

Soft Tissue Fillers: What's New

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Hot Topics

plastic
surgery

THE MEETING

2015

BOSTON
OCTOBER 16-20



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
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Disclosures

RTI Surgical - Advisor

Suneva Medical - Instructor

Angiotech/Surgical Specialties - Advisory Board

Will use brand names due to lack of
distinguishing generic names

Status of Products

Restylane Products (Lyft, Silk) Galderma

- Hyaluronic acids

Juvederm Products (Ultra) Allergan

- Hyaluronic acid

Radiesse Merz

- Calcium hydroxylapatite

FDA Status

- Will discuss new approvals

Presentation Level of Evidence

Levels of Evidence and Qualifying Studies (Therapeutic Studies):

- I High-quality, multi-centered or single-centered, randomized controlled trial with adequate power ($N \geq 100$); or a systematic review of these studies
- II Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
- III Retrospective comparative study; case-control study; or a systematic review of these studies
- IV Case series
- V Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"

Treatment & Costs

- Product \$250 to \$350 per syringe
- Disposables None (injection cannula \$5)
- Treatment Variable number of syringes
- Sessions 1-2
- Patient cost \$600 to \$900 per syringe

FDA Safety Communication

The screenshot shows the FDA website's navigation and content. At the top left is the U.S. Department of Health and Human Services logo. The main header features the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". To the right of the header is a search bar with the text "Search FDA" and a magnifying glass icon. Below the header is a horizontal menu with buttons for "Home", "Food", "Drugs", "Medical Devices", "Radiation-Emitting Products", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", and "Tobacco Products". The "Medical Devices" button is highlighted. Below the menu is a breadcrumb trail: "Home > Medical Devices > Medical Device Safety > Safety Communications". On the left side, there is a sidebar with a "Safety Communications" header and two menu items: "Information About Heparin" and "Preventing Tubing and Luer". The main content area features a large heading: "Unintentional Injection of Soft Tissue Filler into Blood Vessels in the Face: FDA Safety Communication".

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | **Medical Devices** | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Medical Devices

Home > Medical Devices > Medical Device Safety > Safety Communications

Safety Communications

- Information About Heparin
- Preventing Tubing and Luer

Unintentional Injection of Soft Tissue Filler into Blood Vessels in the Face: FDA Safety Communication

Recent FDA Approvals

- 2013 Voluma Cheek augmentation
- 2014 Restylane Silk Lips & perioral lines
- 2015 Restylane Lyft Facial folds
- 2015 Radiesse Hands
- 2015 Juvederm Lips & perioral lines

Filler Rheology

Basics of Dermal Filler Rheology

SÉBASTIEN PIERRE, PHD,* STEVEN LIEW, MD,† AND AUDE BERNARDIN, PHD*

<i>Filler</i>	<i>G' (Pa)</i>	<i>G'' (Pa)</i>	<i>Tan δ</i>	<i>Compression (gmf)</i>
Juvéderm Ultra XC	207	80	0.39	96
Juvéderm Ultra Plus XC	263	79	0.30	112
Juvéderm Voluma XC	398	41	0.10	40
Juvéderm Volift with lidocaine†	340	46	0.14	30
Juvéderm Volbella with lidocaine†	271	39	0.14	19
Restylane-L	864	185	0.21	29
Perlane-L	977	198	0.20	32
Belotero Balance	128	82	0.64	69

