

# New Filler Approval: Juvederm Volbella

*Karol A Gutowski, MD, FACS*

*Hot Topics*

plastic  
surgery

THE MEETING

Los Angeles

September 23-27, 2016



# Disclosures

Angiotech/Surgical Specialties - Advisory Board

AxcelRx Pharmaceuticals - Advisory Board

Suneva Medical - Instructor

Will use brand names due to lack of  
distinguishing generic names

# Status of Product

## **Juvederm Volbella XC**

- Allergan
- Cross-linked hyaluronic acid injectable soft tissue filler
- Produced by *Streptococcus*
- 15 mg HA/mL + lidocaine
- (Ultra & Ultra Plus: 24 mg, Voluma: 20 mg)

**Indications:** Lips & perioral rhytides, >21 years old

**FDA Status:** Approved

**Availability:** October 2016

# 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 cost To be determined
- Disposables None (injection cannula \$5-10)
- Treatment 1 to 6 syringes (2.6 average)
- Sessions 1 or 2
- Patient cost To be determined

# 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
- **2016**      **Volbella**      **Lips & perioral lines**

# Match Filler to Need

## Lips<sup>1</sup>

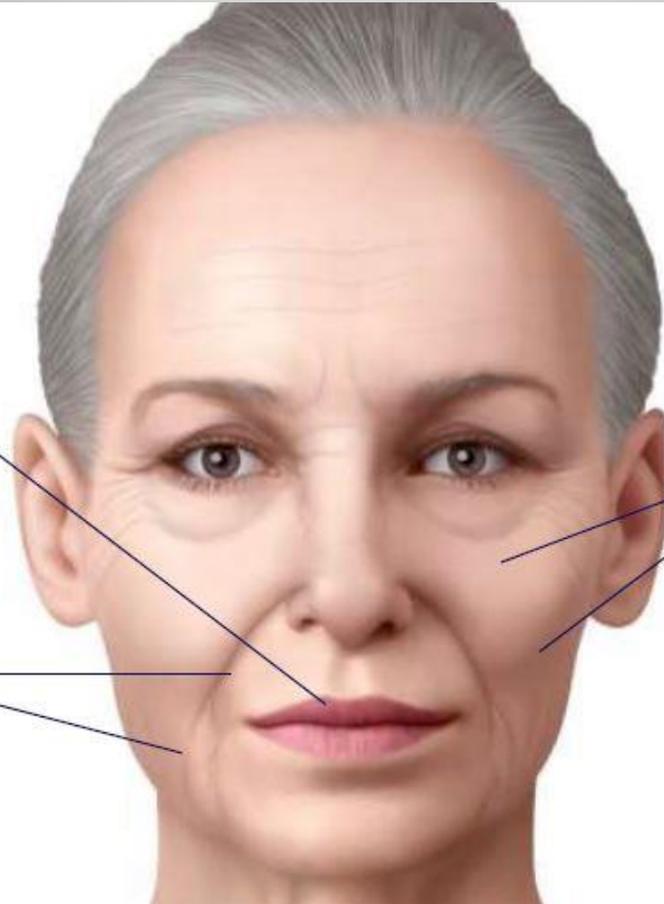
**Goals:** Easy molding and spreadability

**Challenges:** Avoid visible edges and bumps

## Wrinkles/Folds<sup>1</sup>

**Goals:** Moldable, integrate well with movement

**Challenges:** Resist shearing and mild compressive forces



## Midface Volumization<sup>1</sup>

**Goals:** Volume restoration, 3-D contouring

**Challenges:** Resist shearing and compressive forces

# Physical Properties

## Viscoelasticity<sup>1</sup>

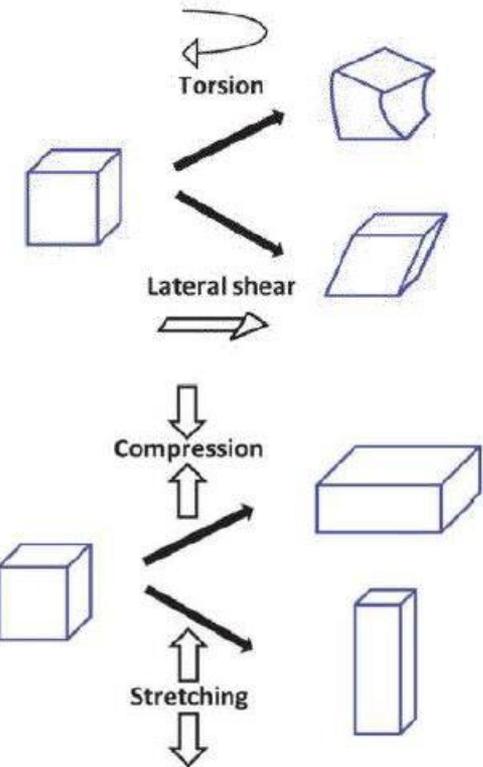
- Affects how the filler behaves when subjected to shearing (lateral) forces created by facial movement

