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Efficacy and Safety of High-Intensity Focused Ultrasound (HIFU) on Reduction of Unwanted Submental Fat in Asian Patients

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Abstract

Background There are several treatment options to improve a double chin, such as contour injections, thread lifting, and double chin liposuction. However, the results of these treatments can be minimal or have a short-lasting effect. Additionally, these treatments may lead to worsened scarring due to repeated skin penetration and can cause prolonged discomfort. The high-intensity focused ultrasound (HIFU) is a non-invasive ultrasound lifting treatment that can improve a double chin without the need for surgical procedures, so the HIFU is considered a very safe way to reduce the submental volume.

Objective This study aimed to identify the clinical and photographic changes observed among patients who received HIFU treatment and to evaluate the efficacy and safety of HIFU for submental fat reduction.

Methods Thirty patients, aged from 25 to 60 years (20 females and 10 males), participated in a 4-week follow-up (n=30). High-intensity focused ultrasound treatment was performed on submental fat using two different focal depth transducers, 4.5 mm and 6.0 mm, with MP (Micro Pulsed) mode. We assessed the treatment effects using Vectra for volume measurement, CR-SMFRS (Clinician Report-Submental Fat Rating Scale) on a 5-point scale (0–4), SSRS (Subject Self-Rating Scale) on a 4–point scale (0–3), as

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well as monitoring weight and photography. Adverse events were evaluated using questionnaires.

Results A total of 30 patients were enrolled in this evaluation at the follow-up visit (4 weeks). The proportion of treatment patients satisfied with appearances and significant submental fat reduction was apparent when comparing the initial CR-SMFRS ratings to the final CR- SMFRS ratings. Initially, CR-SMFRS ratings were categorized as 10 mild, 10 moderate, 8 severe, and 2 extreme. After one session of treatment, the final ratings showed improved submental fat conditions, with 16 mild, 8 moderate, 5 severe, and 1 extreme. This change indicated a significant improvement, with a p-value of <0.000005. The SSRS showed an 82% improvement level, and most patients experienced immediate improvements. No significant side effects or adverse events were reported. Expected common side effects were noted but resolved within 2 weeks.

Conclusion The HIFU treatment using the 4.5 and 6.0 mm focal depth transducers was safe and effective in reducing the submental fat based on the results.

Level of Evidence III This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Non-invasive · High-intensity focused ultrasound (HIFU) · Double chin · Submental fat reduction · Skin tightening

Introduction

A double chin, submental fat occurs when excess fat accumulates between the chin and neck. This excess fat under the chin can be caused by aging, rapid weight gain, and genetics. As a result, the neck may appear thicker, and the chin may sag, leading to a more rounded and less defined appearance. Accumulation of subcutaneous fat in the submental area can lead to the loss of lower facial contour and mandibular definition. This condition gives the appearance of obesity and aging regardless of age and sex, and it has been shown to contribute to negative aesthetic and psychological effects [9]. Liposuction can improve the cosmetic appearance, but it requires anesthesia and an operating room setting and is quite expensive. Fearful of surgery, downtimes, and its complications, patients seek less invasive methods [7]. As a nonsurgical technique, HIFU calls for less recovery time than a surgical facelift. It delivers energy to various layers of the skin, including the upper and lower dermis, the fibrous muscular layer, and even deeper fat layers. By creating thermal coagulation points with ultrasound, HIFU stimulates the regeneration of collagen fibers, allowing for targeted treatments such as reducing a double chin.

Several modalities have been used for non-invasive fat reduction. Due to its safe and non-invasive nature, HIFU treatment for cosmetic purposes, including the reduction of submental fat, has gained widespread popularity around the world. The principle of HIFU is to induce cellular damage and volume reduction of the target area selectively using coagulation by generating instant microthermal lesions at the targeted area. Various penetration depths are targeted by utilizing different size focal depth transducers. The 4.5 and 6.0 mm focal depth transducers contribute to the reduction of submental fat and tightening of tissues [13]. Also, the 6.0 mm focal depth transducer demonstrates the fat reduction in a certain part of the body [2, 12].

