Skill, Technique Are Critical With Permanent Filler

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MIAMI BEACH — With expertise and the right technique, aesthetic surgery patients can get long-lasting results from the first permanent facial filler approved by the Food and Drug Administration, Dr. Marta I. Rendon said at a symposium sponsored by the Florida Society of Dermatology and Dermatologic Surgery.

"You can correct things that need to be corrected long term, such as birth defects," Dr. Rendon said, "but stay away from thin-skin areas, for example, around eyes and lips."

ArteFill (Artes Medical Inc.) became the first nonresorbable injectable filler implant approved for aesthetic use in October 2006. The official FDA indication is for correction of nasolabial folds. Dr. Rendon is a member of Artes Medical's advisory board.

Inject the product deeply using a 26G needle. "You never want to see the gray of the needle when you are injecting," she said. Employ a linear retrograde tunneling technique. Stop the injection before you withdraw the needle to avoid superficial placement.

The filler is thicker than most other aesthetic products. ArteFill is, for example, about three times thicker than Zyplast, said Dr. Rendon of the University of Miami.

ArteFill consists of polymethylmethacrylate microspheres suspended in a gel carrier of rapidly-dissolving bovine collagen. The microspheres are 30-50 mcm and stimulate the patient's own collagen to form a permanent support structure beneath the skin. The manufacturer had to demonstrate the uniformity of these microspheres prior to approval.

Dr. Rendon said that any microsphere smaller than 20 mcm would be absorbed by macrophages.

A closed herd of cattle to provide the collagen and a manufacturing facility in the United States were additional requirements.

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These conditions stem from concerns that the FDA had following studies of an earlier formulation, ArteColl. In a clinical trial of ArteColl in 251 patients, for example, there were 10 reports of lumpiness, including 1 case that was severe.

Granuloma formation is a concern with all injectable fillers. "Most are late onset and the majority are in the perioral area," she said. This is one reason she advises against use of ArteFill in thin-skin areas.

There were no granuloma reports at a 1-year follow-up in the ArteFill clinical trial, but there were two granulomas at a 5-year follow-up. One was excised from a patient's lip and the other was treated with steroid injections into a nasolabial fold.

A total of 142 participants were assessed at a mean of 5.4 years, and 90% reported satisfaction. "Patient cosmetic appearance continued to improve. You can still see an upward slope in improvement over 5 years," Dr. Rendon said.

"These patients look younger at 5 years than before treatment," Dr. Rendon said. "We are almost halting the aging process in these patients." Keep in mind, though, that all fillers are foreign bodies, and they may interact with drugs, trauma, and surgery years after implantation. ■