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Evaluation of the safety and efficacy of home-use micro-focused ultrasound: a preclinical study

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Background: The demand for home-use micro-focused ultrasound (MFU) devices for dermatologic uses like facial skin tightening and treating forms of skin laxity is increasing. However, the procedures used to evaluate such devices remain underdeveloped.

Methods: We performed simulations on ex vivo porcine tissues to calculate the thermal coagulation point (TCP) area corresponding to the applied energy levels. Surface and intradermal temperature distributions posttreatment on porcine dorsal skin were assessed during MFU. Subsequently, we evaluated the safety and effectiveness of the MFU device in vivo after single or repeated treatments. MFU energy was delivered in vivo to porcine skin at 7 MHz and 12 W to a penetration depth of 3.0 mm under different experimental settings. Tissue samples were obtained immediately after treatment and 14 days later and subjected to histological analysis.

Results: TCPs were distinctly observed in ex vivo tissues after MFU. Energy-dependent micro-coagulation zones were small at ~1 mm^3. The temperature escalation was linearly proportional to the number of treatments. Notably, MFU treatment promoted collagen and elastin deposition in vivo and induced neocollagenesis in the mid and deep reticular dermis and neoelastogenesis in the deep reticular dermis.

Conclusion: The novel MFU energy regimen used in this study was effective in our animal model, and the energy settings used may mitigate unwanted side effects. Our results show that a home-use MFU device that provides uniform TCP and precise treatment can be safely applied to the face and effectively tightens skin.

Key words: Micro-focused ultrasound; Skin tightening; Safety; Efficacy; Preclinical

INTRODUCTION

Micro-focused ultrasound (MFU) is a technology that builds upon the principle of focused ultrasound in a high-intensity mode to generate heat. Recently, MFU has gained substantial commercial success in the beauty industry, as it provides a non-invasive, effective alternative to surgical facelifts. Importantly, MFU uses ultrasound technology to accurately target specific tissue while causing minimal damage to surrounding structures [1,2].

The operation of MFU is analogous to focusing light with a magnifying glass. However, instead of light, MFU uses a focused ultrasound beam, generated by a focused acoustic transducer, to target a specific point in space

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known as the focal point. When the ultrasonic waves reach the focal region where the light converges, the energy density increases significantly, leading to two distinct phenomena. One is a thermal response characterized by a rapid temperature increase, and the other is a mechanical nature cavitation resulting in the formation of microbubbles that disrupt the structure. Depending on the power and pulse duration settings, the physical response can be tailored to trigger a reaction ranging from mild local overheating to complete coagulative necrosis and irreversible cell death. This process, involving apoptosis and necrosis, initiates the wound healing process and dermal collagen remodeling, thereby reducing skin laxity [3-5].

In this study, we evaluated the safety and efficacy of single/repeated use of a home-use MFU facial treatment device called the "Dermathera" (BLQ1, Pra.L; LG Electronics) that employs focused ultrasound technology. This technology, designed for home use, targets the deep dermal = layers and induces rapid tissue heating. This increase in temperature stimulates the cells to produce more collagen, resulting in tighter, firmer skin with fewer wrinkles. The high-frequency ultrasound beams from the MFU device focus on a specific site below the skin's surface, thereby causing no damage to the skin's upper layers or adjacent tissue.

In this preliminary study, we investigated the impact of MFU at different energy levels applied through single and repeated treatments on porcine skin in vivo. Additionally, we compared histopathologic findings with an in vivo porcine skin model. While there have been several studies evaluating the rejuvenation effects of MFU devices using in vivo models, none have explored the acute thermal influence of an MFU device observed through an in vivo model. Through our study, we anticipated that an in vivo model could serve as a novel tool for analyzing thermal skin interactions due to varying energy levels and single or repeated usage of an MFU device at different skin depths. This research could provide valuable fundamental information for users and experts.

METHODS

Ethics statement: This study conducted all procedures involving animals according to the Institutional Animal Care and Use Committee of CRONEX, Republic of Korea (Institutional Review Board no. 2021-05012) guidelines.

