

# A randomized, multi center, double-blind, active-controlled, matched pairs design clinical study to evaluate the efficacy and safety of HA IDF plus versus HA IDF in nasolabial fold injection

## OBJECTIVE

The objective of this study was to evaluate the efficacy and safety of HA IDF plus (with lidocaine) injected in the nasolabial fold compared to HA IDF (without lidocaine)

## METHODS

➤ Study Design : Multi center, randomized, active-controlled, matched pairs design, double-blind, comparative clinical study

➤ Subject : **62** Female subjects aged 30 to 60 whose wrinkles in the nasolabial fold at Screening Visit was Stage 3 or 4 in the 5-stage Wrinkle Severity Rating Scale (WSRS).

➤ Protocol :



➤ Treatment : In the face divided bilaterally, HA IDF plus(test device) was injected into the mid-dermal layer in the nasolabial fold of one side and HA IDF(comparator) in that of the opposite side through the randomization. Injection was made in the nasolabial fold of the right first followed by that of the left, in the same injection method in both nasolabial folds. The treatment dose was adjusted according to the size and depth of the wrinkles so that the maximal effect could be obtained by subject, with the maximal dose for a side of the face not exceeding 1.5mL.

## RESULTS

➤ Efficacy

1) Percentage of subjects with at least a 10mm difference in [FA set]



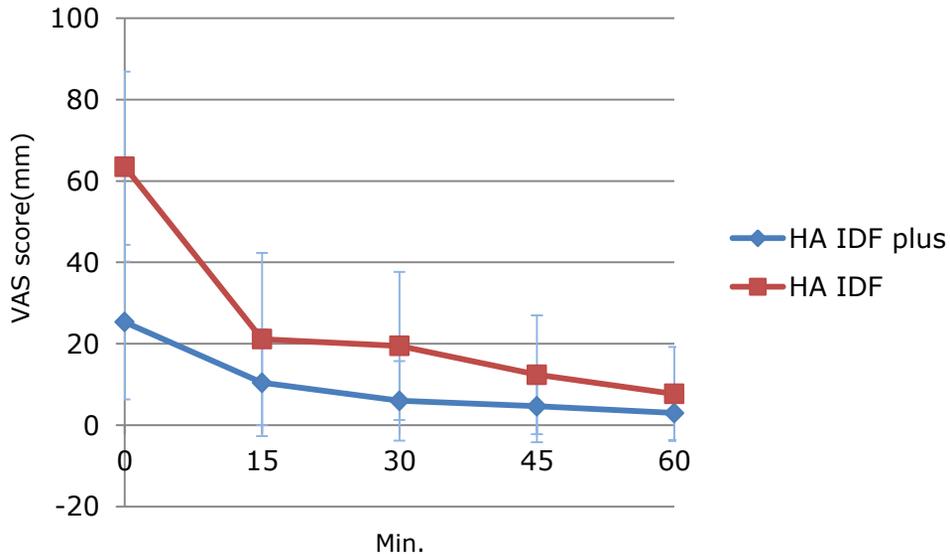
The proportion of the subjects with at least 10mm difference in VAS pain scale scores within the subject immediately after treatment with the investigational devices at Visit 2, was 57 subjects (91.94%). Since the 2-sided 95% exact CI was (0.82, 0.97), of which the lower limit was greater than 0.5, the superiority of the test device was demonstrated.

