

# Efficacy and safety of a home-use multi-energy-based device for skin tightening: a preclinical study

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**Background:** Several studies have investigated the effects of simultaneous application of various energy sources and technologies, such as radio frequencies, light-emitting diodes, and microcurrents, as well as sonophoresis and iontophoresis. The current study aims to develop a safe and effective home-use device that utilizes the synergistic effects of different energies and technologies.

**Methods:** Six pigs were divided into three groups (two pigs each): Group A, 3-minute cooling mode; Group B, 6-minute intensive care mode; Group C, 12-minute intensive care mode. The back of the porcine skin was subjected to the relevant procedure, thrice daily for 15 days. Skin temperature was monitored to evaluate the thermal effects of the home-use device. In addition, changes in the collagen and elastin levels were examined through histological studies.

**Results:** Visual inspection of the skin after device application did not show any skin damage at the treatment site. Examination of the skin surface and intradermal measurement of heat after treatment confirmed the deep heat generated by multi-energy sources. Histological staining revealed that accurate treatment of the target dermis layer effectively enhanced the deposition of both collagen and elastin.

**Conclusion:** This study demonstrates the positive effect of using a home-use multi-energy-based device for skin rejuvenation. Utilizing the simultaneous and dynamic interplay of radiofrequency, light-emitting diode, and microcurrent along with sonophoresis and iontophoresis, proved to be a safe and efficient way to rejuvenate the skin.

**Key words:** Radiofrequency; Light-emitting diode; Microcurrent; Sonophoresis; Iontophoresis

## INTRODUCTION

New emerging combination therapies afford a more convenient method for skin rejuvenation than traditional therapies because the former can be tailored for simultaneously targeting multiple skin quality features

and different anatomical regions, and achieve a multi-layered effect, thereby improving the overall appearance of the skin [1]. This approach can broaden the consumer entitlement and improve the consumer experience and satisfaction by providing an ideal balance between the treatment durability and outcome [2,3].

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We herein propose a novel device that utilizes the radiofrequency (RF), a light-emitting diode (LED), and a microcurrent as well as sonophoresis and iontophoresis technologies.

The RF and LED improve the elasticity of the skin; sonophoresis and iontophoresis improve the absorption of skincare ingredients applied before; and the microcurrent refreshes and soothes the skin and helps tighten the pores [4]. High RFs (>1 MHz) generate an electrical current on the human skin tissue, which in turn generates frictional heat (diathermy) that heats up certain organs and/or tissues of the body and increases the blood flow and circulation, tightens the skin, removes wrinkles, and reverses the signs of aging. Iontophoresis is a non-invasive method of creating an ionic bond with biological molecules (such as ascorbic acid) by using an electric field. Iontophoresis promotes the movement of ions across the skin barrier under the influence of an externally applied small potential difference. This effect is used to deliver therapeutic compounds across the skin [5]. Iontophoresis stimulates cells and promotes deep absorption of active ionic ingredients, such as vitamin C from facial products, to hydrate the skin [6].

Microcurrent is similar to the bioelectric current (or bio-current). It does not stimulate nerves or muscles [7]. Application of a microcurrent of <1 mA generates a bio-current of 40–60  $\mu$ A that stimulates skin cells and directs cell migration and proliferation, stimulates angiogenesis, reduces the inflammatory response, and improves wound healing [8]. Such small microcurrents also stimulate cells and boost the production of adenosine triphosphate, a primary source of energy in cells, by up to five times to promote cell metabolism and the discharge of waste that further improves skin hydration and elasticity [9].

Sonophoresis involves the use of low-frequency ultrasound of 355 kHz to stimulate the cell activity and create micro-vibrations that penetrate deep into the skin and break up dead skin cells to improve the absorption of skincare products and improve the skin elasticity. Our device contains an imbedded contact cooling mode to reduce pain and erythema and to increase patient comfort during the procedure. The cooling mode offers quick, soothing relief and helps tighten pores, leaving the user feeling and looking refreshed. Although RF is very well tolerated, its use still causes certain side effects, such as temporary erythema and swelling, as well as postoperative discomfort. These side effects can be reduced by using a cold mode. Lower temperatures seem to be safer and more comfortable for users [10].

