Progressive Improvement of the Skin Following Use of a Novel Treatment Cleansing Technology

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INTRODUCTION

The human skin plays an important role as the outermost layer of the human body. As the protective barrier, the skin guards the internal organs from outside insults and maintains the barrier from internal influencers, while shedding the outermost layer continuously. The shedding is called desquamation, which is a complex process that the skin goes through for renewal. There are different speculations on the reasons why desquamation occurs. One of the hypotheses is that desquamation is a protective mechanism by which the skin removes the contaminant-exposed outer layer from impacting the skin below [1]. As we age, desquamation slows down [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].

Heathy skin is maintained with proper hygiene, which requires the removal of deposits and harmful microorganisms from the skin surface. People go through different cleansing routines based on their personal preferences. In addition, the area of the skin that's exposed to more filth, like the hands, is cleansed multiple times throughout a day, to prevent diseases and other problems. Facial skin cleansing can be categorized into different forms 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 [3]. Additionally, facial cleansing could use different media, such as handwashing, use of washcloths, or use of automated devices. 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.

METHODS

40 healthy female subjects with normal healthy skin were recruited for two different clinical studies. In the first study, 30 subjects with Fitzpatrick skin type I-IV, between ages 35 and 65 were recruited to participate. In the second study, 10 subjects with ages 30 to 65 were recruited, of which 5 subjects were Fitzpatrick skin type I-III and 5 subjects were Asian. 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 associated treatment/cleansing topical, designed for normal to combination skin. They returned to the clinical facilities for evaluations at Week 1, 2, 4, 8 and 12. No adverse effects or reactions of any kind were observed on any of the subjects from either studies.

The first study was focused on the clinical investigator grading. 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, the dermatologist investigator examined subjects. Each subject was given a treatment cleansing device and the associated treatment/cleansing topical. With written and verbal instructions on the proper execution of the treatment cleansing regimen, subjects used the device on site to assure proper usage. 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. All results were compared to baseline. A Mann Whitney two-tailed paired t-test was used to analyze the nonparametric data, with statistical significance defined at $p \leq 0.05$.

While the second study was designed similarly to the first study, it focused on visual improvement detected by the Matched Scientific Photography™ with PhotoGrammetrix® image analysis system. Instead of the clinical grading and subject self-assessment, high-resolution photographs were taken. Photographs of the whole face were taken with a fixed camera background, distances, angles, settings, lighting, automated subject positioning, color bars, white balance, standardized and digitally certified unretouched. A Student's paired t-test analysis was used to compare post-regimen measurements to baseline with statistical significance of $p \leq 0.05$.

