Efficacy and safety of high-intensity focused ultrasound (HIFU) on reduction of unwanted submental fat

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BACKGROUND A "double chin" medically submental fat has become the enemy in today's beauty standards. This condition gives the appearance of aging and obesity.The high-intensity focused ultrasound (HIFU) is considered a very safe way to reduce the submental volume.

OBJECTIVE This study aimed to evaluate the efficacy of HIFU for fat reduction in the submental area with a safe profile.

METHOD 30 patients, aged 25-60 years (20 females, 10 males) participated in 4-week follow-up(n=30). High-intensity focused ultrasound treatment was performed on submental fat by using two different cartridges with 4.5mm, and 6.0mm with MP mode. We evaluated treatment effects using Vectra (increase in volume measurement), CR-SMFRS, (Clinician Report-Submental fat rating scale) based on point 4 (0~4), SSRS (Subject Self-Rating Scale) based on point 3 (0~3), weight, and photography. The adverse event was done by using questionnaires.

RESULT 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 the submental fat was reduced significantly, CR-SMFRS was 10 mild patients,10 moderate patients, 8 severe patients,2 extreme patients and 16 mild patients,8 moderate patients,5 severe patients, 1 extreme patient after one session of treatment. Significant improvement was noted, $p<0.000005$. SSRS was 82% (Improvement Level) and also immediate improvement is seen for most of the patients. No significant side effects or adverse effects were reported. Anticipated common side effects were recorded which were resolved within 2 weeks.

CONCLUSION The HIFU was safe and effective in reducing the submental fat based on the results.

INTRODUCTION

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 (Kwon et al.,2021) .Liposuction is to improve the cosmetic effect 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 (Kamer & Minoli, 1993). As a nonsurgical technique, HIFU calls for less recovery time than a surgical facelift. Recently, 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 by utilizing different cartridges 4.5mm,6.0mm focal depth contribute to the reduction of submental fat and tightening of tissues (Park et al., 2015). Also 6.0mm cartridge demonstrates the fat reduction in a certain part of the body (Choi et al., 2016, Oni et al., 2014). In this study, we evaluated clinical improvement and adverse effects.

SUBJECTS AND METHODS

30 Koreans participated in this study (Table 1). Subjects were eligible to participate by using a scale CR-SMFRS absent to extreme (point 0 to 4) and describing the overall changes and satisfaction level by using their submental fat SSRS (subject self-rating scale score 0 to 3). Key exclusion included the history of a keloid scar, pregnancy, open wounds, or lesions on the treatment area, skin infections, hemorrhagic disorder, and patients with a body BMI >35kg/m2. also, those undergoing

weight reduction programs or considering a diet were excluded. The consent form was taken from all patients, they were informed of the expected outcomes, possible side effects, and adverse effects. The protocol of this study conformed to the guidelines of the Declaration of Helsinki (1975). Evaluation and photos including the immediate post-treatment were taken by questionnaire after one month of follow-up.

Scale	0	1	2	3	4
Submental convexity	Absent	Mild	Moderate	Severe	Extreme
Description	No localised submental fat evident	Minimal localised submental fat	Prominent, localised submental fat	Marked, localised submental fat	Extreme submental convexity
Photograph of each score					

Adapted from McDiarmird *et al.* (2014). Results from a Pooled Analysis of Two European, Randomized, Placebo-Controlled, Phase 3 Studies of ATX-101 for the Pharmacologic Reduction of Excess Submental Fat. *Aesthetic Plastic Surgery*, 38(5), 849-860.

Figure 1. CR- SMFRS: Submental Fat Rating Scale scale

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

Figure 2. Table 1 Baseline Characteristics of the patients

TREATMENT PROTOCOL

A single device HIFU device (Ultraformer MPT: Classys, Inc., Seoul, Korea) with MP mode was used in this study. The clinician used 2 different types of cartridges 4.5mm,6.0mm with 100 shots, and 120 shots (00.5J/ 0.7J) on submental fat. All the patients received a single treatment by applying topical anesthetic cream for 30~40mins. 1.0cm along the mandibular nerve was spared from the treatment area to avoid the marginal mandibular nerve (Figure 1). Additionally, a 4.5mm 30 shots (0.7J) cartridge with normal mode was used in the jawline for the synergy effect and tightening (Figure 2). Total 250 shots were delivered on average.

