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A Facial Treatment Cleansing Device Enhanced Delivery of Topical Skin Care Products

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INTRODUCTION

The human skin is the outermost protective barrier of human body. The skin goes through constant renewal, while maintaining the tight barrier. Transit time of keratinocytes is about 4 weeks from the basal layer of the epidermis to desquamation, the shedding of the outermost layer [1]. Desquamation rates slow down with age [1]. In many cases, skin diseases and conditions manifest as inadequate desquamation [1]. Proper desquamation is a sign of healthy skin, and skin exfoliation by stimulated desquamation, can alleviate the signs of skin aging [2].

For most people, the face is cleansed twice daily, morning and evening. Surfactants can improve the cleansing efficacy. Mechanical movements on the skin surface can also remove deposits. We developed a novel facial treatment cleansing mechanical device with accompanying treatment cleansers based on common skin types, that will exfoliate the skin by gently stimulating desquamation and remove deposits on the face, maintaining and improving skin health. Skin exfoliation can provide a boosting effect to topical skin care products that are subsequently applied. We evaluated the ability of a skin treatment cleansing device to enhance the efficacy of a topical skin care serum applied after.

OBJECTIVE

To evaluate the ability of a novel mechanical facial treatment cleansing device to enhance the efficacy of a topical skin care serum applied following use of the device.

METHODS

34 healthy Asian female subjects between ages 40-65 years of age, Fitzpatrick skin type II-IV with normal healthy skin were recruited for a single-site clinical study. This study followed the recommendations of the World Medical Association and the general principles of the Good Clinical Practice published by International Conference on Harmonisation (ICH). For 8 weeks, subjects used the novel mechanical facial treatment cleansing device with an accompanying treatment cleanser, designed for a normal to combination skin type. Subjects twice per day used the device on the assigned randomized half of their face, while using the serums and the treatment cleanser on the whole face. They returned to the clinical site for evaluations at Week 1, 2, 4 and 8.

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 and application of the serums. Clinical evaluation was done by the investigator on each side of the face on multiple parameters such as wrinkle severity, skin luminosity, and skin smoothness. Subjects evaluated both sides of their own face for different parameters. In addition, high-resolution digital photographs (COLORFACE, Newton Technologies) were used to assess skin color analysis with normal and cross polarized light.

Results were compared to baseline for each half of the face as well as compared between both sides for serum effects. For clinical and self-assessment, two-tailed Wilcoxon test was used and for the instrumental evaluation, Shapiro-Wilk test was used to check normal distributions, paired student t-test was used the distribution was normal and Wilcoxon test was used for adverse events. Statistical threshold was at 5% except Shapiro-Wilk test which was at 1%. Statistical significance of $p < 0.05$ or limited significance ($0.05 \leq p \leq 0.10$) were used to evaluate the efficacy.

