

VARIOFILL

for Gluteal Augmentation



CE
0297

MADE
IN
GERMANY

ADODERM

CONTENT

1.PRODUCT FEATURES

2.CLINICAL FOLLOW UP

3.COMPETITORS




1. PRODUCT FEATURES




VARIOFILL
for Gluteal Augmentation

Characteristics:

Filled in: 10 ml Syringe
Shelf Expiry: 36 months
Indication: Gluteal Augmentation

Notified Body: 0297 DQS-Med 
Frankfurt, Germany.

■ MADE
■ IN
■ GERMANY



Concentration mg/ml

33mg/ml

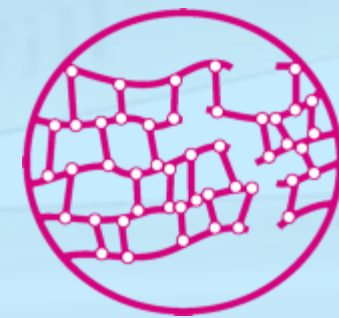
Pure HA of non-animal origin

% Crosslinking

80% of effective Oxygen molecules
bounds between HA Matrix

Rheology values

Highest G' and G'' parameters
among the HA dermal fillers



Gel structure

Highest cohesivity of HA gels.

Particle size: 80 – 150 μm

Extrusion force

For a 10ml HA gel syringe, soft
extrusion force.

Increase treatment precision and
injection control.



