FDA Filler Update: Revanesse Versa

Karol A Gutowski, MD, FACS

Disclosures

Merz – Trainer, 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 ≥ 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

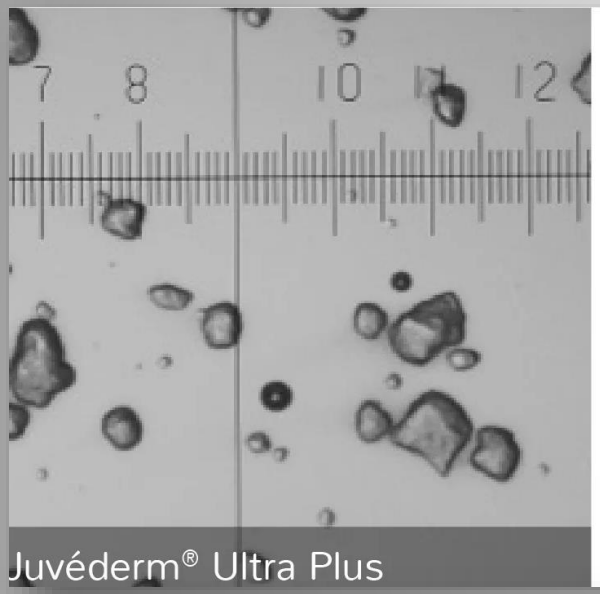
V Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles“

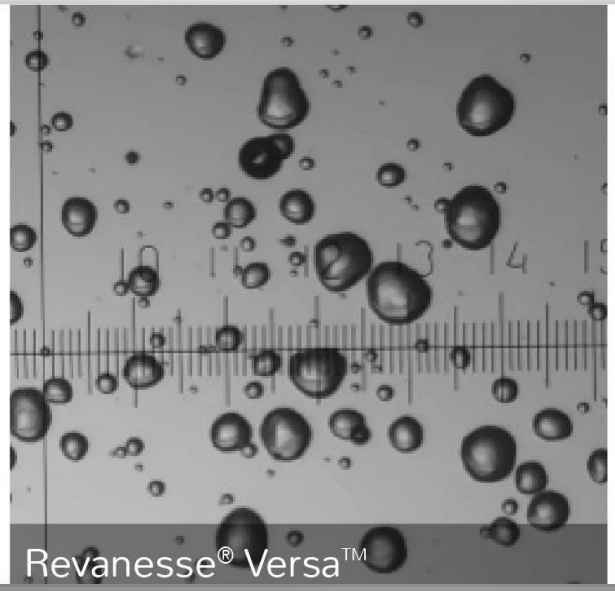
Product Information

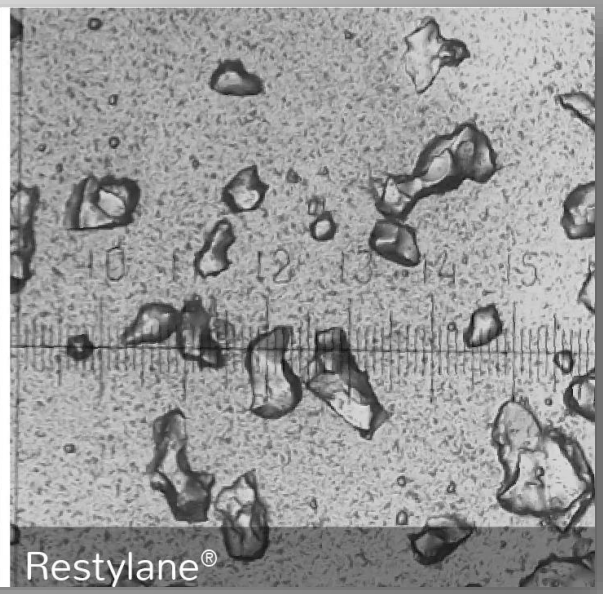
- Cross-linked hyaluronic gel
  - 10% not crosslinked
- 25 mg of HA per 1 mL syringe

