A 12-Week Clinical and Instrumental Study Evaluating the Efficacy of a multisource radiofrequency home use device for wrinkle reduction and improvement is skin tone, skin elasticity and dermal collagen content.

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Abstract

Background

In the last decade Energy based aesthetic treatments, using light, radiofrequency and ultrasound have gained scientific acceptance as safe and efficacious for non-invasive treatment for skin disorders. The phase-controlled multisource radiofrequency (RF) technology (3DEEP™) which is based on the simultaneous use of multiple phase controlled RF generators, was shown to allow significant, pigment independent, dermal heating without pain or the need for epidermal cooling. This study was performed in order to evaluate the safety and efficacy of a new handheld home-use multisource radiofrequency device on wrinkle reduction, improvement in skin tone and elasticity as well as dermal collagen content by expert visual assessment, computerized image analysis and objective measurement of biophysical skin properties.

Patients and methods

Forty-seven (47) male and female subjects, 37-65 years of age, were enrolled into the study with Fitzpatrick skin types II - V. All subjects received a NEWA™ 3DEEP™ home use device (EndyMed Medical, Cesarea, Israel) and a conductive activator gel (EndyMed Medical, Cesarea, Israel) to be used on facial skin three times per week for the first four weeks and then reduced to two times per week for the following eight weeks. Additionally, subjects received a facial moisturizer (Neutrogena® Oil free moisturizer with SPF 15) and soap (Dove® bar soap, Unilever) to be used starting one week prior to initiation of the study treatment period and continuing for the duration of the study. Assessments included expert clinical grading for efficacy, instrumental evaluation, image analysis and photographic documentation and occurred at baseline (BL) prior to product use and 15 minutes after product use (T15m) [expert assessment and subject questionnaires only at T15m], and at weeks 4, 8 and 12 (W4, W8, W12).

Results: 45 subjects completed the study course and all follow-up visits; two subjects did not complete the study due to study unrelated reasons. All subjects reported the treatment to be painless with a mild erythematous reaction post-treatment that lasted up to 15 minutes and resolved spontaneously without sequelae in all instances and no adverse effects were reported. Statistically significant improvements in expert visual assessment for the appearance of skin firmness, lift (jawline) and radiance/luminosity was found between baseline and week 8. At the week 12 visit statistically significant improvements from baseline were calculated for the appearance of marionette lines, skin brightness, elasticity, firmness, lift (facial), lift (jawline), texture/smoothness, tone and radiance/luminosity by expert visual assessment. Statistically significant improvements in skin firmness and elasticity were found using a Cutometer MPA 580 (Courage+Khazaka, Germany) at weeks 4, 8 and 12. as well as in collagen and hemoglobin content of the skin at weeks 4, 8 and 12 using a SIAscope (Astron Clinica, Troft, UK). The 3.8% increase in dermal collagen content, after 12 weeks of treatment was highly significant ($P < 0.001$)

Conclusions: The results of this study clearly indicate that the NEWA™ multisource RF home use device offers a non-invasive, effective, safe and painless treatment option for self-administered skin rejuvenation. Expert visual assessment and biophysical evaluations have shown significant results in wrinkle reduction, lifting effects and increasing the collagen content of the skin.

Key words: Home use, wrinkle reduction, multisource radiofrequency, RF, skin tightening

Introduction

Demand for non-invasive, long-lasting treatments to reduce facial 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 (RF) based systems have been shown to be clinically effective in pigment independent wrinkle reduction both on the face, neck as well as other body areas. [4,5,6] Multisource phase-controlled radiofrequency devices, found in clinical practices, that use the repulsion between independent RF sources to drive heat deeper into the dermis and at the same time significantly reducing epidermal heat and pain [7,8,9]. Moreover, a clinical study using confocal microscopy has shown that after a series of eight multisource RF office treatments there is a significant increase in quantity and quality of collagen fibers that correlates with skin tightening. [10]

The first generation of home use devices emitting either low intensity red / infrared light or bipolar RF have shown to result in modest improvements in wrinkles and/or skin texture, possibly due to superficial penetration of energy. Laser based fractional home use devices, recently FDA cleared for treatment of periorbital wrinkles, present a series of limitations since they cannot treat large areas, are specific to skin type and are associated with pain.

