HOW TO MANAGE COMPLICATIONS OF FILLERS: THE UGLY TRUTH

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Disclosures

- Revance: Research
- Galderma: Research, Advisory Board

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JUST BECAUSE YOU CAN, DOESN'T MEAN YOU SHOULD

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Introduction

Fillers 2023 and Beyond

- New and future fillers and new indications
- Factors for success:
  - Patient Selection
  - Product Selection
  - Technique
- Mid Face Replacement: Volumetric replacement and aesthetic balance
- Indications: Lips, Midface, Jawline, lower lids
- Important Considerations: Collagen stimulation, AE's

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Ablon G: Understanding How to Prevent and Treat Adverse Events of Fillers and Neuromodulators, *Plastic and Resconstructive Surgery Journal* Sept 2016.

HA Fillers: Aesthetic Outcome

Factors Affecting Outcomes

- Product
  - Chemical properties
  - Physical properties (Particle/Gel), G!, Viscosity
- Patient
  - Anatomy
  - Physiology and psychology
- Injector
  - Aesthetic eye
  - *Injection technique**
  - Degree of correction
  - *Treatment (optimization) interval**

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FILLER PRODUCTS TO DATE

Approved Dermal Fillers					
Trade Name (with link to additional information)	Material	Applicant	PMA Number	Decision Date	Approved For
Restylane Lyft with Lidocaine	Hyaluronic Acid, Lidocaine	Q-Med AB	P040024/S069	5/18/2018	Injectable gel indicated for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as nasolabial folds, subcutaneous to supraperiosteal implantation for cheek augmentation and correction of age-related midface contour deficiencies in patients over the age of 21, and for injection into the subcutaneous plane in the dorsal hand to correct volume deficit in patients over the age of 21.
Revanesse Versa	Hyaluronic Acid	Prollenium Medical Technologies Inc.	P160042	8/4/2018	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults 22 years of age or more
Revanesse Versa +	Hyaluronic Acid, Lidocaine	Prollenium Medical Technologies Inc.	P160042/S003	8/2/2018	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults 22 years of age or more
RHA 2	Hyaluronic Acid, Lidocaine	Teoxane S.A.	P170002	10/19/2017	Injectable gel indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds, in adults aged 22 years or older
RHA 3	Hyaluronic Acid, Lidocaine	Teoxane S.A.	P170002	10/19/2017	Injectable gel indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds, in adults aged 22 years or older
RHA 4	Hyaluronic Acid, Lidocaine	Teoxane S.A.	P170002	10/19/2017	Injectable gel indicated for injection into the deep dermis to superficial subcutaneous tissue for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds, in adults aged 22 years or older
JUVEDERM VOLLURE XC	Hyaluronic Acid	Allergan	P110033/S020	3/17/2017	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) in adults over the age of 21.
Restylane, Refyne, Restylane Defyne	Sodium Hyaluronate	Q-Med AB	P140029	12/9/2016	Restylane Refyne is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe facial wrinkles and folds (such as nasolabial fold) in patients over the age of 21. Restylane Defyne is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe deep facial wrinkles and folds (such as nasolabial fold) in patients over the age of 21.
JUVEDERM VOLBELLA XC	Hyaluronic Acid with Lidocaine	Allergan	P110033/S018	5/31/2016	Injection into the lips for lip augmentation and for correction of perioral rhytids in adults over the age of 21.
RESTYLANE LYFT WITH LIDOCAINEMedicalmer Icon	Hyaluronic acid with lidocaine	Galderma Laboratories	P040024 S073	7/1/2015	Moderate to severe facial folds and wrinkles or in patients over the age of 21 who have age-related volume loss.
RADIESSE	Hydroxylapatite	Bioform Medical, Inc.	P050052/S049	6/4/2015	Subdermal implantation for hand augmentation to correct volume loss in the dorsum of the hands.
RESTYLANE SILK	Hyaluronic Acid with Lidocaine	Valeant Pharmaceuticals North America LLC/Medicis	P040024 S072	6/13/2014	Indicated for lip augmentation and dermal implantation for correction of perioral rhytids (wrinkles around the lips) in patients over the age of 21.
JUVEDERM VOLUMA XC	Hyaluronic Acid with Lidocaine	Allergan	P110033	10/22/2013	Deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.
RESTYLANE-L INJECTABLE GEL	Hyaluronic Acid with Lidocaine	Medicis Aesthetics Holdings, Inc.	P040024 S056	8/30/2012	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles/folds (such as nasolabial folds) and for lip augmentation in those over the age of 21 years.
BELOTERO BALANCE	Hyaluronic Acid	Merz Pharmaceuticals	P090016	11/14/2011	Injection into facial tissue to smooth wrinkles and folds, especially around the nose and mouth (nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024 S051	10/11/2011	Lip augmentation in those over the age of 21 years.
JUVEDERM ULTRA XC AND JUVEDERM ULTRA PLUS XC	Hyaluronic Acid with Lidocaine	Allergan	P050047	1/7/2010	The addition of 0.3% Lidocaine into Juvederm Ultra and Juvederm Ultra Plus.
SCULPTRA AESTHETIC	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050 S002	7/28/2009	Use in shallow to deep nasolabial fold contour deficiencies and other facial wrinkles.
EVOLENCE COLLAGEN FILLER	Collagen	Colbar Lifescience l	P070013	6/27/2008	The correction of moderate to deep facial wrinkles and folds (such as nasolabial folds).
PREVELLE SILK	Hyaluronic Acid with Lidocaine	Genzyme Biosurgery	P030032 S007	2/26/2008	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RADIESSE 1.3CC AND 0.3CC	Hydroxylapatite	Bioform Medical, Inc	P050037	12/22/2006	Restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV.
RADIESSE 1.3CC AND 0.3CC	Hydroxylapatite	Bioform Medical, Inc	P050052	12/22/2006	Subdermal implantation for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ELEVESS	Hyaluronic Acid with Lidocaine	Anika Therapeutics	P050033	12/20/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ARTEFILL		Suneva Medical, Inc.	P020012	10/27/2006	Use in facial tissue around the mouth (i.e., nasolabial folds).
JUVEDERM 24HV, JUVEDERM 30, and JUVEDERM 30HV	Hyaluronic Acid	Allergan	P050047	6/2/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024	3/25/2005	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
CAPTIQUE INJECTABLE GEL	Hyaluronic Acid	Genzyme Biosurgery	P030032 S002	11/12/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
SCULPTRA	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050	8/3/2004	Restoration and/or correction of the signs of facial fat loss (facial lipoatrophy) in people with Human Immunodeficiency Virus (HIV).
HYLAFORM (HYLAN B GEL)	Modified hyaluronic acid derived from a bird (avian) source	Genzyme Biosurgery	P030032	4/22/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Q-med Ab	P020023	12/12/2003	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
COSMODERM 1 HUMAN-BASED C	Collagen	Inamed Corporation	P800022 S050	3/11/2003	Injection into the superficial papillary dermis for correction of soft tissue contour deficiencies, such as wrinkles and acne scars.
FIBREL	Collagen	Serono Laboratories	P850053	2/26/1988	The correction of depressed cutaneous scars which are distendable by manual stretching of the scar borders.
ZYPLAST(R)	Collagen	Collagen Corp.	P800022 S011	6/24/1985	Use in mid to deep dermal tissues for correction of contour deficiencies.
ZYDERM COLLAGEN IMPLANT	Collagen	Allergan	P800022	9/18/1981	Use in the dermis for correction of contour deficiencies of this soft tissue.

