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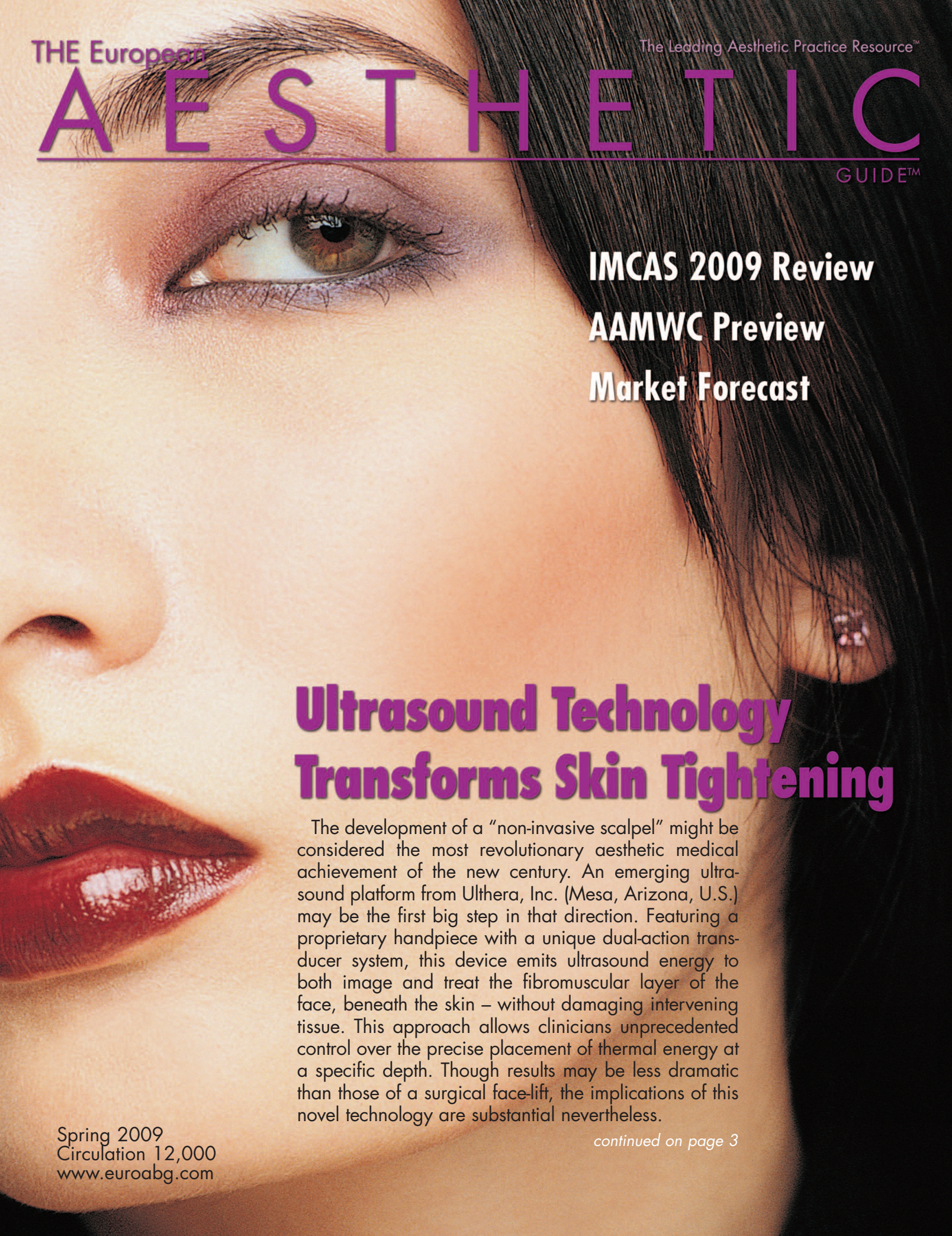

