

Botulinum Toxin  
Type A  
Theory

# myFACE Training

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# DR TIM ELDRIDGE



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# Agenda

- Course objectives
  - Introduction
  - History of Botulinum toxin type A
  - Safety
  - Range of products
  - Pharmacology
  - Anatomy
  - Patient assessment
  - Clinical procedures
  - Photography
  - Marketing and legalities
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# Course objectives

- Name the principal muscles involved in the treatment of the forehead, glabella and crow's feet, using botulinum toxin type A for cosmetic treatments
- Define the mode of action of botulinum toxin type A, explain its therapeutic effects including its limitations of use and any concerns with toxicology.
- Select patients suitable for botulinum toxin type A, identifying contra-indications and cautions, side effect and possible adverse reactions.
- State any pre-treatment care and recognise the need for consent.

- Demonstrate the safe use of botulinum toxin type A in the forehead, glabella, crow's feet, and for the treatment of a gummy smile and bruxist, including the correct equipment, dose and injection techniques.
- Summarise with appropriate written and verbal aftercare advice to patients who have received botulinum toxin type A.
- Demonstrate the appropriate use of clinical record taking and recall good practice, in relation to handling complaints.
- Describe safe storage and disposal methods for products and equipment used
- Explain the insurance requirements to practise these treatments.

# The rise of cosmetic treatments



Illustration by Justin Metz for TIME





# Top 5

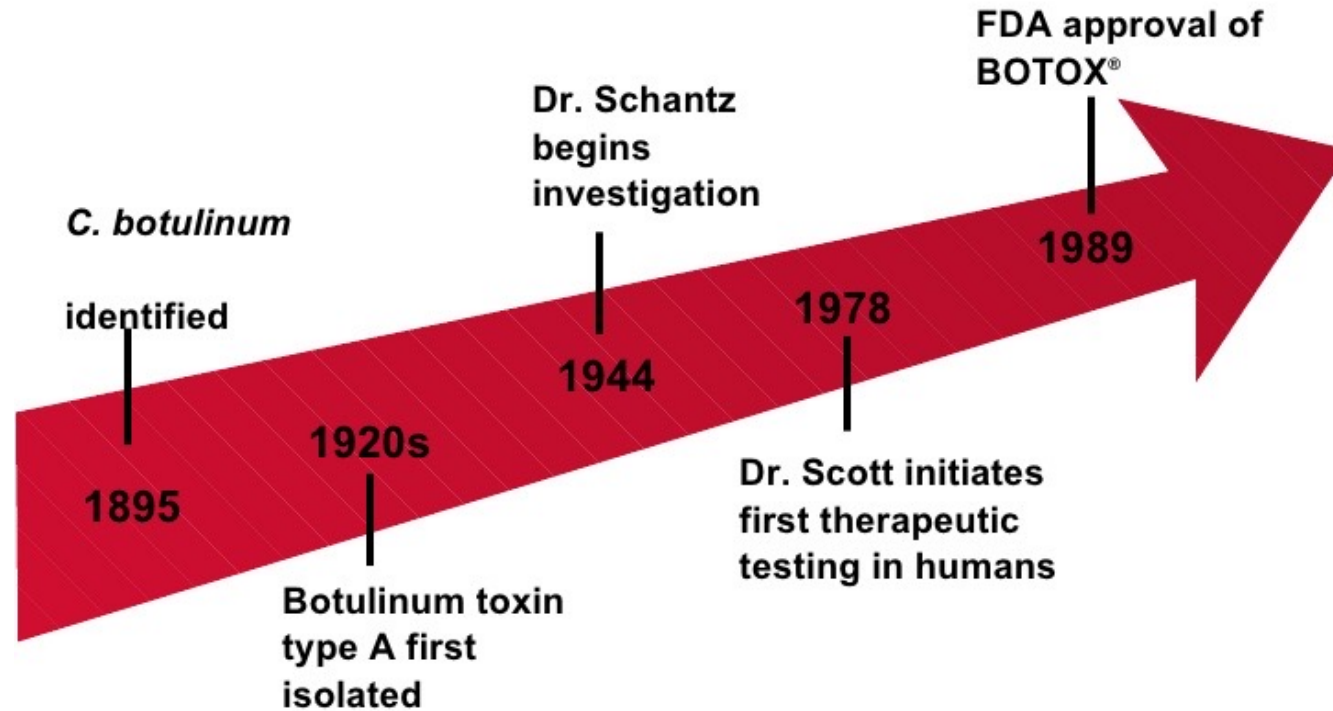
## nonsurgical procedures worldwide

absolute numbers and changes compared to 2017

1. Botulinum Toxin	6,097,516	procedures	+17,4%
2. Hyaluronic Acid	3,729,833	procedures	+11,6%
3. Hair Removal	916,869	procedures	-8,8%
4. Nonsurgical Fat Reduction	473,316	procedures	-1,1%
5. Photo Rejuvenation	436,656	procedures	-25%

# History of Botulinum Toxin Type A

## Botulinum Toxin Type A (BOTOX®): History of Development





# Safety

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- One of the most potent toxins
- Safe when used appropriately
- Irreversible medical complications NOT KNOWN
- High therapeutic index
- Reported adverse events from toxins of dubious origin
- Adverse effects either injection related or product related
- Estimated lethal dose for humans: 2500-3000 units for 70kg individual – BOTOX and Vistabel
- Dysport therapeutic dosage - 3-6 x higher than BOTOX
- Myoblock therapeutic dosage – 50-100 x higher than BOTOX

# Maximising safety

- Injectors understanding of the relevant anatomy
- Injectors understanding how surgery affects anatomy
- Use lowest doses with longest feasible intervals between injections
- Recommended treatment intervals every 4 months
- Correct/recognised injection techniques

# Side effects – Injection

- Pain, oedema, haematoma and rarely localized skin dryness at injection site
- Usually subside after minutes (but can last up to a few days) without treatment

**SIDE EFFECTS**

# Injection pain

- Usually short acting
- Reduce by using topical anaesthetic creams such as Emla or LMX4
- Place ice cube on injection site before injecting
- Dilute the BTX with preserved saline – proven to have an anaesthetic effect

# Bruising

- May be due to co-medication with anti-coagulant drugs, NSAIDS, Vitamin E, ginseng, ginko
- More common around eyes highly vascularised
- Place ice cube to pre cool injection site
- Apply pressure if puncture a blood vessel

# Headaches

- Similar results in reported headaches between BTX patients and placebo patients
- Mild only lasting few hours
- Headaches have been reported after injection in each of the areas
- According to Alam et al. 1% pts developed severe headaches lasting 2-4 weeks
- Some studies demonstrated a decrease in headaches after repeated BTX treatments

# Localised skin dryness

- Rarely reported
- Advise skin moisturizers
- Possibly due to decrease of sweat gland activity

# Side effects - Product

- Common – Headache, blepharoptosis, facial pain, erythema, local muscle weakness
- Uncommon – Skin tightness, paraesthesia, nausea, dizziness, twitch, blepharitis, eye pain, flu syndrome, oedema (face, eyelid, periorbital), asthenia, fever, photosensitivity reaction, pruritus, dry skin, visual disturbance, anxiety, oral dryness, infection

See summary of product characteristics for full information on side effects

# Cautions



- History of Bell's palsy
- Dysmorphia
- Asprin/NSAID, Vit E, Gingo Biboa, St John's Wort



# Contraindications

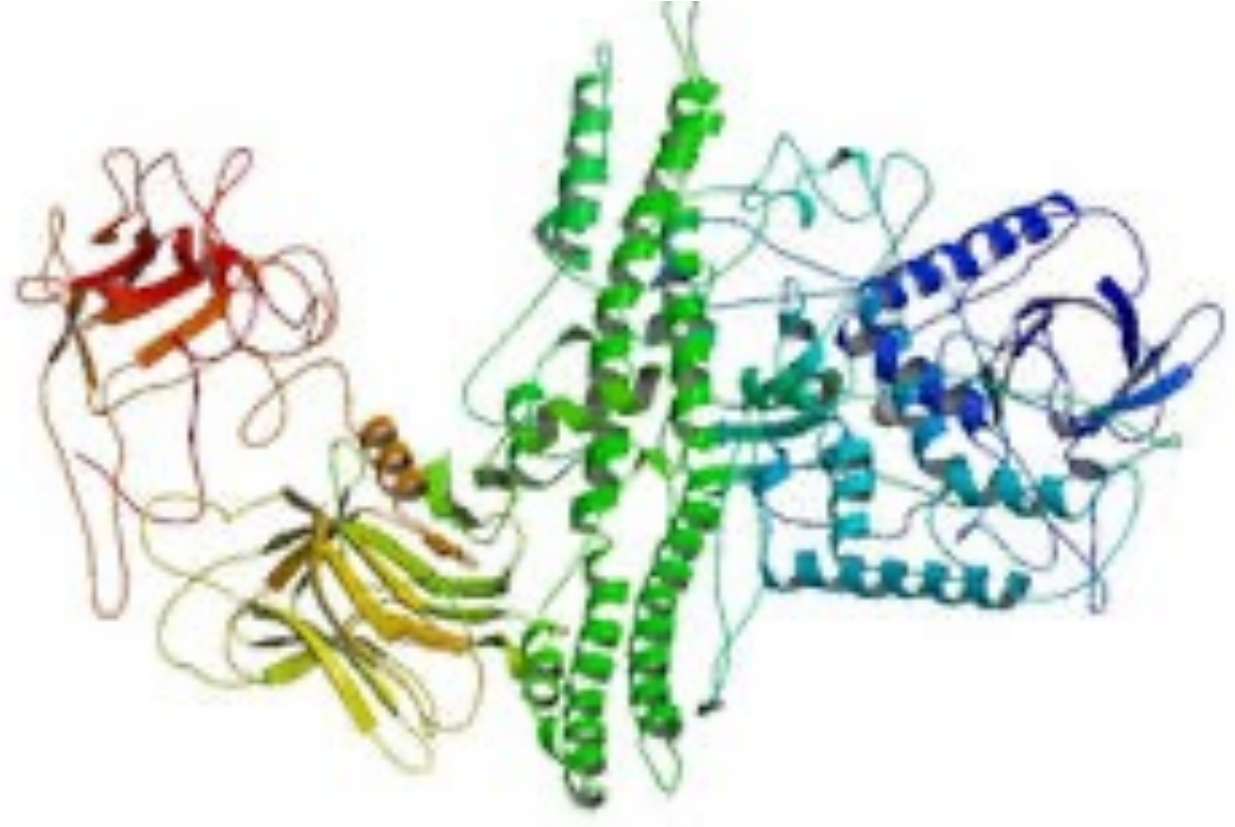
- Infection at proposed injection site
- History of hypersensitivity to constituents
- AVOID pregnant/lactating mothers
- Generalised disorders of muscle activity (myasthenia gravis)
- Co-administration with aminoglycosides or other agents interfering with neuromuscular activity (spectinomycin, calcium channel blockers)
- Bleeding disorders or anticoagulant therapy



# Botulinum toxins

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- Targets release of Acetylcholine
- Seven serotypes A-G different strains
- Human nervous system only susceptible to A, B, E, G (unaffected by C,D)
- A is 10 times more potent than C
- A is 20 times more potent than B
- Works on all striated and smooth muscle and the secretion of glands



# The Brands

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Azzalure®  
(Galderma)

Dysport®  
(Ipsen)

Bocouture®  
(Mertz)

Xeomin®  
(Mertz)

BOTOX®  
(Allergan)

Vistabel®  
(Allergan)

Relixin®

# Azzalure<sup>®</sup> - Abobotulinum toxin

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- Cosmetically licensed name for Dysport<sup>®</sup>
- Manufactured by Ipsen and distributed by Galderma
- 125 speywood unit vial
- Un-reconstituted stored in fridge or freezer
- Lyophilized vial
- 'Licensed' for the glabellar

# Dysport® - Abobotulinum toxin

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- Usually only used in hospitals for ophthalmology and neurology
- Manufactured by Ipsen
- 500unit vial
- Un-reconstituted stored in fridge or freezer
- Lyophilized vial
- In UK 'licensed' to treat Blepharospasm, Cervical dystonia, Cerebral palsy, Hemifacial spasm,

# Bocouture® - Incobotulinum toxin

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- Cosmetically license name for Xeomin®
- Distributed by Mertz
- 50unit vial
- Un-reconstituted stored at room temperature
- 'Licensed' for glabellar, crow's feet and forehead lines
- Lowest protein load purer toxin smaller molecules



# Xeomin<sup>®</sup> - Incobotulinum toxin

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- Used in ophthalmology and neurology
- Distributed by Mertz
- 100unit vial
- Un-reconstituted stored at room temperature
- Lowest protein load purer toxin smaller molecules
- In UK 'licensed' to treat blepharospasm and cervical dystonia

# Vistabel® - Onabotulinum toxin

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**VISTABEL®**  
Botulinum Toxin Type A

- Cosmetically license name for BOTOX®
- First brand to be licensed for cosmetic use in UK
- Distributed by Allergan
- 50unit vial
- Un-reconstituted stored in fridge or freezer
- ‘Licensed’ for glabellar and crow’s feet
- Vacuum dried vial

# BOTOX® - Onabotulinum toxin



- Most popular commercial name
- Distributed by Allergan
- 100unit vial
- Un-reconstituted stored in fridge or freezer
- Vacuum dried vial
- In UK 'licensed' for Hemifacial spasm, Blepharospasm, Cervical dystonia, Cerebral palsy, Axillary hyperhidrosis, migraines and upper limb spasticity in adults post stroke



# Dilution and Preparation

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- Bocouture® - 1.25ml
- Xeomin® - 2.50ml
- Azzalure® - 0.63ml
- Dysport® - 2.5ml
- Vistabel® - 1.25ml
- BOTOX® - 2.5ml
  
- 0.9% Preserved saline
- Once reconstituted all stored in fridge 2° - 8°C
- Dilution affects toxin power and diffusion

# BOCOUTURE®

# Incobotulinum toxin A

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Date of Preparation - August 2021



# Contents

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# BOCOUTURE® : The History

- Botulinum toxin type A first used as a cosmetic treatment<sup>1</sup>

2001

- BOCOUTURE® (incobotulinumtoxinA) gains approval for aesthetic use in Europe for the treatment of glabellar frown lines<sup>2</sup>

2009

- First neurotoxin to receive approval for all 3 areas of the upper face: glabellar frown lines, crow's feet lines and horizontal forehead lines<sup>3</sup>

2016

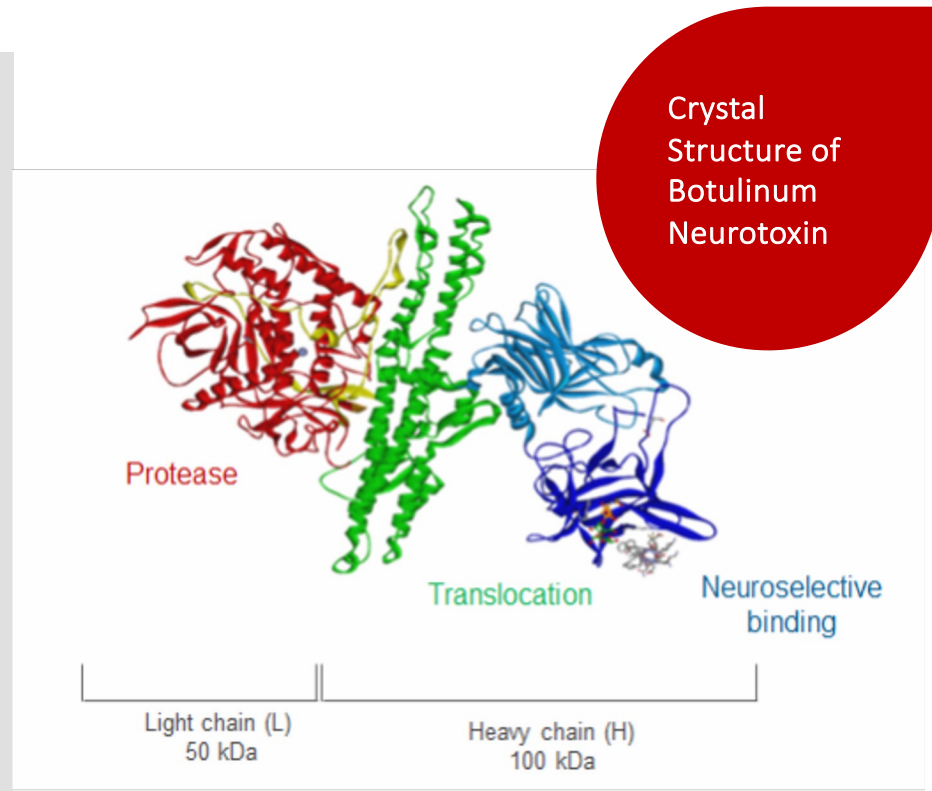
# Dr. Jürgen Frevert

- PhD, Biochemist
- Over 30 years of Botulinum Toxin research
- Head of Botulinum Toxin Research at Merz Pharmaceuticals GmbH in Potsdam, Germany: 2007 - 2017
- Continues to consult for Merz Pharmaceuticals GmbH
- Developed Xeomin® (BOCOUTURE®), a neuromodulator formulation containing neurotoxin, free from complexing proteins<sup>6</sup>



# Botulinum Toxin A: Mode of Action

- The 150kDa active neurotoxin consists of a 100kDa heavy chain and a 50kDa light chain
- The heavy chain binds to cholinergic nerve endings enabling its uptake across the cell membrane
- After internalisation, the light chain binds to the SNARE protein which is subsequently cleaved (SNAP-25)
- This prevents the fusion of the synaptic vesicle with the presynaptic membrane
- This blocks the release of acetylcholine into the synaptic cleft<sup>4,5,7,8</sup>



# Botulinum Toxin A: Mode of Action

MERZ AESTHETICS

Botulinum toxin type A Mode of Action

**BOCOUTURE®**

Botulinum toxin type A  
free from complexing proteins

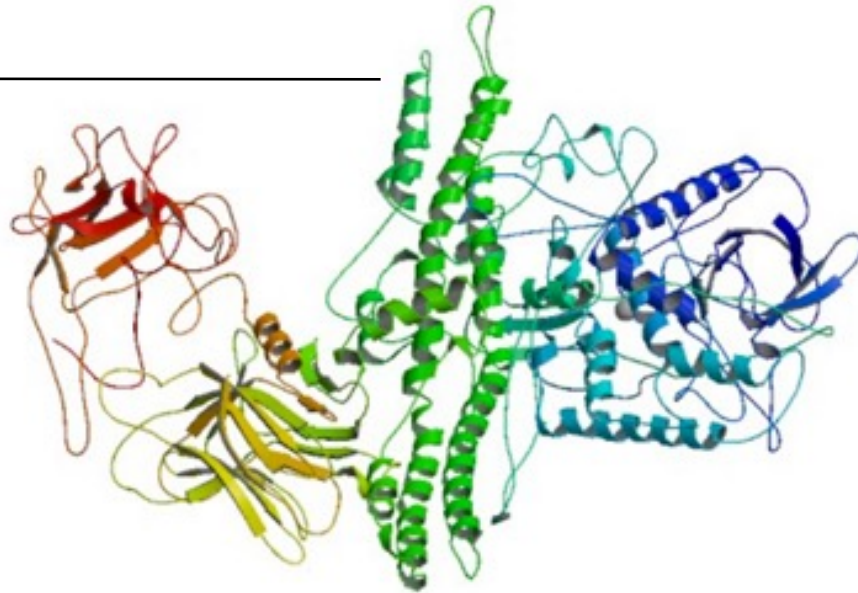
M-BOC-UK-0420 Date of Preparation April 2021



# Molecular Structure

Conventional Botulinum Toxin Complex (900kDa)  
Core Neurotoxin + Complexing Proteins  
(haemagglutinins and a non-toxic non-haemagglutinin)

Botulinum  
Neurotoxin



Purified to 150kDa  
**Botulinum Neurotoxin**  
(Free from Complexing Proteins<sup>4,5,7,8,9</sup>)



# Pharmaceutical Composition and Form

There are two strengths available:

- **BOCOUTURE® 50 units**<sup>4,5,7,8</sup>
  - One vial contains 50 units of Botulinum toxin type A (150kDa), free from complexing proteins\*
- **BOCOUTURE® 100 units**<sup>4,5,7,8</sup>
  - One vial contains 100 units of Botulinum toxin type A (150kDa), free from complexing proteins\*
- Pharmaceutical Form: White powder for solution for injection (reconstituted with sodium chloride 0.9%)



\*Excipients human albumin and sucrose

# Therapeutic Indications

For the temporary improvement in the appearance of upper facial lines in adults <65 years when the severity of these lines has an important psychological impact for the patient:

- Moderate to severe glabellar frown lines at maximum frown  
*and/or*
- Moderate to severe lateral periorbital lines (crow's feet) at maximum smile  
*and/or*
- Moderate to severe horizontal forehead lines at maximum contraction<sup>4,5,7,8</sup>

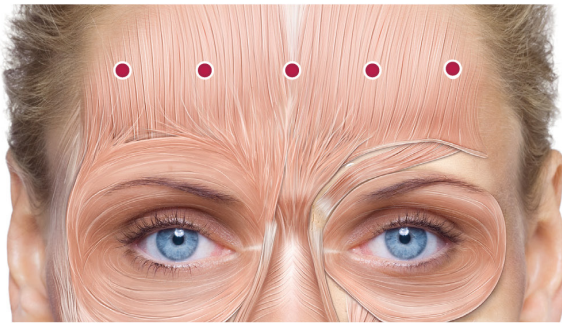
# Reconstitution



## How to reconstitute **BOCOUTURE**<sup>®</sup> (botulinum toxin type A)

# Upper Facial Lines Injection Points & Dosing Information

● Injection site



**HFL:**  
0.25-0.5ml (10-20U according to line severity/muscle mass).  
Five injection points 2-4U per point.

## Horizontal Forehead Lines

Reconstitution of BOCOUTURE<sup>®1,2</sup>:

- 50 units/1.25ml/0.9% unpreserved sodium chloride solution
- 100 units/2.5ml/0.9% unpreserved sodium chloride solution

Horizontal Forehead Lines recommended injection volume: 0.25ml (10 units) to 0.5ml (20 units) is injected into the frontalis muscle in 5 horizontally aligned injection sites at least 2cm above the orbital rim. An injection volume of 0.05ml (2 units), 0.075ml (3 units) or 0.1ml (4 units) is applied per injection point, respectively.



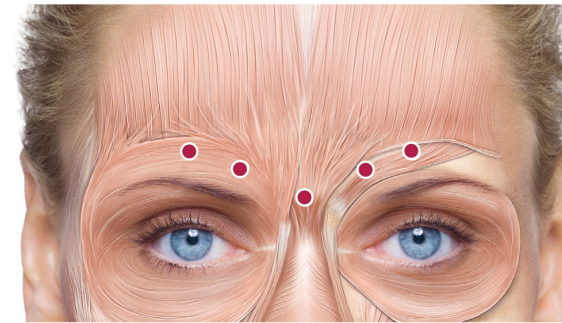
**CFL:**  
0.3ml (12U) per side.  
Three injection points 4U per point 24U in total.

## Crow's Feet Lines

Reconstitution of BOCOUTURE<sup>®1,2</sup>:

- 50 units/1.25ml/0.9% unpreserved sodium chloride solution
- 100 units/2.5ml/0.9% unpreserved sodium chloride solution

Crow's Feet Lines recommended injection volume: 0.1ml (4 units) is injected into each of the 3 injection sites (12 units in total per side of face)



**GFL:**  
0.5ml (20U).  
Five injection points 4U per point.

## Glabellar Frown Lines

Reconstitution of BOCOUTURE<sup>®1,2</sup>:

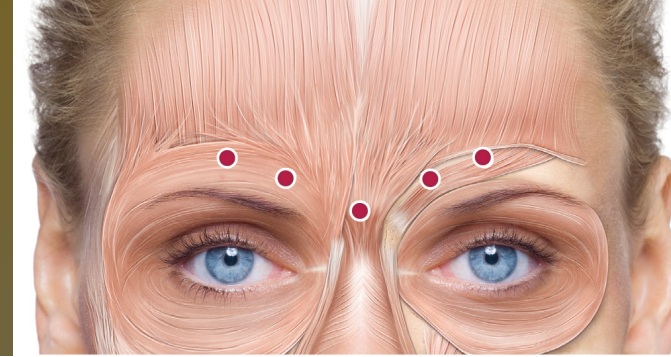
- 50 units/1.25ml/0.9% unpreserved sodium chloride solution
- 100 units/2.5ml/0.9% unpreserved sodium chloride solution

Glabellar Frown Lines recommended injection volume: 0.1ml (4 units) is injected into each of the 5 injection sites (20 units in total)

The dose may be increased by the physician to up to 30 units if required by the individual needs of the patients, with at least 3 months interval between treatments.

