Pathophysiology of Diabetic Foot Lesions and Therapy with the Circulator Boot

Circulator Boot Corporation

Duration of Hospitalization after Leg Amputation in Diabetics

- Cameron (1964): AK's 77 days and BK's 55 days
- Ecker (1970): AK's 5.9 months and BK's 6.7 months if no further surgery (10.2% dead under 30 days, 32% healed by 30 days, 19.5% healed between 30-60 days, 30 % healed after 60 days and 10.2% did not heal)
- Haynes (1981): Mean postoperative period of 65 days for patients discharged (Nondiabetics included)
- Dillon (1978): Peripheral Vascular Disease was the most common diagnostic classification among persons with diabetes over age 40 admitted to the Philadelphia General Hospital from 1955 to 1970.
- Van Houtum (1996): 48.0 days in the Netherlands vs. 16 days in California
- Fusetti et al (2001): 109 days (Switzerland)

Percentage Changes in Baseline Subcutaneous PO_2 Levels Induced by a Single Treatment With the Circulator Boot

Patient	Percentage of Change in PO_2
1	92
2	209 and 244
3	26, 41, and 239
4	163
5	1170 and 1800
6	566 and 771
7	450
	(Range 26–1800 %)

Values are given for each electrode inserted in the patient's feet. The smaller changes were seen in electrodes inserted in relatively normal appearing skin.

Dillon RS: *Effect of therapy with pneumatic end-diastolic leg compression boot on peripheral vascular tests and on the clinical course of peripheral vascular disease.* Angiology 31:614-638, 1980.

The Non-Invasive Vascular Laboratory

TABLE 1 SUMMARY
Means ± *Standards Deviations*

Increases in blood pressure levels	Dorsalis pedis: 43.1 ± 11.2 ($P < 0.001$) Posterior tibial: 32.1 ± 11.1 ($P < 0.01$)
Increases in ankle blood pressure as percentage of arm pressure	Dorsalis pedis: 31.0 ± 8.4 ($P < 0.01$ Posterior tibial: 23.7 ± 8.4 ($P < 0.02$)
Increases in Doppler amplitudes	Dorsalis pedis: 10.8 ± 2.1 ($P < 0.001$) Posterior tibial: 13.7 ± 2.7 ($P < 0.001$)
Increases in oscillometry indices at the ankle	0.80 ± 0.12 ($P < 0.001$)
Number of treatments	47.7 ± 43.7
Duration of treatments	5.8 ± 6.6 weeks

Twenty-two of the 25 severe legs benefitted clinically from therapy.

Angiology 31:614-638, 1980.

Bailar et al and Medical Research without Controls

N Engl J Med 311:156-162, 1984

- (1) The investigators should express before the study that the treatment will affect disease outcome (*In Circulator Boot publications, both the patients and referring physicians were advised the treatments were likely to affect patient outcomes*).
- (2) The data analysis should be planned before the data are generated (*In boot studies, both pertinent vascular data and photographs were obtained both before and after treatments*).
- (3) The investigators should articulate a plausible hypothesis before the results are observed (*The means whereby boot therapy benefits peripheral blood flow was described in our first publications*).
- (4) The results should be of some interest even if "negative" or "opposite" findings are observed (*Negative results would have discouraged interest in the use of boots for vascular diseases while the positive results have led us to extend our use of the Circulator Boot to study its effects in patients with leg infections, neuropathy, venous insufficiency, Buerger's disease, congestive heart failure, angina, and arterial lesions of the arms*).
- (5) There should be reasonable grounds to generalize the results of the study to a broader group of patients (*As just noted , we have generalized the treatment to other areas*).

Therapy with the Circulator Boot A Breakthrough Technology According to Medicare Criteria

- Many patients with no other alternative
- A beneficial result ("Beneficial" if it produces a health outcome better than the natural course of the disease or that produced by alternative therapies)
- A different clinical modality without consideration of cost or magnitude of benefit
- Added value compared to alternative therapies
- Cost effective… equivalent or lower cost versus standard therapies

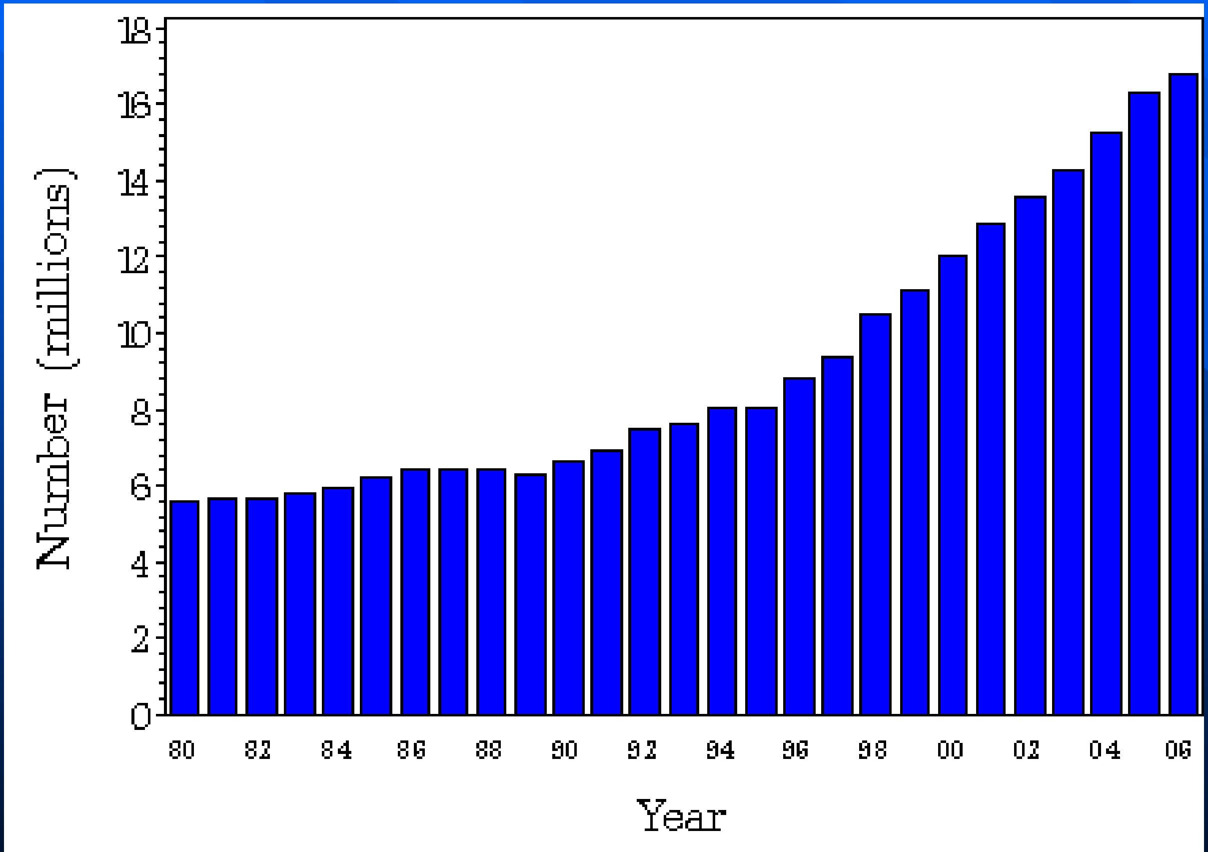
http://www.circulatorboot.com/literature/Medcomments.html

Increased Prevalence of Diabetes Mellitus in Part Related to Lowering of Diagnostic Values

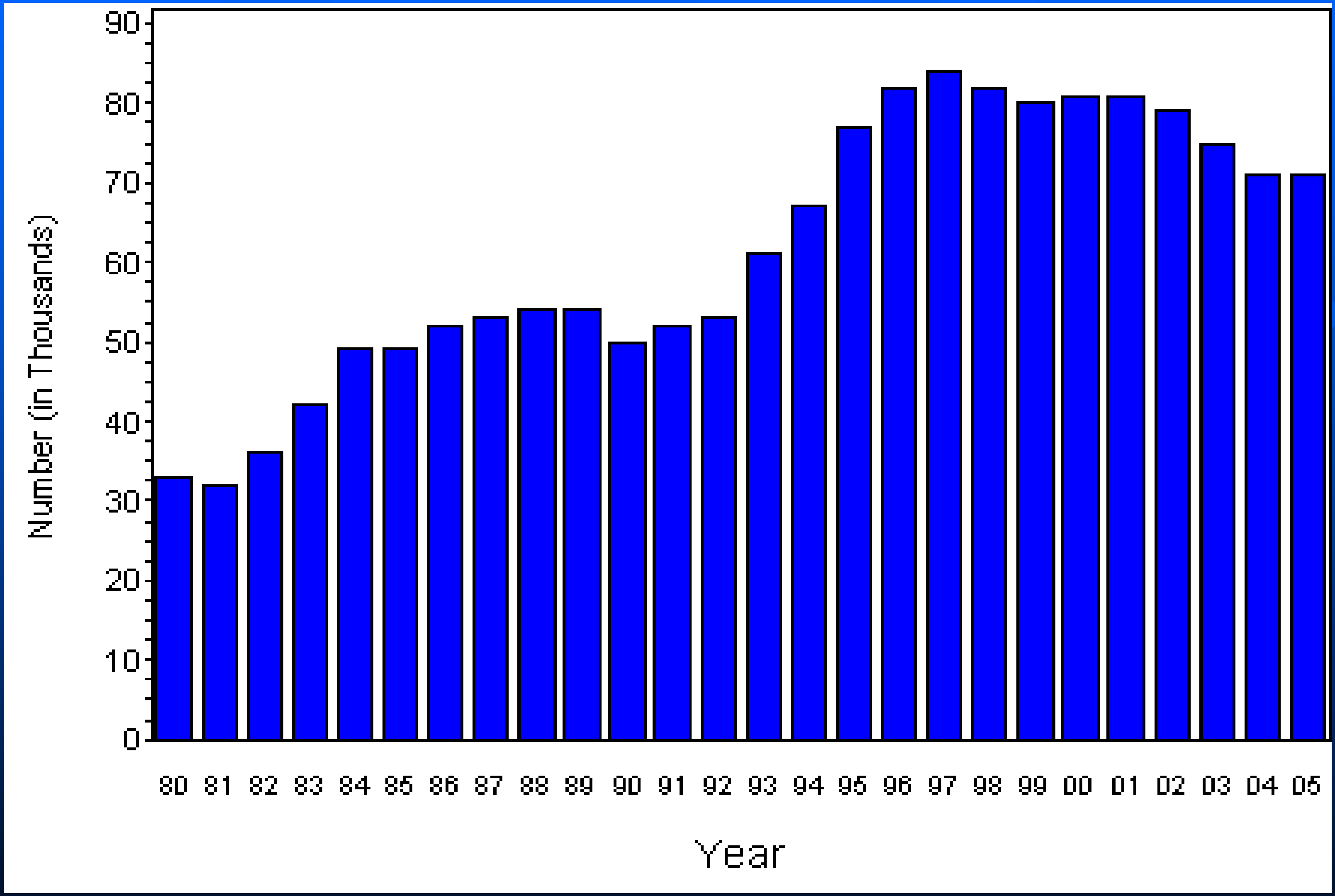
	Today	**1980**
Fasting Plasma Glucose	>=126	>=140

Number (in Millions) of Civilian/Noninstitutionalized Persons with Diagnosed Diabetes, United States, 1980–2006

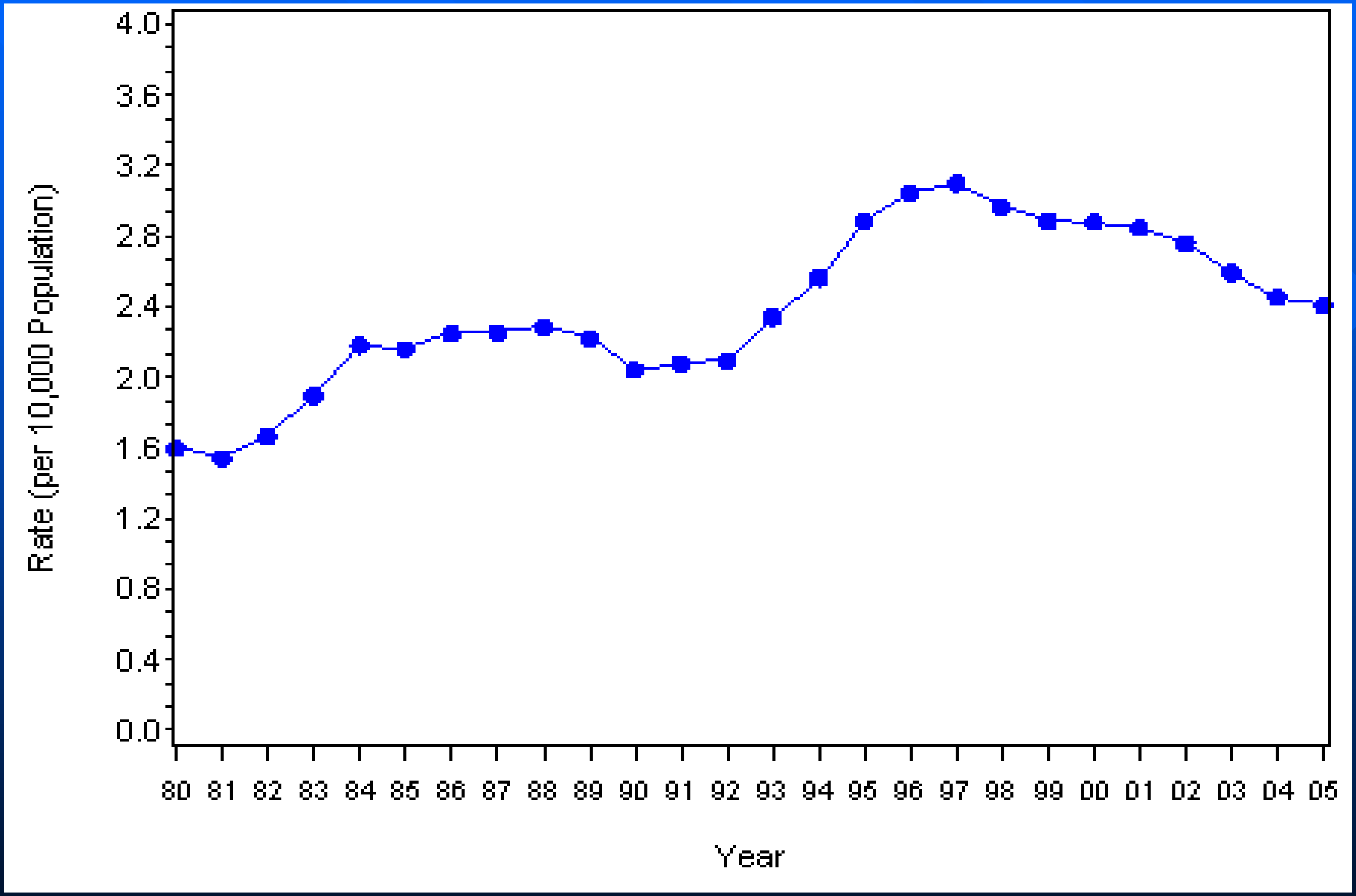
Diabetes is becoming more common in the United States. From 1980 through 2006, the number of Americans with diabetes tripled (from 5.6 million to 16.8 million). As the detailed tables show, people aged 65 years or older account for approximately 37% of the population with diabetes.



Number (in Thousands) of Hospital Discharges for Nontraumatic Lower Extremity Amputation with Diabetes as a Listed Diagnosis, United States, 1980–2005



Age-Adjusted Hospital Discharge Rates for Nontraumatic Lower Extremity Amputation per 10,000 Population, United States, 1980–2005



Average Annual Number and Percent Distribution Of Hospital Discharges Listing Lower Extremity Amputations By Amputation Level and Presence of Diabetes on the Discharge Record U.S. 1989-92

Amputation Level	No Diabetes No.	%	Diabetes No.	%	Totals No.	%
Toe	12,427	24.1	21,671	40.3	34,098	32.3
Foot/ankle	2,967	5.8	7,773	14.5	10,740	10.2
Below knee	11,084	21.4	13,484	25.1	24,527	23.3
Knee disarticulation	778	1.5	704	1.3	1,482	1.4
Above knee	20,028	38.8	8,612	16.0	28,640	27.2
Hip/pelvis	386	0.7	87	0.2	473	0.5
Not specified	3,971	7.7	1,378	2.6	5,349	5.1
Total	51,605	100.0	53,709	100.0	105,309	100.0

Reiber GE, Boyko EJ, Smith DG: Diabetes in America, 2nd edition, Published by the National Diabetes Data Group of the National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, Bethesda, Maryland – Table 18.4, page 409.

2002 Age-Adjusted LEA Rate per 1,000 People with Diabetes by Level of Amputation:

2.6 Toe
0.8 Foot
1.6 Below Knee
0.8 Above Knee

Diabetes and Lower Extremity Amputations
by NLLIC Staff (Revised 2008)

Data Limitations of Diabetes Surveillance System of the National Hospital Discharge Survey

- The number of LEAs is underestimated due to the exclusion of long-term and federal hospitals from the NHDS sample and the omission of LEAs occurring in outpatient settings. Race-specific discharges are particularly underestimated because a substantial proportion of discharges are missing racial classification and missing values for race are not imputed.
- Because NHDS samples hospital discharges and not individual persons, NHDS hospital discharge rates for diabetes-related diseases and procedures may not necessarily reflect rates per person; that is, persons who are hospitalized more than once for the same condition may be counted more than once.
- In 1983, the Center for Medicare and Medicaid Services instituted a prospective payment system that has influenced both hospitalization practices and disease reporting on discharge records.

Mortality Associated with Leg Amputations in Diabetics

Authors (Year)	Postoperative	2yrs	3yrs	4yrs	5yrs	7yrs
Silbert (1952)			35%		59%	
Hoar (1962)	7%	30%				
Cameron (1964)					65%	
Whitehouse (1966)						80%
Ecker (1970)	23% inpatient		39%		58%	
Kahn (1974)	9%					
Kolino-Sorensen(1974)	25%					
Roon et al (1970)	3% inpatient				55%	
Ebslov & Josephsen (1980)	16.3% at 3mos			22.4%		
Hayes (1981)	16.4%at 14 days and 25.5% inpatient					
Rozin (1987)	23.&%					
Eneroth & Persson (1992)	38% at 6 mos		72%			
Apelqvist (1993)	20% at 1yr		41%		73%	
Pohjolainen & Persson (1998)	38% at 1yr	53%			80%	

Incidence of Contralateral Limb Amputation in Diabetic Leg Amputees

Authors (Year) Years

1 2 3 4 5

- Silbert (1952) - 30% - - 51%
- Goldner (1960) - - 40% - 66%
- Hoar (1962) - - 36% - 50%
- Cameron et al(1964) 8.5% - - - -
- Baddeley & Fulford (1965) 20% - -
- Ecker (1970) - 26% - - -
- Roon et al (1977) - - - - 36.6%
- Ebskov & Josephsen (1980) 18% 27% 44% -
- Apelquist et al (1993) 13% - 35% - 48%
- Carrington et al (2001) - 15.4% (from foot care clinic) vs 14% of controls
- Kanade et al (2007) - 22% - - -

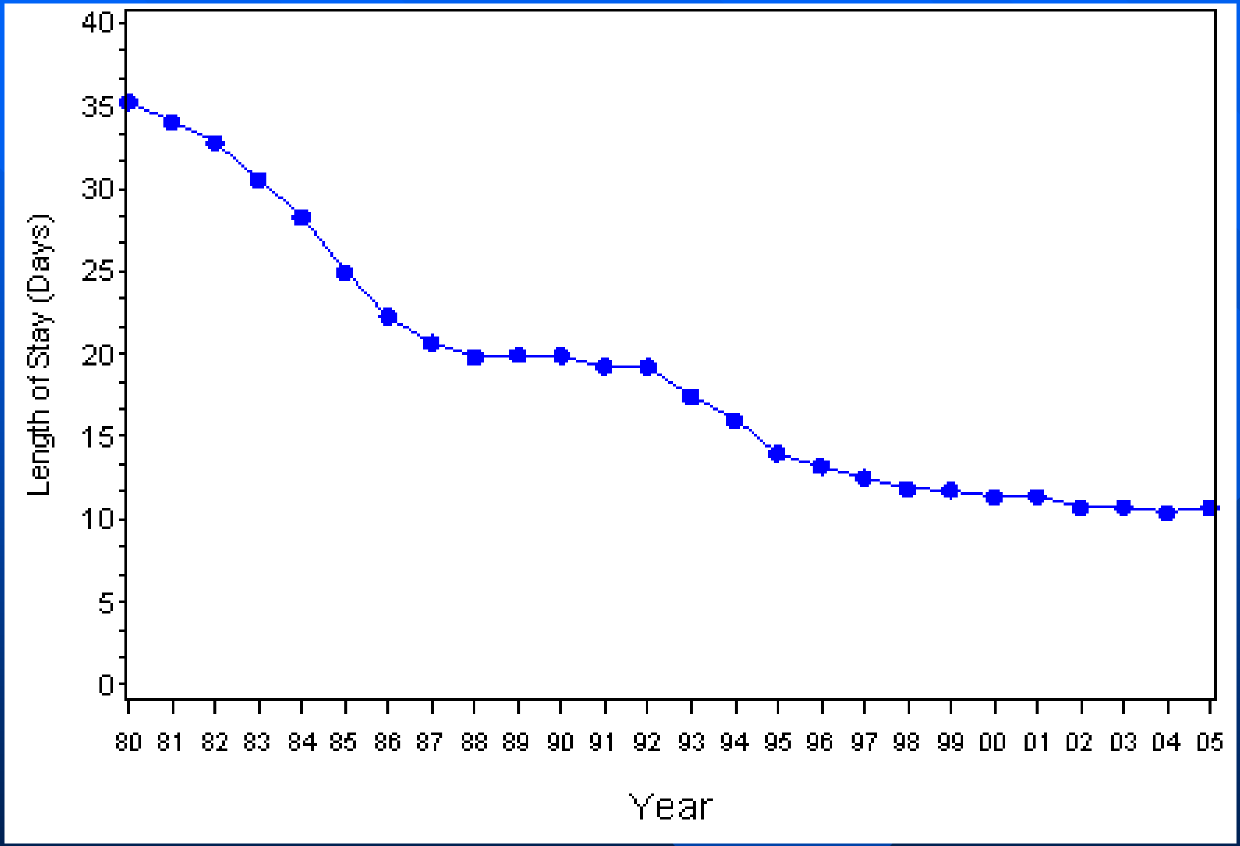
Failure of Therapeutic Shoes to Influence Incidence of Foot Ulcers

- **Reiber GE, Smith DG, Wallace C, Sullivan K, Hayes S, Vath C, Maciejewski ML, Yu O, Heagerty PJ, LeMaster J.**: *Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial.* JAMA 287(19):2552-8, 2002.

