MELINE

Classic | Deep | Volume | No.3

Why Hyaluronic Acid Dermal Fillers?

Safety

Hyaluronic acid is a biopolymer compound composed of N-acetylglucosamine and glucuronic acid.
It is a biocompatible hydrophilic substance that absorbs and stores 300 to 1,000 times its own weight in water and is present in joint fluid, cartilage, tears, etc. along with collagen and elastin, and 1/3 of the body's reserves are degraded and absorbed every day. It helps to regenerate the skin by regulating the function of the skin barrier and moisturizing the wound quickly.

In addition, hyaluronic acid is the most important substance that constitutes the human dermis along with collagen and elastin, has the lowest immune response and allergy induction rate, and it is 100% decomposed and absorbed by the human body's metabolism after injection and 100% discharged outside the body in the form of water.

Therefore, it is the safest of the currently developed dermal filler's raw materials.

Immediate effect

Immediately after injection into the dermis layer of wrinkles and volume loss areas caused by loss of dermal components, it absorbs and expands the surrounding moisture to fill the wrinkles and volume loss areas and brighten the skin color.

Immediate correction and complete removal

If you need to remove the injected dermal fillers due to low cosmetic satisfaction or serious side effects after the procedure, dermal fillers made of substances other than hyaluronic acid require surgical procedures such as skin incision and removal of the treatment site, but hyaluronic acid dermal fillers are easy to correct and remove because they can be 100% removed within 48 hours by injecting hyaluronidase, a type of enzyme.

Highest preference due to proven effectiveness and safety

With its proven safety and immediate effectiveness,
it occupies more than 92% of the global market share of dermal fillers.

Manufactured in South Korea under a strict quality management system

Biostandard has secured the highest level of quality system by obtaining GMP and ISO13485 certification from the Korea Ministry of Food and Drug Safety and ANVISA certification from Brazil and develops and produces the products by establishing high-level quality control standards.

In particular, HA Dermal Filler produced by Biostandard has excellent safety and efficacy in removing temporary wrinkles, restoring lost volume, and regenerating contours.

Biostandard's research center and production team use the latest equipment to develop and produce the best products, and the quality control team complies with the GMP standards of the Korea Ministry of Food and Drug Safety to ensure the safety and stability of products, gaining the trust of customers.

Manufacturer Bio Standard Co., Ltd.

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Fax. +82-31-686-7762
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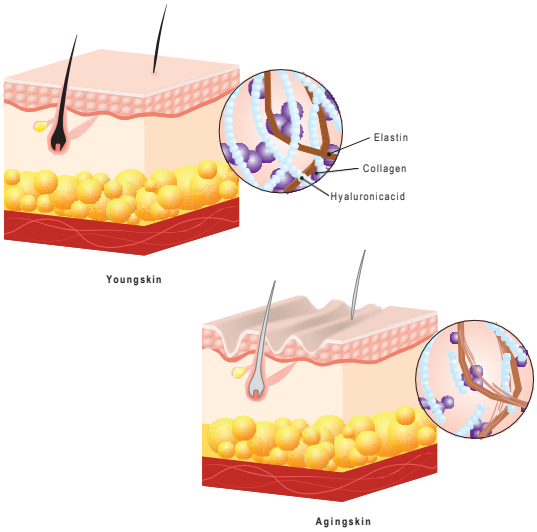
Cause of Skin aging

Structure of young skin and aging skin



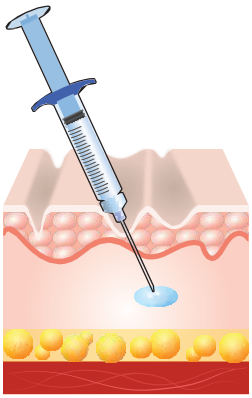
Aging, overwork, drinking and smoking, lack of sleep, stress, etc. reduce the capability to regenerate cells and remove free radicals, leading to a decrease in hyaluronic acid, elastin, collagen, etc. which are the main components of the human dermis. This leads to a decrease in the durability and elasticity of the skin, loss of moisture, and skin aging symptoms such as wrinkle formation, sagging skin, decreased skin tone, and rough skin.

