Efficacy and Safety of a Home-Use Combination of Radiofrequency, Light-Emitting Diode, and Microcurrent Device for Skin Rejuvenation: A Split-Face Study

Rungsima Wanitphakdeedecha MD, MA, MSc,
Chalermkwan Apinuntham MD,
Chadakan Yan MD,
Ma. Christina B. Gulfan MD, DPDS,
Supisara Wongdama MD.

ABSTRACT:

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DEPARTMENT OF DERMATOLOGY, FACULTY OF MEDICINE SIRIRAJ HOSPITAL, MAHIDOL UNIVERSITY, BANGKOK, THAILAND.

From: Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.
Corresponding author: Rungsima Wanitphakdeedecha, M.D., M.A., M.Sc., email: rungsima.wan@mahidol.ac.th

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Background: The use of radiofrequency (RF), light-emitting diodes (LED), and microcurrent have been reported previously for skin rejuvenation. The constant demand for ameliorating the skin signs of aging have been met by more and more home-use devices being available to the public.

Objective: To evaluate the efficacy and safety of a home-use device utilizing RF, red LED, and microcurrent.

Materials and Methods: This was a prospective split-face study with a total of 24 subjects who presented with signs of skin aging. All participants received treatment with the home-use device to their designated hemi-faces for 18 minutes per session, twice a week for 8 weeks. Primary outcomes were improvement in wrinkle size and depth by the Antera 3D® and volume difference in the mid- and lower face by Vectra-3D®. Secondary outcomes were changes in skin texture, elasticity, and skin hydration. Evaluations were done at baseline, and at 2-,4-,6-, and 8-week follow up. Participant's self-improvement scores and adverse effects were also recorded.

Results: Twenty-two (92%) participants completed the study and follow-up assessment. There was no statistically significant improvement in wrinkle size and depth, as well as volume difference in the mid- and lower face. Skin texture was statistically significant improved at all assessment points, whereas both skin elasticity and hydration did not have significant changes. There were no treatment associated adverse effects and all participants tolerated the treatment well.

Conclusion: The home-use device utilizing RF, red LED, and microcurrent is safe and can be used as a self-administered adjunctive treatment for skin texture improvement.

Key words: Radiofrequency, light-emitting diode, microcurrent device

Introduction

Over the past decade, there has been a growing patient demand for non-surgical and non-invasive procedures to address age-related skin changes. Patients also desire procedures that have short to no associated down-time after treatment[1]. In response to this demand, new non-invasive, non-ablative technologies that deliver anti-aging benefits have emerged.

Radiofrequency (RF) has gained popularity for its efficacy as a non-ablative modality for skin rejuvenation, improvement of skin laxity, and body contouring[2]. RF devices deliver electrical current that generates heat through the inherent resistance of tissues known as impedance. The produced thermal effects stimulate contraction of collagen fibers and stimulation of a wound-healing response that brings about dermal collagen remodeling and improvement of skin

laxity[3]. Light emitting diodes (LEDs) are a form of phototherapy that delivers a narrow spectrum of noncoherent light. LEDs have been utilized in both clinical and aesthetic applications[4], with the latter made possible by the observed photobiomodulatory effect of LEDs. Photobiomodulation promotes fibroblast proliferation, collagen synthesis, and production of both growth factors and extracellular matrix, resulting in skin lifting and tightening, as well as improvement of wrinkles[4]. LEDs in the blue (400-470 nm), red (630-700 nm), and near-infrared (800-1200 nm) wavelengths have been utilized the most[5]. Microcurrent is a form of electrical therapy that delivers current in the microampere range, which is below sensation threshold[6]. The delivery of microcurrent aims to mimic the native bioelectric signals within tissue[7], which has been found to promote cellular activities, cell proliferation, and protein synthesis. Early applications of microcurrent have been on the enhancement of muscle and tendon repair, pain management, and healing of chronic wounds. More recently in an in vivo study, its ability to stimulate collagen and elastin biosynthesis has been investigated in combination with 630- and 850-nm LEDs[8].

Since, it has been a growing acceptance for the use of home-use devices, which offer the benefit of patient convenience, less treatment costs, and better patient tolerability due to less pain and discomfort[9]. Multiple home-use devices are now available for skin rejuvenation[10], herein we investigate the efficacy and safety of a home-use device employing the combination of RF, red LED, and microcurrent.

