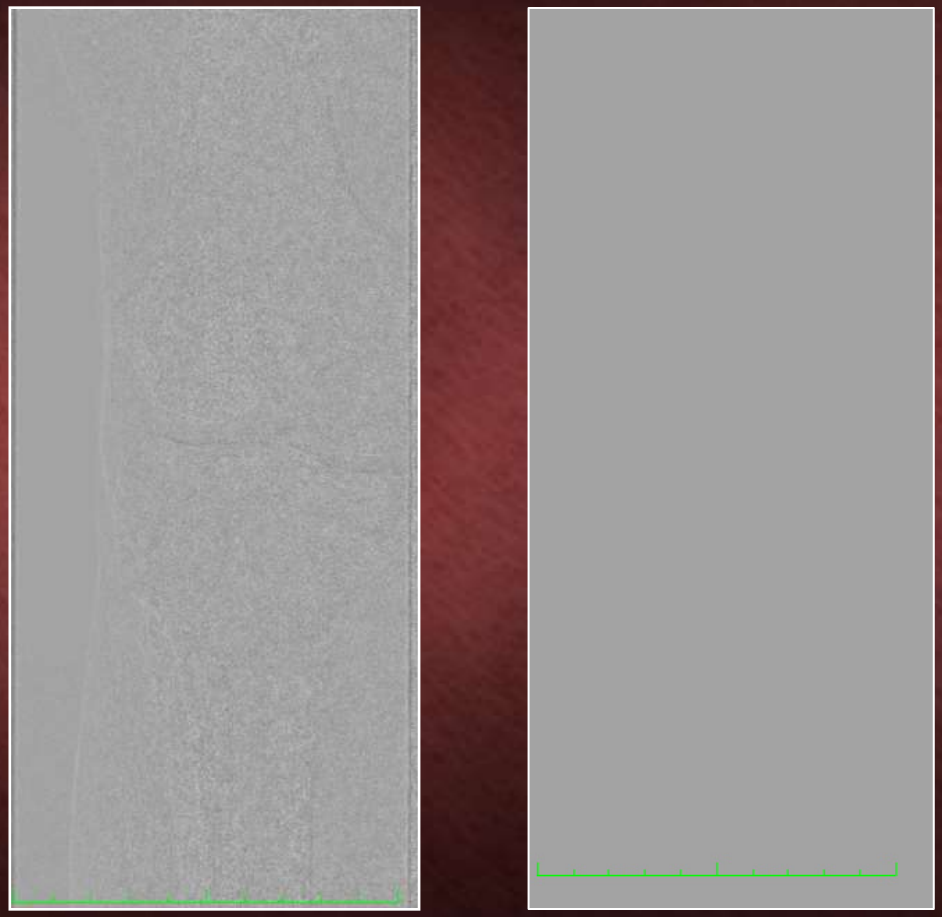


Fig: PTA of Prox. SFA

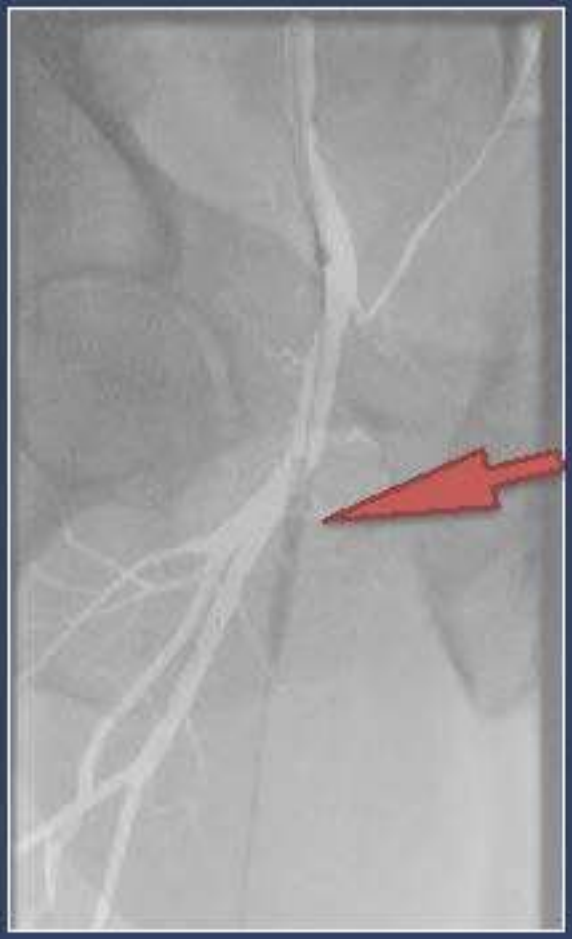
01a. Venous access - introducing 7F sheath in the ipsilateral tibial vein



