

# Ultrasound Therapy for the Skin



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## KEYWORDS

- Ultrasound • Thermal injury zones • Facial rejuvenation • Noninvasive facial rejuvenation
- Skin laxity • Skin tightening • Skin lifting • Ulthera

## KEY POINTS

- Ultrasound therapy is a nonsurgical skin rejuvenation procedure, which induces controlled thermal injury in the tissue, stimulating the wound-healing cascade and neocollagenesis.
- Ultrasound energy can be focused to reach deeper tissues, including the superficial muscle aponeurotic system while sparing the epidermis, allowing for tissue tightening in a plane deeper than other skin resurfacing modalities and avoiding adverse effects of epidermal disrupting techniques.
- The ideal patient has mild to moderate laxity of the skin, desire a “lifting” effect of the eyebrow, submentum, and/or neck, and can be any Fitzpatrick skin type.
- Studies have demonstrated clinically significant improvement in brow lift and in skin laxity of the lower face and neck, with high patient-reported satisfaction.
- Treatments are well tolerated and adverse effects such as edema, erythema, ecchymosis, and post-inflammatory pigmentation are mild, short-lived, and self-limiting in nature.

## INTRODUCTION

Various changes occur to the aging face, from textural and pigmentary changes to the development of wrinkles and loss of volume and skin elasticity. As patients search for facial rejuvenation options, there is an increasing demand for less invasive and effective modalities with decreased recovery time. As such, the use of injectables and energy-based devices has become ever more popular. Although injectable neurotoxins and dermal fillers are most frequently used and help address dynamic rhytids and volume losses of aging, these options have little effect on skin laxity or rejuvenation.<sup>1</sup> In an attempt to close this gap, there has been an influx of minimally invasive skin rejuvenation treatments, broadly categorized as ablative skin resurfacing (ASR) or non-ablative skin rejuvenation (NSR).<sup>2</sup> In general, rejuvenation

by these modalities works by inducing thermal injury to the tissue to stimulate a wound healing response and subsequent collagen remodeling and contraction.

ASR modalities such as carbon dioxide (CO<sub>2</sub>) and erbium-doped yttrium aluminum garnet (YAG) lasers and treatments such as deep chemical peel and dermabrasion have been time-tested to provide significant results in treating superficial rhytides of the aging face. ASR options also target and ablate the epidermis, allowing for reepithelization and neocollagenesis. Subsequently, its use can be associated with prolonged and uncomfortable postoperative recovery as well as risk of scarring, infection, and pigment changes.<sup>3</sup> In addition, it is not for all skin types.

NSR alternatives work by selectively inducing controlled thermal injury within the dermis, but spare the overlying epidermis thus avoiding the

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undesirable post-procedural effects seen with epidermal disrupting techniques.<sup>2</sup> NSR modalities include options such as intense pulsed light, pulse dye laser, neodymium:YAG, radiofrequency (RF) heating. Although the rate of adverse effects is lowest with non-ablative options, improvements are often modest, inconsistent, and often require serial treatments over a 6 to 12 month period.<sup>4</sup>

To continue to meet the demand for a minimally invasive skin rejuvenation that also offers effective and consistent results, ultrasound as an energy modality for esthetic application soon entered the playing field as an NSR alternative. Similar to other NSR energy-based devices, therapeutic ultrasound also works on the premise of creating thermal injury to stimulate new collagen formation, leading to tightening and lifting of the skin. However, ultrasound energy can be tightly focused and offers deeper penetration in the tissue which allows higher temperatures to be reached, without injury to the more superficial tissues. Because of this, it has been found to be superior to other skin tightening technologies.<sup>5</sup>

## ULTRASOUND AS THERAPEUTIC MODALITY AND MECHANISM OF ACTION

Ultrasound energy is focused to a point in the tissue, generating molecular vibration leading to heat formation, up to 60°C to 65°C. At this temperature, collagen denatures followed by neocollagenesis.<sup>6</sup> Coagulative changes to the tissue occur within the focal region of the beam creating a well-defined thermal injury zone (TIZ) or thermal coagulation point (TCP).<sup>7</sup> The focal injured tissue undergoes the wound healing cascade with tissue contracture and collagen remodeling, leading to tightening and lifting of the skin. Suh and colleagues observed that dermal collagen and elastic fibers were regenerated in increased numbers and rearranged resulting in thickening of the reticular dermis and uninterrupted epidermis.<sup>4</sup> Clinical effect of the tissue remodeling may be seen by 3 months and results can last for about 1 year.<sup>7,8</sup>

