



Medical Insight Report

Business Opportunities and Market Analysis

Volume 14 Number 1 January 2005

Published by Medical Insight, Inc.

Editor: Michael Moretti

www.MiiNews.com

E-Mail: MMoretti@MiiNews.com

IN THIS ISSUE:

AAD Preview
Ophthalmic Market
Aesthetic Market
Industry News
Financial Results

AAD Annual Meeting Showcases Latest Wave of Aesthetic Treatments

By Michael Moretti, Editor

The GentleWaves Skin Fitness System from Light BioScience, LLC (Virginia Beach, Va.) recently received FDA clearance for the treatment of periorbital wrinkles and rhytides. "This is the first FDA approval for an LED device for wrinkle reduction," said David McDaniel, M.D. the inventor of LED Photomodulation patents held by the company. "This is also the first FDA approval for a light-based device that is truly non-thermal. We can treat the entire face in seconds. Historically, people have been searching for a low-intensity light device that has a photobiochemical effect rather than a photothermal effect. It appears that GentleWaves stimulates the mitochondria to produce more adenosine triphosphate (ATP). It stimulates the electron transport system. Probably cytochromoxidase is one of the targets. Photomodulation is a mechanism that consists of photons received by an antenna molecule within the mitochondria and converting it photobiochemically into cell energy. Therefore, cells that are environmentally injured, such as from chronic sun damage, will function more effectively."

Gene expression also appears to render the GentleWaves effective. "Genes are selectively increased or decreased in their expression, and thus the cellular machinery produces more or less proteins or affects cell signaling," Dr. McDaniel explained.

The treatment protocol submitted to the FDA for wrinkle reduction consisted of eight sessions, two times a week. "The treatment duration was less than 1 minute for each session," Dr. McDaniel reported. "Treatment is painless because it is non-thermal. There is also no aftercare, wound care or downtime." Approximately 90 patients participated in the multi-center trial. Four months after the final treatment, 85% of subjects showed at least a 25% improvement in the global appearance of their skin. "Wrinkle reduction seemed to peak around four months post-



treatment. But at 12 months, there was still significant improvement above baseline, although slightly diminished from the peak at four months.”

The Sinon Q-switched ruby, the Mydon Nd:YAG and the Arion alexandrite are a family of three German crafted, FDA approved lasers from WaveLight Laser Technologie AG (Erlangen, Germany) that will debut at the AAD annual meeting. Robert Weiss, M.D. uses the Sinon foremost for treating pigmented lesions, followed by tattoos. Because the ruby laser has very good absorption by pigment, “typically patients require only one or two sessions to rid themselves of a lentigo,” Dr. Weiss said. About 80% of patients need just one session. For the remaining patients, a second session is scheduled about four weeks later. Tattoo removal, however, is highly variable, with a minimum of three treatments normally spaced at least six weeks apart. Sinon also allows the physician an exceptionally clear site of the pigmented area being treated because there are no glass inserts or other media to obstruct the view.

The Mydon laser system is used by Dr. Weiss for two indications: leg spider veins and dark hair reduction in darker skinned individuals. After a series of treatments, “patients can expect between 80% and 90% permanent hair reduction,” he reported. The Mydon’s contact cooling also “makes treatments extremely comfortable.” This laser also features a sleep mode, so that cooling continues when the laser is off.

The Arion long pulsed alexandrite laser system operates at a wavelength of 755 nm for hair removal. The innovative air-cooled scanning device is able to treat large areas quickly. Depending on the site, patients are treated every 4 to 12 weeks.

The plasma skin regeneration (PSR) system from Rhytec, Inc. (Dover, Mass.) uses plasma energy to deliver predictable tissue effects and skin regeneration. Plasma is formed in nitrogen and activated by high-power, ultra-high frequency energy. This plasma emanates from the system’s handpiece through a quartz nozzle. “I think this is the best form of ablative resurfacing on the market,” said Ron Moy, M.D., an associate clinical professor of dermatology at the University of California, Los Angeles, Medical School. “In my hands, it has replaced erbium or CO2 laser resurfacing.”

