

# PREVENTING AMPUTATIONS IN DIABETES :

## The Role of Primary Care Clinicians

Gregory M. Caputo, MD, FACP  
Robert E. Dye, M.D. Professor of Medicine  
Chief Quality Officer




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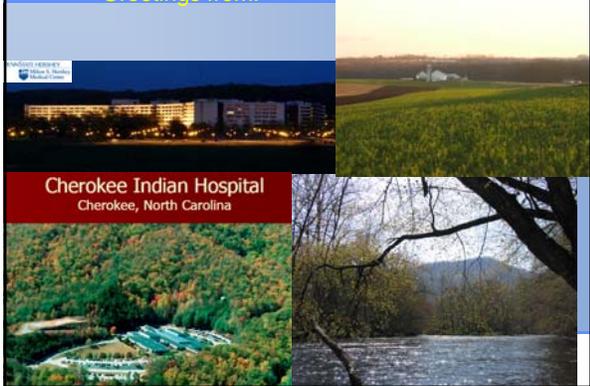
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- Thank you for this privilege.
- Greetings from:



Cherokee Indian Hospital  
Cherokee, North Carolina

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### Special thanks to:

- Jan S. Ulbrecht, MD  
Professor and Medical Director, Diabetes Foot Clinic,  
Mt. Nittany Medical Center and  
Penn State Institute for Diabetes and Obesity
- Peter Cavanagh, Ph.D., D. Sc.,  
Professor and Endowed Chair of Women's Sports  
Medicine and Lifetime Fitness, Univ. Washington  
School of Medicine




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## Definition of an Expert:

Travels a great distance  
Brings a PowerPoint



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- ALL CASE VIGNETTES ARE COMPOSITES, AND CONTAIN NO SPECIFIC INFORMATION ON ACTUAL INDIVIDUALS.

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## Take-home messages

- **Identify high risk patients** with annual foot exam.
  - Structured prevention program if patient at high risk.
- Neuropathic ulcer
  - Management includes effective **pressure relief and debridement**
- Ischemic ulcer
  - **Bedside and non-invasive evaluation**
  - **Specialty consultation**

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## Take-home messages

- Infection
  - Recognize **clues to severe infection**
  - **Milder infection treated as outpatient** with close f/u
  - **More severe infection – admission** with immediate surgical consultation, IV antibiotics
- Acute Charcot foot
  - **Recognize** the clinical presentation.
- Use a **multidisciplinary approach** to treat the **whole person**.



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## The "cost" of diabetic foot complications

Diabetes is the leading cause of non-traumatic lower extremity amputations in U.S.

In 2007, the treatment of DM and its complications in the U.S. generated at least \$116 billion in direct costs.

At least 33% of these costs were linked to the treatment of foot ulcers.



[J Am Podiatr Med Assoc. 2010 Sep-Oct;100\(5\):335-41.](#)

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## Case 1

- 45 year old man with 20 year history of type 2 DM
- Ulcer for 8 months; No pain or drainage
- Doc has prescribed multiple courses of antibiotics, dressings, and told him to "stay off his feet".



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### What do you see? Can this lesion heal?



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### How does Diabetes Cause Foot Ulcers?



A Critical Early Step  
in the Process is  
Loss of Protective Sensation  
(LOPS):

Sensory neuropathy  
severe enough that skin  
injury is no longer painful

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### How does LOPS lead to a foot ulcer?

Sensory Neuropathy  
with elevated plantar  
pressure



Callus



“Pre-ulcer”



Neuropathic ulcer



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### 2011 ADA Foot Care Recommendations:

- For all patients with diabetes, perform an **annual comprehensive foot examination** to identify risk factors predictive of ulcers and amputations
  - Inspection
  - Assessment of foot **pulses**
  - Test for **loss of protective sensation**: 10-g monofilament plus testing any one of
    - Vibration using 128-Hz tuning fork
    - Pinprick sensation
    - Ankle reflexes
    - Vibration perception threshold (B)



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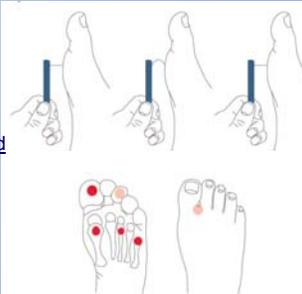
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### 2011 ADA Foot Care Recommendations:

