

# Economic Value of the Prevention and Treatment of Diabetic Ulcers

Fall Managed Care Forum

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# Disclosure Statement

- I have served on clinical advisory board for: KCI, Diabetica Solutions, Merck, Pfizer, Lilly, Cytomedica, Greystone Medical, National Healing
- I am on the speaker's bureau for: KCI, Smith & Nephew, Greystone Medical, Merck
- I have received research funding: KCI
- I am on the board of directors: Diabetica Solutions

# Objectives

- Risk factors
- Foot risk classification
- Standard prevention
- Innovations

# What is the opportunity?

- The lower extremity model...
- Common
- Costly
- Recidivism
- Preventable
- Treatable



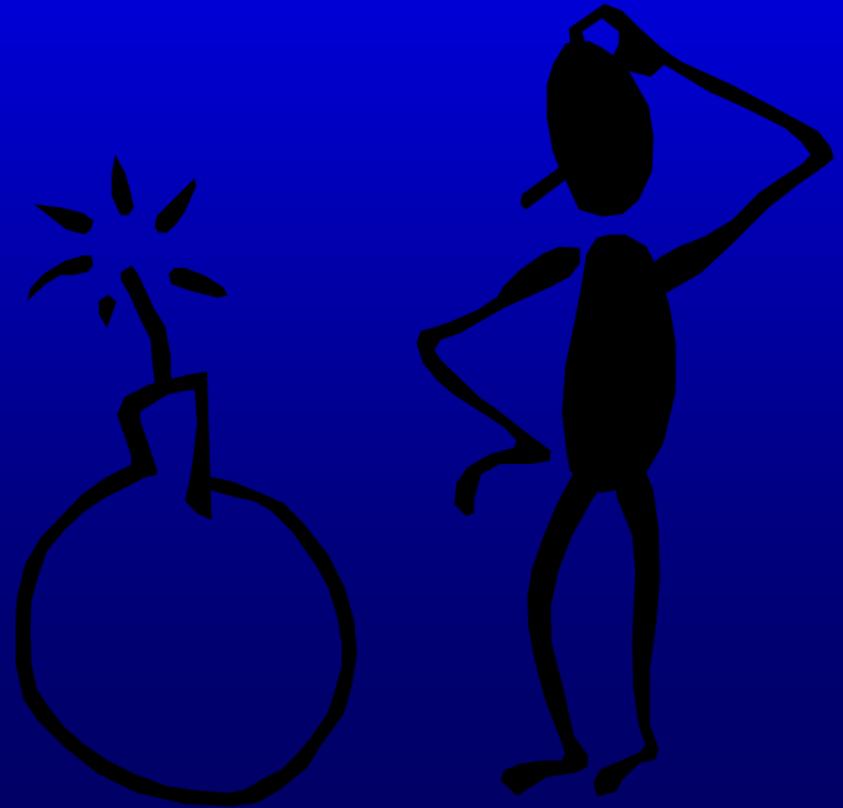
# What are the barriers?

- Not on the radar screen?
- Physicians-Administrators unaware that complications are avoidable...or the tools for prevention
- The target population is wrong
- Neglected, fragmented & incomplete data ...

# Who is the Target Population

**What risk factors can be modified, reduced or eliminated?**

- Clinical pathways
- Risk factors
- Risk stratification



# Risk Factors: Foot Ulcers - Amputations

## Local Risk Factors

History of ulcer-amputation

Sensory Neuropathy

PVD

Abnormal Biomechanics

- limited joint mobility
- structural deformity
- plantar foot pressure

## Global Risk Factors

Male gender

Diabetes > 10 years

Poor vision

Increasing age

Glycemic control >9%

Nephropathy

Retinopathy

0 Normal Risk	No LOPS
1 Low Risk	Diminished circulation Foot deformity Minor infection
2 Moderate Risk	LOPS & additional findings •Diminished circulation •Foot deformity •Minor infection
3 High Risk	Ulcer-amputation history Severe PVD –Charcot ESRD

# Lessons from disease management

- Data from 1666 patients 28 month follow-up
- **Vascular:** ABI & pulses
- **Neuropathy:** 10 gram SWM or VPT >25 volts
- **Deformity:** ROM, structural deformity, foot pressures



