Data Back Perlane's Safety And Bolster Case for Approval

BY TIMOTHY F. KIRN
Sacramento Bureau

PALM DESERT, CALIF. — The larger particle–sized hyaluronic acid product called Perlane has been shown in a trial to be as safe as another approved filler, and the data have been submitted to the Food and Drug Administration as part of the approval process.

"Perlane provides excellent volume correction, with a single injection, and lasts over 6 months in most patients," said Dr. Jeffrey S. Dover, who presented the trial data at the annual meeting of the American Society for Dermatologic Surgery.

Extensive testing performed during the trial and 24 weeks after the corrections showed that Perlane and Restylane 'are completely nonimmunogenic.'

The 6-month trial found no significant difference between Restylane, an FDA-approved hyaluronic acid, and Perlane, said Dr. Dover, a dermatologic surgeon in Chestnut Hill, Mass.

The sole distinction between the two products appeared to be that slightly less Perlane was needed, on average, for the wrinkle corrections.

Perlane and Restylane are both hyaluronic acids made from streptococcus by the same company, Q-Med Esthetics of Uppsala, Sweden. Both products contain the same concentration of hyaluronic acid, 20 mg/mL. The sole difference is the particle size, which is larger for Perlane (700-1,000 mum, vs. 250-500 mum for Restylane), which makes it more viscous and better suited for larger corrections.

Patients in the trial had mesolabial and/or nasolabial folds corrected.

Of the patients in the trial, who were treated at 17 different centers, 141 received the Perlane and 142 received Restylane.

At 2 weeks after treatment, 96% of the subjects who received Perlane had an improvement in their folds of at least one grade according to a wrinkle severity rating score, compared with 92% of those who received Restylane.

At 24 weeks, 63% of Perlane-treated subjects had at least a single grade improvement, vs. 74% of Restylane-treated subjects. The difference was not statistically significant, "despite the large numbers in the trial," Dr. Dover said.

The average amount of each product used per nasolabial fold was 1.1 mL for Perlane and 1.2 mL for Restylane.

Extensive immunogenicity tests were performed during the trial and included skin testing at 24 weeks after the corrections, in which the test area was biopsied a few days later for examination.

"Both of these products are completely nonimmunogenic," Dr. Dover said of all the testing.

Side effects were similar between the two products. The most commonly reported side effect was itching, experienced by about 90% of the subjects.

The itching, as well as any pain, redness, or bruising experienced by patients, "dropped off quickly," Dr. Dover said.

Restylane is distributed in this country by Medicis, which sponsored the trial and would also distribute Perlane. Dr. Dover reported no financial interest in the study. ■

VERBATIM

'If you treat patients with melasma or postinflammatory hyperpigmentation, you know how important HQ is as a therapy. If HQ is banned, many dermatologists might choose to have these products formulated for them in a pharmacy. ...'

Dr. Leslie S. Baumann, on the possible FDA ban on hydroquinone, p. 28