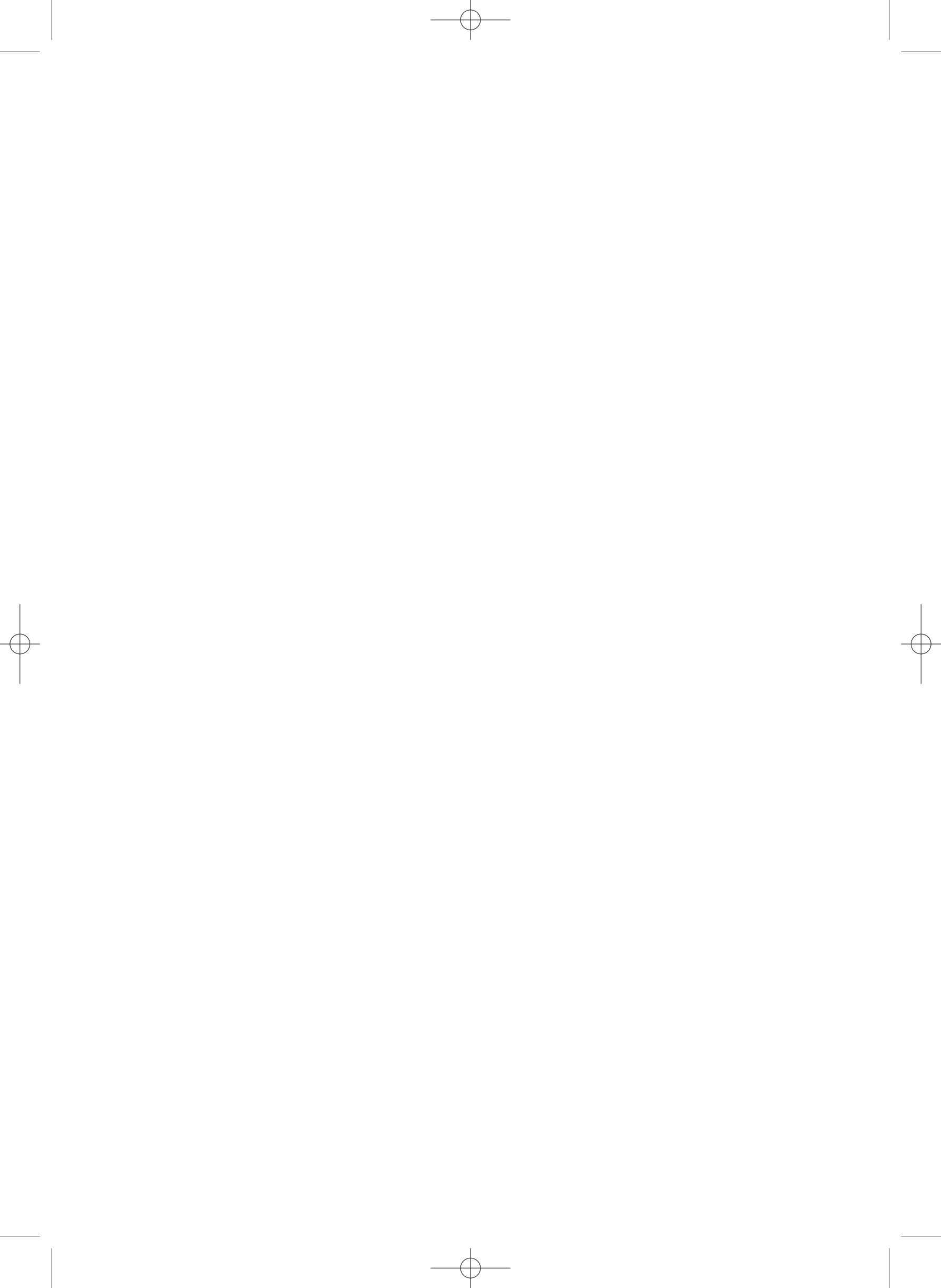




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Contents

- P04 Evaluating the Efficacy of Continuous Water-Cooling 115-Watt 6.78-MHz Monopolar RF Therapy for Fine Wrinkle Reduction

Kim, JongSeo MD

- P18 Subjective evaluation of monopolar radiofrequency treatment by patients in aesthetic rejuvenation

YousunHwang1 | SmithArayaskul2 | VasanopVachiramon3 |
Kyu-HoYi4,5

- P26 A Split-face Study on Rejuvenation Efficacy According to Monopolar Radiofrequency Tip Size

Drs. Yang, Kim, Ha, Ko, Kim, Choi, Song, Hwang, and Sohn are with the Renewme Dermatologic Clinic in Seoul, South Korea. Dr. Ahn is with the Department of Dermatology at Kyung Hee University College of Medicine and Kyung Hee University Hospital in Seoul, Korea.

- P32 Japanese Market Beauty Trends

Dr. Kenta Fujio, M.D, PhD | Japan

- P36 VOLNEWMER: Advanced Monopolar RF with Water Cooling System

Author Human dermatology clinic Ji Won Gye | South Korea

- P40 The present and the future of aesthetics in Japan
Story behind the interest in Korean RF devices

Author Hara Kaya | Japan

- P44 The present and the future of aesthetics in Japan
Continuously growing RF markets and devices to watch

Author Hara Kaya | Japan

- P50 Objective Review of Monopolar RF Device:
Continuous Water Cooling and Single RF Pulse **I**

Author Sang Hyeok Park | South Korea

- P56 Objective Review of Monopolar Radio Frequency Device: Continuous Water Cooling and Single Radio Frequency Pulse **II**

Author Sang hyeok Park | South Korea

- P62 Objective Review of Monopolar Radio Frequency Device: Continuous Water Cooling and Single Radio Frequency Pulse **III**

Author Sang hyeok Park | South Korea



Evaluating the Efficacy of Continuous Water-Cooling 115-Watt 6.78-MHz Monopolar RF Therapy for Fine Wrinkle Reduction



Kim, JongSeo MD

Evaluating the Efficacy of Continuous Water-Cooling 115-Watt 6.78-MHz Monopolar RF Therapy for Fine Wrinkle Reduction

Kim, JongSeo MD

Abstract

Background: Cosmetic procedures using radiofrequency (RF) technology have garnered significant attention as noninvasive approaches to skin rejuvenation and wrinkle reduction. This study investigates the efficacy of RF therapy in enhancing skin texture, firmness, and appearance. By harnessing the 6.78-MHz “VolNewMer” RF device, skin aging concerns, particularly in terms of skin roughness, laxity, and wrinkles, can be treated.

Methods: This study engaged a cohort of 50 participants seeking wrinkle reduction and skin-lifting treatments. Employing noninvasive methods, the efficacy of RF therapy was evaluated immediately posttreatment and 1-month posttreatment. Skin roughness was quantified using a computer-based analysis of standardized 3D scanner images, capturing uniform lighting and angles to ensure accurate measurements..

Results: Among the 45 participants who completed the study, significant improvements in skin roughness were observed. The average roughness (Ra) value decreased from 16.71 to 11.88 arbitrary units immediately posttreatment, signifying a 28.42% enhancement. At the 1-month follow-up, the Ra value further decreased to 12.33 arbitrary units, reflecting a sustained 26.23% improvement. However, 16 participants exhibited even greater improvements at 1 month than immediate.

Conclusions: RF therapy’s profound impact on skin tightening and rejuvenation is rooted in its ability to trigger immediate collagen contraction, bolstering skin elasticity. The dual-phase process of immediate and delayed skin improvement underscores the intricate interplay between thermal stimulation and collagen remodeling. Optimal energy levels and controlled endpoint monitoring ensure safe and effective RF treatments. The use of the VolNewMer device tips and sliding technique contributes to patient comfort and treatment precision.

INTRODUCTION

In recent years, the field of cosmetic dermatology has witnessed a surge in demand for noninvasive procedures that deliver remarkable aesthetic results with minimal downtime and discomfort.¹ Among these, radiofrequency (RF) technology has emerged as a transformative modality, offering a safe and effective means of skin rejuvenation.² This article explores the innovative RF energy-based medical devices (EBDs) and its application in noninvasive cosmetic procedures. By delving into the underlying mechanisms, methodology, results, and implications, we aim to provide a comprehensive understanding of the potential of RF-based treatments in reshaping the

landscape of cosmetic dermatology.

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METHODS

The research was conducted on a cohort of 50 individuals who visited the author's clinic and had not undergone cosmetic procedures such as EBD, filler, and botulinum toxin treatment in the past 6 months. Participants' age was 35- to 88-years-old.

For each patient, the author administered 200–300 shots using V (4 cm²) tips of “VolNewMer” (VNM; Classys, Seoul, Korea) RF device. The intensity of the RF energy from the high-frequency equipment was set to a maximum level of 5 (115 J, 28.75 J/cm²). It is worth noting that reducing the energy level may necessitate an increase in the number of shots. Typically, patients initially receive treatment at level 5, and if the patient experiences discomfort due to the heat, the intensity is lowered to level 4 (95 J, 23.75 J/cm²) and then to level 3 (75 J, 18.75 J/cm²). VNM adopts a continuous stable water-cooling system in which epidermal temperature is maintained appropriately by contacting the tip end, where chilled water circulates, with the skin surface to control the temperature. VNM can irradiate a single 1000-ms RF pulse at a time, whereas the other RF system with gas-cooling system can irradiate multiple times 200-ms RF pulses segmentally, and this can result in more pain.

The author consistently tried to use level 5 as much as possible. To alleviate the sensation of heat discomfort, the author used a “sliding technique” when the patient reacted to the heat. The sliding technique reduces the number of shots required and diminishes the perception of intense heat. Initially, a static technique was used without moving the tip, but if the patient felt too hot, the tip was moved approximately 1 cm. If further discomfort (too hot) appeared, a sliding technique of 2 or 3 cm was adopted.

To assess the efficacy of RF-EBD in improving fine wrinkles on the face and providing skin lifting, a three-dimensional (3D) scanner was used. The skin changes were measured immediately after the procedure and 1 month later. Skin changes were quantified using a 3D scanner image (3D LifeViz mini; QuantifiCare, Sophia Antipolis, France) using computer analysis (Gwyddion data analysis software; Czech Metrology Institute, Jihlava, Czechia) for measuring skin roughness.³

The 3D scanner captures standardized photographs under consistent lighting, distance, and angles (Figs. 1 and 2). This methodological approach ensured reliable and quantifiable data collection, contributing to the robustness of the study's findings. The images using the 3D scanner were obtained and measured immediately and 1 month later. These images were then analyzed using an online computer program for measuring skin roughness, specifically the skin roughness average (Ra) (Fig. 1). [See Video 1 (online), which shows the roughness before the treatment using Gwyddion computer program.] [See Video 2 (online), which shows the roughness after the procedure using Gwyddion computer program.]

Takeaways

Question: This study aims to assess the effectiveness of continuous water-cooling 115-Watt 6.78-MHz monopolar radiofrequency therapy in reducing fine wrinkles in noninvasive cosmetic dermatology.

Findings: The VolNewMer radiofrequency device revealed a significant immediate improvement in skin roughness (28.42%) after the procedure, with sustained enhancement (26.23%) observed at 1 month. The study suggests that the treatment's effectiveness may be influenced by initial wrinkle severity and the age of participants.

Meaning: Notably, the findings indicate that younger individuals tend to experience further improvement in skin texture 1 month after the radiofrequency procedure, suggesting a more active collagen regeneration process in the younger age group over time.

After taking the 3D image, 1 mL of cosmetic product (Gold stem ample; Reteenage, Seoul, South Korea) was sprayed under high pressure to penetrate the ample into the epidermis, and the treated area was covered with plastic wrap. This occlusive dressing was maintained for a few hours. The cosmetic product contains freezing-dry powder of stem cell conditioning media and 1% of hyaluronic acid.

One month after the procedure, patients visited the clinic without applying makeup or any other products to

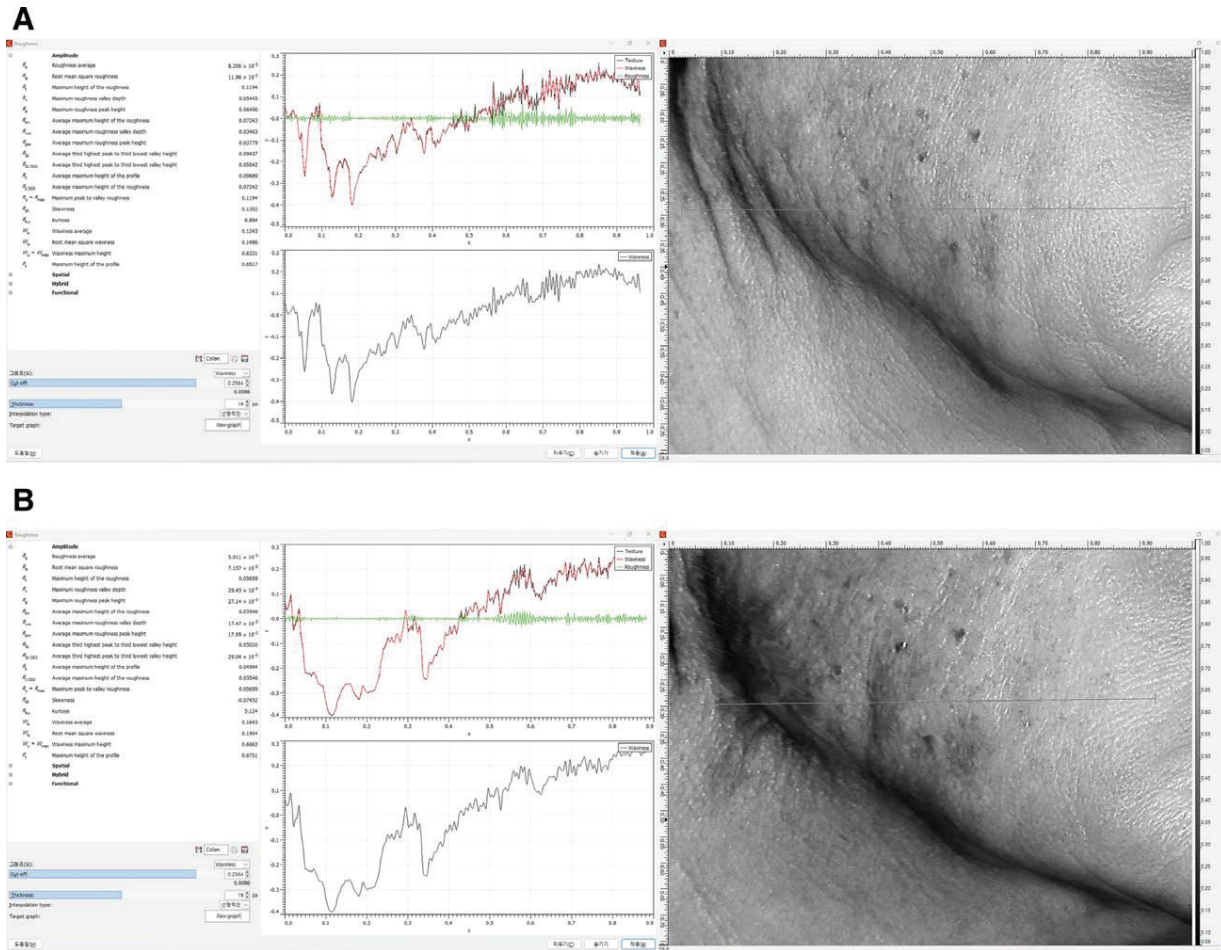


Fig. 1. The evaluation of skin roughness. A, Skin roughness before the RF treatment. B, Skin roughness after the RF treatment. The skin roughness has improved. This means that the skin roughness value, which represents the surface smoothness of the skin, has decreased, indicating a smoother and more even skin texture after the treatment. The RF treatment has contributed to improving the skin's fine wrinkles and roughness, resulting in a more refined and uniform skin surface.

their faces. Three-dimensional photographs were then taken.

The Global Aesthetic Improvement Scale was used for a comprehensive evaluation of the effects of the RF device on skin texture, smoothness, and wrinkles (very much improved: 5, much improved: 4, improved: 3, no change: 2, worse: 1).

RESULTS

Of the initial cohort of 50 participants, five individuals did not return for their 1-month follow-up, resulting in a final sample of 45 participants who completed the study. The participants' mean age was 45.7 years.

Before the treatment, the baseline roughness average (R_a) was measured at 16.71 ± 6.39 arbitrary units. Immediately after the procedure, the R_a value improved to 11.88 ± 4.77 , representing a $28.42 \pm 11.64\%$ enhancement. After 1 month, the R_a value further improved to 12.33 ± 5.84 , indicating a $26.23 \pm 8.65\%$ improvement compared with baseline (Figs. 2–7).

Among the 45 participants who completed the 1-month follow-up, 16 individuals exhibited greater improvement in R_a values than immediate results. Most of these 16 participants had less severe wrinkles at baseline, with initial R_a values below 10 arbitrary units, or were under the age of 40. This suggests that individuals with milder initial skin conditions or younger age may experience



Fig. 2. Improvement of wrinkles and fine lines on the 3D scanner images for an 88-year-old man. A, Before the treatment. The visible wrinkles and fine lines were observed. B, Immediately after the treatment. A noticeable improvement is evident, showcasing the effective reduction of wrinkles and fine lines. Notably, the treatment yields remarkable results in specific areas, including the area below the ear and the mandibular angle area. The skin looks smoother, more youthful, and rejuvenated immediately after the procedure.