IMCAS 2009 Review
AAMWC Preview
Market Forecast

Ultrasound Technology Transforms Skin Tightening

The development of a "non-invasive scalpel" might be considered the most revolutionary aesthetic medical achievement of the new century. An emerging ultrasound platform from Ulthera, Inc. (Mesa, Arizona, U.S.) may be the first big step in that direction. Featuring a proprietary handpiece with a unique dual-action transducer system, this device emits ultrasound energy to both image and treat the fibromuscular layer of the face, beneath the skin – without damaging intervening tissue. This approach allows clinicians unprecedented control over the precise placement of thermal energy at a specific depth. Though results may be less dramatic than those of a surgical face-lift, the implications of this novel technology are substantial nevertheless.

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Novel Modality Unites Ultrasound Imaging and Treatment

By Kevin A. Wilson, Contributing Editor

Employing focused ultrasound to non-invasively lift and tighten soft tissue on the face, the Ulthera™ System from Ulthera, Inc. utilizes the same energy to both image and treat the skin and its underlying support structures. Intervening tissue, from the epidermis down to the point of treatment, is spared, providing for safe, accurate deposition of energy. The Ulthera technology platform is CE marked and currently marketed in Europe and Asia, with FDA clearance pending.

Patented DeepSEE® technology provides physicians a see and treat capability never before experienced in aesthetic medical instrumentation. Two specialized ultrasound modalities – one for imaging and one for emitting and focusing acoustic energy, to create a thermal effect beneath the skin, are combined into one transducer.

"The Ulthera System represents a new category of non-invasive aesthetic modalities," said R. Rox Anderson, M.D., director of the Wellman Center for Photomedicine (Boston, Massachusetts, U.S.) and professor of dermatology at Harvard Medical School (Cambridge, Massachusetts, U.S.). "Ultrasound technology gives clinicians unprecedented control of thermal damage at a clearly specified depth in tissue. This approach can achieve outstanding safety and consistent efficacy when compared with previous technologies for dermal treatments."

R. Rox Anderson, M.D.
Director
Wellman Center for Photomedicine
Boston, MA, USA

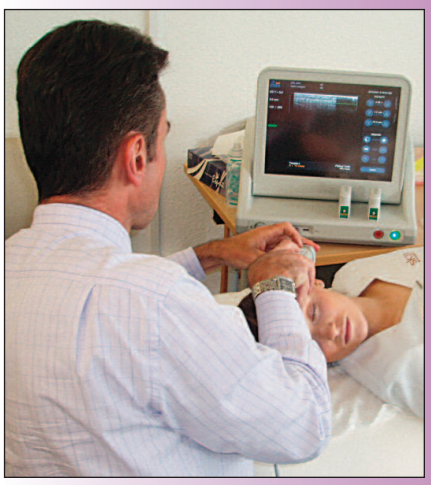
According to Jason Pozner, M.D., plastic surgeon and medical director of Sanctuary Medical Aesthetic Institute (Boca Raton, Florida, U.S.), the Ulthera System represents a natural evolution in response to the growing demand for safer, more effective modalities with minimized invasiveness and downtime. "Ultimately, non-surgical skin tightening comes from the specific application of thermal energy to cause injury and stimulate the natural wound healing response," he conveyed. "Real facial rejuvenation was first seen with the advent of CO_2 laser devices for superficial resurfacing in 1994. This worked very well but we discovered problems with this technology that made it less than ideal for the indication, such as hypopigmentation, scarring and lengthy downtime."

Jason Pozner, M.D.
Plastic Surgeon and Medical Director
Sanctuary Medical Aesthetic Institute
Boca Raton, FL, USA

"Around the year 2000 we began using non-ablative lasers for skin tightening," Dr. Pozner explained. The histology looked great but the results were inconsistent. It took many treatments and a lot of time to see results." As the search continued, non-invasive technology for true facial tightening proved elusive. "Radiofrequency (RF) came onto the scene soon after, which had the capability to treat deeper into the dermis. It was limited, however, by the large amounts of energy delivered at the surface to cause subsurface thermal damage, which at that depth was indiscriminate. This made for an extremely painful procedure with inconsistent results."

