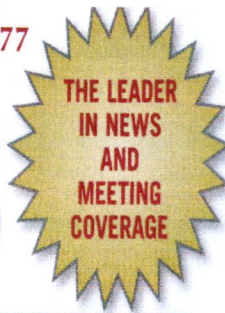




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Fractional Ablative CO₂ Laser Displays Safety and Efficacy

FDA approval for photodamage expected.

BY MITCHEL L. ZOLER
Philadelphia Bureau

GRAPEVINE, TEX. — A new skin-resurfacing laser that applies fractional beam splitting to an ablative carbon dioxide laser is safe and effective for the treatment of photodamage and acne scarring on the face and neck, according to the results of two studies presented at the annual meeting of the American Society for Laser Medicine and Surgery.

In a series of 58 patients, two treatments with this laser led to improvements in photodamage or in acne scarring with no pigment changes or scarring after up to 9 months, Dr. Elizabeth K.

Hale said. The series that she reported included detailed data on 15 patients who underwent resurfacing on the face or face and neck for photodamage and 15 other patients who had face or face-and-neck resurfacing for acne scarring.

Results from a second series of 30 patients were reported by Dr. Zakia Rahman, a dermatologist at Stanford (Calif.) University, and her associates. Dr. Rahman has received consulting fees from, and is a stockholder with, Reliant, manufacturer of the fractional CO₂ laser.

The new ablative laser is "clearly safe," and produces results with one or two treatments that are

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comparable with the cosmetic effects from five to seven treatments using the fractional lasers that are currently on the market, which have less skin penetration and work by coagulation instead of ablation, said Dr. Hale of New York University.

"The results using the fractional CO₂ laser were "very impressive and a significant advance," commented Dr. Jeffrey S. Dover, a dermatologist in private practice in Chestnut Hill, Mass.

The fractional lasers on the market produce results that are "nice but not spectacular," he said in an interview.

The fractional CO₂ laser appears to fill a niche between these two, said Dr. Dover,

who is also a member of the dermatology departments at Yale University in New Haven and Dartmouth University in Hanover, N.H.

Prior experience with conventional CO₂ lasers, also known as erbium:YAG lasers, which emit light at 1060 nm, was that hypopigmentation was seen in about 16% of patients followed for more than 6 months who underwent facial resurfacing.

In the series reported by Dr. Hale, however, none of the patients has shown hypopigmentation in almost 9 months of follow-up, said Dr. Roy G. Geronemus, a coinvestigator of the study who also is with New York University. Dr. Geronemus has received equipment from Reliant and is also a stockholder.

The 3- to 5-day recovery time from each treatment with the fractional CO₂ laser was also much quicker than the usual recovery from conventional CO₂ resurfacing but longer than the 1

day usually needed following treatment with approved fractional lasers.

Based on results from 15 patients with resurfacing for photodamage from Dr. Hale's NYU series and from 114 additional patients at six other U.S. sites, Reliant has applied to the Food and Drug Administration for licensing of the device for treating photodamaged skin. Action by the FDA is expected within the next few months, said a Reliant spokesman. Once approved, the new laser will be marketed as Fraxel repair.

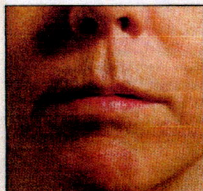
Reliant also plans to submit additional data to the FDA in the near future to support approvals for treatment of acne scarring—using data from about 45 patients—and treatment of atrophic scars—with data from about 60 patients, according to the company spokesman.

In the NYU series, the 15 patients undergoing treatment for photodamage received two treatments. They received a topical anesthetic and a laser dose of 20-40 mJ. The laser was used in three passes with 50% overlap, with a total of 1,200 microthermal zones/cm² on the face. The depth of ablation was 1.0-1.5 mm. The neck was also treated on some patients, a region that cannot be safely treated with a conventional CO₂ laser, Dr. Hale said. The erythema and edema of treatment resolved within 1 week. Overall improvement as scored by patients and physicians was about 3 on a scale of 1-4.

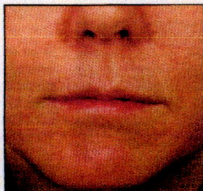
Two treatments will also be used for patients with acne scarring, but at the time of her presentation some of these patients had not yet received their second treatment. The average overall improvement in these patients was about 1.5-1.8 on a scale of 1-4, but the improvement scores may continue to rise with additional follow-up, said Dr. Hale, who had no financial conflicts to disclose.

The series of 30 patients reported by Dr. Rahman included patients treated at three locations in California. All patients were treated for photodamage and were included in the data submitted by Reliant to the FDA. Dr. Rahman previously reported preliminary data on these 30 patients at an international symposium on cosmetic and laser surgery in Las Vegas (SKIN & ALLERGY NEWS, Feb. 2007, p. 16).

All patients received a single treatment, with a dose of 10-20 mJ and a density of about 400-1,600 microthermal zones/cm² on the face, with about half that density for treatment on the neck. The patients reepithelialized within 48 hours, and none has shown hyperpigmentation during follow-up that has extended up to 12 months in 9 patients (the other 21 patients have been followed for 3 months). The efficacy of the cosmetic effect was comparable with what is usually achieved with an ablative treatment with a conventional CO₂ laser, said Dr. Rahman. ■



Patient is shown at baseline with perioral rhytids.



Improvement is seen after two laser treatments.

PHOTO COURTESY: DR. ELIZABETH K. HALE