

Ultrasound Skin Tightening

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KEYWORDS

• Skin tightening • Skin lifting • Photo-rejuvenation • Ultrasound • Photoaging

KEY POINTS

- Skin laxity is a common sign of photoaging.
- Skin lifting and tightening is a desirable outcome by a most patients interesting in photorejuvenation.
- Noninvasive treatment options for skin tightening and skin lifting are limited.
- Intense focused ultrasound has been shown to provide skin lifting and tightening, making it the only device approved by the Food and Drug Administration for this indication.
- Ultrasound is a safe and efficacious treatment for mild skin tightening and lifting.

INTRODUCTION

Photoaging of the face occurs in a semipredictable stepwise progression that includes both textural and pigmentary alterations to the skin. In the initial steps of skin aging, dynamic rhytides are evident in areas of skin movement; these eventuate into static rhytides. With further age, the skin, both facial as well as areas off the face, begin to develop laxity, which is often most evident in the jowls and submental skin. Photorejuvenation of the skin, in its optimum, should therefore address all of these components of the aging skin. Traditionally, various energy-delivery devices were used to treat several components of skin aging, including rhytides, laxity, and dyschromia, such as ablative carbon dioxide or erbium:yttrium-aluminum-garnet devices, as well as treatments such as deep chemical peels and dermabrasion. These methods relied on ablation of the epidermis causing reepithelialization while delivering significant thermal injury to the dermis sufficient to stimulate a robust wound-healing response with subsequent collagen remodeling and contraction

leading to decreased rhytides, improvement in skin texture, skin tightening, and improvement in pigmentation. However, despite significant improvement in these skin characteristics and efficacy of these treatments, significant patient downtime, long and painful posttreatment healing, and substantial side effects were major drawbacks of these ablative procedures.

In recent years, multiple different treatment modalities have become available for treatment of skin wrinkling and laxity in a nonablative manner. These include lasers and light devices, infrared energy devices, and energy-based procedures, including radiofrequency ablation. These allow the use of thermal energy to target the reticular dermis and subcutis in an effort to cause tissue contraction and dermal remodeling while minimizing undesirable epidermal injury. As a result, “downtime” is minimized with expedient postprocedure healing, allowing for the patient to proceed with regular activities shortly after treatment, minimizing the necessity to interrupt a busy patient’s work or social schedule. Additionally, minimal epidermal injury allows for safer

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treatment among a wider range of skin types and reduces the risk of adverse events compared with either ablative resurfacing or more invasive surgical procedures, such as rhytidectomy. However, the drawback of these safer nonablative methods are that, relative to their invasive and ablative counterparts, the results are often modest, less reliable, and inconsistent duration of benefit. Individual variation in responsiveness to noninvasive skin tightening has also been significant. Ultrasound is an energy modality that can be focused and penetrates deeper in the tissue to cause thermal coagulation. Intense focused ultrasound (IFUS) for skin rejuvenation has been shown in recent studies to be safe and effective for skin tightening and lifting.

Ulthera System (Ulthera Inc, Mesa, AZ) is an IFUS device that delivers inducible energy to selected foci within the dermis and subcutis leading to the generation of heat and selective coagulative changes. The generated heat causes initiation of the tissue repair cascade in which the end result is a tightening effect of the skin. Results from several studies have led Ulthera to receive the first and only Food and Drug Administration approval for skin lifting, initially for eyebrow lifting in 2009, followed several years later with an approval for skin lifting of the neck and submentum. A unique added advantage to the use of ultrasound for skin rejuvenation is the direct visualization of the dermis and subcutaneous structures before treatment, which adds an extra level of safety to the treatment. Unfocused ultrasound energy can be used to image the treatment area while focused ultrasound energy can induce thermal injury of the mid to deep reticular dermis without damaging more superficial layers. Direct visualization allows for the identification of key anatomic structures and their depths and adapting the energy deposition to deliberate and precise locations in the dermis or subcutis. The device is particularly efficacious for treatment of patients with moderate laxity of the skin on the face for “lifting” of the eyebrow, neck, and submentum; however, recently it also has been used in various other locations and applications, including tightening of the skin of the buttock, décolleté, and other locations on the face, as well as for the treatment of acne and hyperhidrosis.