Regeneration of aging skin

Skin Rejuvenation by Injecting HA dermal filler

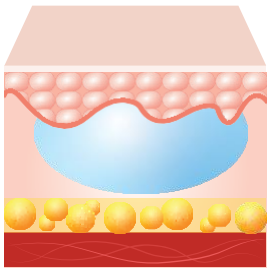
Before

Injecting HA dermal Filler into dermis



After

Injected HA dermal filler corrects wrinkles by expanding through absorbing moisture. Also, it clears skin color with moisturizing effect.



- The only way to repair or regenerate aging skin is to replenish the components of the dermis by injecting substances that stimulate the production of dermis components or dermis components directly into the dermis layer.
- Since cosmetics cannot be supplied in the dermis layer, the only way to supply dermis components to the dermis layer is to inject them into the dermis layer.

MELINE® Line-up

Classic

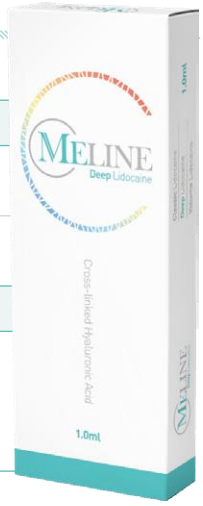
Effectiveness	Duration	Composition
Correction of facia lwrinkles	6 ~ 12 month	Hyaluronic Acid 20mg/ml Lidocaine Hydrochloride 3mg/ml

Features	
Treatment of fine wrinkles	Low swelling

Deep

Effectiveness	Duration	Composition
Correction of facial wrinkles	9 ~15 month	Hyaluronic Acid 20mg/ml Lidocaine Hydrochloride 3mg/ml

Features	
Treatment for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds	Restoring volume of the face



Volume

Effectiveness	Duration	Composition
Correction of facial wrinkles	12 ~18 month	Hyaluronic Acid 20mg/ml Lidocaine Hydrochloride 3mg/ml

Features	
Treatment of shaping the contours of face such as forehead, noses, cheek and chin	Long duration of efficacy

MELINE® Pure Line-up

Classic Non-Lidocaine

Effectiveness	Duration	Composition
Correction of facial wrinkles	6 ~ 12 month	Hyaluronic Acid 20mg/ml

Features	
Treatment of fine wrinkles	Low swelling

Deep Non-Lidocaine

Effectiveness	Duration	Composition
Correction of facial wrinkles	9 ~15 month	Hyaluronic Acid 20mg/ml

Features	
Treatment for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds	Restoring volume of the face

Classic Non-Lidocaine

Effectiveness	Duration	Composition
Correction of facial wrinkles	12 ~18 month	Hyaluronic Acid 20mg/ml

Features	
Treatment of shaping the contours of face such as forehead, noses, cheek and chin	Long duration of efficacy

MELINE® Ultra Line-up

Classic Lidocaine 24

Effectiveness	Duration	Composition
Correction of facial wrinkles	6 ~ 12 month	Hyaluronic Acid 24mg/ml
		Lidocaine Hydrochloride 3mg/ml
Features		
Treatment of fine wrinkles		Low swelling

Deep Lidocaine 24

Effectiveness	Duration	Composition
Correction of facial wrinkles	9 ~15 month	Hyaluronic Acid 24mg/ml
		Lidocaine Hydrochloride 3mg/ml
Features		
Treatment for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds		Restoring volume of the face

Volume Lidocaine 24

Effectiveness	Duration	Composition
Correction of facial wrinkles	12 ~18 month	Hyaluronic Acid 24mg/ml
		Lidocaine Hydrochloride 3mg/ml
Features		
Treatment of shaping the contours of face such as forehead, noses, cheek and chin		Long duration of efficacy

Contour Lidocaine 24

Effectiveness	Duration	Composition
Correction of facial wrinkles	12 ~18 month	Hyaluronic Acid 24mg/ml
		Lidocaine Hydrochloride 3mg/ml
Features		
Treatment of shaping the contours of face such as forehead, noses, cheek and chin		Longer duration of efficacy

Advantages of MELINE

Safety

- Pharmacopeia-listed raw materials
- Removal of residual cross-linkers before sterilization
- Quality standards set at pH 7.0 and osmolarity (appox. 300 mmol/kg) to minimize immune reactions such as erythema, bruising and swelling.
- Use of BDDE, a cross-linker that is approximately 12 times less toxic than DVS

Patient's Satistaction

- Natural volumization

MELINE

Doctor's Satisfaction

- Constant injection pressure for easy & comfortable procedure

Excellent efficacy proven through clinical trials

- Excellent efficacy proven through clinical trials comparing the safety and stability of Galderma Laboratories' Restylane LYFT, one of the world's best products, and MELINE.

