

Energy-Based Treatments for Aging Skin: 2020 Update

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BACKGROUND

As our skin ages, the collagen and elastin within begins to slowly break down over time, which results in loss of elasticity and volume. This can clinically become apparent as wrinkles, rough texture, and laxity, which are associated with an aged look. The gold standard for treatment has been and likely remains the use of ablative technology--either full field or fractional--which removes a volume of tissue plus coagulation of an area around the ablated field. This damaged tissue is eventually replaced with newer collagen and elastin. However, the downtime and risks that are associated with ablative technologies are not acceptable to many patients and providers. As patient interest and indications have now expanded to those who are younger and have less skin damage to treat, ablative treatments can often times be excessive. Because of this, a wide range of devices have been introduced to satisfy this high patient demand and need for alternative devices.



AESTHETIC MARKET

As the awareness and popularity of cosmetic treatments have greatly increased due to the rise in social media, celebrity endorsements, and widespread media coverage, the aesthetic market has witnessed an equally dramatic growth. In response, the depth and breadth of providers have also increased in order to meet this demand. Recently, a staggering number of medical spas have entered the aesthetic market to compete with plastic surgeons and cosmetic dermatologists, who have traditionally dominated the field. These facilities typically have most of their treatments performed by nurses and nurse practitioners. Each practice must make specific decisions as to which services to offer and which patient demographics to specifically target, which determines how they competitively position themselves within the crowded marketplace. This has inevitably increased the market for aesthetic devices so that physicians can meet growing consumer needs.

Below are excerpts from the 2019 Plastic Surgery Statistics Report provided by the American Society of Plastic Surgeons (ASPS), which represents reliable and commonly utilized industry data.

Description	2019 Procedures
Injectables (botulinum toxin and soft-tissue fillers)	10,419,267
Laser skin resurfacing	596,755
Non-surgical skin tightening	334,351
Intense pulsed light (IPL) treatment	685,755
Laser hair removal	1,055,456
Non-invasive fat reduction	386,557

The number of aesthetic practices in the U.S. is estimated to be 40,000. Meanwhile, plastic surgeons, dermatologists, and otolaryngologists combine to represent at best 15,000 sites, which is less than 40%. Statistics indicate that over 12 million anti-aging procedures are performed each year. With per-treatment prices often ranging \$500-6,000, anti-aging devices have high potential for return on investment (ROI).

ANTI-AGING TECHNOLOGIES

Over the years, a wide range of devices have been introduced for anti-aging treatments with varying degrees of success. They can be characterized according to below:

Surface treatments: The skin surface can be injured to relatively shallow depths through the use of microneedles, pins, or electrodes. Although easy to manage, the amount of tissue damaged must be carefully controlled in order to prevent complications, such as scarring and dyspigmentation.

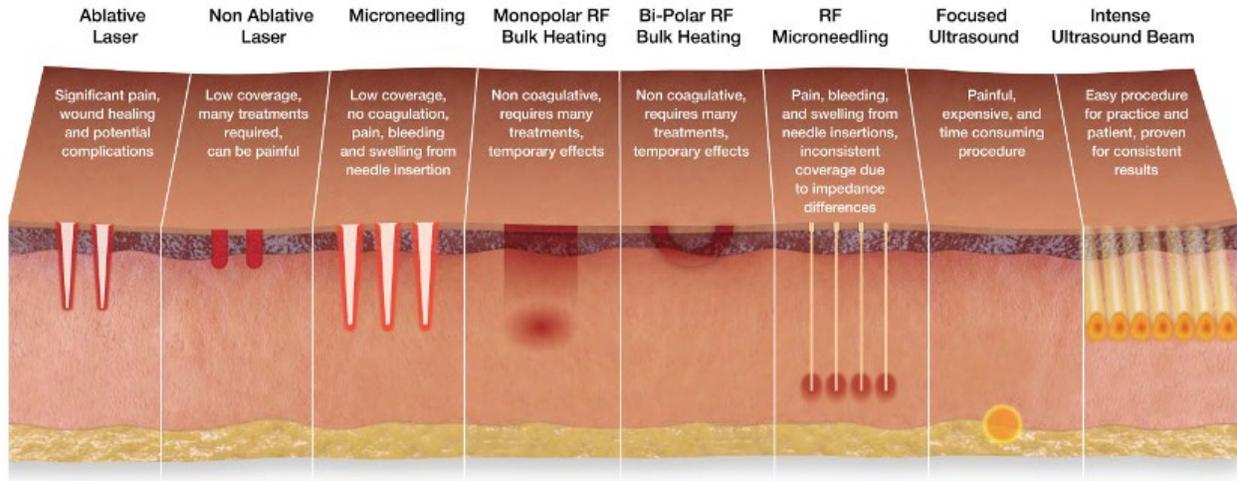
Bulk heating to sub-coagulative temperatures: If the dermis is heated to below 57°C, the result will be some degree of denaturing and short-term effects, but with only suboptimal stimulation of new collagen and elastin. These technologies require several treatments to sustain the effects, which often slowly diminish once treatments are halted.