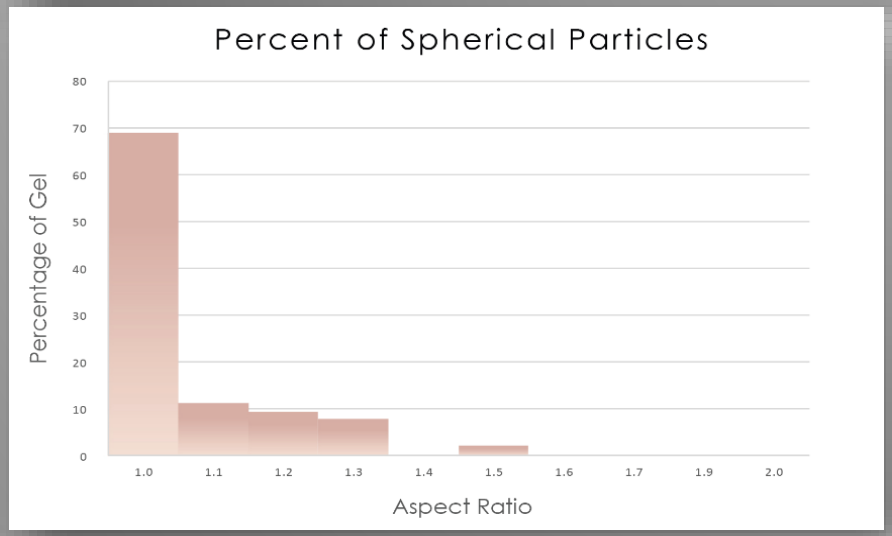
- Unique features
  - Homogenous uniform spherical particles
  - Balanced with skin water content, less swelling