Unit doses of BOCOUTURE<sup>®</sup> are not interchangeable with those for other preparations of Botulinum toxin type A<sup>4,5,7,8</sup>

# Safety Profile – Glabellar Frown Lines<sup>4,5,7,8</sup>



Based on clinical experience, information on the frequency of adverse reactions with the frequency of very common ( $\geq 1/10$ ) and common ( $\geq 1/100$  to  $< 1/10$ ) are summarised below:

▪ **Infections and infestations:**

*Uncommon:* Bronchitis, Nasopharyngitis, Influenza like illness

▪ **Psychiatric Disorders:**

*Uncommon:* Insomnia

▪ **Nervous System Disorders:**

*Common:* Headache

▪ **Eye Disorders:**

*Uncommon:* Eyelid oedema, Eyelid ptosis, Blurred vision

▪ **Skin and subcutaneous tissue disorders:**

*Uncommon:* Pruritus, Skin nodule, Brow ptosis

▪ **Musculoskeletal and connective tissue disorders:**

*Common:* Mephisto sign (lateral elevation of eyebrows)

*Uncommon:* Muscle twitching, Muscle spasm, Facial asymmetry (brow asymmetry)

▪ **General disorders and administration site conditions:**

*Uncommon:* Injection site haematoma, Injection site pain, (local) Tenderness, Fatigue, Discomfort (heavy feeling of eyelid/eyebrow)

▪ **Vascular Disorders:**

*Uncommon:* Haematoma

# Safety Profile – Crow's Feet Lines<sup>4,5,7,8</sup>



Based on clinical experience, information on the frequency of adverse reactions with the frequency of very common ( $\geq 1/10$ ) and common ( $\geq 1/100$  to  $< 1/10$ ) are summarised below:

Lateral Periorbital Lines seen at maximum smile (Crow's feet lines)<sup>4,5,7,8</sup>

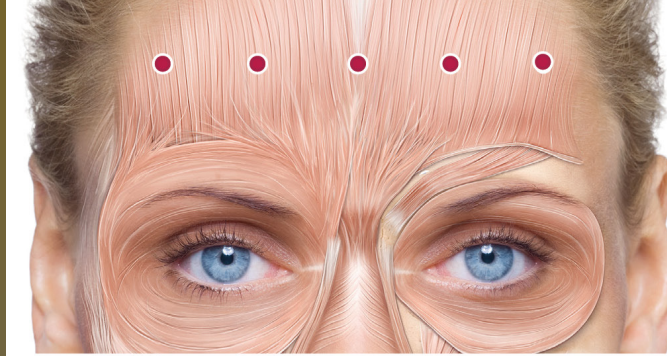
- **Eye Disorders:**

*Common:* Eyelid oedema, Dry eye

- **General disorders and administration site conditions:**

*Uncommon:* Injection site haematoma

# Safety Profile – Horizontal Forehead Lines<sup>4,5,7,8</sup>



Based on clinical experience, information on the frequency of adverse reactions with the frequency of very common ( $\geq 1/10$ ) and common ( $\geq 1/100$  to  $< 1/10$ ) are summarised below:

## Horizontal Forehead Lines seen at maximum contraction<sup>4,5,7,8</sup>

- **Nervous System Disorders:**  
*Very Common:* Headache  
*Common:* Hypoaesthesia
- **General disorders and administration site conditions:**  
*Common:* Injection site haematoma, Injection site pain, Injection site erythema, Discomfort (heavy feeling of frontal area)
- **Eye Disorders:**  
*Uncommon:* Eyelid ptosis, Dry eye
- **Skin and subcutaneous tissue disorders:**  
*Common:* Brow ptosis
- **Musculoskeletal and connective tissue disorders:**  
*Common:* Facial asymmetry, Mephisto sign (lateral elevation of eyebrows)
- **Gastrointestinal:**  
*Common:* Nausea



# Important Safety Information

## **CONTRAINDICATIONS<sup>4,5,7,8</sup>**

- Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation
- Generalised disorders of muscle activity (e.g. myasthenia gravis, Lambert-Eaton syndrome)
- Infection or inflammation at the proposed injection site(s)

## **WARNINGS AND PRECAUTIONS<sup>4,5,7,8</sup>**

BOCOUTURE<sup>®</sup> should be used with caution:

- If bleeding disorders of any type exist
- In patients receiving anticoagulant therapy or other substances that could have an anticoagulant effect.

### **Local and distant spread of toxin effect**

Undesirable effects may occur from misplaced injections of Botulinum neurotoxin type A that temporarily paralyse nearby muscle groups.

Patients or caregivers should be advised to seek immediate medical care if swallowing, speech or respiratory disorders occur.

# Important Safety Information (cont.)

## **WARNINGS AND PRECAUTIONS (cont.)** <sup>4,5,7,8</sup>

### **Pre-existing Neuromuscular Disorders**

The injection of BOCOUTURE® is not recommended for patients with a history of aspiration or dysphagia.

BOCOUTURE® should be used with caution:

- In patients suffering from amyotrophic lateral sclerosis
- In patients with other diseases which result in peripheral neuromuscular dysfunction
- In targeted muscles which display pronounced weakness or atrophy

### **Hypersensitivity reactions**

Hypersensitivity reactions have been reported with Botulinum neurotoxin type A products. If serious (e.g. anaphylactic reactions) and/or immediate hypersensitivity reactions occur, appropriate medical therapy should be instituted.

### **Antibody formation**

Too frequent doses may increase the risk of antibody formation, which can result in treatment failure (see SmPC).

The potential for antibody formation may be minimised by injecting with the lowest effective dose given at the indicated minimum intervals between injections.

# References

1. Carruthers A, Kane MA, Flynn TC, et al. The convergence of medicine and neurotoxins: a focus on botulinum toxin type A and its application in aesthetic medicine--a global, evidence-based botulinum toxin consensus education initiative: part I: botulinum toxin in clinical and cosmetic practice. *Dermatol Surg.* 2013;39(3 Pt 2):493-509
2. Yamauchi PS. Selection and preference for botulinum toxins in the management of photoaging and facial lines: patient and physician considerations. *Patient Prefer Adherence.* 2010;4:345-354. Published 2010 Sep 7. doi:10.2147/ppa.s6494
3. [https://www.merz.com/blog/news/merz-announces-european-approval-of-bocouture-for-the-treatment-of-upper-facial-lines/#\\_ftnref1](https://www.merz.com/blog/news/merz-announces-european-approval-of-bocouture-for-the-treatment-of-upper-facial-lines/#_ftnref1)
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8. BOCOUTURE® 100units SmPC. Available at: [https://www.hpra.ie/img/uploaded/swedocuments/Licence\\_PA1907-003-002\\_19072021153031.pdf](https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1907-003-002_19072021153031.pdf) (last accessed August 2021)
9. Kerscher M, Wanitphakdeedecha R, Trindade de Almeida A, Maas C, Frevert J. IncobotulinumtoxinA: A Highly Purified and Precisely Manufactured Botulinum Neurotoxin Type A. *J Drugs Dermatol.* 2019;18(1):52-57.

Adverse events should also be reported. Reporting forms and information for United Kingdom can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Reporting forms for Republic of Ireland can be found at:

<https://www.hpra.ie/homepage/about-us/report-an-issue>

Adverse events should also be reported to Merz Pharma UK Ltd by email to: [Ukdrugsafety@merz.com](mailto:Ukdrugsafety@merz.com) or call +44 (0) 333 200 4143

# Diluting the vial

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- Similar technique for all products
- Record product name
- Record Batch number/expiry date
- Record Diluent and volume
- Remove plastic cap from the vial of product and NaCl
- Using syringe and 21 gauge (green needle) draw up the required amount NaCl
- Insert needle into vial of product and dilute the toxin
- Shake figure of eight / do not agitate
- VACCUM MUST BE PRESENT
- Remove cap and bung and draw up.



# Care of toxin

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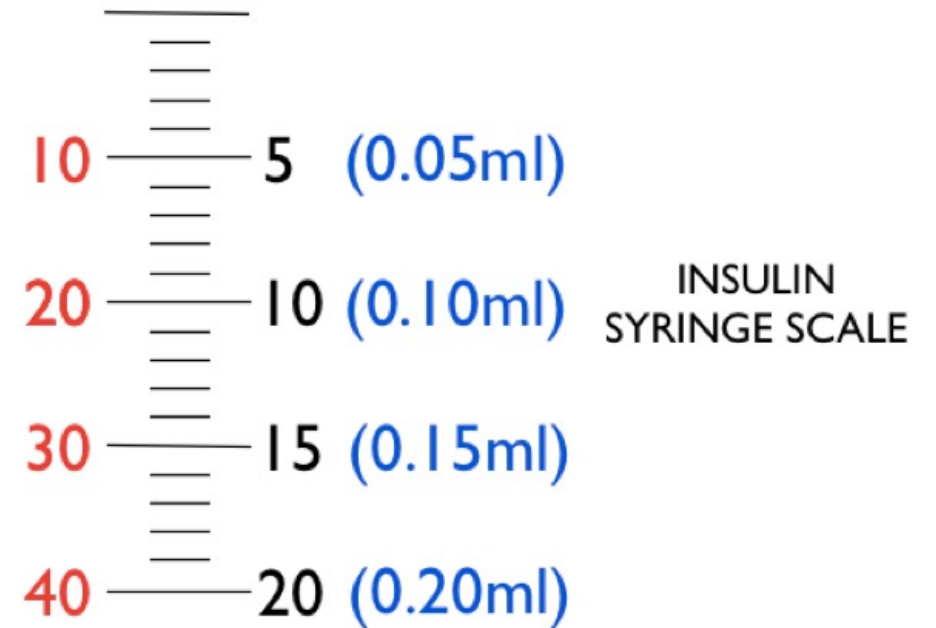
- Alcohol will DENATURE the protein (let it evaporate)
- DO NOT vigourously shake the vial – DENATURE the protein
- Let bubbles settle
- Once reconstituted ONLY store in fridge

**PRECAUTION**

# Azzalure

- 0.63ml 0.9% NaCl (preserved)
- 125 speywood units per vial
- 0.1ml = 20 units (10 on syringe)

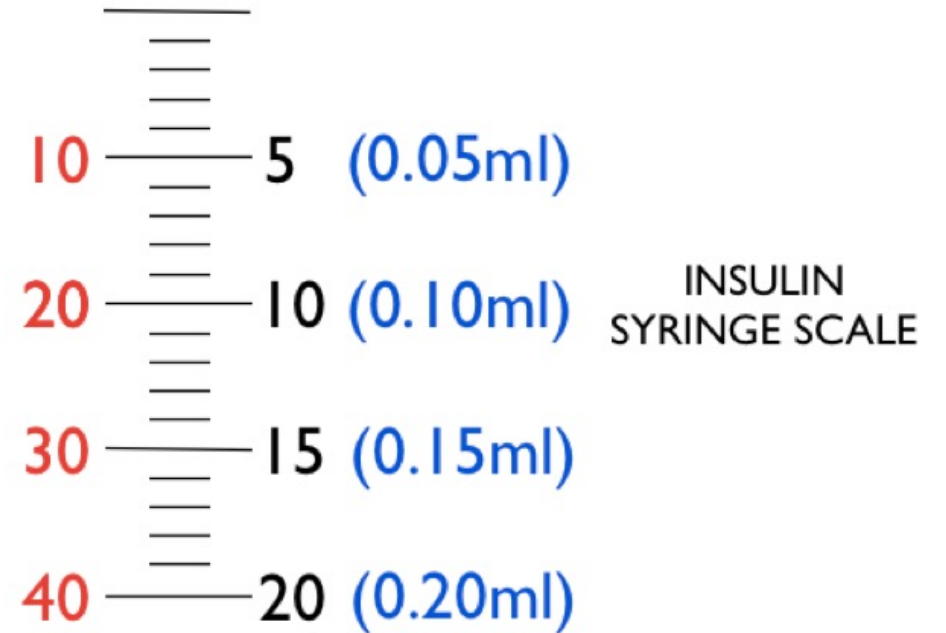
UNITS  
AZZALURE



# Dysport

- 2.5ml 0.9% NaCl (preserved)
- 500 units per vial
- 0.1ml = 20 units (10 on syringe)

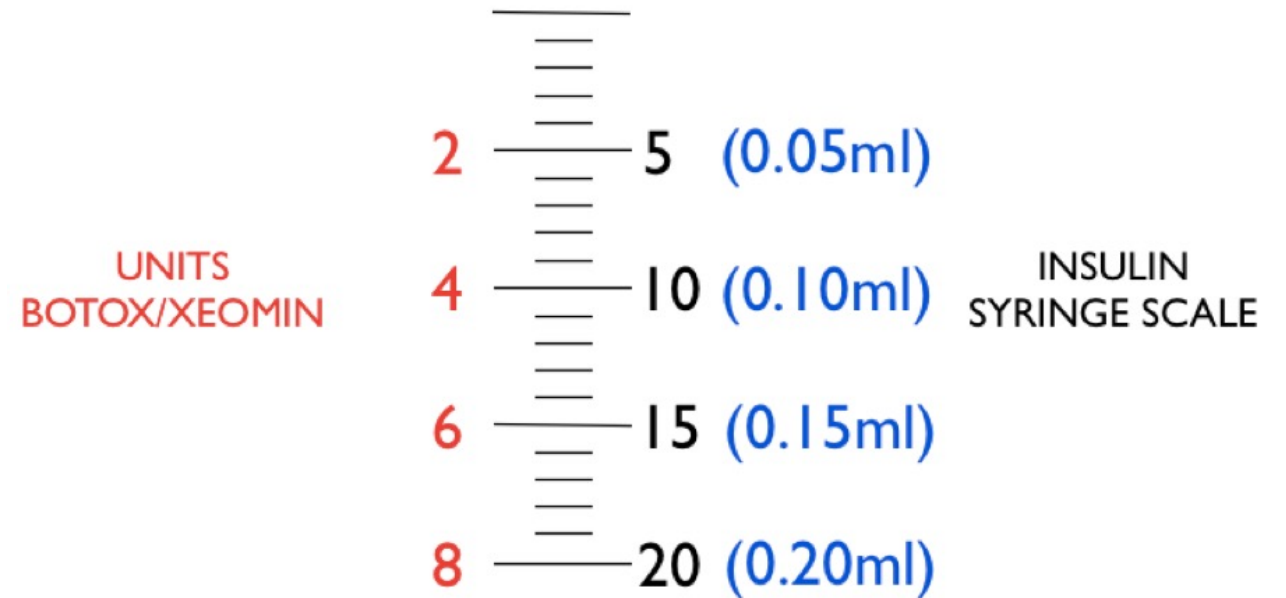
UNITS  
DYSPORT





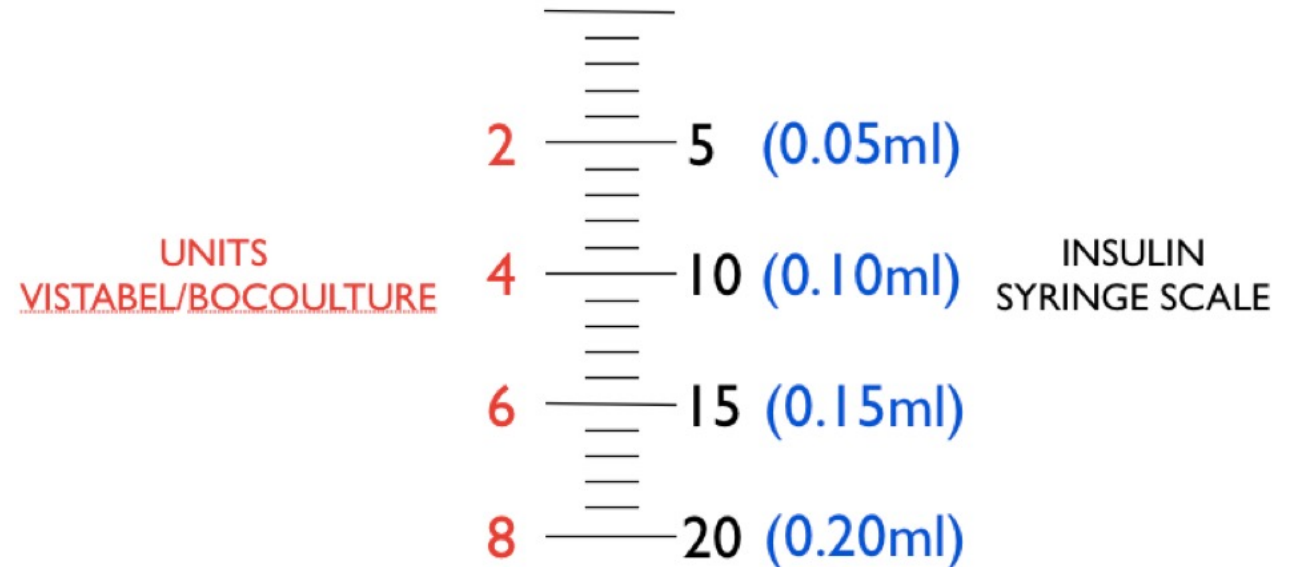
# BOTOX/Xeomin

- 2.5ml 0.9% NaCl (preserved)
- 100 units per vial
- 0.1ml = 4 units (10 on syringe)

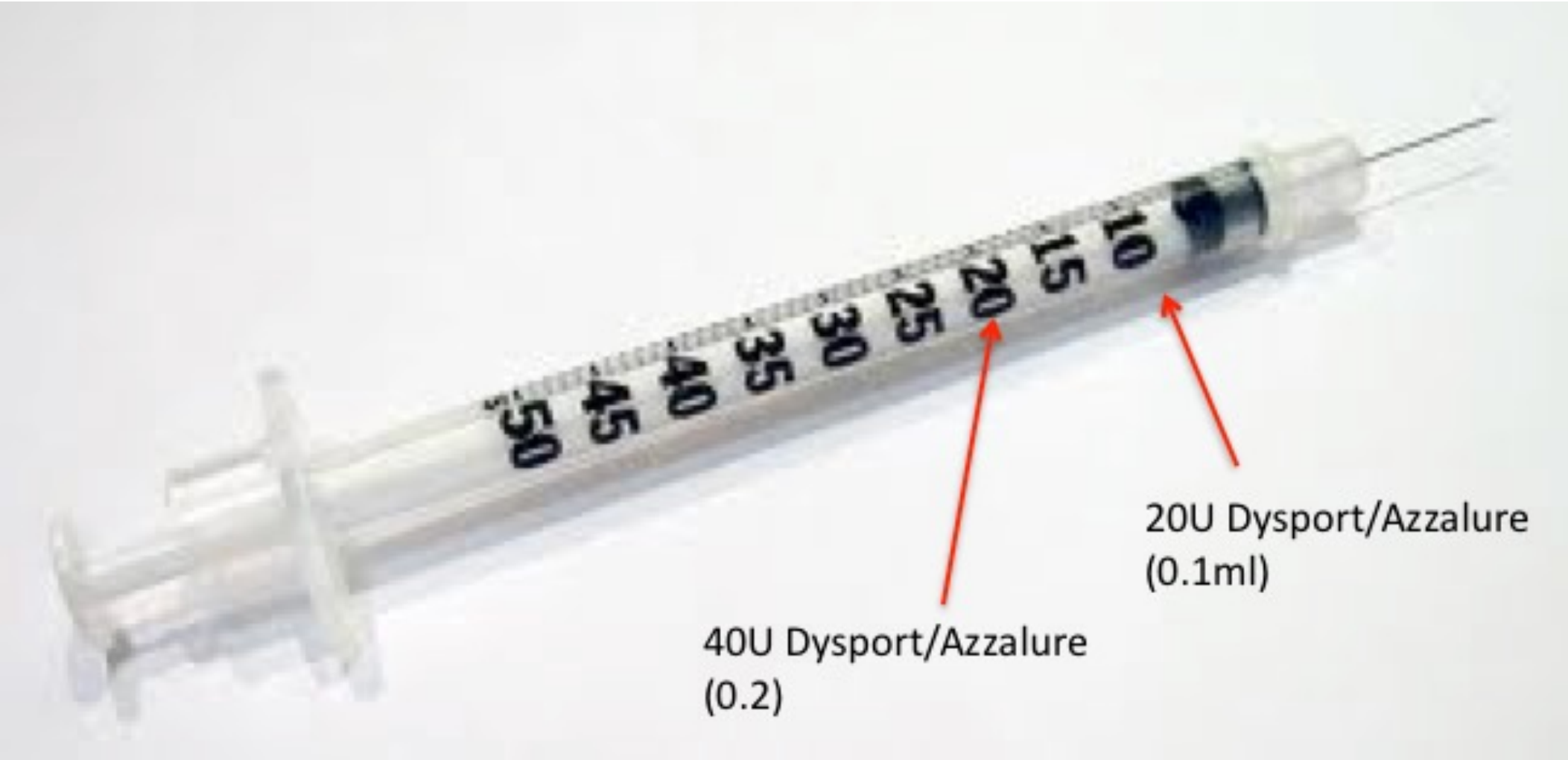


# Vistabel/Bocouture

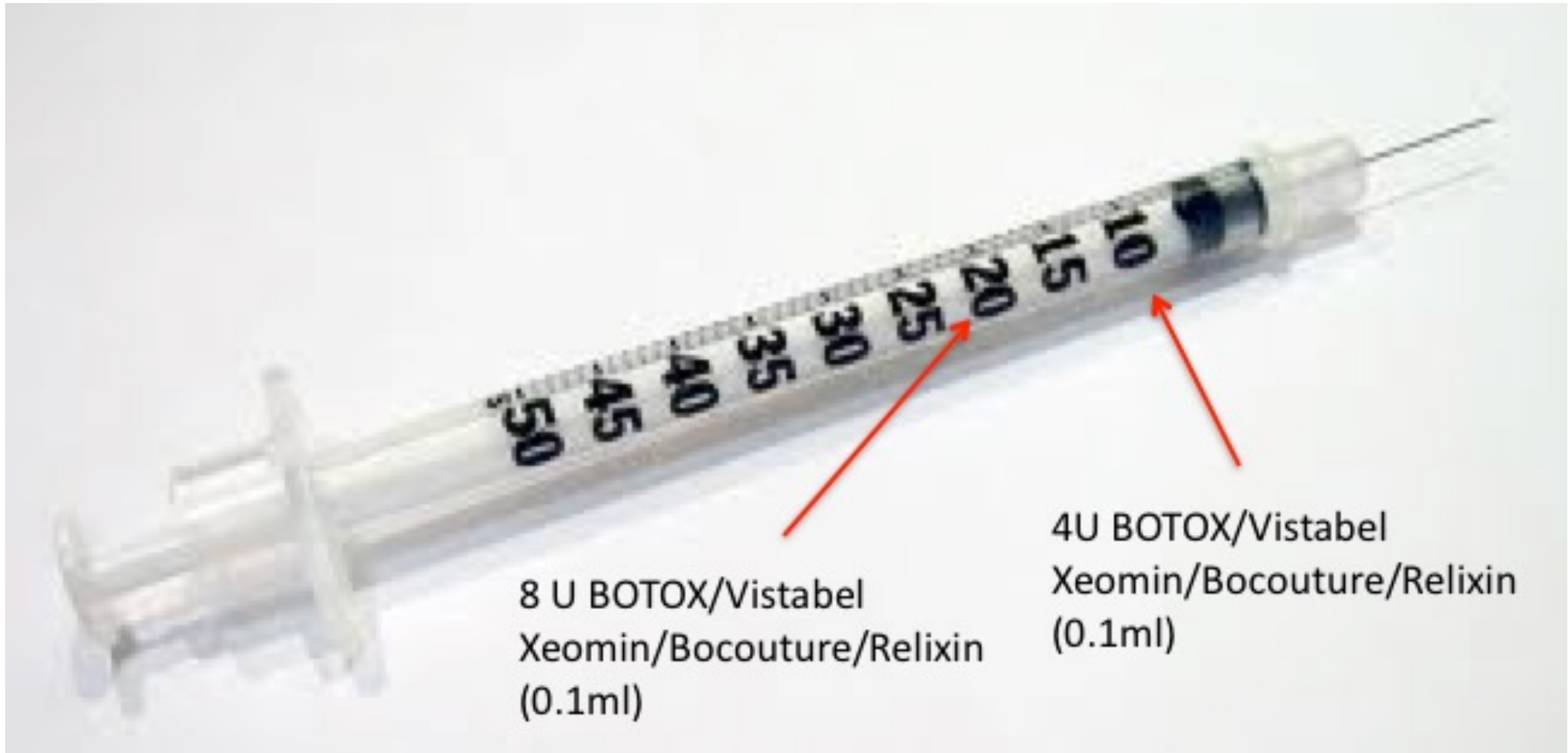
- 1.25ml 0.9% NaCl (preserved)
- 50 units per vial
- 0.1ml = 4 units (10 on syringe)



# Summary Azzalure/Dysport



# Summary BOTOX/Vistabel/Bocouture/Xeomin



# Summary

Product	Units/vial	Shelf life before reconstitution	Volume diluent (NaCl)	Units/0.1 ml	Storage (unconstituted)	Shelf life after reconstituted
Azzalure	125	15 months	0.63 mls	20U	Fridge/Freezer	1 hr
Dysport	500	15 months	2.5 mls	20U	Fridge/Freezer	1 hr
BOTOX™	100	24 months	2.5 mls	4U	Fridge/Freezer	4 hrs
Vistabel	50	24 months	1.25 mls	4U	Fridge/Freezer	4 hrs
Xeomin	100	36 months	2.5 mls	4U	On shelf	4 hrs
Bocouture	100	36 months	2.5 mls	4U	On shelf	4 hrs

