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Ultimate Skin Rejuvenation with the

New MFU Dotting and RF Synergy technology

Human Dermatology Clinic
Dr. Wonkyu Hong

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Skin Rejuvenation

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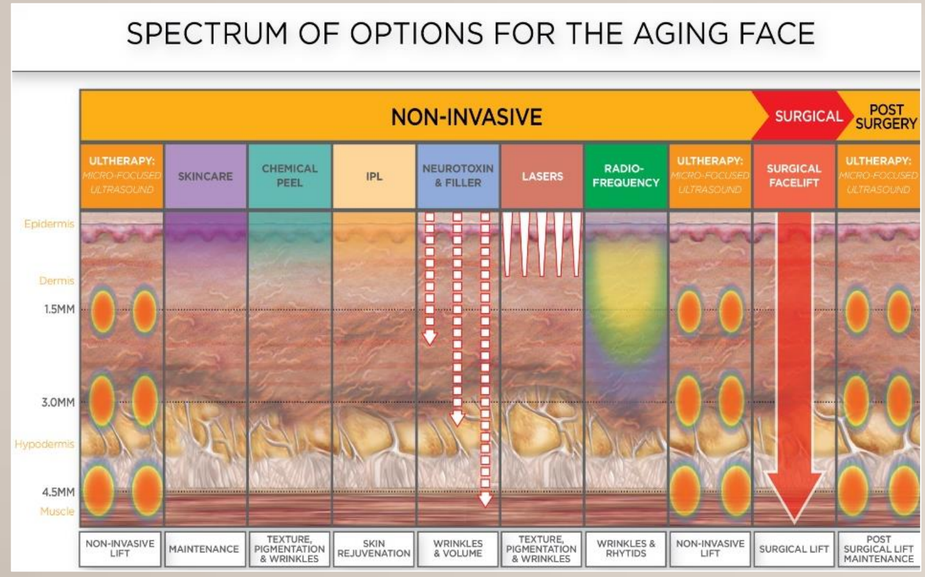
Various signs of aging		**Anti aging treatment, Skin rejuvenation**
Skin Pigmentation	→	Nd-Yag, Alex, IPL..
Skin Wrinkle, Tightening	→	RF, MFU, Microwave
Skin Erythema	→	Dye laser, IPL
Skin Sagging	→	RF, MFU
Volume Loss Volume Displacement	→	Filler, RF, MFU



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Skin Rejuvenation

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doi: 10.1111/srt.12239

Published by John Wiley & Sons Ltd
Skin Research and Technology

High intensity focused ultrasound as a potential new modality for the treatment of pigmentary skin disorder

S. Y. Choi[1], K. H. Yoo[2], C. T. Oh[1,3], T. R. Kwon[1,3], E. J. Choi[3], J. Seok[1] and B. J. Kim[1]

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Background/Purpose: The clinical skin tightening benefits of high intensity focused ultrasound (HIFU) have been established, but its mechanism of action in pigmented skin disorders remains unknown. We macroscopically and histopathologically investigated dermatological changes after HIFU at different exposure doses in a UVB-induced guinea pig model of hyperpigmentation.
Methods: We applied HIFU irradiation at 0.1 and 0.2 J/cm^2 to UVB-induced spotty hyperpigmentation in guinea pig skin. The therapeutic effects of HIFU were judged based on gross appearance using photography, dermoscopy, and chromametry during a period of 3 weeks after HIFU irradiation. Histological assessments were performed using Fontana-Masson staining 1 day before and 3 weeks after HIFU irradiation.
Results: Macroscopically, UVB-induced hyperpigmentation was significantly reduced 2 weeks after HIFU with 0.2 J/cm^2, and 3 weeks after HIFU with 0.1 J/cm^2. Histopathologically, the heavy deposition of melanin in the epidermis induced by UVB exposure was reduced 3 weeks after HIFU irradiation.
Conclusion: We confirmed that HIFU has a positive effect on UVB-induced hyperpigmentation as well as mechanical destructive activity. We suggest that HIFU may be useful as an alternative modality for human patients suffering from skin pigmentary conditions.

Key words: high intense focused ultrasound – hyperpigmentation – pigmentation – UVB

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ORIGINAL ARTICLE

JCD Journal of Cosmetic Dermatology
WILEY

Safety and efficacy of superficial micro-focused ultrasound with visualization for melasma in Asians: An uncontrolled pilot study

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Funding information
Merz Asia Pacific Pte Ltd

Abstract

Background: The pathophysiology of melasma is multifactorial, resulting in treatment resistance and a high recurrence rate. Recent research suggests that focused ultrasound might treat melasma effectively.
Objectives: To investigate the efficacy and safety of superficial micro-focused ultrasound with visualization (MFU-V) for melasma in Asians.
Methods: Patients (n = 20) with mixed melasma on both cheeks received 2 MFU-V treatments spaced 1 month apart. At monthly visits over 5 months, treatment efficacy and safety were evaluated. Standardized photographs were clinically assessed using the modified Melasma Area and Severity Index (mMASI), and 6-point grading scales for melasma lightening and area of involvement. Patients provided pain, global aesthetic improvement scale (GAIS), and satisfaction assessments.
Results: In 40 cheeks, the mean mMASI score was significantly reduced from 13.2 at baseline to 2.4 at month 4, and 2.8 at month 5. Twenty-nine cheeks (72.5%) showed lightening of melasma at month 4 that persisted until month 5, with improvements up to 75% compared to baseline. Melasma area decreased overall, with sites containing >30% melasma involvement decreasing from 55% to 20% by month 5, and none with 70%–89% involvement. Melasma lightening and area improved visibly in 40% and 20% of cheeks, respectively, as early as 1 month after index MFU-V treatment. Improvements continued after the second treatment and persisted until study closure, correlating with patient GAIS and satisfaction scores. Procedure was well tolerated with only mild-to-moderate pain reported in 92.5% of treatments.
Conclusion: Superficial MFU-V is a safe and effective treatment for melasma.

KEYWORDS
melasma, micro-focused ultrasound with visualization, photoaging pigmentation, pigmentary conditions, superficial high intensity focused ultrasound

MFU can be used in pigment treatments

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International Journal of *Molecular Sciences*

MDPI

Article

Evaluating Whether Radiofrequency Irradiation Attenuated UV-B-Induced Skin Pigmentation by Increasing Melanosomal Autophagy and Decreasing Melanin Synthesis

Hyoung Moon Kim [1,2,†], Seyeon Oh [2,†], Jin Young Yang [2], Hye Jin Sun [3], Miran Jang [3], Donghwan Kang [3], Kuk Hui Son [4,*] and Kyunghee Byun [1,2,*]

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† These authors contributed equally to this study.

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Abstract: Autophagy is involved in the degradation of melanosomes and the determination of skin color. TLR4 and tumor necrosis factor (TNF) signaling upregulates NF-kB expression, which is involved in the upregulation of mTOR. The activation of mTOR by UV-B exposure results in decreased autophagy, whereas radiofrequency (RF) irradiation decreases TLR4 and TNF receptor (TNFR) expression. We evaluated whether RF decreased skin pigmentation by restoring autophagy by decreasing the expression of TLR4 or TNFR/NF-κB/mTOR in the UV-B-irradiated animal model. UV-B radiation induced the expressions of TNFR, TLR, and NF-κB in the skin, which were all decreased by RF irradiation. RF irradiation also decreased phosphorylated mTOR expression and upregulated autophagy initiation factors such as FIP200, ULK1, ULK2, ATG13, and ATG101 in the UV-B-irradiated skin. Beclin 1 expression and the expression ratio of LC3-I to LC3-II were increased by UV-B/RF irradiation. Furthermore, melanin-containing autophagosomes increased with RF irradiation. Fontana-Masson staining showed that the amount of melanin deposition in the skin was decreased by RF irradiation. This study showed that RF irradiation decreased skin pigmentation by restoring melanosomal autophagy, and that the possible signal pathways which modulate autophagy could be TLR4, TNFR, NF-κB, and mTOR.

Keywords: melanosomal autophagy; autophagosome; radiofrequency microneedling; ultraviolet B; skin pigmentation

Original Article | Annals of Dermatology 2021;33(6):522-530 • https://doi.org/10.5021/ad.2021.33.6.522

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A Clinical and Biochemical Evaluation of a Temperature-Controlled Continuous Non-Invasive Radiofrequency Device for the Treatment of Melasma

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Background: Melasma shows characteristic histological features of photoaged skin.
Objective: We evaluated the effect of dermal rejuvenation using a temperature-controlled continuous non-invasive radiofrequency (RF) device on melasma.
Methods: Continuous skin heating at the temperature of 43°C for 20 minutes was performed in ten subjects with melasma who underwent 3 tri-weekly RF sessions. Pigmentation was evaluated with Mexameter® and investigator's global assessment (IGA). Immunohistochemical staining and image analysis was performed to evaluate biopsies from melasma skin before and after the treatment.
Results: The lesional melanin index was decreased by 13.7% at week 9. IGA score was improved from 3.50 at baseline to 2.95 at week 9. No significant adverse event was reported. Histologic analysis revealed reduced melanin and increased collagen density and thickness. The expression of procollagen-1 and type IV collagen was increased after the treatment. The number of $p16^{INK4A}$-positive senescent fibroblasts was reduced after the treatment, while the expression of heat shock protein 70 and 90 was increased. Stromal derived factor-1, a senescence-associated anti-melanogenic factor secreted from the fibroblasts, was up-regulated after the treatment, while the level of c-kit was not changed.
Conclusion: Thermal skin stimulation by the temperature-controlled continuous RF device improved melasma through dermal rejuvenation.

Keywords: Fibroblasts, Melanosis, Radiofrequency therapy, Skin aging

INTRODUCTION

Melasma is an acquired pigmentary disorder, which is particularly common in Asian women in their thirties and forties[1]. It appears as bilateral symmetrical light-to-dark brown-colored irregular macules on sun-exposed areas of the skin, especially on the face. Chronic ultraviolet (UV) exposure, genetic predisposition, and sex hormones have been implicated in the pathogenesis of melasma[2]. However, recent evidence supports that melasma is not only a pigmentary disorder, but also a consequence of photoaged skin[3,4]. Histologically, melasma is characterized by solar elastosis, increased vascularization, higher number of mast cells, and disrupted basement membrane, which are characteristic findings of photoaged skin[5]. Therefore, recurrence of melasma is frequently observed despite successful anti-melanogenic treatment[6].

The role of fibroblasts in pigmentation has been studied in several studies. Palmoplantar fibroblasts express a higher level of Dickkopf1 than trunk skin fibroblasts, which suppresses melanogenesis via the inhibition of the Wnt canonical pathway[7,8]. Higher level of neuregulin-1 was expressed in dark skin fibroblasts than in those from lighter skin type, which activates the PI3K and MAPK signaling pathways in melanocytes[9,10]. Fibroblast-derived factors are not only involved in the physi-

RF can inhibit melanin synthesis and be effective in treating melasma.

