MONALISA

Long-term Stability

GENOSS
For Patients & Doctors

Contents

Monalisa Filler

Product Specification

MONALISA Lidocaine: A Variety of Line-up

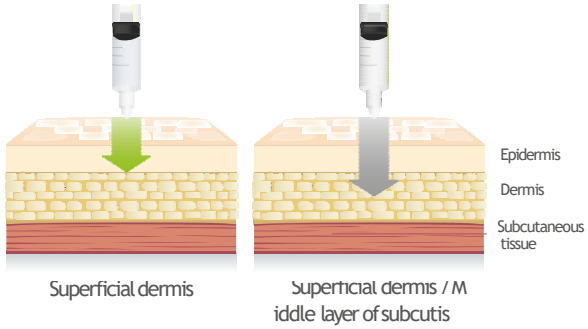
Hyaluronic Acid Dermal Filler MONALISA

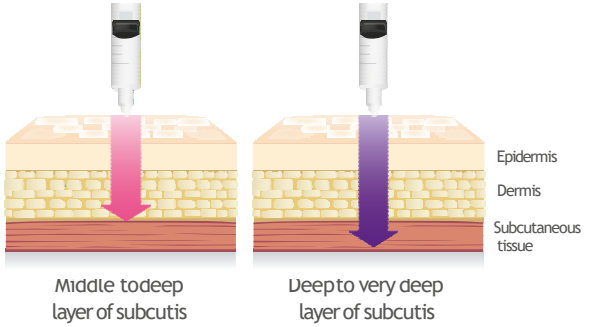
	SOFT	MILD	HARD
REF	HAF10S27T	HAF10M27T	HAF10H27T
Concentration	20 mg/mL		
Particle Size	200 μm	400 μm	600 μm
Needle Size*	30G TW (2ea)	27G TW (2ea)	27G TW (2ea)

Hyaluronic Acid Dermal Filler with **Lidocaine** MONALISA

	SOFT	MILD	HARD	ULTRA
REF	MPF10S	MPF10M	MPF10H	MPF10U
Concentration	24 mg/mL			
Particle Size	200 μm	400 μm	600 μm	900 μm
Needle Size*	30G TW (2ea)	27G TW (2ea)	25G TW ,27GTW	25 G TW ,27G TW

Intended Use





Monalisa Filler

Safety and Clinical Evaluation

Safety

Performance Test[1] | MONALISA

Genoss Research Institute

	Standard	Result
Appearance	No impurities, transparent and colorless gel	Pass
HA^3 Concentration	18 ~ 22 mg	20.1 mg
pH	6.5 ~7.5	7.00
Residual BDDE	< 2 ppm	**Not Detected**
Endotoxin	< 20 EU	**< 0.100EU**
Volume	> 1.0 mL	Pass

Performance Test[2] | MONALISA

	Standard	Result
Appearance	No impurities, transparent and colorless gel	Pass
HA^3 Concentration	21.6 ~ 26.4 mg	24.1 mg
pH	6.5 ~7.5	7.10
Residual BDDE	< 2 ppm	**Not Detected**
Endotoxin	< 20 EU	**< 0.100EU**
Volume	> 1.0 mL	Pass

*** What is BDDE(1,4-butanediol diglycidyl ether, cross-linking agent) ?**

BDDE (1,4-butanediol diglycidyl ether) is a chemical cross-linking agent to make hyaluronic acid into gel form.
The residual amount of BDDE is strictly regulated to less than 2 ppm. It was not detected in Every MONALISA Filler.

High purity raw materials and Proprietary technology

● High Purity Hyaluronic Acid Raw Material

Comply with strict international regulations such as KGMP, ISO 13485, ISO 9001 for global quality Management

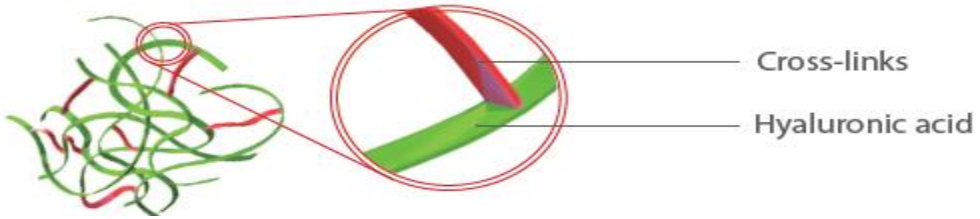
Incubation → Fermentation / Extraction → Refine → Hyaluronic Acid

● Ideal viscoelasticity applied with Hy-BRID Technology

Excellent Volume formation and long-term retention

*** Hy-BRID Technology**

Hyper Cross-linked
Based on non-animal HA
Residue-free
Improved **D**ensity and elasticity



Pharmaceutical grade raw materials

Name	Standard
Hyaluronic Acid Calibration	95.0 ~ 105.0 %
Ultimate Viscosity	90 ~ 120 %
Sterility test	0
Endotoxin	0.5 EU/mg or less
Microbial Limit	aerotropism 100 CFU/g or less
Confirmation Test	Same as Standard
pH	5.0 ~ 8.5
Extreme Viscosity	90 ~ 120 %
Dissolution	Below 0.01
Chloride	Below 0.5 %
Heavy Metal	Below 20 ppm
Nucleic acid	Below 0.5
Protein	Below 0.3 %
Loss of Drying	Below 20.0 %

