SYLFIRM X

# Clinical Paper Summary

Victory of Life

ViOL

# Classification of Clinical Papers by Indication

| - | Continuous Wave | Pulsed Wave |
|---|---|---|
| Skin Reaction | 1 | 1 |
| Skin Rejuvenation | 4 | 3 |
| Scar | | 1 |
| Acne or/and Acne Scars | 5 | 2 |
| Pigmented Lesion | | 8 |
| Vascular Lesion | | 2 |
| Total | 10 | 17 |

**Total 27**

# Contents

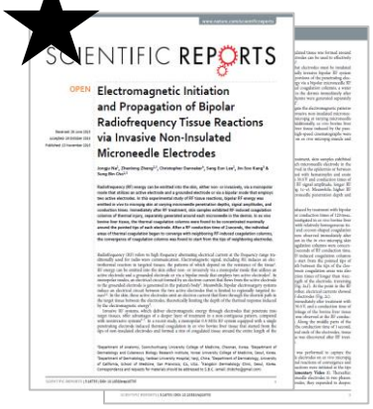
**Continuous Wave**

- Skin Reaction: Na Effect _4
- Skin Rejuvenation _5
- Acne or/and Acne Scar _10

**Pulsed Wave**

- Skin Reaction _15
- Pigmented Lesion _17
- Vascular Lesion _30
- Acne & Acne Scar _32
- Scar _34
- Skin Rejuvenation _35

# Continuous Wave: Skin Reaction




## Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes SCIE

By Jongju Na, Zhenlong Zheng, Christopher Dannaker, Sang Eun Lee, Jin-Soo Kang, and Sung Bin Cho

*Scientific Reports,* 2015; 5: 16735

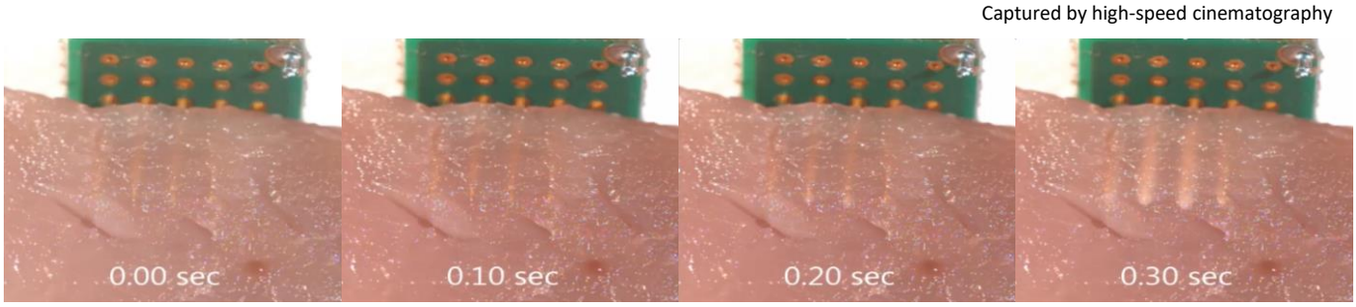
**Methods**

- For an experimental study of RF tissue reactions, bipolar RF energy with non-insulated microneedle electrodes (CELFIRM; ViOL) were delivered to in vivo/ex vivo micropig skin and ex vivo bovine liver tissue at varying microneedle penetration depths, RF signal amplitudes, and RF conduction times.

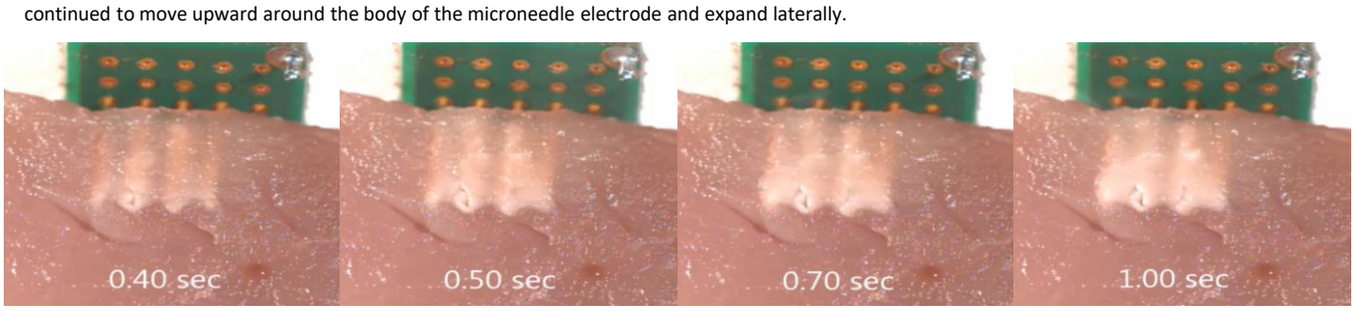
**Results**

- It was found in both micropig skin and bovine liver tissue that coagulation was initiated at the tip of each needle (electrode) when bipolar RF is transmitted to the tissue through non-insulated needles.
- As the conduction time increased, the coagulation zone expanded into a droplet- or cocoon-like shape with minimal relatively few thermal effects on the epidermis - also known as the “Na Effect”

Bipolar RF with non-insulated microneedles irradiated on ex vivo micropig skin at 50V, for 0-7 seconds
Captured by high-speed cinematography




< 300ms : Tissue reactions were initiated at the tips of the microneedle electrodes that penetrated into the tissues. As the reactions propagated up from the tips of the microneedle electrodes, they expanded to deeper, wider, and higher areas around the microneedle. After a brief delay, the reactions continued to move upward around the body of the microneedle electrode and expand laterally.




> 300ms : The propagation of inter-electrode currents between neighboring electrodes became apparent first between the tips of the electrodes, then second between the mid-portions of the electrodes, and lastly between the entire length of the electrodes. After complete convergence of all individual coagulation areas, tissues then began to show vaporization and carbonization.

# Continuous Wave: Skin Rejuvenation


## Comparison of the effects of fractional microneedle radiofrequency and microneedling on modulating the senescent fibroblast milieu in aged skin SSCI

By Jung Min Hwang, Soo Hyun Lee, Eun Jae Baek, Hye-Rin Charlotte Kim, Jang-Hee Oh, Ji Su Lee & Si-Hyung Lee

*Scientific Reports,* (2025) 15:18296

**Methods**

- 30 subjects with periorbital wrinkles were treated with both radiofrequency microneedling (RFMN) and microneedling (MN) (SYLFIRM X; ViOL) in a double-blind, randomized, split-face controlled clinical trial.
- Patients
  - 30 Korean women aged ≥60 years with visible periorbital wrinkles (final analysis: 29 participants; histological analysis: 26).
- Treatment
  - **RFMN (Microneedle Radiofrequency) on one side:** CW4, 1 mm depth, energy level 3–5 (2.42–2.74 J/shot), one pass.
  - **MN (Microneedling only) on the other side**: same needle depth, no RF energy.
  - 4 treatment sessions at 4-week intervals

**Results**

- MNRF-treated sides showed faster and greater wrinkle reduction than the MN-treated side, with significant changes noted at both 3 and 5 months. Elasticity also improved more on the MNRF side.
- Skin hydration increased and TEWL(Transepidermal Water Loss) decreased significantly on the MNRF side at 5 months, indicating better barrier function.
- MNRF increased non-senescent (HSP47+) fibroblasts and reduced senescent ($p16^{INK4\ A+)}$ fibroblasts, unlike MN.
- Higher levels of procollagen-1, collagen, and elastin were observed in the papillary dermis after MNRF.
- Subjects with greater reduction in senescent fibroblasts showed better collagen and hydration outcomes, supporting a regenerative mechanism.
- Adverse effects were mild and similar in both groups, with no serious events reported.

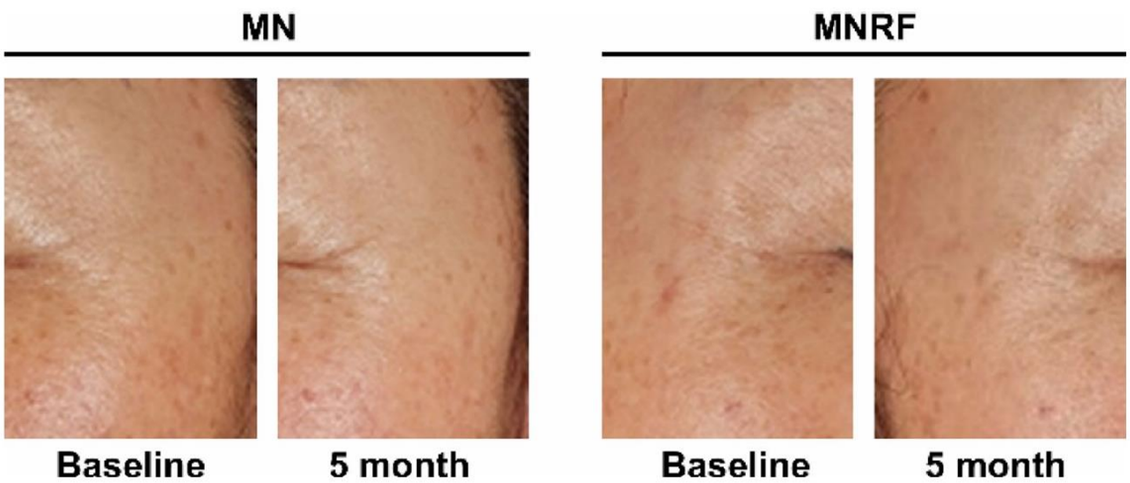
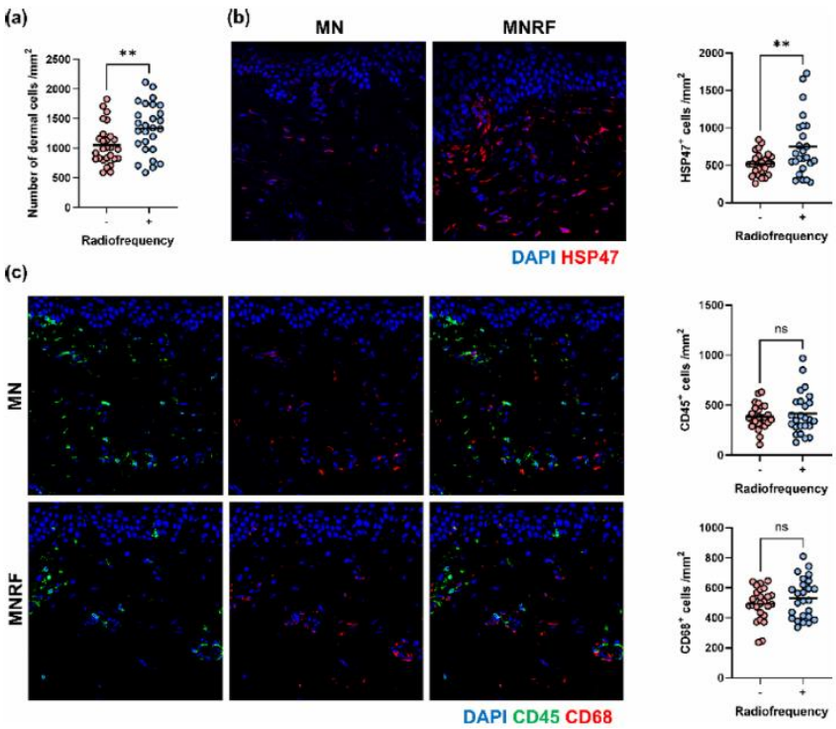



**Fig. 2**. Split-face comparison in a 69-year-old woman treated with MN or MNRF on each side of the face.

# Continuous Wave: Skin Rejuvenation

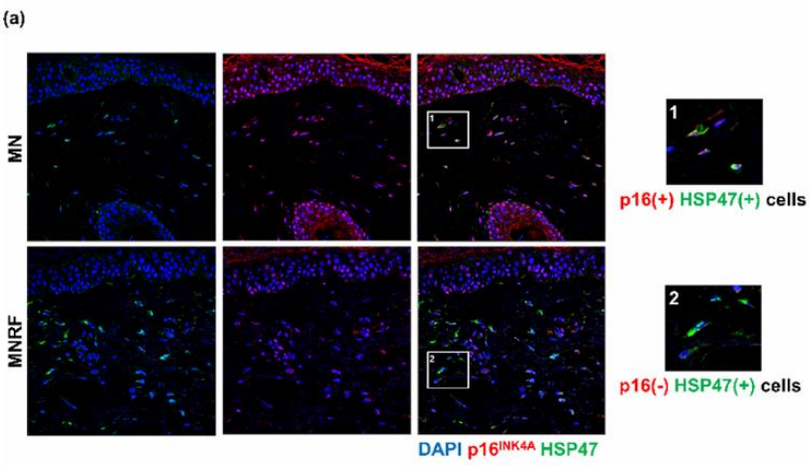



Changes in the cellular milieu in the dermis following MNRF treatment.

(a) Quantification of the total cell number in the dermis after MN and MNRF treatments.

(b) Representative images of immunofluorescence staining for the fibroblast marker, HSP47 (red), and DAPI (blue) in the skin treated with MN and MNRF. The graph on the right indicates the number of HSP47-positive dermal fibroblasts after MN and MNRF treatments (n = 25).

(c) Representative images of immunofluorescence staining for the leukocyte marker, CD45 (green); and macrophage marker, CD68 (red); and DAPI (blue) in skin treated with MN and MNRF. The graphs on the right represent the number of CD45-positive leukocytes and CD68-positive macrophages in the dermis after MN and MNRF treatments (n = 25). Original magnification ×400. Statistical significance: **p < 0.01, ns indicates no significance




Repopulation of senescent fibroblasts by non-senescent fibroblasts after MNRF treatment.

(a) Representative images of immunofluorescence staining for the senescence marker, p16INK4 A, and fibroblast marker, HSP47, after MN and MNRF treatments.

# Continuous Wave: Skin Rejuvenation

**Comparison of efficacy and safety of fractional radiofrequency and fractional Er:YAG laser in facial and neck wrinkles: Six-year experience with 333 patients SCIE**

Zehra A. Serdar, and Asli Tatliparmak

*Dermatologic Therapy,* 2019; 32(5): e13054

**Methods**

- 333 patients with facial wrinkles were treated with fractional RF (SCARLET; ViOL) and fractional Er:YAG laser for skin rejuvenation.
  - Patients: aged between 36 and 85 years, mean age of 49.8±7.9 years
    - Fractional RF group : 133 patient (57.1% Glagou type II, 53.4% Fitzpatrick skin type III)
    - Fractional Er:YAG laser group : 200 patients (53.5% Glagou type II, 60.5% Fitzpatrick skin type III)
  - Treatments : 3 treatment sessions at one month intervals
    - Fractional RF group : F mode, power 8, 1.0-1.5mm on periorbital area, 2.0-2.5mm on nasolabial, jaw line and perioral area, 3.0-3.5mm on submental and neck area
    - Fractional Er:YAG laser group : PSO3 handpiece, short pulse mode, 40-50J/cm2, 10hz on periorbital area / F-runner handpiece, short pulse mode, 40-50J/cm2, 10hz on nasolabial, jawline and perioral area / R11 handpiece, smooth mode, 2J/cm2, 10hz on submental and neck area

❖ Glagou wrinkle scale : type I no wrinkles, type II wrinkles in motion, type III wrinkles at rest, type IV only wrinkles

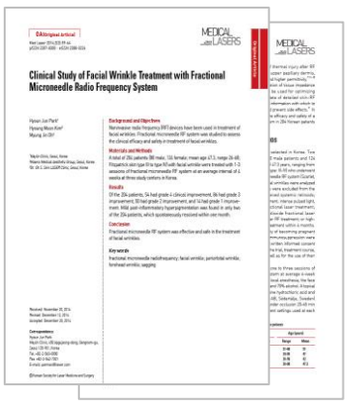
**Results**

- Fractional RF treatment was more effective for perioral, nasolabial, jawline, neck areas whereas fractional Er:YAG laser treatment was more effective for the periorbital areas.
- There are no statistically significant difference in side effects between two treatment groups.