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Synergic effect of on the outcome of skin rejuvenation

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RF + MFU

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Synergic effect of the combined treatment of RF and MFU

Skin Research & Technology
Open Access

ORIGINAL ARTICLE

Interactive thermal tissue reactions of 7-MHz intense focused ultrasound and 1-MHz and 6-MHz radiofrequency on cadaveric skin

Heesu Kim, Keun Jae Ahn, Sugun Lee, Henry Park, Sung Bin Cho

First published: 15 October 2018 | https://doi.org/10.1111/srt.12629 | Citations: 1

Heesu Kim and Keun Jae Ahn equally contributed to this work.

Abstract

Background

Intense focused ultrasound (IFU) and radiofrequency (RF) systems generate thermal tissue reactions in multiple zones in the skin, with the microscopic features thereof varying according to energy sources and treatment parameters.

Objective

To evaluate interactive thermal tissue reactions of IFU and RF in cadaveric skin.

Methods

Thermal reaction patterns generated by IFU, invasive bipolar RF, and non-invasive monopolar RF treatments were analyzed in cadaveric skin of the inner thigh. Additionally, combination treatment, including IFU and invasive bipolar RF, IFU and non-invasive monopolar RF, invasive bipolar RF and IFU, and non-invasive monopolar RF and IFU, was delivered to cadaveric skin and microscopically evaluated.

Results

Combination treatment with 1.5-mm IFU followed by 1.5-mm invasive RF elicited multiple thermal injury zones of coagulation and ablation in the mid to lower dermis. Therein, IFU-induced thermal reactions were indistinguishable from RF-induced thermal reactions. Non-invasive RF treatment on IFU-pretreated cadaveric tissue specimens exhibited greater degrees of thermal injury, with wider and deeper penetration, compared to non-invasive RF treatment alone. Furthermore, RF-pretreated tissues showed marked differences in the patterns of IFU-induced thermal tissue reactions.

Conclusion

Our data suggest that combination treatments with IFU and RF elicit various patterns of interactive thermal tissue reactions.

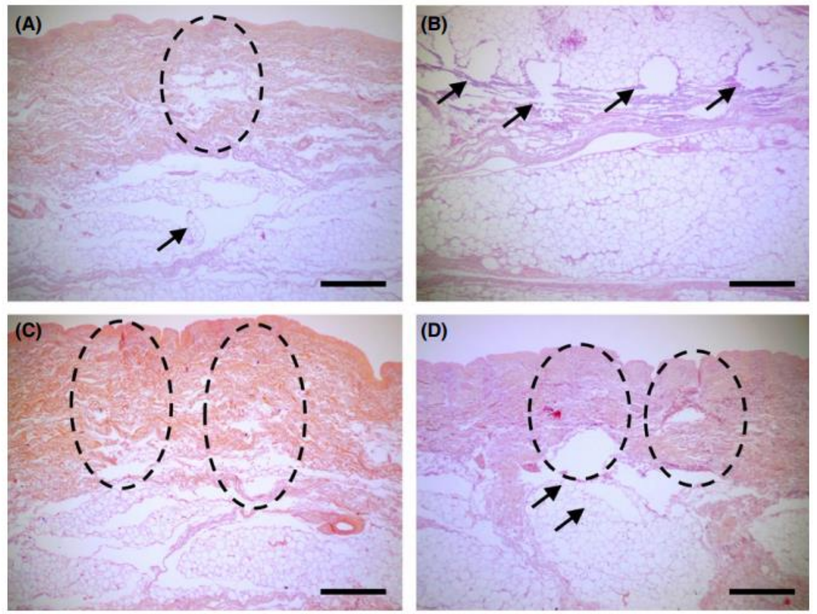

FIGURE 3 Interactive thermal tissue reactions after intense focused ultrasound (IFU) treatment followed by non-invasive monopolar radiofrequency (RF) treatment. (A-C) Patterns of IFU-induced thermal tissue reactions (arrows) are distinct from non-invasive RF-induced thermal reactions (broken lines). Note the wider and deeper zones of non-invasive RF-induced thermal tissue reaction with greater tissue coagulation, compared with non-invasive RF treatment alone. (D) Indistinguishable mixed patterns of IFU- and non-invasive RF-induced multiple thermal reactions in the dermis and upper subcutaneous fat. (A, C) IFU treatment at 1.5 mm and 1.2 J plus RF treatment at 120 W and 1000 msec, (B) IFU treatment at 3.0 mm and 1.2 J plus RF treatment at 120 W and 1000 msec, (D) IFU treatment at 1.5 mm and 1.2 J plus RF treatment at 80 W and 1500 msec. Hematoxylin and eosin stain, original magnification ×40, scale bar = 500 μm [Colour figure can be viewed at wileyonlinelibrary.com]

Skin Res Technol 2019:25:171-178

Tissue responses are more extensive compared to stand alone treatments

it can be expected that the clinical effect will be better

Micro Focused Ultrasound

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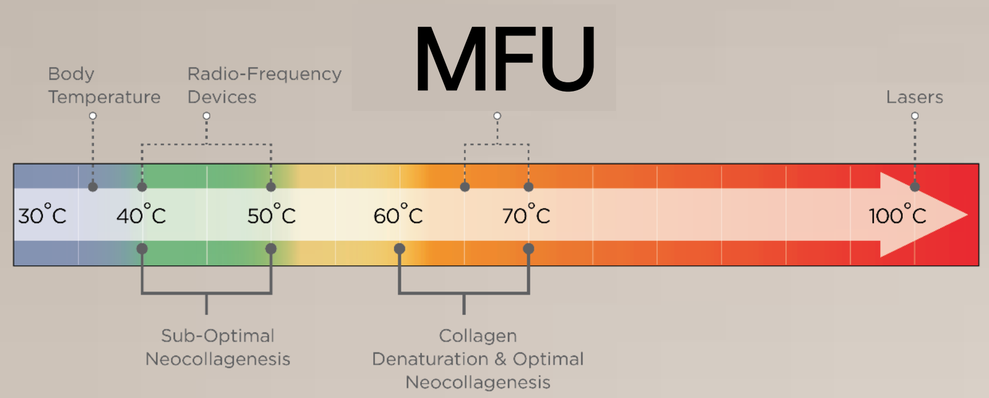
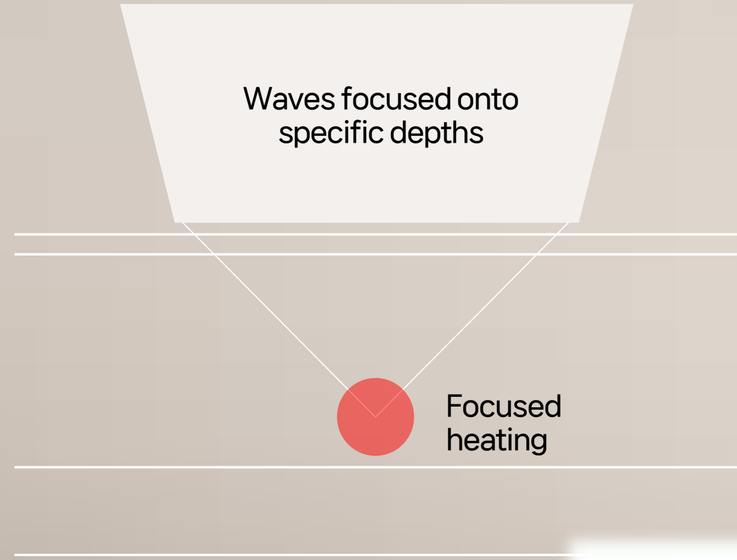


High-frequency ultrasound produce controlled heat

Microthermal coagulation

Natural healing response

Neocollagenesis



Collagen synthesis by forming heat points at around 60 degrees Celsius

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*MFU : Microfocused Ultrasound

MOA of Micro Focused Ultrasound

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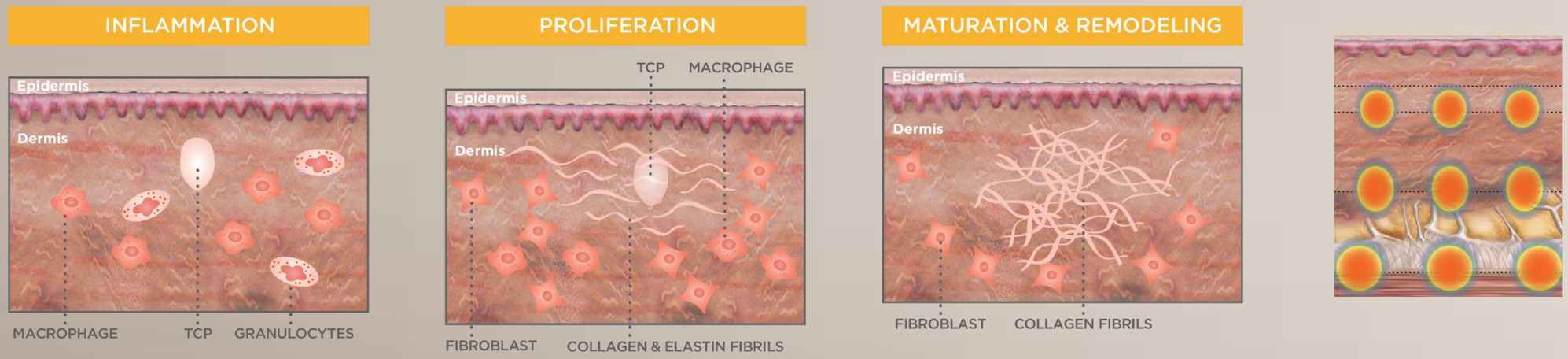
Target of MFU : 1. FIBROUS Layer of Fat/ SMAS -> Lifting, Contouring

2. Dermal layer -> Dermal Remodeling



Clinical benefits become evident as tissues undergo remodeling in the following one or two months

