SAFETY STUDY OF TRANSCUTANEOUS FOCUSED ULTRASOUND FOR NON-INVASIVE SKIN TIGHTENING IN ASIANS

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Background and Objectives: The objective of this study is to determine the safety of a novel focused ultrasound device (Ulthera™ System) in the treatment of facial skin laxity in Asians.

Materials and Methods: The patients received one to two full-face treatments with the transcutaneous focused ultrasound device. Three transducers (7.5MHz, 3.0mm depth; 7.5 MHz, 4.5 mm depth; 4.0MHz, 4.5 mm depth) were used to deliver a single pass of microthermal areas of coagulation without any topical anesthetics. Standardized photos were taken with the Canfield Visia CR System® and all patients were clinically assessed for adverse effects up to six months post treatment. Subjective assessments were also evaluated with patient questionnaires.

Results: Forty-nine Chinese patients (skin type II-IV, mean age 53.3) completed a total of 58 treatment sessions. Focal bruising and numbness were present in up to 1.72% of treatment sessions. Two cases of mild post-inflammatory hyperpigmentation over the forehead were noted within one month post treatment, both of which have responded to topical bleaching agent. The treatments were well-tolerated with an average pain score of up to 6.85 out of 10.

Conclusions: Transcutaneous high intensity focused ultrasound appears to be safe and well-tolerated for non-invasive facial skin tightening in Asians. Adverse events are mild and transient. No permanent or delayed side-effects were noted up to six months post treatment.