According to Dr. Moy, plasma skin regeneration is less traumatic and provides faster healing than traditional ablative resurfacing, while still achieving the same results. “The technology also blends better. It does not leave the demarcation to the same degree. Furthermore, plasma can be applied quickly and it is easy to cover an area. The plasma flows, so you don’t have to feather an area as much.”

One treatment session is usually sufficient. “You can do a full face in 20 to 30 minutes,” Dr. Moy reported. “But in many patients, we often treat just the wrinkles around the eyes and the mouth. This takes less time.” As with many modalities associated with tissue remodeling, optimal results can take months to manifest. “You can undergo a minimal peel with plasma that heals in a weekend or you can do deeper resurfacing that takes seven to ten days to heal. With the deeper resurfacing, you can see improvement of deep wrinkles. But the deeper you go, the higher likelihood of increased erythema. Compared to CO2, though, there appears to be less redness and less complications because of the unique tissue interaction with plasma. Why that occurs, we don’t know.”

“You can undergo a minimal peel with plasma that heals in a weekend or you can do deeper resurfacing that takes seven to ten days to heal.”



The Cynergy III is a multi-wavelength aesthetic workstation from Cynosure, Inc. (Chelmsford, Mass.) that contains a high-powered Nd:YAG laser, a high-powered pulsed dye laser, and an IPL device. “The Cynergy III is particularly appealing to a physician with limited space and cost issues,” said Emil Tanghetti, M.D., an associate professor of dermatology at the University of California, Davis. “Most doctors are confronting space constraints. Space is very expensive. Having three bulky individual units is really inconvenient. But there are cost savings by putting three devices in one box.”

For practices with a medical focus, “the pulsed dye laser will likely be used the most,” Dr. Tanghetti suggested. “However, if you are more cosmetically based, perhaps the IPL will have more usage. The Nd:YAG is used for both medical and cosmetic practices.”

Dr. Tanghetti believes the pulsed dye laser of the Cynergy III “is the most sophisticated pulsed dye laser in the market. It is the most powerful and has the most sophisticated pulse train. The pulse train has six individual spikes, which spreads the energy over the treated area. You achieve less purpura. You can also operate with larger spot sizes and at higher energies than the competition. For vascular lesions, pulsed dye is very effective on the face. For pigmented lesions, though, IPL is better.” The IPL component has integrated contact cooling within the treatment head. “This minimizes patient discomfort and allows for cooling during treatment,” Dr. Tanghetti noted. “Physicians also have the option of supplementing the contact cooling with Cynosure’s air cooling.”

On the other hand, the Nd:YAG component is simply “another device for vascular lesions that is very useful to have, especially for leg veins,” Dr. Tanghetti added. Overall, the Cynergy III “is packaged well and very convenient to operate.”

The Quadra Q4 is an IPL system from DermaMed USA, Inc. (Lenni, Penn.) that features patented low voltage. “As a result, there is little or no patient discomfort,” said George Maguire, chief operating officer at DermaMed. “Unlike a rubber band sting type of feeling that a patient might experience with other IPLs, ours is a slight heat sensation.” The top hat design of the Quadra4 also minimizes pain. “We use a xenon flashlamp, and we’ve cut out some of those little peaks that cause pain.”

Quadra Q4 is approved for benign pigmented and vascular lesions and hair reduction. “We treat mostly skin types I through V,” Mr. Maguire noted. For hair, the company recommends four to six sessions at three to four week intervals. Vascular and pigmented lesions, though, usually require only one to two sessions, “although we tell the patients it can take up to three sessions,” Mr. Maguire said. “It depends on how aggressive the physician wants to be during the first session. Treatment is scheduled about once every two weeks. For both lesions and hair, patients can expect dramatic results.”

Most of the light in the Quadra Q4 is in the visible region of the spectrum. “Pain is increased quite a bit when using far-infrared light,” Mr. Maguire explained. “The visible range provides high pigment absorption. Compared to some other IPL systems, we are able to resolve pigment quicker, even lighter pigments.” The treatment protocol also calls for no gel application. “Instead, we suggest about five seconds of quick cooling. This is not with a Zimmer chiller, but with cold compresses or a small ice bag. We are then able to single or double pulse the area. Afterwards, the area is cooled again for about five seconds.” The treatment head itself is fan-cooled.