Treatment of porcine skin with MFU device

We used a portable Dermathera MFU device for the study. Ultrasound energy was transferred from the transducer, operating at 7 MHz, into the skin via an ultrasound coupling gel applied to the skin surface. The focus depth was set at 3.0 mm below the skin surface. Each probe delivered a series of pulses in a linear array with 1.0 mm spacing, and the total linear array was up to 14 mm in length. Each linear array resulted in 15 thermal coagulation regions per probe discharge. The linear arrays were placed parallel to each other at 1 mm intervals. The ultrasonic penetrating gel (LAVIDA calming gel; COREANA) was applied to the skin, and the handpiece was adhered vertically and firmly to the skin surface. Porcine back skin was treated singly and repeatedly with a 7 MHz, 3.0 mm handpiece at 0.4 and 0.8 J/cm^2. After treatment, the ultrasonic penetrating gel was removed from the pig's back skin. There were one and three treatments at each experimental sequence, followed by a rest period for a total of 2 weeks. We performed all experiments thrice without applying any pretreatment topical anesthesia or posttreatment cooling.

MFU exposure on porcine tissue

We labeled porcine skin tissue to generate grids before MFU exposure. We also used porcine muscle tissue to evaluate the penetration depth of MFU energy, as porcine tissue closely resembles human skin properties [3]. Following MFU exposure on porcine muscle, we identified and measured the white inverted triangle area of the coagulation region reflecting the thermal coagulation point (TCP) induced by MFU. We applied varying MFU parameters (12 W, 0.4 to 0.8 J/cm^2) to the pig skin at a depth of 3.0 mm to assess the effect of the applied energy.

Thermal effects of MFU on tissue and laboratory parameters

We measured skin surface temperature distribution posttreatment on the dorsal skin of porcine using an infrared thermography system (FLIR E85; FLIR Systems, Inc.). We used a thermal camera immediately after treatment under each mode condition. We recorded temperature changes with a subcutaneous thermocouple and a probe thermocouple inserted into the tissue through a small incision. An optical fiber thermometer (FOBS104; Omega Corp.) was positioned in the dermis and epidermis at a depth of 3 mm below the epidermal surface in the abdominal dermal tissue of two animals. We administered MFU energy levels of 0.4 to 0.8 J/cm^2 at a focal depth of 3 mm. The thermocouple recorded temperature

data every 1,000 ms during the treatment period.

Histological examination

We fixed the porcine skin tissues with 4% paraformaldehyde and embedded them in paraffin. Then, we cut 5-μm-thick sections using a microtome, which we transferred to ProbeOn Plus slides (Fisher Scientific) and stained with H&E. The skin biopsy samples were stored at –80°C and placed in a cryomold with optimum cutting temperature (Tissue-Tek; Sakura Finetek Inc.). We transferred 5-μm-thick sections to ProbeOn Plus slides and stained them with Masson's trichrome and Victoria blue. We also analyzed slides stained with Masson's trichrome and Victoria blue by evaluating the area fractions of collagen and elastic fibers, respectively, immediately and 14 days after the treatment at the following areas: the upper reticular dermis and deep reticular dermis.

Statistical analysis

We expressed all data as mean ± standard deviation. We used Student's t-test for statistical analysis of each data set. We considered values of $p < 0.05$ as statistically significant.

RESULTS

The home-use ultrasound device used in the experiments

Tests were conducted on the commercially available, portable Dermathera MFU system. MFU sessions were managed by setting the output level (1-5 steps) directly through the touchscreen software. The system, operating at a frequency of 7 MHz, utilizes a cartridge that targets the 3.0 mm dermis layer primarily made up of fibroblasts, where the thermal effect generates the most notable tightening efficacy. The ultrasonic linear motor, equipped with a dome-shaped piezoelectric actuator, moves the probe precisely during treatment, effectively targeting areas of the skin layer. This advanced core technology fosters a more effective and efficient treatment experience. The MFU device delivers stable ultrasound energy transfer and optimized tightening results by rapidly creating precise coagulation points (Fig. 1).

