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

Neil S. Sadick MD,[1] Yoram Harth MD,[2,3] Hanna Levy PhD,[4] and Avner Shemer MD[5]

[1]Weill Medical College Cornell University, New York, NY
[2]Medical OR, Medical Center, Herzlya, Israel
[3]EndyMed Medical Ltd., Cesarea, Israel
[4]Qsite Ltd, Binyamina, Israel
[5]Departments of Dermatology, Sheba Medical Center and Sackler Faculty of Medicine, Tel-Aviv University, Tel Aviv, Israel

## 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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## INTRODUCTION

Demand for a non-invasive and long-lasting treatment to reduce wrinkles and laxity has grown dramatically over the past few decades as new aesthetic technologies have been introduced into practice. A major cause of wrinkles, laxity and cellulite is the reduction in the quantity and quality of collagen in the dermis and hypodermis.[1,2,3]

Radiofrequency-based systems were shown to be clinically effective in pigment independent wrinkle reduction both on the face, neck and other body areas.[4,5,6] Office-based multisource phase-controlled radiofrequency systems use the repulsion between independent radiofrequency (RF) sources to drive heat deeper into the dermis, significantly reducing epidermal heat

and pain.[7,8,9] A controlled confocal microscopy study has shown increase in quantity and quality of collagen fibers after a series of 8 multisource RF office treatments correlating to significant clinical skin tightening.[10]

First generation of home use devices emitting low intensity red or infrared light or bipolar RF have shown only modest improvement in wrinkles or skin texture possibly due to superficial penetration of energy. The use of laser based fractional home use devices, recently cleared for treatment of periorbital wrinkles, is frequently limited by small treatment area, pain, and skin type.

In this study, we examined the full-face wrinkle reduction efficacy and safety of a novel home use device emitting multisource radiofrequency. The aim of this current study was to quantifiably assess and provide definitive clinical evidence of skin tightening using a handheld home use multisource phase-controlled RF treatment.

"In addition, the tested home use multisource radiofrequency device allows treatment of the full face and neck compared to small periorbital and perioral areas treated by most other FDA cleared home use devices."

## MATERIALS AND METHODS

*Device Description*

The Newa™, EndyMed Medical, Cesarea Israel) emits 12 W of phase-controlled RF energy through six electrodes arranged in a linear fashion. The device is FDA cleared for the home use, reduction of mild to moderate facial wrinkles. 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.

To assure full safety the device, includes a built in real time temperature sensor, built in motion sensor, and a timer emitting a vibratory signal at the end of the treatment. The temperature sensor stops energy emission if epidermal temperature exceeds a predetermined level and the motion sensor will stop energy delivery if the device is not in motion.

*Demographic Data*

A total of 69 participants (age 54.3 ± 8.09; age range 37-72) 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.

Participants were instructed to perform 5 treatments a week, but not more then one treatment a day. They were also instructed to document in the diary, the independent treatments, and any side effects that may relate to treatments. Four follow-up visits were scheduled (once a week) during the period of independent treatments at home. At the follow-up visits, participants were asked to detail any side effects, questions, or difficulties that may occur during the treatments or device maintenance.

*Treatment Efficacy*

Study participants were photographed at baseline (prior to treatment initiation), following 4 weeks of home treatments and 1 and 3 after the end of treatment. Three uninvolved physicians experienced with the Fitzpatrick Wrinkle and Elastosis Scale conducted analysis of pre-and post treatment images. 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.

*Subject's satisfaction Questionnaire*

At the last follow-up visit during home treatments, (following 4 weeks of home use treatments) participants were asked to detail any side effects or problems that occurred during the individual home treatments. In addition, participants were asked a series of questions designed to explore usability concerns and level of satisfaction regarding the device and home treatments. Questionnaire items were scored on a 5-point scale from 1 to 5, with 1 being 'very dissatisfied' and 5 being 'very satisfied'. In addition, patients were asked to rate the level of improvement in wrinkle appearance obtained by the independent home treatment using the device. Score options were >80%; ≤80%; >50%; >20%; and no improvement.

