



Effectiveness of a Radiofrequency Device for Rejuvenation of Aged Skin at Home: A Randomized Split-Face Clinical Trial

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ABSTRACT

Introduction: Several techniques, including the use of radiofrequency (RF) devices, are currently utilized for the treatment of skin aging. This study aimed to evaluate the anti-aging effects imparted by a home-based RF beauty device and to compare these results with those of a marketed anti-aging cosmetic in vivo.

Methods: Thirty-three women aged 35–60 years were enrolled in this randomized, controlled, split-face trial. This study involved a 12-week trial with five repeated measurements (at baseline, 2, 4, 8 and 12 weeks). One side of the face was randomly selected to be part of the experimental group and treated with the RF beauty

device, while the other side was considered as control and was treated with an anti-aging cosmetic. Treatment safety was evaluated. Skin wrinkles, hydration, radiance, elasticity, color and thickness were evaluated using noninvasive equipment.

Results: Thirty-two participants completed the study; one withdrew for personal reasons. Compared with the anti-aging cosmetic-treated facial side, the experimental side showed statistically significant improvements in wrinkles, skin radiance, color and thickness ($p < 0.05$).

Conclusions: The home-based RF beauty device was safe and effective for rejuvenation. The device was more effective than the commercially available anti-aging cosmetics.

Keywords: Home-based radiofrequency beauty device; Wrinkles; Skin elasticity; Skin color and skin thickness

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Key Summary Points

Why carry out this study?

In the past few years, the emergence of RF home beauty devices has generated great interest among dermatologists and consumers. Their efficacy and safety have also become the focus of attention

This study aimed to evaluate the anti-aging effects imparted by a home-based RF beauty device and to compare these results with those of a marketed anti-aging cosmetic in vivo

What was learned from the study?

The results provide further proof of the safety and efficacy of home-based RF beauty devices in rejuvenation

INTRODUCTION

Skin aging is a degenerative process characterized by dryness, deep wrinkles, reduced elasticity and pigment formation and is the result of progressive atrophy of the dermis [1, 2]. With the aging population and their consumption demands, approaches to reduce skin aging have gained significant attention [3]. For decades, there has been an ongoing discussion on the optimal treatment of skin aging. Radiofrequency (RF) is an important ablation method and has become a popular means of rejuvenation, prevention of regional fat loss and contour restoration [4]. RF fractional technologies can be administered from the surface using a grid of electrodes or through the dermis using a grid of microneedles that deliver RF energy to the dermis. Surface electrodes provide a more superficial effect on improving texture and fine lines [5], while longer needles penetrate deeper, providing deeper dermal remodeling [6].

This study was conducted to compare the anti-aging effects of a home-based RF beauty device and gel with those of an anti-aging

cosmetic agent to determine the optimal approach to anti-aging. A 12-week, randomized, controlled, split-face trial was implemented to test the study objectives.

In this trial, the device tested is a home RF anti-aging beauty device using bipolar ring RF and red-light technology. The bipolar ring RF generator provides 1 MHz of RF energy that can penetrate the epidermis to the dermis (Fig. 1). The red-light technology uses a 630 ± 10 nm light source. The device has a ring electrode head that can cover a large treatment area of the skin, a high fitting degree and more uniform energy transfer. The device is equipped with a temperature sensor and a motion sensor that control the skin temperature between 37 and 42 °C. When the temperature sensor detects a high skin temperature, the energy output automatically reduces or the device stops. When the motion sensor detects that the device is stationary for some time, the device will also stop delivering energy. These two sensors



Fig. 1 Home radiofrequency beauty device

improve the safety of the user and avoid skin burns due to overheating .

In this study, participants used the device on the device side based on the randomly assigned table in accordance with the device instructions under the supervision of the investigator. The application area was one side of the neck and one side of the face. The device has three gears, and two gears were used each time. The RF beauty device was used 5 days a week, once a day, for 6 min.

METHODS

Study Subjects

Thirty-three Chinese women were enrolled in this study. Thirty-two participants completed the study, while one withdrew for personal reasons. We included (1) those aged 30–65 years; (2) those in general good health; (3) those with crow's feet of grade ≥ 3 ; (4) those who agreed to actively avoid exposure to sunlight for the duration of the trial period. We excluded participants who (1) were pregnant or lactating; (2) had skin diseases such as eczema, psoriasis, etc.; (3) had birthmarks, tattoos, wounds or other skin conditions on the testing region or nearby and (4) had known allergies to the test substance. This study was approved by

the Biomedical Ethics Committee of West China Hospital, Sichuan University. Written informed consent was obtained from all participants.

All participants wore a black cap over the hair on their heads (to avoid a possible influence of their hair on age perception) and waited for 30 min under ambient conditions ($T = 21 \pm 2^\circ\text{C}$, $\text{RH} \% = 50 \pm 10\%$) before the test.

Materials

The main ingredients of the anti-aging cosmetics and gels are shown in Table 1.

The device is used with a special gel, which aids unified and efficient transmission of RF energy. Gel usage also increases the lubrication between the device and the skin and reduces the level of friction while the device is in motion.

Study Design

This was a randomized, split-face study with treatment over 3 months. Participants were randomly assigned to apply cosmetics alone on one side of the face and to use the RF beauty device and gel on the other side. The test cosmetic and device were applied for 5 consecutive days, followed by a 2-day rest for the first 2 months of treatment and three times per week in the 3rd month. To ensure compliance, all subjects applied the cosmetics and device under supervision at the center.