Cine: Tibial and Femoral Venograms

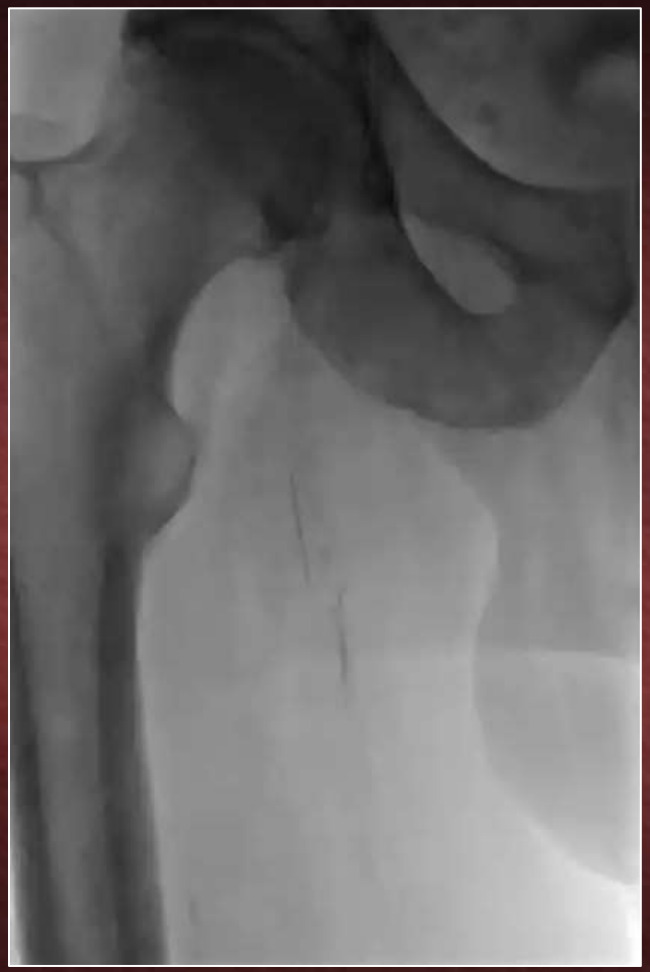
01b. Arterial access - crossover Balkin 8F sheath

