Facial Tightening Effects, Following Focused and Radial Acoustic Wave Therapy Assessment, Using a Three-Dimensional Digital Imaging

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Background and Objectives: Acoustic wave therapy is a novel facial tightening technique that involves non-thermal penetration of the skin and subcutaneous tissue, affecting cells and their metabolism, and resulting in an increased release of unwanted fat and activation of blood and lymphatic flow in tissues. The objective of this study was to investigate the effectiveness of acoustic wave therapy.

Study Design/Materials and Methods: A total of 333 patients underwent multiple facial tightening treatment sessions using focused and radial acoustic waves. Each patient received 2,000–3,000 pulses of focused acoustic waves at a power of 0.45–0.88 mJ/mm^2 with a pulse frequency of 3–5 Hz and 4,000 pulses of radial acoustic waves at 4-bar power at a frequency of 21 Hz. These sessions were performed more than three times, and treatments were repeated at 1-month intervals. Digital photographs superimposed three-dimensional volumetric assessments, and three-dimensional skin surface displacement calculations using vectors were used to evaluate the results 12 months after the last treatment. Patients also evaluated the results using a 5-point Likert scale.

Results: Improvements in skin texture, clarity, and laxity were observed in digital photographs. Superimposed three-dimensional color images showed marked volumetric reduction and/or formative modification for even contour toward the lower mid-face. Most vectors showed three-dimensional skin surface displacement at the lateral sides of the temples, cheeks, and chin, in an upward direction. These results were obtained and sustained for up to 12 months without edematous reactions. Almost all patients reported improvement, with 79% reporting "good" or "excellent" improvement. Complications were minor and transitory. Persistent side effects were not observed.

Conclusion: Acoustic wave therapy could be used as a standard facial tightening treatment, with skin rejuvenation effects shown on digital photographs and three-dimensional quantification assessments. This non-invasive acoustic wave approach was found to be a safe, long-lasting, and effective method for facial tightening. Lasers Surg. Med. 00:00–00, 2020. © 2020 Wiley Periodicals LLC

Key words: acoustic wave therapy; facial tightening; focused and radial acoustic waves; extracorporeal shock wave therapy; mechanotransduction

INTRODUCTION

Demand for a noninvasive, long-lasting method to reduce sagging fat tissue and to induce facial tightening has grown dramatically over the past few decades [1–3]. Regardless of age, sex, and skin type, patients seeking rejuvenation and cosmetic procedures, are primarily interested in combatting the clinical signs of aging and laxity [1–3]. More recently, ultrasound technology has been introduced to perform various body contouring and shaping treatments [4–6]. Three distinct modalities, such as high-intensity focused ultrasound (HIFU), radiofrequency, and acoustic waves, have been used in cosmetics and for aesthetics [4–6]. Ultrasound waves are periodic continuous oscillations with a narrow bandwidth [7,8] (Fig. 1A). Acoustic waves are special pressure waves that are generated when circumstances suddenly change, such as when a jet plane accelerates beyond supersonic speeds or when it thunders. Acoustic waves are pulses characterized by their short lengths, high-peak pressures, and rapid increases in pressure [7,8] (Fig. 1B).

Acoustic wave therapy has been known as extracorporeal shock wave therapy (ESWT), and was initially used to treat kidney stones [9–11], calcifying tendonitis [12,13], injuries in the musculoskeletal system and soft tissue [14–16], and to promote nerve regeneration [17]. Positive effects on tissues

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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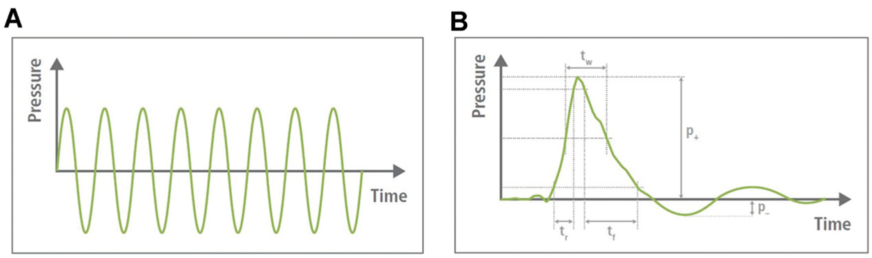


Fig. 1. (**A**) Ultrasound waves are periodic continuous oscillations with a narrow bandwidth; (**B**) acoustic waves are characterized by a single, mostly positive pressure pulse followed by a comparatively small tensile wave component (negative pressure pulse) [5].

