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TREATMENT OF FACIAL VOLUME LOSS BY APPLICATION OF VOLUMEFILLING®

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ABSTRACT

Volumefilling® is a product designed in a dosage form that is easily applied for restoring facial volume in places like the cheeks, the bridge of the nose, the forehead, and the eye rims. In order to confirm the effect of the product up to a maximum of 18 months, a clinical follow-up observation was conducted after the product became available on the market. All patients were applied with the product twice a day for three months on areas where facial volume was lost. Application was conducted according to standard clinical practices, and patients were observed by follow-up at 1, 3, 6, 12, and 18 months or optionally 24 months. The efficiency index included a facial volume loss scale, a general aesthetic improvement scale, and patient satisfaction. Forty patients with volume loss to the lateral cheeks, forehead and eye rims were treated. Scores for the facial volume loss scale largely fell from an average of 2.9 at the standard period to 1.6 on 1 month. Significant volume improvement was observed for every follow-up observation as the average score reached 1.3 on 3 months and 1.8 on month 18. The assessment of the general aesthetic improvement scale by researchers shows that at least 97% of patients were assessed as “very much improved or “much improved” up to the third month. On month 12, all patients still displayed treatment effects, with 73% assessed as “very much” or “much improved”, while 12% were assessed as “improved”. Patient assessments also corresponded to the results of the researchers. Volumefilling® is effective for mid-facial

volume expansion, which continues up to 18 months or maybe even up to 24 months. The aesthetic effect was proven by the efficiency assessment and the high rate of patient satisfaction.

KEYWORDS: facial volume loss, facial augmentation, facial volume restore, volumefilling.

1. INTRODUCTION

Due to the rise in the average lifespan and the historic pursuit of beauty, increased interest in methods for achieving natural, younger, and young-looking appearances is expressed world over, especially by women.[1] Minimally invasive impermanent rejuvenation methods like injectable dermal fillers are one of the most frequently conducted aesthetic surgeries.[2, 3] These methods indicate a variety of graceful instruments for facial sculpting, contour formation, and facial wrinkle treatment.[4] The fillers that are currently used differ according to properties, term of effect, tangibility, injection technique, complications, and miscellaneous factors. Facial volume loss is among the most important aging signals, but it may be caused by genetics or disease or may be acquired through injury.[5, 6] During facial aging, significant contraction of the basal frame causes subcutaneous cell tissue (fat, muscle, and fascia) to gradually degrade so that the shape of fat bodies and the relative location undergo change.[7] Change in volume of mid-facial area is related to the appearance of looking sad or tired.[8] Improvement to the hollow of the lateral cheeks and the cheekbone area recreates mid-facial volume, smooths nasolabial lines, and provides a more harmonious appearance, which is related to looking young.

Hyaluronic acid (HA), the main ingredient in fillers, which is widely used for the treatment of facial volume loss, is a natural glycosaminoglycan with a powerful hydrophilicity.[9] In the extracellular matrix, it provides structural support, so that it not only adds volume and fullness but also acts as a nutrient exchange.[10] The natural HA of the skin displays a very fast turnover ratio due to the catabolism from the endogenous hyaluronic acid.[11] Therefore, HA sold on the market is stabilized by various manufacturing techniques. Consequently, products differ according to medicine, concentration, and cross-linking degree.[12] Such characteristics affect swelling risks after surgery as well as period of effect.

The present study conducted follow-up observations on the treatment effect against facial volume loss by using Volumefilling®, which was designed as a dosage form applied with ease unlike fillers. The main ingredients of the volume effect of Volumefilling® are natural

substances, which were observed to induce increases in the number and size of fat cells by stimulating animal fat cells and human fat cells in previous studies. The purpose of the follow-up observations as to confirm the volume effect of Volumefilling® against the volume loss of facial areas like the lateral cheeks, the bridge of the nose, the forehead, and eye rims. The durability of the aesthetic affect was assessed at a maximum of 24 months.

2. SUBJECTS AND METHODS

The assessment was conducted, by abiding by the usage of the relevant product and by following standard clinical practice procedures, at two private physician's hospitals locate in France. Patients were recruited by researcher judgements, which involved securing written consent forms before treatment. The standard period and application was conducted on the same date. Patients applied Volumefilling® twice every day to at least one area from among the lateral cheeks, the bridge of the nose, the forehead and the eye rims in order to treat facial volume loss from aging. The researcher determined the application amount based on clinical experience and severity pertaining to facial hollowing in addition to the application area. During the standard period and follow-up observation, the researcher recorded the patient's age, treatment area, and injected product amount per facial side.