Recently, a study also observed the effects of fat reduction after HIFU treatment. In that study, histological changes in pig skin samples were examined, revealing not only the destruction of fat cells following HIFU treatment but also additional findings such as new collagen formation and elastin fiber regeneration [5]. These results are consistent with clinical findings reported by other researchers, demonstrating that HIFU is effective in improving skin elasticity and enhancing facial contours. Therefore, this study evaluated the fat reduction effects and adverse events of HIFU in Asian patients with submental fat.

Methods and Treatment Protocol

A total of 30 Asians patients participated in this study. Patients were evaluated before the treatment using the objective CR-SMFRS (Clinician Reported - Supplemental Submental Fat Reduction Score) scale, with the resulting scores set as the baseline, ranging from absent to extreme (0–4 points). The CR-SMFRS is a standardized tool used by healthcare professionals to assess the severity of submental fat, commonly known as a "double chin." This scale evaluates submental fat based on submental convexity and the amount of localized fat. One month after the treatment, the CR-SMFRS scale was evaluated again to determine changes in the scores and objectively assess the clinical efficacy of HIFU in treating a double chin.

Patients described overall changes and satisfaction levels regarding their submental fat using the SSRS (Subject Self-Rating Scale), ranging from 0 to 3 scores. The SSRS is a patient-reported outcome measure designed to assess an individual's satisfaction with the appearance of their submental region, commonly referred to as the area under the chin. This scale is frequently utilized in clinical studies to evaluate the effectiveness of treatments aimed at reducing submental fat. Key exclusion criteria included a history of keloid scars, pregnancy, open wounds or lesions

in the treatment area, skin infections, hemorrhagic disorders, and patients with a body mass index (BMI) > 35 kg/m^2. Additionally, individuals undergoing weight reduction programs or considering a diet were excluded.

Informed consent was obtained from all patients, and they were informed about the expected outcomes, possible side effects, and adverse effects. The study protocol adhered to the guidelines of the Declaration of Helsinki. All evaluations and photographs, including immediate post-treatment, were conducted through a questionnaire after one month of follow-up.

In this study, a single HIFU device (Ultraformer MPT: Classys, Inc., Seoul, Korea) was used with MP mode. The clinician utilized two different types of focal depth transducers, 4.5 and 6.0 mm, delivering 100 and 120 shots (0.5J/0.7J), respectively, to the submental fat. All patients received a single treatment after applying a topical anesthetic cream for 30–40 min. To avoid the marginal mandibular nerve, a 1.0 cm area along the mandibular nerve was spared from the treatment zone (Fig. 1). Additionally, the 4.5 mm focal depth transducer delivering 30 shots (0.7J) in normal mode was used on the jawline to achieve a synergistic effect and skin tightening (Fig. 2). On average, a total of 250 shots were delivered.

Statistical analyses were conducted using SPSS software version 26 (IBM, Armonk, NY, USA). Paired t-tests were done for comparing data before and after treatment. Results are expressed as mean ± standard deviation, with p values less than 0.05 regarded as statistically significant.

Results

Patient Characteristics

A total of 30 Asian patients were included in this study, and they completed the treatment without any dropouts. Their skin types were either Fitzpatrick skin type III or IV. The mean age of the patients was 42 years, and they were all female, with the mean BMI of 26. The demographic data of the patients is shown in Table 1. The before and after the treatment of the patients are supplied in Supplementary Figs. 1–6.

CR-SMFRS and SSRS

In the CR-SMFRS evaluation, the mean score before treatment was 2.37, and the mean score one month after treatment was 1.37. The difference between pre-treatment and post-treatment scores indicated a significant improvement, with $p<0.000005$. The CR-SMFRS (Clinician Report-Submental Fat Rating Scale) of the patients are shown in Table 2.