Sadick and Harth reported in 2014 the results of a clinical study examining the use of the NEWA™ device for the treatment of facial wrinkles. In this study 69 subjects treated five times a week for four weeks showed 91.93%, 96.77% and 98.39% improvement in wrinkle reduction (downgrade of at least 1 score according to the Fitzpatrick wrinkle scale), according to three independent reviewers respectively. The average reduction in Fitzpatrick wrinkle score at 3 months follow-up was 2.24, 2.43 and 1.53 for the 3 reviewers respectively.

In the current study we examined the efficacy and safety of the tested home use device on full-face wrinkle reduction using a modified treatment protocol in which the volunteers used the devices three times a week for the first four weeks and then twice a week for the following two months in order to facilitate the practicality of using the device. Clinical efficacy was evaluated with investigator assessments and instrumental analysis for objective measurement of wrinkle reduction, skin tone and elasticity and collagen content.

Materials and methods

Device description

The NEWA™ (EndyMed Medical, Cesarea, Israel) emits 12W of phase controlled RF energy through six electrodes arranged linearly. 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 (Figure1). To assure full safety, the device includes a built in real time temperature sensor, motion sensor and a timer which emits a vibratory signal at the end of the treatment. The temperature sensor stops energy emission if epidermal temperatures exceed a predetermined level of 42 degrees Celsius and the motion sensor will stop energy delivery if the device is not in motion.

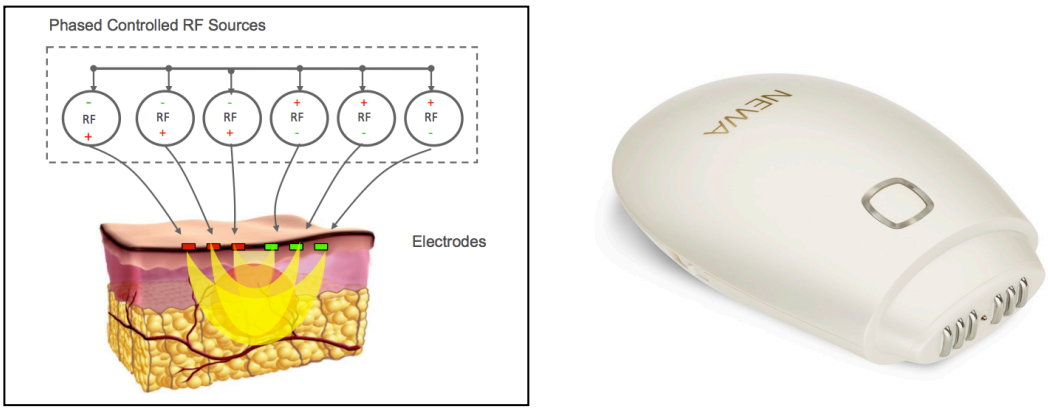

Figure 1: *Rt. 3DEEP™, Multisource Radiofrequency technology in which each electrode phase controlled. Lt. The NEWA™ home use wrinkle reduction device (EndyMed Ltd., Cesarea, Israel).*

This study was conducted according to International Research Services, Inc. research policies and Standard Operating Procedures, U.S. and international standards of Good Clinical Practice (FDA and ICH guidelines) and applicable government regulations. This was a twelve-week single-site, open-label clinical study to evaluate the safety and efficacy of phase-controlled multisource radiofrequency device, the NEWA™, in combination with topical activator gel. Data was analyzed for improvement in skin condition of female and male subjects with photo-damaged skin, specifically for the increase of skin brightness, texture/smoothness, tone/evenness, radiance/luminosity, firmness/elasticity and reduction of wrinkles/fine lines, deep wrinkles, skin sagging.

Enrollment and Demographics:

Forty-seven (47) subjects were enrolled into the study and 45 completed the twelve week protocol. Subjects ranged in age from 37-65 years old with an average age of 58.62. The population was comprised of 93.3% White (non-Hispanic or Latino) subjects and, 4.4% Asian subjects and 2.2% American Indian subjects (Table 1), Fitzpatrick skin type ranging from I-III.