RESULTS
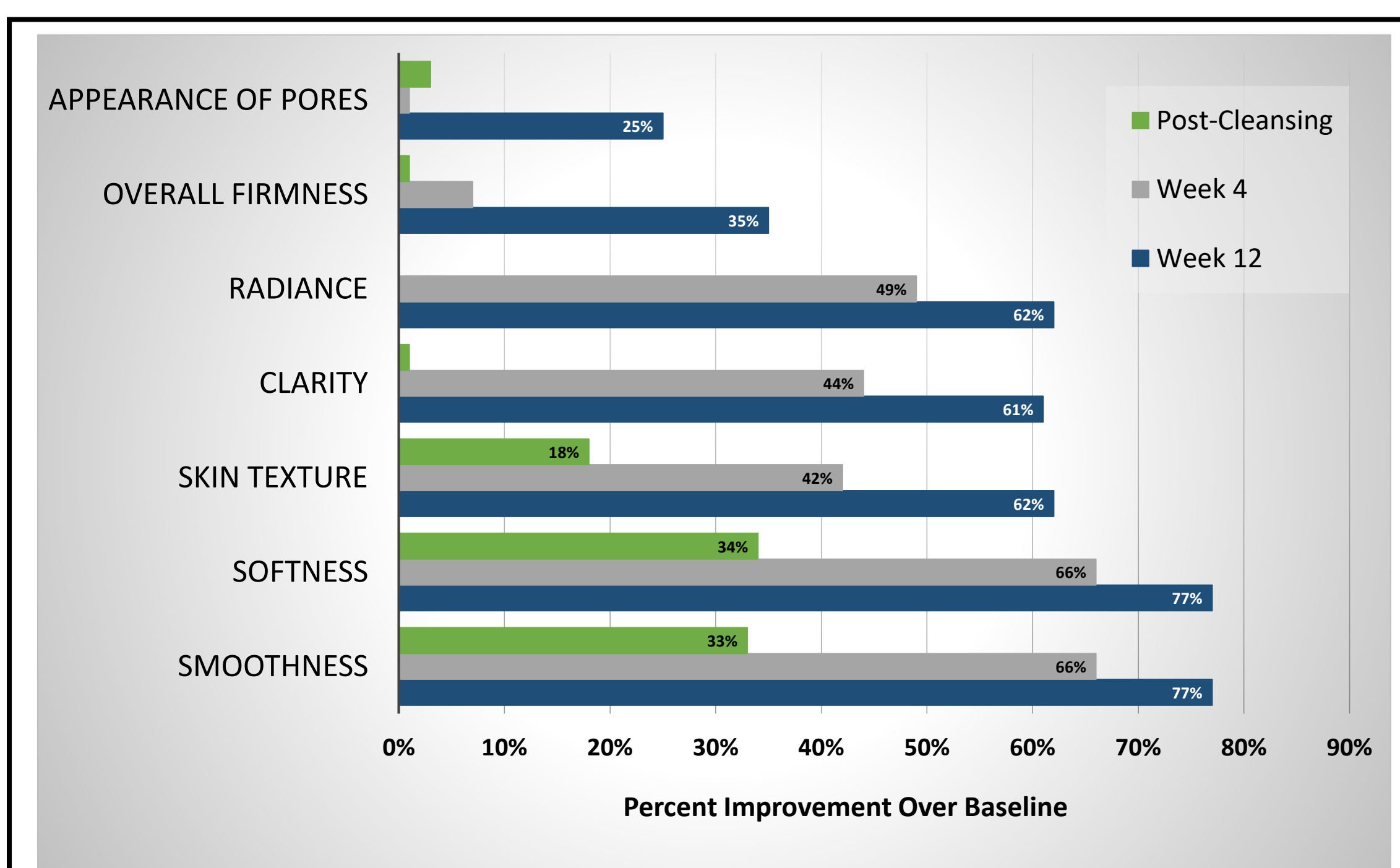
Figure 1: Clinical Grading
Percent improvement over baseline from clinical investigator grading is shown. The clinical investigator assessed skin attributes are shown on the left. Data with percent improvement written next to the bar are statistically significant (p<0.05).