(A), (C) Before
(B), (D) 2 months after 3 sessions of fractional RF treatment


(A), (C) Before
(B), (D) 2 months after 3 sessions of fractional Er:YAG treatment

# Continuous Wave: Skin Rejuvenation




## Clinical Study of Facial Wrinkle Treatment with Fractional Microneedle Radio Frequency System ESCI

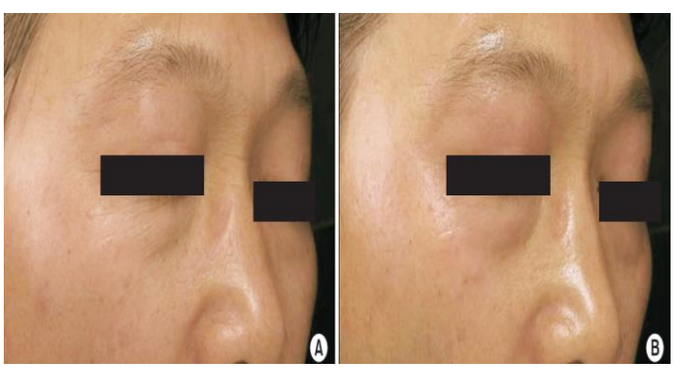
By Hyoun Jun Park, Hyoung Moon Kim, and Myung Jin Oh
*Medical Lasers,* 2014; 3(2): 59-64

**Methods**

- 204 Korean patients with facial wrinkles at 3 study centers, were treated with fractional microneedle RF system (SCARLET; ViOL).
  - Patients: 80 male, 124 female, mean age of 47.3 years, ranging from 26 to 68 years, Fitzpatrick skin type III-IV
  - Treatment: 0.8-3.0mm, level 6-8, 100-200ms, 1-3 passes, 1-3 sessions at average 4-week intervals

**Results**

- Of 204 patients, 54 had near total improvements (>75%), 86 had marked improvement (51-75%), 50 had moderate improvement (26-50%), and 14 had minimal improvement (0-25%).
- Mild post-inflammatory hyperpigmentation was found in only 2 patients, which spontaneously resolved within one month.




(A) Baseline
(B) 2 months after 2 sessions of fractional RF treatment


(A) Baseline
(B) 3 months after 3 sessions of fractional RF treatment


(A) Baseline
(B) 2 months after 2 sessions of fractional RF treatment

# Continuous Wave: Skin Rejuvenation

## Skin Rejuvenation by Microneedle Fractional Radiofrequency Treatment in Asian skin; Clinical and Histological Analysis

**ESCI**

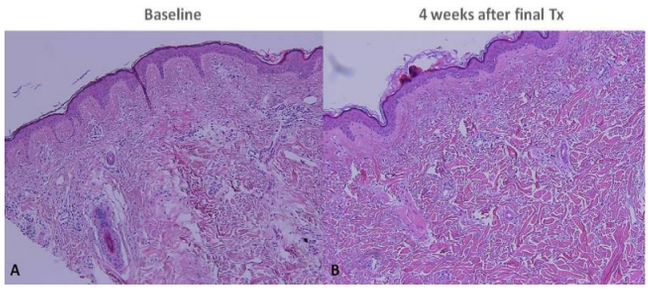
By Kyu Young Seo, Moon Soo Yoon, Dong Hyun Kim, and Hee Jung Lee
*Lasers in Surgery and Medicine,* 2012; 44: 631-636

**Methods**

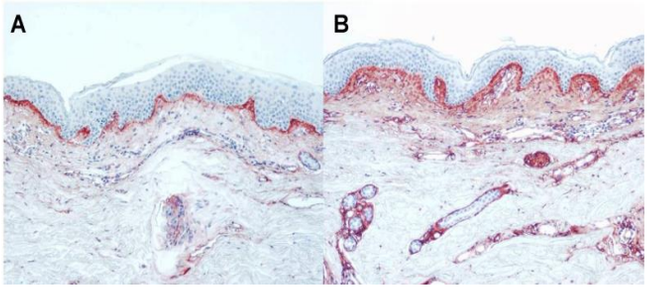
- 25 female patients with various signs of aging such as visible lines, wrinkles, and widened pores, were treated with fractional RF device (SCARLET; ViOL).
  - Patients: ages from 41 to 64 years, mean age 54.2±3.21, Fitzpatrick skin types III and IV
  - Treatment: a single pass, no-overlapping over the indicated area, 0.5mm on periorbital area, 0.8mm on forehead, 1mm on chin and temple, 2mm on cheeks
  - 3 sessions at 4-week intervals.

**Results**

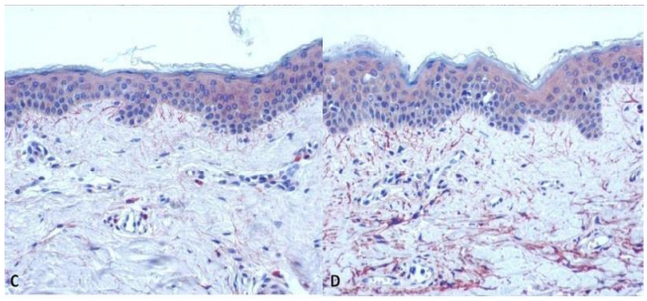
- All patients showed clinical improvement on physician's global assessment and patient satisfaction scores.
- Among objective biophysical measurements, improvement in hydration and skin roughness was noticed.
- Histological examination revealed marked increase in dermal thickness, dermal collagen content and dermal fibrillin content.
- Side effects were minimal.



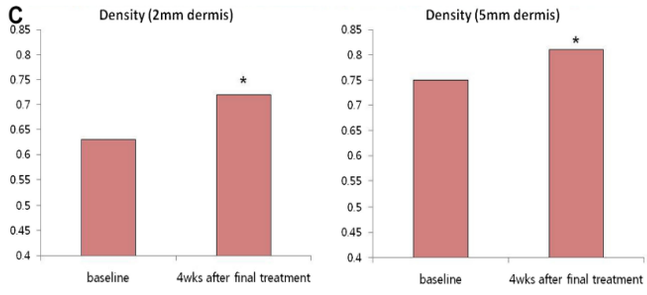

Immunohistochemical staining for collagen
(A) Baseline
(B) 4 weeks after the final treatment




Immunohistochemical staining for procollagen-1
(A) Baseline
(B) 4 weeks after the final treatment

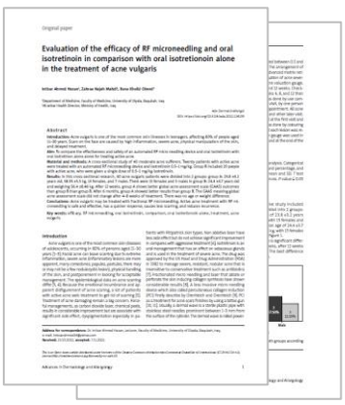



Immunohistochemical staining for fibrillin-1
(C) Baseline
(D) 4 weeks after the final treatment




Quantitative assessment of the density of procollagen-1 within 0.2mm and 0.5mm of dermis from basement membrane

# Continuous Wave: Acne or/and Acne Scar



## Evaluation of the efficacy of RF microneedling and oral isotretinoin in comparison with oral isotretinoin alone in the treatment of acne vulgaris SCIE

By Intisar Ahmed Hasan, Zahraa Najah Mahdi, and Rana Khalid Obeed
*Advances in Dermatology and Allergology,* 2023; 40(1): 111-114

**Methods**

- A cross-sectional comparative study of 40 patients with moderate acne vulgaris was performed.
  - Group A
    - 20 Patients : mean age 23.8 ±3.2 years, mean weight 58.95 ±5.5 kg, 13 females, and 7 males
    - Treatment : Combined therapy with an automated RF microneedling device (SCARLET; ViOL) and isotretinoin 0.5-1 mg/kg in a single dose for 24 weeks with a cumulative dose of 120-150 mg/kg
  - Group B
    - 20 Patients : mean age 24.4 ±3.7 years, mean weight 56.4 ±8.46 kg, 15 females, and 5 males
    - Treatment : Oral isotretinoin monotherapy. Isotretinoin 0.5-1 mg/kg in a single dose for 24 weeks with a cumulative dose of 120-150 mg/kg

**Results**

- After 12 weeks, group A showed better global acne assessment scale (GAAS) outcomes than group B
- After 6 months, group A showed better results than group B.

**Table 4.** Difference in study variables for both groups

| Variables | Type | *N* | Mean | SD | *P*-value |
|---|---|---|---|---|---|
| Age | Group A | 20 | 23.80 | 3.2 | 0.6 |
| | Group B | 20 | 24.40 | 3.7 | |
| Weight | Group A | 20 | 58.95 | 5.5 | 0.26 |
| | Group B | 20 | 56.40 | 8.4 | |
| Isotretinoin dose | Group A | 20 | 30.50 | 3.9 | 0.5 |
| | Group B | 20 | 29.50 | 5.1 | |
| GAAS Baseline | Group A | 20 | 4.05 | 0.6 | 0.57 |
| | Group B | 20 | 3.95 | 0.5 | |
| 4 weeks | Group A | 20 | 3.05 | 0.6 | 0.57 |
| | Group B | 20 | 2.95 | 0.5 | |
| 8 weeks | Group A | 20 | 1.85 | 0.5 | 0.17 |
| | Group B | 20 | 2.10 | 0.5 | |
| 12 weeks | Group A | 20 | 0.70 | 0.4 | 0.001 |
| | Group B | 20 | 1.30 | 0.5 | |
| 6 months | Group A | 20 | 0.20 | 0.4 | 0.009 |
| | Group B | 20 | 0.60 | 0.5 | |

*P-value ≤ 0.05 (significant).*





10

# Continuous Wave: Acne or/and Acne Scar

## Safety of Combined Fractional Microneedle Radiofrequency and $CO_2$ as an Early Intervention for Inflammatory Acne and Scarring Treated With Concomitant Isotretinoin SCIE, SSCI

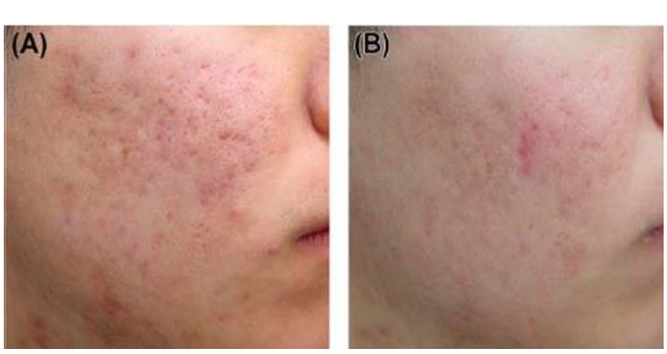
By Jihee Kim, Young In Lee, Jemin Kim, Jin Young Jung, Won Jai Lee, and Ju Hee Lee
*Dermatologic Surgery,* 2020; 46(10): e71-e77

**Methods**

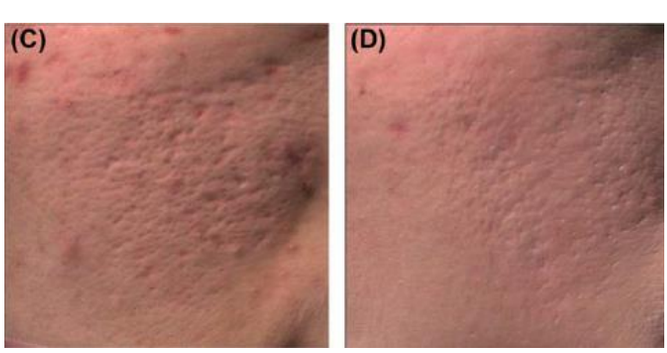
- 71 patients with inflammatory acne and acne scars received combination treatment with fractional microneedling radiofrequency (FMRF) (SCARLET; ViOL) and $CO_2$ ablative fractional laser (AFL).
  - Patients
    - 33 men and 38 women, mean age of 24.8 years (ranging from 19 to 38 years)
    - Fitzpatrick skin types II to IV, Korean (13 type II, 40 type III, 18 type IV)
    - 43 patients with inflammatory lesions and 28 patients with scars only
  - Treatment (Average 3.31 treatments at every 4-6 weeks)
    - FMRF first : 2.0-2.8mm, intensity 8-10 with a density of 25 microscopic treatment zones (MTZ)s/cm²
    - This was followed by AFL: 100mJ with a density of 100 spots/cm², which correlates with 15.6% coverage and an ablation depth of 1,168µm.
- For 43 of the 71 patients, concomitant treatment were conducted with systemic isotretinoin (20mg/daily, targeting 120-150mg/kg) during the intervention or discontinued treatment within 3 weeks.

**Results**

- The mean scar global assessment (SGA) score significantly decreased after 3 sessions of combination treatment.
- Patients with inflammatory acne showed a significant decrease in the number of inflammatory lesions.
- Patients with concomitant low-dose isotretinoin use reported a further decrease in scar global assessment score.
- There were no reported persistent side effects, including prolonged inflammatory reaction or scarring.




(A) Baseline
(B) 4 months after 3 sessions of combination FMRF and AFL treatment while continuing systemic isotretinoin




(A) Baseline
(B) 3 months after 3 sessions of combination FMRF and AFL treatment

# Continuous Wave: Acne or/and Acne Scar


## The Efficacy and Safety of Bipolar Radiofrequency Treatment with Non-Insulated Penetrating Microneedles For Acne Vulgaris And Acne Scars ESCI

By Ganesh S. Pai, Muhamad Kashmar, Young Koo Kim, and Jongju Na
*Medical Lasers,* 2015; 4(1): 10-15

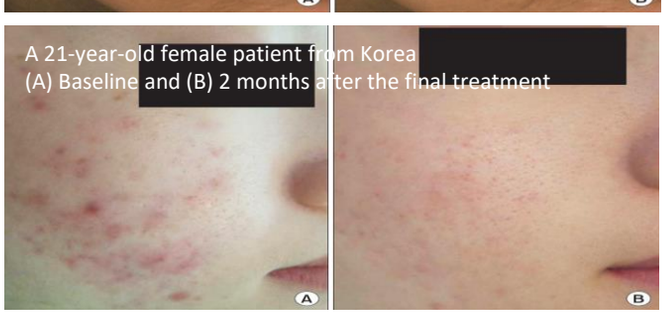
**Methods**

- The medical records and clinical photographs of 316 patients (Indian, Saudi Arabian, and Korean) with moderate to severe acne vulgaris and/or mild to severe acne scarring, treated with bipolar non-insulated microneedle RF treatment (SCARLET; ViOL).
  - Patients: 195 males and 121 females, mean age of 28.2 ranging from 18-34 years; Fitzpatrick skin types IV-V; 119 patients from India, 109 patients from Saudi Arabia and 88 patients from Korea
  - Treatment: 300ms, 3mm, intensity 7, 2 passes over the entire face, additional pass to severe pustular lesions and/or acne scars, 2-4 sessions at 1-month interval

**Results**

- At 2 months after the final treatment, clinical assessment revealed minimal improvement (0-25%) in 21 patients, moderate improvement (26-50%) in 78 patients, marked improvement (51-75%) in 133 patients and near total improvement (>75%) in 84 patients.
- Fractional bipolar RF treatment using non-insulated microneedles was therapeutically effective against all types of acne scarring, including icepick, boxcar, and rolling.
- Distensible retractile and nondistensible scar exhibited remarkable clinical improvement.
- Additional effects of improved skin texture and tone from the delivery of RF energy via the minimally invasive non-insulated microneedles were also observed.
- Inflammatory acne lesions showed improvements in both the number and severity of suppurative lesions.
- No significant differences in overall clinical improvement scores were recorded among the patients from India, Saudi Arabia, and Korea.
- Temporary aggravation of acne vulgaris or folliculitis, which spontaneously resolved within 3 weeks, was noted in 9 patients. Otherwise, no remarkable side effects were recorded.