One month after the treatment, the SSRS score collected from the treated patients was 72 out of 90, indicating that most patients, 82%, were satisfied with the results. Among the 30 patients treated, 15 patients responded noticeable improvement (score 3), 14 patients responded mild

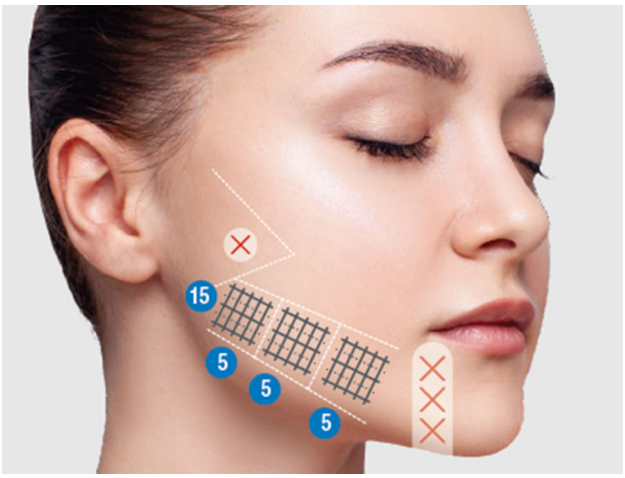

Fig. 2 Treatment diagram l for the cheek fat. The deflated cheek area was marked with an X, and no shots were delivered to that area. Using the blue 4.5mm focal depth transducer with MP mode, 30 shots were delivered to the left and right jaw areas according to the diagram above

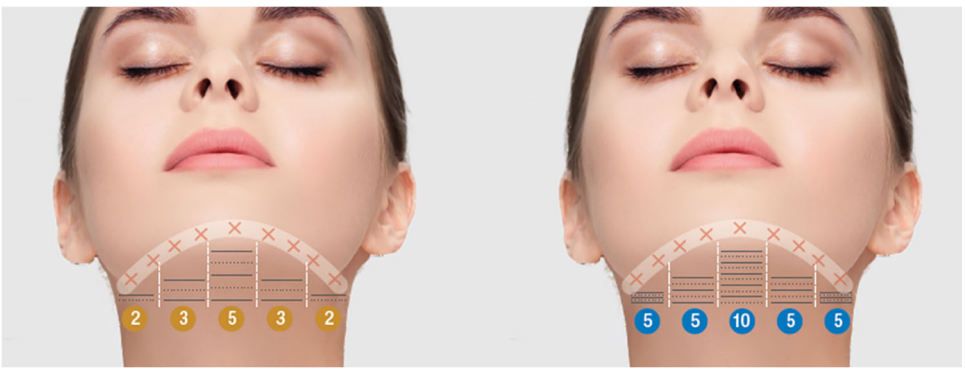

Fig. 1 Treatment diagram for the double chin. The area marked with an X was where shots should not be delivered. Using the yellow 6.0 mm and blue 4.5 mm focal depth transducers with MP mode, 100-120 shots were delivered according to the diagram above

improvement (score 2), and 1 patient responded no change (score 1).

Clinical Efficacy

All clinical photographs, including the three-dimensional images using Vectra, were taken before the HIFU treatment and one month after the treatment. When comparing the 2D clinical photographs before and after the treatment, a noticeable reduction in submental fat was observed. Particularly, as shown in Fig. 3, the Vectra analysis also demonstrated consistent results with the 2D clinical photographs, showing changes in submental fat volume and facial contour.

Safety Profile

During the treatment, patients were observed to experience only minimal pain, and none requested analgesics or sedation. The side effects experienced by patients included mild pain in 46%, erythema in 39%, and edema in 15%, all of which resolved within 3 days. No nerve damage or persistent numbness was reported. In addition, it was confirmed that all patients returned to their daily activities immediately after the treatment without any downtime. Detailed information on the safety profile is shown in Fig. 4.

Table 1 Characteristics of the patients

Characteristics of the patients	
	Subjects, n = 30
Age, mean	42
Female, n	20
Race	Asian
BMI, mean kg/m^2	26

Discussion

As interest in anti-aging continues to grow, the number of both invasive and non-invasive procedures has steadily increased with the emergence of various treatment methods [9]. HIFU (High-Intensity Focused Ultrasound) is a non-invasive procedure that can focus energy on the superficial musculoaponeurotic system (SMAS) layer with minimal damage to the skin surface and without affecting surrounding tissues. As widely known, ultrasound energy induces molecular vibrations at the target site, raising the temperature of the target tissue, which leads to collagen regeneration, tightening of sagging tissues, and coagulative necrosis of fat cells [10, 11].

