INOVA
Join the future of health.

There is still a role for bypass in limb preservation!

Richard F. Neville, MD

Associate Director, Inova Heart and Vascular Institute
Vice-Chairman, Department of Surgery
Director, Vascular Services
Adjunct Professor, Biomedical Engineering, GMU
Clinical Professor, Department of Surgery, GWU

Faculty Disclosures

Richard Neville, MD

Consultant – Graftworx, W.L. Gore

Grant/Research Support – Medtronic, W.L. Gore

Scientific Advisory Board – Graftworx, Tissue Analytics, W.L. Gore

Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.

My opponent

- Cleveland, Ohio in 1978 and completed his residency in Internal Medicine and fellowship in Cardiology at Letterman Army Medical Center (LAMC) in San Francisco (1978-1983).
- After joining the Staff of LAMC as the Director of the Cardiac Catheterization Laboratory and Director of Cardiovascular Research in 1983, he moved to Washington, DC, to Direct the Cardiac Catheterization Laboratory and Cardiovascular Research at Walter Reed Army Medical Center in 1985. After completing his service obligation in 1988, he joined the staff at the Ochsner Clinic in New Orleans, LA, becoming Director of the Catheterization Laboratory. In 1994, Dr. White moved to Glasgow, Scotland as the Director of Invasive Cardiology for HCI Medical Center.
- In 1997, he returned to Ochsner as Chairman of the Department of Cardiology. Currently Dr. White holds the positions of Chief of Medical Services at Ochsner Medical Center, Medical Director for Service Lines and the System Chairman of Cardiovascular Disease for the 14 hospital Ochsner Health System, and Professor and Chairman of the Department of Medicine for the Ochsner Clinical School-University of Queensland.
- He has received Teacher of the Year awards at Letterman (1985) and at Ochsner (2000) and was voted Mentor of the Year by the Cardiology Fellows in 2007. In 2015, he was honored as the Physician Executive Leader of the Year Ochsner. He was also recognized by the American College of Cardiology (ACC) as a 2019 Master of the ACC Award for outstanding contributions to the field of cardiovascular medicine.

  Dr. White is a Past-President of the Society of Cardiovascular Angiography and Interventions (SCAI). He is the past Steering Committee Chairman for the National Cardiovascular Database Registry's (NCDR) carotid and peripheral revascularization efforts. Academically, Dr. White served as Editor-in-Chief of Catheterization and Cardiovascular Interventions (2000-2010), and is currently Editor for Progress in Cardiovascular Disease (2014-), and Associate Editor for JACC Interventions.
- He has published more than 250 manuscripts and presented more than 100 scientific abstracts in the field of interventional cardiology and peripheral vascular diseases. His major research interests involve technology development for non-surgical treatment of cardiovascular disease and includes the co-invention of a coronary angioscope, a laser angioplasty catheter, and the Wiktor™ coronary stent.
- The major areas of clinical interest have been the integration of coronary, peripheral, and neurovascular interventional therapy including the clinical utility of renal and carotid stents, limb-salvage angioplasty, revascularization therapy for acute stroke, and developing peripheral vascular appropriate use criteria. Dr. White was honored as a Master Interventionalist (MSCAI) in 2014, and remains clinically active with a referral practice in interventional cardiology and endovascular interventions.

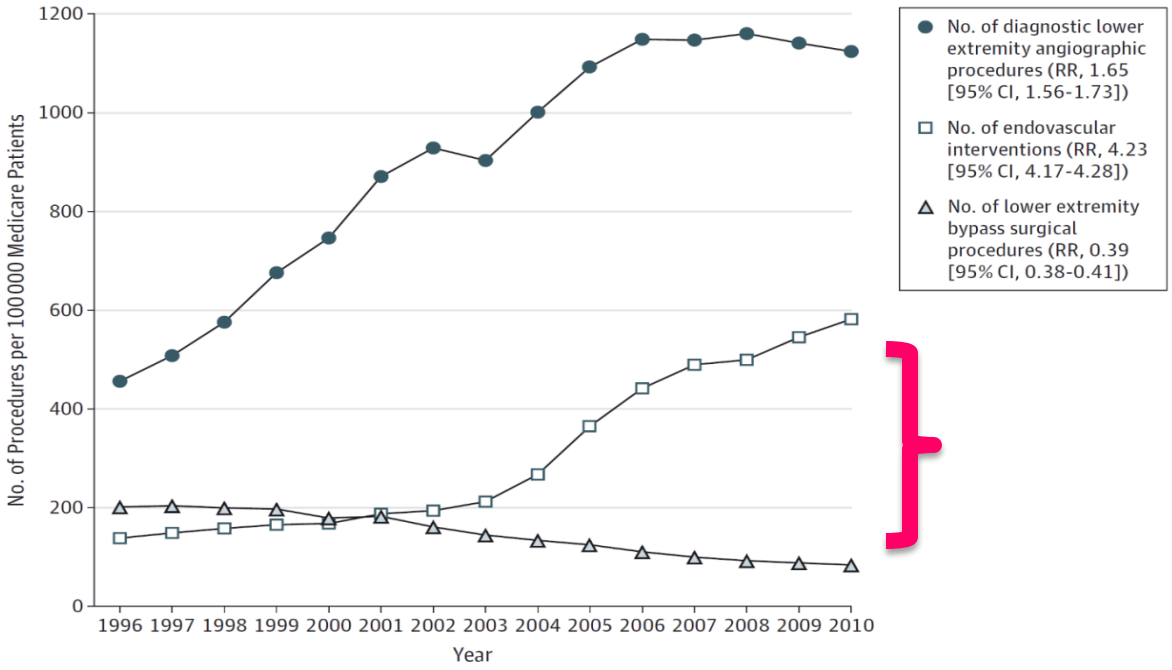
Kinder and gentler…….

Christopher J. White MD, FACC, FAHA, FSCAI, FESC

Professor of Medicine
System Chairman for Cardiovascular Disease
Director, John Ochsner Heart & Vascular Institute

Treatment of Critical Limb Ischemia

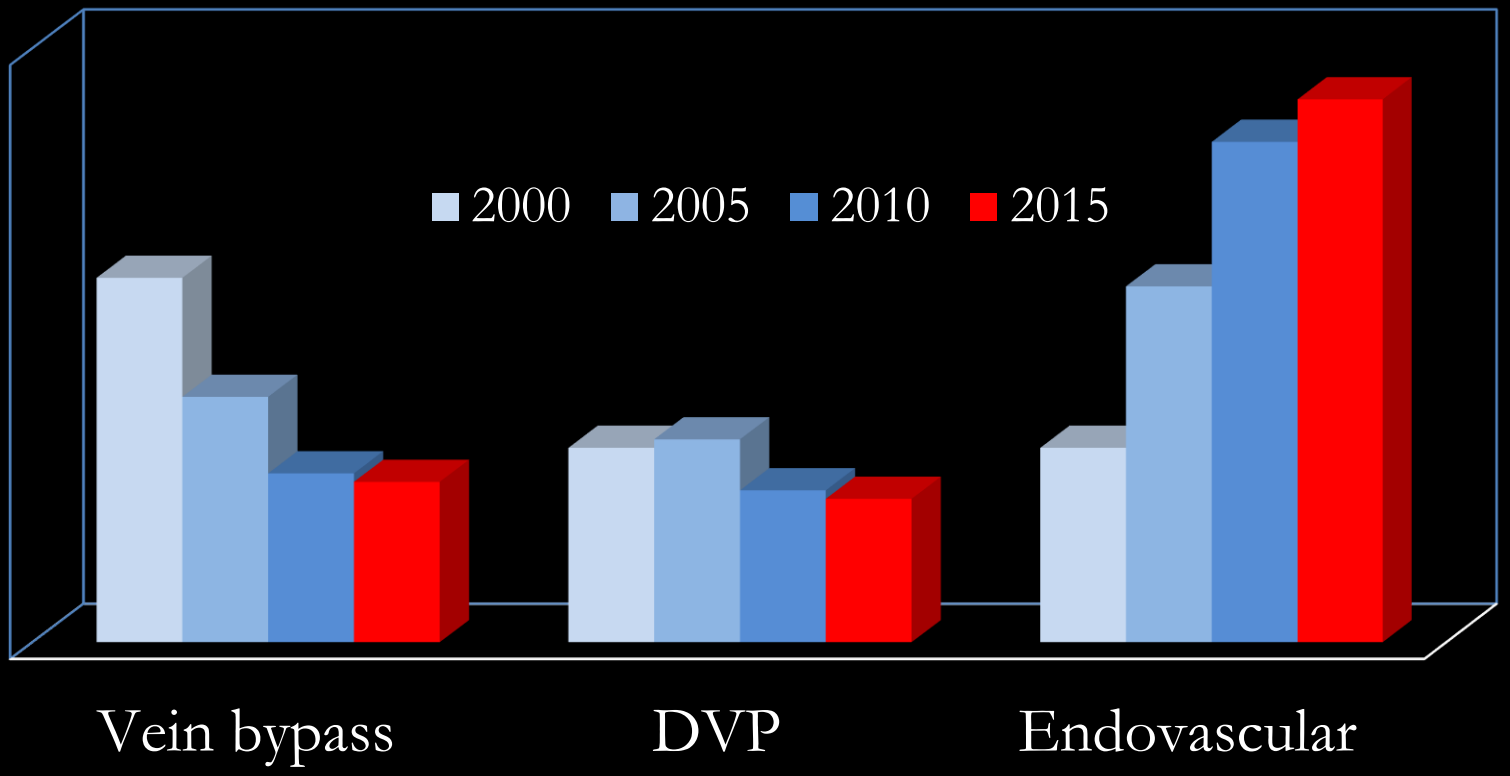
Figure 2. Trends in Diagnostic Angiography, Therapeutic Endovascular Interventions, and Lower Extremity Bypass Surgery, 1996-2010



Goodney PP, et al. JAMA Surg. 2015;150:84-86.

