Plastic and Reconstructive Surgery

Management of complications due to permanent fillers in the face: A treatment algorithm

--Manuscript Draft--

Manuscript Number:	PRS-D-15-01415R2
Article Type:	Original Article
Full Title:	Management of complications due to permanent fillers in the face: A treatment algorithm
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Abstract:	Non resorbable substances are still injected to enhance soft tissue volumes and fill subcutaneous defects. Inflammatory reactions, often named granulomas, to these materials can be functionally and socially disabling. Most therapeutic options used until today are non-specific antinflammatory treatments, targeting an ill-defined immune reaction of undefined aetiology. The minimally invasive Intralesional Laser Treatment, is capable of removing the foreign substance and the inflammatory reaction with an 808-nm diode laser (LASEmAR 800, EUFOTON, Italy). 219 consecutive patients referred from September 2006 until June 2013 for inflammatory reactions to permanent fillers of the face and treated with this technique at our institution with a minimum follow-up of 6 months were included in this study. All patients were screened with an ultrasound soft tissue examination and the lesions classified either in "cystic" (implants inserted by bolus injections) or "infiltrating", (as in microdeposits injection). Our therapeutic approach is summarized in an algorithm: "Infiltrating" patterns were treated with Intralesional Laser Treatment alone, whereas "cystic" distribution cases were also drained through stab wound incisions. Mean age was 49 years (range 23-72); 204 were female. Partial improvement was obtained in 30% of patients, while 8% discontinued the treatment due to lack of satisfaction. Complete disappearance of lesions in 62%. Complications: transient swelling in all cases, hematoma in 2%, secondary sterile abcess 9.5%, minimal scarring 10%. A problem-oriented systematic approach to inflammatory complications from permanent fillers is proposed, based on the comprehensive work from the last 7 years, with an overall improvement rate of 92%.
Manuscript Classifications:	Ambulatory surgery topics; Antibiotic and infectious diseases; Cosmetic; Cosmetic outcome studies; Lasers
Additional Information:	
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What are its implications for plastic/cosmetic surgeons and their patients?	Good treatment option for filler induced complications
What should be the general public's take away from your research?	ILT is a less invasive option
Response to Reviewers:	Dear Sir, as requested •the quality of figures 2, 3b, 5, 6, 7, 14 has been upgraded •the table 1 call–out has been inserted in the body of the manuscript (Results) •the misspelling of the term Polyalkylimides has been corrected •the term Polyacrylamides (Aquamid) is spelled according to the manufacturer

TITLE PAGE (AUTHORS, CORRESPONDING AUTHOR, AFFILIATION, FINANCIAL DISCLOSURE,

Management of complications due to permanent fillers in the face:

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Short running head: "Long term experience with laser assisted technique"

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None of the authors has any commercial associations or financial interests to disclose;
None of the authors received any funding for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s).

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List of all products, devices, drugs, etc., used in the manuscript:

- All laser treatments were performed using the *808-nm diode laser (LASEmAR 800, EUFOTON, Italy)*

Management of complications due to permanent fillers in the face:

A treatment algorithm

ABSTRACT

Non resorbable substances are still injected to enhance soft tissue volumes and fill subcutaneous defects.

Inflammatory reactions, often named granulomas, to these materials can be functionally and socially disabling.

Most therapeutic options used until today are non-specific antinflammatory treatments, targeting an ill-defined immune reaction of undefined aetiology.

The minimally invasive Intralesional Laser Treatment, is capable of removing the foreign substance and the inflammatory reaction with an 808-nm diode laser (LASEmAR 800, EUFOTON, Italy).

219 consecutive patients referred from September 2006 until June 2013 for inflammatory reactions to permanent fillers of the face and treated with this technique at our institution with a minimum follow-up of 6 months were included in this study.

All patients were screened with an ultrasound soft tissue examination and the lesions classified either in “cystic” (implants inserted by bolus injections) or “infiltrating”, (as in micro deposits injection).

Our therapeutic approach is summarized in an algorithm: “Infiltrating” patterns were treated with Intralesional Laser Treatment alone, whereas “cystic” distribution cases were also drained through stab wound incisions.

Mean age was 49 years (range 23-72); 204 were female.

Partial improvement was obtained in 30% of patients, while 8% discontinued the treatment due to lack of satisfaction. Complete disappearance of lesions in 62%.

Complications: transient swelling in all cases, hematoma in 2%, secondary sterile abscess 9.5%, minimal scarring 10%.

A problem-oriented systematic approach to inflammatory complications from permanent fillers is proposed, based on the comprehensive work from the last 7 years, with an overall improvement rate of 92%.

Clinical question: Therapeutic

Level of evidence: IV

INTRODUCTION

Injective treatments with soft-tissue fillers are the second most frequently performed aesthetic procedures (after Botulin toxin A) in the United States.**(1)**

Although resorbable materials, hyaluronic acid in particular, are most frequently used (***2),*** still a number of permanent materials are injected to enhance soft tissue volumes and fill subcutaneous defects. Furthermore, even discontinued non resorbable substances stay for decades in the tissues and can potentially cause inflammation at any time.**(3)**

Regulatory bodies don't easily authorize the use of such permanent substance. However, these limitations are often bypassed by patients that seek cosmetic treatment abroad and are eventually injected with unauthorized fillers.
According to our experience, the most commonly encountered main complaint in case of complications after such procedures are tedious long lasting inflammatory reactions of different grade. ***(4,5)***
In case of non resorbable materials, these complications are rarely self-resolving. Most treatment options used until today have focused on non-specific antinflammatory treatments, postulating the presence of an ill defined immune reaction to the alloplastic substances. ***(5 -15)***

Inflammatory complications after non-resorbable filler injections, are often called granulomas. (**16-19**)

Foreign body granulomas are defined as lesions appearing as lumps or nodules after injection of different materials, showing microscopically a foreign body reaction consisting of: protein absorption, macrophages, multinucleated foreign body giant cells (macrophage fusion), fibroblasts, and angiogenesis.
(**14**,***20,21)***

It is unclear why often the term granuloma is used without the support of such histological diagnosis. We therefore suggest the use of the term "inflammatory nodules" in absence of histology.
Some authors believe that these adverse reactions are caused by a bacterial low-grade infection surrounding the foreign material. The physical properties and inherent characteristics of the implant determine the development of associated fibrosis. ***(14)***
Materials made of microspheres with a smooth surface (Artecoll, New-Fill, Evolution) have been reported of being less prone to inflammation than the ones made of particles with irregular surface (Bioplastique, Dermalive).(**22**). The incidence of "granulomas" is reported to be between 0.01% and 1.0% of such procedures.
Although the overall incidence seems low, the number of patients undergoing non resorbable filler injections (**23**) makes its clinical impact considerable. The prevalence of complications seems to be growing as expected (**3**) and as shown by the numerous reports in the literature.**(16)**
This complication, as many others, is probably under-reported. In the practice of plastic surgeons it is not unusual to have to deal with patients seeking for treatment of subcutaneous-dermal nodules, either because of the disfigurement, the pain or the recurrent inflammatory episodes.

These lesions are challenging to treat. Among described therapeutic approaches are systemic antibiotics and antinflammatory drugs; intralesional corticosteroid and 5-fluorouracil (5-FU) injection; needle aspiration; surgical drainage or excision. **(15).**

A more recent alternative treatment modality for infectious or granulomatous lesions due to foreign material injections is the minimally invasive laser technique.

A preliminary report showed our initial experience (2006-2009) **(24)**, based on which a dedicated regional center was established in 2009 at the University hospital of Modena (Regional referral center for the treatment of fillers complications of the face). This treatment modality is capable of removing the foreign substance together with the inflammatory reaction in a micro-invasive manner.

This article includes our problem-oriented systematic approach to inflammatory complications from permanent fillers and describes the comprehensive results we have obtained in the above mentioned period of time with this technique.

Methods

Patients

219 consecutive patients referred from September 2006 until June 2013, for inflammatory reactions to permanent fillers and treated with the 808-nm diode laser (LASEmAR 800, EUFOTON, Italy) at our institution with a minimum follow-up of 6 months from the end of the treatment were included in the study. Past medical history, on going medications and concomitant medical conditions were recorded. Most patients were referred to our center after being treated elsewhere with local or systemic corticosteroids and antibiotics with limited and temporary improvement, if any.

All patients were screened with an ultrasound soft tissue examination. Performed by an experienced operator, obtaining precise information about the volume, nature and position of the injected material. (**7,25-31)**

The most important information is whether its distribution in the tissues is "cystic", as in bolus injections, or "infiltrating", as in crisscross retrograde injection. This will guide our decision of which type of laser assisted evacuation we shall choose for each case. "Infiltrating" patterns were treated with ILT alone, whereas "cystic" distribution cases were also drained through stab wound incisions. Practically patients were divided in two treatment groups according to their ultrasonographic picture (**FIGURE 1).**

Mean age was 49 years (range 23-72); 204 were female, 15 male. All patients presented with facial lesions (specific locations in **FIGURE 2**) but 3 cases (where fillers were also located in the pectoral, bicipital and calf areas).

Infiltrating

Usually injectables as silicone oil, PMMA (e.g. Artecoll, Artefill, Bioplastique) form an acoustic barrier that does not allow a precise ultrasonographic mapping. Therefore we must rely just on their contour in order to mentally visualize their distribution in the tissues. Furthermore their recommended way of injection is in micro droplets. For these reasons we have never encountered a cystic lesion caused by these materials and we have only treated them with ILT.

However it is possible that silicon oil be injected not according to the standard technique. Therefore it can theoretically appear as a cystic deposit, for example if a big bolus is injected into defined fat compartment.

Dermalive/Dermadeep

These are acrylic gels (hydroxyethilmethacrylate and ethilmethacrylate) (40%) mixed with hyaluronic acid (60%).

After being implanted the hyaluronic acid is progressively absorbed leaving the sharp edges of the acrylic component microstructure exposed. (***32)***

This is to believed to favor the numerous reports of inflammatory complications, most often untreatable, caused by these fillers. (**16,*33,34)***

These fillers have commonly been injected both for wrinkle reduction and volumetric enhancement. Either way after the resorbable gel is absorbed, they acquire a solid state that makes them non-drainable by a simple incision, thus requiring ILT.