No other products such as makeup, skin care products and medications were applied to the face during the trial. Assessments of skin's biophysical properties were carried out at the indicated times.

Objective Assessments

Images captured from the front and those obtained from the left and right sides at 45° were obtained using the VISIA-CR skin analysis imaging system (Canfield Imaging Systems, Fairfield, NJ, USA). Photography and lighting parameters as well as the distance between the

Table 1 Main ingredients of anti-aging cosmetics and gels

No.	Name	Main functional ingredient
1	Anti-aging cosmetic	Aqua, glycerol, nicotinamide, palmitoyl pentapeptide-4, <i>Ceratonia siliqua</i> (carob) fruit extract, sodium hyaluronate, tocopheryl acetate
2	Gel	Water, glycerin, vitamin A palmitate, tocopherol, sodium hyaluronate, ceramide 6 II, <i>Aloe barbadensis</i> leaf extract, <i>Salix alba</i> bark extract, <i>Chrysanthellum indicum</i> extract, <i>Perilla ocymoides</i> leaf extract

face and lens were the same for all subjects at all time points.

The dermal water content was measured using a Corneometer (CM825, Courage and Khazaka, Cologne, Germany).

Skin color measurements were assessed with the $L^*a^*b^*$ system using a Chromameter CM2600d (Minolta Camera Co. Japan). The individual typological angle (ITA°) was calculated as follows:

$$ITA^\circ = [\text{Arctan}(L^* - 50)/b^*] \times 180.$$

The value of lightness L^* reflects perceived lightness, while b^* represents the hue from yellow to blue. The higher the ITA° , the lighter the skin. ITA° was calculated in pigmented and non-pigmented areas [7]. At baseline, the researcher selected an observable pigmentation spot on each side of the participant's face and a non-pigmented area near the spot. The same pigmented and non-pigmented areas were tested at each follow-up.

Skin thickness at the temples was analyzed using Derma Lab Combo (Cortex Technology, Denmark), a high-resolution imaging system with a 20-MHz ultrasound probe, which is very useful for non-invasive observation of changes to the inner layers of the skin.

Skin elasticity was measured in the same forehead area using Cutometer[®] MPA 580 with a 2-mm diameter probe (Courage and Khazaka electronic GmbH, Cologne, Germany), based on a suction method that mechanically deforms the skin.

Clinical Evaluation

The doctor graded the severity of all facial and neck aging signs according to the Skin Aging Atlas Volume 2 [8].

Eight facial signs and three neck signs were graded in all participants. These comprised five signs of wrinkles (forehead wrinkles, crow's feet wrinkles, nasolabial fold, glabellar wrinkles and horizontal neck wrinkles), two signs of facial spots (density of pigment spots, localized cheek pigment spots), one sign of neck skin texture, one sign of facial pores and two signs of sagging

(ptosis) in the lower part of the face and neck. Lower scores corresponded to better skin status.

Self-Assessment

All participants answered a set of questions about skin parameters at each visit (W0, W2, W4, W8 and W12) using a self-assessment questionnaire.

Each parameter was rated on a scale from 0 to 9 points. The higher the score of moisture level, skin texture, firmness, radiance and complexion was, the better the skin; the lower the score of nasolabial folds, crow's feet, forehead wrinkles and horizontal neck wrinkles, the less severity of wrinkles. The durations of adverse events including erythema, edema and crusting on the two face sides of all patients were recorded.

Statistical Analysis

The data were analyzed using SPSS version 23.0 and were expressed as mean \pm standard deviation. If the data met the normal distribution, one-way ANOVA was performed to assess differences at a specific time point. Differences between sides of the face were assessed using a two-sample t test. If data did not meet the normal distribution, Mann-Whitney U and Wilcoxon signed-rank tests were used to compare changes over time and differences between facial sides. $P < 0.05$ was considered statistically significant.

RESULTS

During the 3-month period, none of the participants dropped out of the study because of adverse skin reactions.

Crow's Feet

Crow's feet were examined using the PRIMOS high-resolution system. Four different roughness parameters—average arithmetic roughness (R_a), average quadratic roughness (R_q), maximal

Table 2 Parameters R_a , R_q , R_z and R_{max} values measured at each time point

	W0	W2	W4	W8	W12
Experimental side					
R_a	38.8 ± 9.64	28.8 ± 8.94*	31.6 ± 8.89*	33.4 ± 8.99*	34.0 ± 10.03*
R_q	46.7 ± 11.69	35.1 ± 11.13*	37.6 ± 10.96*	40.2 ± 11.37*	41.2 ± 12.97
R_{max}	222.2 ± 62.64	176.1 ± 75.49*	180.1 ± 65.39*	188.8 ± 66.1	201.7 ± 80.48
R_z	163.3 ± 44.43	124.0 ± 49.94*	131.1 ± 53.12*	139.0 ± 55.83	148.4 ± 59.38
Control side					
R_a	33.5 ± 9.48	27.8 ± 6.92*	30.0 ± 6.96	32.9 ± 10.50	33.8 ± 10.71
R_q	40.4 ± 11.11	33.1 ± 8.88*	36.4 ± 8.78	39.9 ± 13.14	41.2 ± 12.68
R_{max}	198.7 ± 54.33	157.1 ± 49.09*	160.9 ± 48.39*	184.7 ± 70.14	192.5 ± 67.04
R_z	142.4 ± 43.66	115.4 ± 42.50*	123.1 ± 40.33	137.1 ± 53.91	143.8 ± 52.95

* $P < 0.05$ compared with baseline (W0)

roughness (R_{max}) and roughness (R_z)—were analyzed.