- 10-g monofilament test: place the device perpendicular to the skin, apply pressure until the monofilament buckles
- Hold in place for 1 second and then release
- The monofilament test should be performed at the highlighted sites while the patient's eyes are closed



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**2011 ADA Foot Care Recommendations:**

- Provide general **foot self-care education**
  - All patients with diabetes (B)
- Use **multidisciplinary** approach
  - Individuals with foot ulcers, high-risk feet; especially prior ulcer or amputation (B)
- Refer patients to foot care specialists for ongoing **preventive care, life-long surveillance (C)**
  - Smokers
  - Loss of protective sensation or structural abnormalities
  - History of prior lower-extremity complications

ADA. VI. Prevention, Management of Complications. PENNSYLVANIA STATE UNIVERSITY  
 Diabetes Care 2011;34(suppl 1):S37. Milton S. Ebersole  
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**2011 ADA Foot Care Recommendations:**

- Initial screening for peripheral arterial disease (**PAD**)
  - Include a **history** for claudication, assessment of pedal pulses
  - Consider obtaining an ankle-brachial index (**ABI**); many patients with PAD are asymptomatic (C)
- **Refer** patients with significant claudication or a positive ABI for further vascular assessment
  - Consider exercise, medications, surgical options (C)

ADA. VI. Prevention, Management of Complications. PENNSYLVANIA STATE UNIVERSITY  
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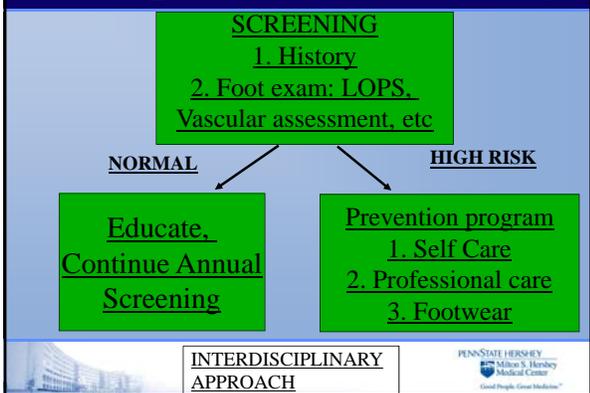
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**Screening and Prevention Summary**



**INTERDISCIPLINARY APPROACH** PENNSYLVANIA STATE UNIVERSITY  
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## Neuropathic ulcer care

- "IT'S NOT WHAT YOU PUT ON A WOUND, IT'S WHAT YOU TAKE OFF"
  - PRESSURE RELIEF
  - DEBRIDEMENT



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## Case 2: Pressure relief: Total contact casting

56 yo man  
Foot ulcer  
for 2 years  
Multiple  
surgeries  
and  
courses of  
antibiotics  
  
Can  
this  
ulcer  
heal?



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## Total Contact Casting

HYPOTHESIS -  
Intimate molding of the cast material to the plantar surface equilibrates loading at all sites thereby decreasing loading at high pressure sites.



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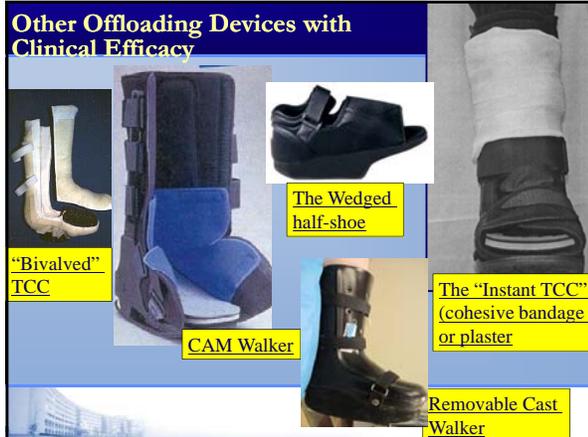
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- Large NIH study is enrolling patients to compare the effectiveness of iTCC, TCC, and Removable Cast Walker.

