

# Vascular Lab as a diagnostic tool for PAD



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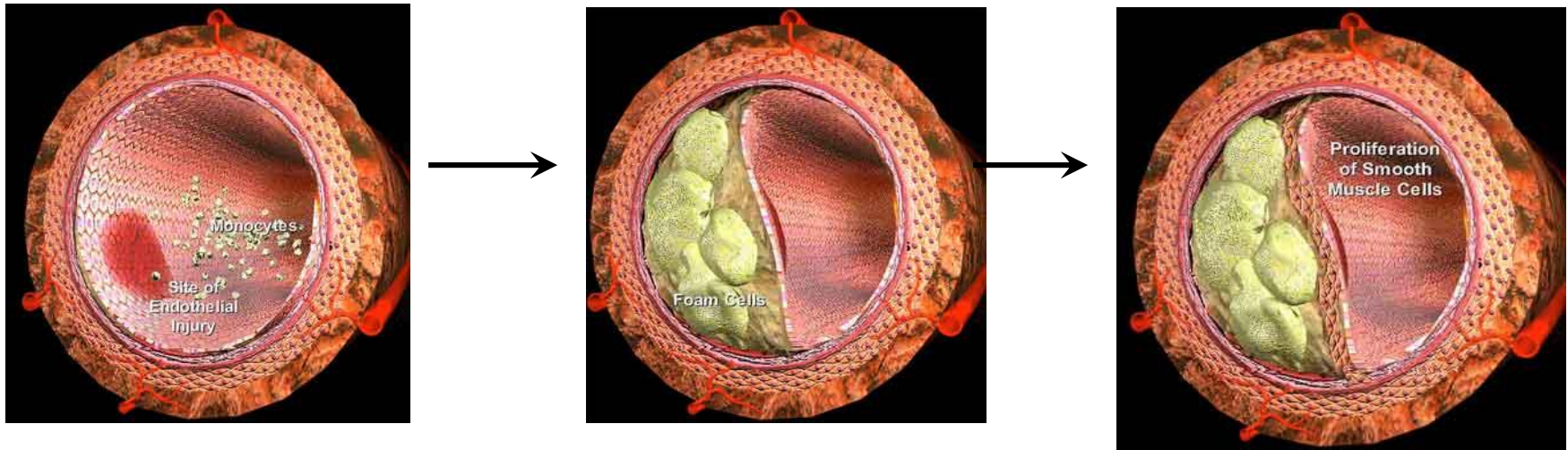
*Vice-Chairman, Department of Surgery*

*Director of Vascular Services*

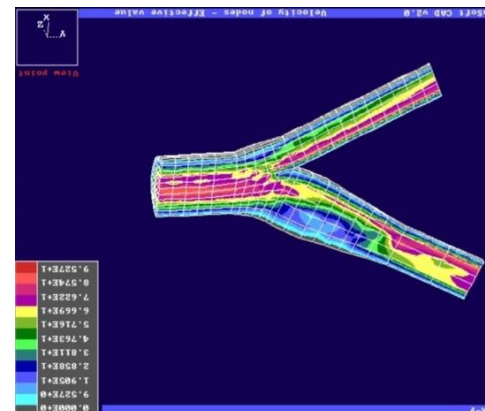
*Clinical Professor, George Washington University*

*Adjunct Professor, Biomedical Engineering, GMU*

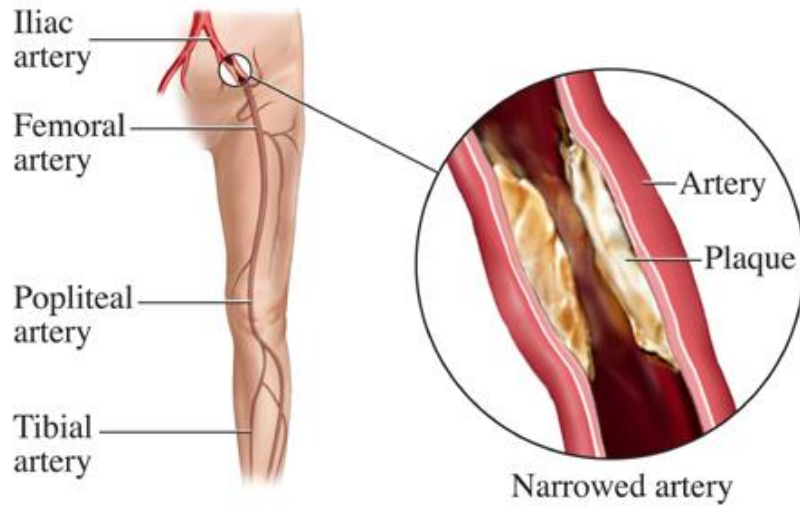
# Peripheral Artery Disease



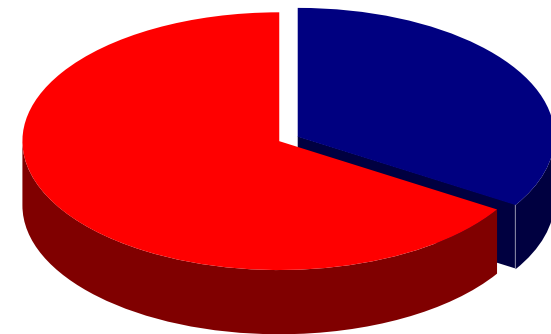
Bifurcation  
Turbulence  
Shear stress  
Increased particle residence time  
Endothelial injury



# Peripheral Artery Disease



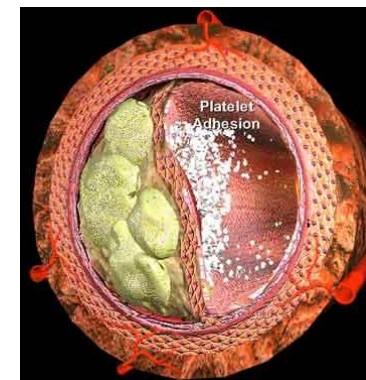
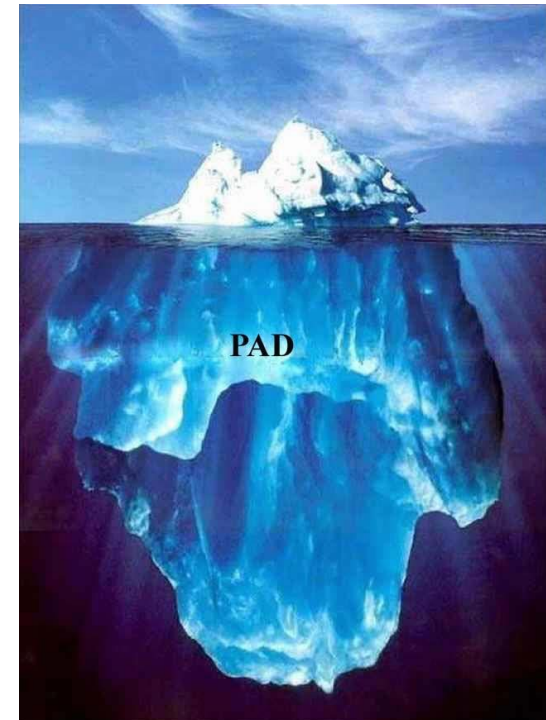
**Symptomatic Disease**  
34%



