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ORIGINAL ARTICLE NON-SURGICAL AESTHETIC

# Clinical Management of Complications Following Filler Injection

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**Abstract**

*Aim* Dermal fillers have been progressively used for cosmetic procedures. Concurrently, the rates of filler complications have also increased. The aim of this study is to describe the clinical management and treatment we performed in patients with complications occurred after filler injection.

*Methods* From March 2000 to February 2020, 197 patients have been evaluated for complications due to filler injection. For each patient type of material, symptoms and signs were recorded. Ultrasound evaluation was used to obtain information about the type, amount and location of the injected material. Magnetic Resonance Imaging was performed in those patients who were candidate for surgery. Based on the clinical manifestations, we performed a targeted therapy.

*Results* The local and systemic medical therapy allowed us a complete remission of the clinical signs and symptoms in all patients presented with edema and erythema. We obtained optimal results with surgery, where a complete removal of the injected material was possible. In all the cases in which the complete removal of the infiltrated area could have led to functional impairments, we performed partial removal with poor outcomes.

*Conclusion* We observed complex clinical manifestations in the patients subjected to permanent fillers. An accurate knowledge upon the effects of the materials on tissues, a specific instrumental evaluation and a targeted therapy are crucial. We suggest the use of absorbable fillers. Patient should be subjected to filler implant in authorized structures by an expert specialist with experience in filler injection and with a thorough knowledge of the anatomical structures.

*Level of Evidence IV* This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

**Keywords** Filler · Soft tissue complications · Siliconomas · Granulomas · Cosmetic procedures

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## Introduction

Dermal filler injections are classified as minimally invasive procedures. In the last decade, American Society of Plastic Surgery (ASPS) has collected data showing a significant increase in minimally invasive cosmetic procedures, principally focused on facial rejuvenation. The number of these procedures was up to 174% when comparing the data obtained from 2020 with those of 2000. In particular, 3.4 million of soft tissue injections were practiced in 2020.[1]

Like any medical procedure, fillers are not excluded from complications: they have been divided in immediate (up to 24 hours), early-onset (24 h to 4 weeks) and delayed (>4 weeks).[2] They can also be classified into mild, moderate and severe or by nature (ischemic or non-ischemic complications).

Fillers complications are influenced by physiochemical composition of the product. Furthermore, the physiologic body response to the filler itself plays an important role. Expertise of physician who carries the procedure out and the early identification of complications and their management are crucial.[3]

Fillers can be classified in biodegradable (moderate or long-lasting duration) and non-biodegradable (permanent). Hyaluronic acid represents the most popular biodegradable filler[4]. Non-biodegradable fillers are mineral oil, silicone, polymethylmethacrylate, etc.[5,6] Liquid silicone had been largely used in the last century: it gained popularity, but it had been related to several and serious side effects and it had been forbidden in European Union (EU) and United State of America (USA).[7,8] Despite any product has different properties and risks, knowledge of fillers and anatomy, proper planning and correct technique are the key points to reduce risk complications.[9]

Development of guidelines and recommendations for identification and management of complications following filler injection have been necessary to guide physicians for a safe and correct procedure.[2,9,10]

The aim of this study is to describe the clinical management and treatment we performed in patients with complications occurred after filler injection.

## Methods

From March 2000 to February 2020 197 patients (188 females, 9 males) had been evaluated at the Filler Complication Ambulatory of the Plastic Surgery Unit in Policlinico Umberto I, Rome.

Study included patients of any age who presented any kind of complications after soft tissue filler injection. The exclusion criteria were breastfeeding and pregnancy. The patients who refused the treatments were reported.

Informed consent was obtained for each patient.

Anamnestic data, clinical history and any previous treatments received were recorded for each patient. All the patients underwent previous procedures for cosmetic reasons.

Evaluated parameters were signs and symptoms of local inflammation, nodularity and paresthesia. At physical examination the following signs were recorded: erythema, edema, ecchymosis, skin discoloration, tissue necrosis, ulceration, nodularity at site of injection or distant from site of injection.

