New era of multilayer EBD with HIFU and RF from Epidermis to SMAS ; Evolution of New Doublo 2.0

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new 2.0 doublo

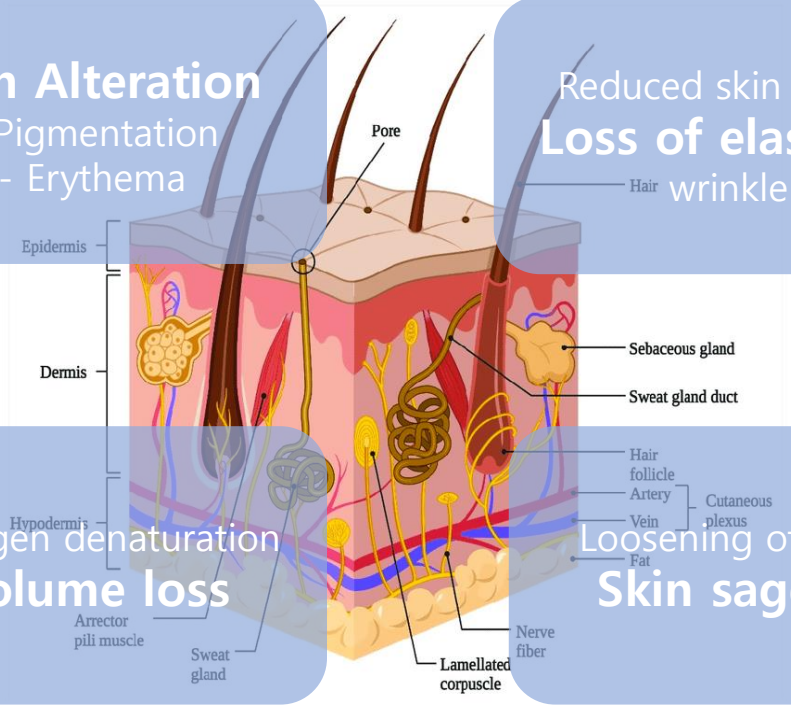
Aging process vs Dermatological approach

Laser

Skin booster
Toxin
Filler

Skin Alteration
- Pigmentation
- Erythema

Reduced skin turgor
Loss of elasticity
Hair wrinkle



Collagen denaturation
Volume loss

Loosening of tissue
Skin sagging

RF

HIFU

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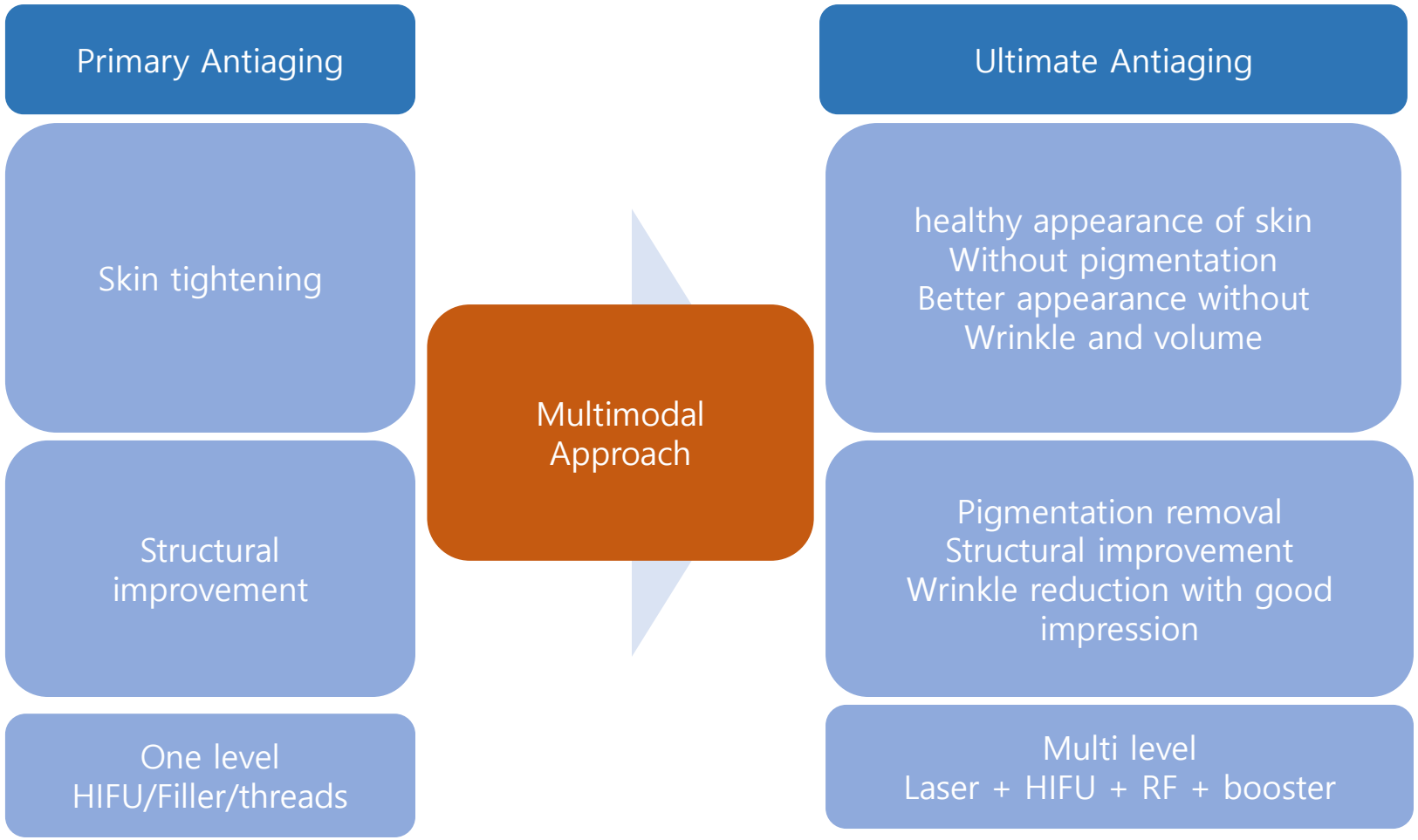
Evolution of needs in patients in antiaging



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Multiflatform device in market

IPL | Er-YAG | 1470 nm | 1064 nm

IPL | 1550 nm | 1064 nm

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Emerging EBDs in Dermatology

Energy Based Device
: Delivering mechanical energy (RF, HIFU, microwave, shock wave, etc.)