# Disposal

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# Dosages

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- Age of patient
- Sex of patient
- Ethnicity of patient
- Severity of wrinkles
- Muscle mass
- Previous BTX treatments
- Patients desired outcome



# Aftercare instructions

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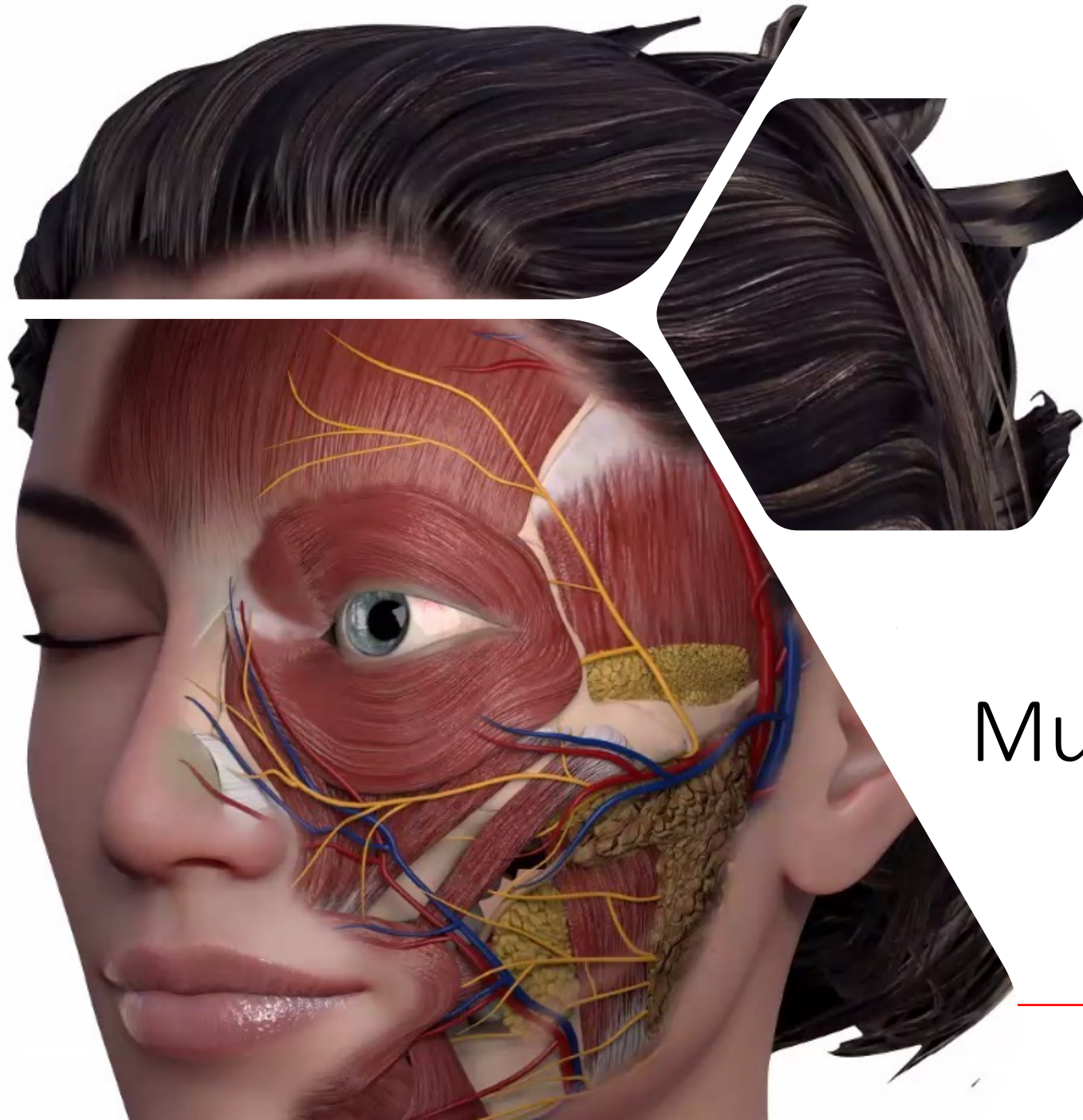


- Written and verbal
- Recorded notes
- AVOID touching area for few hours
- AVOID lying up immediately after treatment
- AVOID vigorous exercise/bending up and down for a few hours
- AVOID lying flat for a few hours
- AVOID facial massage and other treatments



# Treatment agenda

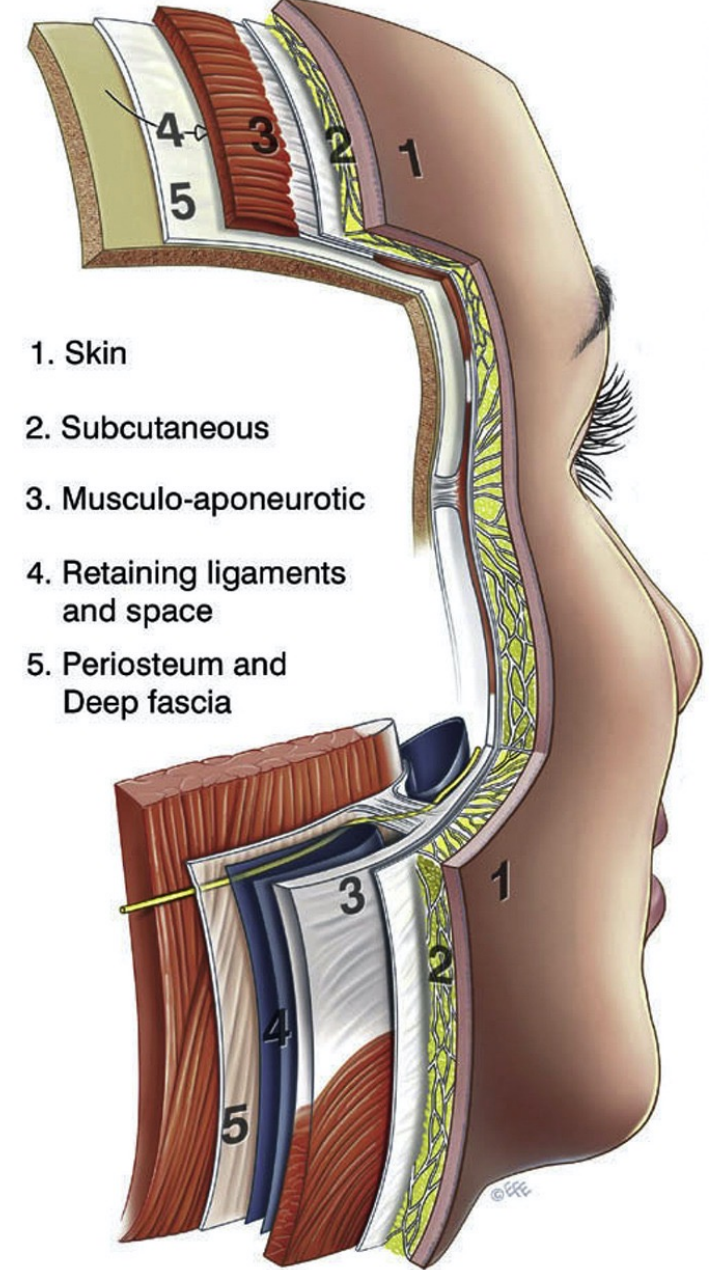
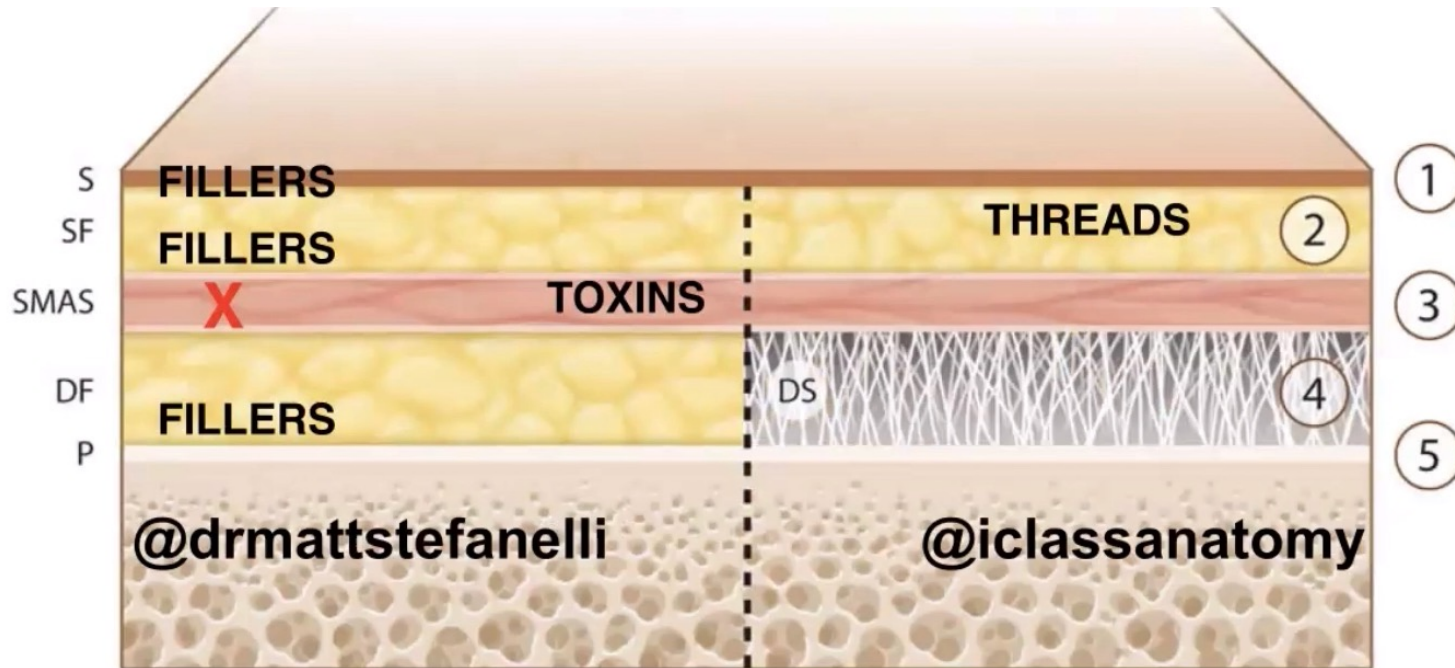
- Relevant Medical History
- Case History and skin status
- Assess patient's expectations
- Explain expected results
- Explain potential risks/side effects
- Explain alternative treatments
- Establish and explain treatment plan
- Consent for treatment/photography
- Photographic case documentation
- Prepare toxin and patient
- Mark patient/photograph/Inject BTX
- Document treatment
- Post operative instructions-
- Book follow up appointment and 2/52 review
- Book 4/12 appointment



# Muscular Anatomy

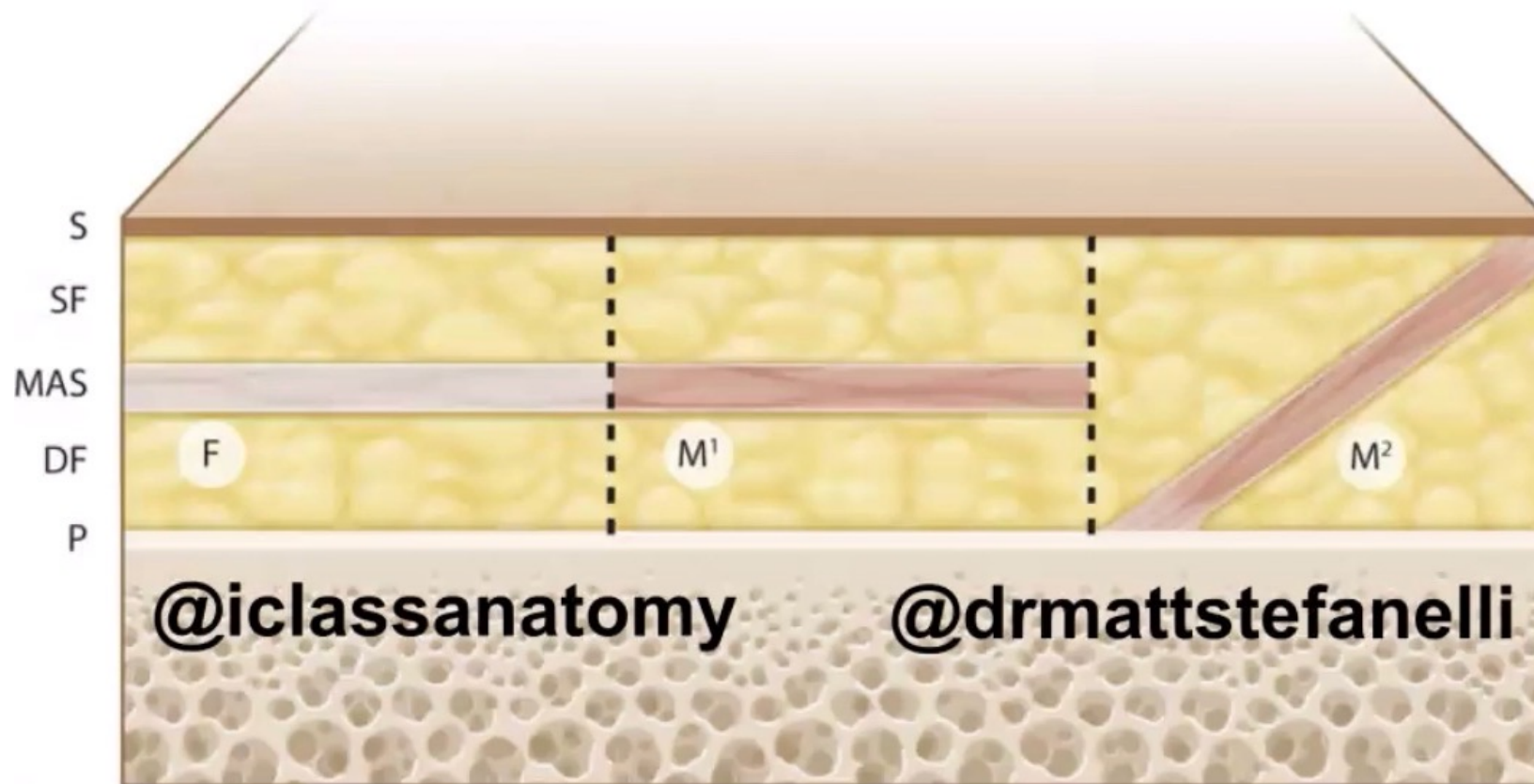
For Botulinum toxin type A

# Layered anatomy

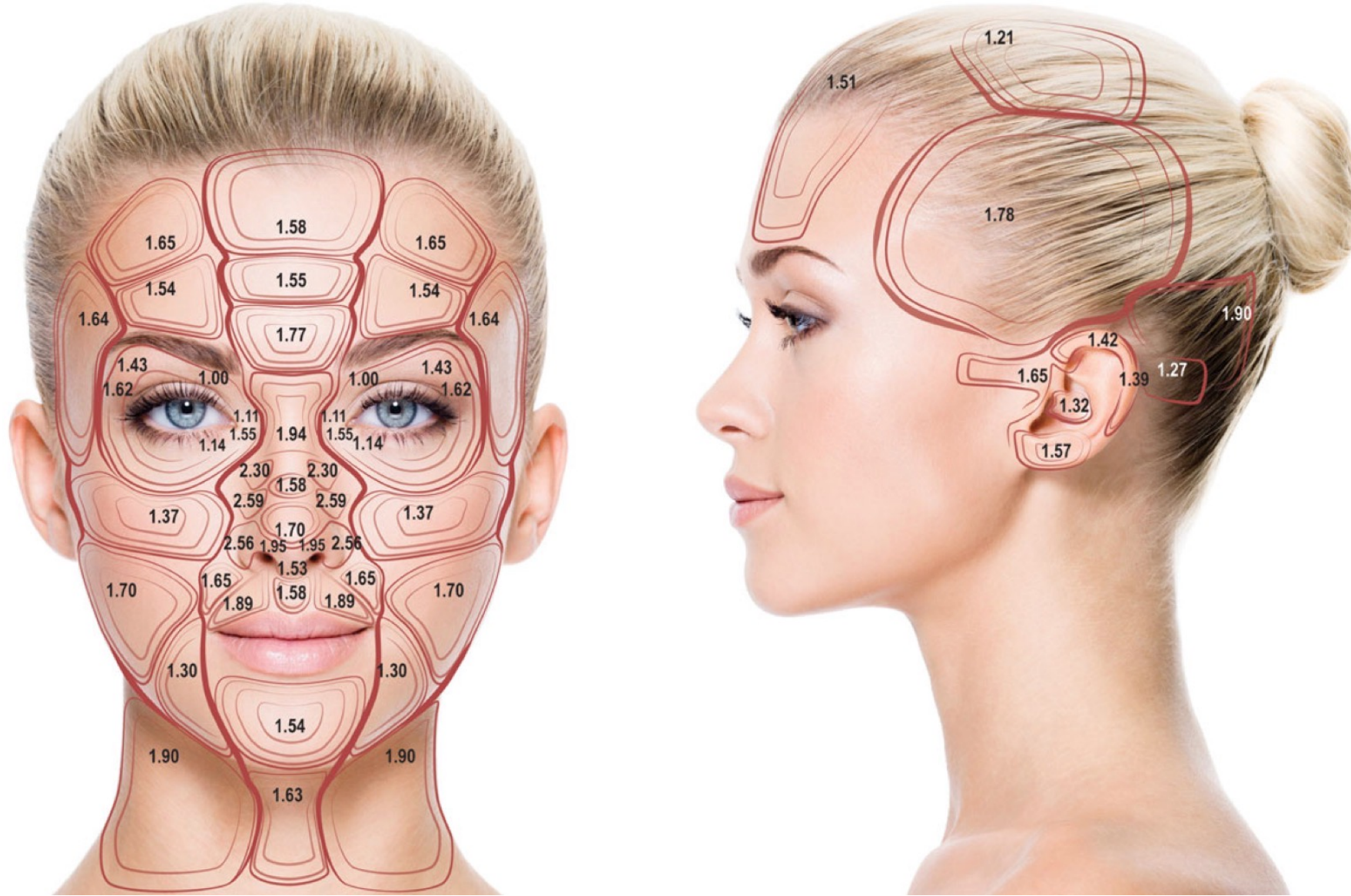


# SMAS

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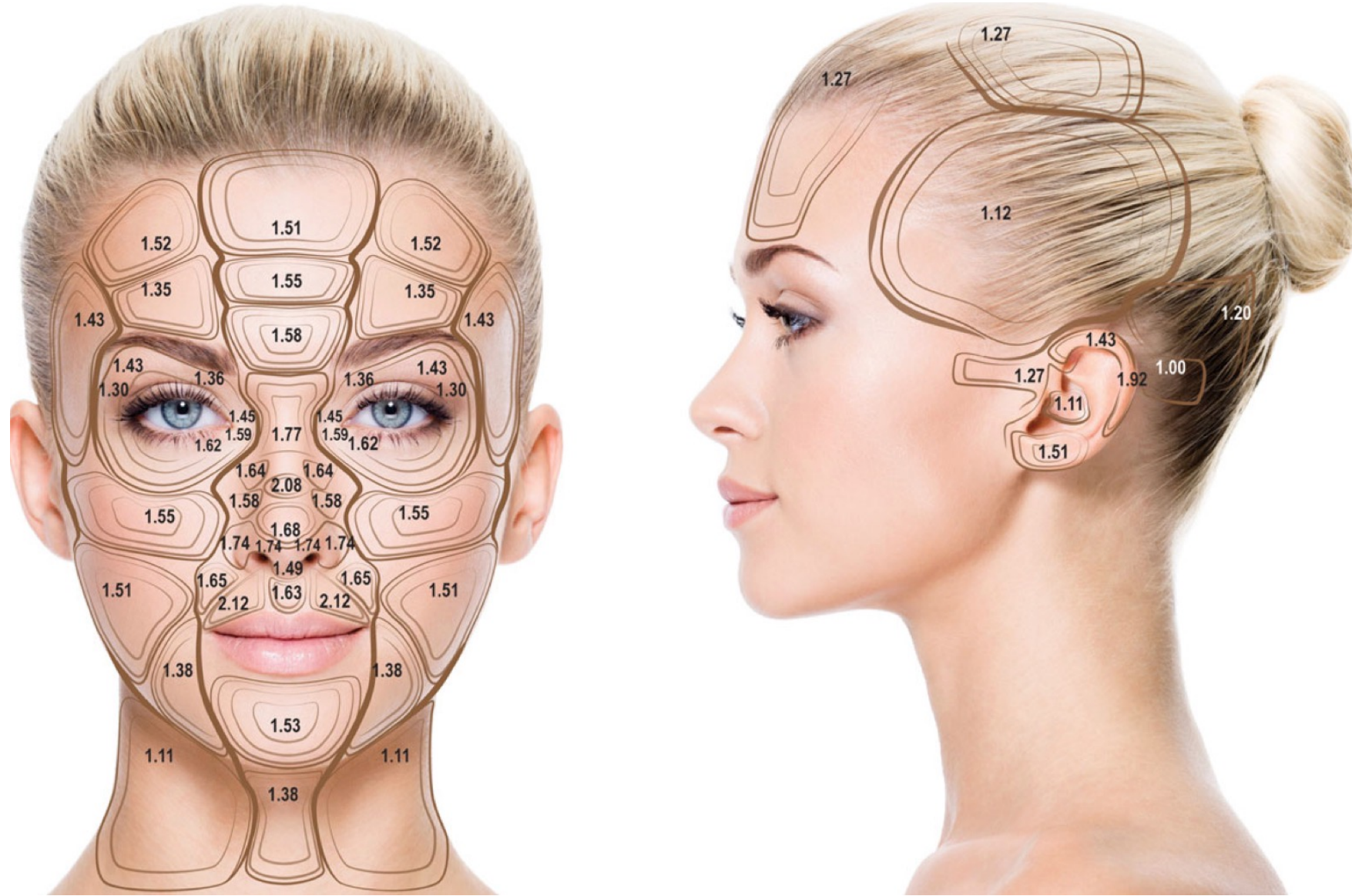


# Epidermal relative thickness



(A Comprehensive Examination of Topographic Thickness of Skin in the Human Face – Chopra et al)

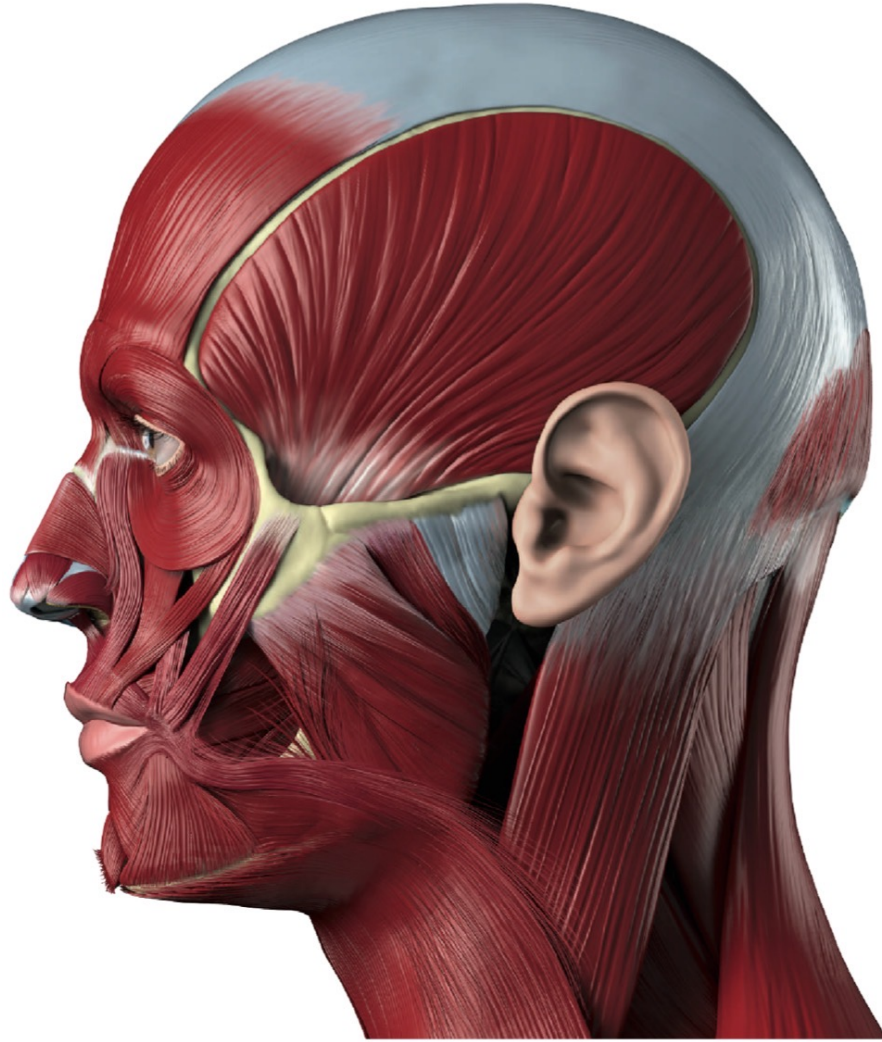
# Dermal relative thickness



(A Comprehensive Examination of Topographic Thickness of Skin in the Human Face – Chopra et al)

