

HIRONIC
Scientific Paper

The Superiority of MFU+RF Synergy Compared to MFU alone

Efficacy of radiofrequency combined with single-dot ultrasound efficacy for skin rejuvenation:
A non-randomized split-face trial with blinded response evaluation (2023)

Abstract

MFU (Microfocused Ultrasound) treatment alone (left side)
vs.
MFU+RF (Radiofrequency) combined treatment (right side)

MFU+Bipolar RF combined treatment =
"Efficacy in reducing pore number, improving skin elasticity,
diminishing eye wrinkle depth, and increasing
skin moisturization."

Bipolar RF can synergistically improve skin rejuvenation
by providing a thermal effect to the upper papillary dermis
rather than the target area of MFU.

Comparative advantage based on 14 criteria was
confirmed for the MFU+RF treatment
(against MFU alone).

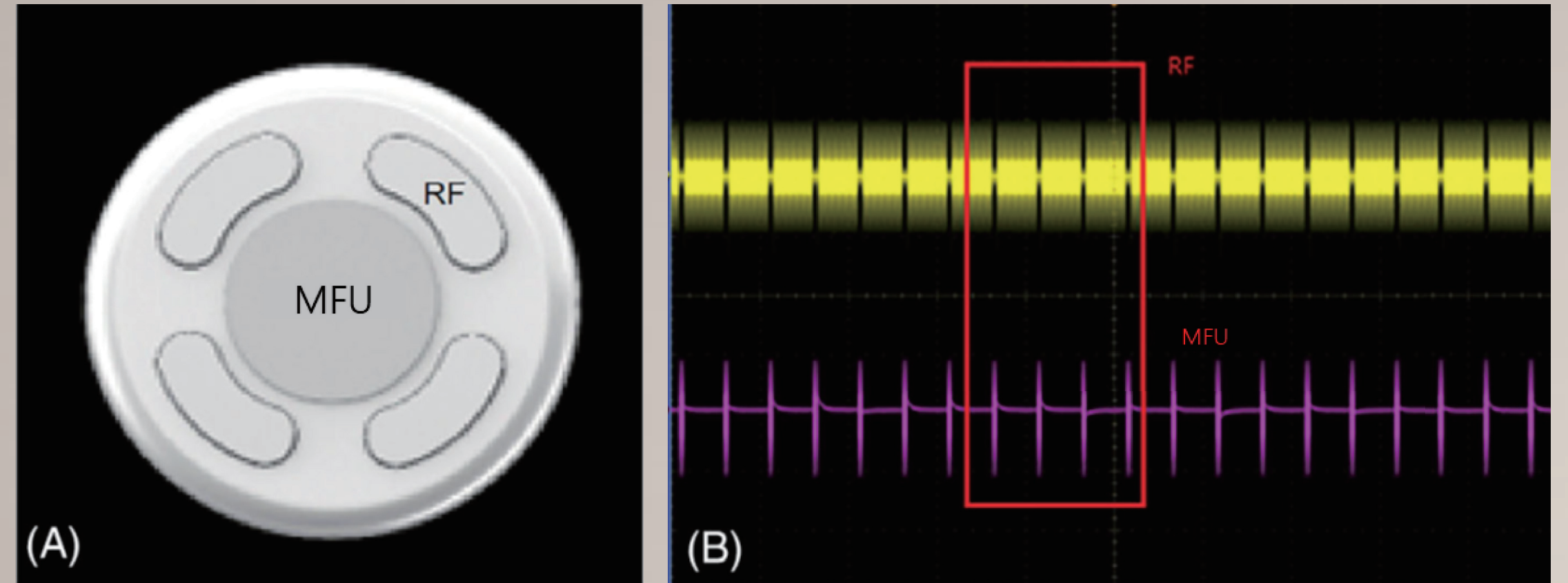
A significant difference was observed in the
improvement of pore density, number of pores,
and inner skin hydration, with an average
improvement of 1.8 times and a maximum
improvement of 13.3 times.

※ Participants were over 30 years old, averaging 42.8 years
(ranging from 30 to 65 years old).

Synergy Effect Introduction | SD Handpiece

SD Handpiece in NEW DOUBLO

MFU(1dot) + Multipolar RF



(A) SD (Synergy Dotting) Handpiece : MFU device that combines RF irradiation into a circular probe with a 2.5 cm diameter.

(B) When bipolar RF is irradiated with a 2 MHz frequency and an 80 ms pulse duration, MFU gets cross-irradiated using a frequency of 7 Hz.

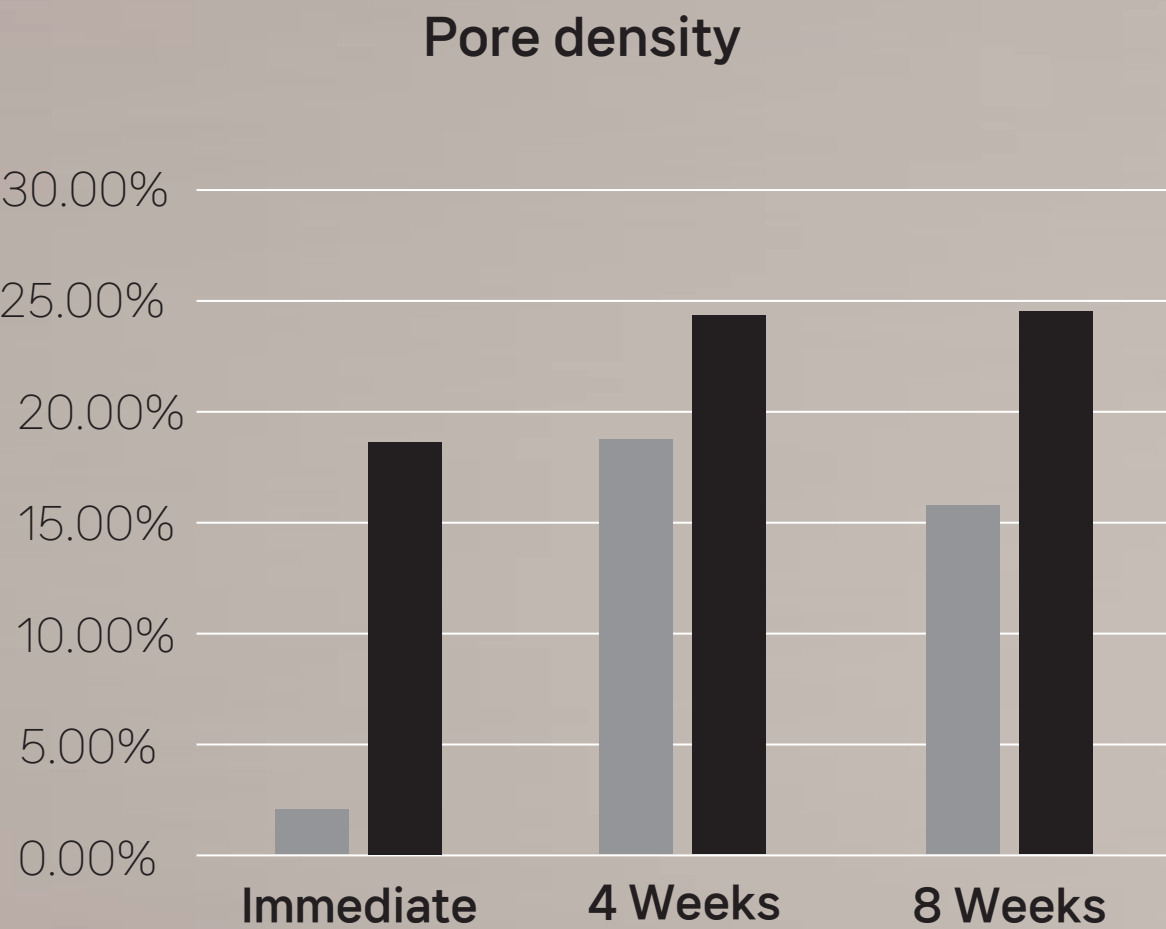
01

Synergy Effect Introduction
| Pore

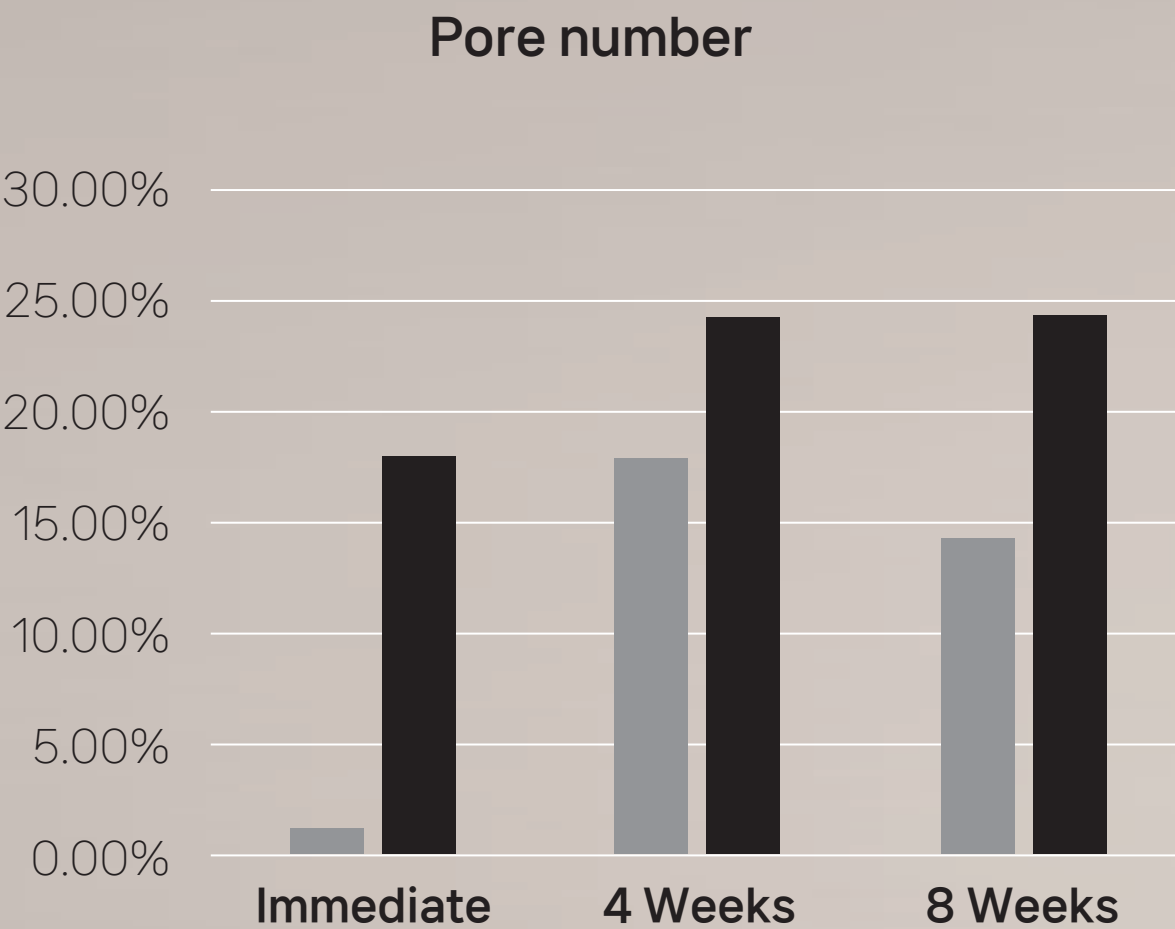
MFU+RF Synergy
Effect: Up to
13.3 times
greater
improvement in
the appearance
of pores

Improvement(%)

- MFU only
- MFU + RF



Period	Immediate	4 Weeks	8 Weeks
MFU	2.04%	19.14%	15.74%
MFU+RF	18.51%	24.15%	24.45%
Comparative Advantage	9.0times	1.3times	1.6 times



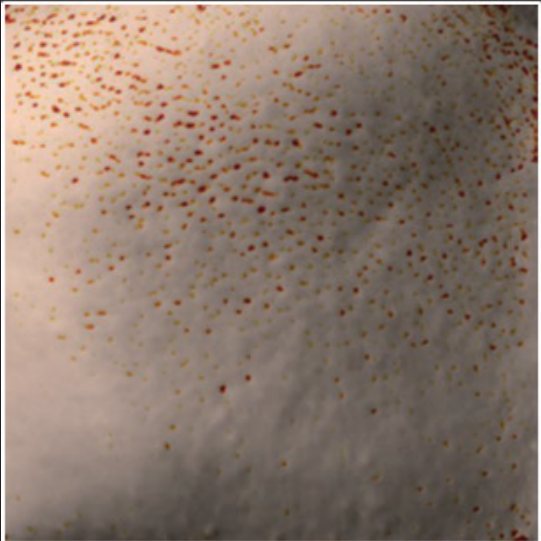
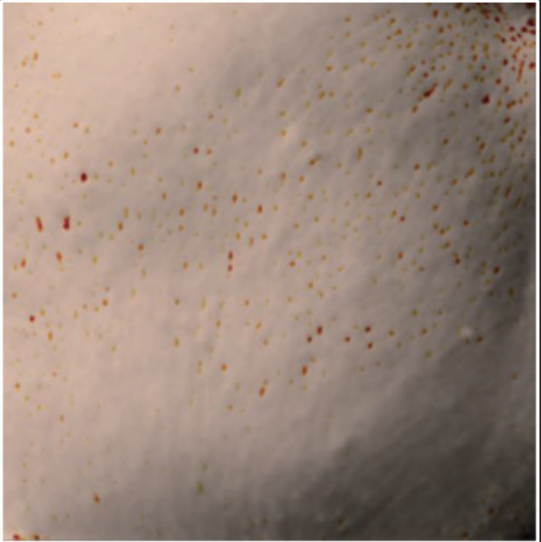
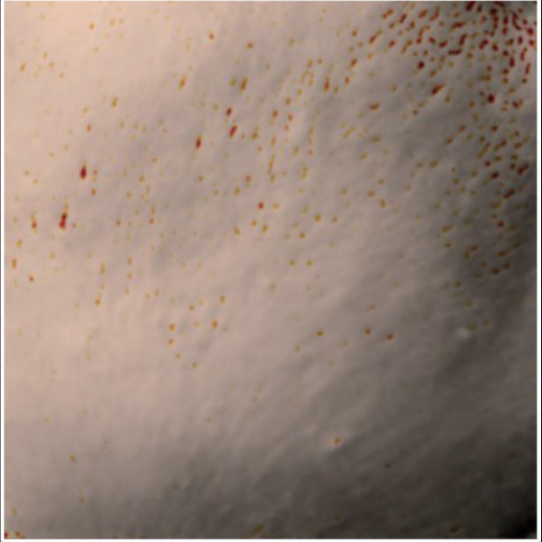
Period	Immediate	4 Weeks	8 Weeks
MFU	1.37%	18.02%	14.51%
MFU+RF	18.31%	24.23%	24.46%
Comparative Advantage	13.3 times	1.3times	1.7times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results.
Comparative advantage over the control group: 100%.

01

Synergy Effect Introduction
| Pore Appearance Improvement (Case 1)

When treated with MFU+RF compared to MFU-only, the skin exhibited considerable synergistic improvements and the pores were noticeably reduced after one treatment.

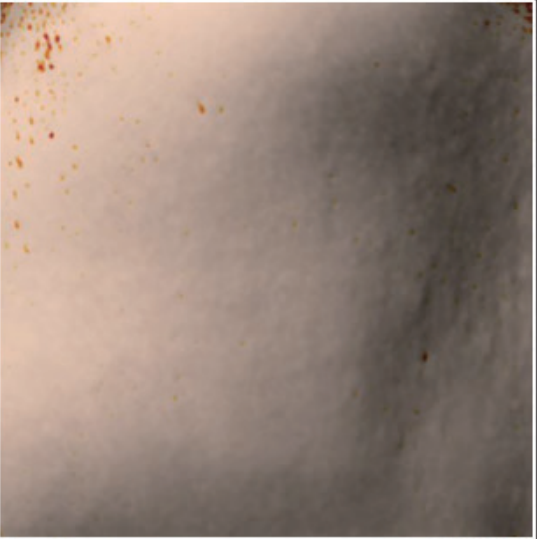
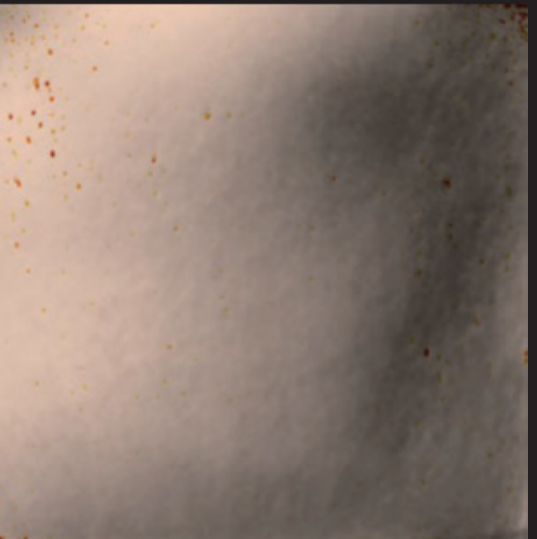
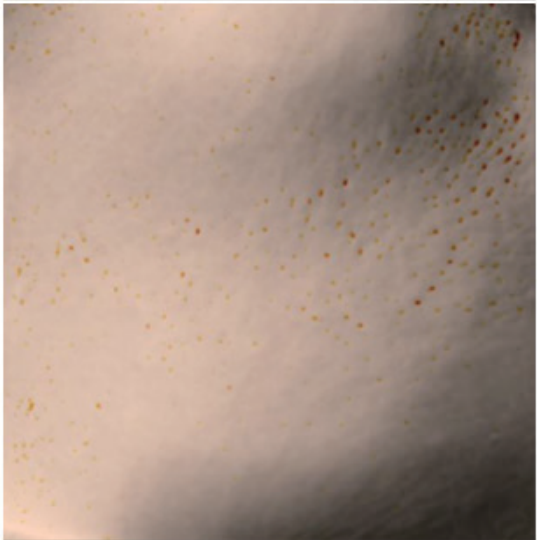
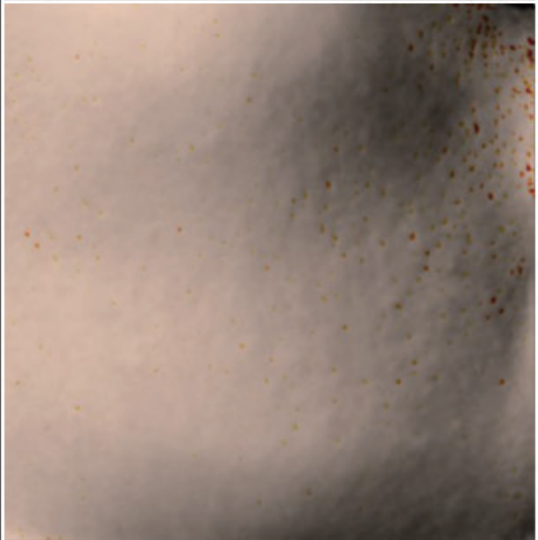
Antera 3D		3D Pore Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.1	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: Checking pore condition according to the number of red dots (pores).