Therefore we include them in the infiltrating group for practical reasons.

Cystic

Polyacrylamides (Aquamid, Evolution, Argiform, Formacryl), Polyalkylamides (, Amazingel, Aquamid, Outline) and Polyalkylimide (Bio-Alcamid) gels are recommended to be injected in well defined implants in order to form an endoprosthesis. **(35-39)**

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Operative procedures

1. ILT: Intralesional Laser Treatment

An 808nm diode laser (Lasemar 800, Eufoton, Trieste, Italy) was used. The Intralesional Laser Treatment (ILT) procedure **(24)** consists of percutaneously inserting a 200 microns optic fiber into the lesions drilling several small holes. Typically no anesthesia is used. Since bacterial presence is hard to rule out, even with negative cultures, local infiltration in this inflamed and contaminated area could be ineffective or even spread the infection further around.

Moreover all polymers are obviously lacking any perception of pain and temperature and so are the giant cells that usually surround them.**(14)**

On the contrary the native host facial tissue is exquisitely sensitive to pain and temperature especially when subject to acute, sub-acute or chronic inflammation.

There is a thermal therapeutic margin between the lesion melting and the pain threshold elicited by excessive diffusion of heat into the surrounding tissues.

The usual laser power setting is at 7 watts in continuous wave (CW) mode and the optic fiber tip is inserted directly into the lesion.

Energy delivery is modulated according to patient tolerance as follows:

if patient immediately shows excessive discomfort, power is reduced to 6 watts and emission is switched from CW to pulsed (500 msec on/500 msec off).

Treatment pattern: the optic fiber tip is inserted into the lesions **(FIGURE 3a)** trying to uniformly heat up the mass. Manual palpation usually reveals a softening of the deposits as the immediate clinical endpoint, due to the polymer increased fluidity. If inadvertently the operator will overheat the lesion, the heat excess will diffuse into the surrounding tissues, the discomfort will gradually become unbearable. Patients are previously instructed to alert the operator in this case in order to prevent untoward tissue damage.

Therefore the total amount of energy applied to each lesion depends on its dimensions and cannot be calculated a priori.

At this point the heat-liquefied materials are evacuated ("squeezed out") **(FIGURE 3b)**, by finger compression, through the skin entrance points of the probe.

If the access is through mucosa the fear for permanent scarring at the laser entry points is minimal, therefore the openings are made wider (up to 1 mm) in order to keep them patent and facilitate drainage for a longer period of time. Particular care is needed when the lesion is intradermal and longstanding. In this case soft tissue atrophy is common, due to the chronic inflammatory process and the repeated steroid injections usually administered before referral to our centers. This makes the skin thinner and less resistant to thermal injury. For this reason, before proceeding, patients are informed that small, acne-like scarring may occur and they are asked permission to continue the treatment (in no cases has the patient refused). When patients have undergone attempts of surgical excision of the lesions before their referral, advancing the laser fiber is made more difficult by the fibrotic scarring and care must be taken in order not to break the delicate optic fiber against the rock hard

tissue. Advancing the laser fiber parallel to the scar lines is preferable to trying to pierce through them.

This treatment modality is applied to all “infiltrating” cases.

2. Stab wound incision

If the clinical and ultrasonographic picture is compatible with a “cystic” implant, a stab incision (11 blade) is performed according to the relaxed skin tension lines RSTL (MTL).

Usually implants subject to long standing inflammatory processes have changed their characteristics. Instead of the light transparent and aqueous gel that was injected at first, a much thicker, fat-like substance is extracted. (**FIGURE 4a)**

In some cases the substance is almost solidified, because of the gradually growing scaffold of thin connective tissue fibers within it. **(40)**

In these cases the optic fiber is introduced through the stab wound incision and the implant is uniformly irradiated with the laser using the above mentioned parameters and modality, in order to disrupt the fibrous scaffold and allow easy evacuation of the liquefied substance.

The empty cavity is irrigated with saline solution in order to rinse out small residuals adhering to the pseudocapsule.

The stab wound is left open for drainage and heals spontaneously in a few days.

3. Post-operative treatment

Patients are instructed to apply frequent lukewarm saline compresses.

Frequent gentle squeezing of the treated area is recommended in order to insure continuous drainage of the liquefied foreign material and necrotic inflammatory tissue.

Oral macrolide antibiotic treatment is recommended in cases at risk of post-op infection: patients with incompletely evacuated cystic lesions, patients under corticosteroid treatment, immunocompromized patients (HIV, diabetes, etc.).

The typical healing time from the combined mechanical and thermal trauma due to the treatment depends on the treated area site and size. Usually up to six months are necessary to fully appreciate the resolution of the lump together with the healing of the surrounding inflammation often extended far beyond the original implant.

Thus, the need for eventual further treatment is evaluated at 6 months.

Treatment is considered successful in the following cases:

- all symptoms are completely cured or judged tolerable by patient,
- lumps visibility is reduced to a degree judged tolerable by patient,
- the possibility to interrupt the steroid therapy without recurrence,

Patients were photographed at first consultation, before each treatment session and at 6 months.

Cosmetic and functional results, adverse events episodes and patient satisfaction were evaluated by two board-certified plastic surgeons at 6 months from the end of treatment.

Results have been classified into three categories (improved, not improved, resolved) evaluating three parameters: Inflammation (Rubor, calor, dolor, functio lesa), Nodules, Paraesthesia.

RESULTS

Different materials have been removed (details in **FIGURE 5**) according to the characteristics of the lesions (**Table1 and Table2**).

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Average number of treatment sessions per lesion: 1.7

Partial improvement (with then more than 50% reduction) was obtained in 30% of cases.

8% of patients discontinued the treatment due to lack of satisfaction.

Complete disappearance of lesions (lumps and inflammation) was obtained in 62% of cases. **(FIGURE 6)**

Out of the 219 patients, 20 were referred to us while on chronic steroid oral therapy. Even though we do not advocate systemic steroid treatment because of possible side effects, highly recurrence rates and rebound effects, we can not stop steroid assumption because of the risk of immediate flare up of their condition and therefore we suggest starting tapering off the drug only one month after the first treatment.

This attempt was successful in 16 out of 20 patients (80%). Only 4 out of 20 needed more (up to 5) laser sessions before it was possible to win them. Not surprisingly these patient had diffused multifocal, almost panfacial disseminated involvement.

The vast majority of complications were transient and due to the inflammatory response to the laser procedure and recurrent squeezing. In 22 cases (10%) the skin was focally atrophic due to unsuccessful attempts of intradermal steroid infiltration performed elsewhere before referral. The inflammatory nodule basically had replaced the dermis as a support to the epidermis.

Eliminating the polymer left a visible depression similar to a deep acne scar.

Similarly to other laser procedures, another potential complication is scarring due to excessive heating of the surrounding tissues by the inexperienced operator.

The other complications are shown in **FIGURE 7**

Clinical cases are shown in figures 8-13

DISCUSSION

Current review of the literature shows that many different treatments are advocated for inflammatory complications from non resorbable fillers. **(41-43)**
However many of these treatments are administered regardless of the possible etiology of the complication, without considering the possible risks and the incidence of relapse.
The "inflammatory response" to the foreign body is often seen as the treatment target, while it could also be just an epiphenomenon.
Limiting treatment to this (e.g. steroids which depress the immune system and antibiotics to help defenses) inevitably results in an unacceptable recurrence rate.**(44)**

Complications from non resorbable fillers are either inflammatory or non inflammatory.
The term granuloma has been indiscriminately applied to both inflammatory and non inflammatory cases for years **(3)** whereas some authors **(22)** postulate that HA implants can not result in granulomatous reactions.**(45)**.
Granuloma is an histological diagnosis, not a clinical one, therefore we suggest avoiding this term unless biopsy-proven and to use instead a problem oriented clinical classification that does not include improper use of unproven histological terms.
This clinical approach is the result of several considerations.
The nature of the injected material, its pattern of injection, and the clinical manifestations of the complication guide us in choosing the safest and most effective way for its removal. Extracting the ill-tolerated substance eliminates the cause of the

problem. We advocate minimally invasive laser assisted drainage through a stab wound for “cystic implants”, while “infiltrative” patterns of injection are treated by intralesional laser treatment (ILT).

Although medical history and physical examination can provide enough information for treatment in selected cases, the distinction between these two categories is best made by a dedicated ultrasound examination.

An experienced radiologist using the appropriate ultrasound frequency and probe can add precious information about each case such as: shape, dimensions and depth of each deposit. Different materials often are injected into the same area: the different densities can be detected and related to the different substances. Sometimes the same material can show different densities according to the time lapse since injection. Many gels are slowly infiltrated by collagen fibers and microscopic blood vessels, so that after years they appear at ultrasound as a low-density tissue, often lobulated and with focal calcifications.(**29-31)**

Implant density is of utmost importance for the choice of the right extraction technique. While recently injected gels maintain their structure and rheological proprieties and are easily squeezed out, older implants can only be extruded through a 3mm stab-wound incision after their density is reduced by an increase in temperature provided by the ILT (**FIGURE 4**).

These principles are summarized as an algorithm flowchart (**FIGURE 14**).

Different filler Materials behavior at laser.

Silicone oil

Among the hydrophobic polymers this is the only one naturally present as a liquid substance. The others (methacrylates) are solid particles suspended in a solution. In order to allow easy extrusion of the silicone through the microscopic holes made by the laser optic fiber, it is enough to increase its fluidity by raising its temperature to 50 degrees Celsius at most.

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Methacrylates are made of solid particles, with a much higher theoretical melting temperature. A higher energy dose is usually needed to liquefy them together with the surrounding inflammatory tissue. However the heating process must be slow and gradual in order to avoid carbonization of the polymer-tissue-compound.

