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A Novel Device for Skin Type-based Treatment while Cleansing

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INTRODUCTION

The human skin acts as a barrier to protect the inside from the outside environment. A healthy skin desquamates continuously while still forming a tight barrier. A damaged skin barrier allows irritants to enter the skin causing problems. To maintain the healthy skin, surface deposits and desquamated skin cells are removed through proper hygiene and treatment. Facial skin cleansing can be divided into different types or different skin types. For example, a cleanser could be foaming or non-foaming for formulation types, as well as different levels or kinds of surfactants can be used to remove deposits and improve the after-feel of the products based on the skin types [1]. Additionally, facial cleansing could use different media, such as handwashing, use of washcloths, or use of automated devices.

There are several ways to divide skin types, including the most well-known Fitzpatrick skin type based on skin color and how skin responds to ultraviolet light. Another skin classification is based on dryness/oiliness. Skin sensitivity to cosmetic products or to the environment also play a role in the skin type classification. We modified the dryness/oiliness skin classification to five skin types to better support our consumers: Normal to combo, Dry, Oily, Sensitive, and Acne-prone. These skin types play a critical role in cosmetic ingredient selection as well as the selection of the base formula for treatment cleanser development. In addition, skin comfort after exfoliant usages guided the treatment cleansing surface (TCS) development, resulting in three surfaces called Interlinks, Split Alpha, and Mushroom, with each varying in gentleness on the skin. Overall, we developed 5 treatment cleansers based on the skin types and 3 TCSs based on gentleness on the skin. These worked together with a novel device technology utilizing counter-oscillating mechanical motion to gently stimulate desquamation and exfoliation while cleansing. The five combinations were used in a clinical study to evaluate the effectiveness, skin benefits, and tolerability of the device.

METHODS

One hundred healthy female subjects between 35-65 years of age and Fitzpatrick skin type I-IV with different skin types were recruited for an IRB-approved clinical study of a skin treatment cleansing regimen consisting of a novel treatment cleaning device and an associated topical product. Self-perceived skin types of subjects were confirmed by the dermatologist investigator. 20 subjects were recruited in each group.

On the day of the first visit, the subjects reported to the facility with their face area devoid of topical treatments. After consenting and acclimation to the ambient environment for 30 minutes, the dermatologist investigator examined subjects and baseline noninvasive measurements were taken. Each subject was given a treatment cleansing device with a TCS and a treatment cleanser for the specified skin type. They were provided with written and verbal instructions on the proper execution of the treatment cleansing regimen. All subjects were required to follow the test regimen and were monitored by clinical staff during execution to assure compliance with the instructions. Following the regimen use, subjects were assessed for tolerability and efficacy by the dermatologist investigator as well as subject self-assessment. Subjects returned to the facility at weeks 1, 2, 4, 8, and 12 for tolerability and efficacy assessments.

The device was designed to record the usage of each subject. Even though 96 out of 100 subjects completed this study, several subjects were not compliant with the usage instruction, which required 2 minutes, twice-a-day usage. At the end, 81 subjects were compliant and the statistical analysis was done on those compliant subjects only. There were 15-18 compliant subjects in each group, who completed the study. No adverse events occurred during the study.

RESULTS AND DISCUSSION

In order to evaluate the efficacy and tolerability of this novel treatment cleansing device, groups of subjects were selected based on their skin type, which was confirmed by the dermatologist investigator. Five skin types with associated treatment cleansing surfaces (TCS) are listed on the Table 1. TCSs were designed to vary in their gentleness/firmness to give different degrees of exfoliation and feel. Mushroom is the gentlest, Interlinks is the intermediate, and Split Alpha is the least gentle among the three. The images of three TCS options are shown in Figure 1. These TCSs and the treatment cleansers are developed together for specific skin types to maximize skin cleansing and gentle exfoliation. One critically important complication in the topical development was slip and grip, which impacted the design of TCSs as well. The outer ring and the inner ring of TCS are counter-oscillating to grip the skin for gentle cleansing and treatment. If it grips too much, then the subject would not be able to tolerate the regimen. If it slips without gripping the skin, then there wouldn't be enough skin treatment cleansing. We were able to develop the topical and TCS combination that optimally work together while being gentle.

