Efficacy of High Intensity Focused Ultrasound (HIFU) for Lifting and Tightening Lax Facial & Neck Skin

Sharmila Nayak | India

INTRODUCTION

To meet increasing public demand about facial wrinkles and laxity due to aging, various noninvasive skin tightening & lifting treatment options are utilized including chemical peeling, fractional laser, radiofrequency & high intensity focused ultrasound; however, the ideal treatment option has yet to be identified[1,2,3,4]. Recently, High Intensity Focused Ultrasound (HIFU) was used as novel treatment for therapeutic and cosmetic purposes[5,6]. Focused ultrasound is highly convergent and uses different frequencies of acoustic energy than medical ultrasound devices. The high-frequency focused ultrasound beam is allowed to target the subcutaneous tissues such as the superficial musculoaponeurotic system (SMAS) passing harmlessly through the upper layers of skin. This HIFU beam generate instant microthermal lesions where collagen around the focal point will reach over 65°C and be denatured & contract within milliseconds leading to additional de novo collagen synthesis and remodeling[7, 9, 10]. HIFU has been demonstrated to be safe and effective in numerous clinical trials as a noninvasive aesthetic treatment and has been cleared by the United States Food and Drug Administration (FDA) to noninvasively lift tissues in the eyebrow, neck, and submentum, and improve lines and wrinkles of the décollete[10].

In proposed study, efficacy evaluation of the Ultraformer III (HIFU) treatment was done on the basis of clinical improvement, adverse effects and patient satisfaction, these parameters were evaluated using clinical photographs and by a Subject Global Aesthetic Improvement Scale (SGAIS) and Physician Global Aesthetic Improvement Scale (PGAIS) scores at 3 months after treatment, in 20 patients older than 25 years of age.

MATERIALS & METHODS

20 healthy subjects consisting of 15 women & 5 men between 25 to 60 years of age with skin laxity and facial wrinkles were enrolled into the study. Each subject was given informed consent & express their willingness to comply with all study requirement. All patients were of Fitzpatrick skin types IV and V. They were treated with HIFU device (Ultraformer III, Classys, South Korea) to the entire face, except for the nose and eyes, by using the following elliptical transducers, 4.5 mm focal depth (4 MHz), 3 mm focal depth (7 MHz) and 1.5 mm focal depth (7 MHz). The pitch (distance between the two high intensity focused ultrasound) was kept constant at 1.5 mm for all the focal lengths and it delivers a shot in less than 35 milliseconds. Before initiating treatment, prior assessment of subjects' skin tissue quality was done based on parameters such as age & gender, BMI & volume of subcutaneous soft tissue in the region to be treated. On the basis of assessment, a customized protocol was developed for the subjects. Mild thick layer of ultrasound gel was applied before starting the treatment on the skin. Treatment for each area was were given in three passes (horizontally, vertically and diagonal) to form a grid pattern which will give a proper lifting and will minimizes the skipped area. The whole face was treated with three different focal depths depending on areas where shoots were given (4.5 mm, 4 MHz; 3 mm, 7 MHz and 1.5 mm, 7 MHz). On the whole face 60% of area was covered by 4.5 mm transducer, 30% area by 3.0 mm transducer and 10% by 1.5 mm transducer.

Standardized two-dimensional photographs of each subject in frontal and 45° angle views, along with profiles from each side, were obtained using fixed camera and lighting conditions before, and 3 months after the treatment. All the subjects were evaluated based on a blinded qualitative assessment compared 90-days post treatment photos with baseline photos and quantitative improvement in skin tissue lift. The Subject Global Aesthetic Improvement Scale (SGAIS), Physician Global Aesthetic Improvement Scale (PGAIS) & Patient Satisfaction Questionnaires (PSQ) were also completed on 90 days post-treatment. Efficacy evaluation criteria's- the primary evaluation criteria is the overall improvement in skin lifting & tightening using blinded qualitative assessment of before & after treatment photographs. Secondary efficacy evaluation was done using PGAIS & SGAIS scale based on PSQ.