# Muscles of the head

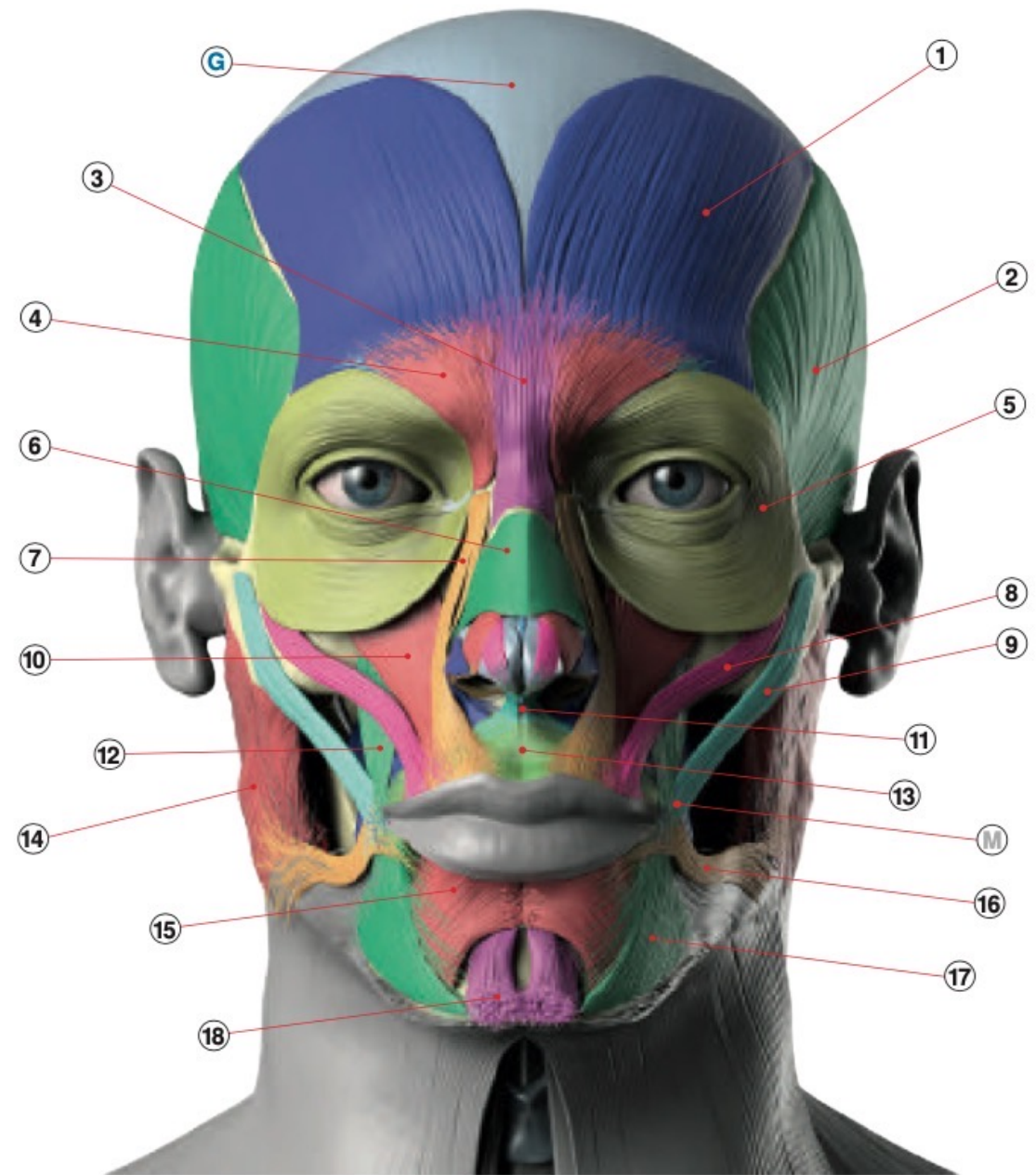
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# Frontal View

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- 1 – Frontalis
- 2 – Temporalis
- 3 – Procerus
- 4 – Depressor Supercili
- 5 – Orbicularis oculi
- 6 – Nasalis
- 7 – LLSAN
- 8 – Zygomaticus Minor
- 9 – Zygomaticus Major
- 10 – Levator Labi Superioris

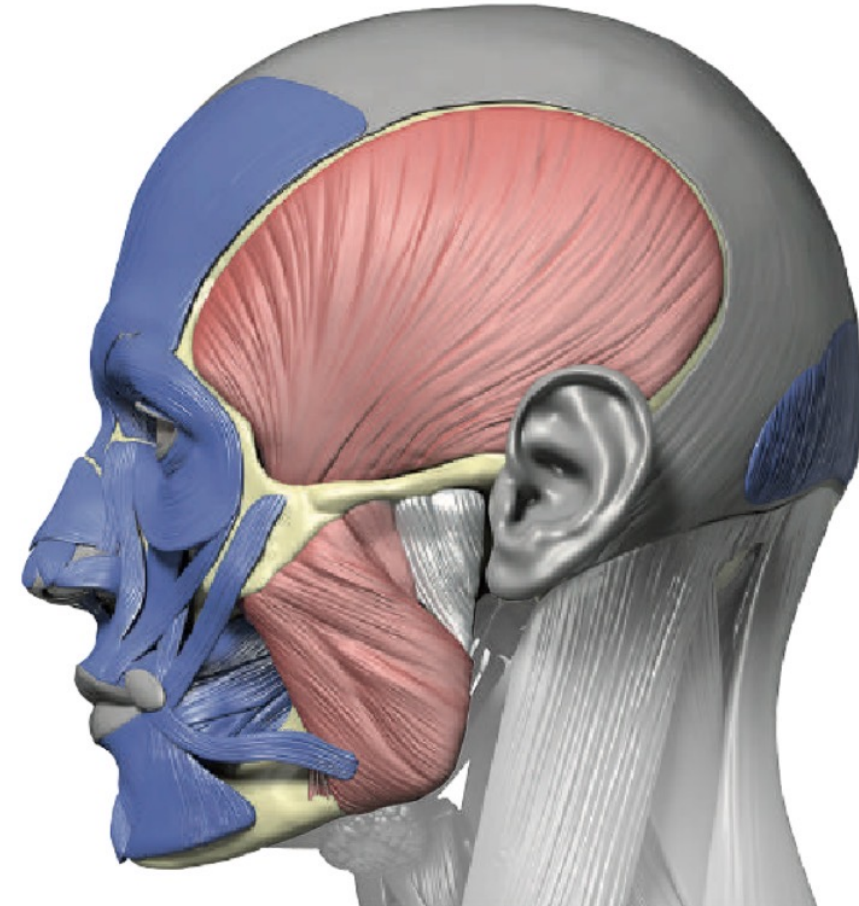
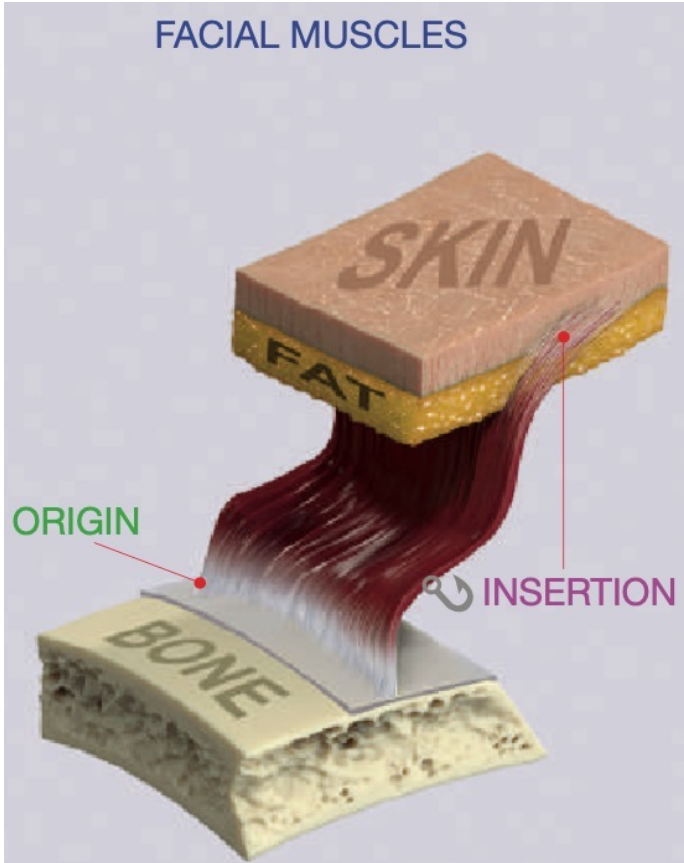




# Facial muscles (in blue)

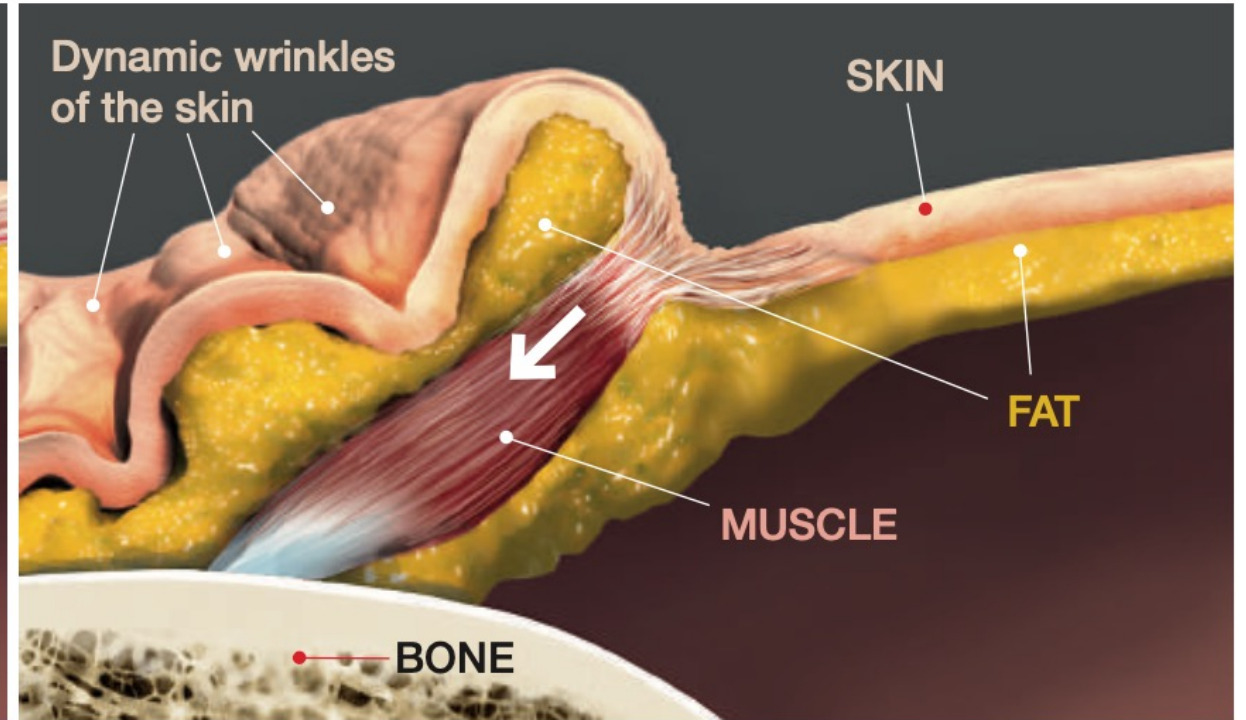
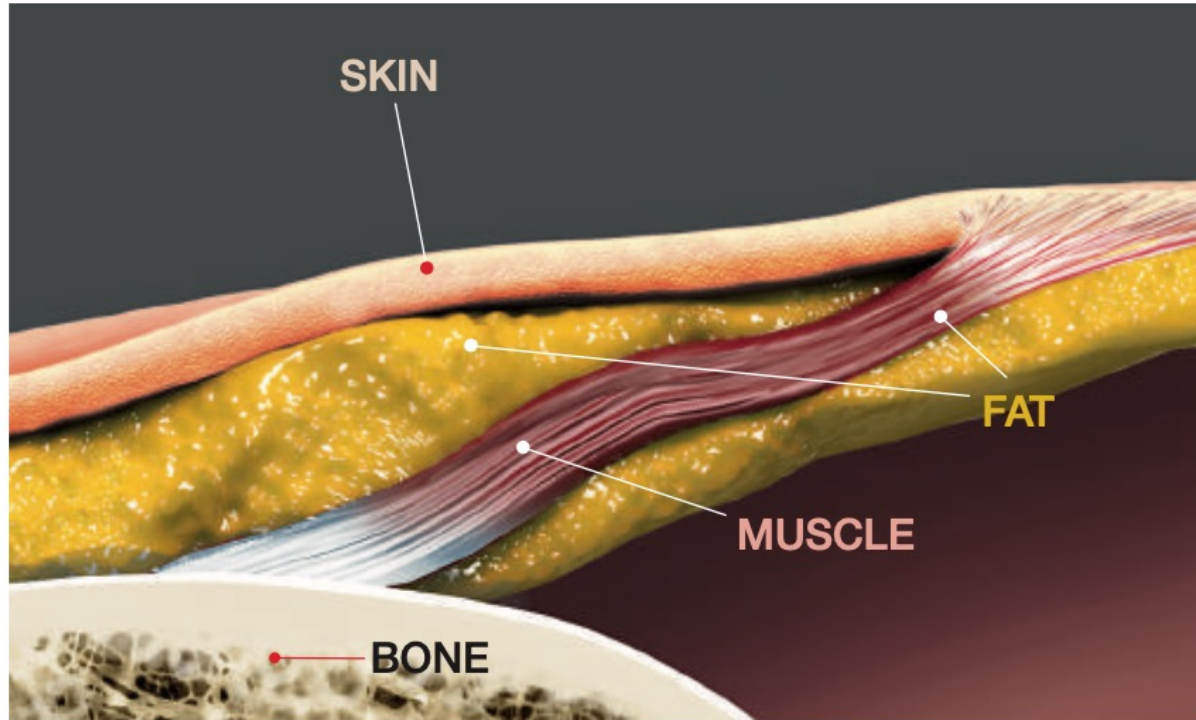
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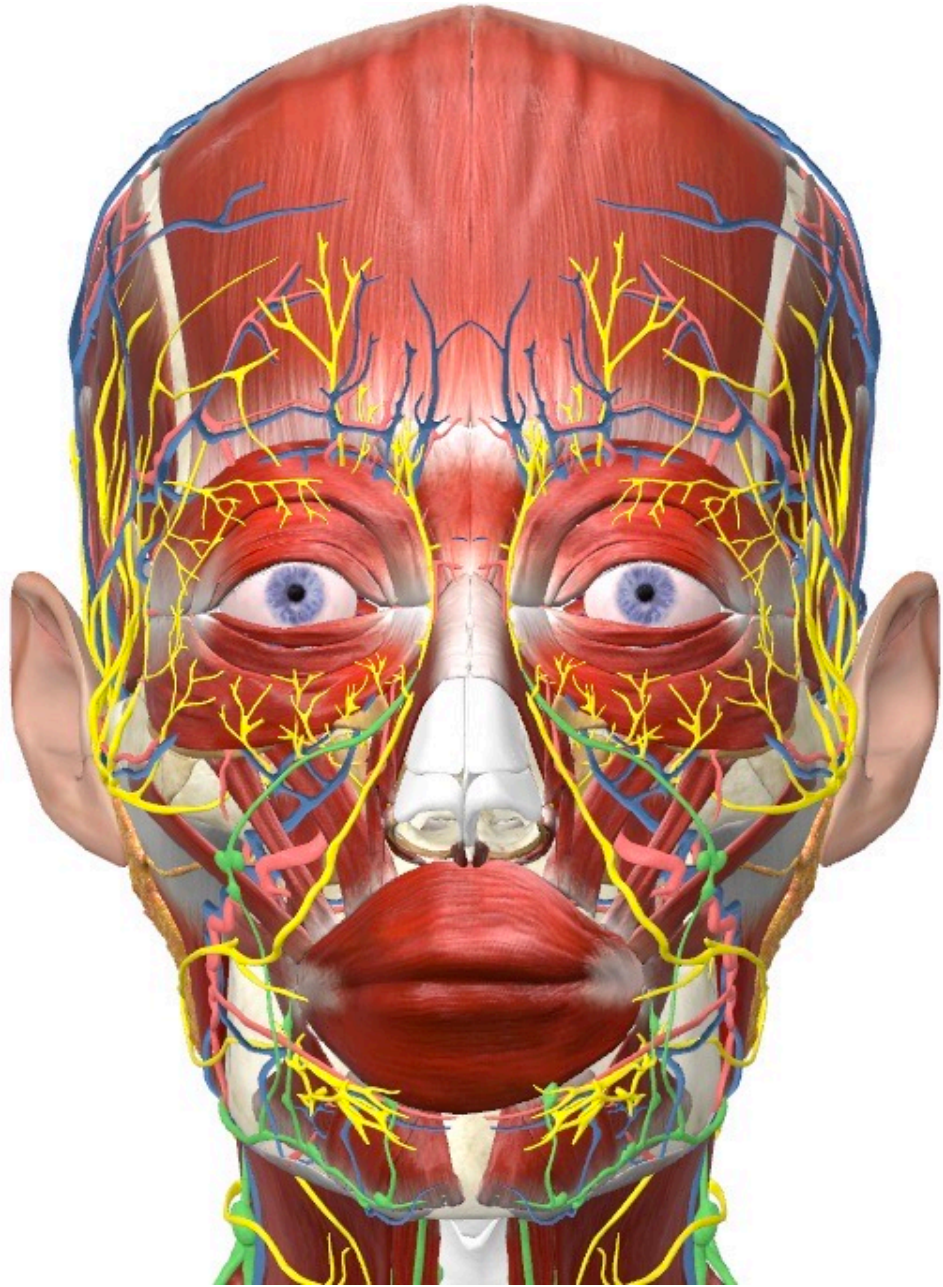
FACIAL MUSCLES



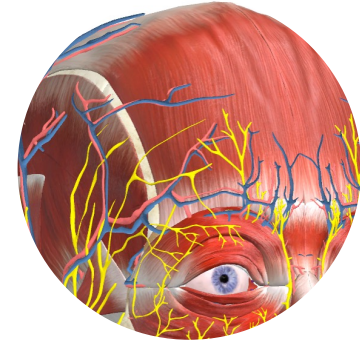
# Wrinkles

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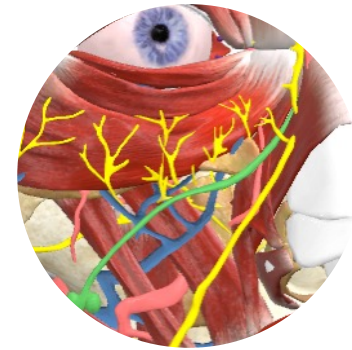




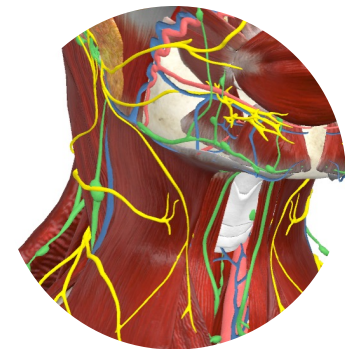
Upper third



Middle third

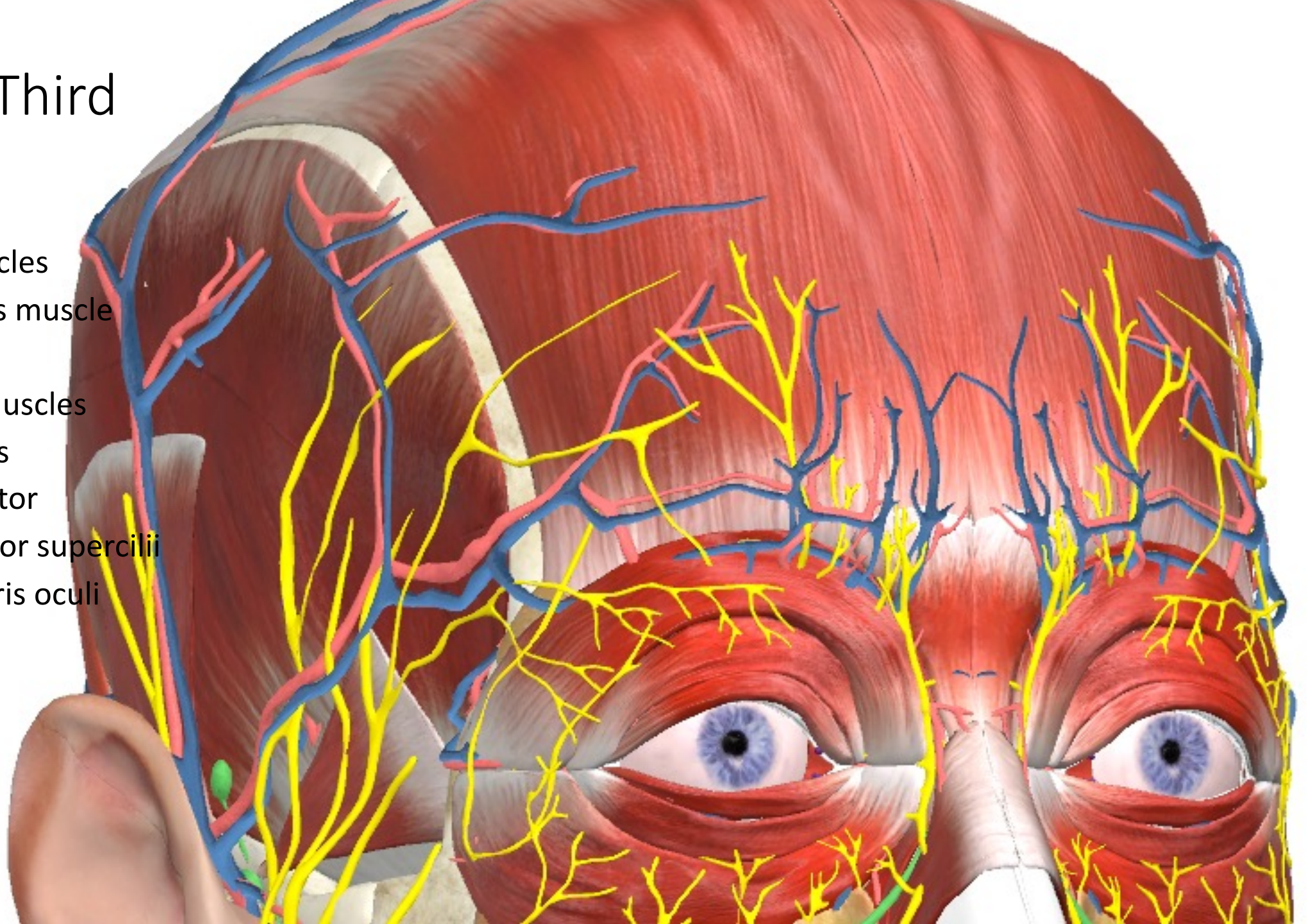


Lower third



# Upper Third

- Levator muscles
  - Frontalis muscle
- Depressor muscles
  - Procerus
  - Corrugator
  - Depressor supercillii
  - Obicularis oculi



