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Complications of Fillers

Alain Tenenbaum, M.D, PhD, D.Sc
Facial Plastic Surgeon,
Switzerland

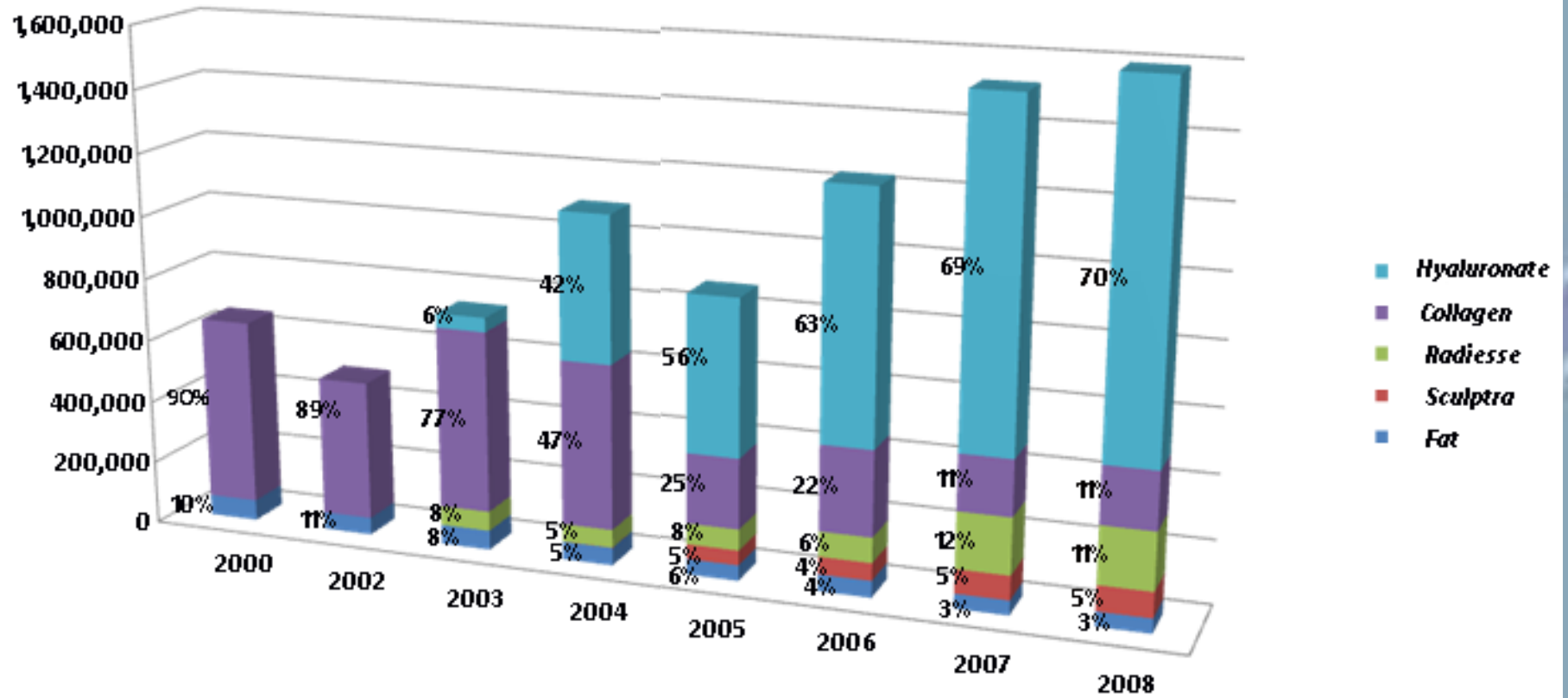


Thanks to friendly Collaborators who shared with me their pictures

- Dr Junfeng Du,China,
- Dr Jean Hebrant,Belgium
- Dr Igor Rudenko,Ukraine
- Prof Milanov, Plastic Surgery, Russia
- Dr Sidorenkov,Plastic Surgery,Russia
- Dr Luitgaard Wiest, Dermatology, Germany
- Dr Romulo Mene, Plastic Surgery, Brasil
- Dr Denis Valente, Plastic Surgery, Brasil
- Dr Ziya Saylan,Cosmetic Surgery, Turkey
- Dr Georghy, General Surgery,Australia
- Prof Gottfried Lemperle, Plastic Surgery, USA
- Prof Hirotaro Fukuoka, Plastic Surgery,Japan
- Prof Ivo Pitanguy,Brazil
- Prof Luiz Toledo, ISAPS Professor,Dubai, UAE
- AND OTHERS

What is a common complication





American Society of Plastic Surgeons statistics on the number of injections made per year by surgeon members

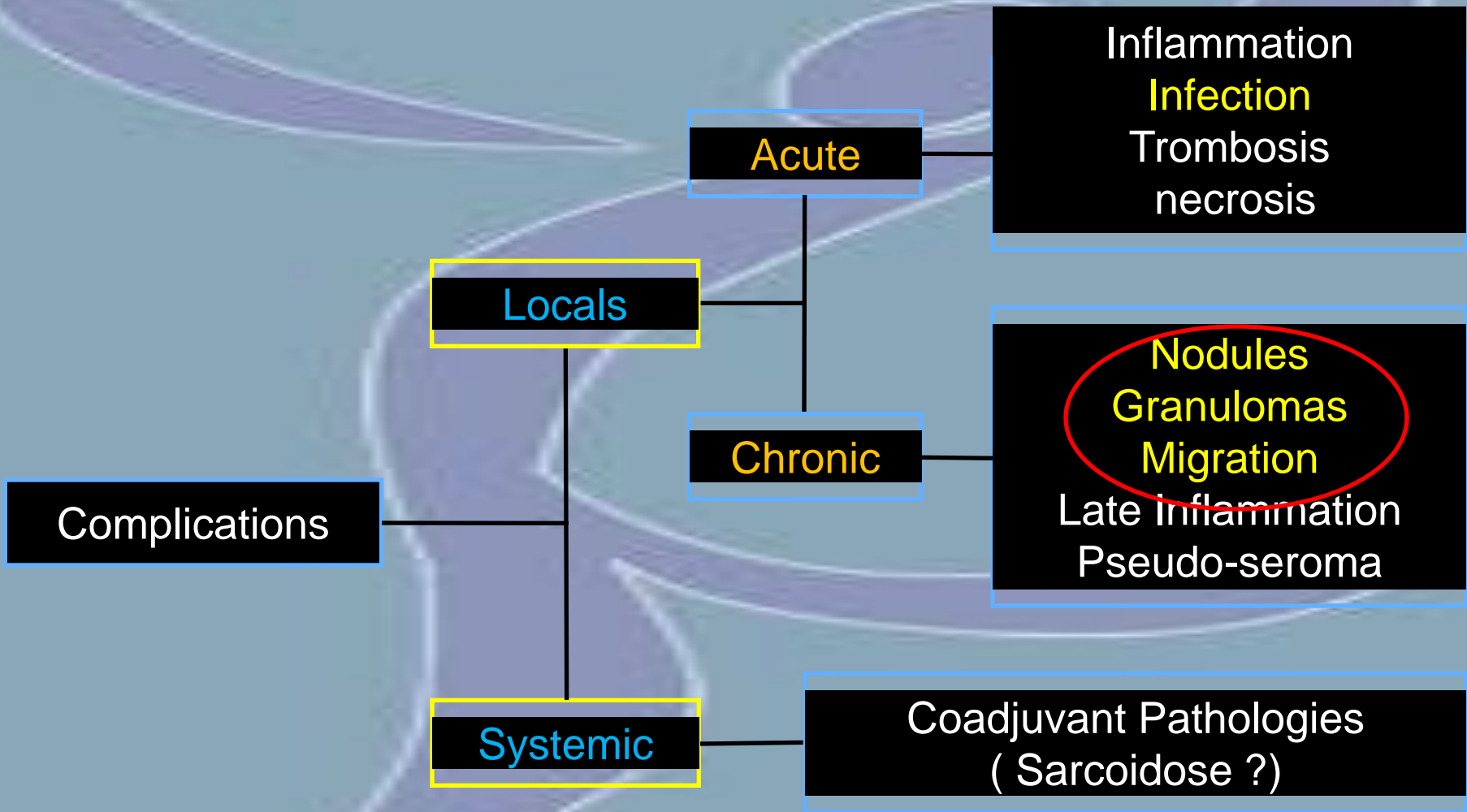
COMPLICATIONS

MINOR

- Dolor
- Edema
- Ecchymosis
- Hiperemias
- Asymetries
- Irregularities
- Motor Anaesthesia
- Herpes activation
- Collections Formations

MAJOR

- Nodules
- Necrosis
- Granulomas
- Late Edema



Collateral Effects on Animals SR

Artecoll PMMA

01 animal died 8 weeks after
injection

Dimethylsiloxane

02 animals died

01 hepatic abscess in 01 animal

01 Tumor in the foot of 01 animal

Metacrill

01 animal died after 2 weeks

Abscess in the skins back of 01
animal

Multiple hepatic abscess

Restylane

02 animais died same day of
injection

Eosinophilic Infiltration
Hipersensibility?

Cheloid in the skins back

Multiple hepatic abscesses in all
lobuls

Fillers are silent killers and medical thrillers

Fillers are silent killers
And medical thrillers

2 Massive killers

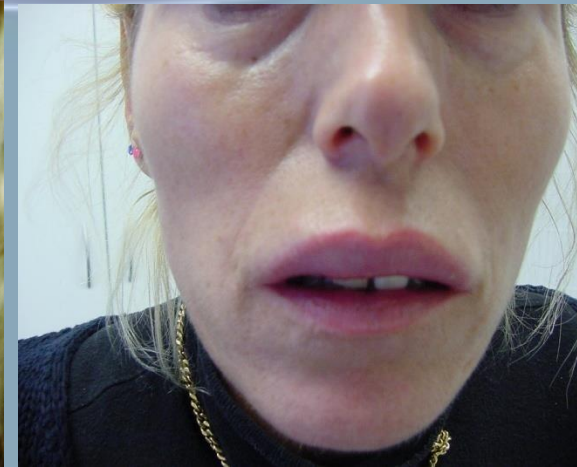


MIGRATION. OF PMMA



PMMA was
injected into
the buttocks area.





Lipodystrophies

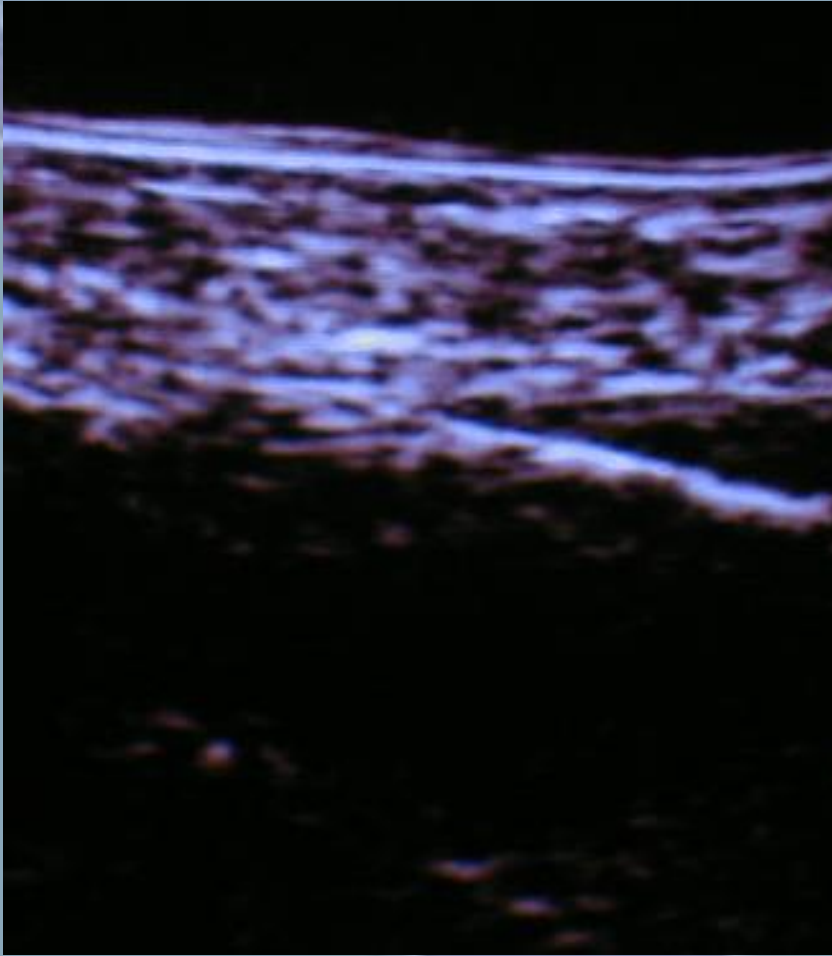
be careful with publications !!!

Before

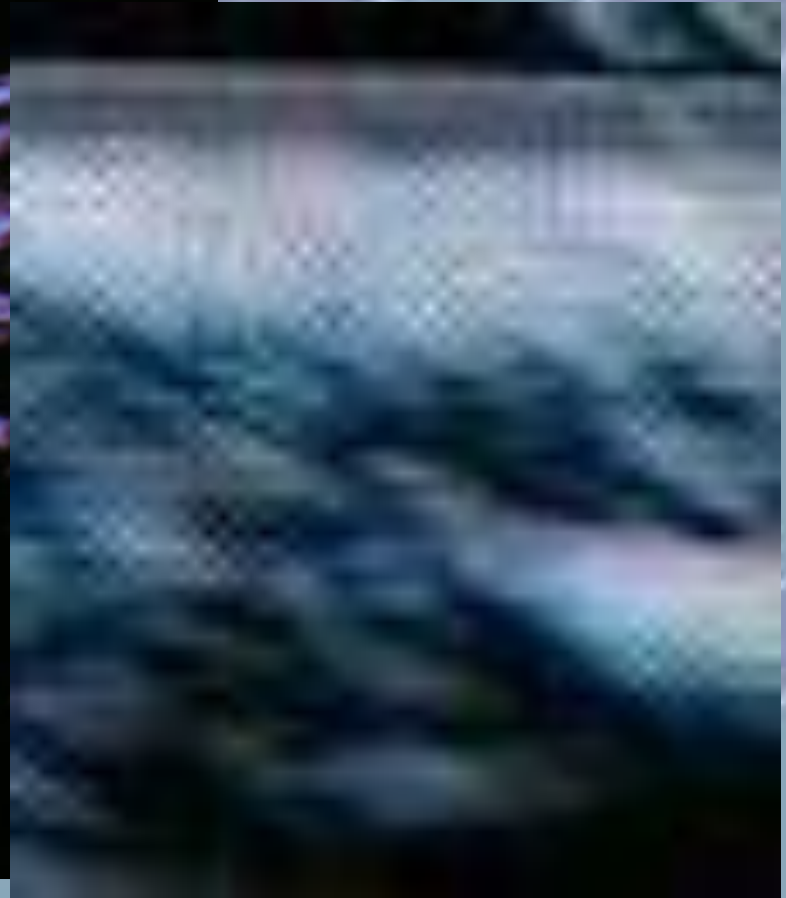


After

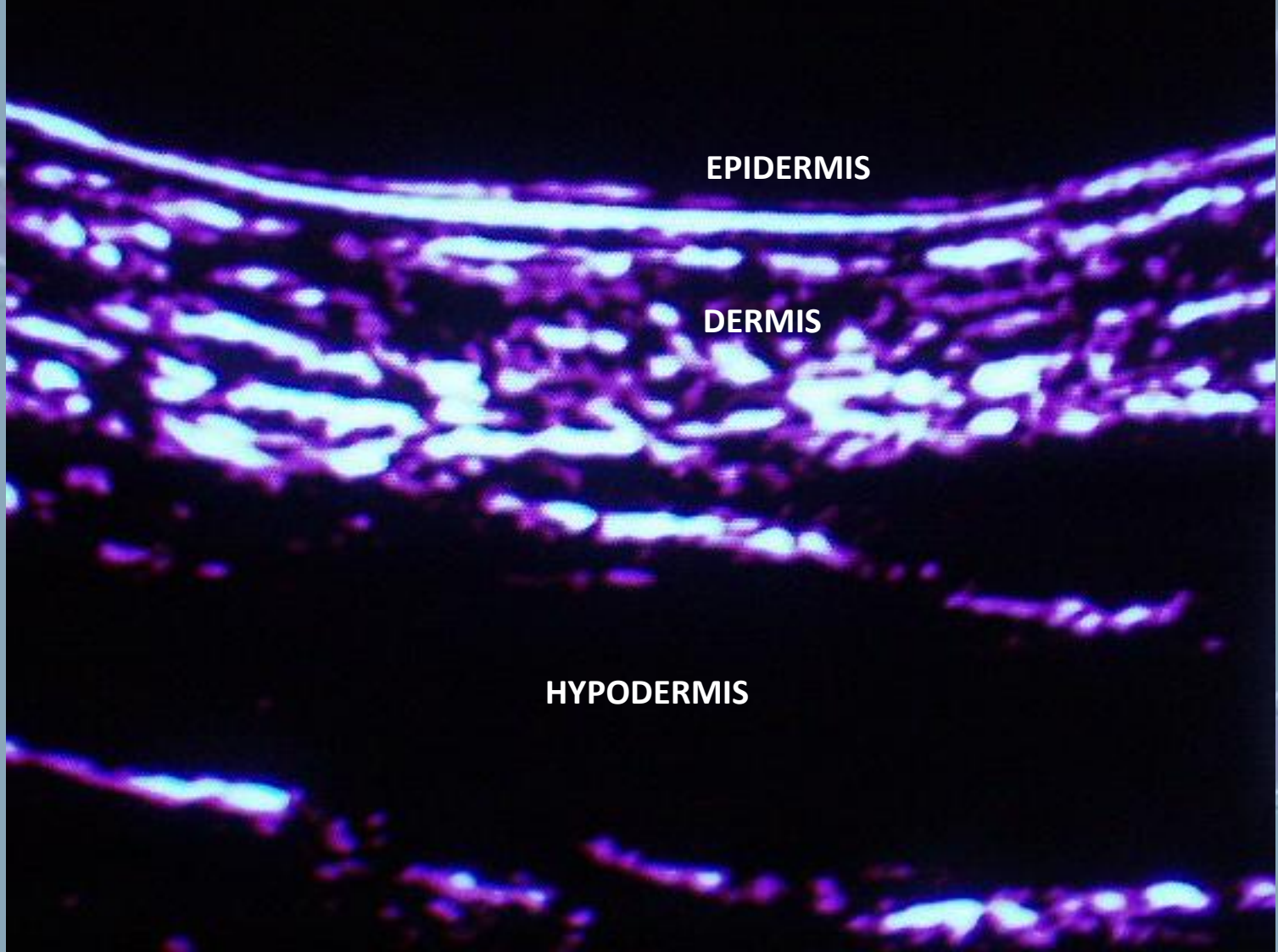




20 Mhz

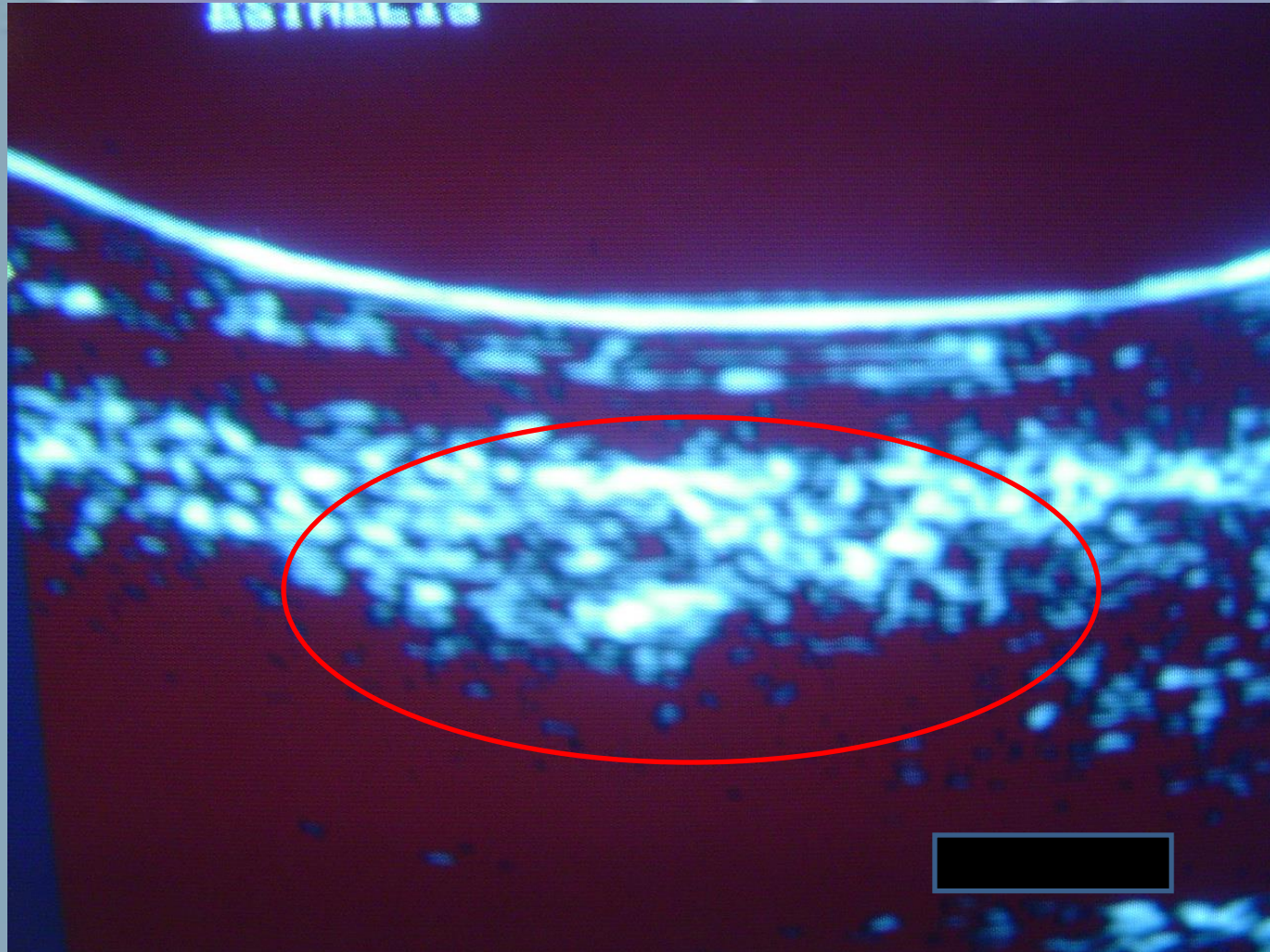


7.5 Mhz



20 Mhz

Ideal filler :
Homogeneous Width of the dermis



Who is the responsible ?

