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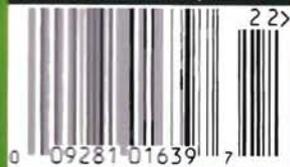
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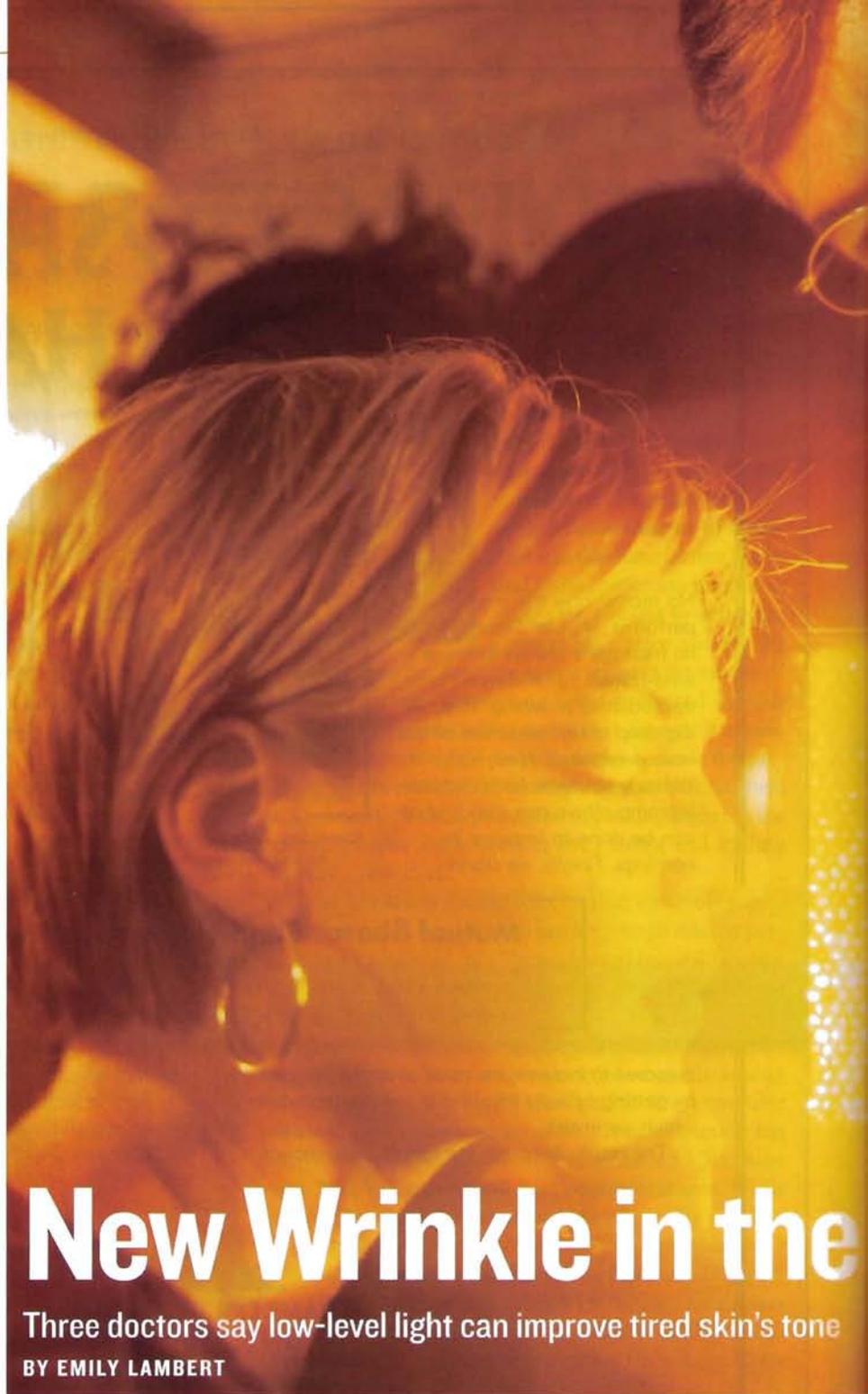
HARLENE BREITKREUZ, A 55-year-old hospital employee in Virginia Beach, spent years tanning on local beaches. In the last two years she began noticing crow's feet around her eyes. When she heard of a patient trial for a new, noninvasive treatment promising to reduce wrinkles, she signed up.

