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EVALUATION OF VOLUMEFILLING® PATCH FOR NASOLABIAL FOLD AUGMENTATION

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ABSTARCT

Medical facial rejuvenation has become very popular amongst East-Asian woman. Previous studies using the Wrinkle Severity Rating Scale (WSRS) have assessed satisfaction with facial rejuvenation procedures. To determine the efficacy of the Volumefilling patch® for improving facial rejuvenation. The clinical features of 87 patients admitted to the Osakura Cosmetic & Plastic Surgery Clinic in Japan between 2011 and 2014 were reviewed. 37 of 87 patients used only the Volumefilling patch®. Immediately after application, the Volumefilling® patch produced definite improvement in 5.4% of cases, improvement in 73% of cases and no improvement in 21.6% of cases. 32.4% of patients were extremely satisfied with the results, 40.5% of patients were satisfied and 27% were not satisfied. The WSRS scores were 0.72 at 3 months, 0.59 at 6 months, 0.54 at 9 months and 0.59 at 12 months. 3 months after application, patients who received the Volumefilling patch® showed significant improvement on the Wrinkle Severity Rating Scale (WSRS). 1 year after application, 72.9% of patients were satisfied with their outcomes.

KEYWORDS: anti-aging, facial augmentation, nasolabial fold, MTR-88, Volumefilling patch.

1. INTRODUCTION

Facial aging occurs when fat cells decrease in size, and when their function and differentiation worsens.[1] It also occurs as a result of changes in the epidermis and dermis, atrophy of muscles and changes in the bones during old age.[2] These changes manifest

themselves as symptoms such as wrinkles on the face, thinning and drying of the skin, and reduction in skin volume.[3] Genetic and environmental factors also play a role in facial aging.[4] Many studies have been performed since 100 years in an attempt to rejuvenate the aging face.[5] Autologous fat grafting for soft tissue augmentation has been performed successfully since 1893[6], with many doctors performing the procedure in the subsequent years and free fat grafting was introduced in the 1950s.[7] With the popularization of liposuction in the 1980s, there was a increase in autologous fat grafting using the fat from liposuction[8] and the ban on the use of silicone implants in the 1990s due to safety concerns increased the spotlight on autologous fat grafting.[9] While fillers such as hyaluronic acid became popular, patients who wanted the procedure to be performed at the same time as removal of the fat from their bellies and thighs preferred autologous fat grafting.[10] But there were some negative views as well, citing possible complications such as calcification and fat necrosis.[11] Many studies have been performed in an attempt to prevent these adverse effects, but none of the studies have provided a fundamental solution.[12] Also, there are no definite research findings with respect to non-invasive facial rejuvenation.[13] The current medical team is presenting a report on facial rejuvenation by using the Volumefilling® patch as a medical device.

2. MATERIALS AND METHODS

Material

The Volumefilling® patch (Monteranc Inc., Republic of Korea) is a medical device, comprising hydrocolloid patches containing 100 mg of the active component MTR-88 in a size of 5 cm x 5 cm (Fig 1). MTR-88 consists of natural substances such as *Anemarrhena asphodeloides* and *Myristica fragrans*.

Figure 1. The Volumefilling® patch.

Study design

This retrospective study was approved by the Institutional Ethical Review Board of the Nihon Skin Research Institute. Patients were identified from a computer-based system and their clinical case notes were reviewed. A retrospective investigation was performed in 87 patients who received facial rejuvenation and a long-term follow-up and who underwent this procedure at our hospital and visited our hospital for more than 1 year, during the period from January 2011 to October 2014. The patients visited our hospital because they wished to improve their sunken cheeks and wrinkles. All patients were females, aged between 19 and 47 years, and had no other diseases. Out of the total 242 patients who received autologous fat grafting, those who underwent any other cosmetic surgery during the study period and those who developed severe postoperative complications for more than 1 week were excluded. Finally, a total of 87 subjects who were followed up for 1 year were included in this study. Among them, 50 patients had received only fat autograft with no other measures taken, and 37 patients had used only the Volumefilling® patch without undergoing any other procedure.

As for the donor site, 25 ml 1% lidocaine, 0.5 ml epinephrine, 0.25 ml triamcinolone acetonide 40 mg/ml and 2 ml sodium bicarbonate were injected into normal saline using a 1 mm multi-hole infiltration cannula. The injection was performed gently and slowly. Anesthesia was administered and there was a 40-minute wait time for adipocyte hydrodissection. For fat harvesting, a 10 cc Luer lock syringe was used, which is a blunt cannula and after removing other unnecessary cells, washing was performed 10-15 times and only the adipocyte layer was used in the autograft. Nerve block was performed at the implant site with 2% lidocaine and 1% lidocaine and epinephrine were injected into the area where facial rejuvenation was to be performed. For fat autograft, a 17 G blunt cannula was used, and about 0.1cc fat/cm3 was injected. Follow-ups were performed at 1 week, 1 month, 3 months, 6 months and 12 months after the date of the procedure. In some patients, additional fat grafting was performed at the 6-month mark.