01

Synergy Effect Introduction
| Pore Appearance Improvement (Case 2)

When treated with MFU+RF compared to MFU-only, the skin exhibited considerable synergistic improvements and the pores were noticeably reduced after one treatment.

Antera 3D		3D Pore Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.14	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: Checking pore condition according to the number of red dots (pores).

01

Synergy Effect Introduction
| Pore

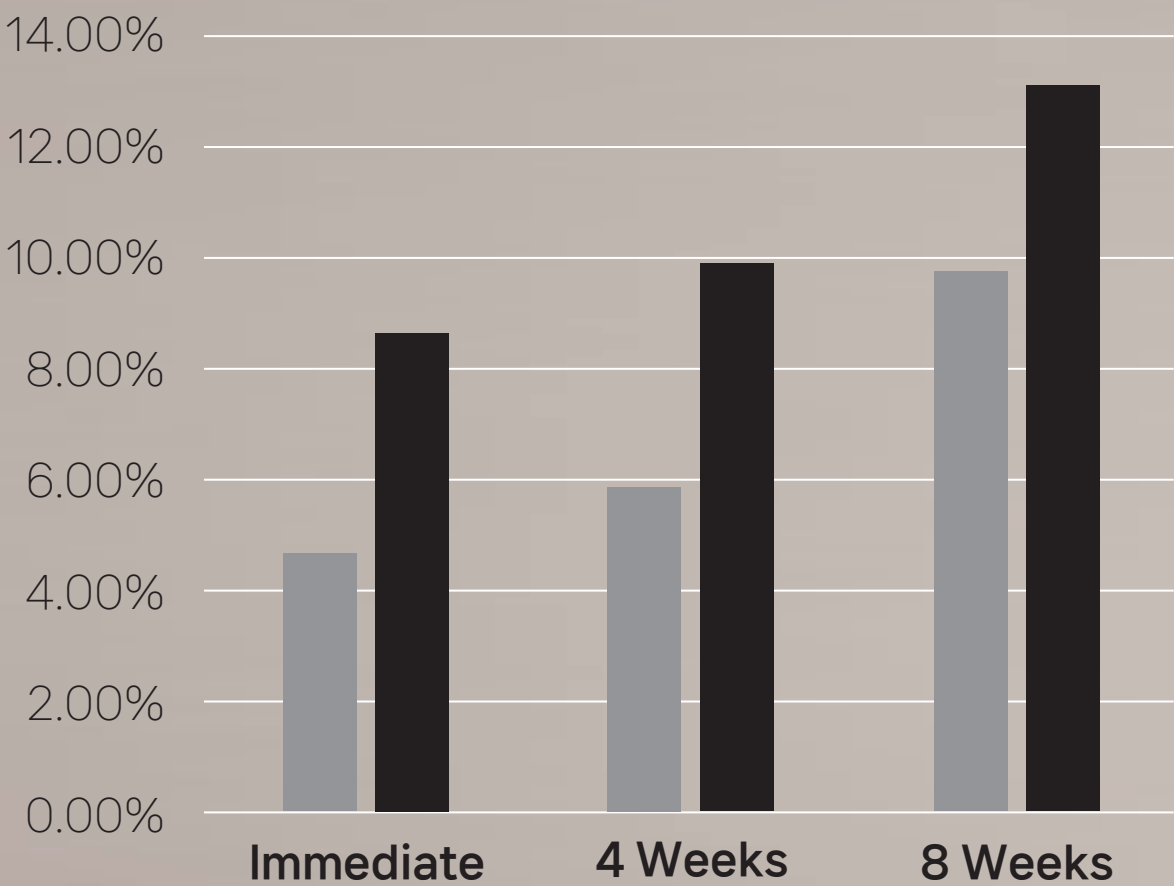
MFU+RF Synergy
Effect: Up to 1.8
times greater
reduction in pore
depth & volume

Improvement(%)

MFU only

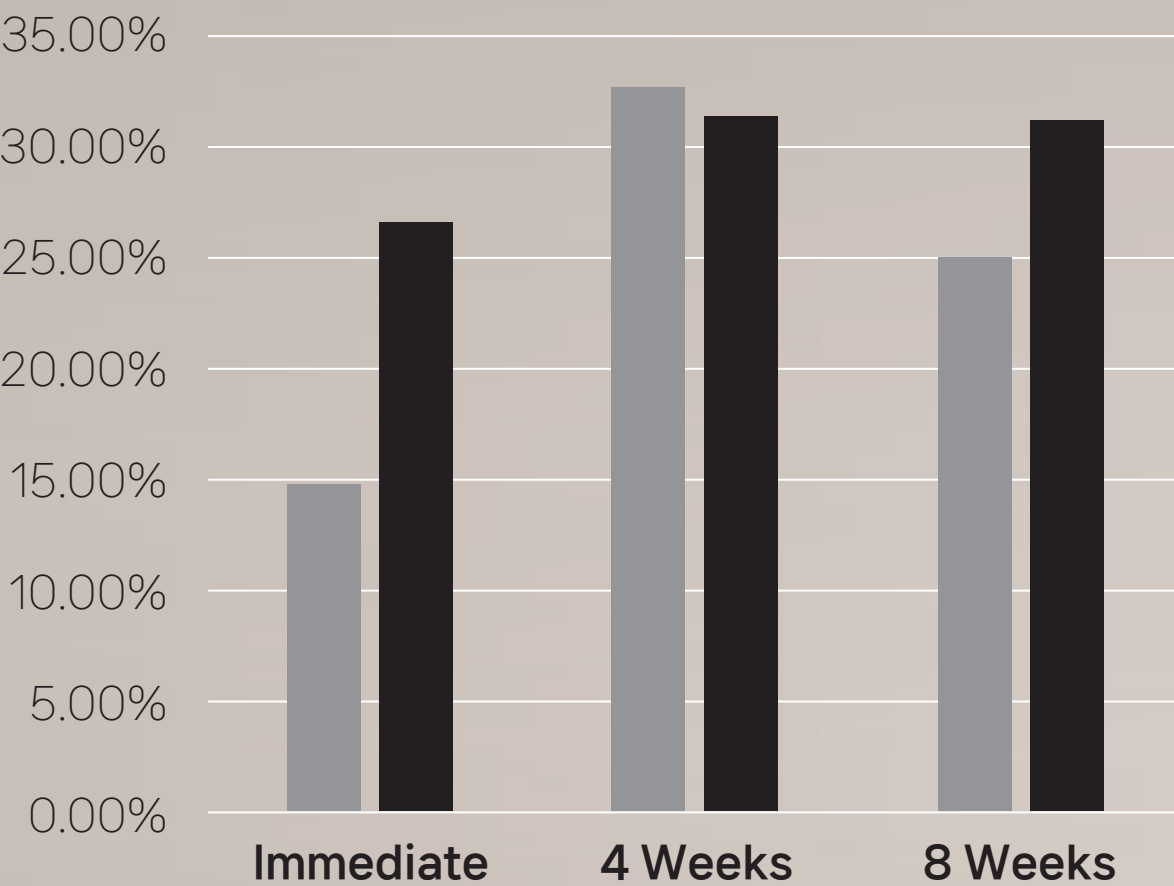
MFU + RF

Maximum depth of pores



Period	Immediate	4 Weeks	8 Weeks
MFU	4.71%	5.85%	9.73%
MFU + RF	8.63%	9.92%	13.1%
Comparative Advantage	1.8 times	1.7 times	1.4 times

Total pore volume



Period	Immediate	4 Weeks	8 Weeks
MFU	14.37%	32.42%	24.67%
MFU + RF	26.26%	31.25%	30.76%
Comparative Advantage	1.8 times	1.7 times	1.3 times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results.
Comparative advantage over the control group: 100%.

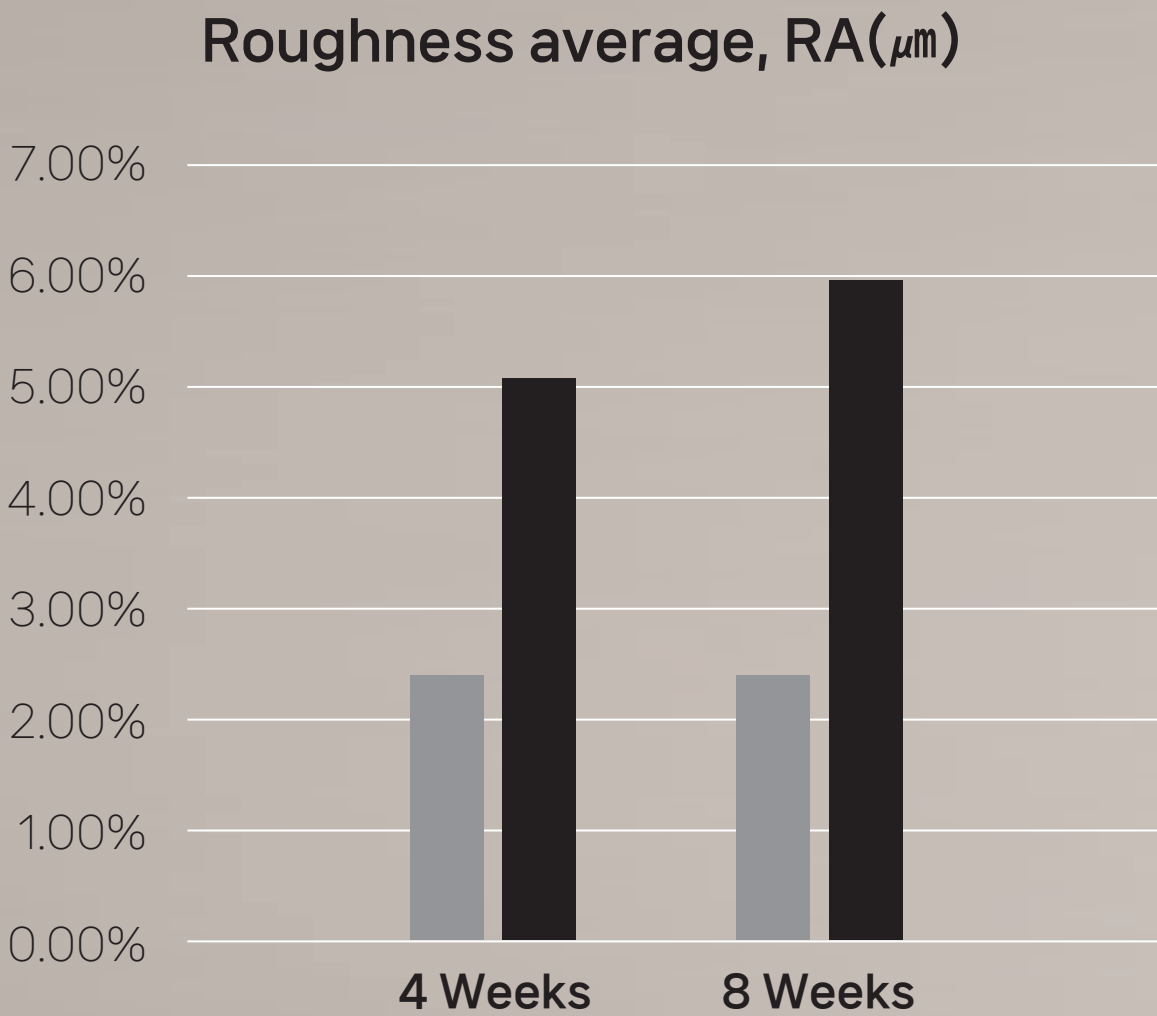
02

Synergy Effect Introduction
| Skin Texture

MFU+RF Synergy
Effect: Up to 2.3
times greater
reduction in
skin roughness

Improvement(%)

- MFU only
- MFU + RF



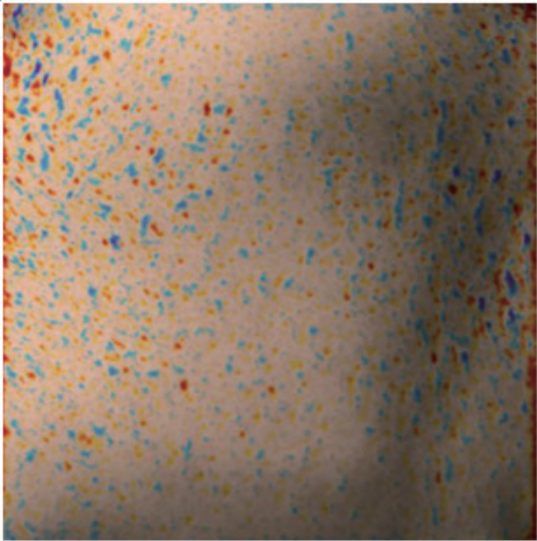
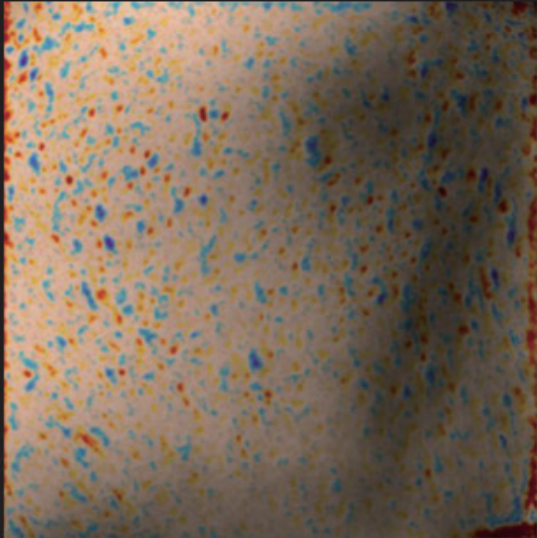
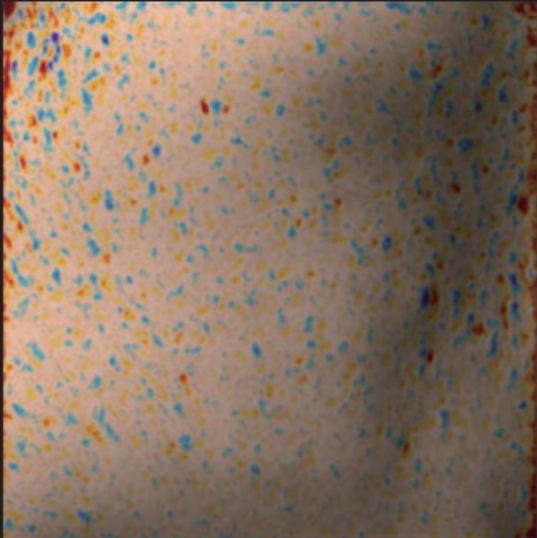
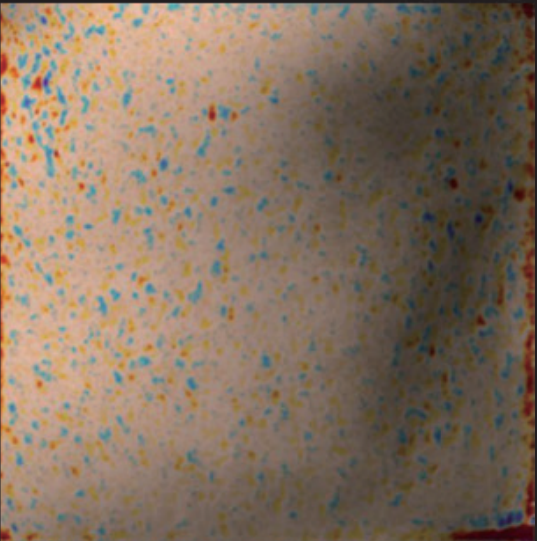
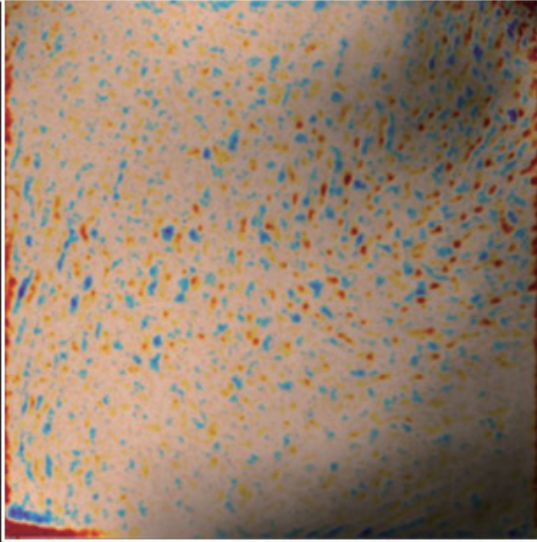
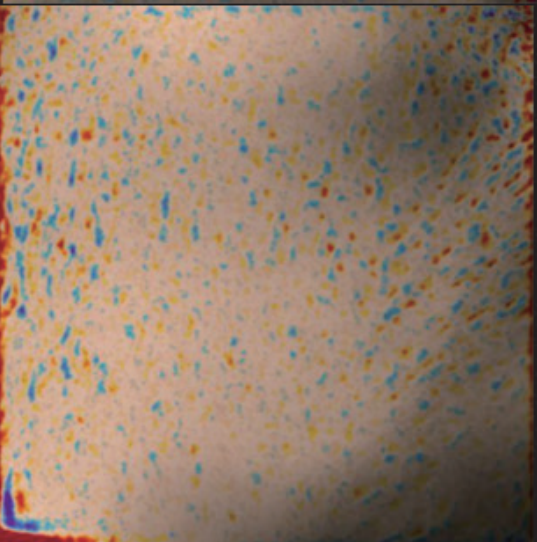
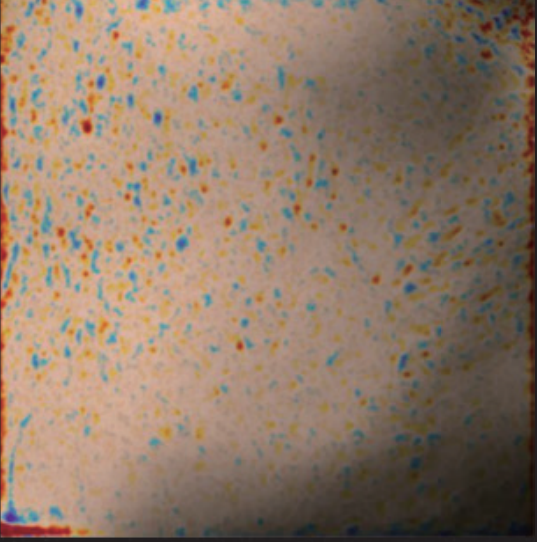
Period	4 Weeks	8 Weeks
MFU	2.63%	2.54%
MFU + RF	5.14%	5.93%
Comparative Advantage	2.0 times	2.3 times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

02

Synergy Effect Introduction
| Skin Texture Improvement (Case 1)

When treated with MFU+RF compared to MFU-only, the skin exhibited considerable synergistic improvements and the tiny bumps were noticeably reduced after on treatment.

