

# New Filler Approvals

## Refyne, Defyne, Vollure, Revanesse

*Karol A Gutowski, MD, FACS*

*Hot Topics*

plastic  
surgery

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THE MEETING

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# Disclosures

Merz - Advisory Board

Suneva Medical - Instructor

Will use brand names due to lack of  
distinguishing generic names

# 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"

# FDA Approvals Since Last Meeting

- 12/9/16 Restylane Refyne (Hyaluronic Acid)
- 12/9/16 Restylane Defyne (Hyaluronic Acid)
- 3/17/17 Juvederm Vollure XC (Hyaluronic Acid)
- 8/4/17 Revanesse Ultra (Hyaluronic Acid)
  - Not yet available in USA

# Match Filler to Need

## Lips<sup>1</sup>

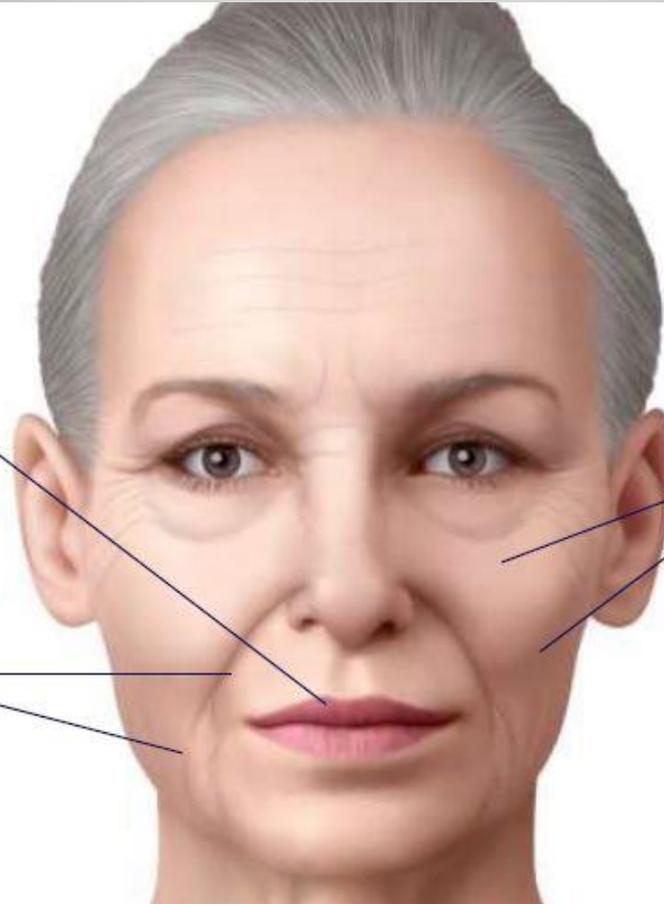
**Goals:** Easy molding and spreadability