Characteristics of Laser	Characteristics of EBD
Target chromophore(+) ; Skin type limit	Target chromophore(-) ; Skin type free
Difficult to measure delivered energy Smaller energy than EBD Purpose ; elimination / coagulation	Easy to measure delivered energy Larger energy than laser purpose; stimulation
expensive	cheap

Mainstream of EBDs in Dermatology ; RF and HIFU

new 2.0 doublo

Skin elasticity improvent by RF + Structural improvement by HIFU
; Gold standard of Non -invasive antiaging

RF

- ECM restoration (PG, GAG, fibronectin)
- Lymphatic drainage
- neocollagen synthesis

Improvement of
skin turgor
skin color
Hydration
Elasticity

Needle RF module

Ablative fractional laser + conventional RF

HIFU

- SMAS tightening
- Collagen remodeling

Improvement of
Sagging
Elasticity

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EBDs, not only for collagen

Radiofrequency irradiation reduces UV induced skin pigmentation by melanosomal autophagy and decreasing melanin synthesis

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

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더 퍼스트 피부과
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EBDs, not only for collagen

HIFU reduces UVB-induced hyperpigmentation by mechanical destructive effect

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Skin Research and Technology

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

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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

Accepted for publication 17 May 2015

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new 2.0 doublo

EBDs, not only for collagen

Evidence of damage in the basal membrane in melasma ; recovery of basal membrane by needle RF

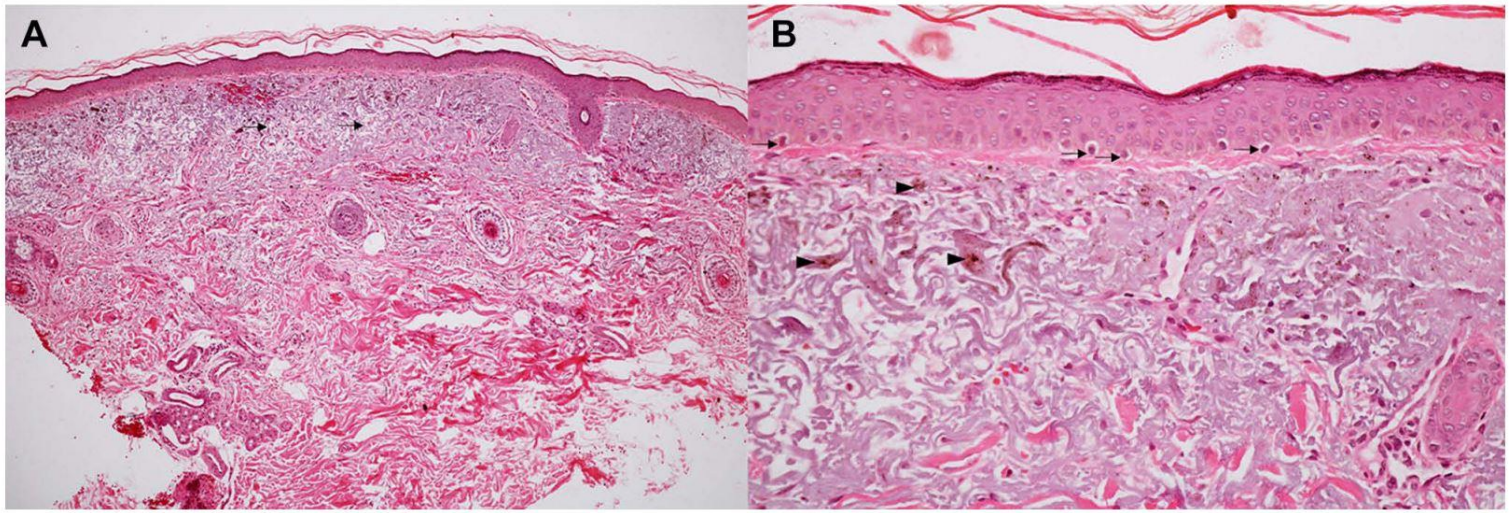

Figure 2 Histopathologic change in the dermis of lesional melasma. (**A**) Melanin deposition in the epidermis and solar elastosis in the dermis (arrow) (Hematoxylin and Eosin, HEx100) (**B**) pendulous melanocytes in the basal layer of epidermis (arrow) and increased dermal melanophages (arrowhead)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

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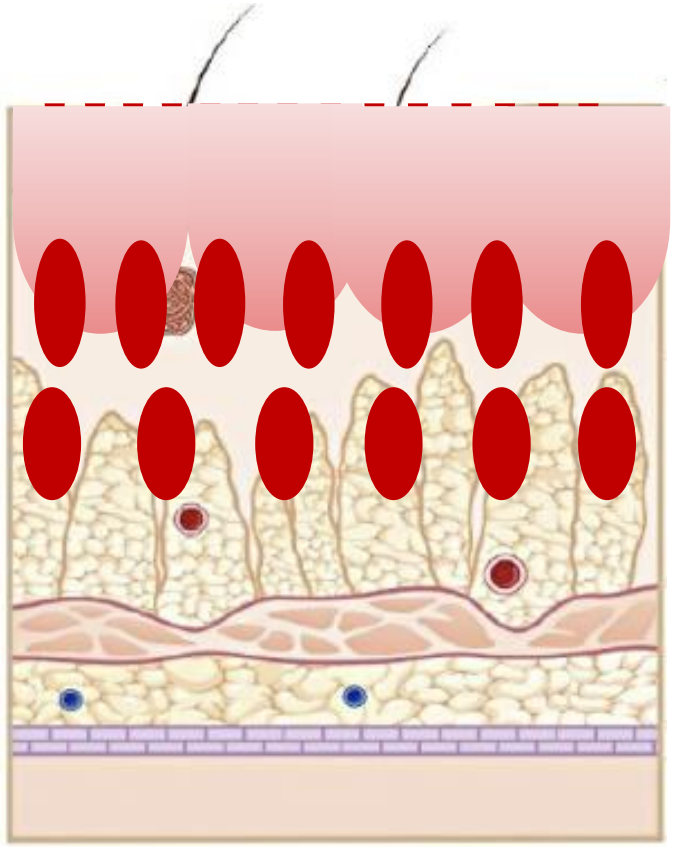
new 2.0 doublo

Multilayer EBD, New Doublo 2.0



RF Microneedle System

Synergy Dotting System
(RF + Dot HIFU)

Focused Linear System
(HIFU)

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Multilayer EBD, New Doublo 2.0 ; 3 major upgrade point

new 2.0 doublo

RF Microneedle System

Pulse step mode

Synergy Dotting System
(RF + Dot HIFU)

RF power upgrade
HIFU speed upgrade

Focused Linear System
(HIFU)

Dot quality upgrade
Linear mode

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Multilayer EBD, New Doublo 2.0 ; Layer 1 : microneedle RF

- Indication
- Pigmentation (Melasma, PIH, etc) by skin barrier recovery
- Erythema (Rosacea)
- Acne vulgaris
- Scar, wrinkle
- Pore reduction

new 2.0 doublo

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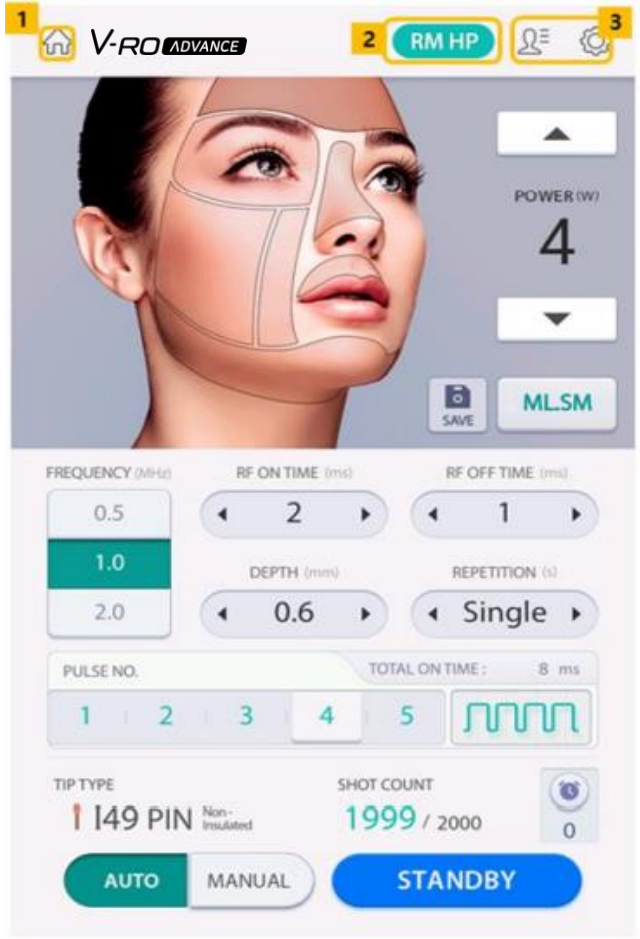
Multilayer EBD, New Doublo 2.0 ; Layer 1 : microneedle RF