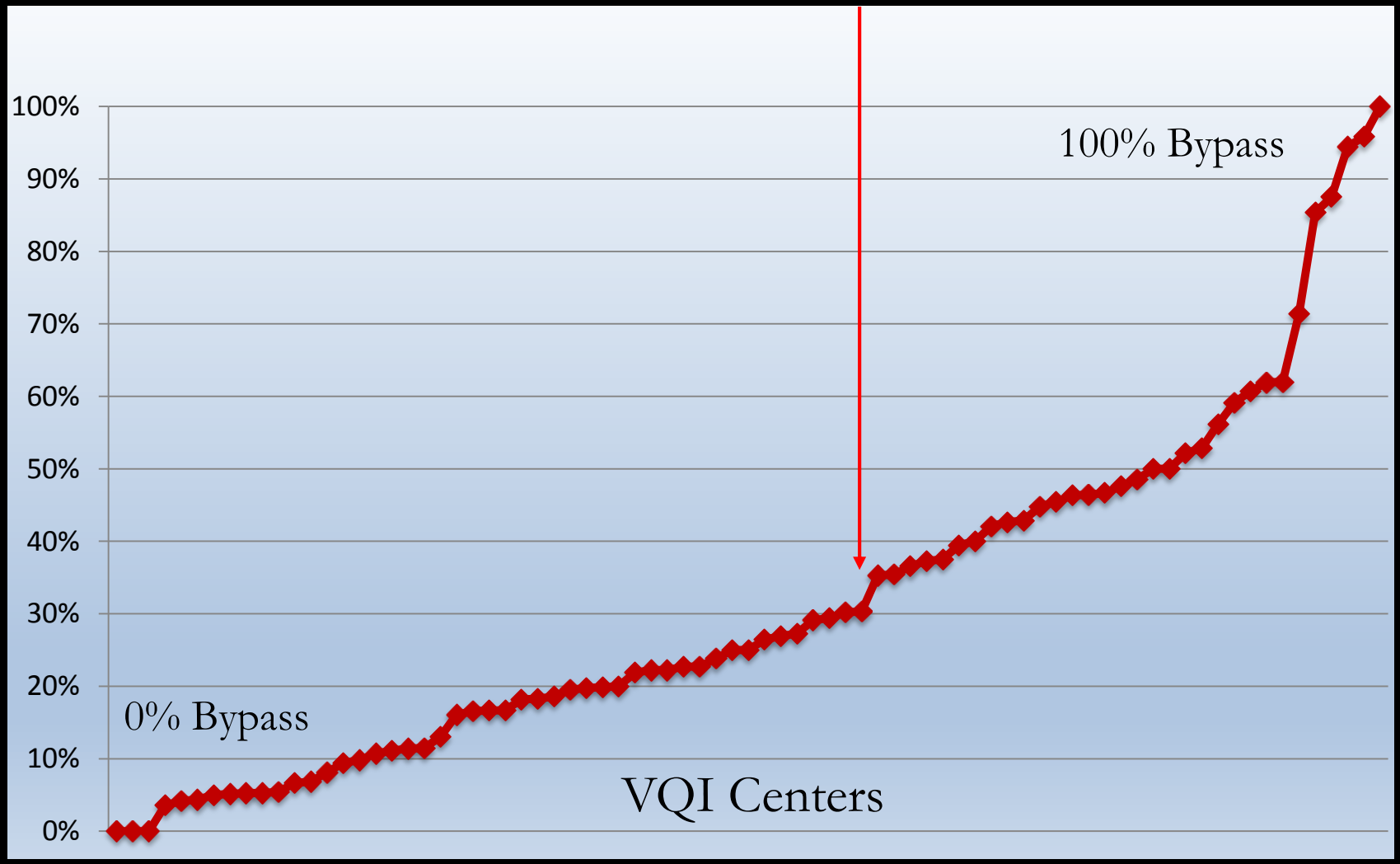
Bypass in a limb preservation practice

Endovascular 76%
Surgical bypass = 24%



Pattern of revascularization

All VQI Centers Mean = 31% bypass



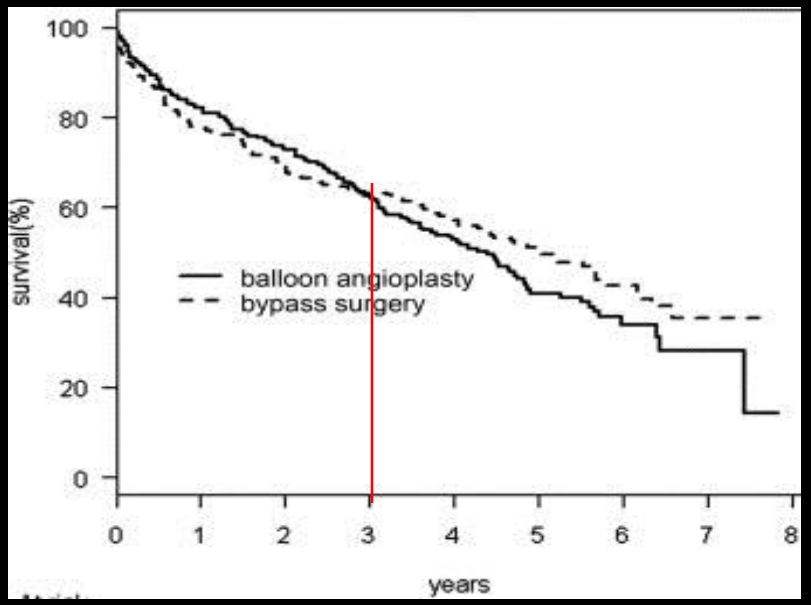
Bypass as the optimal mode of revascularization

- **Medical comorbidity**
  - Good medical risk
  - Reasonable life expectancy and level of function
- **Indication for revascularization**
  - Significant tissue loss (> 2cm)
  - Severe CLI
- **Arterial anatomy**
  - TASC D lesions
- **Angiosome revascularization**
  - To revascularize the appropriate angiosome
- **Failed endovascular therapy**

SURGICAL BYPASS SUMMIT 2014

Medical comorbidity
BASIL Trial

- Life expectancy < 3 years
  - Angioplasty first
- Life expectancy > 3 years
  - Bypass first



Adam AJ, BASIL trial participants. Lancet 2005;366:1925-34

Medical comorbidity

Bypass vs angioplasty for infra-popliteal disease

- Initial treatment success
  - Bypass 86%,
  - Angioplasty 73%
- Advantage with Bypass
  - Time to healing
  - Amputation Free Survival
  - Survival

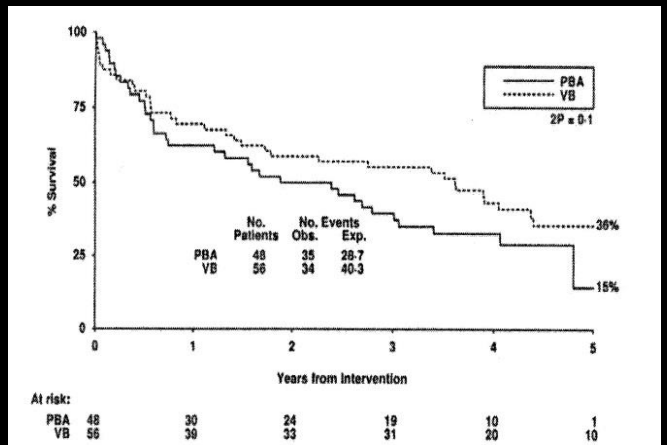


Figure 2. Amputation free survival. HR 0.68, 95% CI 0.42–1.10, $p = .1$.

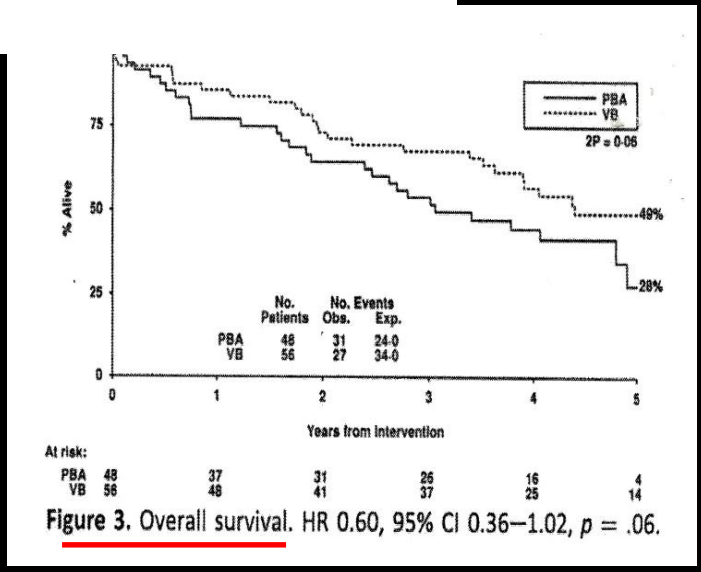
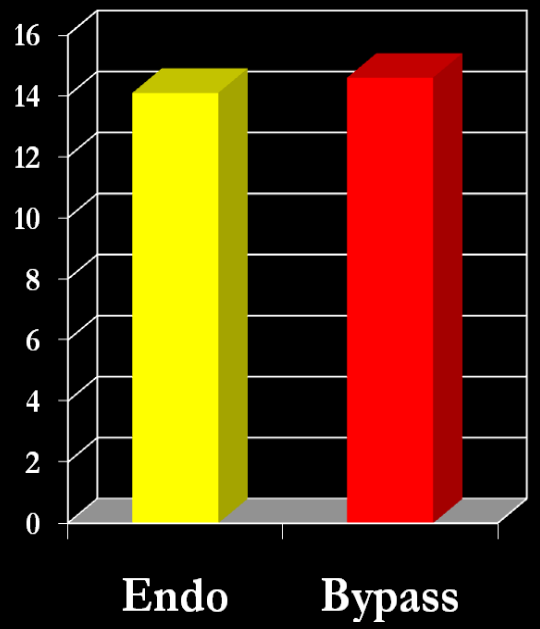


Figure 3. Overall survival. HR 0.60, 95% CI 0.36–1.02, $p = .06$.