- **Litzelman DK, Marriott DJ and Vinicor F**: *The role of footwear in the prevention of foot lesions in patients with NIDDM, Conventional wisdom or evidence-based practice?* Diabetes Care 20:156-162, 1997.

- **Maciejewski ML, Reiber GE, Smith DG, Wallace C, Hayes S, Boyko EJ**: *Effectiveness of diabetic therapeutic footwear in preventing reulceration.* Diabetes Care 27:1774-82, 2004.

Average Length of Stay (LOS) in Days of Hospital Discharges for Nontraumatic Lower Extremity Amputation with Diabetes as a Listed Diagnosis, United States, 1980–2005



Centers for Disease Control and Prevention, National Center for Health Statistics, Division of Health Care Statistics, data from the National Hospital Discharge Survey and Division of Health Interview Statistics, data

Fate of Patients and Their Legs After Transmetatarsal Amputations

Years Since Amputation	Living #	Living %	Healed Incisions #	Healed Incisions %
2	336	78	213	63
3	304	70	173	57
4	281	66	144	51
5	265	60	123	46

From Wheelock, In Joslin's Diabetes Mellitus, Lea & Febiger, 1971

Joslins's Group III of 100 Consecutive Foot Ulcers

Clinical Status

- Cellulitis of more than 2 cm
- Extensive tissue and/or bone destruction
- Systemic toxicity
- Threatened limb loss

Outcomes

- 36% required multiple operations
- 67% had forefoot amputations.
- Over one third had leg amputations.

Joslin's Diabetes Mellitus 12th ed pp717-18

Outcomes of Distal Foot Amputations

Authors (Year)	Amputations	Complications
Gianfortune et al (1985)	Ray Resection	25% chronic ulcers & 41% proximal amps
Turnbull & Chester (1988)	Partial Foot	Early results for 102 limbs: primary healing in 70, re-operation in 20 and leg amp in 12
Sage et al (1989)	Mid-foot	Breakdown in 28% at 3 wks & 42% at 1 yr. Major amputations in 14%.
Hodge (1989)	Distal Foot	121 amputations and 41 re-amputations; Ultimately, 58% healed and 42% had MA'.
Santi et al (1993)	Partial Foot	Data on 80 of 94 healed feet: 15 high amps, 35 with ulcers & revisions. 29% of survivors had re-operations by 4 yrs and 52% by 8 years.
Quigley et al (1995)	Transmetatarsal	39% healed in av 8.5 mos, 31% had further debridements and 46% had major amput.
Mueller et al (1995)	Transmetatarsal	27% had skin breakdown (13% by 3 mos) and 28% had major amps (16% by 1 mos and 15% in spite of recent vascular surgery)
Pollard J et al (2006)	Transmetatarsal	Of 90 pts having 101 TMA's, 42.7% did not heal and 87.1% had complications.
Snyder DC et al (2006)	Forefoot	Follow-up 2+ yrs: 26% more forefoot amp & 37% proximal amp. Follow-up by specialists no benefit.

Wagner Classification of Foot Lesions

- Grade 0: Skin Intact (May have Bony Deformities)
- Grade 1: Localized Superficial Ulcer
- Grade 2: Deep Ulcer to Tendon, Bone, Ligament or Joint
- Grade 3: Deep Abscess or Osteomyelitis
- Grade 4: Gangrene of Toes of Forefoot
- Grade 5: Gangrene of Whole Foot

Wagner FW Jr. In Mann RA, ed. Surgery of the Foot. CV Mosby; 1986:423

Surgical Procedures by Wagner Stage

in Treatment of Diabetic Foot Infections

Calhoun JH et al: Foot and Ankle 9:101-108, 1988

Procedure	Wagner Stage 0	1	2	3	4	5	Total
None	25	103	15	63	5	1	212
Debridement	5	45	32	103	41	7	233
Split thickness skin graft	0	9	5	25	2	1	42
Incision & drainage	0	0	0	44	3	0	47
Toe amputation	0	3	8	59	84	4	158
Metatarsal resection	0	0	2	17	11	0	30
Ray resection	0	2	5	32	35	0	72
Transmetatarsal amputation	0	1	0	4	14	2	21
Ankle disarticulation	0	0	2	2	9	11	24
Syme's amputation	0	0	0	4	4	0	8
Below-the-knee amputation	0	3	6	19	59	34	121
Above-the-knee amputation	0	0	0	1	3	5	9
Vascular Procedure	0	1	4	4	22	1	32
Neurolysis	0	3	0	0	5	0	8
Totals for their 355 patients:	5	65	64	314	292	65	805

Armstrong DG, Lavery DA, Harkless LB: *Validation of a diabetic wound classification system. The contribution of depth, infection, and ischemia to risk of amputation.* Diabetes Care 21:855-859, 1998.

Stage	**Grade "0"**	**Grade "1"**	**Grade "2"**	**Grade "3"**
A **#** **164** 46%	Pre or Post – ulcerative lesion completely epithelized 0 amp	Superficial wound, not involving tendon, capsule or bone 0 amp	Wound Penetrating to tendon or capsule 0 amp	Wound Penetrating to bone or joint 0 amp
B **#** **158** 44%	Infection 12.5% amp	Infection 8.5% amp	Infection 28.6% amp 3.3%MA	Infection 92% amp 13%MA
C **#** **21** 6%	Ischemia 25.0% amp	Ischemia 20.0% amp	Ischemia 25.0% amp 25%MA	Ischemia 100% amp 33%MA
D **#** **17** 5%	Infection & Ischemia 50.0% amp 0MA	Infection & Ischemia 50..0% amp 50%MA	Infection & Ischemia 100% amp 100%MA	Infection & Ischemia 100% amp 91%MA

Peripheral Arterial Disease: Assessment by Arteriography and Alternative Noninvasive Measures

- 3000 patients referred for arteriography
  - 30% rejected for study
    - 15% abnormal EKG, chest x-ray or lab study
    - 15% disease either too mild or advanced to benefit
  - 70% or 2100 patients undergo arteriography
    - 60% (42% overall) had operable lesions
    - 40% (28% overall) inoperable due to lack of patency of a single major vessel in the lower leg
      - Fitzgerald & Carr: Am J Roentgenol 128:385, 1977

Linton’s 10 Requirements for a Successful Femoral-Popliteal Bypass Procedure

- 1. Accurate arteriogram
- 2. Suitable saphenous vein from the patient
- 3. Adequate blood flow into the graft
- 4. Healthy portion of the popliteal artery and a satisfactory runoff
- 5. Aseptic technique and pre-operative and post-operative antibiotics
- 6. Heparin anticoagulation during the procedure
- 7. Blood bank support
- 8. Good surgical technique
- 9. Expert anesthesia avoiding low blood pressure
- 10. Adequate time... the procedure cannot be rushed.

To which one might add:

- 11. Absence of congestive heart failure or active coronary disease.
- 12. Absence of unstable cerebrovascular disease.
- 13. Absence of infection at operative sites.

Medical Treatments Improving the Prognosis of Arteriosclerotic Heart Disease… and ? Peripheral Arteriosclerosis Obliterans

- Aspirin
- Beta blockers
- ACE inhibitors and blood pressure control
- HMG-CoA inhibitors and lipid therapies
- Improved control of diabetes
- Exercise
- Weight reduction
- Pneumatic external counterpulsation boots

(New antibiotics a factor in improved recovery for the diabetic foot)

Lack of Benefit of Invasive Procedures on Long-Term Amputation Rates

- Morris PE et al: Surgery and the progression of the occlusive process in patients with peripheral vascular disease. Radiology 124:343, 1977
- Eickhoff HJ, Hanson B, Lorentzen JE: The effect of arterial reconstruction on lower limb amputation rate. Acta Chir Scand 502: 181-187, 1980.
- Humpfrey LL, Baillard DJ, Butters MA, Palumbo PJ and Hallett JW: The epidemiology of lower extremity amputation in diabetes: a population based study in Rochester, Minnesota. Diabetes 38: suppl 2:33A, 1989.
- Tunis ER, Bass EB and Steinberg EP: The use of angioplasty, bypass surgery and amputation in the management of peripheral vascular disease. N Engl J Med 325: 556-62, 1991.
- Sayers RD, Thompson MM, Varty K, Jager C and Bell PFR: Changing trends in the management of lower limb ischemia: a 17 year review. Br J Surg 80: 1269-1273, 1993.
- Connelly J, Airey M and Chell S:.Variation in clinical decision making is a partial explanation for geographical variation in lower extremity amputation rates. Br J Surg 88(4):529-35, 2001.
- Trautner C, Haastert B, Spraul M, Giani G and Berger M: Unchanged incidence of lower-limb amputations in a German city, 1990-1998. Diabetes Care 24:855-859, 2001.

Common Factors Promoting Progression of Foot Infections in the Elderly

- Obesity and inactivity
  - Poor muscle tone
  - Degenerative joint disease, bunions, hammer toes
  - Stasis
- Cognitive factors delaying treatment:
  - Depression
  - Fatalism
  - Confusion
  - Poor eyesight

Dillon : Geriatric Med Today Vol 6, 1987

- Peripheral arteriosclerosis
  - Diabetes mellitus
  - Hypertension
  - Lipid disorders
- Arteriosclerotic heart dis.
  - Peripheral edema
  - Decreased cardiac output
- Use of multiple drugs
  - Diuretics
  - Vasoconstrictors

Alterations of the Immune System in the Elderly

- Decreased production of thymic hormones
- Increased percentage of immature lymphocytes
- Altered lymphocyte enzymes
- Decreased number of helper T cells
- Decreased generation of cytotoxic lymphocytes
- Increased percentage of suppresser T cells
- Impaired cell-mediated immunity
- Decreased antibody production

Dillon Geriatric Med Today Vol 6, 1987

Immune Factors Decreased with Chronic Hyperglycemia

- Inflammatory response
- Granulocyte response
- Mobilization of leukocytes
- Phagocytosis
- Granulocyte adherence
- Intracellular killing
- Wound healing

Dillon, Geriatrics Med Today Vol 6, 1987

Effects of Hyperglycemia on Nerves and Vessels

- **Thickened capillary membrane**
  - Glycosylated hemoglobin and stiff rbc's
- **Arteriosclerosis**
  - Glycosylated low-density lipoprotein and scavenger-cell uptake
  - Associated hyperlipidemias
- **Hypercoagulable State**
  - Endothelial factors
  - Platelet dysfunction
  - Increased thromboxane A2 synthesis
    Increased von Willebrand factor
  - Increased red cell adherence to endothelium
  - Increased blood viscosity
  - Decreased fibrinolysis
    glycosylated fibrinogen
- **Ischemic and metabolic factors promoting neuropathy**
  - Hammer toes
    Atrophy of small muscles in foot
  - Callus formation at pressure points
  - Decreased sensation

Dillon. Geriatric Med Today Vol 6, 1987

CBC

Neuropathic Diseases and Foot Ulcers, Charcot Feet and Dysesthesias

- Poorly controlled diabetes (most common cause of neuropathic foot ulcers seen in the United States.
- Pernicious anemia
- Chronic alcoholism
- Old spinal cord injuries
- Myelodysplasia
- Syringomyelia
- Tabes dorsalis and Lyme Disease
- Leprosy
- Hereditary sensory syndromes
- Small vessel disease
- Poisoning due to heavy metals or organic chemicals
- Drug toxicity
- Inflammatory states
- Collagen diseases
- Uremia
- Porphyria
- Acromegaly
- Beriberi
- Pyridoxine deficiency or excess
- Entrapment syndromes
- Tendon shortening

Multiple Areas of Breakdown in Right Leg Occurring during Hospitalization for Removal of Left Leg in Patient with Diabetes, Multiple Myeloma and Nicotine Addiction. Patient FF

Subcutaneous PO_2 Levels of Patient FF

Time	1st toe	5th toe	Med Instep	Lat Instep
0	12%	7%	11%	18%
1 wk	45%	24%	30%	22%
2 wks	68%	54%	66%	59%

Composition of Sea Soaks Compared to Sea Water, Tissue Culture Media and Serum

Element	Sea Soaks™	Sea Water	Culture Media	Serum
Calcium	7.87mEq/L	20.5mEq/L	6.0-48.0mEq/L	4.4-5.1mEq/L
Magnesium	21.8mEq/L	107.2mEq/L	0.82-10.0mEq/L	1.5-2.2mEq/L
Potassium	2.98mEq/L	9.963mEq/L	1.0-5.8mEq/L	3.5-5.1mEq/L
Sodium	132mEq/L	470.7mEq/L	130-160mEq/L	136-146mEq/L
Chloride	161mEq/L	548.7mEq/L	110-150mEq/L	98-106mEq/L
Bicarbonate	-	-	6.7-44mEq/L	22-29mEq/L
Phosphate	1.1E-8 to 1.1E-6 M*	3.3E-8 to 3.3E-6 M*	0.3-16.8mEq/L	0.74-3.07E-3 M/L
Sulfate	0.0089M*	0.0268M*	0.000003-0.0015M	0.0001-0.00065M
Chromium	Trace	Trace	1.0 E-9M	2.7 E-9M
Cobalt	Trace	Trace	5.5 E-10 to 1E-6 M	3.4-4.8 E-10 M
Copper	0.53-5.3E-8 M	1.6-16E-8 M	1 E-9 to 2 E-7 M	1.1-2.4 E-5 M
Fluorine	2.5E-5 M	7.5E-5 M	1 E-5 mEq/L	0.5-10.5 E-6M
Iodine	1.3E-7 M	4.0E-7 M	1E-6 mEq/L	0.79-1.2 E-7 M

Composition of Sea Soaks Compared to Sea Water, Tissue Culture Media and Serum, continued

Element	Sea Soaks™	Sea Water	Culture Media	Serum
Iron	1.2-12.3E-8 M	3.7-37E-8 M	3.1E-9 to 2E-5 M	0.9-3.0 E-5M
Manganese	0.6-6E-8 M	1.8-18E-8 M	4E-10 to 9.5E-8 M	7.28-25.5 E-8 M
Molybdenum	1.77E-9 M	5.3E-9 M	7E-10 to 1.4E-7M	3.9-8.2 E-9 M
Nickel	0.58E-9 M	1.75E-9 M	5E-12 to 1E-9 M	1.9-7.8 E-8 M
Selenium	1.73E-9 M	5.2E-9 M	1.4E-10 to 3E-8 M	1.3-4.3 E-6 M
Silicon	**2.4E-7 to 0.5E-4 M**	**7.3E-7 to 1.5E-4 M**	**1E-9 to 1E-5 M**	**1.4 -35.7 E-5 M**
Tin	Trace	Trace	5E-12 to 1E-8 M	-
Vanadium	2E-9 M	6E-9 M	5E-9 to 1E-8M	0.4-1.96 E-9 M
Zinc	2.6E-8 M	7.8E-8 M	1.1E-8 to 3E-6 M	1.1-2.3 E-5 M
Osmolality	285 mOs	862+/-1 mOs**	280-290mOs	275-295mOs

Ischemic Ulcer Improves on Sea Soaks and Turns to Beef on Saline

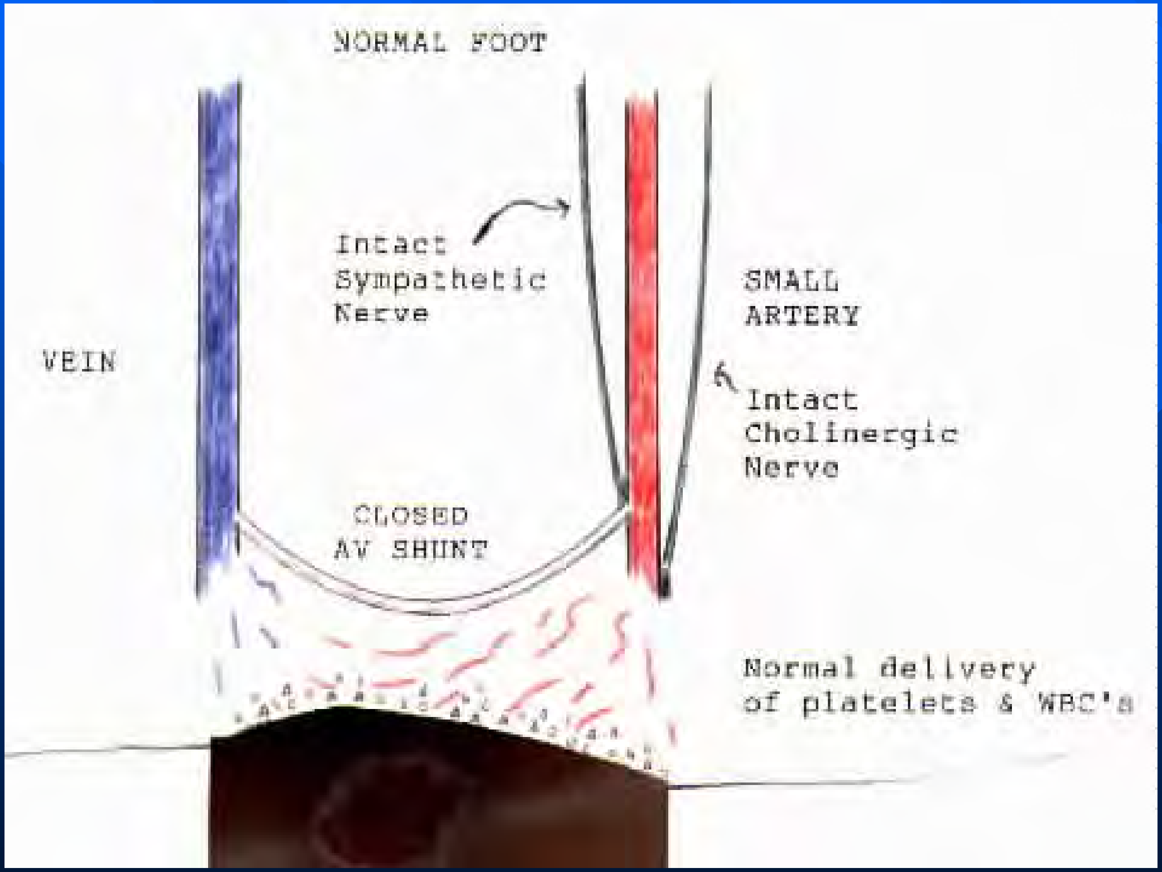
Patient I.O. prior to therapy

After 14 days Sea Soaks

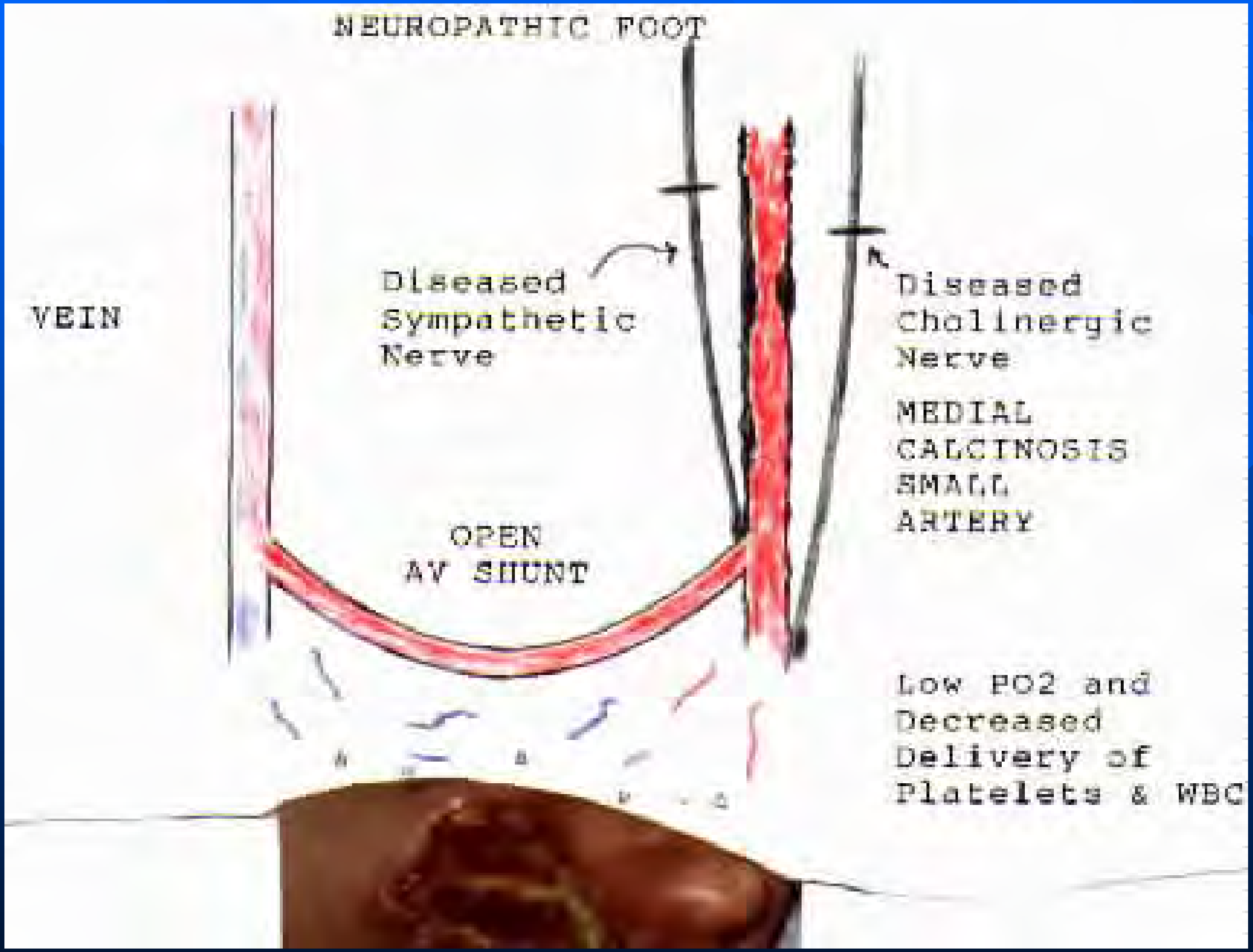
After 3 Days of Topical Sea Soaks and Gentamicin

Out of Sea Soaks and on Saline wet-to-dry dressings

Autonomic Function and the Normal Foot



Autonomic Dysfunction and the Diabetic Neuropathic Foot



Wound Healing as Affected by Saline, Sea Soaks, Atropine and Methacholine

The legs of Patient "RM" are illustrative of the findings in the study. When this study was over, cup #1 was found to have had saline; #2, Sea Soaks and atropine; #3, Sea Soaks and methacholine; and #4, Sea Soaks alone. Here at 24 hours, healing was fastest in #3 and #4. Perhaps seen here and below, as in most patients, the skin color with Sea Soaks (left top) remained unchanged, with metahcholine (right top) became pink, with atropine (bottom left) became pale and with saline (right bottom) became inflamed.