- Strict quality control according to European Pharmacopoeia standards

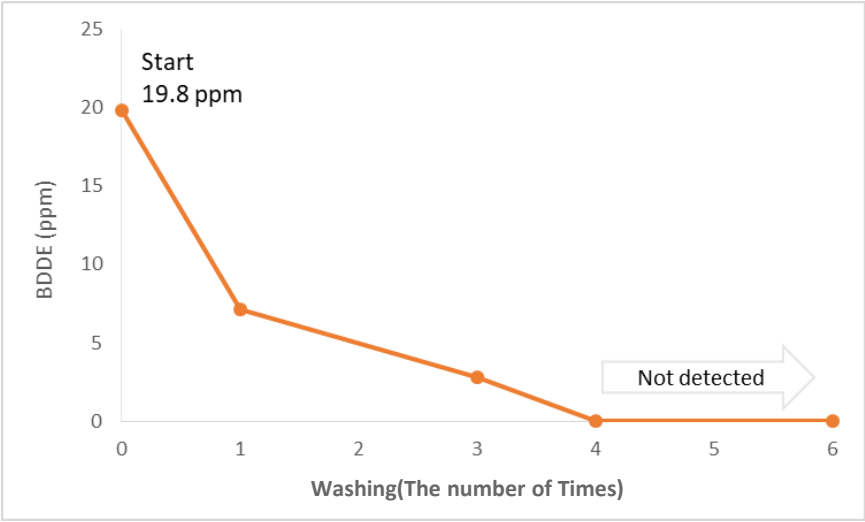
- Safety-oriented inspection management (Focus on Endotoxin and Microbial Environment Management)

Cleaning Method: GENOSS Complete Washing System

Gel before cleaning

Gel after cleaning

- Quality reliability through full automation(2018)
- Cube-Shaped Crosslinked Body



Securing Quality Reliability through National Authorized Institutions

▶ **Physicochecmical Performace**


TEST REPORT

시험결과

KTR 한국화학융합시험연구원장

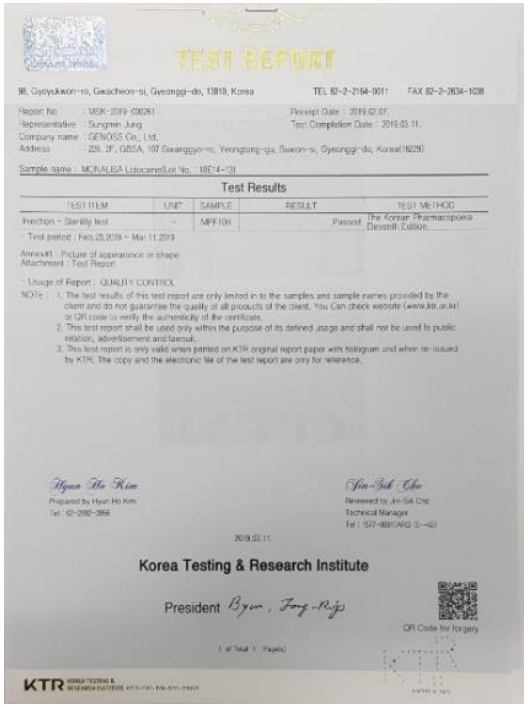
▶ **Biochemical Safety**


TEST REPORT

시험결과

KTR 한국화학융합시험연구원장

▶ **Aseptic Verification of each lot(Certified)**

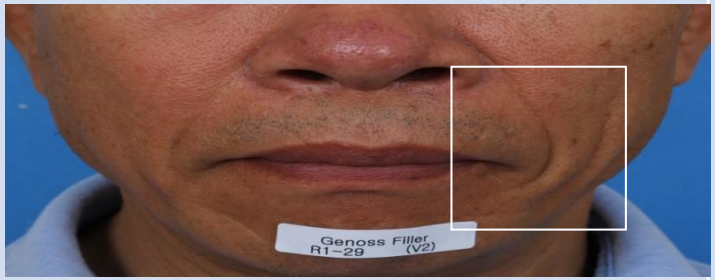

TEST REPORT

Test Results

Korea Testing & Research Institute

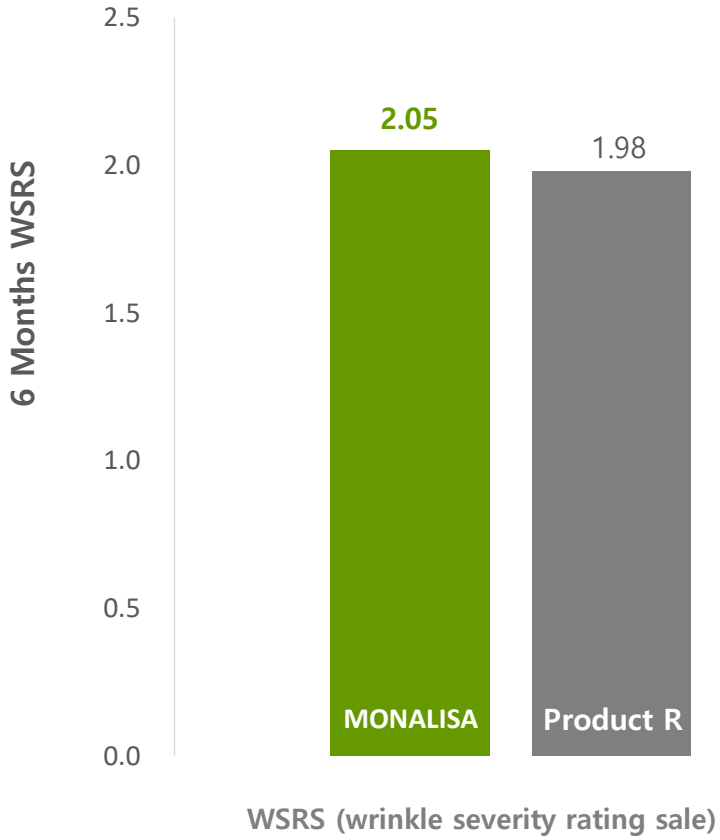
President Byun, Jong-Rip

Clinical Case report

	Male (L-MONALISA, R-Product R)	Female(L-Product R, R-MONALISA)
Before the Procedure		
2 Weeks Later		
24 Weeks Later		

