

If you want to regain the skin's three-dimensional appearance,
FOCUS DUAL provides the answer for the skin care.

FOCUS_{DUAL}



CONTENTS

- 01. Focus Dual ?
- 02. Two function with one device
- 03. Focus Dual Indication
- 04. Fractional micro RF needle
- 05. Literature Review of Fractional micro RF needle
- 06. HIFU
- 07. Literature Review of HIFU
- 08. Clinical Program
- 09. Pre-clinical trial
- 10. Clinical Result
- 11. Specification

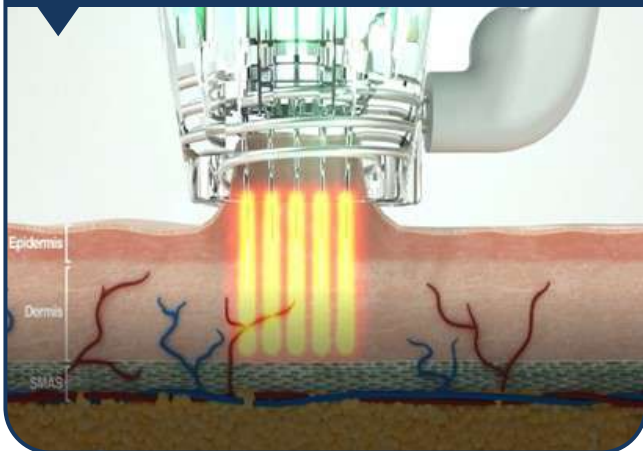




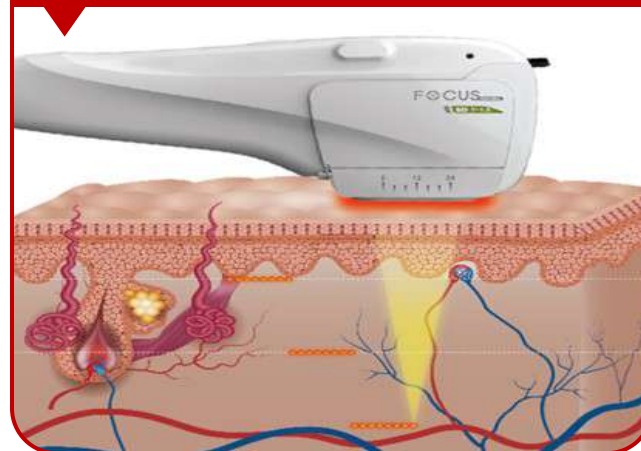
01

Focus Dual?

Fractional RF needle technology



HIFU technology



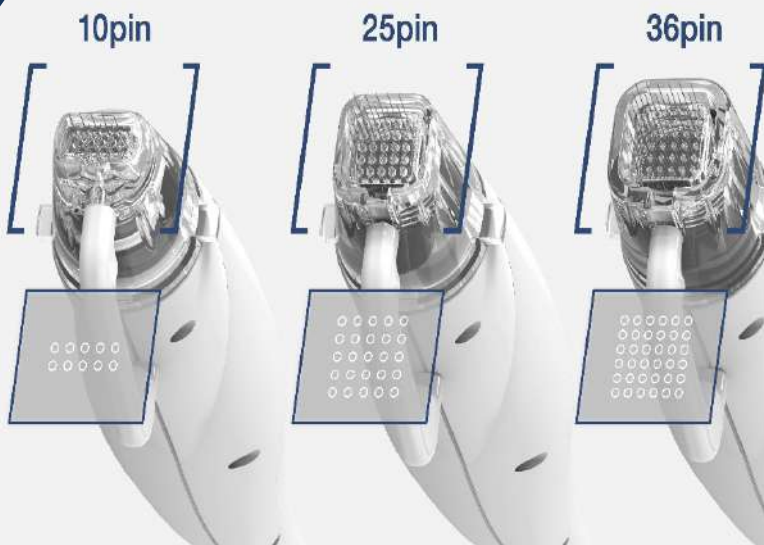
Collagen remodeling & Lifting & Tightening



02

Two function with one device

Fractional RF needle technology



Designed to rejuvenate the skin by applying radio frequency of 2MHz with $\Phi 0.25\text{mm}$ multi needle.

HIFU technology



Designed for skin lifting by using such as 4MHz, 7MHz of ultrasound to create heat at such a deep level(SMAS, Reticular Dermis, and Papillary Dermis) in the skin.



03

Focus Dual Indication

RF needle

- Acne & acne scar
- Various scar
- Pore reduction
- Skin tone improvement
- Stretch marks

- Lifting
- Tightening
- Wrinkle reduction
- Skin rejuvenation
- Collagen regeneration

HIFU

- Eyebrow improvement
- Double chin
- Volume reduction
- Malar elasticity

Fractional RF Needle

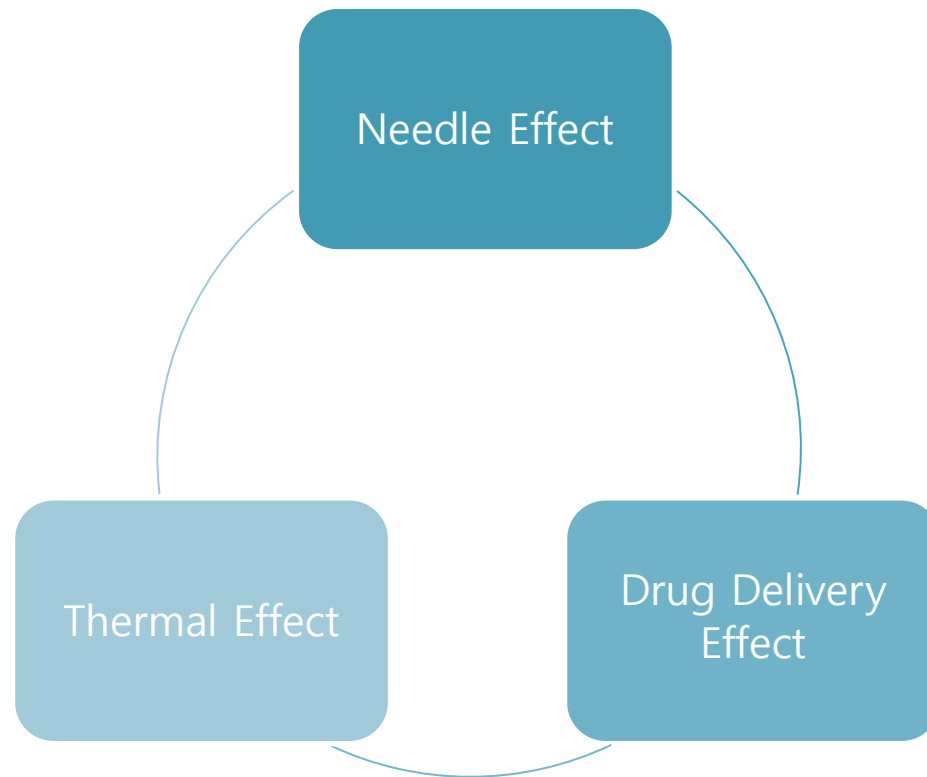




04

Fractional micro RF needle

❖ Effect



1. Micro-needle stamping

: Mechanical stimulation induces healing process

2. Bipolar RF

: Collagen regeneration effect through thermal action

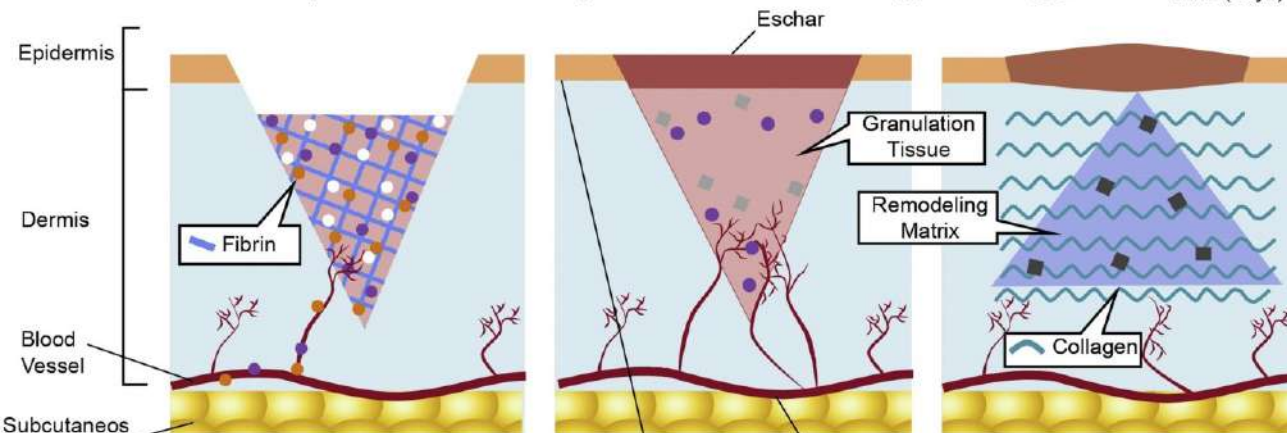
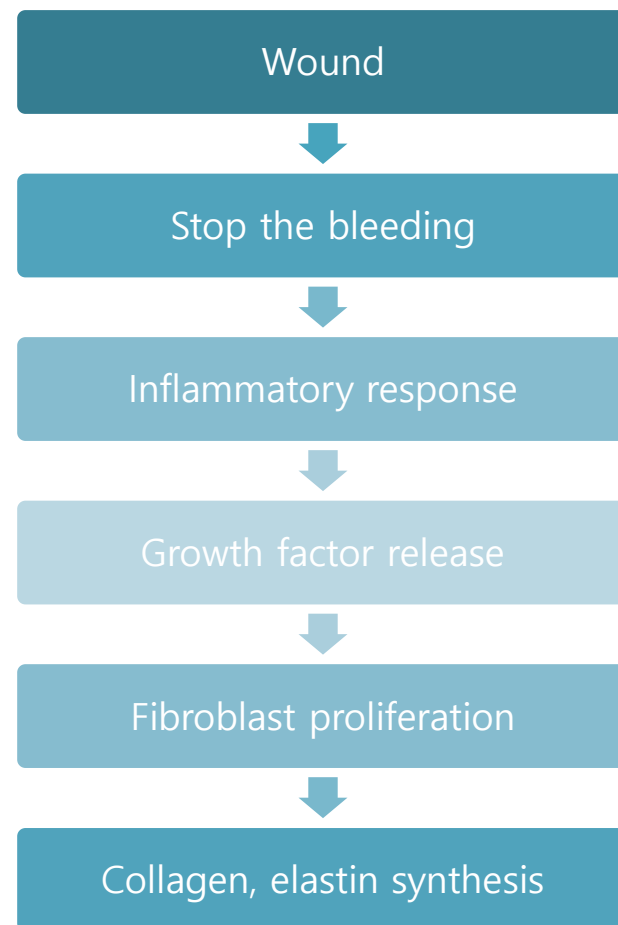
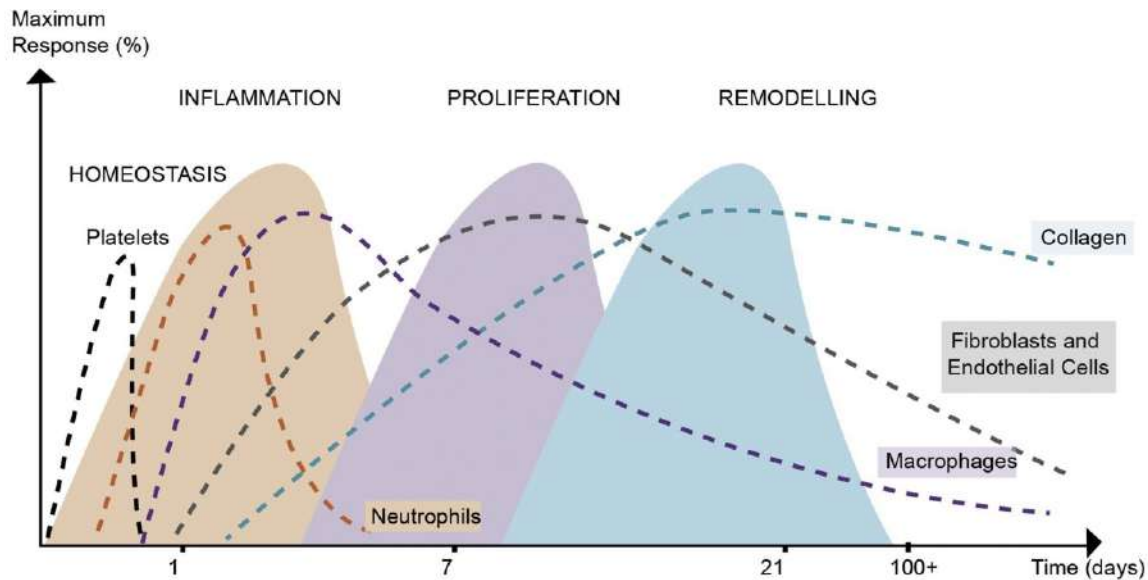
3. Drug delivery effect

