

# Soft Tissue Fillers: Safety & Complications

***Karol A Gutowski, MD, FACS***

24th State-of-the-Art in Facial Aesthetics

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# Disclosures

AxcelRx Pharmaceuticals - Advisory Board

Suneva Medical - Instructor

Will discuss off-label uses

Will use brand names for ease of understanding

# Objectives for Safe Injections

- Learn techniques to minimize complications
- Identify serious complications
- Be able to manage complications
- Review regulatory issues

# Injectable Tissue Filler Options

**Silicone**

**Animal Collagen**  
(Zyderm, Zyplasty, Evolence)

**Human Collagen**  
(CosmoDerm, CosmoPlast,  
Fascian, Autologen,  
Cymetra, LaViv)



**Stimulators**  
PLLA (Sculptra)  
PMM (Bellafill)

CaHA (Radiesse)

**Hyaluronic Acids**  
(Juvederm & Voluma, Volbella  
Restylane, Belotero)

***Reversible***

# Aquamid Abscess



Acute swelling 3 years after  
Aquamid injection



Recurrent abscess

# Factors in Unfavorable Outcomes

- Patient selection
- Undertreatment
- Anatomic site
- Product selection
- Technique
- Judgment (overfill/under correction)
- Patient expectations
- Tissue damage

# Patient Selection

**Volume Loss**

Fillers

**Volume Descent**

Facelift

# Proper Dermal Injection

Too Superficial



Too Deep



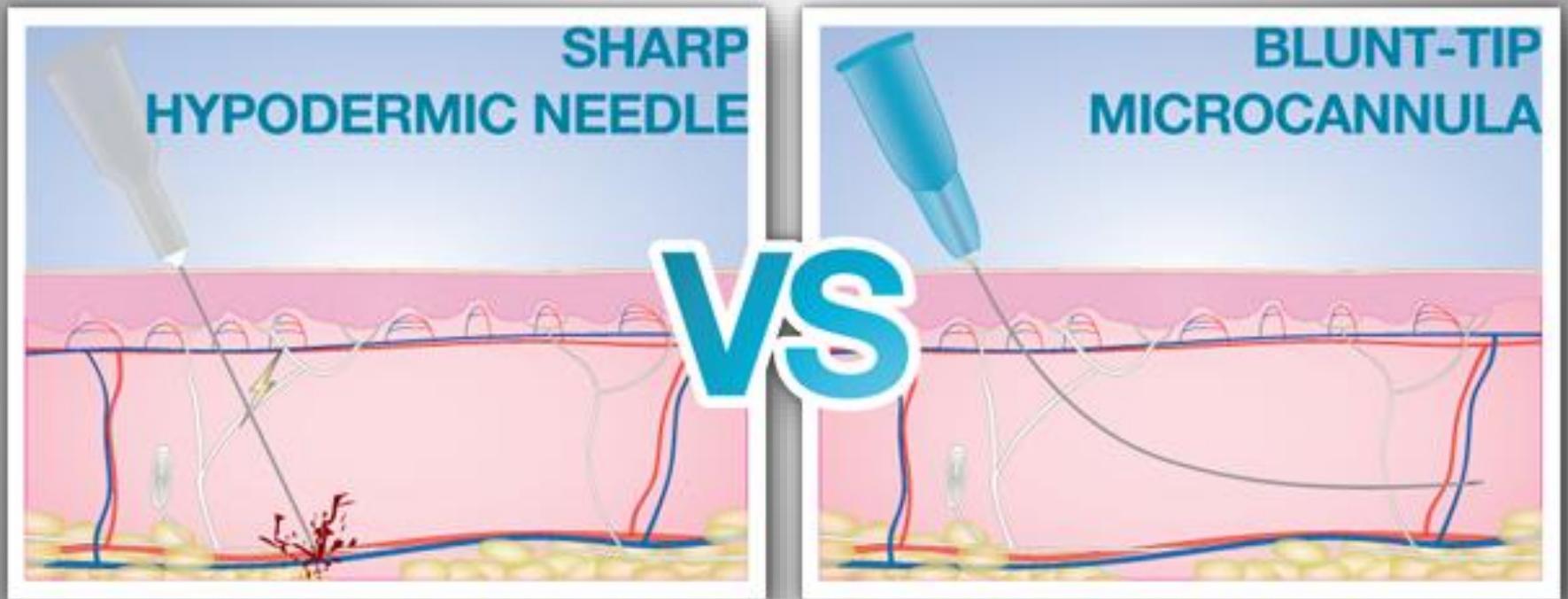
Correct Placement



# Blunt Injection Cannulas



# Blunt Injection Cannulas



# Blunt Injection Cannulas

Safety and effectiveness of injection of calcium hydroxylapatite via blunt cannula compared to injection by needle for correction of nasolabial folds

Kenneth R Beer, MD

*Esthetic, General & Surgical Dermatology, West Palm Beach, FL, USA*

- 20 patients – split face (not enough for adverse events)
- Needle side had more pain, redness, swelling
- Cannula side had better correction at 19 days



# Tear Trough & Lower Lids

- Inject on periosteum
- Expect edema & ecchymosis
- Under correct
  - Touch up in 2 weeks
- Prolonged edema
  - Treat early
  - Hyaluronidase
- May persist for years

**Not for novice injectors**

# Beware the Nose

- Tissue compression, not intravascular injection may lead to necrosis
- Very small volume injections in tip
  - Multiple sessions
- Deep injections in midline
  - On top of bone or cartilage
- Extreme caution in past rhinoplasty or scars
- Done by injectors familiar with rhinoplasty

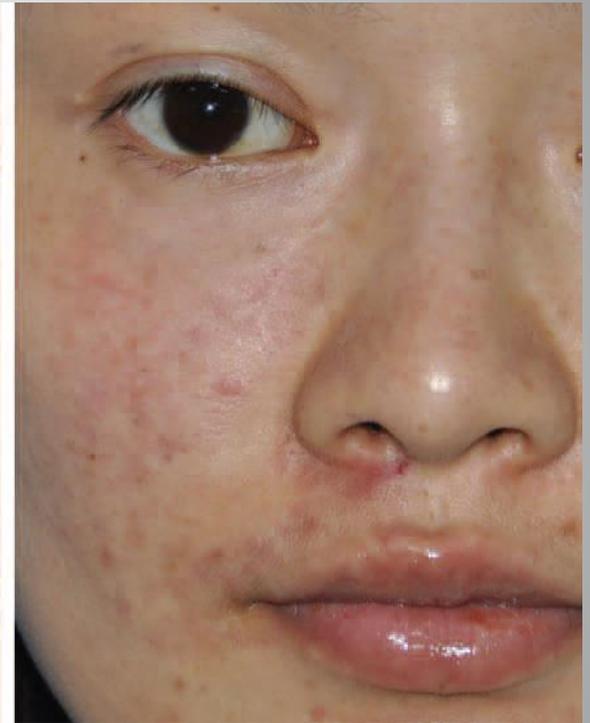
# Impending Necrosis with HA Fillers



3 hours after injection



1 day after hyaluronidase



5 days after hyaluronidase

## COSMETIC

### Clinical Outcomes of Impending Nasal Skin Necrosis Related to Nose and Nasolabial Fold Augmentation with Hyaluronic Acid Fillers

Zhong-Sheng Sun, M.D.  
Guo-Zhang Zhu, M.D.,  
Ph.D.  
Hai-Bin Wang, M.D., Ph.D.  
Xiang Xu, M.D.  
Bing Cai, M.D.