# Diabetic Foot Risk Classification

## incidence of complications (yearly incidence)

N=1,666	Ulcer	Amputation	Hospitalization
1.No disease	2.0%	0	0
2.Neuropathy	4.5%	0	1.0%
3.Neuropathy + deformity	3.0%	0.7%	1.8%
4.PVD	13.8%	3.7%	15.9%
5.Ulcer history	31.7%	2.2%	8.2%
6. Amp history	32.2%	21.0%	50%

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# Diabetic Foot Risk Classification Predicts Outcomes

N=1,666		Ulcer	Amputation	Hospitalization
1.No disease	58.6%	2.0%	0	0
2.PN	5.9%	4.5%	0	1.0%
3.PN + deformity	16%	3.0%	0.7%	1.8%
4.PVD	8.7%	13.8%	3.7%	15.9%
5.Ulcer	20%	70%	90%	
6. Amp history	3.5%	32.2%	20.7%	50%

# Diabetic Foot Risk Classification

Risk Group 0	No neuropathy, no PVD
Risk Group 1	Neuropathy ± Deformity
Risk Group 2	PVD
Risk Group 3	History Pathology

Lavery Diabetes Care 2008

Peters & Lavery, Diabetes Care 2001

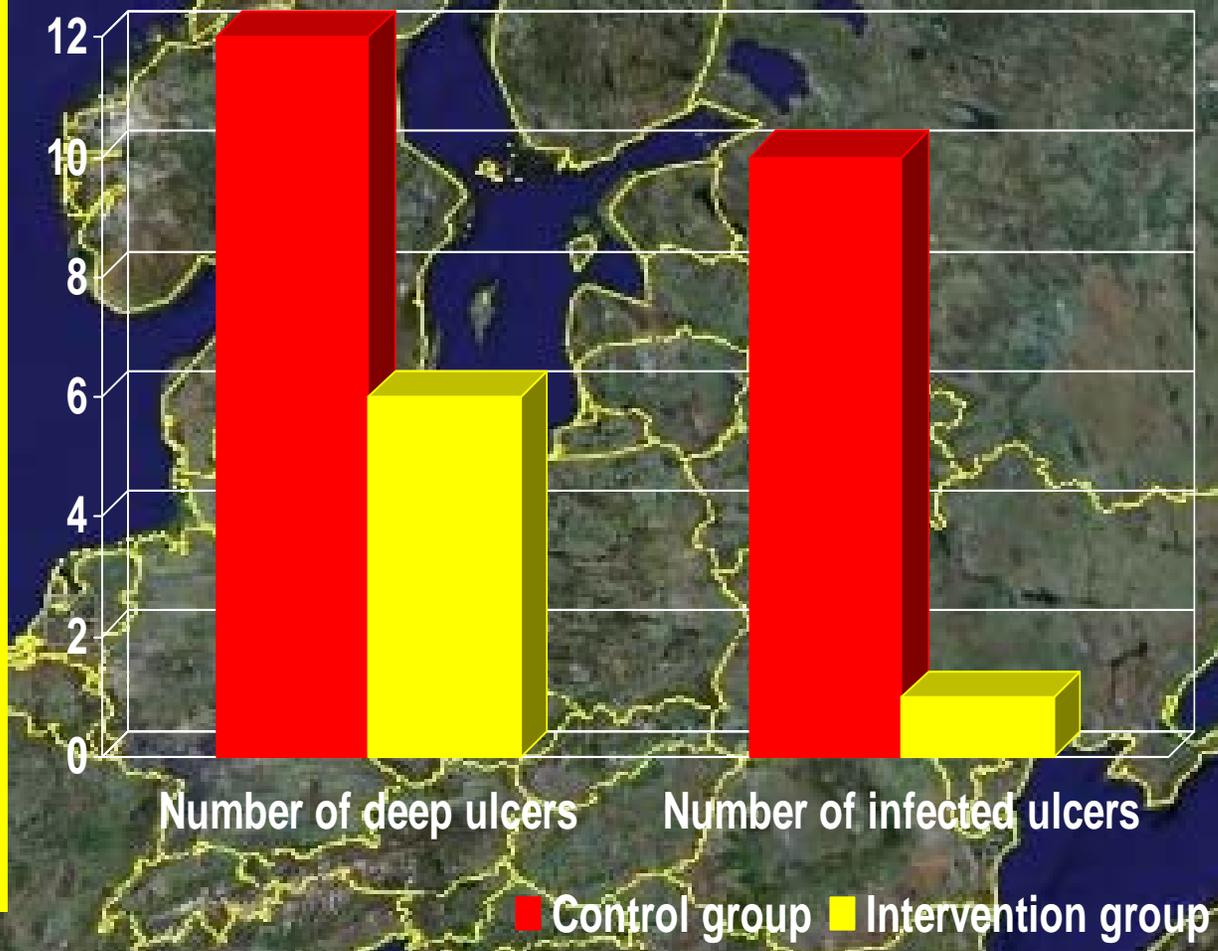
# Prevention

- Regular foot care
- Patient education
- Therapeutic shoes and insoles

Randomized controlled trial  
Study subjects: 498 diabetic patients with neuropathy

- 235 randomized to podiatric care at least twice a year
- 263 to no podiatric treatment

Follow-up time: 3 years



