CLINICAL EVALUATION OF A PRESCRIPTION SKIN THERAPY SYSTEM DESIGNED TO TREAT FACIAL PHOTODAMAGE: Efficacy and Safety Comparison to 0.1% TRETININ REGIMEN, 4% HYDROQUININE REGIMEN, and OVER-THE-COUNTER (OTC) REGIMEN

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ABSTRACT
INTRODUCTION: This 24-week study in 301 women evaluated the clinical efficacy and safety of a proprietary system (Prescription Skin Therapy System) composed of a specific protocol of cleanser, toner, tretinoin, hydroquinone, and SPF 30 (Group 1) compared to other treatments. Each group was balanced for a specific protocol of cleanser, toner, tretinoin, hydroquinone, and SPF 30 in a 1:1:1:1 ratio to the other three groups. Each protocol included 21 treatments. A total of 301 women with Fitzpatrick skin types I to IV were randomized into four treatment groups in a 1:1:1:1 ratio (Table 1).

RESULTS: The Prescription Skin Therapy System outperformed the other three regimens (Drug or OTC) at both 12 weeks and 24 weeks. The Prescription Skin Therapy System showed significantly greater improvements in smoothing of periorbital and periocular fine lines and wrinkles (P<0.0001) at 12 weeks and 24 weeks than the tretinoin regimen, hydroquinone regimen, and the most common over-the-counter (OTC) products recommended by physicians—cleanser, moisturizer, sunscreen, and facial cleanser (Figure 1). The Prescription Skin Therapy System was significantly more effective (P<0.05) in the mean density scores than the tretinoin regimen, hydroquinone regimen, and the most common over-the-counter (OTC) products at all seven variables as demonstrated by change from baseline in evaluations at 12 weeks and 24 weeks (Figures 1 and 2). The Prescription Skin Therapy System and the hydroquinone regimen provided the best improvements in smoothing of periorbital and periocular fine lines and wrinkles (P<0.05) at 24 weeks.

CONCLUSIONS: The Prescription Skin Therapy System was significantly more effective than the other three therapies at more endpoints in women with Fitzpatrick skin type I to IV, and compared favorably to the other three regimens in all seven variables at the end of 24 weeks. The Prescription Skin Therapy System system outperformed the other three regimens (Drug or OTC) at both 12 weeks and 24 weeks.

METHODS AND PROCEDURES
Study Design
A total of 301 women with Fitzpatrick skin type I to IV were randomized into four treatment groups in a 1:1:1:1 ratio (Table 1). Group 1: Prescription Skin Therapy System including cleanser, toner, tretinoin, hydroquinone, and sunscreen (n=75). Group 2: 0.1% tretinoin cream and SPF 30 (Group 2) (n=79). Group 3: 4% hydroquinone cream and SPF 30 (Group 3) (n=79). Group 4: The most common over-the-counter (OTC) regimen (n=78). A subgroup of patients (n=40) agreed to have two facial skin biopsy samples taken; ten were placed randomly into each of the four treatment groups. A total of 301 participants completed the study; all were women (mean age 52 yr) and the majority were Caucasian (91.02%). Each patient was randomly assigned to treatment groups. The study was conducted at five sites in Texas and California.

Efficacy Evaluations
Facial Photodamage
- The change (from baseline) in the facial photodamage score (erythema, edema, scaling, papular rash, burning, stinging, itching, and tightness) was assessed by investigative clinical graders at baseline and 1, 6, 12, 18, and 24 weeks of treatment. Each of the above seven parameters was scored on a 0 (none) to 10 (extensive) scale.

Safety and Tolerability Evaluations
- Adverse events were monitored during the study at each visit. Adverse events were assessed by the investigator (ophthalmologist). Participants were monitored for safety assessments throughout the study.

RESULTS
- A total of 301 patients completed the study at all seven time points (age 52 yr). The majority were Caucasian (91.02%). Each patient was randomly assigned to treatment groups. The study was conducted at five sites in Texas and California.

CONCLUSIONS
- The Prescription Skin Therapy System significantly improved periorbital fine wrinkles, perioral fine wrinkles, facial acne, melasma, hyperpigmentation, clarity, sallowness, tactile roughness, and laxity compared to the other three regimens (Drug or OTC) in all seven variables at 24 weeks.

REFERENCES

Figure 1. Comparative Efficacy at 12 Weeks

Figure 2. Comparative Efficacy at 24 Weeks

Figure 3. Table 1. Study Treatments

Figure 4. Table 2. Study Assessment Criteria

Figure 5. Table 3. Demographics of Study Population