Fractional ablative and non-ablative coagulation: Lasers can create columns of coagulation or ablation in the skin, with the depth limited by the selected wavelength and energy. Due to involvement of the epidermis and limited depth of penetration, the volume/density of coagulation or ablation must be carefully controlled in order to manage pain, downtime, and adverse events, especially in darker skin types. Non-ablative technologies may require several treatments.

Targeted fractional coagulation that bypasses the epidermis: The coagulation bypasses the epidermis and is placed directly in the dermis through the use of needles or deep tissue targeting. The limiting factor can be intense pain, swelling, or bleeding that accompanies procedures. Although, the epidermal layer is not thermally affected, there can be mechanical injury due to the use of needles, which may limit their use in darker skin types. Other concerns include the time required to visualize outcomes and the lack of concurrent treatment of epidermal conditions.

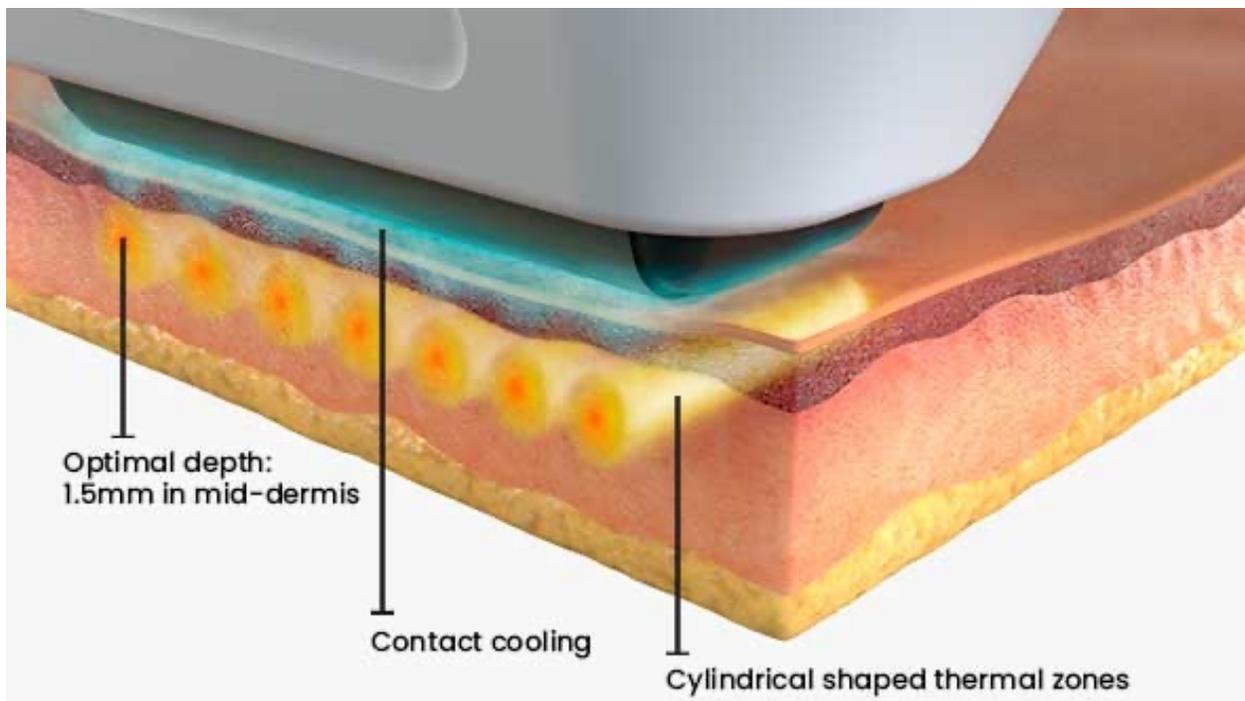
Ultrasound energy can be used to heat dermal tissue and can be targeted to depths in the mid or deep dermis. Please see footnote for more information.[#]

