

LETTER TO THE EDITOR

Efficacy and Safety of Hyaluronic Acid with and without Radiofrequency for Forehead Augmentation: A Pilot Study Using Three-Dimensional Imaging Analysis

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Dear Editor:

The forehead, which occupies approximately one-third of the face, is one of the major determinants of a feminine or masculine look. People consider a broad, convex, and smooth forehead more feminine and attractive than a flat or sunken one¹. Hyaluronic acid (HA) fillers are currently the most widely accepted treatment method for forehead augmentation. However, they have a relatively shortly lived effect, necessitating frequent injections for maintenance². To compensate for the short effect of HA fillers, combination therapies with radiofrequency (RF) regimens are currently being developed³⁻⁵. However, there is no evidence that combination therapy is better than injection of HA filler alone in forehead augmentation.

In order to compare the clinical efficacy and safety of HA filler treatment alone with HA filler and RF for forehead augmentation, we recruited five Korean female volunteers without wrinkles, contours, or asymmetry on their foreheads. This study was approved by the institutional review board of Chung-Ang University College of Medicine (C2012041-736). We used Juvederm (Allergan, Irvine, CA, USA) as an HA filler and INNOfill (Pacific Pharma, Seoul, Korea) as an RF device. First, we administered intradermal RF treatments at 18 W (Level 7 at 1 MHz) with an insulation-coated 27-gauge needle electrode and 10 passes

at one side of the forehead for 30 seconds using a fanning technique. After RF, we injected 1 ml HA filler into both sides of the forehead equally also by using a fanning technique.

To evaluate therapeutic efficacy, the following were evaluated 1, 4, 12, and 24 weeks after the initial treatment: high-quality digital photographs, PRIMOS (GFM, Teltow, Germany) three-dimensional (3D) images, and Global Aesthetic Improvement Scale (GAIS; 3, very much improved; 2, much improved; 1, improved; 0, no change; -1, worse). At each visit, the subjects were queried about adverse events. Statistical analyses were performed using independent t-tests and p -values < 0.05 were considered statistically significant.

The subjects' ages ranged from 28 to 39 years (mean, 33 years). All subjects completed the 24-week follow-up period. After treatment, all foreheads were augmented symmetrically. On PRIMOS imaging, forehead areas that are higher post-treatment than pre-treatment are shown in red. Over time, the red areas of both sides decreased gradually, but the sides treated with both HA and RF appeared to have maintained their shape and size relatively longer than the sides treated with HA alone (Fig. 1).

The increase in mean volume post-treatment in comparison with pre-treatment volume was measured by PRIMOS

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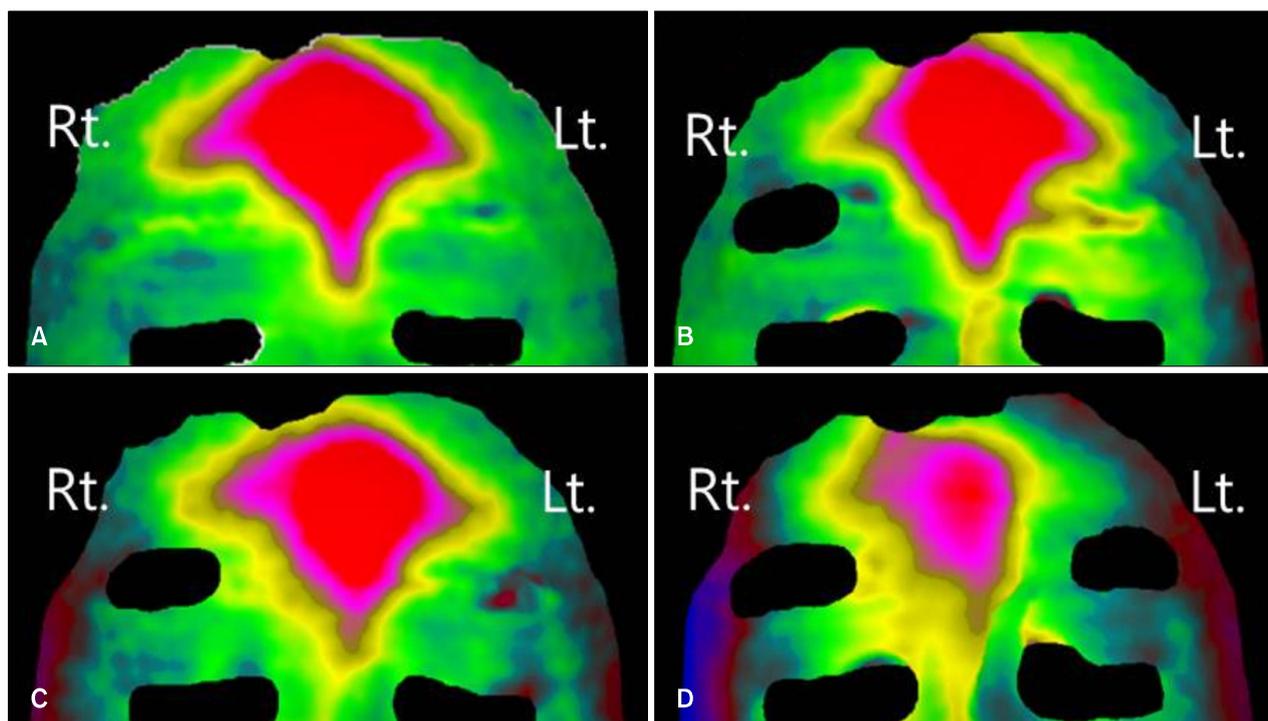


