Accepted: 9 February 2024

DOI: 10.1002/lsm.23771

CLINICAL REPORT

Vectorized facial skin tightening: A study on the Thermal Thread Technique™ utilizing high-intensity, high-frequency, parallel ultrasound beam

Kentaro Oku MD

HILLS GRACE CLINIC, Yokohama, Kanagawa, Japan

Correspondence
Kentaro Oku, MD, HILLS GRACE CLINIC, 2-30 Azamino, Yokohama, Kanagawa, Japan.
Email: kentaro.oku@hillsgrace.or.jp

Abstract

Background: Facial skin tightening with wrinkle/fine line reduction is a highly demanded procedure in the aesthetic field. Although there are studies focused on the types of energy sources, the total amount of thermal energy, and the affected depth, there have been no reports examining the relationship between the shape of thermal energy and the directivity of skin tightening. We have developed a specific method to apply thermal energy to the dermis in continuous parallel lines, resembling a thread, perpendicular to the Relaxed Skin Tension Lines (RSTL) for vectorized collagen contraction using synchronous ultrasound parallel beam technology.

Objective: To evaluate the safety, tightening capability, and directivity of the Thermal Thread Technique™ utilizing a high-intensity, high-frequency, parallel ultrasound beam.

Materials and Methods: A total of 34 cases, both males and females aged between 30 and 70 years with Fitzpatrick skin types 2–4, exhibiting mild to moderate skin laxity, participated. All subjects received one treatment using the Thermal Thread Technique™ utilizing high-intensity, high-frequency parallel ultrasound beam to cover the full face and submental area. 3D clinical images were captured before, 8 weeks, and 24 weeks after the treatment. A quantitative image analysis of captured 3D images was performed to objectively measure the direction and distance of contraction.

Results: The average contraction distance from baseline (0 mm) to 8 weeks and 24 weeks posttreatment were 1.91 ± 0.61 mm ($p < 0.001$) and 1.96 ± 0.67 mm ($p < 0.001$) respectively. Regarding the contraction direction at 24 weeks posttreatment, the angle formed between the contraction direction and the base axis, which is perpendicular to the RSTL, was $+9.85° \pm 32.94°$. Out of 34 cases, 28 met the criteria with the angle within ±22.5° of the base axis ($p < 0.001$). The average pain score on a 0–5 scale (0 being no pain, and 5 being maximum pain) was 2.63 ± 0.78. No side effects were reported during the treatment or observation period.

Conclusion: The Thermal Thread Technique™ utilizing a high-intensity, high-frequency, parallel ultrasound beam was proven to be clinically safe and effective for vectorized facial skin tightening.

KEYWORDS

directivity, parallel beam ultrasound, skin tightening, vectorized

INTRODUCTION

Noninvasive skin tightening treatments aimed at reducing wrinkles and fine lines are among the most sought-after procedures in the field of aesthetic medicine, reflecting the ongoing development of various devices. Studies on the devices developed so far have focused on the type of energy source, total energy dosage, and depth of energy application.[1,2] Reports suggest that if the appropriate heat can be applied to the right location, skin tightening effects can be achieved.[3,4]

Wrinkles and sagging due to skin laxity often correspond to the Relaxed Skin Tension Lines (RSTL). The RSTL represents lines formed by connecting points on the skin where tension is least, even within the same region.[5] Therefore, when considering the tension of the skin tissue, it can be said that "the direction in which the collagen fibers on the face are most stretched is perpendicular to the RSTL." When performing noninvasive skin tightening using energy-based devices, it is hypothesized that maximizing therapeutic effects might be possible if the tightening is directed perpendicularly to the RSTL, aiming to shorten the stretched collagen fibers. Leveraging the fact that an ultrasound device, Sofwave™ (Sofwave Medical Ltd., Yokneam, Israel), uses high-intensity, high-frequency parallel ultrasound beam to generate seven parallel cylindrical heat zone within the dermis, we developed the Thermal Thread Technique™, which applies this cylindrical heat continuously without gap and create thread-like shaped heat zone. The aim of this study is to evaluate the safety, the tightening capability and directivity of Thermal Thread Technique™ utilizing high-intensity, high-frequency, parallel ultrasound beam.

