

Role of Vascular Surgery in the Diabetic Foot

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The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine

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Background: Diabetes mellitus continues to grow in global prevalence and to consume an increasing amount of health care resources. One of the key areas of morbidity associated with diabetes is the diabetic foot. To improve the care of patients with diabetic foot and to provide an evidence-based multidisciplinary management approach, the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine developed this clinical practice guideline.

Methods: The committee made specific practice recommendations using the Grades of Recommendation Assessment, Development, and Evaluation system. This was based on five systematic reviews of the literature. Specific areas of focus included (1) prevention of diabetic foot ulceration, (2) off-loading, (3) diagnosis of osteomyelitis, (4) wound care, and (5) peripheral arterial disease.

Results: Although we identified only limited high-quality evidence for many of the critical questions, we used the best available evidence and considered the patients' values and preferences and the clinical context to develop these guidelines. We include preventive recommendations such as those for adequate glycemic control, periodic foot inspection, and patient and family education. We recommend using custom therapeutic footwear in high-risk diabetic patients, including those with significant neuropathy, foot deformities, or previous amputation. In patients with plantar diabetic foot ulcer (DFU), we recommend off-loading with a total contact cast or irremovable fixed ankle walking boot. In patients with a new DFU, we recommend probe to bone test and plain films to be followed by magnetic resonance imaging if a soft tissue abscess or osteomyelitis is suspected. We provide recommendations on comprehensive wound care and various débridement methods. For DFUs that fail to improve (>50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, we recommend adjunctive wound therapy options. In patients with DFU who have peripheral arterial disease, we recommend revascularization by either surgical bypass or endovascular therapy.

Conclusions: Whereas these guidelines have addressed five key areas in the care of DFUs, they do not cover all the aspects of this complex condition. Going forward as future evidence accumulates, we plan to update our recommendations accordingly. (J Vasc Surg 2016;63:3S-21S.)



Impact of Diabetes

- ▶ One of the leading causes of chronic disease and limb loss worldwide
 - ▶ Currently affects 382 million people
 - ▶ Number of reported diabetes cases will increase to 592 million by 2035
 - ▶ >80% of diabetes deaths occur in low- and middle-income countries
- 



Impact of Diabetes



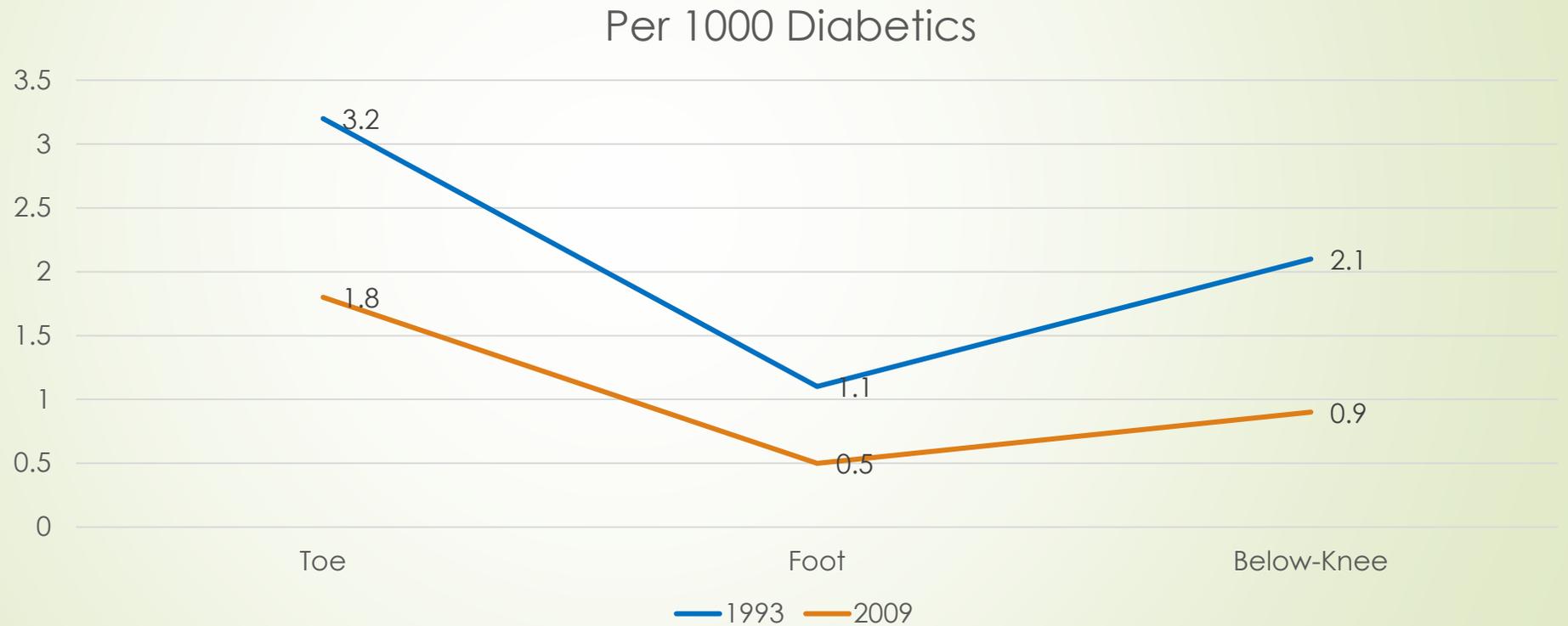
- ▶ WHO projects diabetes will be 7th leading cause of death in 2030
- ▶ >1 million people with diabetes-related amputations per year
- ▶ A diabetes-related amputation occurs every 20 seconds
- ▶ Annual cost of diabetic foot disease in U.S. at least \$6 billion



Risk Factors for Diabetes-Related Amputation

- ▶ Neuropathy
- ▶ Peripheral arterial disease (PAD)
- ▶ Foot deformity
- ▶ Limited ankle range of motion
- ▶ High plantar foot pressures
- ▶ Minor trauma ***
- ▶ Previous ulceration or amputation
- ▶ Visual impairment
- ▶ Presence of a foot ulcer (80%) → infection and PAD → amputation

U.S. Incidence of Diabetes-Related Amputations





Clinical Practice Guidelines

- ▶ Society for Vascular Surgery
 - ▶ American Podiatric Medical Association
 - ▶ Society for Vascular Medicine
- 



Clinical Practice Guidelines Focus Topics

- ▶ Prevention
- ▶ Off-loading diabetic foot ulcers
- ▶ Diagnosis of osteomyelitis
- ▶ Wound care
- ▶ Peripheral arterial disease



Strength of Recommendations

- ▶ Grade 1: recommendations meant to identify practices for which benefit clearly outweigh risk
- ▶ Grade 2: recommendations when benefits and risks are more closely matched, and should be tailored to each specific scenario based on physician and patient preferences