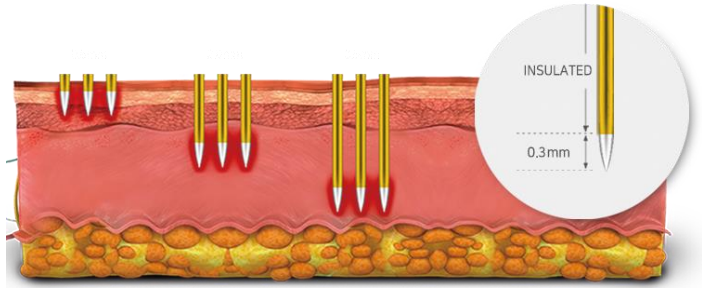


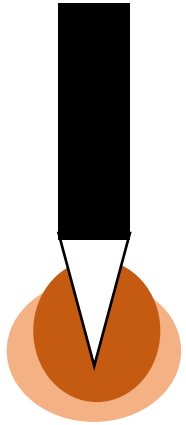
POWER(W)	1~20W(1W)
FREQUENCY(MHz)	0.5 / 1.0 / 2.0㎒
RF ON TIME(ms)	RF on time - 1~30ms(1ms) - 30~100ms(5ms) - 100~950ms(10ms) (400ms, warning sign)
RF OFF TIME(ms)	RF off time - 1~30ms(1ms) - 30~100ms(5ms) - 100~1000ms(10ms)
DEPTH(mm)	- 0.1~3.5mm(0.1mm)
REPETITION	- Single / 0.2~0.8s / 1.0s / 2.0s
PULSE NO	Number of pulses - PULSE NO.: 1~5

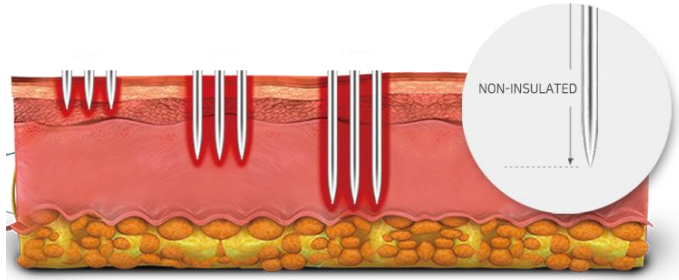
Multilayer EBD, New Doublo 2.0
; Layer 1 : microneedle RF

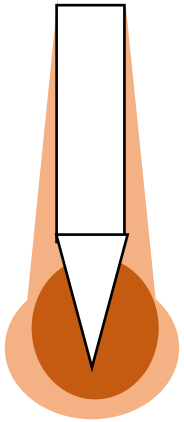
Options
- Insulated/Non-Insulated
- 25 pin/ 49 pin

Strong point
- 0.25Φ thinnest needle, less pain
- 0.1mm~3.5mm depth









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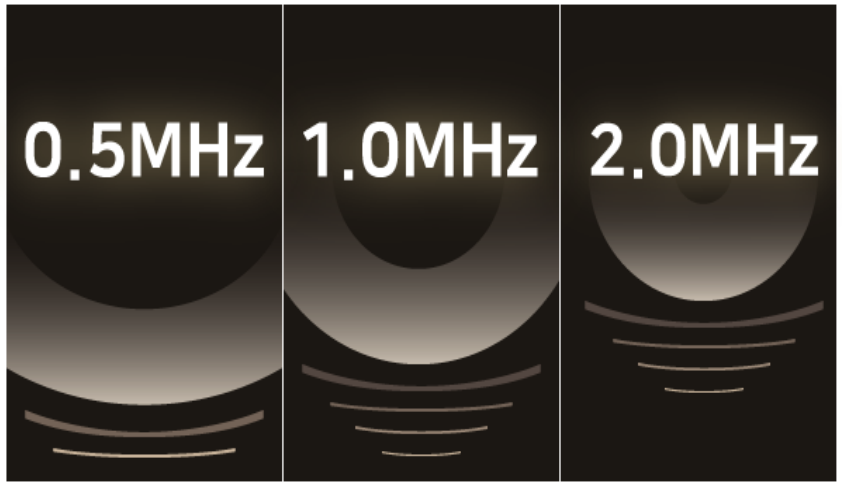
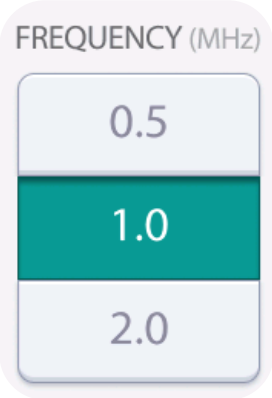
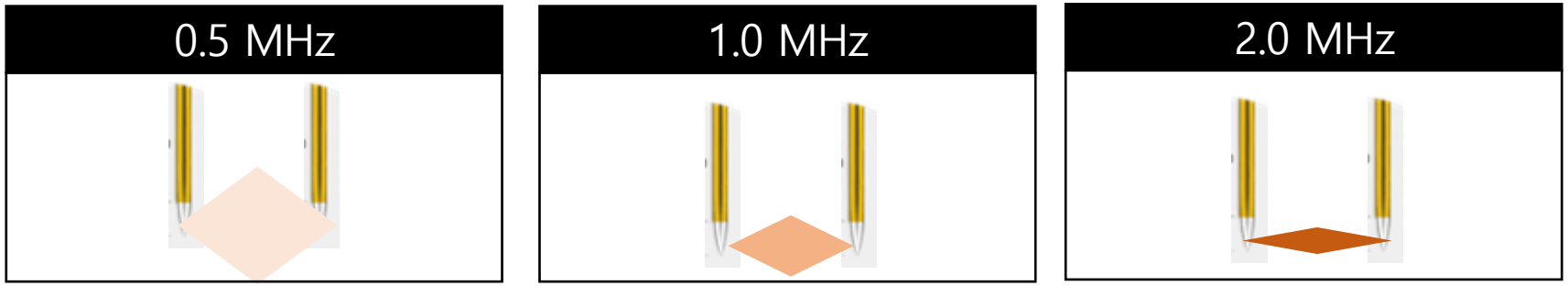
Multilayer EBD, New Doublo 2.0 ; Layer 1 : microneedle RF

