The Foot and Leg at Risk

A Method of Treatment

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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

Work Status

- Job title or description

  _____

- Full time Y/N Dates:
- Part time Y/N Dates:
- Dates last worked

  _____

- Reason for lost work

  _____

- Effect of disability on job
- Performance

  _____

- Effect of job on disability

  _____

- Requirements of job aggravating disability

  _____

Differential Diagnosis of Rest Pain and Claudication

Arteriosclerosis obliterans
Spinal stenosis
Ataxias
Lymphedema
Thrombophlebitis
Stress fractures
Reflex Sympathetic dystrophy
Gout
Raynaud's syndrome
Baker's cyst
Popliteal artery entrapment
Endofibrosis in athletes

Degenerative Joint disease in back, hips, knees, ankles or feet
Weakness
Venous stasis
Arterial emboli
Plantar fascitis
Erythromelalgia
Compartment syndromes
Cellulitis
Cold damage
Nerve entrapment syndromes

Etiology of Venous Disease

- Hereditary change in venous wall
- Venous hypertension (promoting varicose veins and venous valvular incompetency) due to

  Obesity Pregnancy Thrombophlebitis
  Trauma Garters Corsets
  Standing Occupations Baker's cyst
- Dominantly inherited clotting disorders:
  - Deficiency of Protein "C"
  - Deficiency of Protein "S"
  - Deficiency of antithrombin III

Venous Disease and the Circulator Boot

Symptoms of Varicose Veins

After Lofgren

- Aching 71%
- Heaviness 47%
- Itching 30%
- Stasis dermatitis 16%
- Burning 16%
- Cellulitis 6%
- Swelling 60%
- Cramps 37%
- Cosmetic dissatisfaction 25%
- Pigmentation 16%
- Ulcers 8%

CBC Laboratory Testing in Venous Disease

- Hematologic: CBC and differential, Protein "C", Protein "S", Antithrombin III, Cold Agglutinins, serum viscosity
- Venous Reflux test: for venous valvular incompetency (normal ≥ 20 seconds)
- MVO test (assesses venous capacitance and maximum venous outflow)(N≥0.61)
- Doppler studies: noting respiratory variation, spontaneous flow, reflux, and augmentation maneuvers
- PPG and TcPO2: to evaluate arterial flow in and around stasis ulcers
- **Duplex scan**: to evaluate risk for thromboembolism and map veins for potential bypass procedures

Risk Factors …Clues to Current Pathology

- Obesity: Degenerative joint Disease
  Hyperlipidemia Gout
  Hypertension Diabetes Mellitus
- Arteriosclerotic Heart Disease and/or Congestive Failure:
  Concomitant Diffuse Arteriosclerosis
  Decreased Tissue Perfusion
- Stroke: Gait imbalance and Trauma ?Emboli
  Neurovascular changes and stasis
- Renal Failure: Dehydration and Hypotension
  ?Calciphylaxis
- Collagen Disease: Rheumatoid arteritis
  Lupus anticoagulant
  Use of steroids

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

Comfortable and Properly Fitting Shoewear

- Avoid use of shoes with high heels and pointed toes
- **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. Authors' conclusions: "Many variables commonly cited as protective measures in footwear for diabetic patients were not prospectively predictive when controlling for physiologic risk factors. Rigorous analyses are needed to examine the many assumptions regarding footwear recommendations for diabetic patients."
- **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. CONCLUSIONS: "This study of persons without severe foot deformity does not provide evidence to support widespread dispensing of therapeutic shoes and inserts to diabetic patients with a history of foot ulcer…."
- The Galapagos…Flat footed on the lava.
- Contact Casting… Decreased ambulation and no heel-toeing

Checklist for Risk Factors

Risk Factor	Goal
• Smoking	None
• Glycohemoglobin	Normal
• Endocrine visits	Enough to normalize Hgb A1C
• Systolic blood pressure	<130 mm Hg
• Total Cholesterol	<200mg/dl, lower better
• Body Mass Index (Kg/M^2)	Male <27, Female <26
• Shoewear	Appropriate fit
• Drugs and other diseases	Minimal use of steroids and vasoconstrictors

Walking Impairment Questionnaire

A. Walking Distance: For each of the following distances, report the degree of difficulty that best describes how hard it was for you to walk WITHOUT stopping to rest.

During the past week, how much physical difficulty did you have...	None	Some	Much	Did not do	Score x Dist.=Factor
1. Walking indoors such as around your home?	3	2	1	0	____x 20= _____
2. Walking 50 feet?	3	2	1	0	____x 50= _____
3. Walking 150 feet?	3	2	1	0	____x 150= ____
4. Walking 300 feet?	3	2	1	0	____x 300= ____
5. Walking 600 feet?	3	2	1	0	____x 600= ____
6. Walking 900 feet?	3	2	1	0	____x 900= ____
7. Walking 1500 feet? (5 blocks or more)	3	2	1	0	____x 1500= ___
					Sum of Factors = _____

Patient Impairment Distance Score = Sum of factors/10,560 = _____
(10,560 = no impairments)

Regensteiner JG, Steiner JF, Panzer RJ and Hiatt WR: Evaluation of walking impairment by questionnaire in patients with peripheral arterial disease. J Vas Med and Bio12:142-152, 1990.

B. Walking Speed: These questions refer to HOW FAST you were able to walk ONE CITY BLOCK. Tell us the degree of difficulty required for you to walk at each of these speeds WITHOUT stopping to rest.

During the past week, how much physical difficulty did you have...	None	Some	Much	Did not do	Score x Speed=Factor
1. Walking 1 block slowly?	3	2	1	0	____x 1.5 =____
2. Walking 1 block at average speed?	3	2	1	0	____x 2 = _____
3. Walking 1 block quickly?	3	2	1	0	____x 3 = _____
4. Running or jogging 1 block?	3	2	1	0	____x 5 = _____
					Sum of Factors = _____

Patient Impairment Speed Score =
Sum of factors/3.45 = _____

Documentation of Physical Findings

- Why? Pointers to the proper diagnosis — Document the progression of disease
  Legal evidence — Payment of insurance claims
  Prognosis

- What to look for?