Femoral Angiogram

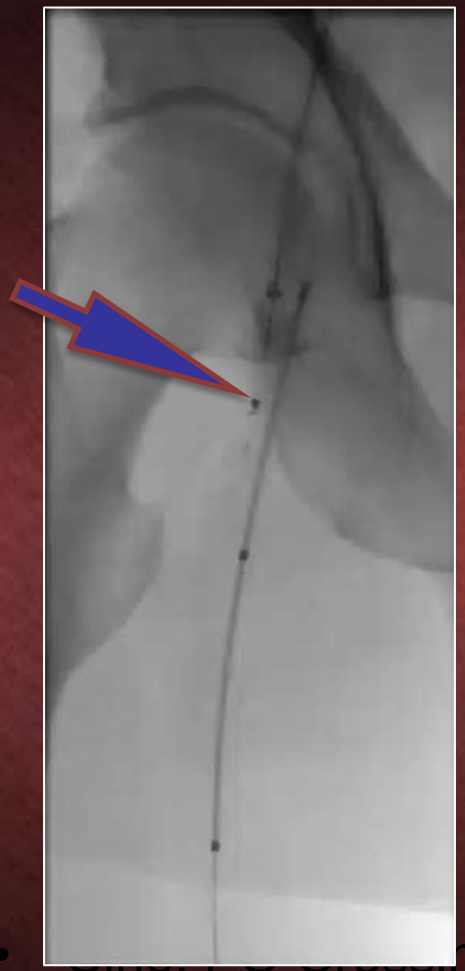


PTA of Prox. SFA

02. Introducing devices



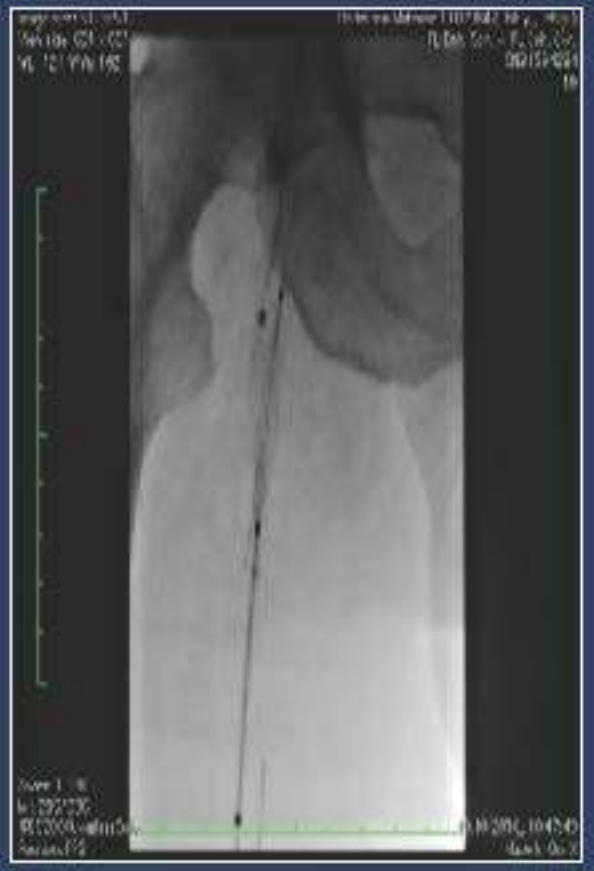
Cine: PQ Snare from the Tibial Vein



- Device from Crossover Sheath

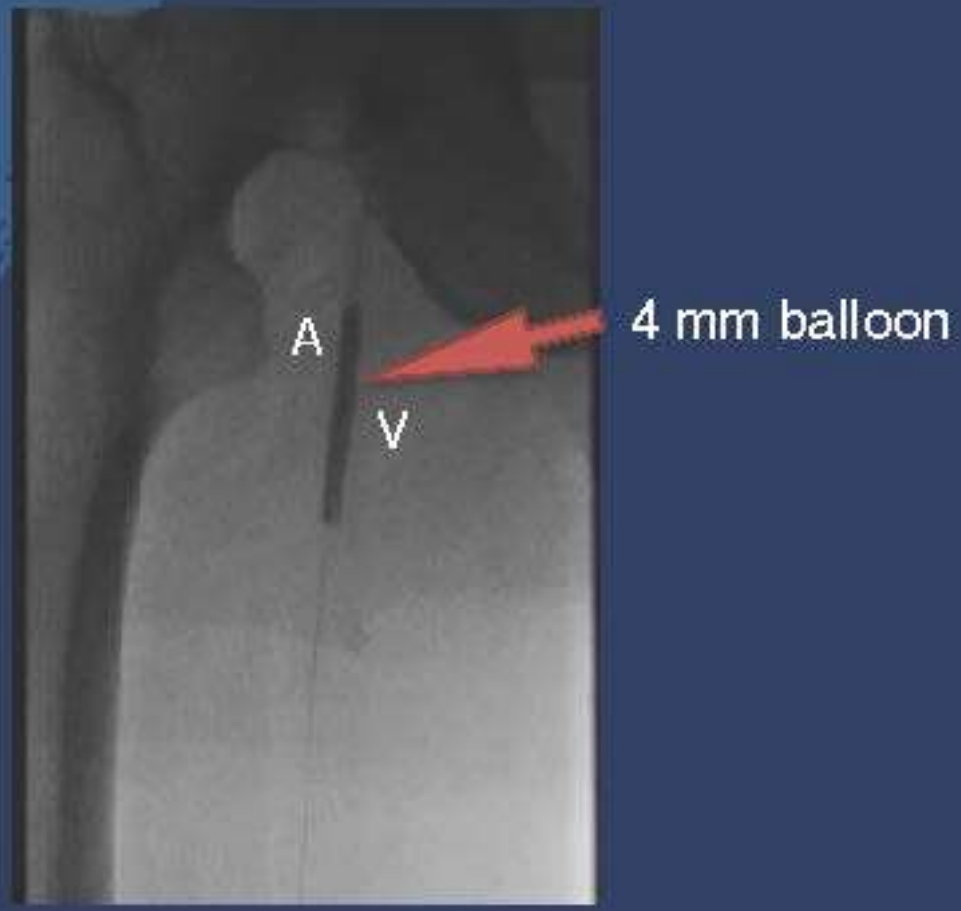
03. Crossing from the artery into the vein and snaring the wire

