



OCULAR SURGERY NEWS 2/1/04

Hyaluronic acid dermal filler expands aesthetic possibilities

Restylane touted as safer and a longer-lasting alternative to collagen.

Beth Herskovits

A non-animal-based wrinkle corrector that has been the talk of the cosmetically savvy for years has finally received regulatory approval.

The Food and Drug Administration approved Restylane (hyaluronic acid, Q-Med) for the treatment of moderate to severe facial wrinkles and folds such as nasolabial folds on Dec. 12. Scottsdale, Ariz.-based Medicis will distribute the product in the United States.

The product has been in use for years in Europe and Canada, noted oculoplastic surgeon Stephen Bosniak, MD. "All across the United States, the people who are really up on their noninvasive cosmetic procedures have known about Restylane, and they've been asking their doctors for at least several years now," he said.

"It's a great advance. We've treated many patients with exquisite results," said dermatologist Jeffrey S. Dover, MD.

"Collagen and Restylane do the same thing, but there's a reason why I don't feel that they will be particularly competitive," Dr. Bosniak said. "And that is because collagen is an animal product, collagen can cause allergies, collagen requires skin testing, and Restylane does none of the above."

Dr. Bosniak, who with colleague Marian Zilkha, MD, published a study of almost 2,200 Brazilian patients injected with Restylane, said that he does not use collagen in his practice. "In countries where Restylane has been available, the use of collagen has decreased markedly," he said.

Side-by-side comparison

But Dr. Dover noted that the formulation of collagen has also improved in the past year. Physicians now have access to human-derived collagen, which was approved by the FDA in March 2003 as an alternative to bovine-derived forms.

Human collagen, made from neonatal foreskins, induces fewer allergic reactions than bovine collagen and does not require weeks of waiting for skin test results, Dr. Dover said. He added that it is more expensive than bovine collagen.

The clinical FDA trials compared Restylane side by side with Zyplast (bovine collagen, Inamed) in a study of 138 patients with prominent nasolabial folds. Patients were injected with one agent on each side of the face. Masked investigators evaluated patients at 2, 4 and 6 months after patients achieved an "optimal cosmetic result," according to the study.

Alternative to Restylane

The introduction of Restylane to the U.S. market may soon be followed by regulatory approval of another collagen alternative.

Inamed, maker of Zyplast, is introducing its own hyaluronic acid-based gel, Hylaform. It was recommended for approval on Nov. 21, the same day as Restylane, but it has not received formal approval from the FDA yet. Hylaform contains avian protein, but a skin test is not required before injection, according to information on the company Web site.

Both Restylane and Hylaform are manufactured in three formulations. Only one Restylane formulation is currently approved for use in the United States.

Restylane Perlane and HylaformPlus contain the largest gel particles and are intended for deep folds. Both products also have a fine lines formulation, which contains the smallest gel particles and is injected into the superficial dermis.

Using two wrinkle assessment scales, investigators rated hyaluronic acid superior to collagen in 56.9% and 62% of patients; collagen received superior marks in 9.5% and 8% of patients on each of the two scales.



Before (left) and after (right) Restylane injection for treatment of glabellar lines.

(Photos courtesy of Medicis.)

Complications

Dr. Dover noted that, in practice, many physicians might favor collagen because it is the substance with which they and their patients are most familiar. He added that Restylane also has a greater tendency to cause bruising and swelling, especially in the lip area.

“With Restylane, we generally tell [patients] not to plan anything for 24 hours,” he said, adding that swelling can persist from 1 to 3 days. “It’s off-putting to some patients.”

On the other hand, he said the complication known as lumping, in which the filler collects under the skin, is more correctable with Restylane. “Sometimes [lumping is] technique-driven, and sometimes it’s because of the material itself. Restylane stays softer, or malleable, longer,” he said.

Restylane lumps can be smoothed for up to 3 months in many patients, Dr. Dover said.

Desired results

Dr. Bosniak noted that hyaluronic acid also has the advantage of a longer-lasting effect. “Collagen lasts 2 to 3 months. Restylane lasts 3 to 6 months, and in our paper, the average time before someone requested another injection was 6 months,” he said.

He noted that results often depend on the physician’s skill.

“You may not call it a complication, but what doctors have to realize is that this is still an art form. It’s like sculpting. It’s not like giving a shot in the arm,” he said. “You have to use it in a very meticulous way, and you have to have a very aesthetic eye, and you have to listen to what patients want. So the material can be great, but if you don’t use it in the appropriate way, the results may not be what the patient desires.”

“Smart molecule”

Restylane is sold prepackaged with a 30-gauge needle, according to Dr. Bosniak, who noted that he typically uses one-third to one-half of a syringe in the glabella and two to three syringes for nasolabial folds. Each syringe contains 0.7 cc of Restylane.

“It’s a very smart molecule,” he said. “You’re injecting a gel through a very tiny needle.”

Unlike Zyplast, which is prepackaged with an anesthetic, Restylane requires physicians to apply a topical anesthetic to minimize discomfort, according to Dr. Bosniak. He added that physicians ultimately inject less volume with Restylane.

Combination therapies

Both physicians noted that a combination of Botox (botulinum toxin type A, Allergan) and Restylane yields the best aesthetic results when used to treat the glabellar region.

Botox, which works by inactivating muscles that cause lines to develop, is introduced first to relax the corrugator and procerus muscles. A dermal filler agent is then injected to fill lines that are present at rest.

For Your Information:

- Stephen Bosniak, MD, can be reached at 135 E. 74th St., New York, NY 10021; 212-769-0740; fax: 516-333-9815; e-mail: bosniakzilkha@mindspring.com. Dr. Bosniak has no direct financial interest in the products mentioned in this article. He is a paid consultant for Medicis and has received travel reimbursement from Q-Med.
- Jeffrey S. Dover, MD, can be reached at Skincare Physicians of Chestnut Hill, 1244 Boylston St., Suite 302, Chestnut Hill, MA 02467; 617-731-1600; fax: 617-731-1601. Dr. Dover has no financial interest in the products mentioned in this article, nor is he a paid consultant for any companies mentioned.
- Medicis, distributor of Restylane, can be reached at 8125 North Hayden Road, Scottsdale, AZ 85258; 602-808-8800; fax: 602-808-0822; Web site: www.medicis.com.

Reference:

- Narins RS, Brandt F, Leyden J, Lorenc ZS, Rubin M, Smith S. A randomized, double-blind, multicenter comparison of the efficacy and tolerability of Restylane versus Zyplast for the correction of Nasolabial Folds. *Dermatol Surg.* 2003;29:588-595.

Copyright ©2004 SLACK Incorporated. All rights reserved.