Noninvasive Lifting of Arm, Thigh, and Knee Skin with Transcutaneous Intense Focused Ultrasound

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ORIGINAL ARTICLE

Noninvasive Lifting of Arm, Thigh, and Knee Skin with Transcutaneous Intense Focused Ultrasound

TINA S. ALSTER, MD, AND ELIZABETH L. TANZI, MD*

BACKGROUND Transcutaneous intense focused ultrasound is a novel Food and Drug Administration–approved technology for noninvasive skin tightening of the face and neck. No studies have reported on its safety and effectiveness on nonfacial areas.

MATERIALS AND METHODS Eighteen paired areas (6 each) on the upper arms, medial thighs, and extensor knees were randomly treated with two different transducers (4.0 MHz, 4.5-mm focal depth and 7.0 MHz, 3.0-mm focal depth). One side was randomly assigned to receive a single pass (single plane) of microthermal coagulation zones over the involved area with the 4.0 MHz, 4.5-mm-depth transducer, and the contralateral side was assigned to receive consecutive single passes (dual plane) using both transducers (4.0 MHz, 4.5-mm depth followed by 7.0 MHz, 3.0-mm depth). Two independent masked assessors determined clinical improvement scores using comparative standardized photographs obtained at baseline and 3 and 6 months after treatment. Subjective assessments of clinical improvement and side effects of treatment were obtained.

RESULTS Global assessment scores revealed significant improvement in all treated areas, with the upper arms and knees demonstrating more skin lifting and tightening than the thighs. Areas receiving dual-plane treatment had slightly better clinical scores than those receiving single-plane treatment in all three sites. Clinical scores from single-plane and dual-plane treated areas continued to improve between 3 and 6 months after treatment. Side effects were mild and transient and included erythema, warmth, and skin tenderness. Rare focal bruising was noted in two patients on the upper arms that resolved within 7 days. No other side effects were reported or observed.

CONCLUSIONS Transcutaneous intense focused ultrasound can be safely and effectively used to improve the clinical appearance (texture and contour) of the upper arms, extensor knees, and medial thighs.

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Facial and nonfacial skin laxity has traditionally been treated using surgical lifting procedures.[1,2] Over the past 2 decades, a wide range of noninvasive treatments such as ablative and nonablative laser skin resurfacing and radiofrequency (RF) have been introduced as alternative therapies to achieve variable degrees and depths of tissue tightening through controlled dermal tissue heating.[3–10] In essence, these treatments deliver infrared light or RF to induce controlled thermal injury as deep as 2 to 4 mm in the dermis.[11,12] Volumetric tissue heating causes immediate collagen contraction and delayed neocollagenesis over a period of 6 months, which leads to clinical skin tightening. Although tightening has been shown with these devices, several shortcomings exist, including inconsistent clinical outcomes, need for multiple treatment sessions, and associated pain and costs.

Most recently, intense focused ultrasound has been introduced to the treatment armamentarium, delivering treatment depths much greater than the

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aforementioned technologies.[13–16] In human cadaveric facial tissue, microthermal zones of coagulation as deep as 7.8 mm with sparing of the epidermis have been reported.[17] As such, thermal contraction of deeper dermal elements such as the superficial musculoaponeurotic system could lead to skin lifting as well as tightening. Intense focused ultrasound has been used safely and effectively to treat facial and neck skin in a variety of skin types, but its effect has not been studied in nonfacial regions.[18–20] The objective of this study was to determine the clinical efficacy of this novel ultrasound device using two different treatment protocols on the upper arms, extensor knees, and medial thighs.

Materials and Methods

Adult women (aged ≥ 18) of any skin phototype (I-VI) with photographically symmetrical lax skin on the upper arms, extensor knees, or medial thighs were recruited for study entry. Exclusion criteria were prior cosmetic or surgical treatments (e.g., laser, RF, surgical lifting, filler injections); skin infection, inflammation, scarring, or pigmentary irregularities; or metal implants in the treatment areas.

