

Coming Soon

FDA ponders approval of New-Fill for wrinkles, volume loss

By LISETTE HILTON Staff Correspondent

San Francisco - The FDA has its eye on New-Fill (Dermik Laboratories), a polylactic acid filler that experts predict could become a popular treatment for moderate to deep wrinkles and volume loss.

□ Clinicians throughout Europe, South America, and Australia have been using New-Fill since 1997 for facial lipodystrophy and to treat creases on the face and hands, according to S. Manjula Jegasothy, M.D., president and medical director of the Miami Skin Institute, Miami, Fla., and volunteer clinical instructor, University of Miami, department of dermatology and cutaneous surgery.

New-Fill Formulation

New-Fill has been formulated into 40 to 60 microspheres. "It consists of polylactic acid in these microspheres, which are then formulated into a lyophilized powder and are placed in a glass vial. The product is reconstituted with anywhere from 3cc to 6cc of preserved saline, non-preserved saline, lidocaine, or any combination thereof. Physicians then put the product into syringes and inject it."

□ Biodegradable and biocompatible, polylactic acid has been in use for more than 40 years, most commonly as a component of dissolvable suture material. Doctors have also used polylactic acid in orthopedics for fixing fractures, in the form of bone plates and screws, and as a vector for more efficient

drug and vaccine delivery.

Results to Date

Gail Humble, M.D., an anesthesiologist with a cosmetic injection practice in Hermosa Beach, Calif., is conducting a Food and Drug Administration trial on NewFill with 100 HIV-positive facial atrophy patients. She and principal investigator Douglas Mest, M.D., also of Hermosa Beach, are about a year into their research but they have a three-year history with the product under an FDA exemption. "Overall, it's quite impressive" Dr. Humble says.

□ Dr. Humble reports seeing significant increases in skin thickness, good patient acceptance of the procedure, and a low complication rate. Patients treated outside the study have experienced retention of up to 18 months after having two to six injections. "Overall the patients have been very pleased



Lipodystrophy patient before and after New-Fill treatment. (Photographs courtesy of Gail Humble, M.D.)

with the results" she said.

□ In Europe, researchers injecting lipodystrophy patients with 2 cc to 4 cc of New-Fill monthly for two to three injections report corrections of facial wasting that last from 12 to 15 months. Doctors in Europe are experiencing similar results for their non-HIV patients, Dr. Jegasothy said.

Drawbacks

A study by researchers in the United Kingdom shows that the most common side effects from New-Fill are similar to other fillers. "Everyone gets edema and erythema, which persist about three or four days after injection. About 10 percent to 15 percent get bruising, which can persist up to one week. And a few people - less than 1 percent - develop palpable but nonvisible nodules which are on the order of 1 mm to 2 mm in size and tend to form mostly when the orbital

rim is injected" Dr. Jegasothy said. There have been no documented allergies to New-Fill, Dr. Jegasothy said. "The nodules that we are seeing seem to be over-exuberant collagen production."

Technique-Dependent

According to Dr. Jegasothy, New-Fill should be injected in a retrograde threading technique, utilizing a 26-gauge needle. It is attached to a 1-cc or 3-cc syringe and injected in a crisscross or lattice fashion to cover the entire defect.

□ "It is best injected in the deep dermis. Hypothetically, the polylactic acid product's microspheres are different shapes and sizes and create a scaffolding for the patient to enhance the patient's own collagen deposition. By injecting New-Fill deep into the tissue, any overexuberant collagen that forms will be deep and not palpable" she said. The injector should always under-correct by at least 30 percent to allow for additional collagen formation over time.

□ Dr. Humble believes New-Fill will be an alternative to silicone for people whose faces are aging and naturally losing volume. "The average human face loses about 4 cc to 5 cc of volume a year. New-Fill is applicable to anyone who has facial wasting - even if it is due to age."

□ Dr. Jegasothy consults for Dermik Laboratories, a subsidiary of Aventis Pharmaceuticals, which owns New-Fill.