## Podiatric Medical Care: The Netherlands

Van Putten M, Schaper NC. Paper presented at International Consensus on the Diabetic Foot, 2003; Noordwijkerhout, The Netherlands.

# High Risk Foot Programs

Author	Journal	Outcomes
Rith-Najarian	J Fam Prac 1998	48% amputation
Patout	Diabetes Care 2000	49% ulceration 79% amputation 89% admissions
Cherry	Diabetes Tech Therap 2002	32% admissions 34% ER visits 49% out-patient visits
Lavery	Diabetes Research Clin Pract 2005	52% amputation 38% admissions 28% length of stay

# Patients cannot participate in their own foot care?

- Visual impairment
- Limited joint mobility
- Obesity



# Barriers to Self-care...

BMI > 35	30.8 ± 5.7 25%
Impaired vision	48%
Legally blind	15%
Limited Joint Mobility	41%
Combination -Unable to see bottom of their foot	54%

# Therapeutic shoes to prevent re-ulceration

Author	Treatment	% ulcers	Sample size
Edmonds 1986	Custom vs. patient selected	26% vs. 83%	Treat=148 Control=53
Dargis 1999	multispec. vs. comm. std.	30% vs. 58%	Treat=56 Control=89
Uccioli 1995	Custom vs. patient selected	28% vs. 58%	Treat=33 Control=36

# Therapeutic Footwear and Insoles

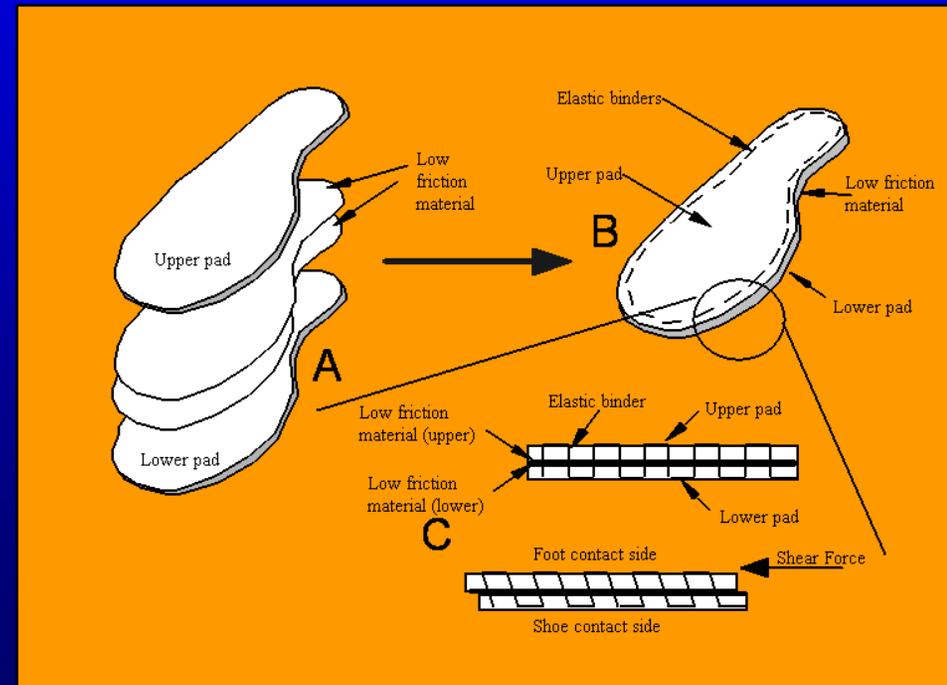
- < 3% of eligible patients receive shoes-insoles
- Not well understood by primary care
- The process is cumbersome
- Patient acceptance???



