

Recent Studies Refute Botox Reconstitution Myths

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NAPLES, FLA. — Several longstanding myths and misconceptions about the botulinum toxin type A technique have recently been refuted, James M. Spencer, M.D., said at the annual meeting of the Florida Society of Dermatology and Dermatologic Surgery.

"When botulinum toxin first came out, we were told a number of things about using it," he said.

Some of the directives propagated included: It must be reconstituted with non-preserved saline; the protein is fragile and cannot be shaken or made to foam; and, it must be used within 4 hours of reconstitution, again because the protein is fragile. "None of these are true," said Dr. Spencer, who is director of Mohs micrographic surgery at Mount Sinai Medical Center, New York, and maintains a private practice in St. Petersburg, Fla.

Many physicians also got the idea that patients could not lie down for 4 hours after a treatment. 'We all believed it [but] it turns out that is ridiculous.'

Preserved saline is actually preferable, he said. The preservative in saline is usually benzyl alcohol, which not only kills bacteria but is a mild anesthetic.

In a recently published study, 93 subjects were treated with botulinum toxin type A (Botox). Sixty of those patients received Botox reconstituted with preserved saline. They had a lot less pain, as measured by a visual analog scale, than did the patients who received Botox in preservative-free saline—a mean score of 1.2 out of 10 for those treated in the face with preserved-saline Botox vs. a mean 4.5 for those treated with preservative-free Botox (*Aesthetic Plast. Surg.* 2005;29:113-5).

"The other good thing about using the preservative is that you don't have to throw it away in 4 hours, because it is preserved," he added.

In a Brazilian study, 88 patients were treated with Botox that was reconstituted the day before, or for various periods of time up to 6 weeks before. There was no difference in efficacy when the patients were followed every 2 weeks for 4 months, with blinded observers evaluating their maximum frown (*Dermatol. Surg.* 2003;29:523-9).

In a third study, investigators treated patients with Botox that was reconstituted gently, or with Botox that was shaken vigorously. Again, there was no difference in efficacy, at 2 months and 4 months, Dr. Spencer said (*Dermatol. Surg.* 2003;29:530-1).

Many physicians also got the idea that patients could not lie down for 4 hours after a treatment. Dr. Spencer said he once told patients that, though he is not sure where he picked up this notion, and in trying to trace it, he could find nothing about its provenance.

"It turns out that is ridiculous," he said. "I've been looking for the holes in the skull that Botox would drain through to get to the brain. And, in fact, those holes are not there. There is no reason not to have patients lay down."

"Somebody must have said that, and we all believed it," he added.

Since Botox has been available, there has been a trend toward using higher and higher doses, with even the most reputable experts advocating doses as high as

80 units for the glabella, Dr. Spencer said. Dosing has not been well studied, until now.

There is one study that compared doses of 10 units, 20 units, 30 units, and 40 units to treat the glabella. And another study looked at Botox dosing for the lateral canthus for crow's feet, using escalating doses.

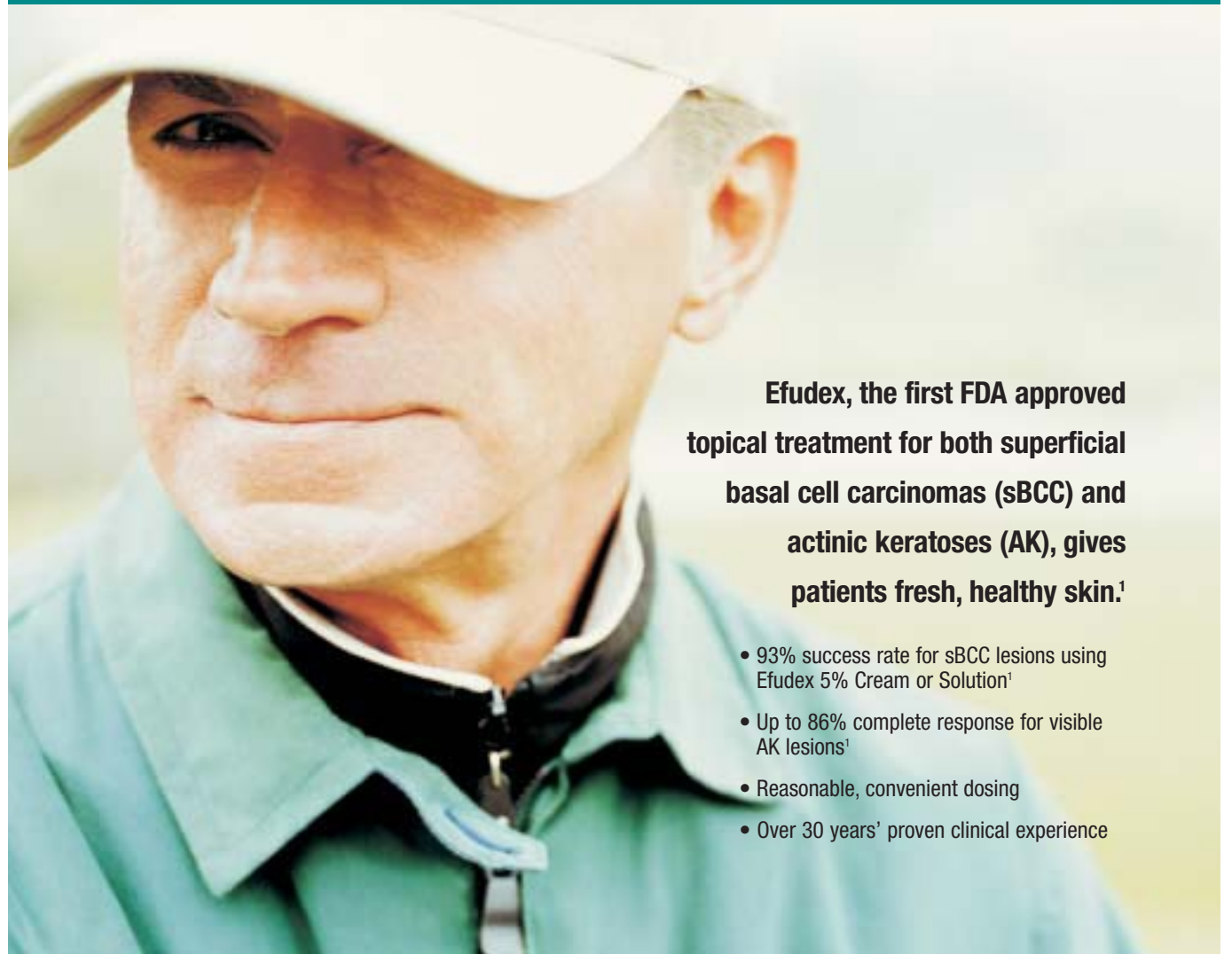
The glabella study said that 10 units was ineffective, but that there was no difference between 20 units and 40 units in

either initial effect or duration of action (*Dermatol. Surg.* 2005;31:414-22). The lateral canthus study likewise reported that efficacy improved with higher dosing, but only to a point, which was about 12 units (6 units per side) (*Dermatol. Surg.* 2005;31:257-62).

"What these two papers said is that the clinical effect and duration of action plateaus at some point, so I am not sure that these higher doses make any sense," Dr. Spencer said. ■

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