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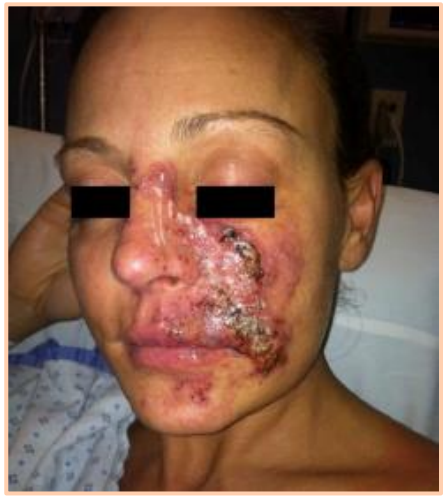
New devices to reduce risk of filler complications

- Ultrasound technology to note danger zones
- Vascular occlusion is a rare but serious complication of dermal filler injection
- Seen more commonly with injection in NL crease,lips, glabella
  - Compression vs occlusionvs vascular spasm



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Injector:

- Understand Anatomy
- Consider advances in injection technique
  - Zone injection
  - Anterograde and retrograde, fanning, bolus placement
  - Volume replacement/Craniofacial recontouring*
  - Important areas
    - Mid-face
    - Malar area – deep (sub-q) injections
  - Layering techniques
  - And ABSOLUTELY KNOW what to do if something goes wrong OR YOU SHOULDN'T BE DOING FILLERS!!

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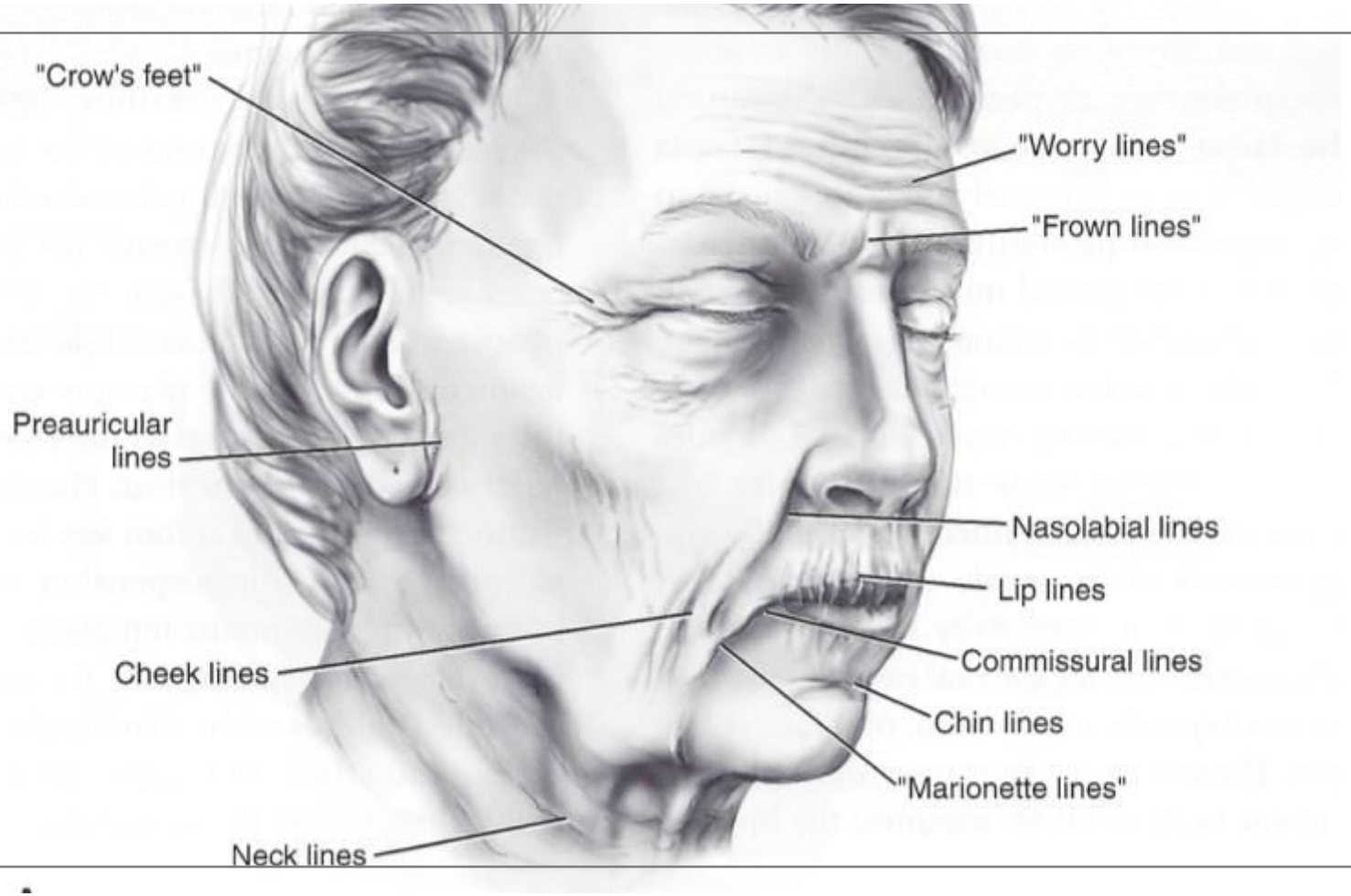
The Aging Face I

What We See



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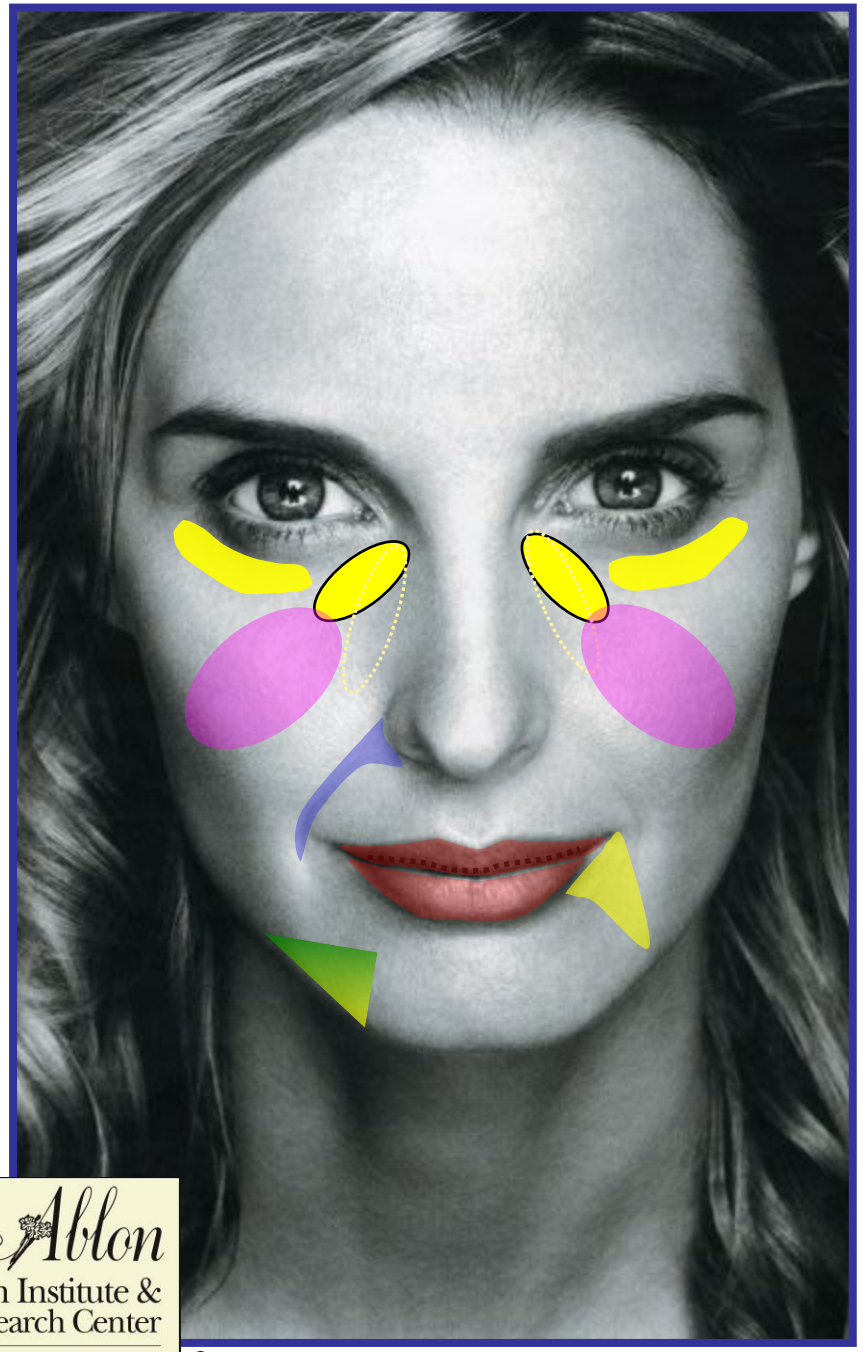
Injectable Sites for Volumization



