Peripheral Artery Disease MEDCAC Panel July 22, 2015

GARY M ANSEL MD

VIVA Physicians

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

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  - Cook inc
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  - Medrad
- Stock
  - Arthrosurface
- Other
  - VIVA Physicians
  - Primacea

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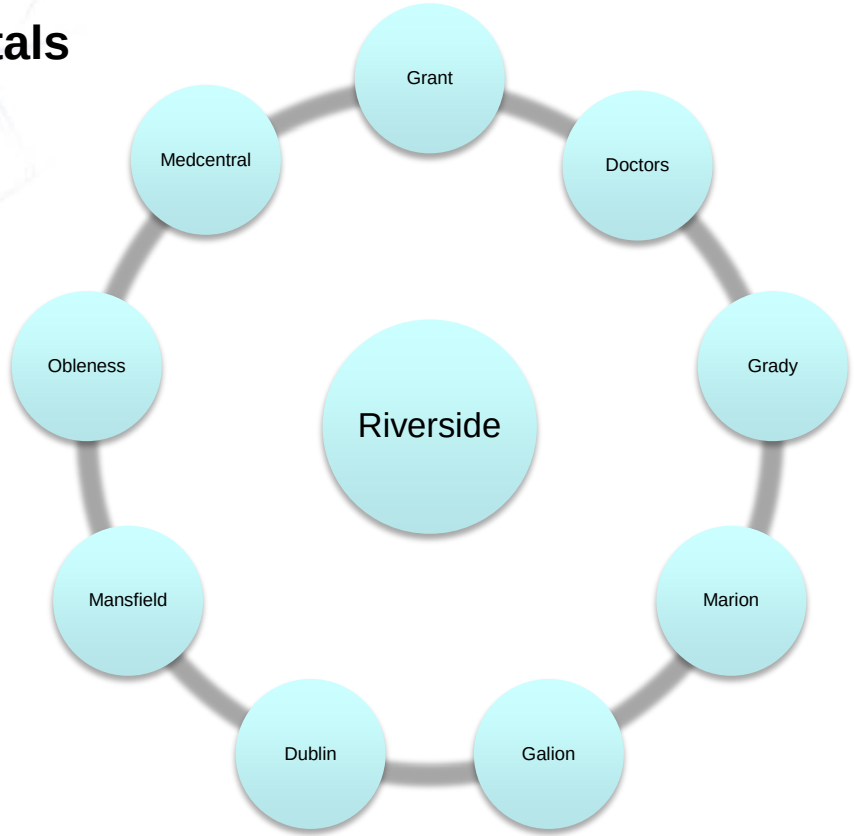
System Medical Chief: Vascular
Ohio Health
Columbus, Ohio

Types of Hospitals
- Tertiary Care
- Urban
- Rural
- Community



Physician Specialties
- Vasc. Surgery
- Thor. Surgery
- Int. Radiology
- Int. Cardiology
- Vascular Medicine

Physician Compensation
- Private
- Employed non RVU
- Employed RVU

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Voting Questions

For each voting question, please use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Confidence — Intermediate — High Confidence

1. For adults with asymptomatic lower extremity PAD, how confident are you that there is sufficient evidence for an intervention that improves:

    a. Immediate/near-term health outcomes?
    b. Long-term health outcomes?

Discussion:
- If intermediate confidence (≥ 2.5), please identify the specific intervention(s) and associated outcome(s).
- Considering the heterogeneity of the Medicare population, discuss which subgroups of the Medicare population the evidence shows are likely to benefit or likely not to benefit from intervention.

2. For adults with lower extremity ***intermittent claudication (IC)***, how confident are you that there is sufficient evidence for an intervention that improves:

    a. Immediate/near-term health outcomes?
    b. Long-term health outcomes?

Discussion:
- If intermediate confidence (≥ 2.5), please identify the specific intervention(s) and associated outcome(s).
- Considering the heterogeneity of the Medicare population, discuss which subgroups of the Medicare population the evidence shows are likely to benefit or likely not to benefit from intervention.

3. For adults with lower extremity critical limb ischemia (CLI), how confident are you that there is sufficient evidence for an intervention that improves:

    a. Immediate/near-term health outcomes?
    b. Long-term health outcomes?

Discussion:
- If intermediate confidence (≥ 2.5), please identify the specific intervention(s) and associated outcome(s).
- Considering the heterogeneity of the Medicare population, discuss which subgroups of the Medicare population the evidence shows are likely to benefit or likely not to benefit from intervention.

Additional Discussion Topics

4. Discuss the important evidence gaps that have not been previously or sufficiently addressed.

5. Discuss any apparent lower extremity PAD treatment disparities and how they may affect the health outcomes of Medicare beneficiaries.

Take Home Points

- Critical limb Ischemia is life threatening
- In experienced hands Endovascular treatment offers a low risk, highly successful option for improving arterial flow that compliments appropriate wound care
- Its less about technology and more about results and follow up

Critical Limb Ischemia (CLI)

- **Most severe form of Peripheral Arterial Disease (PAD).**
- **Over 100,000 lower extremity amputations are performed in the United States (US) every year for CLI.**

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Critical Limb Ischemia: Brittle patient population

- Ischemic rest pain, nonhealing wound, or gangrene; with presence of symptoms for > 2wks.
- The mortality for patients with critical limb ischemia is high

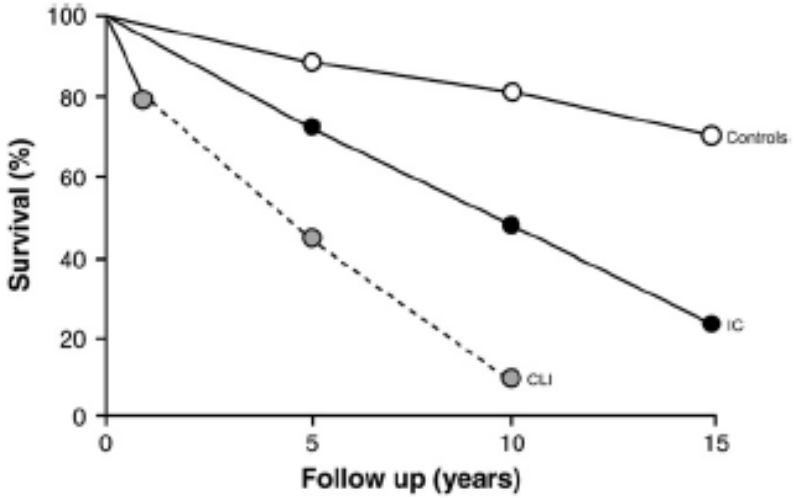

Fig. A8. Survival of patients with peripheral arterial disease. IC – intermittent claudication; CLI – critical limb ischemia.

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Defintion: Critical Limb Ischemia (CLI)

"limb pain that occurs at rest or impending limb loss that is caused by severe compromise of blood flow to the affected extremity"[1]

Fontaine		Rutherford		
Stage	Clinical	Grade	Category	Clinical
I	Asymptomatic	0	0	Asymptomatic
IIa	Mild claudication	I	1	Mild claudication
IIb	Moderate-severe claudication	I	2	Moderate claudication
		I	3	Severe claudication
III	Ischemic rest pain	II	4	Ischemic rest pain
IV	Ulceration or gangrene	III	5	Minor tissue loss
		IV	6	Ulceration or gangrene

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1 Circulation 2006; 113; e463-e465
2 Eur J Vasc Endovasc Surg 2007; 33: S5-S75

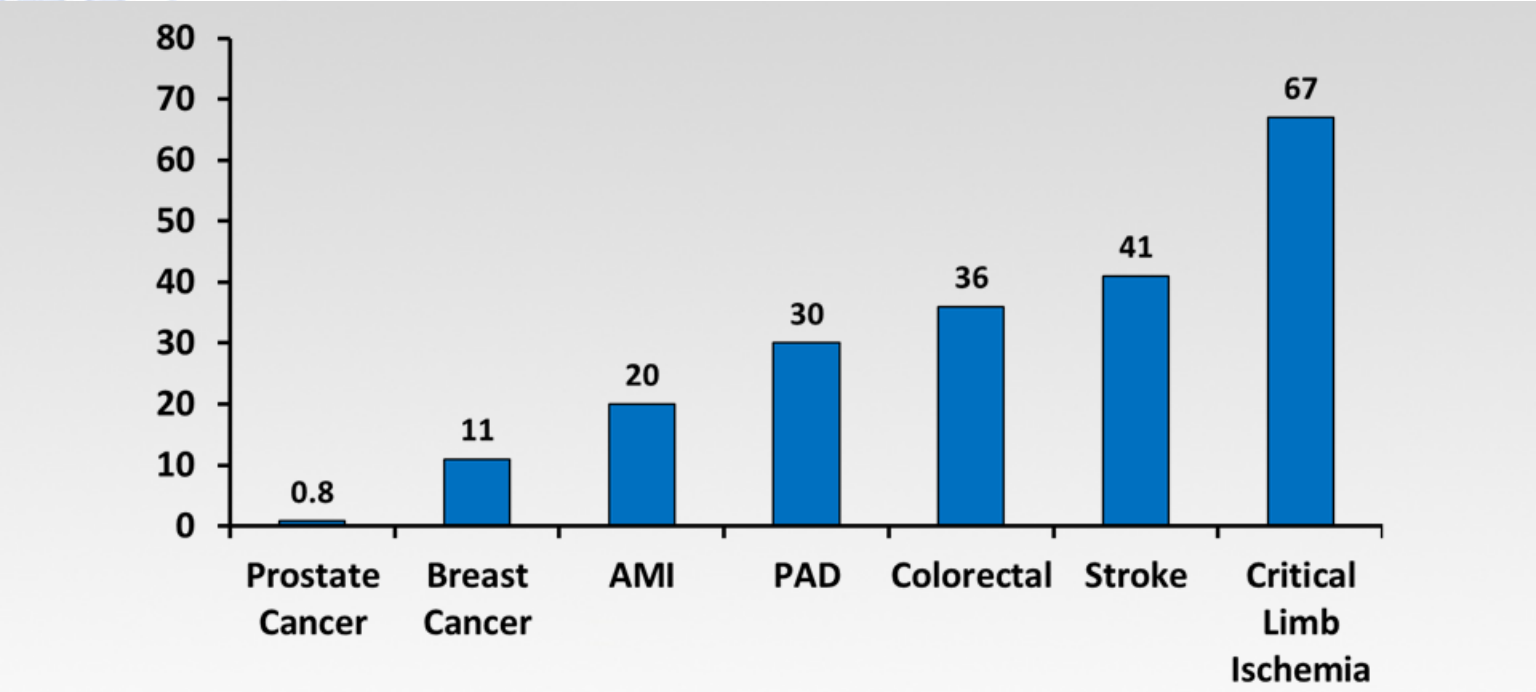
Rutherford Categories

Rutherford 4
Rest pain

Rutherford 5
Minor tissue loss

Rutherford 6
Major tissue loss

5-Year Mortality for CLI Higher than Common Cancers



a. http://seer.cancer.gov/statfacts/html/prost.html; b. http://seer.cancer.gov/statfacts/html/breast.html; c. Kaul P, et al. *Circulation*. 2004;110:1754-1760; d. Weitz JI, et al. *Circulation*. 1996;94:3026-3049; e. http://seer.cancer.gov/statfacts/html/colorect.html; f. Hartmann A, et al. *Neurology*. 2001;57:2000-2005; g. Ljungman C, et al. *Eur J Vasc Endovasc Surg*. 1996;11:176-182.