Ultrasound (US) evaluation was performed by the same operator using a 15 MHz linear probe.US examination documented the type, amount and location of the injected material. Magnetic Resonance Imaging (MRI) was performed with both 1, 5 Tesla and 3 Tesla magnets. It was indicated in surgical candidates, in order to have better details on the depth of infiltration and relationship between the filler and the surrounding anatomical structures.

Photographic documentation was collected during the first consultation and at each follow-up visit. Follow-up was at 1, 3 and 6 months and 1, 2 and 3 years.

### Therapeutic Protocol

Our protocol consisted of both local and systemic medical treatments, and surgery procedures. We proposed: "wait and watch" strategy in case of nodularity without signs and symptoms of inflammation. In all the cases with inflammatory reactions, we opted for local and/or systemic therapy. Local medical therapy consisted in methylprednisolone acetonate 1 mg (0, 1%) cream 2 times a day for one week or until clinical improvement. The systemic treatment consisted of oral prednisone (starting dose of 30–60 mg) in association with broad spectrum antibiotic (amoxicillin/clavulanic acid 1 gr for 10–15 days or minocycline 100 mg for 7–10 days or ciprofloxacin 500 mg for 12–15 days). Antibiotics were selected according to any referred allergies, comorbidities or any other medications the patient was subjected to. Posology and dosage varied on weight of the patients, hepatic and renal functions and severity of clinical cases.

In the patients with localized material/granulomatous reactions, steroid intralesional infiltration was performed. In these cases, diluted methylprednisolone acetate 40mg/1mg was injected. The procedure was performed with 1 ml syringe and 31/2 Gauge needle. A small amount (0, 005-0, 1 ml) of product was gradually injected, starting from the peripheral zones. The dose ranged from 1 ml to 5 ml, depending on severity of the injury and its extension.

In cases of abscesses lesions, the patients were subjected to intralesional drainage and the material drained from abscess cavity was sent to laboratory to perform microbiological culture.

Surgery was indicated in case of nodularity/granulomas associated with aesthetic and functional impairment. Material obtained during surgery was sent to histopathologic laboratory to be examined.

### Statistical Analysis

Categorical variables are presented as frequency or percentage, as appropriate. Continuous variables as mean (± standard deviation) or median (range). For categorical variables, the denominator is specified in every presented result. Statistical analysis was performed by using R v3.3.2 for Windows (The R Foundation for Statistical Computing, Vienna, Austria).

## Results

The time range between the first filler injection and the signs and symptoms appearance varied between 3 months and 35 years. In most of the cases, symptomatology consisted in pain, local tension and paresthesia.

All the treatments performed are summarized in Table 1. Among the 197 patients observed, 5 patients refused any treatment proposed. For 2 patients who did not show inflammatory reactions, filler migration or skin hardening at site of injection, we opted for "wait and watch" strategy (Figure 1). Fifty patients with mild erythema, edema and swelling, were treated with local medical therapy; 55 cases, who had shown moderate or severe edema, inflammatory granulomas or infections were subjected to systemic therapy (Figure 2).

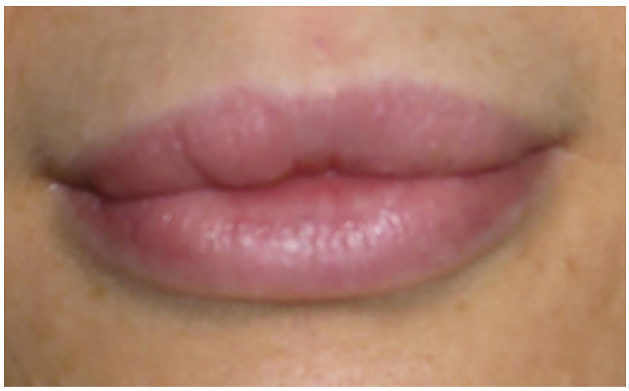

**Figure 1.** A 34-year-old female patient with filler complication. "Wait and watch" strategy.

In seven cases, when injected material was localized or granulomatous reactions were well-identified, we performed steroid intralesional infiltrations.