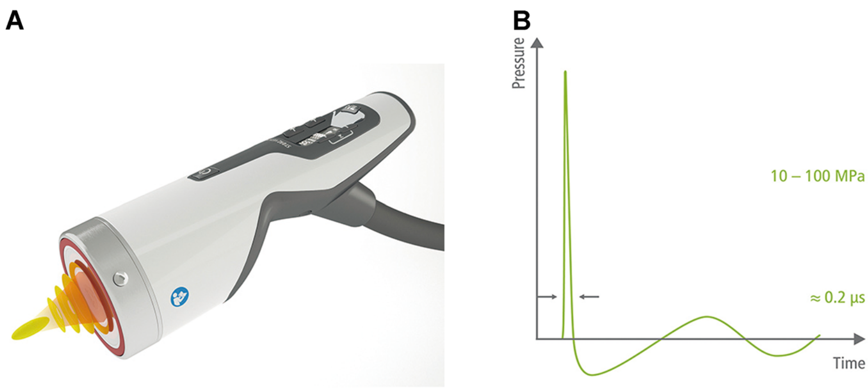


Fig. 2. (**A**) Schema of the focused acoustic wave handpiece used in this study; (**B**) excursion of the focused acoustic wave transmitter used in this study.

have been observed after acoustic waves therapy for cosmetic and aesthetic purposes [18].

Acoustic waves induce a variety of biological reactions through the shear and pressure forces they produce, which are referred to as "mechanotransduction" [7]. Acoustic wave therapy is a noninvasive technique based on the propagation of mechanical waves into the tissues [18]. Acoustic waves stimulate the release of nitric oxide, which leads to vasodilation and an increase in cell metabolism, angiogenesis, and anti-inflammatory effects [19,20]. Acoustic waves also increase cell permeability [21], blood and lymph microcirculation [22,23], self-regenerating processes [24,25], the release of growth factors [19,26–28], cell proliferation of collagen and elastin fibers [24,25,27], stem cells [29,30], and lipolysis [27]. Improvements in the appearance of both cellulite and skin firmness after acoustic wave treatments have been reported [18,31,32]. Most recently, acoustic wave technology has been used for body contouring and cellulite reduction; however, little is known about its effects on facial tightening or its influence on the skin and subcutaneous tissue [3].

The authors believe that acoustic wave therapy is a safe and effective facial tightening and rejuvenation technique for the skin and subcutaneous tissue. Acoustic waves allow for nonthermal penetration of the skin and subcutaneous tissue, causing diverse effects on cells and their

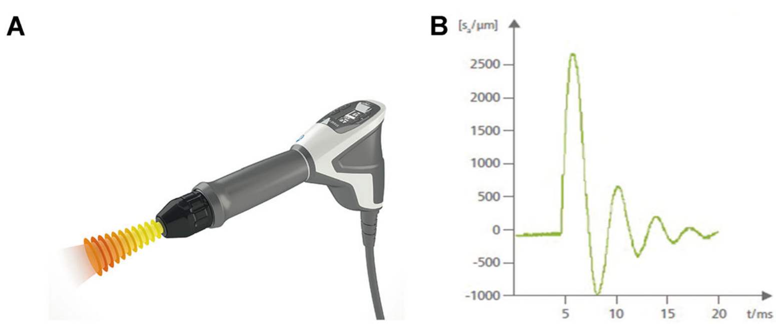


Fig. 3. (**A**) Schema of the radial acoustic wave handpiece used in this study; (**B**) excursion of the radial acoustic wave transmitter in the air at a 4-bar driving pressure.