## Results

Eighty-nine percent of study participants (62) completed the study course. Seven participants did not complete all follow up visits mainly as a result of lack of time. The safety analysis in this study includes the results of all participants that performed at least one home treatment (69 patients; 100%). The efficacy and satisfaction analysis results include all patients that completed the study course (4 weeks of home-use treatments) and showed up to at least one (of 2) follow-up visit (62 participants). All participants were female. Distributions of the study population including skin type and Fitzpatrick score are presented in Table 1.

## Home Treatments

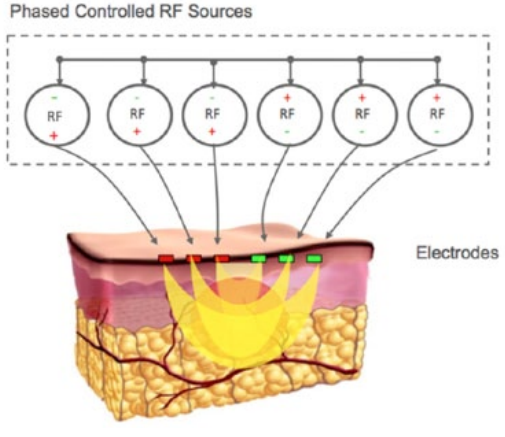
No unexpected adverse side effects were detected or reported. No subject experienced burns, skin breakdown, or scarring. Treatment was well tolerated with minimal to no discomfort. In 59 users, the post-treatment redness was minimal and subsided in less than 15 minutes after treatment. Two users reported moderate redness that subsided spontaneously in less than 30 minutes. One user reported a small spot (1- 2cm) of erythema

**TABLE 1.**

| Demographic Information | | | |
|---|---|---|---|
| | Score | N | % |
| Skin type (Fitzpatrick scale – Skin Color) | 2 | 18 | 29.04% |
| | 3 | 39 | 62.9% |
| | 4 | 5 | 8.06% |
| | **Total** | **62** | **100%** |
| Fitzpatrick wrinkle and elastosis Scale Score | 3 | 9 | 14.52% |
| | 4 | 9 | 14.52% |
| | 5 | 23 | 37.10% |
| | 6 | 14 | 22.58% |
| | 7 | 5 | 8.06% |
| | 8 | 2 | 3.22% |
| | **Total** | **62** | **100%** |

**FIGURE 1. a)** 3DEEP™, Multisource Radiofrequency technology in which each electrode phase controlled. **b)** The NEWA™ home use wrinkle reduction device (EndyMed Ltd., Cesarea, Israel).

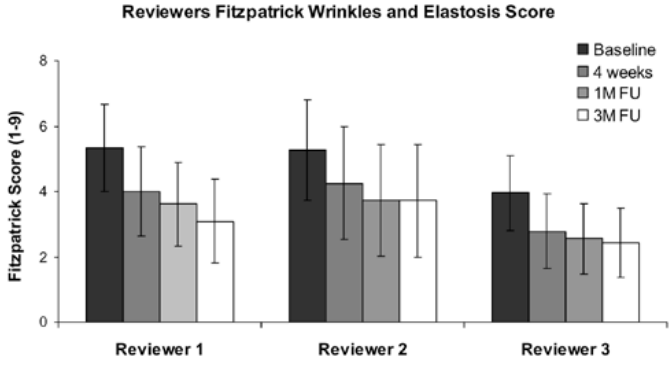
a)




b)

that was completely resolved in 24 hours with the application of non-medical moisturizer. One device replacement was reported due to bad contact at the connector level. No other device problems occurred throughout the period of independent treatments at home. Analysis of results revealed improvement (downgrade of at least 1 score according to the Fitzpatrick scale) in 91.93% (according to first reviewer); 96.77% (according to second reviewer) and 98.39% (according to the third reviewer) of study subjects. Statistical comparison (using paired *t* test) was conducted among the pre treatment Fitzpatrick score (baseline) to each time point as detailed above, for each reviewer. The statistical analysis was conducted using JMP software (version 5.1.1). Score differences were found to be statistically significant while comparing baseline score to the scores obtained at 4 weeks following home use treatment, 1 month follow-up, and 3 month follow-up ($P<0.001$) for all three reviewers, indicating statistically significant treatment efficacy. Figure 2 and Table 2 represent averages (± STDV) of Fitzpatrick scores given by the three reviewers at each time point. Results analysis reveals slight improvement while comparing the 4 weeks score to the 1 month and 3 months follow-up score (not statistically significant). These results may indicate that the treatments have initiated collagen-remodeling process that continues after treatments have been completed. Before and after photographs (Figure 3 and 4) illustrate the beneficial effect achieved by the Newa™ home use device.