Gel Particle Shape



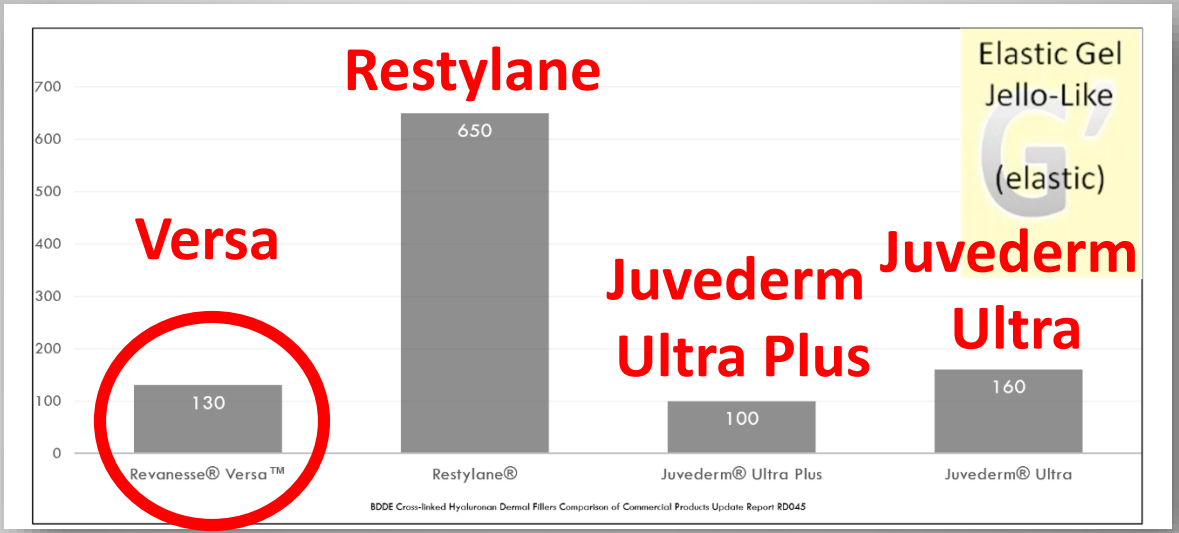


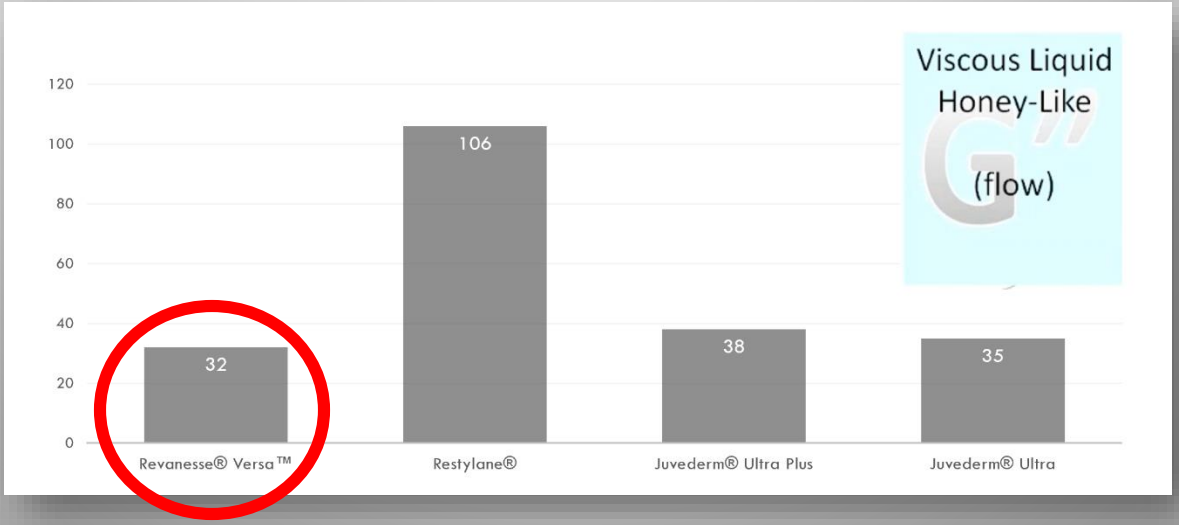




Round particle shape may have less inflammatory response

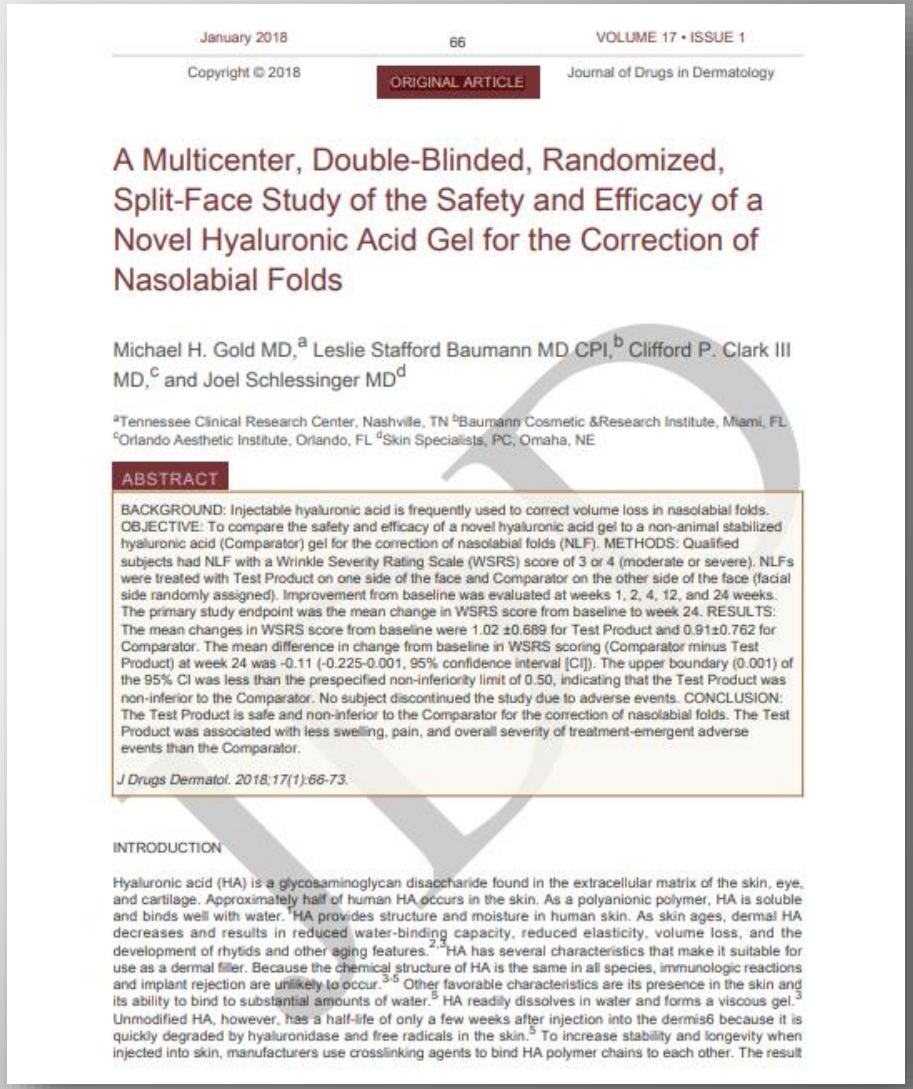
Rheology


Restylane
Versa
Juvederm Ultra Plus
Juvederm Ultra
Elastic Gel
Jello-Like
G'
(elastic)
700
600
500
400
300
200
100
0
130
650
100
160
Revanesse® Versa™
Restylane®
Juvederm® Ultra Plus
Juvederm® Ultra
BDDE Cross-linked Hyaluronan Dermal Fillers Comparison of Commercial Products Update Report RD045


Viscous Liquid
Honey-Like
G''
(flow)
120
100
80
60
40
20
0
32
106
38
35
Revanesse® Versa™
Restylane®
Juvederm® Ultra Plus
Juvederm® Ultra

Pivotal Study: Versa vs Restylane

- Both **without** lidocaine
- Moderate to severe NLF
- Randomized split face
- Blinded evaluators
- Retreatment allowed
- 24 week endpoint