Injection must be DEEP into
Subcutaneous Fat Tissue

Product must be able to lift a big support
of tissue and gives lasting results

Spread pattern must be vertical to
create projection

High visco-elasticity / cohesivity to
reduce risk of gel migration

**IT IS ALL DEFINED BY
RHEOLOGY AND GEL
SPECIFICATIONS**

VARIOFILL® for Gluteal Augmentation

RHEOLOGY

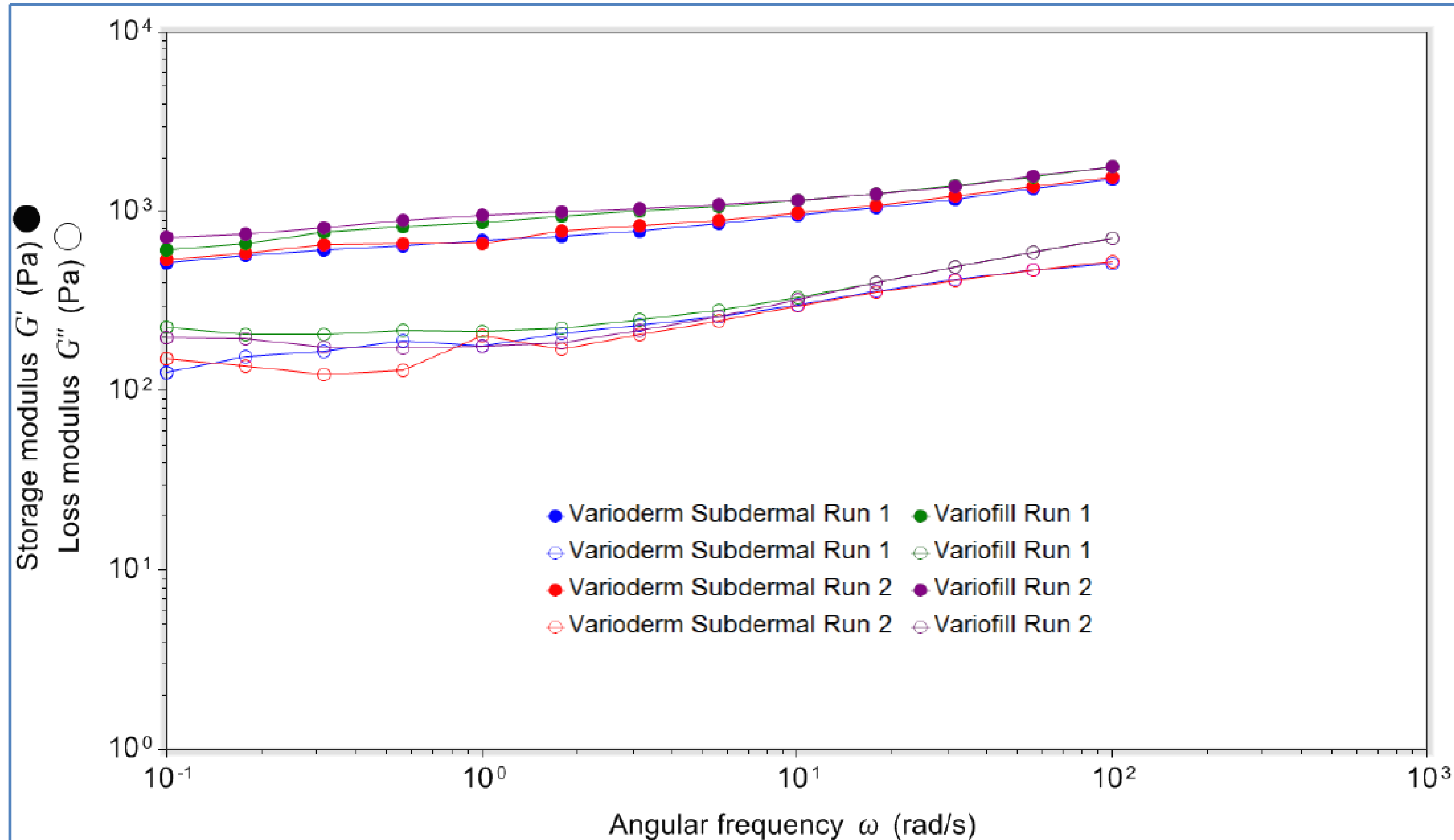


Figure 4: Storage and Loss Modulus (Pa) v Angular Frequency (rad/s) – Varioderm-Subdermal and Variofill

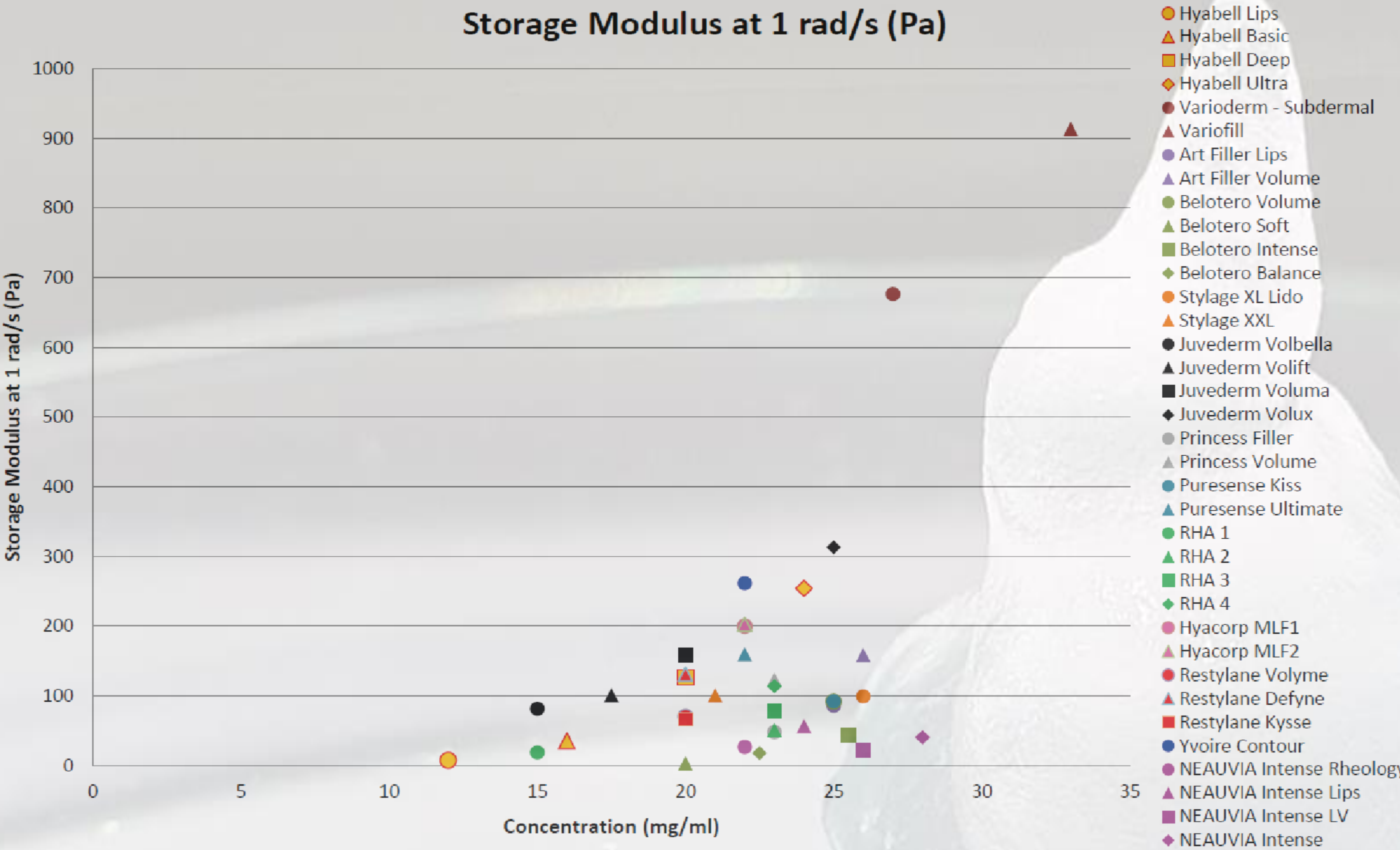


COMPARISON ELASTICITY – G'