Level of Evidence

- ▶ A: high quality
- ▶ B: moderate quality
- ▶ C: low quality

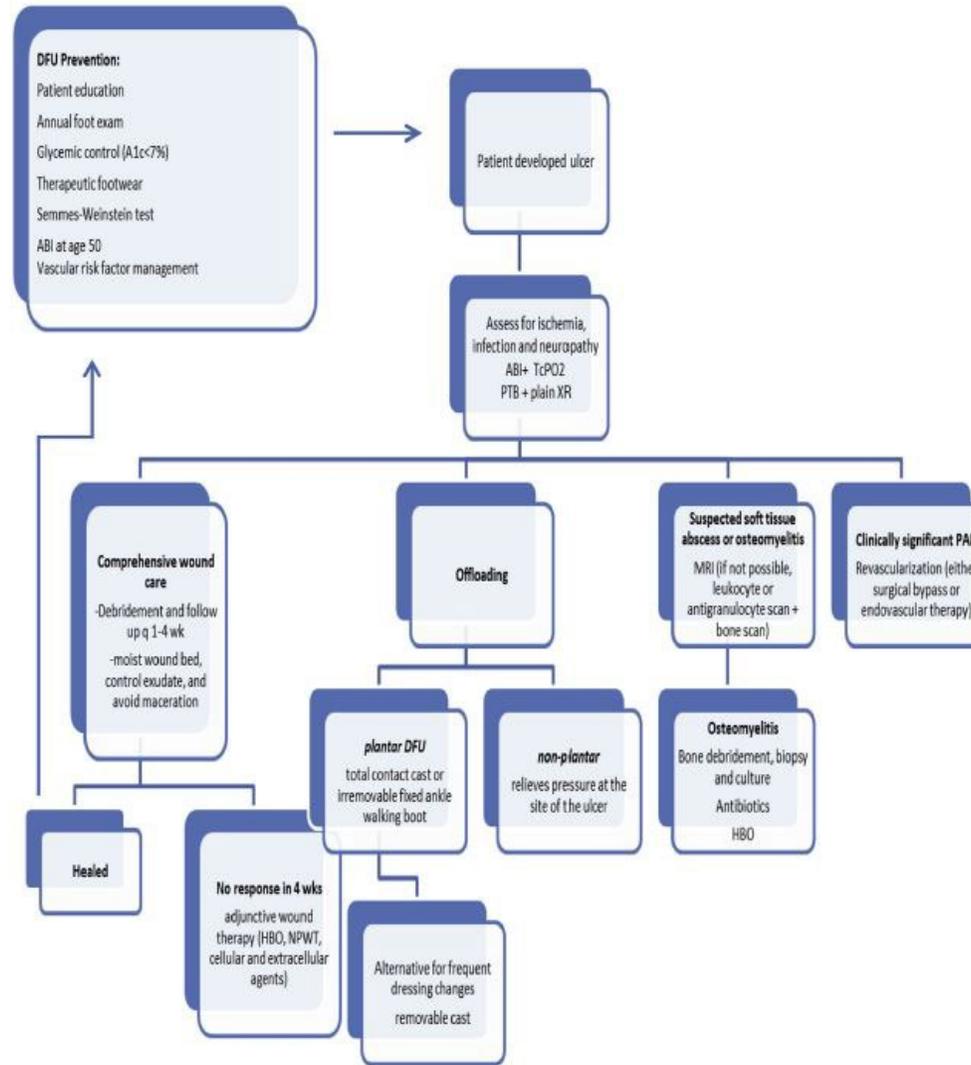


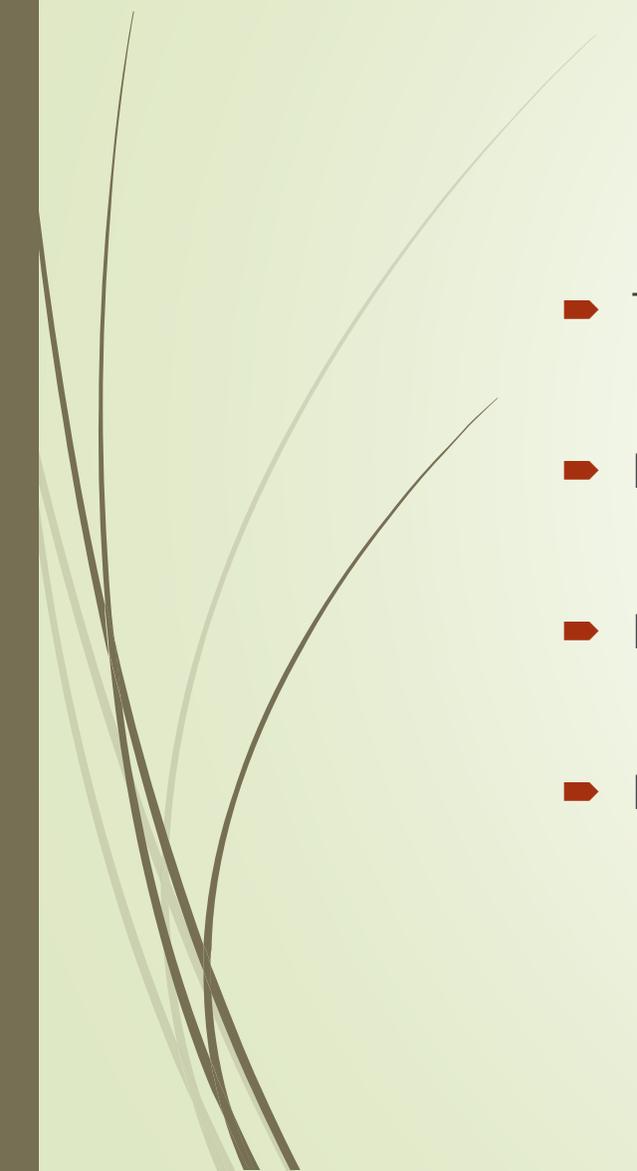
Fig. Algorithm for prevention and care of diabetic foot. *ABI*, Ankle-brachial index; *DFU*, diabetic foot ulcer; *HBO*, hyperbaric oxygen; *MRI*, magnetic resonance imaging; *NPWT*, negative pressure wound therapy; *PAD*, peripheral arterial disease; *PTB*, probe to bone; *TcPo₂*, transcutaneous oxygen pressure; *XR*, radiography.



Prevention of Diabetic Foot Ulceration



Evaluation



- ▶ Testing for neuropathy (monofilament)
- ▶ Presence of healed ulcerations or prior amputations
- ▶ Foot deformity
- ▶ PALPATION OF PEDAL PULSES



Absent Pedal Pulses

- ▶ Ankle-brachial indices (ABIs) are the “gold standard” for limb blood flow
 - ▶ 63% sensitivity & 97% specificity in detecting hemodynamically significant PAD
- ▶ Toe pressures are often more useful in diabetic persons due to medial arterial calcification
 - ▶ Useful for predicting potential for wound healing
 - ▶ Useful for predicting future risk of ulceration (can guide follow-up strategy)
- ▶ aldjfljs



Recommendation

- ▶ Recommend against prophylactic arterial revascularization to prevent diabetic foot ulcers (1C)

Recommendation (1C)

Table. Suggested frequency for follow-up evaluation

| <i>Category</i> | <i>Risk profile</i> | <i>Evaluation frequency</i> |
|-----------------|-----------------------------------------|-----------------------------|
| 0 | Normal | Annual |
| 1 | Peripheral neuropathy | Semiannual |
| 2 | Neuropathy with deformity and/or PAD | Quarterly |
| 3 | Previous ulcer or amputation | Monthly or quarterly |

PAD, Peripheral arterial disease.



