Prevention and Management of Filler Injection Adverse Events
Presentation to the FDA General and Plastic Surgery Devices Advisory Committee

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Edited or coedited several books for physicians, most recent:

Complications In Minimally Invasive Facial Rejuvenation

Prevention and Management

Carniol PJ, Avram MM, Brauer JA Eds.

Thieme Publishers 2021

New York, Stuttgart, Delhi, Rio de Janiero

American Academy of Facial Plastic and Reconstructive Surgery

- Approximately 2,200 members
- Who are our members?
- After medical school our members have completed a five year residency and many of them also have additional fellowship training
- Highly trained and experienced physicians.
  Extensive knowledge of facial anatomy and surgical techniques
- We believe that expertise gives them lower rates of complications

Soft tissue fillers

2nd most popular cosmetic medical treatment

High Satisfaction rate >93%*

360% 2000-2015 ASPS

26% Hyaluronic Acid (most popular) 2009-2015 ASAPS

Facial injectable market expected to double by 2025

25% increase in providers in US 2018-2019
(Who are this large number of new providers?)

AEs

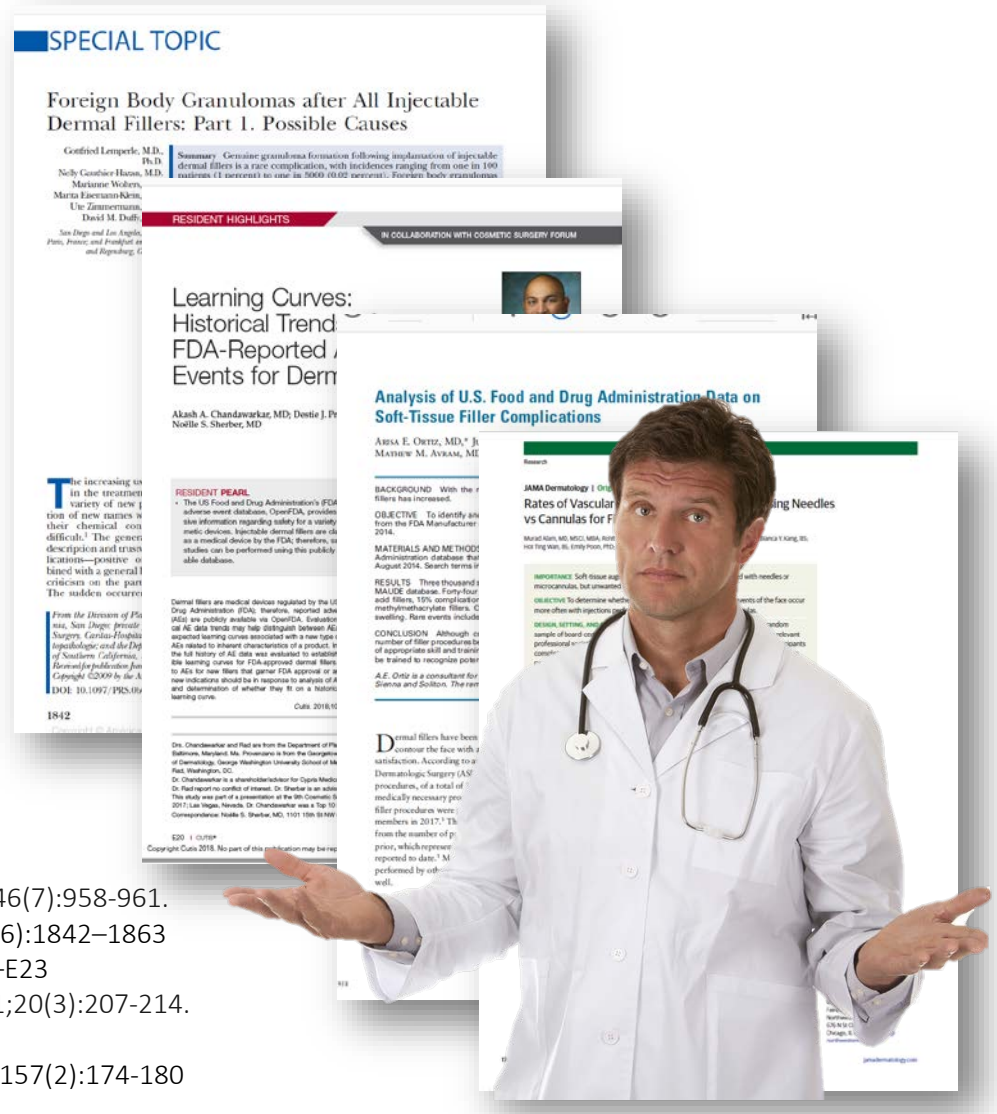
Adverse Events (excluding minor bruising and swelling) for HA fillers is low