The results of this study demonstrated that the 4.5 and 6.0 mm focal depth transducers are effective in providing satisfactory tightening and rejuvenation for unwanted submental fat. Over 80% of patients who received only a single session showed improvement and satisfaction in both clinical and patient assessments, as evidenced by the evaluation scales and clinical photographs. Regarding the safety profile, most patients experienced mild pain during the treatment and mild, transient side effects afterward. Additionally, no serious complications such as scarring, persistent numbness and tingling, or nerve damage were reported following HIFU treatment. These mild pain and temporary side effects are advantages unique to HIFU treatment, which are less likely to occur with other invasive rejuvenation procedures [1, 4].

In addition to the tightening effect observed with existing therapies through collagen remodeling in stimulated skin, the 4.5 and 6.0 mm focal depth transducers with MP function based on this protocol were found to have significant skin lifting effects during follow-up. The heat generated from the absorbed ultrasound energy at each depth in the skin layers causes the liquefaction and destruction of fat cell membranes [3]. Specifically, the MP mode used in this study creates approximately 400 thermal coagulation points per shot, which are densely and precisely delivered, enabling more powerful energy transmission. This can further maximize the lipolytic effects in areas, such as double chins, sagging cheeks, and deep

Table 2 The table provides the statistical analysis of the Clinician Report-Submental Fat Rating Scale (CR-SMFRS) scores before and after treatment with HIFU

	Before treatment	After treatment
Means	2.37	1.37
Variance	0.86	0.65
Pearson correlation coefficient (PCC)	0.87	
t-statistics	12.04	
$P(T<=t)$ two-tailed	0.0000000000008329794	

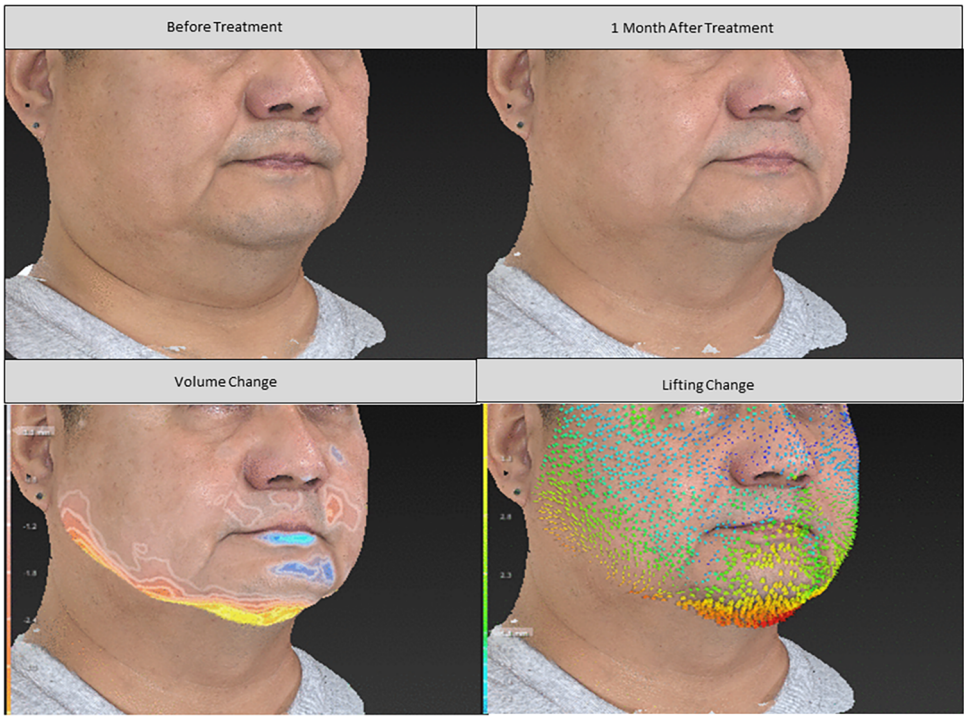

Fig. 3 2D clinical photographs and Vectra 3D analysis. The results from the analysis of 2D clinical photographs and Vectra 3D images show changes in submental fat volume and facial contour after a single HIFU treatment. Areas highlighted in red indicate more significant changes in volume and contour