Study Protocol:

Each subject's facial skin was evaluated at screening for the presence of the following inclusion criteria: crow's feet lines/wrinkles (score of ≥3 cm on 10 cm VAS scale), at least 15 subjects with deep wrinkles in crows' feet area and/or marionette lines (score of ≥5 on 10 cm VAS scale), lack skin tone (score of ≥2cm on 10 cm VAS scale), rough skin texture (score of ≥1cm on 10 cm VAS scale), dull/sallow skin (score of ≥1cm on 10cm VAS scale for radiance), and sagging of the jaw line and face (separately) (score of ≥3 cm on 10 cm VAS scale) . Assessments included expert clinical grading, instrumental evaluation, image analysis and photographic documentation.

All subjects used the test device and gel on facial skin five times a week on facial skin for weeks 1-4, then two times a week for weeks 5-12. Additionally, subjects received a moisturizer (Neutrogena® Oil free moisturizer with SPF 15)

and Dove® soap to be used for facial cleansing starting one week prior to the study treatment period and continuing for the duration of the study.

Assessments occurred at baseline (BL) prior to product use and approximately 15 minutes after product use (T15m), and at weeks 4, 8 and 12 (W4, W8, W12).

Results

45 subjects completed the study protocol, two subjects dropped due to study unrelated reasons.

Variable	**n**	**Mean ± SD**	**Min**	**Max**
Age (years)	45	58.62 ± 5.84	37	65
Height (inches)	45	64.42 ± 2.77	60	73
Weight (pounds)	45	162.93 ± 34.40	108	280
			n	**Percent**
Sex	45	Female	40	88.9%
		Male	5	11.1%
Fitzpatrick Skin Type	45	Skin Type II	7	15.6%
		Skin Type III	27	60.0%
		Skin Type IV	9	20.0%
		Skin Type V	2	4.4%
Facial Skin Type	45	Combination	16	35.6%
		Dry	5	11.1%
		Normal	24	53.3%

Table 1: *Demographic information*

Expert Visual Clinical Grading Assessments:

Visual Analog Scales (VAS) were used for expert grading of the following at baseline, T15m, wk 4, wk 8 and wk 12; fine lines/wrinkles (crows' feet and global), facial skin brightness, firmness/elasticity, lift (facial and jaw line separately), texture/smoothness, skin tone and radiance/luminosity. All efforts were made to maintain the same assessor throughout the duration of the study, if an alternate assessor had to be used; the two assessors conferred on the cases and were trained on repeatability of grading. Grading took place in the same setting for all time points with controlled lighting conditions.

At the week 8 visit, statistically significant improvements compared to baseline scores were revealed for the

appearance of skin firmness, lift (jawline) and radiance/luminosity. At the week 12 visit, statistically significant improvements from mean baseline scores were revealed for the appearance of marionette lines, skin brightness, elasticity, firmness, lift (facial), lift (jawline), texture/smoothness, tone and radiance/luminosity (Figures 2 and 3).

Assessment	**Time Point**	**n**	**Mean ± SD**	**Mean Percent Improvement** *From BL mean*	**Percent of Subjects Showing Improvement** *From BL*	**P-Value** *TX vs. BL*
Marionette Lines^	Baseline	18	5.71 ± 0.45			
	Immediate	17^^	5.68 ± 0.49	0.95%	47.1%	**0.443**
	Week 4	17^^	5.65 ± 0.59	1.16%	58.8%	**0.420**
	Week 8	16^^	5.37 ± 0.81	5.68%	56.3%	**0.061**
	Week 12	18	5.30 ± 0.85	7.28%	66.7%	**0.021***
Brightness	Baseline	45	3.93 ± 0.65			
	Immediate	45	3.83 ± 0.67	2.15%	48.9%	0.098
	Week 4	45	3.99 ± 0.64	NI	35.6%	0.445
	Week 8	44	3.85 ± 0.77	1.35%	54.5%	0.371
	Week 12	45	3.55 ± 0.82	9.07%	62.2%	**0.001***
Elasticity (Tactile)	Baseline	45	3.92 ± 0.69			
	Immediate	45	3.88 ± 0.68	0.58%	42.2%	0.414
	Week 4	45	4.05 ± 0.65	NI	40.0%	0.078
	Week 8	44	3.86 ± 0.62	0.56%	47.7%	0.421
	Week 12	45	3.67 ± 0.67	5.23%	60.0%	**0.009***
Firmness	Baseline	45	4.07 ± 0.64			
	Immediate	45	4.08 ± 0.65	NI	42.2%	0.787
	Week 4	45	4.01 ± 0.60	0.72%	51.1%	0.410
	Week 8	44	3.85 ± 0.67	4.63%	65.9%	**0.017***
	Week 12	45	3.74 ± 0.58	6.95%	66.7%	**0.001***