- Treat areas as “zones” not “lines”
- Tear Trough
- Nasojugal Groove
- Nasolabial Folds
- Replace Volume and Lift
- Restore Vs. Enhance

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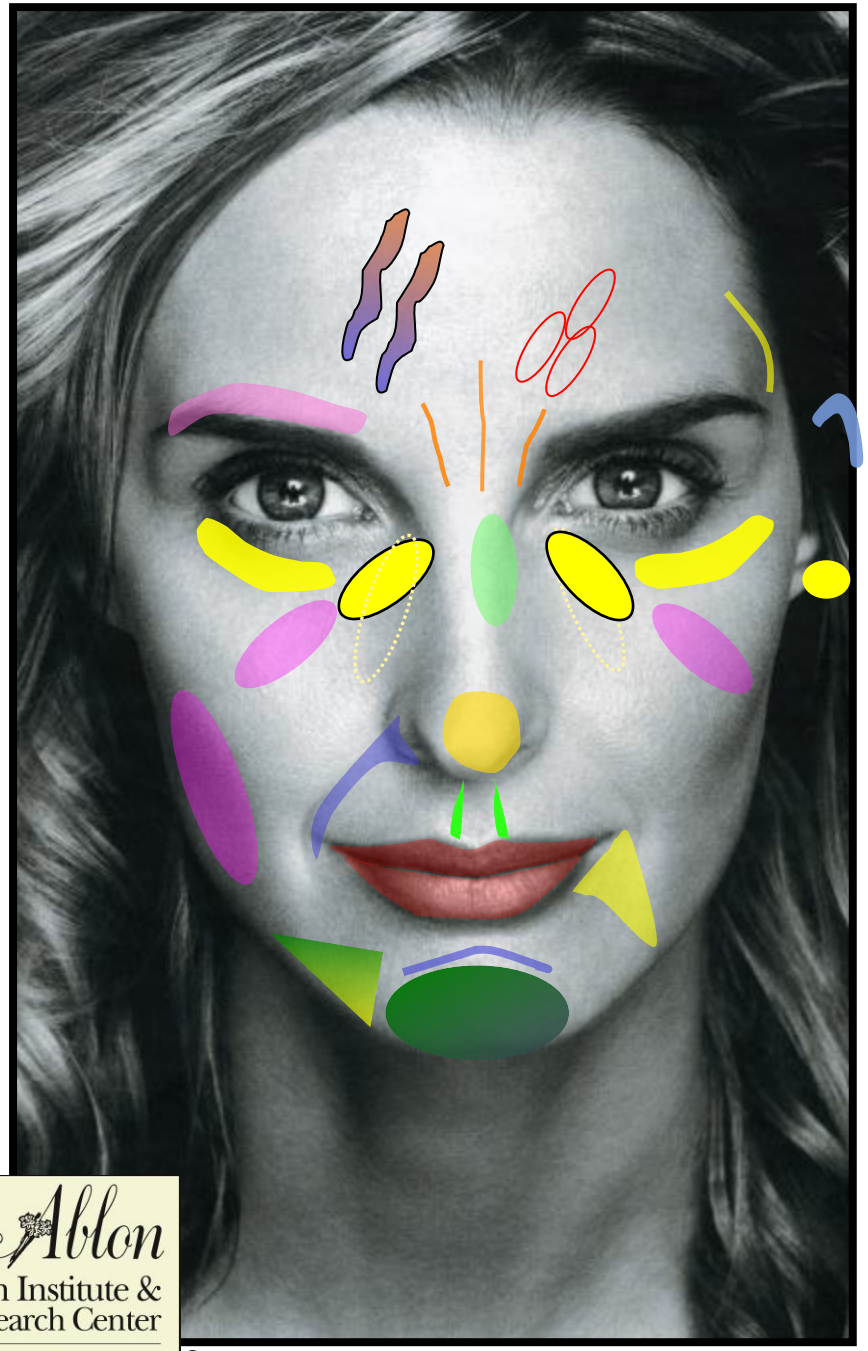