Longevity

- Improved cross-linking reaction and no addition of non-cross-linked hyaluronic acid increases retention period in the body

Safety

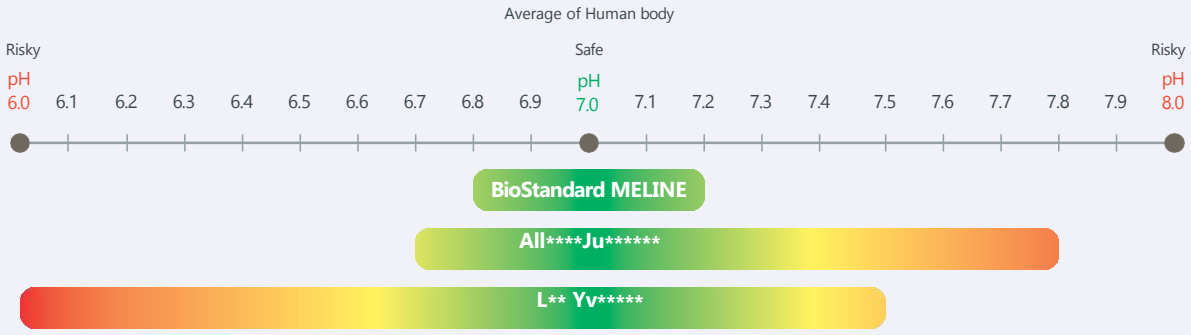
• Minimize allergic reactions by using non-animal hyaluronic acid sources

Non-animal hyaluronic acid raw materials have a significantly lower allergenicity rate than animal products.

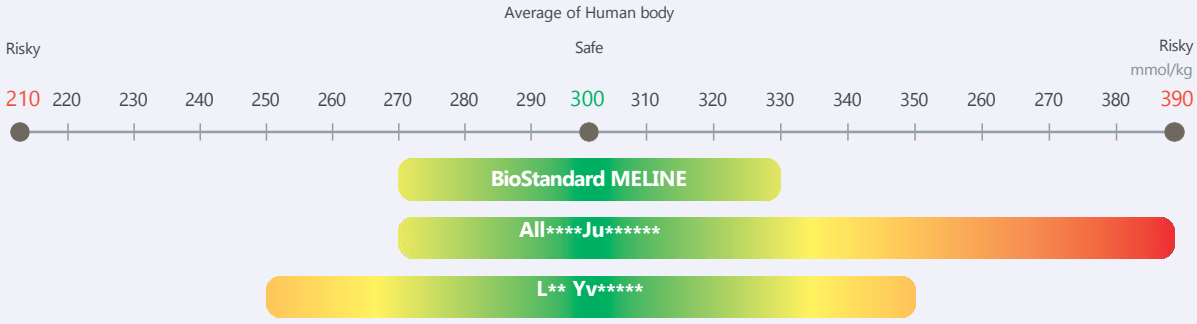
• Quality standards most similar to the human environment

MELINE, manufactured in compliance with quality standards established closest to the human body's average hydrogen ion concentration pH 7.0 and osmotic pressure 300 mmol/kg, minimize human body reactions such as edema, erythema and swelling that occur after injection of extracorporeal substances.

