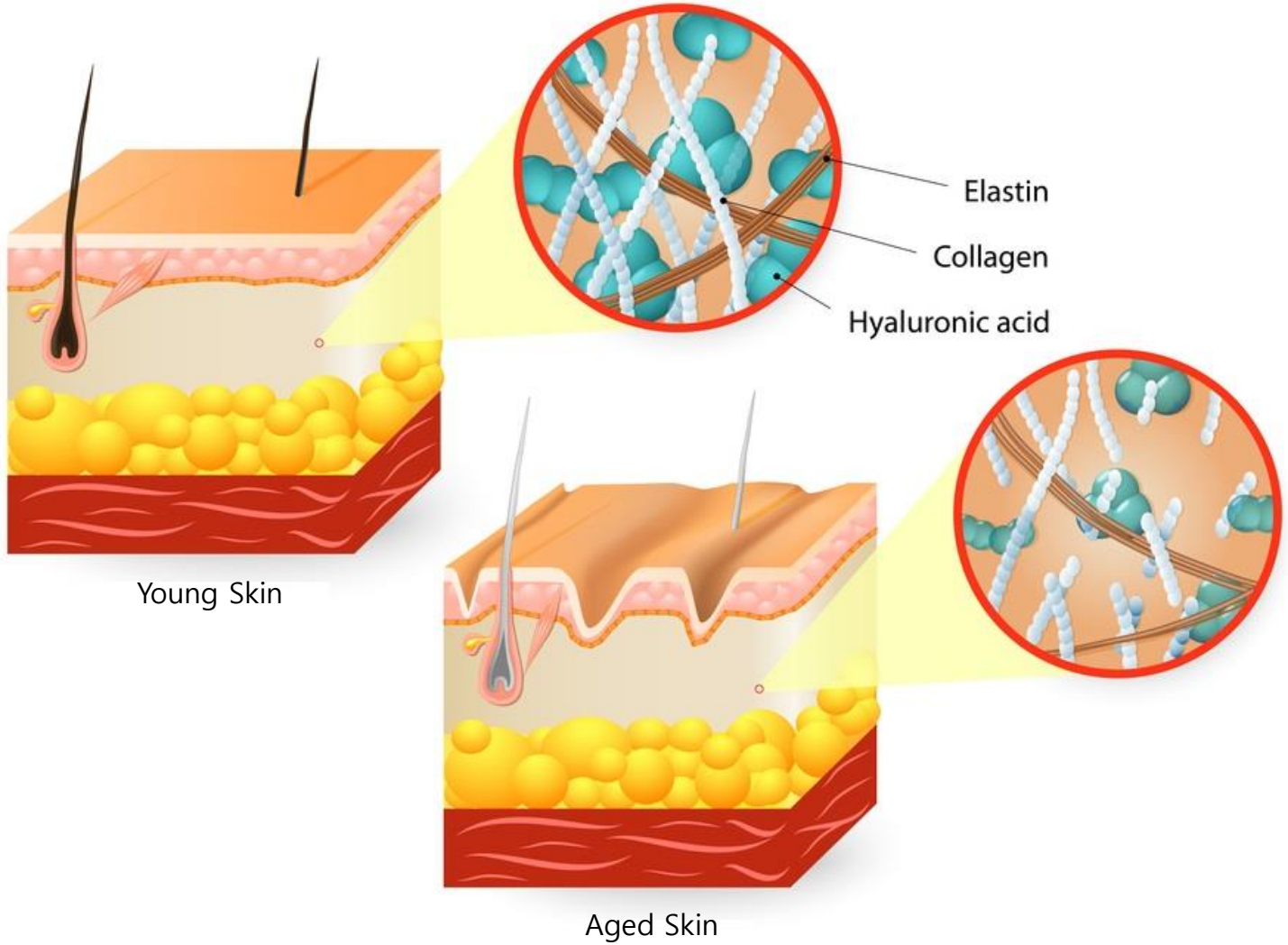
Product Line up

Product Evaluation Criteria and Acceptable Quality Range

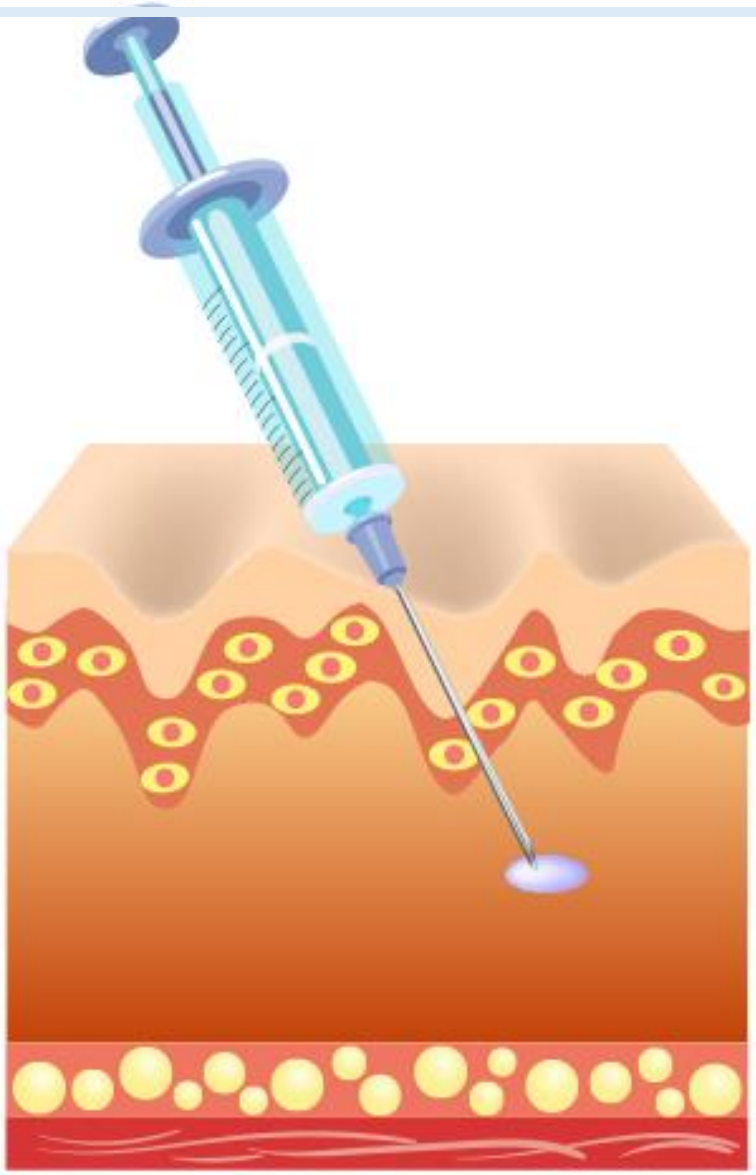
Model Name	MCL-1E	MDL-2E	MVL-3E	UCL-1E	UDL-2E	UDL-3E	UTL-4E	MPC-1E	MPD-2E	MPV-3E
BRAND	**Diamond No.1** Meline Classic Meline Plus Classic Admedic Classic No.1 Admedic Plus No.1	**Diamond No.2** Meline Deep Meline Plus Deep Admedic Deep No.2 Admedic Plus No.2	**Diamond No.3** Meline Volume Meline Plus Volume Admedic Volume No.3 Admedic Plus No.3	Meline Ultra Classic Diamond Plus No.1	Meline Ultra Deep Diamond Plus No.2	Meline Ultra Volume Diamond Plus No.3	**Diamond No.4** Meline Ultra Contour Diamond Plus No.4	Meline Pure Classic	Meline Pure Deep	Meline Pure Volume
pH	6.8 ~ 7.2	6.8 ~ 7.2	6.8 ~ 7.2	6.5~7.5	6.5~7.5	6.5~7.5	6.5~7.5	6.5~7.5	6.5~7.5	6.5~7.5
HA content	20mg/mL	20mg/mL	20mg/mL	24mg/mL	24mg/mL	24mg/mL	24mg/mL	20mg/mL	20mg/mL	20mg/mL
Lidocaine content	3.0mg/mL	3.0mg/mL	3.0mg/mL	3.0mg/mL	3.0mg/mL	3.0mg/mL	3.0mg/mL	N/A	N/A	N/A
Residual BDDE	≤2ppm	≤2ppm	≤2ppm	≤2ppm	≤2ppm	≤2ppm	≤2ppm	≤2ppm	≤2ppm	≤2ppm
Osmorality	270~300mmol/kg	270~300mmol/kg	270~300mmol/kg	250~350 mmol/kg	250~350 mmol/kg	250~350 mmol/kg	250~350 mmol/kg	250~350 mmol/kg	250~350 mmol/kg	250~350 mmol/kg
Endotoxin	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL	< 0.5 EU/mL
