

MEDCAC

MEETING JULY 22, 2015

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Disclosure-slide

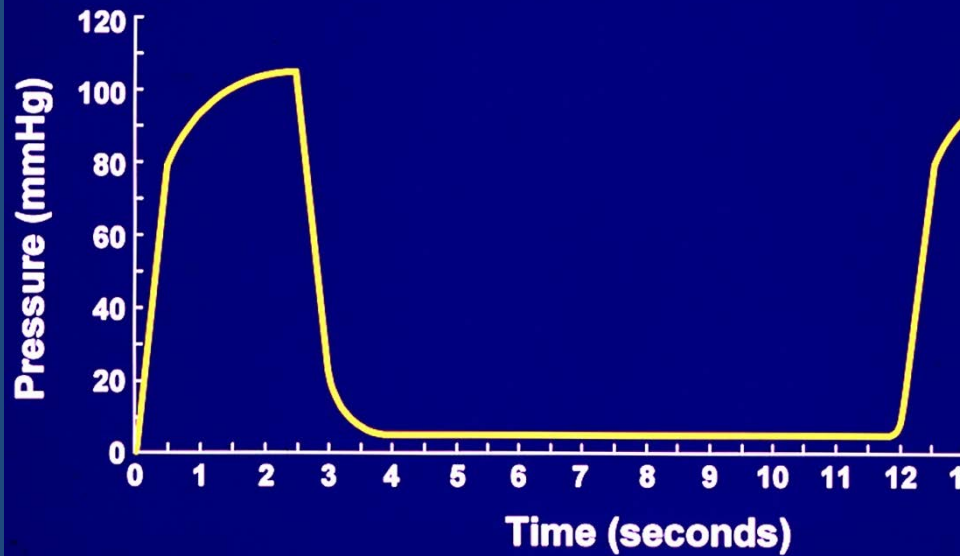
- ▣ 1. US patent 5,218,954 (expired)
- ▣ 2. Consultant (major association): ACI Medical, Inc.

Intervention: arterial compression home device application areas:

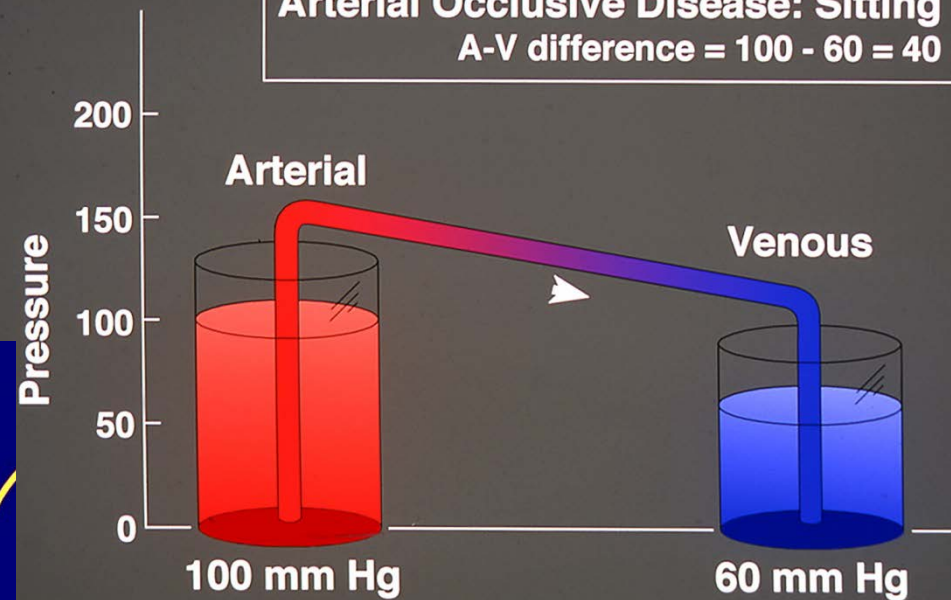
- ▣ Asymptomatic
- ▣ IC intermittent claudication
- ▣ CLI critical limb ischemia