**Background:** Although there are several case reports of facial skin ischemia/necrosis caused by hyaluronic acid filler injections, no systematic study of the clinical outcomes of a series of cases with this complication has been reported.  
**Methods:** The authors report a study of 20 consecutive patients who developed impending nasal skin necrosis as a primary concern, after nose and/or nasolabial fold augmentation with hyaluronic acid fillers. The authors retrospectively

# Impending Necrosis with HA Fillers



Presented after 7 days

After 1 month, NO hyaluronidase

**COSMETIC**

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# Blunt Cannula Lip Injection



COSMETIC

## “No-Touch” Technique for Lip Enhancement

Christopher C. Surek, D.O.  
Eva Guisantes, M.D.  
Kenna Schmarr, B.S.  
Glenn Jelks, M.D.  
Javier Beut, M.D.

*Kansas City, Kan.; Barcelona and  
Palma de Mallorca, Spain; Kansas City,  
Mo.; and New York, N.Y.*

**Background:** The purpose of this study was to examine the anatomical principles of lip structure as they relate to individualized lip enhancement procedures and to describe a technique that does not violate lip mucosa during injection.

**Methods:** A retrospective analysis of patients undergoing lip enhancement procedures between 2001 and 2014 was performed. Preprocedural and postprocedural photographs were analyzed for lip subunit changes. A stepwise treatment algorithm targeting specific anatomical subunits of lip is described.

# Blunt Cannula Lip Injection



COSMETIC

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# Complications

# Immediate Complications

- Over or Under Correction
- Implant Visibility
  - Injection too superficial
    - **HA** blue discoloration
      - Massage, Hyaluronidase
    - Particulate fillers (**CaHA, PMM**) white bumps
      - Needle unroofing & evacuation
- Vascular Compromise
  - Glabella most common?



# Glabellar Vascular Compromise



5 days after HA injection

# Glabellar Vascular Compromise



12 days after HA injection

# Glabellar Vascular Compromise



# Vascular Compromise

	<i>Arterial Occlusion</i>	<i>Venous Occlusion</i>
Presentation	Immediate or early, blanching, severe pain	Delayed, dull pain, dark discoloration
Management	Stop injection, attempt aspiration Massage Warm compresses 2% nitroglycerin paste*  Injection of hyaluronidase (if caused by HA product) Antibiotic therapy (topical, parenteral, or both) in cases of skin breakdown Conservative debridement Frequent follow-up	Massage Warm compresses 2% nitroglycerin paste* Injection of hyaluronidase (if caused by hyaluronic acid product) Consider hyperbaric oxygen in cases of impending massive skin necrosis Antibiotic therapy (topical, parenteral, or both) in cases of skin breakdown Conservative debridement Frequent follow-up
Prevention	Informed consent Smallest possible needle Smallest possible volume injected Proper plane of injection	Informed consent Smallest possible needle Smallest possible volume injected Proper plane of injection

# Early Onset Complications

- Temporary nodules
- Persistent nodules
  - Non inflammatory
  - Inflammatory
    - Fluctuant vs nonfluctuant
    - Treat as infection
- Angioedema

# Delayed Onset Complications

- Persistent nodules
  - Non inflammatory
  - Inflammatory
    - Fluctuant vs nonfluctuant
    - Treat as infection
- May develop into chronic problem
  - Abscess, tissue loss
- Persistent malar swelling

# Case Example 1

## **42 year old female**

- HA (Restylane) injection for acne scars
- 3 hours later - white patch over injection site
- What do you do?

# Case Example 1

## 42 year old female

- HA (Restylane) injection for acne scars
- 3 hours later - white patch over injection site
- What do you do?
  - Nitropaste
  - Warm compressed
  - Hyaluronidase

**Immediate blanching upon injection or delayed reticulated duskiness after injection can identify impending necrosis**

# Case Example 1

## 42 year old female

- HA (Restylane) injection for acne scars
- 3 hours later - white patch over injection site
- 4 days later - skin slough
- Now what?



# Case Example 1

## 42 year old female

- HA (Restylane) injection for acne scars
- 3 hours later - white patch over injection site
- 4 days later - skin slough
- Conservative skin care  
+ Hydroquinone



# Case Example 2

## 46 year old female

- Multiple HA\* injections to lower eyelids over 3 years
- 1 month later developed periorbital swelling
- Allergy testing negative
- What now?



\* Restylane & Juvederm

# Case Example 2

## 46 year old female

- Multiple HA\* injections to lower eyelids over 3 years
- 1 month later developed periorbital swelling
- Allergy testing negative
- What now?    **15 units Hyaluronidase per lower lid**



\* Restylane & Juvederm

# Persistent HA

## Restylane persisting in lower eyelids for 5 years

Steven H Dayan, MD, FACS,<sup>1,2,3,4</sup> John P Arkins, BS,<sup>4</sup> & Michael Somenek, MD<sup>2</sup>



After 5 years, fullness resolved 2 weeks after  
60U hyaluronidase injected per side

# HA Migration

## Delayed Migration of Hyaluronic Acid Fillers: A New Complication?

- 3 patients with tear trough injections resulting in inferior migration years later
- Resolved with hyaluronidase



# Case Example 2

## Lessons Learned from Infraorbital Filler Injections

- Volume replacement is challenging
- Higher potential for complications
- Eyelid skin is unforgiving (produces lumps & bumps)
- Superficial injections produce persistent fullness
- Careful injection technique (small amounts deep)
- Variable longevity in this location
- **Unpredictable edema**

# Case Example 3

## **67 year old female**

- 1 vial (in 5cc) PLLA (Sculptra) injected
- Palpable nodules 10 months later
- What now?



# Case Example 3

## 67 year old female

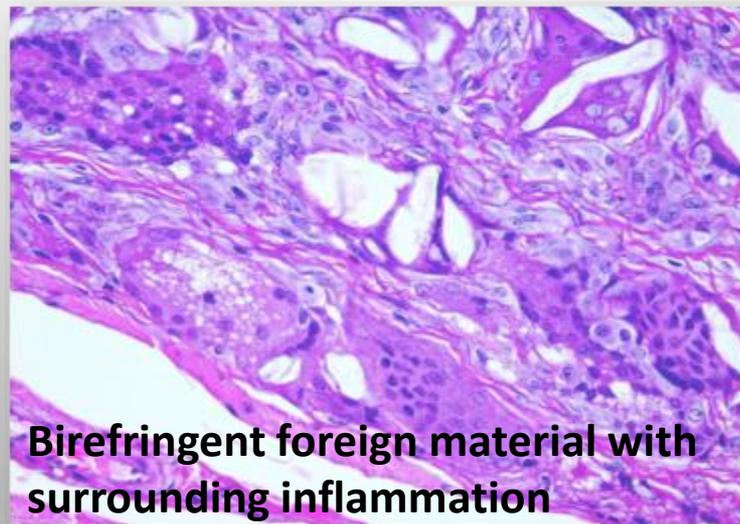
- 1 vial (in 5cc) PLLA (Sculptra) injected
- Palpable nodules 10 months later
- Steroid injection  $\implies$  No Effect



# Case Example 3

## 67 year old female

- 1 vial (in 5cc) PLLA (Sculptra) injected
- Palpable nodules 10 months later
- Steroid injection → No Effect → Excision



**Birefringent foreign material with surrounding inflammation**

# Case Example 3

## Lessons Learned from PLLA Injections

- Use higher dilution (8-10cc per vial)
- Dilute 3-5 days in advance
- Inject in deep plane
- Subperiosteal periorbital injection
- Frequent massage



# Sculptra Nodules

- Inject saline
- 5-FU
- Kenalog

# Case Example 4

## 64 year old female

- Multiple HA injections in NLF
- What is this?



