Diagnosis and Management of Filler Adverse Effects: An Algorithm

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Abstract

Fillers are frequently used in beautifying procedures. Despite major advancements of the chemical and biological features of injected materials, filler-related adverse events may occur, and can substantially impact the clinical outcome. Filler granulomas become manifest as visible grains, nodules, or papules around the site of the primary injection. Early recognition and proper treatment of filler-related complications is important because effective treatment options are available. In this report, we provide a comprehensive overview of the differential diagnosis and diagnostics and develop an algorithm of successful therapy regimens.

Keywords
- injectable fillers
- side effects
- granuloma
- differential diagnosis
- treatment

After neurotoxins, fillers rank on the second place of beautifying procedures. It is an old wisdom that nothing with substantial efficacy does not—from time to time—cause adverse events as well. However, many side effects can be prevented obviating disappointment and ultimately litigation. Some fillers are more prone to cause adverse effects than others, but in principle, any injection, even of autologous material, introduces substances that are first recognized as foreign material. Sometimes, an objective measurement is necessary, which may require three-dimensional scanning.[1] The importance of an in-depth patient history cannot be overestimated and it is central to know whether other procedures have been performed at the same time or previously.[2] As most fillers are indeed predominantly injected into the facial area, an algorithm is given for this particular region. In this article, we present an algorithm for differential diagnosis, diagnostics, and treatment of frequent side effects of injectable fillers.

Differential Diagnosis of Filler-Related Adverse Events

The most important visible filler side effects are swelling, bruising, necrosis, and ulceration.

Swellings are by far the most common and most diverse adverse effects. Important differential diagnoses are listed in ►**Table 1**. This table does not list congenital and other swellings that can easily be differentiated from filler-related complications, such as swellings in children or in the critically ill. The potential differential diagnoses responsible for facial swellings are numerous. It has to be kept in mind that some conditions, such as hereditary angioedema or Melkersson–Rosenthal syndrome can be provoked by the trauma of the injection procedure or by foreign bodies. Immunotherapy was also observed to induce granulomatous reactions to permanent fillers that had been well tolerated for many years. Fever is usually a sign of infection as in erysipelas and sometimes in abscesses, although "cold abscesses" do occur. Ultrasound did not substantially improve the differential diagnosis of solid swellings and cystic lesions such as abscesses. A skin rash may accompany the swelling. Overlying erythema may be a sign of a localized effect, whereas widespread skin lesions may point towards allergic reactions or a random association. An immediate onset is usually a sign of too much injected material, whereas appearance within a few hours or days may be due to allergic reaction. Granulomas and abscesses take many days to several weeks to develop clinically. In case the injected filler was a hyaluronan,

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Table 1 Differential diagnostic evaluation of facial swellings that may be related to filler injections

Swelling	
Family history of swellings and urticaria	Positive/negative
Atopy	Positive/negative
Medication	Yes/no[25,26]
Lymph node swelling	Yes/no
Previous injections	Yes/no[27]
Diffuse	
Onset	Acute/insidious
Event[28]	Single/recurrent
Fever	Yes/no
Skin rash	Yes/no[29]
Papules and pustules	Yes/no[30]
Previous surgery	Yes/no[31]
Localized	
Previous injections[32]	
Hematoma	
Constitutional symptoms	Yes/no[33]
Pain	Yes/no[34]
Paresis	Yes/no[35]
Orofacial granulomatosis (Melkersson–Rosenthal syndrome,[36,37] Crohn disease), oral mucosal lesions	Yes/no
Salivary gland infection	Yes/no
Abscess, infection[38]	
Arthropod assaults[39]	
Dental treatment	Yes/no[40,41]
Tumor, lymphoma	Yes/no[42]

hyaluronidase injection will correct the overdose within a few hours.

Bruising (►**Table 2**) is a common sequel of any injection, and short-lived minor bruises are not listed as a major adverse side effect. However, as soft tissue augmentation is often performed in middle-aged and elderly persons, intake of anticoagulants may be expected and has to be asked for. For a long time, they have been judged as a contraindication for intramuscular injections. It is therefore reasonable to assume that they may increase the risk of major bruises and even large hematomas. These may, in turn, give rise to infection, necroses, and ulceration. Bruises usually disappear within a few weeks depending on their size and localization. Typical is a color change and the swelling may migrate downwards following gravity. Whether or not evacuation of the hematoma is necessary depends on the amount of blood.