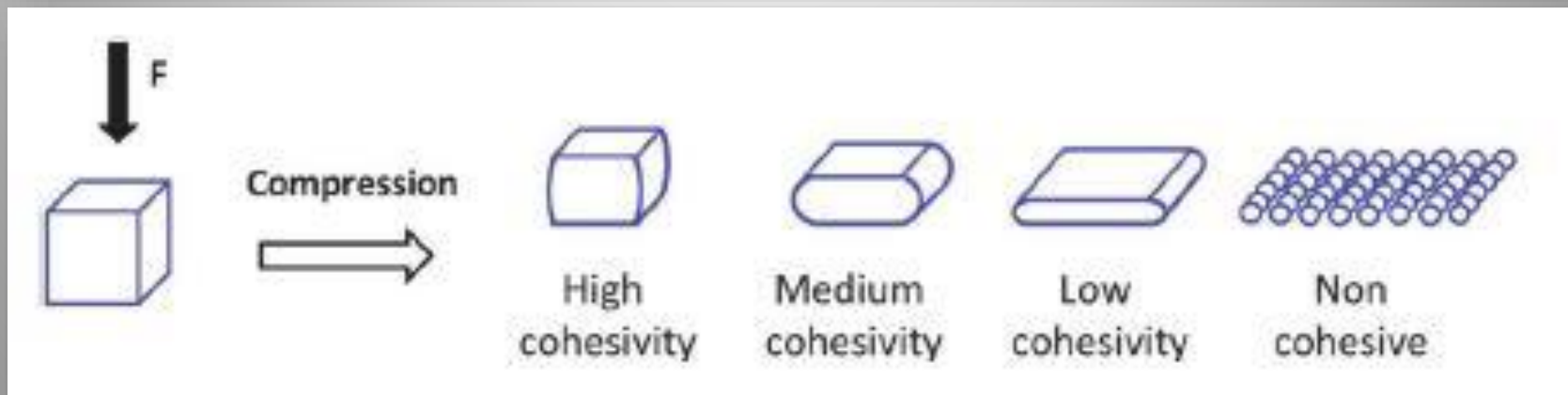
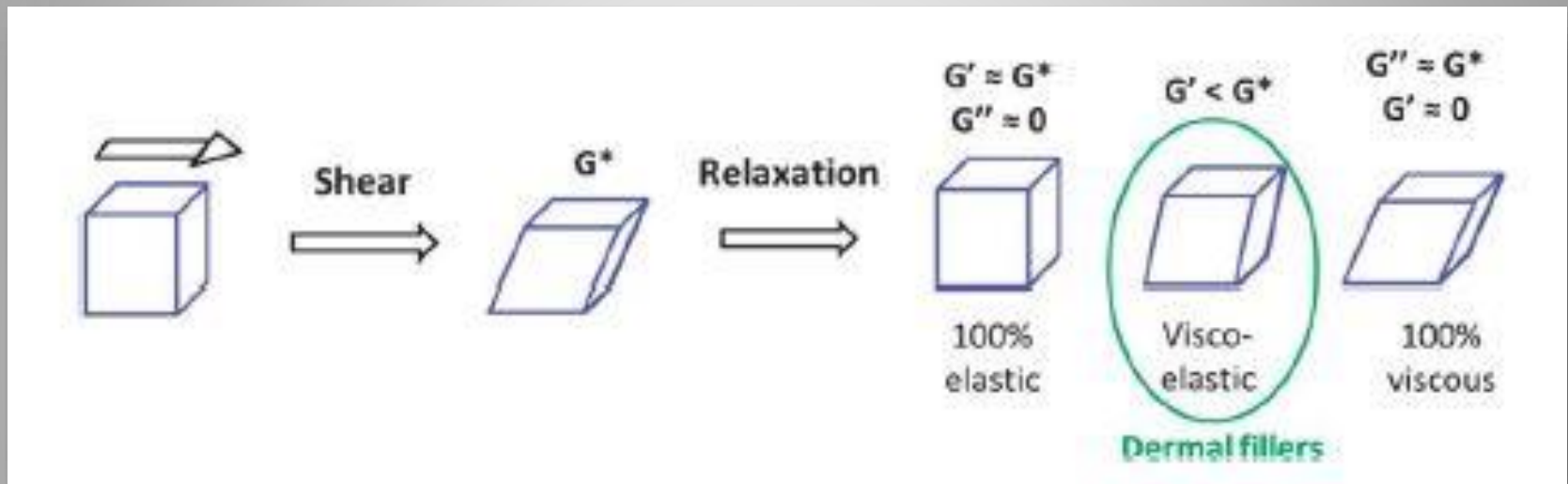
Filler Rheology