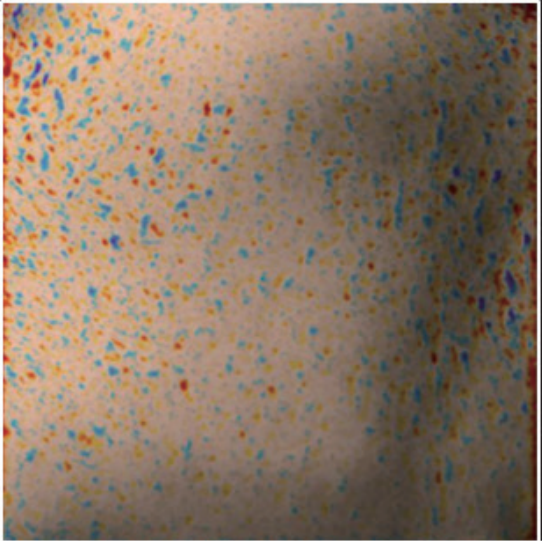
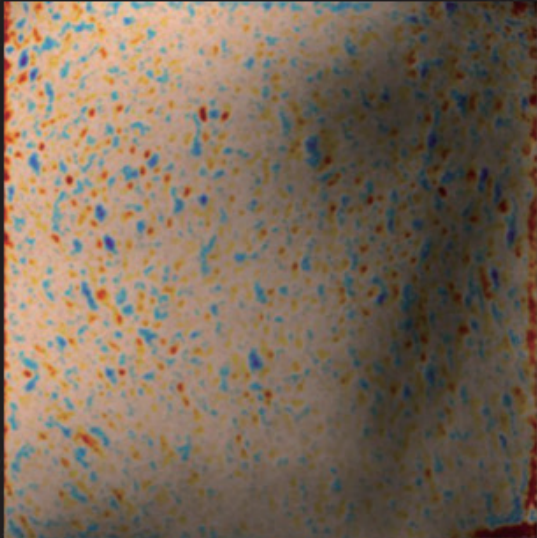
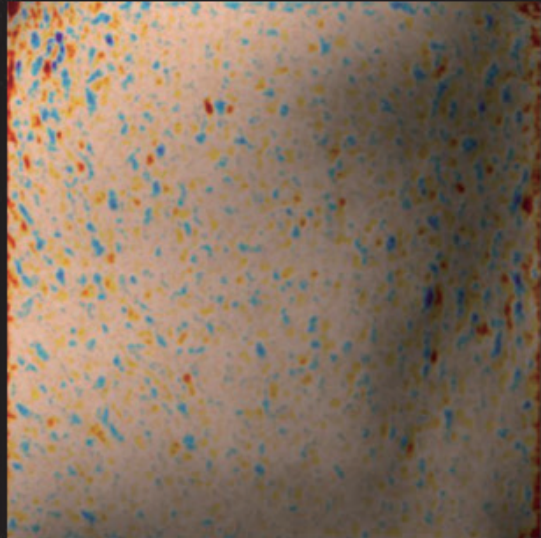
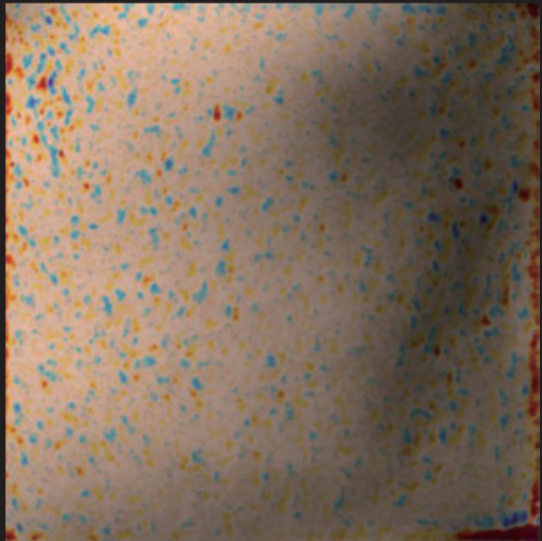
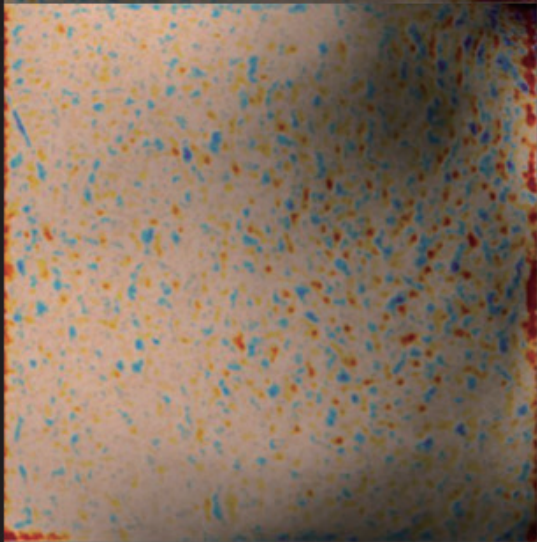
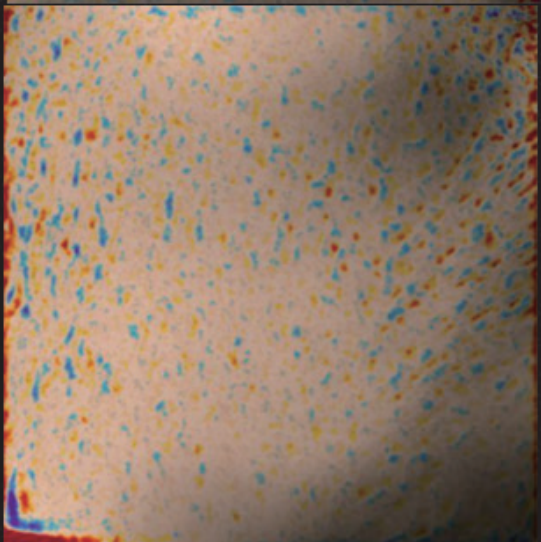
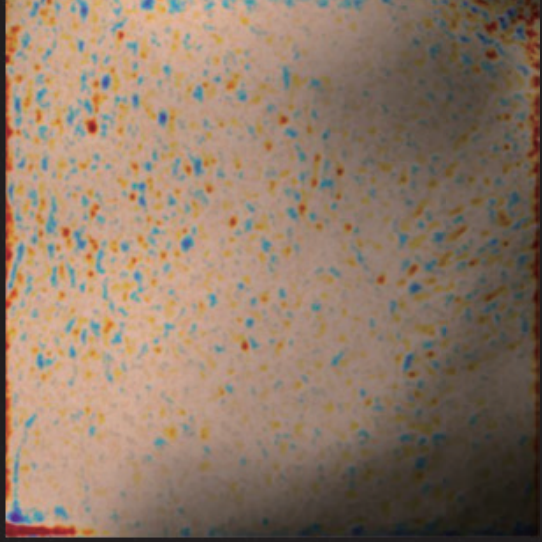
Antera 3D		Skin Texture (Roughness) Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.14	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: Red dot → part that goes lower than the level of the surrounding skin / Blue dot → part that raises above the level of the surrounding skin.

02

Synergy Effect Introduction
| Skin Texture Improvement (Case 2)

When treated with MFU+RF compared to MFU-only, the skin exhibited considerable synergistic improvements and the tiny bumps were noticeably reduced after one treatment.

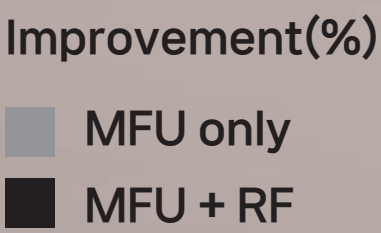
Antera 3D		Skin Texture (Roughness) Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.14	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: Red dot → part that goes lower than the level of the surrounding skin / Blue dot → part that raises above the level of the surrounding skin.

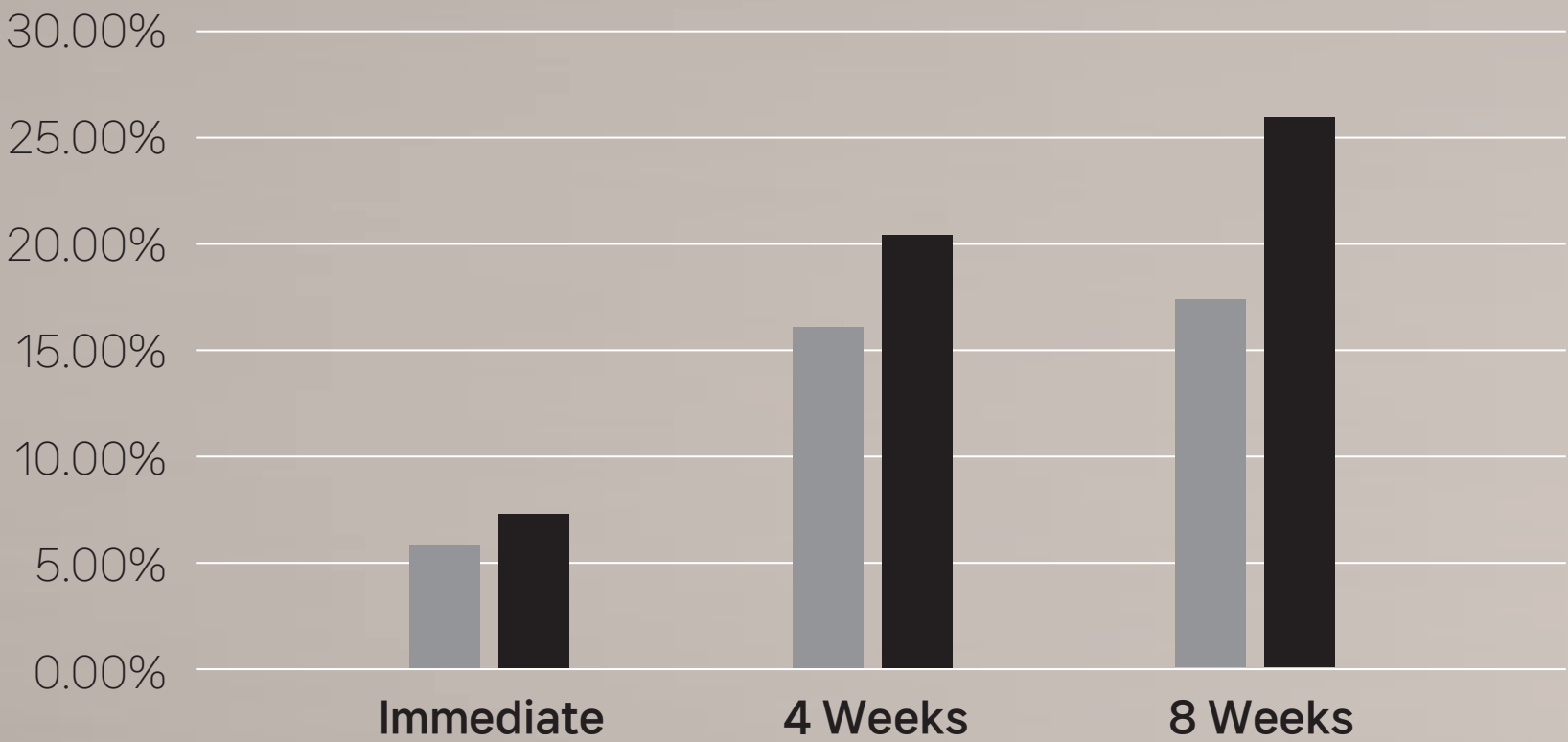
03

Synergy Effect Introduction
| Outer Skin Layer Elasticity

MFU+RF Synergy
Effect: Up to 1.5 times
greater improvement
in outer skin
layer elasticity
(Measured at a depth of 2 mm)



Cutometer® MPA580 R2(Total Recovery/Total Elongation) 2mm probe



Period	Immediate	4 Weeks	8 Weeks
MFU	6.59%	16.22%	16.82%
MFU + RF	8.11%	20.50%	25.42%
Comparative Advantage	1.2times	1.3times	1.5times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

03

Synergy Effect Introduction
| Inner Skin Layer Elasticity

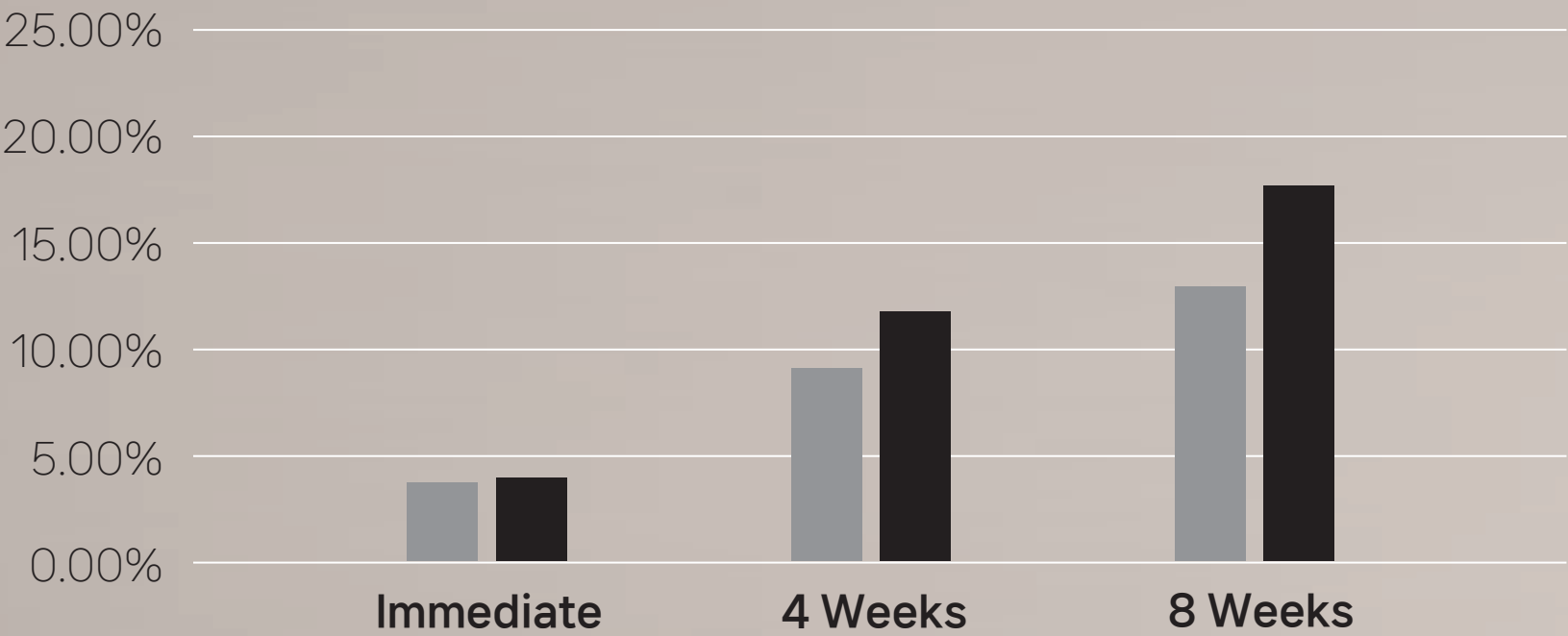
MFU+RF Synergy
Effect: Up to 1.4 times
greater improvement
in inner skin
layer elasticity

(Measured at a depth of 8 mm)

Improvement(%)

- MFU only
- MFU + RF

Cutometer® MPA580 R2(Total Recovery/Total Elongation) 8mm probe



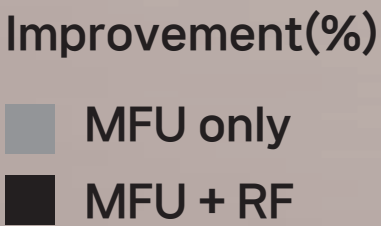
Period	Immediate	4 Weeks	8 Weeks
MFU	3.31%	9.06%	12.23%
MFU + RF	3.32%	11.33%	17.45%
Comparative Advantage	1.0times	1.2times	1.4times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

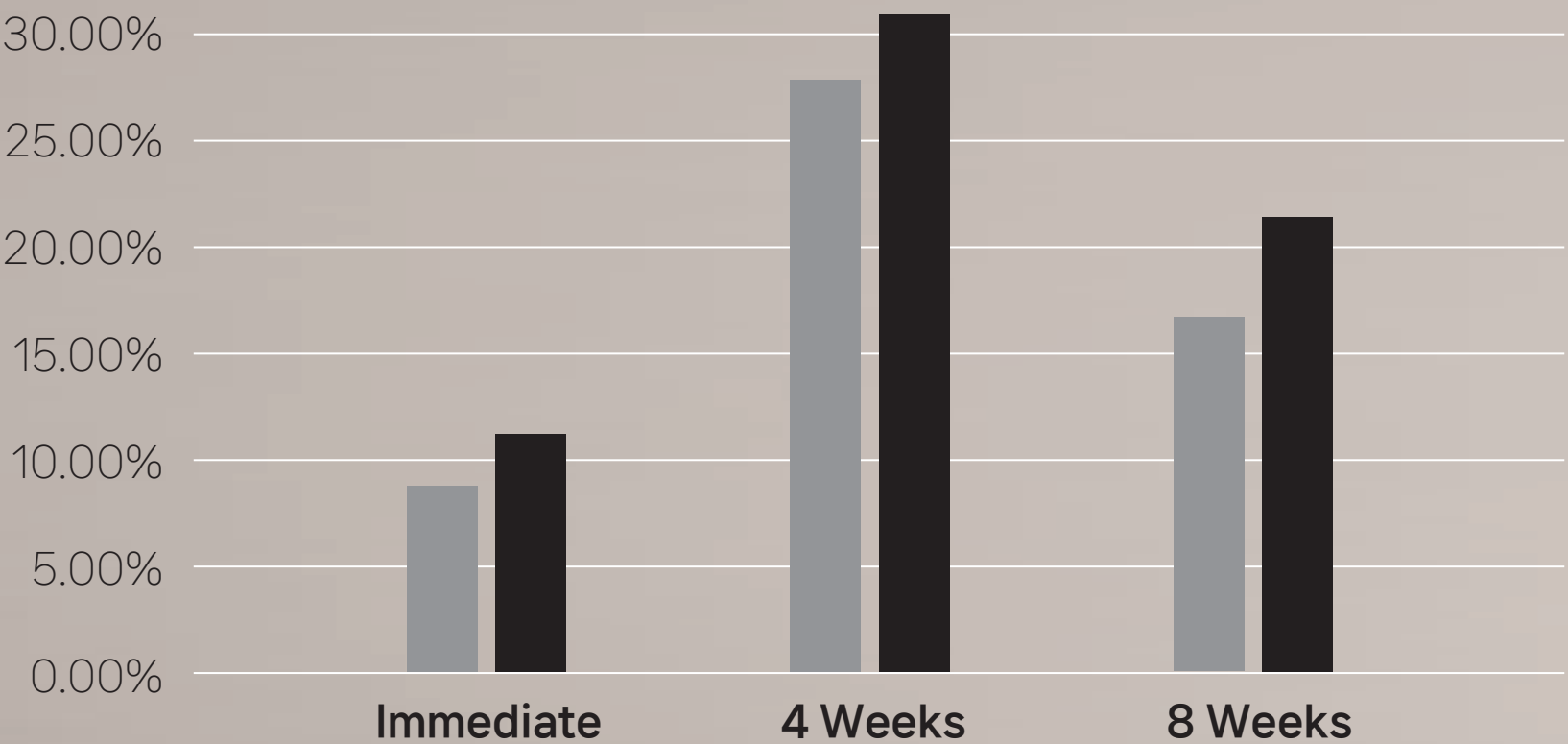
04

Synergy Effect Introduction
| Resilience (Skin Elasticity)