Interventional & Surgery

theheart.org from WebMD

Medscape EDUCATION

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Management of Critical Limb Ischemia

Goals of Treatment

- Restore adequate perfusion to the limb
- Reduce or eliminate ischemic pain
- Achieve wound healing, improve function, and limb salvage
- Keep patient ambulatory and functioning

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Vascular Considerations in CLI

- Most patients are diabetic
- Collateral formation around occlusions less in diabetic population
- Restoration of arterial flow to the foot is more important than in nondiabetic population
- Need to restore tibial pressure > 50mmHg
- Angiosome Base Straight line flow important when plantar arch is diseased
- May need to open plantar arch
- A good wound care program plays a large role in successful outcomes

Diabetics with Ischemic Foot Ulcer
N= 417

- Infrapop lesions 74%
  - > 10 cm lesions 66%
- Occlusions 66%
  - > 10 cm occlusions 50%

- Occlusions as a % of all lesions
  - Posterior tibial 84%
  - Anterior tibial 66%
  - Peroneal 42%

Graziani l et al. EJVES 2007; 33:453

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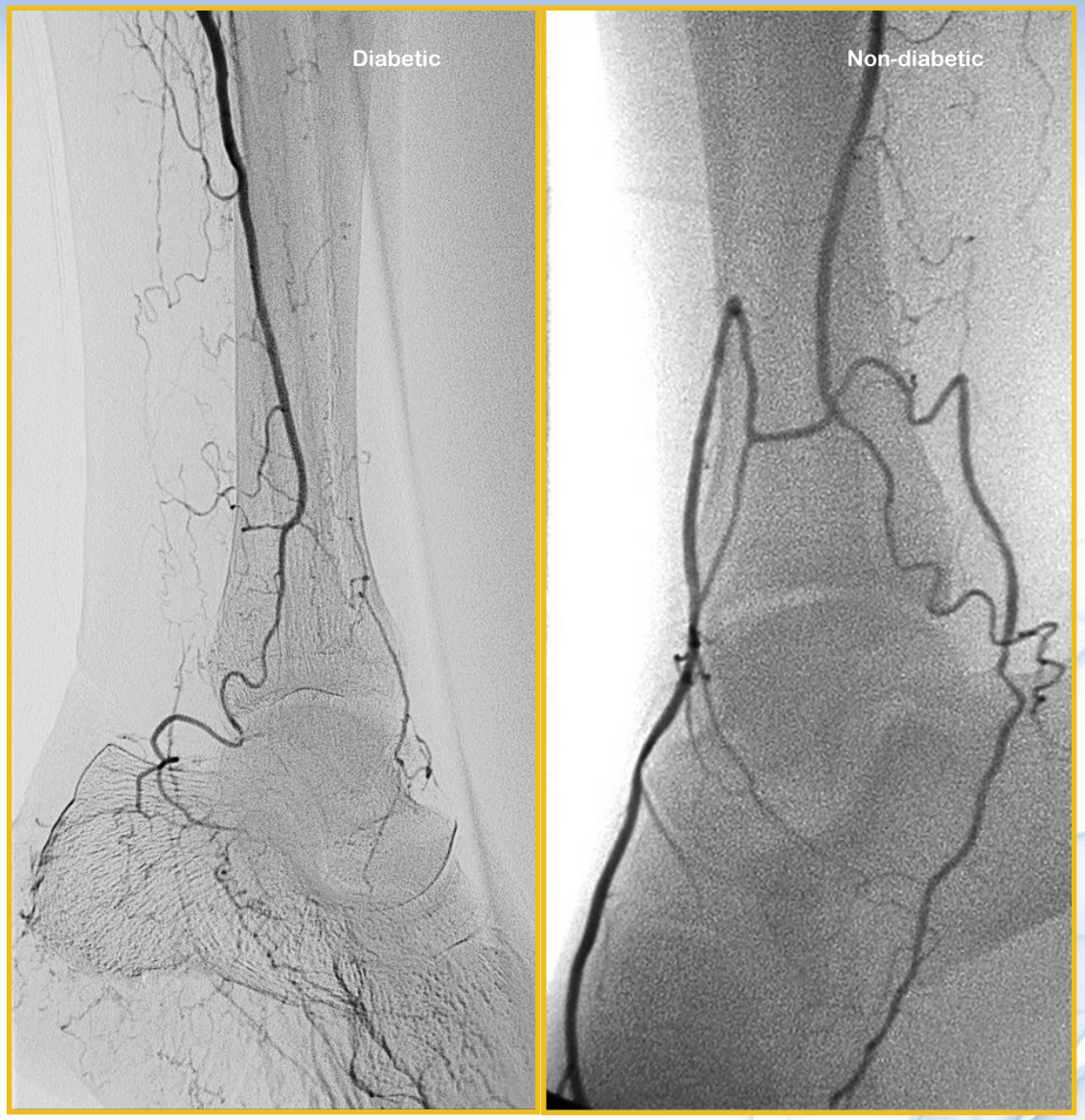
Underlying disease affects Pathology:

In diabetes and renal failure we may have *functional* end arteries due to poor collaterals formation



1.Abaci. Circulation. 1999;99:2239–2242.
2.Weihrauch. Circulation. 2004;109:2343-2348.
3.Ada. Circulation Res. 2006;99:140-148.
4.Boodhwani. Circulation. 2007;116:I-31–I-37.
5.van Golde. Diabetes. 2008;57:2818-2823.
6.Ruiter. Clinical Science. 2010;119:225–238.

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Revascularization: Cornerstone of Treatment

- Surgical Bypass and Endovascular Treatments have matured
- No treatment should be excluded
- Optimal treatment defined by specific patient and anatomy but data still needed to delineated specific populations

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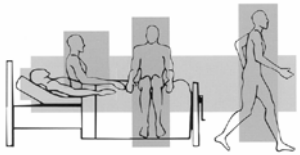
Revascularization Management of Critical Limb Ischemia



Surgical

- When Endo not possible
- Conduit available
- Acceptable surgical skills
- Large tissue destruction
- Poor endo expertise
- Targets acceptable

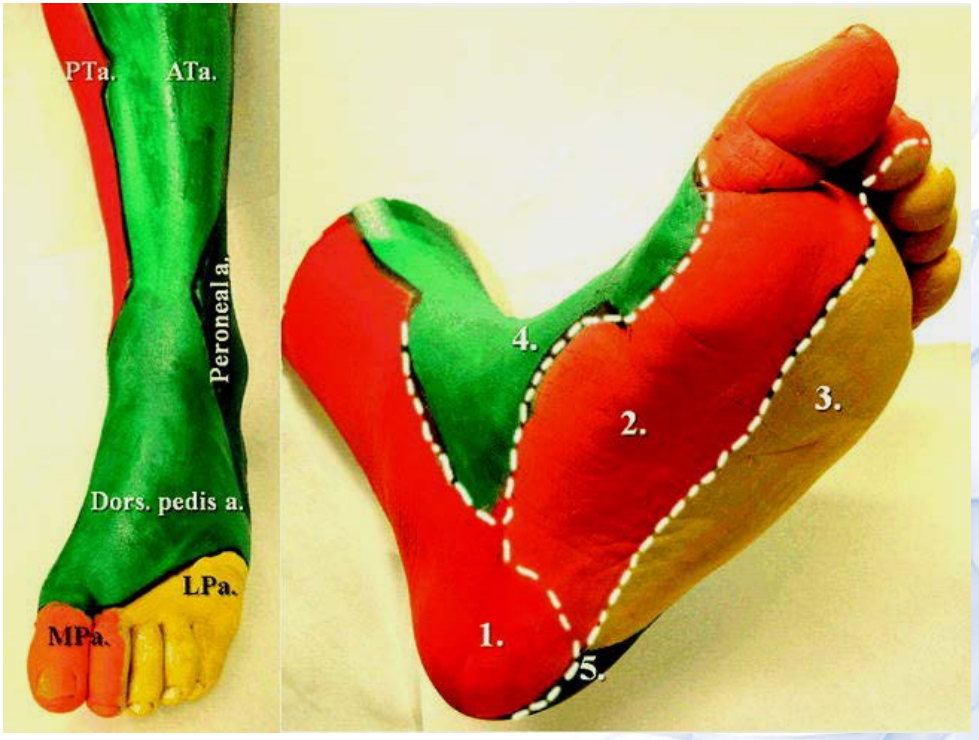
Endovascular

- Technically Possible
- Antiplatelet meds acceptable
- Acceptable renal function
- Follow-up assured
- Advanced operator skills
- Poor targets for bypass

The Angiosome Model Theory* (1998) Leading to Improved Outcomes

- **6 angiosomes of the leg and foot are supplied by 3 main arteries…**
- **In the article, leg and foot arteries are defined "end arteries" supplying 6 angiosomes**

From: J Endovasc Ther. 2008;15:580–593



** Taylor, GI, Pan WR. Plast Reconstr Surg. 1998;102:599-616*

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Since 1993: 15% Major Amputation Is Reported in Subjects With Patent Fem-Distal Bypass if the Artery Feeding the Wound Is Not Directly Perfused

- **Elliott BM. J Vasc Surg. 1993; 18:881-888**
- **Johnson BL. J Vasc Surg. 1995; 22:280-286**
- **Parsons RE. J Vasc Surg. 1998; 28:1066-1071**
- **Berceli SA. J Vasc Surg. 1999; 30:499-508**
- **Treiman GS. J Vasc Surg. 2000; 31:1110-1118**
- **Lofberg AM. J Vasc Surg. 2001; 34:114-121**

In 1998 this evidence generated the

"Angiosome Model Theory"

