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## **Dysport proves safe, effective anti-wrinkle treatment, UT Southwestern plastic surgeons find**

DALLAS – Aug. 3, 2009 – The new anti-wrinkle facial filler Dysport, which could be used as an alternative to Botox, noticeably reduced frown lines between the eyes, according to users and independent reviewers in a study involving plastic surgeons at UT Southwestern Medical Center.

“Our study confirmed that Dysport (abobotulinumtoxinA) is a safe and effective tool in fighting wrinkles,” said Dr. Rod Rohrich, chairman of plastic surgery at UT Southwestern and one of the study’s authors. “It also confirmed that the dosage should be tailored to one’s facial muscle mass to be most effective. So it’s important to visit with a certified plastic surgeon to ensure the dosage is correct.”

The study’s findings showed that Dysport was:

- Most effective in women;
- More effective for African-American patients;
- Longer-lasting for African-American patients;
- Less effective for people 65 and older; and
- As effective for those who had previously been injected with a form of botulinum neurotoxin type A (such as Botox).

The Food and Drug Administration-approved study involved 816 participants with moderate to severe frown lines (called glabellar lines) at 27 centers in the U.S. The study is available online and will appear in *Plastic and Reconstructive Surgery*.

Study participants, who kept diaries for the first 14 days after being injected, were given the Dysport facial filler or a placebo. Surgeons injected Dysport in various levels, dependent on sex and facial mass, at five facial points. Self-assessments and assessments by independent reviewers were performed six times over a five-month follow-up period.

Eighty-seven percent of people given Dysport reported a reduction in wrinkles, compared with 5 percent of patients taking placebos who reported an improvement. An independent assessment showed improvement among 85 percent of patients receiving Dysport, compared with 3 percent of patients receiving the placebo.

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It was found that Dysport took effect as quickly as 24 hours, with the median time about four days. The facial filler lasted 7 percent longer in African-Americans (median of 117 days, compared with 109 days in the overall population) in blinded assessments, and 20 percent longer in African-Americans (129 compared with 107 ) according to self-assessments by study participants.

The study also confirmed that dosing should be adjusted according to a person's facial muscle mass. Participants with the smallest muscle mass had the largest response (96 percent) by 30 days. That rate dropped as low as 80 percent in people with the highest facial muscle masses. The study is the first to examine effects from varying dose levels, which is more common in clinical practice, rather than the standardized dosing used for FDA approval tests.

“Most studies have evaluated Dysport with a standard dosage,” Dr. Rohrich said. “This study evaluated the safety and effectiveness of different doses based on a person's specific muscle mass, which better mirrors what occurs in clinical practice. The size and use of the muscles that produce frown lines varies among individuals, so you want to customize treatment to the patient's face.”

Dysport is a type of botulinum neurotoxin type A, similar to Botox. Both work by blocking nerve impulses to the facial muscles that create wrinkles. Dysport is produced by Scottsdale, Ariz.-based Medicis Aesthetics. Dr. Rohrich is a member of the Reloxin Investigational Group.

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