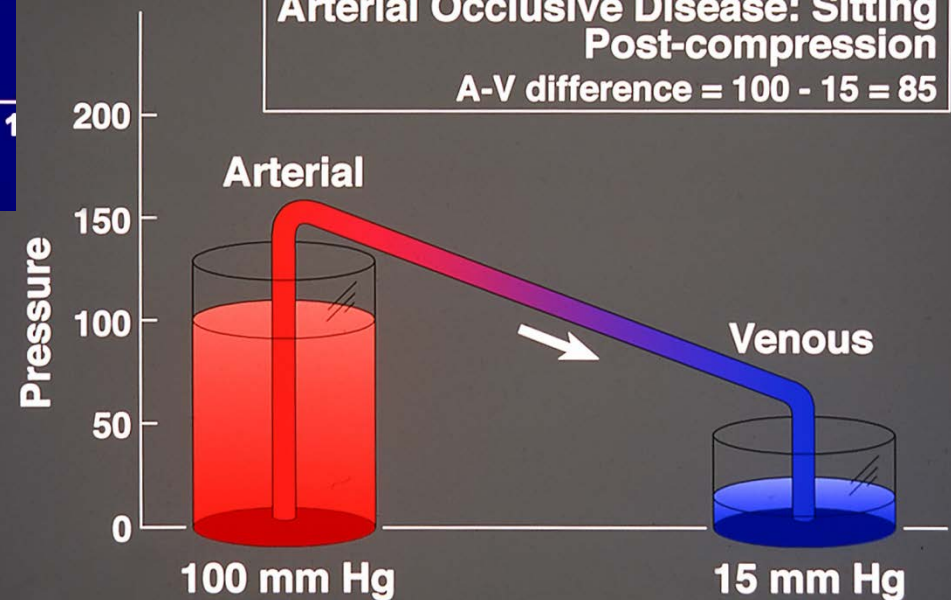
Device output:

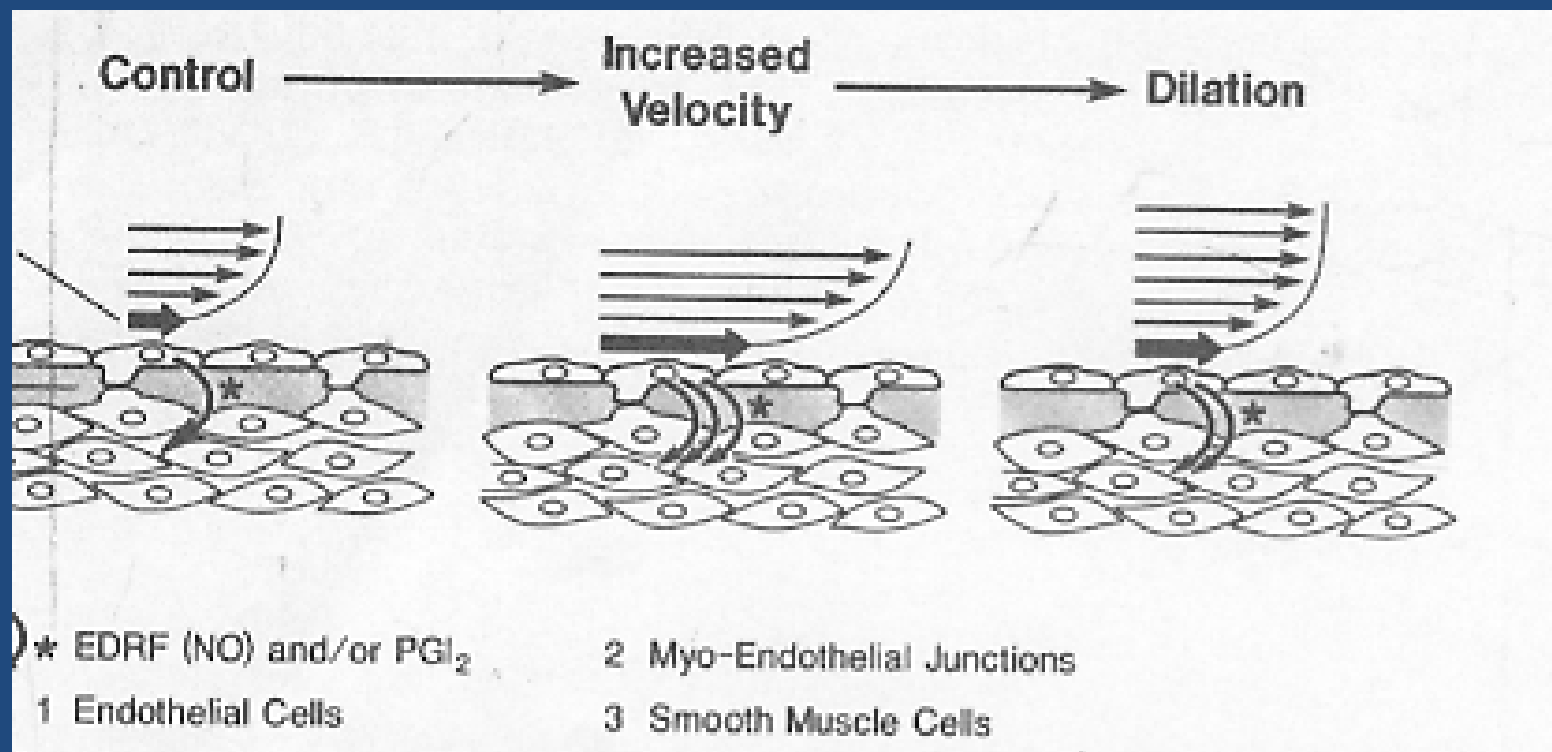


Arterial Occlusive Disease: Sitting
A-V difference = $100 - 60 = 40$



Arterial Occlusive Disease: Sitting
Post-compression
A-V difference = $100 - 15 = 85$





Function of endothelium is secretion of NO

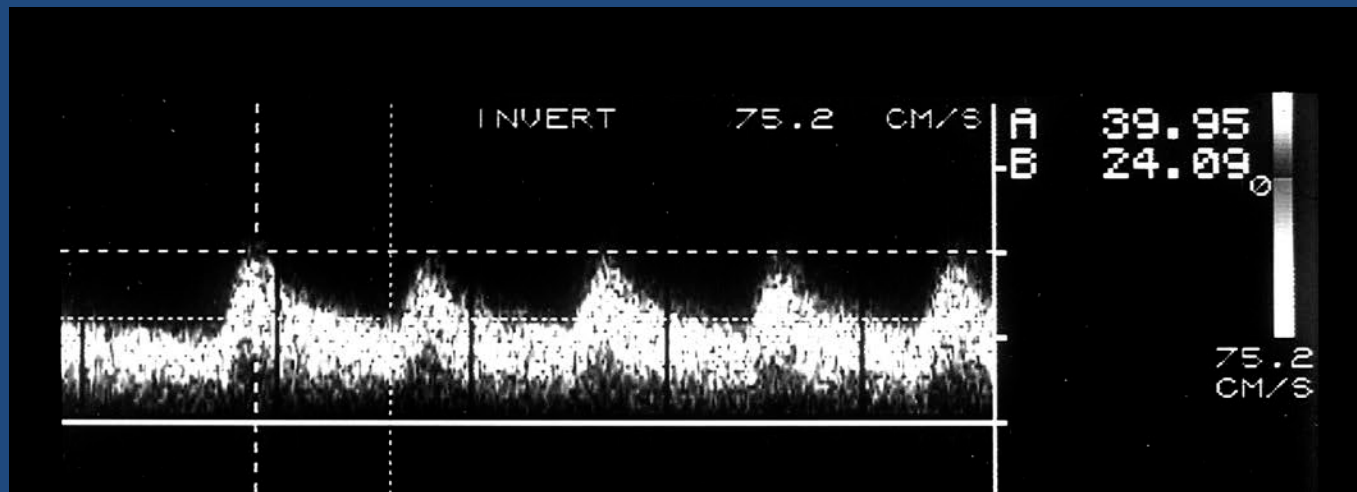
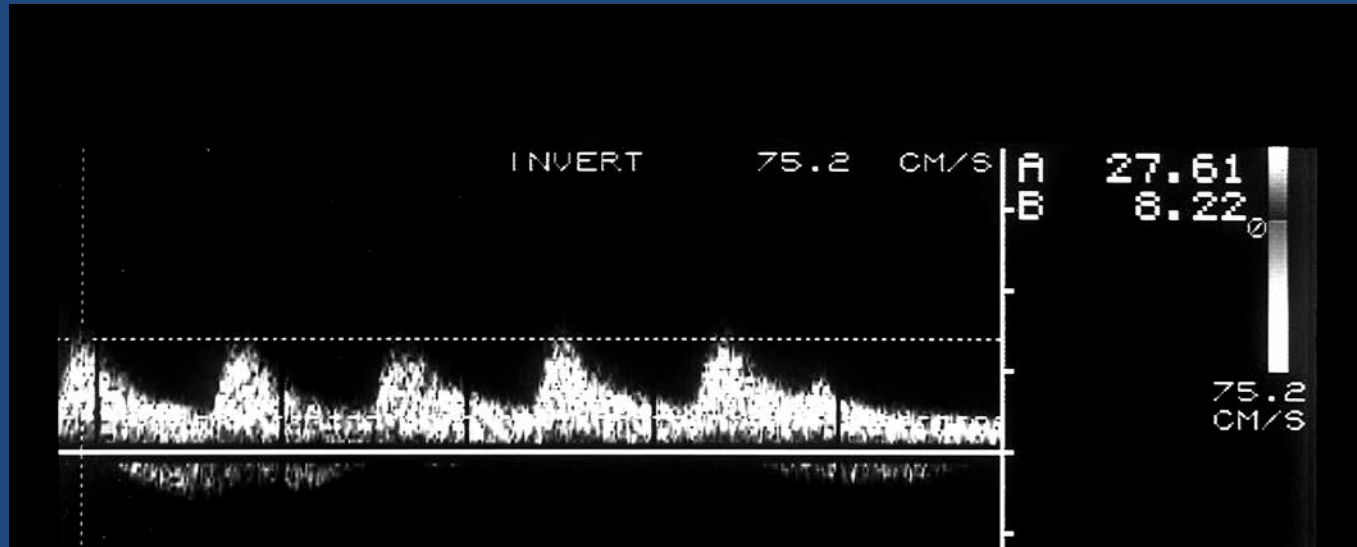
Distal to arterial occlusion: reduced velocity