DEVICE PROPERTIES/TECHNOLOGY

Ultrasound is the sound wave frequencies above the range of human hearing (18–20 kHz). Ulthera operates at 4 to 7 MHz. The ultrasound imaging is adapted to the visualization of the first 8 mm of tissue, thus specifically allowing for imaging of

skin. The dual-modality ultrasound combines the capability of real-time imaging allowing visualizing below the skin’s surface and providing precisely placed “thermal coagulation points” (TCPs) at prescribed depths. This creates small micro-coagulation zones of 1 mm³ to 1.5 mm³, which cause thermal contraction of tissue. The subsequent wound-healing response results in collagen stimulation.

Ulthera Device

The Ulthera device consists of a central power unit, a computer, and interchangeable delivery handpieces. The same handpiece contains a transducer that enables sequential imaging (lower-energy ultrasound, allowing visualization of dermal and subcutaneous structures) and treatment (delivery of higher-energy ultrasound exposures). Multiple source settings can be controlled, including power output, exposure time, length of exposure line, distance between exposure zones, and time delay after each exposure.

The device initially had 3 handpieces:

1. Superficial: 7.5 MHz, 3.0-mm focus depth
2. Intermediate: 7.5 MHz, 4.5-mm focus depth
3. Deep: 4.4 MHz, 4.5-mm focus depth

Most recently, a 19-MHz transducer capable of producing focal TCPs at depths of 1.5 mm into the dermis was introduced to cause more superficial dermal neocollagenesis.

Human cadaveric tissues have demonstrated that penetration depth is determined by frequency, such that higher-frequency waves produce a shallow focal injury zone and lower-frequency waves have a greater depth of penetration to produce TCPs at deeper layers.¹

Each probe delivers the energy in a straight 25-mm line with TCPs 0.5 to 5.0 mm apart at a given depth within the tissue. Short pulse durations (25–50 ms) and relatively low energy (in the 0.4–1.2 J range), depending on the particular transducer, confine the TCPs to their target depth. The handpiece moves in a straight line at the set conditions (power, duration) and at the selective variables (length of treatment, spacing of exposures) to produce uniform tissue exposures for each “line” of IFUS treatment. Human cadaveric studies, as well as preclinical studies in porcine skin and prerhytidectomy excision skin have confirmed consistency in the depth, size, and orientation of TCP created by IFUS, in the subdermal soft tissue and deeper superficial musculoaponeurotic system (SMAS) layers, while preserving immediately adjacent soft tissue and structures.^{2–5}

The thermal injury is confined by keeping the pulse duration relatively short. Providing the energy delivered is not excessive for the given focal depth and frequency emitted by a given transducer, the epidermal surface remains unaffected. Therefore, the need for epidermal cooling is eliminated.^{3,4} Because the tissue is altered by arrays of small zones of focal damage rather than ablation of an entire macroscopic area, rapid healing occurs from tissue immediately adjacent to the thermal lesions. This is somewhat analogous to fractional laser ablation, except IFUS affects only the deep dermal and subcutaneous tissue.

The tightening effect of ultrasound treatment is based on coagulative heating of specific zones of the dermis and subcutaneous tissue. The ultrasound energy is focused, such that thermal coagulation occurs only where the sound waves meet at discrete separated TCPs. The size of the points varies based on the specific frequency and power settings used. This eventuates into nonsurgical tissue lifting without affecting the surface of the skin. Apart from ionizing radiation, ultrasound is the only type of inducible energy that can be delivered arbitrarily deeply into tissue in a selective manner. The treatment is programmable for various depths and spacing based on transducer selection with the variability of energy delivery in the actual treatment occurring only secondary to improper skin contact when the transducer is applied on the skin. For the more superficial treatment depth, the spacing between TCPs is closer. To avoid surface effect, less energy is applied when using the more superficial delivery of energy.

MECHANISM

Transcutaneous application of ultrasound into whole-organ soft tissue produces coagulative necrosis resulting primarily from thermal mechanisms.^{1,6,7} The ultrasound field vibrates tissue, creating friction between molecules, which absorb mechanical energy that leads to secondary generation of heat. Selective coagulative change is affected within the focal region of the beam, with the immediately adjacent tissue spared.²⁻⁵

In IFUS, energy is deposited in short pulses in the millisecond domain (50–200 ms). Avoiding cavitation processes, a frequency in the megahertz (MHz) domain is used with energy levels deposited at each treatment site being on the order of 0.5 to 10 J. It is estimated that the device heats tissue to 65°C to 75°C, the critical temperature at which collagen denaturation occurs with instigation of the tissue repair cascade. Precise microcoagulation zones deep in the dermis, as well as the superficial musculoaponeurotic

system, have been demonstrated.^{3,6} Suh and colleagues⁸ demonstrated histologic evidence that both dermal collagen and elastic fibers were significantly regenerated and increased in number, resulting in thickening of the reticular dermis with no significant change in the epidermis. The investigators concluded that it is via this dermal collagen regeneration that the rejuvenation of infraorbital laxity is achieved.