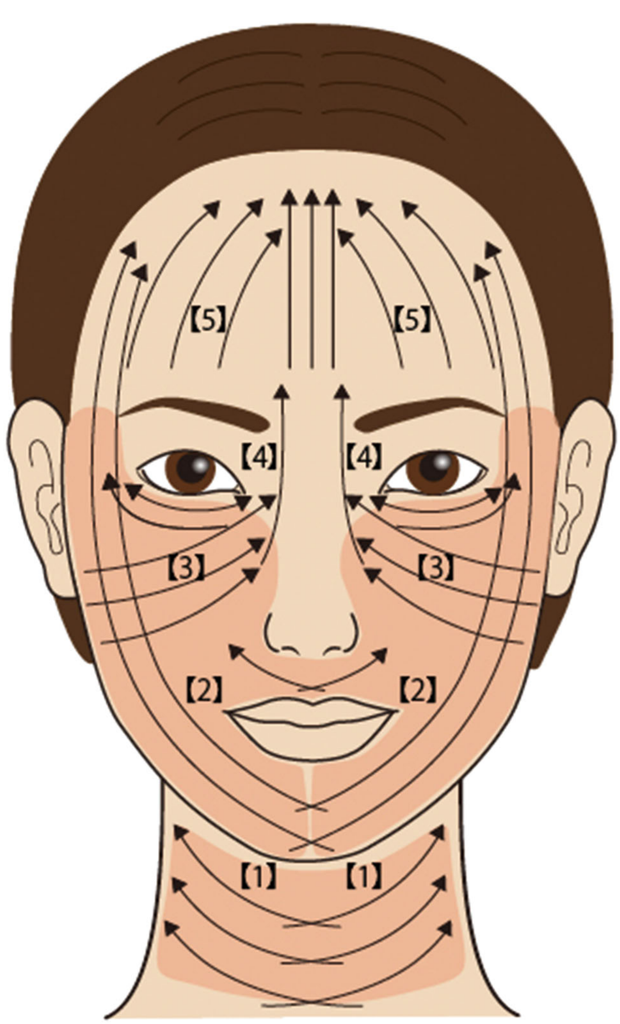


Fig. 4. A brief procedure course was proposed and used in this study for the purpose of facial tightening. The treatment proceeded from bottom to upward. The arrows indicate the direction and treating area by planar-focused handpiece [1–5], and the orange-colored part indicates the treating area of the linear radial handpiece [1–4].

metabolism, resulting in an increased release of growth factors, reducing undesirable fat, and stimulating blood and lymphatic flow.

One limitation of the available studies designed to measure the effects of facial tightening treatments is the absence of an agreed-upon standard for precisely capturing changes. Two-dimensional (2D) imaging has been widely used even though it may not provide an accurate, objective representation. In the author's (Y.T.) prior studies, this limitation was overcome by the addition of a superimposed three-dimensional (3D) color schematic scan to enhance the precision of the data and demonstrate results not visible on 2D imaging [1–3,33,34].

In this study, focused and radial acoustic wave therapy was performed, and definitive objective clinical evidence of facial tightening was assessed using imaging studies. Although the tightening effects induced by various devices have been described in many previous studies [1,2,33–36], 3D volumetric evaluations and the quantification of 3D skin surface displacement using vectors have not been assessed in detail. We hypothesized that acoustic wave therapy would provide long-lasting skin-tightening effects safely and effectively. To test this hypothesis, we used objective 3D assessments to evaluate the effectiveness of acoustic wave therapy in producing formative rejuvenation.

MATERIALS AND METHODS

In this study, 340 healthy international patients (308 females and 32 males) aged 20–85 years were enrolled. All patients had visited our Health & Beauty Clinic, Le Coquelicot, requesting a reduction in undesirable sagging fat tissue and facial tightening, and they were treated with multiple sessions of acoustic wave therapy between October 2016 and October 2019. They were asked to continue having the acoustic wave therapy optionally at 1-month intervals if the treatment seemed effective and beneficial. The treatment session time was approximately 20–30 minutes per person. None of the patients had a significant history of general or skin disease or cosmetic procedures that could have affected the treatment areas within one year of this study. Patients did not adopt any specific diet and were instructed to continue their usual diet. They did not use any particular cosmetics. Since this study involved a retrospective review of previously treated patients, approval by an ethics committee was not required. Patients who exhibited weight gain and loss during the study period were excluded from volumetric measurement analyses because any changes in diet and/or exercise could have affected the results. All patients signed an informed consent form, following an explanation of the study design, and they all agreed to have the results published.

Acoustic Wave Treatment

The acoustic wave device used in this study was the Cellactor SC1 (Storz Medical AG, Tägerwilen, Switzerland), which loads a pair of acoustic waves through each applicator. The planar handpiece generates focused and deep acoustic pulses electromechanically (Fig. 2A), which has a stimulating and breaking effect on cells and their metabolism, resulting in an increased release of fat tissue [4]. The energy level ranges from 0.45 to 0.88 mJ/mm^2 with a pulse frequency of 3–5 Hz (Fig. 2B). The linear handpiece generates shorter and radial acoustic pulses pneumatically, removing the decomposed tissue, and stimulating blood and lymphatic flow (Fig. 3A) [4]. The energy level was set at 4 bar with a frequency of 21 Hz (Fig. 3B). The treatment consisted of 2,000–3,000 pulses of focused acoustic waves followed by 4,000 pulses of the radial waves.

Ultrasound coupling gel and connective oil were applied during each treatment to ensure efficient transmission of energy and smooth movement of the applicators on the skin. No oral analgesics were administered before, during, or after the treatment. Since an acoustic wave does not generate heat, no contact skin cooling was required.

