2018 MID-ATLANTIC
CONFERENCE

8th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2018

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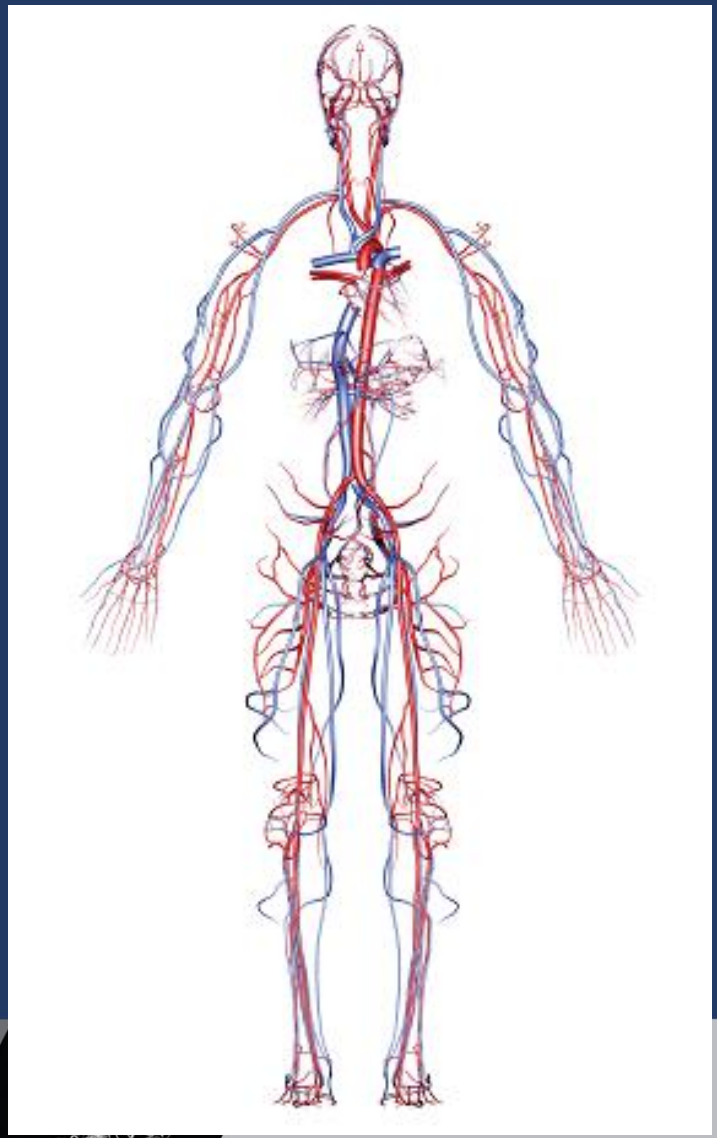
Debate 3: Endovascular Therapies Have Surpassed Surgical Bypass for Limb-Threatening Ischemia

Disclosures

- Consultant/Instructor
  - Medtronic
  - Abbott
  - Bard

Outline

- The Case
- The options
- The comparison
- The data
- The answer



History

History

86 y.o. year old male who presents with pain in the right forefoot at night or with leg elevation. He has a right lateral malleolus ulcer and 2rd toe ulcer

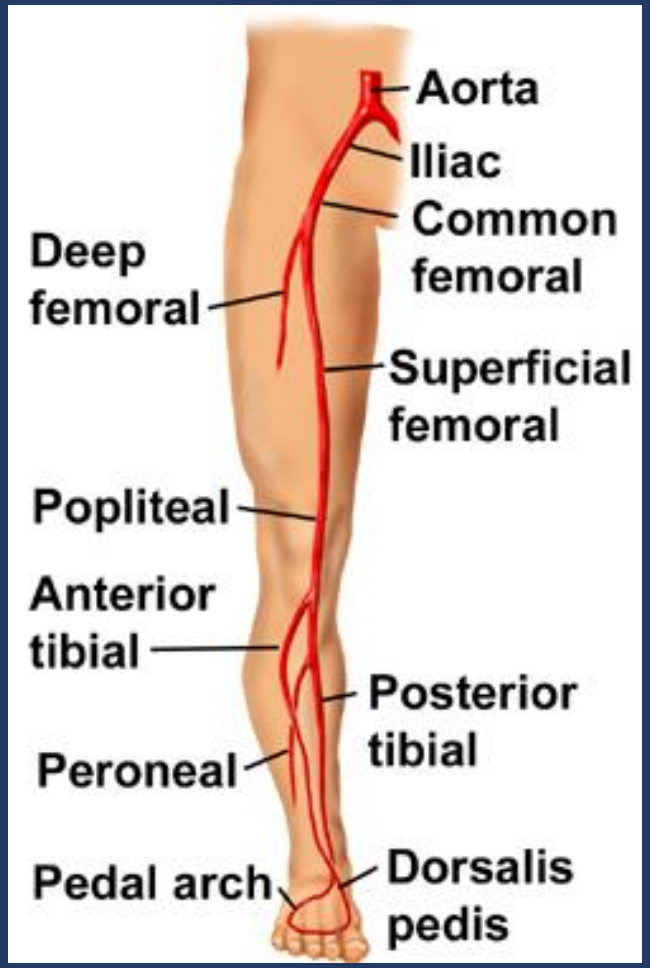
PMH: CAD, HL, HTN

Physical

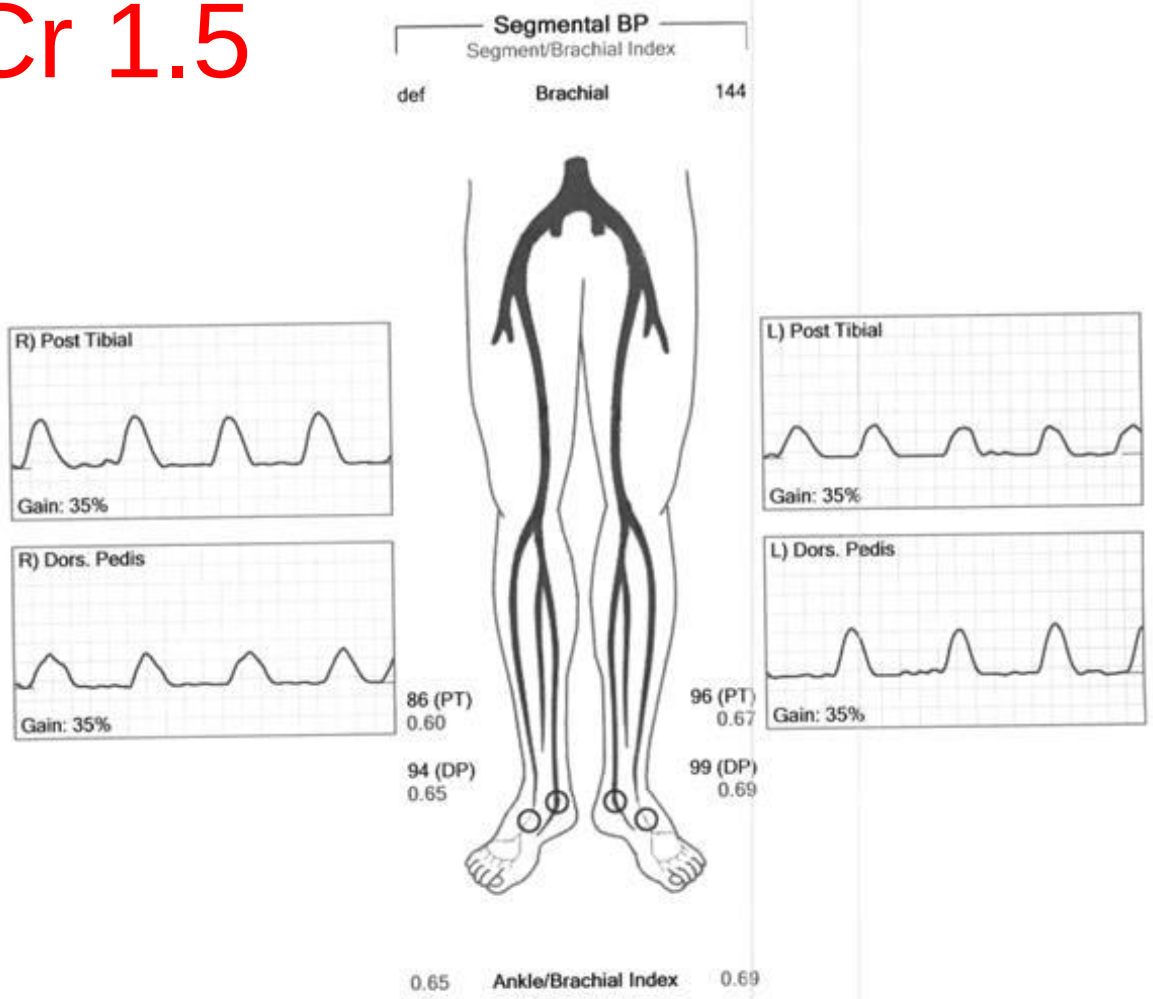
- BP 118/74 mmHg | Ht 5' (1.524 m) | Wt 60.782 kg (134 lb) | BMI 26.17 kg/m2

