APMA National Poster Presentation: Healing Pedal Fissures: SkinIntegra vs. Urea-40

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Background

Fissures caused by increased tensile stress result in epidermis disruptions, which can lead to infections and complications. The current treatment for fissures is Urea-40, which is costly and can lead to irritation of healthy neighboring tissue. Urea promotes healing in the skin's surface through keratolysis and by

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removing dead cells, and lactic acid (alpha hydroxy acid) helps hydrate the skin, thus smooths and softens scaly skin. This research aimed to answer whether 25% urea and lactic acid (SkinIntegra) was a safer, more effective, and less expensive alternative to Urea-40.

Purpose: This research hypothesized that the Skinlntegra patient group would demonstrate improved healing in pedal fissures as compared to urea 40%.

Methods

Subjects with pedal fissures were invited to participate in an IRB-approved study at Western University College of Podiatric Medicine via approved advertising. This prospective, randomized, double-blinded study dispensed Urea-40 or Skinlntegra at random to subjects. 48 adult patients completed



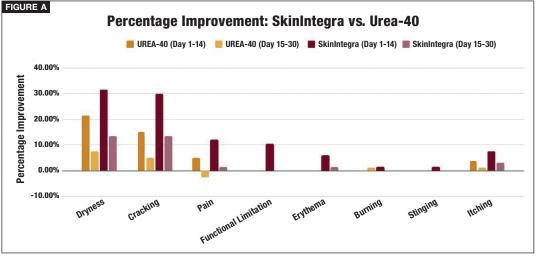
the study: 22 patients were assigned to the SkinIntegra group and 26 patients to the Urea-40 group. Patients were sorted into two groups based on the random tube received and instructed to apply their assigned cream twice daily. A small subset of patients (7/48) received both creams, one to try on each affected foot. Patients underwent three examinations with photos: initially at the start of the study, at 2 weeks, and finally at 4 weeks. Data analysis was based on objective evaluations performed by the DPM and subjective patient survey results. Efficacy parameters, including

dryness, cracking, pain and functional limitation, were investigated along with tolerability parameters including erythema, burning, stinging and itching.

Results

The Skinlntegra group demonstrated a significantly faster rate of healing compared to the Urea-40 group (Figure A). At both the 2-week and 4-week mark, all 8 efficacy and tolerability parameters

showed improvement in the Skinlntegra group with the most notable changes in dryness, cracking, pain and erythema over the first 2 weeks. In comparison the Urea-40 demonstrated less improvement with changes only in 5/8 parameters. The Urea-40 also demonstrated irritation with extended application. The cumulative percentage of improvement over the course of the study demonstrates a greater overall percentage of improvement within the



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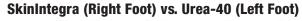
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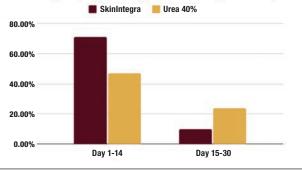
Podiatric Medicine

SkinIntegra (continued)

Skinlntegra group, which is noted across all parameters. The greatest improvement was seen in dryness, cracking, and pain symptoms. Of the total of 48 patients, 7 were included in both study groups, applying 1 assigned cream to each foot. Faster improvement was seen with Skinlntegra compared to Urea-40 (Figure B).

d) FIGURE B





Conclusions

The study findings support that SkinIntegra may offer a more efficacious, tolerable, and cost-effective alternative to Urea-40 for managing pedal fissures. Despite some inherent limitations including a relatively small sample size and limited 4-week study duration, the evidence presented demonstrates some advantages of SkinIntegra over the current standard of

care, Urea-40. While acknowledging these limitations, incorporating prospective, randomized and double-blinded methodologies provides a solid foundation for the observed outcomes. The notable improvements in healing rates, symptoms alleviation, and tolerability parameters observed in the SkinIntegra group, as objectively evaluated by a podiatrist and supported by patient reported feedback, offers compelling evidence in favor of it.

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For more information, visit https://skinintegra.com or click here.

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