

ESTYME® LIFT, A NEW HA DERMAL FILLER FOR NASOLABIAL FOLDS - COMPARATIVE STUDY

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CRO : DERMSCAN – PharmaScan

INTRODUCTION

Over the past 2 decades, the use of **hyaluronic acid (HA) dermal fillers** for the correction of wrinkles, folds and volume loss has increased continuously. Based on 15 years experience in this field associated with delivery devices and the success of its 1st HA dermal fillers generation, **SYMATESE developed its second product generation ESTYME® FILLERS with lidocaine, based on a new cross-linking process that induces less modification of HA able to respond to patient satisfaction and physicians needs.** ESTYME® LIFT, the first product of the range was approved in Europe (CE marking) in 2021 to correct nasolabial folds. The clinical efficacy and safety of the new HA filler indicated for nasolabial folds (NLF) were investigated in a **prospective, single centre, randomized, comparative, double-blinded, split-face trial.**

METHODS

STUDY DESIGN	PROSPECTIVE, SINGLE CENTRE, COMPARATIVE, DOUBLE-BLINDED, SPLIT-FACE, follow-up 9-month	
INJECTED VOLUME (mL)	ESTYME® LIFT Mean: 0.93 [Min; Max]: 0.30; 2.00	Control Mean: 0.95 [Min; Max]: 0.30; 2.00

The study included **45 patients** with **symmetric nasolabial folds**, assessed from moderate (grade 3) to severe (grade 4), according to the WSRS scale. The **mean age** of subjects was **58 years**, ranged from **37 to 70 years**. 84% of subjects were women.

The study compares **ESTYME® LIFT** to a worldwide commonly used HA-lidocaine filler, approved in treatment of nasolabial folds (control). For each patient, both products are injected either on the left or on the right side.

Figure 1 : Main parameters of the clinical study.

RESULTS

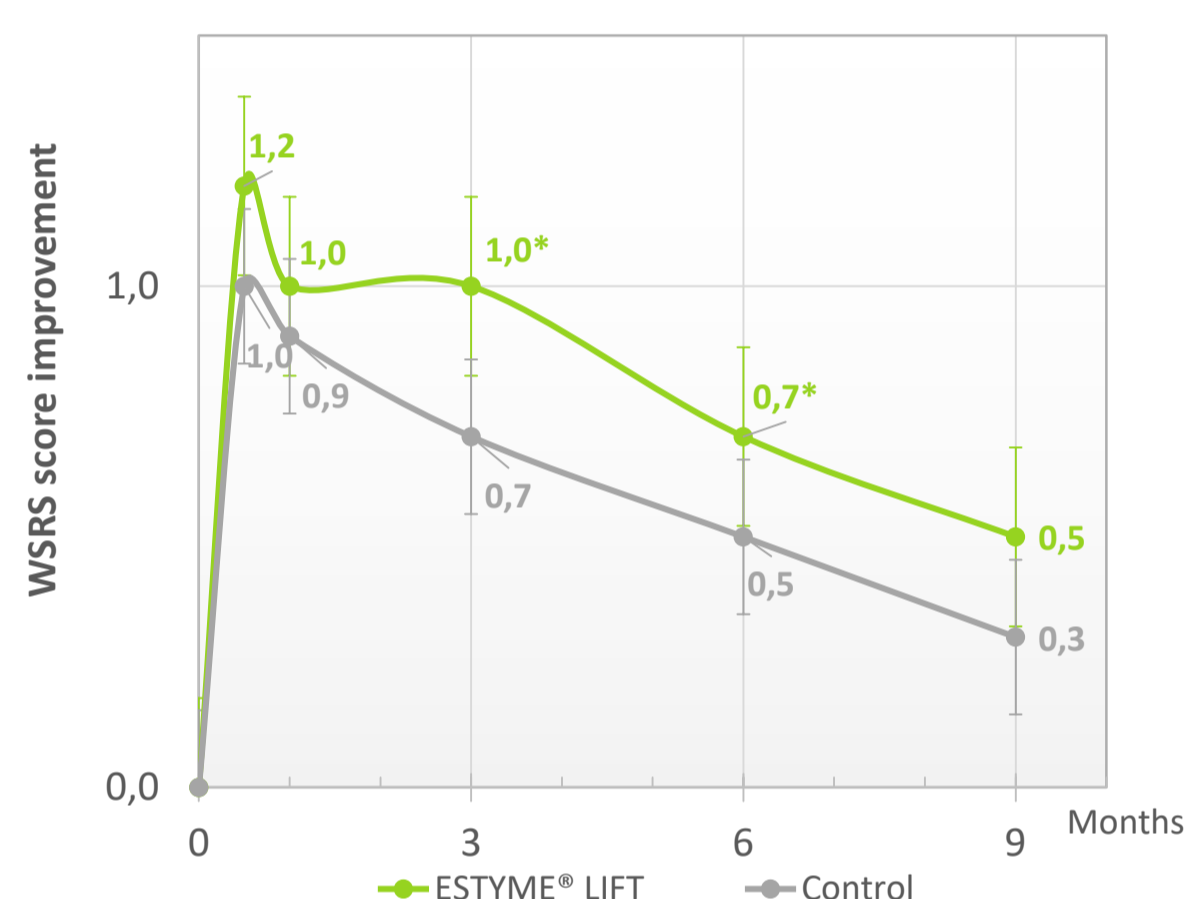


Figure 2 : Improvement of WSRS (live measurement).

The WSRS score improvement for both products increased significantly over 9 months. At 3 months and 6 months, there is a statistically **significant difference** between both products and **in favor of the ESTYME® LIFT.**

Global aesthetic improvement was durably high according to the blinded evaluator and subjects.

