

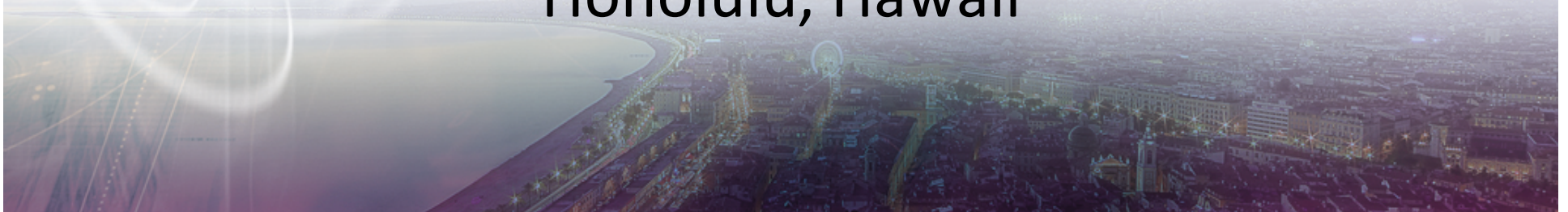


# Distal Bypass in BTK Disease

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## **Disclosure**

Peter A. Schneider

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I have the following potential conflicts of interest to report:

Non-compensated participation in Scientific Advisory Board for Medtronic and Abbott

Shareholder in a healthcare company: Chief Medical Officer and shareholder, Intact Vascular and Cagent

Royalty for intellectual property: Cook (modest)

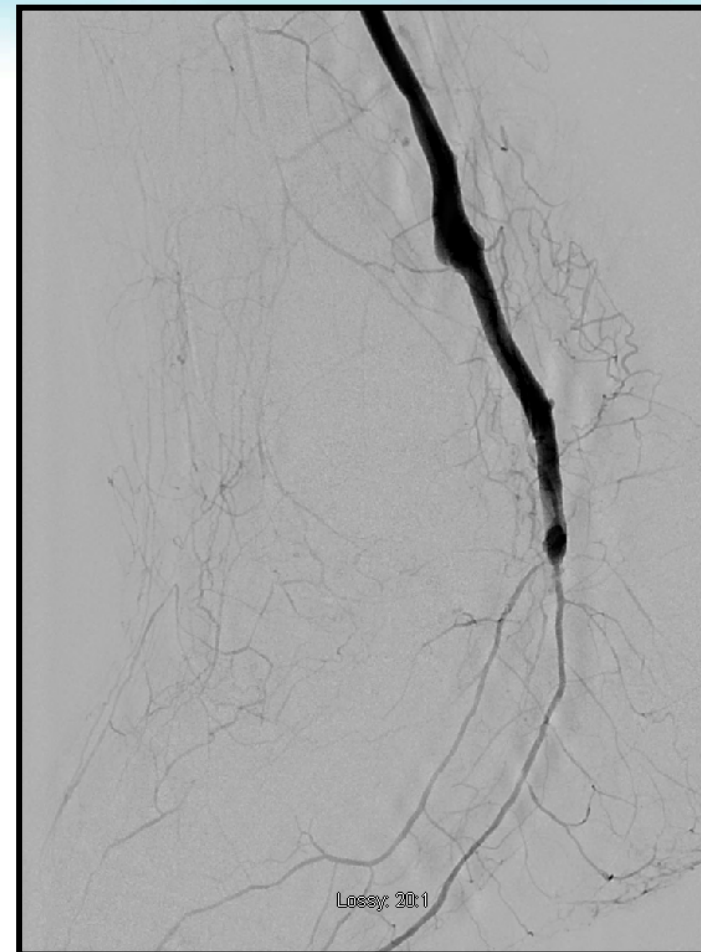


**Disclosure: I am a believer in blood supply**



# Use of bypass is evolving

- Very distal targets
- Endovascular failures
- Wound related artery cannot be revascularized
- Foot damage is worse (Rutherford 6)