The rejuvenating effect of each modality differs depending on the target skin layer. However, because the combination treatment can be used to resolve multiple intradermal issues simultaneously, it theoretically affords more substantial clinical results than those obtained after using any one modality alone.

The present study describes a novel, home-use, handheld, multi-energy-based device for enhancing the skin elasticity and reducing wrinkles by using a low-intensity light, low-dose RF, low-energy microcurrent, and low-intensity ultrasonic wave. This study also evaluates the efficacy and safety of the device in skin rejuvenation and compares the thermal and histological changes before and after device application in vivo.

## METHODS

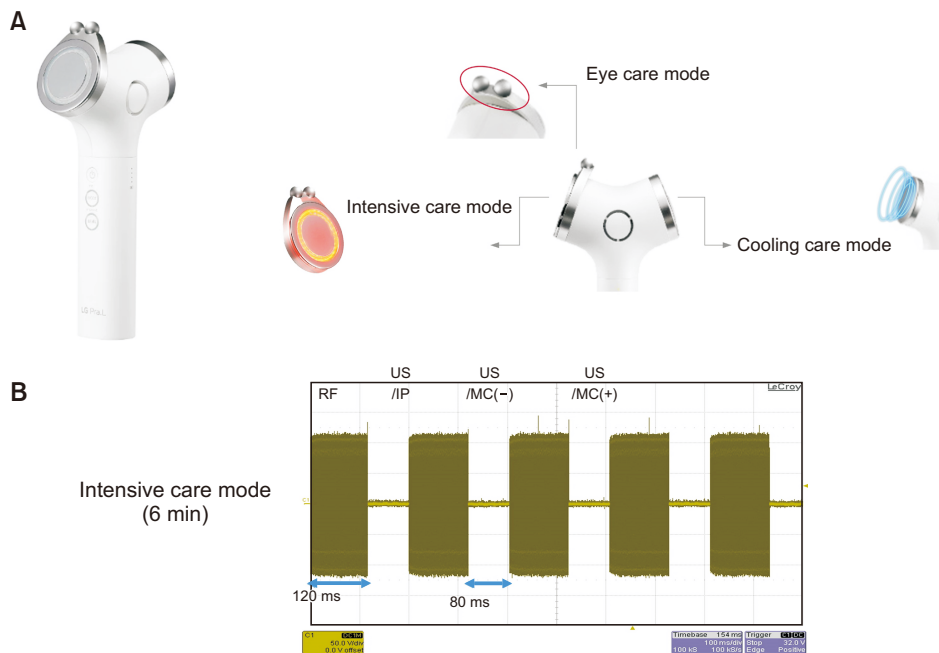
**Ethics statement:** This test was performed after the approval of the Animal Experiment Ethics Committee operated by CRONEX Co., Ltd. (CRONEX-IACUC-2021-05011).

### Statistical analysis

All data are expressed as mean  $\pm$  standard deviation. For statistical analysis of each set of data, Student's t-test was performed. Values of  $p < 0.05$  were considered statistically significant.

### Test device

The Pra.L Intensive Multi-Care (LG Electronics) device (42.3  $\times$  215  $\times$  33.6 mm; weight, 375 g) was used. The technical specifications of the devices are as follows: RF (1 MHz), iontophoresis (1 kHz), microcurrent (150/200/250  $\mu$ A), sonophoresis (355 kHz), and cooling LED (630-nm wavelength). The device utilizes the four core technologies (RF, microcurrent, sonophoresis, and iontophoresis) in a sequence that alternates every 0.12 seconds. This process is performed approximately 600 times for stimulating the cells within the skin to maximize the skin hydration and elasticity (Fig. 1). Each device unit comprises a tip placed in contact with the intended treatment site and a handle that houses the power and treatment-level buttons. The device can be operated under the following three treatment modes: intensive care mode (comprises ultrasound, RF, iontophoresis, microcurrent, and 630-nm LED), eye care mode (comprises RF and microcurrent), and cooling mode (comprises cooling energy). The intensive care mode is 6-minute long, while the cooling mode is 3-minute long. The device exhibits



