

# Light BioScience Releases GentleWaves Photomodulation Science

By Bob Kronemyer, Associate Editor

Several scientific papers presented at the American Society of Laser Medicine and Surgery annual meeting (April 9 – 12, Anaheim, Calif.) revealed the highly anticipated scientific theories behind the proprietary GentleWaves Photomodulation process developed by Light BioScience (Virginia Beach, Va.). Based on these research results, GentleWaves provides an effective light-based, non-thermal photorejuvenation procedure using light-emitting diodes (LEDs) as the energy source.

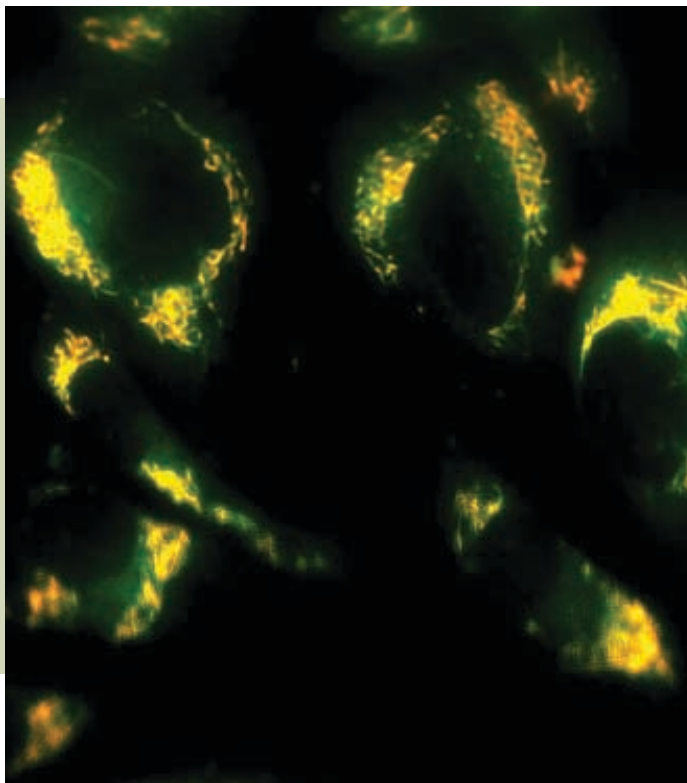
Physician attendees at the ASLMS meeting were fascinated with Photomodulation science, which was presented via three separate papers. The first paper, titled “Non-ablative, non-thermal photo modulation – a multicenter clinical photoaging study,” included data from 90 patients treated with GentleWaves at three separate clinical sites. Followup data was collected at frequent intervals, with the longest period at 24 weeks. PRIMOS digital profilometry and various UV and digital photographic techniques were used to measure and document the results, in addition to standard histopathology and immuno histopathology studies.



Robert Weiss, M.D.

*Photomodulation theory involves transmitting specific packets of light that can be absorbed by receptors or antennae molecules associated with the mitochondria.*

**Results of these studies**, as presented by Robert Weiss, M.D., showed a 62% improvement in periorbital skin appearance one week after final treatment. This research also documented “desirable



Human Fibroblast Mitochondria Post GentleWaves

changes in extracellular matrix proteins,” according to Dr. Weiss and his fellow researchers.

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“One principal site of action appears to be the mitochondria of the cells,” said Dr. Weiss, an assistant professor of dermatology at Johns Hopkins University School of Medicine. “The mitochondria are basically the battery of the cell, providing energy for normal cellular activities and for reproduction of cells.”

**Photomodulation theory involves** transmitting specific packets of light that can be absorbed by receptors or antennae molecules associated with the mitochondria.

Within the mitochondria are certain structures that will absorb these packets of light. Mitochondria then convert adenosine diphosphate (ADP) to adeno-

sine triphosphate (ATP), similar to photosynthesis. "This conversion is one of the ways that a cell can store energy," Dr. Weiss explained. "It's like taking light energy and changing it to battery energy."