Rutherford 5



Rutherford 4

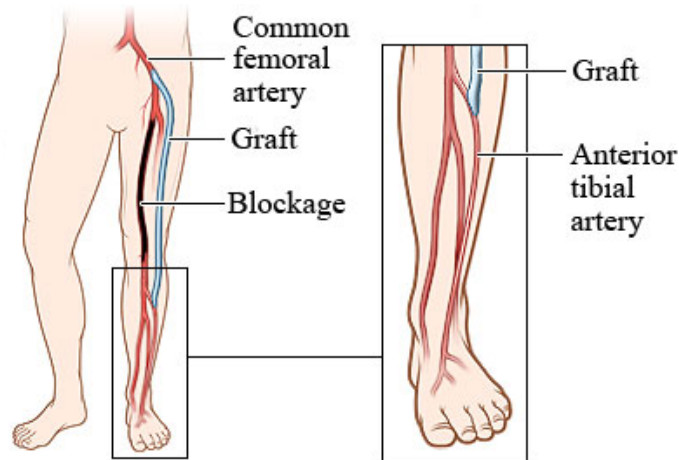


Rutherford 6



# Results of Tibial Bypass Grafts

	1month	1 year	2 years	3 years	4 years
<b>Primary Patency</b>					
Reversed saphenous vein	92%	77%	70%	66%	62%
In-situ bypass	94%	82%	76%	74%	68%
<b>Limb salvage</b>					
Reversed saphenous vein	95%	85%	83%	82%	82%
In-situ bypass	96%	91%	88%	83%	83%



Mills J. Surgical revascularization of infrainguinal occlusive disease. Includes all series 1981-2009 Rutherford 7<sup>th</sup> ed. 2010

**Good long-term patency and limb salvage rates.**

# Bypass for CLI

**Table II.** Meta-analysis results of crural percutaneous transluminal angioplasty and popliteal-to-distal bypass<sup>a</sup>

<i>Result</i>	<i>1 month</i>	<i>6 months</i>	<i>1 year</i>	<i>2 years</i>	<i>3 years</i>
Primary patency					
PTA	77.4 ± 4.1	65.0 ± 7.0	58.1 ± 4.6	51.3 ± 6.6	48.6 ± 8.0
Bypass	93.3 ± 1.1	85.8 ± 2.1	81.5 ± 2.0	76.8 ± 2.3	72.3 ± 2.7
<i>P</i>	<.05	<.05	<.05	<.05	<.05
Secondary patency					
PTA	83.3 ± 1.4	73.8 ± 7.1	68.2 ± 5.9	63.5 ± 8.1	62.9 ± 11.0
Bypass	94.9 ± 1.0	89.3 ± 1.6	85.9 ± 1.9	81.6 ± 2.3	76.7 ± 2.9
<i>P</i>	<.05	<.05	<.05		
Limb salvage					
PTA	93.4 ± 2.3	88.2 ± 4.4	86.0 ± 2.7	83.8 ± 3.3	82.4 ± 3.4
Bypass	95.1 ± 1.2	90.9 ± 1.9	88.5 ± 2.2	85.2 ± 2.5	82.3 ± 3.0
Patient survival					
PTA	98.3 ± 0.7	92.3 ± 5.5	87.0 ± 2.1	74.3 ± 3.7	68.4 ± 5.5
Bypass	NA	NA	NA	NA	NA

NA, Estimates not available; PTA, percutaneous transluminal angioplasty.

<sup>a</sup>Values are pooled estimate and standard error.

## Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia

Marcello Romiti, MD,<sup>a</sup> Maximiano Albers, MD,<sup>a</sup> Francisco Cardoso Brochado-Neto, MD,<sup>a</sup>  
Anai Espinelli S. Durazzo, MD,<sup>b</sup> Carlos Alberto Bragança Pereira, PhD,<sup>c</sup> and Nelson De Luccia, MD,<sup>b</sup>  
Santos and São Paulo, São Paulo, Brazil

J Vasc Surg 2008

# Bypass for CLI

## Prevent III Trial (Level Ib):

- Phase III, double-blinded, placebo-controlled RCT
  - Edifoligide (E2F decoy) to block neointimal hyperplasia
- Endpoint: 30 day and 12 month
  - Primary: graft failure or major amputation
  - **Secondary: patency, graft stenosis, limb salvage, AFS**
- No differences in treatment arms
- Overall one year: primary patency 61%, limb salvage 88%
- **Factors influencing primary patency**
  - **Graft origin: popliteal**
  - **Graft diameter: >3.5 mm**
  - **Conduit type: single piece GSV**
  - **Graft length: <40 cm**



## New Standards for Assessment and Reporting SVS Optimal Performance Goals

Outcome	Efficacy OPG
Major adverse limb events/postop death	71%
Amputation free survival	71%
Reintervention/major amputation	39%
Limb salvage	84%
Survival	80%

Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

Michael S. Conte, MD,<sup>a</sup> Patrick J. Geraghty, MD,<sup>b</sup> Andrew W. Bradbury, MD,<sup>c</sup> Nathanael D. Hevelone, MPH,<sup>d</sup> Stuart R. Lipsitz, ScD,<sup>e</sup> Gregory L. Moneta, MD,<sup>f</sup> Mark R. Nehler, MD,<sup>g</sup> Richard J. Powell, MD,<sup>h</sup> and Anton N. Sidawy, MD,<sup>i</sup> *San Francisco, Calif; St. Louis, Mo; Birmingham, United Kingdom; Boston, Mass; Portland, Ore; Aurora, Colo; Hanover, NH; and Washington, DC*