Taylor, GI, Pan WR. Plast Reconstr Surg. 1998;102:599–616

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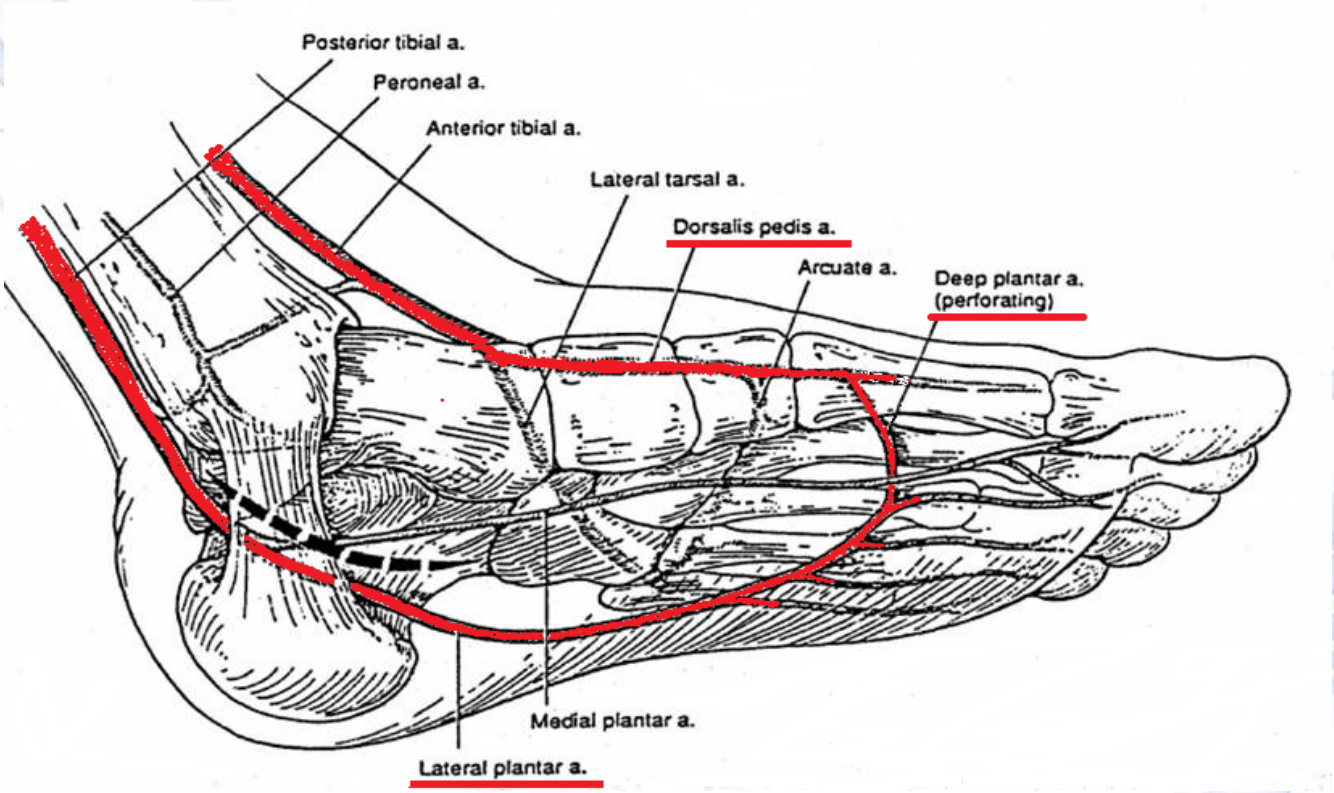
The Plantar Arch: Anastomosis of the Lateral Plantar artery with the Deep Plantar branch of the DP artery.



Anastomosis: a natural bypass to prevent necrosis in case of occlusion of one of the two arteries feeding the same area.

Dorland's Medical Dictionary 2007, W.B. Saunders, Philadelphia, USA

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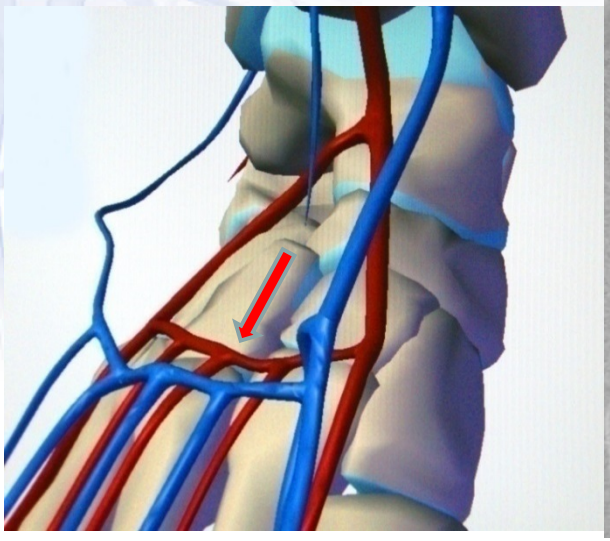
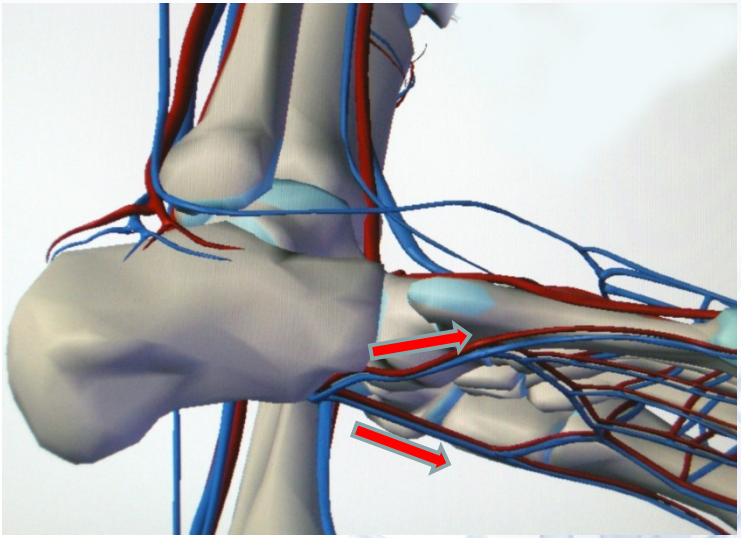
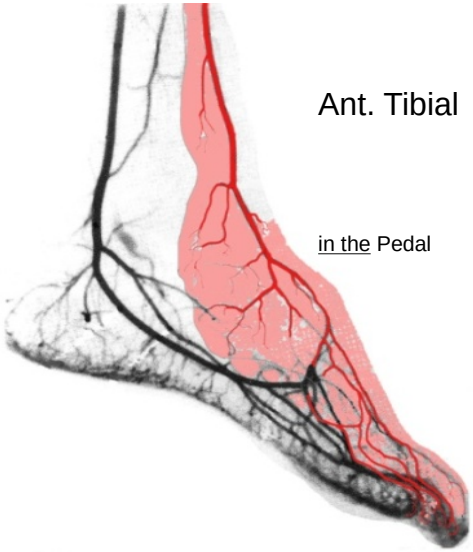
Angiosome Model