The patients who used Volumefilling® patches attached the patch every day and replaced it twice a day at 12-hour intervals for the first 3 months; and for the following 9 months, they attached 1 sheet of the patch for 12 hours per day.

In all patients, an assessment was performed once before the procedure or before using the Volumefilling® patch. Then, after fat grafting was performed, an assessment was performed at 2 weeks, 1 month, 2 months, 3 months, 6 months, 9 months and 12 months. Patients who used only the Volumefilling® patch were assessed at the following time points after the first

Volumefilling® patch was used: 2 weeks, 1 month, 2 months, 3 months, 6 months, 9 months, and 12 months. The assessments were performed by the patients and a cosmetic surgeon. The patients made their own assessments based on the following categories: unsatisfied, satisfied, and extremely satisfied, while the cosmetic surgeons made their assessments based on the following categories: no improvement, improvement and definite improvement. Adult subjects with mild to severe nasolabial folds made their assessments based on a 5-point scale. Also, the Wrinkle Severity Rating Scale (WSRS) (none, 1; mild, 2; moderate, 3; severe, 4; extreme, 5) was included.

Statistical analysis

The primary efficacy endpoint was the WSRS at 12 months post-baseline. All results were expressed as mean ± S.D and the Wilcoxon signed-rank test was used for the statistical processing of the results. Statistical significance was achieved when the *P* value was less than 0.05. The data were analyzed using SPSS ver. 17.0 (SPSS Inc., Chicago, IL, USA).

3. RESULTS

Cosmetic outcomes

All patients were observed for a period of 12 months following FAMI procedure or use of the Volumefilling® patch. At the 1-year mark, a survey was conducted to determine the degree of improvement, and as judged by cosmetic surgeons, the improvement in 50 patients in terms of sunken cheeks and wrinkles was as follows: 19 patients (38%), definite improvement; 26 patients (52%), improvement; and 5 patients (10%), no improvement (Table 1). The following results were found in the survey of the patients' degree of satisfaction: 17 patients (34%), extremely satisfied; 26 patients (52%), satisfied; and 7 patients (14%), not satisfied (Table 2). On the other hand, in the survey of patients who used only the Volumefilling® patch, the following results were obtained: 2 patients (5.4%), definite improvement; 27 patients (73%), improvement; and 8 patients (21.6%), no improvement (Table 1). In terms of the degree of satisfaction, the following results were obtained: 12 patients (32.4%), extremely satisfied; 15 patients (40.5%), satisfied; and 10 patients (27%), not satisfied (Table 2). During the study period, there were no adverse effects after the use of Volumefilling® patch.

Table 1. The results evaluated by cosmetic surgeons at 1 year after the operation or application.

	Significantly improved	Improved	Not improved	Total
FAMI	19 (38%)	26 (52%)	5 (10%)	50 (100%)
Volumefilling patch®	2 (5.4%)	27 (73%)	8 (21.6%)	37 (100%)

Table 2. The results evaluated by patients at 1 year after the operation or application.

	Very satisfied	Satisfied	Dissatisfied	Total
FAMI	17 (34%)	26 (52%)	7 (14%)	50 (100%)
Volumefilling patch®	12 (32.4%)	15 (40.5%)	10 (27%)	37 (100%)

Efficacy

When the degree of improvement was assessed based on the WSRS at baseline, the patients who received fat autograft showed an average improvement of 1.62 ± 0.28 points according to the scale at the 2-week mark after their procedure. The patients who received only fat graft, the WSRS deteriorated to 1.09 ± 0.37 points at the 3-month mark and as a result, an additional procedure was performed. At the 12-month mark, the final WSRS was 1.54 ± 0.34 points. In patients who used the Volumefilling® patch, the WSRS increased slowly from the baseline and became prominent at 3 months when it was 0.72 ± 0.30 points and thereafter, it was 0.59 ± 0.29 points at 6 months, 0.54 ± 0.31 points at 9 months and 0.59 ± 0.34 points at 12 months (Fig 2). 3 months after application of the Volumefilling® patch, WSRS scores improved significantly and the improvement lasted up to 1 year ($p < 0.01$).