Treatment Cleanser Type (Skin Type)	Treatment Cleansing Surface (TCS)
Normal to Combo	Interlinks
Dry	Interlinks
Oily	Split Alpha
Sensitive	Mushroom
Acne-prone	Mushroom

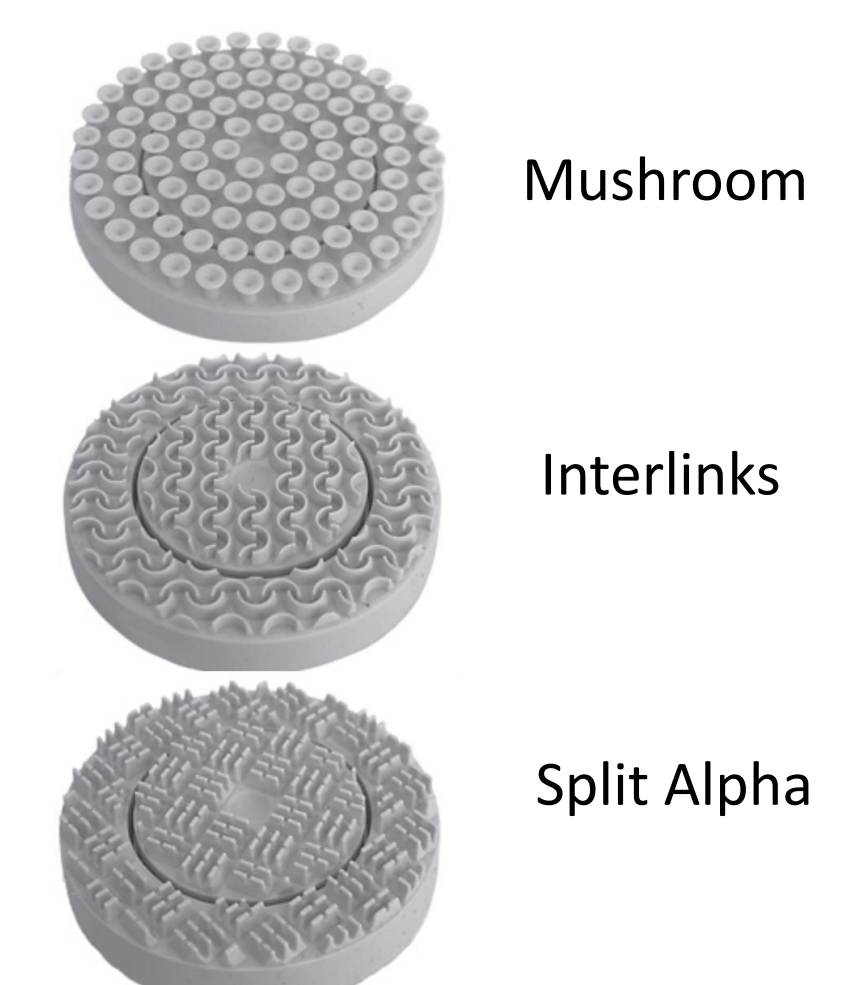


Table 1: Five treatment cleanser types which are skin types and the treatment cleansing surface (TCS) used by each skin type

Figure 1: Three treatment cleansing surface (TCS) options

The clinical study lasted for 12 weeks. In order to evaluate the efficacy and tolerability of the regimen, the dermatologist investigator examined different parameters of the subjects' face. During the study duration, the regimen continually improved several facial skin parameters in all five groups. Most notable improvements were on smoothness and softness in addition to cleansing ability. Different groups showed slightly variance in percent improvement, but overall the direction remained the same. The Week 12 data compared to the baseline is shown in Figure 2. At the end of the study, all groups showed statistically significant improvements in cleansing ability, smoothness, softness, texture, clarity, radiance, firmness, dryness reduction, overall firmness, and overall appearance. All subjects tolerated the regimen well based on the investigator assessment as well as the subject assessment. Three subjects in the Mushroom+Sensitive group had slight irritation early in the study. Once they changed to a different topical regimen, they continued on without any further problems.

In addition to the clinical investigator assessments, transepidermal water loss (TEWL) was measured to evaluate the skin barrier status. Throughout 12 weeks, there were minimal changes with TEWL readings, likely within the range of the instrument accuracy. TEWL assessment confirmed that this treatment cleansing regimen did not damage the skin barrier.

Interestingly, subjects felt that their regimen gradually improve the skin around their eyes in addition to other facial skin attributes. The Mushroom+Acne group showed the highest number attributes improved over 12 weeks, with statistically significant improvements for dark circles, undereye bags, undereye puffiness, fine lines around the eye and skin firmness around the eye in these groups based on the subjective assessments.