For the experimental facial side, the R_a displayed a statistically significant decrease after 2, 4, 8 and 12 weeks of treatment compared with baseline (D0); a statistically significant decrease in R_q was achieved after 2, 4 and 8 weeks of treatment compared with D0; R_{max} and R_z displayed a statistically significant decrease after 2 and 4 weeks of treatment compared with D0. For the control side, R_a , R_q and R_z each displayed a statistically significant decrease after 2 weeks of treatment compared with D0 (Table 2).

However, the changes (follow-up minus baseline value) in R_a , R_q and R_z values were much lower in the experimental side than in the control side. The changes in R_a value were -10.0 ± 6.81 , -7.1 ± 8.11 , -5.4 ± 8.02 and -4.8 ± 5.52 at 2, 4, 8 and 12 weeks, respectively, with statistical significance ($p < 0.05$). Similarly, the changes in R_q value were -11.7 ± 8.46 , -9.1 ± 9.82 , -6.5 ± 9.58 and -5.5 ± 7.48 at 2, 4, 8 and 12 weeks, respectively, with statistical significance ($p < 0.05$). The change in R_z value was -14.9 ± 34.01 at 12 weeks, with statistical significance ($p < 0.05$). (Figs. 2, 3).

Skin Hydration

Stratum corneum (SC) hydration value in each side was detected by a Corneometer CM 825. The mean values increased in both sides after 4, 8 and 12 weeks of treatment ($p < 0.05$) (Fig. 4), but there was no significant difference between the two sides after treatment ($p > 0.05$).

Skin Radiance

Skin radiance by gloss value of light reflectance was measured using a Glossmeter GL200. Statistically significant improvements were observed in both sides at weeks 2, 4, 8 and 12 (all $p < 0.05$) (Fig. 5). There was a significant increase in the experimental side compared to the control side at weeks 2, 4 and 8 (Fig. 6).

Skin Elasticity

Forehead skin gross elasticity (R2) was examined using a cutometer. A significant increase ($p < 0.05$) in R2 was observed in the experimental side compared to D0 at W12. In the control side, R2 did not change significantly during the total testing period (Fig. 7). None of these parameters differed between the two sides.

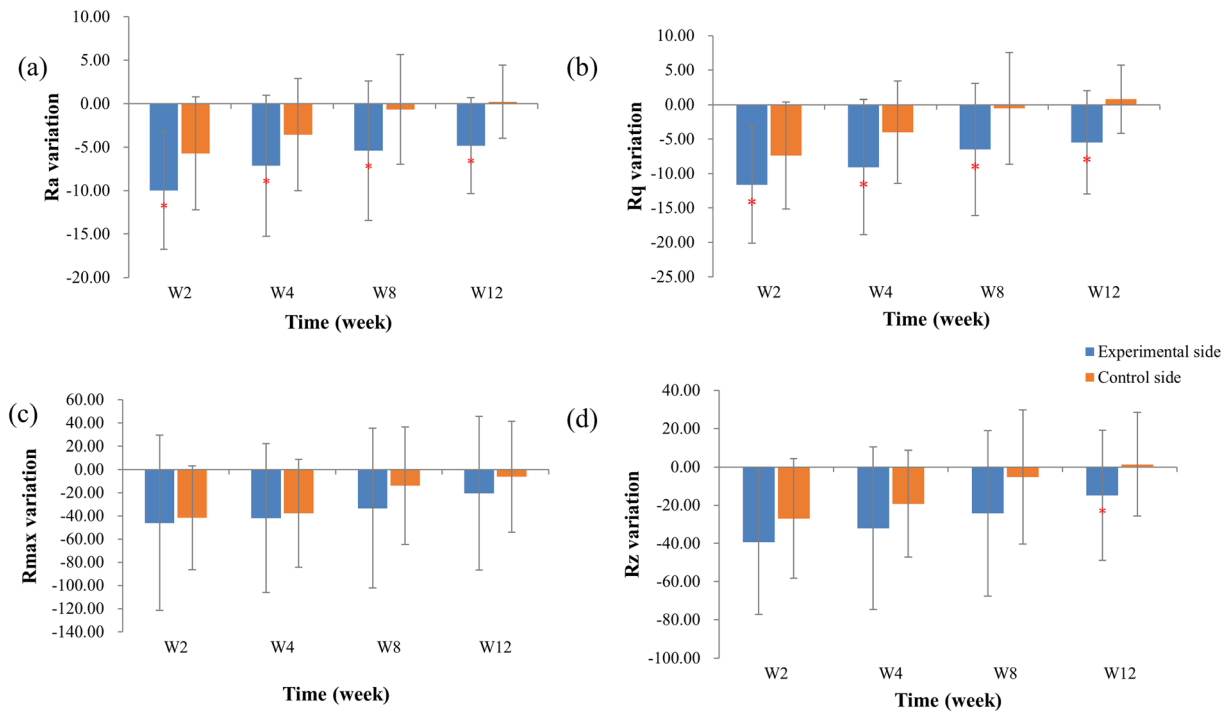


Fig. 2 Degree of decrease of R_a (a), R_q (b), R_z (c) and R_{max} (d) value for crow's feet after treatment compared to week 0. A significant difference was observed between the

experimental side and control side for all parameter decreases from week 0. * $P < 0.05$

Skin Color

A significant difference from the baseline value for ITA° in the pigmented area was observed for the experimental side and control side at week 12 (Fig. 8). The ITA° in the pigmented area of the experimental side showed a significantly greater increase than that of the control side at week 12 (Fig. 9). No significant difference was found in the ITA° in the non-pigmented area on both sides compared with the baseline value, and no significant difference was noted between the two sides ($p > 0.05$).