For the blinded evaluator, the comparison of GAIS assessment was **significantly in favor of ESTYME® LIFT** at 6 months.

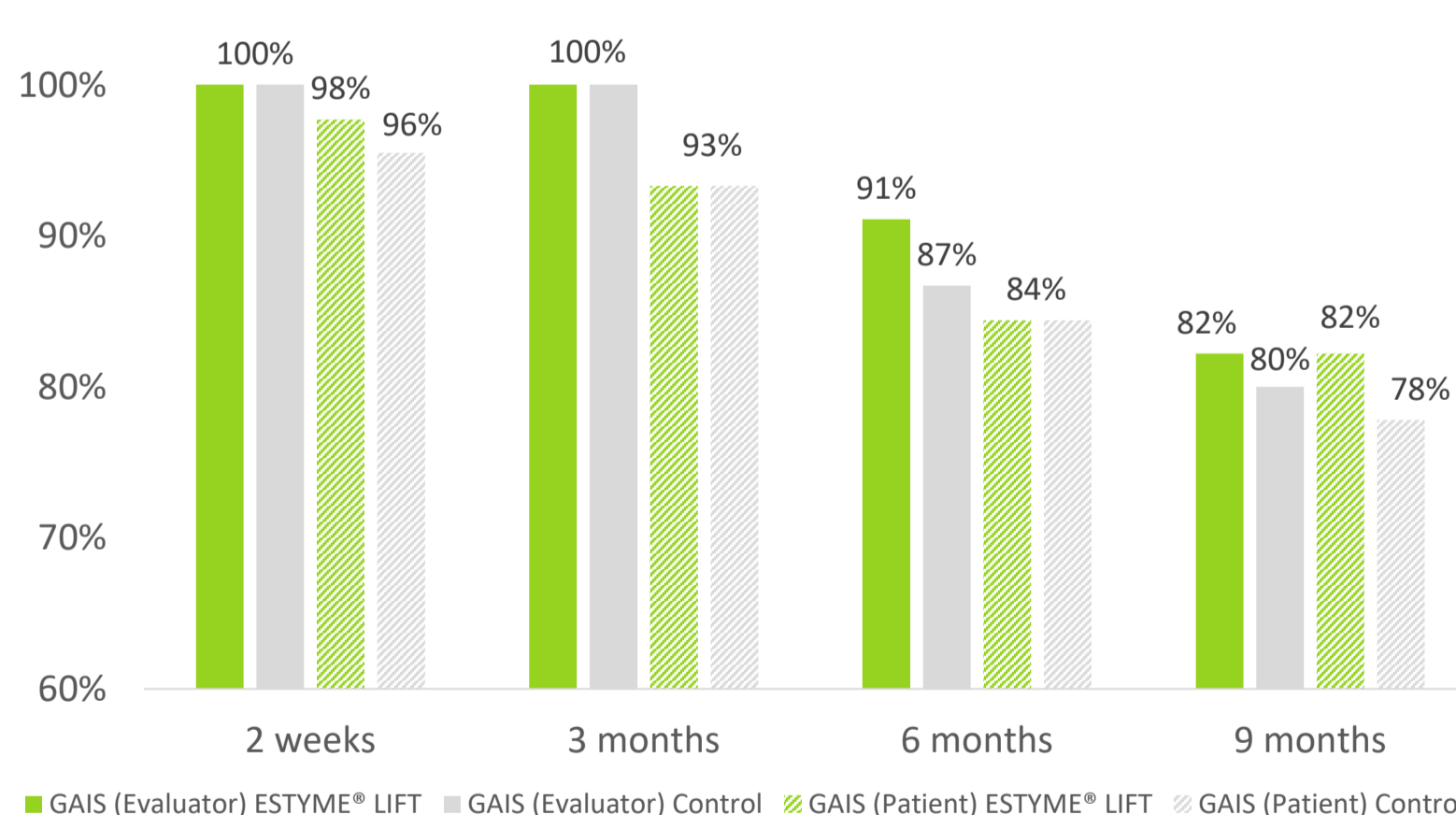


Figure 4 : Global Aesthetic Improvement Scale (GAIS) responder rate.

Regarding safety, no significant difference was observed between both devices throughout the study. Injection site reactions were mostly mild and resolved in a few days. Until Month 9, twenty two subjects (48.9%) experienced at least one adverse device event. All were resolved at 9 months. No unexpected or serious complications were reported.



Figure 5 : Evolution of NLF appearance, before/after injection.

0.9 mL of ESTYME® LIFT on the right NLF (left on the picture) and 0,9 mL of the control on the left NLF (right on the picture). For this subject among many, the wrinkle of each side is clearly less visible from 1 month after injection to 9 months, compared to the initial picture. ESTYME® LIFT seems more sustainable over time.

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CONCLUSION

This comparative study demonstrates the non-inferiority of ESTYME® LIFT to a well-established comparator for the correction of nasolabial folds.

The WSRS assessment highlights an improvement in age-related folds throughout the study with a significant difference at 3 and 6 months in favor of ESTYME® LIFT as well as prolonged effectiveness by 3 months compared to the control. These results are confirmed by volume quantification using fringe projection technique.

No significant difference was revealed with GAIS for the duration of the study, assessed by the blinded evaluator and subjects.

Regarding the safety, no significant difference was observed between both products. Likewise, no unexpected or serious related complications were reported.

Safety and performance of ESTYME® LIFT are good and satisfactory. These results allowed the CE marking and are promising for the entire SYMATESE new dermal filler range ESTYME® FILLERS.