The MFU, a focused ultrasound device, generates heat above 55°C at specific energy levels, leading to the TCP of the target tissue. The production of TCP initiates a healing cascade culminating in neocollagenogenesis and neoelastic production. It can facilitate a lifting effect or

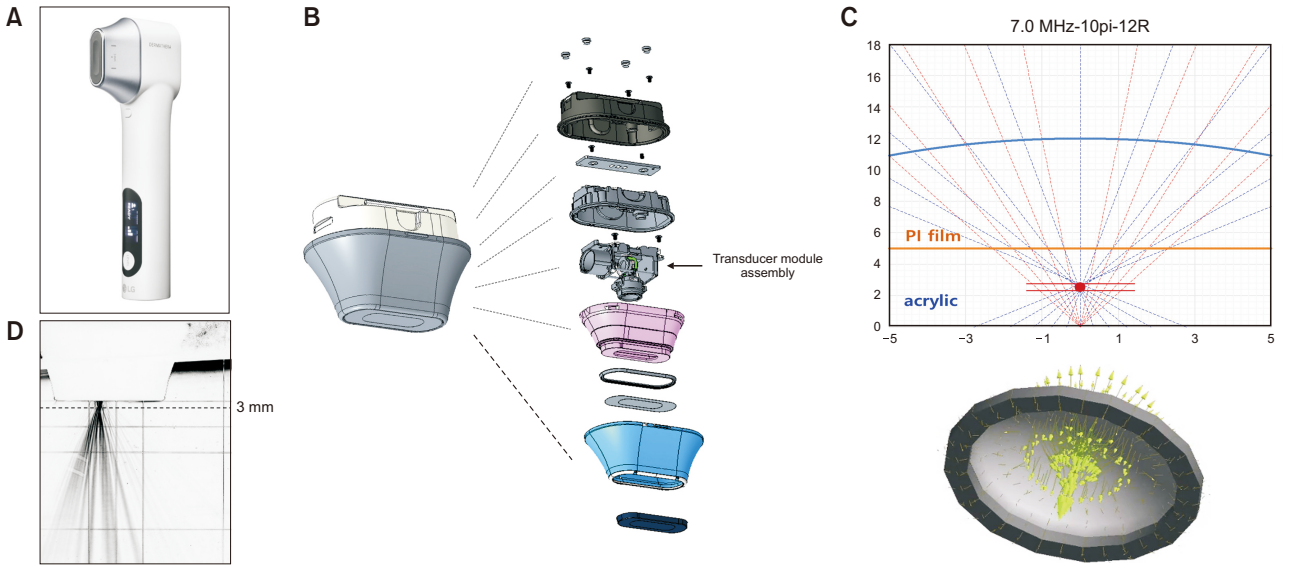

Fig. 1. Device specifications and operational details. (A) The BLQ1, Pra.L Dermathera (LG Electronics), a home-use device that uses micro-focused ultrasound (MFU) technology. (B) Schematic showing the mechanical configuration of the MFU cartridge. The transducer module assembly, a key component, moves precisely during treatment to address targeted areas of the skin layer (reticular dermis, 3 mm). (C) The ultrasonic linear motor using a dome-shaped piezoelectric actuator. Compared to the vibration displacement in the thickness direction of planar piezoelectric ceramic, the dome-shaped piezoelectric linear motor's vibration displacement is increased in the direction of the vibration shaft (piezoelectric actuators were designed and simulated according to the ceramic layer using ATILA® software, with permission from ECODMLAB. Inc.). (D) Schlieren image demonstrating the operation of MFU transducers operating near 7 MHz with in situ spatial average intensities of 12 W at corresponding depths of 3 mm. PI film, polyimide film.

