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Sculptra Outcomes Reassuringly Good In Dark Skin Types



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Injectable poly-L-lactic acid is at least as safe and effective in patients with darker skin as in those with Fitzpatrick skin types I-III, according to a multicenter postmarketing study.

The ongoing study also demonstrated that there were no sex differences in response to treatment. The study was mandated by the Food and Drug Administration as a condition of Sculptra's approval for correction of HIV-related facial lipoatrophy because the original clinical trials were heavily skewed toward white males, Dr. Douglas Mest explained at the seminar.

"What I found most interesting [about the postmarketing study findings] was that there were no hypertrophic scars or keloids in any of the darker skin types. One of the questions about PLLA that people have had from the beginning was, 'Can you use it on darker skin types, or are patients going to produce too much collagen and have problems?' Interestingly enough, darker skin types had less problems than lighter skin types," observed Dr. Mest of a cosmetic medicine group practice in El Segundo, Calif.

He presented 1-year data from the ongoing 5-year open-label study of 290 patients who were treated with PLLA for HIV-related facial lipoatrophy. Unlike patients in prior studies, these participants were roughly equally divided between men and women, and Fitzgerald skin types I-III and types IV-VI.

None of the patients developed hypertrophic scars or keloids. Treatment-related adverse events occurred in 31% of Fitzpatrick type I-III women, compared with 17% of Fitzpatrick IV-VI women, and in 30% of Fitzpatrick I-III men, compared with 18% of Fitzpatrick IV-VI men.

Injection-site nodules occurred in 8.6% and 16.2% of Fitzpatrick I-III women and men, respectively, compared with 2.9% and 6.6% of Fitzpatrick IV-VI women and men, he continued.

At the 1-year visit, physicians rated their satisfaction with treatment efficacy as "very good" or "excellent" in 96% of cases, as did 90% of the patients themselves. Neither patient nor physician assessments varied significantly by patient gender or skin type.

Anecdotally, Dr. Mest said, he and other experienced Sculptra injectors have observed that darker-skinned patients form new collagen in response to PLLA much more quickly than light-skinned ones, whether the treatment was for HIV-related facial lipoatrophy or off label for cosmetic improvement.

"They actually do very well with this product," he said.

Years 2-5 of the ongoing study are expected to provide important new information regarding the long-term efficacy, durability, and safety of injectable PLLA for this indication.

The postmarketing study was sponsored by Dermik Laboratories. Dr. Mest serves as a consultant to the company.

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