Viscoelasticity	30 Pa ≤ G' < 80 Pa	80 Pa ≤ G' < 150 Pa	150 Pa ≤ G' < 300 Pa	40 Pa ≤ G' < 90 Pa	100 Pa ≤ G' < 180 Pa	190 Pa ≤ G' < 290 Pa	300 Pa ≤ G' < 360 Pa	40 Pa ≤ G' < 90 Pa	100 Pa ≤ G' < 180 Pa	190 Pa ≤ G' < 290 Pa
Injectability (25G)	N/A	N/A	18 ~ 22 N	N/A	N/A	9 ~ 15 N	10 ~ 16 N	N/A	N/A	8 ~ 14 N
Injectability (27G)	10 ~ 14 N	14 ~ 18 N	10 ~ 14 N	11 ~ 17 N	14 ~ 20 N	19 ~ 25 N	20 ~ 26 N	10 ~ 16 N	13 ~ 19 N	17 ~ 23 N
Injectability (30G)	16 ~ 24 N	N/A	N/A	20 ~ 26 N	N/A	N/A	N/A	19 ~ 25 N	N/A	N/A

Understanding of Wrinkle improvement mechanism



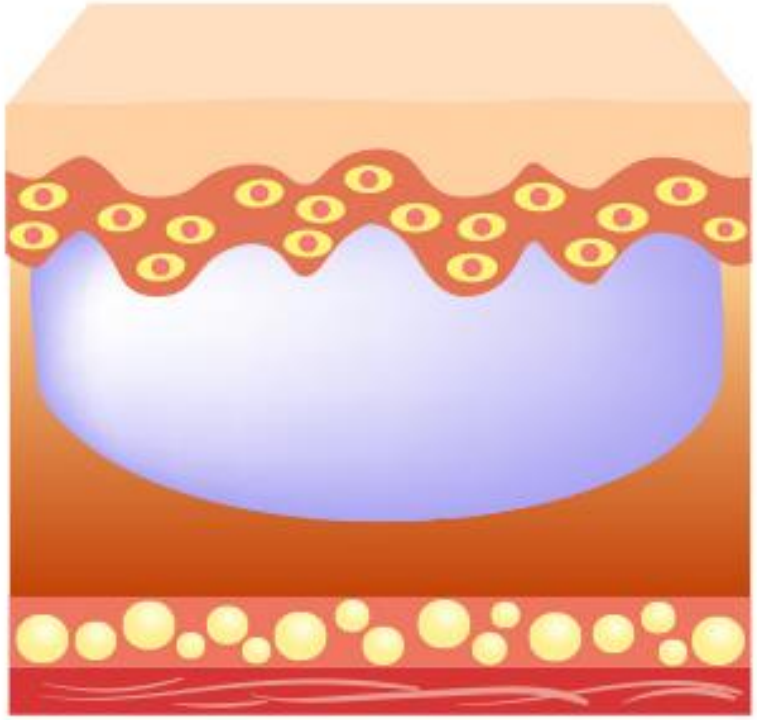
Structure of Younger Skin and Aged Skin

Understanding of Wrinkle improvement mechanism



Before

In general, injected dermal fillers exist in the dermis for 6 to 18 months without chemical changes, and support the lost area to restore volume. However, while they exist in the body, they are gradually broken down into water by the body's metabolic processes and are excreted from the body in the form of moisture.

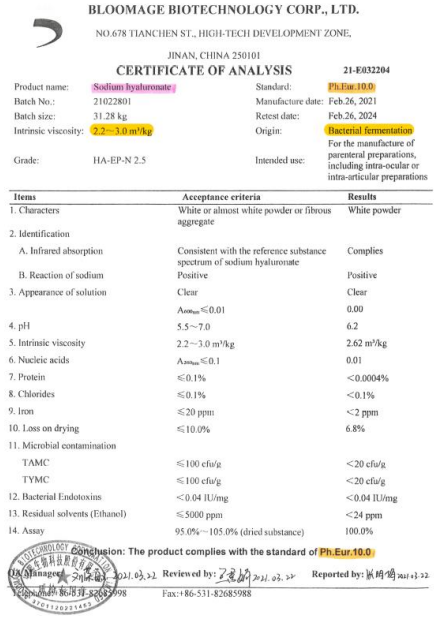


After

Why DIAMOND?

SAFETY - Raw materials

Using **Korea FDA approved materials** such as Non-Animal stabilized Hyaluronic Acid, Lidocaine, and BDDE to ensure quality and safety → **Minimize human allergy incidence**



BLOOMAGE BIOTECHNOLOGY CORP., LTD.