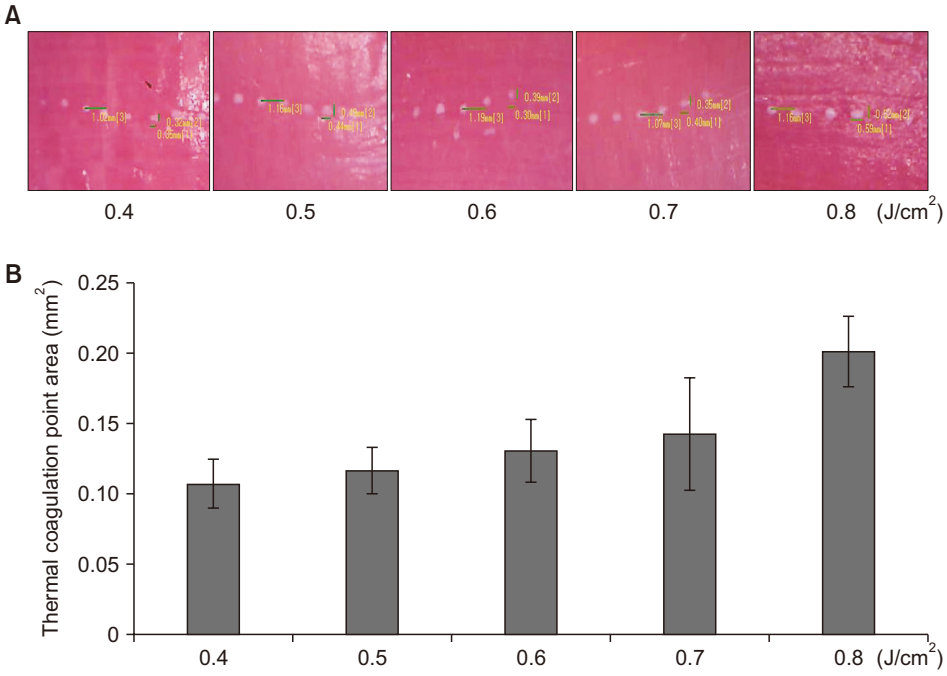

Fig. 2. Visualization and quantification of thermal coagulation in ex vivo porcine muscle tissue during micro-focused ultrasound (MFU) exposure. (A) Transverse cross-sectional images of coagulated tissue captured at various energy levels ranging from 0.4 to 0.8 J/cm^2 during MFU exposure. The MFU lesions are represented by the whitish coagulated areas inside the muscle mass, located precisely 3 mm below the surface. This serves as a representative image of a linear fitting of the coagulation area. (B) Graph illustrating the coagulation area as a function of energy level, indicating a proportional relationship. Data is presented as mean ± standard deviation, where n = 5.

skin tightening at different levels, depending on the target structure. Therefore, visualization via ultrasound and real-time assessment of severity and structural changes are the two pivotal tools for ensuring treatment accuracy and efficacy. We used this cartridge in an ex vivo study designed to identify focal areas in the deep dermis layer of normal human skin. To analyze the pattern and morphology of TCPs induced by MFU energy levels of 0.4 to 0.8 J/cm^2, administered at a focal depth of 3 mm, we studied porcine muscle. The MFU device uniformly generated TCPs in the sample, which maintained a constant distance from each other. As the energy level increased, so did the degree of thermal coagulation. Tissue coagulation, quantified as a function of exposure time in Fig. 2, revealed an area of 0.107 ± 0.017 mm^2 at 0.4 J/cm^2. This was 9%, 22%, 33% and 88% smaller than those at 0.5 J/cm^2 (0.117 ± 0.017 mm^2), 0.6 J/cm^2 (0.131 ± 0.022 mm^2), 0.7 J/cm^2 (0.143 ± 0.040 mm^2), and 0.8 J/cm^2 (0.201 ± 0.025 mm^2), respectively. These results confirm that MFU treatments raise the tissue temperature at a focal region, leading to a quick, consistent, and uniform formation of a thermally coagulated treatment volume.

Temperature of the focal point

The temperature measurements near the focal zone in the porcine muscle tissue corroborated the observations made through visual inspection. Subsequently, the temperature fluctuations, monitored during and after an MFU treatment with varied power or pulse duration, are illustrated in Fig. 3. We used an infrared thermal camera to measure the temperature of the porcine back tissue. This camera, equipped with a cursor (arrow, Fig. 4), was capable of automatically tracking the highest temperature within a specified region, with the temperatures displayed on the camera screen in real time. These images helped record the peak temperature (40.6°C) during repeated treatment. The baseline tissue temperature was measured before each treatment and utilized to compute the relative temperature increase.

Thermocouples were intentionally placed to illustrate that tissue ablation temperatures exceeding 60°C occur only at the focus. We confirmed the correct placement of thermocouples through ultrasound imaging. Fig. 4 provides a direct comparison of the thermal behavior at the tissue-air interface across varying intensity levels and treatment durations. Fig. 4 presents the temperature measurements in-vivo on the back skin situated in the