## Cohesivity<sup>1</sup>

- How well the filler behaves as a gel deposit once it is implanted in the face

## Viscosity<sup>1</sup>

- How well the filler flows when subjected to the high shear forces of injection



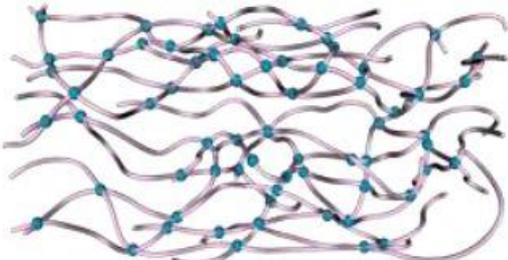
# Hylacross vs Vycross Technology

## HYLACROSS™

100% high-molecular weight  
HA chains<sup>1</sup>



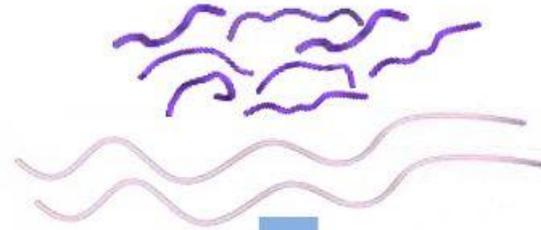
Highly cross-linked



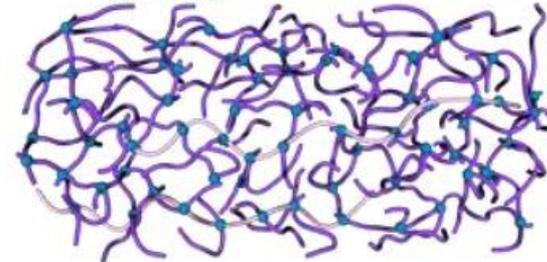
**JUVÉDERM® Ultra**  
**JUVÉDERM® Ultra Plus**

## VYCROSS®

Proprietary mixture of low- and  
high-molecular weight HA chains<sup>1</sup>



Tightly cross-linked

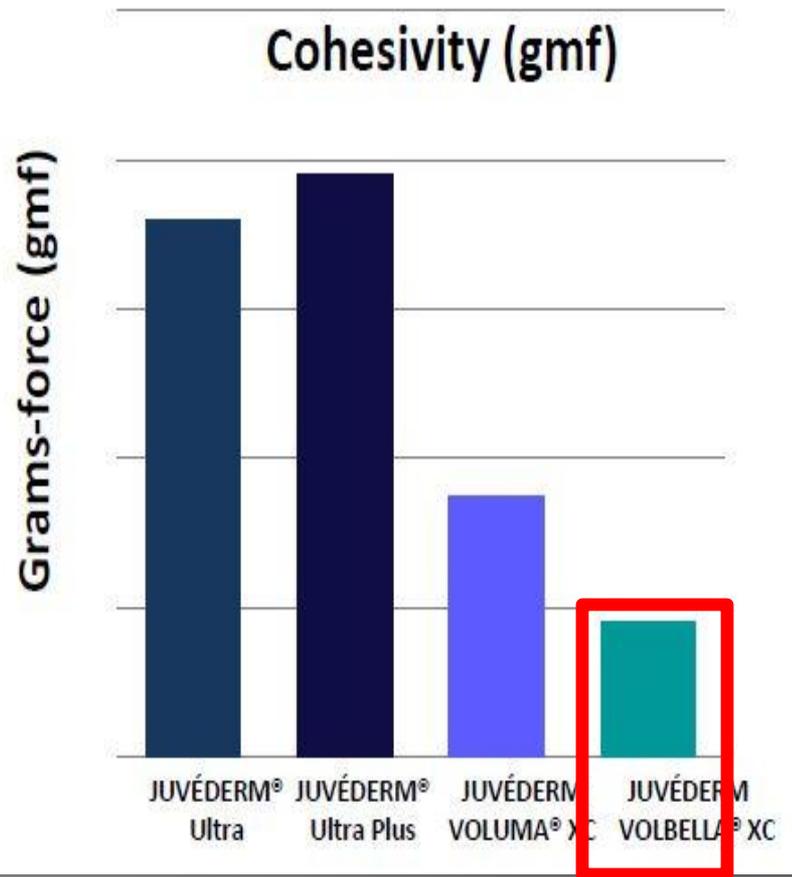
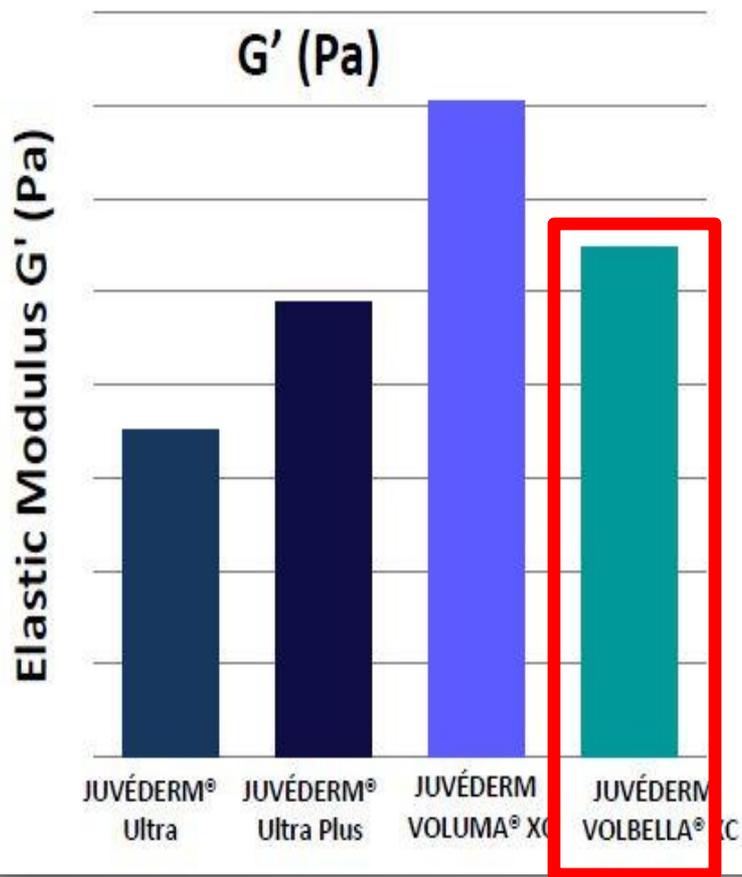


