



NEWA[®] Clinical Studies

NEWA®

Reduce wrinkles,
tighten and lift facial skin



Introduction

NEWA® was created by EndyMed, a medical aesthetic company that offers energy based aesthetic treatment systems for both the professional and consumer markets. EndyMed's innovative, FDA cleared 3DEEP® RF technology is a clinically proven, effective solution for wrinkle reduction, skin tightening for the face and body, cellulite reduction, fractional skin resurfacing, RF microneedling and acne scar treatment. 3DEEP® delivers focused energy deep into the dermis, providing painless, safe treatments. 3DEEP® RF technology has been used in thousands of treatments by dermatologists, plastic surgeons, and skin rejuvenation clinics worldwide.

EndyMed's clinically proven 3DEEP® technology delivers focused RF energy 3 layers deep into the skin, reactivating the skins natural collagen production to remove wrinkles and noticeably lift and tighten skin. EndyMed has taken the same 3DEEP® technology which powers its medical/professional treatment systems and has adapted it for NEWA®, so consumers can enjoy 3DEEP® treatments in the comfort and convenience of their home.

EndyMed consistently invests in clinical studies to ensure that the 3DEEP® RF technology that powers both the professional and consumer lines is the most effective and safest available today. With over 30 published peer-reviewed studies by international renowned dermatologists and plastic surgeons, EndyMed is very proud to offer our clients the next level in the evolution of RF technology.

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Study 01

Clinical Assessment of the One Month
NEWA[®] Treatment Protocol, with Three Months Follow-Up



Study Design:

- **Participants:**
69 participants (average age 54.3 years; 37-72 years old).
Treatments were performed 5 times a week for three weeks, with a follow up evaluation after 3 months (without further treatment).
41 participants, with an average age of 57 (range of 39-77 years).

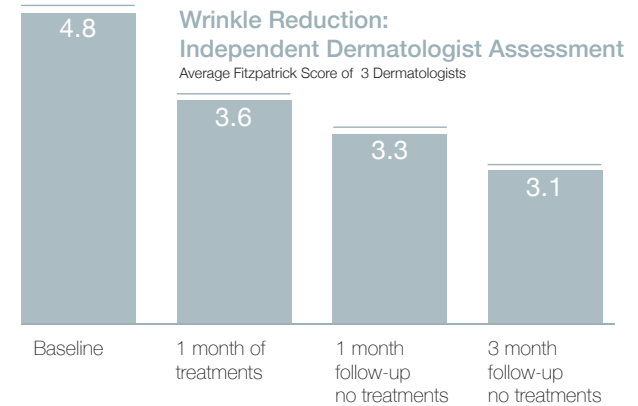
Results:

- **Objective Assessments:**
Objective assessments were performed according to the Fitzpatrick's Wrinkle and Elastosis Grading Scale by three impartial Dermatologists.
 - 36.6% average wrinkle reduction at the three month follow up evaluation
 - 90% of subjects showed improvement at the completion of one month of treatments
 - 79% of subjects showed further improvement 3 months after the completion of the treatment
- **Subjective Assessments:**
 - 89.1% of study participants noticed an improvement in wrinkle appearance
 - 72.7% rated the level of improvement as greater than 50%
 - 91.8% of study participants reported that the NEWA[®] was easy to use during treatments
 - No side effects were reported by any of the study participants.

Conclusions:

- 90% of subjects showed improvement in wrinkle appearance after one month of treatment
- Participants showed continued improvement after three months without additional treatments
- Participants reported that the NEWA[®] was easy to use
- No side effects were reported by the study participants

Source: Neil S. Sadick MD et. al. Home Based Wrinkle Reduction Using a Novel Handheld Multisource Phase-Controlled Radiofrequency Device. *Drugs Dermatol.* 2014;13(11):1342-1347.



Baseline

1 month of treatments



Baseline

1 month of treatments



Baseline

1 month of treatments

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Study 02

Clinical Study on The Safety and Efficacy of The NEWA on Men and Dark Skin Patients Skin Types V And VI

Study Design:

■ Participants:

44 participants, 22 women with skin types V and VI, and 22 men (53.05 ± 6.3 years) used the NEWA 5 times a week for 4 weeks. Objective and subjective skin assessment were performed at Baseline, Week 4, Week 8 and Week 16.

Results:

■ Objective Assessment:

- 40 participants completed the study. Assessments was performed by Clarity™ image computerized wrinkle analysis and by subjective questionnaires.
- At week 16 (12 weeks after the end of 4 weeks' treatment) 89.7% showed a statistically significant objective reduction of Wrinkles Severity (average 11.73%, $p < 0.001$) and 84.6% showed a statistically significant objective reduction of Total Wrinkle Count (average 22.90%, $p < 0.001$).
- No side effects occurred during the treatments. One subject noted to have blotchy skin during the treatment that cleared spontaneously after 1 hour.

■ Subjective assessment highlights:

- 80% of the users would recommend NEWA to their friends.
- 75% stated "My skin looks and feels softer and smoother".
- 72.5% stated they feel more beautiful/attractive.
- 70% of the users look forward to using the NEWA again.
- 70% stated "My skin looks and feels more fresh and rejuvenated".
- 65% stated "My skin pores look smaller and less prominent".

Sadick N, Harth Y: A 12-Week Clinical and Instrumental Study Evaluating the Efficacy of a multisource radiofrequency home use device for wrinkle reduction and improvement in skin tone, skin elasticity and dermal collagen content. Journal of cosmetic and laser therapy, 2016..