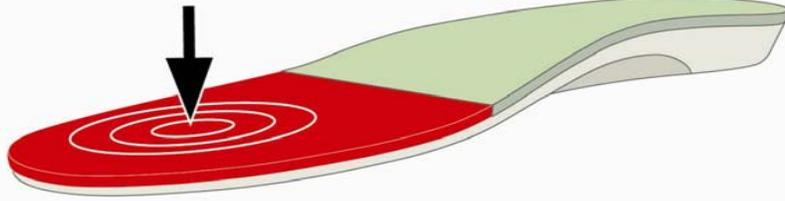
Sugarman, Diabetes Care, 1998  
Rith-Najarian, Reiber, J Fam Practice, 2000

# Innovations

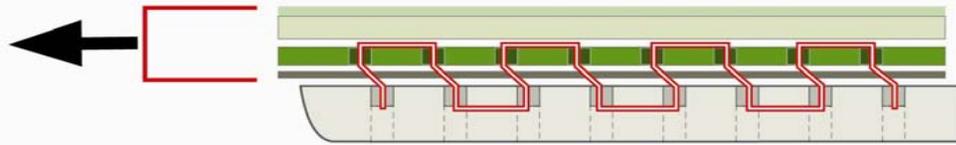
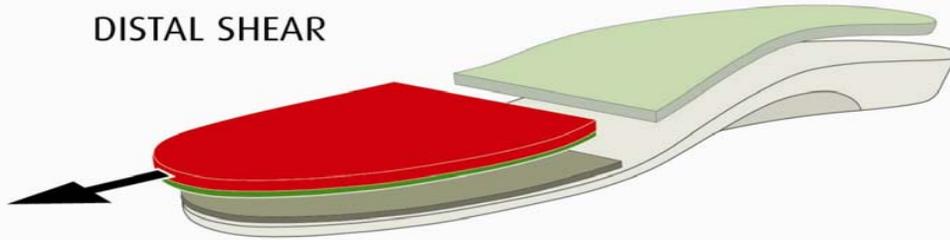
- Fat pad augmentation
- Computer generated shoes and insoles
- Computer activity monitors
- Shear-pressure stockings
- Shear reducing insoles
- Temperature monitoring



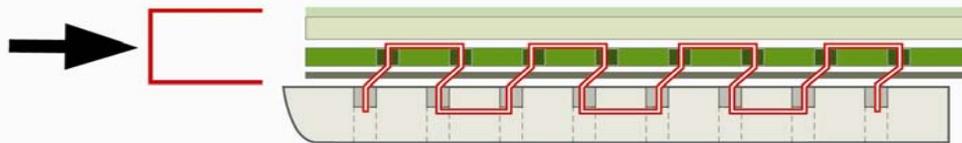
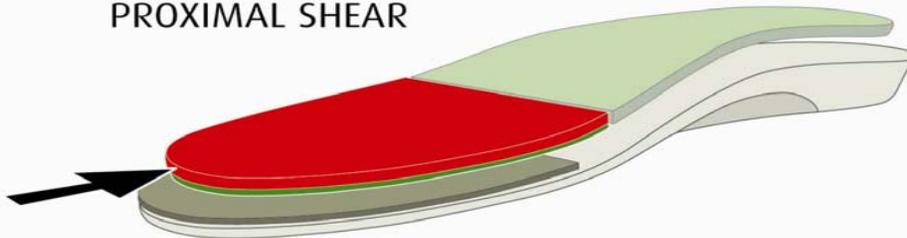
SHEAR REDUCTION ZONE



