



Title	Safety and efficacy evaluation of a combined device using infrared light and bipolar radiofrequency and sublative radiofrequency applicators
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Safety and efficacy evaluation of a combined device using infrared light and bipolar radiofrequency and subablative radiofrequency applicators

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Objective: The combined infrared light and bipolar frequency and subablative radiofrequency dual handpiece device is intended for dermatological procedures requiring ablation and resurfacing of the skin. The objective of this study was to evaluate the safety and efficacy of the combined subablative radiofrequency and subablative applicators for the treatment of wrinkles.

Methods: Twenty subjects were recruited of whom 16 received the treatment and were followed up till 3 months. Each patient was treated once, first with the subablative applicator which used a combination of infrared (700-2000 nm) and bipolar radiofrequency energy; followed by the subablative radiofrequency handpiece, 2 passes of 65 mJ with a 64 pin tip and 30 mJ with a 30 pin tip for different areas. Objective assessment was performed by evaluation of standardised photography by independent physicians. Subjective assessment was performed by the study investigator based on subjective Global Aesthetic Improvement scale and grade the severity of wrinkling based on the Fitzpatrick Classification and elastosis score. The subjects were asked to complete a questionnaire.

Results: All subjects experienced moderate-to-severe pain during treatment. Other adverse effects include swelling, erythema, heat sensation, and crusting. From the preliminary data, three out of 11 subjects felt that there was an increase in pigmentation at 3-month follow-up. They noticed subjective improvements in skin texture, pore size, pigmentation, and skin laxity. The improvement in wrinkles seemed to be the most obvious. Investigator assessment showed statistically significant improvement in Fitzpatrick Wrinkle Scale ($P = 0.025$ and 0.014) and degree of elastosis score ($P = 0.005$ and 0.005) at 6 weeks and 3 months post-treatment, respectively.

Conclusion: From the preliminary data, there is subjective improvement in photoaged skin by the combined device using infrared light and radiofrequency and subablative radiofrequency applicators.

Efficacy of a high-intensity focused ultrasound device for non-invasive body contouring

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Objective: High-intensity focused ultrasound (HIFU) is a non-invasive technology for body contouring. HIFU is focused within the subcutaneous adipose tissue, causing coagulative necrosis and cell death. The objective of this study was to evaluate the effectiveness of a HIFU device for sculpting of the abdomen.

Methods: The system has a set focal depth of 1.3 cm. Twelve subjects with adipose thickness of no less than 2.5 cm who met the screening criteria were recruited. Each subject received one treatment to the abdomen. The total fluence used per site was 150-165 J/cm² with a mean of 161 J/cm². The waist circumference at iliac crest and the point of maximum circumference were recorded at baseline, and 4, 8, and 12 weeks post-treatment, as well as their weight and body mass index. Subjects' rating on comfort level and satisfaction were collected via questionnaires at every follow-up. Standardised photographs were also taken with the Canfield System® at each visit.

Results: Of the 12 subjects, seven were satisfied with the outcome and nine would recommend this treatment to their friends and family. There was statistically significant improvement in the waist circumference measured at both the iliac crest ($P = 0.013$, 0.002 , and 0.005) and maximum waistline ($P = 0.003$, 0.034 , and 0.023) at 4, 8, and 12 weeks post-treatment, respectively. Spearman's rho for correlation of energy level versus improvement showed that at 12 weeks' post-treatment follow-up, the improvement significantly correlated with the total fluence per treatment ($P = 0.041$). The higher the total fluence delivered, the larger the decrease in waist circumference.

Conclusion: HIFU effectively decreases waist circumference in Chinese. The higher the total fluence delivered, the larger the decrease in waist circumference was observed.