MATERIALS AND METHODS

This study was conducted in accordance with the Helsinki Declaration. A total of 34 cases, both male and female aged between 30 and 70 years with Fitzpatrick skin types (FST) 2–4, exhibiting mild to moderate skin laxity participated. Subjects attended the study from November 2022 to November 2023. A signed informed consent was obtained from each participant before joining the study.

Photographs were taken before the treatment, 8 weeks, and 24 weeks after the treatment using a portable VECTRA H2 system (Canfield Scientific, Inc.) that was proved reliable in assessing linear distances, curve distances, and angles.[6] Pain during the procedure was assessed using a 5-point Likert scale, and any side effects related to the procedure were documented by dermatologists throughout the treatment and observation period.

Study plan

The planned time frame of the study was 6 months in total and consisted of three visits. Visit one is defined as the baseline visit and included the screening procedure, the informed consent, and the high-intensity parallel ultrasound beam treatment with Thermal Thread Technique™. The second visit is defined as the follow-up visit at 8 weeks posttreatment. The third one is 24 weeks posttreatment where posttreatment results were evaluated.

All photographs were taken by the same operator who was intentionally excluded from treatment and treatment outcome assessments. To minimize the influence of facial expression changes, patients were instructed to continuously look at a designated point, maintain a purposefully neutral expression, and keep the tongue lightly touching the palate. With three consecutive photographs from three angles of each subject, the computer connected to the camera merged them into one 3D photo using VAM software version 2.8.2 (Canfield Scientific, Inc.). By overlaying baseline and posttreatment photographs, the direction and magnitude (distance) of skin contraction can be shown as vectors. In each case, the direction of contraction and magnitude were recorded as contraction direction and distance, respectively. In this study, a line from the corner of the mouth to the external auditory canal was established as the base axis because the line has multiple points that are perpendicular to the RSTL. If the angle (θ; $-90° < \theta < +90°$) formed between the vector representing skin contraction due to the treatment and the base-axis satisfies $-22.5° < \theta < +22.5°$, it is defined as vectorized skin tightening (Figure 1).

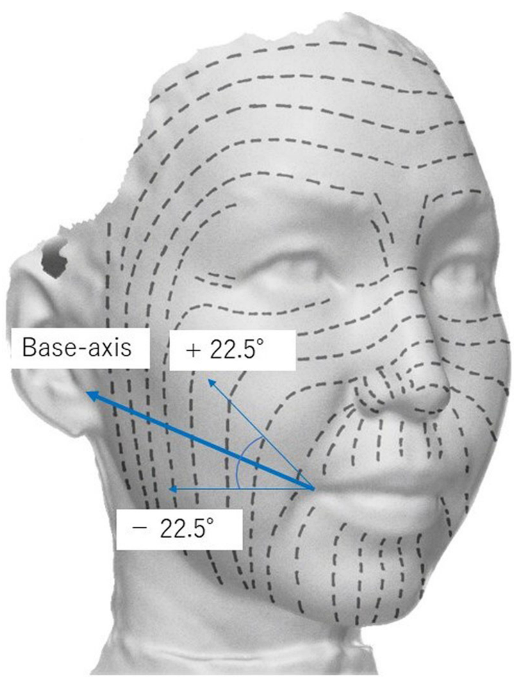

FIGURE 1 Relationship between the relaxation skin tension lines (RSTLs) and the base axes in this study.