"RF was followed quickly by infrared energy, which could provide good skin tightening outcomes, but again, results were inconsistent," Dr. Pozner continued. Fractional technologies came next, with non-ablative methods preceding ablative versions. Many treatments were required to achieve modest results, but risk and downtime were significantly reduced. "Ablative fractional treatment is currently the new thing, with less treatments required. Even so, it tackles the problem from the same direction as other techniques and the deeper structures aren't targeted."

"Ultrasound technology gives clinicians unprecedented control of thermal damage at a clearly specified depth in tissue."



Single 30 minute office visit yields significant lifting and tightening over time

Photo courtesy of Sean Lanigan, M.D.

"The ability to adjust treatment depth will allow us to treat different individual patients effectively, independent of skin color or thickness, despite variations in facial structure."

Although still relying on thermal effect with subsequent wound healing and neocollagenesis for tightening, the Ulthera System successfully treats a familiar indication from an unfamiliar angle: non-invasive acoustic energy focused on a single relevant tissue plane. Combining ultrasound imaging with ultrasound therapy, the device targets the deeper support structures. Treatment energy is emitted from a concave transducer and focused at a precise depth, allowing it to pass through the dermal barrier without disrupting it.

Dr. Pozner feels that the Ulthera System "has phenomenal potential. The ability to adjust treatment depth will allow us to treat individual patients effectively, independent of skin color or thickness, despite variations in facial structure. Nothing else out there is like this. Other ultrasound devices are fixed-focus and go much deeper because they are used to treat fat."

Another unique aspect of Ultherapy, as the treatment is called, is its ability to achieve lifting. "Unlike non-surgical modalities in use today, Ultherapy treats the collagen and elastin fibers of the superficial musculoaponeurotic system (SMAS)," Dr. Pozner explained. "Besides a face-lift, no other modality treats this layer."

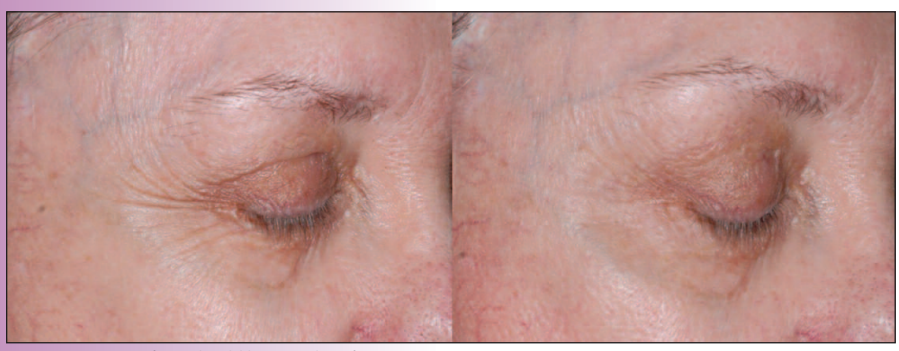
"This system is a remarkable device," said Sean Lanigan, M.D., group medical director of Sk:n Clinics, headquartered in Edgbaston, Birmingham, England. "You can image the treatment area during the procedure, then precisely control the deposition of energy. It's also quite easy to use, not technically challenging for the operator at all. There's almost nothing in terms of downsides or surface effects, which is a big plus."

Sean Lanigan, M.D.
Group Medical Director
Sk:n Clinics
Edgbaston, Birmingham, England

Using the handpiece, the operator scans a two-dimensional, real time, high resolution cutaway image of the treatment site to a depth of approximately 8 mm, which appears on the display interface. With this, the user can determine the ideal depth at which to deposit treatment energy. "You can see the air/skin interface on the display, as well as the layers of tissue below," said Dr. Lanigan. "This gives the user complete confidence in knowing exactly where energy should be applied, and where thermal injury will occur within the tissue. There's no guesswork involved, it's right there on the screen. This represents an unparalleled level of precision as well as ease of use."