Control RF irradiation area and density
By frequency setting

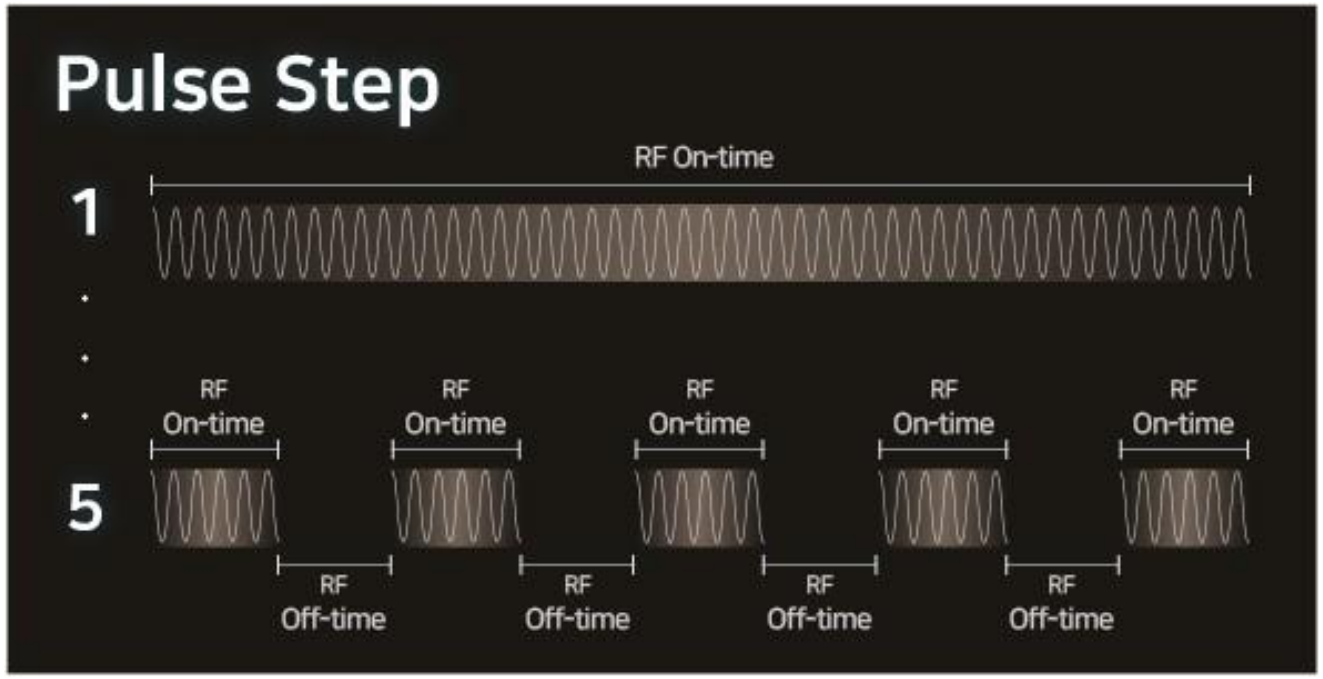


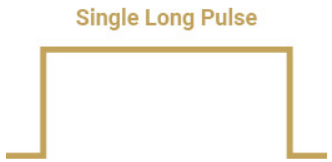




Multilayer EBD, New Doublo 2.0
; Layer 1 : microneedle RF

Reduce tissue damage and elongation of irradiation time by RF energy on-off pulsed mode



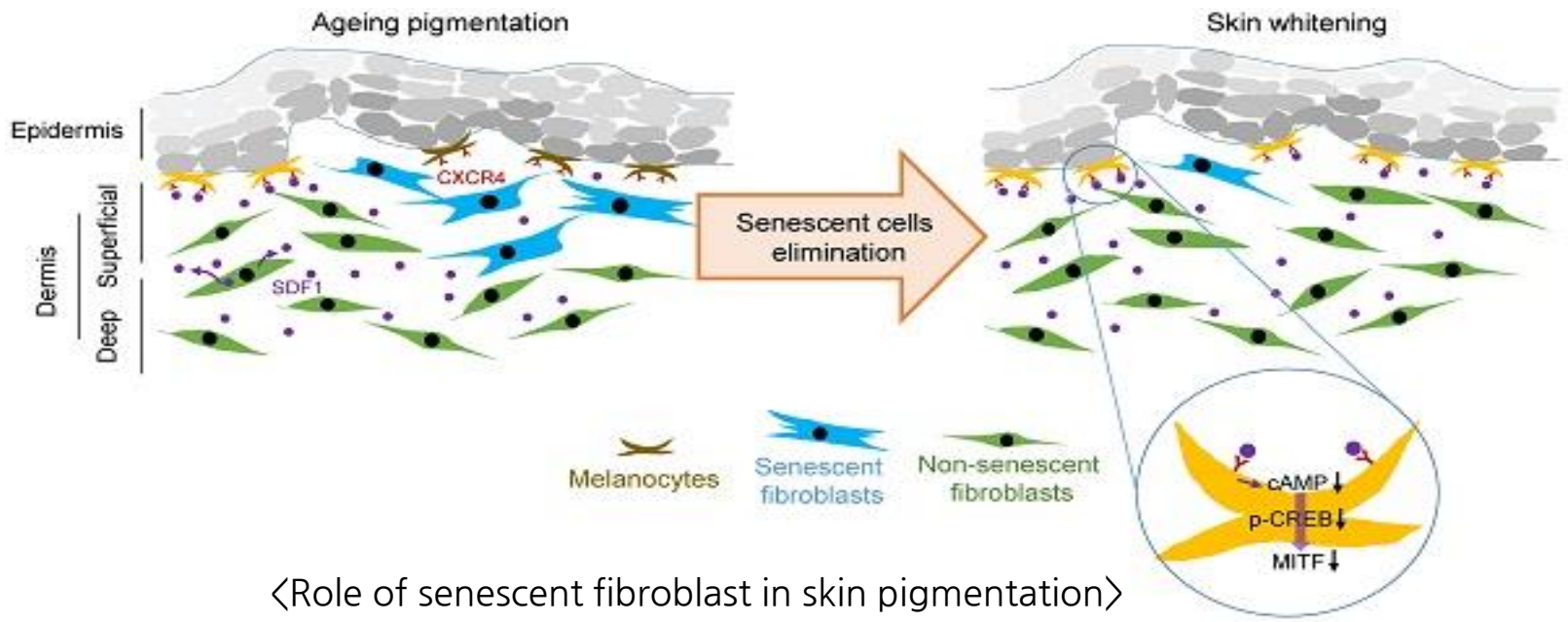


Delivering enegy
Cell alteration

Ix : Scar
Acne vulgaris

Delivering energy
With minimal
tissue damage
Cell stimulation
Ix: Melasma
Rejuvenation

Multilayer EBD, New Doublo 2.0 ; Layer 1 : microneedle RF



〈Role of senescent fibroblast in skin pigmentation〉

GDF15 (major phenotype of pigmentation)

SDF-1 (stromal cell derived Factor-1)

= CXCL12-CXCL4 (C-X-C motif chemokine Ligand)

:

Senescent Fibroblast

: 20X more GDF15 than Normal Fibroblast

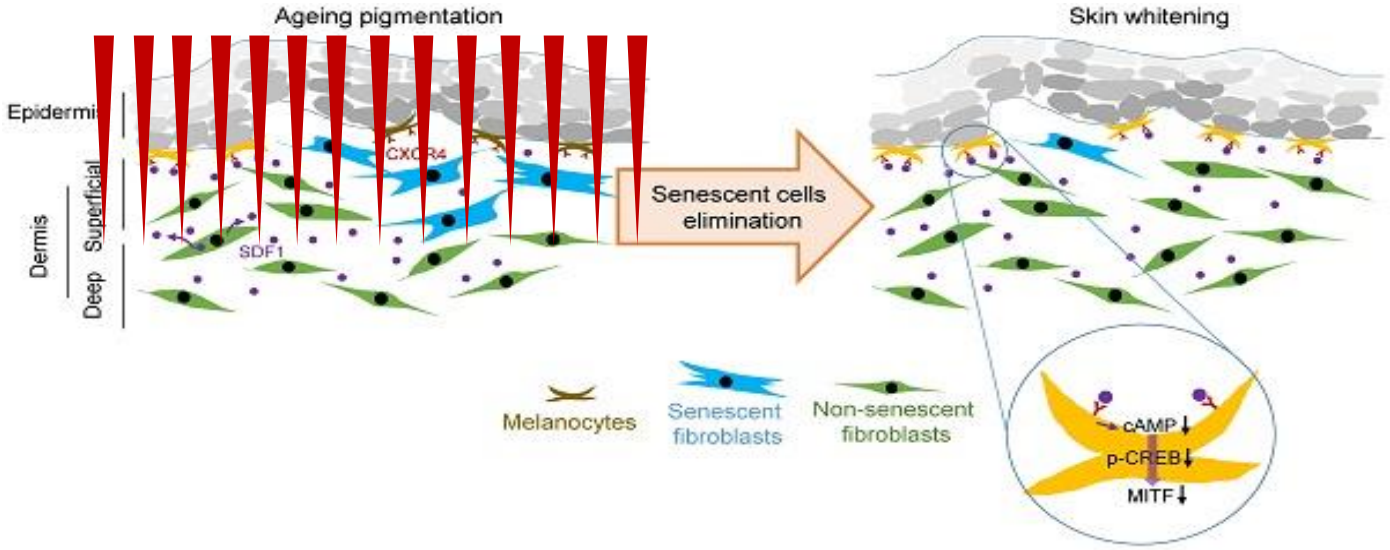
Senescent Fibroblast ↑ ▶ SDF-1 ↓ ▶ GDF15 ↑ ▶ Pigmentation ↑

* Ref.

1) Soon-Hyo Kwon, Jung-Im Na, Chang-Hun Huh, Kyoung-Cahn Park (2021). A Clinical and Biochemical Evaluation of a Temperature-Controlled Continuous Non-Invasive Radiofrequency Device for the Treatment of Melasma., Annals of Dermatology, 2021;33(6):522-530

2) Yeongeun Kim, Bogyeong Kang, Jin Cheol Kim, Tae Jun Park, Hee Young Kang (2020). Senescent Fibroblast-Derived GDF15 Induces skin Pigmentation, Journal of Investigative Dermatology, (2020)140, 2478-2486

Multilayer EBD, New Doublo 2.0 ; Layer 1 : microneedle RF



RF microneedle Tx

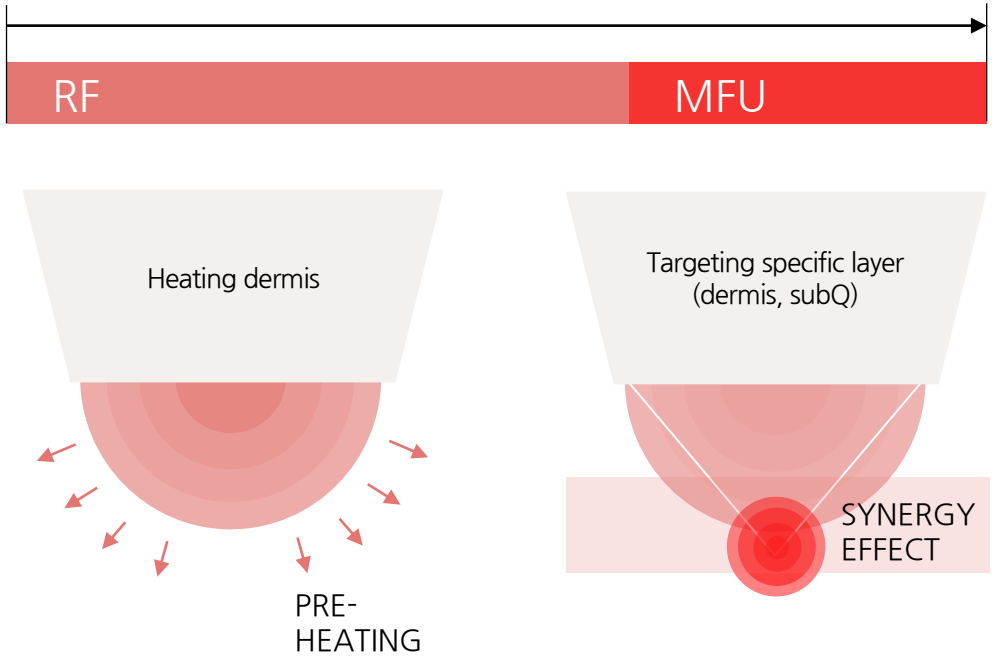
Senescent fibroblast ↓

SDF-1 ↑ GDF15 ↓

Young fibroblast ↑

pigmentation ↓

Multilayer EBD, New Doublo 2.0
; Layer 2 : bipolar RF + Dot HIFU



Bipolar RF: upper dermis Bulk-heating

+

HIFU : targeting dermis and subQ

Stronger, longer effect

By multilayer targeting

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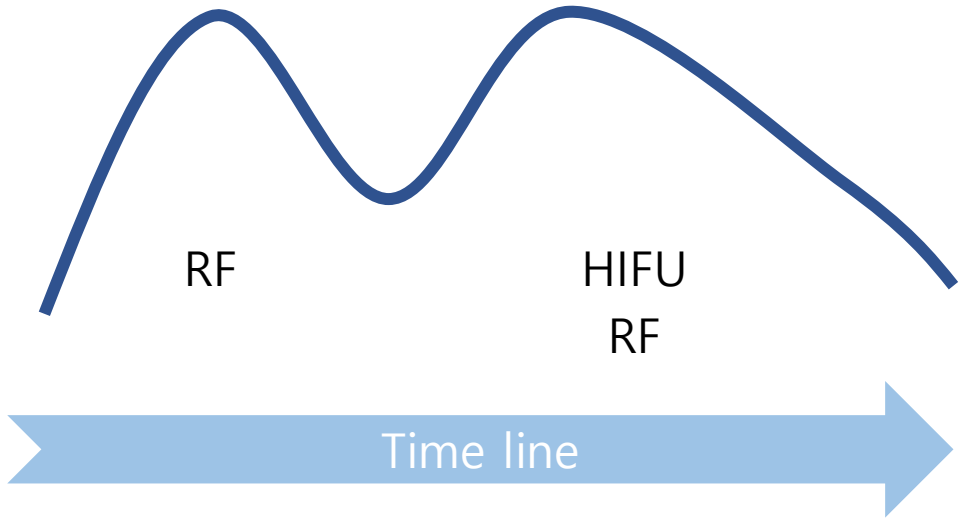
Multilayer EBD, New Doublo 2.0
; Layer 2 : bipolar RF + Dot HIFU



