Microneedling RF Update 2025

South Beach Symposium
Miami Beach, FL

February 6 - 8, 2024

Presented by Michael H. Gold, MD
Gold Skin Care Center
Tennessee Clinical Research Center
Nashville, TN 37215

Academic Appointments

01. Assistant Clinical Professor

- Department of Medicine, Division of Dermatology, Nashville, TN USA
- Vanderbilt University School of Medicine: 2006-2014
- Vanderbilt University School of Nursing: 2006-2020

02. Adjunct Assistant Professor

- Meharry Medical College: 2013 – Present
- School of Medicine, Nashville, TN

03. Visiting Professor of Dermatology

- Huashan Hospital, Fudan University (Shanghai Medical University), Shanghai, China
- The First Hospital of China Medical University, Shenyang, China:
- Guangdong Provincial People's Hospital, Guangzhou, Zhejiang

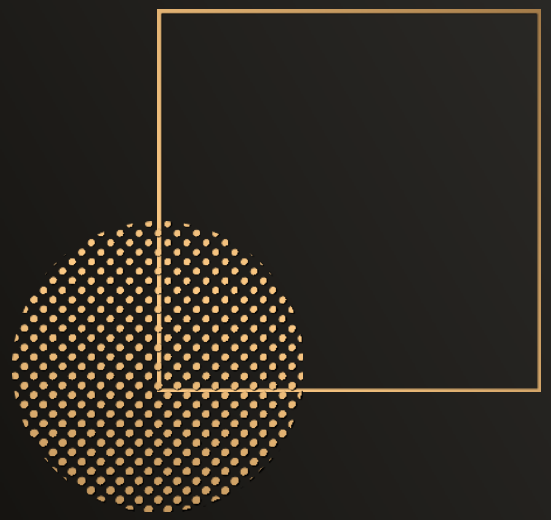
04. Visiting Professor of Plastic Surgery

- First People's Hospital of Foshan University, Guangdong, China
- The First Affiliated Hospital of Zhejiang University, Hangzhou, Zhejiang
- Rongjun Hospital, Jiaxing, China
- The People's Hospital of Hunan Province, Changsha, China

05.

- Editor-in-Chief – Journal of Cosmetic Dermatology – Wiley: 2016-Present
- Editor-in-Chief- Dermatological Reviews – Wiley: 2019 - Present

Conflict of Interest



01. Consultant to many pharmaceutical, cosmeceutical, laser and energy-based device companies

02. Consultant, performs research and speaks on behalf of numerous pharmaceutical and medical device companies

03. For the benefit of this presentation, consultant, Investigator, Speaker for almost every company in this space

Microneedling New Concepts to Consider

- Microneedling is one of the most popular cosmetic procedures in 2025
- From rollers to pens to RF pins to RF needles this field continues to grow
- This talk will highlight some of the concepts that make this technology popular

Microneedling New Concepts to Consider

- We know microneedling can improve skin texture, lines, and wrinkles
- We know microneedling can improve acne scars
- Will needling work for hypertrophic scars and keloids?
- Will needling work to improve the vascular component of aging?
- Will needling work to improve pigment?

Acne scars- Use of needling devices wileyonlinelibrary.com/journal/der2

INVITED REVIEW

Dermatological Reviews

WILEY

Acne scars—Use of needling devices

Marci D. Levy MS, PA-C[1,2] | Michael H. Gold MD[1,2]

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Abstract

Background: Acne scarring is a common concern with psychosocial implications and numerous treatments available. Patient comfort, ease of treatment, satisfaction, and access can all impact adherence.

Objective: To discuss common needling technology available including electronic microneedling pens, fractional radiofrequency (RF) delivery via microelectrodes termed pins, and fractional RF microneedling treatment platforms.

Methods: A literature review of commonly used available platforms and their associated data. Platforms discussed will be electronic microneedling pens (SkinPen, Crown Aesthetics; Collagen P.I.N. [percutaneous induction therapy], induction therapies), RF microneedling pins (eMatrix; Candela, Venus Viva; Venus Concept), and RF microneedling (Intensif, EndyMed Medical; Fractora and Morpheus8, InMode Ltd; Infini and Genius; Lutronic Inc; PiXel8-RF, Rohrer Aesthetics; Legend Pro, Lumenis).

Results: Microneedling, RF microneedling pins, and RF microneedling are well-tolerated and effective for improving acne scarring, skin texture abnormalities, and overall aesthetic status. These modalities have been demonstrated to be safe on darker Fitzpatrick skin types and are often associated with minimal patient discomfort and good patient satisfaction.

Conclusion: Needling technology will continue to improve and is worth considering when offering treatment of acne scarring given shortened downtime, ease of access, and subjective and objective improvement demonstrated in literature.

KEYWORDS

acne scarring, microneedling, microneedling pins, needling, radiofrequency microneedling

Microneedling for the Treatment of Scars: An Update for Clinicians Clinical, Cosmetic and Investigational Dermatology 2020:13 997–1003

Clinical, Cosmetic and Investigational Dermatology

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REVIEW

Microneedling for the Treatment of Scars: An Update for Clinicians

This article was published in the following Dove Press journal:
Clinical, Cosmetic and Investigational Dermatology

Margit LW Juhasz[1]
Joel L Cohen[1,2]

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Background: Microneedling (MN) is used for the treatment of scars, amongst other indications. Although used in Asia and the Middle East for decades, related to the supposed lack of post-procedure pigmentary alterations even in darker skin types, MN only recently gained attention in the United States as an effective, well-tolerated aesthetic treatment.

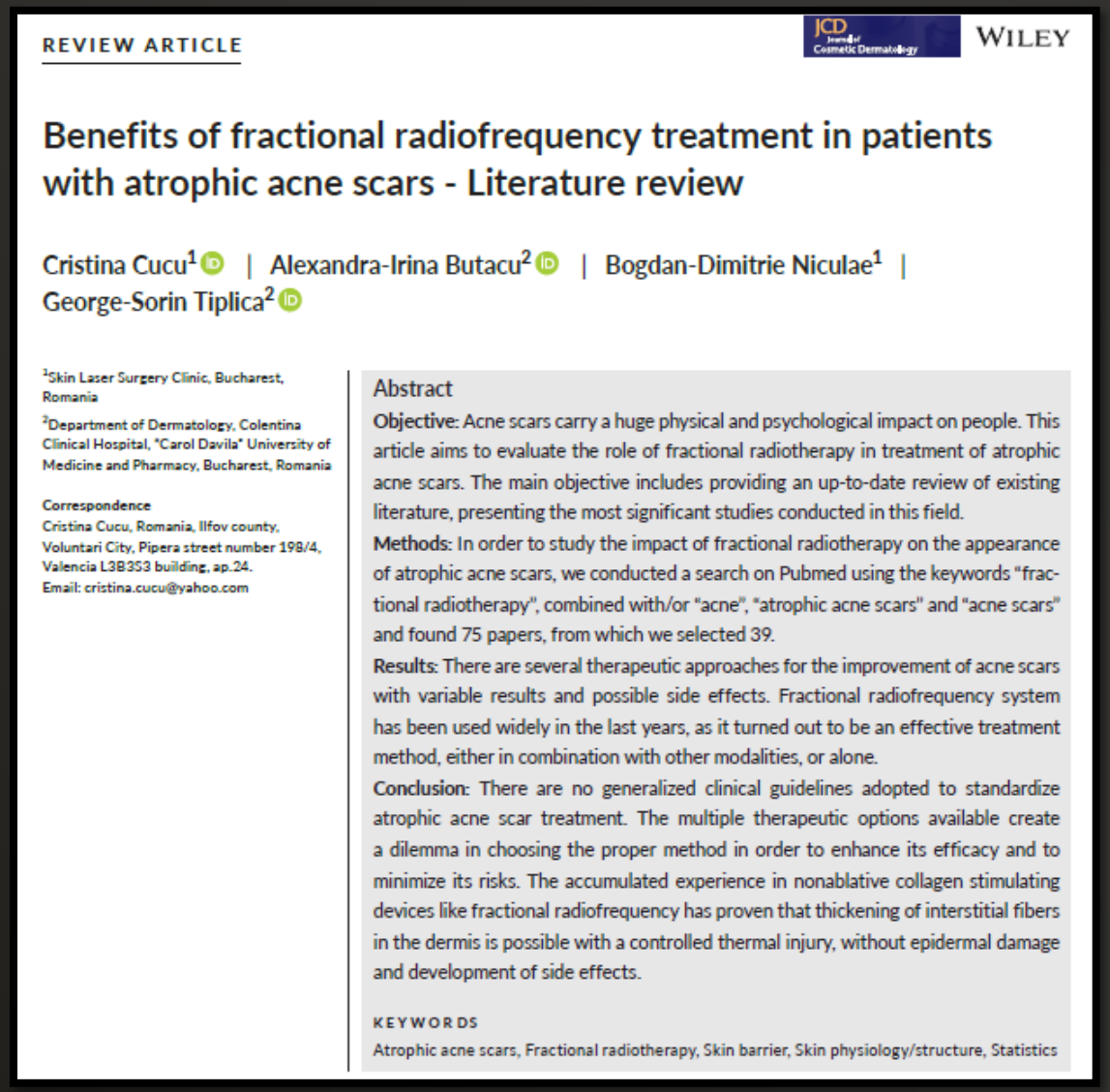
Materials and Methods: A systematic review of the Medline database was completed using search terms "microneedle" or "microneedling" or "micro needle" or "micro needling" and "scar". Included articles were written in English and discussed the use of MN for the treatment of scars in human subjects.

Results: Fifty-eight studies were included for review, with a total of 1845 patients treated for acne scarring, hypertrophic or keloid scars, and those resulting from surgery, trauma, varicella or smallpox. MN and its counterpart fractional radiofrequency MN (FRF-MN) were used as monotherapy or in combination with topical, surgical or systemic modalities. MN and FRF-MN treatment resulted in clinical improvement of scar appearance from baseline. No serious adverse events occurred.

Conclusion: MN is a well-tolerated, minimally invasive procedure that can be used for the treatment of scars with a high level of patient satisfaction. Further clinical studies are needed to develop standardized treatment protocols.

Keywords: microneedling, laser, peel, platelet-rich plasma, scar

Benefits of fractional radiofrequency treatment in patients with atrophic acne scars – Literature reviews
J Cosmet Dermatol. 2021;20:381–385



REVIEW ARTICLE

JCD Journal of Cosmetic Dermatology WILEY

Benefits of fractional radiofrequency treatment in patients with atrophic acne scars - Literature review

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Abstract

Objective: Acne scars carry a huge physical and psychological impact on people. This article aims to evaluate the role of fractional radiotherapy in treatment of atrophic acne scars. The main objective includes providing an up-to-date review of existing literature, presenting the most significant studies conducted in this field.

Methods: In order to study the impact of fractional radiotherapy on the appearance of atrophic acne scars, we conducted a search on Pubmed using the keywords "fractional radiotherapy", combined with/or "acne", "atrophic acne scars" and "acne scars" and found 75 papers, from which we selected 39.

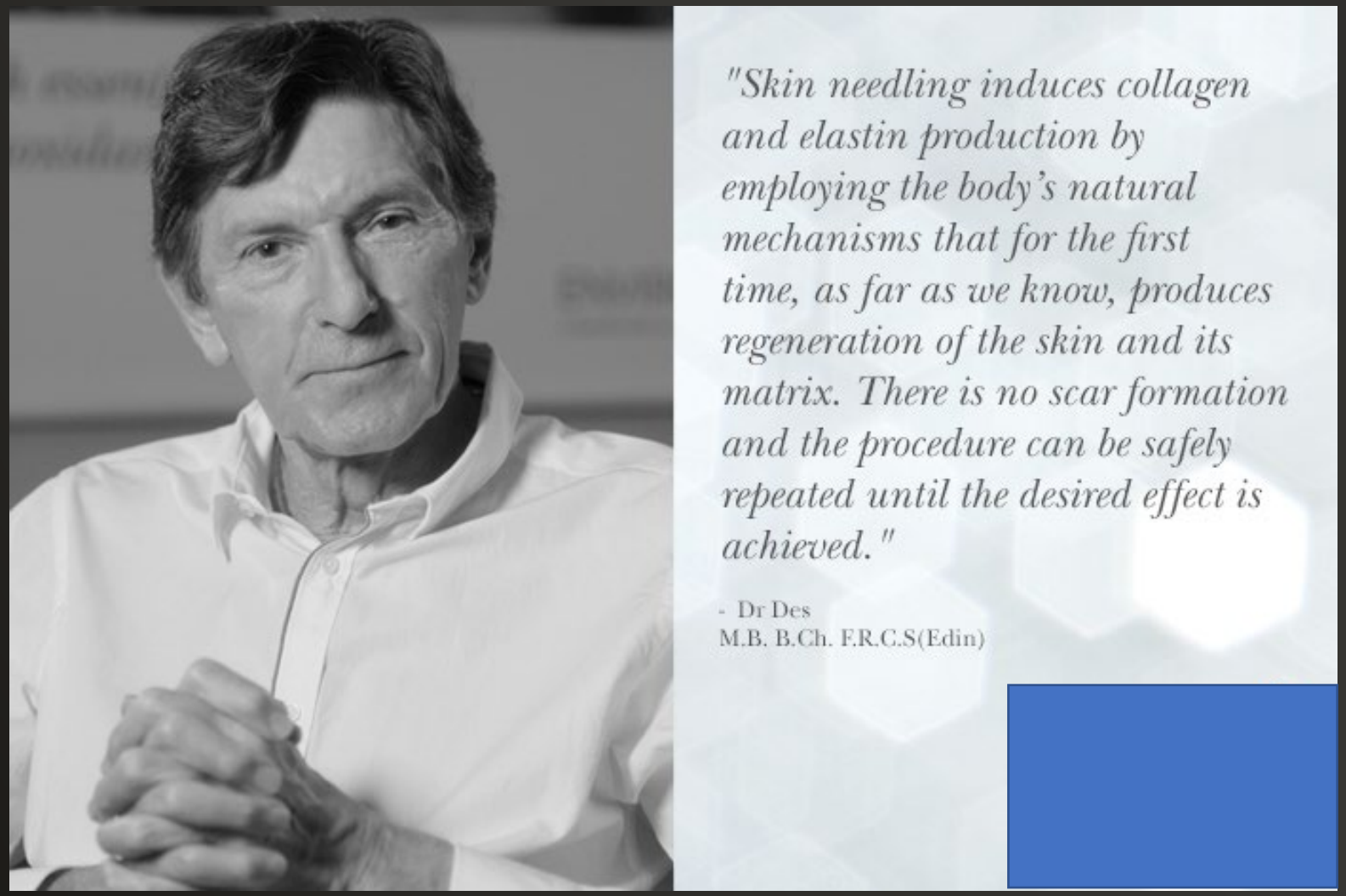
Results: There are several therapeutic approaches for the improvement of acne scars with variable results and possible side effects. Fractional radiofrequency system has been used widely in the last years, as it turned out to be an effective treatment method, either in combination with other modalities, or alone.

Conclusion: There are no generalized clinical guidelines adopted to standardize atrophic acne scar treatment. The multiple therapeutic options available create a dilemma in choosing the proper method in order to enhance its efficacy and to minimize its risks. The accumulated experience in nonablative collagen stimulating devices like fractional radiofrequency has proven that thickening of interstitial fibers in the dermis is possible with a controlled thermal injury, without epidermal damage and development of side effects.

KEYWORDS

Atrophic acne scars, Fractional radiotherapy, Skin barrier, Skin physiology/structure, Statistics

Microneedling – Dermal Rollers



Dr. Des Fernandes is the father of microneedling as we know it
Plastic Surgeon from Cape Town, South Africa
First developed the technique used today

RF Microneedling Pins and Needles

- RF Pins
  - eMatrix – no longer available
  - Viva
  - VivaMD
  - Reverso

- RF Needles – Continuous Wave (>0.1 sec)
  - Profound - bipolar
- RF Needles –Continuous Wave (<0.1 sec)
  - Intensif
  - Fractora, Morpheus8
  - Vivace Ultra
  - Vivace and Vivace Pro
  - Agnes & Scarlet
  - Secret
  - Infini, Genius
  - INTRAcel
  - PiXel8 RF and Fraxis Duo
  - Potenza – monopolar and bipolar
  - Exion – monopolar
- RF Needles –Pulsed and Continuous Wave (up to 0.03 sec)
  - Sylfirm X

eMatrix

2021 : Not Available at this time

RF Microneedling – The Beginning

Hruza G, Taub AF, Collier SL et al.
J Drugs Dermatology 2009;8(3): 259 – 265.

