

ABSTRACT

A PROSPECTIVE CLINICAL STUDY OF NONINVASIVE CRYOLIPOLYSIS™ FOR SUBCUTANEOUS FAT LAYER REDUCTION - INTERIM REPORT OF AVAILABLE SUBJECT DATA

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Background: Published animal studies and unpublished controlled human studies have demonstrated that cryolipolysis (cold-induced apoptotic fat cell death) is safe, well tolerated, and capable of reducing the thickness of the subcutaneous fat layer without damage to the overlying skin or associated structures.

Objective: This study evaluated cryolipolysis for fat layer reduction from the flanks (love handles) and back (back fat pads) when used by clinicians in an environment representative of routine clinical practice.

Methods: This multi-center, prospective, non-randomized, IRB-approved study enrolled male and female subjects >18 years of age with clearly visible fat on the flank or back appropriate for treatment with cryolipolysis. Cooling was applied by a prototype device to the treatment area using pre-programmed treatment profiles that control the rate of heat extraction and treatment duration. A contralateral untreated area (e.g., the opposite flank or portion of the back) was maintained as a control. Efficacy was evaluated by ultrasound measurement of fat layer reduction, comparison of pre and post-treatment photographs and physician assessment.

Results: Based on interim results from 32 subjects, photographic, ultrasound and physician assessment confirm that cryolipolysis results in a visible contour change in a majority of subjects. Ultrasound measurements taken on a subset of 10 subjects demonstrated a fat layer reduction in 100% of these subjects with an average reduction of 22.4% at four months post-treatment. Subjects presenting with modest fat bulges had the best cosmetic results. There were no device related adverse events reported.

Conclusions: Selective cryolipolysis results in reductions in subcutaneous fat without damage to the surrounding tissues. While all subjects for whom ultrasound images were obtained showed a significant reduction in fat layer, cosmetic improvement was more readily observed in subjects with modest fat bulges. Further studies of fat reduction effects in other anatomical areas with optimized treatment parameters are warranted.

CONFIDENTIAL

The Zeltiq device is cleared in the European Union and Canada for use for non-invasive fat layer reduction through cold-assisted lipolysis. It is also cleared by the U.S. FDA for various applications related to skin cooling during dermatologic treatments, with a pending application for non-invasive fat layer reduction. The device is available for sale on a limited basis to physicians in the European Union, Canada, the U.S. and other selected international markets.