Popplewell MA, et al Eur J Vasc Endovasc Surg 2017;54:195-201

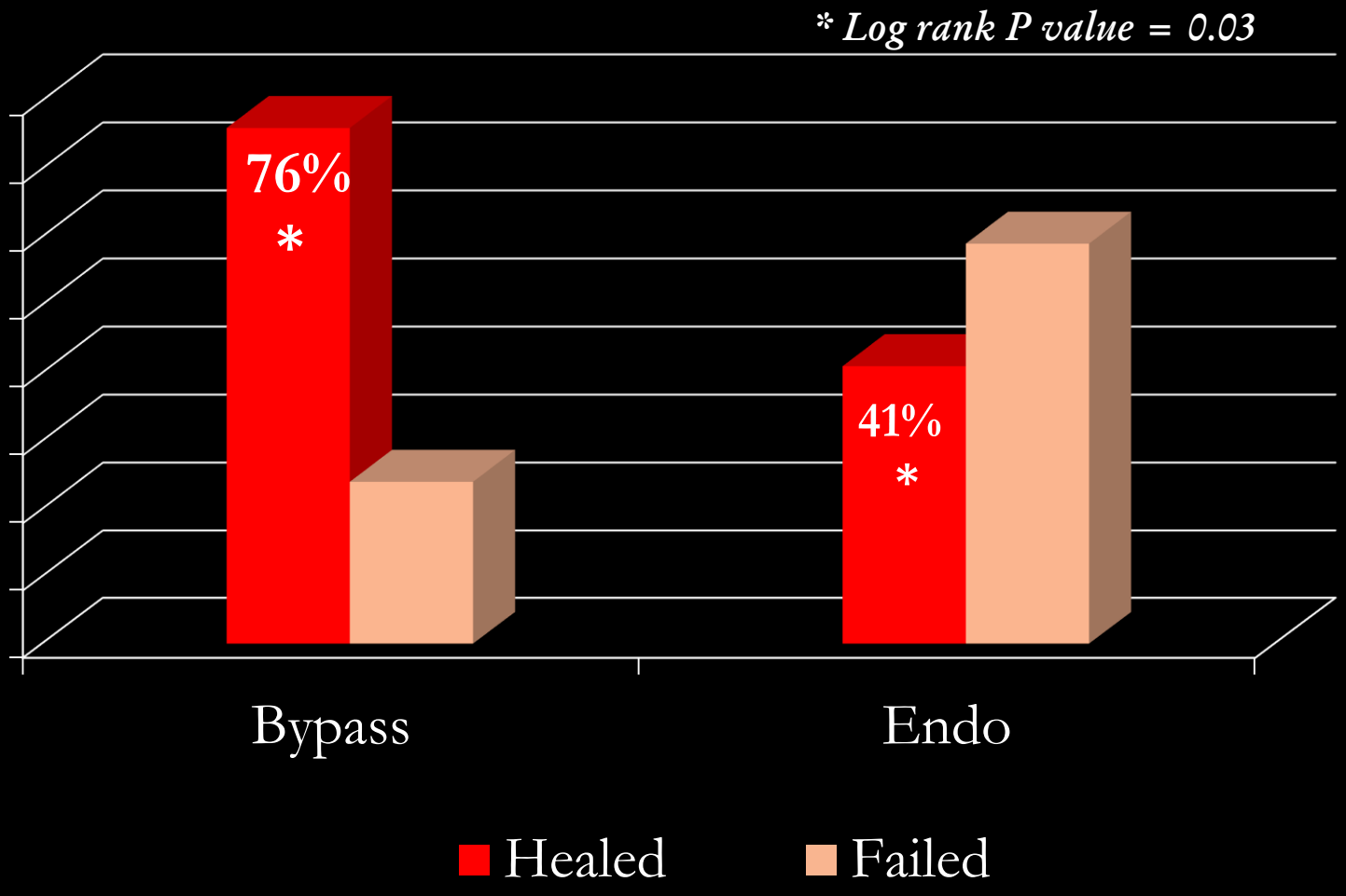
Indication for revascularization
Bypass vs Endovascular

- Effect on wound healing
- 290 patients, prospective data
- Grouped according to initial wound size
  - Group A 0.1 - 5.0 mm
  - Group B 5.1 - 20 mm
  - Group C > 20 mm

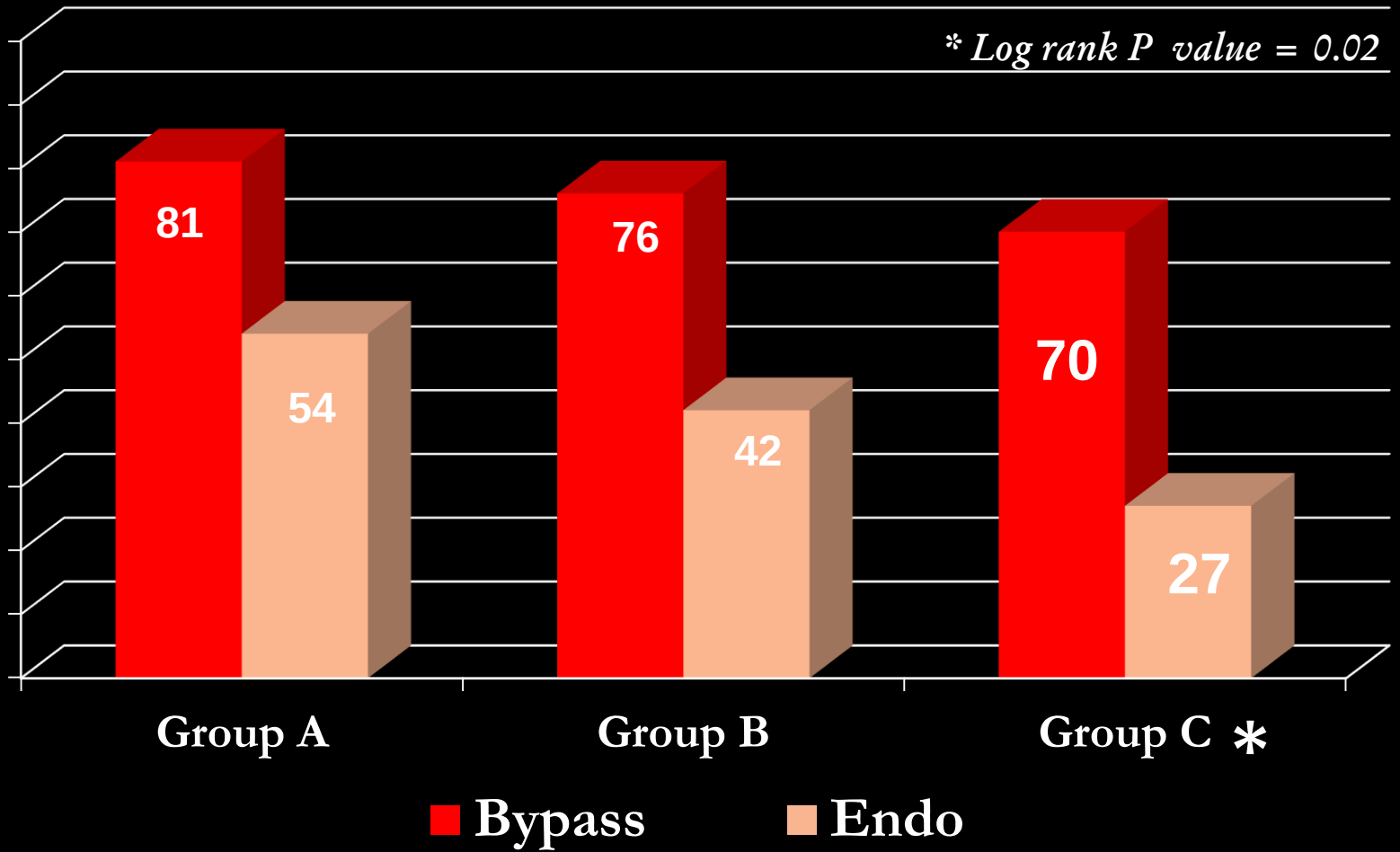


Neville, et al. SVS, 2010

Indication for revascularization
Complete healing



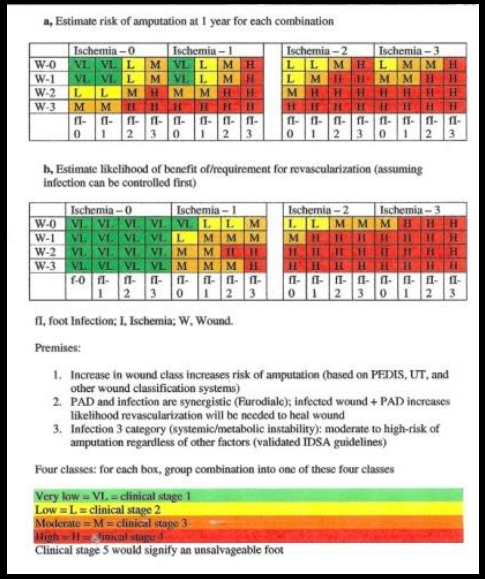
Indication for revascularization
Bypass better for larger wounds



Indication for revascularization
Severity of symptoms

- Patients with severe CLI (WIFI score) had better AFS with bypass compared to endovascular therapy

  Iida O, et al. SPINACH Study (Surgical Reconstruction vs Peripheral Intervention in Patients with CLI) Circ Cardiovass Inter 2017;10:12



a, Estimate risk of amputation at 1 year for each combination

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

b, Estimate likelihood of benefit of/requirement for revascularization (assuming infection can be controlled first)

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	VL	VL	VL	L	L	M	L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M	M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	H	H	H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

fI, foot Infection; I, Ischemia; W, Wound.