**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

# Refyne & Defyne: Status of Product

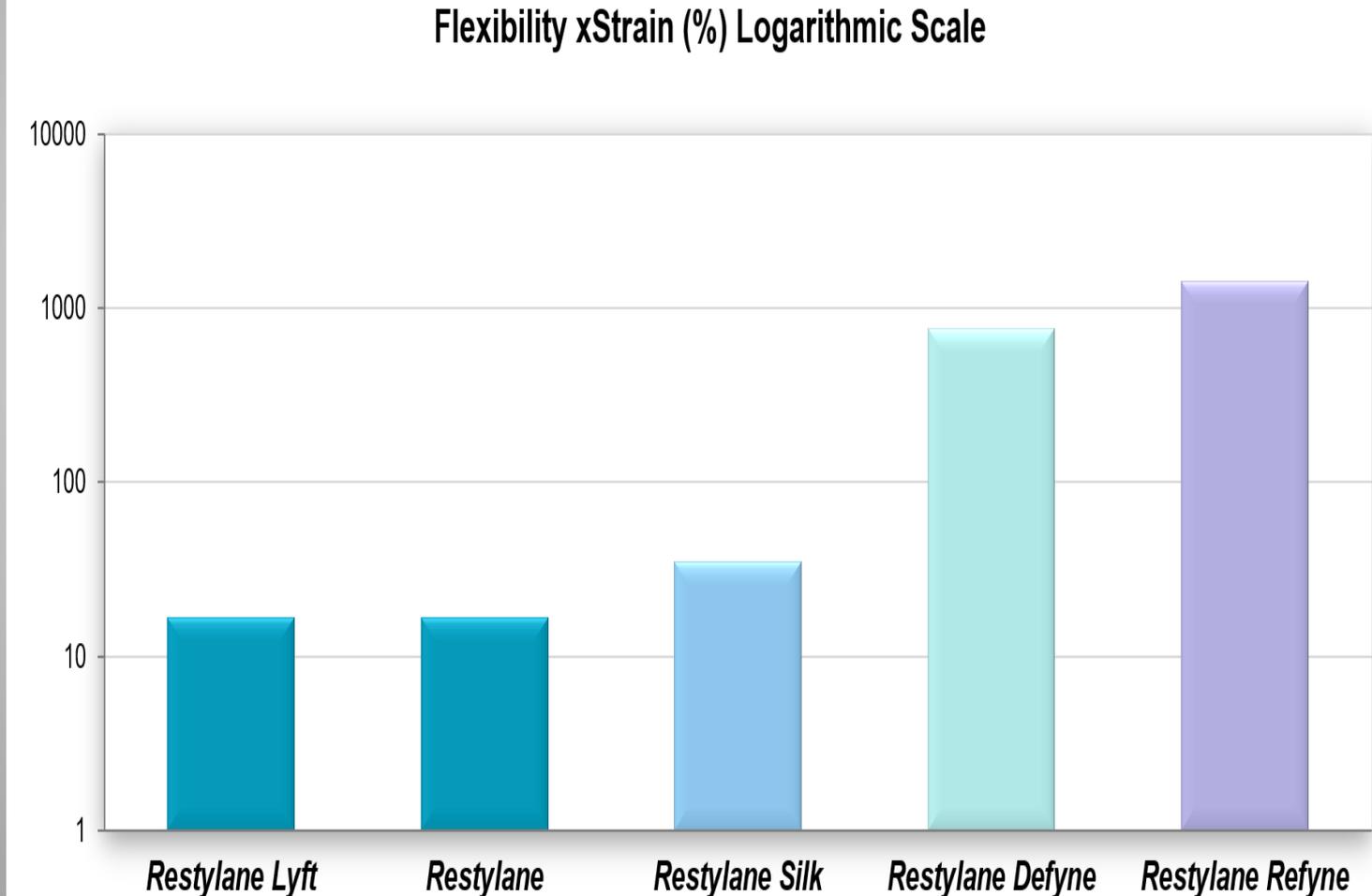
## Restylane Refyne & Restylane Defyne (aka Emervel)

- Galderma
- Cross-linked hyaluronic acid injectable soft tissue filler
  - Defyne is more cross-linked
- Produced by *Streptococcus*
- 20 mg HA/mL + lidocaine
- Duration up to 1 year
- Cost: \$321 for 1 cc syringe (\$265 for Restylane)

**Indications:** Injection into mid-to-deep dermis for correction of moderate to severe facial wrinkles & folds in patients >21 years.