**JUVÉDERM VOLUMA® XC**

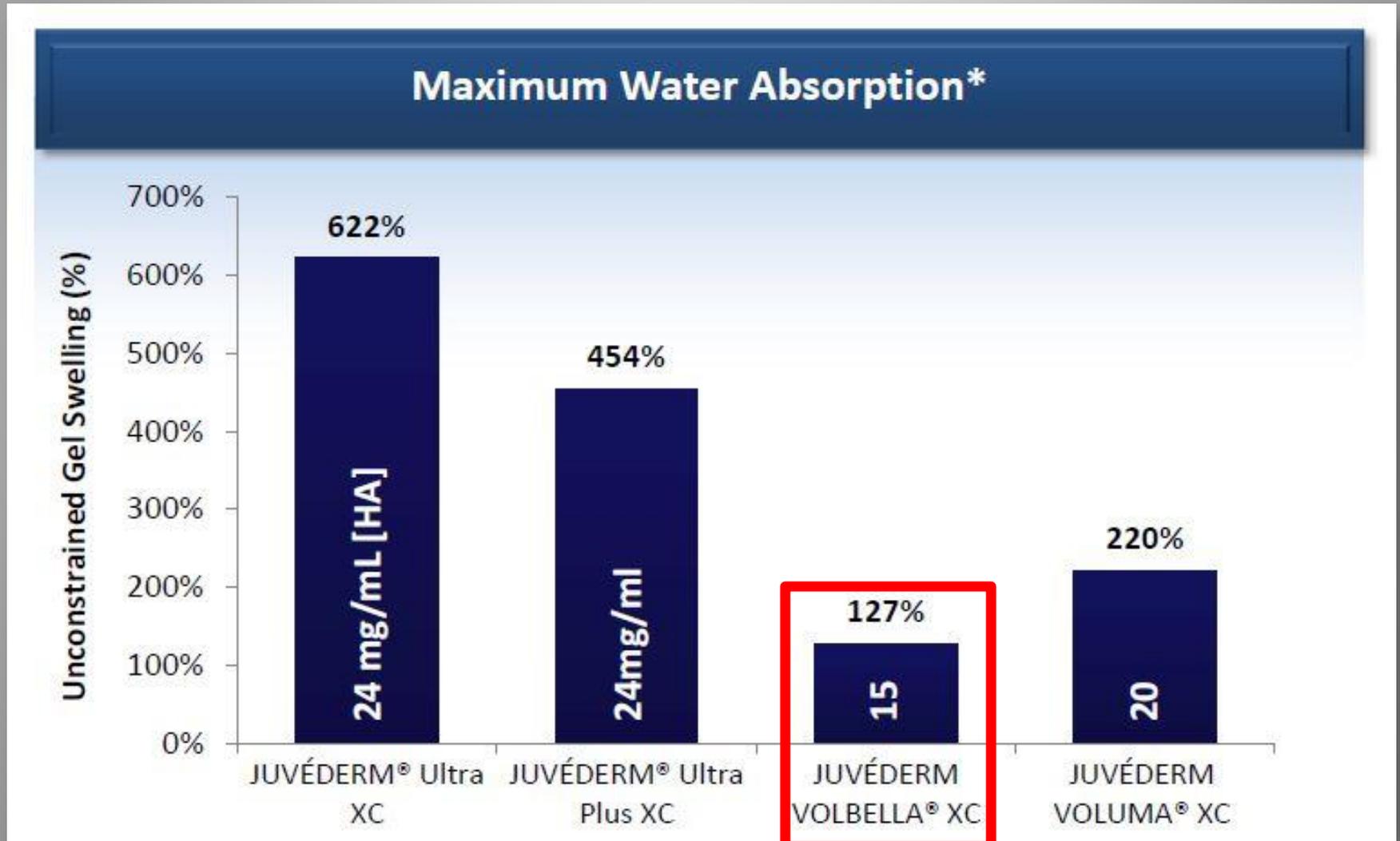
# Juvederm Product Comparison

	JUVÉDERM® Ultra XC	JUVÉDERM® Ultra Plus XC	JUVÉDERM VOLBELLA® XC	JUVÉDERM VOLUMA® XC
				
Indication <sup>1-4</sup>	<ul style="list-style-type: none"> <li>Moderate to severe facial wrinkles and folds (such as nasolabial folds)</li> <li>Injection into the lips and perioral area for lip augmentation in adults over the age of 21</li> </ul>	<ul style="list-style-type: none"> <li>Moderate to severe facial wrinkles and folds (such as nasolabial folds)</li> </ul>	<ul style="list-style-type: none"> <li>Injection into the lips for lip enhancement and for correction of perioral rhytids in adults over the age of 21</li> </ul>	<ul style="list-style-type: none"> <li>Deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21</li> </ul>
Implantation depth <sup>1-4</sup>	<ul style="list-style-type: none"> <li>Mid-to-deep dermis</li> <li>Lip mucosa</li> </ul>	<ul style="list-style-type: none"> <li>Mid-to-deep dermis</li> </ul>	<ul style="list-style-type: none"> <li>Superficial to mid-dermis</li> <li>Lip mucosa</li> </ul>	<ul style="list-style-type: none"> <li>Subcutaneous</li> <li>Upper periosteal</li> <li>Deep dermis</li> </ul>
Total HA concentration <sup>1-4</sup>	24 mg/mL	24 mg/mL	15 mg/mL	20 mg/mL
Formulation <sup>5</sup>	Smooth, viscous gel	Smooth, viscous gel	Smooth, viscous gel	Smooth, viscous gel
Gel hardness/viscosity <sup>6</sup> (G' @ 5 Hz)	176 Pa	244 Pa	274 Pa	353 Pa
Cohesivity <sup>6</sup>	72 gmf	78 gmf	18 gmf	35 gmf
Lidocaine <sup>1-4</sup>	0.3%	0.3%	0.3%	0.3%
Needle gauge and length <sup>1-4</sup>	30 G, ½"	TSK 27 G, ½"	30 G, ½"	25 G, 1" (2.0 mL syringe) 27 G, ½" (1.0 mL syringe)
Gel swelling potential <sup>6</sup> (max unconstrained water uptake)	600-650%	425-475%	100-150%	200-250%
Duration <sup>1-4</sup>	Up to 1 year	Up to 1 year	Up to 1 year	Up to 2 years

