

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

## OBJECTIVE

The objective of this study was to confirm the superiority of HA IDF II plus (with lidocaine) injected in the nasolabial fold compared to HA IDF II (without lidocaine) in the improvement of local pain and evaluate the wrinkle-correcting effect, GAI and safety.

## 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 :

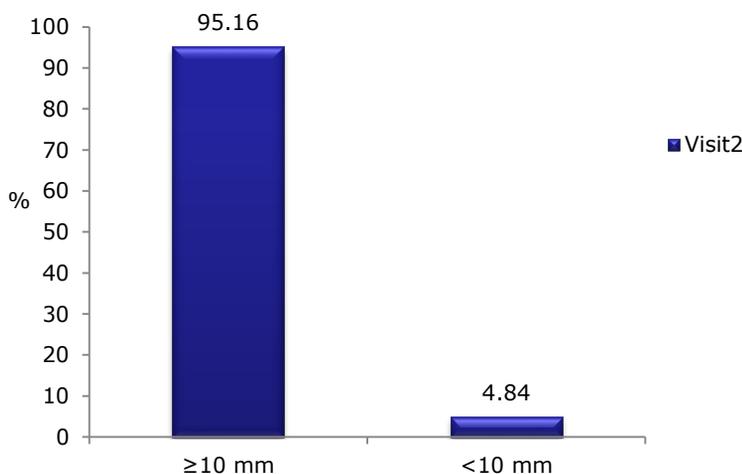


➤Treatment : In the face divided bilaterally, HA IDF II plus was injected into the lower dermal layer in the nasolabial fold of one side and HA IDF II in that of the opposite side through the randomization. The treatment dose was adjusted according to the size and depth of the wrinkles so that the maximal 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 VAS [FA set]



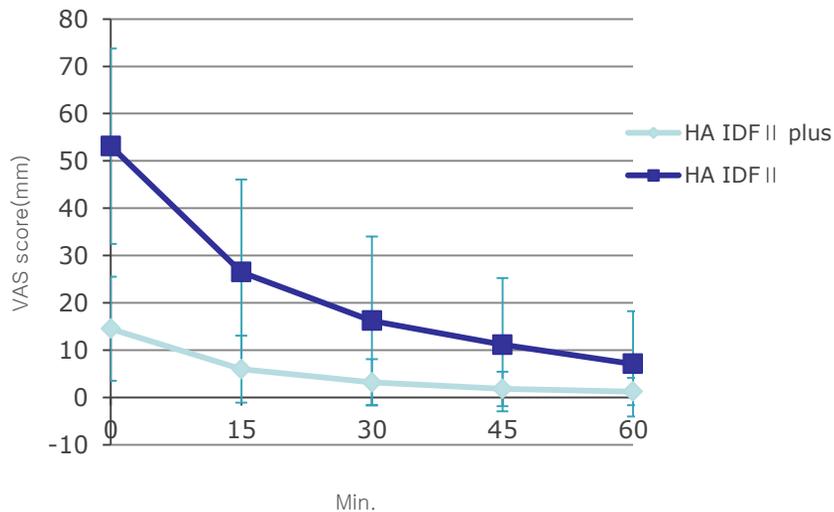
As the 95% exact CI for the proportion of the subjects with at least 10mm difference in VAS pain scale scores was shown to be (0.87, 0.99), the lower limit of CI was greater than 0.5, demonstrating the superiority of the test device.

