

GALDERMA

EST. 1981

# SCULPTRA® TRAINING CURRICULUM

Created with the support of

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**MANY OF TODAY'S PATIENTS  
WANT TO LOOK BETTER  
WITHOUT LOOKING TREATED**

And want gradual, long-lasting  
results



\*Packaging images may vary by country; for illustration purposes only.  
Weinkle S, Lupo M. *J Clin Aesthetic Dermatol.* 2010;3(9):30-33.

# Patients Prefer Long-Lasting Results

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## What do patients want?

- To look good for their age
- Want something other than line and wrinkle treatments
- To experience long-lasting treatment results

**75%** of women surveyed about treatment desires preferred gradual results that last 2 years over immediate results lasting 12 months

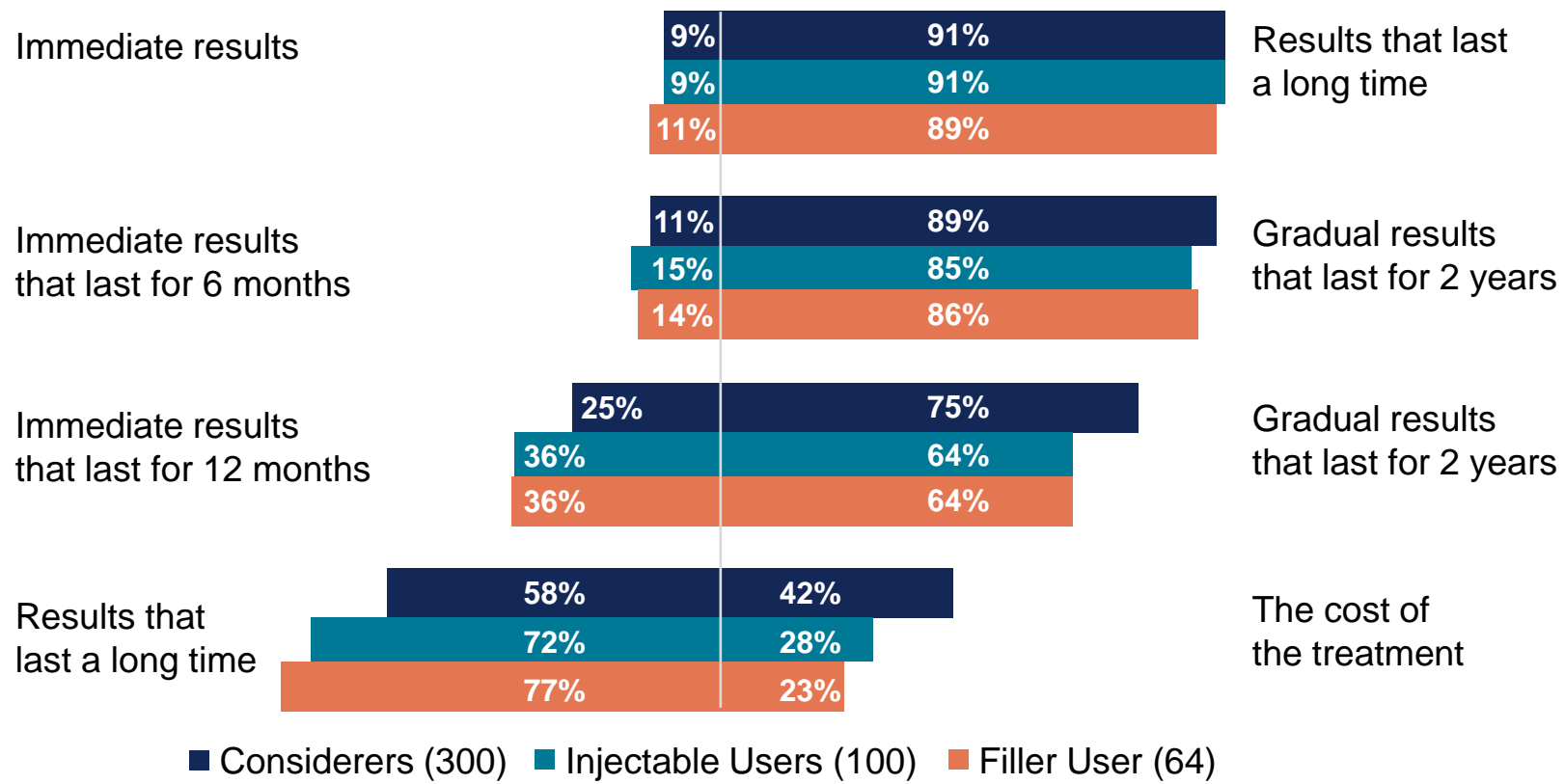


From a survey of consumer attitudes around medical anti-aging treatments for the face conducted with 383 women 35–69 years of age considering medical anti-aging treatments within the next 2 years

# Patients Are Seeking Gradual, Long-Lasting Results

ASDS-Sponsored Survey of Women's Attitudes, Awareness, and Use of Medical Antiaging Techniques (N=383)

## Paired Comparison Analysis of Factors Affecting Women's Treatment Decisions



**>70%** of respondents prioritized gradual, long-lasting results over rapid, short-term results



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Natural-looking results for each and every patient's needs



RELAX

Azzalure®  
Botulinum toxin type A  
Dysport.  
Botulinum toxin type A



REFINE

Restylane



REFRESH

Restylane®  
SKINBOOSTERS™



RENEW

Sculptra®

Lift	Fill	Volumize
Restylane LIFT	Restylane	Restylane KYSSE®
Restylane DEFYNE™	Restylane REFYNE	Restylane VOLYME™

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A patient needs based approach

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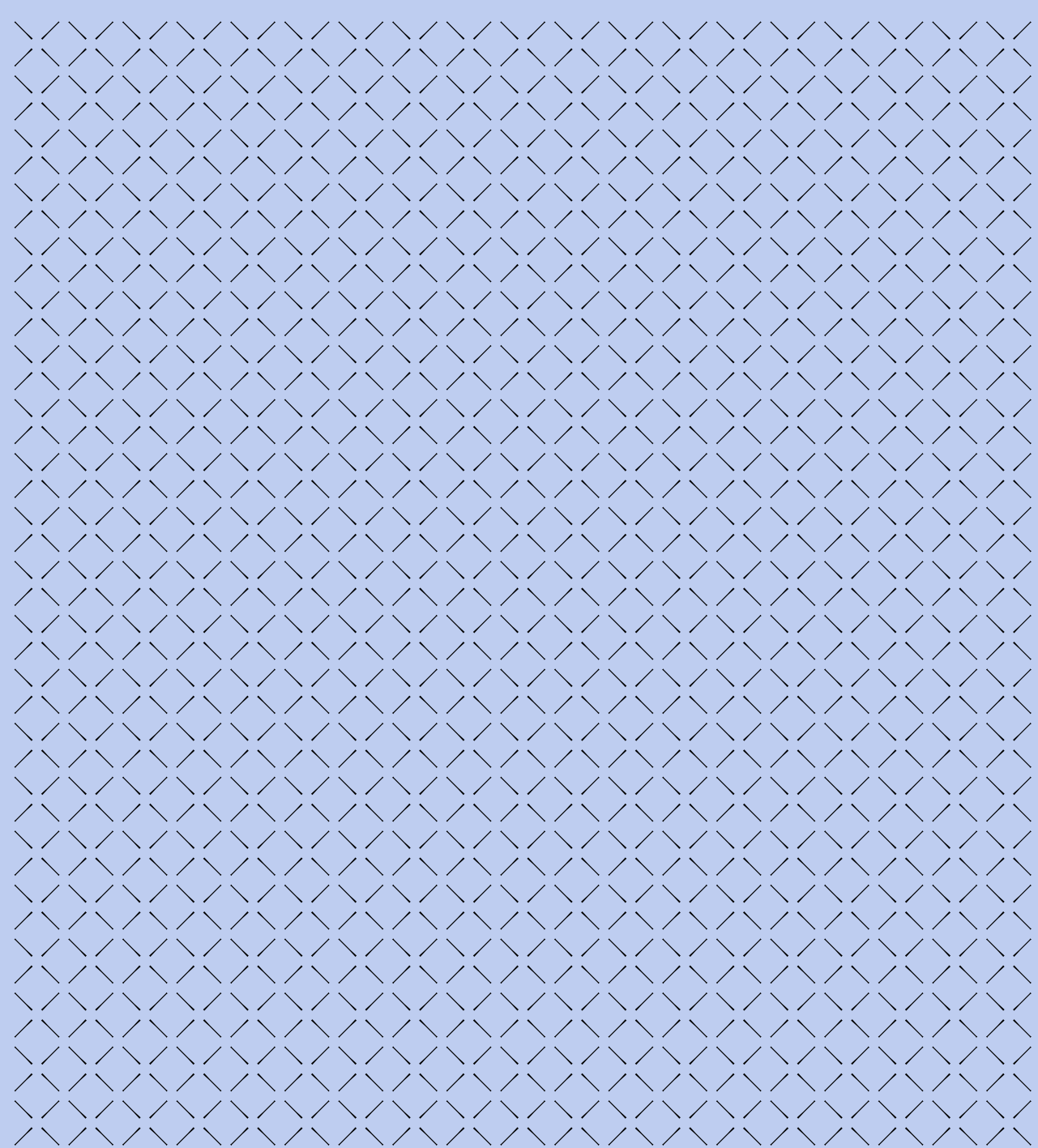
## Pathophysiology of Aging

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# Facial Aging Involves Structural Changes

To surfaces and  
sub-surfaces

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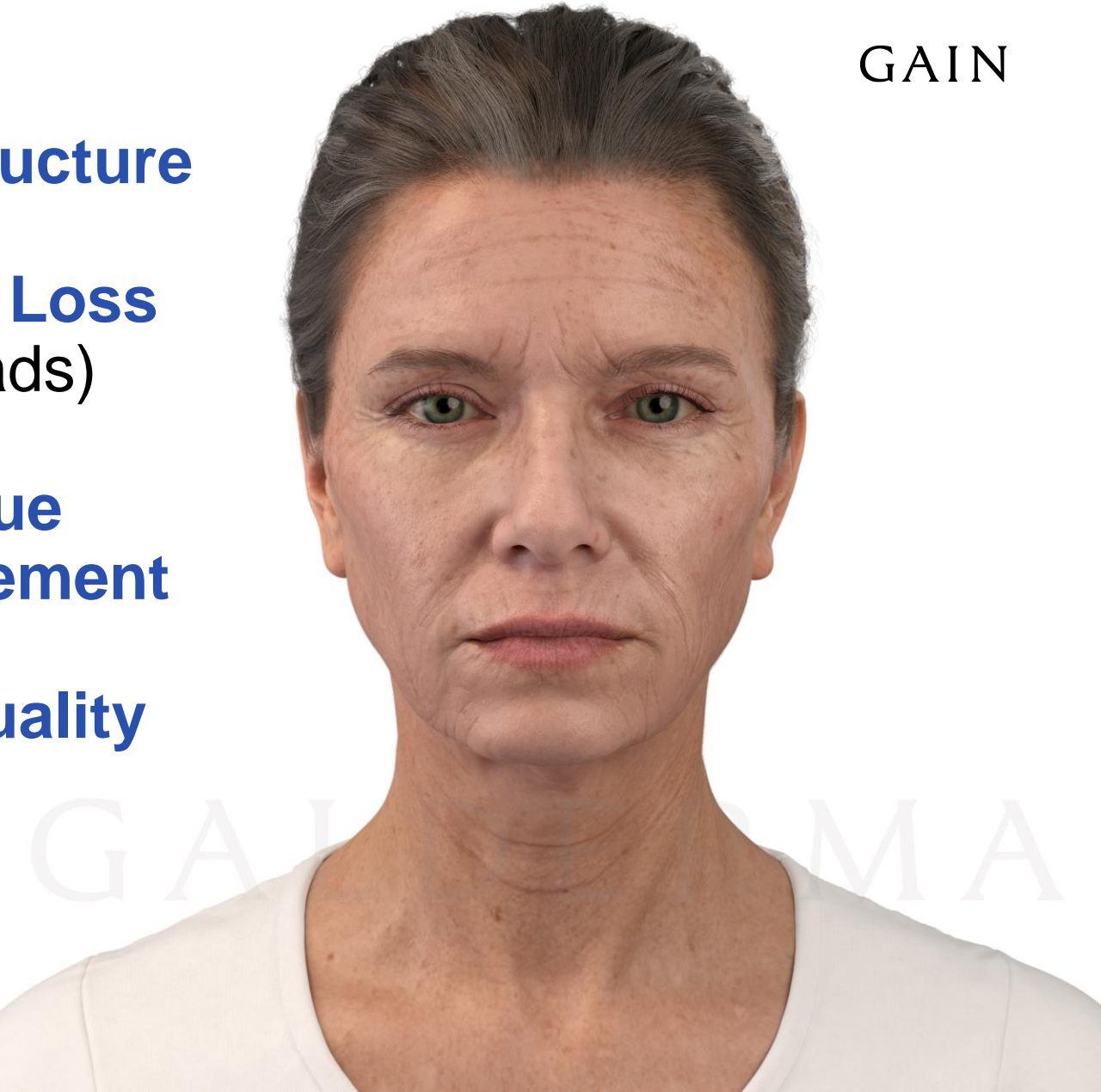
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**Bone Structure**

**Volume Loss**  
(fat pads)

**Tissue Displacement**

**Skin Quality**



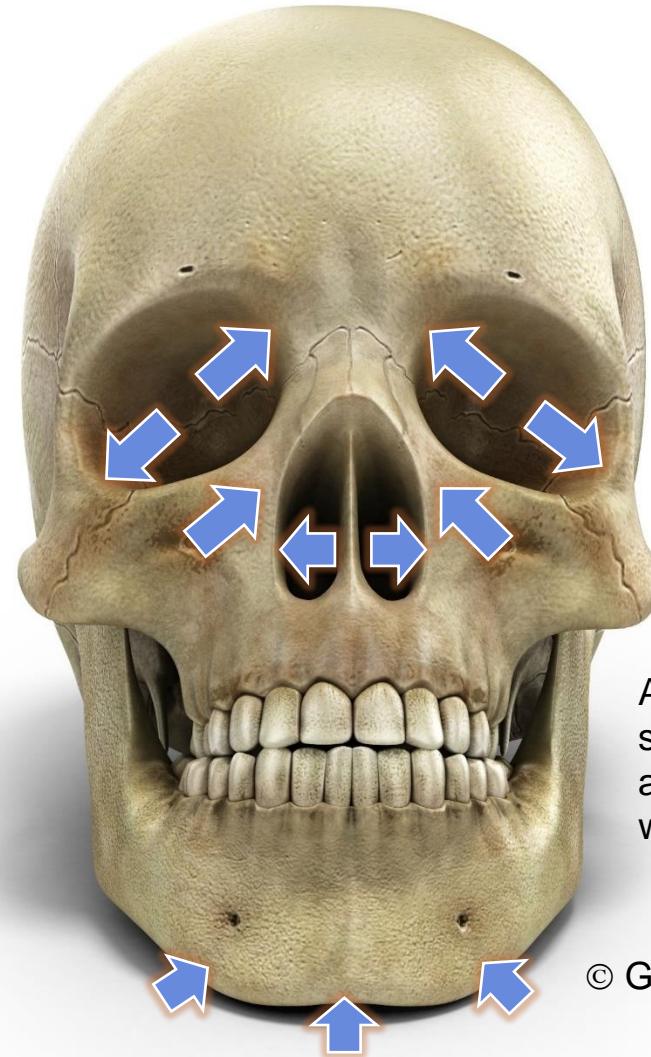
GALDERMA GALDERMA GALDERMA GALDERMA



# Facial Skeleton Is Susceptible to Resorption

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- Changes occur mainly in the periorbital and mid cheek and specifically include the superomedial and inferolateral aspects of the orbit, the medial suborbital and pyriform areas of the maxilla and the prejowl area of the mandible.



Arrows indicate the areas of the facial skeleton susceptible to resorption with aging. The size of the arrow correlates with the amount of resorption.

© Galderma

## Orbit aging



Male, 18 years



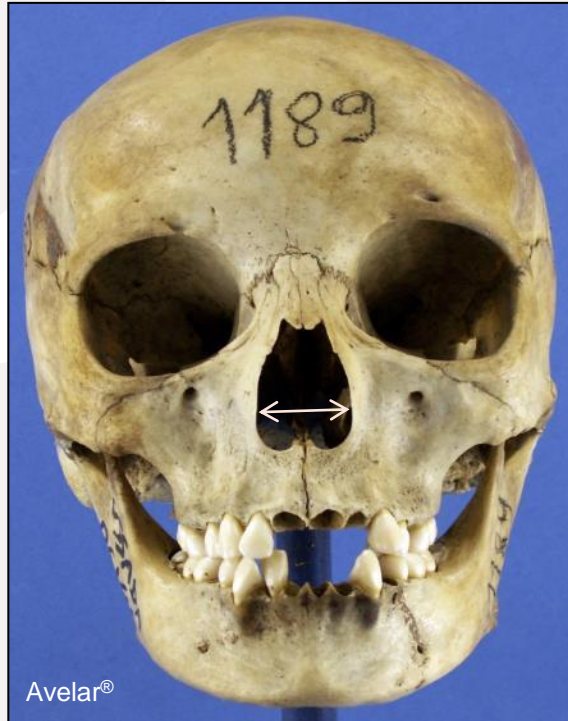
Male, 41 years



Male, 63 years

# Bone structure – Piriform Aperture

## Piriform aperture aging



Male, 18 years



Male, 41 years

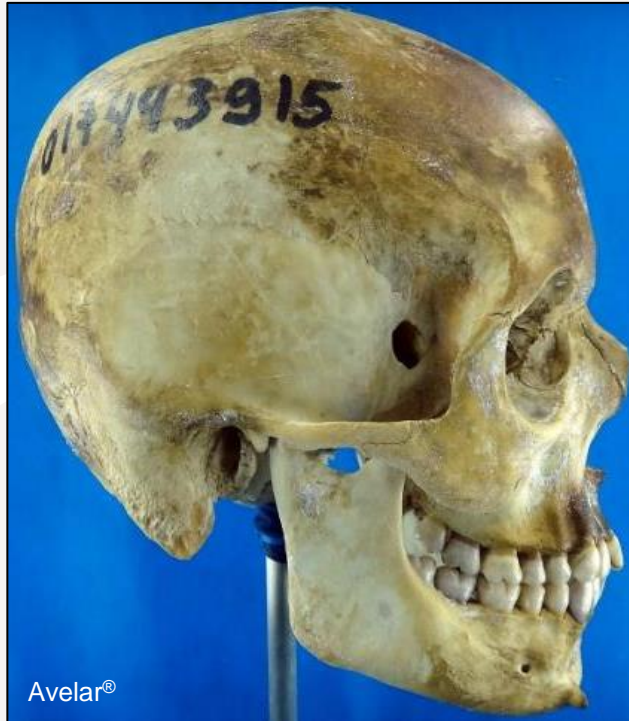


Male, 63 years

Avelar LET et al. PRS Global Open 2017;5(4):e1297



## Aging of the 3 thirds



Male, 18 years



Male, 41 years



Male, 63 years

Avelar LET et al. PRS Global Open 2017;5(4):e1297



# Bone structure – Angle of mandible



Up to 20 years old



Between 20 and 50 years



Over 50 years

Avelar LET et al. PRS Global Open 2017;5(4):e1297

# SUPERFICIAL AND DEEP FACIAL FAT PADS

**GAIN**  
by GALDERMA

RMA

# The aging process

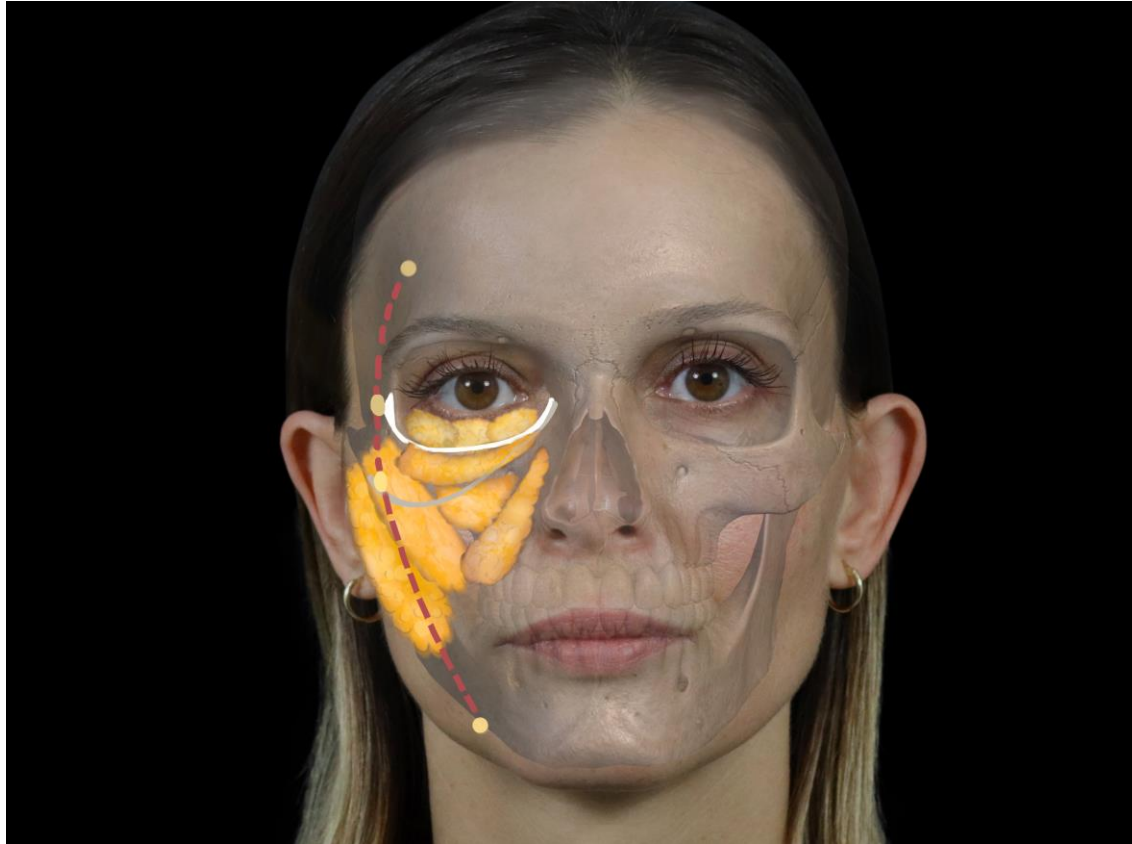


What the fat under your face looks like at age 30 (left) and 60 (right)

Courtesy of Galderma

# Facial Aging

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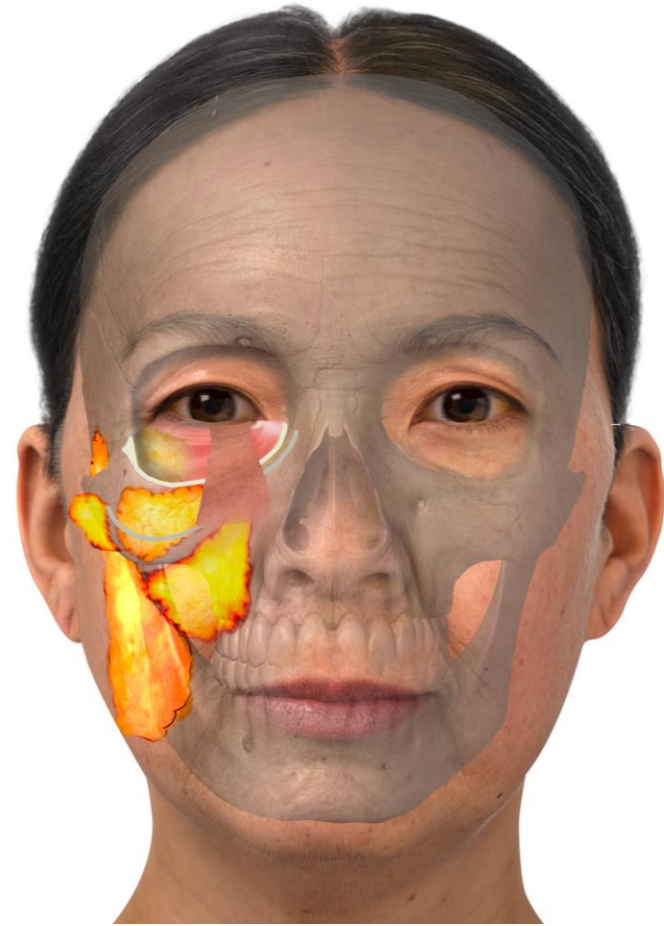
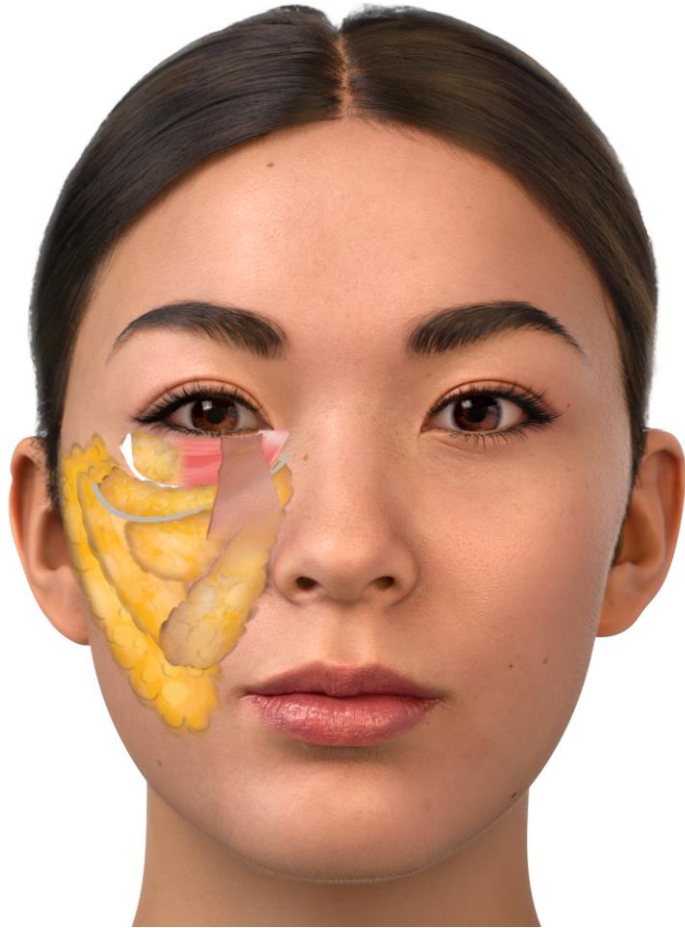
NLF, nasolabial fold.

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# Facial Aging

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NLF, nasolabial fold.

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# Volume Loss

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The face naturally loses volume and fat with age, resulting in a sunken, tired appearance

- Some people require a correction of panfacial volume loss from aging
- Others may need correction to give the appearance of higher cheekbones or a stronger chin, or to enhance a specific area

# Age-Related Changes in Facial Shape Are Caused by Loss of Structural Support

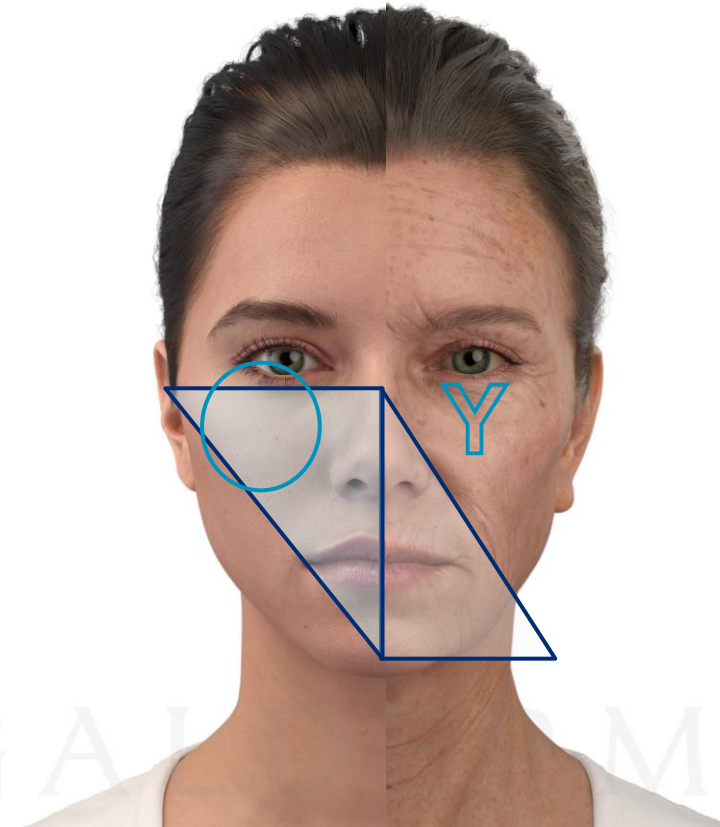
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Triangle  
of youth

Inverted  
triangle

## Facial aging is marked by:

- Degradation of the skeleton and soft tissues<sup>1</sup>
- Descent of cheek fat<sup>2</sup>
- Depletion of cheek fullness<sup>2</sup>



This results in  
volume loss  
and sagging<sup>1,2</sup>

1. Cohen AJ. The mid face facelift. Available from: <http://emedicine.medscape.com/article/1818907-overview>. Accessed April 2019;

2. Coleman SR, et al. *Aesthet Surg. J* 2006;26(1S):S4-S9.



The aging process causes fundamental changes in the skin, soft tissue, and skeletal support structures of the human face. Dermal changes are due to intrinsic and extrinsic factors:

- Intrinsic factors refer to genetically determined hormonal and biochemical processes that cause irreversible degeneration of skin tissue
- Extrinsic factors refer to environmental influences, particularly UV radiation, that damage the skin and compromise skin integrity



# Skin Aging

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## As aging occurs

- The dermis thins owing to collagen loss<sup>1</sup>
- Moisture retention is reduced owing to HA loss<sup>2</sup>
- Elasticity is reduced owing to loss of elastin<sup>3</sup>

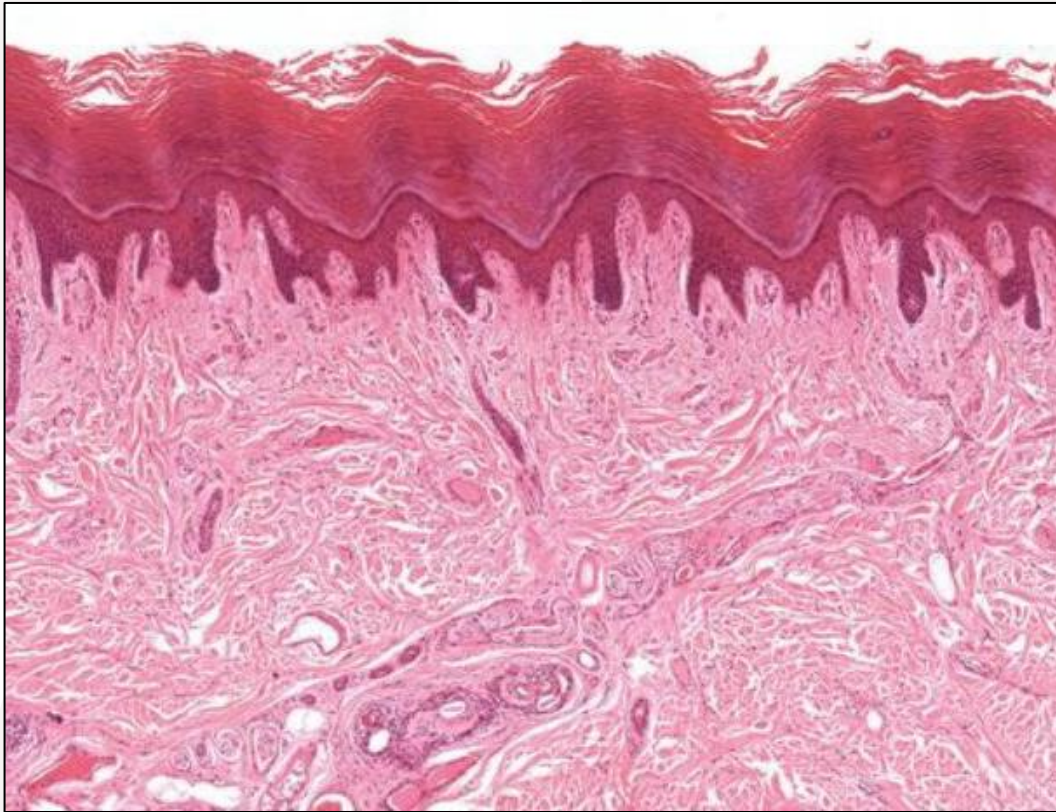


Firm skin that responds to movement and regains a smooth appearance at rest is essential for a youthful appearance

HA, hyaluronic acid.

1. Vlegaar D and Fitzgerald R. *J Drugs Dermatol.* 2008;7:209; 2. Papakonstantinou E, et al. *Dermato-Endocrinology* 2012;4(3):253-258; 3. Farage MA, et al. *Adv Wound Care.* 2007;2(1):5-10.

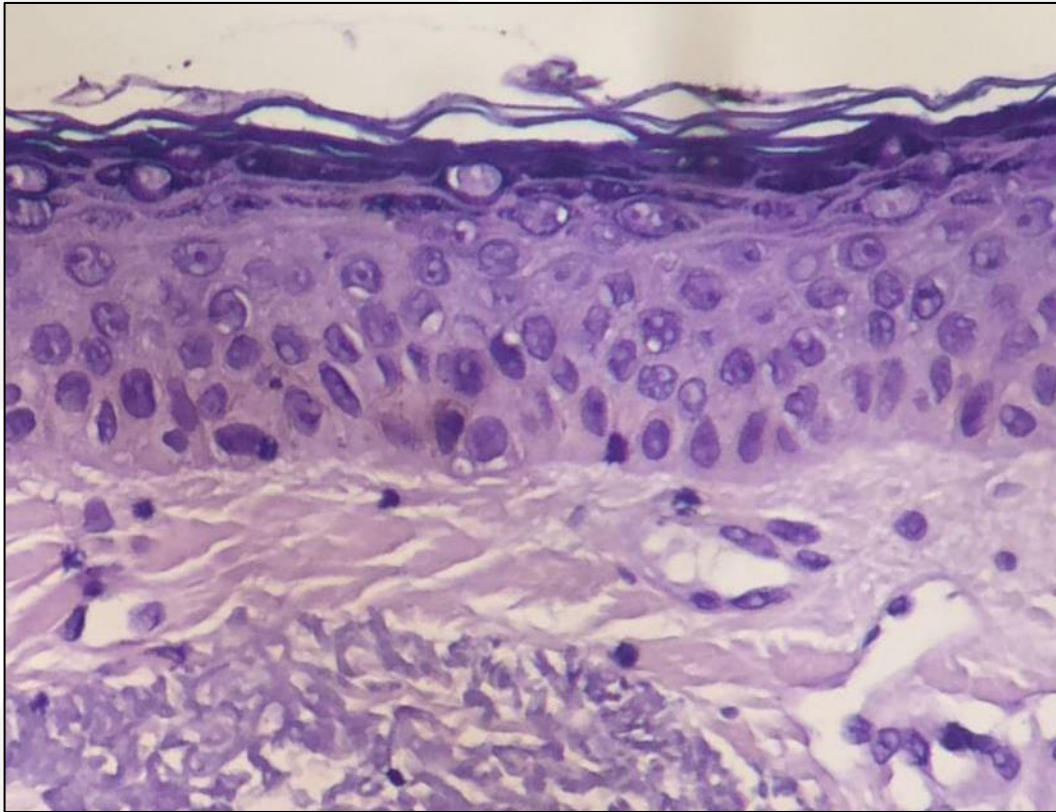
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## YOUNG SKIN

- Thicker corneal layer
- Large number of cells
- Multiple crests and papillae
- Thicker subdermal layer
- High collagen deposit rates

Farage MA et al. *Advances in Wound Care* 2007;2(1):5-10



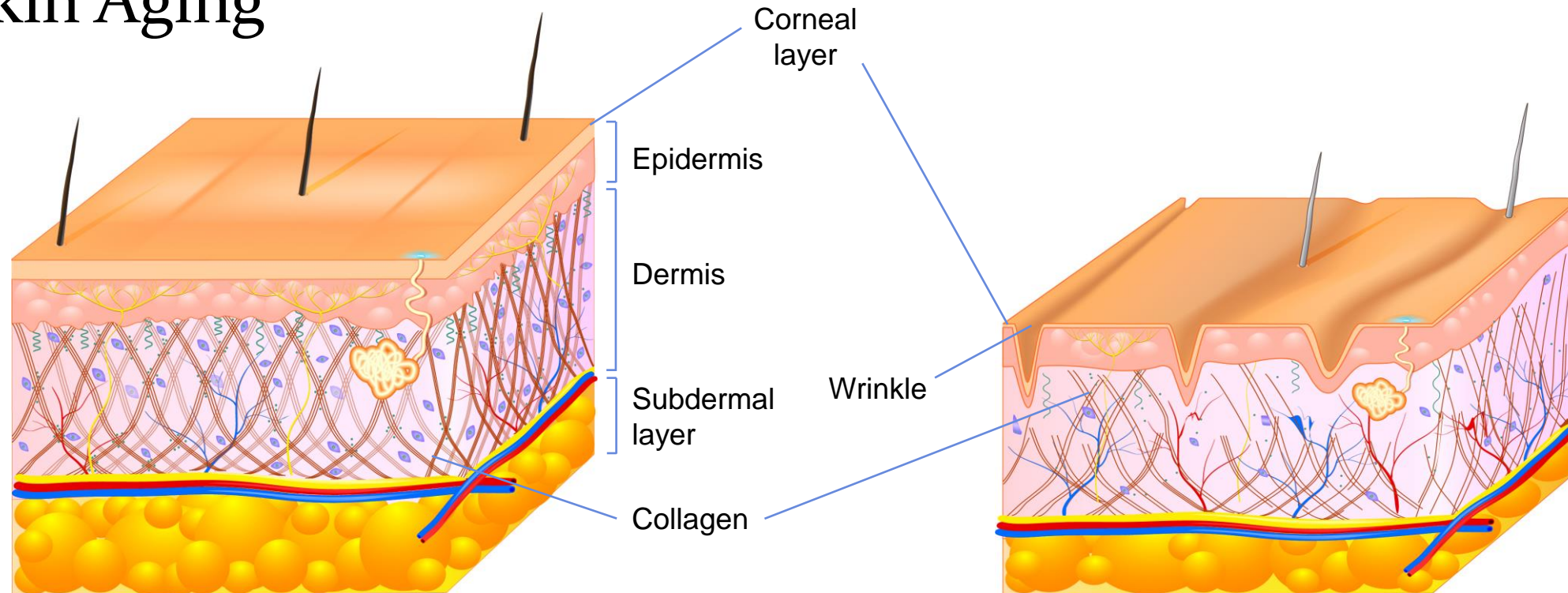
## OLD SKIN

- Thin corneal layer
- Low number of cells
- No or few crests and papillae
- Thin subdermal layer
- Decrease in collagen turnover



# Skin Aging

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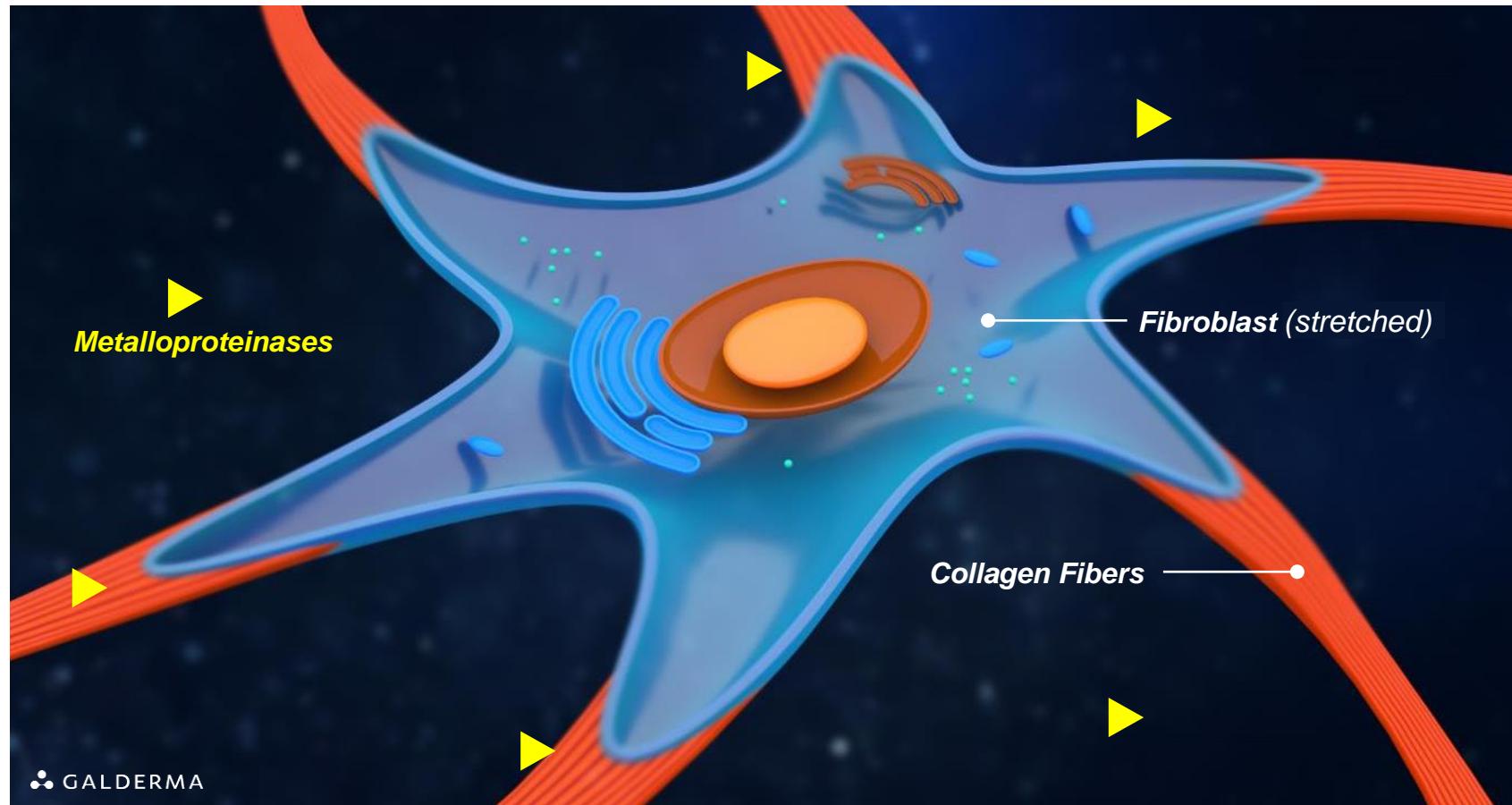