# G' & Cohesivity

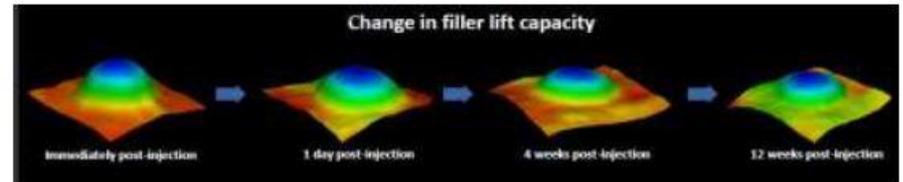


# Water Absorption



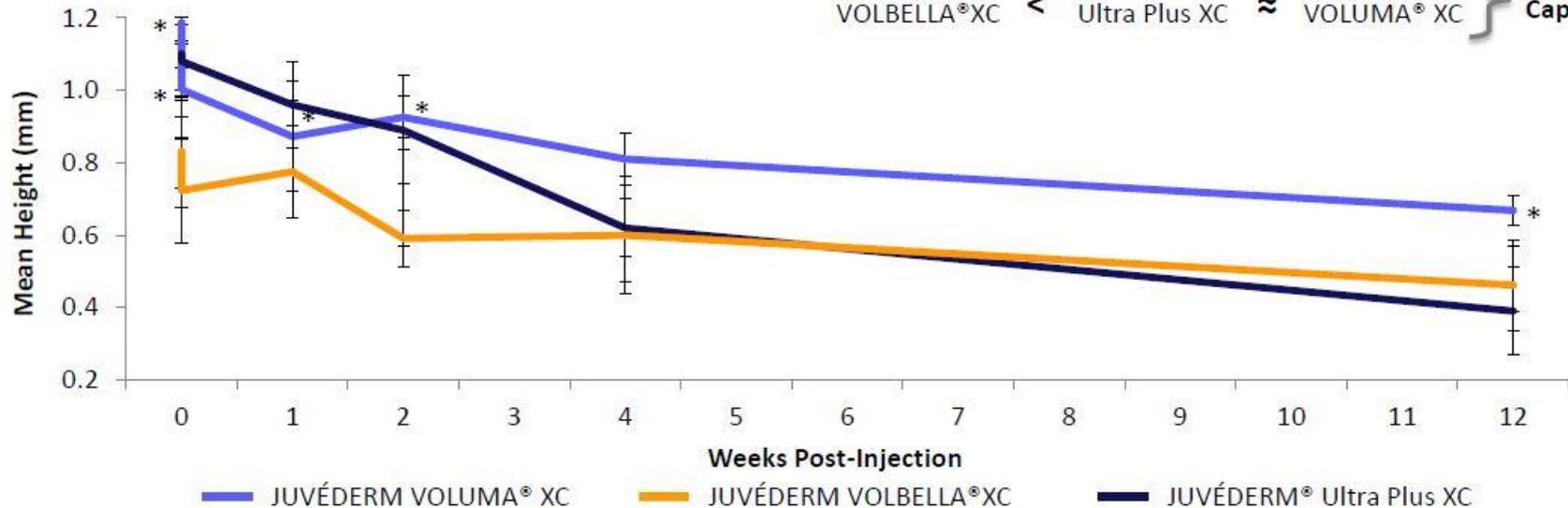
# Lift

- Bolus injection, subcutaneous plane (overlying skull), Sprague-Dawley rat model
- 3D Canfield imaging of projection; significant differences calculated across all time-points

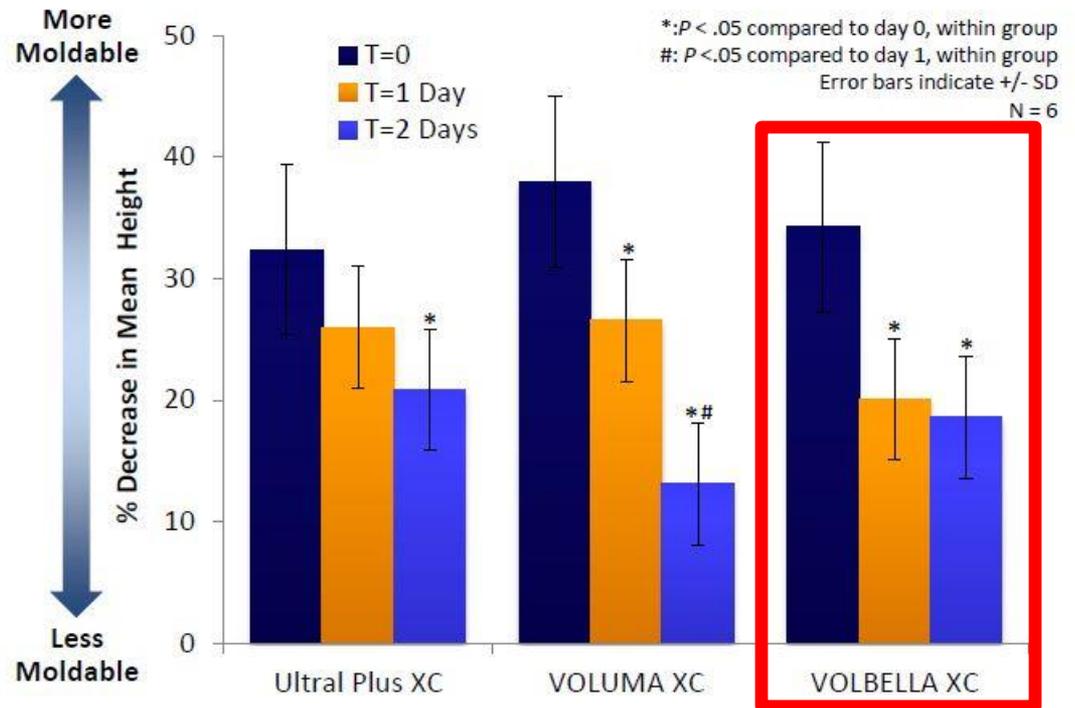
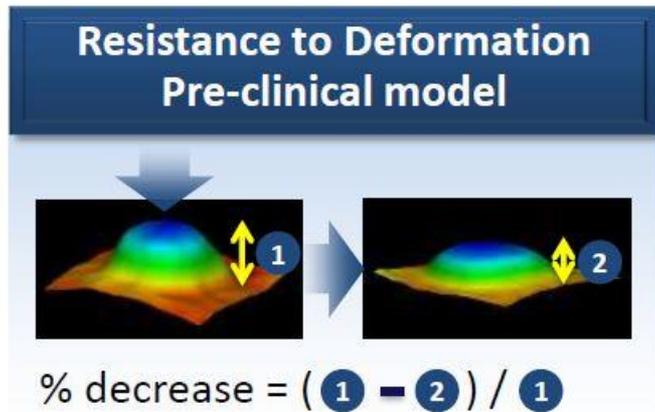