: Solution applying through the hole once needling

04

Fractional micro RF needle

❖ RF needle working mechanism – wound healing

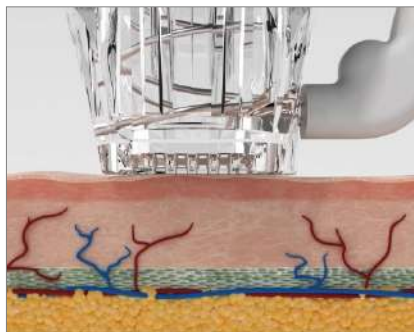




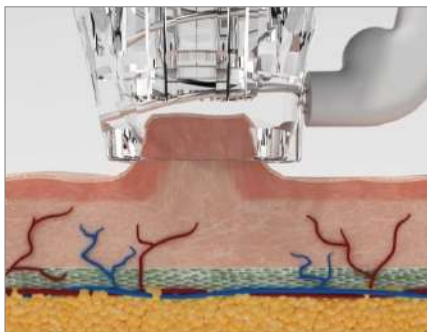
04

Fractional micro RF needle

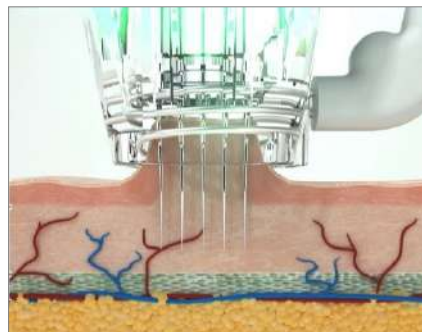
❖ Sequence of RF needle action



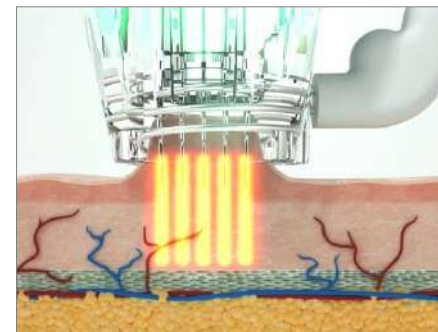
1. Tip contact to skin



2. Vacuum activated



3. Needling



4. RF energy generation

Fibroblast proliferation

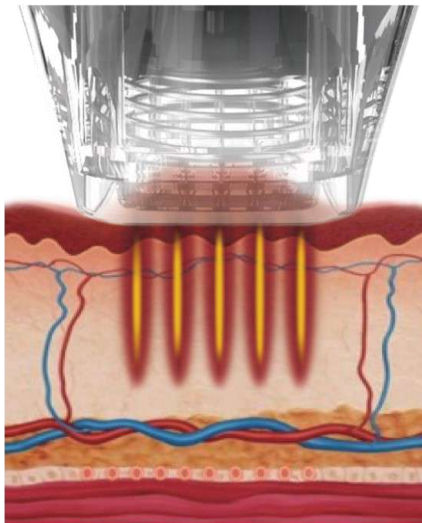
Collagen induction



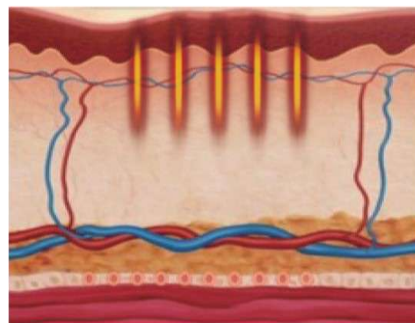
04

Fractional micro RF needle

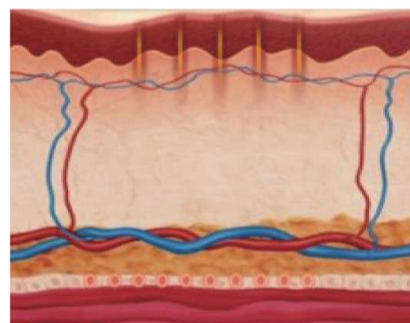
❖ Healing process



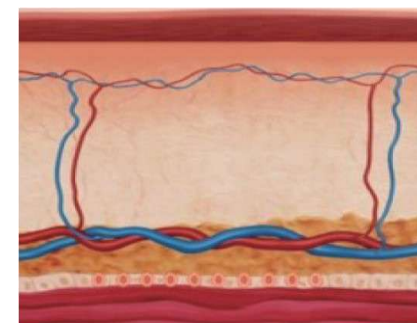
Tissue stimulated through
needling and RF energy goes to
desired depth area.



Wound healing progress
Induction of regeneration
Fibroblast proliferation



Wound healing regeneration period –
about 3 weeks
Collagen, elastin synthesis



Collagen remodeling

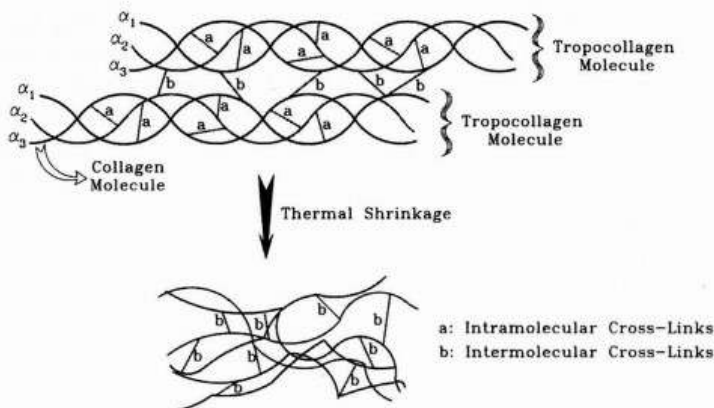


04

Fractional micro RF needle

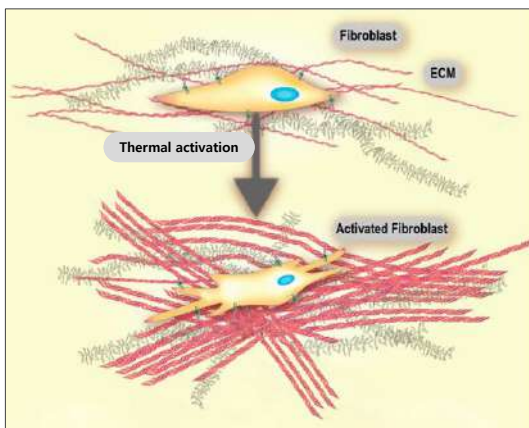
❖ Radio frequency thermal effect

1. First effect: Immediate collagen contraction



- Weakening of hydrogen bond between the collagen molecular and decomposition of denature fiber by heat
- The laxity of collagen fiber structure and collagen molecular aggregation by hydrogen bond in molecular
- Collagen fiber contraction and ECM structure enhancement through relocation of collagen fiber structure

2. Secondary effect : wound healing , Collagen remodeling, tightening over time



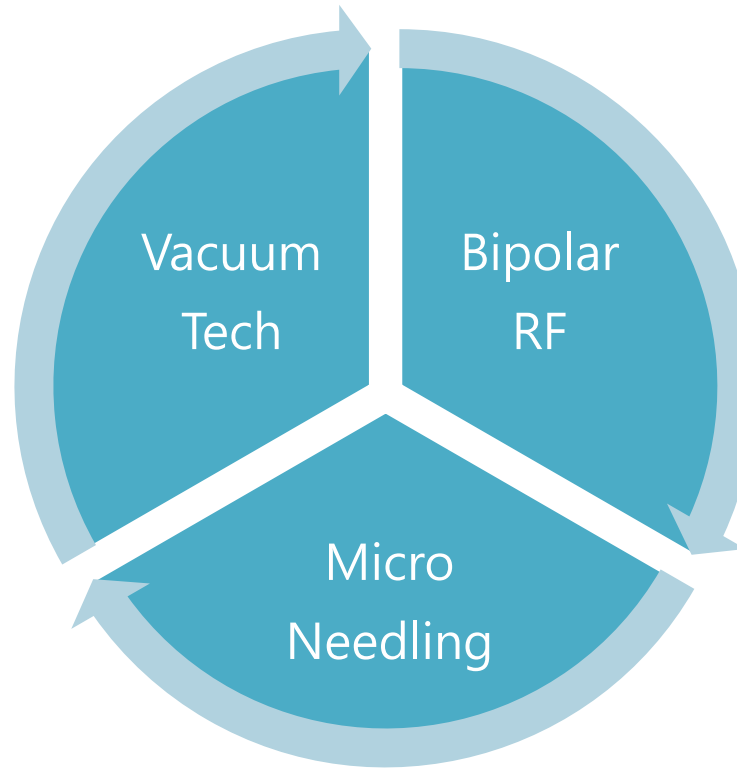
- Induction of collagen production to protect damage by heat in fibroblast
- Induction of ECM structure remodeling through collagen and elastin synthesis
- Improving dermal layer thickness, wrinkle and skin elasticity through ECM synthesis during 3 to 6 months



04

Fractional micro RF needle

❖ Fractional Micro needle RF technology



“Delivering RF energy precisely to the target depth area”

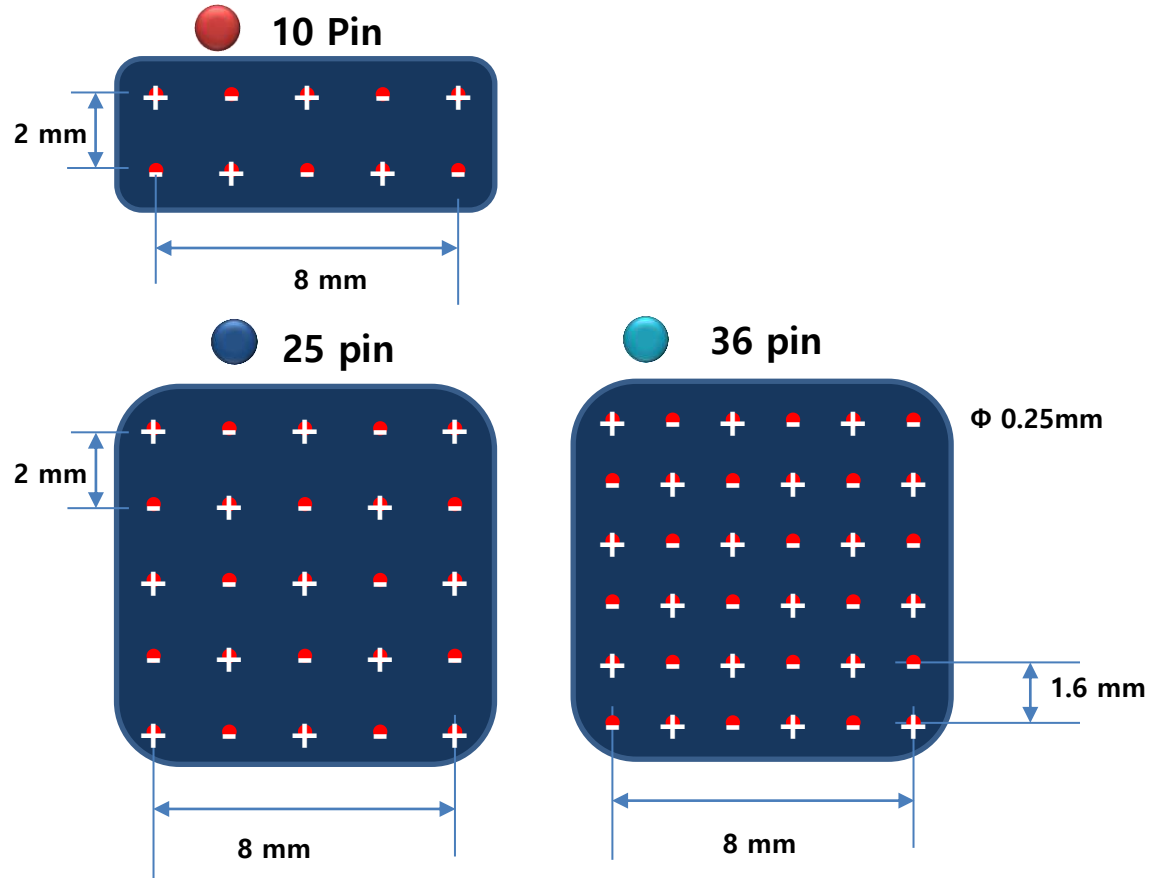
It brings about incredible results by a combination of three of the newest clinically proven technologies.



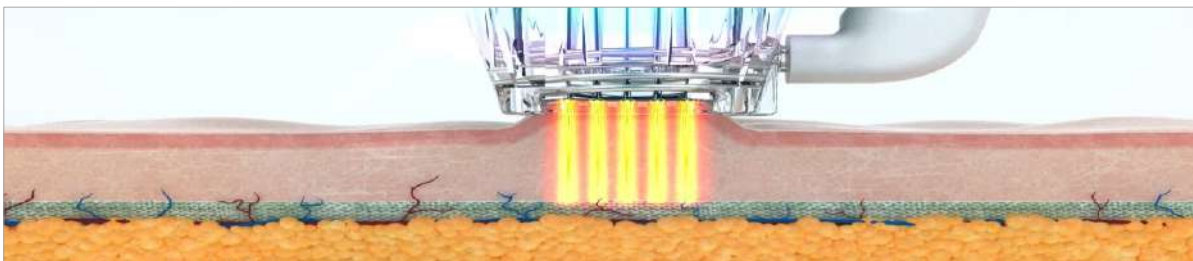
04

Fractional micro RF needle

❖ Needle Technology



- ✓ Uniform and stable energy
- ✓ Minimal energy loss
- ✓ Preventing a rush output by impedance



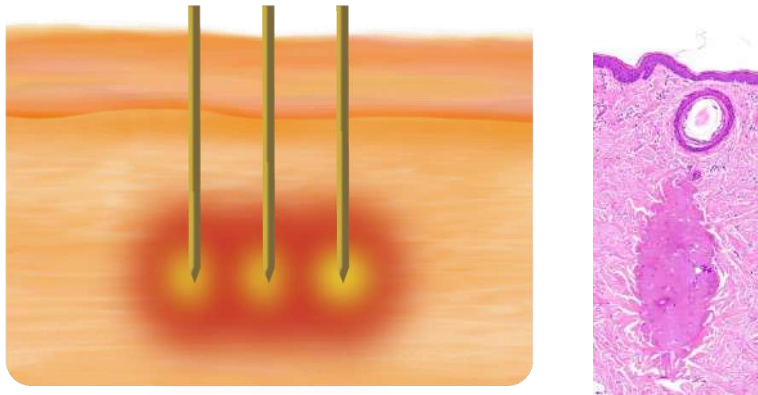


04

Fractional micro RF needle

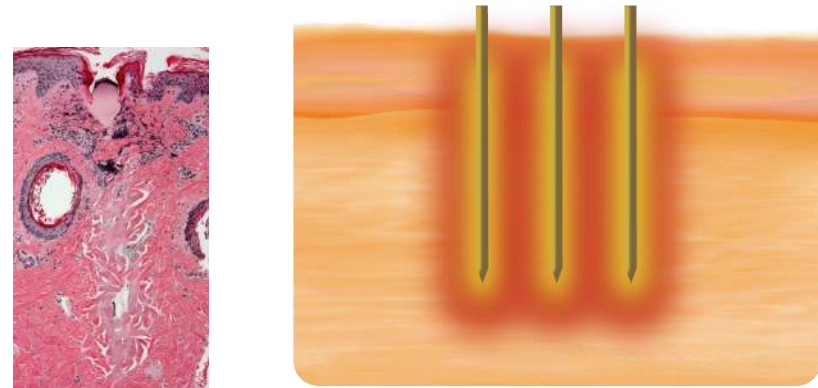
❖ Needle Technology

Insulated needle



- ✓ Intensive RF energy transmission to insulated needle
- ✓ Indicated for dermal lesions (Ex wrinkles, elasticity, etc.)
 - ✓ Short down time
- ✓ Possible to insulation breakage
 - ✓ Minor bleeding possible

Non-insulated needle



- ✓ Full of RF energy transmission to non-insulated needle
- ✓ Indicated for epidermal and dermal lesions (Ex Acne, scar, pore etc.)
 - ✓ Wide treatment area
- ✓ Need to surface cooling
 - ✓ Crust formation



04

Fractional micro RF needle

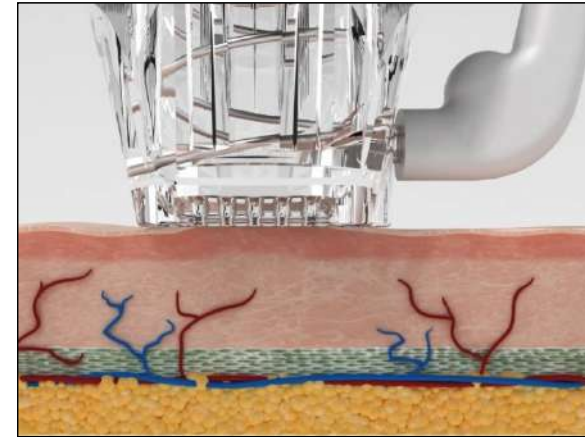
❖ Needle Technology

*** Advanced technology ***

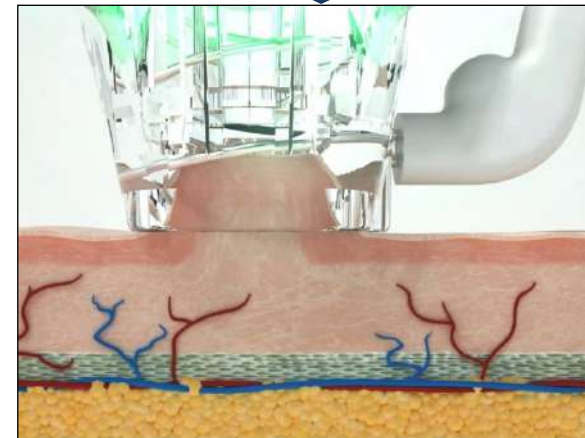
Vacuum technology

enables the target area to be pulled up,
which makes a safe treatment.