Materials and methods

Subjects and Ethics

This prospective split-face study was conducted from February 2019 to February 2020 at the Siriraj Skin Laser Center, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Twenty four volunteer subjects between the ages of 30-60 years old, and with Fitzpatrick skin type III to V were initially enrolled. A board certified dermatologist assessed each participant's face for mild to moderate signs of skin aging based on the Fitzpatrick Wrinkle Assessment scale[11]. The present study excluded patients who were pregnant, or within the post-partum period and were breastfeeding; those with an infectious, inflammatory, or photosensitive dermatoses, or open wound on the face; a positive history of keloid or hypertrophic scar formation; those who were currently on oral Isotretinoin; and those with a history of herpes simplex infection.

This study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital's human research review committee, Mahidol University (SIRB Protocol No.

771/2561) and conformed to the guidelines of the 1975 Declaration of Helsinki. Written informed consent was obtained from all study subjects.

Prior to initiating treatment, block randomization was used to assign one side of each participant's face to treatment with the device plus ultrasound gel, and the contralateral side with only ultrasound gel as a control.

Device description

The Pra.L Total lift up Care (LG Electronics, Inc., Seoul, Korea) device measures 39 x 165.5 x 42 mm, with a weight of 196 grams. Each device unit is comprised of the tip which is placed in contact with the intended treatment site, and a handle that houses the power and treatment level buttons. The tip encloses the LED bulbs (630nm, 3.8mW/cm^2), and two pairs of linear electrodes made with surgical grade material delivering electrical microcurrent and bipolar radiofrequency energy. There are three treatment modes available: 'tightening mode' (630nm LED and radiofrequency energy mode), 'lifting mode' (electrical microcurrent mode), and 'total care mode' (combination of 630nm LED, electrical microcurrent and bipolar radiofrequency energy mode). The 'total care mode' lasts for a total of 18 minutes, with 6 minutes each for three treatment sites. The device is equipped with both vibration and sound effects to facilitate patient guidance during treatment and facilitate safety of treatment delivery.

Treatment protocol

Participants were asked to thoroughly wash and dry their faces before the procedure. Ultrasound gel was applied to both hemifaces, with only the designated treatment side receiving 18-minutes treatment with the Pra.L Total lift up Care device. Gentle, upward massaging motions were delivered on three treatment areas: the lateral neck (taking care to avoid the central area where the thyroid gland resides) from the supraclavicular area up until the mandible; from the chin and along the jawline until the infraorbital area; and from the lateral periorbital all the way up to the unilateral forehead. After cleansing the face, sunscreen is applied thereafter. Broad-spectrum sunscreen needs to be applied on a daily basis, and was not allowed to use other topical products or medications during the study period. Treatment sessions were done twice a week for 8 weeks, for a total of 16 sessions.

Treatment evaluation

Objective assessment

The primary outcome measures were improvement in wrinkle size and depth as determined by the Antera 3D® (Miravex, Dublin, Ireland) imaging system, and volume difference in the lower and midface as measured by Vectra-

3D® (Canfield Scientific, Parsippany, NJ). Secondary outcome measures were improvement in skin texture, elasticity, and hydration as measured by the Visioscan, Cutometer, and Corneometer (Courage-Khazaka, Köln, Germany), respectively. A translucent sheet was used to mark and map the designated areas on the face for consistency of location at each assessment point. Assessment for the primary and secondary outcome measures were performed at baseline, and at 2, 4, 6, and 8 weeks after the last treatment session.

Subjective assessment

Study participants were asked to grade improvement of their wrinkle, skin texture, elasticity, hydration and pore size using a quartile scale (0% = no improvement, 1-25% = slight improvement, 26-50% = moderate improvement, 51-75% = good improvement, 76-100% = excellent improvement) at 2, 4, 6, and 8 weeks after the final treatment session.

Treatment side effects were recorded on each treatment session and follow-up visit. Immediately after each treatment session, study subjects were also asked to rate the pain associated with treatment using a 10-point pain scale (0 = no pain to 10 = severe pain).

Statistical analyses

The obtained three-dimensional digital photographs were analyzed using built-in analysis software systems for both Antera 3D® and Vectra 3D®. Assessment data for the secondary outcome measures were subjected to statistical analysis with a paired sample t-test and repeated measure analysis of variance using PASW Statistics for Windows (version 18; SPSS Inc., Chicago, IL). Descriptive statistics was used for the patients' evaluation of improvement.