▸Comparative analysis of pH



▸Comparative analysis of Osmolality

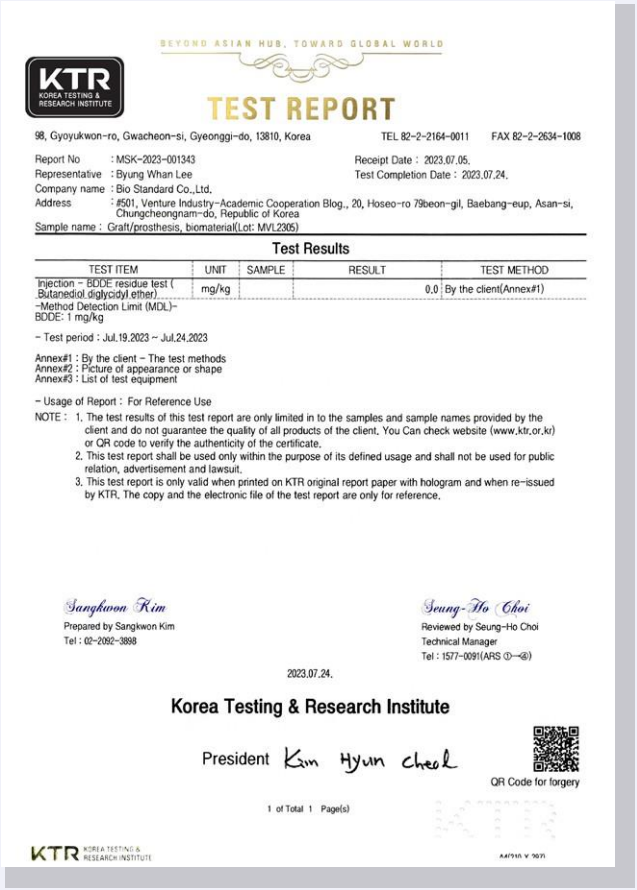


Minimizing sources of side effects

MELINE HA Dermal Fillers have the highest safety by having manufacturing technology that minimizes the detection of endotoxin, unreacted residual crosslinking agent (BDDE), and protein load, which are the main causes of side effects.

0 ppm of residual cross-linker detected

Biostandard performs a dialysis process (more than 6 dialysis sessions over 2 weeks) that is more than twice that of its competitors to completely remove residual cross-linking agents after cross-linking, preventing the possibility of side effects caused by residual cross-linking agents.



BEYOND ASIAN HUB, TOWARD GLOBAL WORLD

KTR KOREA TESTING & RESEARCH INSTITUTE

TEST REPORT

98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do, 13810, Korea TEL 82-2-2164-0011 FAX 82-2-2634-1008

Report No : MSK-2023-001343
Representative : Byung Whan Lee
Company name : Bio Standard Co.,Ltd.
Address : #501, Venture Industry-Academic Cooperation Blog., 20, Hoseo-ro 79beon-gil, Baebang-eup, Asan-si, Chungcheongnam-do, Republic of Korea
Sample name : Graft/prosthesis, biomaterial(Lot: MVL2305)

Receipt Date : 2023.07.05.
Test Completion Date : 2023.07.24.

Test Results

TEST ITEM	UNIT	SAMPLE	RESULT	TEST METHOD
Injection - BDDE residue test (Butanediol diglycidyl ether) -Method Detection Limit (MDL)- BDDE: 1 mg/kg	mg/kg		0.0	By the client(Annex#1)

- Test period : Jul.19.2023 ~ Jul.24.2023

Annex#1 : By the client - The test methods
Annex#2 : Picture of appearance or shape
Annex#3 : List of test equipment

- Usage of Report : For Reference Use

NOTE : 1. The test results of this test report are only limited in to the samples and sample names provided by the client and do not guarantee the quality of all products of the client. You Can check website (www.ktr.or.kr) or QR code to verify the authenticity of the certificate.
2. This test report shall be used only within the purpose of its defined usage and shall not be used for public relation, advertisement and lawsuit.
3. This test report is only valid when printed on KTR original report paper with hologram and when re-issued by KTR. The copy and the electronic file of the test report are only for reference.

Sangkwon Kim
Prepared by Sangkwon Kim
Tel : 02-2092-3898

Seung-Ho Choi
Reviewed by Seung-Ho Choi
Technical Manager
Tel : 1577-0091(ARS ①→④)

2023.07.24.

Korea Testing & Research Institute

President Kim Hyun cheol

QR Code for forgery

1 of Total 1 Page(s)

KTR KOREA TESTING & RESEARCH INSTITUTE

▶Measurement data from the Korea Testing & Research Institute

Safety Data

Item	Effect	MELINE	Company A	Company B
Endotoxin(EU/mL)	Inflammation	<0.03	0.5	0.5
BDDE(ppm)	Allergic Reaction	0	<2	<2
Protein Load(ppm)	Allergic Reaction	<0.03	<0.06	<0.05
pH	Pain causing	7.0	7.2	7.3

Satisfaction

Minimize pain with lidocaine

Optimal viscoelasticity

Since physical properties should be applied differently depending on the treatment area, wrinkle size and volume loss, BioStandard has designed optimal viscoelasticity with the appropriate combination of viscosity and elasticity for each product type.