➢ **Confirmation of improvement of facial nose wrinkles**

Clinical Test: Improving Nasolabial fold



Clinical conducting Institution	Seoul National University Hospital, Keimyung University Dongsan Medical Center
Number of Subjects	66 patients
Clinical Follow-up period	6 months
Control	Product R
Clinical trial completed	Feburary, 2014

Clinical Data

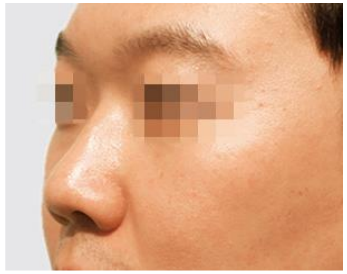
Nasolabial folds

Before

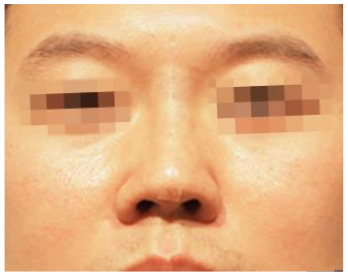
After

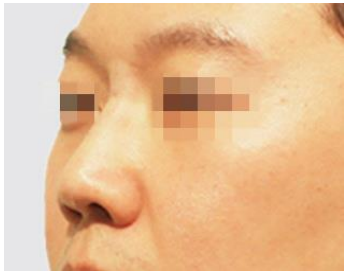
Nose

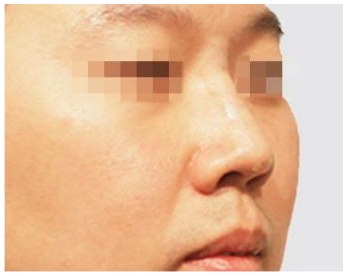
Before



After







Clinical Data

Chin & facial oval

Before

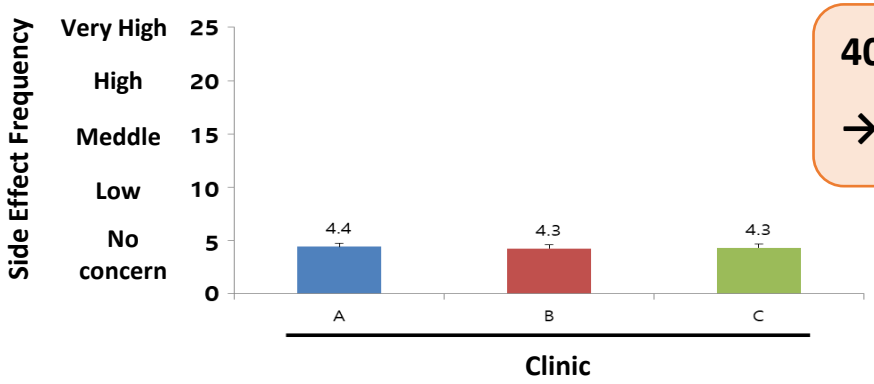
After

Lip volume

Before

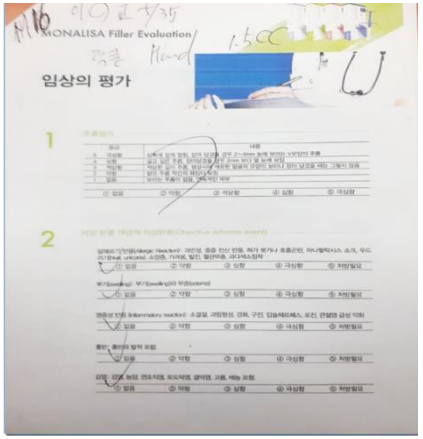
After

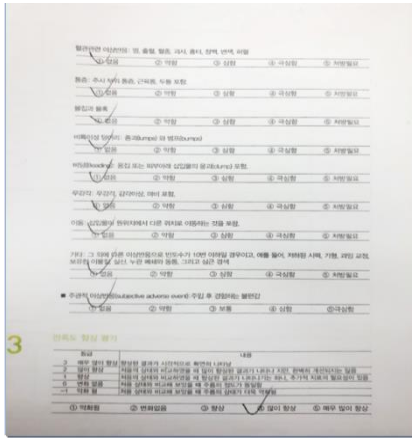
Adverse Field Evaluation Test

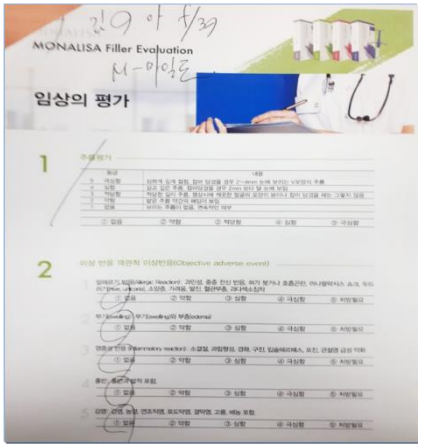