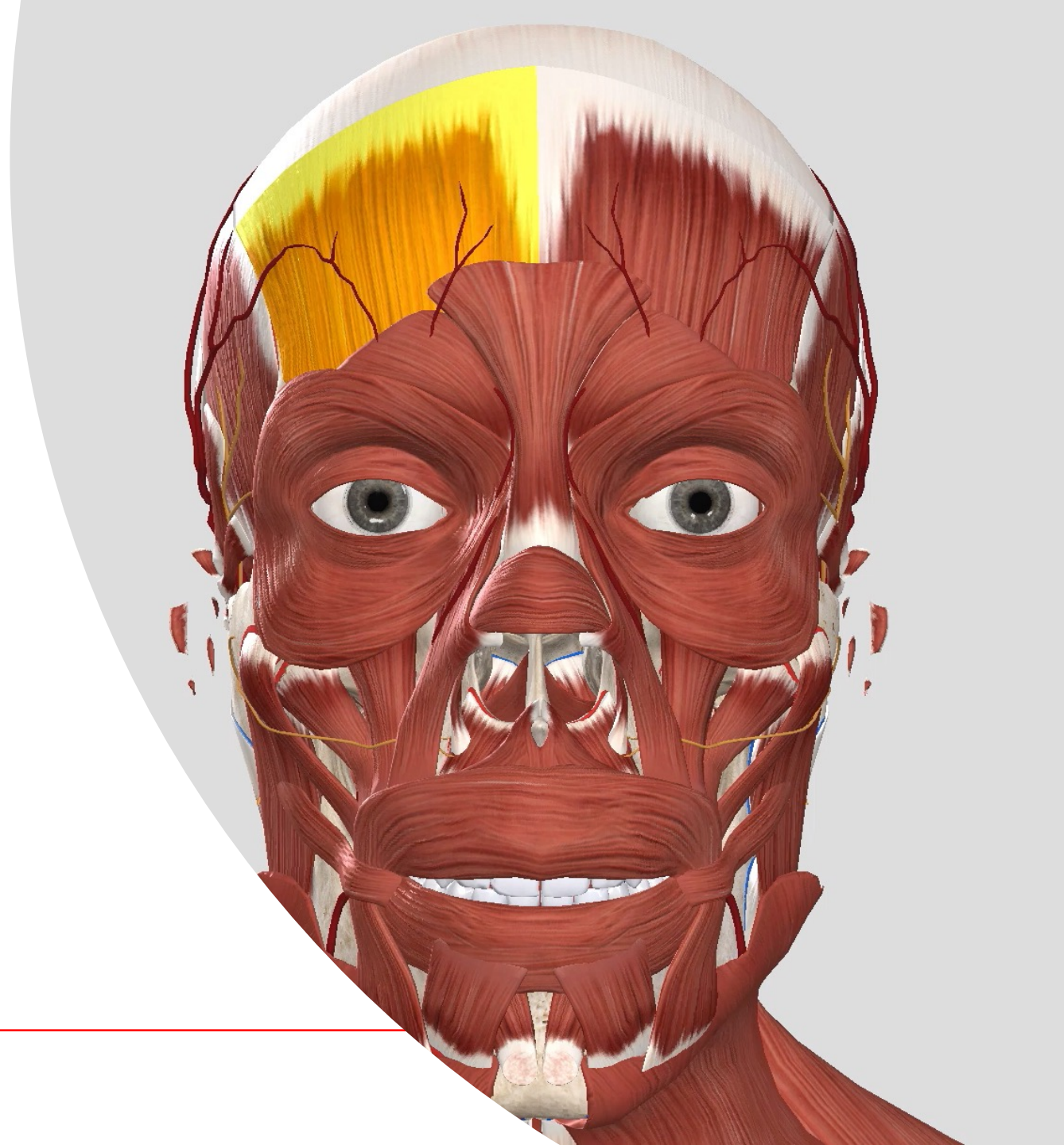


Expression lines	Muscle	Action
Frown lines	Corrugator supercili Procerus Depressor supercili	Eyebrows medially Eyebrow depressors
Horizontal forehead lines	Frontalis	Eyebrow elevator
Crow's feet	Lateral orbicularis oculi	Lateral eyebrow depressor
Eyebrow lift	Superior lateral orbicularis oculi	Superior lateral eyebrow depressor

# Frontalis

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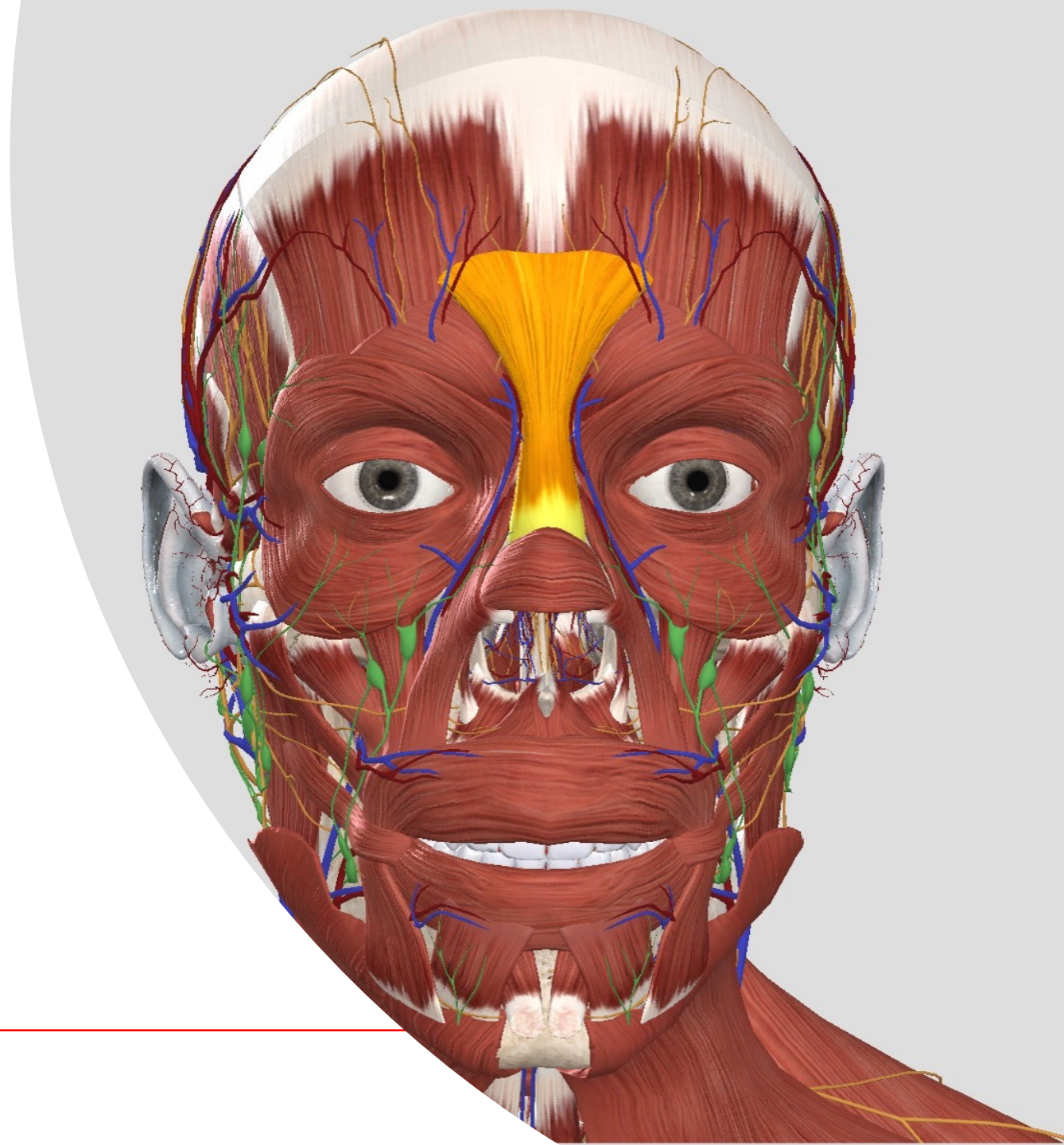
- **ORIGIN:** Epicranial aponeurosis
- **INSERTION:** Skin of eyebrow and forehead
- **ACTION:** Elevates the eyebrow, moving scalp upwards
- **NERVE SUPPLY:** Temporal branches of facial nerve
- **ARTERIAL SUPPLY:** Frontal branch of superficial temporal artery; supra-orbital artery; supratrochlear artery



# Procerus

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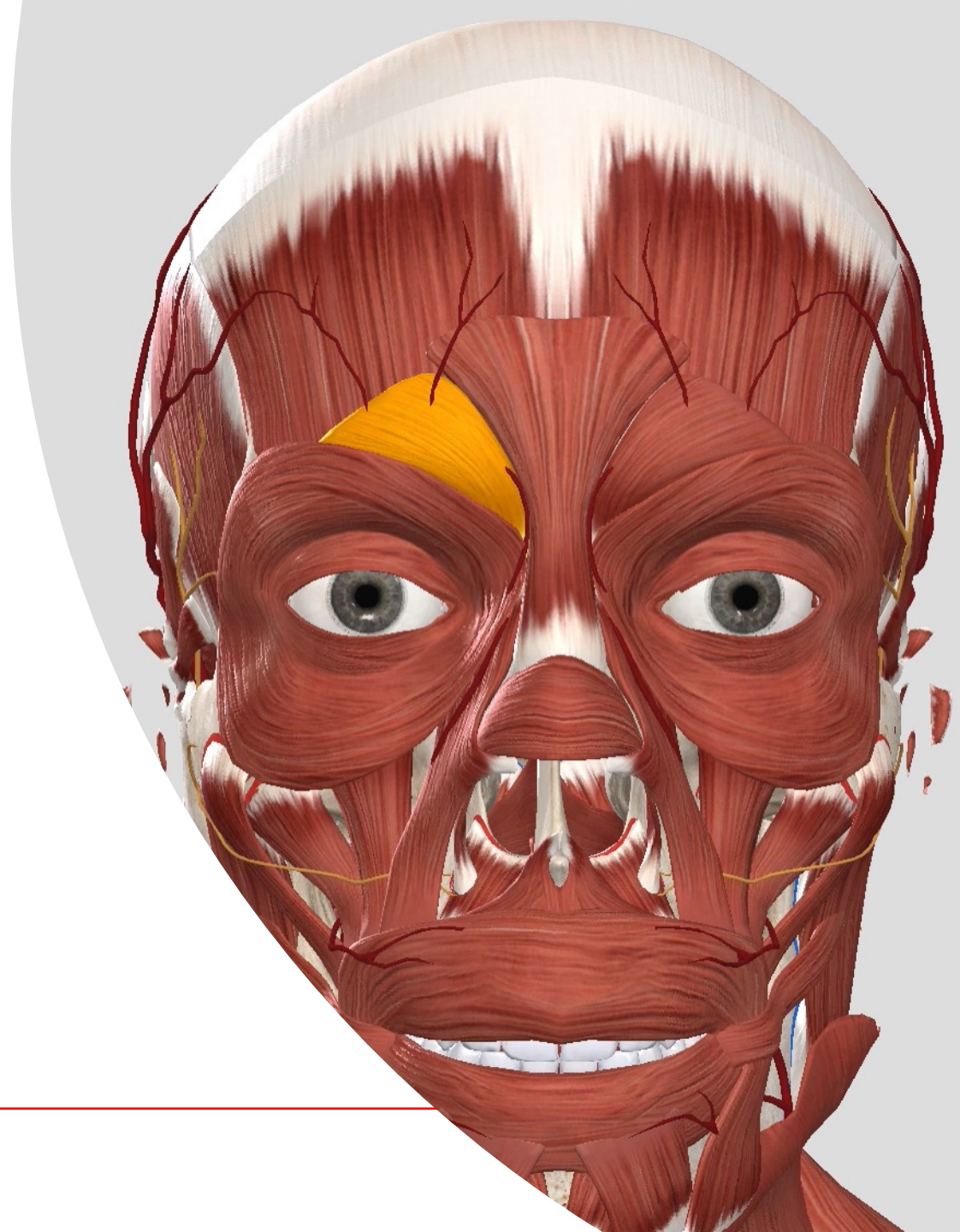
- **ORIGIN:** Fascia covering nasal bone and the lateral nasal cartilages
- **INSERTION:** Skin of lower forehead between the eyebrows
- **ACTION:** Depression of medial angle of eyebrows
- **NERVE SUPPLY:** Temporal branches of facial nerve; zygomatic branches of facial nerve
- **ARTERIAL SUPPLY:** Angular artery; lateral nasal branch of facial artery



# Corrugator

---

- **ORIGIN:** Medial part of orbital margin
- **INSERTION:** Skin and subcutaneous tissue under the eyebrow
- **ACTION:** Pulls the eyebrow and skin above the eye downwards
- **NERVE SUPPLY:** Temporal branches of facial nerve; zygomatic branches of facial nerve
- **ARTERIAL SUPPLY:** Facial artery; maxillary artery; muscular branches of ophthalmic artery; superficial temporal artery

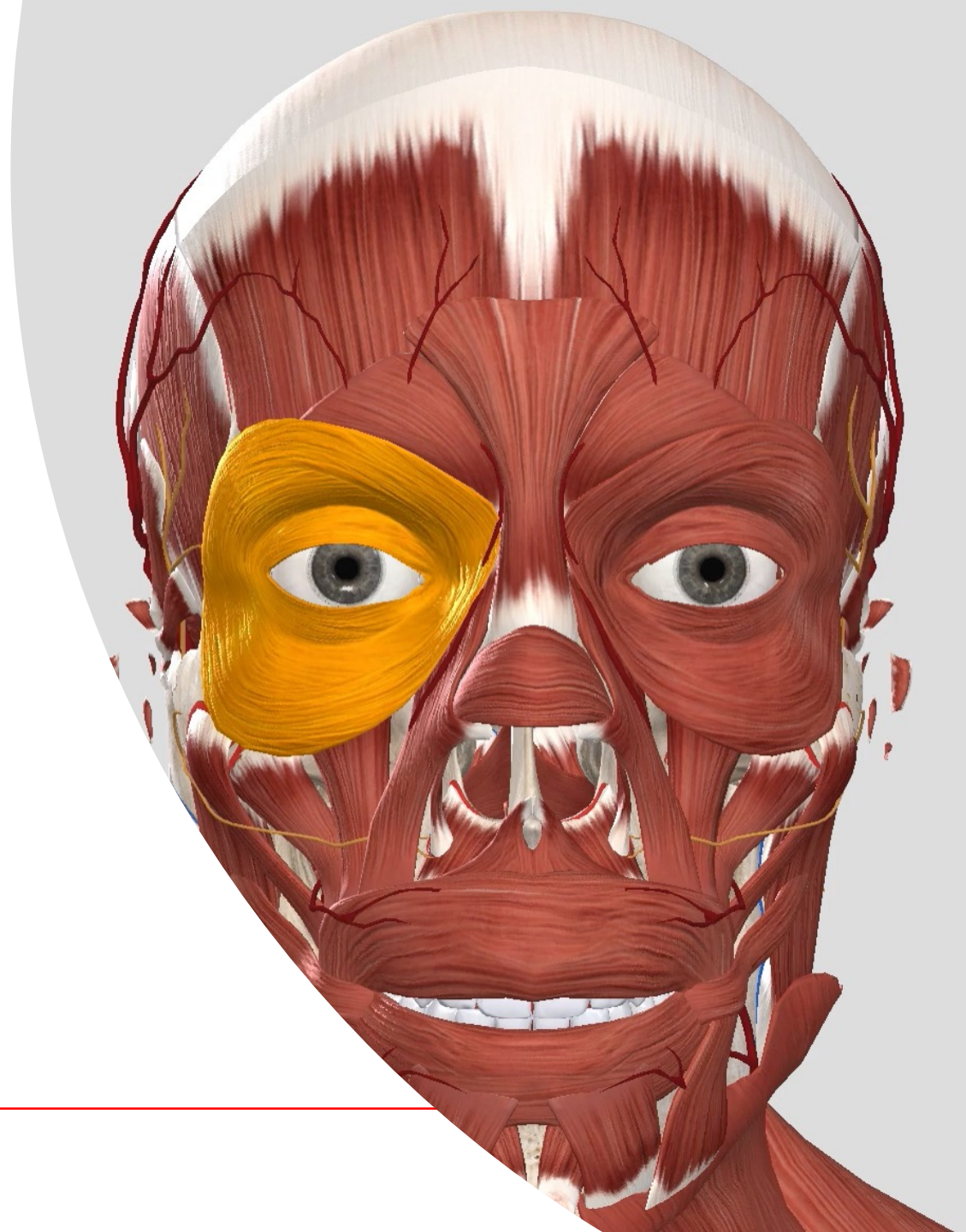




# Orbicularis oculi

---

- **ORIGIN:** Orbital part – medial part of orbital margin; palpebral part – medial palpebral ligament; lacrimal part – lacrimal bone
- **INSERTION:** Skin surrounding the orbit; lateral palpebral raphe; upper and lower eyelids
- **ACTION:** Closes the eyelids
- **NERVE SUPPLY:** Temporal branches of facial nerve; zygomatic branches of facial nerve
- **ARTERIAL SUPPLY:** Facial artery; maxillary artery; muscular branches of ophthalmic artery; superficial temporal artery



# Clinical anatomy of the face



# Middle Third

- Transverse nasalis and alar naris
- Dilator naris anterior
- Depressor septi nasi
- Levator labii alaeque nasi
- Levator labii
- Zygomaticus minor and major
- Levator anguli oris





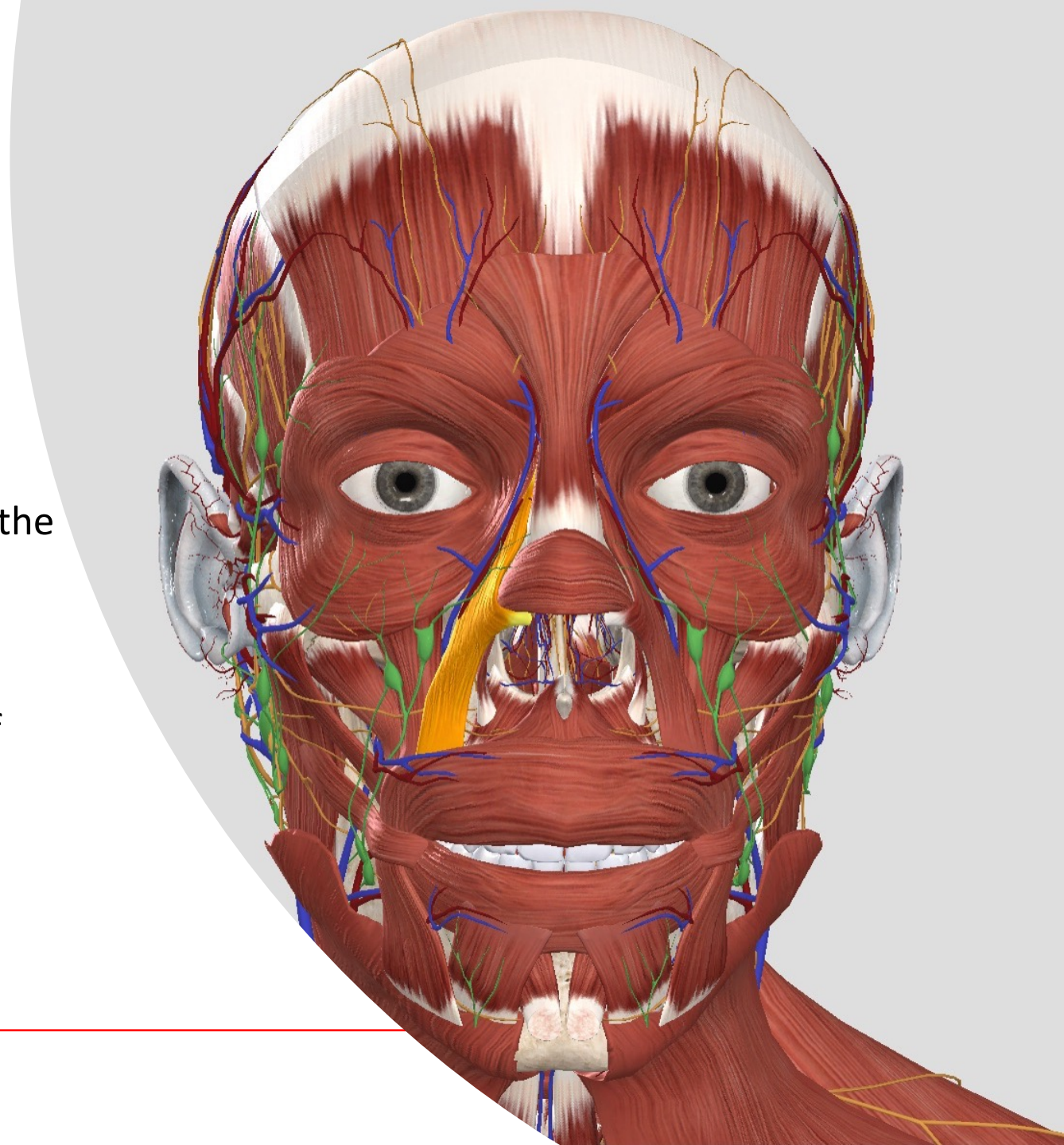
Expression lines	Muscle	Action
Gummy smile and nasolabial fold	Levator labii superioris alaeque nasi	Central lip elevator

- Levator labii alaeque nasi – raises and everts upper lip (lateral part) (LLAN)
- Levator labii – elevates and everts upper lip
- Zygomaticus minor – elevates upper lip and intermediate part NLF
- Zygomaticus major – retracts and elevates modiolus and angle of mouth

# LLAN

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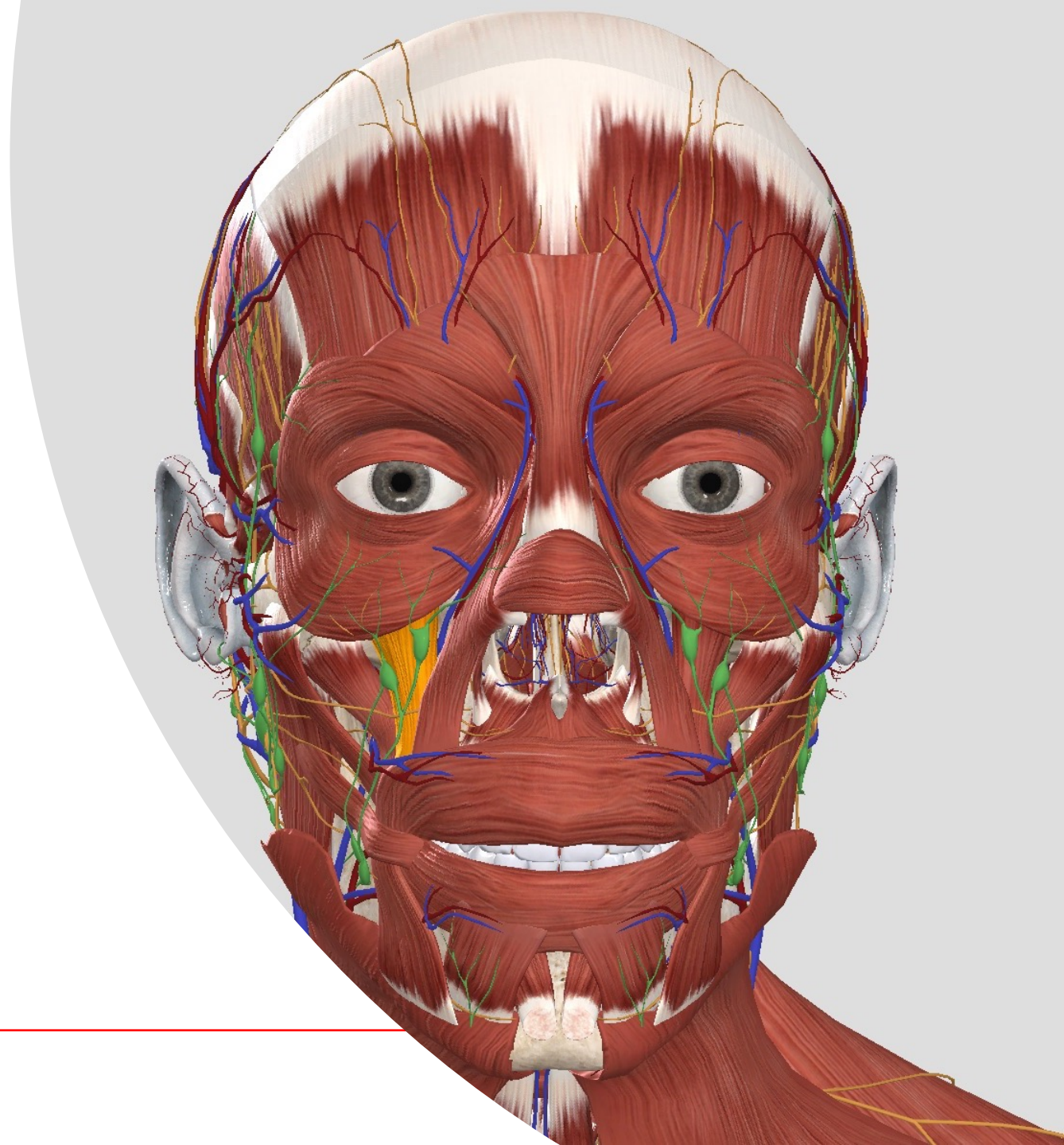
- **ORIGIN:** Frontal process of maxilla
- **INSERTION:** Alar cartilage of the nose and skin of the upper lip
- **ACTION:** Elevation of the upper lip and assists in flaring of the nares
- **NERVE SUPPLY:** Zygomatic and buccal branches of facial nerve
- **ARTERIAL SUPPLY:** Superior labial artery; angular artery; infra-orbital artery