Other Recommendations

- ▶ Education of patients and their family about preventive foot care (1C)
- ▶ Recommend against specialized therapeutic footwear in average-risk diabetic patients (2C). Recommend using custom footwear in high-risk patients, such as neuropathy, foot deformities, or prior amputation (1B).
- ▶ Recommend adequate glycemic control (hemoglobin A1c <7% with strategies to minimize hypoglycemia) (2B)

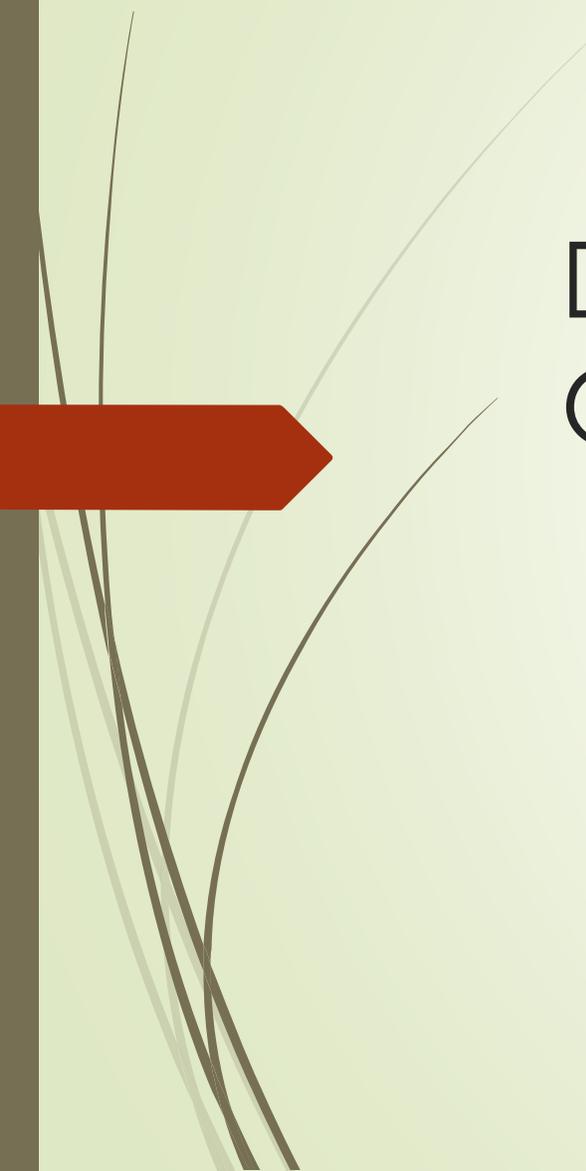


Off-Loading Diabetic Foot Ulcers



Recommendations

- ▶ Plantar diabetic foot ulcers → total contact cast or fixed ankle walking boot (1B)
- ▶ If ulcers require frequent dressing changes → removable cast walker (2C)
- ▶ Non-plantar wounds → any pressure relieving modality (surgical sandal, heel relief shoe) (1C)
- ▶ Prior history of ulcers, partial amputation, Charcot foot → custom therapeutic footwear (1C)



Diagnosis of Diabetic Foot Osteomyelitis



Recommendations

- ▶ Open wound → probe to bone (PTB) to aid in diagnosis
- ▶ New diabetic foot infection → serial plain radiographs (2C)
- ▶ If PTB or plain films inconclusive → MRI/Bone scan (2B)
- ▶ Consider wound culture or bone biopsy to direct care (1C)



Wound Care for Diabetic Foot Ulcers



Recommendations

- ▶ Frequent (1-4 weeks) evaluations with measurements to monitor wound progress (1C)
- ▶ Use of dressing products that maintain a moist wound bed, control exudate, and avoid maceration of intact skin (1B)
- ▶ Sharp debridement of all devitalized tissue and surrounding callus from ulcerations at 1-4 week intervals (1B)
- ▶ For ulcers that fail to improve (>50% wound area reduction) after a minimum of 4 weeks, consider adjunctive wound therapy options (negative pressure, biologics, hyperbaric oxygen therapy) (1B, 2B)



Peripheral Arterial Disease



Recommendations

- ▶ Patients with diabetes should have ankle-brachial index (ABI) measurements when they reach 50 years of age (2C)



Recommendations

- ▶ Annual vascular examination of the lower extremities and feet including ABIs and toe pressures in the following (2C):
 - ▶ Prior history of diabetic foot ulcer
 - ▶ Prior abnormal vascular examination
 - ▶ Prior intervention for peripheral arterial disease
 - ▶ Known atherosclerotic cardiovascular disease (coronary, cerebral, renal, etc)
- ▶ At least 65% of diabetic foot ulcers have an ischemic component, nearly double that reported in the early 1990s.



Recommendations

- ▶ All patients with diabetic foot ulcers should have pedal perfusion assessed by ABI, ankle, and pedal Doppler arterial waveforms and toe pressures (1B)
- ▶ Patients with diabetic foot ulcers in the setting of peripheral arterial disease should undergo revascularization, either by surgical bypass or endovascular therapy (1B)



Further Vascular Workup





Endovascular Intervention



Pressures/SBI/ABI

| | | | |
|------------|-----|-----|------|
| Brachial | 145 | | |
| Above Knee | | SBI | |
| Calf | | SBI | |
| Ankle | 78 | ABI | 0.54 |
| Toe | | TBI | |

Above knee

Calf

Ankle

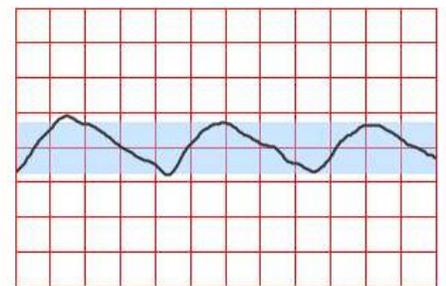


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Toe

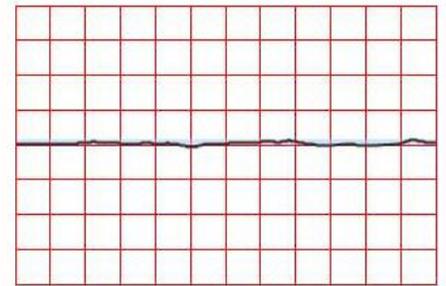


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Pressures/SBI/ABI

| | | | |
|------------|-----|-----|------|
| Brachial | 143 | | |
| Above Knee | | SBI | |
| Calf | | SBI | |
| Ankle | 144 | ABI | 0.99 |
| Toe | | TBI | |