TABLE 1. Procedural Details of 20 Sample Cases

Case	Age (years)	Sex	Volume change (cc)	Number of treatments	Follow-up (months)
1	52	Male	−1.27	3	14
2	33	Female	−20.67	3	14
3	56	Female	−9.97	3	15
4	50	Female	−1.13	3	15
5	57	Female	+6.62	6	14
6	51	Male	+0.98	5	15
7	37	Female	−2.48	3	14
8	43	Female	+2.86	3	17
9	58	Male	−29.94	3	15
10	47	Female	−3.55	3	15
11	50	Female	−0.44	3	13
12	61	Female	−5.21	6	13
13	45	Female	−2.24	3	16
14	54	Female	−7.82	6	17
15	40	Female	−10.10	3	28
16	29	Female	−3.72	3	13
17	52	Female	−3.53	6	24
18	59	Female	−13.33	3	22
19	62	Male	−8.20	4	14
20	66	Male	−18.20	4	32

The acoustic wave emission technique involves a repeated sliding in-motion, beginning with the planar-focused handpiece, followed by the linear radial handpiece. The treatment started from the neck and lower face, aimed at wrinkles on the neck, under the chin, jawline, and perioral areas. The skin of the lower cheeks was pulled up toward the upper cheek and temples in an attempt to lift up the sagging skin. For the area under the eyes, the procedure was performed in the direction of the upper and inner oblique toward the bridge of the nose. To treat the glabella and forehead, where there is a little soft tissue, the procedure was performed only with the planar handpiece by gently lifting the skin to the hairline because the emission of the linear handpiece was accompanied by loud and strong vibration, which would induce pain in bony areas. All treatment sessions were performed by the same physician (K.K.) as it is shown (Fig. 4).

Objective Assessments

Digital photographs and 3D images, obtained using the Canfield Scientific Vectra Handy camera and software (Canfield Scientific Inc., Fairfield, NJ), were used for the objective assessments. This system can capture changes in skin topography and create 2D color representations. The camera image capture sequence was calibrated to less than 3 milliseconds to accurately record facial topography, even if the subject could not maintain perfect stillness. Differences in facial tissue volume pre- and posttreatment were demonstrated via 3D schematics, with relative degrees of facial tightening represented by yellow to red zones (red, −5 mm change). Areas of no change to the face were highlighted as green zones. Areas with white void zones usually indicated that the changes surpassed the red zone (more than −5 mm). This Vectra software was also used to measure local changes in the 3D skin surface position using vectors. Assessments continued for 12 months, and patients were directed to maintain the same neutral facial expression for each image capture session to maintain accuracy. The quantification of volumetric changes was made for 20 sample follow-up cases, including two representative photographed cases. Calculations were performed using Vectra; the whole area of the face was selected and matched through the software's algorithm as pre- and posttreatment of the same face.

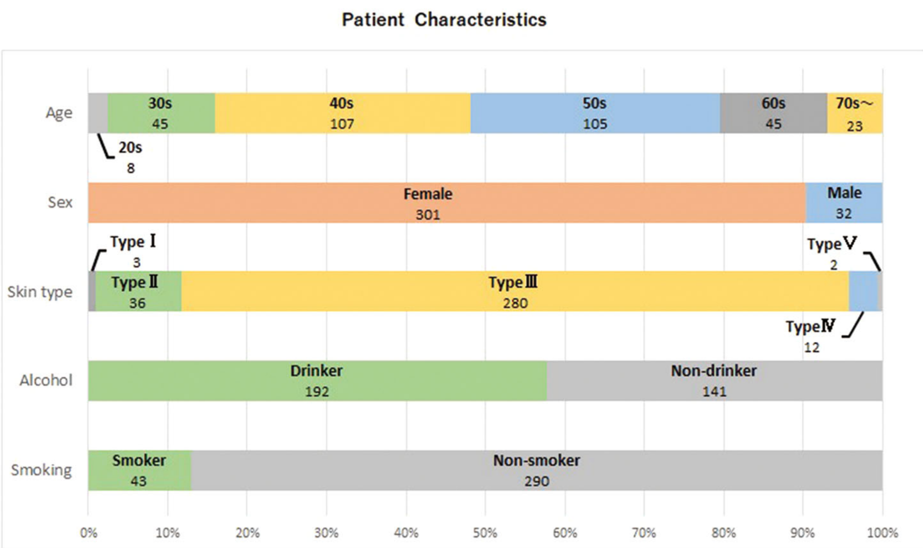


Fig. 5. Patient characteristics regarding age, sex, skin type, drinking, and smoking habits.