This microcoagulation is thought to cause gradual tightening of the skin through collagen contraction and remodeling. The onset of collagen denaturation with subsequent tissue contraction by 3 months, and the duration of clinical lifting responses lasting for about 1 year are similar to treatment with radiofrequency, ultrasonography, or laser energy sources.

INDICATIONS/APPLICATIONS

Results from several studies have lead Ulthera to receive the first and only Food and Drug Administration approval for skin lift, initially for eyebrow lifting in 2009, followed several years later with an approval for skin lifting of the neck and submentum. However, the applicability and indications have expanded in recent years with a multitude of studies exploring off-label use for skin tightening, as well as applying IFUS for treatment of other skin diseases.

The first clinical study in noncadaveric skin was performed by Alam and colleagues.⁹ Thirty-five subjects were treated and evaluated for safety and efficacy of treatment. The investigators found 86% of the subjects achieved significant improvement 90 days after treatment as measured by blinded physician assessment. Photographic measurements demonstrated a mean brow lift of 1.7 mm at 90 days.

Chan and colleagues¹⁰ evaluated the safety of IFUS on skin tightening in 49 Chinese subjects. All of the treated subjects underwent full-facial and neck treatment with no oral analgesia or topical anesthetics. The investigators reported more than half of the treated subjects rated pain as severe and experienced only minor, transient adverse effects.

Suh and colleagues¹¹ evaluated 22 Korean subjects (Fitzpatrick skin types III–VI) after full-face treatment.

- All treated subjects reported an improvement with 91% demonstrating improvement in objective score values at the nasolabial fold and jaw line. The average objective score of nasolabial fold and jaw line improvement was 1.91 (rated on a subjective scale where 1 = improved and 2 = much improved).

- Subjectively, 77% of the subjects reported much improvement of nasolabial folds, and 73% reported much improvement of the jaw line. The average subjective scores of nasolabial fold and jaw line improvement were 1.77 and 1.72, respectively.

Skin biopsies obtained from 11 subjects at baseline and 2 months after treatment confirmed an increase in reticular dermal collagen and dermal thickening, with elastic fibers appearing more parallel and straighter than pretreatment specimens.

Lee and colleagues¹² evaluated multipass IFUSs in a study in which 10 subjects were treated on the face and neck with the 4-MHz, 4.5-mm probe first, followed by the 7-MHz, 3.0-mm probe. The investigators reported an 80% improvement by blinded physician assessment and 90% reported subjective improvement 90 days after treatment.

Suh and colleagues⁸ treated 15 subjects with a single pass to the lower infraorbital region with a 7-MHz 3-mm transducer and demonstrated objective improvement in all study subjects and subjective improvement in most (86%) of the subjects treated.

Alster and Tanzi¹³ first reported the efficacy of IFUS on body sites. Eighteen study subjects were evaluated using paired areas on the arms, knees, and medial thighs where dual-plane treatment with the 4-MHz 4.5-mm-depth and 7-MHz 3-mm-depth transducer was compared with single-plane treatment with the 4-MHz 4.5-mm-depth transducer alone. Global assessment scores of skin tightening and lifting were determined by 2 blinded physician raters and graded using a quartile grading scale. At the 6-month follow-up visit, significant improvement was seen 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 a single-plane treatment in all 3 sites, potentially secondary to more superficial dermal collagen remodeling. The investigators also demonstrated high patient satisfaction, reporting 13 of the 16 patients were “highly satisfied” with the procedure and opted to undergo similar focused ultrasound treatment of different facial and body areas after the conclusion of the study.

