A Facial Treatment Cleansing Device Improves Acne Skin

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INTRODUCTION

Acne vulgaris is a common skin disease that impacts an estimated 50 million people in US annually [1]. Acne usually affects teenagers and young adults; however in more recent years, women in their 30s and 40s are increasingly affected by acne [2]. There are some known factors that trigger or exacerbate acne, while some other factors are unknown. Prescription and/or OTC drugs as well as other remedies are available to treat acne, resulting in the market size close to 5 billion US dollars globally in 2016 [3]. With any acne treatment, the starting point for most patients is proper cleansing, which requires gentle cleansing with removal of excess sebum and skin debris.

We developed and launched a novel facial treatment cleansing mechanical device with accompanying treatment cleansers, that will exfoliate the skin by gently stimulating desquamation and remove deposits on the face, maintaining and improving skin health. Two different surfaces, Interlinks and Mushroom, are designed to work with acne treatment cleanser which contain 0.5% salicylic acid. In order to assess the efficacy of regimens, acne clinical studies were designed using the device with either surfaces to evaluate the skin health.

OBJECTIVE

To evaluate the ability of a novel mechanical facial treatment cleansing device to improve the efficacy of a topical acne treatment cleanser.

METHODS

43 male and female subjects between ages 16 and 25 were recruited for the first clinical study. Subjects used Interlinks surface only one randomized side of their face, while using acne cleanser on both sides of their face. 30 male and female subjects between ages 18 and 45 were recruited for the second clinical study, who used the gentler Mushroom surface on their whole face with acne treatment cleanser. Both studies were reviewed and approved by institutional review boards (IRBs). For 12 weeks, twice a day subjects used a skin treatment/cleansing regimen consisting of a novel treatment/cleansing device and an acne treatment cleanser containing 0.5% salicylic acid. They returned to the clinical facilities for evaluations at Week 2, 4, 8 and 12. No adverse effects or reactions of any kind were observed on any of the subjects from either studies.

On the day of the visit, subjects were rested at least 15 minutes in an environmentally controlled room. On the baseline visit, subjects were trained by the laboratory staff on the usage for the device. Clinical evaluation was done by the investigator on each side of the face in the first study while assessing the whole face on the second study.

