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ORIGINAL ARTICLE

A study of combined microfocused ultrasound and hyaluronic acid dermal filler in the treatment of enlarged facial pores in Asians

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Abstract

Background: Enlarged facial pores are a common cosmetic complaint in practice. Microfocused ultrasound with visualization (MFU-V) and low-degree crosslinked hyaluronic acid filler (L-HA) injection has recently become a popular procedure for skin rejuvenation. The effectiveness of the combined MFU-V and L-HA injection in the treatment of enlarged pores has not been evaluated.

Objectives: To compare the efficacy of MFU-V monotherapy (single technique) and MFU-V combined with L-HA injection (combined technique) for the treatment of enlarged facial pores in Asians.

Methods: We conducted a randomized, single-blinded, split-face study on participants with enlarged facial pores. Each side of the face was randomly assigned to treatment with one session of single technique or combined technique. Pore volume was objectively measured by an Antera 3D® system. Subjective assessment was evaluated by one-blinded physician using a pore grading score (0–4). Patients rated the improvement in terms of satisfaction using the visual analog scale (VAS, 0–10).

Results: Forty-six participants completed the study. The mean pore volume of both sides declined with statistical significance at every visit compared to baseline, with the lowest mean at 4 months post-treatment. The combined technique showed a lower mean pore volume than single technique throughout the follow-ups. Physician's subjective evaluation showed no statistically significant difference between the two techniques. The patient satisfaction score showed a similar trend to the mean pore volume, with a statistically significant difference at 4 and 6 months post-treatment.

Conclusions: Both techniques are effectively minimize enlarged facial pores. The combined technique resulted in more patient satisfaction.

KEYWORDS
energy-based device, high-intensity focused ultrasound, rejuvenation, soft tissue augmentation

1 | INTRODUCTION

Pores are openings to the pilosebaceous gland consisting of hair and sebaceous glands frequently found in the nose and cheeks.[1,2] Pore size varies with age, ethnicity, and gender. Chinese people tend to have smaller pore sizes and lower densities than other ethnic groups.[3] Furthermore, many factors influence the size and diversity of pores.[4] However, enlarged facial pores are common cosmetic concerns that relate to multiple factors. An increase in sebum production, loss of skin elasticity, and increase in hair follicle volume are three leading factors of enlarged pores. Other factors include sex, aging, ultraviolet exposure, washing habits, and inappropriate use of cosmetics. Due to great psychological impact, people have been trying to find treatments for enlarged pores. Several treatment options are available, ranging from topical and systemic medications, including vitamin A and its derivatives, and chemical peeling to light/laser therapy, including diode, radiofrequency, and fractional laser therapy.[1]

In recent years, pore-minimizing treatment studies have been increasingly conducted using different treatment modalities. These include microfocused ultrasound with visualization (MFU-V) and hyaluronic acid filler injection. The principle of MFU-V is ultrasonic waves delivered to deeper skin layers causing thermal coagulation effects resulting in neocollagenesis and neoelastogenesis.[5] In 2014, Lee et al. reported that 86% and 91% of 21 Asians had an improvement in pore size according to physicians' evaluation after a single session of MFU-V treatment using 1.5-mm and 3-mm transducers, respectively. Moreover, it was able to increase skin elasticity and reduce sebum production.[6] In terms of hyaluronic acid filler injection, intradermal injection of low crosslinked hyaluronic acid filler (L-HA) has been reported to improve skin quality.[7,8] According to a study by Qian et al[9] intradermal injection of L-HA could significantly minimize pore size by 40.03 ± 18.41% after 6 months of injection. Despite various studies conducting treatment options to minimize pores, there is no study demonstrating the efficacy of combined MFU-V and L-HA injection in the treatment of enlarged facial pores. In this study, we aimed to compare the efficacy of MFU-V and MFU-V combined with hyaluronic acid filler injection in the treatment of enlarged facial pores in an Asian population.

2 | MATERIALS AND METHODS

2.1 | Study design

This prospective, split-face randomized controlled study was conducted at a university-based hospital (Ramathibodi Hospital, Mahidol University) from June 2020 to December 2020. This study was in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Human Rights Related to Research Involving Human Subjects, Faculty of Medicine Ramathibodi Hospital, Mahidol University (Protocol number MURA2019/909) and Thai Clinical Trials Registry identification number TCTR20210409002. Written informed consent was obtained from all patients before study initiation.

