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Doctors Question Some Skin Therapies

Continued From Page D1

the predicate. An FDA spokeswoman says that consumers shouldn't assume that the agency evaluates the effectiveness of low-risk devices like cosmetic lasers.

The technologies differ, but many use energy to heat the skin's inner layers, tighten collagen fibers and stimulate new collagen production. Hayward, Calif.-based Thermage Inc.'s ThermoCool system uses radio-frequency technology, for instance. Cutera's Titan is a handset used with an infrared light source.

Hybrid devices that combine various instruments and energy sources are also popping up. Israel-based Syneron Medical Ltd., which makes VelaSmooth, also recently launched ReFirme, which combines an existing energy technology with a new applicator. New devices for cellulite include Westford, Mass.-based Cynosure Inc.'s TriActive LaserDermology, and the Accent laser from Israel-based Alma Lasers Ltd., which is awaiting FDA clearance.

Side Effects

Most physicians agree that lasers have improved over the years and work well for some cosmetic treatments, such as removal of unwanted hair, tattoos and brown spots. The devices differ from surgical lasers, which use higher heat to cut tissue. They are generally safe in the hands of a trained physician or technician, but side effects can include burns, redness and bruising if the devices are used improperly, doctors say.

The American Academy of Dermatology has no position on the use of aesthetic laser treatments, other than to recommend that a licensed physician be present during treatment. Impressed by the devices' ability to lessen cellulite or tighten skin. "Some patients show minor improvements, but for the vast majority there isn't a whole lot we can see at this point," says Emil Tanghetti, clinical professor of dermatology at the University of California at Davis.

"On average, patients tend to improve by as little as 5% to 9% in some categories, and by 25%

in others," according to a panel discussion at the Controversies and Conversations in Laser and Cosmetic Surgery seminar in Colorado Springs, Colo. A summary of the continuing-medical-education seminar was published in the January 2006 supplement to "Skin & Aging" magazine.

One of the participants, A. Jay Burns, a plastic surgeon in Dallas, said in a recent interview that Thermage is a "great" procedure when it works, but "that only happens 10% to 20% of the time." Dr. Burns, a former member of the company's scientific advisory board, charges \$2,500 for a Thermage full-face and neck treatment. But he says he is using Thermage "less and less."

"That's not the universal experience. It doesn't ring true of what we hear around the world," says Pamela Buckman, Thermage's vice president of clinical and regulatory affairs.

One point of misunderstanding among consumers, and even physicians, involves the FDA's marketing clearance for the devices. The FDA says it hasn't cleared any laser specifically for skin tightening, body contouring or skin laxity. Syneron's ST device, used in the ReFirme procedure, for instance, is cleared only for "wrinkle treatment," and Cutera's Titan is cleared for "topical heating" of tissue to increase circulation. That may come as a surprise to beauty mavens who are inundated with articles and online messages promising skin tightening not only of the face and neck, but of the abdomen, thighs and upper arms—and touting the devices' stamp of approval from the FDA.

Off-Label Marketing

Once devices are cleared by the FDA for one use, physicians and medical spas are free to use them for whatever they choose. And while the manufacturers can't advertise such "off-label" uses, the medical practitioners are free to do so. For example, the Medical and Skin Spa at the Hyatt Grand Champions Resort in Indian Wells, Calif., promotes Titan on its Web site as "a revolutionary skin and collagen tightening system" whose "clinical studies confirm improvement in better than 90% of the patients treated."

Titan maker Cutera says a typical regimen of two treatments from the mid-face down, including the neck, generally costs \$1,500 to \$2,000 or more in the New York and Los Angeles markets. The spa at the Hyatt Grand Champions charges \$3,000 for a series of three Titan treatments.

Cutera officials say they have been talking for about 18 months with the FDA about a Titan indication for skin tightening or some similar claim. The agency is insisting on measurements to quantify the skin's elasticity. "The challenge is that none of the [measuring] tools is accurate or repeatable enough to see what's going on," says Mike Levermier, vice president of clinical development.

Citing Evidence

Titan says it has positive laboratory studies as well as "clinical white papers and peer-reviewed studies showing a patient response." Company officials acknowledge, however, that results are "variable" and sometimes "random."

Endermologie, introduced into the U.S. over a decade ago, is a therapeutic massager for cellulite, not a laser. A pack-age of 14 sessions costs \$1,200 to \$2,000, says Michel Van Welden, chief operating officer for LPA One Inc., a French-owned company that markets Endermologie in the U.S.

But nothing works very well against cellulite, says New York dermatologist David J. Goldberg. Patients initially showed improvement, but swelling from the Endermologie device's deep massage and suction action temporarily masked the dimpling appearance of cellulite, rather than getting rid of it, Dr. Goldberg says.

LPA One says it has studies showing that results last up to six months after the end of treatments.

Today, Dr. Goldberg offers a rival procedure, VelaSmooth, for \$400 a session; most people get about 16 of them. Dr. Goldberg, who has received research funds from Syneron and other device makers, says he believes VelaSmooth is longer lasting, and at least it is "better than nothing." ■

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