A Pilot Study Investigating the Utilization of Crest Pads for Treatment of Toe Callus and Ulceration (Presentation)

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A Pilot Study Investigating the Utilization of Crest Pads for Treatment of Toe Callus and Ulceration

Doctor of Nursing Practice Scholarly Project

Monica Melo, DNP, RN, ACNS-BC, CWOCN, CFCN

Objectives

- Discuss impact of developing a research question that has potential to improve patient care through innovation and promotion of change
- Discuss barriers to implementation of practice change and strategies to overcome these barriers
- Describe results of project and implications for the future

BACKGROUND & SIGNIFICANCE

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INTRODUCTION

- Foot care is often neglected
- Lesser toe deformities can result in callus or ulcers on distal digits
- Diabetics and patients with peripheral neuropathy are at elevated risk, and the incidence of diabetes continues to increase
- Most common cause of preventable amputations in the diabetic, neuropathic patient population is painless repetitive trauma, which leads to callus and ulceration (King, 2008)

INTRODUCTION

- Crest pads made of gauze and moleskin can reduce pressure on distal digits
- Anecdotally, use of Crest pads appears to reduce callus and ulceration - no prior research studies have been done to evaluate effectiveness
- A descriptive retrospective review of data using a pre-post intervention study design to evaluate Crest pad effectiveness is this doctoral student's Scholarly Project

KEY TERMS

- Offloading
  - Redistribution of pressure
- Callus
  - Hyperkeratotic lesion composed of dead skin cells, develops in areas of high pressure or friction
- Hemorrhagic callus
  - Hyperkeratotic lesion with evidence of bleeding within or under callus layers
- Ulcer
  - Partial or full-thickness breakdown in skin integrity

LESSER-TOE DEFORMITIES

- Include hammertoes, mallet-toes, and claw-toes affecting the 2nd -5th toes
- Caused by:
  - peripheral neuropathy such as with diabetes mellitus;
  - any inflammatory arthropathies such as gout or arthritis;
  - repetitive trauma such as ill-fitting shoes; or
  - neuromuscular diseases including lumbar disc disease or polio
- Cause areas of high pressure on bony prominences during ambulation or while wearing shoes
- Can lead to callus and ulceration

CREST PADS

- Consist of a piece of rolled gauze covered by adhesive moleskin, with an area cut out for the toes – this will mold to the shape of the patient's toes over several days, providing customized offloading of the distal ends of the digits

CONCEPTUAL MODEL

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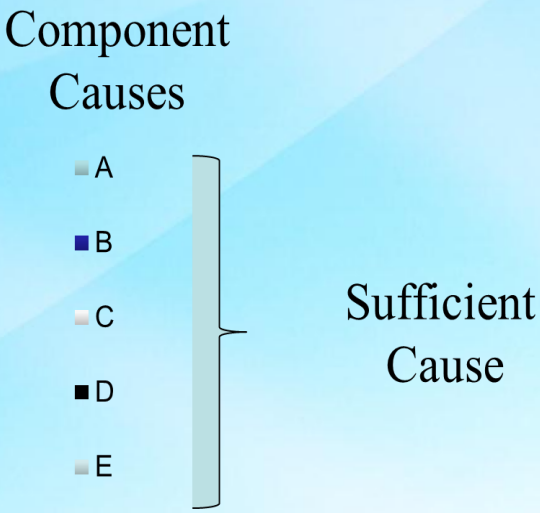
ROTHMAN'S MODEL OF CAUSATION

- *Causes* published in 1976
- Model of disease causation
- Sufficient causes
  - Invariably produce a given effect
- Component causes
  - Multiple components combine to form a sufficient cause
  - Blocking one component cause reduces or prevents the effect

ROTHMAN'S MODEL OF CAUSATION

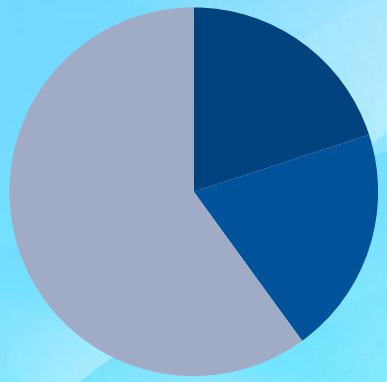
Rothman's Conceptual Model



The component causes taken together represent a sufficient cause, which is capable of producing an illness. Removal of a component cause weakens or eliminates the probability of disease. Adapted from "Conceptual scheme for the causes of a hypothetical disease," by K. J. Rothman, 1976, *American Journal of Epidemiology,104*(6), p. 589. Copyright 1976 by The Johns Hopkins University School of Hygiene and Public Health.