March 2009 259 Volume 8 • Issue 3

ORIGINAL ARTICLES Journal of Drugs in Dermatology

Skin Rejuvenation and Wrinkle Reduction Using a Fractional Radiofrequency System

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d. SpaMedica Infinite Vitality Clinics, Toronto, ON

ABSTRACT

Introduction: Skin resurfacing has evolved rapidly over the past 15 years from ablative techniques to nonablative methods and most recently fractional ablative resurfacing. The purposes of this study were to analyze the degree of tissue ablation, coagulation, and heating; and to evaluate the clinical efficacy and safety of a fractional radiofrequency (RF) device, for the treatment of wrinkles with fractional skin ablation and coagulation.

Material and Methods: Individuals scheduled for abdominoplasty received fractional RF treatment to the abdomen area, using different tips at varying energy densities and coverage rates. Biopsies were performed *ex vivo* following abdominoplasty and tissue samples were routinely processed and stained, using hematoxylin and eosin). Another group of subjects received three facial treatments, scheduled at 3 to 4 week intervals. Clinical improvement and response to therapy were evaluated with standardized photography and clinical assessment by the subjects and investigators.

Results: Histological findings immediately posttreatment revealed demarcated zones of ablation/coagulation/necrosis and sub-necrosis up to a depth of 450 µm. Higher energy levels generated deeper effects. We noticed a tunable balance between ablation and coagulation/necrosis. These effects were coverage mode and energy density dependent. Subjects undergoing facial treatment had minimal pain, no permanent side effects or significant downtime. Investigators' assessment for improvement in skin texture correlated with subjects' evaluation and was greater than 40% for approximately 50% of subjects. Eighty percent of the subjects were satisfied with the results. Higher energy levels and lower coverage rates produced better aesthetic results along with less pain.

Conclusions: The clinical observations and histological findings suggest that fractionated ablative skin resurfacing using Matrix RF resulted in a safe, tolerable and effective improvement in skin texture and reduction of wrinkles. The depth of tissue ablation, coagulation and necrosis and the relative proportions of these phenomena were found to be controllable and could be modulated to optimize treatment of variable dermatologic conditions.

Treatment of acne scars by fractional bipolar radiofrequency energy

Journal of Cosmetic and Laser Therapy, 2012; 14: 172–178

informa
healthcare

ORIGINAL RESEARCH REPORT

Treatment of acne scars by fractional bipolar radiofrequency energy

MICHAEL H. GOLD[1,2] & JULIE A. BIRON[2]

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Abstract

Background/Objective: A variety of modalities are available for the treatment of acne scars. This prospective, IRB-approved study evaluates the efficacy and tolerance of fractional bipolar RF energy in the treatment of facial acne scars. *Methods*: Healthy subjects ($n = 15$, 13 females, aged 35.7 ± 5.6 years [mean $\pm$ SD], skin types I–V) with mild to moderate acne scars received three monthly treatments with a fractional bipolar RF device. Improvement and tolerance were evaluated at each visit, including a 1-month and 3-month follow-up visit. *Results*: Ten subjects completed the study. Physician-assessed acne scar severity was significantly reduced at 1 month and 3 months. Adverse effects were limited to transient erythema. Dryness, bruising and crusting erosion were limited. Subject-assessed stinging/burning, stinging (alone), tingling, itching and burning were also limited and consistent with each treatment. Subject-assessed fine lines and wrinkles, brightness, tightness, acne scar texture, pigmentation were all improved significantly. Satisfaction was high in 67–92% of subjects. *Conclusion*: Fractional bipolar RF energy is a safe and effective modality for the treatment of acne scars.

Key Words: *acne scars, fractional, radiofrequency, bipolar*

Enhanced high-energy protocol using a fractional bipolar radiofrequency device combined with bipolar radiofrequency…

J Cosmet Dermatol. 2017:16:205-209

Enhanced high-energy protocol using a fractional bipolar radiofrequency device combined with bipolar radiofrequency and infrared light for improving facial skin appearance and wrinkles

Michael H. Gold MD[1] | Brian S. Biesman MD[2] | Mark Taylor MD[3]

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Funding information
Syneron Candela;

Summary

Background: Fractional bipolar radiofrequency treatment and treatment with bipolar radiofrequency combined with infrared light have been shown in previous trials to safely and effectively improve the appearance of facial wrinkles.

Aims: To evaluate a high-energy protocol with combined bipolar radiofrequency and infrared light energies for improvement in photoaged facial skin.

Patients/Methods: Seventy-two patients presenting with mild to moderate facial wrinkles underwent a single full-face treatment (n=54) or two treatments (n=18) at 6-week intervals. Independent blinded assessment and investigator assessment were performed, using the Fitzpatrick Wrinkle and Elastosis Scale (0-9) and the Global Aesthetic Improvement scale. Patients also completed a self-assessment questionnaire concerning satisfaction with the treatment.

Results: All patients achieved some degree of improvement in their wrinkles and skin appearance, following a single treatment or two treatments with the enhanced-energy protocol. Blinded evaluation demonstrated 71% and 70% of the patients showing improvement of one unit or greater on the Fitzpatrick Scale, at the 12-week and 24-week follow-ups post-treatment, respectively. Similar results were reported by investigators. Under the Global Aesthetic Improvement Scale, investigators observed 87%, 91% and 81% of patients showing improvement at the 6-, 12-, and 24-week post-treatment end, respectively. Patients tolerated the treatments well and were satisfied with the clinical results.

Conclusion: The enhanced-energy treatment protocol, with fractional bipolar radiofrequency treatment and treatment with bipolar radiofrequency combined with infrared light applications, yields significant improvement of skin texture, wrinkling, and overall appearance following a single treatment. The results appear gradually over time and are maintained for at least 6 months' post-treatment.

Nanofractional RF Microneedling


VENUSCONCEPT
230 v
55%
23 ms
1
2
3
4
1.0
Standby
Ready
80 Pin
696/700

ONE DEVICE.
ALL SKIN TYPES.
ALL SKIN RESURFACING.

HIGHLY CUSTOMIZABLE

Highly tunable power and pulse duration for full control of ablation and coagulation, and two tip options for mild to severe skin conditions.

UNIQUE, CUTTING-EDGE TECHNOLOGY

NanoFractional RF™ with SmartScan™ provides uniform energy distribution and safer energy delivery for optimal results.

SAFE FOR ALL SKIN TYPES

Incidence of PIH is low at 18.1%, compared to CO_2 and Erbium:Glass at 81.8% and 36.4%, respectively.[1]

LOW DOWNTIME

NanoFractional RF™ creates micro-wounds in the tissue by ablating channels in the skin, surrounded by in-tact tissue, leading to lower downtime.

HIGH PATIENT SATISFACTION

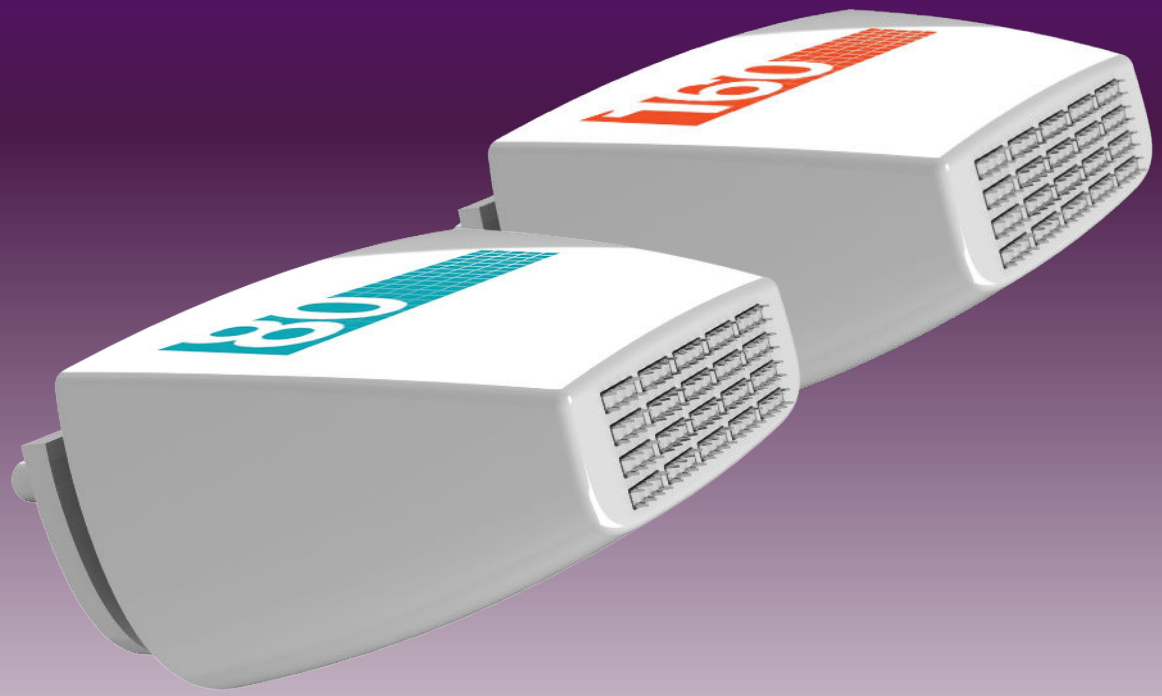
60% of patients rated the comfort, recovery time, and results of NanoFractional RF™ treatments as “Excellent”. [2]

THE APPLICATORs

Now more customizable for mild to severe conditions

MORE
ablation & coagulation

Pin difference



2 Pin Tip Options

Depth of penetration up to **750µ**

Large coverage area for **faster treatments**

2 Tip sizes:

160-pin tip

(with up to 62 mJ/pin)

for milder skin texture irregularities

80 pin tip

(with up to 124 mJ/pin)

for more severe skin concerns-scars, acne scars

No return electrodes – **full, even energy delivery to each pin**

High energy density in each pin tip → **higher depth of penetration**

Energy is delivered to pin groups in a **randomized manner, minimizing discomfort**

Nanofractional Skin Resurfacing

ABLATION

Skin resurfacing to address

- Textural irregularities
- Tonality superficial

Removal of tissue by vaporization. Both the epidermis and dermis are treated to **smooth and remove various lesions i.e.,** enlarged pores, pigment (age spots), scars etc.

COAGULATION

Collagen remodeling to address

- Wrinkles
- Deep acne scars
- Loose skin

Denaturation of the damaged proteins are being replaced with new collagen fibers for tighter skin.

CUSTOMIZABLE AND VARIABLE > BETTER OUTCOMES

SMARTSCAN™ TECHNOLOGY

What is SmartScan™ technology?

- Each tip (160 pin & 80 pin) is divided into groups of 4 or 2 pins , respectively
- During a single pulse, each group takes turns being active (acting as electrodes), while the other groups are receiving the energy as return electrodes
- The pattern is completely random
- SmartScan™ allows higher energy to be delivered safely by having only one group of electrodes (pins) deliver energy at one time
- Discomfort is reduced, risk of adverse skin response is reduced

Bulk RF Treatment Applicator

- With $(MP)^2$ Technology

PROVIDES BULK HEATING TO THE TISSUE THAT CAUSES COLLAGEN CONTRACTION AND STIMULATION, AND THE IMMEDIATE EFFECT OF TIGHTER, FIRMER APPEARANCE OF THE SKIN

- Non-invasive wrinkle reduction
- Proven $(MP)^2$ technology that combines multi-polar RF and PEMF
- No downtime
- Safe for all skin types
- Pain-free

Nanofractional RF 80 Pin Tip Results

Expanding the Clinical Application of Fractional Radiofrequency Treatment: Findings on Rhytides, Hyperpigmentation, Rosacea, and Acne Redness
J Drugs Dermatol. 2015;14(11): 611-617

Expanding the Clinical Application of Fractional Radiofrequency Treatment: Findings on Rhytides, Hyperpigmentation, Rosacea, and Acne Redness

Wichai Hongcharu MD[a] and Michael Gold MD[b]
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[b] Gold Skin Care Center and The Tennessee Clinical Research Center, Nashville, TN

ABSTRACT

While radiofrequency has been used medically for decades to treat a wide variety of conditions, its use therapeutically to target conditions affecting the skin is relatively new. With the development of fractional radiofrequency, which allows for the heat energy to be delivered in a more targeted manner through the use of needles as electrodes, this technique is now the preferred medical treatment option for many skin conditions given the reduction in recovery time and fewer number of reported side effects. The current study examined the clinical effectiveness of SmartScan™ Nano-Fractional RFTM treatment. Participants included 12 healthy female volunteers who reported varying degrees of rhytides, hyperpigmentation, or acne redness. Participants each received one treatment of SmartScan Nano-Fractional RF. The areas receiving treatment were photographed in a standardized way, using high-resolution macrophotography, at baseline (prior to receiving the treatment) and one month after treatment. Baseline and post-treatment photographs were then visually compared for treatment effects and analyzed through software-assisted quantification of variation in pigmentation and skin texture. The results indicated that this SmartScan technique for Nano-Fractional RF is effective in improving skin texture, and pigmentation.

J Drugs Dermatol. 2015;14(11):611-617.

INTRODUCTION

In recent decades there has been a growing demand for safe, efficient, and non-invasive treatments for treating striae, rhytides, hyperpigmentation, rosacea, acne redness, and scarring. Radiofrequency (RF) treatments, which are titrated to be non-ablative, have thus been regarded as an optimal treatment

In contrast to earlier forms of RF treatment, newer devices are associated with fewer side effects when used to treat dermatologic conditions. Previous treatments have been associated with a number of adverse side effects, including erythema, hyperpigmentation, ecchymosis, and burning. Newer RF devices

A Retrospective Study of Patient Satisfaction Following a Trial of Nano-fractional RF Treatment - 2015

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A Retrospective Study of Patient Satisfaction Following a Trial of Nano-fractional RF Treatment

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[b]Gold Skin Care Center and Tennessee Clinical Research Center, Nashville, TN

ABSTRACT

Traditional techniques used to treat dermatological conditions have typically involved surgery or full ablation of tissue. With the emergence of fractional radiofrequency (RF) technology, treatment for various skin conditions no longer requires surgery or full ablation. Instead, these treatment techniques deliver thermal energy, derived from fractional RF energy, in a highly targeted manner through multiple micro-needles, referred to as pins. This technique hastens recovery time and leads to less reported side effects associated with traditional methods of tissue augmentation. While the efficacy of this treatment has been demonstrated, patient satisfaction has not been assessed and documented thoroughly. The current study examined patient-reported satisfaction following treatment with the Venus Viva™ as assessed across five separate domains of self-reported satisfaction; degree of comfort during treatment procedures, recovery time following treatment, convenience and efficiency of treatment appointments, treatment results, and whether the patient would recommend the treatment to a friend. Participants included 43 healthy adult volunteers who reported varying degrees of facial dermatological conditions, such as rhytides, hyperpigmentation, or the redness associated with acne vulgaris. Participants received between one and three treatments with the Venus Viva™ device. Patient satisfaction was assessed three months following the last treatment. Results indicated that patients are highly satisfied with treatments received from the Venus VivaTM device and are highly likely to recommend the procedure to a friend.

J Drugs Dermatol. 2015;14(11):1268-1271.

An efficacy and safety of nanofractional radiofrequency for the treatment of striae alba
J Cosmet Dermatol, 2016, 84-90

Journal of Cosmetic Dermatology, **16**, 84–90

An efficacy and safety of nanofractional radiofrequency for the treatment of striae alba

Napatthaorn Pongsrihadulchai, MD, Thep Chalermchai, MD, PhD, Suwirakorn Ophaswongse, MD, Suriya Pongsawat, MD, & Montree Udompataikul, MD

Skin Center, Srinakharinwirot University, Wattana, Bangkok, Thailand

Summary

Background Striae distensae (SD) is a form of dermal scar. A number of treatments have been proposed, but they usually have unsatisfactory result especially in striae alba. Recently, nanofractional RF has been developed. Its mechanism of action is to stimulate dermal remodeling and epidermal re-epithelization.

Aim To evaluate the efficacy and safety of nanofractional RF in the treatment of striae alba.

Patients/Methods This is an experimental, assessor-blinded, before–after study. Thirty-three subjects, with striae alba on their thighs, abdomen, or buttocks (11 subjects each) were enrolled. Treatments with nanofractional RF were undergone for a total of three sessions at 4-week intervals. Clinical outcomes were assessed, by comparing pre- and post-treatment measurement of total lesional surface area (using digital Pictzar™ software), and length and width of lesions. Histopathological evaluation was also performed.

Results At 4 weeks after the last treatment, the total surface area, and the width and the length of striae alba significantly decreased from the baseline ($P < 0.001$). Postinflammatory hyperpigmentation was reported in six subjects. Regarding histopathology, the average mean number of collagen and elastin bundles was significantly increased ($P = 0.005$ and 0.012, respectively).

Conclusion Nanofractional RF is highly effective with a good safety profile for the treatment of striae alba.