**Data also indicates** that genes for different types of collagen are actually upregulated or activated by the Photomodulation process. "There appears to be a correlation between the activation in the mitochondria due to absorption of light energy and the up and down regulation of human fibroblast genes. There is definitely a correlation," Dr. Weiss said.

According to the ASLMS paper presented by Dr. Weiss, the photoactivation of collagen genes "resulted in an increase in collagen production in the papillary dermis of the study patients. This was confirmed by skin biopsies. Clinically, improvement was observed in the appearance of wrinkles and skin roughness."

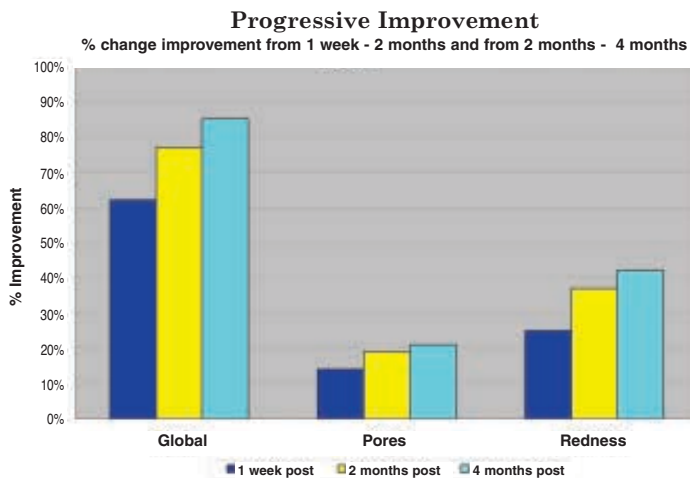
*The photoactivation of collagen genes "resulted in an increase in collagen production in the papillary dermis of the study patients. This was confirmed by skin biopsies."*

**Cell signaling pathways** lead to regulating the activation of matrix metalloproteinase (MMP). "MMP1 is the new term for collagenase," Dr. Weiss explained. "So at the time the LED treatment is activating collagen genes, it is actually downregulating MMP gene activity and thus reducing collagenase. This process further explains why GentleWaves works so well. You are both slowing down collagen breakdown and building up new collagen."

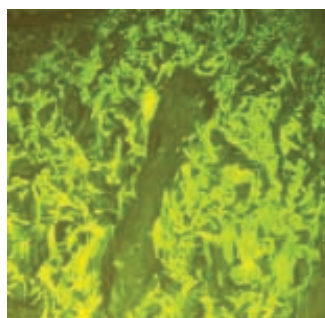
Dr. Weiss was lead author of a study that assessed the effect of applying topical cosmeceutical agents in conjunction with GentleWaves treatment. In a split-face randomized clinical trial of 30 photoaged subjects, these agents statistically enhanced the visible and structural changes produced by non-ablative LED photorejuvenation of skin. Light BioScience developed these products over the last two years based on scientific data from the photomodulation research in collaboration with a team of leading cosmetic chemists. The result is a very sophisticated four-step cosmeceutical kit (cleanser, a morning active product, an evening active product, and sunscreen). Active agents in these topical products were specifically selected to enhance the photomodulation process.



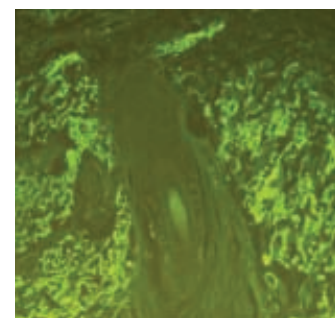
Roy Geronemus, M.D.



Results of this study and others "have exceeded all of our expectations," Dr. Weiss added.



