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Lax Facial Skin Treated with High-Intensity Focused Ultrasound Devices: Efficacy and Safety Evaluations

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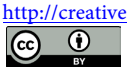

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Abstract

Background: High-intensity focused ultrasound (HIFU) has been introduced to improve skin laxity in recent years. However, very few studies have evaluated the safety and effectiveness of HIFU in Chinese populations. **Methods:** In the study, 30 Chinese participants underwent HIFU (Bolida, Inc., Changsha, China) rejuvenation between February 1, 2022, and September 30, 2022. There were three different focal depths used depending on the area where shots were captured (4.5 mm, 4 MHz; 3 mm, 7 MHz; 1.5 mm, 7 MHz). After 3 months and 6 months of treatment, efficacy and safety were assessed by quantitative analysis. **Results:** Patients were satisfied with the clinical effects of HIFU rejuvenation after one session. In terms of effectiveness, HIFU was most successful in areas around the jawline, cheek, and perioral. In four cases, erythema was observed, in two cases, swollen gums were seen, but all of these effects were transient and mild. **Conclusion:** Bolida system can be safe and effective for facial tightening, additionally, they are most effective for jawline, cheek, and perioral improvements. In clinical practice, the Bolida system can be recommended as a reliable treatment option.

Keywords

High-Intensity Focused Ultrasound, Bolida System, Treatment, Efficacy, Safety

1. Introduction

There are several noninvasive skin tightening and lifting treatment options available to individuals suffering from facial wrinkles and laxity due to aging. These include chemical peels and fractional lasers, etc. [1] [2] Recent innovations have been made in the application of high-intensity focused ultrasound in

medicine and cosmetics and they can also lift lax skin. [3] [4] [5] Ultrasound devices that work on the principle of high-intensity focused ultrasound (HIFU) produce histological changes of coagulation necrosis and acoustic cavitation on a focal area: [6] [7] By coagulating, HIFU produces instant microthermal lesions by generating instant microthermal lesions at the specific target area by causing cellular damage and volume reduction selectively in the target area. High- frequency ultrasound beams are accumulated at the specific tissue site to create instantaneous microthermal lesions without damaging the epidermis or surrounding tissue. [8] [9]

Despite numerous studies that have examined the effects and safety of HIFU on the face, and other body regions, [10] [11] There have been clinical trials of HIFU treatment in Asia, [11] however, at different latitudes, Asian countries have a different skin condition, meanwhile, there have been few comprehensive clinical studies on the effects and safety of HIFU on Chinese patients. In this study, we evaluated the clinical improvements, adverse effects, and satisfaction of Chinese patients using the Bolida system (Bolida, Inc., Changsha, China), By comparing our results with existing clinical studies, we aim to provide new insights into HIFU treatment of skin in the Chinese population.

2. Methods

Based on the suggestion of a statistical committee, we referred to a previous study to determine the number of subjects required for the current study. A total of 30 patients with moderate to severe facial laxity (Fitzpatrick skin types III-V) were recruited for this study. Informed consent was obtained from all patients prior to treatment and photographs. Those excluded included those who had cosmetic procedures involving facial laxity within the past six months, local skin diseases such as psoriasis that might delay wound healing, and scarring around the treatment site. Before the procedure, anesthetic cream (a mixture of 2% lidocaine and 2% prilocaine) was applied with occlusion. The skin was then treated with ultrasound gel. Their entire face was treated with HIFU devices (Bolida, Inc., Changsha, China) with elliptical transducers having focal depths of 4 mm (4 MHz), 3 mm (7 MHz), and 1.5 mm (7 MHz). Different parts of the body have different skin thickness, which affects the choice of HIFU transducers. For all focal lengths, the pitch (distance between the two high-intensity focused ultrasounds) is kept constant at 1.5 mm, and the shot is delivered in under 35 milliseconds. In the clinical assessment, two independent clinicians not involved in the treatment evaluated pre- and post-treatment photographs (3 months and 6 months after one session HIFU treatment). Our qualitative assessment of the before- and after-treatment efficacy of the whole face and different facial areas (supraorbital, zygomatic, infraorbital, perioral, cheeks, preauricular, jawline) relies on the Subject Global Aesthetic Improvement Scale (SGAIS), Physician Global Aesthetic Improvement Scale (PGAIS) and Patient Satisfaction Questionnaires (PSQ). At a follow-up visit, patients were reexamined and asked about

adverse reactions. We asked them about adverse events related to treatment, such as erythema, edema, purpura, hyperpigmentation, hypopigmentation, and scarring. In this study, continuous variables were expressed as mean + standard deviation. It was determined that p values less than 0.05 were statistically significant using SPSS 22.0 (SPSS, IBM Corp, Armonk, NY, USA).