Skin Thickness

Skin thickness was examined using the ultrasound probe of the DermaLab Combo. Both sides showed an increase in skin thickness 12 weeks after treatment. The results showed that skin thickness significantly increased in the experimental side from W4 to W12 (Fig. 10). A significant difference between both sides was

demonstrated for skin thickness value change (follow-up minus baseline value) at W4, W8 and W12 (Fig. 11).

Clinical Evaluation

The RF beauty device with combined gel significantly reduced the severity of several clinical attributes including forehead wrinkles, crow's feet, nasolabial folds, glabellar wrinkles, facial pores and sagging of the lower part of the face at W12 compared with D0. However, clinical attributes were not all significantly different before and after treatment in the control side. There were no significant differences in clinical scores for glabellar wrinkles, density of pigment spots, localized cheek pigment spots, horizontal neck wrinkles, neck skin texture and sagging of the neck between the experimental and control sides. On the other hand, the experimental side had significantly greater improvement in forehead wrinkles, crow's feet, nasolabial folds,

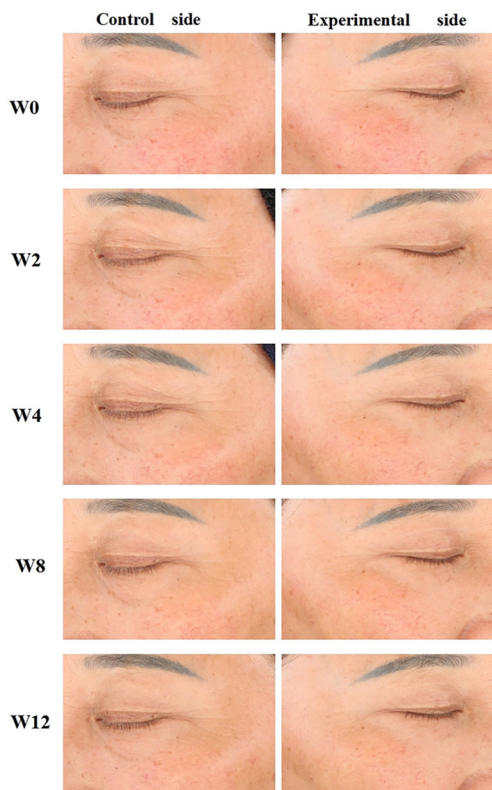


Fig. 3 Photographs of one participant before and 12 weeks after the application of cosmetic on the left side of the face and radiofrequency beauty device on the right

facial pores and sagging of the lower part of the face than the control side at W12.

Self-Assessment

After 3 months of treatment, subjective scores of the RF beauty device combined gel side and the side treated by cosmetic alone were 6.19 and 4.97 in smoothness ($p = 0.000$), 6.50 and 4.66 in skin firmness ($p = 0.000$), 5.75 and 4.81 in radiance ($p = 0.000$), 5.44 and 4.94 in skin color ($p = 0.001$), 4.72 and 5.47 in nasolabial folds ($p = 0.000$), 4.56 and 5.22 in horizontal neck wrinkles ($p = 0.000$), 4.84 and 5.69 in crow's feet ($p = 0.000$) and 5.13 and 5.91 in forehead wrinkles ($p = 0.000$), respectively. There was a significant difference between the two sides.

Safety

No adverse reactions were observed during the study.

DISCUSSION

In the past few years, the emergence of RF home beauty devices has generated great interest among dermatologists and consumers [9]. Their efficacy and safety also became the focus of attention. In this study, we evaluated the anti-aging effects of a home-based RF beauty device and compared these results with those of a commercial anti-aging cosmetic agent in vivo.

At present, many studies on home RF cosmetology are open-label, intra-individual controlled trials [9]. The present trial followed a randomized controlled design, and a commercially available anti-wrinkle cosmetic agent was used as a control. The main active ingredients of this cosmetic are aqua, glycerol, nicotinamide, palmitoyl pentapeptide-4, *Ceratonia siliqua* (carob) fruit extract, sodium hyaluronate, tocopheryl acetate, etc. According to literature reports, niacinamide can inhibit melanin transport from melanocytes to keratinocytes and participate in cell energy metabolism, promote skin renewal and accelerate melanin metabolism [10]. Therefore, niacinamide is often used in whitening products. Palmitoyl pentapeptide-4 is a small, highly specific bioactive peptide that has been reported to improve wrinkles with long-term use [11]. Sodium hyaluronate is known as the ideal natural moisturizing factor and has good lubricity and film-forming ability; it can form a layer of breathable hydration film on the skin surface, so the skin feels lubricated and moist. Sodium hyaluronate can retain water, which leaves the skin softer, smoother and more radiant. A hydrated skin can also slow down the formation of wrinkles and improve deep fine lines and existing wrinkles [12]. Our test results also showed that 12 weeks of continuous use of the studied cosmetics resulted in increased skin moisture content and radiance, improved wrinkles and reduced color spots. Wrinkles, stains and skin thickness improved more on the

