

## COVID VACCINES AND FILLER SAFETY

Many of our patients have contacted us with questions about the safety of Covid vaccines and dermal fillers. In the Moderna clinical trials for FDA approval, 3 patients out of 15,184 vaccine recipients developed swelling around previously placed dermal fillers (0.02%). All 3 reactions resolved. Similar reactions around dermal fillers are very rarely seen when the immune system is stimulated from bacterial or viral illnesses such as influenza, or vaccines. Indeed, Drs. Jones, Wesley, Black and Minokadeh have collectively published their 10-year experience in treating such rare reactions in a leading peer-reviewed scientific journal.

Dr. Jones is the Chairman of the Filler Safety Guidelines Task Force of the American Society for Dermatologic Surgery and was an author on the recently issued guidelines below.

### TAKE HOME POINT:

**Given currently available data, patients already treated with dermal fillers should not be discouraged or precluded from receiving vaccines of any kind. Similarly, patients who have had vaccines should not be precluded from receiving dermal fillers in the future. Swelling reactions around fillers from vaccines are very RARE, and reactions are easily treatable.**



### American Society for Dermatologic Surgery

### Guidance Regarding SARS-CoV-2 mRNA Vaccine Side Effects in Dermal Filler Patients

Based on information available as of 28 December 2020

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#### INTENT

The development of the American Society for Dermatologic Surgery (“ASDS”) guidance on dermal filler reactions after SARS-CoV-2 mRNA vaccine administration is in response to FDA reports of vaccine trial side effects. The goal is to provide information, guidance and perspective for patients and practitioners regarding the incidence of such reactions based on available data.

## BACKGROUND

Review of FDA data from the Moderna vaccine trial reveals that a total of three participants out of 15,184 patients who received at least one dose of mRNA-1273 developed facial or lip swelling presumed to be related to dermal filler placement. All events resolved after treatment. The details are summarized in the table below:

Patient Demographics	Reported Reaction	Time After Vaccine	Time of Dermal Filler Placement	Resolved
Age 51, Female	Facial swelling	2 days	2 weeks prior	Yes
Age 46, Female	Facial swelling	1 day	6 months prior	Yes
Age 29, Female	Lip angioedema*	2 days	Unknown	Yes

FDA reported reactions in patients with dermal filler who had subsequent facial swelling after dose 1 of vaccine. Cases reported as of November 25, 2020. \*Classified as medically significant but not a serious adverse event; this patient had a similar reaction after an influenza vaccine in the past.

Of note, no patients in the placebo group reported any filler-related events. To date, adverse events for SARS-CoV-2 vaccines have only been reported in the Moderna mRNA trial.

## GUIDANCE

The following statements constitute guidance from ASDS on vaccine-related adverse events in patients with dermal fillers:

- Delayed dermal filler inflammatory events very rarely occur with both hyaluronic acid and non-hyaluronic acid fillers.
- Evidence suggests these reactions can be immunologically triggered by viral and bacterial illness, vaccinations such as the influenza vaccine, and dental procedures.
- These rare adverse events are temporary and respond to treatments such as oral corticosteroids and hyaluronidase, and often resolve without treatment.
- Given currently available data, patients already treated with dermal fillers should not be discouraged or precluded from receiving vaccines of any kind. Similarly, patients who have had vaccines should not be precluded from receiving dermal fillers in the future.
- Specifically, with regard to the Moderna mRNA-1273 trial, there were a total of 3 reactions possibly related to dermal fillers out of 15,184 vaccine recipients. It is unknown how many subjects in the trial had previous treatment with dermal fillers.
- ASDS encourages its members to continue their current practices with regards to dermal fillers including obtaining a pertinent medical history on all patients.
- It is the position of ASDS that dermal fillers should be administered by board-certified physicians who are experts in both the injection of dermal fillers and management of complications arising from them.

As new safety data becomes available, ASDS will continue to evaluate and monitor developments and may update its members with educational content, as needed. ASDS encourages its membership to monitor the data and scientific literature as it develops.

**RESOURCES**

Jones D, Fitzgerald R, Cox SE, Butterwick K, Hassan M, Humphrey S, Carruthers J, Dayan S, Donofrio L, Solish N, Yee J, Alam M (in press) Preventing and Treating Adverse Events of Injectable Fillers: Evidence-based Recommendations from the American Society for Dermatologic Surgery Multidisciplinary Task Force. *Dermatol Surg*.

“Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).” U.S. Food and Drug Administration, Dec. 2020, <https://www.fda.gov/media/144637/download>.

“Vaccines and Related Biological Products Advisory Committee Meeting; FDA Briefing Document for Moderna COVID-19 Vaccine.” U.S. Food and Drug Administration, 17 Dec. 2020, <https://www.fda.gov/media/144434/download>.

“Fact Sheet for Recipients and Caregivers - Emergency Use Authorization of the Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 in Individuals 16 Years of Age and Older.” U.S. Food and Drug Administration, Dec. 2020, <https://www.fda.gov/media/144414/download>.

**DISCLAIMER**

This document is designed to share guidance based on the latest available information. ASDS will make reasonable efforts to provide updates as new information becomes available. This document does not constitute legal advice or substitute for individual medical decision-making.