tria®

SEE BEAUTY IN A NEW LIGHT™

THE TRIA AGE-DEFYING LASER

Background and Objectives

Non-ablative fractional lasers have been used by doctors for over a decade to treat aging skin caused by sun damage. These treatments have been largely limited to medical professionals and often require multiple visits to the doctor's office, which can be costly and inconvenient to patients. Self-treatment with a home-use laser device is an attractive option for consumers wishing to effectively treat multiple signs of aging at a time that is convenient to them and with less expense.

Recently, a novel 1440 nm non-ablative fractional diode laser intended to treat multiple signs of aging was developed for consumer use. This study was designed to demonstrate the safety and efficacy of this home-use device for the treatment of fine lines and wrinkles (periorbital and perioral), dyschromia (uneven pigmentation), tactile roughness (textural irregularities), and diffuse redness.

Study Design/Materials and Methods

Thirty-four subjects were enrolled in a split-face study. Each side of the face was randomly assigned to either daily treatments (5 days a week) or biweekly treatments at different treatment levels. Subjects self-treated at the study site for 12 weeks and were followed for 8 weeks after their final treatment. An independent, blinded dermatologist evaluated and scored standardized photographs utilizing a 9-point scale for wrinkles, uneven pigmentation, and diffuse redness. A live assessment of tactile skin roughness was performed by the investigator with a back-of-the-hand methodology using a 9-point scale. Treatment tolerability was assessed daily during the treatment phase using a visual analog scale for pain, where 0 is no pain and 10 is extreme pain. Adverse events were monitored throughout the study. Subject satisfaction surveys were conducted periodically.

Results

All treatment regimens resulted in clinically significant results, defined as having at least a 1-point improvement on the 9-point scale by a blinded dermatologist. Results reflecting the daily treatment group using the device's treatment level 2 are highlighted below.

Blinded Dermatologist Evaluation (TABLE 1)

- 75% of subjects showed at least a 1-point improvement in dyschromia, diffuse redness, periorbital wrinkles, and perioral wrinkles 4 weeks after final treatment as determined by a dermatologist
- Improvement was statistically significant ($p<0.05$)

Investigator Evaluation of Tactile Roughness (TABLE 1)

- 100% of subject had at least a 1-point improvement
- Mean improvement score was 2.5 ± 0.9 ($p<0.01$)

TABLE 1:
Percent of subjects showing at least a 1-point improvement

Dyschromia	75%
Diffuse Redness	75%
Periorbital Wrinkles	75%
Perioral Wrinkles	75%
Tactile Roughness	100%

Subject Questionnaire (TABLE 2)

At 4 weeks post final treatment

- 58% of subjects saw improvement in brown areas/spots
- 67% of subjects saw improvement in redness and wrinkles
- 75% of subjects saw improvement in skin texture
- 92% of subjects were satisfied with their treatment

TABLE 2:
Percent of subjects reporting results

Reduction of Brown Spots	58%
Reduction of Redness	67%
Reduction of Wrinkles	67%
Skin Texture Improvement	75%
Satisfaction with Treatment	92%

Subject Reported Pain

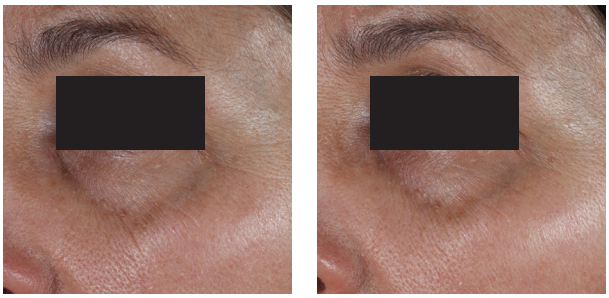
- Mean pain scores from treatment started at 2.9 out of 10 for the first week of treatment, declining to 1.6 by the second week, and dropping to 0.1 by the last week of treatment

Side Effects

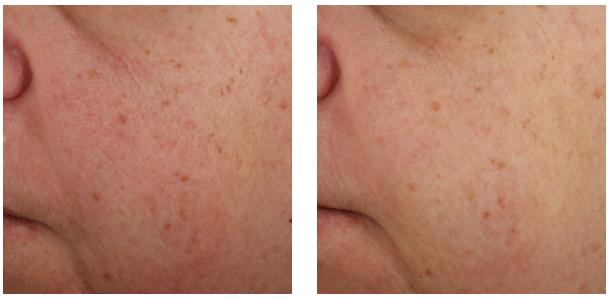
- No severe incidents related to the treatment were reported
- Most common device related incidents were redness, stinging/prickling, and burning sensation
- Most (97%) events were reported as trace to mild and resolved minutes after treatement

CONCLUSIONS

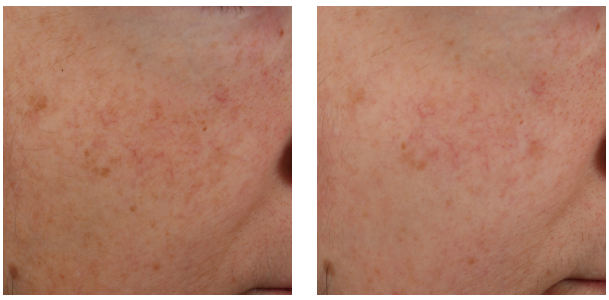
The study showed that the novel consumer 1440 nm fractional non-ablative diode laser is safe for at-home consumer use and well-tolerated. Blinded physician assessed efficacy showed clinically significant improvement in periorbital and perioral wrinkles, dyschromia (uneven pigmentation), diffuse redness, and tactile roughness. A majority of subjects were satisfied with their treatments and saw improvement in each of the parameters assessed.



Baseline (left) and 4 weeks after final treatment (right) showing reduction in periorbital wrinkles



Baseline (left) and 4 weeks after final treatment (right) showing reduction in diffuse redness



Baseline (left) and 4 weeks after final treatment (right) showing reduction in dyschromia

The Tria Age-Defying Laser is FDA cleared for the treatment of periorbital wrinkles (crow's feet) which may result in smoother appearing skin in the treated area

Source: Shaffer N, Biesman B, Ostrowski R. Clinical Outcome of a Randomized Split-Face Treatment with a Novel 1440 nm Skin Rejuvenating Laser [abstract]. In: ASLMS 33rd Annual Conference; 2013 April 3-7; Boston, MA, p 23. Abstract nr 65