Necroses (►**Table 3**) may be due to inadvertent intravascular injection or pressure on blood vessels by the injected material.[3] Hyaluronic acid can be dissolved and degraded by hyaluronidase, which should always be readily available in any practice injecting hyaluronans. It should be injected immediately into the area where the filler has been placed. It has not yet convincingly been proven if the intravenous hyaluronidase infusion is feasible and efficient.[4] It is advisable to use higher doses as these have a faster onset of action.[5] Surgical debridement should be done very cautiously as some of the discolored skin may still recover, particularly areas with epitheliolysis only.

Ulcerations (►**Table 4**) usually develop from preexistent necroses and their treatment depends on the underlying condition. For instance, if the ulceration is due to hyaluronan, injection of hyaluronidase is the treatment of choice.

Papules and nodules may occur immediately and represent just overfilling or are a sign of an uneven injection technique. Frequently, however, papules, nodules, and infiltrates are characteristic signs of chronic inflammatory processes, most commonly of a granuloma or abscess. They represent late complications, some of which may be allergic whereas most are due to chronic histiocyte/macrophage stimulation. In contrast to acute inflammatory conditions, they are usually not warm or inflamed. The history of their development is critical for the correct diagnosis. We would like to emphasize that these complications may occur after injection of any filler, both temporary as well as permanent, and probably without major differences in frequency. However, most of the nodules due to temporary fillers have a limited period of persistence.

Diagnostics

Most patients seeking consultation for filler complication treatment received an external injection. Thus, taking a thorough and specific history is a central cue to the correct diagnosis.

Depending on the onset and the clinical appearance of filler side effects, several different diagnostic means are used. Whereas symptoms such as swelling, bruising or a certain sensation of pressure does not require therapy, a variety of local and systemic treatment options are available in case of moderate and severe complications. These include blood tests and microbiological examinations in case of suspected bacterial infection or if systemic reactions such as fever, headache, muscle pains, fatigue, and malaise are present.

Modern imaging methods and analyses improve the accuracy of differentiated topodiagnosis (►**Fig. 1**).[6] B-mode ultrasound examinations have their special value in the assessment of nodular formations in terms of abscess and lymph node diagnostics and in the therapeutic follow-up. Together with modern nuclear medicine, including white blood cell scintigraphy, high-resolution computed tomography, and magnetic resonance imaging, it is possible to differentiate between infection, granuloma formation, and fibrosis these days.[6–12] Despite these advancements in accurate imaging, the ultimate identification of certain filler substances—if not evident from the patient's history—require histopathological investigation (►**Fig. 2**), or optionally characterization by chromatography, mass spectrometry, or capillary electrophoresis.[10]

Table 2 Differential diagnostic considerations of major bruising that may be related to filler injections

Major bruising	
Family history	Positive/negative
Anticoagulant therapy	Yes/no
Lymph node swelling	Yes/no
Previous injections	Yes/no
Diffuse	
Fulminant sepsis	
Localized	
Hematoma from injection	
Puncture of a larger vessel during injection[43]	

Table 3 Differential diagnostic evaluations of facial necroses that may be related to filler injections

Facial necroses	
Family history	Positive/negative
Medication	Yes/no
Lymph node swelling	Yes/no
Previous injections	Yes/no
Diffuse	
Necrotizing fasciitis[44]	
Localized	
Inadvertent intravascular filler injection	
High tissue pressure from injected material and/or swelling	

Table 4 Differential diagnostic evaluations of ulcerations that may be related to filler injections

Ulceration	
Local infection	Yes/no
Lymph node swelling	Yes/no
Previous injections	Yes/no
Constitutional symptoms	Yes/no
Diffuse	
Multiple ulcerating infiltrates/tumors	
Localized	
Intravascular injection	
Pyoderma gangrenosum	
Atypical mycobacteriosis	

Treatment Options

The selection of an appropriate treatment regimen in filler-induced adverse events depends on filler material, clinical onset of complications, the duration of granulomas, localization, and degree (►**Table 5**). For instance, it makes a big difference whether a swelling and induration occurs one day after treatment with pure hyaluronic acid or a few months after polymethyl methacrylate injection.

