EFFICACY AND CONSUMER PERCEPTION OF A 96% NATURAL CREAM CONTAINING LIME PEARL EXTRACT AND WILLOW BARK EXTRACT WHEN USED BY SUBJECTS WITH CLINICALLY DETERMINED KERATOSIS PILARIS

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INTRODUCTION

Keratosis pilaris (KP) is characterized by small keratotic papules and varying degrees of perifollicular erythema.[1] This common condition can affect all skin surfaces where hair grows but it is most commonly found on the face, buttocks, eyebrows, and extensor surfaces of the arms and thighs.[2,3] The complaints associated with KP are generally limited to cosmetic appearance or mild pruritus[3] and management strategies typically include the avoidance of skin dryness, emollient usage, and the addition of keratolytic agents or corticosteroids when necessary.[3,4] A 96% natural steroid-free KP cream was formulated with a unique blend of lime pearl extract, willow bark extract, bisabolol, shea butter, and natural oils to gently exfoliate, soothe, and moisturize the skin. Lime pearl extract is naturally rich in alpha-hydroxy acids (AHAs) and offers a new mechanism to gently promote skin exfoliation via transient receptor potential cation channel, subfamily V, member 3 (TRPV3), a keratinocyte transmembrane channel. Willow bark is a natural source of salicylic acid, which has been shown to reduce KP lesions[5]. Bisabolol and shea butter constitute a significant source of anti-inflammatory compounds, offering the ability to soothe irritation and redness.[6-8] Finally, natural emollient oils round out the formula to help soften and smooth the skin. This clinical trial was conducted to assess the efficacy and subject perception of this natural KP formulation.

STUDY DESIGN

Subjects

Volunteer subjects were recruited from a pool of healthy males and females aged 18 to 60 years. Subjects with mild to moderate KP that was exhibited equally on either the arms or thighs were included. Subjects presenting with severe erythema were excluded.

Design

This was a two-week single-center, randomized, subject as own control, paired design trial in Fairfield, New Jersey. The test material was randomly assigned to one side of the body and the alternate side remained untreated; the investigators were blinded to the randomization schedule. The study consisted of a visit at baseline and another visit after two weeks.

Treatment

Subjects applied a pearl/dime sized amount of the natural KP cream (Skinfix Renewing Cream) to one assigned treatment site twice daily for two weeks in the morning and evening. The alternate site remained untreated.
Key KP cream ingredients include lime pearl extract, willow bark extract, shea butter, bisabolol, coconut oil, jojoba oil, and sweet almond oil.

Assessments

At each visit, subjects had the test sites independently evaluated by two board certified dermatologists. Visual evaluations were conducted for overall lesions (goose-bumpy skin), elevation of lesions from surface, scaliness, erythema, and skin roughness at each designated site according to a 4-point scale. A subject questionnaire was completed at week 2.

RESULTS

Subjects

Thirty-two subjects aged 19 to 56 years were recruited and 30 subjects completed the trial. One subject did not qualify at baseline due to a lack of severity on the elevation scale and one subject did not complete the trial due to personal reasons unrelated to test material use. The mean age was 34.7 years and the majority of subjects were female (90%).

Clinical grading

Results of the clinical grading of symptom parameters indicated that the KP cream produced statistically significant improvements from baseline in overall lesions ($p<0.001$), scaliness ($p=0.027$), and skin roughness ($p=0.006$). No significant improvements were seen in elevation of lesions from the surface or erythema. The untreated side experienced a significant decrease in overall lesions from baseline ($p=0.011$) but no improvements were seen in the other dermatological parameters (Figure 1). The KP cream produced significantly better improvements from baseline compared to no treatment in overall lesions ($p=0.004$), scaliness ($p=0.003$), and skin roughness ($p=0.012$). No significant differences were seen between the treated and untreated sites in elevation of lesions or erythema (Figure 2).

Figure 1. Average % change in clinical grading from baseline within treatment groups

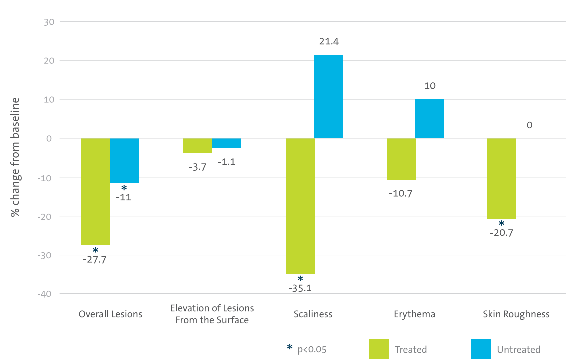
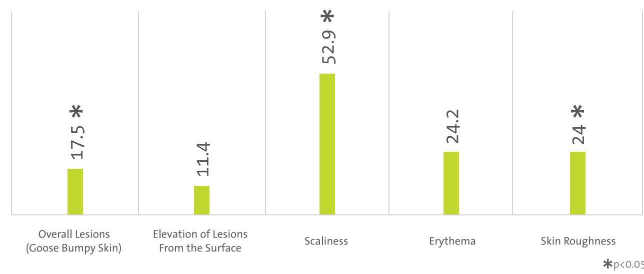


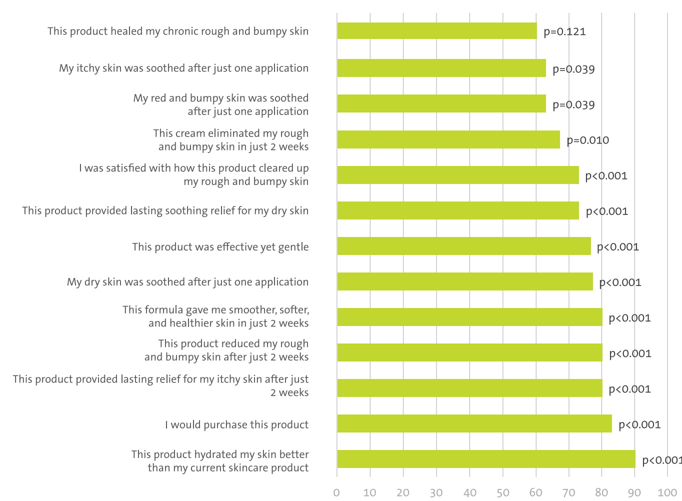
Figure 2. Average % change in clinical grading from baseline between treatment groups



Consumer Perception

Results of the consumer perception questionnaire indicated that subjects were satisfied with the KP cream after 2 weeks of use (Figure 3).

Figure 3. Percentage of subjects who agreed with statements in the consumer perception questionnaire



CONCLUSION

KP can be a notoriously difficult condition to treat. In this single-center, split-body trial, twice daily application of the natural KP cream exhibited a statistically significant decrease in overall lesions (goose-bumpy skin), scaliness, and skin roughness after 2 weeks of use. When comparing the differences from baseline, sites treated with the KP cream exhibited a statistically significantly greater decrease in overall lesions (goose-bumpy skin), scaliness, and skin roughness versus the untreated control sites.

The natural KP cream was perceived positively, which is an important factor influencing compliance and subsequent success of managing this chronic condition.

Therefore, these results demonstrate that this natural KP cream can offer an effective solution for the management of this challenging condition.

References

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Disclosures

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