Skin color changes	Gangrene	Limb hair loss
Mottling	Petechiae	Blistering
Cellulitis	Stasis dermatitis	Tropic nails
Weakness	Lost pulses	Sensory losses
	Ulcerations	Edema

- Why the gangrene? Necrotizing cellulitis and "wet gangrene"
  Uncomplicated ischemia

- Blanching and Rubor indicate inadequacy of tissue perfusion
  - Blanching on elevation related to true blood pressure at the ankle
    - Avoid elevation of feet that blanch.
    - Return of normal skin color within ten seconds
    - Venous filling time within fifteen seconds
  - Rubor …an increasing number of capillaries are patent

- Areas of skin with no blood flow and incipient ischemic gangrene may remain white. Immediate steps are necessary to avoid losing such areas.

CBC

Recording Peripheral Pulses

Classification:

”0” = absent
“trace” = not sure but likely there
“1+” = definite but hard to find
“2+” = definite and easy to find
“3+” = palpable with light touch
“4+” = visible pulsations

- Note Size and Firmness of the vessels.
- Potential Errors: Detecting one’s own pulse.
  Foot tremor and the rhythmical movement of tendons.
- The presence of strong pulses in the feet is strong evidence against diagnoses of ischemic disease in the extremities and makes formal vascular testing unnecessary in most situations.

Laboratory Tests Occasionally Useful in the Diagnosis and Follow-up of Arterial Diseases

- Antineutrophil cytoplasmic antibody (Wegener's granulomatosis)
- C-reactive protein (Infection, inflammation, tissue necrosis, trauma)
- CH50, C1 and C1q, complement (urticarial vasculitis)
- Erythrocyte sedimentation rate (temporal arteritis and osteomyelitis)
- Lupus anticoagulant and anticardiolipin antibodies (venous and arterial thrombi)
- Serum albumin (Acute and chronic inflammation, liver embarrassment, increased losses or metabolism)

Laboratory Assessments of the Arterial Circulation

- Initial history and physical: Is significant arterial insufficiency a possibility? What is the likely nature and location of vascular occlusions?
- Determination of urgency of treatment and danger of immediate tissue breakdown:
  - Toe photoplethysmography tracings (PPG's: Normal tracings usually eliminate possibility of arterial disease sufficient to prevent wound healing and additional testing commonly not necessary. Flat tracing point to danger of tissue breakdown.
  - Transcutaneous PO2 and PC02 levels: TcO2 levels below 20 mmHg are said to be associated with nonhealing. Levels below 10 have been commonly associated with progressing tissue necrosis in our experience. Very low TcPO2 and high TcPO2 levels associated with clear-cut PPG waveforms point to cellulitis, which in our experience may be quickly sterilized with infiltration of the tissues with appropriate antibiotics, administration of a broad- spectrum oral antibiotic and boot therapy; early treatment is desirable.

Laboratory Assessments of the Arterial Circulation, continued

- Noninvasive determination of pathological vascular anatomy if proper prescription of boot therapy in doubt or need to determine possible benefit for bypass surgery (recent arteriograms not available): Segmental blood pressures and pulse volumes determinations and Doppler arterial mapping are considered. If renal function in doubt, and still a possible candidate for bypass, MRI arteriogram then performed.
- Arteriograms: Are never performed as a routine test in patients not disabled enough to consider vascular surgery or in patients with other disabilities severe enough to rule out surgery.

Method of Treatment

1. Hospitalize patient if septic, other medical or surgical necessities or initial need for multiple boot therapies.
2. Drain any obvious abscesses. Limit debridements to removal of clearly dead tissue and loose protruding bone fragments.
3. Stop the cellulitic process immediately.
   a) Administer either orally or intravenously antibiotics to prevent septic emboli.
   b) Soak ulcerated lesions and/or irrigate fistulas and abscesses before first boot treatment with saline-dilute hydrogen peroxide solutions to remove pus and loose debris.
   c) Infiltrate abscessed or cellulitic tissue and osteomyelitic bone with antibiotics usually once daily (e.g. 40 mg gentamicin).
   d) If devitalized ulcerated area present, place foot in plastic bag of multielectrolyte solution (Sea Soaks) containing antibiotics. Avoid prolonged contact with saline.
   e) Place bagged foot in Mini-Boot and pump after each heartbeat (1:1) if a palpable pulse, after every other heartbeat (1:2) if no palpable pulse and after every 3rd heartbeat (1:3) if very ischemic foot. Pump 40 minutes to disseminate the injected antibiotic throughout the cellulitic area, to scrub the infected ulcer and breakup thrombi in the foot secondary to the cellulitic process.
   f) Repeat steps d-e three to four times daily if advanced infection.

Method of Treatment, continued

4. Establish need for vascular reconstruction: avoid booting on a leg with no arterial inflow.
5. Consider angioplasty of the iliac or femoral artery, brachial-femoral bypass or aorto-femoral bypass to establish flow into the leg.
6. In patients with a flat pulse volume at the ankle or no detectable Doppler arterial sounds at the ankle, consider obtaining an early arteriogram.
7. Include in the area of the leg to be booted the ischemic area and a proximal six inches of well-vascularized leg. Patients with diffuse ASO and infected foot ulcers may receive the Mini-Boot therapy above (3b-f) and Long Boot treatments from groin to toes, groin to ankle or to midfoot as needed.
8. Treatments are continued 3-4 times a day in the hospital or nursing home, once daily as an outpatient and tapered as healing progresses.

Routine Orders for Boot Patients with Arterial Insuffiency

Routine Orders	Explanation
1. Bed position: Raise head of bed on blocks. Pubic area should be higher than toes.	1. Blood does not run uphill. The toes may not get blood if they are elevated. Maximal blood flow in the foot is obtained with a 10 degree slant.
2. Pressure sores: Pressure should be removed from the heels and malleoli by some means (a Podus Splint, towels taped in place smoothly around the calf, etc.). Pad side-rails if the patient is at risk of catching the foot in them.	2. In patients with low blood pressure in the feet, the weight of the foot itself against the bed may be sufficient to block blood flow into the skin and, thus, cause skin breakdown.
3. Foot boards or pillows: Placed under the blankets, they may keep weight off of the toes.	3. The weight of bedding on ischemic toes may be painful and block the entry of blood into the toes.
4. Blankets: Make sure the patient is adequately covered so that his/her own blood can warm the legs.	4. Even normal legs have a decrease in blood flow when the body core temperature drops. The speed of healing is decreased in cold tissue.