- **Right lateral malleous ulcer and 2rd toe ulcer**

Right:		Left:	
Femoral	2+	Femoral	2+
Popliteal	0	Popliteal	0
Dorsalis	0	Dorsalis	0
Post Tib	0	Post Tib	0

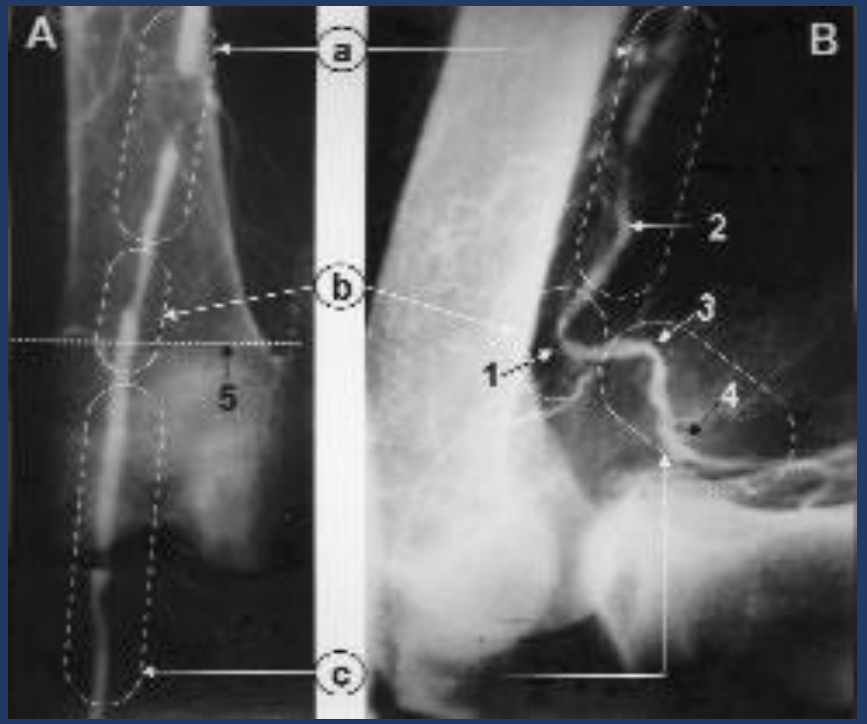


Cr 1.5


Doppler
Segmental BP
Segment/Brachial Index
def
Brachial
144
R) Post Tibial
Gain: 35%
R) Dors. Pedis
Gain: 35%
L) Post Tibial
Gain: 35%
L) Dors. Pedis
Gain: 35%
86 (PT)
0.60
94 (DP)
0.65
96 (PT)
0.67
99 (DP)
0.69
0.65
Ankle/Brachial Index
0.69

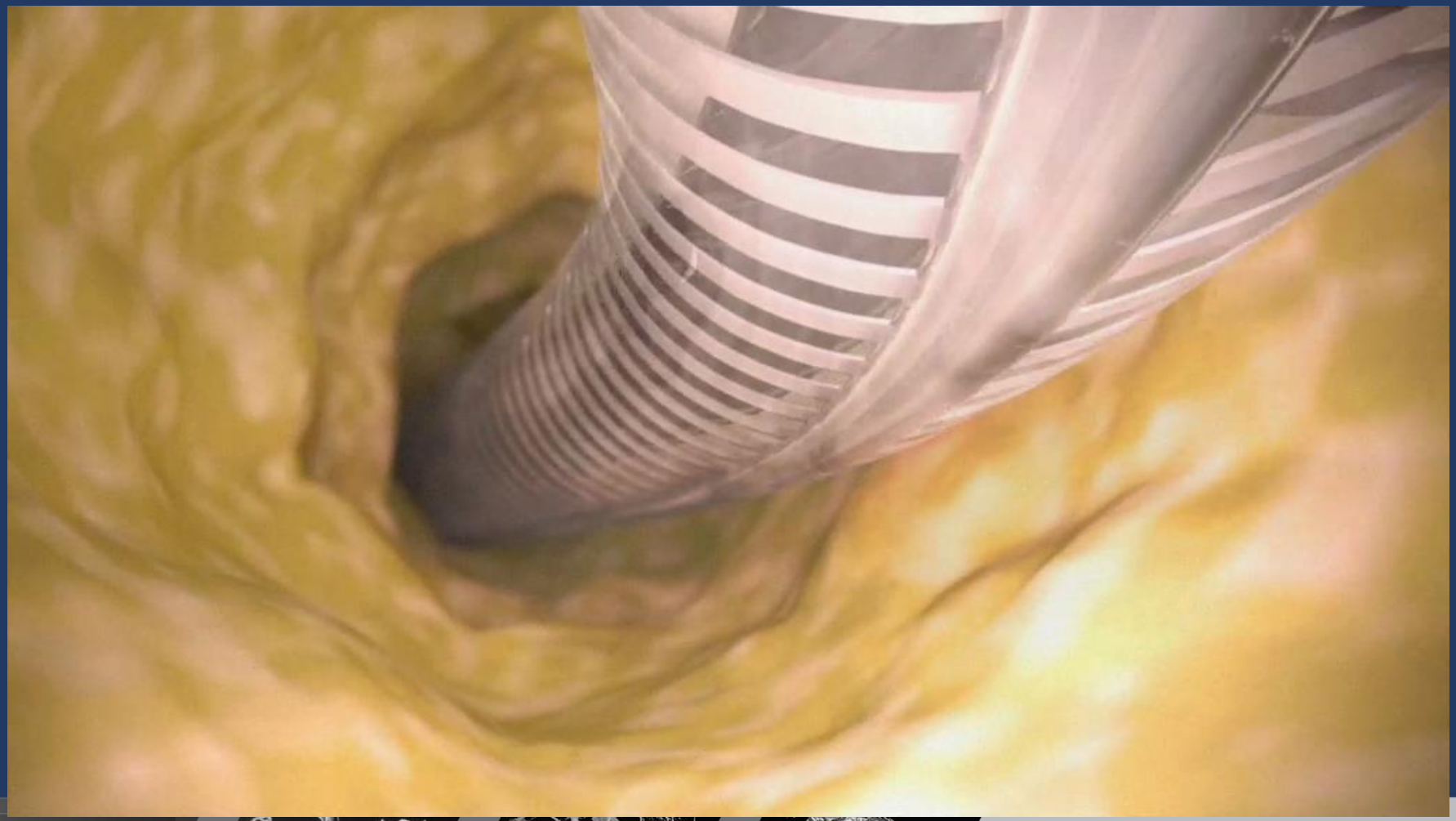
Treatment options

- Angioplasty +/- stent
- Drug coated balloon
- Primary stent
- Drug coated stent
- Atherectomy
- Stent graft