## Overall Significance Among Groups:

JUVÉDERM VOLBELLA®XC < JUVÉDERM® Ultra Plus XC ≈ JUVÉDERM VOLUMA® XC } Lift Capacity



# Moldability



- A significant decrease in moldability was observed at day 1 for all VYCROSS® products with an additional decrease for JUVÉDERM VOLUMA® XC at day 2 compared to day 1<sup>1</sup>.

# Pivotal Clinical Trial

Prospective multicenter, double blinded RCT

- Volbella XC n=168
- Restylane L = 56
- Optional touch up at 1 month (same in both groups)

	<b>Volbella XC<sup>1</sup></b> <b>(N = 168)</b>	<b>Control<sup>2</sup></b> <b>(N = 56)</b>
Total (median, range; mL)	2.6 (0.75-5.80)	2.6 (0.50-6.00)
Upper lip	1.0 (0.20-2.20)	0.9 (0.30-1.90)
Lower lip	0.8 (0.20-2.10)	0.7 (0.10-1.70)
Perioral lines	0.3 (0.05-1.60)	0.3 (0.05-1.30)
Oral commissures	0.5 (0.10-3.40)	0.6 (0.10-3.70)
Philtral columns	0.1 (0.03-0.75)	0.2 (0.10-0.20)

# Primary Endpoint: Change in Lip Score

	<b>Volbella XC (N = 165)</b>	<b>Control (N = 53)</b>	<b>P-value<sup>a</sup></b>	<b>Difference<sup>a</sup> (Lower Limit of 95% CI)</b>
<b>Mean</b>	<b>1.1<sup>1</sup></b>	<b>1.0<sup>1</sup></b>	<b>0.609</b>	<b>0.07</b>
<b>SD</b>	<b>0.75</b>	<b>0.85</b>		<b>-0.15</b>
<b>P-value<sup>b</sup></b>	<b>&lt;0.001</b>	<b>&lt;0.001</b>		