Routine Orders for Boot Patients with Arterial Insuffiency
continued

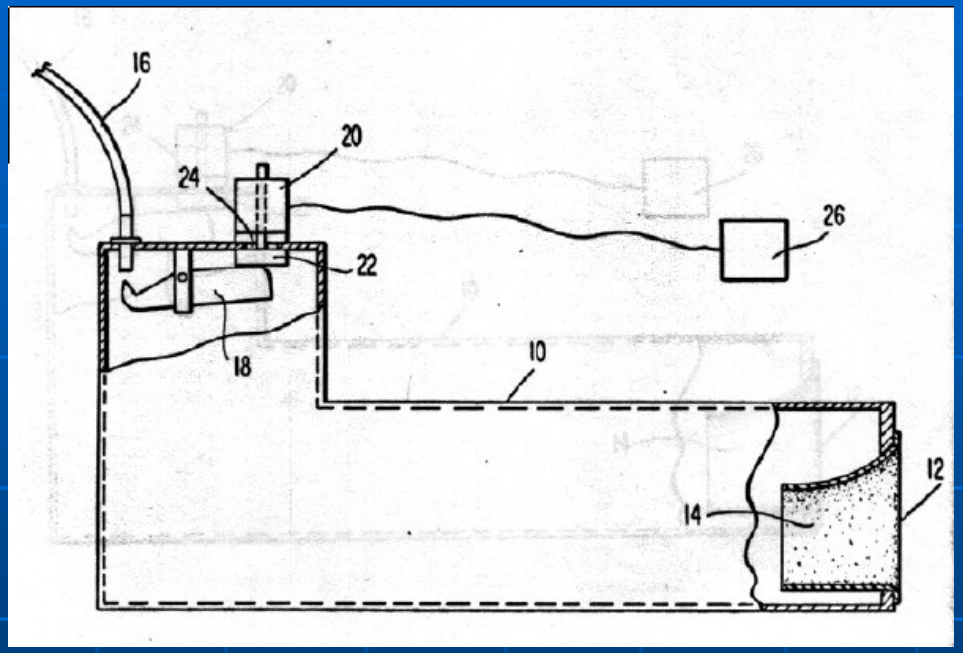
5. Bandages: Change bandages as needed to minimize dampness due to drainage, 1 to 4 times/day. Bandages should not be tight. Do not wedge gauze between toes
6. Bathing: Open lesions are not to be wetted in a tub or shower. Carefully bag such lesions for a quick whole body shower (patient willing). The area of and around the lesions should be separately cleaned with sterile soap and water and rinsed with sterile water, saline or Sea Soaks.
7. Cultures: In addition to initial cultures, weekly cultures should be obtained if lesions continue to drain or if there appears to be any deterioration in the physical status of the lesions.
8. Hot and cold: Avoid exposing ischemic tissue to hot or cold environments.

5. Bacteria can grow in wet bandages. The wet bandage macerates adjacent skin. Drainage can contaminate the bed, the room, and the attending nurse or aide. Blood does not nourish skin compressed by tight bandages.
6. Bacteria, such as Pseudomonas, may commonly be cultured from the water nozzle of baths and showers. The fecal organisms of the patient may be expected to get in a bath.
7. Deterioration of a foot under treatment is more likely to be due to infection with a new organism or abuse of the foot than a falloff in blood flow (except in dialysis patients).
8. External heat (hot pads or sun from the window) increases tissue metabolism and need for oxygen and blood flow. Heat may promote death of borderline tissue.

Topical Oxygen Therapy

- *Indications*: Patients with threatened skin breakdown (mottling, absent capillary refill etc.) may temporarily benefit from topical oxygen. The superficial skin does breathe and the therapy may prolong the life of the skin envelope. Additional time is, thus, gained to allow for revascularization with boot therapy or other methods.
- *Theoretical benefits*: Atmospheric pressure is about 760 mmHg. Twenty percent of the atmosphere is oxygen. The partial pressure of oxygen in the atmosphere is 760/5 or 152 mm Hg. With the placement of the foot in 100% oxygen, the foot is surrounded by 760 mmHg oxygen pressure. If the foot were placed in an oxygen chamber with 100% oxygen and the oxygen pressure was increased 20mm Hg, the oxygen tension would then be 780 mm Hg representing but a 2.5% increase in oxygen tension due to the use of the pressurized chamber.

Topical Oxygen Therapy, continued
The 1976 Circulator Boot



The rubber seal at the opening of the boot had to be tight enough to contain whatever air pressure we introduced into the boot. This band of pressure decreased both arterial inflow and venous outflow. Adverse effects of capillary skin flow was not seen as the pressure was applied intermittently with each pulse wave. Constant pressure within such boots is another thing, however. Capillary flow requires 10 to 20 mm Hg pressure. Pushing on the skin can blanch it and decrease the blood flow to the skin especially in ischemia legs.

Stages of Skin Breakdown

1. Nonblanchable erythema of intact skin.

2. Partial thickness skin loss involving epidermis, dermis or both ... commonly an abrasion, blister or shallow crater.

3. Full thickness skin loss involving damage to or necrosis of subcutaneous tissue maybe extending to but not through underlying fascia.

4. Deep ulcer to muscle, bone, tendon or joint capsule.

U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. Clinical Practice Guideline. Number 15. Treatment of Pressure Ulcers. Pages 12-13. December 1994.

CBC

Wagner Classification

0- Intact skin (may have bony deformities.

1- Localized superficial ulcer.

2- Deep ulcer to tendon, bone, ligament or joint.

3- Deep abscess or osteomyelitis.

4- Gangrene of toes or forefoot.

5- Gangrene of whole foot.

Wagner FW: The diabetic foot and amputations of the foot. In Surgery of the Foot. 5th ed.

Mann, R editor. St Louis, Mo. The C.V. Mosby Company.