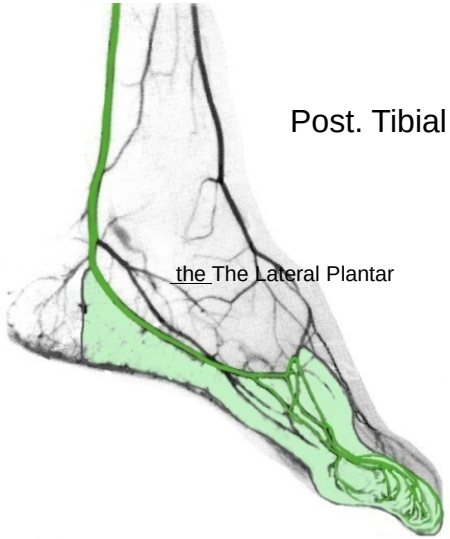






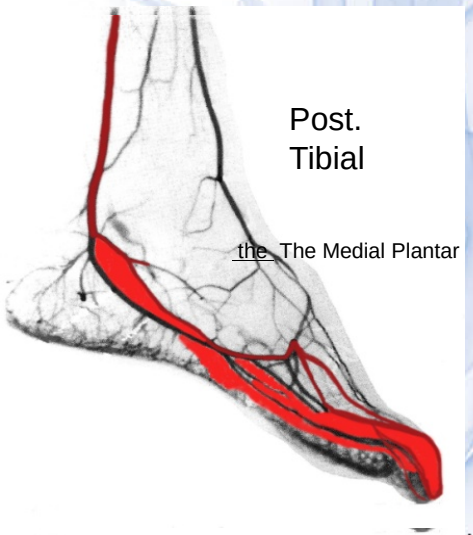
Ant. Tibial

in the Pedal



Post. Tibial

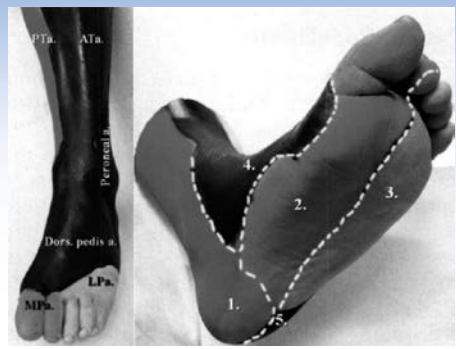
the The Lateral Plantar



Post. Tibial

the The Medial Plantar

After the re-establishment of the forefoot flow ,



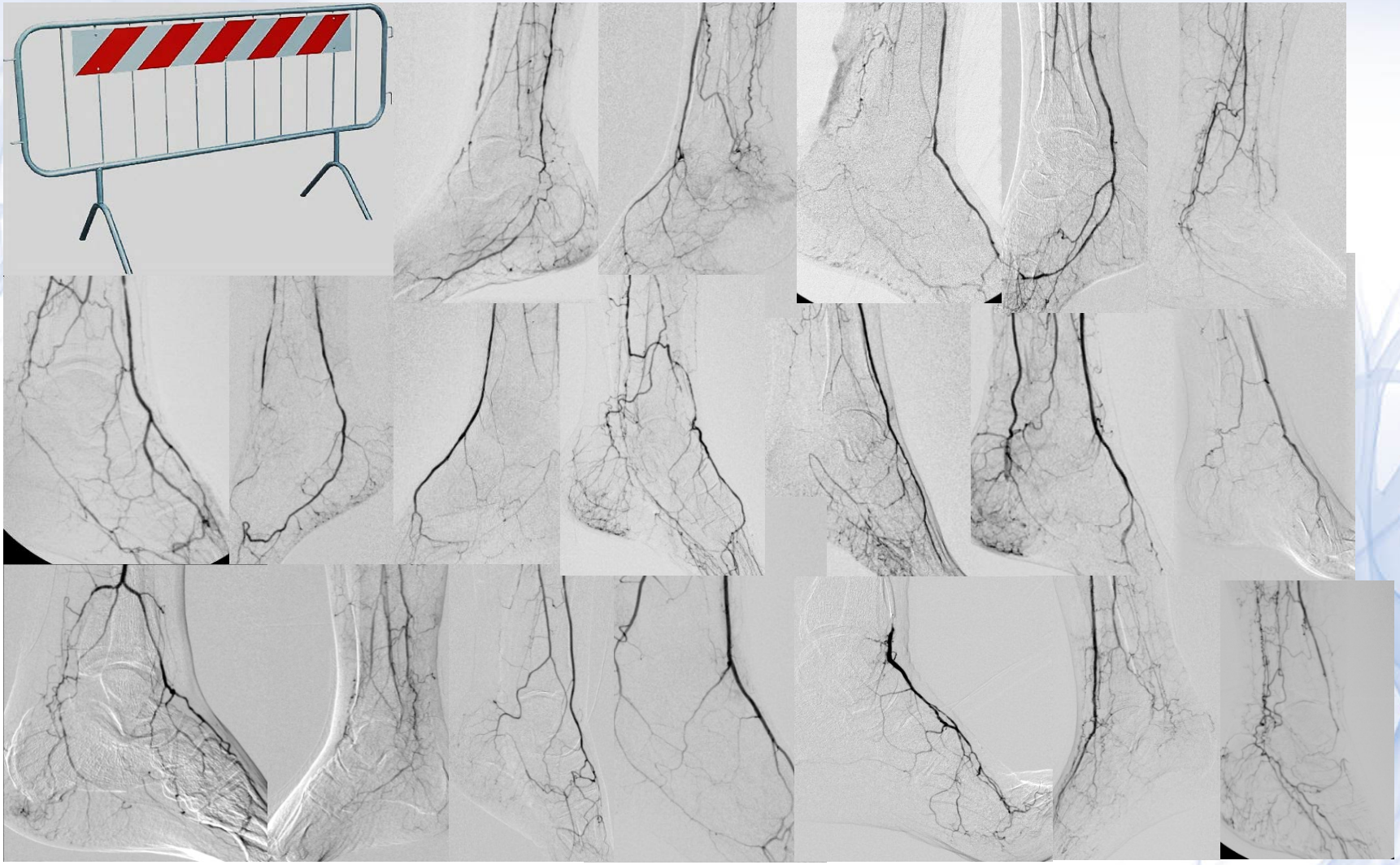
Method of Revasc	Appropriate Angiosome Treated	Boundary Angiosome Treated
PTA	83% healed	59% healed
Bypass	91% healed	62% healed

Alexandrescu et al.
J Endovasc Ther 2008;15:580

Neville et al.
Ann Vasc Surg 2009;23:367

Cause of Failure

Plantar Arch Interruption Was Found in Almost All Amputees



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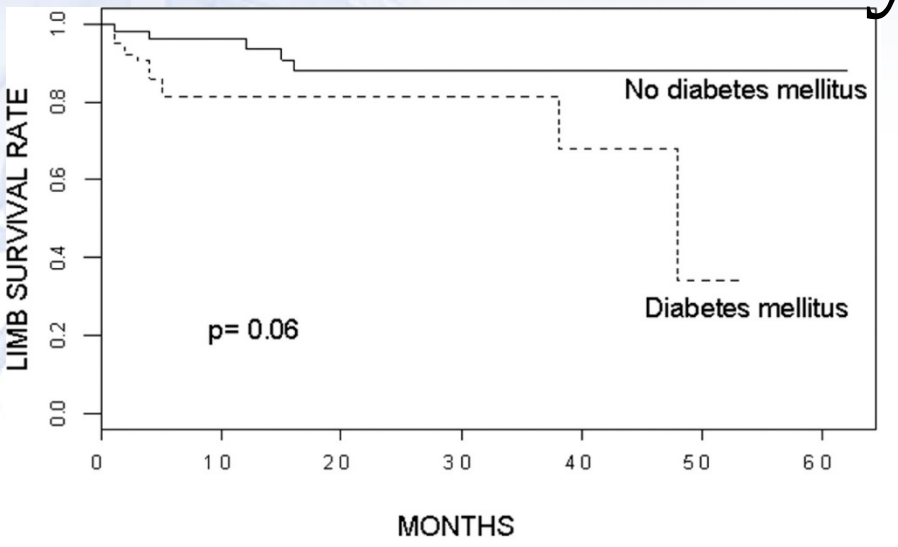
CLI in Dialysis Patients



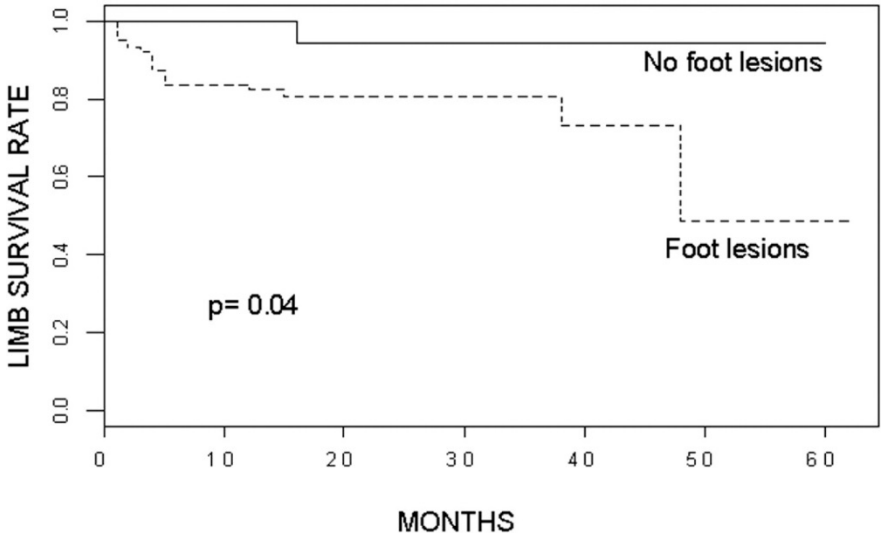


Table II. Independent predictors of primary amputation on multivariate analysis

	P	Odds ratio (95% CI)
Major tissue loss	0.002	5.5 (1.82-16.58)
ESRD	0.005	5.3 (1.62-17.60)
DM	0.03	3.0 (1.06-8.24)
Nonambulatory status	0.05	2.5 (1.01-6.25)

CI, confidence interval.

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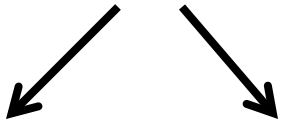
Critical Limb Ischemia

CLI documented:
ABI less than 0.4; flat PVR waveform; absent pedal flow

Systemic antibiotics if skin ulceration and limb infection are present

Obtain prompt vascular specialist consultation:
- Diagnostic testing strategy
- Creation of therapeutic intervention plan



Patient is not a candidate for revascularization

Medical therapy
or amputation (when necessary)

Patient is a candidate for revascularization

Hirsch AT, et al. *J Am Coll Cardiol.* 2006;47:e1-e192.

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Critical Limb Ischemia

When is Patient not candidate for revascularization

- Non-ambulatory
- No target vessel
- Uncooperative((endo) and high surgical risk
- Too much tissue destruction
- Pt preference for amputation

Hirsch AT, et al. *J Am Coll Cardiol.* 2006;47:e1-e192.

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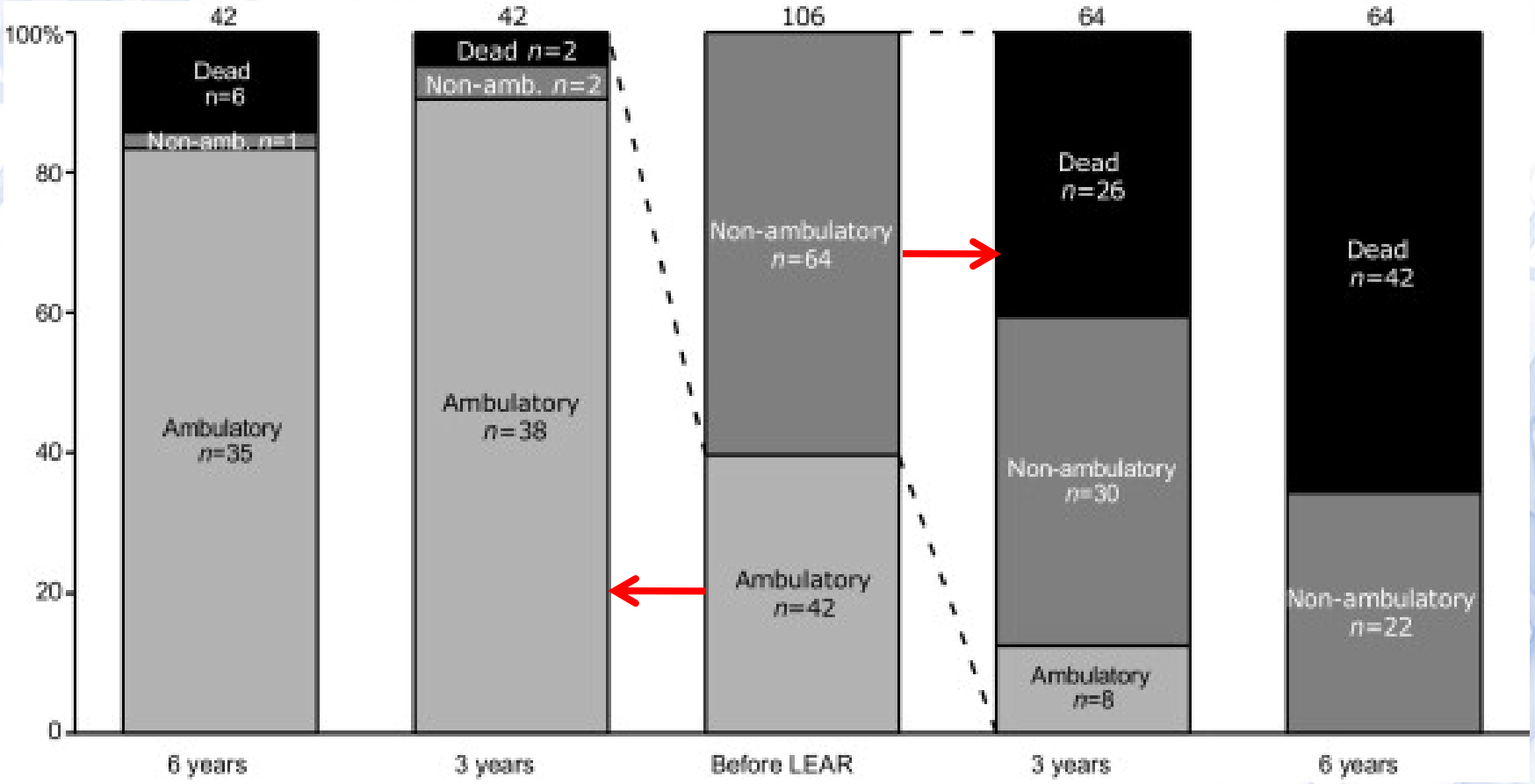
Critical Limb Ischemia