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RF system In Dermatology

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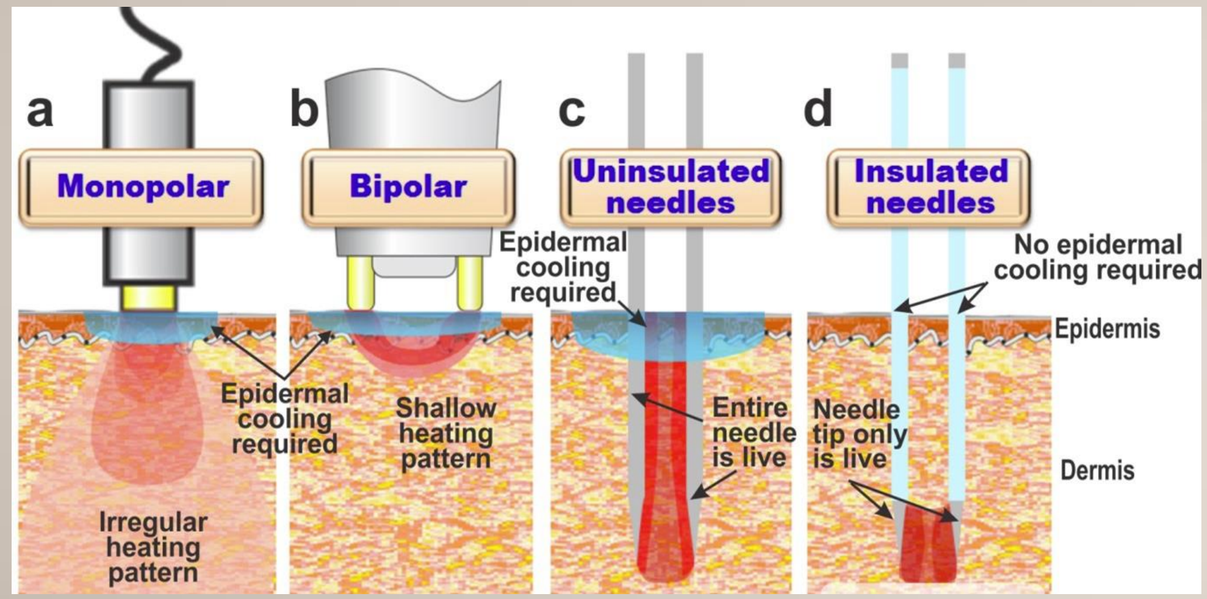
Non-invasive RF system

Mono-polar: single electrode, plate(+)
Bi-polar: active two electrode, plate(-)
Multi-polar: active multiple electrode, plate(-)
Uni-polar: sigle electrode, plate(-)

Invasive RF system

Micro-needle RF: mono-polar, bi-polar
Sublative RF fractional: multiple small electrodes, bi-polar, uni-polar



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MOA of Bi-polar RF

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It does not raise the tissue temperature enough to trigger the collagen contraction mechanism

Dermal collagen shrinkage

Inducing the secretion of HA within the tissue at around 42 degrees Celsius, creating short-term edema, enhancing tissue turgor

- Mild hyperthermia of about 42 ℃
- Significantly lower temperatures than those which are needed for collagen shrinkage
- Immediate improvements after the procedure, but it tends to have limited long-term effectiveness

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Microstructuralinhomogeneityof electricalconductivity in subcutaneous fat tissue. PLOS one 2015 Mar 3;10(3):e0117072.

Synergic effect of Bipolar-RF and HIFU

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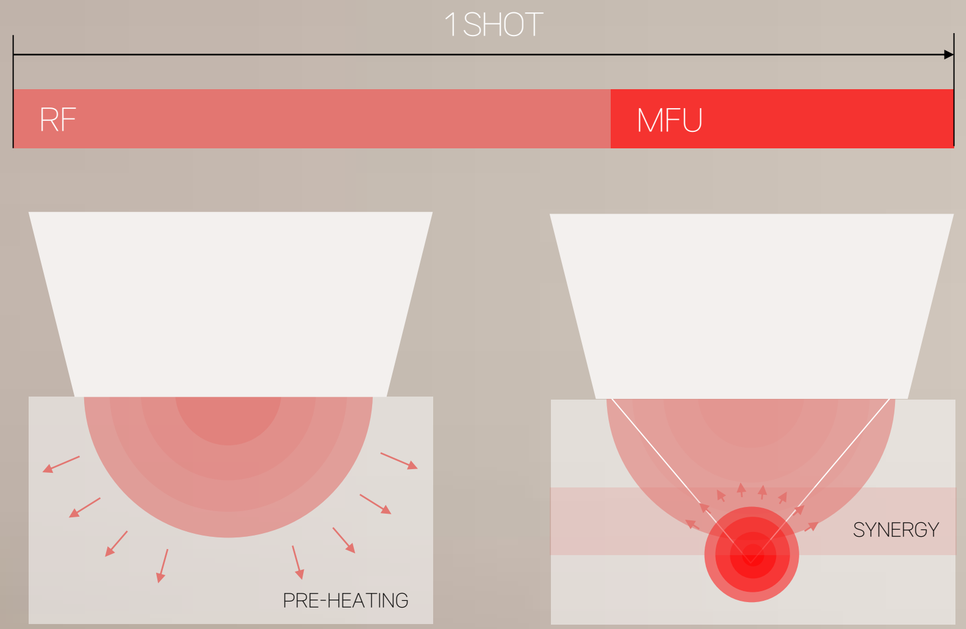
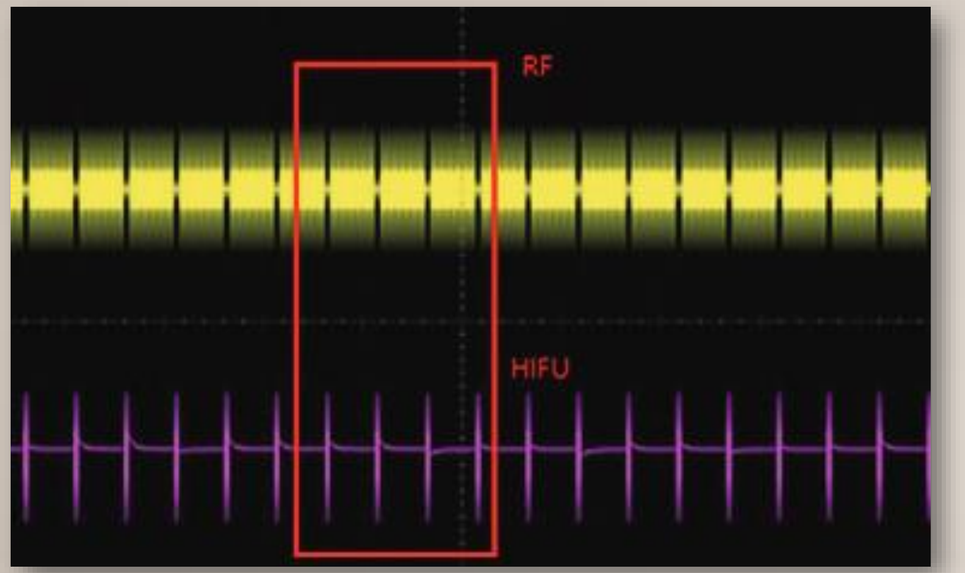
"Synergy Dotting"

First technology globally to allow us to apply RF and MFU at the same time on the skin





if we simultaneously perform bipolar RF and MFU procedures? Not sequentially, but at the same time

More tissue reactions, leading to superior clinical effects

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Synergy Dotting Technology

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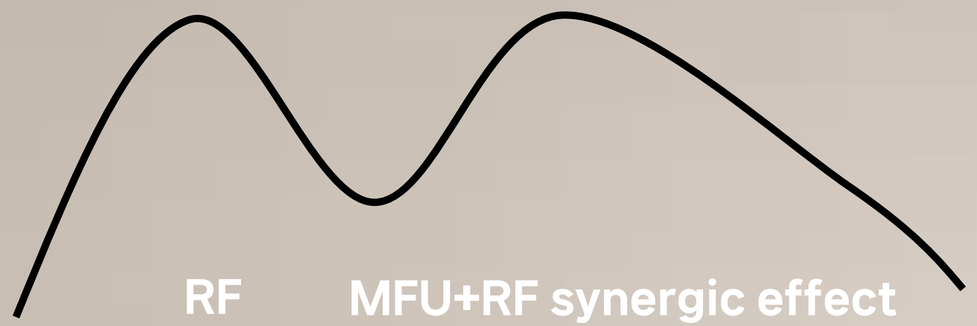

1. Early stage immediate effects from B-RF

- Increased local concentration of glycosaminoglycans (HA)
- Short term edema, Improve tissue turgor
- Immediate effect of RF

2. Synergic effects in the later stages： B-RF+MFU

- collagen synthesis

Immediate effects and long-lasting skin rejuvenation effects

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NEW DOUBLO 2.0 SPECIFICATIONS- "variety of handpieces"

new 2.0 doublo

FL cartridge: Classic MFU dot mode and new line mode

Type	Depth, Frequency	Model Name				DOT Mode	LINE Mode	Spacing	Length
FL (MFU)	1.5mm, 7MHz	S1.5		A1.5		0.1J - 0.5J	0.1J - 0.5J	1.0 - 5.0mm	5.0 - 25mm
	2.0mm, 7MHz	S2.0		A2.0		0.1J - 1.0J	0.1J - 0.8J		
	3.0mm, 7MHz	N3.0		A3.0		0.1J - 1.0J	0.1J - 1.0J		
	4.5mm, 4MHz	N4.5		A4.5		0.1J - 1.5J	0.1J - 1.0J		
	6.0mm, 2MHz	W6.0		A6.0		0.1J - 3.0J	0.1J - 2.0J		
	9.0mm, 2MHz	W9.0		A9.0		0.1J - 3.0J	0.1J - 2.0J		

SD cartridge: Bipolar radiofrequency and a pen-type MFU

Type	Depth, Frequency	RF Frequency	Model Name				Power	Hz
SD (MFU+ RF)	1.5mm, 7MHz	2MHz Bipolar RF	P1.5		L1.5		Lv 1 - 10	Max. 10Hz*
	3.0mm, 7MHz	2MHz Bipolar RF	P3.0		L3.0			
	4.5mm, 4MHz	2MHz Bipolar RF	P4.5		L4.5			
	9.0mm, 2MHz	2MHz Bipolar RF	W9.0		L9.0			

* 7 - 10 Hz depending on power level

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NEW DOUBLO 2.0 SPECIFICATIONS

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Two handpieces for each cartridge type

SD x2

SYNERGY DOTTING HANDPIECE

1 DOT MFU
MULTIPOLAR RF

FL x2

FOCUSED LINEAR HANDPIECE

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NEW DOUBLO 2.0 MAIN ADVANCE POINTS

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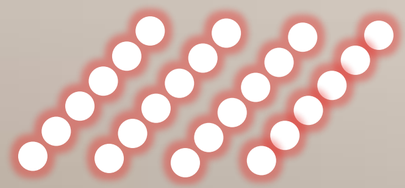
100% COVERAGE WITH LINE MODE

Line mode offers uniform, faster treatments for larger areas minimizing discomfort compared to the dot mode.