APPLICATION OF ROTHMAN'S MODEL

Ulcer Development



- Pressure
- Deformity
- Neuropathy

Ulcer Prevention

- Pressure
- Deformity
- Neuropathy

LITERATURE REVIEW

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NURSE-LED FOOT CARE

- Etnyre, Zarate-Abbott, Roehrick, & Farmer, 2011
- Discussed role of foot care nursing in reducing amputation rates
- Noted an aging population with multiple co-morbidities and physical limitations
  - 2009 – 39.6 million persons over age 65
  - By 2030 – 72.1 million persons over age 65
- Described risk categorization, bony deformities, management guidelines, and patient education

NURSE-LED FOOT CARE

- Fujiwara et al., 2011
- Uncontrolled before & after intervention study on effects of foot care nursing
- Single nonrandomized trial
- Sample of 88 subjects over two years
- Subjects received follow-up and treatment based on risk categorization
- Showed improvement in tinea pedis ($p = 0.017$), callus grade ($p = 0.001$), and no recurrent chronic ulcerations developed

LESSER-TOE DEFORMITIES

- Shirzad, Kiesau, DeOrio, & Parekh, 2011
- DiPreta, 2014
- Coughlin, 2002; Coughlin & Smith, 2009
- McCartan & Rosenblum, 2014

http://www.hendersonpodiatry.com/podiatrist-shop.html

http://www.footiq.com/foot-facts/skin-and-nail-conditions/corns/

FOOT CARE

- Yumang, Hammond, Filteau, & Purden, 2009
  - Qualitative study, 9 subjects
  - Hemodialysis patient perceptions of foot problems
  - Structured interview technique
  - Major themes:
    - Foot problems are not serious
    - Sense of personal protection from foot problems
    - Self-care of feet

FOOT CARE

- Lavery et al., 2010
- Retrospective chart review 300 subjects (150 on hemodialysis, 150 history foot ulcer or amputation)
- Subjects selected from multispecialty physician group 550+ physicians, 14 clinics, 3 dialysis centers, and a 535 bed hospital
- Findings:
  - 30% received professional foot care
  - 7% had therapeutic footwear
  - 1.3% had formal diabetic education
  - Ulcer incidence similar in each group, but amputation rate higher for dialysis subjects

FOOT CARE

- Peterson & Virden, 2012 – Quality improvement review
- Initial review 2006 – Silver City Health Center
  - 18% of 64 diabetics had foot screening
  - None had a comprehensive foot evaluation
  - No follow-up or referrals provided
- Three step improvement process implemented
  - Documentation tool
  - Provider training in foot & nail care problems
  - Referral sources identified
- Follow-up review 2010
  - 30% of 184 diabetics had a comprehensive foot exam
  - From 2006-2010, 188% increase in diabetic subjects, but 400% reduction in foot-related hospital admissions

OFFLOADING

- Waaijman et al., 2014
- Sample – 171 diabetic, neuropathic subjects with history of prior ulcer within past 18 months and new prescription custom footwear
- Compliance with shoe wear assessed with a monitor
- 71 subjects developed recurrent ulcers, 41 were result of unrecognized repetitive trauma
- "Minor lesions" were strongest determinant of ulcer recurrence – these included callus, hemorrhagic calluses, or blisters ($r = -0.23$, $p < 0.01$)

OFFLOADING

- Owings et al., 2008
- Compared custom insoles tailored to barefoot pressure distribution patterns with traditional custom insoles
- Insoles based on pressure readings reduced peak plantar pressures by 32% ($p < 0.0001$) while not increasing peak pressures in non-regions of interest
- Increasing customization improves results