Analgesia was achieved with oral administration of diazepam (5–10 mg) and intramuscular injection of meperidine (50 mg) 20 to 30 minutes before treatment. Baseline photographs were obtained using standardized patient positioning and lighting (Canfield Imaging Systems; Mirror Image, Fairfield, NJ). One side was randomly assigned to receive a single pass of microthermal coagulation zones over the involved area using the 4.0 MHz, 4.5-mm-depth transducer (single-plane treatment), and the contralateral side was assigned to receive consecutive single passes using the 4.0 MHz, 4.5-mm-depth and 7.0 MHz, 3.0-mm-depth transducers (dual-plane treatment). The skin areas were cleansed with mild cleanser (CeraVe; Coria Laboratories, Aliso Veijo, CA) to remove all traces of powder and other surface impurities before application of a layer of ultrasound gel. The 4.0 MHz, 4.5-mm focal depth transducer (Ulthera; Mesa, AZ) was placed on the treatment area until acoustic coupling (as evidenced by the corresponding ultrasound image) was achieved. Treatment lines of ultrasound pulses were manually delivered adjacent and parallel to one another with minimal spacing (<3 mm). Each treatment line was 25 mm long and delivered 17 to 23 thermal coagulation zones measuring 1 mm^3 at 1.1- to 1.5-mm intervals. The involved area was treated with 1.2 J per pulse until the entire region had been covered. The number of treatment lines delivered ranged from 60 to 230 (mean 160) for the arms to 80 to 200 (mean 142) for the knees to 100 to 200 (mean 157) for the thighs. A second treatment line was delivered to the contralateral side (randomly determined) using the 7-MHz, 3.0-mm-depth transducer at 0.45 J per pulse. Adjacent, parallel lines were manually placed in a similar fashion to the first treatment lines. The number of treatment lines delivered ranged from 90 to 235 (mean 153) for the arms to 80 to 150 (mean 136) for the knees to 100 to 200 (mean 152) for the thighs. After treatment, the ultrasound gel was removed with water-soaked gauze, and a thin layer of moisturizer (CeraVe Lotion) was applied. Patients were instructed to care for their skin as they normally would, without any restrictions placed on their activity or sun exposure.

All patients were followed up with 1 and 3 months after treatment, at which time clinical photographs were obtained using consistent patient positioning, camera angles, and room lighting. Baseline and post-treatment photographs were randomly displayed, and two medical assessors masked to study protocol independently evaluated them. Global clinical improvement scores were determined using side-by-side comparisons of 3- and 6-month post-treatment photographs to baseline (0 = no improvement, 1 = 1–25% improvement, 2 = 26–50% improvement, 3 = 51–75% improvement, 4 = >75% improvement). Degree of skin tightening and lifting was determined according to perceived

cumulative smoothing of skin wrinkling, reduction of tissue bulk, and improvement of skin contour.

Results

Eighteen women (aged 44–66, mean age 54.8) with skin phototypes I to IV were included Six patients qualified in each of the three body treatment study zones. All patients completed the 6-month study.

Study subjects tolerated the procedure well with diazepam and meperidine analgesia. Discomfort levels were reported as mild to moderate during treatment. Immediately after treatment, all treatment areas displayed mild to moderate erythema, most prominent on the medial thighs and upper arms. The areas were warm and slightly tender to touch. The warmth and erythema resolved in all patients within 2 hours of treatment, but most patients reported skin tenderness in the treatment areas ranging from 1 to 3 weeks. Focal bruising was noted in two patients on the upper arms that resolved within 7 days. No vesiculation or pigmentary changes were noted in any area receiving treatment. No other side effects were reported or observed.

Mean global assessment scores (GAS) significantly changed over time ($p<.001$) in single- and dual-plane treated areas (Table 1). With single-plane treatment, there were no statistically significant differences in mean scores between body location ($p=.06$), although statistically significant differences were found with dual-plane treatment ($p=.02$). Specifically, mean GAS at 6 months was significantly different between the arms and thighs ($p=.05$) and between the knees and thighs ($p=.002$). When comparing single- and dual-plane treatment, mean change in GAS was statistically significant over time ($p<.001$). There were no statistically

TABLE 1. Treatment Global Assessment Scores

Location and Time	*0 (no improvement)*	*1 (1–25% improvement)*	*2 (26–50% improvement)*	*3 (51–75% improvement)*	*4 (>75% improvement)*	*Mean*
Single plane						
Arms						
3 months	0	5	4	3	0	1.83
6 months	0	3	3	4	0	2.05
Knees						
3 months	0	1	7	3	1	2.33
6 months	0	0	5	5	0	2.45
Thighs						
3 months	0	7	3	0	0	1.30
6 months	0	4	4	0	0	1.48
Dual plane						
Arms						
3 months	0	4	5	3	0	1.92
6 months	0	1	5	4	0	2.25
Knees						
3 months	0	0	5	5	2	2.75
6 months	0	0	4	4	2	2.78
Thighs						
3 months	0	6	4	0	0	1.40
6 months	0	5	2	1	0	1.47

In single-plane treatment, mean GAS changed significantly over time ($p<.001$). No statistically significant differences in GAS between different body locations were apparent ($p=.06$).
In dual-plane treatment, mean GAS significantly changed over time ($p<.001$), and statistically significant differences were observed between body locations ($p=.02$). All body locations were statistically significantly different from baseline to 3 months ($p<.001$) and baseline to 6 months ($p<.001$). At 6 months, the mean scores between the arms and thighs ($p=.05$) and between the knees and thighs ($p=.002$) were statistically significantly different.