**Fig. 1.** (A) BLP1, Pra.L Intensive Multi-Care (LG Electronics). The technical specifications of the devices are as follows: radiofrequency (RF), iontophoresis, microcurrent, ultrasound (US), cooling, 630-nm wavelength light-emitting diode. The device has three heads that allow the simultaneous application of these technologies. (B) Electrical voltage and current were measured with a digital oscilloscope (LS140; LeCroy) connected to circuits as shown. High-frequency US, microcurrent, and iontophoresis are used in a complex cycle (600 ms), in which each step takes 200 ms to complete, for a total period of 6 minutes.

both vibration and sound effects to facilitate patient safety and guidance during the treatment.

### Device treatment

Yorkshire pigs (body weight, 20–30 kg) were purchased. The pigs were maintained under the following conditions: temperature,  $22 \pm 3^\circ\text{C}$ ; humidity,  $50 \pm 10\%$ ; cleanliness, 1,500; ventilation, 15T/HR; internal pressure, 3 mmHg; air flow speed, 5 cm/s; noise, 10 dB. Zoletil 50 and Narcoxyl 2 were diluted in a certain ratio and used as total anesthetics. Next, inhaled anesthesia was performed using a mixture of isoflurane and  $\text{O}_2$  (2.5:2.5). BLP1 was applied on the back skin of the pigs after removing their skin hair. A test area was set by rubbing the porcine skin with a moisture gel (LAVIDA calming gel; COREANA). The power button was pressed to operate the device, which was used for 6 minutes in the prescribed intensive multi-care mode (three levels). The device was applied till day 15 (1 and 2 times) when the pigs were sacrificed (Fig. 2A).

### Safety evaluation

The skin condition of the treated and non-treated areas (only water gel was applied on the non-treated areas) of the porcine skin was observed immediately after the treatment (day 0) and on days 1, 7, and 15. The Folliscope (LeadM Corp.) was used to observe changes in the condition of the skin surface after treatment with the BLP1 device. The visual evaluation was performed as per a set schedule. Any change in the skin temperature owing to

the application of the BLP1 device was confirmed using a thermal camera (FLIR E85; FLIR Systems, Inc.) and a fiber-optic temperature probe (FOBS104; Omega Corp.).