Twice a week for eight weeks, Breitkreuz donned a pair of goggles in a doctor's office and stared into a panel of 2,000 tiny, pulsing orange lights. After six weeks the fine lines were gone and her skin was smoother. "It's almost like going to the tanning booth, but better," she says. "You know it's doing something good for you."

A new theory making the rounds in cosmetic surgery is that a bit of basking under highly tuned cascades of light can reduce wrinkles, remove acne scars and firm up stretch marks. In a process called LED photomodulation, the light stimulates the production of cell-producing proteins under the skin's surface. The LED stands for "light-emitting diode," a semiconductor chip, found in VCRs and radios, that glows when electrified.

The device Breitkreuz used, which resembles the toy Lite-Brite, is called GentleWaves. Its maker, Light Bioscience of Virginia Beach, plans to begin marketing GentleWaves next year, according to its inventor and the firm's founder, Dr. David McDaniel, an assistant professor of Clinical Dermatology & Plastic Surgery at Eastern Virginia Medical School.

The power to eliminate wrinkles with light is a bold claim for a device backed by an unknown, tiny company with scant



New Wrinkle in the

Three doctors say low-level light can improve tired skin's tone

BY EMILY LAMBERT

hard evidence behind it. None of the dozen or so pilot studies performed so far could be called extensive or independent. Each study used only a handful of patients over the course of two to six months, and some patients were indirectly affiliated with the three doctors who started the firm.

The data leave plenty of room for

detractors. "Is it possible? Yes. Is it plausible? Um—maybe. But has it been proven? No," says Dr. Rodney Rohrich, chairman of the emerging trends task force for the Aesthetic Surgery Education and Research Foundation. "Anybody can present data, anywhere, anytime. It's getting it into a peer-reviewed journal based on good science that counts."

Light up my life: David McDaniel beams over GentleWaves device.

Beauty Business

and look—but science has to catch up with their claims.

LED photomodulation translates the process of plant photosynthesis into the workings of human skin cells, deploying the body's own cytochromes to build new proteins the same way plants use chlorophyll to convert sunlight into cellular building blocks. The LEDs on GentleWaves shoot weak light (less than 25 watts) through the skin's epidermis to

fibroblast cells, which produce structural proteins such as collagen and elastin. When the light hits the cytochromes inside the fibroblasts' mitochondria, it stimulates the cell's energy transport system. The cell produces more structural proteins, which in turn puff up the skin and give it the appearance of improved tone and elasticity. The LEDs' cool tem-

peratures don't burn or scar, which laser treatments are known to do.

GentleWaves inventor McDaniel says he can send specific instructions to cells by changing the light's wavelengths, frequency or intensity, but he says the light "codes" he has created are proprietary. The doctors refuse to be more specific about what genes are involved and what happens inside the cytochromes. He acknowledges using yellow and red light, but he refuses to say what power intensity is used or for how long.

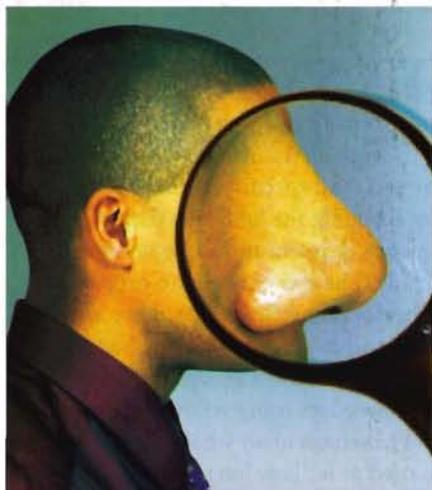
LED photomodulation has fans in broader scientific circles. Scientists working for the Department of Defense's Advanced Research Projects Agency are investigating whether LEDs can heal eye injuries and skin lesions. This year the government's researchers published results showing that LEDs can clear up mucositis, the mouth sores suffered by chemotherapy patients. One day, says McDaniel, his GentleWaves device may even be shown to spur hair growth and, if it can be made to work in reverse, stall the growth of fat or cancer cells.

