The Use of Ultrasound in Aesthetics: Review and Update

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BACKGROUND

Over the years, a variety of medical devices have been developed and investigated for clinical use in aesthetics. Various modalities have utilized light and laser sources, radiofrequency, cryotherapy, plasma, and ultrasound. This paper will review the science and development behind ultrasound technology and also provide an update on the latest available technology.

TREATMENT GOALS

In order to counteract many of the clinical effects of aging, the goal is to increase the formation and amount of new collagen and elastin in the skin, which can be accomplished through stimulating neocollagenesis and neoelastogenesis. Favorable aesthetic treatments should predictably, safely, and effectively injure the skin in a controlled manner in order to trigger this regenerative response. The rejuvenated skin can clinically appear smoother, firmer, and more youthful.

Energy sources that can be safely controlled and targeted to the desired location offer promise. Intense pulsed light (IPL), lasers, non-invasive and invasive radiofrequency, plasma, cryotherapy, and ultrasound technologies are all currently being utilized. These devices can vary tremendously, including in device design, handpiece configuration, and level, density, and depth of the energy being delivered. Treatments can be sub-coagulative, coagulative, or ablative.

With many energy-based treatments, the associated discomfort as well as the duration of downtime generally increase with treatment intensity. The long- term regenerative effects can also vary proportionally. Each cosmetic physician must carefully balance treatment experience, side effect profile, and clinical outcomes with patient goals and preferences. Since the expectations of both patients and physicians can often differ, this has likely contributed to the wide range of devices available on the market today.

With the regular use of devices in real-time clinical practice, some devices may subsequently become less popular with both patients and physicians. They can later be found to be associated with undesirable results or even unacceptable pain, downtime, side effects, and/or cost. Therefore, the aesthetic market continues to search for newer and improved devices.

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Ultrasound technology represents one of the energy sources utilized by aesthetic devices. Although its early introduction was relatively successful in the short-term, first-generation devices may have fell short of patient and physician expectations and now become less popular. However, a new-generation device has recently been introduced that overcomes many of the original shortcomings. This particular device has been demonstrated to safely and effectively treat fine lines and wrinkles.

SCIENCE OF ULTRASOUND

In most applications, ultrasonic waves are generated by a transducer, which includes a piezoelectric crystal that converts electrical energy (electric current) to mechanical energy (sound waves). For over a century, ultrasonic waves have been useful to measure sizes and distances and to detect objects by comparing the reflectance of the waves.

With particular transducer designs (hemispherical surface) and proper choice of frequency, ultrasound waves of high intensity can become focused. When absorbed in tissue, they can induce thermal injury and cause tissue coagulation. This type of therapeutic ultrasound, high-intensity focused ultrasound (HIFU), has been developed to coagulate cancer lesions deep in the body.

A key benefit of using ultrasound for thermal injury of the skin is that energy absorption is not dependent on a particular chromophore, as is the case with lasers. This ensures that the technology will be color-blind. The injury created is a function of the energy absorbed in the tissue without regard to tissue variations that can cause inconsistency as with light-based technologies. The injury can be contained within the targeted zone, and if there is no epidermal injury, then there is also more limited downtime.

DESIGN CONSIDERATIONS

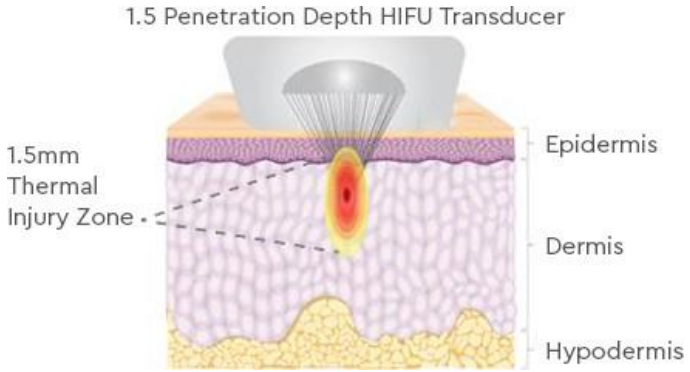
There are many considerations when determining the best modality to optimize clinical outcomes for cutaneous rejuvenation. Sub-coagulative tissue injury does not typically produce the maximal outcomes for skin rejuvenation. Additionally, ablative technologies can create wounds that are associated with increased procedural risks and substantial downtime.

When heated to above 55°C, tissue in the skin can begin to coagulate, which is influenced by the duration of exposure. The degree of coagulation ultimately determines the clinical outcomes. Too little, and the effect will not be as noticeable; too much, and the risks can reach unacceptable levels. If 20-30% of the skin is coagulated without epidermal damage, a noticeable improvement in skin laxity may be safely achieved.

