

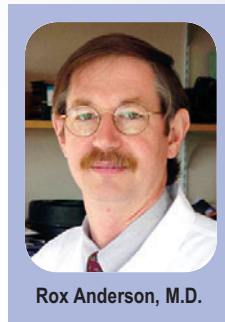
Fractional Photothermolysis Redefines Facial Skin Regeneration Science

Imagine a patient seeking facial aesthetic enhancements as a family portrait requiring touch up. Today family portraits are often digitally altered pixel by pixel to make subjects appear better. Similarly, damaged paintings are delicately “restored” one small area at a time.

The same concept applies to the FRAXEL™SR (FSR) device from Reliant Technologies, Inc. (San Diego, Calif.) and the emerging science of Fractional™ Photothermolysis. This innovative fiber laser system produces microscopic thermal wounds in the skin to achieve facial rejuvenation. A no downtime alternative to CO₂, the Fraxel Laser was developed under the leadership of Len DeBenedictis, Reliant’s president and CTO (former general manager of Coherent Medical).

DeBenedictis and his team worked in collaboration with Dieter Manstein, M.D. and Rox Anderson, M.D., director of the Wellman Laboratories in Boston, Mass., and world-renowned photomedicine expert. “Our treatment approach relies on a treatment concept called Fractional Photothermolysis, that has not been tried until now. The idea is to produce small, almost invisible microscopic sites of heating and space these some distance apart. The value of this approach is our ability to have a very large stimulus without producing very much injury.”

“Every laser on the market causes some tissue heating. Fundamental differences between them are “where” and “how much.” Reliant’s Fraxel Laser



Rox Anderson, M.D.

is a very different version of where and how much,” notes Anderson.

The wound healing response of fractional photothermolysis differs from previous techniques because the areas of epidermal tissue that are spared between treatment zones contain viable cells, including both epidermal stem cells and transient amplifying (TA) cell populations. Thus, re-epithelialization of treatment zones proceeds rapidly, with little or none of the side effects (e.g., pain, fluid drainage and prolonged edema) observed after traditional resurfacing procedures.

If the spacing between microthermal treatment spots creates an average density of 2000/cm², for instance, there are ample viable epidermal cells remaining for rapid resurfacing of both the treatment zone itself and the surrounding heat shock zones. Furthermore, after FRAXEL™ Laser Treatment, the follicular bulge stem-cell population remains intact.

Each microthermal wound field is typically composed of thousands of individual microscopic laser spots and surrounding spared tissue units that comprise “nodes” of cutaneous repair. Each node can be expected to expand beyond its own volume to merge with neighboring nodes, replace photoaged tissue components (including solar elastosis, microvascular ectasia, epidermal atrophy and atypia) and produce complete coverage.

Rapid re-epithelialization is a unique feature of Fraxel Laser Treatment. Each laser hit produces a 30-70 micron plug of microscopic epidermal necrotic debris (MEND). Individual MENDs are not seen, but for example, 2,000 MENDs per square centimeter of treated tissue gives the skin a bronze appearance for about three to fourteen days depending on treatment energy and spacing of the microthermal spots. The MENDs naturally exfoliate.



Richard Fitzpatrick, M.D.