**Asymptomatic Disease**  
66%

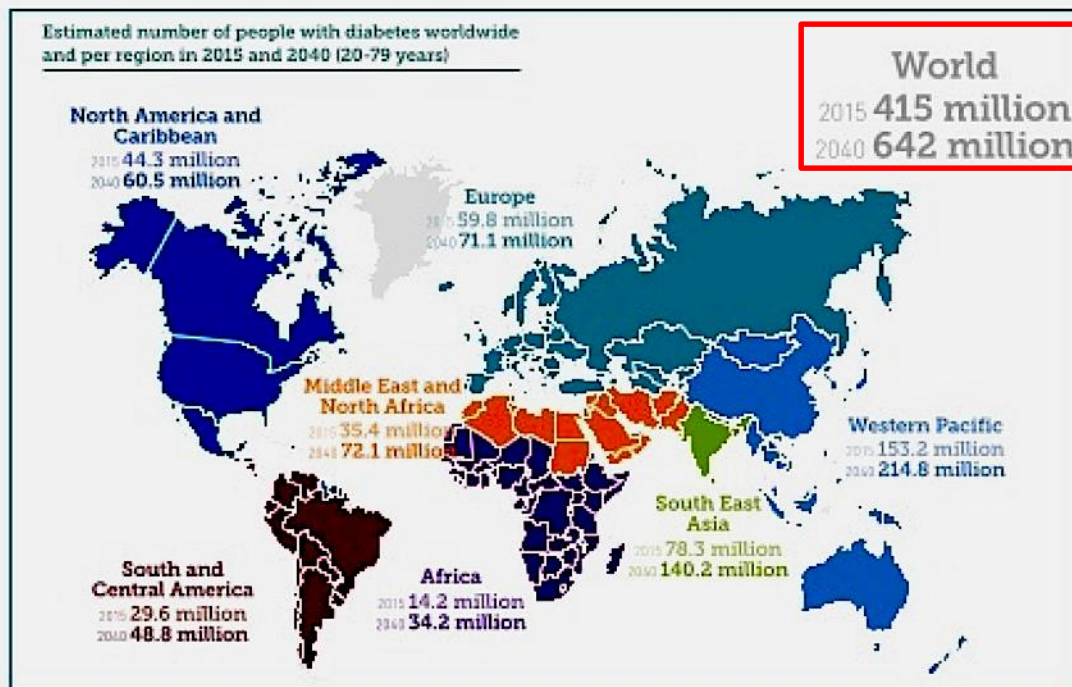
# Prevalence of PAD

- Over 9 million Americans have PAD
- One million new Medicare patients annually
- 30% over 70 years old have PAD
- Without proper treatment, are likely to die in 5 years
- Under-diagnosis of PAD
  - Patients – “part of getting old”
  - Physicians – “don’t ask – don’t tell policy”
- Diabetes mellitus is exploding.....350 million worldwide

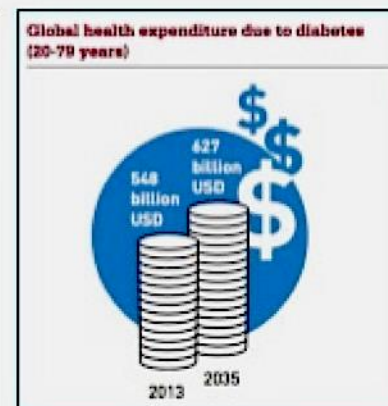


# Diabetes on the rise worldwide

## Number of diabetics globally

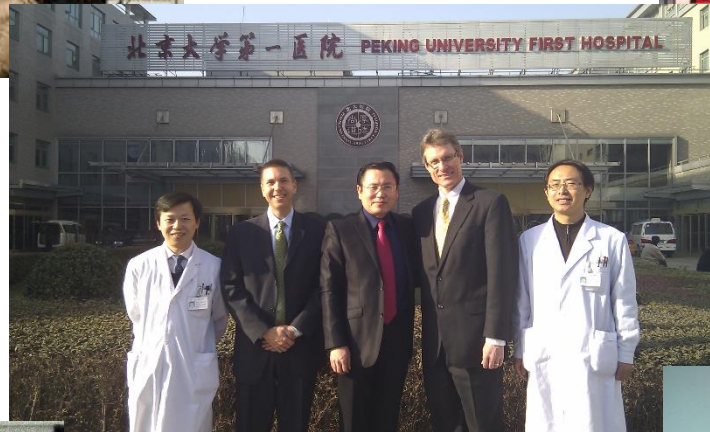


IDF Diabetes Atlas, 2015





# Increasing problem worldwide



# Critical Limb Ischemia (CLI)

- “Condition in patients *without* diabetes with chronic ischemia as the major threat to a limb”
  - 1982, working group of the International Vascular Symposium
- Physiologic criteria
  - $ABI \leq 0.30$
  - Absolute systolic blood pressure  $\leq 50$  mm Hg at the ankle
  - Absolute systolic blood pressure  $\leq 30$  mm Hg at the toe
  - Calcified arteries
    - PVR waveform (ankle, foot, toe):  $\leq 5$  mm
    - PPG waveform (toe):  $\leq 4$  mm

*Raines et al. Surg 1976; Vol 79, No.1:21-29*

*Carter et al. J Vasc Surg 1996;24:258-65*

# Definition of CLI

- Rutherford classification (1986, 1997)
  - CLI under categories 4-6
- TASC II (2008)
  - Chronic ischemic rest pain, ulcers or gangrene due to objectively proven PAD
  - AHA/ACC adopted TASC II definition in 2016
- Society of Vascular Surgery (2014)
  - Classification based on the wound, degree of ischemia, and foot infection (WIFI)



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

	Ischemia - 0			Ischemia - 1			Ischemia - 2			Ischemia - 3						
W-0	VI	VI	L	M	VI	L	M	H	L	L	M	H	L	M	M	H
W-1	VI	VI	L	M	VI	L	M	H	L	L	M	H	L	M	M	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
	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-
	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	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	VI	VI	VI	VI	L	L	M	L	L	M	M	H	H	H		
W-1	VI	VI	VI	VI	L	M	M	M	H	H	H	H	H	H		
W-2	VI	VI	VI	VI	M	M	H	H	H	H	H	H	H	H		
W-3	VI	VI	VI	VI	M	M	H	H	H	H	H	H	H	H		
	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-	fl-		
	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3

fl, 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 (Parodiatic); 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