MFU+RF Synergy
Effect: Up to 1.3 times
greater improvement
in skin resilience
(Measured at a depth of 2 mm)



Cutometer® MPA580 R7(Total Recovery/Total Elongation) 2mm probe



Period	Immediate	4 Weeks	8 Weeks
MFU	8.96%	28.21%	16.65%
MFU + RF	11.28%	30.83%	21.68%
Comparative Advantage	1.3times	1.1times	1.3times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

05

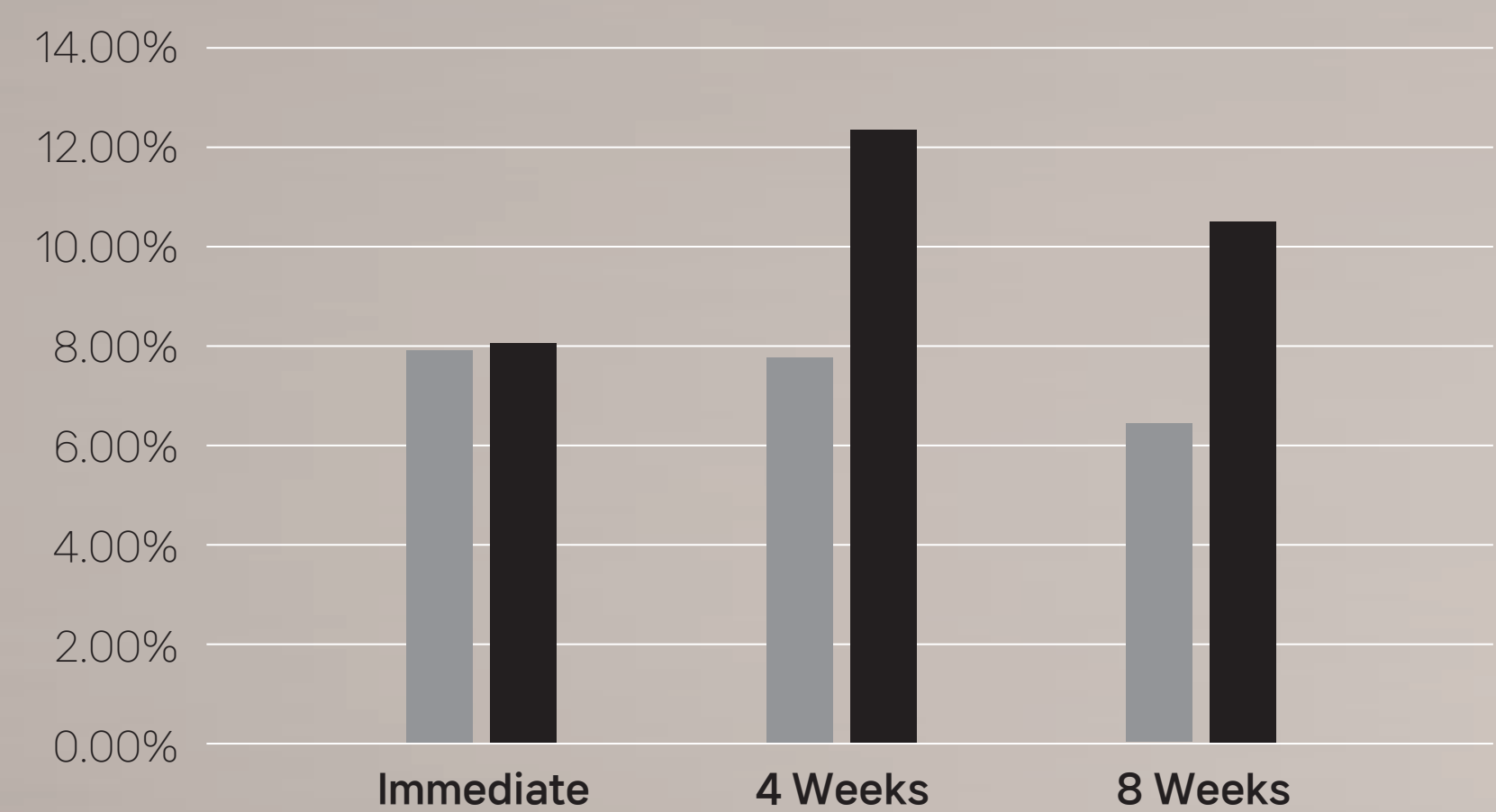
Synergy Effect Introduction
| Eye Wrinkles

MFU+RF Synergy
Effect: Up to 1.6 times
greater improvement
in the appearance
of eye wrinkles

Improvement(%)

- MFU only
- MFU + RF

Average depth of eye wrinkles according to imaging of the eye area









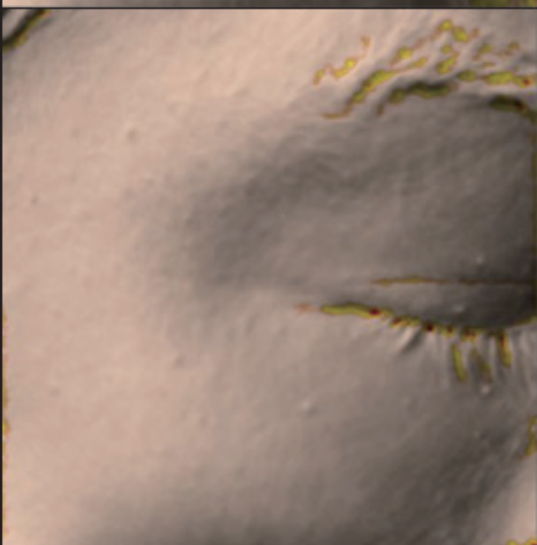
Period	Immediate	4 Weeks	8 Weeks
MFU	7.98%	7.72%	6.38%
MFU + RF	8.21%	12.68%	10.31%
Comparative Advantage	1.0times	1.6times	1.6times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

05

Synergy Effect Introduction
| Eye Wrinkles (Case 1)

The gradual improvement in the wrinkles around the eyes, which appeared in red and yellow colors, was noted. Furthermore, 4 weeks after the MFU+RF combined treatment, the eye wrinkles became nearly invisible.

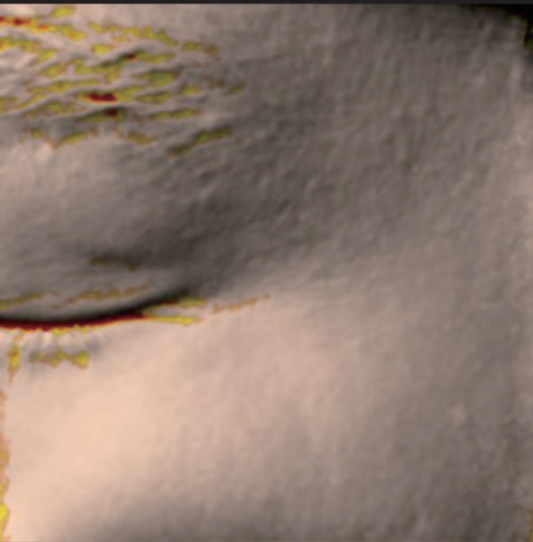
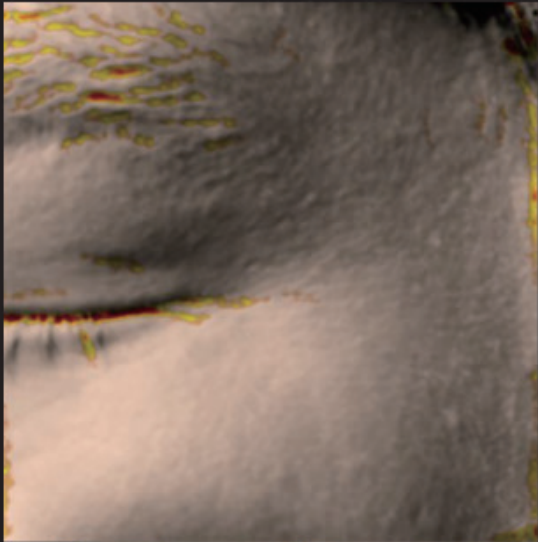
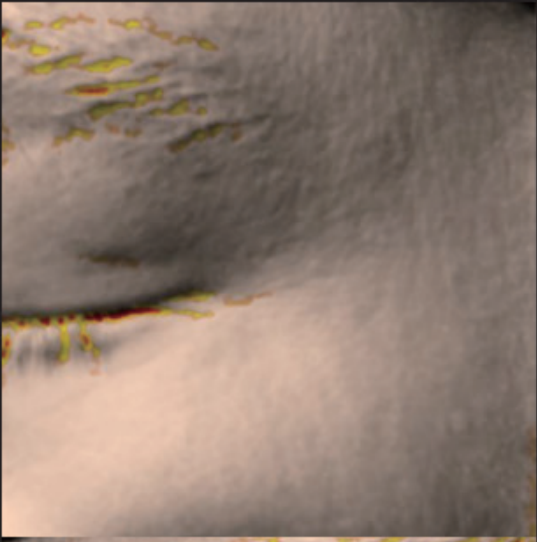
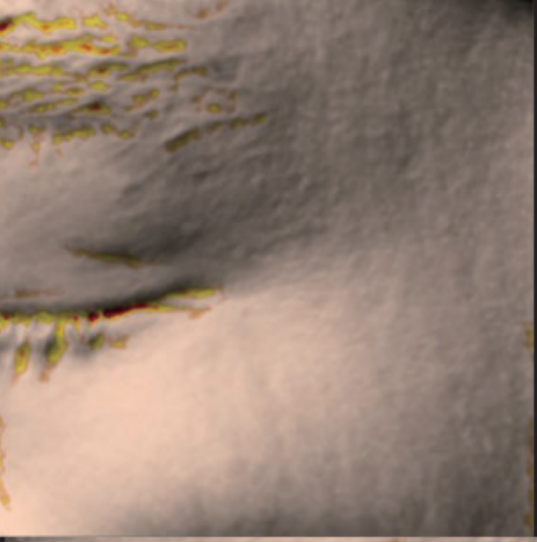
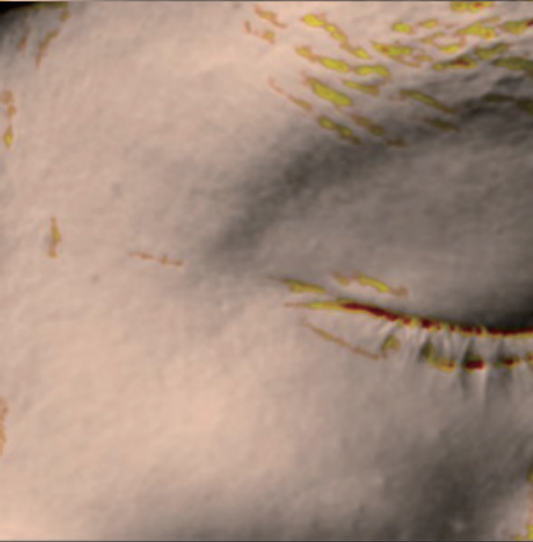
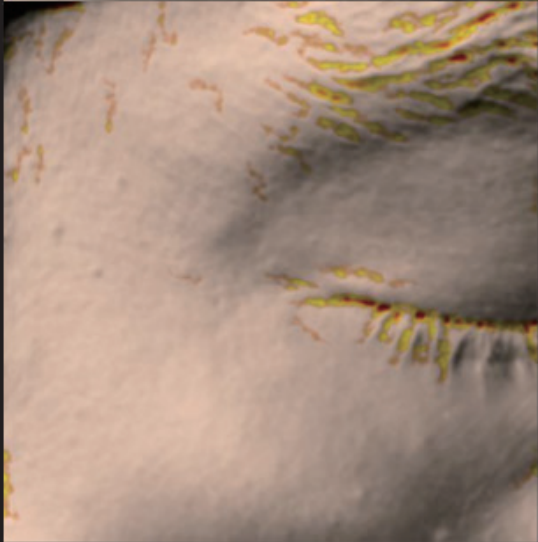
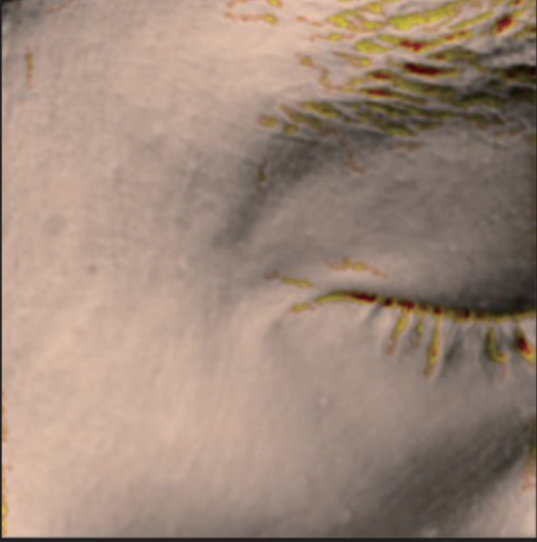

Antera 3D		Eye Wrinkles Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.06	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: The deeper the wrinkles, the more red color appears instead of yellow.

05

Synergy Effect Introduction
| Eye Wrinkles (Case 2)

The gradual improvement in the wrinkles around the eyes, which appeared in red and yellow colors, was noted. Furthermore, 4 weeks after the MFU+RF combined treatment, the eye wrinkles became nearly invisible.

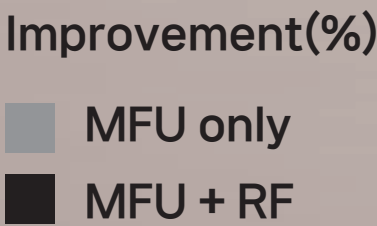
Antera 3D		Eye Wrinkles Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.12	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: The deeper the wrinkles, the more red color appears instead of yellow.

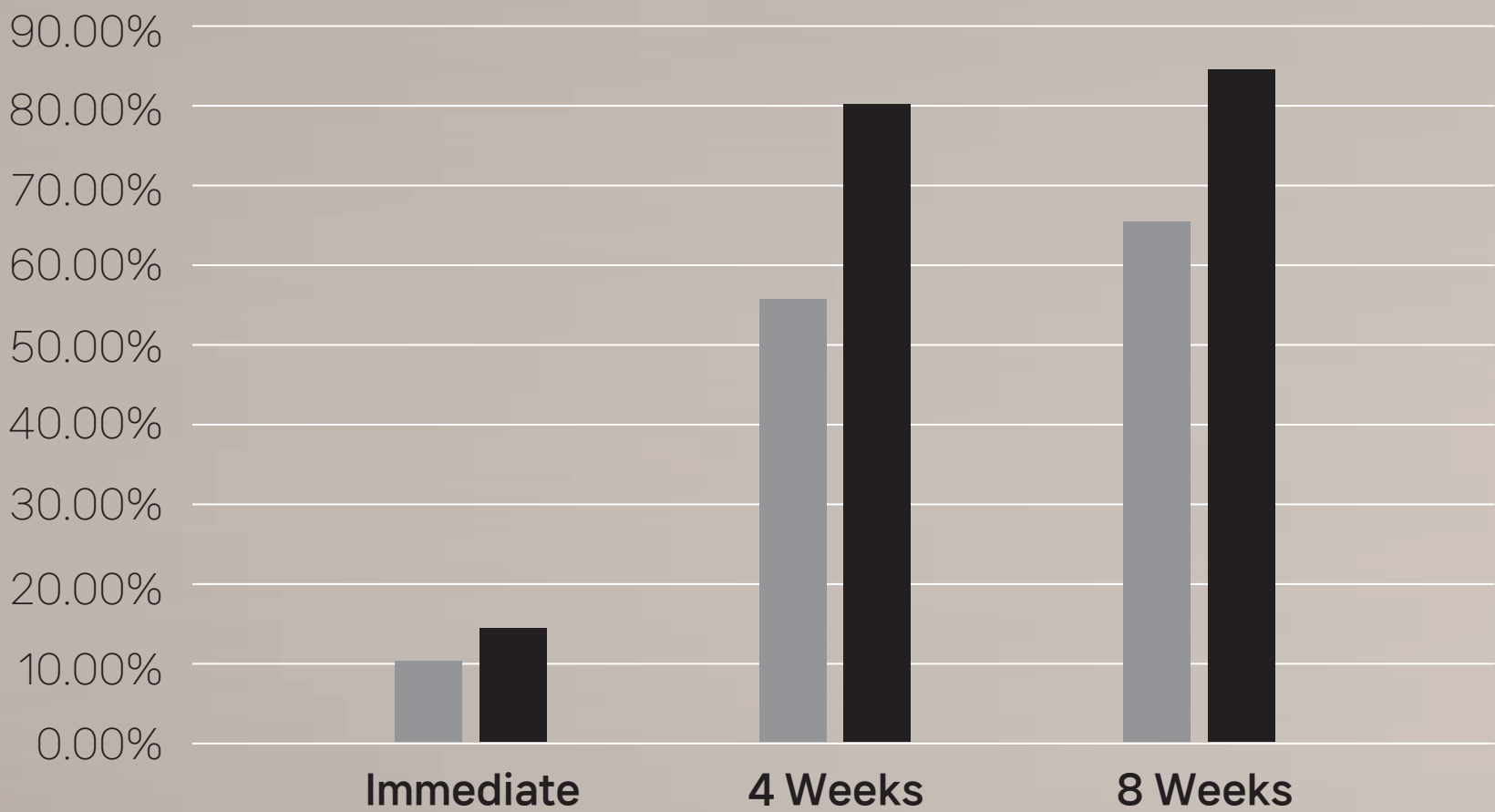
06

Synergy Effect Introduction
| Nasolabial Folds

MFU+RF Synergy
Effect: Up to 1.4 times
greater improvement
in the appearance of
nasolabial folds