Revascularization in Nonambulatory Patients



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Critical Limb Ischemia

Patient is a candidate for revascularization

Angiographic assessment

Surgical vs. Endovascular Revascularization

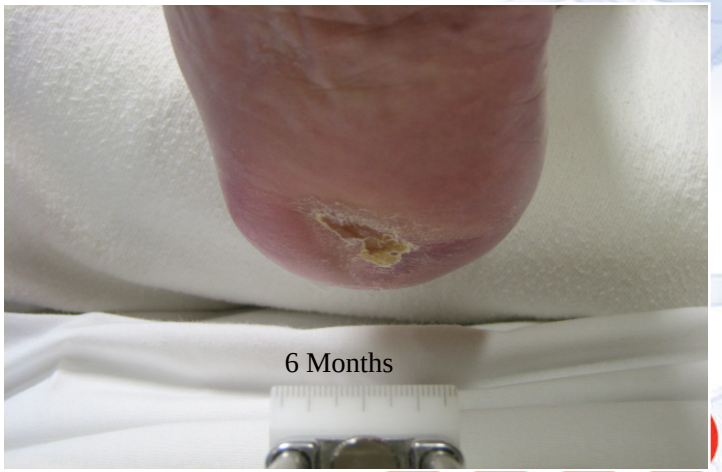
Critical Limb Ischemia

CHOICE VARIABLES

- Number of vasc. levels involved
- Plantar arch patency
- Amount of tissue destruction
- Presence of infection
- Need of debridement or skin grft
- Available conduit for bypass
- Comorbidity
- Nutritional status

Gary Ansel, MD

Healed Wounds



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Limb Salvage

Off loading

Wound care

medical therapy?

LIMB SALVAGE

Straight Line Flow Revascularization

Modern Management of CLI

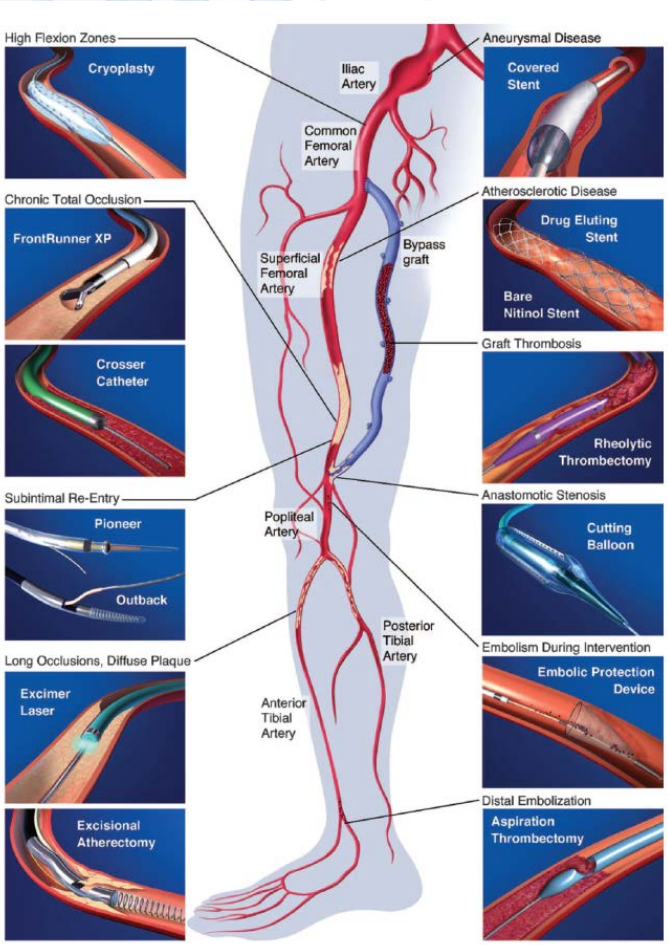


Figure 1. Overview of new technologies for lower extremity revascularization.

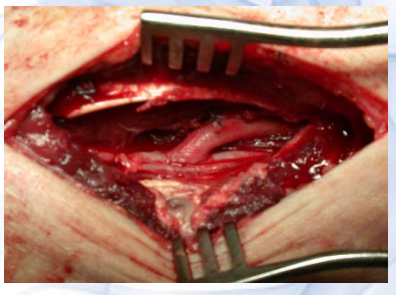
<u>Revascularization Options</u>

Surgical

- Vein vs. Prosthetic bypass

Endovascular

- Balloon angioplasty
- Stent
- Cryo-angioplasty
- Atherectomy
- Laser



Wound care

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Acute Success and 1 year Results of Endovascular Limb Salvage Procedures

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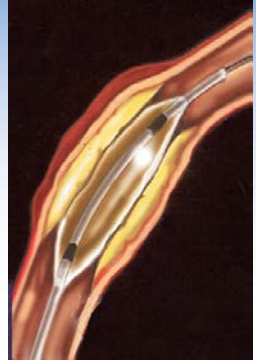
Single Center Results: Tibial PTA for Limb salvage



- N = 993
- 1999-2003
- Basic balloon angioplasty with slow, long inflations
- Over 95% acute technical success
- 5-year limb salvage 88%
- Need for repeat procedure 12.7%

Gratziani et al. Eur J Vasc Endovasc Surg 2005

LACI Laser Trial: 6-Month Results

Total enrollment		**155 limbs**
death		**17**
lost to follow-up		**11**
Reached 6-month follow-up	**127**	
Major amputation among survivors	**9**	
Survival with limb salvage	**118/127 = 93%**	

Recent PTA for CLI Results
Control arm: In.Pact Deep Randomized Multicenter Study

- N = 119
- Average lesion length 12.9 ±9.5cm
- 1-year outcomes
  - TLR = 13.1%
  - Major amputation = 3.5%
  - Death, major amp, TLR = 23.4%

Am Coll Cardio. 2014 Oct 14;64(15):1568-76.

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Longer-Term Results of Endovascular Limb Salvage Procedures

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Single Center Results: Tibial Angioplasty for Critical Limb Ischemia

Tibioperoneal (Outflow Lesion) Angioplasty Can Be Used as Primary Treatment in 235 Patients With Critical Limb Ischemia

Five-Year Follow-Up

Gerald Dorros, MD; Michael R. Jaff, DO; Ari M. Dorros, MD;
Lynne M. Mathiak, RN; Thomas He, PhD

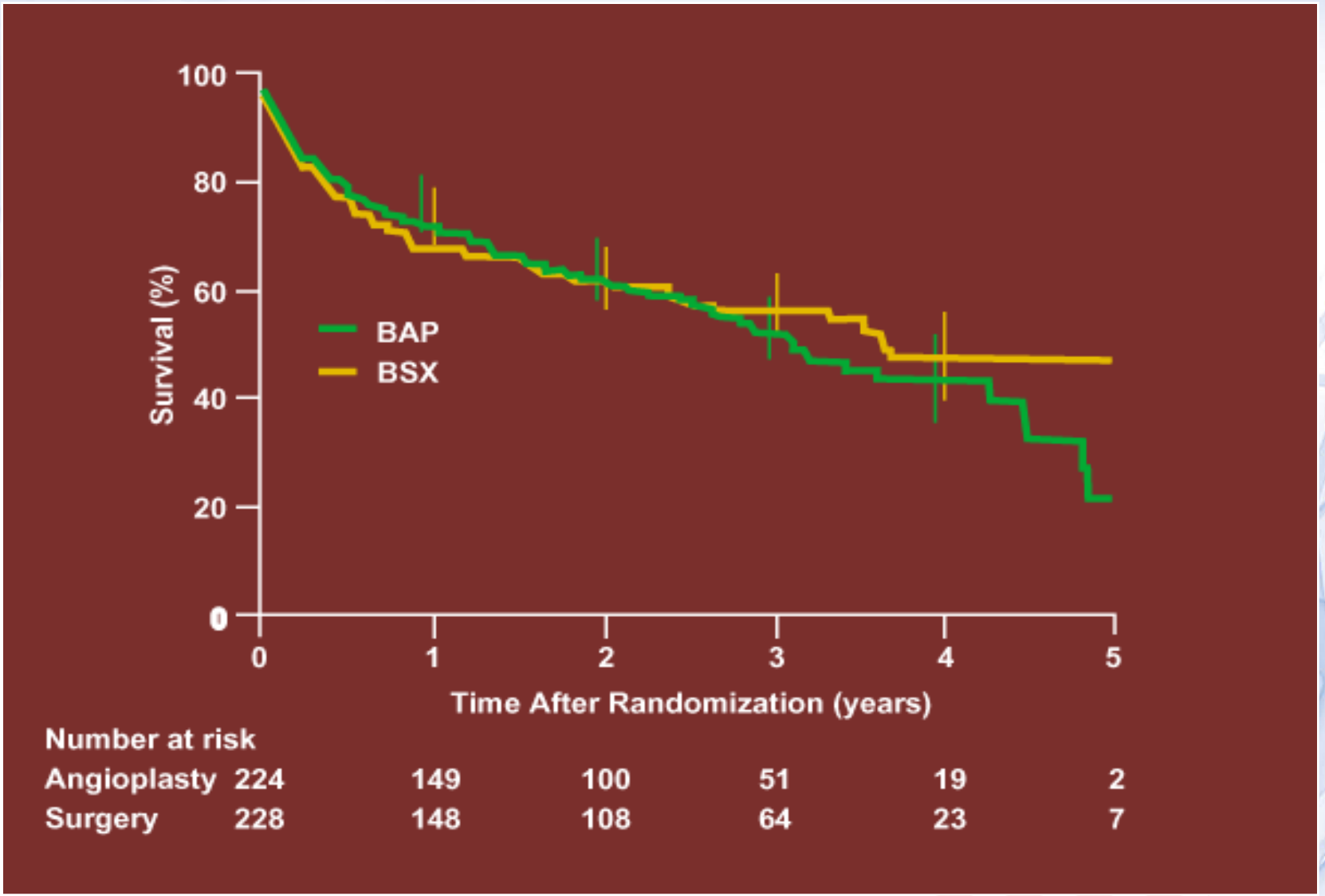
Background—In a prospective, nonrandomized, consecutive series of tibioperoneal vessel angioplasty (TPVA), critical limb ischemia (CLI) patients' data were analyzed with regard to immediate and follow-up success.