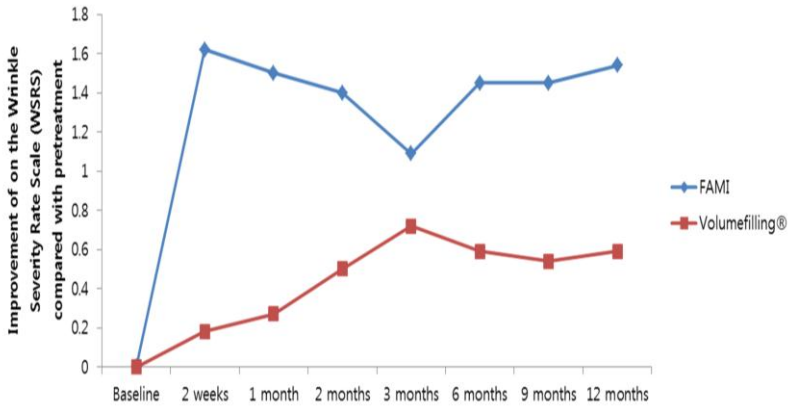

Figure 2. Average level of improvement from Day 0 (Baseline), as measured by the Wrinkle Severity Rating Scale (WSRS).

4. DISCUSSION

Although autologous fat graft has become very popular in the field of cosmetic surgery[14], the fat survival rate is poorer than expected despite the fact that it is widely performed, and there are adverse effects such as fat necrosis and formation of scar tissue.[15] But since there are no other viable alternatives, it is one of the most widely performed procedures in patients who visit the hospital with a chief complaint of facial aging. Due to the increasing number of subjects who want cosmetic improvement and prefer relatively less-invasive procedures, facial rejuvenation techniques have been studied and developed accordingly.[16] Due to the fear of undergoing surgery, financial cost and the possibility of quick recovery, the demand for non-surgical cosmetic procedures is expected to further increase in the future. Furthermore, in order to meet this growing demand, filters which use botulinum toxin and adipose-derived stem cells are being developed.[17] In East Asian countries, anti-aging cosmetic surgeries will be actively attempted going forward.

In East Asian countries, including South Korea and Japan, adipose-derived stem cells, with the research and development in medical devices that use stem cell culture fluids, cosmetic products that can treat at the cellular level are already available in the market and are being used for clinical purposes. Furthermore, good results have been obtained when applied to non-cultured stromal vessels; hence, further inroads in the development of artificial skin and wound dressings will be made in the future.[18] After considering this trend, we used a commercial medical device called the Volumefilling® patch, which consists of A*nemarrhena asphodeloides* and *Myristica fragrans* and the main component is the natural substance MTR-88, for the clinical purpose. It should be noted that it has been confirmed in a previous in vitro study that MTR-88 induces differentiation of preadipocytes into adipocytes and increases the lipid uptake by adipocytes.

During the 1 year of the investigation, according to the WSRS, the efficacy of the Volumefilling® patch manifested at the 3-month mark and during the study period, there was an improvement from 0.54 to 0.59 points according to the scale (Fig 2). At the 3-month mark after the procedure, a comparison between the group that used the Volumefilling® patch and the group that received only fat autograft revealed that the former group had a lower WSRS by 0.37 points and the time for an additional procedure was increased by an average of 3 months. Since the Volumefilling® patch has lower efficacy compared to the fat autograft, we suggest that the Volumefilling® patch containing MTR-88 is less effective for facial

rejuvenation. Due to the non-invasiveness and simplicity of the procedure, patients expressed an approximately equivalent level of satisfaction. But the scientific basis for MTR-88, the main component of the Volumefilling® patch, has not yet been sufficiently verified. Accordingly, medical device such as the Volumefilling® patch would need additional verifications using various methods going forward.

5. CONCLUSION

By targeting 87 patients and as a part of a retrospective study on facial rejuvenation, we assessed the levels of satisfaction as perceived by the patients and cosmetic surgeons for a period of 1 year and we also used the WSRS for assessment. On assessing the satisfaction level in the patients who had used the medical device, the Volumefilling® patch, we found that this group showed lower satisfaction than the FAMI group on average. But, there were improvements compared to the pre-operative conditions based on both patient and cosmetic surgeon assessments and when we compared the improvement in the WSRS, the Volumefilling® patch showed lower efficacy than FAMI but when we compared it to the baseline, there was a statistically significant evidence of efficacy for wrinkle improvement.

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Conflict of interest

The authors declare that there are no conflicts of interest regarding the funding and publication of this paper.

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