Using subject's 2D photographs taken on each follow-up visit quantitative assessment of brow & lower face tissue lift were done. Baseline & post-treatment photos were matched to ensure proper alignment. For lower face, an improved lift measurement

was defined as a submental lift ≥1.0mm. For the upper face, a lift measurement was considered improved if the eyebrow was raised ≥0.5mm.

RESULTS

Demographic information

This study included 20 Indian patients (15 women and 5 men), aged 25 to 60 years (mean, 42.5 years) and All 20 subjects returned for the 90-day follow-up (100%). The number of shots delivered with the HIFU tightening device was 500±50.

Efficacy evaluation results

Among the 20 evaluated subjects, photos of 5 patients were excluded from blinded photography assessment, efficacy results were positive for 15 patients (75%).

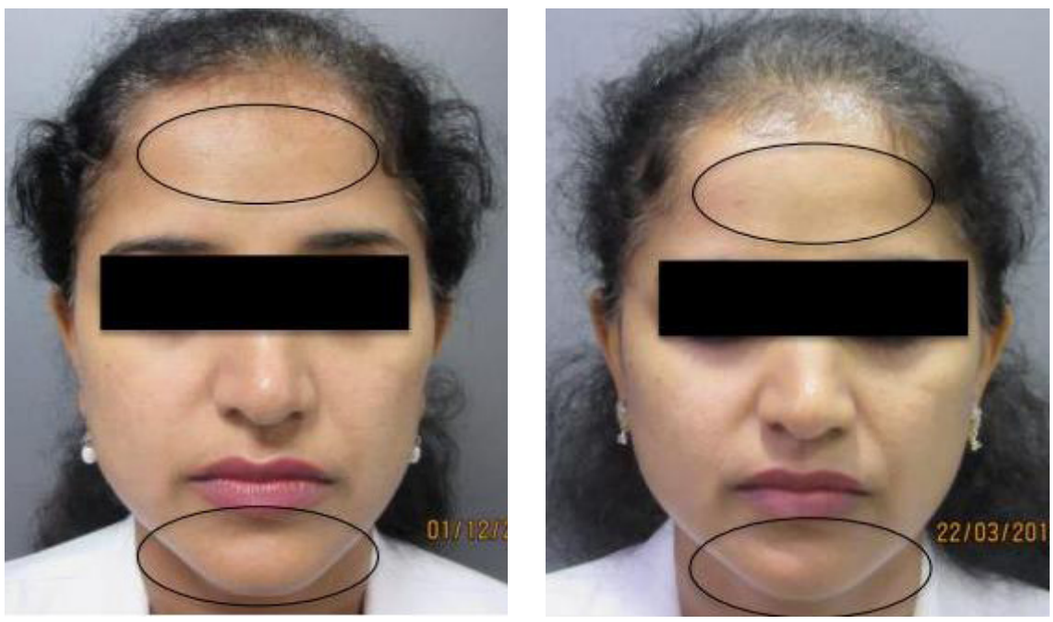

Fig-1 Frontal view of a representative subject at baseline and post-treatment Day 90

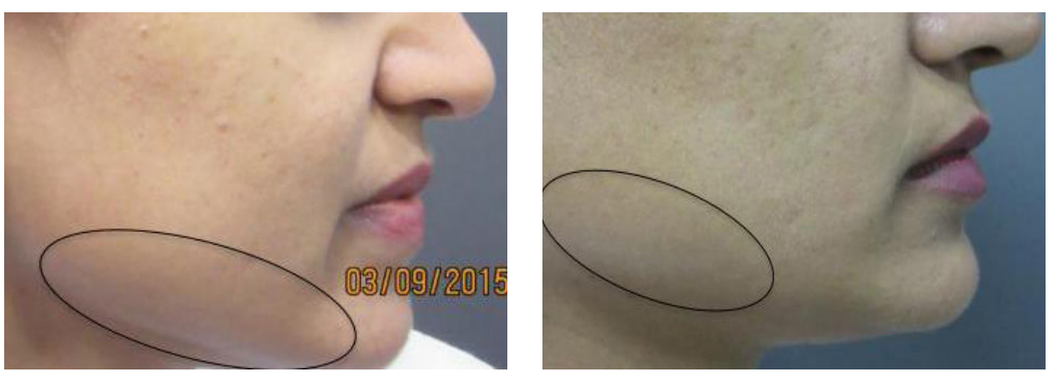

Fig-2 Lateral view of a representative subject at baseline and post-treatment Day 90

