TEOXANE

PRESS RELEASE

Aesthetic Surgery Journal publication: New U.S. data demonstrate favorable safety profile and sustained, natural-looking improvements in lip augmentation with Teoxane's RHA® 3 up to 12 months

Pivotal randomized trial supports FDA authorization of RHA® 3* for lip volumization, showing durable outcomes and high patient satisfaction.

Geneva, Switzerland – August X, 2025 – Teoxane today announced the publication in the *Aesthetic Surgery Journal* of a pivotal randomized, controlled, double-blinded trial evaluating the safety and effectiveness of RHA® 3 for lip augmentation in the U.S. population. Conducted across seven U.S. centers, the study enrolled 202 subjects and demonstrated that RHA® 3 achieved sustained improvements in lip fullness, high patient satisfaction, and a favorable safety profile over 52 weeks.

«The results from this controlled trial make an important contribution to the scientific literature on hyaluronic acid fillers. Demonstrating the long-lasting effectiveness of RHA® 3 alongside favorable safety profile provides essential information for practitioners when selecting treatment options for this central facial feature» explains Dr. Ava Shamban.

Addressing an unmet need in lip augmentation

Hyaluronic acid (HA) dermal fillers are widely used for lip augmentation in the United States; however, current products can present limitations, including unnatural results related to injection technique, filler selection, or overcorrection, as well as the need for large injection volumes and frequent touch-ups. These challenges highlight an unmet need for fillers capable of achieving natural, durable outcomes with reduced injection requirements. RHA® 3, with its unique balance of strength and stretch, has been specifically designed to adapt to facial dynamics and has now been clinically validated in this pivotal trial.

Study design and results

This pivotal randomized, controlled, double-blinded trial evaluated the safety and effectiveness of RHA® 3 versus an active comparator in **202 patients with baseline lip fullness graded 1–3 on the Teoxane Lip Fullness Scale (TLFS)**. Outcomes were assessed over a **52-week** period.

- **Primary endpoint:** Non-inferiority on the Treatment Lip Fullness Scale (TLFS) at Week 12 was achieved (≥1 grade improvement at Week 12).
- **Treatment Lip Fullness Scale (TLFS) responder rates:** 78.1% (RHA® 3) vs 65.9% (comparator). In Grade 3 lips (fuller lips), rates were 62.3% vs 29.4% (p=0.0271).
- **Global Aesthetic Improvement Scale (GAIS):** RHA® 3 demonstrated significantly higher responder rates (evaluated by blinded live evaluators and subjects) between Weeks 24–52 (p<0.05).
- **Patient satisfaction:** At one year, 82.7% of patients treated with RHA® 3 reported satisfaction compared with <70% in the comparator group. More than 92% consistently described results as natural-looking and natural-feeling.
- **Treatment characteristics:** Despite similar initial injection volumes, the RHA® 3 group required a numerically lower volume and fewer touch-up treatments to reach the **optimal cosmetic result (OCR)**.
- **Safety:** RHA® 3 was well tolerated, with no late-onset reactions and no cases of angioedema, both of which are possible though rare with dermal fillers.

"The unique combination of strength and stretch in RHA® 3 allows for results that are both natural in appearance and cosmetically elegant. These specific rheological properties make it especially suitable for lip augmentation, where durability and dynamic adaptation are key to patient satisfaction" concludes Dr. Ava Shamban.

Link to regulatory milestones

This pivotal trial supported the **FDA authorization of RHA® 3 for lip volumization** in the United States, expanding the clinical evidence base for the RHA® Collection. Results build on prior global studies demonstrating the safety and effectiveness of the RHA® range across multiple facial indications.

About Teoxane Lip Fullness Scale (TLFS)

The TLFS is a five-grade photonumeric scale used to assess lip fullness. It provides a standardized method for evaluating changes in lip volume and shape, making it a valuable tool for both clinical studies and practical applications in aesthetic medicine. The scale ranges from grade 1 (minimal lip fullness) to grade 5 (very full lips), allowing for precise measurement of treatment outcomes.

About Teosyal RHA® 3

RHA® 3 is part of the TEOSYAL® Resilient Hyaluronic Acid (RHA) collection, designed to adapt to facial dynamics and provide natural-looking results. RHA® 3 is a viscoelastic, homogenous, and biodegradable gel crosslinked with 1,4-butanediol diglycidyl ether (BDDE). Its unique rheological properties, including high strength and dynamic stretch, make it ideal for lip

augmentation. RHA® 3's ability to adapt to facial animation ensures natural-looking results** with minimal injection volumes and fewer touch-up treatments.

About Teoxane

Founded by Valérie Taupin in 2003, Teoxane Laboratories is the leading Swiss expert in the science of hyaluronic acid. For 20 years, Teoxane has pushed innovation, pioneered the future of aesthetics and opened the door to a new world of natural, expressive, and emotive beauty. The company was founded on a singular vision: to unlock the possibilities of aesthetic treatments through high-performance dermal filler and dermocosmetics, rooted in rigorous scientific research. By consistently listening, educating and laying the groundwork for a safer industry, Teoxane has shaped a new era in aesthetic medicine where small acts of beauty create dramatic changes in the lives of patients and healthcare practitioners alike.

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*RHA® 3 = Teosyal RHA® 3

**Faivre J, Gallet M, Tremblais E, Trévidic P, Bourdon F. Advanced Concepts in Rheology for the Evaluation of Hyaluronic Acid-Based Soft Tissue Fillers. Dermatol Surg. 2021 May 1;47(5):e159-e167

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Reference : Weinkle S, Dayan SH, Draelos Z, Fabi S, Joseph J, Kaufman-Janette J, Shamban A, Magalhães B, Melotti A. Effectiveness and Safety of RHA3 Versus a Comparator Product for Lip Augmentation: A Randomized, Controlled, Prospective, Multicenter Clinical Study. Aesthet Surg J. 2025 Jul 14:sjaf135. doi: 10.1093/asj/sjaf135. Epub ahead of print. PMID: 40659364.