Inclusion and exclusion criteria

Inclusion criteria were healthy males and females aged 30–70 years old, diagnosed with mild to moderate sagging skin at the face and submental areas and seeked for a skin tightening procedure. Subjects were excluded if they had local infections, active skin diseases that might affect wound healing, previous surgical face lifting, previous ablative or non-ablative skin procedures within 6 months before the study, botulinum toxin or filler within 6 months before the study.

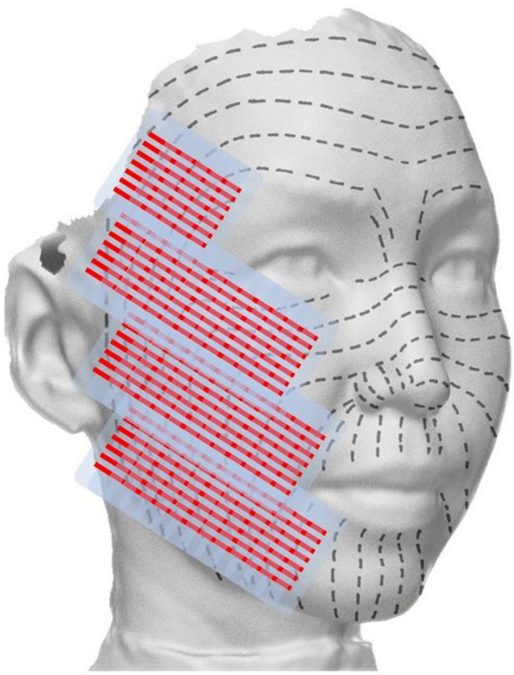

FIGURE 2 Schematic diagram of the thermal zones in the Thermal Thread Technique™.

Treatment

The treatment area was cleansed using a standard facial cleanser and left to dry thoroughly. All make-up and lotions were completely removed. A topical anesthetic cream with 10.56% lidocaine was applied to the treatment area for 15 min. After confirming the effectiveness of anesthesia, synchronous parallel ultrasound is applied to the entire face, but not using the usual grid-like irradiation protocol. Instead, we use the Thermal Thread Technique™.

The Sofwave® handpiece is equipped with seven transducers. Parallel to these, cylindrical heat affects the skin surface to a depth of 1.5 mm in the dermis. As each transducer is rectangular in shape, measuring 1 mm by 5 mm, after completing one shot, the transducer is moved 5 mm parallel to its long axis for the next shot. This process is repeated to create seven parallel thermal zones shaped like "threads in the dermal tissue", which is the fundamental principle of the Thermal Thread Technique™ (Figure 2).