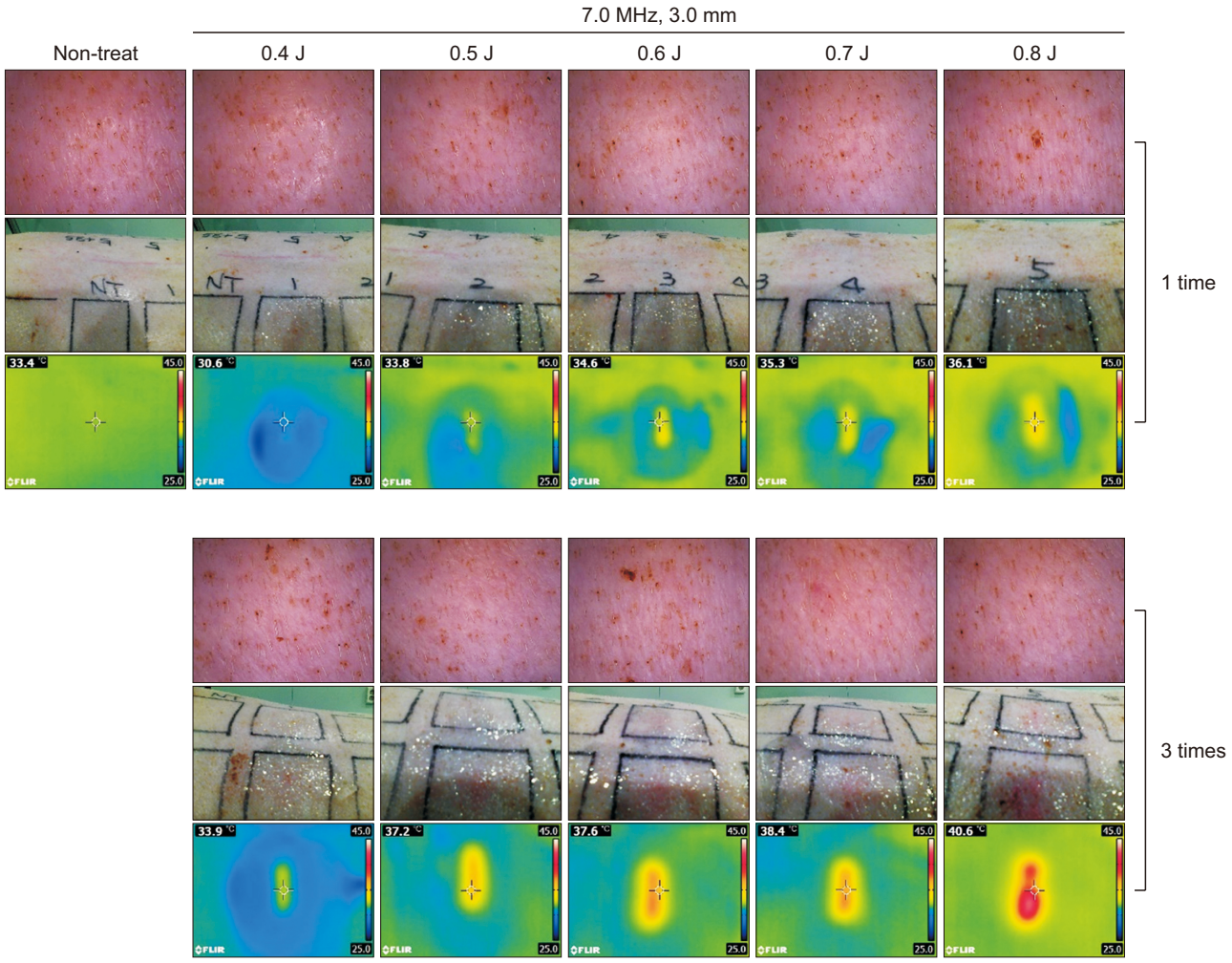

Fig. 3. Examination of the impact of energy on temperature measurements during micro-focused ultrasound (MFU) treatment. The image showcases the thermal reaction of the skin surface before and immediately after one and three applications of the BLQ1, Pra.L Dermathera (LG Electronics). The photograph was captured using a thermal camera to record the temperature changes. No abnormal reactions were observed. The figure represents a typical thermal image of the MFU treatment area.

postfocal region. The temperatures measured ranged from 33.81°C (baseline temperature) to 51.97°C with repeated treatment. Collectively, we observed a consistently dependent temperature rise, attributable to point heating by the MFU treatment. These results suggest that significant thermal energies can be safely generated within the deeper tissue layers.