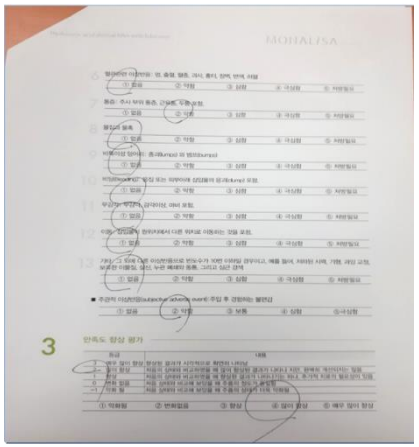
40 cases completed in 4 hospitals

→ ignore frequency of adverse events and severity

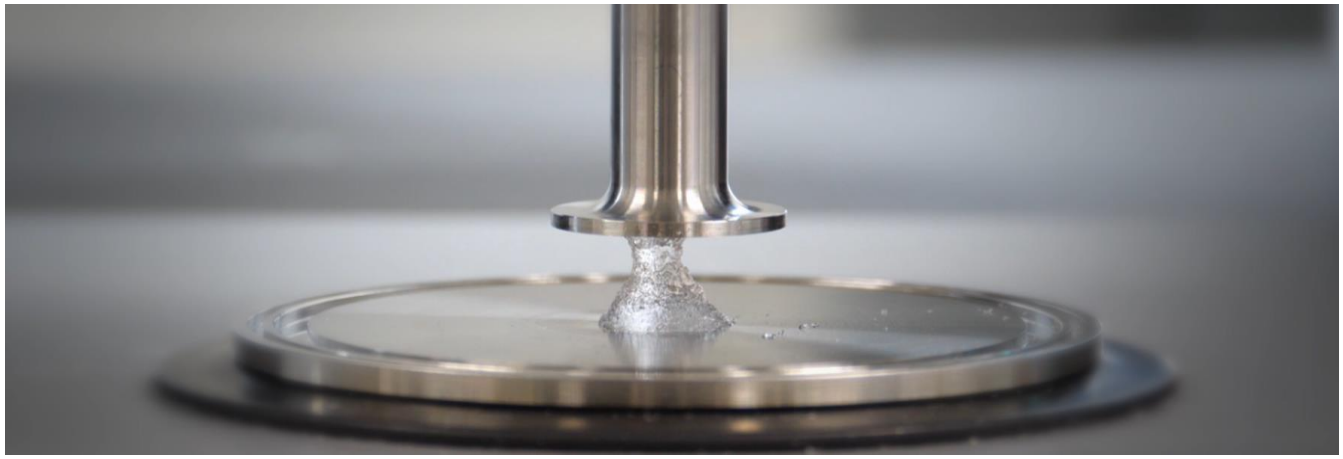


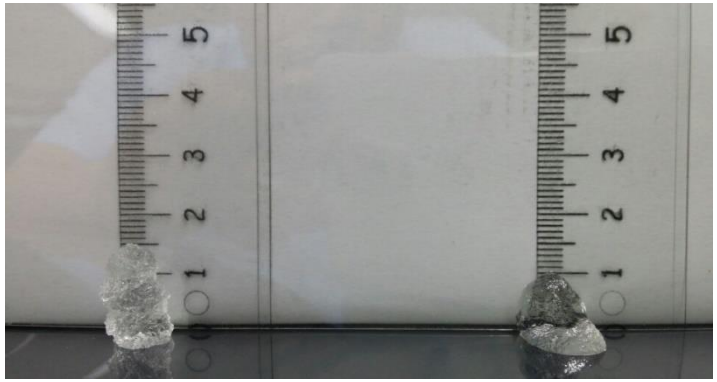


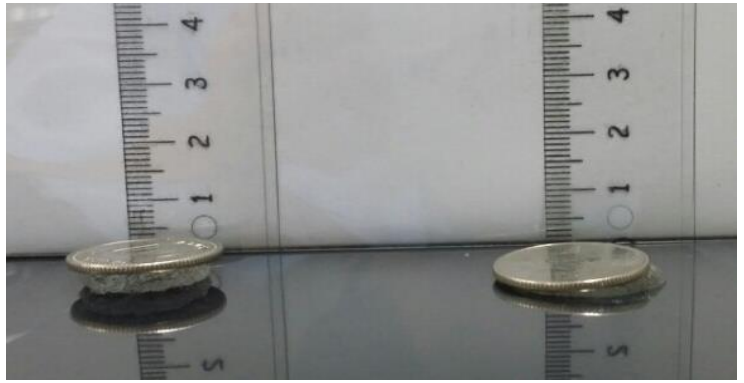




Excellent Volume Maintenance



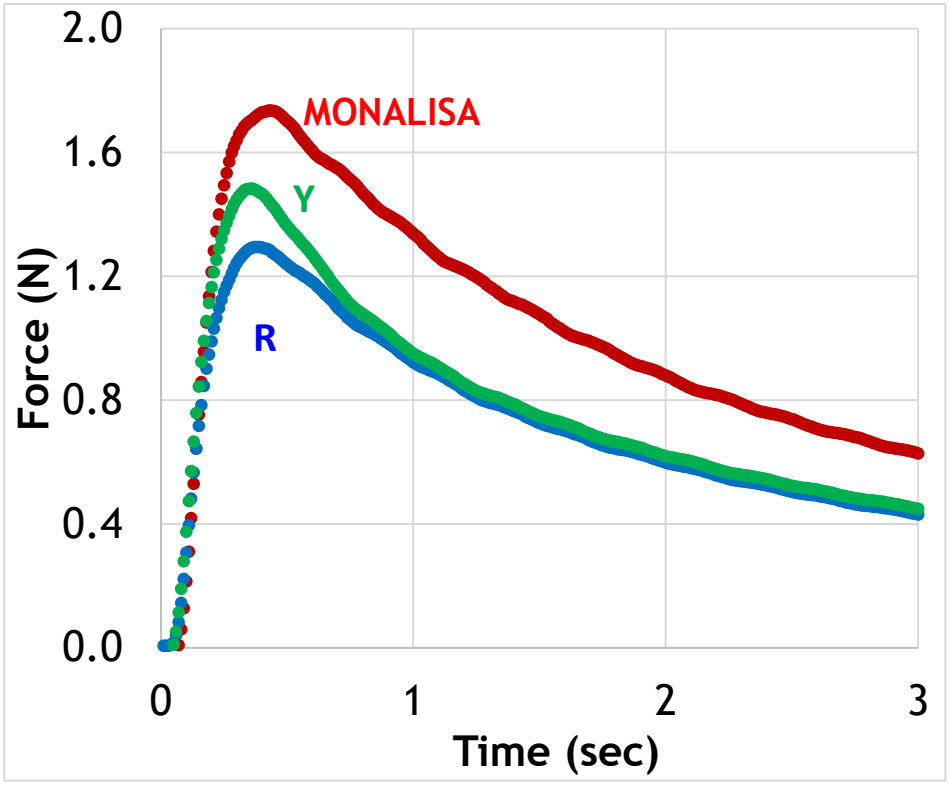


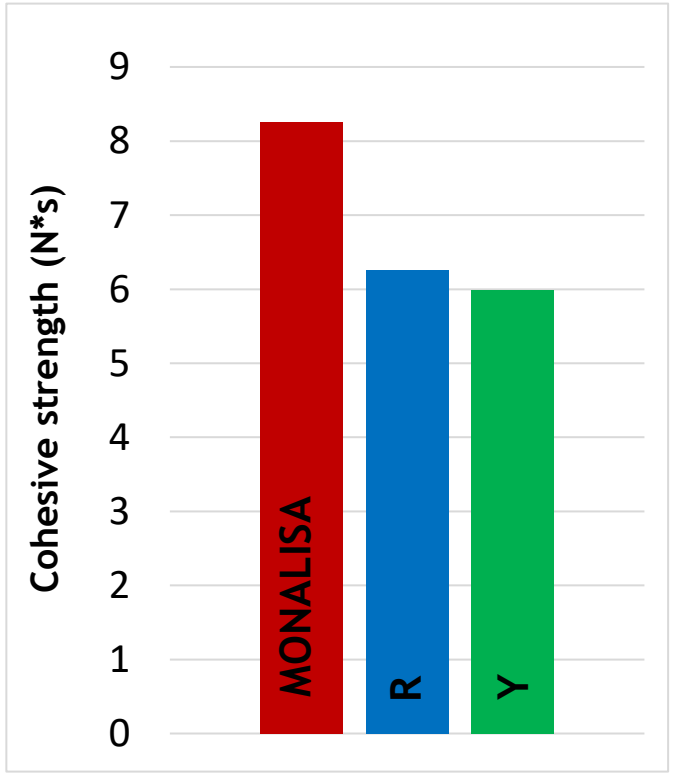


MONALISA HARD Product R

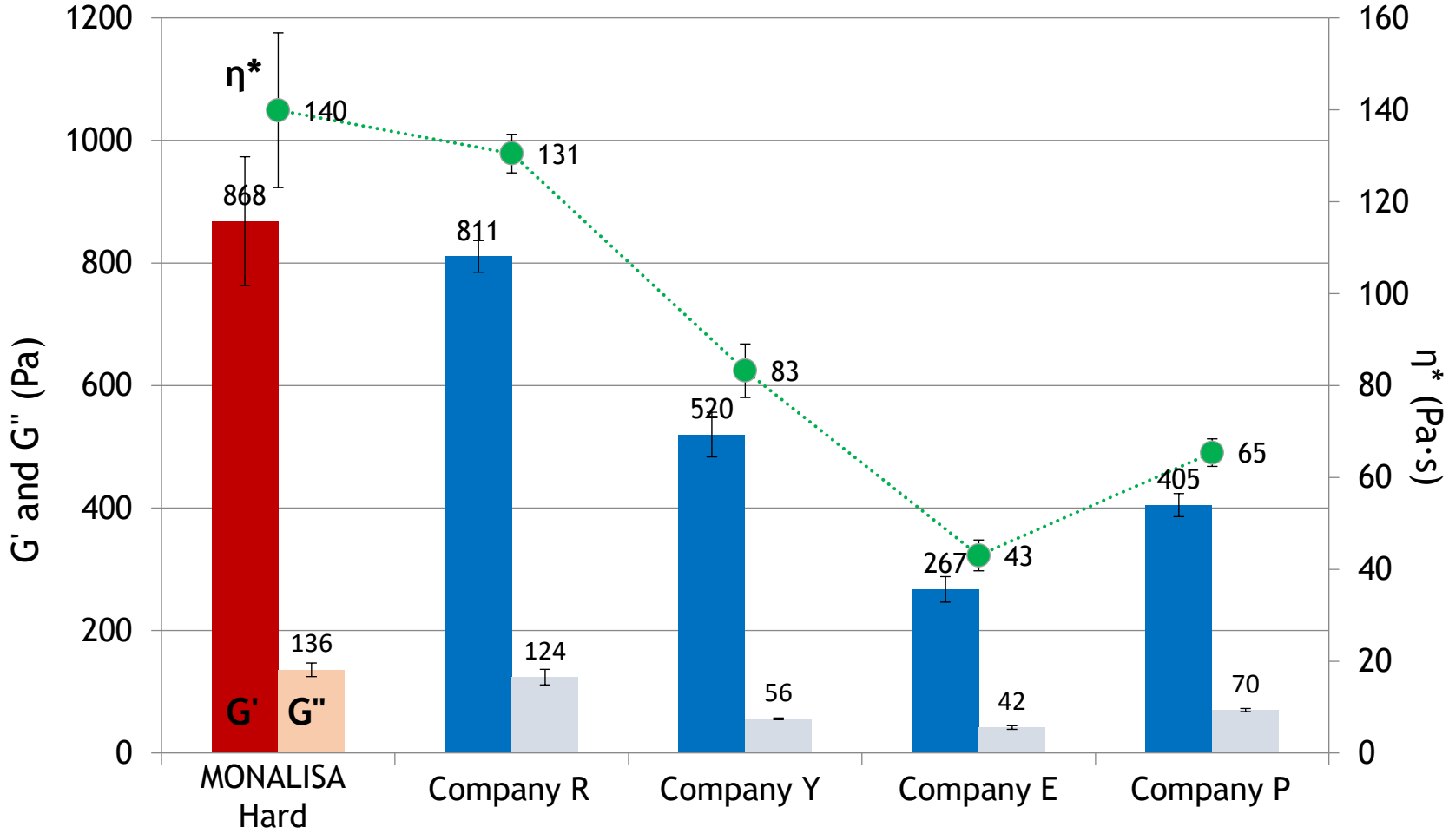
