POST-MARKETING STUDY

OBJECTIVES:

The goal of this prospective, open-label study was to demonstrate the safety and effectiveness of this device for reducing subcutaneous abdominal fat using an improved power delivery curve.

METHODS:

Male and female subjects with Fitzpatrick skin types I-VI (*N*=26) were treated. Up to four abdominal zones, up to 150cm^2 each, customized in size and location for body habitus were treated. Each zone underwent a single 20-minute treatment session. Follow-up visits occurred after 6 and 12 weeks. Using a standardized protocol, ultrasound measurement of subcutaneous abdominal fat thickness, abdominal circumference, reported patient satisfaction and digital images were obtained.

RESULTS:

The mean treatment area was 378.5 cm^2. At Week 12, there was a 21.6% mean reduction in abdominal fat thickness and a 1.6-inch mean reduction in abdominal circumference. Most subjects (96%) were satisfied or very satisfied with their results. The mean pain score was 2.5 on an 11-point ordinal scale. There were no non-responders. Two adverse events were mild transient erythema (n=1) and localized subcutaneous firmness (n=1) which resolved spontaneously within 12 weeks.

Study	Dominion 2018 FDA Study	Dominion 2019 Post-Marketing Study
Sample Size	36	26
Treatment Time	15 minutes	20 minutes
Week 12 Mean Fat Reduction	-3.4 mm	-6.3 mm
Percentage of Fat Reduction	-15.1%	-25.3% Lower Abdomen
Subject Satisfaction	89%	96%
% Subjects with Nodules	11.1% (4/36)	3.8% (1/26)

CONCLUSION:

EON is safe and effective for reducing abdominal fat and represents an improvement on the prior treatment protocol.

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