

A 52-week split face study, on the efficacy and safety of a new type of hyaluronic acid injectable filler for nasolabial wrinkles

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Background

Nasolabial wrinkles (NF) treatment has been widely considered as a strong criterion to estimate efficacy, durability and natural looking results, of different type hyaluronic acid (HA) injectable fillers¹. On that purpose, fillers have been undergone a lot of modifications, classified as monophasic or biphasic with monophasic ones further divided to monodensified or polydensified².

A clinical observation of various HA filler behavior on treating NF, would be a reliable criterion to estimate their cosmetic effectiveness.

Aim

The purpose of this 52-weeks split face study concerned efficacy, duration and skin reaction of two different HA injectable fillers for nasolabial wrinkles: right NF were treated with monophasic, polydensified HA filler, and left one by a scientifically modified HA with molecular basis made up by monophasic monodensified ultrafine multi-spheres, according to the innovative S.C.E.D.I.S.TM

Methods

Fifteen facial aesthetic patients (mean age $52,47 \pm 9,39$) participated, using same injected quantity and technique. The outcome was estimated by Wrinkle Severity Rating Scale (WSRS), Global Aesthetic Improvement Scale (GAIS) and post treatment naturalness feeling with FACE-Q questionnaire^{3,4,5}. Photos were taken in baseline and follow-up visits in 1st, 6th and 12th months.



*Figure 1:
Before and one year after MP
(monophasic polydensified) filler and MM
(monophasic monodensified)
filler respectively*

Results

In figure 1 the most typical cosmetic outcomes are presented. The Evaluation of WSRS revealed statistically significant difference between the baseline and every following visit ($p < 0,001$) as shown in table 1a,1b,1c. The GAIS score demonstrated a similar cosmetic response, for both sides ($p > 0.05$), remaining optimal over one year ($p = 0.3$) and the results are presented in table 2. Interestingly, the FACE-Q questionnaire demonstrated statistical significance, in the injected left side NF, than the right one ($p < 0.01$), as analyzed in table 3. Also the patient's satisfaction is clearly shown in figure 2 with the left side injected offering a more "comfortable feeling" than the right one.

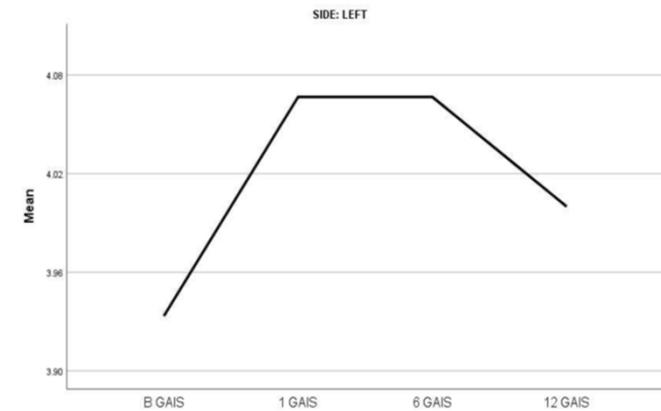
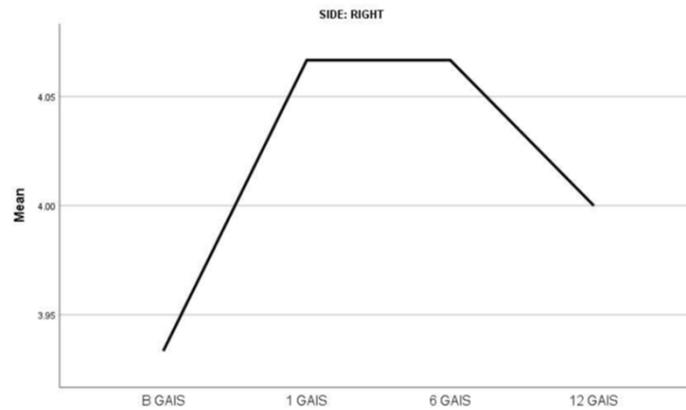
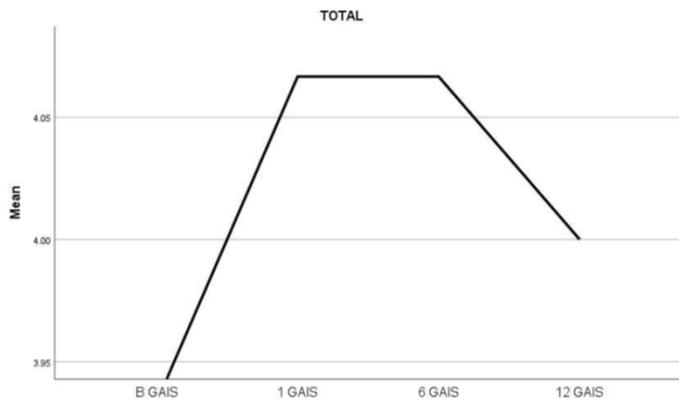


Table 1a,1b,1c: The overall reduction of WSRs after filler application, the reduction of WSRs after filler application on the right and left side respectively.