MONALISA HARD Product R

Excellent Volume Maintenance





Excellent Volume Maintenance

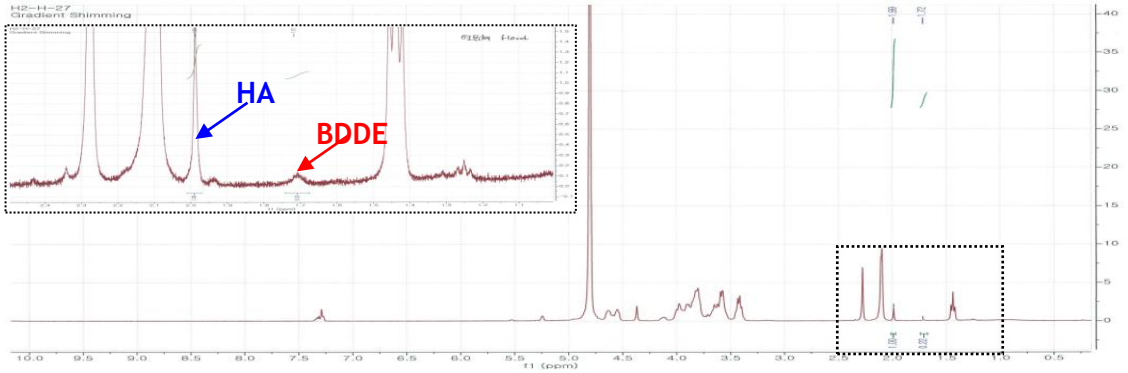


Excellent Volume Maintenance

MoD of MONALISA : under 3 %

▶ relatively free from the adverse reactions caused by crosslinker (BDDE), means safe

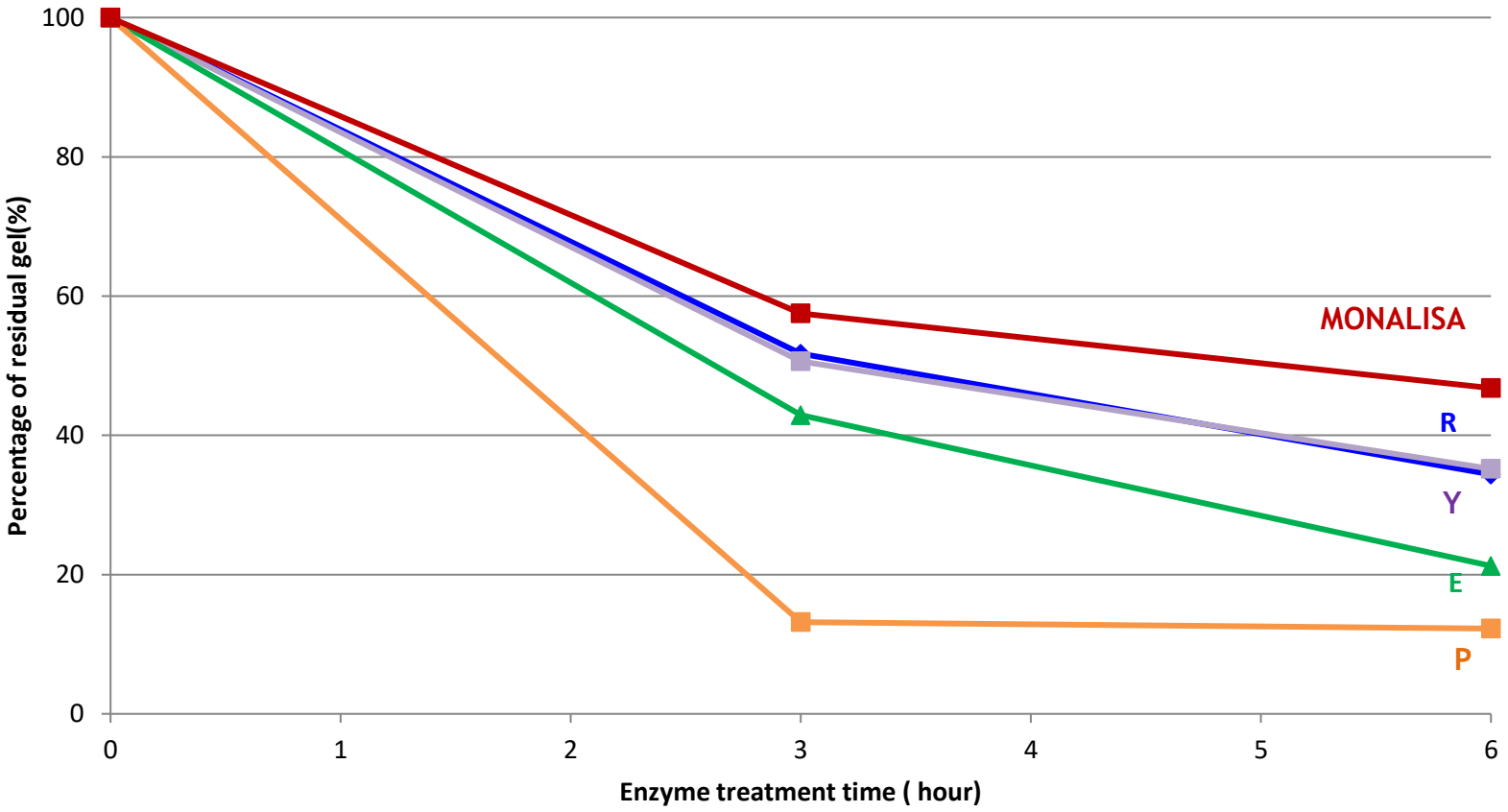
	MONALISA				Competitors			
	Soft	Mild	Hard	Ultra	R	Y	E	P
MoD(%)	1.5	2.0	2.1	2.7	3.5	3.0	10.2	5.4