Less NO - Nitric oxide = endothelial relaxant factor = Less dilation

Artificial increase in velocity/shear results in dilatation

Dilatation = less resistance = more flow

Popliteal artery flow in PVD patient: immediate effect



Chronic effect: collaterals=arteriogenesis



3 mo rapid compression foot + calf



angio- vs arterio-genesis

- ▣ Angio-
- ▣ Ischemia induced
- ▣ VEGF, HIF-1
- ▣ De novo sprouting
- ▣ Size 10-20 microns
- ▣ Arterio = collateral
- ▣ Shear-stress induced
- ▣ MCP-1
- ▣ Remodeling arteriole
- ▣ Size 1 mm = 1,000 micron

Asymptomatic = Rutherford 0

- ▣ Prospective randomized placebo-controlled trial in recent one-side amputees is ongoing in North-Philadelphia
- ▣ Started in Nov 2013
- ▣ Secondary prevention of amputation of the other leg in high-risk group
- ▣ No results available

Intermittent claudication = Rutherford 3

- ▣ Meta-analysis: 4 prospective studies
- ▣ 82 patients
- ▣ 53 controls
- ▣ London, New York, Rome, Taiwan

Outcome: ACD (Absolute Claudication Distance) -ArtAssist

▣ Author	n	% ACD increase	FU
▣ Delis	20	212%	12 mo
▣ Ramaswami	15	96%	6 mo
▣ Berni	24	101%	18 mo
▣ Chang	23	95%	3 mo
▣ Cilostazol	119	29%	4 mo
▣ Exercise*	24	11%	6 mo

* With structured coaching

CLI = critical limb ischemia

- ▣ Pain at rest (Rutherford 4)
- ▣ Tissue-loss: ischemic ulcer limited toe R5/ severe ischemic ulcer heel R6/ (gangrene R6)
- ▣ Reconstructable versus non-reconstructable
- ▣ 3 studies with different designs:
- ▣ Case-series Arch Surg 2001 (van Bemmelen; n=14)