At the standard period, the patient was assessed with the facial volume loss scale (FVLS). The grades were marked as follows. 1 = slight flatness/underlying tissue cannot be seen; 2 = between slight and intermediate; 3 = an intermediate dented concave at one or more facial areas/conspicuousness of bone milestones/basal muscles can be seen; 4 = between intermediate and severe; 5 = severe concave at one or more facial areas/ basal tissue is clearly visible. The effect of Volumefilling® was assessed in each facial side during follow-up observations conducted before application and on months 1, 3, 6, 12, 18 and optionally on month 24 by both patient and researcher. The researcher assessed device efficiency based on FVLS by taking photographs during visitation. The researcher and patient assessed device efficiency based on a general aesthetic improvement index (GAIS) which applied a score from "1=very much improved" to "5=rather worsened". Participation of the follow-up observation visitation is as follows. 1st month = 40 patients, 3rd moth and 6th month = 40 patients, 12th month = 40 patients, 18th month = 36 patients, optional 24th month = 11 patients. Statistical analysis was conducted in an exploratory manner by using observed cases. The individual value of patients was calculated using the left and right facial score averages. For the efficiency assessment, a summary (+/- standard deviation [SD]) in the form

of averages is presented. Also, exploratory p values for t-testing both sides of paired samples were secured to compare the standard period and the visitation values of follow-up observations.

3. RESULTS

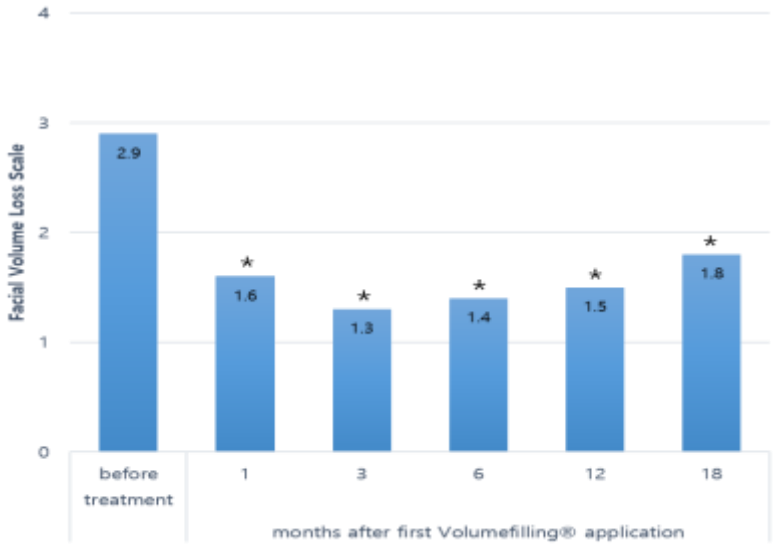

Figure 1. Mean FVLS as evaluated by the clinicians. Mean FVLS per patient was used to calculate an overall mean score for all patients per visit; * *p*< 0.001.

Forty positive patients (n=40) with an average age of 45 (in the range of 25 to 61) were treated using Volumefilling® in order to improve facial volume. Treatment was conducted with a focus on areas of chief complaints, and a total of 16 patients applied an average product amount of 0.8ml to the lateral cheeks and the bridge of the nose on both sides of the face, twice every day for three months. A total of 12 patients applied an average product amount of 1.2ml to the lateral cheeks, forehead and eye rims on both sides of the face, twice every day for three months.

Effect on the facial volume loss (Researcher Assessment).

The researcher assessed the effect of all follow-up observation visitations based on FVLS with scores ranging from "1= slight flatness" to "5=severe flatness". At the standard period, patients were assessed with intermediate to severe facial volume loss (FVLS scores 2-5). Immediately after and up to 6 months, patients were assessed with FVLS scores 1 or 2 which correspond to slight to intermediate flatness in the lateral cheeks, forehead and eye rim areas. At 12 months, patients were assessed with a score of 3 which corresponds to an intermediate degree of hollow lateral cheeks/concaved cheekbones. At the same time, the proportion of

