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"A triple permeation system (TPS) -based soothing treatment for alleviating sensitive skin"

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1. Introduction

Sensitive skin is increasingly recognized as a prevalent dermatological condition characterized by heightened reactivity to various environmental stimuli, affecting a significant portion of the population [1]. Studies suggest that approximately 50% of individuals in China report experiencing symptoms consistent with sensitive skin, reflecting a growing concern within dermatological practice [2]. This condition is often defined by subjective sensations of discomfort, including stinging, burning, erythema and dryness, typically triggered by factors such as temperature fluctuations, UV exposure, and chemical irritants [3]. The underlying pathophysiology of sensitive skin is complex, involving a dysfunctional skin barrier, altered neuro-sensory responses, and inflammatory processes that collectively contribute to its manifestation [4]. Patients with sensitive skin often experience a range of distressing symptoms that can significantly impact their quality of life [5]. These symptoms may include persistent itching, erythema, and a heightened sensitivity to both physical and emotional stressors. This condition can lead to substantial psychological distress, resulting in social withdrawal and decreased self-esteem as patients avoid certain environments, products, or situations that exacerbate their symptoms.

Classic management strategies for sensitive skin primarily focus on maintaining skin hydration, using gentle and non-irritating skincare products for mild sensitive grade, and may using corticosteroid ointments for some severe cases [6-8]. Nevertheless, skincare products frequently fall short when it comes to addressing the inflammation problem, while topical steroid creams can lead to dependency, and recurrence is likely upon discontinuation. Recently, mesotherapy has gained popularity [9]. This approach directly injects active

ingredients into the dermis, enabling rapid onset of action [10]. However, it is an invasive procedure. Patients must grapple with pain, endure a recovery period that could disrupt their daily routines, and face the possibility of post-operative complications. Therefore, there is an urgent need for a non-invasive and effective method for treating SS [11].

In recent years, there has been a rapid advancement in the field of transdermal drug delivery [12-14]. This progress encompasses passive enhancement technologies that primarily utilize nanomaterials [15], as well as active enhancement techniques such as ultrasound, iontophoresis, and electroporation, etc. In 2024, a novel triple-permeation system (TPS) that synergistically combines formulation technology, atomization technology, and photoelectric permeation technology, was proposed to promote penetration from the chain of “formulation to application process to absorption process. Then, the efficacy of TPS in the realms of anti-aging [16] and photo-aging protection [17] were reported, demonstrating its potential as a cutting-edge approach in dermatological care. Based on this, TPS was further upgraded to address sensitive skin issues. In this work, the soothing effect of the TPS-based treatment was comprehensively evaluated by involving 120 subjects with sensitive skin.

2. Materials and Method

2.1 Materials and methods for treatment

The soothing essence combination consists of a hydrating toner (HYDRATING TONER, BMJS01h), a soothing serum (SOOTHING SERUM, BMJJ02h), and a repairing gel (RECOM-BINANT HUMAN COLLAGEN Ⅲ GEL, BMJM01s). The instrument (MOYAL PRO, BM01) consists of an atomization handle, an Ultra-protective handle, a repair handle and a Carved handle. The essences and instrument are produced by Shenzhen Moore Vaporization Health & Medical Technology Co., Ltd. Detailed treatment procedure as follow:

1. After the subjects cleanse their faces, they lie down on a bed to get treatment.
2. Step 1: Install the hydrating toner and follow the procedural instructions to operate the atomization handle for full-face, with a total duration of 300 seconds.
3. Step 2: Install the soothing serum and follow the procedural instructions to operate the atomization handle for full-face, with a total duration of 300 seconds.
4. Step 3: Select the penetration mode, and follow the procedural instructions to operate the repair photoelectric handle for full-face care, with a total duration of 200 seconds.
5. Step 4: Install the gel and follow the procedural instructions to operate the atomization handle for full-face, with a total duration of 300 seconds. At this point, the treatment procedure is complete.

2.2 Subjects selection for human test

West China Sensitive Skin Self-Assessment Questionnaire (SS-14) was used to screen the volunteers [2]. The grading criteria from the questionnaire: Score of 12 to 17: The skin has good tolerance and is classified as tolerant. Score of 18 to 23: Mild sensitivity. Score of 24 to 32: Moderate sensitivity. Score of 33 to 42: Severe sensitivity. A total of 120 subjects with sensitive skin were enrolled in the study, and each group of which 37 had mild sensitivity, 39 had moderate sensitivity, and 35 had severe sensitivity. Exclusion criteria include those with a history of skin diseases or allergies, pregnancy, serious physical illness, etc. who are not suitable to participate in this study.