# Case Example 4

## 64 year old female

- Multiple HA injections in NLF
- What is this?      **Tyndall Effect** (Blue discoloration)



# Case Example 4

## **64 year old female**

- Multiple HA injections in NLF
- How to treat?



# Case Example 4

## 64 year old female

- Multiple HA injections in NLF
- How to treat?    **15 units Hyaluronidase**



# Case Example 4

## Lessons Learned from HA Injections

- Superficial injections can be visible
- Small volume injections, evaluate & re-inject if needed
- Hyaluronidase
  - 10 to 30 units (4 to 7 days to effect)
  - Local skin reactions common
    - **Amphadase** (bovine - skin test)
    - **Hyalenex** (r-human)
    - **Vitraxe** (ovine - skin test)

# Case Example 5

## **51 year old female**

- Pain, redness & swelling 2 weeks after HA injection
- Firm without fluctuance
- Treatment?



# Case Example 5

## 51 year old female

- Pain, redness & swelling 2 weeks after HA injection
- Firm without fluctuance
- Cellulitis, no abscess
  - Antibiotics x 6 weeks
  - Minocycline + clarithromycin



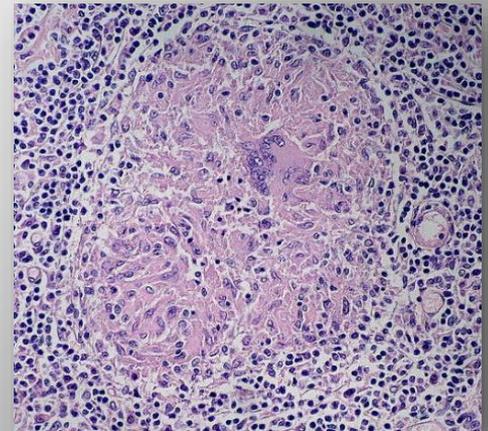
# Case Example 5

## Lessons Learned from Infections after HA Injections

- Sterile skin prep before injection
  - Remove make up
- Culture fluctuant nodules before antibiotics
- Steroids not useful, prolong infection
- Consider atypical mycobacteria & biofilm if infection occurs weeks after injection
  - Multiple antibiotic therapies
  - Enzymatic removal of biofilms controversial
    - Biofilm dissolution → macrophage migration & antibiotic penetration  
verus
    - Bacterial spread

# Granulomas vs Infections

- Resorbable fillers
  - Low incidence of long-lasting or late complications
- Partially or completely nonresorbable fillers
  - More anaerobic infections & granuloma reactions
  - Harder to treat
- Bacterial infection tissue swelling
  - Edema & cellular foreign-body response
- Micro particle filler swelling
  - Foreign body granuloma



Granuloma

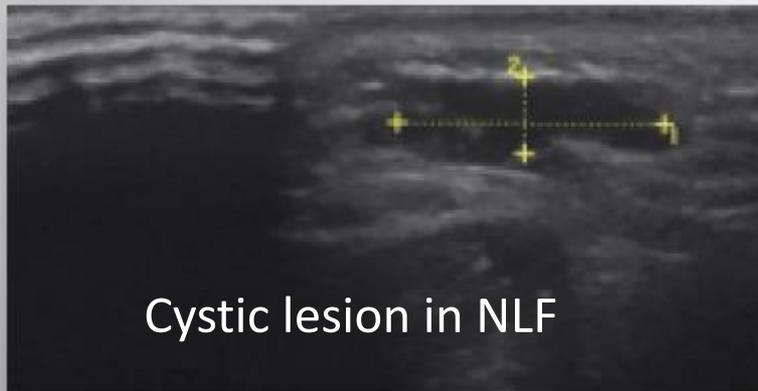
# Granulomas vs Infections

- Infection
  - Progress slowly
  - Anaerobic growth conditions
  - Symptoms 1 to 2 weeks after injection
- Granuloma
  - No detectable bacteria
  - May appear years after injection
  - Associated with microparticles fillers



# Long Lasting Low Grade Infections

- Culture negative nodules
- Mistaken for foreign-body granulomas
- Bacteria in biofilm
- Cysts on US



# Noninvasive therapeutic options

- Aspiration
  - Rarely works after a few months
- Excision
  - Scars & disfigurement
- Antibiotics
  - Effective only before biofilm develops
- Steroids
  - Temporary effect, rebound, skin atrophy & telangiectasias
- 5-Fluorouracil
  - Temporary effect & rebound

# New Concepts on Filler Problems

Many problems assumed to be foreign body granulomas or allergic reactions on the basis of negative bacterial cultures are now thought to be due to biofilms

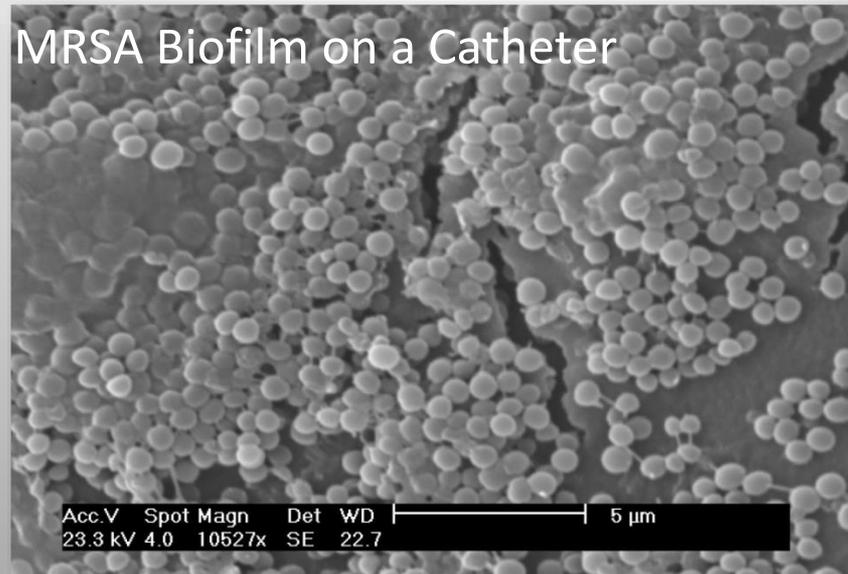
*(Wiest, 2009)*

Biofilms are almost impossible to culture using current standard culture technology and may be treated incorrectly with steroids injections, instead of 2 or 3 antibiotics