The depth of the targeted injury is an important consideration. The treatment goal is for the skin to appear clinically firmer, smoother, and wrinkle-free. Therefore, the coagulation must be delivered at a depth in the dermis that can deliver these results. It is also important to know if topical anesthesia can offer patient comfort at the intended target depth.

EARLY TECHNOLOGY

In 2009, an early device was introduced that utilizes a HIFU beam to lift lax skin and treat lines and wrinkles. As is the case with HIFU-based technology, the absorbed energy induces an elongated zone of thermal injury taking the approximate shape of an ellipsoid. This ellipsoid has its long axis perpendicular to the skin surface, and with this particular device, its length is approximately 2mm.



Each pulse of ultrasound energy produces one elongated thermal injury zone that is perpendicular to the surface. By moving the transducer in the handpiece along the surface of the skin, a series of these ellipsoid zones can be created to form one line. To cover the desired treatment area, the handpiece is moved from one site to the next, and numerous lines are needed to achieve the desired coverage. This results in a lengthy procedure.

Since the elongated zones are perpendicular to the skin surface, the thermal injury may be centered in the mid dermis, but the upper edge can heat both the upper dermis and epidermis. This can contribute to increased procedural pain and risk for epidermal damage. Centering the injury at deeper depths (3-4.5mm) may also result in fat atrophy and injury to blood vessels, nerves, and bones. In many cases, the pain involved with these treatments often requires more aggressive anesthetic options, such as nerve blocks or sedation.

EARLY OUTCOMES

The original HIFU device was cleared by the FDA for lifting of the neck, chin, and brow. The basic principle that ultrasound waves can create enough coagulation to lift lax skin was well-established in earlier studies. Initially, there was an early and wide adoption of this technology.

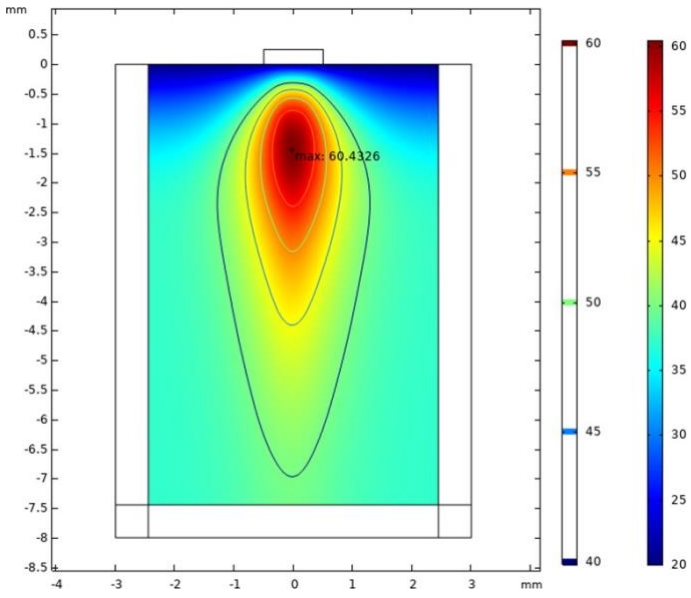
NEW GENERATION TECHNOLOGY

Building on the proven ability of ultrasound technology to coagulate significant volumes of skin, a newer approach was taken to design a novel device that could meet today's rigorous aesthetic demands.

Key design objectives included:

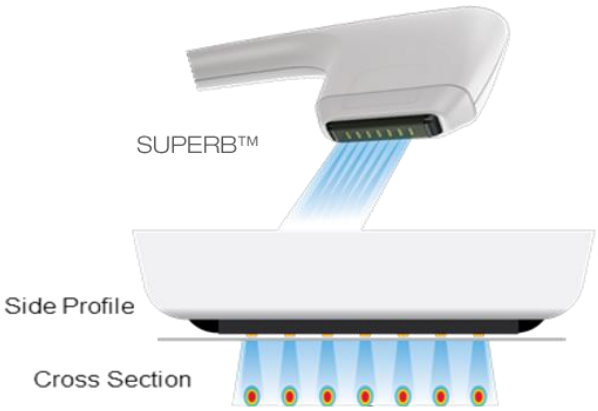
- Larger spot sizes for greater coverage and shorter procedures
- Mid-dermal targeting that can optimally treat fine lines and wrinkles without injury to the epidermis
- Seamless incorporation of feedback-controlled skin cooling to ensure patient safety, protection of the epidermis, and confinement of the thermal zones to the targeted areas
- Feedback mechanisms to control energy deposition in a repeatable, predictable, and consistent manner
- High ease of use and general compatibility with other common aesthetic procedures, such as soft-tissue fillers and IPL