2.2 | Study subjects

A total of 46 participants aged 18 years or more who had enlarged skin pores evenly on both cheeks were enrolled. The exclusion criteria were participants with the following: (i) severe medical conditions, (ii) other skin diseases on the face, (iii) immunocompromised status, (iv) history of skin cancer or keloids, (v) history of adverse reactions to anesthetics or injectable fillers, (vi) history of laser therapy or other facial procedures on the cheek within 3 months prior to the study, (vii) history of treatment with systemic vitamin A and its derivatives within 3 months prior to the study, (viii) history of filler injection within 1 year prior to the study, (ix) metal implants at the area of study, (x) pregnancy or lactation, and/or (xi) dental root canal disease.

2.3 | Treatment

Each side of the cheek was randomly allocated to be treated with either only MFU-V using the DS 10 MHz-1.5 mm transducer (50 lines, 25 mm, 0.2 joules/TCP; Ultherapy®, Merz Aesthetics) or MFU-V using the same parameter followed by 1 ml intradermal injection of L-HA filler (Belotero SOFT®, Merz Aesthetics). The total treatment was 100 lines for both cheeks. To minimize pain, local anesthetic cream (EMLA®, Astra Zeneca LP) was applied under occlusion for 30 min to the treated area before starting the procedure. The protocol flow chart is shown in Figure 1.

2.4 | Outcome evaluation

Standard photographs were taken by VISIA® (Canfield Scientific) and Antera 3D® (Miravex Limited) for evaluation at baseline and after 1, 2, 4, and 6 months. For objective assessment, Antera 3D® provided pore volume (mm^3). The small, medium, and large filters measure all pores up to 0.5, 1, and 1.5 mm^2, respectively. Because any circular shape with a size wider than 0.02 mm^2 was defined by an article as a pore, and enlarged pores were those with diameters between 0.3 and 0.6 mm^2, we used the medium filter to represent enlarged pores in Antera 3D® to evaluate pore volume.[4,10] We avoided using a large filter because it might include other depressed skin surfaces. Subjective assessment was evaluated by a one-blinded physician in terms of improvement on a five-point scale of pore grading score by criteria of visual assessment for pores ranging from 0 to 4 (0 being no visible pore on skin and four being conspicuous and large pores).[11]