(Especially for eye and T-zone procedures are easy).



Vacuum technology





04

Fractional micro RF needle

❖ Needle Technology

* Sophisticated motor mounting *

Sophisticated **Stepping motor** is mounted, enabling delicate procedure without severe recoil when inserting the needle into skin.

Good performance is maintained using our unique motor control technology.



Stepping motor	VS	Solenoid motor
• Available to multiple level control		• Less steps
• Flexible and precise control		• Additional part can be need for precise control
• Stop at accurate location		• Hard to reach at accurate location
• Advantage at slow speed movement		• Advantage of fast speed movement



04

Fractional micro RF needle

❖ Advantages of Fractional Micro needle

Hygiene

Safe and hygienic because
of sterilization with EO
gas

Diversity

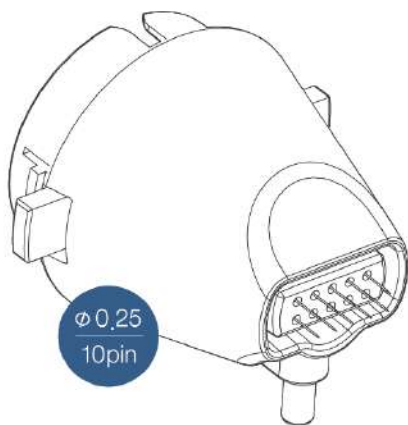
6 type needles are available
10pin / 25pin / 36pin

Vacuum technology

Preventing skin skidding by
applying vacuum technology

Safety

Needle spacing
without RF energy overlap



※ Micro needle tip box(10ea/1box)



04

Fractional micro RF needle

❖ Precaution for treatment

- Before procedure, the procedure site must be sterilized. – Caution for secondary infection
- The procedure should be performed without any openings.
- The procedure is performed while monitoring patient's pain.
- To prevent skin skidding, the procedure is performed operating the vacuum.
- Areas with good skin elasticity such as cheek may not be vacuumed and at this time, the procedure needs to be performed without vacuum.
- During the procedure, the appropriate energy and depth are determined and applied.
- After 1pass procedure, check the patient's condition and then treat only the 2pass or lesion area.
- In case of bleeding, use sterilized gauze to wipe out blood and perform the procedure.
- The day after the procedure, you must follow up the patient's condition and take appropriate action when inflammation occurs.



04

Fractional micro RF needle

❖ Contraindications

- ✓ Keloid skin
- ✓ Diabetic complications and major complications
- ✓ Infectious and hemorrhagic skin disorders
- ✓ Artificial heart pacemakers
- ✓ Abnormal birthmarks
- ✓ Pregnancy
- ✓ Other allergies

05

Literature Review of Fractional micro RF needle

❖ Relief of rosacea(redness) skin

Clinical and Histologic Effects of Fractional Microneedling Radiofrequency Treatment on Rosacea

SEON YONG PARK, MD,*† HYUCK HOON KWON, MD, MS,*† Ji YOUNG YOON, MS,†
SEONGUK MIN, MD, MS,*† AND DAE HUN SUH, MD, PhD*†

BACKGROUND Fractional microneedling radiofrequency (FMR) is an emerging treatment modality, but its effect on rosacea has not been studied yet.

OBJECTIVE To investigate the potential impact of FMR treatment on clinical improvement and histologic changes in rosacea patients.

MATERIALS AND METHODS A 12-week, prospective, randomized, split-face clinical trial was conducted. Two sessions of FMR were performed on one side of the cheeks with 4-week interval and the other side remained untreated. Erythema index from DermaSpectrometer and a* value from Spectrophotometer CM-2002 were measured at each visit for the objective measurement of erythema. Histologic analysis of skin samples was also carried out.

RESULTS Clinical evaluation and photometric measurement revealed the reduction of redness in the treated side compared with untreated side and baseline. Erythema index decreased 13.6% and a* value decreased 6.8% at Week 12 compared with baseline. Reduced expression of markers related to inflammation, innate immunity, and angiogenesis was observed in immunohistochemical staining of tissue obtained after FMR treatment.

CONCLUSION Fractional microneedling radiofrequency treatment showed modest clinical and histologic improvement of rosacea, and it might be used as an alternative or in combination with other treatment methods.

Supported by grant 04-2015-0350 from the SNUH Research Fund and National Research Foundation of Korea grant funded by the Korea government (MSIP) (No. 2014-0142A1A11049397). The authors have indicated no significant interest with commercial supporters.

Journal of clinical effect with fractional micro needle RF treatment



Figure 2. Clinical photographs showing improvement of rosacea. The treated side showed decreased erythema, while the lesion showed minimal improvement in the untreated side.

Needle RF treatment condition:

- 49 pin,
- Lv. 2~3(5~7.5W),
- 50~70msec

Reduced facial rosacea after 12 weeks of needle RF treatment is confirmed

05

Literature Review of Fractional micro RF needle

❖ Improvement of sagging lower-chin

Fractional High Intensity Focused Radiofrequency in the Treatment of Mild to Moderate Laxity of the Lower Face and Neck: A Pilot Study

Matteo Tretti Clementoni, MD¹ and Girish S. Munavalli, MD^{2,3*}

¹Skin House, Milan, Italy

²Dermatology, Laser, and Vein Specialists of the Carolinas, Charlotte, North Carolina

³Department of Dermatology, Wake Forest University, Winston Salem, North Carolina

Background and Aims: The aging process is commonly associated with skin laxity in the lower face and neck. Conventional surgery can correct this at least to some extent, but is invasive. Fractional high-intensity focused radiofrequency delivered to the dermis with insulated microneedles has recently attracted attention in facial rejuvenation. The present pilot study was designed to assess the efficacy of HiFR for skin laxity of the lower face and neck.

Methods: Thirty-three patients (7 males, 26 females, age range 37–74 years) with mild to moderate skin laxity of the lower face/neck participated in the study. Three treatments were given at monthly intervals with protocols developed by the authors, three passes per session, at decreasing dermal depths for each pass. Histologic assessment of skin immediately after treatment was performed to identify the site and area of damage in the dermis. Clinical digital photography was taken at baseline and at 6 months after the final treatment session, based on which standardized computer measurement of improvement in the gnathion and cervicomentalar angles was the primary objective evaluation. A global assessment of improvement was graded by blinded assessors based on the photography. A telephone survey of patient satisfaction was performed at 12 months post-treatment.

Results: A significant post-treatment decrease in the cervicomentalar and gnathion angles was seen of 28.5° and 16.6°, respectively ($P < 0.0001$ for both). Histology immediately post-treatment showed a clear demarcated and roughly oval area of coagulation associated with the tip of the needle, confined to the dermis and not involving the epidermis. In the global assessment 81.8% of the patients achieved moderate or higher results, and 87% of patients were very satisfied or better. Downtime was minimal, lasting 3–4 days, and no persistent adverse events were recorded.

Conclusions: Fractional HiFR proved safe and effective

Lasers in Surgery and Medicine 48:461–470 (2016)

INTRODUCTION

As the facial skin ages, owing to both the photoaging and intrinsic aging processes, progressively deeper lines and wrinkles may appear as the extracellular matrix (ECM) fibrous components of collagen and elastin degrade and lose their resilience. With loss of fat in the mid face and loss of ECM resilience, skin laxity develops in the lower third of the face and under the relentless 10 N/kg force of gravity, unsightly pendulous folds of tissue appear at the jawline and neck, with deep horizontal wrinkling of the neck. Horizontal creases can be exacerbated or form over time by occupations or habits such as typing with a laptop on the lap or reading with a book down low, that lend oneself to constant flexing of the neck or having the chin tipped down over long periods of time.

Of all the visible signs of the aging countenance, sagging jawline and lax neck skin are among the most cosmetically troublesome to the aesthetic patient. Unfortunately, these signs are also among the most challenging to treat.

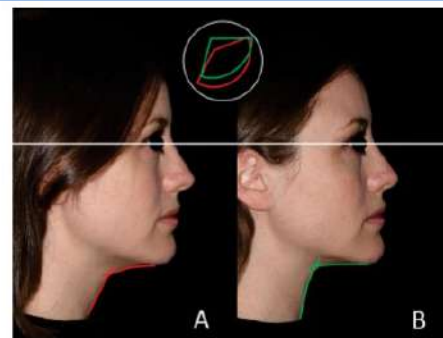
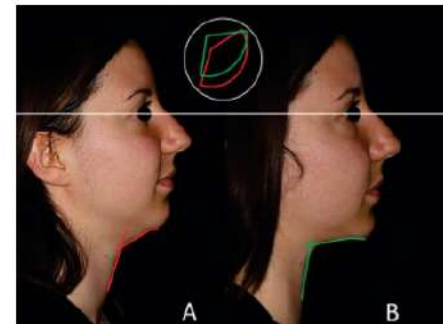
Treatment of complete and photo- and ch- of skin laxity, associated with dermis, in post-scaffolding of fibroblasts th- Traditional but at the co- even then thi-

Conflict of interest and submitted Conflicts of interest have been for the study

TABLE 2. HiFR Settings for Laxity of the Lower Third of the Face and Neck (Developed by MTC, Validated by GM).

Passes	Depth (mm)	Level	Exposure time (s)
Neck			
1	1.5–2.0	8–9	220–230
2	1.0–1.5	6	160
3	0.75–1.0	6	160
Lower third of face/submental region			
1	2.5	8–11	280–320
2	1.5	8–9	230–250
3	1	6	160

Higher end of ranges was used in thicker skin.



Needle RF treatment condition:

- 1MHz,
- 49 pin
- Lv. 1~20(2.5~50W),
- 10~1,000msec

Improved sagging lower-chin after 6 months of needle RF treatment is confirmed

05

Literature Review of Fractional micro RF needle

❖ Improved sagging lower-chin and wrinkle

Non-Insulated Smooth Motion, Micro-Needles RF Fractional Treatment for Wrinkle Reduction and Lifting of the Lower Face: International Study

Michael Gold, MD,^{1*} Mark Taylor, MD,² Kenneth Rothaus, MD,³ and Yohei Tanaka, MD, PhD⁴

¹Tennessee Clinical Research Center, Nashville, Tennessee

²Gateway Aesthetic Institute and Laser Center, Salt Lake City, Utah

³Rothaus Plastic Surgery, New York, New York

⁴Clinica Tanaka Plastic, Reconstructive Surgery and Anti Aging Center, Matsumoto, Nagano, Japan

Introduction: Skin aging occurs through both intrinsic and extrinsic processes. Fractional radiofrequency (RF) with a microneedling array is the newest form of fractional therapy to be useful in treating aging skin. The current study utilized a noninsulated fractional RF microneedling system.

Methods: This multicenter clinical trial saw 49 patients complete 3 monthly treatments with the new fractional RF microneedling treatments and be followed for 3 months following their last treatment. Pain during treatment was recorded as well as overall improvement using a GAIS scale. Adverse events were also noted.

Results: Forty-nine patients completed all of the treatments and follow-ups. Mild to moderate erythema were reported immediately after treatment which lasted up to 12 hours after the treatment. Pain, as measured on a 1-10 VAS, was noted to 4, on average. The average Fitzpatrick's wrinkle scale score at baseline was 5.04 ± 1.22 , 1 month after 3 treatments 3.829 ± 1.69 and 3 months after 3 treatments 3.5 ± 1.66 . These results are statistically highly significant (correlated T-test, $P < 0.001$). Improvement was shown in 100% of patients while 65% of patients had significant improvement (GAIS levels 3-5). Significant skin tightening and skin lifting were also observed. No unusual adverse events were noted throughout the course of the study.

Conclusion: This multicenter study showed significant wrinkle reduction, skin tightening, and lifting of the mid and lower face with the noninsulated fractional RF microneedling system. Lasers Surg. Med. 2016 9699:1-7. © 2016 Wiley Periodicals, Inc.

Key words: microneedling; wrinkle reduction; radio-frequency; skin tightening; lifting; endymed; intensif; 3deep

chemical peels and lasers have proven to be effective but can be usually associated with prolonged downtime and have been associated with multiple short- and long-term risks. Fractional CO₂ laser skin resurfacing ablates, or coagulates small "dots" of skin, leaving most of the skin surface intact reducing the downtime associated with full face resurfacing [3-5]. Nevertheless, reports show that fractional CO₂ laser resurfacing is still associated with postinflammatory hyperpigmentation or hypopigmentation in up to 55.5% of patients, especially in skin types III and IV [6-9].

Radiofrequency (RF) is a nonionizing electromagnetic radiation which has been used in medicine for nearly 100 years. In contrast to most lasers that target specific chromophores, RF is chromophore-independent with better penetration to the dermis and hypodermis as compared to light. RF with frequencies around 1 MHz were proven in the last decade to be safe and effective for both nonablative skin tightening of the face and body and fractional RF skin resurfacing for skin rejuvenation and acne scars. Multiple studies show improved safety profile compared to fractional CO₂ lasers with significantly less cases of postinflammatory hyper- or hypopigmentation [10-14].