- Defyne for deeper folds

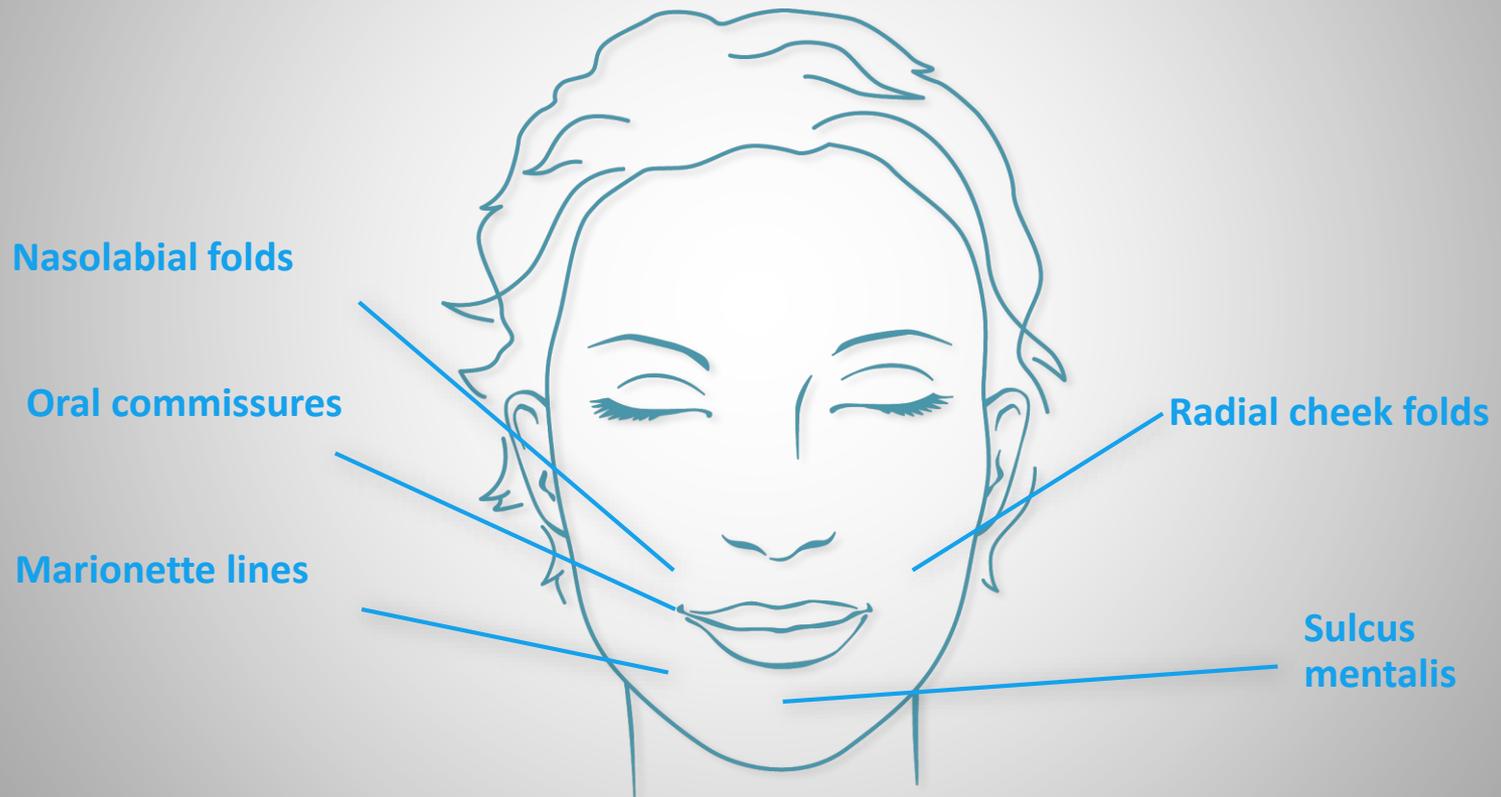
# What's Different? Flexibility



# Natural Expressions Study

**A multi-center, non-comparative study to evaluate the perception of facial expressions following correction of wrinkles and folds in the lower face using *Restylane*<sup>®</sup> *Refyne* and *Restylane*<sup>®</sup> *Defyne* (Emervel<sup>®</sup> Classic and Emervel<sup>®</sup> Deep containing Lidocaine)**

# Treatment Areas



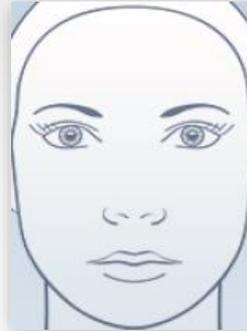
# Photographed Facial Expressions at Maximum Contraction