Polyacrylamides, such as Aquamid and ~~(polyalkylamides~~Polyalkylimides~~)~~, do not contain solid particles. (23,46)

The subcutaneous deposits caused by these ~~Polyacrylamide (Polyalkylamides and Polyalkylimide)~~ gels are in reality cystic lesions. The gel maintains its state and form according to its original placement, with an in-growth of vessels and connective tissue. Later in the years we have observed that it doesn't maintain its original transparent colorless aspect but turns yellowish (similar to fat). (FIGURE 4a) Therefore the timing of onset of complications and eventual need of removal is critical for the treatment choice. In a recently injected case it is possible to extract the material through a puncture or a stab incision. When the lesion is inflamed, intralesional laser treatment is administered in order to decrease or eradicate the material load/biofilm eventually present. The heat is administered to the tissues through the laser fiber in order to achieve other beneficial effects such shrinking of the pseudo-capsule and obliteration of the cavity. In these cases a stab wound may be performed after the ILT. Particular care needs to be addressed to avoid an excessive heating of the product in order to maintain the integrity of the polymer chains. Claims have been made that monomers of polyacrylamide gels are potentially toxic/carcinogenic. Therefore we refrain from overheating these products as with silicone oil.

Technical aspects

Our objective is not overheating the polymer in order to avoid the presence of carbonized residuals in tissues. That increase in temperature is empirically determined until the clinical endpoint of nodule softening is achieved. In our experience this corresponds to a degree of fluidity sufficient to allow for polymer extrusion by gentle squeezing. When using a 200 micron optic fiber we typically start at 4 watts, 100 msec on time and 100 msec off time.

Unlike for dermatological cosmetic treatments, here the laser is used as a surgical tool. As in other intralesional treatments, we look for the clinical endpoint of nodule softening and content extrusion. Number of passes, delivered energy, duration and temperature measurements are not considered as reliable parameters since the treated lesions differ extremely one from the other. Temperature is not measured as treatments are performed without anaesthesia. Pain arises before real tissue damage is caused so temperature monitoring is clinically unnecessary. It could be scientifically interesting but far beyond the scope of our therapeutic work.

This chosen laser wavelength (810nm) was preferred as it resulted less painful than other infrared diodes. The other lasers tried by the author (940, 980, 1064, 1320, 1470) were not as well tolerated by patients, probably due to their higher absorption by water and fat.

An experienced operator can choose to operate in continuous wave mode. The pattern

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of tunneling is designed according to nodule shape, depth and position, but generally the fiber is inserted from the most dependent entry point in order to favor drainage when patients stand/sit up after treatment. Patients' diligent compliance in gently squeezing out the material during the first post-op days is of utmost importance for as successful outcome. When Patients refrain from doing this a much larger number of treatments might be needed. The squeezing should be very gentle in order to avoid mechanical occlusion of the tiny drainage points. This aspect requires good manual ability by the operator and by the patient.

All the patients in our study that were affected by recurrent inflammatory episodes, referred of an improvement both in the frequency and intensity of those events. Possible explanations could be the reduced residuals in the subcutaneous tissue and, possibly, the changes in the inflammatory and contaminated component of the fibrotic tissue of the lesion induced by the laser. (45)

Steroids (and other infiltrative treatments)

Intralesional steroids and 5-FU may give a temporary improvement but they do not address the root of the problem. The risk of rebound effects, skin atrophy and telangiectasias have discouraged us from using them.

The idea of injecting intralesional steroids into inflammatory complications caused by fillers originates in common dermatologic practice, where annular granuloma is routinely treated with steroids with good results. The term granuloma is often applied without justification to many of the complications we are dealing with, because histology is not examined. Nevertheless the same treatment has been projected by analogy without a clinical rationale.(45)

When silicone oil is injected into fine lines, its microdroplets stimulate the formation of fibrotic tissues around them. Over the years this might lead to an overcorrection, even without clinical signs of inflammation, since there is no way to regulate the amount of reactive tissue.

Historically triamcinolone has been used to diminish the fibrotic reaction around the silicone oil micro droplets. In selected cases of overproduction of fibrotic tissues without clinical inflammation, cautious intralesional injections of corticosteroids can be successful and acceptable (e.g. silicone oil), due to its selective inhibition of collagen production by fibroblasts.(47)

In inflamed cases the intralesional injections of corticosteroids should be avoided because of the possible rebound effect after the initial improvement due to the immunosuppressive effect on the possible bacterial contamination.

It should be noted that our patient population is selected. The majority of our patients is referred to our centre after previous treatment attempts, such as intralesional injections of corticosteroids or other substances (5FU et al.), systemic steroids. Some are only partially treated with antibiotics.

Safety studies for fillers have been published with a follow up of up to 5 years.(46)

In our series the typical average onset of inflammatory complications is 6-7 years

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(range 1 day -12 years). Therefore we find that the 5 years safety data do not reflect absolute immunity from long-term complications.

The satisfaction rate was less than complete in a small part of the treated subjects. Even though all patients are correctly informed before the procedure about the possible outcome, too many of them do not fully realize that they are being treated for a pathology. Instead they are probably still considering it a continuation of the initial filler treatment that was supposed to make them " permanently more beautiful" in their perception. Their unconfessed desire is for their pristine aspect to be restored, which is obviously impossible to achieve after many years of aging, bad effects of chronic inflammation and steroids on their faces.

CONCLUSIONS

In the literature there is no consensus on permanent filler complications treatment.

Traditional medical and surgical treatment modalities have not been satisfactory.

A minimally invasive approach, combining laser assisted implant removal and eradication of the eventual bacterial contamination, is proposed in a large series of consecutive patients achieving long standing improvement in 92% of patients.

Though the learning curve for this kind of intralesional treatment is not negligible, we believe this might be a breakthrough for this difficult group of patients.

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LEGENDS

FIGURE 1

Typical ultrasonographic image of different permanent fillers.

A. Polyalkylimide gel nasolabial implant. The material is hypoechogenic. A pseudocapsule is visible.
B. Silicone oil infiltration of the nasolabial fold. The ultrasonographic typical "barrier" is visible as a white wall hiding the underlying structures.

FIGURE 2

Graph showing the different locations of the facial lesions.

Nasolabial folds:	60%
Lips	53%
Malar area	41%
Periocular	27%
Frontal	8%

FIGURE 3: Intralesional Laser Treatment (ILT) operative procedure.

A: the optic fiber tip is inserted into the lesions

B: the heat-liquefied materials are evacuated ("squeezed out") by gentle finger compression through the microscopic openings left by the optic fiber.

FIGURE 4

A. Image of the removal of a"cystic" chronically inflamed Aquamid implant through a stab incision. In this case the implant, subject to long standing inflammatory processes, has changed its characteristics. Instead of the light

transparent and aqueous gel that was injected at first, a much thicker, fat-like substance is easily extracted after being preheated with the intralesional laser.

B. Pre-treatment appearance of a cystic 3 years old upper lip Aquamid implant. Patient complained of pain in motion and excessive volume.

C. Post-treatment result at 2 months. Notice the reduction in lip over-projection. All symptoms resolved.

FIGURE 5.

Graph showing the different materials that have been removed

30% Dermalive

20% Silicone oil

13% Artecoll

12% Bioalkamid

11% Aquamid

14% unidentified

FIGURE 6

Final aesthetic and functional results:

- 8% of patients discontinued the treatment due to lack of satisfaction.

- Partial improvement (with then more than 50% reduction) in 30%.

- Complete disappearance of lesions (lumps and inflammation) in 62%

FIGURE 7.

Complications are shown in the graph

Swelling	100%
Hematoma	5 cases
Secondary sterile abcess	21 cases
Scarring: smallpox like	22 cases

Figure 8

Female Patient, 38 years old.
Silicone injected 15 years before. Treated twice with ILT
Before and 1 year after 2 treatments

Figure 9

Extrusion of PMMA (Polymethyl methacrylate, a synthetic resin produced from the polymerization of methyl methacrylate) in a patient from Brazil.

Figure 10

54 years old Patient. 20 years after silicone injections to the lower lip. 10 years old inflammatory swelling of the lower lip. Before and 2 years after the second of two ILT treatments

Figure 11

32 years old patient with PMMA inflammatory nodule of the right upper lip.
Before and 1 y after ILT

Figure 12

35 years old patient with polyacrylamide inflammatory lesion of the lower eyelid.
Extrusion immediately after ILT.
6 months after treatment.

Figure 13

65 years old patient with longstanding pan facial silicone induced inflammatory reaction.

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inflammatory silicone nodule left lateral canthal area.
Before treatment, extrusion of silicone after ILT, 4 years after treatment

FIGURE 14

Flow chart summarizing the principles of treatment of inflammatory complications after non-resorbable filler injections

The distinction between “cystic implants” and “infiltrative” pattern of injection is best made by a dedicated ultrasound examination.“Cystic implants” are treated by minimally invasive laser assisted drainage through a stab wound, while “infiltrative” lesions are treated by intralesional laser treatment (ILT) only. See text for details