Premises:

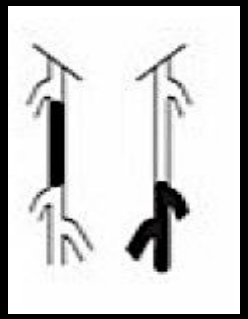
1. Increase in wound class increases risk of amputation (based on PEDIS, UT, and other wound classification systems)
2. PAD and infection are synergistic (Eurodiale); infected wound + PAD increases likelihood revascularization will be needed to heal wound
3. Infection 3 category (systemic/metabolic instability): moderate to high-risk of amputation regardless of other factors (validated IDSA guidelines)

Four classes: for each box, group combination into one of these four classes

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4
Clinical stage 5 would signify an unsalvageable foot

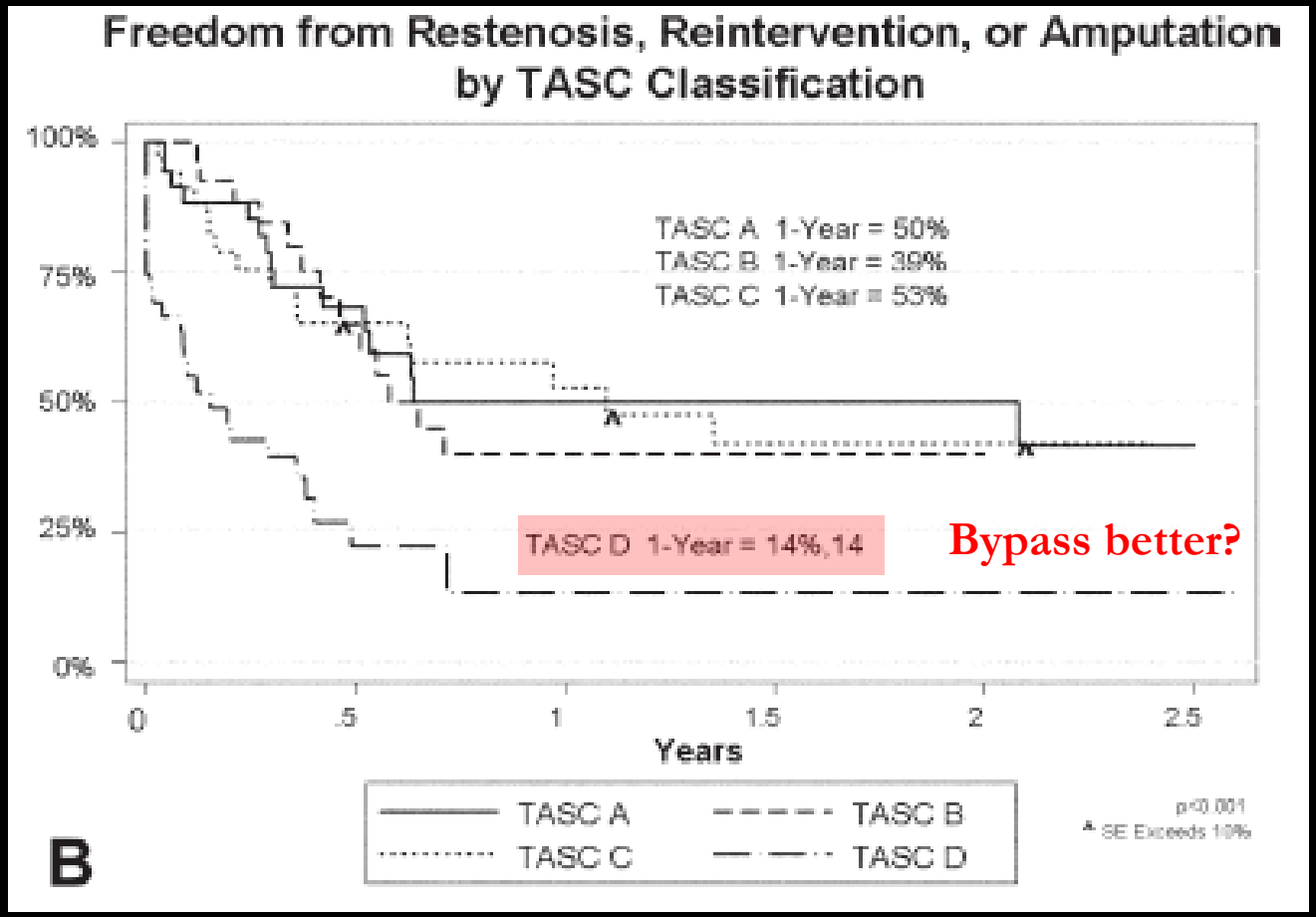
Arterial Anatomy: *femoral-popliteal disease*

- TASC A lesions
  - Endovascular is the treatment of choice [C]
- TASC B lesions
  - Endovascular is the preferred treatment
- TASC C lesions
  - Bypass is the treatment of choice for good risk patients
- TASC D lesions
  - Bypass is the treatment of choice [C]



TASC II
Inter-Society Consensus
for the Management of PAD

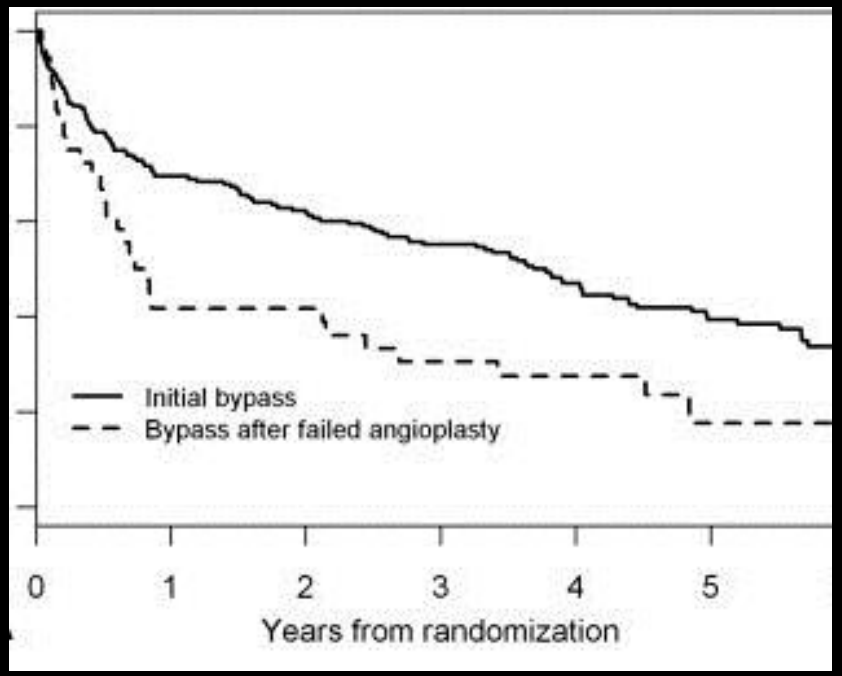
Arterial Anatomy
Endovascular for TASC D lesions



Giles KA, et al. J Vasc Surg. 2008;48:128-136.

Failed endovascular therapy
BASIL Trial

- Bypass after failed angioplasty
  - Worse outcomes



Adam AJ, BASIL trial participants. Lancet 2005;366:1925-34

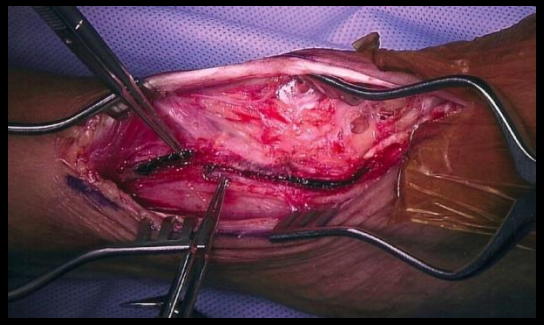
Bypass after failed endovascular therapy

- 20% required a more distal bypass

  Sandford, et al. Eur J Vasc Endo Surg. 2007;34:29-34.

- 30% altered distal target artery

  Joels, et al. J Vasc Surg. 2008;47:562-5.



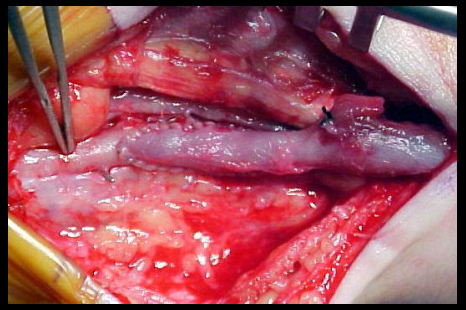
Bypass for treatment of CLI

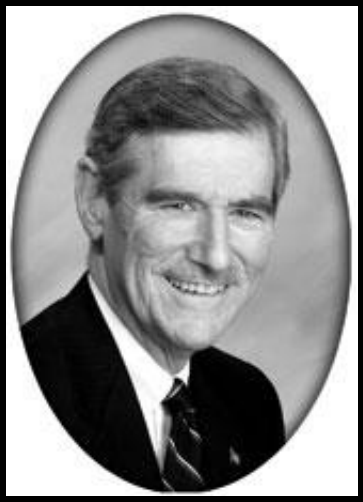
- Survey of "endovascular" surgeons
- Indications for a bypass first approach to CLI
  - Common femoral artery pathology
  - Extensive foot gangrene/sepsis
  - Young patients
  - Patients requiring soft tissue reconstructions (durability is paramount)
  - Long, infrageniculate occlusion with a single, distal tibial target vessel.

Lawrence PF, Chadra A, Eur J Vasc Endovasc Surg 39, S32eS37

But, surgical bypass has changed…..

	Patients	CLI (%)	Operative Mortality (%)	Primary patency (%) 1 yr	2 yrs	3 yrs	5 yrs	Secondary Patency (%) 1 yr	2 yrs	3 yrs	5 yrs
Reversed greater saphenous vein											
Rutherford et al, 1988[27]	100	–	75	–	63	–	–	–	–	–	–
Taylor et al, 1990	22	100	–	75	–	63	–	–	–	–	–
Gentile et al, 1996[18]	268	–	2	98	–	83	74	–	–	–	–
Hall et al, 1985[61]	52	23	–	85	–	68	–	–	–	–	–
In situ											
Belkin et al, 1996	386	100	2	–	–	–	68	–	–	–	80
Feinberg et al, 1990[32]	57	97	–	82	64	–	–	–	–	–	–
Alexander et al, 1996	119	92	1	–	–	81	–	–	–	–	–
Londrey et al, 1991[33]	61	92	4	–	–ó	–	72	83	74	74	74
LS Vether											
Belkin et al, 1996[62]	168	100	1	–	–	–	66	–	–	–	75
Londrey et al, 1991[33]	93	92	4	–	–ó	–	59	76	68	61	59
Londrey et al, 1994[17]	169	88	2	–	–	–	–	78	67	59	52
Myers et al, 1993[64]	537	43	–	80	–	–	73	–	–	–	–