Methods and Results—TPVA was successful in 270 of 284 critically ischemic limbs (95%), with 167 limbs (59%) requiring dilatation of 333 ipsilateral inflow obstructions to access and successfully dilate 486 of 529 (92%) tibioperoneal lesions. A clinical success (relief of rest pain or improvement of lower-extremity blood flow) was attained in 270 limbs at risk (95%). Clinical 5-year follow-up of 215 of 221 successful CLI patients (97%) with 266 successfully revascularized limbs revealed that bypass surgery occurred in 8% and significant amputations in 9% of limbs; 91% of the limbs were salvaged. The cohort's probability of survival was 56%: 58% for Fontaine class III and 33% for class IV patients. Class III compared with class IV patients had significantly ($P<0.05$) fewer surgical bypasses (3% versus 16%) and amputations: above-knee, 1% versus 4%; below-knee, 3% versus 12%; and transmetatarsal, <1% versus 21%.

Conclusions—TPVA, often in combination with inflow lesions, is an effective primary treatment for critical limb ischemia. The poor cumulative survival reflects the existence of severe comorbidities, which could potentially be affected by aggressive and effective cardiovascular diagnostic and therapeutic strategies. (***Circulation.*** **2001;104:2057-2062.**)

Key Words: angioplasty ■ peripheral vascular disease ■ surgery ■ vasculature

BASIL Trial: Amputation-Free Survival



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Recently Published PTA in CLI Meta-analysis

- 30 articles (1990-2006):
  - At least 15 infrapopliteal PTAs reported with 12 mo follow-up; RC 4-6
  - Reported 12 mo cumulative patency or limb salvage
  - Assessed: Immediate technical success, 1º/2º patency, limb salvage, patient survival

- Comparison to distal fem-tibial bypass surgery

Romiti M, Albers M, Brochado-Neto FC, Durazzo AE, et al. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. J Vasc Surg. 2008;47:975-981

Meta-analysis results of crural percutaneous transluminal angioplasty and popliteal-to-distal bypass

Result	1 month	6 months	1 year	2 years	3 years
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
P	< .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
P	*< .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

[a] *NA, Estimates not available; PTA, percutaneous transluminal angioplasty.*
Values are pooled estimate and standard error.

VASCULAR INTERVENTIONAL ADVANCES

Why have non surgical treatments grown

Even in surgical community?

- Brittle population
- Morbidity and Mortality associated with bypass
- No targets for bypass
- Suboptimal conduit

Prevent III Trial: Double Blinded RCT
Autogenous Vein Bypass for CLI ± E2F Decoy

- 2001 – 2003
- 1404 CLI patients undergoing autogenous vein bypass
  - Randomized to molecular E2F Decoy vs. placebo
- Largest prospective study of vein bypass for CLI
- Allowed enrollment of patients
- With complex co-morbid conditions (including renal failure)
  - Requiring complex bypass procedures (including splice vein)
- Study population reflects current ‘real world’ practice for treatment of CLI

Conte MS et al. J Vasc surg 2006;43:742-51

VIVA VASCULAR INTERVENTIONAL ADVANCES

Prevent III Trial: Double Blinded RCT
Autogenous Vein Bypass for CLI ± E2F Decoy

- Mean Age: 69 ± 12 years
- HTN: 82%, Smoking: 74%, Hyperlipidemia: 55%
- CAD: 48%, Renal failure: 12%

- CLI with tissue loss: 75%
- High risk vein conduit (inadequate vein): 24%
- Re-operative bypass: 16%
- Infra-popliteal distal anastomosis: 65%

VIVA VASCULAR INTERVENTIONAL ADVANCES

Prevent III Trial: Double Blinded RCT
Autogenous Vein Bypass for CLI ± E2F Decoy

1404 Autogenous Vein Bypasses

- Perioperative mortality: 2.7%
- Vein graft occlusion: 5.4%

- Primary Patency: 61%
- Primary Assisted Patency: 77%
- Secondary Patency: 80%
- Limb Salvage: 88%

Findings Consistent with
Most Contemporary
Vein Bypass CLI Studies

VIVA VASCULAR INTERVENTIONAL ADVANCES

Conte MS et al. J Vasc surg 2006;43:742-51

Objective Performance Goals: Surgical Treatment for CLI

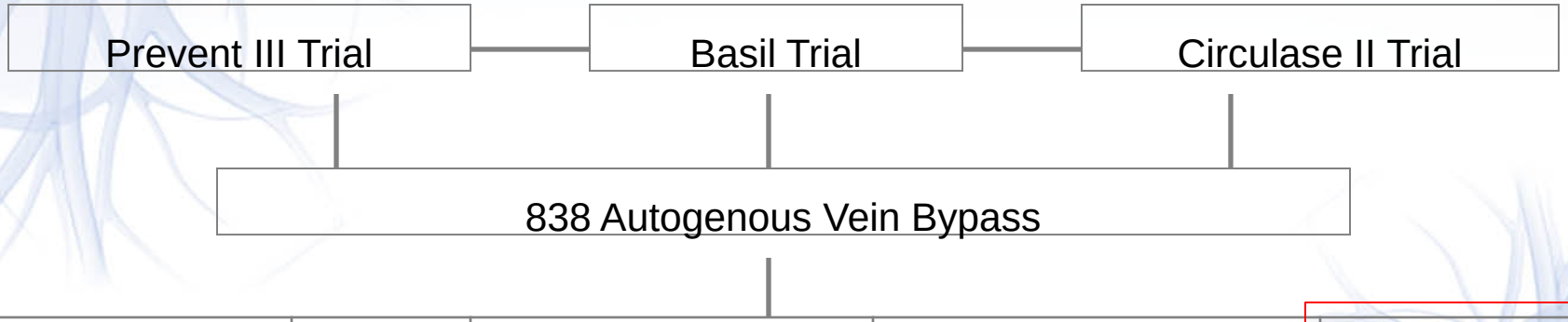
Prevent III Trial — Basil Trial — Circulase II Trial

- Pooled data: Surgical bypass for CLI
- Exclude: Test-drug treatment, Prosthetic, Renal Failure
- MACE: Major adverse cardiac events, 6.2%
- MALE: Major adverse limb events
  - Amputation, major reinvervention (thrombolysis, bypass, interposition)
- MALE (+): MALE + perioperative 30-day mortality

Conte MS et al. J Vasc surg 2006;43:742-51

VIVA VASCULAR INTERVENTIONAL ADVANCES

Objective Performance Goals: Surgical Treatment for CLI



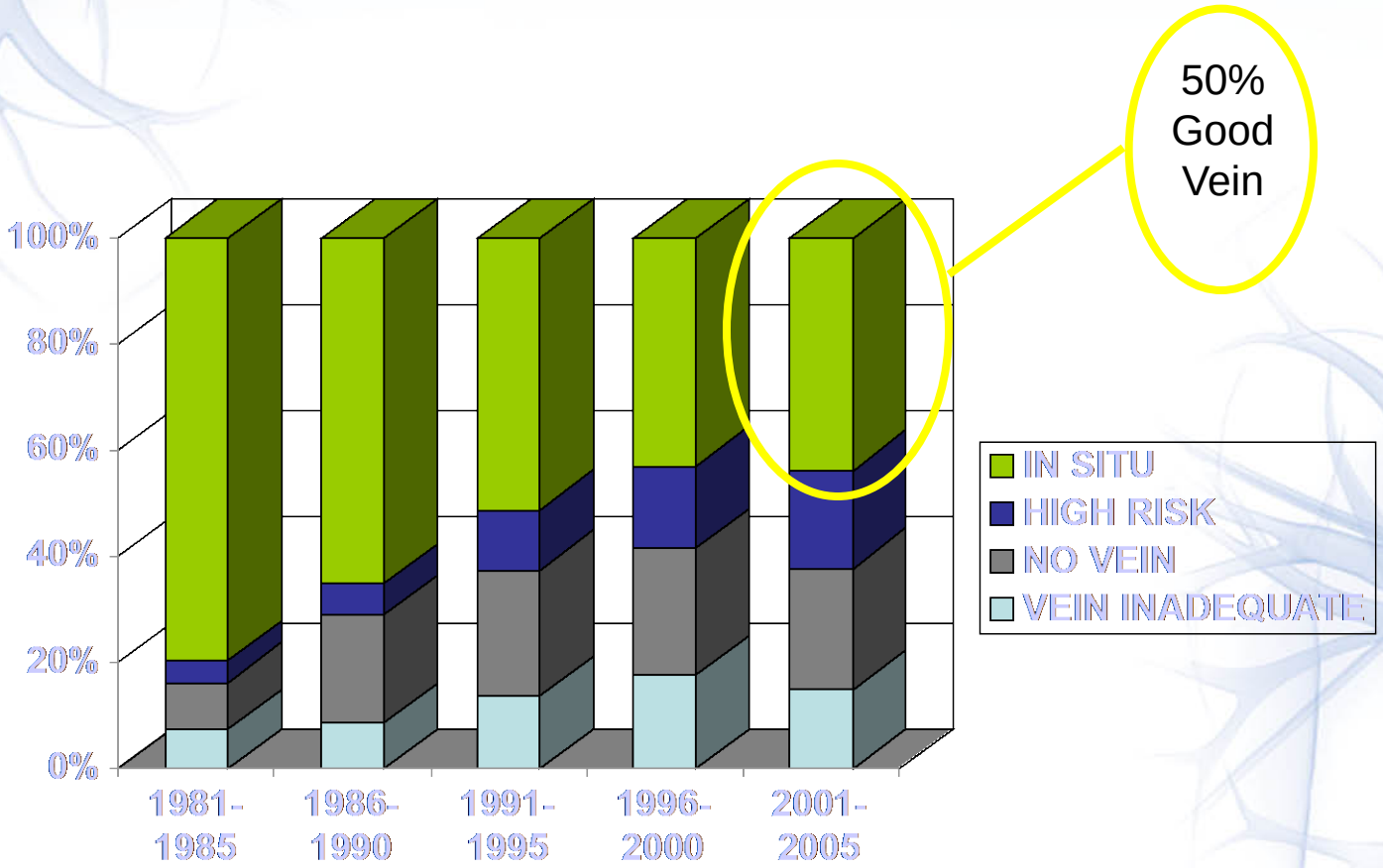
	All Pts.	Age 80 yr + Tissue loss		Infrapop.Outflow Anatomy		High Risk Conduit	
		+	-	+	-	+	-
N	838	136	702	505	333	163	442
MALE +	77%	69%*	78%	74%*	81%	69%*	79%
AFS	77%	61%*	80%	74%	80%	76%	79%

* p<0.05: Proportion free of adverse events

Conte MS et al. J Vasc surg 2006;43:742-51

VIVA VASCULAR INTERVENTIONAL ADVANCES

How Often is Autogenous Vein Conduit Present?