The more severe cases underwent surgical procedures: 6 abscess cavity drainages; 33 nodules or siliconomas removals (Figure 3, *left*). Six cases affected by massive and diffuse non-organized microcystic silicone nodules in the subcutaneous fat tissue were subjected to ultrasonic liposuctions. Eighteen patients were treated with blepharoplasty and canthoplasty, when fillers were injected or were dislocated in the orbital and palpebral regions; 13 patients, accurately selected, underwent endoscopic lifting; for 2 cases with skin necrosis and ulceration (Figure 3, *right*), debridement and skin grafting were performed.

**Table 1** Total cases and treatments performed.

| Complications | Total cases $N = 197$ | Treatment |
|---|---|---|
| Various | 5 | Refused any treatment |
| Nodule without inflammatory reaction | 2 | Wait and watch (no treatment required) |
| Mild inflammatory processes | 50 | Topical therapy |
| Moderate/severe inflammatory processes | 55 | Systemic therapy |
| Localized materials/granulomatous reactions | 7 | Intralesional infiltration |
| Abscesses | 6 | Drainage + systemic antibiotic therapy |
| Nodules/ foreign body granulomas | 33 | Surgical asportation |
| | | Total (14 cases) |
| | | Partial (19 cases) |
| Diffuse subcutaneous tissue infiltration | 6 | Ultrasonic liposuction |
| Orbital/palpebral region infiltration | 18 | Blepharoplasty/canthoplasty removal |
| | | Total (11cases) |
| | | Partial (7 cases) |
| Neck and chin infiltration | 13 | Endoscopic lifting removal |
| | | Total (9 cases) |
| | | Partial (4 cases) |
| Ulceration and skin necrosis | 2 | Surgical debridement + skin grafts |

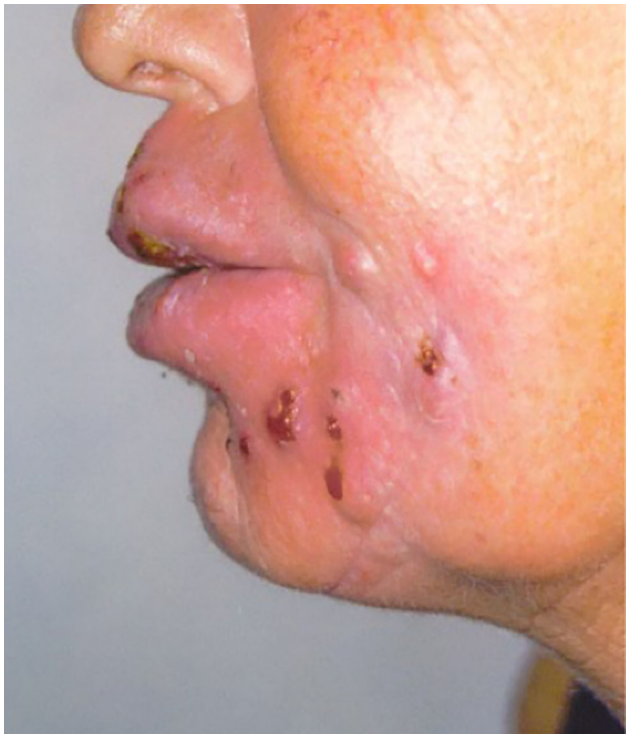

**Figure 2.** A 61-year-old female patient affected by infection at site of injection.

Type of fillers were classified in four categories (Table 2). Most of the patients were subjected to permanent fillers (70%).

Remission results are summarized in Table 3. In 50 patients who presented mild inflammatory process and treated with local medical therapy, we observed complete remission (100%) in a period between 5 and 7 days.

We obtained complete remission for moderate/severe inflammatory processes or infections (55 patients) with systemic therapy (Figure 4) and for localized granulomas (7 patients) with intralesional steroid infiltration in 2–8 weeks.

In six cases of abscess, cavity drainage and antibiotic therapy allowed to us to obtain optimal functional results and resolution of inflammatory symptoms in 2–4 weeks. In five cases, microbiological cultures showed Methicillin resistant Staphylococcus Aureus sensitive to Clarithromycin (MIC <0.25) and Streptococcus Pyogenes sensitive to Amoxicillin (MIC <0.5); in one case, laboratory identified Mycobacterium Chelonae sensitive to Clarithromycin (MIC <0.5).