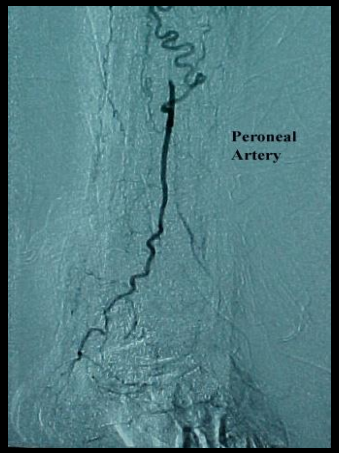




J Vasc Surg 2000;31S:192-274

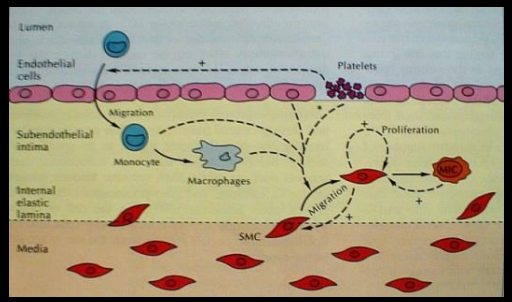
Bypasses are more challenging……

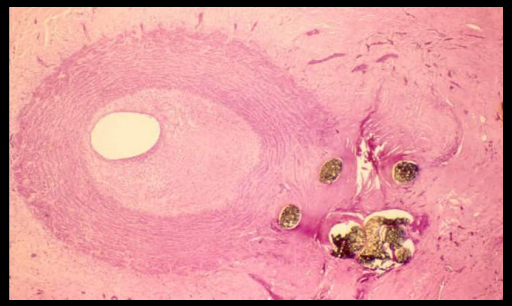
- Absence of saphenous vein
  - 30% in CLI practice
  - 50% after failed prior bypass
- Poor quality vein
- Lack of outflow target artery for bypass

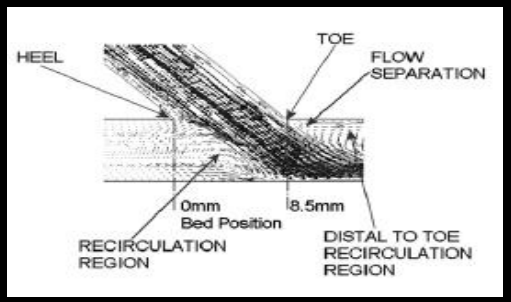


Absence of saphenous vein
Results of bypass with prosthetic grafts

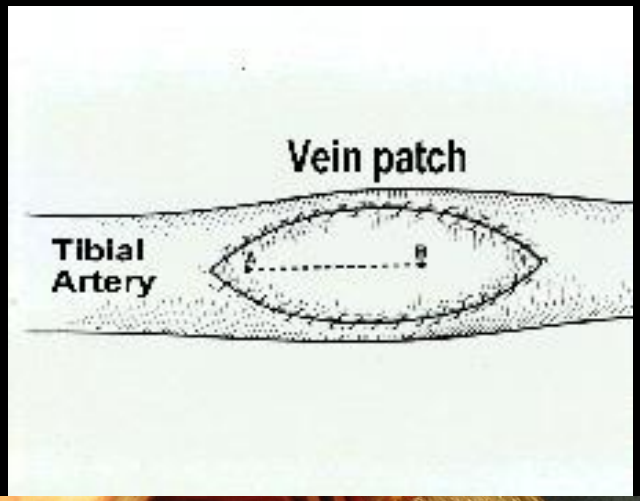
Hobson	1985	14%	2 yr
Ascer	1985	37%	2 yr
Veith	1986	34%	2 yr
Flinn	1988	45%	2 yr
Calligaro	1997	26%	2 yr
Harris (Distaflo)	2003	39%	1 yr

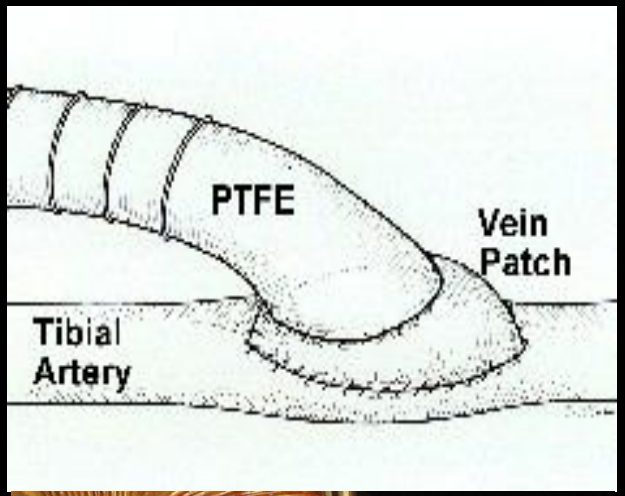


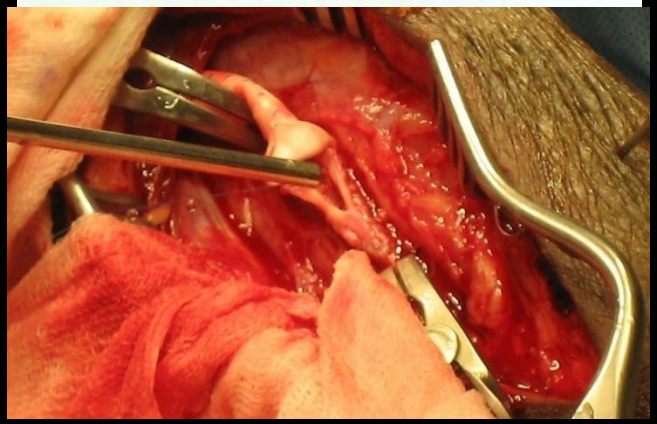


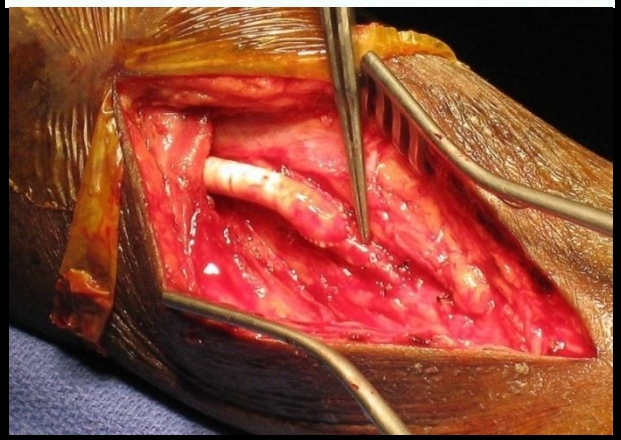


Improve prosthetic graft performance
Distal Vein Patch



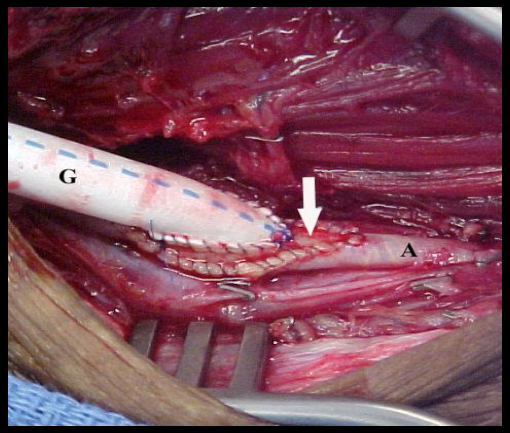


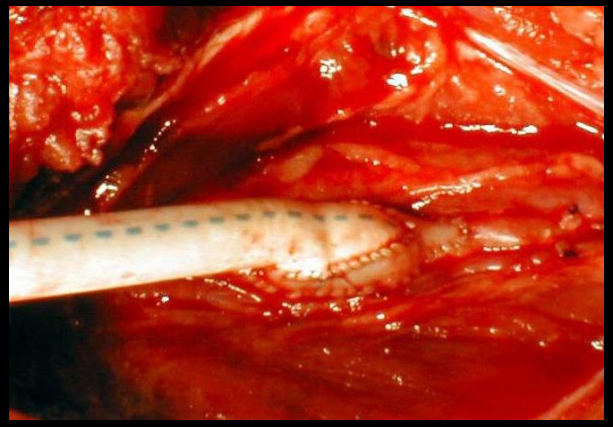


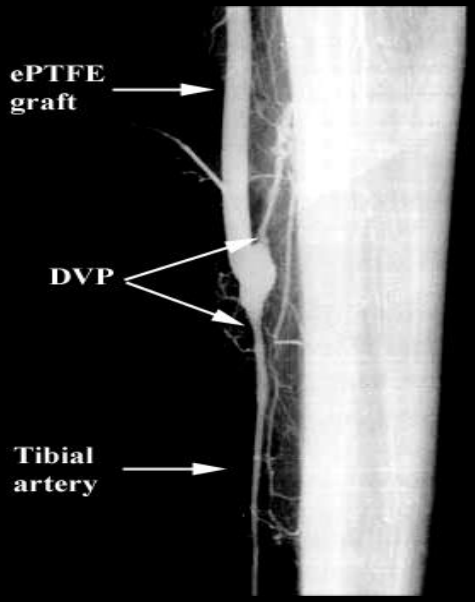


Neville , et al. Am J Surg 1997;174:173-6.