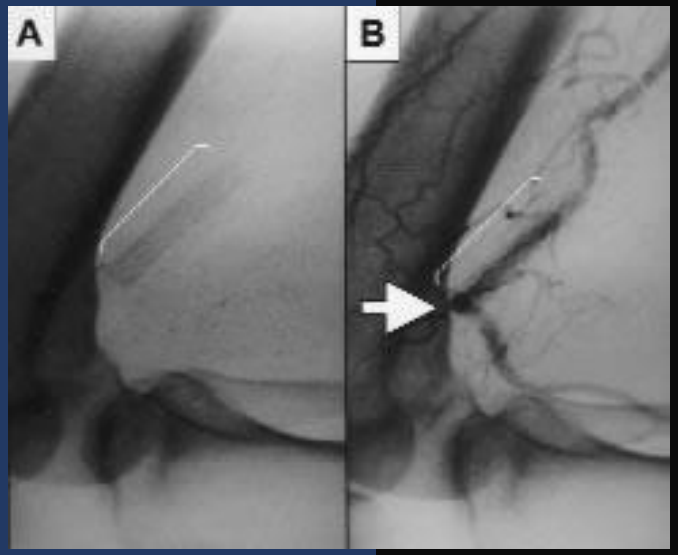
- Stop and do a Bypass?

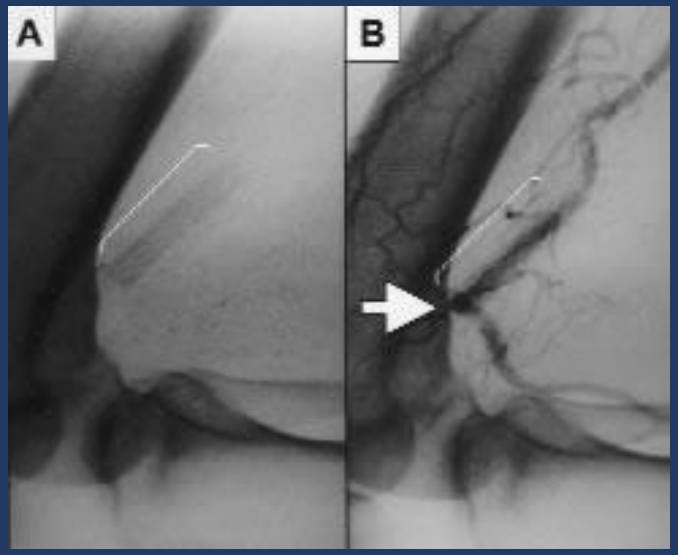
Atherectomy – HawkOne



- Hawk One LX
- 5mm pta

Only available since 2015


A
B



Supera
5.5x60

Not available in the US until 2011

1 month Follow-up

- Healed lateral malleolus ulcer and 2rd toe ulcer

Using state of the art technology in a complementary fashion

Critical Limb Ischemia

- Incidence: 50–100 per 100,000 every year
- Critical limb ischemia (CLI) portends a grim prognosis with half the patients dying from a cardiovascular cause within 5 years, x5 higher than a matched population without CLI.
- In the US: 501,000 new CLI cases each year and an overall population of 1,902,000 patients with CLI

Classification of PAD

Rutherford Stage	Clinical Symptoms	Fontaine Stage	**Clinical Symptoms**
0	Asymptomatic	I	Asymptomatic
1	Mild Claudication	II	Intermittent Claudication
2	Moderate Claudication	IIa	Pain walking more than 200 m
3	Severe Claudication	IIb	Pain walking less than 200 m
4	Rest Pain	III	Rest pain
5	Minor Tissue Loss	IV	Necrosis and gangrene
6	Mayor Tissue Loss	-	-

Imaging

Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial

*BASIL trial participants**

Lancet 2005; 366: 1925–34

- 452 patients, prospective, randomized trial at 27 UK hospitals with severe limb ischemia:

Surgery-first (n=228)