**FIGURE 2.** Averages (± STDV) of Fitzpatrick Wrinkle and Elastosis scores given by the three uninvolved reviewers at baseline, 4 weeks following home use treatment end, 1 month follow-up, and 3 month follow-up.




## Subject's Satisfaction Questionnaire

At the last follow-up visit during home treatments, (following 4 weeks of home use treatments) participants were asked to detail any side effects or problems that occurred during the individual home treatments. All participants indicated that no side effects occurred during the treatments.

In addition, participants were asked a series of questions designed to explore usability concerns and level of satisfaction regarding the device and home treatments. Questionnaire items were scored on a 5-point scale from 1 to 5 with '1' being 'very dissatisfied' and '5' being 'very satisfied'. Table 3 summarizes descriptive statistics of participant's score, Table 4 details the participants score for the different questions.

**TABLE 2.**

**Averages (± STDV) of Fitzpatrick Wrinkle and Elastosis Scores.** Given by the three uninvolved reviewers, at baseline, 4 weeks (following 4 weeks home use treatments), 1 month follow-up, and 3 month follow-up. Grade reduction for each time point was based on comparison to baseline. The statistical analysis results of the comparison are noted.

| Average Wrinkle and Elastosis Score According to Fitzpatrick Scale | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Score time | 1st Reviewer | | | 2nd Reviewer | | | 3rd Reviewer | | |
| | Average Score | Grade reduction (comparing to baseline) | Statistical (TTest) Results of Comparison to baseline | Average Score | Grade reduction (comparing to baseline) | Statistical (TTest) Results of Comparison to baseline | Average Score | Grade reduction (comparing to baseline) | Statistical (TTest) Results of Comparison to baseline |
| Baseline | 5.32 (±1.35) | - | - | 5.27 (±1.55) | - | - | 3.95 (±1.17) | - | - |
| 4 weeks | 4.00 (±1.37) | 1.32 (±0.65) | $p<0.001$ | 4.25 (±1.73) | 1.02 (±0.46) | $p<0.001$ | 2.77 (±1.14) | 1.18 (±0.67) | $p<0.001$ |
| 1 month FU | 3.61 (±1.29) | 1.71 (±0.88) | $p<0.001$ | 3.72 (±1.70) | 1.54 (±0.59) | $p<0.001$ | 2.56 (±1.08) | 1.40 (0.68) | $p<0.001$ |
| 3 months FU | 3.08 (±1.28) | 2.24 (±0.82) | $p<0.001$ | 3.72 (±1.72) | 1.50 (±0.67) | $p<0.001$ | 2.43 (±1.07) | 1.53 (±0.88) | $p<0.001$ |

**TABLE 3.**

**Descriptive Statistics of Participants Score**

**Satisfaction Questionnaire – Last Follow-up Visit of the Independent Home Treatments Session**

| Question | | Score | | | |
|---|---|---|---|---|---|
| | | Mean | Std | Min | Max |
| 1 | Over all, how satisfied are you with the **Newa™** device | 4.32 | ±0.70 | 3.00 | 5.00 |
| 2 | How satisfied are you with the safety of performing wrinkle reduction treatment with **Newa™** device? | 4.69 | ±0.74 | 2.00 | 5.00 |
| 3 | How satisfied are you with the ease of treatment with **Newa™** device | 4.49 | ±0.70 | 2.00 | 5.00 |
| 4 | How satisfied are you with the ease of learning to use the **Newa™** device | 4.96 | ±0.18 | 4.00 | 5.00 |
| 5 | How satisfied are you with the wrinkle reduction obtained by the **Newa™** device? | 3.58 | ±0.86 | 1.00 | 5.00 |
| **Average for All Questions** | | **4.41** | **±0.82** | **1.00** | **5.00** |