MD have to gain back their authorities over ignorant and dangerous burocrats

- The product ?
- The physician?
- The patient?
- The notified body ? Anvisa ,CE, FDA,KFDA,Invicma,Digemid & others !!!
- The Health Ministry ?
- The medias ?
- The bad copies made in some countries ? (Ecuador,South Korea,Argentina,Venezuela,Brasil,China,India,..)
- Ignorant antideontologic colleagues

Nodules & Granulomas

GRANULOMA

- Tissue reaction mediated by monocytes and usually caused by not absorbable agents
- Featured by hardening in all treated areas
- Differential Diagnosis is clinical

NODULE

- Tissue reaction mediated by fibroblasts which may occur by product accumulation or organized hematoma.
- Featured by hardening in some treated areas
- Differential Diagnosis is clinical

TREATMENT OF COMMON COMPLICATIONS POST FILLERS

- **nodules** – surgical resection
- **granulomas** - corticoid intra-lesional infiltration
- **Large necroses** – reconstructive surgery
- **Partial necroses** - chemical or surgical debridement

Generalities

Nodules : Surgery

Good Pronostic

- Technical errors

Granulomas : Medicine

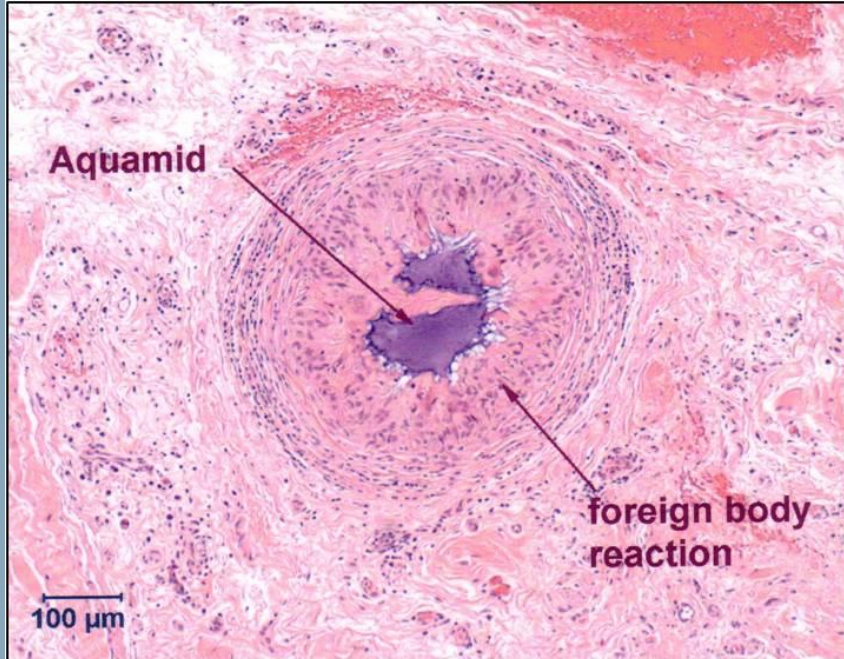
Bad Pronostic

- Technical errors
(anamnesis, US20 Mhz,indications)
- Chemical mistakes
- Patient lyers
- Unknown etiologies

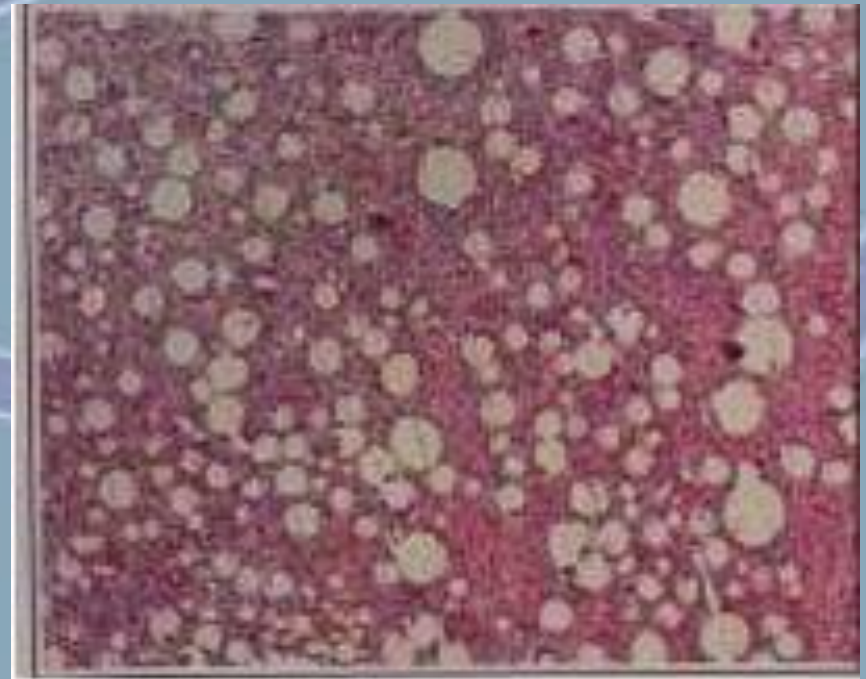
	Nodules	Granulomas
Appear	1-3 months Slowly	6-36 months Suddenly after initial satisfaction
Localization	Some isolated injected sites (lips, crows feet ...)	All injected sites at the same moment
Size	Stable	Growing
Border	Confined by fibrous capsula	Fingerlike project into tissue
Histology	Foreign Body Reaction Packed material as implanted	Foreign Body Granuloma Scattered in cellular reaction
Evolution-Persistence	As long as fillers remain (resorbable, permanent) ??	Seem to disappear if untreated after 1 -5 years
Aspect	Skin normal No edema	Skin discoloration With edema
Treatment	surgical	medical
	No corticoids	Corticoids + - 5 FU

Borders

Nodule
Confined by fibrous capsula



Granuloma
Fingerlike project into tissue



Nodules & Granulomas Mechanisms

NODULE : 5 Mechanisms

1. Inadequate Quantity of injected material
2. Product placed too superficially
3. Lack of proper distribution of the filler
4. Organized hematoma with calcification
5. Application in inappropriate plan or layer

GRANULOMA : 3 Mechanisms

1. Foreign bodies in the injected material
2. Microspheres too small causing acute inflammatory reaction.
3. Pathological Biofilm

MD RESPONSIBLE
SURGERY -> GOOD PRONOSTIC

WHO IS RESPONSIBLE?
MEDICAL TREATMENT -> PRONOSTIC ???

Reported Possible causes of granulomas
after injected fillers

High Correlations

**Mixing fillers in
same location**

Auto immune
thyreosis

Facial trauma

Systemic
infections

acupuncture

**Facelift
operation**

Sinusitis

Hyperthyreosis

Dental focus

Pharyngitis

Colitis ulcerosa

Paradontosis

Bronchitis

Morbus crohn

mesotherapy

Pleurisy

Pemphigus

botulinum

Enteritis

Sarcoidosis

HRT??

Pyelonephritis

Breast cancer

Encephabol

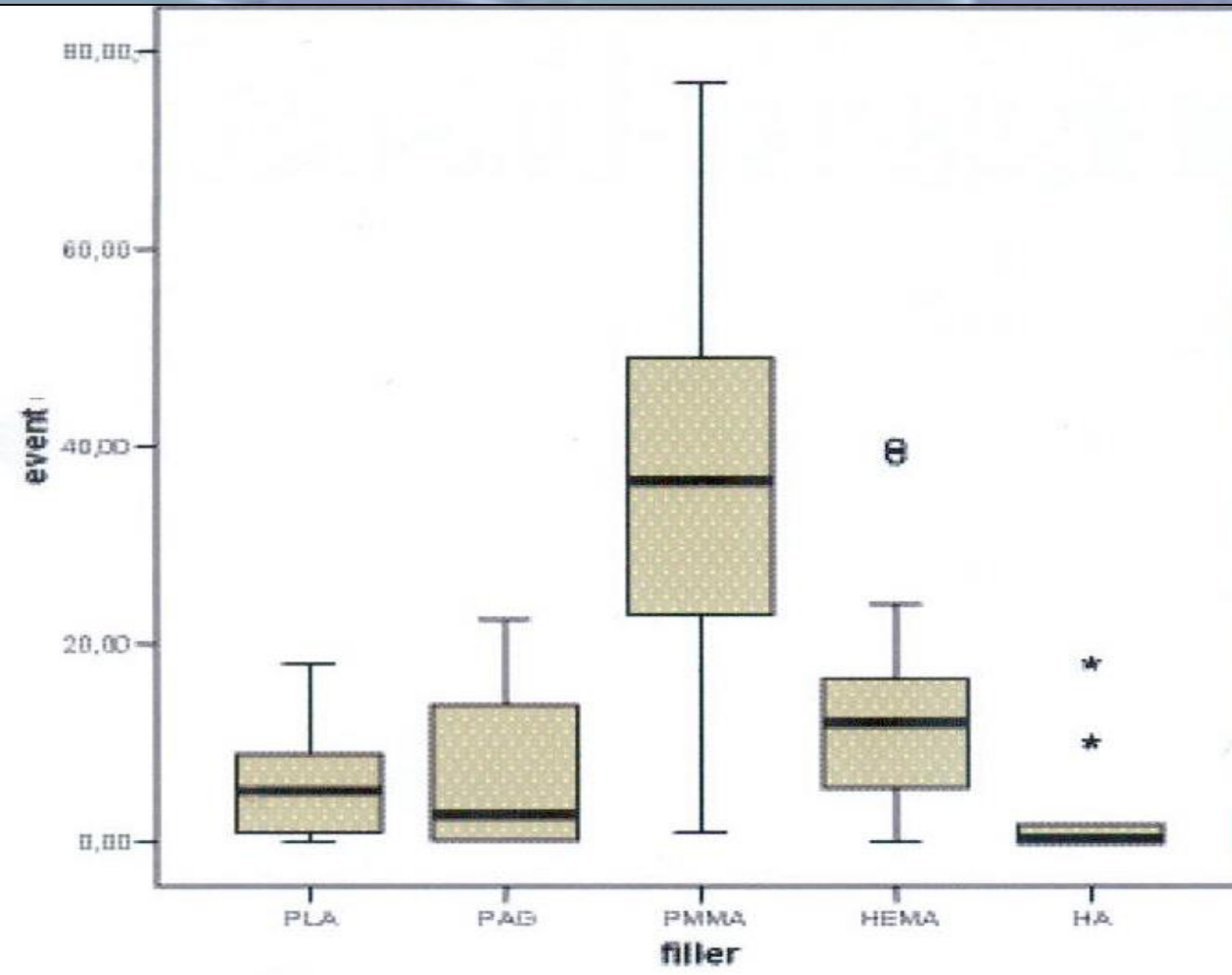
Flu like syndrom

Psychological
shock

Treatment tentatives of Granulomas

- 5FU 5%
- Triancinolon 4%
- Xilitol 2%
- Lidocaín 2%
- Adrenalin 1:50.000
- H2O for injection q.s.p. 10ml
- **4 Cycles INTRALESIONAL 1 X week**
- Prednison 60mg, 40mg, 20mg P.O.
- Alopurinol 300mg P.O. 2 X day – 45days
- imiquimod 250mg topic 2 X day– 45days

Mean time until appearance of adverse reaction after injection of Fillers



Biodegradable Fillers

HA: 3.2 ± 6.0 months

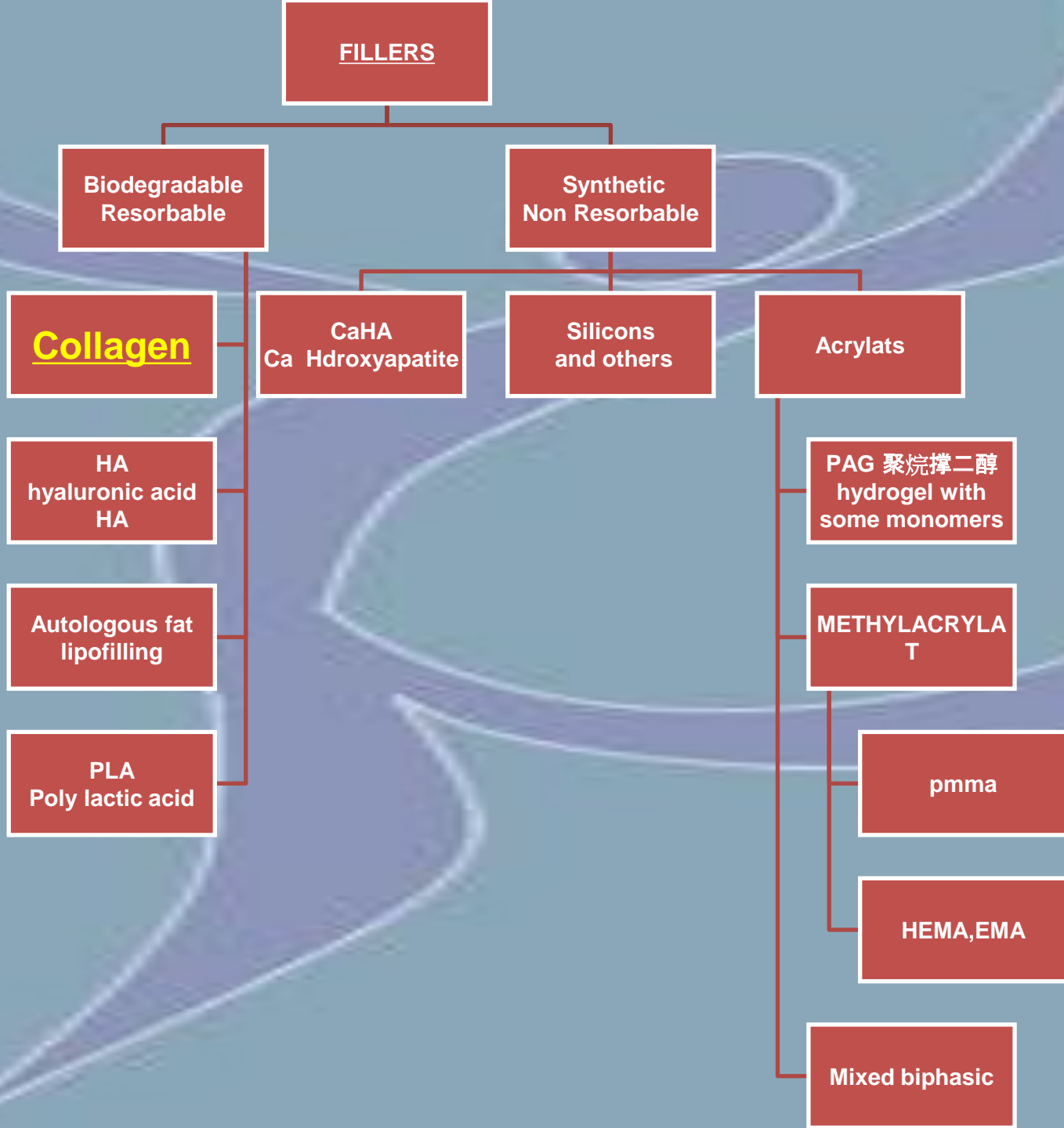
PLA: 5.5 ± 6.3 months

Permanent Fillers

PAG: 7.0 ± 10.6 months

HEMA: 12.3 ± 13.7 months

PMMA: 25.5 ± 37.1 months



Resorbable Collagen fillers(2)

Side effects : Granuloma,Nodule,Necrosis

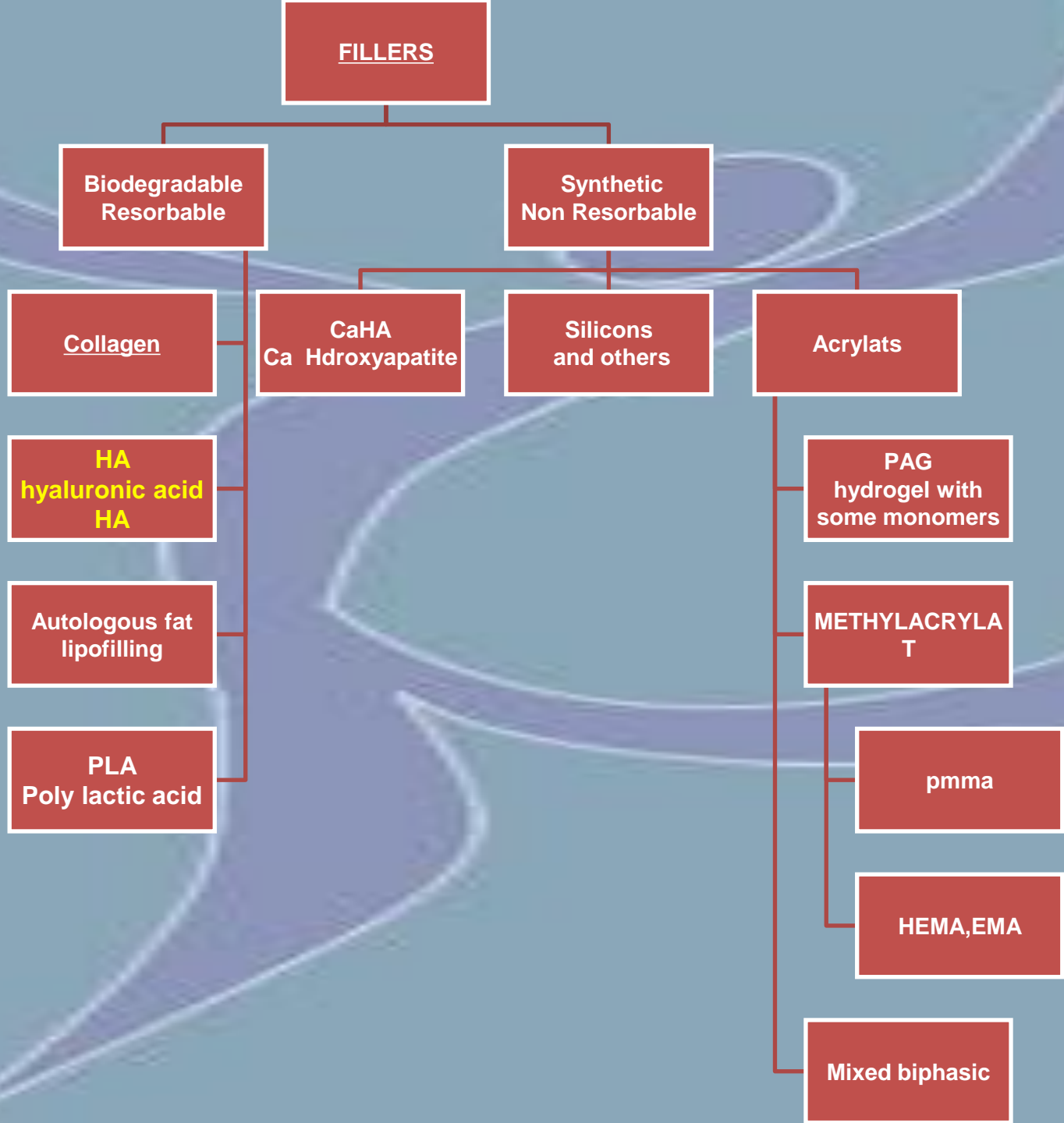


Dr. L.Wiest

Resorbable Collagen fillers(3)

Side effects : Granuloma,Nodule,Necrosis





Granulomas with Hyaluronic acid



Resorbable Hyaluronic Acid fillers(2)