Distal Vein Patch

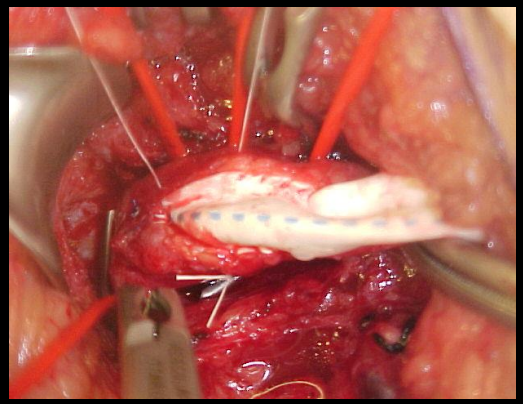


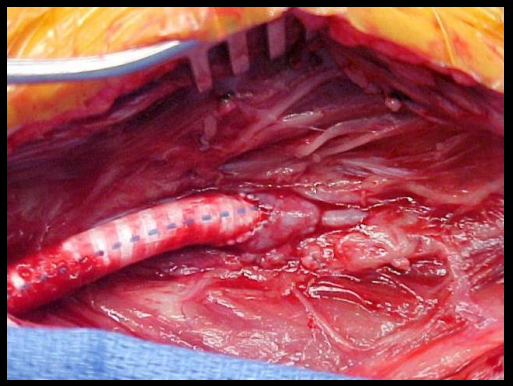




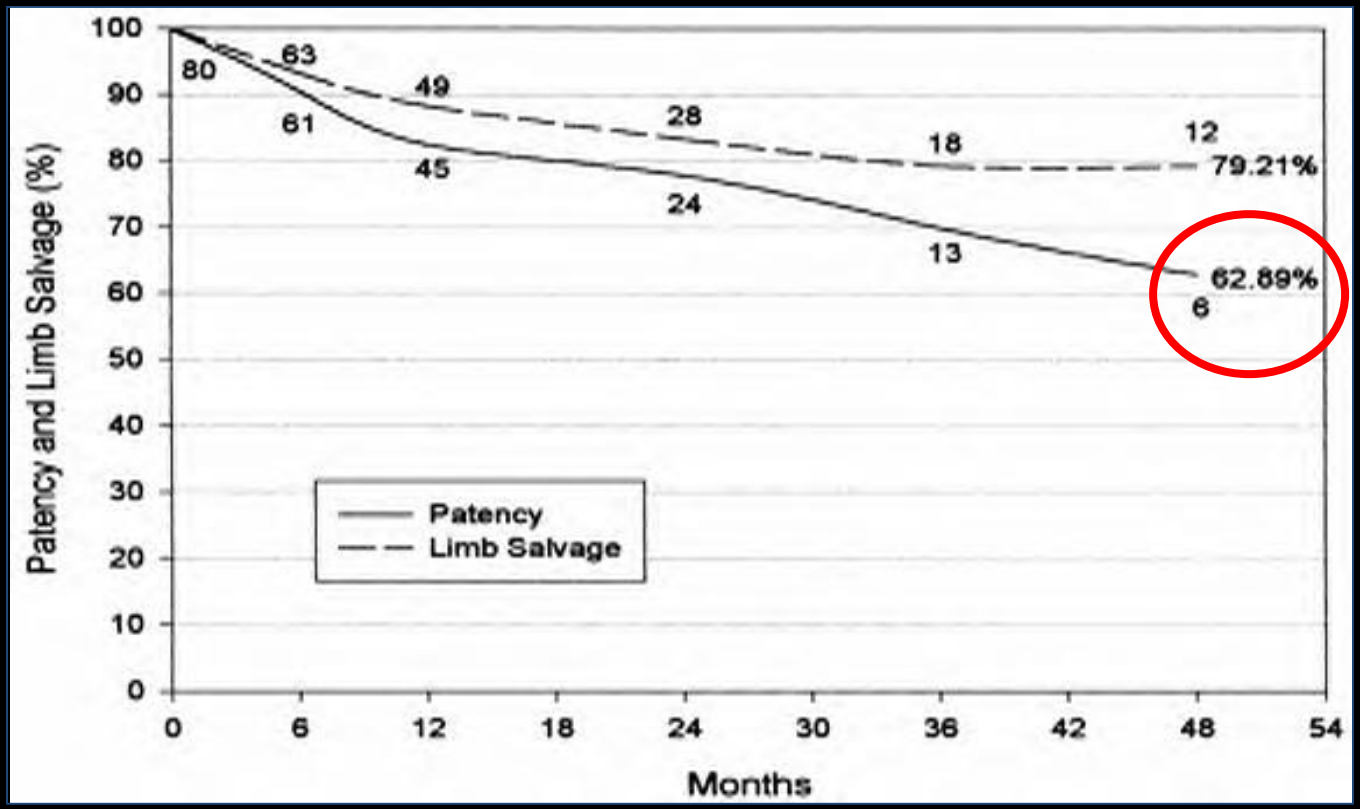
DVP Technique

Minimal incisions
Length not an issue





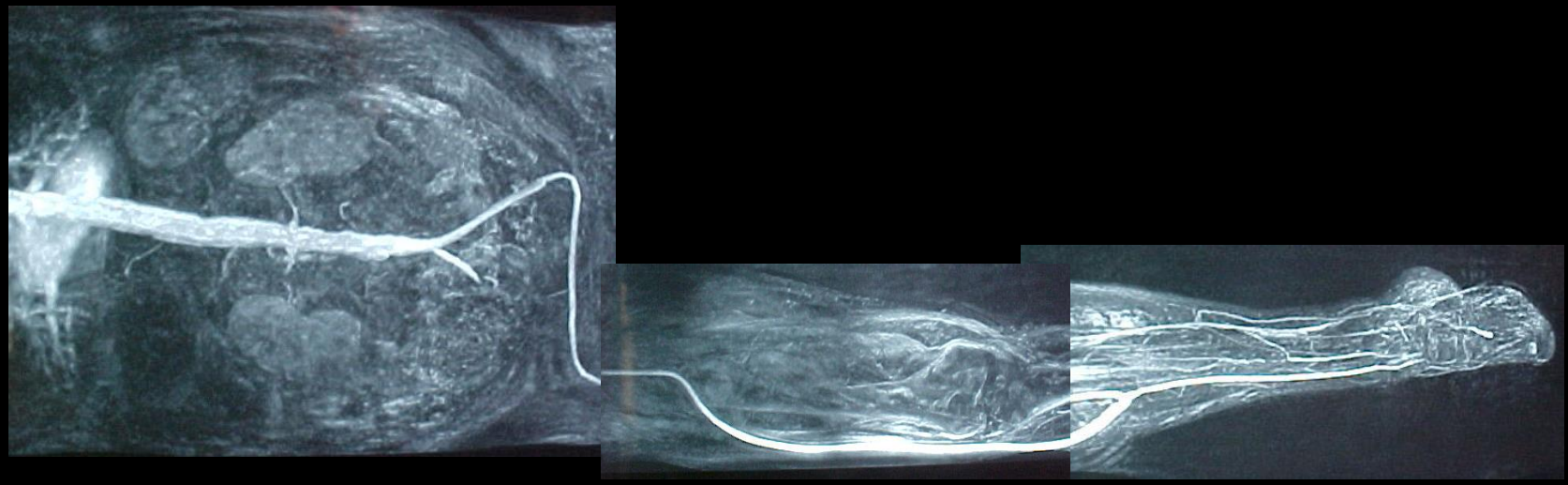
Distal Vein Patch
Results of initial series



Neville, et al. J Vasc Surg 33:266, 2001

Journal of Vascular Surgery®

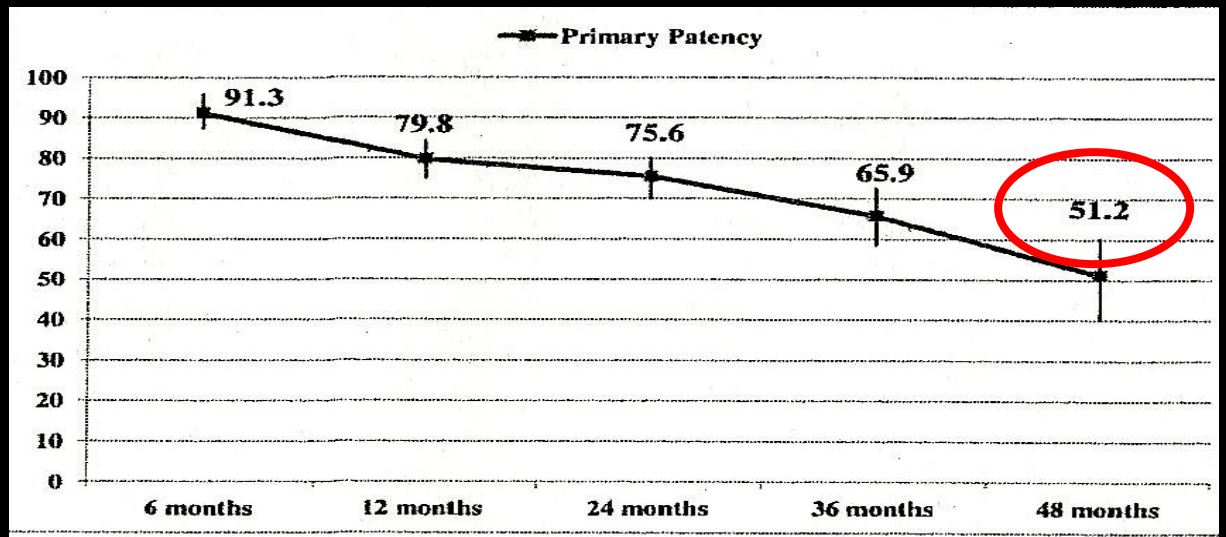
Distal Vein Patch bypass
Durability



7 year follow-up
External iliac to contralateral Anterior tibial

Distal Vein Patch
Results of extended series

290 bypasses

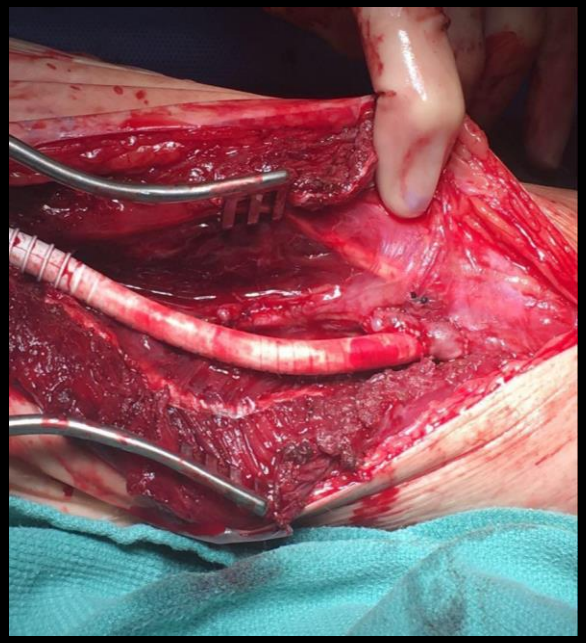


Interval	Patency	Standard Error	N at Start	Events
6 months	91.3%	2.0%	228	13
12 months	79.8%	3.4%	158	12
24 months	75.6%	4.4%	121	3
36 months	65.9%	6.1%	80	4
48 months	51.2%	8.4%	58	3