DISTAL SHEAR



PROXIMAL SHEAR

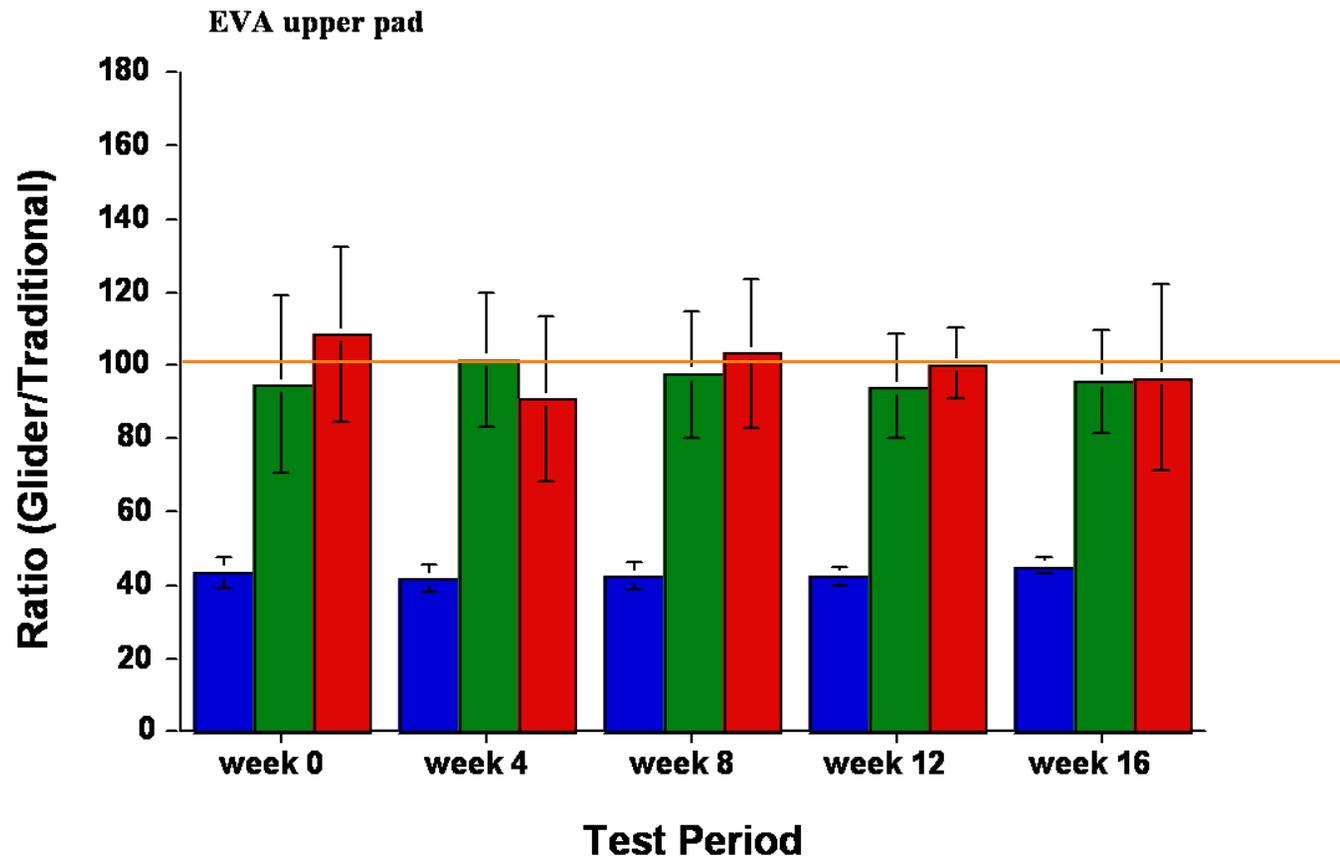


# Shear reducing insole

- 30 healthy volunteers- divided into 3 equal groups
- Bilayered insoles - 3 material combinations tested
- **Top layer either**
  - Poron polyurethane (durometer 20)
  - EVA Ethyl Vinyl Acetate (durometer 45)
  - Plastazote, polyethylene (durometer 30)
- **Bottom layer** always firm density Plastazote (durometer 30)
- Top cover - thin sheet (1.5mm) of soft Plastazote
- Volunteers wore:
  - Left foot: basic bilayer design
  - Right foot: bilayer with shear control