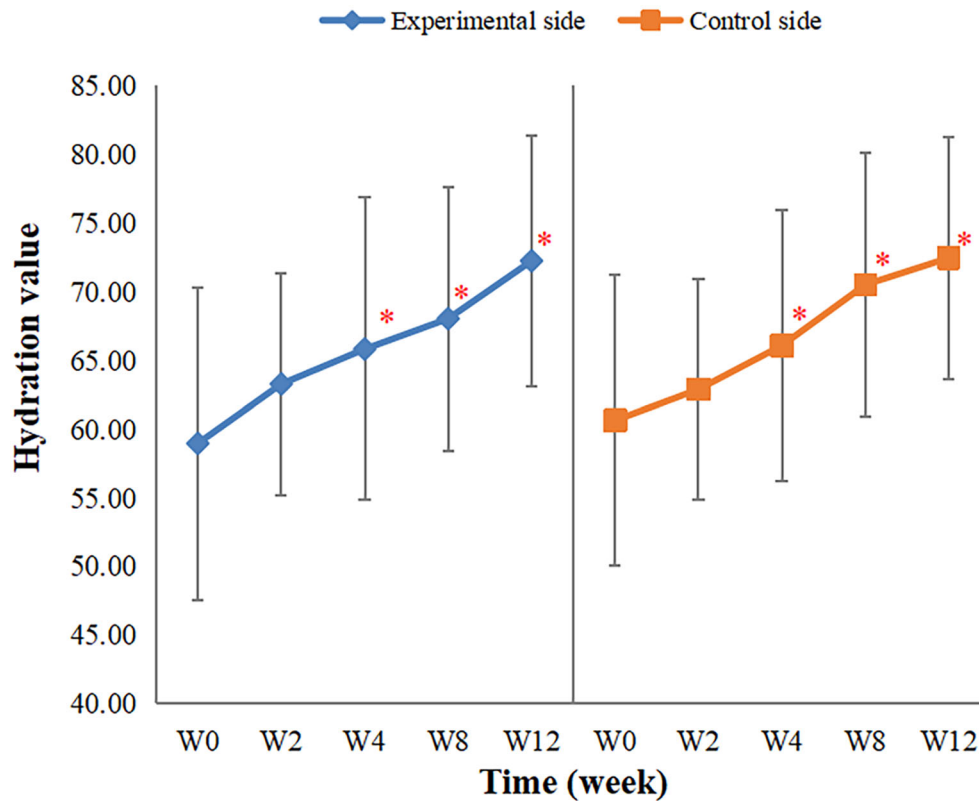


Fig. 4 Hydration value at each time point of measurement. A statistically significant increase was noted at week 4 and week 12 on both sides compared with week 0. * $P < 0.05$

device side than on the control side. Although the gel on the device side contains more active ingredients than cosmetics, the gel was only applied to the area when the device was used and washed off immediately after use. The main purpose of using gels is to achieve even heat conduction.

According to reports of a 12-week trial using an RF home-use device, the clinical evaluation revealed a significant reduction in crow's feet and facial lines/wrinkles [13]. Moreover, instrumental tests demonstrated significant improvements in skin collagen content, firmness and elasticity. These findings are similar to the results of our study. Compared with this study, we used a more noninvasive skin detection device to more comprehensively reflect skin changes.

Noninvasive RF treatment is based on the application of RF electrodes externally to the skin of the treatment area. The applied RF

energy penetrates the tissue up to a few millimeters [14]. To reach collagenous tissue in the dermis and subcutaneous fat, the RF current must pass through the epidermis. By heating deep dermal collagen at a higher temperature than could be safely used at the epidermal level, a much stronger collagen contraction effect can be achieved to improve deep wrinkles and enhance skin tightening [15].

In addition to RF technology, the device was combined with 630 ± 10 nm LED red light. It has been reported that 630-nm LED red light can rejuvenate the skin, as it increases the levels of type I procollagen and collagen types I and III and reduces the levels MMP-1 and MMP-2 in vitro. When using RF and red light, the synergistic effects would be maximized around the subcutaneous fibrous septae and epidermis [16]. Gold et al. evaluated the safety, efficacy and compliance of a home device utilizing RF and LED energy to treat periorbital wrinkles and