2.3 Materials and methods for efficacy assessment

Human test was conducted in Centre Testing International Group Co., Ltd. The human test was approved by the Ethics Committee of Centre Testing International Group Co., Ltd. All subjects signed informed consent forms.

Skin biophysical parameters were detected in a chamber (T = 20 ± 1°C; relative humidity 50 ± 10%). The subjects were required to go to the laboratory at specific time points for treatment (Day 0,3,10,17,24, and 31) and for assessment (Day 0,3,10,17,24,31 before each treatment, and Day 45, 59 to evaluate the post-treatment maintaining effect).

2.3.1 Clinical assessments

Clinical assessments consist of skin redness, radiance and pores grade. Skin redness as rated 1 to 4. 1: very slight redness, 2: more obvious redness, 3: significant redness,4: extremely obvious redness. For skin radiance, 0 indicates no luster, 1 means slight luster, 2 represents relatively good luster, 3 signifies very good luster. For the severity of pores, 0 indicates minimal pores, 1 reflects slightly visible pores, 2 denotes clearly visible pores, 3 represents moderately visible pores, 4 indicates severely visible pores. Adverse effect was also monitored during the whole study.

2.3.2 Instrumental assessment

Instrumental assessments of trans-epidermal water loss (TEWL), skin erythema index (EI), and photo tracking. TEWL and EI value were tested by Tewameter (TM Hex) and Mexameter (MX18). The proportion of the red - area coverage was calculated by analyzing the pictures taken by VISIA-CR via Image-Pro Plus.

2.3.3 Self-assessment

In addition, the subjects scored for their sensitivity via the SS-14 scale and other self-assessment questions. Besides, all participants answered a series of questions about skin parameters using a self-assessment questionnaire. Each parameter was rated on a scale of 1 to 5, with 1 being strongly disagree, 2 being disagree, 3 being indifferent, 4 being agree, and 5 being strongly agree. The scores were given in terms of dimensions such as the feeling of using the product, skin moisturizing, wrinkle improvement, skin soothing, and skin texture.

2.4 Statistical analysis

Data were analyzed by statistical analysis software SPSS to calculate the mean, standard deviation, and rate of change of each parameter each parameter before and after the treatment.

3. Results and discussions

3.1 Skin barrier function

Numerous studies have demonstrated that sensitive skin is characterized by elevated transepidermal water loss (TEWL), a key indicator of compromised skin barrier function [18-19]. To evaluate the barrier repair efficacy of TPS Soothing Treatment, TEWL values were monitored pre- and post-treatment using the Cutometer MPA 580.

As illustrated in Figure 1, TEWL values exhibited a progressive decline across all severity groups and the total population as the treatment advanced. The reduction rate peaked on Day 24 in the total population, mild, and moderate groups, while the severe group reached its maximum reduction rate on Day 31. Notably, on Day 45 (14 days post-final treatment), TEWL values remained stable at the level observed immediately after the last treatment. However, by Day 59 (28 days post-final treatment), TEWL values exhibited a minor rebound, underscoring the importance of consistent daily care to maintain long-term skin barrier integrity.