A new-generation ultrasound device, Sofwave™, was developed to utilize a Synchronous Ultrasound Parallel Beam Technology (SUPERB™), which uses 7 parallel transducers that are in direct contact with the skin in order to deliver coagulative energy to the mid dermis, while protecting the skin surface with cooling. The high-intensity, high-frequency, parallel beams allow most of the thermal injury to remain localized at depths of 0.5-2mm, with the treatment centered at 1.5mm. Targeting of this depth can treat fine lines and wrinkles, while avoiding damage to more superficial and deeper structures.



A thermal heat map of the skin during treatment demonstrates cooling at the level of the epidermis with a defined zone beneath that consists of high enough temperatures to cause controlled tissue coagulation and subsequent tissue remodeling.

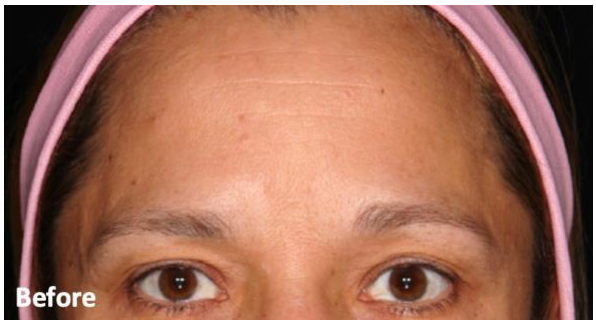
As the parallel beams propagate the tissue, an array of volumetric, cylindrical-shaped thermal zones is created. These coagulated columns lie parallel to the skin surface along the long axis of the transducers. Since all 7 of the transducers are triggered at the same time, a relatively high amount of energy can be delivered at once into the mid dermis to increase tissue temperatures to 60-70˚C. At these temperatures, tissue remodeling occurs via collagen contraction with subsequent neocollagenesis and neoelastogenesis.

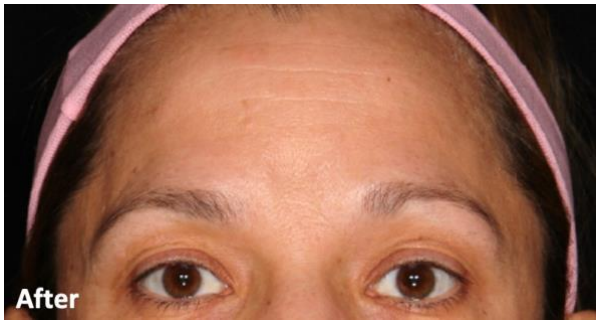


NEW OUTCOMES

Studies have demonstrated improvements in fine lines and wrinkles following tissue coagulation of the mid dermis, which can be located at a depth of 1.5mm on the face. A protocol was recently developed for use with the Sofwave™ device to treat the entire face, which can be completed within 30-45 minutes.

A recent study was conducted at 2 U.S. sites, led by Drs. Roy G. Geronemus and Arielle Kauvar. A total of 58 subjects completed the study, which included darker skin types. Subjects were treated once with the Sofwave™ device on the face and neck. Two blinded reviewers were in agreement in identifying the pre- and post-treatment photographs correctly for 78% of subjects. There was an improvement of 1-3 Elastosis Score (ES) units in 86% of subjects using the Fitzpatrick Wrinkle and Elastosis Scale for perioral and periorbital regions. Overall, 72% of subjects noted improvement in wrinkle appearance, and the majority were satisfied. There were no device-related adverse events reported throughout the study. In addition to this high degree of efficacy with a single treatment, there was minimal downtime for all subjects.





Before and After (3 Months) Single Treatment (Courtesy of Roy G. Geronemus, MD)

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FUTURE DIRECTIONS

Clinical studies are currently in the process of being completed to evaluate the Sofwave™ device for a variety of clinical applications and body sites. The ability to target the mid dermis using a novel high- intensity, high-frequency ultrasound energy to cause controlled coagulation offers immense promise for both cosmetic patients and physicians. Another important consideration is the option to pair this treatment with other modalities to optimize patient outcomes and increase practice revenues.

CONCLUSION

The delivery of ultrasound energy of sufficient intensity to coagulate tissue can provide significant improvements in fine lines and wrinkles. A new- generation ultrasound device, Sofwave™, has been demonstrated to offer clinical improvements and shows promise in the field of aesthetics.

DISCLOSUREs

Jordan V. Wang, MD, MBE, MBA, Author received grant from **sponsor.**