Or

Angioplasty-first (n=224) strategy

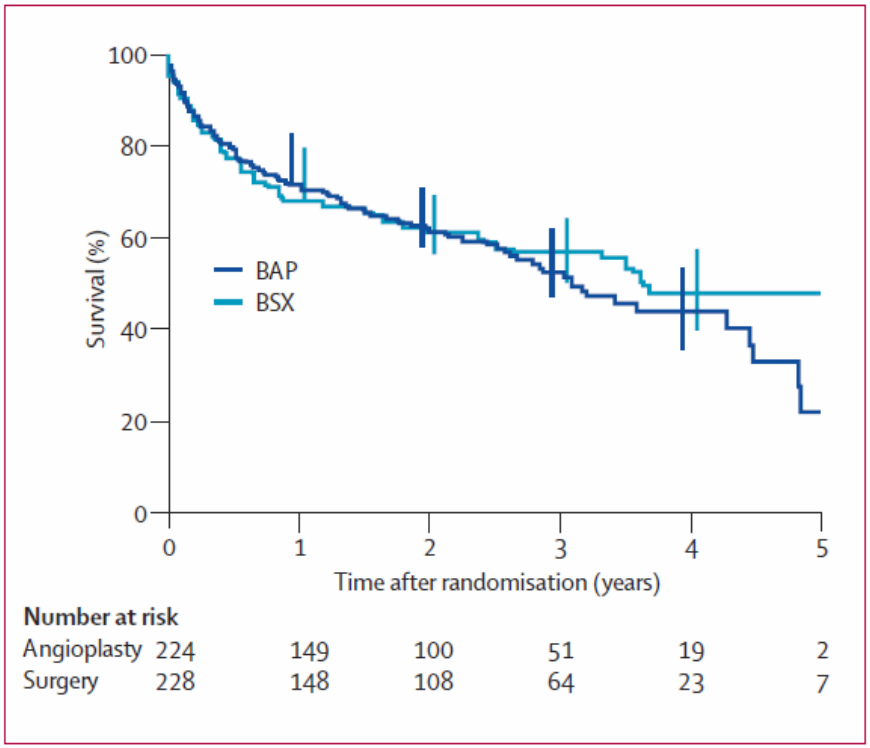


Figure 2: Amputation-free survival after bypass surgery and balloon angioplasty

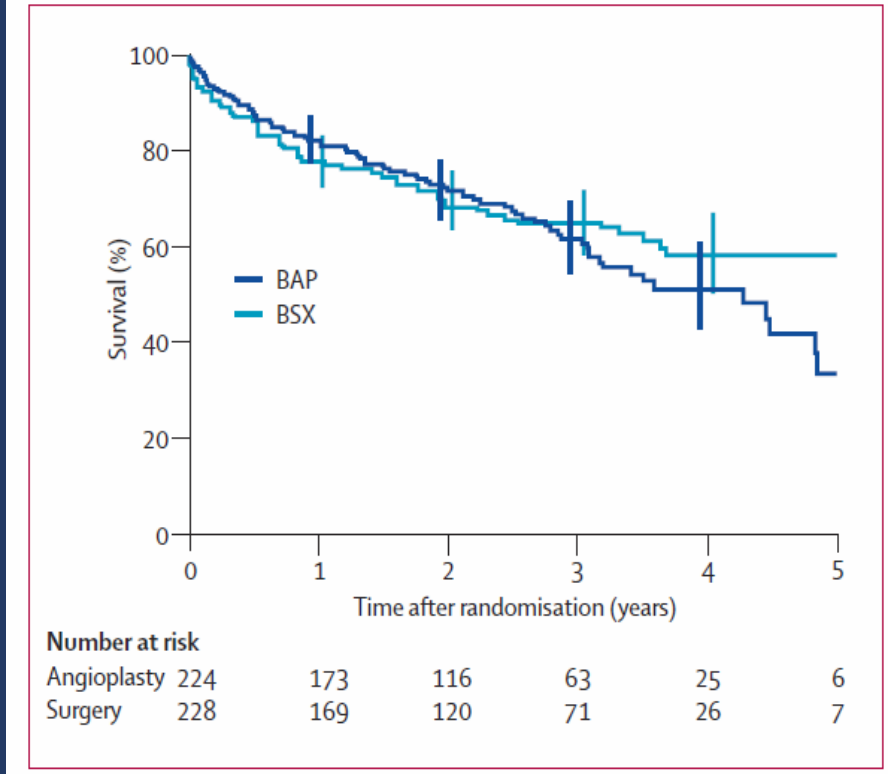


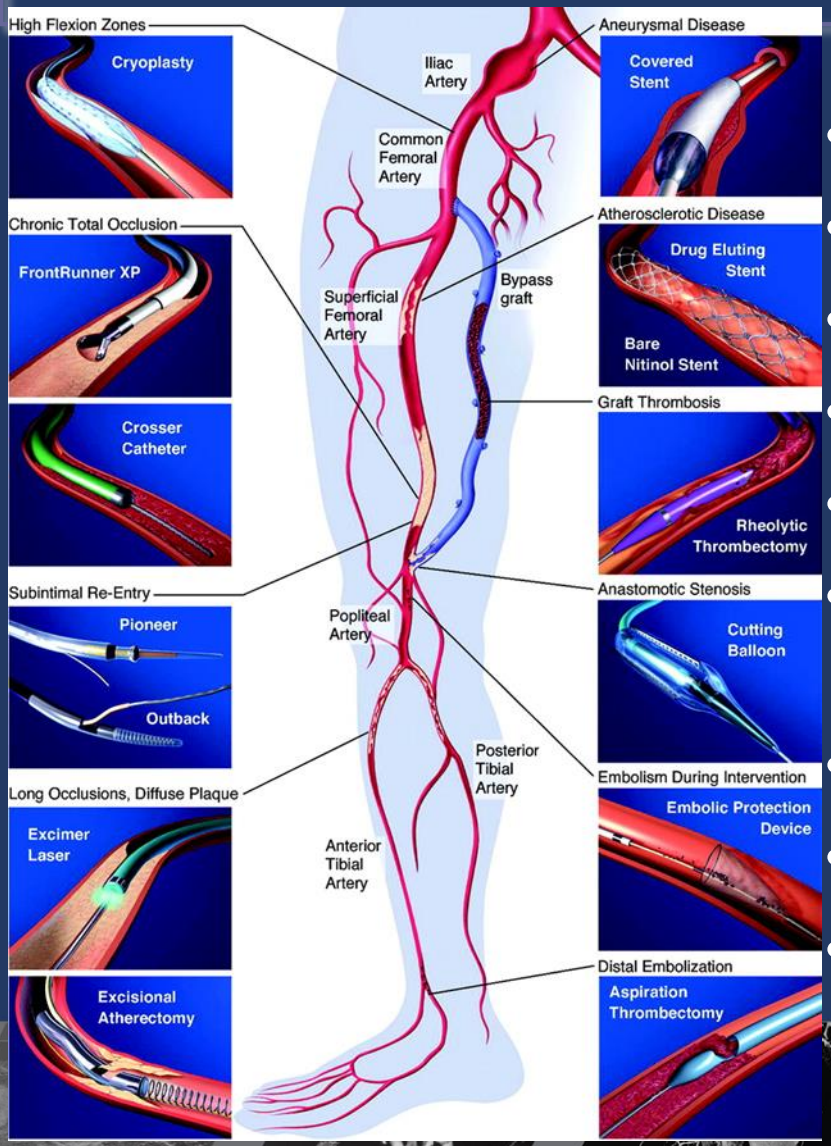
Figure 3: All-cause mortality after bypass surgery and balloon angioplasty

BASIL Outcomes

BASIL Analysis

- In the short term, a surgery-first strategy was associated with:
  - a significantly higher rate of morbidity (57% vs 41%), often due to MI and SSI
  - significantly greater LOS
  - greater use of the ICU
- Hospital costs of surgery for the first 12 months after randomization were 1/3 higher than those of angioplasty

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

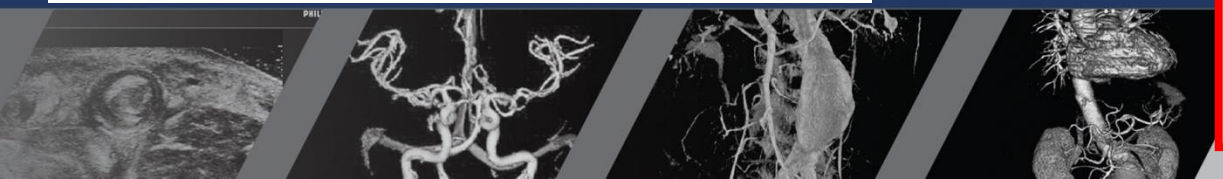
Jason H. Rogers, and John R. Laird
Circulation. 2007;116:2072-2085