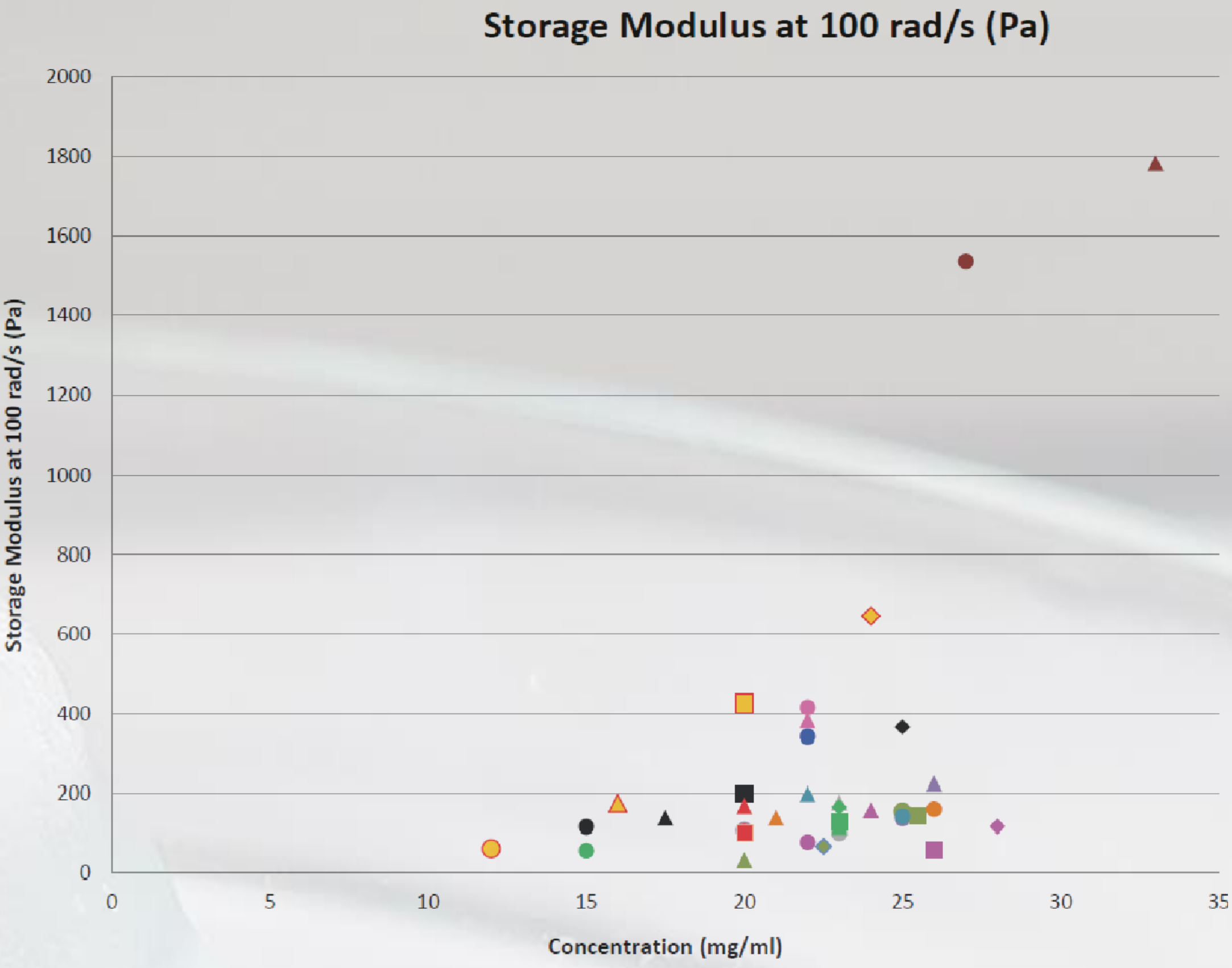
ADODERM Fillers Vs. Competitors

Comparison G'

Storage Modulus at 1 rad/s (Pa)



Storage Modulus at 100 rad/s (Pa)



COMPARISON VISCOCITY – G''