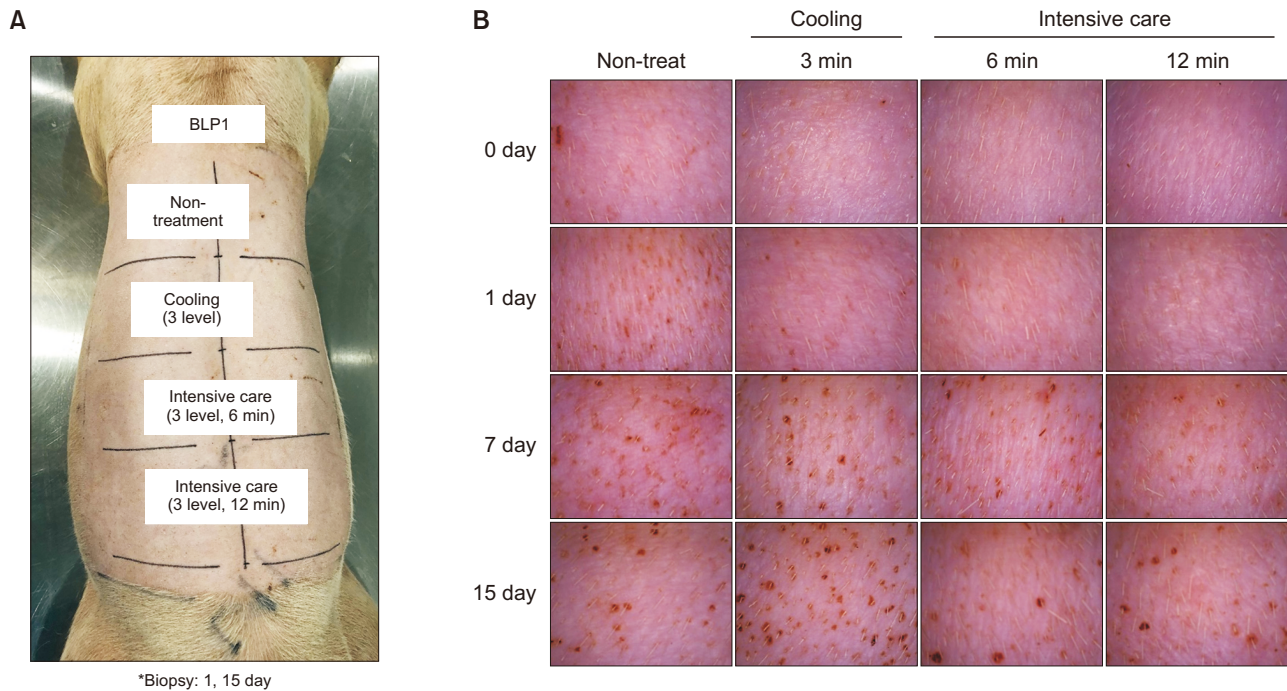
### Histopathologic evaluation

After treatment with the BLP1 device, H&E, Masson's trichrome (M&T), Victoria blue, and toluidine blue staining were performed for histopathological evaluation of the corresponding skin tissue. After 1 and 15 days of treatment, a small sample of the treated skin tissue was removed using an 8-mm punch biopsy and stored in a freezer at  $-20^\circ\text{C}$  before performing the biopsy. Using a surgical blade, the device-application area was incised vertically to a depth of 8 mm. Some of the removed skin sample was stored in a 10% neutral buffered formalin solution. The skin was embedded in paraffin to harden. Next, 5- $\mu\text{m}$  sections of the hardened skin was cut and stained. These sections were then observed with an optical microscope and analyzed. Under the microscope, five randomly selected fields of view were used to collect images for the subsequent analysis.

## RESULTS

### Observation and examination

We used 30-fold magnification to observe changes in the skin-surface condition after treatment with the BLP1 device (Fig. 2B). Of all species, the porcine skin is most similar to the human skin. Therefore, various porcine



**Fig. 2.** (A) Experimental design. As indicated, non-treatment, cooling mode (3 minutes), intensive care mode (3 level, 6 minutes), intensive care mode (3 level, 12 minutes) was applied to the porcine back skin. (B) After application, safety evaluation was conducted using Folliscope immediately after treatment and on days 1, 7, and 15 (original magnification, 30 $\times$ ). Histological examination was performed at days 1 and 15. Animal experiments were conducted in triplicate.

skin models have already been established. All groups were compared immediately after skin treatment (0 day) and 1 day (1 day), 7 days (7 day), and 15 days (15 day) after treatment. We did not observe any thermal damage and erythema of the skin surface during the test period.

To evaluate the skin irritation after the BLP1-device treatment, a visual evaluation was conducted by the research director during the test period. Immediately after device application, temporary erythema was observed on the skin surfaces of both the test group and the control group, depending on the surface temperature of the skin owing to the deep heat generated by RF. However, the symptoms disappeared within a few minutes. After 1 day, the skin of all treatment groups did not show any adverse reactions to device application, such as epidermal damage, erythema with blisters, and heat-damage reactions.