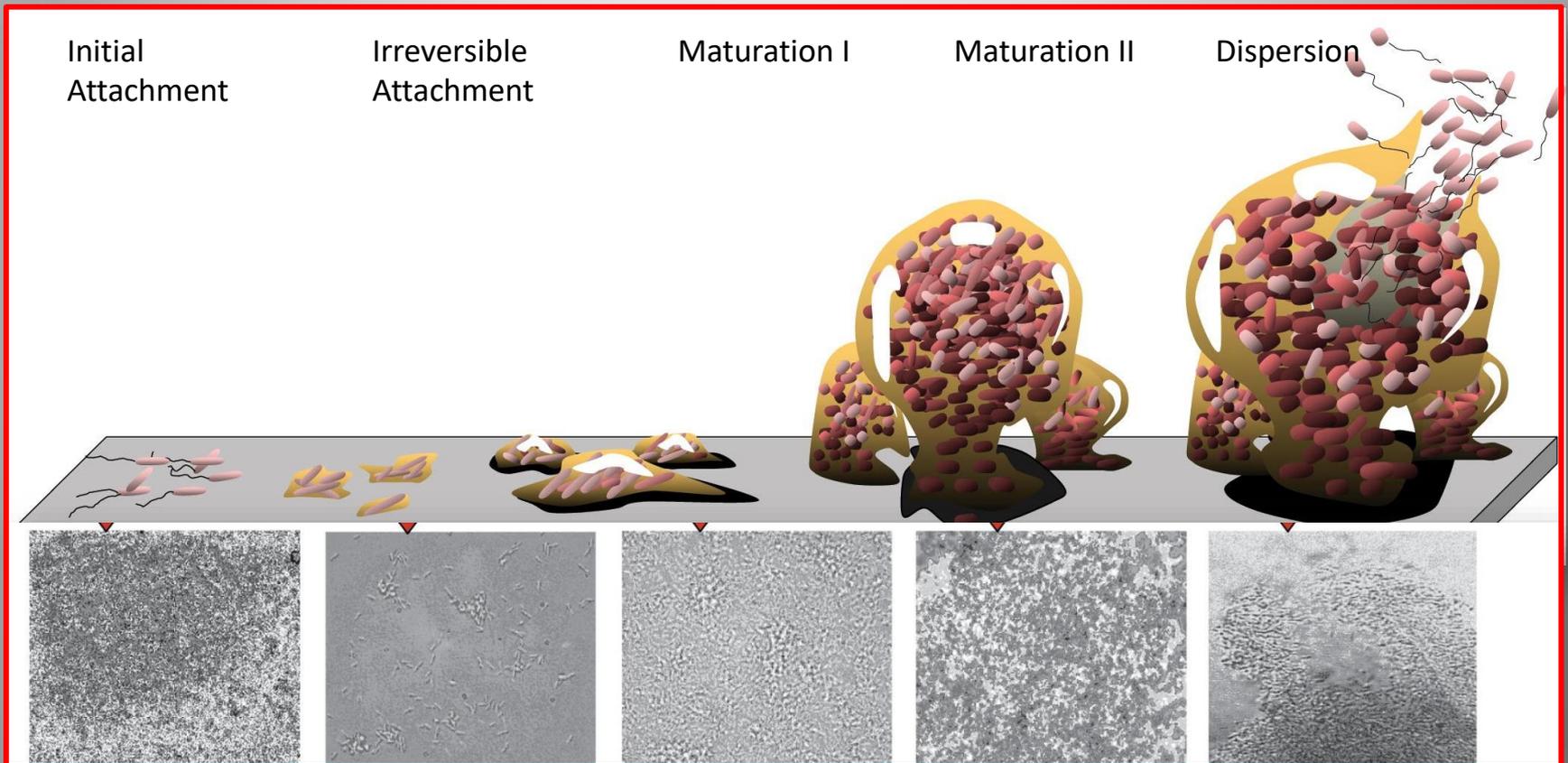
*(Christensen, 2009)*

# Biofilms

- Aggregate of microorganisms adherent to each other or a surface
- Embedded in a self-produced matrix of extracellular polymeric substance
- Cells in a biofilm are physiologically distinct from planktonic cells
- Biofilm growth mode causes large shift in gene regulation
- Increased resistance to antibiotics & detergents



# Biofilm Formation & Cycle



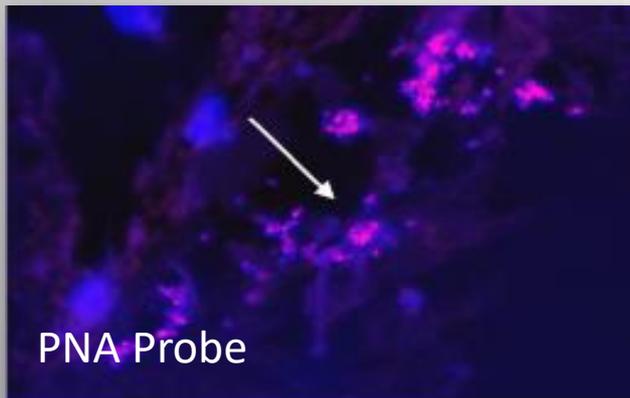
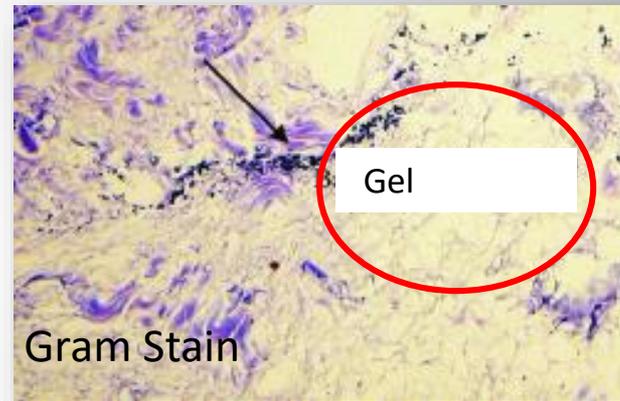
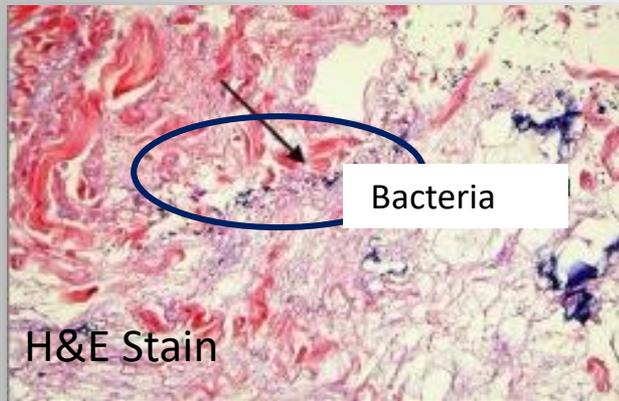
# Biofilm Infection Challenges

- Increased antibiotic resistance (1000x drug needed)
- Leucocytes trapped & made ineffective
- Chemical communication promotes bacterial cooperation
- Dormant (persister) cells have decreased metabolism
  - Difficult to culture
  - Resistant to antibiotics
- Clinical failure to recognize infections
- **RESULT: Low-grade smoldering infection**
  - **Low host response**
  - **High antibiotic resistance**
  - **Low possibility of positive culture**

# Biofilm Detection

- Biofilm detection requires fluorescent DNA stains or other chemical reactions
- May need 4 to 6 weeks on specific agar plates

# Bacteria in Gel



# Fillers Susceptible to Biofilm Complications

## **Combination Gels (more likely)**

- Collagen–PMMA suspensions (Artecoll)
- HA–PMMA suspensions (Dermalive ,Dermadeep, Dermatech)
- Bioplastique (silicone in polyvinylpyrrolidone)
- Evolution (polyacrylamideco-DADMA)
- Bio-Alcamid (polyalkylmide)
- Outline (procollagen)

