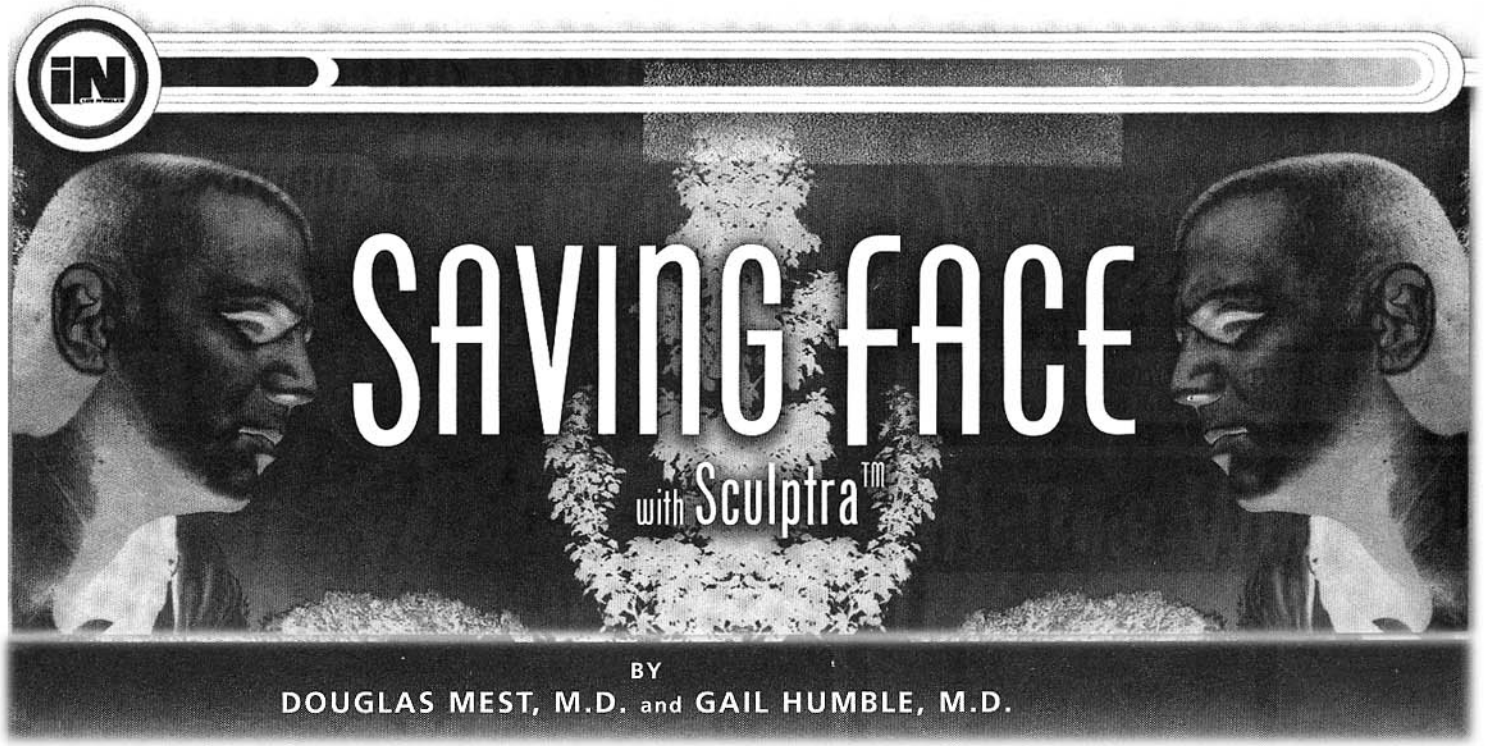

SAVING FACE

with Sculptra™

BY

DOUGLAS MEST, M.D. and GAIL HUMBLE, M.D.

On Aug. 3, the FDA announced approval of the medical device Sculptra (Poly-L-Lactic Acid) for the correction of HIV-associated Lipoatrophy. This approval is significant in that it marks the first treatment for facial wasting specifically studied and formally evaluated and approved under the rigorous FDA process. Facial wasting has become the hallmark of HIV disease, which often causes those persons dealing with this to often become depressed, socially withdrawn, and even non-compliant with their life-saving medications.