High-intensity focused ultrasound (HIFU) has been used for the treatment of benign prostate hypertrophy and tumors of the liver, prostate, uterus, breast, and kidney. Its mechanism is through inducing tissue damage both by thermal injury and the cavitation process. In the esthetic arena, HIFU has been used for lipolysis, using both thermal action to cause adipocyte apoptosis and ultrasonic mechanical fat destruction through cavitation.<sup>9</sup> For facial esthetic use such as skin tightening and lifting, microfocused ultrasound (MFUS) is applied. Unlike HIFU, MFUS only uses the thermal effect due to lower levels of focused

ultrasound energy per unit area (0.4–1.2 J/mm<sup>2</sup>), higher frequencies (from 4 to 19 MHz), shorter pulse durations (50–200 ms), and focal depths of 1.5 to 4.5 mm.<sup>4,9,10</sup>

With these parameters of MFUS, energy can be precisely focused so a microscopically small volume of tissue (<1 mm<sup>3</sup>) can be thermally ablated, leaving surrounding tissue uninjured. This is in contrast to other thermal ablation techniques such as RF, where there is a volumetric heating effect with diffuse energy delivered to the dermis, but can also travel along connective tissue into the subdermis.<sup>4,11</sup> Rather than creating a macroscopic region of ablation, MFUS creates an array of focal damage with a segment of untreated tissue between two TCPs. Analogous to the concept of fractional ablative laser, the bridging undamaged tissue allows for a rapid healing response to the adjacent thermally injured areas.<sup>4,12</sup>

There are several other advantages of MFUS as an NSR alternative. Because MFUS uses a sharp focus of ultrasound beam into the tissue, the power density of the converging beams is much lower as it passes through the epidermis than its focal point. Consequently, there are minimal energy absorption and tissue heating at the epidermal level. This not only leaves the epidermis undamaged but also avoids the need for any skin cooling for epidermal protection that is often required for other energy-based devices that cause unexpected thermal changes within the skin.<sup>12</sup> Its tight focus of energy is also able to reach subdermal tissue of greater depths, such as the superficial muscle aponeurotic system (SMAS), allowing for tissue tightening in a plane deeper than other types of devices.<sup>13</sup> Last, the absorption of ultrasound energy is independent of chromophores or melanin content of the skin. Its absorption is instead determined by the microscopic and bulk mechanical properties of tissue.<sup>12</sup> Because ultrasound therapy does not target melanin or chromophores, it carries a lower risk of pigmentary changes in dark skin types compared with photo-based energy sources<sup>9</sup> and is safe for all skin types.<sup>4,9,11</sup> In a study of 49 Asian patients with Fitzpatrick skin types III and IV by Chan and colleagues, two patients experienced post-inflammatory hyperpigmentation, which fully resolved within 9 months of treatment.<sup>14</sup>

Intense ultrasound beam (IUB) is another ultrasound technology that has recently come into the esthetics market. Unlike MFUS which creates an elongated pinpoint TIZ perpendicular to the skin surface, IUB creates an elongated 3-dimensional (3D) cylindrically shaped TIZ parallel to the skin surface. The TIZ lies parallel to the direction of the collagen fibers, and therefore, the ensuing

collagen contraction creates vector lines of tightening along the direction of facial lines and wrinkles. Because of the geometric, volumetric cylinder shape of the beam, it generates fractional volumetric and directional thermal coagulation of the tissue.<sup>15,16</sup>

**DEVICE TECHNOLOGY**

The Ulthera system (Ulthera, Inc, Mesa, AZ) is MFUS technology that received Food and Drug Administration (FDA) approval for noninvasive eyebrow lift in 2009, submental and neck lift in 2012, and the improvement of lines and wrinkles of the décolleté in 2014.

The Ulthera system consists of a control unit, a central processor with monitor, and a handpiece with four interchangeable transducers. The handpiece is dual functioning with a transducer capable of high-resolution ultrasonography imaging, using lower energy ultrasound, to provide visualization of the targeted tissue up to a depth of 8 mm (Fig. 1). This allows for visualization of dermal and subcutaneous structures before initiation of energy delivery for enhanced safety.

The control unit allows for adjustment of power output, exposure time, length of exposure line, distance between exposure zones, and time delay after each exposure. The interchangeable transducers come with varying focal depths and frequencies.