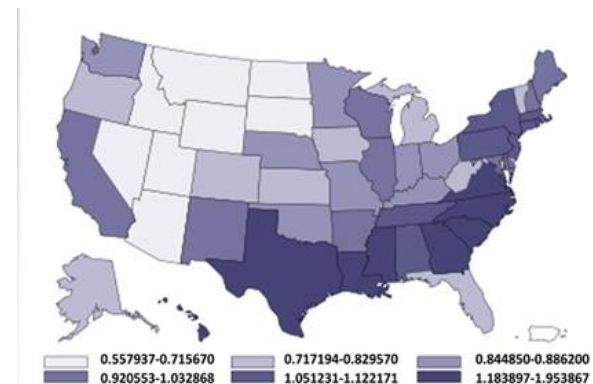
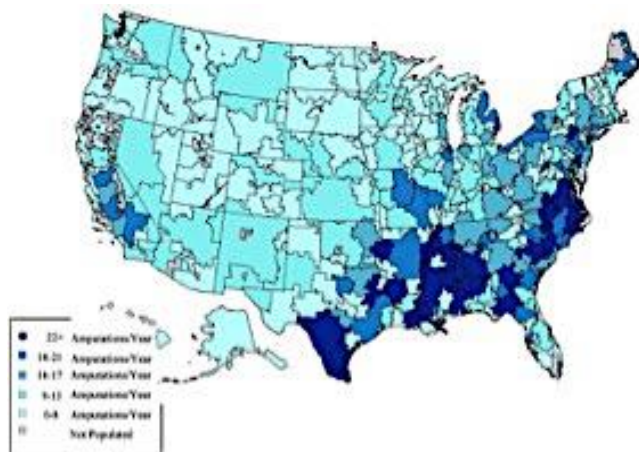
*Gerhard-Herman MD, et al. J Am Coll Cardiol. 2016;doi:10.1016/j.jacc.2016.11.007.*

*Hardman RL, et al. Semin Intervent Radiol. 2014;doi:10.1055/s-0034-1393976.*

*Mills JL, et al. J Vasc Surg. 2014;doi:10.1016/j.jvs.2013.08.003*

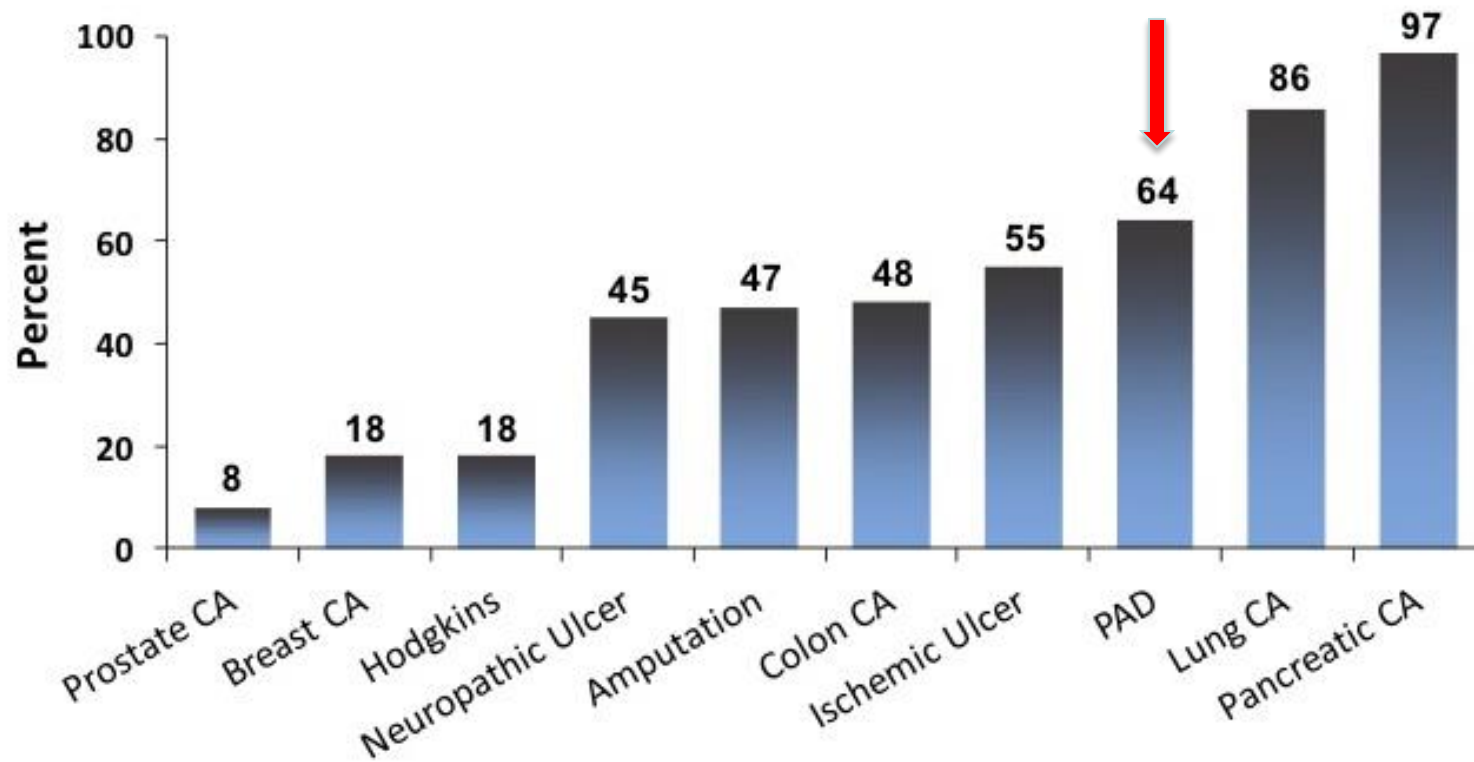


- 1.6 million live with limb loss
- This number may more than double to 3.6 million (2050)
- Regional variation in amputation rates and vascular care
- Post-amputation within 2 years
  - Contralateral amputation – 30%
  - Two year mortality – 30-50%



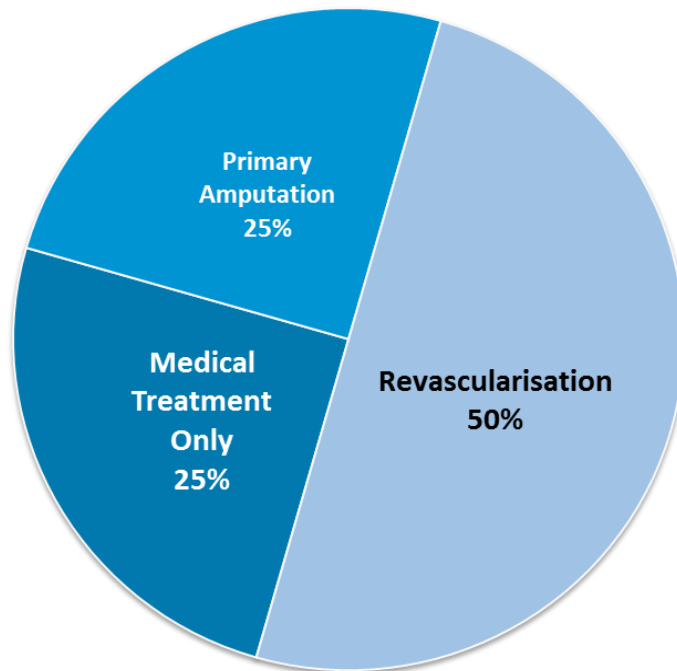
Republished from Schuyler-Jones W, et al. *J Am Coll Cardiol.* 2012;59:E1670, with permission from Elsevier.