Wound Healing: Inhibiting Effect of Saline and of Cholinergic Blockade (Atropine) and Beneficial Effect of Sea Soaks and of Cholinergic Stimulation (Methacholine)

	First Healed	Delayed Healing	Totals
Effects of Drugs Alone - Upper Limb Studies:			
✣ Atropine Vs	0(1)	6(5)	6(6)
Placebo	6(5)	0(1)	6(6)
✣ Methacholine Vs	6(6)	0(0)	6(6)
Placebo	0(0)	6(6)	6(6)
Effect of Vehicle for Drugs - Thigh Studies:			
✣ Sea Soaks Vs	6(6)	0(0)	6(6)
Saline	0(0)	6(6)	6(6)
Effect of Drugs in Preferred Vehicle (Sea Soaks):			
✣ Methacholine Vs	4(4)	0(0)	4(4)
Sea Soaks alone	0(0)	4(4)	4(4)
✣ Atropine Vs	0(0)	3(3)	3(3)
Sea Soaks alone	3(3)	0(0)	3(3)
✣ Methacholine Vs	4(4)	0(0)	4(4)
Atropine	0(0)	4(4)	4(4)
Total Experiments:	29(29)	29(29)	58(58)

Dillon: Angiology 42: 767-777, 1991

Bacterial Virulence Factors

- Enzymes promoting tissue destruction and separation of tissue planes
- Exotoxins and endotoxins
- Mechanisms decreasing local blood flow

  Bacterial endarteritis Local thrombosis

  Pressure from edema
- Polymicrobial infections allowing bacterial synergism

Dillon Geriatric Med Today Vol 6, 1987

Antibiotic Requirements in Treatment of the Elderly with Diabetes

- Activity against infecting organism(s)
- Appropriate levels at site of infection
- Avoidance of common toxicity problems:
  - Increased incidence of drug allergies
  - Increased incidence of nephrotoxicity associated with diabetes and use of diuretics
  - Increased incidence of ototoxicity with aminoglycosides
  - Problems of volume and solute overload
  - Gastrointestinal disturbances

Dillon Geriatric Med Today Vol 6, 1987

Advantages of the Circulator Boot And Local Antibiotic Techniques

Effects of the Circulator Boot-TM:

Thrombolytic effects
Reduction of swelling
Delivery of erythrocytes and oxygen
Delivery of systemic antibiotics and granulocytes
Dissemination of locally injected antibiotics

Use of Locally Injected Antibiotics:

- Ensured immediate ***high local*** concentration
  - Levels higher than achieved in serum
  - Kill bacteria with “wrong” antibiotic
  - Decreased total body exposure
- Fewer Complications
  - No stomach upset or change in bowel flora
  - No renal, liver, CNS or inner ear toxicity
  - No complications from indwelling catheter
- Decreased Costs
  - Decreased amount of drug
  - Outpatient use in doctor’s office
  - No visiting nurse

Use of Antibiotic Solutions within the Boot:

- Use of expensive antibiotics in a small volume of electrolyte solution.
- Debridement of necrotic tissue
- Use of systemically toxic antibiotics with little or no untoward effects (Aminoglycosides & Amphotericin B)

Dillon Geriatric Med Vol 6, 1987

The Multiple Vascular Impairments in the Diabetic Patient

- Autonomic and Arteriosclerotic Cardiomyopathy
- Arteriosclerosis of Large Vessels but Especially Those below the Knee
- Medial Sclerosis of Small Vessels and Calcification of the Pedal Arteries
- Arteriovenous Shunting due to Autosympathectomy
- Decreased Capillary Flow Associated with Cholinergic Autonomic Neuropathy and Decreased Small Fiber Nociceptor Function
- Thickening of the Capillary Membrane
- Abnormal Hemorrheology – Stiff Red and White Cells, increased viscosity and fibrinogen, hypercoaguability and decreased fibrinolysis
- Endothelial dysfunction and abnormalites in reactive hyperemia and capillaroscopy

Proportion of Diabetic Limb Amputations due to Individual Causes and Final Component Cause

Factor	Present	Main Problem
Ischemia	40%	5%
Neuropathy		61%
Gangrene	55%	40%
Infection	59%	41%
Ulceration	84%	
Minor Trauma	81%	
Faulty Wound Healing	81%	14%

Pecora RE et al. Seattle VA Hospital Diabetes Care 13:513-21, 1990

Common Errors in Management of Diabetic Ischemic Feet

- Elevation of the feet (blood does not run up hill)
- Warm or hot foot soaks (heat increases need for blood flow)
- Performance of an arteriogram in an inoperable patient
- Allowing foot soaks in water difficult to sterilize:

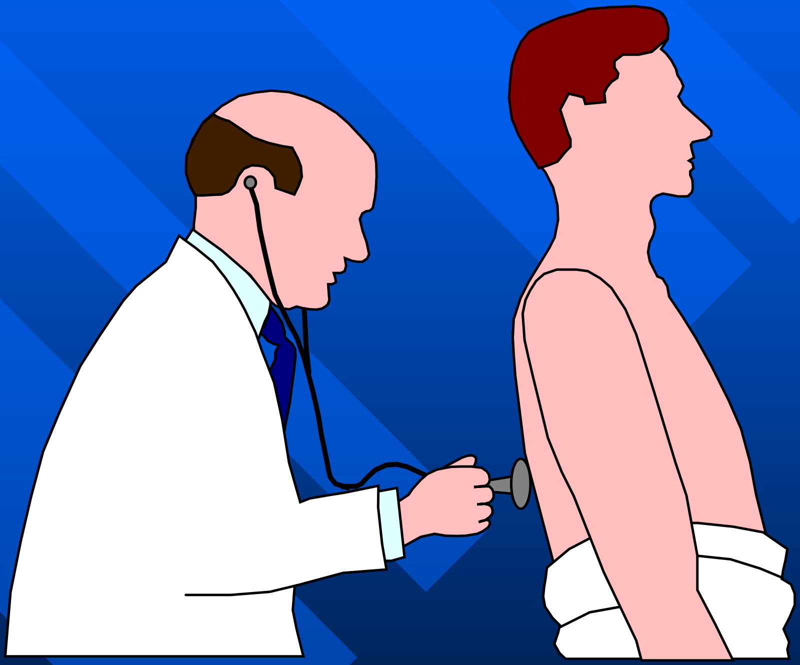
Bathtub	Whirlpool
Tap-water basin soak	Shower

- Infrequent bandage changes allowing bacterial growth in the bandage
- Tight bandages or cast decreasing blood flow
- Failure of preoperative clearance to include noninvasive vascular tests
- Failure to control hyperglycemia
- Allowing hot sun to bake foot through hospital window

Dillon, Geriatric Med Today Vol 6, 1987

Potential Medical Needs of Patients with Foot Lesions

- Lipids
- Diabetes control
- Blood Pressure
- Heart Function
- Renal Function
- Psychiatric state
- Smoking
- Social Support
- Arthritis and Osteoporosis
- Drug allergies
- Exercise Habits

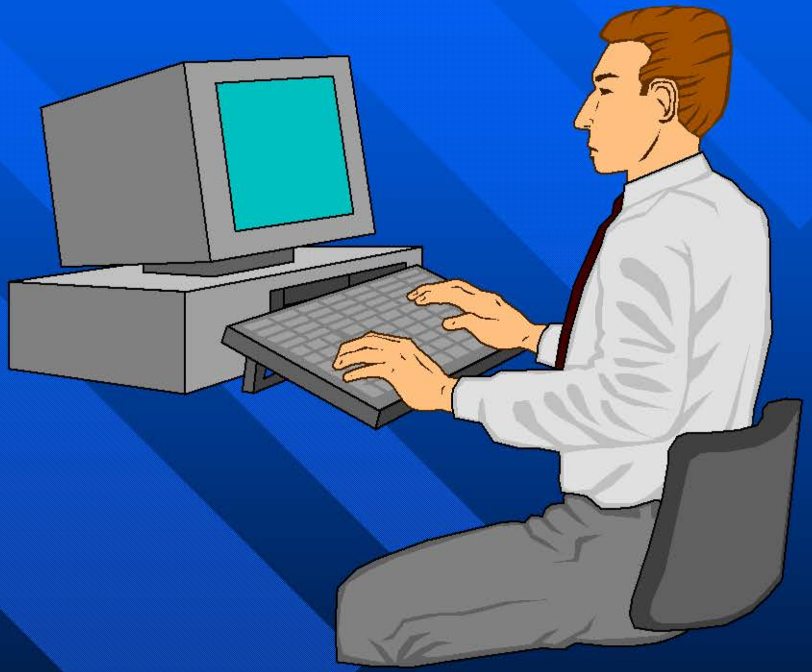


High Risk Feet May Require a Close Look by the Podiatrist

- Neuropathy:
  - Loss of deep tendon reflexes
  - Loss of light touch, pain, position or temperature sensation
  - Loss of sweating
  - Callus over pressure points
  - Foot ulcers
  - Abnormally shaped feet (hammertoes, bunions, flat feet or Charcot joints)

High Risk Feet May Require Assessment by Formal Vascular Testing

- Ischemia
  - Loss of palpable pulses
  - Foot or leg pain with exercise
  - Rest pain
  - Dependent rubor
  - Pallor of foot on elevation
  - Gangrene or ulcers
  - Failure to heal
  - Abnormal vascular tests



Pre-gangrenous Ischemic Changes in the Feet

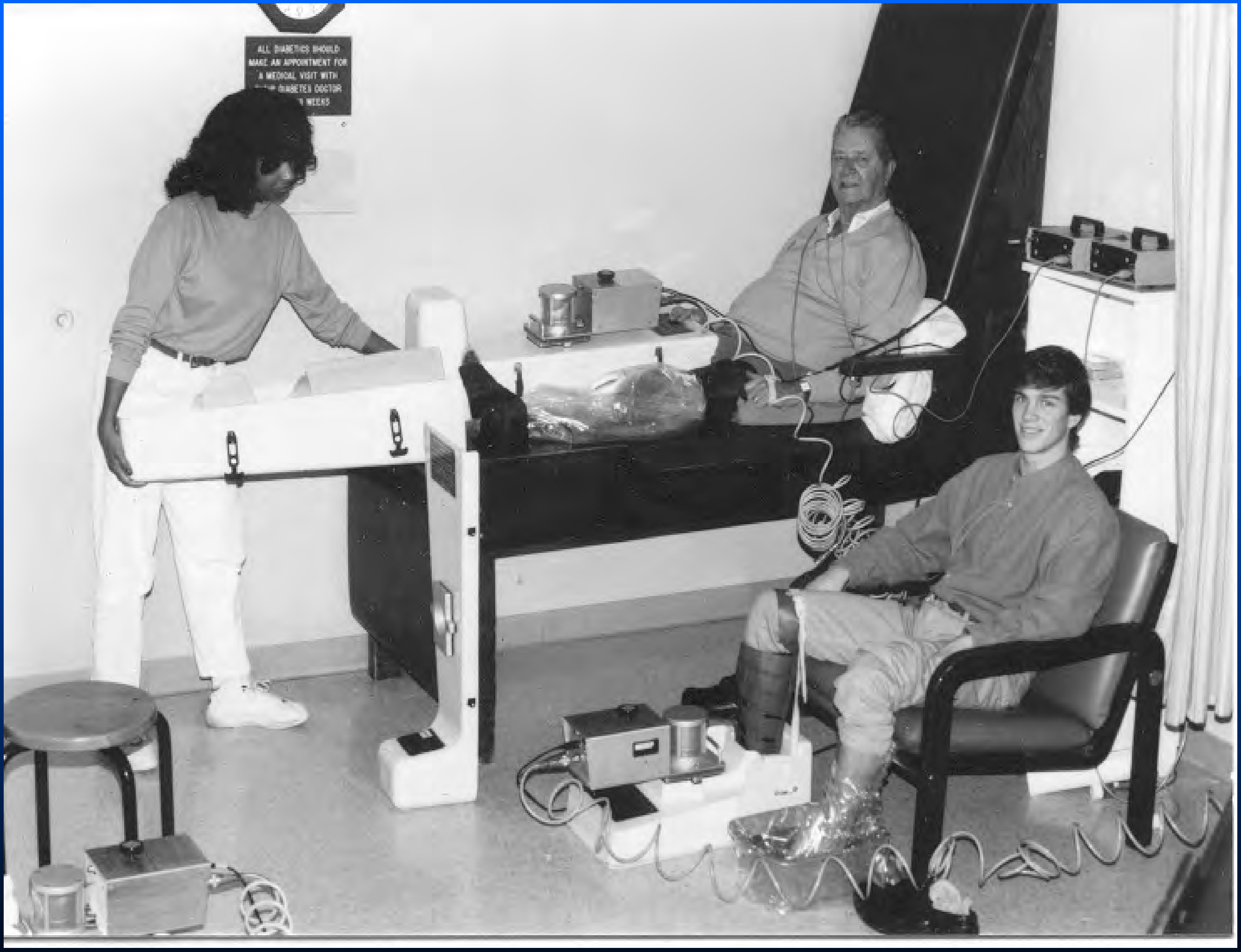
- Coldness (room temperature or below)
- Paralysis of toes
- Numbness
- Mottling
- Lack of capillary refill
- Persistent discoloration after elevation (failure to blanch)
- Persistent pallor on dependency
- Blisters

Classification of Acute Ischemia

Findings	Category I	Category IIa	Category IIb	Category III
Sensory loss	None	Minimal	Yes	Profound
Muscle weakness	No	No	Yes	Profound
Rest pain	No	Yes	Yes	Yes
Arterial Doppler	Yes	No	No	No
Venous Doppler	Yes	Yes	Yes	No
Significance:				
Urgency	No	Yes	Yes	Yes
Reversibility	Yes	Yes	Yes	No
Viability	Yes	Yes	Yes	No

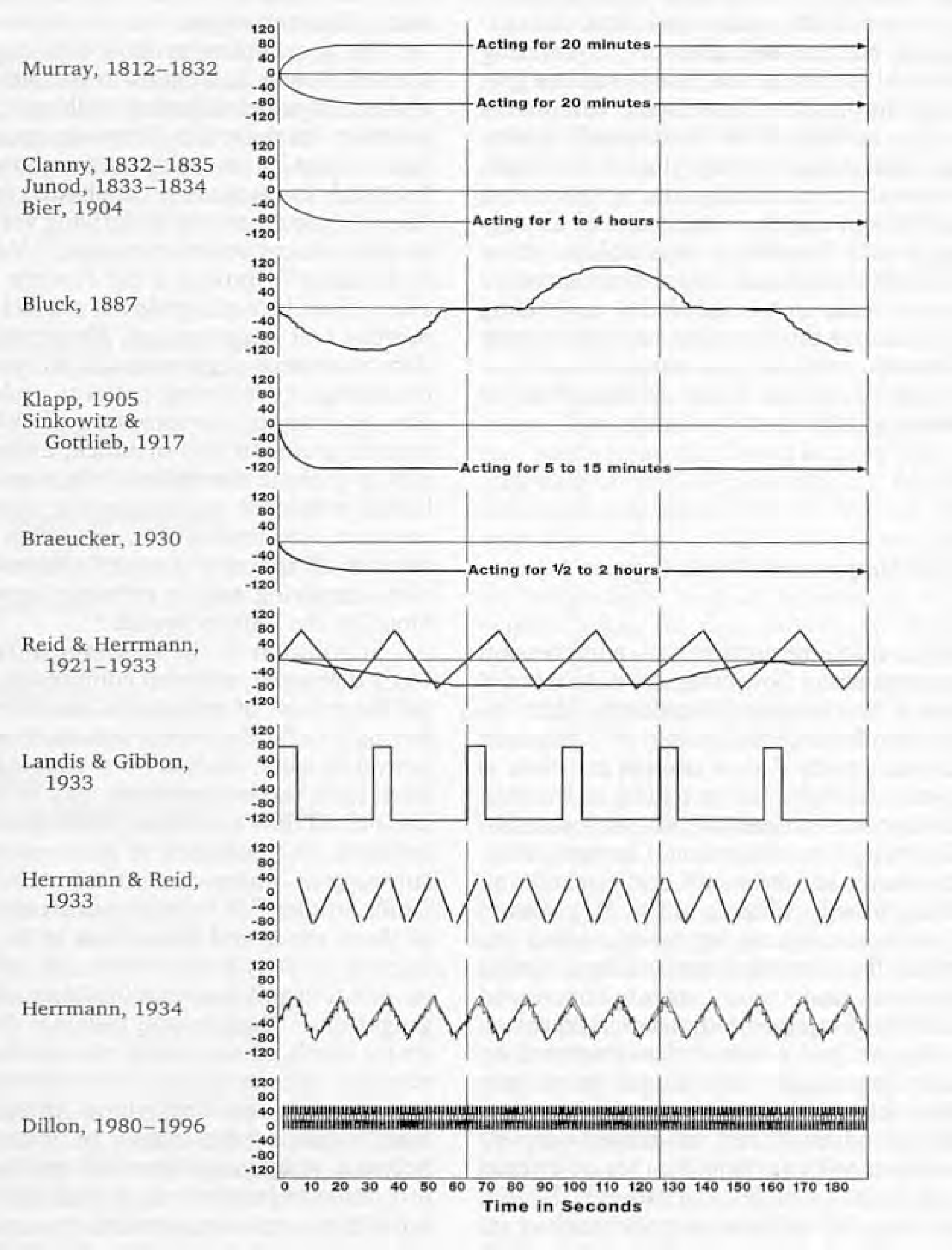
Rutherford RB, Baker JD, Ernst C et al.: Recommended standards for reports dealing with lower extremity ischemia: Revised version. J Vasc Surgery 26: 517-538, 1997

A Corner of Our Boot Room
Long Boot, Mini-Boot And Soaks



Historical Review

Types of alteration of environmental pressure used to improve circulation in the extremities



Dillon, Angiology 37:47-55, 1986

Device	Manufacturer/Distributor	Pressure Range	Cycle Time
Sequential Multichambered Leggings			
Thrombogard	Gaymar Industries Orchard Park, NY	45 mm Hg	16 sec. inflation/60 sec. deflation
Lymphatron Trio	HNE Healthcare Manalapan, NJ	20–98 mm Hg	90 sec. inflation/30 sec. deflation
FlowPlus	HNE Healthcare Manalapan, NJ	30–70 mm Hg	50 sec. inflation/70 sec. deflation
FlowPress	HNE Healthcare Manalapan, NJ	30–100 mm Hg	2 min. inflation/1 min. deflation
Lympha Press	Global Medical Imports Chelsea, MA	30–200 mm Hg	30 sec. inflation/3 sec. hold
Kendall SCD	Kendall Healthcare Products Mansfield, MA	30–55 mm Hg	11 sec. inflation and hold/60 sec. deflation
Jobst Extremity Pump	Beierdorf-Jobst, Inc. Charlotte, NC	10–120 mm Hg	190 sec inflation/50 sec. deflation
Single Chamber Leggings			
Flowtron HC	HNE Healthcare Manalapan, NJ	30–90 mm Hg	90 sec. inflation/90 sec. deflation
Venodyne	Lyne-Nicholson, Inc. Needham Heights, MA	40–45 mm Hg	12 sec. inflation and hold/48 sec. deflation
PAS	American Hamilton Two Rivers, WI	40–45 mm Hg	5 sec. inflation + 15 sec. hold/60 sec. deflation
Foot Pumps			
AV Impulse	Kendall Healthcare Products Mansfield, MA	60–200 mm Hg	0.4 sec. inflation + 3 sec. hold/20 sec. deflation
PlexiPulse	NuTech, San Antonio, TX	140–180 mm Hg	1–5 sec. inflation + hold/20–60 sec. cycle time

Koch has reviewed the types of commercially available devices available largely for the treatment of venous disease and lymphedema.

