

Botulinum Black Box: How Much to Disclose?

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PHOENIX — It may not be necessary to disclose all the potential risks of botulinum toxin that are listed in the black box warning on the label to cosmetic patients, said Dr. David J. Goldberg.

The final answer on how much disclosure is reasonable will likely come only as a result of future litigation, said Dr. Goldberg, director of laser research at Mount Sinai School of Medicine in New York.

"Err on the side of being conservative, but don't scare people with this entire black box warning," he said. "I would argue you have to take a practical approach." Dermatologists must disclose that the black box warning exists as part of the informed consent process, he said.

The Food and Drug Administration took action after the agency received reports of adverse events associated with the spread of the botulinum toxin beyond the local injection site. Unexpected loss of strength or muscle weakness, hoarseness or trouble talking, trouble saying words clearly, and loss of bladder control have been reported hours to weeks post injection. These sequelae occurred primarily in children with cerebral palsy treated off label to control muscle spasticity, he said.

The doses used for off-label indications "are often much higher" than the doses for approved uses, according to a statement released by the FDA.

The release states, in part: "For the FDA-approved dermatologic use of temporary improvement in the appearance of glabellar lines, the agency has not identified any definitive serious adverse event reports of a distant spread of toxin effect producing symptoms consistent with botulism when the botulinum toxin products are used in accordance with the approved label."

"You have to provide reasonable risks. I don't think you have to go down the road of bladder collapse. I don't mention death [during informed consent]. Your [cosmetic] patient is not likely to die," Dr. Goldberg said at a joint annual meeting of the American Society for Dermatologic Surgery (ASDS) and the American Society of Cosmetic Dermatology and Aesthetic Surgery. He said he had no relevant conflicts of interest.

"I was told we have to inform patients about all the risks on the black box warning," said Dr. Susan H. Weinkle, a Mohs surgeon and cosmetic dermatologist in



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DR. GOLDBERG

private practice in Bradenton, Fla.

"Who told you that?" Dr. Goldberg asked.

"Several companies," replied Dr. Weinkle, who moderated the session at the meeting. She disclosed being a consultant for multiple companies, including Allergan Inc.

"The companies have to tell you that because the FDA requires them to. What is less clear is what is required of doctors," Dr. Goldberg said. He reiterated this lack of clarity exists because "there has been no litigation on this black box warning yet."

"I don't think it's reasonable to have to go through every one of those adverse events with them," he added. Protopic (tacrolimus) also has a black box warning. "Do you go over the ... litany of all the [possible] adverse events every time you refill a prescription?" ■

Matching Fillers to Patients Is Considered an Art Form

SAN FRANCISCO — Although changes to the aging face are often complex, knowing filler basics will help optimize results, Dr. Jason R. Michaels said.

"When I approach patients, I try to keep it as basic as possible: who, what, where, why, and when?" Dr. Michaels said. "It is almost back to the grammar lessons we had as kids."

Even so, pairing the appropriate filler to each patient remains an art form. "Think of [fillers] as different types of paint brushes; and I choose depending on whether I want a broader effect or to treat more detail," he said at a seminar on women's and pediatric dermatology sponsored by Skin Disease Education Foundation (SDEF).

"I tend to look at faces in four different categories: furrows, folds, shaping, and volume," said Dr. Michaels, associate clinical professor of dermatology at the University of Nevada, Las Vegas.

For correction of furrows, for example, options include finer-gauge fillers such as CosmoDerm (INAMED Aesthetics), Prevelle Silk (Mentor), Juvéderm Ultra (Allergan), and Restylane (Medicis Aesthetics). These products are generally safe for injections higher up in the skin. "My ideal choice is CosmoDerm because it works great on fine lines and wrinkles, but the downside is it does not last as long as some others," Dr. Michaels said. He is a consultant for Allergan and a consultant and speaker for Medicis.

For treating folds, "the world is your oyster," Dr. Michaels said. Examples include CosmoPlast (INAMED Aesthetics), Elevee (Anika Therapeutics), and Evolence (Ortho Dermatologics). The majority of his patients are aged 25-55 years and filler studies typically include 18- to 65-year-olds. However, "I inject patients well into their 70s and beyond and some teenagers." Juvéderm Ultra-Plus, Perlane (Medicis), and Radiesse (BioForm Medical) are among his pre-

ferred products for folds, particularly in older patients.

Like other enhancements, shaping with fillers is technique dependent. "This is the art of doing fillers—you are creating a shape, defining some characteristic the patient has," said Dr. Michaels. He prefers CosmoPlast, Juvéderm Ultra, or Restylane for shaping.

Volume replacement "is about quantity, and you need lots of product," Dr. Michaels said. "Think of volume fillers as the rug pad under a rug." Evolence, Perlane, Radiesse, and Sculptra (Sanofi-Aventis) are among the options for volume. "The problem with Sculptra is delayed gratification, which is not necessary a bad thing—some patients do not want their friends to know they used a filler," Dr. Michaels said.

Filler products can be used in combination, which "is taking this to a new level," Dr. Michaels said. "It is not uncommon for me to use two or three different fillers on the same patient." An example of a combination is Perlane injected into the low dermis, Restylane in the mid-dermis, and CosmoDerm in the high dermis.

"Its limitation, of course, is going to be cost. Not everyone can afford that," Dr. Michaels said.

Dr. Michaels urged caution with injection of fillers superficially "unless you have a lot of experience." Even with the best intentions, fillers do not always end up at the level a physician perceives, "although the outcomes are fine," according to a histologic study of hyaluronic filler injections in 16 patients (*Dermatol. Surg.* 2008;34:S56-62).

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For a video of Dr. Michaels explaining his strategy for patients on a budget and for use of filler combinations, see www.youtube.com/SkinAndAllergyNews.

Laser, Roller System Found to Reduce Thigh Circumference

PHOENIX — Investigators found significant decreases in thigh circumference following multiple treatments with a dual-wavelength laser system with mechanical manipulation, compared with untreated thighs, in a multicenter study.

Dr. Michael H. Gold and his colleagues assessed 83 women 1 month after treatment with the SmoothShapes dual-energy laser and mechanical manipulation system (Elemé Medical Inc.). Each participant had one thigh selected randomly for treatment twice a week for 4 weeks, while their other thigh served as a control.

Significant reductions in circumference were noted at the

upper, mid, and lower thigh, compared with baseline and the untreated thigh, at each assessment. "The SmoothShapes two-wavelength system was highly effective in producing thigh circumference reduction at each location and at each time point," said Dr. Gold, who is in private practice in Nashville, Tenn., and is also with Vanderbilt University in Nashville. He is a consultant for Elemé Medical, which funded the study.

A total of 59 patients were considered responders (71%), and this group achieved a 3.5-cm average thigh circumference reduction at 1 month, Dr. Gold said at the joint annual meeting

of the American Society for Dermatologic Surgery and the American Society of Cosmetic Dermatology and Aesthetic Surgery.

Mean circumference reductions on the treated thighs were "consistently, statistically significantly greater at all time points," Dr. Gold said. "Three months' follow-up was also statistically significant."

Investigators enrolled participants at one of five sites in the United States and one in France. The laser system features a 915-nm wavelength that liquefies fat. The device also has a 650-nm wavelength to increase fat cell membrane permeability. Contoured rollers then move

liquefied lipids from the interstitial space to the lymphatic system for drainage, according to the manufacturer. The Food

and Drug Administration cleared marketing of the device for the temporary reduction in the appearance of cellulite. ■



With laser and manipulation system treatment, reductions in thigh circumference were noted in patients at 1 month.