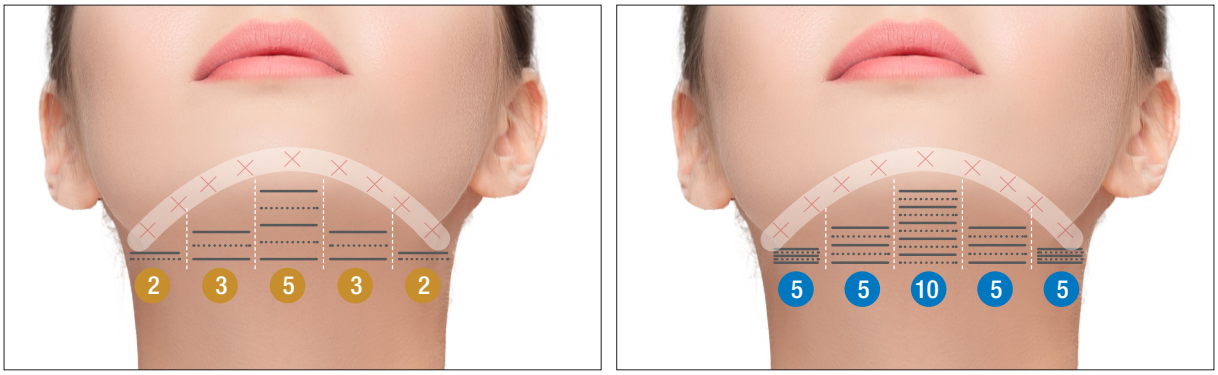


Figure 1. yellow: 6.5mm and blue: 4.5mm cartridges with MP mode were used based on the diagram.

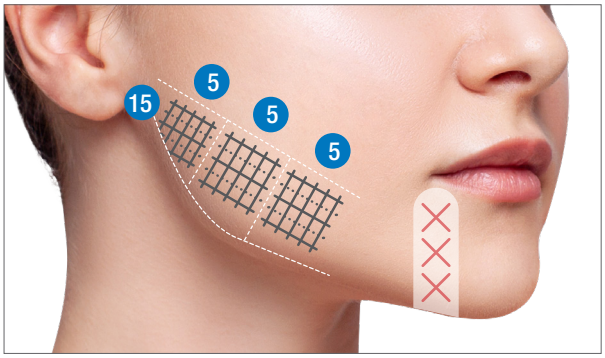


Figure 2. blue: 4.5mm cartridge with normal mode was used based on the diagram.

RESULTS AND CLINICAL EFFICACY

After one month of follow-up, the majority of the patients were satisfied with the result. The objective evaluation SSRS was 82% (74/90) of all treated patients. With 15 patients responded marked improvement (point 3), 14 patients responded mild improvement (point 2) and 1 patient (point 1) responded unchanged. CR-SMFRS is evaluated below Table 2. Signifcant improvement was noted , $p<0.000005$. Furthermore immediate improvement is seen right after the treatment.

	Before Treatment	After Treatment
Means	2.366666667	1.366666667
Variance	0.86091954	0.654022989
Pearson Correlation Coefficient(PCC)	0.871595992	
t-statistics	12.04159458	
P(T<=t) two-tailed	0.0000000000008329794	

Table 2. CR-SMFRS (Clinician Report-Submental Fat Rate Scale)

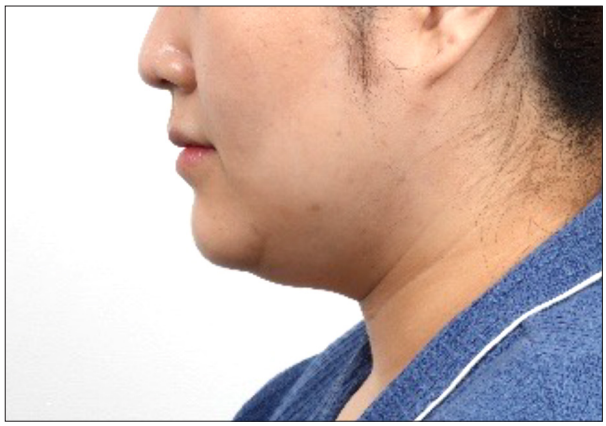



	weight	CR-SMFRS	SSRS
Baseline	55	1	-
Week 4	56kg	0	3


	weight	CR-SMFRS	SSRS
Baseline	50kg	1	-
Week 4	50kg	0	3

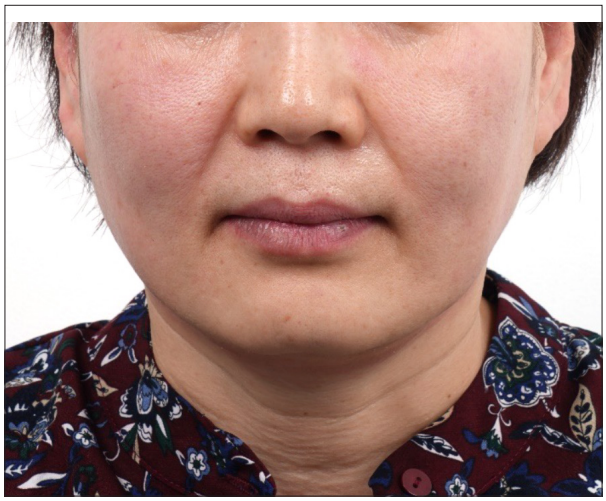

	weight	CR-SMFRS	SSRS
Baseline	90.5kg	3	-
Week 4	90.7kg	2	3


	weight	CR-SMFRS	SSRS
Baseline	68.2kg	3	-
Week 4	68.4kg	2	3




	weight	CR-SMFRS	SSRS
Baseline	79kg	4	-
Week 4	79kg	3	3


Right after the treatment

Right after the treatment


Right after the treatment

VECTRA MEASUREMENT

Three-dimensional image Vectra measurement (Canfield Scientific, Inc) analysis before and after a high-intensity focused ultrasound (HIFU) treatment session. In the side image views, topographical changes in the baseline picture compared with that of the follow-up visit. As it is shown in the diagram it indicates a decrease in submental fat.