Collagenase (MMP) Pre-Tx



Reduced MMP Activity Post-Tx

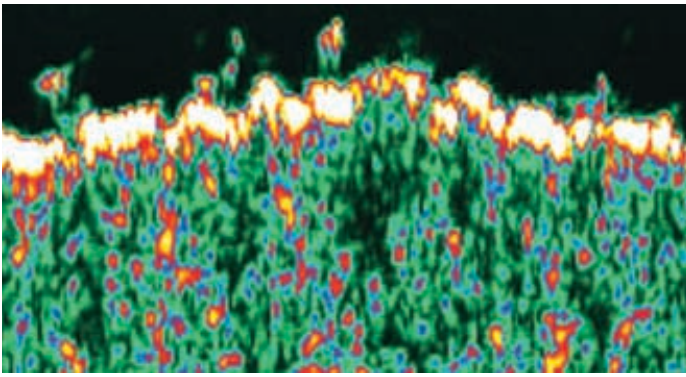
**"Because LEDs** are a very low-energy light source, the panels are positioned only one to two inches away from the skin," Dr. Weiss said. "Treatment sessions last mere minutes."

According to Roy Geronemus, M.D., director of the Laser & Skin Surgery Center of New York in New York City, preliminary evidence "suggests that there is synergy with standard non-ablative therapy. Using GentleWaves in conjunction with CoolTouch or intense pulsed light (IPL) appears to enhance results." With or without combination therapy, "people notice an overall improvement in skin tone. The skin looks creamier," Dr. Geronemus said. "The skin takes on quite an interesting appearance that people seem to like very much."

**For instance, there is** an improvement in the redness of the skin. "This has come as a surprise to us," Dr. Geronemus noted. "Clinically, we're seeing



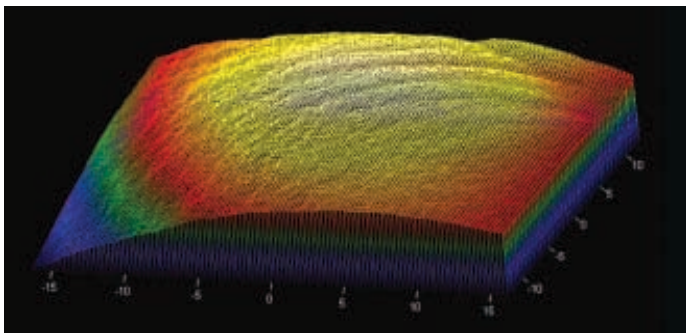
GentleWaves Cosmeceuticals



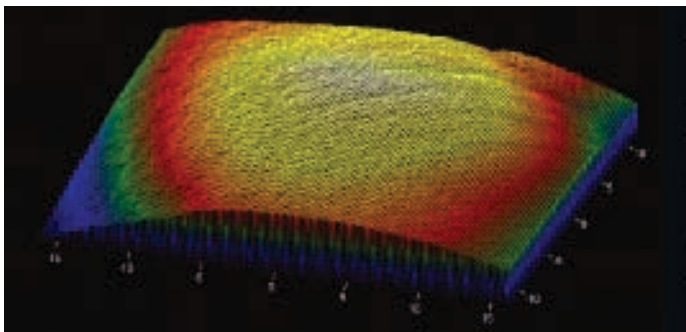
Ultrasonic Imaging Pre-Tx

improvement in the red color. Not necessarily in individual discreet blood vessels, but in the overall redness of small diameter vessels. Initially, I thought this was

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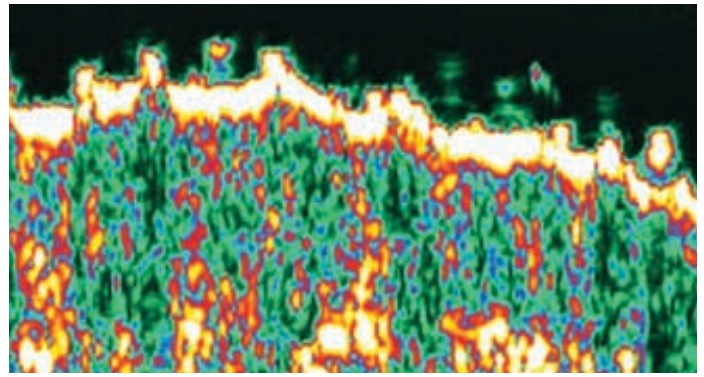


PRIMOS Digital Profilometry of Periorbital Wrinkle Pre-Tx



PRIMOS Digital Profilometry of Periorbital Wrinkle Post-Tx

a photographic issue; however, we have seen it too consistently. Interestingly, cell culture data suggests downregulation of several key cell signaling steps in the pathway for inflammation which may also play a role in the changes in the appearance of skin redness.”