*before any future invasive procedures

Azithromycin: oral 500 mg/day

TABLE 1: Different filler Materials, distribution pattern, behaviour

TABLE 2: characteristics of the lesions in the study population

Figure1a

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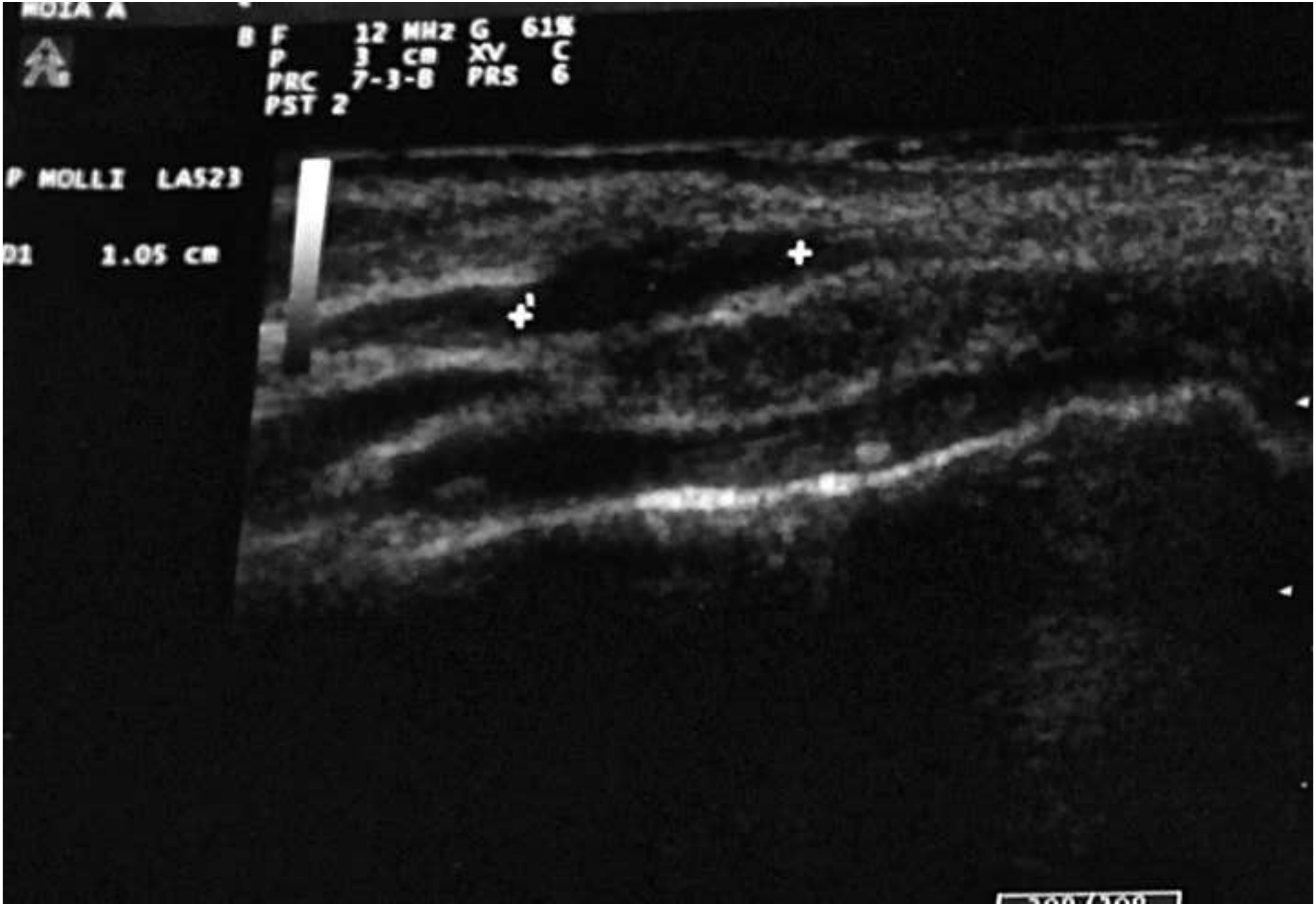

Figure1b

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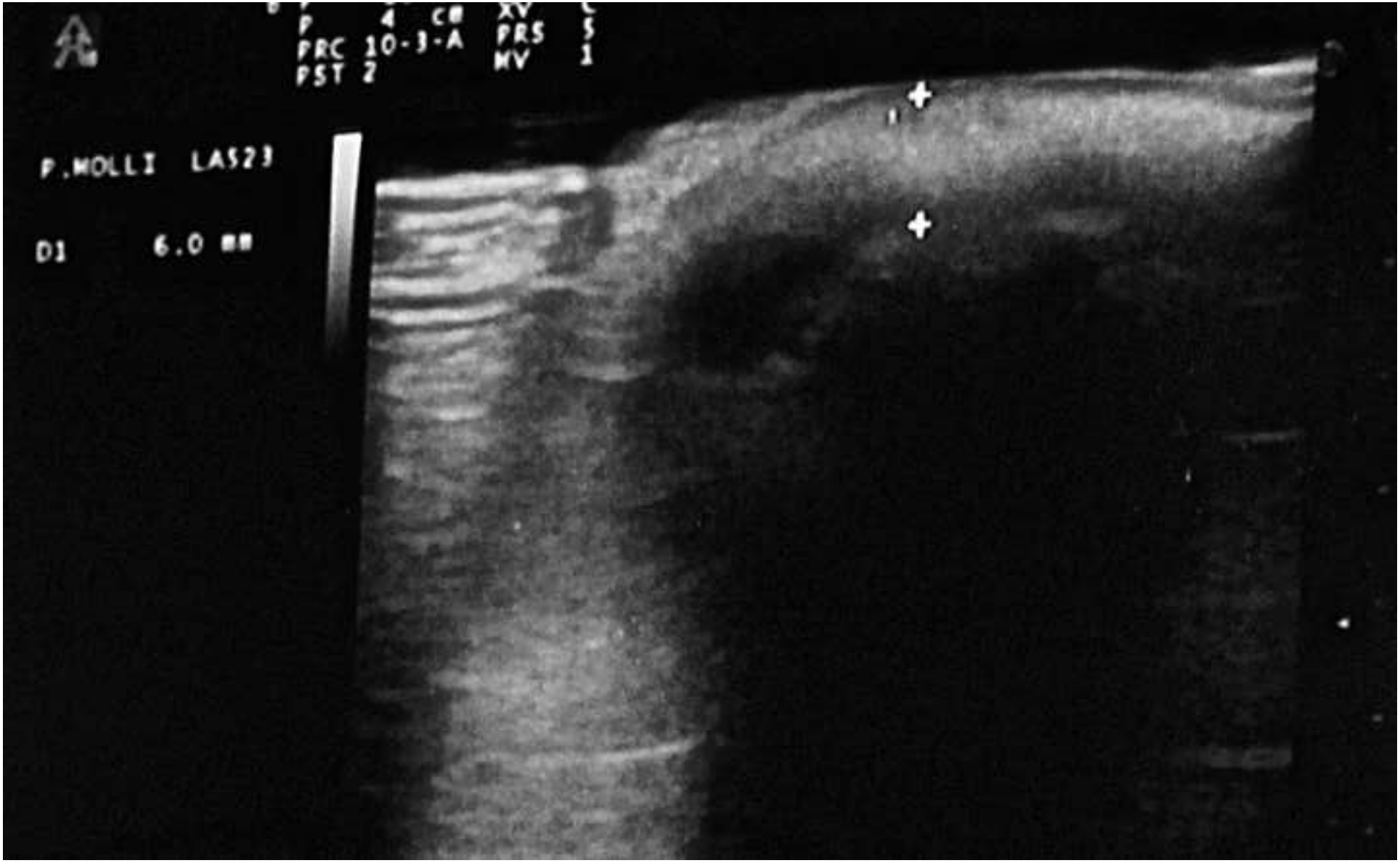

Figure2

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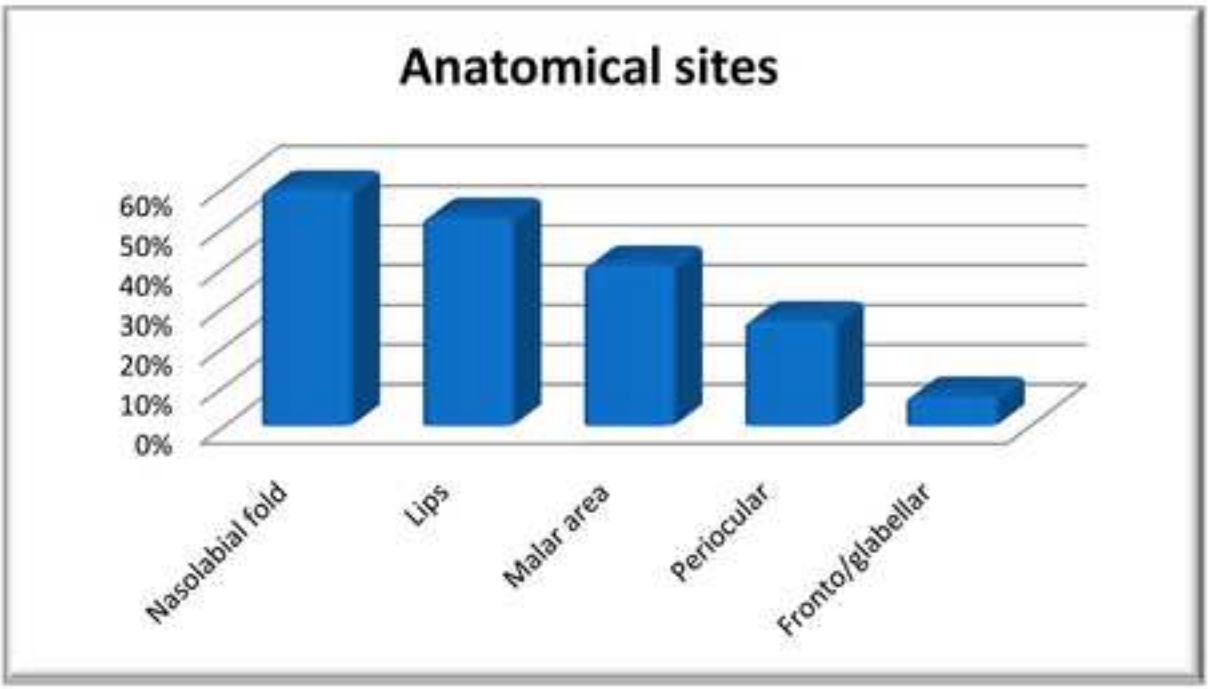