Assessment	Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Lift (Facial)	Baseline	45	4.09 ± 0.62			
	Immediate	45	4.19 ± 0.64	NI	35.6%	0.073
	Week 4	45	4.14 ± 0.68	NI	40.0%	0.431
	Week 8	44	3.89 ± 0.78	4.10%	60.0%	0.053
	Week 12	45	3.89 ± 0.80	4.50%	62.2%	**0.039***
Lift (Jaw Line)	Baseline	45	3.99 ± 0.62			
	Immediate	45	3.93 ± 0.74	1.58%	53.3%	0.311
	Week 4	45	4.08 ± 0.66	NI	44.4%	0.245
	Week 8	44	3.74 ± 0.74	6.11%	66.7%	**0.006***
	Week 12	45	3.60 ± 0.73	9.28%	77.8%	**<0.001***
Texture/Smoothness	Baseline	45	3.75 ± 0.83			
	Immediate	45	3.82 ± 0.83	NI	37.8%	0.289
	Week 4	45	3.76 ± 0.77	NI	42.2%	0.824
	Week 8	44	3.60 ± 0.86	3.48%	59.1%	0.076
	Week 12	45	3.40 ± 0.90	6.23%	68.9%	**0.031***
Skin Tone	Baseline	45	3.80 ± 0.80			
	Immediate	45	3.88 ± 0.63	NI	31.1%	0.283
	Week 4	45	3.91 ± 0.70	NI	42.2%	0.176
	Week 8	44	3.62 ± 0.87	4.00%	59.1%	0.071
	Week 12	45	3.54 ± 0.82	5.61%	66.7%	**0.018***
Radiance/Luminosity	Baseline	45	3.89 ± 0.81			
	Immediate	45	3.87 ± 0.88	NI	55.6%	0.815
	Week 4	45	3.92 ± 0.73	NI	44.4%	0.737
	Week 8	44	3.64 ± 0.80	5.44%	65.9%	**0.010***
	Week 12	45	3.35 ± 0.72	12.99%	84.4%	**<0.001***

NI= No improvement

*Indicates a statistically significant improvement compared to baseline, p≤0.05

^ Only subjects scoring severe (≥5cm on VAS) at baseline were graded throughout study for Marionette Lines

^^One subject (#27) missed the 15m assessment for Marionette lines (17 subjects analyzed), one subject (#21) missed W4 and W8 assessments for Marionette lines (17 and 16 subjects analyzed, respectively).

