Evaluation of microfocused ultrasound with visualization for lifting, tightening, and wrinkle reduction of the décolletage

Sabrina G. Fabi, MD, Ane Massaki, MD, Sasima Eimpunth, MD, Janice Pogoda, PhD, and Mitchel P. Goldman, MD
San Diego and Los Angeles, California

Background: Laxity and rhytides are manifestations of photodamage on the chest.

Objective: We sought to evaluate efficacy and safety of microfocused ultrasound with visualization treatment of décolletage laxity and rhytides.

Methods: In all, 24 subjects with moderate to severe rhytides, as measured by a validated 5-point photumeric scale (Fabi/Bolton Chest Wrinkle Scale), received microfocused ultrasound with visualization treatment. Efficacy was measured at 90 and 180 days by the Fabi/Bolton Chest Wrinkle Scale, mid-clavicular to nipple distance, masked assessment, Physician and Subject Global Aesthetic Improvement Scales, and patient satisfaction. Adverse events were recorded.

Results: Rhytides improved over time (P < .0001), with 46% and 62% of subjects showing a 1- to 2-point improvement at days 90 and 180, respectively. Mean (SD) mid-clavicular to nipple distance decreased (P < .0001), from 20.9 (1.57) cm to 19.8 (1.50) cm and 19.5 (1.59) cm, at days 90 and 180, respectively. At day 90, 100% were improved by Subject Global Aesthetic Improvement Scale score (P < .0001) and 96% were improved by Physician Global Aesthetic Improvement Scale score (P < .0001), with similar findings at day 180. All subjects were satisfied or very satisfied at day 90, with similar results at day 180. Improvement by masked assessment at day 90 was 71%.

Limitations: Single-center study, small sample size, and only Fitzpatrick skin types I and II enrolled were limitations.

Conclusion: There was appreciable efficacy and patient satisfaction after a single microfocused ultrasound with visualization treatment in wrinkle reduction and lifting of the décolletage. (J Am Acad Dermatol 2013;69:965-71.)

Key words: chest; décolletage; microfocused ultrasound with visualization; photoaging; tightening; wrinkles.

Photaging occurs as a result of a combination of both cumulative actinic damage and intrinsic changes. In the chest area, or décolletage, photodamage is characterized by skin laxity, rhytides, hyperpigmentation, erythema, tactile roughness, atrophy, and telangiectasis.1 Photodamage of the surrounding skin of the neck and chest area...
compared with facial skin.3,4 Deep rhytides with a decreased number of pilosebaceous units, as increased thickness of the epidermis and dermis along to a grade 3 or higher on the validated Fabi/Bolton laxity and wrinkles of the skin phototype (I-VI), with desire to improve skin Study population were provided a copy of the informed consent. subjects consented to participation in the study and by the Independent Institutional Review Board. All the 1975 Declaration of Helsinki and was approved (approximately 1-mm³) mi-configured to produce small lactic acid, although several shortcomings exist, including the need for multiple treatment sessions and associated downtime, pain, and costs.1,2,5,6 Microfocused ultrasound with visualization (MFU-V) (Ultherapy Ulthera Inc, Mesa, AZ) is designed and configured to produce small (approximately 1-mm³) microthermal zones of coagulation in the mid- to deep reticular layer of dermis and subdermis, leading to a wound-healing response resulting in new collagen production and tissue contraction while sparing overlying papillary dermal and epidermal layers of skin. The device incorporates ultrasound imaging capability to visualize the skin tissue being treated and to assess proper coupling of the transducer to the skin surface while delivering the treatment. MFU-V is Food and Drug Administration approved for noninvasive eyebrow lift, and only 1 study to date has been published on its safety and effectiveness on nonfacial areas.8 This clinical trial was designed to evaluate the clinical outcomes associated a single, no-downtime, noninvasive MFU-V treatment to improve skin laxity and tightening of the décolletage.

METHODS

The study protocol conformed to the guidelines of the 1975 Declaration of Helsinki and was approved by the Independent Institutional Review Board. All subjects consented to participation in the study and were provided a copy of the informed consent.

Study population

Women between 30 and 65 years of age of any skin phototype (I-VI), with desire to improve skin laxity and wrinkles of the décolleté, corresponding to a grade 3 or higher on the validated Fabi/Bolton Chest Wrinkle Scale (FBCWS) (Fig 1)³ were eligible for enrollment. In all, 24 subjects meeting the inclusion and exclusion criteria were enrolled at 1 study site. Exclusion criteria included a subject with any uncontrolled systemic or local skin disease; scarring, tattoos, or open wounds in the area to be treated; ports or defibrillators; breast size of greater than 400 mL each as measured by water displacement method; marked breast asymmetry, ptosis, excessive dermatochalasis or thick sebaceous skin; history of breast reduction surgery; history of keloid formation or hypertrophic scarring; current smoker or history of smoking in the last 1 year; history of chronic drug or alcohol abuse; history of autoimmune disease; a woman who is pregnant, nursing, or planning a pregnancy during the study; inability to understand the protocol or give informed consent; patient taking antiplatelet or anticoagulants; and the use of retinoid, microdermabration, or prescription-level glycolic acid treatments to the décolleté area within 2 weeks before study participation or during the study.