* One-touch switch between modes

DOT Mode

LINE Mode



less likely to overheat tissues, resulting in less fat destruction

NEW DOUBLO 2.0 MAIN ADVANCE POINTS- for facial skin

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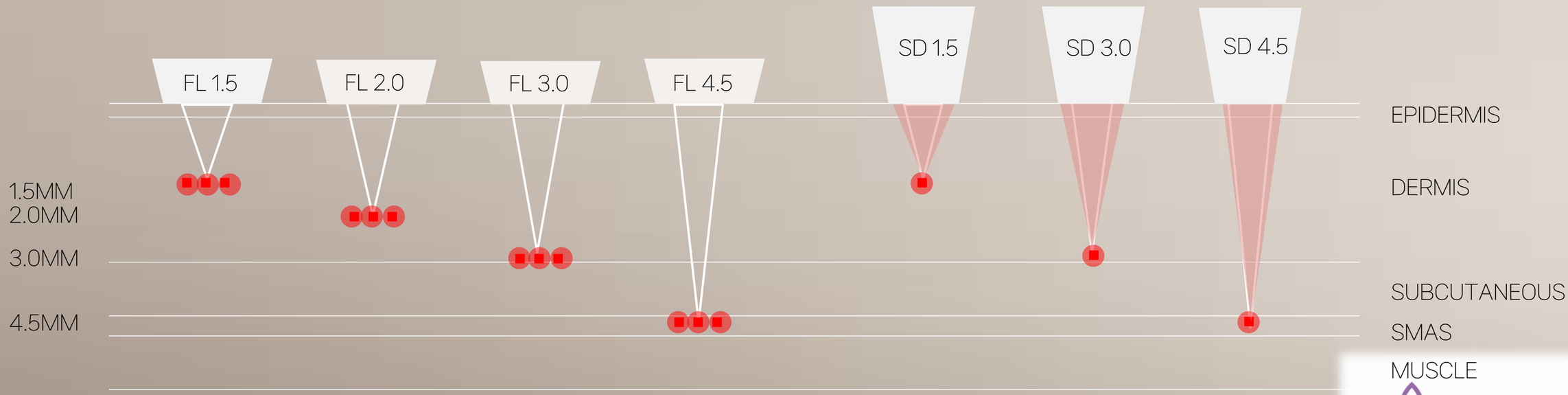
PRECISION IN TARGETING



The FL cartridge can address depths of 1.5, 2.0, 3.0, and 4.5mm,
The SD cartridge targets depths of 1.5, 3.0, and 4.5 mm

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NEW DOUBLO 2.0 SPECIFICATIONS- for body skin

FULL-BODY MFU SCULPTING & SKIN TIGHTENING

The 4 cartridges for body application allow to offer your customers ultimate body sculpting treatments.

IMMEDIATE RESULTS

NO DOWNTIME

NO PAIN

- Abdomen
- Flanks
- Bra Line
- Neck
- Decolletage
- Arms
- Underarms
- Back
- Buttocks
- Hips
- Thighs
- Knees
- Calves
- Ankles

FL offers cartridges for treating depths of 6 and 9mm, while SD provides a cartridge for treating at 6mm depth.

SD | SYNERGY DOTTING

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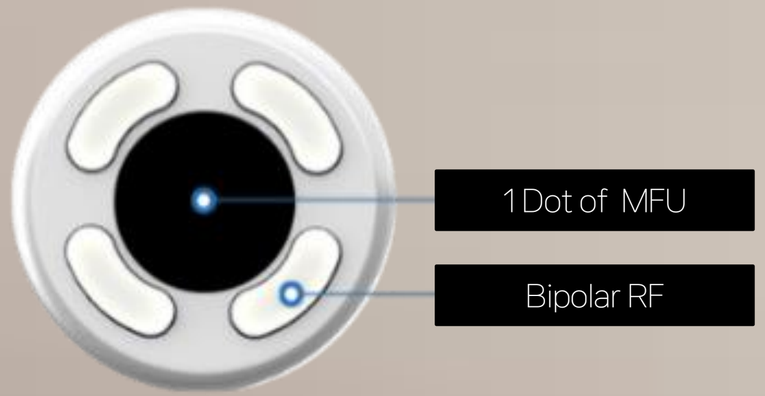
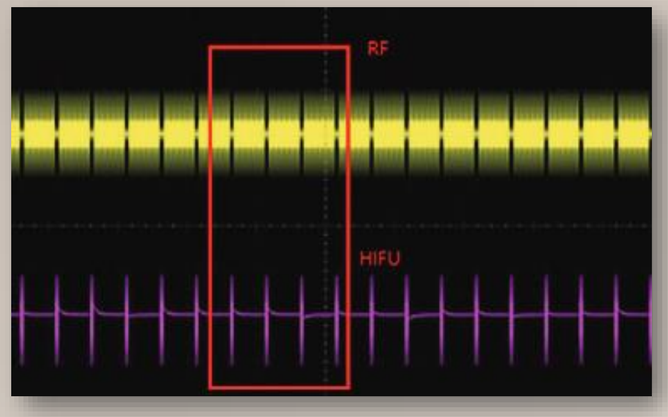
MFU & RF SYNERGY EFFECT





Less Risk of Downtime & Complication

Better Potential for Lasting Improvement

In the center of the pen-type cartridge, one dot of MFU is delivered at a maximum speed of 10Hz, while bipolar radiofrequency is simultaneously applied in the surrounding area

* MFU: Micro Focused Ultrasound
* RF: Radio Frequency

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EVIDENT MFU & RF SYNERGY EFFECT

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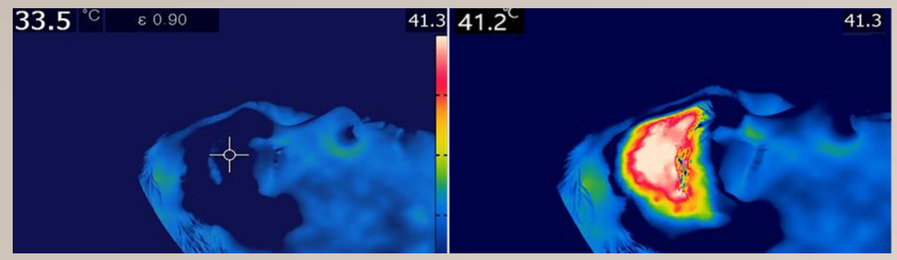
MFU & RF

WORLD'S FIRST SYNERGY
DOTTING SYSTEM

BEFORE AV.+7.7°C AFTER

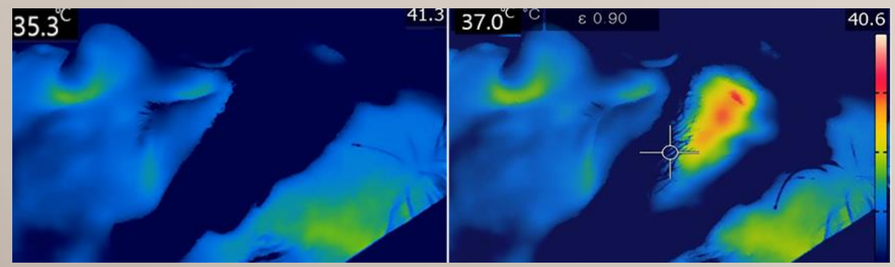


Bipolar RF plays a role in raising the tissue temperature to around 42 degrees celsius

HIGHER HEATING EFFECT

VS. **MFU ONLY**

BEFORE AV.+1.7°C AFTER



MFU is delivered into the skin where the temperature has increased due to RF

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*MFU : Microfocused Ultrasound

SPECIFICATIONS

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CARTRIDGES SD x8

APPLICATION	FACE			BODY
DEPTH	1.5 mm	3.0 mm	4.5 mm	9.0 mm
P – PEN TYPE				
L – LONG TYPE				

DERMAL | SMAS/FIBROUS | SMAS | Fat

MFU alone VS combined MFU and RF treatments

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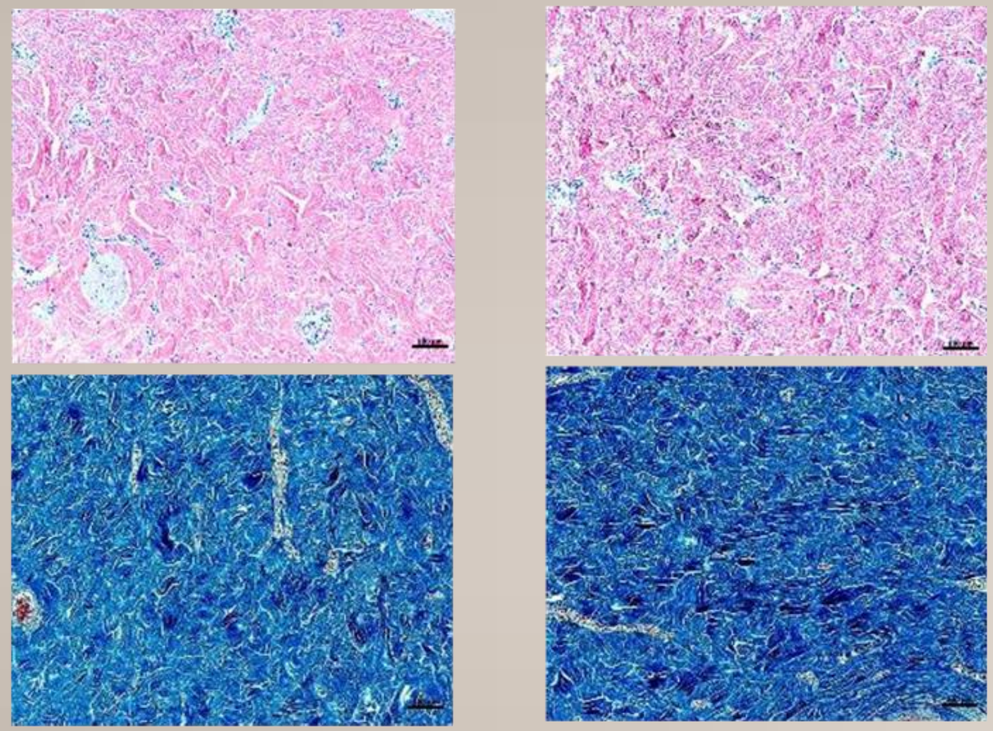
MFU & RF

< Only MFU >

< MFU+RF >



The group undergoing combination treatment showed a significantly higher production of collagen

Preclinical Performance and Safety Evaluation Tests for Focused Ultrasound Stimulator System (Model: NEW DOUBLO / V-RO). Seoul National University Bundang Hospital. 2021.

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EVIDENT MFU & RF SYNERGY EFFECT

To examine the clinical effects of the Synergy Dotting System, we conducted a split-face trial with a sample of 20 individuals

Combining MFU with bipolar RF **SYNERGISTICALLY IMPROVES SKIN REJUVENATION**, including pore reduction, periorbital wrinkle improvement, skin elasticity, and skin moisturization.

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Skin Research & Technology

Open Access

WILEY

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ORIGINAL ARTICLE

WILEY

Efficacy of radiofrequency combined with single-dot ultrasound efficacy for skin rejuvenation: A non-randomized split-face trial with blinded response evaluation

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Funding information
the Human Co., Ltd. Skin Clinical Trial Center

Abstract

Background: High-intensity focused ultrasound (HIFU) and radiofrequency (RF) are non-invasive modalities for skin rejuvenation, but their combined effects have not been evaluated.