Using the marker, orient the needle in the direction of the PQ Snare



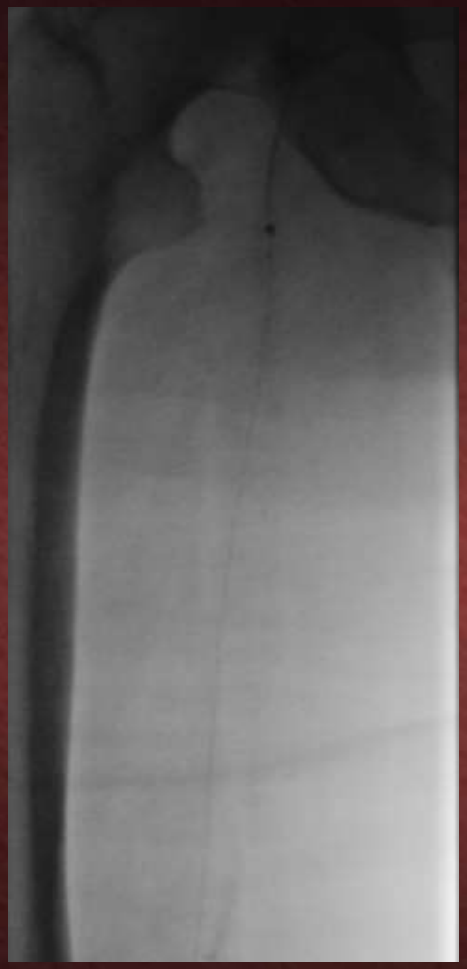
Creating through - and - through with 300 cm 0.014 wire

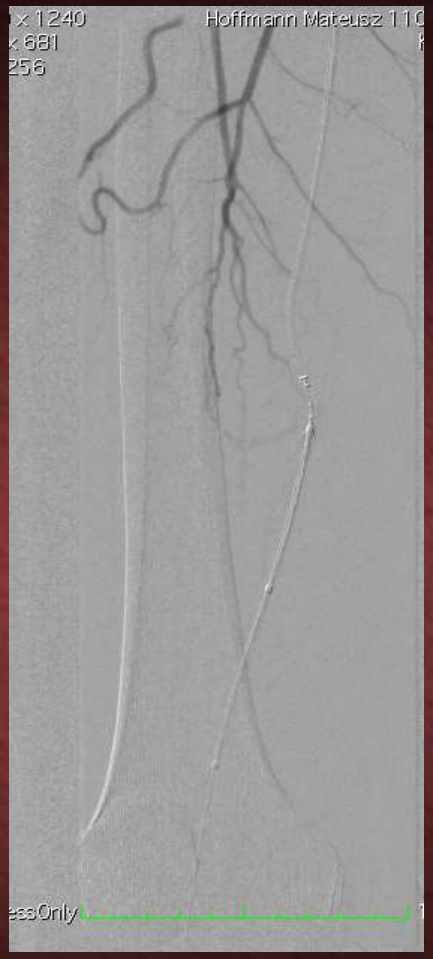
04. Anastomosis dilation



Dilate the Proximal Anastomosis

05. Creating distal anastomosis





- Cines: Going back from the vein to the artery. Using the crown marker band, orientate the needle in the direction of the artery.