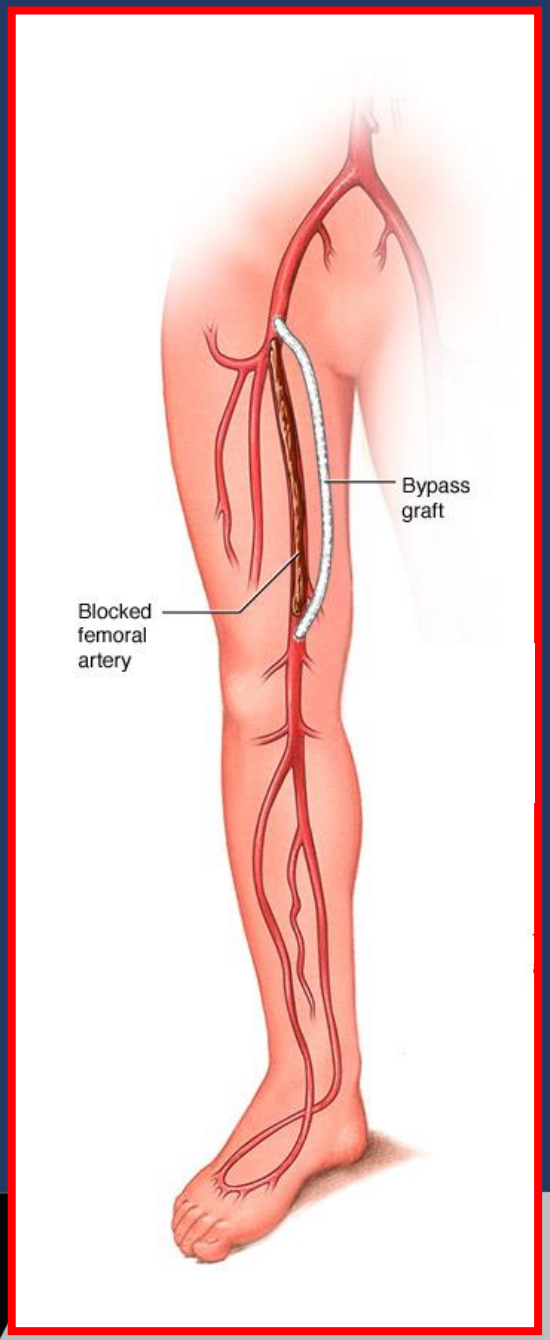
Angiogram
Post-procedure

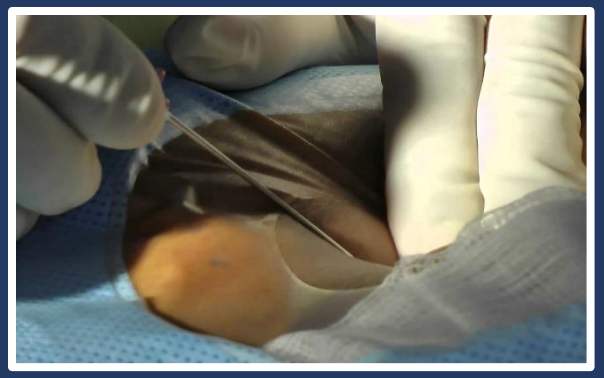
- Ambulatory after 2 hours
- No post-op narcotics necessary
- Can be done safely on clopidogrel
- Discharged home same day
- Routine clinical follow-up with ABIs ± duplex exam at 1,3,6-9,12 months

Surgical Bypass

Figure 1. Occluded left superficial femoral artery







Comparison

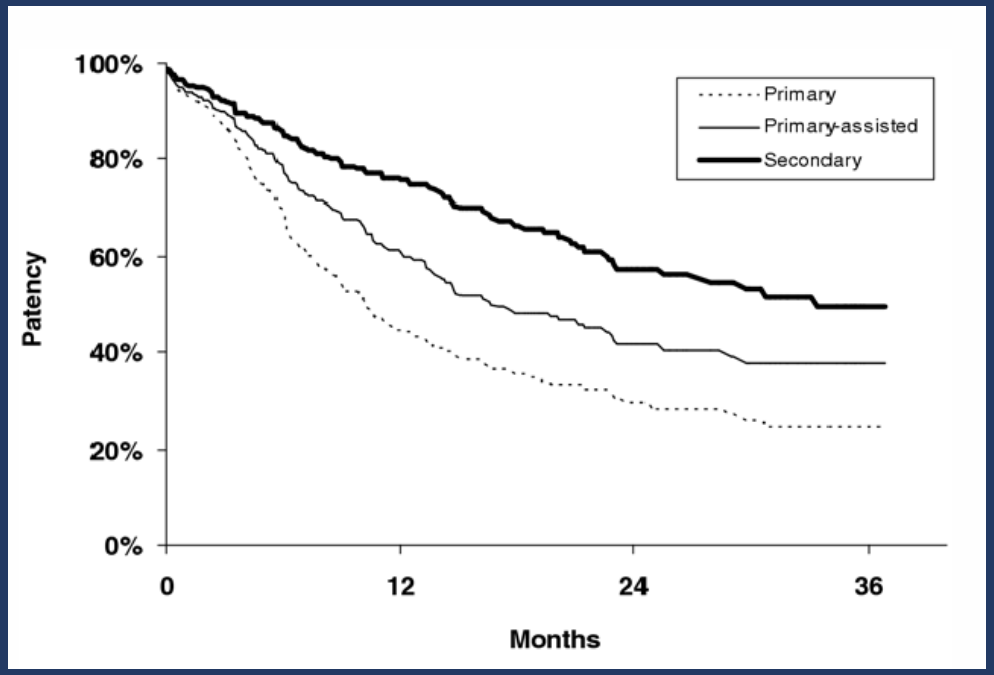
Endovascular

- 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

Subintimal angioplasty: Our experience in the treatment of 506 infrainguinal arterial occlusions



Patency of subintimal angioplasty in 439 limbs with arterial occlusion originating in the superficial femoral artery.

JOURNAL OF VASCULAR SURGERY
October 2008

Retrospective review of 12/2002 – 7/2006

- **63% - CLI**
- **37% - disabling claudication**

Freedom from surgical bypass in patients with either CLI or disabling claudication was 77% at 36 months.

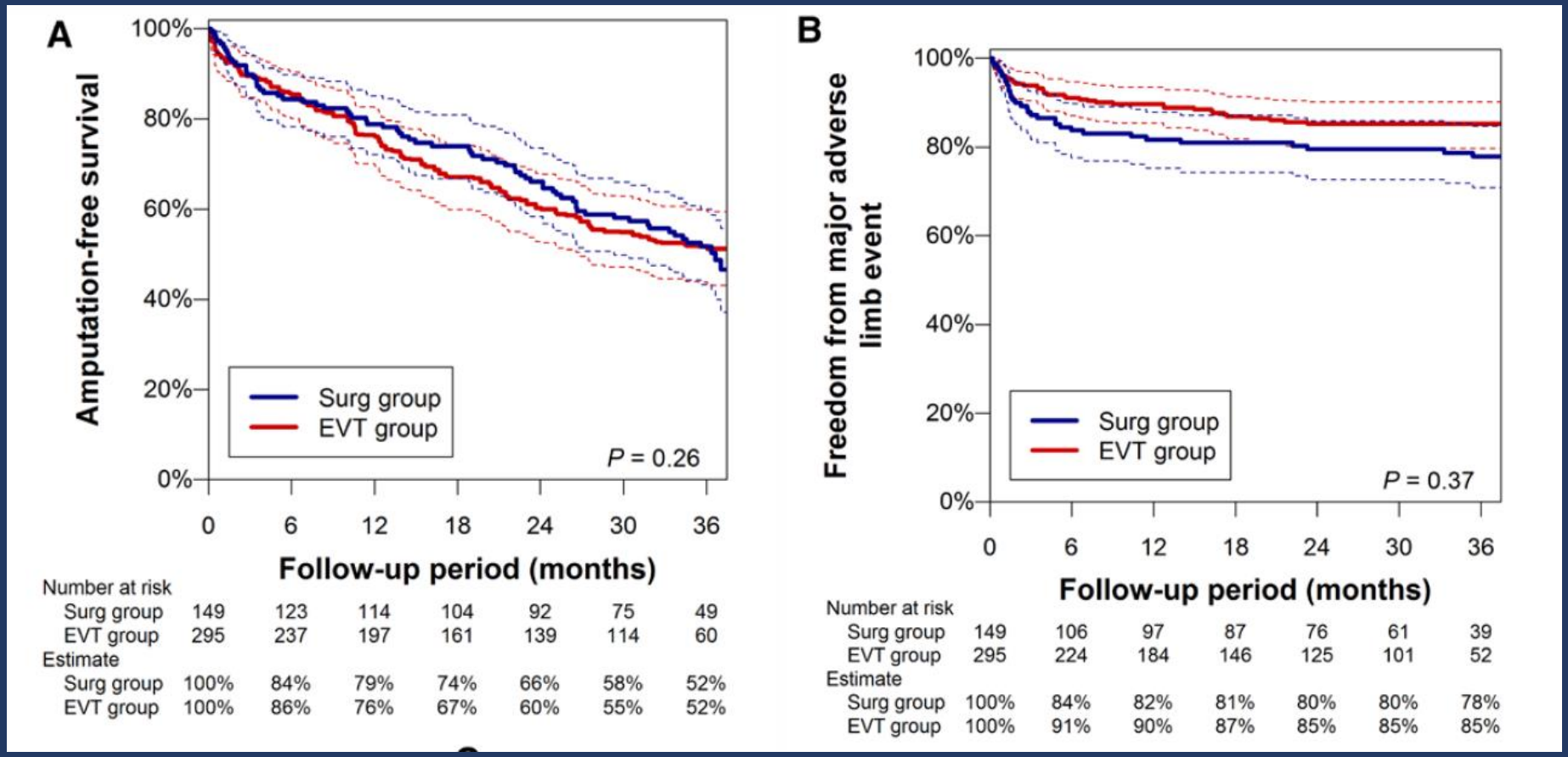
Three-Year Outcomes of Surgical Versus Endovascular Revascularization for Critical Limb Ischemia

