Deep Injection Technique May Prolong Results

Tri-site bolus technique treats an area often uncorrected after facelift or blepharoplasty.

BY JEFF EVANS
Senior Writer

QUEBEC CITY — A series of deep injections with hyaluronic acid fillers to lift the cheek and lower eyelid regions appears to provide long-term cosmetic results, Wayne Carey, M.D., said at the annual conference of the Canadian Dermatology Association.

Deep injections of hyaluronic acids have been thought conventionally to be quickly absorbed if injected below the dermis, but deeper bolus injections appear to have long-lasting effects, said Dr. Carey, director of dermatologic surgery at McGill University, Montreal.

Dr. Carey's "tri-site bolus technique" delivers a bolus of hyaluronic acid to tissue about 3-15 mm deep into subcutaneous, supraperiosteal areas, unlike other procedures that employ a threading or microdroplet technique to inject filler to a depth of only 1-2 mm.

"This is a treatment that addresses the midface aging that is not corrected by facelifts or blepharoplasty," he said.

The technique increases the cheek volume, allows sculpting of the cheek in the zygomatic region, lifts or ablates the palpebral sulcus, and may increase the nasolabial fold indirectly by volumetric expansion of the cheek, he explained. It often makes a lower eyelid blepharoplasty or standard facelift unnecessary.

During the procedure, Dr. Carey asks his patients to sit erect while he delivers a continuous deep injection without anesthesia, without moving the needle, and without massaging the injection area; this forms a nonvisible, subcutaneous nodule. Right-handers inject with the right hand and control the migration of the material with the left hand.

He typically injects 1-5 syringes (each is 0.8 mL) into the upper cheek area on each side, although on average he injects 2.5-3 syringes per side. The first site of injection is usually around the location of the infraorbital nerve, followed by the zygomatic and nasal-jugal sulcus areas.

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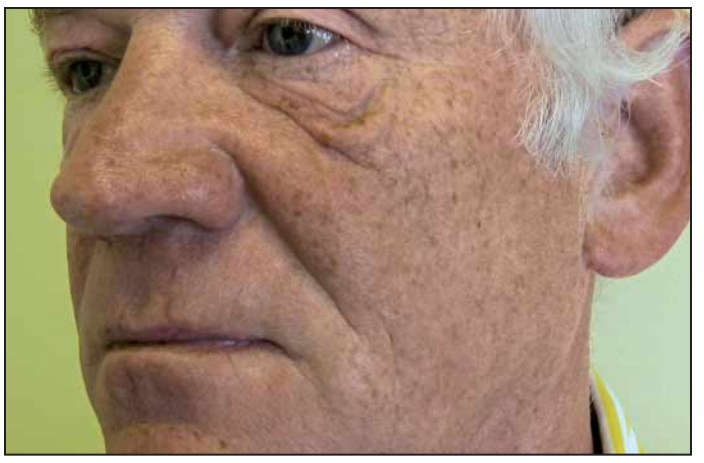
The effects of the technique have lasted over 18-24 months of follow-up and even up to 4 years in one woman, said Dr. Carey, who said he has no conflicts of interest regarding any hyaluronic acid products.

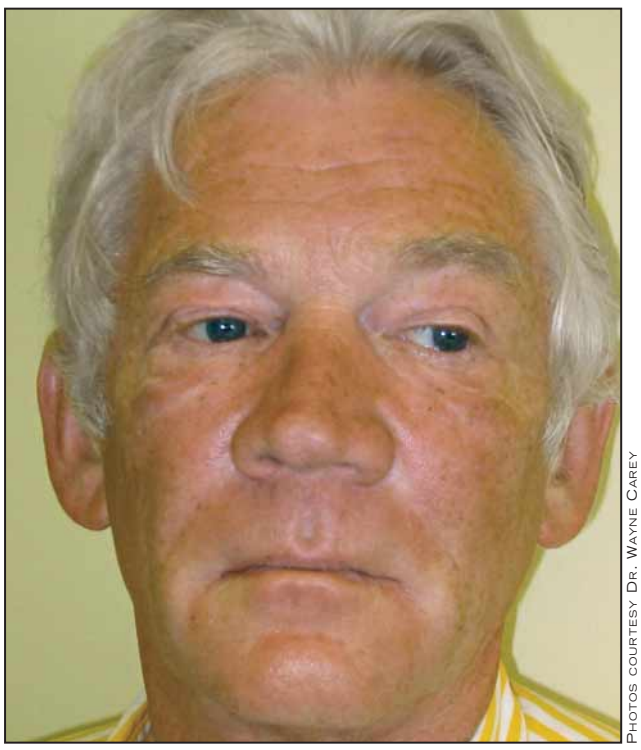
Although Dr. Carey has used only Perlane and Juvederm 30 in more than 75 patients he has treated with his technique, he suggested that deep, bolus injections with Restylane or Hylaform would theoretically give the same longevity seen in his patients, he said in an interview. Perlane and Restylane produce a more swollen appearance in the first few days after injection than other hyaluronic acid products, such as Juvederm, because they draw in more water from their surroundings.

