Procedure for evaluating change in eyebrow position induced by ultrasound skin tightening

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Background

The objective of this study was to demonstrate the effectiveness and safety of the Ulthera™ ultrasound system as a relatively non-invasive treatment of facial rhytids through tissue coagulation and tightening.

The purpose was to develop a reproducible method acceptable for detecting clinically significant change in eyebrow position. This was applied in the context of evaluating an ultrasound device for tightening skin. A photographic method was developed to assess data associated with ultrasound skin effect on brow position.

The Ulthera™ Device

The Ulthera™ system images and delivers focused ultrasound energy to a specific soft tissue layer under the superficial layers of the epidermis. The device is designed to produce small (approx 1mm^3) micro-thermal lesions in the mid to deep reticular layer of dermis and sub-dermis, while sparing overlying papillary dermal and epidermal layers of skin. The device also incorporates an ultrasound imaging capability to evaluate the skin tissue, helping in determining local depth of sub-dermal boundaries.

The Ulthera™ device provides a non-invasive treatment to produce eyebrow lift. Targeted ultrasound therapy is a desirable alternative to more invasive treatments such as face-lifts (rhytidectomy) and the use of fillers which can often lead to undesirable postoperative effects.

Subjects

35 adult subjects enrolled at Northwestern University Department of Dermatology.
Approximately half had received prior cosmetic procedures, though no tightening procedures within 1 year were allowed for enrollment.
Subjects with mild to moderate facial laxity.
Subject mean age was 53 years old (range 40-69).

Methods

This study was a prospective, non-randomized, clinical trial conducted on 35 subjects with facial rhytids. Subjects were treated with the Ulthera™ ultrasound device (Ulthera, Inc., Mesa, AZ). Full face and neck were treated with a single pass of either of two transducers: 7.5 MHz transducer with 4.5mm focal depth for temple, preauricular, submental/neck areas and 4.4 MHz probe with 4.5mm focal depth for the cheeks. The energy level used ranged between 0.4 Joules to 1.2 Joules.

Evaluation tools included:

- Double-blinded rating of pre-and post-treatment photographs taken before and after treatment, and at 2, 7, 28, 60 and 90 days post-treatment.
- Quantitative assessment of browline elevation
- Physician grading of physical features (hypo- and hyperpigmentation, vascularity, ulceration/erosion, fine texture, coarse texture, pliability, laxity)
- Subject self-assessment of efficacy and and subjective pain scores.

Evaluation of Change in Eyebrow Position

A masked clinician assessment method was used to evaluate changes in eyebrow position based on pre-treatment and post-treatment standardized photographs and was validated using the following procedures:

1. Two experienced clinicians reviewed pre- and post-treatment photographs of 25 study subjects side by side in an unblinded manner until reaching a consensus on eyebrow position. The endpoint was change or no change in eyebrow position. The results of this review were the reference standard for the clinical assessment.
2. Three masked, experienced clinicians independently evaluated randomized pre- and post-treatment photographs of 25 subjects side by side. Clinicians were asked to differentiate between pre- and post-treatment photographs based on clinically identifiable changes. The endpoint was change or no change in eyebrow position.
3. A change in eyebrow position between the pre- and post-treatment photographs as identified by the clinicians was defined as clinically significant.
4. The masked clinician assessment method was validated by comparing the results from the 2 unmasked reviewers to the 3 masked reviewers using the Kappa statistic.

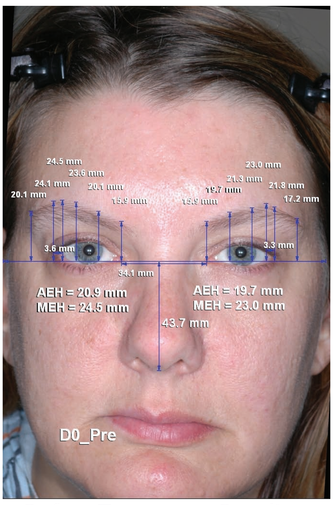
Efficacy Results

- Quantitative brow elevation
  - Greater than or equal to 0.5 mm seen in 89% of evaluable subjects at 90 days
  - Mean change in maximum eyebrow height: 1.9mm.
  - 3 blinded reviewers noted that 85.7% of the 35 subjects were "improved."
- 75% of subjects were either "satisfied" or "very satisfied" with improvement in eyebrow position

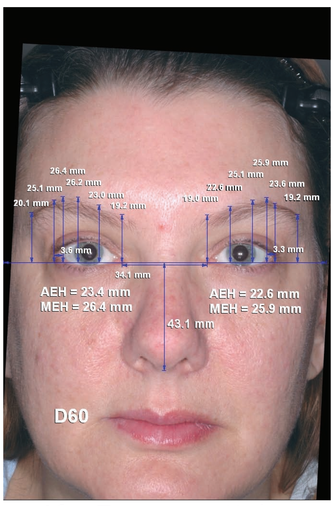
Safety Results

- Subject pain perception on a ten point scale ranged from 2 to 8 with a mean pain score of 4.4.
- Rare high pain values reported by subjects who had no history of cosmetic procedures.
- 71% of patients experienced mild to moderate transient erythema and/or edema.
- No documented scar formation, no erosions, no infection, no treatment-stopping pain, no nerve/muscle dysfunction, and no permanent sequelae.

Before and After Photos



Before Treatment: Baseline



After Treatment: 60 days

1. Matching

All post-op 0° images are matched to the adjusted pre-op image utilizing the match orientation function of Canfield's Mirror software. This aligns all medial canthi for 0° images to the same horizontal line.

2. To Measure Eyebrow Height

a. Measurements from the line drawn through the medial canthi to the top edge of the eyebrow are taken.
b. Starting at the medial canthi to the top of the eyebrow and then extending laterally in 8mm increments 5 measurements in total are taken.
c. The maximum height is pin pointed and measured to the same medial canthi line.

Conclusions

We concluded that validated masked assessment of standardized photographs by experienced clinicians, in addition to subject satisfaction measures demonstrates a positive post-procedure change in eyebrow position.

The Ulthera™ ultrasound device is an effective modality for brow lift of 1-3 mm, which is quantitatively verified. It is also effective in the reduction of forehead and crow's feet and improvement of neck definition, also verified by blinded raters in this study. The device is expected to produce only transient erythema and edema, with no known long term undesired events. Further parameter optimization may permit even greater efficacy given underlying technology.

Additional Information

We acknowledge Ulthera, Inc. as the sponsor of this study.

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