- A 1.5-mm focus depth, 10 MHz (source energy 0.25 J), newest available transducer, which targets more superficial dermis
- A 3.0-mm focus depth, 7.5 MHz (source energy 0.4–0.63 J): targets dermis
- A 4.5-mm focus depth, 7.5 MHz (source energy 0.75–1.05 J): targets subdermal tissues, including SMAS
- A 4.5-mm focus depth, 4.4 MHz (source energy 0.75–1.2 J): targets subdermal tissues, including SMAS



**Fig. 1.** Ulthera handpiece with interchangeable transducer (4 MHz, 4.5 mm treatment depth transducer shown). (Photo courtesy of Merz Aesthetics/Ulthera.)

Tissue penetrance and frequency are indirectly related. Therefore, the lower frequency of the 4 MHz transducer can provide a more robust and deeper treatment depth compared with the 7 MHz transducer at a 4.5 mm focus.<sup>1</sup> The 4 MHz transducer can be used for treatment of the deeper fibromuscular layer of the cheek and jawline. The 3.0 and 1.5 mm transducers deliver less energy and target the reticular dermis, allowing for more superficial treatments that can be used on more sensitive locations with thinner skin such as the forehead and temples.<sup>1,6</sup> Each firing of the device delivers energy in a 25 mm line, creating 17 to 22 TCPs, spaced 1.1 to 1.5 mm apart.<sup>1</sup> Multiple exposure lines are placed 2 to 4 mm apart.

The Sofwave system (Sofwave Medical, Inc, Tustin, CA) is another ultrasound device that has received FDA clearance for improvement of facial fine lines and wrinkles in 2019 and lifting of the eyebrow, submentum, and neck in 2021. It additionally has a new clearance for the treatment of cellulite in the lower body. The Sofwave device uses IUB or synchronous ultrasound parallel beam technology. The device handpiece consists of seven transducers, each 4.5 mm × 1 mm, delivering high-intensity, high-frequency ultrasound energy as seven parallel beams, creating an array of 3D cylindrically shaped TIZ in the mid-dermis (Fig. 2). These coagulated columns of tissue lie parallel to the skin surface along the long axis of the transducers and parallel to the direction of



**Fig. 2.** Sofwave handpiece with parallel beam technology. (Photo courtesy of Sofwave™.)

the collagen fibers.<sup>15</sup> Most of the thermal effect is localized between 0.5 and 2 mm of the dermis, with treatment centered at a depth of 1.5 mm, thereby treating only the mid-dermal layer. Each pulse of Sofwave is equivalent to about 7 to 8 lines of Ulthera. Because of the volumetric effect of the beams, 28% of the mid-dermal tissue is covered in a single-treatment, two-pass procedure.

The handpiece also contains an integrated active cooling mechanism that continuously measures the skin temperature in real time to provide feedback-controlled skin cooling to protect the epidermal layer.<sup>15,16</sup>

### **Comparing Ulthera Versus Sofwave**

The Ulthera system consists of multiple interchangeable hand pieces to target different tissue layers, whereas the Sofwave system consists of a single-hand piece to target a single-tissue layer, the mid-dermis. As such, the Ulthera device has ultrasound imaging to visualize and verify the appropriate targeted tissue layer and underlying deep structures as a safety measure to avoid injury to critical structures. In contrast, the Sofwave device does not have or require ultrasound imaging as its treatment is limited to a depth of 2 mm and therefore pose no risk of injury to underlying bone, fat, or nerves. Although both technologies boast minimal patient discomfort, Sofwave is less painful compared with Ulthera due to Sofwave's more superficial treatment depth. The ability to target the collagen-rich mid-dermal layer was not feasible with Ulthera until their release of the 1.5 mm transducer. With Ulthera, it should be noted that technique becomes more of a critical component when dealing with shallower tissue planes to prevent possible adverse effects.<sup>17</sup> Because of its synchronous beam technology and larger contact surface area of the probe, treatment times with Sofwave are shorter, approximately 30 to 45 minutes for the full face and neck.<sup>15</sup> Depending on the provider experience, patient tolerance, and treatment surface area, treatment times for full face and neck with Ulthera are generally less than 90 minutes (30–60 minutes for the face and 30–45 minutes for the neck).<sup>8</sup> In regard to pricing for the practice, Sofwave has pulse consumables, as price per pulse. Ulthera has a consumable fee for each transducer probe, where each probe has a useable lifespan of about 2100 lines and would require replacement after.