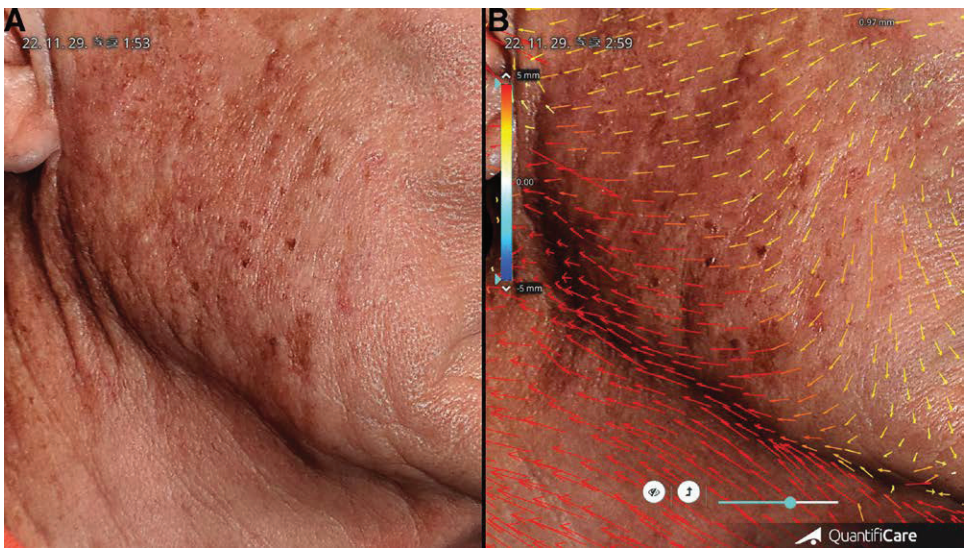
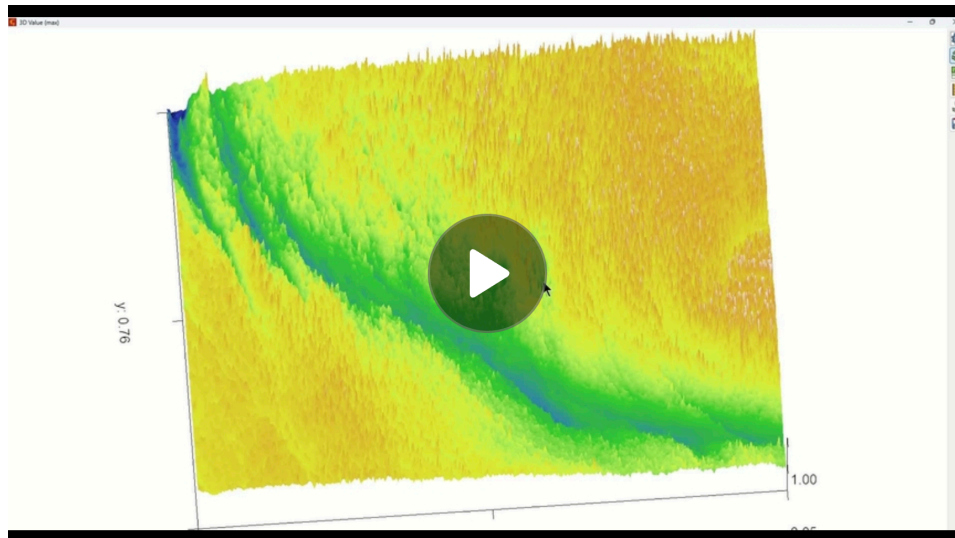


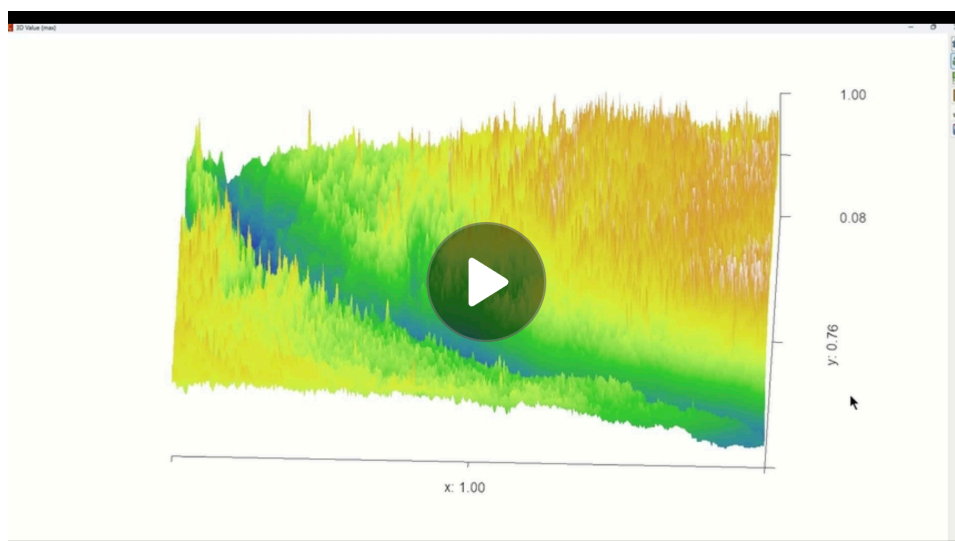
Fig. 3. Visual evidence in 3D analysis of effective lifting. A, Before treatment in the same patient in Figures 1 and 2. B, Immediately after the procedure. The red arrow markings indicate areas where more pronounced lifting has taken place, demonstrating the effectiveness using 3D scanner analysis.

more sustained improvement over the 1-month period through neocollagenesis (Fig. 7). Conversely, among the 35 participants who showed better Ra values immediately posttreatment compared with 1 month later showing relapse of skin roughness, a common trend emerged. Many of these 35 individuals were 50 years of age and above, and they typically

had initial Ra values exceeding 10, indicating more pronounced initial wrinkles. This pattern implies that participants with more significant wrinkles or older age might experience a relatively greater initial improvement that may gradually attenuate over the course of 1 month (Fig. 7). The detailed analysis of the Ra values and their trends



Video 1. shows the roughness before the treatment using Gwyddion computer program.



Video 2. shows the roughness after the procedure using Gwyddion computer program.

over time provides valuable insights into the varying responses of participants to the RF-EBD. The results suggest that the treatment's effectiveness may depend on the initial severity of wrinkles and the age of the participants. This information is essential for clinicians to personalize treatment plans and set realistic expectations for individuals seeking noninvasive wrinkle

reduction and skin-lifting procedures.

Global aesthetic improvement scale score was improved after the procedure. Satisfaction with skin texture and wrinkles was higher immediately after the procedure than 1 month after, and satisfaction with skin texture gradually improved a month later (Fig. 8).

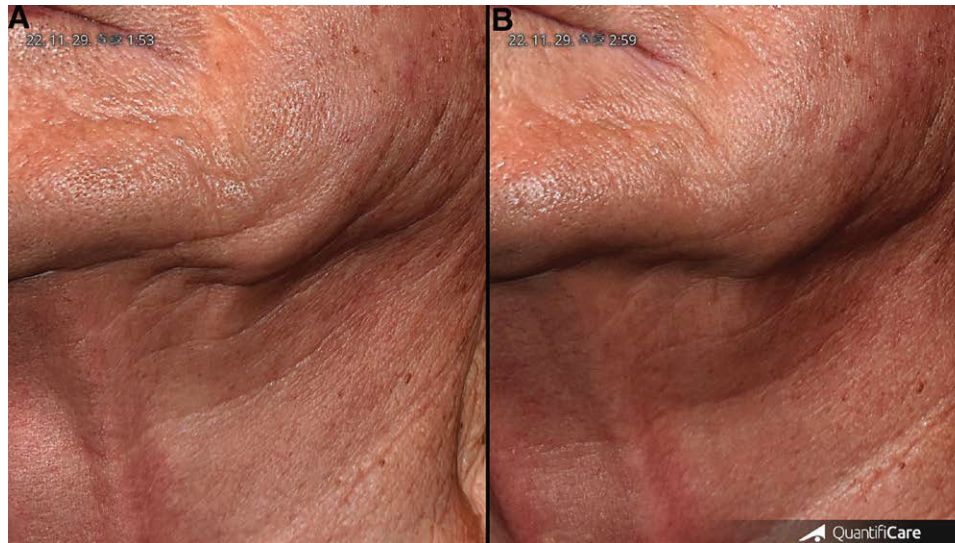


Fig. 4. Improvement of neck fold on the 3D scanner images. A, Before treatment for the same patient in Figures 1–3. The skin and jowl fat were drooping. Prominent neck fold was found. B, Immediately posttreatment. Noticeable improvement in sagging jowls and turkey neck folds.

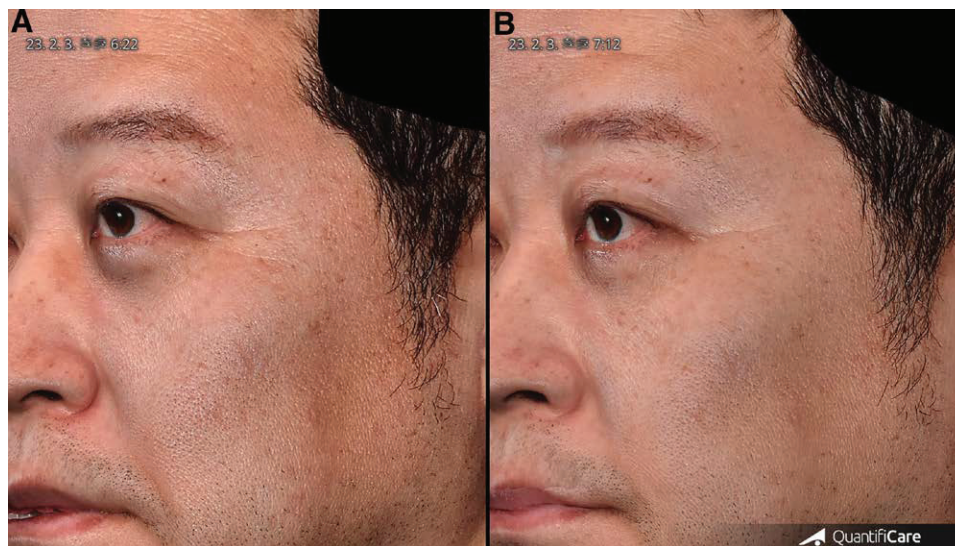


Fig. 5. Before and after photographs of the author's face. A, Before the procedure. B, Immediate post-self-treatment photograph by the author. Noticeable improvement in crow's feet. Overall facial fine lines show enhancement, resulting in a brighter appearance.

DISCUSSION

Mechanisms of RF Therapy: Initial Contraction of Collagen and Remodeling

Following RF treatment, the skin undergoes a dual-phase response. The immediate contraction of collagen fibers in the dermis results in improvement

of skin elasticity. Immediate skin contraction and tightening can be reminiscent of the phenomenon that occurs when squid is briefly soaked in hot water and then taken out.⁴ If you soak squid in lukewarm water when cooking, collagen shrinkage does not occur at all. This immediate contraction is a pivotal precursor for subsequent, delayed skin improvement effects.

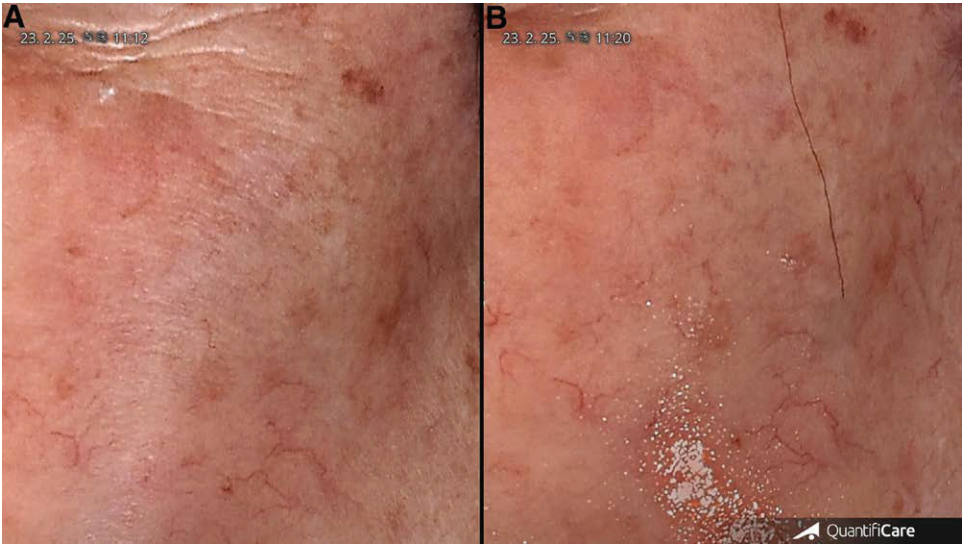


Fig. 6. Three-dimensional scanner images before and after the treatment of an 83-year-old woman. A, Before the treatment. Crow's feet were sound. B, Immediate posttreatment 3D scanner image. Improvement in crow's feet. Overall facial wrinkles have improved.

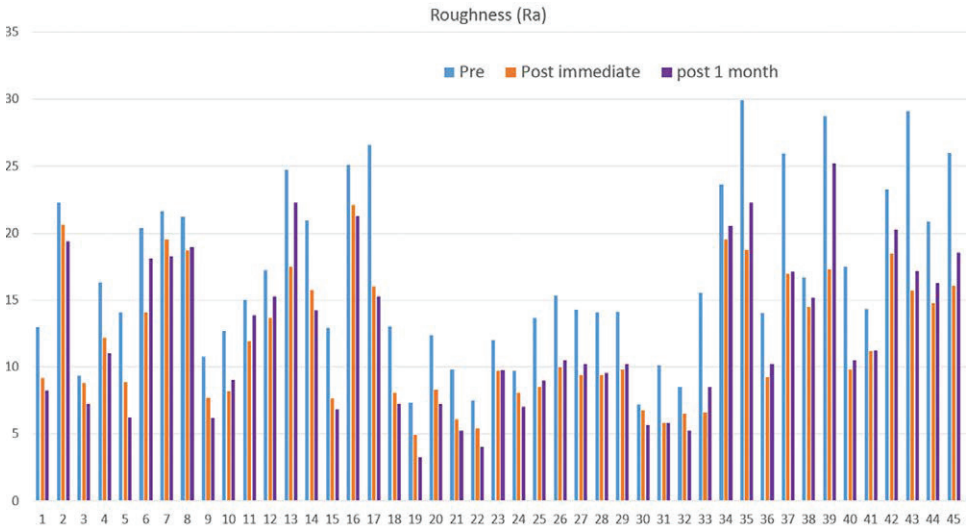


Fig. 7. Changes in skin roughness for 45 participants. This graph illustrates the changes in skin roughness for 45 participants. The blue color represents before the treatment, the orange color represents immediately after the treatment, and the purple color represents 1 month later.

The delayed phase involves collagen remodeling due to thermal damage, characterized by fibroblast activity and the subsequent release of cytokines, the accumulation of leukocytes for wound healing, angiogenesis, and the synthesis of new collagen by fibroblasts.⁵ RF technology orchestrates a symphony of physiological responses that culminate in profound

skin rejuvenation. The initial phase of immediate collagen contraction, attributed to controlled thermal heating, results in visible tightening and enhanced skin texture. This instantaneous gratification sets the stage for the subsequent act: the delayed remodeling phase.⁴ This second act, characterized by fibroblast activation and collagen synthesis, is where the

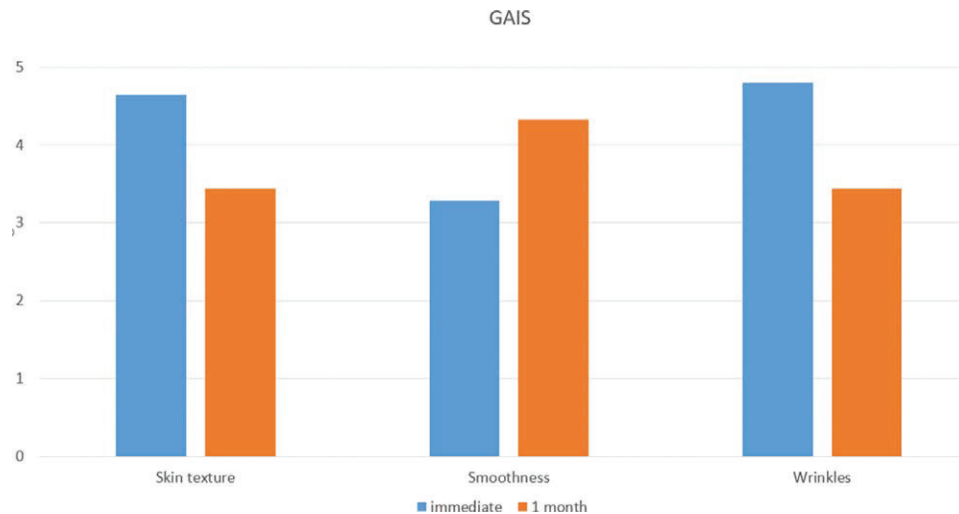


Fig. 8. The changes in GAIS for skin texture, smoothness, and wrinkles. This graph depicts the average GAIS scores for a group of 45 participants. The blue color represents immediately after the treatment, whereas the orange color represents the GAIS scores 1 month after the treatment. Although skin texture and wrinkles exhibited higher satisfaction immediately after the procedure, smoothness showed higher satisfaction 1 month later. This suggests a potential correlation with collagen regeneration, indicating the ongoing effects of the treatment over time. GAIS, global aesthetic improvement scale.

true magic of RF therapy unfolds. Collagen, the architectural framework of the skin, is meticulously rearranged and renewed, ushering in sustained improvements over time. As we navigate this intricate dance of biologic responses, it becomes evident that RF therapy is not a fleeting affair but an enduring commitment to skin health.

The timing and degree of these reactions depend on the balance between adequate energy application and avoiding excessive heat or energy. However, if you cook squid in too hot water for too long, the squid will become tough and hard. Excessive heat during RF treatment can be harmful to the skin and cause burns. When performing RF treatment, the appropriate temperature is to apply heat until the skin becomes tightened. A good target point is when the patient feels tolerably hot. The author measures skin temperature using a noncontact method and uses an increase of about 8 degrees as the standard treatment of end point.

VolNewMer

VNM-EBD, using 115-Watt 6.78-MHz monopolar RF technology with continuous water-cooling employing

5-level water cooling, has garnered significant attention in the high-frequency therapy market in terms of price/performance similar to Thermage (TMG). VNM adopts a continuous stable water-cooling system and irradiates a single 1000-ms pulse, whereas the TMG system adopts a gas-cooling system and irradiates multiple 200-ms RF pulses segmentally, which can cause more pain than single irradiation of 1000ms. TMG with superior cooling capabilities has the advantage of being able to transfer more energy to deep tissues; however, it may be less effective in treating fine wrinkles on the skin surface.

Tip options of VNM are similar to TMG. However, the unique ergonomic design of VNM tips features a curved bottom surface with an added “hidden edge” for enhanced coverage and ergonomic maneuverability. The tilting capability of the tips allows them to adapt to the facial contours, ensuring consistent and optimal contact with the skin. The cushion function of the tips maintains constant pressure on the skin regardless of applied pressure strength.