## **Homogenous Products (less likely)**

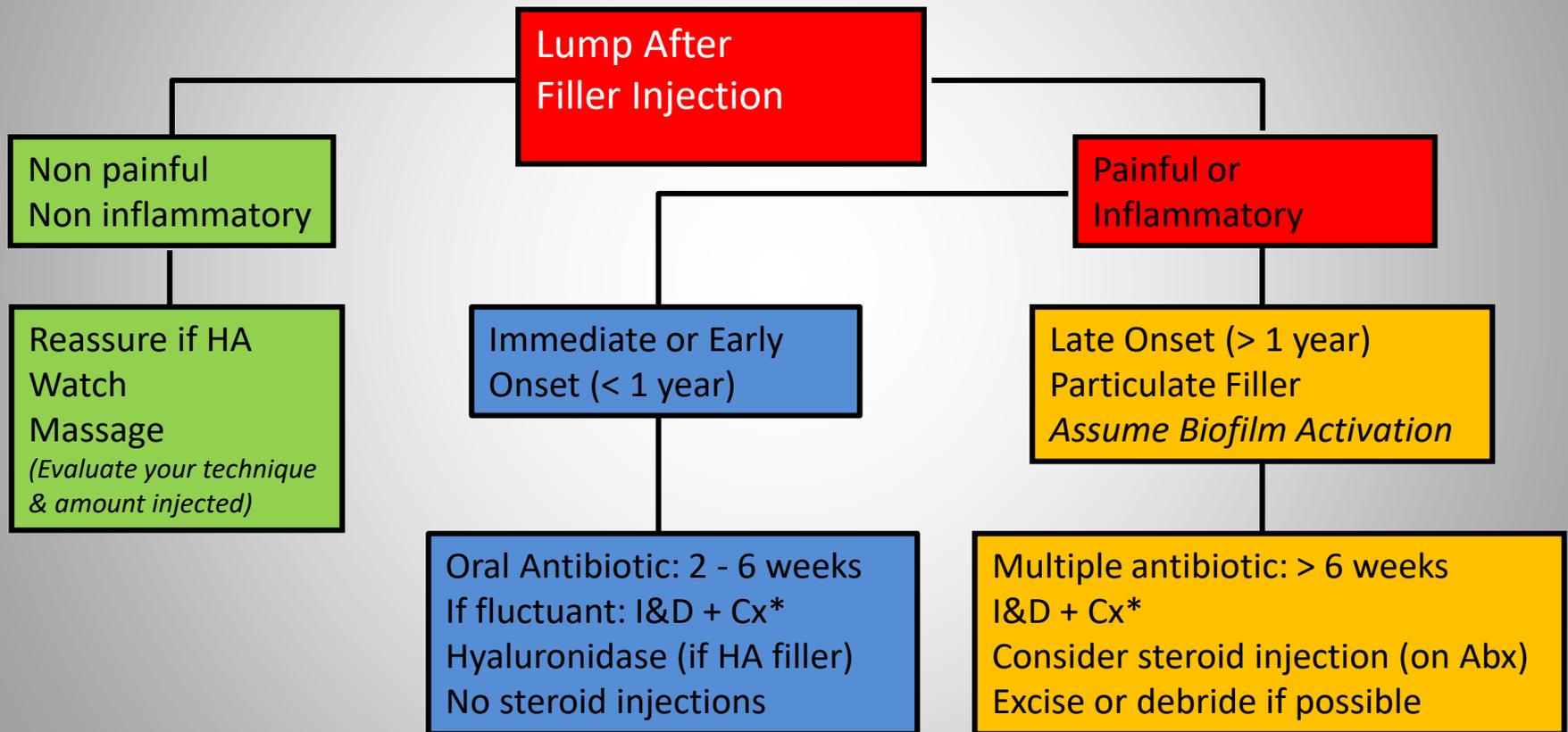
- Radiesse
- Silicone
- Polyacrylamides

# Biofilm 2 Week Window

- 2-week period after implant placement when bacterial contamination can occur and develop a biofilm
- Timeline documented in orthopedic implants & other solid foreign body implanted material
- Avoid needle injections over the implant during the 2 weeks
- Dental procedures, facial trauma, or facial infections can introduce bacteria and produce biofilm



# Treatment Algorithm



# Antibiotic Treatment

## Most Early Infections

- Clarithromycin 500 mg BID x 6 weeks
- Minocycline 100mg BID x 6 weeks

## Recurrent infections suggest active biofilm

- Filler & biofilm must be removed/excised

# Laser Treatment of Filler Lesions

- Infectious lesions
  - 532 nm lithium triborate laser
  - Removal of infected gel & pus
- Granulomas
  - 808 nm diode laser (intralesional technique)
  - Melt & liquefied then granuloma
  - Facilitates evacuation
- Thin laser beam
  - Controlled tissue
- 20 patients had reduction or complete resolution
  - Resolution increased with repeated treatments
  - All had prior antibiotics & steroids without success



# Laser Treatment of Filler Lesions

- Cystic lumps 3 months after HA & dextranomer microspheres injections
- 6 weeks antibiotics & steroids no resolution
- Multiple 532 nm lithium triborate laser treatments



# Laser Treatment of Filler Lesions

- Granulomas after Dermalive\* & Aquamid\*\*
- 808 nm diode laser treatment
- Drill holes for evacuation



\* HA + acrylic hydrogel

\*\* Polyacrylamide

# FDA Safety Communication



The image is a screenshot of the FDA website. At the top, there is a dark blue header with the U.S. Department of Health and Human Services logo and text. Below this is the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". To the right of the logo is a search bar with the text "Search FDA" and a magnifying glass icon. Below the header is a navigation menu with buttons for "Home", "Food", "Drugs", "Medical Devices", "Radiation-Emitting Products", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", and "Tobacco Products". The "Medical Devices" button is highlighted. Below the navigation menu is a section titled "Medical Devices" with a breadcrumb trail: "Home > Medical Devices > Medical Device Safety > Safety Communications". On the left side of the page, there is a sidebar with a "Safety Communications" section containing links for "Information About Heparin" and "Preventing Tubing and Luer". The main content area features a large heading: "Unintentional Injection of Soft Tissue Filler into Blood Vessels in the Face: FDA Safety Communication".