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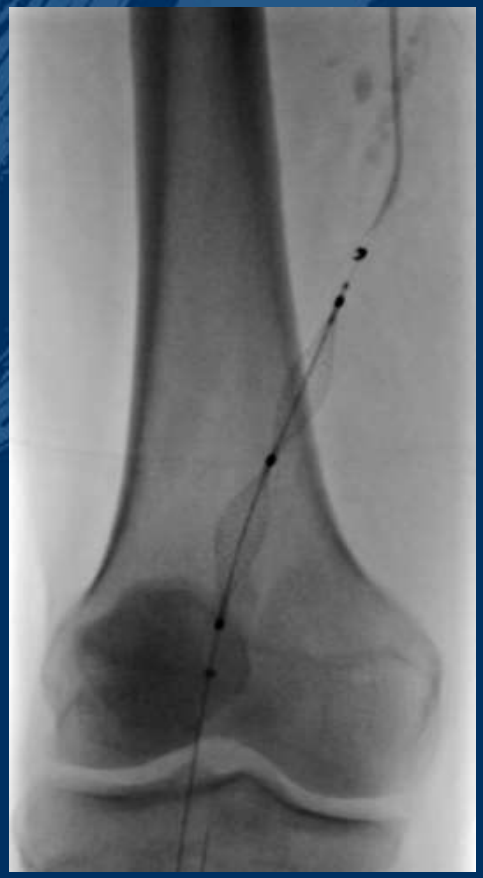
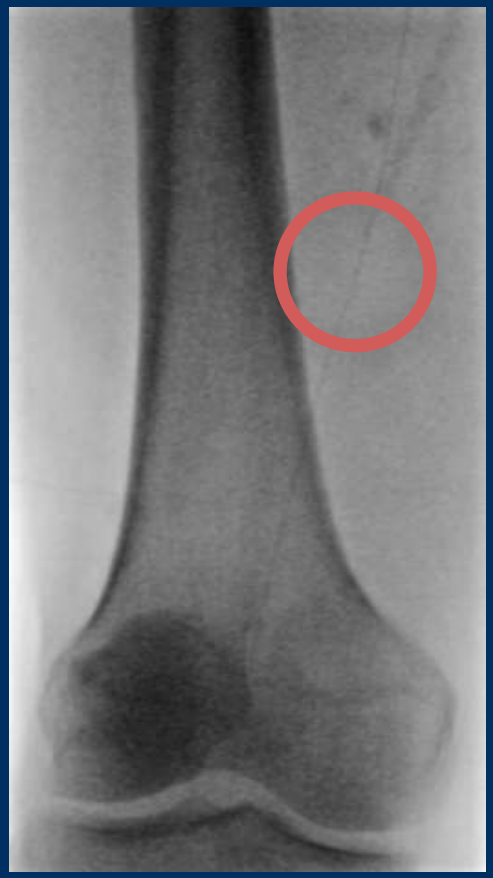
06. Engaging the 0.014" in the tibial and dilating distal anastomosis