Among the most serious adverse effects are prolonged blanching followed by painful vascular compromise, necrosis[13] or ulceration, blindness[14] due to vascular injection in the glabella and granuloma tissue formation.[15] Using blunt cannulas for injections instead of sharp needles markedly reduce the risk for intravascular injections and vascular compromises,[16] avoidance of the use of more than one filler at the same time and the same injection site in general diminishes the complication rate. Unpleasing aesthetic results belong, strictly speaking, not to filler complications, but should be treated similarly. In the vast majority of cases, they are due to asymmetric augmentation or overfilling with hyaluronic acid. Because of its hygroscopic

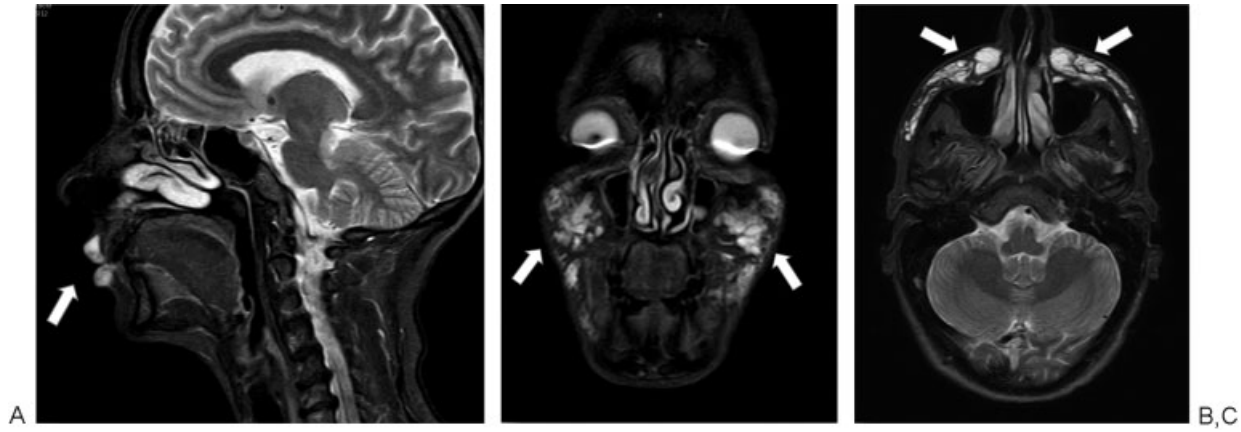

Fig. 1 Assessment of the distribution of hyaluronic acid after lip (**A**) and cheek augmentation (**B, C**) using magnetic resonance imaging with fat-suppression technique.

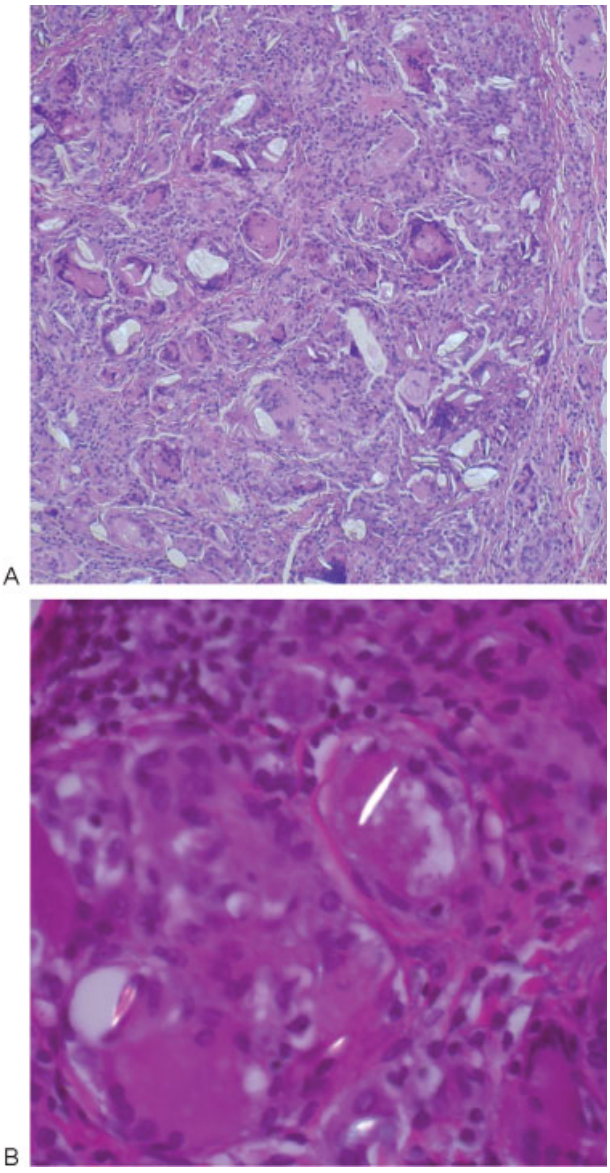

Fig. 2 Varieties of histopathological findings in filler granulomas. (**A**) Granuloma after Dermalive injection showing giant cells and lymphatic infiltration. (**B**) Granuloma due to poly-L-lactic acid presenting multinuclear giant cells and needle-like birefringent structures. HE staining, ×400.

chemical features, an apparently good result immediately after injection may change towards a mediocre outcome on the following day. Particularly, the periorbital area with loose connective tissue is prone to develop swelling and edema exposing visible overcorrection (►**Fig. 3**).