Substantial improvement after 90 days post treatment can be seen in frontal & lateral views of the treated subjects in Fig-1 & 2 respectively. Results of the PGAIS reflects that 100 percent of the subjects were having aesthetic improvement after 90 days treatment, while SGAIS results indicated that 85 percent of subjects perceived aesthetic improvement after 90 days. Detailed PGAIS and SGAIS data are provided in Table 1.

Physician Scores	**90 Days (N=20)**
Very much improved	4 (20%)
Much improved	10 (50%)
Improved	6 (30%)
No change	0 (0%)
Worse	0 (0%)
All improved	20 (100%)
Subject Scores	**90 Days (N=20)**
Very Much improved	10 (50%)
Much improved	3 (15%)
Improved	2 (10%)
No change	2 (10%)
Worse	0
All improved	17 (85%)

Table-1 Global aesthetic improvement scale scores

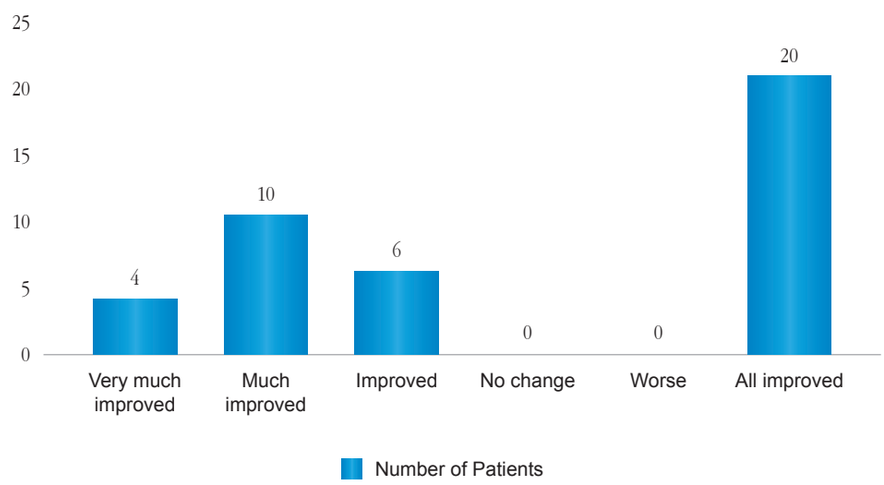

Fig-3 Physician aesthetic improvement scale score (PGAIS)

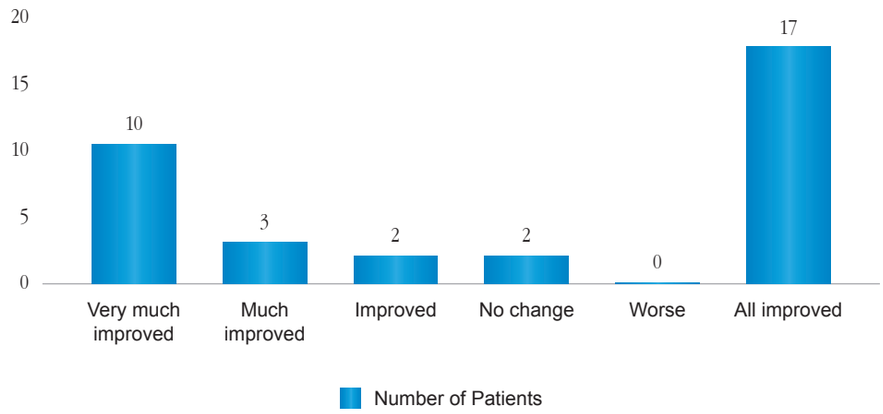

Fig-4 Subject aesthetic improvement scale score (SGAIS)

PATIENTS' SATISFACTION SCORE

Based on analysis of patient satisfaction questionnaires, 17 (85%) patients were found to have less sagging, 10 (50%) with less lines & wrinkles & 8 (40%) with smoother skin texture 8 (40%) (Fig-5).