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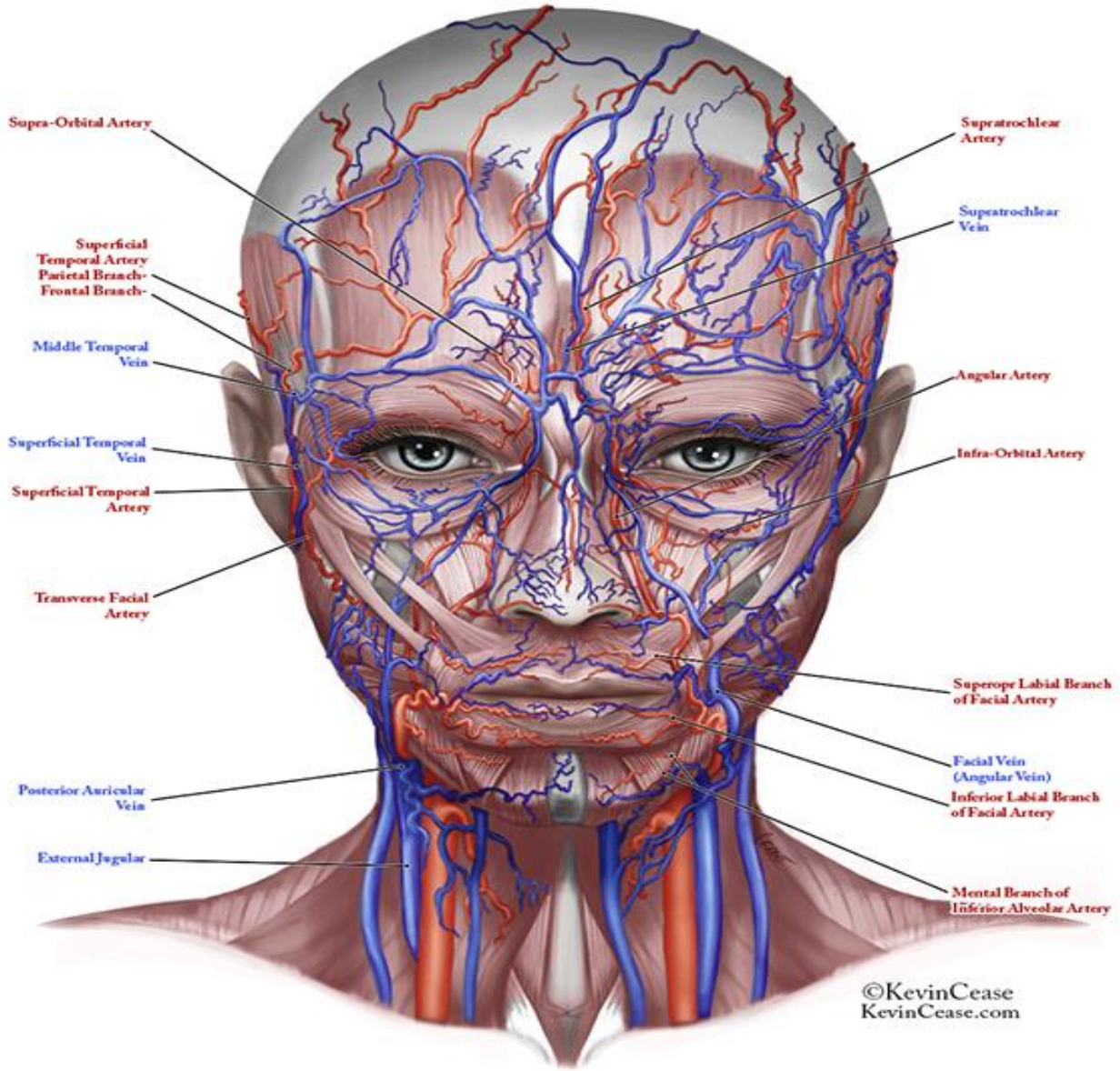
Advanced Injectable Sites

- Treat areas as "zones" not "lines"
- Tear Trough
- Nasojugal Groove
- Lip Enhancement
  - Volume
  - Shape
  - Definition
  - Cupids Bow
  - "Whistle Lines"
- Ear Lobes – Volumize & Reshape
- The "Aesthetic Nose"
- Chin Augmentation



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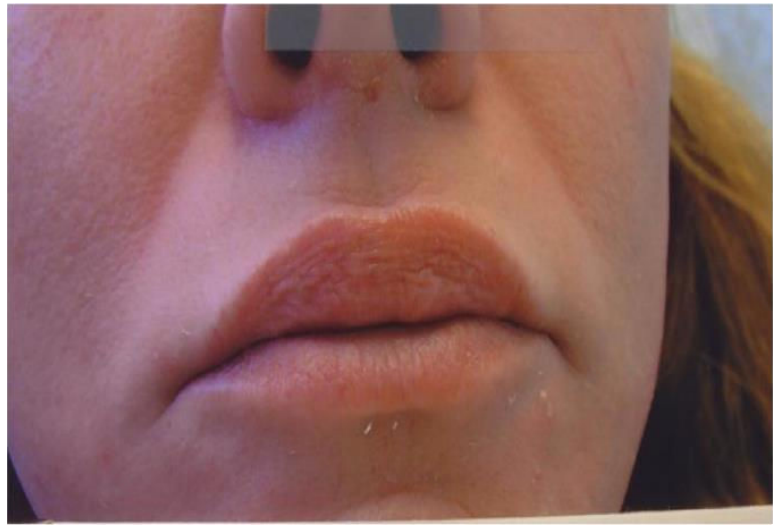
Filler Adverse Events

- Filler AE's: Common and Rare
  - Immediate & transient: Procedure Related (Common)
    - Bruising
    - Swelling
  - Immediate & persistent: Procedure Error (Less Common)
    - Overcorrection
    - Misplacement
    - Vascular compromise
  - Delayed and long term:
    - Host/Product Interaction (Rare)*
    - Hypersensitivity
    - Biofilms



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Potential AE & Complications

Immediate-onset (0-2 d)	Intermediate-onset (3-14 d)	Delayed onset (>14 d)
Erythema*	Angioedema	Persistent erythema
Swelling*	Nodules (inflammatory or noninflammatory)	Nodules (inflammatory or noninflammatory)
Edema*		
Injection site tenderness*		Infection
Ecchymosis*		Granulomas
Under- or overcorrection		Acneiform eruption
Implant visibility (Tyndall effect, white bumps)		Delayed immune-mediated hypersensitivity
Vascular compromise		Telangiectasias

Infectious: HSV

*Often fade quickly

Sclafani AP et al. *Dermatol Surg.* 2009;35:1672-1680.

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Avoiding Filler Complications

Preparation

- Unrealtistic expectations
- Use dissolvable filler (especially to start)
- Know your anatomy
- Educate patients: d/c NSAIDS/ASA
- Prevention tips

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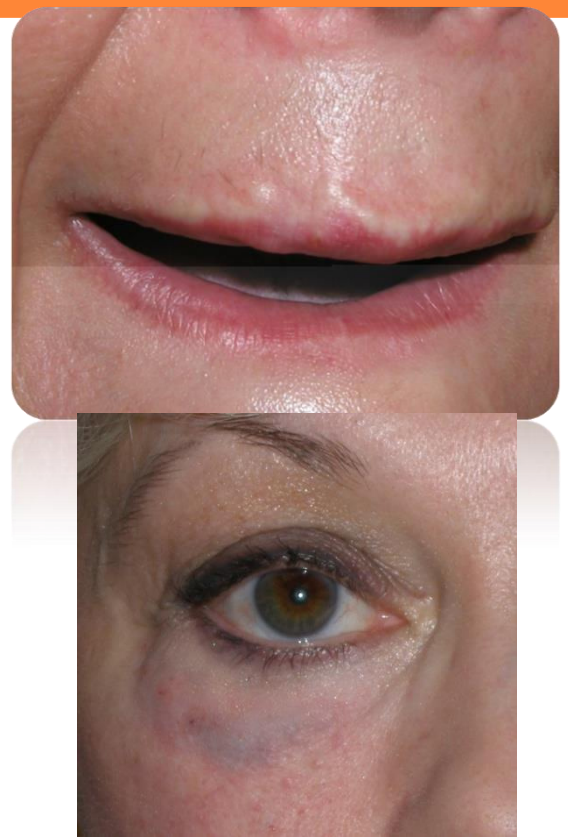
Prevention

- Ice the injected area
- Massage the treated area to smooth out lumps
- Inject the correct product at the appropriate layer of the dermis
- Recent studies have shown a direct correlation with speed of injection and number of adverse events: inject slowly
- Use smaller amounts, withdraw prior to injection
- Consider cannulas

Most Common Complications

1. Lumps & Bumps

- Malleable product
- Most lumps and bumps can be massaged out
- Products can be extruded through 26-gauge needle hole
- Dissolve material if possible (i.e. hyaluronidase, SHOULD ALWAYS HAVE 6 BOTTLES MIN ON HAND)