NO.678 TIANCHEN ST., HIGH-TECH DEVELOPMENT ZONE,

JINAN, CHINA 250101

CERTIFICATE OF ANALYSIS 21-E032204

Product name:	Sodium hyaluronate	Standard:	Ph.Eur.10.0
Batch No.:	21022801	Manufacture date:	Feb.26, 2021
Batch size:	31.28 kg	Retest date:	Feb.26, 2024
Intrinsic viscosity:	2.2~3.0 m³/kg	Origin:	Bacterial fermentation
Grade:	HA-EP-N 2.5	Intended use:	For the manufacture of parenteral preparations, including intra-ocular or intra-articular preparations

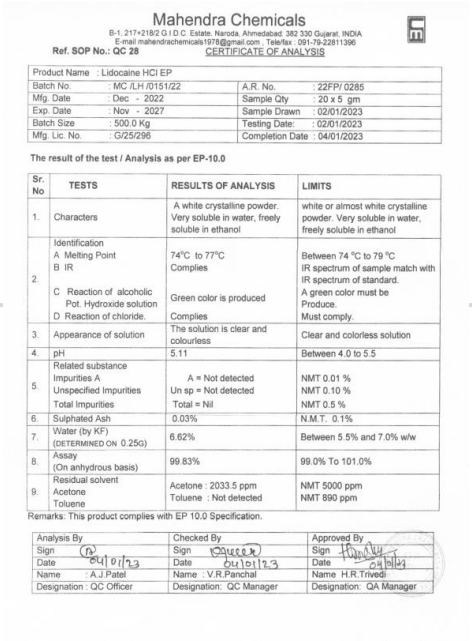
Items	Acceptance criteria	Results
1. Characters	White or almost white powder or fibrous aggregate	White powder
2. Identification		
A. Infrared absorption	Consistent with the reference substance spectrum of sodium hyaluronate	Complies
B. Reaction of sodium	Positive	Positive
3. Appearance of solution	Clear	Clear
	$A_{600nm} \leq 0.01$	0.00
4. pH	5.5~7.0	6.2
5. Intrinsic viscosity	2.2~3.0 m³/kg	2.62 m³/kg
6. Nucleic acids	$A_{260nm} \leq 0.1$	0.01
7. Protein	≤0.1%	<0.0004%
8. Chlorides	≤0.1%	<0.1%
9. Iron	≤20 ppm	<2 ppm
10. Loss on drying	≤10.0%	6.8%
11. Microbial contamination		
TAMC	≤100 cfu/g	<20 cfu/g
TYMC	≤100 cfu/g	<20 cfu/g
12. Bacterial Endotoxins	<0.04 IU/mg	<0.04 IU/mg
13. Residual solvents (Ethanol)	≤5000 ppm	<24 ppm
14. Assay	95.0%~105.0% (dried substance)	100.0%

Conclusion: The product complies with the standard of Ph.Eur.10.0

QA Manager: Reviewed by: Reported by:

Fax:+86-531-82685988

Hyaluronic Acid



Mahendra Chemicals

B-1, 217+218/2 G.I.D.C. Estate, Naroda, Ahmedabad, 382 330 Gujarat, INDIA

E-mail:mahendrachemicals1978@gmail.com , Telefax : 091-79-22811396

Ref. SOP No.: QC 28

CERTIFICATE OF ANALYSIS

Product Name	: Lidocaine HCl EP		
Batch No.	: MC /LH /0151/22	A.R. No.	: 22FP/ 0285
Mfg. Date	: Dec - 2022	Sample Qty	: 20 x 5 gm
Exp. Date	: Nov - 2027	Sample Drawn	: 02/01/2023
Batch Size	: 500.0 Kg	Testing Date:	: 02/01/2023
Mfg. Lic. No.	: G/25/296	Completion Date	: 04/01/2023

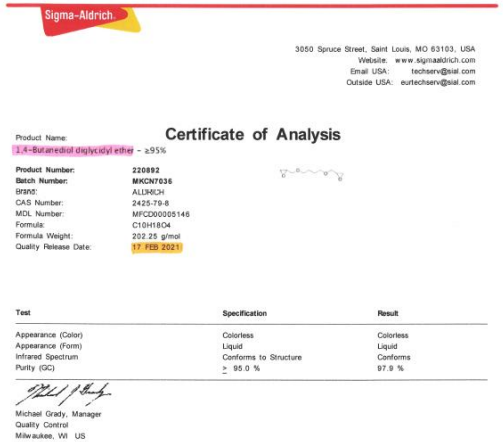
The result of the test / Analysis as per EP-10.0

Sr. No	TESTS	RESULTS OF ANALYSIS	LIMITS
1.	Characters	A white crystalline powder. Very soluble in water, freely soluble in ethanol	white or almost white crystalline powder. Very soluble in water, freely soluble in ethanol
2.	Identification A Melting Point B IR C Reaction of alcoholic Pot. Hydroxide solution D Reaction of chloride.	74°C to 77°C Complies Green color is produced Complies	Between 74 °C to 79 °C IR spectrum of sample match with IR spectrum of standard. A green color must be Produce. Must comply.
3.	Appearance of solution	The solution is clear and colourless	Clear and colorless solution
4.	pH	5.11	Between 4.0 to 5.5
5.	Related substance Impurities A Unspecified Impurities Total Impurities	 A = Not detected Un sp = Not detected Total = Nil	 NMT 0.01 % NMT 0.10 % NMT 0.5 %
6.	Sulphated Ash	0.03%	N.M.T. 0.1%
7.	Water (by KF) (DETERMINED ON 0.25G)	6.62%	Between 5.5% and 7.0% w/w
8.	Assay (On anhydrous basis)	99.83%	99.0% To 101.0%
9.	Residual solvent Acetone Toluene	 Acetone : 2033.5 ppm Toluene : Not detected	 NMT 5000 ppm NMT 890 ppm

Remarks: This product complies with EP 10.0 Specification.

Analysis By	Checked By	Approved By
Sign	Sign	Sign
Date 04/01/23	Date 04/01/23	Date 04/01/23
Name : A.J.Patel	Name : V.R.Panchal	Name :H.R.Trivedi
Designation : QC Officer	Designation: QC Manager	Designation: QA Manager

Lidocaine



Sigma-Aldrich

3050 Spruce Street, Saint Louis, MO 63103, USA

Website: www.sigmaaldrich.com

Email USA: techserv@sial.com

Outside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name: 1,4-Butanediol diglycidyl ether - ≥95%

Product Number:	220892
Batch Number:	MKCN7036
Brand:	ALDRICH
CAS Number:	2425-79-8
MDL Number:	MFCD00005146
Formula:	C10H18O4
Formula Weight:	202.25 g/mol
Quality Release Date:	17 FEB 2021

Test	Specification	Result
Appearance (Color)	Colorless	Colorless
Appearance (Form)	Liquid	Liquid
Infrared Spectrum	Conforms to Structure	Conforms
Purity (GC)	≥ 95.0 %	97.9 %

Michael Grady, Manager

Quality Control

Milwaukee, WI US

BDDE

Why DIAMOND?