The clinical investigator saw statistically significant improvements in different parameters during the 12-week study (Figure 1). Immediately after one-time use, improvements were seen from parameters such as smoothness, softness and texture. These improvements were continued during the study period, while adding additional skin attributes to the statistically significant parameters, such as clarity, radiance, overall firmness and appearance of pores. In addition, subject self-assessments mirrored clinical grader assessment. Throughout 12 weeks, there were progressive improvements on different parameters as shown in Figure 2. Subjects assessed that immediate after the one-time use, they were able to see statistically significant changes in softness. At Week 12, they were able to see statistically significant improvements over baseline on all parameters shown.
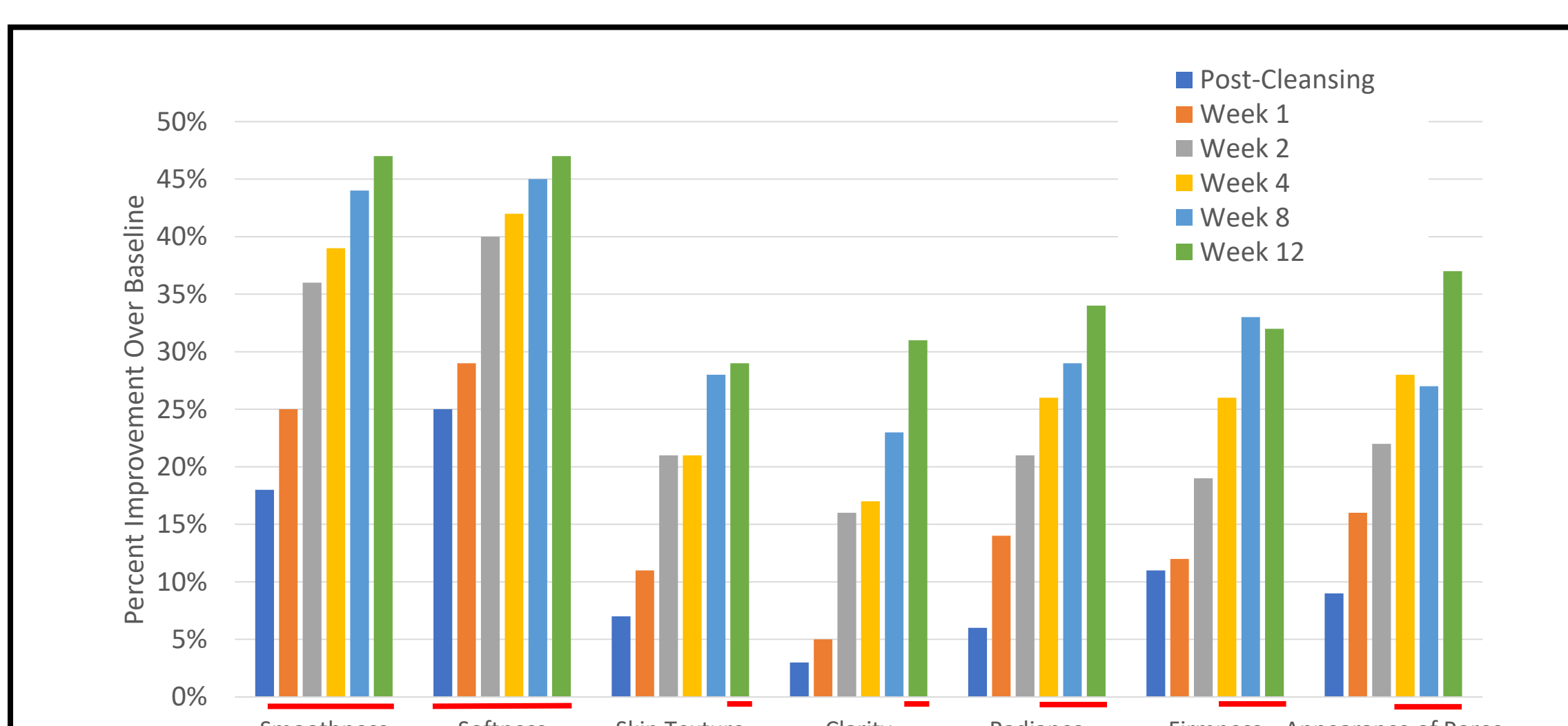
Figure 2: Subject Self-Assessment
Percent improvement over baseline on selected parameters were graphed. Different attributes are listed at x-axis. Different color represents different timepoints. Statistically significant improvements over baseline (p<0.05) marked below with a red bar.