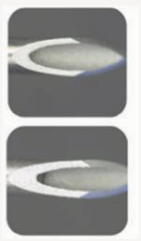
By selecting the appropriate product type according to the skin condition and treatment location, the best skin regeneration effect can be expected during the procedure.

Convenience

Product	Biostandard MELINE	Allergan Juvederm	LG Ycoire
Injection pressure(N)	10 ~ 22	6 ~ 14	≤40

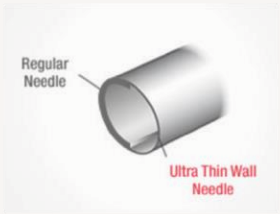
Constant injection pressure for comfortable procedure

Stable and comfortable with constant injection pressure enabling precise procedures

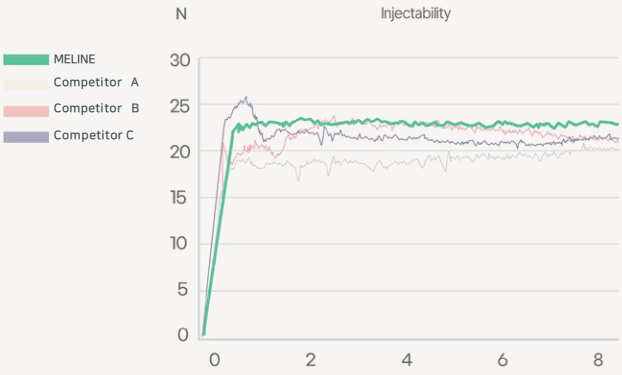


ULTRA Thin Wall

Competitor
Thin Wall



The difference in the inner diameter of the injection needle due to the difference in the thickness of the injection needle wall

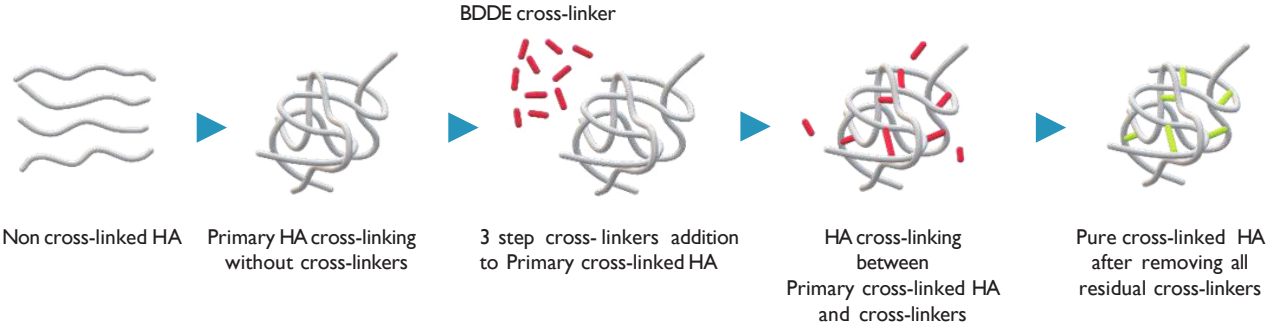


Longevity

Securing long-term volumization through the 3step's cross-linking process using SHINE Technology.

Hyaluronic acid is generally degraded, absorbed, and discharged outside the body within a maximum of 48 hours after injection.

It is essential for hyaluronic acid dermal fillers to extend their retention period in the body through a cross-linking process that strengthens the structure of hyaluronic acid so that it does not easily decompose in the body. SHINE Technology developed by Biostandard is a 3step's cross-linking process that can last in the body for 6 to 18 months depending on the type, so the wrinkle removal and volumization expansion effects are maintained for a long time.