Circulator Boot Systems

Heart Monitor, Valve Assemblies and Miniboots and Long Boots

Circulator Boot Equipment Treatment Variables

Patient Position	Gravity	Boot	Indications
Supine	0	Long	ASHD, lymphedema, stasis, diffuse ASO
Reverse Trendelenburg	17%	Long	CHF, severe diffuse ASO
Sitting, legs horizontal	33%	Long	All of above
Sitting on edge of chair, legs slanted	67%	Long	Severe ASO, unable to tolerate above
Sitting, vertical tibia	67%	Miniboot	ASO below the knee
Standing	100%	Miniboot	Rare, severe ASO and able to stand

Treatment Variables Cont
Choice of Compression Bag

Bags	Area Covered	Indications
Miniboot bag	Toe-to-ankle	Small arterial disease limited to foot
Miniboot bag	Toe-to-knee	ASO below the knee, antibiotic injections into foot, antibiotic solutions within the Miniboot
Sleeve	Groin-to-ankle	Diffuse ASO throughout leg with painful foot
Sleeve	Groin-to-midfoot	Diffuse ASO throughout leg with painful distal foot and toes
Full Bag	Groin-to-toes	ASHD, CHF, lymphedema, diffuse ASO, stasis disease that includes both calf and thigh
Full bag	Knee-to-toes	Stasis disease of calf and ankle

Circulator Boot Heart Monitor Settings

Setting	Indications
1) Internal clock (adjustable rate independent of EKG)	1) Ischemic pain associated with severe iliac disease or associated with a rapid irregular pulse. Those with iliac disease might be given 10 to 20 full leg compressions per minute, each compression 0.40 to 0.45 second.
2) Patient EKG - Computer Pacer	2) Preferred mode. Monitor computer continually averages the last ten RR intervals, uses a formula to predict the duration of the next RR interval, deducts 0.04 seconds from the predicted RR interval to maximize the ventricular cardiac-assist action of the booting, and sets a delay time with each beat accordingly.

Circulator Boot Heart Monitor Settings

Setting	Indications
3) Patient EKG - manual adjustment of delay time	3) Both the "delay time" and the "compression time" are set by the technician. The sum of the two equals the RR interval, which, divided by 60, gives the pulse rate per minute.
4) Compression time - duration of boot	4) Long enough to overcome the inertia of the fluids in the vascular channels: 0.34 second in the Miniboot and 0.40 to 0.45 second in the Long Boots.
5) Delay time	5) Automatically set in preferred mode (above) or manually set to equal the RR interval minus the compression time, thus placing the compression time in the end-diastolic period.

Circulator Boot Heart Monitor Settings

Setting		Indications	
6)	Divide QRS by	6)	a. **1:1** setting (compressing the leg after each QRS complex) used in those with moderate arterial insufficiency of the leg or those with lymphedema, ASHD or stasis disease. Used in Miniboot patients with slow pulse rates (eg, <60). b. **1:2** setting (compressing the leg after every other QRS complex) used in long-boot patients who have more advanced arteriosclerosis and who develop pain on the 1:1 mode. Also used in most Miniboot patients. c. **1:3** setting (compressing the leg after every 3rd heartbeat) used in patients with rapid heart rates and ischemic disease who develop ischemic pain on the 1:2 setting

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

Edema or Interstitial Fluid Pressure Impeding the Microcirculation

To help understand the multiple effects of boot therapy on peripheral arterial blood flow, we shall evolve a formula for peripheral blood flow following each commentary section.

In the previous slide, we have considered edema.

I. Effective Blood Flow = f (variables) / interstitial fluid pressure or EBF = f (V) / IFP

Chronic Venous Disease Impedes Tissue Blood Flow

Effective blood flow = f (variables) / venous pressure or EFB = f (V) / VP
or together with “I”: EFB=f(V) / (VP)(IFP)

Patient RD: diverticulitis and intestinal perforation in 1968 - pulmonary emboli and a caval ligation - Venous stasis disease - 1980 first indolent ulcer which healed - Left supramalleolar ulcer after trauma in auto accident and healed - In early 1983 the supramalleolar ulcer in his right leg spontaneously recurred and persisted in spite of various outpatient treatments (rest, whirlpool, vitamin E, Betadine, peroxide and diuretics) and a 24-day hospitalization that included whirlpool, intravenous antibiotics and hyperbaric oxygen treatments - Referred by his vascular surgeon for boot therapy (above left). He healed with 23 OPD treatments. Above right he returned a year later with a new ulcer above the left ankle… which we healed also.

Patient MM

Neuropathy and Infection

MM a 46 year old women with poorly controlled type 1 diabetes mellitus over 22 years. Her podiatrist had debrided an infected plantar callus beneath her 5th metatarsal head and started her on antibiotics and Epsom foot soaks. Her infection progressed over the next ten days leading to hospitalization on the vascular surgery service. She was begun on intravenous gentamicin and tetracycline with no effect on her fever (101 degrees F) or her leukocytosis (17.7 to 20.2). Her ulcer appeared to be enlarging and the possibility of leg amputation was considered. A boot consultation was requested.

Patient MM, continued

Neuropathy and Infection

- Our routine program for such patients was begun:

  (a) antibiotics to prevent septic emboli

  (b) a cleansing foot soaks

  (c) local antibiotic injections

  (d) Mini-Boot therapy with the foot immersed in 200 ml multielectrolyte solution (Sea Soaks) and gentamicin (80 mg/half gallon).
- She appeared to be responding but Dr. Dillon went on vacation for a week during which her therapy was again limited to intravenous antibiotics. Her fever returned and again her foot infection seemed to be progressing leading the surgeons to urge leg amputation. She refused insisting on waiting a week to restart boot therapy.

Patient MM, continued

Neuropathy and Infection

- The latter was restarted and her foot did well. Her left toe was left atrophied but she lost no parts and was discharged ambulatory to receive boot therapy as an outpatient.