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ORIGINAL ARTICLE Journal of Drugs in Dermatology

A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel for the Correction of Nasolabial Folds

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ABSTRACT

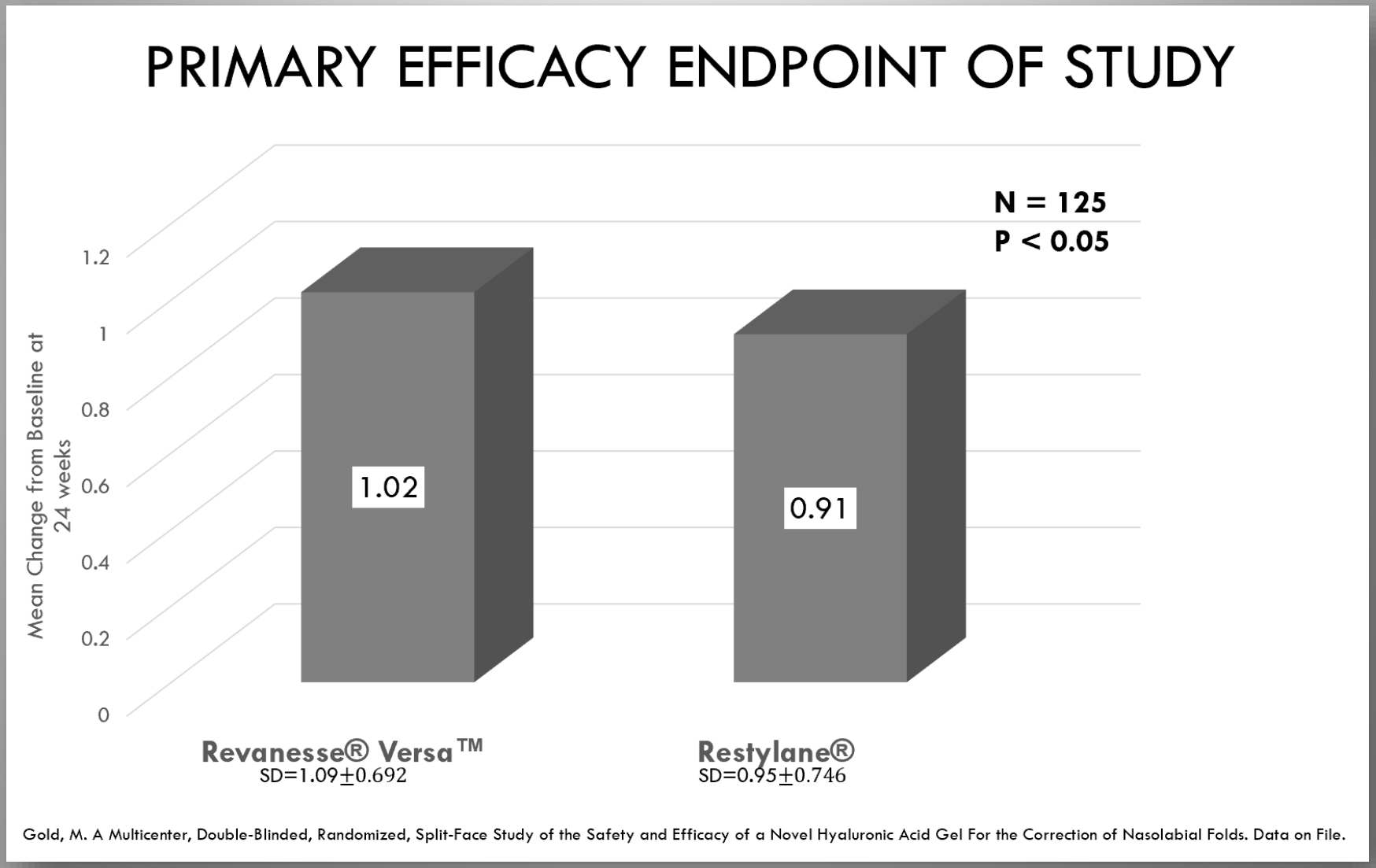
BACKGROUND: Injectable hyaluronic acid is frequently used to correct volume loss in nasolabial folds. OBJECTIVE: To compare the safety and efficacy of a novel hyaluronic acid gel to a non-animal stabilized hyaluronic acid (Comparator) gel for the correction of nasolabial folds (NLF). METHODS: Qualified subjects had NLF with a Wrinkle Severity Rating Scale (WSRS) score of 3 or 4 (moderate or severe). NLFs were treated with Test Product on one side of the face and Comparator on the other side of the face (facial side randomly assigned). Improvement from baseline was evaluated at weeks 1, 2, 4, 12, and 24 weeks. The primary study endpoint was the mean change in WSRS score from baseline to week 24. RESULTS: The mean changes in WSRS score from baseline were 1.02 ±0.689 for Test Product and 0.91±0.762 for Comparator. The mean difference in change from baseline in WSRS scoring (Comparator minus Test Product) at week 24 was -0.11 (-0.225-0.001, 95% confidence interval [CI]). The upper boundary (0.001) of the 95% CI was less than the prespecified non-inferiority limit of 0.50, indicating that the Test Product was non-inferior to the Comparator. No subject discontinued the study due to adverse events. CONCLUSION: The Test Product is safe and non-inferior to the Comparator for the correction of nasolabial folds. The Test Product was associated with less swelling, pain, and overall severity of treatment-emergent adverse events than the Comparator.