Fractional RF skin resurfacing (FSR) can be performed using bipolar or multisource (3DEEP) RF technologies. These modalities use flat electrodes for simultaneous epidermal ablation and volumetric heating of the dermis. Bipolar fractional RF usually provides heat up to a depth of 300 microns while multisource FSR that simultaneously uses six RF generators has been shown to heat the dermis up to 2,800 microns. These devices have been proven to be

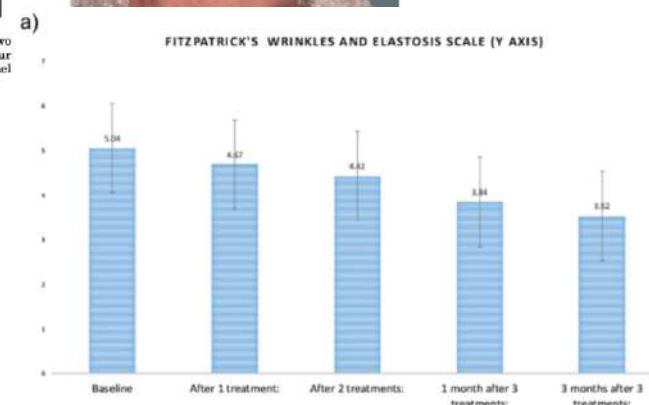
Conflicts of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

*Correspondence to: Prof. Michael Gold, MD, Tennessee

Lasers in Surgery and Medicine



Fig. 3. Female, 60 years old. (a) Before. (b) One month after two microneedle treatments. Significant lifting effect and contour improvement in the mid and lower face. Courtesy of Dr. Michael Gold, Nashville, USA.



Needle RF treatment condition:

부위	Cheek	Neck
Pulse duration	110~140 ms	80~140 ms
Power	10~20 W	10~20 W
Depth	1.8~2.8 mm	1.3~2.5 mm

Improved sagging lower-chin and wrinkle after 3 months of needle RF treatment is confirmed

Literature Review of Fractional micro RF needle

❖ Relief of acne erythema

Acta Derm Venereol 2016; 96: 87–91

CLINICAL REPORT

Fractional Microneedling Radiofrequency Treatment for Acne-related Post-inflammatory Erythema

Seonguk MIN^{1,2*}, Seon Yong PARK^{1,2*}, Ji Young YOON¹, Hyuck Hoon KWON^{1,2} and Dae Han SUH^{1,2}

¹Department of Dermatology, Seoul National University College of Medicine, ²Acne and Rosacea Research Laboratory, Seoul National University Hospital, Seoul, South Korea

*These 2 authors contributed equally to this work

Post-inflammatory erythema is a common result of acne inflammation and is cosmetically unacceptable without effective treatment. Fractional microneedling radiofrequency (FMR) has potential for treatment of post-inflammatory erythema. The aim of this study was to evaluate the efficacy and safety of this treatment. A retrospective chart review was undertaken of 25 patients treated with 2 sessions of radiofrequency at 4-week intervals and 27 patients treated with oral antibiotics and/or topical agents. Efficacy was assessed through an investigator's global assessment of photographs, and the analysis of erythema with image analysis software and photometric devices. Histological changes resulting from the treatment were evaluated by skin biopsy. FMR treatment resulted in significant improvement in erythema with no severe adverse effects. Histological study revealed a reduction in vascular markers and inflammation. FMR is a safe and effective treatment for post-inflammatory erythema, with potential anti-inflammatory and anti-angiogenic properties. **Key words:** acne; post-inflammatory erythema; fractional microneedling radiofrequency.

Accepted Jun 3, 2015; Epub ahead of print Jun 10, 2015

Acta Derm Venereol 2016; 96: 87–91.

Dae Han Suh, Department of Dermatology, Seoul National University College of Medicine, 101 Daehak-ro, Jongno-gu, Seoul 110-744, South Korea. E-mail: dsuh@snu.ac.kr

Acne affects approximately 80% of adolescents and young adults (1, 2). Severe acne inflammation can result in subsequent erythema or hyperpigmentation and even permanent acne scarring. There are many reports of various treatments for pigmentation or acne scarring. However, there are few reports concerning treatment for residual erythema induced by acne inflammation. Post-inflammatory erythema (PIE) is very common following inflammatory acne and is often cosmetically unacceptable to patients (3). Patients usually have persistent red marks after clearing of the acute inflammation following acne treatment. Facial PIE improves with time, but very slowly, and in some cases, complete clearance of PIE cannot be achieved (4).

Radiofrequency devices, associated with preservation of the epidermis, and with fewer complications or

adverse effects and rapid recovery times, are becoming popular (5, 6). Fractional microneedling radiofrequency (FMR) delivers bipolar radiofrequency directly to the dermis using an array of microneedles (7). FMR has been reported to improve skin laxity and wrinkles (7–9). Bipolar radiofrequency has been reported to induce profound neocollagenesis and neocollagenesis, which has been suggested as a potential mechanism of clinical efficacy (10). Moreover, FMR has been shown to have a therapeutic effect on inflammatory skin diseases, such as acne (11). We hypothesized that the dermal remodelling and anti-inflammatory effects of FMR may successfully treat PIE caused by persistent inflammation and destruction of the dermal matrix.

To date, no study has evaluated the efficacy of radiofrequency treatment in post-inflammatory erythema. The aim of this retrospective study was to evaluate the efficacy, safety and histological changes of FMR in post-inflammatory erythema. To the best of our knowledge, this is the first report of FMR for the treatment of PIE induced by acne inflammation.

MATERIALS AND METHODS

Study design and subjects

A retrospective chart review was undertaken of 52 patients who visited the Department of Dermatology, Seoul National University Hospital, South Korea, between August 2013 and February 2014. The study protocol was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Seoul National University Hospital (No. 1407-136-597). Twenty-five subjects with PIE with few or no active acne lesions, who had been treated with FMR on the face, were included in the FMR-treated group. Twenty-seven patients with PIE and little or no active acne, who had been treated with oral and/or topical antibiotics, were included in the control group. Exclusion criteria were: patients with no photographs, hypertrophic or keloid scarring, patients being treated with any other treatment for acne scarring or erythema, including chemical or mechanical skin resurfacing, or use of topical or oral retinoids, for at least 3 months prior to first study. None of the patients underwent other acne scar treatments, including chemical or laser resurfacing during treatments.

Preparation and laser treatment

All treatment procedures were performed by a single surgeon (SNU). Topical anaesthesia with EMLA[®] (AstraZeneca, Sodertälje, Sweden) was administered 30 min before laser treatment



Fig. 2. Clinical photographs showing improvement in post-inflammatory erythema (PIE). The treated group showed improvement in redness 8 weeks after the second session of treatment (B) compared with baseline (A), whereas the control group showed no improvement (D) compared with baseline (C).

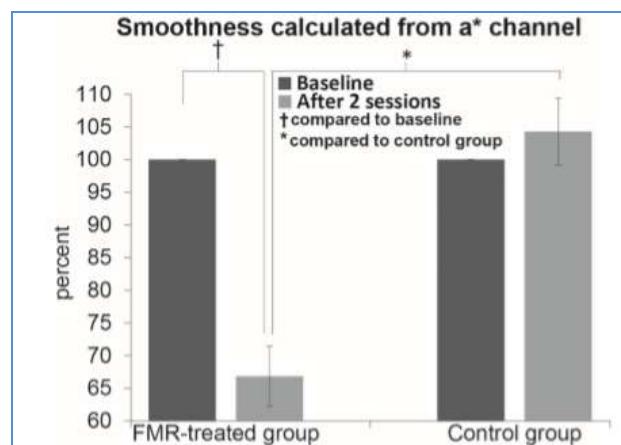


Fig. 3. Computer-aided erythema analysis. A variable "smoothness" showed reduction in post-inflammatory erythema (PIE) 8 weeks after the second session of treatment in the fractional microneedling radiofrequency (FMR)-treated group (*, † $p < 0.05$).

Needle RF treatment condition:

- 1 MHz,
- 49 pin
- Lv. 2~3(5~7.5W),
- 50~70 msec

Improved erythema by acne after 8 weeks of needle RF treatment is confirmed

05

Literature Review of Fractional micro RF needle

❖ Improvement of acne scar

Treatment of Acne Scars on Darker Skin Types Using a Noninsulated Smooth Motion, Electronically Controlled Radiofrequency Microneedles Treatment System

DAVID PUDUKADAN, MBBS, MD

BACKGROUND Noninvasive technologies for treating acne scars use radiofrequency (RF)-emitting micro-needles for both mechanical disruption of fibrotic strands and heat-mediated collagen remodeling.

OBJECTIVE Efficacy and safety evaluation of electronically controlled noninsulated RF microneedling system on acne scars in patients with dark skin.

METHODS Nineteen patients, 24 to 51 years old, skin types III to V, with acne scars were enrolled in the study. Each patient had 3 treatment sessions at monthly intervals using a multisource RF treatment platform with a microneedle RF applicator. Efficacy was evaluated by the Goodman and Barron's Global Qualitative Acne Scarring System.

RESULTS No bleeding points occurred during treatments. Post-treatment erythema was observed immediately after the treatment and lasted up to 10 hours after the treatment. Improvement of at least 1 acne scar grade was noted in 11 of 19 patients (57.9%) after 1 month and in 9 of 9 patients (100%) after 3 months.

CONCLUSION The tested noninsulated electronically controlled RF microneedles were found to be safe and efficient in the treatment of atrophic acne scars in skin types III to V with minimal pain or downtime.

The author has indicated no significant interest with commercial supporters.

Needle RF treatment condition:

- 2.0~3.0 mm depth
- 15~25W,
- 110~140 msec

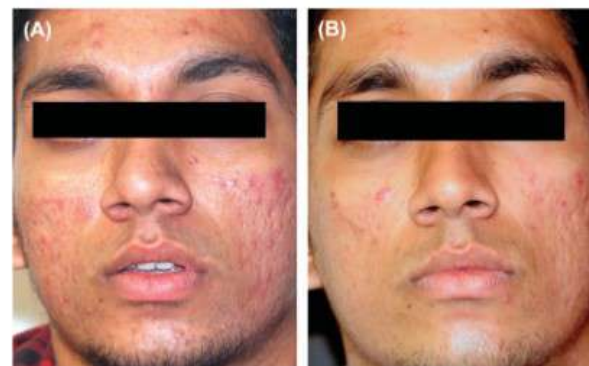


Figure 1. The 26-year-old man treated with 3 sessions of Intensif microneedling (pulse duration, 140 milliseconds; power, 19 to 20 W; and needle depth, 2.5 mm). Acne scar grading was decreased from Grade 4 to 3. (A) Before the treatment and (B) 1-month follow-up after 3 sessions.



Figure 2. The 36-year-old woman treated with 3 sessions of Intensif microneedling (pulse duration, 140 milliseconds; power, 18 to 21 W; and needle depth, 2.5 mm). Acne scar grading was decreased from Grade 3 to 2. (A) Before the treatment and (B) 1-month follow-up after 3 sessions.

Improved acne scar and erythema after 1 month of 3 sessions of needle RF treatment is confirmed

HIFU system





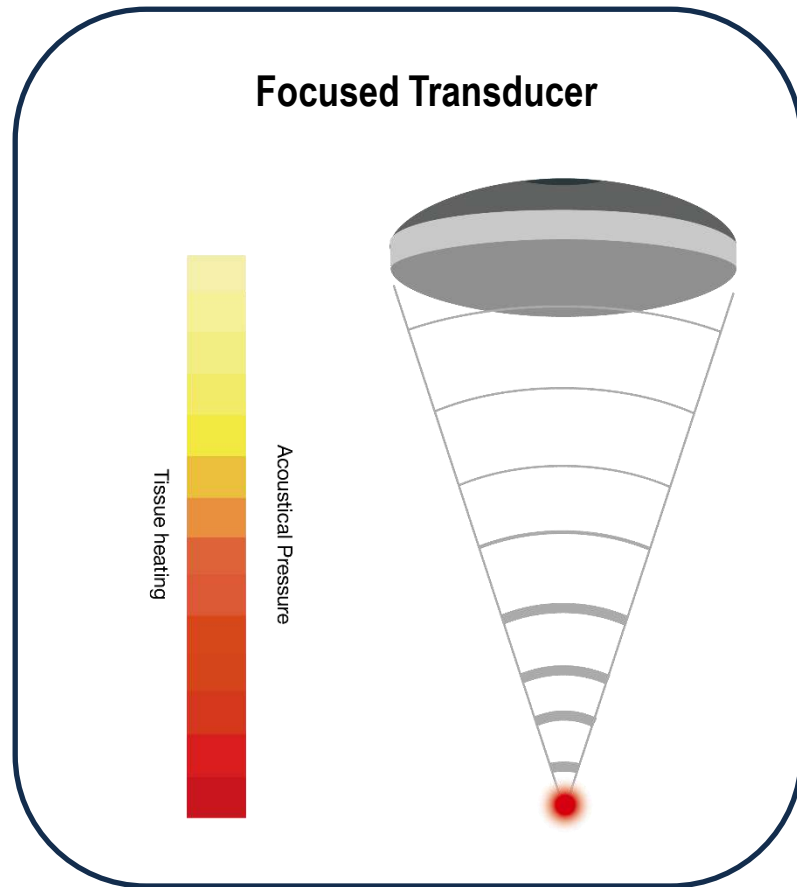
06

High intensity focused ultrasound

❖ HIFU

HIFU is?

Skin lifting procedure
by contracting SMAS (fascia layer)
immediately with formation of coagulation point
of 65 ~ 80°C through 4 MHz and 7 MHz
of high-intensity ultrasound energy