For now, GentleWaves' health claims are likely to be dogged by controversy. Each of the doctors behind it have varying degrees of financial interest in Light Bioscience. The company declined to release financial information, but the primary bankrollers are a local lawyer and two brothers in real estate development.

McDaniel and his colleagues have presented their findings at several dermatology conferences, but they have published no peer-reviewed papers. He says they were ready to publish a paper in a small dermatology journal, but decided last month to pull the paper and publish more definitive results in a bigger journal.

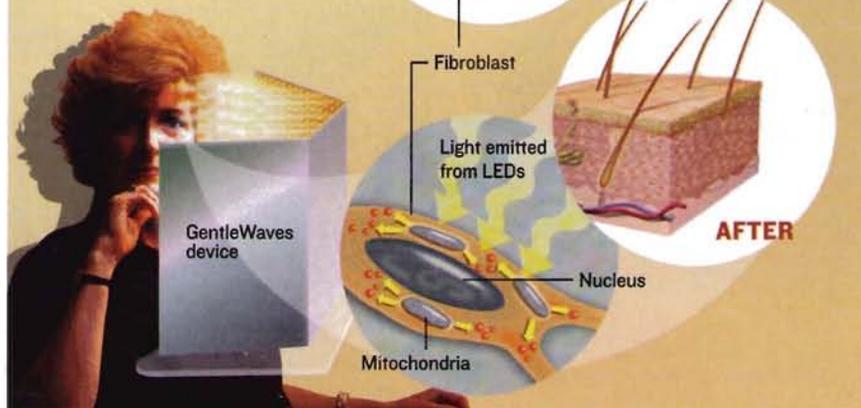
On Oct. 31 McDaniel's partner Dr. Roy Geronemus, director of the Laser & Skin Surgery Center of New York, presented the results of a larger study of 90 people, mostly women, to the American Society for Dermatologic Surgery, of which he is president. He reported that GentleWaves produced a 62% improvement in appearance of the skin in the eye area, 36% in the upper lip area and a 26% improvement in skin roughness around the eyes.

McDaniel says tests are being con-



Antiaging Lamp

LED photomodulation uses pulses of light to stimulate protein production. Over time, wrinkles, acne scars and stretch marks are filled in and smoothed out by new and plumped cells.



ducted at top-notch facilities, notes that all three doctors have university affiliations and says that negotiations are in progress to conduct independent tests next year. "My mission has been science first, commercialization second," he says, promising the science is secure. He plans to release more information at the spring meeting of the American Society for Laser Medicine and Surgery. "I'm pretty comfortable with the technology," says Suzanne Kilmer, president of the ASLMS.

But, given the swarm of vain consumers out there, hard proof may not be prerequisite for success. There were 8.5 million cosmetic surgical procedures performed in 2001, generating \$9 billion in surgeons' fees alone, up 48% from 2000. The closest thing out there to LED photomodulation is a controversial procedure called nonablative laser treatment, which uses heat to burn away sub-surface skin so that new cells will replace it. Doctors performed an estimated 127,000 nonablative laser skin procedures this year, up from 110,000 in 2001.

McDaniel, a laser skin treatment specialist, had been researching LED photomodulation for over five years. He formed Light Bioscience in March 2000, subsidizing his research and patent filings with a second mortgage on his house and a loan

against his life insurance policy. Early this year he brought in fellow laser experts Dr. Geronemus and Dr. Robert Weiss, assistant professor of dermatology at Johns Hopkins University School of Medicine. This summer he raised an undisclosed sum from the local investors to fund the company. The firm plans to file for FDA approval next year, though it isn't required for the device.

McDaniel plans one version of GentleWaves for doctors' offices and a home version. The company has yet to fix a price for the home version, but physician models could run \$55,000. Office treatments will be priced to compete with laser treatments, which are typically \$500.

Several LED devices on the market make claims such as relief of arthritis-related pain. Michael Moretti, editor of trade magazine *Medical Laser Insight*, expects to see 100 LED technologies out next year, most of which he says won't have any more effect than a penlight.

But Sharlene Breikreuz, for one, is convinced it works. Within a month of her first treatment, she says, friends and family were complimenting her on her smoother skin. "Like a baby's heinie," she says, adding that she'd jump at the chance to try GentleWaves again. Who needs scientific proof? "He certainly proved it on me." **F**

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