Before pump



After pump

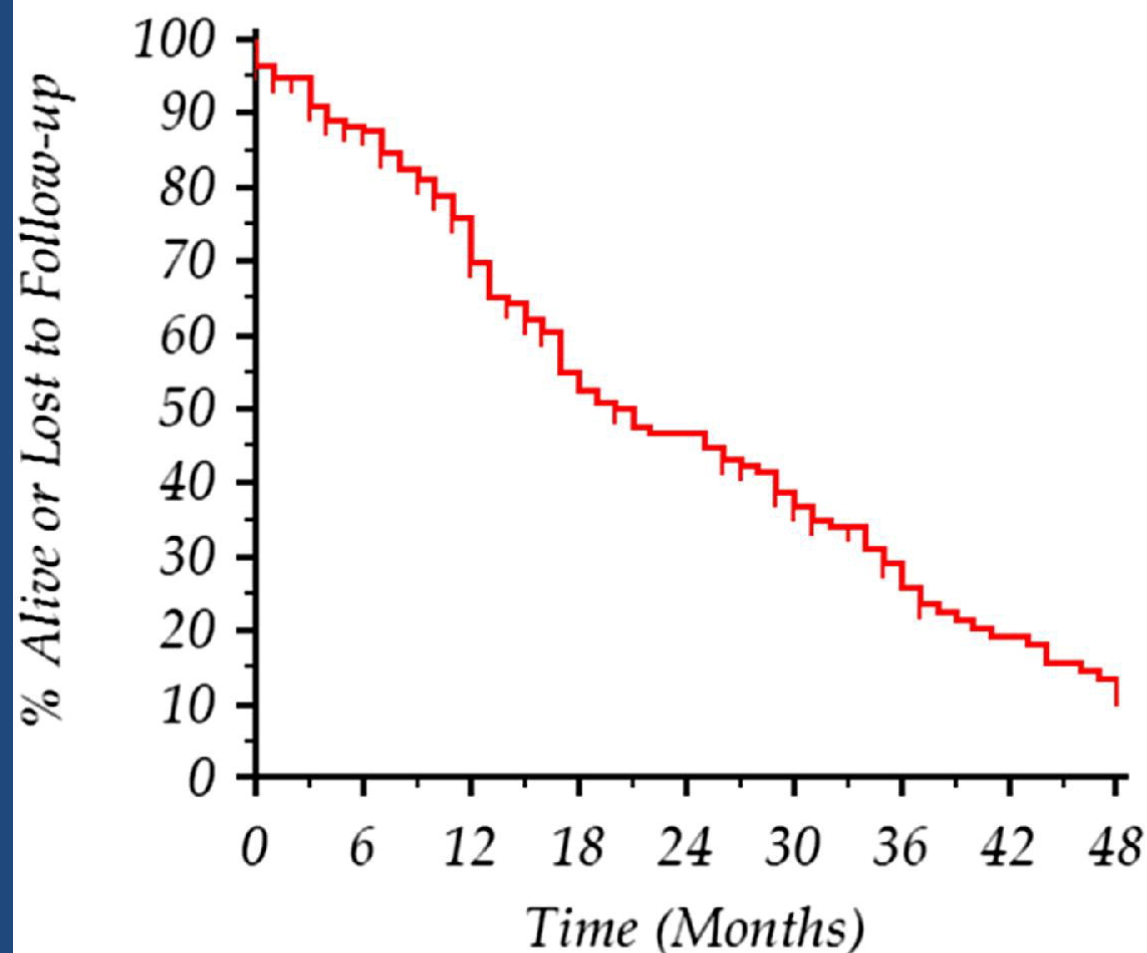
Sultan-Ireland 2011; n = 171

- ▣ Non-randomized 2004-2009 experience in non-reconstructable patients
- ▣ 47% ASA-4 (high Anesthesia-risk for surgery)
- ▣ 14 month median ulcer duration

Sultan-Ireland 2011; n = 171

- ▣ 74% Rutherford 5 (limited toe) or 6 (26% pain = Rutherford 4)
- ▣ 24 month median duration symptoms
- ▣ 2 or more analgesics required for inclusion
- ▣ Historical/no control group

