smarter body contouring

Safety Of A 1064-nm Robotic Laser System For Noninvasive Lipolysis Of The Flanks BY THOMAS FIALA, MD, MBA, FACS, FRCSC

OBJECTIVES:

The primary objective of this pilot study was to confirm the safety of a 1064-nm laser device with a novel robotic arm for noninvasive subcutaneous fat reduction in the flank area. Secondary objectives included: assessing the extent of subject discomfort during treatment, overall subject satisfaction with the results of the procedure, and a determination of subcutaneous fat reduction in the treated area, in preparation for larger upcoming trials.

METHODS:

A 110-cm2 area on both flanks of enrolled subjects (N = 11; 22 flanks) was treated for 20 minutes with a Food and Drug Administration-cleared robotic noncontact 1064-nm laser system (EON®; Dominion Aesthetic Technologies, Inc.). Patients were followed for 12 weeks, and examined routinely at 2 weeks, 12 weeks, and additionally as needed, posttreat-ment. Ad hoc surveys were administered to assess patient satisfaction. A 2-week post treatment ultrasound scan was used to check for changes in the treated area. Ultrasound measurements were also used to determine the subcutaneous adipose tissue thickness at a center of each treatment zone before treatment and at 12 weeks post treatment for efficacy determination, with mean thicknesses calculated per subject. events were noted: mild transient erythema (n = 1, 3.8%) and localized subcutaneous firmness (n = 1, 3.8%) which resolved without intervention within 12 weeks.

RESULTS:

The treatment had a low incidence of adverse effects, with only one subject developing a palpable thickening in the subcutaneous tissue following treatment. This was noted at the 2-week time period and had been resolved by the 12-week post treatment exam. No other predefined adverse effects were noted. On a scale of 0–10, the mean pain score during the procedure was 1.95, decreasing to 0.9 at 30 minutes postprocedure. Subject satisfaction was “Excellent” for all subjects (100%). At Week 12 after one treatment, the mean reduction in subcutaneous adipose thickness on the treated flanks was 6.1 mm per patient (−15%; $p < 0.01$).

CONCLUSION:

Similar to a prior abdominal study with the same robotic laser device, this pilot study confirms the safety of this 1064-nm noncontact laser device for treating subcutaneous fat on the flanks. The procedure is well tolerated with a high degree of subject satisfaction. The amount of subcutaneous fat reduction in the flank area appears similar to that seen in the abdomen, but larger studies are required for confirmation. ClinicalTrials.gov Identifier: NCT04797988.

CLINICAL RESULTS	DETAILS
Zero Non- Responders	11 Subjects ages 24 to 63
Lasered Area Size 110 cm2 per treatment segment	All Fitzpatrick Scale Skin Types
100% Subject Satisfaction	BMIs 22.3 to 34.2
Mean fat reduction 6.1 mm (15%)	Mean abdominal circumference of 97.9 cm (range, 82.2-109.5 cm)
Low incidence of adverse effects	One patient with palpable thickening in the subcutaneous tissue resolved after two weeks