Side effects : Granuloma,Nodule,Necrosis



Dr. L.Wiest



Hyaluronic acid

Persisting oedema after Hyaluronic acid



2002 9 24

Persisting oedema after Hyaluronic acid



HA Complication for medical augmentation mammoplasty

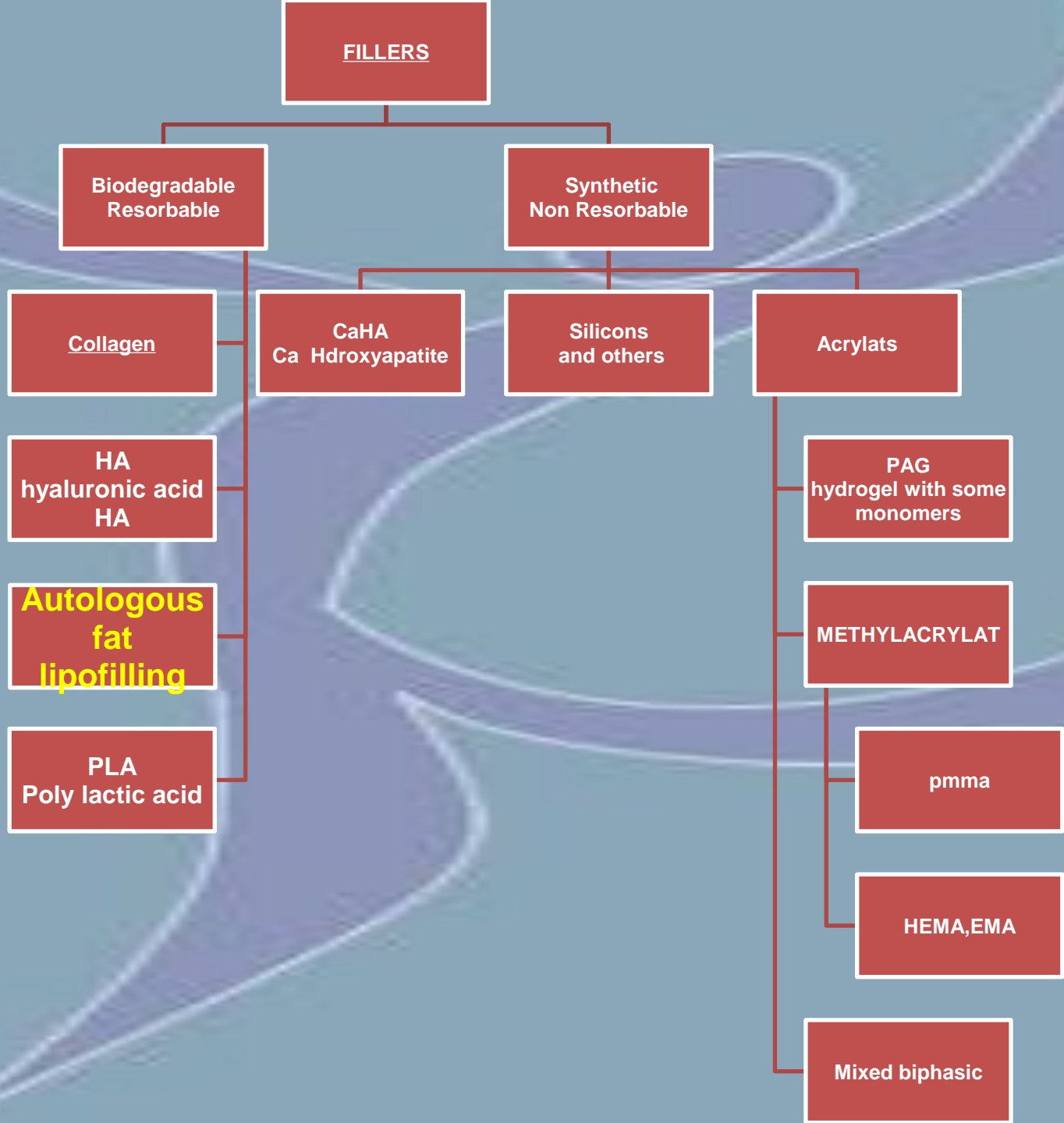


FORBIDDEN IN FRANCE SINCE 05 SEPTEMBER 2011 BY AFSSAPS

HA Spontaneous 自发的 Perforation 穿孔 for medical augmentation mammoplasty



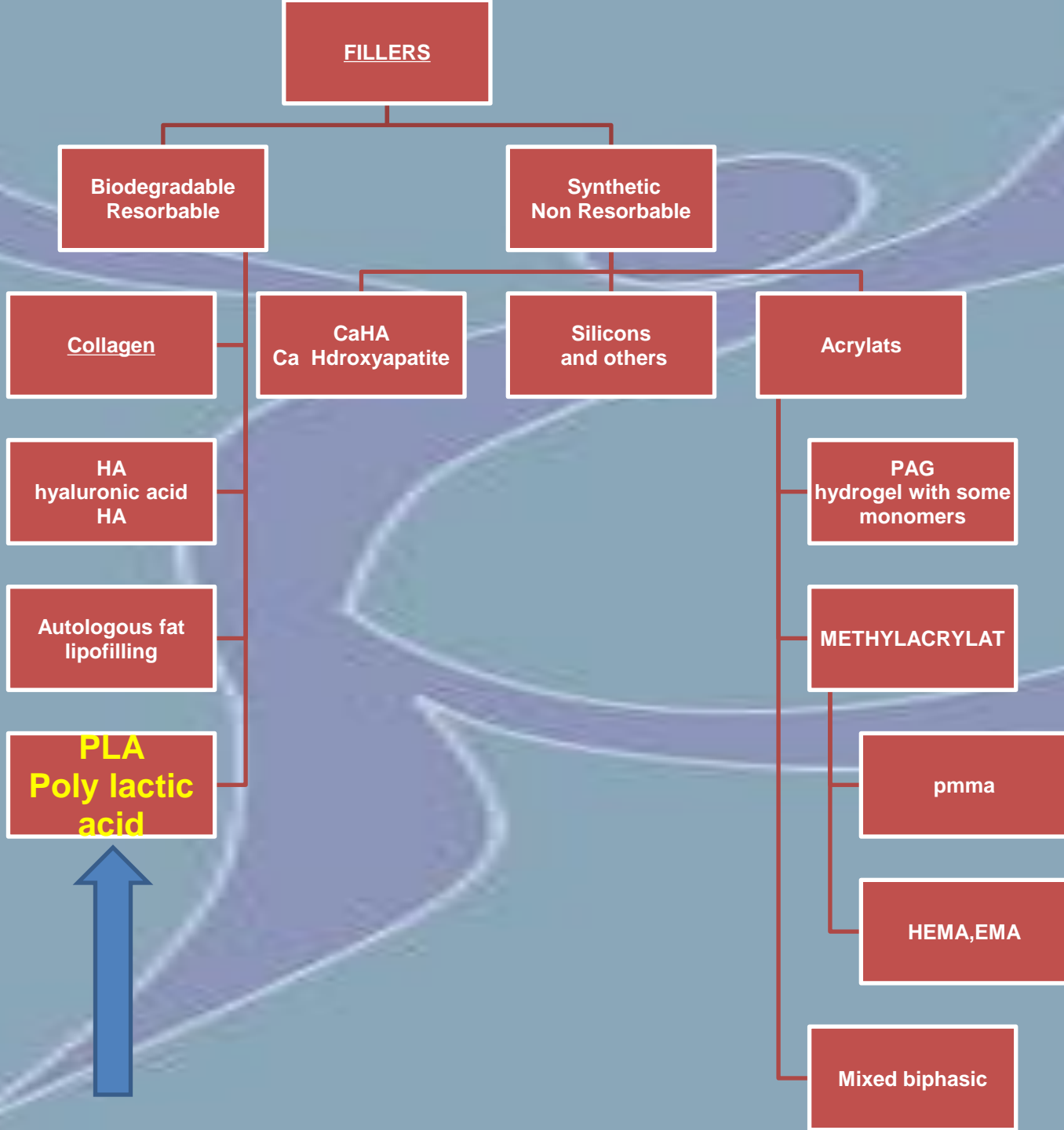
**FORBIDDEN IN FRANCE SINCE 05.09.2011 BY
AFSSAPS**





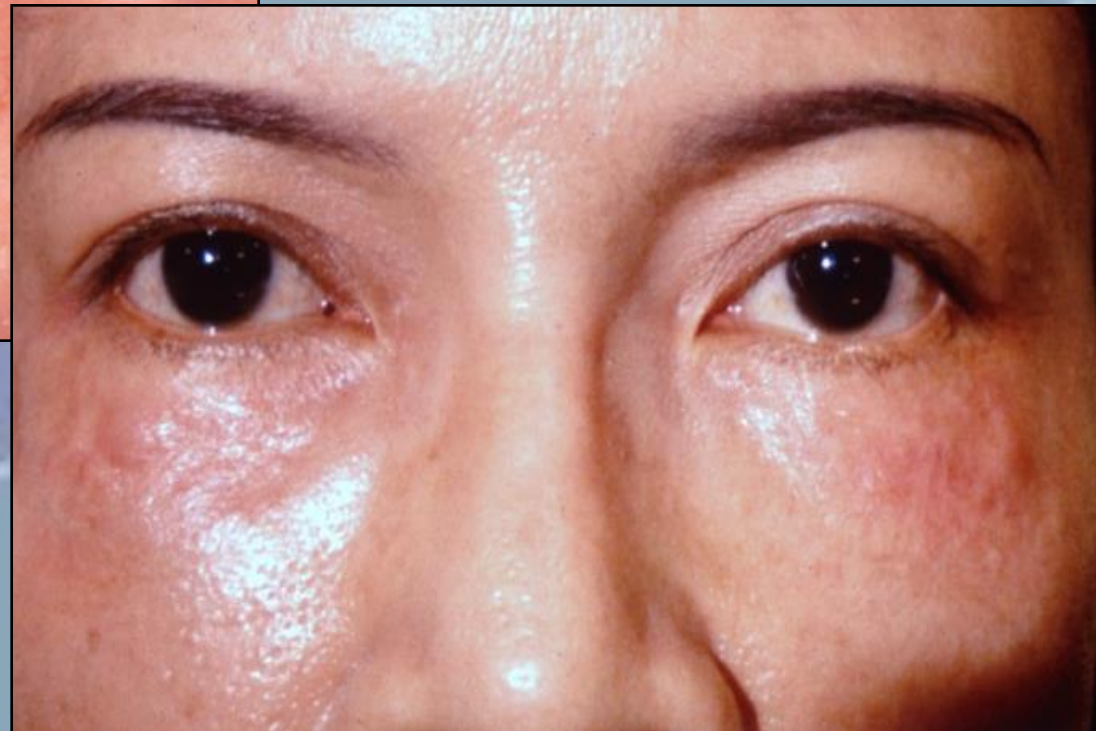
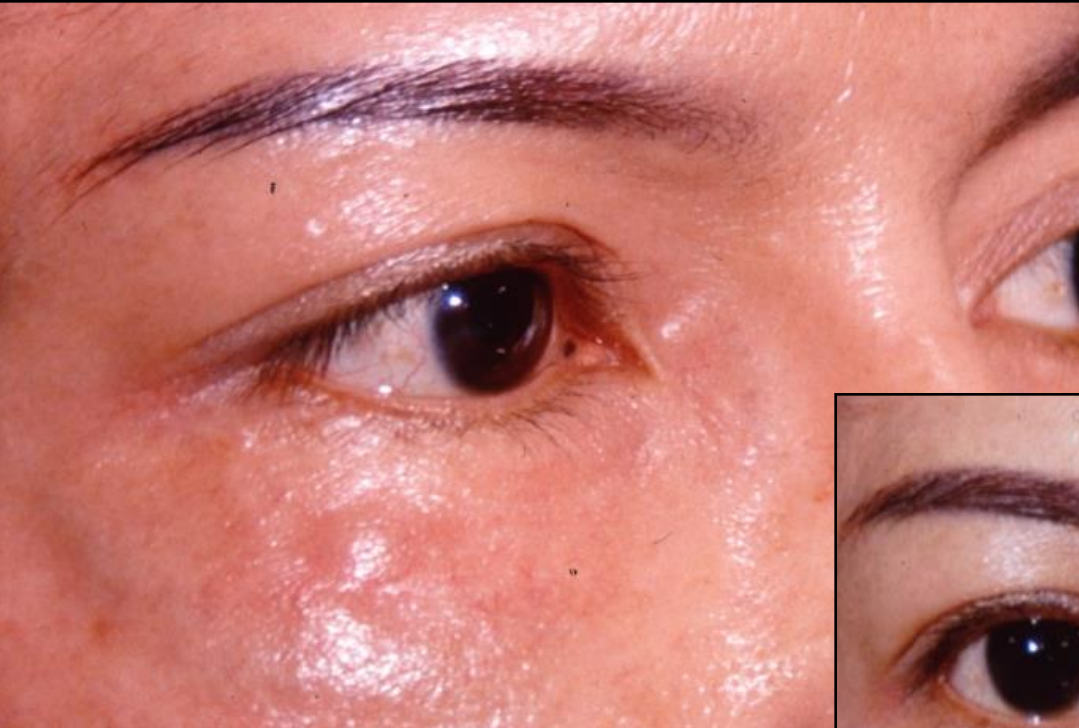
Granuloma and Migration
post autologous fat
lipofilling

Parodontosis?
Dental Focus?



Resorbable Polylactic Acid fillers(1)