**TABLE 4.**

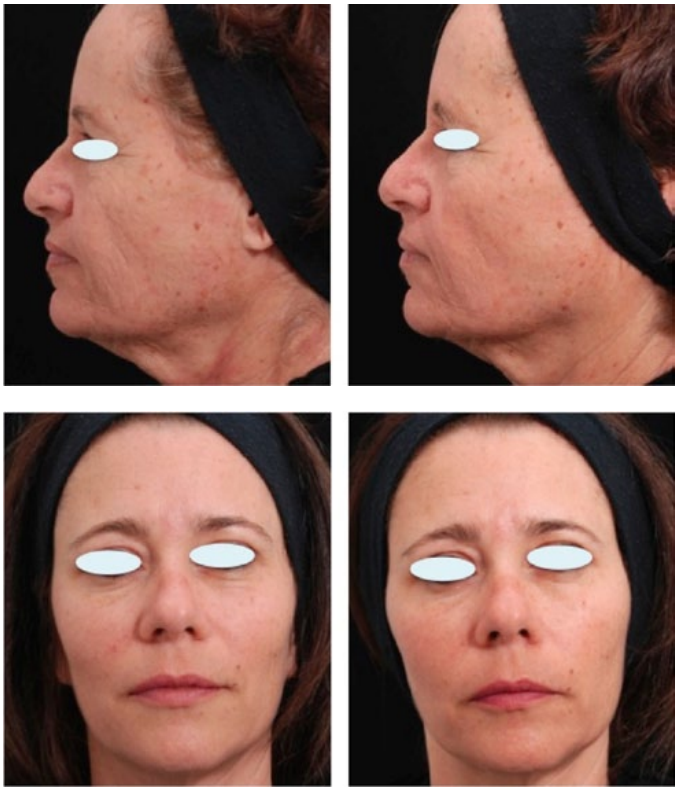
**Detailed Participants' Score**

**Satisfaction Questionnaire –Last Follow-up Visit of the Independent Home Treatments Session**

| Question | | Score | | | | | |
|---|---|---|---|---|---|---|---|
| | | 5 | 4 | 3 | 2 | 1 | N |
| 1 | Over all, how satisfied are you with the **Newa™** device | 28 | 24 | 8 | 2 | 0 | 62 |
| 2 | How satisfied are you with the safety of performing wrinkle reduction treatment with **Newa™** device? | 51 | 5 | 4 | 2 | 0 | 62 |
| 3 | How satisfied are you with the ease of treatment with **Newa™** device | 36 | 20 | 4 | 1 | 0 | 61 |
| 4 | How satisfied are you with the ease of learning to use the **Newa™** device | 60 | 2 | 0 | 0 | 0 | 62 |
| 5 | How satisfied are you with the wrinkle reduction obtained by the **Newa™** device? | 9 | 23 | 26 | 3 | 1 | 62 |

Average score for all items was 4.41 ± 0.82 (of 5). This high score indicates that participants were very satisfied with the independent use and treatment results of the Newa™ device. All study participants (100% - 62) were 'very satisfied' or 'somewhat satisfied' with the ease of learning to use the Newa™ device (item #4); Vast majority of study participants (56 of 62; 90.03%) were 'very satisfied' or 'somewhat satisfied' with safety of performing wrinkle reduction treatment with Newa™ device; with the ease of treatment with Newa™ device (56 of 61; 91.8%) and with the overall satisfaction with the Newa™ device (52 of 62; 87.1%).

**FIGURE 3 and 4.** A 71-year-old patient (upper photos) and 42-year-old patient (lower photos).



Patients were also asked to rate the level of improvement in wrinkle appearance obtained by the independent home treatment using the Newa™ device. Score options were >80%; ≤80%; >50%; >20%; and no improvement. Analysis of results indicates that the vast majority of study participants (89.1%) noticed an improvement in wrinkle appearance following independent home treatment. 72.7% (40 of 55 participants) rated level of improvement of >50% which represents impressive level of improvement. Out of the 72.7%, 29.1%of study participants (16 of 55) rated level of improvement as >80% or ≤80% (51-80%)and 43.6% of study participants (24 participants out of 55) rated level of improvement as <50% (20-50%); 16.3% (9 of 55) rated improvement level as <20% (1-19%). 10.9% (6 of 55 participants) found no visible improvement following the independent treatment.