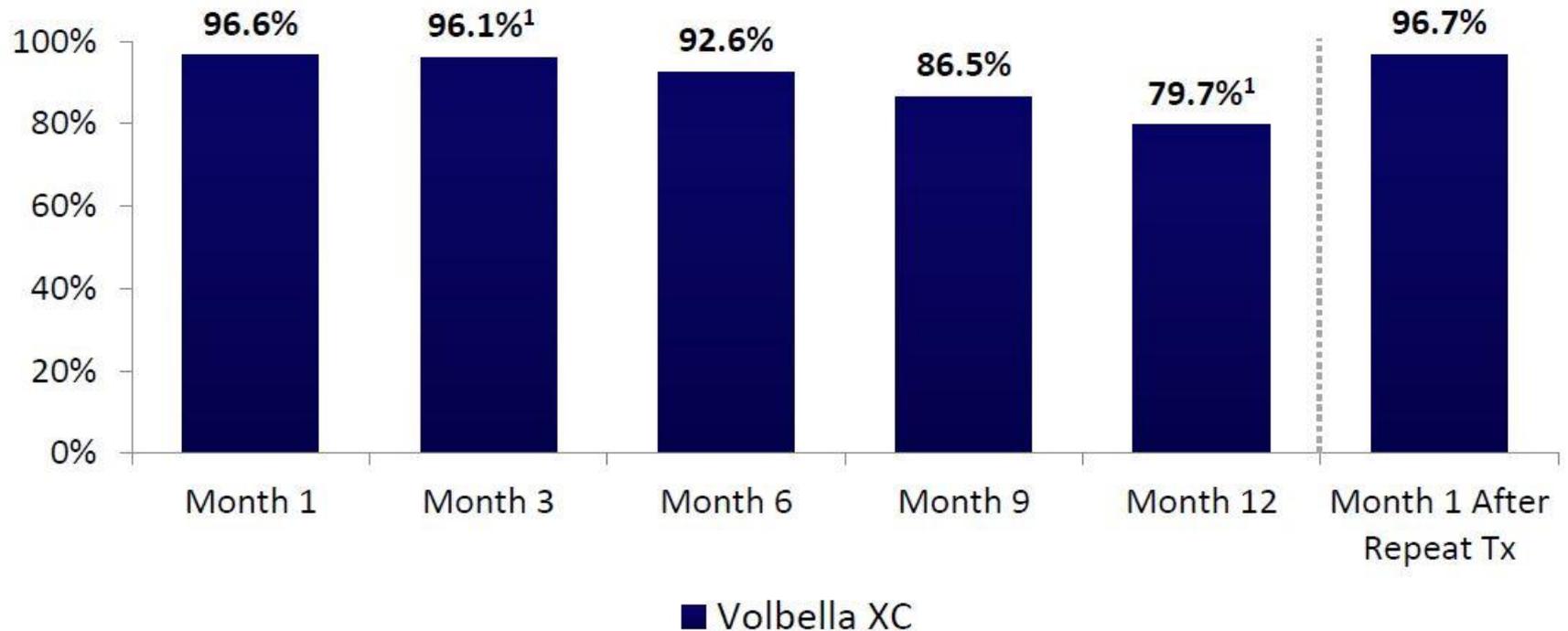
# Lip Lines

**% of Subjects Improved  $\geq 1$ -Point on POLSS**



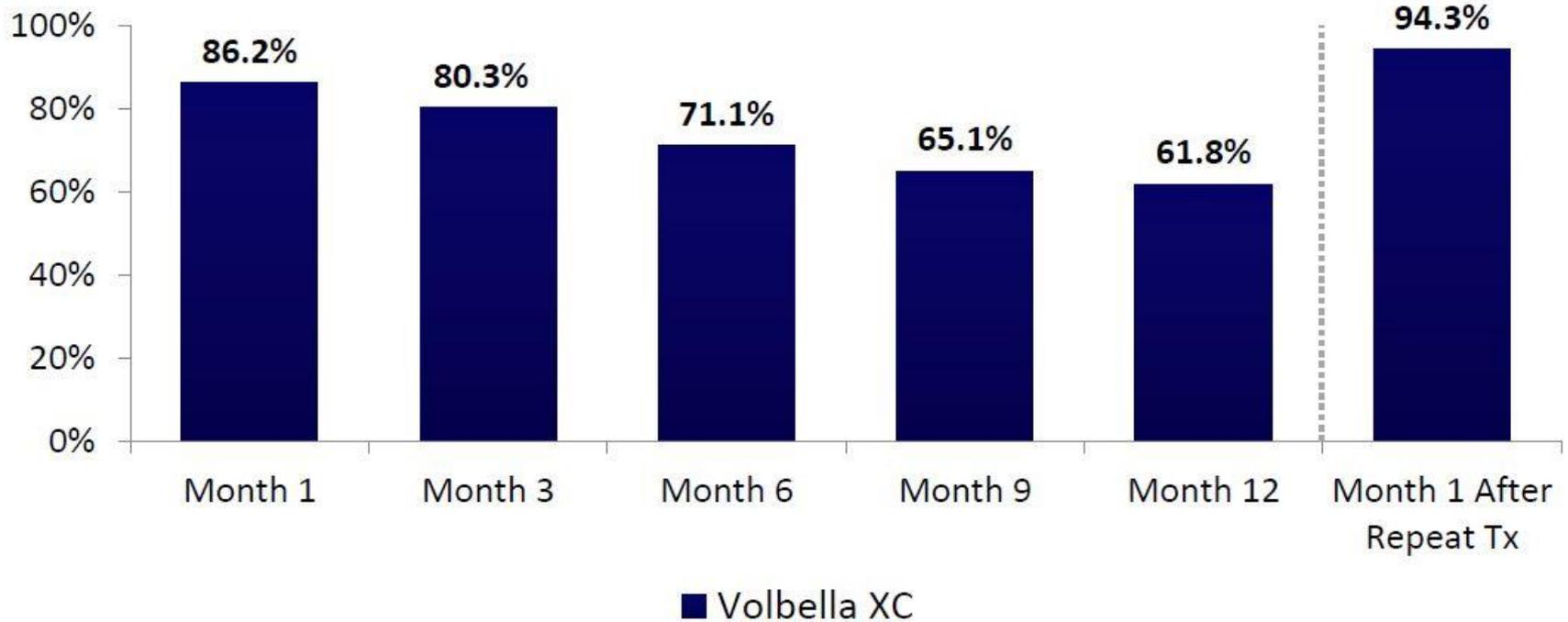
# Lip Satisfaction FACE Q

Mean FACE-Q Score



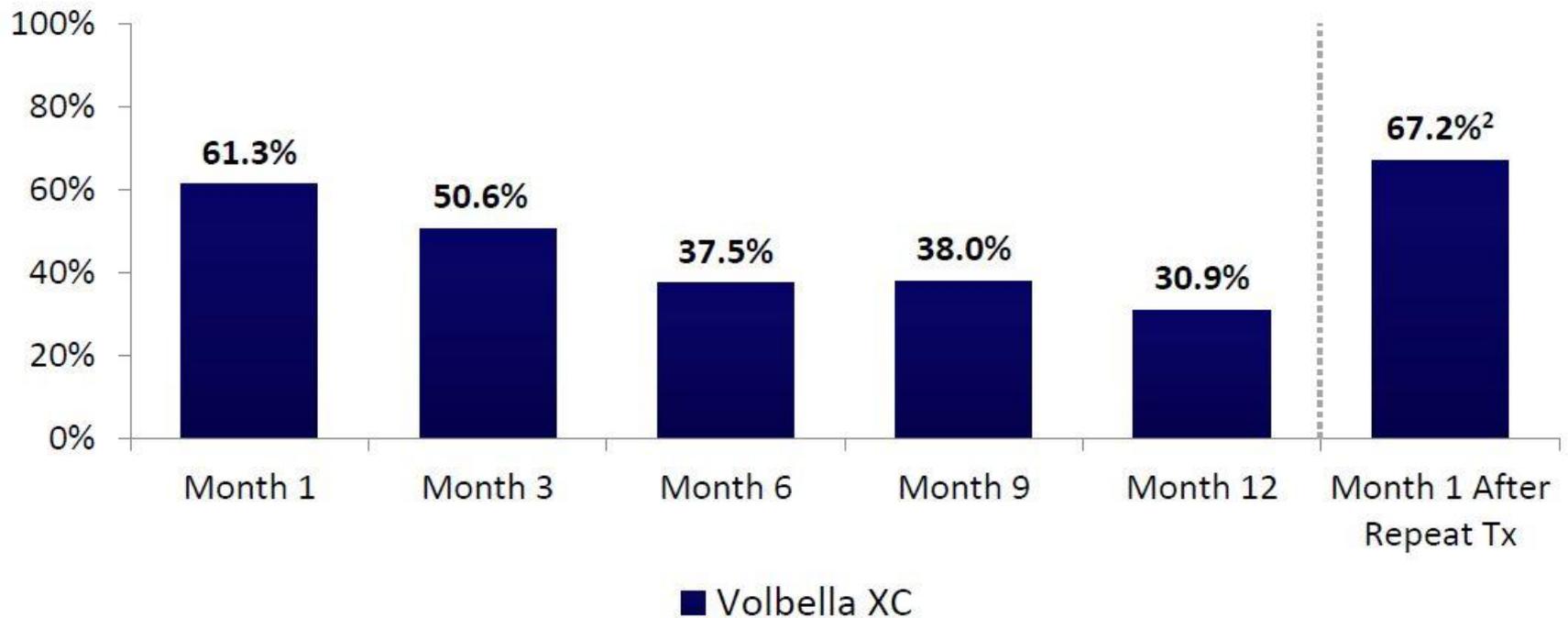
# Lip Fullness

## % Subjects Improved $\geq 1$ -Point on LFS



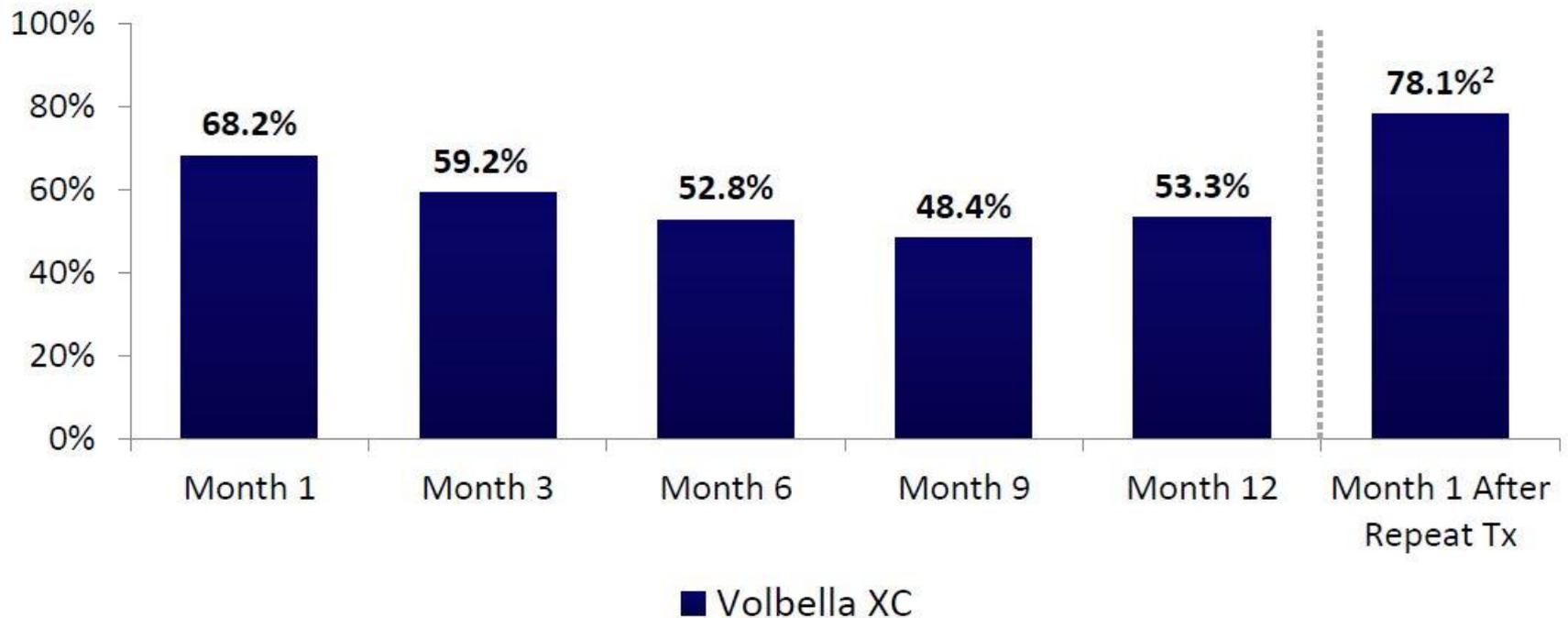