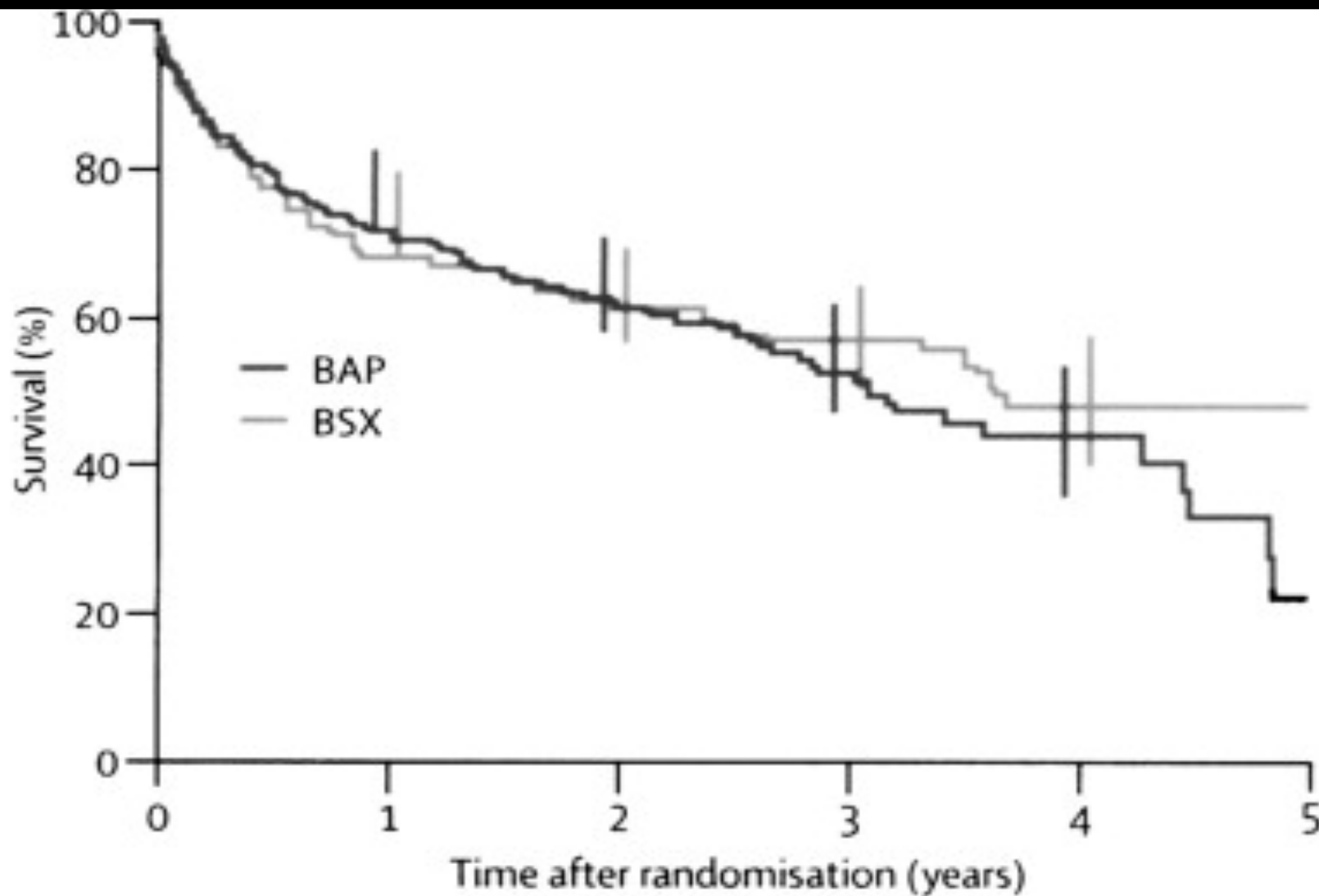
J Vasc Surg 2009;50:1462

# Bypass for CLI Level Ib/IIb Data

Author/Trial	Conduit Type	Primary Patency	Secondary Patency	Limb Salvage
Schanzer-2007 Prevent III (Ib)	Single GSV	64% @ 1yr	84%	90%
	Single LSV/Arm V	52% @ 1yr	72%	81%
Kreienberg-2002 (IIb)	Composite	42% @ 1yr	69%	85%
	Composite	44% @ 2yrs	87%	94%
	Prosthetic w Vein Cuff	49% @2 yrs	59%	83%

Schanzer. JVS 2007;46:1180-90

Kreienberg. JVS 2002;35:299-306



**Number at risk**

	0	1	2	3	4	5
Angioplasty	224	149	100	51	19	24
Surgery	228	148	108	64	23	79

# In Situ Bypass for CLI (Level III Data)

- **Retrospective Review of 2058 Bypasses**
- 1875 (91%) for CLI
- Primary Patency: 84% @1 yr, 72% @ 5yrs
- Limb Salvage: 95% @ 5yrs
- No effect of DM or bypass length on patency
- Vein Diameter
  - > 4mm: patency 90% @ 1yr, 77% @ 5yrs
  - < 4mm: patency 77% @ 1yr, 66% @ 5 yrs

Shah. Ann Surg 1995;222:438-46

# Bypass for CLI: Contemporary Results (Level III Data)

- 314 patients: (71% Tissue Loss)
- **Primary Patency: 61% @ 1yr**, 45% @ 5 yrs
- Limb Salvage: 89% @ 5 yrs
- Amputation Free Survival: 49% @ 5 yrs

Santo et al. JVS 2014; 60(1)

# What we know about bypass for CLI

- Long-term patency can be achieved
- Single segment bypass using arm vein/  
lesser saphenous vein
  - Vein diameter
  - In situ and revascularization results
- Use a distal conduit
- Cryopreserved conduit 6 months
- Revisions are rare



## Challenges: Tibial Bypass Grafts

- 5% mortality rate
- 10-20% develop incisional wound complications
- Prospective NSQIP analysis of >2500 patients: ~20% peri-procedural complication rate, and 49% readmission rate at 6 months (65% bypass related)
- Meta-analysis: 12% decline in ambulation and 15% loss of independent living post bypass surgery
- 30% of bypasses develop stenoses/occlusions at 1 year