Minor Bruising

Nodules/Granulomas

Vascular occlusion 1/5000[7]

Most commonly Lips and Nose



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Vascular Occlusion

Murad Alam et. al. 10 year retrospective review in 2020

- 1.7 million syringes filler, over a 10 year period, were injected among 370 dermatologists who reported in this review
- Vascular occlusion uncommon, 1/5000 injections
- 85% of vascular occlusion resolved without sequelae
- Physicians with over 5 years experience with filler injections had 70% lower odds of vascular occlusion

Vascular Occlusion With Associated Vision Loss

- Retrospective Study World Literature Jan 2015 – September 2018

(Beleznay, Aesthetic Surgery Journal 2019)

- 48 Cases Worldwide, 6 of these were in the U.S. –
  Filler Injection Location: Nasal Region 56% of injections, Glabella 27% of injections, Forehead 18% of injections, Nasolabial Folds 14% of injections
- Treatments varied
- Discussion included treatment of vascular occlusion

Minimizing Incidence of AEs (I)

- Detailed knowledge of facial anatomy, vasculature - training & education
- Experience
- Technique to minimize vascular occlusion
  Avoid high pressure injection, minimal pressure (minimize retrograde filler vascular occlusion)
- Avoid arterial vasculature (requires detailed knowledge of anatomy)

  Controversy whether aspiration before injection reduces vascular complications

  Limited volume injection
  Move needle or cannula during injection

Minimizing AEs (II)

- (Beleznay, Aesthetic Surgery Journal 2019, Alam 2020)
- Injection Level – avoid subcutaneous vasculature, as possible either superficial injection, or deep, above underlying osseous structure
- Consider using a cannula as appropriate – reported lower incidence of vascular occlusion
- Cannula 25 gauge or larger, lower incidence of arterial cannulation

Treatment of AEs

- Possible Ocular Vascular Occlusion
  - Urgent treatment, as appropriate minimize risk retinal injury
  - Ophthalmic evaluation if appropriate
  - Cutaneous evaluation if appropriate
  - Gross neurologic evaluation
  - Recombinant human hyaluronidase
  - ---local injection
  - ---supraorbital, supratrochlear notch injection
  - retrobulbar injection controversial
  - topical timolol
  - rebreathing paper bag
  - aspirin
  - ocular massage

Treatment of AEs

- Other Possible Treatments
  - intravenous acetazolamide
  - mannitol
  - sublingual glyceryl trinitrate
  - anterior chamber paracentesis
  - heparin
  - corticosteroids
  - antibiotics

Summary Filler AEs

- Most are minor AEs
- Major AE is vascular occlusion
  - most episodes resolve uneventfully (85%)
  - vision loss most concerning
    - requires urgent treatment
  - variable response to treatment
  - risk permanent vision loss
- World literature September 2015– June 2018 48 episodes reported
  - only 6/48 episodes occurred in the United States
- Considering the incidence of AEs it is important for fillers to only be used by well trained healthcare providers
- Value of recombinant human hyaluronidase