RESULTS

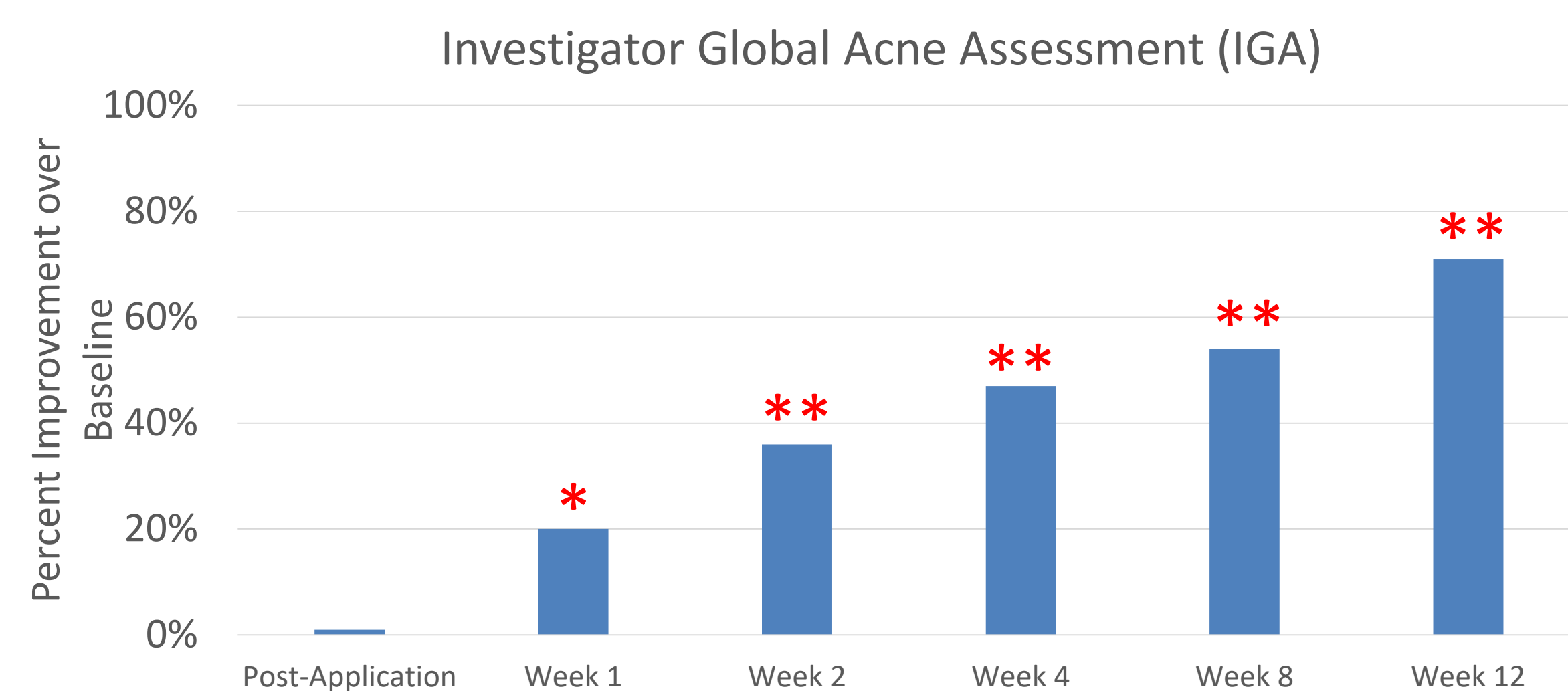### Mushroom: Extra Gentle Treatment Cleansing Surface