Courtesy K. Deloose

La Muraglia et al. Eur J Vasc Endovasc Surg 2012; 43(5):54  
Conte et al. Seminars of Vascular Surgery 2012 25:108-114  
Goodney et al. J Vasc Surg 2011 : 54(1) ; 100-108



# Bypass for CLI

## Technical Aspects

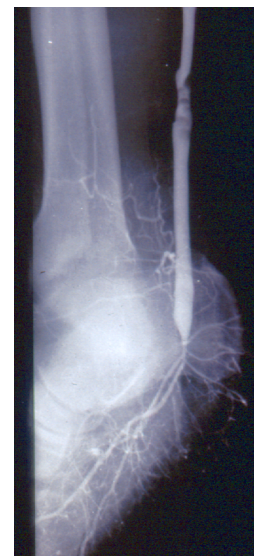
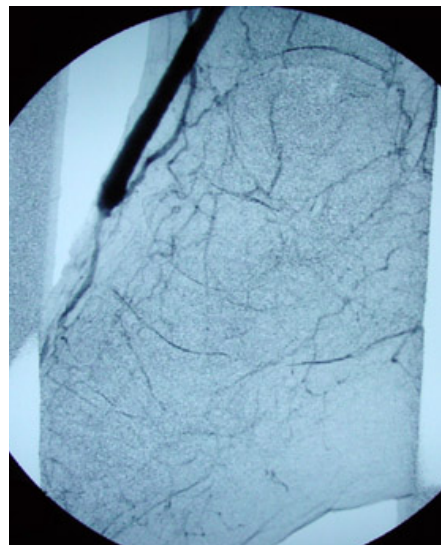
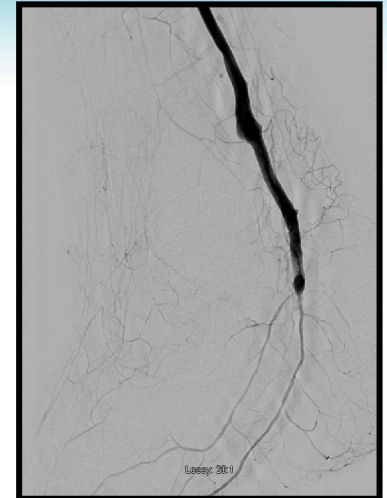
- Treat inflow aggressively
- Vein harvest
  - Always map, two surgeons, skip incisions, avoid flaps
- Minimize lower leg incisions
  - Use ultrasound to guide incision for distal anastomosis
- Post-op
  - Elevate leg immediately after procedure
  - Surveillance



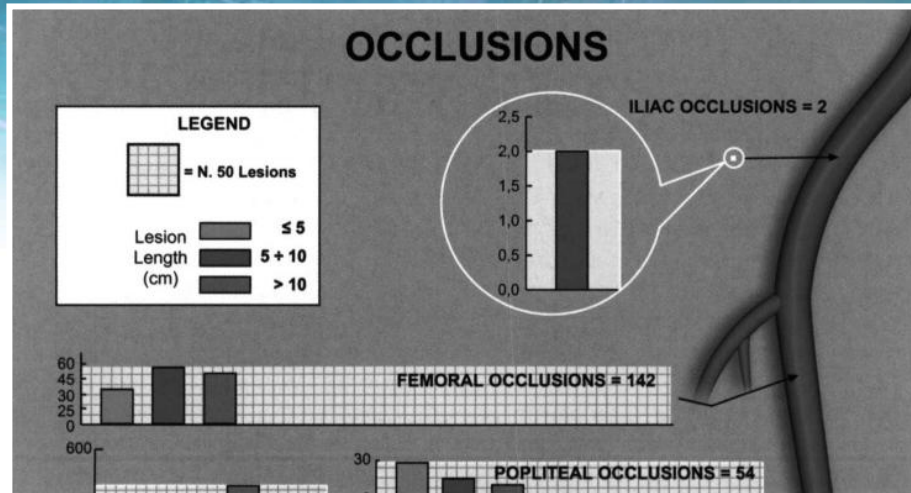
# Bypass for CLI

## Technical Aspects: Selection of Distal Target

- Rare to consider a target proximal to the ankle/foot
- Choice is usually limited by existing occlusions
- Choose wound related artery whenever possible
  - Does not matter in setting of patent pedal arch
- Quality of target vessel



# Bypass Can Manage CLI Patterns of Disease



**417 diabetics with CLI-2893 lesions**  
74% were in the BTK arteries  
66% of BTK lesions were occlusions  
50% of occlusions were >10cm  
Graziani et al. Eur J Vasc Endovasc Surg 2007;33:453.