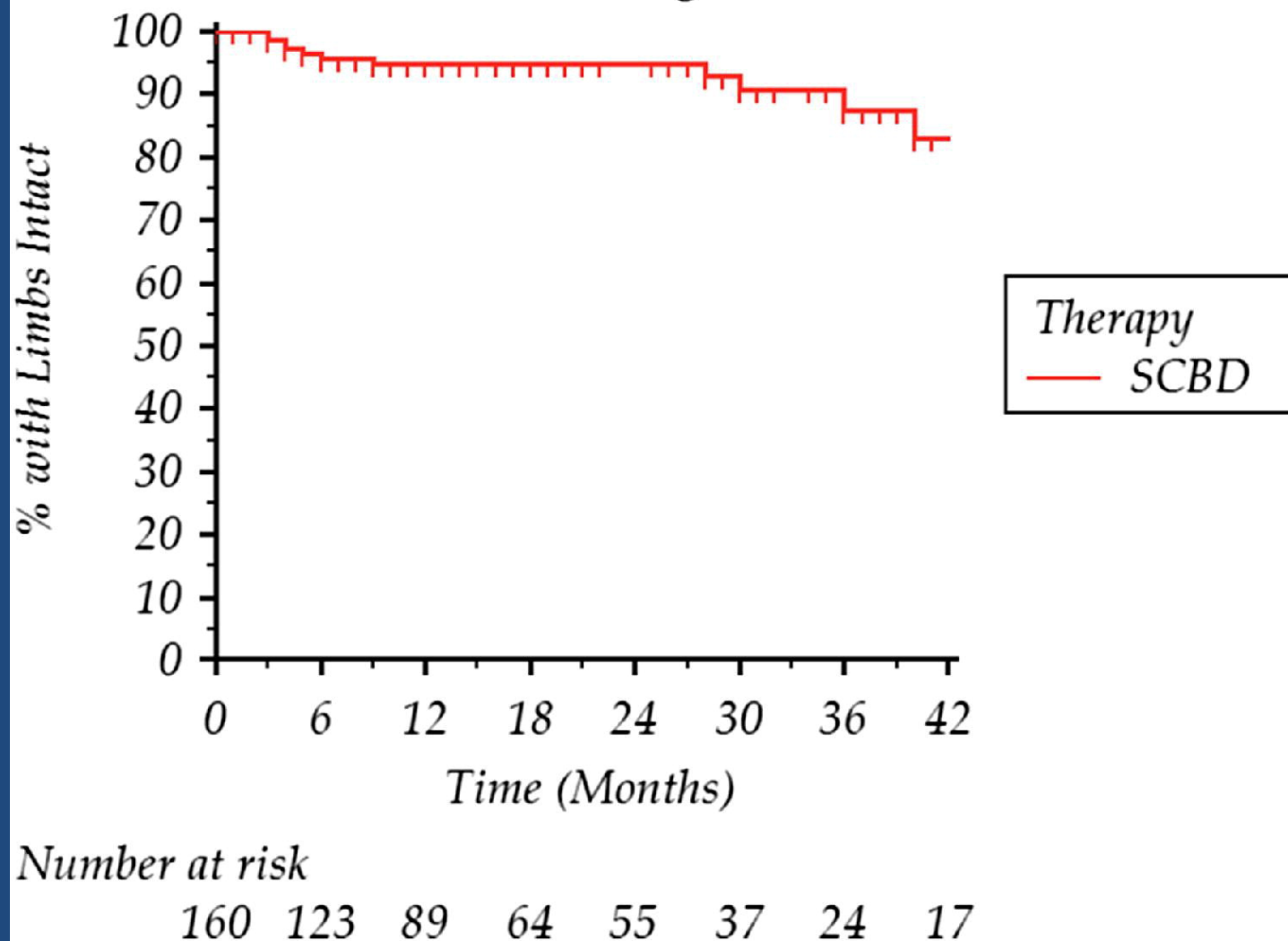
All Cause Survival



Number at risk

159 125 91 65 55 39 24 17 9

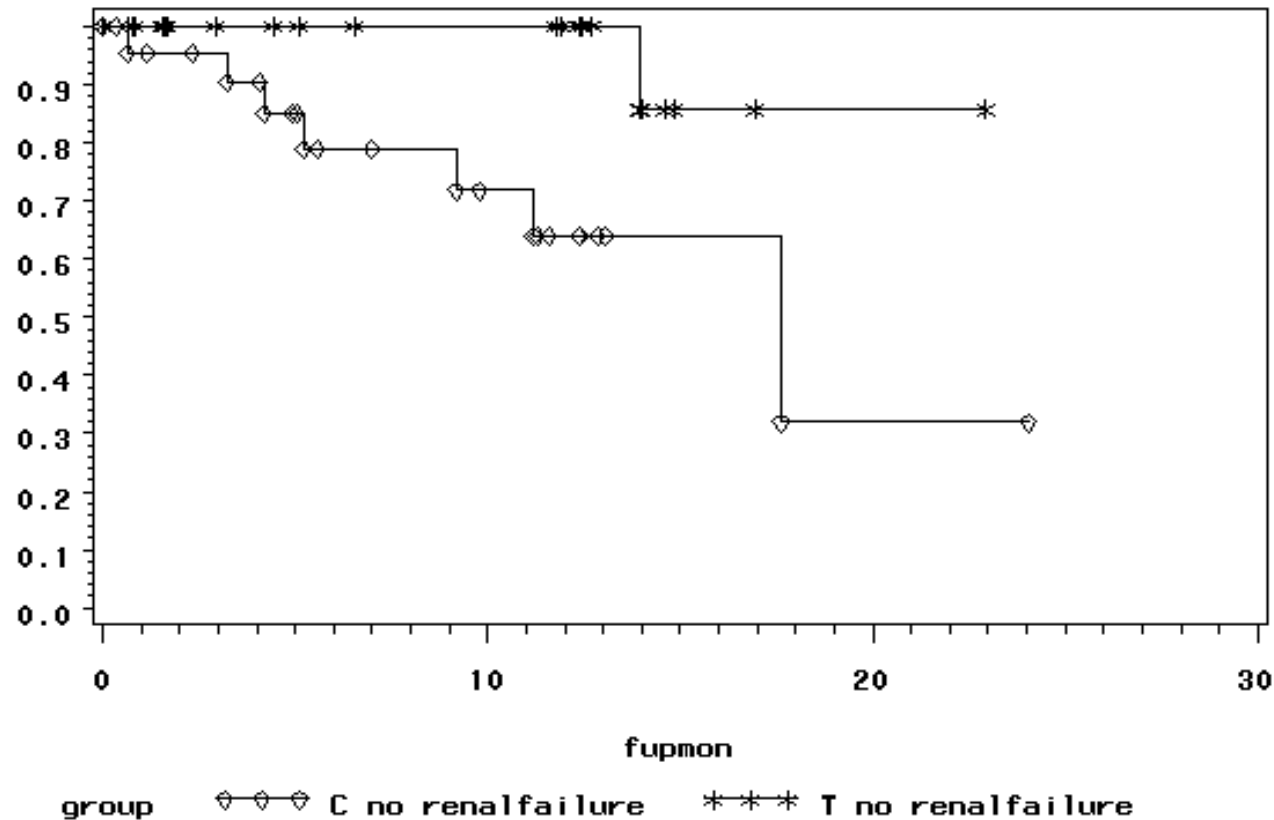
Limb Salvage



Sultan et al. JVS August 2011

- ▣ Limb salvage 94% in 3.5 years
- ▣ Cost-savings: \$32,000 per patient
- ▣ QOL: better than amputation

Louridas et al 2004; Prospective, Randomized,
Placebo-device controlled - Manitoba (n = 99)



IPC
86%

P = 0.014

Control
32%

Cost of managing: healing is slow regardless of treatment + survival is short:



Art-compression
\$ 1,200.-



Tibial
angioplasty
\$23,196.-

Difference: \$22,000 or
factor 20

Summary compression in PAD

- ▣ All above cited studies with ArtAssist device
- ▣ For asymptomatic PAD: benefit not known yet
- ▣ For claudication: 4 studies -effective
- ▣ For CLI-restpain: improved pain-score demonstrated
- ▣ For CLI ulcers/tissue loss: evidence for limb-salvage in non-reconstructable cases

Impact on cost by avoiding amputations/procedures avoid:

- ▣ Direct cost of amputation
- ▣ Cost of single/repeated tibial angioplasty/year
- ▣ Post-amputation Outpatient PT/ home care cost-up to 4 years
- ▣ Prosthetic: \$5,000-50,000 + re-fittings after 1 year
- ▣ Scooter/wheelchair cost: \$1,000-5,000
- ▣ Instead: 3 month device rental: \$1,200
- ▣ Savings possible/likely?

References:

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- ▣ Chang ST, Hsu JT, Chu CM, Pan KL, Jang SJ, Lin PC, Hsu HC, Huang KC: using intermittent pneumatic compression therapy to improve quality of life for symptomatic patients with infrapopliteal diffuse peripheral obstructive disease. *Circ J* 2012;76:971-976.
- ▣ Wullink M, Stoffers HE, Kuipers H: A primary care walking exercise program for patients with intermittent claudication. *Med Sci Sports Exerc* 2001;33:1629 – 34.
- ▣ Mays RJ, Rogers RK, Hiatt WR, Regensteiner JG: Community walking programs for treatment of peripheral artery disease. *J Vasc Surg* 2013;58:1678-87.
- ▣ Louridas G, Saadia R, Spelay J, Abdoh A, Weighell W, Arneja AS, Tanner J, Guzman R: The ArtAssist ® device in chronic lower limb ischemia. *International Angiology* 2002;21:28-35.