A laser system for skin rejuvenation that delivers ablative fractional resurfacing technology made its official debut at the annual meeting of the American Academy of Dermatology.

In May of 2007 the device was cleared by the Food and Drug Administration for ablative, cosmetic skin resurfacing. In December of 2007 it received FDA 510(k) clearance for the treatment of wrinkles, rhytids, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia. The current retail price of the Fraxel re-pair system is $129,000.

Studies of the device have included about 500 treatments over the last 2.5 years. In one recent study of its use on the forearm skin of 24 subjects with Fitzpatrick skin types II-V, researchers tested pulse energies that ranged from 5 to 40 mJ and used hematoxylin and eosin to assess the lesions histologically (Lasers Surg. Med. 2007;39:96-107). They found that changing the pulse energy from 5 to 30 mJ created a threefold increase in lesion depth and a twofold increase in width.

Interestingly, ablative fractional resurfacing demonstrated much more rapid reepithelialization when compared to its nonfractional predecessors, whether powered by erbium or CO₂ lasers,” reported the researchers (some of whom were employed by Reliant), led by Dr. Basil M. Hamzah of Stanford (Calif.) University. “By 48 hours, most subjects demonstrated complete reepithelialization.”

Subsequent studies of the system have used pulse energies that reach 70 mJ. In an interview, one of the other study authors, Dr. Christopher Zachary, chair of the department of dermatology, University of California, Irvine, said that as long as physicians work within the recommended parameters, the Fraxel re-pair system “is going to give you a very predictable and reliable result and it’s going to be much safer than the traditional carbon dioxide or erbium YAG lasers, which were associated with persistent redness, loss of pigmentation—which is delayed and permanent—scarring, and so forth.”

In most cases, one treatment is sufficient and downtime is 2-4 days depending on the parameters used. “On day 3 you have redness and swelling,” said Dr. Zachary, an unpaid consultant to Reliant Technologies.

Dr. Zachary said that he has limited experience using the device in dark-skinned patients, but “I absolutely intend to use it on dark-skinned patients,” he said. “Darker skin types are going to have problems with skin pigmentation. To prevent it, we are pretreating for at least 2 weeks with a bleaching agent such as hydroquinone 4% cream, which will reside within the normal untreated skin of the face. That area that you do not treat will have a reservoir of hydroquinone which tends to prevent increased postinflammatory hyperpigmentation.”

Trials are currently underway to study the device’s potential for treating acne scars, surgical scars, and striae. Dr. Zachary said that patients with severe acne scarring are probably going to have to two to three treatments separated by about a month if they are going to respond.

Dr. Robert A. Weiss, president-elect of the American Society for Dermatologic Surgery, called the Fraxel re-pair system an “elegant device” and noted that ablative fractional technology “is the next phase of fractional. It really does give a lot more improvement.”

Dr. Weiss, who practices in Hunt Valley, Md., said that he currently uses a competing fractional laser procedure from Lumenis Ltd. called ActiveFX, which is delivered by the company’s UltraCool Encore CO₂ system. Dr. Weiss is a member of the medical advisory board for Lumenis Ltd.

Dr. Zachary disclosed that he has received equipment and honoraria from Reliant Technologies and that he serves as a consultant for other laser companies.

A patient is shown before (left) and 1 month after treatment with the Fraxel re-pair laser, which is said to demonstrate “more rapid reepithelialization.”

Porcine Collagen Could Be Answer to Filler Longevity

BY TIMOTHY F. KIRN
Sacramento Bureau

LAS VEGAS — Porcine collagen crosslinked with D-ribose probably lasts as long or longer than does hyaluronic acid when used as a cosmetic filler for lips and nasolabial folds, Dr. Gary Monheit said at the annual meeting of the American Society of Cosmetic Dermatology and Aesthetic Surgery.

The product, Evolence (Dermicol-P35) manufactured by ColBar LifeScience Ltd. (Israel), is approved for use in Europe and Canada and is expected to be approved in the United States, according to Dr. Monheit, principal investigator in the U.S. trial. The company has submitted an approval application to the Food and Drug Administration.

The trial’s split-face design compared Evolence injection with hyaluronic acid (Restylane) injection in the nasolabial folds of 149 patients. After 6 months, there was no significant difference in the mean amount of correction the patients had on either side, said by study observer using the Modified Fitzpatrick Wrinkle Scale score (Dermatol. Surg. 2007;33:S213-21). Dr. Monheit disclosed receiving supplies and financial support from ColBar.

The secret to Evolence’s longevity is thought to be the high level of crosslinking between the individual collagen fibers in the material, he said. “Because of this extra crosslinking, this is a very stable product that lasts over a year, possibly 2 years.”

At 1 year follow-up, 90% of the patients that received Evolence still had some degree of improvement, said Dr. Monheit of the University of Alabama, Tuscaloosa. Evolence has been found to last up to 2 years when implanted into rabbit ears.

Raw material for Evolence comes from the tendons of pigs. In the first step of processing, the pig collagen’s natural crosslinking is broken down by pepin into monomeric collagen. Then the telopeptide of each collagen strand is removed because that part is the most immunogenic.

Pig collagen is used by ColBar because it is probably less immunogenic than beef collagen, he said. Once the telopeptides are removed the material is again crosslinked, but instead of using glutaraldehyde or other potentially problematic chemical to create the crosslinking, ColBar uses D-ribose, Dr. Monheit said.

Deep Heating Skin Found to Improve Fractional Resurfacing

BY BRUCE K. DIXON
Chicago Bureau

CHICAGO — The clinical results of fractional skin resurfacing may be improved by pretreatment with an infrared laser or broadband infrared light source, according to a pilot study presented at the annual meeting of the American Society for Dermatologic Surgery.

“In the treatment of scars and wrinkles, combination deep heating immediately prior to fractional resurfacing gives better results in less time than fractional laser treatment alone,” said Dr. Robert Weiss, of the dermatology department at Johns Hopkins University, Baltimore.

For this study, a control group of 20 patients received the usual fractional resurfacing on the face or neck with the Lux 1340 (Palomar Medical Technologies), while 20 others first received deep heating with an infrared pulsed laser using the 1,320-nm CoolTouch 3 (CoolTouch Inc.).

“Using the CoolTouch, we preheated the skin from a typical baseline temperature of 32° up to 40°, and then we applied the fractional resurfacing to the scar or wrinkle with the 1540 nm stamped mode at 50 mJ per little dot,” Dr. Weiss said.

The control group received four monthly treatments, while the deep heating plus fractional group received two monthly treatments, he said, adding that the results were evaluated out to 3 months after the last treatment.

Down times caused by erythema ranged from 12 to 24 hours in the control group and increased to 48-96 hours for those receiving the combination treatment. That compares with 48-96 hours for patients who receive CO₂ laser fraction treatment, Dr. Weiss explained.

Pretreatment with heat produced both faster and visually better results, Dr. Weiss said, adding that, in some cases, two combination treatments improved scarring as much as five fractional-only treatments.

The investigators concluded that the combination treatment demonstrated a 30% improvement in scars and rhytids, compared with fractional only, and reduced the number of treatments from four to two.

Dr. Weiss is a consultant for Palomar and CoolTouch and performs research for Palomar, Cynosure, and CoolTouch.