

Effectiveness and safety of
Resilient Hyaluronic Acid (RHA) dermal fillers for the
correction of moderate-to-severe nasolabial folds in
subjects with darker skin color:
Post-hoc subgroup analyses of US pivotal clinical data

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Background and Objective

Background

- The latest 2020 US census showed increasing racial and ethnic diversity in the US¹
- People with darker skin types requesting aesthetic treatments represent an increasingly prominent patient base in aesthetic medicine²
- People of color (POC) are often underrepresented in clinical studies evaluating the safety and effectiveness of aesthetic products, and limited clinical data are currently available on the use of HA fillers in POC

Objective

- Compare the safety and effectiveness of a new line of dynamic hyaluronic acid fillers (RHA[®]) for the treatment of moderate-to-severe nasolabial folds in POC and non-POC

1. US Census Bureau, 2020

2. Aesthetic Plastic Surgery National Databank Statistics, 2010-2019

Methods

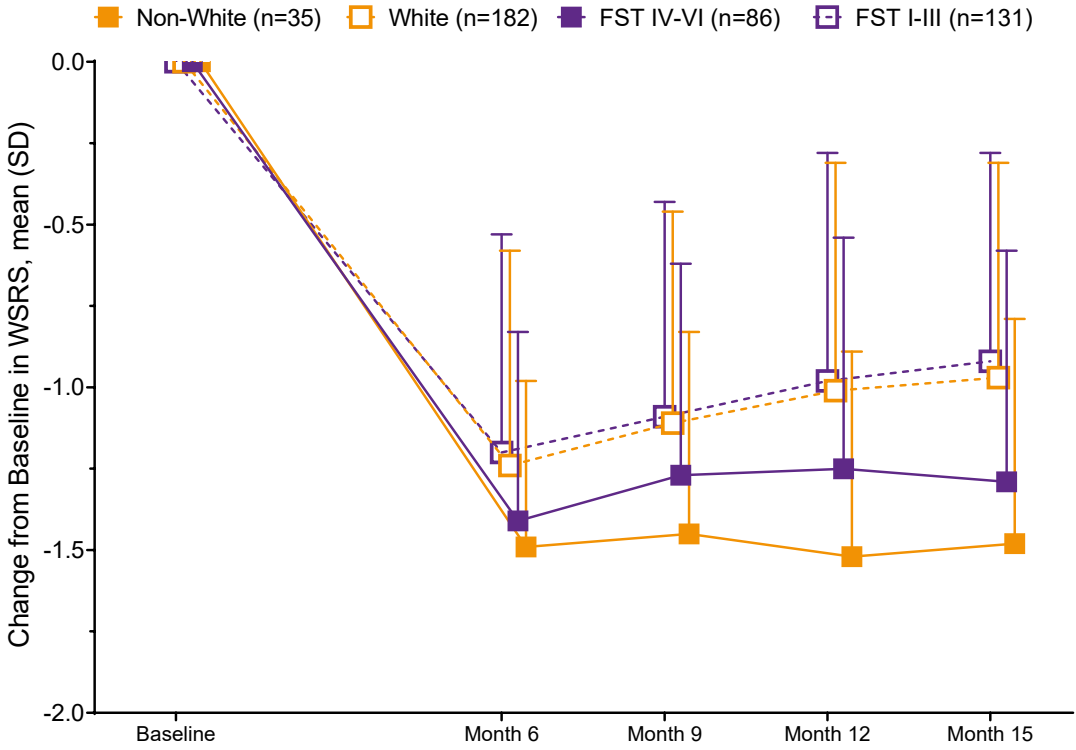
- Post-hoc subgroup analyses compared POC versus non-POC for the pooled Per Protocol population of subjects treated with RHA, correcting for moderate-to-severe nasolabial folds in two pivotal US clinical trials (TEO-RHA-1302 and TEO-RHA-1402)^{1,2} (N=217)
 - By Fitzpatrick Skin Type (FST): High FST (IV + V + VI: POC) versus low FST (I + II + III: non-POC)
 - By subject-reported race: Non-White versus White
- Assessments included Wrinkle Severity Rating Scale (WSRS) scores, Global Assessment of Improvement (GAI), subject satisfaction, and adverse events