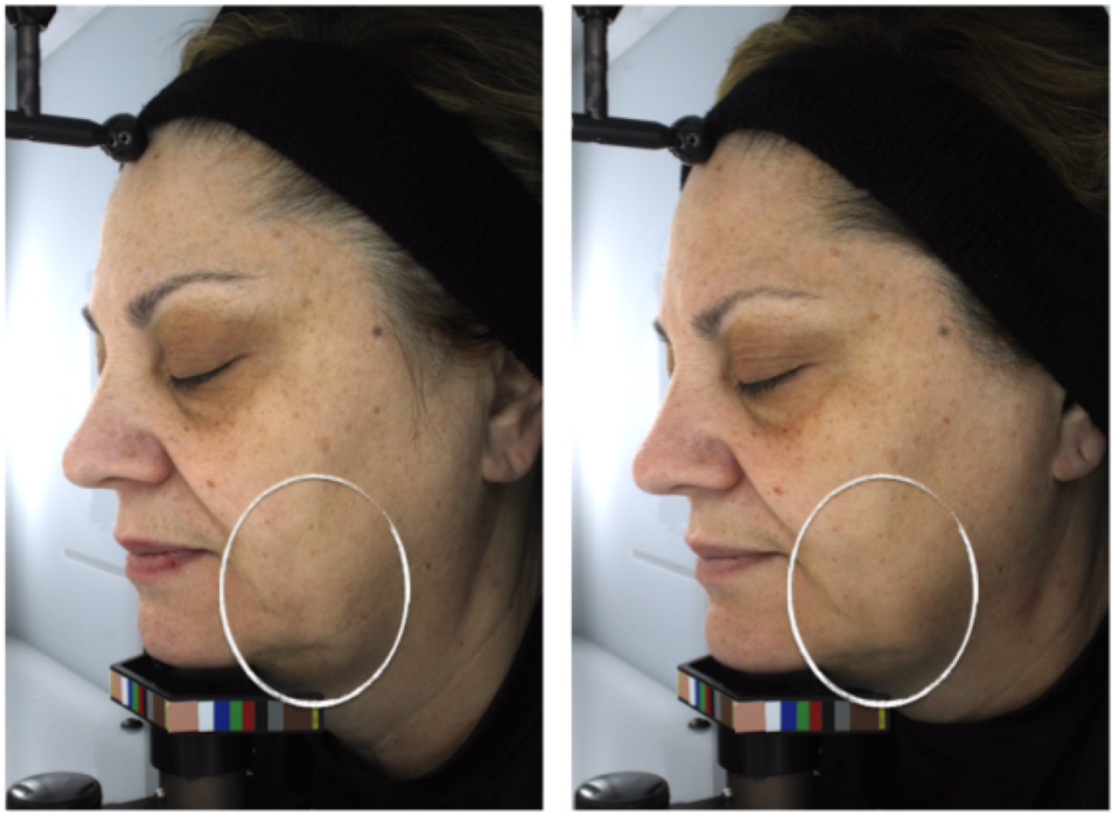

Figure 2: *Lt. Pre-treatment (baseline). Rt. 12W follow-up. Significant lift effect of the lower face, texture improvement and wrinkle reduction.*