G' = Elastic behavior (modulus)

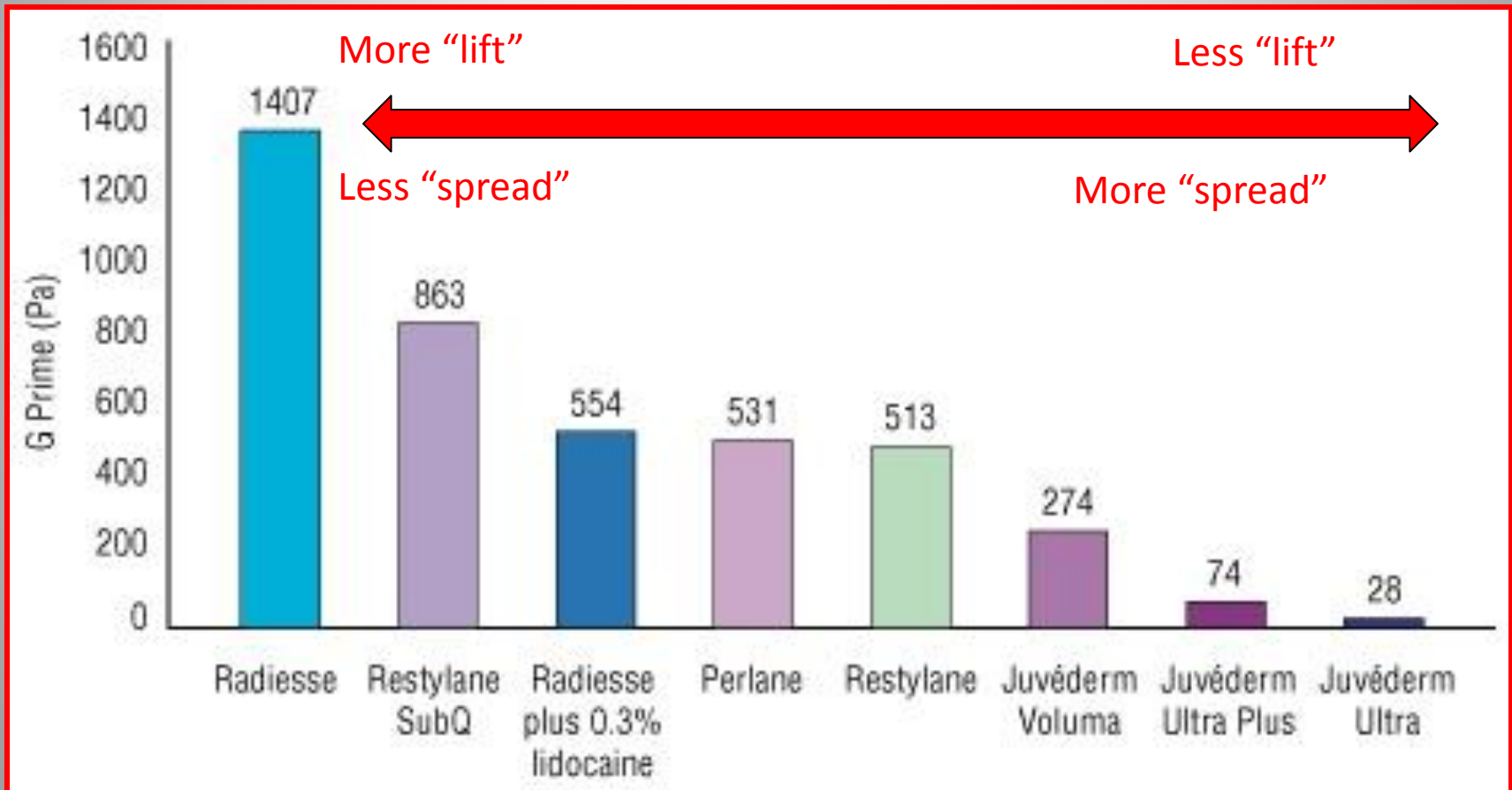
How much it can recover after a stress force