1. Monheit G, et al. *Dermatol Surg.* 2020;00:1-9. doi:10.1097/DSS.0000000000002391

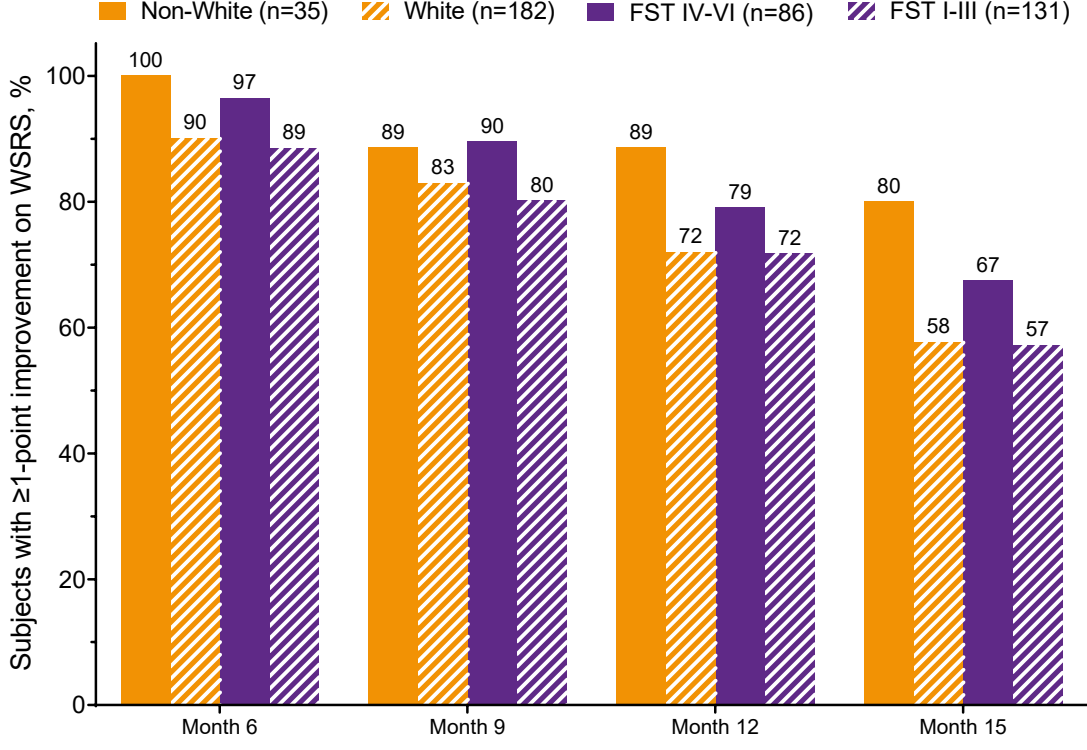
2. Kaufman J, et al. *J Cosmet Dermatol.* 2019;00:1-10. doi:10.1111/jocd.13100

POC consistently showed greater improvement in wrinkle severity compared to non-POC

Change from baseline in WSRS



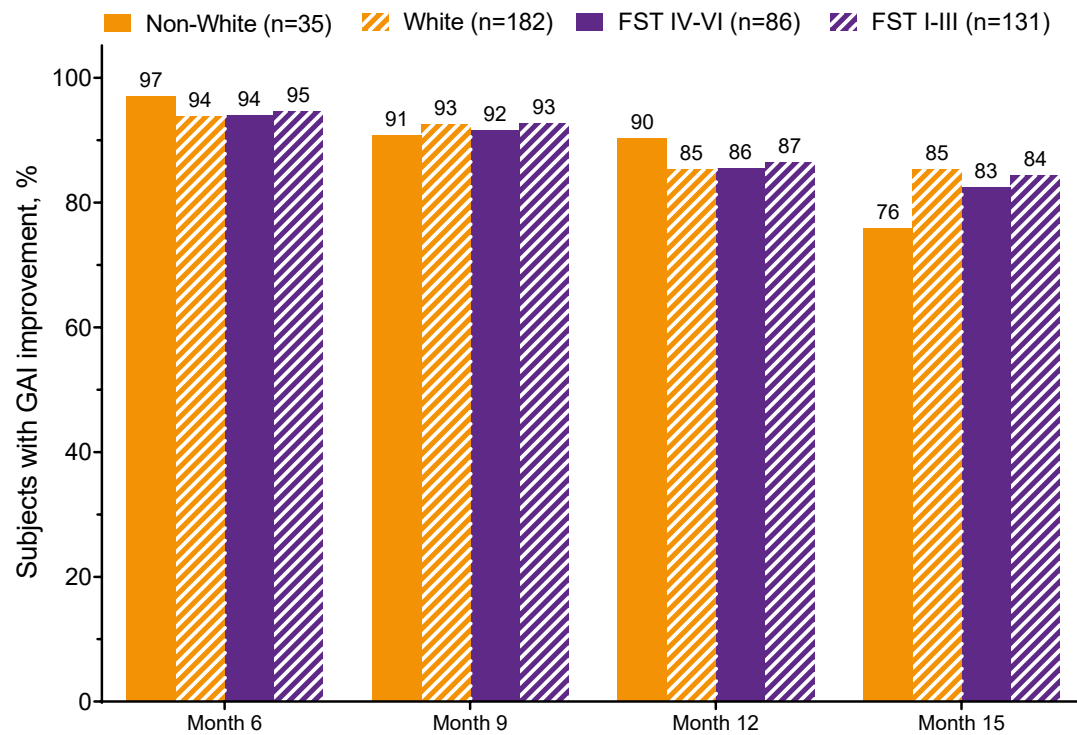
Subjects with ≥1-grade improvement in WSRS