## Young skin

- Thicker corneal layer
- Large number of cells
- Multiple crests and papillae
- Thicker subdermal layer
- High collagen deposit rates

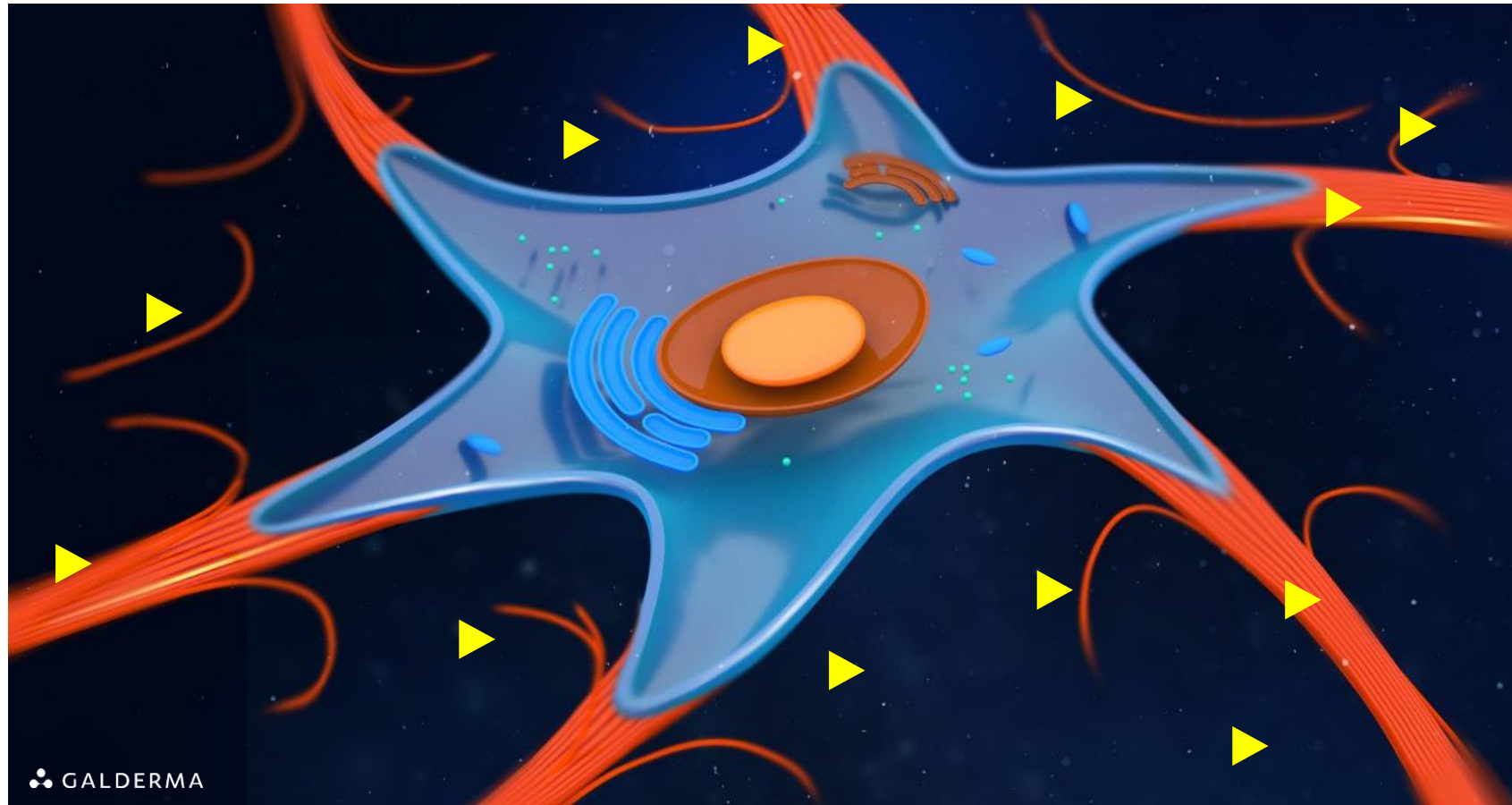
## Old skin

- Thin corneal layer
- Low number of cells
- No or few crests and papillae
- Thin subdermal layer
- Decrease in collagen turnover



# Increase of Metalloproteinase

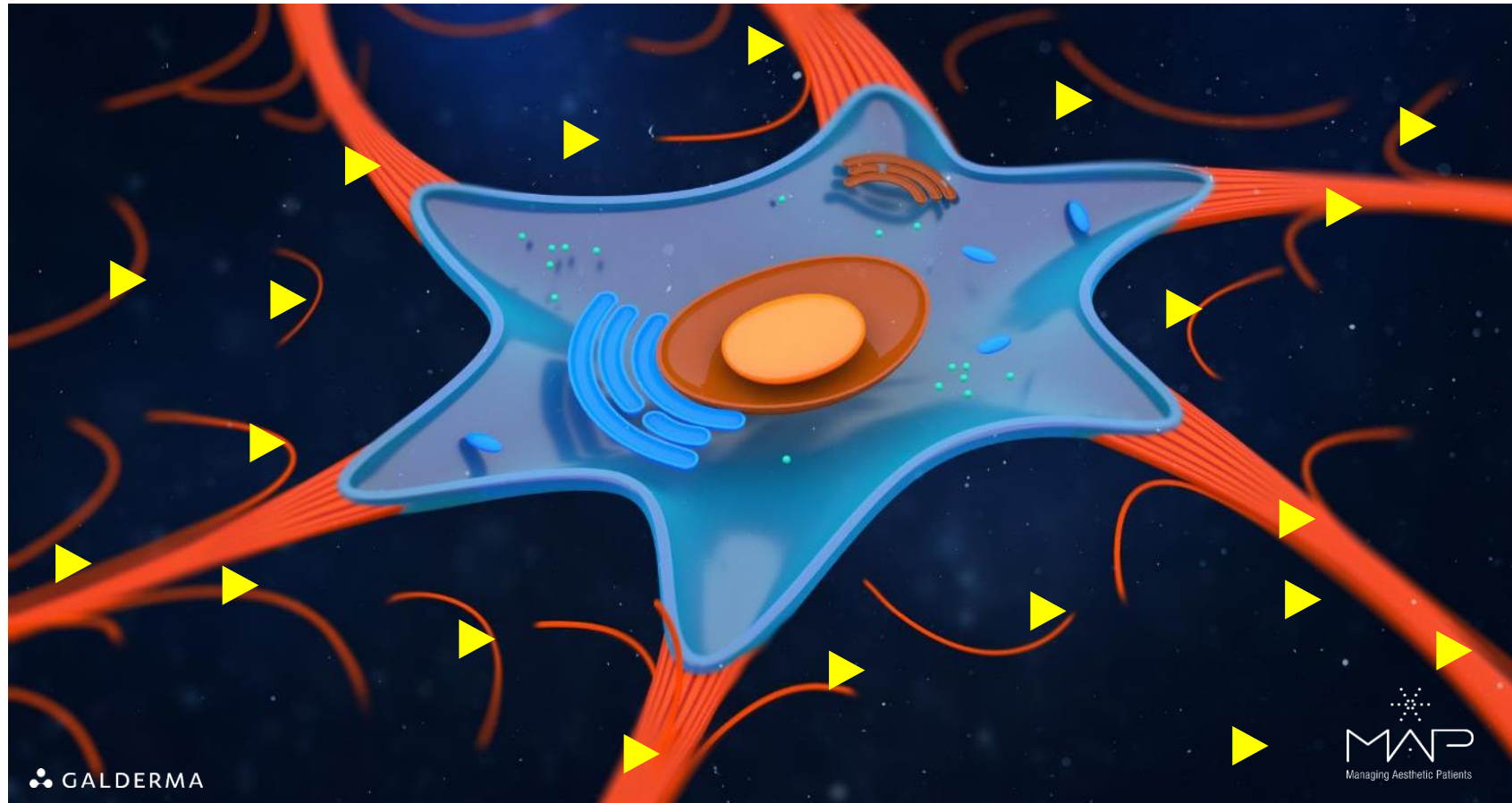
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# Fragmented Collagen Fibers

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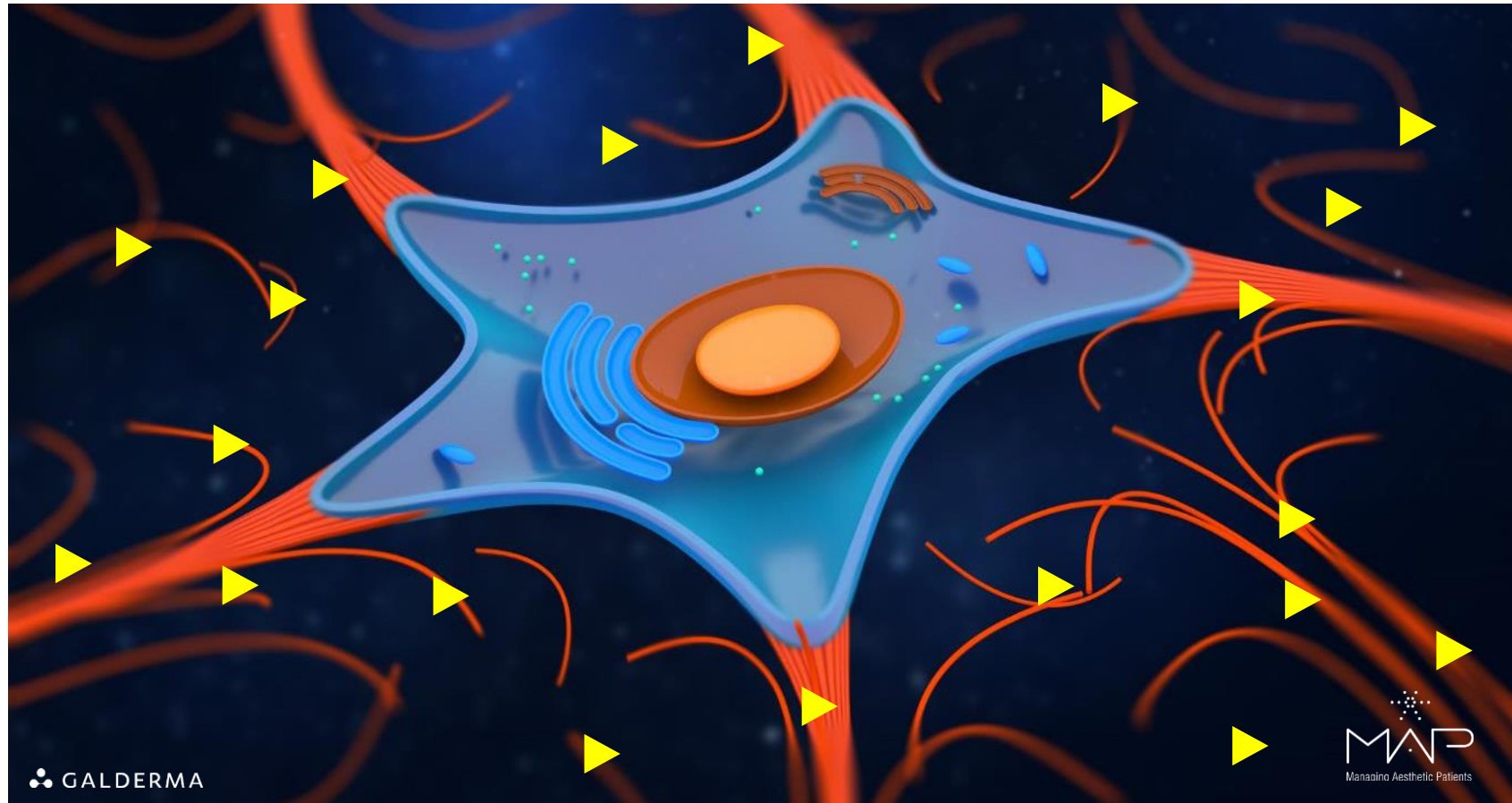


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# Degradation of Extracellular Matrix

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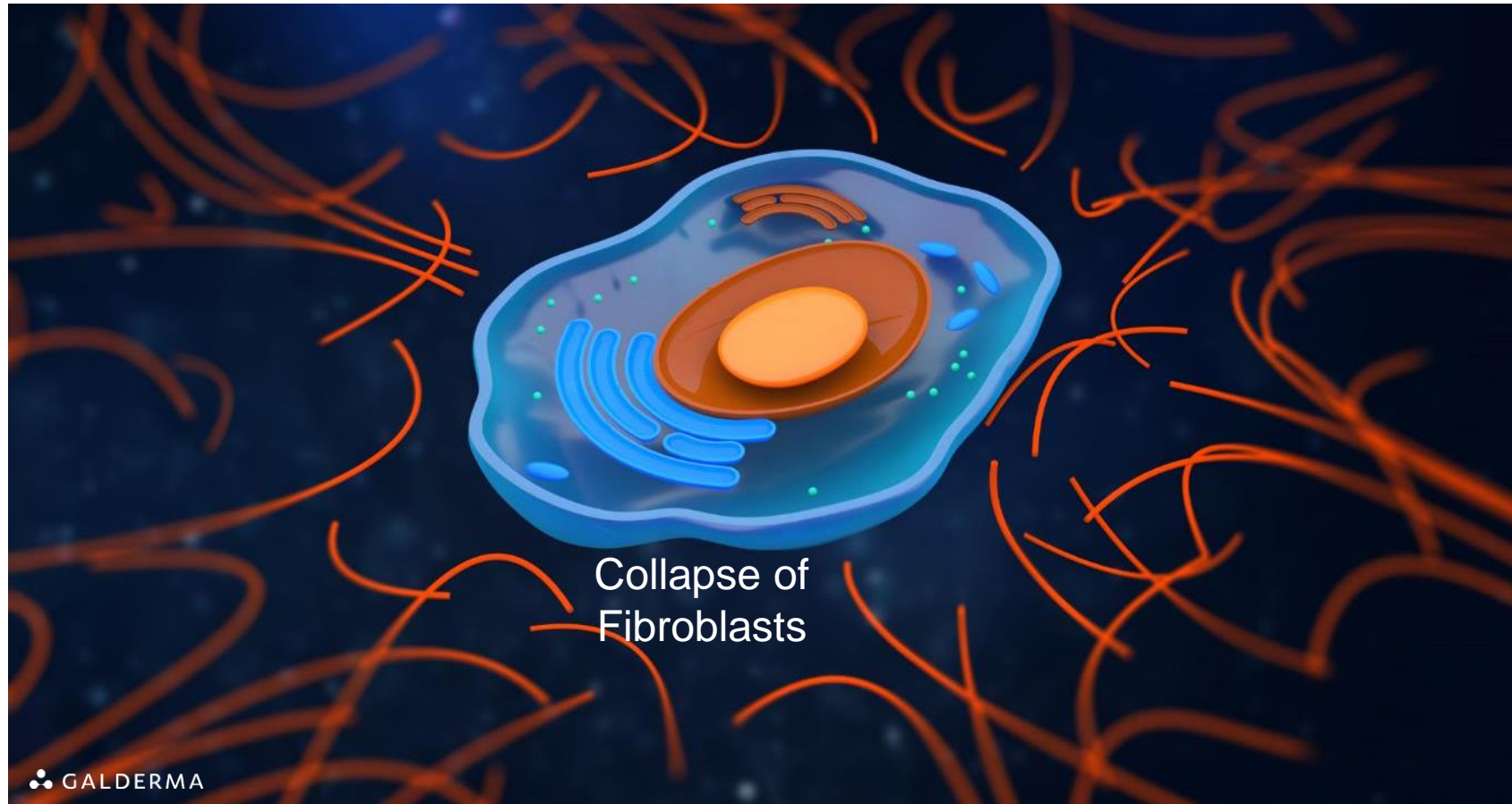


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M.A.P.  
Mansano Aesthetic Patients

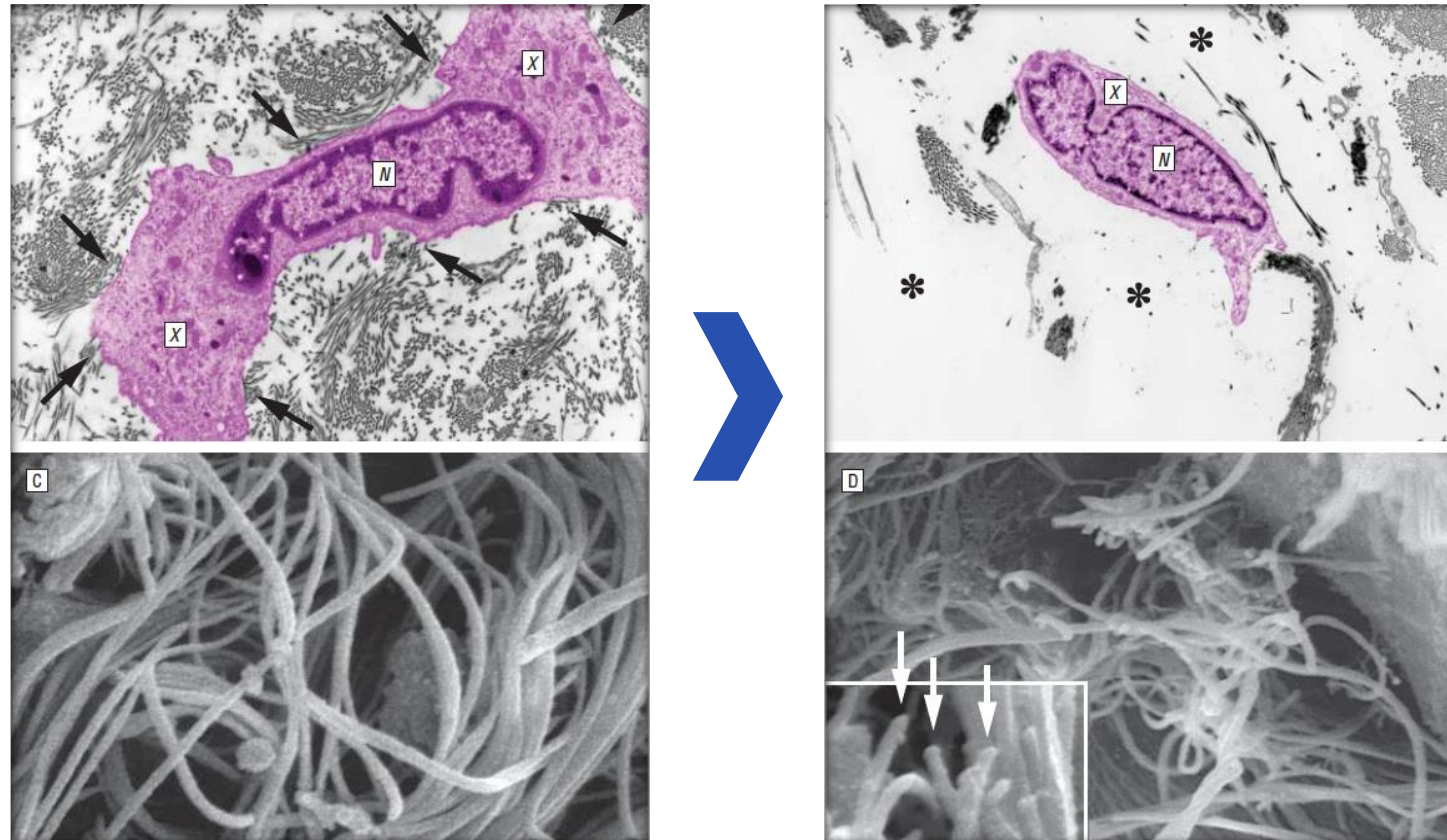
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# Collagen and Skin Aging

GAIN



Photographs © U.S. National Library of Medicine. *Arch Dermatol.* 2008 May; 144(5): 666-672, Gary J. Fisher, James Varani and John J. Voorhees.  
Fisher G, et al. *Arch Dermatol.* 2008;144(5):666-672.

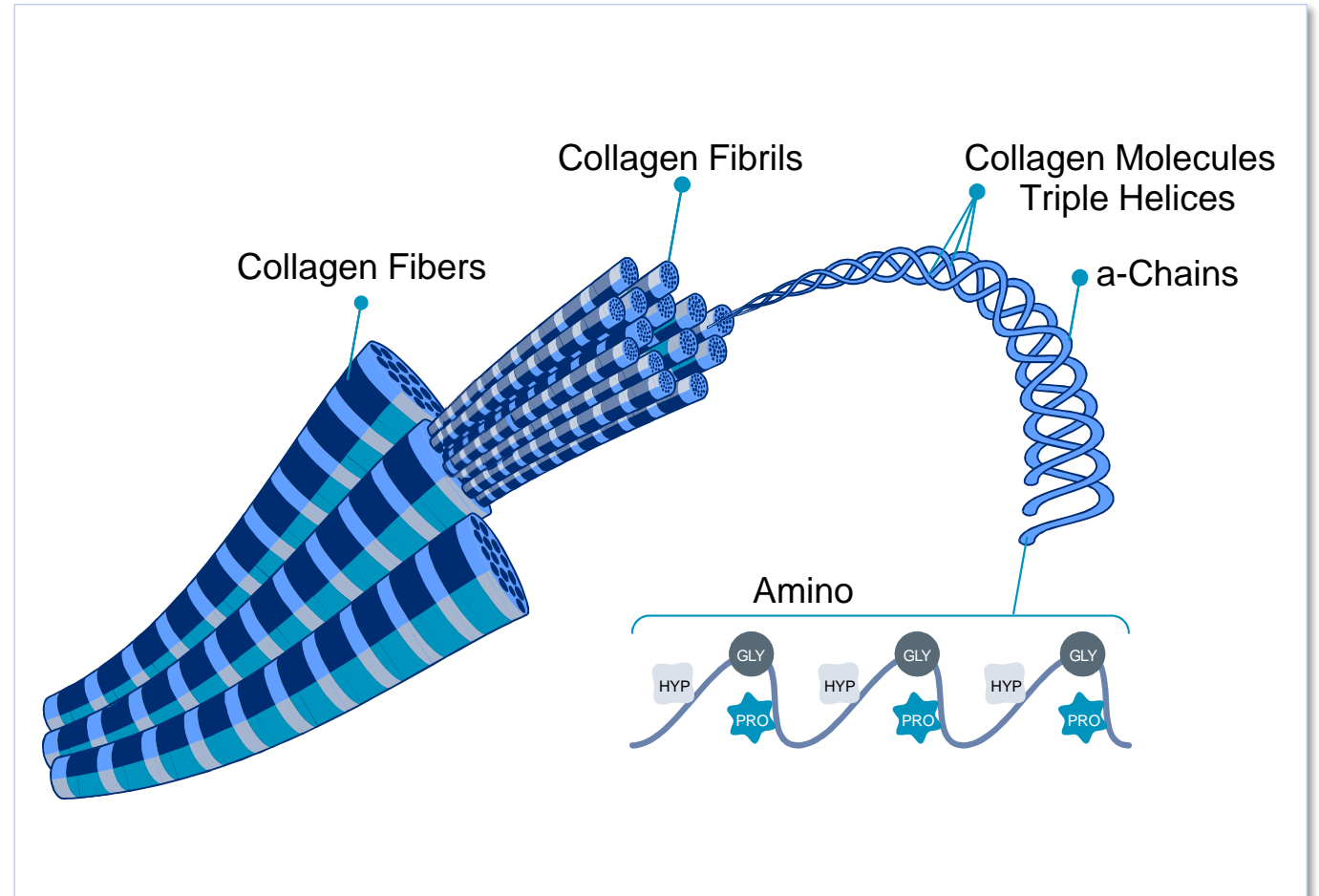
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# Collagen

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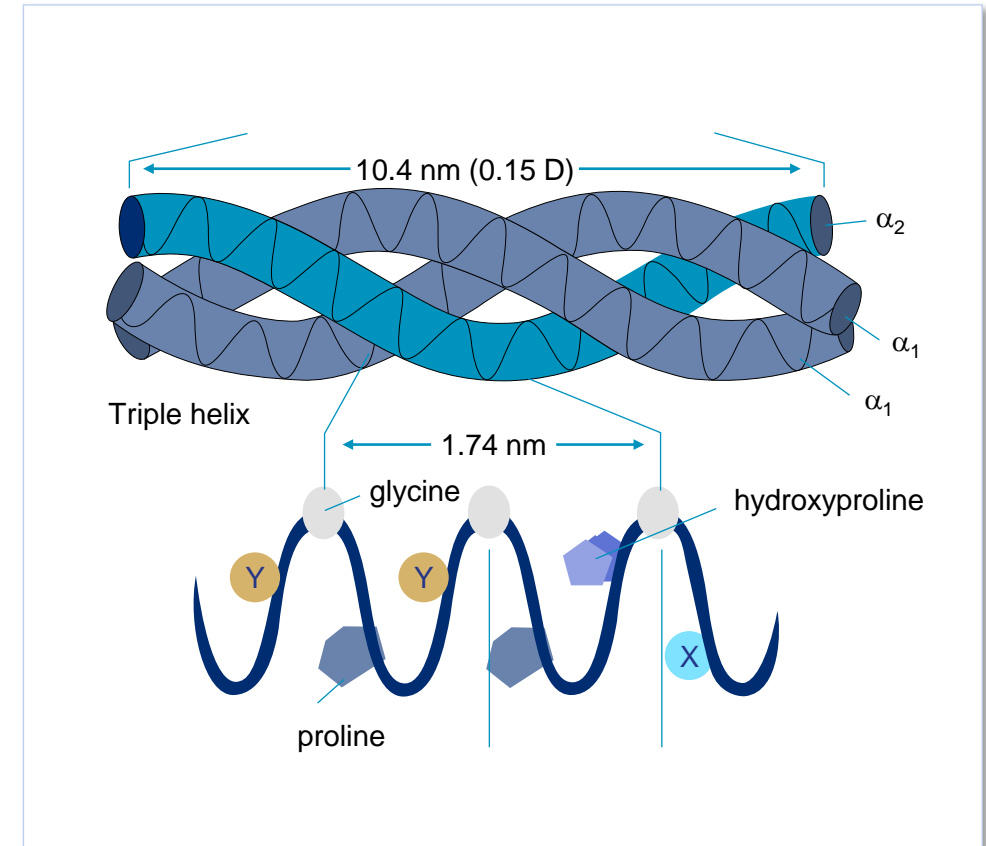
## Function

- Resistance of tissues
- Adherence among structures
- Provides tensile strength to scars



# Collagen

- It corresponds to 95% of the connective tissue of the dermis and to 30% of the overall proteins of the body
  - It consists of a sequence of only 4 amino acids:
    - Glycine (more common)
    - Proline
    - Hydroxyproline
    - Hydroxylysine
- } Vitamin C Dependent
- Different types of collagen

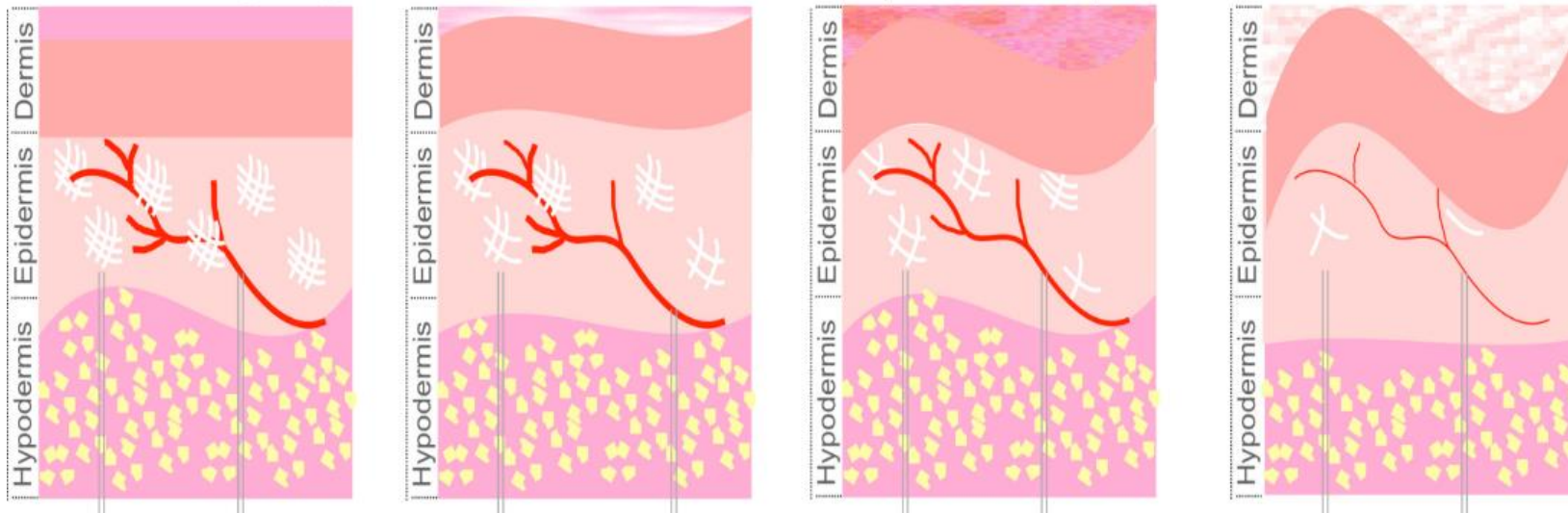




# Collagen and Skin Aging

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**Skin aging starts to show around age 30 and worsens progressively<sup>1</sup>**



**The production of collagen decreases with age, as does the quality of the collagen produced; its degradation also increases with age owing to**

- Fragmented collagen elastic fibers<sup>2,3</sup>
- Collapse of fibroblasts
- Decreased collagen production<sup>4</sup>
- Increased matrix metalloproteinase production<sup>5</sup>
- Degradation of the extracellular matrix<sup>6</sup>

1. Ascher B, et al. *Dermatol Surg.* 2006;32:1058; 2. Ganjoo A. Aging skin. In: ACS(1) Textbook on Cutaneous & Aesthetic Surgery. 2012; 3. Donofrio LM. *Dermatol Surg.* 2000;26:1107; 4. Vleggar D and Fitzgerald R. *J Drugs Dermatol.* 2008;7:209; 5. Helfrich YR, et al. *Dermatol Nurs.* 2008;20:177; 6. Zhang S, Duan E. *Cell Transplantation.* 2018;27(5):729-738.

# Skin Elasticity

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- Ability to stretch and return to normal
- Absence of sagging or laxity
- Degree of elastin support
- Skin thickness/firmness
- Degree of wrinkles and fine lines upon animation



- Loss of skin firmness may initially show only upon animation, but as it becomes more severe, is also present at rest
- At rest, tissue sagging will contribute to the development of lines and folds



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# Product Description

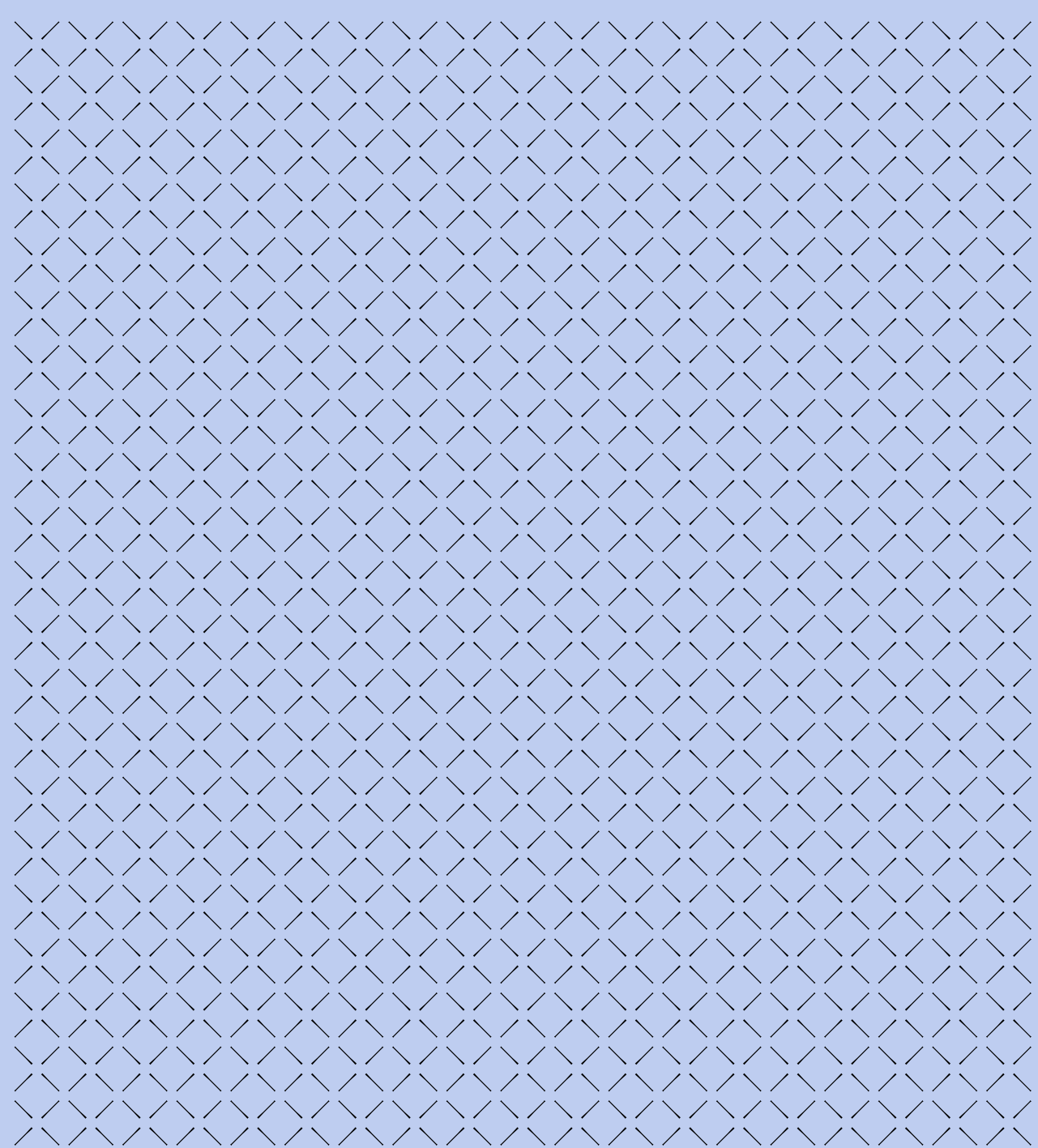
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# PLLA & Product Background

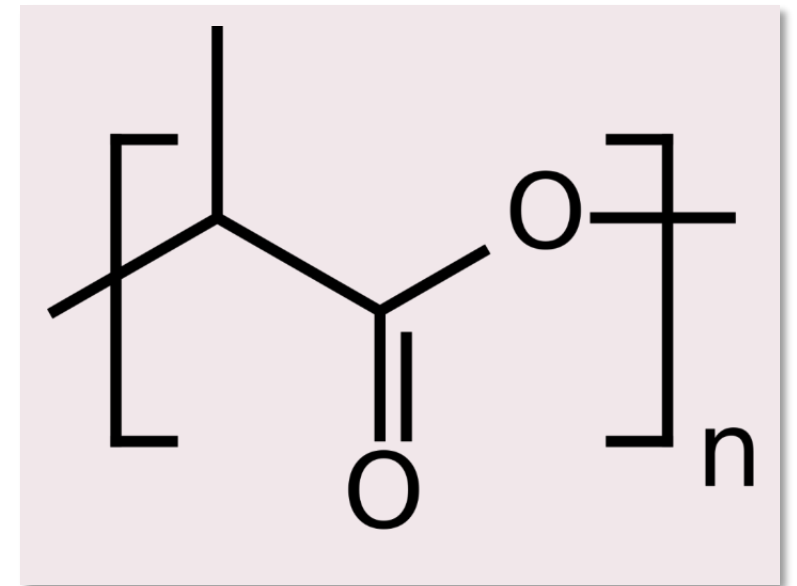
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# What Is PLLA?

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- PLLA is a stereoisomer of polylactic acid (below)
- PLLA is a biodegradable, biocompatible, synthetic polymer<sup>1</sup>
- PLLA has been widely used for many years in medical products, such as<sup>2-4</sup>
  - Pins, plates and screws for reconstructive surgery
  - Intra-bone and soft-tissue implants
  - Carrier for sustained release of bioactive compound<sup>3,4</sup>



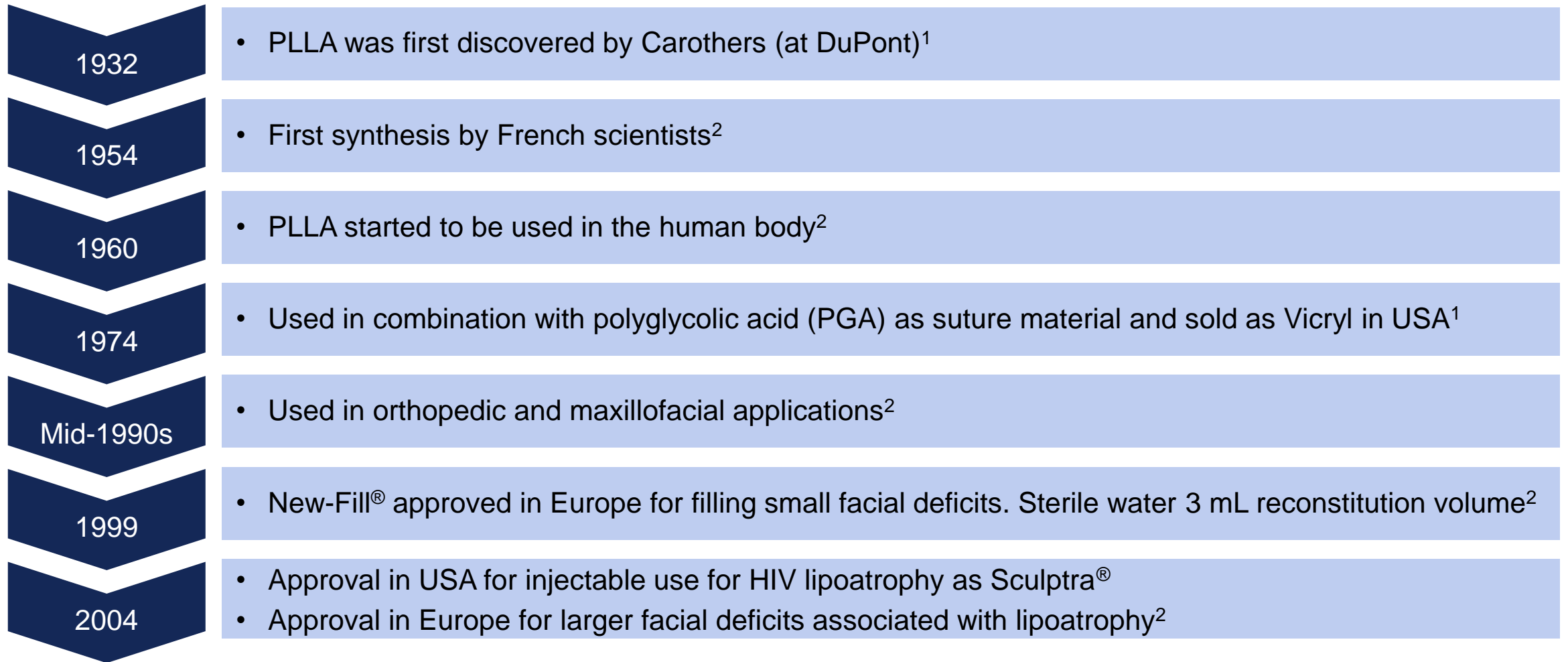
PLLA, poly-L-lactic acid.

