

LATE-BREAKING ABSTRACT

A RANDOMIZED, BLINDED CLINICAL STUDY OF A MICROWAVE DEVICE FOR TREATMENT OF AXILLARY HYPERHIDROSIS

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Background: Current treatment options for axillary hyperhidrosis (excessive underarm sweating) are limited either by duration of effect or efficacy. A novel procedure using an early generation microwave-energy device was tested.

Study: A multi-center, randomized, sham-controlled study involving 120 adult subjects with primary axillary hyperhidrosis was conducted. Subjects were required to have a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 and baseline gravimetric readings greater than 50 mg (5 minutes). Subjects were randomized to the treatment group (n=81) or sham group (n=39) and were treated with the microwave device in one to three sessions. Follow-up was 6 months for sham group and 12 months for treatment group. Responders were defined as subjects reporting a reduction to an HDSS score of 1 or 2.

Results:

Demographics: mean age 32.8 years; 58% female; 84% Caucasian.

Efficacy results for the treatment group were 89% at 30-days; 74% at 3-months; 67% at 6-months and 69% at the 9- and 12-month visits. Sham group results were 54% at 30-days, and 44% for 3- and 6-months. For all time points, the efficacy for the treatment group was statistically significantly greater than for the sham group (p<0.001 at 30 day visit).

Treatment-related adverse events were generally mild and all but one resolved. The most common adverse events in treatment group subjects were transient patches of altered sensation in the treatment limb (n=9, 9.9%) and axillary pain requiring prescription medication (n=5, 6.2%). Most subjects experienced transient post-treatment local sequelae in the axilla such as edema, tenderness and bruising.

Conclusion: This study demonstrated a statistically significant difference in sweat reduction for treated subjects compared to sham subjects with an acceptable safety profile. Follow-up of the treated subjects showed stable efficacy through 12 months. Based on these findings, improvements in the device and procedure will be evaluated in ongoing clinical studies.