- **MoD (%) : Percentage of cross-linker (BDDE) linked with Hyaluronic acid (HA)**
  (Linked BDDE + Pendant BDDE)

※ Comapany P Product MoD: 2.7%

MONALISA Longevity

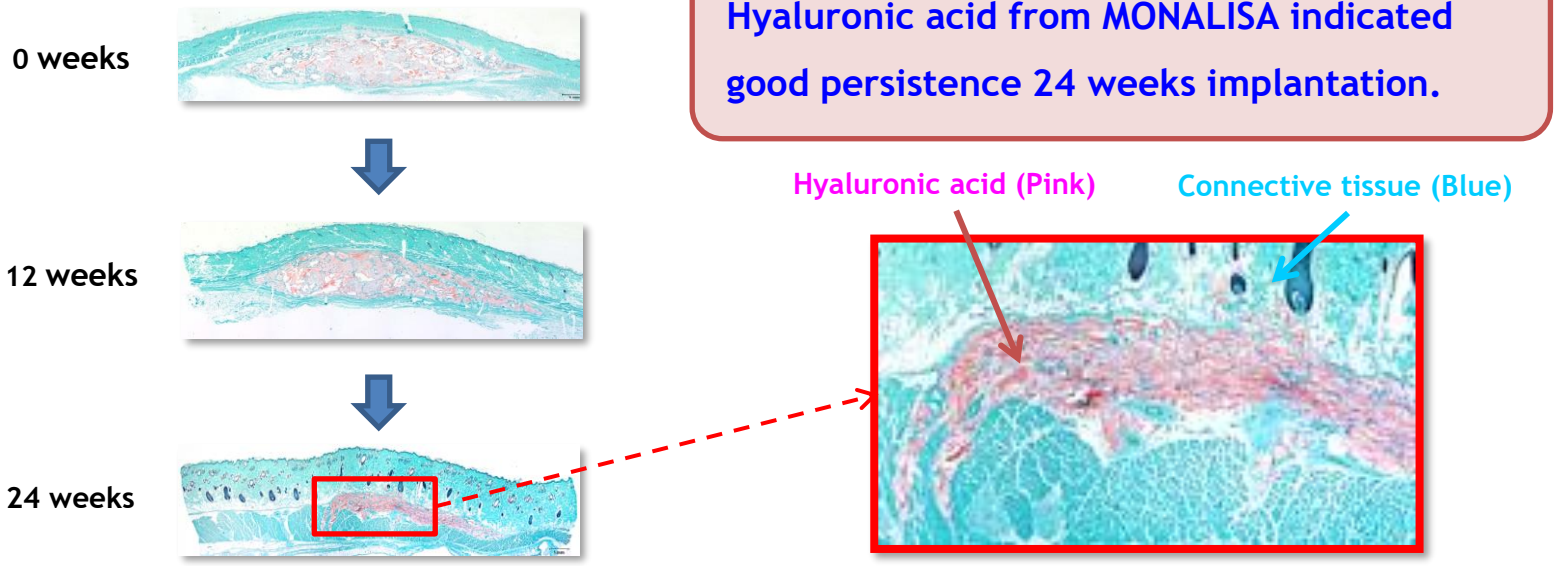


· MONALISA shows excellent sustainability

MONALISA Longevity

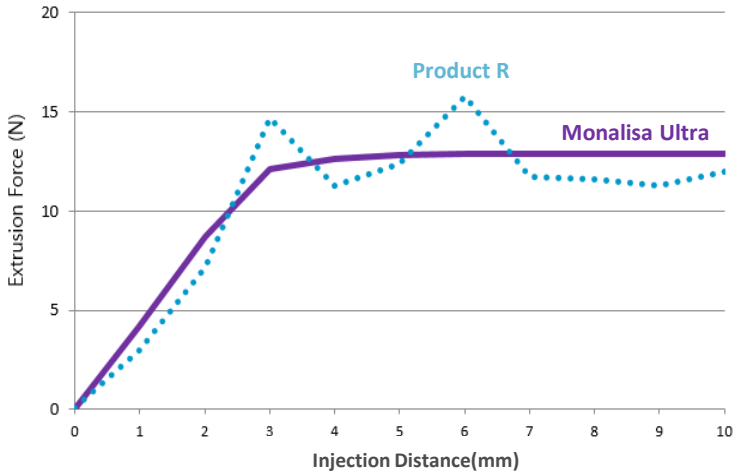
Animal test confirms the good retention of the MONALISA filler.

- **Histopathologic observation of subcutaneous implantation in rat after 12 weeks, 24 weeks**
  - Subcutaneous tissue of rat was prepared at 0, 12, and 24 weeks after injection of MONALISA. Color reaction indicates hyaluronic acid (pink) and connective tissue (blue), respectively after Safranin-O staining.