Patient DC

Neuropathy and Necrotizing Cellulitis

- **33** year old bride with diabetes. **D**eveloped plantar callus on honeymoon.
- **O**ral cephradine and bedrest ineffective in arresting spread of cellulitis.
- **12**-day hospitalization with intravenous tobramycin and cefobid appropriate for the Beta-streptococcus and Eikenella species cultured from her foot, again ineffective in arresting cellulitis.
- **B**one scan: ostemyelitis of her 3rd, 4th and 5th metatarsal heads.
- **I**ncision and drainage procedure shows advanced tissue necrosis.
- **P**eroxide soaks, whirlpool treatments and blood transfusions no help.
- **A**ttending physicians: specialists in diabetes, infectious disease and vascular and general surgery.
- **U**nanimous recommendation for Beneath-the-Knee amputation for following reasons:
- **Uncontrolled** soft tissue and bone infection.
- Persisting systemic toxicity with:
  - Spiking fevers
  - Uncontrolled diabetes
  - Loss of veins and poor access for intravenous treatments.
  - Vaginal and rectal yeast infections

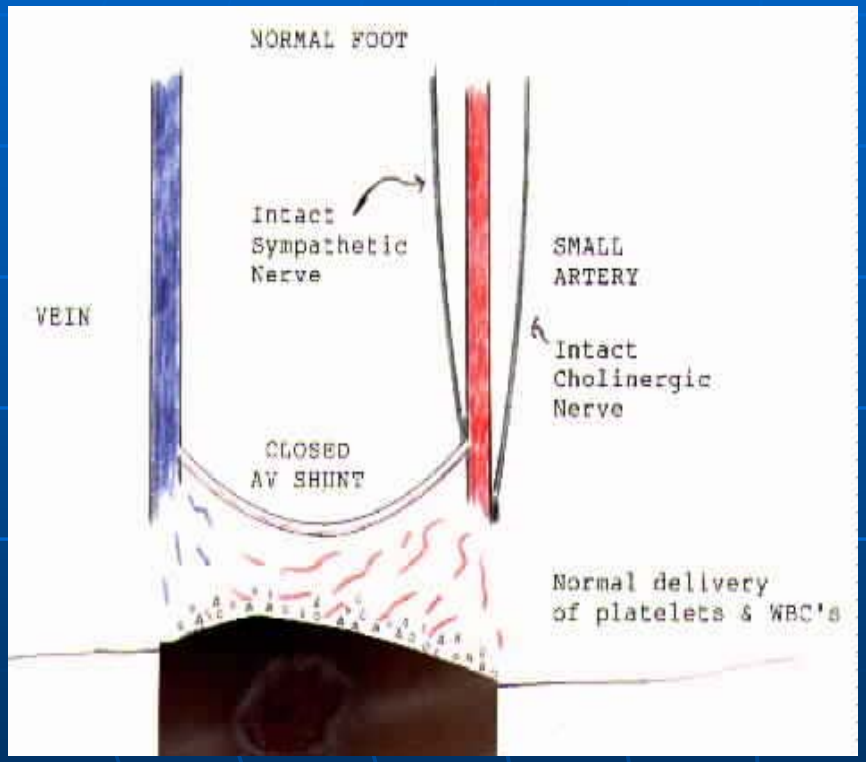
Patient DC, continued

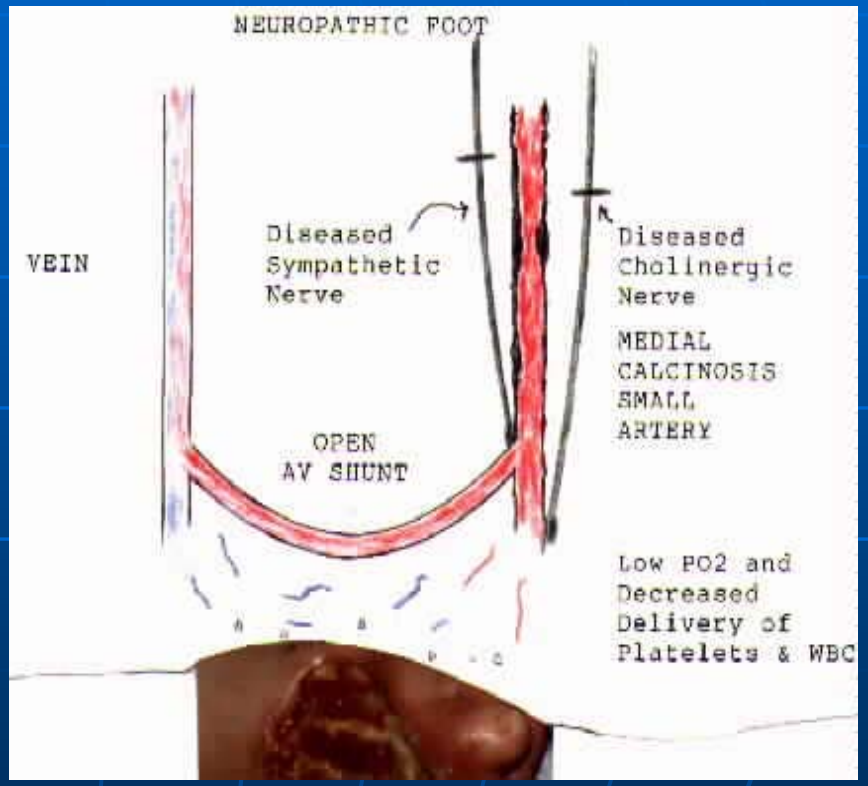
Neuropathy and Necrotizing Cellulitis

Patient DC, continued

Neuropathy and Necrotizing Cellulitis

Diabetic Neuropathy
Infection and Wound Healing





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

Effective Peripheral **B**lood **F**low Inversely Related to **V**enous and **I**nterstitial **F**luid **P**ressure and **Neur**opathy and **Inf**ection

- Effective blood flow = f (variables)/ neuropathy or EBF = f (V) / Neur
- Effective blood flow = f(variables)/infection or EBF=f(V)/Inf
- Effective blood flow = f (variables)/ Effective blood flow = f (variables)/ (VP)(IFP)(Neur)(Inf)

The Circulator Boot in the Treatment of Arterial Disease

Patient MA: an 87 year old diabetic lady who had a previous left AK amputation. Her physicians recommended an AK leg amputation in view of her extensive gangrene. She refused and came 900 miles for boot therapy. She lacked palpable pulses below her groin. Her Doppler sounds in the posterior tibial and peroneal arteries were absent while low broad monophasic waveforms in the anterior tibial were present. Her ankle/arm index was 0.35. Her heel x-ray showed significant osteolysis within the posterior aspect of the os calcis.