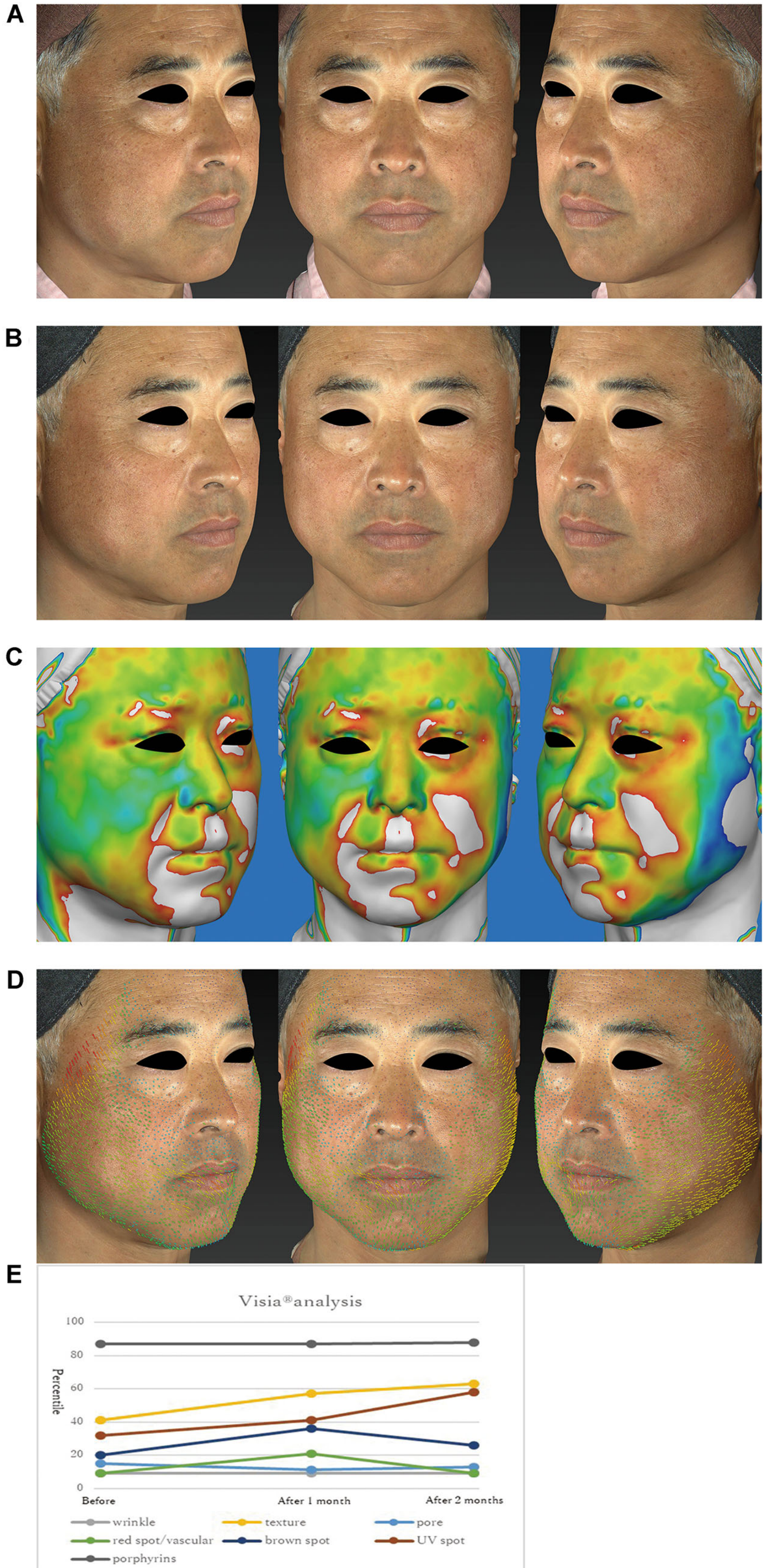


Fig. 6. Continued

Additionally, skin-analyzing digital photographs were taken as the two representative cases using VISIA (Canfield Scientific Inc.). The skin assessments, including seven objective parameter analytics, were executed immediately following image capture with photography modes, including UV, color, and cross-polarized light. Improvements in wrinkles, texture, dilated skin pores, redness, brown spots, UV spots, and porphyrins were evaluated using percentiles, which took into account data variables of sex, age, and ethnicity.

Subjective Assessments

The patients completed a questionnaire 12 months after the last treatment and were asked to rate the results and tolerability of the treatments using a 5-point Likert scale (1 | = | worse; 2 | = | no change; 3 | = | slight improvement; 4 | = | good improvement; 5 | = | excellent improvement) (Fig. 7).