1. Sculptra® Aesthetic Instructions for Use. Galderma Laboratories, L.P. Fort Worth, TX. September 2014; 2. Fitzgerald R and Vleggaar D. *Dermatol Ther.* 2011;24:2; 3. Narins RS, et al. *J Am Acad Dermatol.* 2010;62:448; 4. Vleggaar D and Bauer U. *J Drugs Dermatol.* 2004;3:542.

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# Historical Use of PLLA

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PLLA, poly-L-lactic acid.

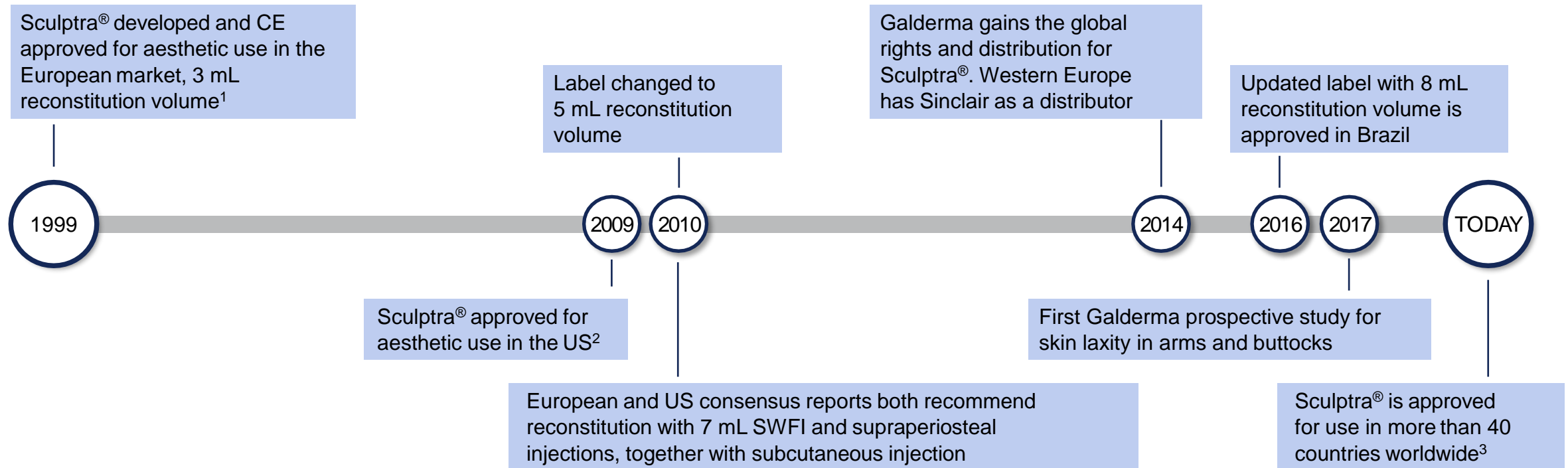
1. Mehta R, et al. *J Macromol Sci Polymer Rev.* 2005;45(4):325-349; 2. Humble G and Mest D. *Facial Plastic Surg.* 2004;20 (2):157-163.

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# Aesthetic Timeline

GAIN

The use of Sculptra® for the restoration of facial volume has evolved since its introduction in 1999



SWFI, sterile water for injection.

1. Mest D, Humble G. *J Clin Aesthet Dermatol*. 2010;3(12):43-49; 2. Chen HH, et al. *JAMA Facial Plast Surg*. 2015;17(1):39-43;

3. <https://www.nestleskinhealth.com/Sculptra>. Accessed 11 April 2019.

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# How Is Sculptra® Supplied?

GAIN

**Sculptra® is supplied as a sterile freeze-dried powder in a clear glass vial**

## **Each vial contains**

- Poly-L-lactic acid – 150 mg
- Sodium carboxymethylcellulose – 90 mg
- Mannitol – 127.5 mg



\*Packaging images may vary by country; for illustration purposes only.

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# Other Components of Sculptra®

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Sodium Carboxymethylcellulose

## Sodium Carboxymethylcellulose (CMC)

- Used as a suspending agent to create even distribution of PLLA particles
  - Following reconstitution with water, undergoes hydration
- Widely used in medical and food industry, and “generally recognized as safe” (GRAS). Included in the FDA Inactive Ingredients Guide for intradermal, intramuscular, intravenous, and subcutaneous injections
- Widely used in parenteral (IV/IM) products

FDA, US Food and Drug Administration; IM, intramuscular; IV, intravenous.

Drugs.com Sodium Carboxymethylcellulose available at: <https://www.drugs.com/inactive/carboxymethylcellulose-sodium-452.html> accessed on 16/04/2019.

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# Other Components of Sculptra®

GAIN

Mannitol

## Mannitol

- Included to enhance lyophilization (freeze drying) in the finishing process; helps produce a stiff, homogenous cake
  - Following reconstitution with water, undergoes hydration
- Used in medical industry, and “generally recognized as safe” (GRAS) by the FDA

# What Is Sculptra®?

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## Sculptra Is a Collagen Biostimulator Poly-L-Lactic Acid (PLLA)

- It is a substance (polymer) that leads to collagen production through a controlled inflammatory response. The response may be influenced by lifestyle habits and individual patient characteristics

**PLLA is NOT a filler**

It is a biostimulator

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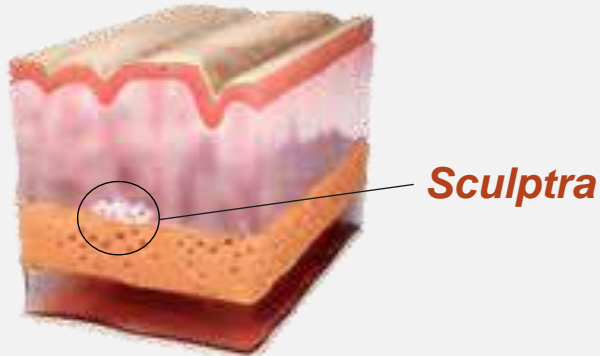
# Mode of Action

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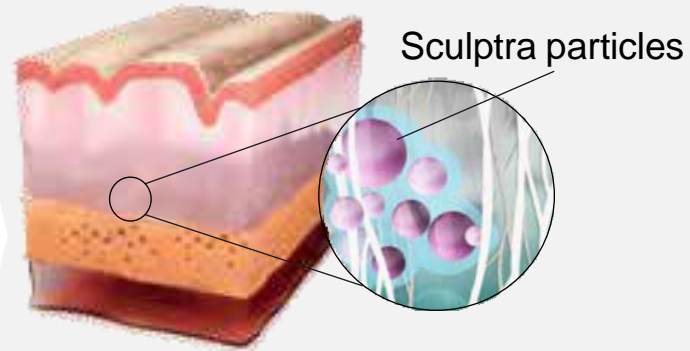
# Sculptra Mode of Action

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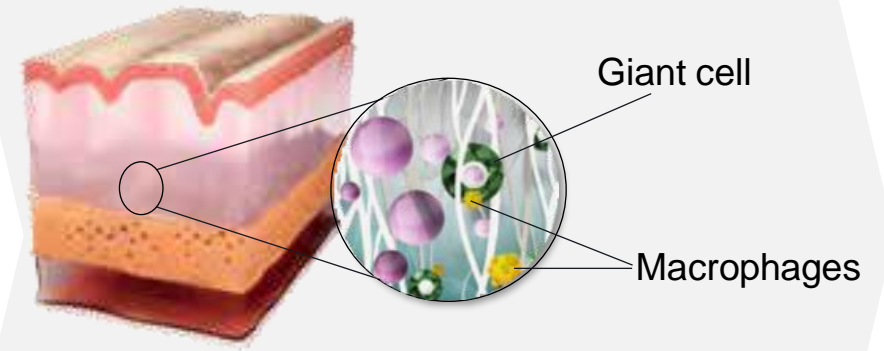
By stimulating the production of type 1 collagen, Sculptra® can help revive fullness and restore volume to the aging face



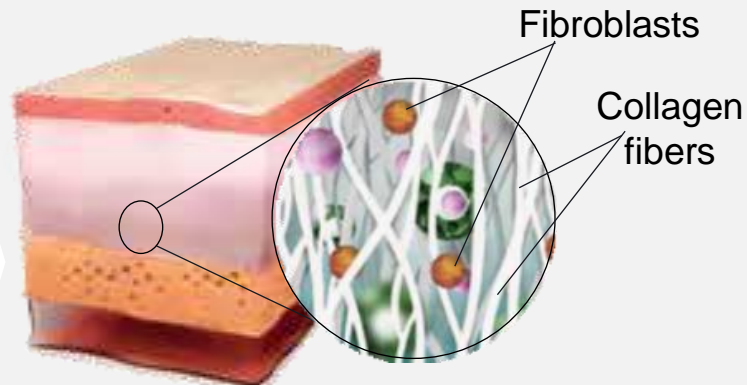
Sculptra is injected into the deep dermis (shown here) or subcutaneous layer<sup>1</sup>



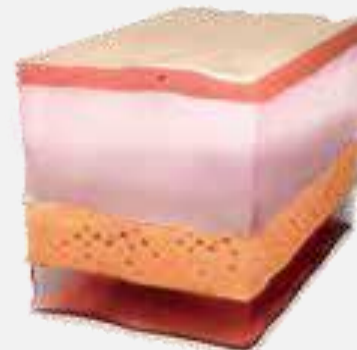
Within a few days after injection, the water and other constituents are absorbed by the body, while the Sculptra particles remain in place<sup>2</sup>



Macrophages are recruited and surround the Sculptra particles. Macrophages fuse to giant cells and recruit fibroblasts<sup>2</sup>



Fibroblasts deposit collagen, which provides a structure for the skin. Wrinkles and volume defects are gradually corrected<sup>2</sup>



Over time the Sculptra particles degrade, but collagen deposits remain, providing long-lasting improvement of wrinkles and volume defects<sup>2</sup>

*"This unique agent is not a filler but a stimulator of the host's own collagen, which then acts to volumize tissue in a gradual, progressive, and predictable manner."<sup>3</sup>*

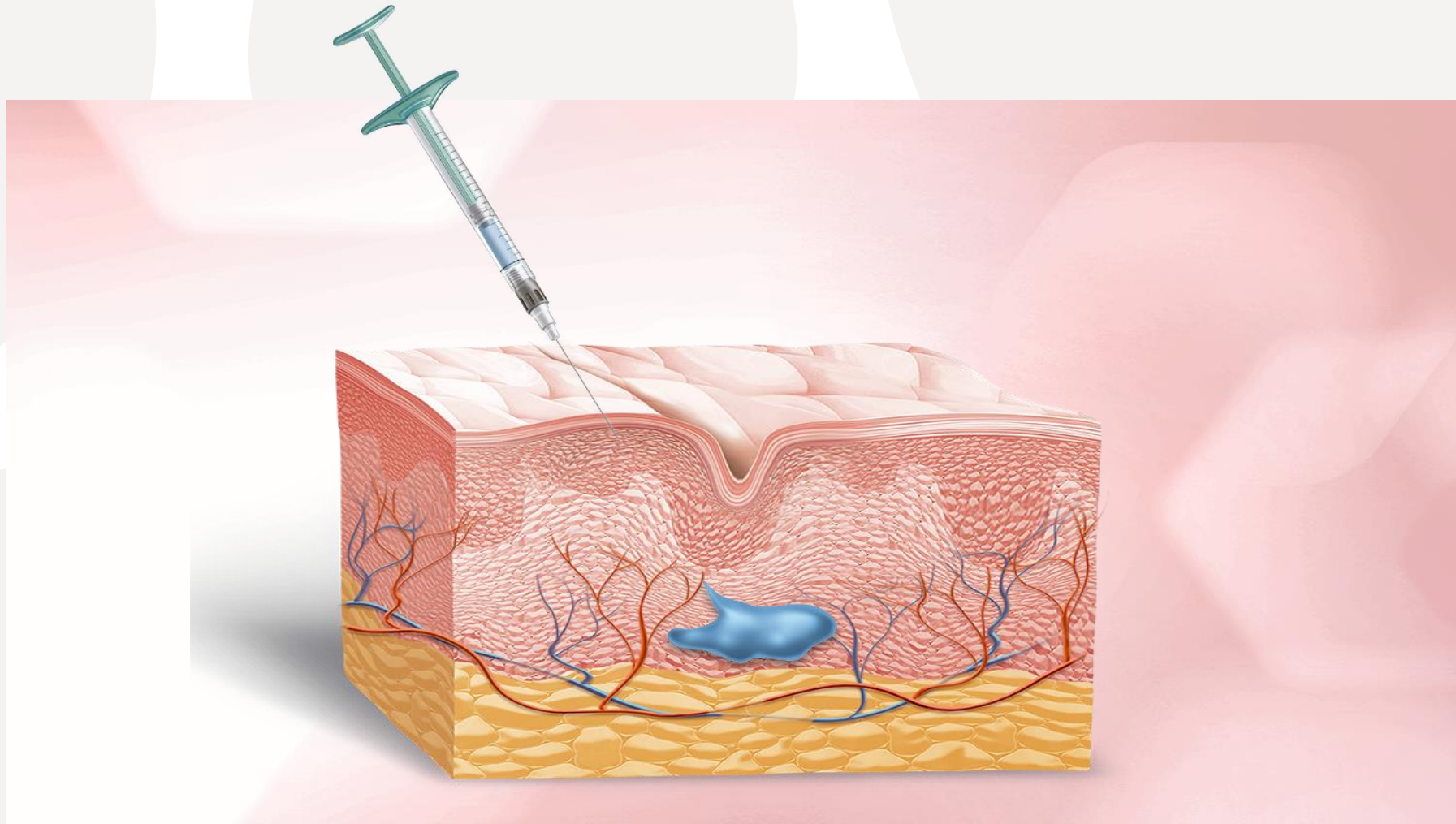
1. Galderma. Sculptra Instructions for Use (EU), 2020; 2. Gogolewski S, et al. *J Biomed Mater Res.* 1993;27(9):1135-1148; 3. Fitzgerald R and Vleggaar D. *Dermatol Ther.* 2011;24(1):2-27.



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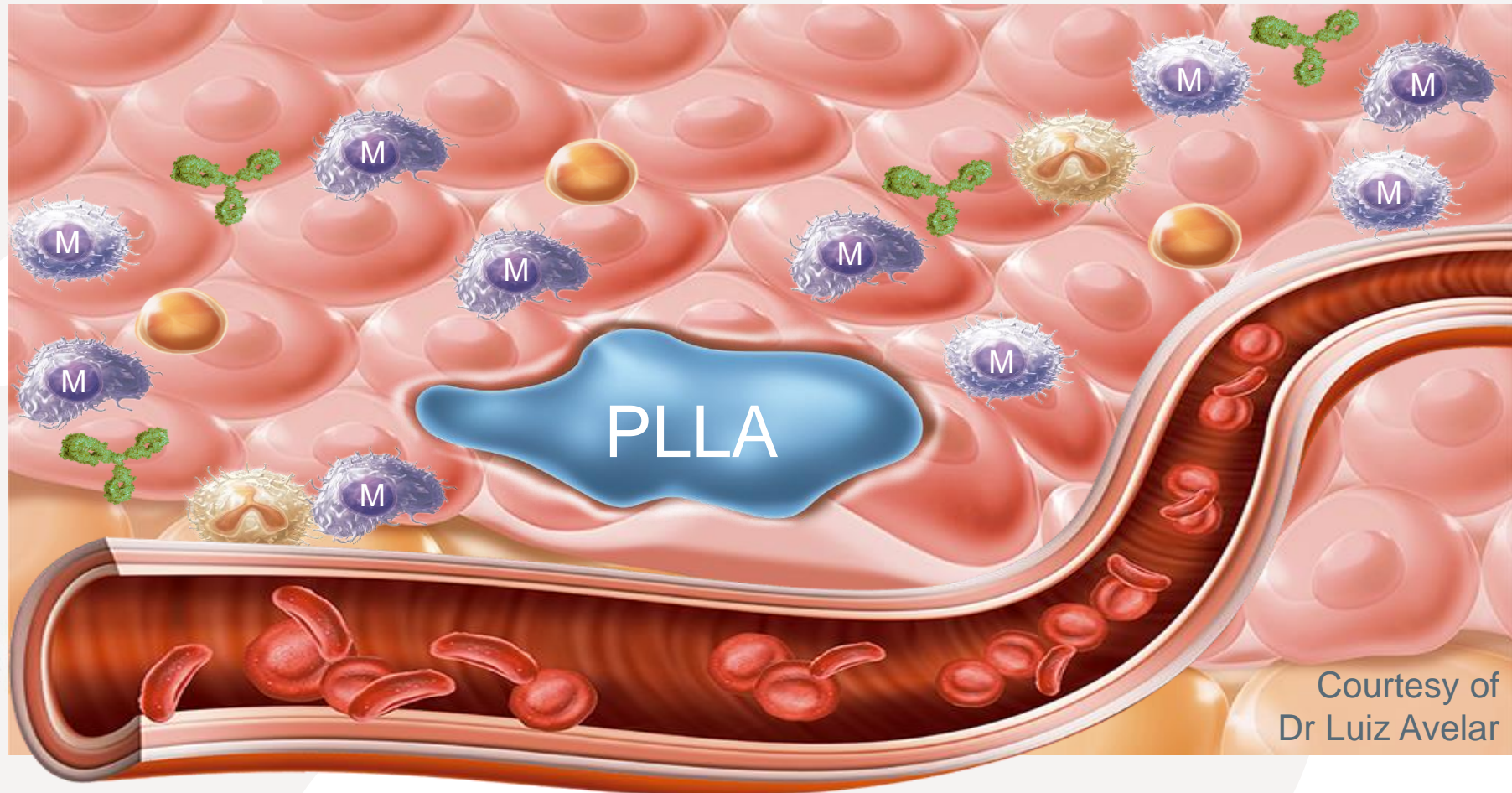


# Foreign body reaction





# Leucocyte migration up to 2 days



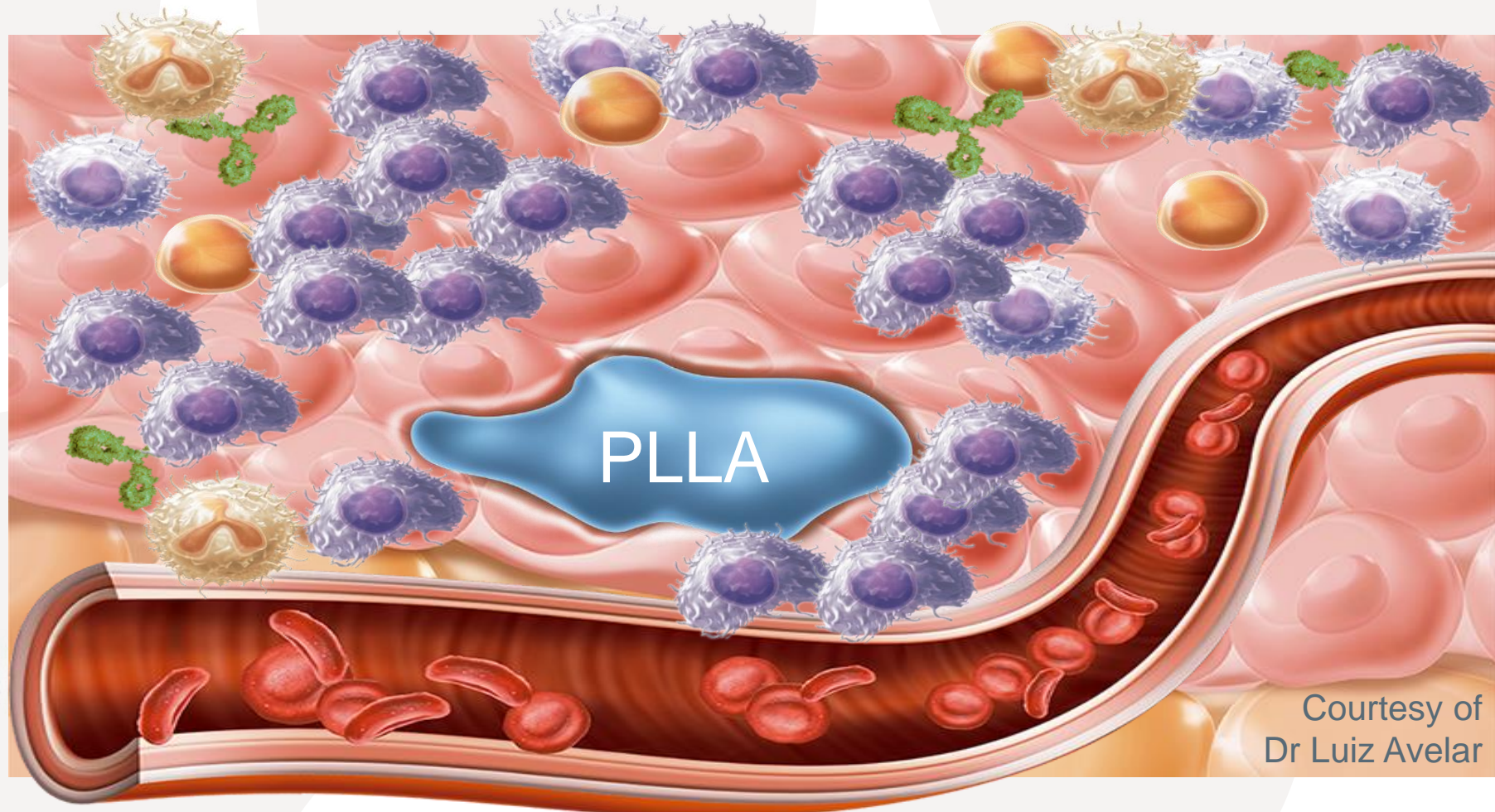
Courtesy of  
Dr Luiz Avelar

**PLLA**



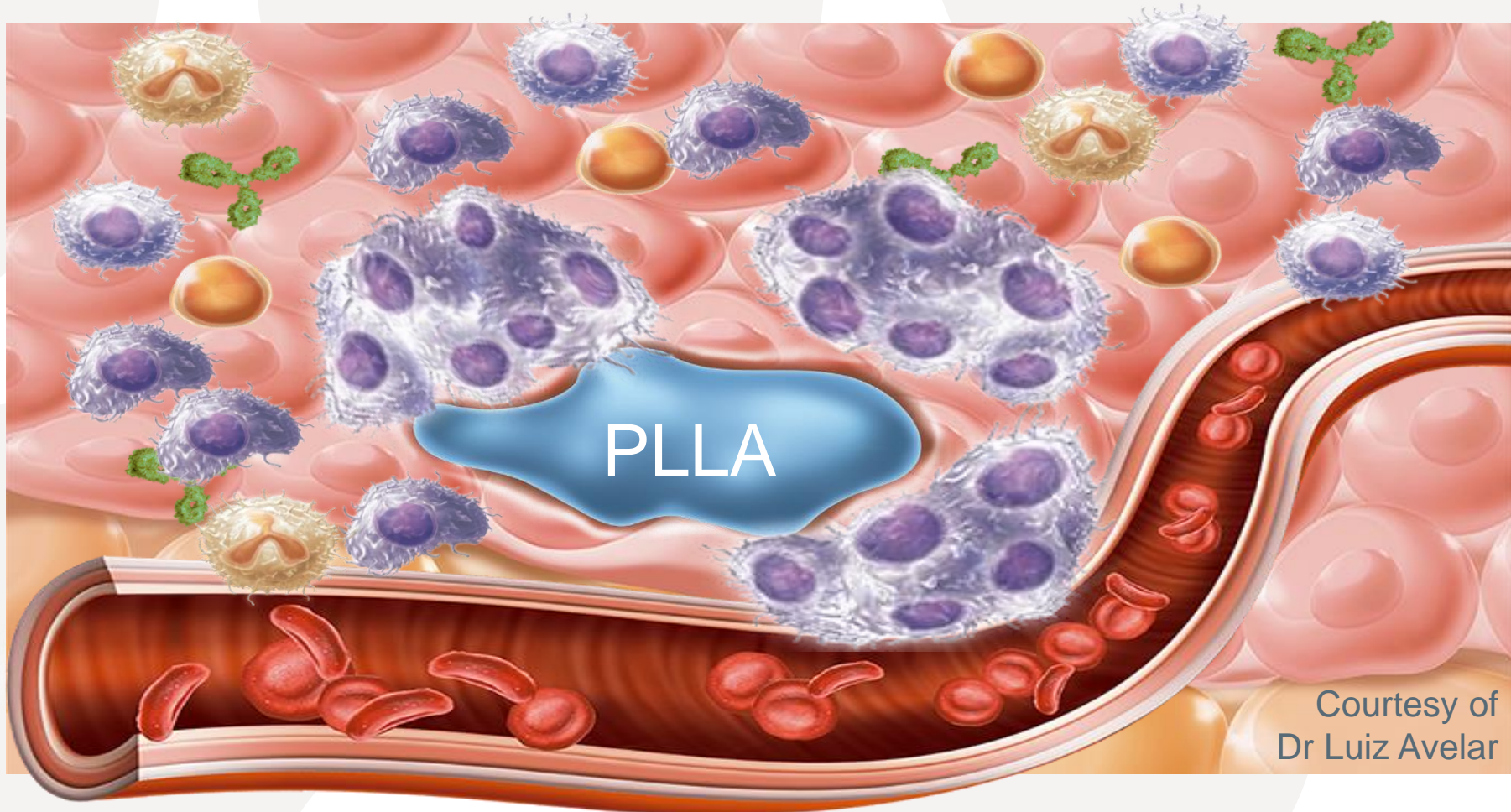
**MACROPHAGE**





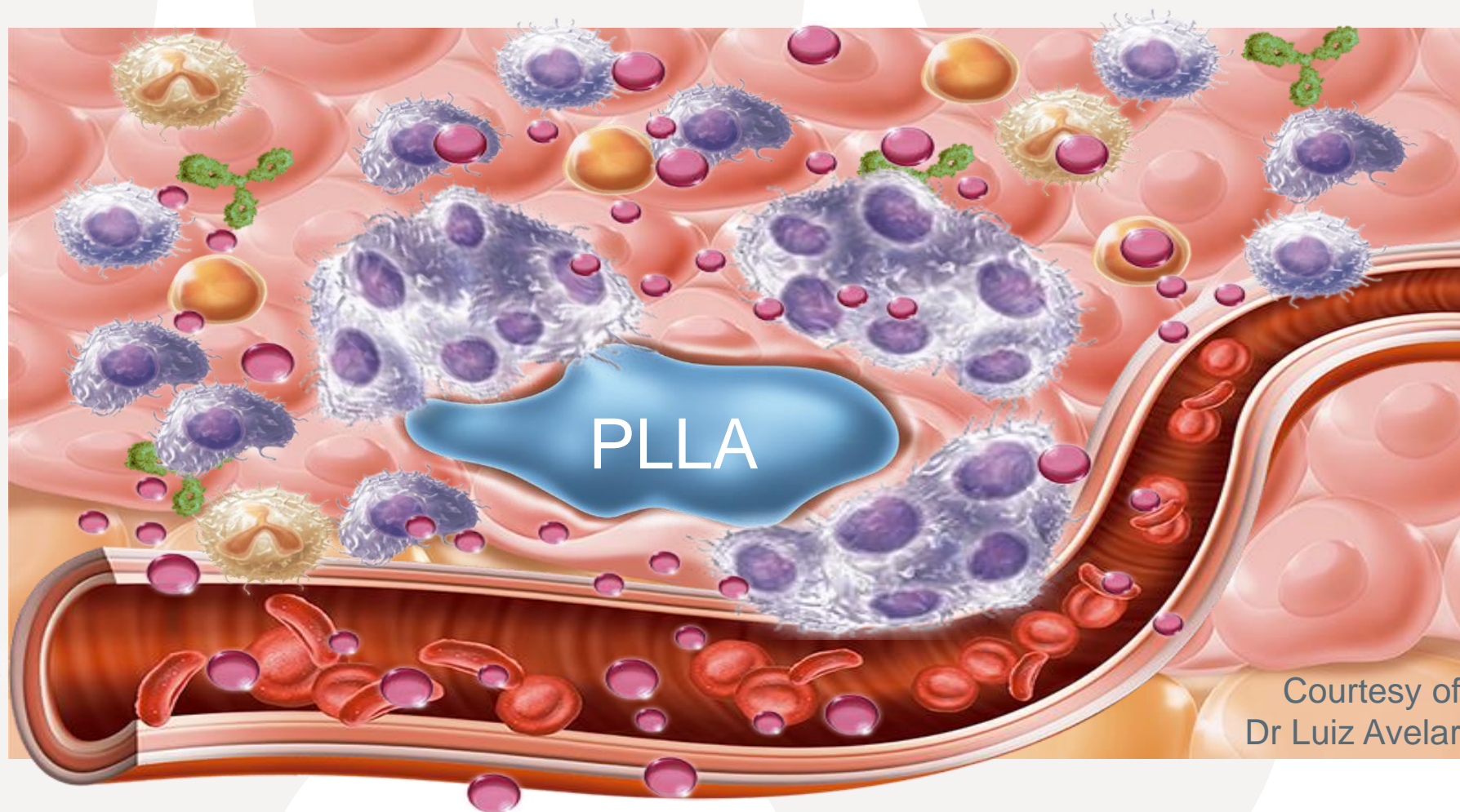


# 10 days – Multinuclear giant cells





# Release of cytokines





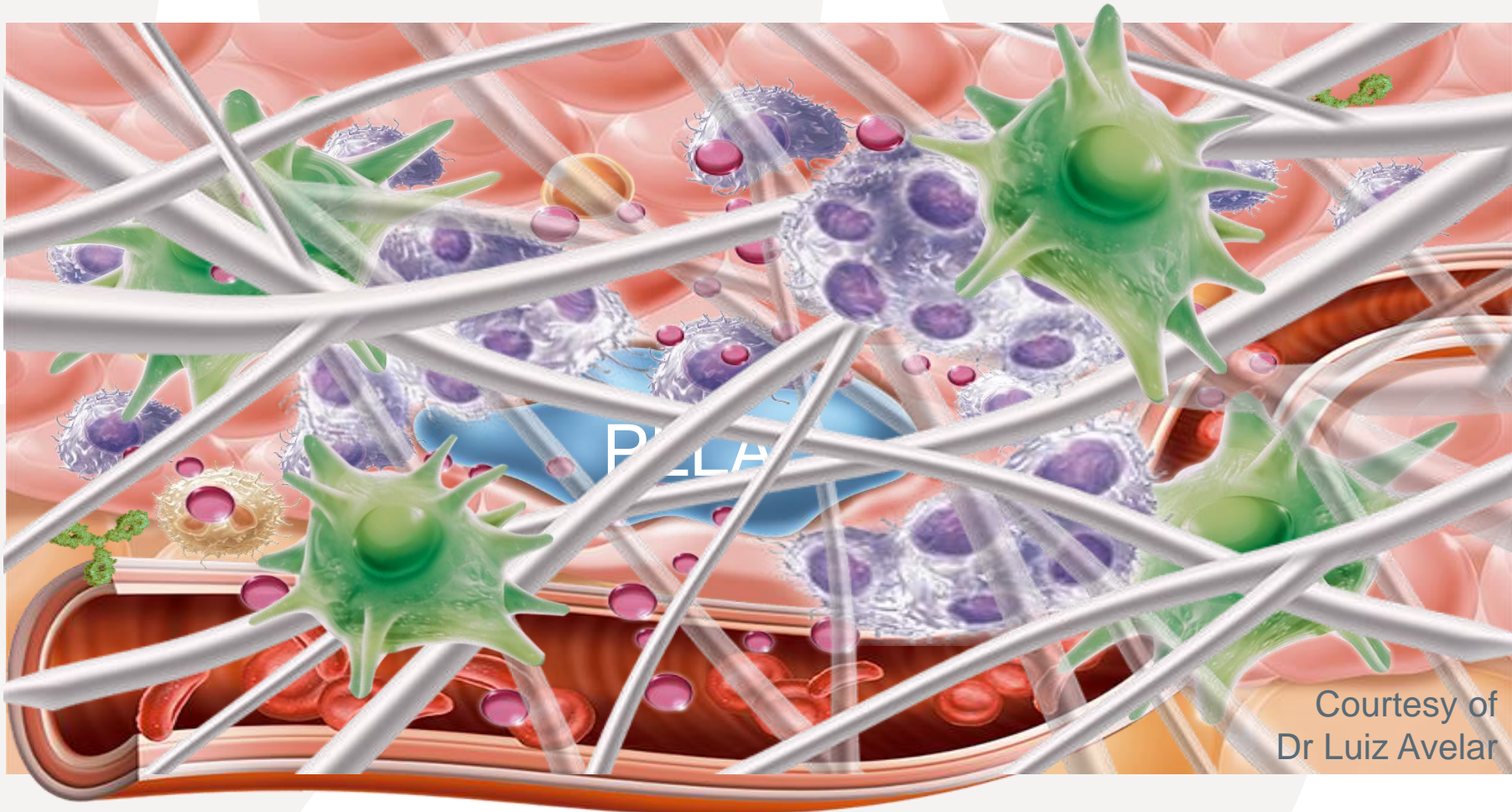
# Fibroblast migration



Courtesy of  
Dr Luiz Avelar



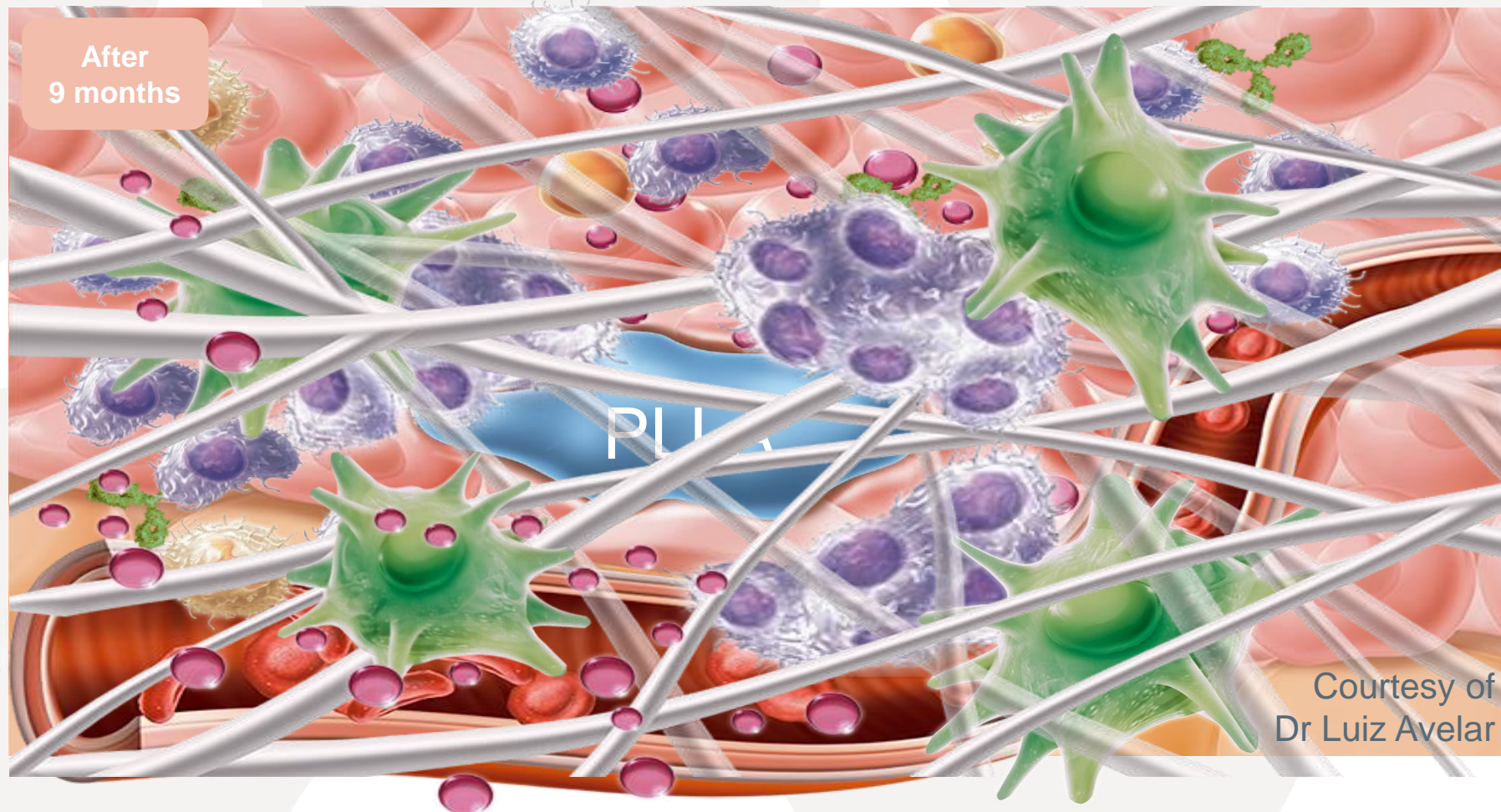
# Deposition of COLLAGEN – 3 weeks later **GAIN** by GALDERMA