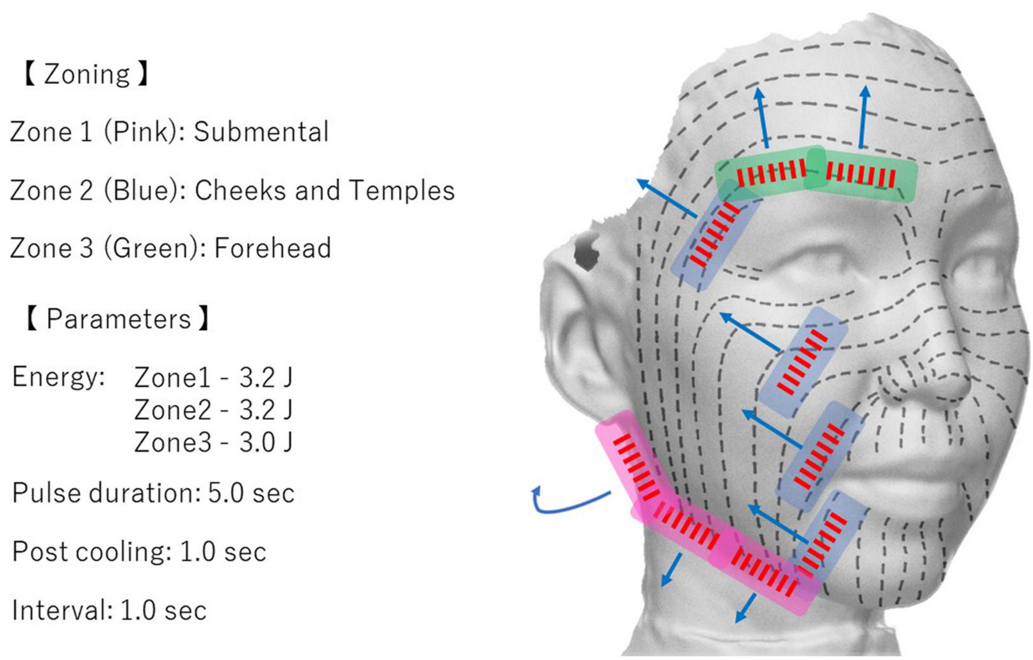

FIGURE 3 Application directions, zoning, and irradiation parameters in the Thermal Thread Technique™.

Since this procedure involves overlaying thermal energy, the energy level is set at 3.0–3.2 J/shot. Irradiation is performed in continuous irradiation mode with a pulse duration of 5.0 s, followed by postcooling for 1 s, and an interval of 1 s between shots.

The face is divided into three zones: (1) submental, (2) cheeks and temples, and (3) forehead, based on the thickness of the skin and the directionality of the RSTL. Irradiation is carried out in the direction shown in Figure 3 such that the direction of the thread-like thermal zone aligns with the base axis. The number of shots required varies depending on the facial area, but on average, the entire face, including submental area, can be covered in <200 shots for a typical subject.

Statistical analysis

Statistical analyses were conducted based on the "Intention-to-Treat" principle. For evaluating contraction degree, a one-sample *t*test was employed. Regarding the direction of contraction, a binomial test was utilized to analyze whether the contraction fell within a specific range (within 45° out of 360°), assuming a success probability of 12.5%. Significance was set at a 5% level ($p < 0.05$ was considered statistically significant). Continuous variables were presented as mean ± standard deviation.

RESULTS

Thirty-four Japanese subjects, three males and 31 females (mean age 49.47 ± 11.04), with FST 2–4 and mild to moderate skin laxity, were included in the study. All participants completed the trial. The number of shots administered during the treatment was 170 ± 24.8. Contraction distance and direction relative to the baseline were visualized and analyzed using 3D images constructed with the VECTRA H2 system. Measuring the contraction distance from a baseline of 0 mm, the mean contraction distance at 8 weeks posttreatment was 1.91 ± 0.61 mm, which was statistically significant ($p < 0.001$), with the maximum tightening distance observed at 3.3 mm. At 24 weeks posttreatment, the mean contraction distance was 1.96 ± 0.67 mm, also statistically significant ($p < 0.001$), with the maximum contraction distance being 3.4 mm (Figure 4). No statistically significant difference was observed between the contraction distances at 8 and 24 weeks posttreatment. Regarding the directivity, the angle θ formed between the contraction direction and the base axis at 24 weeks posttreatment was +9.85° ± 32.94° (Figure 5).Out of the

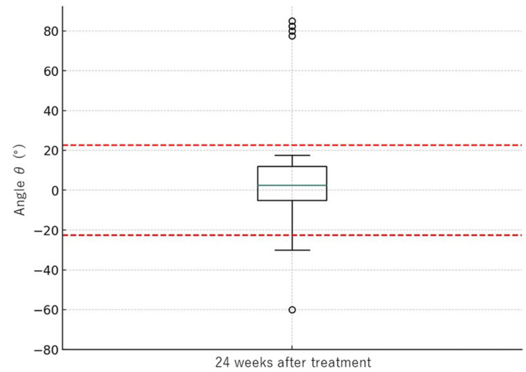

FIGURE 5 Angle θ formed between the contraction direction and the base axis. The red dashed lines represent −22.5° and +22.5°, defined as the significant contraction directions in this study.

