Improvement in the Appearance of Cellulite Resulting from a Single Treatment with Acoustic Subcision: Interim Findings from a Multi-Center Pivotal Trial

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Background:
A rapid acoustic pulse (RAP) device produces high intensity acoustic shock waves at 50 Hz has potential to improve the appearance of cellulite through disruption of the subcutaneous fibrous structures (i.e. acoustic subcision). In a prior proof-of-concept (POC) study, appearance of cellulite in five patients improved following a single RAP session[1,2]. A multi-center pivotal study was initiated and is ongoing. Interim safety, tolerability and efficacy results are provided.

Type of Study:
IRB approved multi-center prospective pivotal clinical trial. Interim findings.

Methods:
Grade II cellulite in 67 women was treated in a single 19-33 minute RAP session. Adverse events and tolerability were recorded after treatment. Results from 12-week followup of the first 26 patients were evaluated. Preliminary assessment of efficacy was measure by having four blinded medical professionals correctly identify the 12-week post-treatment photographs from randomly placed side-by-side comparison of before/after photographs.

Results:
No adverse events were noted other than mild erythema at treatment sites. Overall pain score during RAP treatment was 2.4 (1-10 pain scale with 10 being the worse). For the first 26 patients, the blinded panel correctly identified the 12-week post-treatment photographs at a rate of 94.2%.

Conclusions:
Interim results of this multi-center pivotal clinical trial support the previous POC study results showing that a single RAP session can provide non-invasive, nearly painless improvement in the appearance of cellulite with no down time. A blinded independent dermatologist review panel will assess efficacy for all 67 patients by comparing pre/post photographs at the completion of all 12-week follow-ups.

References: (to be formatted before submission)
[1] SCALE 2019
Improvement in the Appearance of Cellulite from an Acoustic Subcision Device

[2] The Aesthetics Show 2019

Continued Improvement in the Appearance of Cellulite Assessed in Long-Term Follow-up After a Single Treatment with the Acoustic Subcision Device: A Pilot Study With 6 Months Follow-up

Biography

Elizabeth Tanzi, MD; *Capital Laser & Skin Care*

Dr. Elizabeth Tanzi is a board-certified dermatologist proudly serving men and women in the Washington D.C. area. After 15 years of practicing cosmetic dermatology in Washington D.C., she founded Capital Laser & Skin Care. She reeived her medical degree from State University of New York Upstate Medical University and has practiced formore than 20 years.

Michael Kaminer, MD; *SkinCare Physicians of Chestnut Hill*

Michael S. Kaminer, MD is known as a leader, innovator and talented cosmetic surgeon in the Boston area. He is one of the three founding partners of SkinCare Physicians, a 15 physician, 100 employee group that is a recognized world leader in dermatology and cosmetic surgery. He graduated from Tufts University School Of Medicine in 1987 and specializes in dermatology and cosmetic dermatology.

Brenda LaTowsky, MD; Clear Dermatology and Aesthetic Center

Dr. Brenda Latowsky is a dermatologist in Scottsdale, Arizona and is affiliated with HonorHealth Scottsdale Thompson Peak Medical Center. She received her medical degree from University of Nebraska College of Medicine and has been in practice between 11-20 years.

Omer Ibrahim, MD; Chicago Cosmetic Surgery and Dermatology

Dr. Omer Ibrahim joined Chicago Cosmetic Surgery and Dermatology after completing a prestigious fellowship in cosmetic, laser and dermatologic surgery at SkinCare Physicians in Boston, with clinical faculty from the Harvard and Yale Departments of Dermatology. Dr. Ibrahim completed his medical education at Yale University School of Medicine, with an undergraduate degree from University of Cincinnati with a combined B.S. in Chemistry and B.A. in Spanish.