Courtesy of  
Dr Luiz Avelar

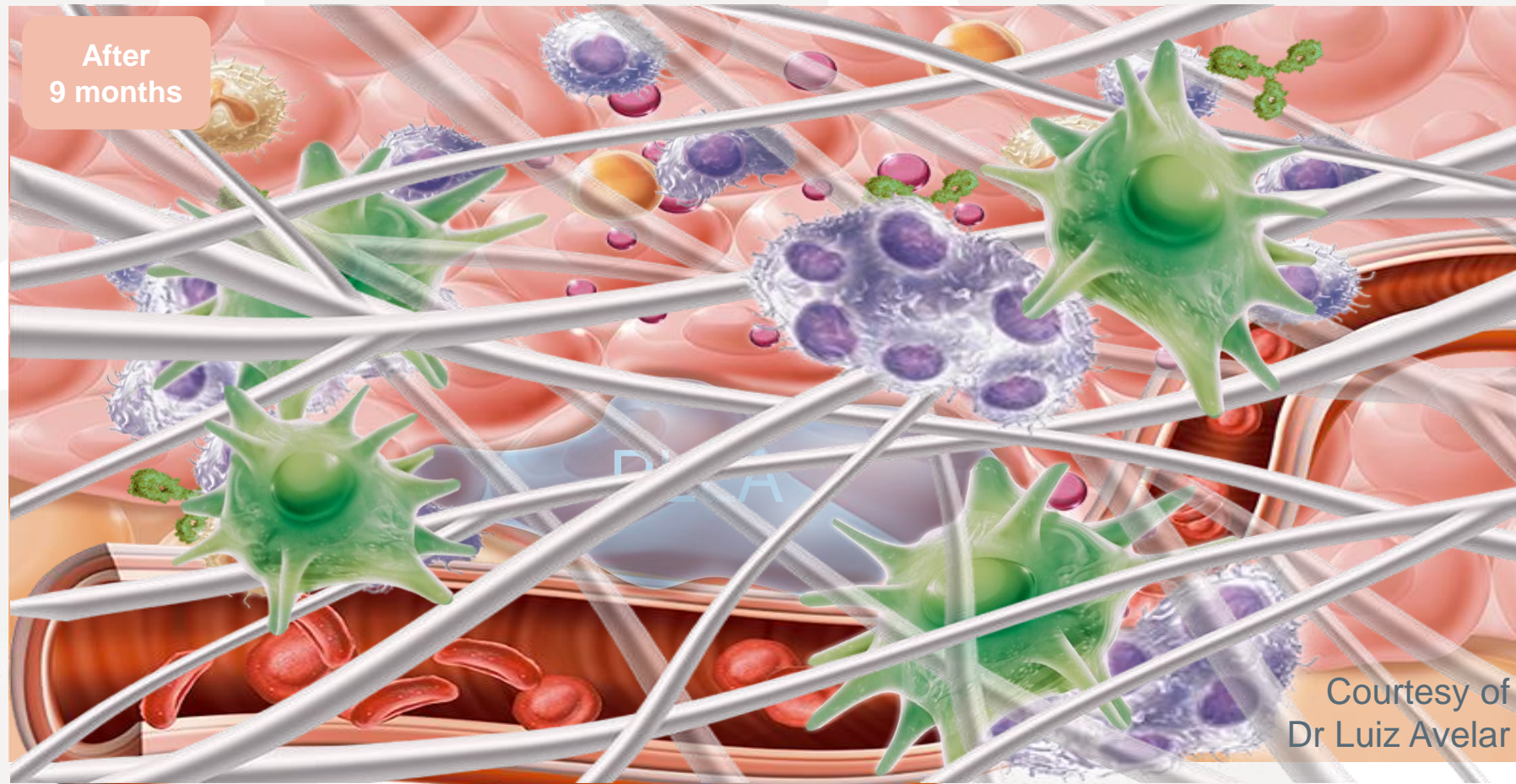


# Controlled inflammatory response

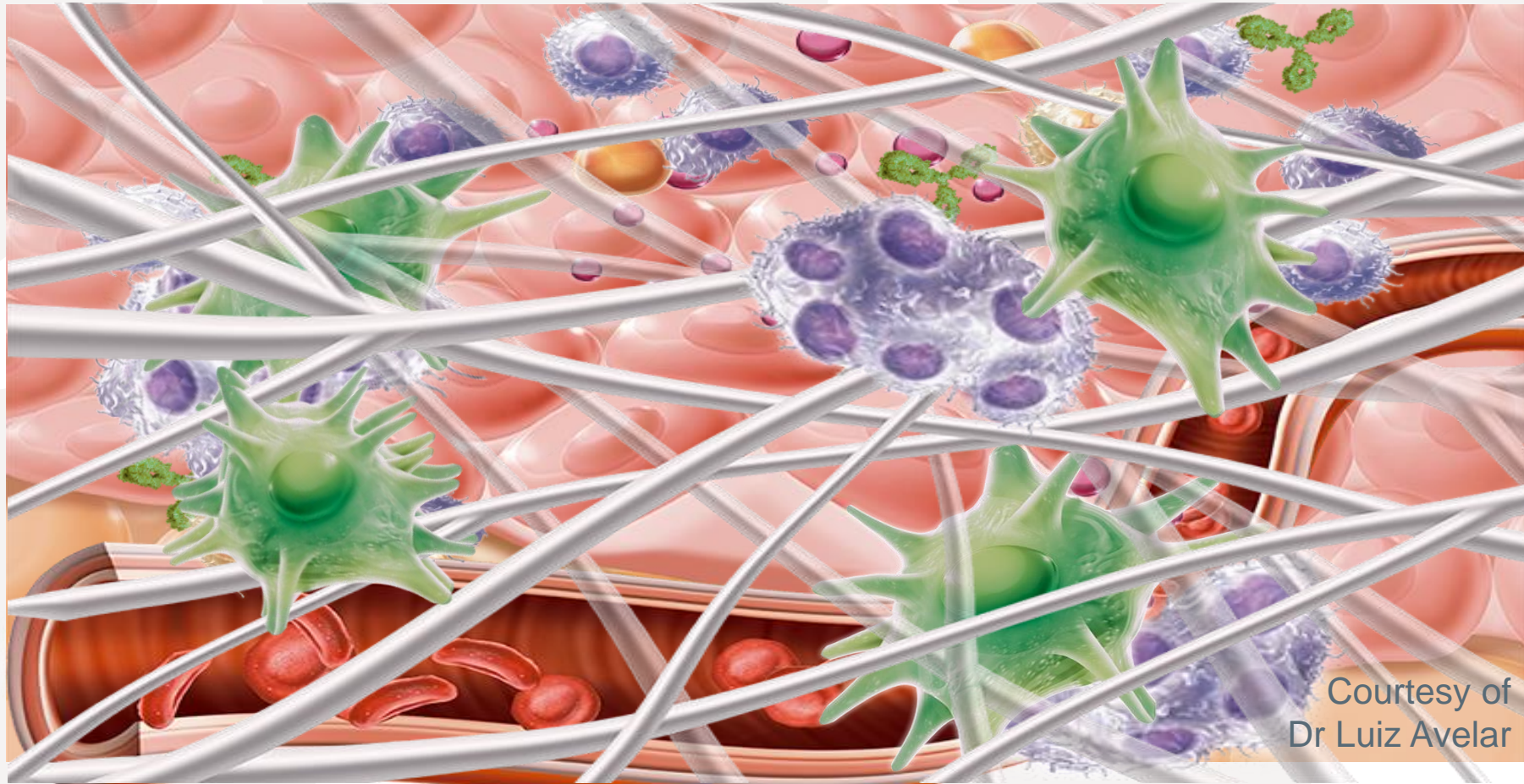




# Controlled inflammatory response

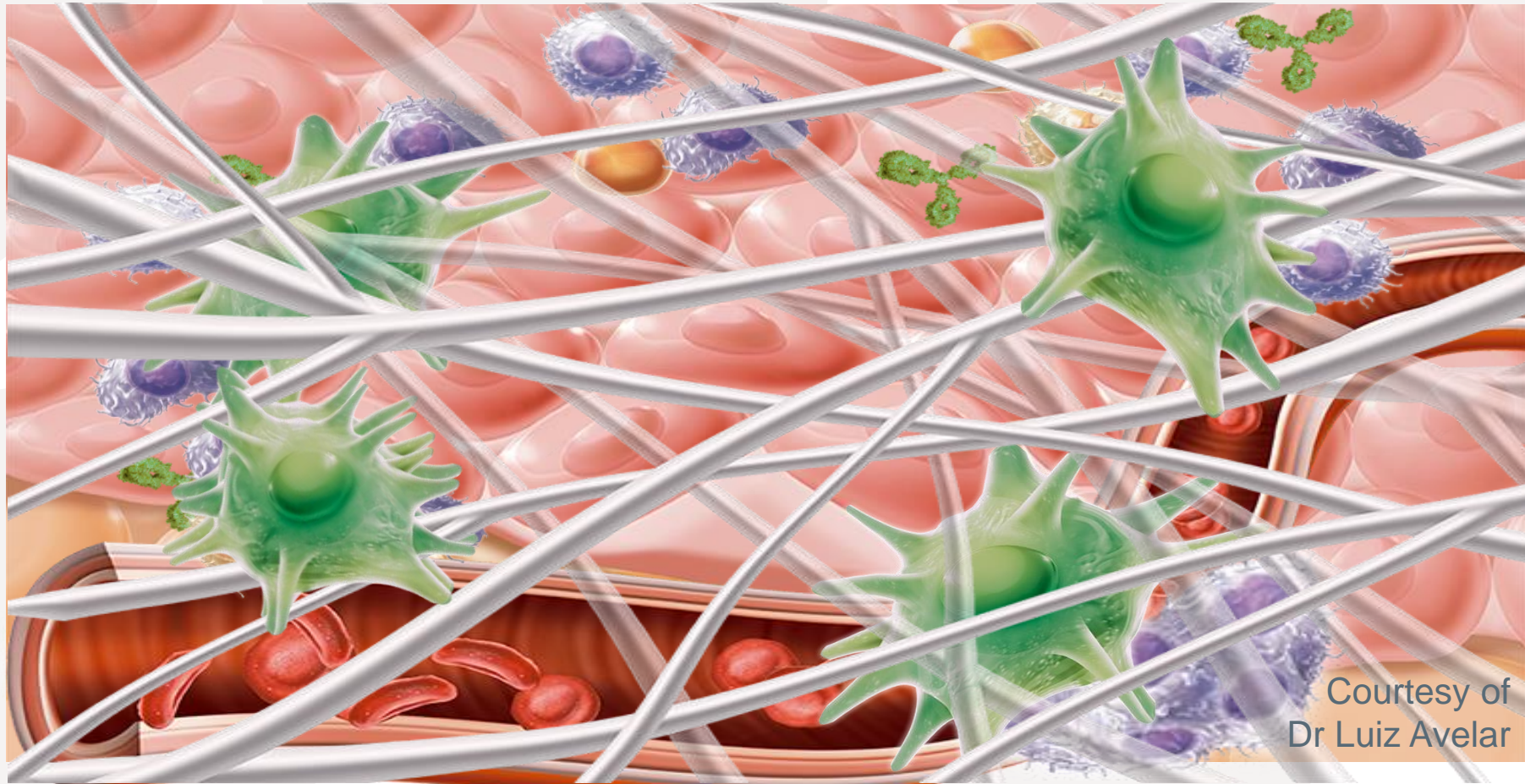






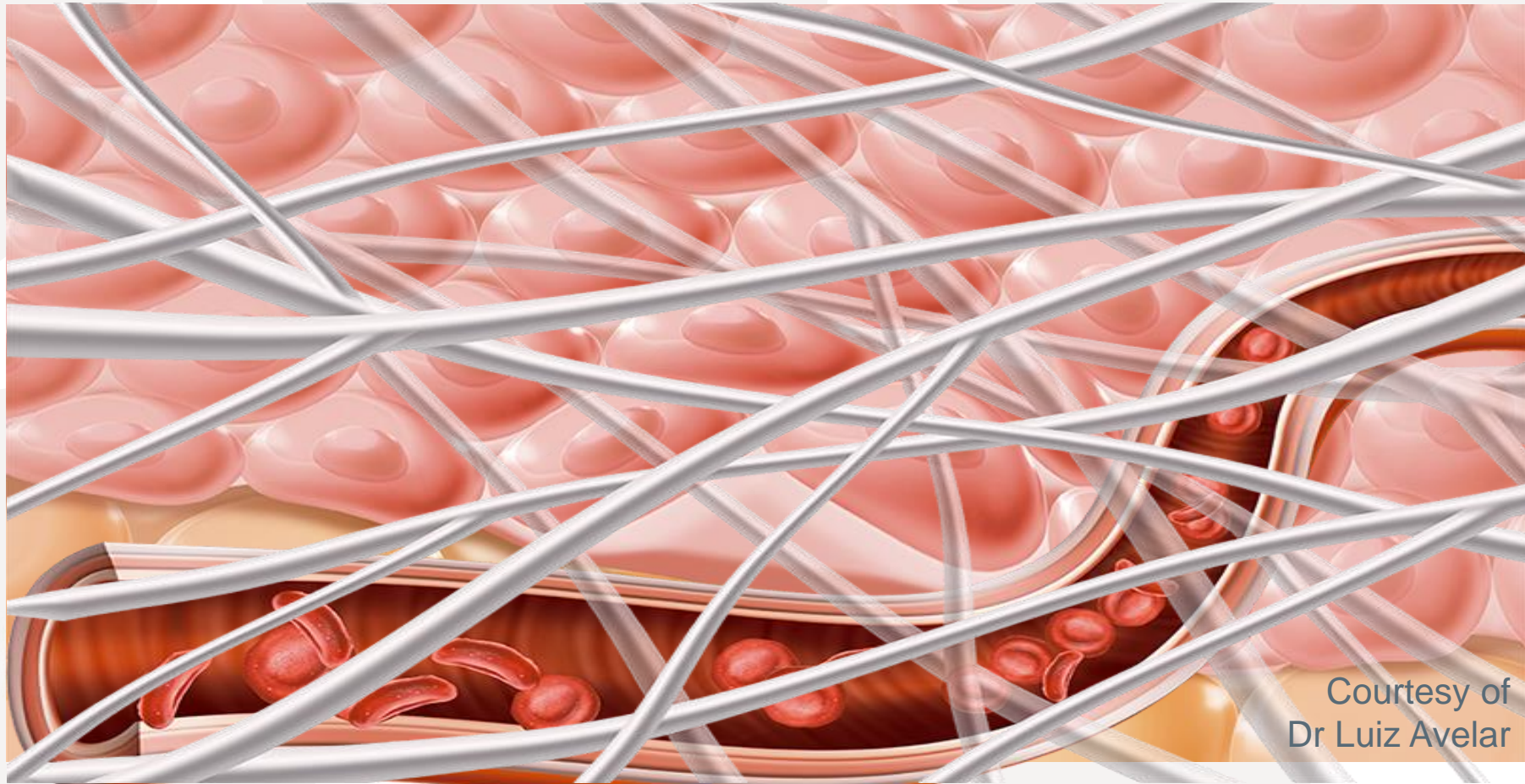
Courtesy of  
Dr Luiz Avelar





Courtesy of  
Dr Luiz Avelar

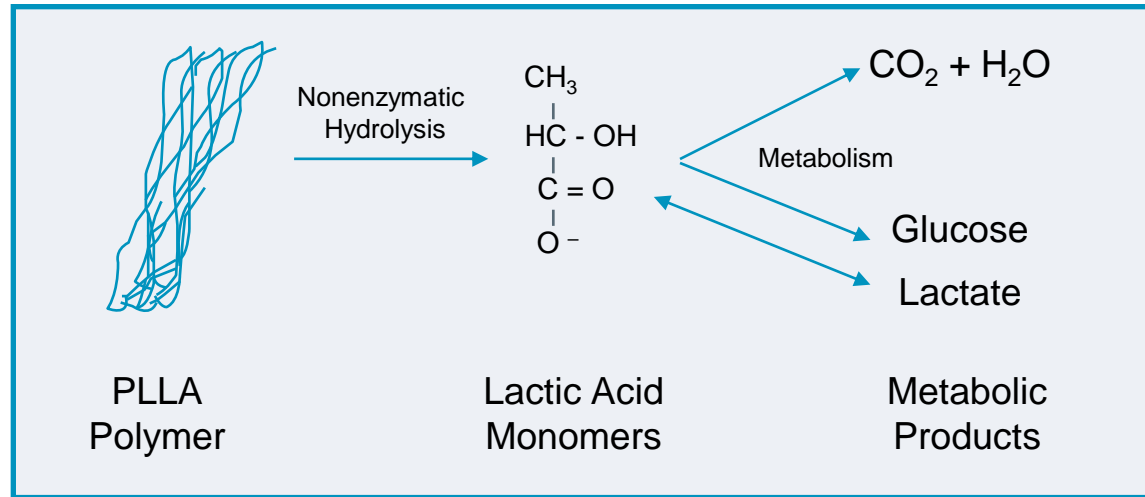




Courtesy of  
Dr Luiz Avelar

# Metabolism of Sculptra®

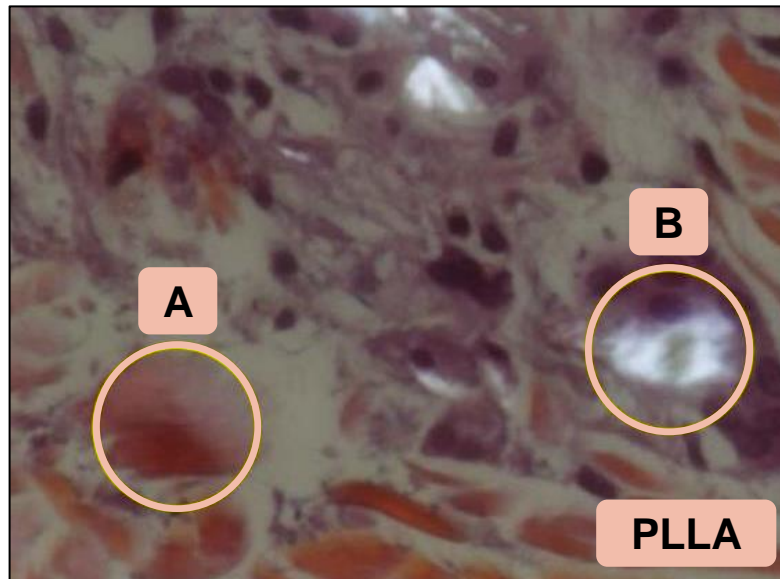
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- ✓ PLLA is itself **INSOLUBLE** in water
- ✓ CMC and **MANNITOL** are **SOLUBLE**

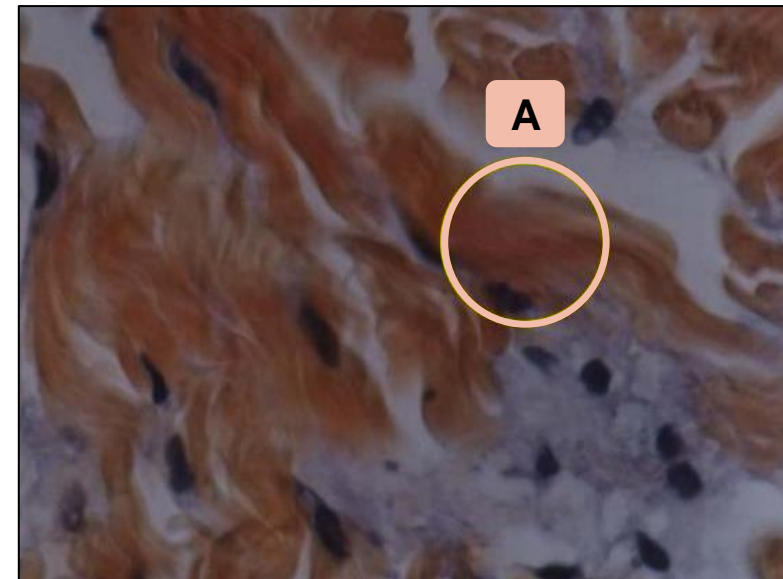
Over time within the tissue, the PLLA polymers break down through non-enzymatic hydrolysis to lactic acid monomers, which are then metabolized to carbon dioxide and water or are incorporated into glucose and naturally eliminated from the body

Clinical study biopsies demonstrate that PLLA gradually promotes collagen growth<sup>1</sup>



## At 12 months

(A) Aggregation of giant cells, histiocytes, and collagen; (B) microparticles of PLLA



## At 30 months

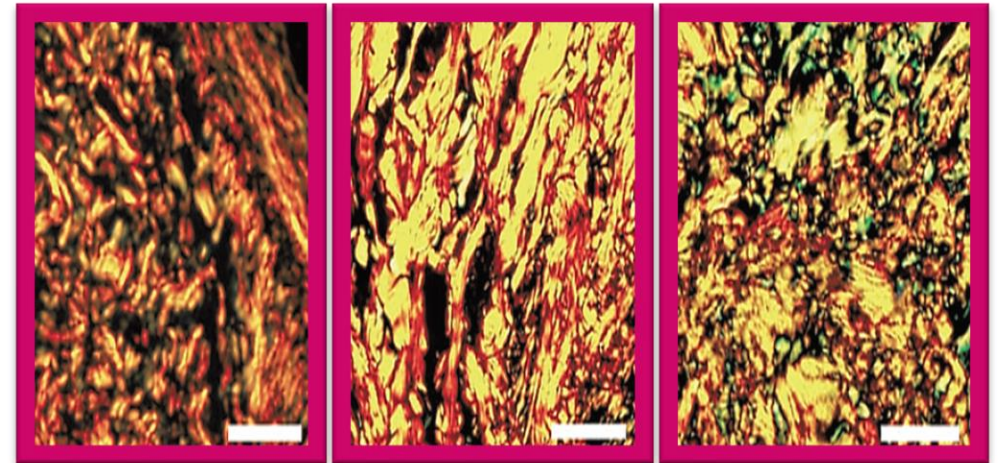
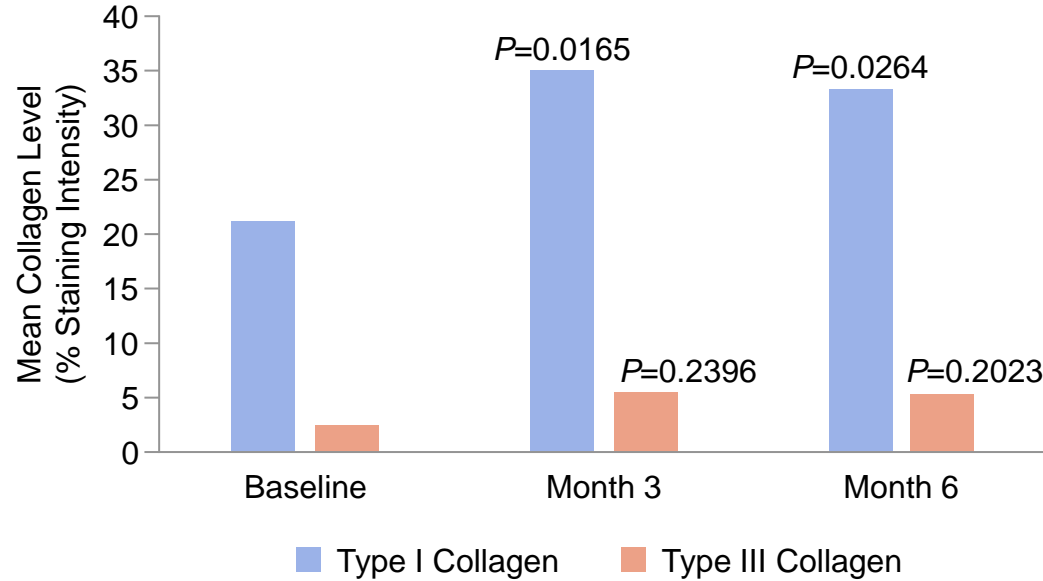
(A) Lack of PLLA microspheres; abundance of collagen in skin

PLLA, poly-L-lactic acid.

1. Vlegaar D and Bauer U. *J Drugs Dermatol.* 2004;3:542.

# Increase in Collagen Type I and III

GAIN



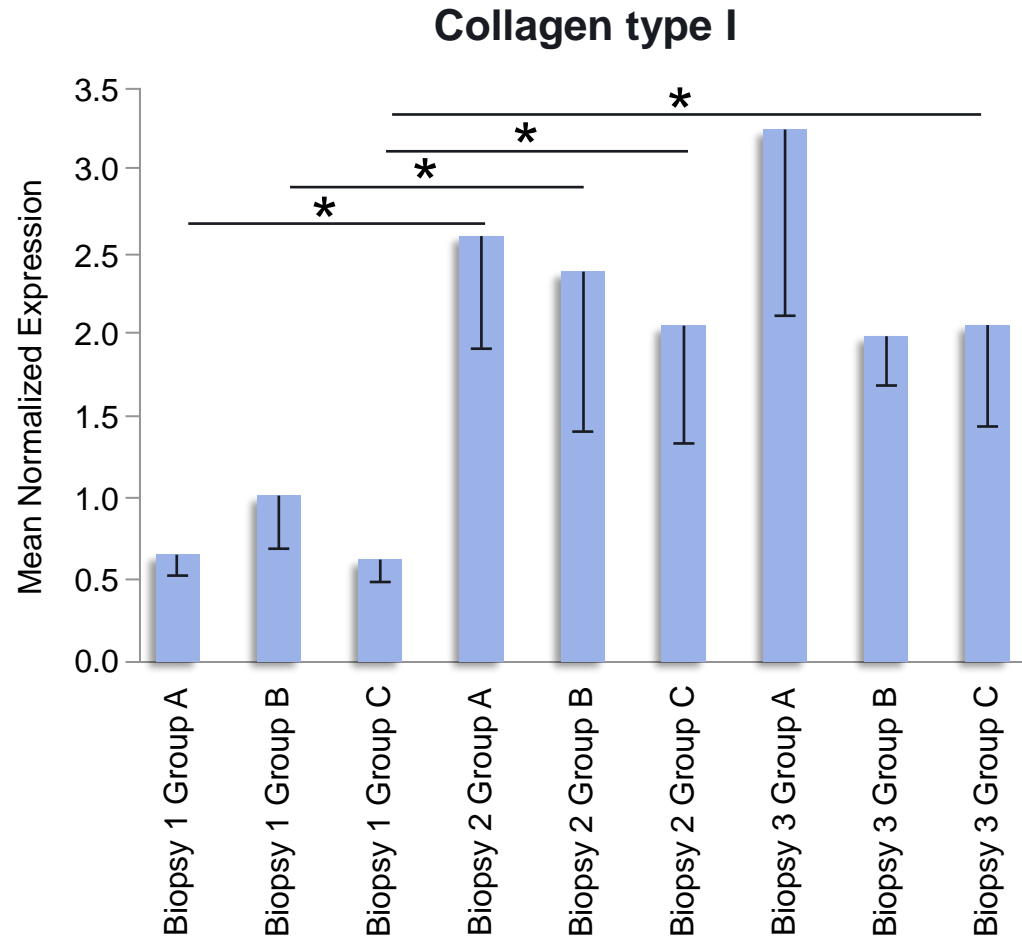
Increase of **66.5%** in type I collagen after 3 months

Collagen fibers in yellow



# Collagen Production

GAIN

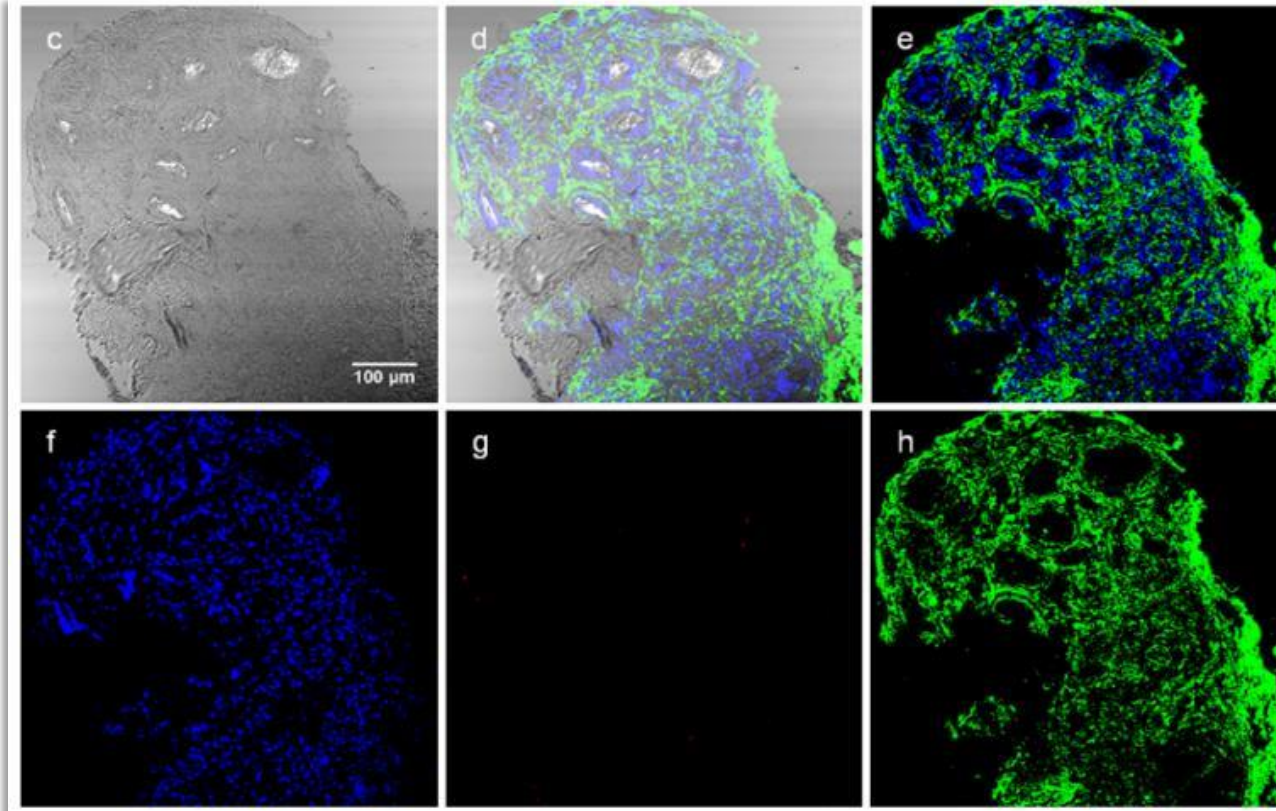


- 21 postmenopausal women
- Follow-up of 20 months
- 4 sessions upper arm
- 1 vial per session
- Studied by biopsies



# Collagen Production

GAIN



- Substantial collagen type III deposition was detected next to PLLA particles and collagen type I was found at the periphery of PLLA encapsulations

## Authors' Conclusions:

*“PLLA-induced augmentation is most likely based on capsule formation orchestrating macrophages, (myo-) fibroblasts, and collagen type I and III fibres. We observed considerably slower degradation of PLLA particles than described previously. Thus, PLLA particles were still retrievable 28 months after subcutaneous application.”*

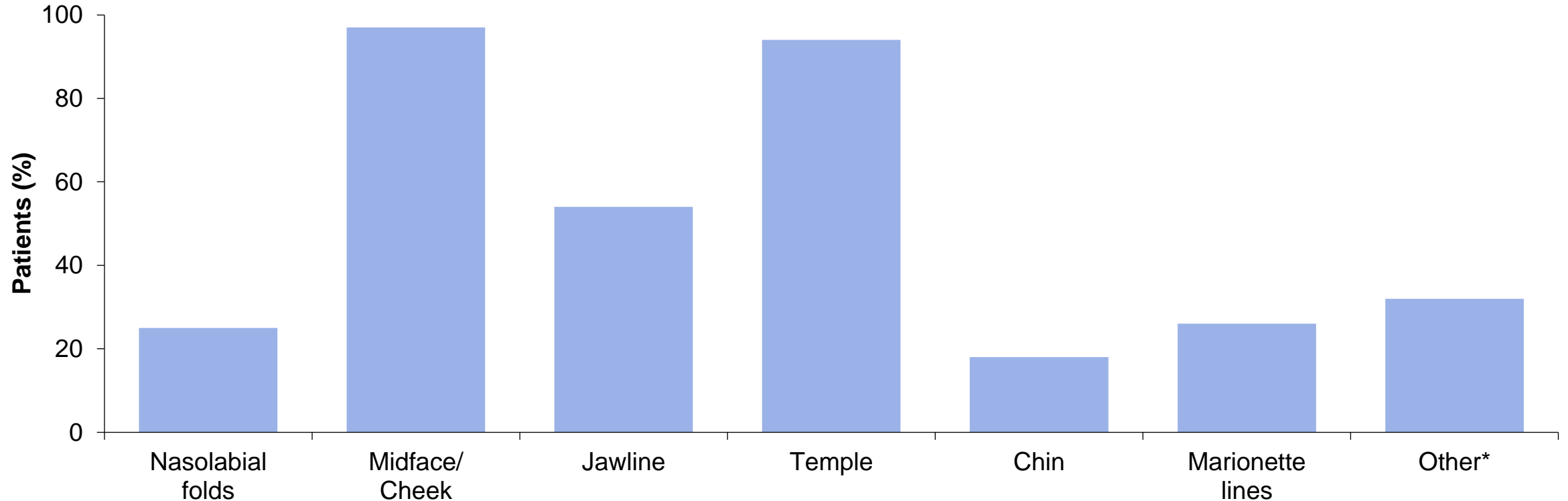
GAIN

# Product Preparation

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# Patients Treated, by Facial Area

GAIN



- Almost all patients were treated in midface/cheek and temple area. More than half received treatment in the jawline

\*Other includes: periauricular, preauricular, oral commissure, perioral, scalp, piriform fossa, mental crease, and prejowl sulcus.

Palm M, et al. *J Drugs Dermatol.* 2021;20(1):118-122.

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- This chart review verifies that aesthetic treatments with PLLA reconstituted to a final volume of 8–10 mL, including anesthetics, are suitable for a number of facial indications:
  - Sculptra was most commonly used in the midface/cheek area (97% of patients), followed by the temple (94% of patients)
  - Supraperiosteal injection was used by the majority of injectors for all prespecified indications including NLFs, midface/cheek, jawline, temples, chin, and marionette lines. Subcutaneous injection was reported by a majority of injectors for jawline and marionette lines

- The treatments were associated with an acceptable safety profile, demonstrated by a low number of reported adverse events
- Results from this retrospective study indicate that the rate of nodules may be low, by using a higher reconstitution volume

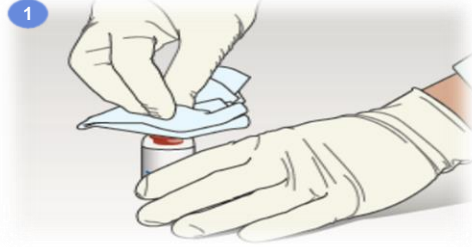
# New Sculptra® Reconstitution Protocol Video



# Sculptra<sup>®</sup> Reconstitution<sup>1,2</sup>

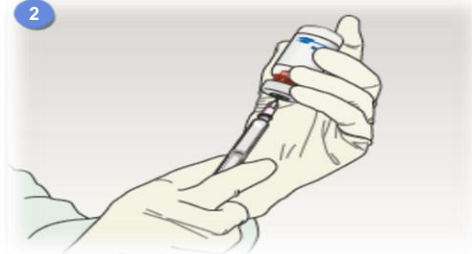
GAIN

## Remove cap and clean



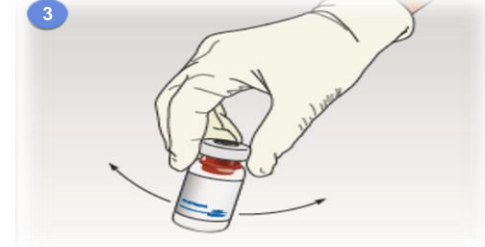
Remove the flip-off cap and clean the penetrable vial stopper with antiseptic.

## Mix with Sterile Water for Injection



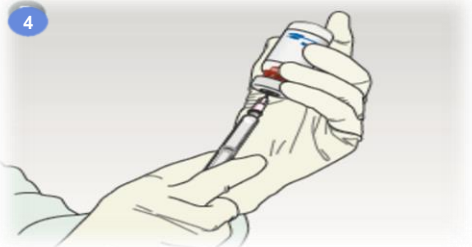
Attach 18G needle to sterile single-use 5-mL syringe, draw 5-mL SWFI into syringe. Invert the vial and introduce needle into stopper and slowly add SWFI into the vial.

## Agitate the vial upright prior to injection



Shake the vial vigorously by hand or by single vial swirling agitator for about 1 minute to dissolve the excipients. Inspect the vial for any remaining lumps, and if needed shake more. A translucent suspension with some foam on the top will be obtained.

## Mix with Sterile Water for Injection



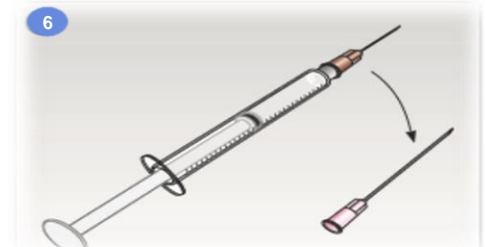
If desired, add up to 3 mL of additional sterile water for injection using the syringe and a new 18G needle. Shake again in order to get a homogenous suspension.

## Withdrawing the suspension



Clean stopper of vial and withdraw suspension using 18G single-use, 1- or 3-mL sterile syringe.

## Switching to a 26G needle



Switch to 25G or 26G sterile needle before injecting. Do not use needles with internal diameter smaller than 26G for injection.

SWFI, sterile water for injection.

1. Sculptra<sup>®</sup> Aesthetic. Product Labeling. Instructions for Use. Sculptra<sup>®</sup> EU; 2. Palm MD and Chayavichitsilp P. *J Drugs Dermatol.* 2012;11:1046.

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Just before injection (max 20 min) add 2 ml of Lido 2%

When reconstituting with the new, recommended 2-step protocol, Sculptra<sup>®</sup> can be used immediately<sup>1</sup>

- The simple 2-step process is as follows:

1. Add 5 mL sterile water and **shake vigorously** for about 1 minute, until homogeneous suspension is achieved\*



2. Add additional 3 mL of sterile water and **shake again** until suspension is homogeneous



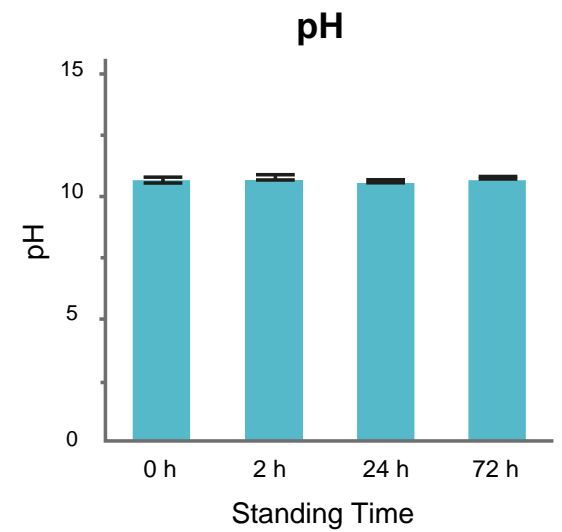
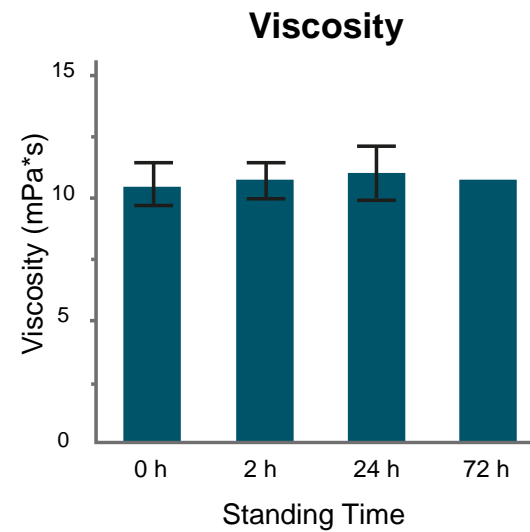
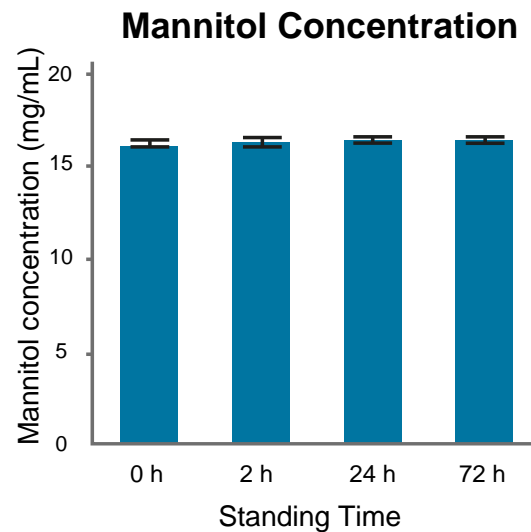
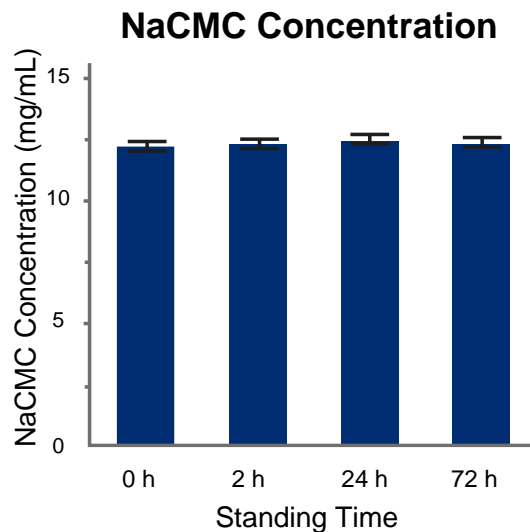
- Sculptra<sup>®</sup> can then be used immediately, or stored for up to 72 hours at room temperature
- To make the injections more comfortable, it is optional to add **2 mL of 2% lidocaine** to the solution immediately before injecting

1. Sculptra<sup>®</sup> Aesthetic European Instructions for Use.

# Immediate Reconstitution Does Not Change Physicochemical Properties

GAIN

- Standing time had no impact on the studied parameters; physicochemical properties of the Sculptra suspension were similar if analyzed immediately or if left standing for up to 72 hours after reconstitution
- Similar results in viscosity and concentration of suspending agents demonstrate acceptable homogeneity of the solution and complete dissolving of excipients regardless of standing time
- pH stability with different reconstitution procedures indicates no degradation of PLLA into lactic acid



*Each error bar is constructed using 1 standard deviation from the mean.*

NaCMC, sodium carboxymethylcellulose; PLLA, poly-L-lactic acid.  
Baumann K, et al. *J Drugs Dermatol.* 2020;19(12):1199-1203.