<i>Filler</i>	<i>G' (Pa)</i>	<i>G'' (Pa)</i>	<i>Tan δ</i>	<i>Compression (gmf)</i>
Juvéderm Ultra XC	207	80	0.39	96
Juvéderm Ultra Plus XC	263	79	0.30	112
Juvéderm Voluma XC	398	41	0.10	40
Juvéderm Volift with lidocainet	340	46	0.14	30
Juvéderm Volbella with lidocainet	271	39	0.14	19
Restylane-L	864	185	0.21	29
Perlane-L	977	198	0.20	32
Belotero Balance	128	82	0.64	69

Filler Rheology



G Prime



*Mathematical description of products tendency to be deformed elastically.

May not match clinical results

Radiesse for Hands

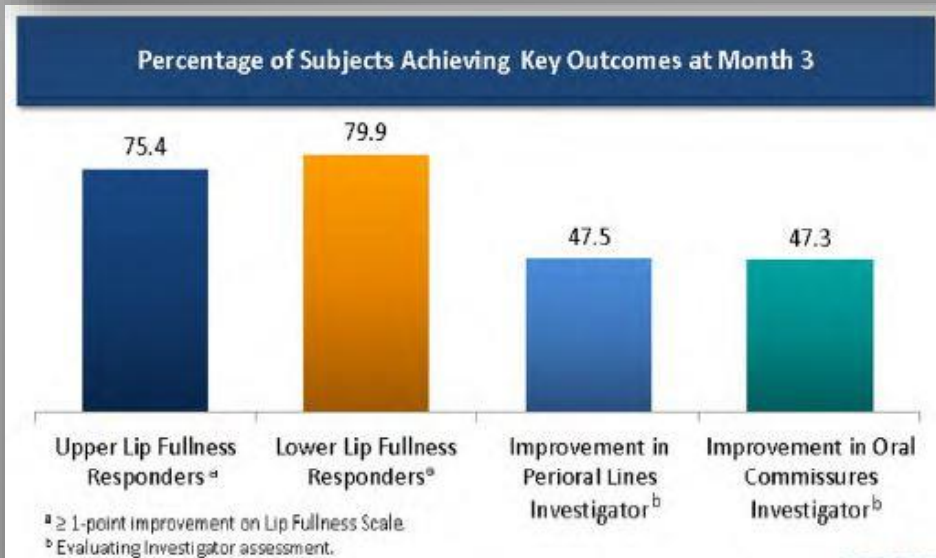
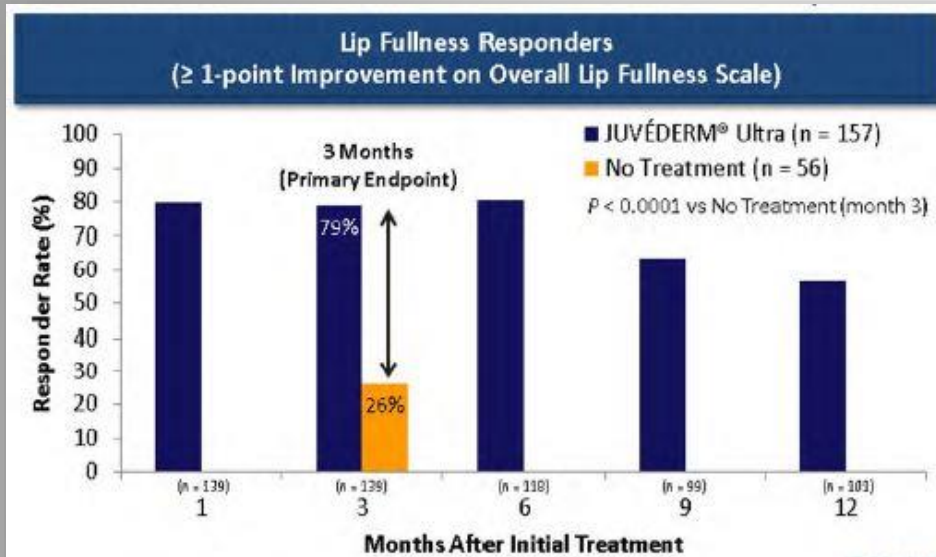
RCT at 6 sites