Histologic analysis

Prior to high-intensity focused ultrasound (HIFU) irradiation, we removed the hair from the porcine back skin, rendering it smooth. There was no evidence of skin burn following the HIFU radiation. Subsequent to MFU treatment, we trimmed the tissue samples to incorporate the resultant lesions and fixed them in 10% neutral buffered formalin for histological processing. This processing included paraffin embedding and histologic sectioning (5 μm). Following this, we stained the tissues with H&E, Masson's trichrome, and Victoria blue staining to examine the structural integrity of the tissues. Generally, when tissue temperature exceeds 50°C for 1 second, it leads to immediate cell death via coagulation necrosis in most tissues, which is the primary mechanism for fibroblast stimulation. Fig. 5 presents the histological changes following a single treatment with HIFU in ex vivo porcine back skin.

We harvested the tissues near the treated MFU device from both the control and treatment groups on days 0 and 14 following the MFU treatment at 0.8 J/cm^2. H&E staining revealed mild inflammatory cell activity in the

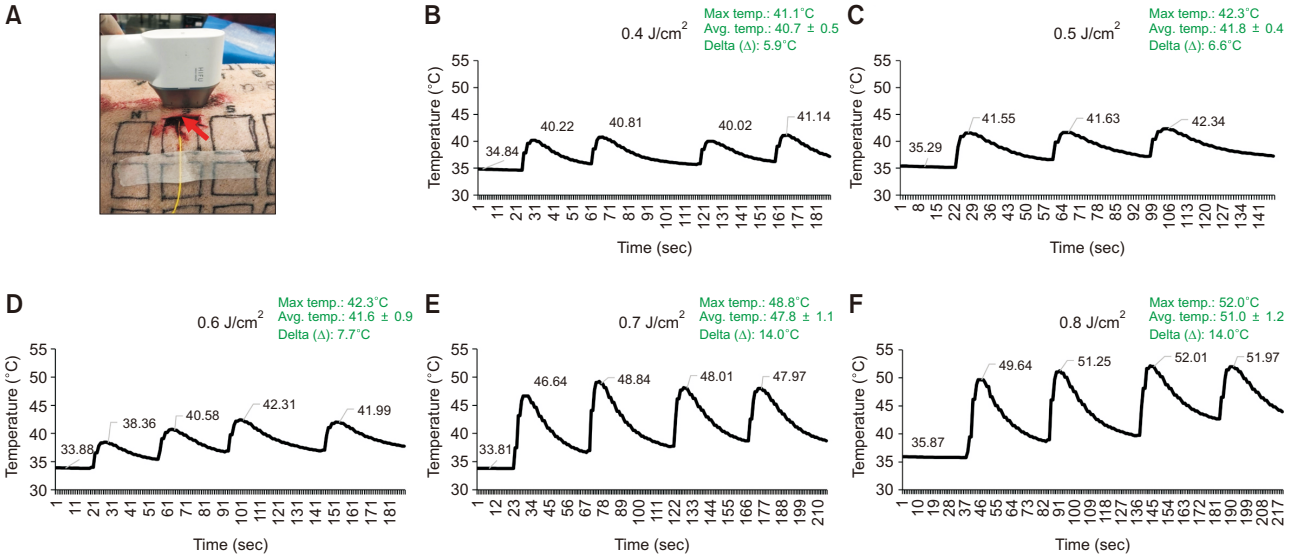

Fig. 4. Temperature measurements in the skin using a fiber-optic thermometer before (0) and immediately after consecutive applications (up to four applications) of the BLQ1, Pra.L Dermathera (LG Electronics) treatment, confirming an increase in the dermal layer temperature. (A) Red arrow indicates the site of fiber-optic sensor insertion. (B) 0.4 J/cm^2, (C) 0.5 J/cm^2, (D) 0.6 J/cm^2, (E) 0.7 J/cm^2, and (F) 0.8 J/cm^2. The figure represents the thermal characteristics of micro-focused ultrasound treatment at different energy levels.

