A novel approach to treating fine lines and wrinkles of the face using Synchronous Ultrasound Parallel Beam Technology SUPERB™

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INTRODUCTION

As skin ages, the collagen and elastin in the skin begin to break down, which results in loss of elasticity and volume. This can clinically translate into wrinkles, irregular texture, laxity, and an overall aged appearance. 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 are not always acceptable to the vast majority of patients and physicians. There are also indications, such as acne scars, stretch marks, and other off-face areas, that can be addressed with remodeled collagen and elastin and would not be good candidates for ablative technologies.

A wide range of alternatives has been introduced for anti-aging treatments with varying degrees 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 (e.g. CO2, Er:YAG), columns of coagulation or ablation are created in the skin from the epidermis to the depth limited by the wavelength and power used, which is typically 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 in order to manage pain and downtime. Non-ablative fractional technologies require multiple treatments and are not very different from the bulk heating methods.

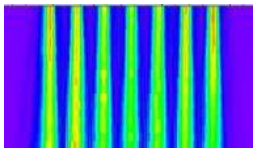
3. Targeted fractional coagulation that bypasses the epidermis. Using either radiofrequency (RF) with microneedling or ultrasound to deliver energy directly into the dermis and/or sub-dermis can create selectively targeted coagulation. However, the use of RF microneedling is still associated with injury to the epidermis.

Although there are several anti-aging treatments performed with many satisfied patients, there remains a substantial opportunity in the field for improved devices. Most practices do not perform as many procedures as they wish at the profitability they desire due to one or more of the following factors: (1) Unpredictability of results, (2) Insufficient degree of improvement, (3) Painful procedure or anesthesia options that are not desirable, (4) Excessive downtime, (5) Complex and lengthy procedure that can be performed only by the physician resulting in very high prices for patients, (6) Equipment that is difficult to use and/or maintain, and (7) Equipment that is not able to treat all of the diverse patients and conditions that are needed to be treated.

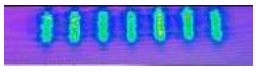
SYNCHRONOUS ULTRASOUND PARALLEL BEAM TECHNOLOGY SUPERB™

A new-generation ultrasound device has been developed to treat fine lines and wrinkles using proprietary technology that generates Synchronous Ultrasound Parallel Beams (SUPERB™ Technology). The device emits an array of high- intensity, high-frequency, parallel ultrasound beams, which are generated by multiple 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.

SUPERB™ Profile



Side Profile



Cross Section

SUPERB™ Handpiece

The applicator's proprietary solid-state energizer module, which holds the 7 individual ultrasound transducers, allows for direct contact to the skin surface. This unique direct skin contact enables the integration of cooling (Sofcool™ Technology) 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 handpiece has no moving parts or optics, which allows for high durability and reliability.

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 depths greater than 2mm, whichleaves 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 repeatable, controllable energy deposition in the skin.

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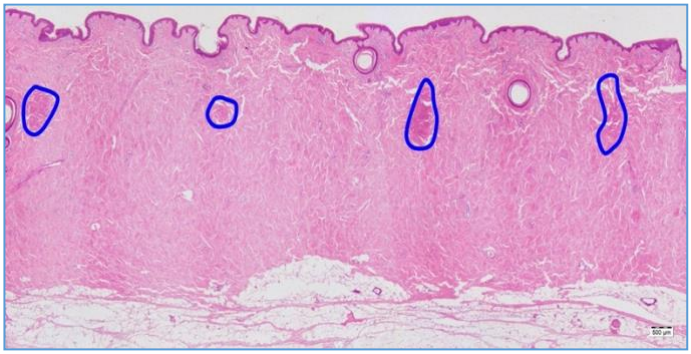
As the 7 parallel beams propagate the tissue, an array of volumetric cylindrical-shaped thermal zones is created. These unique geometric 3-D elongated thermal effects lie in parallel to the skin surface along the long axis of each of the transducers. Since all transducers operate simultaneously, relatively high energy can be delivered at once into the mid dermis, which causes tissue temperatures to increase to 60-70˚C. This creates an inflammatory response, which eventually leads to collagen remodeling involving neocollagenesis and neoelastogenesis. Importantly, the elongated thermal zones lie in parallel to the direction of the collagen fibers. Collagen contraction creates vector lines along the direction of facial lines and wrinkles.

SUPERB™ coagulation zone



SUPERB™ coagulation zones at progressively higher energies

METHODS

A multi-center, IRB-approved clinical study was conducted at Laser & Skin Surgery Center of New York (Roy Geronemus, MD) and New York Laser & Skin Care (Arielle Kauvar, MD) to evaluate SUPERB™ Technology in treating facial lines and wrinkles. Subjects received a single full-face treatment mostly under topical anesthesia and were followed up to 12 weeks post treatment. Primary effectiveness endpoints included blinded evaluation of subject photographs with correct identification of the post-treatment images and rating of improvement in Fitzpatrick Wrinkle and Elastosis Scale of at least 1 unit, as agreed upon by two blinded reviewers.

Additional effectiveness endpoints included investigator assessment of clinical improvement, patient self-assessment of improvement, and patient satisfaction.

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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 correctly identified the pre- and post-treatment photographs for 78% (45/58) of treated subjects (based on agreement of two blinded reviewers) and assessed a reduction of at least 1 unit using the Fitzpatrick Wrinkle and Elastosis Scale in 78%. Investigators determined 88% of subjects to be improved to very much improved and 86% to have improvement of 1-3 units using the Fitzpatrick Wrinkle and Elastosis Scale. The patient satisfaction questionnaire showed that 72% (42/58) of subjects noted improvement in wrinkle appearance. Figure 1 shows an excellent result in reducing wrinkles. Figure 2 demonstrates significant improvement

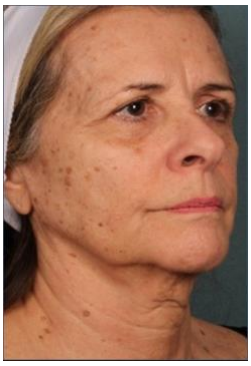
Investigator assessment of the improvement rates in wrinkle appearance at 12- week follow-up is displayed in the following table:

	Number of Subjects (N)	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 demonstrated no device-related adverse events by any subject throughout the study period. No subject withdrew from the study due to significant pain or discomfort, and investigators witnessed minimal post-procedural downtime.

(Figure 1) Single Treatment 3 Months Follow Up

Baseline



3 Months FU

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(Figure 2) Single Treatment 3 Months Follow Up

Baseline 3 Months FU

This novel device utilizing Synchronous Ultrasound Parallel Beam technology has been shown to be safe and effective in a large multi-center study from two of the leading aesthetic research sites in the United States. A single treatment demonstrated significant improvements in the reduction of fine lines and wrinkles with high patient satisfaction. The powerful study results were used by the sponsor to obtain FDA clearance for this device.

Given that the usability of a device should be a key consideration for any purchase, additional benefits of the SUPERB™ technology--as experienced by both practices' hands--are its ease of use and treatment time. The device proved to be exceptionally easy to use and quick to learn with a typical treatment time of less than 45 minutes for a full-face. This makes its use very practical, since it fits in well with the requirements of a busy aesthetic practice.

CONCLUSION

A new-generation ultrasound device is now available for sale and use in the United States, which has proven to be safe and effective in a multi-site clinical trial. This novel technology will likely become the preferred wrinkle reduction 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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