The SPINACH Study (Surgical Reconstruction Versus Peripheral Intervention in Patients With Critical Limb Ischemia)

Osamu Iida, MD; Mitsuyoshi Takahara, MD, PhD; Yoshimitsu Soga, MD, PhD; Akio Kodama, MD, PhD; Hiroto Terashi, MD, PhD; Nobuyoshi Azuma, MD, PhD; on behalf of the SPINACH Investigators

Circulation
Cardiovascular Interventions

- Japanese, prospective, observational study of 548 CLI patients enrolled between January 2012 and March 2013
  - 197 patients were scheduled to receive surgical reconstruction
  - 351 were scheduled to receive EVT

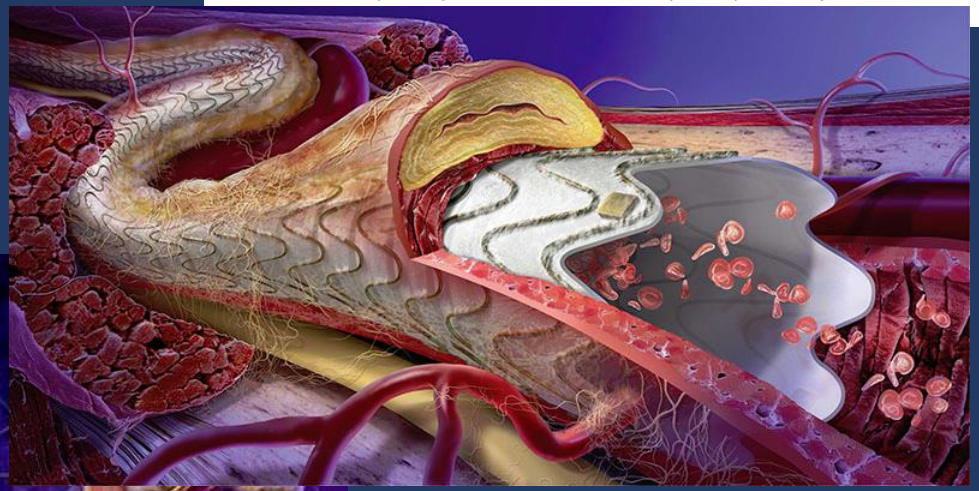


SPINACH registry results

Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease

JOURNAL OF VASCULAR SURGERY
January 2007

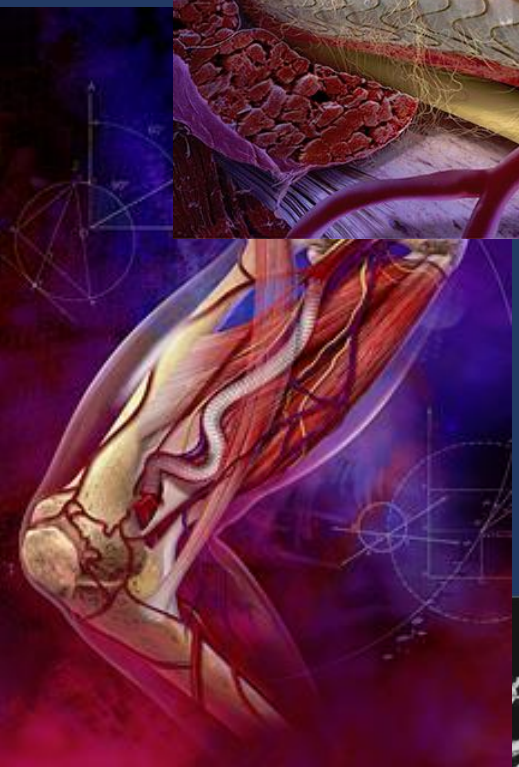
John Kedora, MD, Stephen Hohmann, MD, Wilson Garrett, MD, Cary Munschaur, BS, Brian Theune, MD, and Dennis Gable, MD, *Dallas, Tex*

