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General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting on Dermal Fillers

M. Laurin Council, MD, MBA, President

American Society for Dermatologic Surgery/Association (ASDS/A)

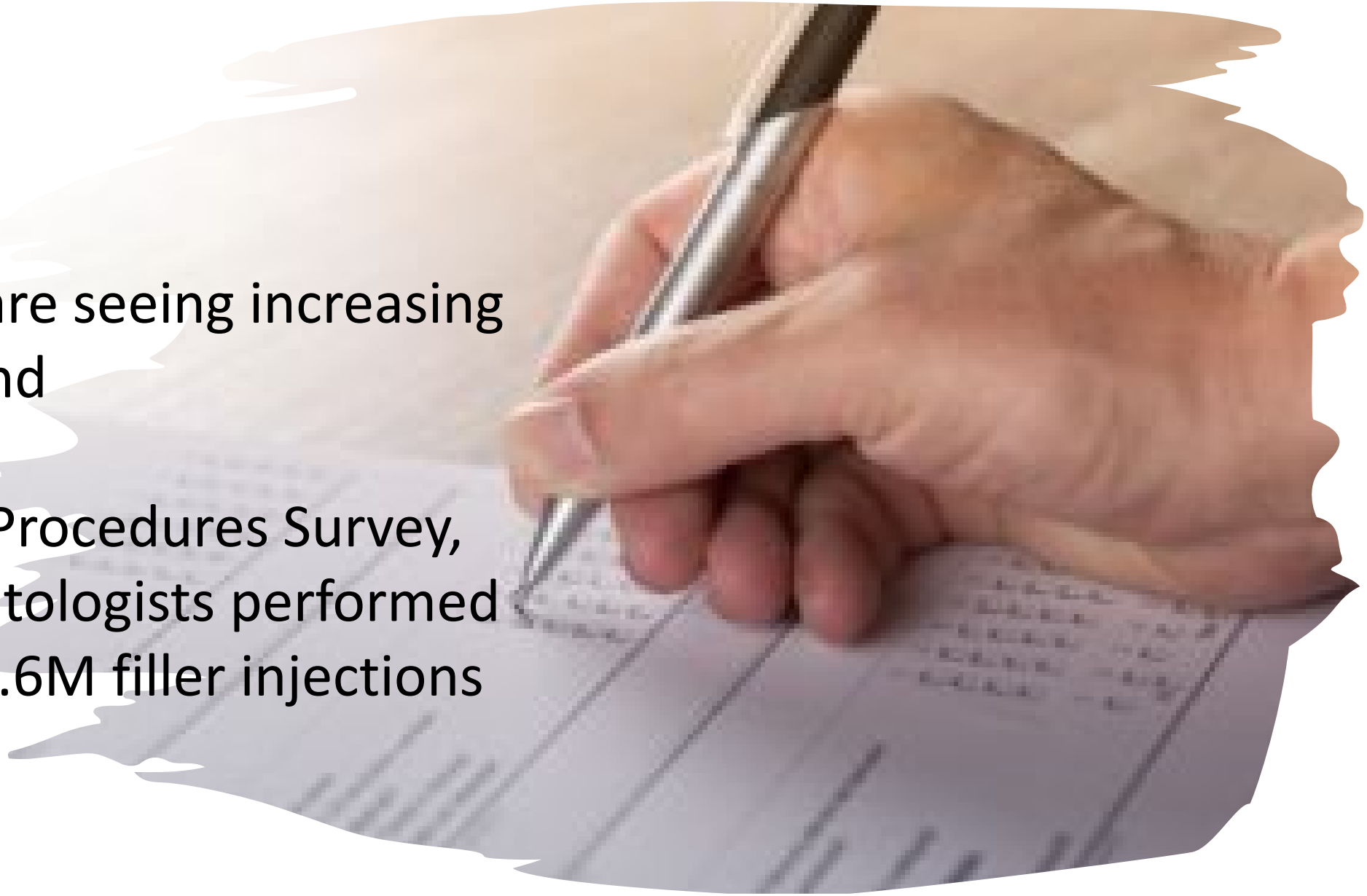
ASDS American Society for Dermatologic Surgery

COSMETIC AND RECONSTRUCTIVE EXPERTISE FOR YOUR *skin health and beauty*™

ASDSA American Society for Dermatologic Surgery ASSOCIATION

Disclosures

- Current President of ASDS/ASDSA
- Consultant and researcher for Regeneron and Castle Biosciences
- Full-time employee at academic medical center



- Filler are seeing increasing demand
- ASDS Procedures Survey, dermatologists performed over 1.6M filler injections

Adverse Events with Dermal Filler Injections

- Knowledge of vascular anatomy is essential for all filler injectors (board-certified dermatologists/physicians have this education)
- Certain anatomic locations are higher risk
- Accidental injection into arteries can cause
  - Embolization leading to vascular occlusion
  - Tissue necrosis
  - Blindness/stroke

- ASDS convened a multidisciplinary Soft Tissue Fillers Evidence-based Guideline Task Force:
  - 8 board certified dermatologists (ASDSA members)
  - 1 plastic surgeon
  - 1 facial plastic and reconstructive surgeon
  - 1 oculoplastic surgeon
  - 2 patient representatives
  - 1 methodologist
- The ASDS-led Fillers Guideline TF determined that the topic of preventing and treating adverse events of injectable fillers required the development of evidence-based clinical practice guidelines to support decision-making in daily practice.

ASDS Guidelines

- The TF recommends the strategies below for treatment of vascular occlusion:

(1) During a patient filler injection, when vascular regurgitation in the syringe (i.e., “red flash”) or tissue blanching in the treatment area is observed by the health care professional injector, the injection should be stopped and treatment with injectable hyaluronidase be considered.

(2) In patients who develop vascular occlusion of the skin of the face after treatment with filler, high-dose hyaluronidase should be injected promptly into the skin at the site of occlusion and any areas of ischemia on the immediate periphery.

(3) Serious adverse events should be reported to device manufacturer and FDA

ASDS Guidelines

- Filler adverse events are likely underreported and increasing in frequency as the popularity of injectable fillers increases
- Physician offices are most likely to report adverse events
- ASDSA/Northwestern University developed the Cutaneous Procedures Adverse Events Reporting Registry
  - Voluntary reporting of adverse events during derm surgery procedures
  - Data used to monitor and identify practice and/or education gaps
  - Identify any potential risk factors

New Potential Indications for Dermal Filler Devices

- Treatment for Decolletage
- Hyaluronic acid injections directly into the breast can be seen on radiological studies
- Other injectable materials, such as polyacrylamide gel and calcium hydroxyapatite are even more radiopaque

The Informed Decision Process

- Few studies evaluating the safety of dermal fillers into the decolletage
- Majority of medical literature focuses on technique
- ASDSA supports informed decision process where patients are allowed to consider risks and benefits to make the appropriate choice for themselves

Thank you!

Questions can be directed to advocacy@asds.net

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