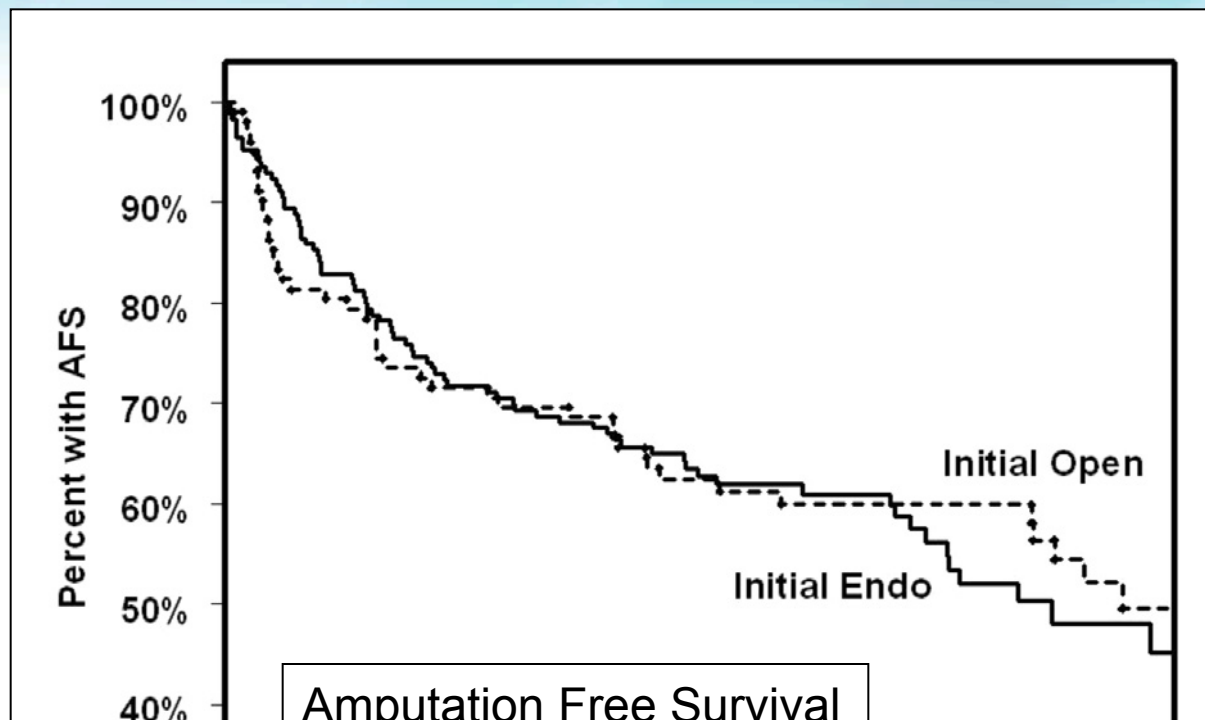
**Table IV.** Distribution of occlusions in arterial groups in patients with critical limb ischemia