In 33 patients treated with nodules removal, only in 14 cases the injected material had been completely removed, thus obtaining good functional and aesthetic results. In the remaining 19 patients, where a complete filler removal was not possible because of an increased risk of aesthetic and functional damages during surgery, we obtained poor outcomes. Among these 19 cases, a new exacerbation in signs and symptoms of inflammation was observed in 15 cases. US evaluation of these 15 cases documented a persistency of inflammatory tissue and material injected (silicone infiltrations in five cases) at level of the fascia and muscle.

The six cases treated with ultrasonic liposuction showed optimal results with thickness reduction at infiltration sites and relief from symptoms. We obtained good aesthetic

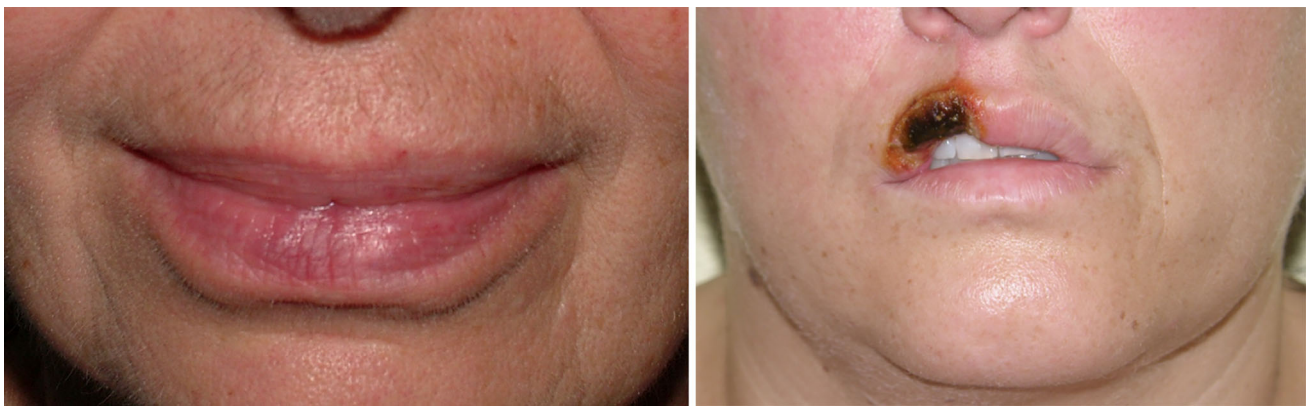

**Figure 3.** *Left* A 61-years-old female patient affected by siliconoma dislocation; *Right* A 50-year-old female patient affected by skin necrosis.

**Table 2** Injected fillers.

| Type of filler | *N* | % |
|---|---|---|
| Permanent fillers | 138 | 70 |
| Semi permanents fillers | 37 | 18,8 |
| Absorbable fillers | 12 | 6.1 |
| Non-identified materials | 10 | 5.1 |

*N* = sample size; % percentage

**Table 3** Complications and remission rate.

| Complications | Remission/affected | Remission rate |
|---|---|---|
| Mild inflammatory processes | 50/50 | 100% |
| Moderate/severe inflammatory processes | 55/55 | 100% |
| Localized materials/granulomatous reactions | 7/7 | 100% |
| Abscesses | 6/6 | 100% |
| Nodules/foreign body granulomas | 14/33 | 42.4% |
| Diffuse subcutaneous tissue infiltration | 6/6 | 100% |
| Orbital/palpebral region infiltration | 11/18 | 61.1% |
| Neck and chin infiltration | 9/13 | 69.2 % |
| Ulceration | 2/2 | 100 % |