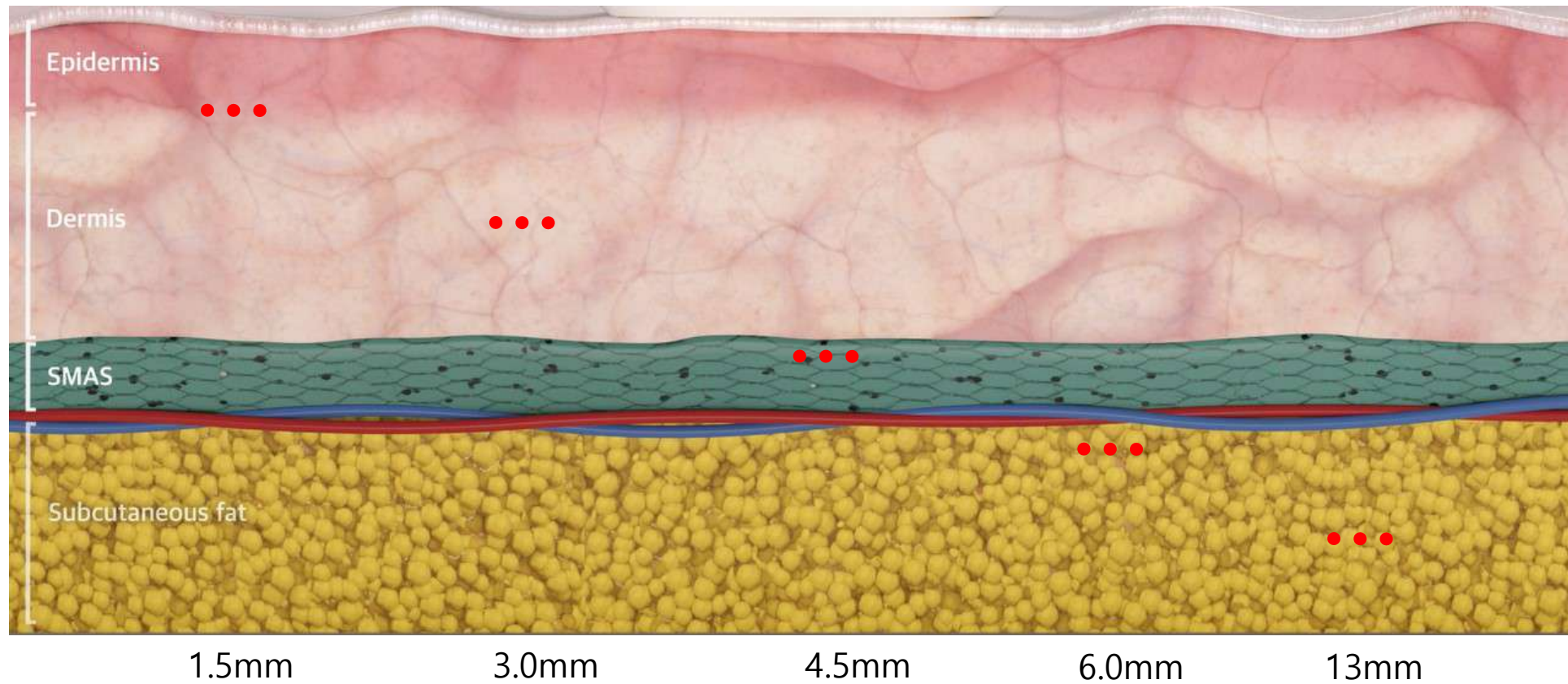




06

Hifu focusing depth

❖ HIFU





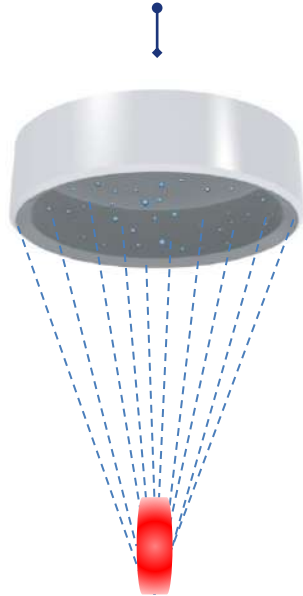
06

Trans hole Technology

❖ HIFU

Regular transducer

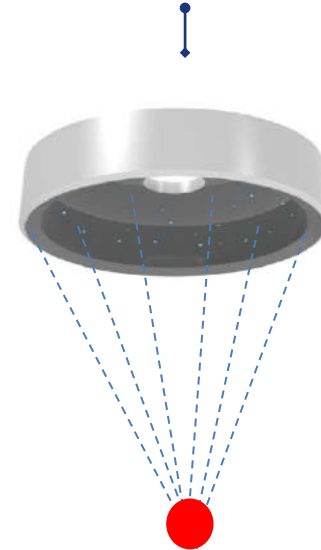
A large amount of air bubbles



- Cavitation phenomenon in cartridge creates large amount of micro bubbles
- Transducer surface bubbles interfere with ultrasound energy transfer

Trans hole transducer

A small amount of air bubbles



- Formation of small amount of bubbles due to transducer hole
- Stable ultrasound energy transfer



06

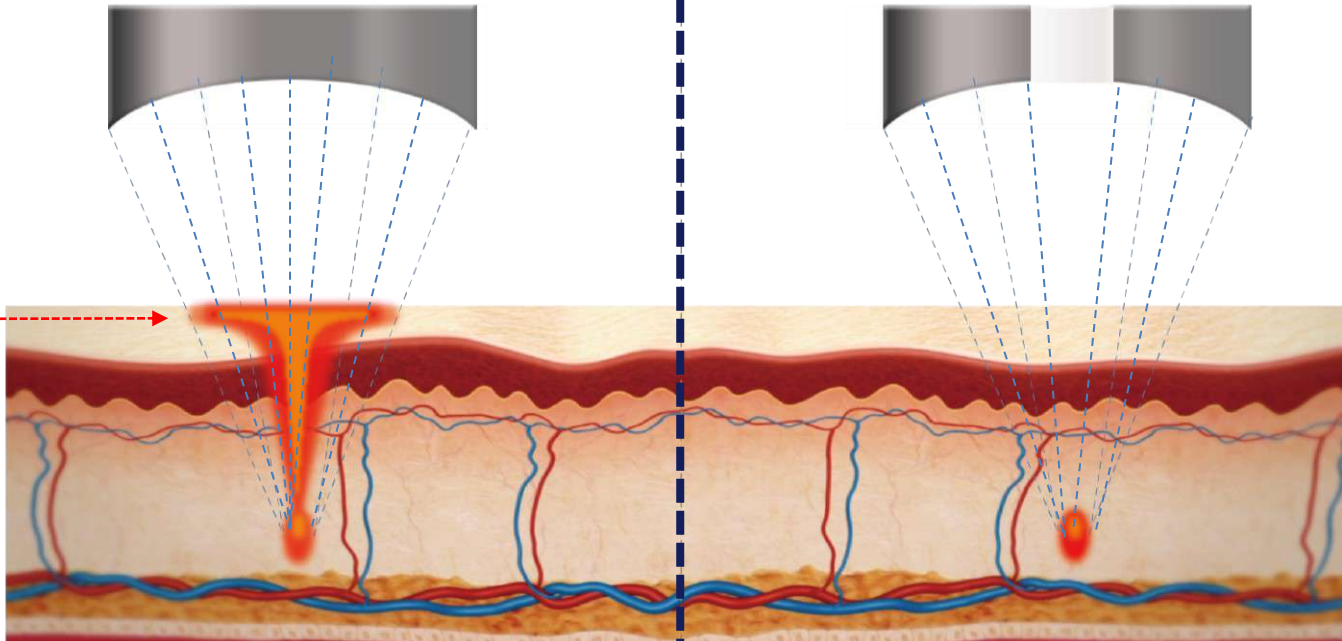
Trans hole Technology

❖ HIFU

Regular transducer

Transhole transducer

Skin damage



- Causes skin damage and side effects
- Excessive heat generation
- Increased pain

- Decreased skin damage and side effects
- Generate stable coagulation point
- Reduced pain



06

Transhole Technology

❖ HIFU

Safety

Non-invasive
safe procedure

Versatility

Various cartridges
available

Trans Hole

Minimize side effects
by applying trans hole
transducer

Accuracy

Accurate coagulation
of the target point

Convenience

User-friendly UI considering
user's convenience and
ergonomic handpiece design

[1.5mm]

[3.0mm]

[4.5mm]

[6.0mm]

[13mm]





High intensity focused ultrasound

❖ HIFU Procedure contraindications

- Those who have a disease that may cause infection in procedure site
- Those who received a metallic stent implantation at procedure site (around face, neck)
- Those who received mechanical implants
- Those who inserted the electric device in the body
- Those with active systemic or skin conditions that can affect wound regeneration

Literature Review of HIFU

❖ Efficacy analysis of HIFU treatment

Skin Research and Technology 2016; 8: 1-8
Printed in Singapore. All rights reserved
doi: 10.1111/srt.12147

© 2016 John Wiley & Sons A/S.
Published by John Wiley & Sons Ltd
Skin Research and Technology

High-intensity focused ultrasound treatment for skin: *ex vivo* evaluation

J.-H. Park¹, S.-D. Lim², S. H. Oh¹, J. H. Lee^{1,3} and U. C. Yeo⁴

¹Department of Dermatology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea.

²Department of Pathology, Konkuk University Medical Center, Konkuk University School of Medicine, Seoul, Korea.

³Department of Medical Device Management & Research, SAHST, Sungkyunkwan University, Seoul, Korea and ⁴Jongno S&U Dermatology Clinic, Seoul, Korea

Background/Purpose: High-intensity focused ultrasound (HIFU) has been used for skin tightening. However, there is a rising concern of irreversible adverse effects. Our aim was to evaluate the depth of thermal injury zone after HIFU energy passes through different condition.

Materials and Methods: To analyze the consistency of the HIFU device, phantom tests were performed. Simulations were performed on *ex vivo* porcine tissues to estimate the area of the thermal coagulation point (TCP) according to the applied energy and skin condition. The experiment was designed in three orientations: normal direction (from epidermis to fascia), reverse direction (from fascia to epidermis), and normal direction without epidermis.

Results: The TCP was larger and wider depending on the applied fluence and handpieces (HPs). When we measured TCP in different directions, the measured area in the normal

direction was more superficially located than that in the reverse direction. The depth of the TCP in the porcine skin without epidermis was detected at 130% deeper than in skin with an intact epidermis.

Conclusion: The affected area by HIFU is dependent on the skin condition and the characteristics of the HP and applied fluence. Considerations of these factors may be the key to minimize the unwanted adverse effects.

Key words: high-intensity focused ultrasound – treatment parameter – skin condition – porcine skin – *ex vivo* experiment

© 2016 John Wiley & Sons A/S. Published by John Wiley & Sons Ltd
Accepted for publication 18 October 2016

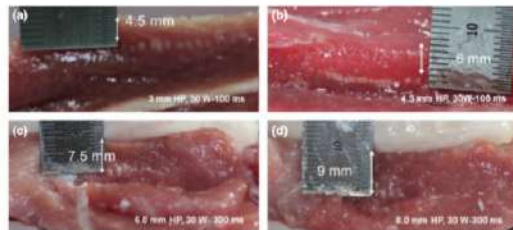


Fig. 2. TCP induced by HIFU in porcine muscle. In porcine muscle, TCP was measured at deeper area, compared with the predicted penetration depth of HIFU energy. Considering ultrasound attenuation in muscle is lower than that in skin, this experiment proved the excellent performances of HIFU device used in this study.

Non-clinical trial outcome for HIFU Efficacy analysis (Phantom, verifying of porcine serum coagulation point and tissue stain)

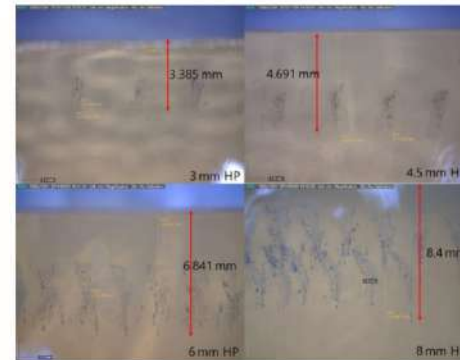


Fig. 1. At the same power (30 W/500 ms), the depth from the surface of the phantom gel to the bottom of the thermal coagulation point (TCP) was 3.385, 4.691, 6.841, and 8.4 mm using a 3.0, 4.5, 6.0, or 8.0 mm handpiece (HP), respectively (error margin = 12.8%, 4.24%, 14.01%, 5.0%).

Phantom test outcome image for HIFU efficacy analysis

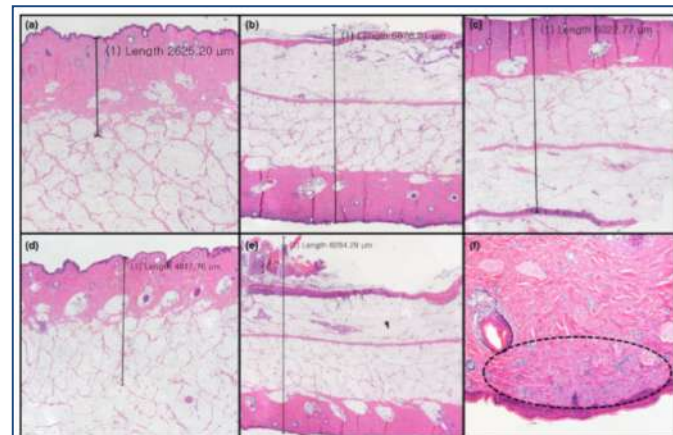


Fig. 5. The depth of TCP (from the surface to the bottom) was measured in each experiment (H&E). All experiments were performed at 35 W and 90 ms: (a) epidermis to fascia using a 4.5 mm HP ($\times 40$), (b) fascia to epidermis using a 4.5 mm HP ($\times 40$), (c) dermis to fascia after removing the epidermis and using a 4.5 mm HP ($\times 40$), (d) epidermis to fascia using a 6.0 mm HP ($\times 40$), (e) fascia to epidermis using a 6.0 mm HP ($\times 40$), (f) thermal coagulation point in the reverse direction (circle, $\times 100$).

Verifying image of porcine tissue coagulation point of HIFU efficacy analysis

Tissue stain image for HIFU efficacy analysis (Removing the epidermal layer, the penetration rate was 130% more than a normal depth according to trial)

Literature Review of HIFU

❖ Efficacy analysis of HIFU treatment

DERMATOLOGIC SURGERY

Ultrasound tightening of facial and neck skin: A rater-blinded prospective cohort study

Murad Alam, MD, MSCI,^{a,b,c} Lucile E. White, MD,^a Nicole Martin, MD,^a Joslyn Witherspoon, MD, MPH,^a Simon Yoo, MD,^{a,b,c} and Dennis P. West, PhD^a
Chicago, Illinois

Background: Nonablative skin tightening technologies offer the prospect of reduction of wrinkles and skin sagging with minimal downtime, discomfort, and risk of adverse events. The excellent safety profile is mitigated by the limited efficacy of such procedures.

Objective: We sought to assess the efficacy of ultrasound skin tightening for brow-lift in the context of a procedure treating the full face and neck.

Methods: This was a rater-blinded, prospective cohort study at a dermatology clinic in an urban academic medical center. Subjects were medicated with topical anesthetic and then treated with an investigational focused intense ultrasound tightening device to the forehead, temples, cheeks, submental region, and side of neck using the following probes: 4 MHz, 4.5-mm focal depth; 7 MHz, 4.5-mm focal depth; and 7 MHz, 3.0-mm focal depth. Standardized photographs of front and side views were obtained at 2, 7, 28, 60, and 90 days; rating scales of pain, adverse events, physical findings, and patient satisfaction were also completed. Primary outcome measure was detection of improvement in paired comparison of pretreatment and posttreatment (day 90) photographs by 3 masked expert physician assessors, cosmetic and laser dermatologists, and plastic surgeons who were not authors. Second primary outcome measure was objective brow elevation as quantitated by a standard procedure using fixed landmarks. Secondary outcomes measure was patient satisfaction as measured by a questionnaire.

Results: A total of 36 subjects (34 female) were enrolled, one subject dropped out, and 35 subjects were evaluated. Median age was 44 years (range 32-62). On the first primary outcome measure, 30 of 35 subjects (86%) were judged by the 3 masked experienced clinician raters to show clinically significant brow-lift 90 days after treatment ($P = .00001$). On the second primary outcome measure, mean value of average change in eyebrow height as assessed by measurement of photographs at 90 days was 1.7 mm.

Limitations: Limitations of this study include the inability to quantitatively measure lower face tightening because of the lack of fixed anatomic landmarks in this area.

Conclusion: Ultrasound appears to be a safe and effective modality for facial skin tightening. A single ultrasound treatment of the forehead produced on average brow height elevation of slightly less than 2 mm. Most treated individuals responded, commonly with accompanying transitory mild erythema and edema. (J Am Acad Dermatol 2010;62:262-9.)