Materials

One MFU-V system (Ultherapy, Ulthera Inc) was used, which consisted of the control unit with integrated touch screen, a hand piece, and 2 of 6 commercially available transducers (4.0 MHz, 4.5-mm depth; and 7.0 MHz, 3.0-mm depth).

Methods

Before treatment the skin was cleansed with a mild cleanser (SkinMedica Gentle Cleanser, SkinMedica Inc, Carlsbad, CA) to remove all traces of powder and other surface impurities, subjects’ chest wrinkle severity was graded using the FBCWS (Fig 1),³ and bilateral chest measurements were performed using the distance from the clavicle to the superior pole of the nipple along the mid-clavicular line. Baseline photographs were obtained using standardized patient positioning and lighting (Canfield Imaging Systems, Mirror Image, Fairfield, NJ).

Analgesia was administered at the discretion of the physician and subject and was achieved with oral administration of diazepam (5-10 mg), 200 mg of

**CAPSULE SUMMARY**

- Microfocused ultrasound with visualization is Food and Drug Administration--approved for a noninvasive eyebrow lift, as well as neck and submental skin lift.
- A single microfocused ultrasound with visualization treatment resulted in significant improvement in chest rhytides 90 and 180 days after treatment.
- Microfocused ultrasound with visualization to the décolletage demonstrated overall aesthetic improvement, with no downtime or serious adverse events.
ibuprofen, or 500 mg of acetaminophen 60 minutes before treatment.

Immediately before treatment the treatment area was marked by the following boundaries: the superior border as a horizontal line across the inferior aspect of the sternoclavicular joint, the lateral borders along the mid-clavicular line stopping inferiorly at the level of the fourth rib, and 2 diagonal lines enclosing the treatment area inferiorly and meeting at the midline (with sparing of the skin overlying the breasts) (Figs 2 and 3). A thin layer of ultrasound gel was placed and the therapy process was initiated in the line pattern shown in Fig 2 with the 4.0-MHz, 4.5 mm—depth transducer, at 1.2 J, advanced 2 to 3 mm along the line until the specified number of treatment lines were delivered, followed by the 7.0-MHz, 3.0 mm—depth transducer, at 0.45 J (dual-plane treatment). A total of 120 lines were delivered with the 4.0-MHz, 4.5 mm—depth transducer and a total of 120 lines with the 7.0-MHz, 3.0 mm—depth transducer. If bone or a breast implant was visualized in the treatment zone using the 4.0-MHz, 4.5 mm—depth transducer, all 240 lines were delivered using the 7.0-MHz, 3 mm—depth transducer. Only 2 subjects did not receive all 120 lines with the 4.0-MHz, 4.5 mm—depth transducer. During treatment, subject assessment of pain was obtained using the validated 10-point numeric rating scale posttreatment. After treatment, the ultrasound gel was removed with water-soaked gauze, and photographs were taken approximately 30 minutes after the procedure using standardized patient positioning and lighting to capture acute adverse events from treatment. Subjects were instructed to care for their skin as they normally would, without any restrictions placed on their activity or sun exposure.

Subjects were followed up at 90 and 180 days after treatment, at which time clinical photographs were obtained using patient positioning, camera angles, and room lighting consistent with baseline photographs. Bilateral chest measurements were recorded, chest wrinkle severity was assessed using the FBCWS, and Physician Global Aesthetic Improvement Scale (PGAIS) and Subject Global Aesthetic Improvement Scale (SGAIS) scores were determined using side-by-side comparisons with baseline photographs (1 = very much improved, 2 = marked improvement, 3 = improved, 4 = no change, 5 = worse). Adverse events were documented. A patient satisfaction questionnaire on improvement of lines/wrinkles, sagging, tighter/lifted skin, skin tone evenness and smoother texture, as

![Fig 1. Five-point Fabi/Bolton Chest Wrinkle Scale.](image-url)
well as patient satisfaction with treatment and likelihood to recommend treatment, was administered at each follow-up visit, while the patient referred to their baseline photographs.