	N	Mean	Std. Deviation	Minimum	Maximum
B GAIS	30	4.00	0.00	4	4
1 GAIS	30	4.07	0.25	4	5
6 GAIS	30	4.07	0.25	4	5
12 GAIS	30	4.03	0.32	3	5

Table 2: Descriptive Statistics for GAIS scores

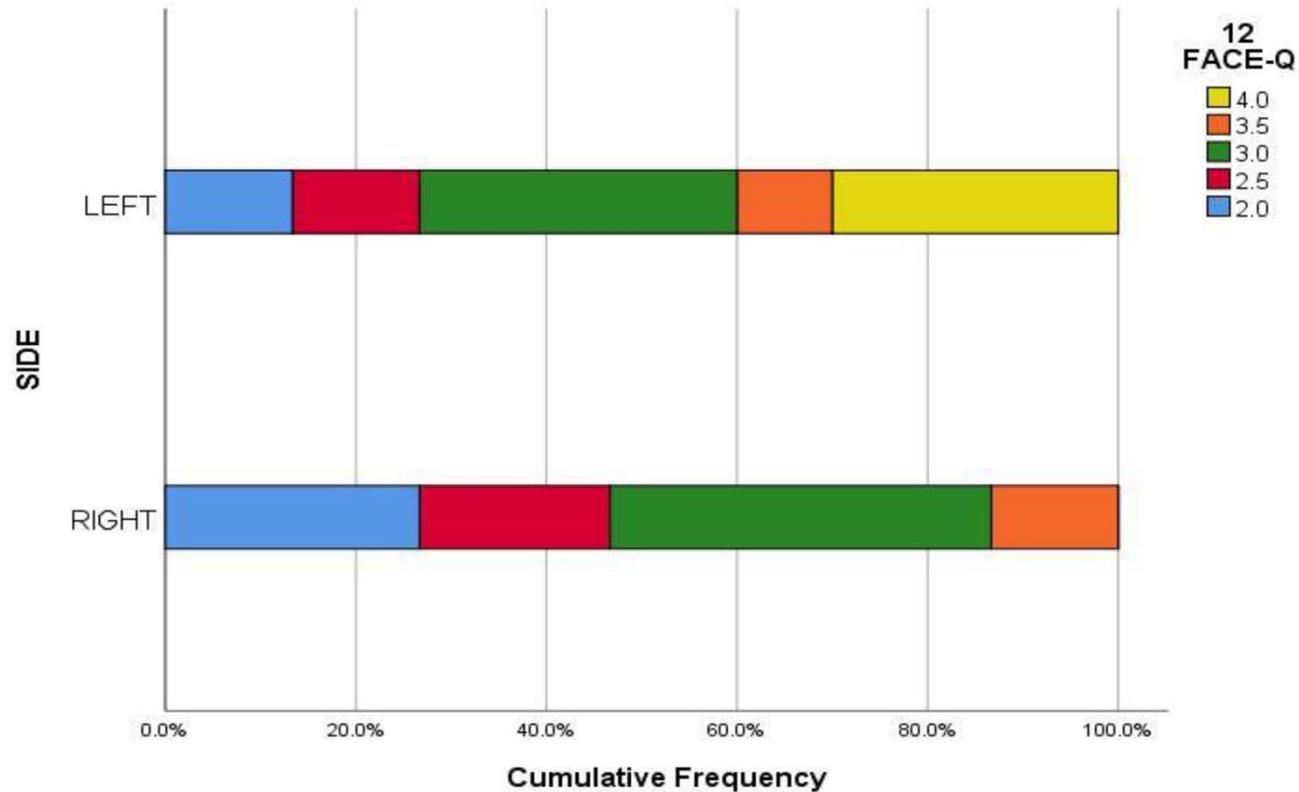


Table 3: Cumulative Frequency Bar Chart for the FACE-Q variable presenting the stacked frequencies of the medians of each category for the two sides. The x axis presents the two sides. The categories presented in the y axis are: 2, somewhat dissatisfied (blue block); 3, somewhat satisfied (green block); 4, very satisfied (yellow block).

The subcategories are a result of the median function used to calculate the FACE-Q variable from the 10 items and occur between two categories: 2.5, (red block); 3.5, (orange block). The overall conclusion strongly supports the subjects feeling of naturalness after NF filling with monophasic monodensified HA product

Discussion

In the present study, both HA offer similar effectiveness and duration, clearly depicted by photographic documentation, WSRS and GAIS score. However, FACE-Q results, were decisive about the subjective feeling or naturalness, in favor of the monodensified HA products ($p < 0.05$). All subjects expressed the feeling of intracutaneous tension in the right NF, but not in the left one (treated with the monodensified molecule). As more compatible with natural sensation, the modified monophasic monodensified HA injectable filler provides a reasonable argument for strong application support in everyday common aesthetic clinical practice.

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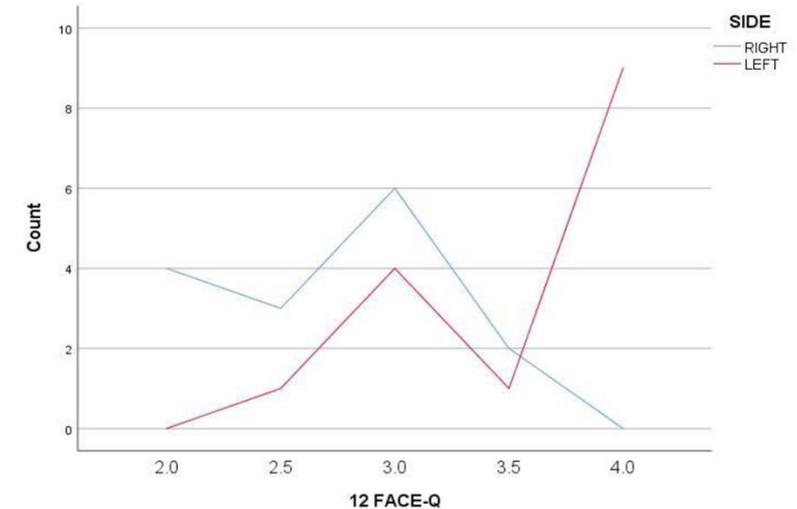


Figure 2: The patient's satisfaction evaluated with FACE-Q after filler application on the left and right side comparatively