# Mortality

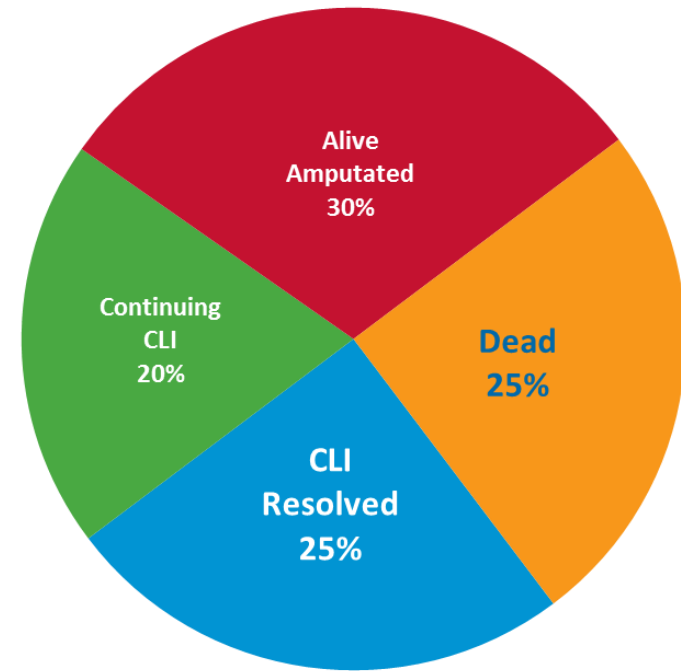


# Outcomes of Patients with CLI

**Primary Treatment**

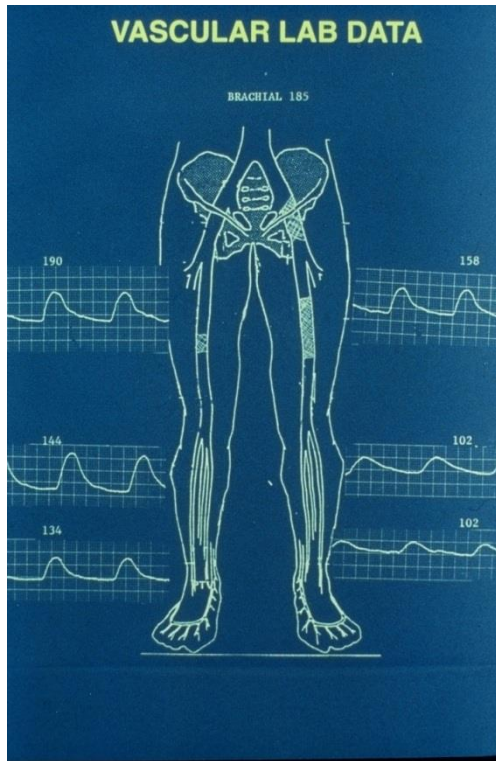


**One Year Later**



- History
  - Risk factors
  - Symptoms at presentation
- Physical Exam
- **Noninvasive vascular testing**
- Arterial imaging
  - Arteriography
  - MRA
  - CTA





- ABI
- Segmental waveforms
- Segmental pressures
- Pulse Volume Recordings
- Digital pressures
- Duplex imaging
- Tissue perfusion
  - TcO<sub>2</sub>
  - Skin perfusion pressure
  - Photoplethysmography
  - Hyperspectral imaging

# Ankle-Brachial Index

- Vascular “EKG”
  - Brachial blood pressure
  - DP / PT blood pressure
  - Calculate ABI
    - DP-PT/Brachial ratio
- Falsely elevated in diabetics

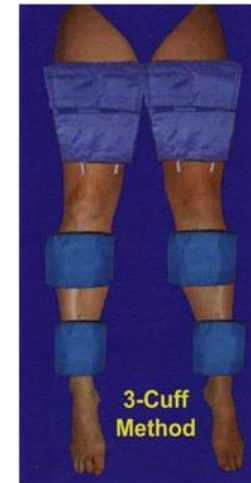
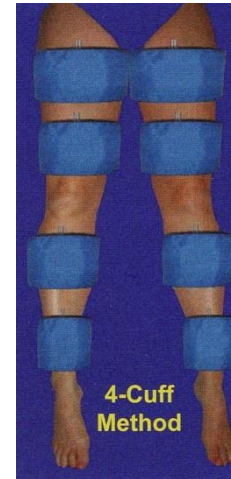
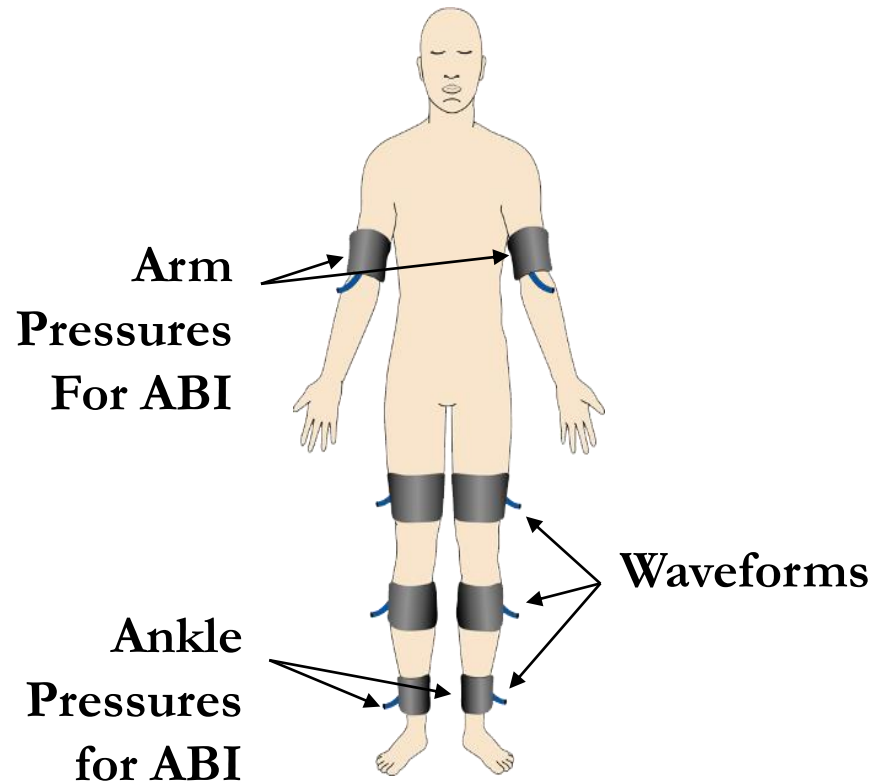