Sasaki and Tevez¹⁴ studied efficacy of IFUS for multiple indications. Using the new 19-MHz 1.5-mm superficial transducer, they treated 19 subjects in the periorbital region with 45 lines on each side, and an additional 45 lines using the 7-MHz 3-mm as the second depth over the orbital

rim. A single treatment produced an average elevation between 1 and 2 mm (7%–8% increase from baseline) in each of the 19 subjects. Periorbital skin tightening was rated as moderate between a 3-month and 6-month period. Beneficial effects were noted as early as 6 weeks (particularly eyelid and periorbital skin) but most subjects appreciated a smoothing and tightening effect between 3 and 6 months. Observed responses lasted about 6 months to 1.5 years. Body sites treated in this study included brachium (44), periumbilicus (6), décolletage (5), knee (4), buttocks (2), inner thigh (1), and hand (1). Treatment protocols varied according to skin thickness at the treated location. Blinded evaluator assessment scores revealed moderate improvement in the periorbital area, inner brachium, periumbilicus, and knees. Improvement was less consistent in the inner thighs, décolletage, hands, and buttocks.

In a larger series of pilot studies and clinical investigations, which in total included 197 patients, Sasaki and Tevez¹⁵ compared horizontal and vertical vectors in the brow and marionette regions while maintaining constant depth and energy. Vertical vectors produced significant lifting over horizontally placed treatment lines. The investigators also showed that significantly greater lifting was achieved at sites with more treatment lines and higher joule energy.

Recently reported studies and presentations at scientific meetings have demonstrated the growing number of investigations under way evaluating the applicability of IFUS for a multitude of treatment sites as well as expanding list of indications. Data also have been presented supporting the use of IFUS for wrinkling around the knee,¹⁶ tightening of the neck,¹⁷ tightening of the décolletage,¹⁸ and lifting of the buttock.¹⁹ Additionally, IFUS is being explored for the treatment of axillary hyperhidrosis²⁰ and acne. Successful treatment of silicone lip deformity using IFUS also has been described.²¹ The same group also used IFUS to control edema and shape the nasal skin after rhinoplasty.²²

PATIENT SELECTION

Patients who would be good candidates are those wishing to avoid surgical facelift but would like treatment of skin laxity. The ideal patient for nonsurgical tissue tightening displays mild to moderate skin and soft tissue laxity. Preferably, patients should be nonsmokers and not obese and ideal candidates should not have major sagging or excessive photoaging, as their ability to create collagen in response to thermal injury may be inadequate.

Additionally, younger patients would be better suited for the thermal energy treatment, as they should possess collagen fibers of optimal quantity and size as well as the most advantageous fiber orientation to allow maximal thermal absorption. Moreover, younger patients tend to have a more robust wound-healing response. Severe aging, tissue heaviness, and fullness would also negatively impact results, as it may impede the lifting effects after thermally induced collagen shortening.

IFUS is safe across all skin types. Suh and colleagues¹¹ was the first to demonstrate safety and efficacy of IFUS in Asian skin (Fitzpatrick skin type III–VI). The few absolute contraindications include active infection or open skin at the treatment site, cystic acne, and pregnancy. Relative contraindications include medical conditions and/or medications that alter or impair wound healing.

Of paramount importance before treatment is setting realistic expectations for patients. A patient with unrealistic expectations of treatment would be a relative contraindication to treatment, as the clinical improvements are often subtle, with most studies demonstrating mild to moderate improvement, unlike that of surgical treatment options. It is helpful to have good photography obtained before and following treatment, as well as a detailed discussion of expected results, limitations, and potential for no appreciable clinical improvement.

TECHNIQUE/TREATMENT PROTOCOL

General

The depth of treatment, and therefore probe to use for a specific area, is dictated by the thickness of the skin at the treatment site, such that areas of thinnest skin (ie, neck and periocular area) should be treated with superficial depth probes, whereas cheeks and submentum should be treated with deepest depth probes followed by additional treatment with a superficial probe. Initial treatments had lower density of lines placed at just one depth.

There has been a growing trend toward the targeting of multiple depths of TCPs to affect collagen at multiple treatment planes for enhancing the efficacy of treatment.^{13–15} With dual-depth treatment, with the deeper plane treated first, a higher concentration of treatment lines can be delivered in uniform matrices in the targeted anatomy.