# Continuous Wave: Acne or/and Acne Scar

## A split-face comparison of a fractional microneedle radiofrequency device and fractional carbon dioxide laser therapy in acne patients SCIE

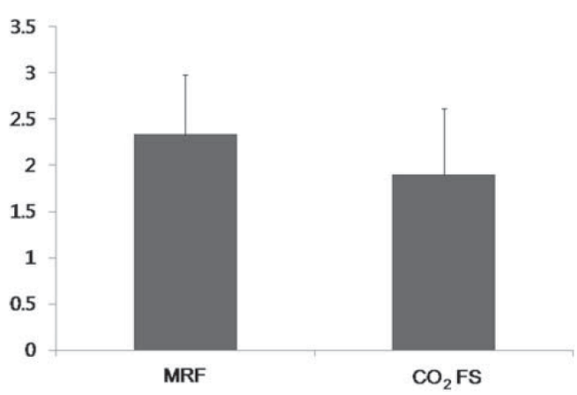
By Jun U. Shin, Soo Hyun Lee, Jin Young Jung, and Ju Hee Lee
*Journal of Cosmetic and Laser Therapy,* 2012; 14: 212-217

**Methods**

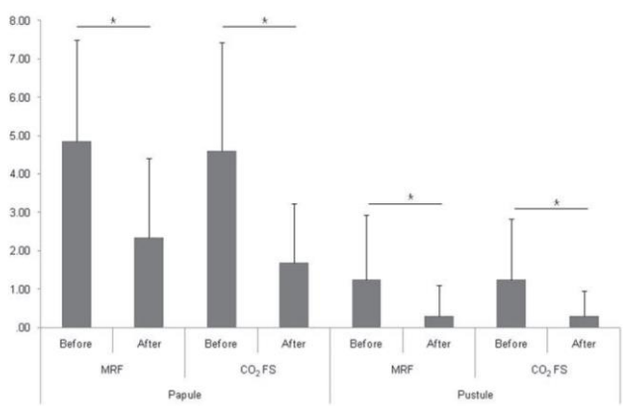
- 20 East Asian patients with acne vulgaris were treated with fractional microneedle radiofrequency (MRF) (SCARLET; ViOL) and $CO_2$ fractional laser system (FS) for a split-face study.
  - Patients: 9 women and 11 men, aged 15-28, Fitzpatrick skin types III-IV
  - One side: MRF treatment
    - 1.5-2.5mm, intensity 8 with a density of 25 MTZ/cm2, 2 passes
  - The other side: FS treatment
    - 80mL with a density of 100 spots/cm² (15.6% coverage and an ablation depth of 1168μm), 2 passes
  - 1-2 sessions

**Results**

- Most of the patients demonstrated improvement based on clinical and photographic assessments 3 months after the treatment.
- No significant differences in clinical improvement grades assessed by physicians, the number of papules and pustules, and patient satisfaction levels.
- Sebum production, erythema index (EI) and melanin index (MI) were additionally assessed and sebum production was decreased on both sides, EI and MI were not increased at 3 months after the last treatment.
- No patients experienced noticeable adverse events but two patients reported transient hyperpigmentation on the $CO_2$ FS-treated site which was spontaneously resolved before a 3-month visit.
- The $CO_2$ FS-treated side demonstrated a higher pain score than the MRF device-treated side, but the difference was not statistically significant.

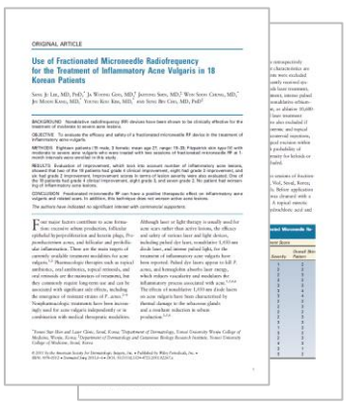



Mean grade of clinical improvement; MRF versus $CO_2$ FS ( $p$>0.05).




The mean ± SD number of papules and pustules on the MRF or CO2 FS-treated sides FS ( $p$>0.05).

# Continuous Wave: Acne or/and Acne Scar



## Use of Fractionated Microneedle Radiofrequency for the Treatment of Inflammatory Acne Vulgaris in 18 Korean Patients SSCI

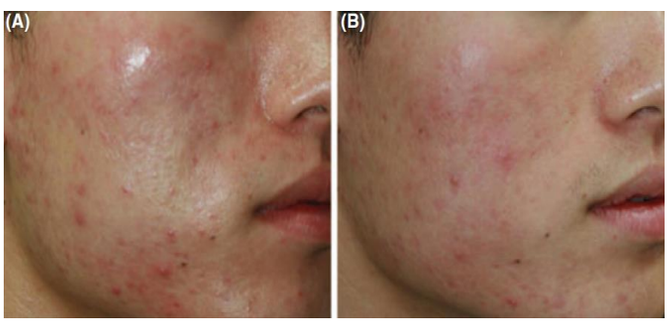
By Sang Ju Lee, Ja Woong Goo, Jaeyong Shin, Won Soon Chung, Jin Moon Kang, Young Koo Kim, and Sung Bin Cho
*Dermatologic Surgery,* 2012; 38(3): 400-405

**Methods**

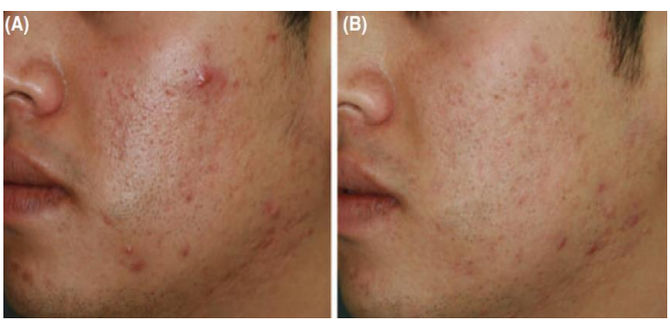
- 18 patients with moderate to severe acne vulgaris, were treated with fractionated microneedle RF (SCARLET; ViOL).
  - Patients: 15 male and 3 female, mean age 23.9 years, ranging from 21-34 years, Fitzpatrick skin type IV
  - Treatment: 100(off)–500(on)–100(off) ms, 3mm, intensity 7, 2 passes over the entire face, additional pass to severe pustular lesions
  - 2 sessions at 1-month intervals

**Results**

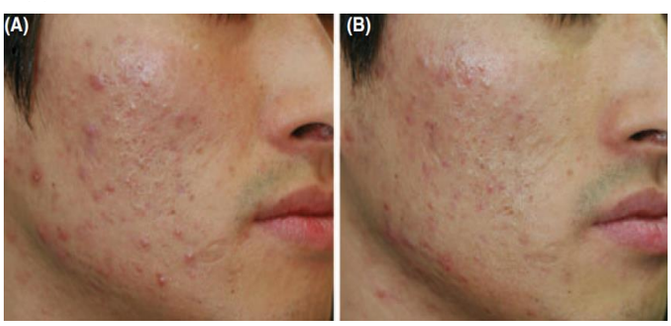
- Improvement scores in terms of the number of inflammatory acne lesions, assessed 2 months after the final treatment, showed that 2 patients had near total improvement (>75%), 8 patients had marked improvement (51-75%), and 6 patients had moderate improvement (26-50%).
- Improvement scores in terms of the severity of the lesions showed that 1 patient had near total improvement, 8 patients had marked improvement, and 7 patients had moderate improvement .
- No patient had worsening of inflammatory acne lesions.




(A) Before
(B) 2 months after the final treatment




(A) Before
(B) 2 months after the final treatment




(A) Before
(B) 2 months after the final treatment

# Pulsed Wave: Skin Reaction


## In vivo skin reactions from pulsed-type, bipolar, alternating current radiofrequency treatment using invasive noninsulated electrodes SCIE

By S.B. Cho, J. Na, Z. Zheng, J.M. Lim, J.-S. Kang, J.H. Lee, and S.E. Lee
*Skin Research and Technology,* 2018; 24(2): 318-325

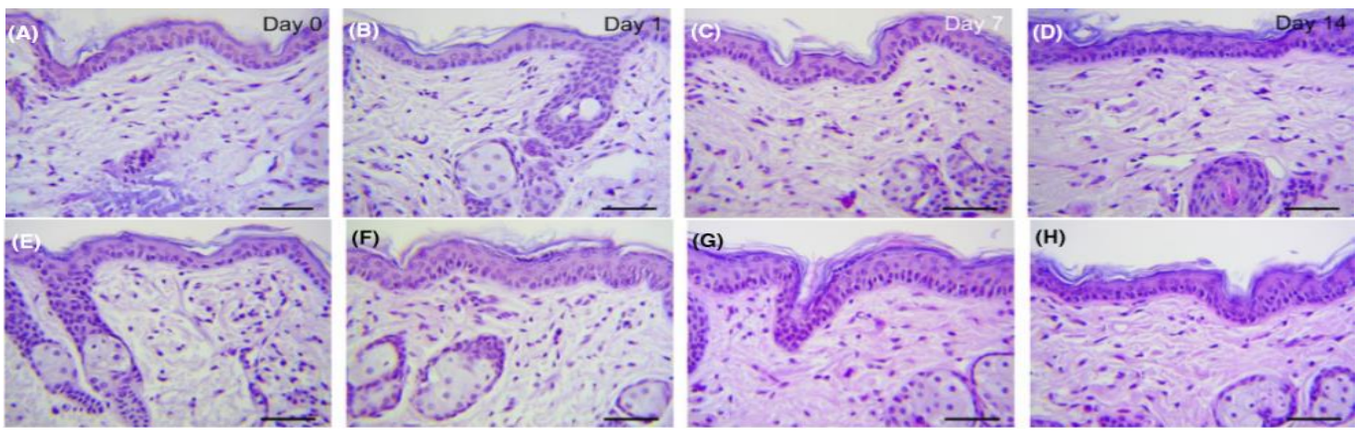
**Methods**

- A pulsed-type, bipolar alternating current RF device equipped with noninsulated microneedle electrodes (SYLFIRM; ViOL), were performed on hairless mice skin in vivo with 2 different treatment settings to evaluate structural and ultrastructural changes in vascular components and basement membranes.
  - Type A treatment: 3 pulse cycles at an on-time pulse width of 40ms and a power of 3.3 watts/pulse pack
  - Type B treatment: 5 pulse cycles at an on-time pulse width of 30ms and a power of 3 watts/pulse pack
  - With 3.0mm over 1 pass without overlapping
- At baseline and at immediately 1, 3, 7, and 14 days after treatment, skin specimens of full thickness from the hairless mice were obtained for histologic evaluation.

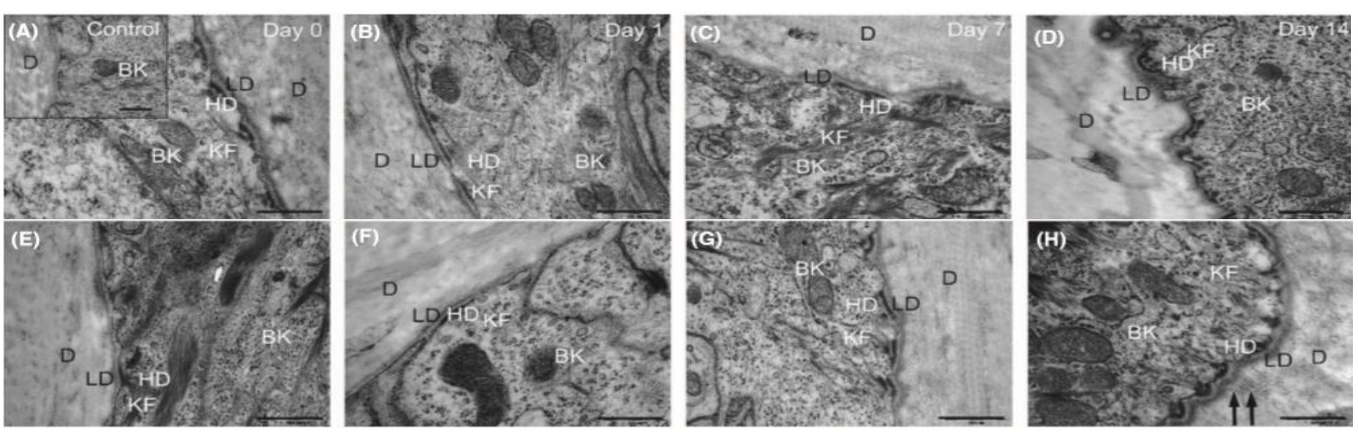
**Results**

- Immunohistochemical staining for type IV collagen and for periodic acid-Schiff (PAS) revealed marked thickening of basement membranes in both groups, although the expression thereof was more remarkable with type B-RF treatment.
- Transmission electron microscopy (TEM) demonstrated higher electron-dense and remarkably thicker lamina densa, as well as increases in anchoring fibrils in both groups, although type-B irradiation induced more increase in the thickness of the lamina densa.
- Furthermore, CD31-positive blood vessels were smaller in size with a slit-like luminal appearance, although the vascular features were more remarkable with type B-RF treatment. However, no signs of excessive damage to vascular components were found for either group.

# Pulsed Wave: Skin Reaction

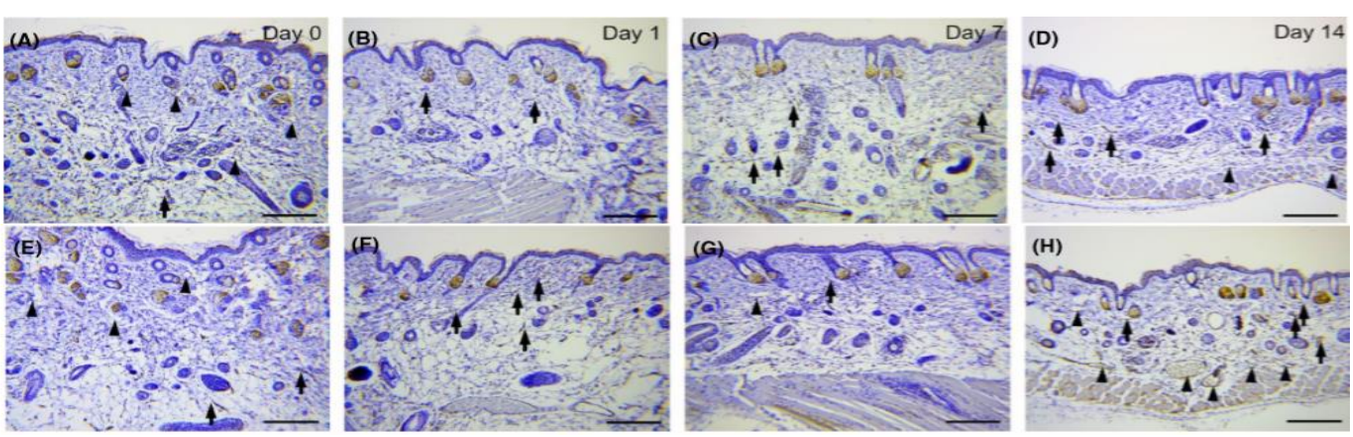



Effects of invasive, pulsed-type, bipolar RF on basement membranes. PAS stain, original magnification ×400, scale bar = 50 μm
Skin specimens present increased thickness of periodic acid-Schiff (PAS)-positive areas along the basement membrane (BM) on posttreatment days 7 and 14, which is more remarkable in the type B-RF treatment group.
(A-D) Type A-RF treatment group (3 pulses of 40ms and 3.3W)
(E-H) Type B-RF treatment group (5pulses of 30ms and 3.0W)




Transmission electron microscopic features TEM of basement membranes. TEM photographs present remarkable thickening of lamina densa on posttreatment days 7 and 14, which is more remarkable in the type B-RF treatment group. Scale bar = 500 nm
(A-D) Type A-RF treatment group (3 pulses of 40ms and 3.3W)
(E-H) Type B-RF treatment group (5 pulses of 30ms and 3.0W)

- BK: Basal Keratinocyte, D : Dermis *HD: hemidesmosomes, KF: Keratin Filament, Ld : Lamina Densa




Effects of invasive, pulsed-type, bipolar RF on vascular components. CD31-immunohistochemical stain, original magnification ×100, scale bar = 200 μm
Vascular components small in size and with a slit-like luminal structure (arrows) in the subcutaneous fat layer and distended blood vessels with a smooth luminal surface (arrowheads) in the dermis on days 0 and 1.
(A-D) Type A-RF treatment group (3 pulses of 40ms and 3.3W)
(E-H) Type B-RF treatment group (5pulses of 30ms and 3.0W)

- CD31: platelet endothelial cell adhesion molecule-1, a multifunctional cell adhesion molecule involved in numerous physiologic processes within the vasculature




16

# Pulsed Wave: Pigmented Lesion


## Targeting the dermis for melasma maintenance treatment SCIE

By Hee Jeong Han, Jin Cheol Kim, Young Joon Park, Hee Young Kang

*Scientific Reports,* 2024; 14: 949

**Methods**

- 15 subjects with melasma were treated with conventional therapy with microneedling RF (SYLFIRM X; ViOL) for 2 months and the 11 subjects ~~were~~ continued maintenance therapy for 6 months.
  - **Conventional therapy for 2 months**
    - Oral Tranexamic acid (TA) 250mg twice daily
    - Triple combination cream (TCC) composed of 5% hydroquinone, 0.003% tretinoin, and 1% hydrocortisone to the entire face once a day
    - Microneedling RF on the randomly assigned half face: PW2, level 4-6 targeting mild erythema, 0.3mm for 2 passes and 0.8mm for 1 pass
  - **Maintenance therapy for 6 months**
    - Oral TA and TCC were discontinued
    - RF microneedling continued every month

**Results**

- **Conventional therapy**
  - All the 15 subjects marked improvement after 2-month conventional treatment with a 64% reduction in modified melasma area severity index (mMASI) score on average.
  - Both L* (lightness) values of the RF treated and untreated side increased.
  - From the perspective of the synergistic effect of RF, there was no significant difference in the RF group in addition to the combination treatment of oral TA and TCC, although RF group showed better improvement.
- **Maintenance therapy**
  - In untreated side, the Δ L* (mean change of L*value from the baseline) gradually decreased, returning to the baseline after the conventional therapy ended.
  - In contrast, the RF treated side helped maintaining the treatment effect after cessation of the 2-month previous treatment.