Boot Therapy and Local Care for Patient MA

- Limited debridements to allow the skin margin access to the newly forming granulations
- Periodic cultures
- An initial daily rinse with multi-electrolyte solution (Sea Soaks)
- Injections of gentamicin into the necrotic areas – Later, a 30-second exposure to ultraviolet light to minimize the growth of molds and resistant staphylococci
- Wet-to-dry dressings soaked with multi-electrolyte solution containing appropriate antibiotics
- Vaseline gauze applied over the ulcer and Valisone cream to adjacent irritated skin
- Leg pumped from groin to toes with the monitor at the 3:1 setting three to four times in the hospital daily until her leg was stabilized (10 days) and thereafter in a nearby nursing home
- When her leg was close to healed, she was referred back to her hometown academic center in the hope that the therapy could be continued there (next slide).

Improvement with Boot Therapy
Deterioration with “Standard Care”
Cure with More Booting

When her physicians found they could perform no surgery, they prescribed soaks and dressings. Her leg deteriorated (upper right) leading her to return to our nursing home. We continued our previous program and cured her leg (lower right).

The Circulator Boot in the Treatment of Arterial Diseases

Indications listed in our manual as allowed by the FDA include:

- **Poor arterial flow in the leg associated with:**
  - Ischemic ulcers
  - Rest pain or claudication
  - Threatened gangrene
  - Insufficient blood supply at an amputation site
  - Persisting ischemia after embolectomy or bypass surgery
  - Pre and Post-arterial reconstruction to improve runoff
- **Diabetes complicated by the above or other conditions possibly related to arterial insufficiency:**
  - Nocturnal leg cramps
  - Necrobiosis diabeticorum
- **Venous diseases (once risk of emboli minimized):**
  - Prophylaxis of deep vein thrombophlebitis
  - Edema and induration associated with chronic venous stasis
  - Venous stasis ulcers
- **Lymphedema:**
  - Recent (therapy is most effectively initiated before secondary fibrosis has become established)
  - Chronic
- **Congestive Heart Failure**

The Circulator Boot in the Treatment of Arterial Diseases

1) History of boots designed to improve arterial blood flow dating back to 1812. Each shown to have effect by the technology of their era.
2) Circulator Boot shown to improve transcutaneous oxygen, pulse volume, Doppler velocity, Ankle/Brachial Indices (ABI) determinations (Dillon, 1980)
3) Humoral factors elicited by Boot therapy likely important in promoting vascular effects:
   a) Fibrinolysins
   b) Prostacyclin
   c) Nitric oxide
   d) Vascular endothelial growth factor
4) Effect on entire treated area versus vascular surgery which provides a single conduit, removes a vein, scars the leg and ties off many small vessels (bleeders)
5) Success in large numbers of difficult cases where treatment allowed by FDA guidelines.

Effective Peripheral **B**lood **F**low

Inversely Related to

Venous and **I**nterstitial **F**luid **P**ressure, **Neur**opathy and **Inf**ection and Arteriosclerosis Obliterans (ASO)

- Effective blood flow = f (variables)/ arteriosclerosis obliterans or

  EBF = f (V) / ASO
- Effective blood flow = f (variables)/ (VP)(IFP)(Neur)(Inf)(ASO)

Combined Disease: Heart, Venous, Cellulitis and Osteomyelitis with Sixteen Year Follow-up

Born on August 17th, 1920, this obese diabetic lady had no distal pulses since 1981 and had retinal hemorrhages since 1982. She received boot treatments in 1986 for stasis disease and cellulitis of both legs and did well. She had hypertensive arteriosclerotic heart disease and episodes of congestive heart failure. High risk heart surgery was under consideration. **S**he presented January 7th, 1988 in a wheelchair with recurrent venous stasis, cellulitis and osteomyelitis of her left fifth toe and metatarsal head secondary to an insulin needle under her proximal phalanx.

Combined Disease: Heart, Venous, Cellulitis and Osteomyelitis. Follow-up at Five Years

She was treated with local antibiotic injections and both long and Miniboot therapies. Her foot and leg did well. As she attributed a sense of well-being to her boot treatments, she hired a nurse from our boot clinic and purchased a boot system to take home. She has continued to receive boot treatments daily to both legs. A compulsive eater, however, she has been unable to control her diabetes; her blood glucose levels have varied from 170 to 350 mg/dl. Nonetheless, her vision and cardiac function stabilized. Her cardiologist dismissed her from his immediate care.

Picture (right): five year follow-up

Continued Follow-up and Boot Therapy Pays Dividends

- Follow-up visit at Boot Clinic on November 10th, 1995: asymptomatic bradycardia (pulse rate 40)and first degree AV heart block (PR interval 0.26). An A-V pacemaker was subsequently inserted.
- Angina and on January 18th, 1996, coronary bypass with her saphenous veins. Postoperatively, treatment of her edematous and cellulitic suture line (ankle to her midcalf). with local antibiotic injections and Long-Boot therapy.
- In June of 1996, an ingrown toenail and an ulcer that penetrated through callus over her second left hammer toe; Enterococcus was cultured from the ulcer which was treated quickly and successfully in the Mini-Boot with local gentamicin injections.
- She continued with her business ventures which took her to a building site where she unfortunately stepped on a nail on the 24th of September, 1997.

Continued Follow-up and Boot Therapy Pays Dividends

Her many drug allergies limited her therapies. Her toe PPG tracings showed minimal pulsatile flow. Local gentamicin was injected into the nail hole and Mini-Boot therapy and oral doxycycline were prescribed. Yeast, coagulase-negative staphylococci and Pseudomonas aeruginosa (gentamicin-resistant) were recovered. Hence, local injections of ceftazidime and gentamicin, and oral fluconazole prescribed.

Continued Follow-up and Boot Therapy Pays Dividends

What Dividends?

