

# Are DM Shoes Successful in Preventing Ulcers?

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# Ulcer Epidemiology

- About 5-7% of diabetics suffer from foot ulceration
- Annual incidence is 2%
- Lifetime risk of ulceration is 15%
- Ulcer healing is not definitive
  - One study estimated the reulceration rates after healing were 34%, 61% and 70% at 1, 3, and 5 years
  - Recent AHRQ study has even higher rates

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# What About the Shoes?

Effect of Therapeutic Footwear on  
Foot Reulceration in Patients With Diabetes  
A Randomized Controlled Trial

- 2002 study included 400 patients with healed ulcers
- Followed for two years
- 121: therapeutic shoes, customized medium density cork inserts, neoprene closed cell cover
- 119: therapeutic shoes, prefabricated polyurethane inserts, nylon cover
- 160: their own shoes
- Cross over from control to treatment group was expected
- Patients returned to clinic every 17 weeks
- Shoes: extra depth in toe box, width at metatarsal heads, semirockered rigid forefoot
- Cork insert made by scanning plantar aspect of patients' feet
- Prefab 5/8" tapered polyurethane insert

# Shoes Don't Matter?

- There was no difference in the cumulative reulceration rate between the groups: 15, 14, 17%
- In each group only 10-15 died, or had amputation, or a serious medical event
- These patients were relatively healthy
  - in their early 60s
  - >50% had neuropathy
  - none had major foot deformity, 32% with moderate deformity
  - all were ambulatory
  - no prior amputations
- Neuropathy predisposed to reulceration
- Type of ulcer is not clear

# It's Gotta be the Shoes!

- The study was controversial:
  - These are low risk patients:
    - relatively few patients with neuropathy
    - previous ulcers tended not to be neuropathic
  - The definition of new ulcer is too strict
  - The shoes are inappropriate and outdated, and not well described, pressures are not described
  - The shoes **APPEAR TO BE** effective in those with neuropathy
  - The patients were not as compliant as required
- In their response, Reiber et al. mention that pressure is not sensitive for predicting ulcers...

# It's Gotta be the Shoes!

## **Effectiveness of Diabetic Therapeutic Footwear in Preventing Reulceration**

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- A systematic review of 9 articles about diabetic footwear in 2004
  - Reulceration rates ranged from 8 to 60%
  - A benefit was seen in general, but study quality was poor
  - Observational evidence of effectiveness in those with deformity or prior amputation
- Most studies were not RCT, or included the use of a specialized clinic
  - Did the specialized care in general, or shoes specifically, reduce risk of reulceration
- Two further earlier reviews claim that evidence is poor and equivocal for effectiveness of diabetic footwear

# It's Gotta be the Shoes!

## Therapeutic footwear for people with diabetes

Peter R. Cavanagh\*

- Footwear is causative in 21-76% of ulcers/amputations
- Cavanagh laments that the lessons of the pioneers (Baum, Girling, Brand) have not borne fruit...
- “Although there is almost universal clinical opinion and experience that appropriate therapeutic footwear can reduce the incidence of primary and secondary ulceration, the evidence base for such a view is equivocal.”
- The appropriate trial has not yet been designed or carried out

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# Why Does it Matter?

- Why is there this discrepancy between evidence and opinion, and why is this a concern?
- 21-76% of ulcers/amputations are caused by shoe problems
- 85% of amputations preceded by ulcer

**A shift in priority in diabetic foot care and research:  
75% of foot ulcers are preventable.**

Bus SA<sup>1,2</sup>, van Netten JJ<sup>2</sup>.

- “A shift in priority in diabetic foot care and research: 75% of foot ulcers are preventable”
  - Far more money is spent on healing than prevention
  - Far more studies are done on healing than prevention
  - We need directed studies examining the interventions already in place, and we need economic analyses
    - Are shoes a cost-effective SOLUTION?



# What do Shoes Do?

## Offloading effect of therapeutic footwear in patients with diabetic neuropathy at high risk for plantar foot ulceration

M. L. J. Arts, R. Waaijman, M. de Haart, R. Keukenkamp, F. Nollet and S. A. Bus

- In high risk patients with neuropathy and history of ulcer, is offloading effective at reducing pressure?
  - 61% of the time pressures are successfully reduced
  - success rates varied by location of the ulcer/deformity

## Evaluation and Optimization of Therapeutic Footwear for Neuropathic Diabetic Foot Patients Using In-Shoe Plantar Pressure Analysis

SICCO A. BUS, PHD<sup>1,2</sup>

ROB HASPELS<sup>2</sup>

TESSA E. BUSCH-WESTBROEK, MD<sup>1</sup>

- An iterative process of altering shoes to address high pressure points can reduce pressure successfully
  - Diabetic neuropathic patients with history of plantar ulceration, and foot deformity
  - Custom made shoes or inserts were modified up to three times using in shoe plantar pressure sensors
  - All regions of interest had successful pressure reduction

# What do Shoes Do?

## Data-driven directions for effective footwear provision for the high-risk diabetic foot

M. L. J. Arts<sup>1</sup>, M. de Haart<sup>1</sup>, R. Waaijman<sup>1</sup>, R. Dahmen<sup>2</sup>, H. Berendsen<sup>3</sup>, F. Nollet<sup>1</sup> and S. A. Bus<sup>1</sup>

- 85 diabetic patients with neuropathy and healed ulcer were given either custom made shoes or custom insoles for off the shelf shoes
- Shoes were made from cast lasts, and insoles using foot impressions in a foam box
- Outsoles of stiffened rubber
- In shoe pressure measured every 3 months for 15 months
- Adjustments made when pressure was high
- 1152 modifications were made
- Pressure was successfully reduced in many regions of interest, though it rose again between visits
- BUT... 30 reulcerated within 15 months..., 9 of whom were “adherent”

# What does Pressure Reduction Do?

## **The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study**

A. Veves, H.J. Murray, M.J. Young and A.J.M. Boulton

- Previous work showed that ulcers in diabetics appeared at points with high pressure
- But high pressure in the absence of neuropathy was not necessarily associated with ulcer
- In this prospective study, 86 middle aged diabetics with long disease history were followed to see if pressure PREDICTED ulceration
- Roughly two year follow up
- Pressures increased in all diabetic patients, though more in neuropathic patients
- All patients who developed plantar ulcers had high pressure at baseline
- Most patients who developed ulcer were neuropathic

# What does Pressure Reduction Do?

## Screening Techniques to Identify People at High Risk for Diabetic Foot Ulceration

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- 248 patients were followed for up to 40 months to see if plantar pressure could predict ulcers
- While some patients were lost to follow up, 73 eventually ulcerated
- They had diabetes longer, were likely to be neuropathic, and had higher plantar pressure
- But the PPV of high pressure was very low, as were sensitivity and specificity
- Both tested BAREFOOT pressure

# Put it all Together

## Effect of Custom-Made Footwear on Foot Ulcer Recurrence in Diabetes

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- By putting together an iterative process of shoe improvement with a program to ensure compliance, one could improve outcomes
- 171 patients, 85 with iterative shoe improvement, as described earlier
- Patients were followed for 18 months or until ulceration
- 39% reulcerated in the iterative repair group, compared to 44% in the usual care group - not a significant difference
- Among 79 adherent patients, 26% in the iterative repair group reulcerated, whereas 48% in the usual care group reulcerated

# Are DM Shoes Successful in Preventing Ulcers?

- Yes, BUT
  - Not universally
  - Not always
  - Not easily
  - Not in all patients
- Pressure reduction appears necessary, BUT
  - Not sufficient
  - This should be an iterative process
  - Compliance is the key

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