Immediate effect of RF

- Increased GAG (HA)
- Improve tissue turgor

Late effect of RF and HIFU

-Increased elasticity by collagen remodeling

Patient's satisfaction

By multimodal approach

Multilayer EBD, New Doublo 2.0
; Layer 2 : bipolar RF + Dot HIFU

- RF power upgrade
  - Level 10 14W ->25W
  - Bulk heating effect

- Dot HIFU speed upgrade
  - 7Hz -> 10Hz

- Stability upgrade
  - Prevention of overheating of cooling water by long cartridge

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Multilayer EBD, New Doublo 2.0
; Layer 2 : bipolar RF + Dot HIFU

Doublo 2.0

Power Level	P1.5[W]	P3[W]	P4.5[W]
1	1.562	1.599	1.415
2	2.885	2.526	2.675
3	4.428	4.471	4.220
4	6.279	4.964	5.769
5	7.957	6.114	7.253
6	9.305	7.873	8.253
7	10.896	8.780	10.437
8	11.459	9.925	12.769
9	12.938	10.661	13.374
10	13.470	11.908	14.250

New Doublo 2.0

Power Level	Face type MAX [w]
1	2.62
2	5.11
3	7.48
4	10.06
5	13
6	15.38
7	17.96
8	20.56
9	23.03
10	25.54

88%
RF power upgrade

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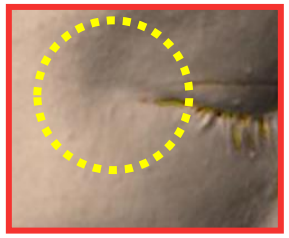
Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

Combination Tx with RF and HIFU improved lower eyelid laxity 62% more than HIFU only Tx.

MFU & RF

BEFORE

AFTER



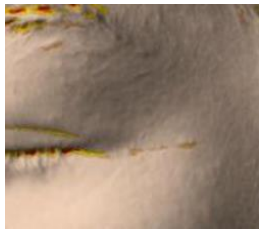
62%

EYE WRINKLES IMPROVEMENT

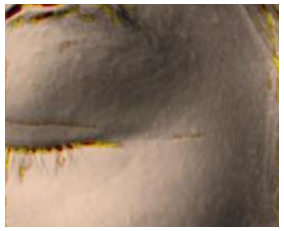
*8 WEEKS

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.

Received: 29 December 2022 | Revised: 18 January 2023 | Accepted: 26 January 2023
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).

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

Combining MFU with bipolar RF synergistically improves skin rejuvenation including **pore reduction**, **periorbital wrinkle improvement**, **skin elasticity**, and **skin moisturization.**

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DOI: 10.1111/srt.13452

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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Email: hwk0417@gmail.com

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

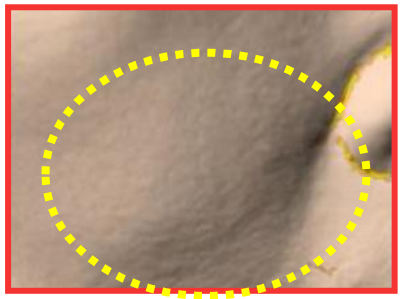
Various non-ablative modalities have been developed for skin rejuvenation, including High-intensity focused ultrasound (HIFU) and radiofrequency (RF) are non-invasive modalities for skin rejuvenation that selectively induce thermal injury in the dermis while sparing the overlying epidermis.[1,2] These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

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

MFU & RF

BEFORE

AFTER



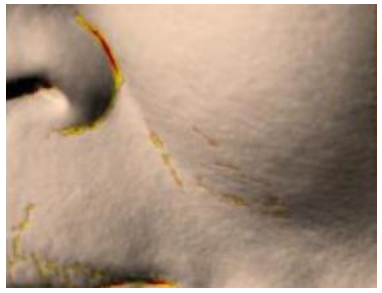
27%

SMILE LINES IMPROVEMENT

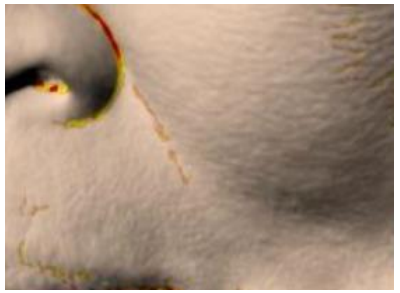
*8 WEEKS

VS. MFU ONLY

BEFORE



AFTER



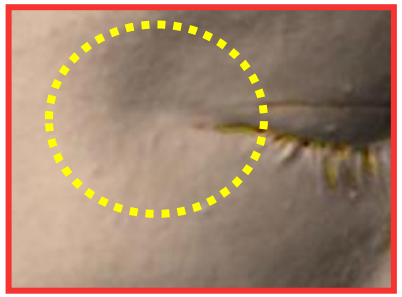
Superiority of MFU + RF Synergy compared to MFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

MFU & RF

BEFORE

AFTER



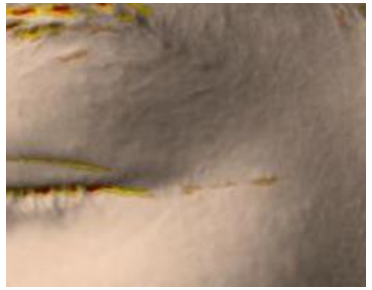
62%

EYE WRINKLES IMPROVEMENT

*8 WEEKS

VS. MFU ONLY

BEFORE



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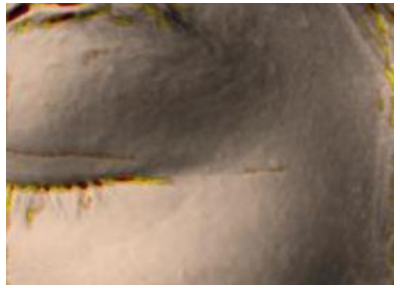


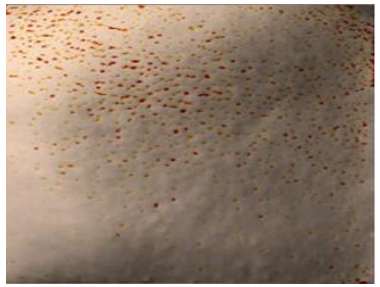
Superiority of MFU + RF Synergy compared to MFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

EVIDENT MFU & RF SYNERGY EFFECT

MFU & RF

BEFORE



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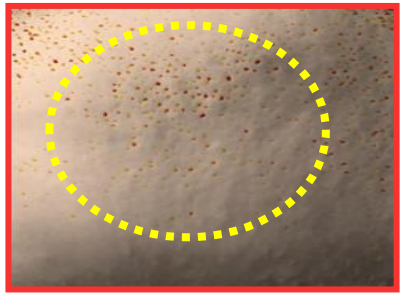
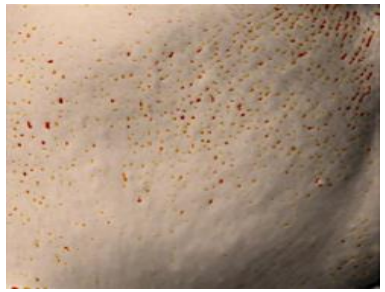