The VNM features a sensor that alerts the user and halts energy emission when skin contact is incomplete. It is important to note that procedures interrupted in

this manner are not counted as completed treatments by the device. This distinguishes VNM from other high-frequency devices such as TMG, Tentherna, or Oligio, where interrupted sessions are counted as treated instances. Its versatile tip options, cooling system, and innovative technology make it a promising tool for noninvasive skin rejuvenation procedures, offering safety, efficacy, and patient comfort.

One of the most intriguing applications of RF therapy lies in face slimming in the author's clinic, where it offers a nonsurgical avenue for facial sculpting. Research on Asian women revealed that RF therapy led to a reduction in fat accumulation in the lower face for more than 90% of participants, accompanied by high levels of satisfaction. The minimal postprocedure side effects, primarily mild redness, underscore RF therapy's safety profile.

Amid the array of benefits, the discussion candidly addresses potential risks and side effects. Temporary swelling, redness, tingling, and even pigmentation alterations can manifest post-RF therapy. However, these effects are generally transient and manageable, especially when overseen by certified practitioners. Importantly, the article reassures readers that, despite uncertainties surrounding long-term low-energy RF effects, current evidence does not substantiate any significant health risks posed by RF energy.

Underscoring its scientific foundation, the article navigates the landscape of skin aging, unraveling the dual processes of intrinsic and extrinsic aging. The former encompasses the inexorable tissue degeneration associated with the natural aging process, whereas the latter, exemplified by photograph-damaged skin, reflects the toll of chronic UV radiation exposure. With its collagen-inducing and remodeling effects, RF therapy stands as a formidable contender in offsetting these age-related skin challenges, offering tangible solutions to sagging skin and wrinkles.⁶

Intriguingly, the discussion delves into the realm of histological and immunostaining techniques, which provide an objective lens through which to evaluate the effects of monopolar RF therapy.⁷ By scrutinizing collagen content, presentation, and formation, researchers gleaned valuable insights into

the therapy's intricate interplay with skin tightening and appearance. The comprehensive approach encompassing multiple facets of collagen biology reinforces the robustness of RF therapy's impact on skin health.⁸

The discussion culminates with a resounding endorsement of RF therapy as a potent and secure modality for skin tightening and rejuvenation. By activating collagen synthesis, promoting tissue remodeling, and enhancing overall skin aesthetics, RF therapy occupies a pivotal niche in the arsenal of noninvasive cosmetic procedures. The discussion champions the use of RF therapy as a pivotal resource for individuals seeking to rejuvenate their skin's firmness, alleviate wrinkles, and embrace a more youthful and revitalized appearance.

Synergy with Ancillary Treatments: Elevating Rejuvenation to New Heights

In the pursuit of excellence, the integration of ancillary treatments harmonizes with RF therapy to amplify outcomes. Platelet-rich plasma (PRP) infuses growth factors, serving as a catalyst for cellular regeneration and accelerating tissue repair.⁹ Within PRP, the concentrations of growth factors are notably elevated, ranging approximately 3–5 times higher than those found in regular plasma. This augmentation of growth factors significantly contributes to tissue healing processes. Among the plethora of growth factors encapsulated within PRP are platelet-derived endothelial growth factor, platelet-derived growth factor A + B, transforming growth factor β , insulin-like growth factor 1 and 2, vascular endothelial growth factor, ECGF, and basic fibroblast growth factor, predominantly housed within the α granules of platelets.^{9,10} This rich reservoir of growth factors plays a pivotal role in initiating and orchestrating the intricate cascade of cellular events necessary for tissue regeneration and repair. This synergistic collaboration reinforces the body's natural healing mechanisms, propelling the rejuvenation process forward. Weekly PRP injections can increase rejuvenation delayed effects after RF treatment.¹¹

Polydeoxyribonucleotide (PDRN) and polynucleotide have gained significant attention for their potential

in skin antiaging therapy.¹² PDRN, composed of DNA fragments extracted from salmon trout or chum salmon sperm cells, has demonstrated various therapeutic properties in both preclinical and clinical studies. These properties include anti-inflammatory, antiapoptotic, antiosteoporotic, antimelanogenetic, antiallodynic, antiosteonecrotic, bone regenerative, tissue damage preventive, antiulcerative, and wound healing effects, which are mediated through the activation of the adenosine A2A receptor and salvage pathways.^{12,13} PDRN also promotes angiogenesis, cellular activity, collagen synthesis, soft-tissue regeneration, and skin revitalization and can even be used to treat hyperpigmentation. PDRN enters the scene as a key player, engaging adenosine A2A receptors and orchestrating a chorus of collagen synthesis and tissue reconstruction. Another crucial aspect is PDRN's ability to enhance angiogenesis, crucial for tissue repair. PDRN's promotion of vascular endothelial growth factor expression through A2A receptor activation leads to improved blood vessel formation and tissue regeneration. Furthermore, PDRN inhibits melanin synthesis, making it a potential treatment for hyperpigmentation disorders. It suppresses melanogenic gene expression and inhibits tyrosinase enzymatic activity, contributing to skin whitening.^{12,13} Weekly PD or PDRN injections can increase delayed rejuvenation effects.

Stem cell conditioning media (SCM) is a powerful conductor that creates an environment conducive to cellular revitalization.¹⁴ SCM has emerged as a novel therapeutic approach in regenerative medicine, showing successful outcomes in certain diseases.¹⁵ The emergence of SCM suggests the potential use of SCM as a new and promising alternative for skin wound healing. Despite numerous preclinical data demonstrating the potential and efficacy of this treatment, the injection of SCM is not feasible. An approach involving the use of small particles extracted for injection of SCM, known as exosomes, exists. Exosomes refer to small vesicles (30–120 nm) with a double lipid membrane structure secreted by cells. However, with the discovery of various forms of vesicles secreted by cells, the term “exosome” has been extended to encompass a broader category of

extracellular vesicles.¹⁶ Exosomes were first discovered in 1983 and were initially perceived as a cellular “garbage bag” without clear biologic functions.¹⁷ However, exosomes contain diverse ligands, cell-derived proteins, growth factors, nucleic acids, etc., and have been found to play a significant role in intercellular communication.¹⁸ They carry various biologic information released by cells, contributing to disease diagnosis, new biomarker discovery research, therapeutic development using effective substances for cell signaling, and the development of drug delivery systems using the bilayer membrane structure for drug detection. Exosomes released in cell culture media, which were previously discarded, have sparked interest among researchers studying cells. According to data from the US National Library of Medicine's PubMed database, the number of published articles has exponentially increased since 2010, with more than 46,000 articles published from 2010 to 2022, including 8721 published in the past year alone. As the growing number of publications suggests, many scientists are enthusiastic about exosomes. Exosomes maintain the functional role of traditional cell therapies while overcoming safety issues associated with cell therapies, such as immune rejection, cancer induction, and vascular occlusion, due to their nonliving nature. As a result, exosomes are recognized as a novel concept of cell-free therapeutics, advantageous for storage, transportation, and management. Immune cell-derived exosomes are being developed as targeted anticancer agents or immunotherapies, and stem cell-derived exosomes are being explored for rare and refractory disease treatments. However, because exosomes are extracted from SCM, their quantity may not surpass the effects of SCM. The extraction and concentration of exosomes present challenges for validation by the general consumers. Together, these adjunctive treatments weave an intricate tapestry of rejuvenation, heralding a holistic approach to skin health.

Limitations and Future Directions: Paving the Road to Advancement

Although the RF-EBD showcases remarkable potential, it is vital to acknowledge the limitations

inherent to any study and treatment modality. The cohort size, albeit robust, offers a snapshot rather than an exhaustive panorama of the diverse patient population. Further exploration with larger and more diverse cohorts is warranted to validate and extend the findings.

CONCLUSIONS

This study proved that fine wrinkles were improved with VNM RF equipment. Measuring skin roughness or fine wrinkles requires a standardized instrumentation method. It is significant that skin roughness was objectively measured numerically using a computer program using a standardized 3D scanner.

RF-based cosmetic procedures, particularly those involving the VNM-EBD, represent a significant advancement in the realm of noninvasive skin rejuvenation. The dual-phase mechanism of immediate collagen contraction and delayed remodeling underscores the transformative potential of RF therapy. The integration of ancillary treatments further amplifies the holistic approach to skin health, offering patients comprehensive solutions for their aesthetic concerns.

As the field of cosmetic dermatology continues to evolve, RF-based procedures are poised to play an increasingly prominent role in delivering effective and personalized treatments. The synergy between RF therapy and emerging technologies, coupled with a deeper understanding of biologic responses, promises to reshape the landscape of aesthetic enhancements. With RF-based procedures, individuals can embark on a journey to revitalized and youthful skin, embracing the possibilities of noninvasive treatments while minimizing risks and downtime.

The VNM RF-EBD exemplifies the convergence of innovation, science, and artistry in modern cosmetic dermatology. With its transformative potential, this technology stands as a beacon of hope for individuals seeking effective, safe, and minimally invasive solutions for their aesthetic aspirations.

DISCLOSURE

The author has no financial interest to declare in relation to the content of this article.

PATIENT CONSENT


Patients provided written consent for the use of their images.

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Subjective evaluation of monopolar radiofrequency treatment by patients in aesthetic rejuvenation



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Subjective evaluation of monopolar radiofrequency treatment by patients in aesthetic rejuvenation

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Abstract

Objective: To assess the subjective experiences of patients following monopolar radiofrequency (RF) treatment for facial rejuvenation and anti-aging purposes.

Methods: A study involving 50 female patients (aged 30–70 years, Fitzpatrick skin type III and IV) who received a single session of RF treatment. Exclusion criteria comprised active infections, skin diseases, pregnancy, or history of recent anti-aging treatments. Thirty-four patients completed a 10-question questionnaire after 3 months of treatment.

Results: Among the respondents, 82% expressed satisfaction with the RF treatment, reporting significant improvements primarily in the mid and lower face, and eyelids. Mainly, patients noted improvements in skin laxity (52.9%), skin texture (17.6%), and skin tone (11.7%). Notably, 73.5% noticed changes within 1–2 months post-treatment, with the peak effect observed at 1–2 months. Mild complications (swelling and erythema) were reported, usually resolving within a week. The mean pain score was 1.94 (± 0.66), indicating mild to moderate discomfort.

Discussion: Monopolar RF devices, apply high-frequency electric currents generating heat, stimulating collagen production for skin tightening. This study's unique focus on detailed subjective patient experiences provides insights valuable in clinical settings, aiding clinicians in managing patient expectations and achieving optimal results. The satisfaction rates align with previous findings, emphasizing RF treatment's efficacy in addressing facial laxity, especially in the mid and lower face. Positive feedback extended beyond skin tightening, encompassing skin texture and tone improvements. While the study's observation period was 3 months post-treatment, longer-term studies are warranted for comprehensive assessments.

Conclusion: The study underscores the efficacy of monopolar RF device, as a non-invasive and effective anti-aging treatment. The findings contribute to diversifying the RF market, potentially aiding clinicians in optimizing patient care. Considering the growing complexity of patient demands and treatment responses, this study serves as a valuable reference for clinicians engaging in RF treatments.

1 INTRODUCTION

For a considerable duration, cosmetic surgery has remained the cornerstone of Aesthetic Medicine. Nonetheless, concerns regarding significant side effects and prolonged recovery periods have spurred a shift towards less invasive methods. This surge in demand for innovative approaches has led to notable advancements in technologies. Conventional techniques like ablative lasers and chemical peels have evolved into more sophisticated methods such as fractional laser, radiofrequency (RF), and high-intensity focused ultrasound (HIFU) treatments, all aiming to offer more natural results while minimizing downtime.¹

Monopolar RF devices possess a unique feature: the high-frequency electric current they generate produces heat capable of penetrating the deep dermal layers and fat tissues while safeguarding the epidermis. This heating process has been associated with the alteration of collagen, resulting in its thickening and shortening, thereby gradually tightening the skin over a span of 4–6 months.²

Numerous studies have sought to explore the effects of RF treatment, employing histologic analysis,² patient assessments,³ and evaluations conducted by impartial physicians.⁴ While these studies have generally reported favorable outcomes, their assessments have often centered on specific criteria, such as the Global Aesthetic Improvement Scoring system, Fitzpatrick Wrinkle Classification, and Laxity Classification.⁴

Our study aims to delve deeper by gathering more comprehensive feedback from patients following RF treatment. This endeavor is crucial in clinical settings, offering valuable insights for clinicians to better anticipate and understand patients' experiences. To achieve this goal, we conducted a survey involving 34 patients and administered a 10-question questionnaire tailored to assess their RF treatment outcomes.¹

2 METHOD

Fifty female participants aged between 30 and 70 years, exhibiting mild to moderate facial sagging and categorized as Fitzpatrick skin types III and IV, received a single session of RF (Radiofrequency) treatment using the Volnewmer device from Classyc Inc. Korea, between March 1, 2023, and August 31, 2023. Exclusion criteria encompassed active infections, skin diseases, history of keloidal scarring, pregnancy, or undergoing any anti-aging treatment within the past 6 months. All participants provided informed consent upon enrollment and agreed to complete a questionnaire 3 months post-treatment, although only 34 participants returned the completed questionnaire.

Following informed consent, participants' faces were cleansed, and without the application of topical anesthetic cream, 300 shots were administered to the entire face using an initial energy level of 3 J/cm², which was reduced to 2.5 in cases where participants reported severe pain during the procedure. Post-treatment, participants returned home. The questionnaire, comprising 10 questions, was sent to each participant 3 months after the treatment, primarily consisting of multiple-choice questions, with an option for participants to provide subjective answers when applicable.

One of the questions asked participants to rate their overall satisfaction on a 0–4 scale using the Global Aesthetic Improvement Scoring system, which defines the levels of improvement from “Very much improved” to “Worsened.” Participants also rated their pain levels based on the Verbal Rating Scale (VRS) from 0 to 3, ranging from “No pain or discomfort” to “Severe pain,” characterized by verbal responses, facial expressions, or tears.

The questionnaire included inquiries regarding the level of improvement, specific areas of satisfaction on the face, aspects of change satisfaction, the timeline for noticing changes and peak effects, pain during treatment, any adverse effects post-treatment,

downtime duration, willingness to undergo treatment again, and concerns if opting for the treatment in the future (Figure 1).

Questionnaire

1. How would you rate the level of improvement on a scale of 1 to 5?

(1) Very much improved - Excellent corrective result

(2) Much improved - Marked improvement of the appearance, but not entirely optimal

(3) Improved - Improvement of the appearance, better compared to the initial condition, but a touch-up is advised

(4) Unchanged - The appearance remains substantially the same compared to the original condition

(5) Worsened - The appearance has worsened compared to the original condition

2. If your score is less than 4, which area of the face are you most satisfied with?

(1) Lower face

(2) Mid face

(3) Forehead

(4) Eyelids

3. Which aspect of the change are you most satisfied with?

(1) Skin laxity

(2) Skin texture

(3) Skin tone

(4) Pores

(5) Wrinkles

4. When did you start noticing the change?

(1) Immediately after the treatment

(2) 1-2 months after the treatment

(3) 3 months after the treatment

5. When do you think you experienced the peak effect?

(1) 1 month

(2) 1-2 months

(3) More than 3 months

6. How intense was the pain during the treatment? 0) No pain or discomfort

(1) Mild pain: pain reported in response to questioning only without any behavioral signs

(2) Moderate pain: pain reported in response to questioning and accompanied by behavioral signs or pain reported spontaneously without questioning

(3) Severe pain: strong verbal response accompanied by face grimacing, withdrawal of the hand, or tears

7. Have you experienced any unwanted effects after the treatment?

(1) Swelling

(2) Erythema

(3) Burn

(4) None

(5) Others (please describe)

8. What was the duration of the downtime?

(1) None

(2) Less than 3 days

(3) Less than a week

(4) More than a month

9. Are you willing to receive the treatment again?

(1) Yes

(2) No

(3) Not sure

10. What is your biggest concern if you decide to receive the treatment again?

(1) Pain during the treatment

(2) Downtime

(3) Lack of any effect

(4) Price

(5) None

Fig. 1. Participants were asked to rate the improvement level on a scale from 1 to 5, specify the facial area they were most satisfied with if their score was below 4, identify the aspect of change they were most content with, report when they first noticed the treatment's effects, indicate when they felt the maximum effect, describe the intensity of pain during treatment using a scale of 0–3, disclose any post-treatment unwanted effects, state the duration of downtime, express their willingness for retreatment, and pinpoint their primary concern if considering the treatment again.

3 RESULTS

Out of the 50 patients who underwent the treatment, 34 successfully completed the study, with ages ranging from 36 to 66 years (mean: 49.21 ± 7.91 years). Among them, 23 patients exhibited Fitzpatrick skin type III, while 11 had Fitzpatrick skin type IV. Impressively, over 80% (82%) of the individuals treated with RF expressed satisfaction with the outcomes. The average Global Aesthetic Improvement Scale (GAIS) score stood at 2.71 ± 0.87 (Figure 2). Notably, participants reported the most significant improvements in the mid-face (13 patients; 38.2%), lower face (12 patients; 35.2%), and eyelids (three patients; 8.8%), with no notable improvements reported on the forehead. Skin laxity enhancement was identified as the most noticeable change (18 patients; 52.9%), followed by improvements in skin texture (six patients; 17.6%) and skin tone (four patients; 11.7%). Around 73.5% of patients (25 patients) noticed differences after 1–2 months (15 patients; 44%) or at 3 months (three patients; 8.8%), while 29.4% (10 patients) observed changes immediately after treatment. The peak effect was observed at 1–2 months by 52.9% (18 patients) and at 3 months by 20.6% (seven patients), with 8.8% (three patients) experiencing the greatest effect in less than a month. A majority (55.9%) reported no treatment-related complications, although mild issues like swelling (nine patients; 26.5%) and erythema (six patients; 17.6%) occurred, usually resolving within a week (12 patients; 35.3%) or a month at most (three patients; 8.8%). The mean pain score was $1.94 (\pm 0.66)$, indicating mild to moderate pain during the procedure. Nonetheless, 61.7% (18 patients) expressed their willingness to undergo the treatment again, with the primary concern for the next treatment being pain (14 patients; 41.2%), followed by concerns about the treatment's effectiveness (10 patients; 29.4%).