“The Quadra Q4 is a portable system that is extremely competitively priced,” Mr. Maguire stated. “Doctors are becoming savvier. They want something that works at a better price.” He also noted that an approval for acne is pending.

Palomar Medical Technologies, Inc. (Burlington, Mass.) will debut the Palomar DermaType™ Skinphotometer, a reflectance spectrophotometer (pigmentometer). “There have been a lot of these types of devices available in the past, which measure the amount of light that reflects off the skin with certain wavelengths of light,” said Paul Wiener, vice president of sales at Palomar. “These devices can be used to determine the amount of melanin, therefore pigment, or the erythema level of the skin. The problem with these other devices, though, is that they are usually very nonlinear. The readings are variable because light coming off the skin varies, depending on the time of day and the kind of lighting in the room. So these nonlinear devices really don’t provide information that is worth very much.”

On the other hand, the Palomar DermaType™ Skinphotometer is an extremely linear device. “Our device is not dependent on the ambient background room light. This ultimately gives you a much more comparable piece of information about the amount of melanin in anyone’s skin,” Mr. Wiener explained. “Our device also permits you to measure the amount of blood levels in the epidermis. And these measurements can be quantitatively compared.”

Although there are other linear pigmentometers on the market, “they are very expensive,” Mr. Wiener pointed out. The introductory price of the Palomar product is \$3,995, compared to around \$10,000 for similar technology. “We believe that our product will ultimately provide a much, much greater level of safety for anyone doing cosmetic procedures. We’re trying to take the subjective, qualitative valuation of skin and turn it into a quantitative, objective numerical measurement of pigment and vascularity. This should enable anyone’s procedures to have a much safer outcome for the patient.”

The CoolTouch CTEV from CoolTouch, Inc. (Roseville, Calif.) is a 1320 nm endovenous laser for treating varicose veins. “This is the first wavelength approved by the FDA for endovenous use that actually uses water as the target,” said Robert Weiss, M.D., an assistant professor of dermatology at Johns Hopkins University School of Medicine. “The big advantage of targeting water instead of hemoglobin or blood is that there are no more vein explosions. Unlike the other three wavelengths approved for this procedure (810, 940, 980), the 1320 maintains a stable temperature and there are no vein perforations or mini-explosions.”

“This is the first wavelength approved by the FDA for endovenous use that actually uses water as the target.”

A single treatment with the CoolTouch CTEV is all that is necessary for resolution of incompetence or leaking of the greater or lesser saphenous veins. Treatment time lasts about 20 to 30 minutes, and “Patient discomfort is minimal,” according to Dr. Weiss. “The most pain occurs when injecting tumescent anesthesia around the vein, which isolates it from all the adjacent structures. But after the injection, patients feel nothing – no heat or burning.”

Overall, 98% of patients treated with the CoolTouch CTEV by Dr. Weiss continue to achieve successful feeling of their vein and resolution of venous hypertension at two years. “This is the best device I’ve ever used to treat varicose veins related to reflux or reverse flow in the saphenous system. This is also the first device to have an automatic pullback system. The fiber



is moved back at a steady 1 mm per second rate. This provides much more uniform heating of the vein. It also adds to the safety of the procedure and patient comfort.”

Patient feedback has been very positive. “Patients are really happy because they feel virtually nothing when the anesthetic wears off. No pain medications are needed,” Dr. Weiss added. “Within one day, the leg is feeling a lot better and veins start to shrink within the first few days. Typically, within two weeks, the leg is looking a lot better, too. The CoolTouch CTEV represents a significant advance in the treatment of varicose veins.”

The Transderm Ionto from Mattioli Engineering Corporation (McLean, Va.) is a powered drug delivery system for the local administration of ionic drug solutions into the body. “This is for medical purposes and can be used as an alternative to injections,” said Simon Parenti, sales manager for the company. As with any iontophoresis device, the Transderm Ionto can be used on both small and larger areas, due to its electrode shape.