Average depth of nasolabial folds according to imaging of mouth area



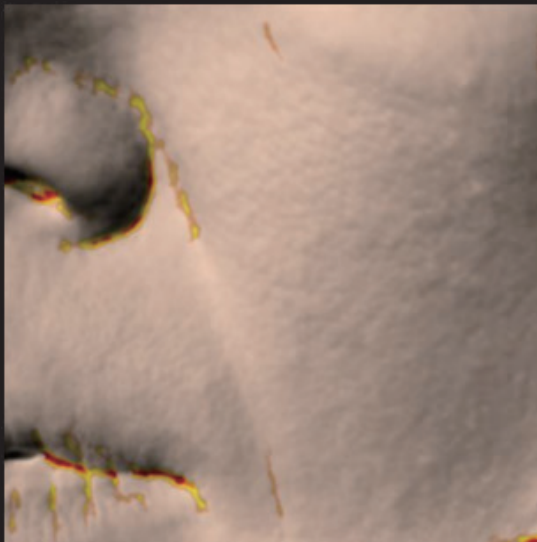
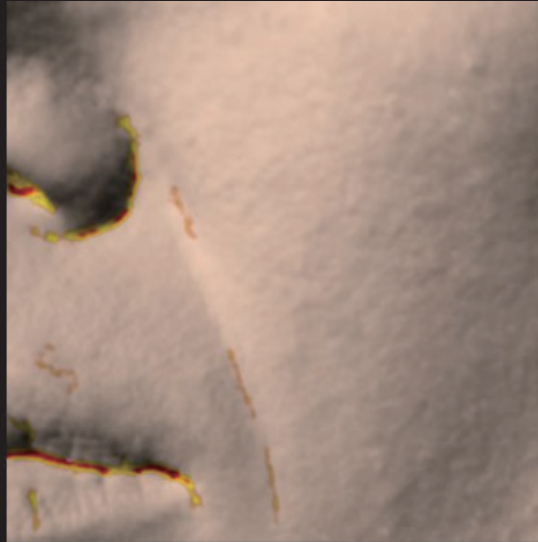

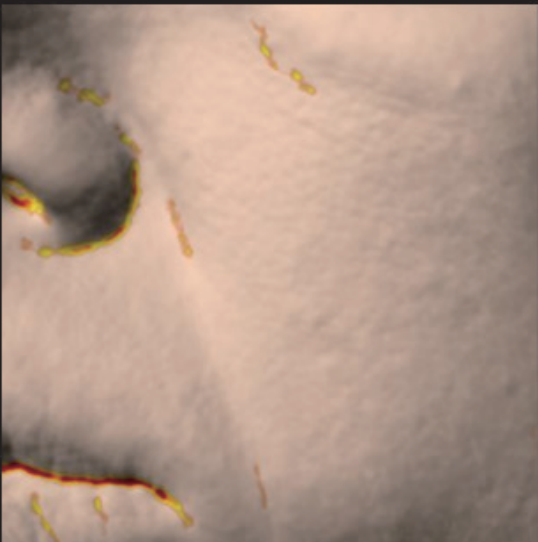

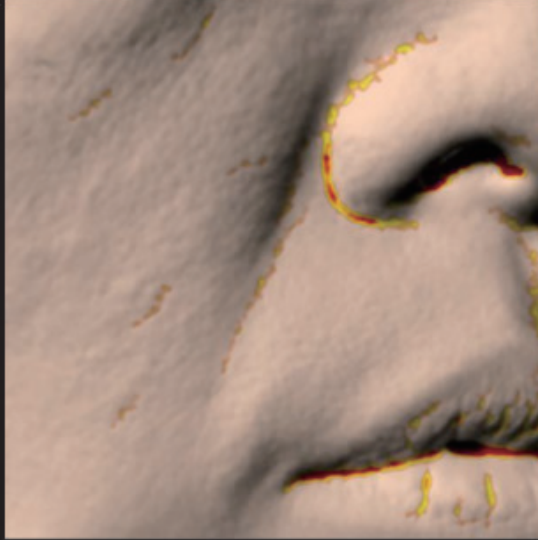


Period	Immediate	4 Weeks	8 Weeks
MFU	9.59%	55.99%	65.19%
MFU + RF	12.04%	79.17%	82.67%
Comparative Advantage	1.3times	1.4times	1.3times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

06

Synergy Effect Introduction
| Nasolabial Folds (Case 1)

The gradual improvement in the nasolabial folds, which appeared in red and yellow colors, was noted. Furthermore, 4 weeks after the MFU+RF combined treatment, nasolabial folds became nearly invisible.


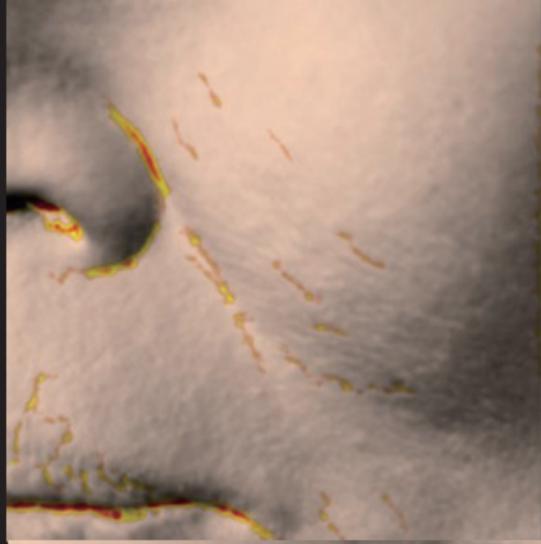
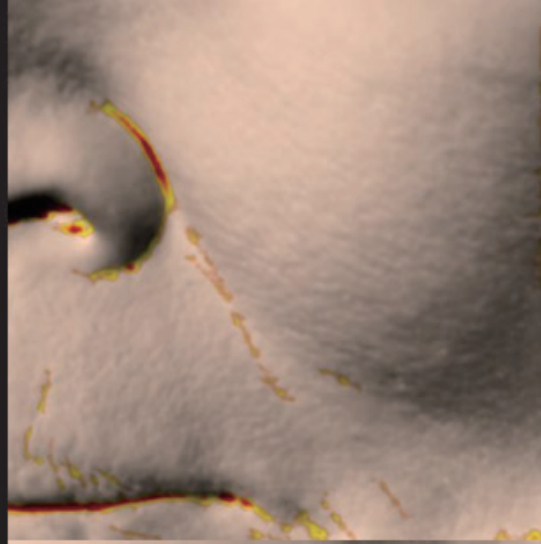
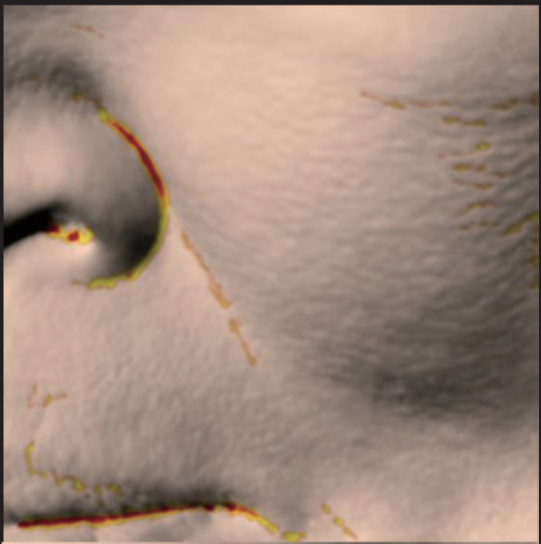
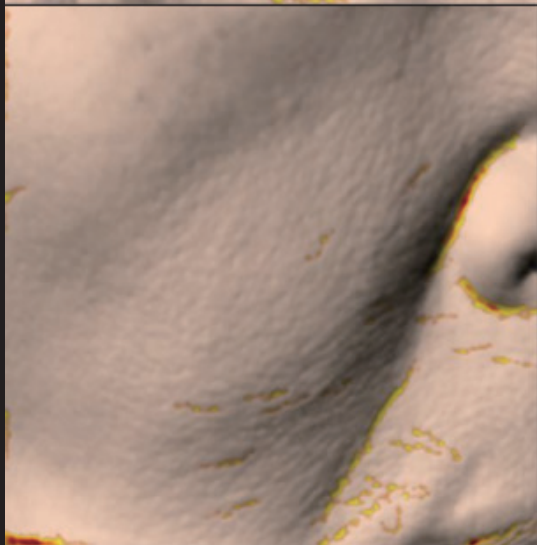
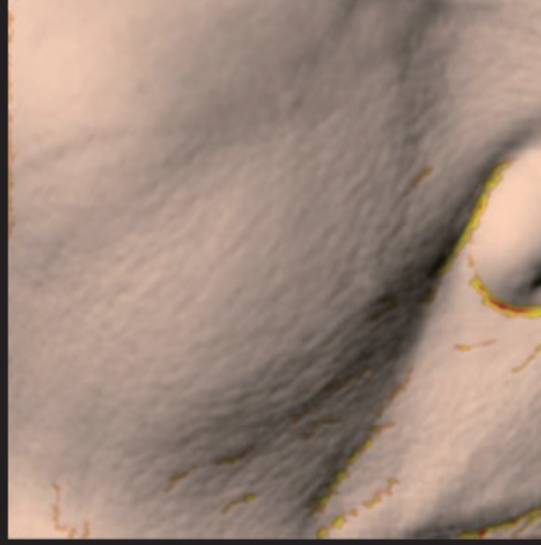
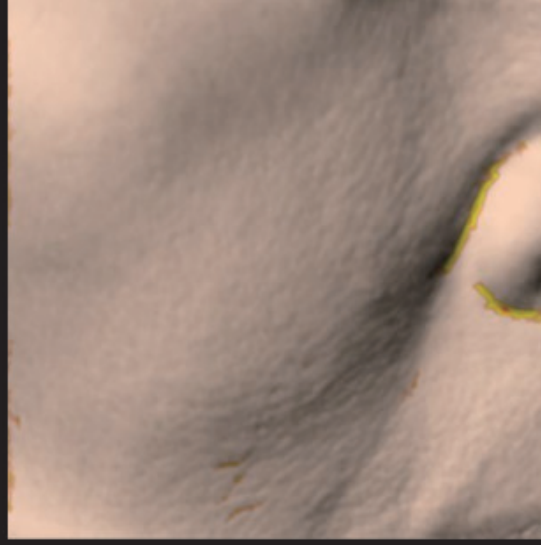
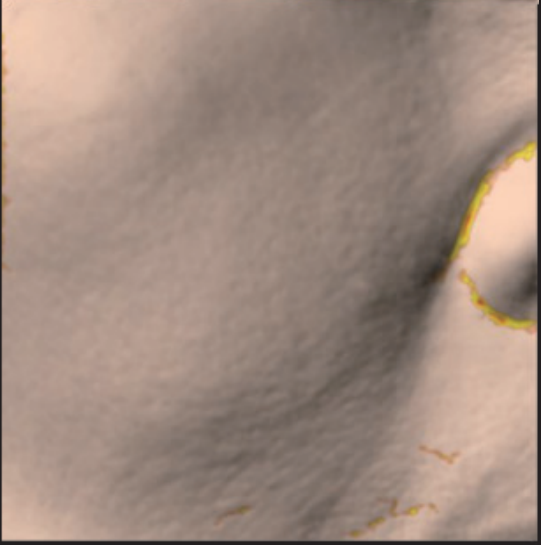
Antera 3D		Nasolabial Folds Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.06	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: The deeper the wrinkles, the more red color appears instead of yellow.

06

Synergy Effect Introduction
| Nasolabial Folds (Case 2)

The gradual improvement in the nasolabial folds, which appeared in red and yellow colors, was noted. Furthermore, 4 weeks after the MFU+RF combined treatment, nasolabial folds became nearly invisible.

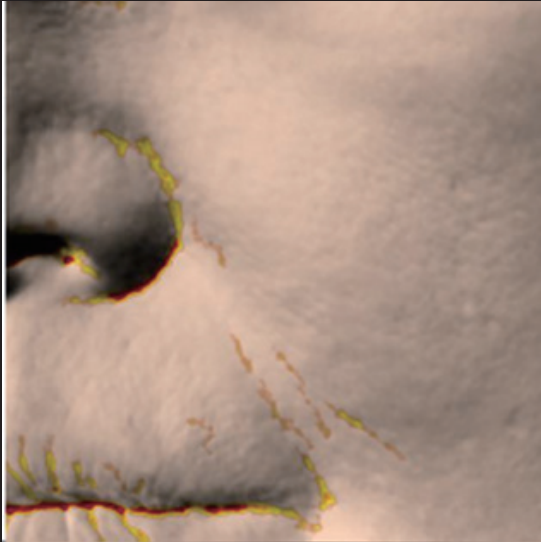

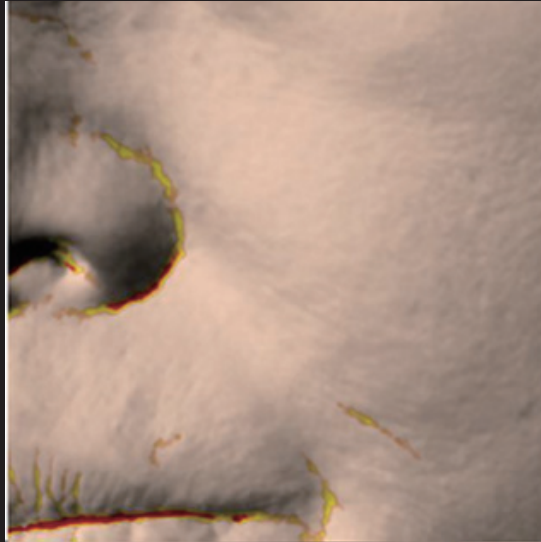
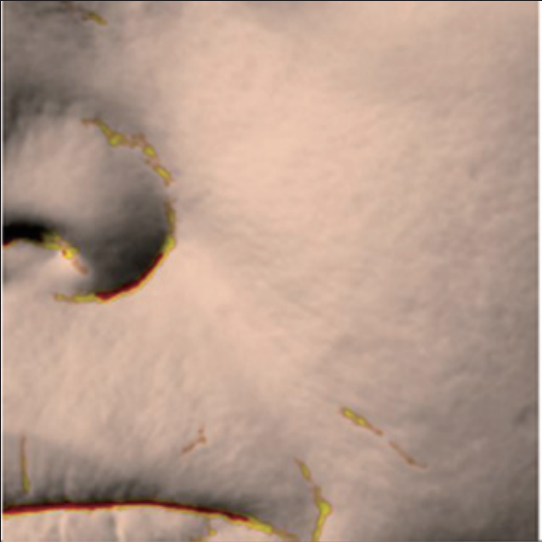
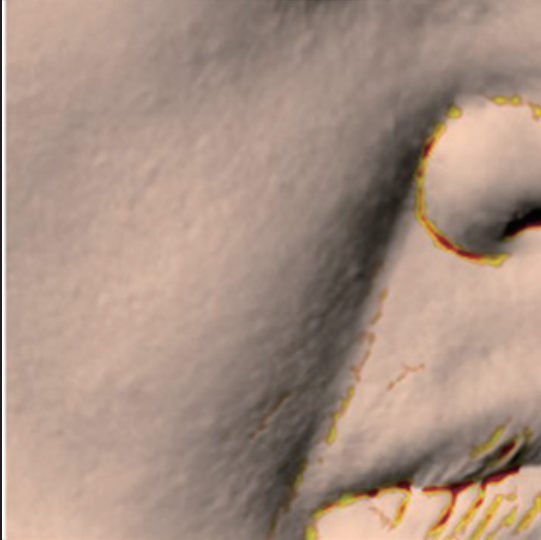


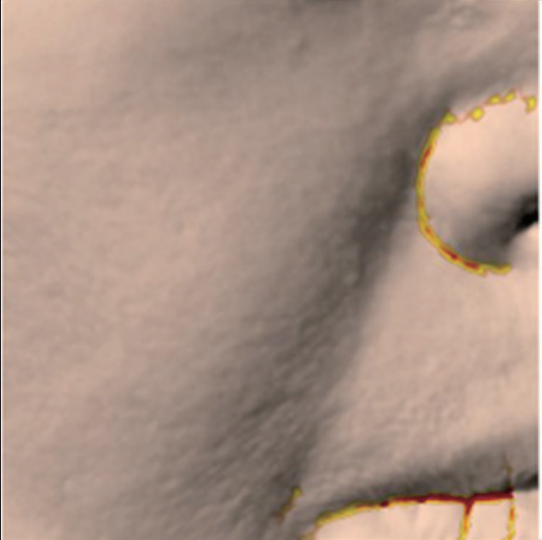
Antera 3D		Nasolabial Folds Imaging			
Period		Before NEW DOUBLO (V-RO) treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.16	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: The deeper the wrinkles, the more red color appears instead of yellow.

06

Synergy Effect Introduction
| Nasolabial Folds (Case 3)

The gradual improvement in the nasolabial folds, which appeared in red and yellow colors, was noted. Furthermore, 4 weeks after the MFU+RF combined treatment, nasolabial folds became nearly invisible.

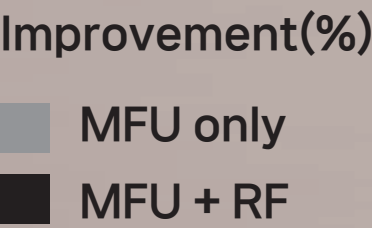
Antera 3D		Nasolabial Folds Imaging			
Period		Before NEW DOUBLO (V-RO) treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.17	Left side (MFU)				
	Right side (MFU+RF)				

※ Antera 3D: The deeper the wrinkles, the more red color appears instead of yellow.