Conclusions:

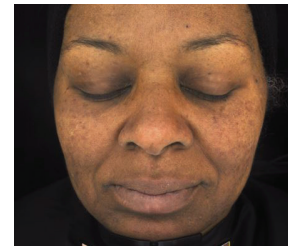
- The Newa skin rejuvenation system was tested on users with dark skin and in men without any side effects.
- No side effects occurred during the treatments" and delete the rest which is very minor: "One subject noted to have blotchy skin during the treatment that cleared spontaneously after 1 hour.



Baseline



4 weeks follow up

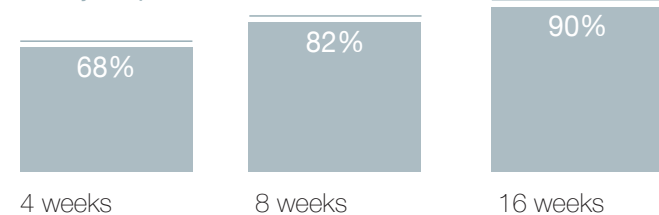


Baseline



4 weeks follow up

% of users with improvement in wrinkle severity compared to baseline



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Study 03 Clinical Study of the Efficacy of the NEWA[®] in Combination with Lift Activator gel

Study Design:

- Participants:
47 participants (ages 37-65)
3 treatments per week for the first 4 weeks, then twice a week for 8 more weeks

Results:

■ Objective Assessment:

Methods used: expert assessment, image analysis, Cutometer, Siascope.

Statistically significant results at the 12 week follow-up:

- 93% of participants showed improvement in wrinkle severity
- 100% of participants showed improvement in overall wrinkle appearance
- 72% of participants showed improvement in deep lines
- Other statistically significant improvements reported at the 12 week follow-up:
 - reduced marionette lines (67% of users)
 - increased elasticity (60% of users)
 - lift effect (facial) (62% of users)
 - lift effect (jaw line) (78% of users)
 - increased radiance/glow (84% of users)
 - improved skin texture/smoothness (69% of users)
 - improved skin tone (67% of users)
- 84% of participants showed an improvement in firmness by an average of 22.4%
- 55% of participants showed an improvement in elasticity by an average of 48.6%
- 75.6% of participants showed a statistically significant increase in skin collagen content (an average increase of 3.82%)

■ Subjective assessment:

Comments from study participants at the 4 week follow up:

- 89% stated “the test product immediately made my skin look and feel tighter”
- 78% stated “the test product immediately made my skin feel lifted”
- 82% stated “I would recommend to my friends”
- 87% stated “I look forward to using the device again”

Sadick N, Harth Y: A 12-Week Clinical and Instrumental Study Evaluating the Efficacy of a multisource radiofrequency home use device for wrinkle reduction and improvement in skin tone, skin elasticity and dermal collagen content. Submitted.

Conclusions:

- An average increase of 3.82% of collagen production was reported. (Skin loses 1.5% of its collagen content every year after the age of 30)
- 100% of participants showed an improvement in the appearance of wrinkles



Baseline

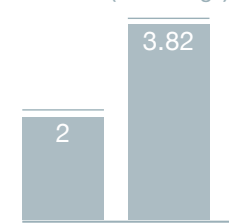
1 month of treatments



Baseline

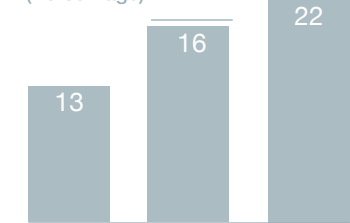
1 month of treatments

Increase in Skin Collagen Content (Percentage)



4 weeks 12 weeks

Increase in Skin Firmness (Percentage)



4 weeks 8 weeks 12 weeks

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Study 05 Hypoallergenic Test

■ Products Tested:

- NEWA® Lift Activator gel
- NEWA® Lift Activator gel for Delicate Skin
- Branded ultrasound gel

■ Study Design:

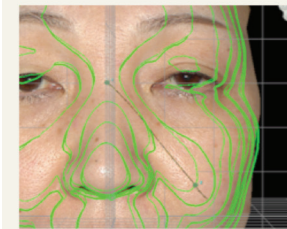
IRB approved, 60 participants were tested for a duration of 6 weeks. The original patch sites exhibited no reactions during the induction phase and the rest period. No other reactions were noted.

Lab conclusion: all three tested products did not induce dermal irritation and/or sensitization in human subjects.

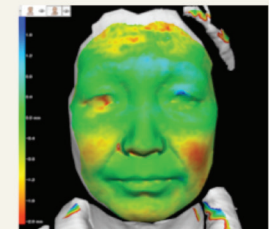
Study 06 NEWA® Effect On Skin Laxity (Japan)

Lift effect was assessed 15 minutes after a NEWA® treatment. Using Vectra Face Camera comparisons, before and after treatment images showed a significant elevation of 4.19mm on average ($P < 0.001$) of contour lines drawn on the cheek area.

- Volume of the cheek increased by 6.3 cc on average
- Photographic-based evaluation noticed an average improvement of 0.76 VAS (Visual Analogue Scale, $p < 0.01$)
- No adverse effects were observed



Measurement of the fifth contour line



Measurement of volume by Vectra Face
(distance from nose)

Published : Takahiro Fujimoto, Ph.D. The immediate result of facial skin laxity treated by NEWA® lift BIO Clinica 29 (5), 2014 (No. 380) pp. 89-95.

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