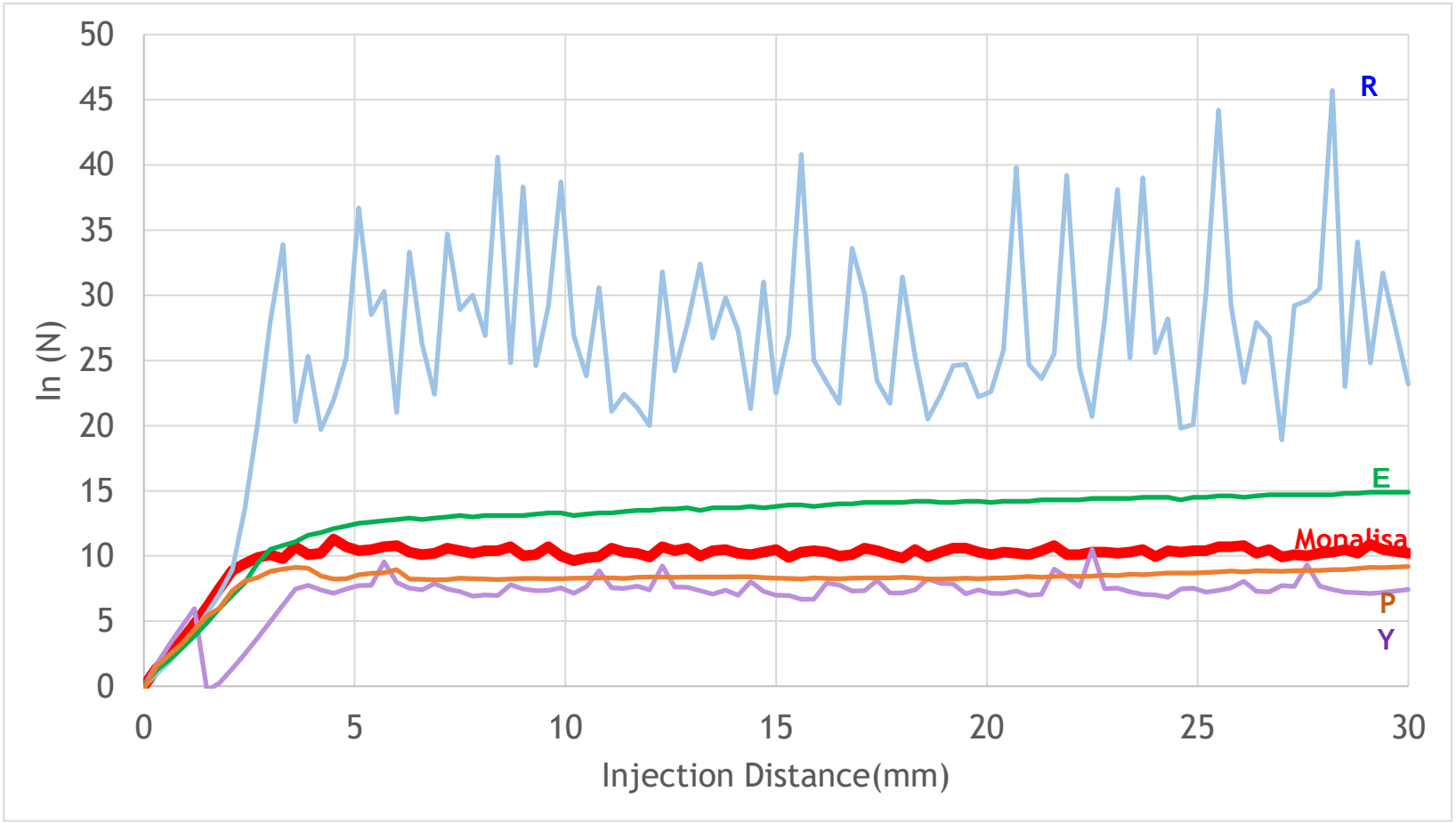


Excellent grip & Constant Injection Force

* Constant Injection Force



Constant Injection Force

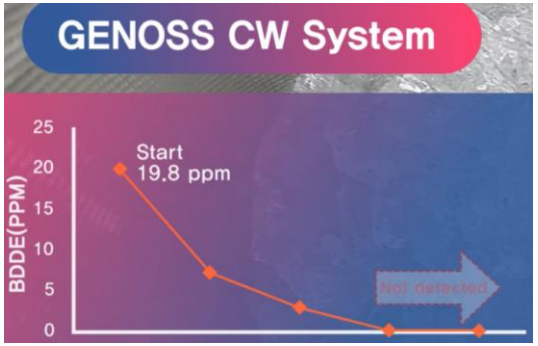


Summary

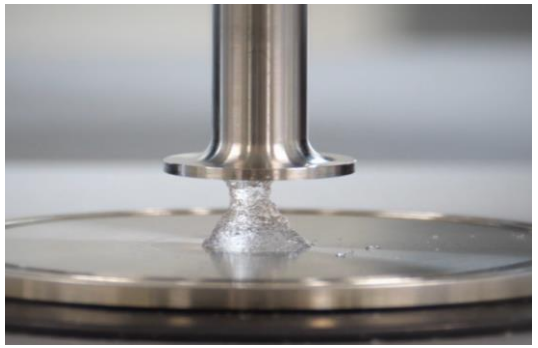

Hyaluronic Acid Dermal Filler with Lidocaine
MONALISA
Long-term Stability
Volume Effect and Retention
Safe to Use on Patients
Highly Pure Hyaluronic Acid
www.monalisamall.co.kr
GENOSS
For Patients & Doctors

For Patients & For Doctors

- Safe



- Sustainable



- Convenient

Strengths of Monalisa Filler(Korean Plastic Surgeon)

1. Syringe handle color to distinguish by filler type
   (Provide convenience for the procedure)
2. Convenient grip for filler injection
3. In the case of some existing fillers when using other needle or cannula connection often exploded under excessive pressure but never experienced
4. Relatively large volume effect when injecting the same amount compared to other Korean equivalent fillers (Provide economics of the procedure)
5. Not found any Initial foreign body reaction, lump formation during Monalisa Filler Injection

Thank You