Normal	>0.9
Claudication	0.5 – 0.8
Rest pain	<0.5
Critical ischemia	< 0.3

# ABI vs other common Screening Tests

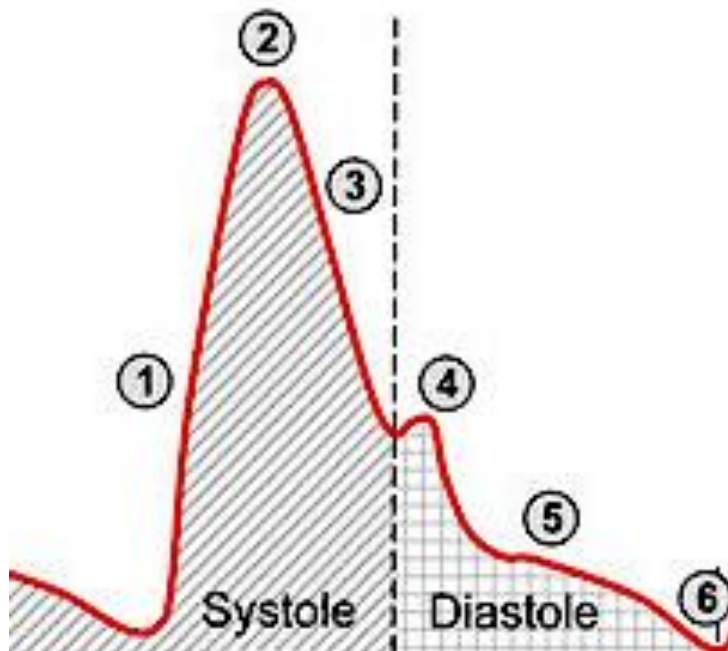
Diagnostic Test	Sensitivity, %	Specificity, %
Pap smear	30-87	86-100
Fecal occult blood test	37-78	87-98
Mammography	75-90	90-95
<b>ABI</b>	<b>95</b>	<b>99</b>

# Segmental pressures/waveforms





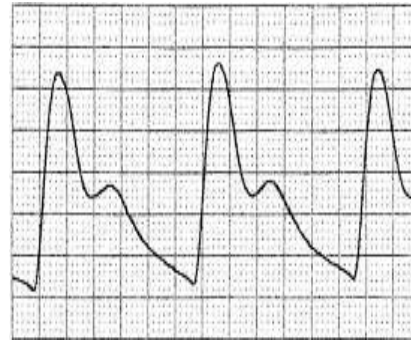
# Segmental waveforms



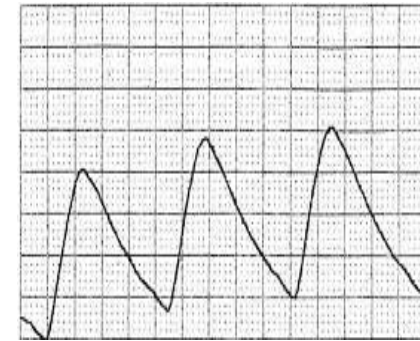
- 1 Systolic upstroke
- 2 Peak systolic pressure
- 3 Late systolic decline with slowing forward movement
- 4 Dicrotic notch related to the aortic valve closure
- 5 Diastolic runoff
- 6 End-diastolic pressure.

# Pulse Volume Recordings

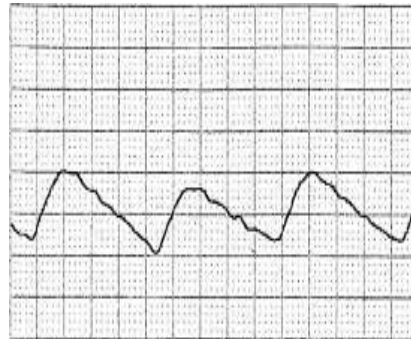
- Measure change in volume
- Amplitude < 15mm
  - Ischemia
- Amplitude < 5mm
  - Non-healing



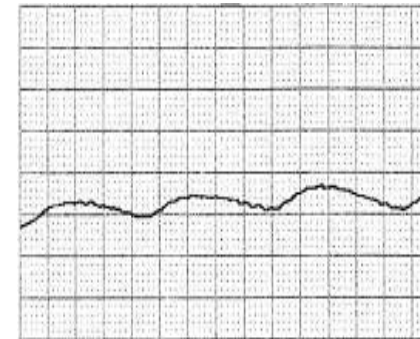
*Normal characteristics*



*Mild obstruction*



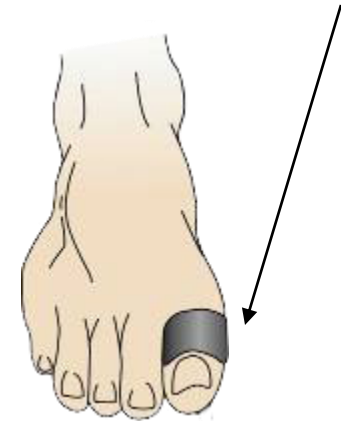
*Moderate obstruction*



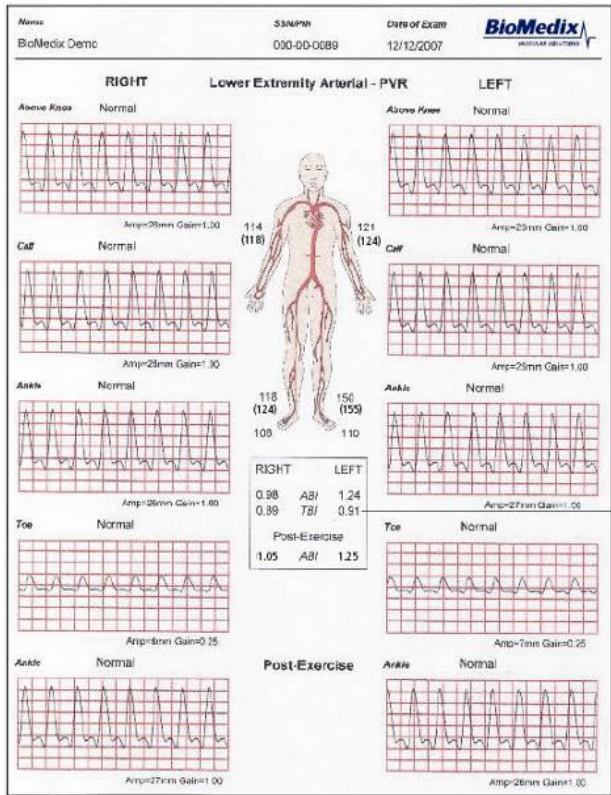
*Severe obstruction or occlusion*

- Reflection of light in microcirculation
- Toe pressures
  - Toe Brachial index ( $> 0.4$ )
- Non-healing  $< 30$ - $40$  mmHg