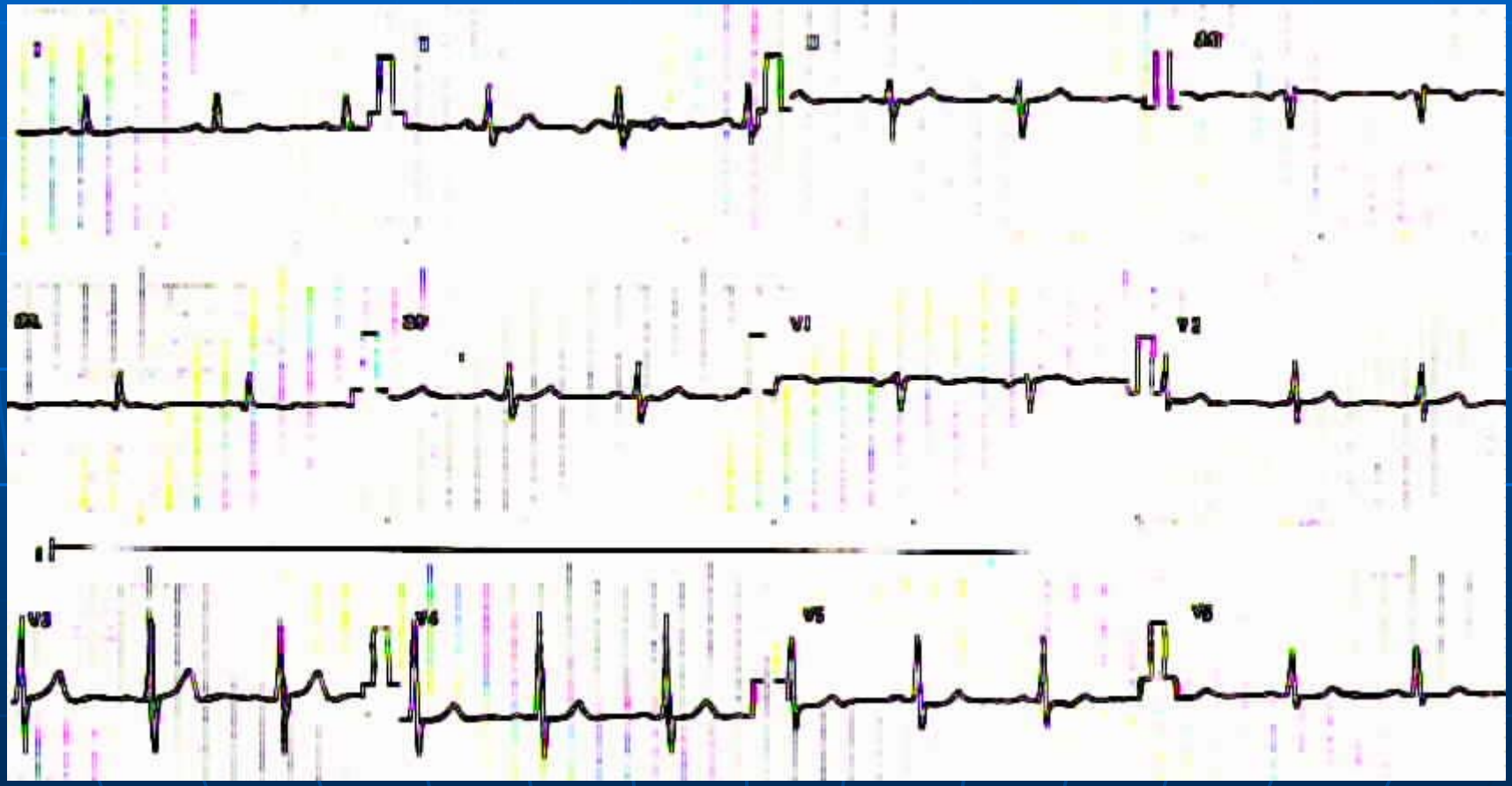
- Greatly improved venous stasis disease (the stasis disease being one early contraindication to consideration of bypass surgery by her physicians),
- Supporting her heart
- Healing two episodes of osteomyelitis associated with foreign bodies (a needle and a nail)
- Healing an infected hammer toe
- Healing her cellulitic leg after her heart surgery
- Improving her overall mobility
- Now in the year 2002, she still has intact feet and vision and is functioning well. Not too bad a feat for a non-compliant 82 year old lady with chronic hyperglycemia, known loss of peripheral pulses for 21 years and documented retinal hemorrhages 20 years ago.

Case 26: An Acute Myocardial Infarction? You Did What?

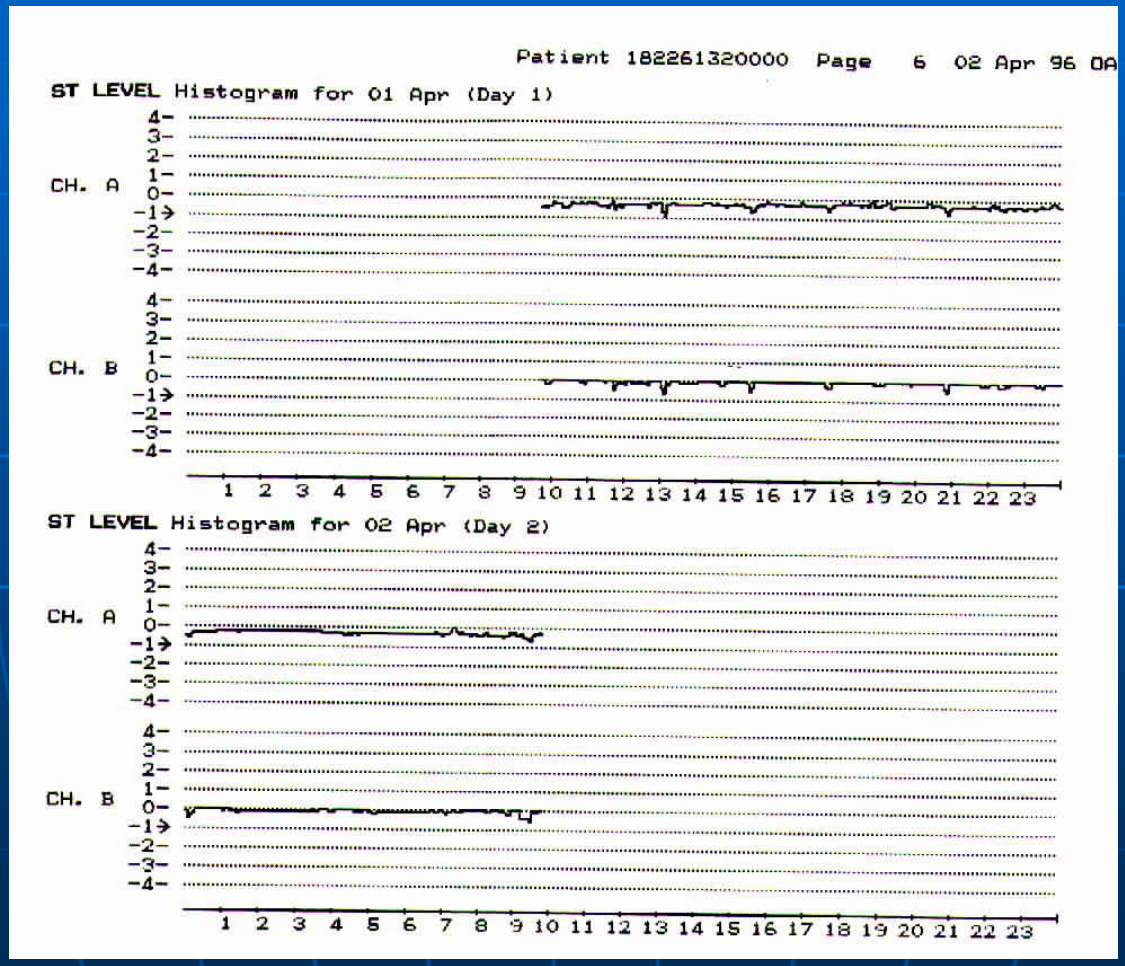
- 62 year old lady with a 35 year history of insulin-dependent diabetes, a history of multiple foot ulcers, peripheral arteriosclerosis obliterans, peripheral neuropathy and recent chest pain. She had refused coronary angiography for evaluation of her angina. She had intermittent boot therapy relieving both her claudication and angina.
- She returned from a few months vacation in Florida again with heavy legs and angina. A few days later, she had noted chest pain persisting through much of the day and worsening after supper. Three nitroglycerine tablets and bedrest offered no relief. At 11:30 PM she called the medical service And was advised to go to the Emergency room. She preferred to go to the office.
- She arrived at 12:30 AM pale, faint, weak and diaphoretic. A fingerstick glucose determination quickly ruled out a hypoglycemic reaction. Her EKG showed new large RST depressions from V2 to V5. Her blood pressure was hard to obtain. She appeared to be in cardiogenic shock.