Results

Twenty four participants were initially enrolled, two subjects withdrew from the study because of inability to comply with the follow-up schedule. Twenty-two participants, of which 16 were female (72.7%), with a mean age of 35.0 $\pm$ 5.1 years (Table 1), were included in the final analysis. Wrinkle size and depth as determined by the Antera 3D® and lifting effect by Vectra 3D® did not show any change from baseline for both treated and untreated sides on all assessment points. Moreover, these were also not statistically significant when comparing both treatment and control sides (Table 2). Visioscan measurements showed an improvement in skin texture on the treated side on the 4th ($p= 0.015$), 6th ($p= 0.002$), and 8th ($p= 0.031$) weeks after the last treatment compared to baseline (Figure 1). Skin elasticity as measured by the Cutometer showed a statistically significant increase on the 2nd week on the treated side ($p <0.001$), which was, however, not sustained on subsequent assessment points. As for skin hydration measured with the

Corneometer, there was no significant difference between treatment and control sides on all assessment points. As for the subjective assessments shown in Figure 2, approximately 25-37.5% of patients had excellent improvement in wrinkle, skin texture, skin elasticity, skin hydration, and skin tightening at 8th-week post treatment. The patients did not experience any pain or discomfort during all treatment sessions with the investigational device, and there were no reported treatment side effects throughout the study period. Clinical photographs are shown in Figure 3.

Table 1 Demographic data of subjects enrolled in the study

Characteristics	Total, n (%)(n=22)
Sex, n (%)	
• Male	6 (27.3)
• Female	16 (72.7)
Age (years), mean ± S.D.	35.0 ± 5.1
Fitzpatrick's skin type, n (%)	
• Type III	13 (59.1)
• Type IV	7 (31.8)
• Type V	2 (9.1)

Table 2 Evaluation of wrinkle size and depth by Antera3D® and lifting effect by Vectra-3D®

	Treatment	Control	p-value
Wrinkle size and depth by Antera3D®			
Baseline	32.3 ± 0.8	31.9 ± 0.6	0.593
2-week follow-up	29.7 ± 0.6	30.7 ± 0.8	0.239
4-week follow-up	31.6 ± 0.5	32.7 ± 0.4	0.062
6-week follow-up	31.7 ± 0.5	31.9 ± 0.4	0.749
8-week follow-up	30.9 ± 0.5	31.6 ± 0.4	0.209
p-value	0.080	0.056	
Lifting effect by Vectra-3D®			
Baseline	-	-	
2-week follow-up	1.1 ± 0.3	0.8 ± 0.2	0.429
4-week follow-up	1.0 ± 0.2	1.0 ± 0.2	0.925
6-week follow-up	1.5 ± 0.3	1.2 ± 0.2	0.337
8-week follow-up	1.1 ± 0.2	0.9 ± 0.1	0.358
p-value	0.690	0.324	

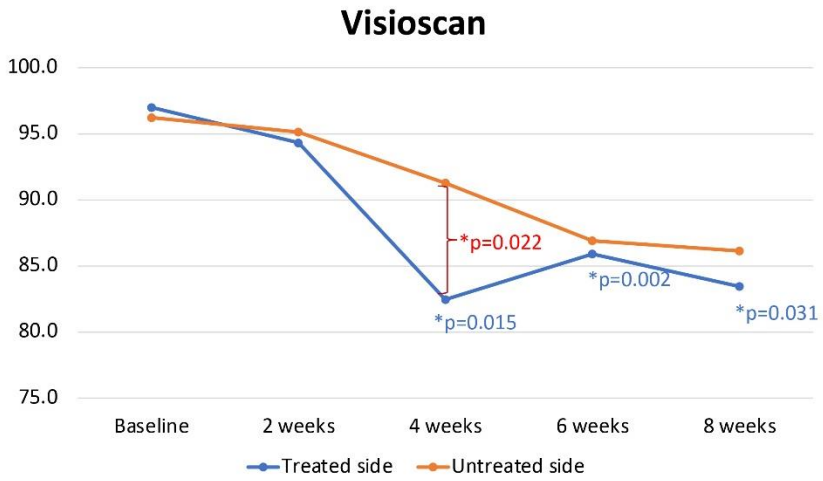

Figure 1 Visioscan® measurements showed an improvement in skin texture on the treated side on the 4th , 6th , and 8th weeks after the last treatment compared to baseline.