Fig. 1. Representative case. The right and left sides were treated with hyaluronic acid filler injection with and without prior radiofrequency treatment, respectively. Photographs 1 week (A), 1 months (B), 3 months (C), and 6 months (D) after treatment. The augmentation effect of the right side was longer lasting. Rt.: right, Lt.: left.

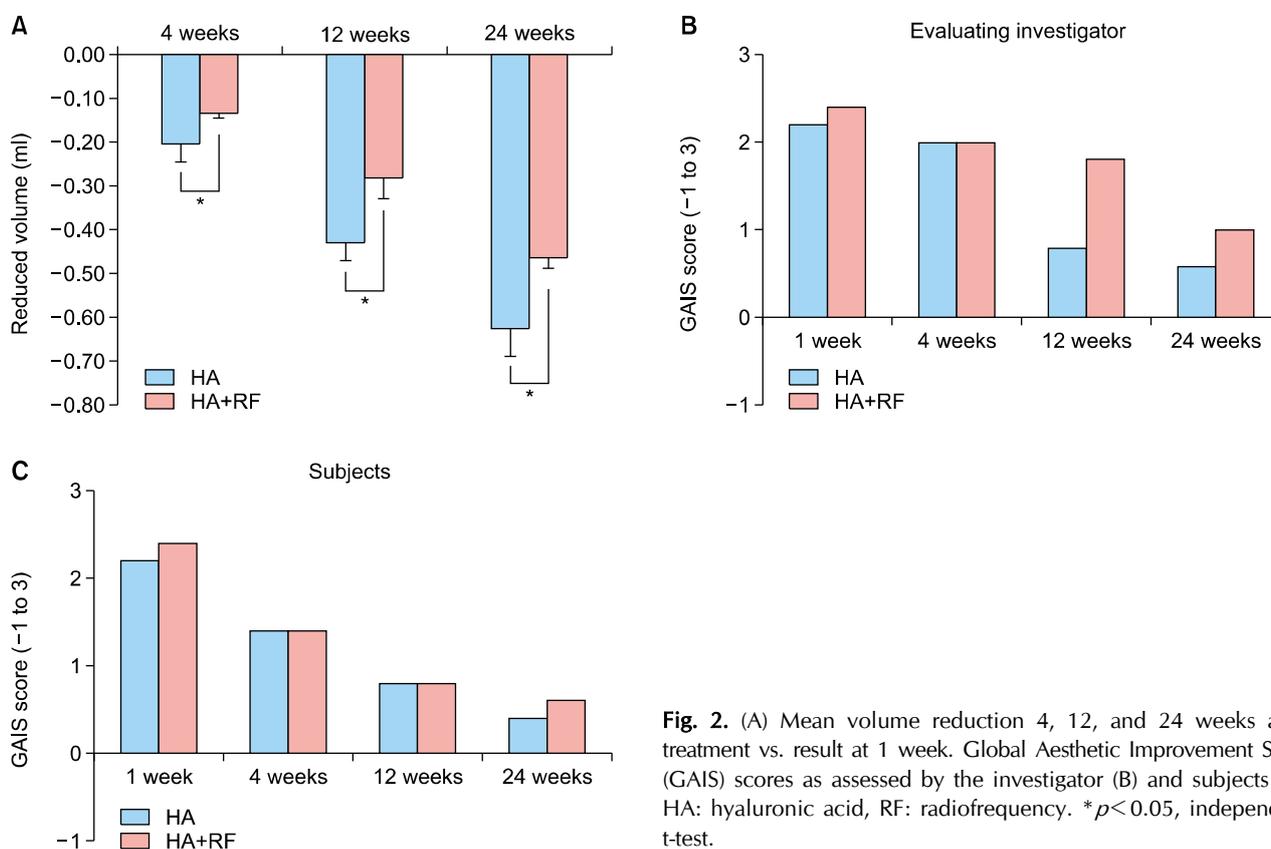


Fig. 2. (A) Mean volume reduction 4, 12, and 24 weeks after treatment vs. result at 1 week. Global Aesthetic Improvement Scale (GAIS) scores as assessed by the investigator (B) and subjects (C). HA: hyaluronic acid, RF: radiofrequency. * $p < 0.05$, independent t-test.

3D analysis. Mean increased volume at 1 week after augmentation was 0.865 ± 0.023 ml at the HA with RF treated side and 0.872 ± 0.023 ml at HA without RF treated side. The volume reduction each visit compared to that volume 1 week after treatment was also calculated. The volume reduction of sides treated with HA and RF was significantly less than that of sides treated with HA alone at 4, 12, and 24 weeks (Fig. 2A).

The GAIS scores by the investigator and subjects are presented in Fig. 2B and C, respectively. There were no significant differences in the GAIS scores between the investigator and subjects. However, the investigator's scores for the sides treated with HA with RF were slightly higher than those for the sides treated with HA alone at 12 and 24 weeks. The GAIS scores of the subjects were almost the same. The experimental procedure was well tolerated by all subjects, none of whom reported any serious adverse events other than pain.

Choi et al.⁵ report RF treatment prior to HA filler injection may provide synergistic and long-lasting effects for the reduction of nasolabial fold wrinkles. Needle-type RF is capable of delivering high RF energy directly to the dermis and can also pass injection materials via a needle electrode. This needle creates tunnel-like coagulation