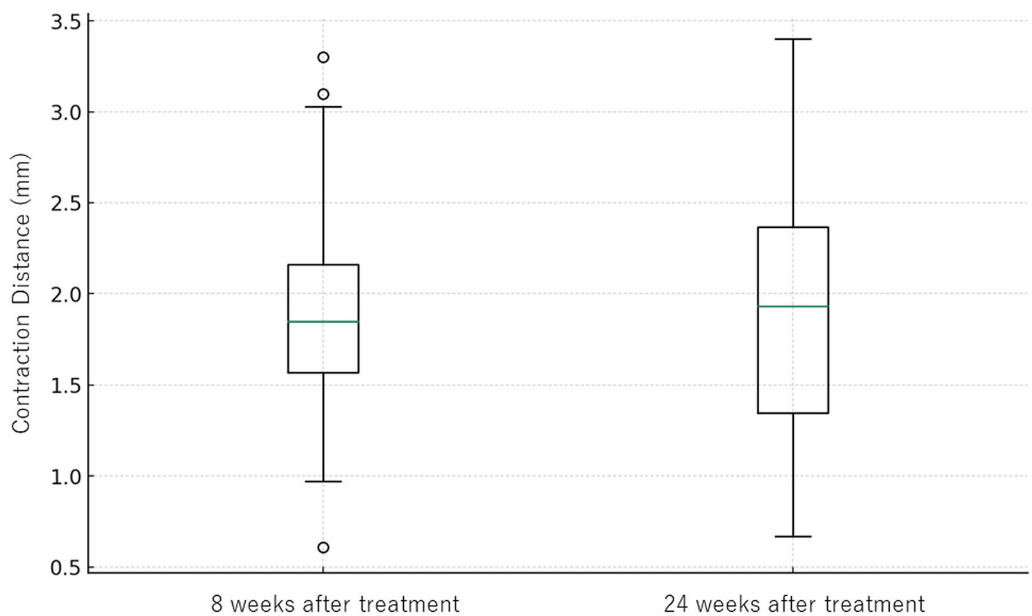

FIGURE 4 Contraction distance (mm) at 8 and 24 weeks posttreatment, with pretreatment (baseline) established at 0 mm.