SAFETY - Purification process

Through Separation Refining Technology, remove of residue of cross-linkers by **6 times in 12 days** Dialysis process before sterilization

Enhance safety, reduce side effects

Item	Effect	Diamond	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


KTR

TEST REPORT

Test Results

Korea Testing & Research Institute

President Kim Hyun Cheol

Measurement data from Korea Testing & Research Institute

Why DIAMOND?

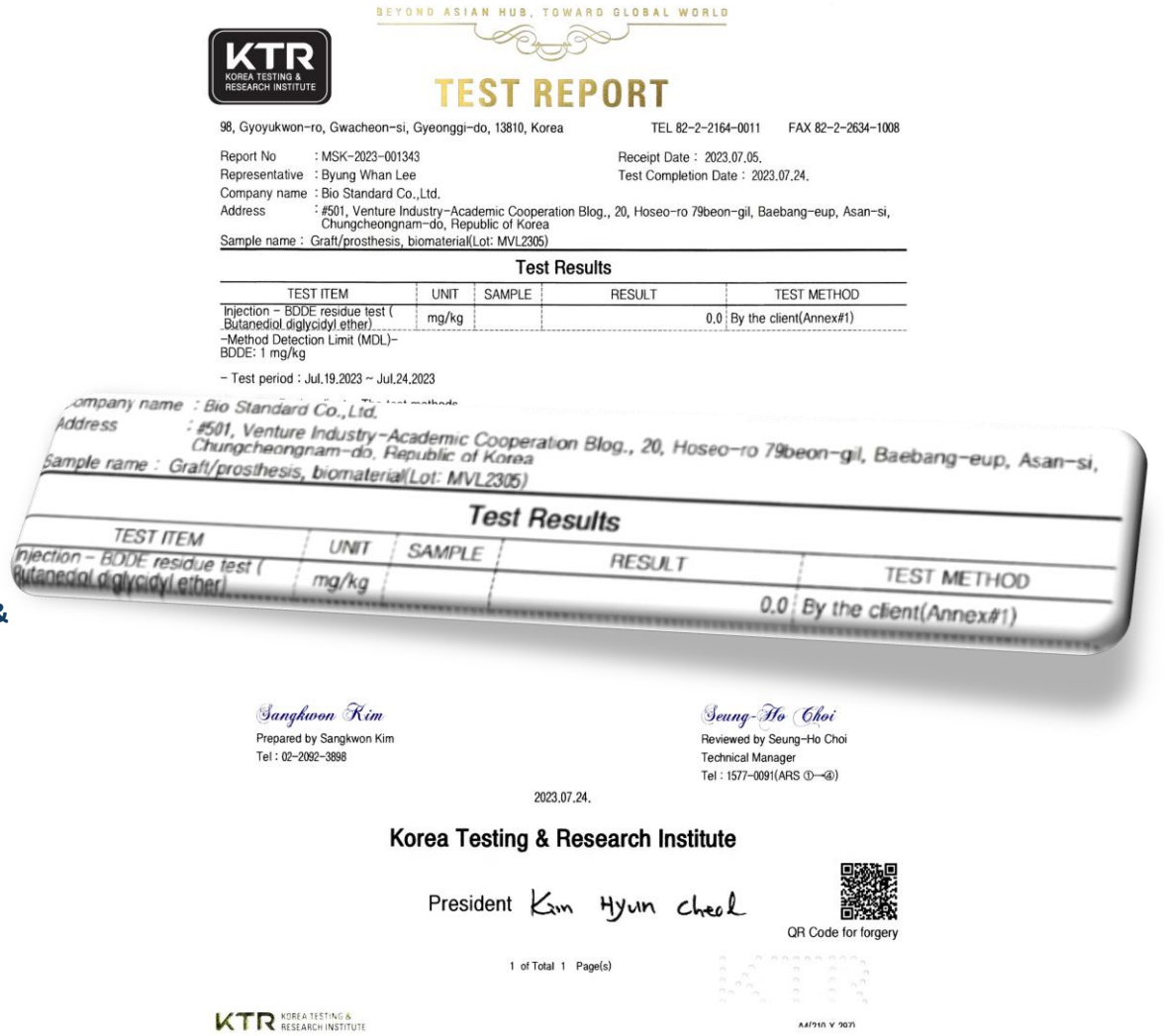
Diamond

SAFETY - Purification process

The BDDE residue test results for BioStandard products conducted by KTR (the Korea Testing & Research Institute) shows 0 ppm, confirming the safety of BioStandard products.

As a Korean government agency, the results of tests conducted by KTR are recognized for their fairness and objectivity.

Measurement data from Korea Testing & Research Institute



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)	mg/kg		0.0	By the client(Annex#1)

-Method Detection Limit (MDL)-
BDDE: 1 mg/kg

- Test period : Jul.19.2023 ~ Jul.24.2023

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

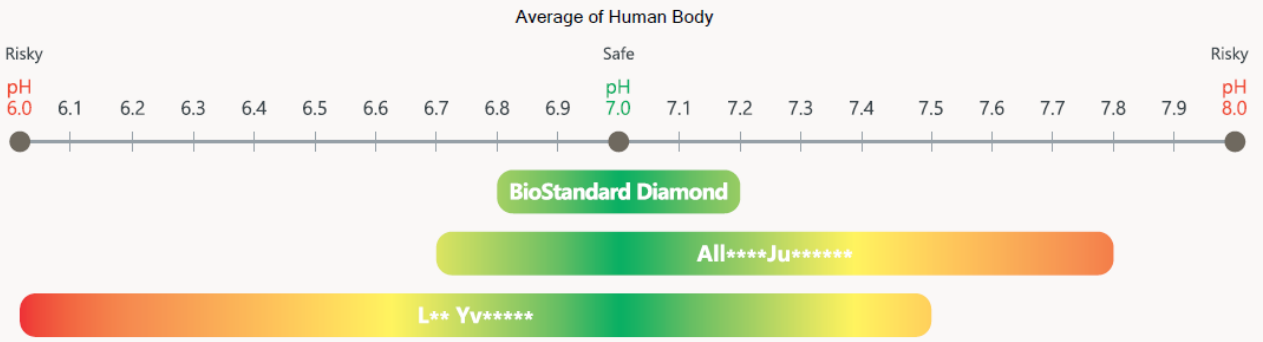
1 of Total 1 Page(s)