**Toe Cuffs Here**



# Arterial Study



Physician Associates, PC  
123 Main Street  
Anytown, MN 55555  
(555) 123-4567



### LOWER EXTREMITY ARTERIAL TESTING

Name: BioMedix Demo	Telephone #: (812) 123-4567	SSNIPW: 000-00-0089	Sex: Male	Age: 72	Date of Exam: 12/12/2007
Referring Physician: Ankle Doctor	Telephone #:	Account #:	Date of Birth: 09/16/1935	Previous Exam: 12/12/2007 (PAD)	

**Risk Factors:** Diabetes: Yes Hypertension: Yes Tobacco: No Hyperlipidemia: No  
**Assoc. Illness:** Cardiac: No Carotid: Yes Pulmonary: No Renal: No  
**Indications:** Claudication (both sides), Rest pain (both sides), Extremity trauma (both sides)

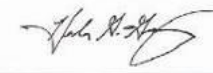
**Notes:** Patient currently taking two drugs for hypertension. c/o tingling in toes and tightness in calves and buttocks during exercise.  
**Post-Exercise Note:** Exercise period 0 sec.

	Right	Results	Left
<b>Pressures (Post-Exercise)</b>			
Brachial	114 (118)		121 (124)
Ankle	118 (124)	ABI 0.98 (1.05)	150 (155)
Toe	108	TBI 0.89	110
<b>PVR Waveforms</b>			
Above Knee	Normal		Normal
Calf	Normal		Normal
Ankle	Normal	(Normal)	Normal
Toe	Normal		Normal

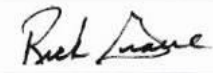
**Interpretation**

No evidence of significant peripheral vascular occlusive disease at rest in the right leg. No evidence of significant peripheral vascular occlusive disease at rest in the left leg. The right ankle/brachial index is 0.98 and the left ankle/brachial index is 1.24.

Patient shows no signs of disease. Please use other testing methods to determine reasons for reported indicators.



Hansul Gary  
Technologist: 12/12/07

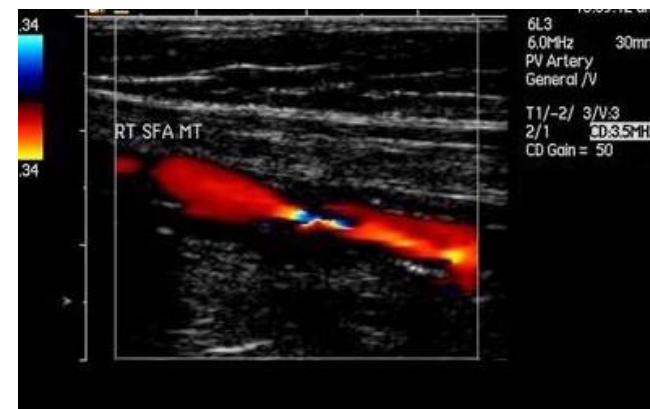
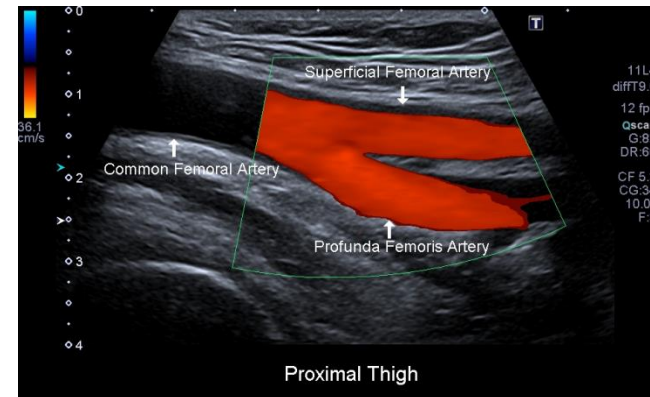


Rick Gens  
Physician: 12/12/07



# Duplex images

- Duplex
  - B mode images
  - Velocity data
- Advantages
  - Noninvasive
  - Available
  - Anatomic
- Disadvantages
  - Labor intensive
  - Technician dependent
  - Best for focal disease



# Tests for tissue perfusion

- Toe pressures / TBI
- TcO<sub>2</sub>
- Skin perfusion pressure
- Hyperspectral imaging
- SPY Elite camera



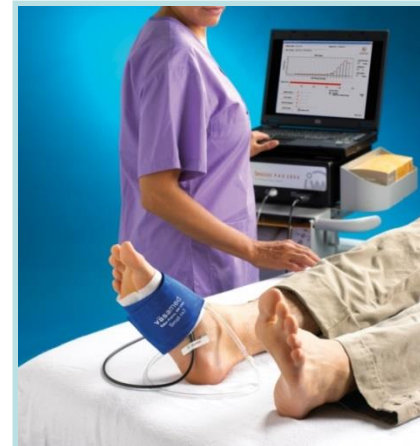
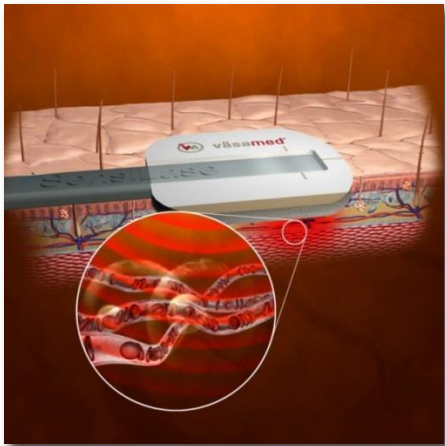
# Transcutaneous Oxygen

- Healing potential and tissue perfusion
- Values measured at foot and chest wall
- Non-healing
  - Value < 20-30 mmHg
  - Chest – foot index < 0.4
- TcO<sub>2</sub> peaks two to four weeks after revascularization