Local injection with hyaluronidase (Hyalase [Riemser Pharma, Greifswald, Germany]), the antidote of hyaluronic acid, will effectively solve this problem.[17–19] The solution for injection contains 75 U/0.5 mL NaCl added to 1.5 mL lidocaine, supplemented with 1% adrenaline. In general, 5 to 50 U of hyaluronidase are used per nodule. Response to injection can be expected within 24 to 72 hours, reinjection after 1 week is possible.

To quickly and most effectively treat severe early adverse effects such as vascular compromise physicians should be

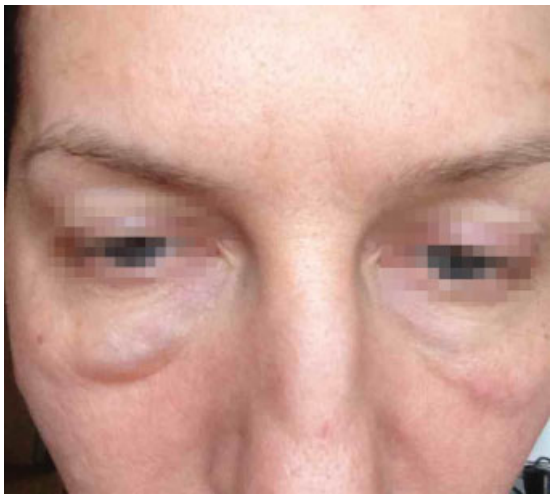

Fig. 3 Overtreatment with volumizing hyaluronic acid. Photo taken 1 day after the treatment.

trained in early detection and medical handling. Agents such as nitro paste or hyaluronidase (►**Fig. 4**) and cool or warming pads should be ready to handle.

The treatment modalities of granulomas are different. They require great experience and proper selection of a treatment regimen out of many possibilities (►**Table 6**). Interdisciplinary planning and profound knowledge of the pharmacology of eligible agents are basic conditions for a successful outcome. The first-line therapy of granulomas is based on the intralesional injection of crystalline steroids, even despite the risk of skin atrophy. Topical immunomodulating agents and immune response modifiers such as imiquimod (Aldara, Zyclara), 0.1% tacrolimus ointment (Protopic), and pimecrolimus cream (Elidel) are best suited for initial therapy of superficial granulomatous inflammation (►**Fig. 5**).

In cases resistant to steroidal and immunomodulatory treatment, mostly side effects of permanent fillers, intralesional 5-fluoruracil (5-FU) injections can be considered[15,19] (►**Fig. 6**). A possible solution for injection contains 0.8 mL 5-FU 250 mg/mL added by 0.1 mL triamcinolone 10 mg/mL and 0.1 mL of 1% scandicaine. In patients with permanent recalcitrant filler granuloma, this treatment may be combined with the oral administration of allopurinol.[20] Initially 200 mg/d is given in the first 2 weeks, followed by an increase to 400 mg/d in week 3, and a further increase to 600 mg per day from week 4 as maintenance dose. This treatment extends several months, depending on the clinical course. It may be flanked by systemic corticosteroids in acute inflamed granulomas as well as and antibiotics if superinfection is suspected clinically.

Surgical excision of granuloma tissue formation is an option of last resort, if all other conservative treatment options fail. Dangerous filler migration, tumor growth, and increasing aesthetic compromise are some indications (►**Fig. 7A**). Due to the finger-like growth pattern of the diffusely distributed filler substances, the recurrence rate is high and complete removal cannot be achieved in most cases.