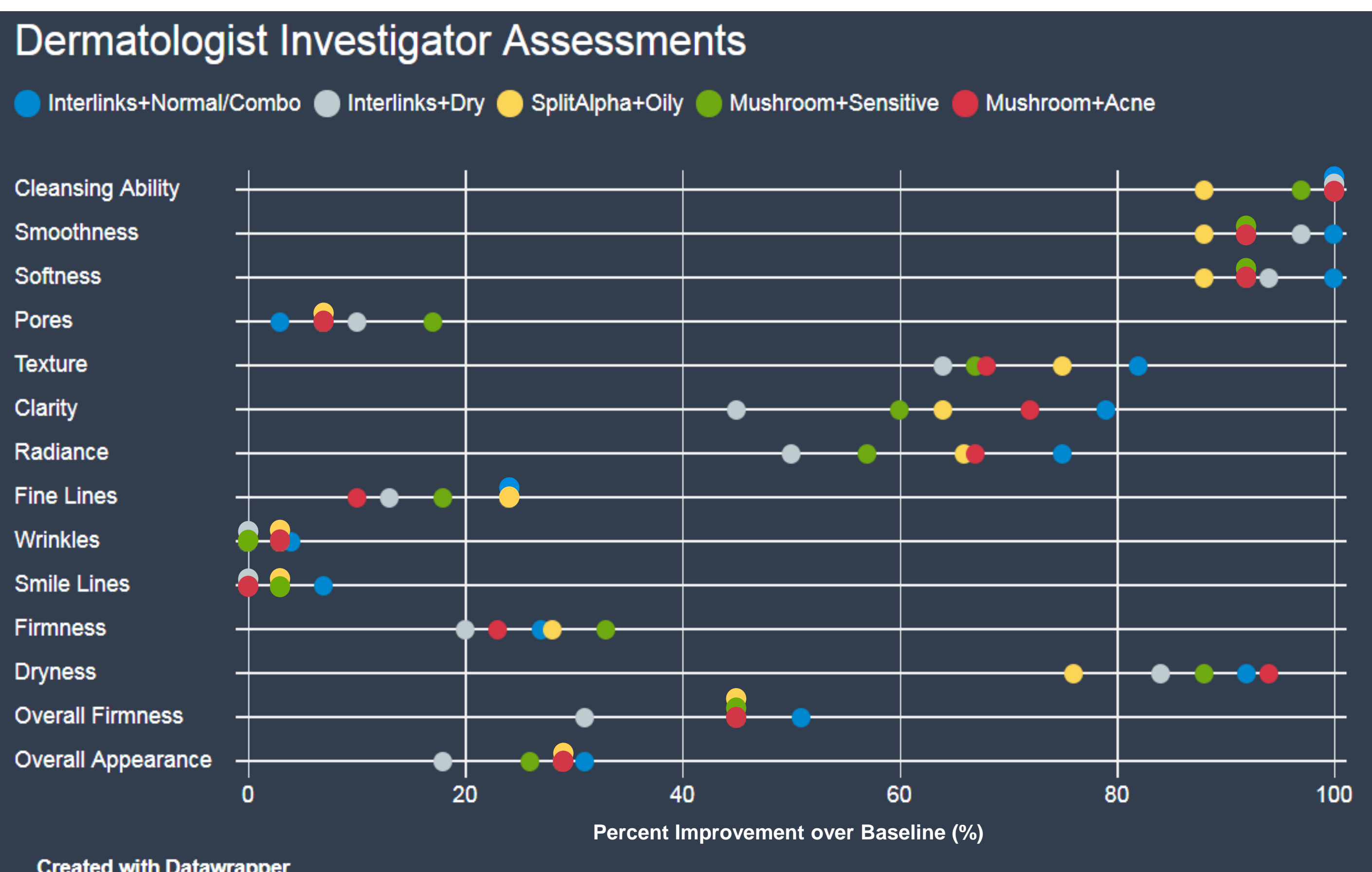


Figure 2: Dermatologist Investigator Assessments. Percent improvement over baseline was calculated for Week 12. Each group is represented by a different color circle. The partial list of assessed facial attributes are shown on the left side.

REFERENCE

1. Abbas S, Goldberg JW and Massaro M. Personal cleanser technology and clinical performance. *Dermatologic Therapy*. 17: 35-42 (2004)

CONCLUSIONS

- The novel counter-oscillating mechanical treatment cleansing device was shown to gently cleanse and exfoliate the skin for skin attribute improvements.
- The treatment cleansing regimen was able to improve with statistical significance on cleansing ability, softness and smoothness the best in all five groups, immediately after one time use and continued to improve during the study. At the end of 12 weeks, additional parameters showed statistically significant improvements.
- Once the subject-appropriate regimen was used, the product regimen demonstrated efficacy without tolerability issues.