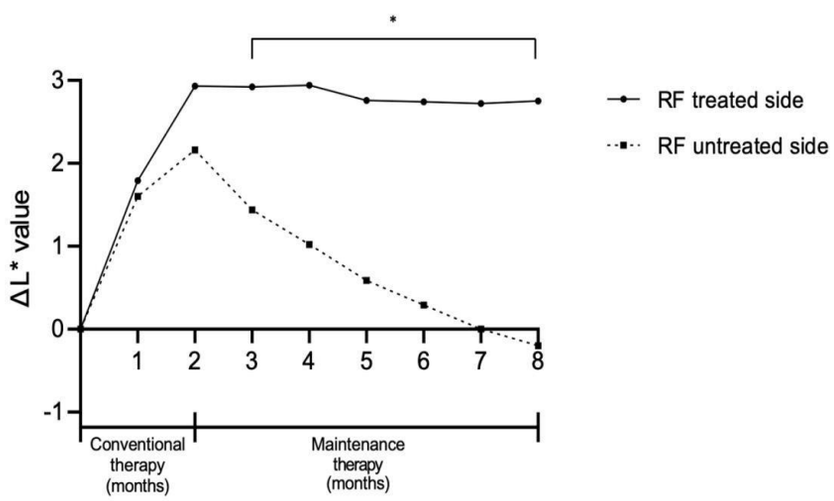


17

# Pulsed Wave: Pigmented Lesion

| | Conventional therapy[1] (N = 15) | | Maintenance therapy[2] (N = 11) | |
|---|---|---|---|---|
| | Mean | SD | Mean | SD |
| Age (years) | 47.07 | 7.83 | 47.27 | 8.46 |
| Duration of melasma (years) | 9.73 | 5.22 | 10.36 | 5.92 |
| Baseline mMASI[1] score | 5.02 | 2.27 | 5.27 | 2.22 |
| Baseline L* value | | | | |
| RF treated side | 59.79 | 1.79 | 60.54 | 1.18 |
| RF untreated side | 60.44 | 1.91 | 60.94 | 1.76 |
| After 2-month L* value | | | | |
| RF treated side | 62.86 | 1.74 | | |
| RF untreated side | 62.55 | 2.03 | | |

Baseline demographics of subjects




The continuous radiofrequency treatment maintains the treatment effect of conventional therapy.

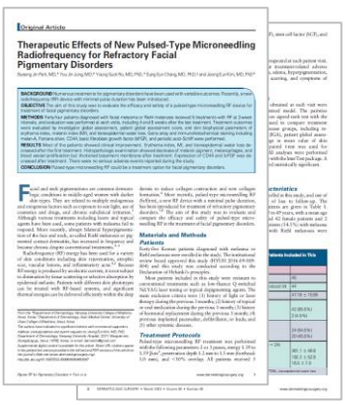

Efficacy of conventional and maintenance treatments in a 46-year-old woman with melasma

(a-e) The combination therapy of oral tranexamicacid and triple combination cream markedly improved the melasma

(c) whereas it returned to the baseline on the untreated side after discontinuation of conventional therapy

(f) The improvement maintained on the radiofrequency treated side after discontinuation of conventional therapy

# Pulsed Wave: Pigmented Lesion


Original Article

Therapeutic Effects of New Pulsed-Type Microneedling Radiofrequency for Refractory Facial Pigmentary Disorders

## Therapeutic Effects of New Pulsed-Type Microneedling Radiofrequency for Refractory Facial Pigmentary Disorders

**SCIE**

By Byeong Jin Park, You Jin Jung, Young Suck Ro, Sung Eun Chang, and Jeong Eun Kim
*Dermatologic Surgery,* 2022; 48(3): 327-333

**Methods**

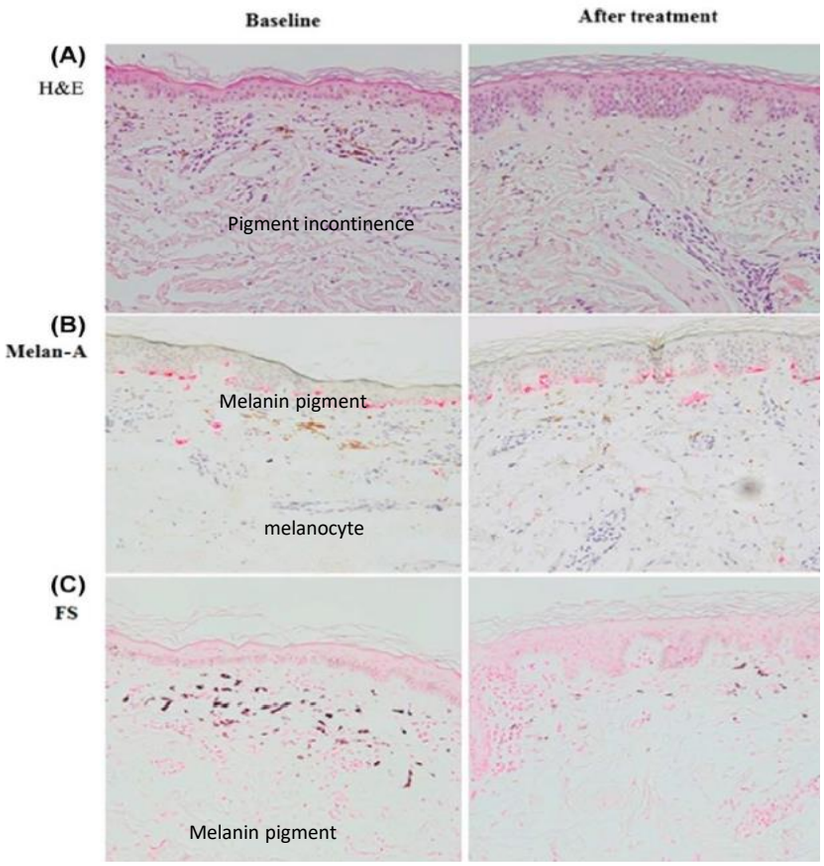
- 44 patients with melasma or Riehl melanosis received pulsed-type microneedling RF (SYLFIRM; ViOL) treatment.
  - Patients: age from 25 to 69 years, mean age of 47.18 years; 42 female and 2 male; 24 with melasma and 20 with Riehl melanosis
  - Treatment: 1.0-1.5mm, 1.39-1.59J/cm², 2-3 passes and < 10% overlap for 5 treatments at 2-week intervals
- Treatment outcomes were evaluated by investigator global assessment, patient global assessment score, and skin biophysical parameters of erythema index (EI), melanin index (MI), and transepidermal water loss (TEWL).
- Gene array and immunohistochemical staining including melan-A, Fontana silver (FS), CD44, basic fibroblast growth factor (bFGF), and periodic acid–Schiff (PAS) were performed.

**Results**

- EI, MI, and TEWL showed significant improvement after treatment.
- Histopathologic examination showed decreased of melanin pigment, melanophages, and blood vessel proliferation but thickened basement membrane after treatment.
- Expression of CD44 and bFGF was decreased after treatment.
- There were no serious adverse events reported during the study.

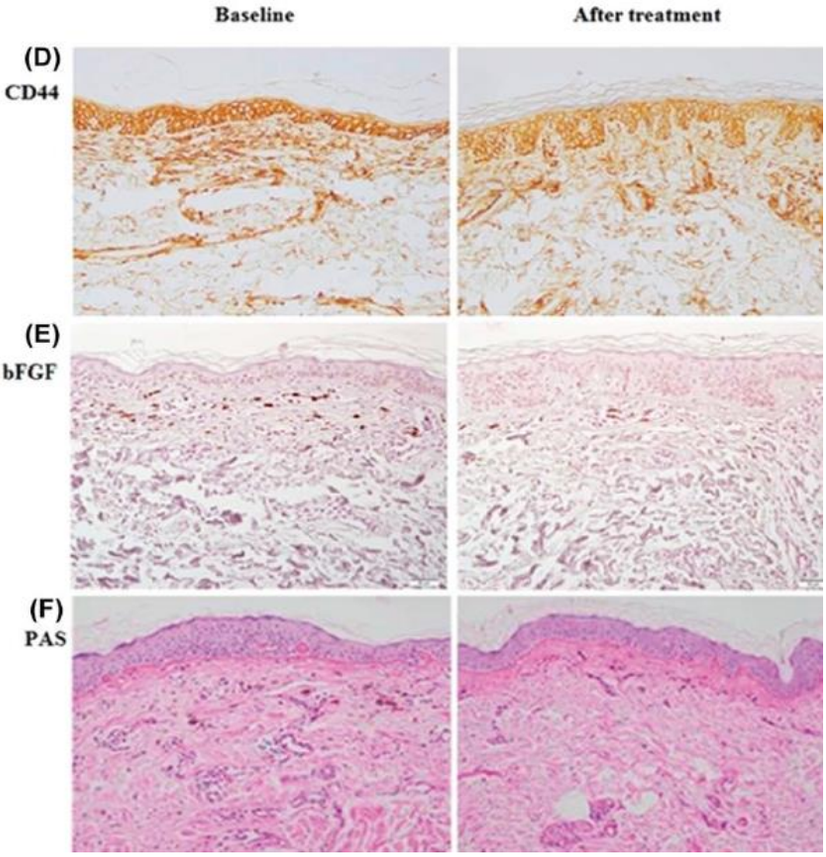
- ❖ Melan-A : to visualize melanocytes
- ❖ FS : Fontana silver, it is to visualize melanin pigment
- ❖ CD44 : a cell-surface glycoprotein involved in cell-cell interactions, cell adhesion and migration.
- ❖ bFGF : basic fibroblast growth factor, a growth factor signaling protein involved in the proliferation, differentiation, and migration of a variety of cell types of mesodermal and neuroectodermal origin.
- ❖ PAS : Periodic acid-Schiff, it is to detect glycogen, and mucosubstances such as glycoproteins, glycolipids and mucins in tissues.

# Pulsed Wave: Pigmented Lesion




(A-C)
Histopathologic evaluation revealed that mild vacuolar alteration of the basal layer and pigment incontinence in the upper dermis were mainly found before treatment.
4 weeks after the final treatment, the amount of melanin pigment in the epidermis and dermis was reduced.
The proliferation of melanophages and blood vessel in the dermis was reduced compared with the pretreatment state.

- Melan-A : to visualize melanocytes
- FS : Fontana silver, it is to visualize melanin pigment




(D) CD44 was decreased in the epidermis and dermis.
(E) bFGF was decreased in the dermis after treatment.
(F) PAS showed basement membrane thickening after treatment

- CD44 : a cell-surface glycoprotein involved in cell-cell interactions, cell adhesion and migration.
- bFGF : basic fibroblast growth factor, a growth factor signaling protein involved in the proliferation, differentiation, and migration of a variety of cell types of mesodermal and neuroectodermal origin.
- PAS : Periodic acid-Schiff, it is to detect glycogen, and mucosubstances such as glycoproteins, glycolipids and mucins in tissues.

# Pulsed Wave: Pigmented Lesion


Efficacy and Safety of Using Noninsulated Microneedle Radiofrequency Alone Versus in Combination with Polynucleotides for the Treatment of Melasma: A Pilot Study

ABSTRACT

## Efficacy and Safety of Using Noninsulated Microneedle Radiofrequency Alone Versus in Combination with Polynucleotides for the Treatment of Melasma: A Pilot Study

**SSCI**

Ma. Christina B. Gulfan, Rungsima Wanitphakdeedecha, Supisara Wongdama, Nuttagarn Jantanapornchai, Chadakan Yan, Sarawalai Rakchar

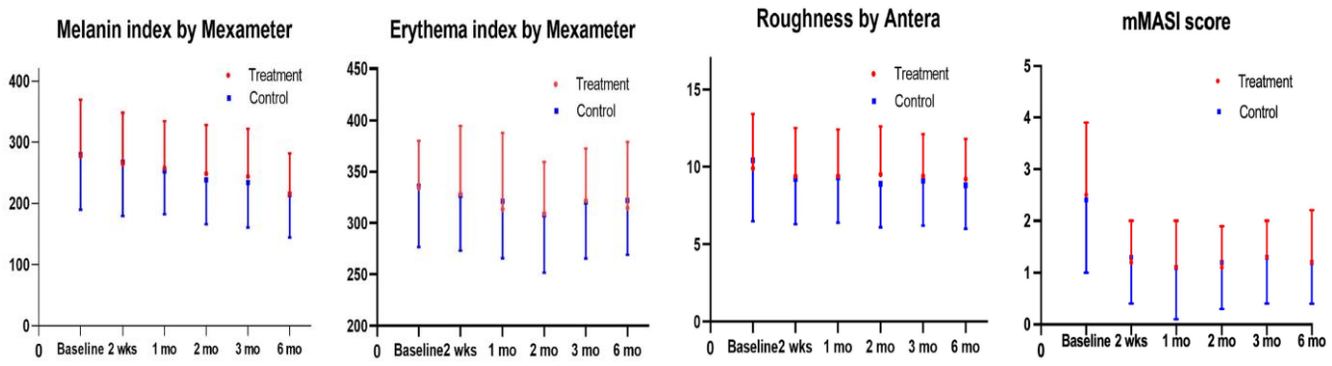
*Dermatology and Therapy,* 2022; 12(6): 1325-1336

**Methods**

- 30 patients with melasma received 3 treatments every 2 weeks with an invasive, bipolar, pulsed-type microneedling RF device (SYLFIRM; ViOL) on both sides of the face.
  - Patients
    - All women, mean age of 43.2±7.0 years, Fitzpatrick skin types III-V
    - Mixed melasma 61.5%, the mean duration of melasma 8.9±6.5 years
  - RF treatment
    - 1st pass: 1.5mm depth, power2 on whole face
    - 2nd pass: 1.5mm depth, power2 on melasma lesion only
    - 3rd pass: 0.8mm depth, power 2, on whole face
    - 10-30% overlap
- After RF treatment, different solutions were randomly applied to each side of the face.
  - Control group: normal saline solution (NSS) applied to one side of the face
  - Treatment group: 3-5 drops (approx. 0.2ml) of the 0.3% polynucleotides (PN) on one side of the face

**Results**

- 30 participants initially enrolled, 26 participants were followed up to the 6-month assessment point.
- The melanin index (MI), erythema index (EI), skin roughness, and modified melasma area severity index (mMASI) score were decreased in both sides at 6 months compared with baseline, with no statistically significant differences between the sides.
- Subjects in both groups rated their improvement as ‘‘good to excellent’’ (51% to ≥ 75%) as early as 2 weeks after the last treatment session, with a gradual and steady increase in the number of patients reporting a higher rating of improvement at 1, 2, and 3 months after the last treatment.
- This trend continued until the 6 month, and was similar for both treatment and control sides.



