

combined 1064/1320 nm multiplex system however caution should be used when exceeding external skin temperatures of 40 degrees Celsius to avoid unwanted thermal burns. Future studies comparing the end temperature and wavelengths independently may help to uncover the optimal system needed for skin contracture.

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### A PROSPECTIVE CLINICAL STUDY OF NONINVASIVE CRYOLIPOLYSIS FOR SUBCUTANEOUS FAT LAYER REDUCTION—INTERIM REPORT OF AVAILABLE SUBJECT DATA

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**Background:** Published animal studies and unpublished controlled human studies have demonstrated that cryolipolysis (cold-induced apoptotic fat cell death) is safe, well tolerated, and capable of reducing the thickness of the subcutaneous fat layer without damage to the overlying skin or associated structures. This study evaluated cryolipolysis for fat layer reduction from the flanks (love handles) and back (back fat pads) when used by clinicians in an environment representative of routine clinical practice.

**Study:** This multi-center, prospective, non-randomized, IRB-approved study enrolled male and female subjects > 18 years of age with clearly visible fat on the flank or back appropriate for treatment with cryolipolysis. Cooling was applied by a prototype device to the treatment area using pre-programmed treatment profiles that control the rate of heat extraction and treatment duration. A contralateral untreated area (e.g., the opposite flank or portion of the back) was maintained as a control. Efficacy was evaluated by ultrasound measurement of fat layer reduction, comparison of pre and post-treatment photographs and physician assessment.

**Results:** Based on interim results from 32 subjects, photographic, ultrasound and physician assessment confirm that cryolipolysis results in a visible contour change in a majority of subjects. Ultrasound measurements taken on a subset of 10 subjects demonstrated a fat layer reduction in 100% of these subjects with an average reduction of 22.4% at four months post-treatment. Subjects presenting with modest fat bulges had the best cosmetic results. There were no device related adverse events reported.

**Conclusion:** Selective cryolipolysis results in reductions in subcutaneous fat without damage to the surrounding tissues. While all subjects for whom ultrasound images were obtained showed a significant reduction in fat layer, cosmetic improvement

was more readily observed in subjects with modest fat bulges. Further studies of fat reduction effects in other anatomical areas with optimized treatment parameters are warranted.

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### STUDY USING EXTERNAL FOCUSED ULTRASOUND FOR BODY CONTOUR WITH THE NEW 1 HZ HAND PIECE COMPARED TO THE 3 HZ HAND PIECE

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**Background:** We describe our experience in treating body contouring using the technologies of focused ultrasound (Contour I- Ultrashape, Tel Aviv, Israel), comparing the results obtained applying 1 Hz pulse hand piece to the 3 Hz.

**Study:** After two years of experience with the Contour I- Ultrashape device, in last 12 months we performed 354 treatments of 83 patients with localized fat tissue for the purpose of this study as mono therapy. 85% women and 14% men, aged 23-65 were treated. All patients underwent 3 sessions with at least 800 pulses with a 2 weeks interval. Areas treated: abdomen (33%) flanks (40%), outer thighs (14%), inner thighs (3%), knees (3%), axillary's fold (3%), and buttock's fold (4%). 63 (76%) were treated with the 3 Hz and 20 (24%) with the new 1 Hz. All patients were pictured by Vectra 3D system (Canfield, NJ, USA). Efficacy determined by circumference measurements, 3D pictures and patient satisfaction.

**Results:** We measure all patients, that showed significant reduction with at least 1,2 cm in circumference each session and 1.8 cm average, showed also on the 3D pictures and satisfaction related to the improvement on the appearance of body silhouette was 86%. Pain was present in 7 patients (35%), even with cold oil and lowering the level of energy. Other side effects referred in all patients were mild transient erythema, 2 (1,6%) cases of epidermolysis and without any other major side effect.

**Conclusion:** Non invasive body contouring by focused ultrasound is safe and efficient for localized fat tissue with both, 1 and 3 Hz devices. We achieved with the new 1 Hz hand piece the same results and safety issues. As expected, the new hand piece optimized the treatment time in 30%.

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### CELLULITE TREATMENT WITH PHOTOMOLOGY® TECHNOLOGY

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**Background:** Photomology® technology combining dual-band light with mechanical massage and suction provides moderate temperature elevation and mechanical manipulation that improves local blood circulation, metabolic activity including lipolysis and stimulates chemical reactions.

