

**FILLER SAFETY
FDA PANEL
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DERMAL FILLER RISKS – MUST INCLUDE IN INFORMED CONSENT

- Early Onset
 - Bruising, Swelling, Pain
 - Vascular Occlusion/Necrosis *
 - Blindness *
- Late Onset
 - Infection
 - Poor Cosmetic Result
 - Nodules – Product vs Reaction to Product
 - Granulomas

*complications associated with intravascular injection of filler

VASCULAR OCCLUSION

- Occurs when filler is injected within a vessel
- Can spread to areas outside of injection area via embolism
- Choke Phenomenon (body's protective mechanism) might exacerbate ischemia
- Recent literature suggests occurrence of ~ 1:6000 syringes (1.5M syringes)*
- 28% of surveyed Dermatologists has at least one occlusion *
- 70.7% less occurrence with injectors >5 experience *
- **77% less likely with cannula vs needle injections ***
- Most common areas occluded – Lips and Nasolabial Folds *
- Eye injury 1:500,000 (3 in survey) *

*Rates of Vascular Occlusion of Cannulas vs Needle Survey, JAMA 12/20

FILLER ASSOCIATED BLINDNESS

- 1906 -2015 98 Documented Cases (Worldwide) *
- 2015-2018 48 Documented Cases **
- Frequency is increasing – ?Higher Risk Areas, More Injections, Less Knowledgeable or Less Experienced Injectors?
- Most Common Areas – Nose, Glabella, Forehead
- Etiology is retrograde embolism of filler into Central Retinal Artery or other arteries supplying retina
- 20.8% Recovered Completely, 16.6% Partial Recovery **
- Reversibility is difficult and controversial

*Belezny and Carruthers, Avoiding and Treating Blindness from Fillers 2015

**Belezny and Carruthers, Update Avoiding and Treating Blindness from Fillers 2019

PROTOCOLS FOR VASCULAR OCCLUSION (EXCLUDING BLINDNESS)

- The most common filler, Hyaluronic Acid, can be broken down with hyaluronidase. All others are not reversible
- There is varying degrees of HA filler susceptibility to hyaluronidase which depends on cross-linking, concentration of filler, and manufacturing process
- Current protocols are based on flooding the area of suspected occlusion with high doses of hyaluronidase and evaluating clinical response every hour – improvement in capillary refill and pallor
- Typically, multiple injections are required and response to treatment is difficult to assess. Trans-arterial diffusion of hyaluronidase is questionable

THE VALUE OF HIGH FREQUENCY ULTRASOUND

- Very rapidly can evaluate vascular anatomy – vascular mapping
- Localize and characterize previously placed fillers and complications
- Can identify areas of vascular occlusion – decreased or no flow
- Using guided injections, can precisely inject hyaluronidase into offending pocket of filler
- Re-establishment of vascular flow can be instantly evaluated without relying on less accurate assessments such as capillary refill
- Significantly reduce time to reverse VO and number of injections of hyaluronidase

HYALURONIDASE

- Currently, no forms of hyaluronidase are approved for dissolving HA filler
- Consequently, none of the filler companies can discuss treating complications with hyaluronidase
- If hyaluronidase was approved for treatment of HA complications, there would be much more time dedicated to training and education in filler complications
- Ultimately, there would be better outcomes for our patients with approval

PROPOSED IMPROVEMENTS IN FILLER SAFETY

- Improve training – Including cadaver anatomy dissection lab
- Improve standards – There are NO national standards for injectors
- While there are a few cannula indications for fillers, consider broadening approvals of all fillers for cannula use – 25g or larger (smaller cannulas not as safe).
- Recommend injectors incorporate High Frequency Duplex Ultrasound for patient assessment and treating complications
- Future:
 - Needles (galvanic) that sense blood flow
 - Fillers that dissolve when injected intravascularly – One is CE approved