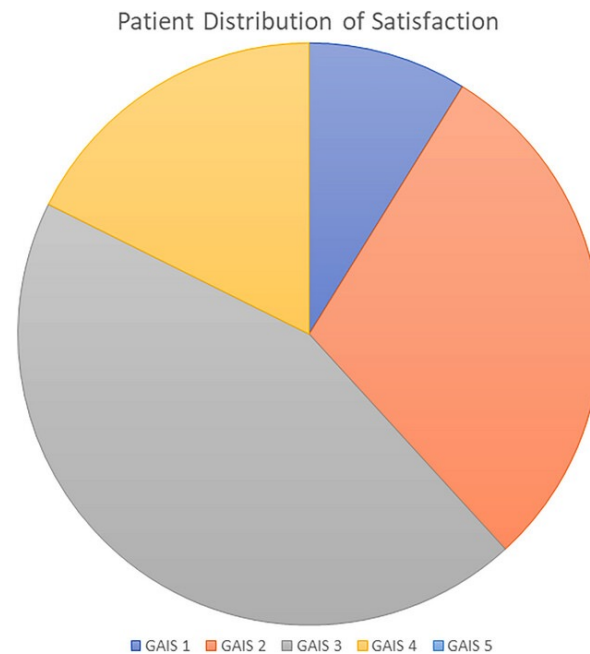


Fig. 2. The figure illustrates the Global Aesthetic Improvement Scale (GAIS) scores, ranging from 1 to 5, denoting: (1) Very much improved, (2) Much improved, (3) Somewhat improved, (4) Unchanged, and (5) Worsened.

Radiofrequency (RF) technology employed in skin rejuvenation operates within an electromagnetic frequency spectrum spanning from 0.5 to 40 MHz. Tissue impedance to electrical currents generates heat, and the energy can be computed using the formula: $\text{Energy (J)} = I^2 \times R \times T$ (where I represents Current, R denotes Impedance, and T signifies Time in seconds).⁵ The correlation between heat production, electrical current potency, and tissue resistance yields varying outcomes across different tissues and individuals. Following the market introduction of Thermacool (Solta Medical, Inc., formerly Thermage, Hayward, CA, USA) for skin tightening and facial wrinkle treatment, numerous RF devices emerged, each embracing

slightly varied technologies. Among these, Volnewmer, a monopolar RF device manufactured by Classys Inc. in South Korea, shares comparable frequency (6.78 MHz) and power (watt) with Thermacool but distinguishes itself through several noteworthy features. Its convex-shaped tip, adaptable to surface angles, facilitates uniform energy dispersion into the dermis while ensuring steadfast surface attachment. Moreover, its innovative cooling mechanism employing water instead of gas provides instant surface cooling, reducing pain during treatment while effectively delivering RF energy into the deeper dermis.

The choice between monopolar and bipolar radiofrequency therapies hinges on treatment objectives, targeted skin regions, and the desired skin penetration depth. Palmieri et al.⁶ indicated that monopolar electrodes exhibit deeper penetration into skin layers, reaching subcutaneous tissues for substantial collagen remodeling, which is crucial in skin rejuvenation treatments aiming for comprehensive tightening effects. They're also versatile, applicable to various body areas. Monopolar RF excels in treating larger areas and achieving profound skin tightening by penetrating deeply into subcutaneous tissues, enabling substantial collagen remodeling. Its versatility allows application across various body areas and offers notable clinical improvements, especially in addressing mild to moderate wrinkles or post-lifting concerns. Conversely, bipolar RF, while precise and safer for delicate areas, may have limitations in penetration depth and coverage area, potentially resulting in less pronounced effects, particularly for extensive skin tightening or larger treatment zones.⁶⁻⁸

Diverse evaluation methodologies have been employed to gauge RF treatment efficacy. Subjective assessments,^{9, 10} histopathological evaluations,^{11, 12} and radiological appraisals¹³ have all been utilized to appraise outcomes. Most subjective findings underscore the clinical significance of RF treatment,^{9, 10} while histopathological analyses demonstrate heightened collagen synthesis.^{11, 12} This study, unlike prior research, prioritized a comprehensive exploration of patients' subjective experiences through a detailed

questionnaire. This approach, within clinical settings, aids clinicians in understanding patients' nuanced needs, establishing realistic expectations, and attaining more optimal results.

The satisfaction rate among subjects was notably high, albeit the reasons behind their ratings varied. Notably, the mid-face and lower face garnered the most satisfaction, aligning with prior research underscoring RF treatment efficacy for middle and lower face laxity.¹⁴⁻¹⁶ Plausibly, this could relate to the treatment's impact on subcutaneous fat tissue, contributing to volume loss around marionette lines and an overall slimming effect. Furthermore, the Energy(J) = $I^2 \times R \times T$ equation posits that, given the higher impedance of fat compared to the skin or muscle, the lower face, being relatively more fat-dominant than the forehead, might receive higher penetrating energy, potentially explaining the observed outcomes. Although RF treatment can benefit eyelid sagging, none reported improvements in forehead appearance.¹⁷

Additionally, it is crucial to note that positive feedback extended beyond skin tightening to include skin texture and tone. RF treatment typically yields gradual improvements; while this study observed peak improvement at 1–2 months post-treatment, previous research has reported significant enhancement at 3 and 6 months post-treatment.¹⁸ Nonetheless, longer follow-up periods beyond 3 months would offer deeper insights.

Most patients exhibited tolerance to mild to moderate pain, as reflected in the Verbal Rating Scale (VRS) used in this study instead of the Numerical Rating Scale (NRS) for its simplicity and high correlation with NRS, ensuring higher response rates.¹⁹ Reported complications, such as swelling and erythema, dissipated within a month, affirming the non-invasive nature of the treatment. Interestingly, the study revealed that treatment cost did not emerge as a primary concern, which contrasts with prior research highlighting price as a significant consideration among female Asian patients.^{20, 21}

The enduring quest for enhanced physical appearance, epitomized by the popularity of plastic surgeries in the 21st century, has evolved with the advent of less invasive techniques. However, meeting patients' intricate needs in this multifaceted landscape remains challenging. Though critiques persist regarding the subjective basis of some influential RF treatment studies,²² subjective assessments remain crucial, representing the voices of patients that clinicians encounter daily. As the RF device market expands annually, understanding patients' nuanced responses and concerns equips clinicians with the confidence to provide more tailored treatments.

Limitations of the study conducted on Radiofrequency (RF) treatment in skin rejuvenation include the relatively small sample size, with only 34 out of 50 participants completing the survey, potentially limiting the representativeness of the findings. The study focused on female participants aged between 30 and 70 years with mild to moderate facial sagging, which may restrict the generalizability of the results to other age groups or individuals with different skin concerns. Additionally, the research utilized a single device, the Volnewmer from Classyc Inc., which may not account for variations in outcomes that could arise from using different RF devices or technologies. Moreover, while the questionnaire method offered subjective feedback from participants, it may introduce response biases or limitations inherent to self-reported data. Lastly, the absence of a control group or comparative analysis with alternative treatments could restrict a thorough assessment of RF treatment efficacy in relation to other available modalities.

Cosmetic procedures, while offering aesthetic enhancements, pose challenges in catering to diverse patient needs. Our study exploring patients' subjective responses to RF treatment via a questionnaire underscores monopolar RF effectiveness as a non-invasive anti-aging treatment. This finding broadens the horizon of the burgeoning RF market and stands as a reference for clinicians actively engaged in RF treatments.

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This study was conducted in compliance with the Declaration of Helsinki. There is no financial disclosure to report.

CONFLICT OF INTEREST STATEMENT

There is no conflict of interest for all authors.

DATA AVAILABILITY STATEMENT

The author has provided the required Data Availability Statement, and if applicable, included functional and accurate links to said data therein.

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A Split-face Study on Rejuvenation Efficacy According to Monopolar Radiofrequency Tip Size



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abstract: Monopolar radiofrequency (RF) non-invasively tightens and rejuvenates the skin by stimulating collagen fiber production. Since the introduction of the monopolar RF device in the early 2000's, RF devices have advanced and they can rejuvenate of periorbital and forehead wrinkles, as well as skin laxity of the lower face and neck. We compared the differences in the treatment effects based on the tip size. This randomized split-face study comprised 31 participants aged 29 to 75 years old (three males and 28 females) who underwent one session of monopolar RF; one side of the face was treated with a 3cm² tip and the other with a 4cm² tip. Facial wrinkle scores were measured on the upper face and the lower face before and after treatment for up to three months. Significant improvement was observed in the periorbital area ($p<0.001$), forehead ($p=0.72$), and glabellar ($p=0.63$) treated with a smaller tip. However, nasolabial folds ($p=0.8$) and marionette lines ($p=0.13$) showed better improvement when treated with a larger tip.

keywords: face, monopolar radiofrequency, rejuvenation, wrinkle

Aging is an inevitable process characterized by wrinkles and fine lines on the face, thereby affecting its appearance. Various rejuvenation treatments have been developed to reverse the signs of aging. One such treatment is the monopolar radiofrequency (RF) technology, which tightens and rejuvenates the skin. RF treatment results in conformational changes in the collagen network and stimulation of collagen production de novo induced by elevated temperatures.¹ Reportedly, monopolar RF improves the facial skin structure; however, the results vary in different facial areas and subareas in the same individual.² This study aimed to perform a split-face comparison evaluating RF efficacy using a 3cm² tip versus a 4cm² tip on different facial areas.

Methods

This randomized split-face trial comprised 31 participants (three males and 28 females) with Fitzpatrick Skin Types III and IV, aged 29 to 75 years old (mean age 52.45 years). They were included when both wrinkles were symmetrical grade. Informed consent was obtained from all participants. The treatment was performed under local anesthesia (topical application of 5-MC cream, Lidocaine 96mg/g; The-U Pharmaceutical Co., Ltd., South Korea; 30 min before treatment). After the application of the conductive fluid, each participant underwent a single session of monopolar RF (Volnewmer, Classys, South Korea). The newly developed monopolar RF device

in this study was equipped with two handpieces; therefore, the clinician could apply the 3cm² and 4cm² tips without changing the tip. One side of the face was treated with a 3cm² tip, and the other with a 4cm² tip, 300 shots each. It was treated with 2.5~3 level energy, depending on the individual. The total delivered energy was 16-19kJ/cm², and the average delivered energy for the 3cm² tip and the 4cm² tip was 16.4J/cm² and 16.6J/cm², respectively. Before and 1 and 3 months after clinical photographs were taken using a facial skin analyzer (MarkVu, PSI plus, South Korea) to compare the wrinkle scores in different facial areas. Two dermatologists blindly measured the mean facial wrinkle scores³ on the upper face, including the periorbital and forehead lines, and the glabella,

and the lower face, including the nasolabial folds and marionette lines (Table 1). The participants' comfort level on a 5- point scale (0, no pain; 1, mild pain; 2, moderate pain; 3, severe pain; 4, intolerable pain) and participants satisfaction assessment on a 4-point scale (1, worse; 2, <25% mild improvement; 3, 25-49% improvement; 4: >50% major improvement) was assessed.

TABLE 1. Classification of facial wrinkles (by Lemperle et al³).

FACIAL WRINKLES	SCORE
No wrinkles	0
Just perceptible	1
Shallow wrinkles	2
Moderately deep wrinkles	3
Deep wrinkles, well-defined edges	4
Very deep wrinkles, redundant folds	5

A linear mixed model was used to compare the changes in the wrinkle scores before and after treatment according to the tip size. Statistical significance was set at $p < 0.05$. Data were analyzed using the IBM SPSS software (version 27.0; IBM Corp., Armonk, NY, USA).

Results

In the upper face, the periorbital area treated with the 3cm² tip showed significant improvement (Figure 1). In the upper face wrinkles, including the forehead, glabella, and periorbital line, wrinkle scores were 1.48, 1.81, and 1.29 in pretreatment, respectively. The wrinkle score of forehead after treatment were 1.06 with the 3cm² tip and 1.26 with the 4cm² tip at three months, the wrinkle score of glabella were 1.23 with the 3cm² tip and 1.32 with the 4cm² tip at three months, and the wrinkle score of periorbital line were 0.84 with the 3cm² tip and 1 with the 4cm² tip at three months (Table 2). The upper face wrinkle treated with the 3cm² tip showed better improvement than the area treated with the 4cm² tip, although the difference was not significant between two tips ($p = 0.845$). However,

on the lower face, the nasolabial folds and marionette lines treated with the 4cm² tip showed better improvement than the area treated with the 3cm² tip (Figures 1 and 2). In the lower face wrinkles, including the nasolabial folds and marionette line, wrinkle scores were 2.13 and 2.13 in pretreatment, respectively. The wrinkle score of nasolabial folds after treatment were 2 with the 3cm² tip and 1.77 with the 4cm² tip at three months and the wrinkle score of marionette line were 1.87 with the 3cm² tip and 1.48 with the 4cm² tip at three months (Table 2). The improvements after one month were usually well maintained for up to three months in the clinical photographs.

The mean comfort level score was 0.61. Seventeen participants (54.8%) reported no pain, nine (29%) reported mild pain, and five (16.1%) reported moderate pain. No participants reported severe or intolerable pain. The mean participants satisfaction assessment one month after treatment was 2.42, thirteen participants (41.9%) reported 25 to 49 percent improvement, and eighteen (58.1%) reported less than 25 percent mild improvement. After three months of treatment, the average satisfaction score slightly decreased to 2.32, and 10 patients (32.3%) maintained a 25 to 49 percent improvement in satisfaction. No serious side effects were reported, except for one participant who was treated with the 4cm² tip and had a mild erythematous burn on the forehead, which healed spontaneously within a week.

TABLE 2. Comparisons of mean wrinkle scores before and after treatment.				
TIP LENGTH	PERIORBITAL LINE (N=31)	1 MONTH	3 MONTHS	P-VALUE
	PRETREATMENT			
Periorbital line (n=31)				
3cm² tip	1.29	0.84	0.84	0.001
4cm² tip	1.29	1	1	0.85
Forehead (n=31)				
3cm² tip	1.48	1.03	1.06	0.72
4cm² tip	1.48	1.26	1.26	0.21
Glabella (n=31)				
3cm² tip	1.81	1.19	1.23	0.63
4cm² tip	1.81	1.29	1.32	0.75
Nasolabial folds (n=31)				
3cm² tip	2.13	2	2	0.31
4cm² tip	2.13	1.77	1.77	0.8
Marionette line (n=31)				
3cm² tip	2.13	1.9	1.87	0.12
4cm² tip	2.13	1.45	1.48	0.13

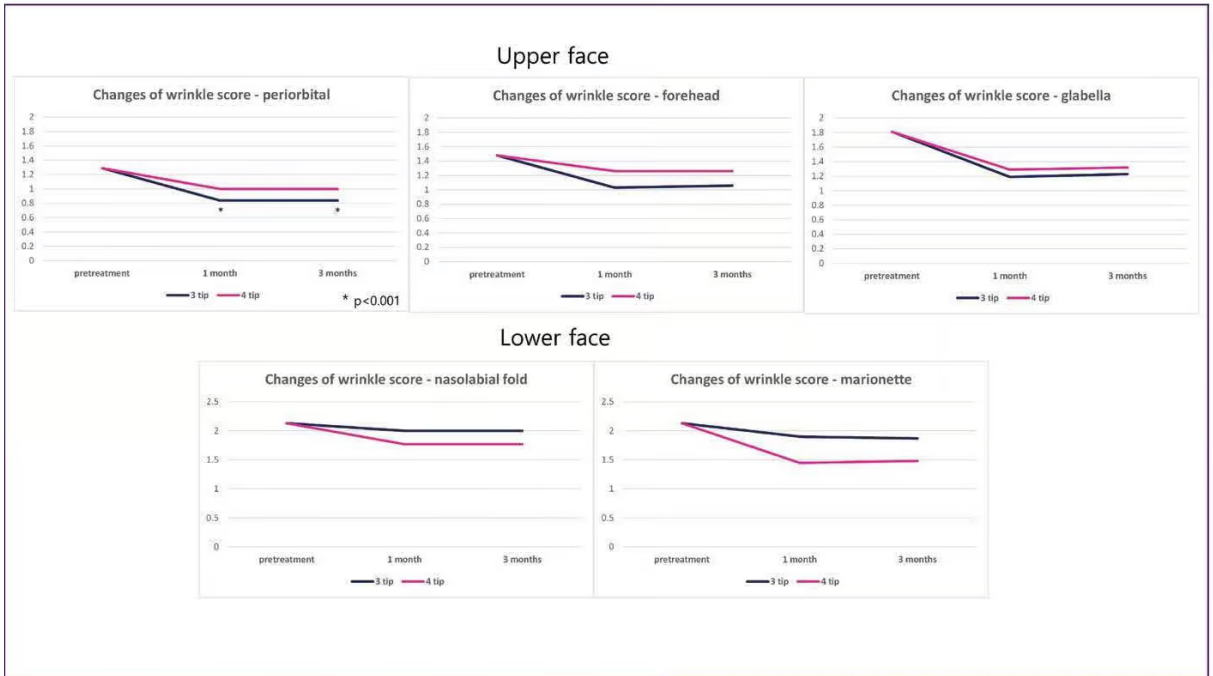
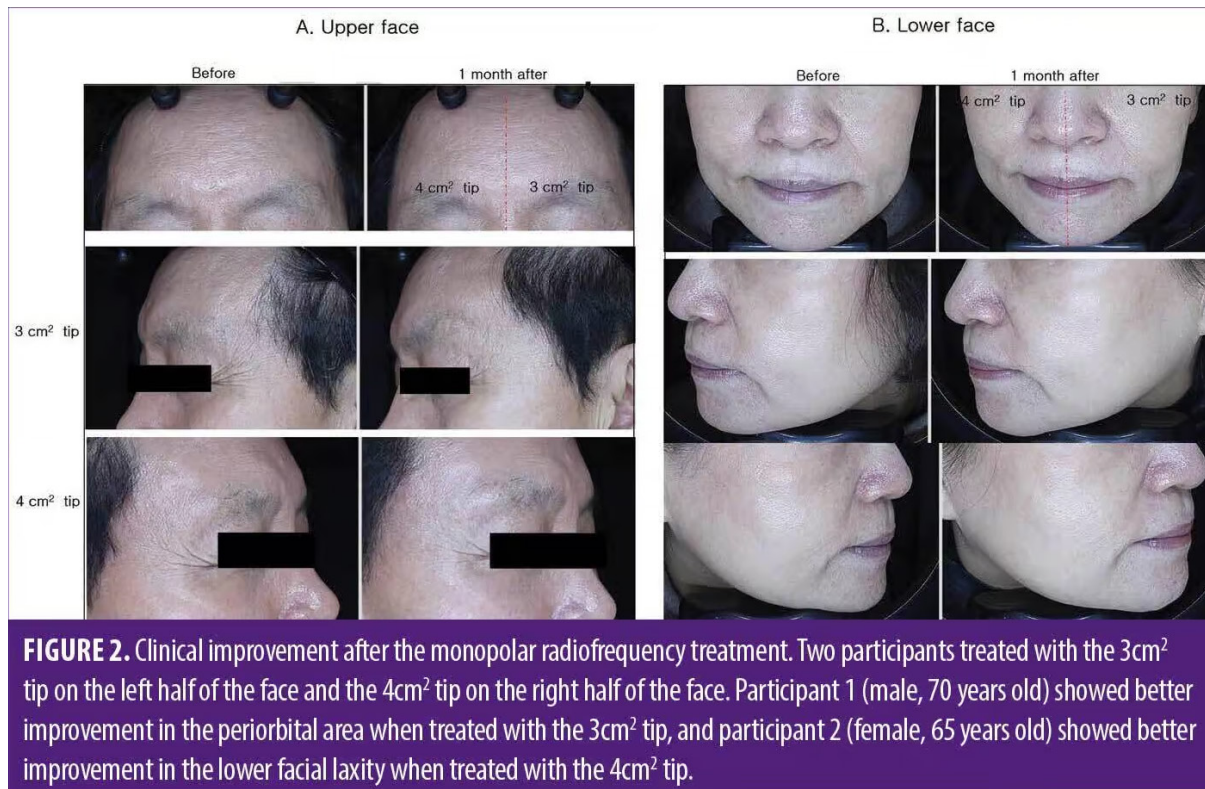


FIGURE 1. Comparison of the wrinkle scores in different facial areas before and after the monopolar radiofrequency treatment (n=31).