### **TECHNIQUE**

Before treatment, the skin is cleaned, medicated with topical anesthetic, and the treatment areas defined and marked with a planning card. Treatment

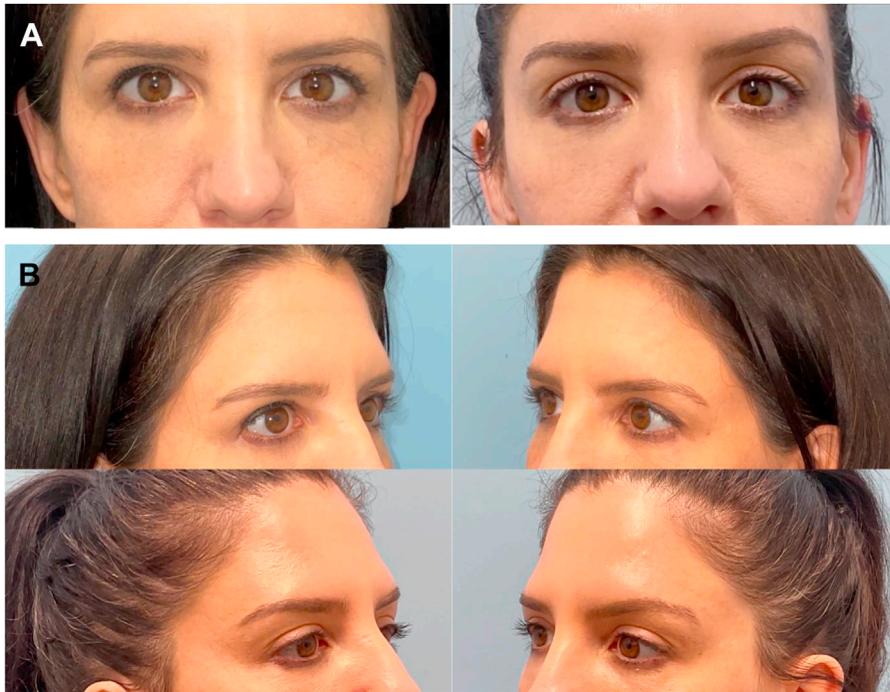
areas can include the cheek, periorbital areas (outside the orbital rim), brow, and neck. The depth of treatment and therefore selection of transducer to use for a specific area is determined by the skin thickness of the treatment site. Next, ultrasound gel is applied to the target site and the selected transducer is placed perpendicular and firmly to the skin. With the Ulthera device, the correct placement of the ultrasound probe is verified through ultrasound images on the monitor. The treatment is typically completed at two depths, with one pass of the 4.5 mm transducer for deeper penetration, followed by the 3 or 1.5 mm transducer for more superficial penetration.<sup>18</sup> With the exception of the infraorbital region, where the tissue is thin, treatment is completed only at the superficial focal depth.<sup>1</sup> The thyroid and the orbital area should be avoided.<sup>6</sup> A full-face treatment consists of 600 to 800 lines for best results.<sup>7,8</sup> With the Sofwave device, there is no verification with ultrasound imaging. Treatment similarly consists of two passes.

### **PATIENT SELECTION**

As with any procedure, patient selection and establishing realistic expectations are important components of the treatment process. The ideal patient for noninvasive tissue tightening has mild to moderate laxity of the skin on the face and desire a “lifting” effect of the eyebrow, submentum, and/or neck. Patients who are concerned about risk and recovery and are willing to accept moderate efficacy in exchange for minimal risk are ideal candidates for non-ablative modalities. Factors such as the patient's age, extent of photo-damage, and smoking may adversely affect collagen remodeling.<sup>6</sup> Younger patients tend to have greater results as they typically have a more robust healing response and better inherent skin elasticity.<sup>1</sup> Improved treatment outcomes have been shown to correlate with patient age, body mass index (BMI), skin type, and immune response.<sup>9</sup>

### **PRETREATMENT AND POSTTREATMENT**

Pain associated with the treatment can be variable. Patient rated their pain as severe after a single-pass treatment in the absence of topical anesthetic in 54.4% of treatment sessions.<sup>14</sup> Different areas of the face have differing levels of sensitivity: the eyebrow and periorbital area were associated with greater pain (5.7 of 10) than that of the face (3.7 of 10) and neck (3.6 of 10).<sup>19</sup> In addition, the submental and submandibular areas are more sensitive than cheeks, possibly due to thinner tissue and proximity to bony prominences.<sup>11</sup>



**Fig. 3.** A 45-year-old woman with eyebrow lift results from a single treatment of Sofwave at 6 weeks follow-up. (A) Before/after frontal images. (B) Before/after lateral images.

