



**A Study of the efficacy of
K5 Neuropathy Relief+ in
treating lower extremity skin
problems in patients with
Diabetes and Peripheral
Vascular Disease.**

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JANUARY 2020

OVERVIEW

For patients with diabetes and peripheral vascular disease (PVD), achieving skin health in the lower legs and feet can be very difficult. When skin health is compromised it is more likely that wounds develop, including diabetic ulcers, which can be challenging to heal. Additionally, patients with diabetes and/or PVD often experience decreased circulation to the lower legs and feet. This reduction in blood flow reduces delivery of vital nutrients to the skin tissue.

The common treatment for these patients is application of creams to moisturize the skin. Experience teaches that these products are usually ineffective in achieving positive clinical outcomes.

K5 Neuropathy Relief+ was developed as a topical cream with over 25 nutritional elements provided at significant levels. K5's design is to deliver vital nutrients to the skin topically, bypassing the normal vascular delivery system of the body.

K5 products are OTC Drugs, manufactured under the USFDA OTC Drug Monograph. The K5 Neuropathy Relief+ formula is made in an FDA registered facility.

K5 Neuropathy Relief+ has been in use for several years in Southwest Ohio. We have chronicled patient feedback and noted significant improvements in skin health of the lower legs and feet. This study is a direct result of patient and clinician comments regarding the efficacy of the product.



INTRODUCTION

A six-week study was conducted to test the efficacy of K5 Neuropathy Relief+ in treating various skin conditions of the lower legs and feet of patients diagnosed with diabetes or peripheral vascular disease (PVD). The study was conducted in a controlled environment and the patients were under continuous medical observation and care.

HYPOTHESIS

The hypothesis to be tested in this study was that the K5 Neuropathy Relief+ formula would measurably improve skin health, pain levels, and other medical conditions on the lower legs and feet of the patients selected for the study.

METHODOLOGY

The study was conducted over a six-week period in a licensed and certified Skilled Nursing Facility located in Southwest Ohio. Four patients selected by the facility Director of Nursing participated in the study. The criteria for patients selected included the documented diagnoses of diabetes and/or peripheral vascular disease and significant skin health issues in the lower legs and feet.

Physician's orders were obtained to treat the patient's lower leg and feet with K5 Neuropathy Relief+ two times per day. A treatment record was established and all treatments were administered by the facility staff RNs and LPNs. Each treatment was documented according to facility protocol.

A pre-treatment assessment of the lower legs and feet was conducted by an independent Registered Nurse with Wound Care Certification (WCC) and extensive clinical experience in wound care. The pre-treatment and post-treatment areas of assessment included:

- ✓ Overall skin integrity
- ✓ Skin color
- ✓ Skin turgor/hydration
- ✓ Wounds/ulcers
- ✓ Edema
- ✓ Pain/neuropathy
- ✓ Circulatory/pedal pulses

The services of a professional photographer were secured. Photography was utilized to document the appearance of the lower legs and feet of the patients both pre-treatment and post-treatment and are included in this document.



K5 Neuropathy Relief+ Study Results:

Patient 1: 75 year old male

Diagnoses: Type 2 diabetes & peripheral vascular disease

History: Venous stasis ulcers/skin graft & edema with compression therapy



Pre-treatment Assessment

1. 4+ pitting edema from the knees to the feet
2. Severe discoloration below knees with hemosiderin staining
3. Pain/neuropathy below knees = 8 (Scale 0-10)
4. Pedal pulses (on palpation) faint
5. Serous weeping and draining

Post Treatment Assessment

1. 1+ edema
2. Mild discoloration
3. Pain/neuropathy below knees = 0 (Scale 0-10)
4. Pedal pulses (on palpation) Strong
5. Serous weeping resolved below knees

Note: Photo #1 taken immediately after removal of elastic compression wraps.

Comment: Patient denies pain at week six of the study and refuses further compression therapy.



K5 Neuropathy Relief+ Study Results:

Patient 2: 81 year old female

Diagnoses: Peripheral vascular disease & thrombophlebitis of unspecified deep vessels



Pre-treatment Assessment

1. Severe hyperkeratotic skin with plaques
2. Pain/neuropathy in lower extremities = 5
(Scale of 0-10)
3. Pedal pulses (on palpation) are faint

Post Treatment Assessment

1. Hyperkeratotic skin with plaques resolved
2. Pain/neuropathy = 1
(Scale of 0-10)
3. Pedal pulses (on palpation) improved

K5 Neuropathy Relief+ Study Results:

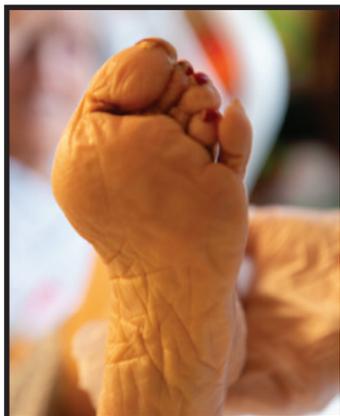
Patient 3: 86 year old female

Diagnoses: Peripheral vascular disease & dementia



Pre-treatment Assessment

1. Skin turgor (hydration) is poor
2. Severe hyperkeratotic skin from knees to toes
3. Trace edema
4. Pedal pulses (on palpation) faint



Post Treatment Assessment

1. Skin turgor normal
2. Hyperkeratotic skin resolved
3. Edema resolved
4. Pedal pulses (on palpation) moderate

K5 Neuropathy Relief+ Study Results:

Patient 4: 90 year old female

Diagnoses: Type 2 diabetes

History: Lower leg diabetic ulcers



Pre-treatment Assessment

1. Diabetic ulcer on left great toe
2. Eschar cap on left great toe
3. Severe hyperkeratotic toe nails
4. Moderate dry skin with plaques
5. Pain/neuropathy below knees = 6 (Scale 0-10)



Post Treatment Assessment

1. Diabetic ulcer resolved
2. Eschar cap resolved
3. Moderate hyperkeratotic toe nails
4. Dry skin and plaques resolved
5. Pain/ neuropathy below knees = 0 (Scale 0-10)

SUMMARY OF RESULTS

The results from the four patients studied are measurable and conclusive. K5 Neuropathy Relief+ was effective in treating the patients as follows:

- ✓ Eliminating severely dry skin with plaques
- ✓ Treating and resolving hyperkeratotic skin
- ✓ Healing a diabetic ulcer with eschar cap
- ✓ Reducing and eliminating pain/neuropathy
- ✓ Improving skin hydration/turgor
- ✓ Reducing and eliminating lower leg edema
- ✓ Improving skin color and reducing hemoasiderin staining
- ✓ Improving pedal pulse strength
- ✓ Eliminating serous weeping and drainage due to severe edema
- ✓ Improving overall skin health in the lower legs and feet

All four patients tolerated the K5 treatments well. There were no patient complaints noted. Clinical staff did not note or report any adverse side effects from the K5 treatments.

DISCUSSION

A review of the treatments available for patients diagnosed with diabetes and peripheral vascular disease reveals very few options that improve skin health in the lower legs and feet. The medical community often offers palliative measures and begins active treatment only when wounds appear. These wounds can be severe, difficult to heal and require extensive and sometimes painful interventions including surgery. The worst cases result in amputations. The options for patients with these conditions are, in fact, limited.

The results of this study are clinically significant for patients with diabetes and PVD. The promising results indicate patients with these diagnoses and lower leg and feet skin conditions should consider active or preventive treatment with **K5 Neuropathy Relief+**.



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