effects : Granuloma,Nodule,Necrosis



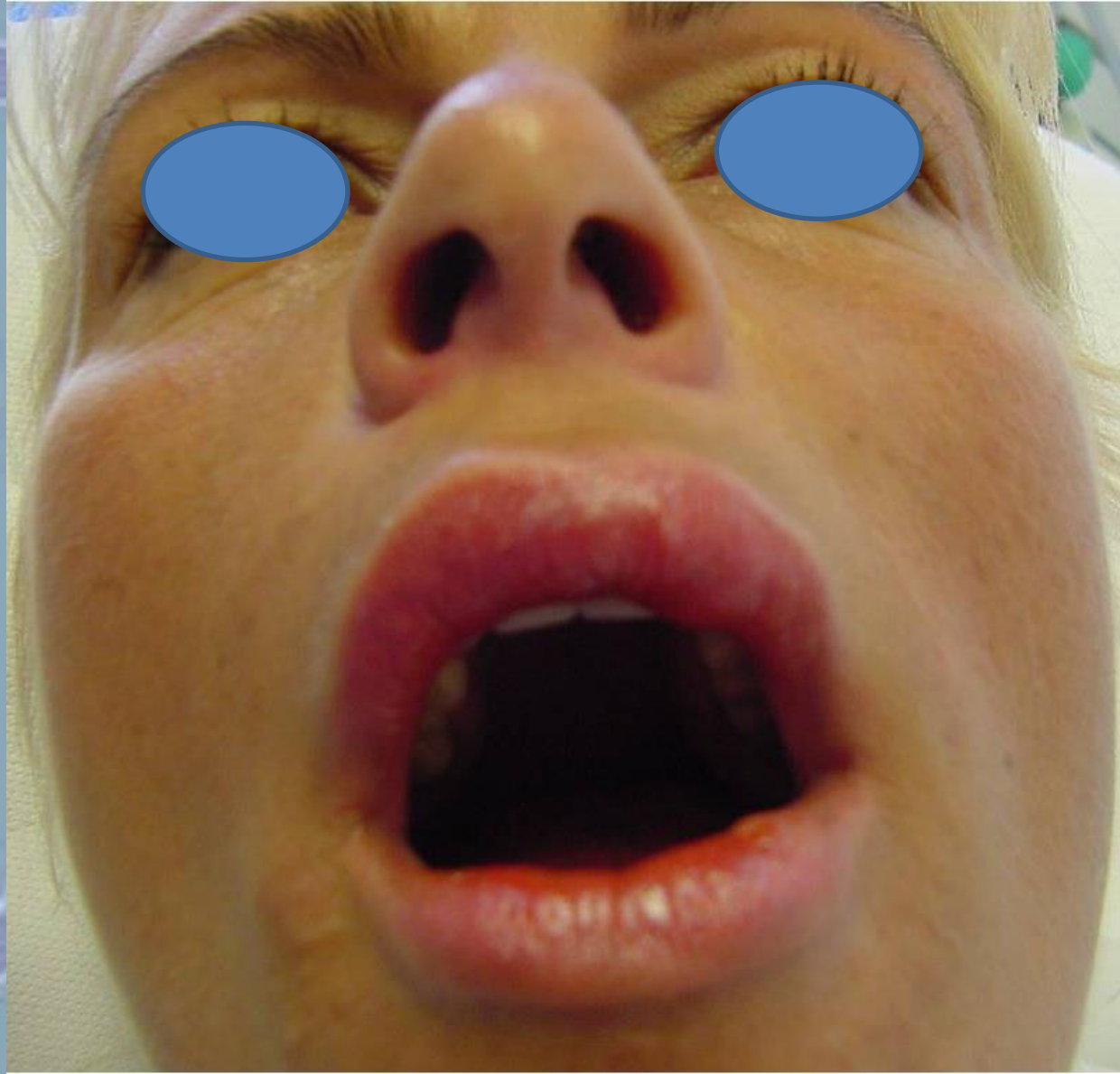


PLA



2 7 2002

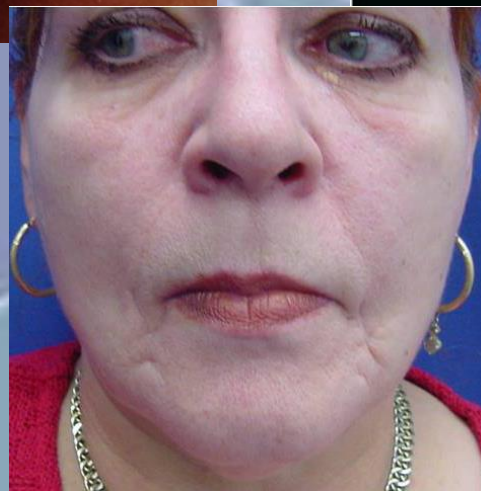
Poly(lactic acid) PLA



PLA granuloma



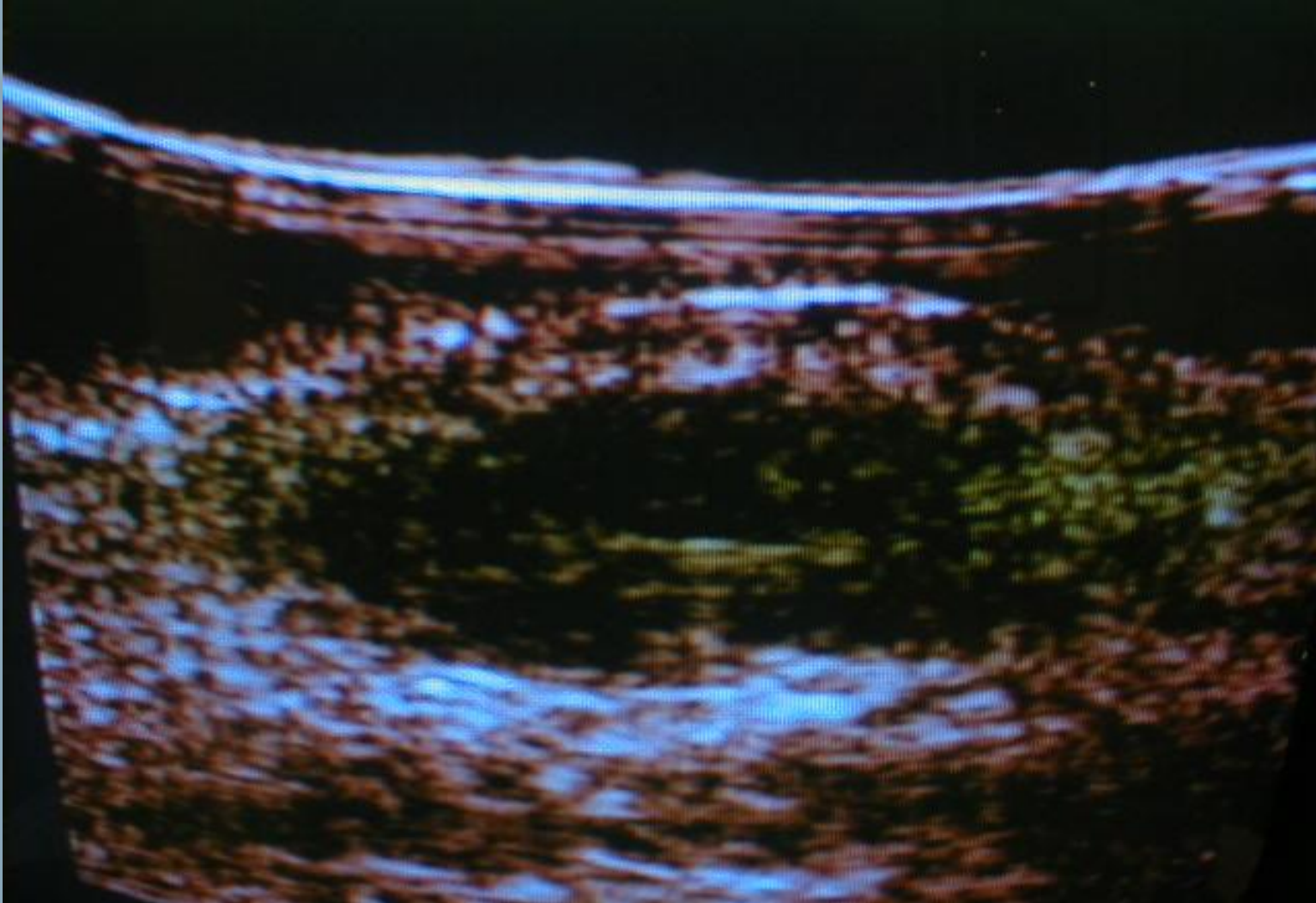
PLA infected



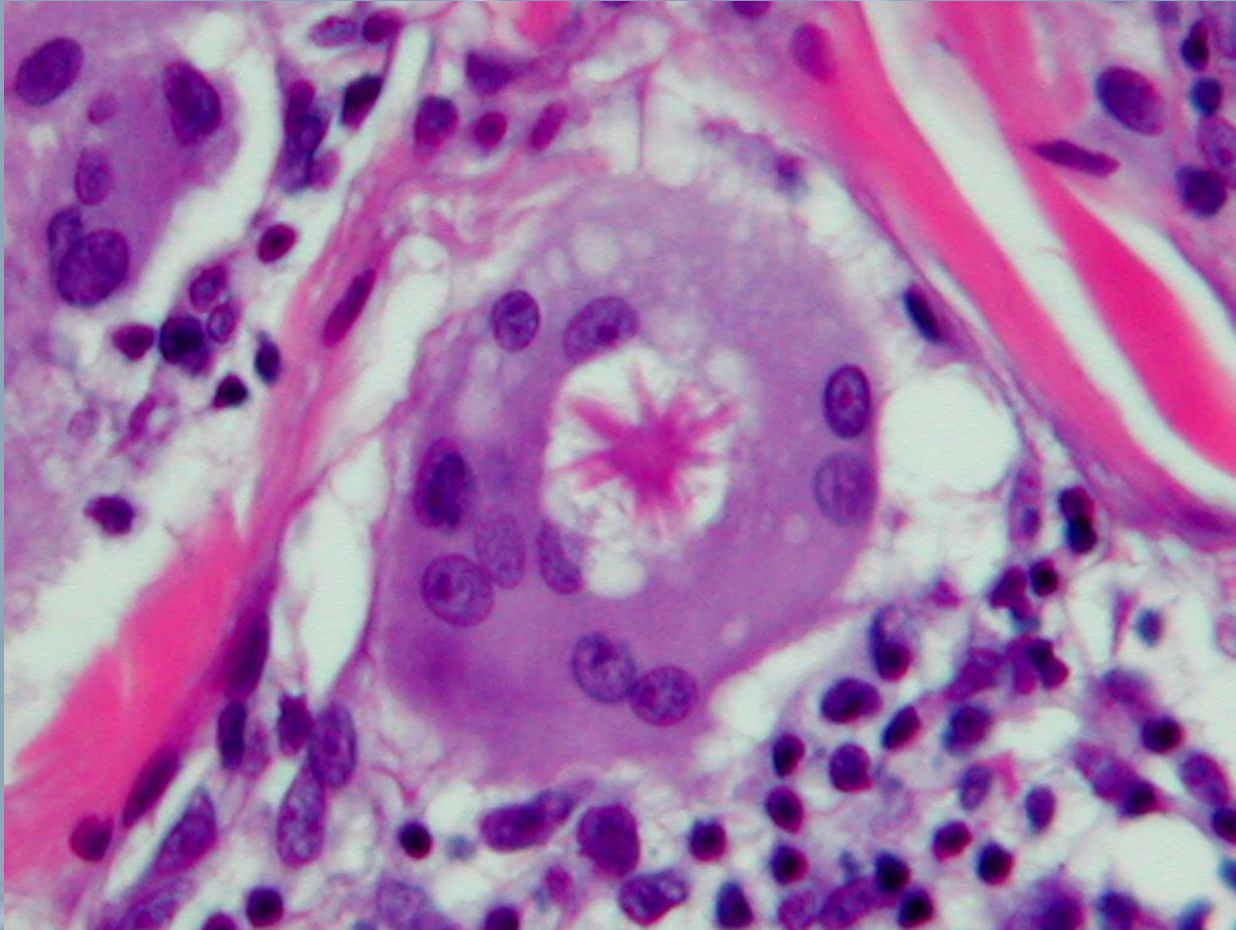


PLA INFECTED

– Polylactic acid
Granuloma on foreign body
without anfractuositities



„PLA,,Inclusion or Granule inside the gigant cell



Fillers & endoprosthesis



Synthetic not resorbable fillers(1) Ca OH apatite

Side effects : Granuloma,Nodule,Necrosis



Fillers & endoprosthesis



Silicon Injected in 1979



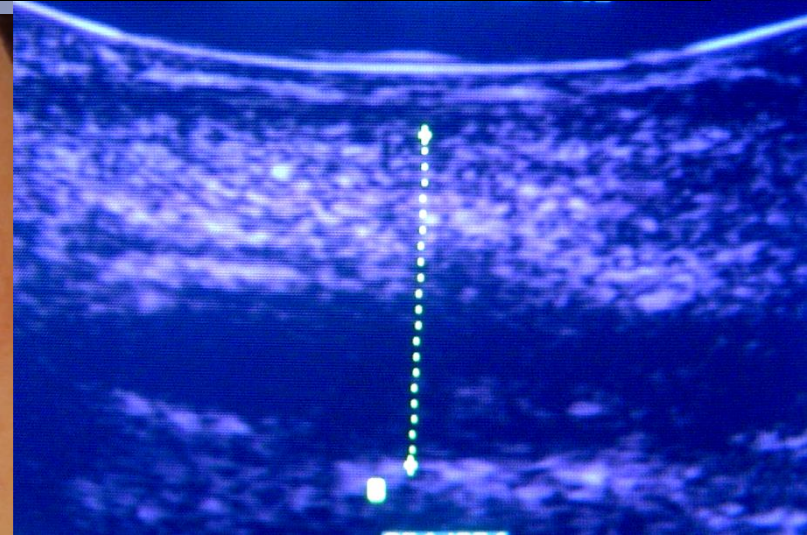
Thai Transsexual using silicon for ,, feminilization,,
Granulomas made her not masculine nor feminine nor
trans but looking like a Monster !



Granulomas for Face Feminilisation instead of 11 Operations Facial Plastic Surgery !



Silicons Granuloma in the deep dermis :
low destroyer- less inflammation



RP

LA

NAQ-1
39.0x33.0cm
7mm
Time 2:05

1/1 4/20

E1 1: 57.4 / 97.70%





COMPLICATIONS. OF ACRYLATS HYDROGELS FILLERS

Migration

Geleoma formation

Inflammation

Purulo-necrotic process

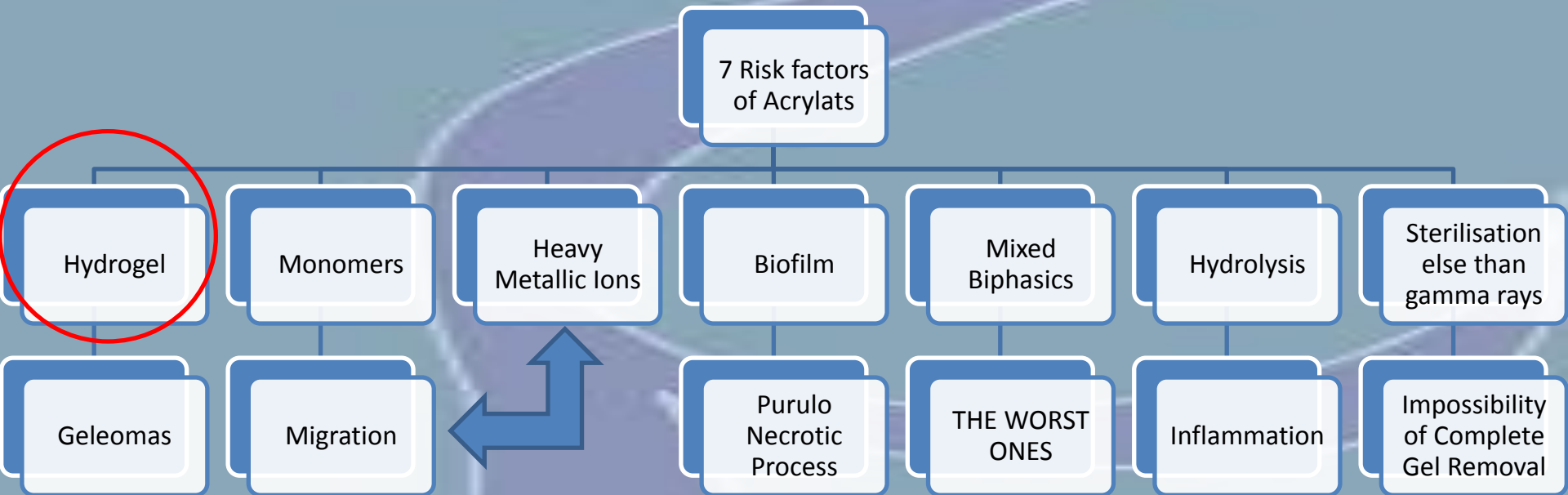
Trophic disturbances of the tissues

Aesthetic problems

Impossibility of the complete gel removal.



Acrylats Classification by Alain TENENBAUM



CONTACT@FACIAL-PLASTICSURGERY.ORG

Risks factors of Acrylats(1)



MADE IN CHINA = CHEAP TO BUY
= HIGH COST FOR COMPLICATIONS

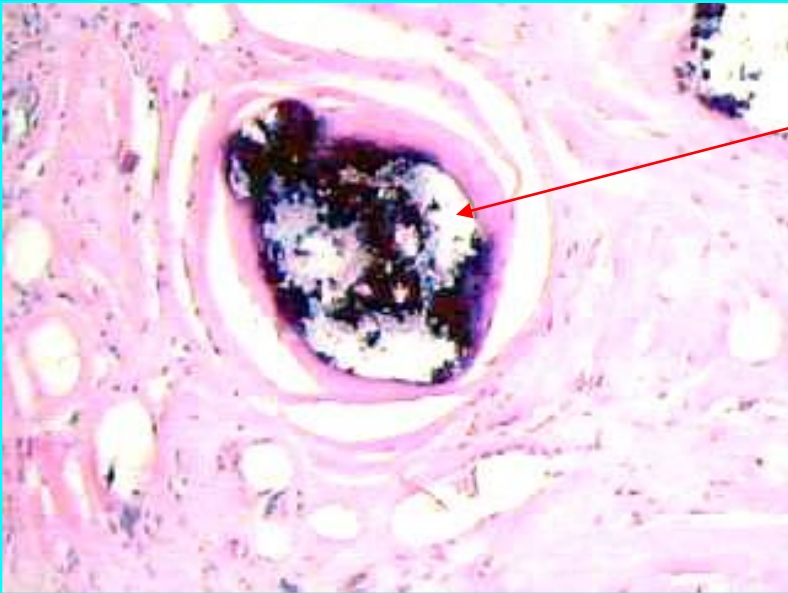




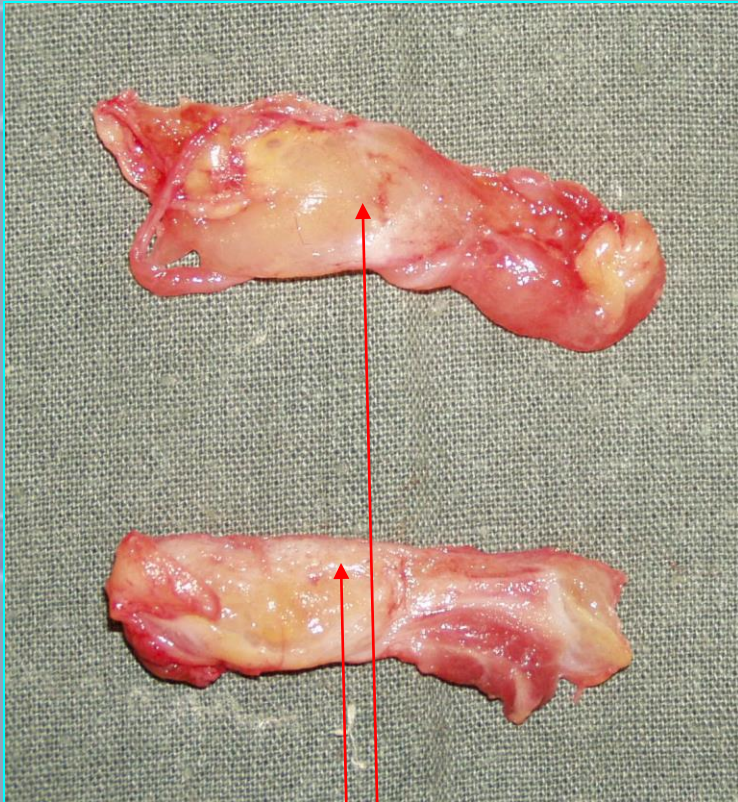
Amazing Gel



GELEOMA FORMATION.



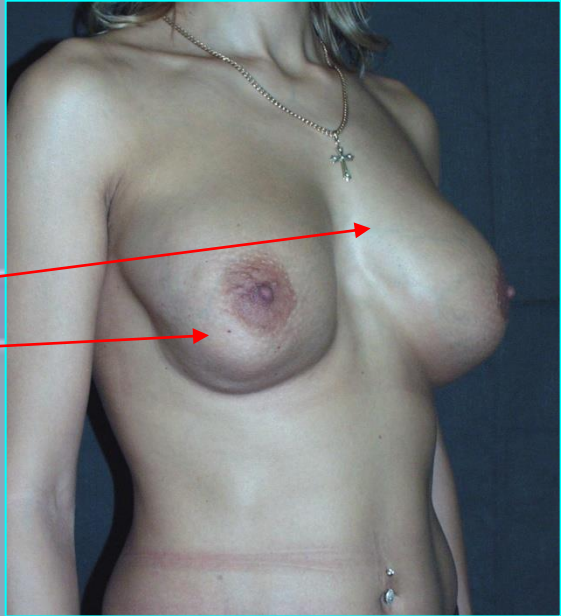
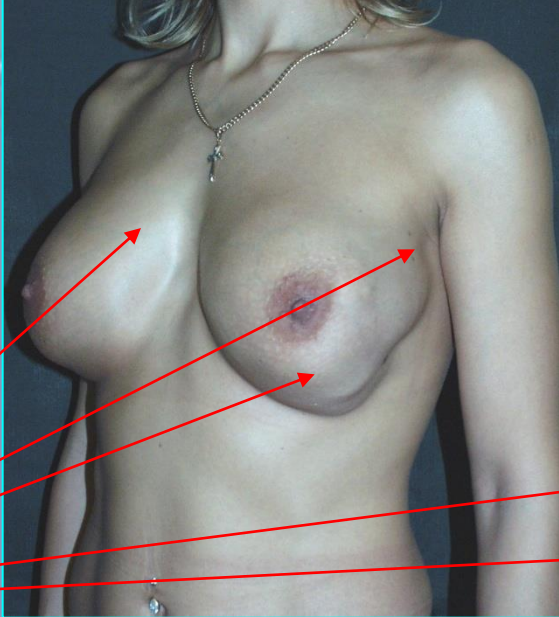
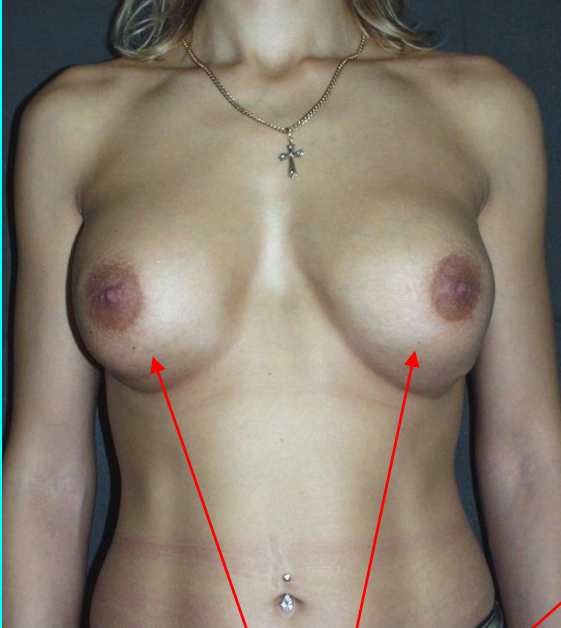
Focus of calcification



Geleomas in the calf

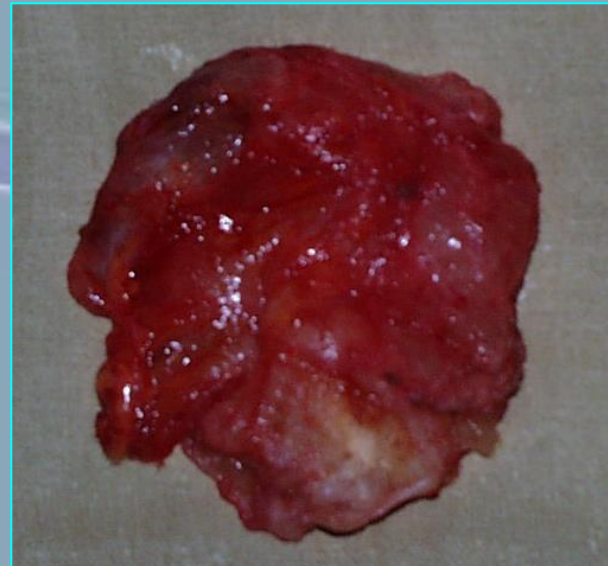
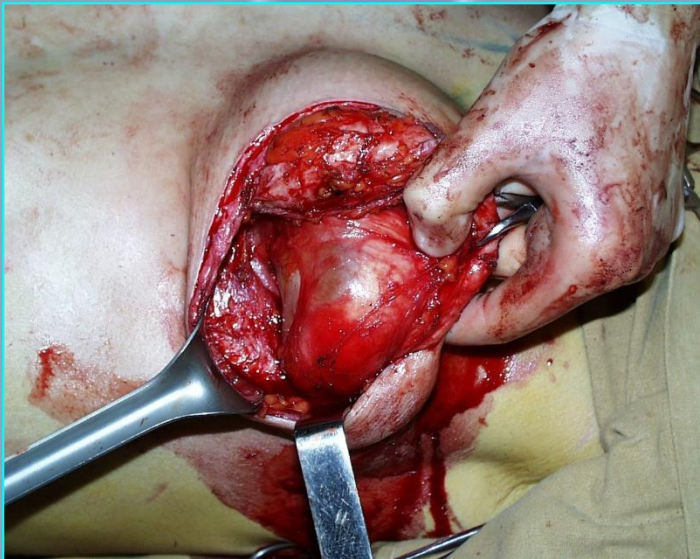
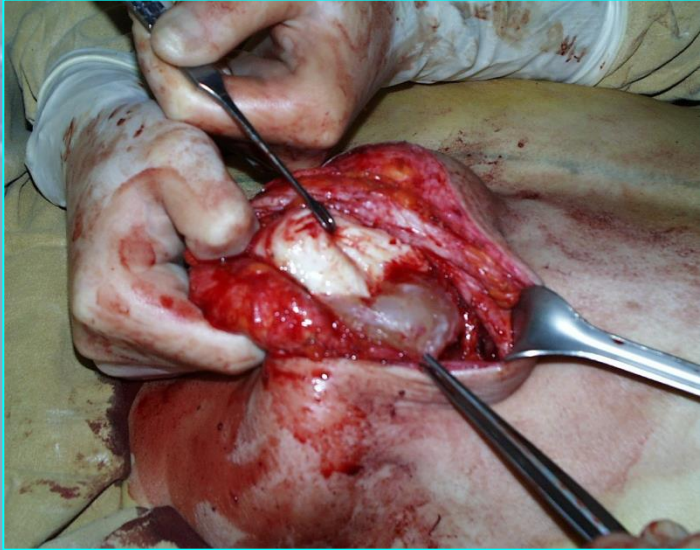
GELEOMA FORMATION.

5 years after the retromammary
PAAG injection.



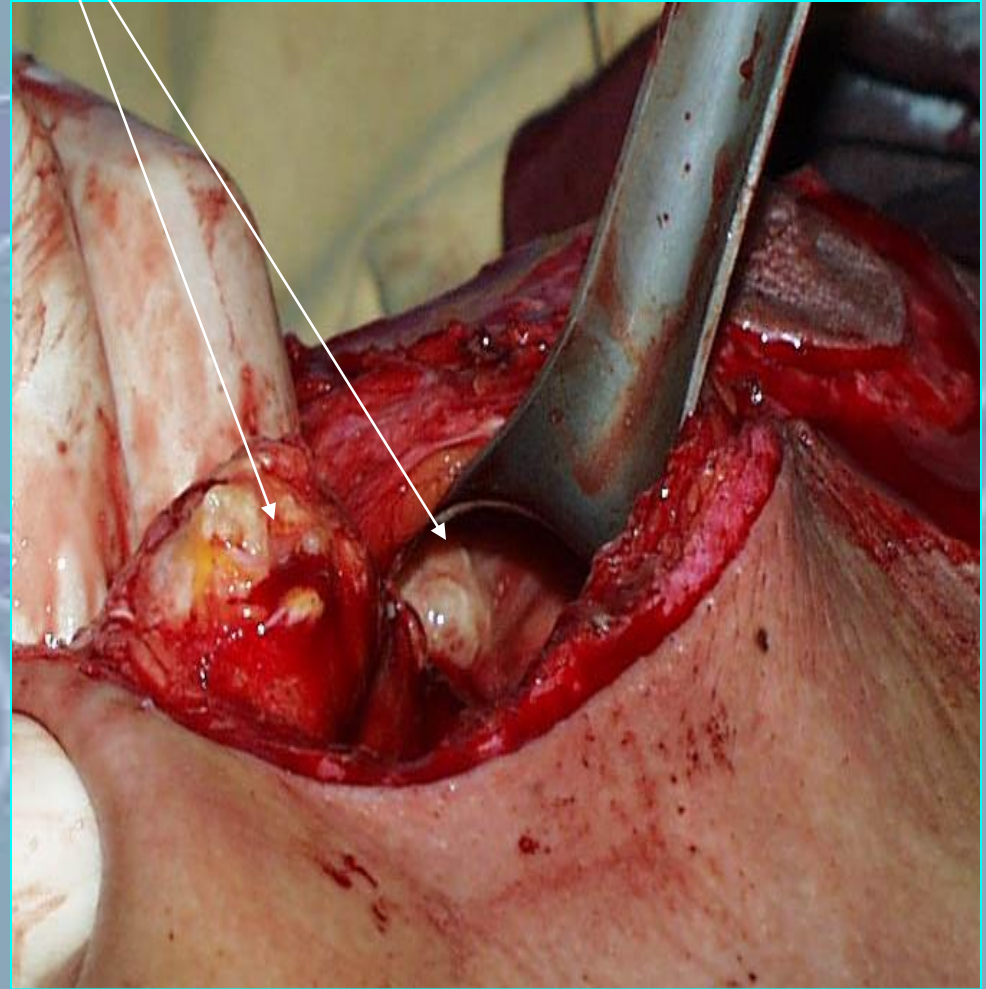
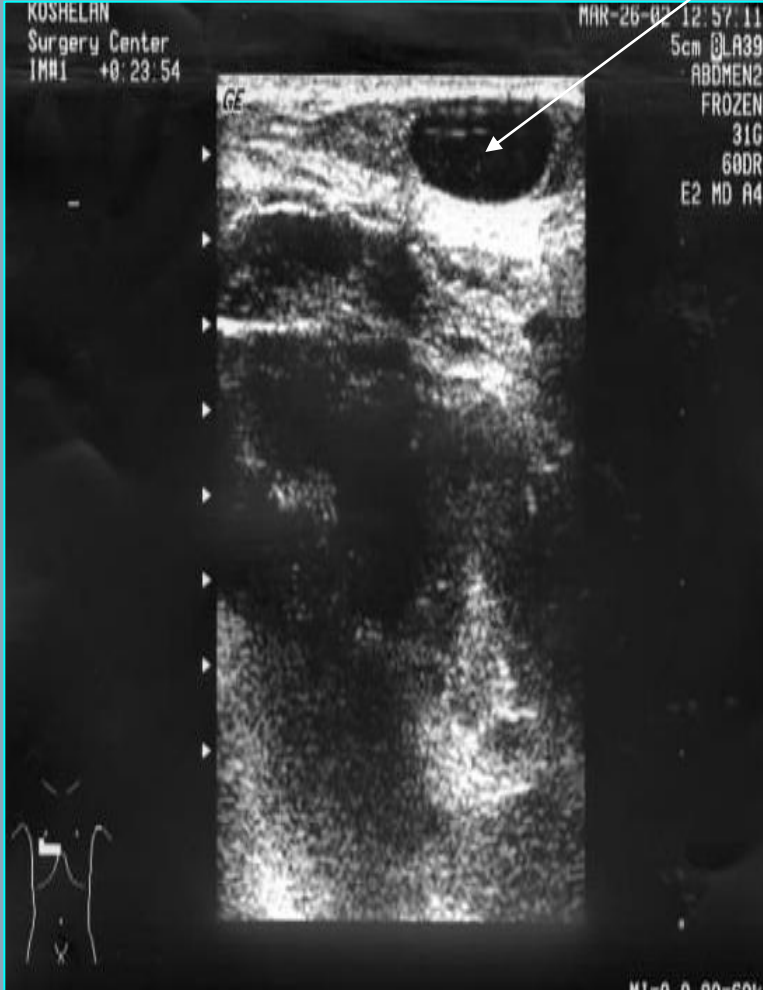
Multiple geleomas of the mammary glands.