We also assessed the efficacy and adverse effects 3 months after the treatment. Among 17 patients who replied, 5 patients answered that partial effects were still present in some areas.

Parameter	90 Days (N=20)
Patient Satisfaction	
Very Satisfied	15 (75%)
Satisfied	2 (10%)
Dissatisfied	3 (15%)
Very Dissatisfied	0 (0%)
Very Satisfied +Happy	17 (85%)
Improvement Noticed	
Lines / Wrinkles	10 (50%)
Less Sagging	17 (85%)
More Even Skin Tone	2 (10%)
Smoother Skin Texture	8 (40%)
Other	2 (10%)
No Improvement	3 (15%)
Would Continue & recommend treatment	
Yes	17 (85%)
No	3 (15%)

Table-2 Patient satisfaction Questionnaires

REFERENCES

1. *Lee YB, Eun YS, Lee JH, Cheon MS, Cho BK, Park HJ. Effects of multi-polar radiofrequency and pulsed electromagnetic field treatment in Koreans: case series and survey study. J Dermatolog Treat.2014;25:310–313.*
2. *Shapiro SD, Eros Y, Abrahami Y, Leviav A. Evaluation of safety and efficacy of the TriPollar technology for treatment of wrinkles. Lasers Surg Med. 2012;44:453–458.*
3. *Bloom BS, Emer J, Goldberg DJ. Assessment of safety and efficacy of a bipolar fractionated radiofrequency device in the treatment of photodamaged skin. J Cosmet Laser Ther. 2012;14:208–211.*
4. *Lee HS, Lee DH, Won CH, Chang HW, Kwon HH, Kim KH, et al. Fractional rejuvenation using a novel bipolar radiofrequency system in Asian skin. Dermatol Surg. 2011;37:1611–1619.*
5. *Kleinerman R, Whang TB, Bard RL, Marmur ES. Ultrasound in dermatology: principles and applications. J Am Acad Dermatol. 2012;67:478–487.*
6. *Suh DH, Oh YJ, Lee SJ, Rho JH, Song KY, Kim NI, et al. A intense-focused ultrasound tightening for the treatment of infraorbital laxity. J Cosmet Laser Ther. 2012;14:290–295.*
7. *White WM, Makin IR, Barthe PG, Slayton MH, Gliklich RE. Selective creation of thermal injury zones in the superficial musculoaponeurotic system using intense ultrasound therapy: a new target for noninvasive facial rejuvenation. Arch Facial Plast Surg. 2007;9:22–29.*
8. *Brobst RW, Ferguson M, Perkins SW. Ulthera: initial and six month results. Facial Plast Surg Clin North Am. 2012;20:163–176.*
9. *Laubach hJ, Makin Ir, Barthe Pg, et al. Intense focused ultrasound: evaluation of a new treatment modality for precise microcoagulation within the skin. Dermatol Surg 2008;34:727–*
10. *Fabi Sg, goldman MP, Dayan Sh, et al. A prospective multicenter pilot study of the safety and efficacy of microfocused ultrasound with visualization for improving lines and wrinkles of the décolleté. Dermatol Surg. 2015;41:327–335.*
11. *Alam M, White LE, Martin N, Witherspoon J, Yoo S, West DP. Ultrasound tightening of facial and neck skin: a raterblinded prospective cohort study. J Am Acad Dermatol. 2010;62:262–269.*
12. *Suh DH, Shin MK, Lee SJ, Rho JH, Lee MH, Kim NI, et al. Intense focused ultrasound tightening in Asian skin: clinical and pathologic results. Dermatol Surg. 2011;37:1595–1602.*
13. *Chan NP, Shek SY, Yu CS, Ho SG, Yeung CK, Chan HH. Safety study of transcutaneous focused ultrasound for noninvasive skin tightening in Asians. Lasers Surg Med. 2011;43:366–*