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**Consider gait stabilizing devices (cane, walker, etc) as appropriate.**

**Clearly document the patient's understanding and acceptance of the benefits, risks of any treatment modality.**

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## Neuropathic ulcer management: Sharp debridement



Limited evidence, although most authorities believe it is an important component of management for neuropathic wounds.



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## Local Care for Neuropathic Ulcers: Dressings

- \*Healing is accelerated in occluded, moist wounds.
- \*No clear evidence for one type of dressing/product.
- \*Antiseptics and detergents may delay healing.
- \*The role of “Advanced Therapies” (human skin equivalents, wound modulators, and growth factors) continues to be evaluated.



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Supplement to April 2010: **OWM**

Ostomy Wound Management, April, 2010

## Consensus Recommendations On Advancing The Standard Of Care For Treating Neuropathic Foot Ulcers In Patients With Diabetes

Robert J. Snyder, DPM, CWS  
Robert S. Kiranet, MD, PhD  
Robert A. Wainner III, MD, FACA, FCCP, FCCWS, ABPM/UHM  
Lawrence A. Lavery, DPM, MPH  
Jason R. Hanft, DPM, FACS  
Peter Sheehan, MD



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## Neuropathic Ulcers: BOTTOM LINES

- Neuropathic foot ulcers require **pressure relief** in order to heal.
- Sharp **debridement** is also recommended.
  - Limited evidence for this, however.
- Ensure a **moist wound environment**.
- Management requires a **multi-disciplinary** approach.



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## Case 3

- 78 yo woman with type 2 DM, CAD, nicotine dependence, HTN, high cholesterol, COPD, osteoporosis, and mild dementia; lives in nursing home
- Recently hospitalized for diverticulitis, then got pneumonia
- Feet as shown



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## What do you see? Can this heal?



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## Critical Ischemia

- At-rest pain, ulcers, or gangrene
- In one or both legs
- Attributable to objectively proven arterial occlusive disease.

Critical Ischemia: Novo, et al Curr Drug Targets Cardiovasc Haematol Disord. 2004 Sep;4(3):219-25.



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## Critical Ischemia (ischemic ulcer)

- Initial wound management:  
Protect the wound.  
Dry Dressing.  
No debridement, casting.
- Specialty consultation.
  - This does not imply that all patients with ischemic ulcers are candidates for surgery.
  - But restoration of arterial flow is usually required for healing.



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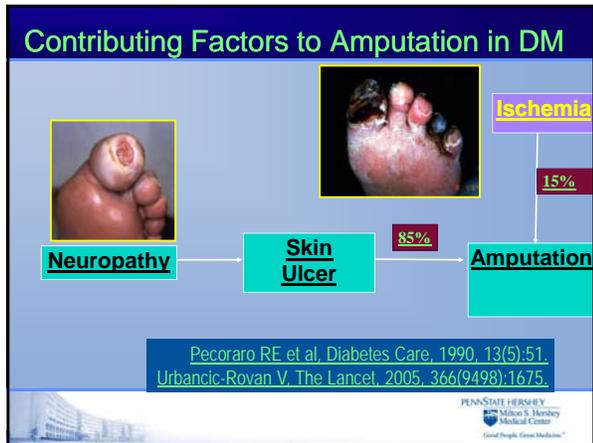
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**INFECTION: Can complicate and accelerate either of these pathways.**

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### Infection

- The diagnosis of infection is typically made at the bedside, not in the microbiology lab

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## Clues to the Severity of a Diabetic Foot Infection

### SEVERE IF:

- Penetration into subcutaneous tissues
- Leukocytosis, fever, chills, hypotension, confusion, volume depletion, poor metabolic control
- Complicating features: foreign body, puncture wound, abscess, venous insufficiency, lymphedema
- Progression on apparently appropriate antibiotics
- Ischemia

NB: SYSTEMIC SIGNS AND SYMPTOMS OF INFECTION ARE OFTEN ABSENT, EVEN IN SEVERE INFECTION

Lipsky, et al. International Consensus on the Management and the Prevention of the Diabetic Foot 2003



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## Empiric Antimicrobial Agents: Mild infection