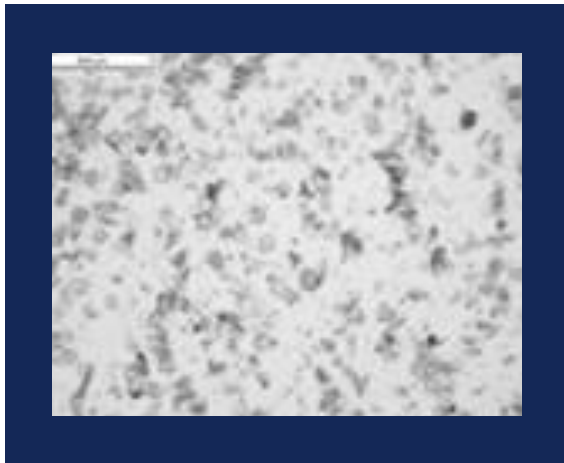
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# Immediate Reconstitution Does Not Change Physicochemical Properties

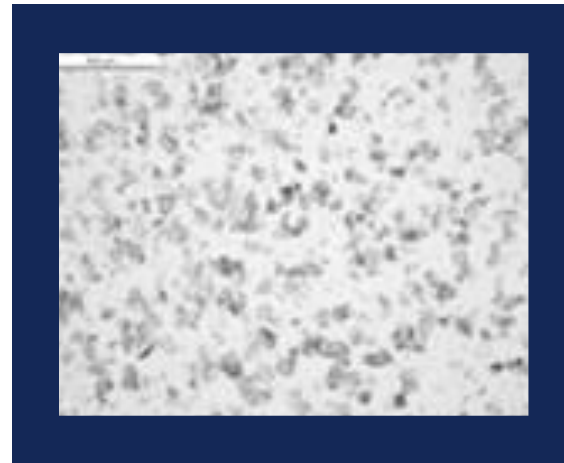
GAIN

- Standing time had no impact on PLLA particle shape or size distribution as observed from microscopy images
- Lidocaine content was equivalent between measurements, and no degradation products above the quantitation limit were observed

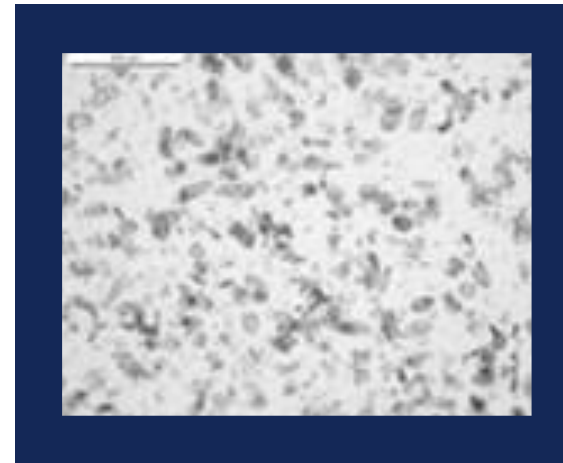
**Standing Time: 0 h**



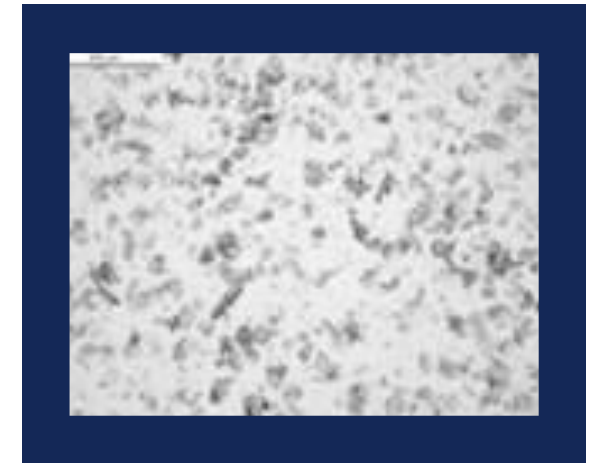
**Standing Time: 2 h**



**Standing Time: 24 h**



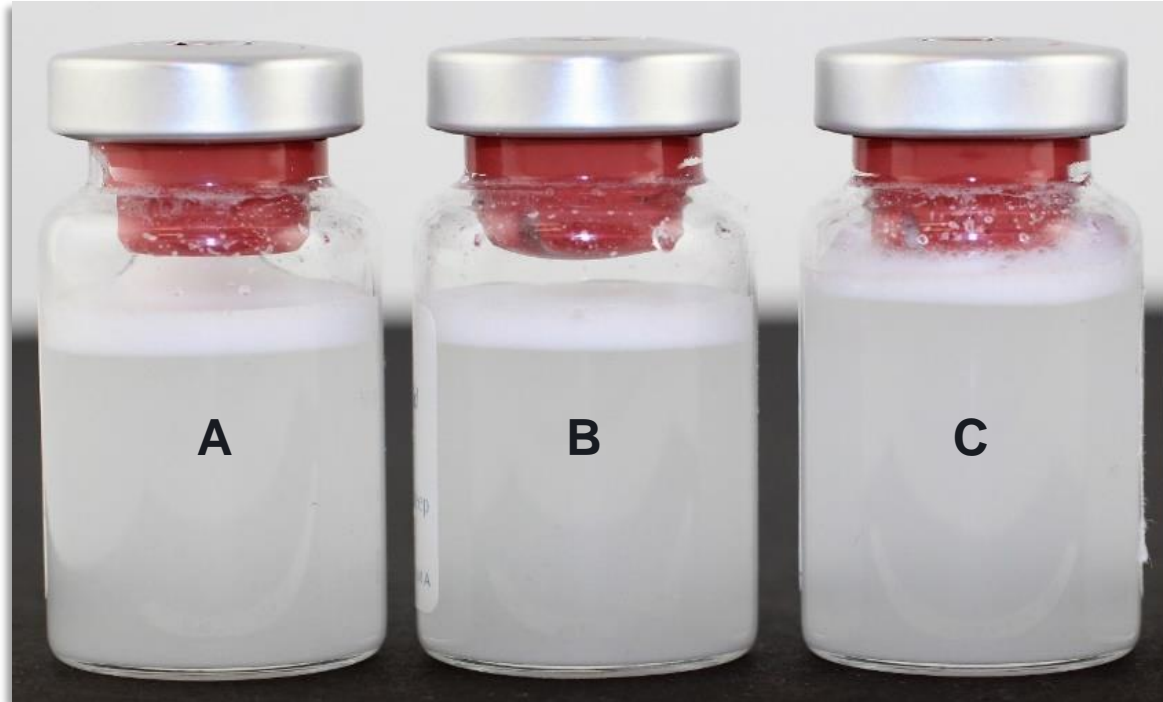
**Standing Time: 72 h**



PLLA, poly-L-lactic acid.  
Baumann K, et al. *J Drugs Dermatol*. 2020;19(12):1199-1203.

# Immediate Reconstitution Does Not Change Physicochemical Properties

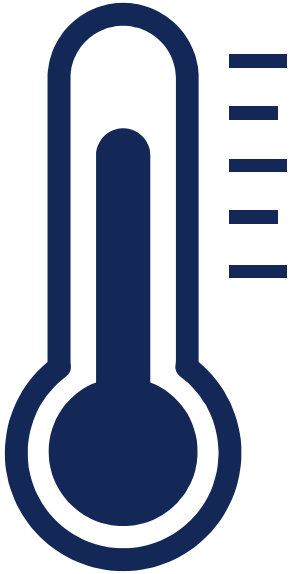
GAIN



- A. 0 hours standing time, immediately shaken for 1 minute
- B. 72 hours standing time before shaken for 1 minute
- C. 0 hours standing time, immediately shaken for 1 minute with addition of 1 mL 2% lidocaine HCl

- From visual inspection, no difference was observed regarding presence of foam in the upper layer of the samples
- Increasing the reconstitution volume to 8 mL may help the withdrawal of product suspension from the vial without withdrawing foam





Reconstituted Sculptra<sup>®</sup> can be stored  
with refrigeration (2–8 °C)  
or at room temperature (up to 30 °C)  
during hydration

- If the solution is not used immediately, the reconstituted product can be stored for 72 hours

GAIN

# Clinical Use

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# Sculptra<sup>®</sup> Label – Europe

GAIN

- Sculptra<sup>®</sup> is suitable for increasing the volume of depressed areas, particularly to correct skin depressions, such as in skin creases, wrinkles, folds, scars, and for skin aging
- Sculptra<sup>®</sup> is also suitable for large volume corrections of the signs of facial fat loss (lipoatrophy)

# Current Aesthetic Indications

GAIN

Region/Country	Indication
Europe	<ul style="list-style-type: none"> <li>• Sculptra® is suitable for increasing the volume of depressed areas, particularly for correcting skin depressions, such as skin creases, wrinkles, folds, scars, and aging skin</li> <li>• Sculptra® is also suitable for large volume corrections of the signs of facial fat loss (lipoatrophy)</li> </ul>
APAC	<ul style="list-style-type: none"> <li>• Sculptra® is suitable for increasing the volume of depressed areas, particularly for correcting skin depressions, such as skin creases, wrinkles, folds, scars, and aging skin</li> <li>• Sculptra® is also suitable for large volume corrections, such as the signs of facial fat loss (lipoatrophy)</li> </ul>
USA	<ul style="list-style-type: none"> <li>• Sculptra® is indicated for correction of <u>shallow to deep nasolabial fold contour deficiencies</u> and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate</li> <li>• Sculptra® is indicated for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (HIV)</li> </ul>
Brazil	<ul style="list-style-type: none"> <li>• Sculptra® is a biostimulator which should be injected into the deep dermis, subcutaneous tissue, or supraperiosteal region to improve sagging skin as a result of the intrinsic and extrinsic aging process and for volume correction of depressed areas such as furrows, wrinkles, skin depressions, atrophic scars, and changes due to lipoatrophy of the treated area</li> </ul>
Region/Country	Indication
Europe	<ul style="list-style-type: none"> <li>• Sculptra® is suitable for increasing the volume of depressed areas, particularly for correcting skin depressions, such as skin creases, wrinkles, folds, scars, and aging skin</li> <li>• Sculptra® is also suitable for large volume corrections of the signs of facial fat loss (lipoatrophy)</li> </ul>

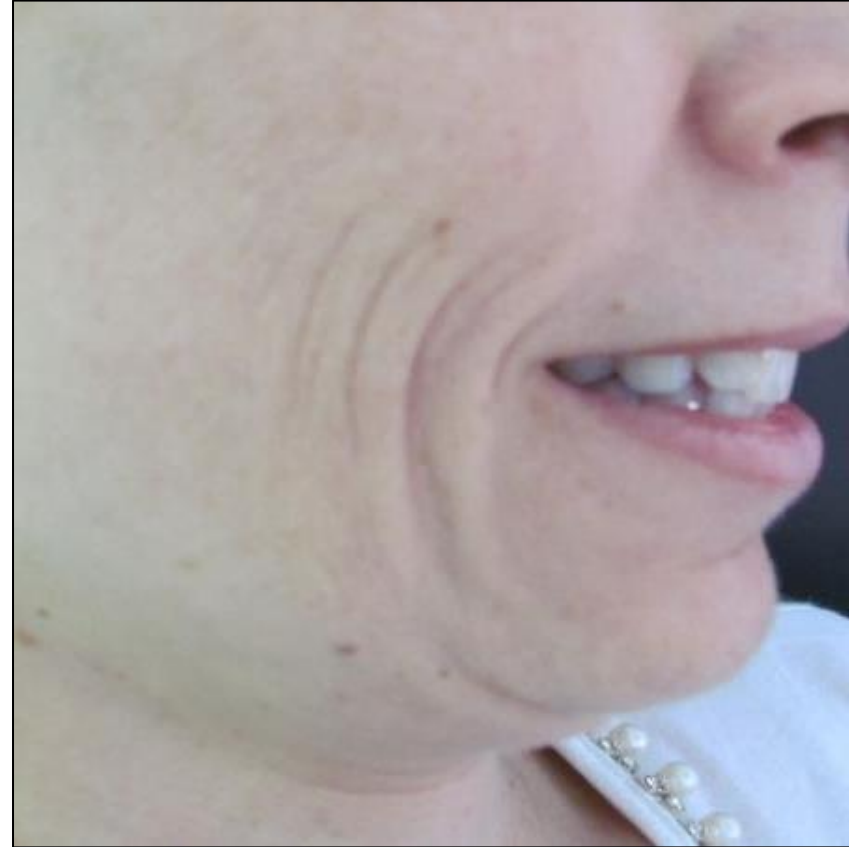


# What Can We Treat With Sculptra®?

GAIN



**Fat loss**



**Skin aging / laxity<sup>a</sup>**

<sup>a</sup>Sculptra EU Instructions for Use.

# When Not to Apply Sculptra®

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- Active local inflammation or infection
- Areas of hyperdynamic muscles
- History of keloids and hypertrophic scars
- Connective tissue diseases
- **Active immunological disease**
- Pregnancy or lactation



\*Packaging images may vary by country; for illustration purposes only.  
Sculptra® Aesthetic Instructions for Use.

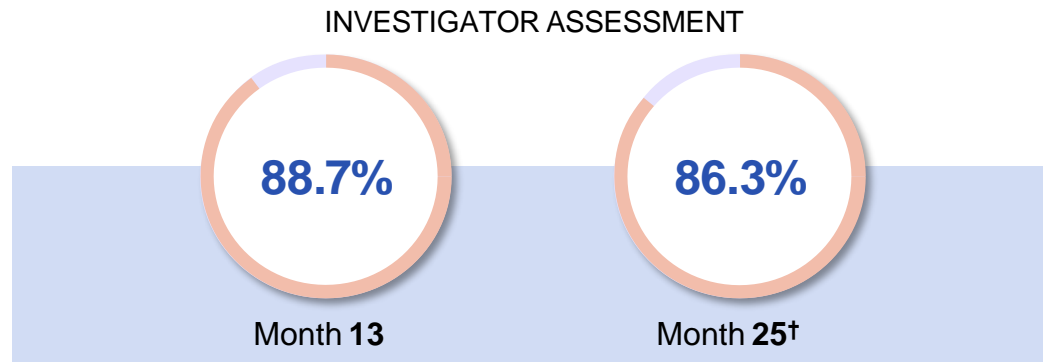
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# Long-Lasting Results

GAIN

Sculptra® helps patients achieve long-lasting, satisfying results

## Treatment results lasted up to 25 months\*

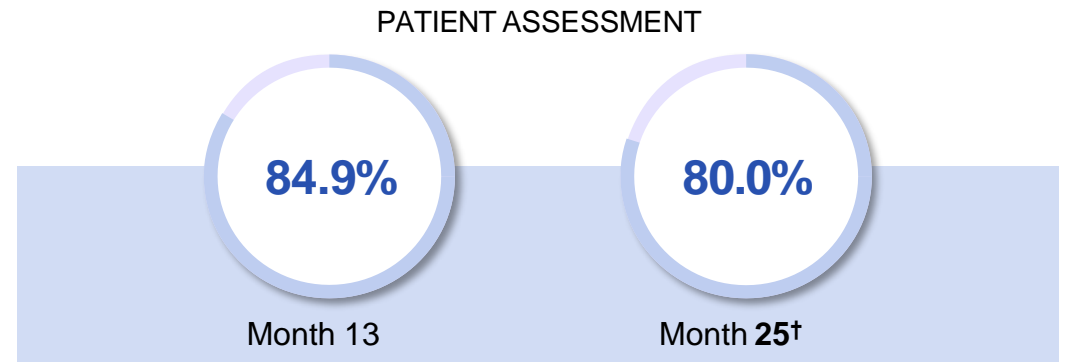


\*Investigators used a 5-point scale for global evaluations (0=no wrinkles; 1=just perceptible wrinkle; 2=shallow wrinkle; 3=moderately deep wrinkle; 4=deep wrinkle, well-defined edges; 5= very deep wrinkle, redundant fold).

Randomized, evaluator-blinded, parallel-group, multicenter study of 233 patients; 116 patients received Sculptra® (106 completed) and 117 received collagen (111 completed). The long-term surveillance phase included 106 patients who received Sculptra® (95 completed)

INVESTIGATORS SAW IMPROVEMENT IN 86.3% OF PATIENTS 2 YEARS AFTER TREATMENT WITH SCULPTRA®

## High levels of patient satisfaction were maintained through 25 months



†These patients all received Sculptra®, and were followed up as part of a surveillance phase for almost twice the amount of time as the original study group (25 vs 13 months; n=95 patients)

80.0% OF PATIENTS WHO RECEIVED SCULPTRA® STILL RATED THEIR RESULTS AS "GOOD" OR "EXCELLENT" AT 25 MONTHS

## Clinical results achieved with a series of repeated treatments

- A Sculptra® treatment program typically includes 2 or 3 treatment sessions given every 6 weeks, with 1–2 vials per session to achieve the desired effect

## Gradual improvement<sup>1-6</sup>

- Sculptra® effects develop gradually because of the time needed for the body to stimulate collagen production and resultant changes in skin appearance
- Gradual results that are natural looking

## Durable

- Results are visible and noticeable for at least 25 months<sup>6</sup>

1. Stein P, et al. *J Dermatol Sci*. 2015;78:26-33; 2. Goldberg D, et al. *Dermatol Surg*. 2013;39(6):915-922; 3. Valantin M-A, et al. *AIDS*. 2003;17(17):2471-2477; 4. Mest DR, et al. *Dermatol Surg*. 2006;32(11):1336-1345; 5. Moyle GJ, et al. *HIV Med*. 2004;5:82-87; 6. Narins RS, et al. *J Am Acad Dermatol*. 2010;62:448.



GAIN

Facial Assessment  
&  
Injection Techniques

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46YO

- Good lateral projection in the midface
- Good midface volume except for mild anterior malar loss
- Very good bone structure in the lower face, good contour for her age



- Skin laxity



Courtesy of  
Dr R Ferraz



# Treatment Plan – Area of Injection

GAIN



X - Volume loss  
/// - Skin aging/laxity

# Subcutaneous Injection

GAIN

## Needle

Subcutaneous  
injection using 25G  
or 26G needle

Goal: Treatment of  
volume loss



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# Subdermal Injection

GAIN

## Needle

Subdermal injection  
using 25G or 26G  
needle

Goal: Treatment of  
facial skin laxity



GALDERMA



# Treatment Plan – Volumes

GAIN

0,1 ml / injection point

26G needle

34 points (3,4 ml)



0,1 ml / injection

6 points (0,6 ml)

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# Facial Assessment

GAIN

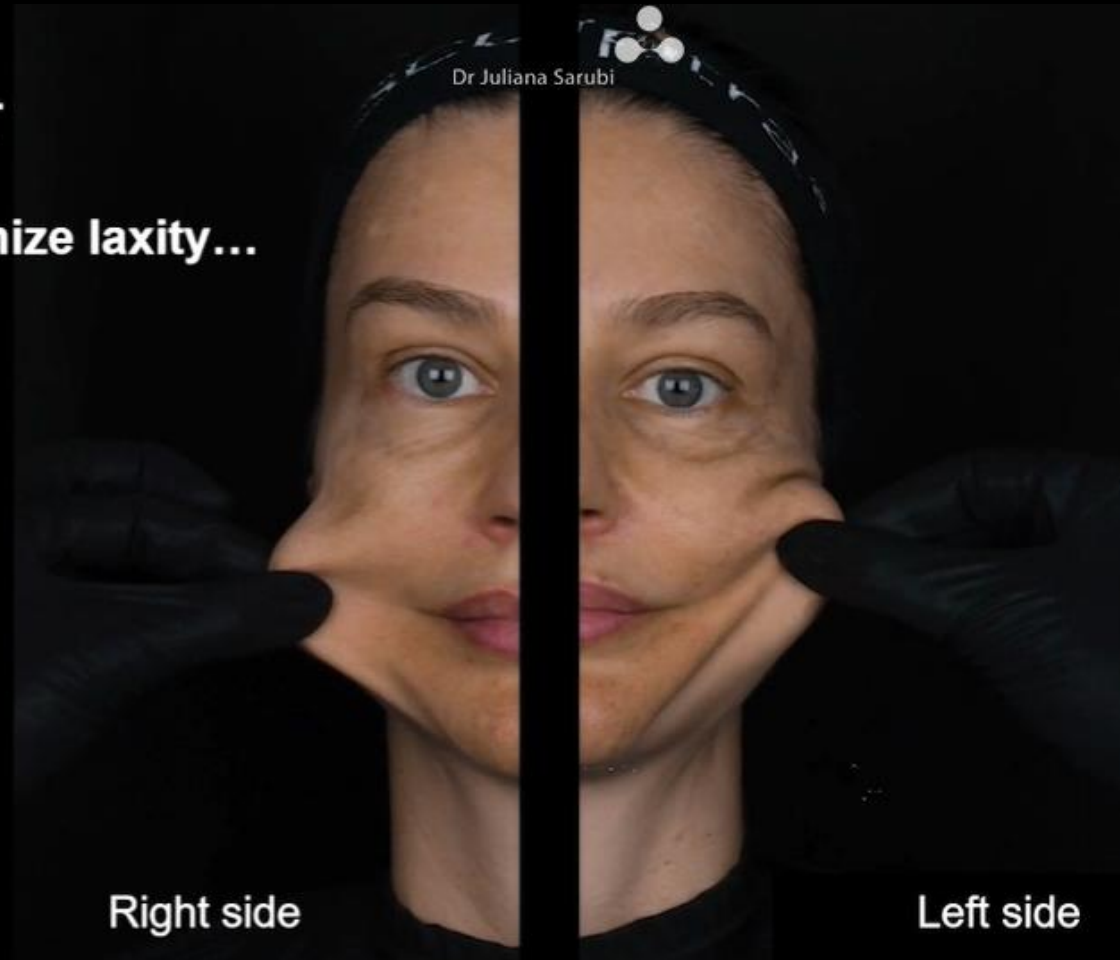


- Square face
- Good bone structure
- Volume loss – anterior malar and submalar

46 YO

## FACIAL ASSESSMENT

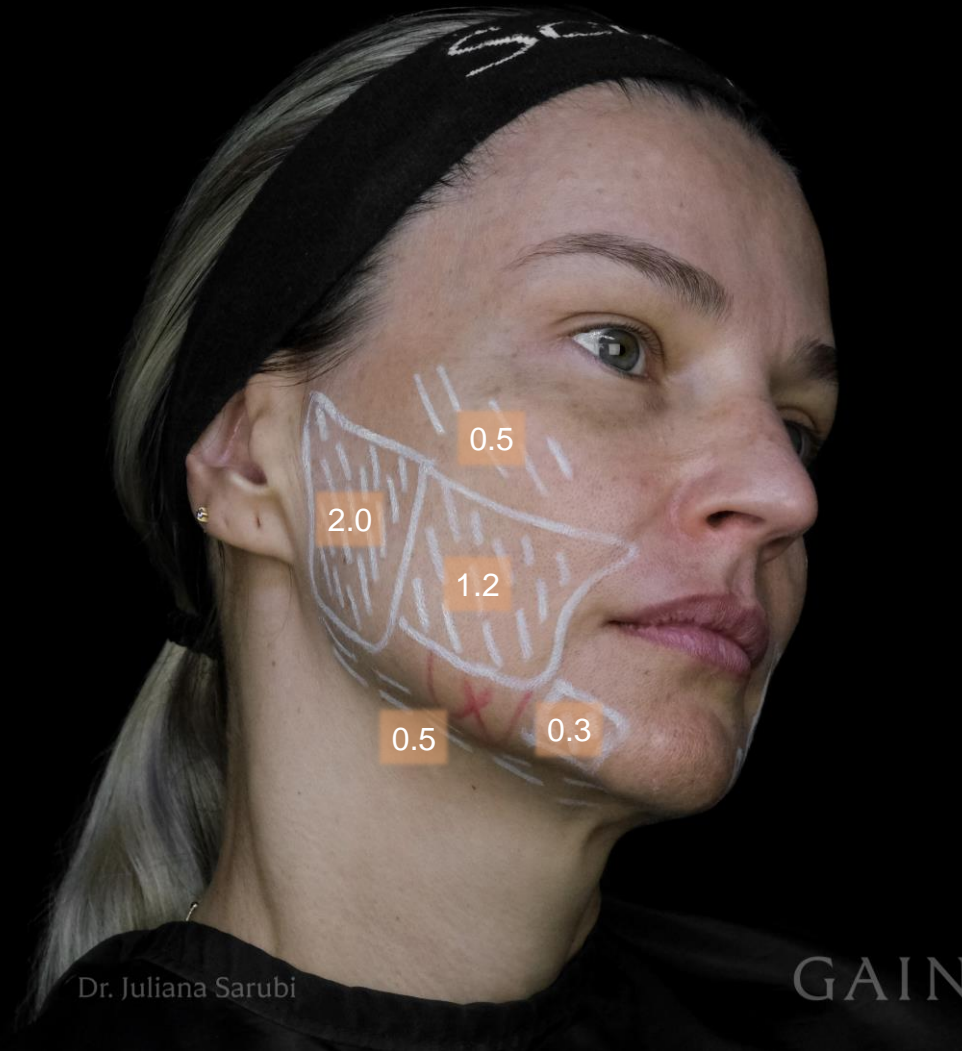
The best way to recognize laxity...



Courtesy of  
Dr J Sarubi

# Treatment Plan – Area and Volumes

GAIN

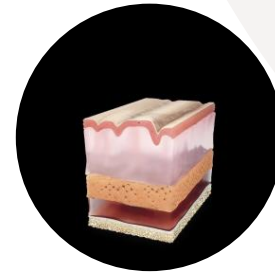


Note: Volumes are in milliliters.

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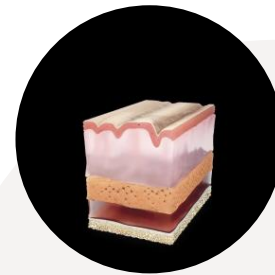
# Treatment plan – depth of injection

Volume loss / lipoatrophy



Subcutaneous

Skin laxity

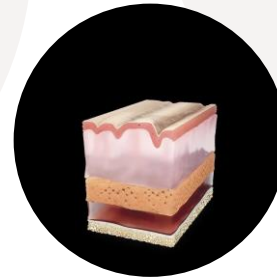


Subdermal



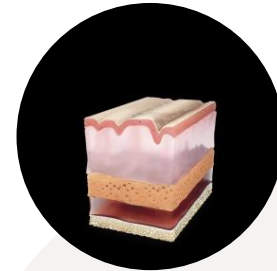
# Treatment plan – depth of injection

Bone resorption only in Zygoma



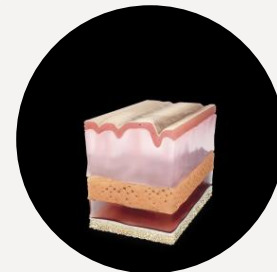
**Periosteal**

Volume loss / lipoatrophy



**Subcutaneous**

Skin laxity



**Subdermal**

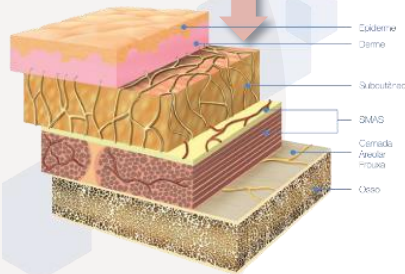
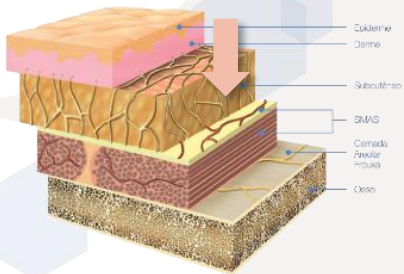
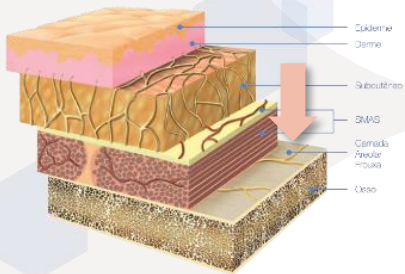
# Sculptra® addresses multiple signs of aging



Bone resorption

Fat loss

Skin laxity



# Subcutaneous injection



## Cannula

- Subcutaneous injection in zygoma to restore the malar projection



Courtesy of  
Dr Luiz Avelar

# Subcutaneous injection



## Cannula

- Subcutaneous injection in the temporal fossa



Courtesy of  
Dr Luiz Avelar



# Subcutaneous injection



## Cannula

- Subcutaneous injection in lower face



Courtesy of  
Dr Luiz Avelar

# Subcutaneous injection



## Needle

- Subcutaneous injection with needle

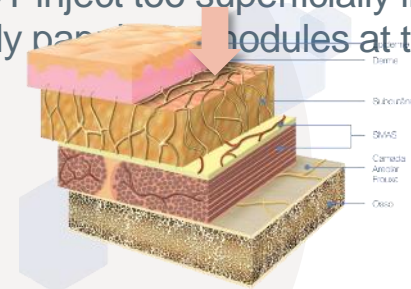


Courtesy of  
Dr Luiz Avelar

# Skin aging / laxity



- **Plane of injection:** Subdermal
- **Needle** 25G or 26G
- **Cannula** 22G
- **Aspirate before injection!**
- **Volume per injection:** The maximum volume of Sculptra per each individual injection should be limited to 0.1 mL – 0.2 mL, spaced at a distance of 0.5 – 1 cm. Avoid overcorrection.
- **Volume per treatment area:** The volume of product injected per treatment area will vary depending on the surface area to be treated.
- **Important:** Do NOT inject too superficially in order to avoid the appearance of early paronychia nodules at the injection site



# Subdermal injection

- Needle or cannula
- The main goal is to make the adherence between skin and the deeper planes of face
- Do not inject too much product and maintain a homogeneous distribution in the region of the face you want to treat
- If the needle becomes occluded or dull during an injection session, replacement may be necessary
- Massaging the treated area helps to evenly distribute the product (use of an appropriate cream may reduce the friction on the skin surface during massaging)
- The patient should periodically massage the treated areas for the first week



# Subdermal injection



## Cannula

- Subdermal injection using cannula
- Goal: Treatment of facial skin laxity



Courtesy of  
Dr Luiz Avelar

# Injection Recommendations<sup>1</sup>

GAIN

- Aspirate before each injection to avoid intravascular deposition
- To maintain a homogeneous suspension throughout the procedure, intermittently agitate the product in the syringe
- If clogging occurs, remove the needle, expel a small amount of product, attach a new sterile needle, and then expel a few drops of Sculptra<sup>®</sup> to eliminate the air and re-check for needle blockage
- Thoroughly massage the treated area(s) to evenly distribute the product (use of an appropriate cream may help reduce the friction on the skin surface during massaging)
- Avoid superficial injections in order to avoid the appearance of early papules or nodules at the injection site, which could be suggestive of improper injection techniques (superficial placement, excessive amount of product, incorrect reconstitution)

1. Sculptra<sup>®</sup> Instructions for Use.

How to  
inject  
SCULPTRA  
with  
different  
Goals?



Heavy faces



Skin quality

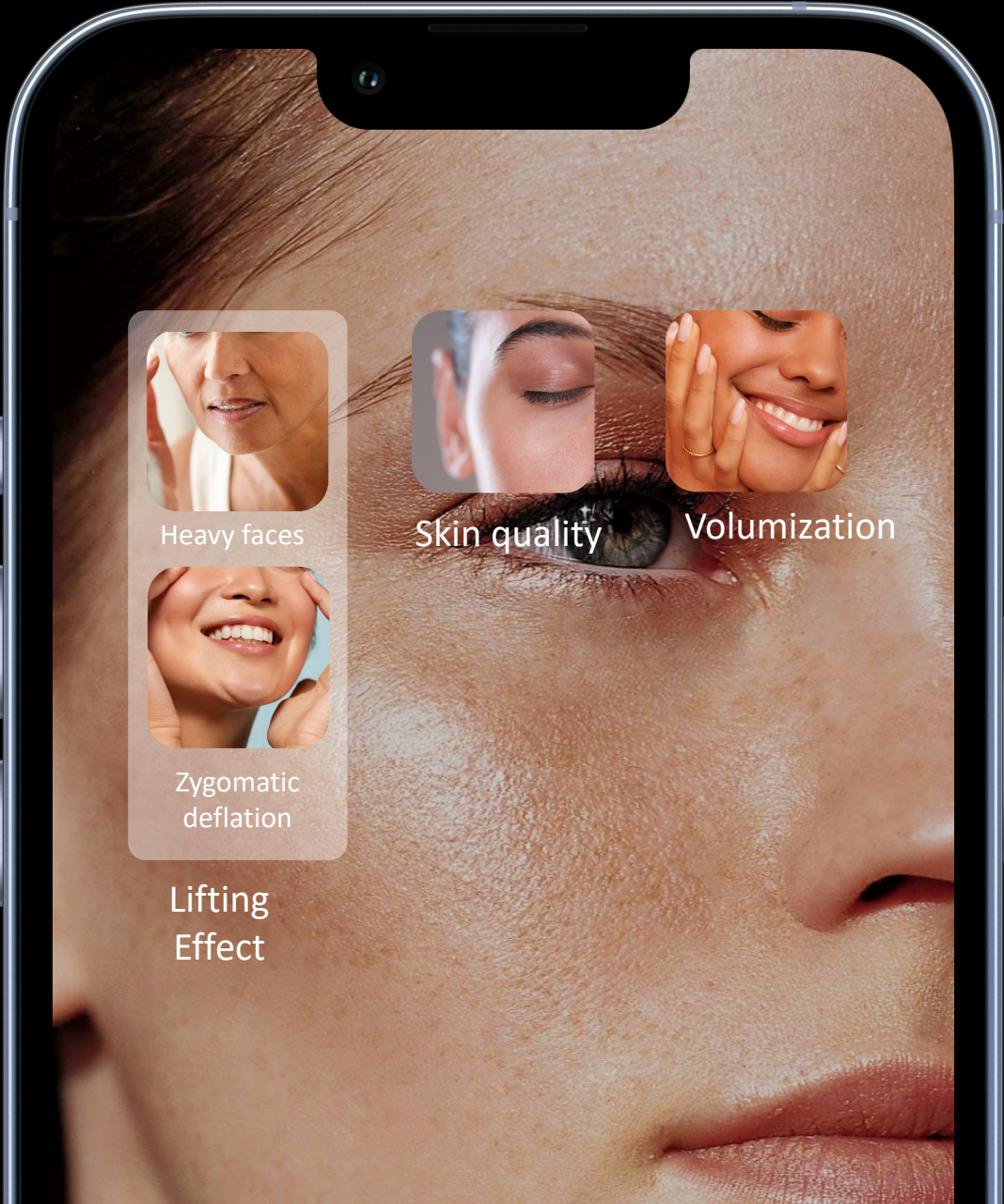


Volumization

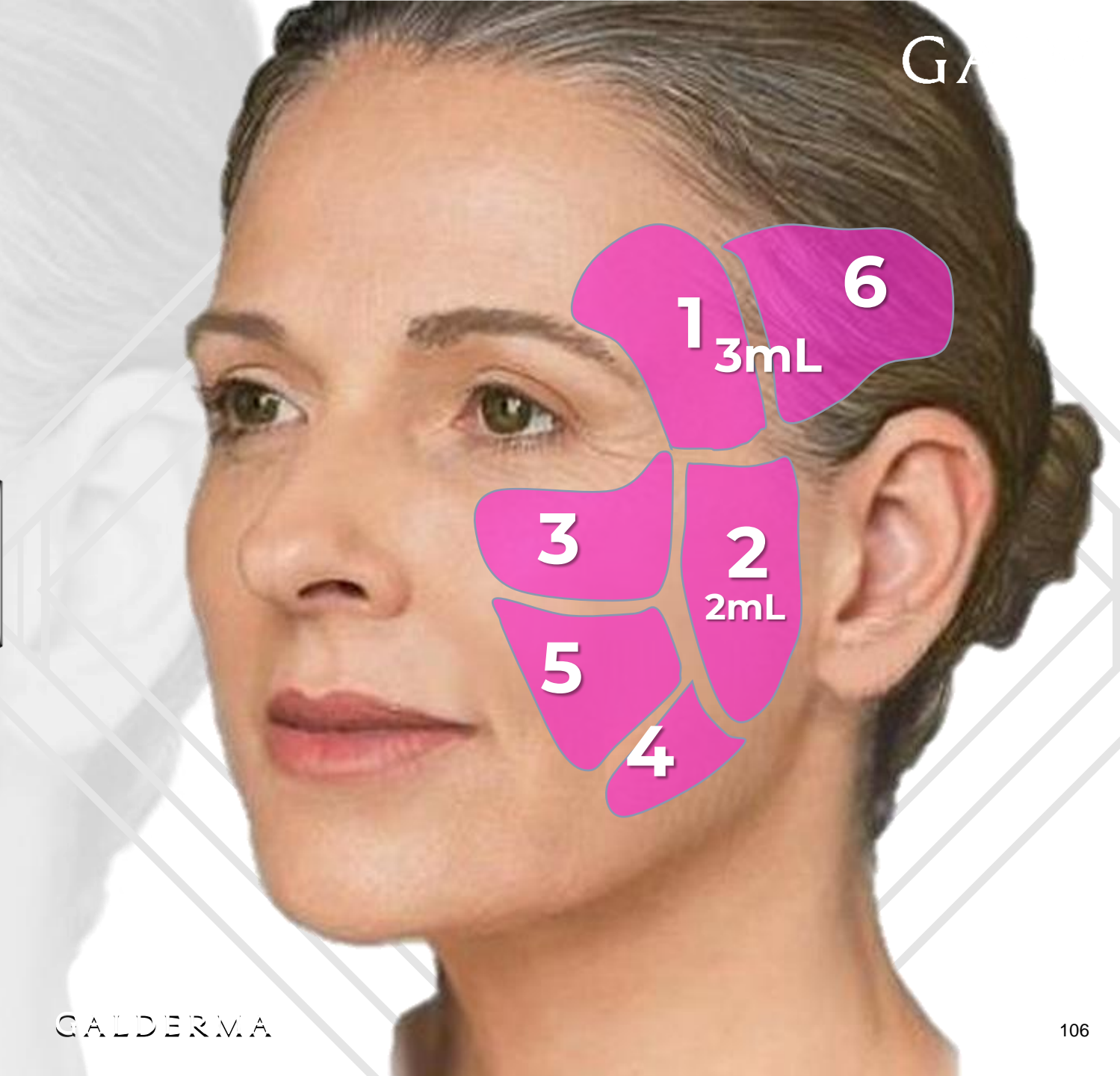


Zygomatic  
deflation

Lifting  
Effect

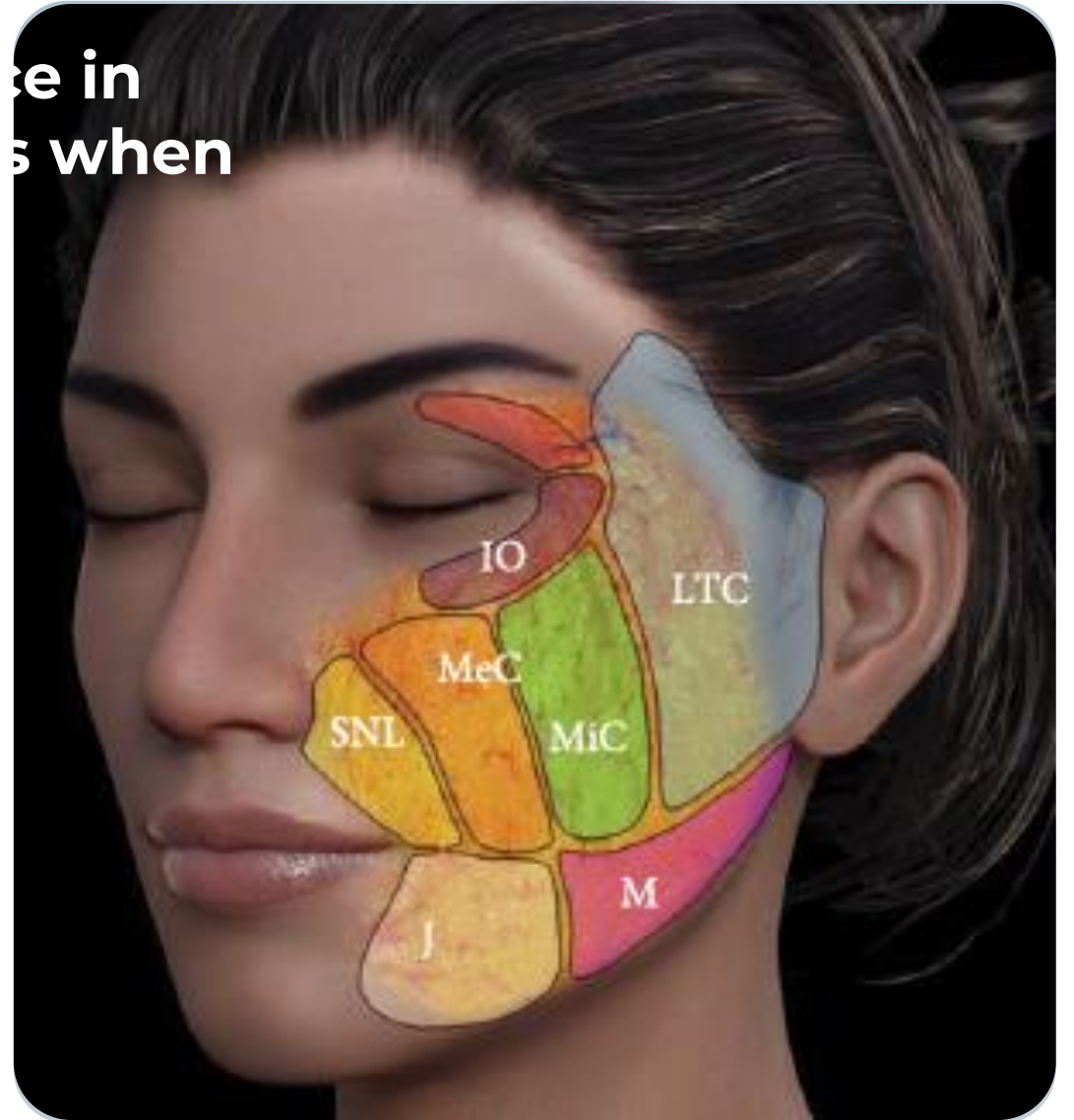








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### Poly-L-Lactic Acid Injected in the Temples Improves Excessive Upper Eyelid Skin

We report 2 patients where upper eyelid skin tightening was observed after poly-L-lactic acid (PLLA) treatment into the temples, indicating the role of PLLA as a biostimulator capable of amplifying the effects of fibroblast activation in the neighboring tissues.

The second patient was a 40-year-old woman presenting with malar volume loss and early skin sagging, likely because of extreme exercise (Figure 2A). The patient had received previous treatments, including malar region volumization 2 years before and neuro-modulators 3 months earlier. To improve skin laxity and facial structural support, we administered



**Figure 1.** (A and B) Improvement of the eyelid 1 year after 2 poly-L-lactic acid treatment sessions. Two vials were used.