### Thermal changes after treatment

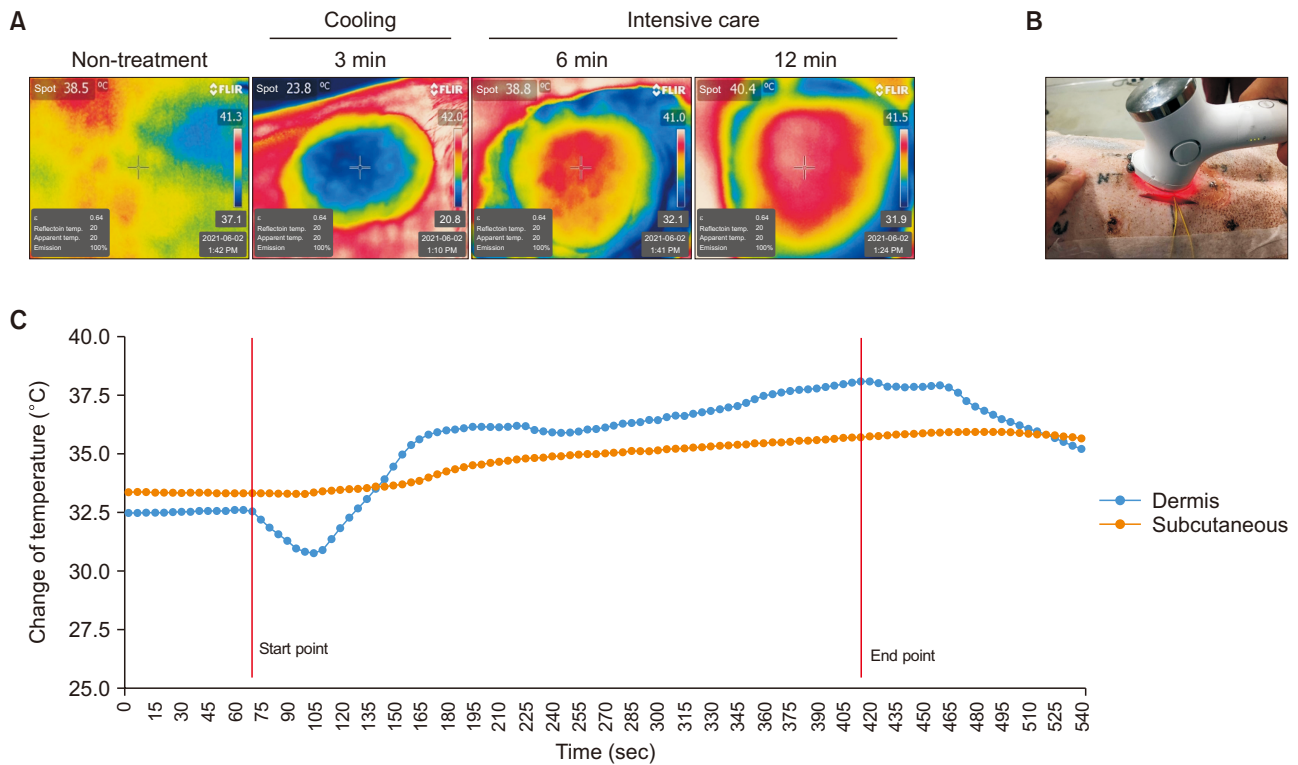
To evaluate the thermal change profile underlying the activation of collagen synthesis in this model, any change in the temperature of the skin surface owing to an increase in the deep heat following the BLP1-device treatment was measured using a thermal camera. The width of the thermal area appeared to be correlated with energy, and the temperature was measured. In the case

of the control equipment, the maximum temperature was 40.5 $^{\circ}$ C. In addition, there was a feeling of heat on the skin immediately after using the device, although we visually confirmed that the skin condition was restored to its normal condition. These results confirmed that the skin-surface temperature reduced to 23.8 $^{\circ}$ C under the cooling mode (Fig. 3A).