- 85 patients, maximum 3 cc Radiesse per hand
- Mean age: 53-54 years
 - Mostly white females
- 3 months
 - 75% had ≥ 1 point improvement (vs 3.4% of controls)
 - 76% rated “much” or “very much improved”
- Lasts up to 1 year
 - Some had retreatment
- Has lidocaine

Juvederm Ultra XC for Lips

- Previous indication
 - Mid to deep dermis, facial wrinkles & folds
- Has lidocaine
- Single blinded MC-RCT
 - 157 Juvederm patients + 56 controls (then crossed over)
 - Touch up at 2-4 weeks if needed
 - Validated 5 point scale
 - **Total volume (initial + touch up): 2.1 cc**
 - Upper lip 0.9 cc Lower lip 0.7 cc
 - Upper lip lines 0.2 cc Lower lip lines 0.1 cc
 - Oral commissure 0.4 cc

Juvederm Ultra XC for Lips



- Lasts up to 1 year
- Lip Improvement
 - 3 Months - 79%
 - 1 year - 78%

Restylane Update

New Product

Restylane
Silk

No Change

Restylane[®]

Name Change

Perlane[®]



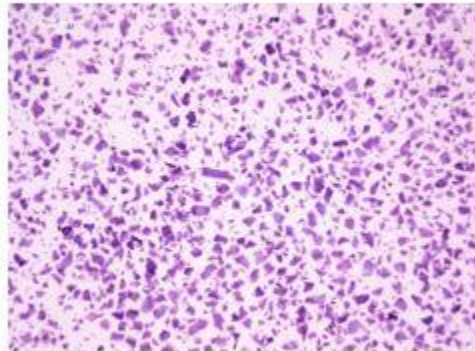
Restylane[®]

LYFT

Restylane Product Particle Size

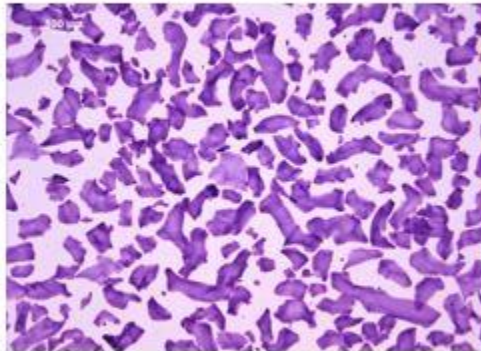
All 3 have 20 mg HA per mL
Particle size is different