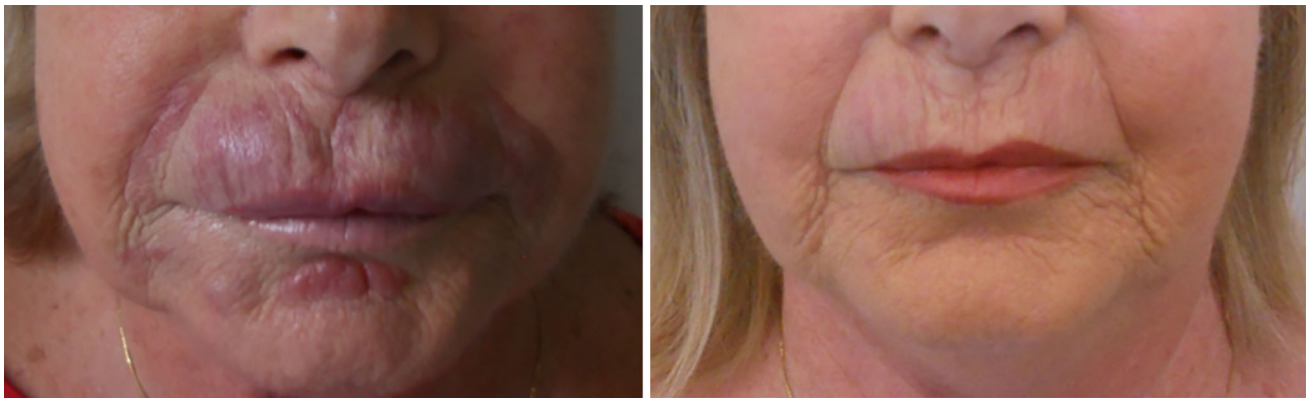

**Figure 4.** A 56-years-old female patient with severe granulomatous reaction after permanent filler injection (silicone). *Left* Pre-treatment. *Right* Complete remission after systemic antibiotics and steroid treatment.

result; thanks to the fact that no local additional scars were needed, postoperative complications were not recorded.

Among the 18 patients treated with blepharoplasty or canthoplasty, seven of them could not achieve a complete removal of the injected material not to damage important anatomical structures during surgery. It resulted in loss of motility in the frontal region accompanied with troubles in palpebral motility, still present after three years from surgeries.

Endoscopic lifting allowed us to achieve a complete resolution when it was possible to completely remove injected material in subcutaneous tissues (9/13 cases). Poor outcomes were obtained when the material was diffused to the fascia and mimic muscles, and it could not be safely removed (four cases).

Among the two patients with ulcerations, one case was treated with fistula removal, surgical debridement and skin graft.

In the case presented with skin ulceration (cm 5, 5x 3, 2) in the gluteal region, mechanical and chemical debridement allowed us to obtain a complete wound closure.

When silicone deposits were suspected, US evaluation detected hyperechoic pattern on the superficial planes. In fewer cases, deposits appeared as hypoechoic and anechoic confluent areas. When a limited soft tissue alteration was observed by US, MRI was not accomplished.

Fluid collections, showed as hypoechoic or anechoic at US evaluation, appeared hypointense in T1 weighted sequences and hyperintense in T2 weighted sequences. In comparison with simple fluid collections, they showed hypersignal when T2 weighted fat-suppression sequences (TSE T2 SPIR) were performed. Silicone-specific sequences with water and fat suppression (Turbo IR) showed these fluid collections as hyperintense.

Both US and MRI imaging findings varied on the base of dimension of silicone accumulations. US showed silicone micro globules as a diffuse hyperechoic pattern because of the different acoustic impendence between silicone and the surrounding tissues.

Small amount of silicone (5- to 10-mm diameter) were identified easier by US in comparison to MRI. Anyway, the echo graphic pattern did not allow us to identify the nature of different type of fluid collections. In our experience, MRI is a useful tool to overcome the US limits. Fat and water suppression sequences provided the highest contrast between silicone and the surrounding tissues, which made easier to identify the nature of the collection.

In our experience we detected the "snowstorm" pattern by using US when granulomatous reaction due to micro globules of silicone were found in the subcutaneous tissue. In these cases, inflammatory reaction was detected as hyperintensity in T2 weighted images by using MRI.

Histologic findings for silicon oil injection documented for foreign body granuloma with empty vacuoles (due to dissolved silicone after fixation procedures) surrounded by fibrous tissue, giant cells of foreign body type containing silicones and inflammatory cells.

Most of the patients with poor outcomes or no remission had been subjected to permanent materials injection.

## Discussion

Filler injections are considered a minimally invasive procedures, but they are not free from complications.