Above knee

Calf

Ankle

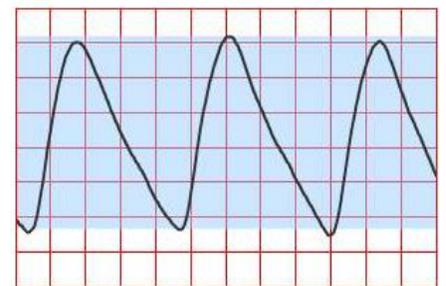


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Toe



RIGHT



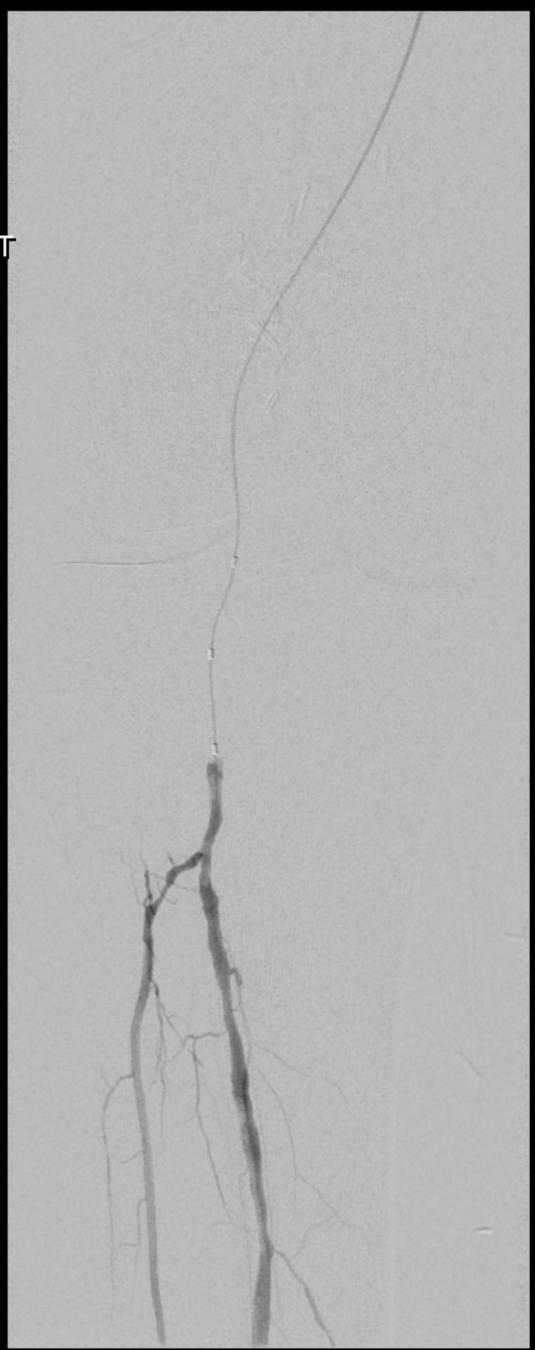


RIGHT





RIGHT





RIGHT



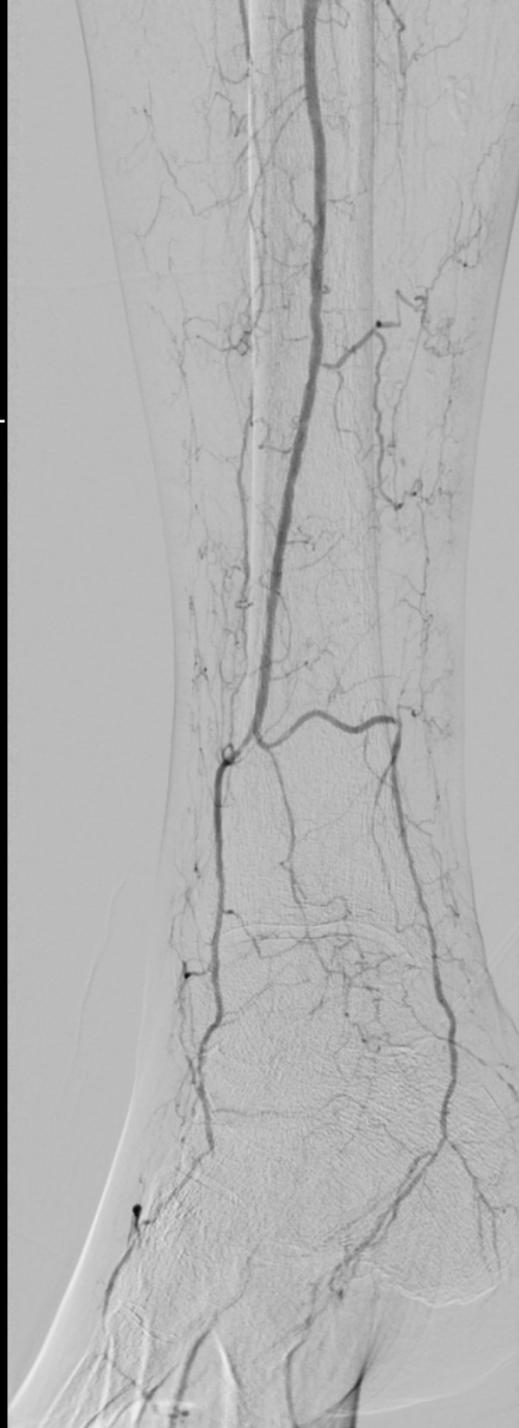


RIGHT





RIGHT



Right**Pressures/SBI/ABI**

| | | | |
|------------|-----|-----|------|
| Brachial | 157 | | |
| Above Knee | | SBI | |
| Calf | | SBI | |
| Ankle | 138 | ABI | 0.88 |
| Toe | | TBI | |

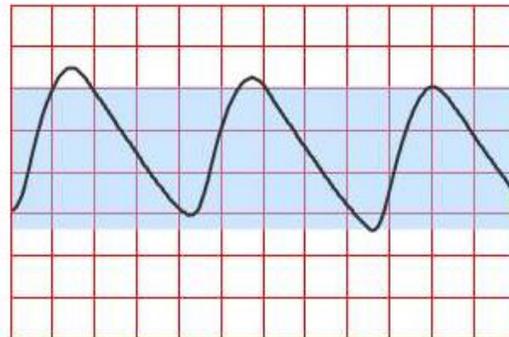
Above knee Calf Ankle 

Chart Speed: 25 mm/sec Amp=17mm; Gain=1.00

Toe **Left****Pressures/SBI/ABI**

| | | | |
|------------|-----|-----|------|
| Brachial | 149 | | |
| Above Knee | | SBI | |
| Calf | | SBI | |
| Ankle | 155 | ABI | 0.99 |
| Toe | | TBI | |

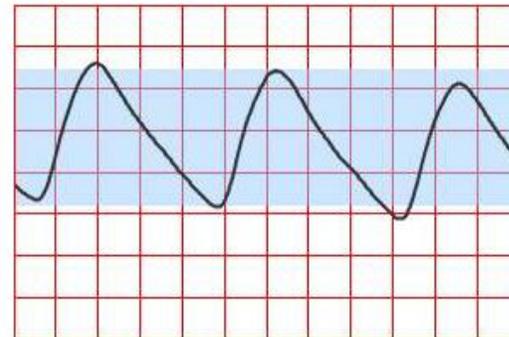
Above knee Calf Ankle 

Chart Speed: 25 mm/sec Amp=16mm; Gain=1.00

Toe



Surgical Revascularization

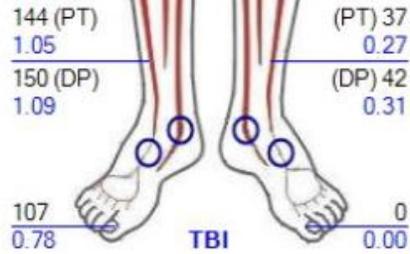
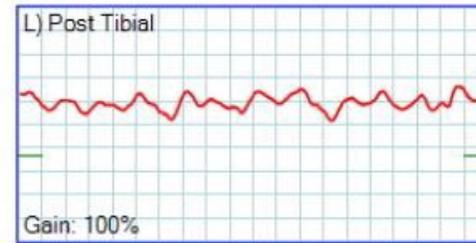
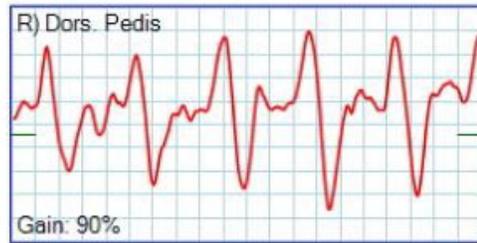
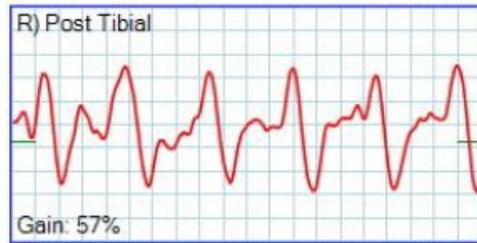
Segmental BP