*, statistically significant (p-value < 0.05) compared to baseline

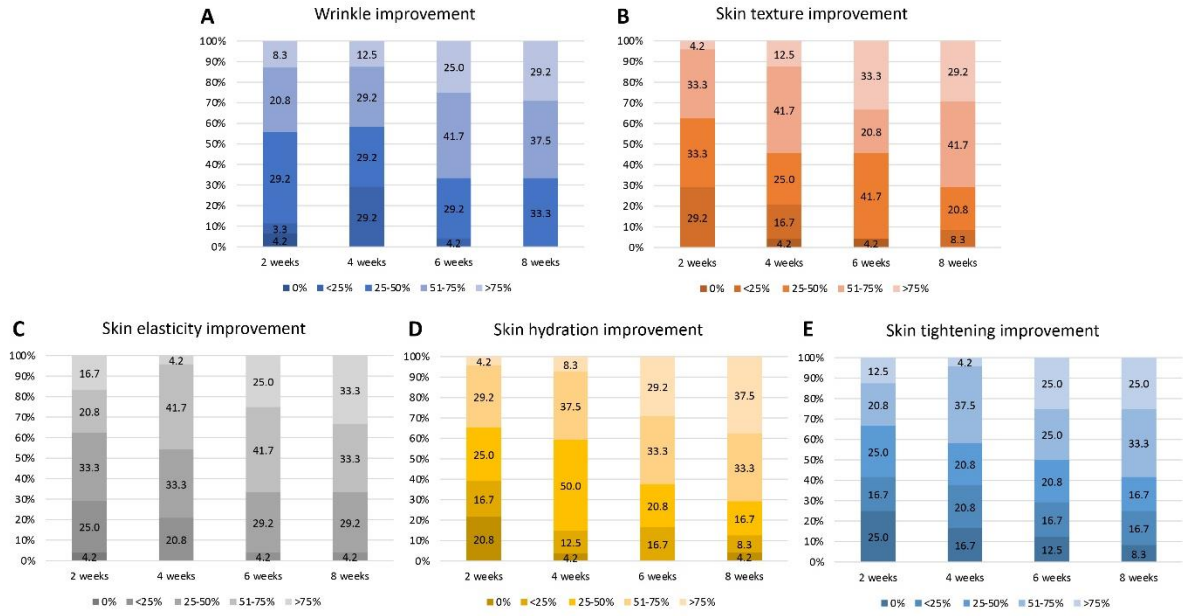

Figure 2 Each stack graph demonstrates patient-grading clinical improvement by quartile grading scale.

A. Wrinkles, B. Skin texture, C. Skin elasticity, D. Skin hydration, and E. Skin tightening

(0% = no improvement, 1-25% = slight improvement, 26-50% = moderate improvement, 51-75% = good improvement, 76-100% = excellent improvement)

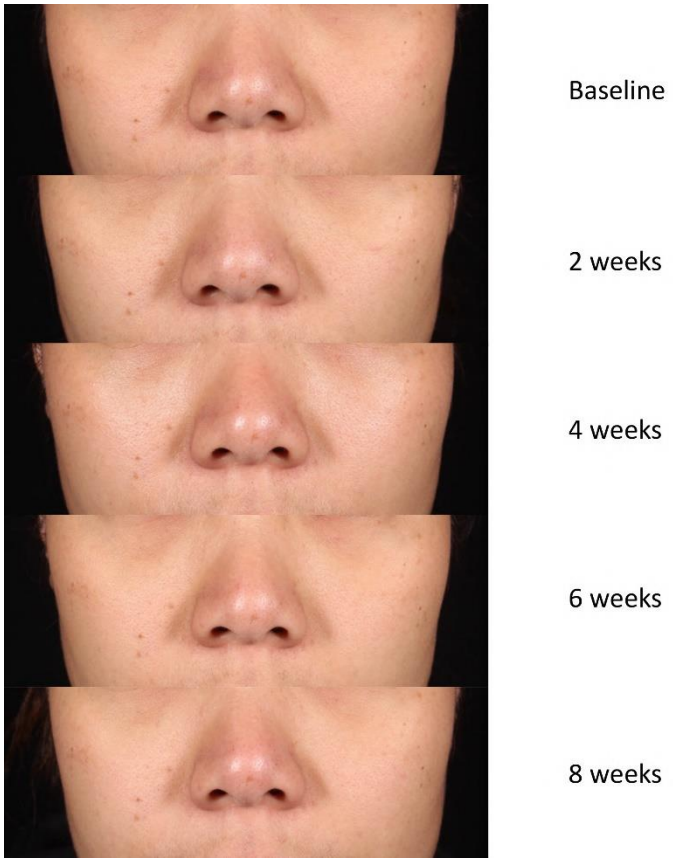

Figure 3 Clinical photographs of a participant treated on left side of face with a home-use device employing the combination of radiofrequency, red light emitting diodes, and microcurrent.

