Adverse Reactions Seen With Cosmetic Fillers

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BELFAST — In the burgeoning world of injectable cosmetic fillers, nothing is actually inert, Debjani Sahni, M.D., said at the annual meeting of the British Association of Dermatologists.

The new so-called biologically inert fillers have become increasingly popular, because bovine collagen is associated with allergic reactions in up to 3% of patients, Dr. Sahni said, and there is at least a theoretical risk of transmission of bovine spongiform encephalopathy.

"Manufacturers claim that these fillers are nonmigratory and that adverse reactions are rare, but we have seen three patients who developed disfiguring allergic reactions to inert injectable fillers," said Dr. Sahni of the department of dermatology, Ealing Hospital, Southall, Middlesex, England.

The first patient was a 49-year-old woman who had received injections of Artecoll to the nasofacial sulcae. This filler contains polymethylmethacrylate microspheres. Although classified as inert, it also contains 3.5% bovine collagen, she said.

Inert fillers are classified as medical devices and not drugs and therefore do not undergo the same degree of scrutiny as drugs prior to release onto the market.

Within 3 weeks of receiving the injections, the patient developed marked inflammation at the injection sites. She required hospitalization and treatment with intravenous antibiotics and dexamethasone. Although the inflammation subsided, it never completely resolved, Dr. Sahni said.

A year later, the patient presented with an inflamed nodule in the right nasofacial sulcus, and a skin biopsy revealed sinus tracts extending to the deep dermis. Along the walls of these tracts a granulomatous reaction was visible, with multiple foreign body giant cells and distinctive spheres of uniform shape and size that under polarized light were negatively birefringent. "These features are typical of a granulomatous reaction to Artecoll, not to the bovine component of the filler," she said.

The second patient was a 51-year-old woman who underwent lip augmentation, first with Restylane, a derivative of hyaluronic acid, and then Dermalive, which is hyaluronic acid plus hydroxyethylmetacrylate.

A year later, the patient presented with chronically sore, inflamed lips characterized by erythematous, nodular indurated areas. A skin biopsy demonstrated that much of the reticular dermis had been taken up by an inflammatory infiltrate. Histological features were typical of a granulomatous reation to Dermalive, Dr. Sahni said.

The third patient was a 71-year-old woman who had undergone multiple injections of bovine collagen, Restylane, and several other unidentified fillers. She had also undergone a permanent lip-line tattoo. She presented with a 4-month history of sore, indurated, inflamed lips. Histologic evaluation revealed a chronic inflammatory infiltrate and macrophages containing tattoo pigments.

She also had a granulomatous reaction, with florid foreign-body giant cells that were positively birefringent. A literature search suggested this reaction was typical for New-Fill, an inert filler consisting of polylactic acid.

These cases raise a number of issues, Dr. Sahni noted. "First, although classified as inert, these fillers clearly are able to stimulate a clinically evident granulomatous reaction. Second, none of the patients had been forewarned of the possibility of such a reaction, so informed consent was not adequate," she said. There also had been no skin testing prior to the injections.

Inert fillers are classified as medical devices and not drugs and therefore do not undergo the same degree of scrutiny as drugs prior to release onto the market. Many fillers have not undergone prior animal testing or human trials and, in fact, are not required to do so, Dr. Sahni said.

"Physicians should be aware of the potential for adverse reactions to these fillers," she said. "As they become more popular, we may see an increase in the frequency of granulomatous reactions. It is imperative that adequate informed consent be practiced so that patients can make an educated decision." ■