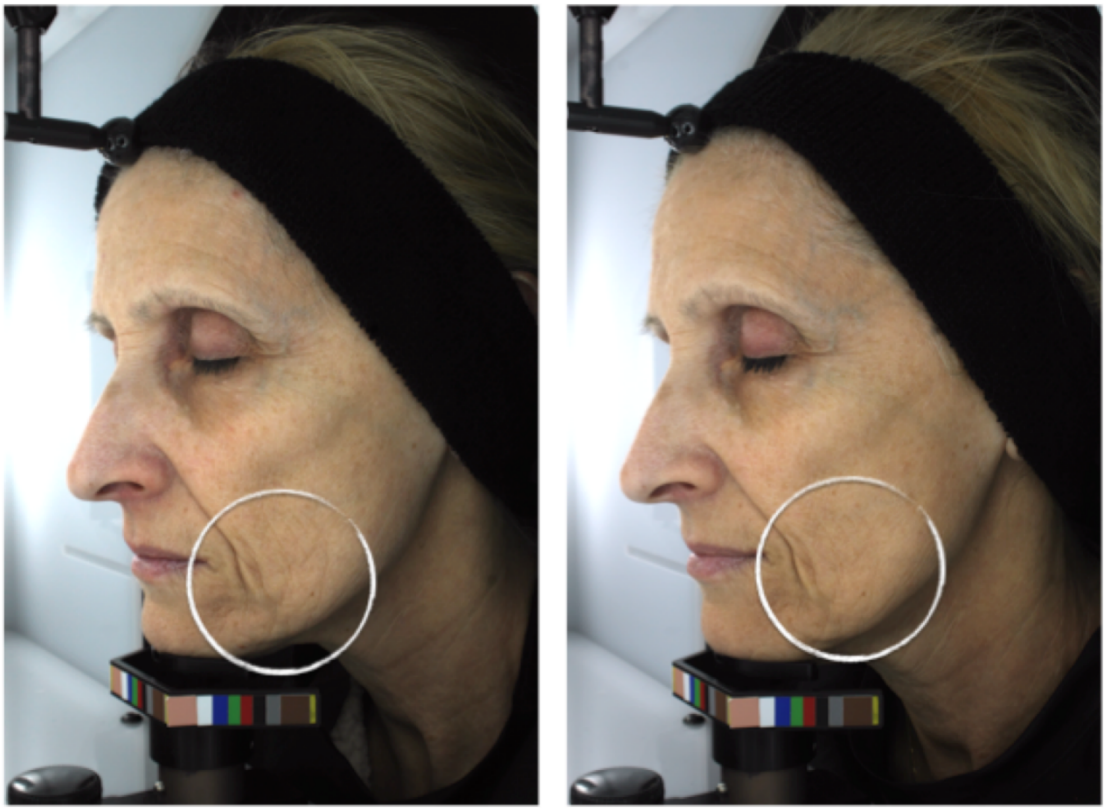

Figure 3: *Lt. Pre-treatment (baseline). Rt. 12W follow-up. Significant lift effect of the lower face, texture improvement and wrinkle reduction.*

Instrumental Biophysical Assessments:

Spectrophotometric intracutaneous analysis (SIA)scopy is a skin-imaging technique that allows noninvasive in vivo quantification and assessment of (eu) melanin, (oxy) hemoglobin and dermal collagen content within human skin.
The Siascope emits light 400 to 900 nm to the skin. By computing the spectral composition of light remitted from the skin it allows the evaluation of changes in collagen, melanin and hemoglobin content of the skin. Statistically significant improvements from mean baseline scores were observed for hemoglobin and collagen content in skin at weeks 4, 8 and 12.

The Cutometer is a biophysical measurement probe which creates a temporary vacuum when pressed on the skin, lifting, stretching and then releasing the test skin segment. These deflections are optically recorded and evaluated providing a measurement of skin firmness and elasticity. Statistically significant improvements from mean baseline scores for were observed at weeks 4, 8 and 12.

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
SIAScope	Hemoglobin	Baseline	45	116.02 ± 21.04			
		Week 4	45	101.84 ± 19.15	11.33%	77.8%	**<0.001***
		Week 8	44	97.84 ± 15.83	14.00%	86.4%	**<0.001***
		Week 12	45	97.53 ± 21.29	15.22%	84.4%	**<0.001***
	Collagen	Baseline	45	160.35 ± 14.29			
		Week 4	45	165.85 ± 12.15	2.14%	60.0%	**0.016***
		Week 8	44	168.39 ± 17.56	4.05%	75.0%	**0.012***
		Week 12	45	168.42 ± 12.05	3.82%	75.6%	**<0.001***
	Firmness R0 (Uf)	Baseline	45	0.04 ± 0.01			
		Week 4	45	0.03 ± 0.01	12.94%	66.7%	**0.006***
		Week 8	44	0.03 ± 0.01	16.08%	75.0%	**0.002***
		Week 12	45	0.03 ± 0.02	22.42%	84.4%	**0.003***
Cutometer	Elasticity R5 (Ur/Ue)	Baseline	45	0.33 ± 0.11			
		Week 4	45	0.43 ± 0.25	46.79%	66.7%	**0.017***
		Week 8	44	0.43 ± 0.21	36.22%	81.8%	**0.001***
		Week 12	45	0.44 ± 0.27	48.86%	55.6%	**0.012***

NI= No improvement

*Indicates a statistically significant improvement compared to baseline, p≤0.05

Image Analysis

For computerized image analysis we used the Clarity™ 2D Research System. (BrighTex Bio-Photonics, USA). Statistically significant improvements from mean baseline scores were observed for the following lines/wrinkles [crow's feet] variables: average width, average severity, total count and fine line count at weeks 4, 8 and 12 and for average length and deep lines count at weeks 8 and 12.

Statistically significant improvements from mean baseline scores were observed for the following lines/wrinkles [global (full face)]) variables: average length, average width, average severity and total count at weeks 4, 8 and 12 and for fine line counts and deep line counts at the Weeks 8 and 12.