KTR KOREA TESTING & RESEARCH INSTITUTE

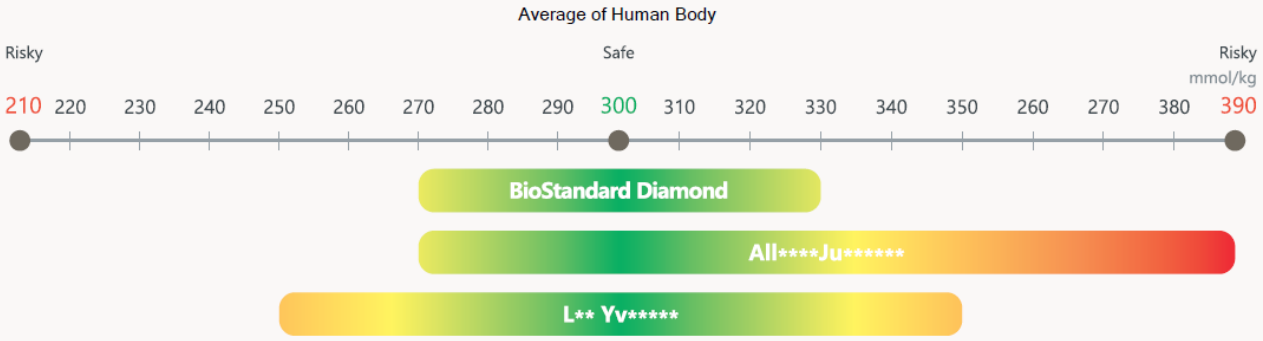
Why DIAMOND?

SAFETY - pH & Osmolality

▶ Comparative analysis of pH



▶ Comparative analysis of Osmolality



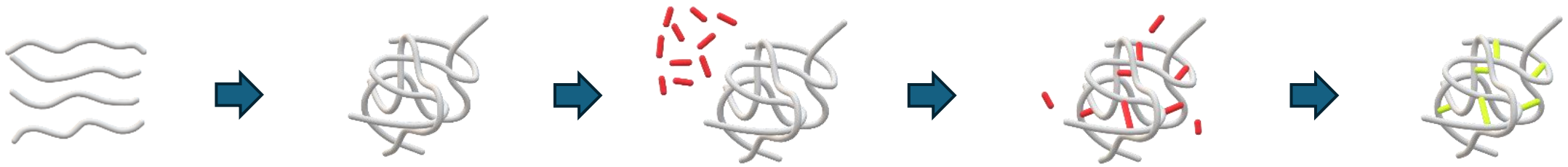
The quality standards closest to the human body's average hydrogen ion concentration **pH 7.0** and **osmotic pressure 300 mmol/kg**

- ✓ **Minimize human body reactions**
- ✓ **Reduce side effects**

Why DIAMOND?

EFFECTIVENESS - Longer Longevity with Shine Technology

SHINE Technology is developed by Bio Standard. This process consists of **3 steps cross-linking** that can last in the body for 6 to 18 months.



Non cross-linked HA

Primary cross-linking without cross-linkers

Adding Cross-linkers to Primary cross-linked HA

Secondary HA cross-linking b etween Primary cross-linked HA with cross-linkers

Pure Cross-linked HA secured by perfect removal of residual cross-linkers

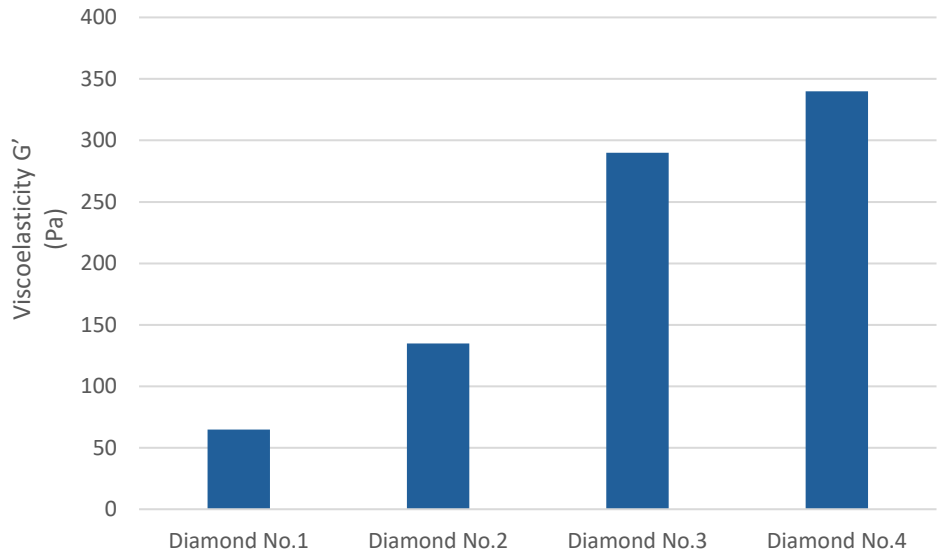
Stabilized Hyaluronic acid & Improved Novel Efficacy - SHINE Technology

Why DIAMOND?

EFFECTIVENESS - Optimal Viscoelasticity

The optimal viscoelasticity is designed by combining the appropriate viscosity and elasticity for each product type. **Optimal viscoelasticity** by combining the appropriate viscosity and elasticity for each product type

- ✓ **Best for skin generation effect**
- ✓ **Excellent volume effect for a long time**



Comparative analysis of Viscoelasticity between DIAMOND Dermal Fillers

Why DIAMOND?

EFFECTIVENES - Optimal viscoelasticity

Injection location	Fine wrinkles around the eyes, earlobes, lips, between the eyes	Lips, nasolabial folds, nose,	Deep nose, nasolabial folds, smile line, forehead	Cheekbones, cheeks, chin, forehead
Model	**DIAMOND No.1** MCL-1E	**DIAMOND No.2** MDL-2E	**DIAMOND No.3** MDL-3E	**DIAMOND No.4** UTL-4E
Shape				
Elasticity	Low	Medium	High	Very High
Viscosity	High	Medium	Low	Low
Longevity	6 Months	12 months	15 months	18 months or more

PRODUCT INTRODUCTION – Why DIAMOND?

