A SPLIT-FACE COMPARISON OF TWO HYALURONIC ACID DERMAL FILLERS IN THE TREATMENT OF SEVERE NASOLABIAL FOLDS --- A 12-MONTH RANDOMISED AND EVALUATOR-BLINDED STUDY

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Background: The efficacy and safety of a novel hyaluronic acid (HA) dermal filler HA(a) was compared to those of a currently available HA filler HA(b) in the treatment of severe nasolabial folds (NLF).

Methods: Subjects with severe NLF (defined as having a score 4 on the Wrinkle Severity Rating Scale [WSRS] ranging from 1 to 5) were randomised to receive HA(a) and HA(b) in their left and right NLFs at baseline. Efficacy was evaluated by blinded investigators. Local tolerability was evaluated daily for the first 3 weeks after injection, based on the diaries of the blinded subject. Safety was also evaluated by monitoring adverse events throughout the study by the blinded investigator.

Results: Similar volumes of both products were injected. At Week 24, the mean change of WSRS from baseline was -1.65±0.86 for HA(a), significantly greater than that for HA(b) (-1.41±0.81; $P<.005$). HA(a) was also significantly more efficacious than HA(b) at Week 12, 36 and 48 (all $P<.01$). At the end of the study (Month 12), significantly more subjects willing to be re-injected preferred HA(a) to HA(b) (72.4% vs. 27.6%; $P<.001$). The two products were similarly well-tolerated. The number of related adverse events associated with HA(a) and HA(b) was 3 and 1, respectively, none of which was severe.

Conclusions: Both HA(a) and HA(b) were efficacious and safe in the treatment of severe NLF. Compared to HA(b), the novel filler HA(a) demonstrated a similar safety and a significantly greater efficacy starting from Week 12 until Week 48.

Keywords: hyaluronic acid filler, severe nasolabial folds, efficacy