RESULTS

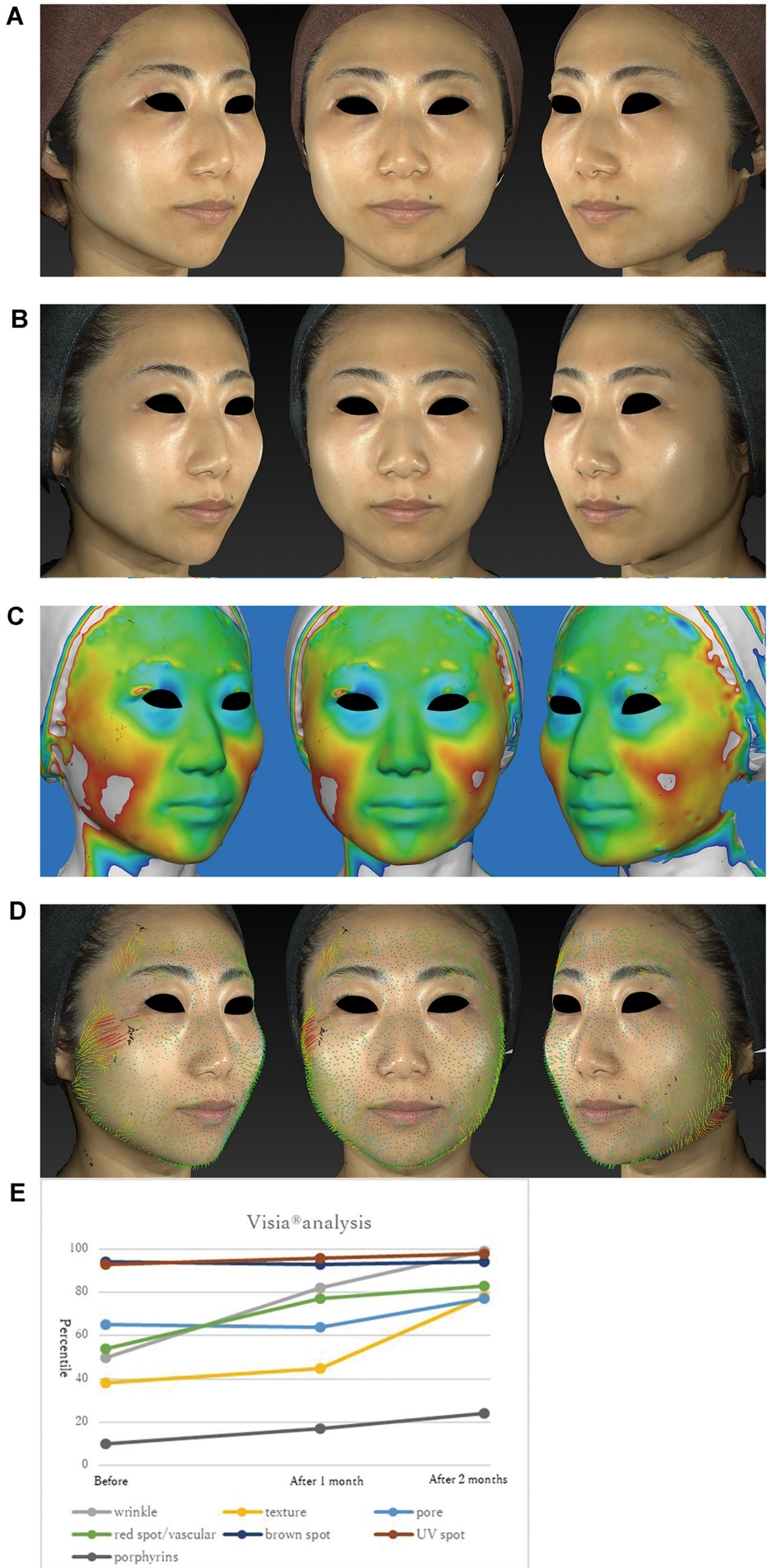
A total of 333 patients (301 females and 32 males) aged 20–85 years (mean age 50.70 ± 12.07 years) with Fitzpatrick skin type I–V were evaluated (Table 1). Seven of the original 340 patients enrolled dropped out for personal reasons or due to a change in the circumstance. All 333 patients repeated having the acoustic wave therapy optionally at 1-month intervals. The average treatment session they received was 4.8 times (3–24 times). There were 43 cigarette smokers, but none of them was a heavy smoker; the average consumption was 11.3 pieces/day. One hundred and ninety-three alcohol drinkers had kept the moderate intake, such as a couple of glasses of wine or beer. No special relevance to the skin type, smoking, and drinking habits was observed to the efficacy of the acoustic wave therapy.

Almost all patients reported that their skin looked and felt rejuvenated, tighter, and lifted. 3D volumetric assessments showed a reduction in volume compared with the pretreatment volumes in all patients (Figs. 5C and 6C). A skin-tightening effect was observed on the lower one-third of the face, including the perioral and lower cheeks, as shown in the orange illuminated area. Most vectors, which indicated each point of the 3D skin surface, showed upward skin displacement (Figs. 5D and 6D). Each point on the forehead, lateral sides of the cheeks, and around the chin were also displaced in an upward direction. Displacement of the central area of the face, including the orbital, periorbital, nasal, peri nasal, and medial sides of the cheek, was subtle but also detectable. These results were obtained without edematous reactions and were sustained for 12 months. The volumetric changes of the whole face were calculated using Vectra software. The facial volume reduction of a 52-year-old male patient was 1.271 cc (Fig. 6), while that of a 33-year-old female patient was 20.67 cc (Fig. 7). Including these two representative cases, 20 follow-up cases were evaluated to enhance the predictability of our acoustic wave therapy (Table 1). The average age of the subgroup was 50.10 ± 9.64 years.