# Pulsed Wave: Pigmented Lesion

## Synergistic Effect of 300 µm Needle-Depth Fractional Microneedling Radiofrequency on the Treatment of Senescence-Induced Aging Hyperpigmentation of the Skin

**SCIE**

By Young In Lee, Eunbin Kim, Dong Won Lee, Jemin Kim, Jihee Kim, Won Jai Lee, and Ju Hee Lee

*International Journal of Molecular Sciences,* 2021; 22(14): 7480

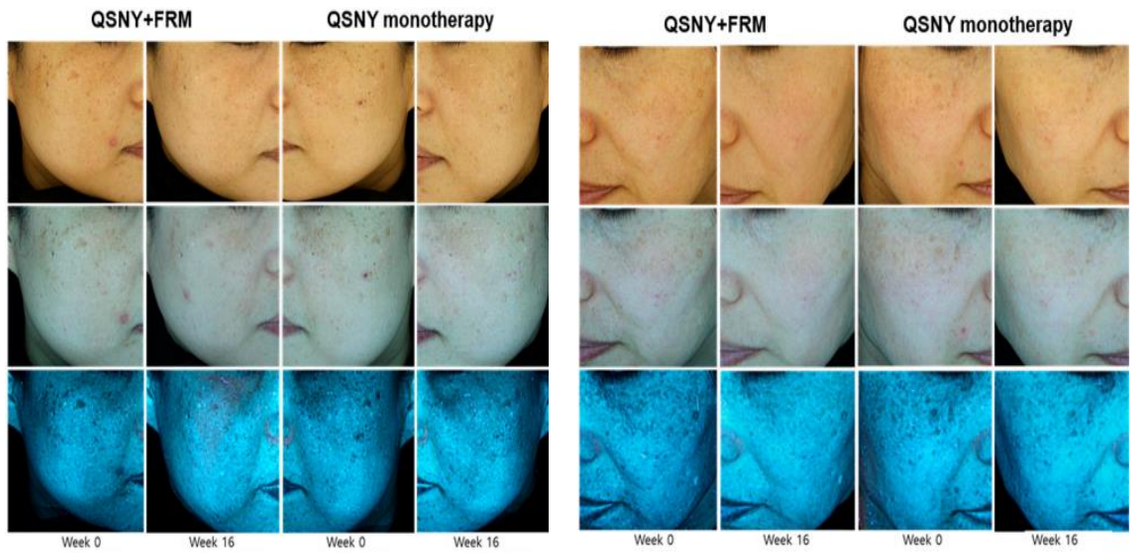
**Methods**

- A split-face study was conducted using fractional microneedling radiofrequency (FMR) (SYLFIRM X; ViOL) and Q-switched 1064nm Nd:YAG laser toning (QSNY) in 25 Asian women with aging-associated hyperpigmentation.
  - Patients
    - The mean age of 51.4±7.56 years, range 39-63 years, Fitzpatrick skin type III-IV
    - 11 with a single type of pigmentation, melasma and 14 with a mixed type of age-related hyperpigmentation, including melasma and senile lentigo
  - Treatment
    - QSNY + FMR on one side / QSNY alone on the other side
    - Treatment Parameters:
      - QSNY: 6mm, 2.5-3.5J/cm², 10hz, 3 overlapping passes
      - FMR: PW2 mode, 300µm (0.3mm), level 4-6, 2 passes
      - A total of 5 treatment sessions
      - 2 treatment sessions were performed each week for a total of 5 weeks (weeks 0, 2, 4, 6, and 8)
- An additional human ex vivo study was conducted by dividing tissue specimens (control, UVB, and UVB+FMR group) to explore the pathophysiologic mechanism with aging-associated hyperpigmentation.

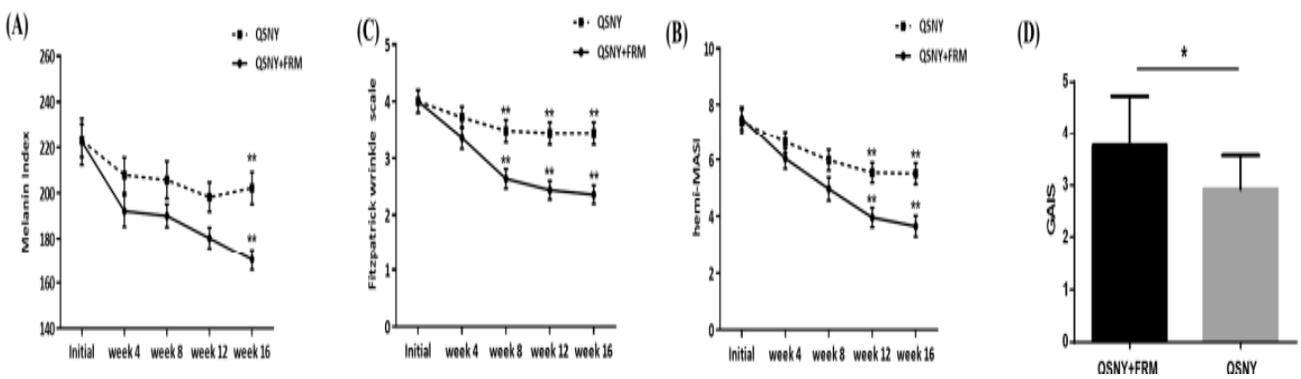
**Results**

- A split-face study
  - The QSNY+FMR group showed a significantly higher reduction in melanin index(MI), hemi-melasma area and severity index (hemi-MASI), Fitzpatrick wrinkle and elastosis scale, and global aesthetic improvement scale (GAIS) than the QSNY group.
- Ex vivo study
  - Additional ex vivo study revealed significant reduction of pro-melanogenic markers as well as senescent keratinocytes, while increased expression of collagen type IV on the epidermal basement membrane, after additional FMR treatment on UV-irradiated human tissues.

# Pulsed Wave: Pigmented Lesion

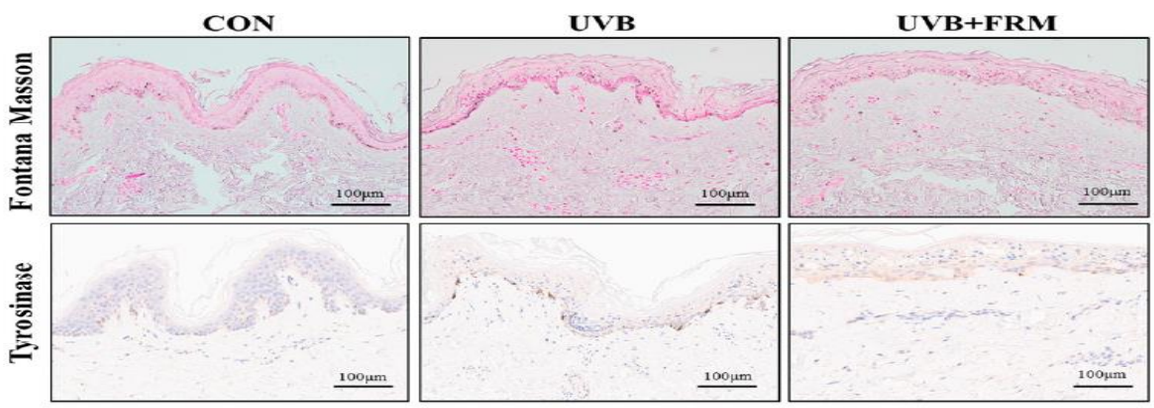



The comparison of the improvement of aging-associated facial pigmentation between the QSNY+FMR group and QSNY group at baseline and week 16.




Clinical efficacy of adjuvant FMR treatment after QSNY for aging-associated hyperpigmentation.

(A) Melanin index (MI)
(B) Hemi-melasma area and severity index (hemi-MASI)
(C) Fitzpatrick winkle and elastosis scale
(D) Global aesthetic improvement scale (GAIS) by investigators on week 12.

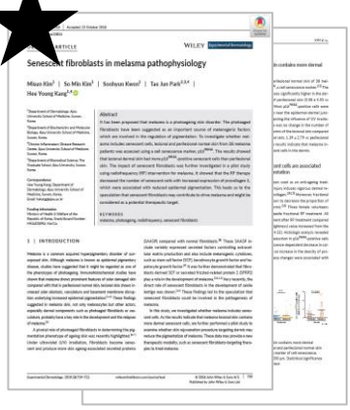



Effect of FMR irradiation after UVB exposure on skin pigmentation.
Fontana-Masson staining and tyrosinase IHC staining show significant reduction of pigmented area % and the tyrosinase activity of UVB-irradiated skin tissue after FMR.

- Fontana Masson : to detect melanin of dematiaceous fungi in tissue
- Tyrosinase : an enzyme that regulates the production of melanin and is involved in the reaction of melanin synthesis.

23

# Pulsed Wave: Pigmented Lesion


Senescent fibroblasts in melasma pathophysiology

## Senescent fibroblasts in melasma pathophysiology ESCI

By Misun Kim, So Min Kim, Soohyun Kwon, Tae Jun Park, and Hee Young Kang
*Experimental Dermatology,* 2019; 28(6): 719-722

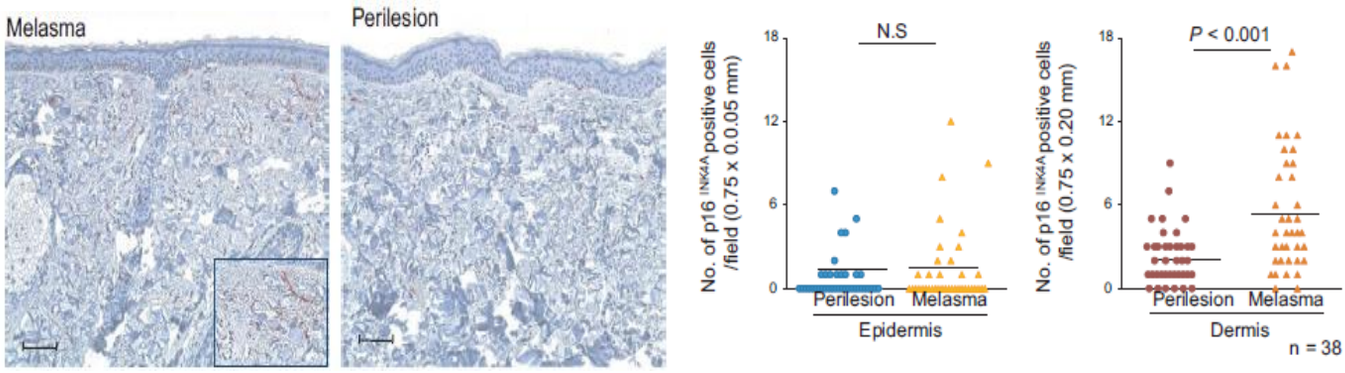
**Methods**

- To investigate whether melasma includes senescent cells, lesional and perilesional normal skin from 38 patients with melasma was assessed using a cell senescence marker, $p16^{INK4A}$ by using biopsy samples.
  - Patients : all women, mean age 45, Fitzpatrick skin type III-IV
- To further investigate the impact of senescent fibroblasts, a bipolar pulsed-type RF (SYLFIRM; ViOL) treatment were performed to 3 patients
  - Patients : all women, 32-45 years old, Fitzpatrick skin type III-IV
  - RF treatment: 1.5mm, level 2 for 5 sessions every 2 weeks

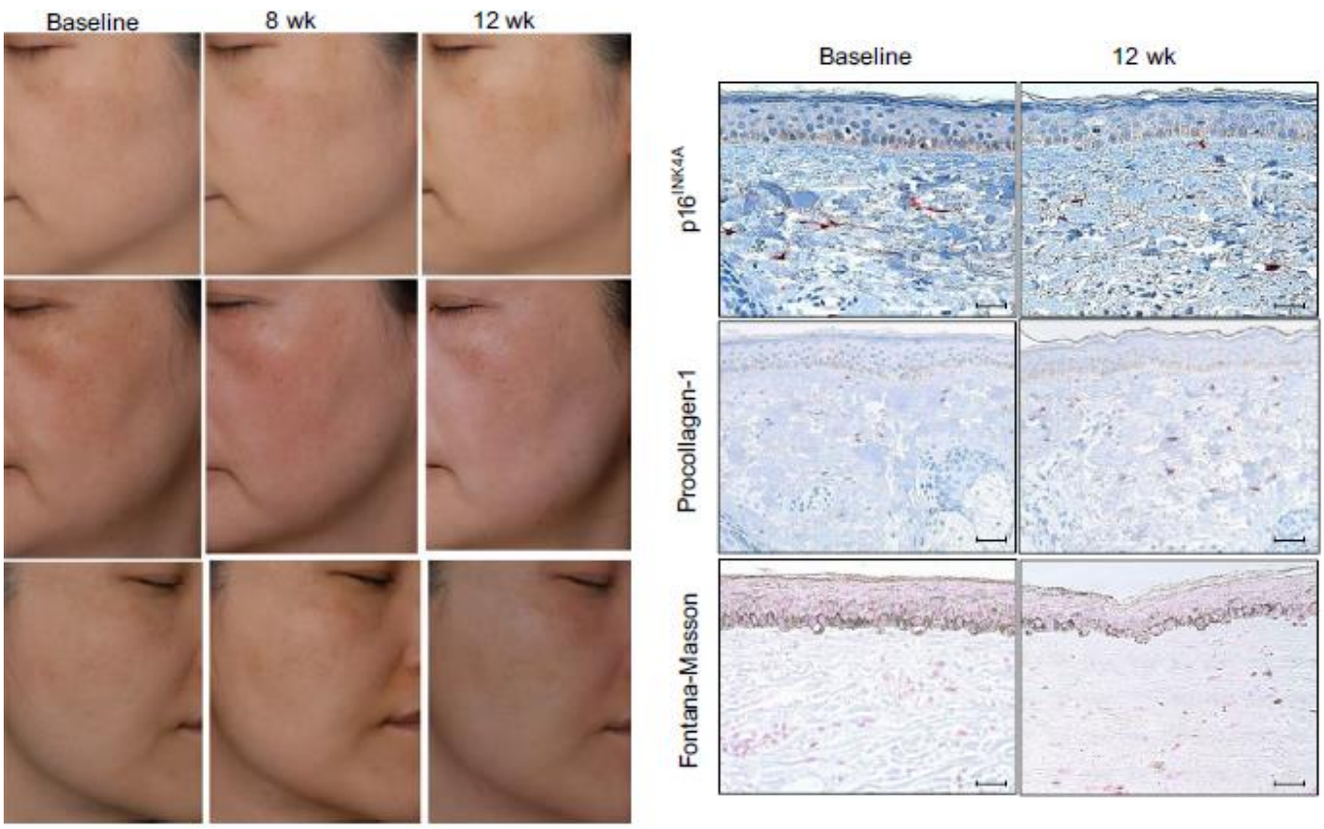
**Results**

- Biopsy samples
  - The number of $p16^{INK4A}$ -positive cells was significantly higher in the dermis of lesional skin than in that of perilesional skin.
  - Most $p16^{INK4A}$ -positive cells were observed in the superficial dermis near the epidermal-dermal junction, not in the deep dermis.
- RF treatment
  - All subjects showed clinical improvement after RF treatment compared with baseline.
  - The L* (lightness) value increased from the baseline.
  - Histologic analysis revealed that the RF treatment showed a reduction in $p16^{INK4A}$ -positive cells and appeared to reverse the senescence-dependent decrease in collagen response, that is, there was an increase in the density of procollagen-1 after RF treatment.
  - These changes were associated with decreased pigmentation in the epidermis, that is Fontana-Masson staining demonstrated a marked decrease in pigmentation of lesional skin compared with baseline values.

# Pulsed Wave: Pigmented Lesion




Melasma lesional skin contains more dermal senescent cells.
Biopsies of lesional and perilesional normal skin of melasma were assessed using a marker of cell senescence, $p16^{INK4A}$. The scale bar indicates 200 µm.




Reduction of senescent cells is associated with improvement of pigmentation.
(Left) Clinical photographs of participants at 0, 8 and 12 wks of microneedle fractional radiofrequency (RF) treatment, showing gradual improvement in pigmentation.
(Right) Changes in the number of $p16^{INK4A}$ –positive cells and expression of procollagen-1 and melanin pigmentation in lesional skin after RF treatment. The scale bar indicates 200 µm.