Figure3a

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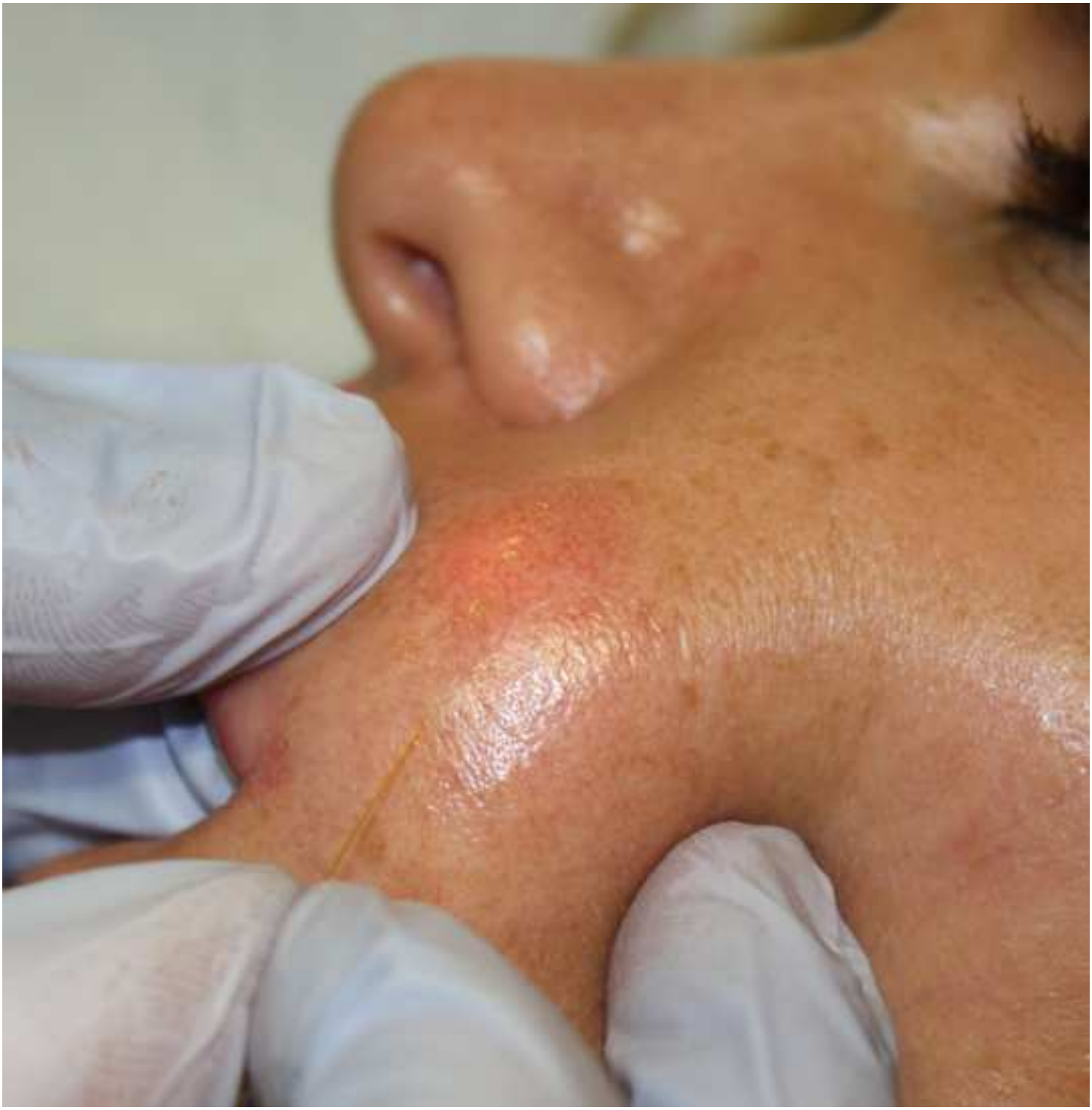

Figure 3b

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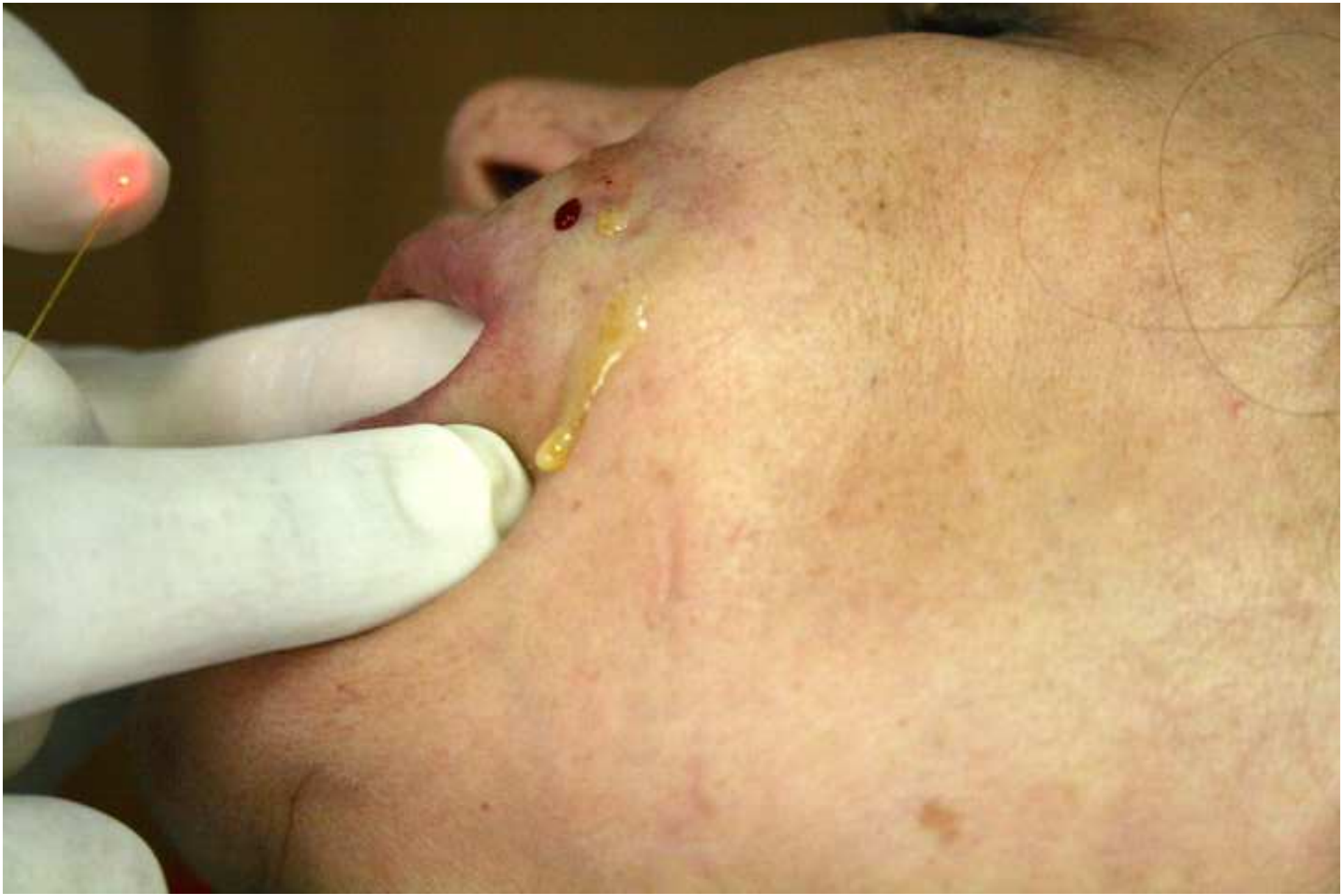

Figure4a

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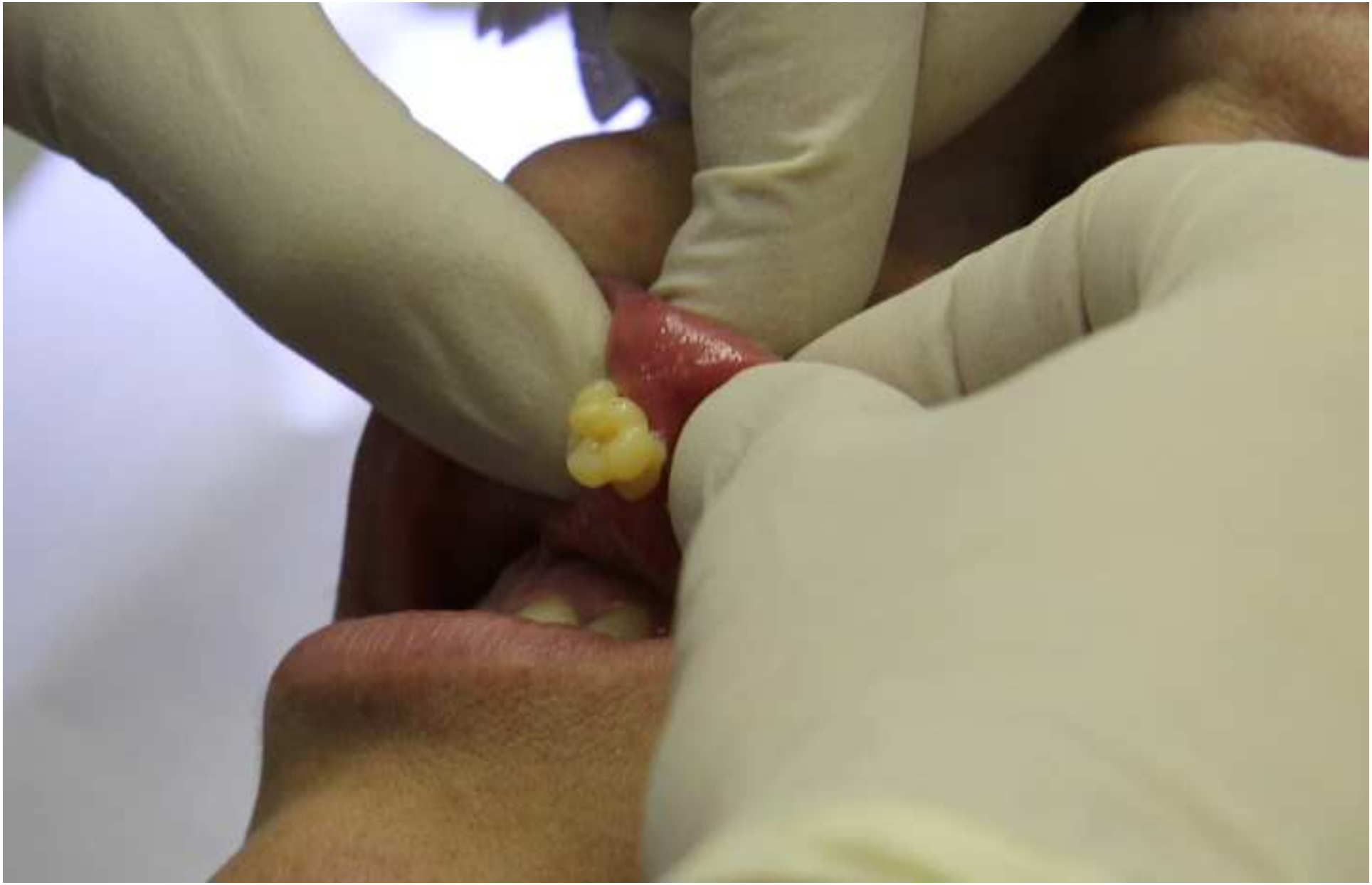