Discussion

The findings of this study suggest that the efficacy of monopolar RF treatment varies depending on the tip size and facial area. As RF energy is produced by an electric current rather than a light source, it is not subject to diminution by tissue scattering or absorption by epidermal melanin, and significant thermal energies can be generated safely within the deeper tissue layers causing collagen contraction and new collagen formation.⁴ The effect of monopolar RF on laxity mainly occurs as a result of uniform volumetric heating of the dermis.⁴ A previous study reported that dermal thickness and subcutaneous fat influence RF current distribution and interarea variations in the clinical results.² Dermal thickness is thicker in the order of eyelids, followed by the forehead, glabella, and submandibular areas, with differences observed among individuals.^{5,6} Generally, the dermal thickness of the upper face is relatively thinner than the lower face. Thus, for increased efficacy, a monopolar RF device should be able to deliver volumetric heating to

an optimal depth. The optimal depth might differ based on the patient's age and facial area. Small monopolar RF tip targeting the thinnest area around the eyes are currently in use, and a 0.25cm² monopolar RF tip has been reported to be safe and effective for skin tightening on the upper and lower eyelids.⁷

The larger the monopolar RF tip size, the more energy can be delivered to the deeper layers.⁸ RF energy penetration depth is about one third of electrode radius and treatment effects with monopolar devices depend on RF power and size of electrode.⁹ Heat distribution which is strong at the surface of the active electrode and is reduced dramatically at a distance exceeding the size of electrode, thereby limiting penetration depth.⁹

In our study, the upper face demonstrated better improvement for the 3cm² tip than the 4cm² tip, particularly in the periorbital area, which is the thin skin area (Figure 2). However, in the lower face, better results were observed in areas treated with

the 4cm² tip. The results suggested that the larger tip size could affect deeper dermis than the smaller tip size. In addition, the larger the tip size, the larger the overlapping area, which can enlarge thermal zone effect.

No serious side effects or complaints of severe pain were reported. The improved safety and decreased pain reported in this study were because of the continuous water-cooling system of this new monopolar RF technology, which constantly kept the skin surface temperature at 12–14°C. In the 1-month follow-up, most participants reported mild to moderate improvement, and the satisfaction was well maintained for three months. However, unlike the existing literature reporting that collagen formation continues even after 3 to 6 months,^{10,11} no further clinical improvement was observed at the 3-month follow-up. A long-term follow-up comparison after the repetition of several treatment sessions is required in future studies. The limitations of this study included small number of participants and wide range of age discrepancy, and a short follow-up period of three months.

In conclusion, our results found a smaller tip size (3cm²) is better for upper facial wrinkles, and a larger tip size (4cm²) is better for lower facial laxity. The new monopolar RF device with a continuous water-cooling system is less painful, safer, and effective for whole-face rejuvenation.

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Japanese Market Beauty Trends

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Beauty trends in the Japanese market

The popularity of lifting procedures remains strong in the Japanese market. In the past, there were many procedures for elderly individuals, but recently, the age range has been gradually younger. As the popularity of procedures spreads, interest in lifting procedures, which can be applied to people of all ages and genders, is growing even more, alongside specialized procedures such as pigmentation.

Especially in Japan, the popularity of non-invasive procedures that are low in pain and do not require anesthesia are gradually increasing. Among these, the most popular lifting procedure is undoubtedly High-Intensity Focused Ultrasound (HIFU) treatment. Various brands of HIFU procedures are still popular.

The device operating at 4MHz, which was once a trend in Japan, gained popularity as a "pain-free high-frequency" device. However, despite providing temporary effectiveness, the popularity quickly faded

due to the inconvenience of short treatment intervals, as the effects of the procedure did not last.

Here at our clinic, we offer four types of lifting procedures, including one ultrasound lifting device and three high-frequency devices. Ultrasound procedures remain highly popular, but our clinic is enhancing patient satisfaction through various high-frequency procedures.

Clinical application

The sustained effect is perhaps the most crucial factor in the technical aspect of high-frequency procedures.

Due to the nature of the high-frequency procedure, it is easily accessible to the epidermis or shallow layers. However, monopolar high frequency, which targets deep layers with bulk heating, is difficult to handle, and this is one of the procedures where special attention to potential side effects is particularly necessary. For this reason, when choosing a monopolar high frequency, it is important to check its safety features.

In our clinic, we mostly perform a high-frequency procedure targeting the deepest layers using Volnewmer. Before and after the procedure, we use a 3D camera to show the effects and conduct patient consultations directly. We proceed by allowing individual patient to directly observe the effects of lifting and volumizing with their own eyes. The effect of Volnewmer is most noticeable after one month, and since the F/U is carried out at that time, there is a positive effect when patients repurchase it. If the effect of the procedure is insufficient, it is difficult to use the above consultation method, but as some effects can certainly appeal to the patient, both the practitioners and the patients are very satisfied.

More than 70% of our patients in our clinic revisit continuously. I think the reason why the visit to the hospital continues is that the rapport formation has been well formed due to the satisfactory treatment effect.



Lian Clinics is located in Omotesando, Japan, and although it is not a large hospital, it treated about 90 patients a month in the early days using the Volnewmer procedure. Recently, the number of patients has gradually increased, and it usually provides the procedures ten patients a day. For Japanese people, about 400 shots are considered to be appropriate for the entire face, and the procedure is performed in different modes depending on the skin type.

In the case of 6.78Mhz high frequency, the Stacking mode is mainly used, and some hospitals stick to this method, but in our hospital, if there is much fat, the Stacking mode is used, and if the skin is thin and there is a problem of sagging, the procedure is performed in the Sliding mode in the direction of the vector. Depending on the procedure area, concurrent modes may also be utilized.



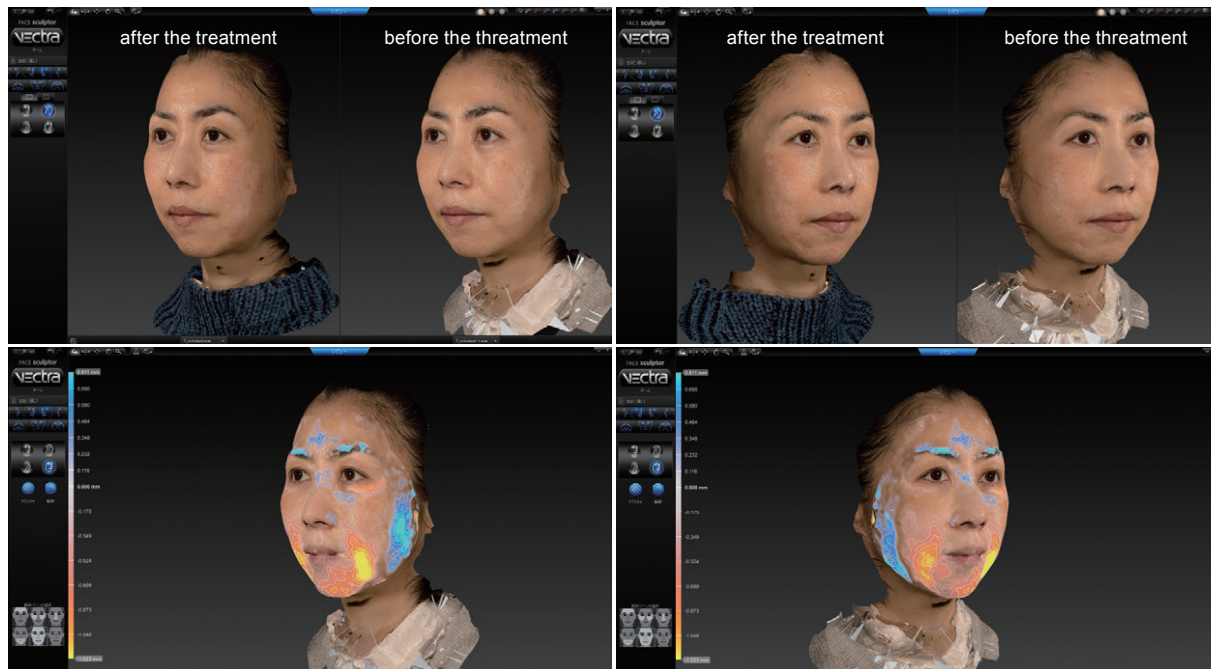
Pulling the skin to the upper direction and adjusting the skin layer thinly while checking the feeling of heat directly is also a procedure tip unique to our hospital.

Of course, the mode may be performed in parallel depending on the treatment site, but the procedure is performed while adjusting the thickness of the skin by pulling the skin up and checking the heat directly. The factor that has the greatest influence on the treatment effect is to perform wider bulk heating on the skin surface while reducing pain. VOLNEWMER is a water-cooling method that cools the skin surface at an appropriate level to reduce the pain of the procedure, and uniformly transfers heat without damaging the skin to increase the effectiveness of the procedure. Therefore, the stability of the device is very important, and I think VOLNEWMER is appropriate to transfer heat uniformly without damaging the epidermis.

While conducting monopolar high frequency using Volnewmer, there was one reported case of side effects. There was an instance where trembling around the eyes persisted for approximately 2 to 3 days after the procedure. However, it is difficult to determine a direct association with the high-frequency procedure, as this symptom could arise for various reasons. Therefore, it is not appropriate to consider it definitively as a side effect of the procedure.

There have been no experiences of burns or other types of side effects so far. Since we use cooling, there might be some discomfort during the procedure. However, most patients experience pain levels that allow them to consider revisiting, and overall, they are generally satisfied with the results.

Lapport is well formed between patients who have improved their skin with VOLNEWMER and me, so patients want to visit the hospital whenever they have skin problems.



It shows the volume improvement post VOLNEWMER treatment



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Expansion of the monopolar RF markets

Currently, the energy source for lifting or improving tightness is largely divided into RF (radiofrequency) and ultrasound. RF devices that use various polarities and RFs have been released in the past few years. Moreover, RF devices can implement various types of skin rejuvenation by delivering the intended amount of energy to different layers of the skin using the conversion of current and tissue-specific resistance into thermal energy using impedance. Specifically, they have an advantage over high intensity focused ultrasound (HIFU) devices using ultrasound, which is another energy source, in terms of dermal bulk heating, and are used for improving wrinkles and skin laxity. Among different polarities of RF, monopolar RF mostly uses a low frequency of 6.78 MHz, thereby allowing deep penetration of RF, compared with bipolar RF devices, and delivering high energy to the dermis with less effect on the fat layer. The skin surface is maintained at around 40 °C using cooling to reduce pain and burn risk, and a known skin tightening effect of 4 to 6 months occurs by inducing regeneration after collagen shrinkage by heating the dermis to 50–60 °C. Also, compared with other devices, it has almost no recovery time, and the treatment effect can be maintained with repetition. Although individual differences may be present in skin aging, findings such as sagging, wrinkles, and skin laxity can be commonly found in middle-aged patients. As this device can be used for patients whose symptoms cannot be

improved with HIFU-based devices alone, it has high utility, and several companies have recently released RF devices to reflect this trend.

A newcomer on the scene – monopolar RF, what are the features of VOLNEWMER?

VOLNEWMER is a monopolar RF device released by Classys in October 2022. “Thermage™” and “Oligio™,” using the same principle, have already been released. Although VOLNEWMER is a late-comer on the scene, it is a result of several years of development, as product disclosure was made in 2019. In fact, when I first came across it for testing, my impression was that a lot of effort has gone into intuitive user interface (UI) (Fig. 1) and design, compared with that of other devices. Since existing monopolar RF devices using the frequency of 6.78 MHz are already well known, I will explain by focusing on the basic features and differences of VOLNEWMER.



Fig. 1. VONEWMER exterior and UI

The most remarkable feature of the VOLNEWMER is the surface cooling method. Surface cooling, by nature, plays the role of reducing pain and the risk of burns by maintaining a skin temperature of 40 °C. While existing monopolar RF devices from other companies use gas cooling systems, VOLNEWMER uses water cooling; this is because water cooling allows for smoother heat delivery with less pain by cooling to a constant temperature, thereby being safer than transient gas cooling. No position-dependent difference exists in cooling despite the water cooling method in which the water circulates, and no burden of replacement is present due to the lack of cooling gas. Indeed, one might question the new cooling method when so many users are used to the potent gas cooling method, but no difference is evidently present from existing methods, as no problems were found in the official safety test, and no complaints from patients or side effects during actual use, such as burns, were present.

Also, tilting technology (Fig. 2) was used primarily for the connecting part of the tip and the handpiece for maximal contact between the handpiece and the skin. The contact surface for the tip and the skin protrudes, and care was taken to prevent side effects, such as burns, and for efficient RF delivery by preventing RF from being focused around angled edges as that in existing devices using hidden edges. VOLNEWMER can have four different tips depending on the tip surface area, including V (4.0 cm², face/body) / F (3.0 cm², face) / S (16 cm², body) / I (0.25 cm², periorbital area). VOLNEWMER can be used on the neck/eye area, knees, and back of the hand, all areas that are difficult to localize or have close contact. However, because of the protruding surface, pressure must be

controlled around areas with fillers. Additional cooling allows manipulation from step 1 (20 °C) to step 5 (12 °C) using the quick (Q)-cooling system, and discomfort such as heat/pain during the procedure can be mitigated by a markedly smoother vibration system, compared with those of existing devices. Although no repeat mode exists for the procedure rate, it is expected to be introduced, and face procedure is possible with easy mode settings. Tip cost, which has the biggest effect on the overall cost of the procedure for monopolar RF devices, is relatively reasonable. Since no time lock exists, shot numbers can be adjusted along with the unit price, and it can be used in combination with other devices.

Procedure protocol and combination therapy

As with other monopolar RF devices, the target patient for the procedure includes a wide range of ages, but it is most effective for mild to moderate skin laxity without significant fat and wrinkles. Rather than a dramatic one-time change, repeated procedures are recommended. For the face, the V or F tip is used starting at level 2.0 or 2.5. I usually overlap 20–30% of the shots using at least 300 REPs (start at level 1.0, additional 300 REPs when the neck is included). After performing 2 initial uniform passes, I focus on the lower face to mid-face to the temple along the anti-sagging vector to improve the jaw line. Rather than having a fixed alignment, I tend to focus on the lower face or areas with severely low elasticity/fine wrinkles, adjusting the level depending on how well the patient can tolerate the pain. The endpoint is when there is slight redness or heat after the procedure. For sensitive areas such as around the eyes, I start with a

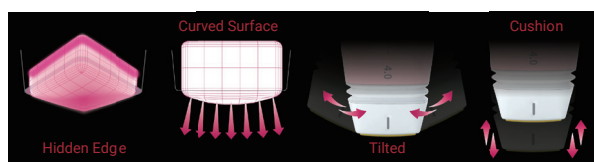


Fig. 2. VOLNEWMER tip improvements



Fig. 3. Before and after procedure on the lower face

tip level of 1.5–2.0 and perform at least 200 REPs in total (Fig. 3, 4).

Although dependent on the progress and extent of aging, when sagging of the eyes such as that in the jowl is visible, I combine with HIFU (i.e., shrink universe) to treat all layers of the skin, and I use skin booters or fillers or botulinum toxin procedures wherever necessary. The procedure takes place from the shallow layer to the deep layer; HIFU is first irradiated, followed by VOLNEWMER, and is finished with Botox or skin booster.

CONCLUSION

Monopolar RF devices are verified effective devices without recovery times for anti-aging procedures. VOLNEWMER has all the advantages of monopolar RF devices with added improvements such as well-crafted intuitive UI and safety applied to the tip. The novel water cooling method is a valuable addition. Fast, safe procedures are now possible, and patients have high satisfaction with a reasonable procedural cost, which is the advantage of a domestic product.

Furthermore, this allows for periodic long-term treatment plans. A well-weaved marketing structure can be used based on the device called “shrink” from Classys on top of the advantage of the monopolar RF device. Therefore, we predict that a synergistic effect will be seen in terms of promotion and anti-aging procedures in combination with HIFU. Improvements in VOLNEWMER and new findings are believed to be catalysts in the development of non-invasive aesthetic devices including monopolar RF devices. I hope there will be lots of feedback, as it is widely used as an effective treatment tool.



Fig. 4. Before and after procedure on the eye area

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Q&A TAKING QUESTIONS

If you have questions while reading the Journal of Association of Korean Dermatologists, send an e-mail to the address below and you can find the response in the next volume of the journal. Questions will be randomly selected for a small prize.

*Questions will be posted anonymously.

*Not all questions may be selected.