Objective: We evaluated and compared the efficacy of HIFU alone and combined HIFU and bipolar RF using a newly designed probe.

Methods: Twenty-two Korean adults with facial wrinkles and aging underwent treatment on both sides of their face: HIFU-only on the left and HIFU combined with RF on the right. Skin parameters were measured at different time points to evaluate the improvement in skin rejuvenation.

Results: HIFU treatment significantly improved skin parameters, including pore volume and number, skin elasticity, depth of eye wrinkles, degree of sagging in the eye area, nasolabial folds and cheeks, volume of the jawline, skin density, and permittivity. Furthermore, combining bipolar RF with HIFU treatment enhanced efficacy in reducing pore number, improving skin elasticity, diminishing eye wrinkle depth, and increasing skin moisturization. These findings indicate that bipolar RF can synergically improve skin rejuvenation by providing a thermal effect to the upper papillary dermis, which is more superficial than the target area of HIFU.

Conclusion: Combining HIFU with bipolar RF synergistically improves skin rejuvenation, including pore reduction, periorbital wrinkle improvement, skin elasticity, and skin moisturization.

KEYWORDS
bipolar radiofrequency, facial lifting, high intensity focused ultrasound, skin rejuvenation

INTRODUCTION

Various non-ablative modalities have been developed for skin rejuvenation, including High-intensity focused ultrasound (HIFU) and radiofrequency (RF) are non-invasive modalities for skin rejuvenation that selectively induce thermal injury in the dermis while sparing the overlying epidermis.[1,2] These techniques target dermal collagen for remodeling and have been used for lifting eyebrows, nasolabial folds,

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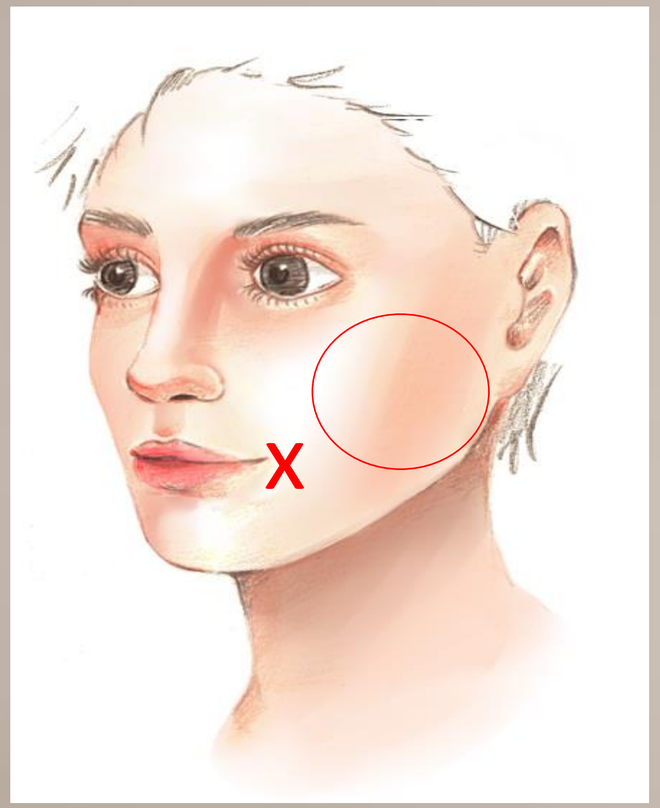
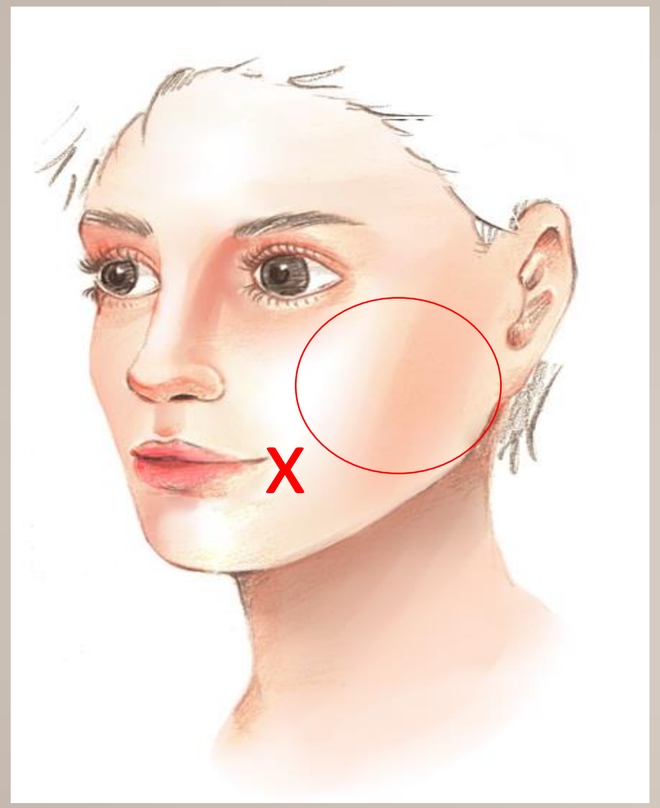
Treatment

new 2.0 doublo



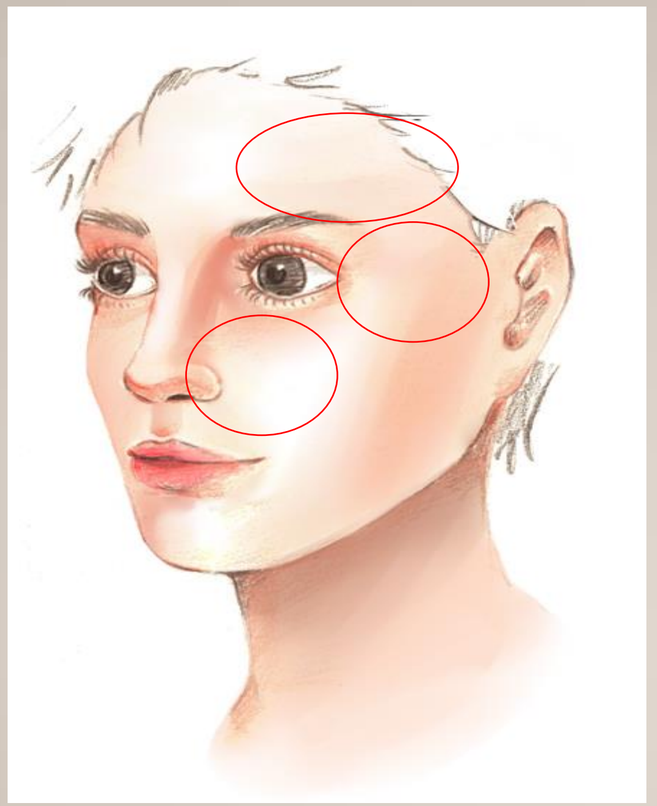
SD 4.5

Rt: MFU 1500 dot, 1.1j +RF 13.7W, 2Mhz
Lt: MFU only



SD 3.0

Rt: MFU 1500 dot, 0.35j+RF 13.7W, 2Mhz
Lt: MFU only



SD 1.5

Rt: MFU 1000 dot, 0.15j+RF 13.7W, 2Mhz
Lt: MFU only

MFU-only treatment on the left side and a combination of MFU and RF on the right side
Assessing factors such as pore size, skin elasticity, eye wrinkles, nasolabial folds, cheek lifting, and jawline lifting

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SD | SYNERGY DOTTING: Eye wrinkles

new 2.0 doublo

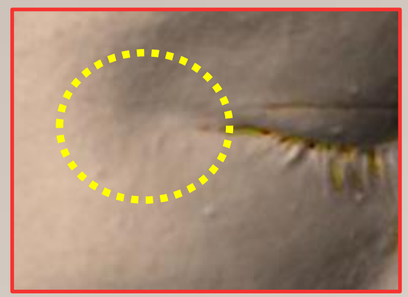
MFU & RF

WORLD'S FIRST SYNERGY
DOTTING SYSTEM

VS. **MFU ONLY**

BEFORE

AFTER



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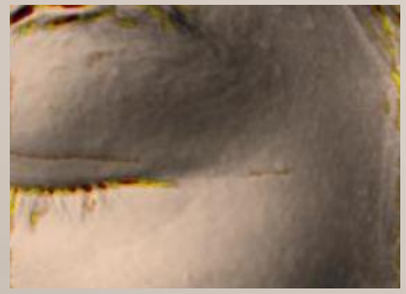

62%
MORE EFFECTIVE
EYE WRINKLES IMPROVEMENT

*8 WEEKS

Superiority of HIFU + RF Synergy compared to HIFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

62% greater improvement in eye wrinkles in the combined treatment group compared to the group that used MFU alone

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SD | SYNERGY DOTTING: Skin pores

new 2.0 doublo

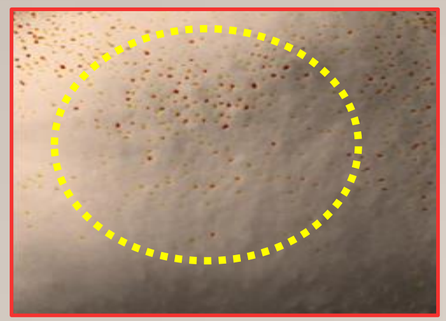
EVIDENT MFU & RF SYNERGY EFFECT

MFU & RF

WORLD'S FIRST SYNERGY DOTTING SYSTEM

BEFORE

AFTER



69%

MORE EFFECTIVE

PORE IMPROVEMENT

*8 WEEKS

VS. **MFU ONLY**

BEFORE

AFTER

Superiority of MFU + RF Synergy compared to MFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

69% greater improvement in the combined treatment group compared to the group that used MFU alone

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SD | SYNERGY DOTTING : Dermal density

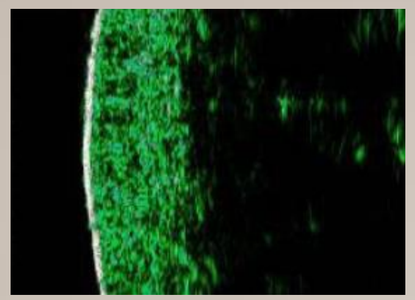
new 2.0 doublo

EVIDENT MFU & RF SYNERGY EFFECT

MFU & RF

WORLD'S FIRST SYNERGY
DOTTING SYSTEM

BEFORE



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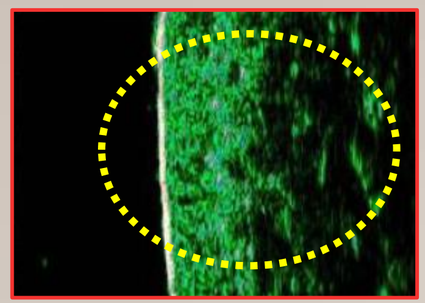
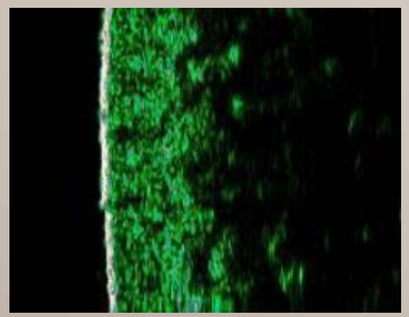