U.S. Department of Health and Human Services

**FDA** U.S. Food and Drug Administration  
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## Medical Devices

Home > Medical Devices > Medical Device Safety > Safety Communications

**Safety Communications**

- Information About Heparin
- Preventing Tubing and Luer

# Unintentional Injection of Soft Tissue Filler into Blood Vessels in the Face: FDA Safety Communication

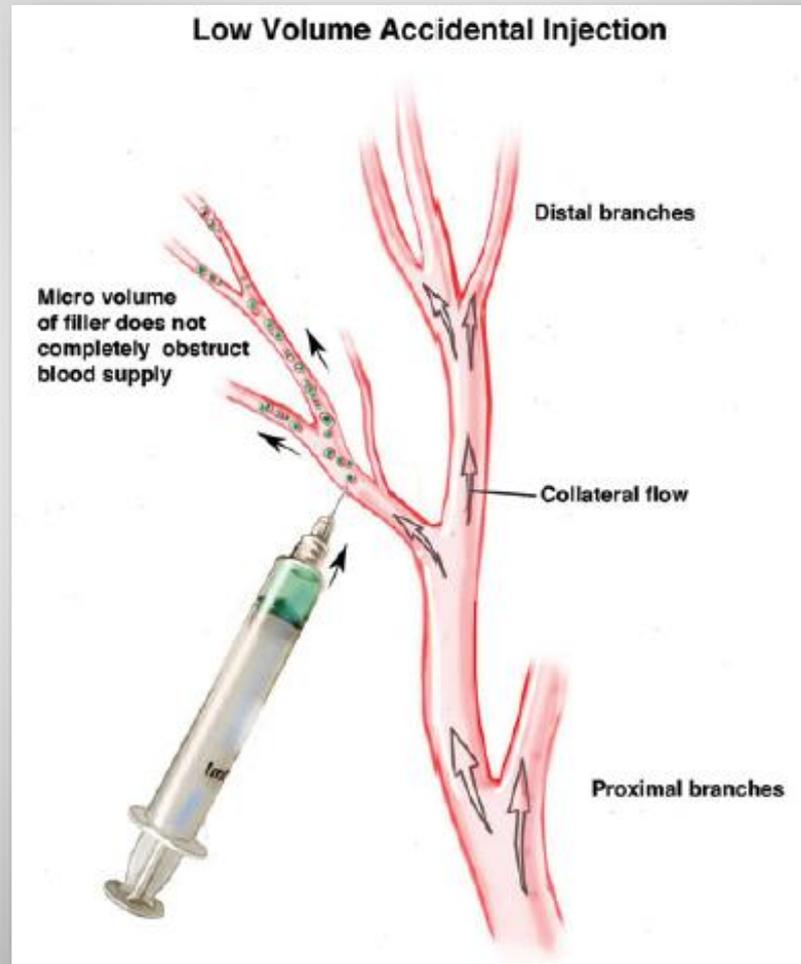
# Signs & Symptoms of Intraarterial Injection

- Skin
  - Pain
  - Skin blanching
  - Slow capillary refill
  - Demarcation
- Eye
  - Vision loss/blindness
- Stroke
  - “FAST”: facial drooping, arm weakness, speech impediment, time (act fast!)

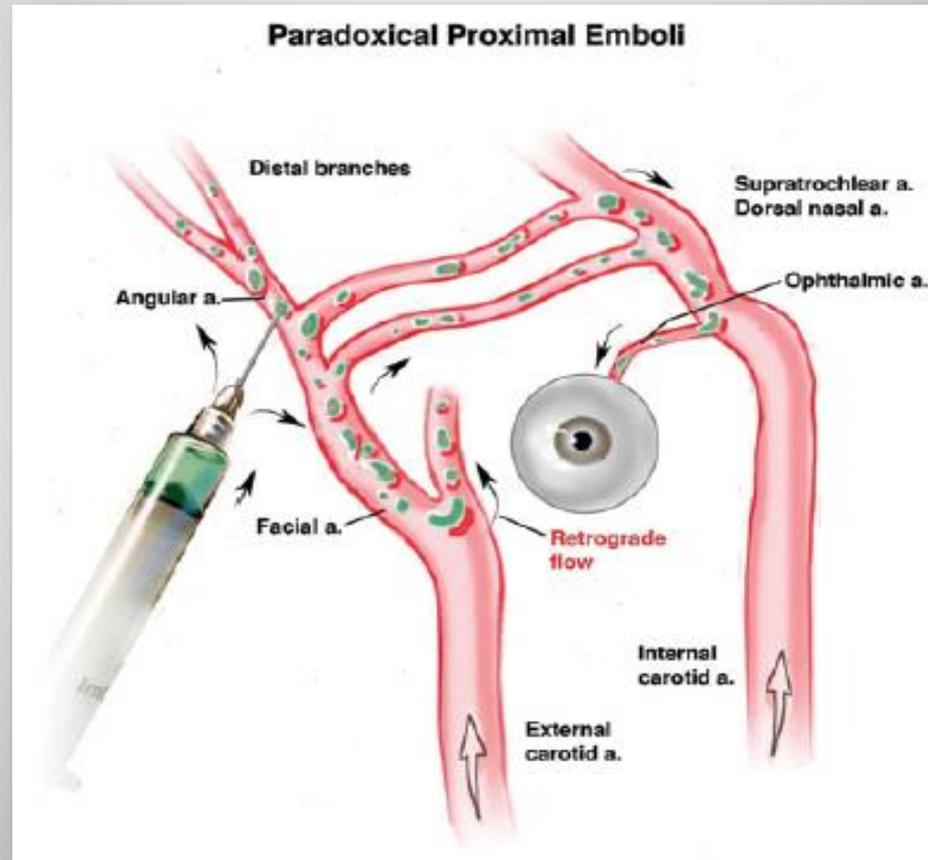
# Progression of Skin Changes

Findings	Timing
Blanching	Seconds
Reactive hyperemia or livedo pattern	Minutes up to 10 minutes
Blue-black discoloration	10 minutes to hours
Blister/bullae formation	Hours to days
Skin breakdown, ulceration, slough	Days to weeks

