

## **HIGH INTENSITY, HIGH DENSITY DELIVERY OF ULTRASOUND PULSES IMPROVES FACIAL AND NECK WRINKLES: RESULTS OF IN VIVO PIG SKIN HISTOLOGY AND HUMAN CLINICAL STUDIES**

Controlled thermal heating of dermal connective tissue has been shown to improve skin laxity and wrinkling. We describe a novel, non-invasive, high intensity ultrasound (U/S) with multiple array of low divergence beams technology generating isolated regions of tissue coagulation in the mid-dermis with no epidermal damage. The results of the numerical simulation and in vivo animal model will be presented. A prospective, IRB- approved 60 patient multi-center clinical study evaluated the clinical effects of this U/S technology on facial and neck lines and was the basis of FDA clearance.

The technology utilizes multiple ultrasonic transducers that simultaneously emit low divergence ultrasonic beams perpendicularly to the skin surface and into the dermis. Simultaneous skin surface cooling is applied via the applicator and real time measurement of skin temperature ensures the prevention of epidermal thermal damage. A numerical simulation of the ultrasonic beam was performed using a proprietary 3D time dependent code to solve the bio-heat equation in order to analyze temporal and spatial temperature distribution in the tissue at different U/S power levels.

Treatment parameters were further optimized in an in vivo pig model. Sixty patients with mild to moderate facial wrinkles were enrolled. A single full face and anterior neck was performed after the application of an anesthetic (7% tetracaine/30% lidocaine) cream. Overall, 295 areas were treated. Standardized 35 mm photography was performed before treatment and at the 1 week and 3 months follow up visits. The treatment endpoints were a change in the Fitzpatrick Wrinkle Score (FWS) and improvement in a 5-point global aesthetic improvement score (GAIS).

Well-defined volumetric cylindrical shaped fractionated coagulation zones in the mid dermis with no epidermal and fat damage were shown by histology. Control of coagulation volume was achieved by varying ultrasonic intensity. At 3 months, investigators rated 88% of the subjects to be improved to very much improved on the GAIS and 86% of the subjects were improved by either -1 or -2 or -3 FWS scores. 72% of the subjects were satisfied with their results and rated them as improved to very much improved on the GAIS. Safety profile was excellent with no adverse events reported.

This novel, non-invasive, U/S technology resulted in no downtime, no unanticipated adverse events and produced demonstrable improvement in wrinkles of the face and neck. Histologic studies showed cylindrical volumetric fractionated mid-dermal coagulation zones with sparing of the epidermis and no damage to fat. Stimulation of long-term tissue remodeling and associated generation of inflammatory mediators is likely the result of the activation of the wound healing cascade leading to unique induction of directional collagen remodeling to restore natural skin tightening.