43%
MORE
EFFECTIVE
INNER SKIN
DENSITY
IMPROVEMENT

*8 WEEKS

VS. **MFU ONLY**

BEFORE



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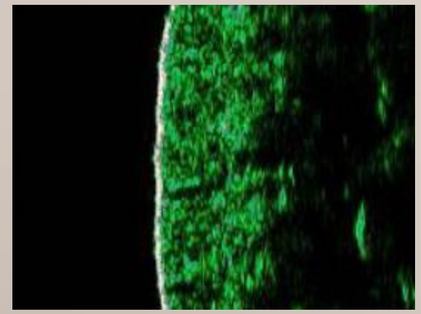

Superiority of MFU + RF Synergy compared to MFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

Dermal density - 43% improvement in the combined treatment group
-> More collagen has been generated in the dermal layer

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SD | SYNERGY DOTTING: Nasolabial lines

new 2.0 doublo

EVIDENT MFU & RF SYNERGY EFFECT

MFU & RF

BEFORE

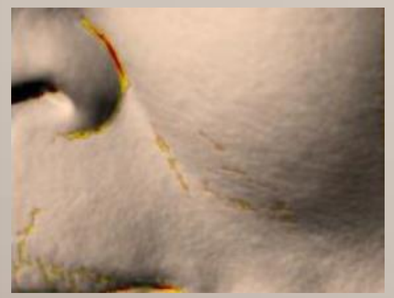
AFTER

27%
MORE
EFFECTIVE
SMILE
LINES
IMPROVEMENT

*8 WEEKS

VS. **MFU ONLY**

BEFORE



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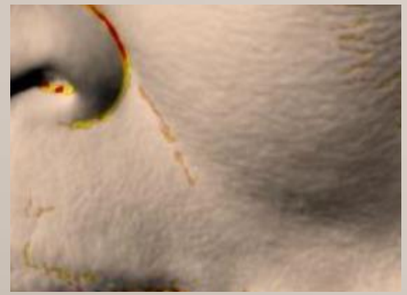

Superiority of MFU + RF Synergy compared to MFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

The treatment effect on nasolabial lines showed a relatively modest difference

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SD | SYNERGY DOTTING

new 2.0 doublo

MFU & RF

WORLD'S FIRST SYNERGY DOTTING SYSTEM

Average comparative advantage of Synergy Dotting (MFU&RF) of the New Doublo to MFU treatment in terms of effects

Superiority of HIFU + RF Synergy compared to HIFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

Category	Parameter	MFU	MFU & RF Synergy
Skin Tightening & Contouring	Eye Wrinkle Improvement	x 1	x 1.6
	Smile Lines Improvement	x 1	x 1.3
	Inner Skin Density	x 1	x 1.8
	Jawline Improvement	x 1	x 1.4
Elasticity	Elasticity of Outer Skin	x 1	x 1.4
	Elasticity of Inner Skin	x 1	x 1.3
	Elasticity Recovery	x 1	x 1.2
Skin Texture	Pores Density	x 1	x 1.8
	Pores Count	x 1	x 2.0
	Pores Depth	x 1	x 1.6
	Pores Volume	x 1	x 1.2
	Skin Irregularity	x 1	x 1.7
Skin Moisturizing	Outer Skin	x 1	x 1.7
	Inner Skin	x 1	x 4.8

As seen in the table, the combined treatment group demonstrated superior effects in most clinical parameters

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Case report using SD 3.0 to treat lower eyelid laxity.

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DOI: 10.1111/jocd.15668

LETTERS TO THE EDITOR

Efficacy of single dot ultrasound combined with radiofrequency for low eyelid laxity

To the editor

Aging of the lower eyelid is a major cosmetic concern and noninvasive correction of skin laxity have long been elusive goals of aesthetic surgery. Various non-ablative skin resurfacing techniques such as high-intensity focused ultrasound (HIFU) and radiofrequency (RF) have been designed to selectively induce thermal injury within the dermis while sparing the overlying epidermis.[1,2] They have been used successfully for lifting eyebrows, nasolabial folds, and jaw tightening. However, as the linear irradiated energy has a large area in contact with the skin, there has been a limit to the treatment around the eyes and curved areas.[3,4]

Recently, a newly developed lifting HIFU device that combines RF technology in one flat handpiece with a diameter of 2.5 cm was introduced. The ultrasound energy is irradiated in the single dot form rather than a line composed of dots and therefore it is expected to optimize to treat delicate areas such as the area around the eyes (Figure 1). In this case report, we report the clinical effectiveness of single dot HIFU combined with RF for the improvement of low eyelid laxity.

A 53-year-old female patient visited with a complaint of low eyelid laxity (Figure 2A). The HIFU combined bipolar RF device (V-RO, Hironic Corp.) applied on periorbital area and mid face with parameters of a 3.0 mm depth, 0.5 J power, 4.0 RF level, 5 Hz after obtaining written informed consent. Topical anesthetics was applied on the treatment area 30 min prior to the procedure. For the eye protection, eye shield was inserted. Total 300 shots per session were irradiated. Immediately after irradiation, the treated area was cooled with ice packs; no prophylactic antibiotics were prescribed. Photograph was taken and evaluated by non-treating dermatologist and the efficacy point was clinical improvement in the tightening of infraorbital laxity at 1 month after one session treatment compared to the initial photograph using grading scale (0, worse; 1 no change; 2, improved; 3, much improved). One month after the single treatment, there was an improvement (score = 2) in eyelid laxity (Figure 2B). No notable side effect was reported. Another 55-year-old female patient presenting with low eyelid laxity (Figure 2C) received two sessions of the treatment with 2 weeks of interval after obtaining informed consent. Total 300 shots per session with parameters of a 3.0 mm depth, 0.5 J power, 4.0 RF level, 5 Hz were irradiated. One month after the last session, much improvement (score = 3) in skin laxity was noted (Figure 2D).

In this report, we demonstrated improvements in infraorbital laxity which was achieved using single dot ultrasound combined with RF. The device produces the energy in the single dot form rather than a line composed of dots and therefore offers to treat delicate areas such as the area around the eyes. This provided advantages of minimizing side effects and enabling precise treatment for the low eyelid laxity. Another advantage of the device include the synergy dotting handpiece in which HIFU and RF are combined in one handpiece. Both HIFU and RF causes a contraction of the deep dermal layer and superficial muscular aponeurotic system (SMAS) and remodeling of the targeted collagen fibers, resulting in significant skin

FIGURE 1 Scheme of synergy effect in single dot high-intensity focused ultrasound (HIFU) and radiofrequency (RF).

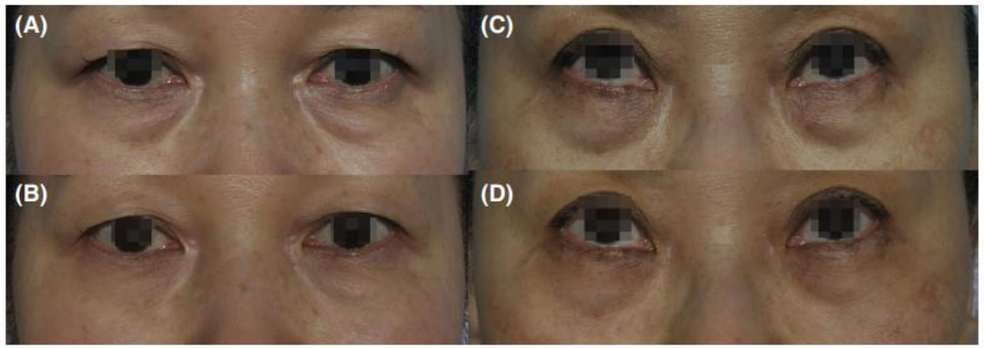

FIGURE 2 (A) Case 1: Before treatment, (B) 1 month after one session of treatment, there was an improvement in low eyelid laxity of 53-year-old female. (C) Case 2: Before treatment, (D) 1 month after two session of treatment, there was much improvement in eyelid laxity in 55-year-old female.

Improvement in the lower eyelid laxity of two cases

SD 1.5 and SD 3.0 are effective treatment options for addressing periorbital aging!

new 2.0 doublo

How to Design and Use The SD

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Variation of superficial fascia depth

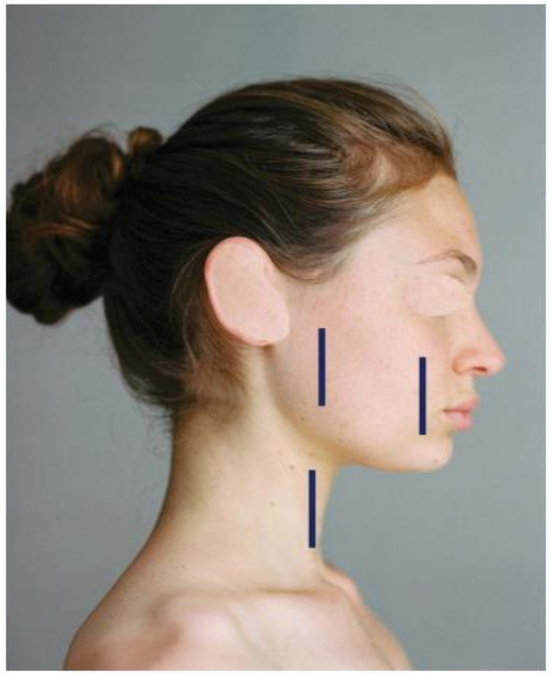


Figure 1. Photograph of a female volunteer. The locations where ultrasound imaging was performed are indicated by the longitudinal blue lines: Buccal region, Premasseteric region, Lateral neck.

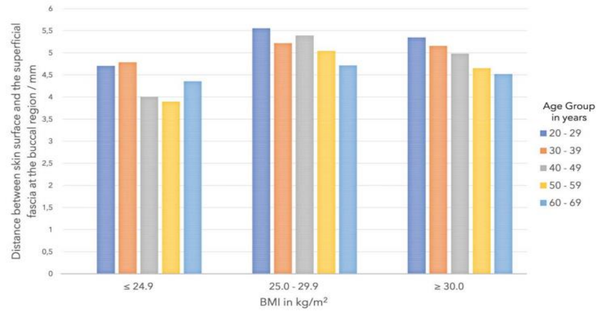


Figure 2. Bar graph showing the distance between skin surface and the superficial fascia at the buccal region in mm for individuals with a BMI ≤24.9 kg/m², between 25.0 and 29.9 kg/m², and higher than 30 kg/m². Measurements have been stratified within the BMI groups for the different age decades investigated. BMI, body mass index.