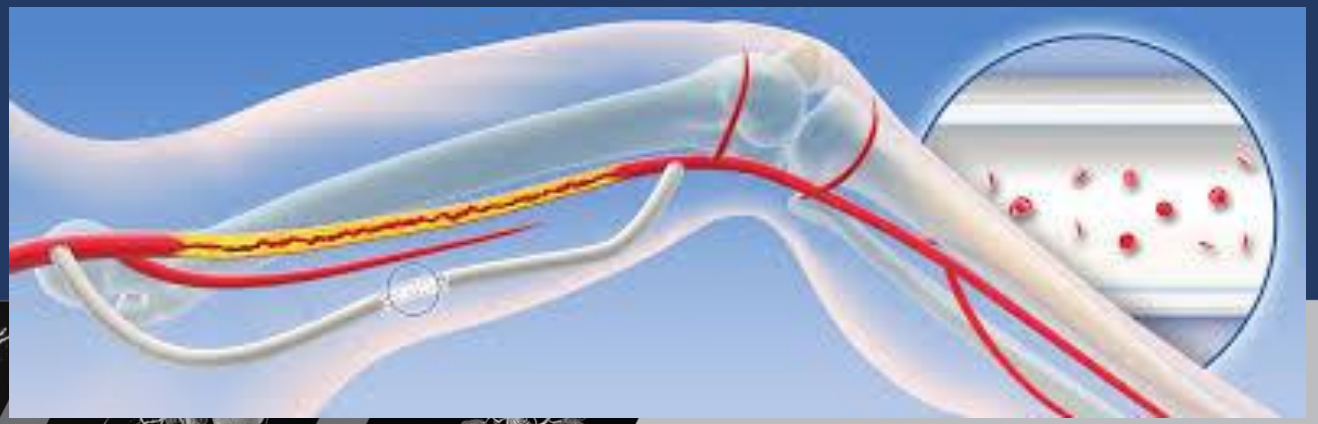


Prospective Randomized

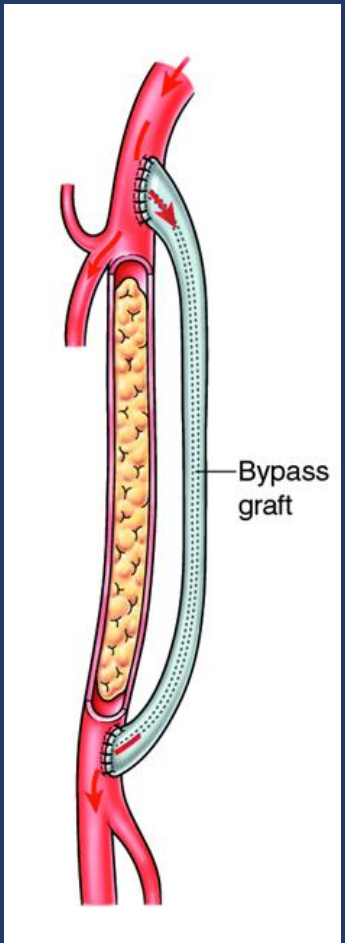
←Stent graft - 50 patient

↓Fem-pop bypass with synthetic – 50 patients



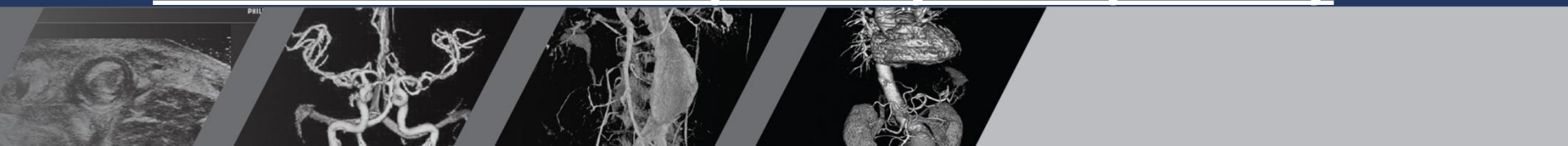


The “internal bypass”



Stent Graft vs. Fem-pop bypass

- **Follow up – 18 months**
- **Primary patency at 3, 6, 9, and 12 months**
  - **Stent Graft - 84%, 82%, 75.6%, and 73.5%**
  - **Open Surgery- 90%, 82%, 79.7%, and 74.2%**
- **2° patency rates at 12 months**
  - **Stent graft- 83.9%**
  - **Open Surgery- 83.7%**
- **No difference in 1° patency or 2° patency**



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease

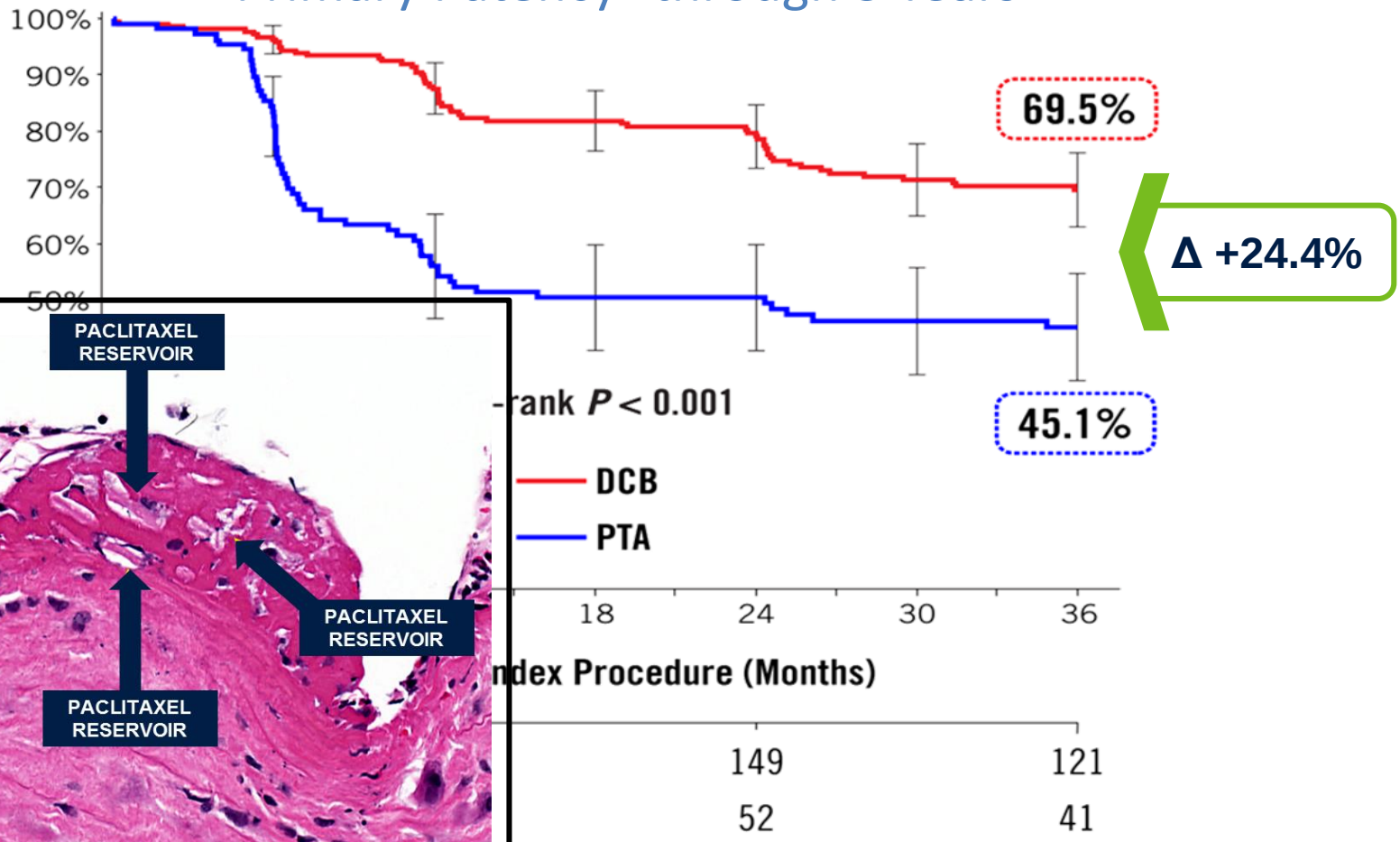
Kenneth Rosenfield, M.D., Michael R. Jaff, D.O., Christopher J. White, M.D., Krishna Rocha-Singh, M.D., Carlos Mena-Hurtado, M.D., D. Christopher Metzger, M.D., Marianne Brodmann, M.D., Ernst Pilger, M.D., Thomas Zeller, M.D., Prakash Krishnan, M.D., Roger Gammon, M.D., Stefan Müller-Hülsbeck, M.D., Mark R. Nehler, M.D., James F. Benenati, M.D., and Dierk Scheinert, M.D., for the LEVANT 2 Investigators*

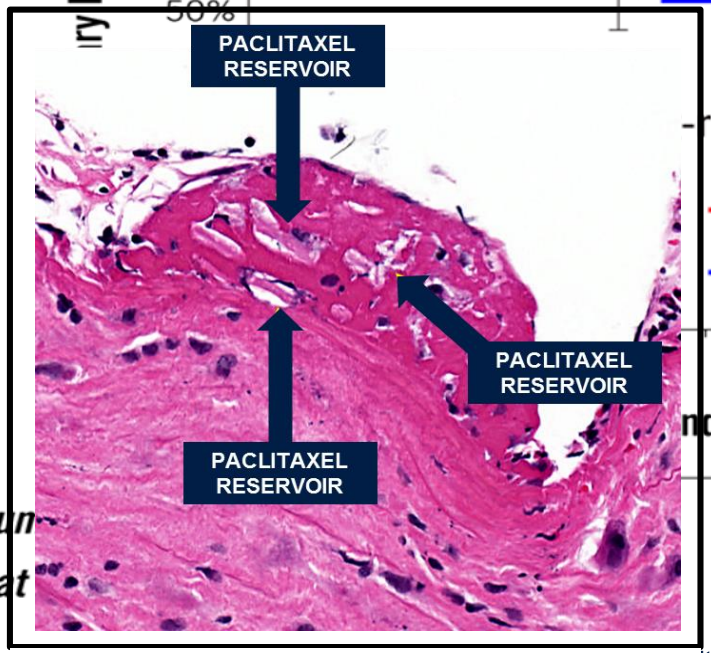
JULY 9, 2015

Drug-Coated Balloon (N=316)

