# Home-Based Wrinkle Reduction Using a Novel Handheld Multisource Phase-Controlled Radiofrequency Device

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## Abstract

BACKGROUND: In the last decade, energy-based aesthetic treatments, using light, radiofrequency (RF), and ultrasound, have gained scientific acceptance as safe and efficacious for non-invasive treatment for aesthetic skin disorders. The phase-controlled multisource radiofrequency technology (3DEEP™), which is based on the simultaneous use of multiple RF generators, was proven to allow significant pigment-independent dermal heating without pain or the need of epidermal cooling. This study was performed in order to evaluate the efficacy and safety of a new handheld device delivering multisource radiofrequency to the skin for wrinkle reduction and skin tightening in the home setting.

PATIENTS AND METHODS: A total of 69 participants (age 54.3 years ± 8.09; age range 37-72 years) were enrolled in the study after meeting all inclusion/exclusion criteria (100%) and providing informed consent. Participants were provided with the tested device together with a user manual and treatment diary, to perform independent treatments at home for 4 weeks. The tested device, (Newa™, EndyMed Medical, Cesarea, Israel) emits 12 W of 1Mhz, RF energy through six electrodes arranged in a linear fashion. Independent control of RF polarity through each one of the 6 electrodes allows significant reduction of energy flow through the epidermis with increased dermal penetration. Participants were instructed to perform at least 5 treatments a week, for one month. Four follow-up visits were scheduled (once a week) during the period of independent treatments at home, following 4 weeks of home treatments, 1 month follow-up visit (1 month after treatment end) and at 3 months follow-up (3 months following treatment end). Analysis of pre-and post treatment images was conducted by three uninvolved physicians experienced with the Fitzpatrick Wrinkle and Elastosis Scale. Fitzpatrick Wrinkle and Elastosis score of each time point (4 weeks following home use treatments; 1 month follow-up, 3 months follow-up) was compared to baseline.

Participants were asked a series of questions designed to explore usability concerns and level of satisfaction regarding the device use and subjective efficacy.

RESULTS: Altogether, 62 subjects completed the study course and follow-up visits. No unexpected adverse effects were detected or reported throughout the independent treatment. All study participants did not experience any difficulties while operating the tested device for independent wrinkle reduction treatments. Photographic analysis of pre- and post-one month of independent home use treatments, and one and three months follow-up after end of treatment course, was conducted by three uninvolved board certified dermatologists. Analysis of results revealed improvement (downgrade of at least 1 score according to the Fitzpatrick scale) in 91.93%, 96.77%, and 98.39% of study subjects (according to the first, second, and third reviewer, respectively). Results were found to be statistically significant. The majority of study participants were very satisfied from the results of the independent treatment using the tested device for wrinkle reduction.

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