A novel approach to treating wrinkles and laxity of the face and neck using Intense Ultrasound Beam, Ruthie Amir, MD

Introduction

As skin ages, the collagen and elastin in the skin start to break down, resulting in loss of elasticity and volume. The result is wrinkles, poor texture, laxity, and an overall aged look. The gold standard for energy-based treatment was the use of ablative technology (whether full field or fractional) that removes a volume of tissue plus coagulation of an area around the ablated area that is replaced with healthier, younger looking tissue. However, the downtime and risks associated with ablative technologies is not acceptable to the vast majority of patients and providers. In addition, as patients and indications have expanded to those younger and with less damage to treat, ablative technologies are overkill for most patients. There are also indications such as acne scars, stretch marks, and other off face areas that can be addressed with remodeled collagen and elastin that would not be good candidates for ablative technologies.

A wide range of alternatives have been introduced for anti-aging treatments with a varying degree of success including:

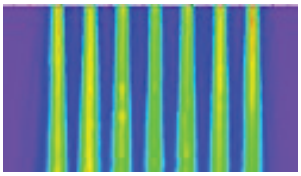
1. Bulk heating to sub coagulative temperatures. Bulk heating technologies require multiple treatments to generate an effect and to sustain it and minimal long-term results are seen once the treatments are stopped.
2. Fractional ablative and non-ablative coagulation – Typically using a laser at a wavelength with high water absorption (such as CO^2 and ErYag), columns of coagulation or ablation are created in the skin, from the epidermis to the depth limited by the wavelength and power used and which is typically at a depth of less than 1mm in the dermis. Because of the inherent treatment complexity, injury of the epidermis and shallow penetration, the volume/density of coagulation or ablation must be carefully controlled per treatment to manage pain and the recovery period. Non-ablative fractional technologies require multiple treatments and are not very different from the bulk heating methods.
3. Targeted fractional coagulation that bypasses the epidermis – Using either RF with insulated microneedles or ultrasound to deliver energy directly into the dermis and/or sub-dermis and create selectively targeted coagulation resulting in a significant lifting effect and reduction of deep wrinkles. Still the use of RF needles is associated with significant injury to the epidermis and is associated with significant patient down-time.

While there are many anti-ageing treatments performed with many satisfied patients, in general there remains a substantial opportunity for improved devices. Most practices do not perform as many procedures as they wish at the profitability they wish due to one or more of the following factors: 1) Unpredictability of results 2) Insufficient degree of improvement (not enough tightening for example) 3) Painful procedure, anesthesia options not desirable 4) Excessive downtime 5) Complex and lengthy procedure that can be performed only by the doctor resulting in very high price for the patient 6) Equipment difficult to use and/or maintain 7) Equipment not able to treat all the variety of patients and conditions they want to treat.

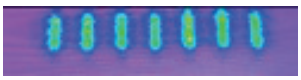
Intense Ultrasound Beam Technology

A new generation ultrasound device has been developed to treat fine lines and wrinkles. Using a proprietary technology that generates an Intense Ultrasound BeamTM (IUB). The device emits an array of high intensity, high frequency, parallel ultrasound beams generated by multiple transducers which are in direct contact with the skin. The high frequency, parallel beams enable the majority of the thermal effect to remain localized between 0.5 and 2mm within the dermis, with the center of the treatment effect at a depth of 1.5mm.

IUB beam profile



Side Profile



Cross section

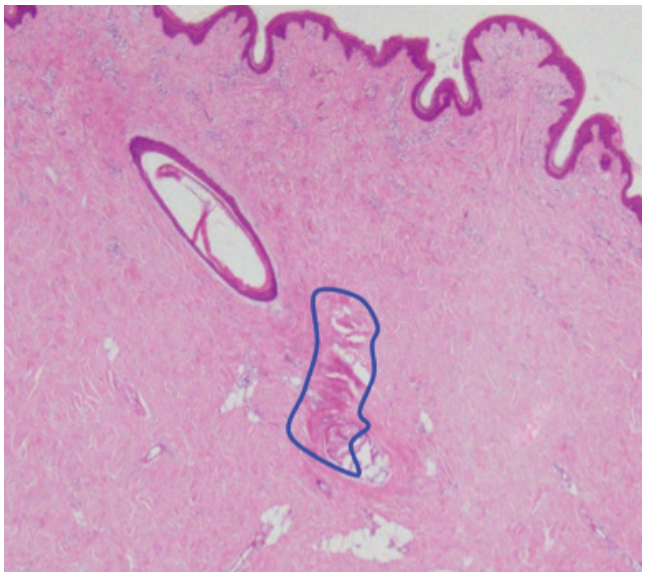
The applicator's proprietary solid-state energizer module which holds the multiple ultrasound transducers, allows for direct contact of the ultrasound transducers to the skin. This unique direct skin contact enables the integration of cooling and real-time temperature monitoring for excellent epidermal protection, accurate targeting of the thermal effect and optimal pain management. Additionally, the unique solid-state energizer module located in the hand piece, is robust and highly reliable with no moving parts, or optics.