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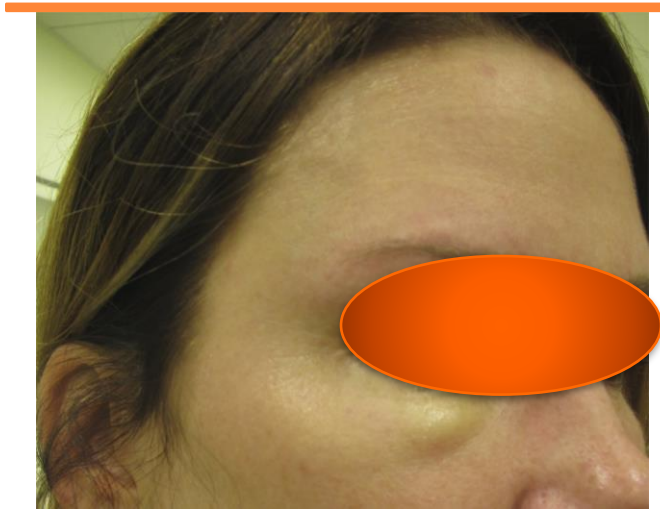
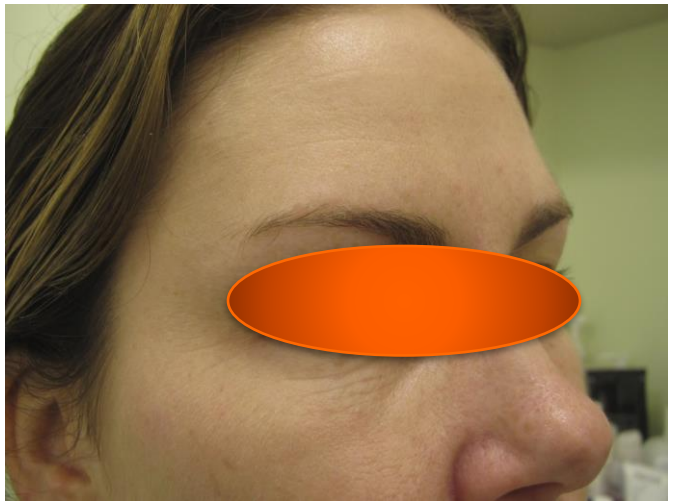
Common Complications Continued

2. Overcorrection/ need to remove product

- Hyaluronidase: enzymatically dissolves HA fillers (Hylenex or Vitrase) saline for Cahyroxyapetite
- Different protocols:
  - Restylane-L and Restylane Lyft most easily dissolvable HA fillers(2.5 units RHH/0.2 mL. Juvéderm Ultra, Belotero, Restylane Silk, and Restylane) Defyne had moderate resistance to RHH. Restylane Refyne, Juvéderm Ultra Plus, Vollure, Versa, and Voluma were most resistant (requiring more than 20 units RHH/0.2 mL for complete dissolution). Vobella was moderately resistant up to 20 units RHH (pronounced dissolution with 40 units RHH).





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Ryu et al. Response of twelve different hyaluronic acid gels to varying doses of recombinant human hyaluronidase. *J Plast Reconstr Aesthet Sur* 2021 Apr;74(4):881-889.

Common Complications Continued Further

3. Vascular Occlusion

- **Watch** for blanching, pain, dusky purple discoloration, cool skin
- Assess **capillary refill time**: > 3 sec suggests vascular compromise
  - moderate pressure with finger applied to the area being assessed for five seconds then released. Time for the skin to return to inormal color recorded. Test should be conducted over the entire area on both affected and unaffected sides.
- **Massage** to improve vascular supply
- **Heat** to area
- **Dissolve** filler immediately
- **Aspirin**: stat dose of 300mg immediately, followed by 75mg/day until vascular occlusion resolved
- Apply **nitropaste** to area*
- **Refer** to ophthalmologist if around eye or any vision changes per patient
- Always check location before injecting, go slow, and watch for skin changes

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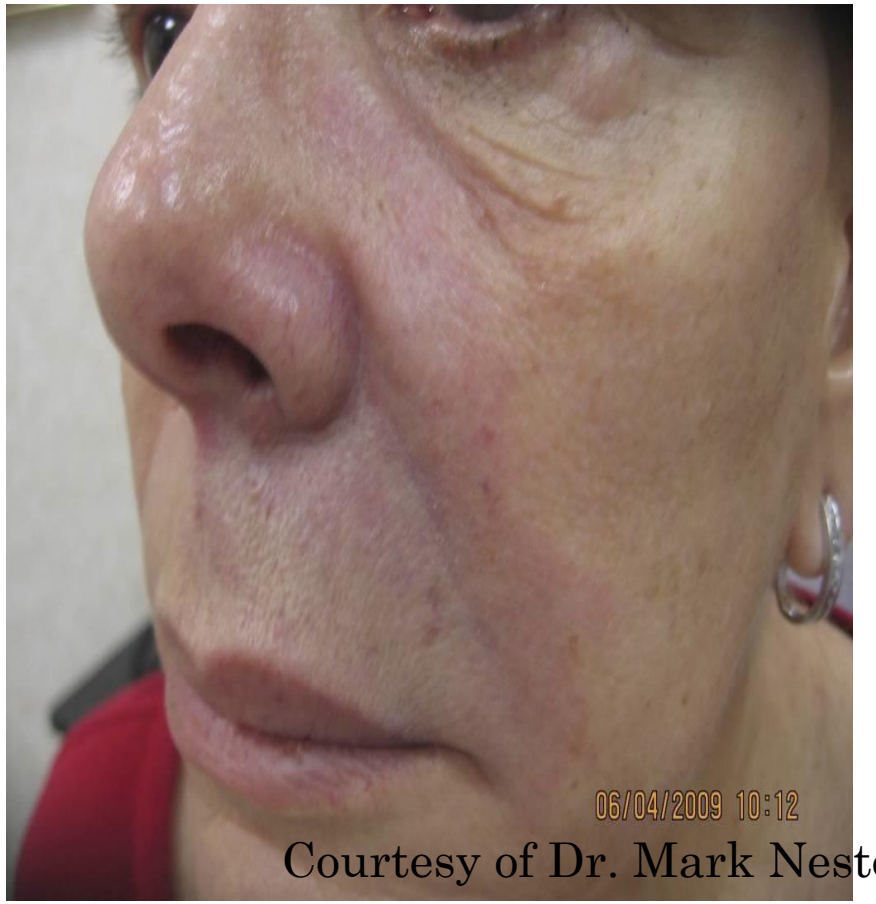
Impending necrosis:nasal alar