**Study:** SmoothShapes® system uses 915 nm (10 W) laser light that is preferentially absorbed in lipids with temperature

elevation for fat liquefaction and 650 nm (1 W) light for changes in adipocytes permeability. Suction and massage assist in evacuation of liquefied fat from intracellular space. Volunteers with mild-moderate cellulite received 8 to 12 twice-a-week treatments on one thigh, while the contra-lateral thigh served as a control.

**Results:** 30 female patients, phototypes I to V, mean age 40 years, underwent the treatment. The mean circumferential reduction on the high level of the thigh was 1.58 cm after 5 sessions, 2.44 cm after 8 sessions, 1.4 cm at one month after the last session on the treated thigh. In comparison, the non treated side had circumferential reduction of 0.55 cm at 5 treatments, 0.01 cm at 8 treatments, and 0.81 cm at one month after the last session. At 3 months results were stable or decreasing on some patients. Results at 6 months were still interesting but showed necessity of performing new sessions. Patient's weights were stable without any diet. Patients' high level of satisfaction was due to the comfort and the efficacy of the treatment.

**Conclusion:** Photomology is a comfortable treatment and had high percentage of responders with improvement in cellulite.

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

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**Background:** 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.

**Study:** The patients received one to two full-face treatments with the transcutaneous focused ultrasound device. Three transducers (7.5 MHz, 3.0 mm depth; 7.5 MHz, 4.5 mm depth; 4.0 MHz, 4.5 mm depth) were used to deliver a single pass of microthermal areas of coagulation without any topical anaesthetics. Standardized photos were taken with the Canfield Visia CR system® and all patients were clinically assessed for adverse effects up to 6 months post treatment. Subjective assessments were also evaluated with patient questionnaires.

**Results:** 49 Chinese patients (skin type III–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.

**Conclusion:** 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 6 months post treatment.

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### FRACTIONAL RADIOFREQUENCY TREATMENT SPARES SKIN STRUCTURES VITAL TO THE WOUND HEALING PROCESS

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**Background:** Noninvasive bipolar and monopolar radiofrequency (RF) deep dermal heating devices have previously been described. The thermal effects of Renesis™, a novel minimally invasive RF device, on human skin in vivo were characterized for the first time.

**Study:** The device was configured to operate in bipolar mode delivering energy directly within the dermis using 5 micro-needle electrode pairs with real-time feedback of tissue temperature for treatment control. Superficial cooling was achieved using a Peltier device. A range of pulse durations between 1 and 25 seconds, and lesion temperatures between 60 and 80°C were tested in vivo on 15 human subjects. Thermal effects were assessed histologically using either hematoxylin & eosin (H&E) or nitroblue-tetrazoliumchloride (NBTC) staining.

**Results:** The investigational bipolar RF device delivered controlled heating within dermal tissue. Histological staining with H&E revealed the presence of zones of denatured collagen within the reticular dermis. Fractional lesions separated by zones of sparing as well as contiguous lesion patterns were demonstrated. Histological staining with H&E and NBTC revealed sparing of adnexal structures and adipose tissue.

**Conclusion:** A novel fractional RF device utilizing a minimally invasive bipolar micro-needle delivery system for the treatment of human tissue was developed. To our knowledge, this is the first report to describe use of a direct real-time temperature and impedance feedback system to control energy delivery during deep dermal heating. Treatment of 15 human subjects illustrated the controlled creation of dermally located thermal coagulation zones, known as radiofrequency thermal zones. We discovered that varying the pulse length allowed for fractional sparing of epidermal, dermal, and adipose tissue, as well as vasculature and key adnexal structures. Our findings provide novel insights regarding the concept of fractional treatment with an extension of the definition to include sparing of all skin structures vital to the wound healing process.

## COMBINED BASIC SCIENCE, CUTANEOUS LASER SURGERY, AND OTOLARYNGOLOGY

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### LASER GENERATED SHOCKWAVE FOR CLEARING MEDICAL DEVICE BIOFILMS Yosef Krespi, Victor Kizhner, Paul Stoodley

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**Background:** Biofilm has emerged as a new threat not amenable to most antibiotic treatments. Biofilms as opposed to planktonic bacteria develop exopolysaccharide matrix to facilitate adherence to tissue or prosthetic surface forming a resistant shield. A new