Angiology 48:S8, 1997

The Standard Reactive Hyperemia Test and

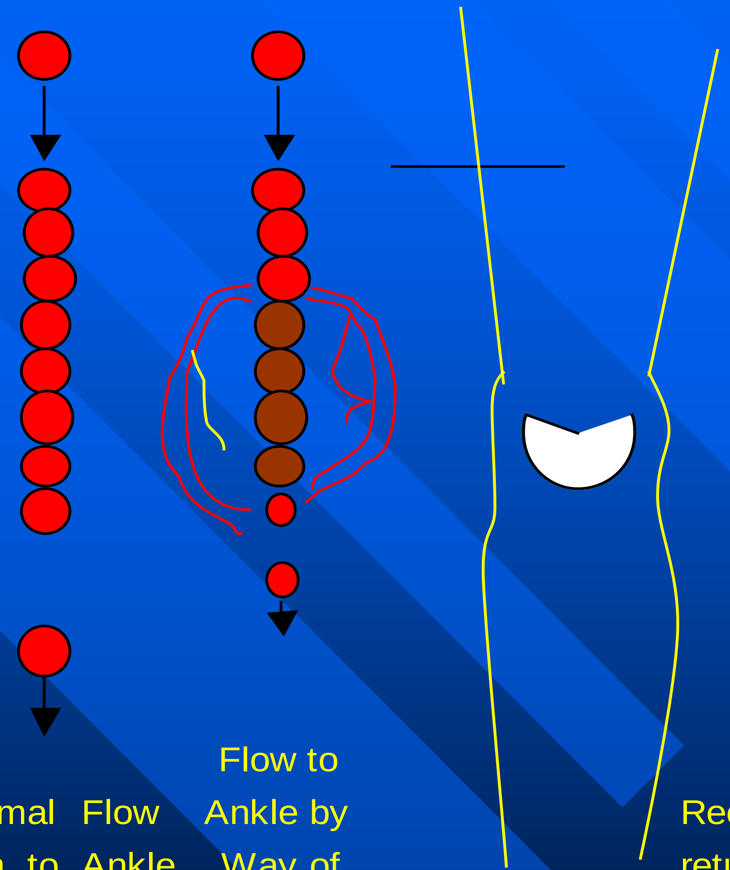
Potential Leg Ischemia during Compression Boot Therapy

Cardiac Output 6 L
Pulse 60
Stroke Volume 100ml
15-20ml/beat into
each leg at rest

A Quick time as blood goes to ankle and upper leg simultaneously

B Delay as blood goes to tissues fed by collaterals first.

Model explains potential obstruction in arterial flow by ECP and other boots that expel arterial blood during their inflation



Normal Flow Groin to Ankle

A

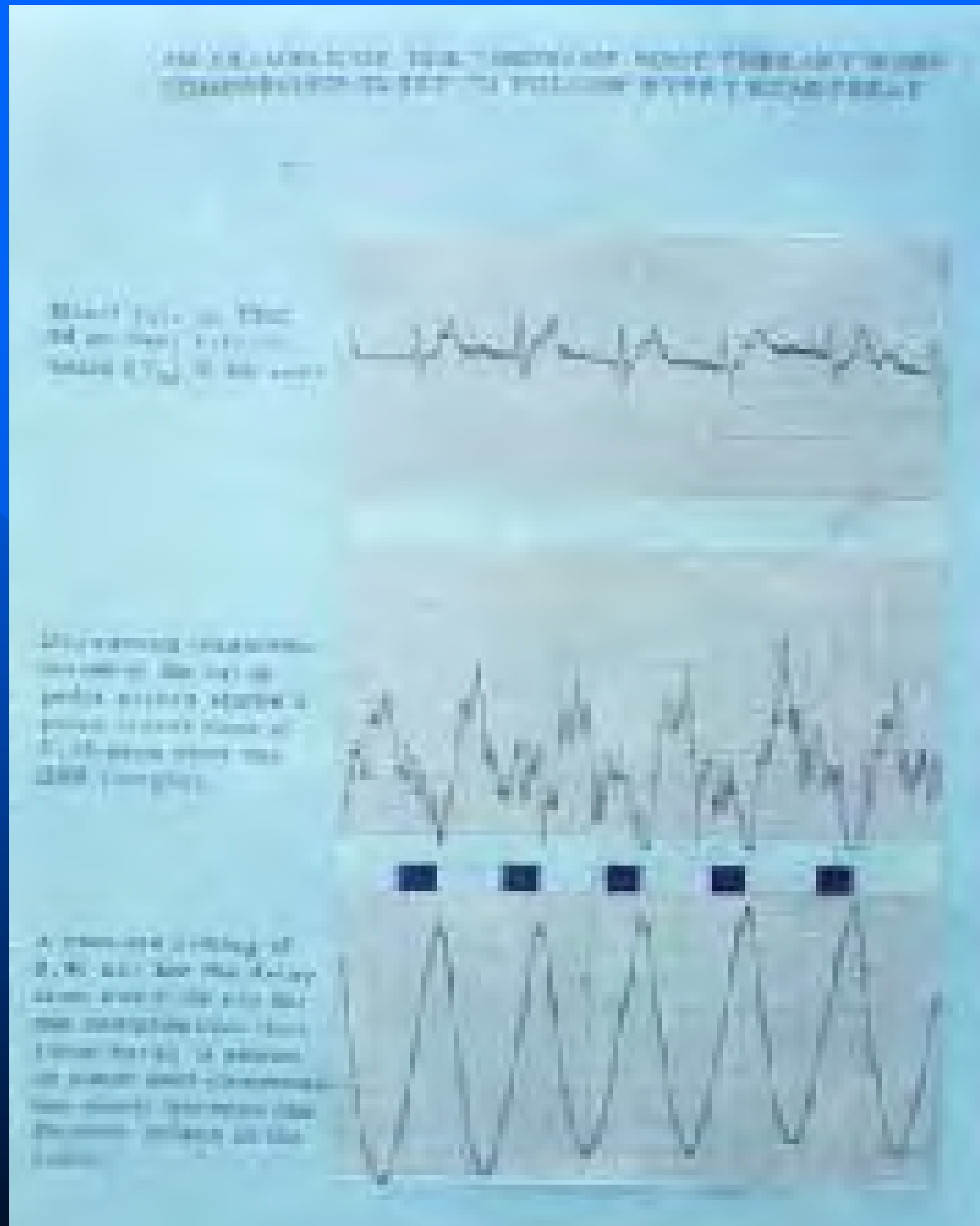
Flow to Ankle by Way of Collaterals

B

Reactive Hyperemia Test

Rec
retu
at ankle

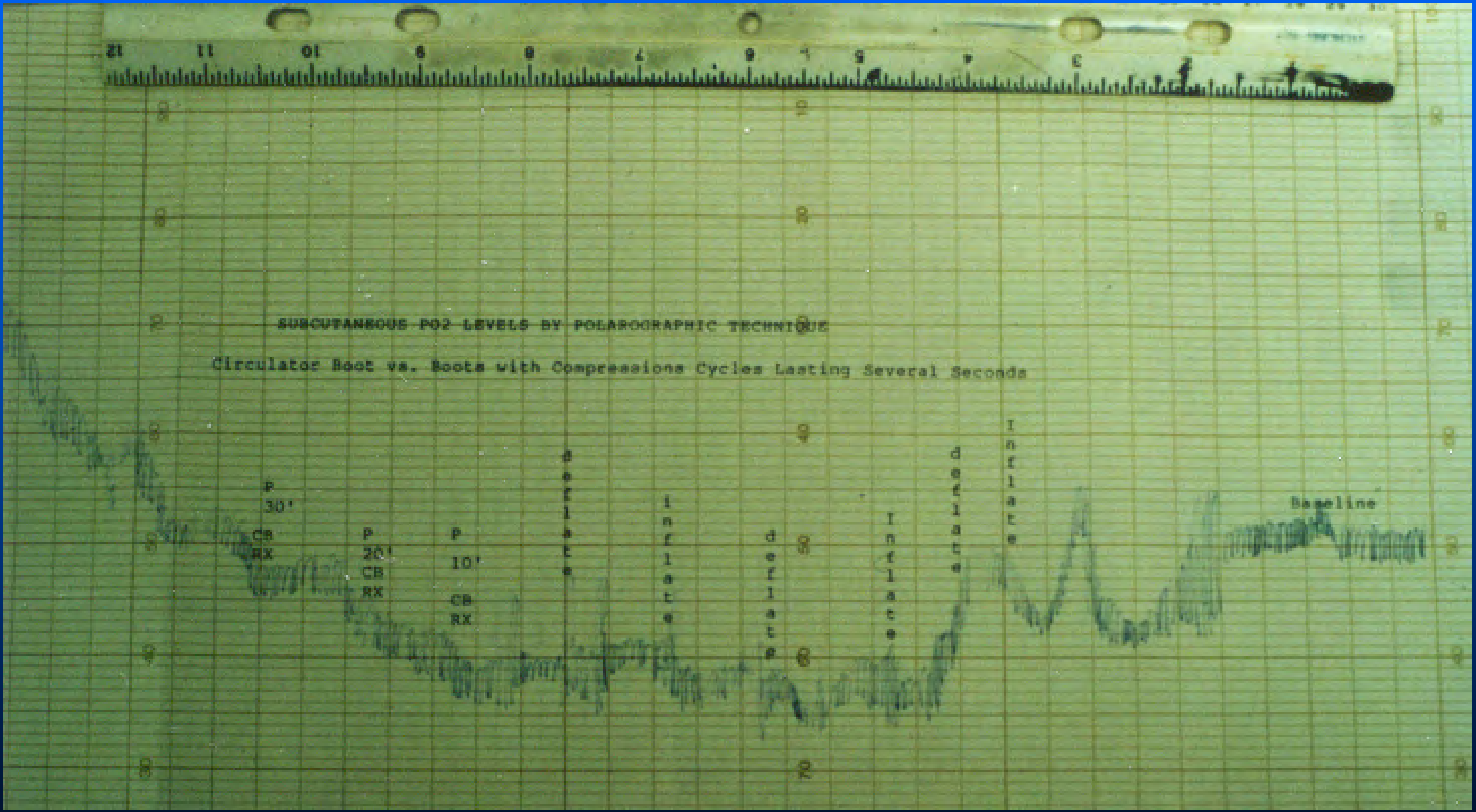
pressure cuff on for 3 minutes



Circulator Boot vs ECP

CB	ECP	Significance
End-diastolic	Mid-diastolic	↓ time for blood inflow & afterload reduction ↓
Single Bag	Three bags	Space between bags dampens compressions
Diastolic pressure	Above systolic BP	Block inflow to leg & may push arterial blood out of legs
Simultaneous force to whole leg	Sequential distal to proximal	Forces arterial flow backwards out of leg
Pumps 1:1, 1:2 or 1:3	Pumps 1:1	1:2 or 1:3 & CB allows inflow with severe ASO
Multiple modes of use	Single Mode Use	ECP with limited application
Medicare: Arterial leg disease Venous disease Lymphedema	Medicare: Chronic angina	Leg ischemia a contraindication for ECP
Cost: $	Cost: $$$$$	

Subcutaneous PO2 Levels (right to left) Shown to Fall with Compressions Lasting Several Seconds and to Rise with Use of Circulator Boot.



Influences of Inflation Rate and Duration on Vasodilatory Effect by Intermittent Pneumatic Compression in Distant Skeletal Muscle

Variable	Inflation Rate	Peak Pressure Duration	Vasodilation Response*
A	0.5sec	5sec	++++
B	5sec	0	++
C	5sec	5sec	++
D	10sec	0	0
E	10sec	5sec	0

Liu K et al: J Orthop Res 17: 415-20, 1999
J Orthop Res 17: 88-95, 1999
J Appl Physiol 92:559-66, 2002

*Blocked by NG-monomethyl L-arginine

An Example of a Patient Untreatable by Means Other than the Circulator Boot Systems

- Noncompliant lady with insulin-dependent Diabetes Mellitus
- Foreign Body imbedded in 5th toe leading to osteomyelitis
- Stasis disease
- Peripheral arteriosclerosis obliterans
- Peripheral neuropathy
- Congestive arteriosclerotic cardiomyopathy

(Patient histories, case #2)

Common Risk Factors for Venous Stasis in Older Subjects

Chronic Venous Hypertension due to

Obesity Pregnancy Intra-abdominal masses

Corsets Garter Belts Baker's cysts

Standing Occupations Age & less activity

Venous obstruction due to phlebitis

All leading to venous valvular Insufficiency and Reflux

Origins of Stasis Disease in Younger Patients

Chronic Venous Hypertension and Reflux due to:

Scarring or thrombophlebitis associated with:

- Abdominal or pelvic surgery
- Trauma
- Hereditary clotting Disorders
  - Deficiency of Protein “C” or “S”
  - Deficiency Antithrombin III

Sequellae of Chronic Venous Hypertension

Increased permeability of dermal capillaries:

Edema

Leaking of macromolecules, e.g. fibrinogen, into pericapillary tissue

Decreased dermal fibrinolytic activity

Formation of peri-capillary fibrin cuffs

Barrier to O_2 → Tissue Hypoxia

Trapping Activated leukocytes → Release inflammatory mediators

Cell damage and fibrosis

Subsequent microthrombi, erythrocyte extravasation and hemosiderin deposition

ALL ABOVE ⟶ ULCERS ⟵ Trauma and Infection

Intermittent Pneumatic Compression Boots and Venous Stasis Disease

Helpful in all stages
of venous dermatological disease once the microvascular complications described above have developed.

Historic Role and Mechanism of Action of Slow-Acting Pneumatic Boots

Historic role: prevention of thrombophlebitis during surgery, the postoperative state and prolonged bedrest especially in the latter for immobile or unconscious patients.

Mechanism of action and effects:

______*reduction of edema*

______*prevention of stasis*

______*stimulation of fibrinolysins.*

______*Shortened venous outflow times*(Blackshear 1987)

______*Improved cutaneous blood flow adjacent to ulcer* (Malanin 1999)

______*Quickens healing of venous ulcers and decreases costs* (Alpagut 2005)(McCulloch 1994)(Smith 1990)

Advantages of End-Diastolic Pneumatic Boots which have all of the actions listed on the previous slide Plus:

- Stimulate endothelial humoral factors (nitric oxide, prostacyclin, fibrinolysins and vascular endothelial growth factors) in proportion to the sheer force applied to the endothelium (Liu 1999, Toyota 1999).

- Speed healing compared to slower-acting boots (Nikolovska 2005) and promote healing of chronic venous ulcers unresponsive to standard therapies (Dillon 1986).

- End-diastolic pumping supports the heart and improves peripheral arterial blood flow. It is especially indicated in patients with combined venous, arterial and coronary heart disease (2nd illustration above), who have a poor prognosis for life and limb (Bohannon 2002).

Difficult Patient Continued

- Insulin needle embedded in the 5th toe
- Osteomyelitis of the 5th metatarsal-phalangeal joint

(Staples in upper left and lower right holding picture to patient chart)

42 Consecutive Episodes of Osteomyelitis Treated Successfully in 35 Patients

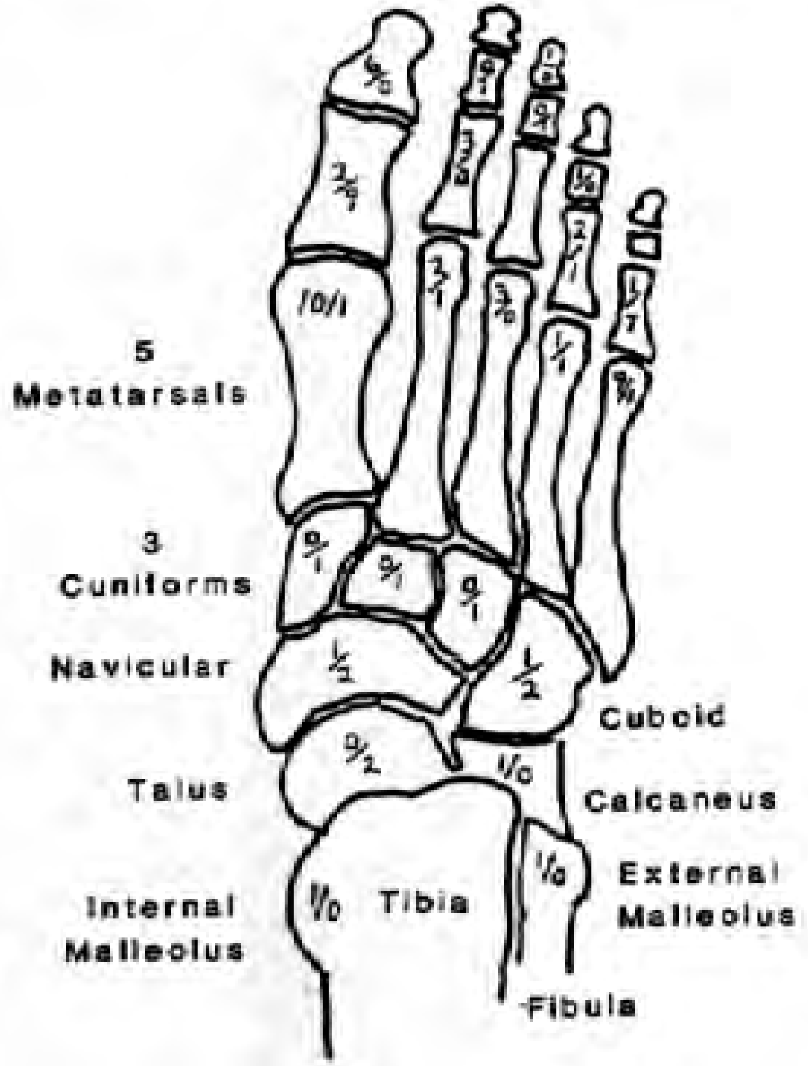


Fig. 1. Location of osteomyelitic lesions. The number of times each bone was the most prominent site of osteomyelitis is shown in the numerator and the number of times it was a lesser site in the denominator. The malleoli were involved in 2 patients who had dislocated ankle joints secondary to fractures. Primary infection of the navicular and cuboid was found in 1 patient presenting nonhealing of an open transtarsal amputation. The first and fifth metatarsal heads were most frequently involved.

60 Examples of Osteomyelitis Treated Successfully with Local Antibiotics and the Circulator Boot

Case Numbers in Case History Section on CBC Website

1, 2, 4, 8, 21, 29, 31, 34, 36, 38, 42, 43, 50, 51, 53, 55, 62, 67, 73, 74, 76, 83, 84, 87, 89, 92, 93, 95,97, 101, 102, 108, 109, 110, 114, 115, 120, 141, 144,149, 152, 156, 157, 159, 160, 165, 170, 173, 179, 180, 184, 185, 188, 190, 191, 192, 193, 198, 199, 200i

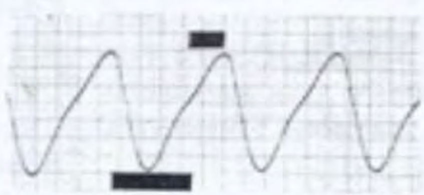
Difficult Patient Continued

- Five year Follow-up
- Treated as an Outpatient
- Ambulatory all the time (perhaps a mistake as her shoe pushed the 5th toe out of position as it healed)

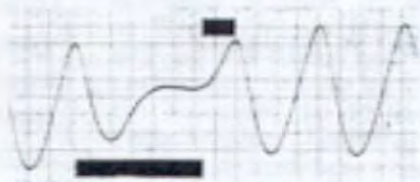
FIGURE 3
EXAMPLES OF BOOT RESPONSE
CHANGES IN PRESSURES WITHIN
THE BOOT DURING TREATMENT

Automatic pacemaker set to a rate of 122 compressions per minute. Boot pressure 55 mm Hg.