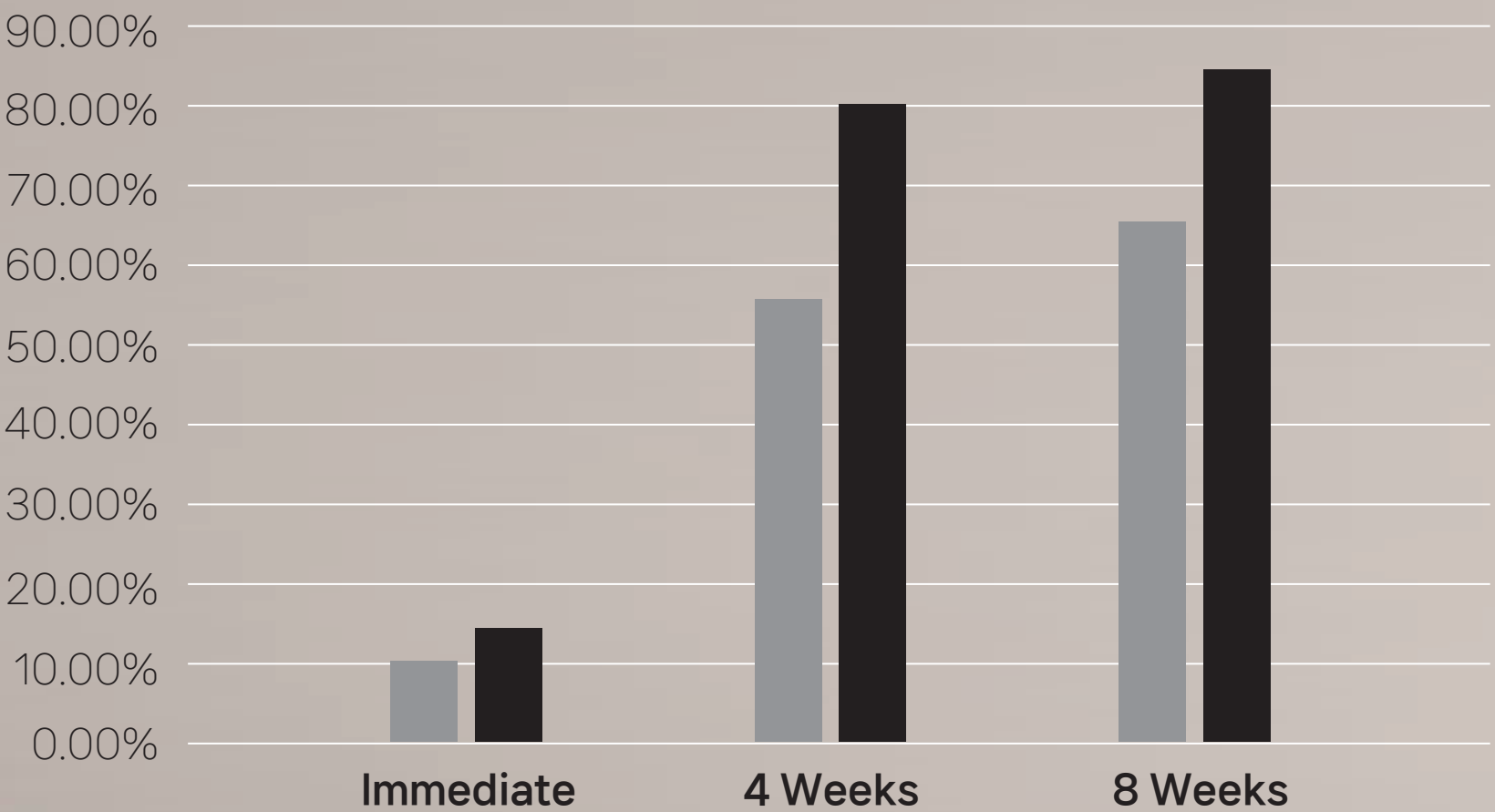
07

Synergy Effect Introduction
| Jawline

MFU+RF Synergy
Effect: Up to 1.6 times
greater improvement
in jawline definition



Comparison of jawline volume through VECTRA XT imaging



Period	Immediate	4 Weeks	8 Weeks
MFU	6.23%	19.37%	22.23%
MFU + RF	8.21%	30.49%	29.09%
Comparative Advantage	1.3times	1.6times	1.3times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

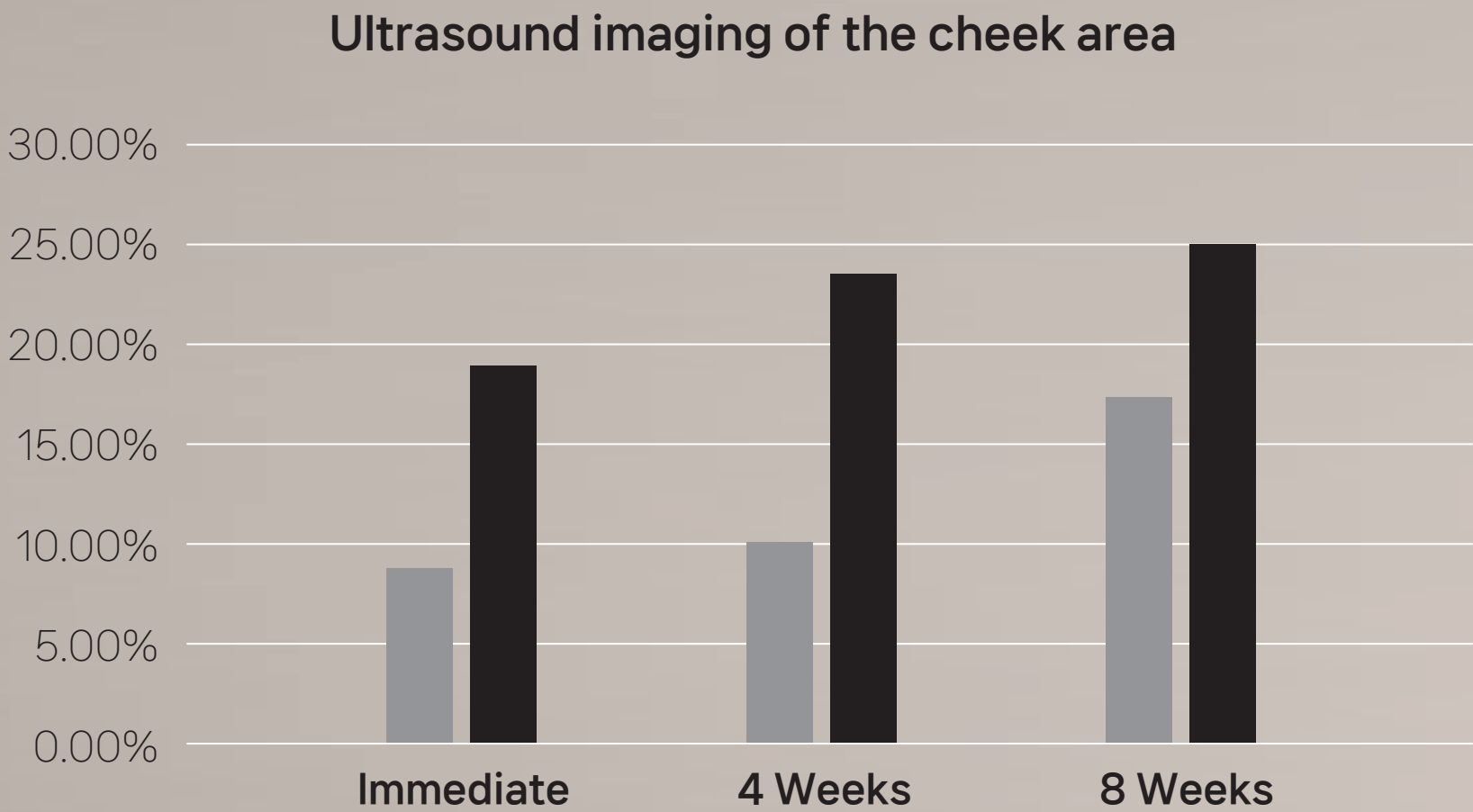
08

Synergy Effect Introductio
| Skin Density

MFU+RF Synergy
Effect: Up to 2.3 times
greater improvement
in skin density

Improvement(%)

- MFU only
- MFU + RF



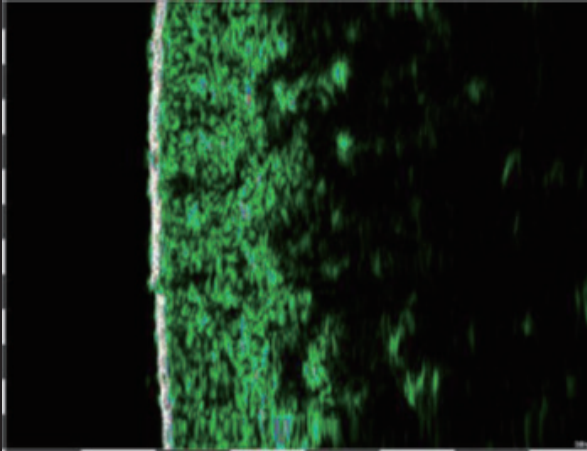
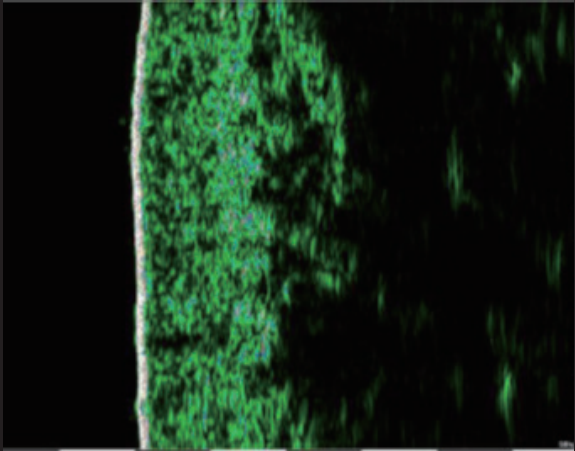
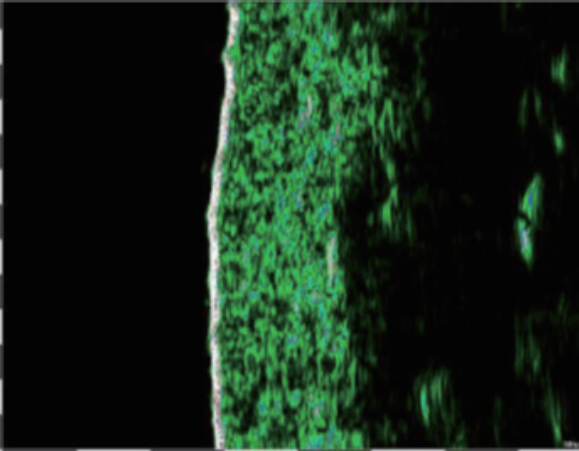
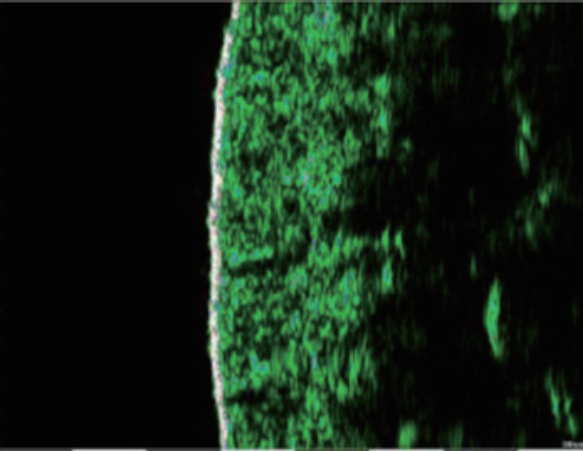
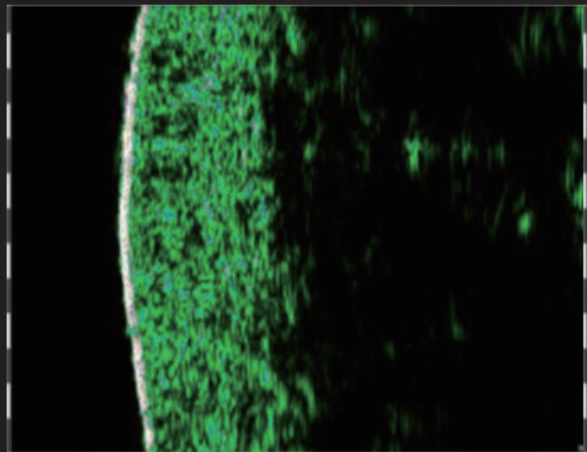
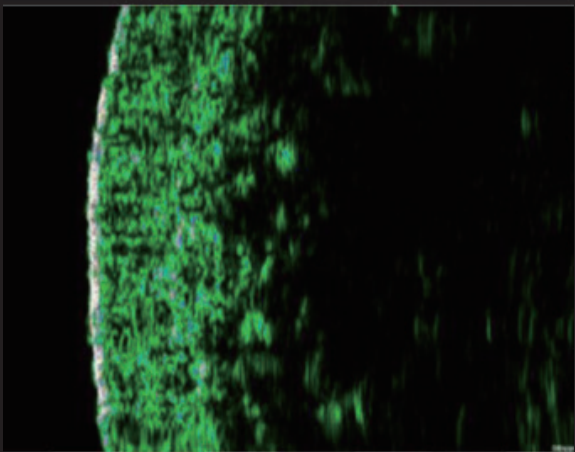
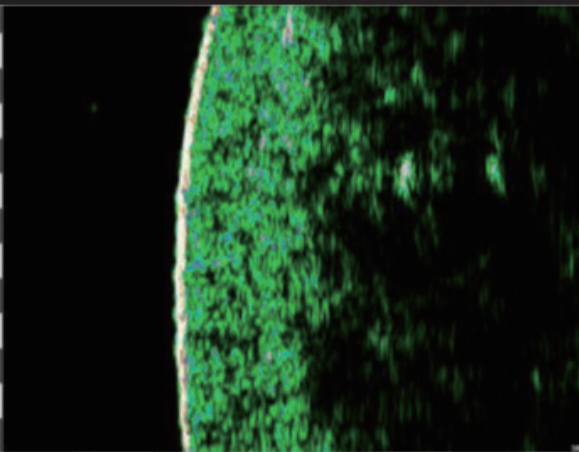
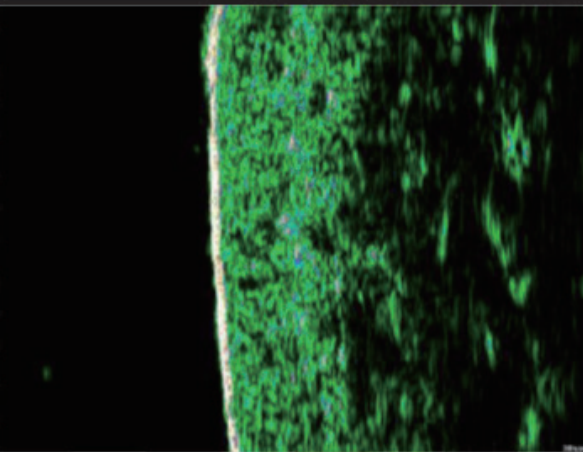
Period	Immediate	4 Weeks	8 Weeks
MFU	9.48%	10.19%	17.48%
MFU + RF	18.23%	23.34%	24.99%
Comparative Advantage	1.9times	2.3times	1.4times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

08

Synergy Effect Introduction
| Skin Density (Case 1)

Using ultrasound imaging, it was confirmed that the thickness and density of the dermal layer have increased. Moreover, when it comes to the MFU+RF combined treatment, the overall thickness and density of the skin increased from the 1st treatment.