# Low Volume Injection & Arterial Occlusion

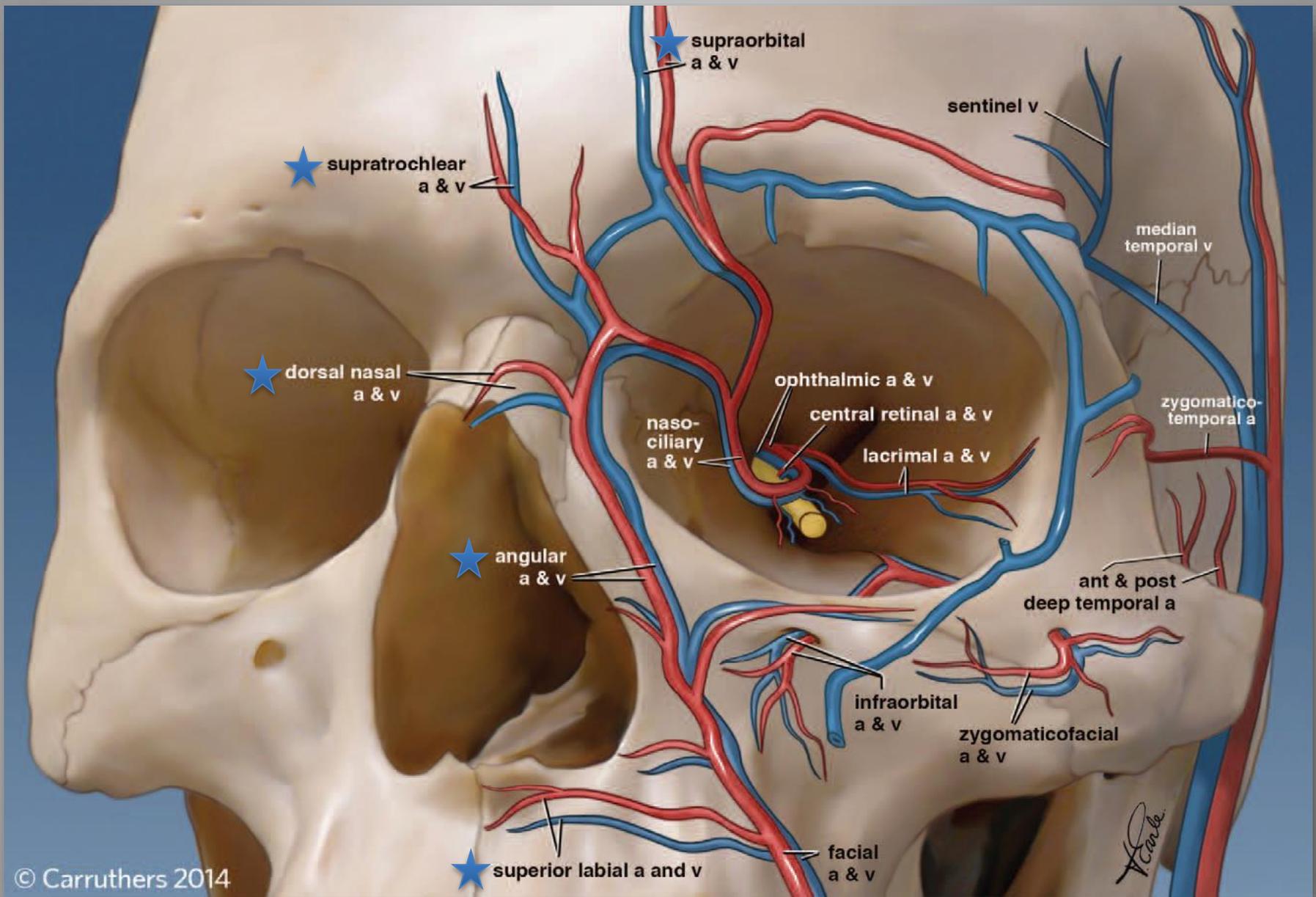


# High Injection Pressure & Retrograde Propagation



# Avoid Arterial Injection & Propagation

- Withdraw before injection
- Avoid deep injection near named vessels
- Low pressure injection
- Avoiding injecting excess volume in one area
- Blunt cannulas
- Small bore
- Inject slowly in small aliquots
- Avoid injection in previously traumatized areas
- Stop injection if complaints of pain/vision loss

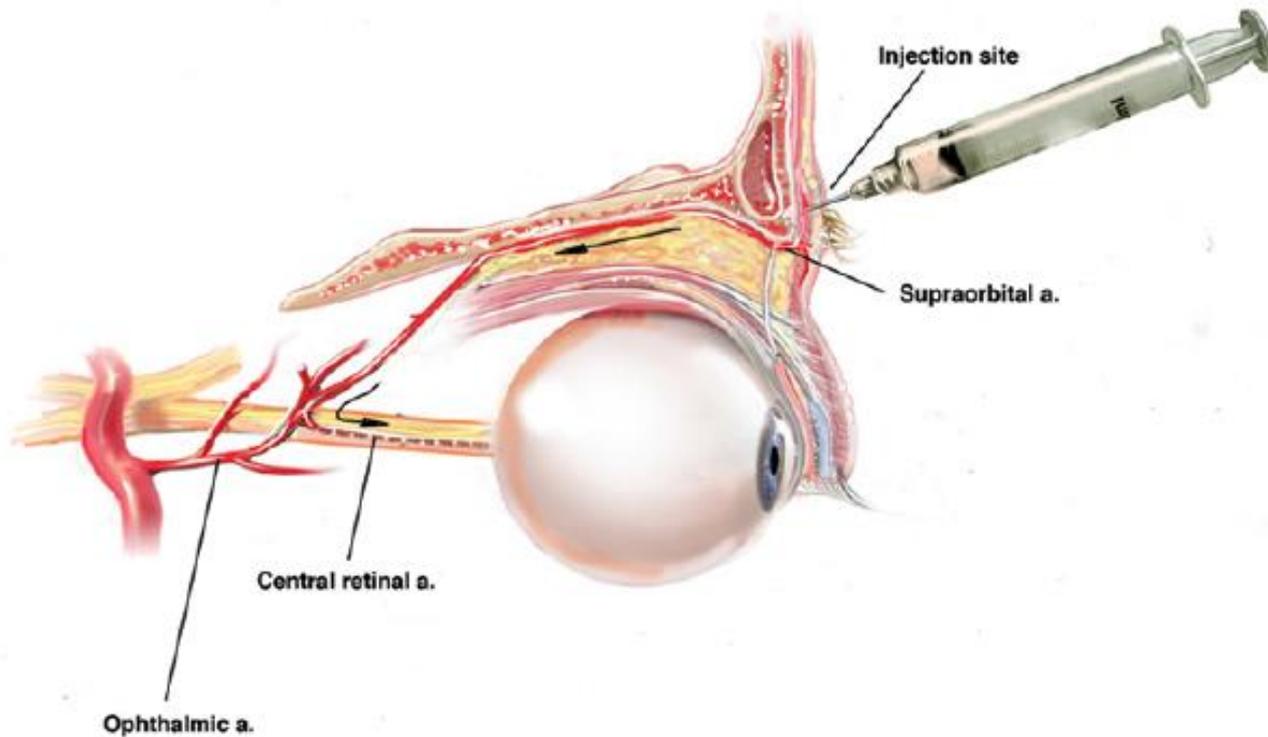


© Carruthers 2014

Carruthers JDA, Fagien S, Rohrich RJ, Weinkle S, Carruthers A. Blindness caused by cosmetic filler injection: a review of cause and therapy. PRS. 2015.

# Blindness

Retrograde Flow / Blindness



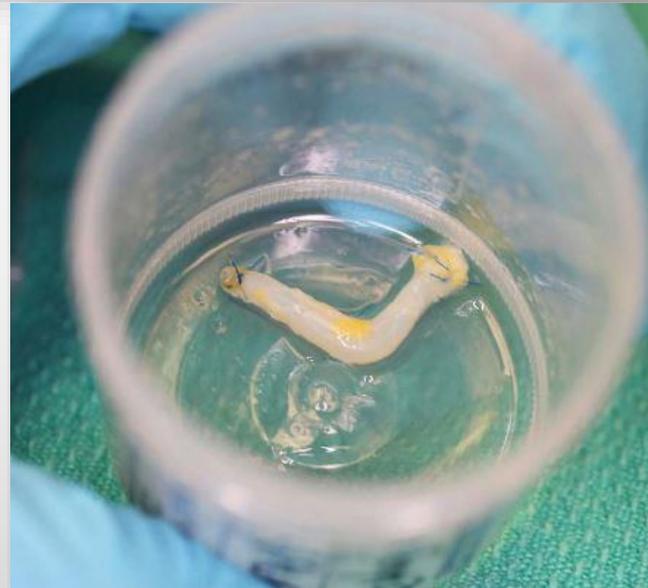
# Crash Kit

- Warm compress
- Nitropaste
- Baby ASA
- Supplemental O2
- **HYALURONIDASE**
  - 400u into subcutaneous area (2cc in a 3cc syringe with 0.2cc plain lidocaine 2%, 27 g-needle)