EFFECTIVENES - Applying Area

Diamond No.1 (MCL-1E)
Fine wrinkles around eyes
Between Eyebrows
Earlobes, Lip

Diamond No.2 (MDL-2E)
Lips, Nasolabial folds,
Nose tip

Diamond No.3 (MVL-3E)
Deep nose, Nasolabial folds, Smile line,
Forehead

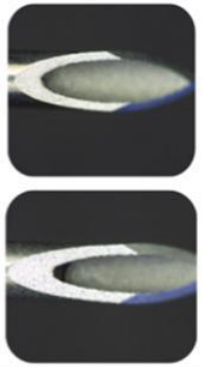
Diamond No.4 (MVL-3E)
Cheek, Chin, Forehead

PRODUCT INTRODUCTION – Why DIAMOND?

Diamond

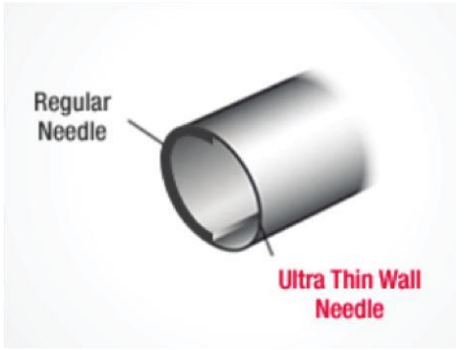
SATISFACTION - Needle

CE-marked & advanced ultra-thin wall Needle



Ultra Thin wall

Competitor Thin wall

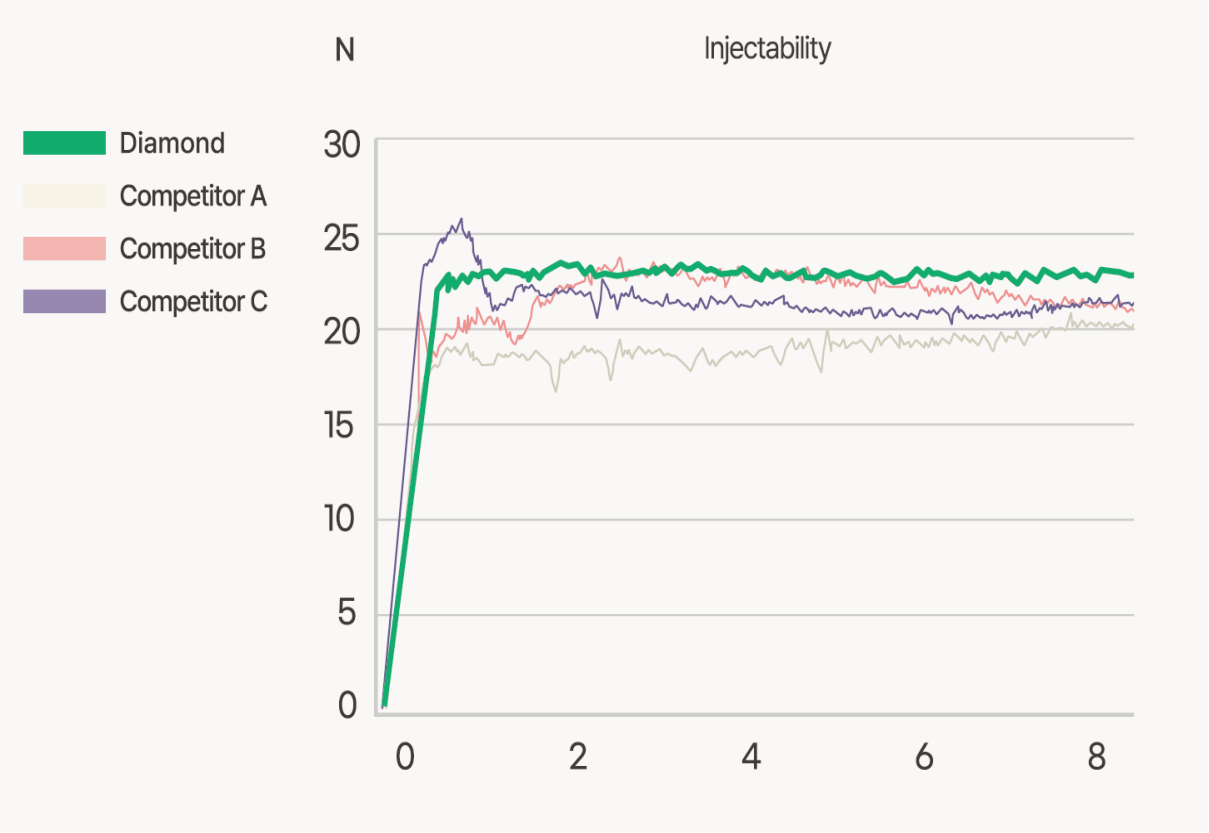


The difference in the inner diameter of the injection needle due to the difference in the thickness of the injection needle wall

Due to the thinner wall of needle, the outer diameter of needle is the same as that of the competitor's, but the inside diameter is larger, so the **injection pressure is low**. This makes the procedure easier.

PRODUCT INTRODUCTION – Why DIAMOND?

SATISFACTION - Even Extrusion force



Compared to competing products, Diamond dermal fillers offer less variation in injection pressure and greater consistency.

Constant injection pressure ensures the practitioner can perform a stable, comfortable, and precise procedure.

SCIENTIFIC PAPERS - Before & After photo

Diamond

Lips

Before

After

Nasolabial folds

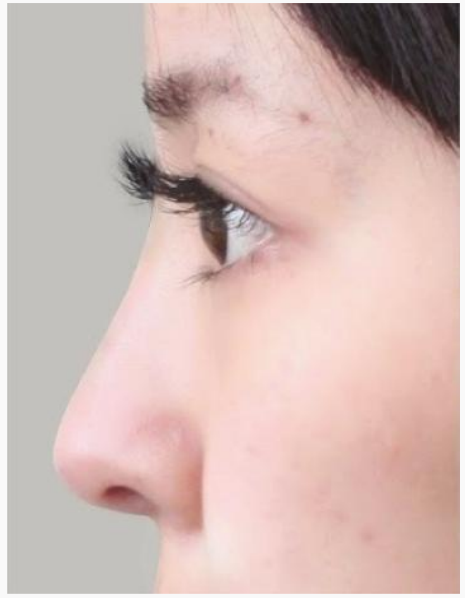
Before

After

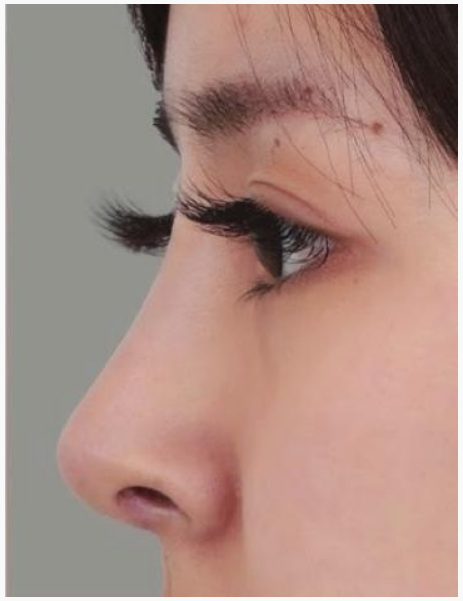
SCIENTIFIC PAPERS - Before & After photo