Valid Characteristic

Useful product for deep wrinkles with both monophasic and biphasic properties

Eulji University Medical Center research team who conducted the clinical trial confirmed and stated that the newly developed MELINE Volume No.3 (MHA) was less painful during procedure (VAS) and had a superior wrinkle improvement effect (WSRS) compared to Restylane LYFT (BHA) which is very strong at improving deep wrinkles.

※Lower WSRS scores indicate superior wrinkle improvement. ※ Lower VAS scores indicate less pain.

In addition, it was stated that "MELINE Volume No.3 (MHA) appears to be a material that has the characteristics of both monophasic and biphasic polydensified filler."

ORIGINAL ARTICLE

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pISSN: 2234-0831 eISSN: 2288-9337

aaps Archives of Aesthetic Plastic Surgery

Comparison of the efficacy and safety between a new monophasic hyaluronic acid filler and a biphasic hyaluronic acid filler in correcting facial wrinkles

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[2]Department of Plastic and Reconstructive Surgery, Nowon Eulji Medical Center, Eulji University School of Medicine, Seoul, Korea

This work was supported by a grant from the Korea Medical Device Development Fund, funded by the Korean government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health and Welfare, the Ministry of Food and Drug Safety) (Project Number: 1711138448, KMDF_PR_20200901_0215).

Background The longstanding and common use of hyaluronic acid (HA) has driven the expanded development of various commercial HA fillers. However, differences in the components of these HA fillers lead to variations in their effect. We compared the in vivo safety and efficacy of biphasic HA (BHA) and a new monophasic HA (MHA) for improving facial wrinkles. We investigated differences in outcomes after their injection into nasolabial folds (NLFs) using the Wrinkle Severity Rating Scale (WSRS), patient satisfaction using the Global Aesthetic Improvement Scale (GAIS), and pain using a visual analog scale (VAS). We also performed a safety assessment of the two fillers.
Methods This matched-pair, double-blind, randomized study compared the degree of temporal wrinkle improvement in the NLFs of 91 participants using the BHA filler versus the new MHA filler. Safety and efficacy were compared at 8 and 24 weeks.
Results At 24 weeks after application, the average WSRS scores were 2.17±0.72 (BHA) and 2.07±0.71 (MHA) (P=0.034). The average GAIS scores, as measured by a treating investigator at 8 weeks and 24 weeks, were 0.94±0.76 (BHA) and 0.98±0.78 (MHA) at 8 weeks (P=0.181), and 0.44±0.64 (BHA) and 0.49±0.69 (MHA) at 24 weeks (P=0.103). The VAS pain score was 0 points at 30 minutes after filler application in both groups.
Conclusions Both the BHA filler and the new MHA filler were safe and effective for improving facial wrinkles in NLFs, but the new MHA filler was more effective for the cosmetic improvement of wrinkle severity than the BHA filler.

Keywords Skin aging / Hyaluronic acid / Dermal fillers / Efficacy / Safety

Source :
https://doi.org/10.14730/aaps.2023.00836

Monophasic monodensified fillers such as MELINE Volume No. 3 with lidocaine, share the characteristics of both biphasic and monophasic polydensified fillers; therefore, they can exhibit clumping. (144page)

