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
LESSTER-TOE DEFORMITIES

- Include hammertoes, mallet-toes, and claw-toes affecting the 2\textsuperscript{nd} - 5\textsuperscript{th} 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;
  - 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
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
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
LESSETER-TOE DEFORMITIES

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

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

- Initial presentation callus & hemorrhagic callus ...
... but with severe ulcer identified post-debridement
TREATMENT

- Crest pad
EXAMPLE

- 1st Followup ...
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/Worsenened
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

Sample

- Males
- Females

N = 22

Sample age ranges

50-59 60-69 70-79 80+
RESULTS - INSURANCE

Insurance - Primary

- Medicare
- Medicare Replacement

Insurance - Secondary

- Commercial
- None
DIABETES

Diabetes in Study Participants

- Not diabetic
- NIDDM
- IDDM

HgbA1c Ranges for Study Diabetics

- < 5.7
- 5.8 - 6.4
- 6.5 - 9.0
- > 9.0
- Unknown
SMOKING STATUS & BMI

Smoking Status
- Never
- Former
- Current

BMI Ranges
- < 18.5
- 18.5 - 24.9
- 25.0 - 29.9
- > 30.0
PERIPHERAL ARTERIAL DISEASE

Ankle-Brachial Index

- > 1.3
- 0.91 - 1.3
- 0.71 - 0.90
- 0.41 - 0.7
- < 0.4
- Unknown

Pedal Pulses

- Normal
- Abnormal
NEUROPATHY & DEFORMITIES

Neuropathy

- Present
- Absent

Deformity

- Lesser-toe
- Hallux valgus
- Other
- Charcot foot
AMPUTATION STATUS & FOOTWEAR

Prior Amputation

- Toe
- Below-knee
- N/A

Footwear

- Inappropriate
- Appropriate non prescription
- Prescription
- Custom molded
INITIAL CLINICAL FINDINGS

Callus
- Distal digit - 21

Hemorrhagic callus
- Distal digit - 8

Ulcer
- Distal digit - 9
POST-INTERVENTION FINDINGS

Scholarly Project
# POST-INTERVENTION FINDINGS

<table>
<thead>
<tr>
<th>Initial Findings</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; Follow-up</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; Follow-up</th>
<th>3&lt;sup&gt;rd&lt;/sup&gt; Follow-up</th>
<th>4&lt;sup&gt;th&lt;/sup&gt; Follow-up</th>
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</thead>
<tbody>
<tr>
<td>Callus n = 21</td>
<td>R / I = 20</td>
<td>R / I = 13</td>
<td>R / I = 10</td>
<td>R / I = 5</td>
</tr>
<tr>
<td></td>
<td>U / W = 1</td>
<td>U / W = 1</td>
<td>U / W = 0</td>
<td>U / W = 0</td>
</tr>
<tr>
<td></td>
<td>P &lt; 0.0001</td>
<td>P = 0.0002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhagic Callus n = 8</td>
<td>R / I = 8</td>
<td>R / I = 5</td>
<td>R / I = 4</td>
<td>R / I = 2</td>
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<tr>
<td></td>
<td>U / W = 0</td>
<td>U / W = 0</td>
<td>U / W = 0</td>
<td>U / W = 0</td>
</tr>
<tr>
<td>Ulcer n = 9</td>
<td>R / I = 9</td>
<td>R / I = 7</td>
<td>R / I = 7</td>
<td>R / I = 4</td>
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<td>U / W = 0</td>
<td>U / W = 0</td>
<td>U / W = 7</td>
<td>U / W = 0</td>
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<tr>
<td>Mean follow-up days: 45</td>
<td>Mean follow-up days: 97.4</td>
<td>Mean follow-up days: 111.9</td>
<td>Mean follow-up days: 236.1</td>
<td></td>
</tr>
</tbody>
</table>

Note: R / I = Resolved / Improved, U / W = Unchanged / Worsened
### MCNEMAR’S TEST

Callus Initial & 1st Follow-up

<table>
<thead>
<tr>
<th>Classification B</th>
<th>Classification A</th>
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<th></th>
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<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>20</td>
<td>20 (95.2%)</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td></td>
<td>0 (0.0%)</td>
<td>21 (100.0%)</td>
<td>21</td>
</tr>
</tbody>
</table>

**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 & 2\textsuperscript{nd} Follow-up

<table>
<thead>
<tr>
<th>Classification B</th>
<th>Classification A</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>13 (92.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.0%)</td>
<td>(100.0%)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>14</td>
<td>1 (7.1%)</td>
<td></td>
</tr>
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</table>

### McNemar test

<table>
<thead>
<tr>
<th>Difference</th>
<th>92.86%</th>
</tr>
</thead>
<tbody>
<tr>
<td>95% CI</td>
<td>46.98 to 92.86</td>
</tr>
</tbody>
</table>

### 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
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**
REFERENCES

REFERENCES


REFERENCES

Questions?

Thank you!