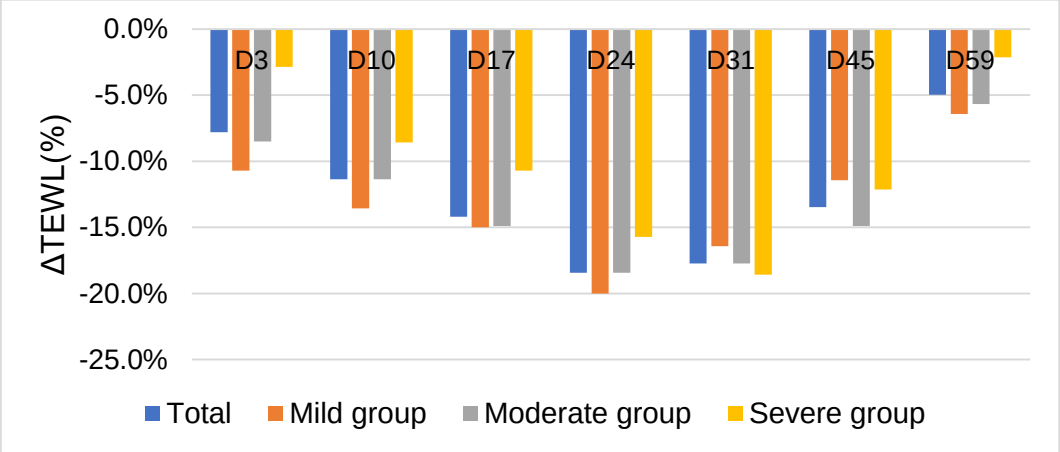

Figure 1. The change rate of TEWL values at different time points when compare to baseline. The total population included participants from three severity groups: mild, moderate, and severe.

3.2 Skin redness level

Erythema and redness are hallmark clinical features of sensitive skin, often serving as critical indicators of skin barrier disruption and inflammation. To comprehensively evaluate therapeutic efficacy, we employed a multi-dimensional approach to assess redness improvements, including erythema index (EI) measurements, VISIA imaging, and clinical erythema scoring.

3.2.1 Erythema Index (EI) Value

The erythema index (EI) is a validated biomarker of skin redness, calculated based on the specific absorption spectrum of hemoglobin in the skin. This non-invasive metric, measured using the Mexameter MX18, provides an indirect quantification of surface erythema, with lower values indicating reduced hemoglobin levels and diminished redness.

As illustrated in Figure 2, the EI values of subjects across all severity groups and the total population demonstrated a progressive decline as treatment progressed. Notably, on Day 31, the reduction rates of the EI value reached 14.7% in the total population group, 13.0% in the mild group, 16.5% in the moderate group, and 13.9% in the severe group. This reduction was sustained through Day 45 (14 days post-final treatment), with EI values remaining stable at the level observed immediately after the last treatment session. By Day 59 (28 days post-final treatment), while a slight rebound in EI values was observed, values remained significantly lower than baseline measurements.

These findings underscore the therapeutic potential of the treatment regimen in reducing erythema and redness, with sustained benefits observed during the post-treatment period. However, the minor rebound in EI values at Day 59 highlights the importance of consistent skincare practices to maintain long-term improvements in sensitive skin conditions.

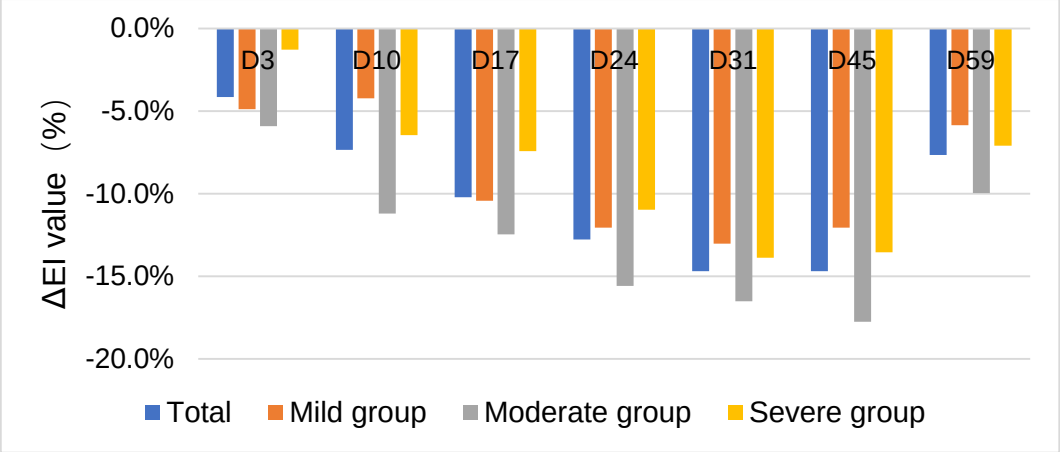

Figure 2. The change rate of EI values at different time points when compare to baseline. The total population included participants from three severity groups: mild, moderate, and severe.

3.2.1 The proportion of the red area

VISIA-CR imaging technology was employed to capture high-resolution facial images, providing a non-invasive method to visualize and quantify erythema patterns. The concentrated darker red areas detected in these images may correlate with various clinical conditions, including inflammation or telangiectasia (spider veins). To objectively evaluate therapeutic efficacy, the percentage of red areas on the cheeks of subjects was calculated as a key metric for assessing redness improvement.