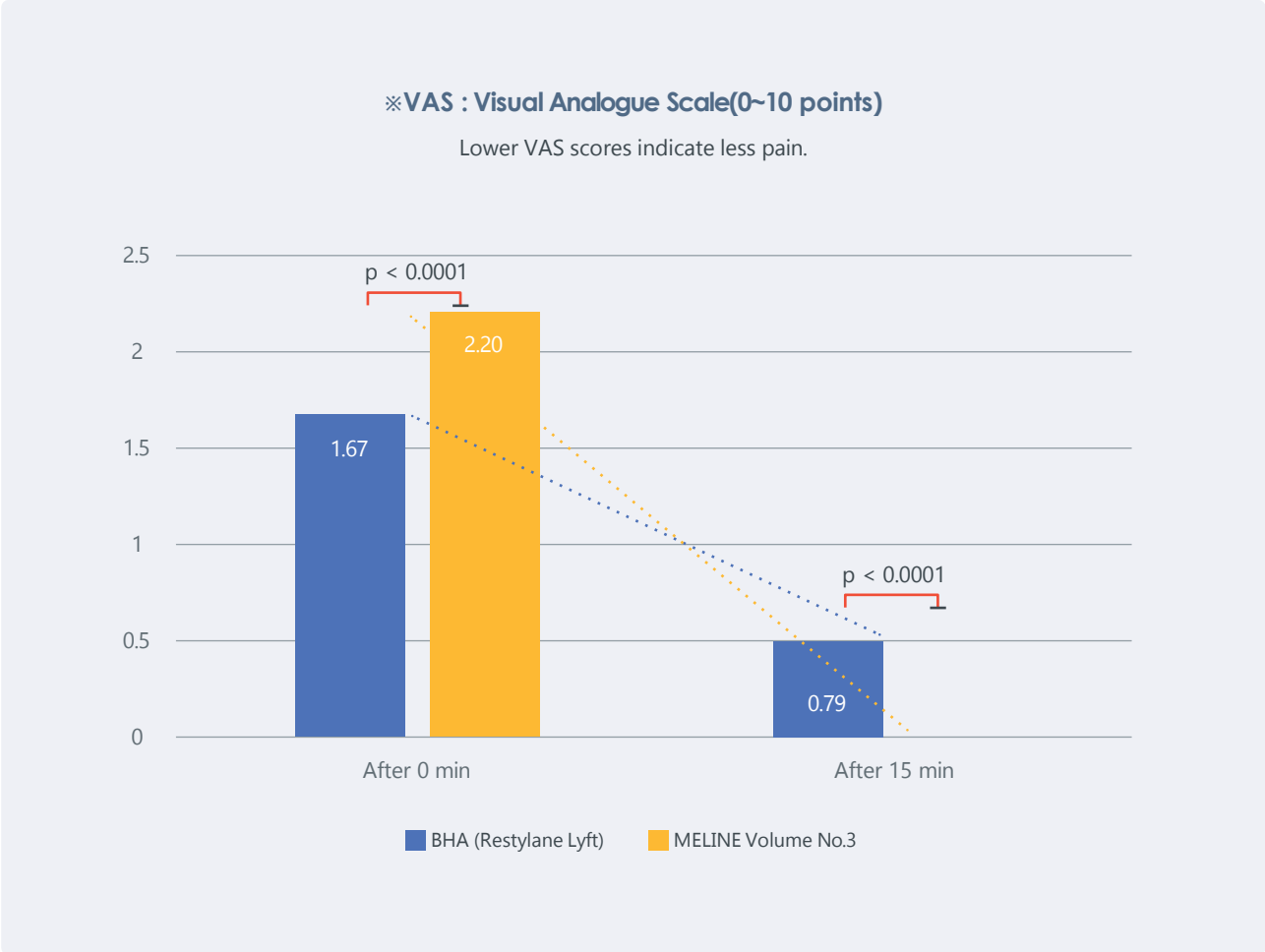
Superior efficacy proved by clinical trials

Eulji University Medical Center research team in Korea conducted a clinical trial comparing the efficacy of Meline Volume No.3, with Retylane LYFT with Lidocaine, one of the world's best HA dermal fillers, and was officially recognized by the Korean Society of Aesthetic Plastic Surgery.

Through a paper published on July 28, 2023 in the journal AAPS (Archives of Aesthetic Plastic Surgery which is the official Journal of the Korean Society for Aesthetic Plastic Surgery), the outstanding efficacy of MELINE Volume No.3 was verified as follows.

MELINE Volume No.3 (MHA) has lower persistence of pain compared to Restylane LYFT (BHA)

The Visual Analogue Scale (VAS) measured immediately right after the procedure showed that MELINE Volume No.3 (MHA) had a relatively higher pain level than Restylane LYFT (BHA). Restylane LYFT was 1.67 points and MELINE Volume No.3 (MHA) was 2.20 points. But at 15 minutes after the injection, the VAS of MELINE Volume No.3 (MHA) was 0 points and Restylane LYFT was 0.79 points confirming that MELINE Volume No.3 (MHA) was less painful than Restylane LYFT (BHA)15 minutes after the procedure.