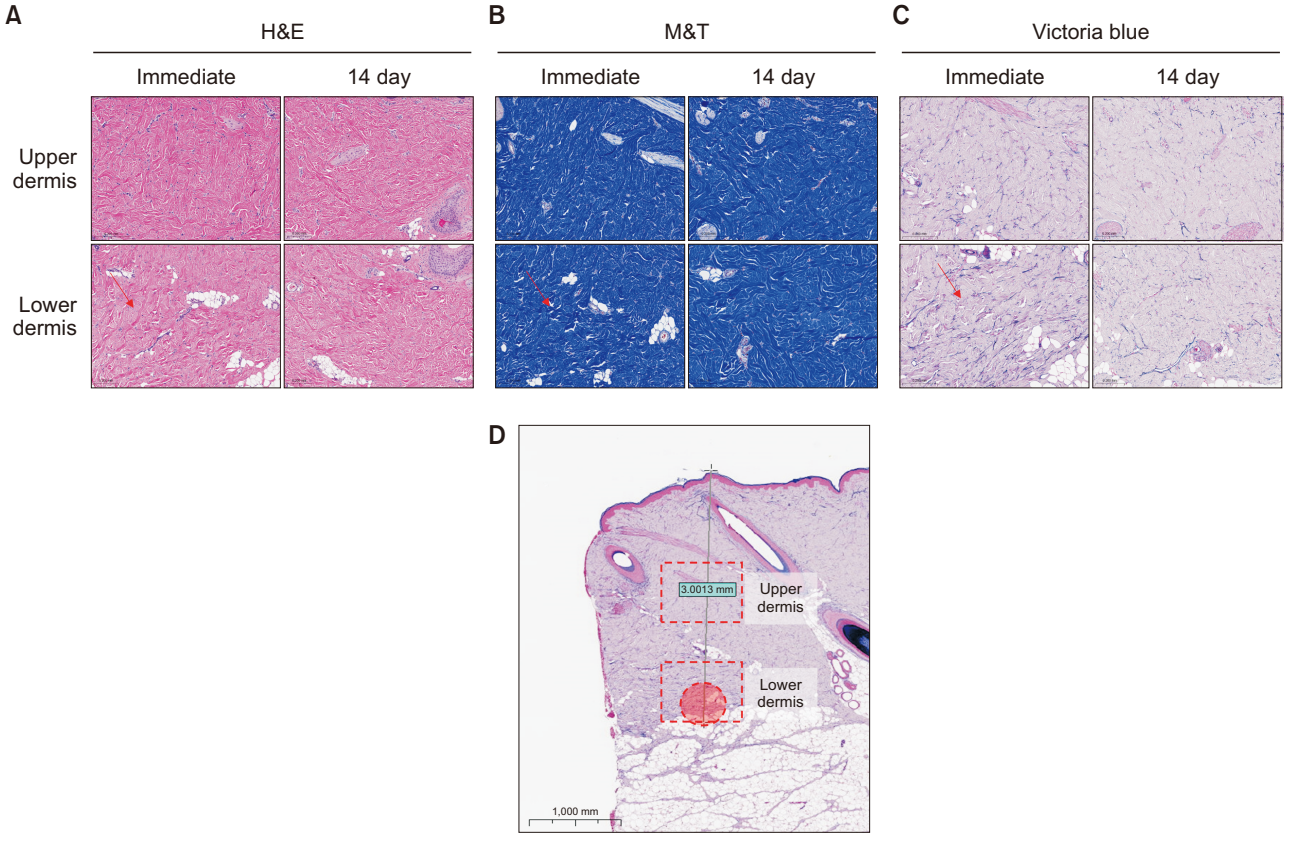

Fig. 5. Histological analysis of the effect of the device on porcine dorsal skin using: (A) H&E staining, (B) Masson's trichrome (M&T) staining, and (C) Victoria blue staining (×100 magnification). These are representative images out of a total of 5 samples. There was a significant increase in the amount of elastin (stained in blue) posttreatment compared with the control. (D) Thermally injured area in deep dermis layer was changed in the skin exposed to a 3.0 mm cartridge. The inside small red circle area clarified the thermal damage in this condition. The micro-focused ultrasound treatment group showed greater vascularization, denser organization, and increased thickness of connective fibers compared with the control group (red arrows). Details of the dermis are shown with a scale bar representing 200 μm.

control group (Fig. 5A). The examination of collagen deposition exposed unorganized, dense, and irregular collagen fibers in the deep dermis area of the treatment group, compared with the control group (Fig. 4B). The treatment also resulted in the elastic fibers becoming more parallel and straighter in both the upper and lower dermal layers (Fig. 4C). These findings distinctly indicate stimulation of dermal collagen and elastic fibers.