# Perioral Lines Maximal Contraction

% of Subjects Improved  $\geq 1$ -Point on POLM



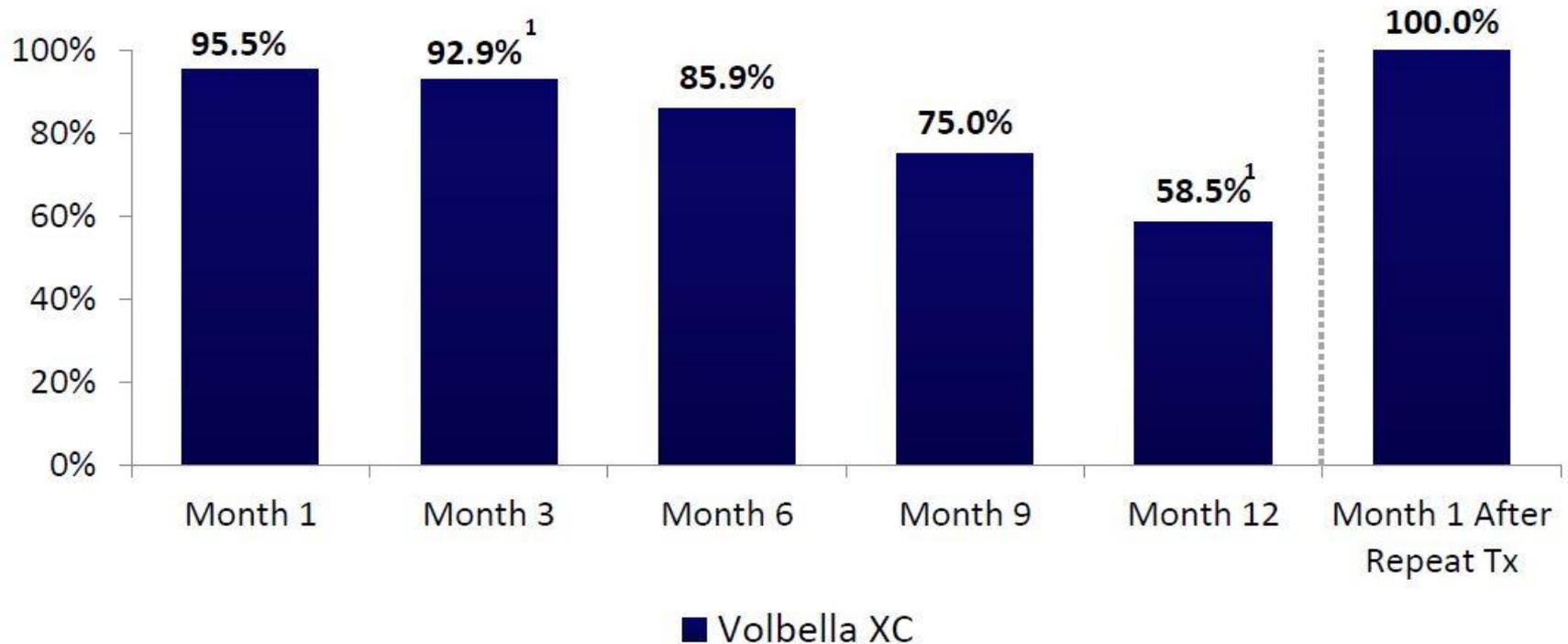
# Oral Commissure

% of Subjects Improved  $\geq 1$ -Point on OCSS



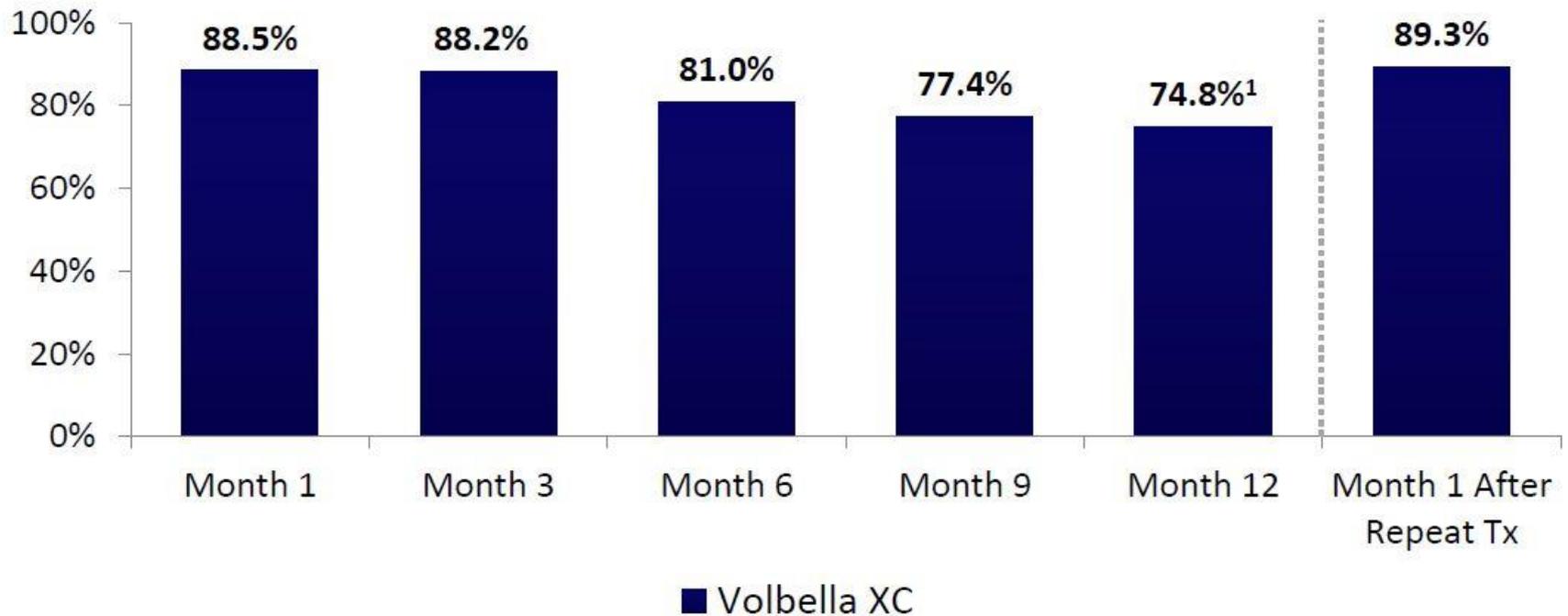
# Global Aesthetic Improvement

## % of Subjects Improved or Much Improved on GAIS



# Lip Lines FACE Q

Mean FACE-Q Score



# Volbella Summary: Perioral & Lips

- Safe & effective
- 2 to 3 syringes for full effect
- Expect 6 to 9 month results
  - Duration of effect depends on site
- Similar results as Restylane but lower G'?

# New Filler Approval: Juvederm Volbella

*Karol A Gutowski, MD, FACS*

*Hot Topics*

plastic  
surgery

THE MEETING

Los Angeles

September 23-27, 2016