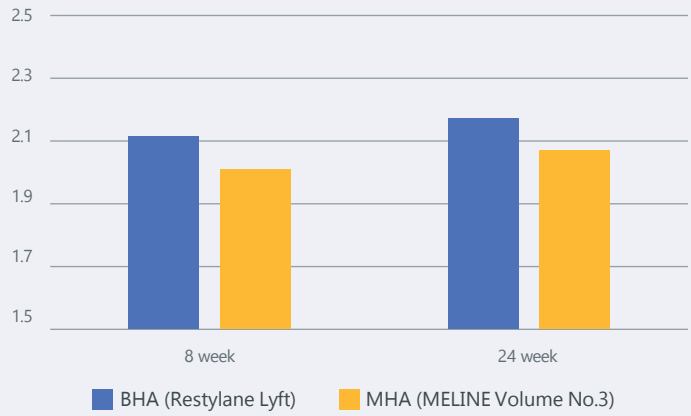
Outstanding wrinkle improvement

Results of a clinical trial to compare the efficacy, safety, and sustainability of wrinkle improvement through the wrinkle improvement visual evaluation (WSRS) 6 months after the procedure of MELINE Volume No.3 (MHA) and Restylane LYFT (BHA), MELINE Volume No.3 (MHA) showed approximately 0.10 better efficacy than Restylane LYFT (BHA) in WSRS values.

※Number of subjucts : 91 (FA set), 90 (PP set)

Table 1. comparison of the efficacy of BHA and MHA fillers for wrinkle improvement

Variable	Evaluator	Time	Mean±SD		Range		P-value
			BHA	MHA	BHA	MHA	
Average WSRS score (n=91)	Independent evaluators	8 wk	2.11±0.72	2.01±0.71	1.0 ~ 0.4		0.055
		24 wk	2.17±0.71	2.07±0.71	1.0 ~ 0.4		0.034

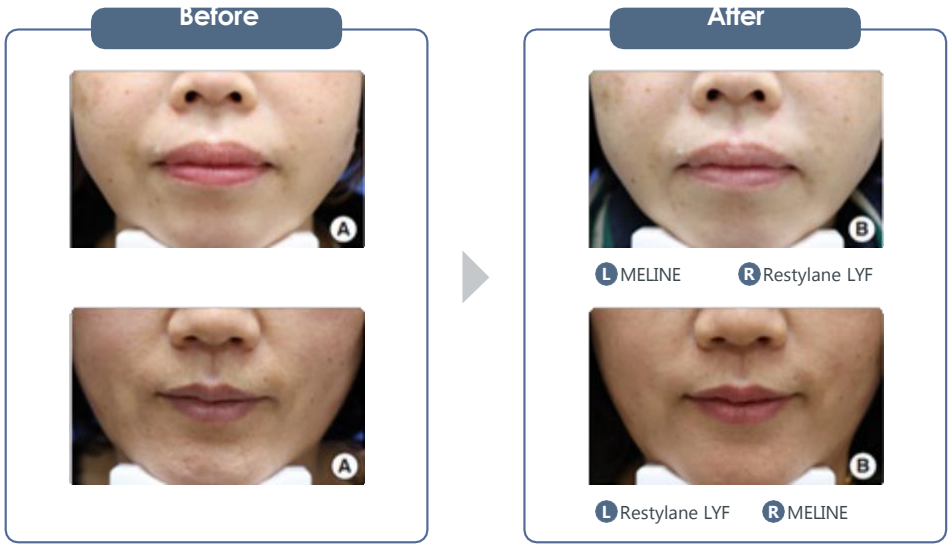


※ WSRS : Wrinkle Severity Rating Scale

Lower WSRS scores indicate sperior level of wrinkle improvement

1 point	2 point	3 point	4 point	5 point
Asent	Mild	Moderate	Severe	Extreme

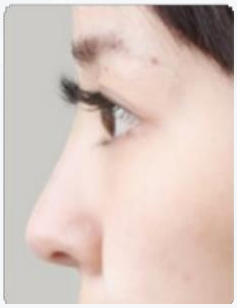
Comparison photos of MELINE Volume No.3 and Restylane Lyft before and after the procedure of nasolabial folds



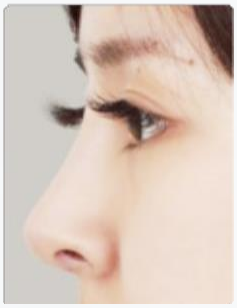
Before & After

Nose

Before



After



Dark circle

Before

After

Lips

Before

After

Nasolabial folds

Before

After