DISCUSSION

Non-invasive and minimally invasive treatments are often preferred for facial rejuvenation over traditional cosmetic surgery. These treatments can involve diverse energy modalities, such as lasers, visible light, infrared, radio frequency (RF), ultrasound, and even injection therapies. Furthermore, home-use devices and hair removal products are gaining popularity due to their convenience compared to treatments traditionally administered at medical institutions. As these devices are commonly used by non-professionals at home, safety is of paramount importance. However, there is a dearth of medically validated evidence regarding the safety of these devices [6,7]. This study aimed to evaluate the safety and efficacy of a portable MFU device (Dermathera) through both ex vivo and in vivo experiments.

Various types of energy-based technologies are employed in aesthetic surgery and cosmetic medicine, including RF, laser energy, and electrical energy. However, there are key differences between these energy sources and focused ultrasound. In particular, light and RF waves—when applied externally—cannot be focused deeply within tissue and cannot achieve the same subcutaneous energy-focusing effect as MFU. This limitation restricts laser applications to adjuvant treatments involving ablation and non-ablation, skin tightening, and liposuction. Other radial ultrasonic devices use relatively low-energy ultrasonic waves to create thermal effects through cavitation [1,8,9].

The MFU device investigated in this study can accurately elevate the temperature of the target site. Our home-use focused ultrasound device, operating at 7 MHz, safely induces an effective temperature increase only in the targeted reticular dermis at a 3-mm depth.

In our study, we assessed the potential of using MFU, delivered by a dome-shaped piezoelectric linear motor, to produce TCPs in porcine skin. Our results demonstrated that MFU effectively produced distinct TCPs. The transducer, an integral part of HIFU technology, facilitates stable and rapid treatment, producing TCPs not as inverted cones but as near-perfect circles. This precision is beneficial for home use as it prevents side effects on the epidermis or subcutaneous tissue by targeting specific skin points.

Focused high-intensity ultrasound energy generates heat (60°C), delivered accurately to the skin. This thermal injury likely impacts the vasculature, triggering an inflammatory cascade involving fibroblastic proliferation and increased collagen expression. Thus, heat damages targeted skin cells, prompting the body to repair itself and produce collagen for cell regrowth. Since HIFU operates at a deep level within the skin, no surface damage occurs [2,10,11]. Therefore, MFU has emerged as a non-invasive therapy with low complication rates, capable of reversing the skin's morphological effects from various aging causes. Our results suggest this safe and effective procedure provides a non-surgical, non-invasive way to enhance skin elasticity.

Focusing ultrasound energy on tissue immediately induces cell injury and well-defined coagulative necrosis in the focal region absorbing ultrasound energy. These focal regions experience cytotoxic temperature fluctuations of up to 60°C while the surrounding tissue remains cool. However, the effects of low-dose focused ultrasound treatment on skin target regions have not been thoroughly assessed [12,13]. We measured the temperature generated on the skin surface and within the intradermal layer, establishing safety standards for once or thrice treatments—this represents a significant non-clinical achievement.

MFU was recently developed in response to public demand for significant non-invasive skin lifting and tightening [14]. Applying MFU to small, discrete TCPs within the dermis and the middle to deep reticular layer results in collagen fiber contraction and stimulates new collagen production. However, additional studies are needed to assess the long-term therapeutic efficacies of MFU-induced focal coagulation areas, as well as the biological effects of prefocal and postfocal zones of tissue coagulation [15]. Based on the promising results from the porcine model, subsequent studies will assess the safety of MFU for skin tissue coagulation in clinical trials.

In conclusion, the home-use HIFU device could serve as an effective therapeutic modality for skin tightening by promoting collagen and elastin formation. Moreover, the controlled thermal effect of our MFU device appears to provide a safe and effective means for skin tissue coagulation.

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AUTHOR CONTRIBUTIONS

Conceptualization: KHY. Data curation: DWM, JL, KRK. Formal analysis: TRK, DWM, SYL. Investigation: JK, YSK, KRK. Methodology: JL, HSH. Project administration: SYC. Software: JK, HSH. Validation: TRK, SYL. Visualization: YSK, 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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SUPPLEMENTARY MATERIALS

None.

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