patients who received a score of 1 or 2 slightly decreased during each visitation. The results proposed in figure 1 show that the FVLS scores greatly improved from an average value of 2.9 (+/-1.1) before application to an average value of 1.3 (+/-0.5) at 3 months. Next, a significant volume improvement was maintained during every follow-up observation, with an average score spanning from 1.4 at 6 months to 1.5 at 12 months. The passage of time allowed a slight increase in FVLS scores as displayed in figure 1, but the efficiency of Volumefilling® was still significantly long-term. At 18 months, the average FVLS score was 1.8, which corresponds to slight flatness, indicating a significant volume increase in comparison with the standard period. Researchers also assess efficiency based on GAIS, which has scores ranging from "1=very much improved" to "5=rather worsened". Up to the month 6 of application, 94% of patients were assessed as either "very much improved" or "much improved". A few more patients were assessed as "improved" at month 12, while the proportion of patients displaying "very much improved" or "much improved" scores somewhat decreased. Average GAIS scores were calculated with all patients per visitation as subjects. The results revealed that a score of 1.3 (+/-0.5) for 3 months of applications, which corresponds to maximum improvement in terms of aesthetic appearance. Subsequently, throughout the follow-up observation, average value ranged from 1.3 at 3 months to 1.8 at 18 months, as the average GAIS score lined up between "very much improved" (score 1) and "much improved" (score 2). Figure 2 shows the distribution of GAIS scores during follow-up observations. Most patients (n=68%) were "very much improved" at 3 months of treatment. This proportion decreased with ups and downs during the period of follow-up observation. The "much improved" (score 2) patient ratio also tended to continue to decrease from 1 month to 18 months. On the other hand, the proportion of "improved" (score 3) patients increased with the passage of time. Two patients experienced "no change" (score 4) at 12 months, and their data is absent for 18 months. The GAIS results of 24 months could not be analyzed due to data omissions. The results obtained from the FVLS assessment of the researcher corresponded to the GAIS results. Researchers assessed the average aesthetic appearance of patients using GAIS as ranging from "much improved" to "very much improved" at 18 months. All patients (n=100%) were assessed as at least "improved" during all follow-up observation visits excluding 12 months (n=95%).

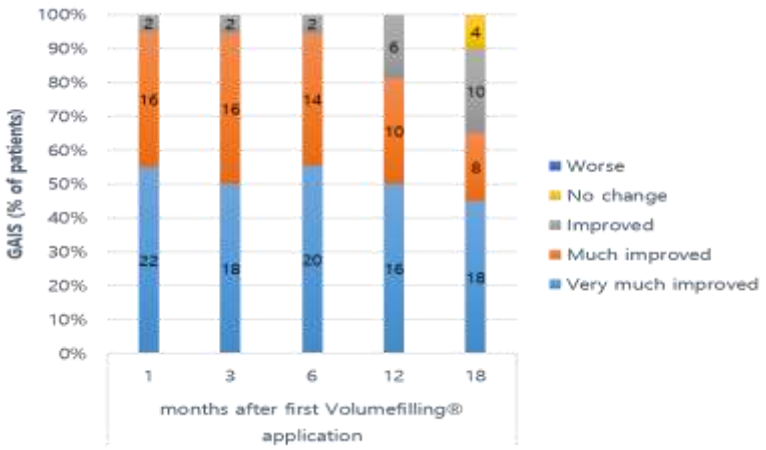

Figure 2. The results of GAIS over follow-up as evaluated by the clinicians.

Effect on the facial volume loss (Patient Assessment). The patients assessed efficiency based on the GAIS which has scores ranging from "1=very much improved" to "5=rather worsened". The study calculated the average GAIS scores of all patients per visit. The results show that the average GAIS scores of all patients range from 2.1 at month 1 to 2.2 at month 18 following follow-up observation visits. At month 12 and month 18, the average GAIS scores were between "very much improved" and "improved". Figure 3 displays the distribution of GAIS scores during follow-up observation visits. The proportion of patients that self-assessed themselves as "very much improved" (score 1) was somewhat constantly maintained as around 20% showed signs of ups and downs during the follow-up observation period. The proportion of "much improved" (score 2) patients decreased with the passage of time, whereas "improved" (score 3) patients increased. A single patient stated "no change" at month 12 and month 18. This patient did not participate in the month 24 visit. To assess patient satisfaction on treatment at month 12 and month 18, patients were asked if they would repeatedly receive this treatment and whether they recommended it to friends and family. Patients answered these two questions in the same way. Satisfied with the results, all patients at month 18 said they would repeatedly receive the treatment and would recommend it to friends and family. The 22 patients participating in the month 24 visit reported identical results, as they stated they would recommend it to friends. Eighteen patients did not participate in the optional month 24 visit. At the standard period, one patient's cheeks were separated in several areas to a visible extent, which involved exposed cheekbones and excessive nasolabial line volume separated by the lacrimal groove and much extended up to the concave area of the frontal cheeks. The researchers used Volumefilling® to improve soft tissue support in order to emulsify the cheeks by hiding concave areas between such areas.