The Mattioli system may be powered by the Crystal T-Type Microdermabrader. “This configuration provides the most reliable microdermabrasion system,” according to Mr. Parenti. “In addition, our new Dermoelectroporation technology offers accurate transdermal delivery of any type of ionic substances.” The configuration also allows users to achieve higher transdermal delivery flux than traditional iontophoresis devices. “This is very comfortable for the patient. The vibration feature allows the perception of the electrical pulses being delivered to decrease significantly.”

Due to the absence of electrolysis at the electrodes and no variation in the ionic drug solution pH, “Transderm Ionto is able to deliver ionic solutions faster than other systems,” Mr. Parenti stated. “You can now perform a controlled microdermabrasion without any side effects. The transdermal delivery rate is boosted by a combination of microdermabrasion and pulsed delivery. Macromolecules previously not transdermally deliverable by classical iontophoresis are now successfully delivered, thanks to Dermoelectroporation technology.”

Another advantage of the Transderm Ionto is that the microdermabrasion enables a standardization of the skin characteristics, so that the drug delivery rate is reproducible.

“Up until now, that has been the biggest problem with traditional iontophoresis,” Mr. Parenti noted. “Our system allows both positive and negative ions of the drug to be transdermally delivered. The technology works like an injection, but is not nearly as invasive.”

Whisper is a new solid-state erbium YAG laser from Radiancy, Inc. (Orangeburg, N.Y.) with a 6 mm spot size, energy up to 8.5 J/cm², and a repetition rate of 9 Hz. Similar to the MediDerm, the Whisper features a new color scheme and contemporary control-panel graphics for a more aesthetically pleasing and user-friendly device.

“It appears that this technology will be somewhat more effective than current microdermabrasion technologies,” said Neil Sadick, M.D., a clinical professor of dermatology at Weill Medical College of Cornell University in New York City. “We treat patients with early skin aging, acne with acne scarring, and pigmentation.” This low-energy device takes about five minutes to treat the entire face. Most patients schedule three to five sessions, spaced one or two months apart. Maintenance treatment is suggested every three to six months.

“I think the skin is smoother and there is more evenness in pigmentation,” Dr. Sadick observed. “However, compared to microdermabrasion, patients may end up with a little bit of



desquamation that can last one or two days. So it appears that patients treated with the Whisper achieve deeper penetration.”

Dr. Sadick is one of the investigators for an ongoing study of the Whisper. “Treatment time is fast, painless, and we have observed no side effects. The laser is also easy to use. Aestheticians can perform the treatment. We usually apply a facial cleanser beforehand. This laser also has a large handpiece that rapidly covers the entire face. Afterwards, a tissue repair gel is applied.”

The long 2940 nm wavelength is suitable for treating darker skin phenotypes. In addition, no particles (e.g., aluminum oxide crystals) are used, “so there is no risk of aerosol ingestion,” Dr. Sadick said. “The Whisper appears to represent the next generation of skin rejuvenation technologies. It seems to remove the stratum corneum and the outer layer of the epidermis.” Dr. Sadick commonly uses the Whisper in conjunction with pulsed light or pulsed light/radiofrequency. An at-home hydroxy acid/hydroquinone derivate or retinoid derivative is also recommended nightly for maintenance.

Fotona (Ljubljana, Slovenia) will premier its FDA pending, Q-switched Fotona QX system for tattoo removal. “This dual wavelength laser fires both an Nd:YAG (1064 nm) and KTP (528 nm) nearly simultaneously,” said Thomas Sult, M.D., a family practitioner in private practice in Willmar, Minn. “This is an extremely unique feature, since other systems do not fire in tandem. Basically, we feel the Fotona achieves better penetration of the KTP wavelength, which closely follows the Nd:YAG wavelength, with less skin injury.”

The QX also has extremely small pulse widths. “This should allow us to target both natural and artificial tattoos better than any other system to date,” Dr. Sult stated.