EKG pacing at a rate of 78 compressions per minute. Boot pressure 50 mm Hg. Compression and decompression times 0.31 and 0.46 seconds respectively. The bar at the top denotes the compression time and the bar at the bottom denotes the decompression time.



Same patient as above, but rate set on automatic pacemaker to 54 compressions per minute. Compression and decompression times 0.33 and 0.78 seconds respectively.



Same as in "B" above. A heartbeat was dropped to prolong the decompression time to 1.23 seconds.

How Does the Boot Work?

Effective Peripheral Blood Flow = “EBF”

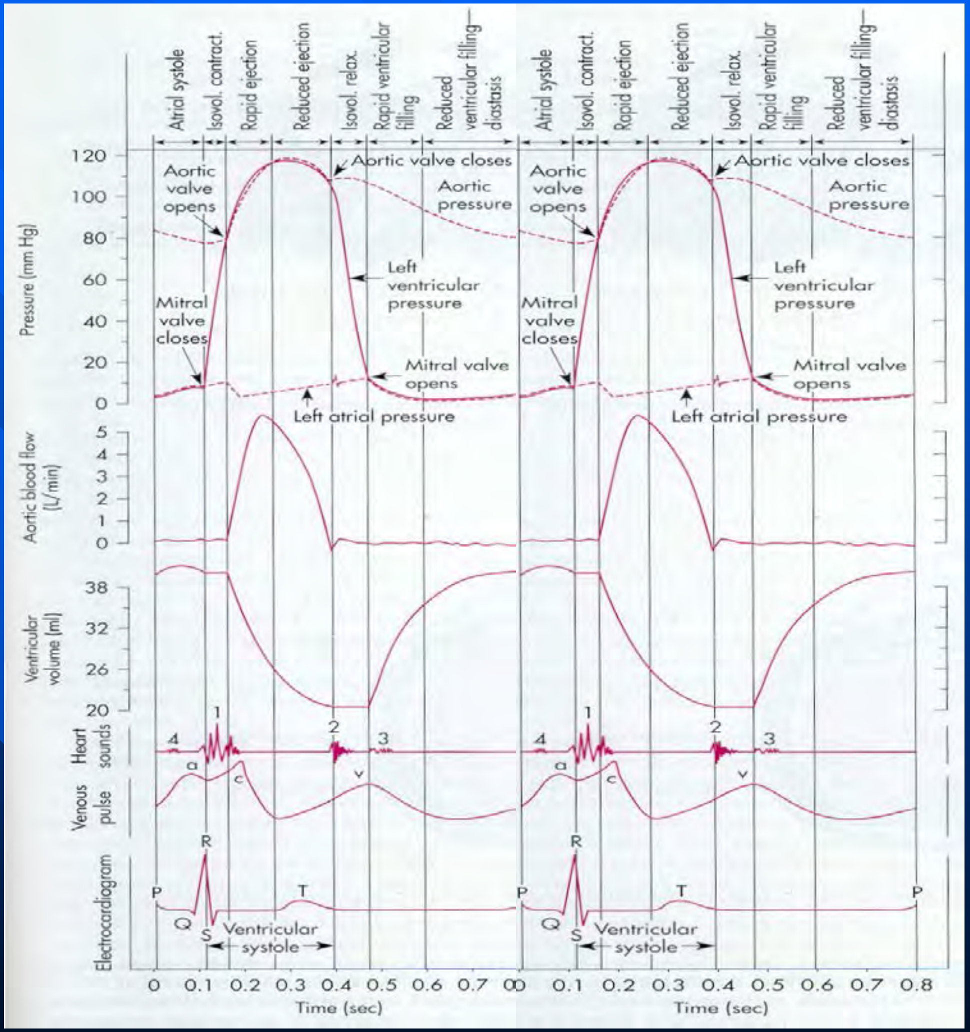
EBF=Function of Multible Positive and Negative Variables

Effective Blood Flow is a Function of Cardiac Output

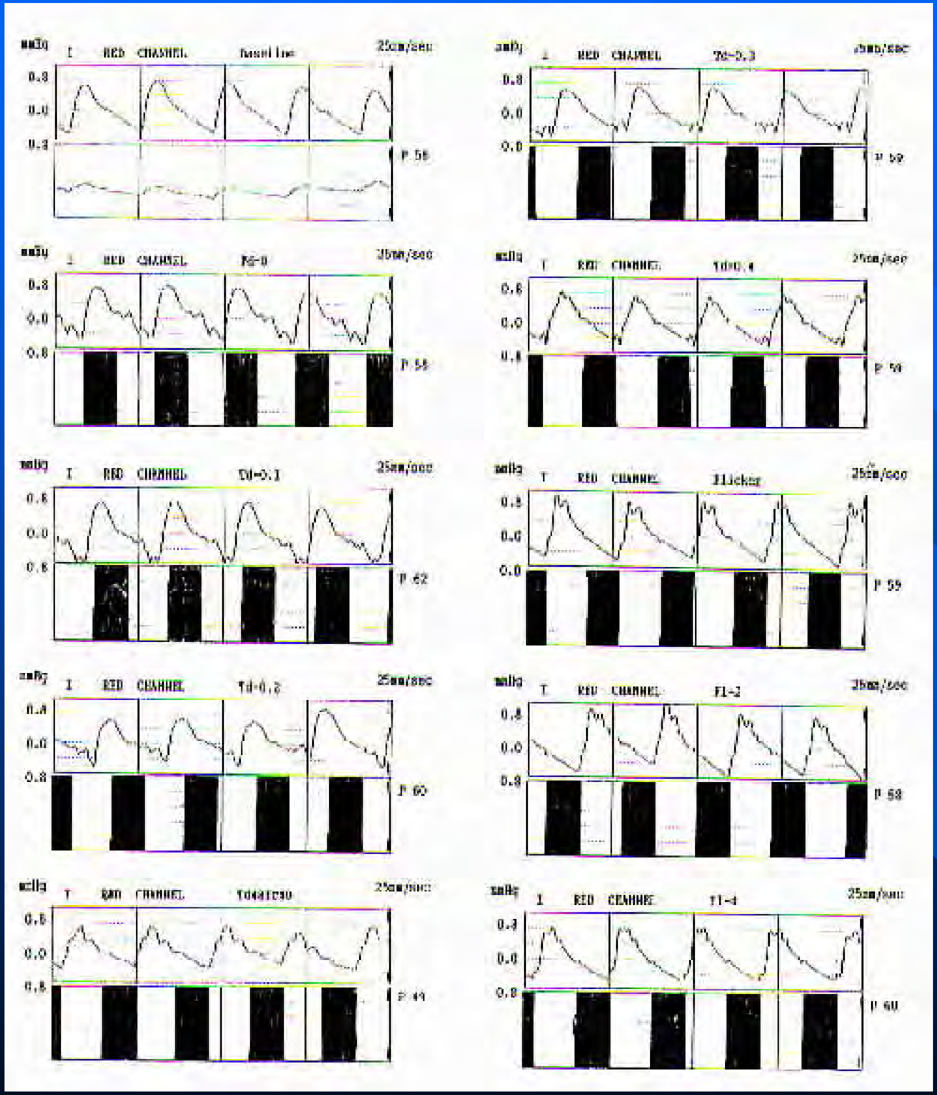
EBF = F(CO)

Left Atrial, Aortic, and Left Ventricular Pressure Pulses Correlated with Aortic Flow, Ventricular Volume, Heart sounds, Venous Pulse and the EKG

The Circulator Boot Monitor releases the leg 0.04 seconds before the next anticipated QRS complex (bottom) acutely dropping aortic pressure as the aortic valve opens (upper left). Boot pressure is reapplied in end-diastole after the aortic valve has closed and the pulse wave has entered the leg.

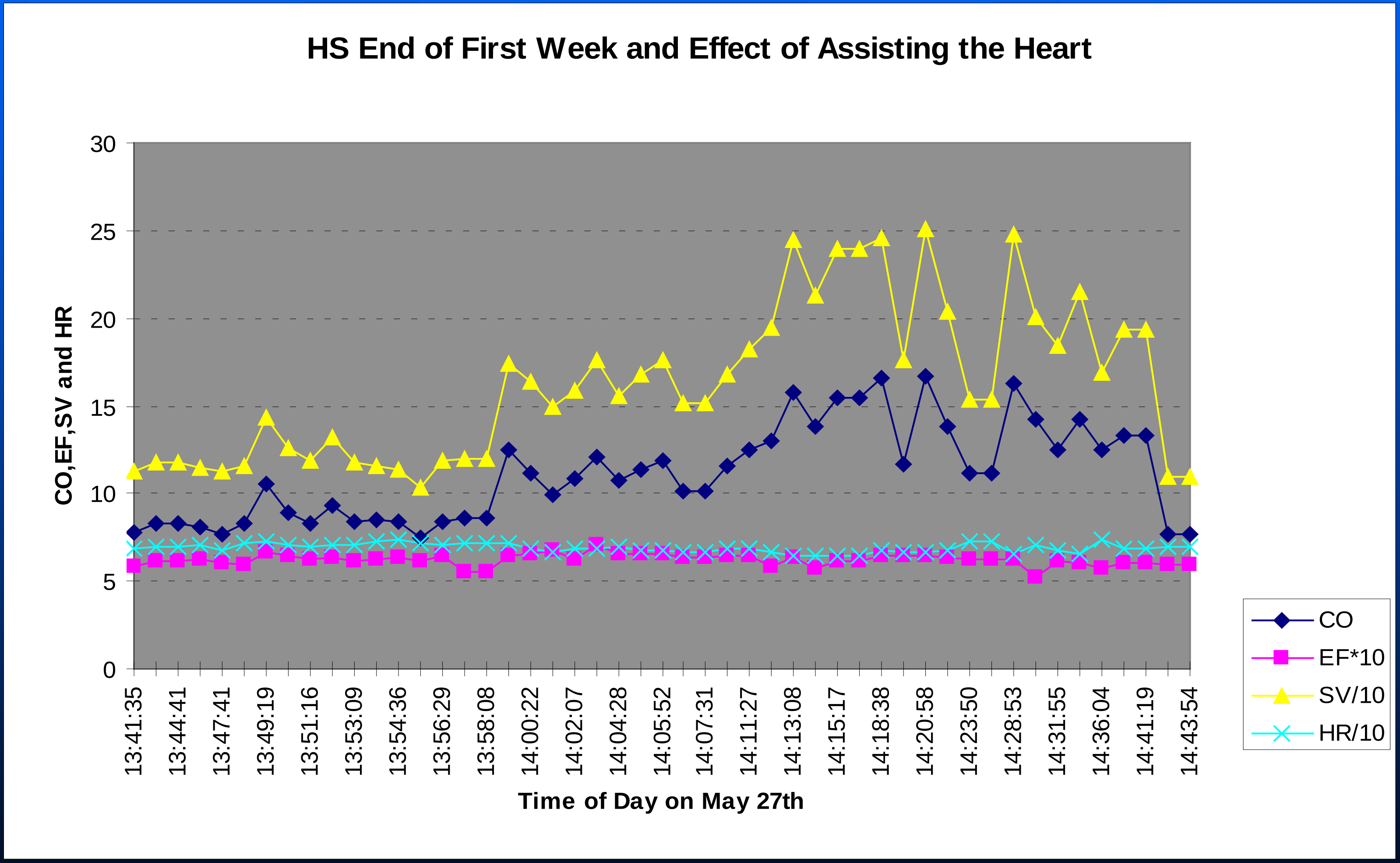


Boot Compressions (Dark Bars) Are Followed by a Dropoff in the Arm Pulse Volume Curve



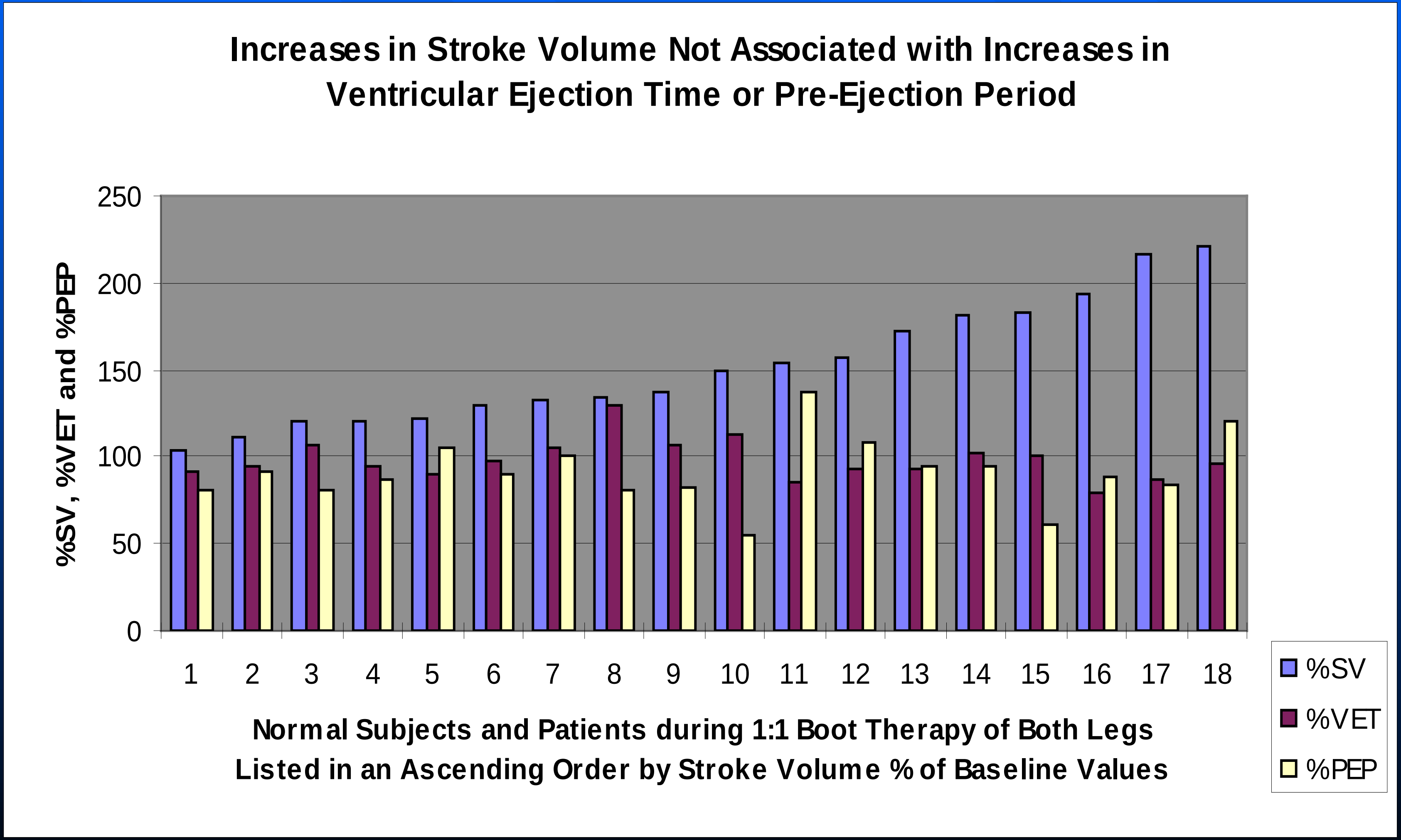
Arm pulse volume curves are shown with no leg pumping (upper left) and with leg pumping as the compression time (black bars) is slowly moved through the RR interval. With end-diastolic pumping, the dropoff accompanying decompression is buried in the following pulse wave.

An Example of Changes in Cardiac Output & Stroke Volume during Long-Boot Therapy
(Case #107)



Electric Impedance Data and Cardiac Assist in Patients with Angina and Normal Controls

Dillon, Angiology 49: 523-535, 1998



Duration of ST Changes in Patients Receiving a 3-Week Course of Long-Boot Therapy

Dillon, Angiology 49:523-535, 1998

Patient	Baseline 1 mm	2 mm	3 mm	Score	Follow-up 1 mm	2 mm	3 mm	Score	Clinical Status
1	0:01:52	0	0	4	0	0	0	0	Improved
2	9:03:24	15:10:16	0:10:40	3684	0:26:48	0	0	59	Improved
3	0:20:09	0	0	44	0	0	0	0	Improved
4	0:10:22	0:02:34	0	30	0:09:02	0	0	20	Improved
5	0:28:26	0:06:58	0	81	0:40:09	0:00:49	0	90	Improved*
6	0:03:02	0	0	7	0:02:54	0	0	6	Improved†
7	0:00:51	0	0	2	0	0	0	0	Improved‡
8	5:52:13	0	0	775	0:56:18	0	0	124	Improved
9	0:00:00	24:07:41	0	3888	22:48:59	0	0	3012	Improved§
10	0:01:31	0:00:50	0	6	0	0	0	0	Improved
11	22:23:52	0:43:31	0:01:28	3078	18:23:39	0:16:34	0	2473	Improved

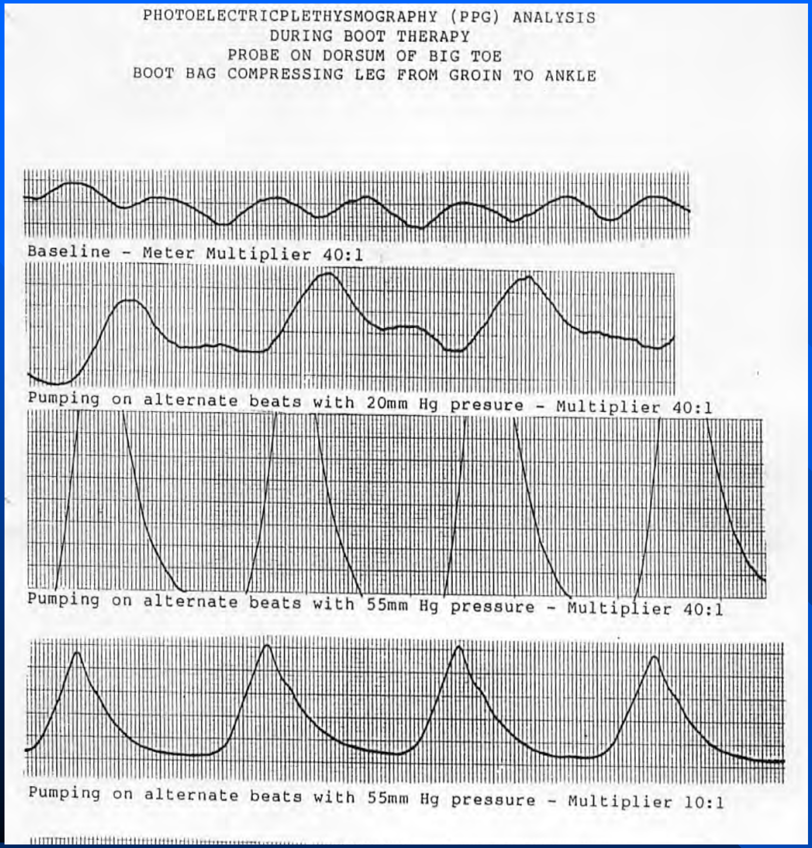
The duration of ST depressions in hours:minutes:seconds for 1 mm, 2 mm, and 3 mm is shown for each patient both before and at the end of the 3-week treatment program. ST depression scores were weighted per minute at 2.2 for 1 mm, 2.7 for 2 mm, and 2.9 for 3 mm. The total scores before and after treatment were found to be statistically changed with a Sign Test (two-sided), $p = 0.012$.[18] ST Data from Q-Med Monitor.

*Symptomatic angina with 2 mm depressions during baseline; silent angina on follow-up. †Follow-up RST changes associated with tachycardia and increased exercise. ‡Two week follow-up, RST changes at third week with moving furniture. §Left bundle branch block.

Gravity or Dependency Increases Peripheral Blood Flow

EBF = F(G) or combining with cardiac output, EBF=F(CO)(G)

Photoelectricplethysmography Tracings of Big Toe during Boot Therapy



Baseline tracings (top line) multiplied 40:1 were but 5 mm high in this arteriosclerotic patient. On the 2nd to 4th line the boot pumped on alternate beats with 20 mm Hg pressure (40:1), 55 mm Hg pressure (40:1) and 55 mm Hg pressure (10:1). The baseline beats are barely seen on the 2nd line. On the 4th line, the waveform is 25 mm high… correcting for the multiplier, 20 times higher than on the baseline. On the bottom line the boot is pumping on every beat at 55 mm Hg with a waveform about 18 times baseline.

Boot Compressions end-diastolic in timing and diastolic in pressure disseminate the pulse volume around the leg much like water is disseminated through a partially wet sponge by squeezing it.

