
Multi-Center Study of SmoothShapes® System for Reduction of Thigh Circumference

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Background and Objective: The SmoothShapes® device incorporates laser and light wavelengths with mechanical manipulation and is a proven technology for the treatment of cellulite. Previous findings using the device prompted further investigation into the resulting decrease of subcutaneous fat. The study was undertaken to evaluate the effectiveness, reproducibility and longevity of the SmoothShapes System for the treatment of thigh circumferential reduction.

Study Design/ Methods: Six clinical sites in the US and Europe participated in the multi-center, IRB approved, single-blinded clinical study where female subjects between the ages of 21-66, skin type I to VI, with various BMI's ranging from normal BMI to overweight, were randomly assigned to have one thigh treated and the other serve as control. The number of subjects per site varied from 10 to 26. Weight, digital photographs and thigh circumference was recorded pre –treatment, during treatments and at 1 month and 3 month follow-up visits. Both thighs had 3 measurements taken, by a blinded investigator, with a spring-loaded tape at each of three locations on the thigh: upper, mid and lower. Location for measurement was determined with a laser-based level device and recorded in the subjects chart for accuracy and reproducibility during follow-up measurements. Treatment regimen consisted of 8, twice-a-week, 30 minutes treatments of the entire thigh.

Results: Eighty-three (83) subjects who completed one month follow up and had no data points missing throughout the study were included in the final one month data analysis. At one month post treatment, when comparing the treated and control thighs, the circumference reduction was statistically significant ($p < 0.001$, Student's t-test) with positive responding subjects recording a combined average loss of 3.5cm ranging from -0.2cm to -8.7cm.

Seventy-two (72) subjects who completed 3 month follow up were included in the final 3 month data analysis. When comparing the treated and control thighs, the circumference reduction was statistically significant ($p < 0.001$, Student's t-test) with positive responding subjects recording a combined average loss of 2.9 cm ranging from -0.1cm to -8.7cm.

Conclusions: SmoothShapes system was highly effective in producing thigh circumferential reduction at one month and three month follow-up visits. The treatment protocol consisting of eight, twice-a-week, 30 minutes treatments proves to be an effective treatment protocol for the efficacy and longevity of thigh circumferential reduction.

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