

## Delayed adverse effects may occur following injection with cosmetic skin fillers

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Polyalkylimide implants—injections used as cosmetic fillers primarily in Europe—may be associated with infrequent but sometimes severe immune-related adverse effects months following the procedure, according to a report in the May issue of *Archives of Dermatology*.

Polyalkylimide implants consist of a compound of gel and water, according to background information in the article. They are used to improve the appearance of facial features such as the lips, cheeks, forehead and nasolabial folds, lines that develop between the nose and mouth.

"According to the manufacturer's information, polyalkylimide structures do not change over time and do not move or migrate," the authors write. "In the early reports on polyalkylimide implant injections for cosmetic purposes, there were no significant signs of bioincompatibility [rejection of or reaction to the foreign material]. However, more recent evidence refutes these statements, and so the complete safety of polyalkylimide implant gels can no longer be assured."

Jaume Alijotas-Reig, M.D., Ph.D., of Vall d'Hebron University Hospital and Autonomous University of Barcelona, Spain, and colleagues assessed 25 patients who developed adverse effects 12 months or longer (an average of 13.4 months) after polyalkylimide implant injection. These include swelling, hardening and swollen or tender nodules (skin lesions) near the injection site, as well as systemic effects such as fever, arthritis and dry eyes or mouth.



"Eight patients were previously injected with another implant," the authors write. "Tender inflammatory nodules were seen in 24 patients. Systemic or distant manifestations appeared in six cases. Laboratory abnormalities were found in 20 cases. After an average of 21.3 months of follow-up, 11 patients appeared to be free of adverse effects and 10 still had recurrent bouts."

The exact prevalence of these types of delayed adverse effects is unclear, the authors note. Many physicians may not report negative events, and the researchers do not have complete information about all patients injected with polyalkylimide implants in the given time period.

"Although infrequent, delayed, moderate to severe immune-mediated adverse effects may be caused by polyalkylimide implants, occasionally with systemic manifestations," the authors conclude. "Perhaps in predisposed hosts, the use of more than one source of dermal filler may increase the risk of the onset of delayed immune-mediated reactions related to bioimplants.

Source: JAMA and Archives Journals

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