GELEOMA FORMATION.



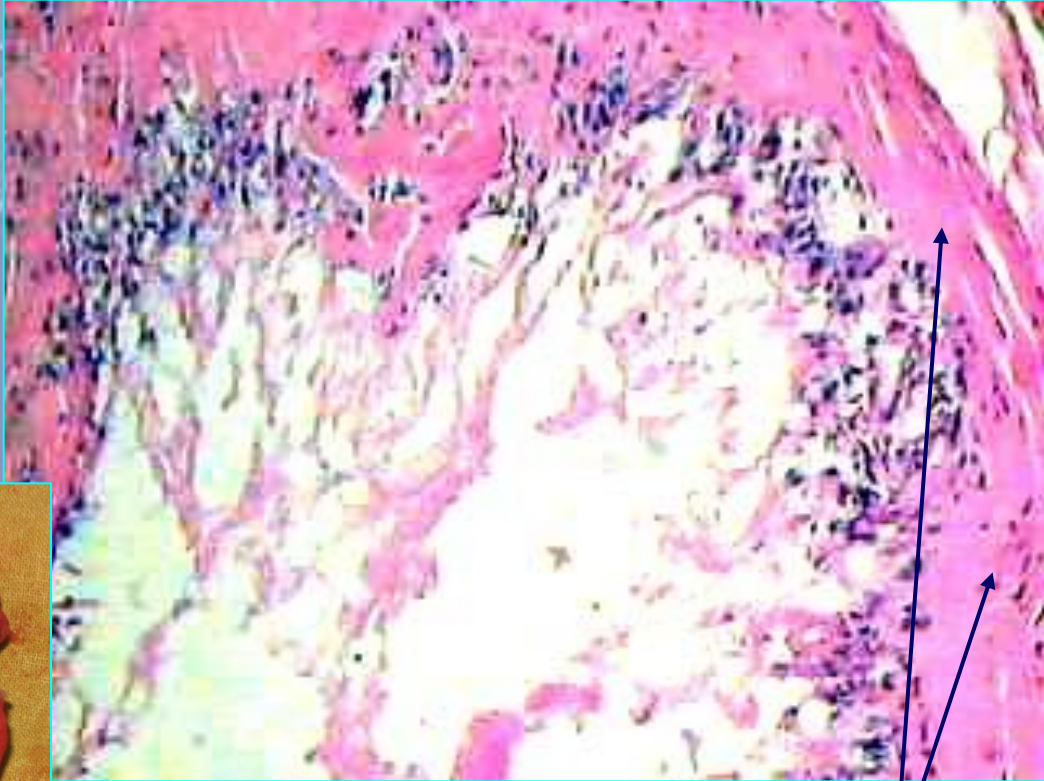
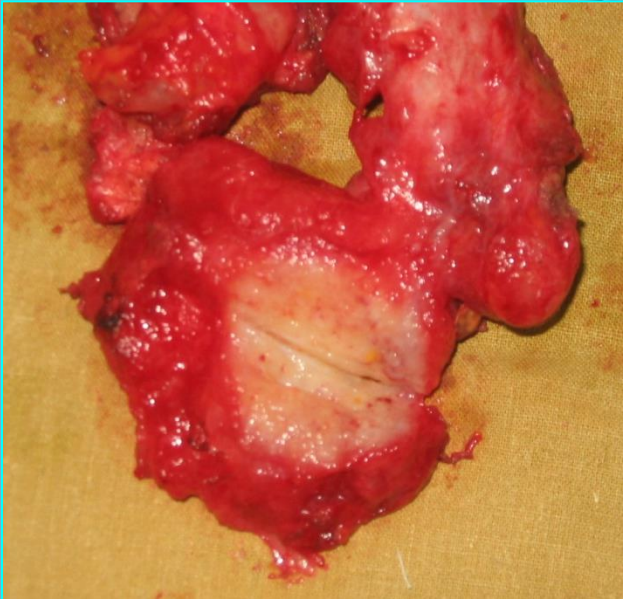
Geleomas of the mammary glands.

GELEOMA FORMATION.



Geleomas of the mammary glands.

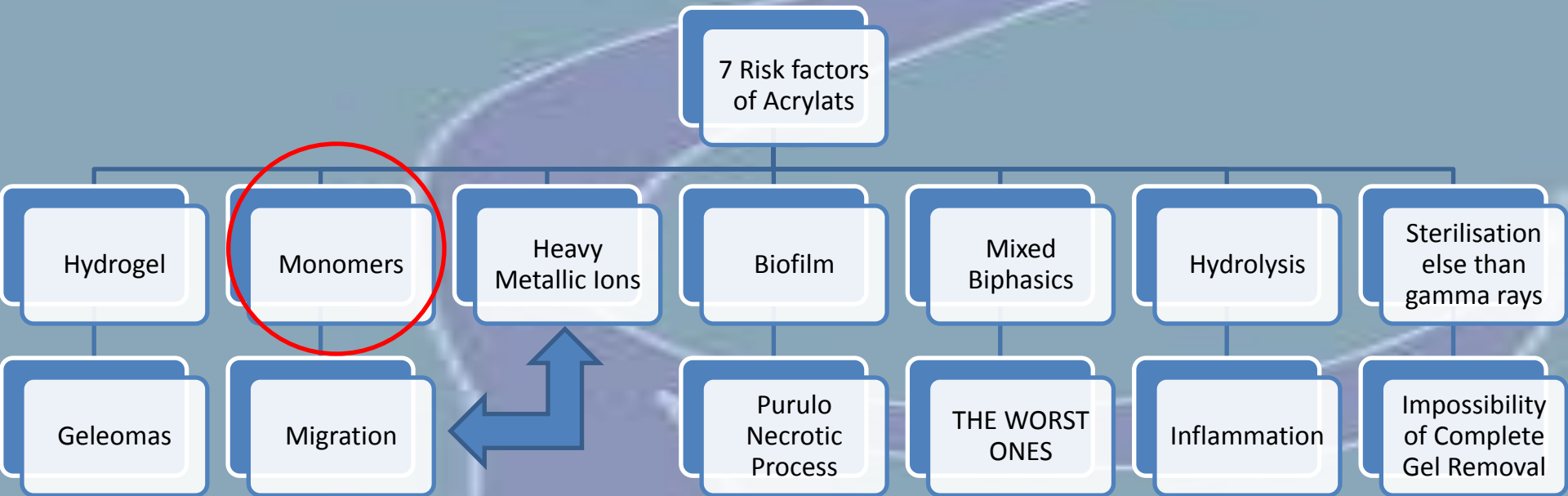
GELEOMA FORMATION.



Fibrous capsule

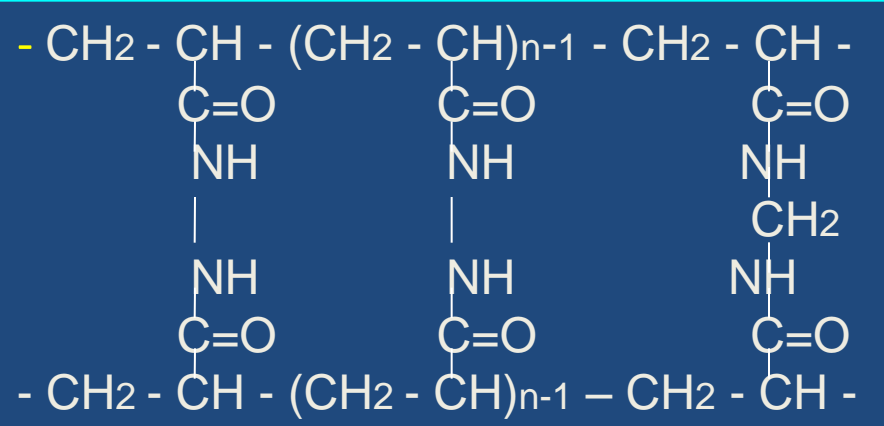
Geleomas of the mammary glands.

Acrylats Classification by Alain TENENBAUM



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POLYACRILAMIDE HYDROGEL 水凝膠 FILLER (PAAG)



Inert

Biocompatible

Resistible for biological degradation with time.

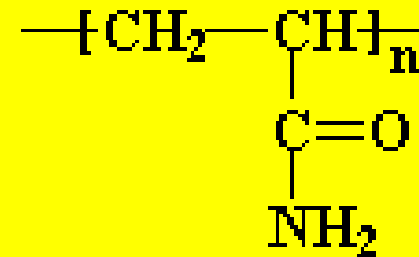
Hydrophilic „polymer „for injection.

95-97% - water,
 3-5% - true polymer.
But how many % true monomers ?

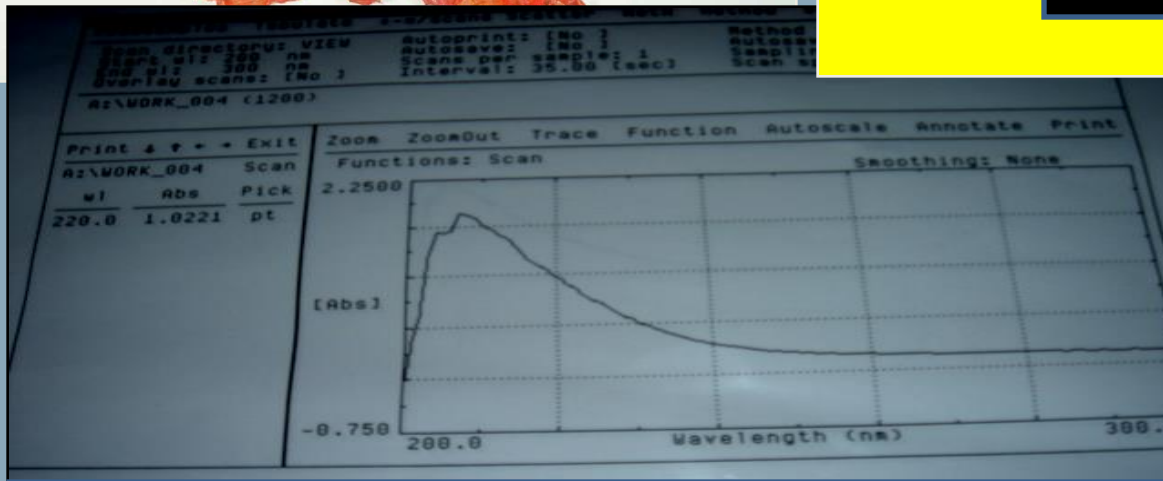
Easy to inject , minimal tissue trauma during procedure.

PERMANENT

Risks factors of Acrylats (2)



Monomer



Peak at 220 nm =
presence of
monomers
(A.Tenenbaum)

DANGER

Risks factors of Acrylats(2)



Naso genian sulcus
Heterogeneous aspect
3 1/2 months after Injection

—
Dermis
—

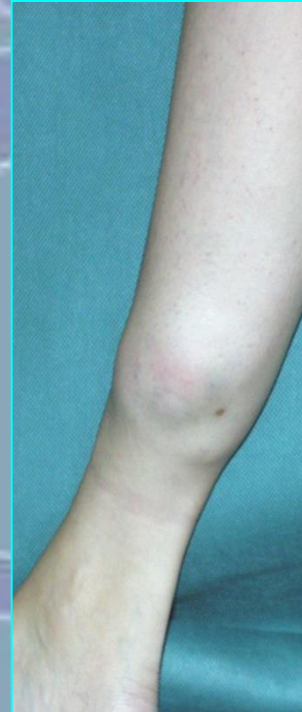


POLYACRYLAMIDE

POLYACRYLAMIDE is colonised by
Refringent structures
Fibroblasts ?



MIGRATION.

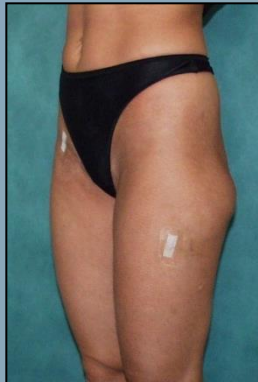


PAAG was injected 3 years ago for the calf thigh correction.

MIGRATION.



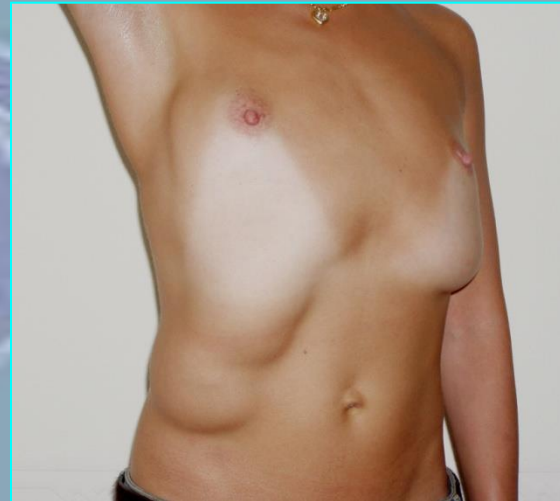
PAAG was injected into the buttocks area.



MIGRATION.



3 years after the augmentation mammoplasty using PAAG.

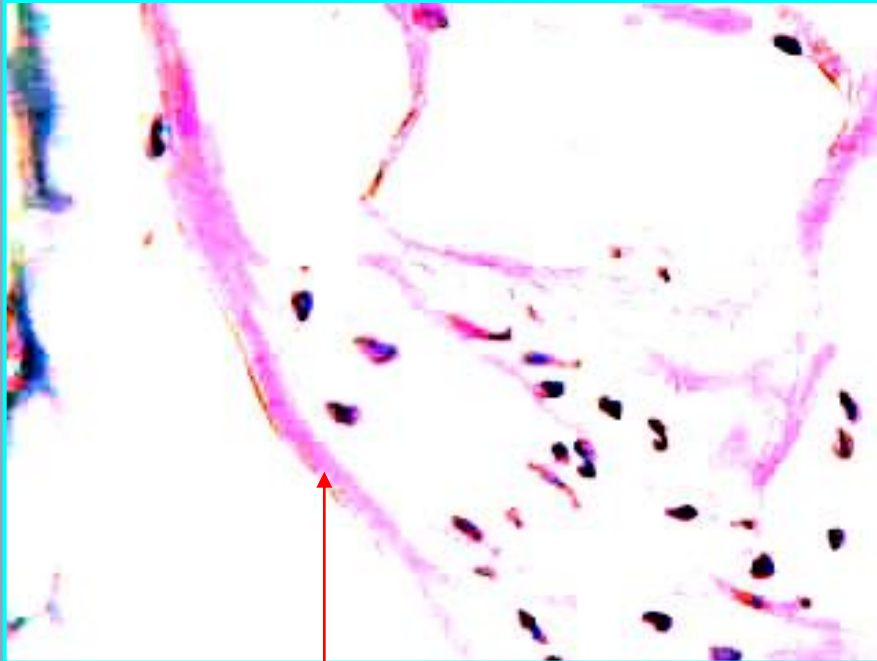


MIGRATION.

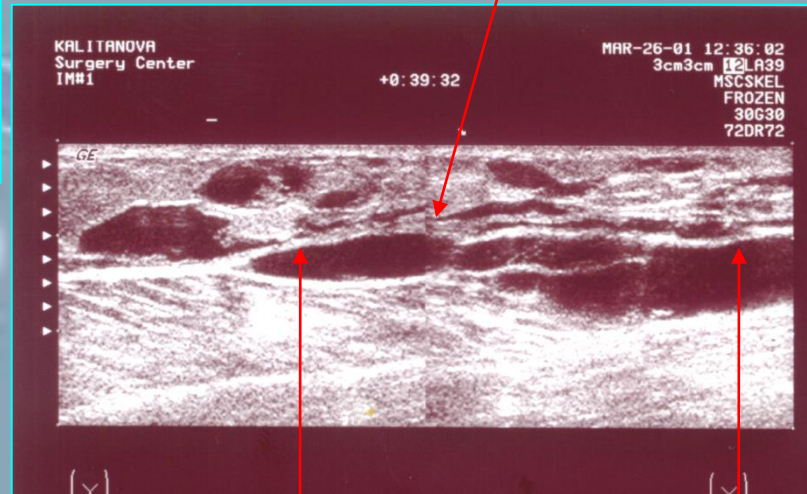
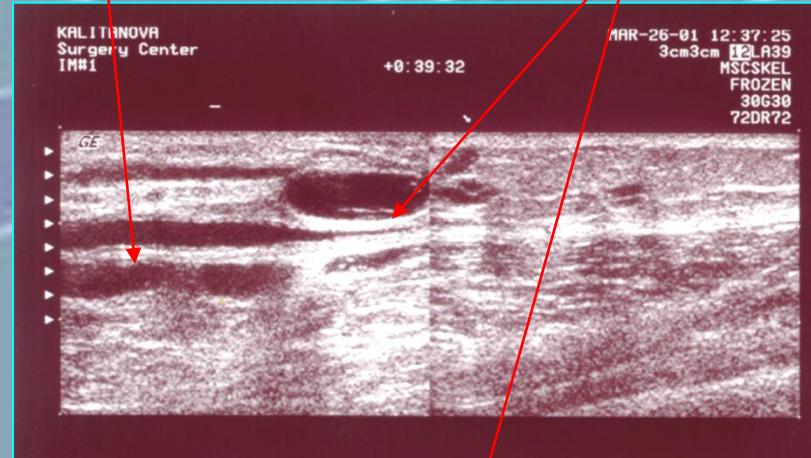
Ultrasound examination of calf.

Accumulation of the gel under the fascia.