Silk



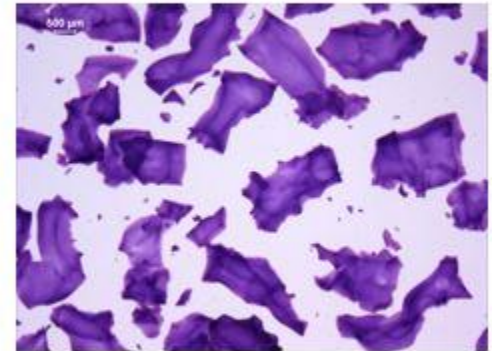
Small Particle HA
Range of 50–220 μm^*

Restylane



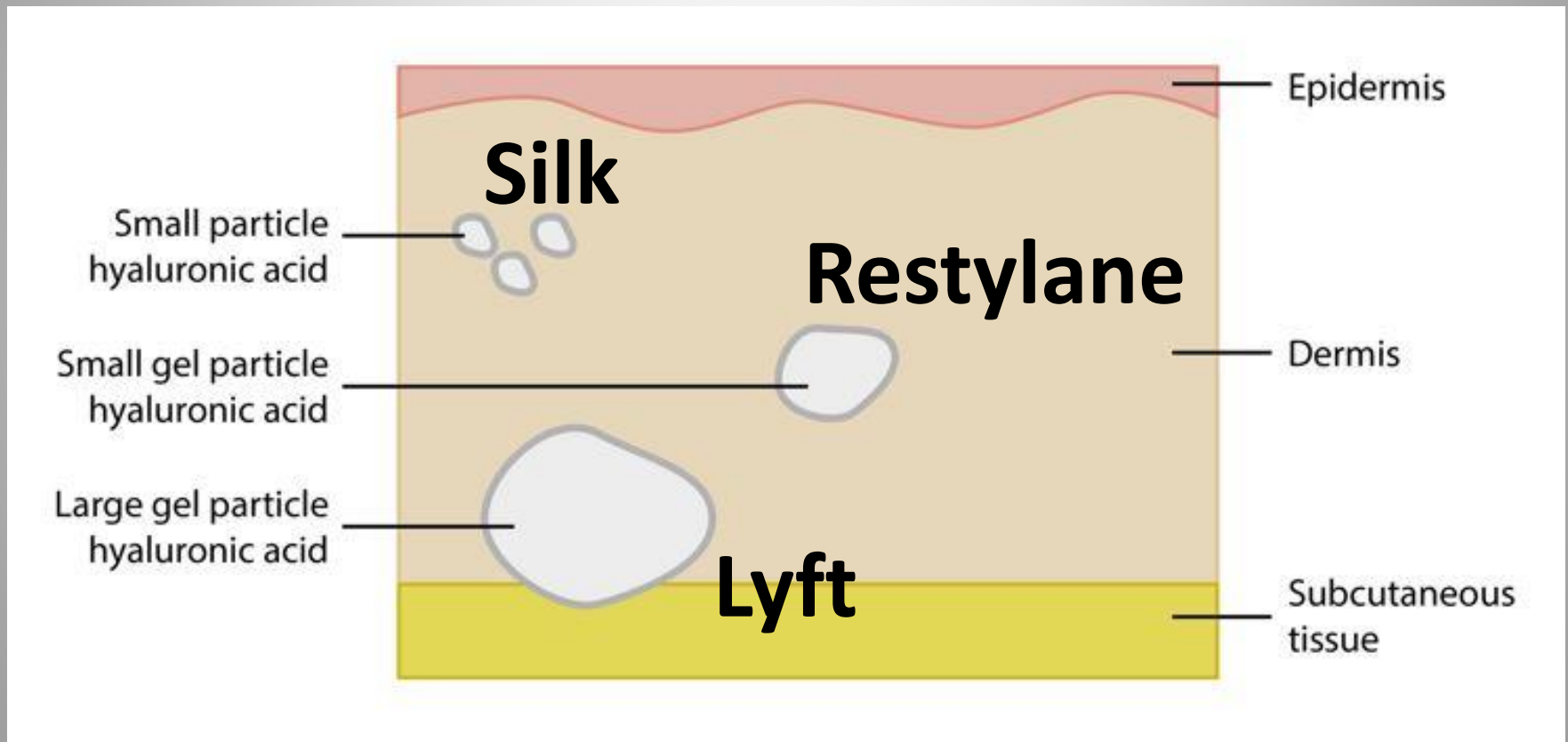
Small Gel Particle HA
Range of 330–430 μm^*