# Results - EVA/Plastazote

■ friction      ■ stiffness      ■ in-shoe pressure



# Shear Reducing Insole Clinical Trial

- NIH Funded Clinical Trial for Shear Reducing Insole (SRI)
- 299 patients risk groups 2 and 3 using the Diabetic Foot Risk Classification System. 18 month study
  - Divided into 2 groups
  - Standard - education and therapeutic shoes and insoles
  - Test - Standard + Shear Reducing insoles



# Shear Reducing Insole Clinical Trial

Risk Category	Standard	Shear Insole
2 Neuropathy and deformity	3/113	0/108
3 History of ulcer or amputation	7/38	3/40

Odds Ratio 3.5 (1.08-12.89) p=0.04

## Home monitoring of skin temperature to prevent ulceration

- Rationale – Provide a self-monitoring tool to reduce the incidence of diabetic foot ulcers among high-risk patients

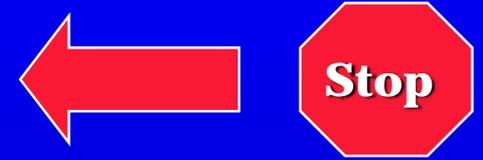


NIH 1 R43 DK54559-01

VA HSR&D Merit Award 20-059

Nerve Damage + Mechanical Stress

Inflammation



Ulceration + Faulty Healing

Infection

Vascular Disease

Amputation



# Pressure Ulcer Staging Criteria

## National Pressure Ulcer Advisory Panel

Stage I	Non-blanchable erythema...an observable pressure related alteration of intact skin...
Stage II	<ul style="list-style-type: none"><li>•skin temperature (warmth or coolness),</li><li>•tissue consistency (firm or boggy feel)</li></ul>
Stage III	<ul style="list-style-type: none"><li>•sensation (pain, itching).</li><li>•area of persistent redness in darker skin tones,</li></ul>
Stage IV	the ulcer may appear with persistent red, blue, or purple hues.

# Home monitoring of skin temperature

	<b>Study Population</b>	<b>Sample Size</b>	<b>Outcomes</b>	
Lavery Diabetes Care 2004	Ulcer history Neuropathy- deformity	N=85 6 mos	Temp Standard OR 10.3	2% 20%
Lavery Diabetes Care 2007	Ulcer history	N=173 15 mos	Temp Standard Structured OR 4.5	8.5% 29.3% 30.4%
Armstrong Am J Med 2007	Ulcer history Neuropathy- deformity	N=225 18 mos	Temp Standard OR 3.0	4.7% 12.2%

# Study Design

Lavery Diabetes Care 2007

- 3 center
- Randomized Clinical Trial
- Single blinded - Physician blinded
- Patient and nurse coordinator unblinded
  - Standard Therapy
  - Structured Examination
  - Temperature Therapy

# Study Groups

- Standard Therapy (N=58)
  - Therapeutic shoes & insoles
  - Foot specific education
  - Foot care  $\leq$  10 weeks
- Structured Examination Therapy (N=56)
  - Therapeutic shoes & insoles
  - Foot specific education
  - Foot care  $\leq$  10 weeks
  - **Mirror to inspect feet**
  - **Log book to record findings of examination**