CLINICAL PRACTICE GUIDELINES

American Diabetes Organization, 2013

- Relevant for diabetes complications including:
  - Neuropathy
  - Nephropathy
  - Retinopathy
  - Cardiovascular disease, and
  - Foot ulcerations
- Heavy focus on medication management

Wound, Ostomy, Continence Nurses Society, 2012

- Focused entirely on neuropathy and ulceration
- Described comprehensive foot examination in detail
- Incorporated more nursing interventions
- Recommended callus debridement and offloading pressure

OBJECTIVE

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OVERALL OBJECTIVE

- To evaluate the efficacy of Crest pads in the treatment of toe callus and ulceration on the distal ends of digits affected by lesser-toe deformities, using a pre-post intervention design with subjects acting as their own controls.

CLINICAL EXEMPLAR

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EXAMPLE

- Initial presentation callus & hemorrhagic callus …

EXAMPLE

- … but with severe ulcer identified post-debridement

TREATMENT

- Crest pad

EXAMPLE

- 1st

  Followup …

EXAMPLE

- After debridement – only tiny ulcer remains.

12 days

PROJECT DESIGN & METHODS

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METHODOLOGY

- Retrospective chart review to gather data
- Subjects seen by doctoral student at vascular surgery practice
- Pre-post intervention design
- Subjects acted as their own controls
- McNemar's test was used for statistical analysis

POPULATION & STUDY SAMPLE

- Setting
  - Six-surgeon vascular surgery practice
- Population & Sample
  - Institutional Review Board approval obtained 10/2014, data collection started 1/2015
  - Subjects who were seen by the doctoral student between 8/1/11 and 12/31/14
  - Subjects with a callus, hemorrhagic callus or ulcer on the distal end of a digit
  - Were treated with a Crest pad during the above time frame
  - Had to have a follow-up visit after initiation of Crest pad
  - All over 18 years of age
  - Subjects with known osteomyelitis were excluded

DATA SOURCES

- Medent - vascular practice's electronic medical record 8/2011 to 2/2015
  - Visit type
  - Appointment listings by date
  - Keyword search "Crest Pad"
- Centricity - electronic medical record for affiliated health network during data collection
  - Hemoglobin A1c levels
  - Ankle-brachial index

DATA COLLECTION & MANAGEMENT

- Initial visit variables
  - Demographics
  - Clinical information
    - Smoking status, body-mass index, hemoglobin A1c, ankle-brachial index
    - Presence of diabetes, neuropathy, arterial disease, end-stage renal disease
    - History of prior amputation
    - Presence of callus, hemorrhagic callus, and ulceration
    - Footwear

DATA COLLECTION & MANAGEMENT

- Follow-up visit data
  - Number of days from treatment initiation
  - Callus, hemorrhagic callus & ulcer characteristics
- Data were assigned values according to a coding plan
- Data were placed onto an Excel Spreadsheet to facilitate statistical analysis
- In order to use McNemar's test, data were assigned to two groups upon completion of data collection
  - Resolved/Improved
  - Unchanged/Worsened

DATA ANALYSIS

- Independent variable – the use of Crest pads over time
- Dependent variables – callus, hemorrhagic callus, and ulceration
- Nominal level data
- Pre-post intervention design, subjects act as their own controls
- McNemar's test is recommended for paired samples and nominal level data (Polit & Beck, 2012; Sylvia, 2014)