IUB Handpiece

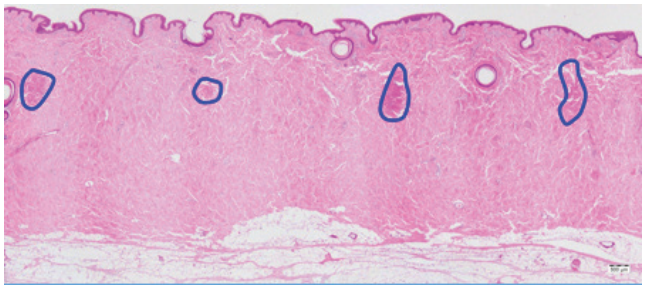
The unique low divergence, high intensity beam eliminates the need for the beam to be focused, and the high ultrasound frequency causes thermal energy to dissipate rapidly at depth of more than 2mm, thus leaving the underlying structures of nerves, facial fat and bones, unaffected. The parallel delivery of ultrasound beams and the large contact area allow for low sensitivity to tissue inhomogeneity. This ensures a uniform effect in the tissue and a repeatable, controllable energy deposition in the skin.

It is important to distinguish IUB technology from HIFU. IUB parallel ultrasound beam is less sensitive to scattering by skin inhomogeneity since the power density is generated by the transducer directly with no need to focusing which depends on tissue acoustic properties; the use of high power focused US beam for targeting the 1.5mm depth is practically impossible without potential risk of damaging the epidermal layer due to the 2mm elongated thermal zone lying perpendicular to the skin surface. Furthermore, since IUB transducers are in direct contact with the skin, an active integrated cooling mechanism continuously measures skin temperature and protects the epidermal layer. HIFU transducers are extracorporeal to the skin and the intermediate coupling media that is essential to their use does not allow for cooling or energy control mechanisms to be implemented.

As the parallel beams propagate the tissue, an array of volumetric cylindrical shaped thermal zones are created, thereby creating a fractional Volumetric and Directional Thermal Impact™ (VDTI). These unique geometric 3D elongated cylindrically shaped thermal effects, lie in parallel to the skin surface along the long axis of each of the transducers. Since all transducers operate simultaneously, relatively high energy is delivered at once into the mid-dermis, causing the tissue temperature to increase to 60-70˚C, leading to inflammatory response and eventually to collagen remodeling involving neocollagenesis and neoelastinogenesis. Importantly, the elongated thermal zones lie in parallel to the direction of the collagen fibers. Collagen contraction creates vector lines of tightening along the direction of facial lines and wrinkles leading to restoration of the natural skin appearance.



IUB Coagulation zone



IUB coagulation zones at progressively higher energies

Methods

A multi-center IRB approved clinical study was conducted at NY Laser Skin Care (Principal Investigator Arielle Kauvar), and Laser Skin Surgery of New York (Principal investigator Roy Geronemus), to evaluate Intense Ultrasound Beam Technology to treat facial and neck lines and wrinkles. Patients received a single full face and upper neck treatment under topical anesthesia and were followed up to 12 weeks post treatment. Primary effectiveness endpoint included masked evaluation of patients' images with correct identification of the post treatment images and based on improvement in Fitzpatrick Classification and Degree of Elastosis Scale of at least one-unit (1-point elastosis degree reduction), as agreed by two blinded reviewers. Additional effectiveness endpoints were investigator assessments of patients' improvement based on wrinkle reduction (using Fitzpatrick Classification and Degree of Elastosis Scale) and based on the Global Aesthetic Improvement Scale (GAIS; a 5-point scale from very much improved to very much worse) as well as patients' self-assessment of improvement and patient satisfaction.

Results

Sixty patients were enrolled with 58 completing the study across the two sites, including 10 patients with Fitzpatrick skin type IV-VI.

The results demonstrate that the blinded reviewers identified correctly the pre- and post-treatment photographs for 78% (45/58) of the treated subjects (based on the agreement of two blinded reviewers) and assessed a reduction of at least 1 Elastosis Score (ES) unit using the Fitzpatrick Wrinkle and Elastosis Scale. Investigators assessed 88% to be improved to very much improved with 86% of the patients showing improvement of 1, 2, or 3 Elastosis Score (ES) units. The patient satisfaction questionnaire showed that 42/58 (72%) of subjects noted improvement in wrinkle appearance. See figure 1 for an excellent result in reducing wrinkles of the neck. Figure 2 shows significant improvement of jowl laxity. Investigator Assessment of the Improvement Rates in Wrinkle Appearance at 12- week FU is shown in the following table:

	Number of Subjects	Rate %
Worse	0	0%
No change	7	12%
Improved	29	50%
Marked Improvement	19	33%
Very much improved	3	5%
Total	58	100%

The clinical study also demonstrated an excellent safety profile for the IUB technology. Throughout the study, no device related adverse events were reported. No subject withdrew from the study due to pain or discomfort and now down-time was recorded by the patients following the treatment.

Single treatment 3 months follow up

Figure 1

Single treatment 3 months follow up

Figure 2

Discussion

The novel Intense Ultrasound Beam device presented in this paper has been shown to be safe and effective in a large multi-center study from two of the leading aesthetic research sites in the US. A single treatment demonstrated significant improvement in wrinkle reduction and skin tightening with an excellent safety profile, zero downtime and high patient satisfaction. The study results were used by the sponsor to obtain FDA clearance for the treatment of lines and wrinkles. Given that the usability of any device should be a key consideration of any purchase, additional benefits of the IUB technology as experienced by both practices' hands are its ease of use and treatment time. The device proved to be exceptionally easy to use, a very steep learning curve and with a typical treatment time of less than 40 minutes required for a full face and upper neck treatment which very practical in fits well with the requirements of busy aesthetic practices.

Conclusion

A new generation ultrasound device is now available for sale and use in the United States and has proven safe and effective in a multi-site clinical trial. This novel technology will likely become the preferred anti-aging device among discriminating aesthetic practices.

Disclosures

Both investigational sites received grants from the Sponsor and free use of the device for the study.

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