Despite exhaustive research by countless scientists not only here in the United States but around the world, the exact cause of lipoatrophy is unknown. We do know that several factors play into the chance of a person developing the condition. It is now clear that some of the classes of HIV medications are more associated than others in developing facial wasting. However, this is *not* a cause-and-effect relationship in that some long-term HIV patients will develop lipoatrophy having never been on medication. As physicians treating the devastating effects of lipoatrophy, the exact cause is not as important as ensuring that all persons affected should be able to have treatment. But until now, there has been a lack of safe and effective treatment options available in the U.S. Our office is proud of the role we played in helping to correct at least the availability problem.

When lipoatrophy first started to appear over five years ago, many wrinkle fillers were tried in an attempt to correct the fat loss. Most were quickly abandoned due to either cost or lack of efficacy. Reports of Poly-L-Lactic Acid's success in correcting facial lipoatrophy were first reported by Dr. Patrick Amard out of Paris in April 2001. Our office, as well as Dr. Peter Engelhard in Miami, were the only two sites in the US that successfully organized and submitted clinical studies to the FDA on Poly-L-Lactic Acid (PLA).

Sculptra™
injectable poly-L-lactic acid

DOUGLAS MEST, M.D.

GAIL HUMBLE, M.D.

Starting in August 2002, we enrolled 100 patients, most of whom are now completing their one year follow-up. Briefly, our results to date confirm the experience of French and British researchers that PLA provides significant and prolonged correction of HIV-associated lipoatrophy. Our patients have been very satisfied with their results at one year (rating of 4.8 on scale of 1-5) and 100 percent of patients have stated that they would recommend this treatment to a friend. Psychological well-being questionnaires revealed an increase in confidence and improved self-image with treatment.

A scientific advisory panel of the FDA met in March 2004 to hear the scientific evidence regarding the safety and efficacy of Poly-L-Lactic Acid (now called SculptraTM) in the treatment of HIV-associated lipoatrophy. Data from two peer-reviewed and published studies from Europe showing persistent results of up to two years were presented to the panel. Additional safety data from the study performed at Blue Pacific was also presented. In addition to the scientific data, two of our own patients personally appeared before the panel in Washington, DC to share their experience with Sculptra™ and how it literally changed their lives.

Many readers will know Sculptra™ by its old name "New-Fill." They are in fact the same substance, Poly-L-Lactic acid (PLA). PLA is a synthetic polymer that is of non-animal origin. Sculptra works by stimulating the patients own collagen to form in response to the product. A series of treatments is needed initially with touch up treatments required around 12-16 months. The exact number of treatments will depend on the degree of facial wasting. This process is gradual and the correction very natural in appearance. In gradually filling the fat loss, patients have told us that they have not had to explain to their friends and colleagues that they have had anything done to their faces. Rather, patients are often told that they simply look healthier or more rested. Sculptra is designed to dissolve over time from Poly-Lactic Acid to Lactic Acid-a naturally occurring substance. We, as well as many patients, believe that since the product degrades over time leaving the persons own collagen in place, that there is a degree of safety not seen with other, permanent, treatments.

While we would like to think that the problem of access to treatment has been remedied by the approval of Sculptra, much more work remains to be done. Due to cost of the product, significant access issues still exist. Activism on the part of the community is needed to educate and convince the government and private insurance companies of the medical necessity of treatment. It is only then, that the goal of safe and effective treatment for all will be reached.

Drs. Mest and Humble are cosmetic injection specialists. For the past two years they have been conducting one of the two U.S. studies on Poly-Lactic Acid in the treatment of HIV Lipoatrophy. Dr. Mest and Dr. Humble are clinical and medical directors of Blue Pacific Aesthetic Medical Group, located at 1301 Manhattan Ave., Suite 201, Hermosa Beach. For more information, call (310) 374-0347 or 877-374-0347, or visit www.bpacific.com and email them at info@bpacific.com.