DEMOGRAPHICS & INITIAL CLINICAL FINDINGS

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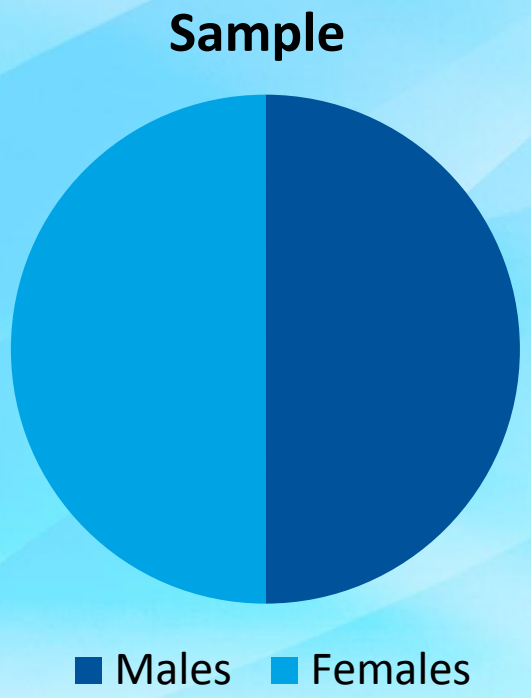
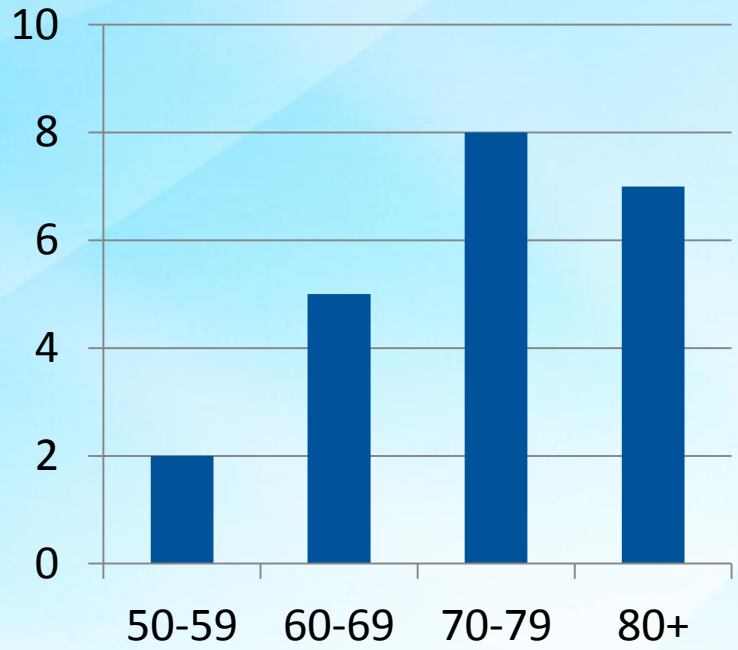
RESULTS - DEMOGRAPHICS