Keywords: striae alba, fractional radiofrequency, nanofractional RF

Use of nanofractional radiofrequency for the treatment of acne scars in Indian skin
J Cosmet Dermatol, 2017, 16. 186-192

ORIGINAL CONTRIBUTION

WILEY JCD Journal of Cosmetic Dermatology

Use of nanofractional radiofrequency for the treatment of acne scars in Indian skin

Apratim Goel MD | Vallari Gatne DDV

Cutis Skin Studio®, Mumbai, India

Correspondence
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Email: mdcutis@hotmail.com

Summary

Background: Pitted acne scars of all types remain notoriously challenging to treat with no satisfactory treatment modality, particularly true for darker Fitzpatrick skin types such as Indian skin.

Aim: Nanofractional radiofrequency has been shown to be an effective treatment modality for the cosmetic improvement of acne scars.

Methods: Twenty healthy male and female Indian patients aged 16–60 years with Fitzpatrick skin types IV-V and moderate-to-severe acne scar lesions received 1–3 treatments with a nanofractional radiofrequency device (Venus Viva) at baseline and at 3- to 6 week intervals and were evaluated with photographs at each treatment visit and up to 6 months after the final treatment session. Patients reported on their satisfaction with the treatment. The safety of treatments was evaluated by the frequency, severity, and type of adverse events.

Results: The majority of study patients achieved improvement in the appearance of their acne scar lesions. There was less improvement on ice pick scar compared to box and rolling type scars, with less impact on ice pick scar type. Overall patient satisfaction from treatment at the 6-month follow-up visit was very high. Adverse events were mild but transient in nature.

Conclusion: The data and results presented here support the efficacy of nanofractional radiofrequency used for the cosmetic improvement of acne scar lesions in facial skin. Moreover, the favorable adverse event profile witnessed in this trial underscores the safety of this technology for cosmetic facial treatments such as facial acne scar lesion therapy in darker Fitzpatrick skin types.

KEYWORDS
acne scars, darker skin types, nanofractional radiofrequency, venus viva

Clinical Evaluation of Fractional Radiofrequency for the Treatment and Reduction of Wrinkles: A Prospective Study
J Drugs Dermatol. 2022.21(1): 43-48

ORIGINAL ARTICLE JOURNAL OF DRUGS IN DERMATOLOGY

Clinical Evaluation of Fractional Radiofrequency for the Treatment and Reduction of Wrinkles: A Prospective Study

Alison Kang MD and Suzanne L. Kilmer MD
Laser and Skin Surgery Center of Northern California, Sacramento, CA

ABSTRACT

Background: Fractional radiofrequency (FRF) technology has been shown in clinical studies to improve skin laxity, and to treat various skin conditions related to aging and alternate collagen structures such as rhytids. The objective of this clinical study was to evaluate the safety and performance of FRF (up to 124 mJ per pin) for the treatment of facial rhytids, emphasizing the upper lip and perioral areas.
Methods: Enrolled subjects received a series of 3 FRF treatments to the full face, 3 to 5 weeks apart. Immediately after treatment, the subjects were given a scale to assess pain and tolerability of the treatment. Subject satisfaction questionnaires were completed at follow-up visits at 6 and 12 weeks post final treatment. Before and after photographs were graded for change by three blinded evaluators using the Fitzpatrick Wrinkle and Elastosis Scale (FWES) and the Global Aesthetic Improvement Scale (GAIS).
Results: Image sets of 10 enrolled subjects (average age 62.7 years) were assessed by blinded evaluators. The overall face FWES score improved from 5.97 (SE 0.20) at baseline to 5.78 (SE 0.22) at 12-week follow-up. The GAIS improved by 0.4 points and was significant compared to baseline ($P = 0.0004$). Subject satisfaction was high with subjects giving an average satisfaction score of 3.2 ("satisfied") out of 4. Pain was rated "mild to moderate" with an average of 3.9 on a 11-point Wong Baker FACES Scale. Ninety percent (90%) of subjects reported either a mild, moderate, or significant improvement to their treatment area. Eighty percent (80%) of subjects reported that they would recommend the treatment to a friend. There were no reports of adverse events or unanticipated side effects during the duration of the study.
Conclusion: A statistically significant reduction in rhytids of the upper lip and the perioral area, was found, as evaluated by independent blinded evaluators. There were no adverse events. Treatment pain was low and tolerable, and subjects had high levels of satisfaction with the results at last follow-up.

J Drugs Dermatol. 2022;21(1):43-48. doi:10.36849/JDD.6492

Subject Satisfaction of Wrinkle Reduction Following Treatment with Fractional Radiofrequency: A Prospective Study
J Drugs Dermatol. 2022.21(11):1221-1227

ORIGINAL ARTICLE
JOURNAL OF DRUGS IN DERMATOLOGY

Subject Satisfaction of Wrinkle Reduction Following Treatment with Fractional Radiofrequency: A Prospective Study

Edward V. Ross MD and Briana Wischnack NP

Scripps Clinic, San Diego, CA

ABSTRACT

Background: Fractional radiofrequency (FRF) technology reduces skin laxity and treats aging-related skin disorders such as wrinkles. The objective of this study was to evaluate participant satisfaction of FRF for the treatment of facial wrinkles.

Methods: A total of 25 male and female patients (average age 60.5 years) were enrolled in this prospective, single center study. Patients received 3 FRF treatments at 3- to 5-week intervals on both sides of the face, using 80-pin (up to 124 millijoule/pin) or the 160-pin tip (up to 62 millijoule/pin) applicator. Follow-up visits were conducted at 6 and 12 weeks after the last treatment. Participant satisfaction was evaluated by individual self-assessment of wrinkle reduction and a patient satisfaction questionnaire. Pain, tolerability, and safety were monitored throughout.

Results: The individual satisfaction was high with participants giving an average satisfaction score of 2.8 ("satisfied") out of 4. Pain was rated "mild" with an average of 4.0 on a 10-point Visual Analog Scale (VAS). Tolerability was rated 3.3 out of 4.0, correlating to "very tolerable". Ninety percent (90%) of subjects reported a mild or moderate improvement in their treatment area at 12-week follow-up.

Conclusion: This study demonstrates that under the FRF pre-sets used, patients are satisfied with results of FRF modality for improvement of their wrinkles. No unanticipated side effects were observed. Treatment was tolerable, and individuals had high levels of satisfaction and tolerability with the results at last follow-up.

J Drugs Dermatol. 2022;21(11):1221-1227. doi:10.36849/JDD.6986

NanoFractional RF™

- Fractional Radiofrequency and Oral Isotretinoin—A Prospective Randomized Controlled Split-Face Trial Comparing Concurrent Versus Delayed Fractional Radiofrequency Treatment for Acne Scars
- Clinical evaluation of the efficacy of fractional radiofrequency for the treatment and reduction of stretch marks
- Subject Satisfaction of Wrinkle Reduction Following Treatment with Fractional Radiofrequency
- Fractional radiofrequency-assisted delivery of fluorescent tracer dyes in ex vivo and in vivo skin
- Clinical Evaluation of Fractional Radiofrequency for the treatment and Reduction of Wrinkles
- Safety and efficacy of fractional radiofrequency for the treatment and reduction of acne scarring

(MP)²

- Effects of MP RF and PEMF Treatment for Face and Neck Rejuvenation
- PEMF in the treatment of postoperative delayed union of long-bone fractures
- Pulsed electromagnetic field therapy effectiveness in low back pain
- Pulsed electromagnetic field applications: A corporate perspective

Clinical Papers & Studies

Intensif

3Deep

Microneedle Skin Remodeling (Intensif)

Tightening & Contouring (TC)

- Facial tightening
- Body tightening & contouring

Fractional Micro Needle Radiofrequency

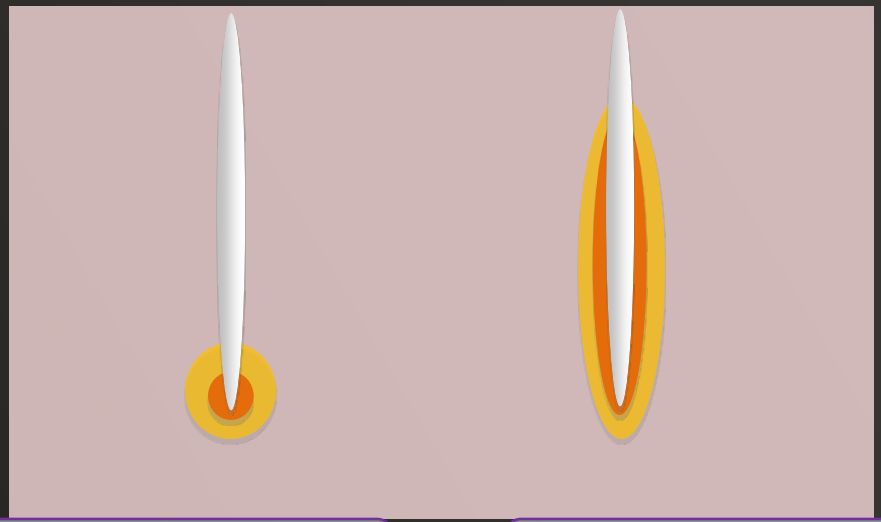
Collagen remodeling solution

RF energy for simultaneous fractional coagulation & deep dermal heating.

- Acne scars
- Deep wrinkles
- Dilated Pores
- Stretch marks

Insulated vs. Non-Insulated

Two main RF emitting methods

Insulated RF Needles	**Non-Insulated** RF Needles
	
RF is emitted only <u>at the tip</u> of the needle	Coagulation along <u>all</u> needle
No coagulation on along the needle → bleeding points	Coagulation along all the needle → No bleeding points
Need more than one pass	Only one pass is needed

• Efficacy – Published Clinical Studies

In vivo histological evaluation of non-insulated microneedle radiofrequency applicator with novel fractionated pulse mode.
Harth Y, Frank I
J Drugs Dermatol. 2013 Dec;12(12):1430-3

Depressed Acne Scars - Effective, Minimal Downtime Treatment with a Novel Smooth Motion Non-Insulated Microneedle Radiofrequency Technology
Yoram Harth, Monica Elman, Einat Ackerman, Ido Frank
Journal of Cosmetics, Dermatological Sciences and Applications, 2014,4,212-218

Long-Term Three-Dimensional Volumetric Assessment of Skin Tightening Using a Sharply Tapered Non-Insulated Microneedle Radiofrequency Applicator with Novel Fractionated Pulse Mode in Asians
Yohei Tanaka, MD, PhD
Lasers in Surgery and Medicine, August 2015

Kaplan, Haim, and Lilach Kaplan. "Combination of microneedle radiofrequency (RF), fractional RF skin resurfacing and multi-source non-ablative skin tightening for minimal-downtime, full-face skin rejuvenation.“
Journal of Cosmetic and Laser Therapy 18.8 (2016): 438-441.

Gold, M., Taylor, M., Rothaus, K., & Tanaka, Y. (2016). Non-insulated smooth motion, micro-needles RF fractional treatment for wrinkle reduction and lifting of the lower face: International study.
Lasers in Surgery and Medicine, 48(8), 727-733.

Treatment of Acne Scars on Darker Skin Types Using a Noninsulated Smooth Motion, Electronically Controlled Radiofrequency Microneedles Treatment System
Pudukadan, David MBBS, MD
Dermatologic Surgery: January 2017 - Volume 43 - Issue - p S64–S69

Tanaka, Y. (2017). Long-term Nasal and Peri-oral Tightening by a Single Fractional Noninsulated Microneedle Radiofrequency Treatment.
The Journal of Clinical and Aesthetic Dermatology, 10(2), 45–51

Non-Insulated Smooth Motion, Micro-Needles RF Fractional Treatment for Wrinkle Reduction and Lifting of the Lower Face
Laser in Surgery and Medicine, published online May 25, 2016

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

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, PhD[4]

[1]*Tennessee Clinical Research Center, Nashville, Tennessee*

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

[3]*Rothaus Plastic Surgery, New York, New York*

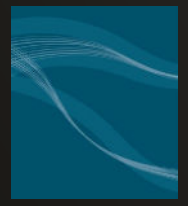
[4]*Clinica Tanaka Plastic, Reconstructive Surgery and Anti Aging Center, Matsumoto, Nagano, Japan*

wrinkle reduction, skin tightening, and lifting of the mid and lower face with the noninsulated fractional RF microneedling system. Lasers Surg. Med. 2016 9999:1–7.

Key words: microneedling; wrinkle reduction; radiofrequency; skin tightening; lifting; endymed; intensif; 3deep

Peer-Reviewed Publications 2020-2021

Efficacy and safety of non-insulated fractional microneedle radiofrequency for treating difficult-to-treat rosacea: a 48-week, prospective, observational study
Ben Wang,MD & Yu-xuan Deng, MD
Arch Dermatol , 01 July 2021



Skin laxity and stretch marks, therapies supplemented with Endymed 3DEEP® RF needles and bio stimulation with PROFHILO® body
Fabrizio Melfa, MD
January 2021, Book ,Chapter 7

A retrospective study of neck rejuvenation using a non-insulated microneedle radiofrequency in Chinese subjects
Bihuan Xiao, MD
October 2020, Lasers Med Sci

Nonsurgical facial tightening after a fractional non-insulated micro needling radiofrequency treatment in Asians
Yohei Tanaka MD, PhD
Dermatological Reviews. 2020;1–7

- # Efficacy And Safety Of Non-Insulated Fractional Microneedle Radiofrequency For Treating Difficult-To-Treat Rosacea: A 48-Week, Prospective, Observational Study

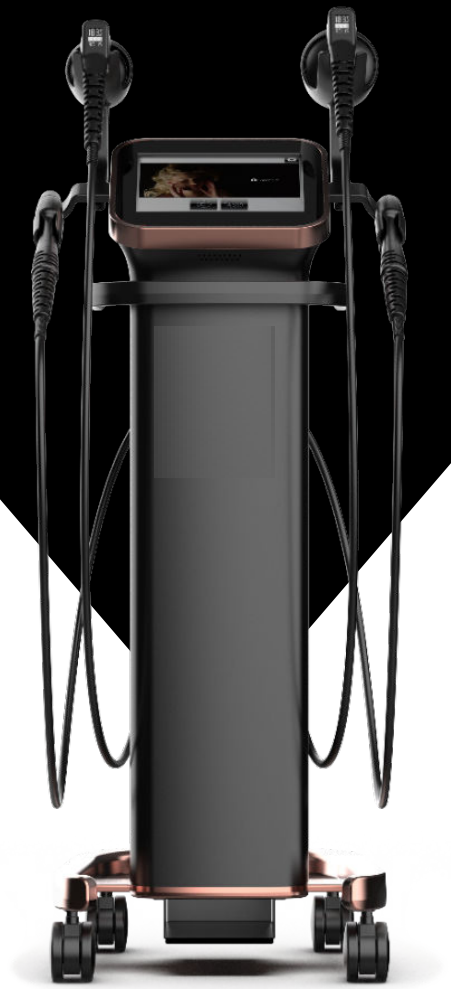
Rosacea is a common chronic facial inflammatory skin disease. However, treatment for “difficult-to-treat rosacea” cases has not been established. This 48-week, prospective, observational study analyzed patients who underwent three non-insulated fractional microneedle radiofrequency (NFMRF) sessions at 2-month intervals. Among 34 patients, 22 reported “excellent” or “good” improvement and 30 were “very” or “relatively” satisfied. Skin barrier results revealed that hemoglobin content significantly decreased. No serious side effects were observed. NFMRF alone results in visible improvement and has great efficacy for difficult-to-treat rosacea without compromising patient safety or damaging the skin barrier.

Ben Wang,MD & Yu-xuan Deng, MD
Arch Dermatol , 01 July 2021

Fig. 3 **a–d** The photographs of a female subject with recalcitrant granulomatous rosacea at visits 0, 1, 2 and 3. **e** Histopathological examination showing infiltration of inflammatory cells around blood vessels and hair follicles, epithelioid tissue cells and multinucleated giant cells constitute granuloma (H and E, × 100)

3 platforms in one device

Reach both the muscle & the skin



Dynamic Muscle Stimulation (DMSt)

- **Activate muscles for a well-defined, toned and lifted look**
- Quick, visible effect, no-downtime
- Unlike traditional technologies, triLift targets the muscle, not the nerves and is X100 stronger[1]
- FDA indicated for muscle conditioning to stimulate healthy muscles

RFMN: Smooth RF assisted Microneedling

- **Increases the natural volume and tightens and smoothens the skin texture**
- 3 times more natural production of Hyaluronic Acid*
- No numbing, low-downtime

TriPollar® RF

- **Thickens and strengthens the dermal layer to treat facial wrinkles**
- Regenerates collagen and elastin
- 50% increase in dermal thickness**

1 compared to home use EMS / TENS devices

*compared to baseline levels, for natural volume in a laboratory study Boisnic S, Branchet MC. Ex-vivo study of hybrid energy technology using a human skin model. Eur J Dermatol 2014; 24(1): 46-52 oi:10.1684/ejd.2013.2233. Ex vivo study results may not translate into actual clinical results.