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Lines/Wrinkles (Crow's Feet)	Average Length (Pixels)	Baseline	43	144.54 ± 34.37			
		Week 4	41	142.01 ± 32.18	NI	48.8%	0.918
		Week 8	43	133.79 ± 32.46	5.64%	83.7%	**0.006***
		Week 12	43	134.14 ± 33.43	6.36%	81.4%	**0.001***
	Average Width (Pixels)	Baseline	43	25.17 ± 1.91			
		Week 4	41	24.47 ± 1.85	2.71%	82.9%	**<0.001***
		Week 8	43	23.70 ± 1.60	5.60%	95.3%	**<0.001***
		Week 12	43	23.02 ± 1.75	8.13%	93.0%	**<0.001***
	Average Wrinkles Severity	Baseline	43	5052.96 ± 784.58			
		Week 4	41	4761.17 ± 758.60	4.43%	78.0%	**<0.001***
		Week 8	43	4619.55 ± 691.28	7.84%	90.7%	**<0.001***
		Week 12	43	4352.60 ± 966.13	13.33%	93.0%	**<0.001***
	Total Wrinkle Count	Baseline	43	51.77 ± 9.62			
		Week 4	41	49.10 ± 8.55	5.04%	63.4%	**0.001***
		Week 8	43	48.35 ± 9.26	6.67%	76.7%	**<0.001***
		Week 12	43	45.30 ± 8.93	11.33%	83.7%	**<0.001***
	Fine Lines Count	Baseline	43	22.36 ± 7.42			
		Week 4	41	19.80 ± 6.98	8.42%	58.5%	**0.002***
		Week 8	43	19.53 ± 6.69	11.34%	81.4%	**<0.001***
		Week 12	43	19.40 ± 7.42	9.49%	81.4%	**0.002***
	Deep Lines Count	Baseline	43	6.09 ± 4.06			
		Week 4	41	5.71 ± 3.76	NI	29.3%	0.525
		Week 8	43	4.86 ± 3.19	13.27%	60.5%	**0.001***
		Week 12	43	4.58 ± 3.24	19.43%	62.8%	**0.001***

NI=No Improvement

*Indicates a statistically significant improvement compared to baseline, p≤0.05

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Lines/Wrinkles (Global)	Average Length (Pixels)	Baseline	43	141.41 ± 32.34			
		Week 4	41	134.51 ± 24.47	3.88%	75.6%	**0.011***
		Week 8	43	129.84 ± 23.01	6.50%	83.7%	**<0.001***
		Week 12	43	127.04 ± 26.54	9.08%	95.3%	**<0.001***
	Average Width (Pixels)	Baseline	43	29.10 ± 2.51			
		Week 4	41	28.13 ± 2.49	3.31%	90.2%	**<0.001***
		Week 8	43	27.65 ± 2.29	4.73%	93.0%	**<0.001***
		Week 12	43	26.91 ± 2.31	7.41%	95.3%	**<0.001***
	Average Wrinkles Severity	Baseline	43	4302.10 ± 930.30			
		Week 4	41	4123.96 ± 817.97	3.11%	73.2%	**0.001***
		Week 8	43	4012.08 ± 831.95	5.54%	76.7%	**<0.001***
		Week 12	43	3835.72 ± 993.97	11.19%	88.4%	**<0.001***
	Total Wrinkle Count	Baseline	43	172.09 ± 84.29			
		Week 4	41	160.44 ± 75.91	4.06%	82.9%	**0.008***
		Week 8	43	156.23 ± 78.57	8.92%	97.7%	**<0.001***
		Week 12	43	152.40 ± 77.74	11.92%	100%	**<0.001***
	Fine Lines Count	Baseline	43	136.98 ± 65.33			
		Week 4	41	129.22 ± 59.90	2.72%	68.3%	0.077
		Week 8	43	125.93 ± 61.82	6.94%	86.0%	**<0.001***
		Week 12	43	120.88 ± 61.65	12.00%	95.3%	**<0.001***
	Deep Lines Count	Baseline	43	9.45 ± 8.68			
		Week 4	41	8.78 ± 8.65	NI	43.9%	0.437
		Week 8	43	7.14 ± 7.19	22.35%	67.4%	**0.001***
		Week 12	43	6.63 ± 7.07	33.03%	72.1%	**<0.001***

*Indicates a statistically significant improvement compared to baseline, p≤0.05.