EBF = F(BC) or

EBF=F(CO)(G)(BC)

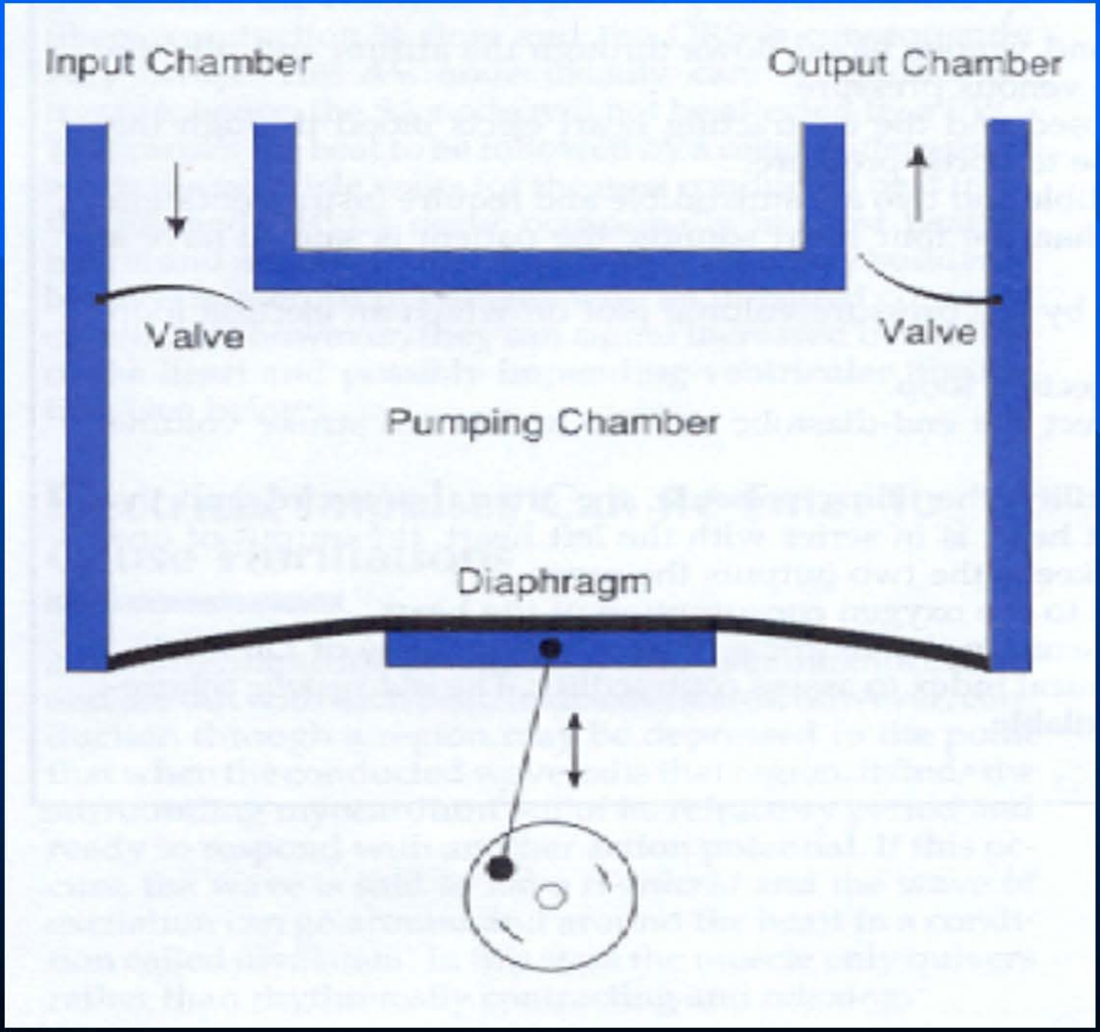
Venous Pressure impedes arterial inflow and is reduced by pumping in patients with intact venous valves.

EBF =F(1/VP) or

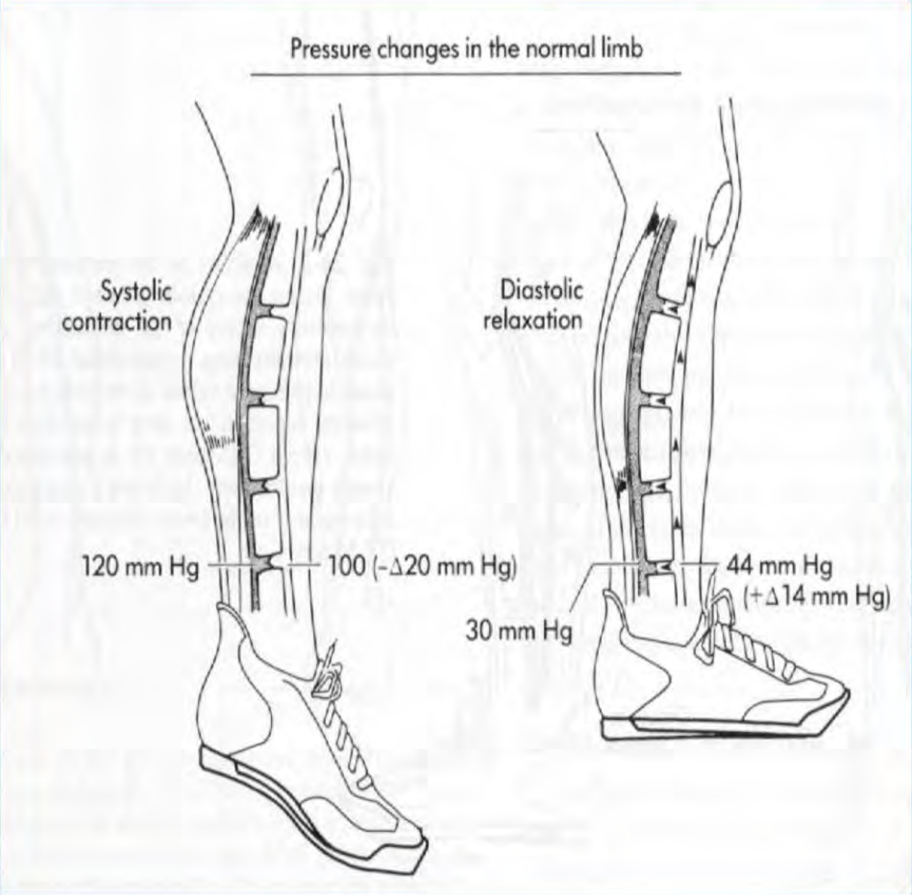
EBF=(CO)(G)(BC)/(VP)

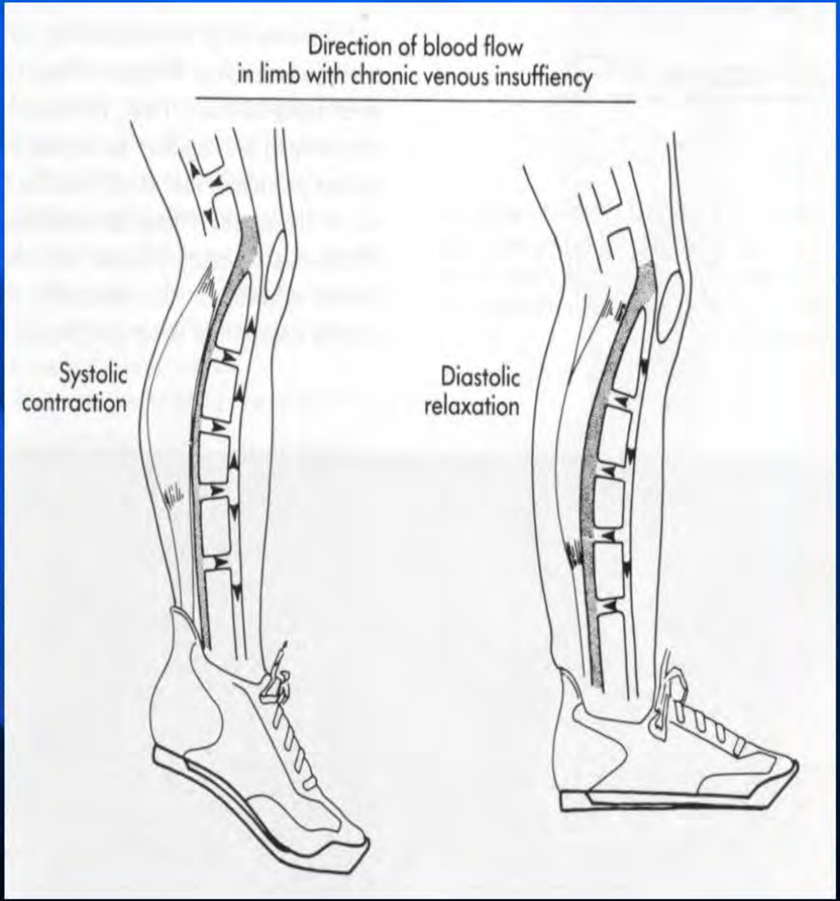
The heart represented as a reciprocating pump with input and output valves oppositely oriented and input of necessity controlling output.

Leonard R. Johnson – Essential Medical Physiology

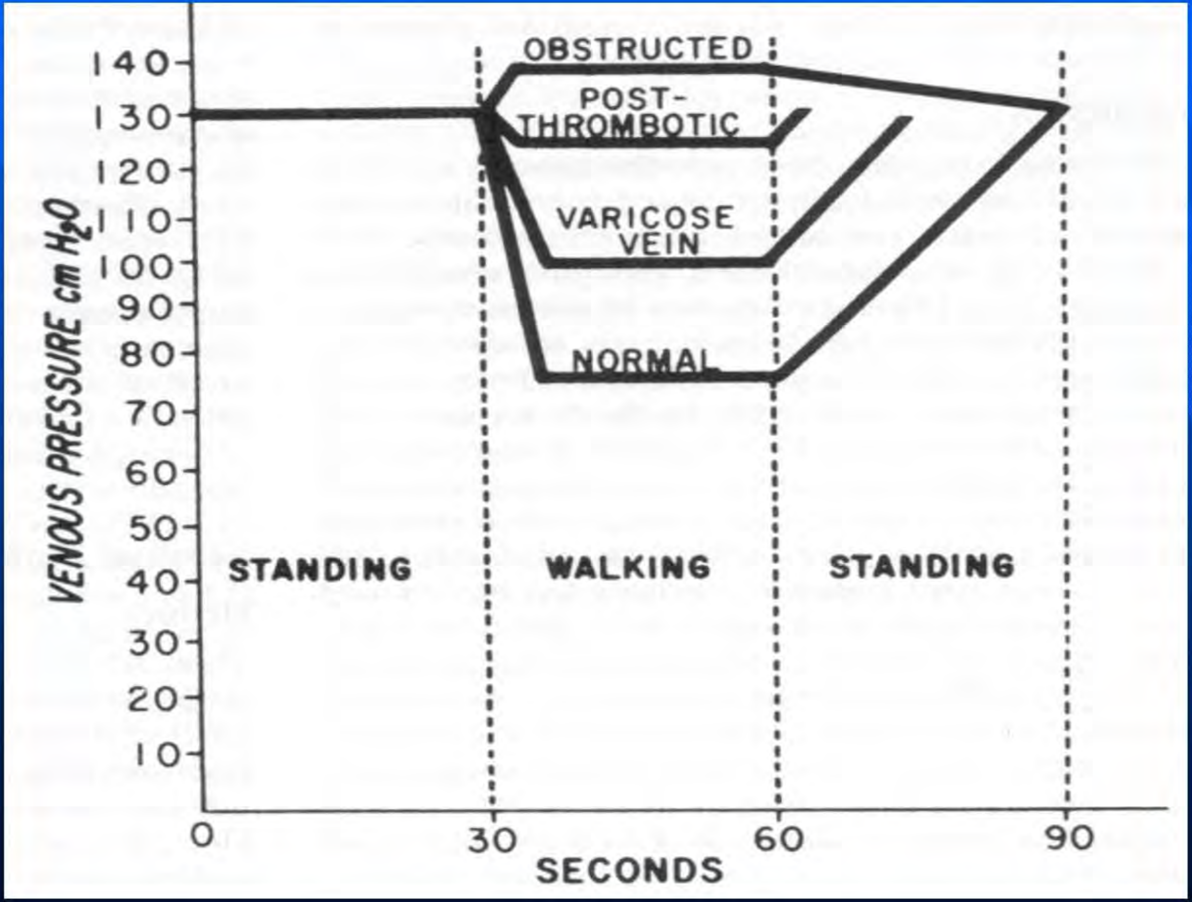


The deep veins (dark) and superficial veins (clear) are depicted. During calf contraction (systole), the pressure in the deep system may reach 120mm Hg but is blocked from the superficial veins by intact valves. If the valves are not intact, the pressure is transmitted to the superficial veins and flow back to the heart is lessened. Booting forces blood back to the heart through both systems.





Pedal venous pressure rises with quiet standing to equal the column of blood back to the heart. It is reduced about 40% with walking in normal subjects and less so in others. Booting may reduce it to zero in subjects with normal valves.



Edema or increased Interstitial Fluid Pressure impedes arterial inflow and is decreased by pumping.

EBF=F(1/IFP) or

EBF=F(CO)(G)(BC)/(VP)(IFP)

Chronic Lymphedema, case 139

Changes in Leg Circumferences after Eight Treatments

Leg circumference	Six inches above patella	Midcalf	Ankle
Right	22.5 to 22.1	18.0 to 16.2	13.1 to 11.3
Left	22.3 to 21.1	17.2 to 16.0	12.5 to 11.5

The plaque of Arteriosclerosis Obliterans may obstruct blood flow.

EBF=F(ASO) or

EBF=F(CO)(G)(BC)/(VP)(IFP)(ASO)

Doppler velocity curves may be obtained anywhere in the leg or foot. The waveform, normally traveling 20-40 feet per second, wells up in the distal leg and is reflected backward. Plaque may disturb the flow pattern.

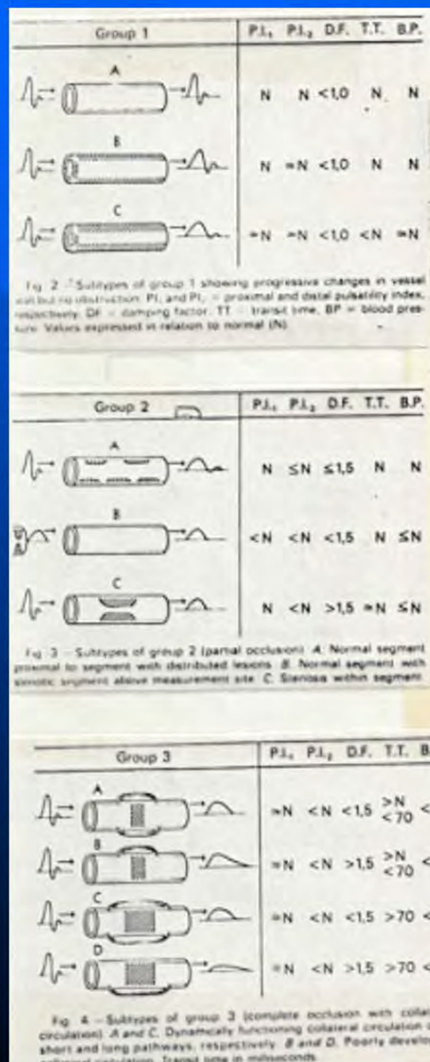
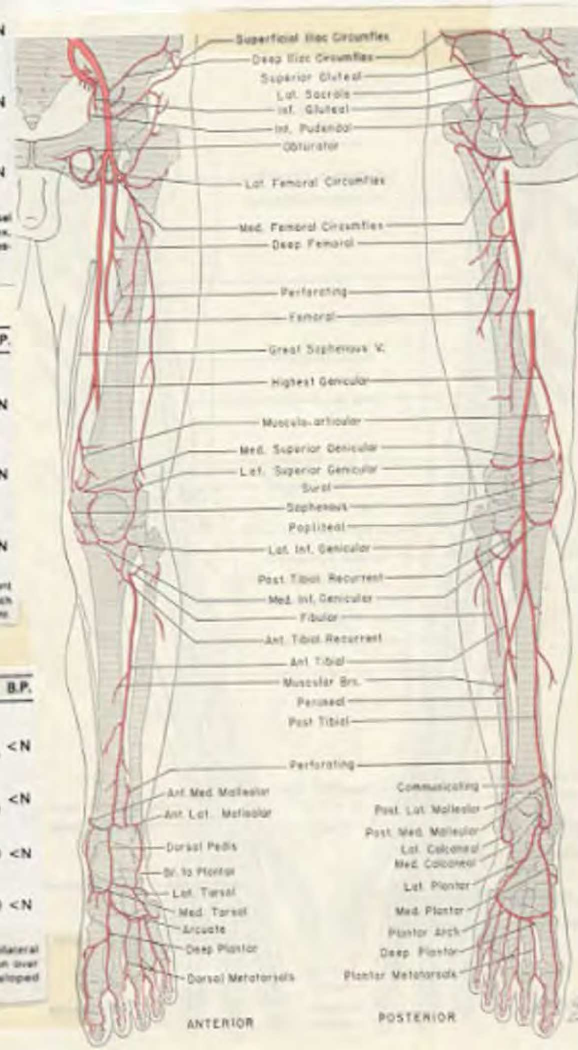


Fig. 2 – Subtypes of group 1 showing progressive changes in vessel wall but no obstruction. PI₁ and PI₂ = proximal and distal pulsatility index, respectively. DF = damping factor. TT = transit time. BP = blood pressure. Values expressed in relation to normal (N).

Fig. 3 – Subtypes of group 2 (partial occlusion). A. Normal segment proximal to segment with distributed lesions. B. Normal segment with stenotic segment above measurement site. C. Stenosis within segment.

Fig. 4 – Subtypes of group 3 (complete occlusion with collateral circulation). A and C. Dynamically functioning collateral circulation over short and long pathways, respectively. B and D. Poorly developed collateral circulation. Transit time in milliseconds.



Improvement in Arteriograms in Both Thigh (left)and Calf) right) with Long Boot Treatments

(CaseHistory #37)

Peripheral NEURopathy may produce AV shunts (sympathetic deficit) and vasoconstriction (cholinergic deficit)… both decreasing capillary flow.

EBF=F(NEUR) or

EBF=F(CO)(G)(BC)/(VP)(IFP)(ASO)(CLOT)(NEUR)

The adverse effects of INFection include increased tissue need for oxygen, tissue swelling, and thrombotic lesions associated with bacterial arteritis.

EBF=F(INF) or
EBF=F(CO)(G)(BC)/(VP)(IFP)(ASO)(CLOT)(NEUR)(INF)

How Does the Boot Work?

EBF=f(V)(CO) (G)(VDF)(F)/(VP)(IFP)(Neur)(ASO)(Inf)

- EBF = Effective Flood Flow
- f(V) = function of a variable
- "CO"= cardiac output
- "G"= Gravity
- VDF = Endothelial vasodilating factors (nitric oxide, prostacyclin, VEGF)
- F = Fibrinolysis of thrombotic occlusions
- "VP" = Venous pressure
- "IFP" = Intertitial fluid pressure
- "Neur" = Shunting and vasoconstriction due to neuropathy
- "ASO" = Arterial blockages due to arteriosclerosis obliterans"
- "Inf" = Adverse effects of infection: increased need for oxygen, tissue swelling, arteritic lesions

Modified from Dillon RS: Angiology Supplement 48: s35-S57, 1997

Threatened BK Amputation due to Treatment Failure in 33Year Old Bride with Diabetes

- Developed plantar callus on honeymoon at Disney Land
- Oral cephradine and bedrest ineffective
- 12-day hospital intravenous therapy with tobramycin & cefobid appropriate for the cultured bacteria (Beta-Streptococcus and Eikenella species)
- Bone scan: Osteomyelitis of 3rd, 4th and 5th metatarsal heads
- Incision and drainage procedure showed advanced tissue necrosis
- Peroxide soaks, whirlpool and blood transfusions
- Attending physicians include certified specialists in diabetes, infectious disease, vascular surgery and general surgery.
- Unanimous recommendation for BK-amputation because of:

  a) Uncontrolled soft tissue and bone infection

  b) Persisting systemic toxicity with spiking fever, loss of veins, uncontrolled diabetes and vaginal and rectal yeast infection

▲ Patient transfers to your hospital for you to save her leg. How to do it?

The Foot of the Bride and Her X-ray on Admission to Bryn Mawr

Intact Foot and Healed Osteomyelitis Four Months Later

Patient DC: Liability and Statistics

- Patient DC considered a suit against Dr. Dillon for boot monoply and then a suit against the ADA for suppression of data.
- Annals Int Med, "N=1".
- No longer anecdotal material. Indeed, the 2177 Episodes in Angiology (Dillon 1997) may be the largest case series in the world's literature. The other leg a control.
- Bailar et al (N Engl J Med 311:156-162, 1984): 1) Predict beneficial outcome; 2) Plan for subsequent data analysis; 3) Hypothesis for results; 4) Data of interest if positive or negative; 5) Reason to generalize results.
- Medicare criteria for coverage summarized in our website: Breakthrough technology… http://www.circulatorboot.com/literature/Medcomments.html


Your husband is suffering from a very severe stress disorder. If you don't do the following he will surely die. Each morning fix him a healthy breakfast. Be pleasant at all times. For lunch make him a nutritious meal. For dinner prepare an especially nice meal No chores. No nagging. Oh yes, and make love several times a week. Do this for the next year and he'll regain his health completely!


What did the doctor say ?
You're going to die!

Patient CM

Intermittent Boot Therapy over 14 Years for Ulcers and Osteomyelitis

- Birthdate July 12th, 1901
- Discovery of diabetes in 1946
- Leg amputation in 1971 for peripheral arteriosclerosis
- Subsequent serial lesions of right leg and foot:
  - Big toe paronychia 1976
  - Bunion ulcer and plantar ulcers
    - Podiatric and surgical consultations one year - no healing
    - No healing with "clot therapy" or buffy coat therapy 1979
    - Boot therapy and healing

Patient CM

Intermittent Boot Therapy over 14 Years for Ulcers and Osteomyelitis, cont

- He was now an experienced boot believer. On December 4th, 1985 he developed a small abrasion of his 5th knuckle from which he noted a little pus that grew out Staphylococcus epidermis and Staphylococcus aureus, both sensitive to first generation cephalosporins. Cephalexin (Keflex) and hot hand soaks were prescribed without effect. He returned 12/9/85 with his hand swollen and obviously in trouble.

