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ABDOMINAL LASER LIPOLYSIS USING A MICROPROCESSOR- CONTROLLED ROBOTIC ARM WITH NONCONTACT HEATING AND COOLING BY THOMAS FIALA, MD, MBA, FACS, FRCSC

BACKGROUND:

A novel FDA-cleared device uses a 1064-nm laser to noninvasively induce apoptosis for lipolysis of subcutaneous abdominal fat while maintaining comfortable skin temperatures with a proprietary jet cooling system (eon; Dominion Aesthetic Technologies, Inc., San Antonio, TX). A programmable articulated robotic arm moves the treatment head without any subject contact, maintaining an appropriate 3-dimensional treatment path, compensating for patient movement.

OBJECTIVES:

The goal of this prospective, single center, open-label study was to demonstrate the safety and effectiveness of this device for reducing subcutaneous abdominal fat when operated with an updated power delivery curve.

METHODS:

Male and female subjects with Fitzpatrick skin types I to VI (N = 26) were treated. Four abdominal zones up to 150 cm2 each customized in size and location for body habitus, were treated. Four underwent a single 20-minute treatment session. Follow-up visits occurred after 6 and 12 weeks. A standardized protocol was used to obtain ultrasound measurement of subcutaneous abdominal fat thickness, abdominal circumference, reported patient satisfaction and digital images.

RESULTS:

The mean treatment area was 378.5 cm2. At Week 12, there was a 21.6% or 6.3 mm mean reduction in abdominal subcutaneous fat thickness and a 4.1-cm (1.6-inch) mean reduction in abdominal circumference. Most subjects (84.6%) were satisfied or very satisfied with their results. The mean pain score was 2.5 on an 11-point ordinal scale. There were no nonresponders. Only 2 adverse 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.

CONCLUSION:

This contact-free device is safe and effective for reducing subcutaneous abdominal fat and represents an improvement on the prior treatment protocol.

CLINICAL RESULTS	DETAILS
Average upper abdomen fat reduction was 21.6% measured by ultrasound	20 females and 6 males - ages 21 to 61
Average lower abdomen fat reduction was 25.3% measured by ultrasound	All Fitzpatrick Scale Skin Types
Circumferential average loss was 6.3mm / 2.3 in (equivalent to 2+ belt sizes)	BMIs 17.8 to 32.2
Over 73% of patients showed greater than 20% fat reduction measured by ultrasound	Mean treatment area 378.5 cm2 (full abdomen)
Over 96% of patients would recommend this procedure	Zero Non-Responders

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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