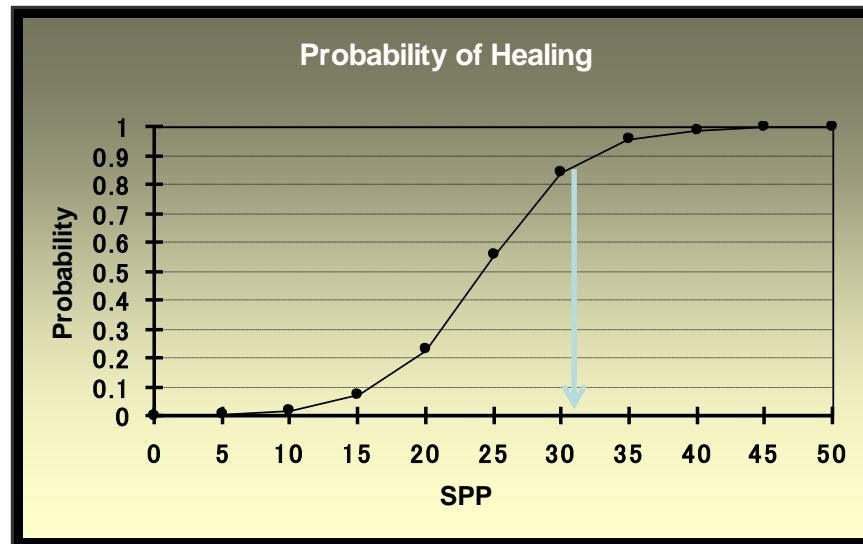
# Skin perfusion pressure (SPP)

- Laser Doppler technology
  - Laser signal below skin surface (1.5mm)
  - Measures blood flow to capillary/tissue
- Pressure cuff occludes capillary flow
- System performs a controlled release of pressure
- Laser uses the Doppler “shift effect” of capillary flow return
- Automatically calculates the Skin Perfusion Pressure - the pressure at which blood flow first returns to the capillaries



# Wound Healing Potential

- SPP diagnoses CLI with  $> 80\%$  accuracy
- SPP  $< 50\text{mmHg}$  = CLI in dialysis patients
- $\leq 30\text{ mmHg}$  – 80% wound healing failure rate
- $> 30\text{ mmHg}$  predictor of wound healing

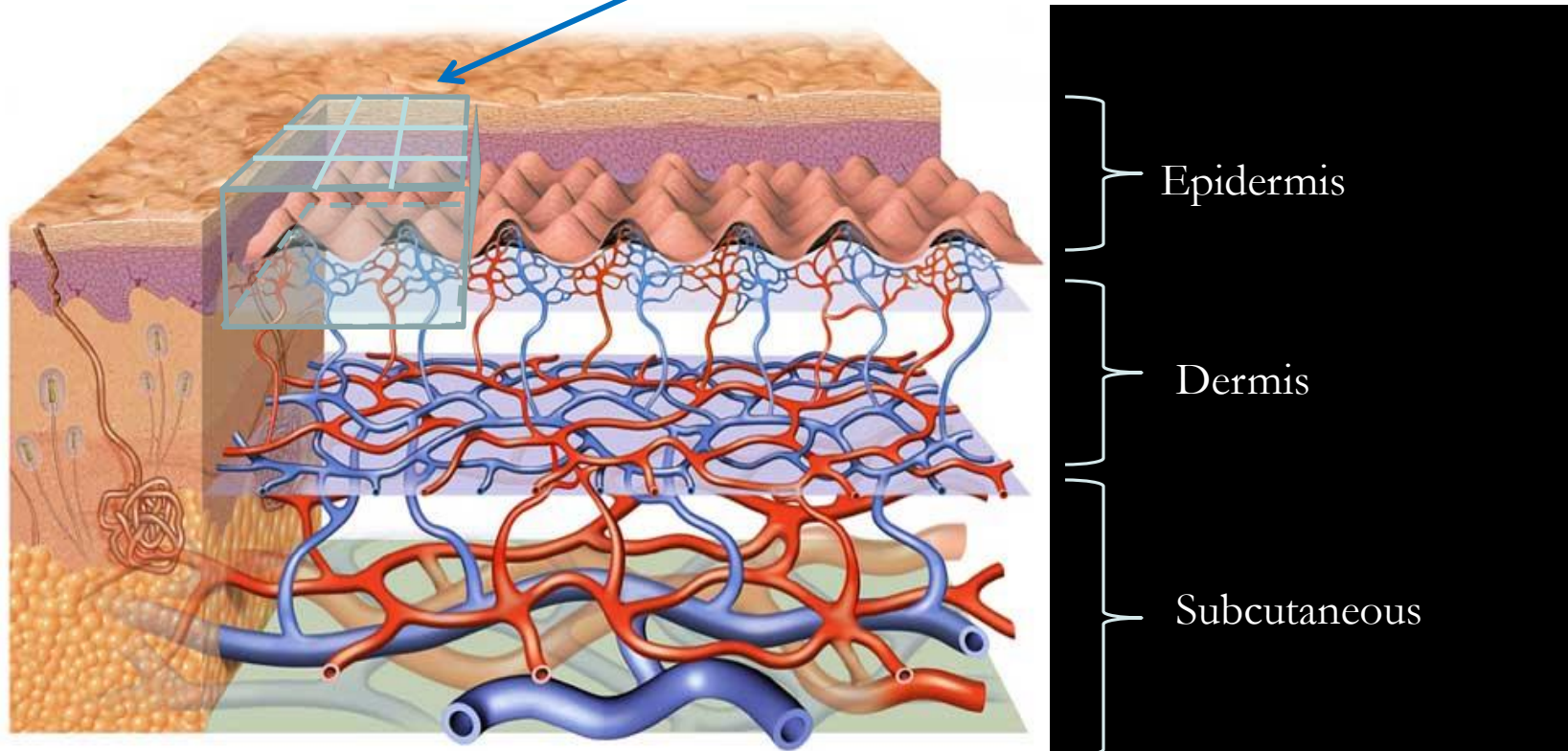


*Castronuovo, et al. J. Vasc. Surg. 1997, 26, 629-637.*

*Okamoto, et al. American Journal of Kidney Diseases. 2006;48(2):269-276.*

# Hyperspectral imaging

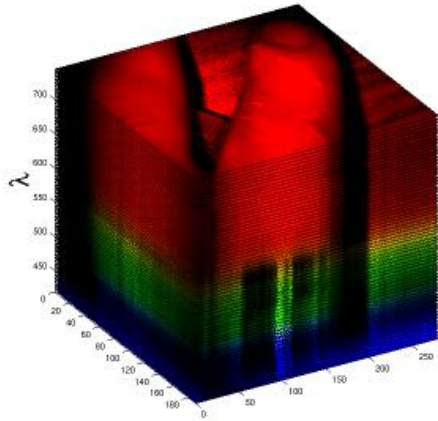
One Pixel = 90 x 90 microns  
2mm depth



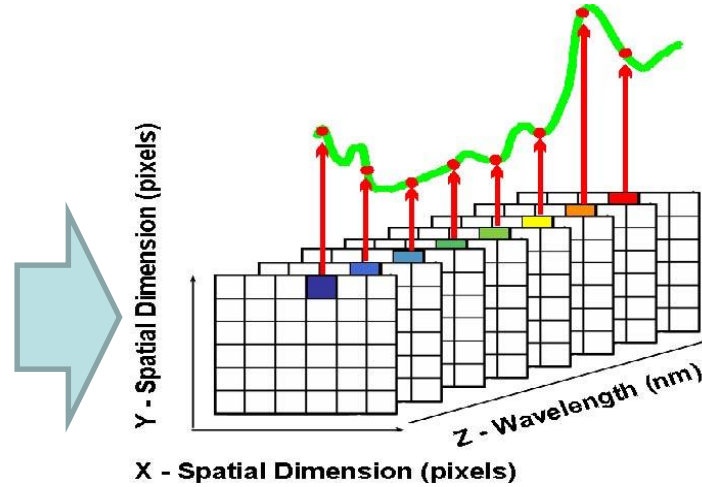
Measures the functional capacity of tissue to process oxygen