# Hyaluronidase

## Transarterial Degradation of Hyaluronic Acid Filler by Hyaluronidase

CLAUDIO DeLORENZI, BA, MD, FRCS



Intravascular HA liquefied in cadaver arteries & veins after 4 hours

# Hyaluronidase

**Hyaluronidase works for  
Juvederm**

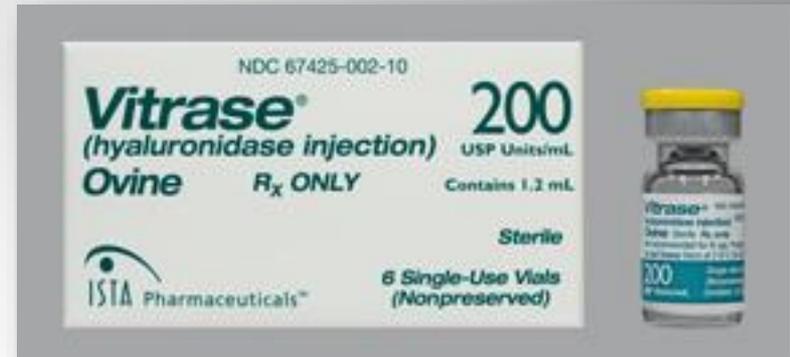
Ultra & Ultra Plus  
Voluma & Volbella

Restylane

Lyft & Silk

Belotero

**Always have  
Hyaluronidase available  
when doing HA injections**



# Filler Emergencies

- Soft tissue intravascular occlusion
- Stroke
  - Standard emergency stroke protocol
- Vision loss/blindness
  - Emergency ophthalmology consult
  - Retrobulbar hyaluronidase injection

# Retrobulbar Injection Technique

- Local anesthesia into lower eyelid over inferotemporal orbit
- Blunt, 25g cannula advanced in inferotemporal quadrant of orbit for 1 inch
  - Inferior and lateral to optic nerve
- 2 to 4cc hyaluronidase

## IDEAS AND INNOVATIONS

### Blindness Caused by Cosmetic Filler Injection: A Review of Cause and Therapy

Jean D. A. Carruthers, M.D.  
Steve Fagien, M.D.  
Rod J. Rohrich, M.D.  
Susan Weinkle, M.D.  
Alastair Carruthers, M.D.

*Vancouver, British Columbia, Canada*

**Summary:** Vascular occlusion causing blindness is a rare yet greatly feared complication of the use of facial aesthetic fillers. The authors performed a review of the aesthetic literature to ascertain the reported cases of blindness and the literature reporting variations in the vascular anatomy of the human face. The authors suggest a small but potentially helpful addition to the accepted management of the acute case. Cases of blindness, mostly irreversible,

# Retrobulbar Injection Technique



# What Next?

- Wound care
- See patient daily
- Consider Hyperbaric Oxygen

# Complications



# Posted on Real Self



**Use Informed Consent Forms!**

# Filler Complications

- All fillers have potential complications
- Long lasting
  - More persistent
  - More difficult to treat
- Complications due to technique vs material
  - Learn technique on temporary fillers
  - Experience decreases technique complications
- **Train ALL STAFF on filler emergency calls**
  - **Text a picture of any “bruising”**

# Recommendations

- Know the filler material you are using
- Start with temporary & reversible products
  - Hyaluronic acids
- Use sterile techniques
- Limit amount injected & areas treated
  - Easier to add than to take away
- Deal with inflammatory nodules
- Know the regulatory issues

# Regulatory Issues

# Fillers & the Law

- Product purchase source
- Non-FDA approved fillers
- Patient supplied fillers
- Off label filler use
- Reimporting FDA approved fillers
- Physician vs non-physician filler injector
- Non-clinical treatment settings



# Purchase Directly from Manufacturer

## 5 Docs Plead Guilty in Bogus Botox Rap; Stems From Toxin Research International Case

*By Jim Edwards | Aug 14, 2009*

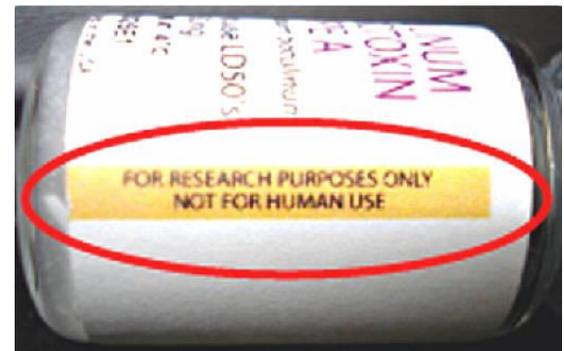
Five prominent New York State doctors pled guilty this week to injecting patients with an unapproved version of **Botox**, and not telling those patients they weren't getting the real thing. They face a possible year in prison and a \$100,000 fine on a misdemeanor misbranded drugs charge.

The doctors bought the Botox from **Toxin Research International** in Arizona. The doctors maintain they thought it was the real thing, and no patients were injured.

The president of Toxin Research International is currently serving nine years in prison for fraudulently selling misbranded Botox on the web.

The case is a warning to doctors: get your supplies through established channels, not the secondary market.

These weren't sleazy docs operating out of strip malls. Their resumes read like pillars of the community.



# Non FDA Approved Fillers

**Is it legal for a physician to obtain and use a product from outside of the United States that is not approved by the FDA?**

- An individual who enters the country with a non-approved injectable filler could be sanctioned by the FDA
- A physician who orders a non-approved injectable filler through a non-US mail-order pharmacy could be sanctioned by the FDA
- State medical board involvement if any patient complaints result
- Exceptions for investigators working under FDA-approved studies



# Patient Provided Fillers

If a patient brings a non-approved drug or device to a physician, is it legal to treat the patient using this drug or device?

- Federal law prohibits such conduct
- Risk of significant liability exposure, invalidation of professional liability insurance coverage, criminal penalties and action by regulatory agencies



# Off-Label Filler Use

## **What is the risk exposure of off-label use of approved drugs?**

- Off-label use of FDA approved drugs does **not** carry the risks cited above, provided patient acceptance and understanding, and the treatment rationale, are well documented
- For example, Botulinum toxin type A is a FDA-approved product for use in the glabellar area. Use of the product in other areas is legal and a clinical decision

## **Can a physician advertise non-approved or off-label use?**

- It is illegal to commercially advertise any non-approved or off-label use; only FDA-approved uses may be commercially advertised

# Reimported Fillers

**Is it legal for a physician to purchase and use an FDA approved drug/product that is reimported from foreign sources?**

- The act of importing drugs manufactured or approved in the U.S. and approved by the FDA is called “reimportation”...which remains illegal and dangerous
- Currently, only manufacturers are allowed to reimport their own drugs



# Non-Physician Filler Administration

## **What level of training or licensure is required to administer injectables or fillers?**

- Injections may be administered by a licensed professional nurse or physician assistant as determined by the supervising physician & local and state professional practice regulations
- Physician's responsibility to ensure the non-physician possess proper education and training

## **What are the legal requirements for physician supervision of non-physician personnel who administer injectables and fillers?**

- Supervisory regulations vary from state to state
- Physician of record is ultimately responsible

# Non-Clinical Treatment Settings

- **Administration of injectables & fillers outside a clinical setting**
- Concern about non-clinical sites where treatments offered
  - Shopping malls, private homes, office parties, and group social gatherings
- Inappropriate for several reasons:
  - Inadequate patient selection
  - Possible peer pressure for an individual to consent to treatment
  - Providers who are not trained or qualified to treat or deal with complications
  - Lack of control over dosage and inadequate post-treatment supervision
  - Alcohol influencing decision making
  - Dealing with adverse event

**Update In Process**



# Soft Tissue Fillers: Safety & Complications

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