Table 5 General treatment recommendations in filler side effects

Clinical symptom	Therapeutic strategy
Physiological reactions such as swelling, sensation of pressure	Cooling, nonsteroidal antiphlogistics
Overtreatment of hyaluronic acid (HA)	Hyaluronidase (Hyalase) = antidote of HA
Asymmetry	Touch-up filler injection, in case of HA localized hyaluronidase injection
Vascular compromise	Nitro paste, acetylsalicylic acid, heparin-infusion, warming, hyaluronidase after HA
Necrosis, ulcerations	Sterile, antiseptic wound treatment, surgical debridement
Hematoma	Heparin ointment
Discoloration	Bluish discoloration due to vessel dilatation: intense pulsed light (IPL), laser
Nodules	Puncture to distinguish sterile from bacterial abscess
	Sterile abscess: intralesional corticosteroids (cave atrophy), excision of superficial nodules resistant to topical therapy
	Suppurative abscess: antibiotics, incision
Hypertrophic scar at injection site	Intralesional steroid, dermabrasion
Granuloma	Anti-inflammatory and/or immunomodulatory therapy, surgical removal
All kinds of side effects	Compelling information on treatment, medicolegal aspects, and payment Good psychological support

Beside all therapeutic efforts, proper patient selection may prevent from later calamities. Patients suffering from acute systemic infections or skin infections at injection sites, known allergies to injection materials or egg white, severe autoinflammatory disorders, and major cardiac dysfunction should not be treated, neither those reporting multiple intolerance reactions.[21,22] If allergic reactions are suspected clinically, skin testing has to be considered

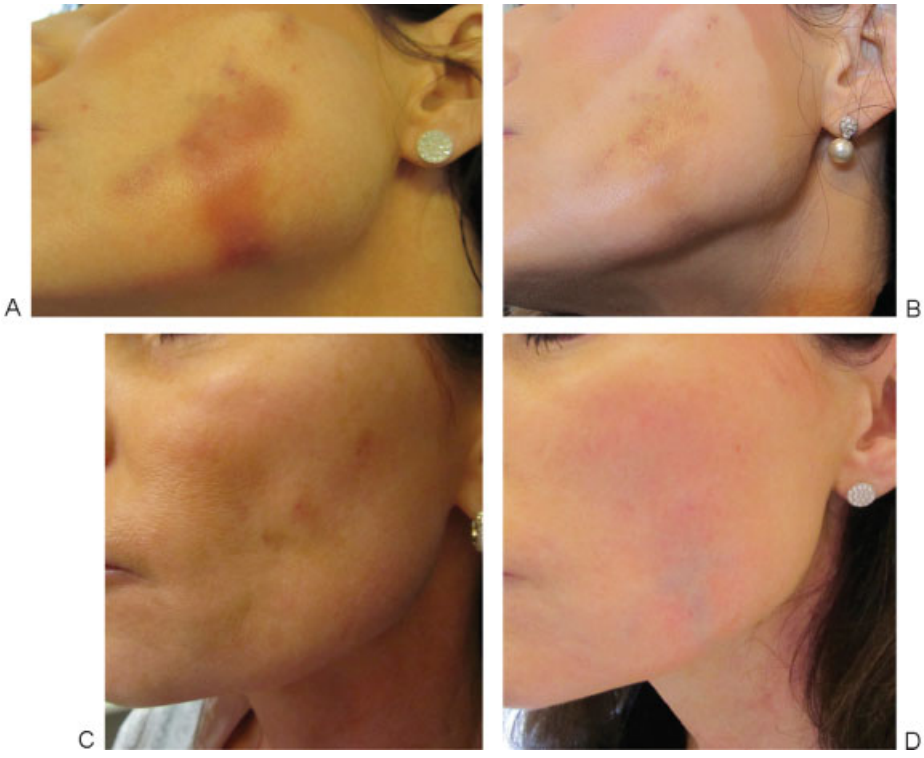

Fig. 4 Vascular compromise due to injection of hyaluronic acid with a sharp 27 G needle. After development of a painful blanching, the concerned area of facial artery and vein was injected by Hylase Dessau 150 U/mL NaCl and also superficially treated with the vasodilative nitro paste. Pain and swelling quickly decreased, but on day 1 after treatment (**A**) the patient presented with a dusky red discoloration, with significant relief on day 3 (**B**), day 7 (**C**), and day 14 (**D**). White area shown in (**B**) resulted from the removal of makeup.