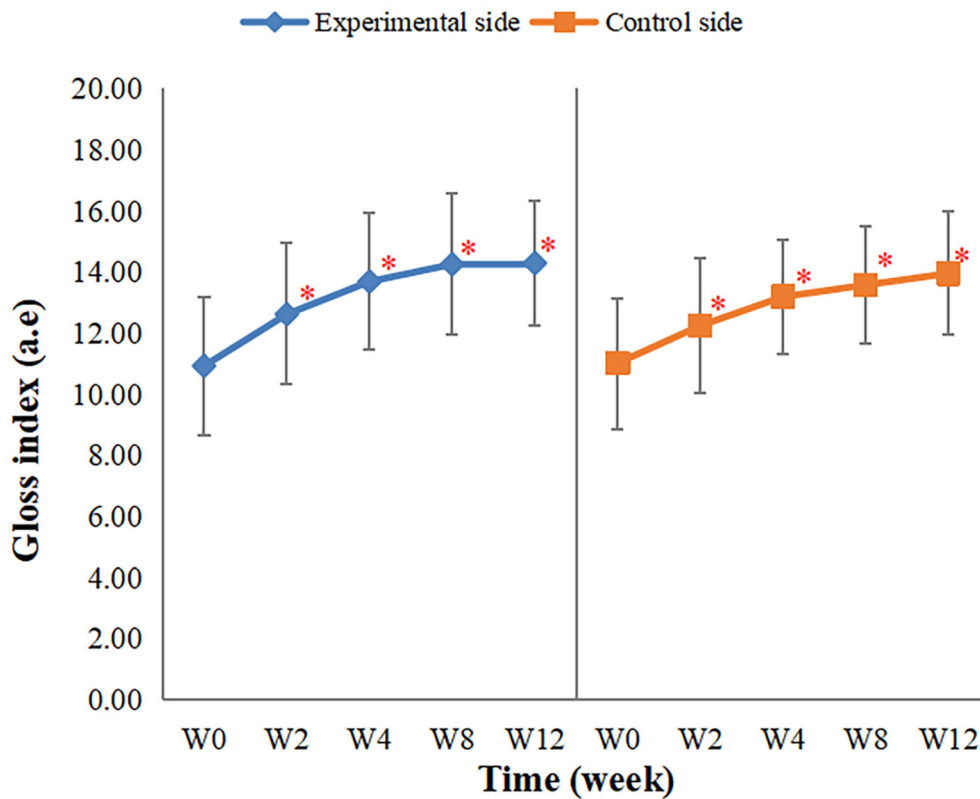


Fig. 5 Gloss index at each time point of measurement. A statistically significant increase was observed at week 2 and week 12 on both sides compared with week 0. * $P < 0.05$

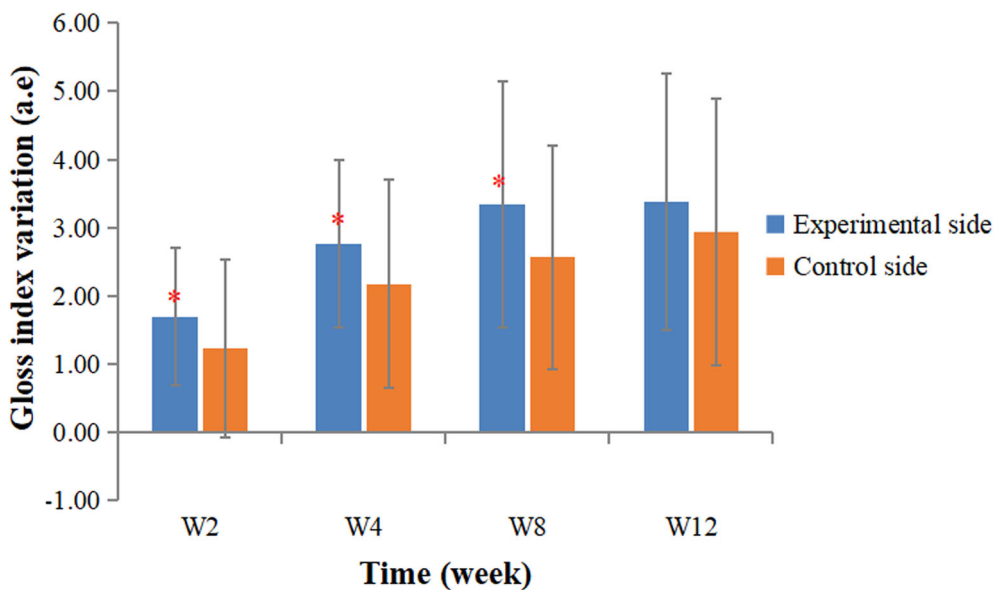


Fig. 6 Degree of increase in gloss index after treatment compared to week 0. A significant difference was observed between experimental side and control side in terms of gloss index increase from week 0. * $P < 0.05$

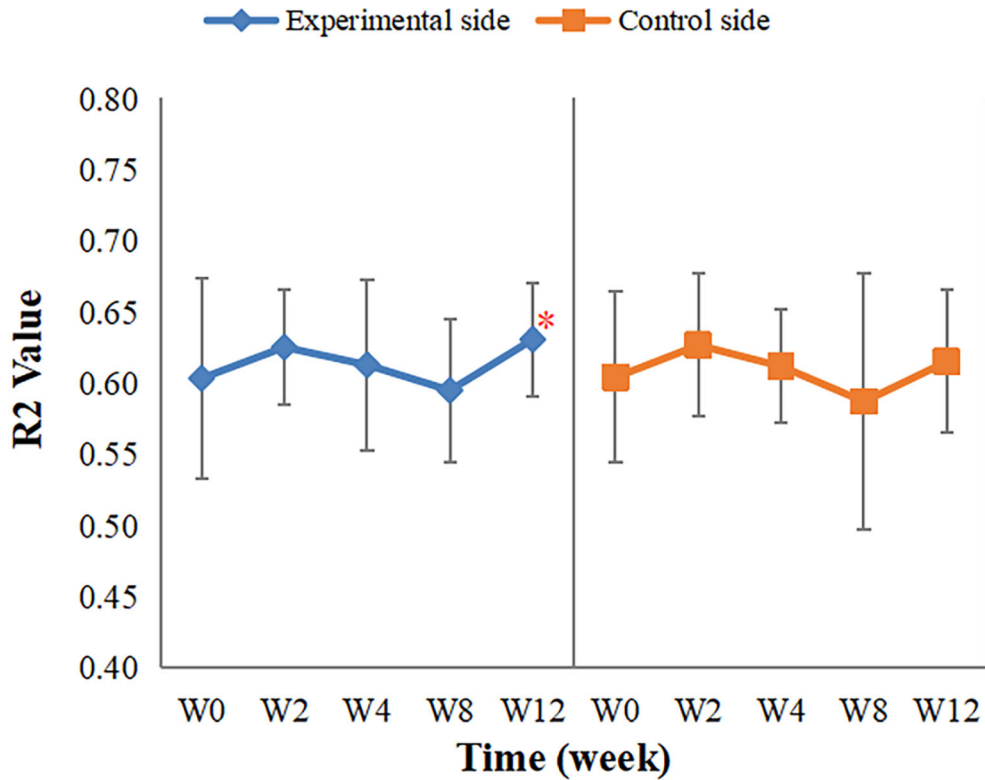


Fig. 7 R2 value at each time point of measurement. A statistically significant increase was seen at week 12 on the experimental side compared with week 0. * $P < 0.05$