Arteries	DM, No. (%)	Non-DM, No. (%)	ESRD, No. (%)	Non-ESRD, No. (%)	Fontaine stage, No. (%)	
					III	IV
A-I + Fem + Pop-Tib	8 (3)	12 (7)	2 (1.5)	18 (6)	8 (7)	12 (4)
A-I + Fem	0 (0)	4 (2)	0 (0)	4 (1)	4 (3)	0 (0)
A-I + Pop-Tib	4 (1)	4 (2)	2 (1.5)	6 (2)	3 (2)	5 (1)
A-I	4 (1)	11 (7)	1 (1)	14 (5)	9 (7)	6 (2)
Fem	12 (5)	6 (4)	4 (3)	14 (5)	6 (5)	12 (4)
Fem + Pop-Tib	70 (27)	61 (36)	30 (24)	101 (33)	44 (37)	87 (28)
Pop-Tib	164 (63)	70 (42)	87 (69)	147 (48)	47 (39)	187 (61)
Total	262	168	126	304	121	309

Rueda et al. J Vasc Surg 2008;47:995

Endovascular-first approach is not associated with worse amputation-free survival in appropriately selected patients with critical limb ischemia

302 patients  
62% Endo first  
35% Open first  
3% Hybrid

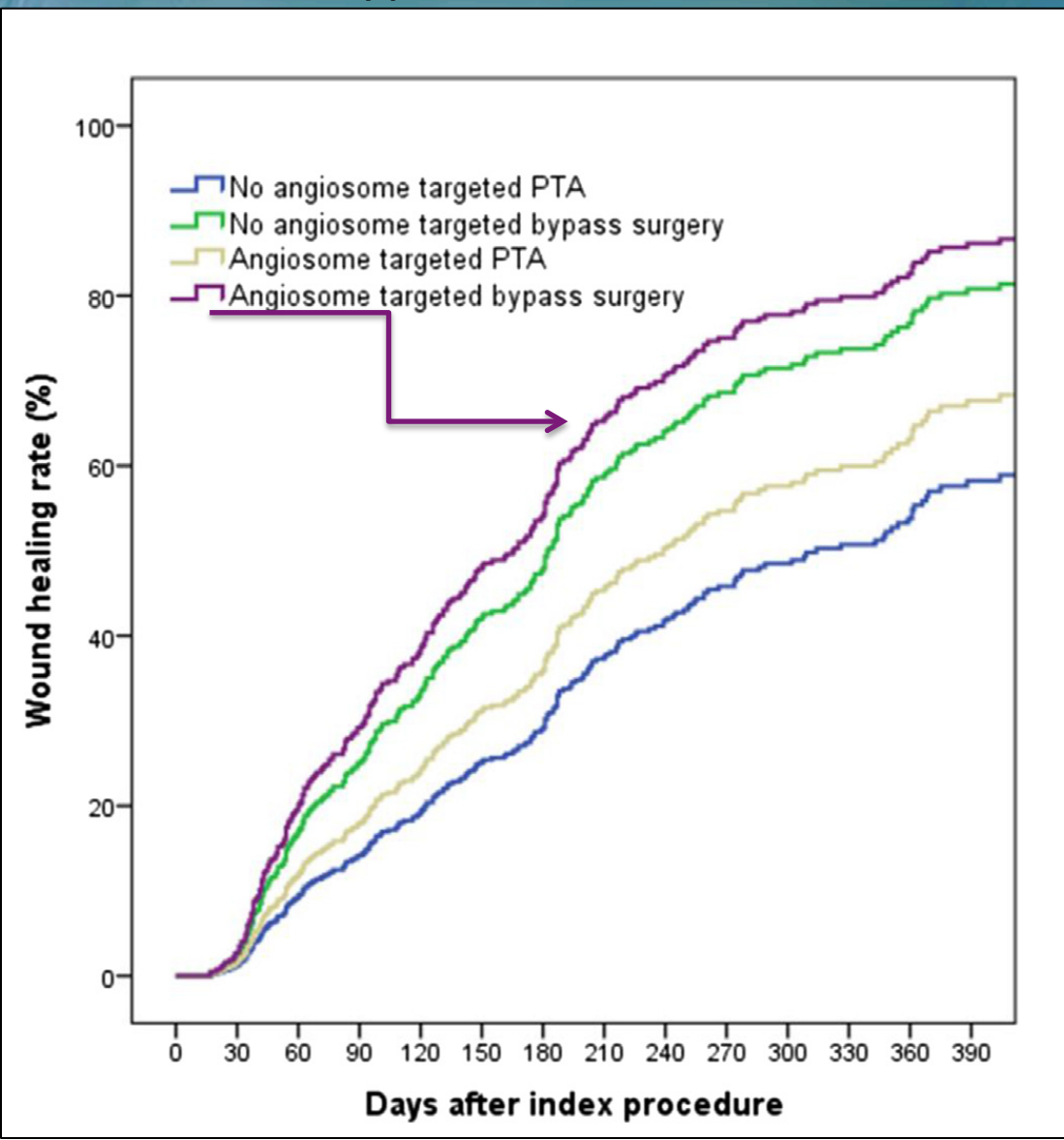
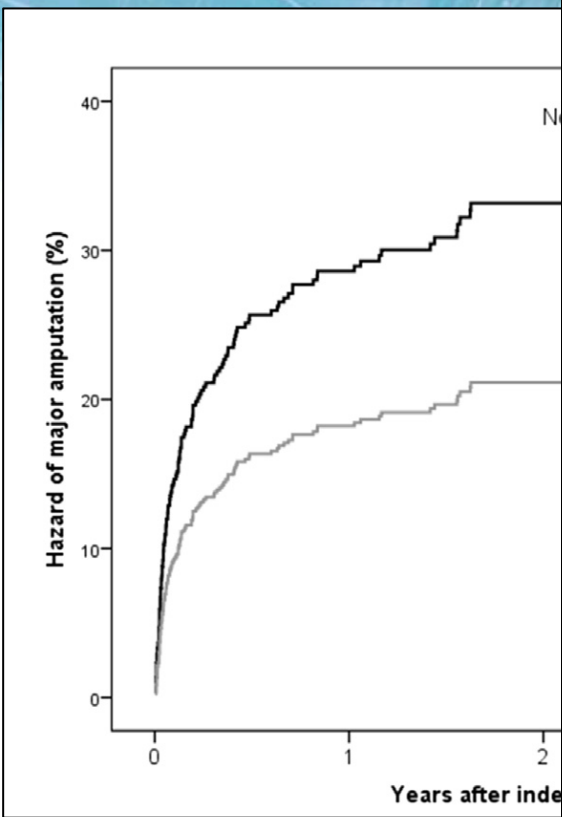


