New Article

Plastic and Reconstructive Surgery

Neuramis®
NEW ARTICLE

A Randomized Clinical Trial to Evaluate the Efficacy and Safety of Lidocaine-Containing Monophasic Hyaluronic Acid Filler (Neuramis® Deep Lidocaine) for Nasolabial Folds*

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* Reference: Plast. Reconstr. Surg. Journal. 137: 799, 2016.

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A Randomized Clinical Trial to Evaluate the Efficacy and Safety of Lidocaine-Containing Monophasic Hyaluronic Acid Filler (Neuramis® Deep Lidocaine) for Nasolabial Folds*

OBJECTIVE

To compare the clinical efficacy and safety in moderate to severe nasolabial fold with HA filler of Neuramis® Deep Lidocaine and product A(Biphasic HA filler).

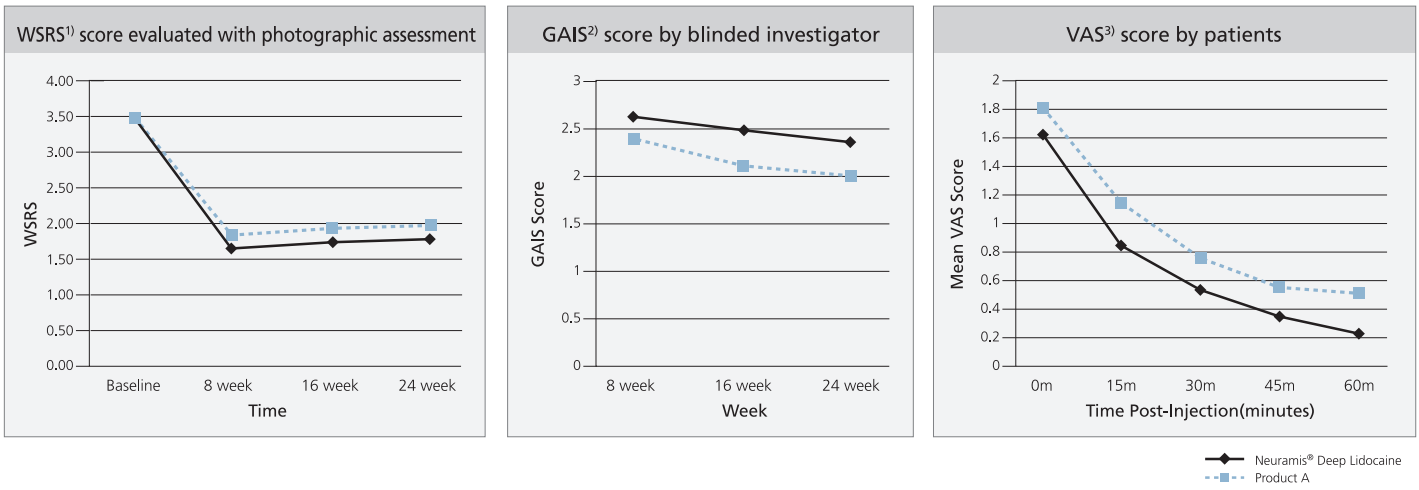
STUDY DESIGN

- A randomized, multicenter, double-blinded, intra-individual trial was designed to compare a lidocaine-containing new monophasic HA filler(Neuramis® Deep Lidocaine) with a lidocaine-containing biphasic HA filler(Product A) in moderate to severe nasolabial folds.
- Fifty-eight patients with moderate to severe nasolabial folds were randomized to an injection of Neuramis® Deep Lidocaine or Product A in the left or right side of the face. Clinical efficacy and safety were assessed by blinded investigators, independent expert panels, and patients based on the Wrinkle Severity Rating Scale(WSRS) and the Global Aesthetic Improvement Scale(GAIS) at weeks 8, 16, and 24 after the injection.

RESULTS

- Efficacy

WSRS improvement from baseline with Neuramis® Deep Lidocaine(1.64±0.74) was significantly greater than with Product A(1.45±0.54) at week 24($p<0.05$). The mean GAIS score at week 24 was 2.36±0.55 for Neuramis® Deep Lidocaine and 2.00±0.50 for Product A($p<0.05$). However, the difference in pain reduction between Neuramis® Deep Lidocaine and Product A treated sides was not statistically significant.



- Safety

The safety population included all 60 patients, who were randomized and received a safety evaluation at least one time after treatment. Both products were well tolerated, with the majority of patients reporting no or only mild injection site reactions. The number of treatment-related adverse events was six(20.69%: five were injection site pain and one was swelling/edema) for Product A and one(3.45%, injection site pain) for Neuramis® Deep Lidocaine. All adverse events were mild in intensity and resolved spontaneously without additional treatment.

CONCLUSION

The efficacy and safety of Neuramis® Deep Lidocaine are comparable to those of Product A in WSRS and GAIS improvement for the management of nasolabial folds. Further, the difference in pain reduction between the two fillers was not clinically significant.

1) WSRS: Wrinkle Severity Rating Scale 2) GAIS: Global Aesthetic Improvement Scale 3) VAS: Visual Analogue Scale

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