The physician has to describe all the possible complications of the filler to the patient before undergoing filler injection. Indeed, the patient must be aware of every detail of the filler injection, its complications, and possible results.[11] The plastic surgeon always has "*obligations of means*",[12] which must lead to a better result than the previous one. So, physician should guarantee the patient the best possible assistance and obtain the best aesthetic result based on the starting situation (physiognomy of the patient) and the techniques available. Physician must avoid giving the patient unrealistic expectations about the aesthetic result, avoiding claims and complaints by disappointed patients.

Aesthetic interventions are not urgent for the health of the patient. According to the jurisprudential orientation, the information given to the patient should be as accurate as possible.

These patients often present a psychological rather than organic problem, relating to an aspect of their body which they are not satisfied with.[13] Additionally, physician must be trustworthy and expert: the most malpractice claims are associated with medical negligence, usually due to incorrectly informed consent (mainly due to a superficial risk assessment).[14] Risk assessment of the potential adverse effect occurring during a medical procedure is a necessary step of doctor-patient communication.[15]

Aesthetic procedures are generally a private event between patient and doctor, and often it happens in private clinics. Official data are hard to find,[13] so it is difficult to estimate the risk in terms of professional liability.

Before the procedure, anamnestic data and physical examination of patients should be collected, fillers to inject should be accurately selected and allergies tests should be performed, when needed. Pre-treatment procedures should be accurately carried out.

An informed consent should be taken. It should include detailed information about the filler, the procedure, indications and possible complications. Pre-treatment findings should be documented.[16]

Approval status asserts the safety and the authenticity of the products.

All these procedures are important to let the patients understand that fillers are medical devices and the physician should be sure that the patients are well aware of this.

A great number of fillers is now available on the market. A review article identified that biodegradable soft tissue fillers produce immediate and short-term reactions; as opposed, for non-biodegradable ones long-term cutaneous reaction (such as granulomatous) can occur.[17] Illegal fillers have been associated with chronic onset complications.[18,19]

In the last decades, the literature has widely described the use of illegal fillers, not approved by Conformitè Européenne (CE) or Food and Drug Administration (FDA). Injection of unapproved materials for body contouring has become epidemic in several countries all over the world.

"Foreign modelling agent reaction" (FMAR) is a clinical consequence of different unapproved high-viscosity fluids: skin necrosis, ulceration, deformity can be its manifestations. Migration of particles through the vessels can lead to death, when pulmonary embolization occurs.[20]

Despite several disastrous consequences has been described in the literature, liquid silicone injections are still illegally performed for body contouring: side effects can be life-threatening and need in-patient recovery, different surgeries, local and systemic therapies.[21] In these complex cases, it is unlikely to obtain both functional and aesthetic satisfactory results.

Granulomas and fullness due to excessive or incorrectly placed substances were recorded after polymethylmethacrylate (PMMA). These cases seemed to respond quite well to intralesional steroid injections.[22] In our study, four localized granulomatous reactions were successfully treated with intralesional steroid injections.

Foreign body granuloma characteristics vary depending on the fillers used. Low rate of incidence was recorded after bovine collagen filler injections. Paraffinomas and siliconomas can occur, respectively, after 20 and 15 years from injections. Identification of histologic features is required to perform a differential diagnosis to allow the proper treatment.[23]

Vascular complications which led to soft tissue necrosis, impending necrosis and visual impairment have been associated with various types of filler, such as hyaluronic acid (HA), collagen, calcium hydrolylapatite (CaHa) or polymethylmethacrylate (PMMA).[24]

Imaging can offer an important view in localizing injected material and its distribution in the anatomic

structures. US has the ability to identify filler agents, their size and their presence in the skin or even in ectopic sites.[25] Furthermore, it can provide specifics about the nature of material or inflammatory reactions.[26] Echography should be the first line imaging technique to investigate cosmetic fillers and their complications.[27] It should be performed by an expert radiologist, specialized in soft tissue and who is familiar with filler injections. US evaluation may become an integral part in the prevention and management in vascular occlusion during after dermal filler injection.[28] In our study, patients were evaluated by using both US and MRI. We selected MRI when patients were proposed to surgery, with the aim of a better identification of the fillers and their distribution. MRI, however, should not be considered as first imaging technique. Kadouch JA et al. suggested to use MRI when complex cases are identified, complications related to permanent filler migration are suspected or when surgery is indicated (with low to moderate indication).[29] Nevertheless, MRI has shown ability in accurately identifying injected facial materials.[30,31]

Several protocols have been developed to manage any sort of complications.