RESULTS

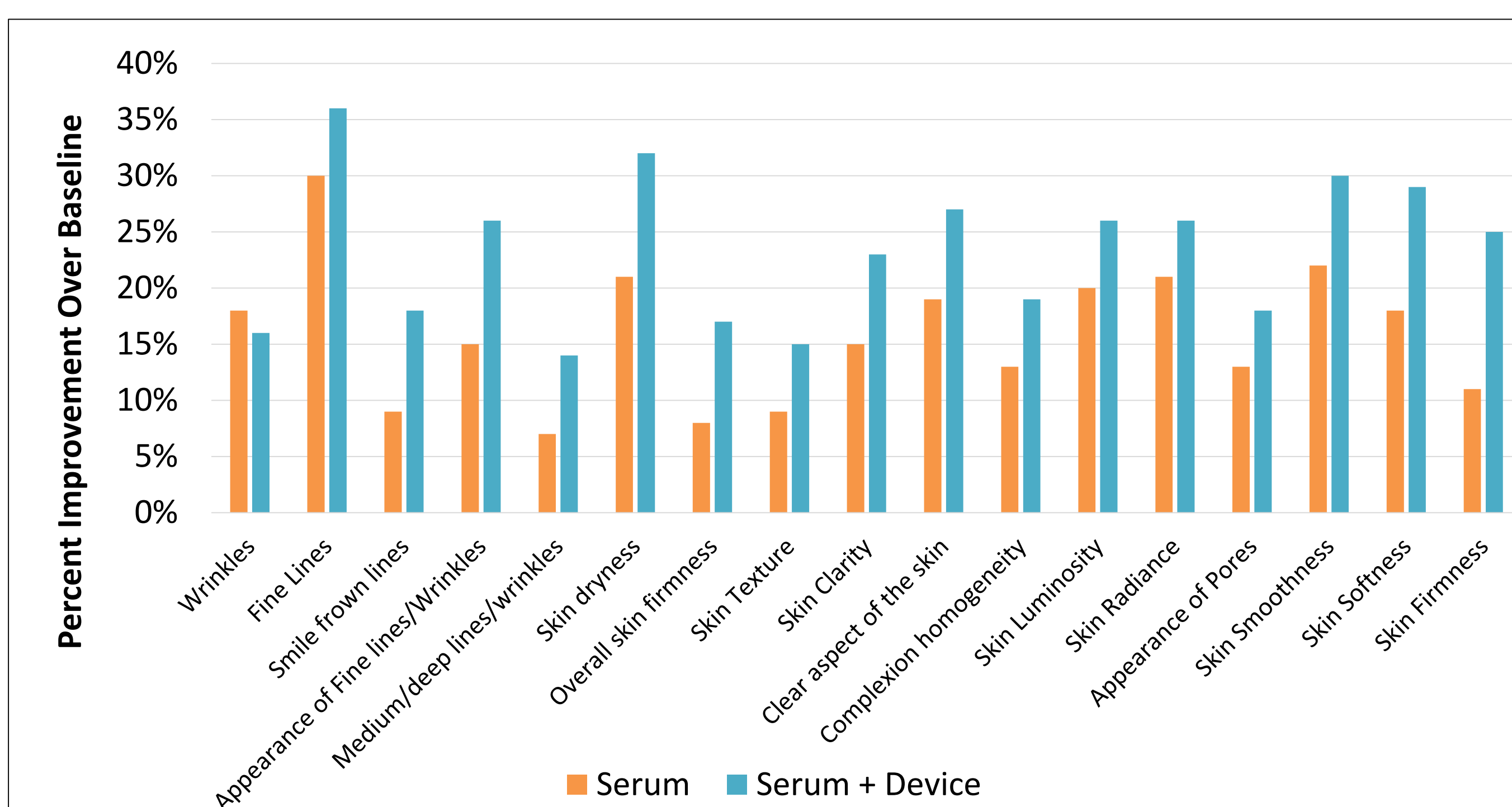


Figure 1: Clinical Grading (Week 8)

Percent improvement over baseline from clinical investigator grading is shown. The clinical investigator assessed skin attributes are shown on the x-axis. Orange bar represents Serum alone and aqua bar represents Serum+Device. All data shown are statistically significant ($p < 0.05$).