# Levator labii

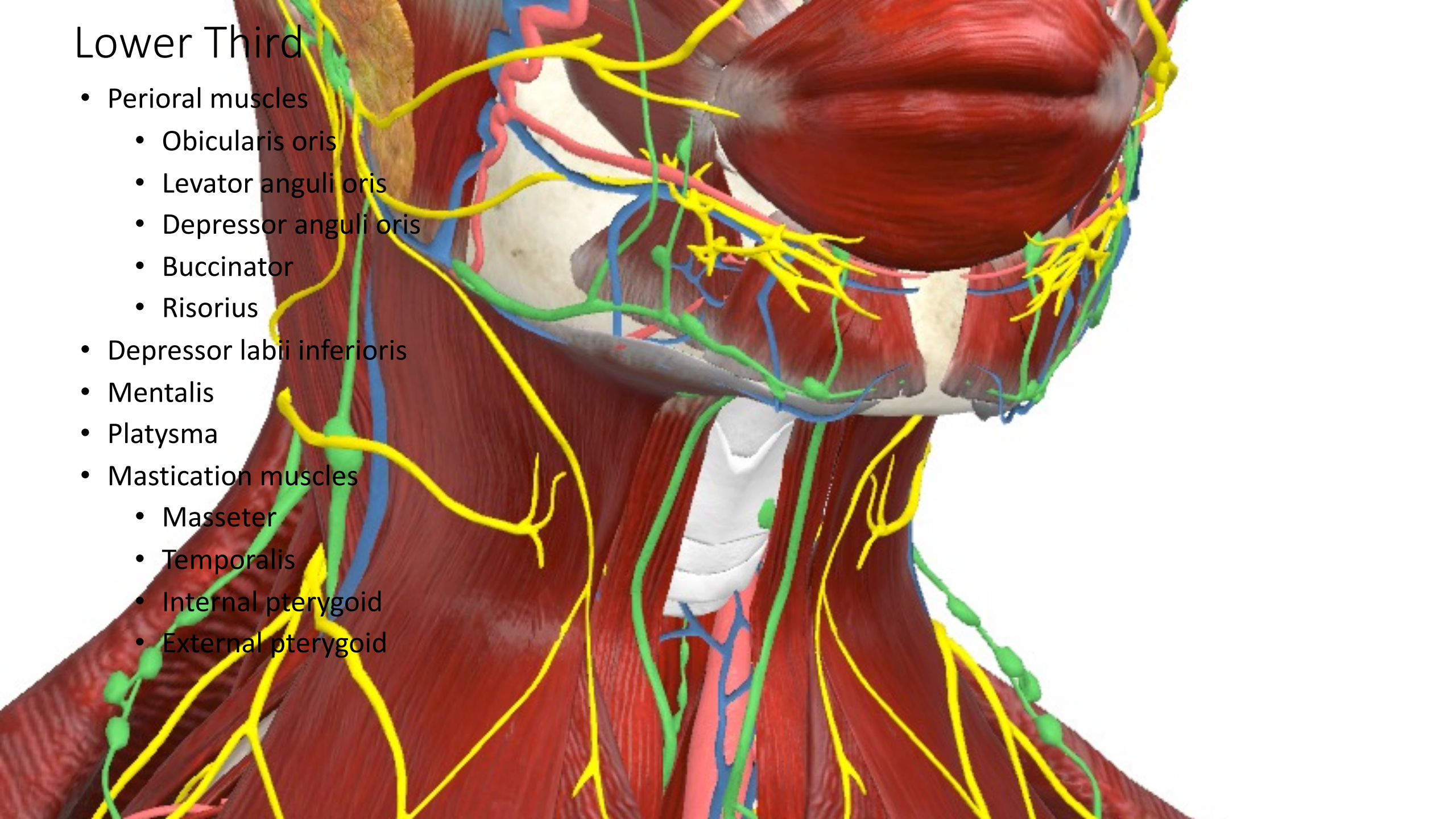
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- **ORIGIN:** Infra-orbital margin of maxilla
- **INSERTION:** Skin of the upper lip
- **ACTION:** Elevation of the upper lip
- **NERVE SUPPLY:** Zygomatic and buccal branches of facial nerve
- **ARTERIAL SUPPLY:** Superior labial artery; angular artery; infra-orbital artery



# Lower Third

- Perioral muscles
  - Orbicularis oris
  - Levator anguli oris
  - Depressor anguli oris
  - Buccinator
  - Risorius
- Depressor labii inferioris
- Mentalis
- Platysma
- Mastication muscles
  - Masseter
  - Temporalis
  - Internal pterygoid
  - External pterygoid

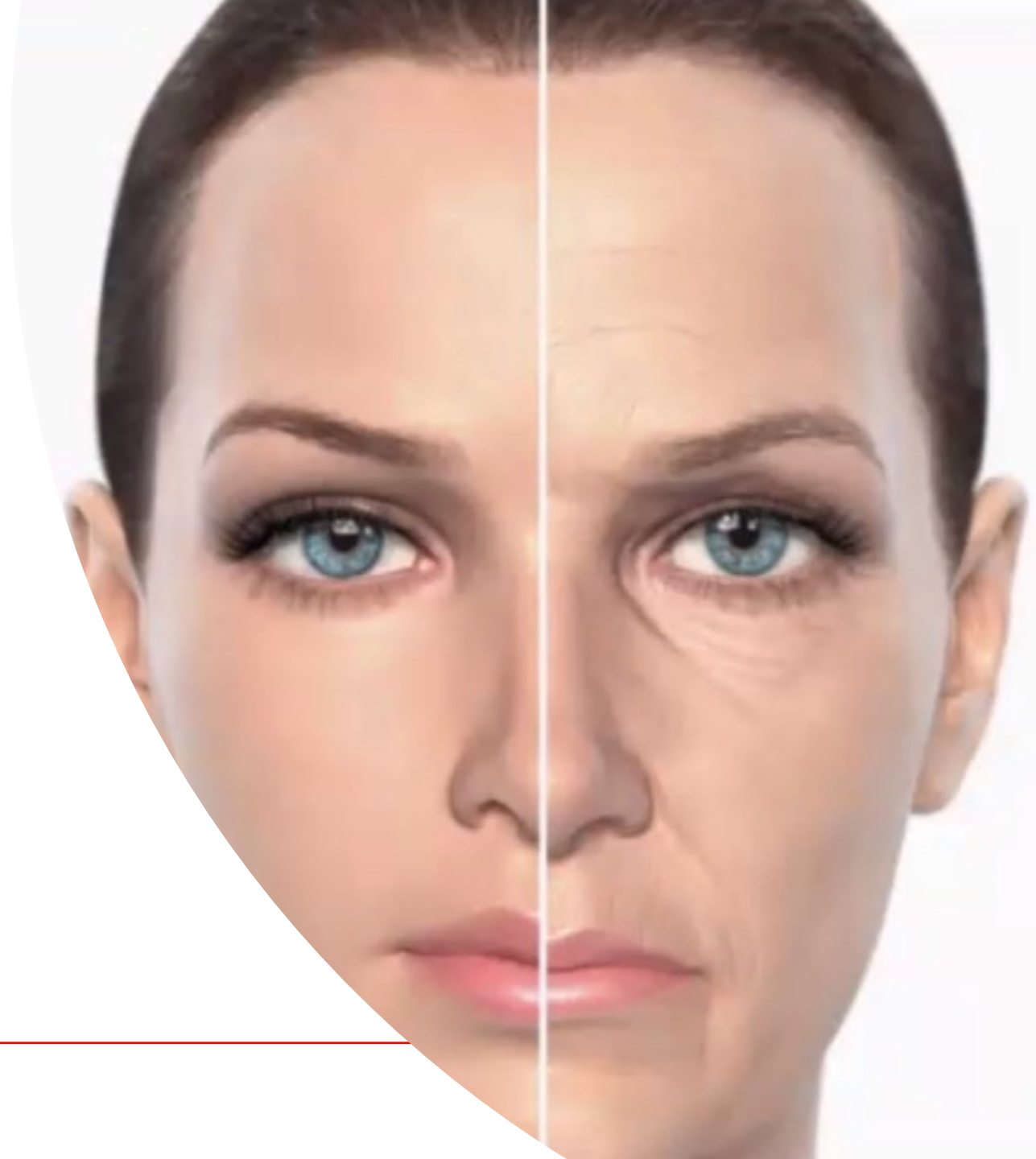




# Ageing

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- Sum of genetic and environmental influences
- Ageing signs are the result of a slow rate of cell renewal, collagen loss, and a decrease of the glandular and vascular net.
- Two types of ageing:
  - **Intrinsic ageing**
  - **Extrinsic ageing**



# Intrinsic ageing

- Also known as chronological ageing
- Occurs over time
- **Genetic:** Replication rate slower over time
- **Hormonal:** Oestrogen (menopause), testosterone, growth hormone
- **Oxidative stress:** alters cell renewal cycle, causes DNA damage and releases pro inflammatory mediators
- **High blood sugar levels:** Oxidative stress, premature ageing



# Extrinsic ageing

---

- Also known as environmental ageing
- Environment and lifestyle
- **Photo damage:** brown spots, wrinkles, collagen loss
- **Tobacco:** Loss of skin elasticity, more wrinkles
- **Alcohol:**
- **Tanning:**
- **Diet:** Unbalanced



# Kinetic Patients    ‘express emotions when they want’

---

- Treatment can last longer
- Static analysis – no wrinkles visible
- Concordance of emotion and mimetic expression
- Most ideal patients to treat

# Hyperkinetic patients

- Results normally last +/- 4 months
- Involuntary contraction of muscles
- Most common group to treat
- Often need extra dose at review appointment
- No concordance between muscular contraction and the emotion to be expressed
- Usually want to return before muscular contraction returns

# Hypertonic patients 'cannot relax'

- Shortest duration of treatment
- Limitations of treatments
- Many treatments/year
- Improve results by including fillers
- Inability of specific muscles to relax

# Treatment outcomes

- Avoid 'frozen' look
- 'Natural' look – correct balance of fully and partial blocking
- Youthful look elevators more important than depressors
- 'Refreshed look' target depressors

With ageing depressors become more dominant than elevators

# Patient assessment

- Divide face into vertical fifths
- Assess and document any asymmetries
- Type of patient – hyperkinetic.....
- Glogau Wrinkle scale





# Glogau classification

Photodamage classification system

Referenced worldwide by dermatologists and plastic surgeons





### **Type 1: 'No Wrinkles'**

Early photo-aging, Mild pigment changes, Minimal wrinkles No 'age spots'



### **Type 2: 'Wrinkles in Motion'**

Patient age: 30s to 40s

Early to moderate photo-aging, Appearance of lines only when face moves, Early brown 'age spots', Skin pores more prominent, Early changes in skin texture



### **Type 3: 'Wrinkles at Rest'**

Patient age: 50s & older

Advanced photoaging, Prominent brown pigmentation, Visible brown 'age spots', Prominent, small blood vessels, Wrinkles now present with face at rest



### **Type 4: 'Only Wrinkles'**

Patient age: 60s or 70s

Severe photoaging, Wrinkles everywhere, at rest or moving, Yellow-grey skin colour, Prior skin cancers, Pre-cancerous skin changes (actinic keratosis)

# Injection technique

**Standard technique** - Perpendicular or beveled into skin

- Most common technique
- Volumes 0.1-0.2 mls
- Often injected deeper in well targeted muscles

**Microinjection technique** - Lower doses/volumes 0.05

- Injections more superficially
- Often used for treating crow's feet or lower eyelid
- Post injection white papule seen



CLINICAL  
PRACTICE OF  
THE FACE

# Common areas

Shaping eyebrows

Bunny lines

Peri-oral rhytides

Dimpled chin

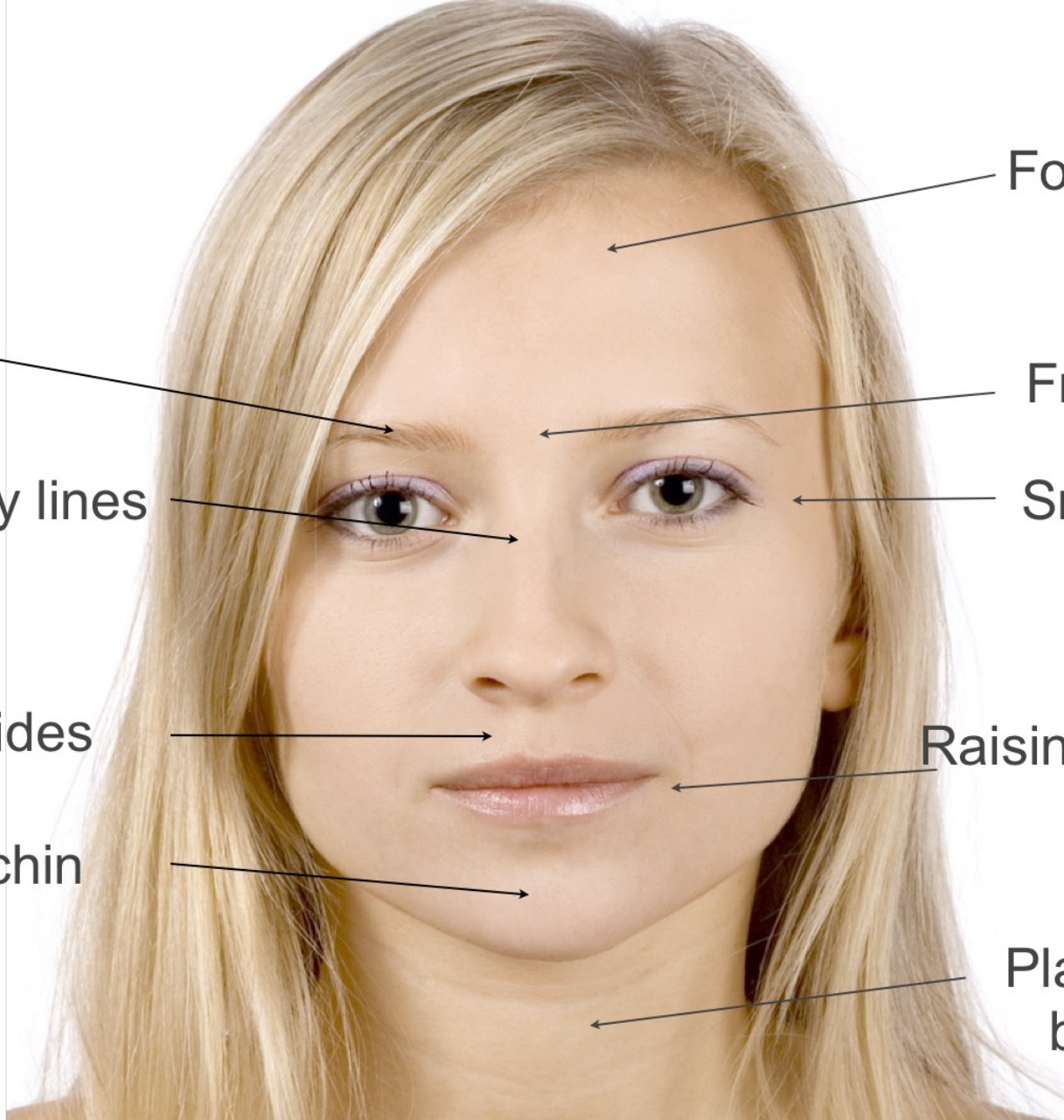
Forehead

Frown lines

Smile lines

Raising corners of mouth

Platysmal bands



# Upper third of the face

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- Frown lines
- Forehead lines
- Smile lines / crow's feet

# Forehead

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INNER  
BROW  
RAISER



**FRONTALIS**  
(medial part)



OUTER  
BROW  
RAISER

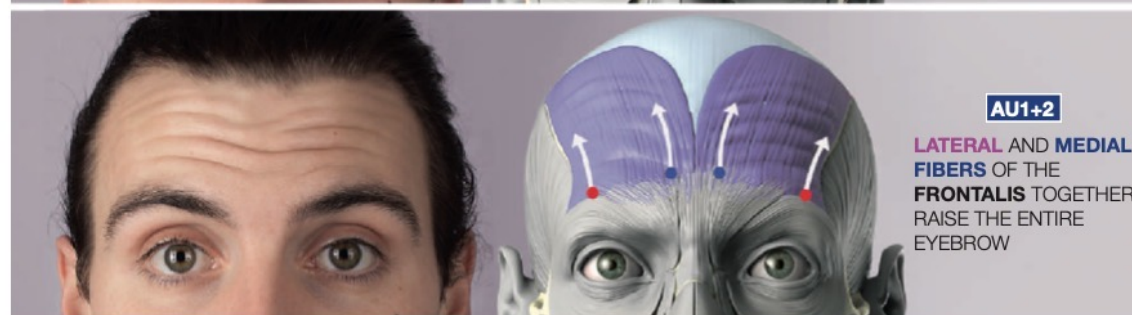
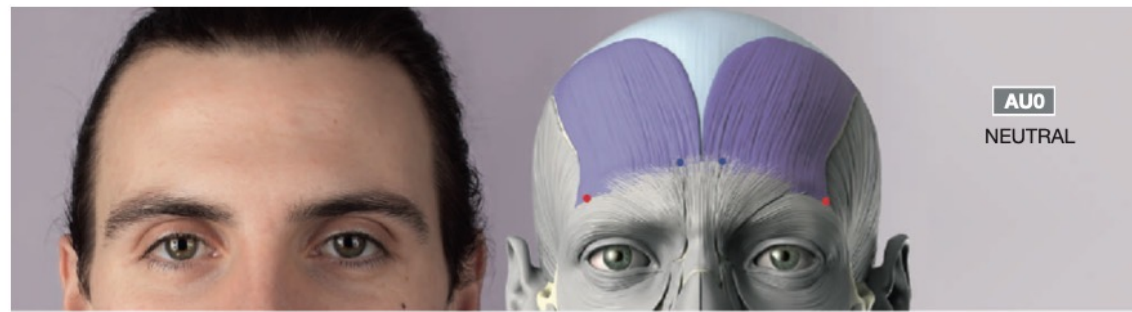


**FRONTALIS**  
(lateral part)



# Forehead lines

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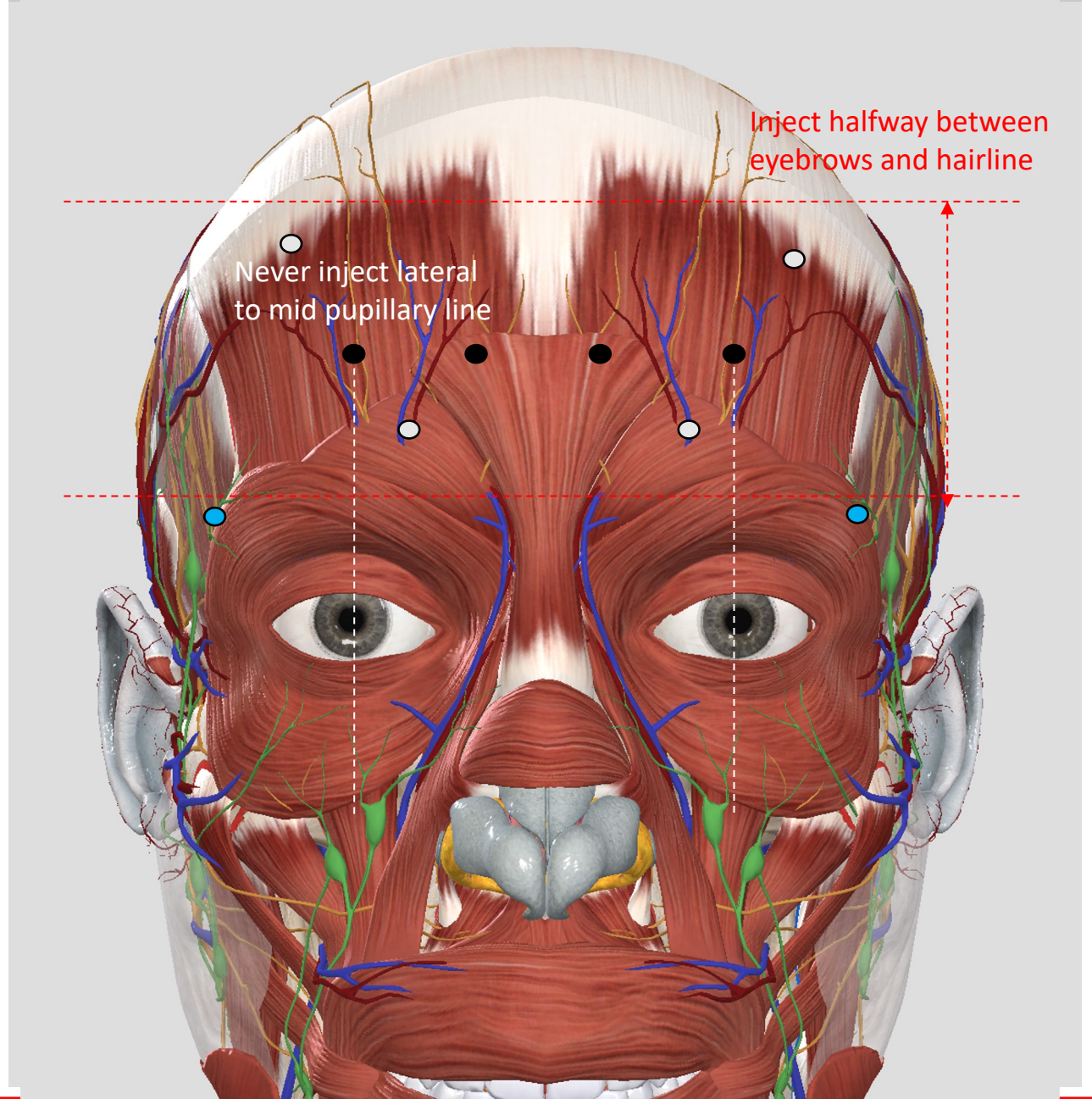
# Patient selection

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- Kinetic patient's best results – complete line removal (static and dynamic) reduced risk brow ptosis
- Hyperkinetic and hypertonic patient's brow ptosis inevitable
- Avoid patients who present with brow ptosis

# Marking up

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# Dosages

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Muscle	Mild wrinkling (units/injection site)	Moderate wrinkling (units/injection site)	Severe wrinkling (units/injection site)	Extra injections (units/injection site)
Frontalis	2 units Bocoulture 5 units Azzalure 1 unit BOTOX	3 units Bocoulture 10 units Azzalure 2 units BOTOX	4 units Bocoulture 12 - 15 units Azzalure 3 -4 units BOTOX	1-2 units Bocoulture 5-10 units Azzalure 1-2 units BOTOX

# Tips

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- Forehead variable skin thickness – insert needle 3-4mm depth
- Long/high foreheads second row injections
- Near hairline can inject lateral to mid pupillary lines
- Short foreheads inject higher
- Look for natural brow ptosis
- Look for natural mephisto
- Small doses keep movement
- Caution in hypertonic patients with elastosis
- If combination with glabella lower the doses
- Older patients place higher with larger dose and lower with lower dose

# BOCOUTURE® Horizontal Forehead Lines Injection Technique by Dr Simon Ravichanchan MBChB.MRCS

# BOCOUTURE®

Botulinum toxin type A  
free from complexing proteins

**BOCOUTURE® is indicated for the temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines has an important psychological impact for the patient:**

- Moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar frown lines) and/or
- Moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or
- Moderate to severe horizontal forehead lines seen at maximum contraction

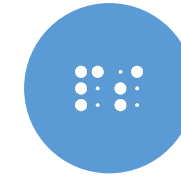
**Prescribing information can be found;**  
**Website: at the top of the page**  
**Presentation: at the end of the presentation**



# Complications

# Eyebrow ptosis

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Occurs 1-5% cases



Occurs when treating forehead lines

---

# Preventing eyebrow ptosis



Patient selection



Correct anatomical assessment



Correct treatment planning



Examine full range of frontalis muscle



Consider injecting depressor muscles



Low dose



Split areas to be treated



Caution with older patients (>50 years)



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# Treatment of eyebrow ptosis

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Corrugator supercili

---

Procerus

---

Depressor supercili

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Obicularis oculi medially

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Obicularis oculi laterally

# Mephisto effect / Dr Spock

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# Frown

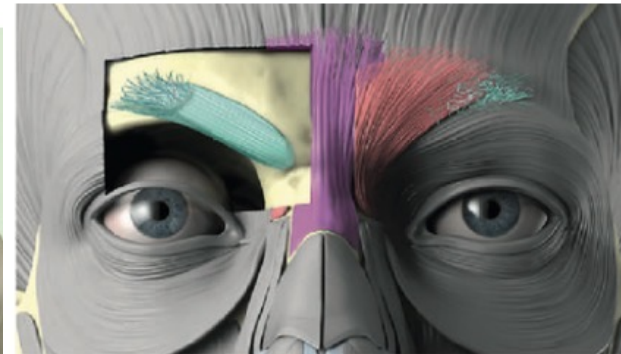
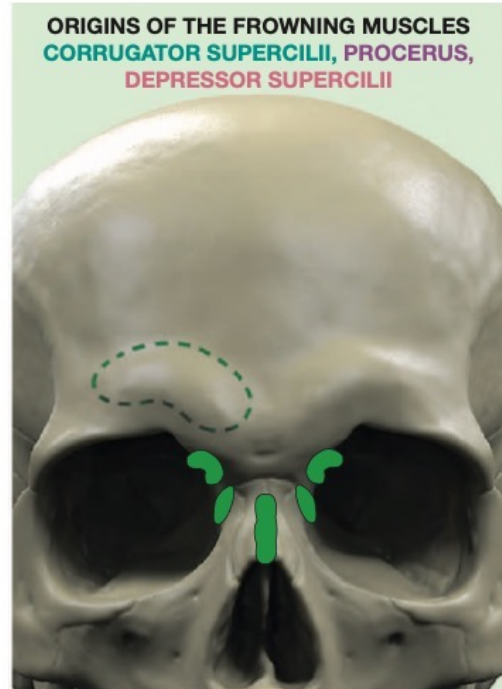
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BROW  
LOWERER