Fascia



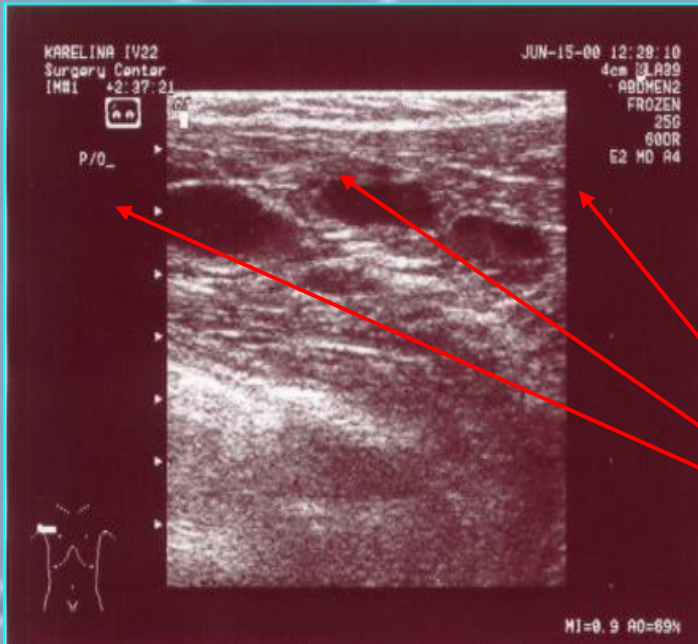
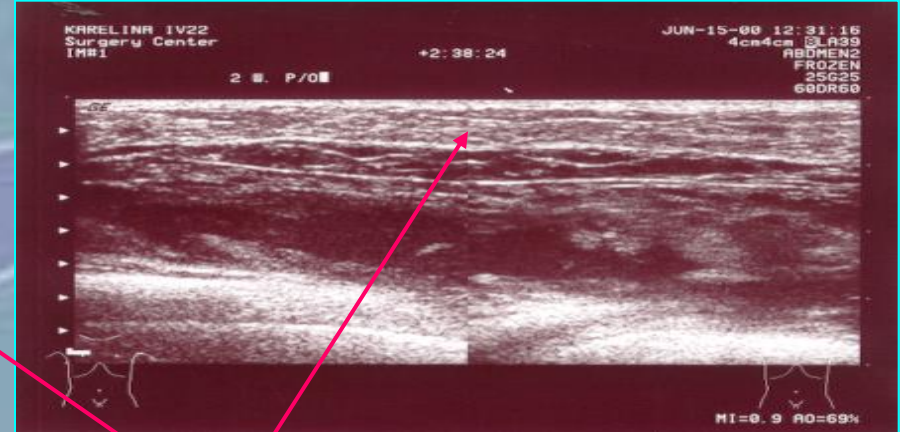
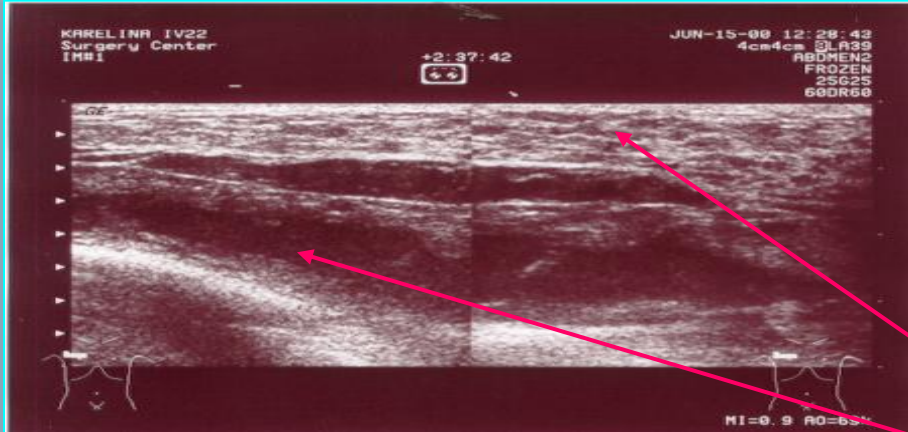
Thin fibrous capsule



Gel accumulation in the subcutaneous fat.

MIGRATION.

Ultrasound examination of the mammary glands.



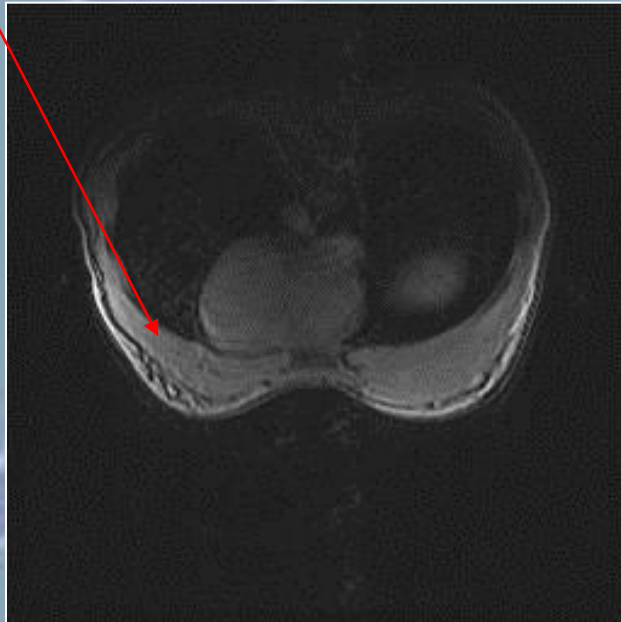
15 days after the retromammary gel injection.

Migration of the gel to the subcutaneous fat.

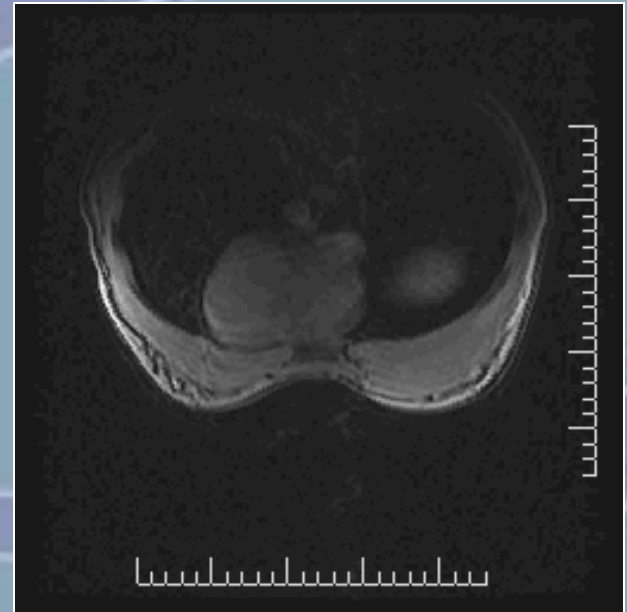
MIGRATION.



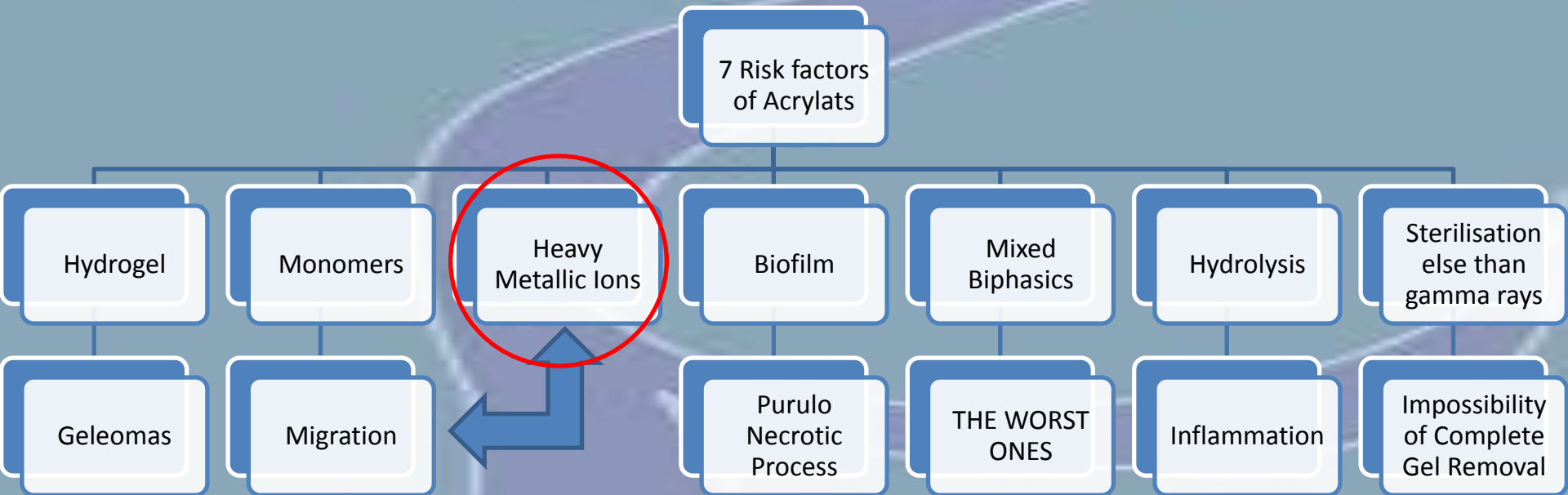
Gel



MRI of the mammary glands.



Acrylats Classification by Alain TENENBAUM



contact@facial-plasticsurgery.org

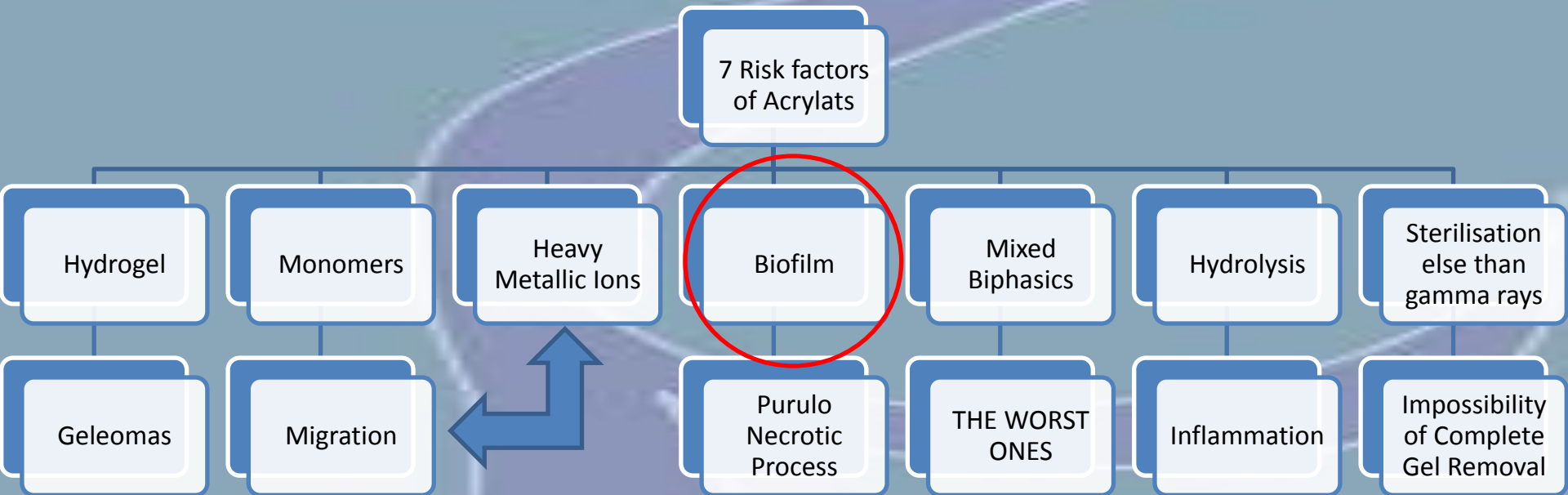
Risk factors of Acrylats(3) Argiform has metallic ions

Argiform

Dr. R. Mené



Acrylates Classification by Alain TENENBAUM



BIOFILM

- Structured colonies of micro encapsulated in a matrix which surround a foreign body
- Contains nutrients and metabolites which protect the micro organisms for a long period.
- Almost all bacteria can lead to a biofilm
- Biofilms are responsible of granulomas, aseptic inflammatory reactions and late infections.

Complications of Biofilm





PURULO-NECROTIC PROCESS.



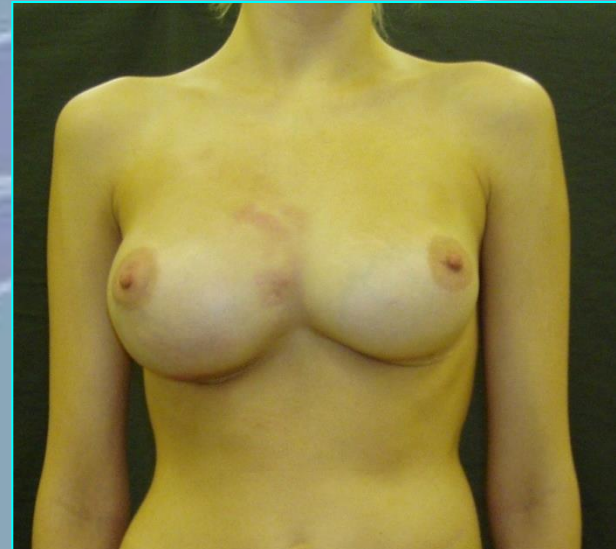
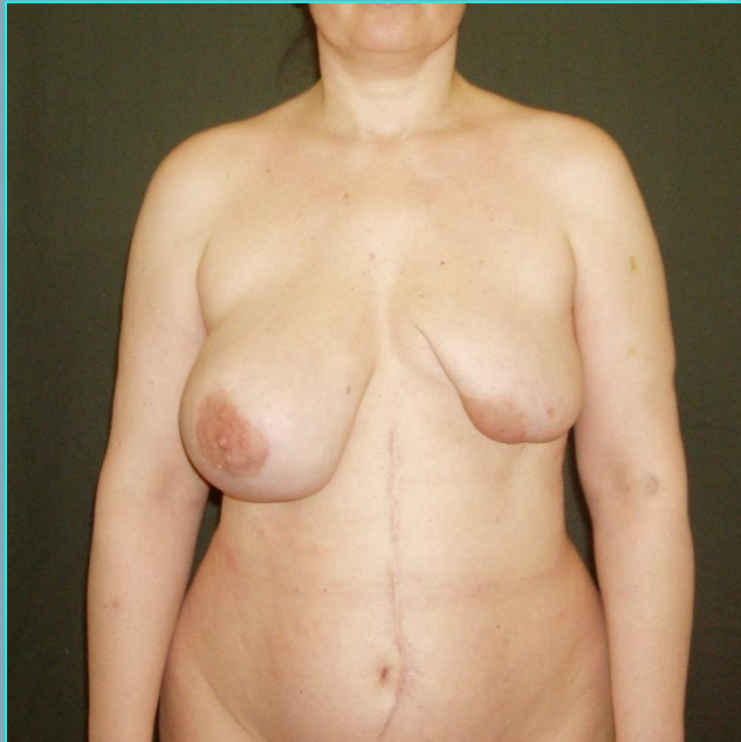
Chronic inflammation.

PURULO-NECROTIC PROCESS.

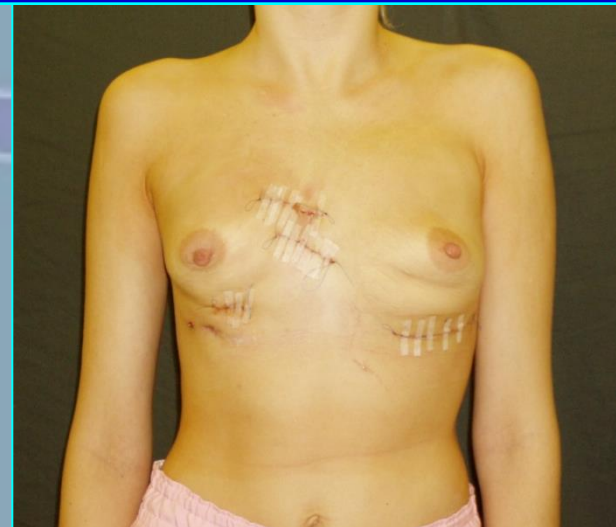


PURULO-NECROTIC PROCESS.

Outcomes of the recurrent purulent mastitis.



Initial view



After four surgical procedures

PURULO-NECROTIC PROCESS.



Cavernous body necrosis after the PAAG injection six years ago for the impotence treatment.



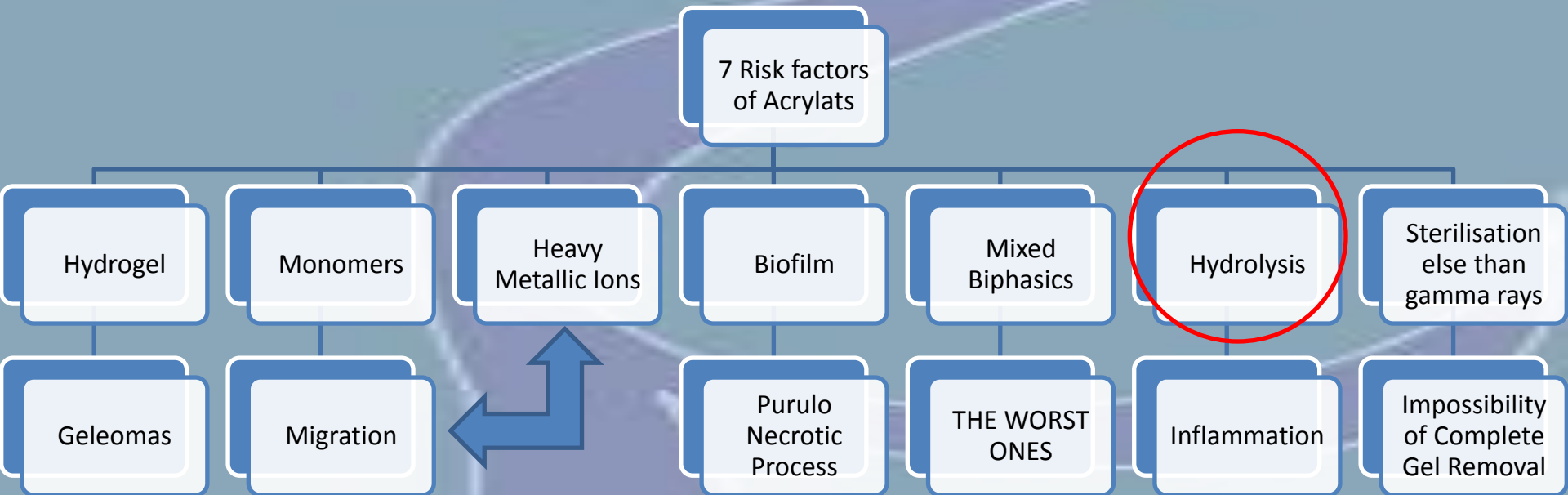
Polyalkylamide with
abscess



Polyalkylamide Complication



Acrylates Classification by Alain TENENBAUM



contact@facial-plasticsurgery.org

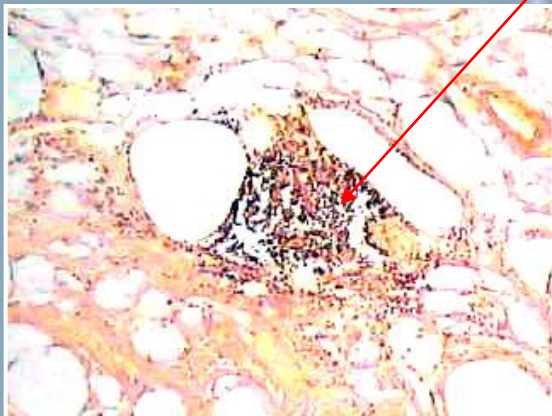


INFLAMMATION.

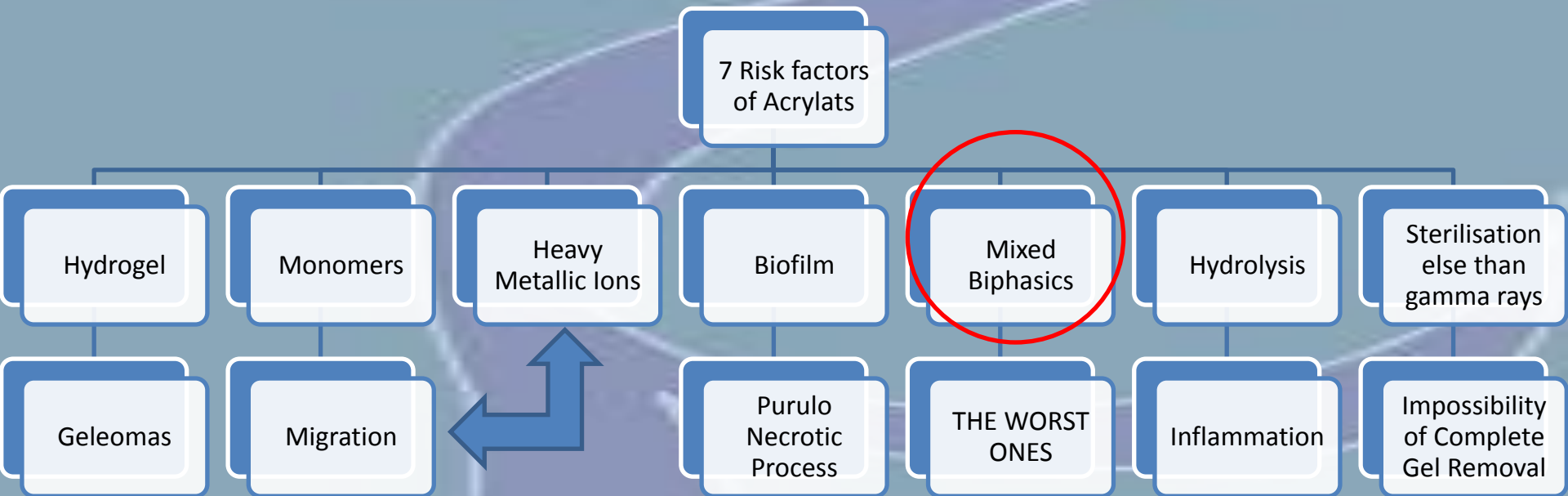
At palpation :
like wet
sugar
(A.Tenenbaum)

Acute inflammation of calf soft tissue in the area of the gel injection.