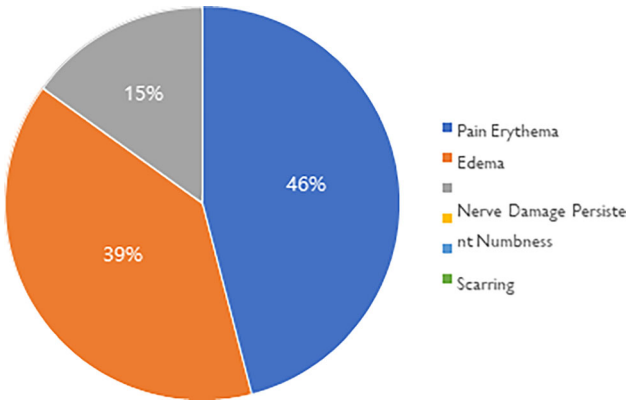

Fig. 4 List of side effects. The result of the side effects experienced by patients during or up to one month after HIFU treatment through the follow-up visit

cheek fat. For these reasons, HIFU is recognized as a precise and safe treatment option for skin lifting, tightening, and fat tissue removal.

These clinical effects can also be observed in a recent study, which analyzed the histological changes in porcine skin samples following high-intensity focused ultrasound (HIFU) treatment. The results demonstrated a significant fat reduction effect. Notably, the group treated with transducers at focal depths of 4.5 and 6.0 mm with the MP mode, exhibited a more pronounced fat reduction effect. Furthermore, the study confirmed additional changes following HIFU treatment, including not only the destruction of adipocytes but also the formation of new collagen and the regeneration of elastin fibers [5].

Another study involving 50 patients examined the effects of HIFU treatment on fat reduction in the neck and submental region. The findings revealed a significant improvement in neck contour and a noticeable reduction in submental fat following HIFU treatment [8]. Moreover, HIFU treatment resulted in a reduction of wrinkles and an increase in skin elasticity in the neck region, which consequently improved the jawline appearance when viewed from the side [8]. These research findings support the efficacy of HIFU treatment in providing lifting and rejuvenation effects across various facial regions. Furthermore, they establish HIFU as an effective therapeutic approach for improving skin elasticity and facial contouring.

Recent aesthetic trends indicate that patients increasingly prefer non-invasive procedures that are effective, comfortable, safe, and require minimal recovery time [6]. In this study, all patients were able to return to their daily activities immediately after treatment without any downtime, further enhancing the safety profile and making HIFU a highly reliable treatment option for patients.

This study, however, has several limitations. First, due to the individual characteristics of patients' skin and varying degrees of aging, conducting a direct comparative clinical trial was nearly impossible. Consequently, we had to rely on within-group comparisons of clinical effects before and after treatment. Second, we did not compare the efficacy of the 4.5 and 6.0 mm focal depth transducers used in this study, and the sample size was small, analyzing only

the skin types of Asian patients. Therefore, additional research with a larger and more diverse patient population is needed to understand the clinical outcomes across different ethnic groups. Third, this study included only a 30 day follow-up period, which limited our ability to observe any long-term side effects.

Conclusion

We conducted this study to evaluate the clinical efficacy and safety of HIFU treatment for unwanted double chin using transducers with penetration depths of 4.5 and 6.0 mm. The results demonstrated that even after a single treatment session, there was an improvement in the double chin as measured by the objective CR-SMFRS scale, and patients also reported high levels of subjective satisfaction with the improvement. Side effects were observed to be temporary and mild, with all side effects resolving within three days. By combining various penetration depths and treatment sessions according to the patient's skin characteristics and degree of aging, it is likely that more effective results can be achieved, maximizing the overall aesthetic effect on the patient's face.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00266-025-04890-0.