Ultrasonic Imaging Post-Tx showing Increased Collagen/ECM

In a study of 90 photoaged females, skin biopsies were obtained at intervals of 1, 4, 8, 12 and 16 weeks post-treatment with non-ablative LED photomodulation, then evaluated for extracellular matrix changes. “We definitely demonstrated new collagen formation through routine histology,” said Dr. Geronemus, the lead author. “Through special staining techniques, you can see the new collagen formation. The science is there.”

**This clinical study** involved eight sessions of treatment (twice a week for four weeks). Immuno-



Before GentleWaves



After GentleWaves

fluorescence showed changes in a variety of structural proteins such as collagen I and procollagen I. “Increases of these proteins were observed in both skin biopsies and fibroblast tissue culture,” Dr. Geronemus said. “Collagen I was distributed diffusely throughout the dermis. This was in contrast to the upper dermal grenz zone typically associated with ablative thermal photorejuvenation.” A grenz zone is a narrow area of uninvolved dermis between the epidermis and a dermal inflammatory or neoplastic infiltrate.

*“In a non-thermal way, research indicates GentleWaves can either stimulate or inhibit cellular activity.”*

“In a non-thermal way, GentleWaves can either stimulate or inhibit cell activity,” Dr. Geronemus said. This device appears “to have a significant effect

upon new collagen formation and a decrease in collagenase." In addition, Dr. Geronemus likes the fact that GentleWaves is very easy to use.

**David McDaniel, M.D.**, inventor of GentleWaves LED photomodulation and co-founder of Light BioScience, was also lead author of the multicenter clinical trial of GentleWaves on 90 photoaged subjects. Skin biopsies were evaluated with standard histopathology and immuno histopathology for various extracellular matrix proteins. One week after final treatment, the global improvement in the appearance of skin in the periorbital region was 62%. Other observations in the periorbital area included a reduction of 27% in skin roughness, 30% in elastosis, 14% in pore size, and 25% in redness.

"We're excited that the post-treatment results show continued improvement one week, two months and four months after final treatments," Dr. McDaniel commented. "The appearance of the skin continues to improve for up to four months after the last treatment." A high percentage of patients also showed at least some response. "In contrast, many of the other



David McDaniel, M.D.



Before GentleWaves



After GentleWaves

cells, but demonstrates it is a very safe, fast, affordable, effective, painless, no-downtime clinical therapy for reducing the appearance of aging skin. We appear to be witnessing a means to produce a group of beneficial changes in human cellular activities by using LED photomodulation to alter the activity of the genes which code for specific patterns of changes in cellular activities. According to our clinical studies, these benefits include improvement in the appearance of photoaged skin," Dr. McDaniel concluded.

LightBioScience is currently organizing expanded clinical studies of Gentlewaves for a number of clinical applications. Participants in these multicenter studies will include some of the leading dermatology and cosmetic surgery researchers in the world. ■

*All photos courtesy of David H. McDaniel, M.D./Light BioScience, LLC*



GentleWaves System

non-ablative treatment options achieve a satisfactory response in only a small percentage of patients," Dr. McDaniel observed. Furthermore, patients treated with GentleWaves "appear to respond more rapidly. People like to see results quickly."

**Research suggests** that LED photomodulation not only has "the ability to regulate the activity of living

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Editor: Michael Moretti

Email: [mmoretti@MiiNews.com](mailto:mmoretti@MiiNews.com)

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27796 Soller

Mission Viejo, CA 92692

Telephone: (949) 830-5409

Facsimile: (949) 830-8944

Website: [MiiNews.com](http://MiiNews.com)