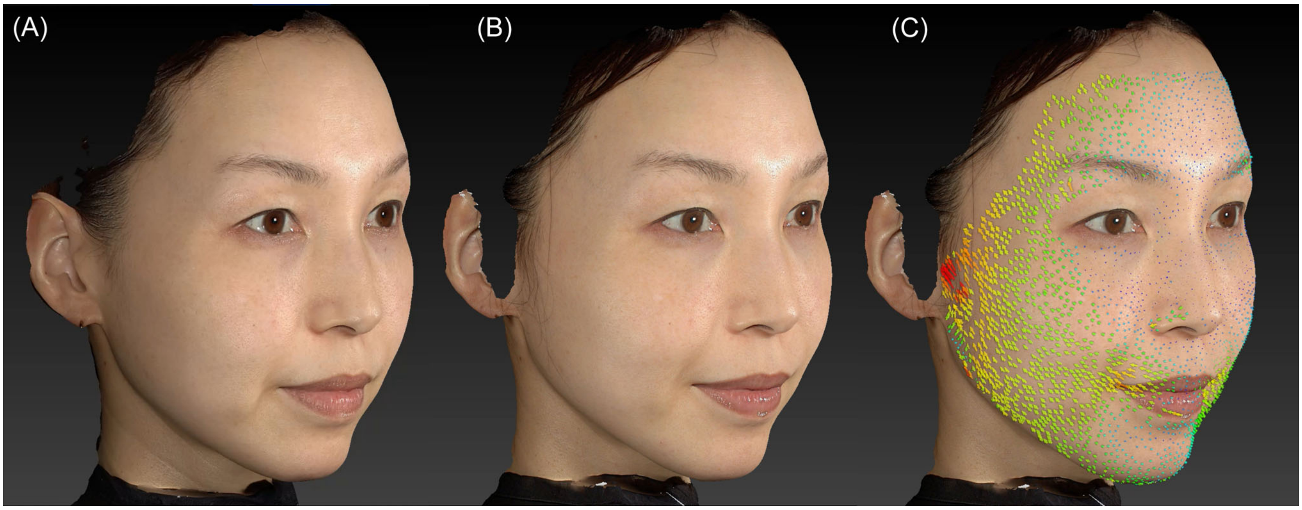

FIGURE 6 Case 1: Female in her 40s (A) Pretreatment. (B) 24 weeks posttreatment. (C) Contraction direction and distance analysis results using the Vectra H2 system.

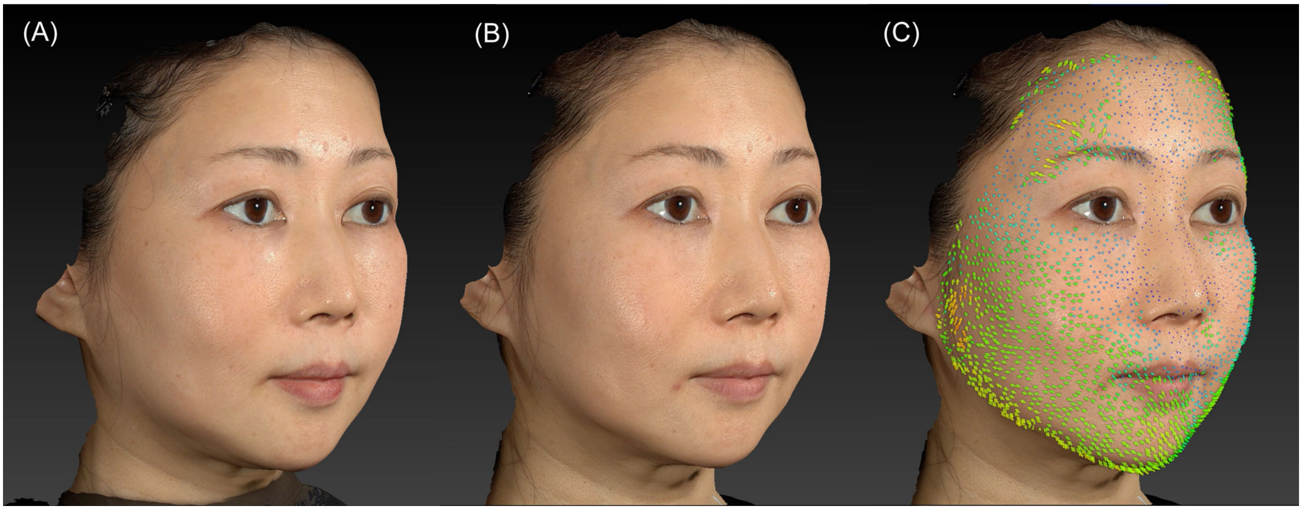

FIGURE 7 Case 2: Female in her 30s (A) Pretreatment. (B) 24 weeks posttreatment. (C) Contraction direction and distance analysis results using the Vectra H2 system.

34 cases, 28 met the criteria ($p < 0.001$), demonstrating that the Thermal Thread Technique™ significantly induced skin tightening with directivity aligning the base axis (Figures 6 and 7). Regarding the treatment's safety, all subjects could endure the pain with a topical anesthesia. The average pain score on a 0–5 scale (0 being no pain, and 5 being maximum pain) was 2.63 ± 0.78. No side effects were reported during the treatment or observation period. All participants were able to resume their daily activities immediately after the treatment.

