

Facial Wasting

Filler puts new face on HIV-related lipodystrophy

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Hermosa Beach, Calif. — New treatment options for patients with HIV-related facial lipodystrophy are proving as effective at boosting the spirits as they are at filling out the face. The distinctive outward appearance of facial wasting stigmatizes AIDS patients and contributes to heightened levels of anxiety and depression. Until recently, treatment options were either too short-lived or, conversely, too invasive and “fixed.”

But a new-generation of treatment options is in the works, including one that leverages polylactic acid (PLA). Douglas R. Mest, M.D., and partner Gail Humble, M.D., of Blue Pacific Medical Group here, said they applied to the FDA at the urging of their patients and have received approval for an investigational device exemption.

“There’s a big push in some places to treat facial lipodystrophy with silicon [SilSkin], but some of our patients expressed concern about migration of the material and about the permanence of the implants,” Dr. Mest said.

For his part, Dr. Mest appreciates the long history of PLA, a biomaterial belonging to the aliphatic polyester fam-

ily, in medical devices. PLA has been used in resorbable sutures, bone implants, and soft tissue reconstruction for more than 40 years and is deemed safe and effective for those applications by the FDA. It has not, however, been cleared for use as filler treatment for facial wasting.

Induced Thickening

Injected into multiple planes of the skin covering the buccal fat pad, the hydrogel suspension immediately begins to fill the hollows. In the meantime, the PLA starts to induce the formation of a fibrous dermal layer to thicken the skin and reduce the visible effects of wasting. The biodegradable, bioresorbable polymer degrades over time, ultimately evacuating the body with no residual active metabolite. Even then, claims maker Biotech S.A., new collagen continues to form and restructure the skin over the following weeks and months.

New-Fill already is an accepted treatment for facial lipodystrophy in Europe, with one AIDS-related journal reporting that as many as one in six patients in France with HIV-related facial wasting has received New-Fill treatments. PLA is also a popular cosmetic filler treatment for wrinkles in some European countries. However, Dr. Mest emphasizes that for HIV-related facial lipodystrophy, New-Fill should be viewed as a reconstructive treatment intended to restore, not enhance, the facial appearance.



Lipodystrophy patient before (left) and after New-Fill treatment. (Photographs courtesy of Douglas R. Mest, M.D.)

Dr. Mest and other proponents emphasize that wasting can worsen medical conditions such as depression and anxiety, while treatments such as New-Fill can help to improve them. In a presentation at the 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy in San Diego in October, Graeme Moyle, M.D., reported that a recent randomized study of 30 patients receiving New-Fill treatments at the Chelsea and Westminster Hospital in London documented improved appearances and significantly lower anxiety levels within 12 weeks.

Dr. Mest believes his patients are experiencing similar physical and emotional benefits. "There appears to be a much more natural restoration of normal facial appearance than is usually achieved with approaches such as cheek implants or injections of filler substances like silicon, Fascian [preserved particulate fascia] and collagen," he said.

And while emphasizing that it is too early in Blue Pacific's clinical trial to analyze data, his anecdotal observations leave little doubt in his mind that patients feel as good as they look. "They

tell us that New-Fill has changed their lives," Dr. Mest said. "They urged us to apply for the exemption because they wanted their friends to have access to the same treatment."

Treatment Parameters

For the best results, Dr. Mest recommends three to five treatments (depending on the individual patient), spaced three to four weeks apart. He describes the injection technique as simple but requiring a trained hand. "We have treated several patients with New-Fill who weren't satisfied with the results because their previous physician hadn't received the proper training," he said.

Blue Pacific currently is just halfway through its clinical trial, but Dr. Mest said New-Fill recently moved much closer to entering the U.S. market. The company wasn't ready to make a formal announcement, but Dr. Mest confirmed that the U.S. division of a multi-national pharmaceuticals firm recently inked a deal to acquire North American rights to New-Fill.

Dr. Mest has no financial interest in New-Fill or its manufacturers. **DT**