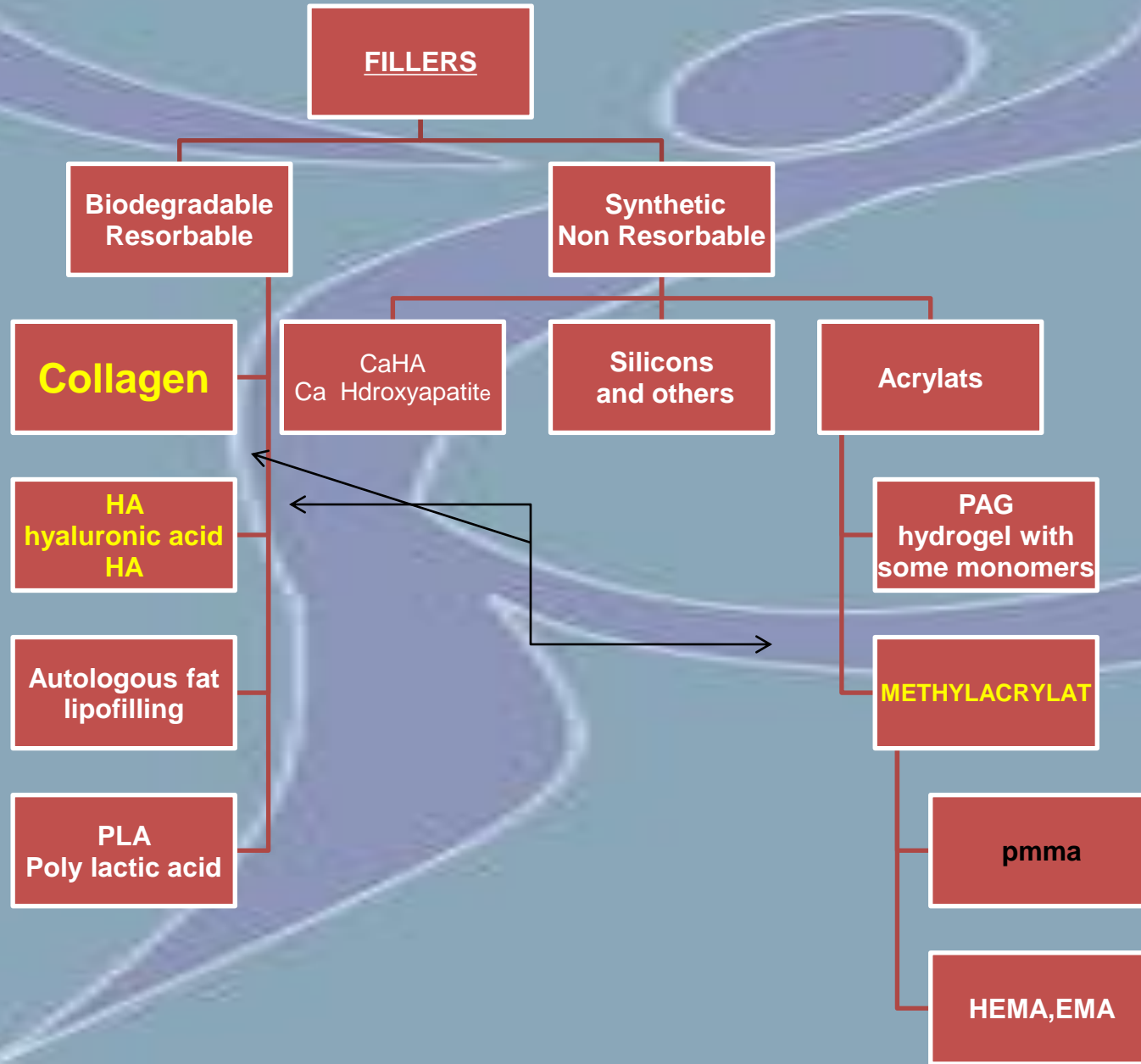
Site of lymphocytes inflammation. Macrophages.



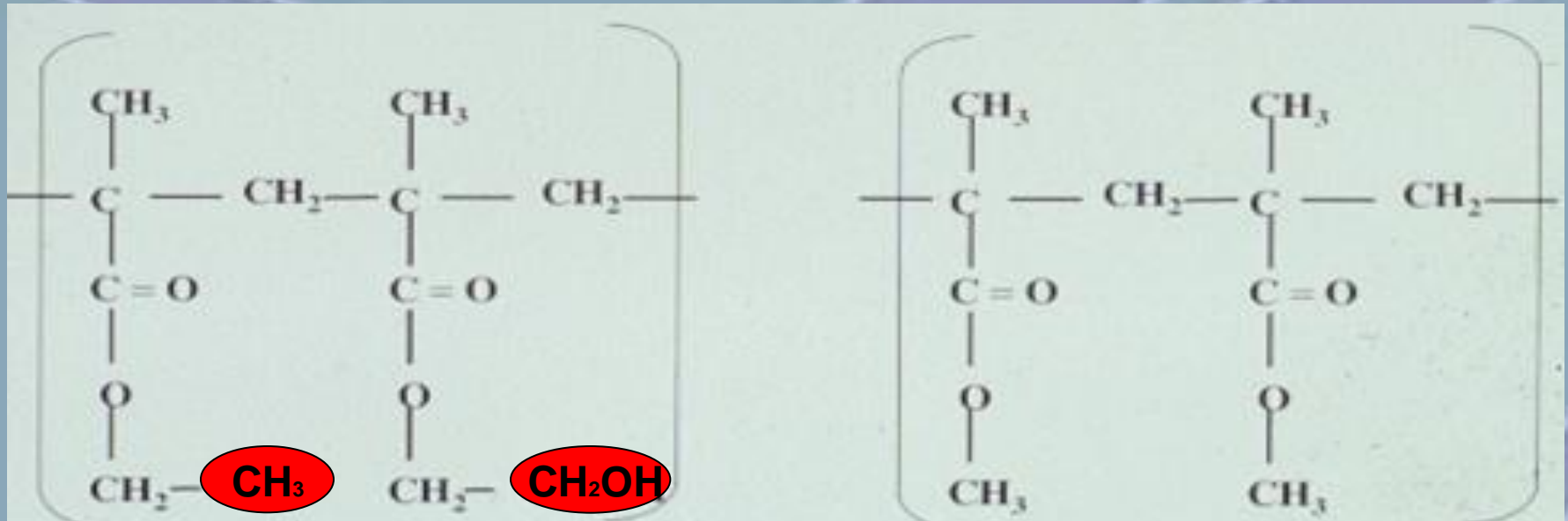
Acrylats Classification by Alain TENENBAUM



Mixed biphasic ones
so called resorbable fillers with longer duration



Risk factors of Acrylats(4) Metacrylates



PHEMA-EMA Acrylic hydrogel
Copolymer of
Hydroxyethylmetacrylate
(HEMA) & Ethylmetacrylate
(EMA)

PMMA

PMMA Infection



Risk factors of Acrylates(4)

METACRILATE



Risk factors of Acrylates(4)



Metacrylate



2 days after PMMA



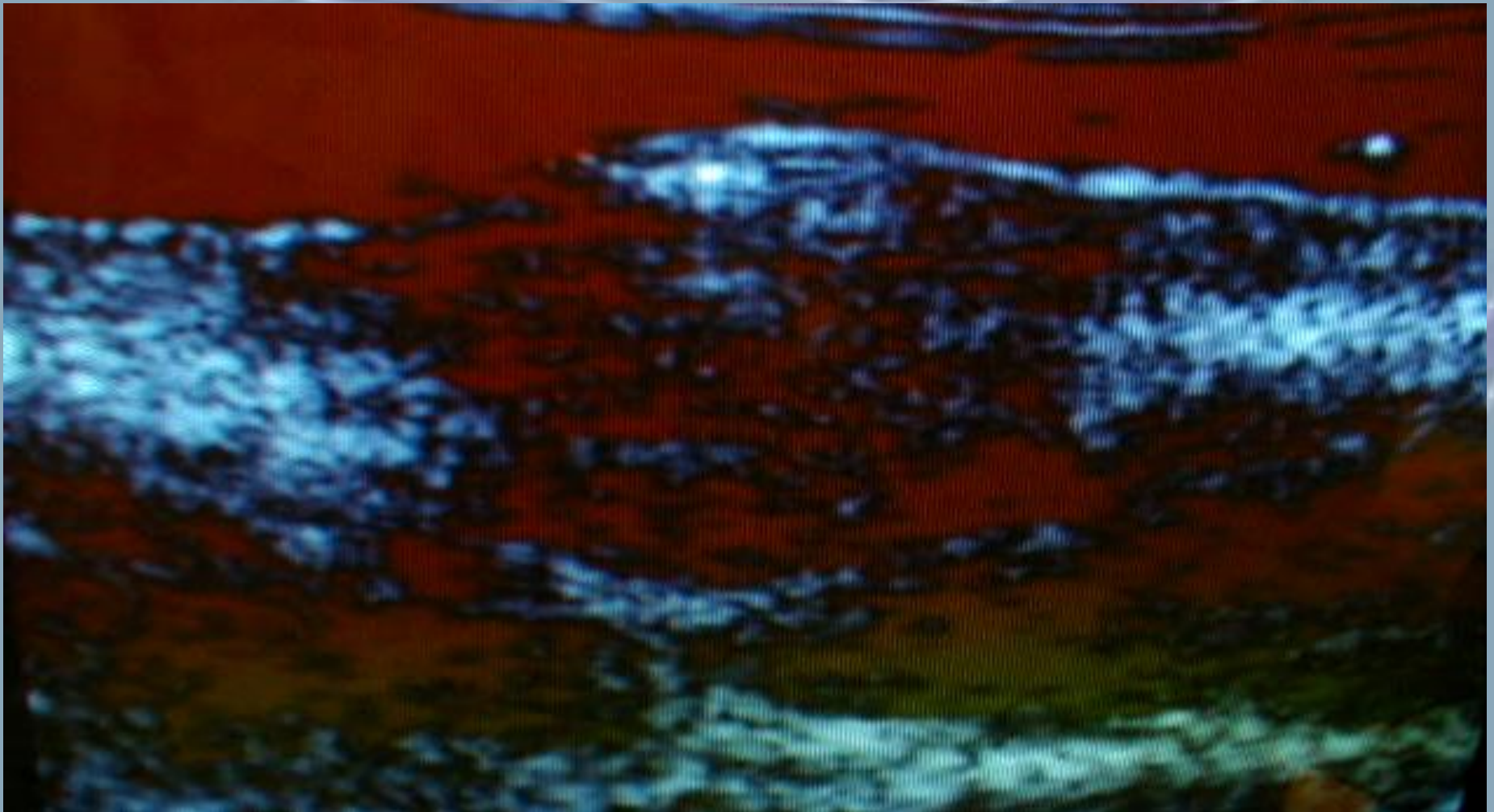
After PMMA



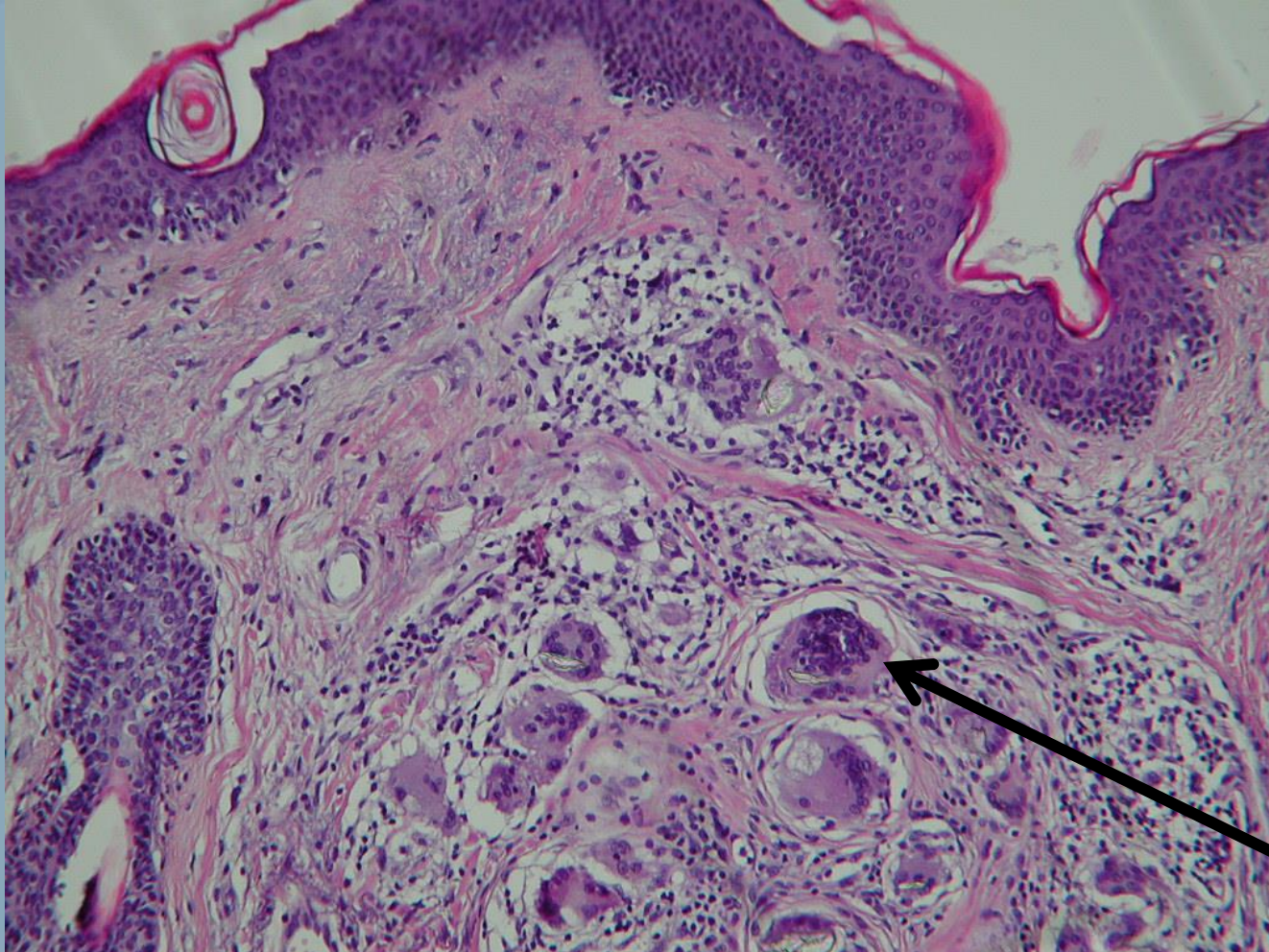
Granuloma treated with 5 FU
on depressed scar
treated with Dermalive--- HA+PMMA



The treated granuloma by 5 FU + Corticoids
still attacks hardly the dermis
(Dermalive and depressed scar)



Gigant cell after Dermalive (Metacrylate + Hyaluronic acid)

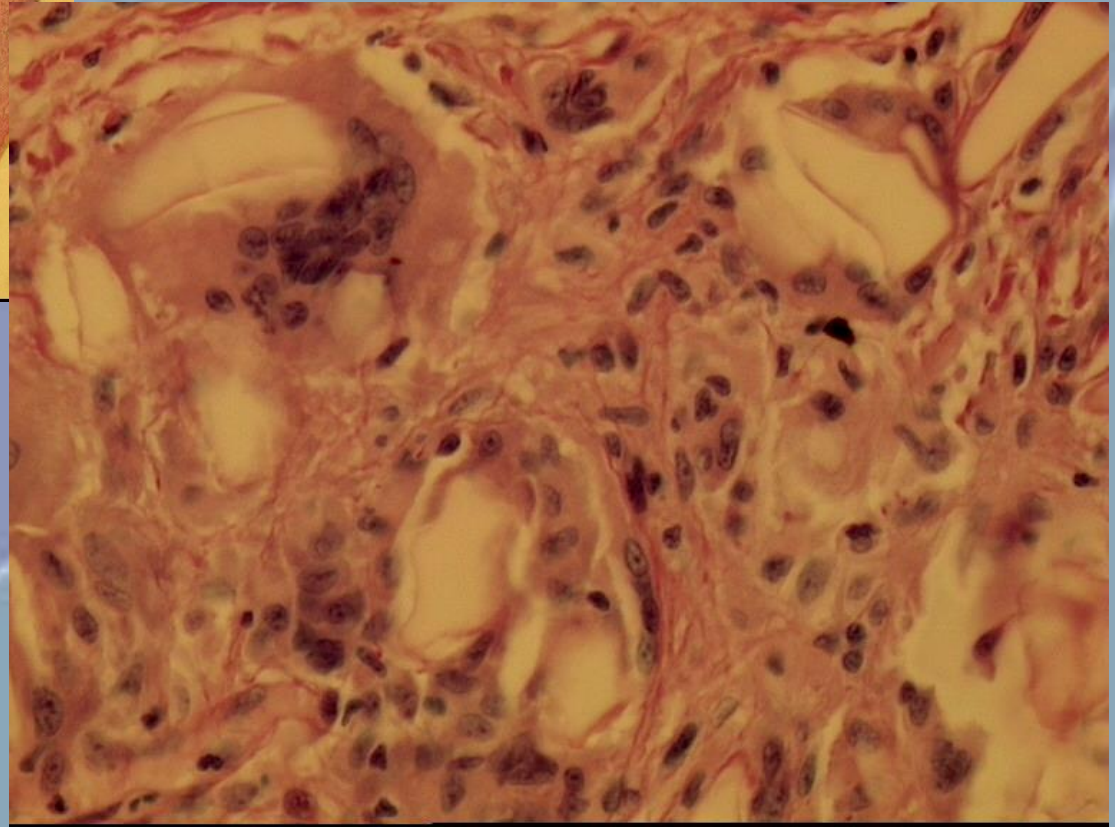
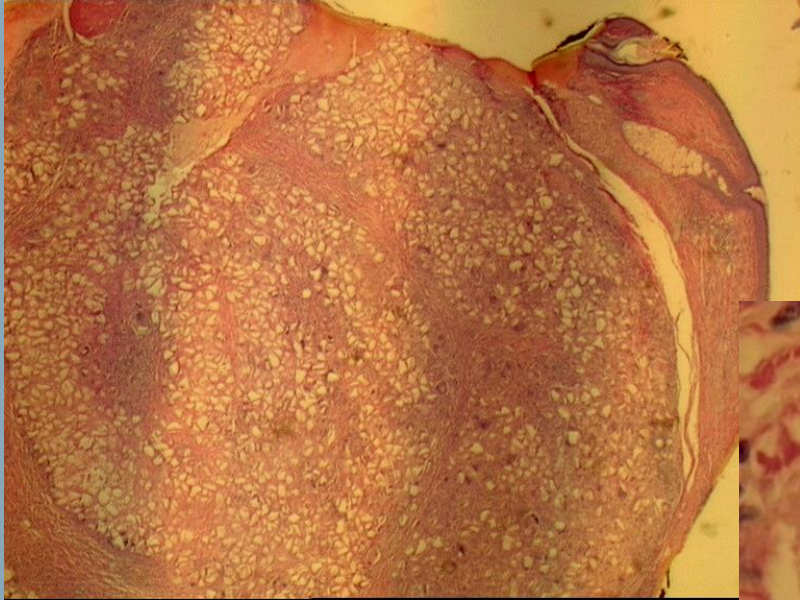


Surgical treatment of the Dermalive Granuloma pre treated by 5 FU and corticoids



Histology post Surgery

Foreign body granulomas with giant epithelioid cells



Infection 11years after Artecoll



Infected Acryloma 2 years post Artecoll

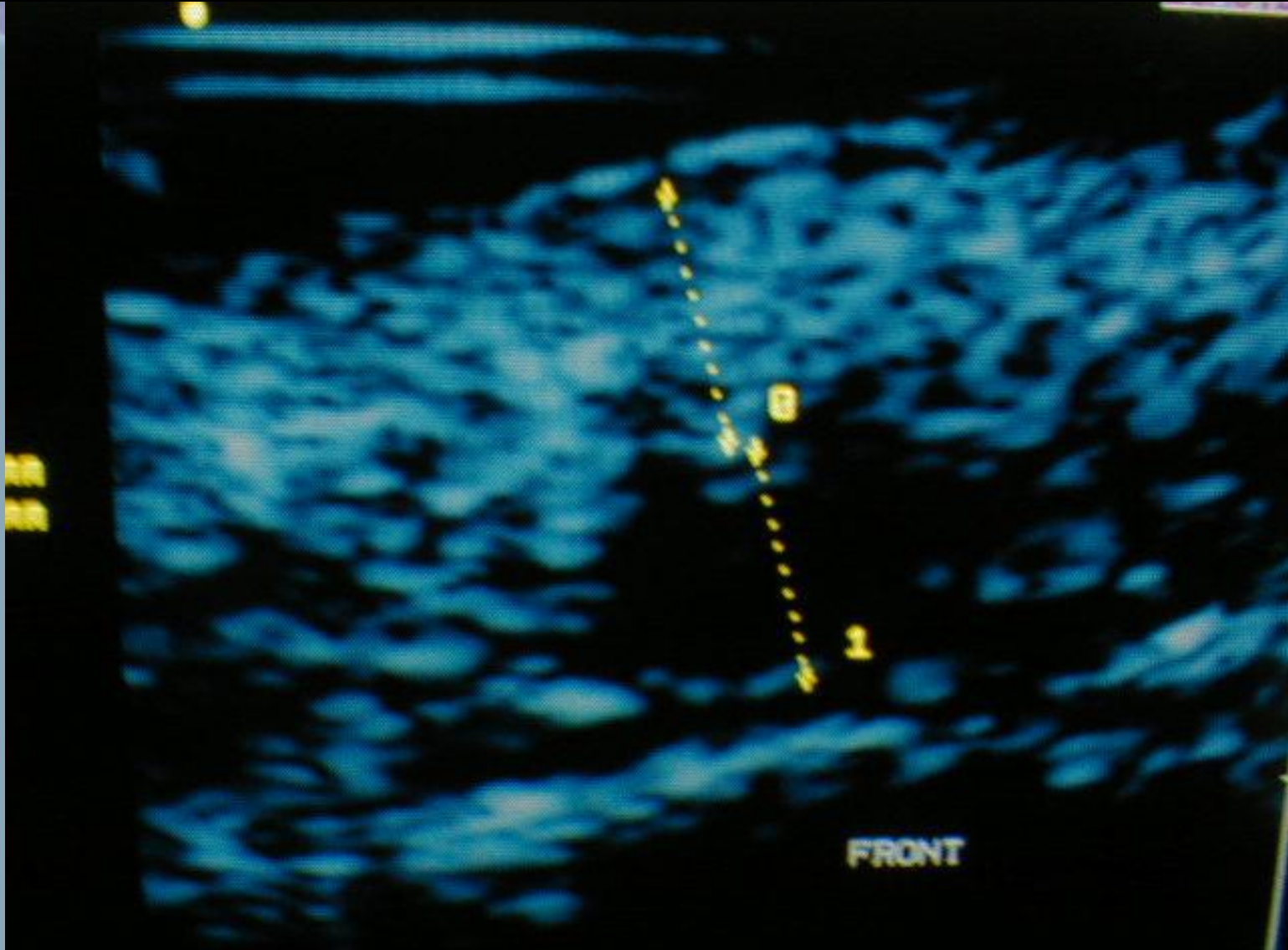


Artecoll Infected Permanent Redness and Hardening

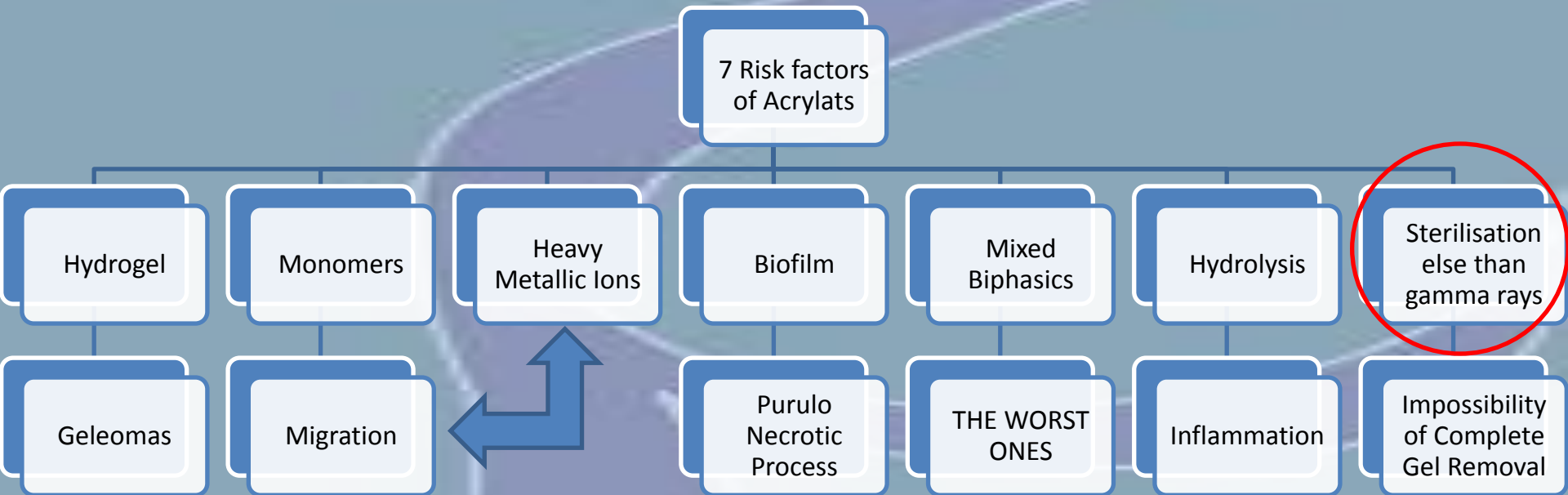


Artecolls Granuloma big destroyer

1 : Granuloma 2 : Dermis



Acrylats Classification by Alain TENENBAUM



CORRECTION OF THE CONSEQUENCES OF THE PAAG INJECTION.