FIGURE 1 Protocol flow chart

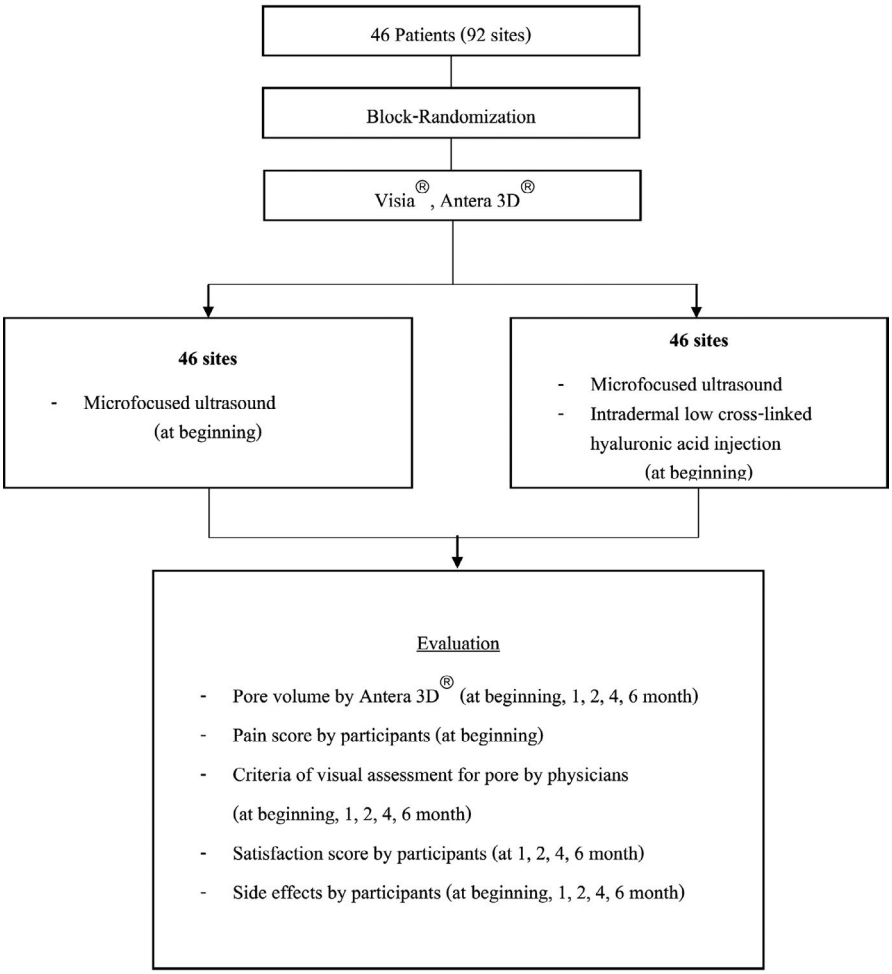

TABLE 1 Demographic data

Characteristics	Data ($n = 46$)
Mean age, years (SD)	36.70 ± 8.61
Sex	
Female, *n* (%)	32 (69.6%)
Male, *n* (%)	14 (30.4%)
Fitzpatrick (FPT) skin type	
III, *n* (%)	45 (97.8%)
IV, *n* (%)	1 (2.2%)
Previous treatment, *n* (%)	
Chemical peels (4 months ago)	1 (2.2%)
Intense pulsed light (12 months ago)	1 (2.2%)
Fractional Er:Glass laser (5 years ago)	1 (2.2%)

Another subjective assessment was performed by participants in terms of satisfaction using a visual analog scale (VAS) on a scale from 0 to 10 (0 means not satisfied at all and 10 means extremely satisfied). Pain score was also recorded using VAS (0–10). All possible adverse reactions were closely monitored throughout the study.

2.5 | Statistical analyses

All statistical tests were performed using STATA/SE version 14.2 (STATA CorpLLC, College Station, TX). Categorical data (ie, sex, underlying disease, Fitzpatrick skin type, visual pore score) are presented as percentages. Continuous data (ie, pore volume, patient satisfaction score) are presented as either the mean with standard deviation or median with interquartile range. Multilevel mixed-effect ordered logistic regression was used to evaluate the difference (improvement score by blinded physician). Moreover, pore volume and patient satisfaction scores were analyzed by a linear mixed-effect model. A p-value <0.05 was considered statistically significant.

3 | RESULTS

3.1 | Subject demographics

A total of 46 healthy participants were enrolled in this study. All subjects completed the study and were statistically analyzed. Fourteen male and 32 female subjects were included. Mean age of patients was 36.70 ± 8.61 years. Forty-five subjects (97.8%) had Fitzpatrick

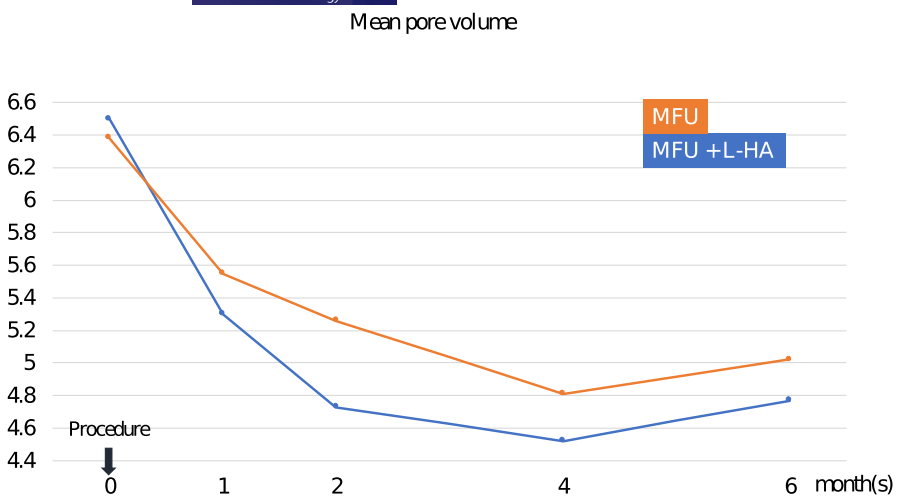

FIGURE 2 Mean pore volume measured by Antera 3D® using a medium filter between MFU-V monotherapy vs. combined MFU-V and L-HA

skin type (FPT) III, and one patient (2.2%) had FPT IV. Three patients (6.6%) had a history of previous pore treatment, and the median duration from the last treatment was 12 (4–60) months. All demographic data are demonstrated in Table 1.