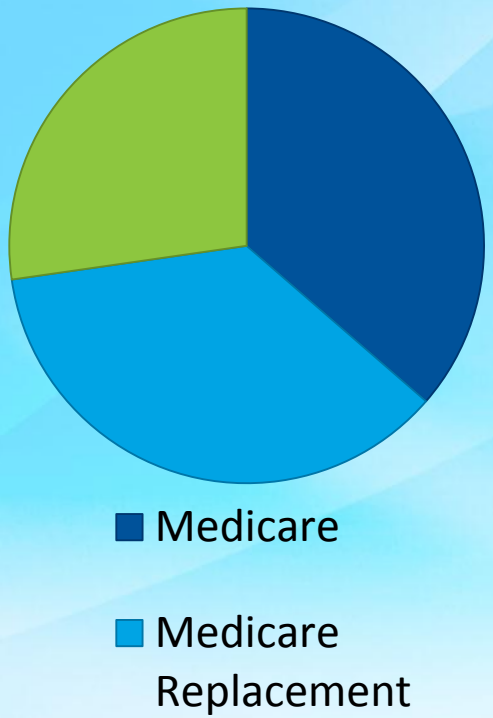
N = 22



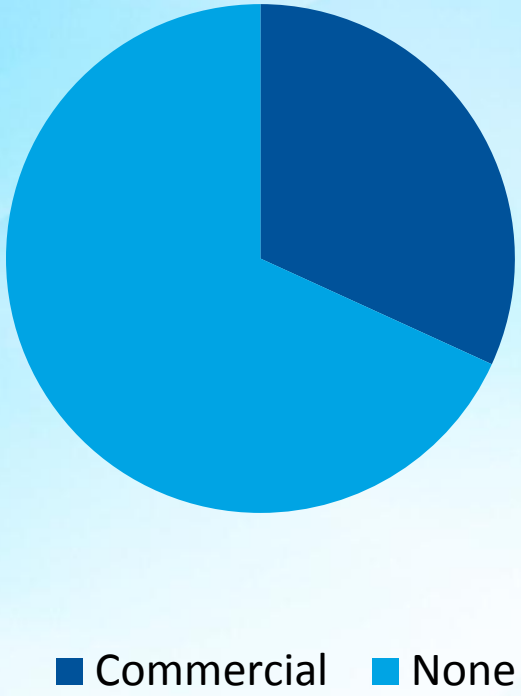
Sample age ranges

RESULTS - INSURANCE

Insurance - Primary

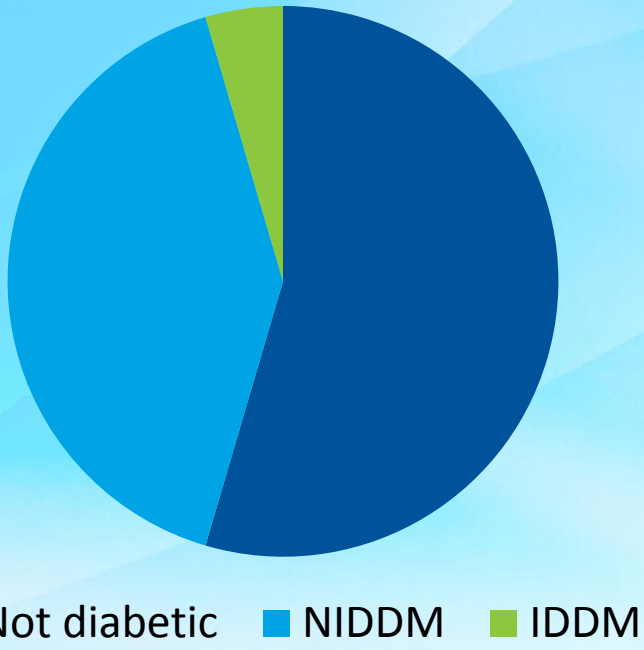


Insurance - Secondary

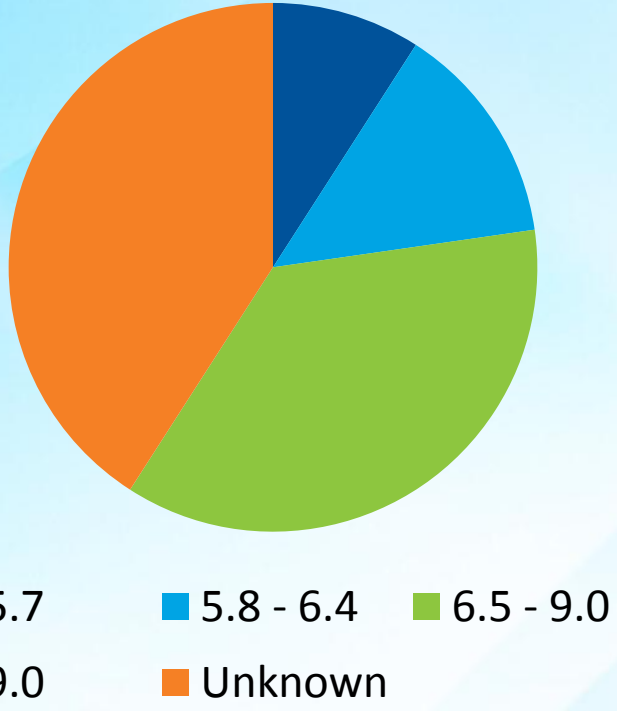


DIABETES

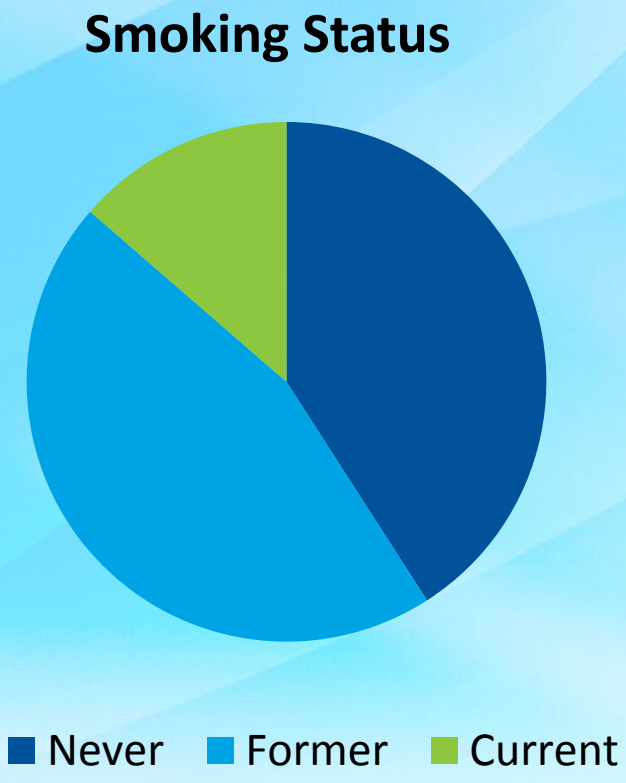
Diabetes in Study Participants

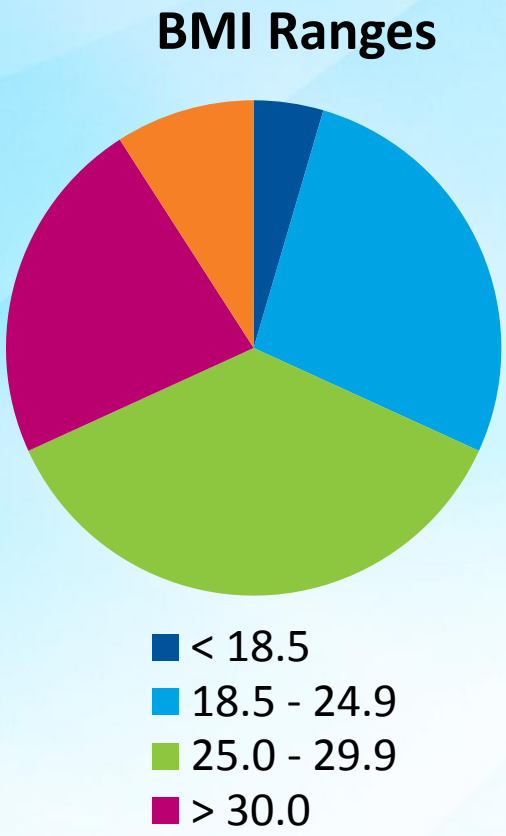


HgbA1c Ranges for Study Diabetics



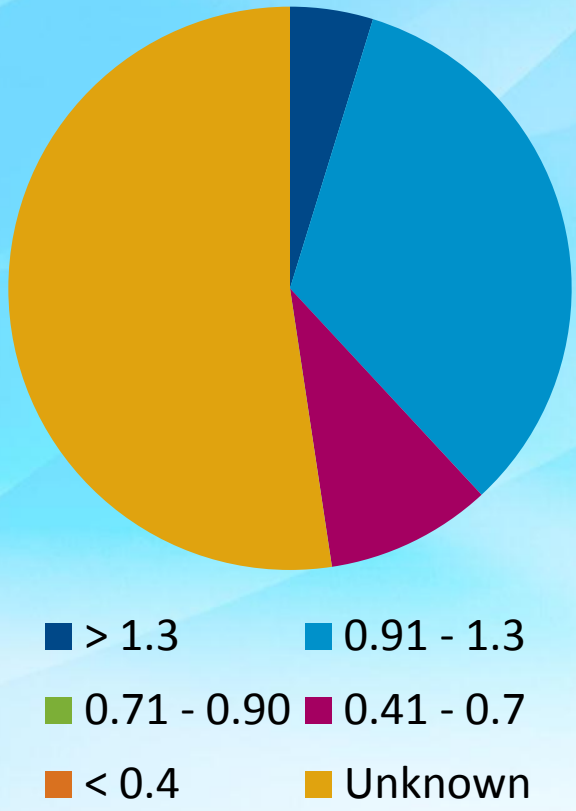
SMOKING STATUS & BMI



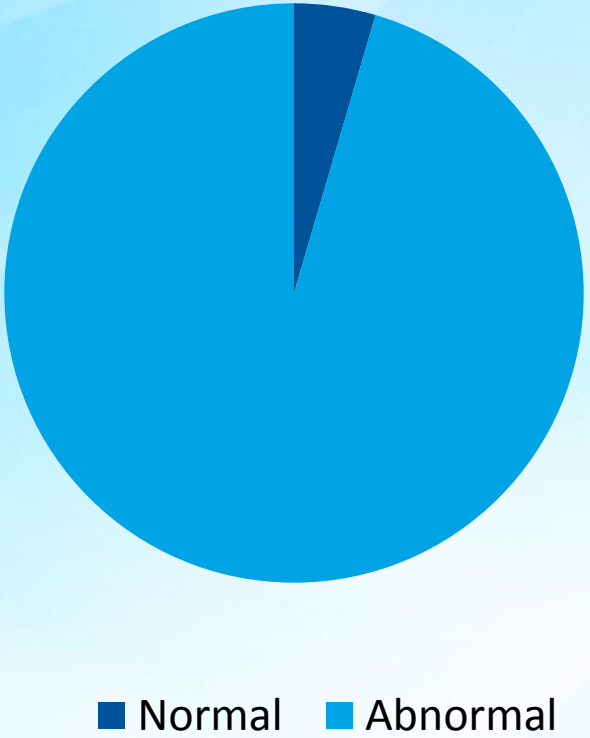


PERIPHERAL ARTERIAL DISEASE

Ankle-Brachial Index

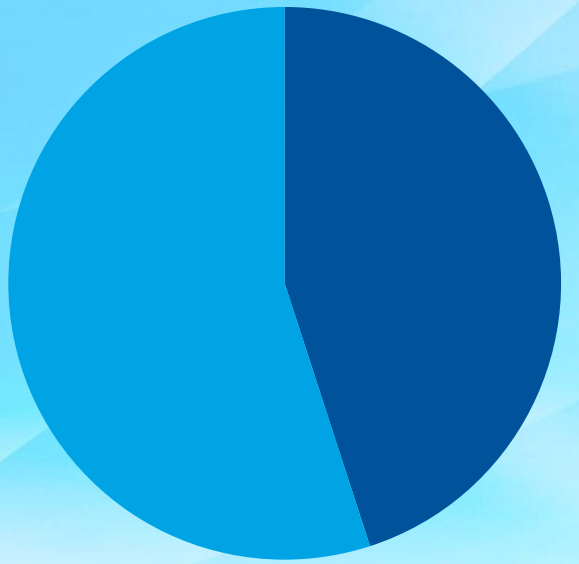


Pedal Pulses

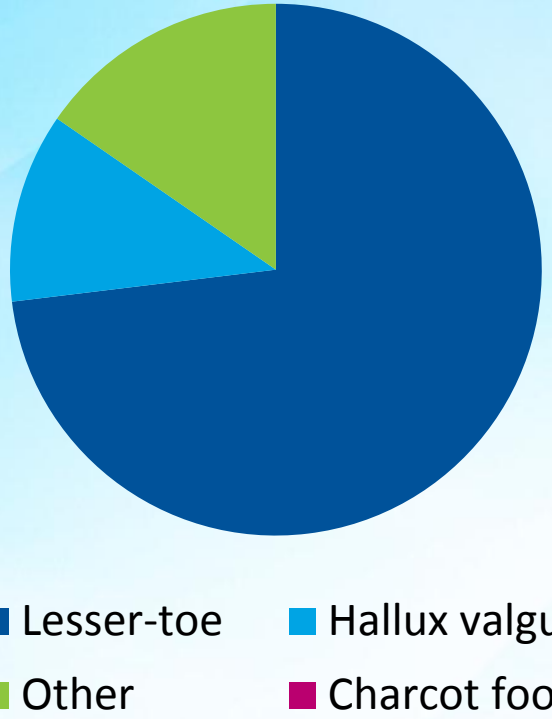


NEUROPATHY & DEFORMITIES

Neuropathy



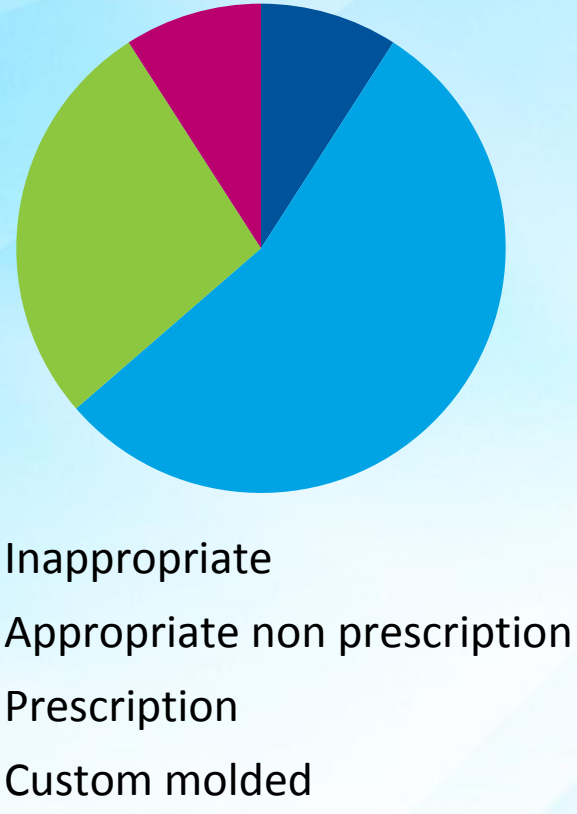
Deformity



AMPUTATION STATUS & FOOTWEAR

Prior Amputation