*Send to: Committee of the Journal of Association of Korean Dermatologists E-mail. admin@akd.or.kr

Fig. 4



The present and the future of aesthetics in Japan

Story behind the interest in Korean RF devices



Author/Hara Kaya (Director at Yaes Plastic Surgery/Dermatology Clinic)

The present and the future of aesthetics in Japan Story behind the interest in Korean RF devices

Author/Hara Kaya (Director at Yaes Plastic Surgery/Dermatology Clinic) | Japan

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Director Hara Kaya is a specialist at a plastic surgery in Tokyo. She lectures at academic conferences and symposiums, and started researching non-invasive procedures after discovering a huge potential while learning laser procedures at Tokyo Women's Medical School. Dr. Hara writes about the latest trends in aesthetics in Japan as a trusted source with a passion for aesthetics in general while pursuing research.

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The cold winter has passed, and the warm sunlight is shining on us.

As I am writing this, it's getting increasingly warmer in Tokyo, and even wearing a light shirt can make you sweat. I feel hopeful for tomorrow under the bright sunlight. Although many unstable factors remain, such as COVID-19 and the Russia–Ukraine conflict, I hope that everything will work itself out in the end.

Device introduction comes with many concerns

My latest interest is to buy a new device for my clinic. I assume many clinic owners periodically have similar concerns. For small clinics, purchasing a medical device is an important matter that can affect the management of the clinic, and careful review is required in every aspect. For example, I must consider combinations of the procedures with devices that I currently own, needs of patients, severity of pain, recovery periods, size of devices, purchasing costs, maintenance costs, procedure times, procedure costs, effects of one procedure, availability in nearby clinics, use in large general hospitals, possibilities of differentiation according to procedure methods, responses in case of malfunction, and frequency of malfunctioning.

If devices are properly operated during procedures, the initial and maintenance costs may not be a large concern. However, if the price decreases due to price competition, small clinics cannot compete against large franchises or hospitals with huge capital. Therefore, we must consider whether a clear differentiating point exists other than the price itself. Furthermore, as my clinic does not advertise, my clients include only existing patients. Ignoring their needs leads to a marked drop in device usability.

Decreasing popularity of HIFU due to pain

Patients who visit my clinic do not like procedures that involve pain. Even if less effective, they prefer to have small procedures that are not painful. Patients are often

even reluctant to try HIFU, the most common of all procedures for lifting the skin. For IPL and long-pulsed lasers, patients regularly come for procedures without special explanations or consultations. However, in comparison, usability is rather low. As I explain in great detail, I think the patients who visit my clinic are aware of procedures for sagging skin. However, they care more about lowering the pain experienced than increasing the effect.

Considering this situation, I am looking for a device with a low degree of pain. While THERMAGE lifts sagging skin, and I am fully aware of the effectiveness, the cost of introduction or the time limit for the tip created barriers. I was looking for a device that is effective but relatively economical without excessive maintenance cost. Such a device was difficult to find since lifting/tightening devices do not show effects immediately after the procedure, and determination of effectiveness is tricky. In the meantime, several Korean manufacturers recently released new RF devices, and I am currently testing some of them.

Korean RF devices may expand in market share

One of the most interesting devices among those demonstrated was an RF device called VOLNEWMER by Classys. Not yet formally released in the Korean market, I heard it was initially released in the Japanese market. It may be sold under a different name when sales start in Korea.

I was impressed with the design of the rounded tip and the head part of the handpiece, as it was designed to move in close contact with the skin's surface. The rounded curved tip allows uniform irradiation, reduces pain, and significantly reduces the stress on the part of the administrator. No time limit exists for the procedure, and the overall cost is low since it uses water cooling rather than gas cooling. The procedure's effect is also great. I would like to introduce a case by director Koromohara Kumiko, one of the doctors that introduced effect is clearly VOLNEWMER in Japan and who uses the device in the clinic. She gladly provided the



Fig. 1. Before procedure (left), 1 month after VOLNEWMER procedure (right). 4cm2/200 shots/level 4.5~3.5 on the left cheek, 3cm2/200 shots/level 4.5~3.5 on the right cheek, and 3cm2/200 shots/level 2.0 on the neck were administered. Changes were seen in the cheeks and procedure was performed on neck lines. Provided by Koromohara Kumiko.



Fig. 2. 3D picture before and after VOLNEWMER procedure. When the movement of the skin is indicated in arrows, it can be seen that the skin has moved towards the center of the cheeks. Provided by Koromohara Kumiko.

procedure photographs which became the reason for my interest in the device.

The effect is clearly seen thanks to the 3D camera (<Fig. 1, 2>). When I used the VOLNEWMER with the same output as that in <Fig. 1>, the level of pain was within the allowable range. The devices at my clinic do not involve severe pain based on the gate control theory. However, if VOLNEWMER can show marked results, I felt as though I must try it. Many RF devices are sold by a variety of manufacturers. However, few devices have clear tightening effects by heating the fiber tissues

through impedance rather than simple heating. The monopolar RF device market was long monopolized by THERMAGE, but Korean devices may soon take up the market share in Japanese monopolar RF treatment, as they did for the current HIFU market. I hope that more people can take advantage of the new lifting/tightening procedures available with the benefits of this technology.

Translation/Soo Bin Yim (Continued on the next volume)



Fig. 3. VOLNEWMER.
Provided by Classys Japan.

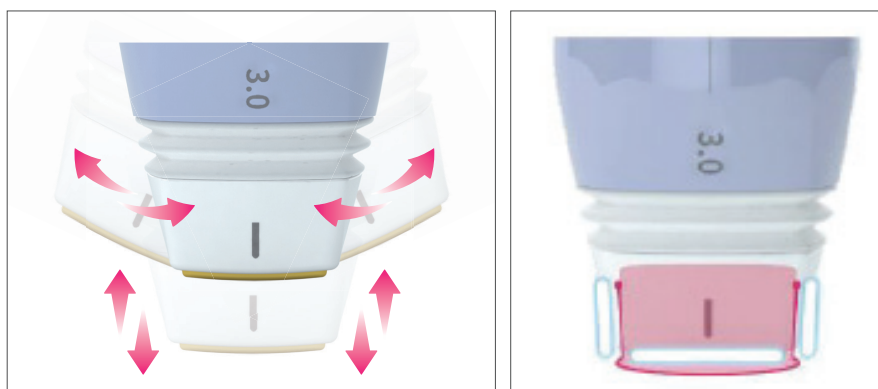


Fig. 4. VOLNEWMER handpiece. Effective procedure is possible as the head tilts along the skin's surface for close contact (left). Also, skin is continuously cooled using the contact cooling water system (right). Provided by Classys Japan.



The present and the future of aesthetics in Japan

Continuously growing RF markets and devices to watch



Author/Hara Kaya (Director at Yaes Plastic Surgery/Dermatology Clinic)

The present and the future of aesthetics in Japan Continuously growing RF markets and devices to watch

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How are you all doing? In Japan, there is a long period of holidays called the “Golden Week” from the end of April to early May. This is the peak time for most aesthetic clinics, as many patients undergo procedures that require recovery time during this period. However, our clinic closed during this period, and I went on a family trip to England where the coronation of Prince Charles was occurring. The streets were decorated with the national flag and paper crowns, stirring up a festive mood by giving out chocolates. After the England trip, I participated in the 111th Aesthetics Conference in Japan held in Osaka. I did not have the opportunity to listen to other doctors, as I was scheduled to give 2 presentations during the sponsor seminar and 1 presentation at the symposium. This conference certainly showed off the wide network of Chairperson Ikeda Yoshio.

A perfect implementation of the catchphrase “Aesthetics creating a beautiful future, with lessons from colleagues” the contribution by young doctors under the age of 40 was most notable for me. The SNS sessions were live-streamed, and one session was posted on Youtube or Instagram for the public to see. Medical service providers other than doctors were present, and SNS influencers were requested to pose for photos like idol groups. This conference made good use of the SNS, as photos were frequently posted as stories and on the feed of Instagram account (@JSASJAPAN). Those who are interested can follow this account.

Growing high RF markets

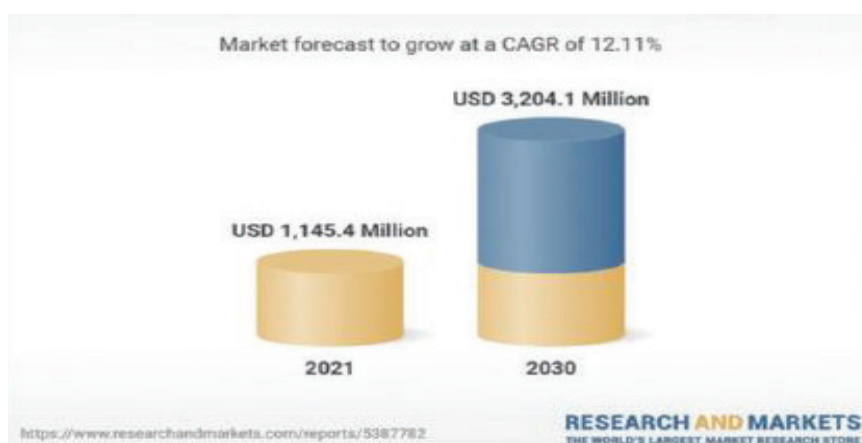
In this volume, I would like to introduce the monopolar high-frequency device VOLNEWMER from Classys, as good results have been obtained for over the past six months. First, the need for non-invasive procedures is on the rise globally. Similarly, in Japan, the data from a 2021 survey show that non-invasive procedures accounted for 88.5% of all procedures in Japan, which is an 84.3% increase compared with that



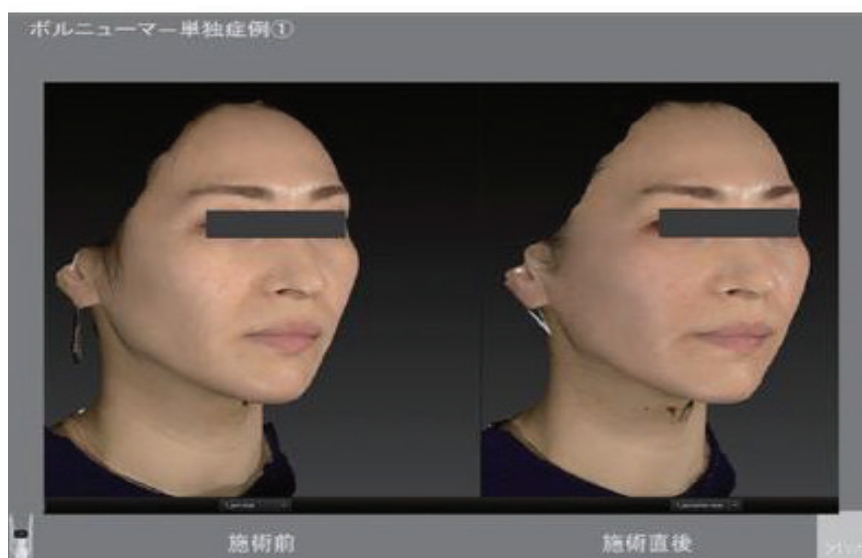
Model of the royal crown on top of a bus stop in England

of the previous year. Among non-invasive procedures, facial anti-aging procedures accounted for 33.7%, showing an increase from that of the previous year, 29.1%. Now that COVID-19 restrictions are lifted, and people are no longer wearing masks, treatments that are highly effective with no recovery time are in demand. Based on this trend, the RF markets are expected to grow in the future. I often see patients who never go through with the treatments. For example, they may believe that face-lifting is good for sagging skin, but a certain number of them think, "I don't want surgery; lifting injections are scary." These are the potential customers for future laser and RF markets. Specifically, patients who have been repeatedly

receiving procedures such as peeling or IPL can definitely see effects with less pain once prices go down, and they are likely to receive treatments with fewer side effects. As such, demand for the RF device is expected to rise. Existing monopolar RF treatment devices were effective but involved significant pain. However, new devices from different manufacturers take this into account. I feel that VOLNEWMER was manufactured with considerations for safety and complications in this regard. I felt that safety was considered important in the development based on the head that irradiates with close contact, the design with a contact surface for preventing burns, the lightly curved surface area, the water-based contact cooling,



Global radiofrequency-based aesthetic devices market.



Before (left), after VOLNEWMER procedure (right) alone. Provided by Hara Kaya

etc. Because burns are not likely based on the structure, the treatment can be more aggressive, and nurses can safely administer the procedure.

Safety is important, but how about effectiveness? I examined before and after procedure results using VECTRA. Clear effects were identified for nasolabial folds, marionette lines, and dents under the cheekbones, along with the appearance immediately after the procedure, which is directly connected to patient satisfaction. The effect was retained for nasolabial folds, marionette lines, and dents under the cheekbones even one month following the procedure after temporary changes disappeared.

Moreover, many patients said that their skin textures improved. Their responses included “I got rid of dullness,” “skin texture became softer,” and “make-up stays on better.” When the skin is examined under VECTRA, skin texture and melasma have improved. I'm glad that patients repeatedly request this

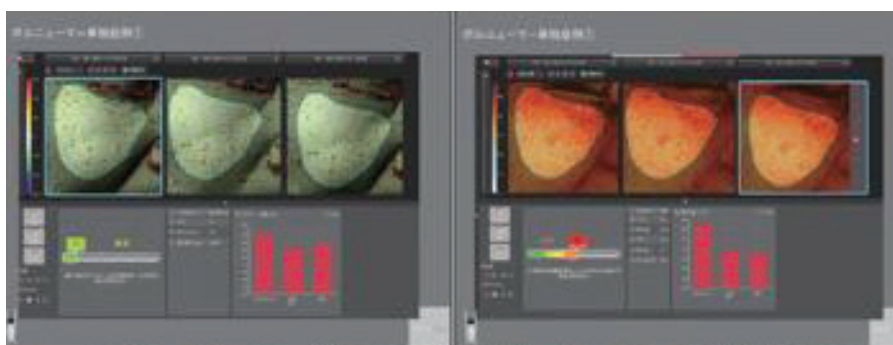
procedure due to the painless procedure and lack of recovery time.

VOLNEWMER + ULTRAFORMER III

VOLNEWMER alone is good, but the combination of VOLNEWMER and the HIFU device from Classys called ULTRAFORMER III, also known as “VOLFORMER,” is administered for maximized effect with no recovery time. I believe that many have combined HIFU and RF until now. A well-known problem associated with such procedures is pain. In our clinic, we perform RF first for combination procedures because of the severe pain, but since VOLNEWMER is equipped with appropriate water-based contact cooling, we initially irradiate with ULTRAFORMER III to the deep layer of the skin. VOLNEWMER is then applied, and few patients complain of pain. Combination procedures can



Change in volume (left) after VOLNEWMER procedure alone under VECTRA and vector of changes (right). Provided by Hara Kaya



Skin texture before VOLNEWMER procedure, 1 month after procedure, and 2 months after procedure and melasma (right) changes. Provided by Hara Kaya

multiply the lifting and tightening effects of HIFU, and significant effects have been seen in many patients.

The effect of 1 VOLFORMER treatment on a woman in her 40s with a voluptuous face and small bone frame was examined over time (<Fig. 1-5>). Immediately after the procedure, swelling due to proper heat application is apparent. We can observe that the black spot, which can measure changes, has risen slightly. In addition, when comparing 1 month after the procedure with 3 months after the procedure, the skin became firmer at 3 months, making the face appear more three-dimensional.

In our clinic, the target patients for the VOLNEWMER procedure alone are underweight women in their

30s and 40s who start to feel concerned about their marionette lines and nasolabial folds. They tend to have high satisfaction with a single procedure.

Elderly patients who are thin and have less fat with sagging skin tend to receive the VOLNEWMER procedure after we explain to them that device alone can give them satisfactory results. Often, the procedure is combined with ECM formulations. In that case, ECM formulations are applied first. In other cases, the VOLFORMER procedure is performed mostly as the effects are clear, and patients have a high satisfaction rate, leading to repeat visits. Although the number of shots becomes the approximate reference when performing the procedure, I believe



Fig. 1. From the left, before VOLFORMER (VOLNEWMER + ULTRAFORMER III) procedure, immediately after procedure, 1 month after procedure, 3 months after procedure. Provided by Hara Kaya



Fig. 2. Before and immediately after VOLFORMER procedure (left), change in facial volume (center), vector of changes (right). Provided by Hara Kaya

that it is necessary to check the temperature by touching the skin to determine the endpoint for an effective procedure since temperature increases may vary depending on moisture content and the fat layer of the skin. Almost all patients feel improvements in skin texture after the VOLFORMER procedure and feel low levels of pain; therefore, it is believed to be a good fit for repeated procedures. Rather than combining it with HIFU each time, the VOLNEWMER procedure

alone might be effective in between procedures.

In the future, I plan to perform more cases focusing on the differences in effects depending on the increase or decrease in the number of shots, procedure frequency, and duration of effects; furthermore, I plan to adjust patient body weight, which is a permanent issue for procedures that improve sagging.