3.2 | Pore volume

Mean pore volume measured by Antera 3D® using a medium filter was evaluated. At baseline, there was no statistically significant difference in mean pore volume between MFU-V monotherapy and combined MFU-V and L-HA injection. Overall, the mean pore volume of both sides declined, with a statistically significant difference at every visit when compared to baseline. The lowest mean pore volumes were 4.81 ± 2.34 mm^3 and 4.52 ± 2.11 mm^3 for the MFU-V monotherapy and combined MFU-V with L-HA-treated sides, respectively. These values were almost observed at the 4th visit. At the last visit, we observed a slight resurgence in the mean pore volume of both sides. Overall, the combined MFU-V with L-HA-treated site had a lower mean pore volume than MFU-V monotherapy at all follow-ups. However, there was no statistically significant difference in the mean pore volume between MFU-V monotherapy and MFU-V with L-HA at any visit. The mean pore volume was demonstrated in Figure 2. The clinical photographs of the patient at baseline and 2 months, 4 months, and 6 months post-treatment are shown in Figures 3 and 4.

3.3 | Physician assessment

For subjective evaluation, the visual pore score was also evaluated by a one-blinded physician. The scores of MFU-V monotherapy and MFU-V combined with L-HA showed a similar pattern of declination as pore volume. At baseline, 18 (39.1%), 24 (52.2%), and 3 sites (6.6%) on the MFU-V monotherapy-treated side were graded to 2, 3, and 4, respectively. In the combined MFU-V and L-HA-treated side, 19 (41.3%), 24 (52.2%), and 3 sites (6.6%) were scored as 2, 3, and 4, respectively. However, at the last visit, the visual grading score tended to decrease compared to that at the first visit. Eight (17.4%) and 7 sites (15.2%) were graded as one for MFU-V monotherapy and MFU-V combined with L-HA, respectively. There was no statistically significant difference between the treatment groups. The percentage of patients categorized in each visual pore grading system is shown in Table 2.

3.4 | Patient satisfaction

Patients subjectively evaluated their satisfaction level by VAS, as shown in Table 3. Slightly superior satisfaction was observed on the combined MFU-V- and L-HA-treated side at 1 month and 2 months post-treatment. There was a statistically significant difference in the mean patient satisfaction score between MFU-V monotherapy and MFU-V combined with L-HA therapy at 4 months and 6 months post-treatment. The maximum mean satisfaction scores were 6.84 ± 2.86 and 7.41 ± 2.84 at 6 months post-treatment for MFU-V monotherapy and combined MFU-V with L-HA therapy, respectively.

3.5 | Adverse events

The pain score of both treatment sites was collected immediately after the procedure. There was no statistically significant difference in pain score between the two techniques. The median pain score was 1.59 (0–6) for MFU-V monotherapy and 1.70 (0–5) for MFU-V combined with L-HA ($p = 0.536$). Two patients (4.4%) had erythematous welt on the combined MFU-V with L-HA-treated side. It spontaneously resolved in 3 hours without any treatment. Two patients developed bruising on the combined MFU-V and L-HA-treated side, which subsided spontaneously in 7 days.

4 | DISCUSSION

Enlarged pores are one of the greatest cosmetic concerns that could deteriorate quality of life. High sebum production,