Lyft



Large Gel Particle HA
Range of 750–1000 μm^*

Particle Size & Injection Depth

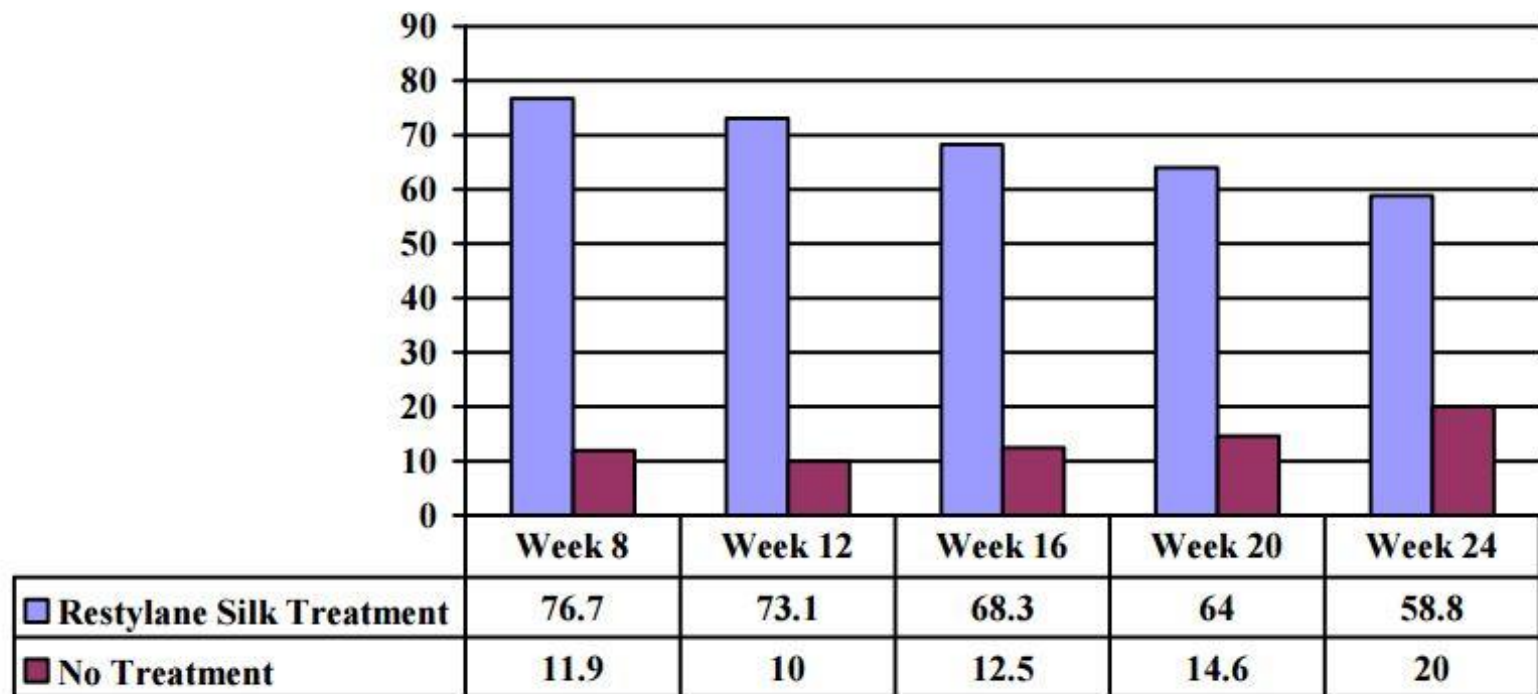


Restylane Silk Approval

- RCT 221 subjects at 14 centers
- Effectiveness: ≥ 1 grade improvement
- Injection volume
 - Upper & lower lip: Mean 2.2 cc
 - Perioral lines: Mean 0.5 cc