Figure4b

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Figure4c

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Figure 5

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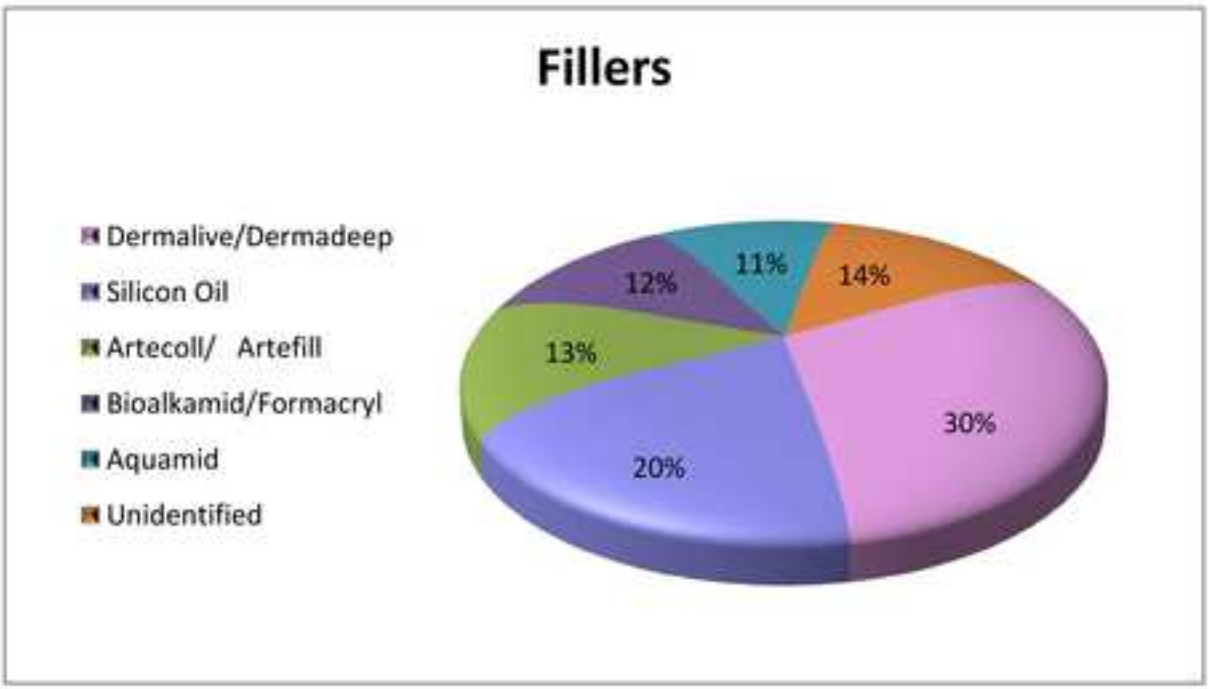

Figure 6

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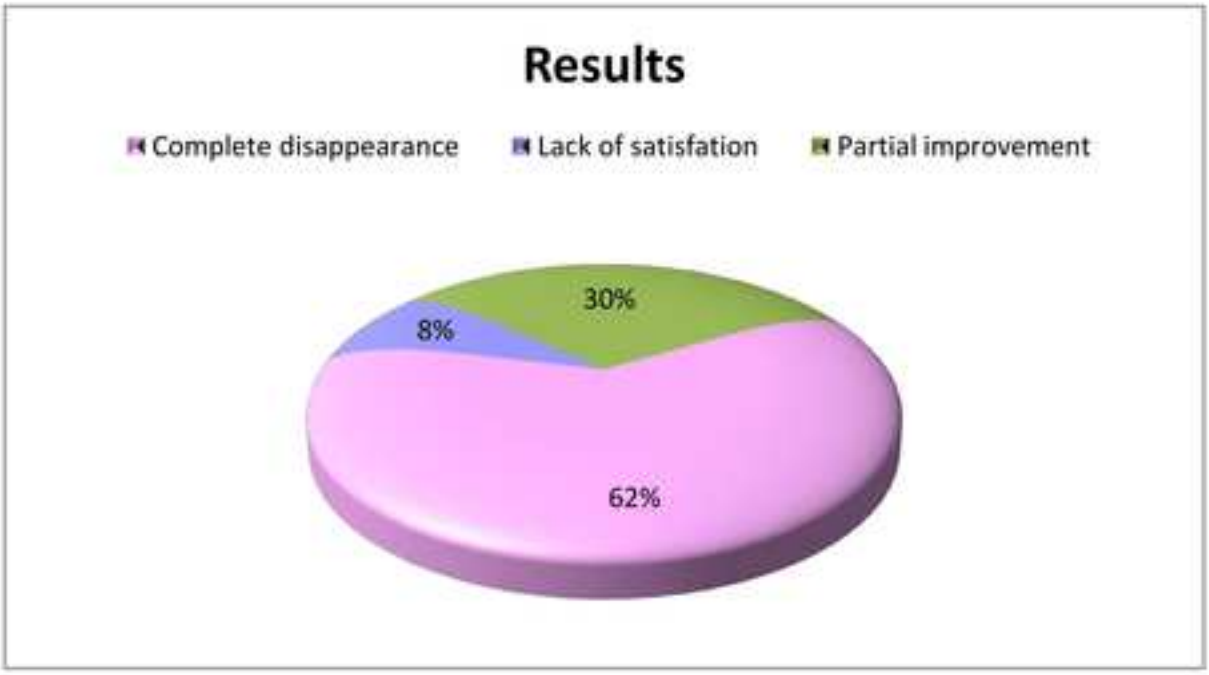

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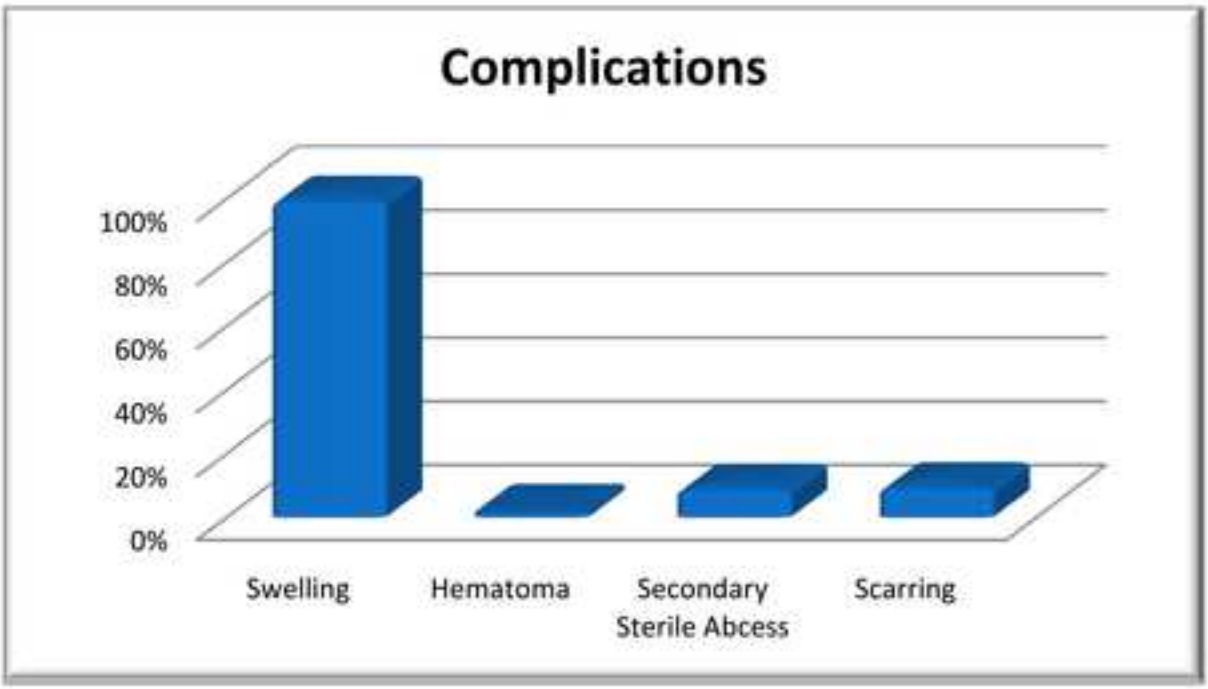

Figure 8

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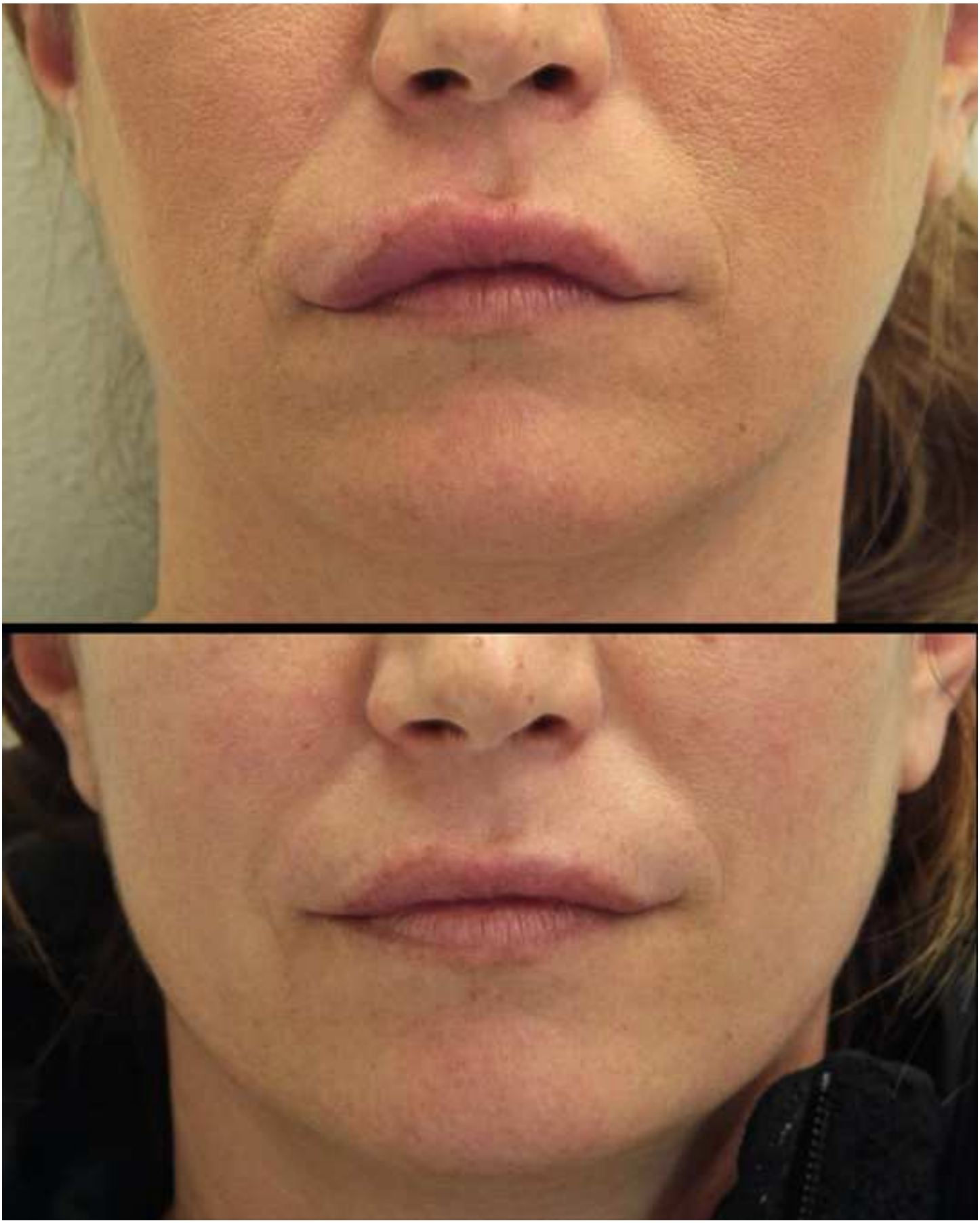