Figure 1. Investigator Global Acne (IGA) Score
The dermatologist investigator assessed the total facial acne severity in the acne group as 0=clear, 1=almost clear, 2=mild, 3=moderate, and 4=severe. The subject came into the study with an acne IGA between mild and moderate. The average rating at the end of the study was between clear and almost clear representing a 71% reduction in acne lesions. * Indicates $p \leq 0.01$ and ** indicates $p \leq 0.001$.
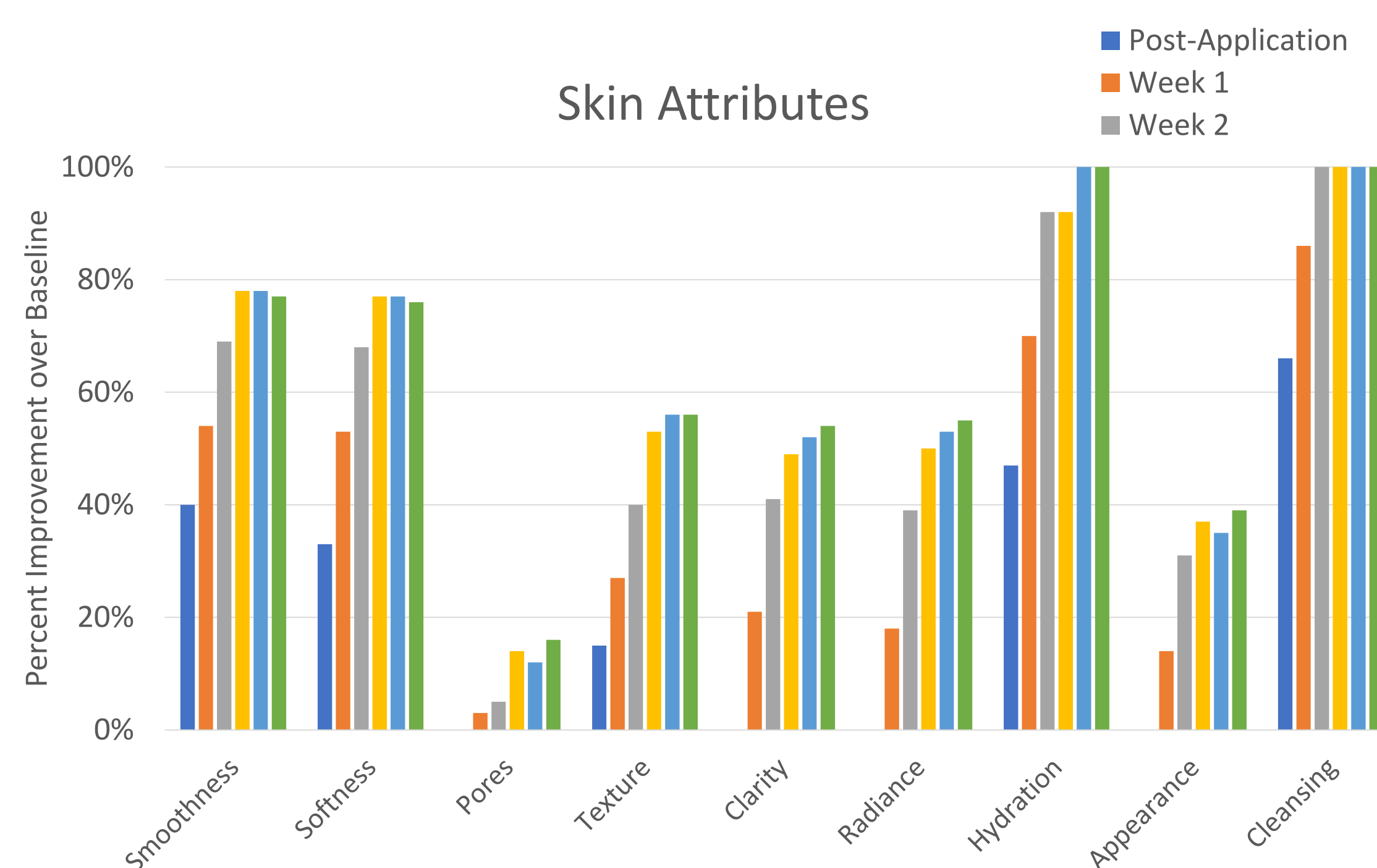

Figure 2. Skin Attributes
Multiple skin attributes were assessed by the dermatologist investigator throughout the study. Selected attributes are shown above. Most of these attributes are shown to be statistically significant right after one-time use and continue to improve during 12-week study periods. Improvements on the pores were statistically significant after 4 weeks of use.

No tolerability issues were seen during the study.