Segment/Brachial Index

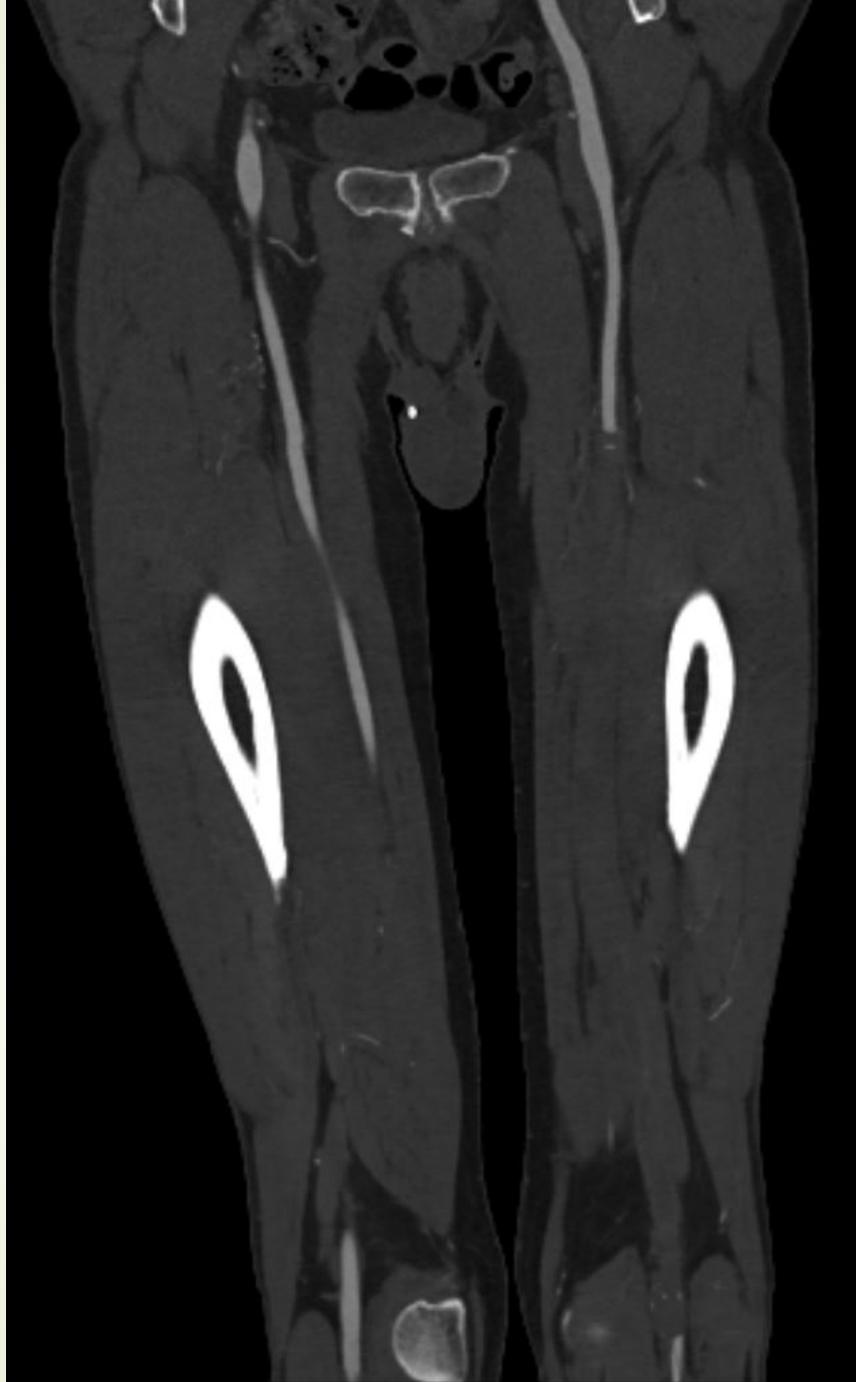
R

L

135 — Brachial — 137



1.09 Ankle/Brachial Index 0.31

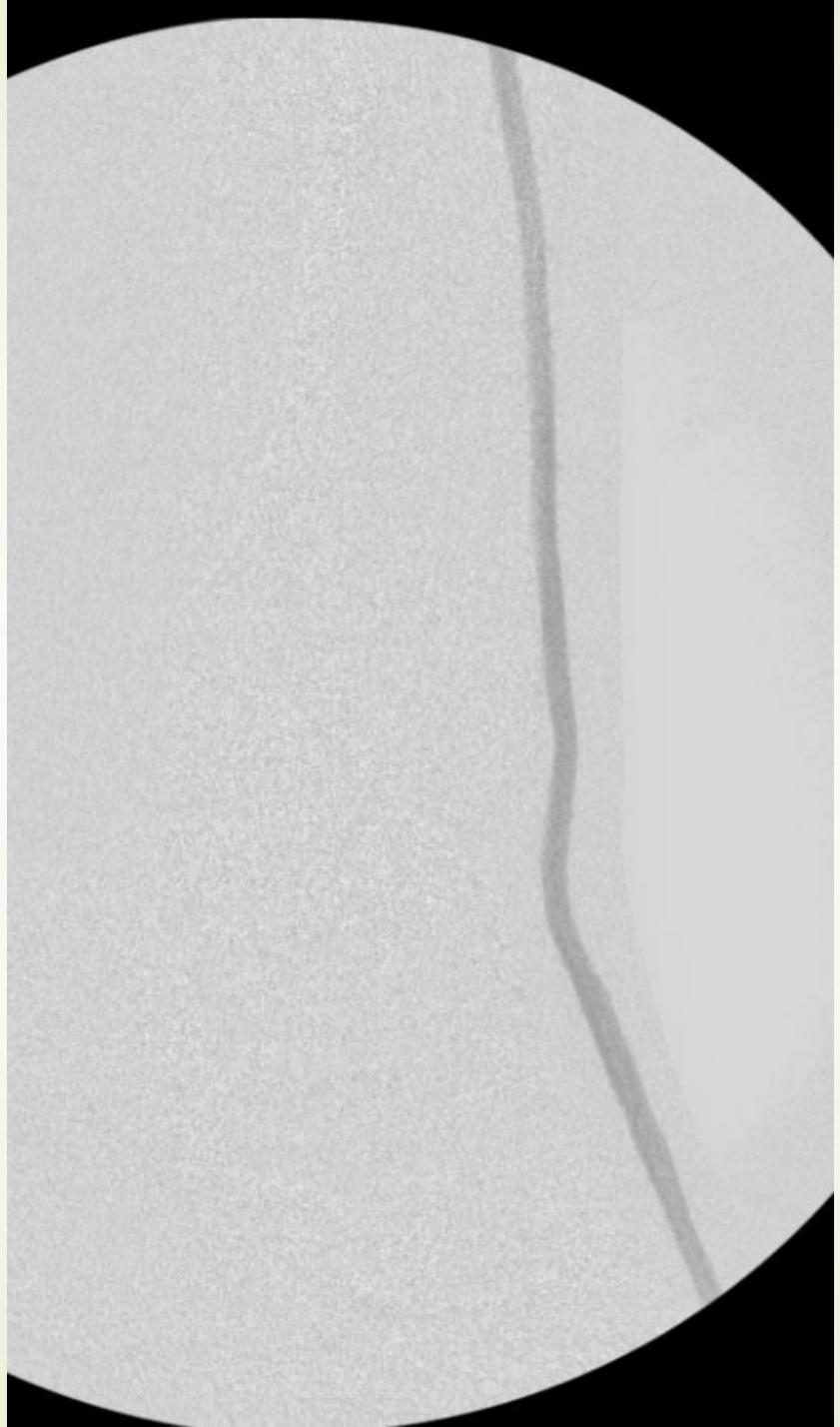












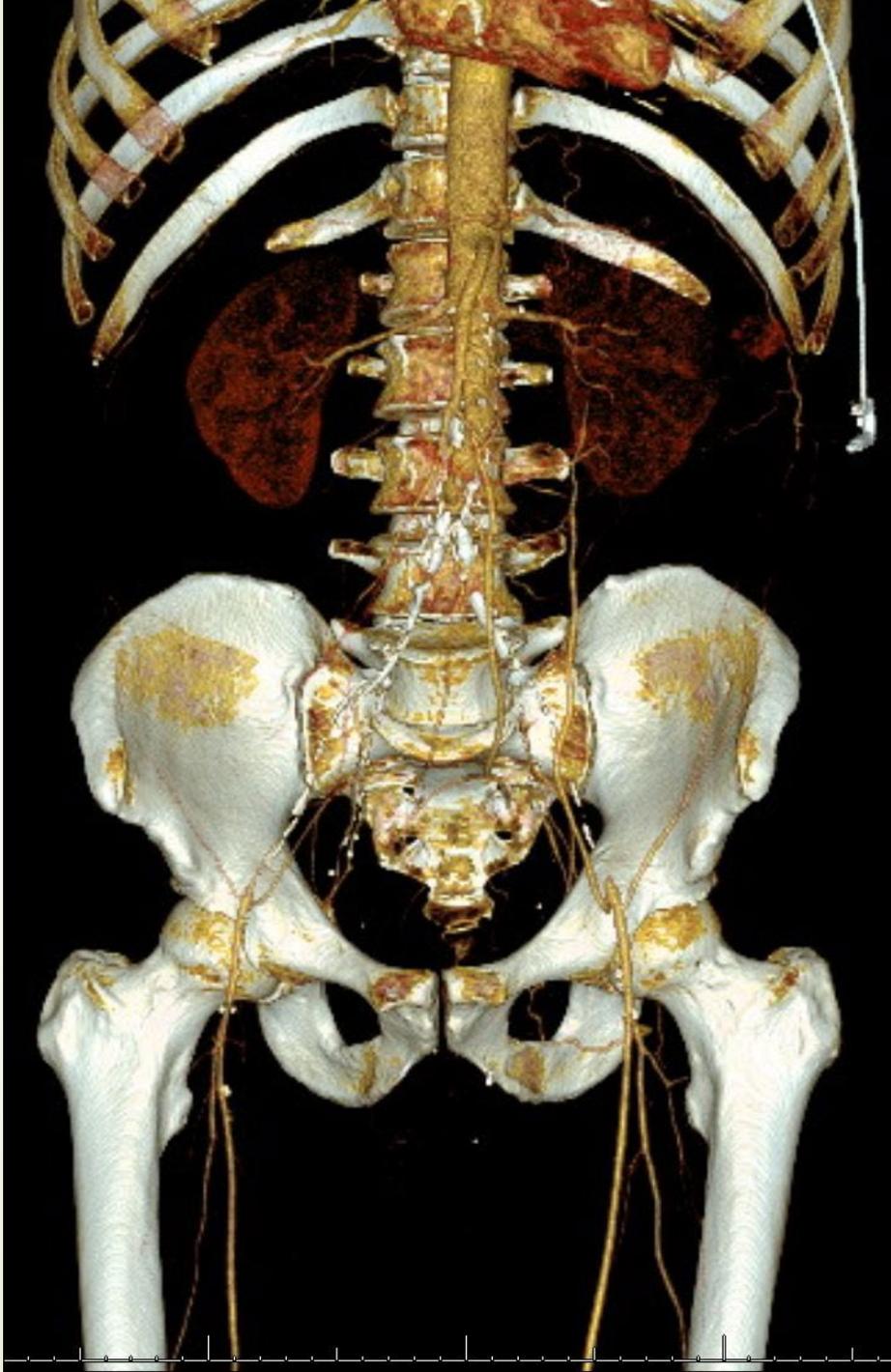


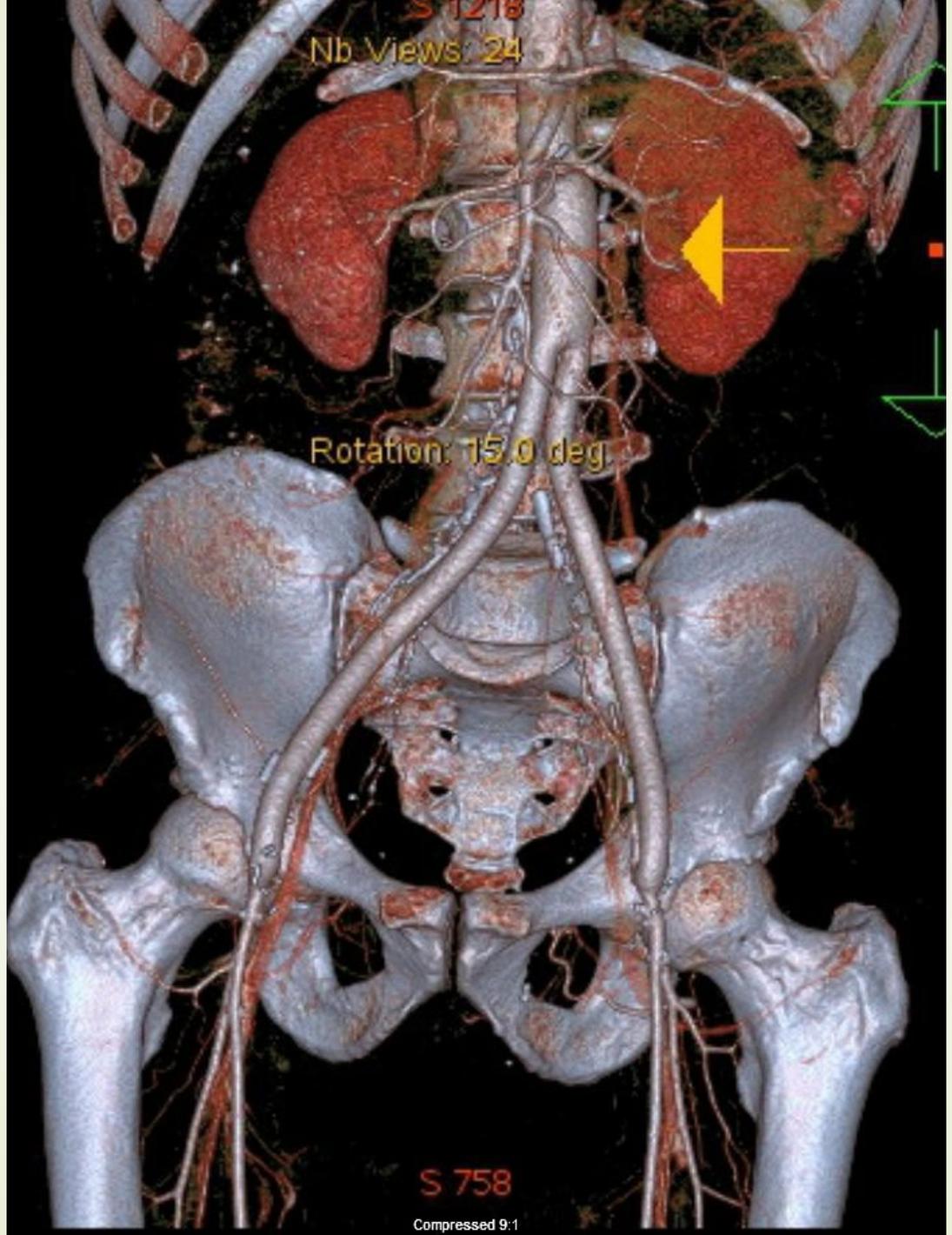


FINDINGS: Adequate Doppler signal to measure pressures and calculate ABIs were not obtainable in either the right or left dorsalis pedis or posterior tibial arteries. Minimal spectral waveforms in the posterior tibial arteries noted with velocities of