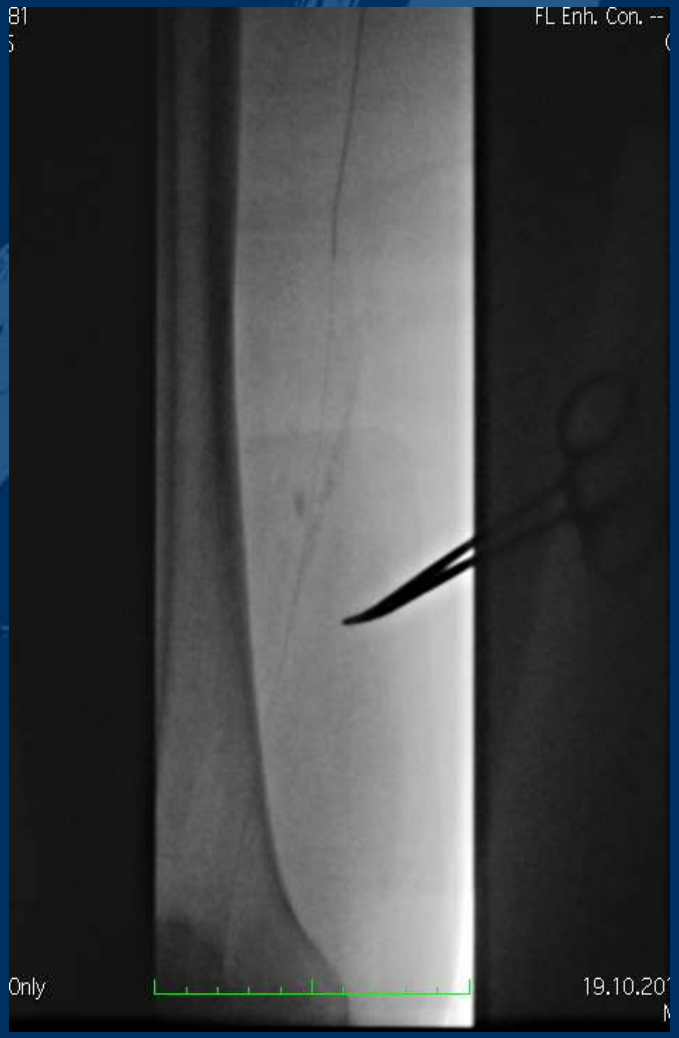


Cine: Advance the 0.014” guidewire into the artery



Cine: Remove the PQ Crossing Device and PQ Snare, then dilate anastomosis

07. Distal Torus Stent Graft Deployment

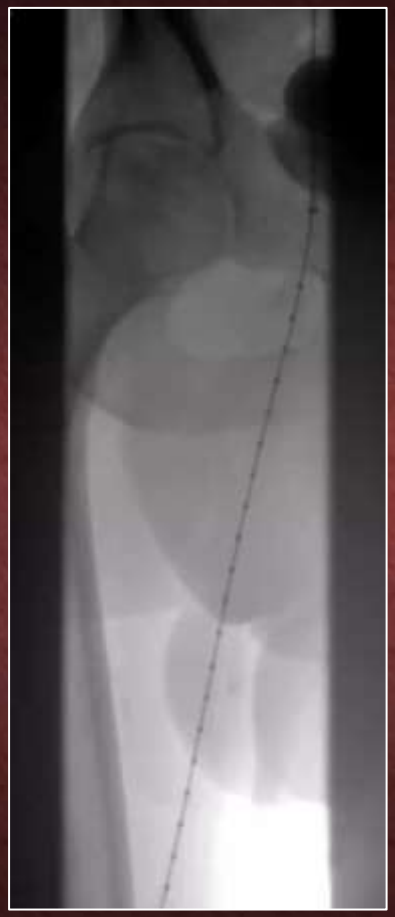


Cine: Exchanging the 0.014 for 0.035 Supracore GW

Cine: Distal Torus placement, at least 3 cm of the Stent Graft in the distal artery