Photography was used as a visual record and tool for measuring the efficacy of the test regimen. All photographs for before and after the treatments were analyzed independently followed by comparison to subject-specific images. Before and after photographs were taken using the Matched Scientific Photography™ protocol developed by AMA labs. The pixel image analysis comparing subject photographs before to after product regimen use demonstrated efficacy in improving the appearance of skin texture, luminescence and pores. Selected results are shown in Figure 3.
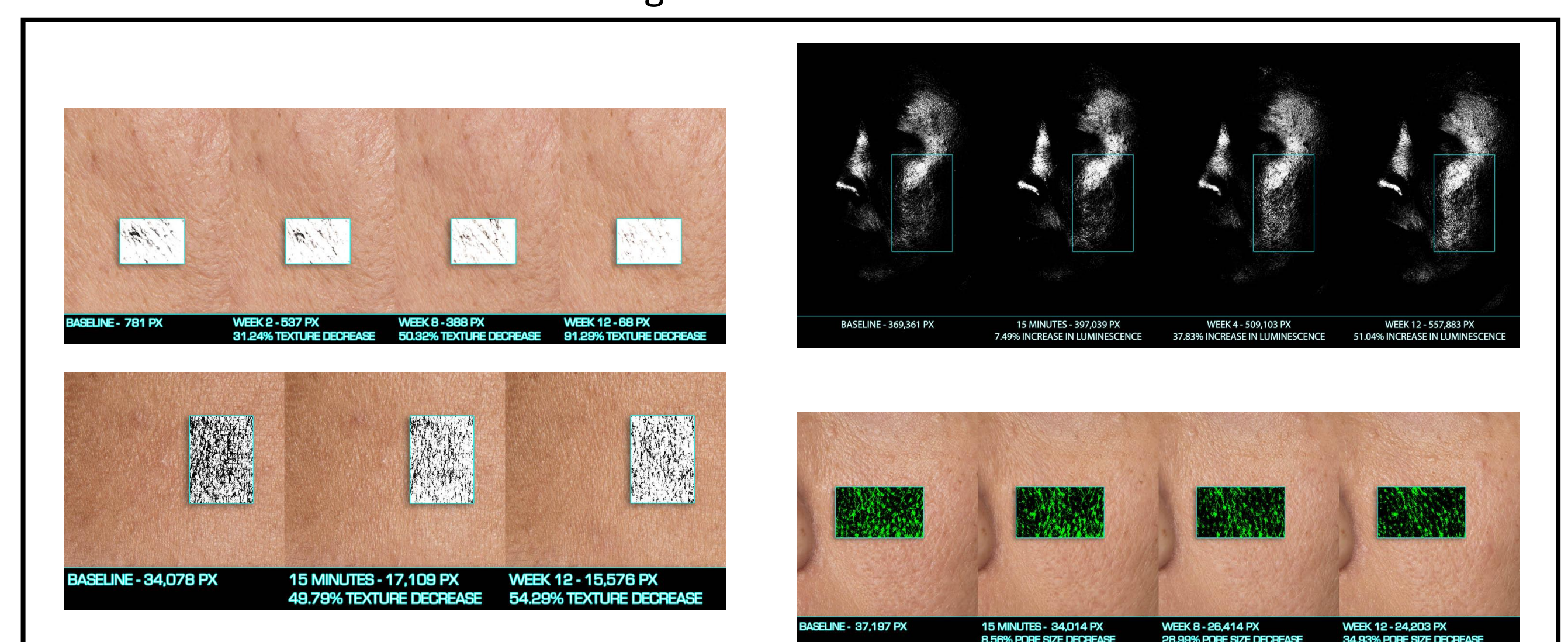
Figure 3: Photographic Analysis of Skin
From each image, different parameters are analyzed using individual pixels and the proprietary software to analyze these pixels. Two figures on the left are from two different subjects for skin texture evaluation. Counts and percent reduction is shown below each image. Top right figure analyzed luminescence and bottom right figure analyzed the pore size.

Both studies demonstrated the effectiveness of the treatment cleansing regimen immediately after one-time use as well as continual improvement during 12-week period without any adverse effects.

CONCLUSIONS

✓ The novel treatment cleansing regimen was able to improve skin softness and smoothness immediately after one use.

✓ The novel treatment cleansing regimen was able to improve appearance of pores, skin texture and firmness after 12 weeks.

✓ The novel treatment cleansing regimen was shown to provide increasing skin benefits with continued use.

✓ We demonstrated that mechanical stimulation of the skin brings about in vivo skin treatment benefits while simultaneously cleansing.

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