DISCUSSION

The efficacy of skin tightening using this device, as well as the minimal side effects, has been demonstrated in multiple prior studies.[7–10] The results from our study regarding contraction distance and safety evaluations are consistent with these findings. In addition to these observations, our study aimed to evaluate whether the Thermal Thread Technique™ could induce vectorized skin tightening. Consequently, we observed a statistically significant alignment between the major axis of the thermally affected zone and the direction of tightening contraction. While there isn't an established theory on the relationship between the shape of the thermally affected zone and the direction of tissue contraction, our results suggest that by applying heat energy with axial properties (e.g., in a rectangular or cylindrical shape) to the collagen fibers within the dermis—which are the primary targets in skin tightening—it may induce collagen contraction that aligns with major axis of heat zone. In a simulation of the skin tissue exposed to synchronous parallel ultrasound beams, which was conducted independently of this study, the three-dimensional contraction ratios of collagen fibers within the dermis were found to be dominant along the long axis that matches with long axis of heat zone, specifically a contraction ratio of 7:1 to 5:1 for the long axis versus the short axis. These simulation results agree with the clinical outcomes of our study, supporting the aforementioned inference.

CONCLUSIONS

Thermal Thread Technique™ utilizing the high-intensity, high-frequency, parallel ultrasound beam was proven to be clinically safe and effective for vectorized facial skin tightening. Future studies should consider examining the effects of other energy sources aside from ultrasound to create thermally affected zones with axial properties, validating the same protocol with a larger sample size, and investigating the relationship between energy levels and contraction distance and evaluating whether it is possible to induce contraction with directivity other than the base axis.

ORCID

Kentaro Oku http://orcid.org/0009-0009-9308-7523

REFERENCES

1. Greene RM, Green JB. Skin tightening technologies. Facial Plast Surg. 2014 Feb;30(1):62–7.
2. Dierickx CC. The role of deep heating for noninvasive skin rejuvenation. Lasers Surg Med. 2006 Oct;38(9):799–807.
3. Alexiades-Armenakas M, Newman J, Willey A, Kilmer S, Goldberg D, Garden J, et al. Prospective multicenter clinical trial of a minimally invasive temperature-controlled bipolar fractional radiofrequency system for rhytid and laxity treatment. Dermatol Surg. 2013 Feb;39(2):263–73.
4. Alexiades M, Berube D. Randomized, blinded, 3-arm clinical trial assessing optimal temperature and duration for treatment with minimally invasive fractional radiofrequency. Dermatol Surg. 2015 May;41(5):623–32.
5. Borges AF. Relaxed skin tension lines. Dermatol Clin. 1989 Jan;7(1):169–78.
6. Fan W, Guo Y, Hou X, Liu J, Li S, Ju S, et al. Validation of the portable next-generation VECTRA H2 3D imaging system for periocular anthropometry. Front Med. 2022 Mar 11;9:833487.
7. Hongcharu W, Boonchoo K, Gold MH. The efficacy and safety of the high-intensity parallel beam ultrasound device at the depth of 1.5 mm for skin tightening. J Cosmet Dermatol. 2023 May;22(5):1488–94.
8. Wang JV, Ferzli G, Jeon H, Geronemus RG, Kauvar A. Efficacy and safety of high-intensity, high-frequency, parallel ultrasound beams for fine lines and wrinkles. Dermatol Surg. 2021 Dec 1;47(12):1585–9.
9. Wang JV, Bajaj S, Kauvar A, Geronemus RG. Eyebrow lifting from high-intensity, high-frequency, parallel ultrasound beams. Dermatol Surg. 2023 Jul 1;49(7):718–20.
10. Wang JV, Bajaj S, Geronemus RG, Kauvar A. High-intensity, high-frequency, parallel ultrasound beams for submental lifting. Dermatol Surg. 2023 May 1;49(5):532–4.

How to cite this article: Oku K. Vectorized facial skin tightening: a study on the thermal thread technique™ utilizing high-intensity, high-frequency, parallel ultrasound beam. Lasers Surg Med. 2024;56:355–60. https://doi.org/10.1002/lsm.23771