**compared to baseline levels

Address the root cause of facial aging: the muscles

Now, you're able to lift and contour the face for youthful appearance, achieving an effect similar to a **face lift**, by targeting the muscles in the face**.**

Thickens and strengthens the dermal layer, increases natural volume and evens out the texture of the epidermal layer

Achieve a face life like- effect, naturally with no injections or surgery

Baseline **3 months After 4 treatments**

Photos courtesy Michael Mirmanesh, MD
Garden Med Spa, Voorhees NJ

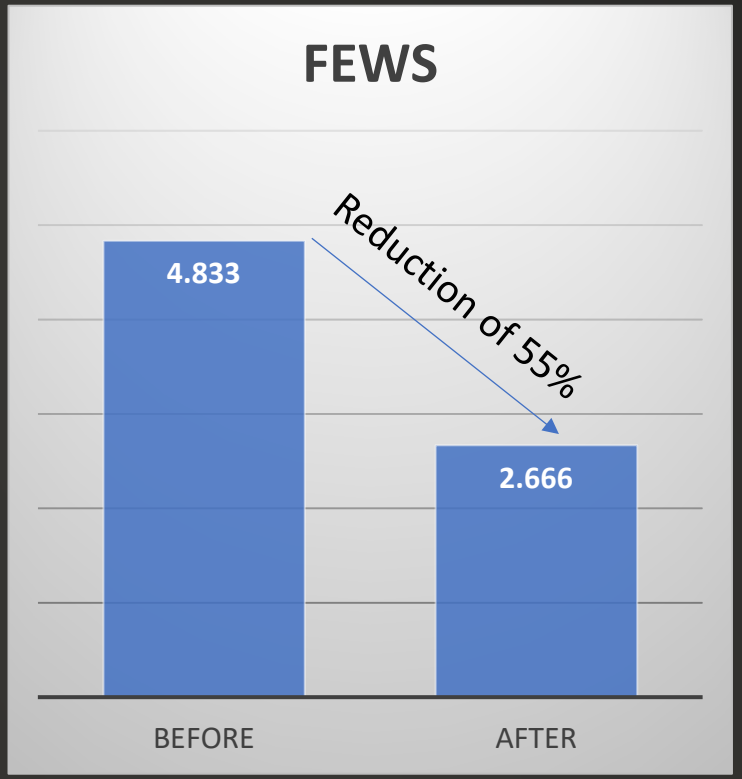
Novel RF assisted ultra thin electrode technology

- In this study we investigated for the first time the safety and efficacy of a novel Radiofrequency (RF) ultra-thin electrodes tip consist of an array of 100 ultra-thin electrodes 0.15mm width and 0.6mm length.

Novel RF assisted ultra thin electrode technology

- Results:

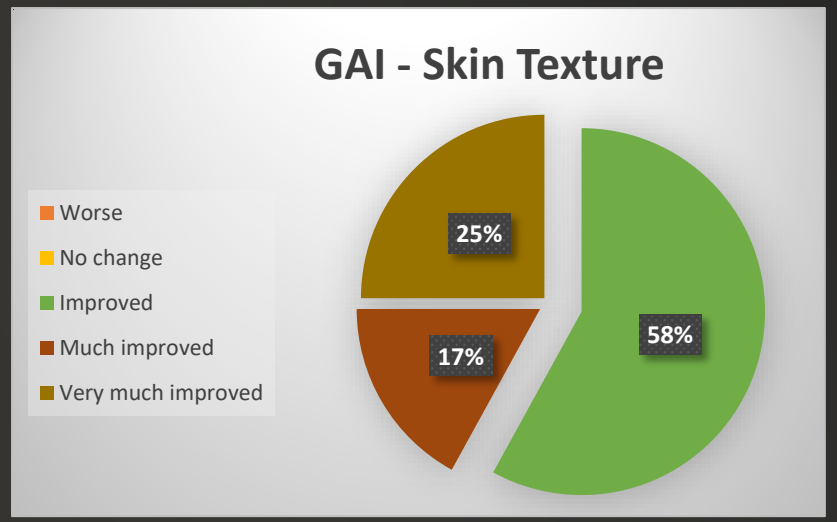
- No Adverse events were recorded.
- All the participants felt comfortable to go out in public.
- Three months after the last treatment, significant improvement in facial wrinkle and texture was noted; FEWS scores decreased significantly from 4.833 ± 0.687 to 2.666 ± 1.178 ($p<0.0001$).



Novel RF assisted ultra thin electrode technology

- Results:

- According to the GAI scale, all patients (12/12) had an improvement in skin texture; 25% (3/12) of participants were very much improved, 17% (2/12) were much improved and 58% (7/12) were improved.
- Immediate response included mild-moderate erythema and only trace-mild edema (in 4/12 patients) in the treatment area.
- Pain during the treatment was minimal with a mean VAS pain score of 3.26/10.

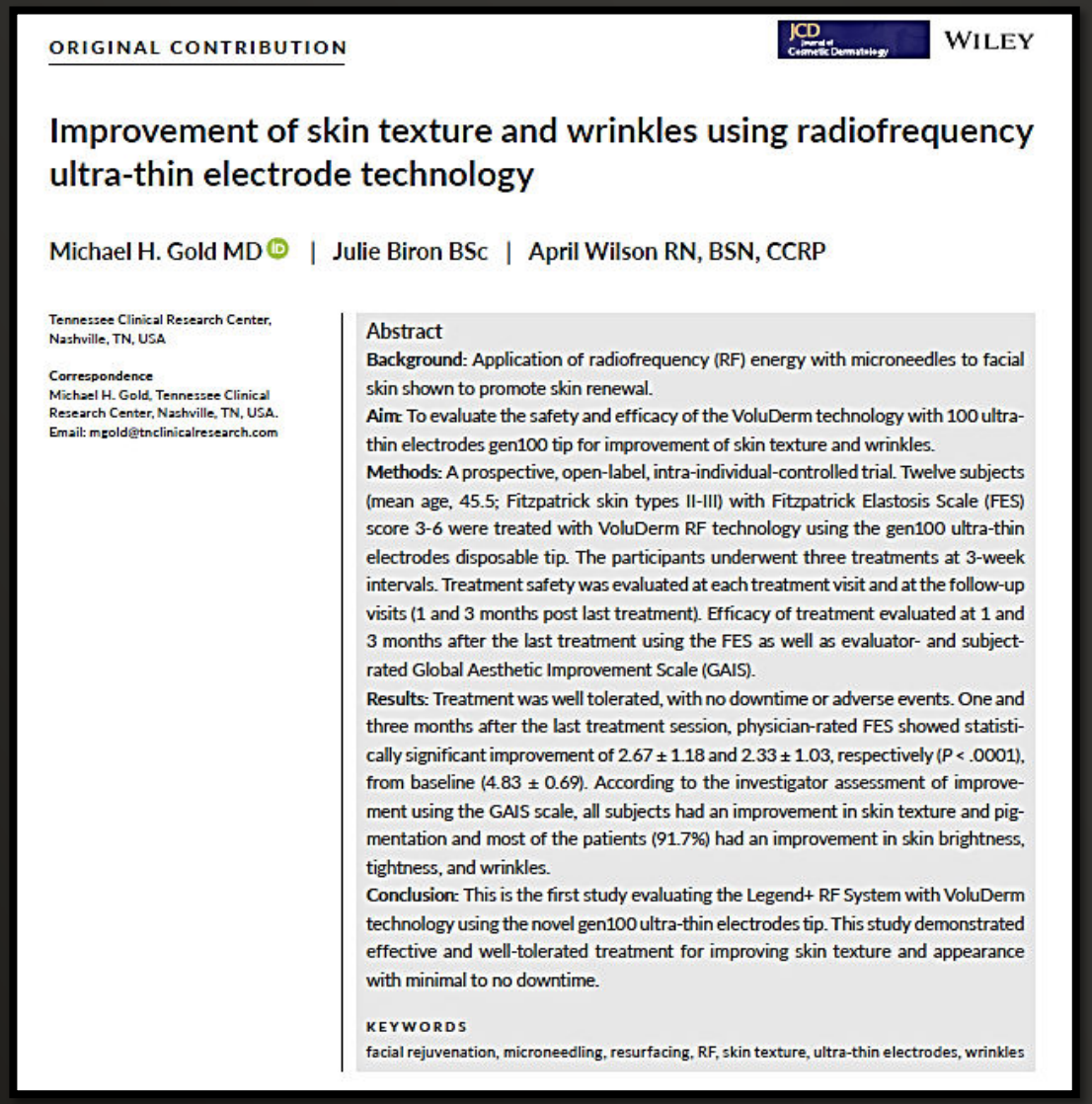


Novel RF assisted ultra thin electrode technology

- Conclusion:

- The novel RF ultra-thin electrodes tip tested in this study for the first time was found to be an effective, tolerable and safe method for the treatmen t of wrinkle and skin texture. The Smooth RF assist ablation of the ultra-t hin electrodes contributes to the safety and patient’s comfort during the treatment ,minimal pain sensation and reduced downtime.

Improvement of Skin Texture and Wrinkles Using Radiofrequency Ultra-thin Electrode Technology
J Cosmetic Dermatol, 2019-001-5



ORIGINAL CONTRIBUTION

JCD Journal of Cosmetic Dermatology | WILEY

Improvement of skin texture and wrinkles using radiofrequency ultra-thin electrode technology

Michael H. Gold MD | Julie Biron BSc | April Wilson RN, BSN, CCRP

Tennessee Clinical Research Center, Nashville, TN, USA

Correspondence
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Abstract

Background: Application of radiofrequency (RF) energy with microneedles to facial skin shown to promote skin renewal.

Aim: To evaluate the safety and efficacy of the VoluDerm technology with 100 ultra-thin electrodes gen100 tip for improvement of skin texture and wrinkles.

Methods: A prospective, open-label, intra-individual-controlled trial. Twelve subjects (mean age, 45.5; Fitzpatrick skin types II-III) with Fitzpatrick Elastosis Scale (FES) score 3-6 were treated with VoluDerm RF technology using the gen100 ultra-thin electrodes disposable tip. The participants underwent three treatments at 3-week intervals. Treatment safety was evaluated at each treatment visit and at the follow-up visits (1 and 3 months post last treatment). Efficacy of treatment evaluated at 1 and 3 months after the last treatment using the FES as well as evaluator- and subject-rated Global Aesthetic Improvement Scale (GAIS).

Results: Treatment was well tolerated, with no downtime or adverse events. One and three months after the last treatment session, physician-rated FES showed statistically significant improvement of 2.67 ± 1.18 and 2.33 ± 1.03, respectively ($P < .0001$), from baseline (4.83 ± 0.69). According to the investigator assessment of improvement using the GAIS scale, all subjects had an improvement in skin texture and pigmentation and most of the patients (91.7%) had an improvement in skin brightness, tightness, and wrinkles.

Conclusion: This is the first study evaluating the Legend+ RF System with VoluDerm technology using the novel gen100 ultra-thin electrodes tip. This study demonstrated effective and well-tolerated treatment for improving skin texture and appearance with minimal to no downtime.

KEYWORDS
facial rejuvenation, microneedling, resurfacing, RF, skin texture, ultra-thin electrodes, wrinkles

Clinical and Histologic Evaluation of a fractional Radiofrequency Treatment of Wrinkles and Skin Texture with Novel 1-mm long ultra-thin Pins Lasers Surg Med, April, 2021

Clinical and histologic evaluation of a fractional radiofrequency treatment of wrinkles and skin texture with novel 1-mm long ultra-thin electrode pins

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[2]Department of Dermatology, New York University Grossman School of Medicine, New York, New York, USA

[3]Lumenis, Yokneam, Israel

Correspondence
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Email: info@nylaserskincare.com

Abstract

Background: Fractional radiofrequency (RF) microneedling technologies have shown effectiveness in treating skin laxity and wrinkles. We report the first experience using a novel device with 1-mm long ultrathin electrodes that utilizes a smooth RF-assisted ablation mode.

Objective: To evaluate the safety and effectiveness of treatment with a fractional RF device using 1.0-mm long × 0.15-mm diameter ultrathin electrode tips for improvement of facial skin texture and wrinkles.

Methods and Materials: This was a prospective, open-label, intraindividual-controlled trial. Nine participants (mean age: 47.6, Fitzpatrick skin type II–IV, Fitzpatrick Elastosis Wrinkle Scale [FEWS] score: 3–6) underwent six treatment sessions with a fractional RF technology utilizing an array of 6 × 6 1-mm long ultrathin electrodes. Treatment effectiveness was assessed by FEWS and the Global Aesthetic Improvement Scale (GAIS). Safety and tolerance were evaluated.

Results: Three months after the sixth treatment session, blinded, investigator-assessed FEWS decreased from baseline 4.33 ± 0.67–3.33 ± 0.67 ($p < 0.005$); 88.9% of participants showed overall skin improvement using the physician-assessed GAIS, and all of the participants reported improvement in skin texture and wrinkles. Treatment was well tolerated, with no adverse events and no downtime. Histological analysis in a porcine model showed a fractional pattern of epidermal ablation and dermal coagulation with intervening zones of normal healthy tissue. These changes were followed by progressive epithelialization over a period of 13 days.

Conclusion: The fractional RF technology with the novel 1.0 long × 0.15 mm ultrathin electrodes tips was effective in improving skin texture and wrinkles without impacting the participants' daily activities.

KEYWORDS

fractional, photodamage, radiofrequency, rejuvenation, resurfacing, skin texture, wrinkles

Evaluation of the safety and efficacy of Radiofrequency technology combined with Dynamic Muscle Activation for the treatment of facial wrinkles and skin tightening

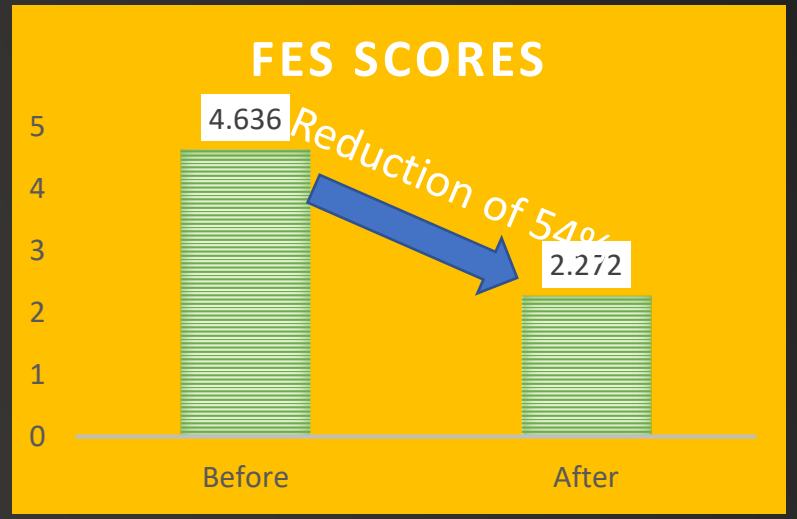
2019 – The Tennessee Clinical Research Center

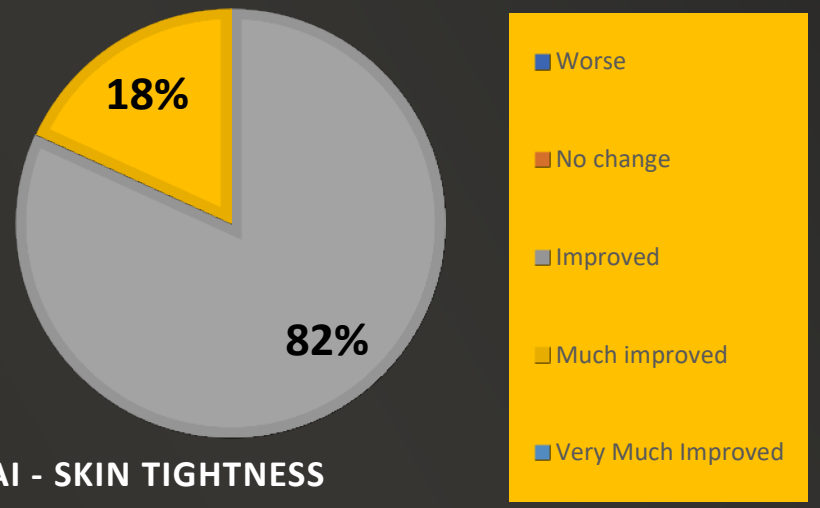
Novel combination of Radio frequency and muscle stimulation

- The aim of this study was to evaluate the safety and efficacy of
- RF technology combined with Dynamic Muscle Activation (DMA)
- for wrinkles improvement and facial skin tightening, as well as patient tolerance.