Footwear



INITIAL CLINICAL FINDINGS

Callus

- Distal digit - 21

Hemorrhagic callus

- Distal digit - 8

Ulcer

- Distal digit - 9

POST-INTERVENTION FINDINGS

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POST-INTERVENTION FINDINGS

Initial Findings	1st Follow-up	2nd Follow-up	3rd Follow-up	4th Follow-up
Callus n = 21	R / I = 20 U / W = 1 P < 0.0001	R / I = 13 U / W = 1 P = 0.0002	R / I = 10 U / W = 0	R / I = 5 U / W = 0
Hemorrhagic Callus n = 8	R / I = 8 U / W = 0	R / I = 5 U / W = 0	R / I = 4 U / W = 0	R / I = 2 U / W = 0
Ulcer n = 9	R / I = 9 U / W = 0	R / I = 7 U / W = 0	R / I = 7 U / W = 7	R / I = 4 U / W = 0
	Mean follow-up days: 45 Range: 9 – 93	Mean follow-up days: 97.4 Range: 19 -240	Mean follow-up days: 111.9 Range: 27-191	Mean follow-up days: 236.1 Range: 183-272

Note: R / I = Resolved / Improved, U / W = Unchanged / Worsened

MCNEMAR'S TEST

Callus Initial & 1st Follow-up

Classification B	Classification A		
	0	1	
0	0	20	20 (95.2%)
1	0	1	1 (4.8%)
	0 (0.0%)	21 (100.0%)	21

McNemar test

Difference	95.24%
95% CI	63.16 to 95.24

Exact probability (binomial distribution)

Significance	P < 0.0001

MCNEMAR'S TEST

Callus Initial & 2nd Follow-up

Classification B	Classification A		
	0	1	
0	0	13	13 (92.9%)
1	0	1	1 (7.1%)
	0 (0.0%)	14 (100.0%)	14

McNemar test

Difference	92.86%
95% CI	46.98 to 92.86

Exact probability (binomial distribution)

Significance	P = 0.0002

RESULTS

- Only two comparisons could be calculated with McNemar's test
- Both demonstrated statistical significance
- All other comparisons demonstrated 100% improved/resolved findings

SIGNIFICANCE & FUTURE RECOMMENDATIONS

Scholarly Project

CLINICAL SIGNIFICANCE

- Clinical Nurse Specialist domains include:
  - Nurses
  - Patients & families
  - System/organization
- The outcomes of this study affect:
  - Nurses – can be instructed in a simple-to-make, evidence-based intervention
  - Patients – improved quality of life, reduced disease burden
  - Organization – decreased number of foot ulcers and hospital admissions

CLINICAL SIGNIFICANCE

- These outcomes are compatible with the Triple Aim of Healthcare:
  - Safe and effective care with quality outcomes
  - Cost containment
    - A typical hospital admission for a non-healing diabetic foot ulcer in 2010 cost $13,258
  - The care experience

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Scholarly Project

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Questions?

Thank you!