The average volume change of the whole face was −6.57 cc, the number of treatment sessions was 3.95 times (3–6 times), and the follow-up period was 17 months (13–32 months). No remarkable correlations for age, sex, number of treatment sessions, or follow-up period with volumetric changes were observed among the sample cases. An increase in a volume change of the whole face was observed in three patients, although their faces appeared to be tightened according to Vectra digital color imaging.

The patients' skin showed improvements in wrinkles, texture, dilated skin pores, redness, brown spots, UV spots, and Porphyrins (Figs. 5E and 6E). On their self-assessments, 79% of the patients expressed "good" or "excellent" improvement (Fig. 7). Complications observed were minor and transitory, mainly consisting of tingling sensations in the teeth and jaw, and a slight disturbance to the dental pulp around the oral palate during treatment. However, the patients were able to tolerate this stimulation better when a stuffed cotton roll was applied to the oral cavity, and the degree of stimulation decreased as they underwent more treatment sessions. Other patients had a cough and itchy throat during the neck treatment, and some other patients felt a pressing sensation on the cheekbones, all of which were eased by reducing the intensity of acoustic pulses. Mild erythema, which got resolved within 24 hours, was observed in three

Fig. 6. Representative photographs of the results following acoustic wave therapy; (**A**) a 52-year-old Japanese male. Images from top to bottom show pretreatment; (**B**) 2 months posttreatment; (**C**) superimposed three-dimensional (3D) volumetric assessment comparing pre- and 2 months posttreatment; and (**D**) quantification of 3D skin surface displacement with vectors comparing pre- and 2 months posttreatment; (**E**) skin data observed by VISIA analysis. (**A**,**B**) Marked improvements in skin texture and clarity were observed in 2D color digital photographs compared with the pretreatment. (**C**) Volumetric reduction in 3D volumetric assessment was observed compared with the pretreatment.The varying degrees of tightening achieved are shown in colors ranging from yellow to red (−5.0 mm). Green areas are unchanged from pretreatment. Tightening effects on the lower one-third of the face, as well as the lower cheeks and perioral area that were induced by the treatment, lasted for 12 months. (**D**) Each skin surface point in the perioral and chin areas and the lateral sides of the cheek were displaced three-dimensionally in a centrifugal direction. The varying degrees of 3D movement of the skin is shown from blue (0.3 mm) to red (2.6 mm). Green vectors indicate areas that were three-dimensionally displaced from 1.3 to 1.8 mm. (**E**) The skin data observed by VISIA analysis showed improvements in the texture and ultraviolet (UV), brown, and red spots after 1 month, and the texture and UV spot improvements lasted for 2 months.



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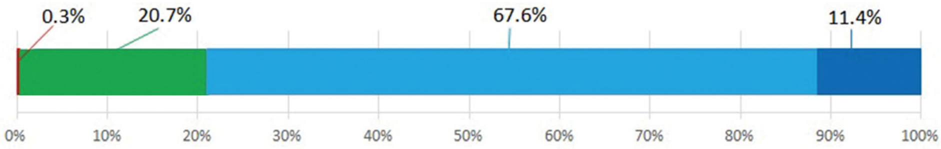

1	2	3	4	5
worse	no change	slight improvement	good improvement	excellent improvement
0	1	69	225	38
0.0%	0.3%	20.7%	67.6%	11.4%

Fig. 8. Subjective satisfaction rating of the results of acoustic therapy 12 months posttreatment ("excellent improvement" [blue], "good improvement" [light blue], "slight improvement" [green], and "no change" [red]).

patients. Side effects, such as epidermal burns, adipose tissue atrophy, and contractures, were not observed in this study (Fig. 8).

DISCUSSION

One of the most common requests of cosmetic patients is for facial contour defect and skin laxity treatment. Although invasive procedures, such as liposuction and incisional surgeries, are effective in reducing undesirable fat tissue in one session, the downtime and unavoidable scar formation are not well received [34]. In fact, a major complaint is the sagginess and uneven proportions of subcutaneous fat tissue and not simply a matter of the quantity. Dermabrasive procedures, such as laser resurfacing, may be effective for skin tightening; however, the recovery time and potential adverse events such as hyper- and hypopigmentation are unattractive aspects [34]. However, noninvasive facial-tightening procedures are easily applicable to not only most Asian people but also to those who have colored and sensitive skin because these procedures are skin type independent [35].

Acoustic wave therapy was first used in urology for the disintegration of kidney stones, followed by its application in the treatments of various orthopedic disorders for more than 30 years [27]; hence, the general safety and affinity of this treatment for the human body have been established. More recently, acoustic wave therapy was found to strengthen connective tissue and improve skin elasticity. Studies examining its effects on the reduction of localized adipocytes and cellulite have had promising results [31].