A transducer is then chosen based on the desired depth of thermal effect. Currently, three transducers are available that penetrate to depths between 3 mm and 4.5 mm. "The correct choice of transducer directly affects the efficacy and safety of treatment with this system," Dr. Pozner advised. Treatment transducers are disposable, but are designed for multi-patient use.

Treatment energy is then applied in linear rows into the tissue at the treatment site, causing thermal damage to lift and tighten the fibromuscular layer. "During traditional surgery we've observed that cautery to the SMAS causes it to shrink," stated Dr. Pozner. The Ulthera System accomplishes this non-invasively, taking us to new levels of non-surgical tightening."



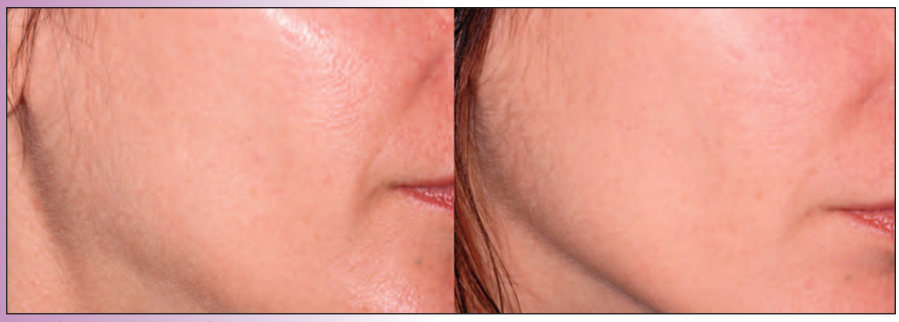
Improvement in crow's feet and eyelid laxity, 90 days after one Tx
Photos courtesy of Brian Zelickson, M.D.

A full-face procedure takes approximately 30 minutes, as the physician systematically images and treats each facial region.

There is virtually no downtime with Ultherapy. Thermal coagulation occurs sub-clinically and healthy tissue in between the mapped matrix of coagulation points is undisturbed. "Its safety profile is excellent. We see occasional redness, lasting maybe a few hours, but patients can resume normal activity immediately after treatment," reported Brian Zelickson, M.D., director of Zel Skin and Laser Specialists (Edina, Minnesota, U.S.), and among those overseeing U.S. clinical trials for the Ulthera System. No anesthetic or cooling is required, though Dr. Zelickson expects this may change. "Treatment is somewhat uncomfortable so we may see the addition of anesthesia, especially with more aggressive protocols."

Brian Zelickson, M.D.
Director
Zel Skin and Laser Specialists
Edina, MN, USA

Dr. Lanigan does not use cooling, anesthesia or analgesia with Ultherapy. "In my experience, treatment is very well-tolerated and discomfort during treatment is energy dependent," he said. "It can also vary by treatment location. I talk patients through it and if necessary, reduce the energy level. The energies we use still produce significant tightening."



More defined jawline, 90 days after one Tx

Photos courtesy of M. Alam, M.D.

In addition to its emergence as a novel modality, there are other advantages to the physician. The Ulthera System is lightweight and portable, which is a major benefit to practitioners, for many of whom office space is at a premium. "The prototype investigational version of the device we have is a little bit larger than a standard desktop computer," said Dr. Zelickson. In addition, Ultherapy can be easily integrated into the practice, given its brief learning curve for the operator and convenience for the patient.

According to Dr. Lanigan, the Ulthera System is poised to become an essential addition to the aesthetic practice. "This device is in a category of its own, and it has a lot of interesting prospective applications, but we're nowhere near realizing its full potential. This deep treating modality is a natural complement to lasers, dermal fillers and neuromodulators for an even greater total improvement."