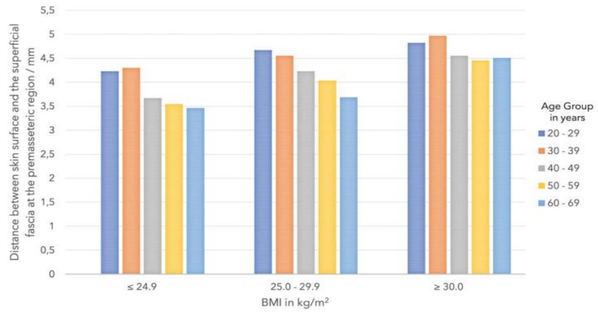
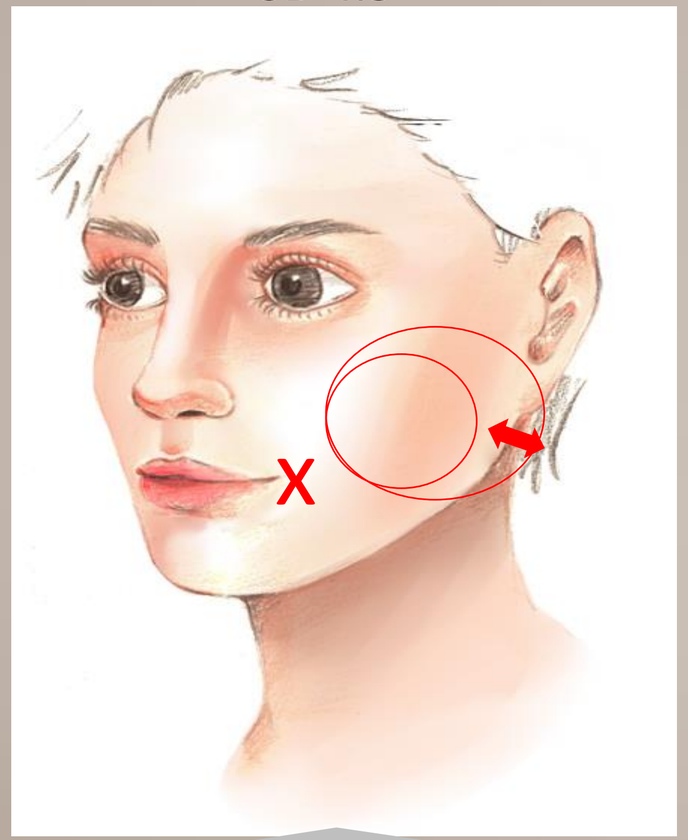
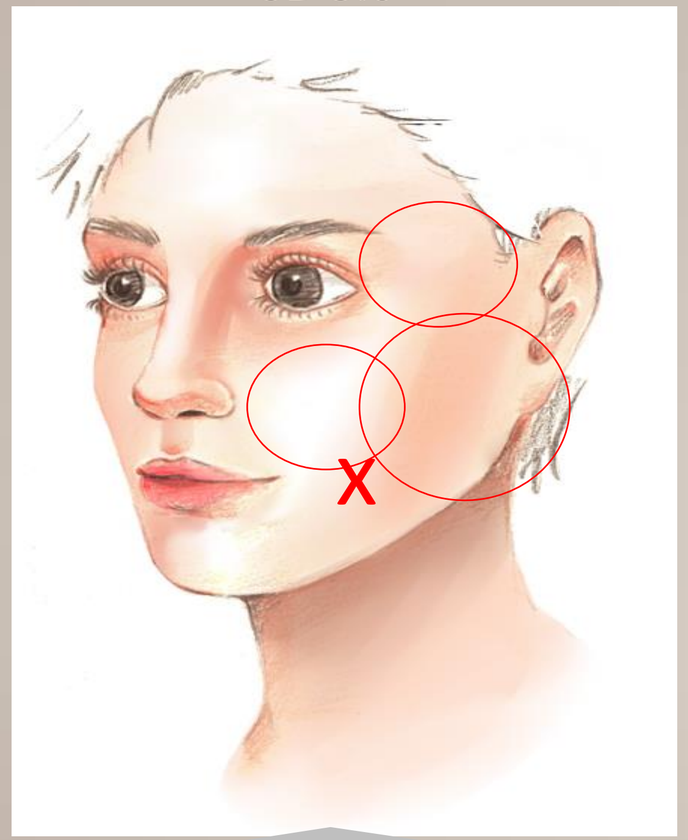
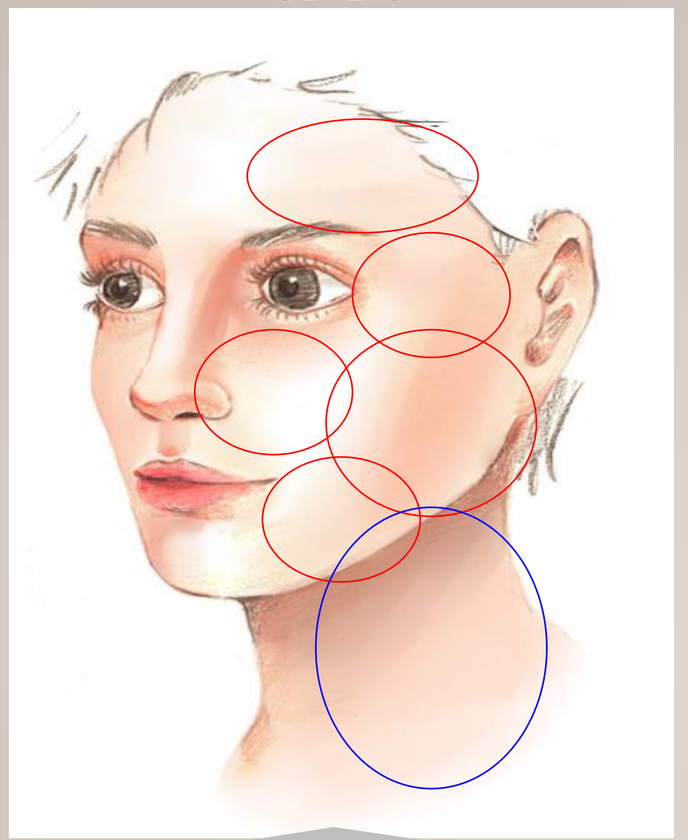


Figure 3. Bar graph showing the distance between skin surface and the superficial fascia at the premasseteric region in mm for individuals with a BMI ≤24.9 kg/m², between 25.0 and 29.9 kg/m², and higher than 30 kg/m². Measurements have been stratified within the BMI groups for the different age decades investigated. BMI, body mass index.

SMAS in the buccal region is positioned deeper compared to the premasseteric region.
The depth of the SMAS was found to increase with higher BMI and decrease with advanced age.

How to Design

new 2.0 doublo

SD 4.5	SD 3.0	SD 1.5
		
SMAS	SMAS/FIBROUS	DERMAL

Customize treatment area based on the patient's face
SD 3.0 can be used for treating pores on the midface, as well as addressing around eye wrinkles, in addition to the lower face
SD 1.5 is effective for dermal remodeling across the entire face, including the neck, forehead, and eye area.

My Best treatment program using SD

new 2.0 doublo

1. combining laser toning with SD 1.5
-help Improve pigmentation quickly and suppresses recurrence

Laser Toning + SD 1.5 treatment 1500 dots with RF, every 2 weeks interval

After improvement in pigmentation

SD 1.5 only treatment 1500 dots with RF , every 4 weeks interval

2. SD 3.0 and 4.5 treatments before standard MFU lifting for additional effects

SD 3.0, 4.5 1500 dot with RF + 400~ 800 line of MFU

Combining SD treatment with conventional MFU yields enhanced immediate patient satisfaction and improved clinical outcomes.

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new 2.0 doublo

Clinical Cases

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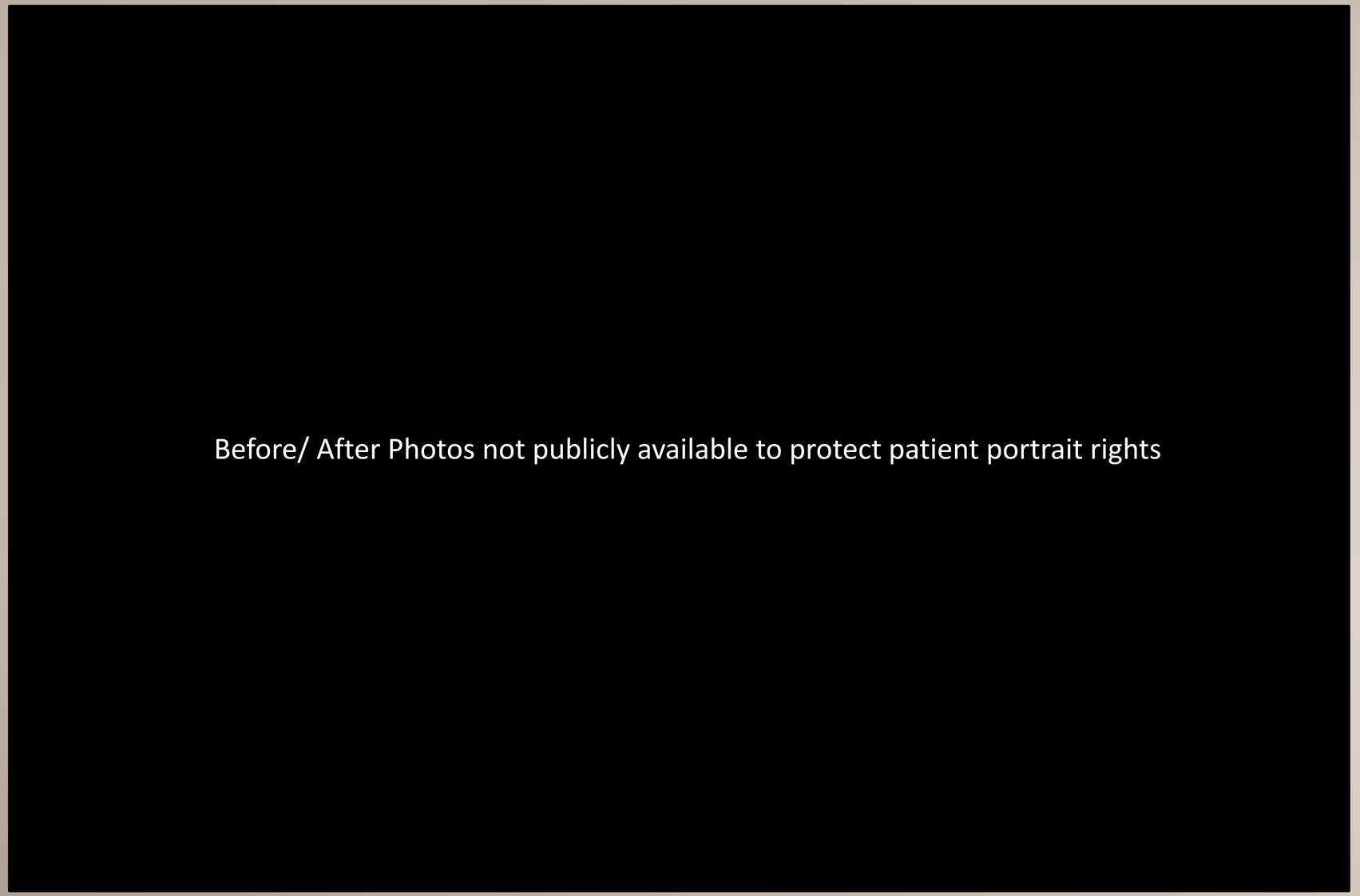
Persistent melasma recurrence even after laser toning