A notable characteristic of acoustic waves is their availability both as a means of destruction as well as a method for healing disorders and suppressing inflammation. This contradictive transition of acoustic wave usage suggests that emission intensity is the essential factor contributing to its effectiveness. The mechanisms of action brought about by acoustic wave therapy are collectively called mechanotransduction, whereby mechanical stimulations exert versatile biological functions on reactive tissue.

The planar-focused acoustic wave is reportedly effective in cell membrane destruction, causing shear stress, while the linear acoustic wave emits short radial pulses stimulating angiogenesis [4]. Noninvasive technologies that use ultrasound, such as HIFU, induce their tightening effect through thermal tissue damage, whereas acoustic wave employs a nonthermal tightening effect, resulting in the release of various natural cytokines such as vascular endothelial growth factor from platelets [36] and may bypass fatal tissue damage.

In this study, we observed a 52-year-old male patient whose VISIA analysis appeared to be incomplete and irregular, partially because the software's precision accuracy was so high that the patient's frequent outdoor activity might have been reflected. Nevertheless, without any cautious skincare other than applying sunscreen, the texture and UV spot data showed improvements over two months. Additionally, one 33-year-old female patient's skin data showed impressive and significant improvement. The authors unexpectedly also discovered skin rejuvenating effects in this formative study, and skin quality improvements after acoustic wave therapy were common and consistent with the impression of our medical examination.

Regarding facial volume change, although the tendency of improved facial tightening images appeared similar and even, the amount of volume reduction differed considerably, possibly due to physical differences or in view of the relative impacts and sensitivity of individual facial tissues to treatment. Interestingly, while Vectra color

Fig. 7. A 33-year-old Japanese woman. (**A**,**B**) Marked improvements in skin texture and clarity were observed in two-dimensional (2D) color digital photographs compared with the pretreatment assessment. (**C**) Tightening effects on the lower half of the face and perioral area were observed on three-dimensional (3D) volumetric assessment. (**D**) In the perioral and chin areas and the lateral sides of the cheek, each point on the skin surface was displaced three-dimensionally in a centrifugal direction. The varying degrees of 3D movement of the skin is shown from blue (0.5 mm) to red (7.8 mm). Green vectors indicate areas that were three-dimensionally displaced from 1.6 to 2.5 mm. (**E**) The skin data observed by VISIA analysis showed significant improvement in almost all examination items.

images and subjective assessments were generally volume reductive, there were three cases whose facial volume increased among the 20 sample cases. One possibility was that the intensity or amount of acoustic pulses was insufficient for their faces. It is also possible that acoustic wave therapy is not only a simple slimming therapy but also one that improves the metabolism of fat tissue and fibrous malfunctional tissue, such as cellulite.

We did not encounter any cases of deformed or uneven contouring of the face after acoustic wave therapy. On reflection, however, minor latent side effects of excessive correction, such as adipose tissue atrophy, may occur at a later point since definite volume reduction was achieved in many cases.

While literal calculated volume reduction was not so drastic in some patients, the level of treatment is noninvasive, there is no downtime, and there is very little associated risk. Further investigations are needed on the core mechanism of acoustic wave therapy.

The authors evaluated the efficacy of acoustic wave therapy objectively and subjectively and found that the treatment could provide satisfactory results without significant side effects. Nonsurgical volumetric reduction and skin tightening are usually achieved by radiofrequency, near-infrared, or other thermal approaches. In previous studies, the author (Y.T.) has reported that these treatments could provide impressive results on 3D volumetric assessment [1,2,33,34]; however, these treatments were always accompanied by thermal damage to the dermis, and edematous reactions can last up to 2 months after the treatment [2,34]. Interestingly, acoustic wave therapy is novel for facial use and provided preferable facial tightening effects and improvement of various skin conditions without the thermal damage or edematous reactions reported in our prior radiofrequency or near-infrared studies [1,2,33].

Even though the volumetric assessment performed 12 months after treatment ended showed marked volumetric reduction and sustained facial tightening compared with pretreatment assessments in most patients, further studies of volumetric assessments with a longer follow-up time are needed. In addition, to determine an appropriate emission intensity, a treatment frequency is necessary.

Moreover, we cannot exclude the possibility that more minute lifestyle habits, such as food and salt intake, may have affected the results. Therefore, further studies in this area are warranted with larger sample sizes and longer posttreatment periods to evaluate variations in treatment parameters and correlations to patients' environmental factors. The clinical benefits of acoustic wave therapy are its safety and high efficacy, as demonstrated by the objective 3D volumetric assessments, and quality of the results without significant downtime or side effects. The acoustic wave approach is a safe, long-lasting, and effective strategy for facial tightening.

CONCLUSION

Acoustic wave therapy has the potential to become a standard noninvasive and effective energy source for facial tightening and rejuvenation. It can easily be adopted by socially active people and may develop widespread acceptance regardless of age, sex, and skin type.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.