Figure 9

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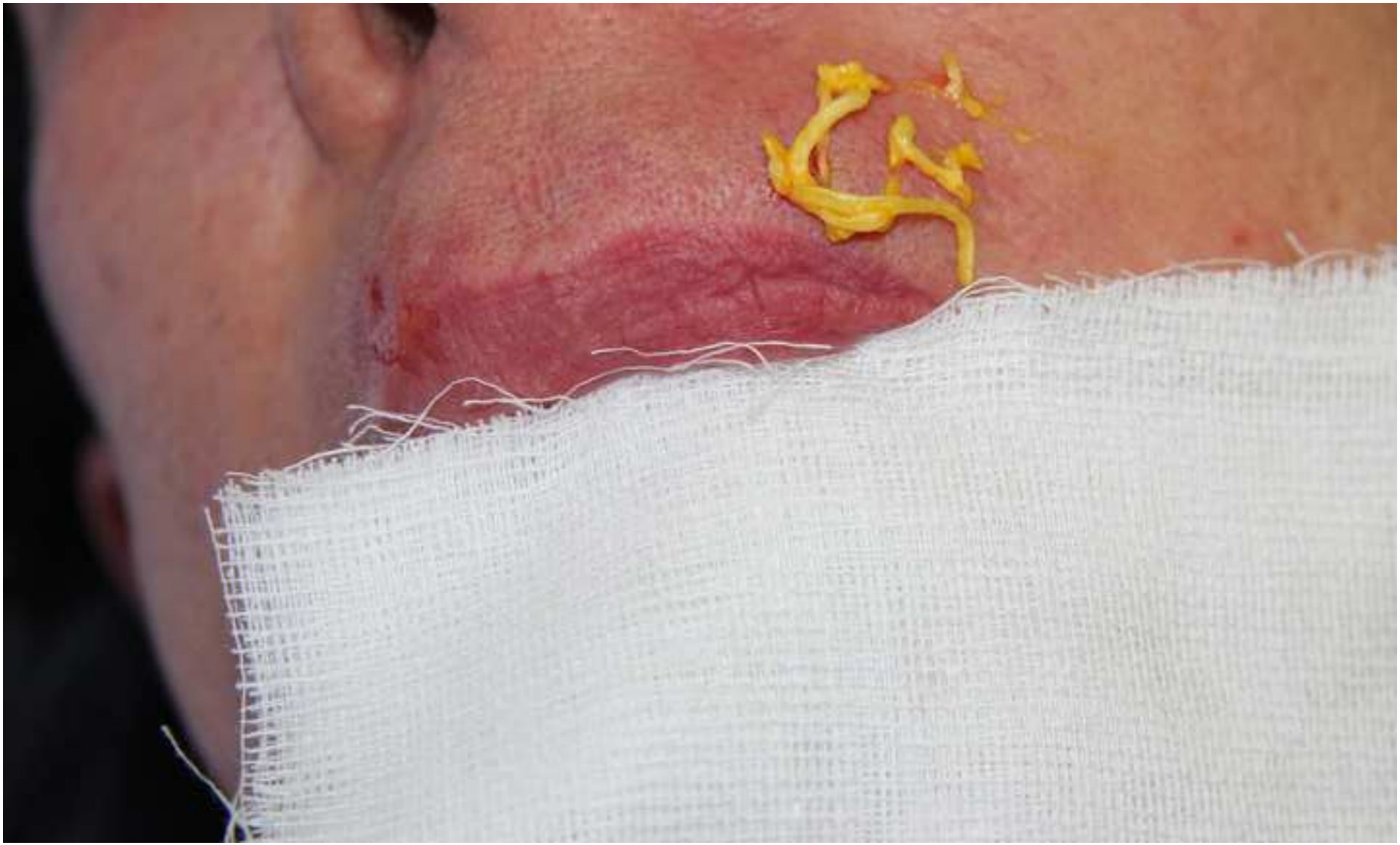

Figure 10

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Figure 11

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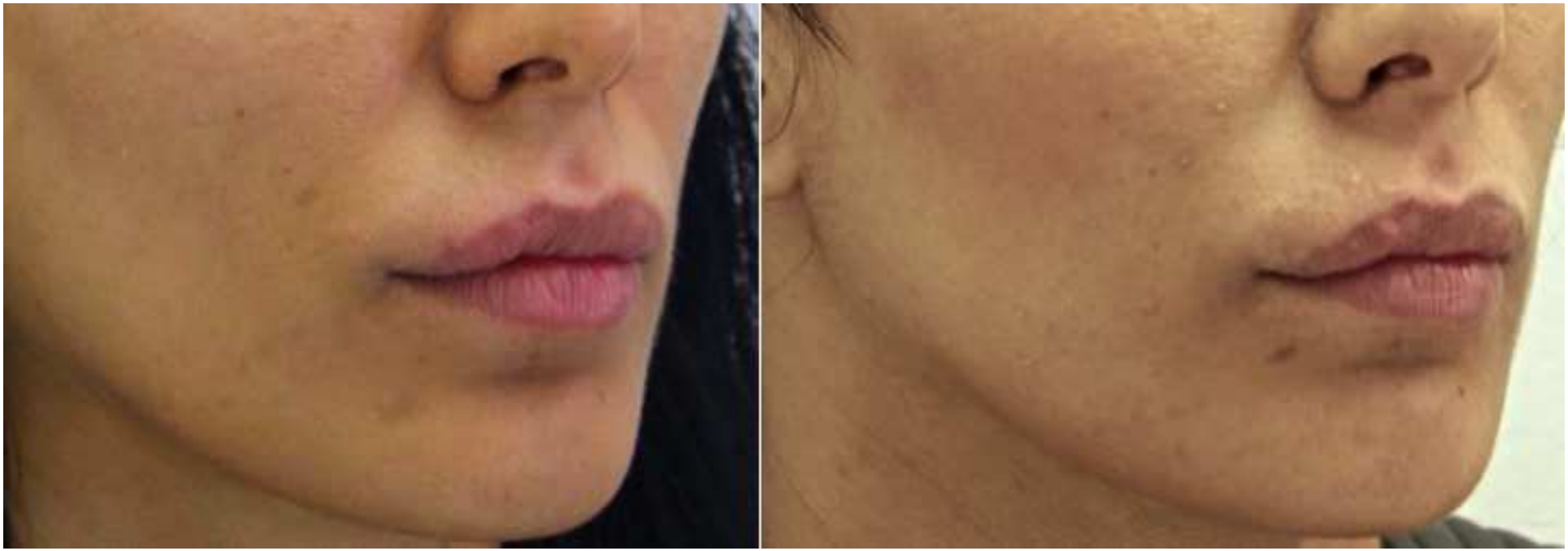

Figure 12

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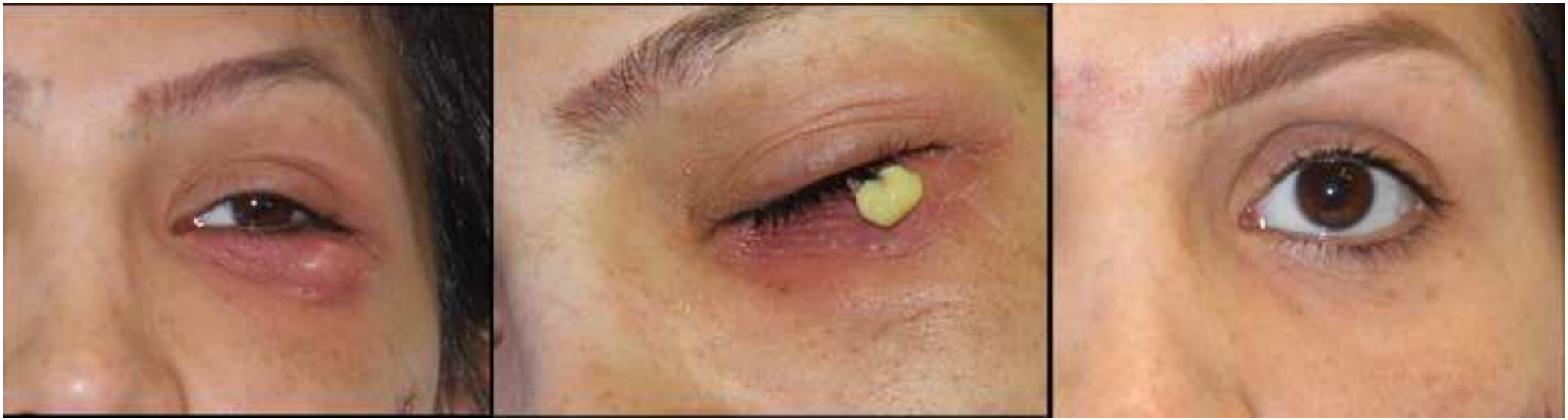