Neville, Eur J Vasc Endovasc Surg 2012;44:177-182

esvs Journal
European Journal of Vascular & Endovascular Surgery

Reported on DVP bypass

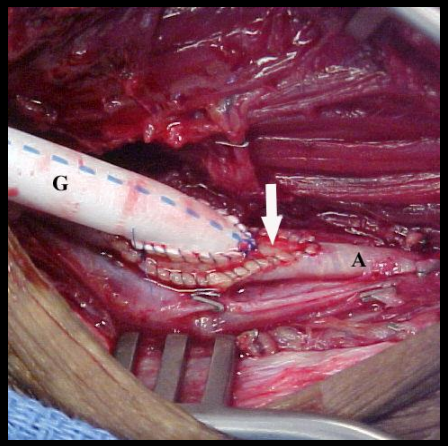


Courtesy of Charles West, MD

• Charles West	Texas
• Xian Jang	Bejing, China
• Walter Dorigo	Rome, Italy
• Eric Adams	Pennsylvania
• Greg Hayes	California
• Joe Mills	Texas
• Hiroshi Yasuhara	Osaka, Japan
• Jeff Siracuse	Boston

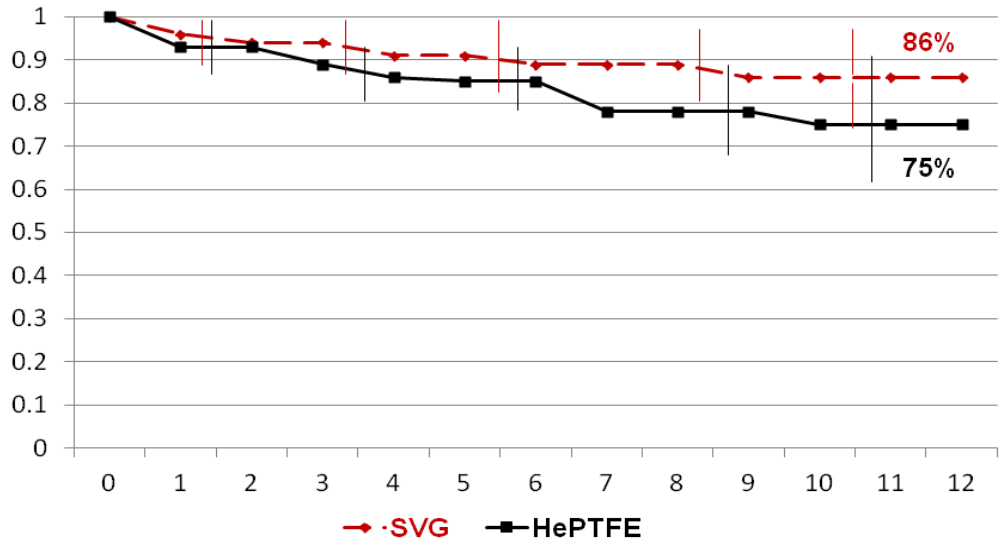
Heparin bonded PTFE

First tibial bypass in USA, November 2006



HePTFE vs Vein; Tibial bypass
Our experience

Primary Patency



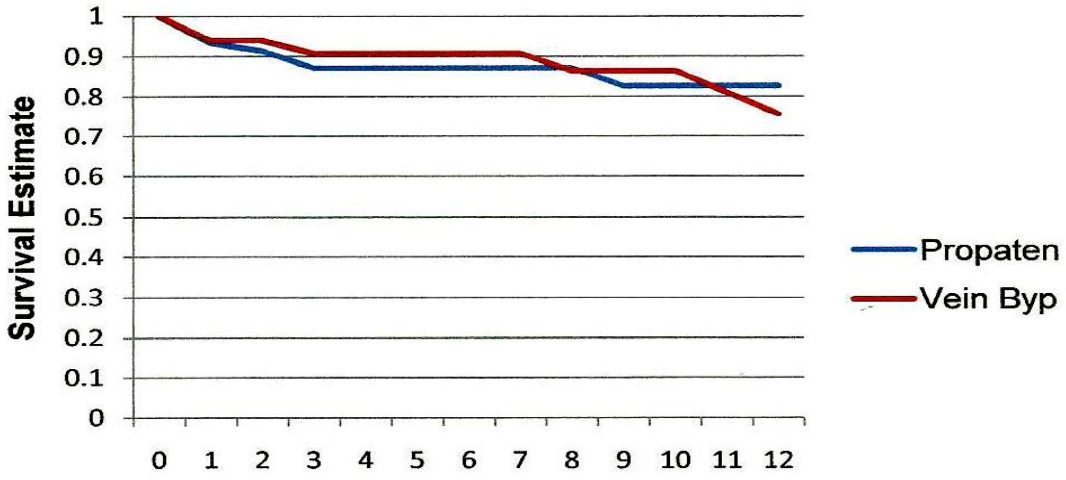
HePTFE	62	57	57	52	51	47	47
Vein	50	48	48	43	43	43	43

Neville RF, et al. J Vasc Surg 2012; 54(4): 1008-1014

Journal of Vascular Surgery®

HePTFE vs Vein; Tibial bypass
Our experience

Amputation Free Survival



Summary of the Number of Censored and Uncensored Values

Treatment	Stratum	Graft	Total	Amputation	Censored	%Censored	%Amputation
Propaten	1	1	62	9	53	85.48	14.52
Vein Bypass	2	2	50	7	43	86.00	14.00
Total			112	16	96	85.71	14.29

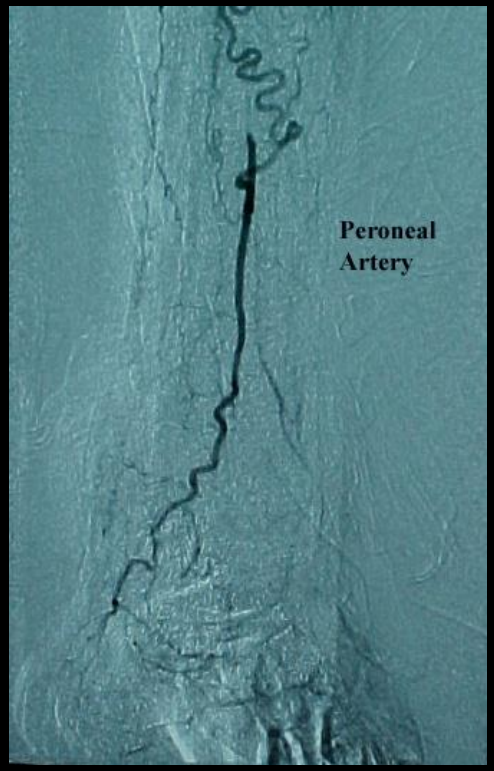
Test of Equality over Strata

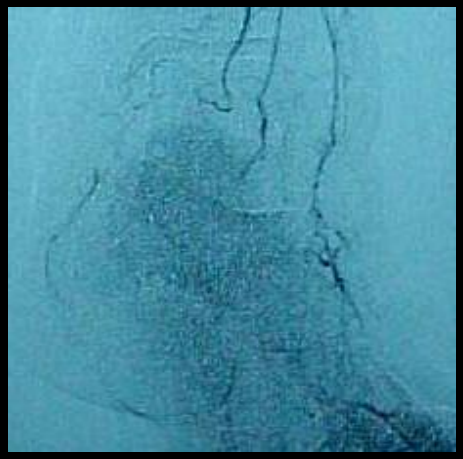
Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.1093	1	0.7409

Neville RF, et al. J Vasc Surg 2012; 54(4): 1008-1014

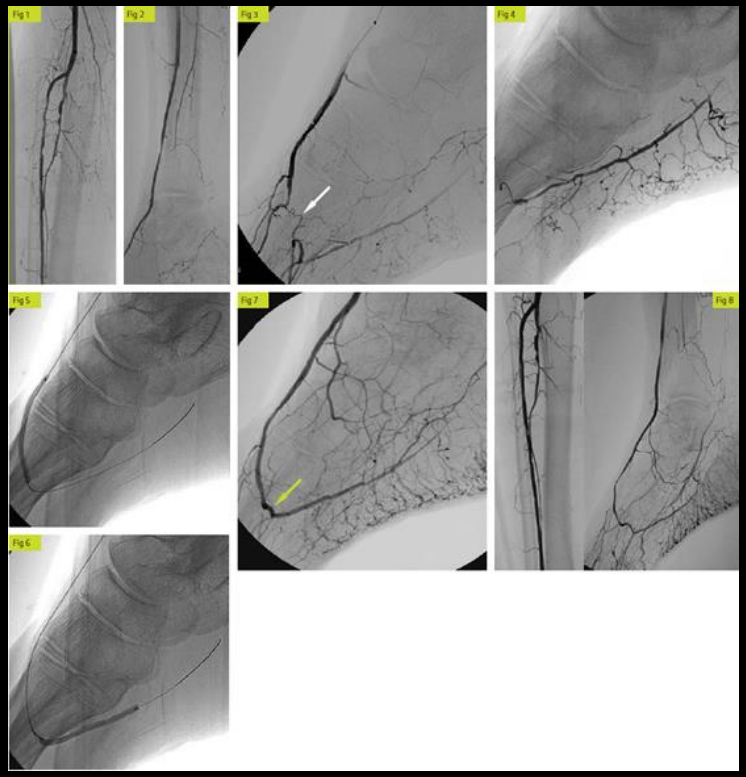
Journal of Vascular Surgery®

What about bypass in the face of severe outflow disease?