Key words: lifting; nonablative; tightening; ultrasound.

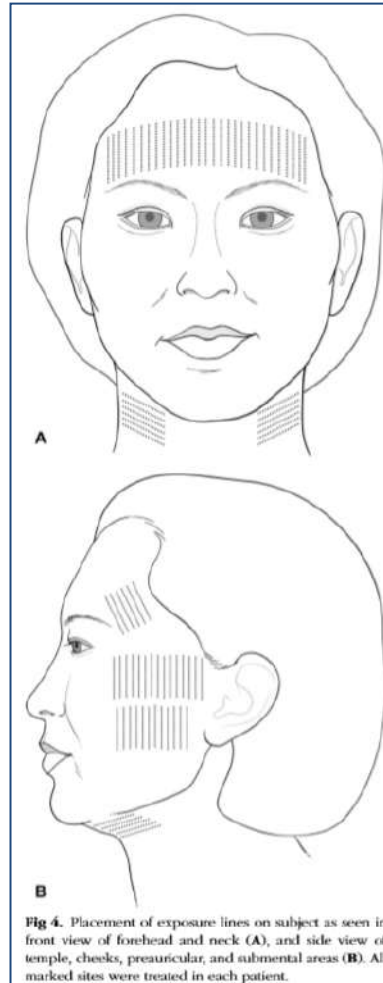


Fig 4. Placement of exposure lines on subject as seen in front view of forehead and neck (A), and side view of temple, cheeks, preauricular, and submental areas (B). All marked sites were treated in each patient.



Clinical trial outcome of HIFU efficacy analysis

Treatment method

Eyebrow's height was elevated as per skin lifting after HIFU treatment

Literature Review of HIFU

❖ Efficacy analysis of HIFU treatment

Body Contouring by Non-Invasive Transdermal Focused Ultrasound

J. Moreno-Moraga,* T. Valero-Altés, A. Martínez Riquelme, M.I. Isarría-Marcosy, and J. Royo de la Torre
Instituto Médico Laser, Madrid, Spain

Background and Objectives: The risks of currently available invasive procedures in body contouring motivate a need for safer, non-invasive technologies for improving the appearance of body silhouette. A new device has been developed that uses focused therapeutic ultrasound to reduce adipose tissue non-invasively. The aim of this study was to assess the efficacy and safety of a novel non-invasive focused ultrasound system (UltraShape Ltd, Tel Aviv, Israel) in reducing localized fat deposits to improve body contours.

Study Design/Patients and Methods: A prospective study was conducted on 30 healthy patients. All patients underwent three treatments, at 1-month intervals, and were followed for 1 month after the last treatment. Areas treated were the abdomen, inner and outer thighs, flanks, inner knees, and breasts (males only). No other body contouring procedure was used during the study. Efficacy was determined by change in fat thickness, assessed by ultrasound measurements, and by circumference measurements. Weight change was monitored to assess whether reduction in fat thickness or circumference was dependent on or independent of weight loss. Safety was determined by clinical findings, assays of serum triglycerides, and liver ultrasound evaluation for the presence of steatosis.

Results: All patients showed significant reduction in subcutaneous fat thickness within the treated area. The mean reduction in fat thickness after three treatments was 2.28 ± 0.80 cm. Circumference was reduced by a mean of 3.95 ± 1.99 cm. Weight was unchanged during the treatment and follow up period. No adverse effects were observed.

Conclusions: This study shows the efficacy and safety of focused ultrasound, using the UltraShape™ *Contour I*, as a non-invasive transdermal method for reducing unwanted fat deposits in the body. Multiple treatments combined with appropriate patient and treatment area selection can produce dramatic improvements in body contour. *Lasers Surg. Med.* 39:315–323, 2007. © 2007 Wiley-Liss, Inc.

Key words: body contouring; focused ultrasound; non-invasive lipolysis

INTRODUCTION

Greater demand in body aesthetic medicine for non-invasive procedures has motivated researchers to develop

new techniques to replace traditional treatments for body contouring. In the past, the only way to achieve dramatic improvement in body silhouette was by removing local fat deposits through liposuction or other surgical procedures. These surgical approaches have drawbacks for patients (hospitalization, general or tumescent anesthesia, pain, post-operative bruising and swelling, long post-operative recovery, and other risks inherent to surgical procedures) and create technical challenges for surgeons [1–4]. Such drawbacks prompted the development of a new device (*Contour I*, UltraShape Ltd, Tel Aviv, Israel) to reduce subcutaneous fat volume in areas that would normally be treated by liposuction, and to provide significant improvement in the contour of these areas while avoiding invasive techniques and their associated disadvantages.

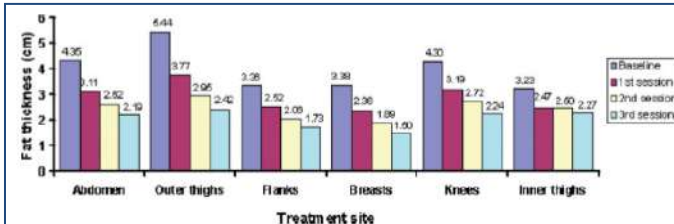
Ultrasound can be used in medicine as a diagnostic method, when used in imaging, or as a therapeutic modality. The UltraShape™ system applies ultrasound in a therapeutic manner. The system emits focused ultrasound waves to deliver concentrated energy into a focal volume at a precise depth in the subcutaneous tissue. This system was designed to use mechanical (non-thermal) energy to disrupt fat cells and without damaging neighboring structures (skin, blood, and lymph vessels, muscles, and nerves), due to their differential susceptibility to mechanical stresses induced by the ultrasound.

The approach of using non-invasive focused ultrasound for tissue disruption differs from other therapeutic ultrasound devices in important ways (Fig. 1). The first and most obvious distinction is between invasive therapeutic ultrasound, such as is used in internal ultrasound assisted liposuction (UAL), and external therapeutic ultrasound of various types. Among external ultrasound treatments, the approach of tissue or substance destruction should be distinguished from tissue warming. As a rough generalization of currently marketed systems (which are

*Correspondence to: Prof. J. Moreno-Moraga, Instituto Médico Laser Pº General Martínez Campos, 33 #28010, Madrid, Spain.
E-mail: jmoreno@iml.es

Accepted 1 December 2006
Published online 26 April 2007 in Wiley InterScience
(www.interscience.wiley.com).
DOI 10.1002/lsm.20078

Lasers in Surgery and Medicine 39:315–323 (2007)



Fat thickness change by treatment

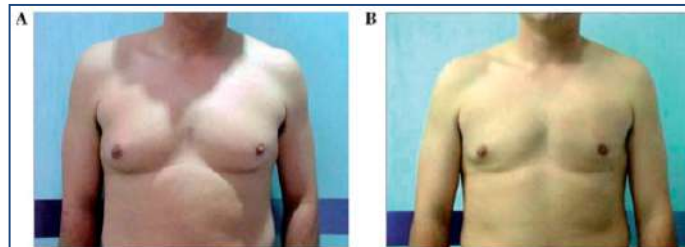


Fig. 5. Pseudo-gynecomastia (A) before treatment and (B) after treatment.

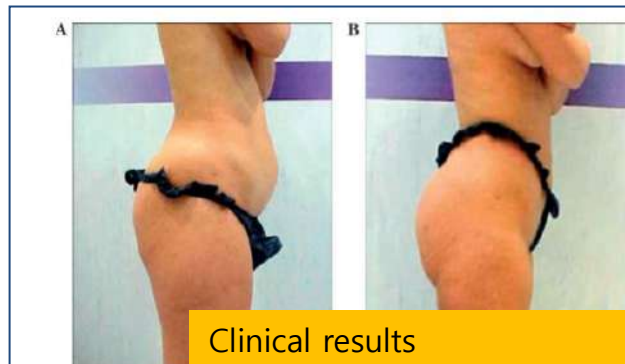


Fig. 6. Abdomen (A) before treatment and (B) after treatment.

Clinical results

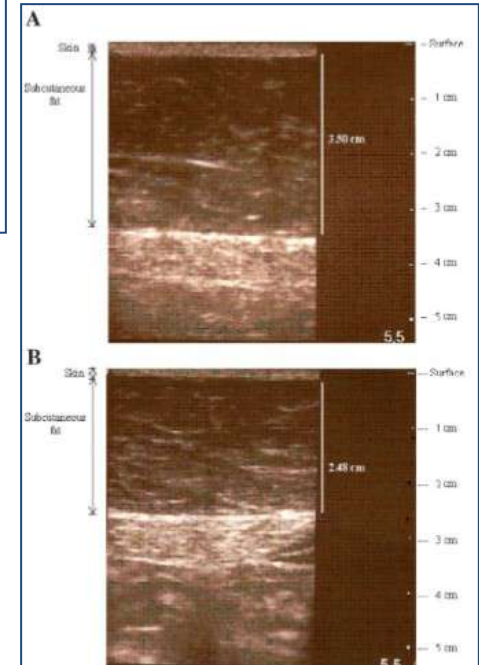


Fig. 3. Fat thickness assessment by ultrasound (A) before treatment and (B) after treatment.

Fat thickness change by treatment

Literature Review of HIFU

❖ Efficacy analysis of HIFU treatment

JOURNAL OF COSMETIC AND LASER THERAPY
<https://doi.org/10.1080/14764172.2018.1511987>

Taylor & Francis
Taylor & Francis Group

Check for updates

Efficacy and safety of noninvasive focused ultrasound for treatment of subcutaneous adiposity in healthy women

Viviane Mancinelli Fonseca^a, Priscila Soares Campos^a, Thays Fernanda Certo^a, Luana Tais de-Faria^a, Priscila Bianchi Juliano^b, Dennys Esper Cintra^c, Richard Eloi Liebano^d, Caroline da Silva^{e,f,g}, Renata Michelini Guidi^{c,h,i}, and Estela Sant'Ana^{d,j}

^aDermatofunctional Aesthetics and Cosmetic Department, Ibramed Center for Education and Advanced Training (CEFAI), Amparo, Brazil; ^bDermatofunctional Clinical Physiotherapist, Campinas, Brazil; ^cLaboratory of Nutritional Genomics, School of Applied Sciences, University of Campinas (UNICAMP), Campinas, Brazil; ^dPhysiotherapy Department, Federal University of São Carlos (UFSCar), São Carlos-SP, Brazil; ^eResearchers at Research, Development & Innovation Department Ibramed, Ibramed Research Group (IRG), Amparo, Brazil; ^fClinical Laboratory, Ibramed Center for Education and Advanced Training (CEFAI), Amparo, Brazil; ^gDepartment of Physical Education, Institute of Biosciences, São Paulo State University (UNESP), Rio Claro, Brazil; ^hBiomedical Engineering Department, Faculty of Electrical Engineering and Computing, University of Campinas (UNICAMP), Campinas, Brazil

ABSTRACT
 Introduction: In recent years, a new method focused ultrasound (FUS) has been used in the treatment of localized fat. The objectives of this work were to evaluate the efficacy and safety of the FUS in the treatment of abdominal subcutaneous fat. Materials and Methods: Thirty-one healthy women were divided into two groups: G1 (N = 7), 6 sessions, 3 passes, once a week and G2 (N = 23), 10 sessions, 2 passes, twice a week. Outcome measures were reduction of circumference and fat thickness. Safety monitoring included laboratory testing (serum lipids profile and liver function tests) and adverse events were also assessed. Patient satisfaction and tolerance questionnaires were also applied. One patient underwent abdominoplasty and received a single session of FUS 24 h before surgery and a skin sample was collected for histological analysis. Results: The results showed improvement in body contouring and reduction of the thickness of the fat layer observed by ultrasonography in both groups: G1 (P < 0.001) and G2 (P < 0.0001). The histology showed disrupted adipocytes and collapsed membranes 24 h after the FUS treatment. Conclusion: FUS represents an effective and safe treatment for reducing localized adipose tissue by adipocytolysis.

ARTICLE HISTORY
 Received 18 August 2017
 Accepted 7 August 2018

KEYWORDS
 HIFU; cavitation; adipocytolysis; adipocyte

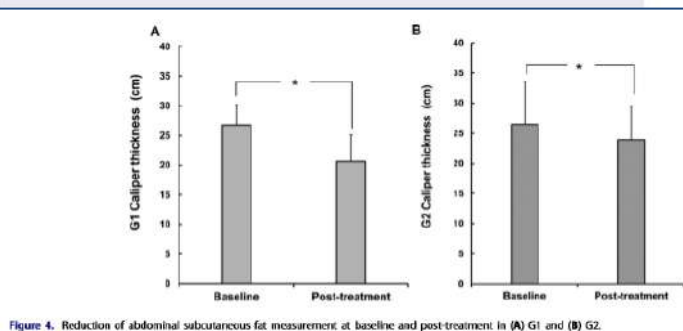
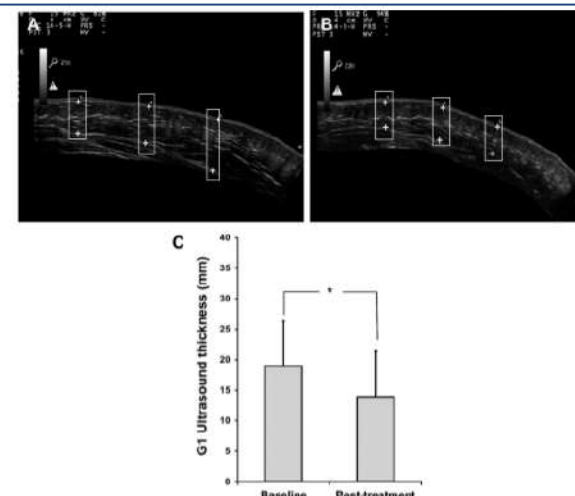
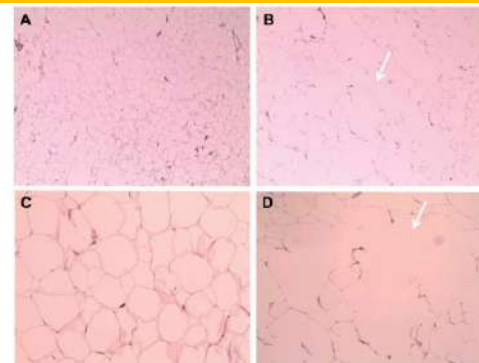


Figure 4. Reduction of abdominal subcutaneous fat measurement at baseline and post treatment in (A) G1 and (B) G2.