As depicted in Figure 3, the proportion of red areas exhibited a progressive decline across all severity groups and the total population as treatment advanced. Notably, even after a single treatment on Day 3, significant reductions in red area proportions were observed across all groups. By Day 31, the average proportion of red areas in the total population decreased by 27.4%, and this reduction was maintained at a consistently low level through Day 59 (28 days post-final treatment).

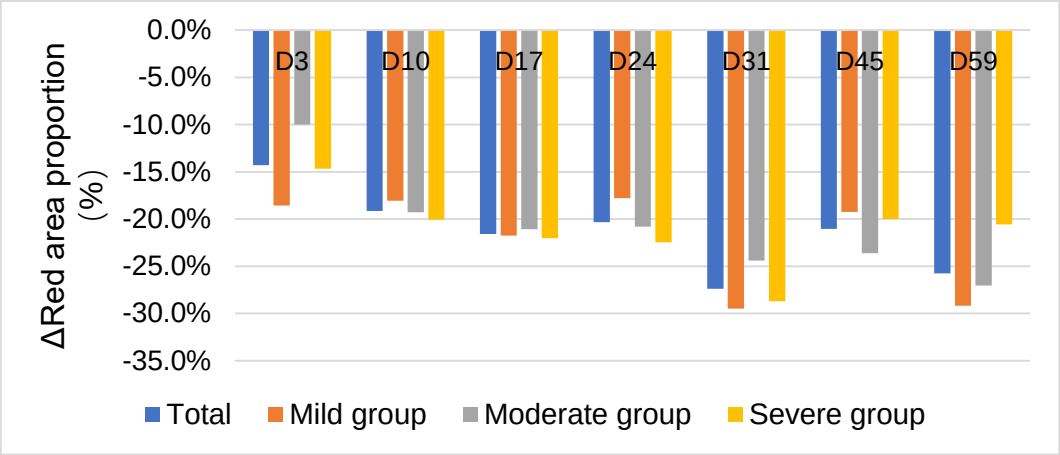

Figure 3. The change rate of red area proportion at different time points when compare to baseline.

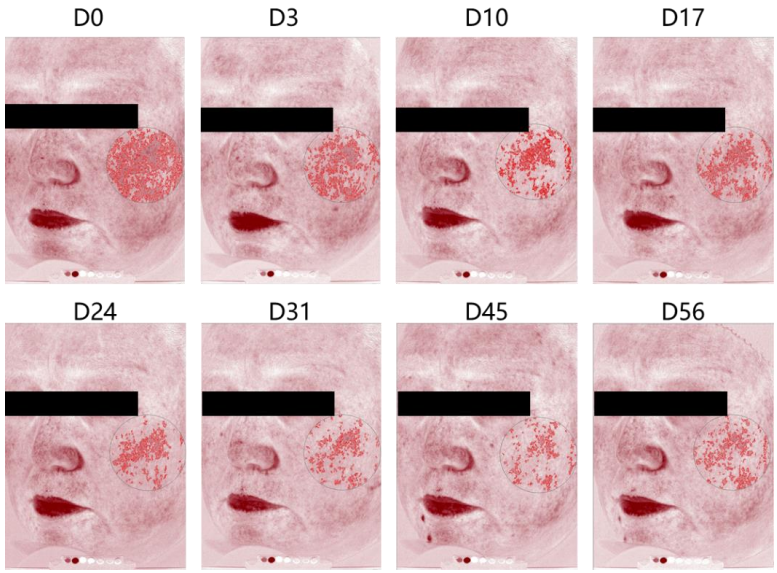

Figure 4. Representative VISIA CR red area images at different time points.

Figure 4 illustrates a series of images from a representative participant, visually demonstrating the reduction in redness over the treatment period. These findings corroborate the quantitative data, highlighting the treatment's rapid onset of action and sustained efficacy in diminishing erythema, even in the absence of ongoing treatment. The stability of results during the post-treatment phase further underscores the regimen's potential for long-term management of sensitive skin conditions.

3.2.2 Clinical erythema scoring

Clinical erythema scoring was performed by dermatologists at baseline and during each follow-up visit to objectively assess treatment outcomes. As illustrated in Figure 5, the grading scores exhibited a statistically significant reduction beginning on Day 10, achieved stabilization by Day 17, and maintained this stable improvement through Day 59 (28 days post-treatment).