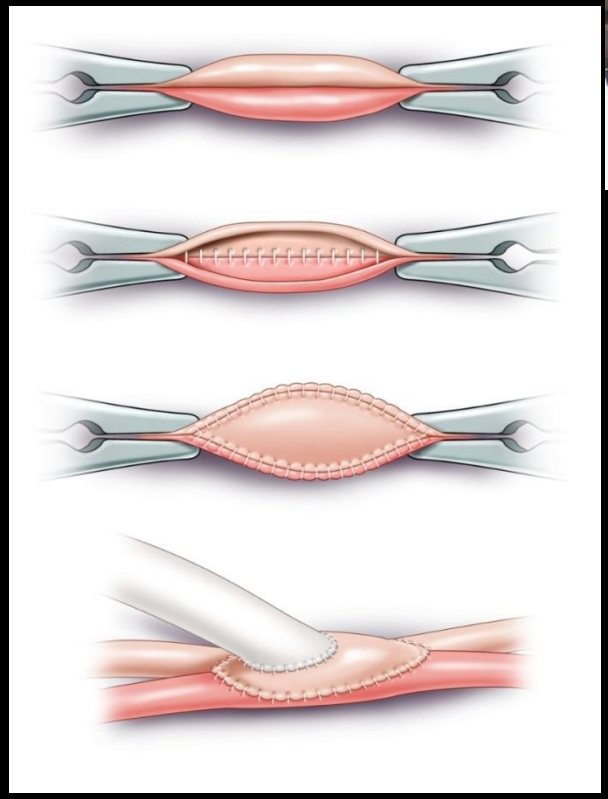


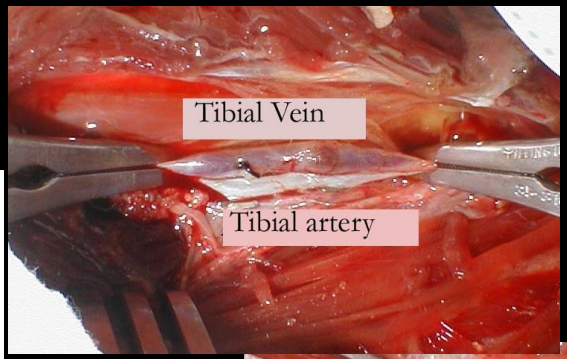
Endovascular approach

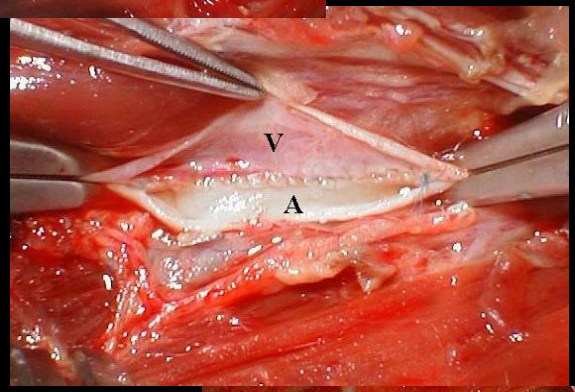


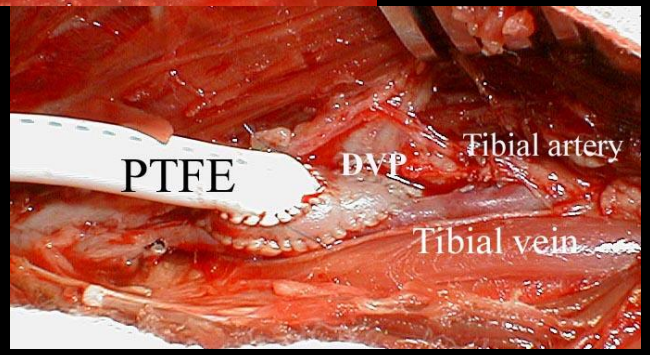
Pedal loop
Retrograde pedal access

DVP with common-ostium dAVF
"Patchula"



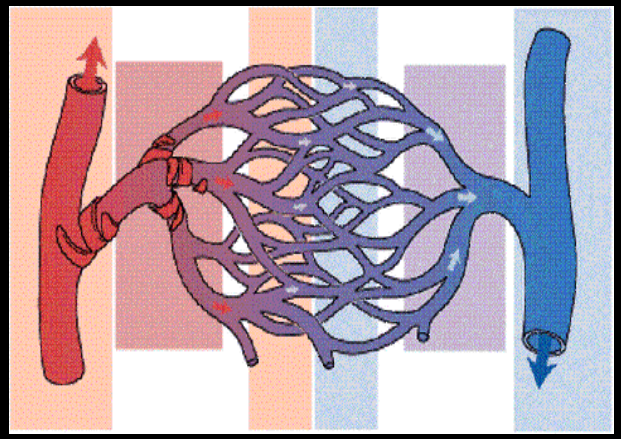






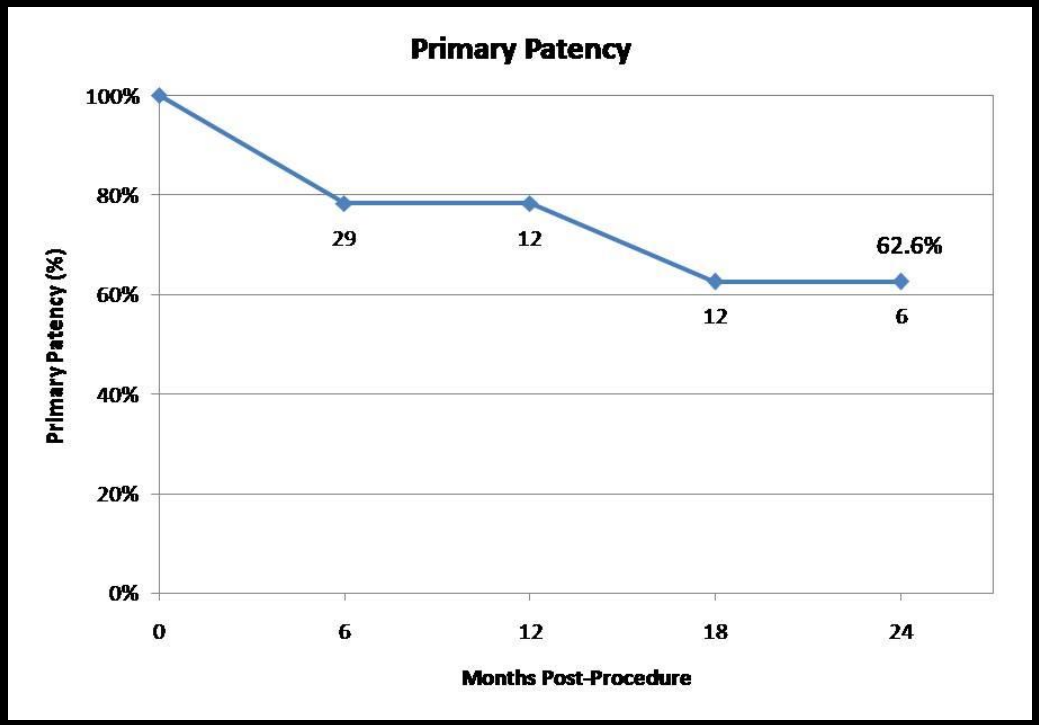
AV fistula at distal anastomosis

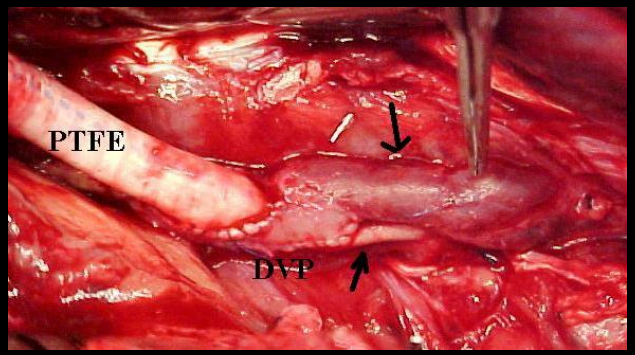
- Reduce outflow resistance
- Increase flow above the *critical thrombotic threshold*
- Deliver retrograde flow to capillary bed



Johansen K, Bernstein EF. Ann Surg 1979;190:243-53.
Strandness et al. Hemodynamics for surgeons. 1975;346-9.
Sauvage et al. Surg Clin North Am 1974;54:213-8.

DVP with AVF: "Patchula"





Neville RF, etr al. J Vasc Surg 2009;50:83-88.

Journal of Vascular Surgery®

Summary

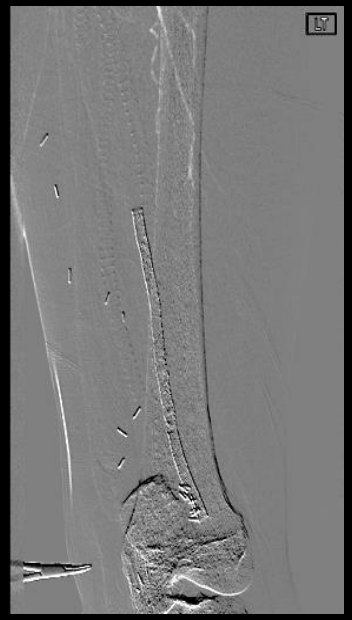
- Role of surgical bypass in a CLI practice (25%)
  - Patients with good life expectancy
  - Significant tissue loss
  - Long segment occlusions (TASC D)
  - Failed endovascular therapy
- Need for prosthetic bypass in today's practice (50%)
  - Patients with absent or poor quality GSV
- Adjuncts for prosthetic bypass
  - Distal vein patch technique
  - Heparin bonded ePTFE
  - "Patchula"

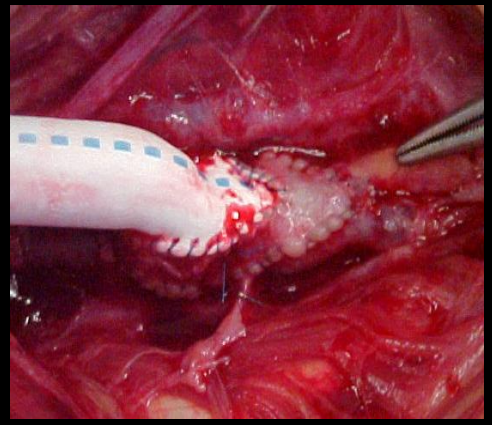
Clinical trials to determine optimal method of revascularization

- Randomized controlled trials to provide Level 1 evidence for the ideal revascularization strategy
  - ***BASIL-2*** (Bypass vs Angioplasty in Severe Ischemia of the Leg)
  - ***BEST-CLI*** (Best Endovascular vs Surgical Therapy in Patients with CLI)

Endovascular intervention or distal bypass?

Tissue loss of forefoot, failed stent angioplasty, long segment tibial occlusive disease





CFA TE
femoral – peroneal
DVP/'patchula' bypass

Yes, Dr. White there still is a role for bypass in limb preservation