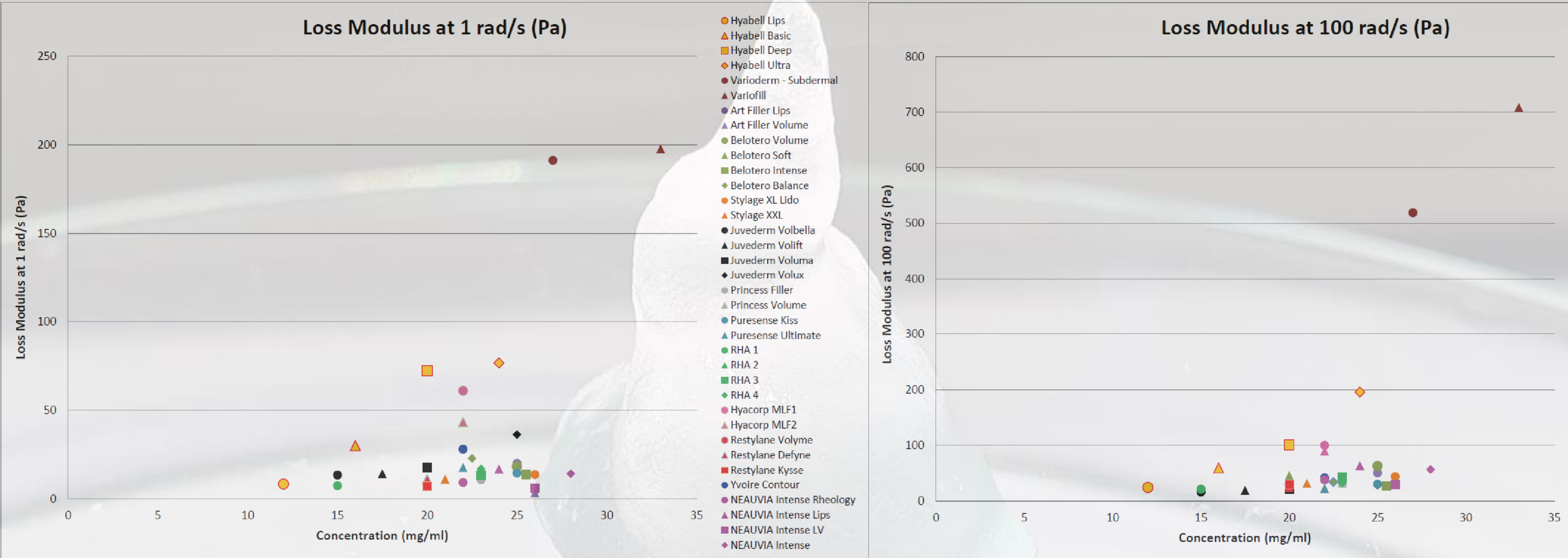
ADODERM Fillers Vs. Competitors

Comparison G''

Centre for
**Industrial
Rheology**

Rheology Lab
Rheology School
Rheology Consultancy

The Long Barn Lippen Lane Warrford Hampshire GU32 1LX UK
Tel: +44 (0)1730829858 Email: lab@rheologylab.com



HOW DO VARIOFILL® OUTSTAND AGAINST HIS COMPETITOR?

- The majority of the samples display well-formed gel behaviour, with the storage modulus showing a gel plateau over the full range of frequencies applied. This means that even deformations at the lowest frequencies applied in this report elicit a mostly elastic (solid-like) response.



- The Hyabell samples stand out as they show a greater degree of frequency dependence than the other samples tested. Under low frequency conditions the Hyabell Lips and Hyabell Basic samples are showing near liquid-like behaviour, only moving towards a gel plateau at the higher frequencies applied.




- The Varioderm-Subdermal and Variofill samples are also revealed as clear outliers, they show a gel structure similar in frequency dependence to the remaining gel-like samples but with repeatably higher modulus values across the range. This indicates that these two samples have more rigid gel structures than the remainder of the samples tested.

2. CLINICAL EVALUATION



CLINICAL EVALUATION¹

Follow-up patients:  53  6

 : 5  : 2  : 2  : 1

PMS protocol:
1 session – no touch-up
Age: 25 – 60 (Avg: 42,03 +-8,84 years)

Quantity injected / side:

Min: 40 ml (4 Variofill)
Avg: 82,46 ml (8,2 Variofill)
Max: 125 ml (12,5 Variofill)

TOTAL QUANTITY ml	PATIENTS
30 - 70	2
70 - 100	11
100-150	14
150 - 200	19
200 - 250	13

Patients were repeatedly seen in the clinic by routine to check product performance, any adverse events and patient satisfaction at 1, 3, 6, 9, 12 and 18 months after the procedure was recorded. Cases were closed 24 months after injection.

¹Clinical Evaluation Report, Internal Document Adoderm GmbH, 2020.

CLINICAL EVALUATION

Table 10: Distribution and degree of side effects during hour 0 to 48

	%
no reaction	64.97%
light	17.51%
medium	13.56%
strong	3.95%
very strong	0.00%
total	100.00%

Table 11: Distribution and degree of side effects during day 2 to 7

	%
no reaction	80.60%
light	10.17%
medium	8.47%
strong	0.75%
very strong	0.00%
total	100.00%

Table 12: Distribution and degree of side effects after 7 days and during the follow-up period

	%
no reaction	93.99%
light	2.62%
medium	1.08%
strong	0.15%
very strong	0.46%
total	100.00%

CLINICAL EVALUATION

Table 13: Side effects within 48 hours following the injection

Table of site reactions 0-48 h						
Side effect	light	medium	strong	very strong	no	total
pain	15	32	5	0	7	59
swelling	15	19	16	0	9	59
redness	20	15	0	0	24	59
bruising	25	4	0	0	30	59
itching	18	2	0	0	39	59
impending necrosis	0	0	0	0	59	59
discoloration	0	0	0	0	59	59
turned purple aspect	0	0	0	0	59	59
other	0	0	0	0	59	59
% of side effects						
VARIOFILL site reaction n=59	light	medium	severe	very strong	no	total
pain	25,42	54,24	8,47	0	11,86	
swelling	25,42	32,2	27,12	0	15,25	
redness	33,9	25,42	0	0	40,68	
bruising	42,37	6,78	0	0	50,85	
itching	30,51	3,39	0	0	66,1	
impending necrosis	0	0	0	0	100	
discoloration	0	0	0	0	100	
turned purple aspect	0	0	0	0	100	
other	0	0	0	0	100	