#### Changes in Facial Morphology Using Poly-L-lactic Acid Application According to Vector Technique: A Case Series

July 1, 2022



*J Clin Aesthet Dermatol.* 2022;15(7):38-42.

by Christine Munia, MD; Meire Parada, MD; and Marcus Henrique de Alvarenga Morais, MD

*Drs. Munia and Parada are in private practice in Sao Paulo, Brazil. Dr. Morais is in private practice in Belo Horizonte, Brazil.*

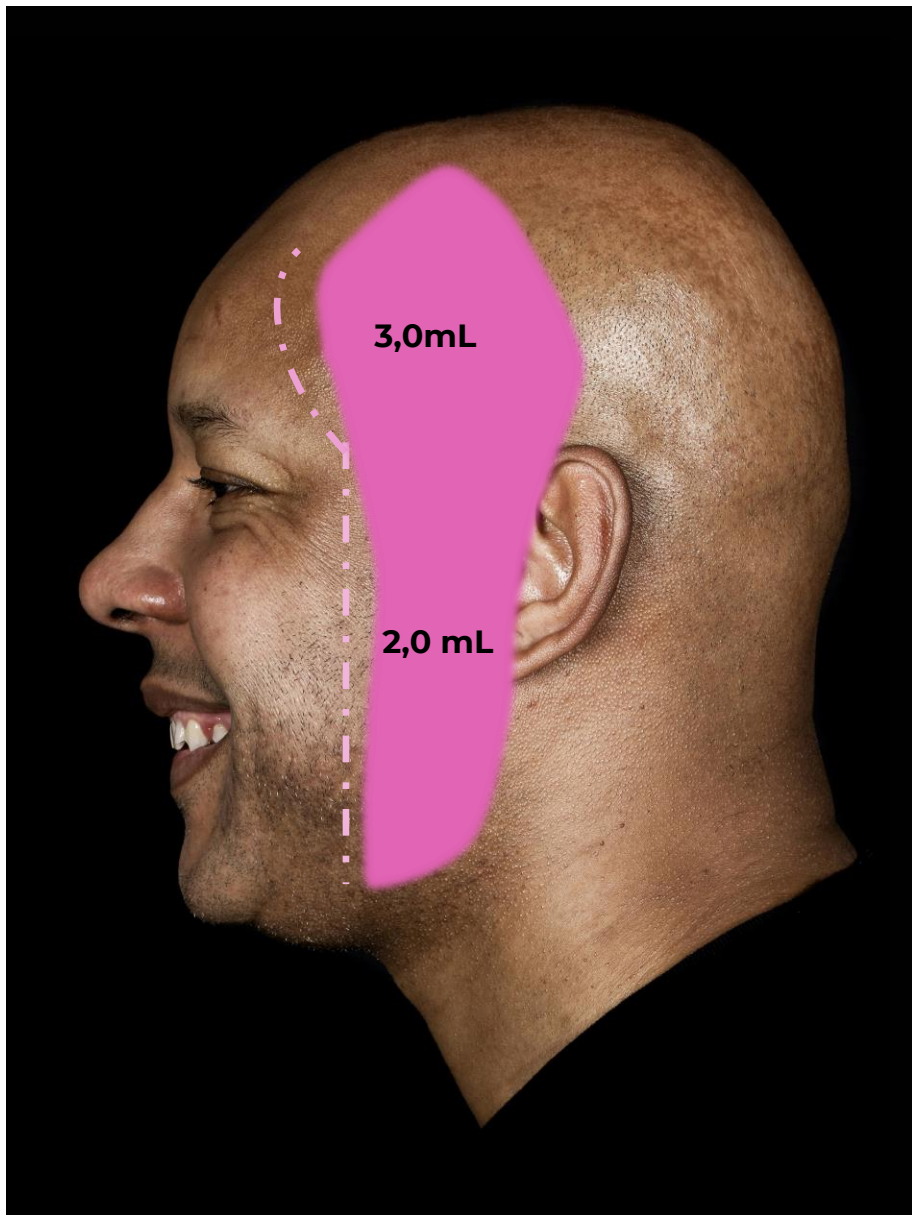
FUNDING: No funding was provided for this article.

DISCLOSURES: The authors report no conflicts of interest relevant to the content of this article.



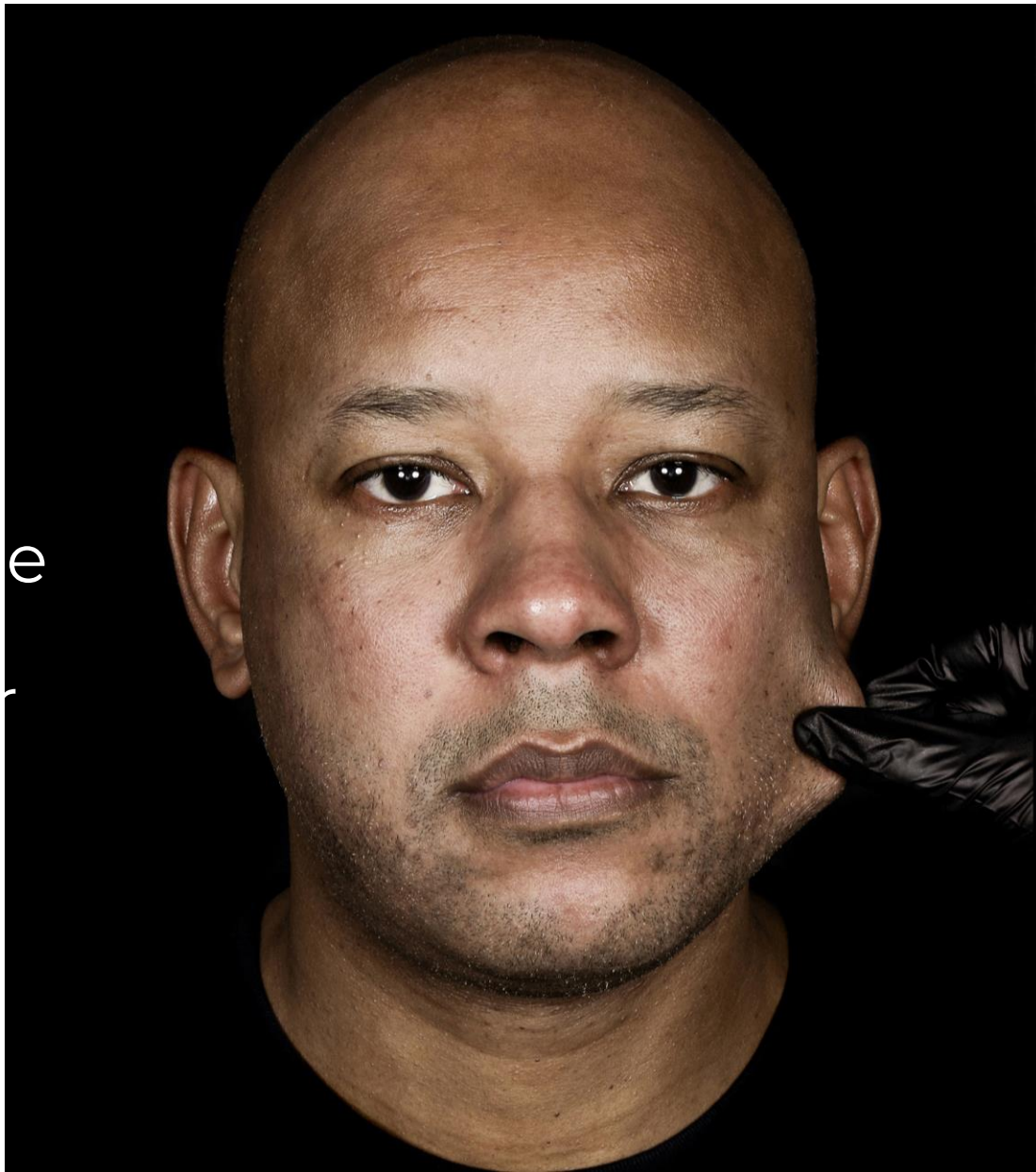
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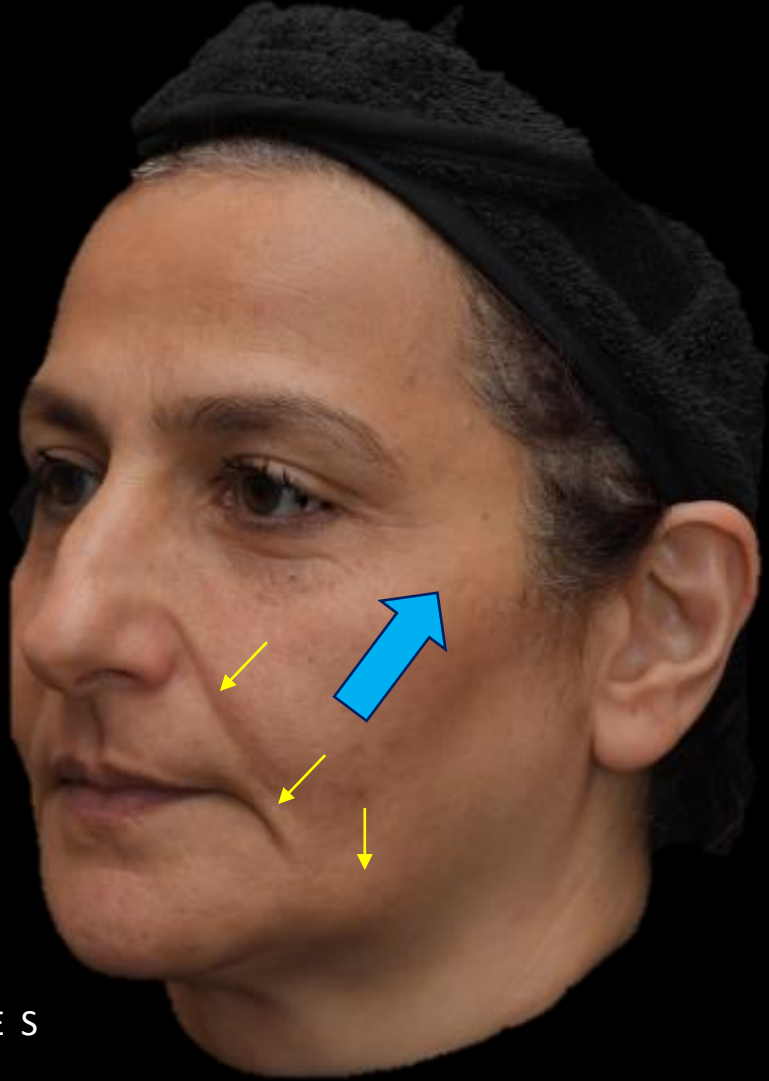
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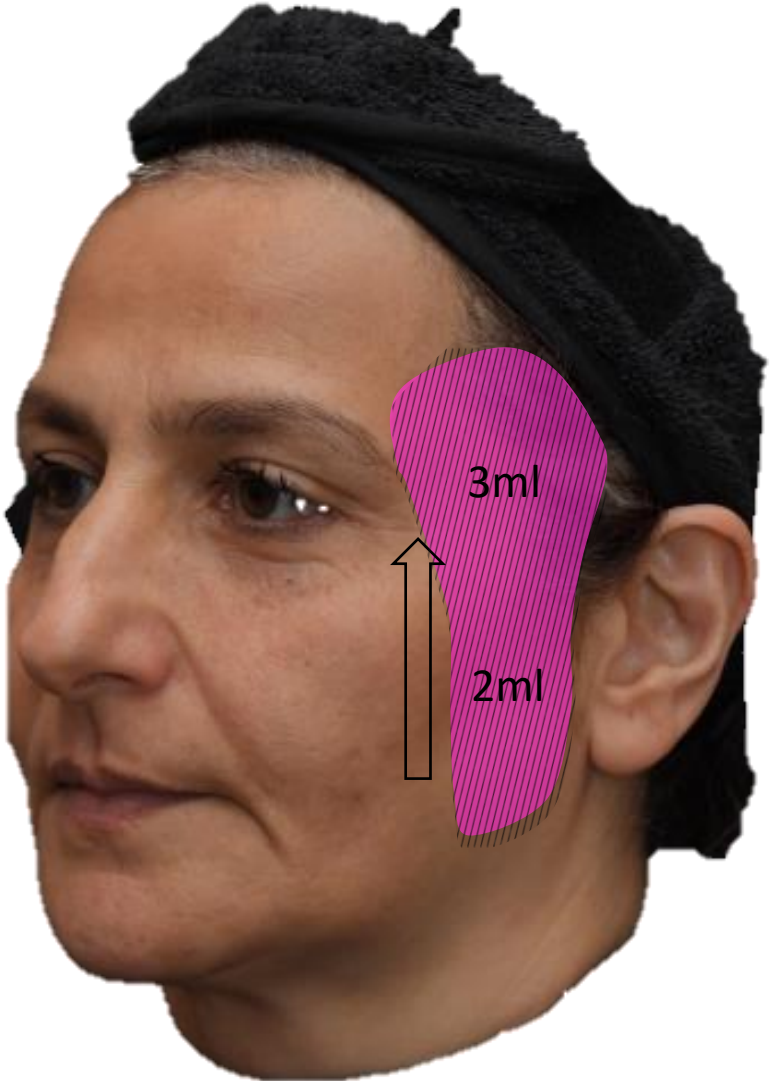


LIFTING EFFECT IN HEAVY FACES

GALDERMA



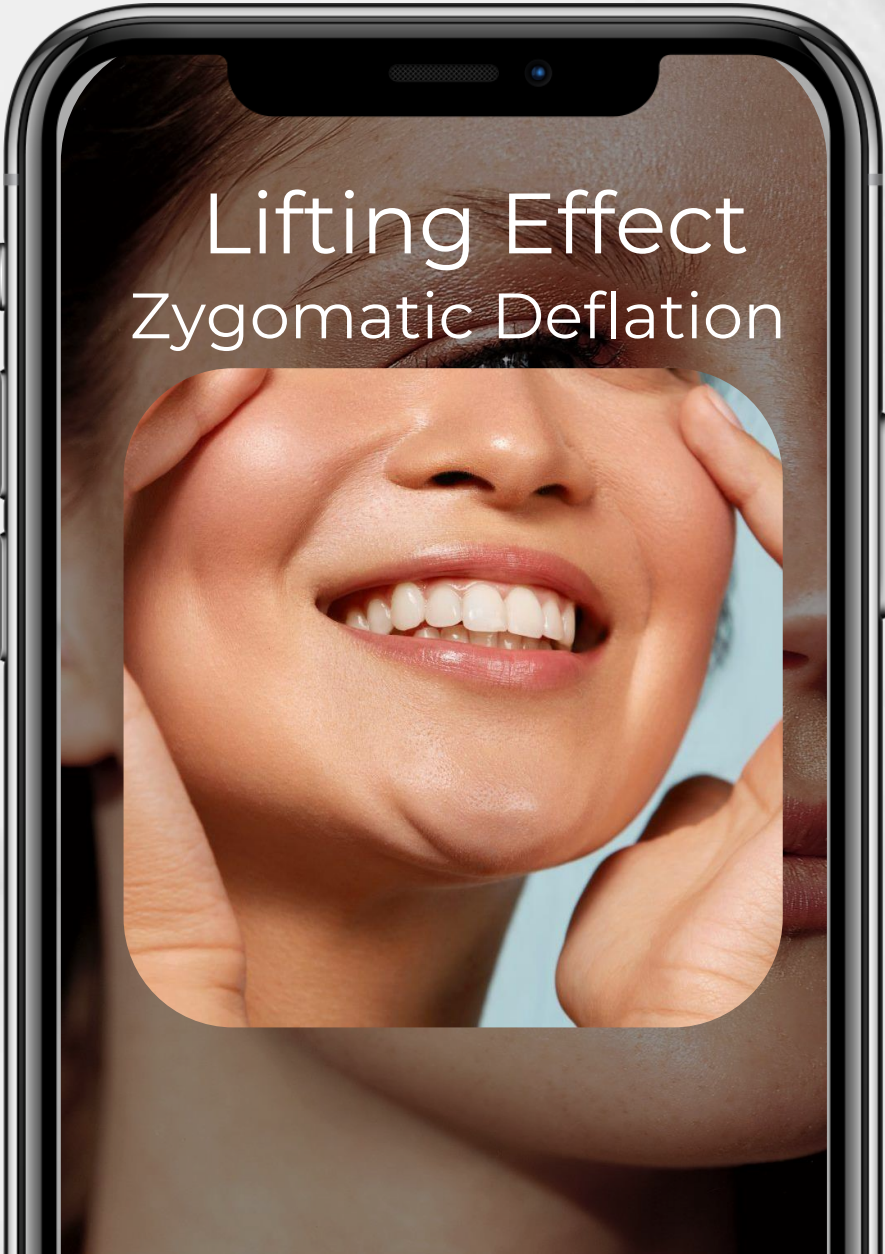
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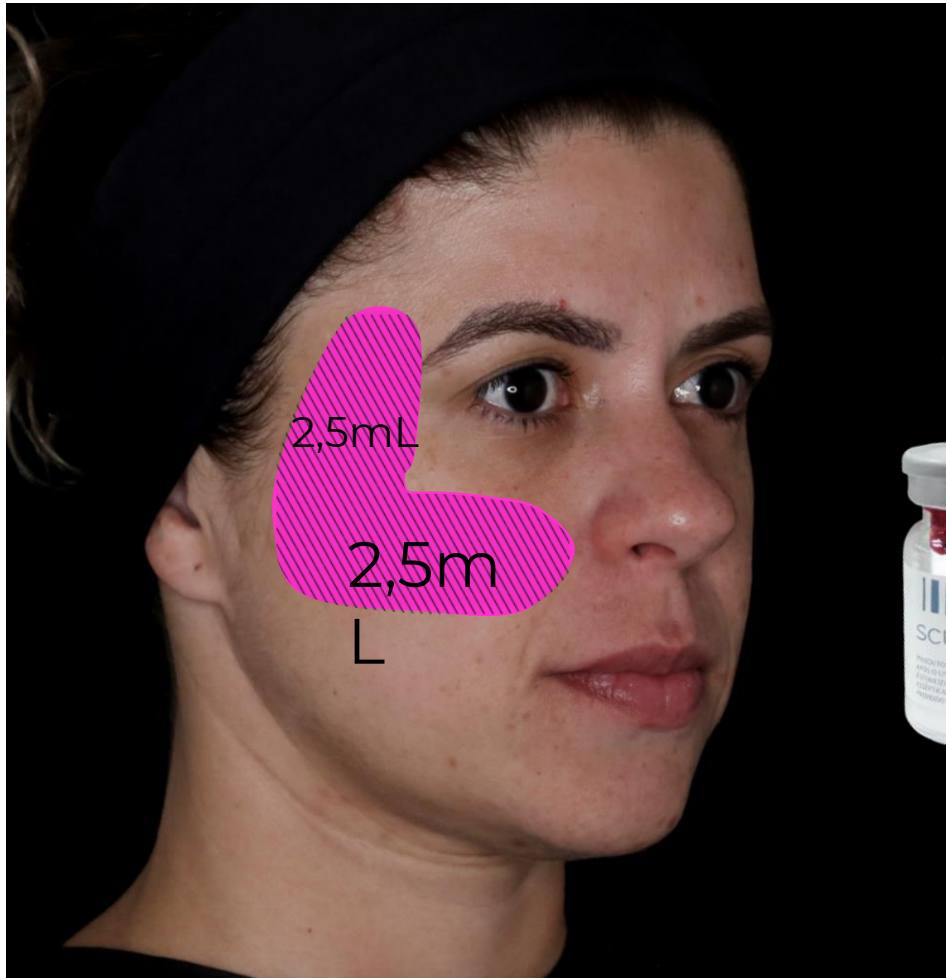
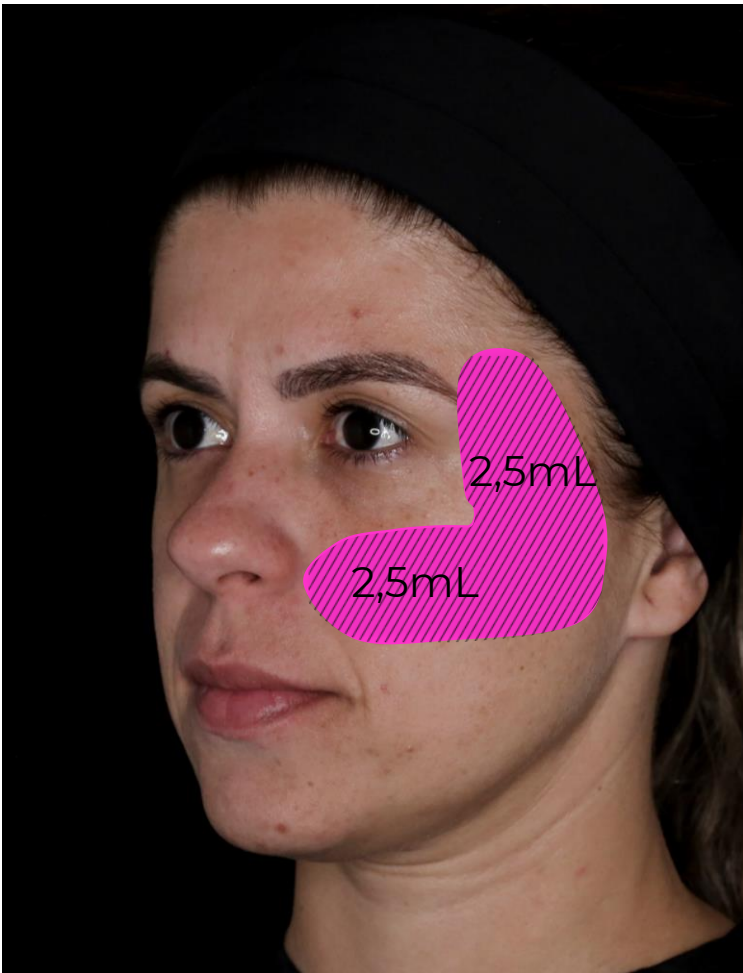
45



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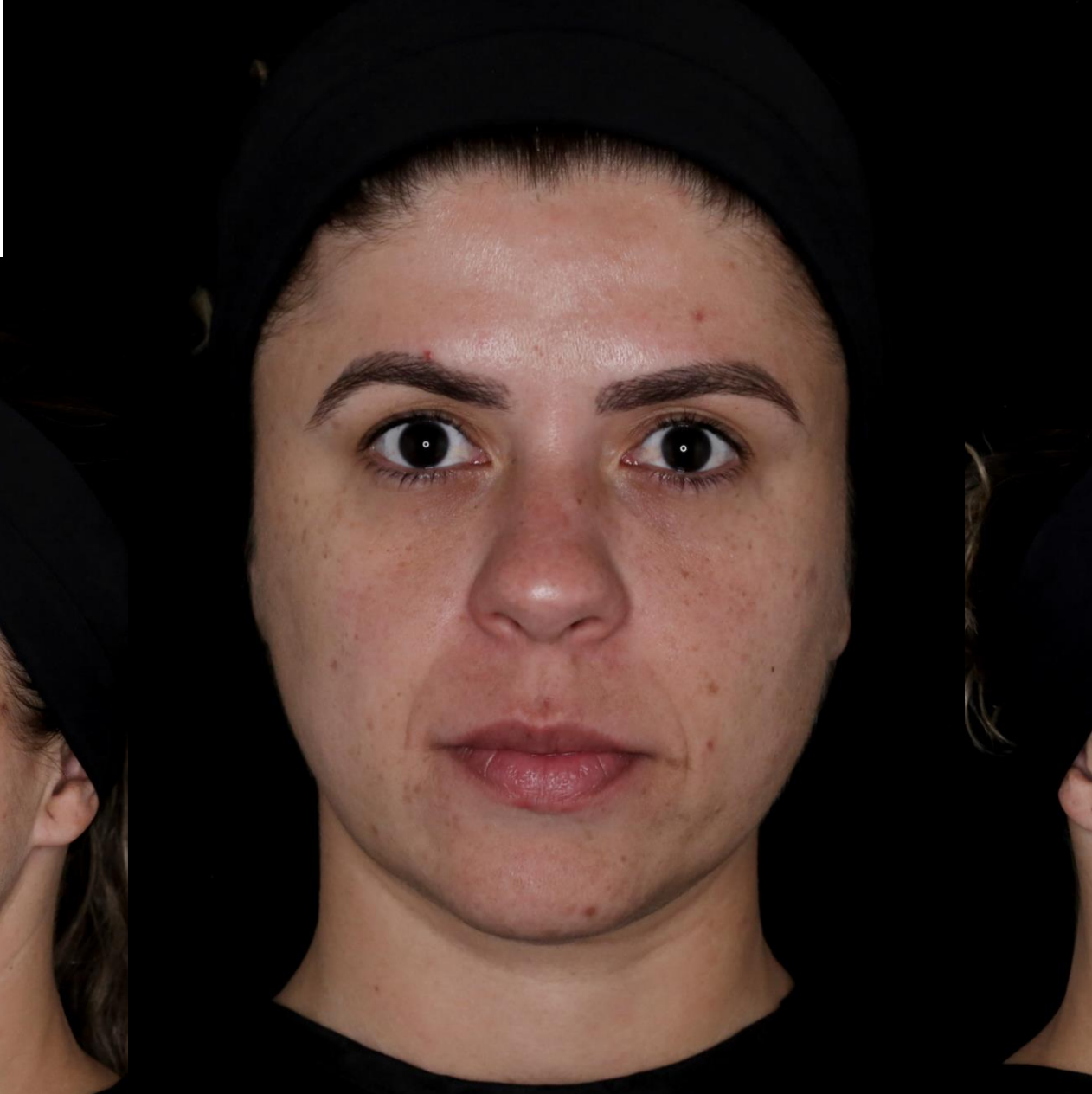






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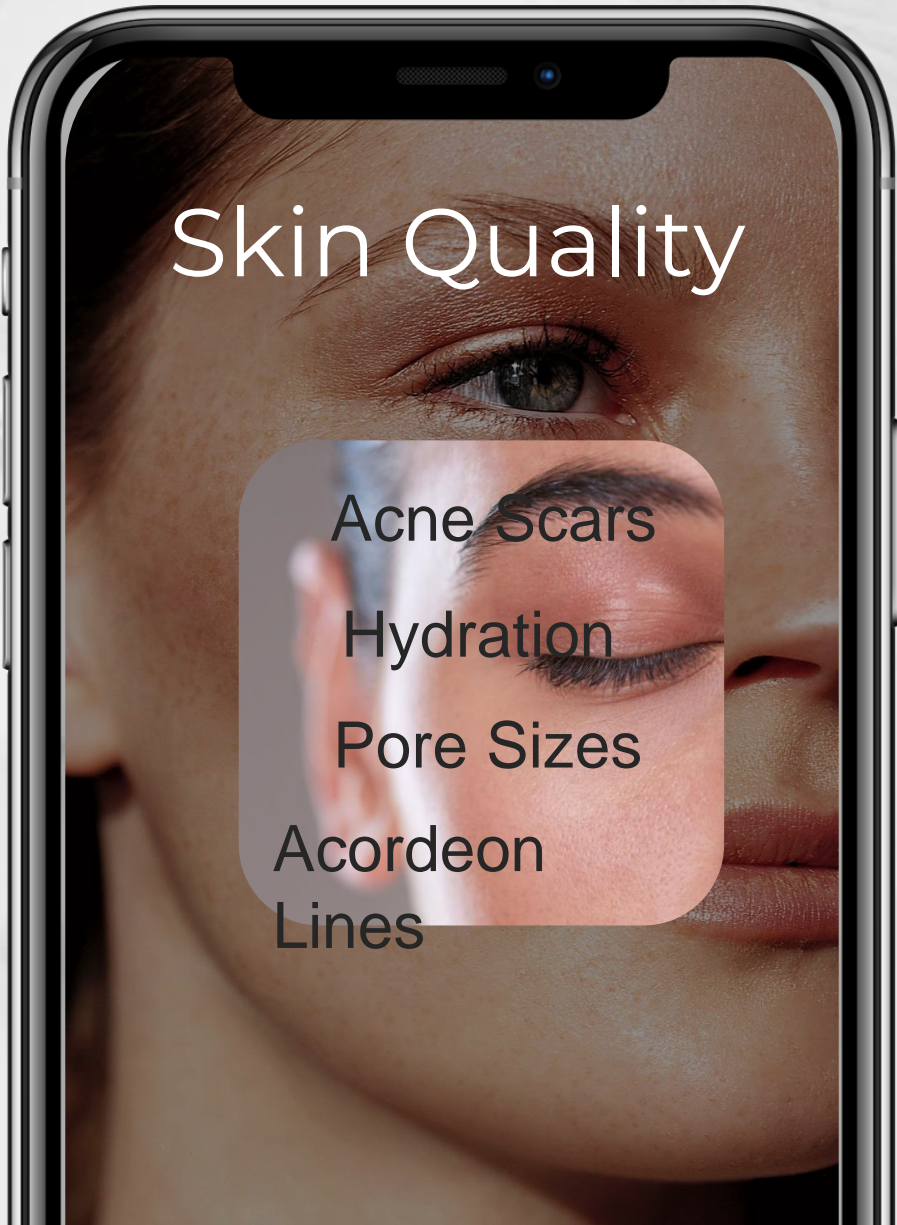
CALDERMA



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# Skin Quality

Acne Scars

Hydration

Pore Sizes

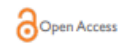
Acordeon Lines

Lines





Case Report



## The improvement of the skin quality with the use of PLLA

### Abstract

When a patient is seeking PLLA treatment, the focus is usually on compensating for different losses she or he may have in regards to volumization and laxity. However, the improvement of skin quality is one of the unexpected benefits invariably seen in final results. The objective of this manuscript is to call attention to this aspect, to understand how it occurs and to demonstrate how this can be obtained using one specific technique, among many others.

**Keywords:** PLLA, skin laxity, skin quality, rejuvenation

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## Randomized, Controlled, Multicentered, Double-Blind Investigation of Injectable Poly-L-Lactic Acid for Improving Skin Quality

KRISTA BOHNERT, BS,\* ANDREW DORIZAS, MD,† PAUL LORENC, MD,‡ AND NEIL S. SADICK, MD\*§

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**BACKGROUND** Poly-L-lactic acid (PLLA) is an injectable filler used for restoring facial fat volume loss.

**OBJECTIVE** To evaluate the effect of repeated PLLA injections on skin quality.

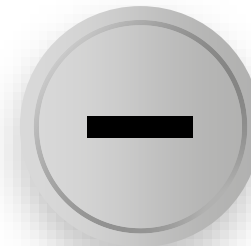
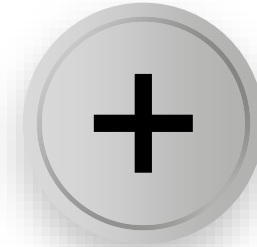
**METHODS** Forty healthy women were enrolled in this randomized, controlled, double-blind, multicenter study. Eligible subjects received 3 treatments every 4 weeks with either PLLA (treatment group) or saline (control group) injections, into both sides of the face. Follow-up visits were at 6, 9, and 12 after the last treatment. Assessments included biophysical measuring instruments, live ratings, patient questionnaires, and rating of standardized pictures by a blinded evaluator.

**RESULTS** At the 12-month follow-up, there was a statistically significant increase of skin elasticity and hydration in PLLA-treated subjects and a decrease in transepidermal water loss in both groups. Pigmentation, erythema, and pore size were significantly decreased, whereas radiance and smoothness were significantly increased at 12 months per blinded investigator rating in this group. No treatment-related adverse events occurred.

**CONCLUSION** Repeated PLLA treatments may improve skin quality in a time-dependent manner.

*The authors received funding for this research from Galderma who also provided the PLL. The authors have indicated no significant interest with commercial supporters.*

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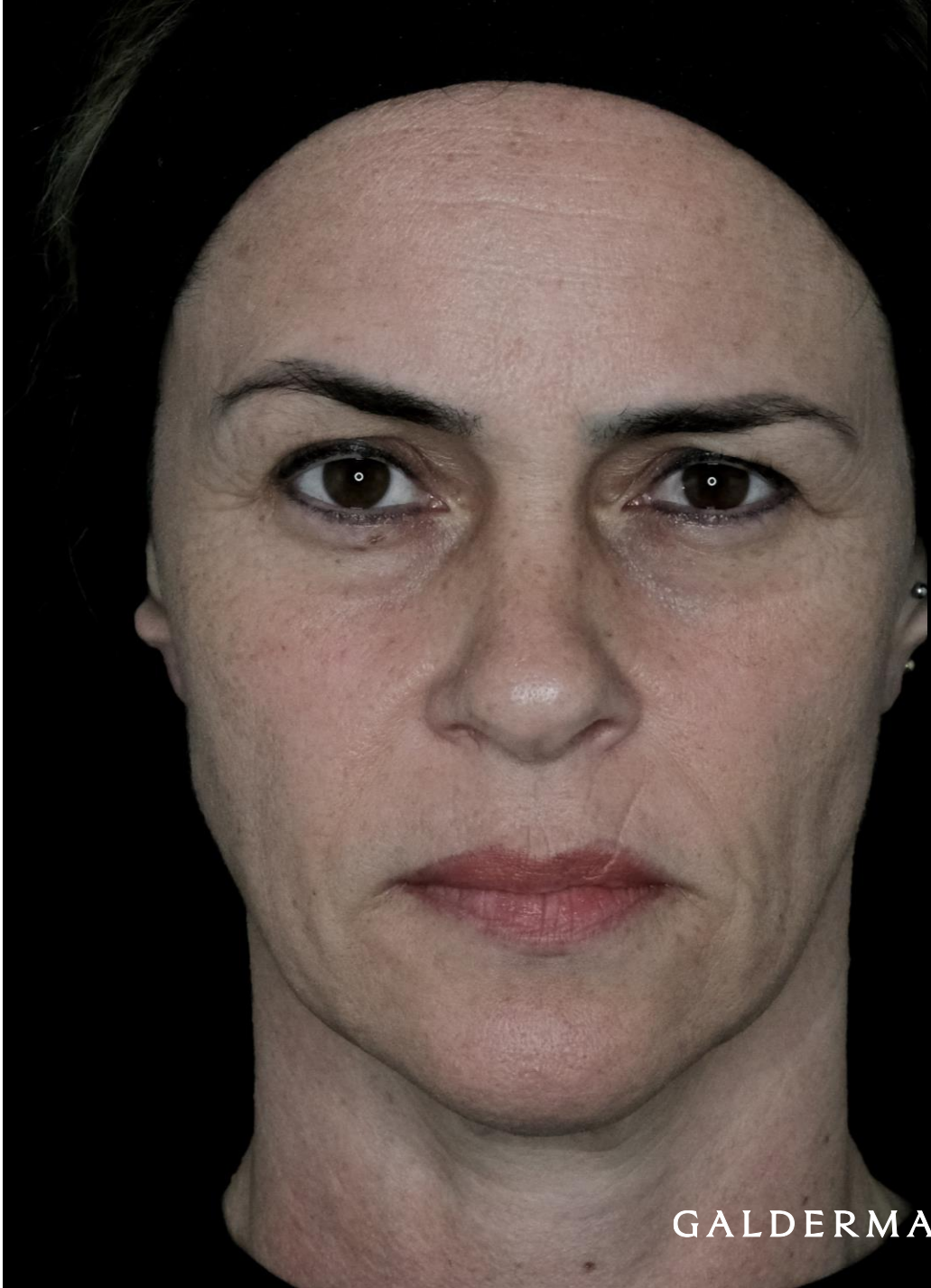
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GAIN

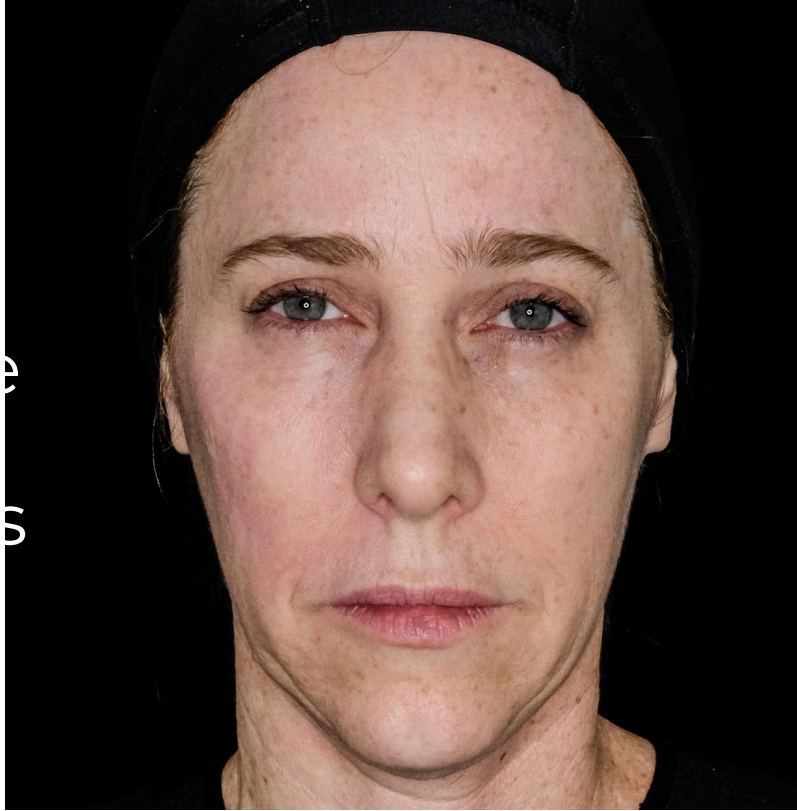


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CALDERMA



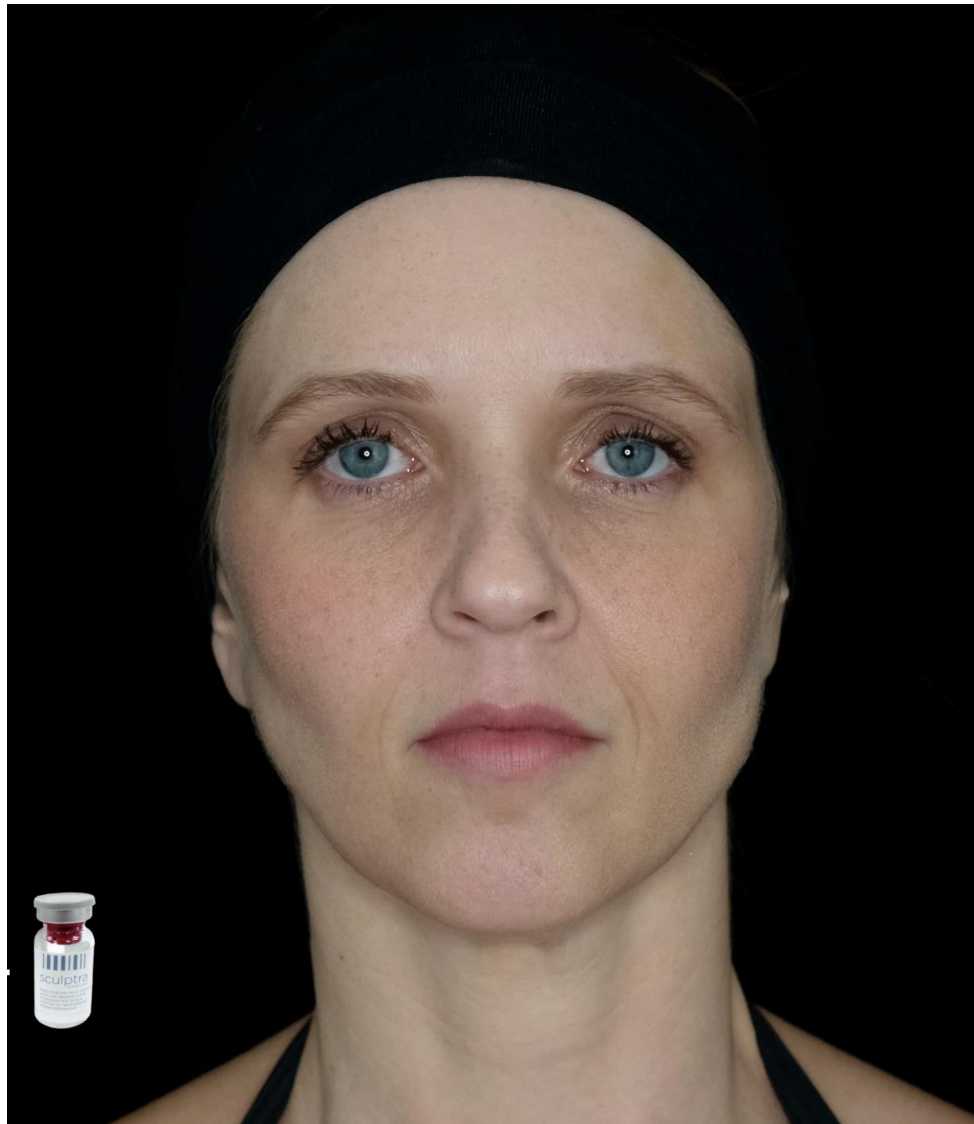




CALDERMA



Feb 2019



Sep 2019

GALDERMA



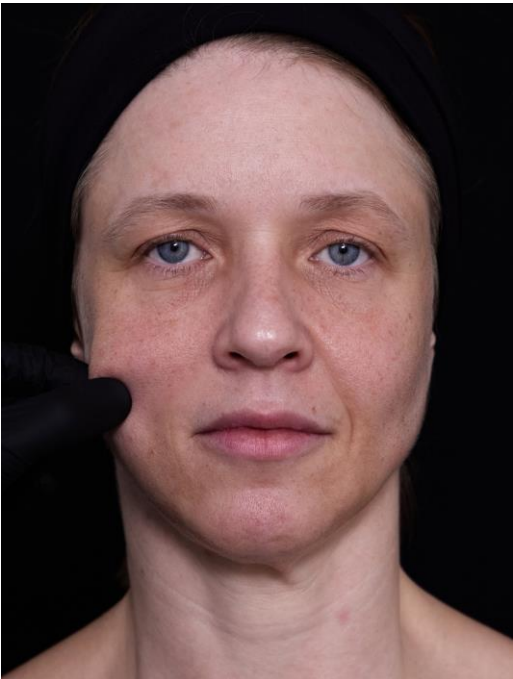


Feb 2019

Sep 2019



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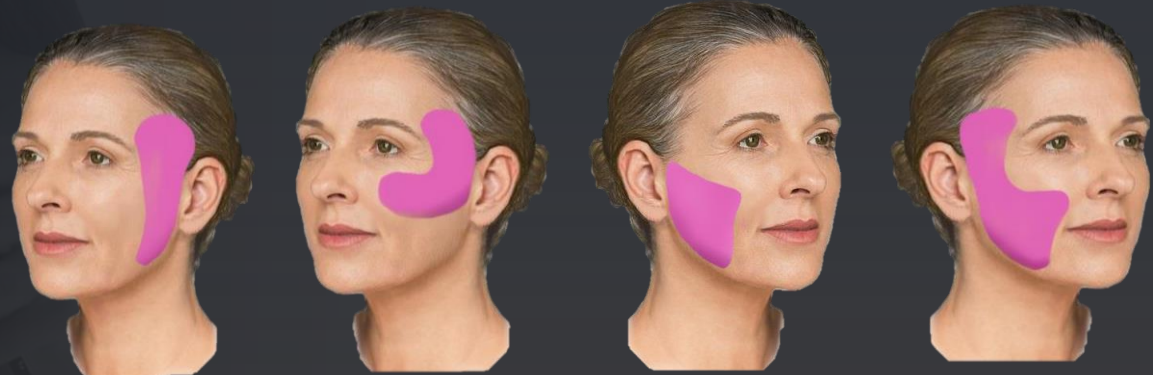


Oct 2022



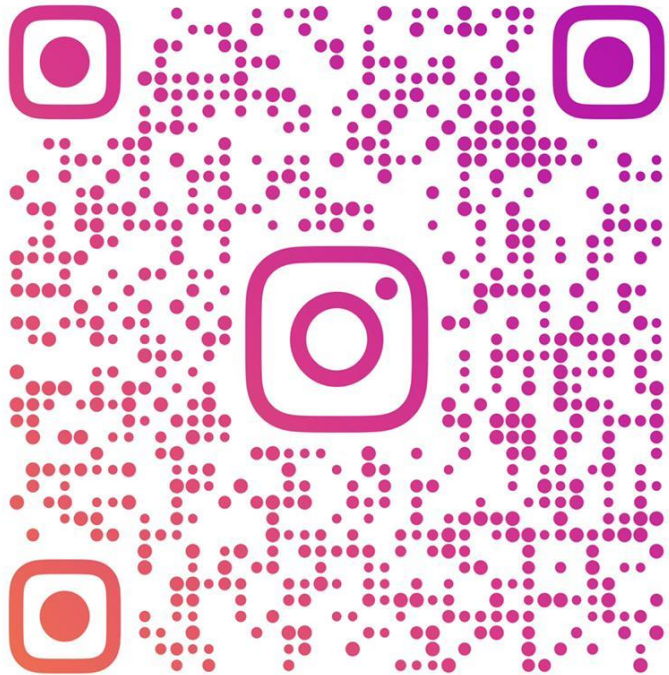
GAIN

# Customize the Treatment



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COLLAGEN  
BOOM GALDERMA.AESTHETICS.BR



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**FOLLOW OUR  
PROFILE ON  
INSTAGRAM**



**JOIN OUR VIP  
GROUP ON  
WHATSAPP**



**Dr. Luiz**

@clinicaavelar

@institutoarhaddad



# Injection Areas to Avoid

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## PLLA should not be used in these areas (marked in red):

- Subdermal such as eyelid/crow's feet
- Hyperdynamic areas such as depressor anguli oris muscle, commissures, perioral area including upper lip perioral lines and periorbital area
- Red of the lips
- Front head lines and vermillion border of the lip to avoid nodularity irregular collagen formation
- Nose

PLLA, poly-L-lactic acid.  
Redaelli A, et al. *J Drugs Dermatol.* 2014;13(9):1057-1066.