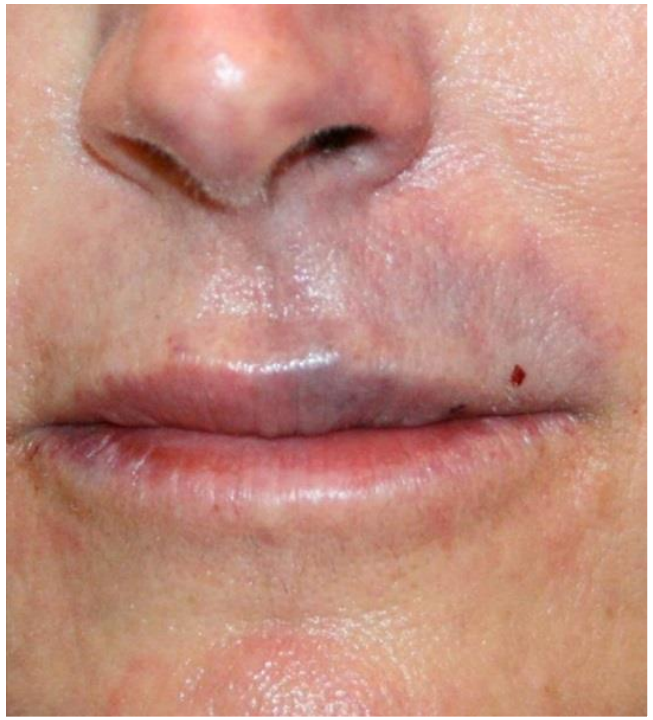
Courtesy of Dr. Mark Nestor

Acute: Arterial Occlusion

3. Vascular Occlusion

- Presentation: delayed, dull pain, dark mottled bluish discoloration, could use U/S to determine compression vs occlusion
- Slow injections with small aliquots and cannula(25g or >) reduces occlusion risk but doesn't eliminate
- Compression may not always lead to necrosis
- Immediate Treatment either way!

Impending necrosis:lip



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Chang et al.**External Compression Versus Intravascular Injection: A Mechanistic Animal Model of Filler-Induced Tissue Ischemia** *Ophthalmic Plast Reconstr Surg*. Jul-Aug 2016;32(4):261-6.
De Freitas Lima et al.**External vascular compression by hyaluronic acid filler documented with high-frequency ultrasound** *J Cosmet Derm*. 2019 Dec;18(6):1629-1631.

Acute: Arterial Occlusion

3. Vascular occlusion

- Presentation: immediate or early, blanching, severe pain
- Immediate Treatment!
  - Stop injecting/aspirate
- Assess **capillary refill time**: > 3 sec suggests vascular compromise
  - moderate pressure with finger applied to the area being assessed for five seconds then released. Time for the skin to return to inormal color recorded. Test should be conducted over the entire area on both affected and unaffected sides.
  - Massage, warm compresses, 2% nitroglycerine paste (based on patient's medical condition)
  - Inject hyaluronidase (300 units) or consider higher doses
  - Aspirin 325, viagra
  - Consider hyperbaric O2
  - If skin breakdown, start antibiotic therapy and debridement
  - Referal to ophthalmologist

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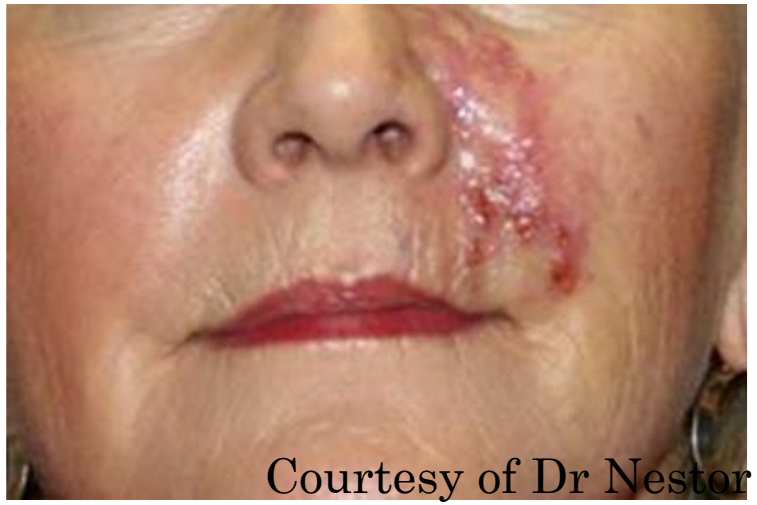
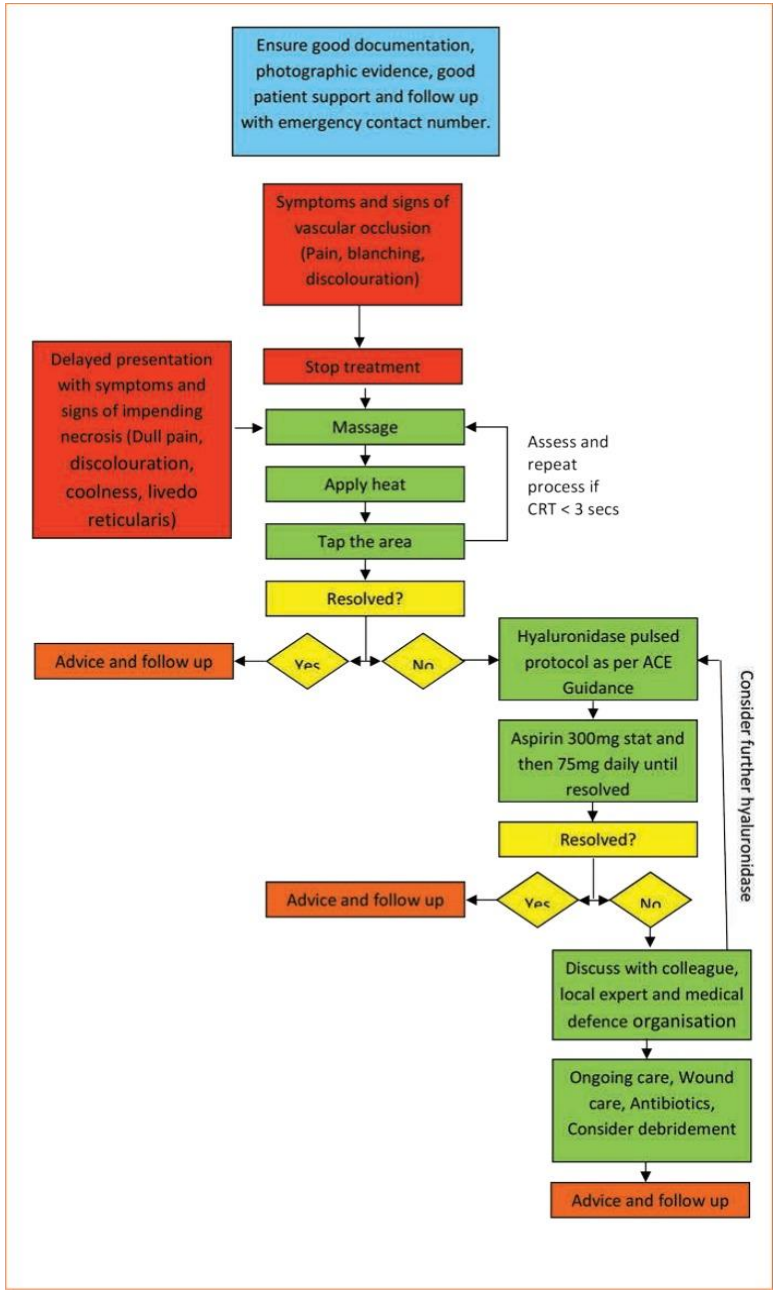
Complete Blockage



Courtesy of Dr Nestor



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King et al. Vascular occlusion associated with cosmetic injections *JCAD*2020 Jan; 13(1): E53–E58.