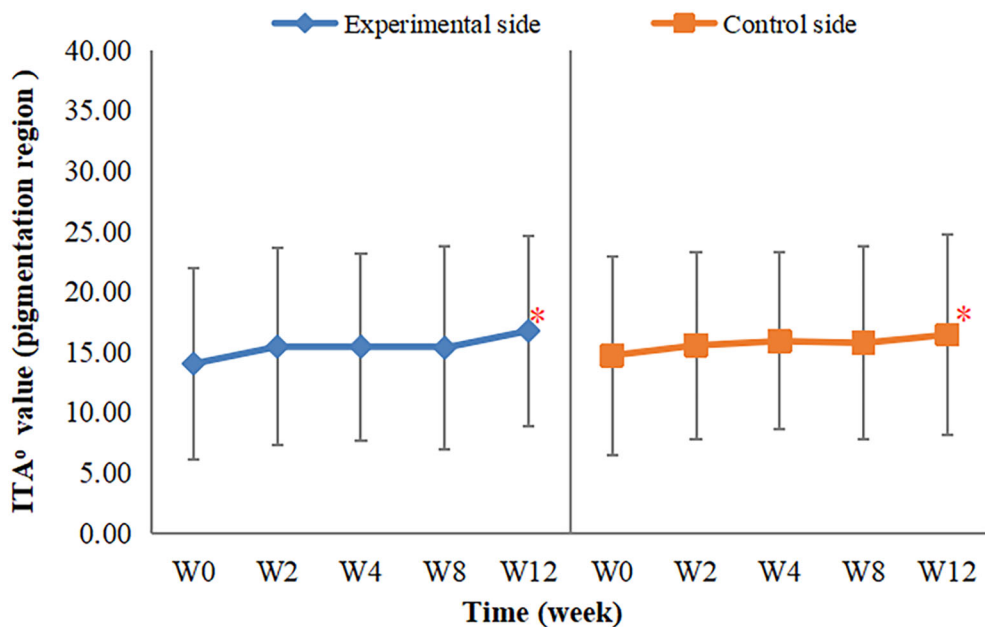


Fig. 8 ITA° value at each time point of measurement. A statistically significant increase was seen at week 12 on both sides compared with week 0. * $P < 0.05$

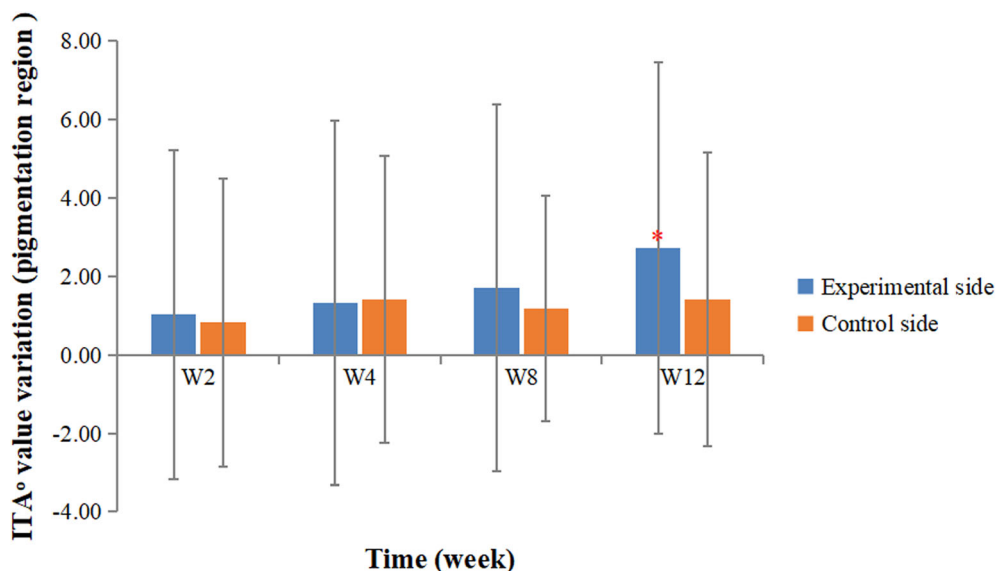


Fig. 9 Increase degree of ITA° after treatment compared to week 0; a significant difference was observed between experimental side and control side for ITA° value increase from week 0. * $P < 0.05$