Next, to check changes in the temperature occurring in the skin layer because of the deep heat generated following the BLP1-device treatment, the temperature sensor of the fiber-optic temperature probe was inserted into the dermis layer and subcutaneous tissue, and any temperature change was determined while the device was still being used (Fig. 3B, C). The temperature of the dermal layer increased by 5.6 $^{\circ}$ C (starting temperature, 32.5 $^{\circ}$ C; treatment-end temperature, 38.1 $^{\circ}$ C) when the intensive care mode was used for 6 minutes.

### Histological changes after treatment

After BLP1-device treatment, H&E staining was performed for the histopathological evaluation of the skin. The skin tissue biopsied using the punch biopsy (8 mm) after day 1 and day 15 of the treatment was stored in a freezer at -20 $^{\circ}$ C. Next, the device-application area was vertically incised to a depth of 8 mm using a surgical



**Fig. 3.** Thermal change in the skin surface and intradermal location. (A) Before BLP1 device treatment (0) and after application, a thermal reaction to the skin surface was confirmed in a photograph using a thermal camera. No abnormal reaction was observed (skin-surface temperature,  $\leq 40.4^{\circ}\text{C}$ ). (B, C) Temperature inside the skin using a fiber-optic thermal probe was measured before (0) and after using the BLP1 device for 6 minutes. The result confirmed that temperature of the dermal layer was  $5.6^{\circ}\text{C}$  higher than the initial temperature.

blade. Some of this area was fixed in a 10% neutral buffered formalin solution, embedded in paraffin to harden,  $5\text{-}\mu\text{m}$  sections were prepared, stained with hematoxylin and eosin, and optically observed under a microscope. No abnormal infiltration of inflammatory cells or dermal necrosis was observed in all the skin tissues of the treatment group. Additionally, neither epidermal damage nor adverse reactions in the dermis were observed (Fig. 4A).

Next, toluidine blue staining was performed to determine whether the infiltration of mast cells occurred after the device was used (Fig. 4B). Unfortunately, we could not confirm whether mast cells infiltrated or the number of cells increased in all groups. Therefore, it can be confirmed that the use of the device does not cause adverse reactions of the skin, such as itching and inflammation.