[#]Use of Ultrasound to Treat Aging Tissue: Review and 2020 Update. Sofwave white paper. 2020.



● INTENSE ULTRASOUND BEAM TECHNOLOGY

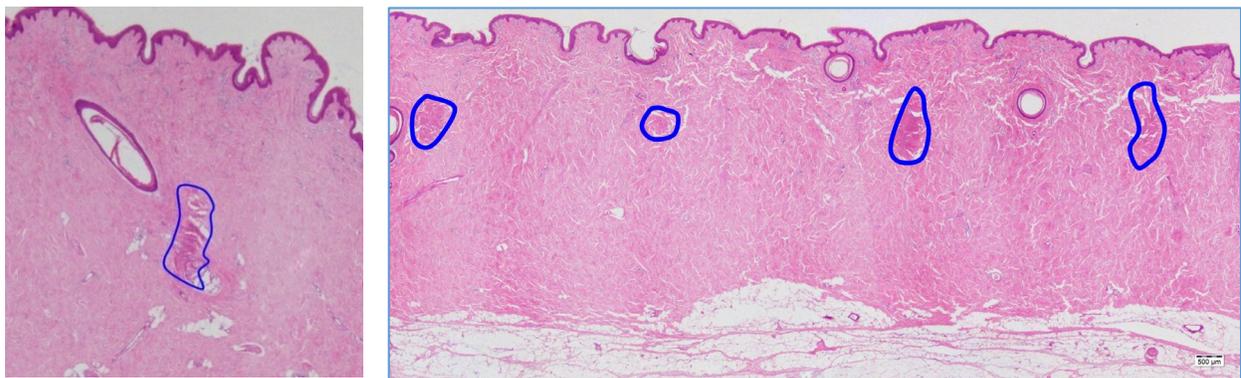
A new-generation ultrasound device--Softwave™--has been developed to treat anti-aging conditions. Using a proprietary technology that generates an Intense Ultrasound Beam™ (IUB), the device emits a high-intensity, high-frequency, parallel ultrasound array through seven transducers that are in direct contact with the skin. The high-frequency, parallel beams allow the majority of the thermal effect to remain localized between 0.5-2mm within the dermis, with the center of the treatment effect at a depth of 1.5mm.



The applicator's proprietary solid-state energizer module, which holds the seven ultrasound transducers, allows for direct contact of the transducers to the skin. The direct contact integrates surface cooling and real-time temperature monitoring to provide for epidermal

protection, accurate targeting of the thermal effect, and optimal pain management. The parallel delivery of ultrasound beams and the large contact area allow for low sensitivity to tissue inhomogeneity, which ensures uniform and repeatable effects in the tissue.