J Drugs Dermatol. 2018;17(1):66-73.

INTRODUCTION

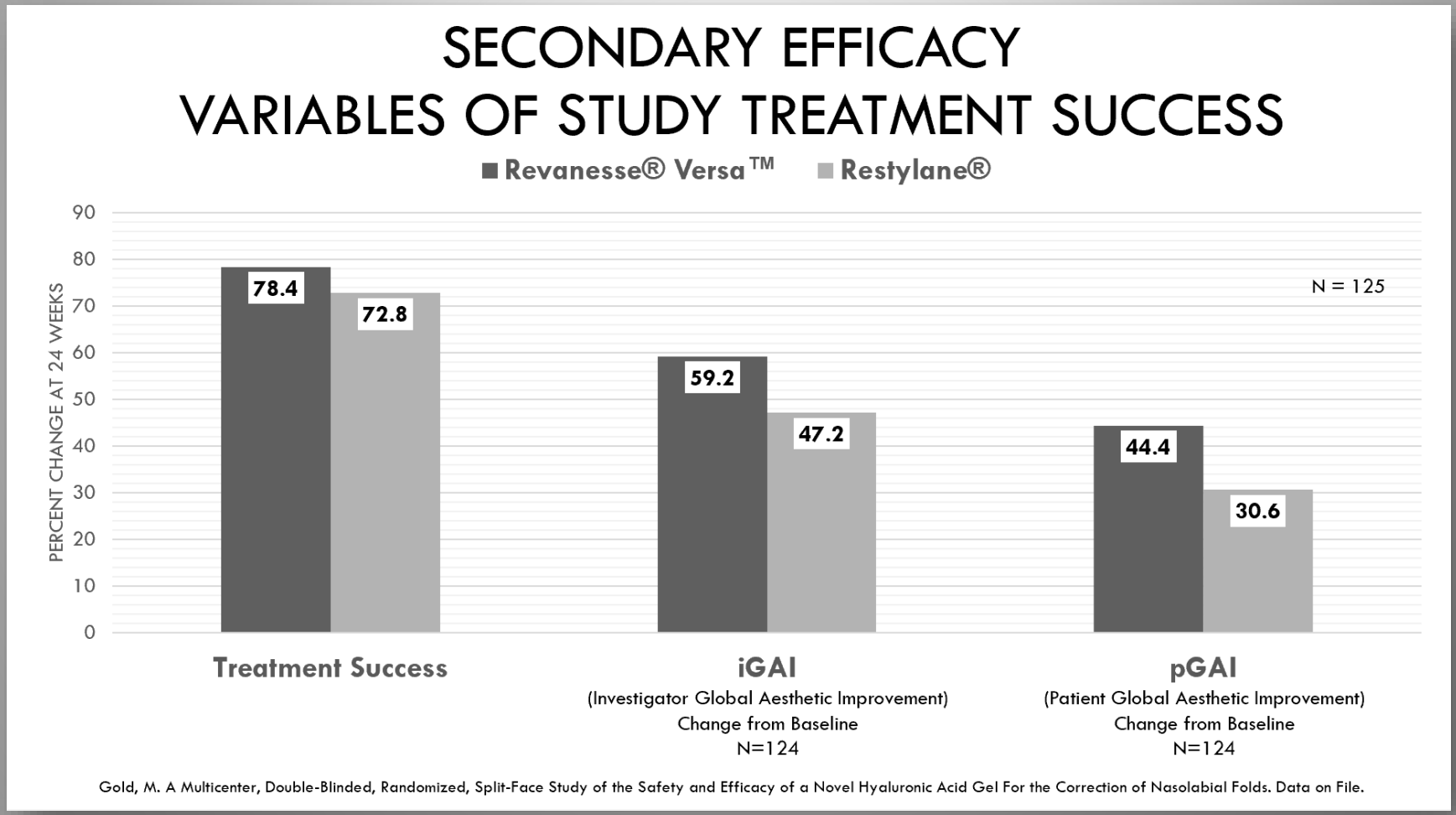
Hyaluronic acid (HA) is a glycosaminoglycan disaccharide found in the extracellular matrix of the skin, eye, and cartilage. Approximately half of human HA occurs in the skin. As a polyanionic polymer, HA is soluble and binds well with water.[1] HA provides structure and moisture in human skin. As skin ages, dermal HA decreases and results in reduced water-binding capacity, reduced elasticity, volume loss, and the development of rhytids and other aging features.[2-5] HA has several characteristics that make it suitable for use as a dermal filler. Because the chemical structure of HA is the same in all species, immunologic reactions and implant rejection are unlikely to occur.[3-5] Other favorable characteristics are its presence in the skin and its ability to bind to substantial amounts of water.[5] HA readily dissolves in water and forms a viscous gel.[3] Unmodified HA, however, has a half-life of only a few weeks after injection into the dermis6 because it is quickly degraded by hyaluronidase and free radicals in the skin.[5] To increase stability and longevity when injected into skin, manufacturers use crosslinking agents to bind HA polymer chains to each other. The result

Results: Primary End Point



Gold, M. A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel For the Correction of Nasolabial Folds. Data on File.