Standard Angioplasty Balloon (N=160)

IN.PACT SFA Trial:
Primary Patency[1] through 3 Years

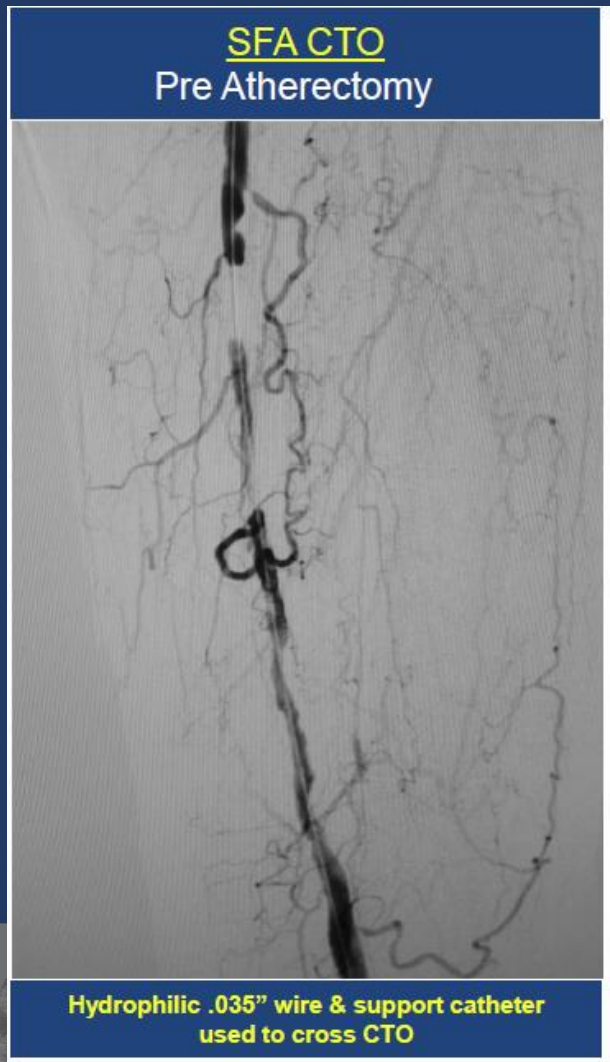




Representative micrograph 28-days post drug delivery.[1]

1. Fr… ltrasound PSVR ≤2.4) or clinically-driven target lesion revascularization through 36 m… …o the assigned treatment).
2. Nu… …t the beginning of each 30-day window.

Atherectomy and Drug coated balloon angioplasty



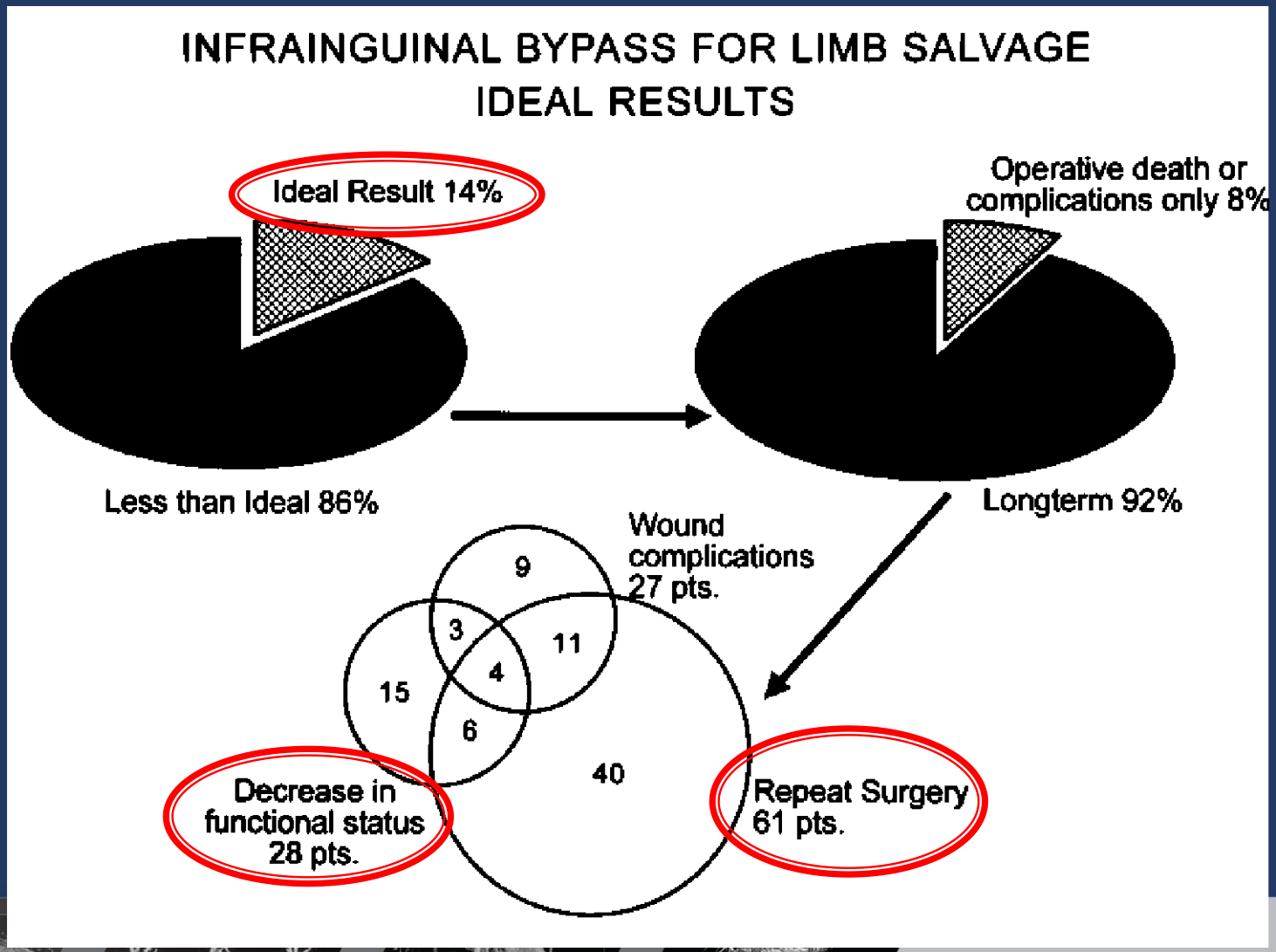
Patient recovery after infrainguinal bypass grafting for limb salvage

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



Ongoing Research

BEST-CLI

Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

ABOUT BEST-CLI STUDY SITES AND LEADERSHIP STUDY DESIGN
PUBLICATIONS AND PRESS CONTACT

Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

Learn More

Final thoughts

- Peripheral artery disease is a progressive, lifelong disease
- Open surgery has the potential for much more morbidity and mortality
- After 30 minutes of discussion, and your still not sure –

Choose the needle over the knife