Gel removal



**One-stage gel removal and
prosthesis placement**



Secondary gel removal and correction



GEL REMOVAL.



ONE-STAGE GEL REMOVAL AND PROSTHESIS REPLACEMENT.



Before operation

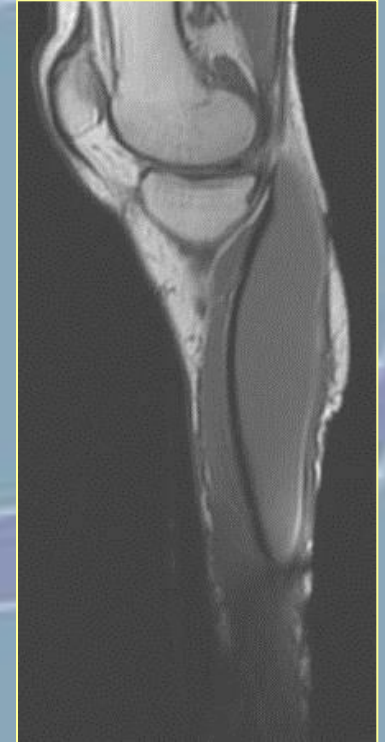


Two month after replacement, 120 cc.



IMPOSSIBILITY OF THE COMPLETE GEL REMOVAL.

MRI of the calf.



Two years after gel removal.

Aesthetic Medicine

Mini Invasive Procedures leading to More Invasive Surgery

- Cases of Mammary breast fillers
(Macrolane, Aquamid, Amazinggel)
- Incomplete removal is the problem

ONE-STAGE GEL REMOVAL AND PROSTHESIS REPLACEMENT.



ONE-STAGE GEL REMOVAL AND PROSTHESIS REPLACEMENT.



Before operation

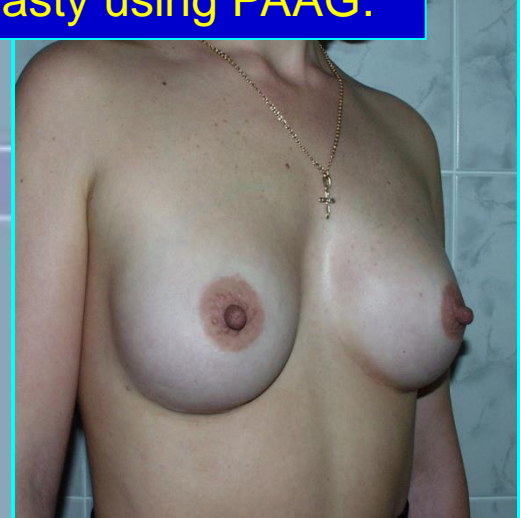
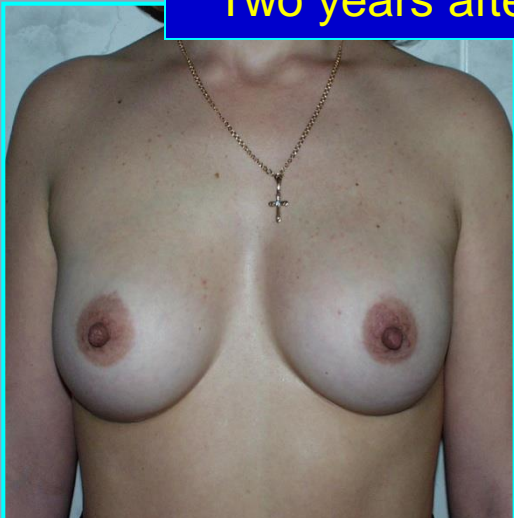


One year after the gel removal and retromammary endoprosthesis replacement, 225cc.

ONE-STAGE GEL REMOVAL AND PROSTHESIS REPLACEMENT.



Two years after augmentation mammoplasty using PAAG.



Six month after the gel removal and retropectoral endoprosthesis replacement, 225cc.

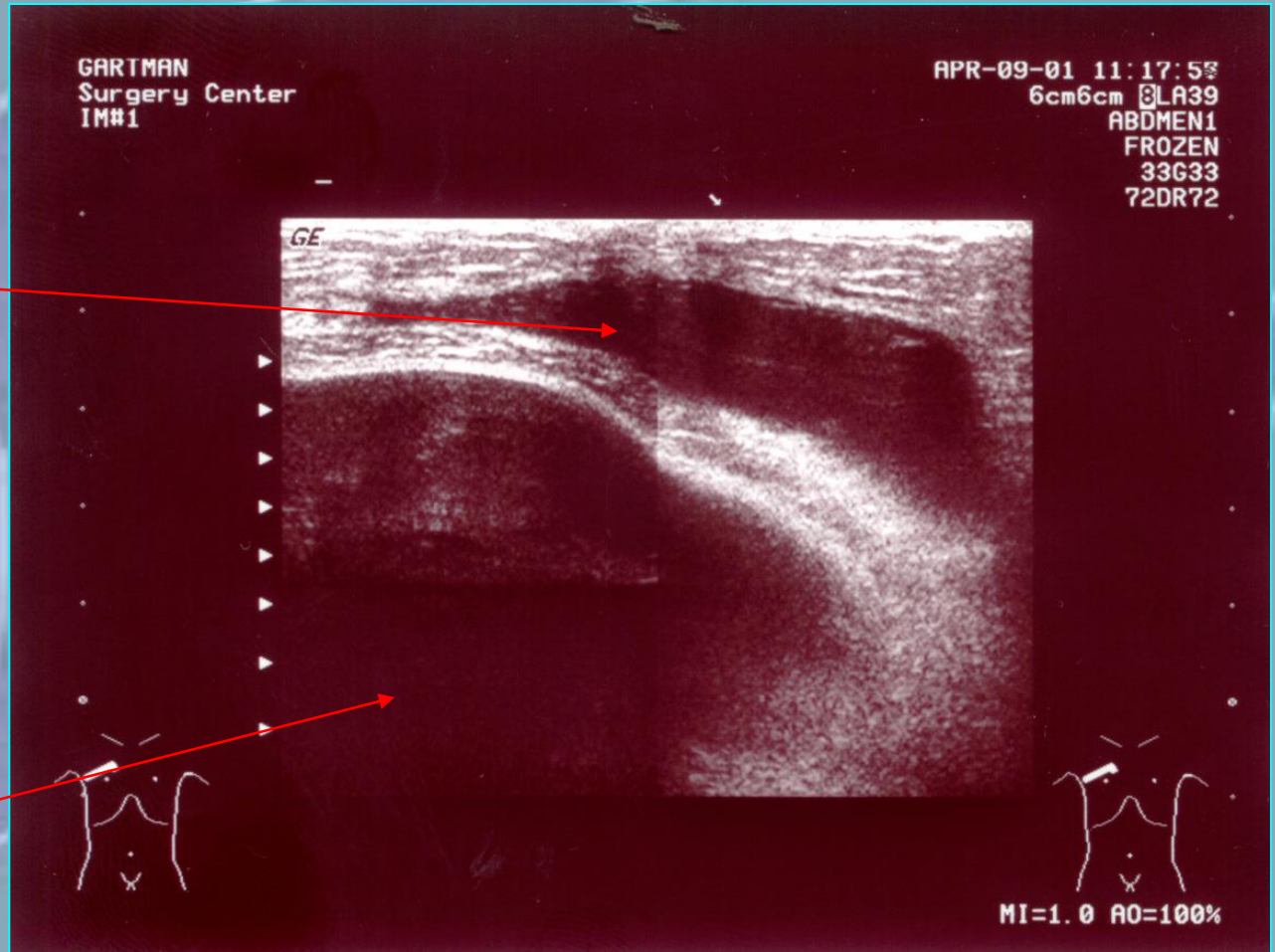


IMPOSSIBILITY OF THE COMPLETE GEL REMOVAL.

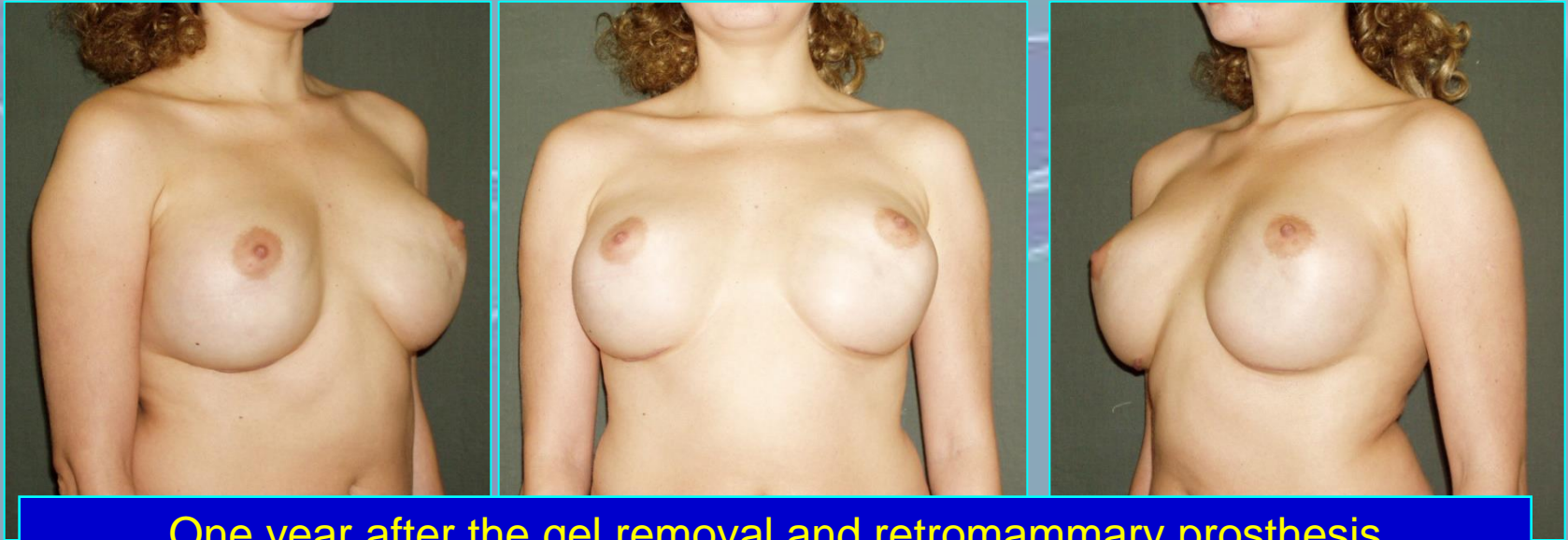
Right mammary gland in seven days after PAAG removal.

Vestige of the PAAG in mammary gland tissue over prosthesis.

Silicone prosthesis



IMPOSSIBILITY OF THE COMPLETE GEL REMOVAL.



One year after the gel removal and retromammary prosthesis replacement, 450.

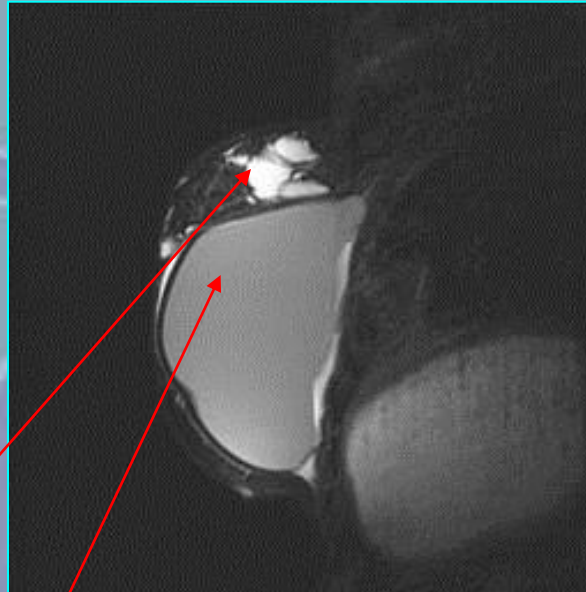


IMPOSSIBILITY OF THE COMPLETE GEL REMOVAL.

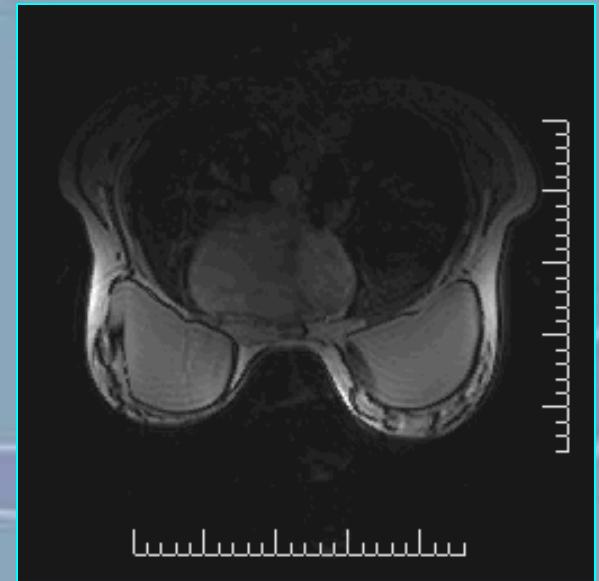


Accumulation
of the gel in the
mammary gland tissue

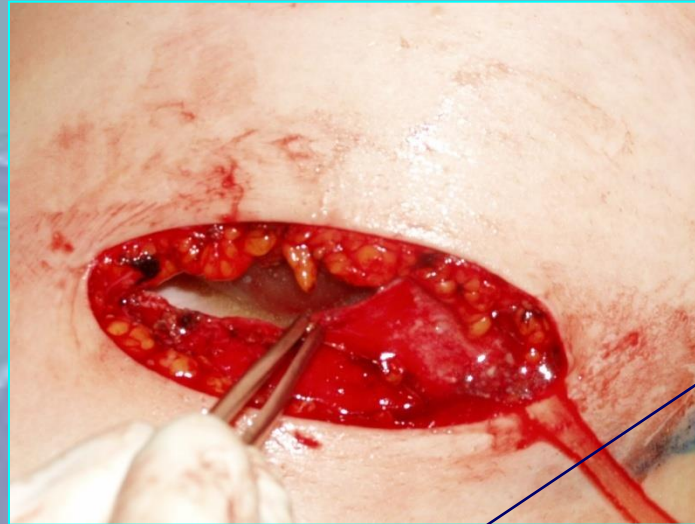
Silicone prosthesis



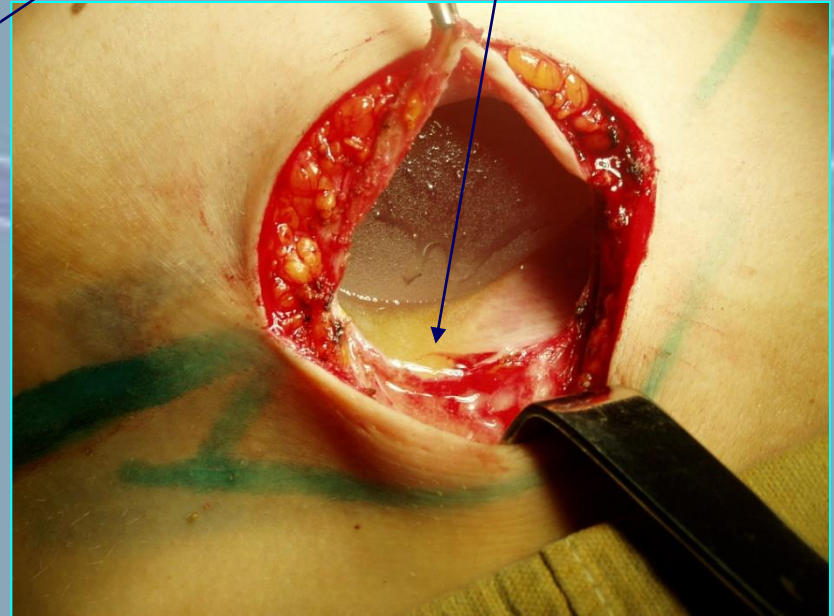
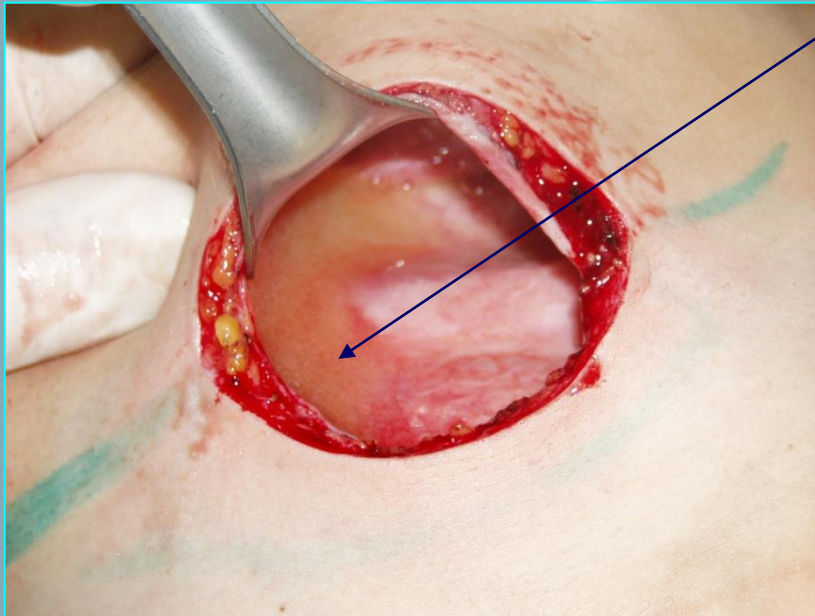
MRI of the mammary
glands.



IMPOSSIBILITY OF THE COMPLETE GEL REMOVAL.



Gel in the prosthesis capsule cavity.



Complication of Buttock Gel Injection



**Patient with skin necrosis one month after
removal of gel injected in the buttocks.**
luiztoledo.com – Dubai – ISAPS Professor

Complication of Buttock Gel Injection



**Patient with skin necrosis one month after
removal of gel injected in the buttocks.**
luiztoledo.com – Dubai – ISAPS Professor

Conclusions

- Authorities should not have competences to authorize to put on the market fillers or other medical devices.
- Don't be influenced by key speakers sponsored by big companies in big commercial congresses
- Knowledge and Experience Forum between independent MD is a must
- Patients should be too responsabilised as they mostly lie and change of physician
- Do not fall in commercial advertisements which seem to be scientific
- Not permanent fillers participate also to a high rate of complications , which are shadowed in commercial Congresses sponsored by big companies infiltrating their „ key,, speakers .

THANKS FOR YOUR KIND ATTENTION

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