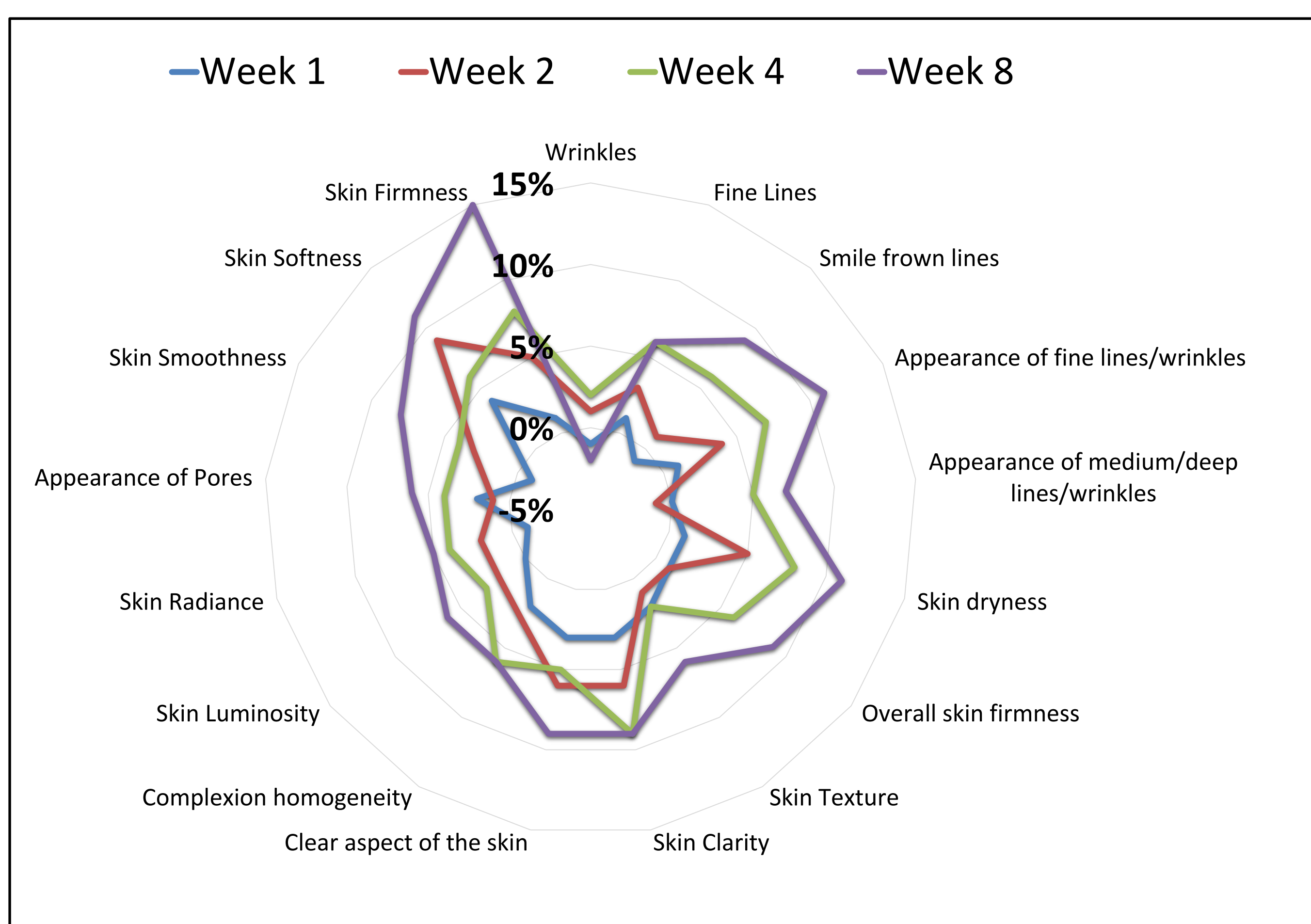


Figure 2: Difference between Serum+Device vs Serum only

Based on Figure 1, differences in percent improvement were graphed for all time points. Throughout the study, differences between Serum+Device and Serum only became larger. At Week 1 (blue), only skin softness was a difference with statistical significance. At Week 2 (red), appearance of fine lines/wrinkles, skin dryness, skin clarity, clear aspect of the skin and skin softness were statistically significant differences. At Week 4 (green) and Week 8 (purple), more attribute differences were statistically significant.

The clinical investigator saw statistically significant improvements in different parameters during the 8-week study. At Week 1, there were 7 parameters that had $p < 0.05$ and 4 parameters that had limited significance ($0.05 \leq p \leq 0.10$) for the Serum+Device side, where as 3 parameters had statistical significance and 2 limited significance for the Serum only group. They continued to improve in every parameter showing statistical significance on both Serum+Device and Serum only sides. An example of percent improvement over the baseline at Week 8 is shown in Figure 1. In addition, the difference between Serum+Device and Serum is shown in Figure 2. Although progressive improvements were seen throughout the duration of the side as the weeks progressed, there were larger differences between the two sides, suggesting Serum+Device had greater improvements overall. All parameters shown on Figure 2 are statistically significant differences between the two sides, except Fine Lines, Complexion Homogeneity, Appearance of Pores (limited significance) and Wrinkles (no difference). Serum+Device had greater improvements compared to the Serum only side.

Subject self-assessments mirrored clinical grader assessment. Throughout 8 weeks, there were progressive improvements on all parameters as shown in Figure 3. Subjects assessed that even at Week 1 they were able to see improvements over baseline on all parameters.

Skin color analysis based on the high resolution photography did not show any statistically significant differences from the baseline as well as between the sides. One subject withdrew the consent and three subjects were withdrawn from efficacy analysis. Among the three, one had unrelated adverse events and two had protocol violations (used the device on the whole face and unable to come in for Week 8 visit). At the end, there were 30 subjects who completed the study as designed.