Results

- No adverse events or downtime was recorded.
- Three months after the last treatment, significant improvement in facial wrinkle and skin tightness.
- FES scores decreased significantly from 4.636 ± 0.881 to 2.272 ± 0.445 ($p<0.0001$).
- VAS pain score of 0.63, the minimal discomfort during the treat ment
- GAI, all the patient had an improvement in fine lines & wrinkles as well as in skin tightness;
- 18.18% (2/11) of participants were much improved and 81.82% (9/11) were improved.





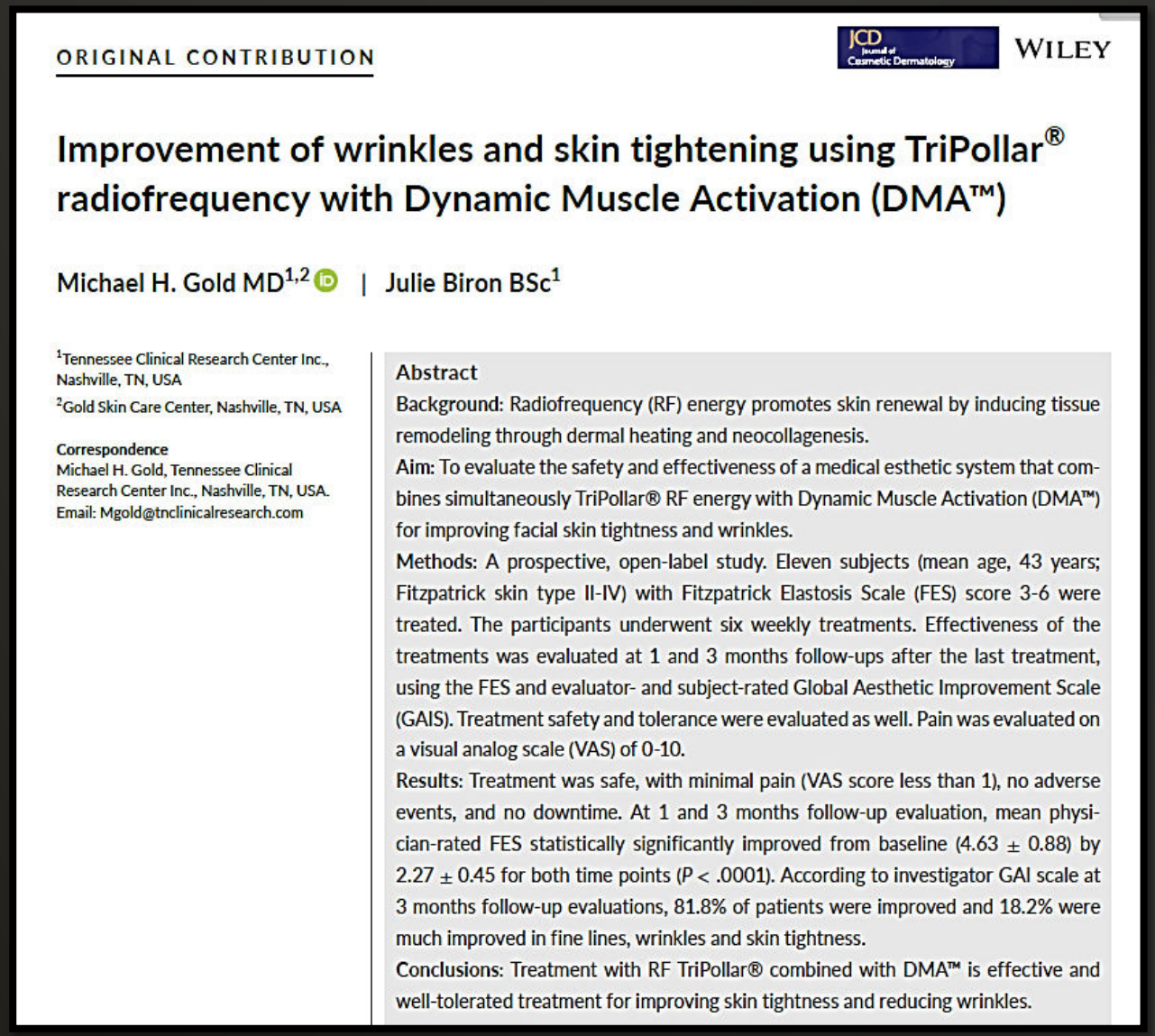
GAI - SKIN TIGHTNESS

Novel combination of Radio frequency and muscle stimulation

- Conclusion:

- RF combined with DMA was found to be an effective, safe and painless method for the treatment of wrinkle and skin tightening without any downtime.

Improvement of wrinkles and skin tightening using TriPollar radiofrequency with Dynamic Muscle Activation (DMA)
J Cosmet Dermatol. 2020;00:1–6



ORIGINAL CONTRIBUTION

JCD Journal of Cosmetic Dermatology | WILEY

Improvement of wrinkles and skin tightening using TriPollar® radiofrequency with Dynamic Muscle Activation (DMA™)

Michael H. Gold MD[1,2] | Julie Biron BSc[1]

[1]Tennessee Clinical Research Center Inc., Nashville, TN, USA

[2]Gold Skin Care Center, Nashville, TN, USA

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Email: Mgold@tnclinicalresearch.com

Abstract

Background: Radiofrequency (RF) energy promotes skin renewal by inducing tissue remodeling through dermal heating and neocollagenesis.

Aim: To evaluate the safety and effectiveness of a medical esthetic system that combines simultaneously TriPollar® RF energy with Dynamic Muscle Activation (DMA™) for improving facial skin tightness and wrinkles.

Methods: A prospective, open-label study. Eleven subjects (mean age, 43 years; Fitzpatrick skin type II-IV) with Fitzpatrick Elastosis Scale (FES) score 3-6 were treated. The participants underwent six weekly treatments. Effectiveness of the treatments was evaluated at 1 and 3 months follow-ups after the last treatment, using the FES and evaluator- and subject-rated Global Aesthetic Improvement Scale (GAIS). Treatment safety and tolerance were evaluated as well. Pain was evaluated on a visual analog scale (VAS) of 0-10.

Results: Treatment was safe, with minimal pain (VAS score less than 1), no adverse events, and no downtime. At 1 and 3 months follow-up evaluation, mean physician-rated FES statistically significantly improved from baseline (4.63 ± 0.88) by 2.27 ± 0.45 for both time points ($P < .0001$). According to investigator GAI scale at 3 months follow-up evaluations, 81.8% of patients were improved and 18.2% were much improved in fine lines, wrinkles and skin tightness.

Conclusions: Treatment with RF TriPollar® combined with DMA™ is effective and well-tolerated treatment for improving skin tightness and reducing wrinkles.

The procedure: what should patients expect?

Non- invasive procedure

No injections or surgery- and without having to go under the knife

Immediate, quick visible effect

For the best and longer lasting effects-

a course of 4-6 treatments once a week is recommended

Short treatment with no downtime

- Takes about 16 minutes only for the lift mode (DMSt+RF)
- Additional 10 minutes when combined with triFX RF micro needling

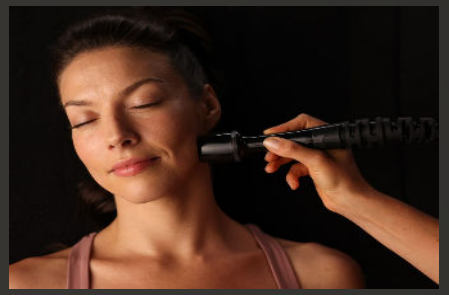
(3Xtreatments from the total of 4-6)

After the first treatment

Patient should expect to see and feel an immediately natural-looking improvement

Lift Mode (DMSt + RF)-
Big Hand Piece

Lift Mode (DMSt + RF)-
Small Hand Piece



triFX RF-
Micro Needling

Build the *ultimate* Aesthetic package

Customizable multi-modality workstation

- Advanced & customizable

The multi-modality workstation offers a complete selection of complementary handpieces to suit your business needs. Expand your system at any time by simply plugging in a new handpiece.

BUILD YOUR SYSTEM

BARE 808

LUCENT IPL

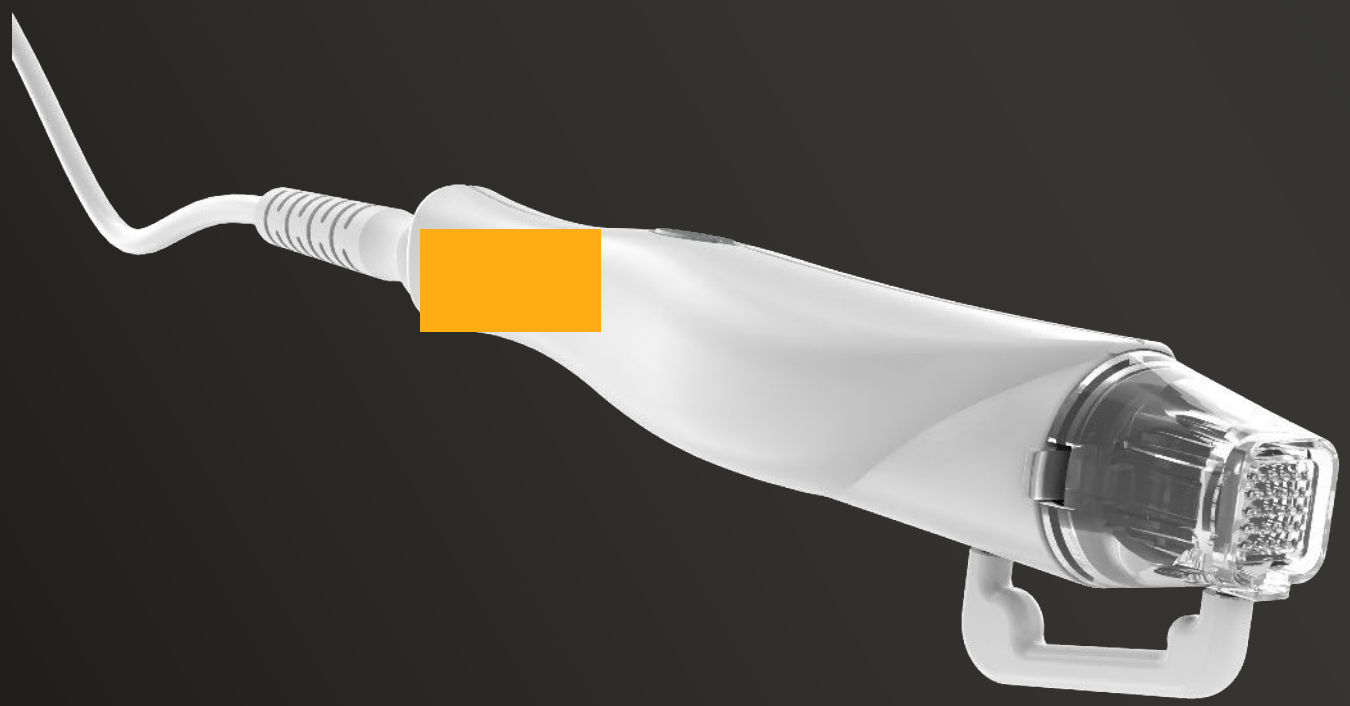
PROLIFT RFM

PROLIFT HIFU

REFRESH RF

RF Microneedling(RFM) Handpiece

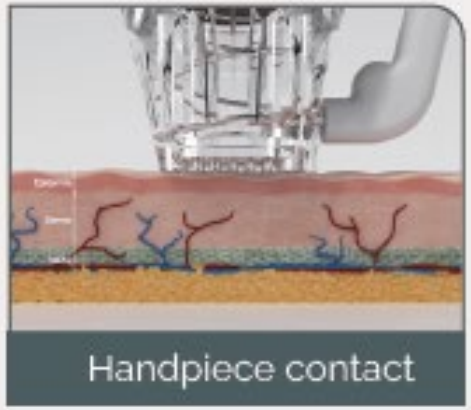
RF Microneedling is a popular treatment that can safely and effectively address a range of face and body concerns. This innovative handpiece combines the benefits of Microneedling with Radio Frequency (RF), taking skin rejuvenation to the next level.

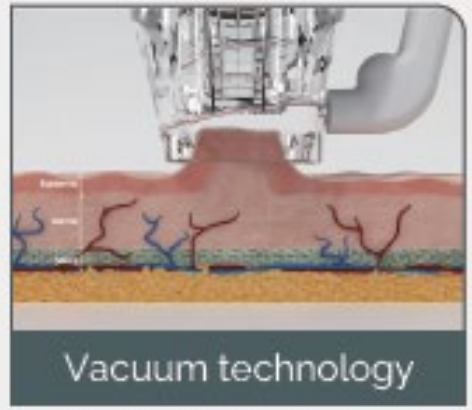


- RFM features & benefits

Advanced vacuum technology & 2Mhz delivery for improved comfort

- The latest move from 1 to 2Mhz allows for the most comfortable RF microneedling treatment on the market.
- The unique vacuum feature gently pulls the tissue into the tip resulting in even and accurate treatment depth, increased safety, and improved comfort for the patient.
- Vacuum is a major benefit when treating sensitive areas around the eye and t-zone.

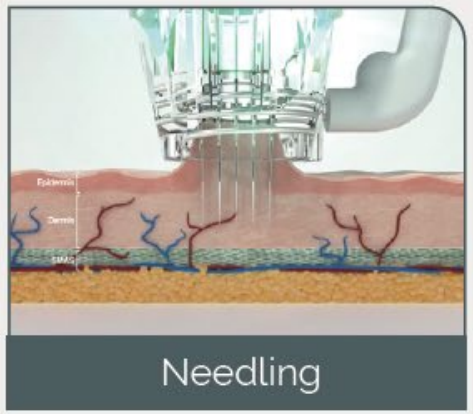

Handpiece contact


Vacuum technology

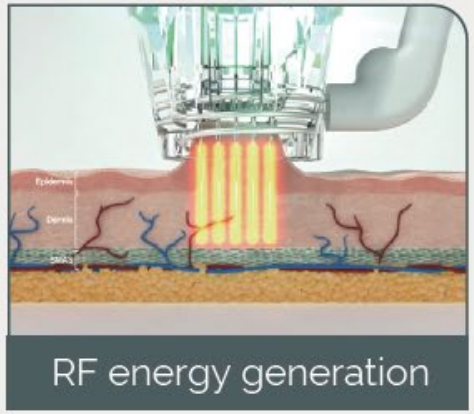
- RFM features & benefits

Non-insulated needles for optimized results

- Fractional radio frequency energy is delivered through the entire length of the needle for uniform and consistent energy delivery.
- Tips are available in 25 and 10 pin options.
- Maximum needle depth is 3.5mm.



Needling

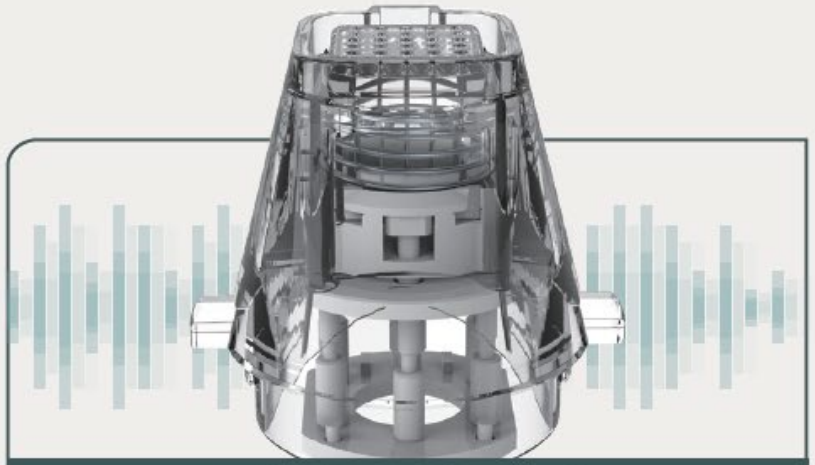


RF energy generation

*Insulated needles available also

- RFM features & benefits

Sophisticated motor for smooth & fast performance

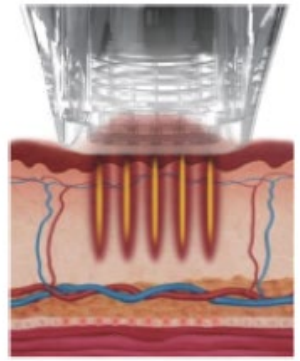


Prolift rfm 25pin needle

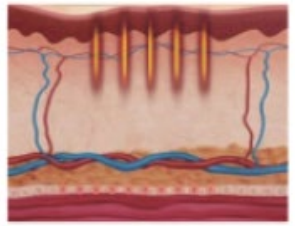
- Smooth and fast insertion of needles is maintained using unique motor mounting control technology.
- Patients will experience a delicate procedure without severe recoil when needles are inserted into the skin.

