Soft Tissue Fillers: What’s New

Karol A Gutowski, MD, FACS

Hot Topics
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
Levels of Evidence and Qualifying Studies (Therapeutic Studies):

I  High-quality, multi-centered or single-centered, randomized controlled trial with adequate power (N ≥ 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>$250 to $350 per syringe</td>
</tr>
<tr>
<td>Disposables</td>
<td>None (injection cannula $5)</td>
</tr>
<tr>
<td>Treatment</td>
<td>Variable number of syringes</td>
</tr>
<tr>
<td>Sessions</td>
<td>1-2</td>
</tr>
<tr>
<td>Patient cost</td>
<td>$600 to $900 per syringe</td>
</tr>
</tbody>
</table>
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*

<table>
<thead>
<tr>
<th>Filler</th>
<th>$G'$ (Pa)</th>
<th>$G''$ (Pa)</th>
<th>$\tan \delta$</th>
<th>Compression (gmf)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juvéderm Ultra XC</td>
<td>207</td>
<td>80</td>
<td>0.39</td>
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<td>Belotero Balance</td>
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<td>82</td>
<td>0.64</td>
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**Filler Rheology**

\[ G' = \text{Elastic behavior (modulus)} \]

How much it can recover after a stress force

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Filler Rheology

Shear

G*

Relaxation

100% elastic

G' = G*

G'' = 0

Visco-elastic

Dermal fillers

G' < G*

100% viscous

G'' = G*

G' = 0

Compression

High cohesivity

Medium cohesivity

Low cohesivity

Non cohesive
G Prime

*Mathematical description of products tendency to be deformed elastically. May not match clinical results
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
- No Change
- Name Change
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

Silk

Restylane

Lyft
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)

<table>
<thead>
<tr>
<th></th>
<th>Week 8</th>
<th>Week 12</th>
<th>Week 16</th>
<th>Week 20</th>
<th>Week 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restylane Silk Treatment</td>
<td>76.7</td>
<td>73.1</td>
<td>68.3</td>
<td>64</td>
<td>58.8</td>
</tr>
<tr>
<td>No Treatment</td>
<td>11.9</td>
<td>10</td>
<td>12.5</td>
<td>14.6</td>
<td>20</td>
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Restylane Silk Approval: Perioral Lines

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

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<th>Week</th>
<th>Treatment of Rhytids + Lip</th>
<th>Treatment of Lip Only</th>
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<tr>
<td>8</td>
<td>56.5</td>
<td>20.9</td>
</tr>
<tr>
<td>12</td>
<td>61.3</td>
<td>22.9</td>
</tr>
<tr>
<td>16</td>
<td>59</td>
<td>21.4</td>
</tr>
<tr>
<td>20</td>
<td>47.5</td>
<td>20.6</td>
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<td>24</td>
<td>57.6</td>
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Questions?

Karol@DrGutowski.com

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[For Physicians]

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