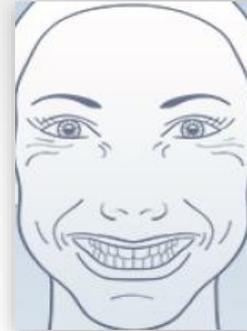
**Relaxed Face**  
Right



**Big Smile**  
Right



**Relaxed Face**  
Frontal



**Big Smile**  
Frontal



**Closed Big Smile** Frontal



**Grimace\***  
Frontal



**Pursed Kiss**  
Frontal



**Blowing Candle**  
Frontal



**Relaxed Face**  
Left



**Big Smile**  
Left

# Animation 1 Month After Injection



## Treatment:

1.7 mL Defyne: each NLF 0.6, mental sulcus mentalis 0.5

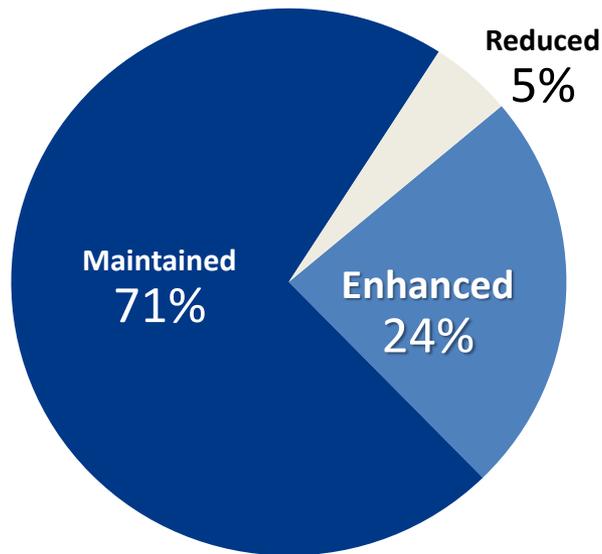
2.6 mL Refyne: each radial cheek folds 0.3, each marionette 0.4, each oral commissure 0.6