(Continued on the next volume)

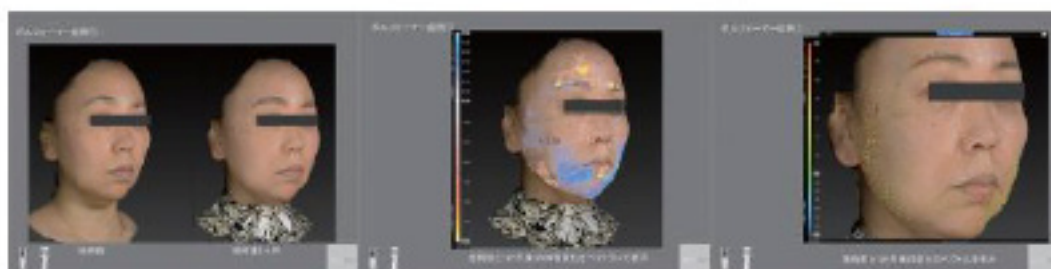


Fig. 3. Before VOLFORMER procedure and 1 month after procedure (left). Change in facial volume (center). Vector of change (right). Provided by Hara Kaya



Fig. 4. Before VOLFORMER procedure and 3 months after the procedure (left). Change in facial volume (center). Vector of change (right). Provided by Hara Kaya

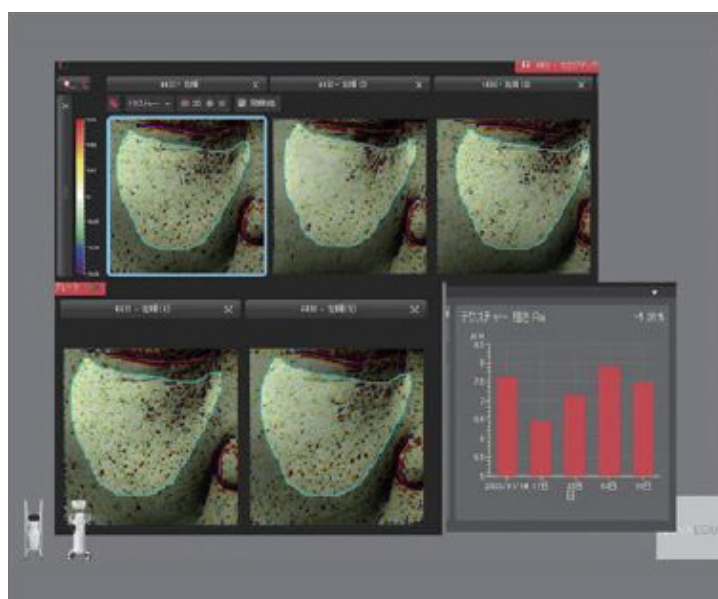


Fig. 5. Change in skin texture after VOLFORMER procedure. From left to right: day of procedure, 17 days after, 35 days after, 53 days after, 91 days after the procedure. Provided by Hara Kaya

Objective Review of Monopolar RF Device: Continuous Water Cooling and Single RF Pulse I

Author Sang Hyeok Park (Director at ES Clinic)

Objective Review of Monopolar RF Device: Continuous Water Cooling and Single RF Pulse I

Author Sang Hyeok Park (Director at ES Clinic) | South Korea

Director Sang Hyeok Park at Sinchon ES clinic, who is also the vice chairperson of KOAT, is interested in various non-invasive aesthetic procedures. He is currently focusing on monopolar RF with continuous water cooling method and single RF pulse. The key point is that the temperature can be raised with heat expansion effect while greatly reducing side effects, as there is no heat loss from pulse division. We introduce the story of RF procedures by Dr. Park in 3 series.

Aging skin and treatment

Skin aging can be classified into endogenous aging, which naturally occurs with age, and extrinsic aging, which is caused by external factors including photoaging by ultraviolet (UV) rays, i.e. solar elastic fibrosis. When persistently exposed to UV rays, collagen synthesis decreases, and skin loses elasticity as the dermis is replaced by elastic fiber. This aging process leads to wrinkles, laxity, pore dilation, flushing, and dyschromia. Traditionally, these outcomes can be treated with rhytidectomy, blepharoplasty, and brow lifts, or by promoting collagen synthesis and removing damaged tissues using non-surgical methods such as chemical peeling, microdermabrasion, and laser peeling.

However, surgical improvements require recovery time. The ablative rejuvenation that damages the epidermis requires a lengthy recovery period and has the risk of complications such as infections, scarring, skin redness, and pigmentation. Thus, non-ablative rejuvenation is currently preferred.

The collagen absorption curve only exists at $\geq 3 \mu\text{m}$, peaking at $6\sim 7 \mu\text{m}$ (<Fig. 1>). The application of direct heat at this wavelength would be ideal, but free

electron lasers using this wavelength have not yet been commercialized. Thus, rejuvenation involves a laser that has an absorption coefficient for water or blood vessels, or induces collagen remodeling by delivering heat to collagen indirectly using a device that delivers heat to water.

This methods include lasers such as the 1450-nm diode laser that uses mid-infrared, the 1320-nm/1064-nm Nd:YAG laser that targets water, a laser that targets blood vessels such as the PDL to indirectly deliver heat to collagen, or indirect delivery of heat to collagen with a device that delivers heat to water using a high radiofrequency (RF). Here, I would like to discuss the monopolar RF devices that target water.

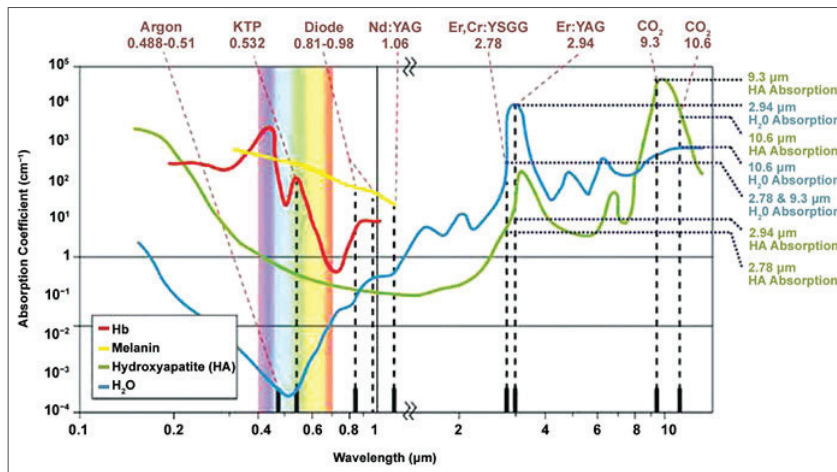


Fig. 1. Correlation of material absorption coefficient and laser wavelength; both axes are exponential1.
 Courtesy of Daniel Fried/University of California, San Francisco.
 (http://www.photonics.com/Articles/High-Precision_Laser_Therapy_Transforms_Dentistry/a63797)

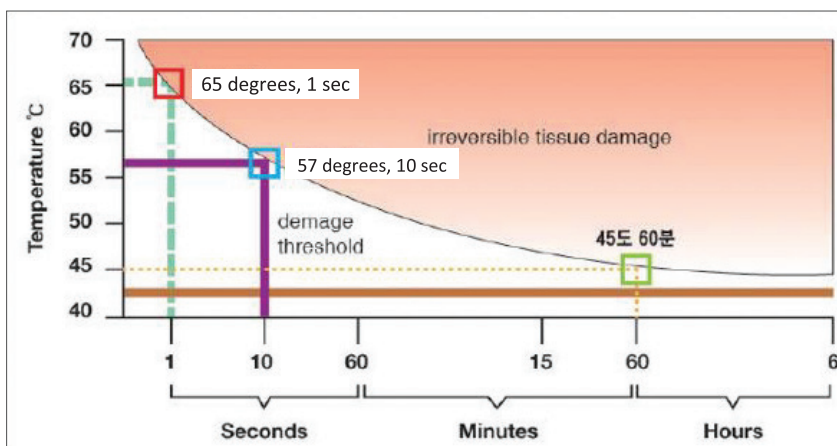


Fig. 2. Relationship between time and temperature in tissue damage.

Arrhenius Equation

When a laser meets the chromophore or the high frequency meets resistance, heat is generated, and depending on its degree, processes of coagulation, vaporization, carbonization, and melting occur. Among them, the Arrhenius equation is applied at a temperature of $\leq 100^\circ\text{C}$, at which vaporization does not occur.

Temperature and time are involved in tissue degeneration. For example, the same level of tissue degeneration occurs at 65°C in 1 s, 57°C in 10 s, and 45°C in 60 min. Thus, no absolute temperature

for tissue degeneration exists, but various parameters consider temperature and time (<Figure 2>).

The effect is shown once the threshold for effect has been reached, and side effects occur past the survival threshold. If high energy can be used in the range permitted by the patient's pain and the cooling ability of the selected device, the same effect can be obtained using a lower number of shots.

Structural changes occur when collagen is stimulated at $42\sim 45^\circ\text{C}$, and heat-induced shrinkage occurs while three dimensional (3D) covalent bonds break, up to 1/3 of the original size. Partially denatured

42~45℃	Beginning of hyperthermia, conformational changes, and shrinkage of collagen
50℃	Reduction of enzymatic activity
60℃	Denaturation of proteins, coagulation of collagens, membrane permeabilisation
100℃	Tissue drying and formation of vacuoles
> 100℃	Beginning of vaporization and tissue carbonisation
300~1000℃	Thermoablation of tissue, photoablation and disruption

Table 1. Changes in skin tissues by temperature.

collagen sends triggers for synthesizing new collagen or acts as scaffolding. However, past 60 °C, the 3D structure becomes a two-dimensional (2D) structure due to denaturation and coagulation, so the cell is completely destroyed before being regenerated (<Table 1>). At this temperature, the epidermis is damaged, and epidermal sparing through cooling is required. The most appropriate temperature for the dermis for collagen regeneration through coagulation can be estimated as 55~68 °C based on various literature sources reporting that 63% of collagen is denatured with 1-s exposure at 65 °C, that subcutaneous temperature of 65~68 °C and epidermal temperature of 38~42 °C are required, and that collagen synthesis reaches its peak when heat is applied for 3 s at 67 °C on the dermis. These reports require further research. However, to allow high temperatures, adequate epidermal cooling must take place to avoid burning of the epidermis. Further, pain induced by high energy must be controlled.

Epidermal cooling

When targeting the collagen in the dermis using a monopolar RF device, the energy does not go directly to the dermis but goes through the epidermis. To prevent side effects such as burns that may occur when the temperature rises too high and to prevent the pain and edema that accompanies the procedure, cooling the epidermis during high RF procedure increases resistance in the epidermis, and the heat energy reaching the dermis increases.

Thus, epidermal cooling is an important part of the monopolar RF procedure. Existing THERMAGE/OLIGO/10THERMA uses a contact cooling method through intermittent cooling agent spraying. Spraying a -26 °C cooling agent such as HFC-134a on the skin has an excellent effect and is not affected by variables such as reverse thermal diffusion caused by long-time contact with the dermis, which increases in temperature during the procedure, for a period of time around 1,500 ms.

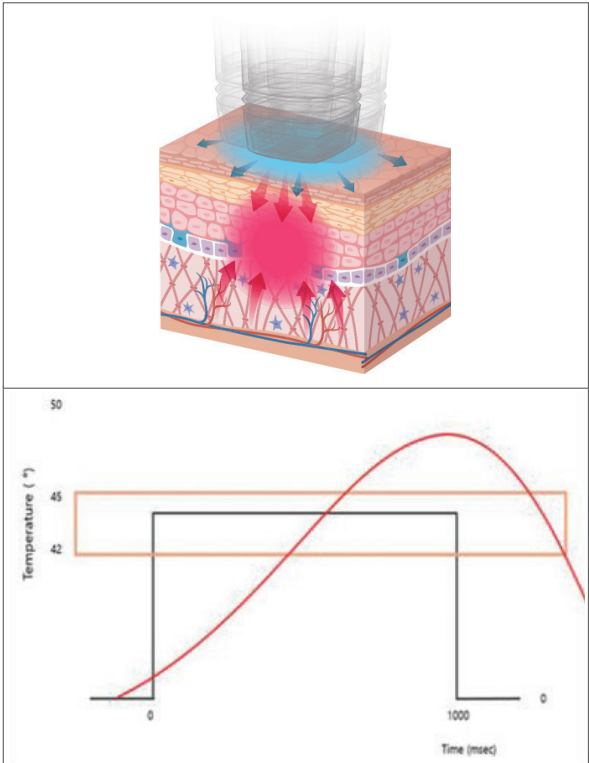


Fig. 4. 1000ms single RF pulse. Provided by Sang Hyeok Park.

In addition, an advantageous predictable cooling effect can be maintained through regular cryogen injection. However, as the cooling time increases, the risk of frostbite and pigmentation increases, so spraying time should be limited to <100 ms. In addition, since the TRT of the epidermis, which is about 100- μ m thick, is about 10 ms, a limitation is introduced, as it must be cooled by spraying for >10 ms to achieve a cooling effect by thermal diffusion. Taking these limitations into consideration, the existing monopolar RF devices were designed to raise dermis temperature only to >60 °C while maintaining the epidermal temperature at 38~42 °C by irradiating energy in 5~6 pulses for 200 ms while performing contact cooling 4~7 times as pre/parallel/post. However, 10THERMA was designed with automatic control so that the cooling agent spraying time is 15~45 ms depending on the energy level. In this case, the temperature drops when the pulse is

delayed at 200 ms (<Figure 3>). We also examined the effects of the novel energy delivery method of a 1000-ms single RF pulse and the meaning of continuous cooling using chilled water. A device with a new method of cooling water circulation was released, rather than the previous method of spraying a cooling agent. It enabled continuous contact cooling over 1000 ms by circulating cooling water at a relatively high temperature of 12~20 °C while considering the limitation of short-duration contact cooling due to side effects associated with a very low temperature of -26 °C for contact cooling with a cooling agent. Since the epidermis could be protected with contact cooling for 1000 ms, a 1000-ms single RF pulse could be irradiated without dividing the pulse into 5~6 200-ms instances.

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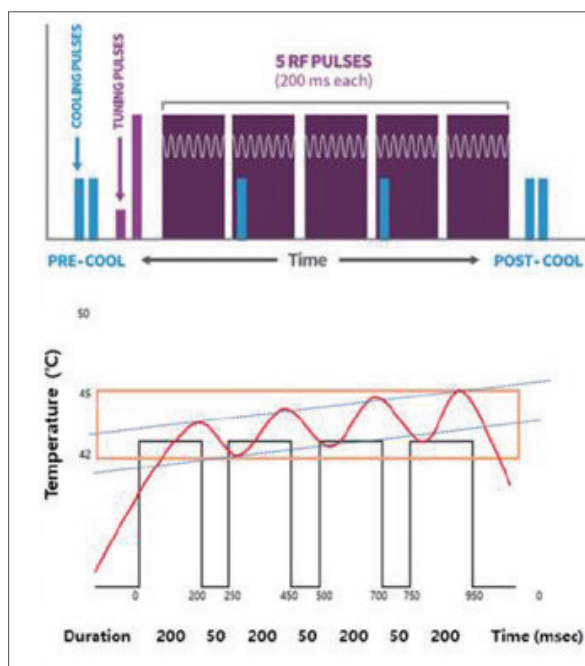




Fig. 3. RF irradiated by 200ms unit. Provided by Sang Hyeok Park.



Objective Review of Monopolar Radio Frequency Device: Continuous Water Cooling and Single Radio Frequency Pulse II



Author: Sang hyeok Park (Director, ES Clinic)

Objective Review of Monopolar Radio Frequency Device: Continuous Water Cooling and Single Radio Frequency Pulse II

Author: Sang Hyeok Park (Director, ES Clinic) | South Korea

Director Sang hyeok Park of Shinchon ES Clinic, Vice President of the Korean Academy of Obesity & Aesthetic Treatment, is enthusiastic about a variety of non-invasive cosmetic treatments. His current focus is on a monopolar radio frequency (RF) with continuous water-cooling method and single RF pulse. With this method the temperature can easily be increased while greatly reducing side effects. This is achieved through the accumulating thermal diffusion effect as there is no heat loss caused by pulse division. We are presenting Director Sang hyeok Park's RF treatment story over three articles.

Following the last article, I would like to discuss the meaning of continuous cooling using chilled water and the method of delivering energy with a single RF pulse at 1,000 ms.

The prolonged contact cooling of 1,000 ms has its limitations as well. First, as the cooling is performed by contact over a long time, it should be considered that parts of the dermal area shallower than 1 mm, or the vicinity of the papillary dermis, may be unnecessarily cooled depending on the thermal diffusion. Areas deeper than 1 mm are not cooled even with contact lasting up to 1,000 ms.

Second, in clinical practice, the temperature is raised to 38-42°C for the epidermis and to 60°C or more for the dermis in a state of contact with the skin between 1,000 and 1,500 ms in which one shot is irradiated. At this time, the contact surface temperature inversely rises due to reverse thermal diffusion from the skin in which the temperature has risen. In such a case, the contact surface temperature can be rapidly lowered by using a newly irradiated refrigerant in conjunction with the existing method of cooling the epidermis with a sprayed refrigerant. It allows for the procedure to be performed with a consistent cooling effect with each shot. On the other hand, the cooling method

of circulating the chilled water should be performed considering that the contact surface temperature decreases gradually with the circulation of the chilled water immediately following irradiation. If the shot intervals are maintained for a long time regardless of the procedure duration, the next shot may be performed by predicting the cooling temperature after the contact surface temperature is sufficiently lowered. However, when the shots are performed while moving the tip with short intervals, as in actual clinical practice, it can be inferred that contact cooling is performed with a significantly higher contact surface temperature than the set chilled water temperature. As such, it should be noted that the actual set chilled water temperature and contact surface temperature may vary depending on the physician's shot interval.

Continuous Water Cooling with a Single RF Pulse

Figure 1 illustrates temperature changes according to the contact duration per depth in a contact cooling experiment using a sapphire tip at -10°C. Curve 3 shows that the temperature of the epidermal basal layer dropped rapidly by at least 15°C after a brief contact lasting 50 ms or less and that the temperature remained low by 30°C after longer contacts of 1,000 ms. Significant temperature changes did not occur for

contacts of 1,000 ms for the dermis at the depths of 1 mm (curve 4) or 2 mm (curve 5). The temperature of the dermis at different depths and contact durations during the contact cooling experiment using a sapphire tip at -10°C is displayed in Figure 2. ① shows that there is no cooling effect on the skin at a depth of 0.1 mm or less with contact cooling of 10 ms. The area shallower than the papillary dermis at a depth of 0.3 mm was cooled with contact cooling of 50 ms (②) and 100 ms (③).

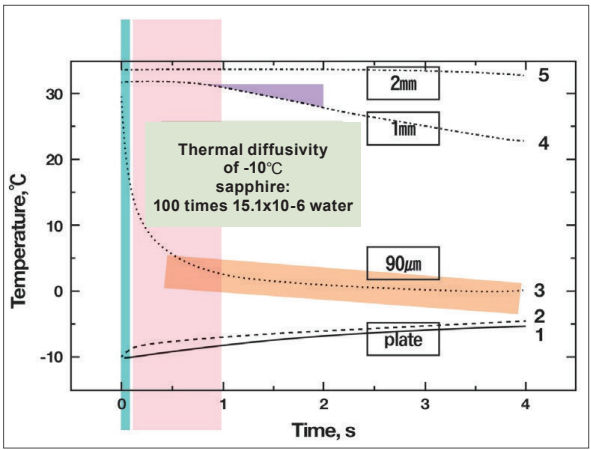


Fig. 1. Contact cooling experiment using a sapphire tip

Coolant	Density (kg m ⁻³)	Specific heat (J kg ⁻¹ °C ⁻¹)	Thermal conductivity (W m ⁻¹ °C ⁻¹)	Thermal diffusivity (m ² s ⁻¹)
Chilled water	1000	4180	0.6	1.43×10 ⁻⁷
Gel	1000	3200	0.5	1.56×10 ⁻⁷
Ice	917	1930	2.2	1.24×10 ⁻⁶
PMMA	1200	1500	0.2	1.11×10 ⁻⁷
Melted quartz	2650	890	1.36	5.77×10 ⁻⁷
Sapphire	4000	760	46	15.1×10 ⁻⁶ <small>100 times</small>
Copper	8960	385	400	1.16×10 ⁻⁴
Diamond	3400	331.2	2300	2.04×10 ⁻³

Thermal parameters of the plate materials.