VIVA
VASCULAR
INTERVENTIONAL
ADVANCES

Albany Vascular Institute for Health & Disease Experience: 1981-2005

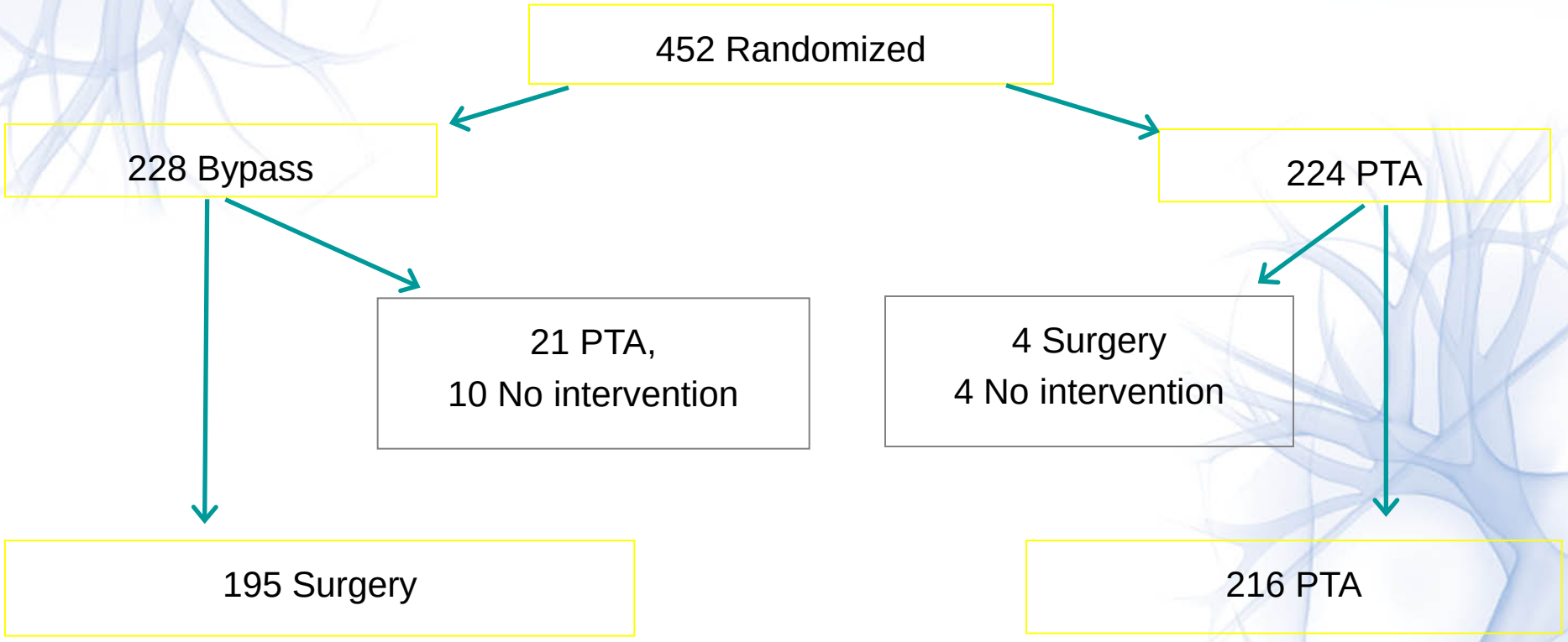
Modern Management of CLI

BASIL Trial

- Multicenter Randomized (1:1) Surgery or Angioplasty First
  - Primary Outcome
    - Amputation Free Survival & Death
  - Secondary Outcomes
    - All Cause Mortality
    - 30-day Morbidity and Mortality
    - Re-interventions
    - Health Related Quality of Life (EuroQol & SF36)
    - Use of Hospital Resources

VIVA VASCULAR INTERVENTIONAL ADVANCES

BASIL Trial

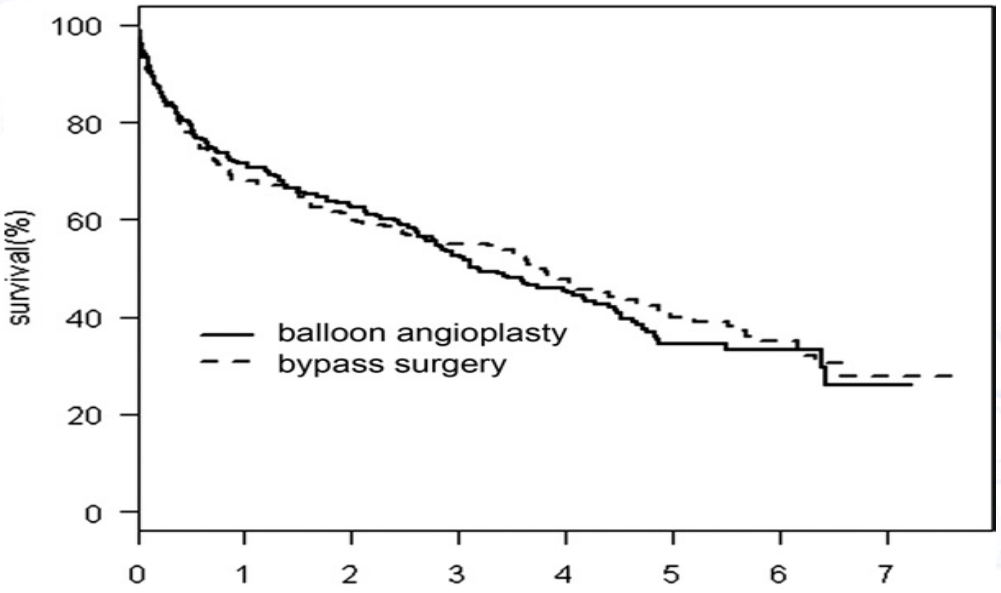


Bradbury el al. J Vas Surg 2010;51:5S-17S

VIVA VASCULAR INTERVENTIONAL ADVANCES

BASIL Trial

Amputation free survival -



At risk								
Balloon angioplasty	224	160	139	117	87	41	16	5
Bypass surgery	228	154	138	124	93	53	24	6

VIVA
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INTERVENTIONAL
ADVANCES

BASIL Trial: < 2 Years

- Surgery First Strategy
  - Increased morbidity (wound infections)
  - Increased hospital length of stay
  - Increased cost
  - NO difference in 30-day mortality
- PTA First Strategy
  - Significantly increased immediate failure

Bradbury el al. J Vas Surg 2010;51:5S-17S

VIVA VASCULAR INTERVENTIONAL ADVANCES

BASIL Trial: Beyond 2 Years

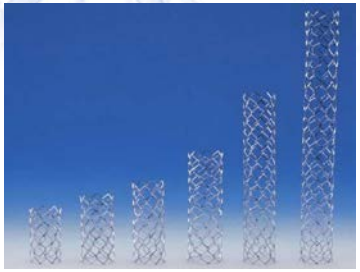
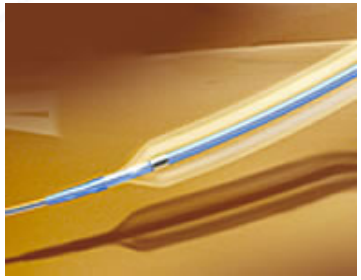
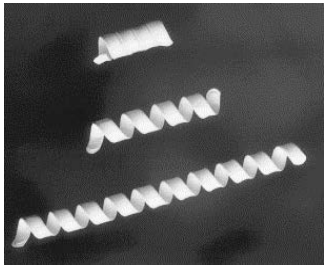
- <u>Surgery First Strategy</u>
- Significantly Better Mortality (p=0.02)
  - Trend towards Better Amputation Free Survival (0.06)
  - No difference in cost

Bradbury el al. J Vas Surg 2010;51:5S-17S

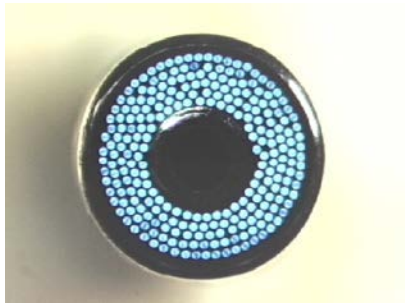
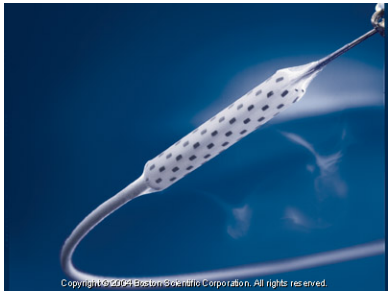
VIVA VASCULAR INTERVENTIONAL ADVANCES

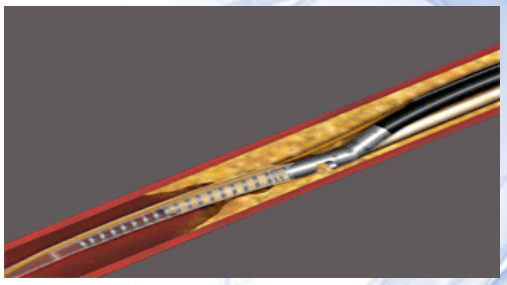
Many Technologies not available for Basil Trial