Nose

Before

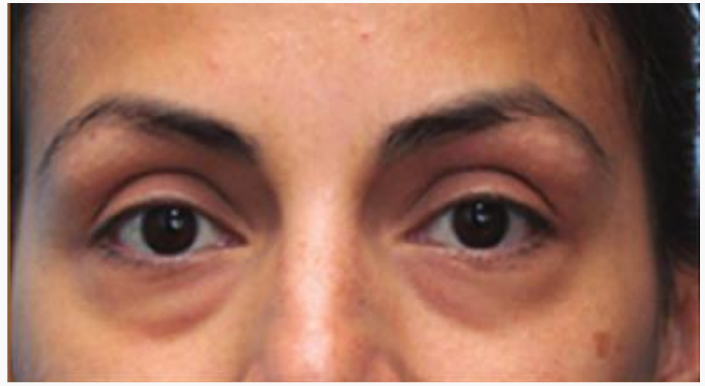


After



Dark circle

Before



After

SCIENTIFIC PAPER - Scientific papers

INTRODUCTION

Eulji University Medical Center research team in Korea conducted a clinical trial comparing the efficacy of Meline Volume No.3_**DIAMOND No.3**(MHA), with Restylane LYFT (BHA), and it was officially recognized by the **Korean Society of Aesthetic Plastic Surgery**.

ORIGINAL ARTICLE

https://doi.org/10.14730/aaps.2023.00836
Arch Aesthetic Plast Surg 2023;29(3):141-146
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

Jung Soo Lim[1], Geon Hwi Kim[2], Jong Hun Lee[2]

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

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

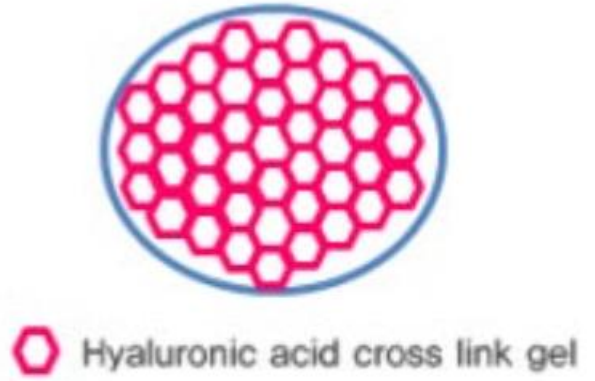
This work was supported by a grant from the Korea Medical Device Development Fund, funded by the Korean government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health and Welfare, the Ministry of Food and Drug Safety) (Project Number: 1711138448, KMDF_PR_20200901_0215).

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

Monophasic monodensified fillers such as Meline No. 3_**DIAMOND No.3** with lidocaine (Bio Standard Co., Ltd) share the **characteristics of both biphasic and monophasic polydensified fillers**; therefore, they can exhibit clumping. Overall, however, they spread homogeneously throughout the implanted tissue.

SCIENTIFIC PAPER - Scientific paper

MONOPHASIC VS BIPHASIC

	Monophasic	Biphasic
Structure		
Product	Juvederm Diamond-**Meline** Neuramis	Restylane Yvoire Perfectha

SCIENTIFIC PAPER - Scientific paper

MONOPHASIC VS BIPHASIC

	Monophasic	Biphasic
Structure	Homogeneous single-phase product of High cross-linked gel	Two-phase product that mixes cross-linked gel and Non cross-linked gel.
Viscosity	Higher	Lower
Migration	Less Uniform particles penetrate and fill the spaces between collagen and elastin fibers, resulting in very strong cohesion.	More Its larger agglomerate cannot easily penetrate between collagen and elastin fibers, so it is less cohesive.
HA distribution (Spreading)	Homogeneous (Even)	Heterogeneous (Uneven)
Molding	Easier to mold as desired with homogeneous HA distribution.	Hard to mold as desired with uneven heterogeneous HA distribution
Injectability	Easier with even Injection Pressure	Harder with uneven Injection Pressure
Elasticity	Slightly Lower	Higher
Volumization	Slightly less	Superior
Product Classification by Cross-linking	Juvederm DIAMOND_**Meline** Neuramis	Restylane Yvoire Perfectha

SCIENTIFIC PAPER - Scientific paper

CONCLUSION

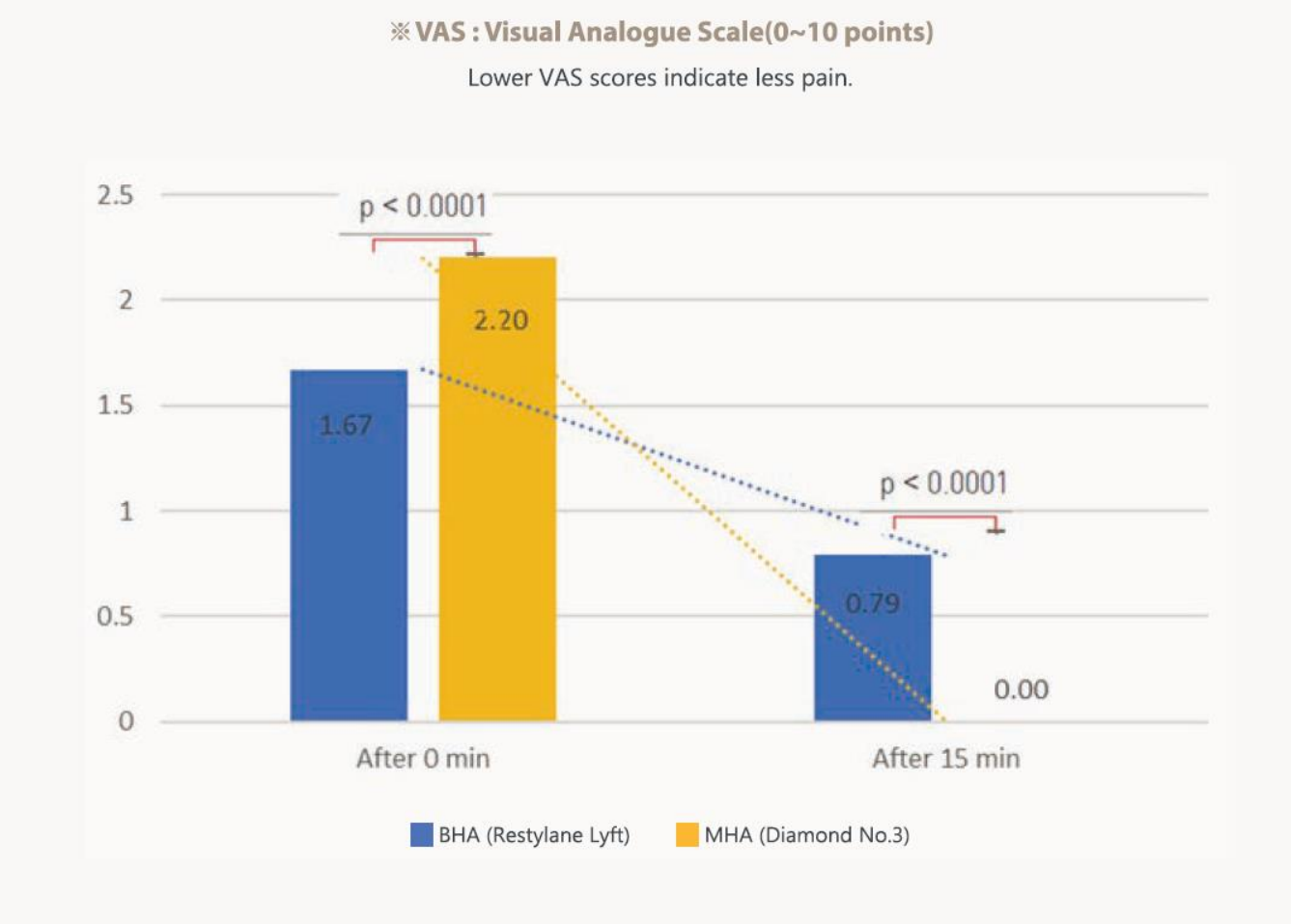
Hybrid filler with both monophasic and biphasic properties

