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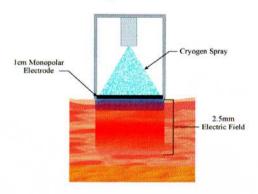
Radiofrequency device offers advantages of its own

Nonablative technology delivers high amount of deeper, focused energy

BY NANCY GROVES STAFF CORRESPONDENT

Atlanta — A new radiofrequency energy device that can nonablatively change the morphology of the dermis and allow the physician to put a high amount of energy into the skin is a huge step forward in the treatment of cosmetic conditions, said Karl Pope, director of research, Thermage, Hayward, Calif. Thermage is developing an RF device for treatment of skin in

ThermaCool cooling/ heating schematic



(Image courtesy of Thermage Inc.)

dermatology and plastic surgery applications.

"One of the things that's really unique and special about this technology is the fact that it's not light-based," Pope said. "That has some huge advantages, and some disadvantages as well. It depends on what you're trying to achieve. If you're trying to heat up the structure of the dermis, there's probably nothing better to do that with than radio waves."

Moderate heating of the dermis increases colla-

gen production with few side effects at the same time as it improves skin texture, said Pope, who discussed the device at the annual meeting of the American Society of Laser Medicine and Surgery.

"Radiofrequency works by creating an electric field underneath the electrode on the skin. You rapidly alternate the electric field from positive to negative, and by doing that, you cause molecules

> that are charged to move within that electric field. Resistance to that movement or rotation of molecules creates heat," he explained.

> Energy level can be tailored with electrode change. With RF, the use of larger electrodes allows the physician to put energy deeper into the tissue. In contrast, with a light-based system, increasing the depth of penetration requires changing the wavelength. "We're able to increase the depth simply by changing the size or geometry of our electrode," Pope said. "We're able to tailor the electrode to tell us where we're going to put energy into the tissue. We can put a huge amount of energy into the skin safely, and we can put it where we want to."

"With a simple change of the treatment tip, you can go from a very shallow, very small treatment area to a very large, deep treatment area," Pope said.

Thermage and the physicians using the RF device are still in a learning curve, Pope said, but the adaptability of the device should enable them to learn how deeply to direct the heat to treat certain conditions. "If we were looking at treating tissue that's a scar, such as an acne scar, we might want to put the energy more shallow than if we were trying to get a deeper contraction, for instance if we were trying to remodel a scar," he explained.

The Thermage prototype RF system consists of:

- a radiofrequency generator;
- a controlled modular cooling system that houses a cryogen canister and related cooling control components; and
- a hand-held treatment probe that couples both the cryogen cooling and the RF heating device to the treated area.

According to Thermage, research and development efforts are focused on potential aesthetic applications such as wrinkle reduction, skin rejuvenation, and various other therapeutic applications

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eight months, results seem to be long-lasting, suggesting that structural changes in the skin have occurred"

> Karl Pope director of research, Thermage Inc.

for which noninvasive RF heating of the skin and subcutaneous tissue may be beneficial.

The Thermage device has not yet been proven safe and effective for these potential uses and is not available for commercial sale at this time.

Device undergoing beta testing

The device has a U.S. Food and Drug Administration 510(K) clearance for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. Several devices are being used for various procedures in clinical settings in a "pre-beta release," and a full-fledged release is expected soon, Pope said.

"We're getting some good results," Pope said. More than 100 patients have been treated so far at various locations. In cases where patients have been followed for six to eight months, results seem to be long-lasting, suggesting that structural changes in the skin have occurred, he added.

Brian D. Zelickson, M.D., department of dermatology, University of Minnesota, has performed transmission electron microscopy studies of the tissue following RF treatment and has "We're looking for only a mild amount of denaturation. You don't want to denature it all, or it would turn into a scar."

Brian D. Zelickson, M.D. Department of dermatology, University of Minnesota found what appears to be denaturation or shrinkage of the collagen. These studies at the molecular level support the results observed in clinical settings, Pope said.

"We're looking for a mild amount of denaturation. You don't want to denature it all or it would turn into a scar," he added. "We think that a small amount of denaturation will lead to a contraction of skin."

While RF could bring about dramatic changes in cosmetic surgery, the technology is unlikely to put laser companies out of business. "There's some things that lasers are great at," Pope said. James Tunnell, a graduate student at Rice University in Houston, helped Pope with his research. DT

Atlanta — Radiofrequency heating appears to have significant potential as a noninvasive method for achieving tissue tightening, although further study is needed to develop optimum parameters for such use, Richard E. Fitzpatrick, M.D., said at the annual meeting of the American Society of Laser Medicine and Surgery.

His conclusion was based on experience from a study designed to evaluate the safety and efficacy of higher fluence treatment with the radiofrequency device (ThermaCool TC System) for browlifting and improving wrinkles in the periorbital area. Initial patients were treated with energy levels of 110 J/cm² using topical anesthesia to minimize discomfort, but pain became a limiting factor when attempting to raise the treatment fluence. With nerve block anesthesia, however, it was possible to increase the energy to 130 J/cm² with good tolerability.

"Browlifting is an interesting result of the radiofrequency treatment, and it was enough in some patients so that laxity of the upper eyelid was decreased. Our experience indicates it is possible to raise the energy level to improve the outcome without causing damage to the underlying tissue, Dr. Fitzpatrick said. DT