Using bypass for worse disease morphology  
and worse foot damage

# Results of Angiosomal Perfusion

Method of Revasc	Study	Appropriate Angiosome	Boundary Angiosome
Bypass	Neville Ann Vasc Surg, 2009	91% healed	62% healed
	Kret J Vasc Surg 2014	85% healed/1y	62% healed/1y
PTA/Bypass	Kabra J Vasc Surg 2013	96% healed/6m	83% healed/6m
PTA	Alexandrescu J Endovasc Ther 2008	83% healed	59% healed
	Alexandrescu J Endovasc Ther 2011	90% limb salvage/2years	78% limb salvage/2years
	Iida CCI 2010	86% limb salvage/2years	69% limb salvage/2years

# Angiosome Revascularization: Bypass vs PTA



# Recommendations for Critical Limb Ischemia: Endovascular and Open Surgical Treatment for Limb Salvage

*J. Am. Coll. Cardiol.* published online Sep 29, 2011

Class IIa

Balloon angioplasty



1. For patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less or in patients in whom an autogenous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal blood flow (54). (Level of Evidence: B)

New recommendation

Bypass



2. For patients with limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow (54). (Level of Evidence: B)

New recommendation

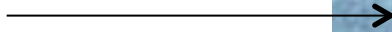
**PRACTICE GUIDELINE**

## 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (Updating the 2005 Guideline)

A Report of the American College of Cardiology Foundation/  
American Heart Association Task Force on Practice Guidelines

*Developed in Collaboration With the Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery*

Isolated dorsalis pedis artery



Bypass has a special role in patients with poor arterial anatomy

# Bypass first?