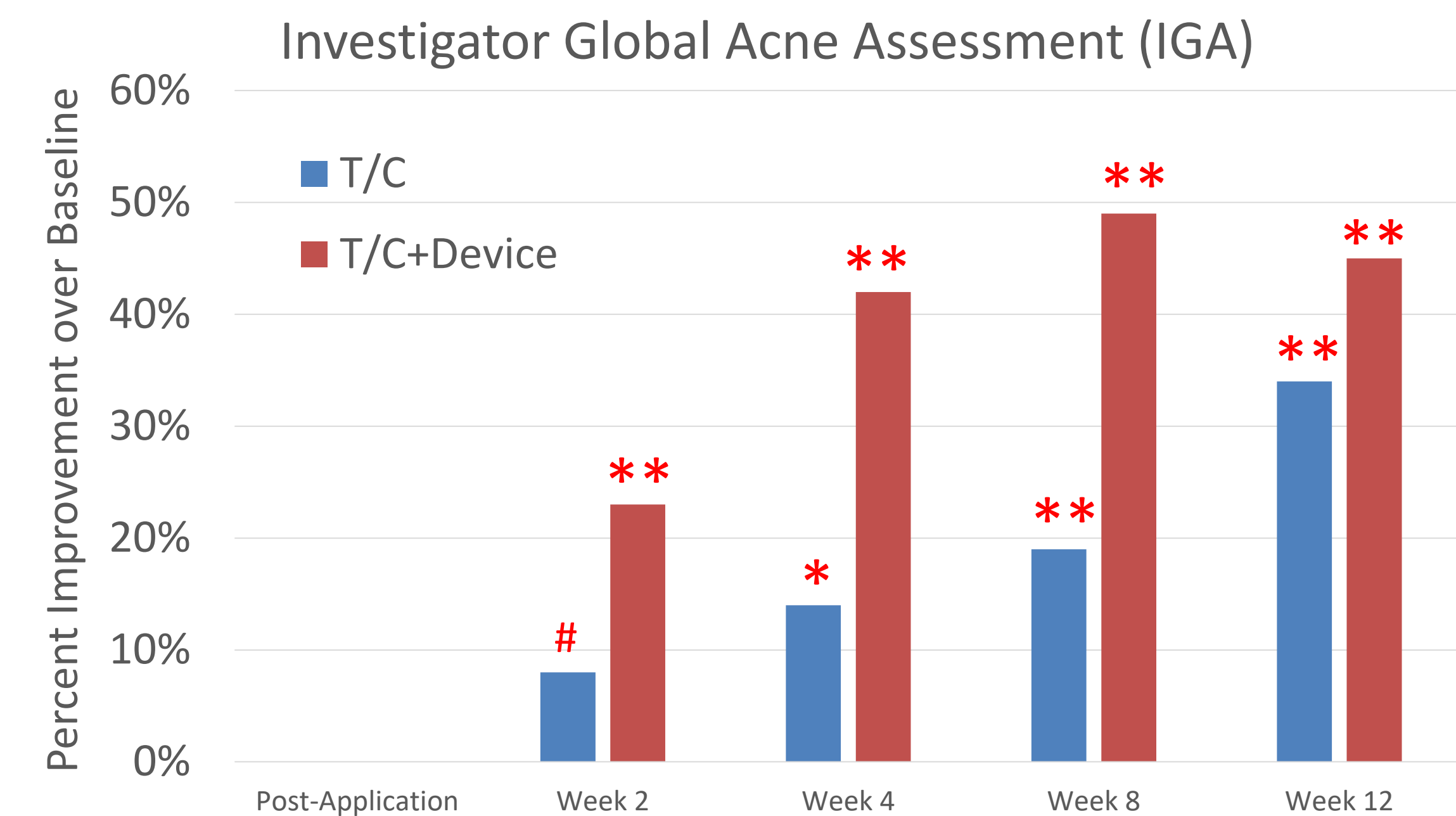### Interlinks: Normal Treatment Cleansing Surface

Figure 3. Investigator Global Acne Assessment (IGA)
The investigator provided a global assessment (IGA) separately for both sides of the face at each time point. The longitudinal analysis demonstrated that the cleanser was effective in improving acne. After 2 weeks of use and throughout the 12-week treatment period, there was a statistically significant improvement in acne as assessed by the investigator with the cleanser only. # indicates $p \leq 0.05$, * indicates $p \leq 0.01$ and ** indicates $p \leq 0.001$.

An additive acne treatment effect was seen with the addition of the treatment device. The investigator rated a statistically superior reduction in IGA after 2 weeks of treatment (p=0.005) with highly significant improvement at weeks 4 and 8 (p<0.001). There was no statistically significant difference at week 12 because both sides of the face improved over time and the number of acne lesions was very small not allowing for much differentiation.

No tolerability issues were seen throughout the study.

CONCLUSIONS

- The acne treatment cleanser with 0.5% salicylic acid improved acne.
- An addition of a mechanical device to support the treatment cleansing improved acne earlier than when the topical was used by itself.
- Gentler treatment surface reduced acne burden and there were additional skin attributes improved such as texture, smoothness, etc.

REFERENCES

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