Table 14: Side effects from day 2 to day 7 following the injection

Table of site reactions, Observation 2 to 7 days						
Observation 2 to 7 days	light	medium	strong	very strong	no	total
swelling	16	24	3	0	16	59
pain	12	18	1	0	28	59
bruising	16	2	0	0	41	59
redness	9	1	0	0	49	59
itching	1	0	0	0	58	59
impending necrosis	0	0	0	0	59	59
discoloration	0	0	0	0	59	59
turned purple aspect	0	0	0	0	59	59
other	0	0	0	0	59	59
% of side effects						
VARIOFILL® site reaction n=59	light	medium	severe	very strong	no	total
swelling	27,12	40,68	5,08	0	27,12	
pain	20,34	30,51	1,69	0	47,46	
bruising	27,12	3,39	0	0	69,49	
redness	15,25	1,69	0	0	83,05	
itching	1,69	0	0	0	98,31	
impending necrosis	0	0	0	0	100	
discoloration	0	0	0	0	100	
turned purple aspect	0	0	0	0	100	
other	0	0	0	0	100	

Table 15: Side effects after 7 days and during the follow-up period

Table of site reactions, Observation after 7 days						
	light	medium	strong	very strong	no	total
oedema	10	15	0	3	31	59
hypersensitivity with oedema	4	3	1	0	51	59
hematoma	2	0	0	0	57	59
fever	1	0	0	0	58	59
discoloratin	0	0	0	0	59	59
super.implant.	0	0	0	0	59	59
migration	0	0	0	0	59	59
infection	0	0	0	0	59	59
necrosis	0	0	0	0	59	59
lumps	0	0	0	0	59	59
nodules	0	0	0	0	59	59
% of Adverse Event						
VARIOFILL® n=59	light	medium	severe	very strong	no	total
oedema	16,95	25,42	0	5,08	52,54	
hypersensitivity	6,78	5,08	1,69	0	86,44	
hematoma	3,39	0	0	0	96,61	
fever	1,69	0	0	0	98,31	
discoloratin	0	0	0	0	100	
super.implant.	0	0	0	0	100	
migration	0	0	0	0	100	
infection	0	0	0	0	100	
necrosis	0	0	0	0	100	
lumps	0	0	0	0	100	
nodules	0	0	0	0	100	

CLINICAL EVALUATION

Table 16: Injection technique

Injection Technique	N	%
retrotracing	27	45.76%
fan	7	11.86%
criss-cross	0	0.00%
retrotracing and fan	19	32.20%
retrotracing and tower	1	1.69%
retrotracing, fan and criss-cross	4	6.78%
other	1	1.69%
total	59	100.00%

Table 17: Needle size/cannula

Needle size/cannula	N	%
16G	12	20.34%
18G	38	64.41%
16G and 18G	9	15.25%
total	59	100.00%