Random sets (baseline, 90-day follow-up) of chest photographs were used for masked qualitative assessment by 3 board-certified dermatologists. Without knowing the order of the photograph sequence, assessors chose the correct order then rated improvement as “slight” (1%-25% improvement), “fair” (26%-50%), “good” (51%-75%), or “excellent” (76%-100%), or did not identify the correct order and rated the photograph sequence as “no change.”

Statistical analysis

All efficacy outcomes except mid-clavicular to nipple distance were analyzed as categorical variables. The method of generalized estimating equations was used to test for longitudinal differences in category distributions over time using the SAS procedure GENMOD (SAS, Version 9.2, SAS Institute Inc, Cary, NC). The $\chi^2$ goodness-of-fit tests were used to test the hypothesis of equal proportions of subjects at each category level at a given time point. Mid-clavicular to nipple distance was derived for each subject as the mean of left- and right-side distances. Longitudinal differences in subject means were tested with a random effects model using the SAS procedure MIXED (SAS Institute Inc, Cary, NC). An exact Clopper-Pearson 95% confidence interval was calculated for percent of subjects rated as improved by masked assessment (vs no change or incorrect sequence) as a binomially distributed variable. All tests were 2-sided with .05 significance levels.

RESULTS

All 24 subjects completed the 90-day visit and 21 subjects completed the 180-day visit. Two subjects were lost to follow-up and 1 patient became pregnant and was dropped from the study. The mean age of subjects enrolled was 51.3 years (range 38-60), 29% were a Fitzpatrick skin type I and 71% were a Fitzpatrick skin type II. At baseline, 62.5% of subjects had a FBCWS score of 3, 37.5% had a FBCWS score of 4, and the mean (SD) distance between mid-clavicle and nipple was 20.9 (1.57) cm. The mean (SD) pain during treatment scores were 5.1 (2.00) and 4.0 (2.19) for 4.5- and 3-mm depths, respectively. Of subjects, 42% received pretreatment medication. Erythema and edema were acute responses and were mild to moderate and transient.

Per inclusion criteria, all 24 participating subjects had a FBCWS score of 3 or higher at day 0. At day 90, 11 of 24 subjects (46%) had a FBCWS score of 1 or 2; by day 180, 13 of 21 subjects (62%) had a score of 1 or 2 ($P < .0001$ for trend of decreasing FBCWS score over time) (Fig 4).

Mean distance between mid-clavicle and nipple significantly decreased over time ($P < .0001$). Mean (SD) distance was 20.9 (1.57) cm at day 0, 19.8 (1.50) cm at day 90, and 19.5 (1.59) cm at day 180.

Seventeen of 24 subjects (71%, 95% confidence interval 49%-87%) were noted to have improved by majority masked assessment at day 90. Based on mean masked assessment score, among the 20 of 24 subjects (83%) for whom the correct order of photographs was selected, 5 (25%) were assessed as “no change,” 8 (40%) as “slight to fair improvement,” and 7 (35%) as “good to excellent” improvement (Figs 5 and 6).
At day 90, 23 of 24 subjects (96%) were noted to have improved by PGAIS score: 13 (54%) were graded as "marked improvement" and 10 (42%) as "improved." The remaining subject was graded as "no change." At day 180, 19 of 21 subjects (86%) were noted to have improved: 8 (38%) were graded as "very much improved," 5 (24%) as "marked improvement," and 5 (24%) as "improved." The distribution of PGAIS scores was significantly different from equal proportions of subjects at each grade at day 90 (P < .0001). There was no statistical difference in PGAIS score distribution between days 90 and 180.

At day 90, all 24 subjects were noted to have improved by SGAIS score, ie, noted some type of overall aesthetic improvement in their chest texture, contour, tone, or rhytides: 4 (17%) graded themselves as "very much improved," 6 (25%) as "marked improvement," and 14 (58%) as "improved." At day 180, 20 of 21 subjects (95%) were noted to have improved: 8 (38%) graded themselves as "very much improved," 3 (14%) as "marked improvement," and 9 (43%) as "improved." The distribution of SGAIS scores was significantly different from equal proportions of subjects at each grade at day 90 (P < .0001). There was no statistical difference in SGAIS score distribution between days 90 and 180.

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All of the 24 subjects (100%) were either satisfied (62.5%) or very satisfied (37.5%) with treatment at day 90. At day 180, 20 of 21 (95.2%) subjects were either satisfied (52%) or very satisfied (43%) with treatment. Both day-90 and -180 satisfaction levels were significantly different from equal proportions at each satisfaction level (P < .0001 and .0007, respectively). Patient satisfaction questionnaires demonstrated that 83% and 90% of subjects reported improvement in lines/wrinkles at days 90 and 180, respectively. Improvement in sagging was reported by 50% and 29% at days 90 and 180, respectively; improvement in tightening/lifting was reported by 29% and 24% at days 90 and 180, respectively; and improvement in texture was reported by 25% and 33% at days 90 and 180, respectively.