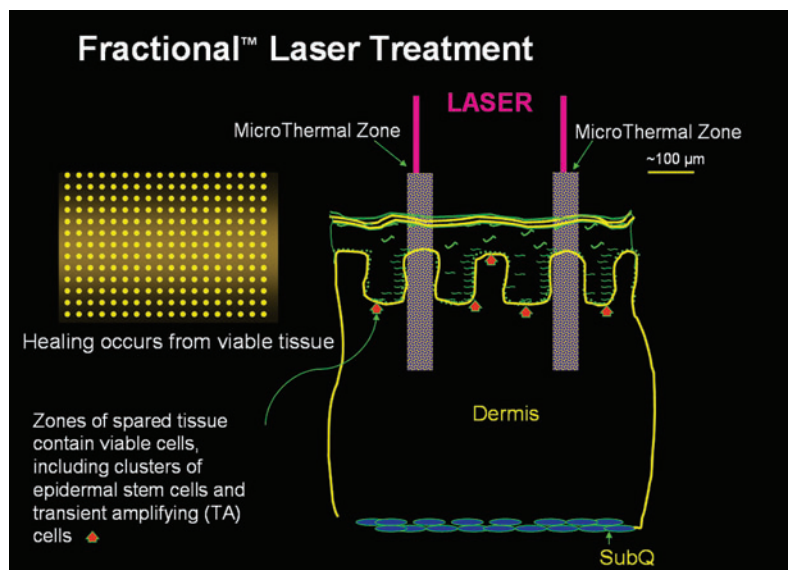
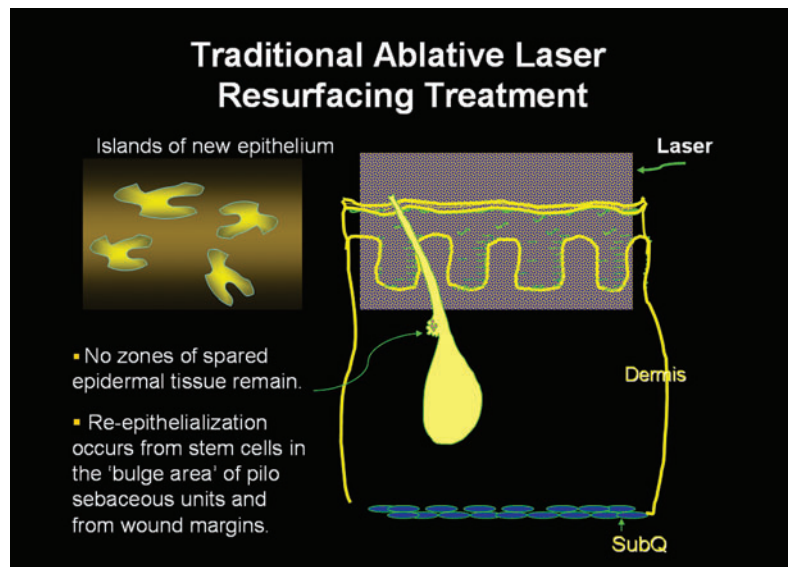
Richard Fitzpatrick, M.D., a dermatologist in private practice in Encinitas, Calif., and former President of ASLMS, has served as a scientific advisor for Reliant. He is most excited by the fact “that you can achieve significant cosmetic improvement and rejuvenation of photodamaged skin without any significant downtime. It also appears there is no significant risk. This is a brilliant expansion by Rox Anderson and Dieter Manstein at Wellman of the original theory of selective photothermolysis from the early 1980s. Instead of having a specific target that you differentiate from the rest of the skin, you are now selectively treating only a very small fraction of the skin at a time.”

Traditional laser resurfacing mostly consists of treating roughly the outer 200 microns of skin, whereas the Fraxel SR device “treats depths of 400 to 700 microns,” said Dr. Fitzpatrick, a voluntary associate clinical professor of dermatology at the University of California, San Diego. “The spots are so small that you cannot see them without unaided vision, but they are close enough together that the cumulative effect results in remodeling of the outer layer of the skin. It is an incredibly innovative approach to a very, very difficult problem. It takes away the problematic postoperative healing time. It also takes away a lot of the risks. But it preserves the capability of rejuvenating the outer layers of the skin.”

Treatment results are gradual. “You achieve step-wise improvement in surface appearance and texture from consecutive treatment sessions,” Dr. Fitzpatrick conveyed. “There is also some improve-

ment in tightening that is seen immediately, which is secondary to edema. It takes about three months to achieve the full tightening effect and from what I’ve observed, results are very similar to CO₂ results. But the mid-infrared wavelength of the Fraxel Laser allows deeper penetration into the tissue. This is a more efficient and effective tissue reaction than I would have expected. This procedure could be what we’ve all been waiting for to revolutionize the whole field of laser resurfacing. But, of course, it is still in the early stages of evolution. Still, I’m very impressed and enthusiastic about the technology.”

According to Barry Weintraub, M.D., who is in private practice in New York City and Los Angeles and is a national spokesperson for The American Society of Plastic Surgery, the Fractional™ Laser treatment protocol is currently being honed down to



four sessions, approximately five to seven days apart. “Treatment produces the result of a CO₂ laser, but with no ablation and no downtime,” said Dr. Weintraub. “I firmly believe that this system will replace CO₂. Although CO₂ can produce excellent results, it is very aggressive and destructive. In contrast, the Reliant device splits up the laser beam into tiny microthermal spots of laser impact. There is no blistering, oozing or crusting. Because the treatment targets water as the chromophore, it leaves an intact stratum corneum. This allows patients to put on makeup or to shave after the procedure. The bottom line is that the patient returns back to work following treatment.”



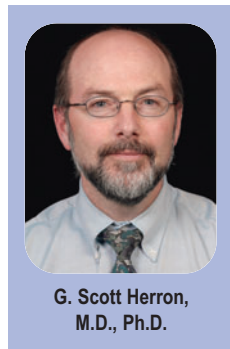
Barry Weintraub, M.D.

Another major advantage over CO₂ is the ability to do this treatment as an office procedure with acceptable pain levels. Using the current pain-management protocol, patients are totally comfortable during the procedure,” Dr. Weintraub explained.

Ease of use is another advantage of the system. “The handpiece contains robotics and an Intelligent Optical Tracking System™ (IOTS),” Dr. Weintraub explained. “The robotics glide along the skin and track velocity to maintain a consistent pattern of microthermal spots, regardless of the operator’s speed. The physician simply slides the handpiece like an optical mouse, with the face serving as a mousepad.”