Topical skin care products, such as topical retinoids and alpha and beta hydroxyacids, should be discontinued about 2 weeks before treatment. Patients should be advised not to apply facial creams, lotions, powders, and foundations on the treatment day. All metal facial jewelry should be removed. Patients with a history of viral

infections should be placed on prophylactic antivirals 2 days before and 6 days after the procedure. Before treatment, the skin is cleaned of any facial products, makeup, or sunscreen. Each treatment region is outlined with a planning card to determine the number of treatment columns. Next, ultrasound gel is applied to the target site, and the selected transducer is placed firmly on the skin and activated, taking care to ensure that the entire transducer is evenly coupled to the skin surface. The ultrasound gel may need to be reapplied frequently to ensure proper tissue imaging and coupling. The correct placement of the ultrasound probe is confirmed on the screen as acoustic coupling can be visualized on the ultrasound images. Focal depth also can be visualized on the monitor in the ultrasound image and depending on the probe used and targeted site, this can be lined up with the corresponding layer of the deep dermis to SMAS. A parallel linear array of ultrasound pulses is manually delivered with minimal spacing. The total number of lines placed in a treatment area will depend on the size of the treatment area and particular parameters chosen with up to 600 to 800 lines of ultrasound pulses for a full face treatment. Caution should be exercised (and treatment avoided) over soft tissue augmentation material and implants, over the thyroid gland, and inside the orbital rim (currently, there are no commercially available eye shields that have been shown to effectively block ultrasound energy). Following completion of treatment, the ultrasound gel is removed and an emollient cream applied. Patients may return immediately to their usual activities. Medical skin care regimens can be resumed within 1 week.

Pain

Individual published reports of pain in response to the treatment range from mild to severe. Sufficient pain management is important to affect the overall treatment experience for the patient. The specific type of pain control varies based on physician preference. MacGregor and Tanzi²³ report using a combination of oral anxiolytics (5–10 mg of diazepam) and intramuscular narcotics (50–75 mg meperidine) 20 to 30 minutes before treatment to alleviate discomfort in most patients. Other investigators have described a variety of methods of pain control, including use of high-dose nonsteroidal anti-inflammatory drugs, narcotics (oral or intravenous), anesthetics (topical or local injection), conscious sedation, distracting massages, and cold techniques.²⁴ Logically, the higher energy and deeper probe is associated with increased pain. According to Sasaki and Tevez,¹⁵

the most patients who received treatment to the midface and neck did not require a local nerve block or lidocaine, whereas patients treated on the forehead/brow may require local anesthesia or nerve blocks because of the thinness of tissues overlying the frontal bone. Moderate to significant intraoperative pain was experienced most commonly to the décolletage, brachium, knee, and periumbilical sites.¹⁴

Safety

In general, IFUS has a good side-effect profile, with most side effects being temporary. Side effects include minimal pain, transient erythema, edema, and purpura, which are typically minimal and not persistent. Uncommonly, striated linear skin patterns occur and spontaneously resolve within a few weeks but also can be treated with high-potency topical steroids.

The most concerning complication in the immediate posttreatment period of IFUS is motor nerve paresis. This complication is limited to case reports.²³ The areas at the greatest risk for injury are locations in which the branches of the facial nerve take on a superficial course, namely the temporal branch of the trigeminal nerve at the temple as well as the marginal mandibular nerve at the jawline. Symptoms typically occur within the first 1 to 12 hours posttreatment, likely secondary to nerve inflammation. Complete resolution is expected in 2 to 6 weeks.²³ In patients who notice facial muscle twitching during treatment, the area should be iced immediately and consideration given to an anti-inflammatory medication. Sasaki and Tevez¹⁵ reported 3 patients who developed transient dysesthesia (numbness or hypersensitivity) to the deep branch of the supraorbital nerve that lasted for 3 to 7 days, and 4 patients developed numbness along the mandible after treatment on the cheeks that resolved without sequelae 2 to 3 weeks after IFUS treatment.¹⁵

SUMMARY

IFUS delivers ultrasound energy to predetermined depths in the deep dermis and subdermal tissue, creating TCPs that cause subsequent neocollagenesis and tissue contraction, which leads to lifting and tightening of the skin over the ensuing months posttreatment. As the energy delivery is precisely focused, deeper and more superficial, as well as immediately adjacent, tissue is spared, contributing to a very good safety profile and allowing treatment of dark skin phototypes. Clinical parameters of treatment are always evolving to maximize effectiveness of treatment. Likewise, indications of treatments have expanded vastly

to include nonfacial skin tightening and experimental treatment of other dermatologic conditions, as well as treatments in various other medical fields.

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