More Complications

Retinal embolus

- Extreme caution in glabellar complex
- Flush with Hyaluronidase 500IU (Large amounts) 200 to 250IU/kg IV if other treatment strategies have failed to restore vision*
- Lower ocular pressure
  - Ocular massage
  - Topical glaucoma medications (β-blocker)
  - Acetazolamide (Diamox 500 mg)
  - Anterior chamber paracentesis
- Induce vasodilation
  - Breathe in paper bag (increase CO_2)
- Aspirin
- Involve ophthalmologist immediately

Extreme Caution near:

- Nasolabial Fold/nasal tip/alar triangle
  - Facial artery
  - Angular artery
  - Lateral nasal artery
- Glabellar (50% of cases of vascular occlusion are here)
  - Supratrochlear
  - Supraorbital
  - Cutaneous branches of ophthalmic artery
- Lateral lips:
  - Labial artery

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Salinas-Alvarez et al. Hyaluronic Acid Embolism Treated With Subcutaneous High and Low Hyaluronidase Doses: Efficacy and Surrounding Tissue Effect. *Plast Reconstr Surg*. 2021 Dec 1;148(6):1281-1288

*McCann. Intravenous Hyaluronidase for Visual Loss Secondary to Filler Injection: A Novel Therapeutic Approach. *JCAD* 2019 Dec; 12(12): 25–27

Even More Complications

4. Delayed AEs

- Nodules and Granulomas
  - Discrete, non erythematous vs. erythematous, potentially tender and fluctuant
  - Product misplacement or overplacement
  - Foreign body hypersensitivity?
  - Biofilm Infection?
- Induration
  - Diffuse, erythematous, firm, less tender
  - Foreign body hypersensitivity?
  - Biofilm Infection?

Theoretical Causes

- Hypersensitivity
  - Most often thought to be type IV Delayed Hypersensitivity reaction to foreign substance
  - T Cell mediated
  - Histology: Granuloma
  - Reaction to Filler or Infection (Biofilm)
- Infectious (Biofilm)
  - Protected complex bacterial aggregates with filler
  - Difficult to diagnose but may be primary

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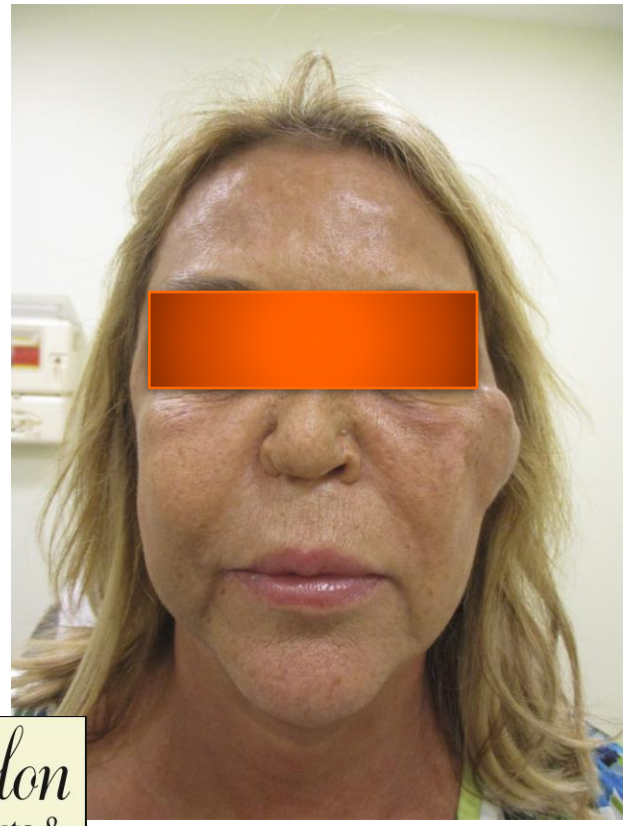
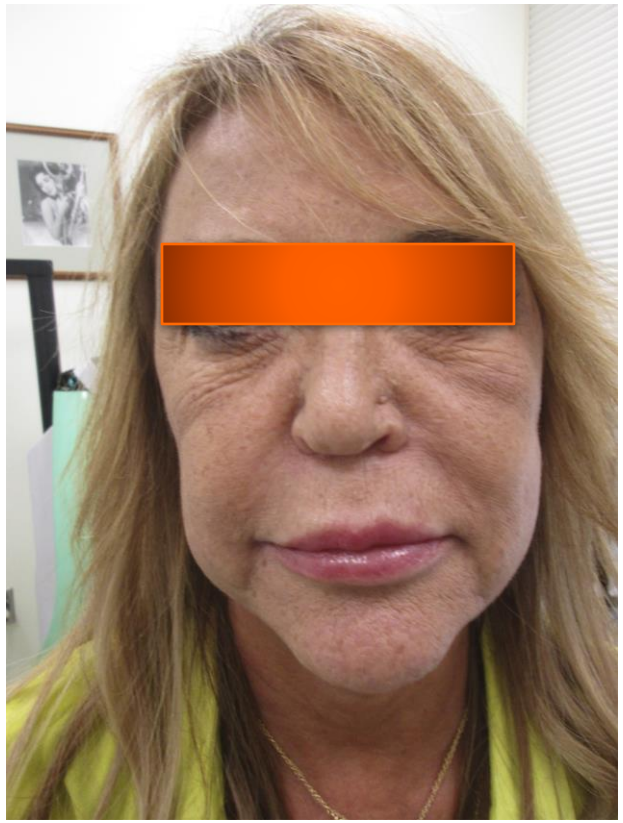
Biofiolm and vycross nodules

5 months after filler



Two months after MRI, vitrase and biaxin



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Delayed Nodules, Granulomas and Induration

Biofilm: Risk Factors

- Long-lasting or permanent*
- Volumizing Fillers
- Injected as mass volume
- Encapsulated
- Susceptible to trauma and/or bacteria
- Inadequate Skin Prep
- Intraoral injection
- Bacteremia at time of injection or shortly after

Prevention

- Proper technique
- Avoid patients with active infections: Skin, oral, etc
- Consider risks of different fillers: Permanent >> Stimulatory >HA
- Prep skin well: Alcohol, chlorhexidine, betadine
- Avoid large bolus
- Prophylactic antibiotics for selected patients
- Avoid teeth cleaning around the time of injection or prophylaxis with antibiotics

