

ASOPRS/AAO FDA Presentation

- Foremost we would like to acknowledge dermal filler injections are generally safe and effective for facial enhancement with a high patient satisfaction.
- Patients have a variety of filler options based on brand, cost, filler properties, loyalty programs and indications.
- There is a continually increasing choice of dermal fillers available, with specific FDA labels approvals.

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- Practitioners use their judgement in product placement, as FDA indications may not be applicable to all patient scenarios.
- For example, fillers are often used off-label in many adjacent facial areas, based on desired outcomes, treatment goals, convenience and cost control without compromising safety or efficacy.
- Some of these off-label areas are awaiting FDA approval, such as tear trough treatment for infra-orbital hollows.

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- Adverse events are rare, but side effects and complications are possible.
- Most side effects of dermal filler agents are transient and minor.
- HA fillers can be reversed with the enzyme hyaluronidase.
- More serious and uncommon adverse events of dermal filler injections include delayed nodules and intravascular injection.
- Inadvertent vascular injection can cause vessel occlusion and ischemia. This can result in very rare events such as tissue necrosis, blindness or stroke.

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- Certain facial areas pose a higher risk for vascular events.
- The risk of ischemic events is highest in the forehead, temple, glabella, nasal dorsum, tear trough and lip. Regions with large vessels may pose additional risk.
- Keen knowledge of facial anatomy and attention to proper injection technique is paramount when injecting these areas.
- Informed consent outlining possible adverse events is critical. It is important that patients be advised of these serious and the less serious complications prior to deciding to proceed with filler injections, so they can make a proper decision.

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- Filler can be injected with either a needle or cannula at the discretion of the injector, and skilled injectors can achieve safe results with either device.
- In order to mitigate intravascular events, recommendations such as aspiration, slow injection speed, blunt cannula use, attention to tissue response, and closely monitoring patient signs for excessive pain may be helpful to clinicians.

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- ASOPRS members and many ophthalmologists are familiar with complications in the peri-ocular area and are available to consult with colleagues when issues after dermal filler injections occur.
- Potential benefits for the treatment of intravascular adverse events in the peri-orbital region have been supported by experimental studies and anecdotal evidence.
Ophthalmologists have unique specialty training and equipment that may be useful in treating such rare events as tissue necrosis, and potentially restoring compromised vision.

References

Protocol for Treating Filler Induced Skin Necrosis:

New High Dose Pulsed Hyaluronidase Protocol for Hyaluronic Acid Filler Vascular Adverse Events. Claudio DeLorenzi. *Aesthetic Surgery Journal*, July-August 2017; Pages 814–825.

Protocol for Treating Filler Induced Delayed Nodules:

Global Approaches to the Prevention and Management of Delayed-onset Adverse Reactions with Hyaluronic Acid-based Fillers. Philipp-Dormston WG, Goodman GJ, De Boulle K, et al. *Plastic & Reconstructive Surg Global Open* April 2020.

Cannula vs. Needle for Dermal Fillers:

Rates of Vascular Occlusion Associated With Using Needles vs Cannulas for Filler Injection. Murad Alam, Rohit Kakar, Jeffery Dover, et al. *JAMA Dermatology* 2021.

Protocol for Treating Filler Induced Vision Loss:

Standardized approach to treatment of retinal artery occlusion after intraarterial injection of soft tissue fillers: EYE-CODE. Sheila Barbarino, Tanuj Baker, John Fezza. *Journal American Academy of Dermatology*. December 2020.