- How RFM works

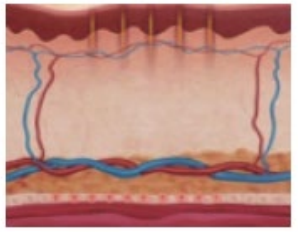
The [redacted] RFM handpiece uses a combination of vacuum technology and fractional Radio Frequency Microneedling (FRM) for precise delivery of thermal energy into the skin. The thermal energy in combination with the slight injury caused by the microneedles, stimulates the production of collagen and elastin to regenerate the skin and improve tone and texture.
Common treatment benefits include: increased skin elasticity, fine line and wrinkle reduction, improved skin texture, a reduction in scaring and stretch marks.



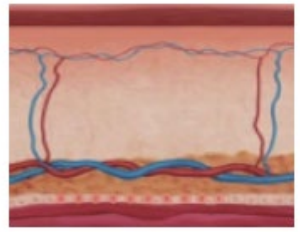
- Tissue stimulus through needling
- RF irradiation to desired depth



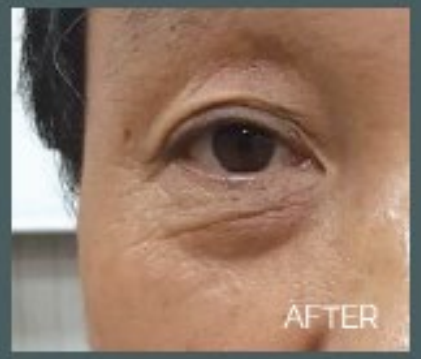
- Wound healing
- Induction of regeneration



- Wound healing regeneration period - about 3 weeks
- Collagen elastin synthesis

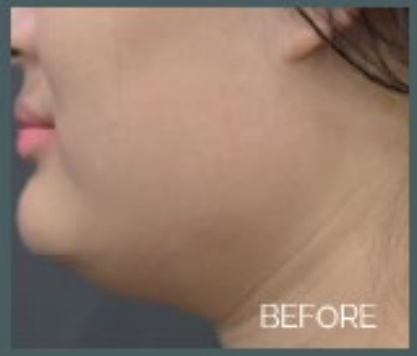


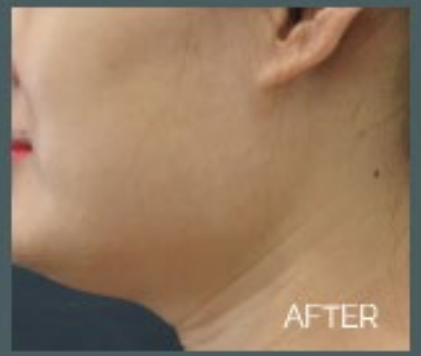
- Collagen remodeling



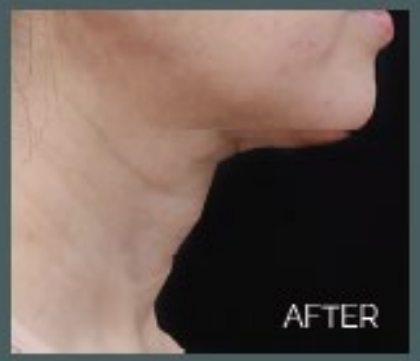
2 TREATMENTS

9 TREATMENTS





RFM + HIFU 3 TREATMENTS



1 TREATMENT

WHAT IS SYLFIRM X

- next generation of biopolar RF microneedling
- The only device with dual mode capability specifically designed to treat all skin layers*: epidermis, basement membrane and dermis
- Developed by the pioneer in RF microneedling technology, Dr. Na
- Patented microneedle technology delivers RF energy efficiently to the target area minimize discomfort and downtime.
- Satiety and efficacy is documented in 26 publications
- High patient satisfaction rate offering the most asked about cosmetic procedures

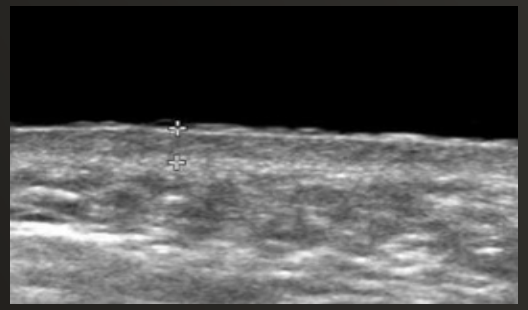
*Through hemostasis and tissue coagulation

BUILT ON SCIENTIFIC EVIDENCE

Ultrasound measurement after Microneedling (DermaStamp) in 2009
Pathologic human skin study after Microneedling in 2009

Microneedling alone shows significant improvement in skin

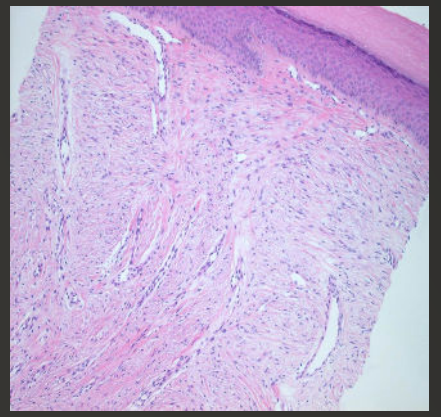
Before



Dermis longitudinal : 2.1mm

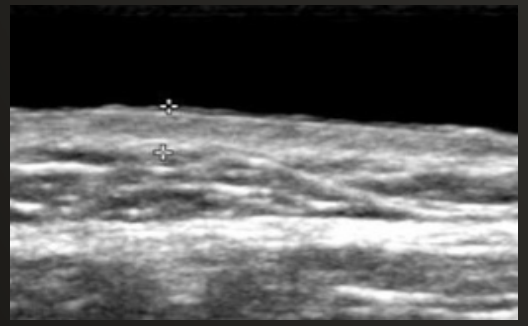
Ultrasound shows an average of 28.3% skin thickness increase after VITICAL MICRONEEDLING treatment

85%-90% o patients experienced dermal thickening



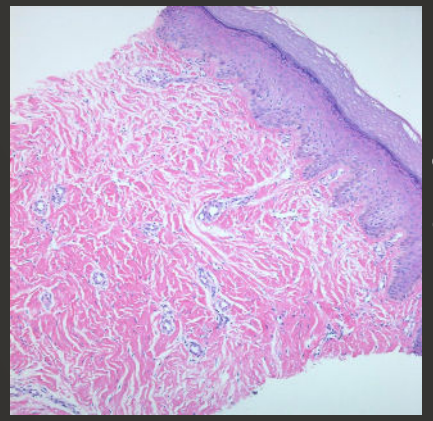
Baseline

After TX



Dermis longitudinal : 2.69mm

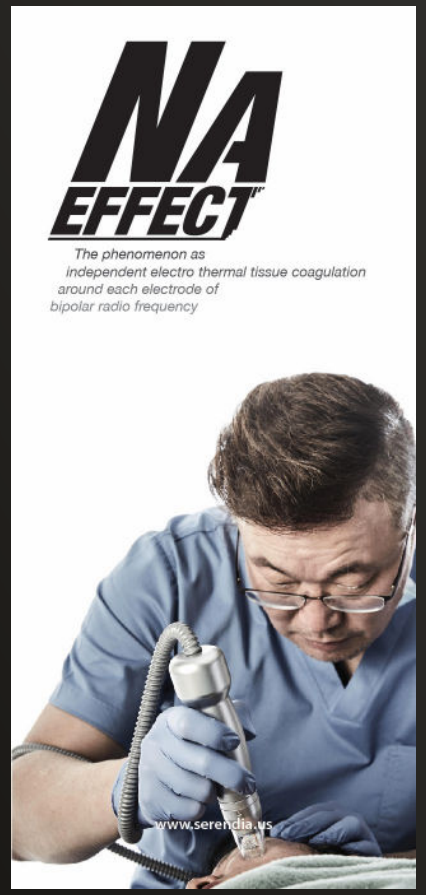
Histology shows neocollagenesis and reorganization of collagen fiber building a stronger foundation in the dermis



3 months after Tx.

HOW it WORKS – “THE NA EFFECT”

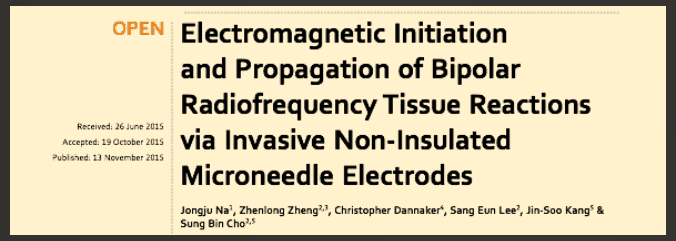
Independent Coagulation via Bipolar RF Microneedling in 2015



Na effect: “Independent electro thermal coagulation around each electrode of bipolar radio frequency.”

“It is distinguished from other bipolar radio frequency tissue reactions which are electro thermal coagulation between both electrodes.”

SCIENTIFIC REPORTS

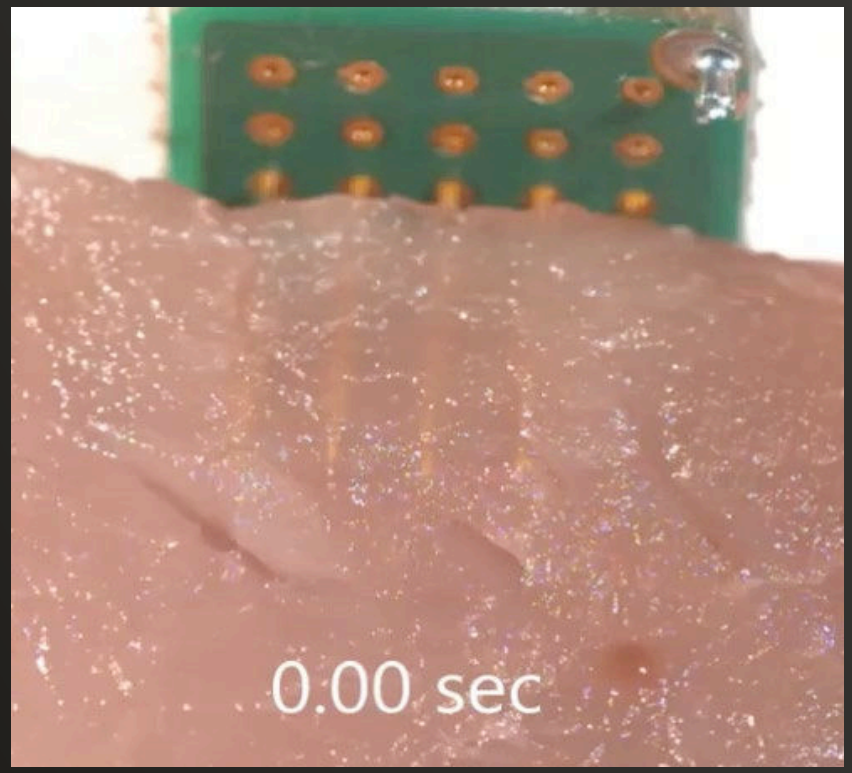

OPEN

Received: 26 June 2015
Accepted: 19 October 2015
Published: 13 November 2015

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

Jongju Na[1], Zhenlong Zheng[2,3], Christopher Dannaker[4], Sang Eun Lee[1], Jin-Soo Kang[5] & Sung Bin Cho[2,3]

THE NA EFFECT



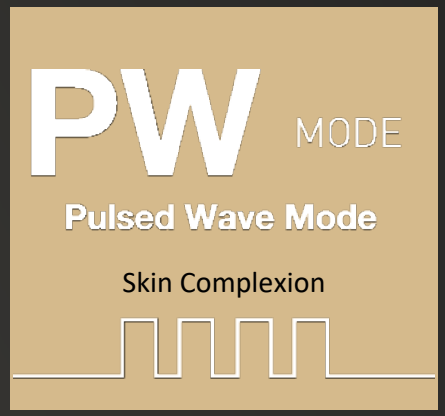
The Experiment:

- A high-speed digital video camera: Phantom v710 (Vision Research Inc., Wayne, NJ, USA) with capture rate of 1,000 frames/s
- A maximum conduction time of 7 seconds
- A signal amplitude of 50V
- Time x Frequency x Power = Jule

PULSED WAVE (PW) AND CONTINUOUS WAVE (CW)

SYLFIRMX® by BENEV

- **PW** mode, unique to SYLFIRM X, targets epidermis and basement m embrane to improve sun damaged skin
- **CW mode** targets the dermal layer providing controlled heating to induce c ollagen remodeling

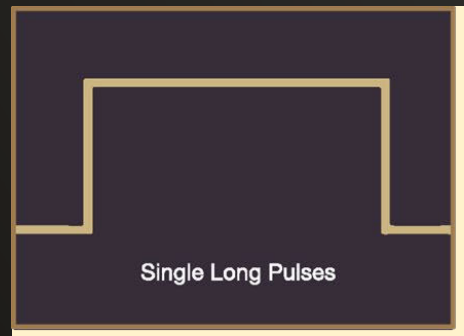


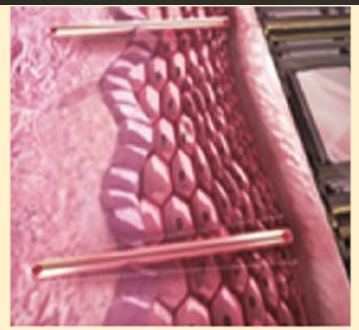
- Uniquely addressing the entire skin*
  - Epidermis for improving the appearance of photodamaged skin
  - Basement membrane (at DEJ) to fortify the skin structure
  - Dermal layer by inducing neocollagenesis and dermal remodeling

*Through hemostasis and tissue coagulation

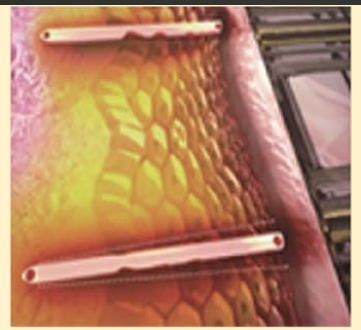
PULSED WAVE (PW) AND CONTINUOUS WAVE (CW)

The Continuous Wave Advantage

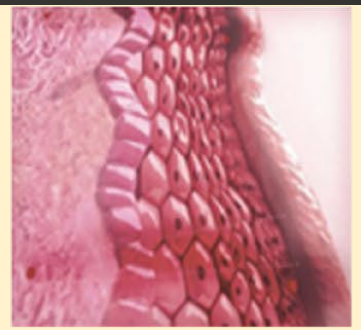




Electrodes inserted into the dermal tissue.



Short pulse RF shooting 55~60°



Thermal energy are delivered along electrodes in total dermal layer.