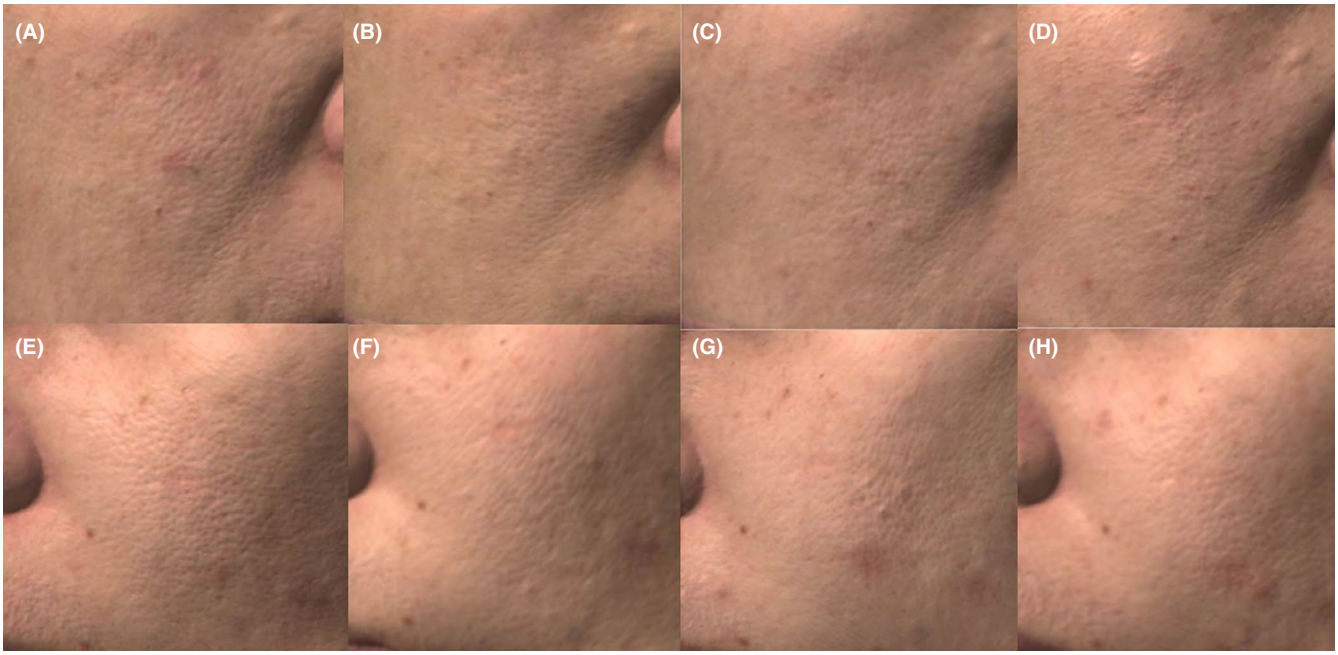

FIGURE 3 Photographs of patients at baseline and 2 months, 4 months, and 6 months post-treatment. The patient was treated with MFU-V monotherapy on the right side (A-D) and MFU-V combined with L-HA on the left side (E-H)