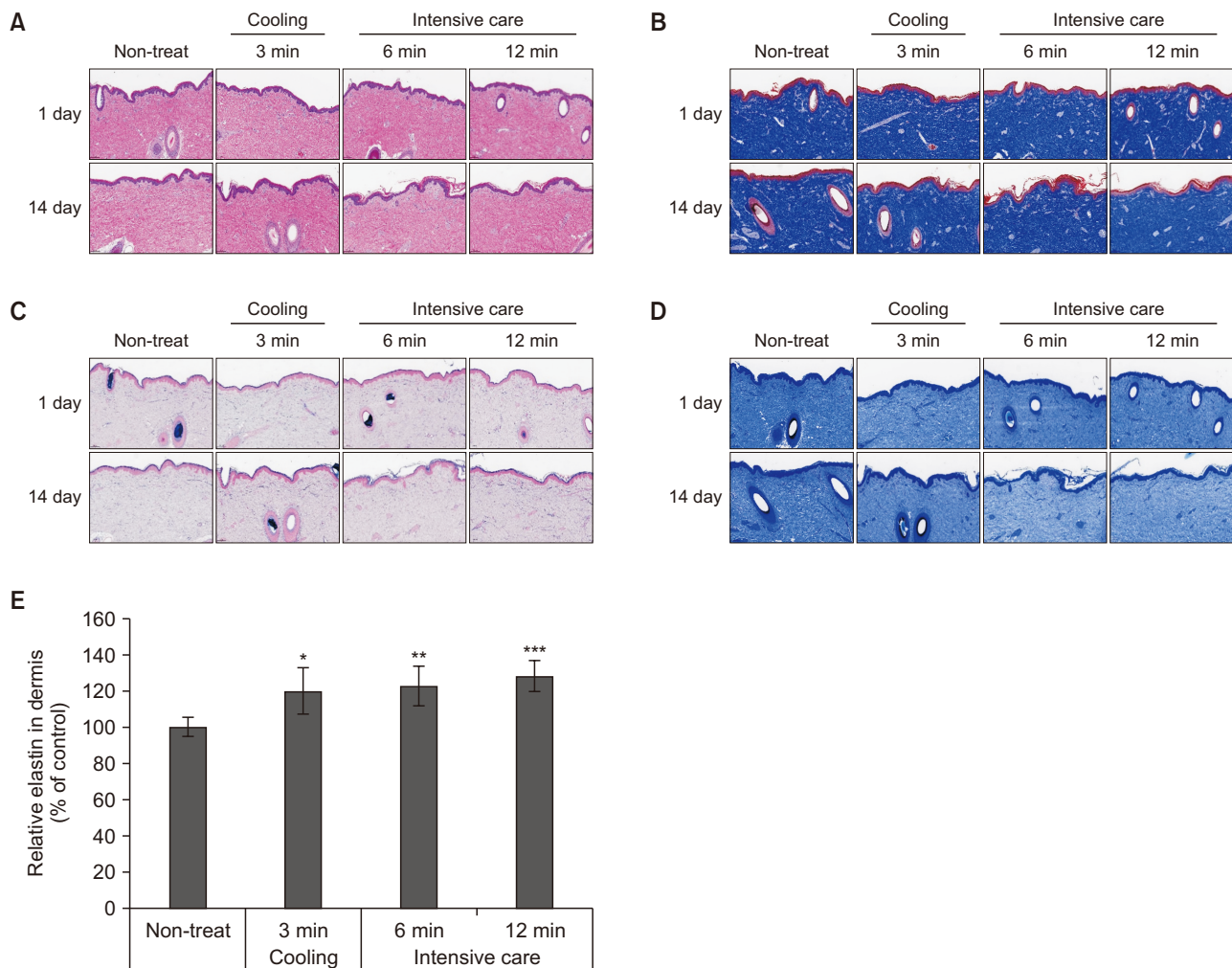
Any morphological changes in the collagen fibers were observed under an optical microscope during tissue restoration after device application. All test groups had relatively dense and regularly arranged collagen fibers compared to those of the control group after device treatment.

Changes, loss, amount, and shape of the elastic fibers

in the dermal layer of the skin were observed through Victoria blue staining (blue; elastic fibers). Overall, an increase in the number of elastic fibers was identified in all regions of the skin after the treatment. Therefore, it was confirmed that the complex energy generated from BLP1 was evenly transmitted to the skin layer, which significantly improved the skin elasticity (Fig. 4C-E). These differences strongly suggest a synergistic effect between RF and iontophoresis, microcurrent, sonophoresis when they are applied simultaneously.

## DISCUSSION

This study investigated the safety and effectiveness of a new home device that utilizes multiple technologies and energies simultaneously. This device is unique because it allows simultaneous stimulation of the epidermal and deep dermal layers. In addition, it activates the crosstalk mechanism, thereby increasing the overall efficiency of the entire treatment method. Because of the diverse parameters employed with this device, in vivo studies to optimize the parameters and confirm the device safety



**Fig. 4.** Histological effect of the device on porcine dorsal skin was analyzed using (A) H&E, (B) Masson's trichrome (M&T), (C) Victoria blue, and (D) Toluidine blue stain (representative images, scale bar = 200  $\mu$ m). The amount of blue-stained elastin greatly increased after the treatment compared with that of the control. Intensive care group showed greater vascularization, denser organization, and higher thickness of connective fibers compared with that of the control. (E) Relative elastin density in dermis. Statistically significant variations were indicated as \* $p < 0.05$ , \*\* $p < 0.01$ , and \*\*\* $p < 0.001$  (vs. control).

and efficacy were conducted before beginning the clinical trials. Interestingly, each technology is applied quickly within a short period to reduce the use time, for improved results, and for rapid efficacy.