Patient CM

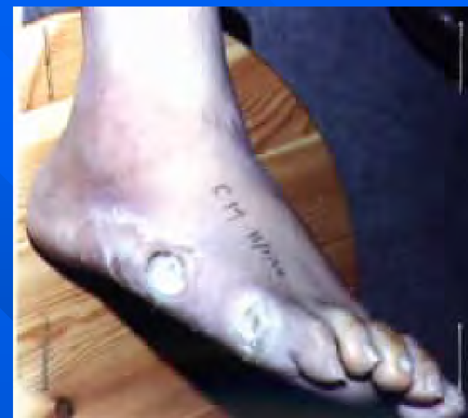
Intermittent Boot Therapy over 14 Years for Ulcers and Osteomyelitis

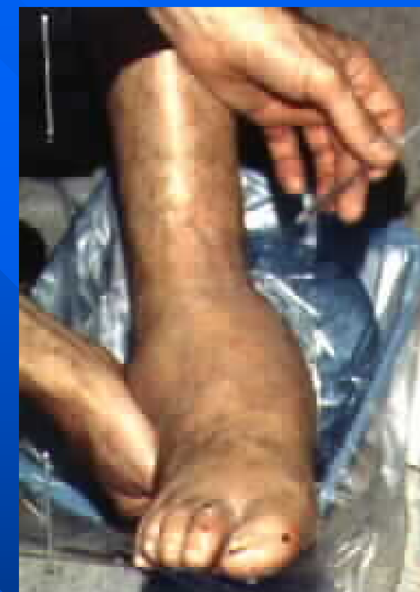
- X-rays of his hand showed generalized osteoporosis, severe degenerative changes involving the 1st carpometacarpal joint and the distal interphalangeal joints, cystic changes in the carpal bones, deformities of the distal radius and ulna from old trauma, marked arteriosclerosis and chrondrocalcinosis. His wedding ring was stuck on his 4th finger. The latter was removed intact by winding a rubber band around his finger from his fingernail to the edge of the ring, thus forcing the fluid from the finger. The ring was easily passed over the rubber band which was soaped. He was advised to enter the hospital for parenteral antibiotics and possible surgical drainage. A "real booter", he asked why we could not treat his hand like we had treated his foot. So we did. Gentamicin was injected into his hand which was then pumped in the Mini-Boot. He was so treated six times as an outpatient. His hands did well

Patient CM

Intermittent Boot Therapy over 14 Years for Ulcers and Osteomyelitis, cont

- Lateral foot ulcers with osteomyelitis 1986 - Healing with outpatient local gentamicin and boot therapy
- Ankle fracture - Pseudomonas aer. pyoarthritis 1987 - Healed with local gentamicin, bracing and boot
- 1992 ambulatory and moves to Connecticut near daughter





Patient MM

Gangrene of Foot and Congestive Cardiomyopathy

- 65 year old Saudi diabetic male presents in wheelchair, May 1992
- Chronically ill - Height 65 inches - Weight 88 lbs
- Arteriosclerotic cardiomyopathy - ejection fraction 20%
- Recent failure of bypasses to posterior and anterior tibials
- Nonhealing and amputations of 1st, 2nd and 5th toes and necrosing of amputation sites, distal foot, heel and ankle

Patient MM

Gangrene of Foot and Congestive Cardiomyopathy, continued

- Unlimited funding for his potential treatments
- Status August 1997: Weight 135 lbs, ambulatory and ejection fraction 68% (by electrical impedance)

Patient HL

Neuropathy, Ischemia and Osteomyelitis

- 61 year old female smoker with narcolepsy, an 18-year history of diabetes and 41pack-years of smoking.
- Occluded femoral-tibial bypasses 1982 and 1988
- Presents with a malleolar ulcer, 1/2 block claudication, insensate feet, background retinopathy, nephropathy and an old anterior myocardial infarct
- Malleolar ulcer heals with boot therapy.
- Subsequent plantar ulcer and osteomyelitis

... treated as an outpatient in a walking cast

... refuses oral antibiotics

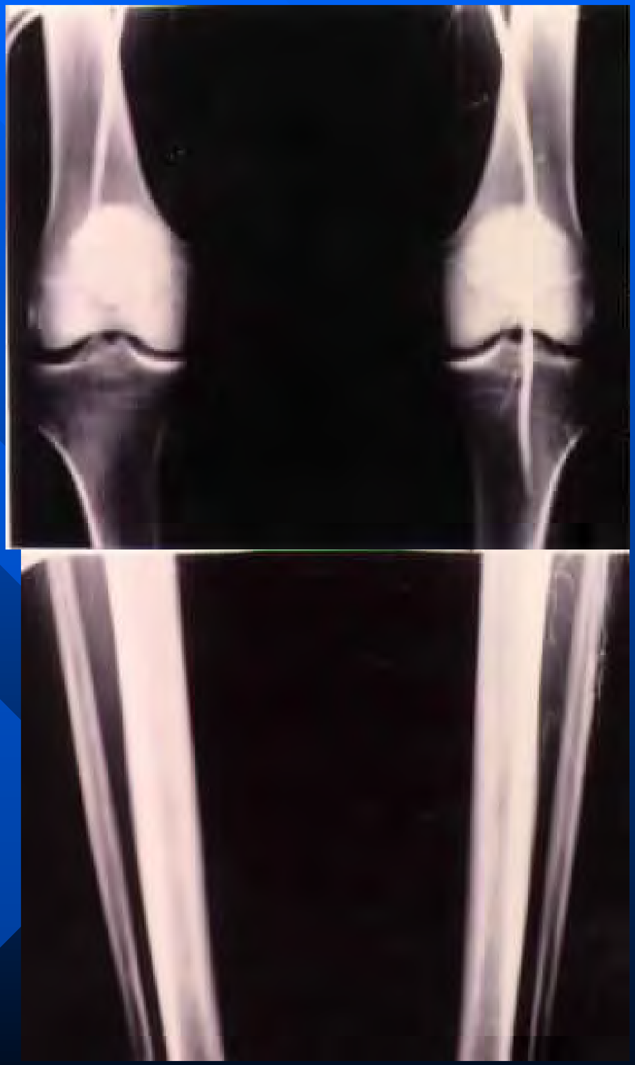
... treated with local antibiotic injections and soaks

Case 8 and Case 152 were two patients with ulcerated insensate feet who regained sensation with their boot therapy. They respond to tickling their feet.

Patient RB

Tibial Disease in Diabetic

- 75 year old engineer
- 22 year history of diabetes and 13 year history of angina
- Numb white foot leading to arteriogram and sympathectomy in July 1982
- Second opinion and arteriogam at Philadelphia University Center August 1982 - advised to try boot or amputate leg



Patient RB

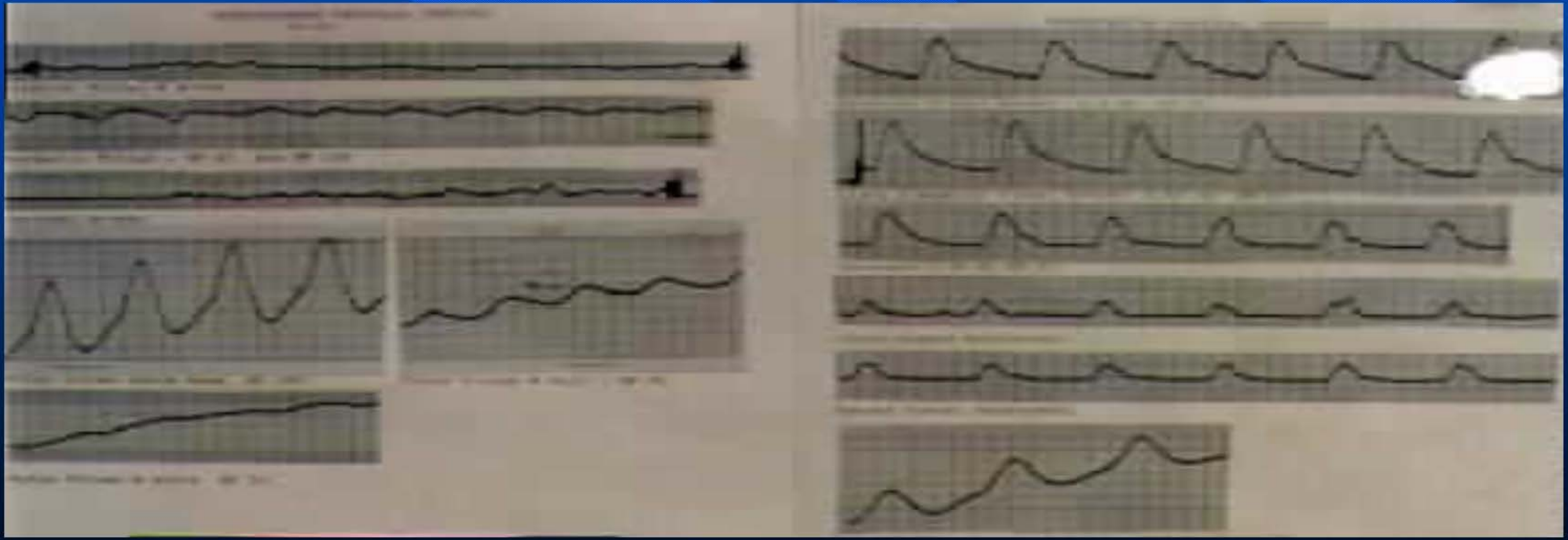
Tibial Disease in Diabetic, continued

- Buys Mini-Boot system
- Ambulatory and working until death Dec 1986

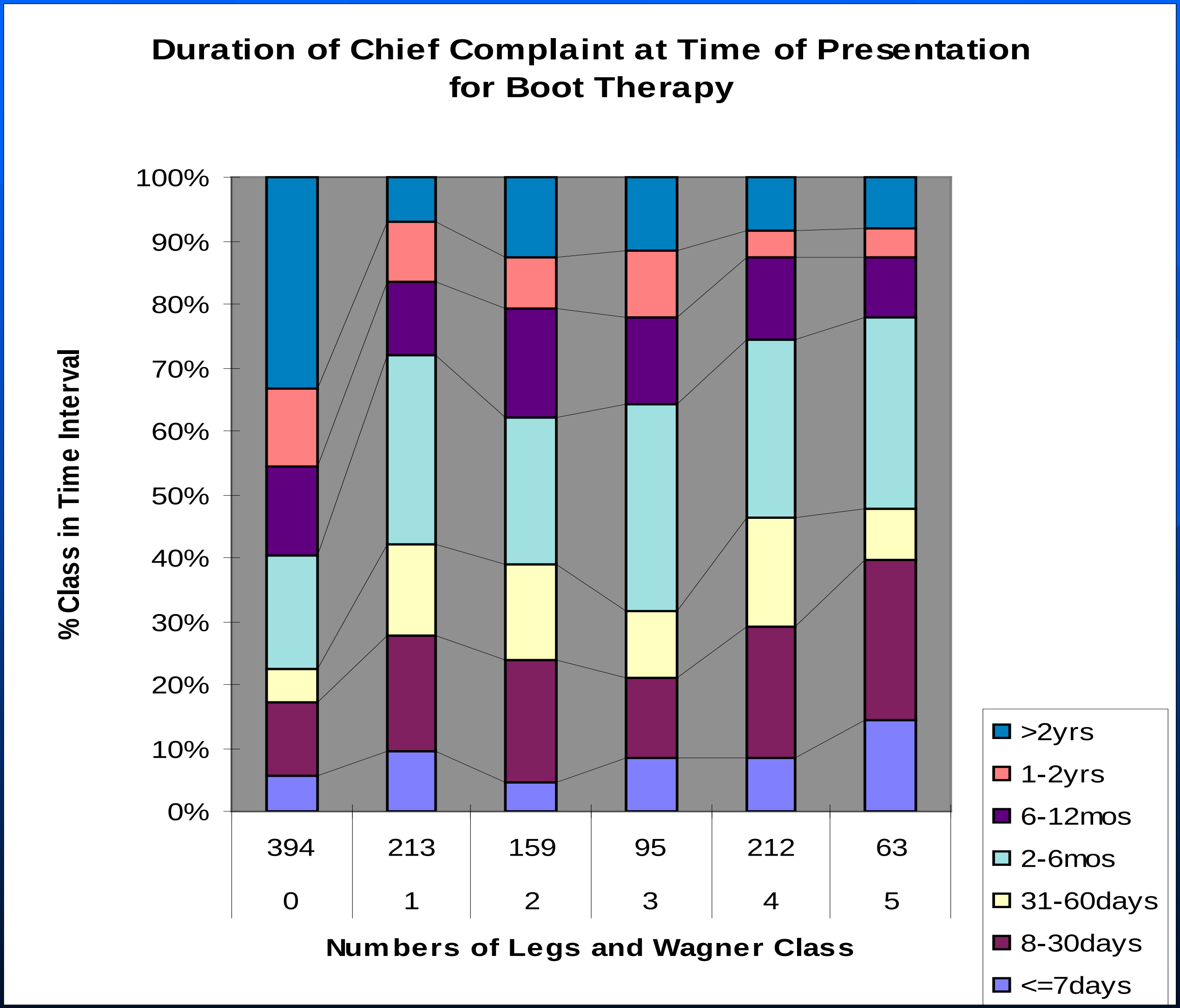
Patient RB

Tibial Disease in Diabetic, continued

Repeat arteriograms would have been interesting… but serial Doppler studies were more practical. Singificant improvements in flow were documented in all three tibial arteries at the ankle level.



Fifteen Years of Experience in Treating 2177 Episodes of Foot and Leg Lesions with the Circulator Boot- Dillon, Angiology 1997



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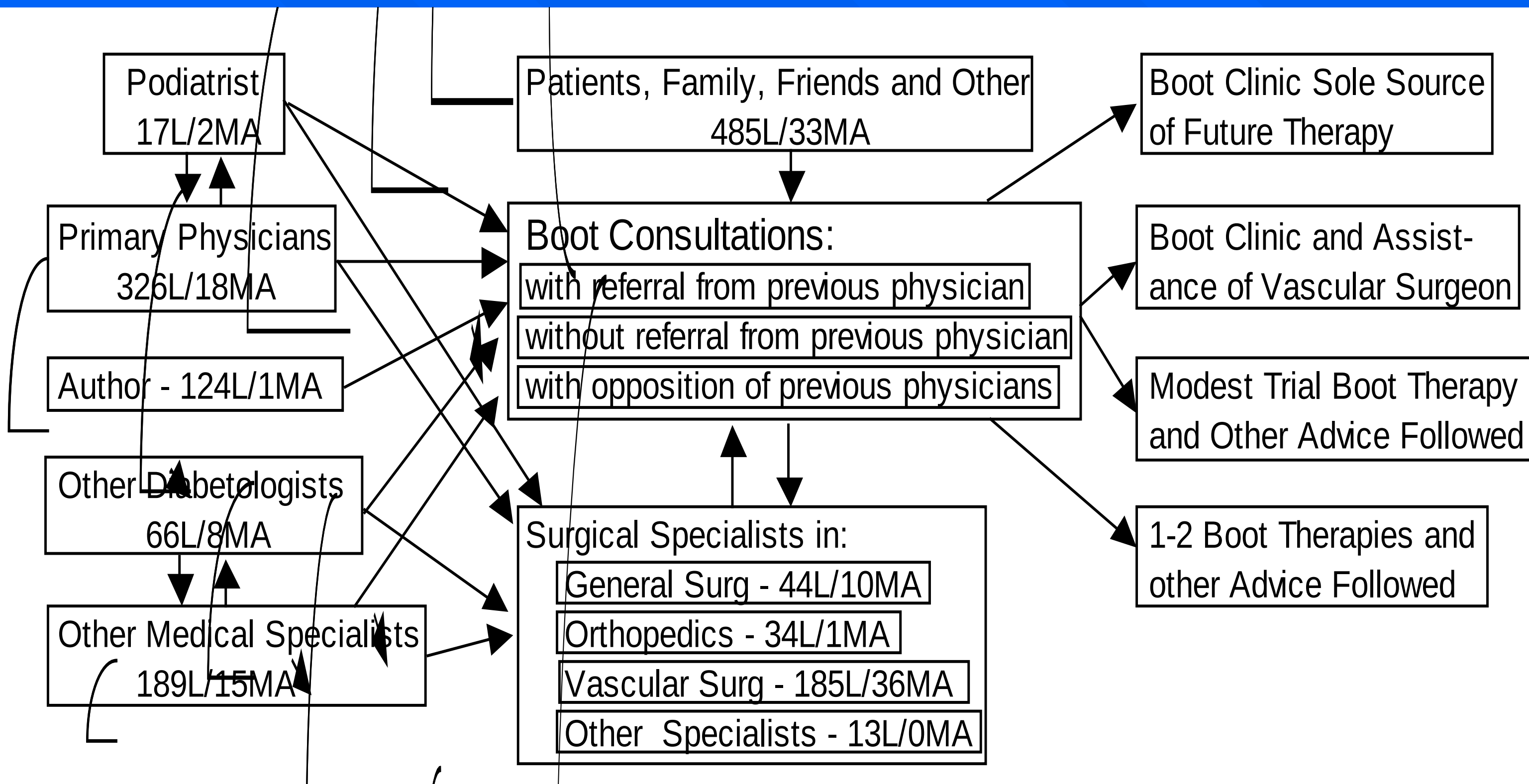

Origins of Patient Referrals for Boot Therapy

Number of Legs and Major Amputations Associated with Source

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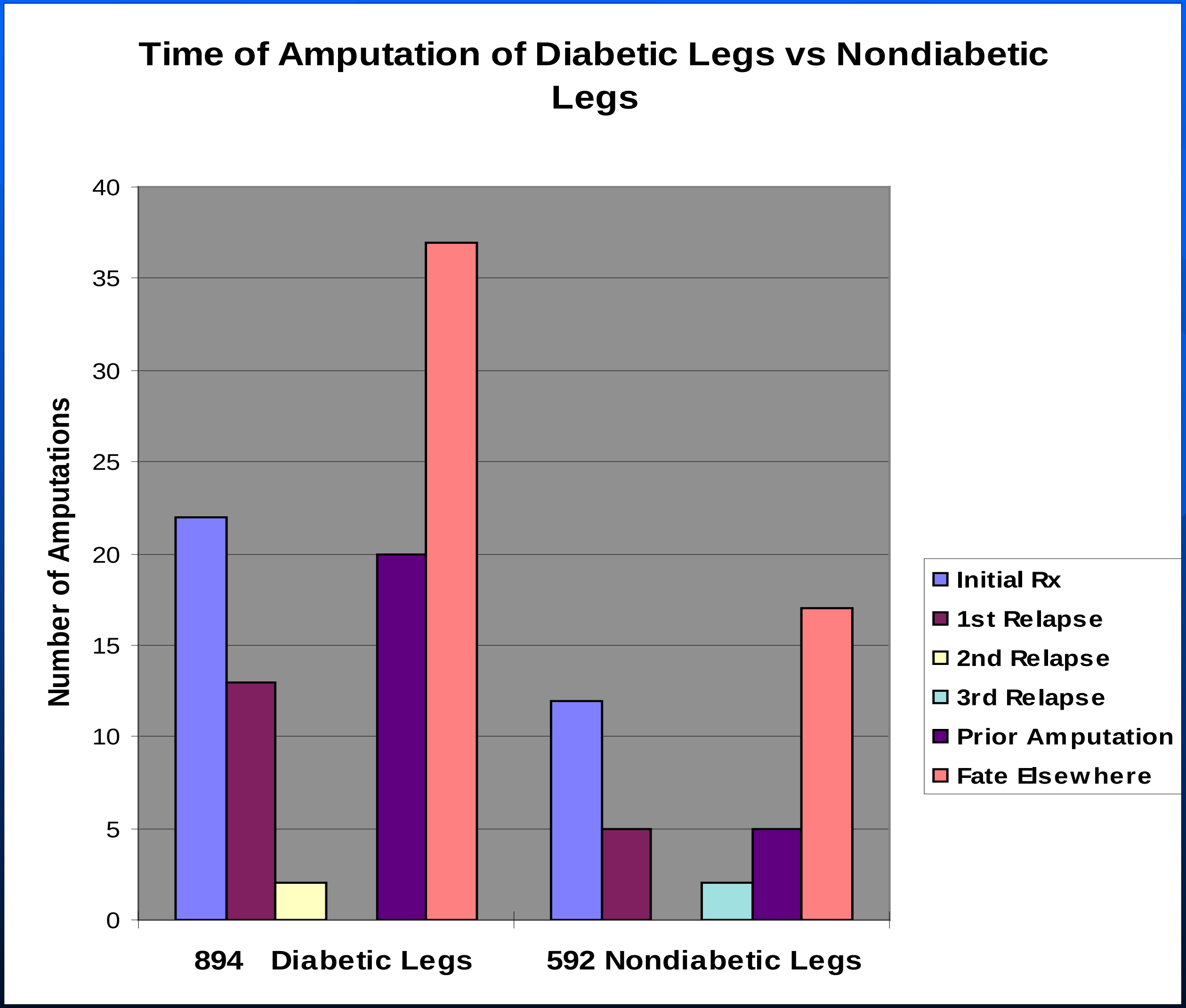