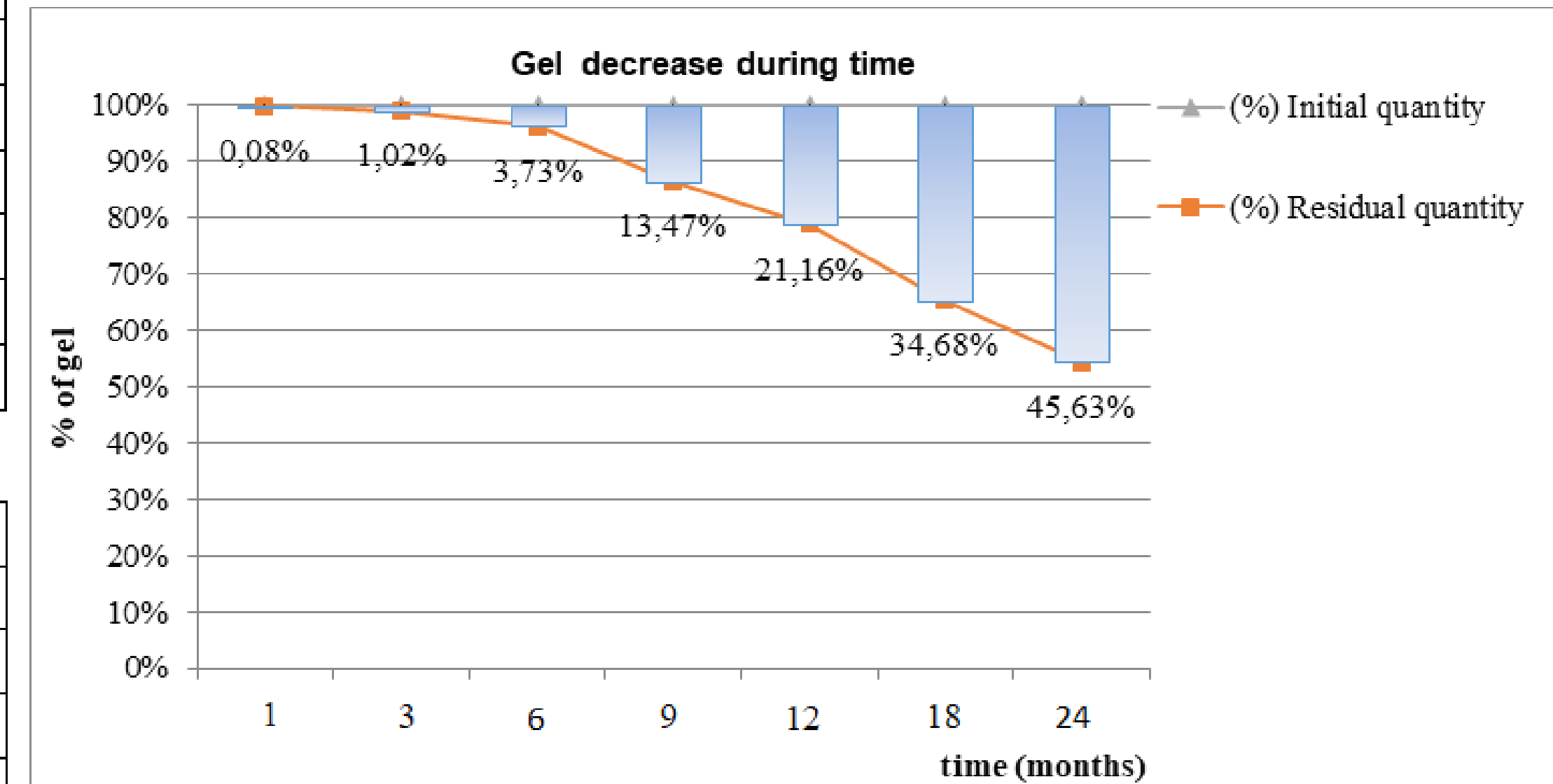
CLINICAL EVALUATION

Table 8: Summary of efficiency (physicians' rating)

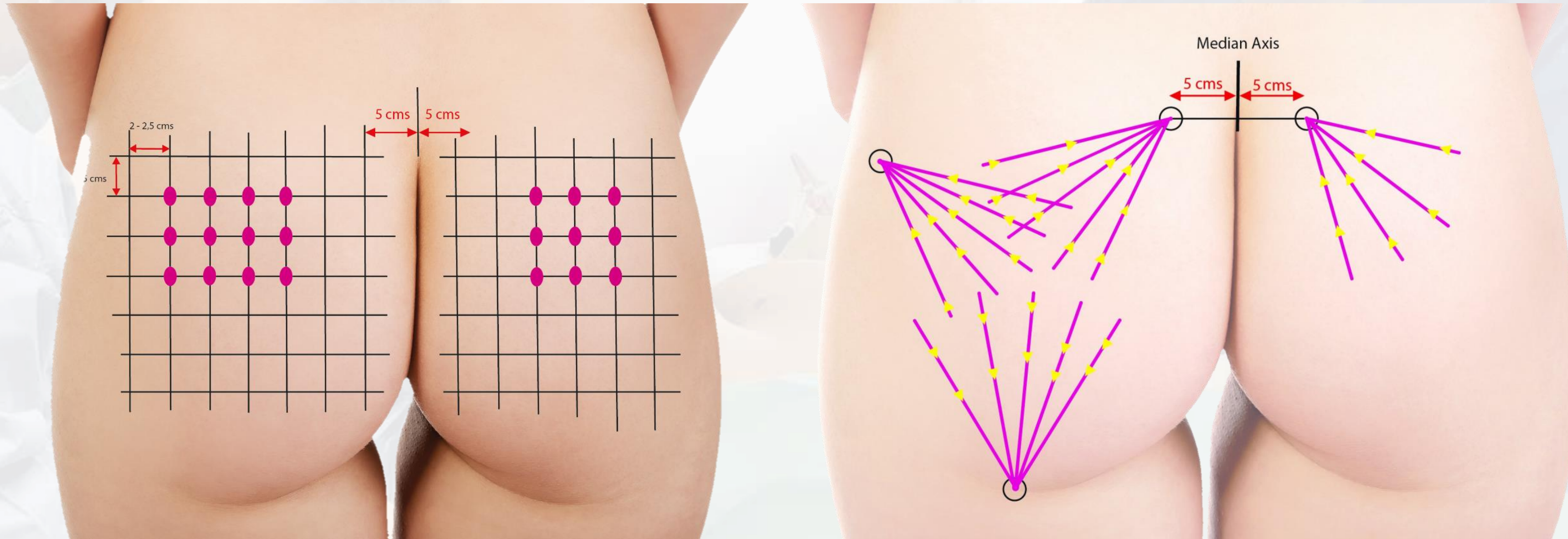
Efficiency							
time	1 month	3 months	6 months	9 months	12 months	18 months	24 months
excellent	59	59	58	52	20	5	2
good	0	0	1	7	36	32	22
poor	0	0	0	0	0	10	0
total number	59	59	59	59	56	47	24
%							
excellent	100,00%	100,00%	98,31%	88,14%	35,71%	10,64%	8,33%
good	0,00%	0,00%	1,69%	11,86%	64,29%	68,09%	91,67%
poor	0,00%	0,00%	0,00%	0,00%	0,00%	21,28%	0,00%