The ability to utilize three different applicators, representing three different technologies on the same device, makes the treatment combination highly useful and accessible without the need of several devices [11-13]. Therefore, it can be suggested that the BLP1 device is safe and effective for simultaneously achieving facial skin tightening and rejuvenation. It is possible to use these different technologies with a single device because of the unique construction of the device.

This study demonstrated the anti-aging and skin-rejuvenating effects of a home-use portable multi-energy-

based device that simultaneously emits low levels of RF and microcurrent and utilizes sonophoresis and iontophoresis. The following results confirm the safety and efficacy of this device. First, the use of this device did not damage the skin surface. In addition, it did not cause any abnormal inflammation and laceration of the dermis, nor did it cause tissue necrosis. Second, measurement of the skin surface/intradermal heat generated after the application of the device confirmed that up to 43°C of deep heat was produced. Third, based on the change, loss, amount, and shape of the elastic fibers in the dermis under the test conditions, it can be suggested that the energy under each condition was well delivered to the skin, confirming the regeneration of collagen and elastic fibers both in the entire upper and lower layers

of the dermis. Although no study has yet reported on the change in skin temperature by home-use devices, the method described herein can be a good basis for identifying important safety factors such as the heat-generation radius and heat-generation time for the skin.

This study based on a porcine model indicates that the cross-application of complex techniques in a short period of time can be used as a suitable treatment for various skin conditions such as the overall care of the face and for improving skin elasticity and regeneration. Several previous studies have shown that the simultaneous application of these energies affords enhanced synergistic effects. Compared with the sequential application of different modalities, the simultaneous use of these two fields is more beneficial for the density and thickness of the connective fibers of the dermis and subcutaneous tissues.

Histological studies have confirmed changes in heat generation, including immediate collagen production, when RF and other techniques are used simultaneously. Overall, both collagen expression and fiber thickness increased when the combination method is used within a short period. However, more research is needed to confirm these findings and to clarify the effects of heat-generating RF and the simultaneous use of multiple treatments on the skin. Our study has several limitations also, such as a small sample size and a short follow-up period.

Our study proved the safety and efficacy of the home-use multi-energy-based device with a cooling technology for skin-tightening treatments to achieve increased deposition of collagen and elastin. We proposed a basis for safe and effective energy setting and performed ex vivo and clinical tests to determine the abnormal mechanisms (such as the production of inflammatory cytokines) in the human skin. We plan to examine the effect of each technology on the skin through a histological analysis in future. Further experimental studies are needed to investigate whether a synergistic effect for anti-aging or improved skin-barrier function can be observed under simultaneous irradiation of various energies at a low intensity. Our goal is to develop a maximum efficacy protocol that can be used with other technologies through a home-use device.

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## AUTHOR CONTRIBUTIONS

Conceptualization: KHY. Data curation: DWM, JL, WGL. Formal analysis: TRK, DWM, YHL. Investigation: JK, HMS, WGL. Methodology: JL, HSH. Project administration: SYC. Software: JK, HSH. Validation: TRK, YHL. Visualization: HMS, SYC. Writing—original draft: TRK, KHY. Writing—review & editing: all authors.

## CONFLICT OF INTEREST

Tae-Rin Kwon, Dong Wook Moon, Jungwook Kim, Yun Seok Kang, and Jungkwan Lee are employees of LG Electronics, but they have no conflict of interest to declare. Kwang Ho Yoo is the Editor-in-Chief, Tae-Rin Kwon and Hye Sung Han are editorial board members of the journal, but they were not involved in the review process of this manuscript. Otherwise, there is no conflict of interest to declare.

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## DATA AVAILABILITY

Contact the corresponding author for data availability.

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None.

## SUPPLEMENTARY MATERIALS

None.

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