NI=No Improvement

Subject Questionnaire

The majority of subjects (>50%) indicated in their responses to the consumer perception questionnaires that the test product immediately (T15m) made skin look and feel tighter, more fresh and rejuvenated, supple and elastic, softer and smoother, made wrinkles look and feel more shallow and less prominent, made jowls look better, made chin and neckline show improvement, made skin feel lifted. They also reported that the use of the device was comfortable, painless and more pleasant compared to other devices subjects had tried. The majority also liked the activator gel's smell and texture. Responses at weeks 4, 8 and 12 did not show any change in reduction of acne breakouts, receipt of compliments from friends and family and comfort of treatment compared to others tried. Notably, more than 90% of subjects indicated that the test product made skin look and feel fresh and rejuvenated throughout at weeks 4, 8 and 12.

Discussion

This study was designed in order to evaluate the efficacy and safety of facial wrinkle reduction by the NEWA® (EndyMed Medical Ltd.), a phase-controlled multisource radiofrequency home use energy device, the first energy based hand held device FDA cleared for home use of wrinkle reduction. Throughout the three month study, no adverse events occurred, no treatment side effects or application issues were reported by any of the study participants. Assessment analysis of the 45 subjects that completed the treatment course revealed that at the end of three months of treatment most participants had clinically significant improvement in the texture, luminosity, tactile elasticity and firmness of their skin. Notably, a statistically significant visual facial lift effect and jaw line lift effect was demonstrated in 62.2% (<0.05) and 77.8% (<0.0.01) of subjects respectively.

Computerized image analysis Clarity™ 2D Research System revealed improvements from mean baseline scores for multiple parameters. Statistically significant changes were noted in both crow's feet and global lines/wrinkles in respect to; average length, width and severity. Total line counts significantly decreased at weeks 4, 8 and 12 and for fine lines and at weeks 8 and 12 for deep lines. The fact that treatment progression resulted in increased improvement corroborates the collagen remodeling theory in which collagen buildup starts at 4 weeks and progresses to a maximum level at 3-6 months post treatment. [14]

It is accepted that our skin loses 1-2% of its collagen content after the age of 30 [15]. Evaluation of changes in collagen content using the SIAscope showed an increase in collagen content after 4 weeks of treatment that peaked at 12 weeks of treatment. The average increase in collagen content after 12 weeks of treatment was 3.8% (<0.001), found in 75.6% of subjects.

Furthermore, statistically significant improvements in skin firmness were demonstrated using the Cutometer which started after 4 weeks of treatment (12.94% improvement in 60 % of subjects) and continued to improve at weeks 8 and 12 (22.42% improvement in 84.4% of subjects at week 12). [16] Elasticity also improved, starting at an average

improvement of 46.79% at week 4 and increasing to 48.86% at week 12.

Conclusions:

This study establishes that use of NEWA® Anti-Aging Device in combination with conducting gel can lead to significant improvements in facial skin condition and rejuvenation after 3 months of use. Results showed a significant reduction in crow's feet and facial lines / wrinkles throughout the 12 weeks of product use. Additionally, instrumental assessments showed significant improvements in skin collagen content as well as firmness and elasticity throughout the 12-week study. Interestingly, the most improvement first appeared after 4 weeks of use and gradually increased in effect and statistical significance at 8 and 12 weeks. We believe that this dose dependent improvement is due in part to the physiology of heat based collagen remodeling.

The patient questionnaire results revealed subject satisfaction with the device and activator gel at all time points. Subjects responded favorably to questions regarding the device and gel as well as overall performance of the products combined. The results of this study indicate that the NEWA® multisource RF home use device offers a non-invasive, effective, safe and painless treatment option for self-administered skin rejuvenation. To our knowledge this is the first time that an energy based home use wrinkle reduction device has been tested in a controlled clinical study using both visual and instrumental assessments for multiple signs of skin aging. Follow-up studies are in place to investigate different protocols and synergistic combinations with topical products.

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