Monophasic monodensified fillers such as Meline No. 3_**DIAMOND No.3** with lidocaine (Bio Standard Co., Ltd) share the **characteristics of both biphasic and monophasic polydensified fillers**; therefore, they can exhibit clumping. Overall, however, they spread homogeneously throughout the implanted tissue.

SCIENTIFIC PAPER - Scientific papers

CONCLUSION

1. DIAMOND No.3 has **lower persistence of pain** compared to Restylane LYFT.



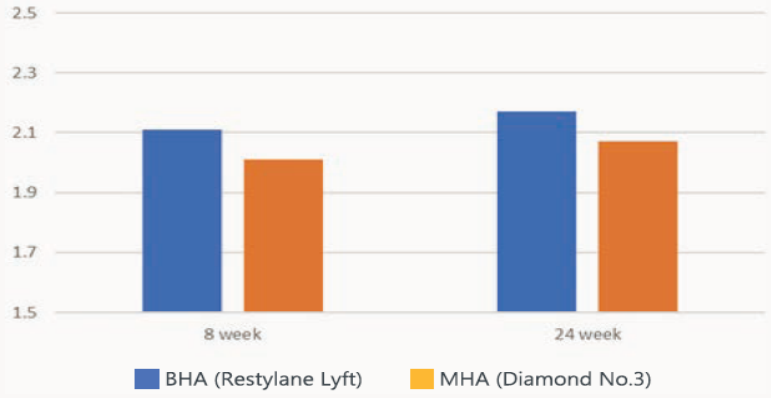
SCIENTIFIC PAPERS - Scientific papers

CONCLUSION

Outstanding wrinkle improvement: DIAMOND No.3 showed approximately **0.10 better efficacy** than Restylane LYFT in WSRS (Wrinkle Severity Rating Scale)values.

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

Wrinkle Severity Rating Scale Evaluation

WSRS is evaluated on a total of 5 levels.

The more serious the wrinkle, the higher the score.
The shallower the wrinkle, the lower the score.

In other words, a lower WSRS evaluation score means a better wrinkle condition means that the wrinkles have improved more after injection.

Competitors

Types of dermal fillers by main ingredient

Main Ingredient	Product	Longevity	Features
Collagen	Zyderm	6 Months	Animal-derived protein extract natural polymer - Maintains skin tissue structure - High allergy-causing rate
Hyaluronic acid	Restylene Diamond	6~18 Months	Natural polymer material purified by fermenting microorganisms - Wrinkle removal, volume recovery, and skin tone improvement with moisture storage function - Easily can be removed by enzyme (Hyaluronidase), if not satisfied with the results or a medical accident occurs. - More than 80% share due to safety and ease of use
Calcium Hydroxyapatite	Radiess	18 Months	- Cannot be decomposed in the body, so surgical removal is required - A large amount remains, so nodules or limp may occur when a large amount is injected
Poly-L-lactic acid (PLLA)	Scultra	12~24 Months	Promotes collagen production for fine wrinkles - At least 4 times injections at 4-week intervals are required - Continuous message is required - High incidence of granulomas with lumpy is found

Competitors

Types of dermal fillers by main ingredient

Main Ingredient	Product	Longevity	Features
Polymethylmethacrylate (PMMA)	Artefill	24 Months	- Induces collagen production as an artificial bone component - Synthetic polymer material used in bovine collagen 80% + PMMA 20%, etc. - Crystals can be created under the skin - Cannot be decomposed in the body, surgical operation required for correction - Absolutely prohibited for use on eyes or forehead, etc.
Poly-caprolactone (PCL)	Elansse	24 Months	- Plant-derived synthetic polymer material - Initial volume effect is small, so multiple treatments are required - After the treatment, collagen production is induced - PCL component itself is safe because it is degraded nd absorbed, but the collagen produced by PCL can only be corrected and removed through surgery. - Absolutely prohibited for use on the eyes or forehead
Polyacrylamide	Aquamid	24 Months	- Particle surface is uneven and granulomas occur, - Severe movement in the body without settlement at the injected parts. - No decomposition in the body, surgical operation required for correction of procedure - Absolutely prohibited for use in the eyes or between the eyebrows

Competitors

Position

	Big Player			Middle Tier	Small Player	Illegal
	Overseas	Korean	Legal Chinese	Biostandard		
Brand	Restylane Juvederm Belotero Perfectha	Neuramis Elavie Yvoir Eptq Revolax(Chaeum)	IMEIK Technology Development / Bloomage Biotechnology / Shanghai Haohai Biological Technology	DIAMOND Sardenya Elasty Replengen Regenovue HyalDew Richesse Rejeunesse	OEM BRAND from Korea, China	A lot from Korea, China, the Third World
Distributor Price	Very High 130 USD ~	High 16 ~ 25USD	Similar to or higher than Korean Products	Low, ~13 USD	~ 7 USD	Very low, less than 5 USD