10 sessions of SD 1.5 1500 dots with laser toning at two-week intervals
-> SD 1.5 1500 dots once a month

Maintaining the results without any recurrence

Dermal change of Melasma

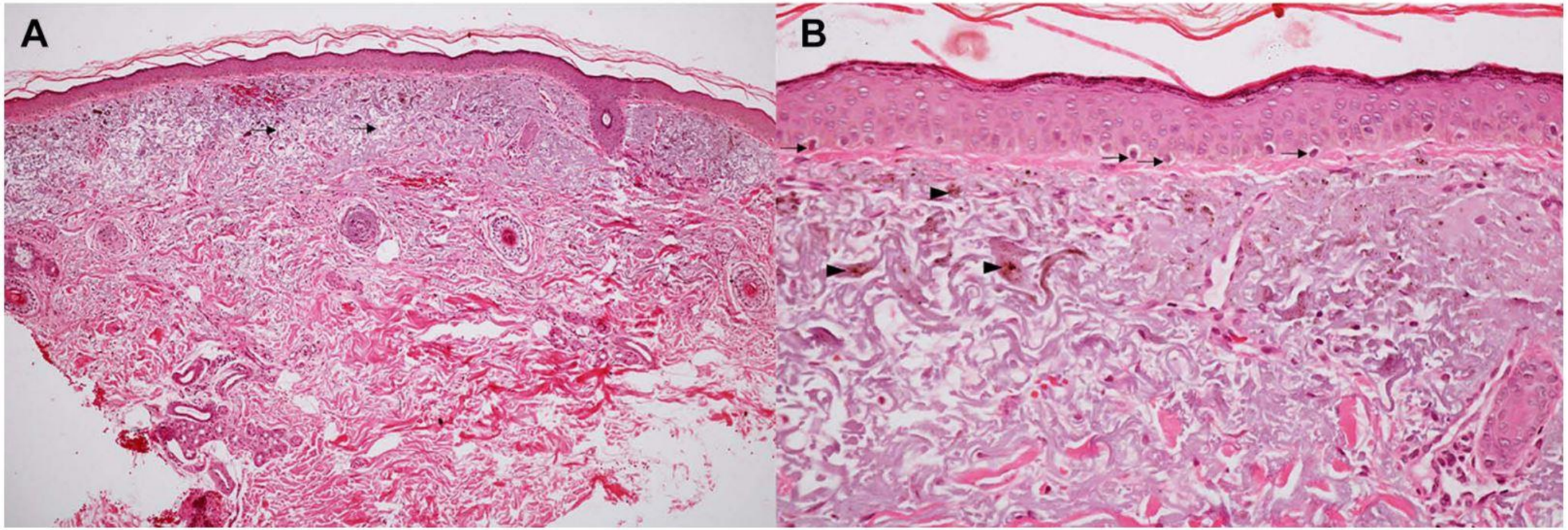


Figure 2 Histopathologic change in the dermis of lesional melasma. (**A**) Melanin deposition in the epidermis and solar elastosis in the dermis (arrow) (Hematoxylin and Eosin, HEx100) (**B**) pendulous melanocytes in the basal layer of epidermis (arrow) and increased dermal melanophages (arrowhead) (HE x400).

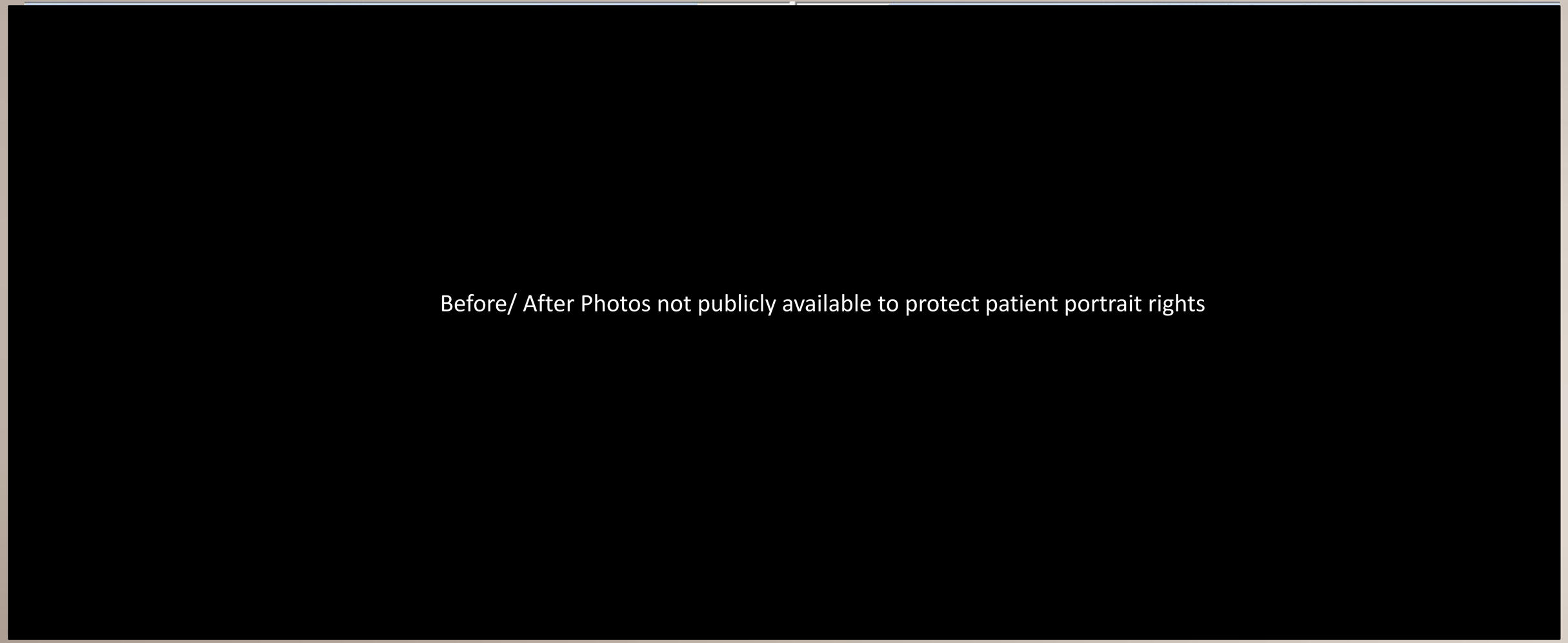
Torres-Álvarez B, Mesa-Garza IG, Castanedo-Cázares JP, et al. Histochemical and immunohistochemical study in melasma: evidence of damage in the basal membrane. Am J Dermatopathol. 2011;33 (3):291–295. doi:10.1097/DAD.0b013e3181ef2d45

persistent inflammation, discoloration, and wrinkles

10 sessions of laser toning and SD 1.5 treatment at two weeks interval

general improvement in pigmentation, reduction in wrinkles, and refined pores, leading to a brighter complexion

persistent inflammation, discoloration, and skin pores



10 sessions of laser toning and SD 1.5 treatment at two weeks interval

general improvement in pigmentation, reduction in wrinkles, and refined pores, leading to a brighter complexion

Chin and Neck line

Before/ After Photos not publicly available to protect patient portrait rights

1cc chin filler + 3 sessions of SD 4.5 and 3.0 treatments with conventional MFU 400 lines one month interval

Observable improvement in the jaw and neck lines was noted.

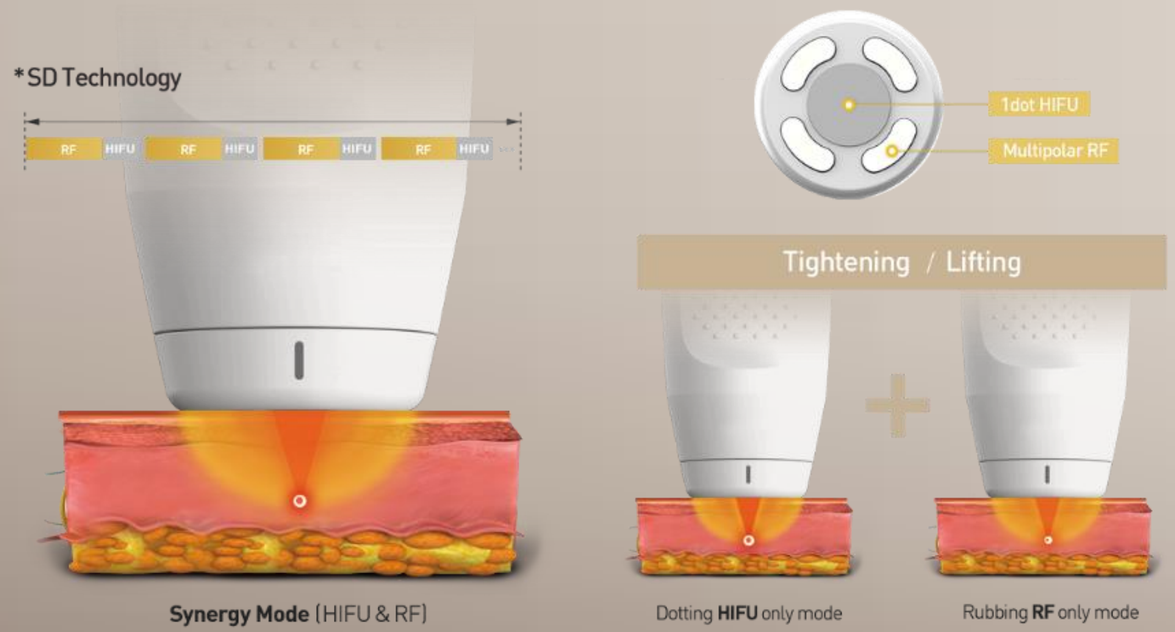
Summary

new 2.0 doublo

-New Doublo 2.0 ：MFU+RF multiplatform

-Synergy dotting system

-The first technology globally to apply RF and MFU at the same time on the skin
- Safe and easy way to achieve outstanding skin rejuvenation effects



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doublo™

new 2.0

Double Effect,
Double Safety

Thank you for your attention

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