the right posterior tibial 8 cm/s in the left posterior tibial 14 cm/s. No spectral wave forms of the dorsalis pedis artery could be obtained bilaterally. Findings suggest extensive occlusive disease which could be further evaluated with CT angiography.

Impression

Adequate Doppler signal and waveforms at both ankles were not obtainable. Pressures could not be measured and ABIs could not be calculated. Minimal spectral waveforms noted as described. Findings suggest severe occlusive arterial disease bilaterally with markedly decreased pressures and velocities. Further evaluation with CT angiogram could be performed.







Surgical Treatment of Tissue Loss

Ray Amputation

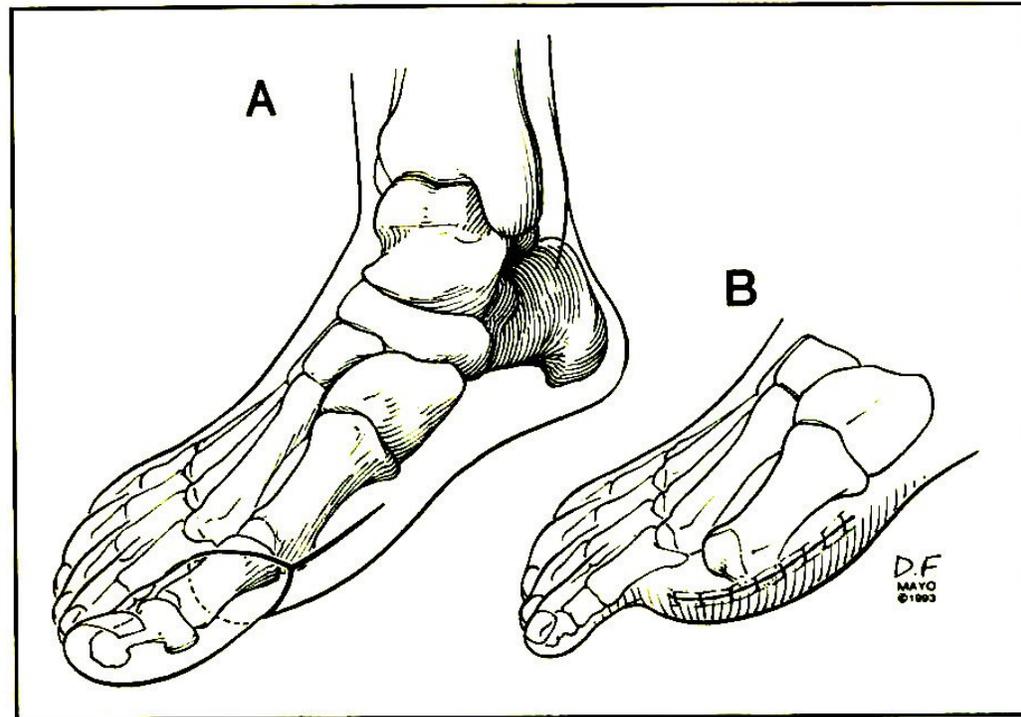
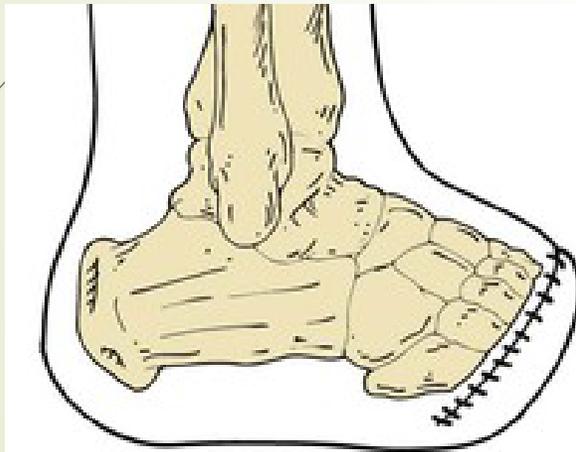
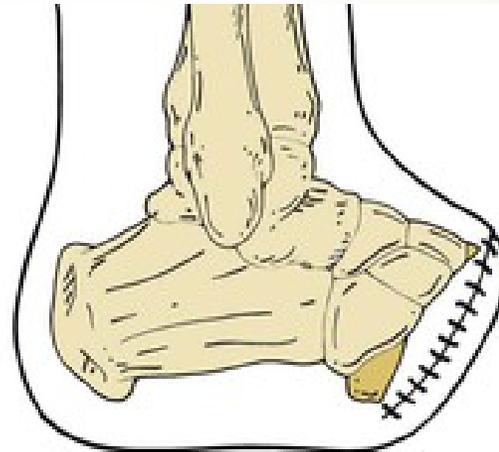


Fig 8: Great toe amputation through a racquet-shaped skin incision (A) with disarticulation (B) at the metatarsophalangeal joint. This incision also may be extended proximally for ray resection. (Copyright ©1997, Mayo Foundation.)