VS. MFU ONLY

BEFORE



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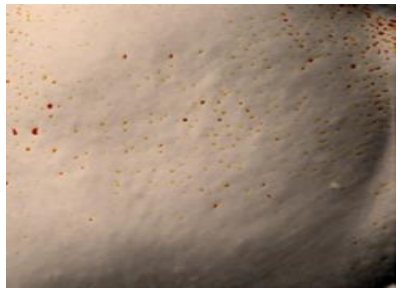

69%

PORE IMPROVEMENT

*8 WEEKS

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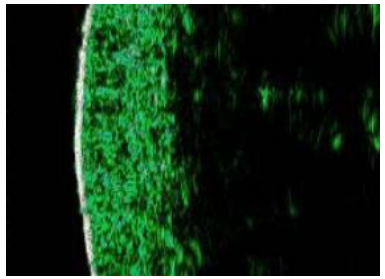
Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

MFU & RF

BEFORE



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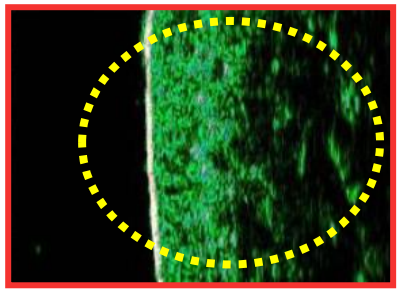
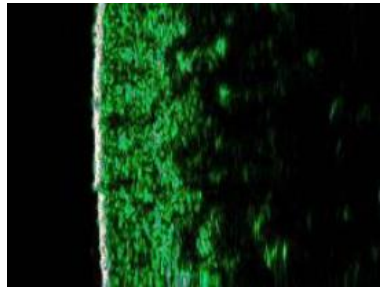


43%

VS. MFU ONLY

BEFORE



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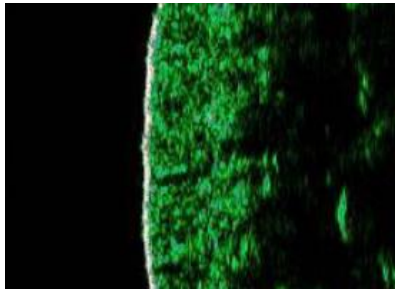


INNER SKIN DENSITY IMPROVEMENT

*8 WEEKS

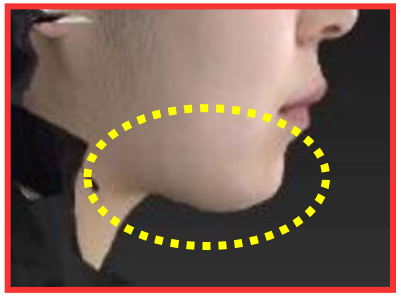
Superiority of MFU + RF Synergy compared to MFU. Human body application test results from Human Skin Clinical Trial Center. August 2022.

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

MFU & RF

BEFORE

AFTER



31%

JAWLINE LIFTING EFFECT

*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.

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

+83%
MARIONETTE LINES IMPROVEMENT

+25%
DENSITY OF INNER SKIN

+22%
SKIN ELASTICITY IMPROVEMENT

+35%
MOISTURIZING OF OUTER SKIN

+29%
JAWLINE IMPROVEMENT

+10%
EYE WRINKLES IMPROVEMENT

+24%
SKIN PORES IMPROVEMENT

+6%
SKIN TEXTURE IMPROVEMENT

Multilayer EBD, New Doublo 2.0 ; Layer 2 : bipolar RF + Dot HIFU

MFU & RF

SYNERGY DOTTING TECHONOLOGY

Superiority of MFU + RF Synergy compared to MFU. 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

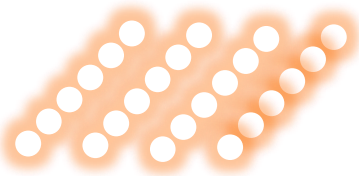
Multilayer EBD, New Doublo 2.0 ; Layer 3 : HIFU

- Stronger, clear DOT
- Linear mode : fast treatment

BEFORE

AFTER

Focal Zone (R12.5)



Multilayer EBD, New Doublo 2.0 ; Layer 3 : HIFU


Doublo


Doublo-S


Doublo-S gold


Doublo-gold


Doublo 2.0


New Doublo 2.0


Ulthera


Shrink 2.0


Shrink universe

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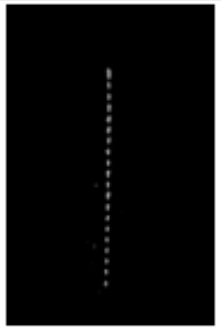
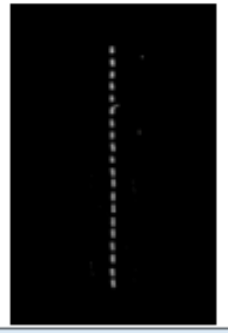
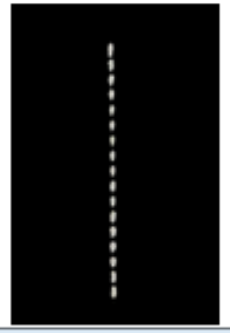
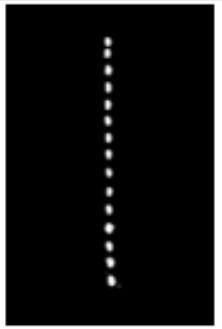
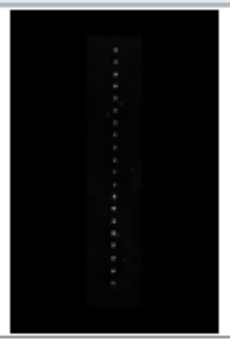
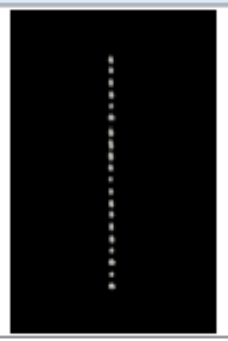
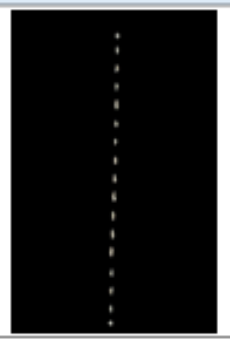
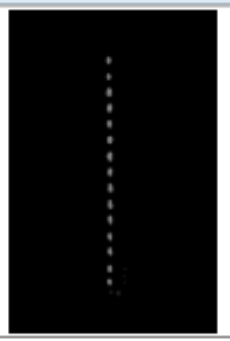
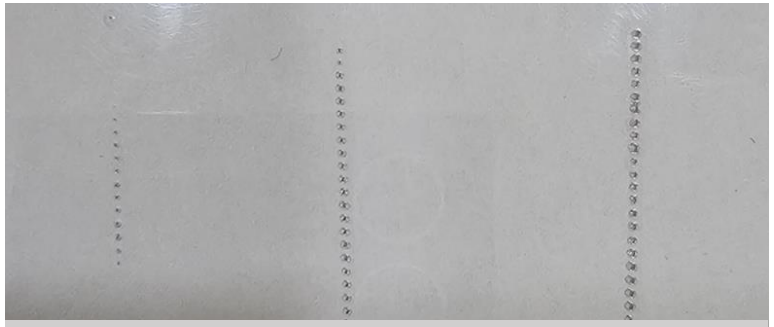
THE FIRST DERMATOLOGIC CLINIC