Figure 13

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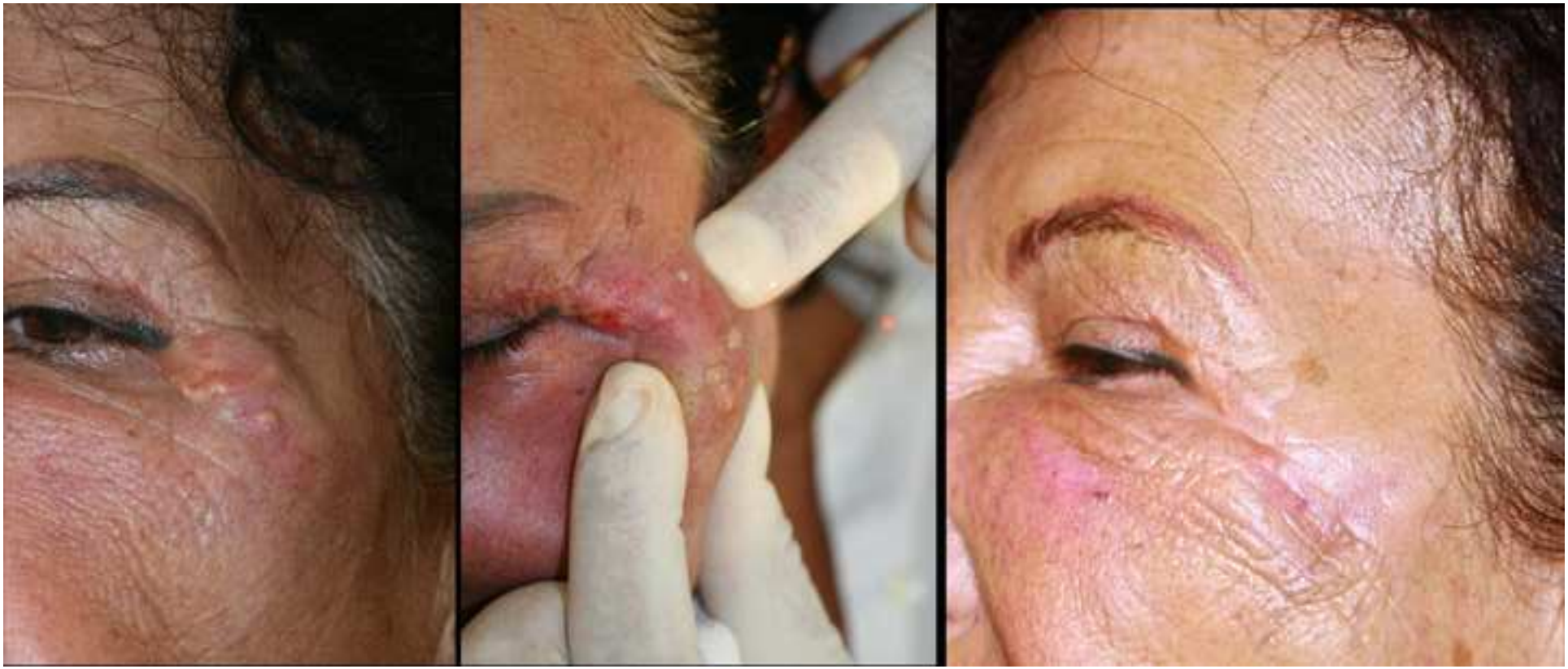

Figure 14

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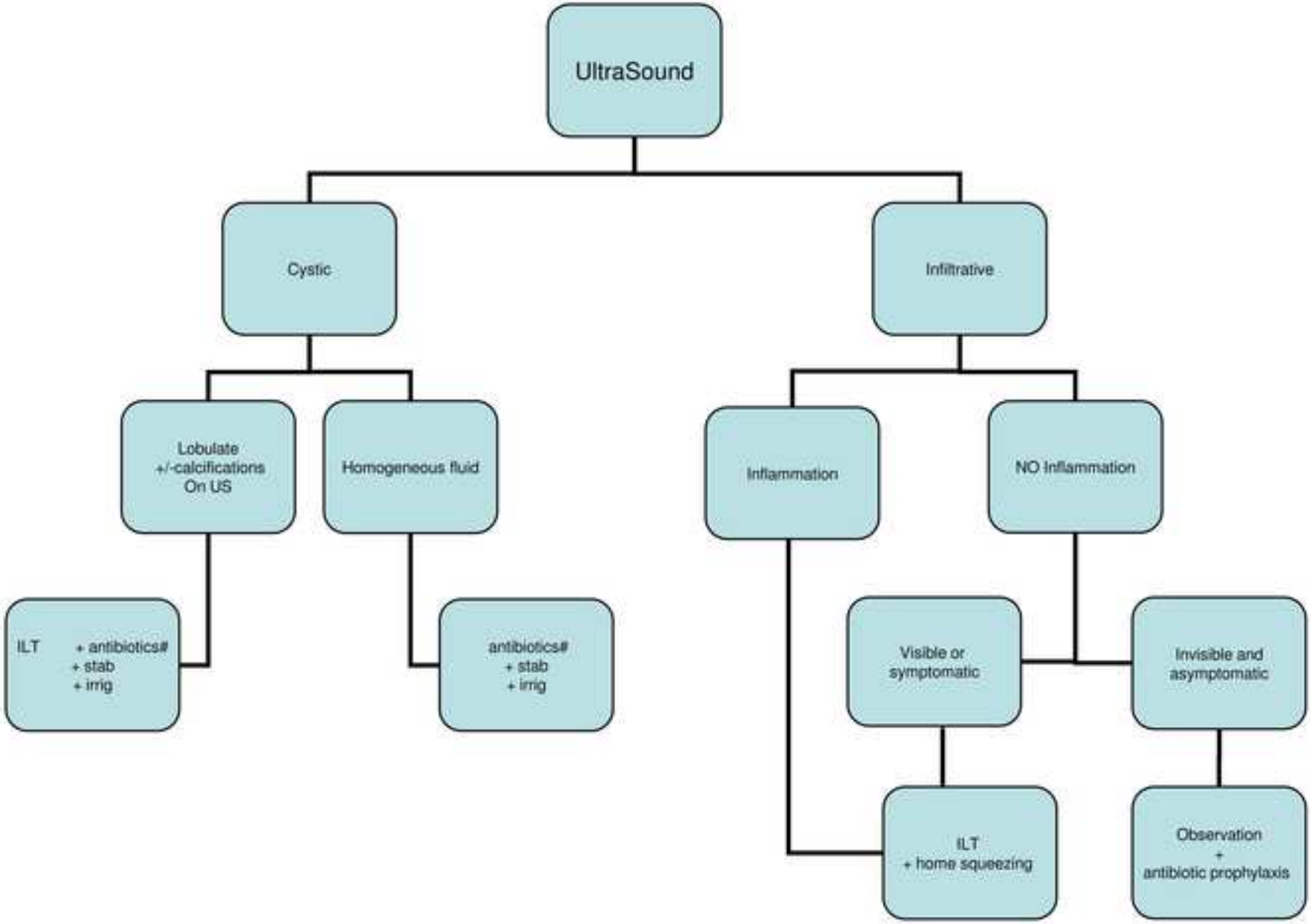

TABLE 1: Different filler Materials, distribution pattern, behaviour

DIFFERENT FILLER MATERIALS			
POLYACRYLAMIDE	**POLYALKYLIMIDE GEL**	**METHACRYLATE**	**SILICONE**
Evolution Argiform Bio-Formacryl ***Aquamid*** Amazingel	***Bio-Alcamid***	Dermalive Dermadeep Artecoll Artefill PMMA (Arteplast)	Silicone oil Bioplastique
Cystic	**Cystic**	**Infiltrating**	**Infiltrating**
These gels maintain in the subcutaneous deposits their state and form according to the original placement, with an in-growth of vessels and connective tissue. In years their color turn to yellow (similar to fat). **(FIGURE 4a)** Therefore the timing of onset of complications and need of removal is critical for the treatment choice. In a recently injected case it is possible to extract the material through a puncture or a stab incision. When the lesion is inflamed, intralesional laser treatment is administered in order to decrease or eradicate the bacterial load/biofilm and may help shrinking the pseudo-capsule and obliterating the cavity. In these cases a stab wound may be performed after the ILT. Particular care needs to be addressed to avoid an excessive heating of the product in order to maintain the integrity of the polymer chains. Claims have been made that monomers of polyacrylamide gels are potentially toxic/carcinogenic. Therefore we refrain from overheating these products as with silicone oil.		Methacrylates are made of solid particles, with a much higher theoretical melting temperature. A higher energy dose is usually needed to liquefy them together with the surrounding inflammatory tissue. However the heating process must be slow and gradual in order to avoid carbonization of the polymer-tissue-compound	Among the hydrophobic polymers this is the only one naturally present as a liquid substance. To obtain easy extrusion of the silicone through the microscopic holes made by the laser optic fiber, it is enough to increase its fluidity by raising its temperature to 50 degrees Celsius at most.

TABLE 2: characteristics of the lesions in the study population

Cystic	23%
Infiltrating	65%
Inflammatory	70%
Non-Inflammatory	30%

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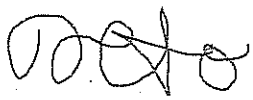
Daniel Cassuto Signed:  Date: 2.3.15

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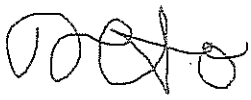
Daniel Cassuto	Signed:		Date: 7.5.15
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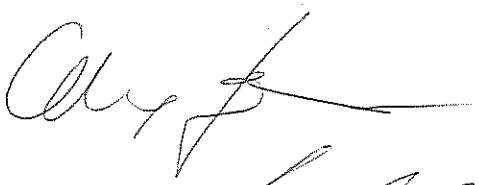
Giulia Boscaini	Signed:		Date: 7.5.15
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