08. Establishing the proximal landing zones and length of the bypass

- Cine: Proximal landing zone



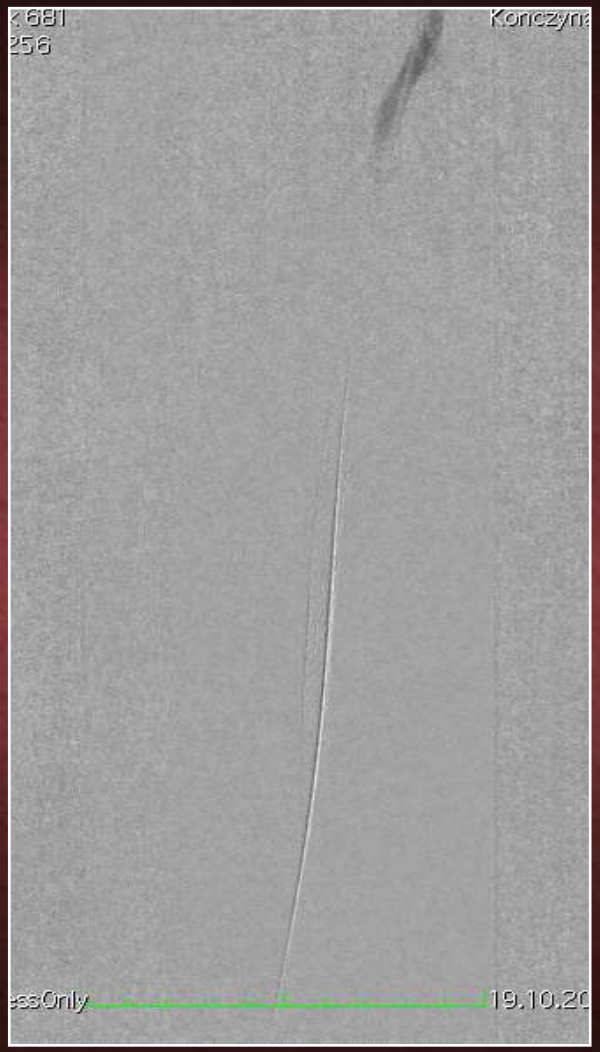
- Cine: Determine the remaining required Stent Graft lengths to implant ensuring a minimum 6 cm overlap between two grafts