The thickness of fat layer was confirmed to be reduced for all groups according to the analysis using the caliper



The thickness of fat layer was confirmed to be reduced significantly according to the fat layer analysis with ultrasound



Dissolved fat cell (arrow) after 24 hours of HIFU treatment on human fat cell

Clinical Program





08

Clinical Program

❖ Skin thickness of KOREAN adult

	Epidermis (mm)	Dermis (mm)	Total skin Thickness (mm)
Forehead	0.1	0.8	0.9
Periorbital	0.05	0.47	0.53
Cheek	0.1	1.1	1.2
Chin	0.08	0.75	0.83
neck	0.1	1.3	1.4

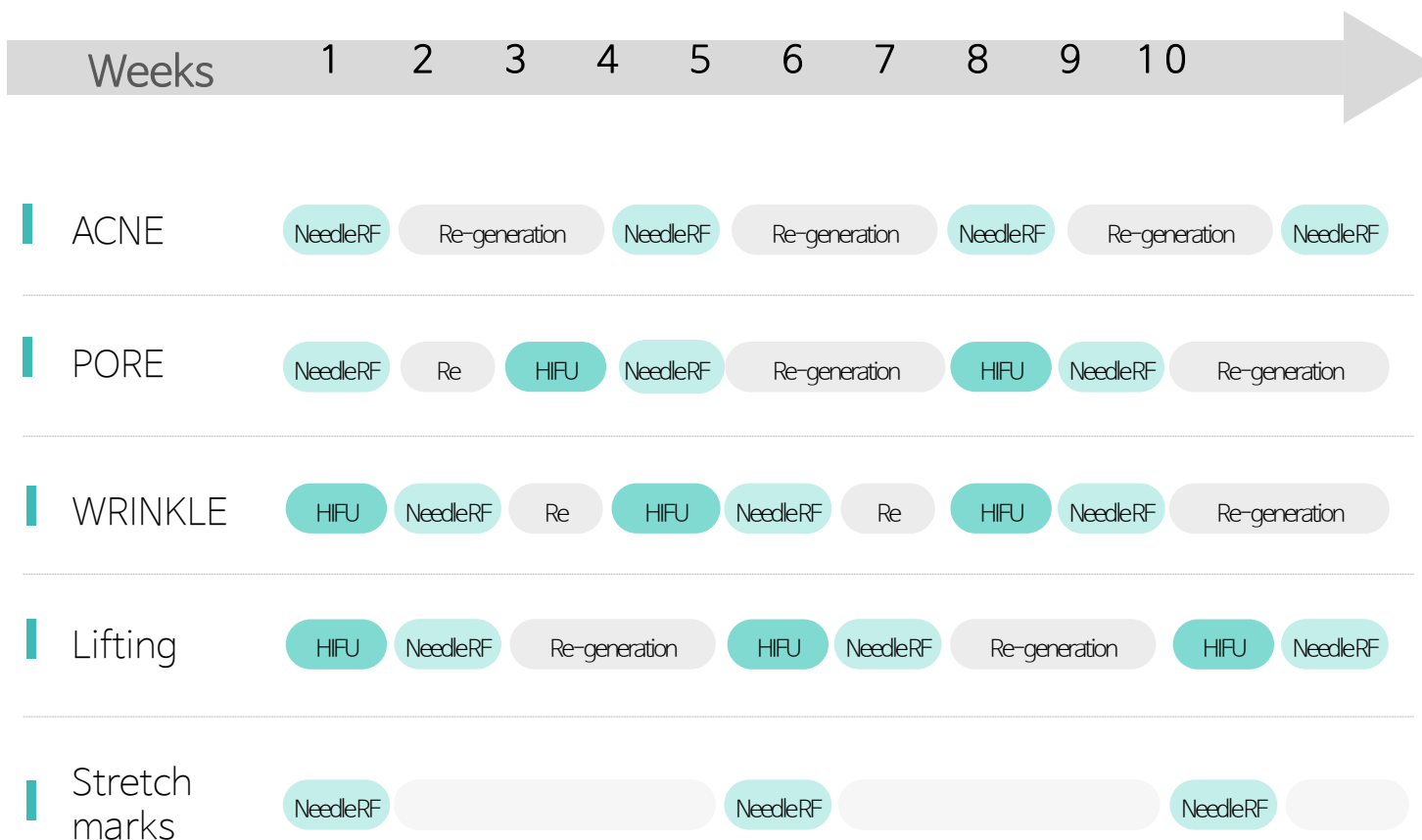
(Surg Radiol Anat.2002 Aug-Sep;24(3-4):183-9.Skin)



08

Clinical Program

❖ Treatment guide



Pre-clinical trial



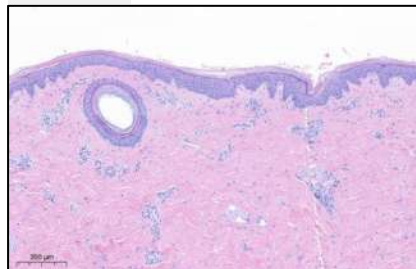
09

Pre-clinical trial

❖ Comparison result when RF level of RF needle handpiece is '0' and when it is '10'

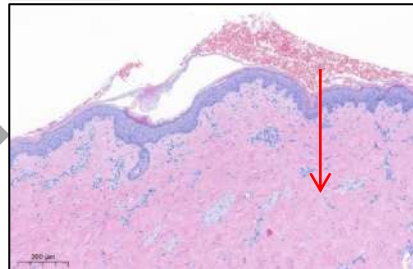
※ RF
level
'0'

before



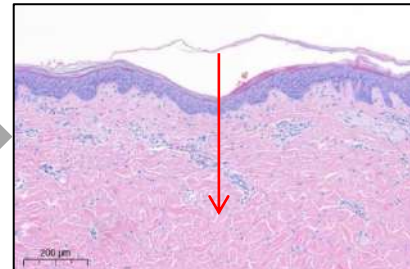
Normal skin structure

1 day



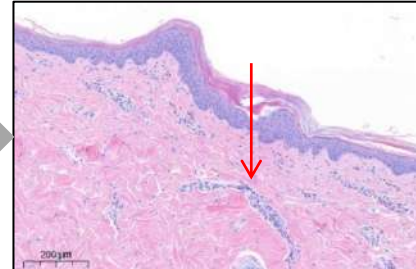
Differentiation of stratum corneum
along the needle, None change of dermis

7 day



Normalization of skin

30 day

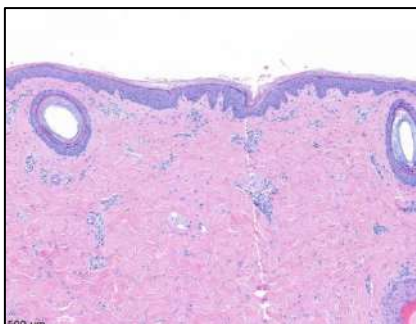


Normalization of skin

✓ *Only the wound healing effect by the needle was temporarily confirmed, but collagen change of the dermal layer was not observed*

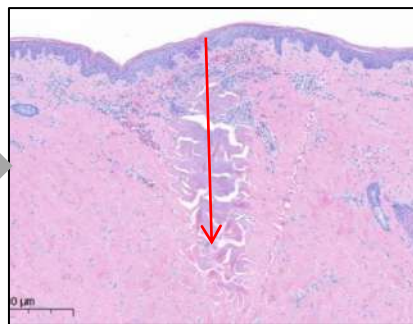
※ RF
level
'10'

before



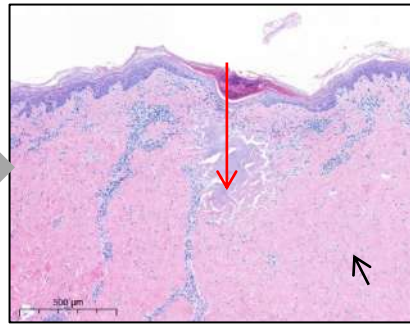
Normal skin structure

1 day



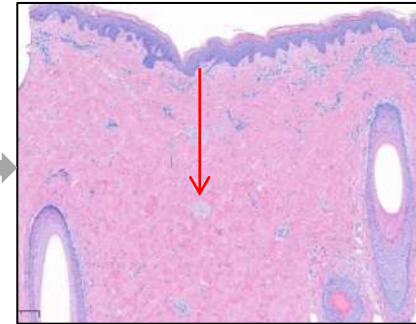
Wound healing response progresses along
the extent of thermal damage zone to dermis

7 day



Re-epithelization of epidermis on needle
Site Collagen remodeling

30 day



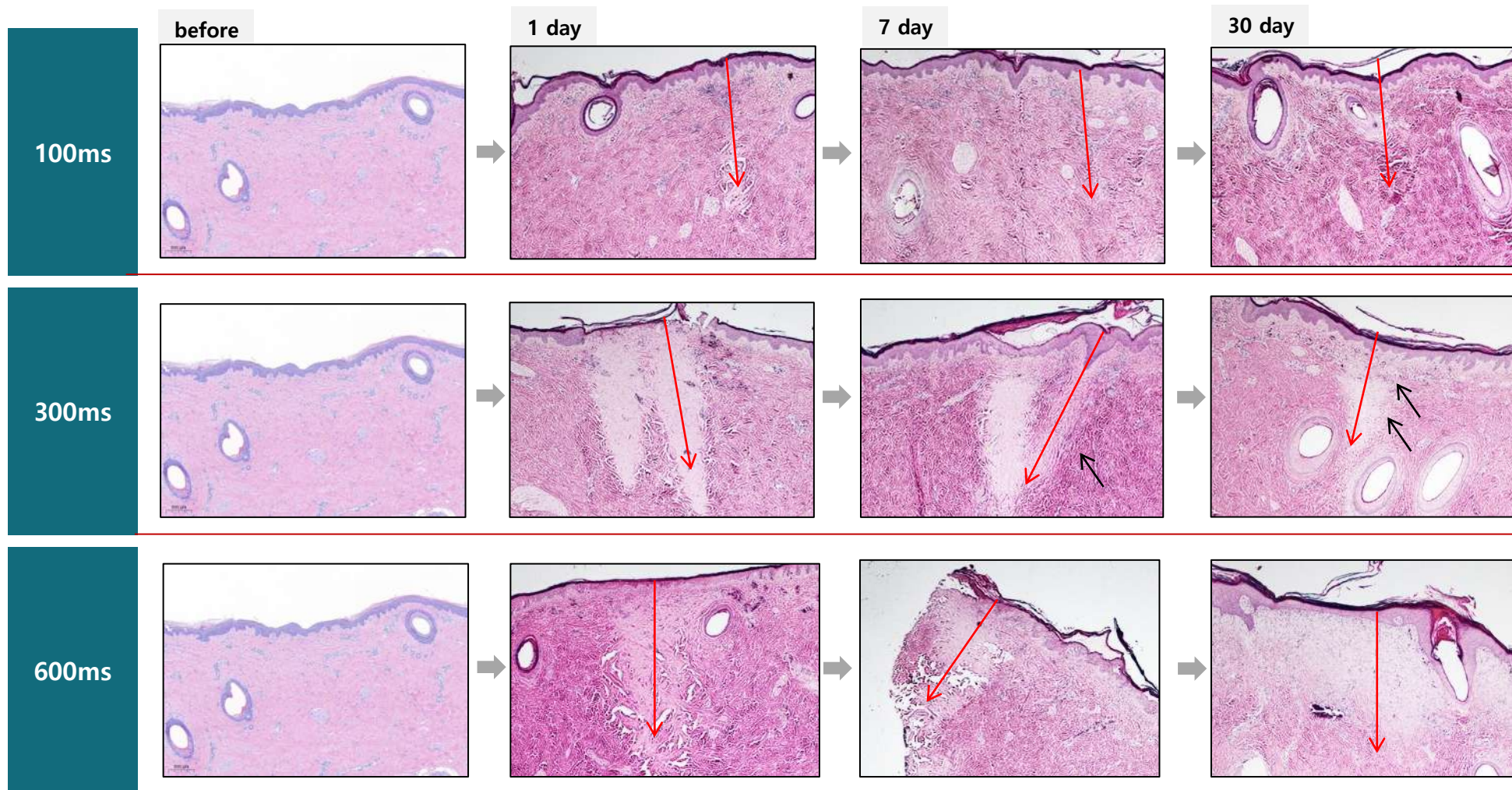
Recovered skin structure
Enrichment of collagen structure in dermis

✓ *Remodeling of the dermis and epidermis due to thermal damage to the skin by needle radiofrequency.*

09

Pre-clinical trial

❖ Cell aspect of on time when RF Level of the RF needle handpiece is '10'



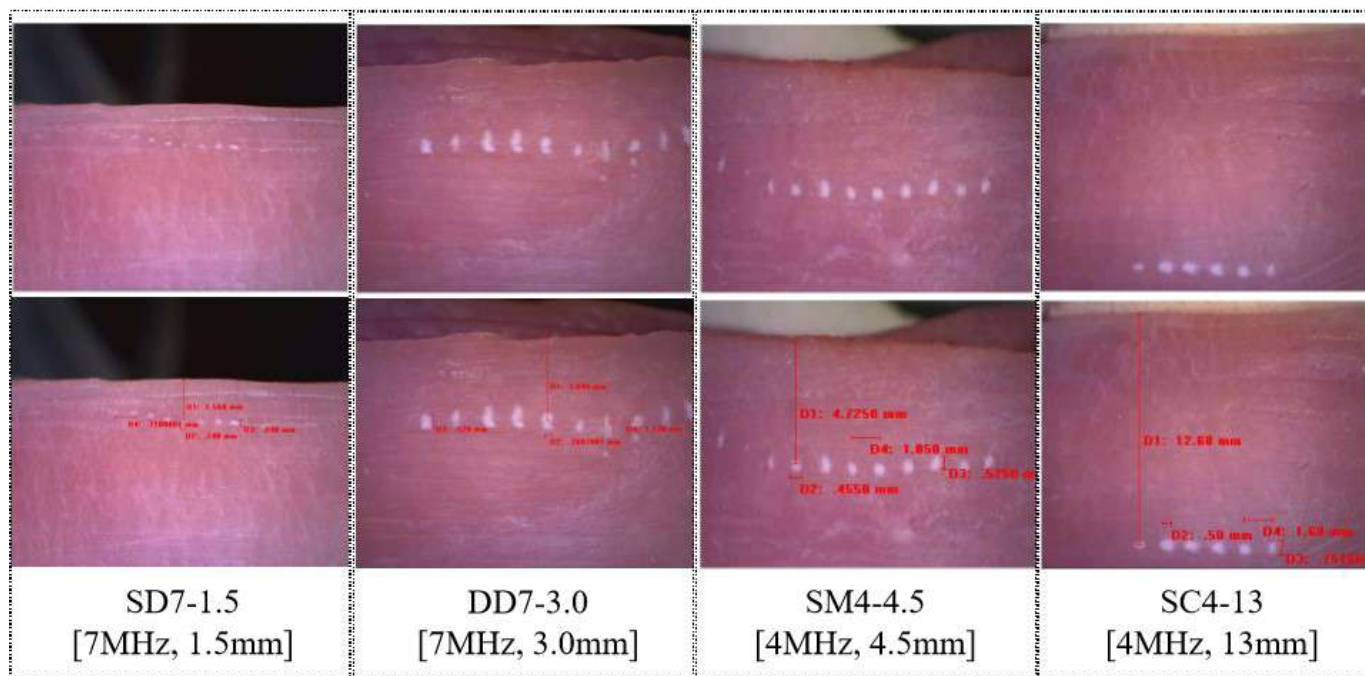
✓ *The longer the on time of the RF energy, the wider the thermal damage site and thus the collagen structure of the dermal layer is strengthened*