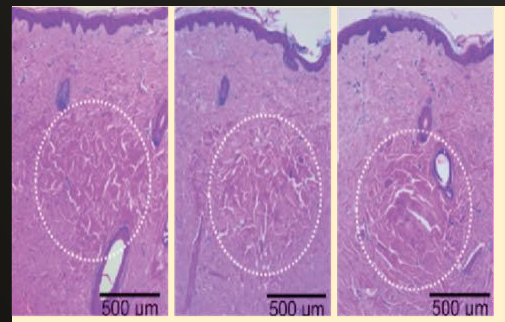


Fig. 5(a)

▶ Thermal coagulation at the target depth

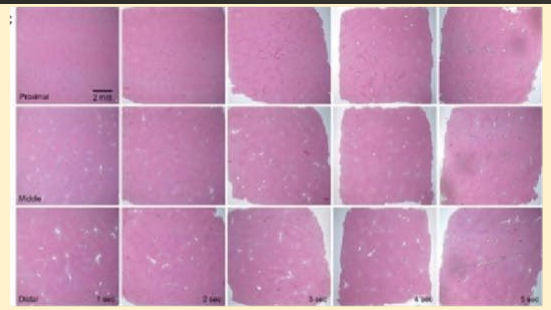


Fig. 5(b)(c)

▶ Safety of Non-insulated needle

WAVE FORM	CW1	CW2	CW3	CW4
PULSE DURATION	120 msec	160 msec	200 msec	300 msec

CW MODE

Continuous Wave Mode

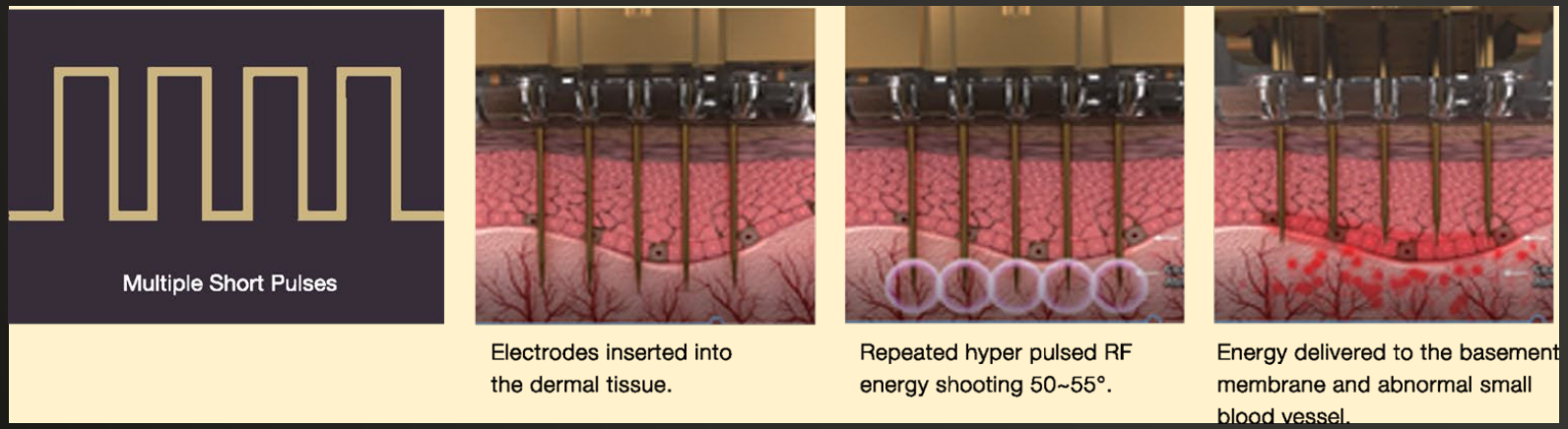
Skin Revitalization

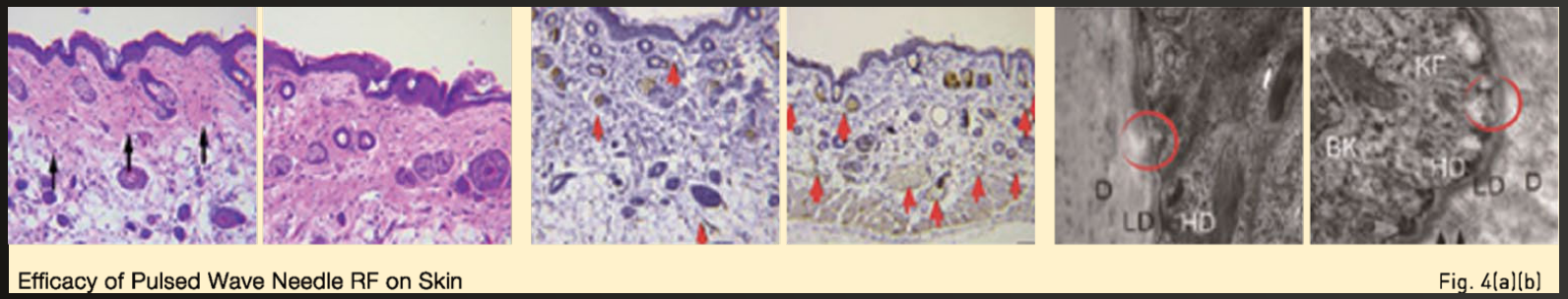
Proven by 10 Clinical Papers

Reference:
Fig. 5[a] Electromagnetic Initiation and Propagation of Bipolar Radio frequency Tissue Reactions via Invasive Non-Insulated.
Fig. 5[b] Micro needle Electrodes. Sci Rep. 2015; 5; 16735.
Fig. 51c] Clinical Study of Facial Wrinkle Treatment with Fractional Micro needle Radio Frequency System. Med Laser 2014;3[2]:59-64

PULSED WAVE (PW) AND CONTINUOUS WAVE (CW)

The Pulse Wave Advantage





Efficacy of Pulsed Wave Needle RF on Skin

Fig. 4(a)(b)

WAVE FORM	PW1	PW2	PW3	PW4
PULSE DURATION	30 msec (75% Duty Cycle)	40 msec (80% Duty Cycle)	50 msec (83.3% Duty Cycle)	60 msec (85.7% Duty Cycle)

PW MODE

Pulsed Wave Mode

Skin Complexion'

Proven by 10 Clinical Papers

Reference

Fig. 4la] Senescent Fibroblasts Drive Aging Pigmentation: A Potential Therapeutic Target for Senile Lentigo. Theranostics 2018, Vol. 8, Issue 17.

Fig. 4lb] Senescent Fibroblasts in Me las ma Pathophysiology. Experimental Dermatology. 2018; 1-4

PULSED WAVE (PW) AND CONTINUOUS WAVE (CW)
300 MICRON

Little To No Pain And Anesthesia-Free Treatment

300 Micron depth is the only treatment that is capable of treating three layers at the same time: epidermis, basement membrane, papillary dermis.

	Target Depth
0.3~0.5 mm	Superficial Layer (Papillary Dermis)
0.8~1.2 mm	Upper Layer (Dermoepidermal junction)
1.5~2.5 mm	Middle Layer (Upper & Mid Dermis)
3.0~4.0 mm	Deeper Layer (Deeper Dermis & S.Q.)

ECM (Extracellular Matrix)

- Provides a physical environment for cells to grow
- Takes a role of connecting cells
- The role of sorting and supplying the necessary biochemical factors
- Composition: collagen, elastin, structural proteins, GAG (glycosaminoglycan), growth factors

BM (Basement Membrane)

- ECM' s composition
- Collagen Type IV is located on lamina densa of the Basement Membrane
- Support of epidermal stem cells
- Connection of epidermis to dermis

CLINICAL SUPPORT - REBUILDING THE BM

Histology Showing Collagen Remodeling and Repair of EDJ

- Basement Membrane or the epidermal dermal junction (EDJ) is damaged due to photoaging
- Damage to the BM can accelerate the aging process
- SYLFIRM specifically targets the BM with PW pulse format to induce nucleogenesis and strengthen the stricture

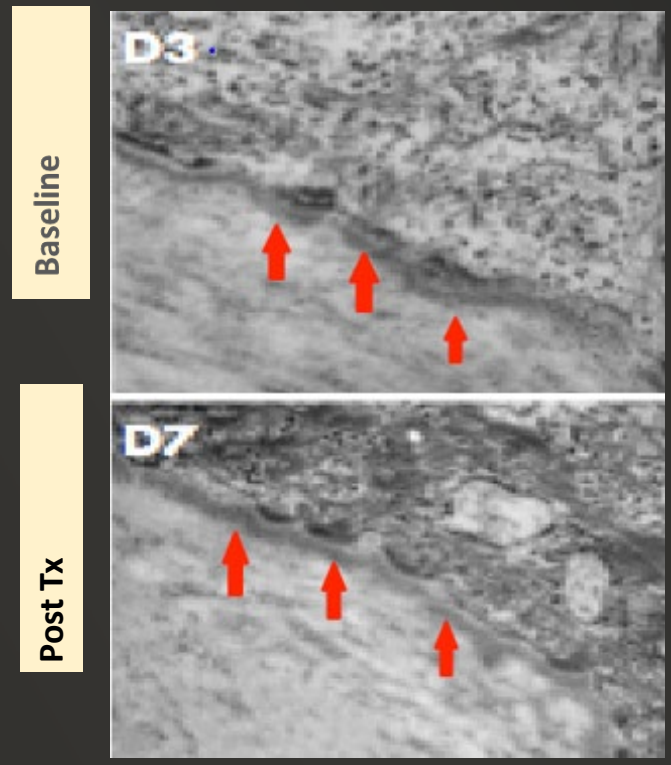
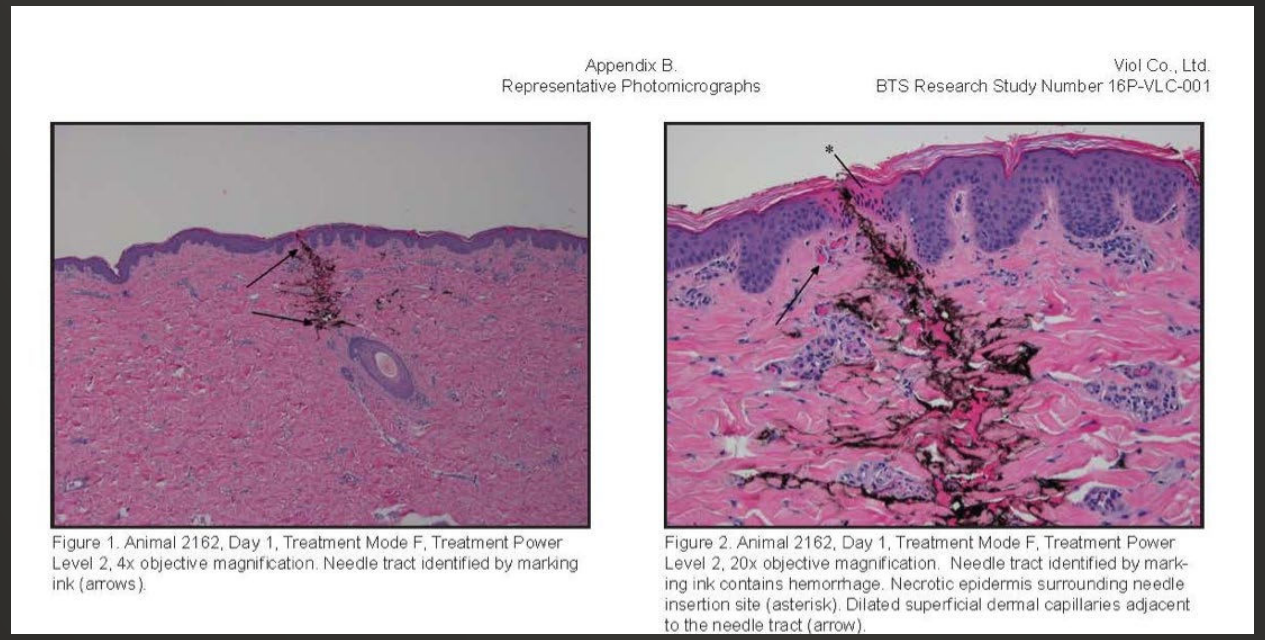


Image shows enhanced Basement membrane of Dermo-epidermal junction

CLINICAL SUPPORT
EFFICIENT DELIVERY OF TOPICALS

- SYLFIRM X provides the ability to induce collagen via controlled heating and create channels for topicals to penetrate the skin

- Helps patients recover faster and fortify their results with a post treatment topical “skin energy boost” **Exosome Regenerative Complex**.



Appendix B.
Representative Photomicrographs

Viol Co., Ltd.
BTS Research Study Number 16P-VLC-001

Figure 1. Animal 2162, Day 1, Treatment Mode F, Treatment Power Level 2, 4x objective magnification. Needle tract identified by marking ink (arrows).

Figure 2. Animal 2162, Day 1, Treatment Mode F, Treatment Power Level 2, 20x objective magnification. Needle tract identified by marking ink contains hemorrhage. Necrotic epidermis surrounding needle insertion site (asterisk). Dilated superficial dermal capillaries adjacent to the needle tract (arrow).

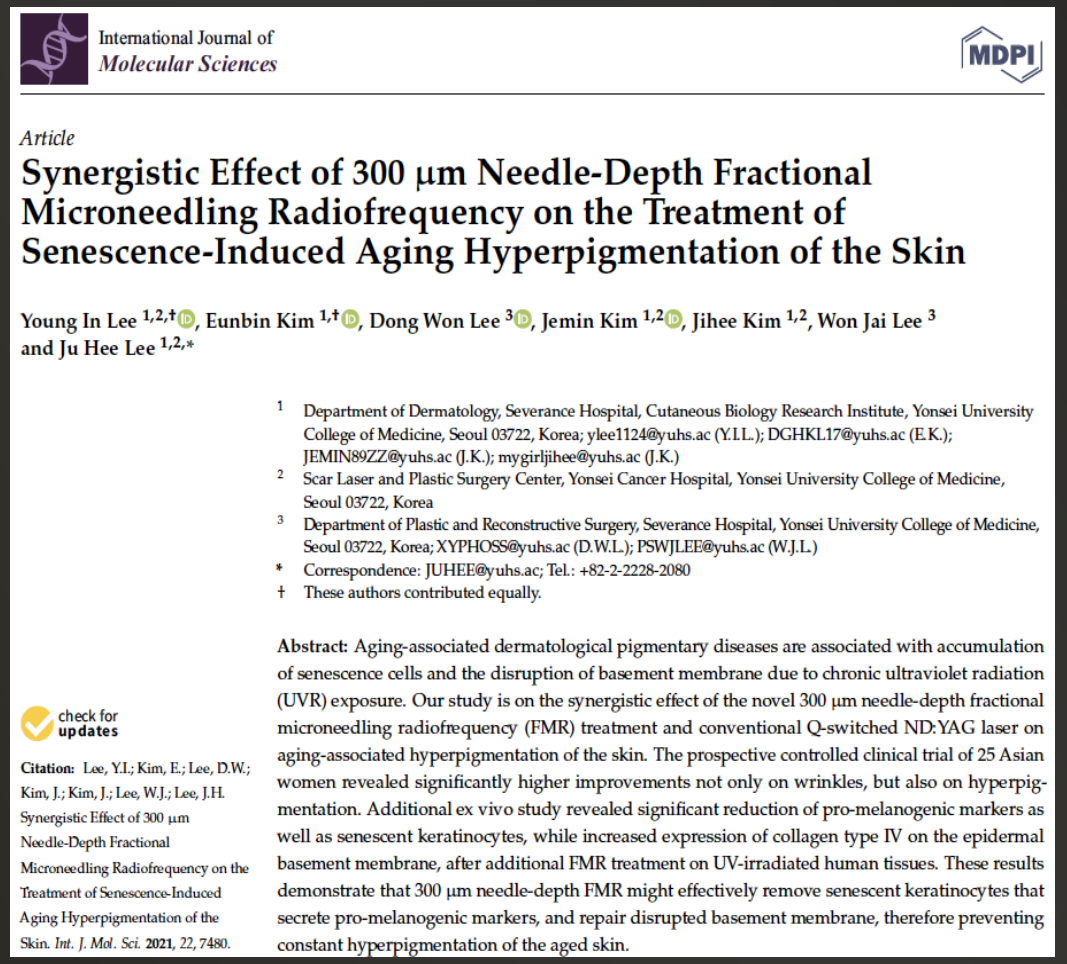
CLINICAL EVIDENCE
BACKED BY 26 PUBLISHED ARTICLES

Selected Publications

1. Suhyun Cho et.al, Improvement of Periorbital Wrinkles Treated with an Invasive Non-Insulated Microneedle Pulsed Electric Signal Device; ed Laser 2016; 5(1):34-38, pISSN 2287-8300・eISSN 2288-0224
2. Jongiu, Na, Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions viaInvasive Non-Insulated Microneedle Electrodes; 2015, Sci Rep, 5: 16735
3. Moon Choi, et.al, Successful Treatment of Refractory Melasma Using Invasive Micro-Pulsed Electric Signal Device; ed Laser 2015;4(1):39-44, pISSN 2287-8300・eISSN 2288-0224
4. Sung Bin Cho1,2,3 Hei Sung Kim4 High-Frequency Alternating Electrical Current: Selective Electromagnetic Tissue Reaction; ed Laser 2016;5(1):1-6, pISSN 2287-8300・eISSN 2288-0224
5. Hyoung Moon Kim, Min Ji Lee, Therapeutic Efficacy and Safety of Invasive Pulsed-Type Bipolar Alternating Current Radiofrequency on Melasma and Rebound Hyperpigmentation: Med Laser 2017;6(1):17-23
6. Tae Hwan Ahn, Sung Bin Cho, Invasive Pulsed-Type, Bipolar, Alternating Current Radiofrequency Treatment Using Microneedle Electrodes for Nasal Rosacea Med Laser 2017;6(1):32-36
7. Tae Hwan Ahn, MD, PhD* Sung Bin Cho, MD, PhD, Adjuvant Therapy for Revision Rhinoplasty of Contracted Nose Using Polydeoxyribonucleotide and Invasive Bipolar Radiofrequency; PRS Global Open • 2018
8. S.B. Choi, et.al, In vivo skin reactions from pulsed- type, bipolar, alternating current radiofrequency treatment using invasive noninsulated electrodes; Skin Res Technol. 2018;1–8.
9. Jung Eun Yoon, Senescent fibroblasts drive ageing pigmentation: A potential therapeutic target for senile lentigo; Theranostics 2018, Vol. 8, Issue 17
10. Ana Korosec et.al, Isolation of Papillary and Reticular Fibroblasts from Human Skin by Fluorescence-activated Cell Sorting, Journal of Visualized Experiments, 5/7/2019
11. You Jin Jung,et.al, Therapeutic effects of a new invasive pulsed- type bipolar radiofrequency for facial erythema associated with acne vulgaris and rosacea, Journal of Cosmetic and Laser Therapy, DOI: 10.1080/14764172.2021.1880599 To link to this article: https://doi.org/10.1080/14764172.2021.1880599

New Treatment Parameter for Melasma (currently under study for FDA indication)

Melasma clinical study combined with LASER toning



International Journal of *Molecular Sciences*

MDPI

Article

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

Young In Lee [1,2,†], Eunbin Kim [1,†], Dong Won Lee [3], Jemin Kim [1,2], Jihee Kim [1,2], Won Jai Lee [3] and Ju Hee Lee [1,2,*]

[1] Department of Dermatology, Severance Hospital, Cutaneous Biology Research Institute, Yonsei University College of Medicine, Seoul 03722, Korea; ylee1124@yuhs.ac (Y.I.L.); DGHKL17@yuhs.ac (E.K.); JEMIN89ZZ@yuhs.ac (J.K.); mygirljihee@yuhs.ac (J.K.)
[2] Scar Laser and Plastic Surgery Center, Yonsei Cancer Hospital, Yonsei University College of Medicine, Seoul 03722, Korea
[3] Department of Plastic and Reconstructive Surgery, Severance Hospital, Yonsei University College of Medicine, Seoul 03722, Korea; XYPHOSS@yuhs.ac (D.W.L.); PSWJLEE@yuhs.ac (W.J.L.)
* Correspondence: JUHEE@yuhs.ac; Tel.: +82-2-2228-2080
† These authors contributed equally.