Table 6 Therapy options in filler-induced granulomas

Hyaluronidase for treatment of hyaluronidase injection-induced granuloma	Solution for injection: 75 U/0.5 mL NaCl + 1.5 mL lidocaine supplemented with 1% adrenaline Use 5–50 U hyaluronidase per nodule Response to injection can be expected within 24–72 h, reinjection after 1 week possible
Topical immunomodulating agents and immune response modifiers (imiquimod: Aldara, Zyclara; tacrolimus: 0.1% Protopic ointment; pimecrolimus: Elidel cream) for superficial granulomatous inflammation	Treatment twice daily for a minimum of 14 d Treatment duration up to several months in case of good response
Intralesional triamcinolone (10 mg/mL) in bigger nodules caused by degradable or permanent fillers	Initially, 0.1 mL per granuloma in weekly intervals (up to 4 wk) In case of good response, injections should be performed monthly for 3–6 mo (cave of skin atrophy)
Intralesional 5-fluoruracil (5-FU) injections for granuloma due to permanent fillers (Dermalive, and so on) (Protective eyewear during injection procedure)	Solution for injection: 0.8 mL 5-FU 250 mg/mL + 0.1 mL triamcinolone 10 mg/mL, supplemented with 0.1 mL scandicaine 1% At maximum 1–1.5 mL each session Therapy at weekly intervals initially, intervals can be expanded in the course of treatment Duration of treatment: months to years
Oral allopurinol for permanent filler granuloma, where applicable combined with 5-FU injections	200 mg/d in the first 2 wk, increase to 400 mg/d in wk 3, and further to 600 mg/d from wk 4 as maintenance dose Duration of treatment: months
Systemic corticosteroids in acute inflamed granuloma, for example, after polylactic acid (Sculptra)	Prednisolone 20–80 mg/d, adjusted to body weight Duration and tapering: up to 4 wk depending on the clinical course
Surgical excision as final treatment option	
Oral antibiotics if superinfection is suspected clinically	Cefuroxime 500 mg twice a day

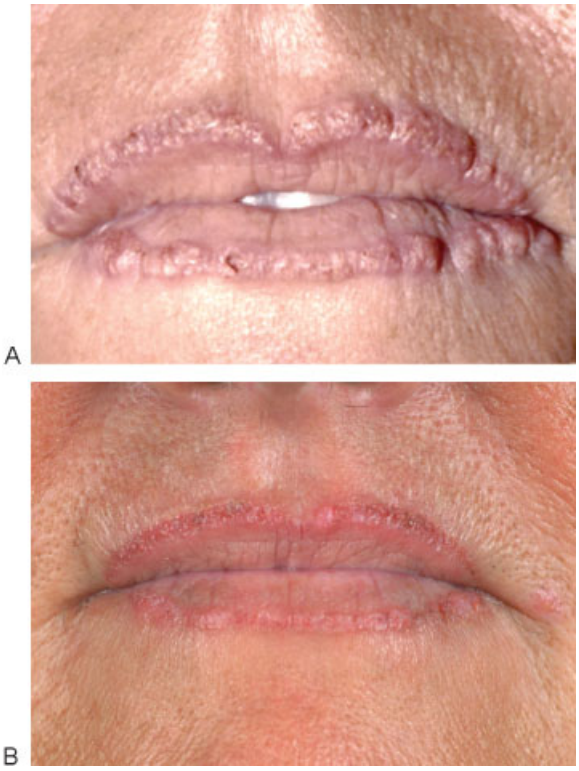

Fig. 5 Granulomatous inflammation due to permanent makeup (**A**). Good remission after local immunomodulatory treatment with pimecrolimus cream (Elidel) for 2 weeks, twice daily (**B**).

in advance.[23,24] To keep the risk of a filler side effect as low as possible patients are advised to refrain from extensive sun exposure, sauna, and substantial physical exertion.

Not to be forgotten in the context of filler complications are medicolegal aspects. Patients must be informed about all possible complications and informed consent must be obtained before injection. Also, they should be advised that all costs of treatment have to be covered at their own expense, since aesthetic procedures and their complications are non-insured medical events.

A good psychological support from the very beginning of the onset of a filler side effect is just as important as medical care. It is of paramount importance to provide the patient with all necessary information. This should be best done in a reassuring but concise way in an empathetic and professional atmosphere.

Whenever signs of psychological decompensation first appear the indication of immediate psychiatric treatment should be considered.

Conclusion

The use of injectable fillers in aesthetic medicine is safe if applied professionally according to the principles of good clinical practice. Before injection, patients should be comprehensively informed about the actual procedures.