The bolus technique may last longer than other procedures that inject hyaluronic acid products into the dermis because the nodule that is formed with the technique has a lower surface-area-to-volume ratio, making less hyaluronic acid available for hyaluronidase to break down. The body also might wall off the nodule, which would also make it less susceptible to hyaluronidase, Dr. Carey suggested. In a report, a biopsy of an injection site where Restylane persisted for 5 years showed a fibrotic reaction (Ophthal. Plast. Reconstr. Surg. 2004;20:317-8).

Heavy bruising lasting up to 1 week has been a significant problem in most patients who received the injections. One patient had prolonged pigmentation, which might be deposits of hemosiderin or postinflammatory hyperpigmentation, he said. Another patient has had persistent, unilateral lymphedema for about 2 months, but has improved during the last few weeks, Dr. Carey said. He is considering injecting hyaluronidase into the treatment site to relieve the complication. ■



Before treatment, this patient had malar bags and considerable loss of subcutaneous tissue of the cheeks.



PHOTOS COURTESY DR. WAYNE CAREY

Final results were achieved after injection of 13 syringes of hyaluronic acid.

FDA Unveils iPLEDGE Program

Isotretinoin *from page 1*

say is long overdue," said Sandra Kweder, M.D., deputy director of the FDA's Office of New Drugs.

The program's implementation will be incremental, starting with the Oct. 31, 2005, deadline for registration of wholesalers and pharmacies to obtain isotretinoin from a manufacturer. Prescribing physicians and their patients will then have 2 more months to be registered and in full compliance. Under the program, wholesalers of Accutane or the four currently approved generic equivalents will distribute isotretinoin only to pharmacies that have registered with the safety program and continue to demonstrate ongoing compliance.

Those pharmacies will only dispense prescriptions when the prescribing physician has registered the individual patient being treated and certified that the patient has been informed of the teratogenicity risks and has had two negative pregnancy tests performed by a laboratory or in the physician's office. Patient registration will be done over the Internet or by phone.

Patients must also register themselves and sign a consent form agreeing to use two forms of birth control while on the drug. Patients will be required to have repeat pregnancy testing every month while they are on the drug and another 1 month after they stop. Prescriptions will need to be filled within 7 days of pregnancy testing.

The package insert and the patient informed consent form have been updated and now contain a new warning that there have been suicides reported in patients taking isotretinoin. Both inform patients about what signs to watch for and tell them to contact their health care provider if they recognize any of those signs.

In its information sheet for health care providers, the FDA says that the reported number of suicides of patients taking isotretinoin between 1982 and 2002 was actually lower than the number of suicides that would be expected in that population (165 reported suicides vs. 220 expected). However, laboratory studies in animals have shown that isotretinoin can affect the brain and behavior, which means that the contention that isotretinoin could be associated with depression and suicide is biologically plausible.

In concert with the new dedication to monitor and control access to the drug very tightly, the FDA is also going to make a renewed effort to prevent Internet sales and discourage drug importing from abroad, Dr. Kweder said.

The new program replaces the old SMART program and the other similar programs for the generic products. Under SMART, physicians who wanted to prescribe Accutane needed to complete an education program to obtain the yellow stickers that needed to be attached to the paper prescriptions for pharmacies to fill the prescriptions. When attaching a sticker, the physician was also required to register the patient and to certify that the patient had undergone pregnancy testing and that the results were negative.

FDA determined that the SMART program needed to be replaced with a more stringent program because data from the first 2 years of the program, which went into effect in 2002, showed that it had not significantly reduced the rate of pregnancies occurring in patients on isotretinoin, which was its aim. Some also claimed that not all physicians were being fully compliant with the pregnancy testing requirement of the program.

Moreover, too few patients were signing up with the voluntary patient registry that was a part of the program.

Kenneth Bloom, M.D., a pediatric dermatologist in Minneapolis, said he was unnerved by the lack of details that were available about the new program.

One purported advantage of the new program is that it will make things simpler for physicians by combining the specialized programs unique to each isotretinoin manufacturer.

But the purpose of the new program is not to lessen restrictions on the drug, Dr. Bloom noted, adding that he is not harboring hope that the new program will ease what physicians are required to do.

"I have no idea what I am getting myself into," Dr. Bloom said. "I think it is going to be more time consuming."

The FDA estimates that 100,000 prescriptions are written for isotretinoin in the United States every month. The number of prescriptions written initially dropped about 20% when the SMART program went into effect, but it has remained stable since then.

Physicians can find out more by calling 866-495-0654 or by visiting www.ipledge.com, which will be available soon. ■