Discussion

We present the results of our study investigating the efficacy and safety of a home-use device employing radiofrequency, red LED, and microcurrents for the improvement of wrinkles, skin laxity, skin texture, elasticity, and hydration. Twenty-two out of twenty-four patients were able to complete the study, with each of them receiving twice-weekly sessions for 8 weeks, for a total of 16 treatment sessions. There was no notable improvement in wrinkle size and depth upon assessment during the 2nd, 4th, 6th and 8th week after the last treatment. Only transient improvements in both skin elasticity and skin laxity were observed during the 2nd and 4th week, respectively. Significant improvements in skin texture on the treated side were observed on all assessment points.

In 2011, the first home-use low RF power device based on the TriPollar technology was studied.[12] Twenty-three patients underwent 18 treatment sessions, done three times a week for

six weeks. Both volume and wrinkle depth analyses revealed statistically significant volume reduction of perioral and periorbital wrinkles, and an evident reduction in wrinkle depth, respectively. By 2014, Sadick et al[13] demonstrated the efficacy of a home-use phase-controlled multi-source RF device. Sixty-two subjects underwent 5 treatment sessions per week for one month and were followed up for a total of three months. At the end of the study, significant improvement of wrinkle scale scores were obtained. A modified protocol utilizing the same phase-controlled multi-source RF device was done by Sadick et al[14] in 2016. By increasing the treatment sessions to five times a week for one month then twice a week for another two months, clinically significant improvement in the texture, luminosity, tactile elasticity, and skin firmness were observed. Notably, statistically significant visual facial lift and jaw line lift effects were demonstrated as well. The same device though, failed to produce favorable results when it was given as every other day treatments for only 4 weeks,[15] underlying the necessity for multiple treatments sessions done at regular treatment intervals. A home-use device emitting electrostatic pulses containing RF energy in a burst mode was studied for its brow lifting effects in 50 participants[16]. Statistically significant reduction in brow to hairline distances (1.338 ± 0.170 cm) were obtained on the treated hemiface at the end of the investigation. Gold et al[9] demonstrated the efficacy of a novel home-use device utilizing both low-level RF and light energies (red and infrared LEDs) for the improvement of periorbital rhytids. Thirty patients each received 23 treatments (every other day for 6 weeks, then twice a week for the 12 weeks) and were followed up until 12 weeks after the last treatment session. Significant improvement of both wrinkle severity scores and subject's satisfaction evaluation were observed.

The aforementioned studies underline the importance of having regularly-administered treatments with shorter treatment intervals. As home-use devices deliver only lower energies compared to their medical and clinic-grade counterparts, a higher frequency of treatment is necessary if at all to produce appreciable results. Furthermore, the various home-use devices that are currently available all vary in their mechanisms of action and up until the present, no standard home-use device exists. To the best of the authors' knowledge, this is the first study investigating a home-use device utilizing the combination of RF, red LED, and microcurrent. RF produces bulk tissue heating leading to neocollagenesis and subsequent tissue tightening[3], while LED emits specific narrow spectrum wavelength of light triggering photobiochemical reaction which limitation of penetration to dermis[4]. Specifically, microcurrent

activates biologic system, promotes cell proliferation, and protein synthesis[17]. Regarding different mechanisms of RF, LED, and microcurrent, this combination may have synergistic effects on facial skin rejuvenation. The home-use device under investigation has a low power RF, and only small red LED bulbs as compared to other home-use LED devices, let alone medical grade device. Only modest, and non-sustainable results were obtained, and it remains to be determined with a longer follow-up if any clinical benefit can be obtained with its use. On the other hand, as it is a safe and well-tolerated, patients may combine this home-use device with other devices for home-use as well[18], and may also use it as an adjunct to treatments they receive from the clinic.

The limitations of our study include a small sample size and the lack of participant blinding. The patients knew which side received treatment, and this could have led to erroneous grading of patient improvement for the different skin parameters and subjective outcome measure including patient satisfaction may be susceptible to bias. Moreover, the patients may intentionally or unintentionally use the device on both sides of their faces. It is recommended that larger randomized controlled trials with higher number of treatments should be conducted in the future.

In conclusion, the home-use device utilizing RF, red LED, and microcurrent is safe and can be used as a self-administered adjunctive treatment for skin texture improvement.

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