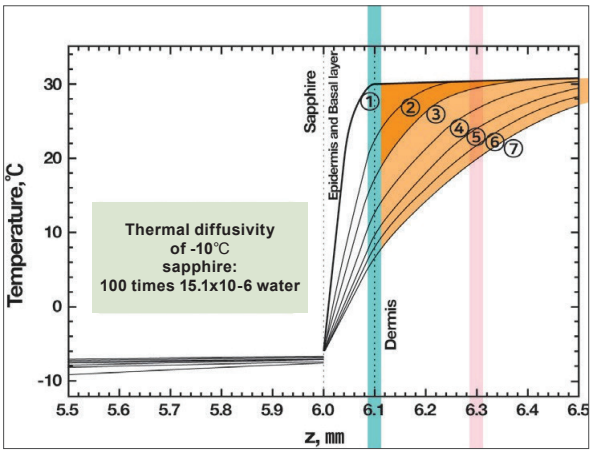


Fig. 2. Temperature per depth by contact duration in contact cooling experiment using a sapphire tip

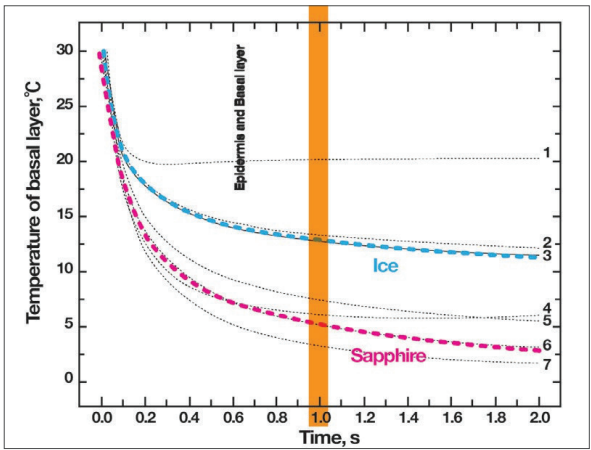


Fig. 3. Comparison of contact cooling between an ice tip and a sapphire tip

The temperature of the epidermal region was sufficiently lowered without cooling the deeper area. However, when contact cooling is performed over an extended time of 500 ms or longer (7), while there was no cooling of the dermis deeper than 1 mm, as shown in Figure 1, undesired cooling occurred in shallower areas of 1 mm or less, i.e., shallow dermis around the papillary dermis.

The above experiments were conducted assuming a contact temperature of -10°C , and there was a limitation that the sapphire used in the experiment has a thermal diffusivity of approximately 100 times higher than that of water. Subsequently, it was aimed to reduce unnecessary cooling near the papillary dermal layer of 1 mm or less and obtain more precise experimental results by using water with 1/100 thermal diffusivity and a cooling device with a cooling temperature set high between 12 and 20°C .

The comparison of contact cooling using a sapphire tip at -8°C and an ice tip with a thermal diffusivity 100 times lower than the sapphire tip is displayed in Figure 3. The basal layer temperature according to contact duration was examined, and then the difference in cooling efficiency was analyzed. With contact cooling of 1,000 ms, ice at -8°C induced a temperature change of -17°C from 30°C to 13°C , while sapphire, which has a 100-fold higher thermal diffusivity, at -8°C induced a temperature change of -25°C from 30°C to 5°C . Figure 4 compares contact cooling using a sapphire tip at 5°C and a chilled water tip with a 1/100 thermal diffusivity of a sapphire tip. Again, the basal layer temperature according to contact duration was examined, and the difference in cooling efficiency was analyzed. After contact cooling of 1,000 ms, Figure 6. Temperature changes in the basal layer and papillary dermis by contact cooling method chilled water of 5°C induced a temperature change of -11°C from 30°C to 19°C , and sapphire, with 100-fold thermal diffusivity compared to water, at 5°C induced a temperature change of -17°C from 30°C to 13°C . In this experiment, contact cooling using chilled water at 12°C and 20°C , adopted by VOLNEWMER, decreased epidermal temperature by only 8°C and 5°C , respectively (Figure 5).

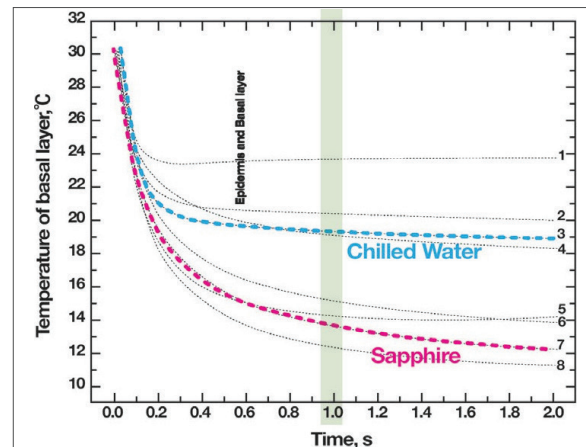


Fig. 4 Comparison of contact cooling between a chilled water tip and a sapphire tip

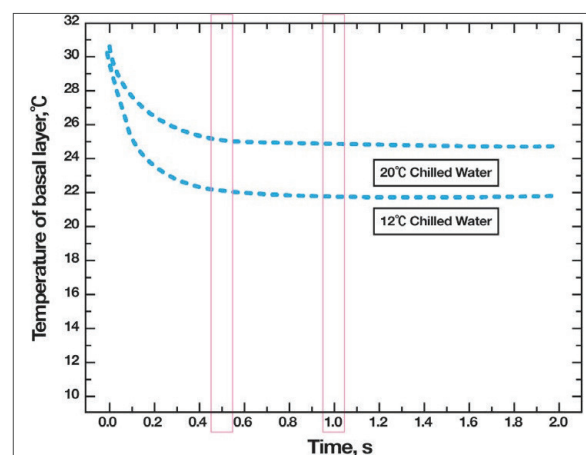


Fig. 5. Comparison of contact cooling using chilled water tips at 20°C and 12°C

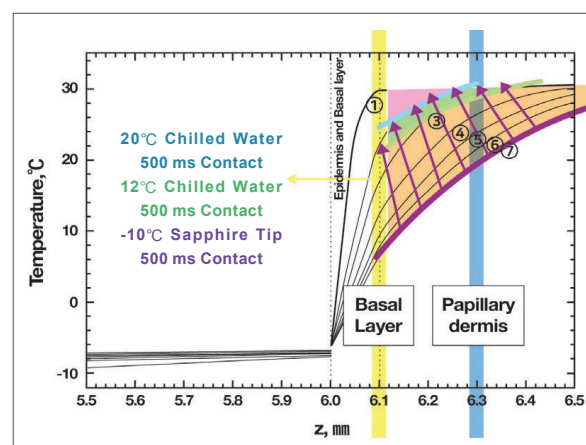


Fig. 6 . Temperature changes in the basal layer and papillary dermis by contact cooling method

In the 500 ms contact cooling experiment using sapphire with a thermal diffusivity 100-fold higher than water at a temperature of -10°C , unnecessary cooling of shallow dermal tissues around the papillary dermis was observed. VOLNEWMER used a relatively higher temperature between 12 and 20°C to compensate for this, selecting chilled water with a thermal diffusivity of $1/100$ of sapphire as the medium. Unnecessary cooling was significantly reduced when the degree of unnecessary cooling around the papillary dermis after 500 ms contact cooling was inferred, assuming the chilled water temperatures of 12°C and 20°C . These results highlight the advantages of irradiating high energy with a single RF pulse. That is, it can be inferred that utilizing chilled water for contact cooling, which has a $1/100$ thermal diffusivity of sapphire, at a higher temperature range of 12 to 20°C can sufficiently cool the epidermal area, which constitutes the basal layer, and minimize the unnecessary cooling in the papillary dermal area of 1 mm or less that occurred during contact cooling using a -10°C sapphire tip. The temperature changes after 500 ms contact cooling were sufficiently inferred, as the degrees of cooling of the dermal area did not significantly differ between 500 ms and 1,000 ms contact coolings, and neither showed a cooling effect in areas deeper than 1 mm.

(To be continued in the next issue)

Objective Review of Monopolar Radio Frequency
Device: Continuous Water Cooling and Single
Radio Frequency Pulse III

Author: Sang Hyeok Park (Director, ES Clinic)

Objective Review of Monopolar Radio Frequency Device: Continuous Water Cooling and Single Radio Frequency Pulse III

Author: Sang Hyeok Park (Director, ES Clinic) | South Korea

Director Sang Hyeok Park of Shinchon ES Clinic, Vice President of the Korean Academy of Obesity & Aesthetic Treatment, is enthusiastic about a variety of non-invasive cosmetic treatments. His current focus is on a monopolar radio frequency (RF) with continuous water cooling method and single RF pulse. With this method the temperature can easily be increased while greatly reducing side effects. This is achieved through the accumulating thermal diffusion effect as there is no heat loss caused by pulse division. We are presenting Director Sang Hyeok Park's RF treatment story over three articles.

There are two additional issues to consider when using circulating chilled water. The first is reverse thermal diffusion resulting from extended contact cooling, and the second is a surface cooling delay due to a short pulse interval. Due to these two phenomena, the cooling temperature of the epidermis becomes significantly higher than the set chilled water temperature during the actual procedure.

To assess the degree of epidermal protection, the author measures the epidermal temperature immediately after the single radio frequency (RF) pulse using an infrared thermometer, keeping the safe temperature range (38–42°C) in mind, with a finger on the opposite side. At this time, the skin surface and the temperature change of the contact cooling surface are measured and assessed (Figure 1).

The temperature of the dermis can exceed 60°C. The contact duration is 1,000 ms for a single shot using VOLNEWMER, during which the contact surface temperature rises in reverse due to reverse thermal diffusion on the skin with an elevated temperature. In the case of an instantaneous cooling method using sprayed refrigerant, the epidermal cooling is uniformly maintained by the sprayed refrigerant. It does not affect the procedure even if the surface temperature

rises due to reverse thermal diffusion. However, in the case of slow cooling using circulating chilled water, the temperature of the contact surface, which has increased >30°C due to reverse thermal diffusion immediately after energy irradiation, gradually decreases as the chilled water circulates.



Fig. 1.1 Skin temperature measurement according to each single RF pulse procedure using an infrared thermometer

More than a few seconds are required for the temperature to drop to $\leq 20^{\circ}\text{C}$. If the procedure is performed while maintaining long shot intervals, regardless of the total treatment time, the next shot can be performed with a predictable cooling effect after the contact surface temperature is sufficiently lowered. However, it can be inferred that cooling of the contact temperature will be performed at a significantly higher temperature than the set chilled water temperature while moving the tip with shot intervals of 0.4 or 0.6 seconds. It should be noted that the set chilled water temperature and contact surface temperature range at high levels depending on the treatment shot interval. The shorter the shot interval, the higher the contact surface temperature can be. On the one hand, unnecessary dermal cooling due to prolonged cooling time may be judged to be almost insignificant. On the other hand, the contact surface temperature may be significantly higher than the device setting. It is crucial to consider the above points and not overestimate the cooling effect. Nevertheless, the author's experience is that the procedure could be performed (over 100 cases) without side effects such as burns even when the maximum output level of 5.0 (115W) in 0.4 s repeat mode was used, and the patient's pain was controlled entirely with sedation. Even today, the procedure generally begins at level 4.5 and ends at levels 4.0 or 3.5, with a pulse interval of 0.4 s. While it will be necessary to derive the optimal balance between the pulse interval and energy level from more cases, it can be inferred that the chilled water temperature set to $12\text{--}20^{\circ}\text{C}$ maintains the epidermal temperature at $\geq 30^{\circ}\text{C}$ in practice. There is no increased risk of side effects when performing the procedure with a high energy level, even with this level of contact surface temperature, if contact cooling is performed for a duration of 1,000 ms. Ultimately, VOLNEWMER should provide safe combinations of pulse interval and energy level parameters by studying multiple treatment cases in the short term and demonstrating the cooling temperature of the contact surface according to procedure speed through experimental measurements in the long run. A Key Factor for an Effective Procedure: Pain In monopolar RF treatment, the epidermis is maintained at $38\text{--}42^{\circ}\text{C}$

through cooling, but the heat-induced pain on the dermis cannot be avoided due to heat transfer at $\geq 60^{\circ}\text{C}$. The cooling system has great significance in pain control because excellent epidermal cooling decreases pain and enables higher energy level procedures. The gate control theory of pain is applied to most devices, and they are equipped with a horizontal or vertical vibration function. This function produces the analgesic effect of non-pain stimulation, such as vibration, which closes the pain transmission gateways and blocks the pain sensation from being transmitted to the brain. To use much higher-power energy, the epidermal cooling capacity must handle the high-power energy, but patients must also be able to withstand the heat pain. In other words, even if the skin is protected by excellent cooling, the devices' high-power energy cannot be utilized if the patient cannot tolerate pain. The epidermal cooling capacity is determined the moment a device is introduced. Anesthetic cream application, minimal sedation through nitrous oxide inhalation, or moderate sedation procedures using sedatives, such as propofol, can be additional pain control. Pain control allows for maximum utilization of the output of a device. Without sufficient pain control, it will be impossible to determine the superiority of devices currently on the market.

Discussion

Differences and Meaning of the Maximum Output
When comparing RE devices, there is a tendency to evaluate their performance based on the highest output claimed by each manufacturer. Based on the details of the Ministry of Food and Drug Safety approval of 4 cm² cartridges, the maximum output of device A is 173W, 115W for device B, 140W for device C, and 115W for VOLNEWMER. The better the epidermal cooling capacity and the more effective the pain control, the higher the device's energy can be used. For a device's maximum output to be meaningful, a sufficient condition should be satisfied in which the epidermal cooling capacity of a device prevents burns even at high power and the patient can withstand pain. When pre-procedure treatment

for pain on the treatment site is a simple application of anesthetic cream or not provided at all, the procedure must be performed using relatively low energy, requiring more shots to yield a significant result. Accordingly, devices with outstanding epidermal cooling capacity reduce pain and need fewer high-energy shots, allowing more efficient procedures. When pain is fully controlled through sedation, it is also possible to perform procedures utilizing the highest permitted energy for the device's cooling capacity. Subjective Clinical Evaluation Device A's output is lower than the peak power at the most frequently used energy levels of 2.5–3.0 compared to its peak power of 173W at level 8.0. Device B has an output of 115W at level 9.5, but its output is 65–75W at the most used levels of 4.5–5.5. The risk of burns is present at level 7.0 with an output of 90W or higher, even when pain is controlled completely. Device C has an output of 140W at level 6.0, and the most commonly used energy levels of 2.0–2.5 have an output of 55–64W. However, when the level is increased to 3.0, DCD cooling that is prolonged to 20–30 ms becomes activated and enables procedures using levels 3.0–4.0 with an output of 74–96W without burns. VOLNEWMER has an output of 115W at level 5.0, and the following should be considered. First, its continuous cooling function of 1,000 ms using chilled water of 12–20°C is excellent. Even the most frequently used high-power levels of 2.5–3.0 (65–75W) can be used without risk of burns. Second, continuous cooling enables single RF pulse procedures. As there is no heat loss from pulse division, the thermal diffusion effect can be accumulated, and the temperature can be easily raised. In other words, the efficiency of the single RF pulse procedure is better than the same output method that raises the temperature using 5–6 pulses of 200 ms.

Multicooling & Multi RF Pulse .vs. Continuous Cooling + Single RF Pulse

The value of multi-cooling and multi-pulse is significant in laser procedures that can cause damage to chromophores distinct from surrounding tissues, such as epidermal melanin or dermal blood vessels.

However, in the conventional monopolar RF that uses DCD and contact cooling methods for epidermal cooling, the DCD temperature of -26°C poses the risk of frostbite and pigmentation when cooling is longer than 100 ms, and the epidermis cannot be sufficiently cooled due to insufficient diffusion time when cooling is shorter than 10 ms (so DCD is used for a duration of 10–100 ms). Because procedures using long pulse duration cannot be performed due to the above limitations, it has been intended to increase the dermal temperature gradually using the 20 ms multi-cooling of DCD and the 200 ms multi-RF pulse method. While this method has historical significance as the origin of monopolar RF devices, contemplation on whether it is the best energy transfer method is necessary. In this respect, VOLNEWMER's continuous cooling and single RF pulse methods are innovative.

General Review

The particularities brought about by VOLNEWMER's new ideas are as follows. First, it has an excellent continuous cooling function of 1,000 ms using chilled water at 12–20°C. Even the most frequently used energy levels of 2.5–3.0 (65–75W) can be performed without pre-procedure treatment. From personal clinical experience, if pain can be controlled more, burns are not of concern even at a higher output of 3.5–4.5 (85–105W).

Second, continuous cooling enables single RF pulse procedures without heat loss from pulse division. This accumulates the thermal diffusion effect and enables a smooth temperature increase. The efficiency of the single RF pulse procedure is considered better even when compared to the same output method that raises the temperature with 5–6 pulses of 200 ms. Third, unnecessary cooling at shallow dermal areas is minimized using chilled water, whose thermal diffusivity is 1/100, as a medium at a relatively high temperature of 12–20°C. Nevertheless, there are also limitations to new ideas. In slow cooling with chilled water circulation, the contact surface temperature drops gradually due to reverse thermal diffusion immediately after energy irradiation. That is, the procedure is performed without the temperature

DEEP EXPLORATION

of the procedure site decreasing to the set chilled water temperature due to the surface cooling delay phenomenon. If the shot intervals are maintained for a long time regardless of the procedure duration, the next shot can be performed after the contact surface temperature is sufficiently lowered. However, when the shot intervals are short, as in actual clinical practice, it can be inferred that the contact surface is cooled significantly higher than the set chilled water temperature. It should be noted that the procedure can be performed at various levels depending on the physician's shot interval.