“We now have the ability to treat photodamaged skin by adjusting the laser parameters to achieve precise levels of tissue damage and subsequent wound repair,” said G. Scott Herron, M.D., Ph.D., the Medical Director for Reliant Technologies. “With current laser technologies, there is either little effect, both cosmetically and biologically, or there is a severe, maximum effect, both clinically and bio-

“Treatment produces the result of a CO₂ laser, but with no ablation and no downtime.”



G. Scott Herron, M.D., Ph.D.

logically. Ablative CO₂ and erbium resurfacing procedures are at one extreme. With those procedures, you have significant levels of unwanted side effects. At the other extreme, non-ablative lasers tend to have little efficacy. Fraxel Laser Treatment allows you to create any desired degree of change, with a controlled level of side effects.”

Dr. Herron is one of several investigators involved in an ongoing study of Fraxel Laser Treatment based on fractional photothermolysis. All 30 patients are being treated in the lateral periorbital area. “In this study, patients are treated a total of four times over a period of several weeks, with three to seven days between treatments,” Dr. Herron said. “We offer topical anesthesia, even though many don’t really need it for this small area of skin.”

According to Dr. Herron, “With our novel system the practitioner sets the fiber laser at the desired treatment energy. The practitioner then moves the

handpiece across the skin. The computer has a scanning device that tells it how fast the probe is moving. Using the intelligent handpiece and tracking system, the practitioner can move at any speed and the IOTS adapts the treatment parameters to

lay down a fixed pattern of microscopic wounds.” Treatment of the face will typically take about 30 minutes, with approximately another 15 minutes to treat the neck and hands. A patient will generally require a series of three to five treatments, and each treatment session addresses approximately 17-20% of the skin surface. “Patients can expect between mild to moderate improvement in all of the clinical indices of photodamaged and aging skin,” Dr. Herron said.

With conventional non-ablative photorejuvenation, low fluences are typically used to spare the epidermis. “But such low levels are generally inadequate to promote the kinds of stimulation required to cause the desired dermal effect, hence resulting in minimal efficacy,” observed Dr. Herron. “Thus, in most cases, minimal dermal matrix remodeling is accomplished by these procedures. Clinical responses also appear to be minimal.”

In contrast to existing ablative and non-ablative technologies, "Fraxel Laser Treatment avoids complete destruction of both the epidermal and dermal compartments, while at the same time achieving enough stimulation to be clinically effective, added Dr. Herron. "Only fractional volumes of the target tissue are thermally altered, as opposed to conventional treatments where the entire target is thermally altered." Similar to digital alteration of photographs and paintings, the clinical effect of this novel technique will be to alter the appearance of photoaged skin via the creation of microthermal wound zones that will heal to produce rejuvenated skin surfaces.

"The Fraxel Laser introduces both a new category of treatment and a new science," said Mark Tager, M.D., vice president of sales and marketing at Reliant Technologies. "We now have the ability to safely and effectively treat a variety of skin types in a gradual manner that allows us to achieve both resurfacing and collagen remodeling." Initially, the Reliant Fraxel Laser will be placed in the hands of physician thought leaders who are the most knowledgeable and involved with lasers. "Many of these physicians have already had significant experience with the CO₂ laser," Dr. Tager said. "Unlike CO₂, the Fraxel Laser is a very tolerant and very forgiving product. We have built in unprecedented safety features and are confident that the Fraxel SR will usher in a new paradigm in aesthetic laser medicine."

According to Dr. Anderson, the first applications of the Reliant Fraxel "will focus on the major advantages of traditional skin resurfacing that deal with treating fine wrinkles, epidermal pigments and remodeling scars." Anderson notes another benefit to the treatment, namely that "the microspot pattern can be feathered easily so that there is no abrupt demarcation of treatment area."

Looking toward the future, Dr. Anderson sees other possible applications for this technology, among them, targeting sebaceous glands. "We know that the Fraxel Laser's micro-beams can affect seba-

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ceous glands. This is evidenced by less oily skin following treatment and changes in pore size. The beam is smaller than the sebaceous gland itself. In fact, it is closer to the size of the duct. Of course, this has not yet been studied, but it does bring up an

interesting area for research. I am also personally very excited to see how we might deal with scars from surgical wounds, trauma, acne or burns. I am hopeful that future clinical trials will show benefit from this type of treatment."

The Reliant Fraxel SR device will debut at the American Society for Laser Medicine and Surgery (ASLMS) meeting in April. "There will be a number of scientific presentations on this subject. Among the presenters will be Drs. Rox Anderson, Dieter Manstein and Scott Herron," Dr. Tager said. "I think that the Fraxel Laser has potential to be a breakthrough technology. It can potentially replace both ablative and non-ablative products in the marketplace." ■

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