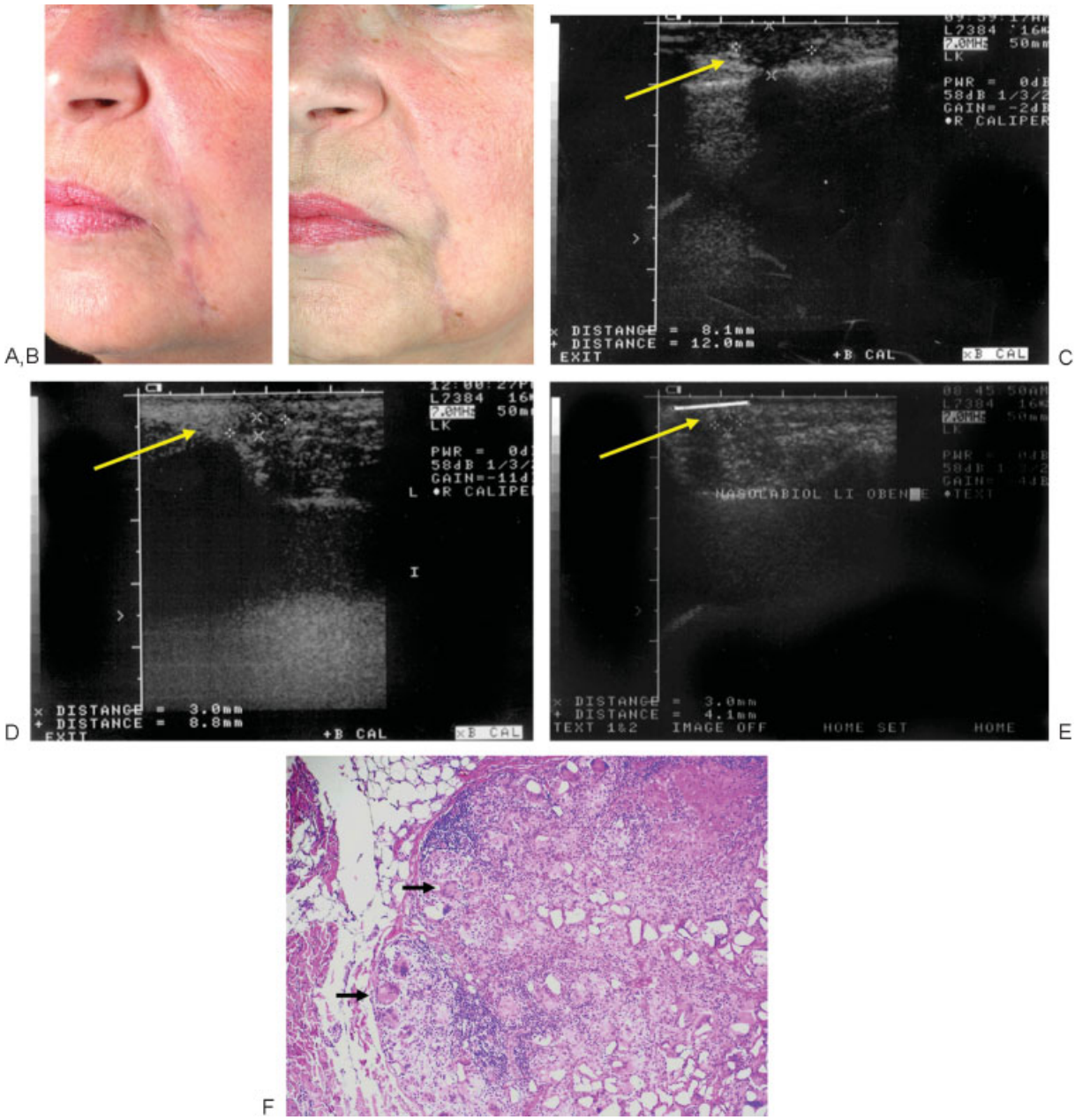

Fig. 6 Successful treatment of a patient suffering from therapy-resistant granulomas after Dermalive injections (hydroxy-ethyl-methacrylate, ethyl-methacrylate, hyaluronic acid) into the nasolabial fold 7 years after injection. Clinical view before (**A**) and 6 months after therapy (**B**) with 5-fluorouracil (5-FU). Intralesional injections of 1 to 1.5 mL of 5-FU 250 mg/0.8 mL, supplemented with triamcinolonacetonid 0.1 mL and scandicaine 1% 0.1 mL, according to the treatment scheme of Table 6. Sonographic checks before (**C**), after 7 months (**D**), and 9 months (**E**) show significant reduction of granuloma formation. Biopsy taken before treatment shows foreign-body giant cells (*arrows*), macrophages, and lymphatic infiltration (**F**).