09

Pre-clinical trial

❖ Coagulation Test of HIFU handpiece



Output (J)	0.25	1.0J	0.9J	1.7J
Focus depth (mm)	1.56	3.04	4.72	12.60
X axis length (mm)	0.14	0.26	0.45	0.50
Y axis length (mm)	0.24	0.52	0.52	0.75
Focus interval (mm)	0.72	1.14	1.05	1.60



Clinical Result



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	Treatment
50s	Needle RF / 3 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	Treatment
60s	Needle RF+HIFU / 1 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	Treatment
50s	Needle RF+HIFU / 5 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	Treatment
34s	Needle RF+HIFU / 5 times



10

Clinical Result

❖ Before & After



[Before]



[After]

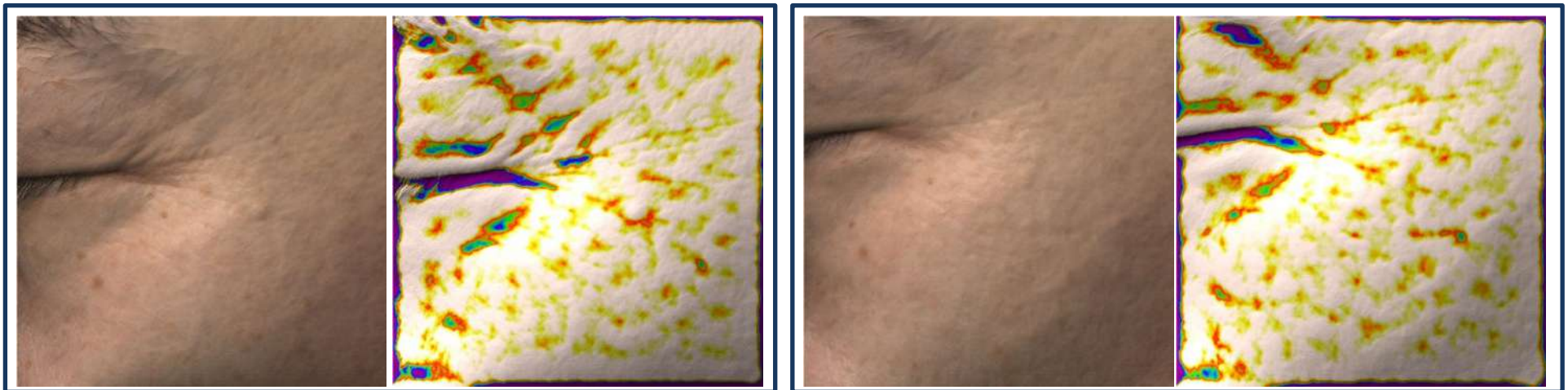
Age	Treatment
34s	Needle RF+HIFU / 3 times



10

Clinical Result

❖ Before & After



[Before]

[After]

Age	Treatment
46s	Needle RF / 5 times

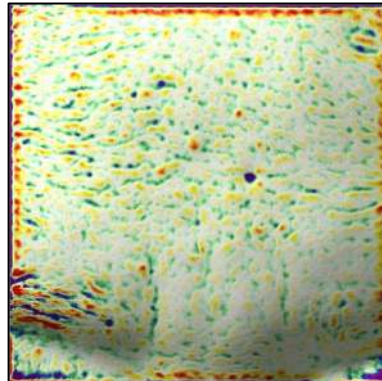
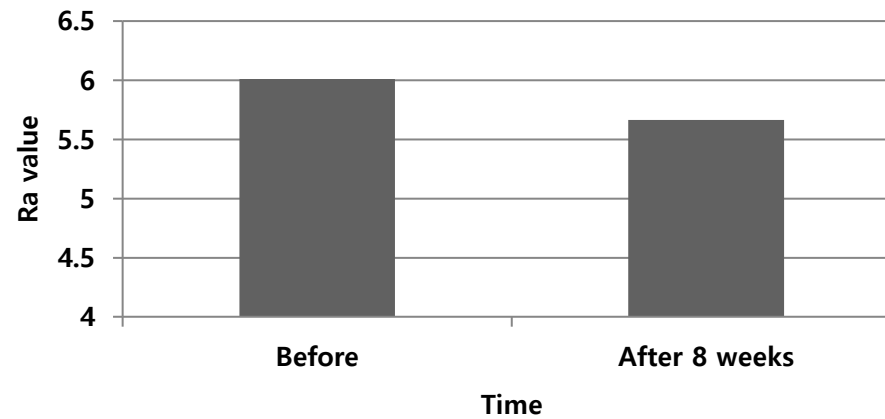


10

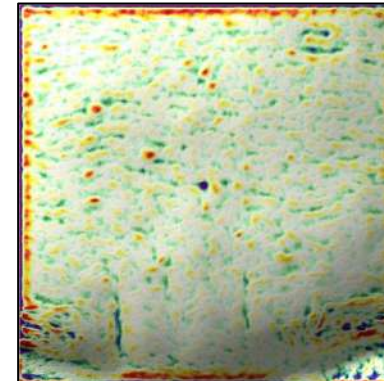
Clinical Result

❖ Before & After

Skin texture



Before



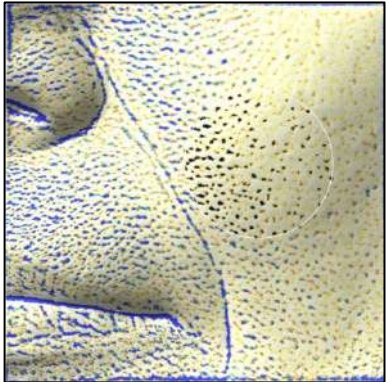
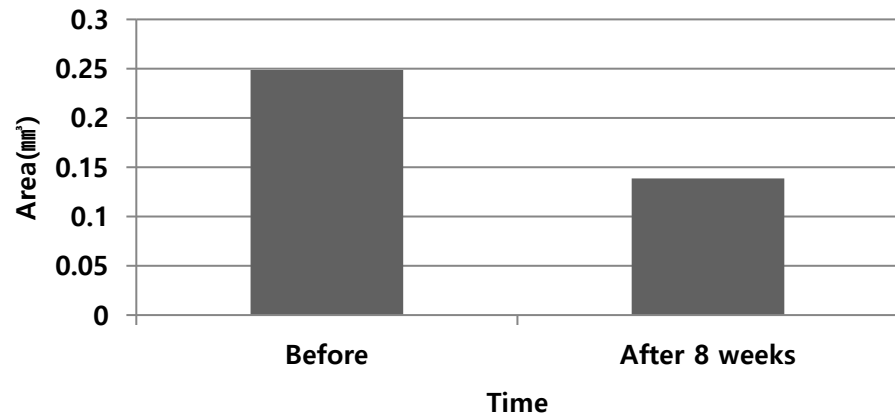
After 8 weeks



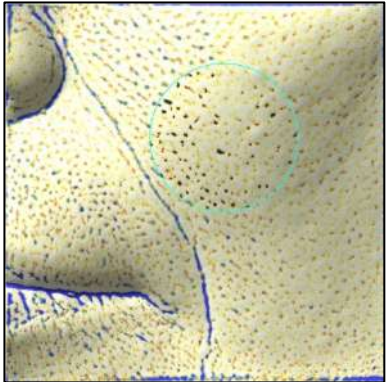
10

Clinical Result

❖ Before & After
Pore



Before



After 8 weeks

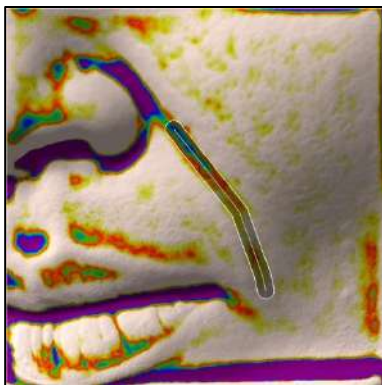
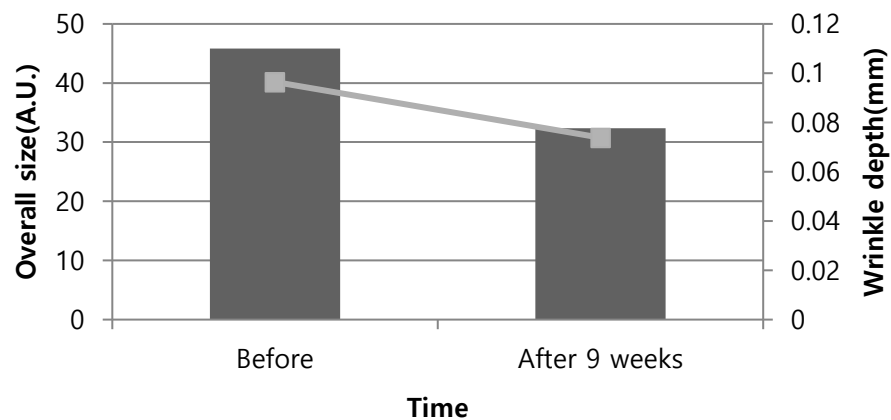


10

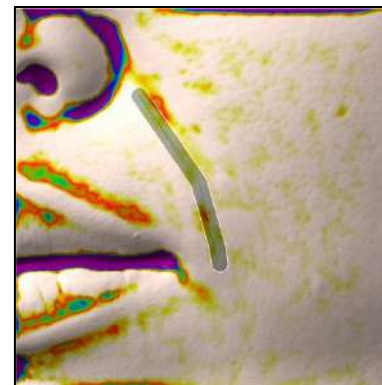
Clinical Result

❖ Before & After

Wrinkle



Before



After 9 weeks



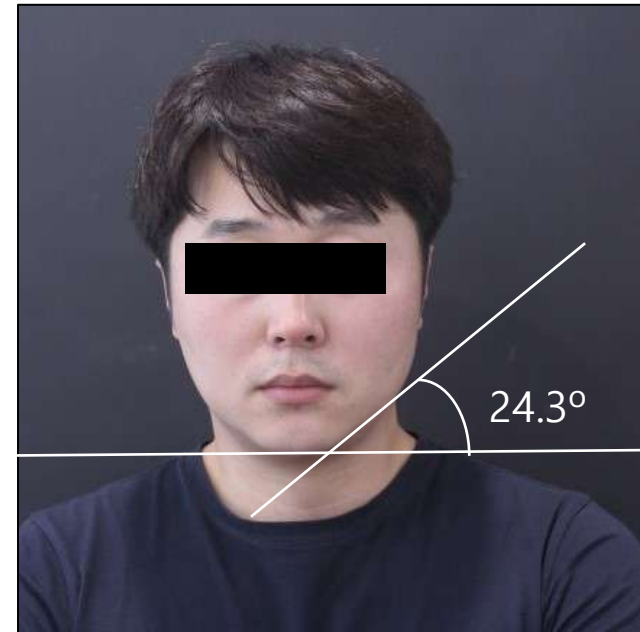
10

Clinical Result

❖ Before & After



Before



After 9 weeks



10

Clinical Result

❖ Before & After



[Before]



[After]

Sex / Age	Treatment
M / The latter of 20's	1 months later
	2 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	50s
Sex	M
Treatment	HIFU + Needle RF 3 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	50s
Sex	M
Treatment	HIFU + Needle RF 3 times



10

Clinical Result

❖ Before & After



[Before]



[After]

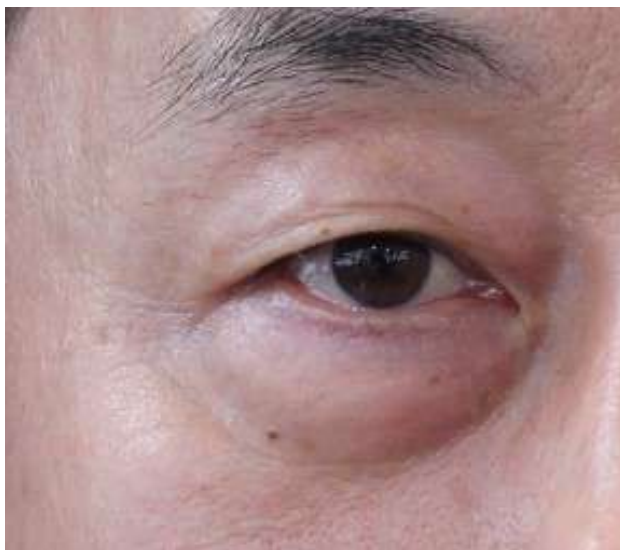
Age	40s
Sex	M
Treatment	HIFU + Needle RF 3 times



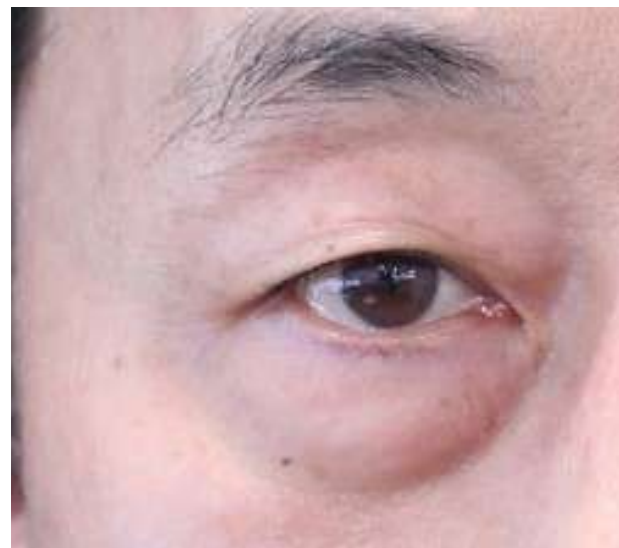
10

Clinical Result

❖ Before & After



[Before]



[After]

Age	40s
Sex	M
Treatment	HIFU + Needle RF 5 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	40s
Sex	M
Treatment	HIFU + Needle RF 5 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	40s
Sex	M
Treatment	HIFU + Needle RF 5 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	40s
Sex	M
Treatment	HIFU + Needle RF 5 times



10

Clinical Result

❖ Before & After



[Before]



[After]

Age	30s
Sex	F
Treatment	Needle RF 9 times



11

SPECIFICATIONS

	RF needle system	HIFU system
Energy Type	2MHz Radio frequency	• 7MHz ultrasound • 4MHz ultrasound
Handpiece	RF Needle handpiece	HIFU handpiece
Pin, Cartridge	• 10 pin (Insulated, Non-insulated) • 25 pin (Insulated, Non-insulated) • 36 pin (Insulated, Non-insulated)	• SD 7-1.5 • DD 7-3.0 • SM 4-4.5
Input Power	AC 100 ~ 240 V, 50/60 Hz	
Dimension (WxDxH mm)	497 x 437 x 329	

FOCUS_{DUAL}