To enhance patient comfort, many methods have been attempted to mitigate pain, including oral nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, oral narcotics, oral anxiolytics, topical anesthetics, inhaled nitrous oxide and oxygen systems, anesthetic nerve blocks, and distraction techniques. In addition to oral NSAIDs or acetaminophen before treatment sessions, the lowest feasible energy setting should be used based on patient tolerance.<sup>3</sup> Topical lidocaine and narcotic analgesia were found to be superior to NSAIDs when user deeper transducers, but had no improvement in pain when using the 1.5 mm transducer.<sup>20</sup> One group shared that they have garnered positive patient experience with a combination of 30%

topical lidocaine and oral ibuprofen or intramuscular ketorolac.<sup>6</sup>

After completion of the treatment, the ultrasound gel is cleaned and an emollient cream is applied.<sup>6</sup> Patients are typically educated on the expected posttreatment effects of mild erythema and edema and are discouraged from vigorous exercise for 3 to 5 days.<sup>21</sup> Any evidence of edema from the treatment typically subsided within 7 to 10 days.<sup>11</sup> Patients may resume their normal skincare regimens, and no specific aftercare is needed.

### COMPLICATIONS

Pain associated with treatments is the most commonly reported adverse effect associated



**Fig. 4.** A 51-year-old woman with submental and neck lift results from single treatment of Sofwave at 2 weeks follow-up. Before/after lateral images.



**Fig. 5.** A 54-year-old woman with submental lift results from single treatment of Ulthera at 3 months follow-up. Before and after lateral images. (Courtesy of Dr Jennifer Levine, New York, NY.)

with MFUS. Posttreatment adverse effects include edema, erythema, ecchymosis, transient facial asymmetry, and post-inflammatory pigmentation and are self-limiting in nature.<sup>4,14,22,23</sup> In a review of 307 patients who underwent facial MFUS treatments, the most commonly reported events were transient erythema and edema posttreatment.<sup>22</sup> Other events include wheals or striations likely secondary to inadequate coupling of the transducer to the skin.<sup>22</sup> Rare events include post-inflammatory hyperpigmentation due to the use of the 4.5 mm transducer where there was insufficient tissue depth ( $n = 2$ ) and paresis ( $n = 1$ ).<sup>22</sup> In a single-center study in Paris, France, all 233 patients experienced temporary (<1 hour) erythema posttreatment, and 7 patients had continued erythema 12 to 24 hours posttreatment. In the same cohort, six patients had edema lasting 3 days, eight experienced continued pain that did not interfere with social activities, and six experienced transient numbness.<sup>22</sup>

### CONTRAINDICATIONS AND LIMITATIONS

MFUS is a well-tolerated procedure; few contraindications have been documented in literature.<sup>24</sup> Absolute contraindications include infection or open skin lesions at the proposed treatment areas, active severe or cystic acne, electric implants, or metallic implants. Relative contraindications

include treatment directly over keloid, implants, dermal fillers, or patient health indications that would impair healing and smoking.<sup>11,25</sup>

MFUS and IUB are limited to patients with mild to moderate skin sagging and wrinkling. Those with severe sagging and wrinkling would more likely benefit from surgical face-lift procedures.<sup>21,26</sup> Patients with severe sagging were more likely to be nonresponders to MFUS.<sup>26</sup> In addition, MFUS was less likely to be successful in patients with BMI higher than 30 as demonstrated by Oni and colleagues, in which no change was detected in 54.5% of patients whose BMI exceeded 30 kg/m<sup>2</sup> or in 12.2% of patients whose BMI was  $\leq 30$  kg/m<sup>2</sup>.<sup>11</sup>

### RESULTS IN LITERATURE

The efficacy of MFUS has been well-documented and demonstrated in clinical practice. Kerscher and colleagues demonstrated that at day 3 posttreatment, skin temperature remained in the physiologic range, with stable transepidermal water loss, hydration, and erythema.<sup>24</sup> Suh and colleagues in a cohort of 11 patients assessed histologic changes after one-single treatment. Based on the skin biopsy of these 11 patients, 2 months after treatment, they found that skin after treatment greater dermal collagen with thickening of