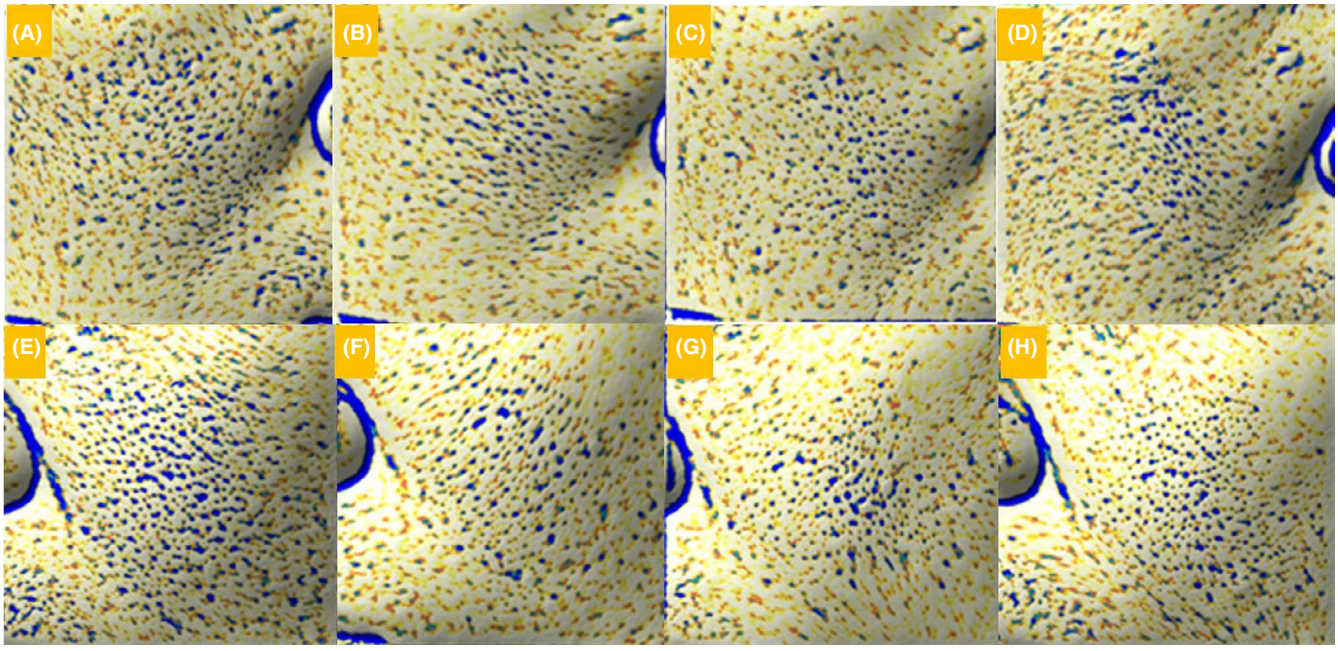

FIGURE 4 Photographs of patient by Antera 3D® using medium filter at baseline, 2 months, 4 months, and 6 months post-treatment. The patient was treated with MFU-V monotherapy on the right side (A-D) and MFU-V combined with L-HA on the left side (E-H)

decreased elasticity of skin around pores, and increased hair follicle volume are three main causes of enlarged pores.[1] To the best of our knowledge, this is the first study comparing MFU-V monotherapy and MFU-V combined with L-HA for the treatment of enlarged facial pores with both objective and subjective evaluations. We found that the mean pore volume of both sides significantly improved from baseline throughout follow-ups after receiving a single treatment session of both techniques. However, the pore volume reached the lowest level at 4 months after the procedures and slightly rebounded at 6 months after the procedures. These patterns were observed in both treatment techniques. According to a previous study by Lu et al[12] the maximum improvement of

pores was observed at 90 days after MFU-V treatment. The mean pore score returned to baseline at 180 days post-treatment. This could be explained by the difference in treatment settings between each study. In our study, a 1.5 mm transducer was used for a total of 100 lines on both cheeks compared to a combined 3 mm and 4.5 mm transducer for a total of 800 lines on entire face and neck in a study by Lu et al. Regarding the pathology of enlarged pores, the architecture around facial pores consists of elongated epidermis hanging down into the dermis such as stalactites and dermal papillae rising into the epidermis like stalagmites. The undulating dermo-epidermal junction, the so-called stalagmite-like structure, is a characteristic structure observed in enlarged pores and correlated with large hollowing skin.[10,13,14] In addition, pore size has been demonstrated to be associated with age and correlated with skin elasticity using a Cutometer.[4,10] The primary mechanism of MFU-V is to create thermal coagulation points at a desired depth. The heat that occurs at each thermal coagulation point causes collagen fiber denaturation, contraction, and stimulation of de novo collagen.[5,15] Therefore, it is reasonable to use MFU-V with a 1.5 mm transducer to correct the pathology of enlarged pores.

Although there was no statistically significant difference, the pore volume with the combined MFU-V and L-HA technique seemed to be lower than that with MFU-V monotherapy throughout the follow-up period. According to a study by Zheng et al[16] aged-associated reduction of extracellular matrix protein (microfibril-associated glycoprotein-1), which is essential for elastic fiber assembly, might contribute to loss of dermal integrity and perifollicular structural support. This could lead to skin fragility and enlarged pores. The proposed mechanism of L-HA for pore reduction was thought to be stabilization of the extracellular matrix that supports fibroblasts, increasing dermal hydration, improving skin elasticity, and stimulating collagen synthesis.[7,8,17,18] For this reason, the addition of intradermal L-HA injection with MFU-V therapy might have a beneficial effect on pore improvement. This finding was confirmed by a study by Qian et al.[9] They demonstrated that there was a 40% significant reduction in pore size after 6 months of intradermal L-HA injection. However, the less promising result in our study could be explained by the different intradermal L-HA injection protocols. In their study,[9] 2.5 ml of L-HA was injected for 2–5 sessions with an interval of 4–6 weeks, compared with a single session of 1 ml of L-HA in our study.