Filler-related adverse events should be part of the informed consent, specifically, granulomas, papules, nodules, subcutaneous swelling, bruising, necrosis, and ulceration. If these side effects are recognized early prompt therapy should be initiated, based on the clinical symptoms and the injected materials. Proper handling can help to improve the clinical outcome and mitigate disappointment. Hyaluronic acid-products have found to be the safest fillers and the only ones with a real antidote.

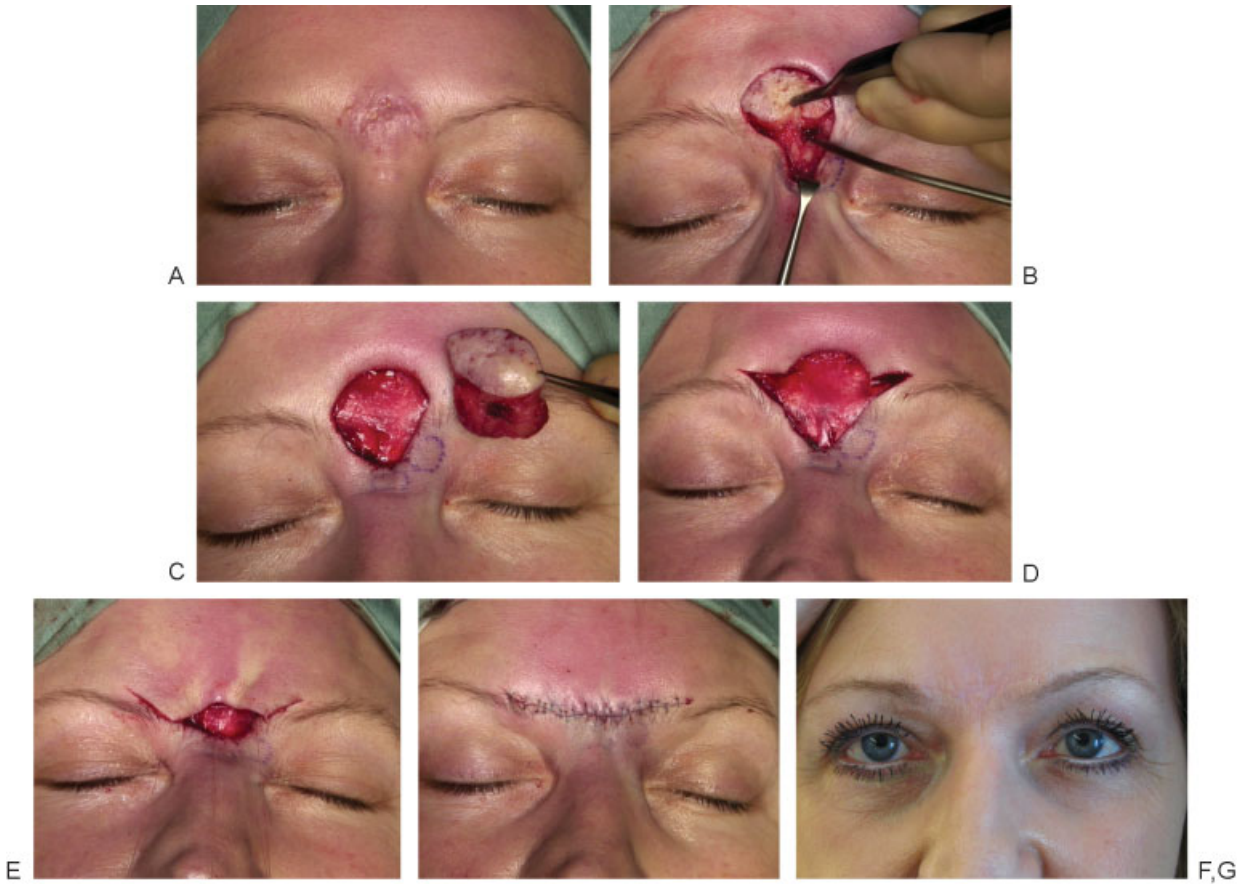

Fig. 7 Therapy-resistant supperative granuloma in the glabella area with tendency to migrate into the upper lid. (**A**) Clinical view before surgery, (**B**) dissection, (**C**) situs after tumor excision, (**D**) tailoring of the defect, (**E**) closure of the defect after wide undermining of the adjacent tissue by stretch plasty, (**F**) complete closure, (**G**) aesthetically pleasing result with scars running along relaxed skin tension lines. (Image courtesy of Werner J. Heppt).

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