## DISCUSSION

The efficacy of office based, FDA cleared, phased-control multisource radiofrequency wrinkle reduction is well documented. This study was designed in order to evaluate the efficacy and safety of facial wrinkle reduction performed with a hand held device in the home setting. The subjects were provided with the tested multisource RF based device (Newa™, Endymed Medical Ltd.) for 4 weeks of independent treatment at home. The one-month treatment course was followed up in control visits, one, and three months later. Pre and post-treatment photos were introduced to three uninvolved board certified dermatologists for blinded evaluation. No adverse events occurred throughout the independent wrinkle reduction treatments for all study participants. No treatment side effects or treatments problem were reported by any of the study participants. Analysis of assessment of the 62 users that completed the treatments course revealed improvement (downgrade of at least 1 score according to the Fitzpatrick scale) in 91.93%, 96.77%, and 98.39% according to the first second and third reviewer, respectively). Results were found to be statistically significant.

The quantitative analysis of decrease in Fitzpatrick wrinkle and elastosis scale by the first uninvolved reviewers showed reduction of 1.32 grades after 4 weeks, 1.71 at one month after the end of treatment, and 2.24 three months after the end of treatment. Assessment of the other two reviewers showed similar results (1.02, 1.54, 1.50, respectively, by the second reviewer and 1.18, 1.40, 1.53 by the third reviewer). This reduction was statistically significant (<0.001). These numbers match an average decrease in wrinkles at the 3-month follow-up of 36.6 % (42% by the first reviewer, 29% by the second, and 39% by the third).

To our knowledge, only two home use devices were subjected to clinical examination in controlled setting. Leyden et al reported results of home use fractional laser for the periorbital areas. Fitzpatrick Wrinkle Scale scores showed improvement by one or more grades in 90% of subjects at the completion of the active phase and in 79% of subjects at the completion of the maintenance phase.[11] These authors found average FWS reduction of 0.6 after 1month of daily treatment (compare to 1.17 wrinkle reduction achieved by the 4 weeks home use treatment using Newa™ device), and average of 1.1 wrinkle reduction at the 8-weeks visit. Beilin et al performed a small study on twenty-three female subjects used a tripolar RF home device at home for a period of 6 weeks followed by a maintenance period of 6 weeks.[12] They reported that reduction of perioral and periorbital wrinkles was achieved in 90% and 95% of the patients, respectively, with an average periorbital wrinkle reduction of 41%.

In our current study, we examined full-face wrinkle reduction as compared to the previous studies that looked only on the decrease of periorbital and perioral wrinkles. We also looked documented long-term follow up (up to 3 months after the end of the treatment) as compared to immediate post-treatment results documented in with other systems. Based on the objective and subjective data, we can conclude that treatment with the tested device seems more confortable that home use fractional laser treatment that is usually associated with some pain. In addition, the tested multisource radiofrequency device allows large area treatment of the full face and neck compared to small periorbital and perioral areas examined in the studies with the above two devices.

## CONCLUSION

This clinical study, which employed both objective and subjective skin analysis techniques, demonstrates the safety and efficacy of NEWA, the first home-use RF device employing the phase controlled multisource radiofrequency technology. Assessment by three uninvolved dermatologists showed objective wrinkle reduction in a more than 90 users, with high subjective satisfaction. The treatment was painless and had no adverse effects expect for mild redness immediately after treatment. The results of this study indicate that the Newa™ device offers a noninvasive, effective, safe, painless and easy to manipulate wrinkle reduction home use treatment.

## DISCLOSURES

Yoram Harth MD is the Medical Director of EndyMed. Devices for the study were supplied by the producer. Dr. Sadick, Dr. Levy, and Dr. Shemer have no financial interest in the product or the submission.

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## AUTHOR CORRESPONDENCE

**Yoram Harth MD**
E-mail:..... skin58@gmail.com