For the subjective evaluation, a five-point scale graded visual assessment was evaluated by one-blinded physician. In our study, some subjects were graded into lower scores at the last visit. The results demonstrated that the subjective evaluation by visual grading score and the objective evaluation by the Antera 3D® had a similar trend. These findings correspond with research conducted by Kim et al and Dissanayake et al[19,20] which demonstrated a high correlation between visual pore score and pore volume measured from 3-D images. Again, declining patterns of pore volume and visual pore score were similar. In our study, no significant difference in visual pore score in each treatment was detected from baseline, unlike the mean pore volume. We elucidated that visual pore scores subjectively evaluated by visual assessment were less sensitive at detecting any changes in pores than pore volume measured by 3-D images. Moreover, the 5-point

TABLE 2 Subjective evaluation by blinded physician graded by criteria of visual pore assessment[11]

Score grading	MFU-V and L-HA, *n* (%)	MFU-V, *n* (%)	*p*-value
Baseline			
0	0	0	0.919
1	0	1 (2.2%)	
2	19 (41.3%)	18 (39.1%)	
3	24 (52.2%)	24 (52.2%)	
4	3 (6.5%)	3 (6.5%)	
6 months post-treatment			
0	0	0	0.757
1	7 (15.2%)	8 (17.4%)	
2	16 (34.8%)	15 (32.6%)	
3	20 (43.5%)	21 (45.7%)	
4	3 (6.5%)	2 (4.4%)	

Abbreviations: L-HA, low-crosslinked hyaluronic acid filler; MFU-V, microfocused ultrasound with visualization.

TABLE 3 Mean patient satisfaction score by VAS

Visit	Month	Mean pore volume (mm^3)		
		MFU-V + L-HA (mean ± SD)	MFU-V (mean ± SD	*p*-value
1 (Baseline)	0	NA	NA	NA
2	1	4.63 ± 3.18	4.43 ± 3.12	0.452
3	2	5.70 ± 2.94	5.53 ± 2.82	0.508
4	4	6.99 ± 2.69	6.42 ± 2.60	0.029[a]
5	6	7.41 ± 2.84	6.84 ± 2.86	0.031[a]

Abbreviations: L-HA, low-crosslinked hyaluronic acid filler; MFU-V, microfocused ultrasound with visualization; mm^3, cubic millimeter; SD, standard deviation.

[a]Statistically significant difference

scale had a large scale from 0 to 4, making it difficult to grade small changes in pores by the naked eye.

In terms of satisfaction, patients assessed satisfaction with the VAS. Patient satisfaction scores slightly increased at every visit compared to baseline and reached the most satisfactory level at the last follow-up with both treatment techniques. Patients were more significantly satisfied with the treatment outcome of combined MFU-V with L-HA than MFU-V monotherapy at 4 and 6 months after the procedures. This could be attributed to the improvement in skin appearance, such as skin radiance and texture, which may affect patient satisfaction.[9,21] Although statistical significance was not observed in the objective and subjective outcomes assessed by the investigator, the significance found in the patient-reported satisfaction outcome is considered important because patient satisfaction contributes substantially to success in aesthetic practice.

Our study had some limitations. First, our sample size was small, which may not be strong enough to detect a difference in pore volume and visual pore assessment. Second, the L-HA injection protocol should be adjusted (ie, increased dosage and frequency of injection). In addition, we did not perform transepidermal water loss measurements. This parameter would potentially explain other possible mechanisms that are related to pore minimization.

In conclusion, MFU-V using a 1.5 mm transducer and MFU-V combined with L-HA can effectively and safely minimize enlarged facial pores with no downtime in terms of pore volume and pore index. Nonetheless, combining the intradermal L-HA injection immediately after MFU-V therapy showed more patient satisfaction.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

Vasanop Vachiramon and Natthachat Jurairattanaporn conceived and planned the study. Amornrut Namasondhi and Tanaporn Anuntrangsee analyzed the data and drafted the manuscript. Chaninan Kositkuljorn, Amornrut Namasondhi, and Tanaporn Anuntrangsee take responsibility for data collection and data interpretation. Vasanop Vachiramon interpreted the data and revised the manuscript.

ETHICAL APPROVAL

This study was in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Human Rights Related to Research Involving Human Subjects, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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