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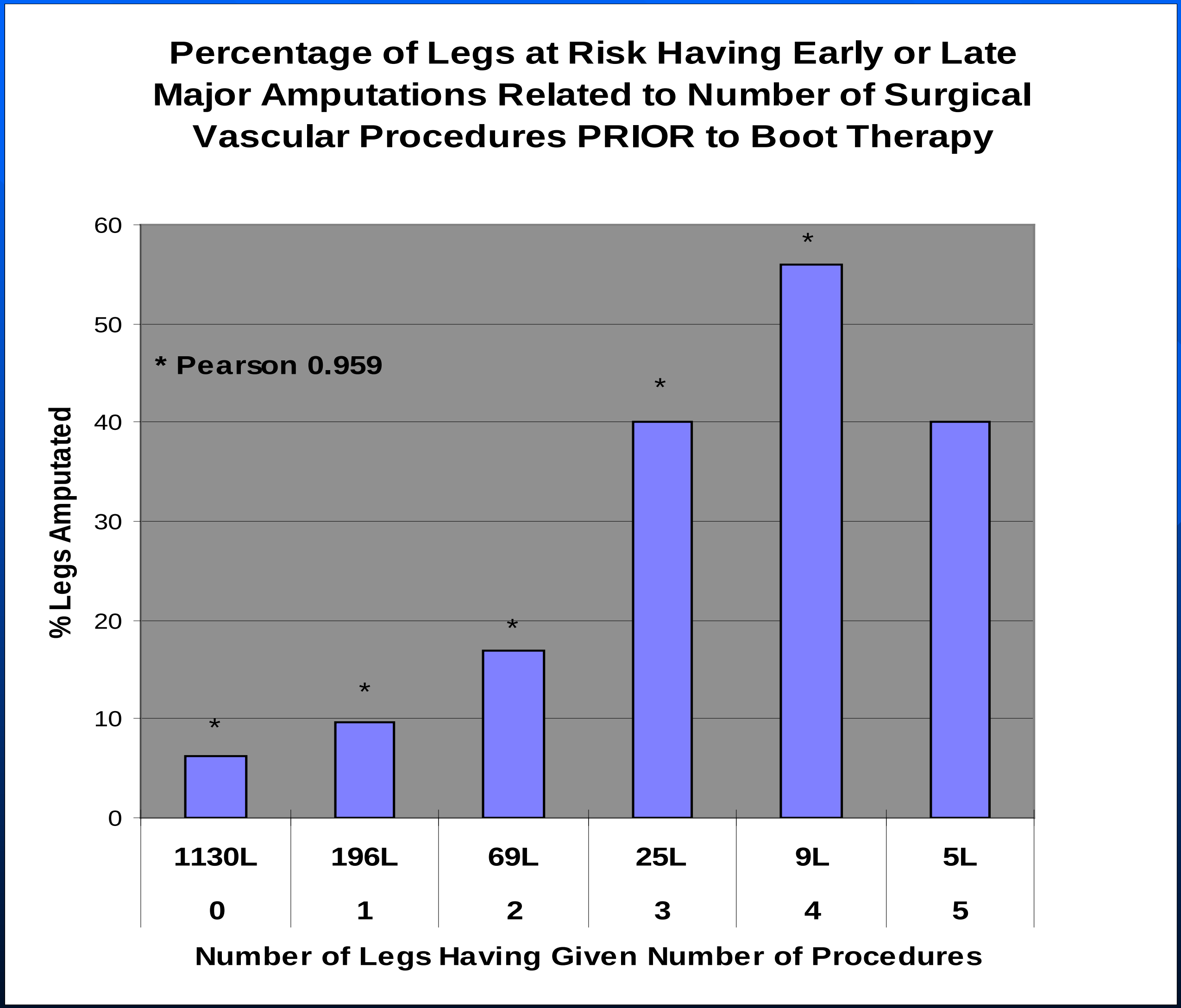

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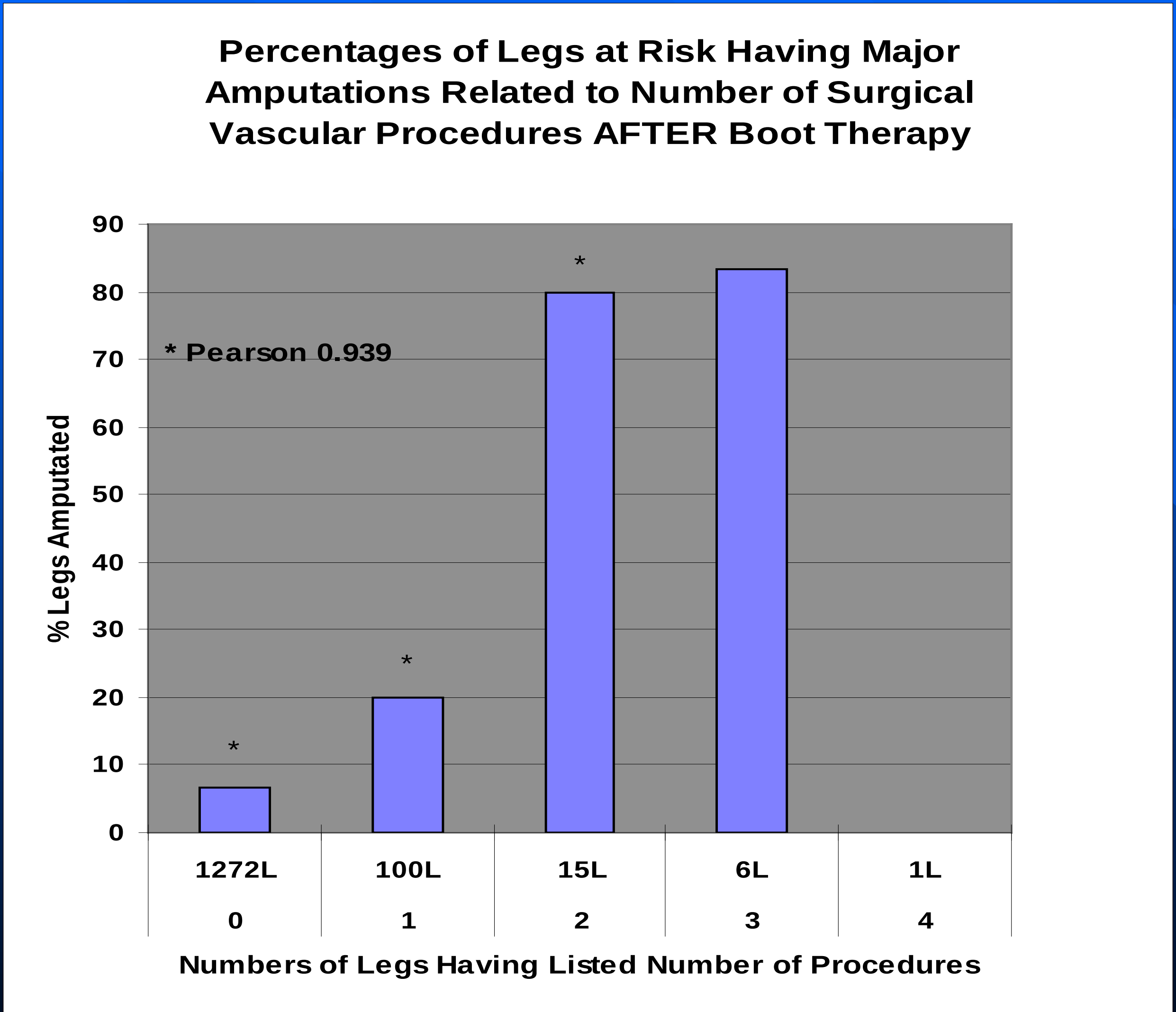

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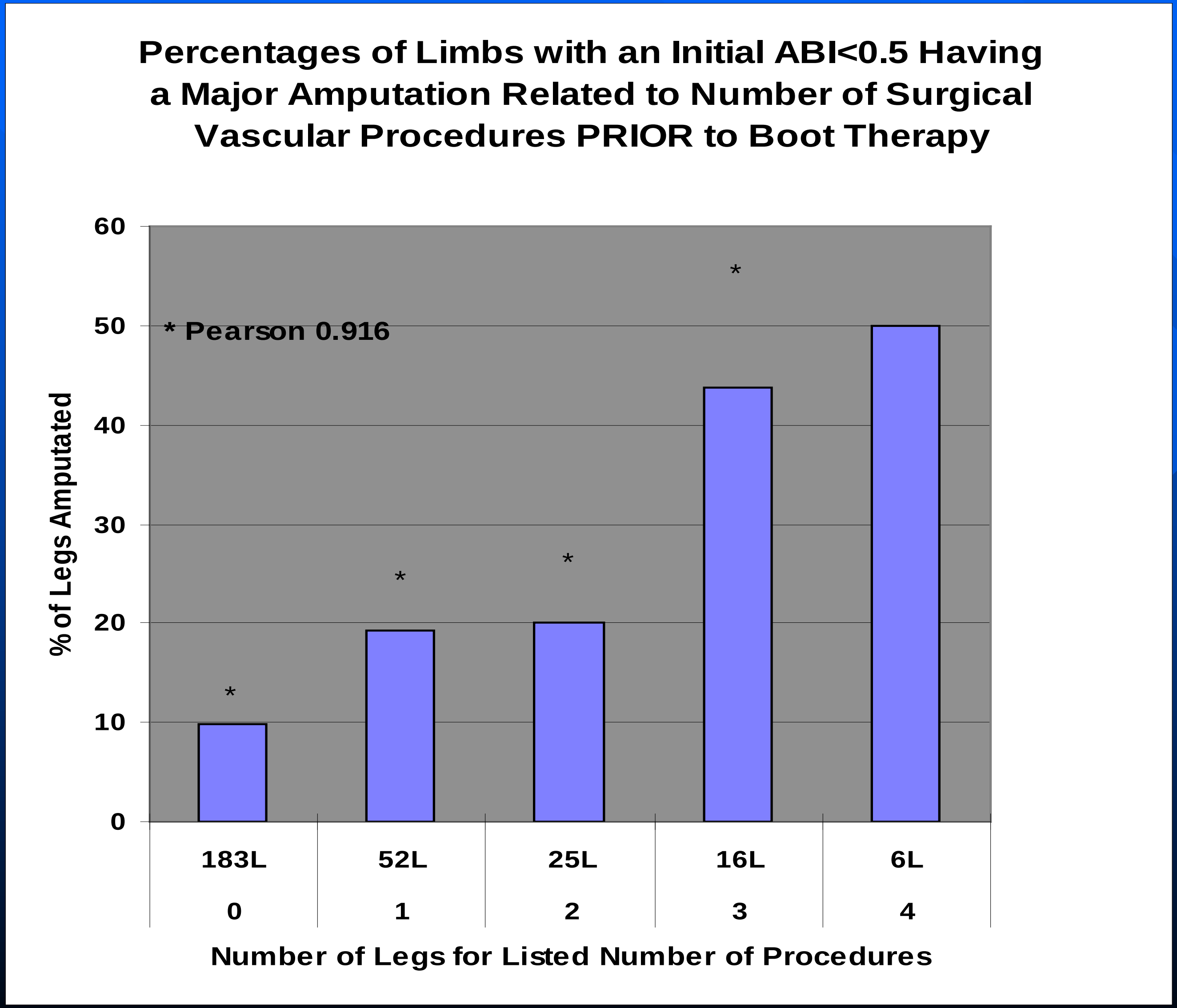

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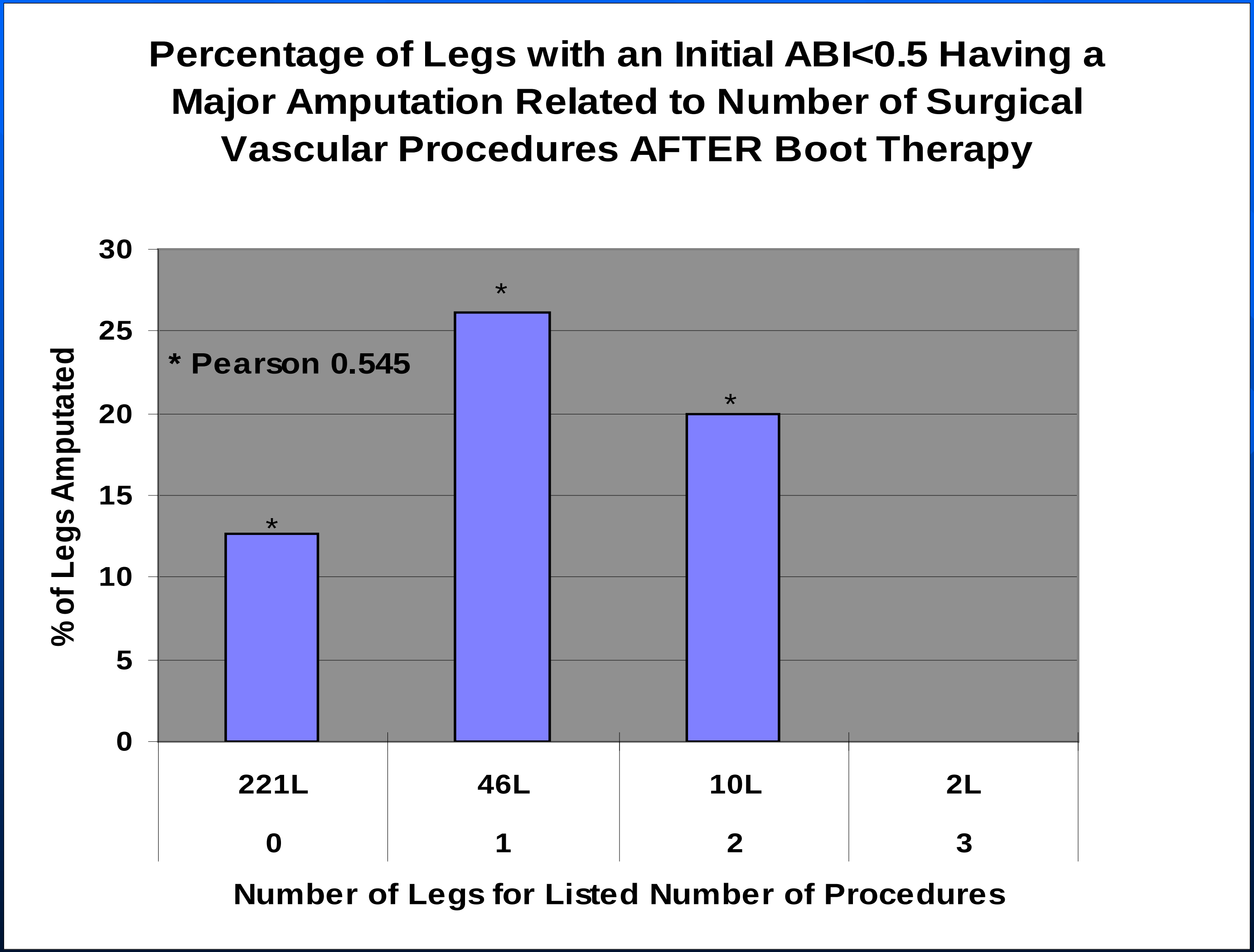

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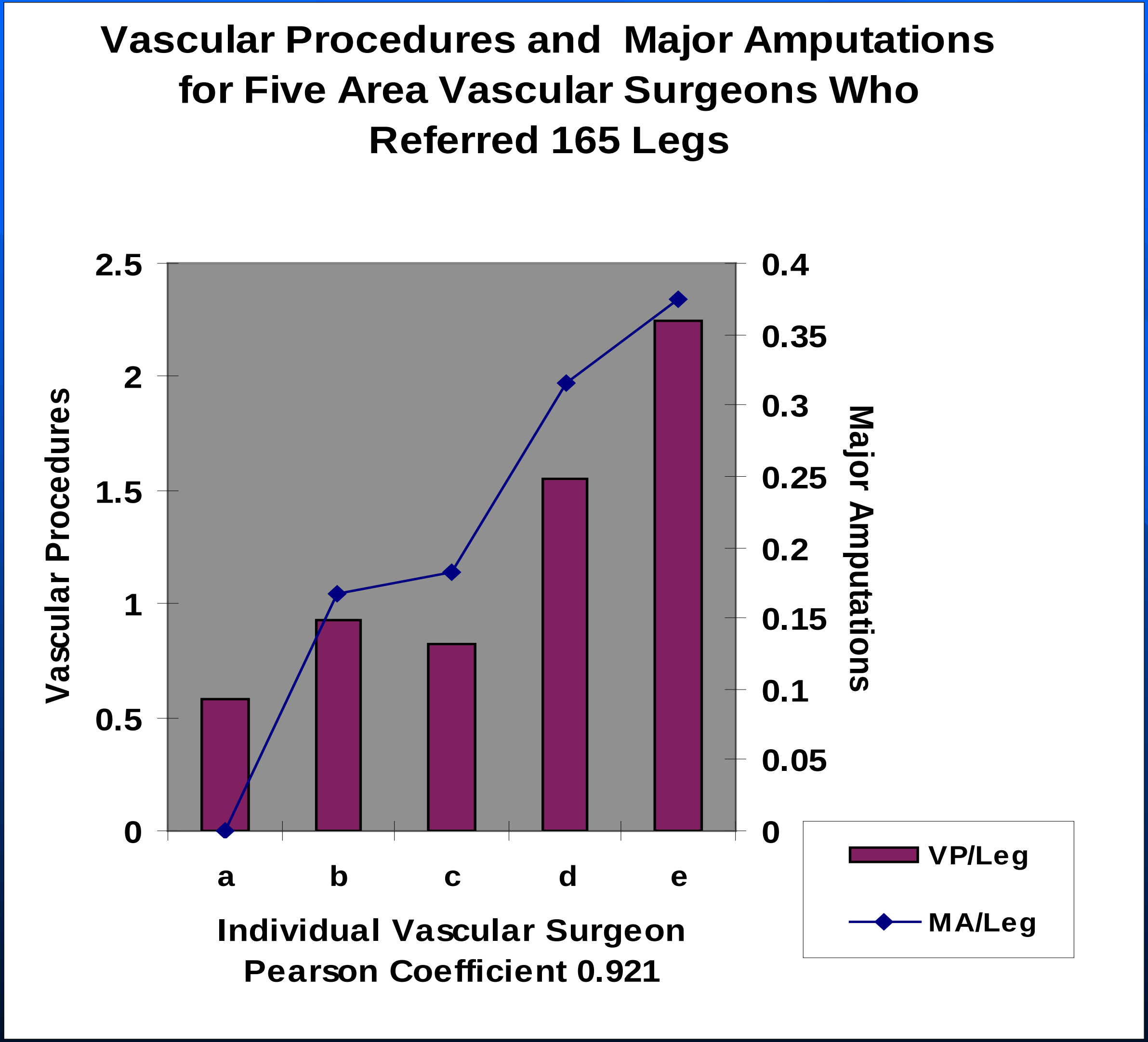

The Fate of the Other Leg as "Control Data" in Patients with Arteriosclerosis (ASO), Neuropathic Ulcers (Neur) and Stasis Disease (Sts)

Dillon: Angiology 48, Number 5, Part 2: S17-S34, 1997

	1-Leg Only	Both Legs	Initial	Remain Intact	Breakdown
Males ASO	138	376	239	129*	110(46.0%)
Females ASO	145	218	205	137*	68(33.1%)
Total ASO	283	594	444	266	178(40.0%)
Males Neur	37	44	93	37	56(60.2%)
Female Neur	29	18	47	29	18(38.3%)
Total Neur	66	62	140	66	74(52.9%)
Males Sts	17	42	25	17	8(32%)
Female Sts	37	40	51	37	14(27.4%)
Total Sts**	54	82	76	54	22(28.9%)
Males, All	207	568	348	198	150(43.1%)
Females, All	221	394	323	213	110(34.1%)
Total, All	428	962	671	411	260(38.7%)

*Not including previous AKA's or BKA's (male 9 and female 8)

** Includes 21 diabetic legs

Other Studies, but without Long Term Follow-up

Vella A et al: Circulator Boot therapy alters the natural history of ischemic limb ulceration. Vascular Med 5:21-25, 2000. (Mayo Clinic) 65% patients with $TcPO_2 < 20$ had favorable outcomes as did 87% those between 20 and 40 mmHg.

Gruenes J, Nelson JP et al: An evaluation of the efficacy of the Circulator Boot in altering hemodynamics of the ischemic lower extremity and foot. Podiatry Management in press. (Barry Univ School of Grad Med Sci) Every pumped extremity had increased perfusion after 4 weeks with an average increase of 43%. Twelve of 13 long term ulcers healed during the study.

Therapy with the Circulator Boot A Breakthrough Technology According to Medicare Criteria

- Many patients with no other alternative
- A beneficial result (“Beneficial” if it produces a health outcome better than the natural course of the disease or that produced by alternative therapies)
- A different clinical modality without consideration of cost or magnitude of benefit
- Added value compared to alternative therapies
- Cost effective… equivalent or lower cost versus standard therapies

http://www.circulatorboot.com/literature/Medcomments.html