**Fig. 6.** A 30-year-old woman with submental lift results from single treatment of Ulthera at 3 months follow-up. Before and after lateral images. (Courtesy of Dr Jennifer Levine, New York, NY.)

the dermis and straightening of elastic fibers in the reticular dermis.<sup>4</sup>

Clinically, Suh and colleagues found that in 22 patients, 77% reported much improvement of nasolabial folds.<sup>4</sup> Oni and colleagues demonstrated in 93 patients in a blind reviewer study that there was observed improvement in skin laxity in 58.1% of patients. In those patients, at day 90, 65.6% of patients perceived improvement in the skin laxity of the lower half of their face/neck.<sup>11</sup> In a 36-subject blind rater prospective cohort study, Alam and colleagues demonstrated that there was clinically significant brow lift, with a mean elevation in eyebrow height of 1.7 mm ( $P = .00001$ ) at 90 days after treatment.<sup>27</sup> Lee and colleagues in 10 patients demonstrated that two treatment passes with a 4-MHz, 4.5-mm probe was used first, followed by the 7-MHz, 3.0-mm probe yielded 80% clinical improvement 90 days after treatment based on two blinded clinician assessments and 90% subjective improvement.<sup>18</sup>

Subjectively, patients report high satisfaction with treatment results. Montes and colleagues in a survey of 52 patients who underwent lower face and submental MFUS demonstrated that half of patients undergoing MFU-V were Very Satisfied or Satisfied with their results and a large number reported their treatment outcome met or exceeded their expectations. Fifty percent believed they looked 1 to 15 years younger and 73% would recommend the treatment to others.<sup>28</sup>

A multicenter study of 58 subjects treated with IUB technology on the face and neck found an improvement of 1 to 3 Elastosis Score units in 86% of subjects using the Fitzpatrick Wrinkle and Elastosis Scale for perioral and periorbital regions. Surveys also demonstrated that 72% noted improvement in wrinkle appearance. No device-related adverse events were reported.<sup>15,16</sup> Examples of clinical results with Sofwave for eyebrow lift (**Fig. 3**) and submental lift (**Fig. 4**) are shown. Examples of clinical results with Ulthera for submental lift (**Figs. 5 and 6**) are shown.

## SUMMARY

Ultrasound energy can be delivered to the dermal tissues, while sparing the epidermis, to induce thermal injury and subsequent collagen remodeling, leading to a lifting and tightening effect of the skin. The results are apparent, consistent, and reproducible with significant changes both at the histologic and clinical level. Boasting high patient satisfaction rates, minimal recovery time, and an excellent safety profile, ultrasound modalities serve as an attractive option for patients with mild to moderate laxity of the skin looking

for noninvasive facial rejuvenation in the eyebrow, submentum, and/or neck region. As a relatively newer modality with ongoing research, ultrasound technology is an effective, nonsurgical option for facial rejuvenation available in our armamentarium that will continue to evolve and expand in its clinical applications.

## CLINICS CARE POINTS

- The ideal candidate for ultrasound therapy for facial rejuvenation is patients who have mild to moderate laxity of the skin on the face and desire a nonsurgical “lifting” effect of the eyebrow, submentum, and/or neck.
- Careful patient selection and management of expectations are essential to achieving a satisfied patient.
- Because ultrasound is not chromophore-dependent, it is safe for all Fitzpatrick skin types.
- The Ulthera system can target various tissue depths between 1.5 and 4.5 mm and uses in-unit ultrasound imaging to verify targeted tissue depth and underlying structures, whereas the Sofwave system targets the mid-dermis up to 2 mm with no need for ultrasound imaging.
- Both the Ulthera and Sofwave systems require two passes for each treatment, with the exception of treatment of thinner-skinned periorbital area, which only require one pass with the Ulthera system.
- Pain associated with the treatment is well tolerated and patients do well with a combination of topical anesthetics and oral NSAID.

## DISCLOSURE

Dr J.D. Bloom is a consultant, advisory board member, speaker's bureau member, trainer and clinical investigator for Galderma and Allergan. He is also a consultant, advisory board member, speaker's bureau member and trainer for Revance Aesthetics. Dr A. Wong and Dr A.S. Lowery have no disclosures.

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