As the parallel beams propagate the tissue, an array of volumetric, cylindrical-shaped thermal zones is created, which generates a fractional Volumetric and Directional Thermal Impact™ (VDTI). These novel, three-dimensional thermal effects lie in parallel to the skin surface along the long axis of the transducers. Since all seven transducers operate simultaneously, relatively high energy can be delivered at once into the mid dermis, which causes the tissue temperature to increase to 60-70°C. This produces an inflammatory cascade with subsequent collagen remodeling, involving neocollagenesis and ne elastogenesis. Importantly, the multiple elongated thermal zones lie in parallel to the direction of the collagen fibers and altogether, can cover at least 25% of the mid dermal layer in a single treatment. Collagen contraction creates vectors of tightening along the direction of facial lines and wrinkles, leading to restoration of natural skin appearance.



Histologic samples of Intense Ultrasound Beam™ coagulation zones from Sofwave™ (left) and at progressively higher energies (right).

COMBINATION TREATMENTS

Patients typically desire treatment of multiple skin conditions, including photodamage and skin laxity. Unsurprisingly, patients would like as many of these issues addressed in a single visit as possible, and in most cases, multiple devices may be needed. A practice can differentiate itself by promoting its ability to effectively combine devices into a total treatment package unique to that patient. Therefore, desired features of devices are its ease of use and its ability to be combined with a wide range of injectables and other devices. A device, such as Sofwave™, offers minimal effects to the epidermis and subdermis, which would allow for combination treatments.

PURCHASING PEARLS

It can be challenging for any practice to determine which devices and treatments best fit them. However, there are a few basic questions that are helpful to ask before making any purchase.

- 1) *Has the device been validated to work in a properly designed clinical study by credible investigators?* No matter how new or hyped a technology may be at first glance, a poorly

performing device will negatively impact the practice in both the short- and long-term. Many devices and technologies are often marketed ahead of the science and data behind them. Highly satisfied patients are more likely to return for additional treatments. A high-performing device can lead to improved patient outcomes, satisfaction, and retention rates.

- 2) *Do the before-and-after photographs contain all of the relevant data, including treatment parameters, number of treatments, and follow-up duration? Is the photograph from a trusted physician? Are there enough photographs to indicate consistent results?* All devices are presented to potential buyers using their best before-and-after photographs. Unfortunately, they can often come from unknown or untrusted sources, or even withhold the relevant treatment information that is important to know. Anyone evaluating the purchase of the device should request a wide range of photographs containing complete information from respected and known physicians in the cosmetic field.
- 3) *During device evaluation, are the parameters used the same as the ones in the before-and-after photographs and available studies?* Devices are often tested in training and evaluation settings that are often organized by the company representative. These training sessions can be influenced and biased to demonstrate simple and easy treatment procedures that produce low pain scores on those who are tested. Therefore, the practice may not truly understand the true pain response or real-time clinical outcomes that are associated with settings that will eventually be used on a consistent basis.
- 4) *Do the physician referrals reflect your own practice needs? Have they used the device long enough to know how it works in their own practice?* It is critical to confirm that the physician referrals come from similar practice environments to your own, especially in terms of patient demographics and procedural demand. It is important to ensure that the device has been used for several treatments over a considerable length of time in order to understand how patients are responding in real-time clinical practice.
- 5) *Is the device cleared by the U.S. Food and Drug Administration (FDA) for treatments expected to be of primary use?* Many aesthetic devices are promoted to physicians for off-label use to treat several cosmetic conditions. A device should be purchased bearing in mind the treatment indications that are approved by the FDA, including from 510(k) clearance. The scope of FDA clearance can also shed light on the degree of scientific evidence and controlled clinical studies that support the safety and efficacy of the device. This can help the practice to properly forecast the patient demand and value of the device.

CLOSING REMARKS

Although there are several anti-aging treatments that are available, there still remains a substantial opportunity to incorporate new and improved devices. Countless practices currently do not perform as many procedures as they wish at the profitability that they desire. Fortunately, the introduction of Sofwave™ uniquely meets the needs of today's practices without the limitations and issues found with several other devices available on the market today.