Abstract: Aging-associated dermatological pigmentary diseases are associated with accumulation of senescence cells and the disruption of basement membrane due to chronic ultraviolet radiation (UVR) exposure. Our study is on the synergistic effect of the novel 300 µm needle-depth fractional microneedling radiofrequency (FMR) treatment and conventional Q-switched ND:YAG laser on aging-associated hyperpigmentation of the skin. The prospective controlled clinical trial of 25 Asian women revealed significantly higher improvements not only on wrinkles, but also on hyperpigmentation. 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. These results demonstrate that 300 µm needle-depth FMR might effectively remove senescent keratinocytes that secrete pro-melanogenic markers, and repair disrupted basement membrane, therefore preventing constant hyperpigmentation of the aged skin.

check for updates

Citation: Lee, Y.I.; Kim, E.; Lee, D.W.; Kim, J.; Kim, J.; Lee, W.J.; Lee, J.H. Synergistic Effect of 300 µm Needle-Depth Fractional Microneedling Radiofrequency on the Treatment of Senescence-Induced Aging Hyperpigmentation of the Skin. *Int. J. Mol. Sci.* **2021**, *22*, 7480.

SUMMARY

- MINIMALLY INVASIVE
- MININIMAL DOWTIME
- COMFORTABLE TREATMENT
- IDEAL FOR:
  - SKIN REVATALIZATION
  - IMPROVES SKIN TONE AND TEXTURE
  - MINIMIZES APPEARANCE OF SCARS
  - IMPROVES SKIN TEXTURE & TONE

- CAN BE COMBINED WITH TOPICAL EXOSOMES

THE FOUNDATION

Equipped with a RF microneedling handpiece to help support the vital foundation of younger looking skin, collagen, working from the inside out to stimulate the body's natural wound healing response to promote neocollagenesis.[1,2]

Signature Treatments

- Secret Radio Frequency Microneedling
- The Secret Gentle Peel (CO_2)

THE FOUNDATION OF SKIN REVITALIZATION AND REMODELING

Advantages of RF Micro needling

Two handpiece sizes and two tip sizes and tip styles for customized treatments on the face and body, on all skin types

- 25 and 64 pin
- Non-insulated (25) and semi-insulated (25/64)

Ability to deliver energy with precision at varying depths

- Adjust by 0.5 mm increments, up to 3.5 mm for multi-layered remodeling

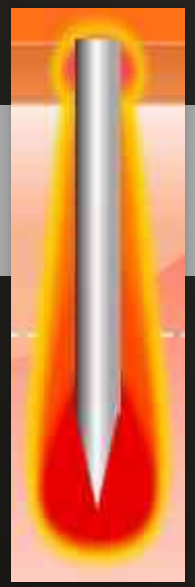
Adjustable levels of Radiofrequency intensity

- Controlled level of injury to manage outcomes and downtime
- Results on challenging/delicate areas

Advantages of RF Microneedling

- Multi-layered dermal remodelling - from the inside out
- Precise delivery of fractional injuries and RF energy
- Largest treatment area provides - 20 min treatments
- Minimal to no downtime
- Can be delegated to maximize ROI
- Intuitive interface for customized treatments
- Safe for all skin types, all body areas, all year-round

Non-insulated & Semi-insulated Needles



Non Insulated Needles

Strong concentration of energy at tip (50%)

Heating from down up delivers controlled injury

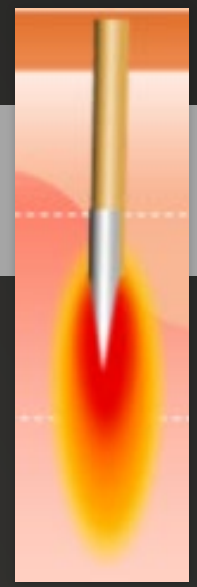
Epidermis remodelling

Semi Insulated Needles

Concentration of energy only at tip (80%) for deeper concerns

All skin types and All seasons

Treat dark skin types as aggressive as light skin types



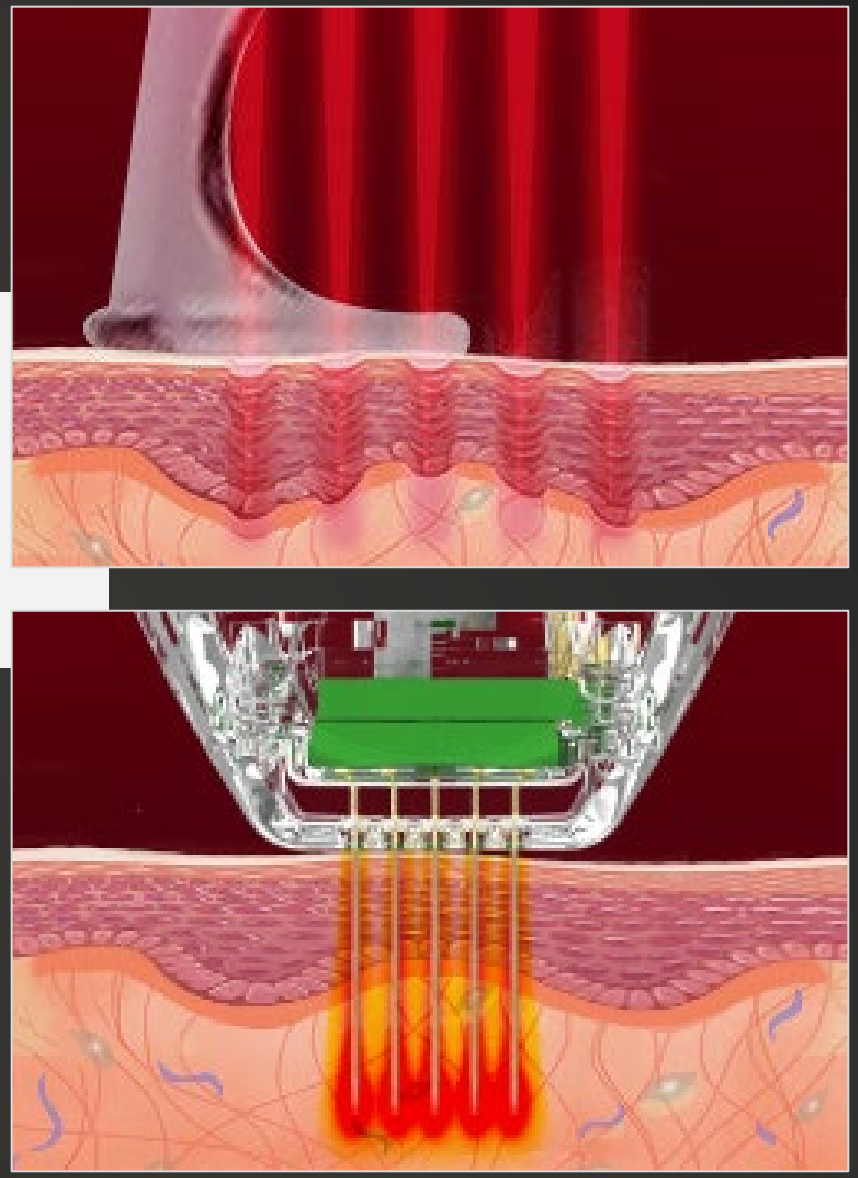
A Dynamic Duo

MULTI-TECHNOLOGY PLATFORM

With 2 unique modalities for defined results and optimal outcomes.

Secret PRO combines 2 gold-standard energy sources for full thickness skin revitalization.

While the fractional CO2 lasers targets the epidermal dermal layers all the way down to deep dermis, the RF microneedles can target deeper layers while preserving the epidermis

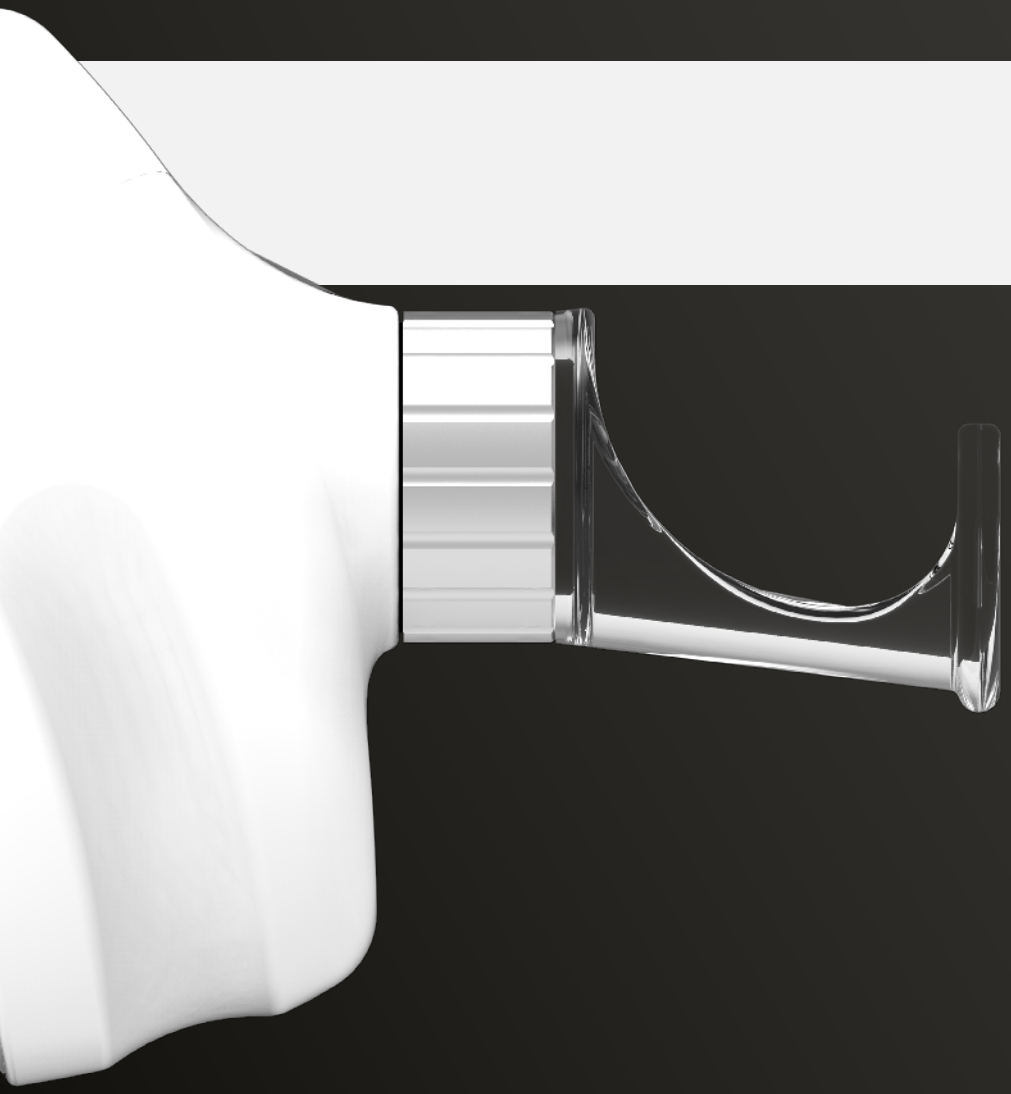


Combination Treatment for Greater Effect

Post Secret PRO

The histology analyses show an intense superficial fibroblast stimulation with CO_2 but a middle and deep fibroblast stimulation using micro-needle fractional RF.

Biopsies courtesy of Michael Naouri MD



Advantages of CO_2

- Technology of choice for skin resurfacing
- Targets epidermal layers and delivers heat to upper dermis
- Customizable to patients' needs and downtime requirements
  - Micropeel
  - Fractional CO_2
  - Combination Tx w RF microneedling
- Optimized for skin types I-III

Fractional CO_2 Features

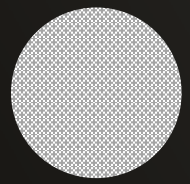
SCAN SIZE:

1x1 ~ 20x20mm

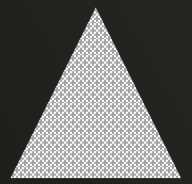
DOT DISTANCE:

0.1 ~ 2.0mm

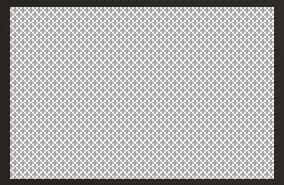
6 different scan patterns for more treatment options



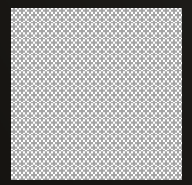
Circle



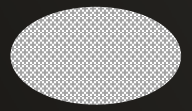
Triangle



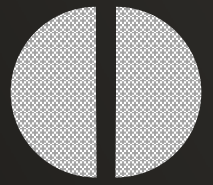
Rectangle



Square



Ellipse



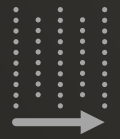
Half Circle

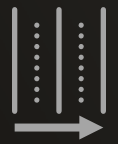
Fractional CO_2 Features

9 various scan modes to control energy delivery patterns for comfort treatment


Convergence

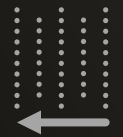

Sequence

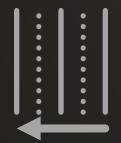

Diagonal


Even/odd


Random + motion


Sequence

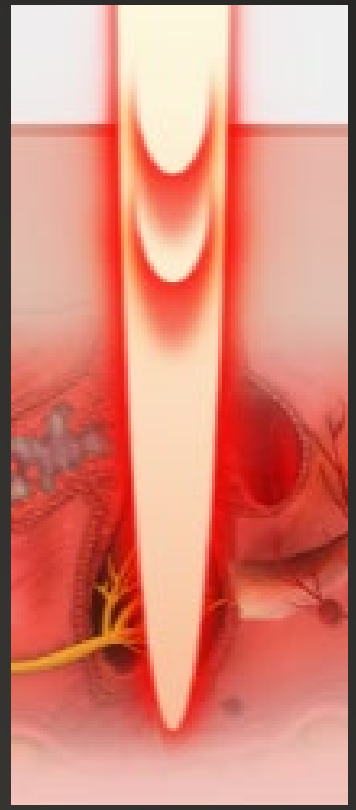

Diagonal


Even/odd

Fractional CO_2 Features

“i-stack” function”

- Deepest ablative effect
- Minimal damage to surrounding tissue
- Optimal effect especially for deep & depressed scars



Advantages

Safe on all skin types (RF microneedling)

Treats high, in-demand procedures

- Revitalization, skin quality / scarring, dermal remodelling

Precision and Customization

- Targeted depths and power to treat superficial and deep remodelling

All in one solution

- Aggressive >> Gentle
- Youngest >> Oldest
- January >> December

Microneedling – Conclusions

- Microneedling is one of the most popular cosmetic procedures in 2025
- From rollers to pens to RF pins to RF needles this field continues to grow
- Many new technologies to consider == all can provide benefits to your patients