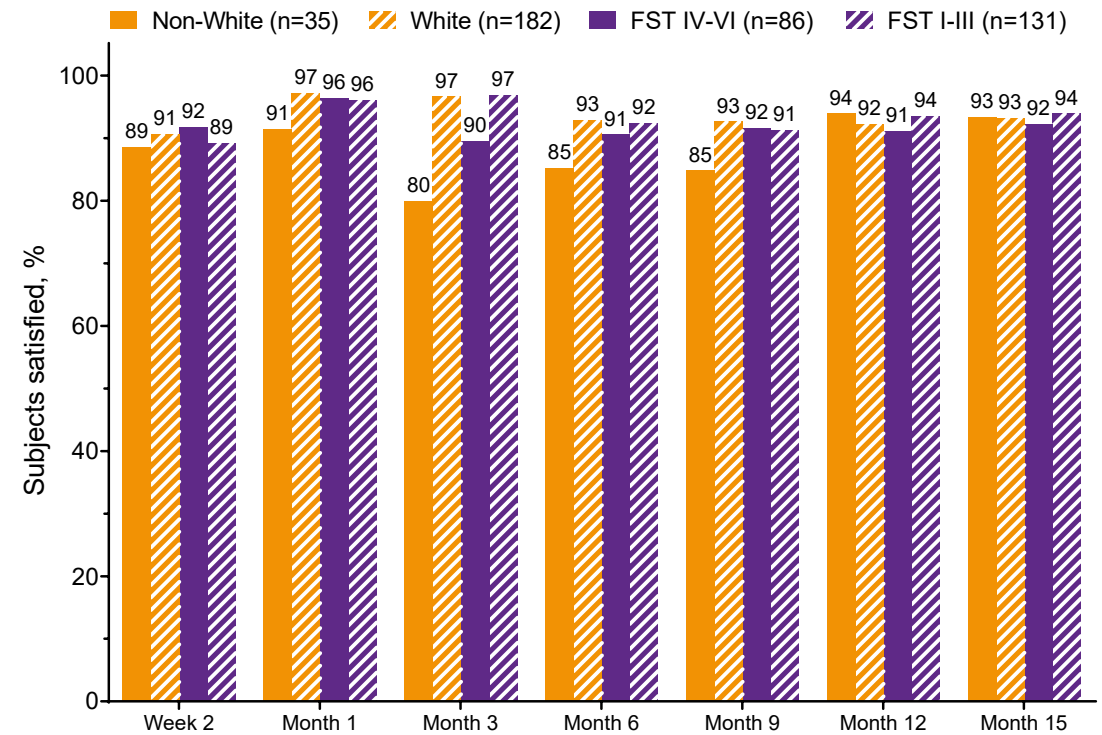
WSRS was assessed by blinded live evaluator. The WSRS is a validated 5-point static scale (1-absent; 5-extreme) assessing nasolabial fold severity. FST, Fitzpatrick Skin Type; POC, people of color; SD, standard deviation; WSRS, Wrinkle Severity Rating Scale

Global Aesthetic Improvement scores and subject satisfaction were similar between POC and non-POC

GAI improvement rate^a



Subject satisfaction^b



^a Subjects who were improved or much improved on the GAI scale, assessed by blinded live evaluator. GAI is a subjective five-point scale (1- much improved; 5-much worse) assessing global aesthetic improvement.

^b Subjects who were satisfied or very satisfied

FST, Fitzpatrick Skin Type; GAI, Global Assessment of Improvement; POC, people of color

Adverse events in subjects treated with RHA

- Treatment-related adverse event (AE) rates were generally lower for subjects with high FST (35%) compared with low FST (56%)
- Treatment-related AE rates were similar for subjects of non-White (54%) and White (46%) race
- The most frequently reported treatment-related AEs for both POC and non-POC were injection site mass, induration, swelling, and tenderness

Summary

- POC consistently showed greater improvement in wrinkle severity compared to non-POC
- Responder rates (≥ 1 -grade) among POC were higher than for non-POC across all visits
- Global aesthetic improvement scores assessed by the blinded live evaluator were similar for POC and non-POC across all time points
- Subject satisfaction remained high throughout the course of the study up to 15 months, with similar results between POC and non-POC when analyzed by FST
- The RHA line of dynamic fillers was well tolerated and effective for the correction of moderate-to-severe facial wrinkles and folds, such as nasolabial folds, in POC