## Touch-up:

0.2 mL Refyne: each radial cheek folds 0.1

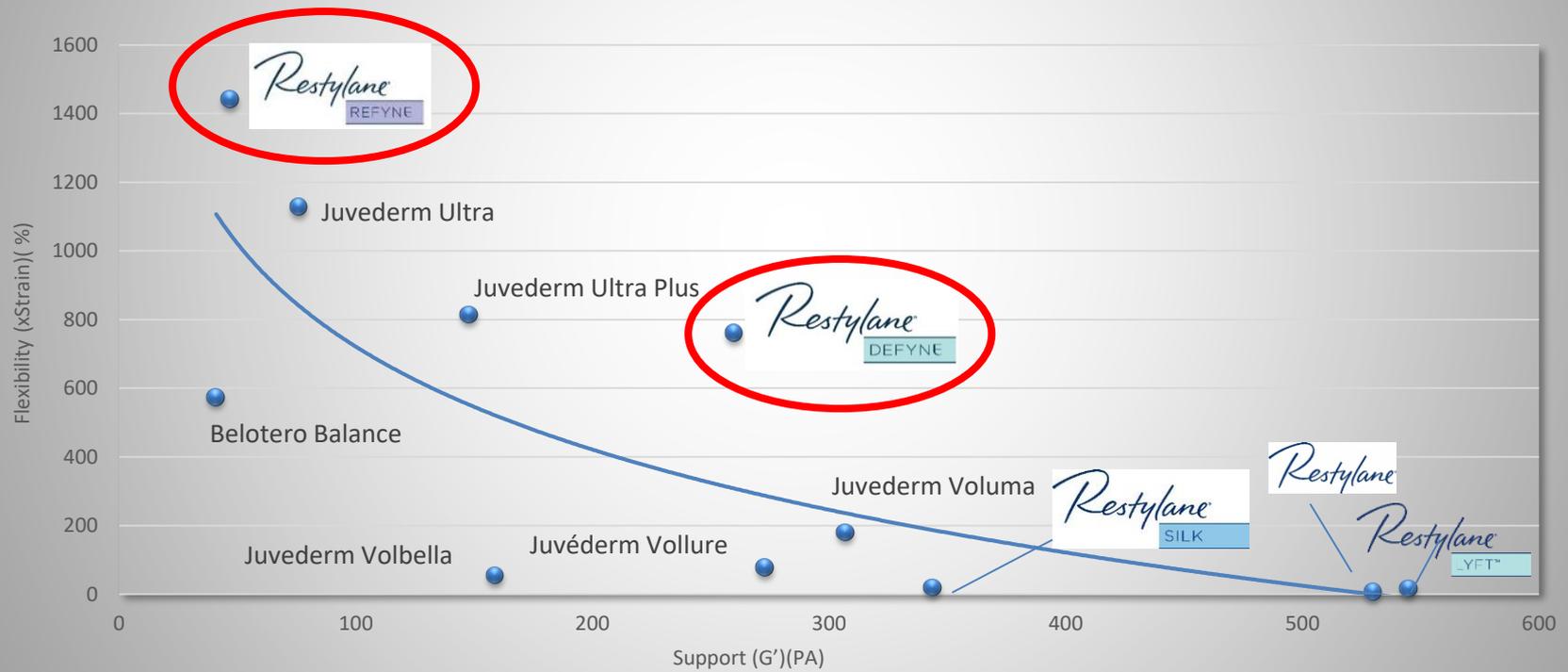
# One Month Investigator Assessment

## Naturalness of Expression



- **79% looked younger**
- **89% looked more attractive**

# Flexibility vs Lift (G')



# Vollure: Status of Product

## Juvederm Vollure XC

- Allergan
- Cross-linked hyaluronic acid injectable soft tissue filler
- Produced by *Streptococcus*
- 17.5 mg HA/mL + lidocaine
  - (Ultra & Ultra Plus: 24 mg, Voluma: 20 mg, Volbella 15 mg)
- Duration up to 18 months
- Cost: \$365 for 1 cc syringe

**Indications:** Injection into mid-to-deep dermis for correction of moderate to severe facial wrinkles & folds in patients >21 years.

# Vollure: Pivotal Study

- Double blinded split face NLF injections
  - Touch up injection at 30 days
  - Median 1.7 cc per NLF
  - Compared to Restylane
- At least 1 point improvement (Scale 1 to 5)
- Effectiveness
  - 93% at 6 months
  - 85% at 9 months
  - 58% at 12 months
  - 59% at 18 months

# Vollure Role in Facial Injections

- Compared to Juvederm Ultra & Ultra Plus
  - All less water absorption
  - Less cohesive (spreads more in tissue)
- Volbella: Low  $G'$ 
  - Thinnest, most spread
  - Fine lip lines, tear troughs
- Vollure: **Intermediate  $G'$** 
  - **Nasolabial folds**
  - **Allows for natural facial movements**
- Voluma: Highest  $G'$ 
  - Thickest, least spread
  - Deep malar injection

# Revanesse: Status of Product

## Revanesse Ultra

- Prollenium (Canada)
- Cross-linked hyaluronic acid injectable soft tissue filler
- Produced by *Streptococcus*
- 25 mg HA/mL
  - (Revanesse Pure: 15 mg, Revanesse: 25 mg, Revanesse Lips: 15 mg)
- Duration up to 9 to 12 months
- Cost: TBD

**Indications:** Injection into mid-to-deep dermis for correction of moderate to severe facial wrinkles & folds in patients >21 years.

# Revanesse Ultra: Clinical Trials

- Double blinded split face NLF injections
- At least 1 point improvement (Scale 1 to 5)
- 78% maintained improvement at 6 months

# Summary

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- New fillers for dynamic lines
- New filler for static lines
- New filler from new manufacturer to USA
- Clinical relevance?

# Botox Approved for Forehead

- Botox (onabotulinumtoxinA) past approvals
  - Moderate to severe glabellar lines with corrugator and/or procerus muscle activity (20u)
  - Moderate to severe lateral canthal lines with orbicularis oculi activity (24u)
- FDA Approval October 2017
  - Moderate to severe forehead lines associated with frontalis muscle activity (20u + 20u in glabella)

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