Acne Scar Approval Is Next Focus

Laser *from page 1*

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.

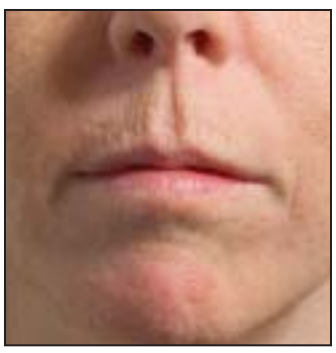
The results using the fractional CO_2 laser were "very impressive and a significant advance," commented Dr. Jeffrey S. Dover, a dermatologist in private practice in Chestnut Hill, Mass.

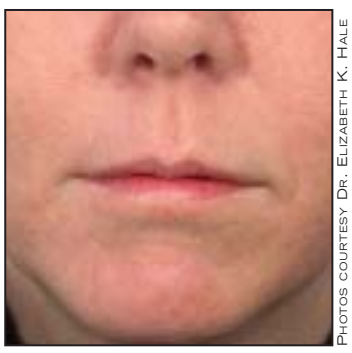
The fractional lasers on the market produce results that are "nice but not spectacular," he said in an interview.

The fractional CO_2 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 CO_2 lasers, also know 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.





PHOTOS COURTESY DR. ELIZABETH K. HALE

Patient is shown at baseline with perioral rhytids.

Improvement is seen after two laser treatments.

The 3- to 5-day recovery time from each treatment with the fractional CO_2 laser was also much quicker than the usual recovery from conventional CO_2 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 re:pair.

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/cm^2 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 CO_2 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/cm^2 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 CO_2 laser, said Dr. Rahman. ■

Complications With Fillers, Botox Injections Can Be Avoided

BY DAMIAN McNAMARA
Miami Bureau

MIAMI BEACH — Inappropriate placement and potential sensitivity reactions are possible complications of fillers, and asymmetry, swelling, and bruising can occur after injections with botulinum toxin, Dr. Joel L. Cohen said at a symposium sponsored by the Florida Society of Dermatology and Dermatologic Surgery.

"Most people have moved away from injecting Radiesse in lips—it can migrate superficially and give a 'popcorn' appearance," he said. "Most of our patients are of the age that they think back to Goldie Hawn in the 'The First Wives Club.' "

Permanent fillers can be less forgiving and require more expertise to inject. ArteFill became the first nonresorbable, injectable filler implant approved for aesthetic use in the United States in October 2006. Complications reported with an earlier formulation approved outside the United States, ArteColl, might apply to ArteFill as well. "If placed too superficially, like any filler, it can cause nodules, but these are long-term nodules," said Dr. Cohen, a dermatologist in Englewood, Colo.

Adverse events associated with poly-L-lactic acid (Sculptra) include granulomas reported in several studies, especially from the European experience (Dermatol. Surg. 2005;31:772-6), and infections. "Infraorbital skin can be thinner, so infraorbital area injections with Sculptra can be problematic," Dr. Cohen said. To avoid pitfalls, "inject deeper and use higher volume reconstitutions."

When hyaluronic acid fillers are not injected deeply enough, especially in the tear-trough area, there can be a Tyndall effect, he said. Treatment of this adverse event is to nick the skin and try to express the product, or treat with a laser, or try to dissolve the product with hyaluronidase.

Dr. Cohen treated a woman who had previously been injected with a hyaluronic acid product and then developed delayed erythematous nodules (Dermatol. Surg. 2006;32:426-34). It is hard to know if this was an infection or a type of sensitivity. Three negative cultures were performed, and her indurated nodules finally cleared after a few courses of antibiotics over several months, he added.

Other adverse scenarios with fillers include the potential of inducing a herpes simplex virus (HSV) sore. "Think about prophylaxis [for HSV] when doing lip augmentation or injecting etched-in lip lines, especially in patients with a significant history of cold sores. Though, fortunately, I have not yet seen a postprocedure HSV flare with an aesthetic patient, I did see this in one of my Mohs surgery patients a few days after a lip repair," he said.

Many poorly trained physicians are inadequately supervising poorly trained nonphysician providers.

DR. COHEN

Necrosis is really the complication of most concern. This process can occur from excessive product placement compressing arterioles or from frank intravascular placement of product, Dr. Cohen said.

To avoid this complication, know the facial vasculature of the areas being injected, he advised. "I have participated in treatment of three patients that received hyaluronic acid fillers who were diagnosed by their injecting physicians with 'impending necrosis' a few hours later. The skin was developing localized areas of patchy, purple reticulated discoloration [visible] on photos sent to me. I recommended hyaluronidase injections in and around the area to try to decompress the vessels and to facilitate flow, and fortunately this was successful." (Case report in press.)

There are fewer adverse events reported with use of botulinum toxin, compared with fillers, but asymmetry, unwanted migration, swelling, and bruising have all been seen and have been reported to the FDA after botulinum toxin injections (J. Am. Acad. Dermatol. 2005;53:407-15).

"Complications from fillers, botulinum toxins, and lasers are very often related to inexperienced injectors/providers or … unsupervised and inadequately trained nonphysician providers," he said.

The physicians who are supposed to be supervising these procedures are rarely present and "have no training or experience themselves in the procedures in which they are supervising and just want to make a buck," said Dr. Cohen, chair of the American Society for Dermatologic Surgery's patient education committee.

COURTESY DR. JOEL L. COHEN

When fillers are not injected deeply enough, lumps under the eye can result.

He applauded the Florida legislature for passing "very appropriate" supervision guidelines in 2006 and said that these kinds of guidelines are needed on a national basis.

For any procedure, appropriate patient selection is important to minimize complications. For example, "some patients with a significant redundancy in their brow and lid skin should not be treated with botulinum toxin in their lower forehead, as this will only accentuate the problem and exacerbate the brow ptosis and redundant eyelid skin," Dr. Cohen said.

Dr. Cohen evaluates patients while they are animated to help determine botulinum toxin dosing and placement, but he recommends injecting while the patient's face is relaxed. A zygomaticus muscle pulled up at the cheekbone when the lower crow's-feet are being injected, for example, might have a higher risk of inadvertent spread to the muscle that would cause an asymmetric smile for 3-4 months, he said.

Dr. Cohen is a consultant, speaker, clinical trial investigator, and instructor for Allergan (Botox); a consultant, speaker, clinical trial investigator, and instructor for Medicis (Restylane); and a consultant and clinical trial investigator for BioForm, manufacturer of Radiesse. ■