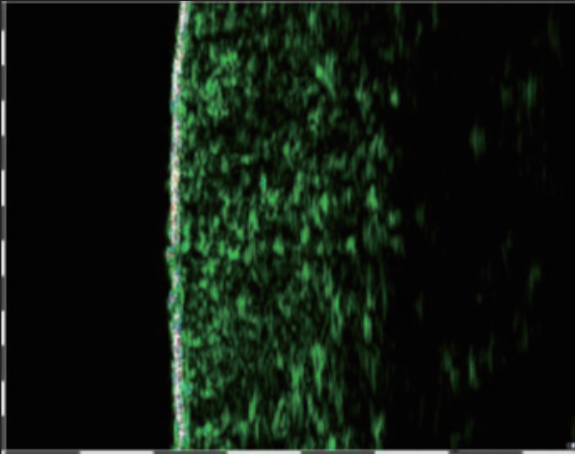
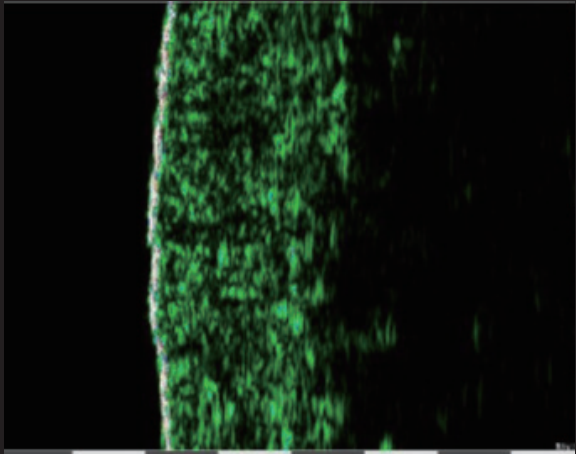
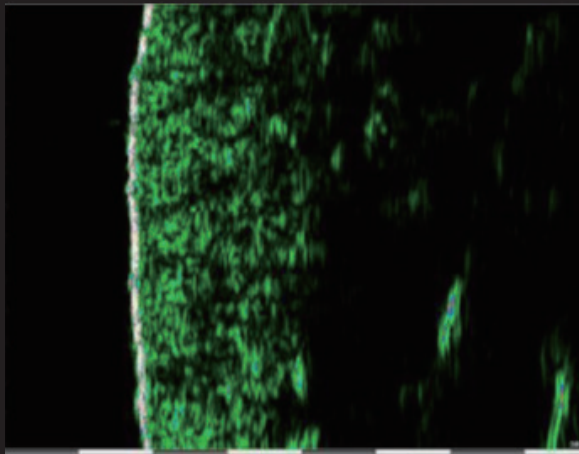
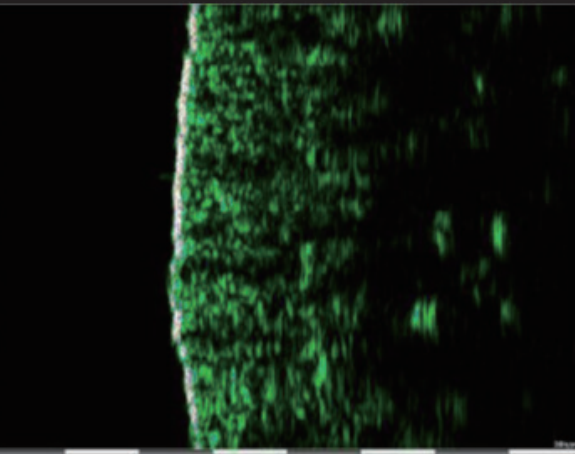
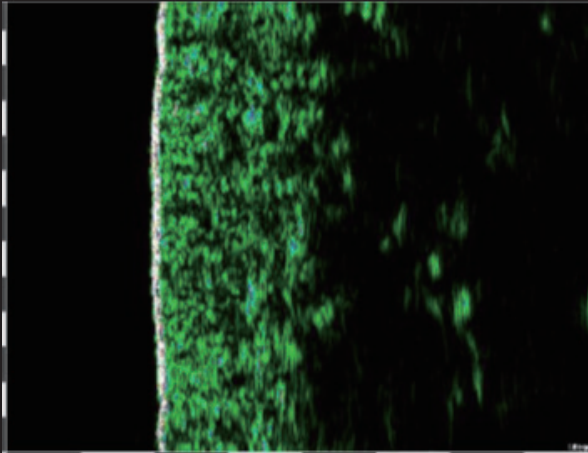
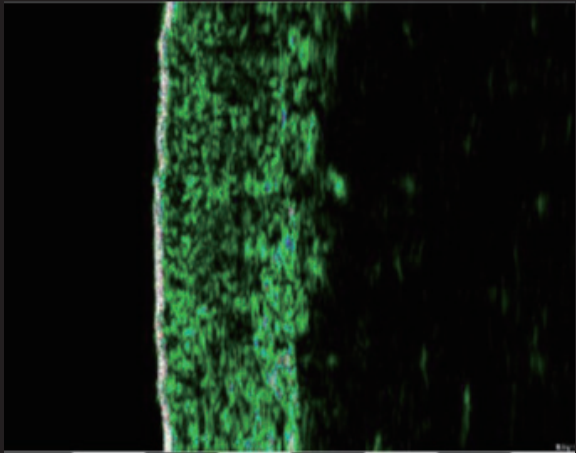
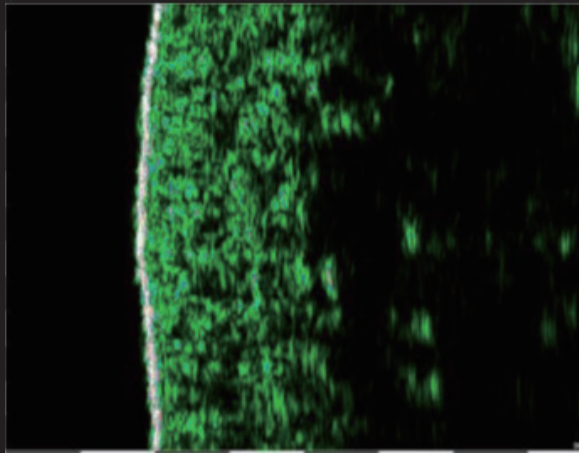
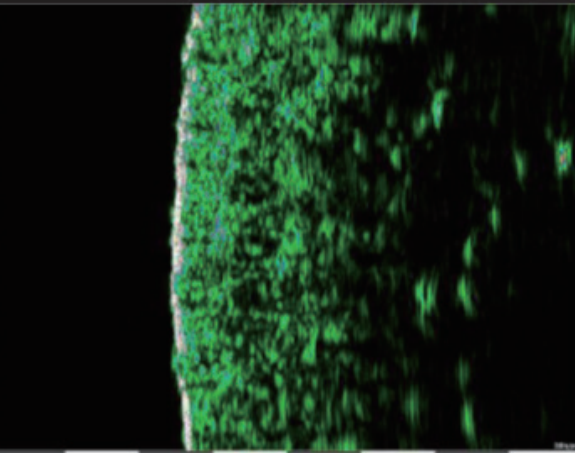
Antera 3D		Skin Density Improvement Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.2.0	Left side (MFU)				
	Right side (MFU+RF)				

※ DUB SkinScanner: Checking the thickness of both cheeks through ultrasound imaging.

08

Synergy Effect Introduction
| Skin Density (Case 2)

Using ultrasound imaging, it was confirmed that the thickness and density of the dermal layer have increased. Moreover, when it comes to the MFU+RF combined treatment, the overall thickness and density of the skin increased from the 1st treatment.

Antera 3D		Skin Density Improvement Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.06	Left side (MFU)				
	Right side (MFU+RF)				

※ DUB SkinScanner: Checking the thickness of both cheeks through ultrasound imaging.

09

Synergy Effect Introduction
| Skin Hydration

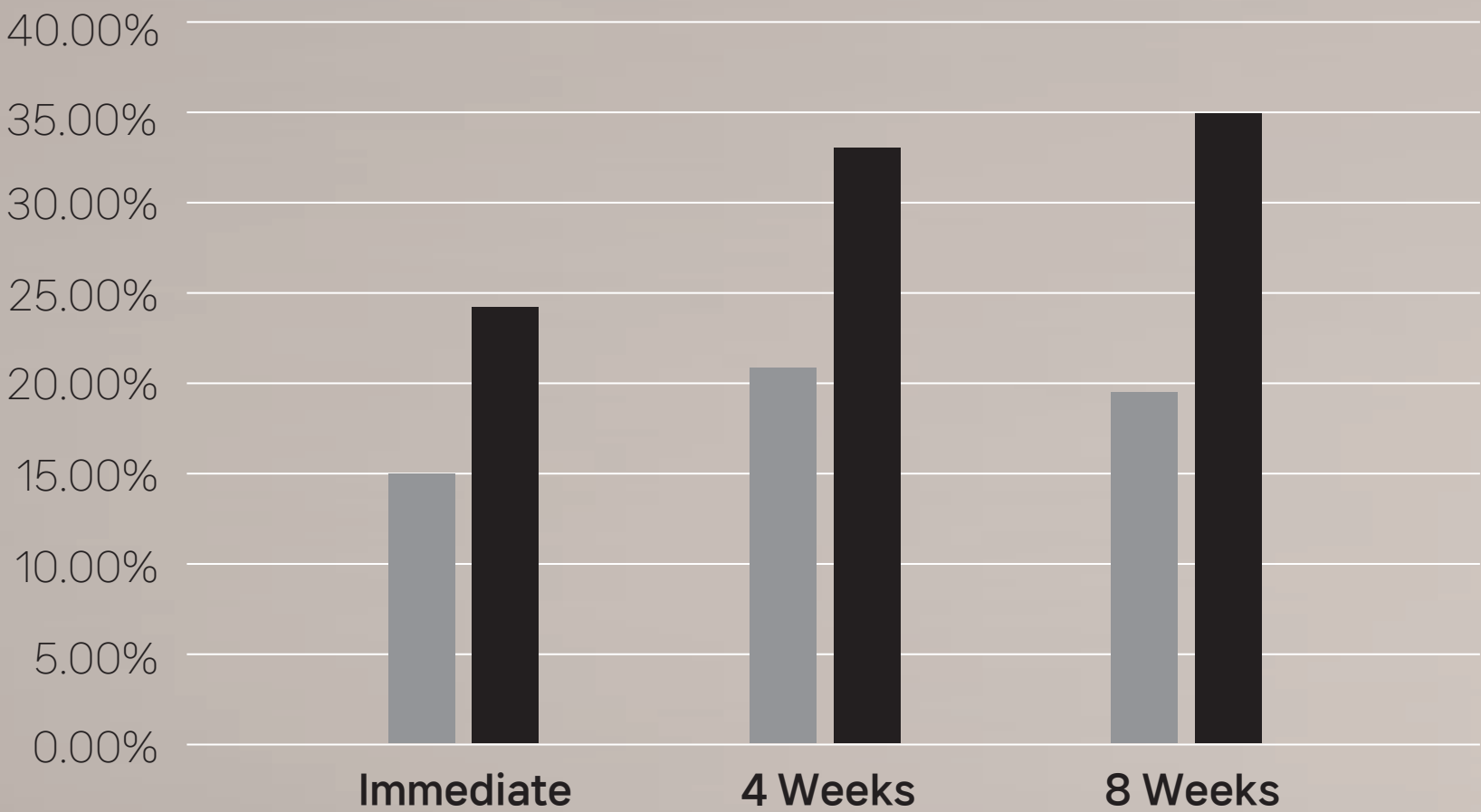
MFU+RF Synergy
Effect: Up to 1.8 times
greater improvement
in the hydration level
of the outer skin layer

Improvement(%)

MFU only

MFU + RF

Comparison of average permittivity after imaging the skin surface of the cheek area



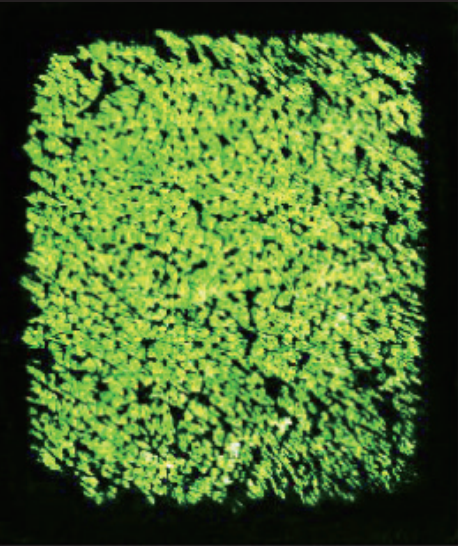
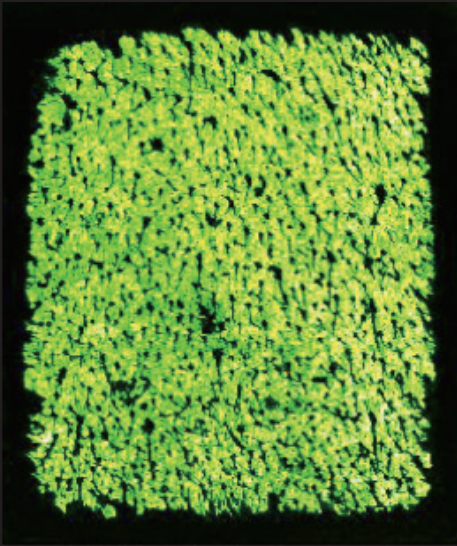
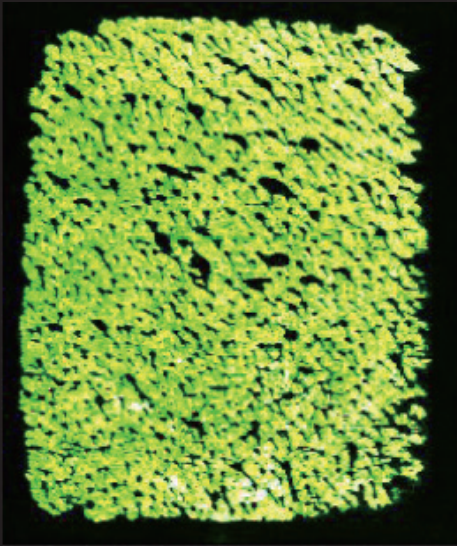

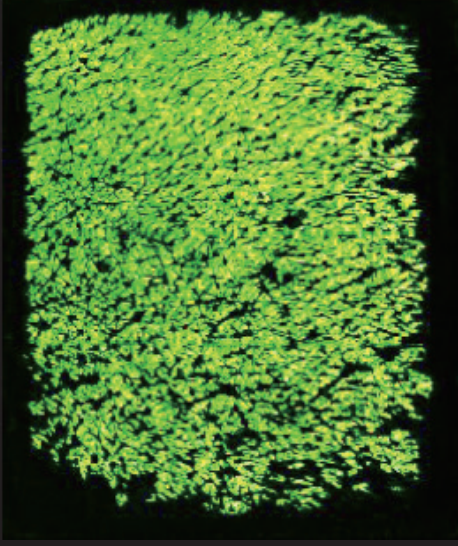
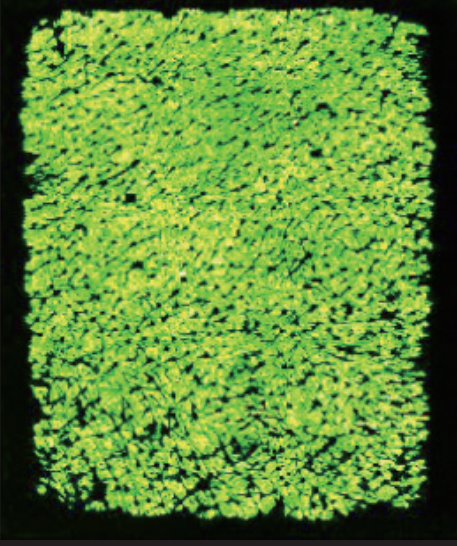
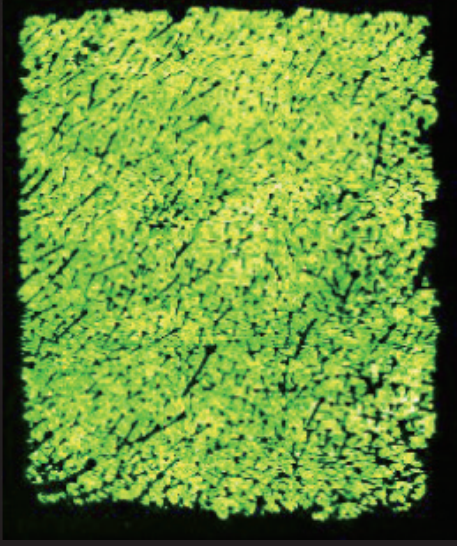
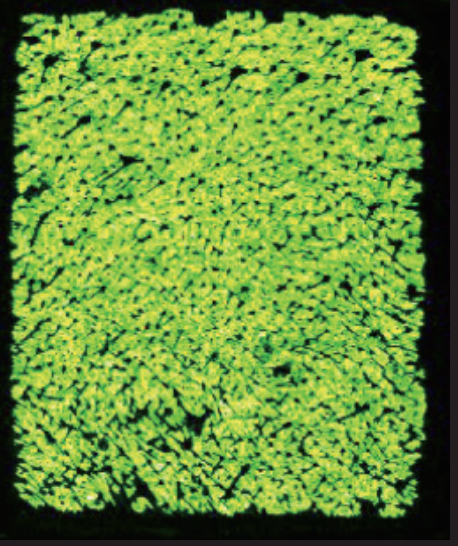
Period	Immediate	4 Weeks	8 Weeks
MFU	15.59%	20.93%	19.26%
MFU + RF	24.02%	33.21%	34.90%
Comparative Advantage	1.5times	1.6times	1.8times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

09

Synergy Effect Introduction
| Skin Hydration (Case 1)

Through skin surface imaging, it was confirmed that the average dielectric permittivity of the outer skin layer has increased. Moreover, when looking at the MFU+RF combined treatment, the overall average dielectric permittivity has increased from the 1st treatment.

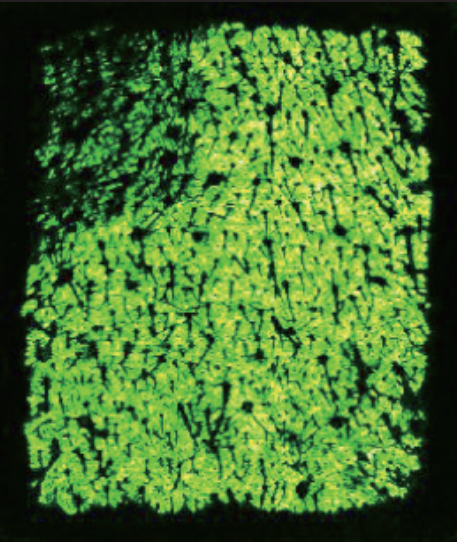
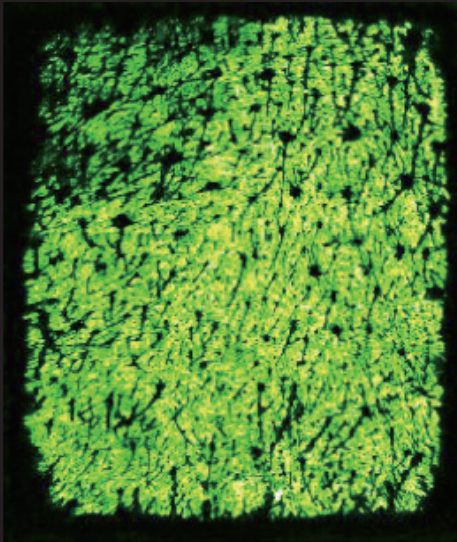
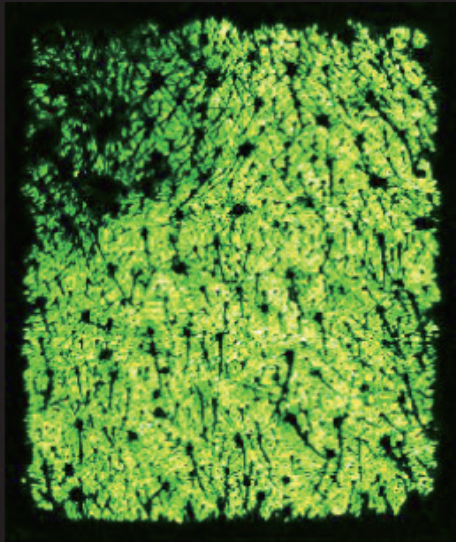
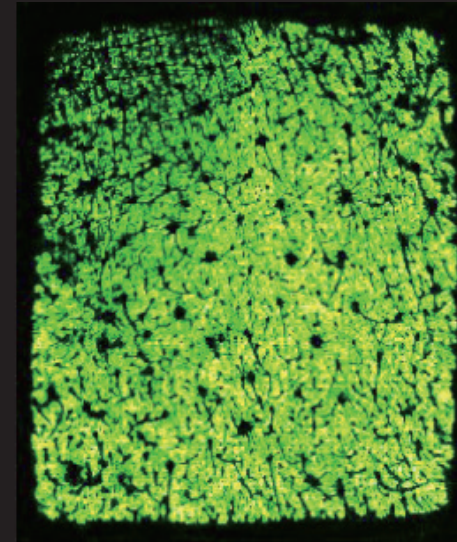
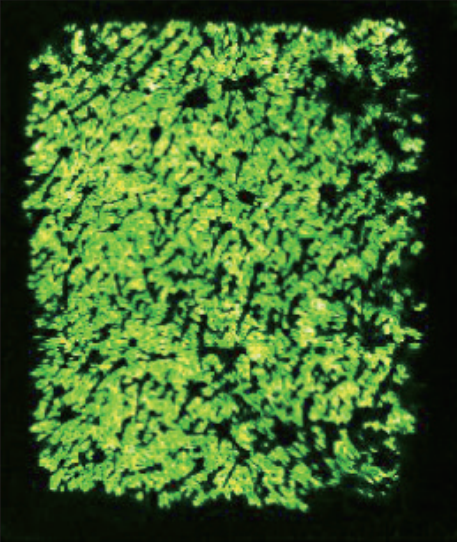
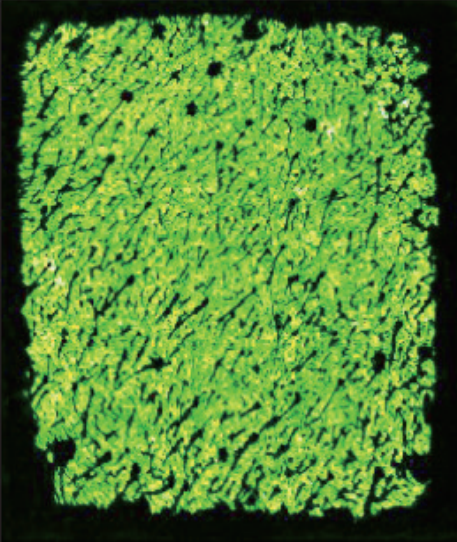
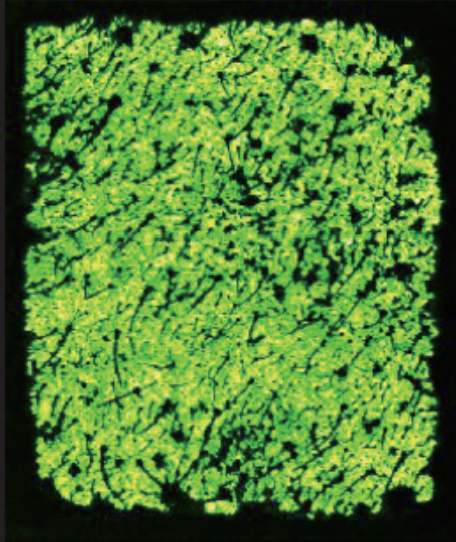
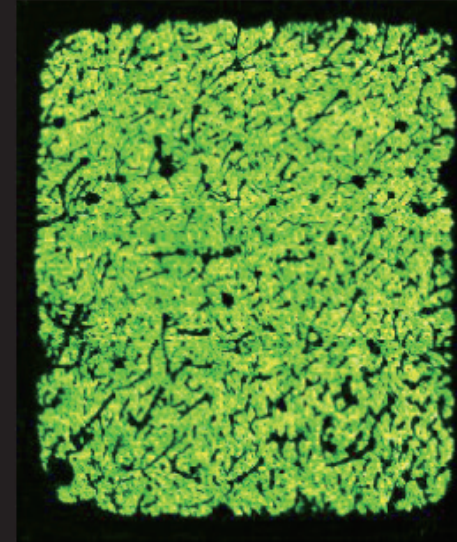
Antera 3D		Outer Skin Layer Hydration Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.05	Left side (MFU)				
	Right side (MFU+RF)				