TABLE 2. Single- Versus Dual-Plane Treatment Global Assessment Scores (GAS)

Treatment and Time	*0 (no improvement)*	*1 (1–25% improvement)*	*2 (26–50% improvement)*	*3 (51–75% improvement)*	*4 (>75% improvement)*	*Mean Score*
Single-plane						
3 months	0	13	14	6	1	1.85
6 months	0	7	12	9	0	2.07
Dual-plane						
3 months	0	10	14	8	2	2.06
6 months	0	6	11	9	2	2.25

When comparing single- and dual-plane treatment, the mean change in GAS was statistically significant over time ($p<.001$). There were no statistically significant differences in mean scores between single and dual plane treatment ($p=.18$), regardless of body location.

significant differences in mean scores between single- or dual-plane treatment ($p=.18$), regardless of body location (Table 2). In general, the upper arms and knees showed more skin lifting and tightening than did the thighs (Figures 1 3A and B).

Thirteen of the 16 patients were highly satisfied with the procedure and opted to undergo similar focused ultrasound treatment of different facial and body areas since the conclusion of the study. The thee patients who were less than satisfied had received treatment on the medial thighs ($n=2$) and upper arms ($n=1$). These patients opted to undergo additional focused ultrasound treatment of the same (and other) body areas.

Discussion

Skin laxity of nonfacial areas has traditionally been difficult to treat. Unsightly scarring in these regions has hampered surgical management, whereas nonsurgical options (e.g., laser, RF) have yielded only modest success.[2,8–10] The intense focused ultrasound technology used in this study is better able to address the problem by delivering deep dermal energy at tissue planes in the subdermal connective tissue as well as in the superficial dermis to effect collagen contraction and remodeling. As such, it has been used successfully for lifting eyebrows, cheeks, and neck.[18–20] In addition, the technology can be applied to a wide range of skin phototypes because of its ability to avoid unintended cutaneous injury from secondary energy and heat scatter in the dermis and because melanin does not absorb ultrasound energy.[20] Similar to different facial areas, nonfacial areas have a wide range of thicknesses. The ability of the device to focus thermal

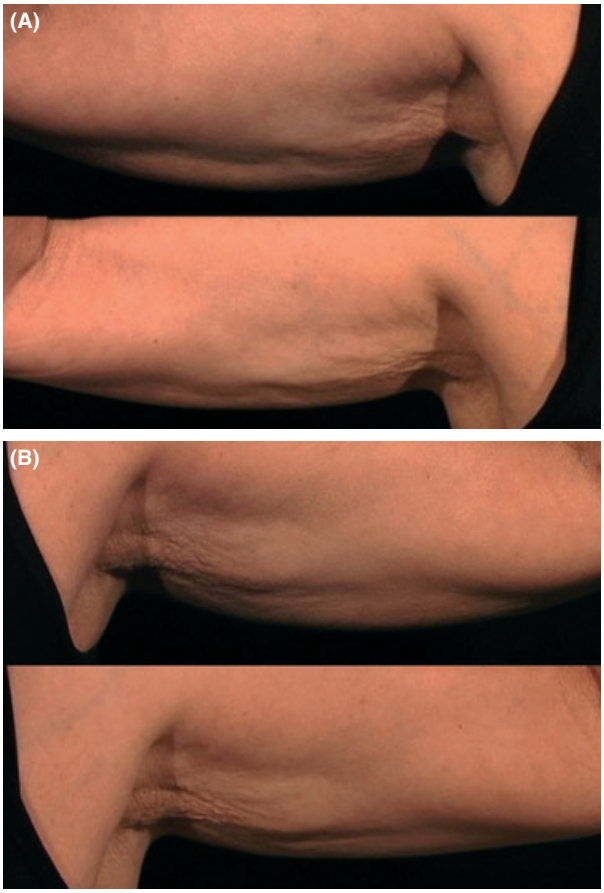

Figure 1. Upper arms before (above) and 6 months after (below) dual-plane focused ultrasound treatment (right arm, global assessment score [GAS] 2) and single-plane treatment (left arm, GAS 2).