Erythema and edema were the only 2 acute responses noted and were transient. Only 1 nonserious adverse event was noted, where a subject immediately developed indurated, erythematous linear plaques, corresponding to sites of MFU-V line delivery with the 7.0-MHz, 3.0 mm—depth transducer. A class-I topical steroid and ice were immediately applied. The subject was instructed to massage the sites and apply a class-V topical steroid twice a day to the affected area for 2 weeks. The plaques resolved in 3 weeks with no sequelae.

**DISCUSSION**

In an effort to minimize postprocedural adverse events and downtime, physicians have attempted to develop various nonablative skin resurfacing methods (eg, monopolar and bipolar radiofrequency) to induce collagen shrinkage and remodeling while preserving the epidermis. Ultrasound is an energy modality that can be focused to penetrate deeper in the tissue and cause thermal coagulation to avoid the undesirable postprocedural effects observed with carbon-dioxide laser resurfacing of the superficial layers. Ultrasound can also be used to image the region of interest. The MFU-V system (Ultherapy, Ulthera Inc) used in this study has the ability to deliver focused ultrasound energy selectively, at preselected depths using different transducers, ensuring accurate energy delivery to the intended tissue plane. MFU-V is an ideal treatment in a number of anatomic regions as different facial and nonfacial areas have a wide range of thicknesses allowing one to target both cutaneous layers in the skin, such as the reticular dermis, and fibromuscular layers, such as the submuscular aponeurotic system on the face and fibromuscular tissue encasing the pectoralis major on the chest. Treatment with MFU-V creates small focal thermal coagulative zones in the skin and fibromuscular planes, causing thermally induced contraction of tissue and a wound-healing response to stimulate the formation of new tissue and collagen remodeling. Focused ultrasound heating has several potential advantages over lasers and radiofrequency devices such as monopolar radiofrequency devices. Focused ultrasound energy...
is able to confine heating to small focal regions with a combination of precision and depth not possible with lasers or radiofrequency devices. This ability to focus the energy and completely bypass the reticular dermis also allows a higher temperature to be reached at the focal point (60-70°C), while optimizing collagen production. With a different transducer selection, the system can create small focal spots of tissue coagulation up to approximately 5-mm deep.

The lack of chromophore specificity combined with the precise confinement of the focal thermal coagulation points at depths well below the basal layer allows for the safe treatment of darker skin types. Chan et al studied the safety of MFU-V for noninvasive skin tightening in Asians. In the study, 49 Chinese subjects (Fitzpatrick skin types III [36.7%] and IV [63.3%]) underwent 68 treatments to the full face with the highest energy settings (4.0 MHz, 4.5-mm depth; 7.0 MHz, 4.5-mm depth; and 7.0 MHz, 3.0-mm depth). Two subjects developed 2-2mm macules of postinflammatory hyperpigmentation (PIH) confined to the forehead, which resolved 9 months after treatment. The authors hypothesized that treatment with the 7.0-MHz, 4.5 mm—depth transducer over an area with such close proximity to bone caused reflection of heat off the bone, leading to an inflammatory response and subsequent PIH. After the 2 cases of PIH were noted, the 7.0-MHz, 4.5 mm—depth transducer was replaced by the more superficial-depth transducer (7.0 MHz, 3.0-mm depth) when treating the forehead to minimize any possibility of bone reflection, and no further incidences of PIH were noted. This illustrates the importance of not delivering microfocused ultrasound energy if bone is visualized in the treatment zone, especially when treating darker skin types.

This study demonstrated significant improvement in the décolletage 3 months after a single treatment and continued improvement 6 months after treatment. Given the improvement noted in this study, we recommend repeated treatments, as needed, scheduled at intervals no shorter than 6 to 12 months. Adverse events were limited to transient erythema and edema in all subjects. Only 1 patient developed indurated linear plaques corresponding to the lines delivered by the 7.0-MHz, 3.0 mm—depth transducer. These were thought to have developed from too much gel between the transducer and the skin, leading to delivery of the focal thermal points of coagulation more superficially than the intended preselected depth. The plaques resolved in 3 weeks.
with the immediate application of a class-I topical steroid and ice, and use of a class-V topical steroid twice a day for 2 weeks with intermittent massage.

CONCLUSION

This study demonstrated overall aesthetic improvement and lifting of the décolletage at 3 and 6 months after a single MFU-V treatment. Patient satisfaction was high and no serious adverse events were reported. Further studies are warranted to determine timing of additional treatments to optimize clinical outcomes in the décolletage and other body regions.

REFERENCES