The concave areas were minimally treated to avoid excessive frontal cheek rounding. During 1 month, the researchers observed the restoration of a single cheek curvature which reached from the nasolabial line to the hairline, and from the eye socket to the bite plane of the molars, and this restoration brought about a younger appearance. At month 12, the cheek contour seemed to continue to improve. However, the effect of the Volumefilling® naturally subsided with the passage of time.

Figure 3. The results of GAIS over follow-up as evaluated by patients.

4. DISCUSSION

The functional-anatomical components of the facial structure create various facial expressions as they permanently move.[13, 14] Therefore, when conducting a volume facial improvement to create a younger looking face, it is important to consider not only wrinkle improvement but the three-dimensional aspect as well as the complexity of interaction.[15, 16] Treatment from a three-dimensional aspect is obviously for volume loss, and simply applying Volumefilling® to increase facial volume and improve upon wrinkles is effective against subcutaneous fat layers. At the same time, this differentiates and stimulates fat cells, inducing a volume effect, which enables the maintenance of a natural younger-looking face which goes against aging.[17, 18] Since its release, Volumefilling® has proven its effect for facial volume increase in various patient demographics in Europe, the US, and Asia. Its excellence in terms of safety has been confirmed in previous studies, and its significant improvement effect for the nasolabial fold has been reported previously. Volumefilling® was designed to be absorbed deeply into subcutaneous or soft tissue layers just by applying it twice a day on volume loss areas in order to restore facial volume. In order to reduce product misuse and risks that could lead to unwanted side effects or disappointments, takers must abide by standards like the

determined usage amount and number of dosages. Unlike injectable fillers, the greatest characteristic of this product is that it displays a natural and gradual volume effect over three months and that there are no artificial facial results due to excessive facial deformations. Also, the absence of an invasive and painful process like that of an injection increases patient compliance and results in the strong will to continue to use. Furthermore, in other studies, Volumefilling® had no side effects when used after injecting several types of fillers, and a synergy effect was confirmed in terms of wrinkle improvement and facial volume increase.[19]

This clinical follow-up observation of Volumefilling® was undertaken in the European region. A total of 40 patients applied the product twice every day for three months on the lateral cheeks, bridge of the nose, forehead and eye rims by the two researchers who were conducting daily clinical practices. The researchers assessed the effect of the product based on the two aesthetic scales of FVLS and GAIS, which were used generally for the aesthetic research. Patients assessed their satisfaction in terms of product efficiency and treatment based on GAIS. According to the FVLS assessment of the researchers, all patients displayed improvements in facial volume by 3 months, which is explained by the change in height of the bar from the standard period to 1 month and 3 months, figure 1. When statistically significant post-application values were observed during each follow-up observation visit, the treatment effect lasted by a maximum of 18 to 24 months. The results showed dramatic improvement levels during the month 3 visit. In subsequent visits, the average facial volume loss scores displayed slight increases, and some patients displayed intermediate flatness which began at the month 12 visit. Repetitive treatment by Volumefilling® may be considered when clinically needed. The researcher assessment using FVLS and GAIS scores provided consistent results. All patients were assessed with at least “improved” in terms of GAIS during all follow-up observation visits excluding month 18(n=95%). Despite patients revealing a more critical tendency toward their aesthetic improvement compared to the researchers, the GAIS results reported by the patients corresponded to the assessment of the researchers. Patient satisfaction was positively expressed as intentions to repeat the treatment and recommend it to friends. Overall, the results imply that the volume improvement achieved after three months of Volumefilling® use is maintained in the long-term, which shows the efficiency and durability of the product for facial volume improvement. This clinical follow-up observation, subsequent to the sale of the product on the market, is limited due to omitted particular data like the month 24 visit and the relatively small number of

patients receiving the treatment. Nevertheless, a promising data on the effects and durability of Volumefilling® has been obtained.

5. CONCLUSION

In consideration of the results of the clinical follow-up observation conducted in this research, the application of Volumefilling® twice every day for three months on areas including the cheeks, the bridge of the nose, forehead and eye rims, continuously improved three-dimensional volume up to three months, for patients concerned with facial volume loss due to aging, with both doctors and patients expressing agreement in terms of its great effect. Subsequently, the durability of Volumefilling® was maintained for 18 months, proving its high satisfaction to the extent that all patients participating in the study stated they would like to use it more and recommend it to those around them. Researchers expressed high satisfaction in terms of Volumefilling®'s convenient usage and natural volume effect, which was unlike fillers that produce artificial looking facial shapes.

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CONFLICT OF INTEREST

All authors declare that there are no conflicts of interests.

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