- Microbiology: Gram positive cocci (S.aureus, streptococci)
- Consider MRSA
- No clear need for cultures (unless prior treatment)
- Consider for empiric treatment:
  - First - generation cephalosporin
  - Alternatives: clindamycin, amoxicillin/clavulanate, or levofloxacin
  - TMP/SMX or doxycycline for MRSA if needed
  - Duration of antibiotics: 7-14 days



AN INTERDISCIPLINARY APPROACH IS NEEDED FOR WOUND MANAGEMENT



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## SEVERE INFECTION



REMEMBER: Systemic symptoms and signs of infection may be ABSENT



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## Empiric Antimicrobial Agents: Severe infection

Microbiology: polymicrobial

Aerobic Gram positive cocci (staphylococci, streptococci), enteric Gram negative bacilli, strict anaerobes

Consider for empiric treatment:

- Beta-lactam / beta-lactamase inhibitor OR
- Clindamycin PLUS Gram - negative agent (eg., fluoroquinolone, 3rd generation cephalosporin, or aztreonam)
- Add vancomycin if MRSA likely – recent antibiotic treatment, hospitalization, etc
- Duration – 2- 4 weeks



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## DIAGNOSIS OF PEDAL OSTEOMYELITIS IN DIABETES

- An ulcer area larger than 2 cm<sup>2</sup>, a positive probe-to-bone test result, an ESR >70 mm/h, and an abnormal plain radiograph result are helpful in diagnosing the presence of lower extremity osteomyelitis in patients with diabetes.
- A negative MRI result makes the diagnosis much less likely when all of these findings are absent.
- No single historical feature or physical examination reliably excludes osteomyelitis.
- The diagnostic utility of a combination of findings is unknown.

Butalia et al JAMA. 2008 299(7):806-13.

Does this patient with diabetes have osteomyelitis of the lower extremity?  
Toronto, Canada.



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- RECOGNIZING THAT BOTH NEUROPATHY AND ISCHEMIA CONTRIBUTE TO MANY FOOT ULCERS IN DM...



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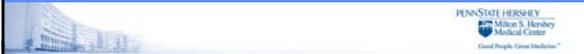
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## Charcot: Bottom Line in Primary Care and Emergency Department

- Must recognize that acute warmth and swelling in the neuropathic foot as the hallmarks of the acute Charcot process.
- Often misdiagnosed as infection or DVT



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## Take-home messages

- **Identify high risk patients** with annual foot exam.
  - Structured prevention program if patient at high risk.
- Neuropathic ulcer
  - Management includes effective **pressure relief and debridement**
- Ischemic ulcer
  - **Initial bedside and non-invasive evaluation**
  - **Specialty consultation**



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## Take-home messages

- Infection
  - Recognize **clues to severe infection**
  - **Milder infection treated as outpatient** with close f/u
  - **More severe infection – admission** with immediate surgical consultation, IV antibiotics
- Acute Charcot foot
  - **Recognize** clinical presentation
- Use a **multidisciplinary approach** to treat the **whole person.**



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## Thank You!



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## MRSA in Diabetic Foot Infection

- Nasal MRSA carriage in diabetic patients is a significant risk factor for foot ulcer MRSA infection.
  - Stanaway S et al Diabetes Res Clin Pract. 2007 Jan;75(1):47-50.
- 30-50% prevalence of MRSA in diabetic foot ulcer S. aureus isolates
  - Diabet Med. 2003 Feb;20(2):159-61.
  - Clin Microbiol Infect. 2006 Feb;12(2):186-9
- "MRSA should be covered in high risk patients"
  - Lipsky BA, Clin Microbiol Infect. 2007 Apr;13(4):351-3.
- Linezolid =Vanco for MRSA in diabetic patients
  - Lipsky et al S Int J Infect Dis. 2011 Feb;15(2):e140-6. Epub 2010 Dec 4.