Dr. Lanigan is currently performing clinical trials with Ultherapy in Europe, on 20 subjects, each undergoing one full-face treatment. "Preliminary assessments show obvious visible improvement already occurring in some of the patients," he observed, adding that follow-up assessments at six months post treatment are still needed before final results can be reported.

"In the combined U.S. studies so far, we've performed one or more procedures on 35 to 40 patients," said Dr. Zelickson. "There is clinically observable brow lifting in 80% to 90% of subjects. Preliminary results also point to a consistent dose response, which we haven't seen as much with other tightening procedures of the brow. Lower face trials are ongoing, and although we don't have data at this time, we're beginning to see tightening in the neck and jaw line. Protocols resulting from these studies will optimize outcomes. It will be interesting to see where the capabilities of this device take us in the future."

"There is clinically observable brow lifting in 80% to 90% of subjects. Preliminary results point to a consistent dose response as well."

Dr. Pozner believes the Ulthera System could be the final piece of the puzzle for those seeking the true prototype non-surgical face-lift, albeit with comparatively modest results. "Besides a face-lift, no other modality treats the SMAS for tightening," he said. "You could use the Ulthera System for rejuvenation of the SMAS and the platysma, and follow with laser or RF devices for more superficial tightening. Resurfacing can be added to handle textural and pigment issues, plus something for vascular lesions if necessary. If the patient wants, we use dermal fillers and neuromodulators."

"In the immediate future, this device will be used primarily for patients who want observable skin tightening results without surgery," Dr. Zelickson conveyed. "With the unique combination of visualization and the ability to specifically target structures beneath the skin, we'll soon see this device used for many other indications. That alone separates the Ulthera System from other skin tightening technologies, even before we see it in wide use."

Dr. Lanigan agreed, "We'll see the Ulthera System tightening the lower face and jowls, probably with benefits for the neck and décolletage as well. It has potential for many areas where skin tightening is desirable, such as the upper arms, buttocks and abdomen."

Brow lifting is simply the gateway to other indications advised Matt Likens, Ulthera president and CEO. "Right now our initial focus will be on the face and neck, but eventually we envision the Ulthera System being used all over the body for a variety of conditions. We will continue to augment our clinical development programs with scientific research as we add clinical indications to the Ulthera platform, which is currently being launched in Europe and Asia. The possibilities for this device are numerous."

"Since the Ulthera System is a platform technology," Mr. Likens continued, "we have more than a dozen clinical indications we're pursuing and will unveil over the next few years. Our development plan is very aggressive but more than that, it is scientifically rigorous. Some indications are aesthetic, some medical." According to Mr. Likens this means, among other things, the development of additional transducers to increase the variety of depths with which to reach targeted connective tissue.

Another strength is the patent portfolio owned by Ulthera. "This technology is protected by more than 100 patents," Mr. Likens stated. "From a competitive standpoint we're in a strong position to protect our interests using this unique approach. Combining ultrasound imaging and coagulation capabilities in a portable device represents a significant engineering advance."

Ulthera's marketing strategy began with the fourth quarter delivery of units to sites in Europe and Asia, and the firm has reached agreements with highly regarded distributors outside the U.S. A measured roll-out is planned for the U.S. once FDA clearance is acquired. "We'll start selling the Ulthera System in the U.S. within 30 days of receiving clearance, but placements will be limited throughout 2009," said Mr. Likens. "We know the platform is safe, simple and straightforward, but we will implement a conservative roll-out plan. Every user must be comfortable with this new technology, and it's important to us that the science continues to be emphasized."

"In the immediate future, this device will be used primarily for patients who want observable skin tightening results without surgery."

Reduced eyelid laxity with brow lift, 90 days after one Tx

Photos courtesy of Sean Lanigan, M.D.