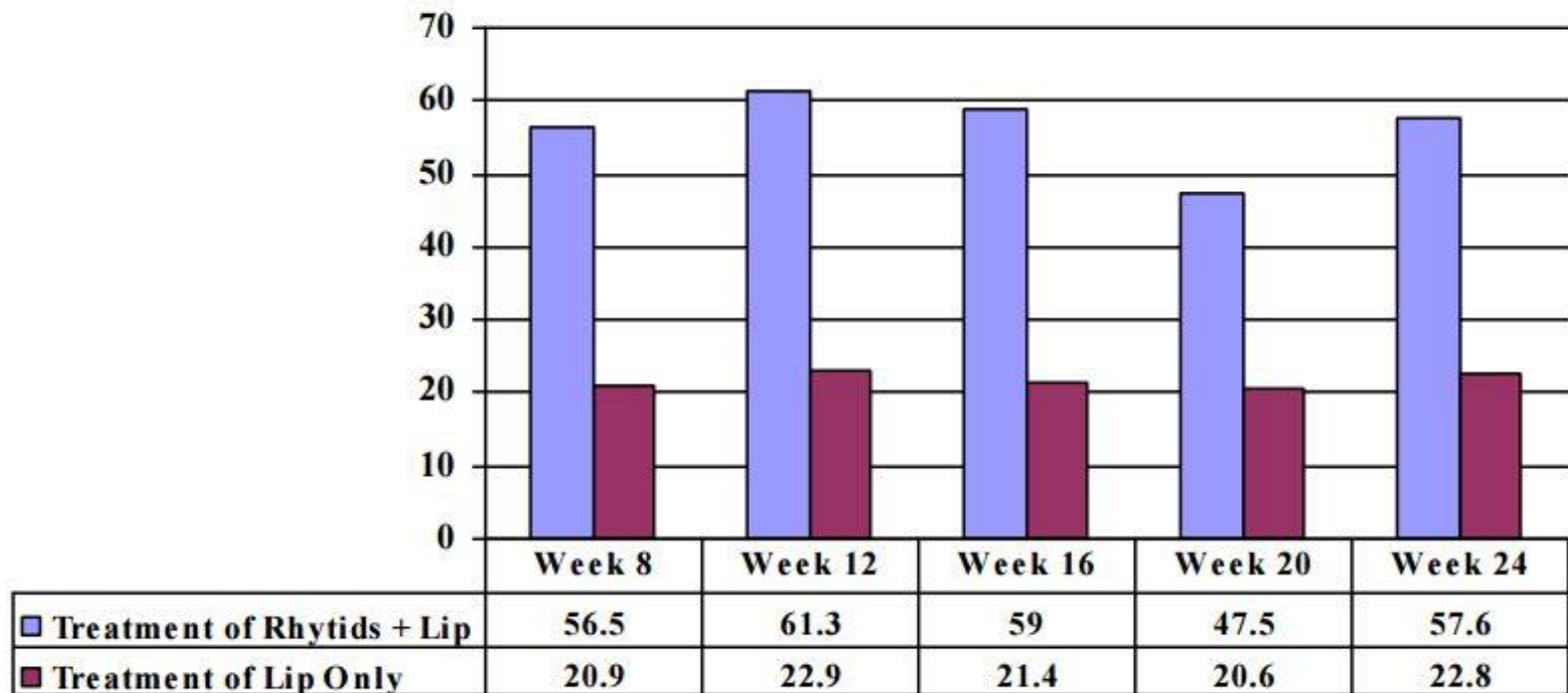
Restylane Silk Approval: Lips

**Proportion (%) of MLFS Responders Measured by the Blinded Evaluator
(Upper and Lower Lip Combined)**



Restylane Silk Approval: Perioral Lines

**Proportion (%) of Responders Measured by the Blinded Evaluator
for Upper Perioral Rhytids**



Questions?

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[For Physicians]

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