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

## RESULTS

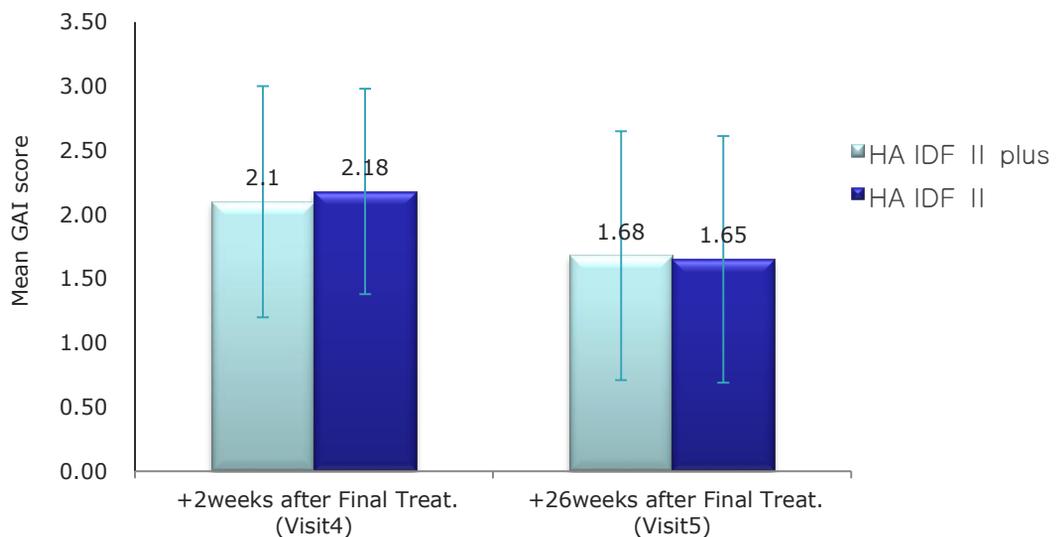
### ➤ Efficacy

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



It showed a gradual decrease over time after treatment with the investigational devices. The difference in the VAS pain scale scores within the subject was statistically significant at all the time points (significance level: 5%)

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



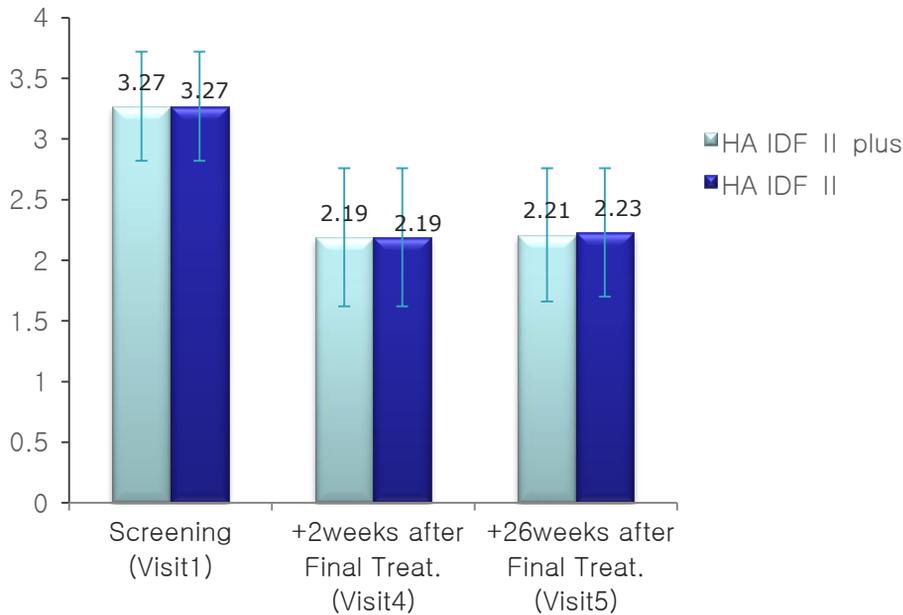
The GAI difference between the test device and the comparator at Week 2 (Visit 4) and Week 36 (Visit 5) after the final treatment with the investigational devices was not statistically significant

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

## RESULTS

### ➤ Efficacy

#### 4) WSRS difference evaluated 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

During 2 weeks starting from the treatment day with investigational devices, no statistically significant difference in the onset of local reactions between the test device and the comparator. No additional local reaction was found after Week 2 of the treatment (Visit 4) by Week 52 (Visit 6), and there was neither a serious adverse event nor a local reactions requiring medical treatment.

## Conclusion

In the Korean female subjects with some degree of wrinkles in which HA IDF II plus and HA IDF II were injected in the nasolabial fold of each side of the face, HA IDF II plus showed the significant pain-improving effect compared to HA IDF II immediately and at 15, 30, 45 and 60 minutes after treatment and no difference was found in the GAI and the wrinkle-correcting effect for 26 weeks after treatment. In addition, HA IDF II plus was similar to HA IDF II in the adverse events and local reactions by Week 52 after treatment, confirming the safety of HA.