※ Checking the average permittivity after imaging the skin surface of the cheek area using Epsilon E100.

09

Synergy Effect Introduction
| Skin Hydration (Case 2)

Through skin surface imaging, it was confirmed that the average dielectric permittivity of the outer skin layer has increased. Moreover, when looking at the MFU+RF combined treatment, the overall average dielectric permittivity has increased from the 1st treatment.

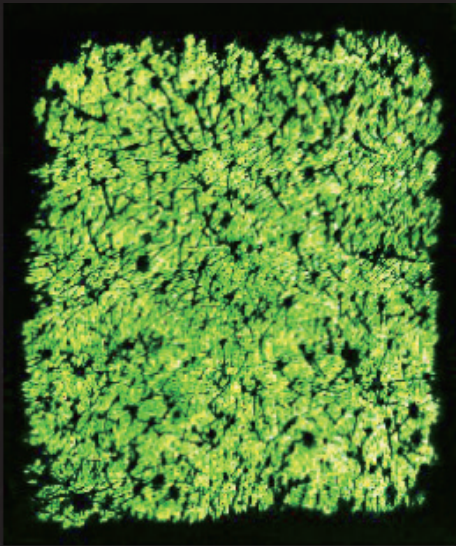
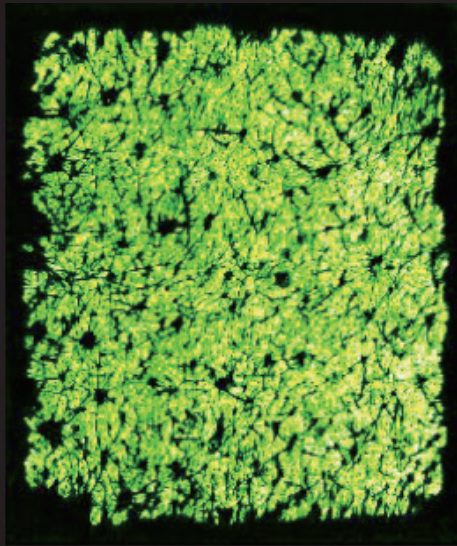
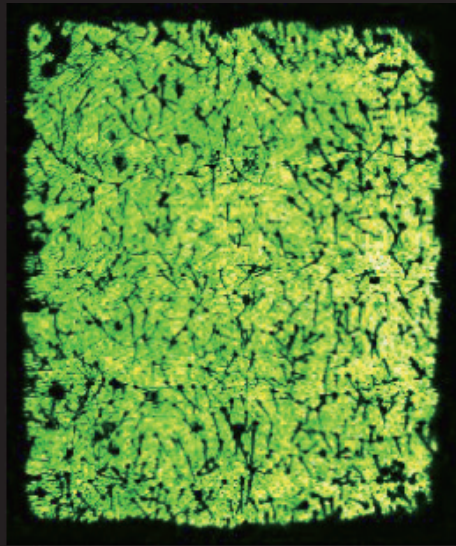
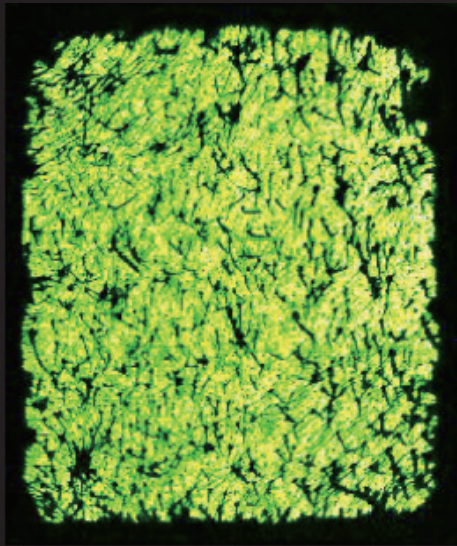
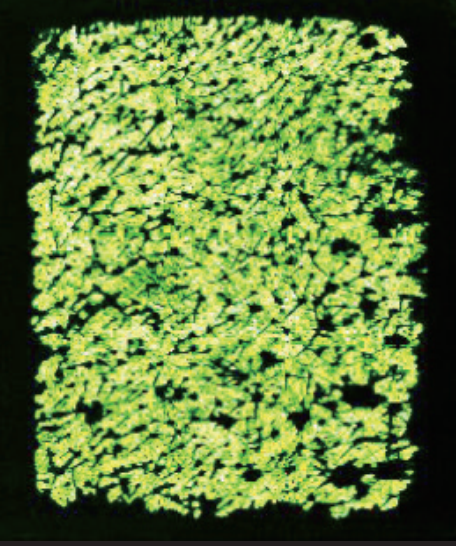
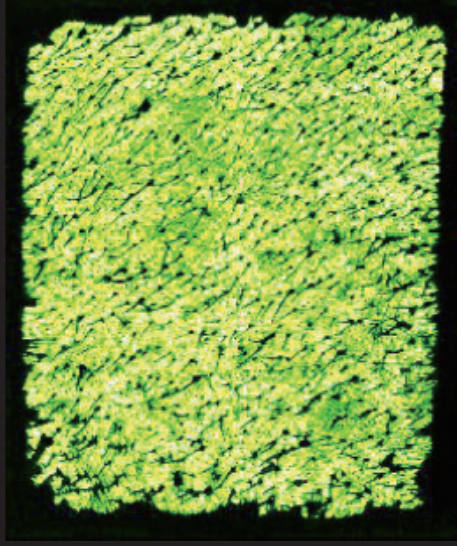
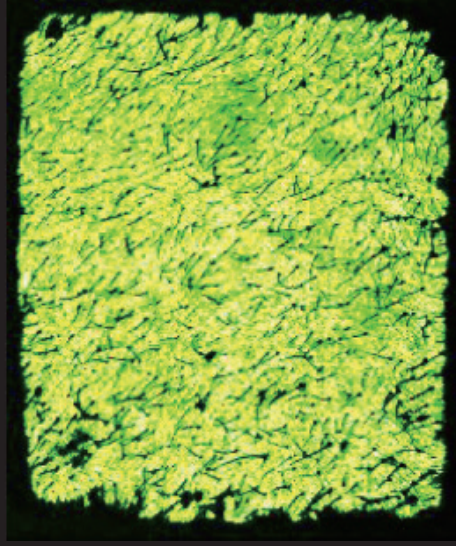
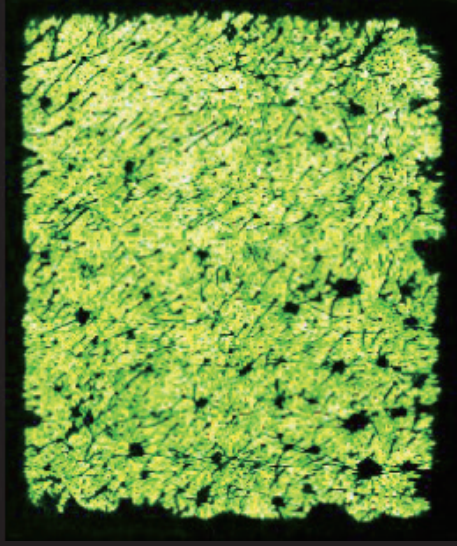
Antera 3D		Outer Skin Layer Hydration Imaging			
Period		Before NEW DOUBLO treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.14	Left side (MFU)				
	Right side (MFU+RF)				

※ Checking the average permittivity after imaging the skin surface of the cheek area using Epsilon E100.

09

Synergy Effect Introduction
| Skin Hydration (Case 3)

Through skin surface imaging, it was confirmed that the average dielectric permittivity of the outer skin layer has increased. Moreover, when looking at the MFU+RF combined treatment, the overall average dielectric permittivity has increased from the 1st treatment.

Antera 3D		Outer Skin Layer Hydration Imaging			
Period		Before NEW DOUBLO (V-RO) treatment (Baseline)	Immediately after treatment	After 4 weeks	After 8 weeks
No.16	Left side (MFU)				
	Right side (MFU+RF)				

※ Checking the average permittivity after imaging the skin surface of the cheek area using Epsilon E100.

09

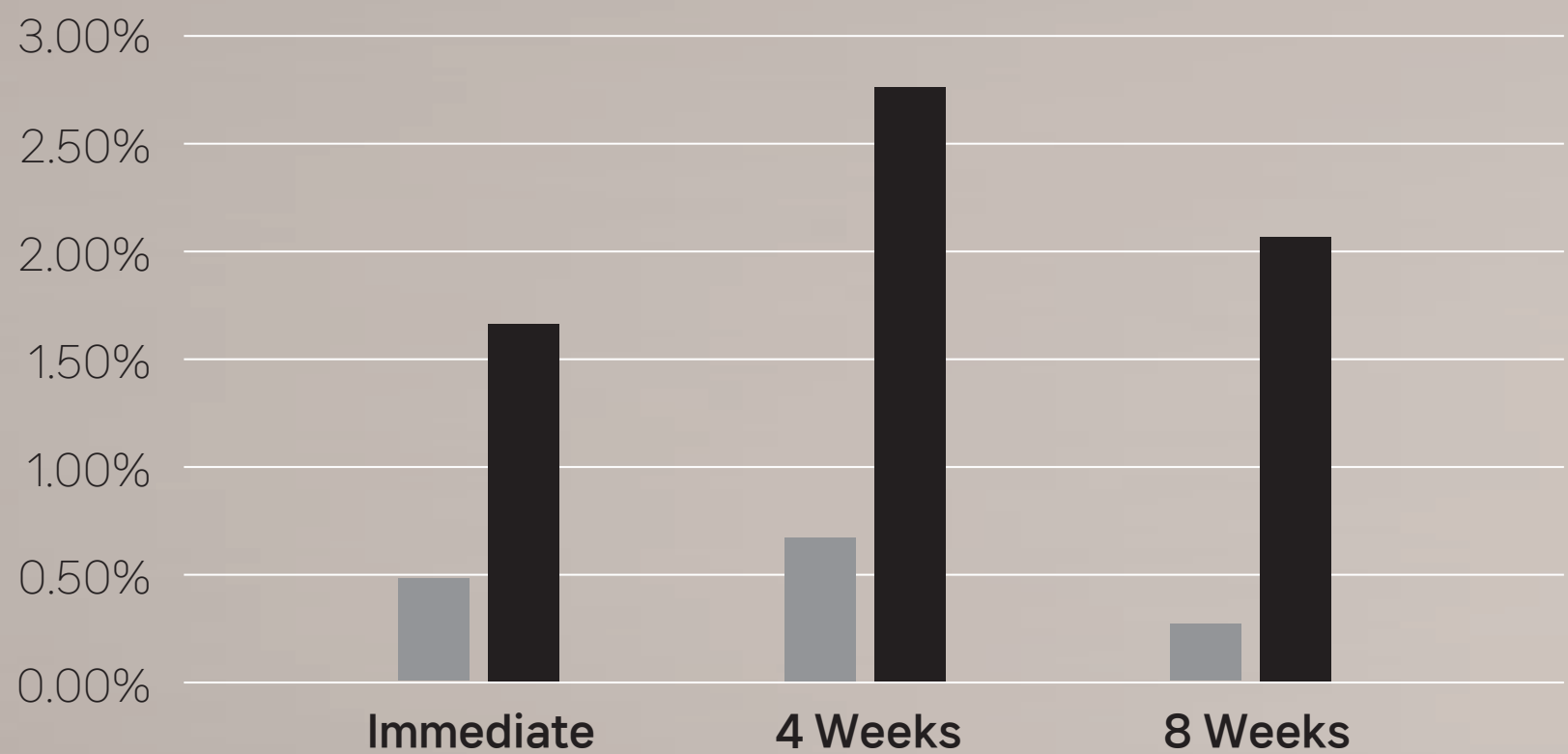
Synergy Effect Introduction
| Skin Hydration

MFU+RF Synergy
Effect: Up to 13.6 times
greater improvement
in the hydration
level of the inner
skin layer

Improvement(%)

- MFU only
- MFU + RF

Moisturemeter D M25 Probe(2.5mm Depth) Tissue Dielectric Constant

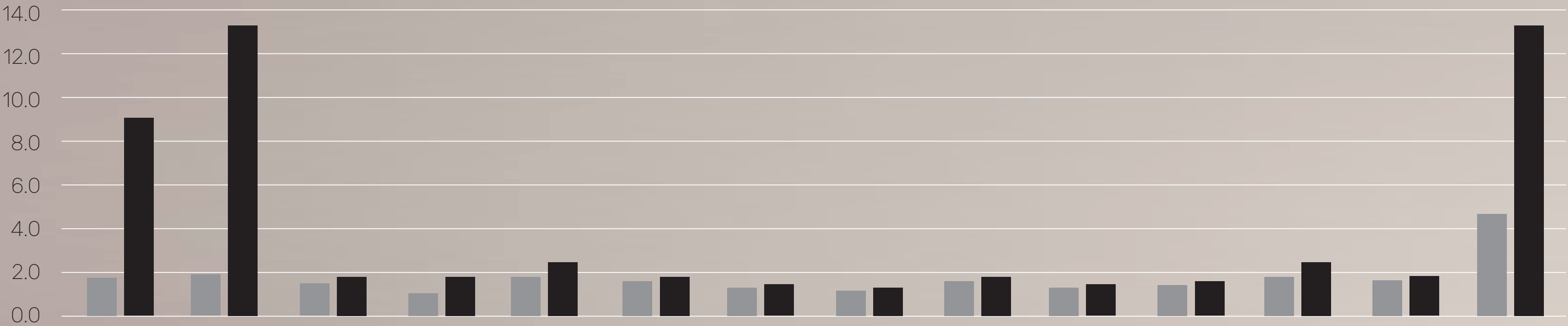


Period	Immediate	4 Weeks	8 Weeks
MFU	0.49%	0.69%	0.15%
MFU + RF	1.59%	2.70%	2.04%
Comparative Advantage	3.3times	3.9times	13.6times

※ Ref. Comparison of MFU+RF cross-irradiation mode and MFU-alone irradiation mode in NEW DOUBLO H/P: Human application test results. Comparative advantage over the control group: 100%.

Summary

Comparative advantage in the improvement rate of MFU+RF treatment compared to MFU alone treatment within the test period



	Pore density	Pore number	Max pore depth	Pore volume	Average roughness	Outer skin elasticity	Inner skin elasticity	Skin resilience	Eye wrinkles	Nasolabial folds	Jawline lifting	Skin density	Outer skin hydration	Inner skin hydration
Average	1.8	2.0	1.6	1.2	1.7	1.4	1.3	1.2	1.4	1.3	1.4	1.8	1.7	4.8
Maximum	9.0	13.3	1.8	1.8	2.3	1.5	1.4	1.3	1.6	1.4	1.6	2.3	1.8	13.6

Comparative advantage based on 14 criteria was confirmed for the MFU+RF treatment (against MFU alone). A significant difference was observed in the improvement of pore density, number of pores, and inner skin hydration, with an average improvement of 1.8 times and a maximum improvement of 13.3 times.

NEW DOUBLO is the world's first MFU+RF combined technology implementation. Through MFU+RF synergy effect, it provides outstanding treatment effects in terms of skin hydration, elasticity, and wrinkle improvement.

※ This product is a 'medical device,' and its intended purposes of use are as follows:

- 1) Focused ultrasound stimulation system: A device used for eyebrow lifting by coagulating tissue using focused ultrasound.
- 2) General-purpose electrosurgical device: A device used for coagulation using radiofrequency.
- 3) Radiofrequency stimulator: A device used to relieve pain by applying radiofrequency energy to the human body.

※ Please note that the results of 'Collagen and elastin activation (HBSI-PFU-22020, preclinical performance and safety evaluation test)' and 'Effect of improving wrinkles around the eyes and nasolabial folds (HM-P22-0270, human application test)' are provided to help medical staff understand the test. This data is for informational purposes and does not imply the effectiveness or intended purpose of use of the medical device.