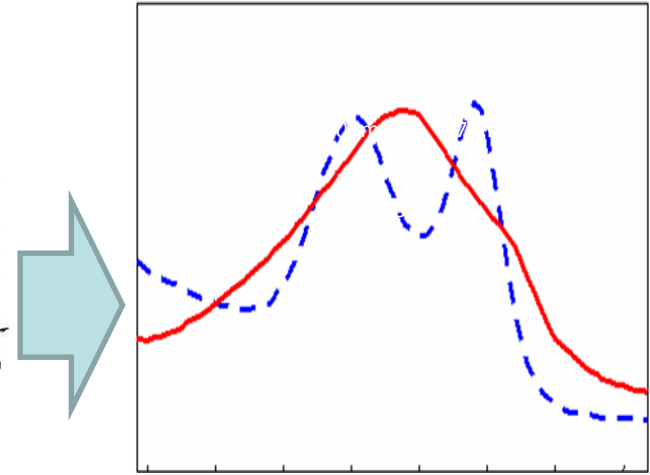
# Hyperspectral imaging process



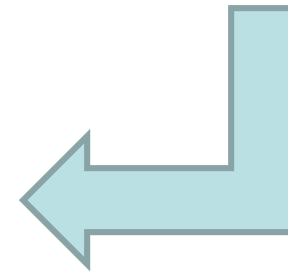
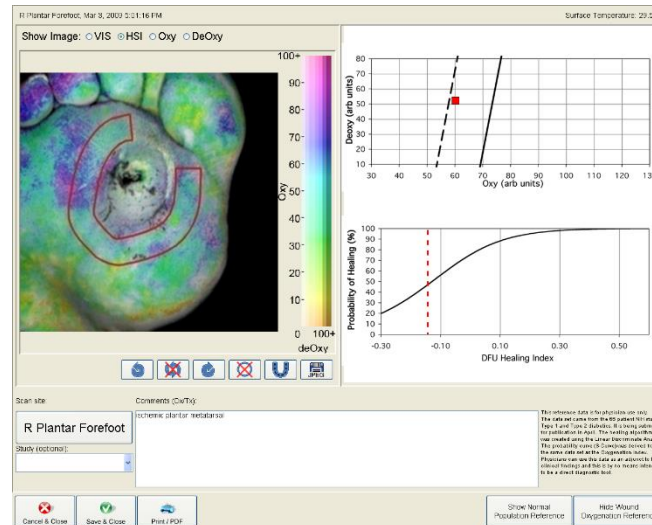
Optics Acquire  
Hyper Cube



Spectra Isolated



Oxy- and Deoxyhemoglobin  
Oxygen Delivery and Extraction



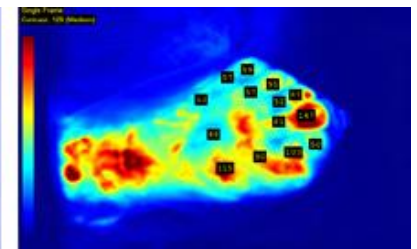
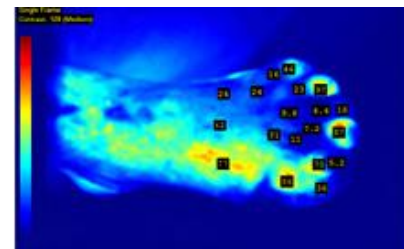
# Hyperspectral analysis

- Oxyhemoglobin low
- DeOxy low
- O2 Sat low relative to the normal population values
- Results consistent with decreased perfusion

Value	Observed	Normal Mean	Std. Dev.
<b>Oxy</b>	19	38	18
<b>DeOxy</b>	28	40	12
<b>O2 Sat</b>	40	48	10



# Other systems to assess tissue perfusion



# Who needs further arterial imaging?

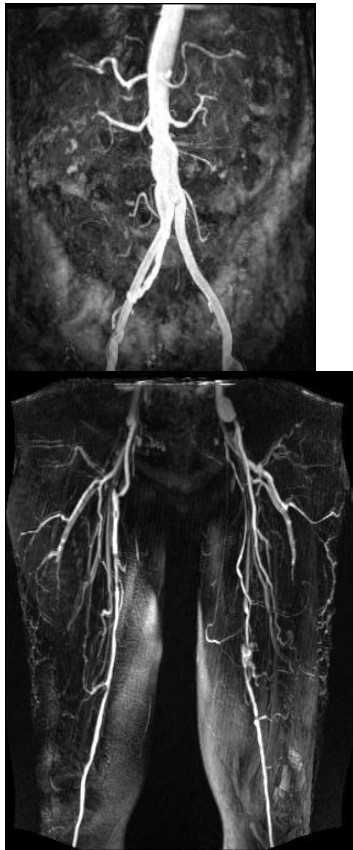
- Functional ischemia
  - Disabling claudication
  - Severe ischemia on noninvasive testing
- Limb threatening ischemia
  - Rest pain
  - Tissue loss

# Arterial imaging: CT angiography



- Advantages
  - No arterial puncture
  - 3D reconstruction
  - Shows calcium
- Disadvantages
  - Use of contrast
  - Timing of bolus
  - Images impeded by calcium

# Arterial imaging: MR angiography



- Flow dependent
- Poor distal image quality
- Overestimate stenosis
- Time to acquire images



# Arteriography still important

- Plan revascularization
- Rarely diagnostic
- Complications
  - Nephrotoxic dye
  - Bleeding
  - AV fistula
  - Pseudoaneurysm
- Distal tibial occlusive disease
- Limb Center
  - 533 initial diagnostic
  - 276 primary interventions



- **Role of Vascular lab**
  - Screening
  - Determine need for further imaging and intervention
  - Determine success of therapy
    - Medical
    - Endovascular
    - Surgical
  - Follow up revascularization procedures
- **Vascular lab in a CLI practice**
  - Is there adequate perfusion for a wound to heal?
  - Has the intervention provided adequate perfusion for healing?
  - Is perfusion maintained or is a re-intervention required?

# Thank you