- Significant a

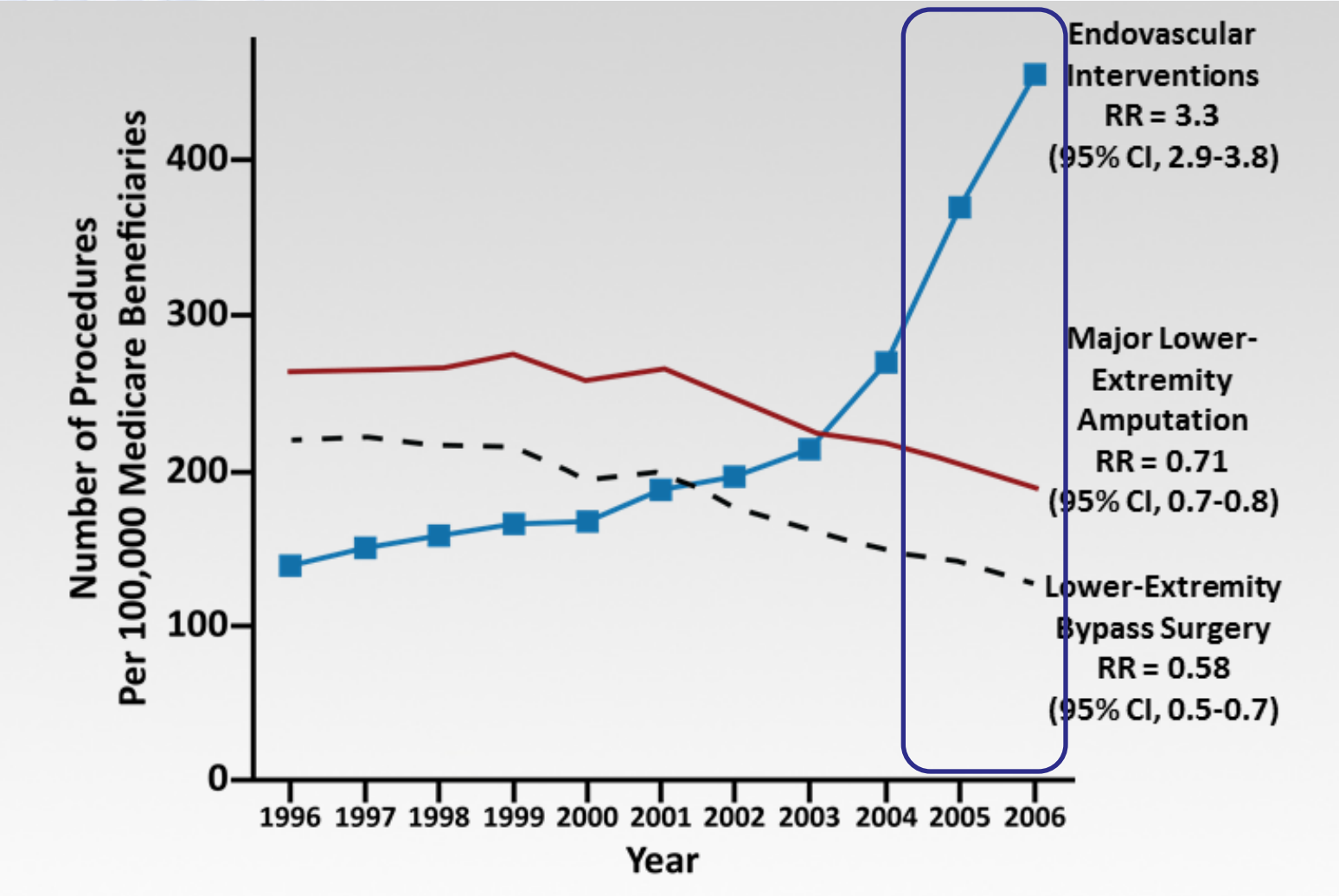


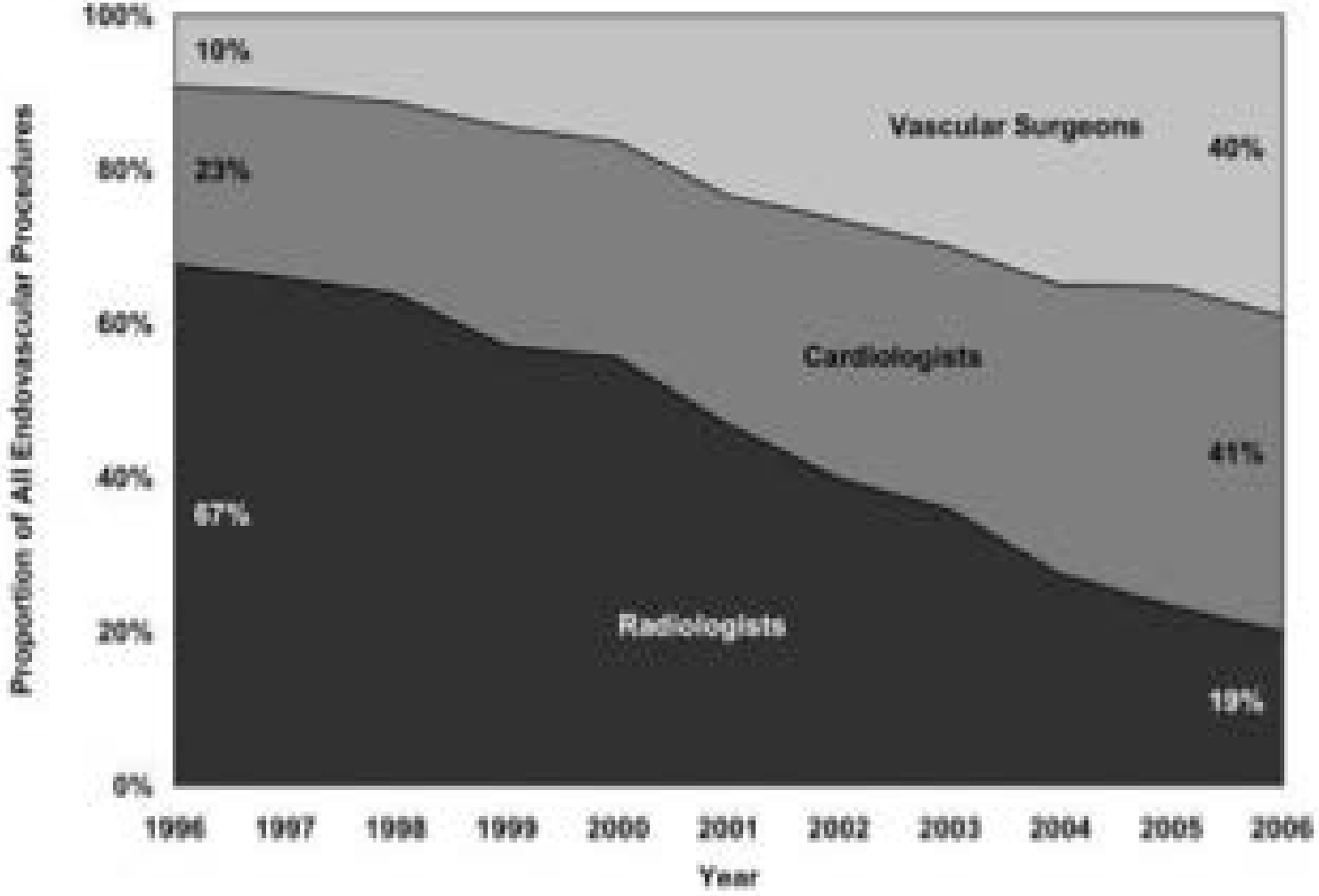


VIVA VASCULAR INTERVENTIONAL ADVANCES

Decade of LE Endovascular Interventions



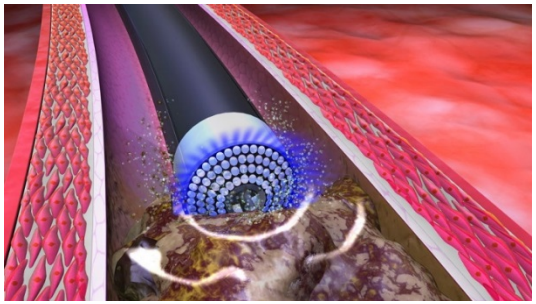
VIVA VASCULAR INTERVENTIONAL ADVANCES

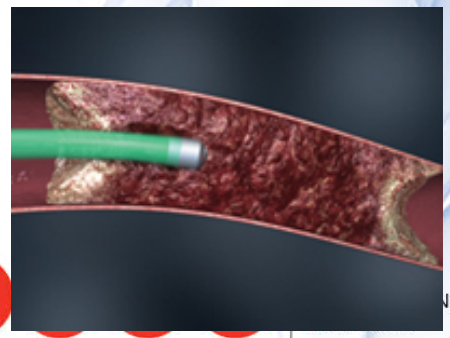


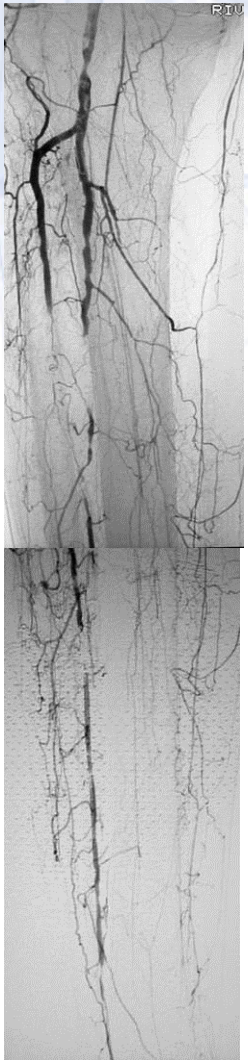
Goodney et al. J Vasc Surg 2009;50:54-60

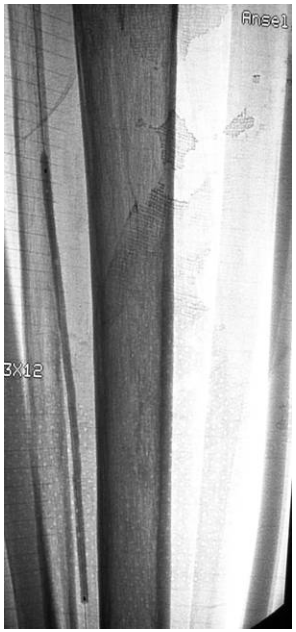
Complex Infra-inguinal Technology Directed at CTO and Calcifications

- Guidewires and support catheters
  - 0.014in coronary CTO wires
- Re-entry devices (with care)
- Differential dissection
- CTO devices for BTK
- PTA/Cryoplasty/Laser/Atherectomy/Stent
- Tibial retrograde options









- Long balloon
- Inflate very slowly
- Long inflations

Gary Ansel, MD

VASCULAR
INTERVENTIONAL
ADVANCES

Pedal Puncture

Plantar arch PTA

VIVA VASCULAR INTERVENTIONAL ADVANCES

BEST-CLI

Best **E**ndovascular versus Best **S**urgical **T**herapy
in Patients with **C**ritical **L**imb **I**schemia

Take Home Messages for Now

- **Modern management of CLI is a balance between arterial or conduit patency vs limb preservation and a patient's functional outcomes.**

- **Technology and techniques will continue to evolve and allow us to improve on current treatment options both endovascular and surgical**

- **Future trial data sets will hopefully help define best treatment guidelines for specific patient populations**

VIVA VASCULAR INTERVENTIONAL ADVANCES