Dr. Sult owns both the DualisSP and DualisXP Plus from Fotona. The SP is a family of lasers that has two wavelengths (Nd:YAG and erbium), but through two different delivery systems. “The erbium comes through a rigid arm and is used for resurfacing, while the Nd:YAG component is used for hair and veins,” Dr. Sult explained. In contrast, the DualisXP Plus has only one wavelength (1064 nm): a high-powered Nd:YAG also used to treat hair and vascular. “By using transillumination techniques with the XP Plus, we have been able to obtain superior results to scleral therapy.”

Overall, Fotona medical lasers “have internal calibration, reliability and safety,” Dr. Sult noted. “The company has designed the beam profile for optimal results with minimal side effects.”

“I like the fact that this laser is compact and portable. It is about one-third the size of other Nd:YAG systems.”

The Q-Clear laser from Light Age, Inc. (Somerset, N.J.) is a Q-switched Nd:YAG with dual wavelengths (1064 and 532 nm) ideal for age spots and sundamaged skin, tattoos, nevi and certain vascular lesions. “I like the fact that this laser is compact and portable. It is about one-third the size of other Nd:YAG systems,” said Albert Poet, M.D., a facial plastic surgeon in private practice, with offices in Manahawkin and Montclair, N.J. “This laser is lightweight, which makes it easily portable between

offices. It is also extremely affordable (\$35,500), selling for about half the price of other lasers with comparable performance. The Q-Clear is very effective, too.”



Dr. Poet noted the ease of switching from one wavelength to another. "My two most popular indications are solar lentigos and tattoos. A typical treatment protocol for both indications would be a 2 mm spot size. For a solar lentigo, I use the 532 wavelength and a fluence per pulse of 300 mJ/cm². For tattoo removal, depending on the color, I use both wavelengths, along with a fluence of either 300 or 450." Lentigos will normally clear after one treatment, whereas tattoos require a minimum of three sessions. "The 532 wavelength is very well absorbed by blood vessels and melanin. Therefore, this wavelength will work on almost anything that is red or green," Dr. Poet said. "The 1064 wavelength provides deep penetration and allows you to treat lesions down in the dermis."

JLJ United, Inc. (Austin, Texas) is a service and parts manufacturing company for IPL devices. Around the beginning of February, the firm will receive its first shipment of light guides (external filters). "Our chief engineer designed the crystals himself with the correct tolerance," said president Geoffrey Loveless. "Our manufactured glass will be equivalent or better in transmission properties than the light guides produced by Lumenis."

The popular consumable light guide will be available to physicians at \$79, compared to approximately \$150 that Lumenis charges. "These are the same light guides that the doctor is already using. There is nothing new or different about our light guides," Mr. Loveless stressed. The light guides will be available in all wavelengths and for all procedures. "We are also now in a position to offer next-day service. We can provide an onsite technician within 24 hours," said Mr. Loveless, whose company specializes in refurbishing IPL treatment heads and repairing all modules, external light guides, computers and software for any Lumenis IPL device.

Dermesse from LycoScience (a division of Dermacia Inc., Newport Beach, Calif.) is a prescription strength hydroquinone and tretinoin therapy. The Dermesse line includes specially formulated skincare products that work at the cellular level to help correct and improve skin conditions and skin texture. "Major improvements are seen in the reduction of fine lines and wrinkles, smoothing and tightening of the skin, increasing natural hydration and circulation, and reducing areas of excess discoloration and hyperpigmentation," said James Krulisky, vice president of sales and marketing at LycoScience. "The major advantage over competitors is in the stabilization of the hydroquinone, resulting in an odorless product and an improved delivery system which provides maximum results."

The Dermesse line consists of 5% and 10% vitamin C serum, moisturizers, suncare products and an eye cream. According to Mr. Krulisky, patient compliance is higher with Dermesse. Hence, "improvements are achieved quicker and are more long-lasting." In addition, regimens can be completely modified by the physician. "All regimens are clearly presented on preprinted, easy-to-use instruction cards."

The company will introduce a full line of acne products in early 2005, as well as other post-procedure products. "LycoScience may not yet be a household name, but it has made phenomenal inroads since it entered the medical arena last year," Mr. Krulisky noted. "The main thrust of our company is to offer cost-effective, innovative, and cutting-edge over-the-counter and prescription topical skincare products."