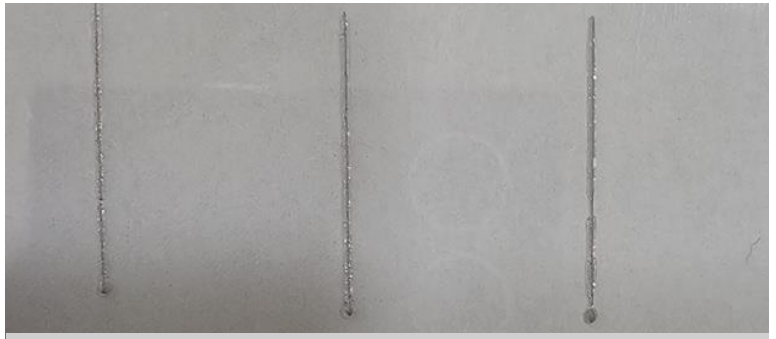
Multilayer EBD, New Doublo 2.0
; Layer 3 : HIFU

Cartridges Type	Dot Quality			
Advanced Type	A1.5 (0.20J)	A2 (0.20J)	A3 (0.40J)	A4.5 (1.20J)
				
Slim & Normal Type	S1.5 (0.20J)	S2 (0.20J)	N3 (0.40J)	N4.5 (1.20J)
				

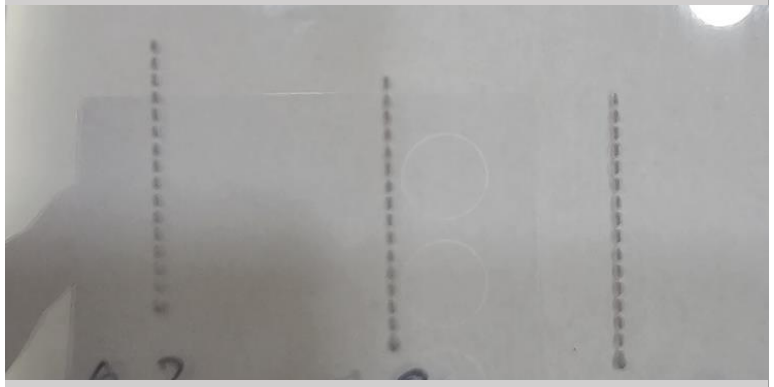
Multilayer EBD, New Doublo 2.0 ; Layer 3 : HIFU



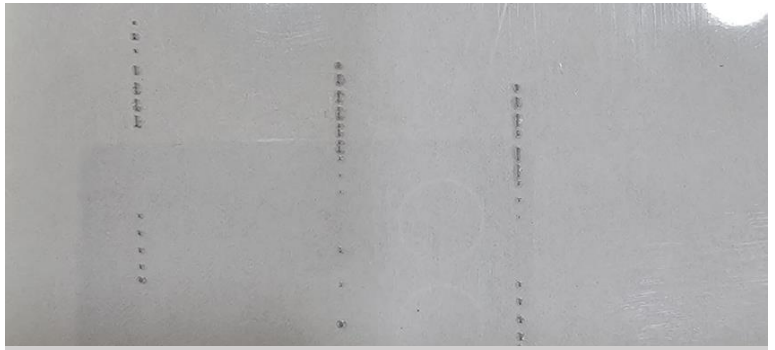
0.30J 0.35J 0.45J
Ulthera 3.0mm



0.30J 0.35J 0.45J
A 3.0mm - linear



0.30J 0.35J 0.45J
A 3.0mm - dot



0.30J 0.35J 0.45J
N 3.0mm

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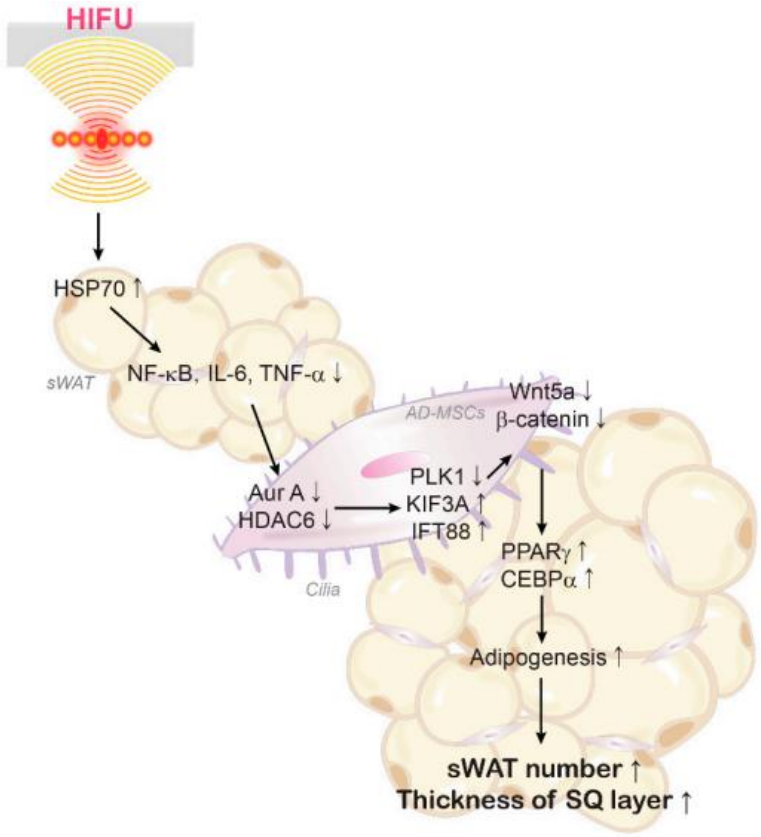
THE FIRST DERMATOLOGIC CLINIC

Multilayer EBD, New Doublo 2.0 ; Layer 3 : HIFU



<MFU 조사 시 지방 생성 과정>

Low energy HIFU

- HSP70 stimulation in adipocyte
- sWAT(subQ adipose tissue) Adipogenesis ⬆

HIFU ▷ NF-kB, IL-6, TNF-α (in sWAT) expression ⬇

⇒ HSP70 ⬆

⇒ **Adipogenic signal (PPARɣ 및 CEBPα)expression**

No. of sWAT ⬆

SubQ thickness ⬆

⇒ **Adipogenesis**

더 퍼스트 피부과 THE FIRST DERMATOLOGIC CLINIC

* Ref. Kyung-A Byun, Hyun Jun Park, Seyeon Oh, Sosorburam Batsukh. (2023). High-Intensity Focused Ultrasound Decreases Subcutaneous Fat Tissue Thickness by Increasing Apoptosis and Autophagy. Biomolecules, 2023,13,392.

new 2.0 doublo

Summary

RM (microneedle) : Pigmentation(melasma, senile skin)
trans epidermal elimination, D-E jx restore,
Pore, skin texture
papillary fibroblast activation

SD(RF + dotHIFU) : Skin texture, superficial elasticity
epidermal GAG restore,
dermal fibroblast activation

FL(HIFU) : Dermal elasticity, facial contour improvement
SMAS tightening
dermal fibroblast activation

Flatform antiaging device with multilayer treatment
; 3 full function independent devices in one device
; Evidence based approach in each purposes

Thank you for attention