An Acute Anterior Wall Myocardial Infarction

Normal Follow-up EKG

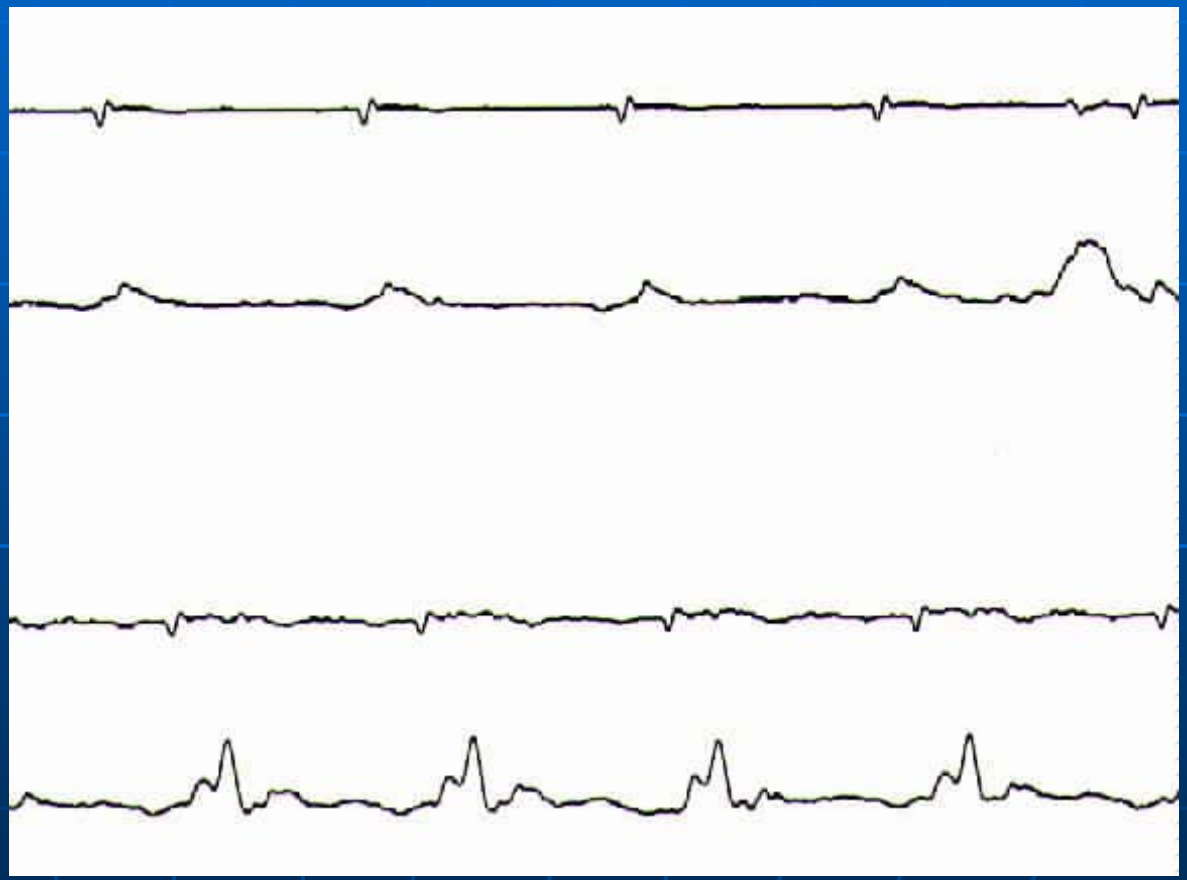


Minimal Ischemic Changes on 24-Hour Heart Monitor



IQ electrical impedance apparatus shows increases in cardiac output of 64% and in stroke volume of 58.5% during boot therapy

First and Third Row are the EKG complexes before and during boot therapy respectively. The Second and Fourth row are the pulse waveforms in the aortic root again before and during boot therapy.



Summary of How the Boot Works

- Effective blood flow = f(variables)(Cardiac Output)(Gravity) or EBF=f(V)(CO)(Grav)
- or EBF = f(V)(CO)(Grav) / (VP)(IFP)(Neur)(ASO)(Inf)

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