**PROCERUS**  
**DEPRESSOR  
SUPERCILII**  
**CORRUGATOR  
SUPERCILII**

# Frown lines

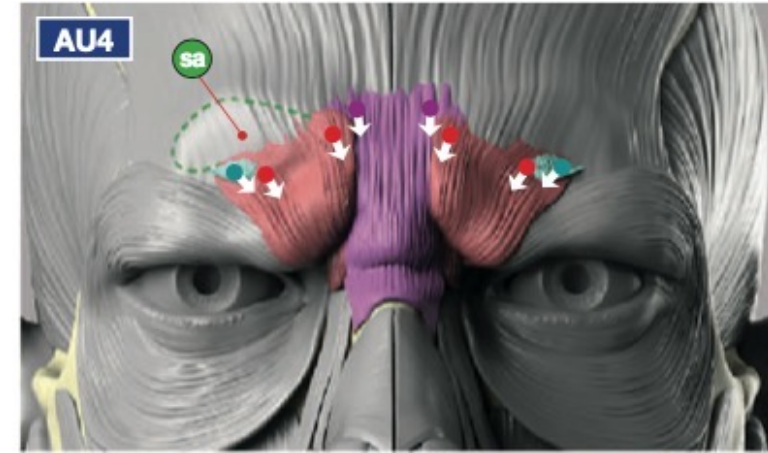
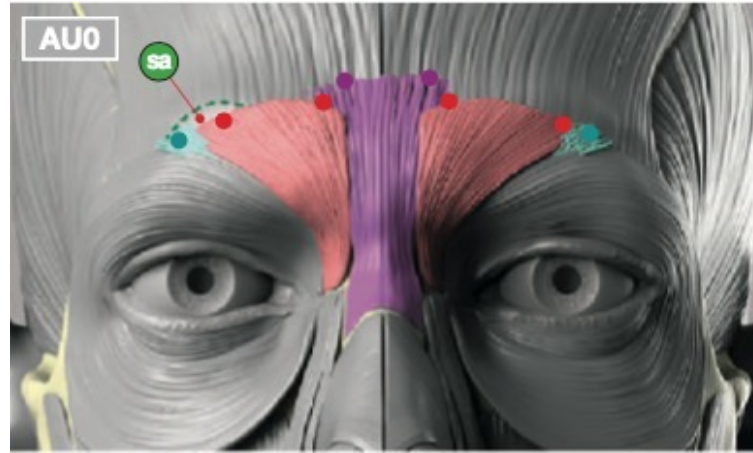
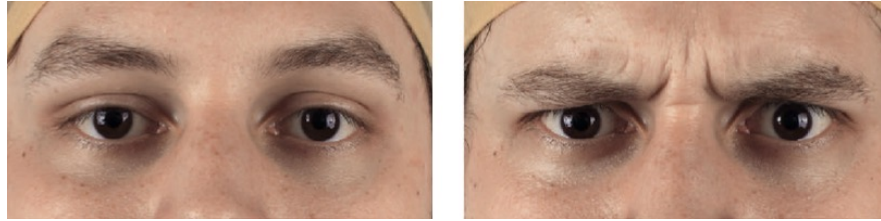


NAME:	<b>DEPRESSOR SUPERCILII</b> (D)
ORIGIN:	LATERALS OF THE NASAL BRIDGE
INSERTION:	FLARES OUT ACROSS THE INTERCANTAL REGION, FRONTALIS MUSCLE, AND UNDER THE SKIN ABOUT LEVEL WITH THE EYEBROWS
ACTION:	DRAWS DOWN THE EYEBROWS, ALONG WITH THE <b>PROCERUS</b> , THE HORIZONTAL WRINKLE AT THE BRIDGE OF THE NOSE

NAME:	<b>PROCERUS</b> (P)
ORIGIN:	MIDLINE OF THE NASAL BONE AND NASAL CARTILAGE
INSERTION:	THE SKIN OF THE LOWER TO MID FOREHEAD BETWEEN THE EYEBROWS, MERGING WITH FIBERS OF THE FRONTALIS MUSCLE
ACTION:	THE PROCERUS HELPS DRAW DOWN THE SKIN BETWEEN THE EYEBROWS, AND ASSISTS IN FLARING THE NOSTRILS. IT ALSO CONTRIBUTES TO AN EXPRESSION OF ANGER OR INTENSITY

NAME:	<b>CORRUGATOR SUPERCILII</b> (C)
ORIGIN:	MEDIAL SUPERCILIARY ARCH
INSERTION:	FOREHEAD SKIN NEAR THE EYEBROWS
ACTION:	PULLS THE EYEBROWS DOWNWARD AND TOWARD THE MIDLINE OF THE NOSE

# Frown lines



- THE **CORRUGATOR** AND **DEPRESSOR SUPERCILII** PULLS THE EYEBROWS TOGETHER AND DOWNWARDS, PARTLY COVERING THE UPPER EYELID, CREATING VERTICAL WRINKLES BETWEEN THE EYEBROWS AND BECAUSE THE EYEBROW MOVES DOWN, IT MAKES SUPERCILIARY ARCHES MORE VISIBLE (**sa**).
- THE **PRO CERUS** PULLS THE SKIN OF THE GLABELLAR REGION DOWN AND CREATES A LINE ACROSS THE BRIDGE OF THE NOSE.



# Patient selection

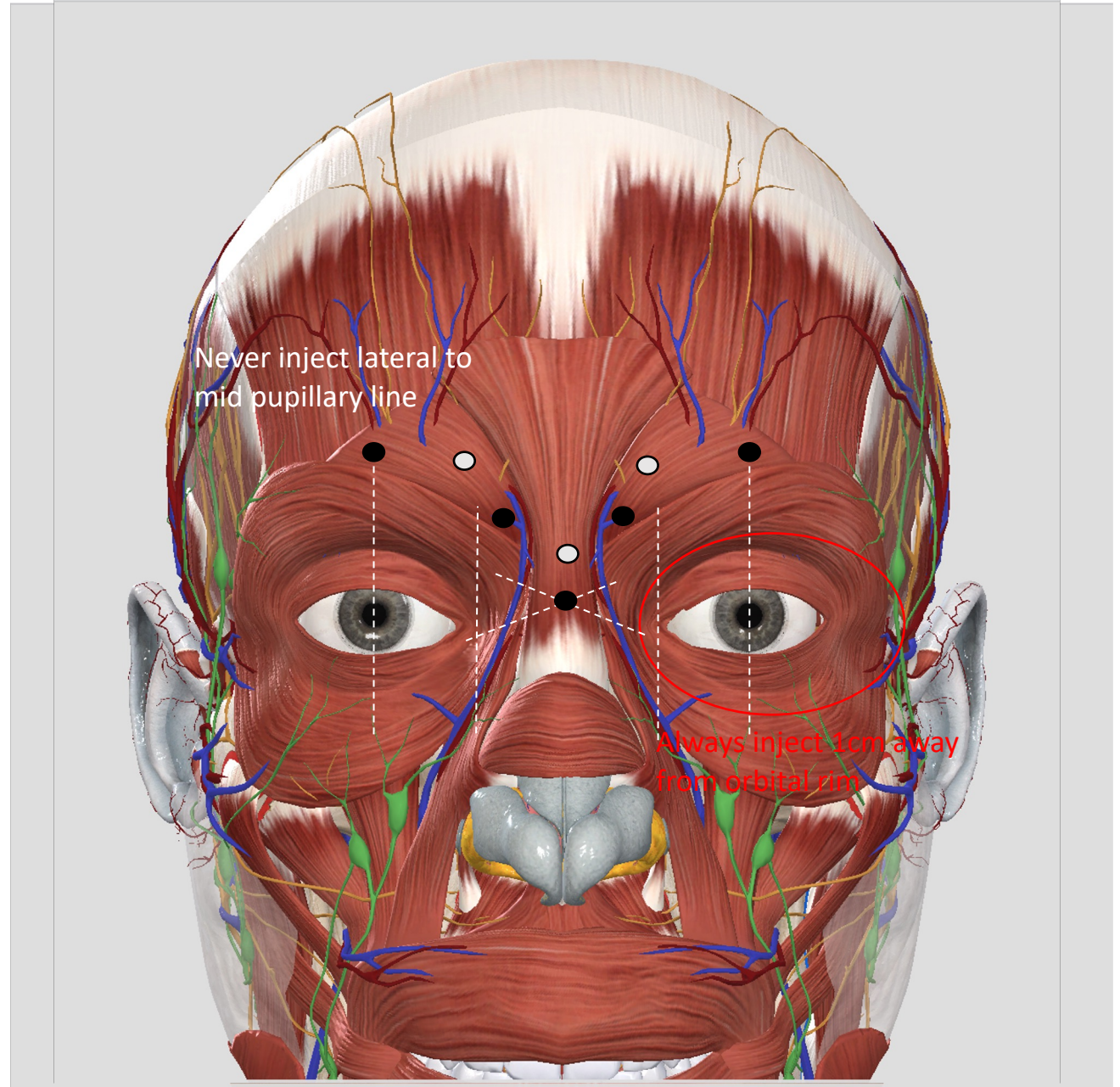
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- Kinetic and hyperkinetic patients best to treat
- Kinetic patient's lines only with movement and usually superficial
- Hyperkinetic patient's lines seen in dynamic situations and are deeper
- Hypertonic patients more difficult to treat with BOTOX alone
- Lines at rest so may need additional fillers
- Avoid patients who present with brow ptosis

# Marking up

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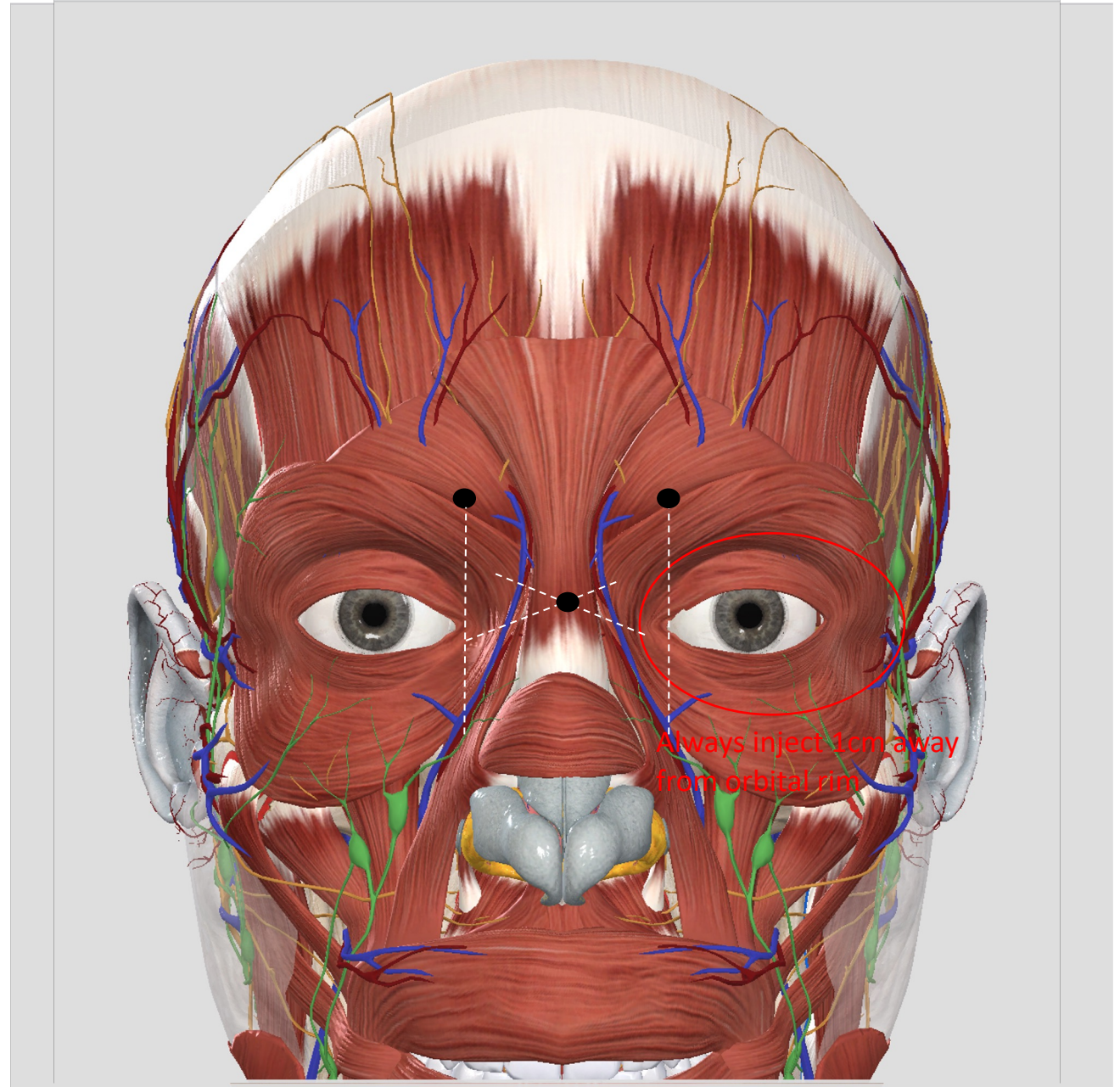
- **Keeping eyebrows same shape**
- Higher doses medially
- Lower doses laterally
- For flat eyebrows higher dose on lateral corrugator than arched eyebrows



# Marking up

---

- **Arching eyebrows**
- Higher doses medially
- No dose laterally





# Dosages – Eyebrows same shape

Muscle	Mild wrinkling (units/injection site)	Moderate wrinkling (units/injection site)	Severe wrinkling (units/injection site)	Extra injections (units/injection site)
Procerus	2 units Bocoulture 10 units Azzalure 2 units BOTOX	4 units Bocoulture 15 units Azzalure 3 units BOTOX	6+ units Bocoulture 20 units Azzalure 4 units BOTOX	Half the first injection
Medial Corrugator	2 units Bocoulture 10 units Azzalure 2 units BOTOX	4 units Bocoulture 10-12 units Azzalure 2-2.5 units BOTOX	6+ units Bocoulture 12-15 units Azzalure 2.5-3 units BOTOX	Half the first injection
Lateral Corrugator	1 unit Bocoulture 5 units Azzaliure 1 unit BOTOX	2 units Bocoulture 10 units Azzalure 2 units BOTOX	3 units Bocoulture 10-12 units Azzalure 2-2.5 units BOTOX	Half the first injection

# Tips

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- Deep injection in procerus and corrugators medially
- Higher dose central muscles, lower dose lateral muscles
- Identify architecture of eyebrows and any asymmetry
- Open eye up by raising tail of eyebrow
- Stay 1 cm above orbital rim – WRONG
- Men need higher doses



# BOCOUTURE® Vertical Lines (Glabellar Frown Lines) Injection Technique by Dr Simon Ravichanchan MBChB.MRCS

# BOCOUTURE®

Botulinum toxin type A  
free from complexing proteins

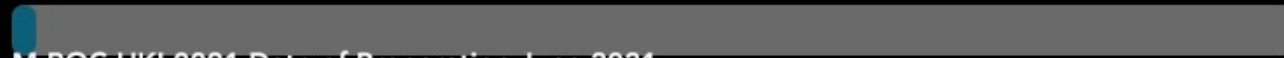
**BOCOUTURE® is indicated for the temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines has an important psychological impact for the patient:**

- Moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar frown lines) and/or
- Moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or
- Moderate to severe horizontal forehead lines seen at maximum contraction

Prescribing information can be found;  
Website: at the top of the page  
Presentation: at the end of the presentation



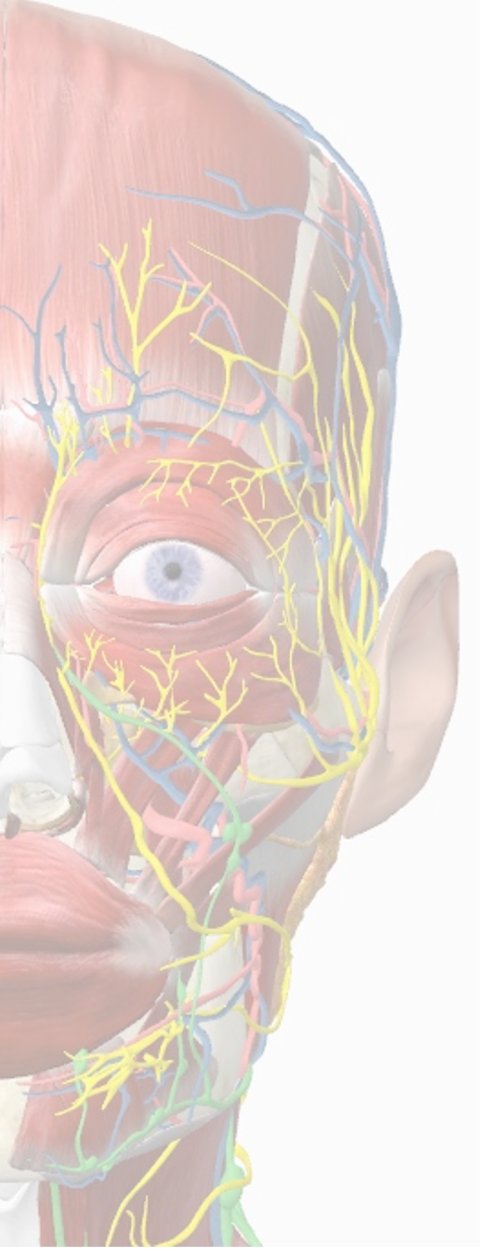
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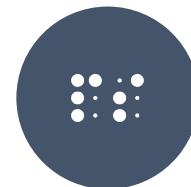
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# Complications

# Upper eyelid ptosis

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OCCURS 6.5-11% CASES



LEVATOR PALPEBRAE  
SUPERIORIS MUSCLE



CAN OCCUR 2-10 DAYS  
POST TREATMENT



RANGE FROM PARTIAL  
TO FULL COVERAGE OF  
THE EYE



P/O HEAVY EYELID LOOK  
WORSENING  
THROUGHOUT THE DAY

---

# Preventing upper eyelid ptosis

---

Patient selection

---

Correct anatomical assessment

---

Good injection technique

---

May be pre-existing ptosis

---

History of facial surgery

# Treatment of upper eyelid ptosis



- 1-2 drops TDS
- 1-3mm elevation of upper eyelid
- Targets mullers muscle
- OR inject more toxin in upper eyelid

# Crow's feet

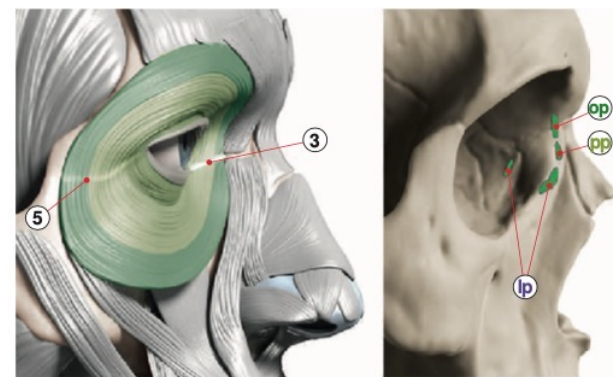
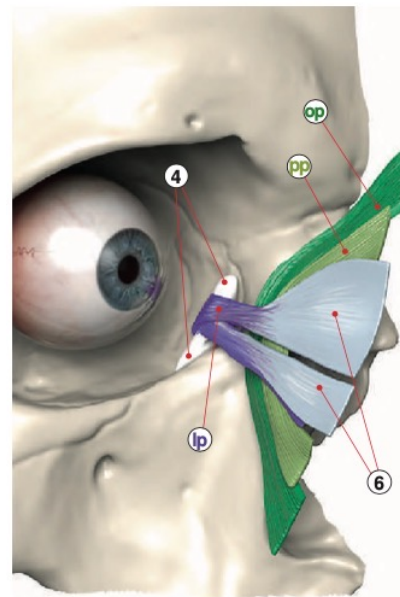
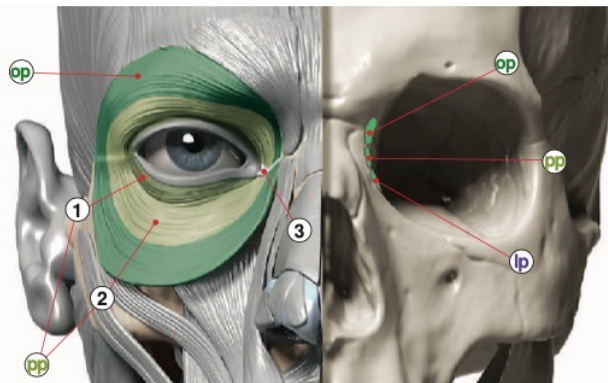
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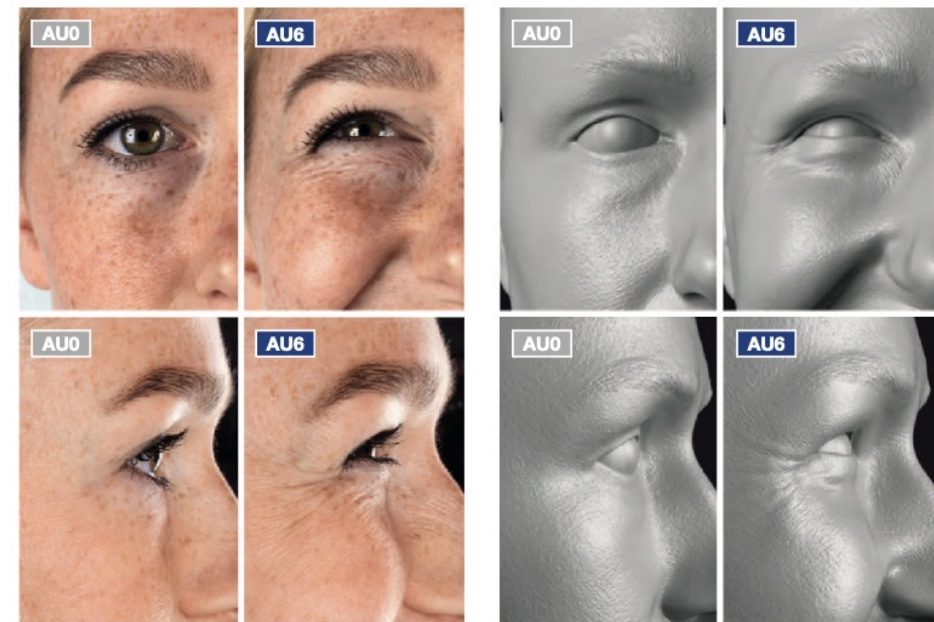
THE **ORBICULARIS OCULI** MUSCLE IS DIVIDED INTO THREE PARTS:

- 1) THE **ORBITAL PART (op)** ENCIRCLES THE ENTIRE EYE ABOVE AND BELOW. THE **op** FIBERS FORM A COMPLETE ELLIPSE AROUND THE ORBIT WITH THE UPPER FIBERS BLENDING WITH THE **FRONTALIS** AND **CORRUGATOR** MUSCLES.
  - 2) THE **PALPEBRAL PART (pp)**, WITH PRETARSAL AND PRESEPTAL PORTIONS IS A THIN LAYER WHICH IS ESSENTIALLY PART OF THE EYELID. THE PALPEBRAL PART IS ALSO KNOWN AS THE TENSOR TARSII. IT IS A SMALL THIN MUSCLE SITUATED BEHIND THE MEDIAL **PALPEBRAL LIGAMENT** AND **LACRIMAL SAC**.
  - 3) THE **LACRIMAL PART** PULLS **THE EYELIDS**, THE TARSUS OR TARSAL PLATES MEDIALLY, REGULATES THE LACRIMAL FLUID ON THE EYE, AND RESHAPES THE EYEBALL POSITION.
- THE **OCULI MUSCLE** IS PRIMARILY RESPONSIBLE FOR CLOSING THE EYELIDS AND BLINKING, AND ALLOWS HUMANS TO SQUINT OR WINK THEIR EYES.