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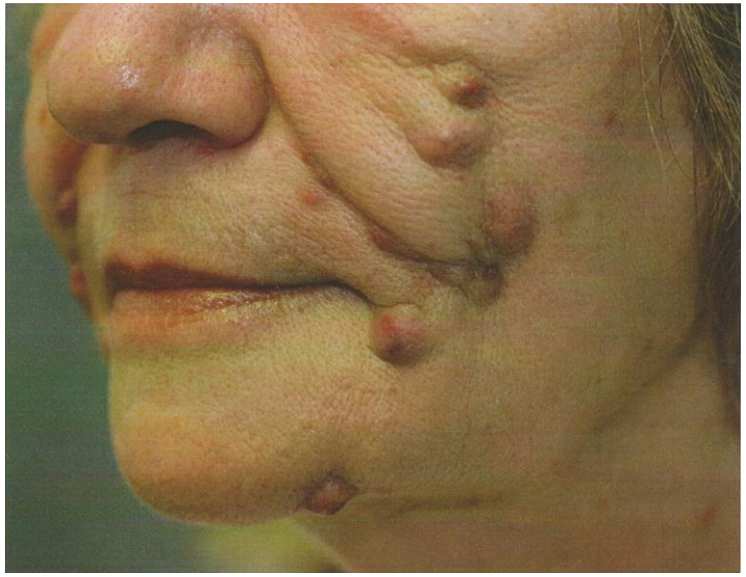
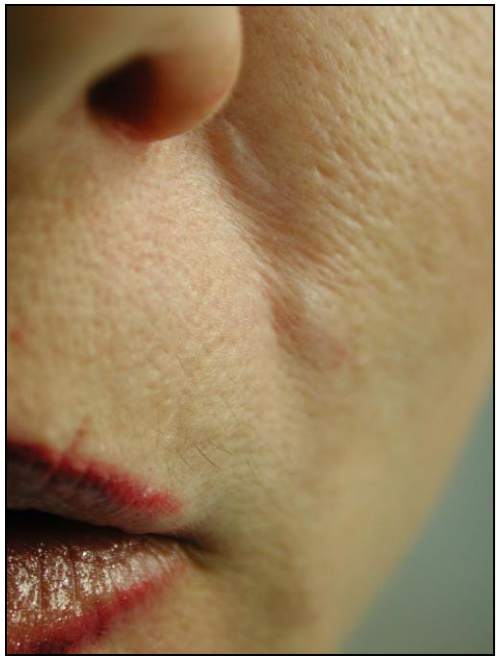
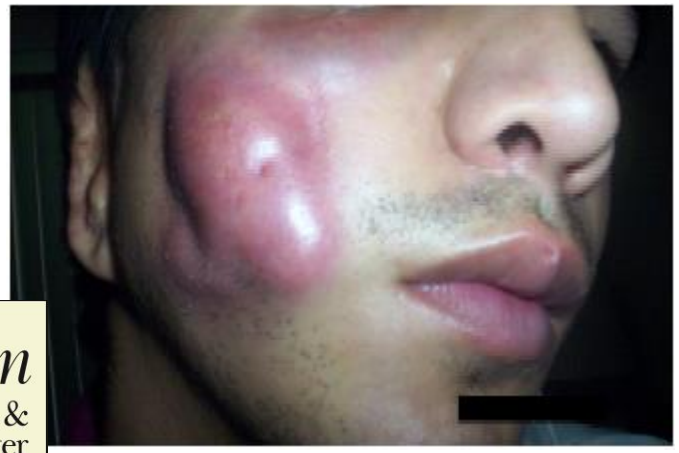
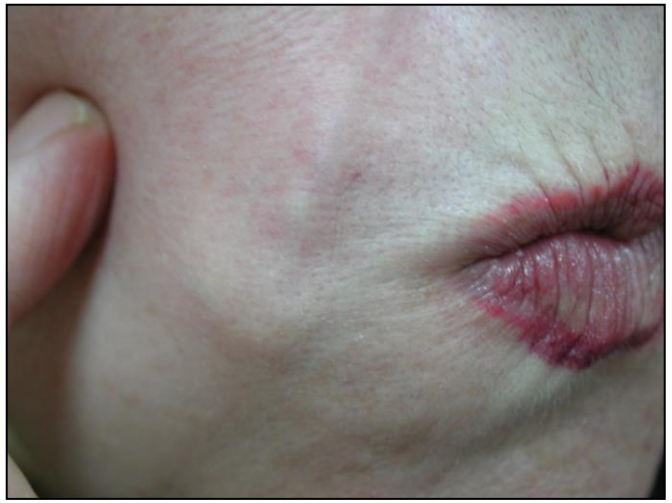
Inflammatory and Non Inflammatory Nodules









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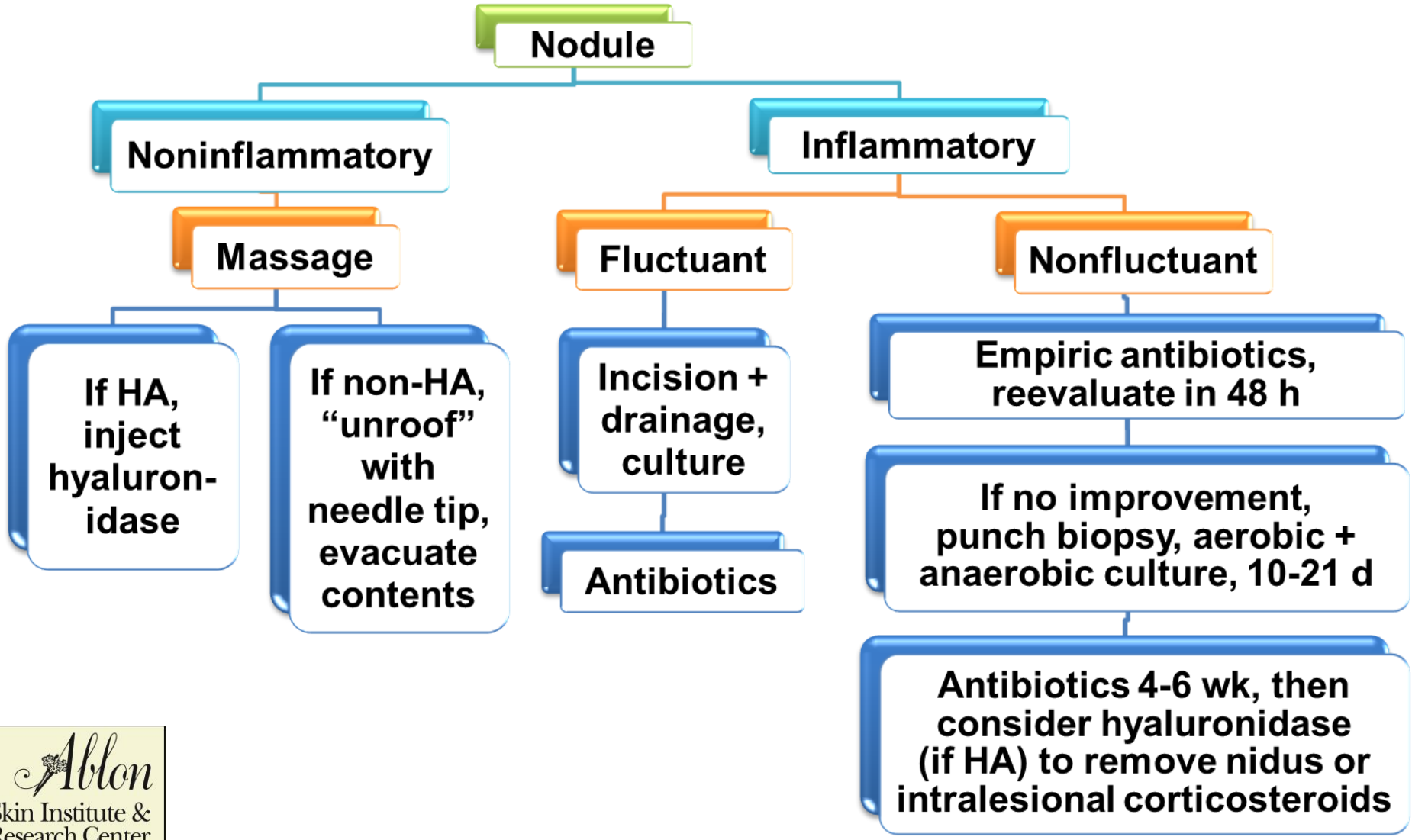
Evaluation and Management



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Summary and Conclusions

- Understand filler properties and best product for each location(higher G!, higher risk occlusion)
- Make sure you are expert on facial anatomy(or any anatomy of treatment area)
- Go slow, consider cannulas
- Use devices to locate vessels when needed
- Understand filler complications, how to avoid them, but more importantly how to treat them

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