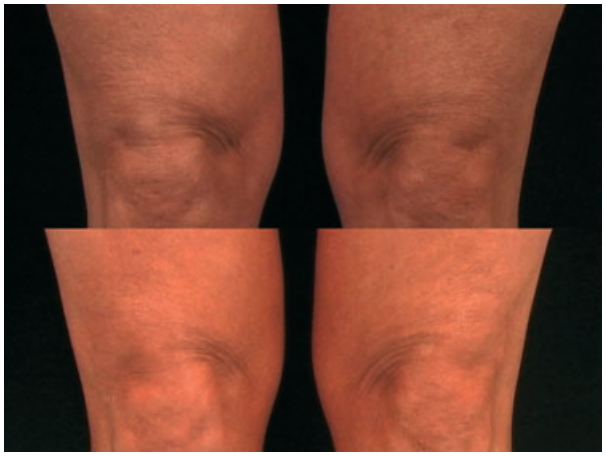

Figure 2. Extensor knees before (upper) and 6 months after (lower) dual-plane focused ultrasound treatment (right knee, global assessment score [GAS] 3) and single-plane treatment (left knee, GAS 2).

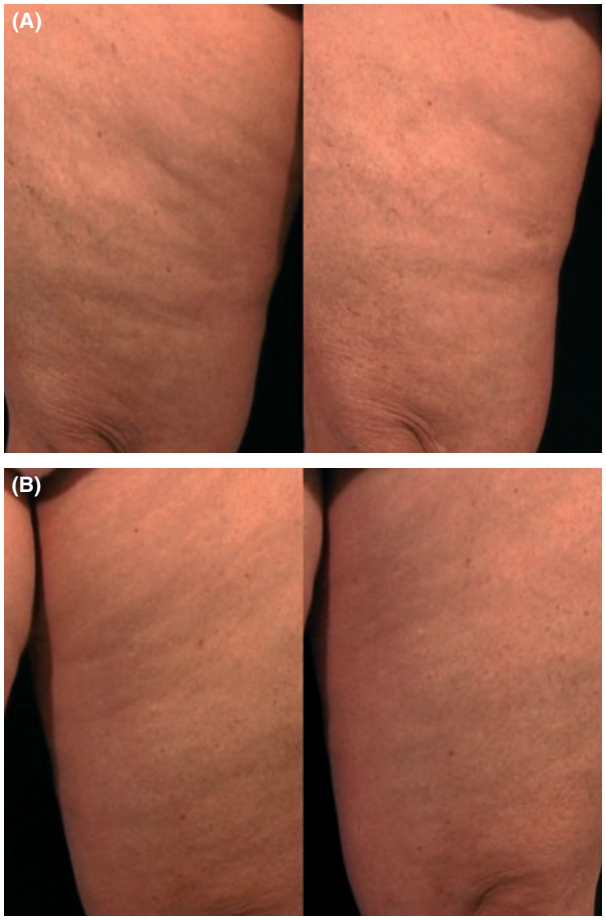

Figure 3. Medial thighs before and 6 months after (A) dual-plane focused ultrasound treatment right thigh, global assessment score, (GAS) 2 and (B) single-plane treatment left thigh, GAS 1.

energy selectively at preselected depths using different transducers, as well as to provide direct visualization of the skin layers to ensure accurate energy delivery to the intended tissue plane, makes focused ultrasound an ideal treatment in a number of anatomic regions.

This study demonstrated significant improvement of the three body zones (arms, knees, thighs) targeted for treatment. Adverse events were limited to transient erythema and tenderness in all patients and occasional localized bruising (arm regions). Focal bruising is likely due to inadvertent heating and injury to underlying cutaneous vasculature and has been reported to occur in the facial region.[20]

Dual-plane treatment was found to yield slightly higher clinical improvement scores than single-plane treatment, although both showed significantly improved skin contours (indicating lifting and tightening). The dual-plane treatment areas showed substantially more improvement in skin texture, which led to higher overall improvement scores. This trend was most noticeable in the knee and arm regions because both of these areas were more wrinkled at baseline, and the superficial transducer (7 MHz, 3.0-mm depth) would be expected to induce more-superficial dermal neocollagenesis.

We did not study the additional benefits of repeated treatments, but given the significant improvement seen at 3 months and the slight continued improvement at 6 months after treatment, we would recommend repeat treatments being scheduled at intervals no shorter than 3 to 6 months. Given the marked clinical improvement seen in the upper arm and knee skin, in particular, we advocate the use of intense focused ultrasound treatment for these areas. Because of the milder clinical response of the medial thigh area and the lengthy time for treatment (particularly when circumferential treatment is warranted), we have not been recommending ultrasound treatment for this region until further technologic advancements are made and treatment protocols are optimized.

Conclusions

Transcutaneous intense focused ultrasound can be safely and effectively used to improve the clinical appearance (texture and contour) of the upper arms, extensor knees, and medial thighs. Further studies are warranted to determine specific treatment parameters and the necessity and timing of additional treatments to optimize clinical outcomes in these and other body regions.

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