# Pulsed Wave: Pigmented Lesion

## Senescent fibroblasts drive ageing pigmentation: A potential therapeutic target for senile lentigo SCIE

By Jung Eun Yoon, Yeongeun Kim, Soohyun Kwon, Misun Kim, Young Hwa Kim, Jang-Hee Kim, Tae Jun Park, and Hee Young Kang

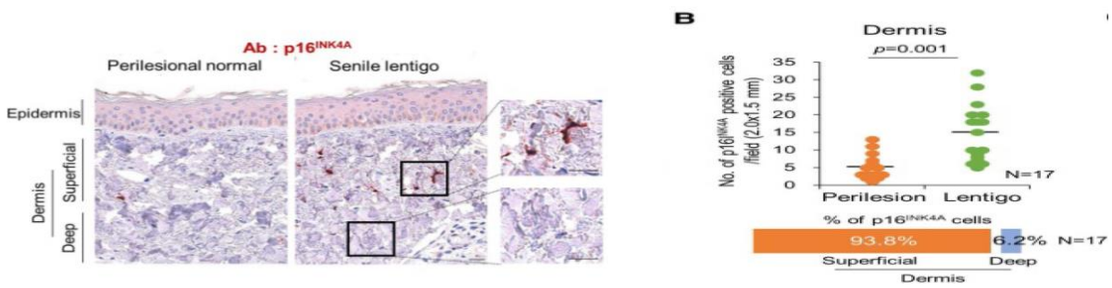
*Theranostics,* 2018; 8(17): 4620-4632

**Methods**

- Biopsies obtained from senile lentigo and perilesional normal skin of 17 volunteers, were assayed for a marker of cellular senescence, $p16^{INK4A}$.
- To determine the secretory phenotypes of senescent fibroblasts, microarray, RNA sequencing and methylation array analyses were performed in senile lentigo and senescent fibroblasts.
- To further investigate the impact of senescent cells on ageing-related pigmentation, an intervention that targeted senescent cells using RF microneedling (SYLFIRM; ViOL) treatment was performed at with level 6, with 6 sessions at 1-week intervals.

**Results**

- Senescent fibroblasts accumulated at the sites of age-related pigmentation.
- Stromal-derived factor 1 (SDF1) suppresses melanogenesis via stromal-epithelial interactions, and its loss in senescent fibroblasts promotes age-related pigmentation.
- The elimination of senescent fibroblasts from pigment skin using RF microneedling was accompanied by skin lightening rendering it a potential target for treatment.

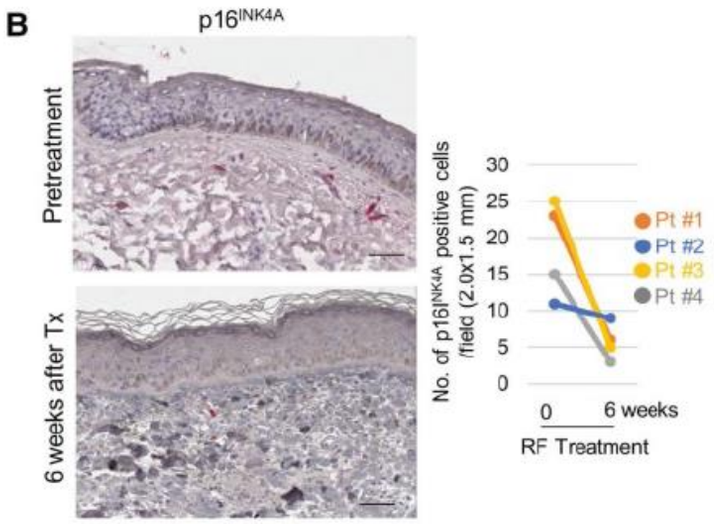



Biopsies obtained from the facial senile lentigo (SL) and perilesional normal skin of 17 volunteers were immunostained for p16INK4A. The proportion of p16INK4A-positive cells is shown according to the depth of the skin. The bar graph indicates the percentage of p16INK4A-positive cells in the dermis. The superficial dermis is defined as cells within 500 μm of the epidermal-dermal junction.


SDF1 immunostaining of SL (scale bars: upper, 100 μm; lower, 50 μm). The expression levels were graded as none, weak, moderate, or strong

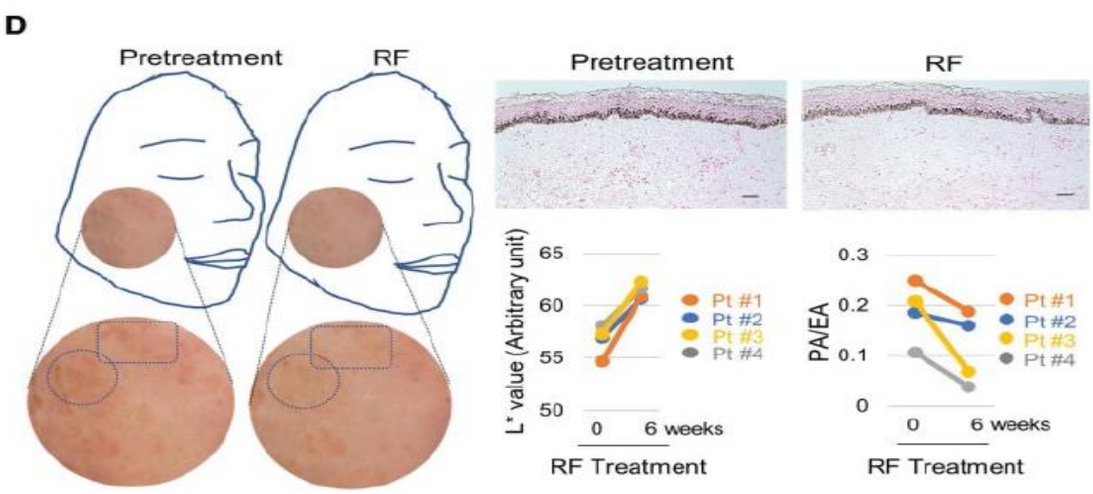
❖ SDF1 : Stromal derived factor-1, C-X-C motif chemokine ligand 12 (CXCL12), a widely expressed constitutive chemokine that regulates tissue homeostasis and inflammatory responses

# Pulsed Wave: Pigmented Lesion

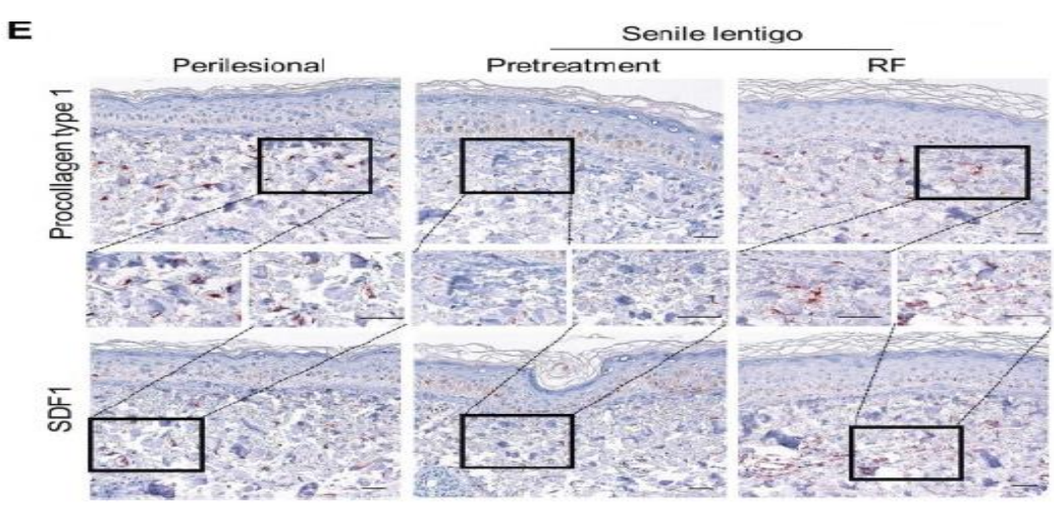



(B) Following RF treatment, the number of senescent fibroblasts was significantly reduced.

- ❖ $p16^{INK4A}$ : a cell senescent marker



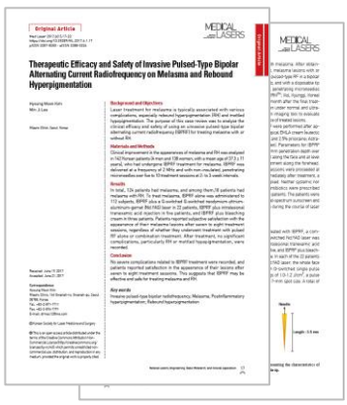

(D) The elimination of senescent fibroblasts from SL was accompanied by skin lightening. The L (lightness) values measured by chromameter increased relative to baseline, and histopathological analysis demonstrated a consistent reduction in epidermal melanin deposition.
L* value : lightness, PA : pigmented area, EA : epidermal area




(E) RF treatment increased the synthesis of collagen and restored SDF1 expression to levels comparable to those observed in perilesional normal skin.

- ❖ SDF1 : Stromal derived factor-1, C-X-C motif chemokine ligand 12 (CXCL12), a widely expressed constitutive chemokine that regulates tissue homeostasis and inflammatory responses.

# Pulsed Wave: Pigmented Lesion



## Therapeutic Efficacy and Safety of Invasive Pulsed-Type Bipolar Alternating Current Radiofrequency on Melasma and Rebound Hyperpigmentation SCIE

By Hyoung Moon Kim, and Min Ji Lee
*Medical Lasers,* 2017; 6(1): 17-23

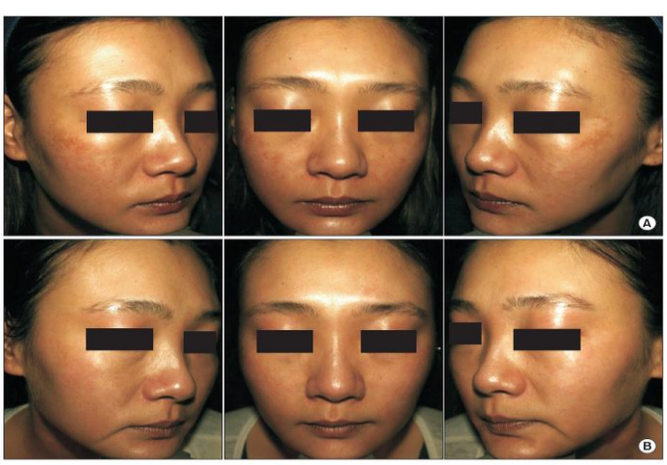
**Methods**

- Clinical improvement in the appearances of melasma and rebound hyperpigmentation (RH) was analyzed in 142 Korean patients who had undergone invasive pulsed-type bipolar radiofrequency (IBPRF) (SYLFIRM; ViOL) treatment with or without other methods.
  - Patients
    - 4 men and 138 women, a mean age of 37.3±11 years,
    - 15 with melasma for < 1 year, 64 for 1-5 years, 53 for < 5years, 10 for > 10 years
  - Treatment Methods
    - IBPRF alone : 112 patients
    - IBPRF plus a Q-switched Nd:YAG laser : 22 patients
    - IBPRF plus intralesional tranexamic acid injection : 5 patients
    - IBPRF plus bleaching cream : 3 patients
  - Treatment Parameters
    - IBPRF: level 3, 1.5mm on the face / level 2, 1.0mm on the forehead
    - Q-switched Nd:YAG laser: 1064nm, 5-10ns, 7mm, 1.0-1.2J/cm², 2,000-2,500 shots on the entire face
    - 5-10 treatment sessions at 2-3 week intervals

**Results**

- Patients reported subjective satisfaction with the appearance of their melasma lesions after seven to eight treatment sessions, regardless of whether they underwent treatment with pulsed RF alone or combination treatment.
- No significant complications, particularly RF or mottled hypopigmentation, were recorded.

(A) Baseline
(B) 1 month after 10 sessions of IBPRF monotherapy



(A) Baseline
(B) 1 month after 6 sessions of combined IBPRF and laser toning

28

# Pulsed Wave: Pigmented Lesion


Successful Treatment of Refractory Melasma Using Invasive Micro-Pulsed Electric Signal Device

## Successful Treatment of Refractory Melasma Using Invasive Micro-Pulsed Electric Signal Device SCIE

By Moon Choi, Seohee Choi, Jin-Soo Kang, and Sung Bin Cho
*Medical Lasers,* 2015; 4(1): 39-44

**Methods**

- 5 female patients with refractory facial melasma, were treated using invasive micro-pulsed electric signal device (IMPES) (SYLFIRM; ViOL) added to their baseline of low-fluence Q-switched Nd:YAG laser (LFQSNY) / topical lightening agents (TLA) treatment.
  - Patients: Fitzpatrick skin types III-IV, aged between 42-53 years, mean 48 years
  - IMPES: 1.2-1.7mm, level 3-5, single pass, <10% overlap
  - LFQSNY: 8mm, 1.89J/cm², 10hz, <10% overlap
  - 4-7 treatments at 1-week intervals

**Results**

- At the last treatment, assessments showed greater than 50% clinical improvement in melasma in all 5 patients.
- No recurrence was reported during the follow-up at 8 weeks.
- No significant adverse effects were noted.


(A) Baseline (B) 1 week after the last treatment *received an additional procedure to remove facial seborrheic keratosis prior to receiving IMPES


(A) Baseline (B) 1 week after the last treatment


(A) Baseline (B) 1 week after the last treatment




29

# Pulsed Wave: Vascular Lesion

## Therapeutic effects of a new invasive pulsed-type bipolar radiofrequency for facial erythema associated with acne vulgaris and rosacea ESCI

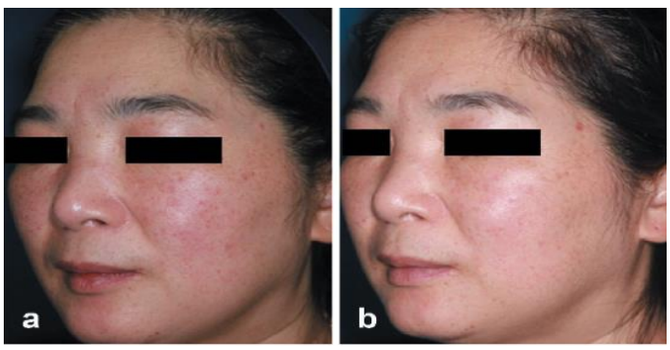
By You Jin Jung, Young Suck Ro, Hwa Jung Ryu, and Jeong Eun Kim
*Journal of Cosmetic and Laser Therapy,* 2021; 22(4-5): 205-209

**Methods**

- 31 Korean patients with facial erythema from rosacea or acne vulgaris, underwent an invasive short pulsed-type bipolar radiofrequency (IPBRF) (SYLFIRM; ViOL) treatment.
  - Patients: 26 females and 5 males, mean age 30.9 years, range 14-51, Fitzpatrick skin type III-IV
  - IPBRF: level 4-6, 1.5mm on face, 1.0mm on forehead, 2-3passes, with <10% overlap for 2-5 treatment sessions at 2-week intervals

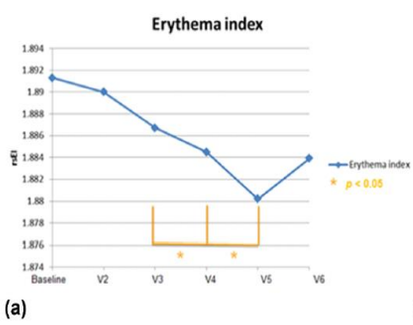
**Results**

- Most patients showed significant clinical improvement.
- Investigator's global assessment (IGA) scores for erythema, pore size and skin smoothness improved after treatment.
- Patient global assessment (PGA) also showed a trend toward improvement.
- Mean erythema index (EI) was significantly improved after the second treatment compared to baseline, which maintained until the study period.
- Melanin index (MI) and transepidermal water loss (TEWL) showed a tendency toward improvement.
- There were no serious adverse events reported during the study.

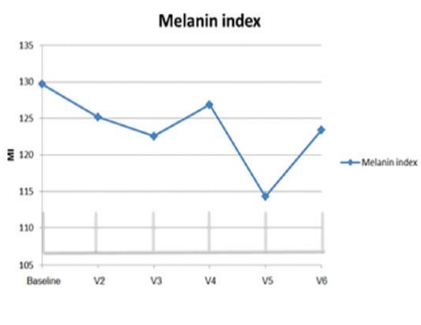



(a) Baseline, (b) post-treatment of 3 successive treatments.

