HIGH FREQUENCY (20 MHZ) FOCUSED ULTRASOUND (HIFU), A NOVEL METHOD FOR TATTOO REMOVAL: PRE-CLINICAL EXPERIENCE AND FIRST EXPERIENCE IN MAN

Jørgen Serup[1], Torsten Bove[2], Tomasz Zawada[2]

[1]Bispebjerg University Hospital, the Tattoo Clinic
[2]TOOsonix A/S, Denmark

Background:

High-intensity focused ultrasound applied at high-frequency in the dermis is a novelty. Temperatures about 65 degrees Celsius and an additional effect, i.e. cavitation, are dosed precisely in the skin wherever intended, guided by a camera.

Studies:

Preclinical evaluation in the laboratory and in skin equivalents have shown that the sound energy (System ONE-R, TOOsonix, DK) can be dosed reproducibly in a highly controllable manner with different transducers defining the depth of the focal point, and at settings of the energy in the range 0.4 to 1.5 J, at selected shot duration of 150 ms. The geometry of the acoustic lesion is conical with a broader field of thermal effect over the focal point thus towards the surface of the treated object. This was confirmed in isolated liver and muscle samples from pigs.

Studies in anesthetized mini pigs with three months follow up confirmed the reproducibility, linearity and precision of the method, with superficial crust formation of the epidermis occurring after 1-3 weeks. Dosing was immediately followed by a wheal and flare reaction. Histology demonstrated no fibrosis at the 3-month endpoint using high dose i.e. 1.2 J at single shot. Fields formed by 5x5 shots grouped together showed reproducible crust formation, and minor fibroid reaction in the very outer dermis only, leaving no or subclinical scarring. Crusts were epidermal tissue with no collagen on Masson stain. Ultrasound scanning (20 MHz, Cortex Technology, DK) showed echo-lucent fields in the dermis depending on dosage and in agreement with histology and preclinical findings. Human studies included an initial case experiment using high dose applied to a black tattoo, which after one treatment and prominent crustation was removed.

In an ongoing clinical experiment on tattoo removal it has been confirmed that tattoos can be removed after 1-3 treatments. Ultrasound is independent of optical properties and color of the pigment and can be applied to any tattoo. In the clinical experiment, skin diseases such as actinic keratosis, basal cell carcinoma and Kaposi sarcoma also have been addressed. Larger clinical protocols are under preparation. The system is primarily launched for tattoo removal.

Conclusion:

This novel ultrasound HIFU method has passed initial animal safety studies. The system is ready for further application in various fields of dermatological therapy, primarily the indication tattoo removal. The method has the potential to supplement or replace lasers, depending on indication. The method offers new options such as removal of any tattoo with one system only; independent of tattoo color, using 1-3 treatments.