Table 9: Summary of patients' satisfaction

Satisfaction							
patient	1 month	3 months	6 months	9 months	12 months	18 months	24 months
excellent	59	59	58	53	21	5	2
good	0	0	1	6	35	37	22
poor	0	0	0	0	0	5	0
total number	59	59	59	59	56	47	24
%							
excellent	100,00%	100,00%	98,31%	89,83%	37,50%	10,64%	8,33%
good	0,00%	0,00%	1,69%	10,17%	62,50%	78,72%	91,67%
poor	0,00%	0,00%	0,00%	0,00%	0,00%	10,64%	0,00%



INJECTION TECHNIQUES



According to patient need, type of buttock, doctors' own experience and expertise either blunt cannula or needle technique is performed. Variofill® for Gluteal Augmentation Treatment guidelines describing each method and videos are available.



3. COMPETITORS

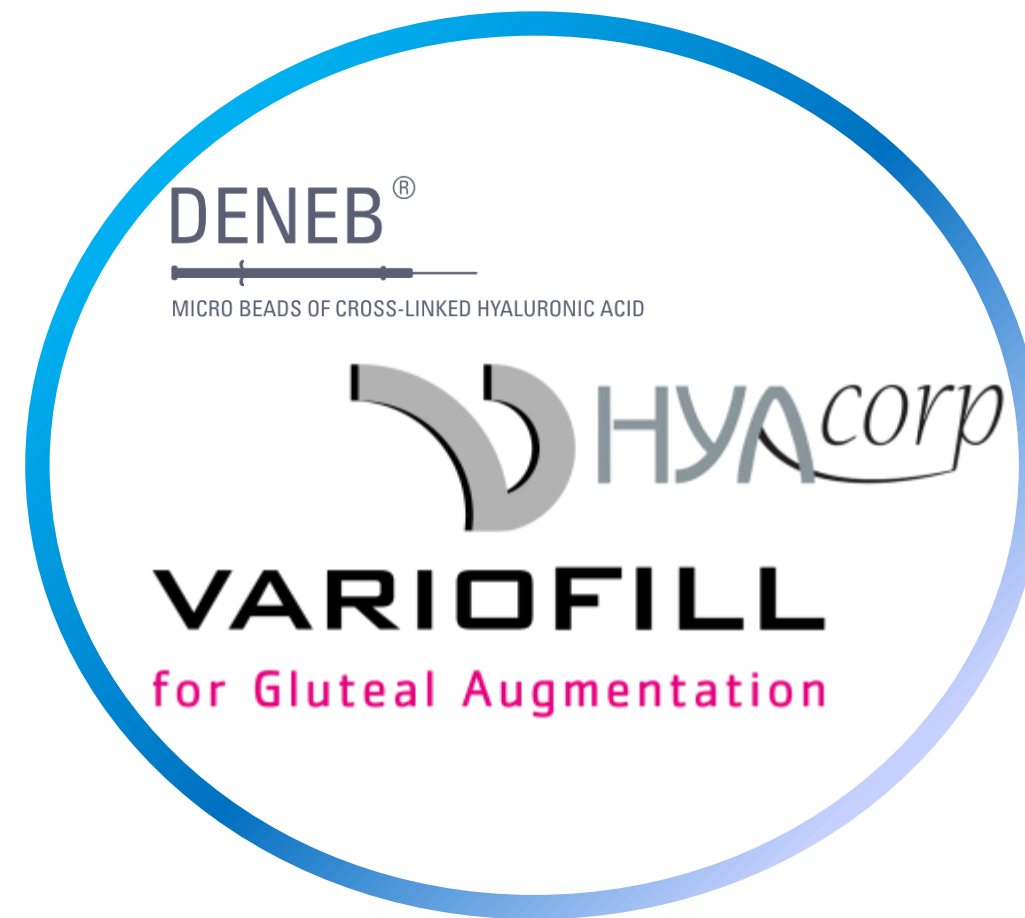

VARIOFILL
for Gluteal Augmentation

3. COMPETITORS



Hyaluronic Acid

If complication or
undesired result:
Can be dissolved.



Poly-L-Lactic Acid

If complication or
undesired result:
Cannot be dissolved.



Made in Germany

According to package
information.

CE Mark Approved by German Authority

According to CE Mark
Number.



24
MONTHS


VARIOFILL
for Gluteal Augmentation

Poly-L-Lactic Acid

sculptra[®]
poly-L-lactic acid

Complication
undesired result:

Can be dissolved.

Can be dissolved.