1 Month After

SAFETY PROFILE

During the treatments, patients felt only minimal pain. No patient requested additional analgesic medication or sedation during the treatment. 18,15 and 10 patients had anticipated mild pain, erythema, and edema which resolved within 3 days. There were no adverse effects such as persistent numbness, nerve damage, and scarring after the treatment. Detailed information on the safety profile is shown in Diagram 1. All the patients were able to return to their daily activity right after the treatment.

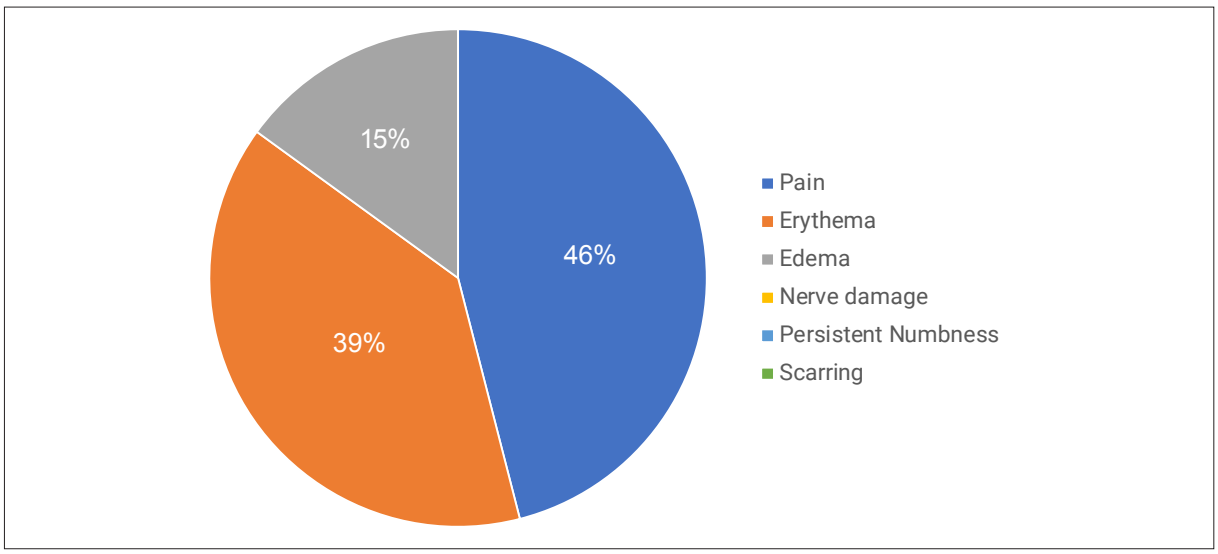


Diagram 1. Based on the questionnaires “what adverse effect have you experienced?”

CONCLUSION

The number of non-invasive with less time procedures is constantly growing in cosmetic dermatology (Kwon et al.,2021). HIFU energy destroys target adipocytes without affecting the surrounding tissues. Due to the large convergence of the ultrasounds at high frequencies, tissue destruction is limited to a small focal point. Ultrasound energy causes molecular vibrations in the area, it increases the temperature in the target

tissue above and causes the necrosis of fat cells by coagulation (Nelson et al., 2009, Laubach et., al). The results of this study demonstrated satisfactory efficacy of this triple-layer regimen for SMF. More than 80% of the treated patients subjected to only a single session showed improvements and satisfaction from the perspectives of clinician-reported and patient-reported evaluations, which was consistent with the results of the 3D Vectra result.The safety profile demonstrated only slight and transient post-treatment side effects and mild pain for most patients, which is anticipated and commonly known as the advantages of HIFU compared with other treatment approaches (Humphery et al., 2016, Scher et al., 2014). There was no serious complication such as scarring, persistent numbness and tingling sensation, nerve damage by HIFU. In addition to the tightening effects of conventional regimens, the novel 6.0-mm cartridge with MP based on the protocol showed marked improvement based on the evaluation and the follow-up. HIFU provides precise and safe means for the removal of fatty tissues. The heat from the absorbed ultrasound energy triggers liquefaction and disruption of the membrane of adipocytes (Ets & Smoller 2011). The mechanical and thermal effects can occur together, and the mechanical activity enhances local heat deposition. There has been a great deal of research into nonsurgical devices that might replicate its benefits (Gadsden et al., 2011). This parallels the general trend toward more noninvasive procedures. Despite its potential benefits, many patients inherently do not want surgery. They would prefer a noninvasive method for fat reduction and body contouring that is effective, yet comfortable and safe, with minimal downtime (Coleman et al., 2009). HIFU can is a safe, effective, and non-invasive option for fat reduction and facial lifting. Further studies should be considered with more patients conducted at multiple institutions. Additionally, there is a need for further studies using different patients and different methods such as different shots and modes.

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