09. Implantation of proximal Torus Stent Grafts and postdilataton

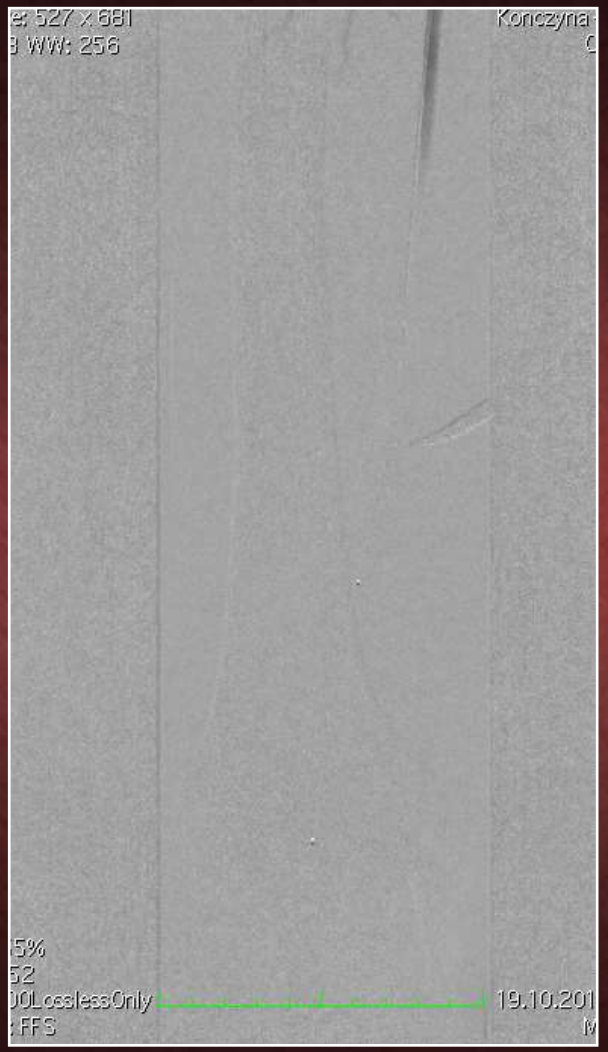
Proximal SG placement

Postdilatation

10a. Completion angiography



Cine: Proximal part of the bypass



Cine: Distal part of the bypass

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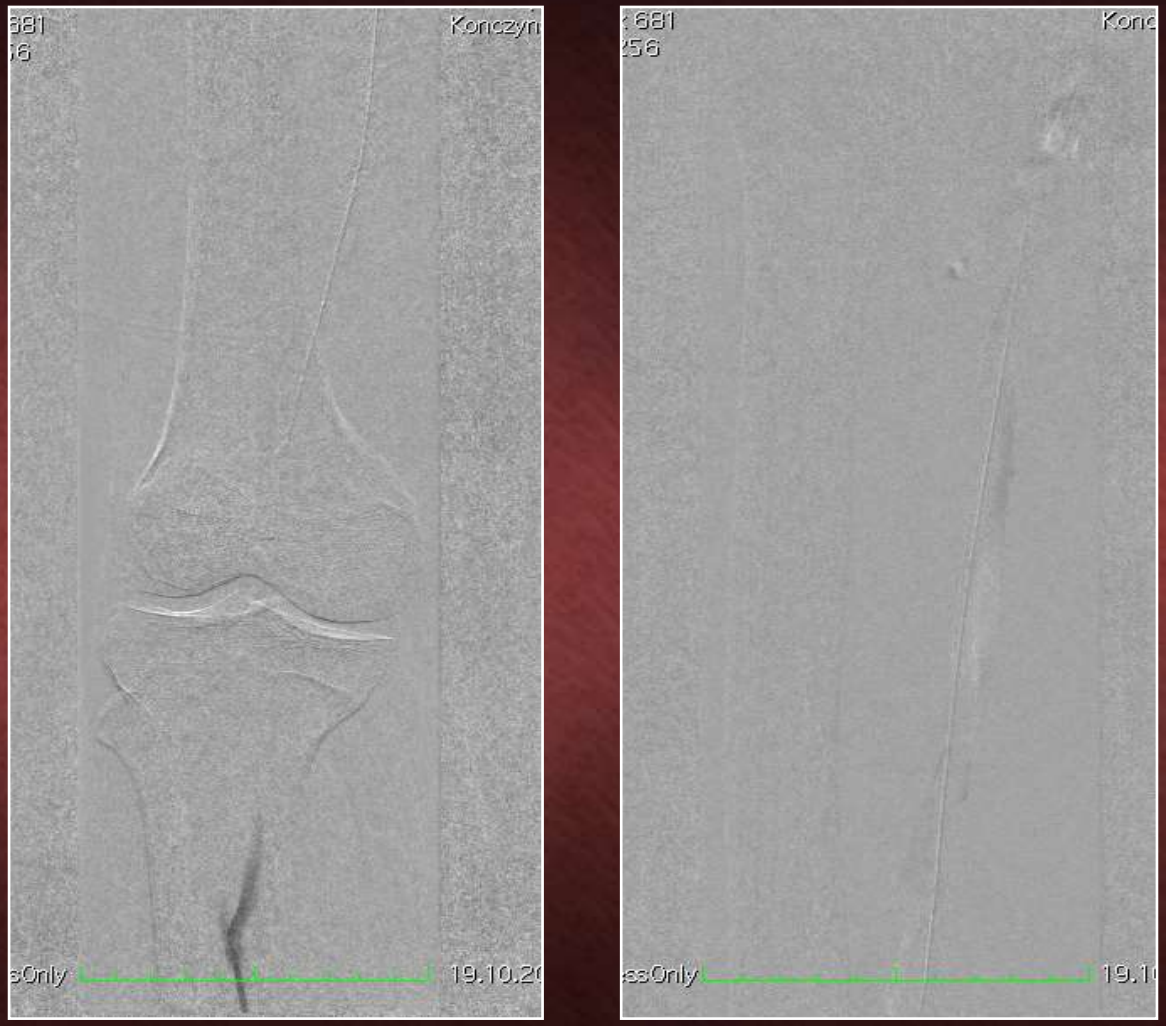
10b. Completion venography



- Cine: Unimpaired venous flow around the graft