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## RESULTS

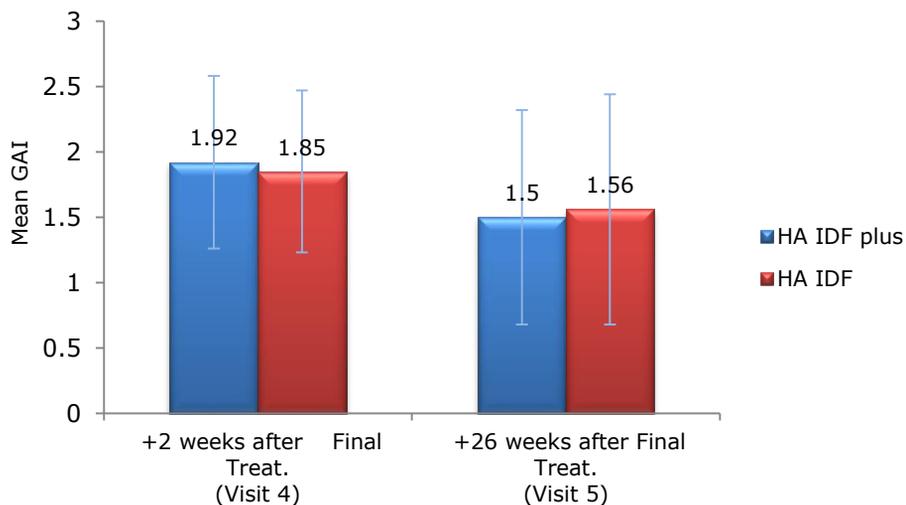
### ➤ Efficacy

#### 2) Mean VAS scores assigned by subjects at Visit 2 [FA Set]



The mean of the difference in VAS pain scale scores between the test device and the comparator within the subject also showed a gradually decreasing tendency from the immediate pre-treatment to 60 minutes after treatment. As the 95% CI of the difference in VAS pain scale scores within the subject (VAS of the comparator - VAS of the test device) did not include 0 immediately and at any time point after treatment, it showed a statistical significance (the significance level of 5%).

#### 3) Average GAI(Global Aesthetic Improvement) evaluated by the subject [FA set]



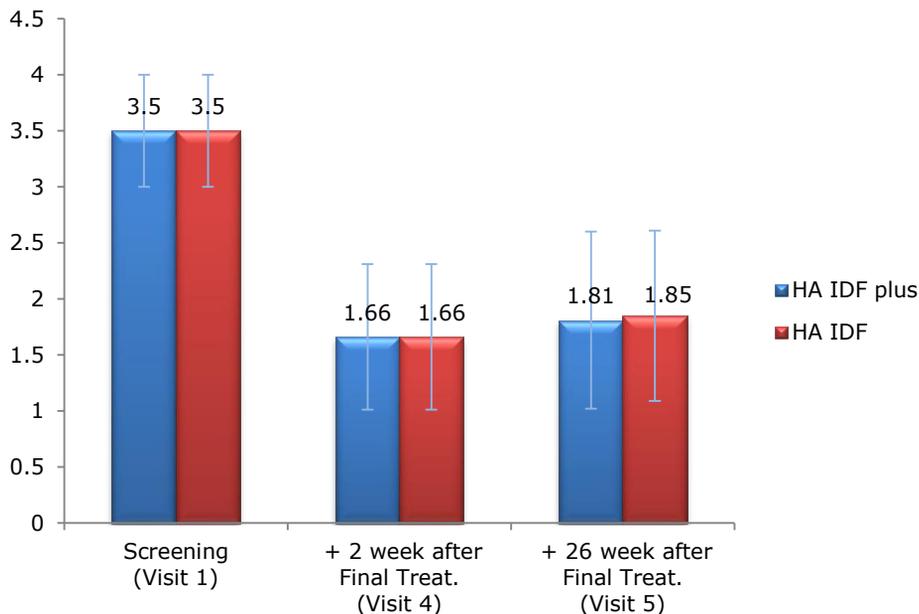
The GAI difference between the test device and the comparator at Week 2 (Visit 4) and Week 36 (Visit 5) after the final treatment with the investigational devices was not statistically significant between the test device and the comparator.

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## RESULTS

### ➤ Efficacy

4) WSRS difference at Visit 4 and Visit 5 from Visit 1 by treating investigator [FA Set]



The difference in WSRS changes at Visit 4, Visit 5 from Visit 1 within the subject was not statistically significant.

### ➤ Safety

In the local reactions confirmed for 14 days from the treatment day with the investigational devices, no statistical significance was observed in the onset of the local reactions between the test device and the comparator. Most of the reported local reactions were mild in severity, and there was no local reaction confirmed additionally after Week 2 (Visit 2) through Week 52 (Visit 6) after the treatment. Neither a serious adverse event nor a local reaction requiring treatment was observed. Based on the results, it is judged that HA IDF plus has no concern in safety in terms of local reactions and adverse events compared to HA IDF by Week 26 after treatment with the investigational devices.

## Conclusion

In the female subjects with some degree of wrinkles in which HA IDF plus and HA IDF were injected in the nasolabial fold of each side of the face, HA IDF plus showed the significant pain-improving effect compared to HA IDF immediately and at 15, 30, 45 and 60 minutes after treatment. In addition, it was confirmed that there was no difference in the GAI and safety for 26 weeks after treatment. As HA IDF Plus also showed no difference in safety compared to HA IDF Plus by Week 52 after the treatment, the safety of HA IDF Plus was confirmed.