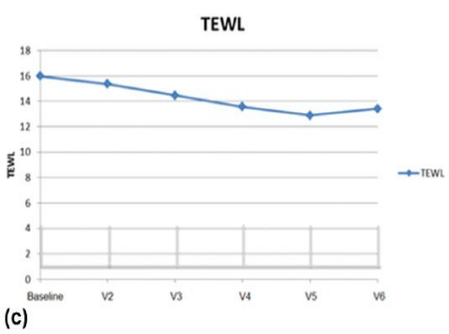

(c) Baseline, (d) post-treatment of 3 successive treatments.




(a)




(b)




(c)

# Pulsed Wave: Vascular Lesion


Case Report

MEDICAL LASERS

Invasive Pulsed-Type, Bipolar, Alternating Current Radiofrequency Treatment Using Microneedle Electrodes for Nasal Rosacea

## Invasive Pulsed-Type, Bipolar, Alternating Current Radiofrequency Treatment Using Microneedle Electrodes for Nasal Rosacea SCIE

By Tae Hwan Ahn, and Sung Bin Cho

*Medical Lasers,* 2017; 6(1): 32-36

**Methods**

- 2 Korean patients with nasal rosacea, were treated with invasive pulsed-type, bipolar alternating current RF using microneedle electrodes (SYLFIRM; ViOL) at 1.5mm, level 3, 2-3 passes.
  - First patient : male, 24-year-old, Fitzpatrick skin type IV / localized, recurrent erythematous papulopustular lesions on the nose, along with a few pustules on the perioral area / 6 sessions at 2-week intervals
  - Second patient : male, 76-year-old, Fitzpatrick skin type IV / markedly telangiectatic lesions on a mildly phymatous nose / 12 sessions at 2-week intervals

**Results**

- The first patient presented marked clinical improvement with respect to both the overall redness and papulopustular lesions.
- The second patient exhibited noticeable improvement in both the texture and telangiectatic lesions on the nose.
- No remarkable side effects, including immediate excessive bleeding or oozing, worsening of the nasal rosacea, folliculitis or furuncle, post-therapy prolonged erythema, post-therapy dyschromia, or scarring, were reported.


Papulopustular rosacea along the nose in a 24-year-old man
(A) Baseline
(B) 2 sessions
(C) 4 sessions
(D) 4 weeks after 6 sessions of RF microneedling treatment


Erythematotelangiectatic nasal rosacea in a 76-year-old man
(A) Baseline
(B) 2 weeks after 2 sessions
(C) 2 weeks after 7 sessions
(D) 4 weeks after 12 sessions of RF microneedling treatment





31

# Pulsed Wave: Acne or/and Acne Scar


## Combination of Fractional Microneedling Radiofrequency and Ablative Fractional Laser versus Ablative Fractional Laser Alone for Acne and Acne Scars SCIE

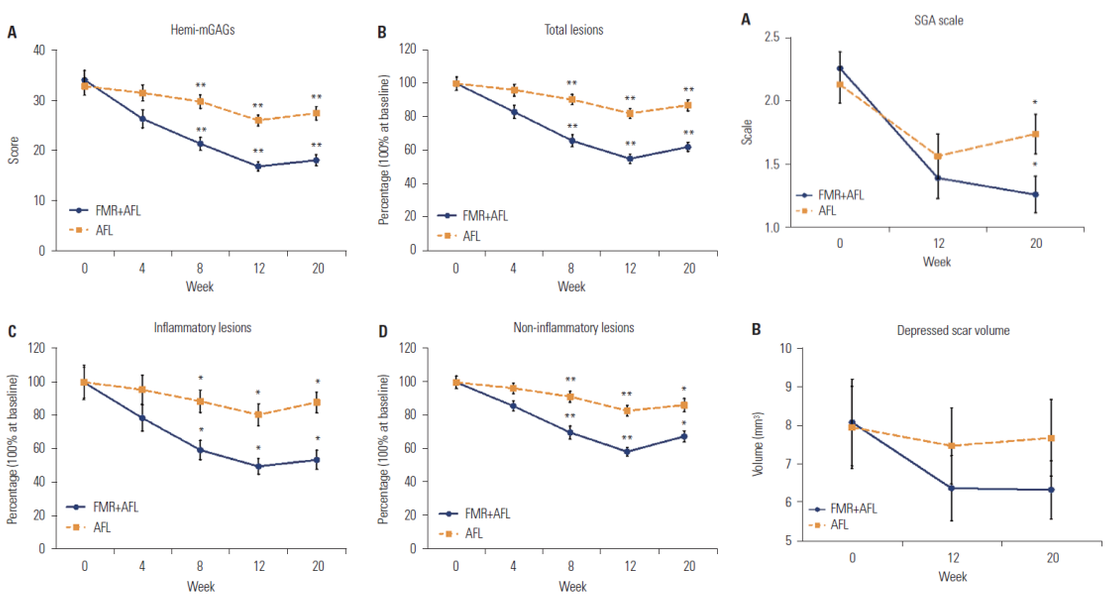
By Jemin kim, Sang Gyu Lee, Sooyeon Choi, Joohee Lee, Jihee Kim, and Ju Hee Lee
*Yonsei Medical Journal,* 2023; 64(12): 721-729

**Method**

- To assess the safety and efficacy of the combination of fractional microneedle radiofrequency (FMR) (SYLFIRM X; ViOL) and ablative fractional laser (AFL) versus AFL alone in treating acne and acne scars, 23 Korean patients with facial acne and acne scars treated in a split-face design.
  - Patients : 16 male, 7 female, Fitzpatrick skin types III-IV, average age 24.1±4.76 (age range 19-36)
  - Split study
    - Combination of FMR and AFL on one face / AFL alone on the other side
    - 3 treatments at 4-week intervals
  - Treatment Parameters
    - FRF: PW4 Mode, 1.6-2.0mm depth, level 4-6, one pass with <20% overlap
    - AFL: 100mJ, 100spots/cm$^2$ (15.6% coverage and ablation depth of 1168μm)

**Result**

- The FMR+AFL treatment demonstrated superior efficacy compared to AFL alone in terms of inflammatory acne and acne scar grading, lesion counts, and subjective satisfaction.
- The side effects were minimal and well-tolerated in both groups.
- Immunohistochemical findings from skin biopsy samples revealed that the application of FMR+AFL could induce an inhibitory effect on sebum secretion at the molecular level.




❖ hemi-mGAGs : hemi-modified Global Acne Grading Score, SGA : Scar Global Assessment scale

# Pulsed Wave: Acne or/and Acne Scar

## Efficacy Assessment of a Pulsed-Type Bipolar Radiofrequency Microneedling Device for Treating Facial Acne Vulgaris Using a Skin Color Imaging System: A Pilot Study SCIE

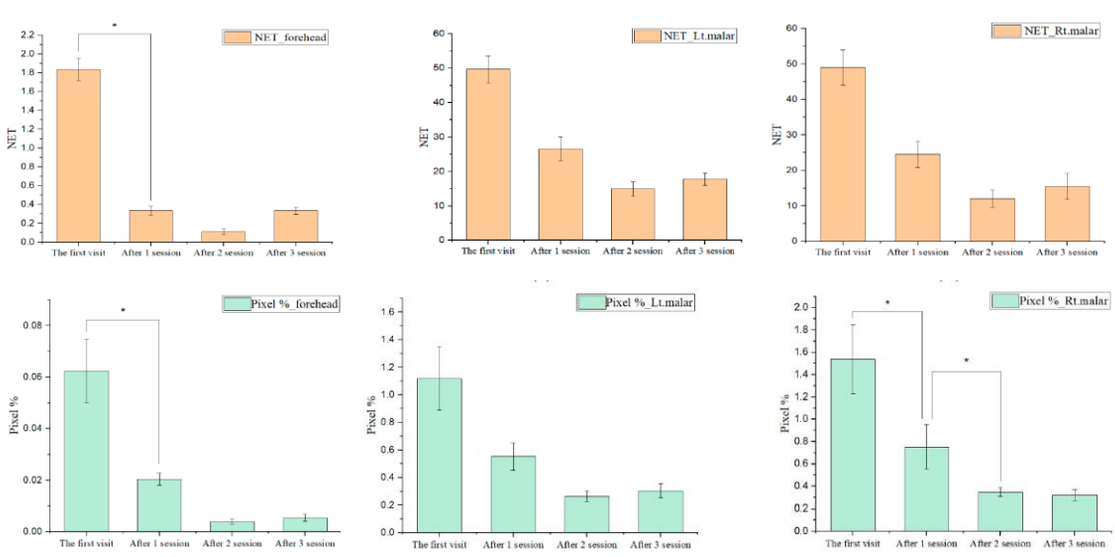
By Tae Woong Seul , Jong Heon Park, Jae Young Kim, and Hwa Jung Ryu
*Applied Sciences,* 2023; 13(4): 2114

**Methods**

- 18 Patients with acne vulgaris and post-inflammatory erythema were treated on both sides of their malar areas as well as their forehead using a pulsed-type bipolar radiofrequency device with non-insulated microneedles (SYLFIRM; ViOL).
  - Patients
    - 10 males and 8 females, a mean age of 22.7 years, ranging from 16 to 35 years
    - 5 patients were taking oral antibiotics for acne (doxycycline and minocycline)
  - RF Treatment: 1.5mm, level 3, <10% overlap, 1-2passes, 3 sessions at 4 week intervals

**Results**

- Almost all patients experienced decreases in the number and area of lesions.
- The mean number of lesions exceeding the erythema threshold was significantly decreased from the first visit to final visit.
- The mean number of summation of the area exceeding the erythema threshold was significantly decreased from the first visit to the final visit for the left malar and the right malar.
- Mild and transient side effects, including pain, tingling sensations, and erythema, were reported following treatment; however, all symptoms resolved spontaneously within one to two days.
- During RF treatment and after the final treatment, temporary aggravation of acne vulgaris or folliculitis was not found.




❖ NET : number of lesions exceeding the erythema threshold, Pixel % : summation of the area exceeding the erythema threshold

# Pulsed Wave: Scar


## Adjuvant Therapy for Revision Rhinoplasty of Contracted Nose Using Polydeoxyribonucleotide and Invasive Bipolar Radiofrequency ESCI

By Tae Hwan Ahn, and Sung Bin Cho

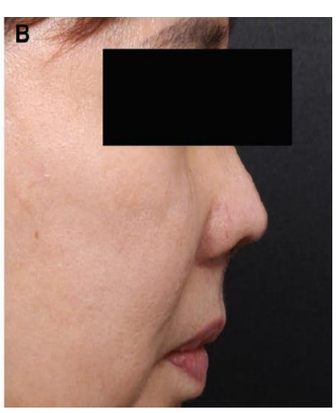
*Plastic and Reconstructive Surgery Global Open,* 2018; 6(1): e1645

**Methods**

- 30 Korean patients with contracted nose were treated with intralesional injection of PDRN and invasive RF using microneedle electrode (SYLFIRM; ViOL) for revision rhinoplasty and septoplasty.
  - Patients :
    - 12 males and 18 females, a mean age of 37.7 years, ranging from 23 to 62 years
  - Treatments :
  - 8 preoperative sessions – revision rhinoplasty and septoplasty after 1 week - 8 postoperative sessions after 1 week
    - PDRN: a total amount of 0.3mL at 3 points using a 31-gauge, 1-mL insulin syringe
    - RF Treatment: 1.5mm, level 3, over 2-3passes
    - 1 week intervals

**Results**

- 1 week after the final combined pretreatment using PDRN and invasive bipolar RF, the skin of contracted noses was sufficiently softened, and nasal skin mobility was notably improved in all the patients.
- During revision rhinoplasty and septoplasty, the contracted nasal skin in each patient was adequately released for proper covering of the nasal tip without tension.
- Postoperatively, 8 sessions of adjuvant therapy elicited marked clinical improvements in persistent nasal tip dimpling and contracture, septal deviation, and warping from the incomplete recovery of nasal contracture after revision surgery.


(A) Baseline
(B) At 18 months after revision surgery with 8 sessions of preoperative and 8 sessions of postoperative adjuvant therapy



(A) Baseline
(B) At 18 months after revision surgery with 8 sessions of preoperative and 8 sessions of postoperative adjuvant therapy





34

# Pulsed Wave: Skin Rejuvenation

## Efficacy and Safety of Using Noninsulated Microneedle Radiofrequency Alone versus in Combination with Polynucleotides for Treatment of Periorbital Wrinkles SSCI

By Yuri Yogya, Rungsima Wanitphakdeedecha, Supisara Wongdama, Yanisorn Nanchaipruek, Chadakan Yan, Sarawalai Rakchart
*Dermatology and Therapy,* 2022; 12(5): 1133-1145

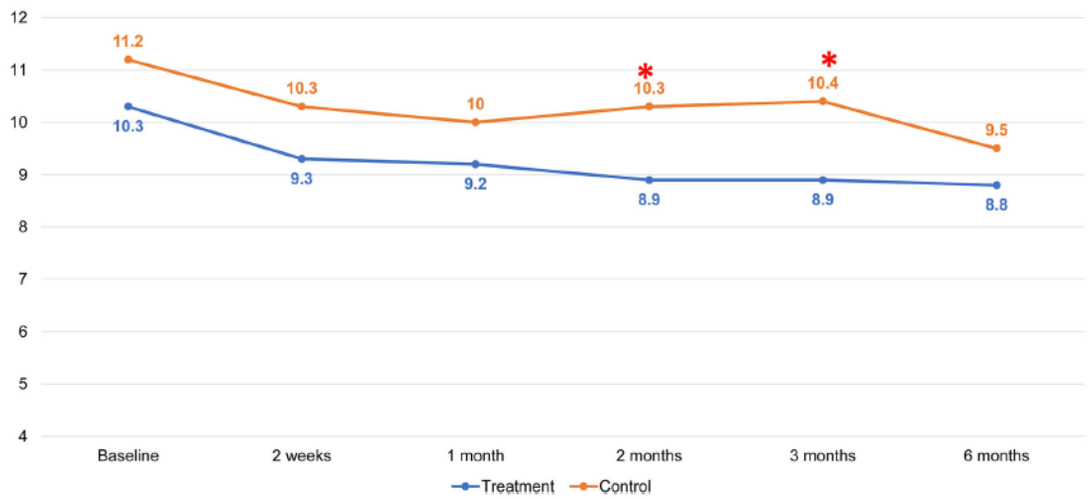
**Methods**

- 30 subjects with facial wrinkles were treated with a noninsulated radiofrequency microneedling (RFMN) (SYLFIRM; ViOL) for prospective, double-blind, randomized, controlled and split-face study, and 29 subjects completed the study.
- Patients
  - Thai women, mean age of 42.9±6.7 years, Fitzpatrick skin types III-V
- Treatment
  - RFMN + application of polynucleotides (PNs; treatment group) on one side / RFMN + application of normal saline solution (control group)
  - RFMN : 0.8-1.5mm, levels 2-3, 3passes with 10-30% overlap, 3 sessions at 2-week intervals
  - PNs : Each 3 ml vial contained 9 mg PNs *The other main components were 0.3% hyaluronic acid (1.4 million Da), amino acids, minerals, vitamins, and peptides.