Results: Secondary End Point



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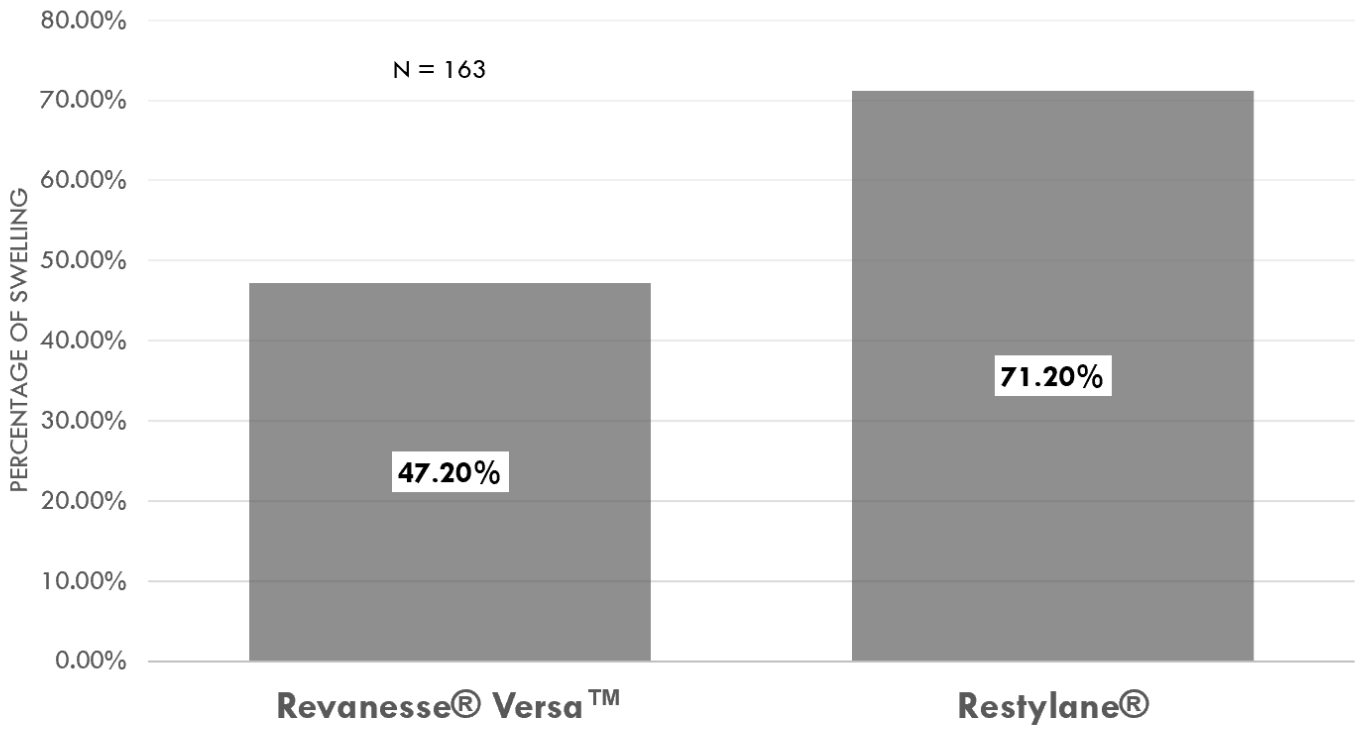
Patient Reported Swelling

PERCENTAGE OF STUDY PATIENTS (N) REPORTED SWELLING



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Safety

- No subjects discontinued the study due to AEs
- ***TEAEs were reported***
  - ***69.9% of Revanesse® Versa ™ subjects***
  - ***84% of Restylane ® subjects***
- Most common injection site TEAEs were:
  - Hematoma (50.3% versa ™ /47.2% Restylane ®)
  - Swelling (47.2% versa ™ /71.2% Restylane ®)
  - Pain (38% versa ™ /66.3% Restylane ®)
- Only 2 subjects reported non-injection site TEAEs (headache 3.1%, arthralgia 1.85)

Conclusions

STUDY CONCLUSION

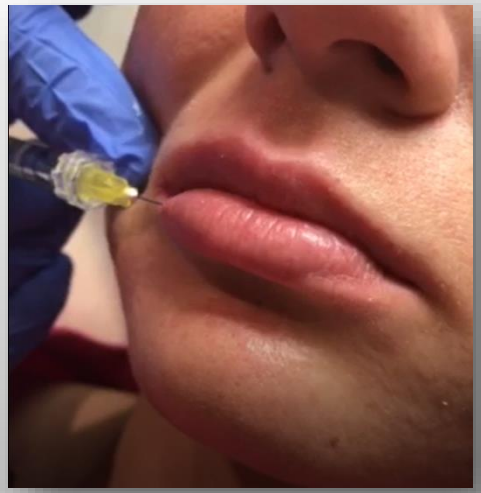
THE TEST PRODUCT, **REVANESSE VERSA, IS SAFE AND NON-INFERIOR TO THE COMPARATOR, RESTYLANE,** FOR THE CORRECTION OF NASOLABIAL FOLDS.

THE TEST PRODUCT WAS ASSOCIATED WITH LESS SWELLING, PAIN, AND OVERALL SEVERITY OF TREATMENT-EMERGENT ADVERSE EVENTS THAN THE COMPARATOR

Personal Experience

Compared to Restylane-L (my preferred HA)

- Nice results for lip enhancement
- Harder to inject with 30G x 1 inch needle
- **More** pain (no lidocaine)
  - Lidocaine may be added soon
- Maybe less swelling
- Good price point



FDA Filler Update: Revanesse Versa

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