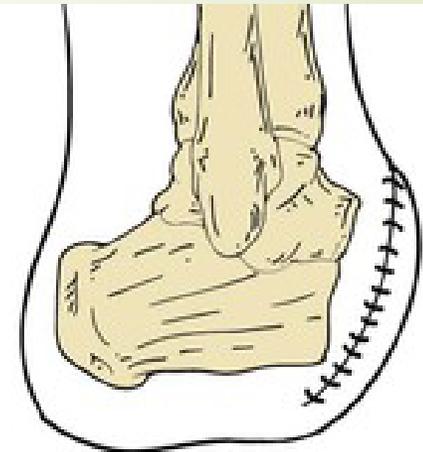
Forefoot Amputation



Transmetatarsal

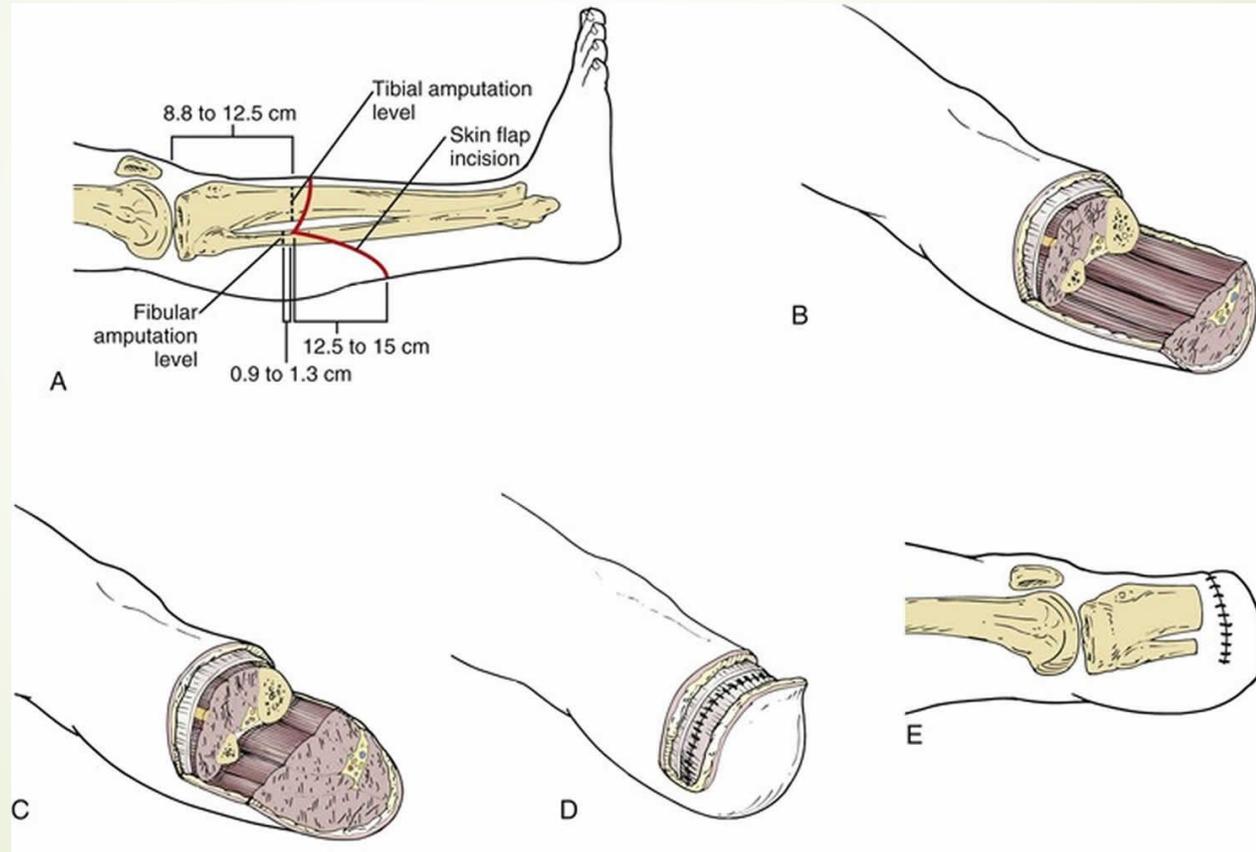


Lisfranc's



Chopart's

Below-Knee Amputation



Above-Knee Amputation



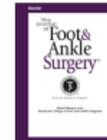
Outcomes after Major Lower Extremity Amputation



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Long-term Mortality After Nontraumatic Major Lower Extremity Amputation: A Systematic Review and Meta-analysis



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ABSTRACT

Chronic wounds that lead to major lower extremity amputation have immense consequences on quality of life, and ultimately, mortality. However, mortality rates after lower extremity amputation for a chronic wound are broad within the literature and have escaped precise definition. This systematic review aims to quantify long-term mortality rates after major lower extremity amputation in the chronic wound population available in the existing literature. Ovid MEDLINE was searched for publications which provided mortality data after major, non-traumatic, primary lower extremity amputations. Lower extremity amputations were defined as below and above the knee amputation. Data from included studies was analyzed to obtain pooled 1-, 2-, 3-, 5- and 10-year mortality rates. Sixty-one studies satisfied inclusion criteria representing 36,037 patients who underwent nontraumatic major lower extremity amputation. Pooled mortality rates were 33.7%, 51.5%, 53%, 64.4%, and 80% at 1-, 2-, 3-, 5- and 10-year follow-up, respectively. Within the 8184 diabetic patients (types 1 and 2), 1- and 5-year mortality was 27.3% and 63.2%. Sources of mortality data were varied and included electronic medical records, national health and insurance registries, and government databases. Mortality after nontraumatic major lower extremity amputation is high, both in patients with diabetes as well as those without. Methods used to measure and report mortality are inconsistent, lack reliability, and may underestimate true mortality rates. These findings illustrate the need for a paradigm shift in wound management and improved outcomes reporting. A focus on amputation prevention and care within a multidisciplinary team is critical for recalcitrant ulcers.

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BASIL Trial Participants. Lancet 2005;366:1925-34.

| | Balloon angioplasty first (n=224) | Bypass surgery first (n=228) |
|------------------------------------------------------------------------------------|-----------------------------------|------------------------------|
| Male sex | 128 (57%) | 141 (62%) |
| Age | | |
| <70 years | 67 (30%) | 80 (35%) |
| 70-79 years | 104 (46%) | 89 (39%) |
| ≥80 years | 53 (24%) | 59 (26%) |
| Right leg used as trial leg | 103 (46%) | 99 (43%) |
| Smoking status | | |
| Never smoked | 48 (21%) | 41 (18%) |
| Current smoker | 72 (32%) | 92 (40%) |
| Ex-smoker (not smoked for more than 1 year) | 104 (46%) | 95 (42%) |
| Diabetes | | |
| Not known to have diabetes | 129 (58%) | 133 (58%) |
| Insulin-dependent | 39 (17%) | 39 (17%) |
| Non-insulin-dependent | 56 (25%) | 56 (25%) |
| Angina | 42 (19%) | 41 (18%) |
| Previous myocardial infarction | 44 (20%) | 35 (15%) |
| Previous stroke or transient ischaemic attack | 40 (18%) | 57 (25%) |
| Previous intervention in trial leg | 40 (18%) | 27 (12%) |
| Previous intervention in other leg | 36 (16%) | 47 (21%) |
| Symptomatic arterial disease in other leg? | | |
| No | 151 (67%) | 145 (64%) |
| Yes: intermittent claudication* | 21 (9%) | 24 (11%) |
| Yes: severe limb ischaemia | 52 (23%) | 59 (26%) |
| Pain at rest or at night only in trial leg | 207 (92%) | 205 (90%) |
| Tissue loss (ulcer or gangrene) in trial leg | 169 (75%) | 167 (73%) |
| Randomisation stratification group | | |
| A: pain at rest and at night only; ankle pressure ≥50 mm Hg | 45 (20%) | 48 (21%) |
| B: pain at rest and at night only; ankle pressure <50 mm Hg | 10 (4%) | 13 (6%) |
| C: tissue loss with or without pain at rest and at night; ankle pressure ≥50 mm Hg | 108 (48%) | 114 (50%) |
| D: tissue loss with or without pain at rest and at night; ankle pressure <50 mm Hg | 61 (27%) | 53 (23%) |
| On a statin† | 77 (34%) | 75 (33%) |
| On drug treatment for hypertension | 141 (63%) | 134 (59%) |
| On antiplatelet drug‡ | 120 (54%) | 141 (62%) |
| Creatinine concentration (μmol/L, mean [SD]) | 113 (62) | 116 (65) |

Data are number (%) unless otherwise stated. *Pain in leg when walking but not at rest or at night, no tissue loss. †For hypercholesterolaemia. ‡In most cases, aspirin 75 mg daily.

Table 1: Baseline characteristics of trial patients