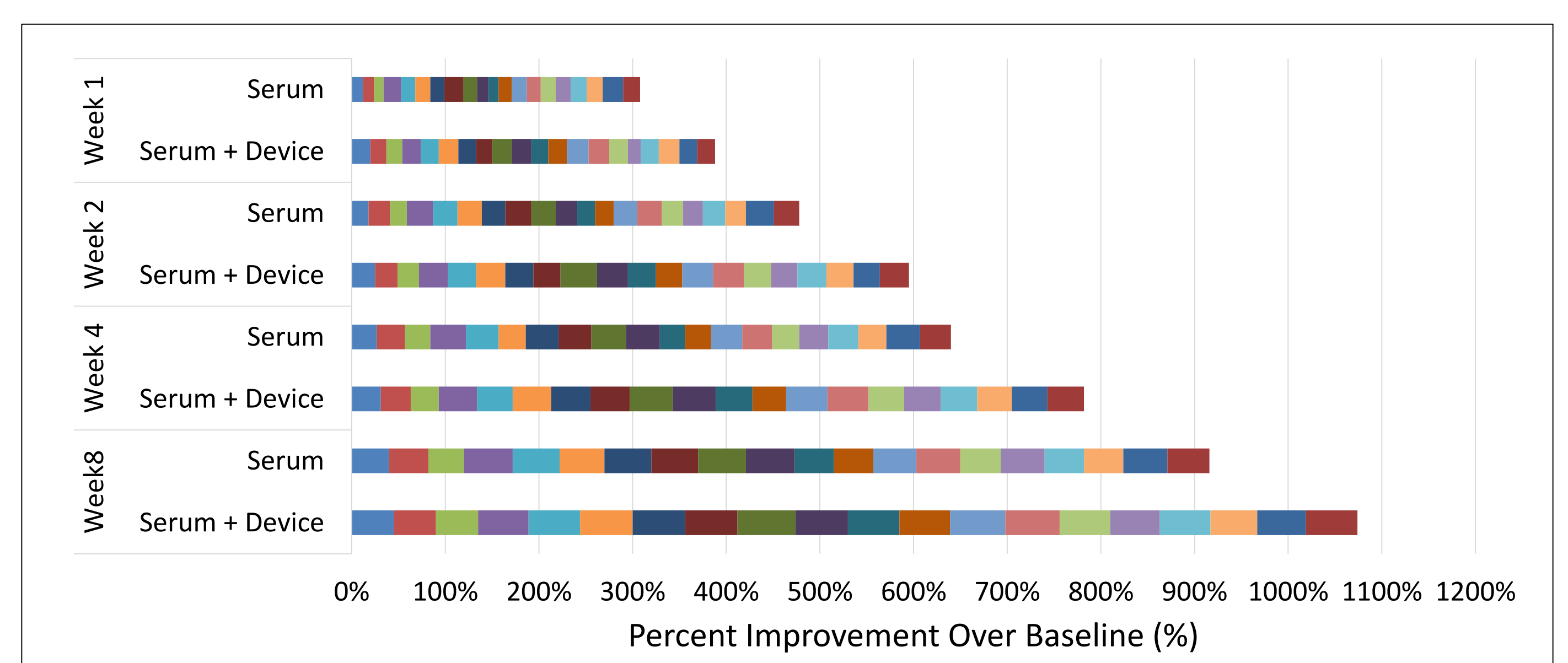


Figure 3: Subject Self-Assessment

Percent improvement over baseline on each parameter were graphed on a stack to see overall changes. Each block of color represent different parameters assessed by subjects. All values were statistically significant improvements over baseline ($p < 0.05$).

CONCLUSIONS

- The novel mechanical facial treatment cleansing device enhanced the efficacy of a topical skin care product applied following use of the device.
- Using the device prior to serum application resulted in greater improvement in skin attributes as well as faster speed to benefit.

REFERENCES

1. Millstone, LM. Epidermal desquamation. *Journal of Dermatological Science* **36** 131-140 (2004).
2. Rawlings, AV. Molecular basis for stratum corneum maturation and moisturization. *British Journal of Dermatology* **171** 19-28 (2014).