Lavery Diabetes Care 2007

# Study Groups

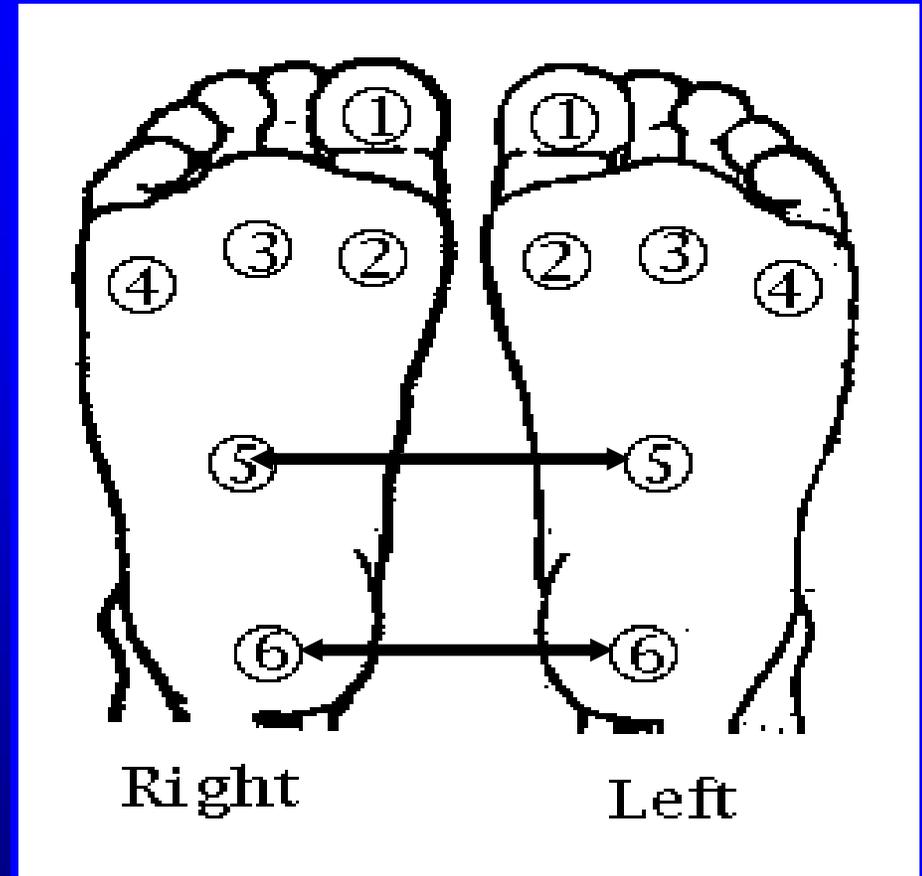
- Temperature Therapy (N=59)
  - Therapeutic shoes & insoles
  - Education
  - Foot care  $\leq$  10 weeks
- temperature monitoring device