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## Preventive Care for the High Risk Patient

- Footwear
  - Plantar ulcer risk, i.e. pressure redistribution
  - Non-plantar ulcer risk, i.e. fit
- Self-care (education and motivation)
- Professional Care (>every 60 days)
  - Nail care
  - Callus care (callus acts as a foreign body and increases local plantar pressure ~30%)
  - **Reassessment, (re)education & (re)motivation**

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## Principles of Footwear Prescription for Patients with Sensory Neuropathy

- Added depth in “toebox”
- Soft, supportive, “uppers”
- Maximum depth bi-density insert for all shoes
- Take into consideration patient’s activity
- Consider more advanced modifications for patients with significant foot deformity and moderate-high activity level
- Typical Rx = “Added depth walking shoes with maximum depth PPT/plastizote inserts”
- Custom molding; roller or rocker outsoles, etc



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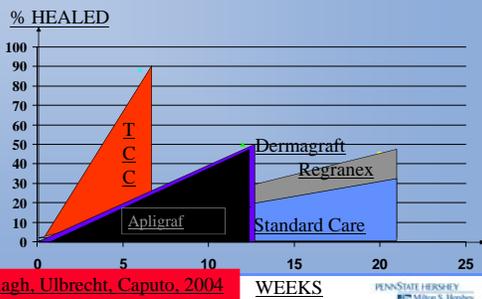
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## Wound care: The relative impact of pressure relief and topical preparations



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## CHARCOT NEURO-OSTEOARTHROPATHY

Dislocation is usually followed by fragmentation



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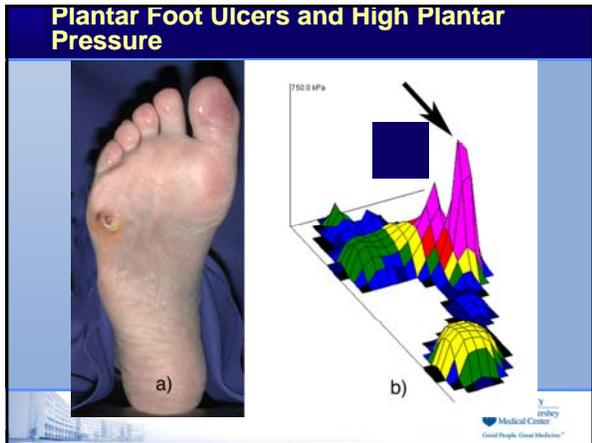
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the nerves (peripheral neuropathy) and/or the blood supply to their legs (peripheral vascular disease). People with ulcers due to diabetes will sometimes need an amputation (surgical removal of part of the limb). Foot ulcers not only lead to physical disability and loss of quality of life, but also to economic burden (health care costs, industrial disability). The aim is therefore to prevent foot ulcers occurring, for example, by showing patients with diabetes how to look after their feet or by prompting doctors to check their patients' feet more often. The results of single prevention strategies alone have so far been disappointing therefore, in clinical

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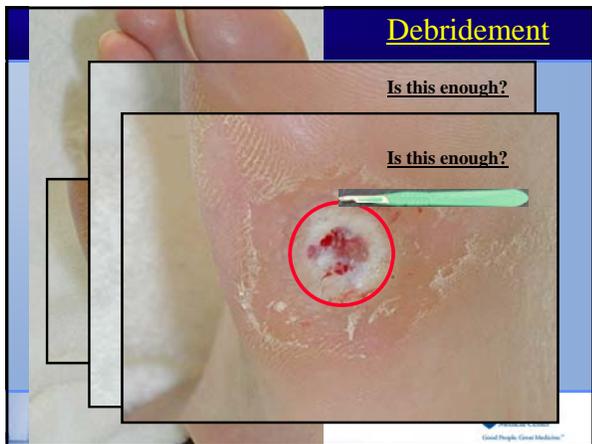
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## Removable Cast Walker Boots vs. Total Contact Cast (TCC)

- 23 pts with neuropathic plantar ulcers randomly assigned to **removable cast walker boots (n=12)** or **TCC (n=12)**.
- Cast walker boots had **greater reductions** in a variety of pressure relief measures than the TCC.
- Healing times similar, but **greater proportion of ulcers healed in TCC** compared to cast walker boots.
- "The less effective ulcer healing in cast walker boots despite superior forefoot off-loading suggests an important role for **patient compliance** in ulcer healing."



Gutekunst, et al Clin Biomech  
(Bristol, Avon). 2011 Apr 13.



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