When acute inflammation or infection are suspected, broad spectrum antibiotics should be prescribed. First line therapy for abscess is drainage and antibiotics. If delayed onset infections are encountered, a microbiological culture and sensitivity tests should be performed.[2]

When it comes to granulomas, surgical treatment is not considered first line therapy.[23] It allows good results, when complete removal of material can be performed.

Ultrasound assisted liposuction had been demonstrated to be a useful tool when surgical excision could not achieve an aesthetic and functional satisfactory result. It may be used to remove silicone in areas which have been diffusely infiltrated. Relieves from symptoms can be reduced after the first treatment and it can be safely repeated.[32–34]

Vascular complications are infrequent but severe: symptomatic arterial occlusion involves necrosis, ophthalmoplegia, permanent vision loss and even stroke. Prevention and prompt treatments have been analyzed and summarized in the literature.[35] Early detection of filler intra-vascular injection is necessary. The signs and symptoms after arterial embolization are usually skin blanching in geographic distribution and intense pain at the site of injection, while venous congestion is characterized by delayed, dull pain and dark discolouration.[36]

This complication seems to be connected in particular to the amount of injected filler and not necessarily to its composition.[37]

Hyaluronidase is the mainstay of treatment when HA filler has been injected.[37] Various are the indications, such as vascular occlusion, Tyndall effect, unacceptable cosmetic outcomes or late delayed nodules. When it comes to vascular occlusions, hyaluronidase should be administered as soon as the complication occurs (within four hours). Complication can be prevented or reduced in severity if treatment is administered within 48 hours.[38]

## Conclusions

Dermal fillers play an important role in cosmetic procedures. A correct identification of complication and the choice of a tailored therapy allowed us to achieve good results in most of our cases. Clinical detection of complications is the first line but sometimes imaging evaluation, such as US and MRI, is needed. Ultrasound evaluation should be the first line technique to identify the materials injected, their amount and their distribution in the anatomical structures. MRI should be used when surgical treatments are indicated.

We performed a targeted therapy based on clinical manifestations and imaging evaluation when it was needed.

Local and systemic medical therapy are of considerable importance when, respectively, mild or moderate and severe inflammatory processes are detected. Steroid therapy (both systemic and topical) plays an important role in acute manifestation's resolution. Despite this, it is important to be aware of chronic steroid administration being related to long-term side effects.

Surgical therapy allows, whenever possible, the removal of nodules. Ultrasound assisted liposuction may be safely used when a diffuse soft tissue infiltration is recorded.

When silicone or other permanent materials are localized in deep structures (fascia, muscle), their asportation is not possible without a high risk of functional loss or disfigurement. In these cases, conservative treatments are recommended in order to obtain symptoms relief. Poor outcomes were recorded when partial removal of injected material was possible.

It is of paramount importance to take into account that some nodules or granulomas, such as siliconomas, should be considered as foreign bodies and so they could be colonized by bacteria, even when a probable inflammatory process is distant from the injection site (i.e., in course of tonsillitis, cystitis). In these cases, antibiotic therapy is highly suggested. Antibiotic prophylaxis is recommended before a probable invasive procedure.

All type of filler injections can be associated with complications. Complex clinical manifestations have been observed in patients who were subjected to permanent fillers, so the use of absorbable materials is suggested. Permanent fillers, such as silicone, have been mostly associated with delayed and long-term complications. The use of biodegradable fillers is more frequently associated

with immediate and short-term complications, such as infection.

Filler injection should be performed in authorized structures by an expert specialist with experience in managing probable filler complications and with a thorough knowledge of the anatomical structures. It is necessary to inform the patient about every aspect of the intervention. A person uncomfortable with their physical appearance may decide to undergo surgery. The patient may ask the surgeon about unattainable results. The healthcare professional has the duty not to promise the patient unrealistic results, considering every possible complication.

**Acknowledgment** The study was conducted in accordance with the 1964 Helsinki declaration.

**Declarations**

**Conflict of interest** The authors declare that they have no conflicts of interest.

**Informed consent** Informed consent was obtained from all participants.

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