canals inside the dermis and hypodermis through collagen degeneration the injection site; these collagen canals may act as protective shields against external oxygen radicals while simultaneously containing the injected HA filler, thereby preventing HA from spreading away from the targeted area.

Needle-type intradermal RF has some limitations. It is difficult to perform the fine sculpting required to correct fine wrinkles and recesses. Furthermore, it can induce pain more easily than other procedures. In the present study, all subjects complained of slightly more pain on the sides treated with HA and RF than HA without RF. The skill of the practitioner and adequate anesthesia are very important for increasing accuracy and decreasing pain. However, needle-type RF treatment also has a major advantage. Prior treatment with intradermal RF potentially coagulates vessels in the areas where RF is transmitted; this decreases the risk of HA leakage into adjacent vessels and associated bruising. This study has some limitations. First, this study is limited by the small number of subjects and lack of blinding of the

evaluating investigator and subjects. Another limitation is the possibility of deviation owing to the subtly varying positioning of the subjects when the PRIMOS images were captured. In order to evaluate pre- and post-treatment volume changes, it is necessary to capture images in same position with exactly the same direction, height, and angle. Although we tried to minimize this variability, it could not be completely eliminated.

In conclusion, intradermal RF treatment prior to HA filler injection may provide synergistic and long-lasting effects, making it a safe treatment modality for forehead augmentation. Therefore, further studies with more subjects are warranted to confirm the efficacy and safety of combination RF and HA therapy for forehead augmentation.

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