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# Massage After Injection

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- Massaging the treated area helps evenly distribute the product (use of an appropriate cream may reduce the friction on the skin surface during massaging)
- The patient should periodically massage the treated areas for the first week

# When to Choose Sculptra® Over HA?

GAIN

	HA	Sculptra
Volumization	++++	+
Laxity treatment	+	++++
Indications	Specific sites	Multiple areas
Results	Instant result	Natural gradual results
Lasting	++	++++

HA, hyaluronic acid.

ELISSA, 49 YEARS OLD  
TREATED WITH 5 VIALS OF SCULPTRA

SCULPTRA®



Before



25 months after the last injection

CARA, 42 YEARS OLD  
TREATED WITH 3 VIALS OF SCULPTRA



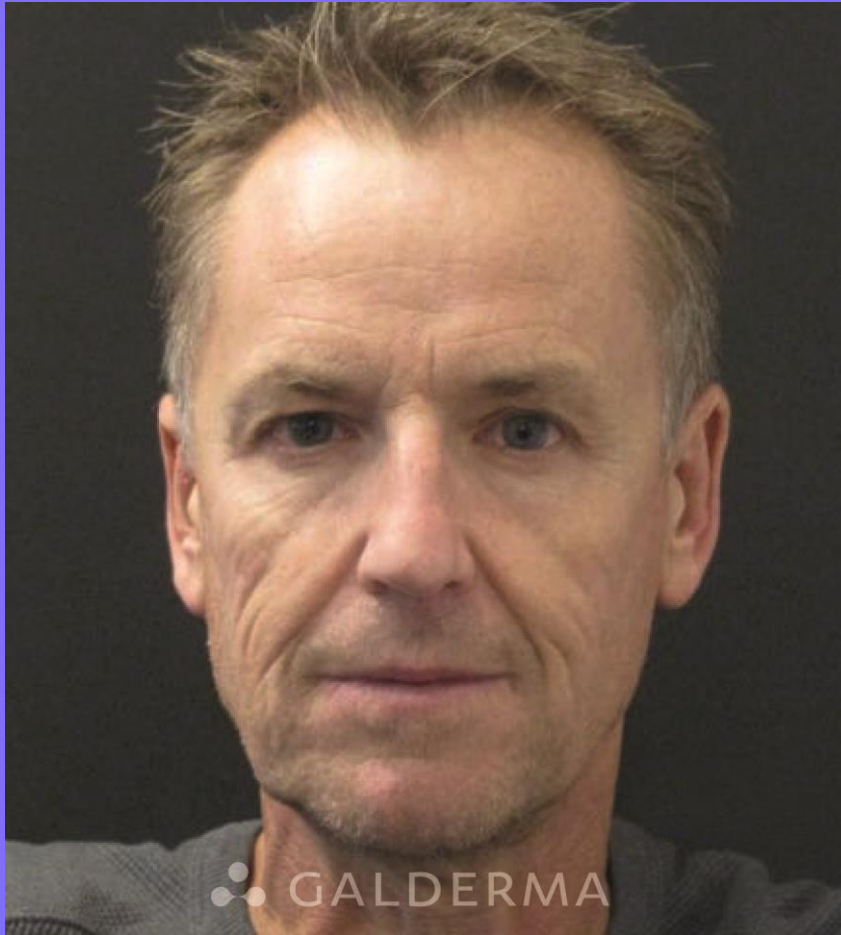
Before



8 months after the last injection



STEWART, 54 YEARS OLD  
TREATED WITH 5 VIALS OF SCULPTRA

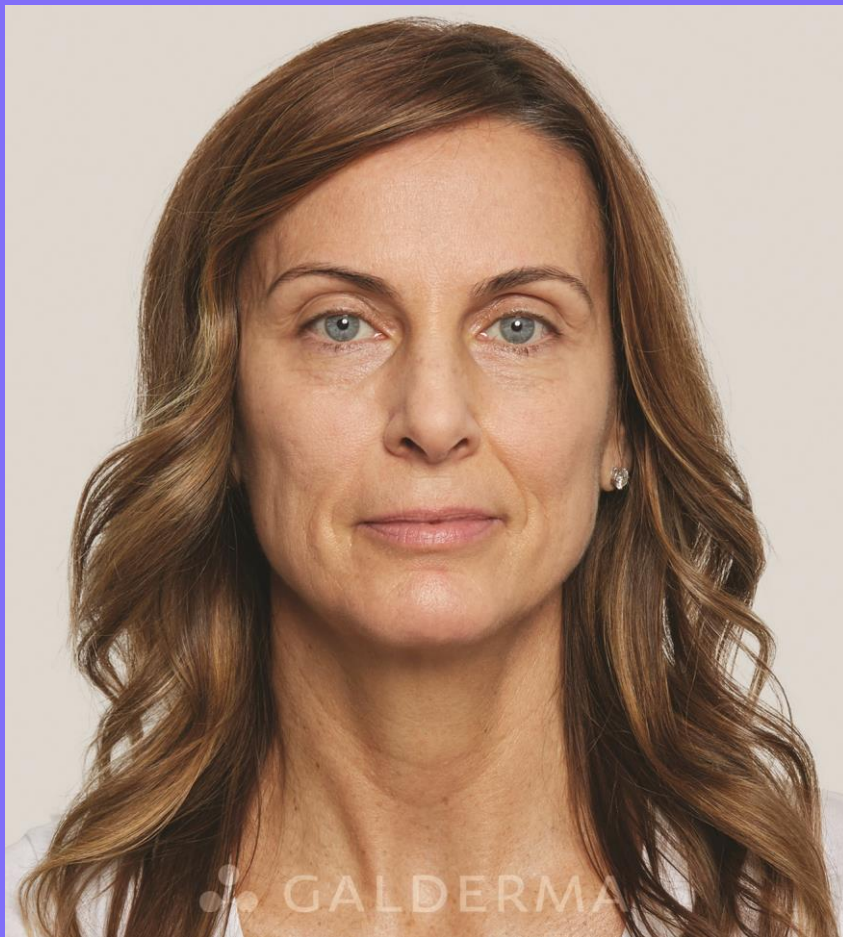


Before



7 months after the last injection

KATHERINE, 53 YEARS OLD  
TREATED WITH 3 VIALS OF SCULPTRA



Before



27 weeks after the last injection



SANNE, 41 YEARS OLD  
TREATED WITH 5 VIALS OF SCULPTRA

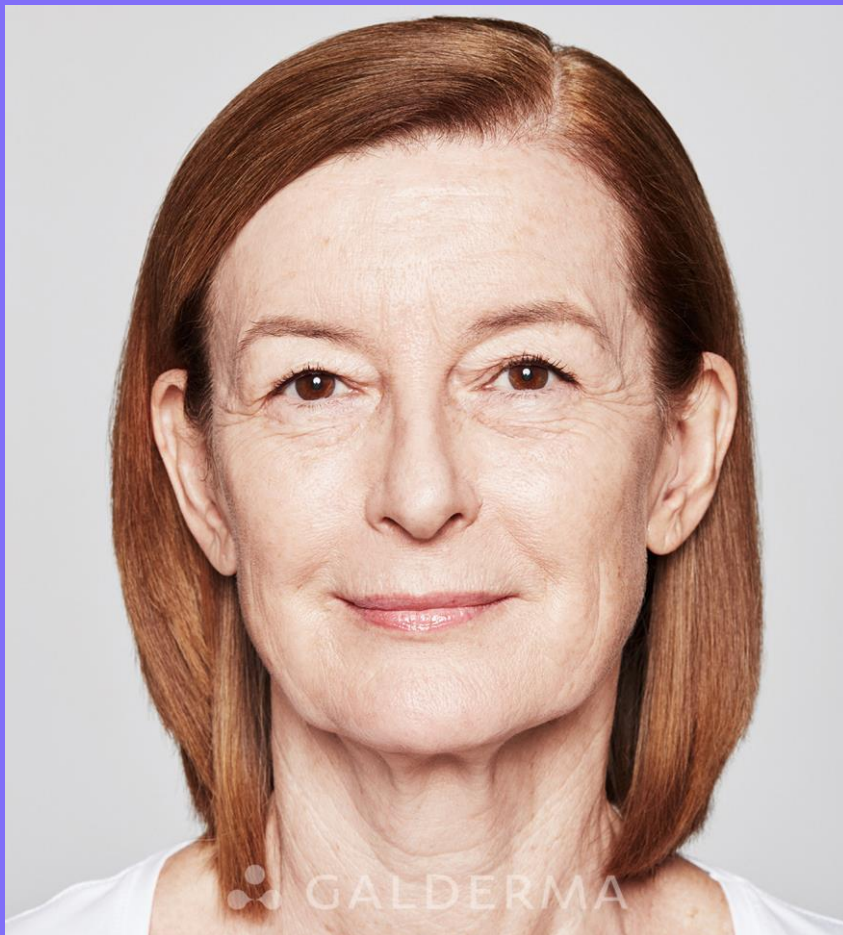


Before

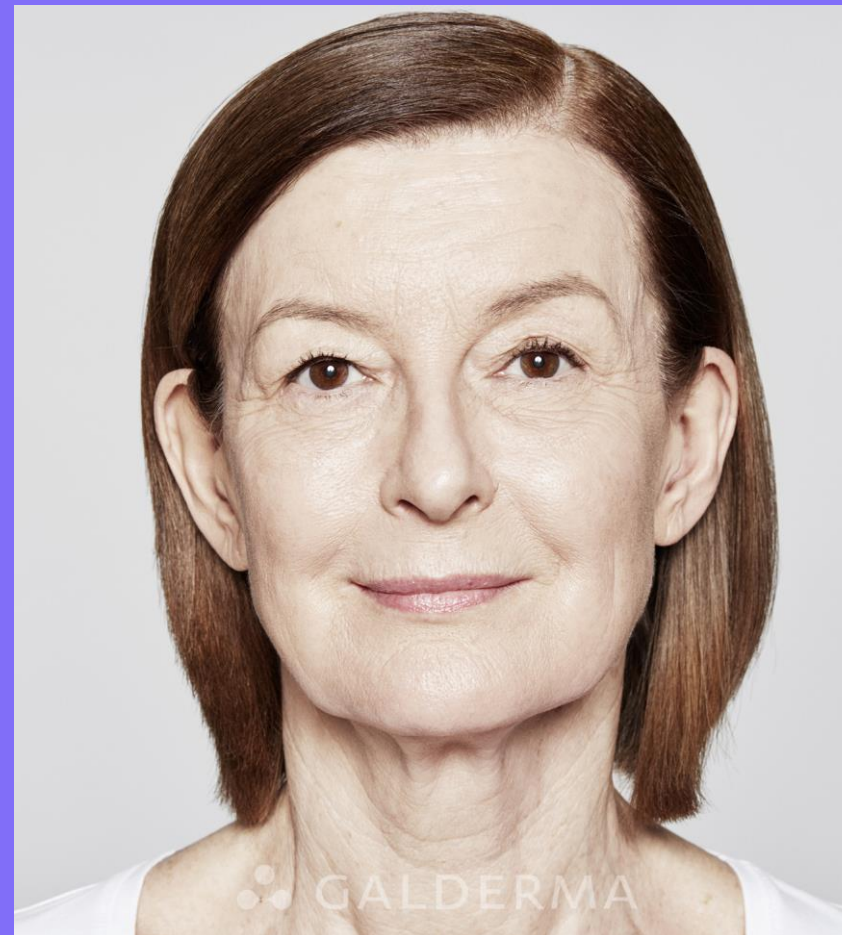


4 months after the last injection

HILARY, 56 YEARS OLD  
TREATED WITH 6 VIALS OF SCULPTRA



Before



4 months after the last injection



FRANCA, 42 YEARS OLD  
TREATED WITH 5 VIALS OF SCULPTRA



Before



12 months after the last injection

# Treatment results

Before treatment



Session 2 results



After 7 months



After 25 months



**Elissa, 49** (5 vials over 3 sessions)

Individual results and treatment regimes may vary

# Treatment results

Before treatment



After 25 months



Before treatment



After 25 months



**Franca, 42** (5 vials over 4 sessions)

Individual results and treatment regimes may vary

# Treatment results

Before treatment



After 12 months



**Vivian, 53** (4 vials)

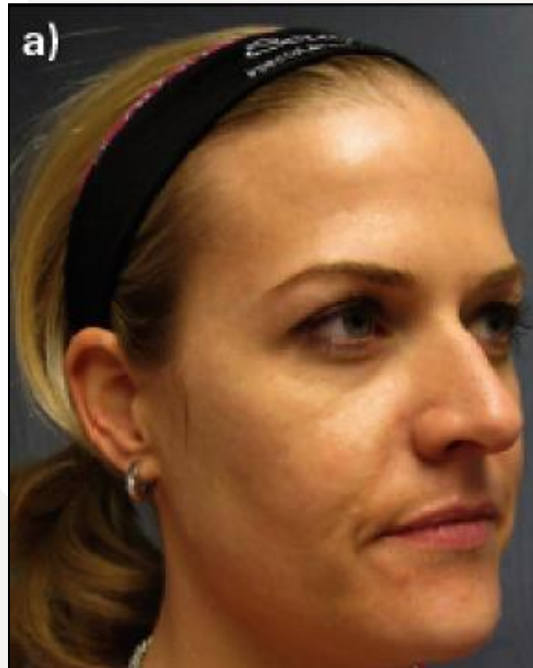
Individual results and treatment regimes may vary

Photos courtesy of Rebecca Fitzgerald, MD



# Treatment results

Before treatment



After 5 months



Application in temporal region, malar, pre auricular,  
piriform fossa, mento, mentolabial sulcus  
3 Sessions, 1 vial per session

Adapted from Fitzgerald R, Vleggaar J. Drugs Dermatol Ther 2014 13 (suppl 4) s44-s51;24:2-27

# Treatment results



2 sessions: 1 vial per session

Adapted from Fitzgerald R, Vleggaar D. Dermatol Ther 2011;24:2-27.

# Treatment results



Before

45 days after 2<sup>nd</sup> session

6 months after treatment

2 sessions, 1 vial per session, interval: 45 days

Photos courtesy of Luiz Avelar, MD

# Treatment results



Before

After 1<sup>st</sup> session

3 months after 2<sup>nd</sup> session

2 sessions, 1 vial per session, interval: 45 days

Photos courtesy of Luiz Avelar, MD

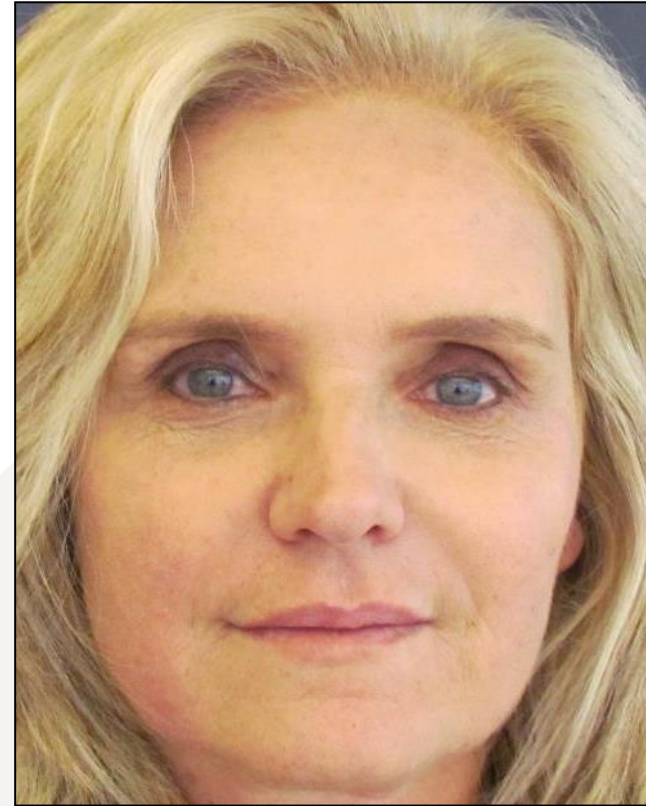


# Treatment results

Before

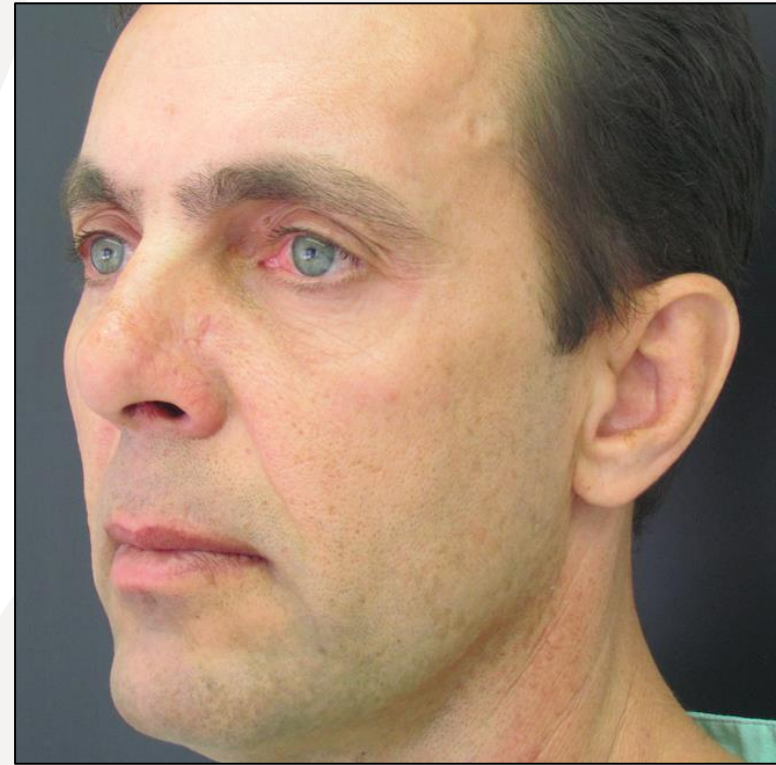


After 2 sessions, 2 vials/session



Photos courtesy of Luiz Avelar, MD

# Treatment results



3 sessions, 1 vial per session, interval: 45 days.

Photos courtesy of Luiz Avelar, MD

GAIN

Journey thru time....  
1 vile per year maintenance  
stopping aging

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GAIN



38 years

GALDERMA

46 years

72



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2012, 43y

DR. LUÍZ AVELAR

1ml 1ml 1ml 1ml

Restylane LYFT  
5 ml

0.5ml 0.5ml

Fillers NASHA



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[www.galderma.me](http://www.galderma.me)



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EST. 1981



[www.galderma.me](http://www.galderma.me)

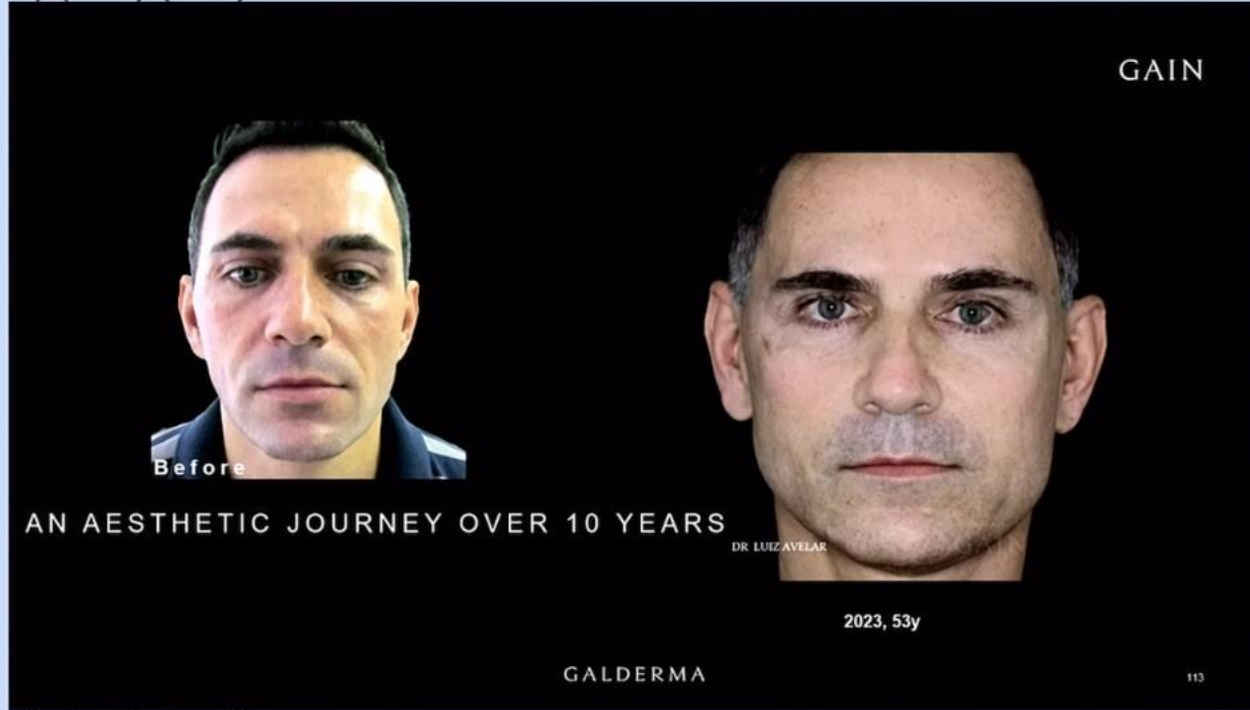
GALDERMA  
EST. 1981

A composite image showing a man's face before and after treatment. The left side is the 'before' state, and the right side is the 'after' state. The 'after' side has white markings indicating treatment areas: 1.0ml on the forehead, 2.0ml on the left cheek, 0.5ml on the right cheek, and 1.0ml on the chin. A central image shows a single SCULPTRA vial with the text 'One 3675 mg Vial'. Below the 'after' photo are three smaller vials with plus signs between them, representing the total treatment volume. Text labels include 'GAIN' in the top right, 'DR LUIZ AVELAR' in the bottom left, and 'GALDERMA' in the bottom center.



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[www.galderma.me](http://www.galderma.me)

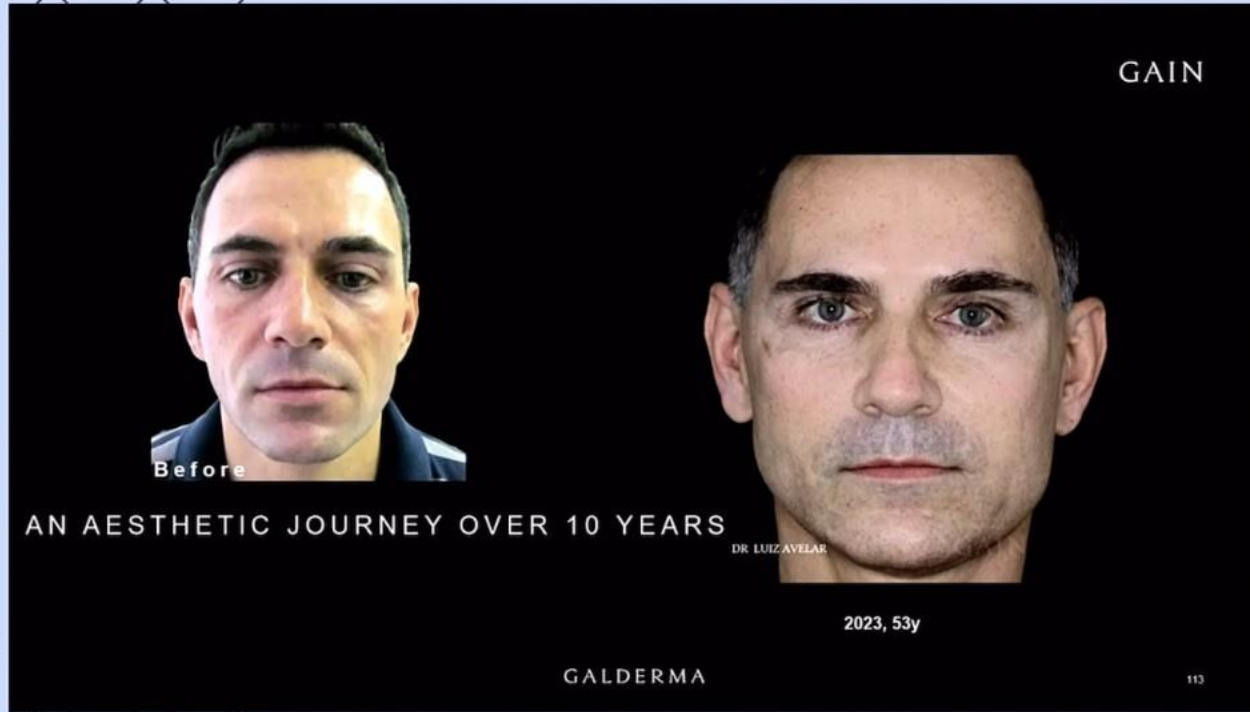
GALDERMA  
EST. 1981



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EST. 1981



[www.galderma.me](http://www.galderma.me)

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EST. 1981



GALDERMA

EST. 1981



[www.galderma.me](http://www.galderma.me)

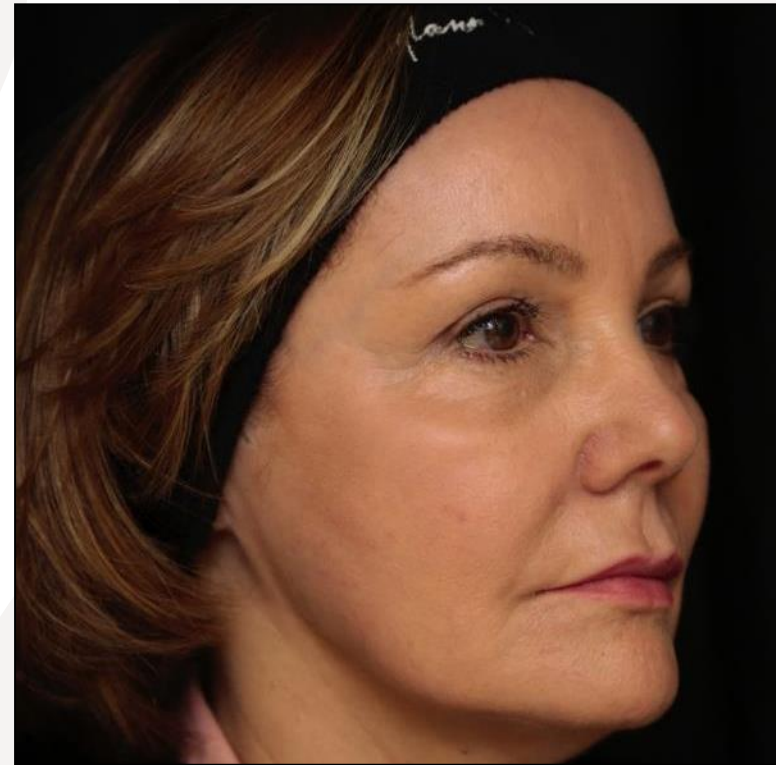
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EST. 1981

COMBINED TREATMENT  
PHOTO LIBRARY



# Combined treatment



**SCULPTRA** (3 sessions, 1 vial per session) + **HYALURONIC ACID**  
(Restylane Defyne and Restylane Kysse)

Photos courtesy of Luiz Avelar, MD

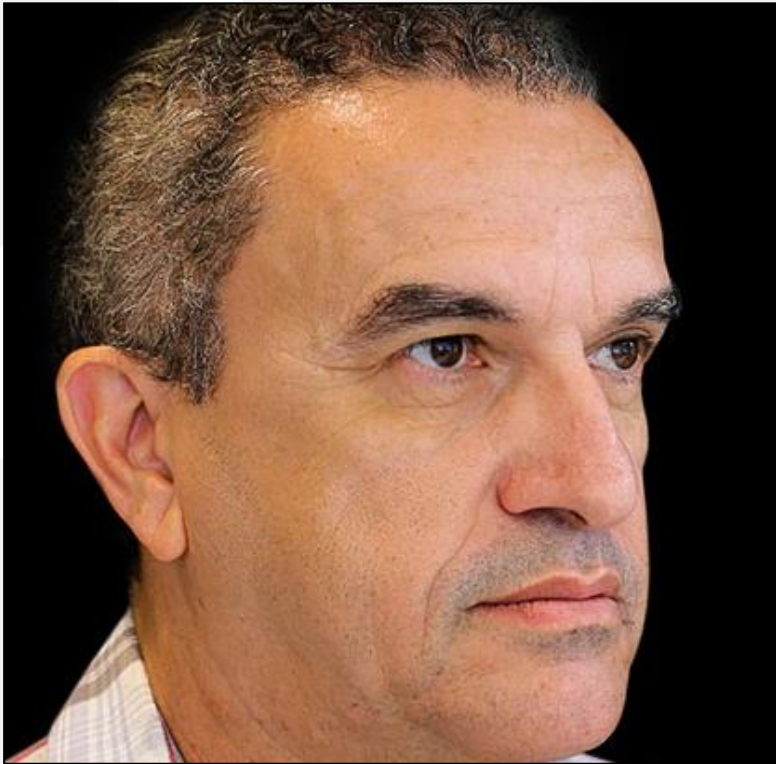
# Combined treatment



**SCULPTRA** (3 sessions, 1 vial per session) + **HYALURONIC ACID**  
(Defyne) + **SKINBOOSTER** (2 mL)

Photos courtesy of Luiz Avelar, MD

# Combined treatment



**SCULPTRA** (3 sessions: first session 2 vials, other 2 sessions –1 vial per session.  
TOTAL: 4 vials) + **HYALURONIC ACID** (Restylane Lyft + Restylane Volyme)

Photos courtesy of Luiz Avelar, MD



# Combined treatment



**SCULPTRA** (2 sessions, 1 vial per session) + **HYALURONIC ACID**  
(Restylane Defyne)

Photos courtesy of Luiz Avelar, MD



GAIN

# Adverse Events and Their Management

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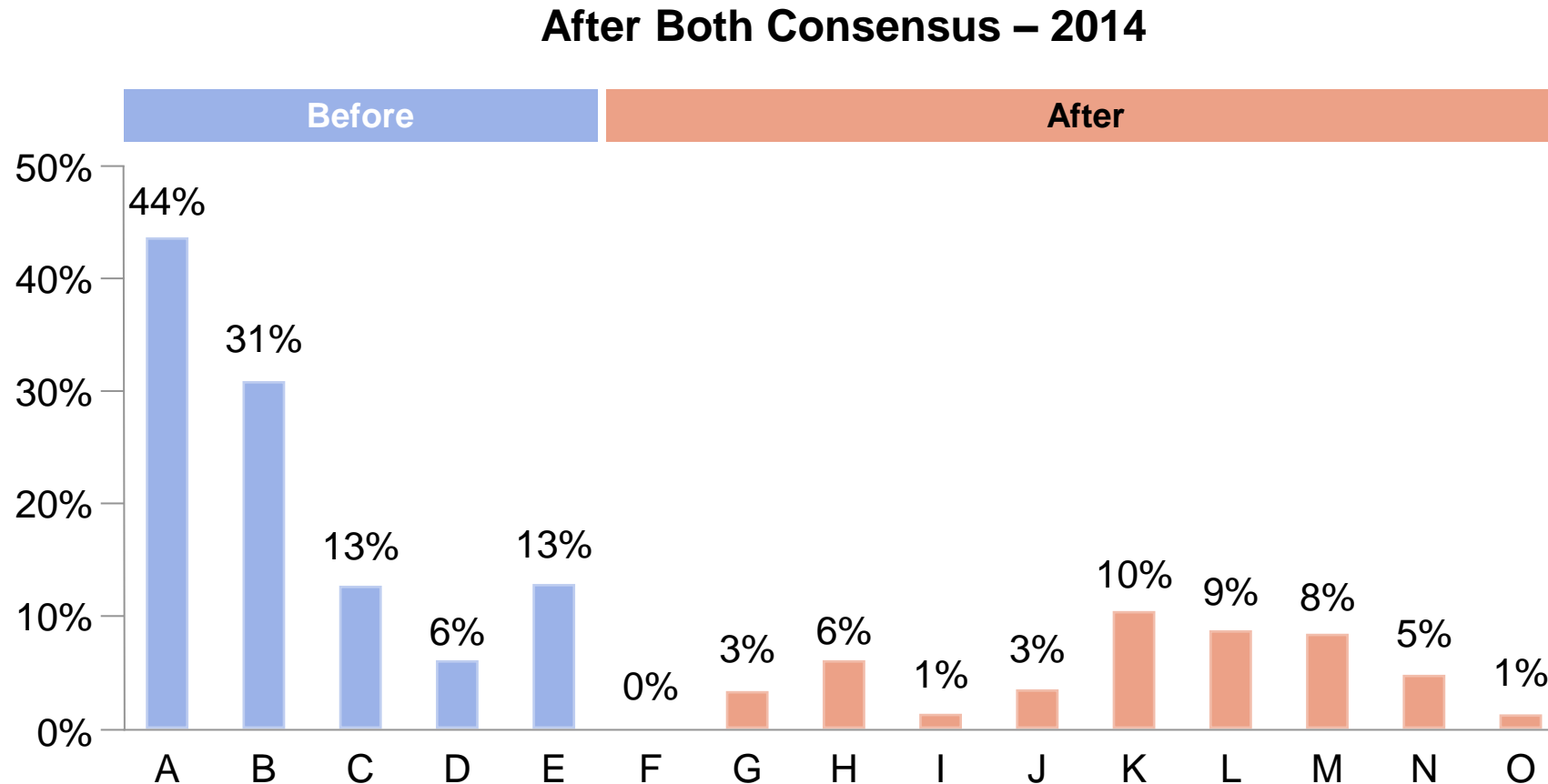
# Most Common Adverse Reactions

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- Edema
- Bruising
- Granuloma
- Product visibility or palpability (including nodules and papules)
- Vascular compromise

# Reduced Incidence of AEs After Consensus Publication

GAIN



AEs, adverse events.

A: VEGA 2003 (N=50); B: Chelsea & Westminster 2004 (N=30; data for 29/30 patients were included in the analysis); C: Blue Pacific 2004 (N=99); D: APEX002 2004 (N=99); E: Lafaurie 2005 (N=94); F: Borelli 2005 (N=14); G: Vleggaar 2006 (N=2131); H: Levy 2008 (N=65); I: Redaelli 2009 (N=566); J: Mazzuco 2009 (N=36); K: Lee 2010 (N=40); L: Narins 2010 (N=116); M: Palm 2010 (N=130); N: Schierle 2011 (N=106); O: Rendon 2012 (N=100).