Number of
Treatments

1
(max 2 according to technique
of injection, 9/12 months
after)

**3 to 4 treatments, 8
weeks apart.**

Number of
Syringes / Vials

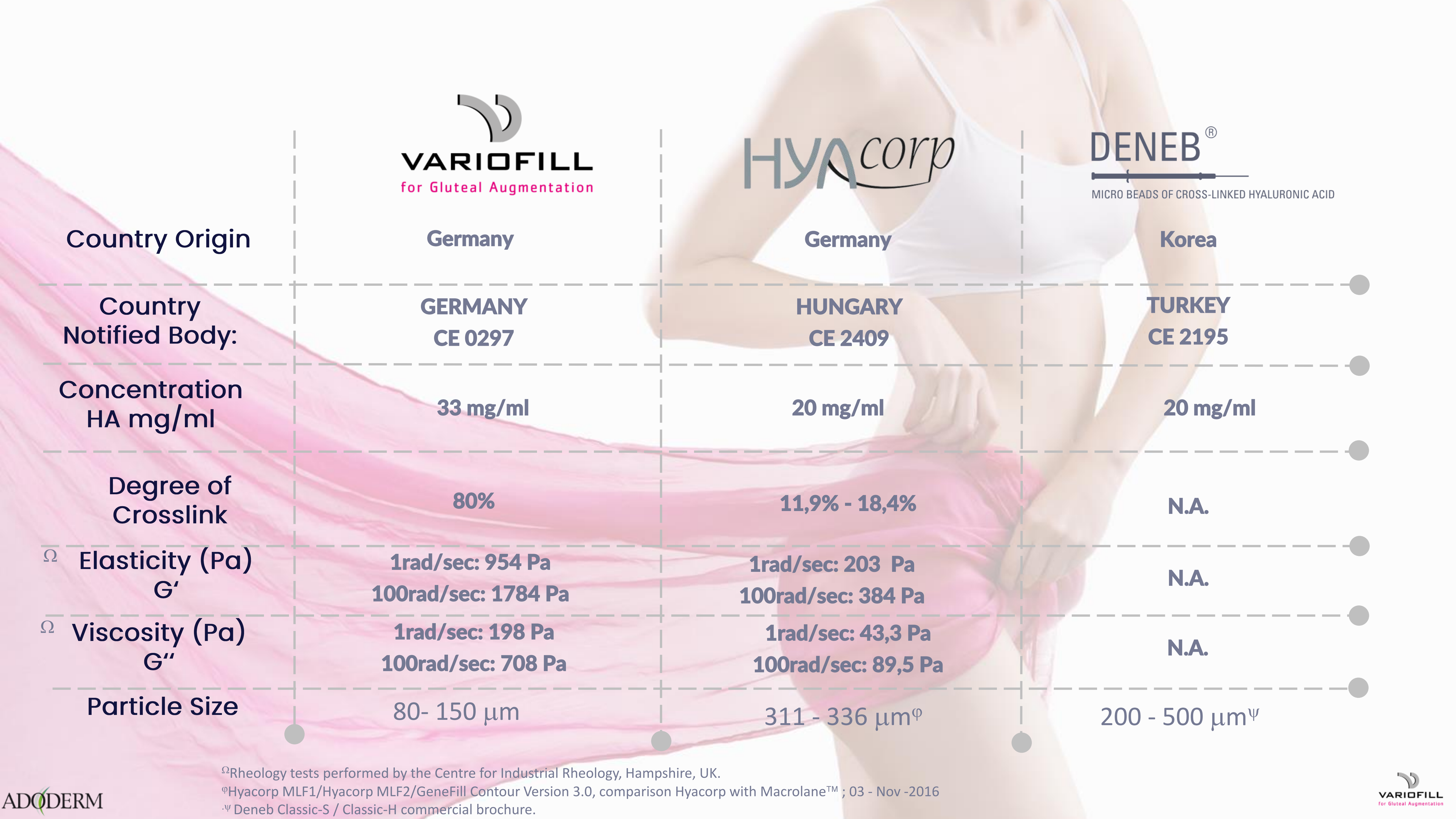
**Min.: 8
Max: 25.**

**Min.: 24
Max: 40**

Cost of
Treatment

AFFORDABLE

VERY EXPENSIVE



Country Origin	Germany	Germany	Korea
Country Notified Body:	GERMANY CE 0297	HUNGARY CE 2409	TURKEY CE 2195
Concentration HA mg/ml	33 mg/ml	20 mg/ml	20 mg/ml
Degree of Crosslink	80%	11,9% - 18,4%	N.A.
Ω Elasticity (Pa) G'	1rad/sec: 954 Pa 100rad/sec: 1784 Pa	1rad/sec: 203 Pa 100rad/sec: 384 Pa	N.A.
Ω Viscosity (Pa) G''	1rad/sec: 198 Pa 100rad/sec: 708 Pa	1rad/sec: 43,3 Pa 100rad/sec: 89,5 Pa	N.A.
Particle Size	80- 150 μm	311 - 336 μm^{Φ}	200 - 500 μm^{Ψ}

Ω Rheology tests performed by the Centre for Industrial Rheology, Hampshire, UK.
 Φ Hyacorp MLF1/Hyacorp MLF2/GeneFill Contour Version 3.0, comparison Hyacorp with Macrolane™ ; 03 - Nov -2016
 Ψ Deneb Classic-S / Classic-H commercial brochure.

OTHER KEY FEATURES:



Package made with selected secondary fibers from providers certified FSC.



Package material certified ISO Medical Degree Printer Edelman Group. Heidenheim, Germany.



Security features in Package.



Product traceability.



Get Ready for Summer
www.variofill.com