



# Efficacy, safety and duration of benefit for ITU (Intense Therapy Ultrasound) home treatments

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## **Abstract**

**Background:** High frequency ITU, designed specifically for longer exposures (seconds) and lower intensities ( $<500\text{w}/\text{cm}^2$ ) could be preferentially used for home applications where repeated treatments are typical and tolerable. **Aim:** Clinical studies goals: Show statistically significant efficacy and safety of handheld devices used daily. Estimate the duration of the benefit during and after treatment regimen. **Materials and Methods:** A prototype of novel battery-powered handheld ITU device was clinically investigated in 2 studies (total 70 subjects). Both clinical studies required daily treatment for 28 and 24 days respectively. Therapy lines were delivered at 5.9MHz and 5.0MHz frequency with the duration of 9.5 and 6 seconds/line respectively. Range of 120 – 220 lines to the same areas were applied for the first and second studies. Independent live clinical assessments were performed at the baseline and during the regimen. Photographs were independently assessed using 4 point scale (“no change” to “significant improvement”). Second study included clinical assessments up to 120 days after the regimen. **Results:** Tightening submental and lower cheek areas per clinical live assessment yielded statistically significant ( $p\leq 0.05$ ) improvements in 83% of the subjects. Photographic assessment produced 79% improvement in subjects with 96% satisfaction at 2 weeks and 88% satisfaction in 4 weeks by self-assessment. Additional improvements combined firmness, fine line and pore size reduction by clinical assessment and were statistically significant ( $p\leq 0.05$ ) in 88% of the subjects. Clinical assessment (120 days) and self-assessment (210 days) post-regimen in 2nd clinical study showed no reduction in improvements across clinical indications. **Conclusions:** Battery powered handheld ITU devices are feasible for statistically significant improvements for lower facial tightening and skin quality improvements. Clinical benefits last at least 120 days post treatments in groups clinically assessed and 210 days by self -assessment. Transient side effects were limited to erythema and slight edema within 12 hours post treatments.