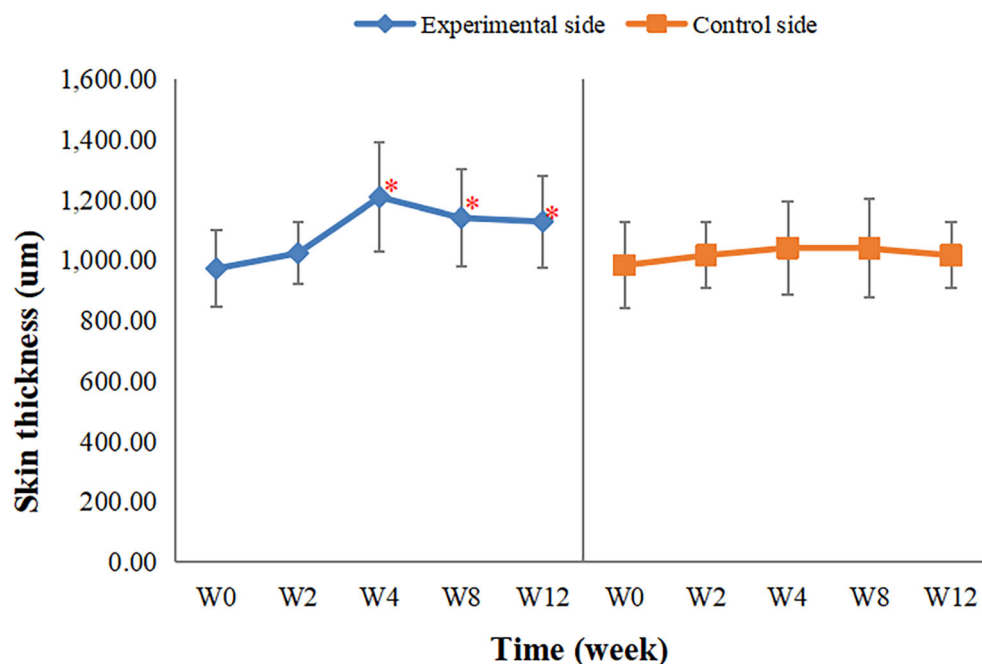


Fig. 10 Skin thickness at each time point of measurement. A statistically significant increase was observed at week 4 and week 12 on the experimental side compared with week 0. * $P < 0.05$

improve skin appearance [15]. However, this study was limited because only periorbital clinical evaluation was performed, and no noninvasive testing equipment was used.

In the present study, we compared a home beauty device with an anti-aging cosmetic and used a more noninvasive skin detection device to evaluate skin moisture, radiance, elasticity,

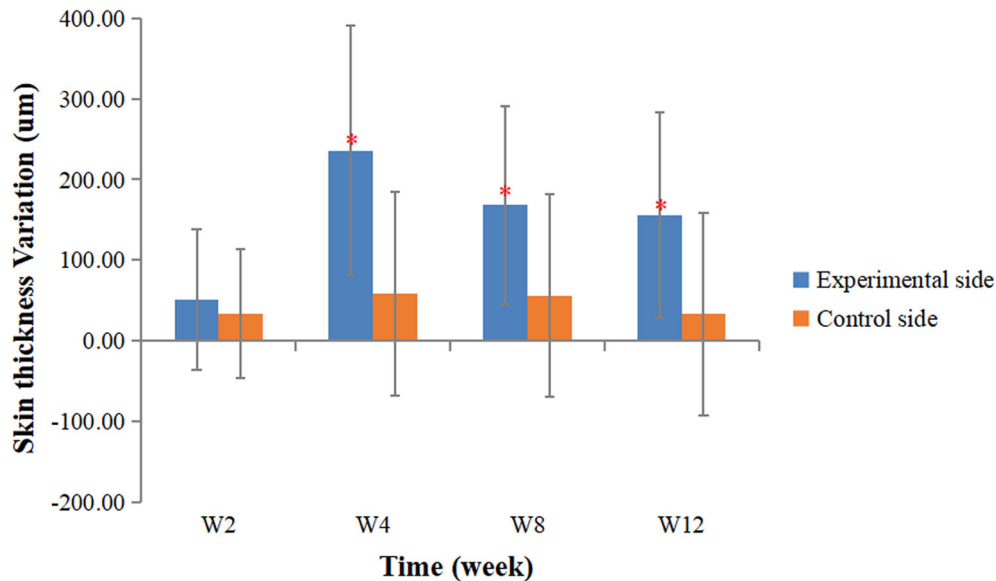


Fig. 11 Increase in the degree of skin thickness after treatment compared to that at week 0. A significant difference was seen between the experimental and control sides in terms of the increase in skin thickness increase from week 0. * $P < 0.05$

color and skin thickness related parameters and obtain more comprehensive evaluation data. At present, China, Japan, South Korea and the European Union have issued relevant policies and guidelines on the efficacy evaluation of cosmetics. In the future, it is essential to ensure that home beauty devices are sufficiently safe to protect consumers, and their effectiveness should be fully evaluated.

Our study was limited by the use of cosmetics on one side of the face and the tested device on the other. During the trial, participants were aware of the device side and the cosmetic side, which may lead to information bias in their ratings. We will make further comparisons with other household beauty devices in the future. In addition, future studies should include long-term follow-up to investigate the long-term efficacy of home beauty devices and the persistence of their effects.

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Author Contributions. Conceptualization, methodology and design: Li Li and Xi Wang; Data acquisition, data analysis and interpretation: Xiaohong Shu, Wei Huo, Zhaoxia Li, Lin Zou and Ying Tang; Writing—original draft preparation: Xiaohong Shu, Ruoyu,Wan,Wei Huo, Zhaoxia Li; Writing—review and editing: Li Li and Xi Wang.

Disclosures. Xiaohong Shu, Zhaoxia Li, Lin Zou, Ying Tang, Li Li, Wei Huo and Xi Wang are all employees of the West China Hospital of Sichuan University. Ruoyu Wan is a student at West China Hospital of Sichuan University.

Compliance with Ethics Guidelines. This study was approved by the Biomedical Ethics Committee of West China Hospital, Sichuan University. Written informed consent was

obtained from all participants. The study was carried out in accordance with the Declaration of Helsinki and the good clinical practice criteria. The patients in this manuscript have given written informed for the publication of their photographs included in Fig. 3.

Data Availability. The datasets generated during and/or analyzed during the current study is available from the corresponding author on reasonable request.

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