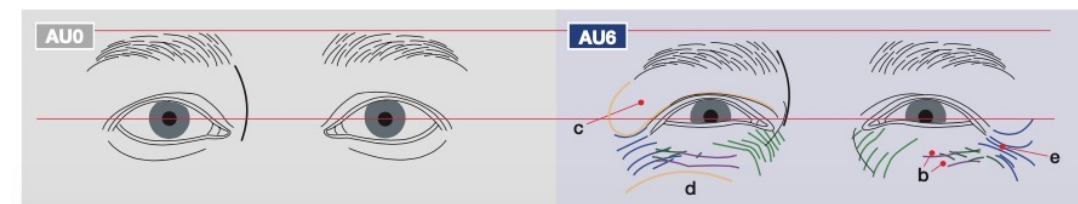
<b>op</b>	<b>ORBITAL PART</b>
<b>pp</b>	<b>PALPEBRAL PART</b>
<b>lp</b>	<b>LACRIMAL PART</b>
1	PRETARSAL PORTION
2	PRESEPTAL PORTION
3	MEDIAL PALPEBRAL LIGAMENT
4	LACRIMAL SAC
5	LATERAL PALPEBRAL RAPHE
6	TARSAL PLATES

NAME:	<b>ORBICULARIS OCULI</b>
ORIGIN:	FRONTAL, LACRIMAL, MAXILLA BONE, MEDIAL PALPEBRAL LIGAMENT
INSERTION:	LATERAL PALPEBRAL RAPHE
ACTION:	CLOSES EYELIDS



**AU6** DRAWS SKIN TOWARDS THE EYE FROM THE TEMPLE AND CHEEKS. AS THE **ORBITAL PORTION** OF THE **O.O.** MUSCLE CONSTRICTS IT:

- a** - NARROWS THE EYE APERTURE
- b** - BAGS OR WRINKLES THE SKIN BELOW THE EYE
- c** - PUSHES THE EYE COVER FOLD DOWN
- d** - RAISES THE CHEEK UPWARDS
- e** - POTENTIALLY CAUSES CROW'S FEET "LAUGH LINES" OR WRINKLES



# Patient selection

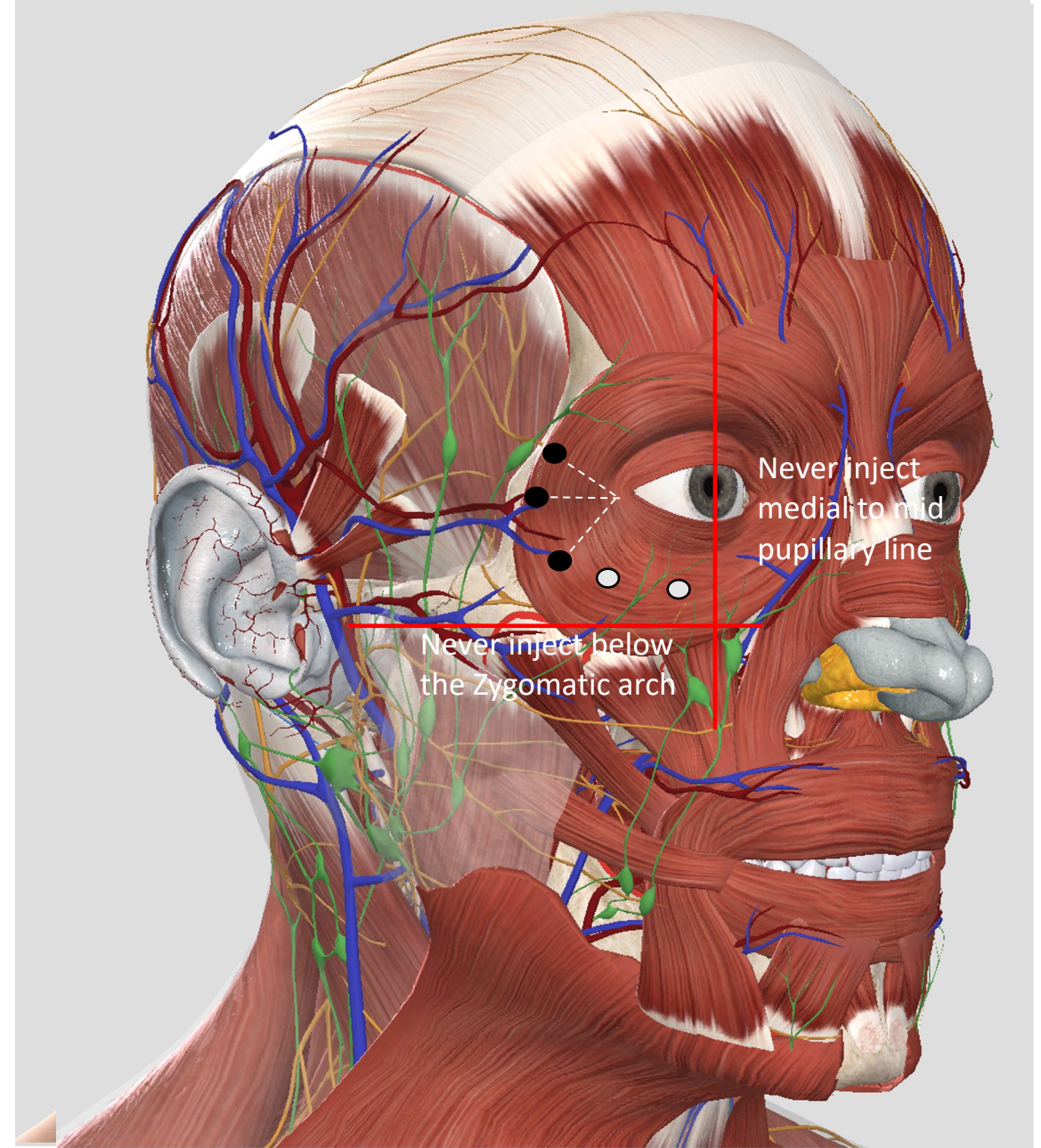
- Blue/green eyed patients often more lateral periorbital wrinkling
- Thinner skin patients more delicate wrinkling
- Thicker skin patients more prominent deeper wrinkles
- More atrophic the skin the more finer lines
- Wrinkle extension related to muscle size
- Avoid patients with pseudo-herniation
- Avoid patients with scleral show

# Patient assessment

- How deep are the lines
- How strong/active are the muscles
- How lax is the skin under the eye – snap test
- Presence of blood vessels
- Extent of the lines – how far they radiate – micro-injection technique
- Does the patient want to soften them or eradicate them completely
- Are lines present at rest

# Marking up

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# Dosages

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Muscle	Mild wrinkling (units/injection site)	Moderate wrinkling (units/injection site)	Severe wrinkling (units/injection site)	Extra injections (units/injection site)
Obicularis Oculi	2 units Bocoulture 5 units Azzalure 1 unit BOTOX	3 units Bocoulture 10 units Azzalure 2 units BOTOX	4 units Bocoulture 15 units Azzalure 3 units BOTOX	2-4 units Bocoulture 5-10 units Azzalure 1-2 units BOTOX

# Crow's feet tips

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- Cautious of blood vessels in fair haired people
- Always inject 1 cm away from orbital rim
- Always inject above the zygomatic arch
- NEVER inject medial to mid pupillary line
- ALWAYS perform snap test beneath the eye
- Women tend to want to eradicate completely
- Keep superficial



# BOCOUTURE® Lateral Periorbital Lines (Crow's Feet Lines) Injection Technique by Dr Simon Ravichanchan MBChB.MRCS

# BOCOUTURE®

Botulinum toxin type A  
free from complexing proteins

**BOCOUTURE® is indicated for the temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines has an important psychological impact for the patient:**

- Moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar frown lines) and/or
- Moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or
- Moderate to severe horizontal forehead lines seen at maximum contraction

Prescribing information can be found;  
Website: at the top of the page  
Presentation: at the end of the presentation



00:00

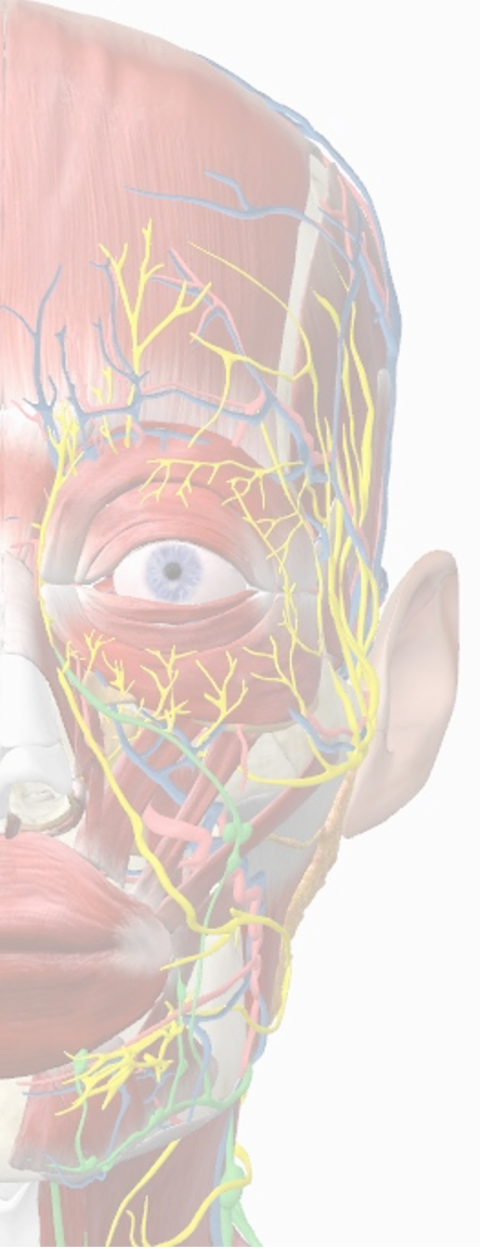
M-BOC-UKI-0090 Date of Preparation June 2021

00:47



HD

1x



# Complications



# Complications

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- Ecchymosis
- Lip asymmetry
- Cheek ptosis
- Pseudo-herniation
- Impaired blink reflex and forced eyelid closure
  - Dry eyes
  - Corneal exposure

# Middle third of the face

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- Gummy smiles

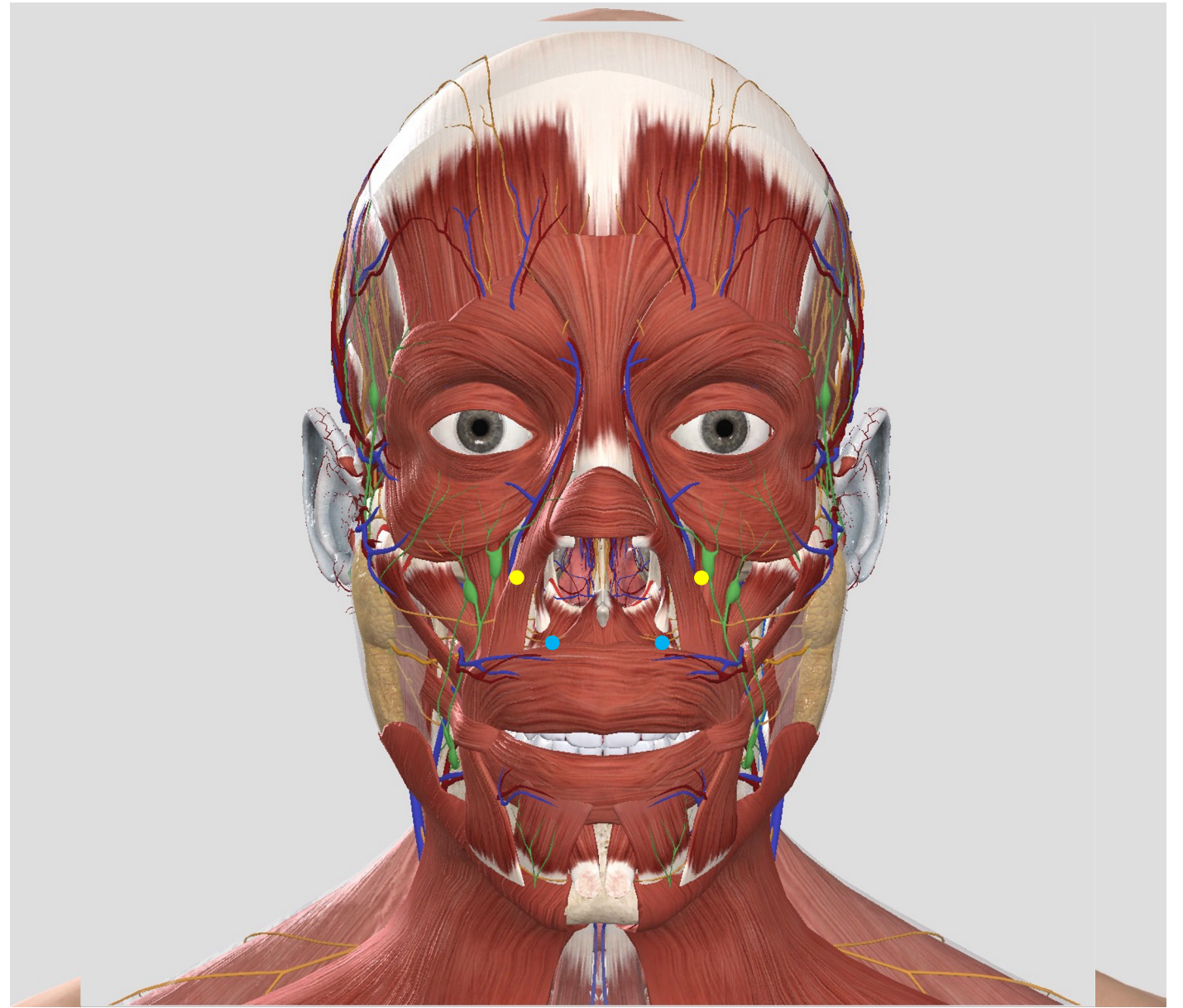
# Gummy smiles



# Marking up

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- Smile at maximum contraction
- Examine lip length
- Presence of nasolabial folds
- ● superficial injection (if NLF)
- ● deep injection
- Levator labii superioris ●
- Levator labii superioris alaeque nasi ●



# Dosages – Gummy smile

Muscle	Minor gummy smile (units/injection site)	Moderate gummy smile (units/injection site)	Severe gummy smile (units/injection site)	Extra injections (units/injection site)
Levator labii superioris alaeque nasi	2 units Bocoulture 5 units Azzalure 1 units BOTOX	3 units Bocoulture 10 units Azzalure 2 units BOTOX	4 units Bocoulture 12units Azzalure 2.5 units BOTOX	Half the first injection
Levator labii superioris	2 units Bocoulture 5 units Azzalure 1 units BOTOX	3 units Bocoulture 10 units Azzalure 2 units BOTOX	4 units Bocoulture 12 units Azzalure 2.5 units BOTOX	Half the first injection

myFACE.

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training

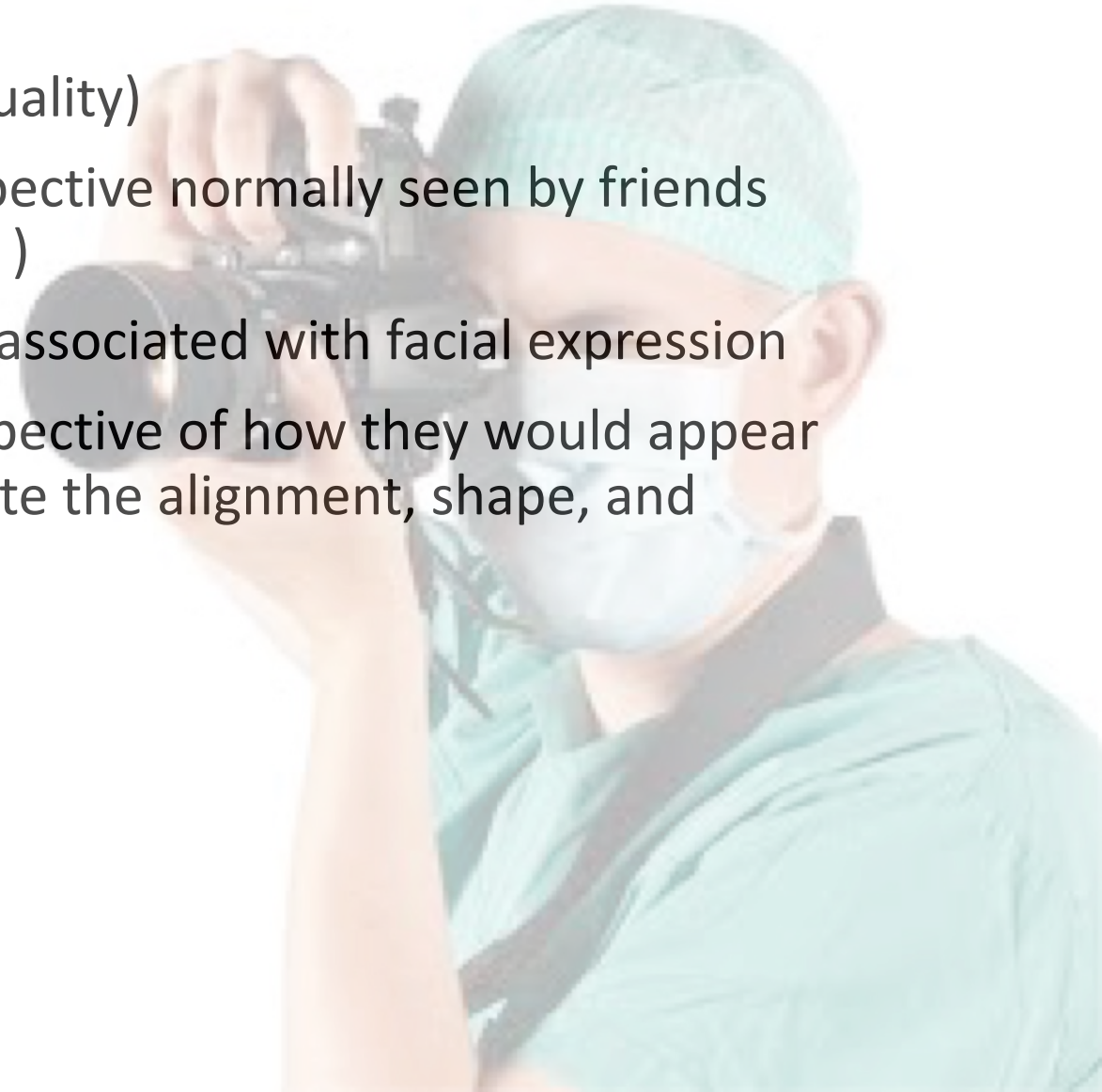
# Photography

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- Pre-treatment status of patient
- Standardised photographs at rest in motion and marking up
- Include video of movement if available
- Similar for post-treatment status of patient
- Clinic Ipad



- Ideally use black back drop (compensation & quality)
- Create a series of photographs of a visual perspective normally seen by friends and colleagues (not always apparent to patient )
- Relaxed/active groups demonstrating wrinkles associated with facial expression
- Relaxed/smile groups give the patient the perspective of how they would appear if their faces had more volume, and demonstrate the alignment, shape, and colour of the dentition





# Record keeping

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- Record product expiry date and batch number
- Record diluent
- Record date diluted
- Record areas treated and dose
- Record local anaesthesia type
- Record batch number and expiry date of LA
- Standard POIG, review date etc
- Record photographs taken
- Record consent for treatment and photographs



# Consent

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- Appropriately manage patient's expectations
- Written informed consent paramount
- **State off license use** if injecting other areas
- Patient's aware pre-treatment appearance
- Photography consent
- Only treat hyperdynamic lines
- Specific to area of treatment
- Include complications
- Explain review after 14 days/retreatment

# Marketing

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The Advertising Standards Authority will request companies who advertise prescription medicines to remove any references from their adverts and the Medicines and Healthcare Products Authority are responsible for enforcing the law



# Marketing

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- Internal marketing
- External marketing
- Social media
- Word of mouth





## Enforcement Notice: Advertising Botox and other botulinum toxin injections

### What if I administer POMs and non-POMs?

Non-POMs, such as dermal fillers, may be advertised provided there is no implication that a POM is also available.



**Be specific** and use terms such as "dermal fillers" or "cosmetic fillers" to be expressly clear that you are only advertising your non-POM "filler".



**Do not** describe your non-POM product range in an ambiguous way. For instance, avoid juxtapositions such as "anti-wrinkle injections and dermal fillers" which would imply that the "injections" in question are POMs.

### What if I only administer POMs?

In short, POMs such as Botox cannot be advertised to the public. You should focus on aspects of your service which do not relate directly to the provision of a POM. You could:



**Promote** the service you provide and the consultation itself. Claims such as "a consultation for the treatment of lines and wrinkles" may be acceptable – but if using this approach you must be careful not to directly or indirectly advertise the POM.

### Appendix: Code rules, legislation and useful reading

This guidance should be read in conjunction with the [MHRA's The Blue Guide: Advertising and Promotion of Medicines in the UK](#) which explains the provisions and requirements laid down in the legislation on advertising medicines. Specifically, [Appendix 6](#) of the Blue Guide outlines the requirements for treatment service providers to help you ensure you don't break the law.

#### Relevant [CAP Code](#) rules:



**12.12** Prescription-only medicines or prescription-only medical treatments may not be advertised to the public.

#### Relevant legislation:



The [Human Medicines Regulations 2012](#) prohibit the publishing of an "advertisement that is likely to lead to the use of a prescription only medicine", as laid out in Chapter 2, *Advertising to the public*, 284 (1).

**Want more?** See CAP's advice on: [Anti-ageing: Botulinum toxin products](#), [Hyperhidrosis and Healthcare: Prescription-only medicine](#)

Or contact the CAP [Copy Advice team](#), which offers a free and confidential bespoke pre-publication advice service



## Enforcement Notice: Advertising Botox and other botulinum toxin injections

### Who we are

We are the [Committee of Advertising Practice](#) (CAP). We write the advertising rules, which are enforced by the Advertising Standards Authority (ASA), the UK's independent advertising regulator. You can read about the UK advertising regulatory system [on the ASA website](#).

The [Medicines and Healthcare products Regulatory Agency](#) (MHRA) is the UK statutory regulator for medicines, medical devices and blood components for transfusion.

### Why are we contacting you?

We understand that businesses in your sector have advertised botulinum toxin injections on social media. Botulinum toxin injections – most commonly Botox, but also Vistabel, Dysport, Bocouture, and Azzalure – are prescription-only medicines (POMs).

POMs cannot be advertised to the public. Ads for POMs breach [Rule 12.12 of the CAP Code](#) and the [Human Medicines Regulations 2012](#) (HMRs). This applies even if the POM is administered by a registered medical professional.

Please take immediate action to review your social media ads and make changes as needed. **After Friday 31<sup>st</sup> January, we will take targeted enforcement action using monitoring technology to automatically find problem posts for removal.** This can include – where advertisers are unwilling to comply – referral to the MHRA or your professional regulatory body.

### Scope

This notice applies to all promotion of botulinum toxin injections to UK consumers on social media platforms. This includes paid-for ads, non-paid-for marketing posts on your or others' pages and influencer marketing. Ads that are aimed only at healthcare professionals are excluded from the rule (but we understand almost all ads/posts on social media could be seen by the public). This notice does not apply to non-POM products e.g. dermal fillers.

### Guidance

Take care not to directly or indirectly promote POMs to the public when promoting the treatment services you offer on social media.



**Remove** direct references to Botox or other POMs. This includes names such as "Beautytox" or "Beautox" where the obvious inference is a reference to Botox.

- **Remember** – this includes [references in images](#) and [hashtags e.g. #botox](#)
- **Also** – this covers all promotional marketing, like offering "Botox parties" or "[Botox treatment](#)" as a competition prize or in a sale package.



**Do not** substitute direct references to POMs with indirect phrases that can only refer to a POM such as "wrinkle relaxing injections". This is [indirect promotion of a POM](#), and just as much of a problem.



**Be aware** the ASA considers that a reference to "anti-wrinkle injections" alongside a price that relates to a POM [will be seen as an ad for that POM](#) (also see below re "anti-wrinkle injections" claims)



**Avoid** references to treating medical conditions in a way that could indicate the promotion of a POM, for example ["injections for excessive sweating" \(hyperhidrosis\)](#). If you offer non-POM treatments, you could instead refer to "treatments for excessive sweating" or similar.



# Digital boom – Allergan 360 report

The study found that 28% (n=14,584) of global consumers turn to the internet as their first stop when searching for a dermatologist or plastic surgeon for an aesthetic treatment and 82% (n=351) of U.S. consumers (ages 21-35) turn to Instagram as their leading source of information.\*

Social media IS KING !



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# Regulations

- Unregulated
- Save face
- Dental indemnity
- Facial aesthetic malpractice
- Cosmetic insure
- Hamilton Fraser



# Malpractice vs Indemnity

Medical malpractice	Medical indemnity
Contractual between insurers and the insured	Contractual between insurers and the insured
Cover only provided whilst policy in force, run off cover must be purchased once stop practising	Cover for treatment provided at the time the policy was in force
Excess payment for each claim	No excess

# Save Face

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Save Face is a national register of Accredited practitioners who provide non-surgical cosmetic treatments such as anti-wrinkle injections and dermal fillers. Our Register is accredited by Professional Standards Authority and is recognised by the Government, The Department of Health, NHS England and The Care Quality Commission.



# Materials

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- FMS 32gauge 8mm 0.3ml syringe
- BD insulin 30gauge 8mm 0.3ml syringe
- 21gauge green needles (drawing up)
- 2.5ml (max) syringe
- Preserved NaCl (0.9%)
- Marking up pen
- Skin cleanser – Natrasan or Clinisept
- Gauze
- Make up remover

# Fee per area

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	Lowest	Highest	Average
One area	£97	£350	£194
Two areas	£147	£350	£262
Three areas	£167	£400	£317
Armpits	£300	£560	£447



# Vat rules

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- Medical treatments aren't subject to VAT
- Cosmetic procedures ARE subject to VAT
- VAT threshold is £85,000
- If exceed threshold – VAT registered, Pass onto client, or absorb yourself
- 'positive effect on quality of life and confidence'.

(A recent tribunal judge was not satisfied that the 'principal purpose' of the 'injectable treatments' was to 'protect, restore or maintain' health, rather than 'for cosmetic reasons').

# Further Reading

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- [www.oeofirenze.com](http://www.oeofirenze.com)
- Archidemia.com
- Illustrated Guide to Injectable Fillers – Gerhard Sattler & Uliana Gout
- Injectable fillers in aesthetic medicine – Mauricio de Maio & Berthold Rzany
- The New Face – Federico Loreto & Paola Rosalba Russo
- Botulinum toxin A in aesthetic medicine – Alessio Redaelli



# Disclaimer

- This course is run by myFACE training. This course is believed to be based on good practice and current research.
- It includes discussions of un-licensed indications
- myFACE courses are recognised by Hamilton Fraser Insurance
- Certification of this course is on an attendance basis only and is not necessarily a statement of competency
- myFACE does not take any responsibility for your technique or subsequent actions as a result of attending this course



# Contact details

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# Questions