3. Results

A total of 30 subjects were evaluated (22 women and 8 men), ranging in age from 35 to 70 years (mean, 50.1 ± 7.6 years). A thorough assessment can reveal substantial improvement after 3 and 6 months post-treatment. According to PGAIS results, after 3 months and 6 months of treatment, 96.67% of the subjects had improved in aesthetics, whereas SGAIS results showed 93.33% had improved in aesthetics. In Table 1, we can see that clinical performance improved at 3 and 6 months, but the two groups did not differ statistically.

After analyzing patient satisfaction questionnaires, 93.33% of patients expressed satisfaction with the treatment and exhibited less sagging (86.67%), less lines & wrinkles (50%), and smoother skin texture (46.67%) after 3 months of treatment. Similarly, 93.33% of patients who have had 6 months of treatment have felt more satisfied and have less sagging (80%), less lines & wrinkles (46.67%), with smoother skin texture (40%) (Table 2). Clinical improvements were also observed in various face areas after 3 and 6 months compared to baseline. After 3 months of treatment, there was a significant improvement, and the efficacy continued for 6 months. Jawline and Perioral areas experienced the biggest decreases in wrinkles and skin laxity scores. Surveys were conducted at 3- and 6-month intervals and patient satisfaction scores were three or higher. In terms of satisfaction, jawline, perioral, and cheek areas showed the highest scores (Table 3 and Table 4).

Table 1. Clinical efficacy evaluation after HIFU treatment (n = 30).

Physician Scores			Subject Scores		
Scores	After 3 months (percentage)	After 6 months (percentage)	Scores	After 3 months (percentage)	After 6 months (percentage)
Very much improved	16.67%	20%	Very much improved	50%	56.67%
Much improved	50%	53.33%	Much improved	20%	16.66%
Improved	30%	23.34%	Improved	16.66%	20%
No change	3.33%	3.33%	No change	6.67%	6.67%
Worse	0%	0%	Worse	0%	0%
All improved	96.67%	96.67%	All improved	93.33%	93.33%

Table 2. Evaluation of clinical satisfaction after HIFU treatment (n = 30).

Patient Satisfaction			Improvement Noticed		
Parameter	After 3 months (percentage)	After 6 months (percentage)	Parameter	After 3 months (percentage)	After 6 months (percentage)
Very Satisfied	80%	76.67%	Lines/Wrinkles	50%	46.67%
Satisfied	13.33%	16.66%	Less Sagging	86.67%	80%
Dissatisfied	6.67%	6.67%	More Even Skin Tone	16.67%	13.33%
Very Dissatisfied	0%	0%	Smoother Skin Texture	46.67%	40%
			Other	0%	0%
Very Satisfied + Happy	93.33%	93.33%	No Improvement	6.67%	6.67%

Table 3. Physicians' evaluation scores for different treatment areas of the face (n = 30).

Treatment areas	Baseline	After 3 months	After 6 months	*p*-value
Supraorbital	2.45 ± 0.51	1.64 ± 0.35	1.62 ± 0.34	<0.01
Zygomatic	1.79 ± 0.38	1.16 ± 0.26	1.14 ± 0.25	<0.01
lnfraorbital	2.12 ± 0.26	1.49 ± 0.19	1.44 ± 0.17	<0.01
Perioral	1.95 ± 0.64	1.19 ± 0.37	1.18 ± 0.37	<0.01
Cheek	1.72 ± 0.33	1.10 ± 0.21	1.03 ± 0.19	<0.01
Preauricular	1.88 ± 0.30	1.37 ± 0.24	1.29 ± 0.22	<0.01
Jawline	2.64 ± 0.31	1.61 ± 0.19	1.52 ± 0.18	<0.01
Overall	2.08 ± 0.52	1.36 ± 0.33	1.31 ± 0.31	<0.01

$p < 0.01$ vs. Baseline.

Table 4. Scores of patient satisfaction for different areas of the face treated (n = 30).

Treatment areas	After 3 months	After 6 months	*p*-value
Supraorbital	3.90 ± 0.79	3.74 ± 0.76	0.38
Zygomatic	3.81 ± 0.83	3.67 ± 0.80	0.51
lnfraorbital	3.64± 0.79	3.45 ± 0.76	0.34
Perioral	3.89 ± 0.65	3.77 ± 0.63	0.50
Cheek	3.95 ± 0.77	3.91 ± 0.76	0.81
Preauricular	4.07 ± 0.90	4.04 ± 0.89	0.89
Jawline	3.88 ± 0.76	3.73 ± 0.75	0.46
Overall	3.87 ± 0.79	3.76 ± 0.78	0.11

At 3 and 6 months after treatment, we assessed any adverse effects. Following 3 months of treatment, two patients experienced swollen gums and four patients

reported erythema. It took 3 weeks for these complications to resolve, but they did not result in any permanent complications. It is possible that these short-term adverse effects are caused by the thermal effect of treatment. As a result, clinicians may avoid adverse effects by selecting precise treatment parameters based on the characteristics of each patient during treatment. In the course of treatment, there were no serious adverse events noted, such as neuralgia, nerve palsy, severe edema, blistering, or fat atrophy. Furthermore, the 30 patients who responded after six months did not report any long-term adverse effects. As a final question, we asked patients if they would like more treatments and if they would recommend them to other people, and most of them answered positively. As a result of unsatisfactory effectiveness, two patients did not want retreatment, while two others did not know whether or not they would recommend the treatment to other patients because of the cost (**Table 5**).

