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CONTACT (NAME ONLY): W Matthew White

CONTACT (E-MAIL ONLY): mattent2b@comcast.net

TITLE: Clinical pilot study utilizing Intense Ultrasound (IUS): a novel approach for the transcutaneous delivery of energy to facial skin

AUTHORS (ALL): Gliklich, Richard¹; White, W Matthew¹; Makin, Inder Raj S.²; Slayton, Michael H.²; Barthe, Peter G.².

INSTITUTIONS (ALL): 1. Otolaryngology, Mass Eye and Ear Infirmary, Boston, MA, USA.
2. Ulthera, Inc, Mesa, AZ, USA.

ABSTRACT BODY: Intense Ultrasound is a novel approach to transcutaneously focus energy in tissue to induce selective (0.5 – 5 mm³) micro-ablative thermal regions (MATR) in deep dermal or subcutaneous tissues, while sparing the overlying epidermis. This study was an open label, prospective pilot phase-I human study to determine the skin response after exposure to an investigational ultrasound device. Thirteen (13) patients scheduled to undergo a mini-facelift were enrolled in this study. Patients were divided into 2 groups with respect to the timing of their surgery after IUS treatment: early (within 24 hours) and delayed (4 to 8 weeks). Prior to treatment, preauricular areas were mapped, such that IUS exposure was performed only on skin destined for surgical excision. An average of five lines of IUS exposure spots were placed on each side of the face using three probe types (superficial, mid, deep). After each exposure, the subjects were asked to rate sensation using a 0 to 5 point ordinal scale. Histologic analysis of excised tissues using nitro-blue tetrazolium chloride (NBTC) viability stain confirmed the thermal denaturation of collagen within the deep reticular dermis by IUS exposure. Exposure power levels of ≥ 0.5 Joules were necessary to create MATR within the dermis for all probes. This threshold source power reliably produced transient superficial skin erythema, and correlated with an average pain sensation score of 3 out of 5. There were no changes in sensory or motor nerve function. Initial clinical experience with the IUS system confirms that exposures to facial skin can be performed in a safe manner. Within the source condition regime of probe type, exposure time and power, MATR were created with minimal skin changes and discomfort. Further studies are necessary to determine the efficacy of facial tissue treatment with IUS.

KEYWORDS: Rhytidoplasty/methods, ultrasound, Skin aging.