This temporal pattern underscores the treatment's rapid onset of action, with noticeable improvements observed within the first week of therapy. The sustained reduction in clinical redness grading over the extended post-treatment period further highlights the regimen's efficacy in addressing sensitive skin conditions and reinforcing barrier function. These findings align with quantitative EI measurements and VISIA imaging data, collectively reinforcing the treatment's ability to deliver both rapid and enduring improvements in erythema and skin sensitivity.

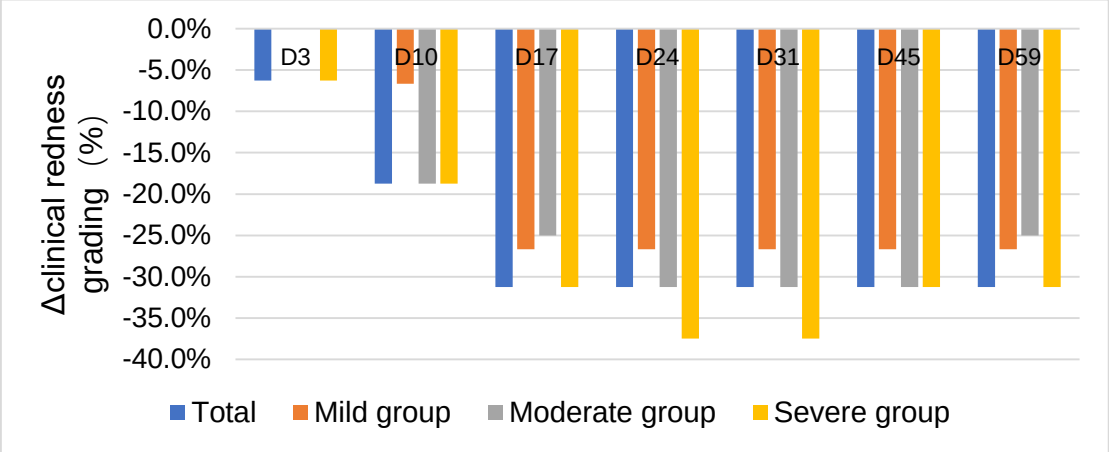

Figure 5. The change rate of clinical erythema scoring at different time points when compare to baseline.

3.3 Improvement of sensitive scale

Subject self-evaluations revealed a notable reduction in skin sensitivity following treatment. As shown in Figure 7, the average sensitivity score across the total population decreased significantly from 27.6 to 20.1 on Day 3, marking a shift from moderate to mild sensitivity according to SS-14 grading criteria. This improvement was sustained throughout the study period, with scores remaining consistently below 20. By Day 59, the average score further decreased to 18.6, nearing the lower threshold of the SS-14 scale.

Notably, the mild sensitivity subgroup demonstrated a rapid and pronounced response, achieving a tolerance level as early as Day3 after a single treatment session. This early and sustained improvement highlights the treatment's immediate efficacy in alleviating symptoms of sensitive skin.

These subjective improvements align with objective clinical assessments, reinforcing the treatment's dual action in addressing both perceptible symptoms and measurable biomarkers of skin sensitivity.

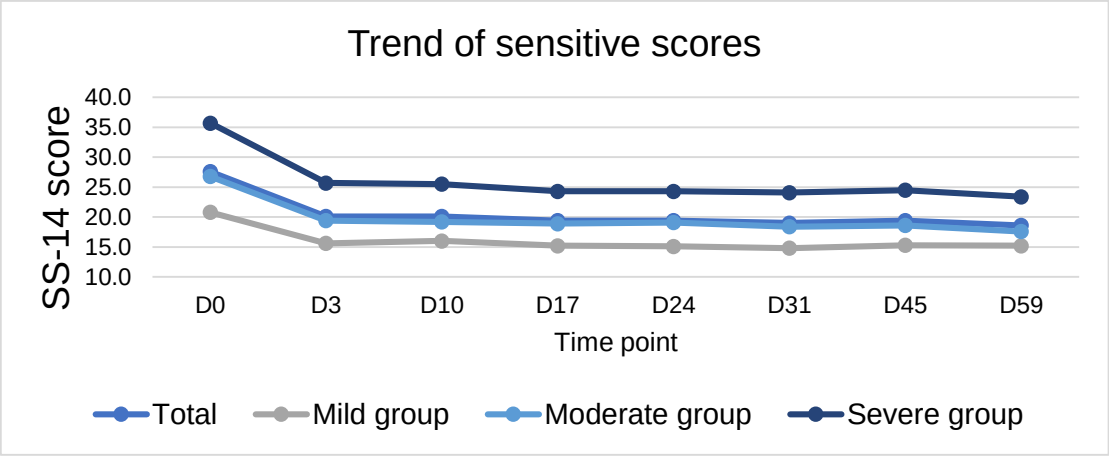

Figure 6. The trend of sensitive scores at different time points. West China Sensitive Skin Self-assessment Questionnaire (SS-14) was used to evaluate sensitive level.