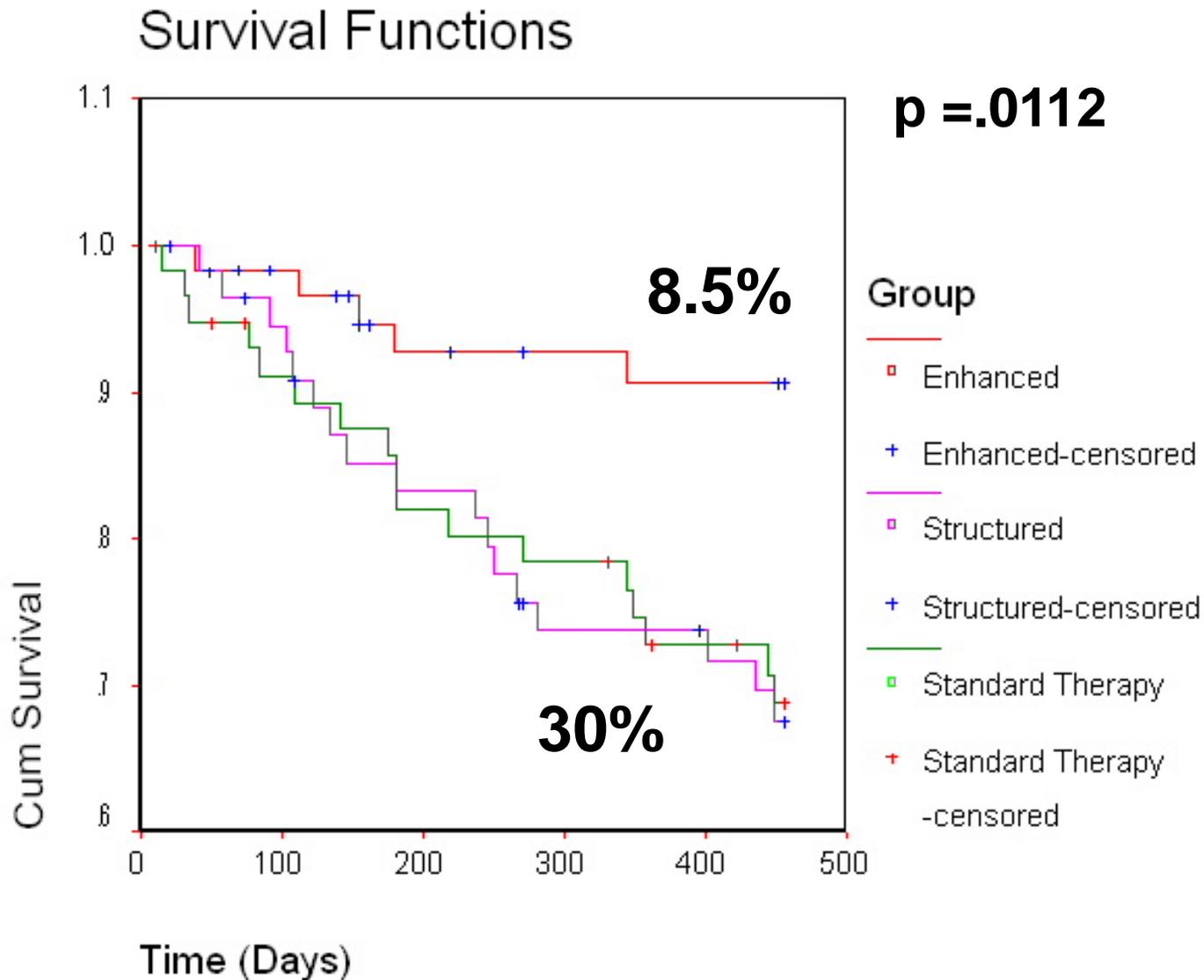
# Methods

## Temperature Therapy

- 6 sites tested
- Performed once a day
- Recorded in log book
- Skin temperatures elevated by  $>4$  degrees F° (2.2 ° C)
  - Contact the study nurse
  - Decrease their activity



# Kaplan-Meier: Survival Analysis Time to Ulceration



# Is visual inspection effective?

- By the time subjects recognized injury = ulcer
- Standard            18 contacts; 17 ulcers
- Structured           17 contacts; 17 ulcers

97%

Lavery Diabetes Care 2007



## Number needed to treat in prevention

Study subjects	Outcome	No trials	NNT
Ace Inhibitors			
Microalbuminuria	Macroalbuminuria 2 years	9 studies n=650 10% v. 24%	30
Overt Proteinuria		n=1400 %	9
Lipid Lowering			
Primary prevention	Death MI-stroke 5 years	7 studies n=29,683 Chol ↓13% v. ↑1%	69
2° - 3° prevention	Death MI-stroke 5 years	9 studies n=18,452 Chol ↓13% v. 0	16

Number Needed to Treat  
for Home Temperature  
Monitoring is 4-7

# Disease Management Model “diabetic foot prevention”

- VA has been the leader in diabetic foot prevention
- overlooked as a disease management opportunity
- Prevention process is low-tech
- Time to realize effect is short
- Organization – Information
- Early impact on clinical outcomes

# Remote Temperature Monitoring



# Effect of Therapeutic Footwear on Foot Reulceration in Patients with Diabetes: A Randomized Controlled Trial

- RCT of 400 DM patients with **history of ulcer**
- Outcome measure: 2-yr incidence of foot re-ulceration
- Interventions
  1. Extra Depth Shoes (3) **custom cork/neoprene insoles**
  2. Extra Depth Shoes (3) **prefabricated P.U. inserts**
  3. Controls: self-selected shoes

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  2. Extra Depth Shoes prefabricated P.U. inserts
  3. Controls: patient selected footwear
- Outcome measure: 2-yr incidence of foot re-ulceration
  - Minor lesions vs. ulcers (present  $\geq$  30 days)

# Effect of Therapeutic Footwear....

## Results:

62 patients had 95 re-ulcerations in 84 episodes

- 482 non-ulcerative lesions by definition

2 yr cumulative incidence of ulcers (16%)

• Cork inserts	Prefab inserts	Self-Selected
15%	14%	17%

## Study Groups seemed to be low risk

### Foot Risk

- Neuropathy 58%
  - Non-palpable pulses 1%
  - Foot deformity 32%
- Patients with severe deformities (I.e. Charcot) excluded

# Diabetic Foot Risk Classification

	Shoes-insoles	others
Risk Group 0	None	Yearly evaluation
Risk Group 1 Neuropathy	Fit correctly OTC insoles	Education
Risk Group 2 PVD	Inlay depth OTC vs. custom	Intensive education, frequent care
Risk Group 3 History Pathology	Shoes +/- modifications Custom insole	+ Temperature