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Author Contributions All authors have reviewed and approved the article for submission. Conceptualization, Eunjae Kim, Kyuho Yi, Boncheol Goo, Carlos Bautzer, Lucas Basmage, Jovian Wan. Writing—Original Draft Preparation, Boncheol Goo, Eunjae Kim, Patricia Leite, Isaac Wong Kai Jie Writing—Review & Editing, Boncheol Goo, Eunjae Kim, Kyuho Yi, Dongwoo Shin, Kyu-Ho Yi. Visualization, Boncheol Goo, Eunjae Kim, Kyu-Ho Yi, Jovian Wan, Song Eun Yoon. Supervision, Kyu-Ho Yi

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Declarations

Conflict of interest I acknowledge that I have considered the conflict of interest statement included in the "Author Guidelines." I hereby certify that, to the best of my knowledge, that no aspect of my current personal or professional situation might reasonably be expected to significantly affect my views on the subject I am presenting.

Ethical approval This study was conducted in full compliance with the ethical principles outlined in the Declaration of Helsinki.Informed consentInformed consent was obtained from all participants involved in this study.

References

1. Ascher B, Hoffmann K, Walker P, Lippert S, et al. Efficacy, patient reported outcomes and safety profile of ATX-101 (deoxycholic acid), an injectable drug for the reduction of unwanted submental fat: results from a phase III, randomized, placebo-controlled study. J Eur Acad Dermatol Venereol. 2014;28(12):1707–15.
2. Choi SY, No YA, Kim SY, Kim BJ, Kim MN. Tightening effects of high-intensity focused ultrasound on body skin and subdermal tissue: a pilot study. J Eur Acad Dermatol Venereol. 2016;30(9):1599–602.
3. Gadsden E, Aguilar MT, Smoller BR, Jewell ML. Evaluation of a novel high-intensity focused ultrasound device for ablating subcutaneous adipose tissue for noninvasive body contouring: safety studies in human volunteers. Aesthet Surg J. 2011;31:401–10.
4. Humphrey S, Sykes J, Kantor J, Bertucci V, et al. ATX-101 for reduction of submental fat: a phase III randomized controlled trial. J Am Acad Dermatol. 2016;75:788–97.
5. Hwang Y, Wan J, Yi K. Do different high-intensity-focused ultrasound frequencies have different effects? A histological analysis correlated with patients' subjective assessments. J Cosmet Dermatol. 2025. https://doi.org/10.1111/jocd.70069.
6. Jewell ML, Desilets C, Smoller BR. Evaluation of a novel high intensity focused ultrasound device: preclinical studies in a porcine model. Aesthet Surg J. 2011;31:429–34.
7. Kamer FM, Minoli JJ. Postoperative platysmal band deformity: a pitfall of submental liposuction. Archiv Otolaryngol Head Neck Surg. 1993;119(2):193–6.
8. Kim JS. Three-dimensional analysis of lifting effects after high-intensity focused ultrasound (ultraformer-MPT) across seven facial aesthetic units considering sonoanatomy. Plast Reconstruct Surg Global Open. 2024;12(10):e6203.
9. Kwon HH, Yang SH, Choi M, Jung JY, Park GH. Tightening and reduction of unwanted submental fat using triple-layer high-intensity focused ultrasound: clinical and 3-dimensional imaging analysis. Dermatol Surg. 2021;47(12):1595–600.
10. Laubach HJ, Makin IR, Barthe PG, Slayton MH, et al. Intense focused ultrasound: evaluation of a new treatment modality for precise microcoagulation within the skin. Dermatol Surg. 2008;34:727–34.
11. Nelson AA, Wasserman D, Avram MM. Cryolipolysis for reduction of excess adipose tissue. Semin Cutan Med Surg. 2009;28:244–9.
12. Oni G, Hoxworth R, Teotia S, Brown S, Kenkel JM. Evaluation of a micro-focused ultrasound system for improving skin laxity and tightening in the lower face. Aesthetic Surg J. 2014;34(7):1099–110.
13. Park H, Kim E, Kim J, Ro Y, Ko J. High-intensity focused ultrasound for the treatment of wrinkles and skin laxity in seven different facial areas. Ann Dermatol. 2015;27(6):688–93.