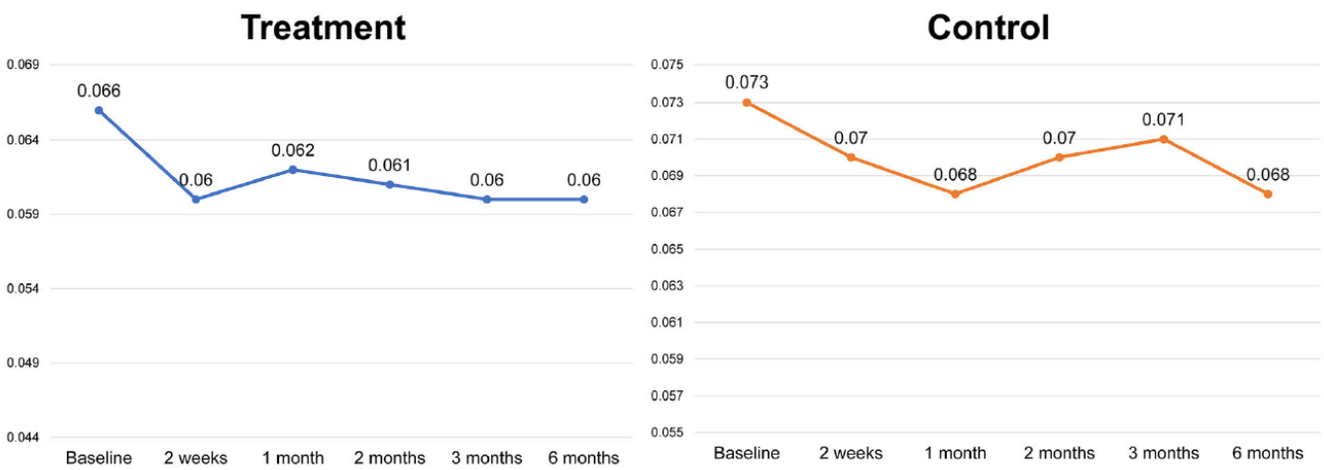
**Results**

- There were no statistically significant differences in the baseline values of the wrinkle indentations, the maximum wrinkle depth, or the mean gross elasticity of the control and treatment sides.
- The indentation of the wrinkles on the treatment side began to improve at the 2-month follow-up and a better improvement was observed on the treatment side than on the control side.
- A steady improvement was noted on the treated side and on the control side until the 6-month follow-up.
- No statistically significant differences were observed in the maximum depth of wrinkles on the treatment and control sides at any follow-up visit.
- All patients tolerated the procedure well, and there were no reports of injection, hyperpigmentation, hypopigmentation, persistent erythema, or scarring.

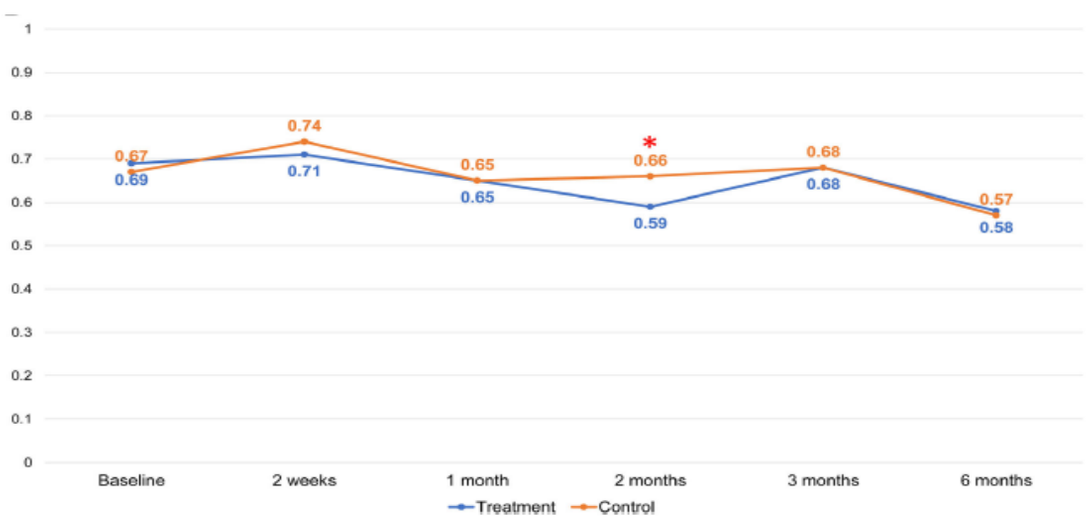
# Pulsed Wave: Skin Rejuvenation




Comparison indentation of wrinkles scores of the treatment and control sides




mean scores for maximum depth of wrinkles of the treatment and control sides




Comparison of the mean gross elasticity (R2) scores of the treatment and control sides

# Pulsed Wave: Skin Rejuvenation


## Laser-assisted Delivery of a Combined Antioxidant Formulation Enhances the Clinical Efficacy of Fractional Microneedle Radiofrequency Treatment: A Pilot Study SSCI

By Jihee Kim, Soo Min Kim, Bok Ki Jung, Sang Ho Oh, Young-Koo Kim, and Ju Hee Lee
*Medical Lasers,* 2021; 10(3): 161-169

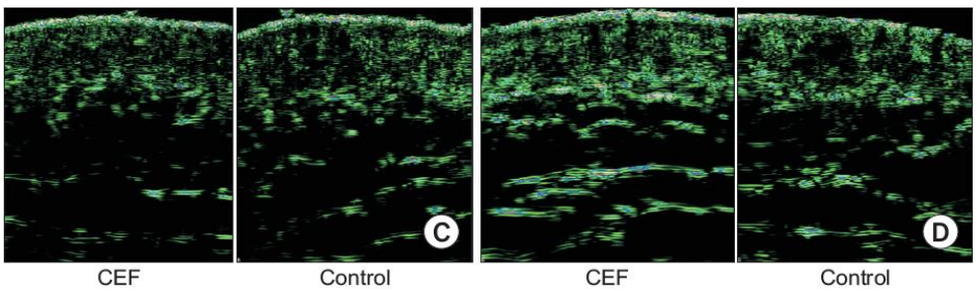
**Methods**

- 6 women with mild to moderate photodamage, underwent a single session of a pulse-type fractional microneedling RF (FMRF) (SYLFIRM; ViOL) treatment for a prospective, split-face, single-blind, controlled pilot study.
  - Patient : mean age of 48.0 years, range of 35-57 years; Fitzpatrick skin types III-IV
  - Study
    - FMRF only on one side (control/untreated side) / FMRF + application of L-ascorbic acid, vitamin E, and ferulic acid (LADD; antioxidants) on the other side (treated side)
    - FMRF: 2.0-2.4mm, 100-150J
    - LADD: 4-5 drops
- Ex vivo model was used to assess potential molecular and histological changes after RMFR or/and LADD application.

**Results**

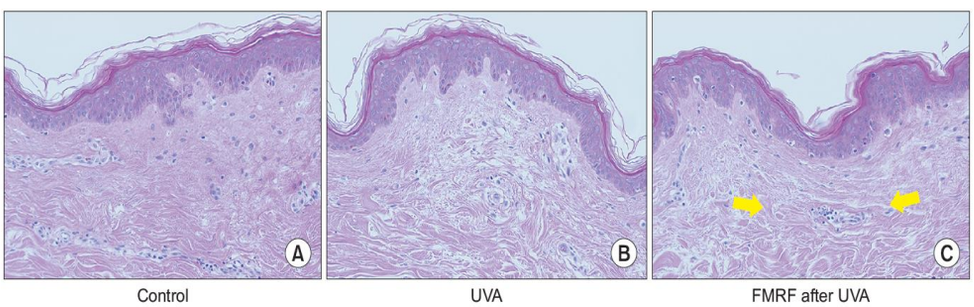
- Treatment
  - The clinical signs of photorejuvenation, such as midface curvature length and dermal thickness, improved more on the treated side than on the untreated side of the face.
  - Skin elasticity increased in the antioxidant-treated and control sides, with no statistically significant difference between them.
  - No adverse effects were encountered and there were no cases of patient dropout due to side effects.
  - Both sides exhibited a decrease in the melanin index and erythema index.
- Ex vivo model
  - UV-A exposure induced downregulation of transforming growth factor-beta (TGF-β), type III collagen (COL3A1), and fibroblast growth factor 2 (FGF2).
  - After FMRF treatment, TGF-β and COL3A1 were significantly upregulated, and FGF2 levels were even increased.
  - Treatment with the antioxidant formulation resulted in a further increase in FGF2 transcription and COL3A1 expression.

# Pulsed Wave: Skin Rejuvenation

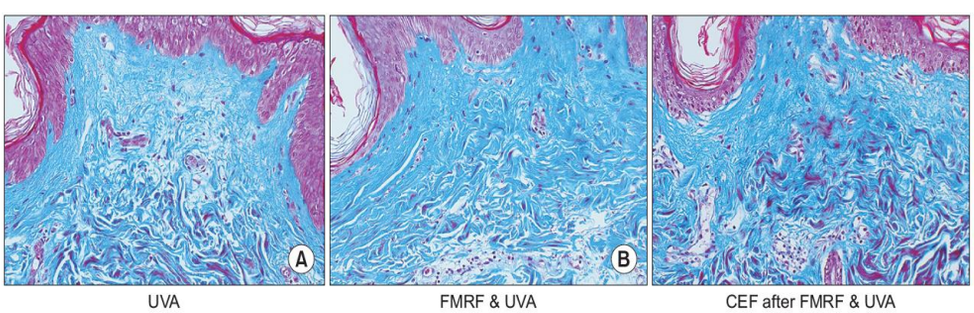



(Control) FMRF treated side
(CEF) FMRF + antioxidants treated side

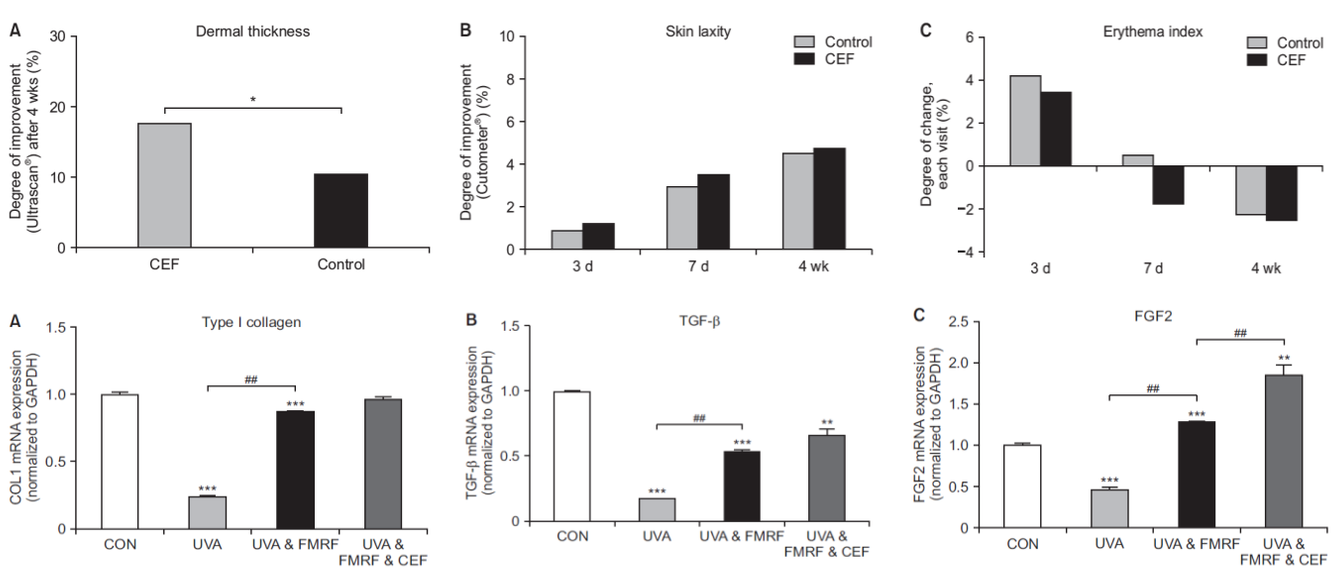
The increase in mean dermal thickness after 4 weeks, was higher on the treated side than that of the non-treated side. Ultrasound analysis.




(A, B) H&E staining of UV-A irradiated skin revealed solar elastosis and hyalinization of collagen on the upper dermis (×100).
(C) FMRF treatment induced microthermal zones (indicated by yellow arrows), which induced the generation of thicker collagen bundles (H&E, ×100).




(A, B) A single pulse-type FMRF treatment induced neocollagenesis on the photoaged skin (Masson's trichrome, ×100).
(C) Subsequent treatment with the antioxidant formulation induced a further increase in collagen deposition in the FMRF-treated skin (Masson's trichrome, ×100).




- CEF: side treated with RMRF + antioxidant formulation
- COL3A1: collagen type III alpha 1 chain, provides instructions for making type III collagen
- TGF- β : transforming growth factor-b, a multifunctioning cytokine belonging to the transforming growth factor superfamily that includes three different mammalian isoforms and many other signaling proteins.
- FGF2: Basic fibroblast growth factor (bFGF) and FGF-β, a growth factor and signaling protein encoded by the FGF2 gene

# Pulsed Wave: Skin Rejuvenation


Case Report

MEDICAL LASERS

Improvement of Periorbital Wrinkles Treated with an Invasive Non-Insulated Microneedle Pulsed Electric Signal Device

## Improvement of Periorbital Wrinkles Treated with an Invasive Non-Insulated Microneedle Pulsed Electric Signal Device SCIE

By Suhyun Cho, Yoon Jin Choi, and Jin-Soo Kang

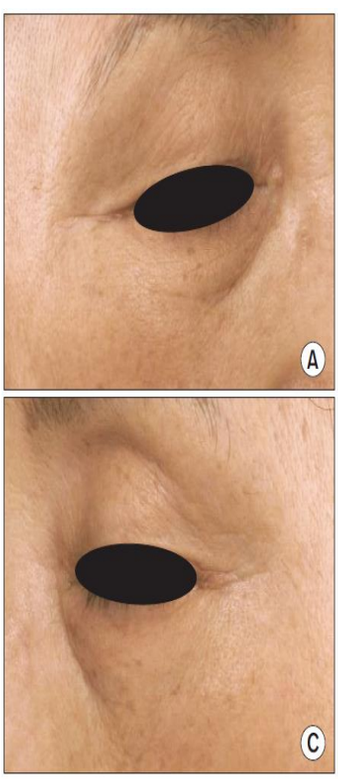
*Medical Lasers,* 2016; 5(1): 34-38

**Methods**

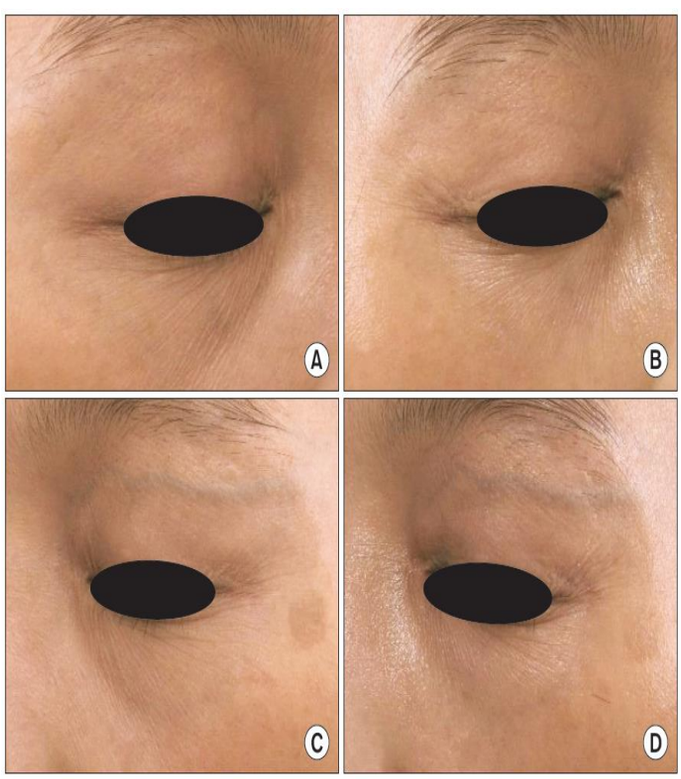
- 3 female Korea patients with variable degrees of periorbital wrinkles, were treated using an invasive non-insulated microneedle pulsed electric signal device (SYLFIRM; ViOL).
  - Treatment: 1.0-1.5mm, level 3-4, single pass, <10% overlap for 2 treatment with 1 month interval

**Results**

- All patients showed objective improvements with their periorbital wrinkles with only 2 sessions and all accompanied patient's subjective satisfaction.
- Patients reported mild to moderate pain during the procedure.
- No noticeable side effects including epidermal shedding, crust formation or bruising was observed.




Many deep wrinkles nearly covering the entire periorbital area, with coarse wrinkles extending into the cheek
(A), (C) Before
(B), (D) 2 weeks after 2 sessions of RF microneedling treatment




Shallow wrinkles with some deeper wrinkles on the corner of the eyes
(A), (C) Before
(B), (D) 2 weeks after 2 sessions of RF microneedling treatment

Victory of Life

ViOL