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 methodology 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 is designed to deliver 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) micro-thermal lesions in the end 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 desirable alternative to more invasive treatments such as face-lifts (rhytidectomy) and the use of fillers which can produce temporary results. Ultrasound treatment of the brow is non-invasive, with no visible marks or bruising. Furthermore, this procedure is usually well tolerated with only transient erythema and edema, with no known long term undesired effects. In 2013, the Food and Drug Administration approved the use of Ulthera™ device for the non-invasive treatment of facial skin laxity in the submental/neck area.

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

Subjects

35 adult subjects enrolled at Northwestern University Department of Dermatology. Approximately half had received prior cosmetic procedures, though no prior cosmetic procedures. All subjects had facial rhytids. Subjects were treated with the Ulthera™ device.

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: 1.9 mm
• 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

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 the cheeks. 4.4 MHz probe with 4.5mm focal depth for temples, preauricular, submental/neck areas and lateral aspect of forehead and crow’s feet. Subjects were treated at 100 W/cm² 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.

Evaluation of Change in Eyebrow Position

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.

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.

Conclusions

We concluded that validated masked assessment of standardized photographic images is an acceptable method to evaluate subject satisfaction measures demonstrates a positive post-procedure change in eyebrow position.

Additional Information

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

Principal Investigator:
Mural Alen, MD
Chief, Section of Cutaneous and Aesthetic Surgery
Department of Dermatology
m-alen@northwestern.edu