



UltraSmooth™ Clinical Trials available at ClinicalTrials.gov

UltraSmooth™ is second only to UltraSlim® as the most effective FDA-cleared device for fat reduction. Instead of using a 20-minute treatment for cellulite, fat reduction incorporates four 8-minute treatments to the waist, hips, and thighs.

Clinical trials were conducted for the FDA in order to demonstrate the effectiveness of UltraSmooth™ for fat reduction with circumferential reduction (**ClinicalTrials.gov NCT03647748**). The study was a double-blind, placebo-controlled randomized evaluation of the effect of UltraSmooth™ for aesthetic use for the noninvasive reduction in fat layer for body contouring and reduction of cellulite. A total of 52 patients participated in the study (25 Active UltraSmooth™ and 27 Placebo Control). Patients were all female, with a median age of 42.5 years old with a range of patient ages from 18 years to 69 years old.

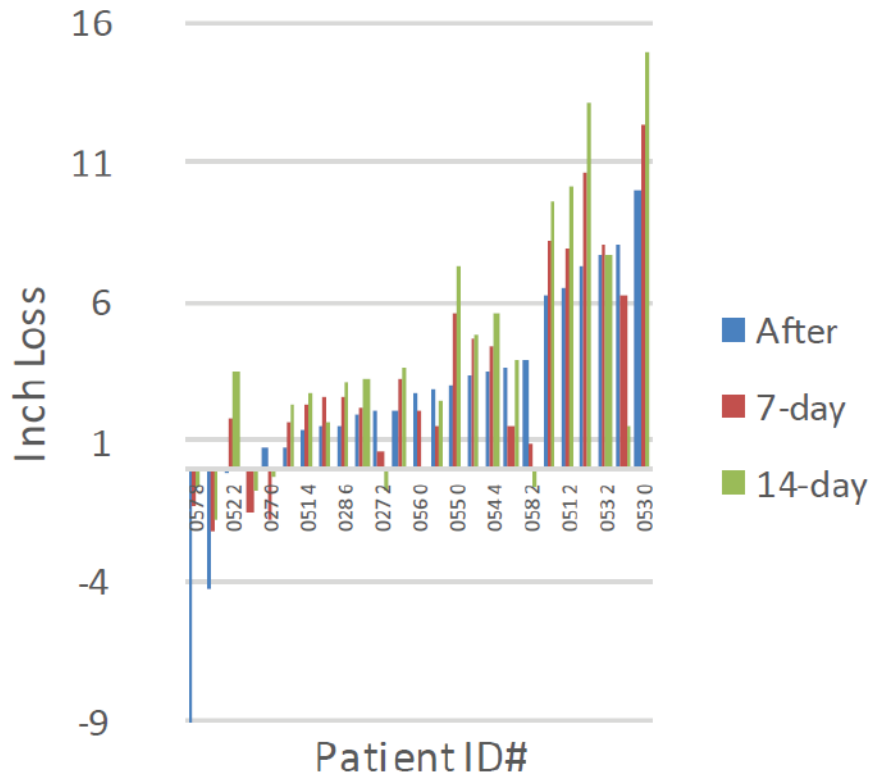
Ethnic origins of the patients were represented from Asian, African American, Caucasian, Latino, and Pacific Islander. Cumulative circumferences of waist, hip, left and right thighs for each patient were calculated before and after treatment.

The study demonstrated that UltraSmooth™ causes immediate inch loss in subjects after a regimen of six treatments of 32 minutes (8 minutes on each of four positions) compared to individuals subjected to a placebo device for an equivalent treatment. In a typical regimen, patients lost an average cumulative 2.67 inches of circumference compared to placebo average of 0.5 inch. This meets the anticipated primary outcome measure “Average Change in Inches of Total Circumference Measurements for effect of UltraSmooth™, a LED 532nm green light low level laser system for aesthetic use for the noninvasive reduction in fat layer for body contouring from baseline measurements, and after treatment.”

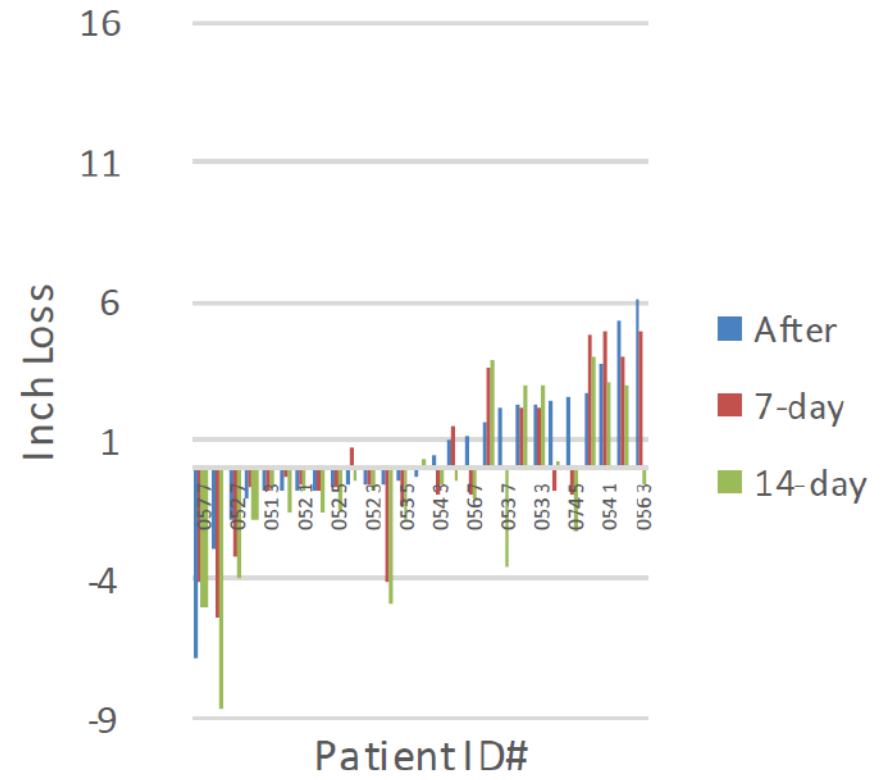
While durability of effect is also impacted by extrinsic factors after treatment such as diet, it was demonstrated that subjects were more likely to show continued inch loss upon following up with each subject at 7 days and again at 14 days.

UltraSmooth™ patients continued losing inches for at least 14 days after treatment, with an average continued loss of an additional 1.20 inches and a total average inch loss of 3.87 inches where average placebo measurements after 14 days yielded a net gain (not a loss) of 0.875 inches. This implies that UltraSmooth™ meets the expected primary outcome of demonstrated durability of effect for circumferential reduction after short-term follow up of 2-weeks.

UltraSmooth™



Placebo



Shown above is a graphical summary of inch loss for patients in the UltraSmooth™ active group and the Placebo control group respectively.