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# Adverse Reactions for Biostimulators and Fillers (From Clinical Studies)

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The following adverse reactions considered to be possibly or probably related to the administration of poly-L-lactic acid have been obtained from clinical studies or detected from postmarketing surveillance and literature reports

## **Injection site reactions**

- Injection site hemorrhage
- Injection site pain
- Injection site induration
- Injection site swelling

## **Immune system disorders**

- Hypersensitivity
- Angioedema
- Skin sarcoidosis

## **Infections and infestations**

- Injection site infection, including cellulitis (facial), staphylococcal infection
- Injection site abscess

## **Skin and subcutaneous tissue disorders**

- Bruising & hematoma
- Injection site atrophy, skin hypertrophy
- Injection site erythema redness can be used locally
- Injection site urticaria
- Telangiectasis
- Subcutaneous papules, nonvisible, typically palpable, asymptomatic
- Visible nodules, including periorbital nodules, with or without inflammation or discoloration
- Granuloma



# Edema

GAIN

- ✓ Generally lasts up to 3–4 days
- ✓ If persistent edema is present, allergy and infection must be excluded
- ✓ Treatment
  - Anti-inflammatory
  - Antihistamines
  - Corticosteroids

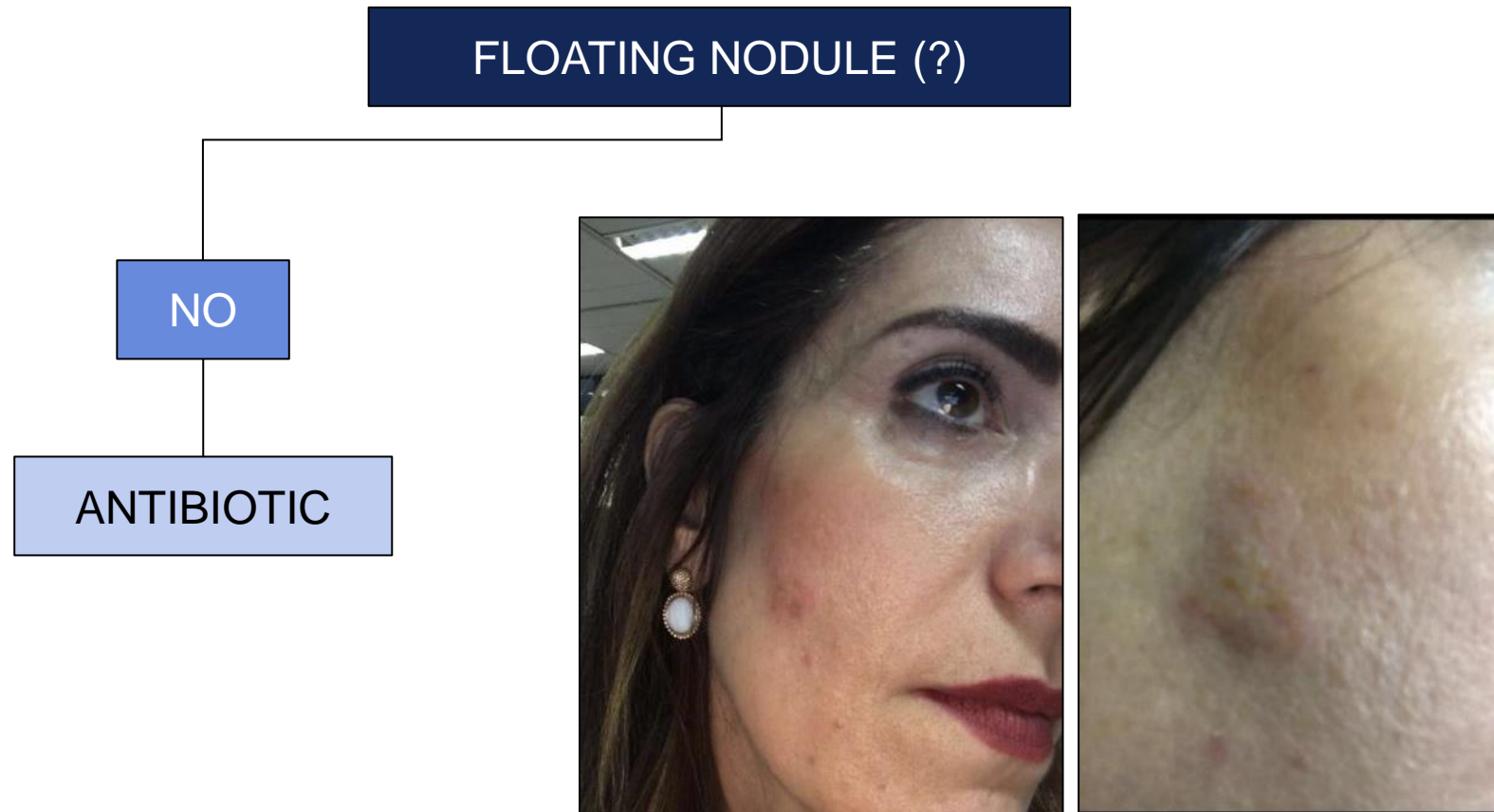


## Bacterial

- *Staphylococcus sp.*
- *Streptococcus sp.*
- *Mycobacterium sp.*

## Viral

- *Herpes*



## Persistence of symptoms and negative cultures:

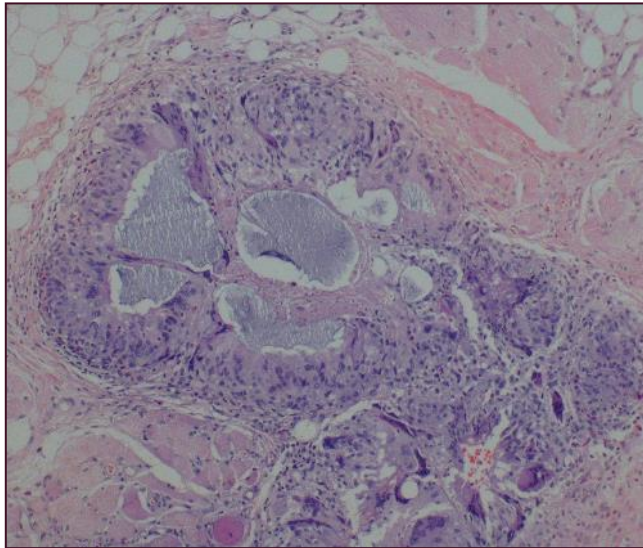
- ✓ Mycobacterium
- ✓ Biofilm
- ✓ Bacterial resistance

## Antibiotics:

- 1st choice: MACROLIDES (azithromycin and clarithromycin)
- 2nd choice: FLUOROQUINOLONES (moxifloxacin or ciprofloxacin)

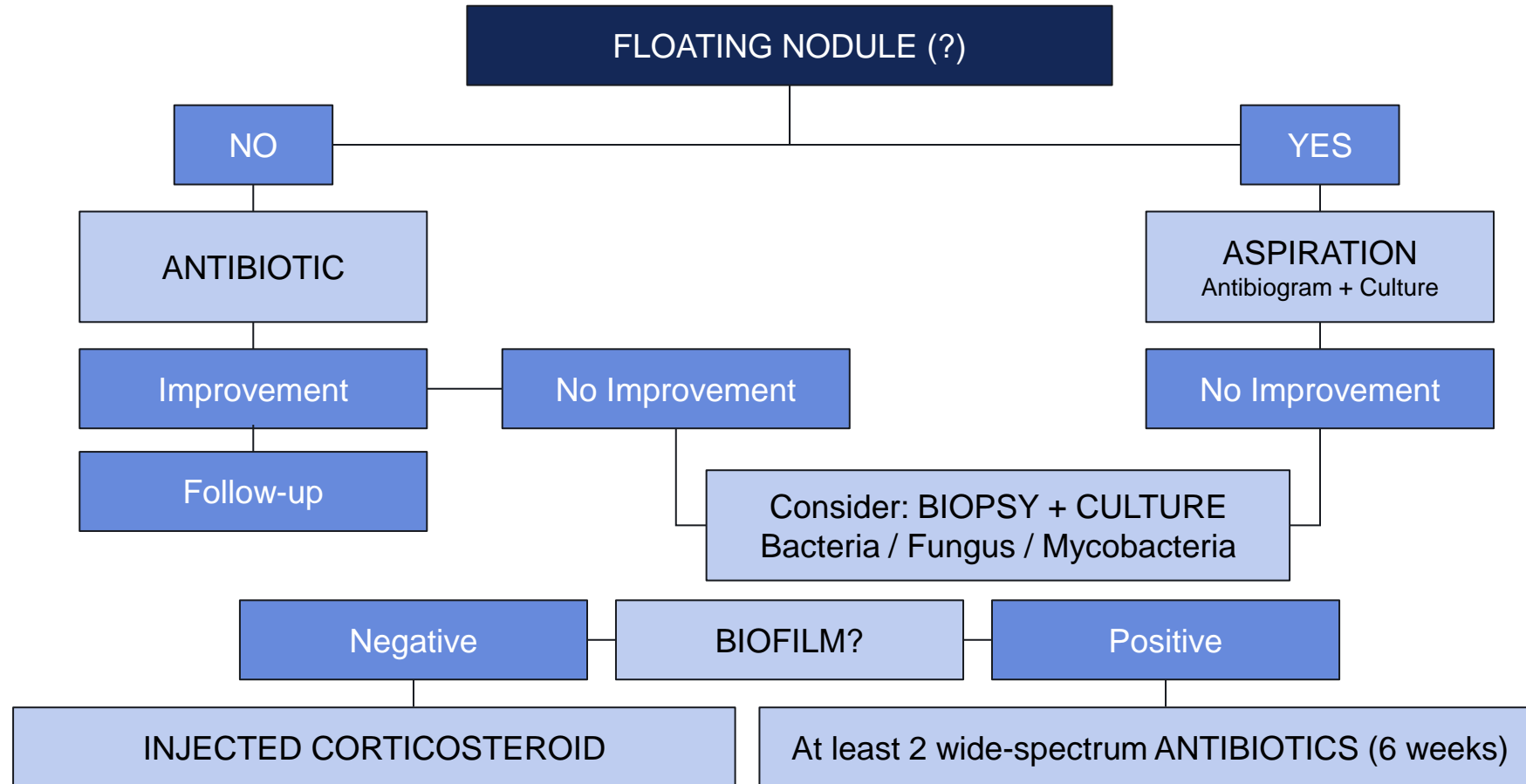


FLOATING NODULE (?)



YES

ASPIRATION  
Antibiogram + Culture



# Viral Infection

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ACYCLOVIR – 400 mg 3x a day / 10 days

VALACYCLOVIR – 500 mg 2x a day / 7 days



# Possible Causes of Nodule Formation

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## Failure to respect indications:

- ✓ Product too concentrated (dilution <5 mL)
- ✓ Too much product injected in same area
- ✓ Interval between sessions too short
- ✓ No massage or insufficient dispersion of PLLA into the tissue
- ✓ Hyperkinetic regions
- ✓ Injection plane too superficial. Thin dermis



# Nodule

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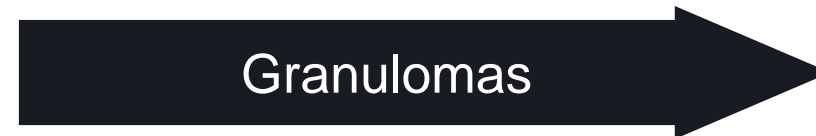
**Non-Inflammatory**

**Inflammatory  
(Granuloma)**

**Acute** (up to 48 h)

**Subacute** (up to 2 wk)

**Chronic** (after 2 wk)



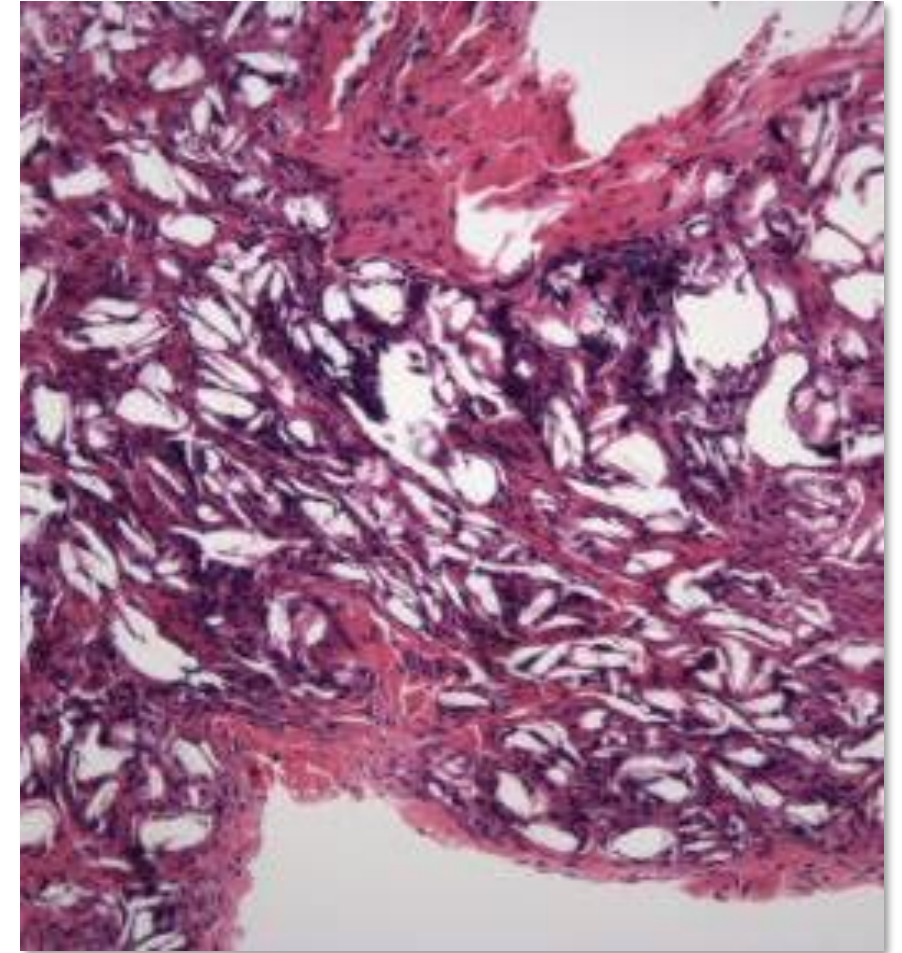
1. Narins RS, et al. *Dermatol Surg.* 2009;35:1667-1671; 2. Parada MB, et al. *Surg Cosmet Dermatol.* 2016;8(4):342-351.

# Nodule vs Granuloma

GAIN

## Nodules

- **Appearance:** 1–2 months after injection, after swelling dissipates
- **Location:** single nodules, close to facial muscles particularly lips
- **Size:** remain the size of a lentil or a pea
- **Border:** well confined by fibrous capsule
- **Persistence:** until resolved (usually <1 year)
- **Histology:** foreign body reaction; particles or microspheres form aggregates
- **Treatment:** little effect of corticosteroids; must wait for absorption or interlesional normal saline and subcision

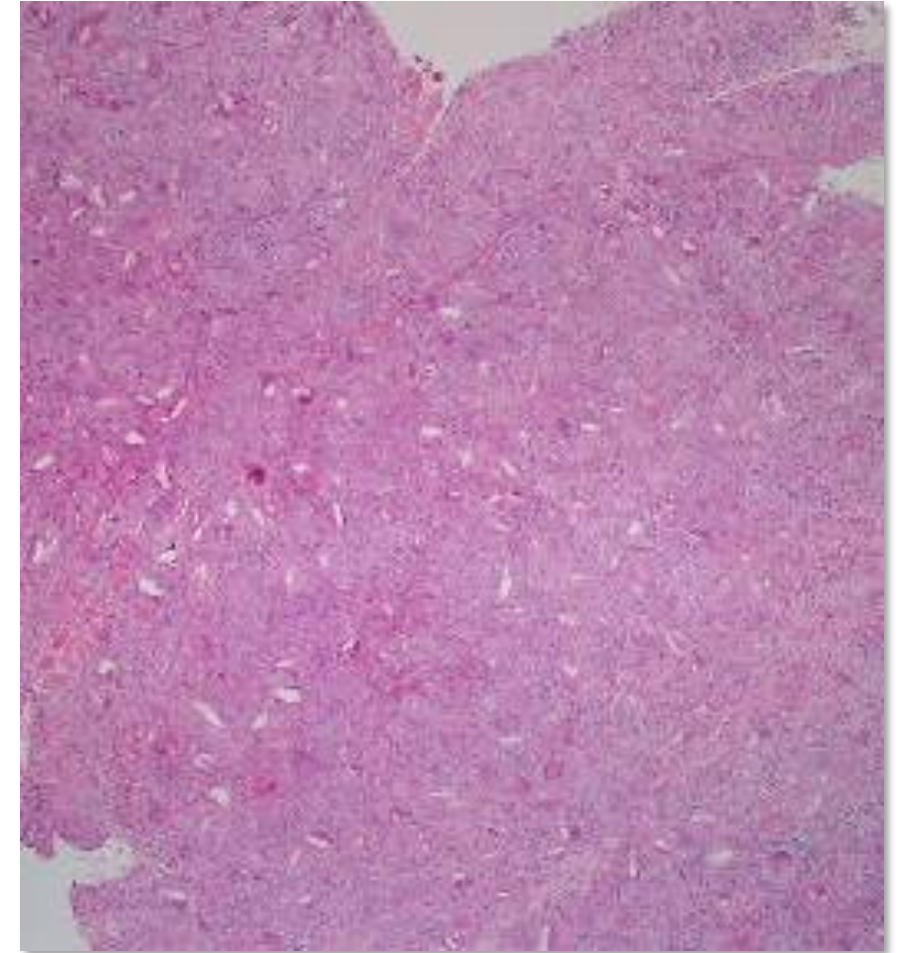


# Nodule vs Granuloma

GAIN

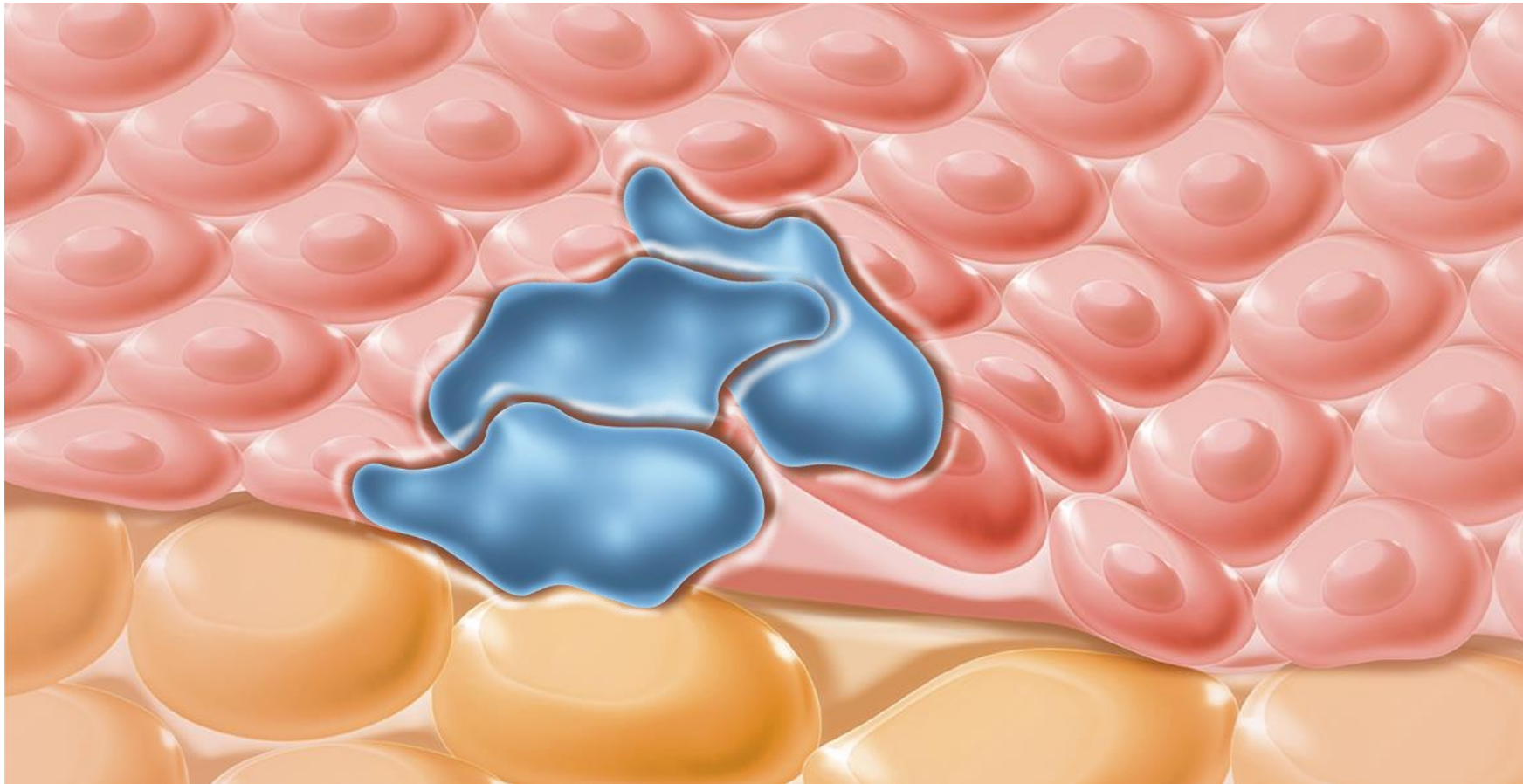
## Granulomas

- **Appearance:** delayed onset (6–24 months)
- **Location:** at injected sites at the same time
- **Size:** grow to the size of a bean, with skin discoloration, edema
- **Borders:** finger-like into surrounding tissue
- **Persistence:** if untreated, they disappear after 1–5 years
- **Histology:** foreign body granuloma; particles or microspheres are scattered
- **Frequency:** >0.5%



Nodule

GAIN

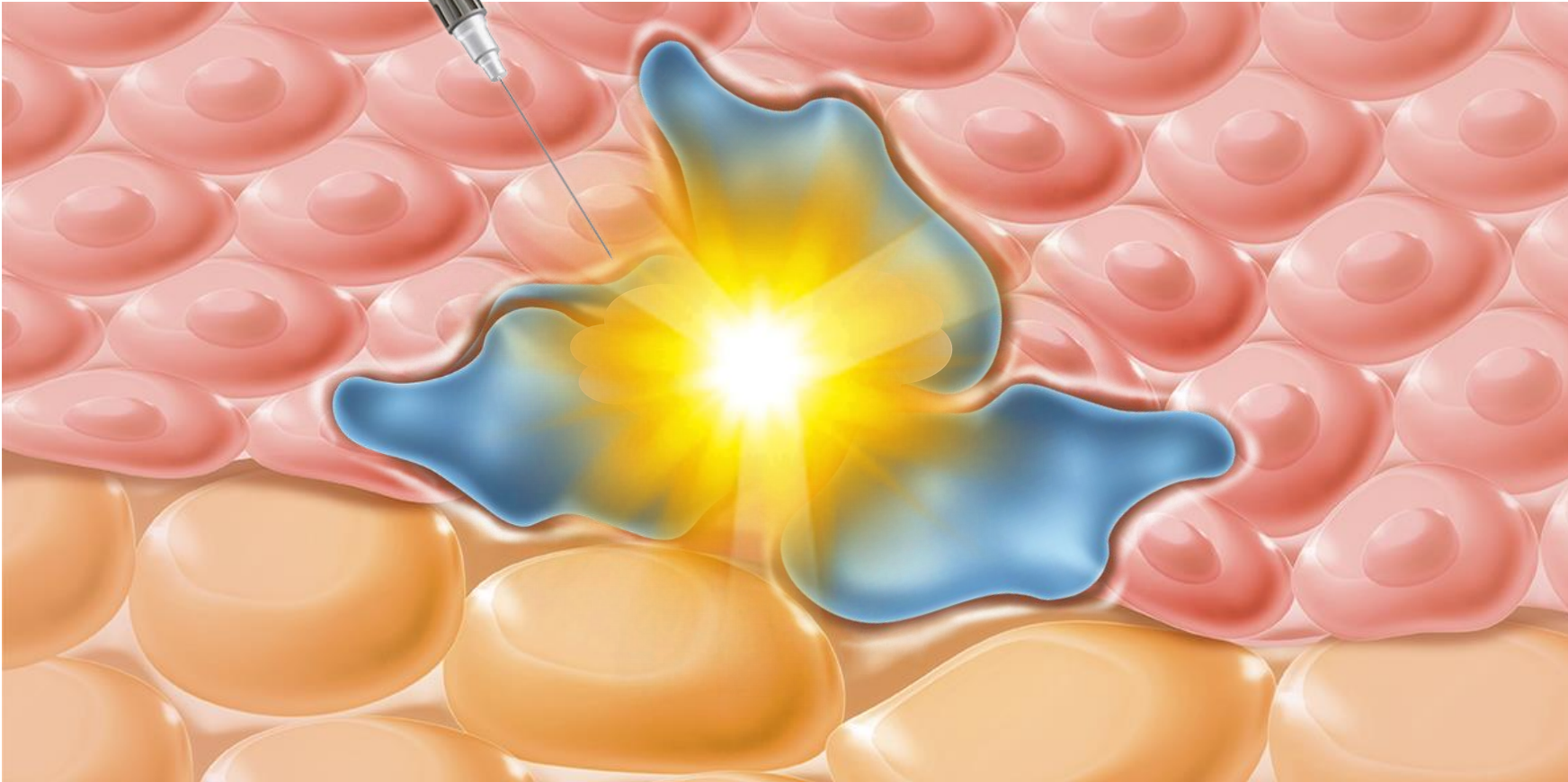


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# Nodule Treatment

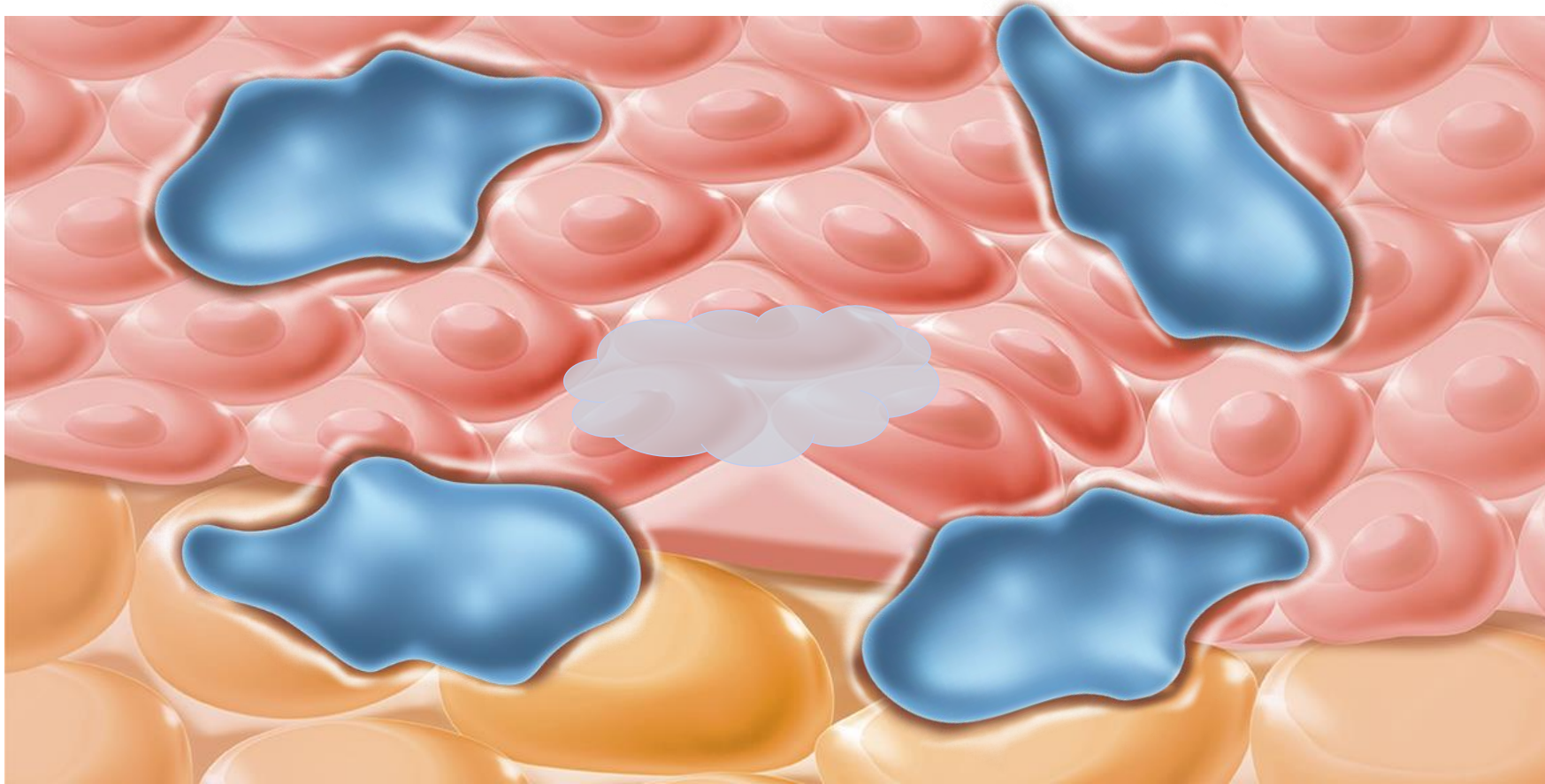
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# Nodule Treatment

GAIN



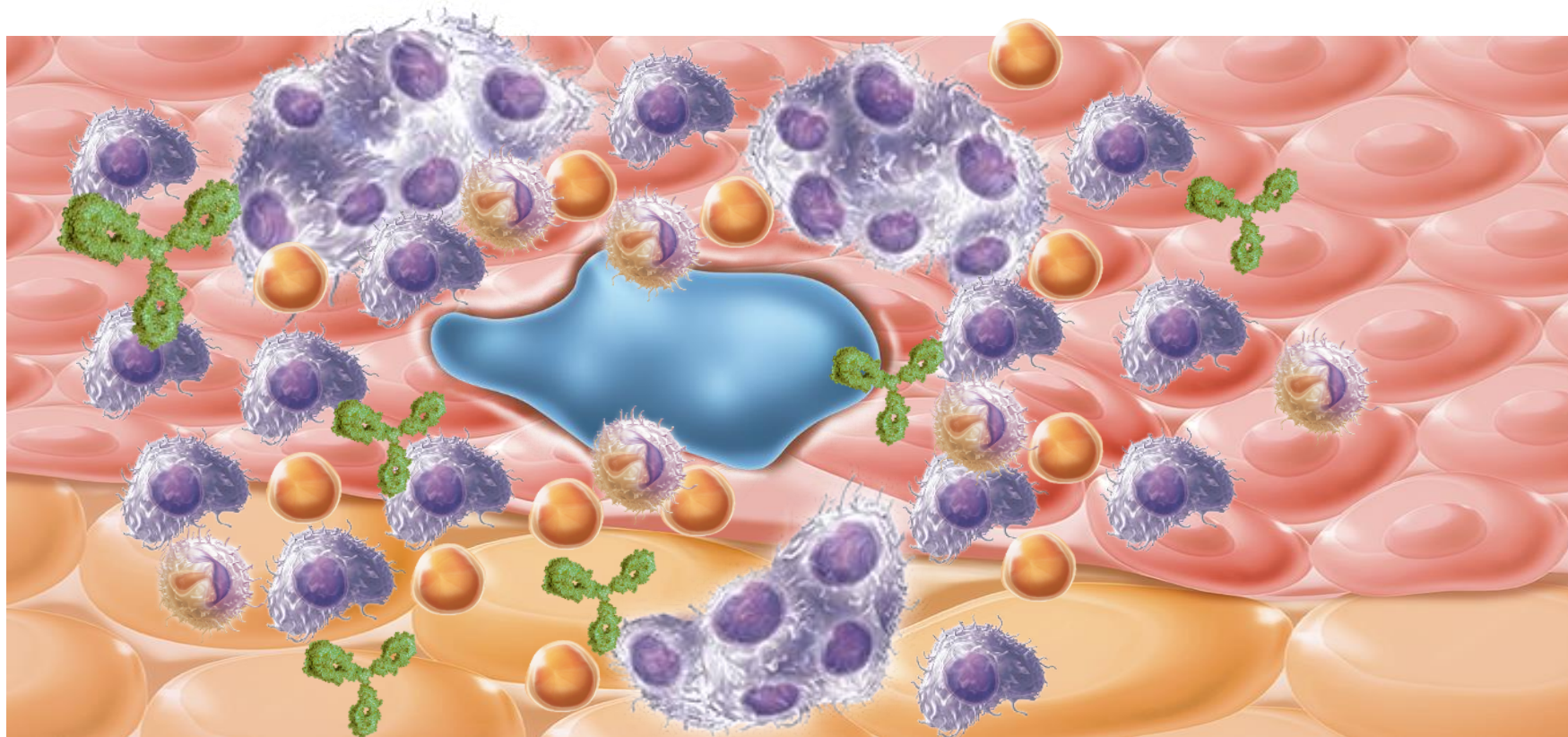
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# Granuloma

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## Severe Inflammatory Response



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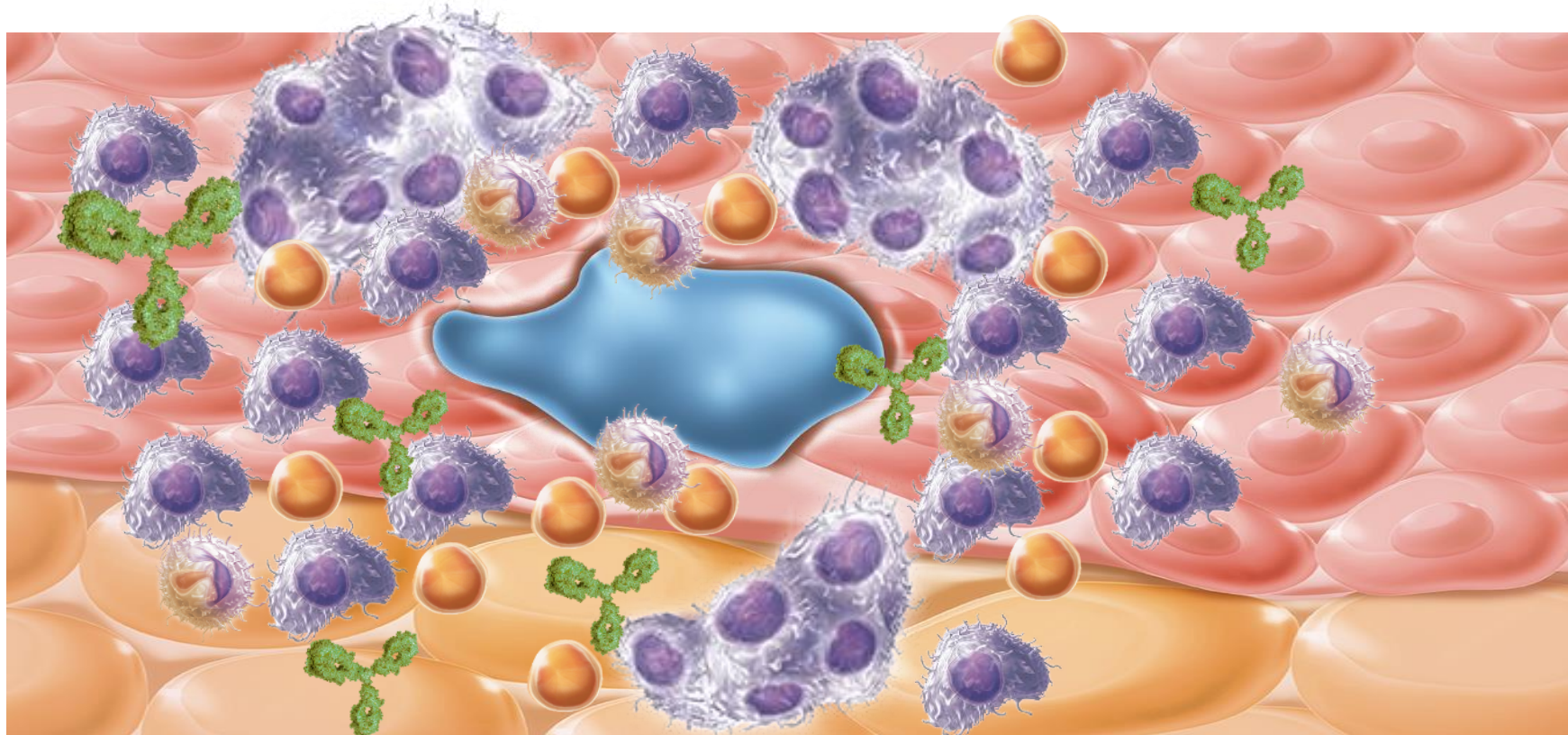
# Granuloma – Histology

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**Giant Cells**

**Macrophages**

**Lymphocytes**

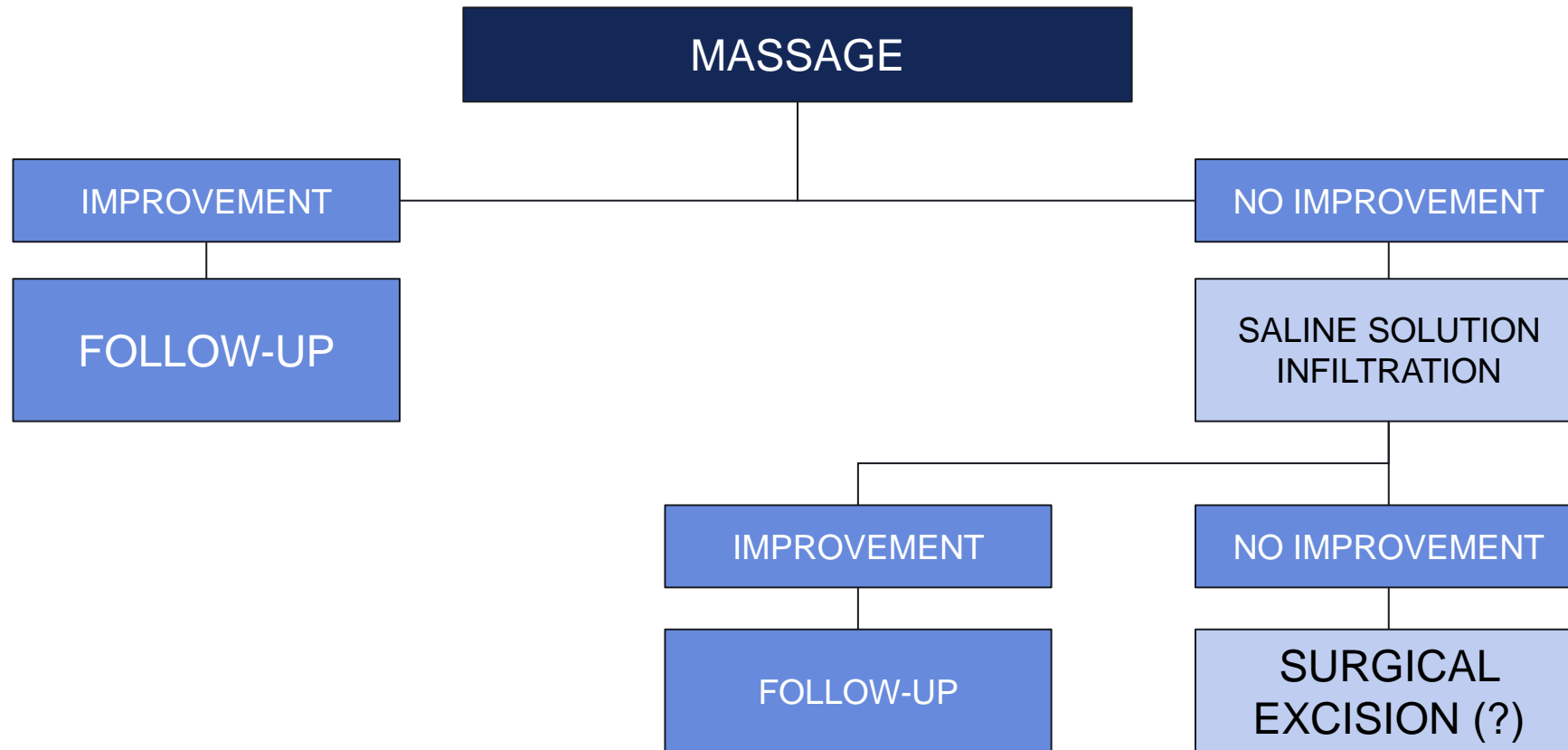


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# Nodule Treatment

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# Example of Subcutaneous Nodules

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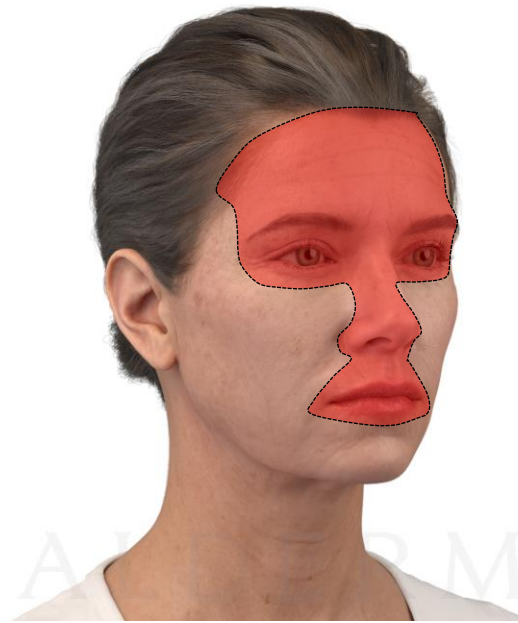
Saylan Z, et al. *Surg J.* 2003;23:221-224.

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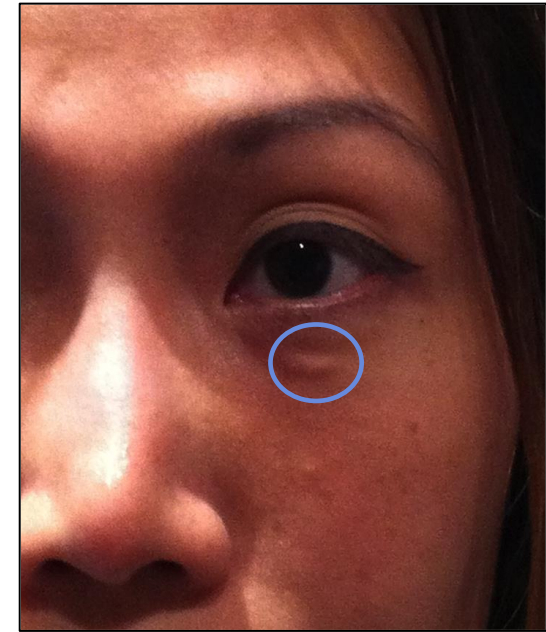
## Examples of injections in areas where PLLA should not be used



Forehead



● Higher risk of adverse effects



Lower eyelid

# Granuloma

GAIN



Courtesy of  
Dr Luiz Avelar

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# Granuloma

GAIN

After an insect bite, 3 months after the last treatment session



Courtesy of  
Dr Meire Parada

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## Proven treatments for granulomas

- Triamcinolone (Kenalog, Volon-A) 20–40 mg intralesionally
- Triamcinolone (1 mg/mL) = 5-fluorouracil (50 mg/mL) intralesionally
- Prednisolone (Depo-Medrol) 20–40 mg undiluted
- Betamethasone (Diprosone) 5–7 mg intralesionally
- 1:3 Betamethasone (Diprosone) 3.5 mg + 1:3 5-fluorouracil (1.6 mL) + 1:3 lidocaine intralesionally