3.4 Participant satisfaction rate

Beside of efficacy test, a subjective survey on satisfaction rate was conducted. On Day 31, the participant's feedback on improvements in various skin-related outcomes were collected. Firstly, the majority of participants across all groups reported that their skin felt comfortable and appeared more radiant. Secondly, a significant proportion of participants experienced reduced redness and a soothing sensation. Then, the treatment was effective in improving skin irritation and stabilizing skin condition. Lastly, the overall skin condition improvement was high across all groups, with 86.49% (mild), 94.87% (moderate), and 94.29% (severe) of participants reporting positive changes.

On Day 45 and D59, the participant's feedback on improvements in skin radiance, redness tendency, and stability across mild, moderate, and severe skin sensitivity groups were collected. A notable proportion of participants reported that their skin retained its radiance. The treatment demonstrated effectiveness in reducing skin redness tendency. Stability of skin condicton improvements were observed across all groups, with 81.08% of mild group participants, 92.31% of moderate group participants, and 88.57% of severe group participants noting enhanced skin stability.

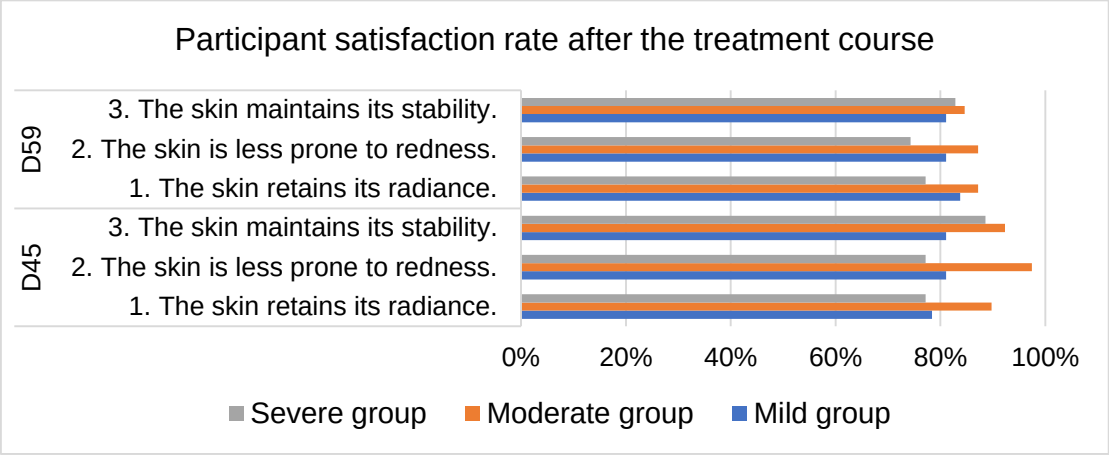

Figure 7. Participant satisfaction rate after treatment course.

4. Conclusion

Sensitive skin is highly prevalent and its incidence is on the rise, yet there is still a lack of non-invasive and effective treatment options. With the advancement of transdermal drug delivery technology, TPS has been integrated and launched to non-invasively and efficiently deliver active ingredients or drugs to the target sites in the skin for therapeutic effects. Based on the characteristics of sensitive skin, three serums were developed in combination with a device to form the TPS-based soothing treatment. Human efficacy testing showed that all tested indicators exhibited significant improvement in all attributes assessed by both clinical and instrumental evaluations, with no adverse reactions occurring during this period.

In conclusion, the TPS technology offers a novel approach to the treatment of sensitive skin. It not only provides a non-invasive and effective solution but also has the potential to be further explored and applied in the management of other skin conditions. Future research should focus on optimizing the treatment protocols and expanding the application scope of TPS to benefit more patients with sensitive skin and other dermatological issues.

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