4. Discussion

Cosmetic dermatology is gradually replacing surgical intervention with minimally invasive or non-invasive procedures. [12] [13] HIFU facial rejuvenation treatment is increasingly popular due to its minimal invasiveness and non- damaging effects on the epidermis. [14] [15] As of yet, no articles have demonstrated the effectiveness of Chinese HIFU skin-tightening devices. A prospective study was conducted to determine whether Chinese HIFU devices (BOLIDA system) are effective and safe for lifting face skin.

As evaluated by blinded reviewers, the Bolida system improved clinical outcomes by 93.3%, which was also similar to other studies (ranging from 65.6% to 95%). [16] [17] Based on quantitative measurements of the changes after treatment, both reviewers and patients evaluated HIFU devices for clinical efficacy. Several different focal depths were used according to the different areas where shots were captured (4.5 mm, 4 MHz; 3 mm, 7 MHz; 1.5 mm, 7 MHz). Different facial tightenings were objectively analyzed using quantitative scores. In HIFU, tissue necrosis is primarily caused by heating from an acoustic source, followed by dermal neocollagenesis and contraction. [6] [18] Therefore, it is practical to measure the changes on a variable point before and after treatment. It was noted that physicians' assessments of HIFU's clinical effects and patients' satisfaction were similar across all areas. Among physicians' evaluations and patient satisfaction scores, the top 3 areas with the highest scores were the jawline, cheek, and perioral areas, in decreasing order for physicians' evaluations, and the jawline, perioral, and cheek areas, in decreasing order for patients' satisfaction. Additionally, there was no statistical difference in patient satisfaction at 3 and 6 months. Our study uses penetrating probes to reach specific layers of skin at different depths. A possible treatment mechanism is as follows: facial laxity is not merely caused by subcutaneous fat atrophy, primarily fatty hypertrophy, especially around the infraorbital space, the lateral temporal cheeks, and the submental area. By using HIFU transducers, collagen, and adipocytes are modified, resulting in tissue matrix shrinkage and collagen remodeling, ultimately lift skin.

Table 5. Treatment willingness to continue with HIFU (n = 30).

Would Continue & recommend treatment	
Yes	86.67%
No	6.67%
Without reply	6.66%

[19] [20]. During the treatment period, two patients reported swollen gums and four patients reported erythema, the complications resolved within three weeks. It is possible that the thermal effect of treatment causes these short-term adverse effects. As a result, clinicians may avoid adverse effects by selecting precise treatment parameters based on the characteristics of each patient during treatment.

This study showed that clinicians' evaluations on Chinese patients after HIFU treatment in the whole facial area and patients' satisfaction with them were similar throughout. In general, patients were more satisfied with these treatments when they could improve their jawline, cheeks, and perioral area. It is a safe treatment, no serious adverse effects have been reported during the treatment. By comparing our results with existing clinical studies, our patient satisfaction rate is higher, and the proportion of adverse effects is lower than that of Park H *et al.*, [21] which may be due to the three transducers of the Bolida system. Based on our results, the Bolida system can recommended as a reliable treatment option and promoted for clinical use.

There are some limitations to this study. To begin with, the sample size (n = 30) of our study was relatively small, the relatively small sample size may result in some indices differing between groups, but the difference will not be significant. Secondly, there was a relatively short follow-up period, so no long-term efficacy evaluation could be done. It is therefore necessary to conduct long-term cohort studies with large sample sizes in the future. Additionally, it was not possible to determine the degree and consistency of efficacy of the HIFU device by comparing histological changes such as the size and depth of the thermal coagulation zone produced by it. As a result, further histological studies need to be conducted in the future.

5. Conclusion

In conclusion, using the Bolida system, we performed facial lifting on 30 Chinees patients. This showed the safety and efficacy of three different depths of transducers (1.5, 3, and 4.5 mm) in HIFU treatment for face rejuvenation. Observed improvements in clinical effectiveness and patient satisfaction after treatment, most noticeable on the jawline, cheeks, and perioral area. According to our research, Bolida system is a safe, effective, and noninvasive way of improving facial wrinkles and lifting, in clinical practice, the Bolida system can be recommended as a reliable treatment option. However, it is necessary to conduct more studies with more patients to gain additional evidence.

Ethical Statement

In all cases, the procedures followed were in accordance with the Helsinki Declaration. [22] Written informed consent was obtained from all patients.

Contribution

In the creation, editing, and approval of this manuscript, all authors contributed equally.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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