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Systematic review

Introduction to the management of intravascular filler injection, including support for Intra-Vascular Combination Management (IVCM)

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Abstract. *Background:* dermal filler popularity comes with an increased risk of adverse events including blindness and death, through inadvertent intravascular injections. Existing treatment modalities are not as reliable as we would like them to be. *Aim:* to explore existing preventative measures and treatments for intravascular obstruction and to define, support and propose a definitive treatment that injecting practitioners can rely on. *Method:* a review of the existing evidence was performed taking into consideration the authors' experience to provide a summarised suggested protocol for the prevention and management of intravascular filler injections. *Results:* preventative steps, in room management and referral instructions are provided for practitioners along with a description of the supported neurovascular management. *Conclusions:* given the evidence of existing treatments for the management of strokes, arterial occlusion, combined filler dissolution and intravascular thrombolysis in animals, emboli and filler, there exists sufficient evidence to support the use of intravascular thrombolytics and hyaluronidase in combination with mechanical thrombectomy to treat intravascular fillers and their accompanying thrombi and emboli.

Key words: dermal fillers adverse effects, arterial occlusion, mechanical thrombolysis, blindness, embolism, reperfusion

Introduction

Background and literature review

Growing numbers of aesthetic procedures, such as soft tissue fillers, are performed annually. Fillers can be used for volume correction and enhancement. The materials which are mostly used include autologous fat, hyaluronic acid (HA) gel and calcium hydroxylapatite, to name a few[14].

The purpose of this paper is to raise awareness amongst practitioners of the existence of a viable and reliable treatment that is available to their patients if they encounter a vascular occlusion, as well as to provide a simple guide which references existing literature, to recognize approach treatment and access the specialized neuro-vascular surgery service. The second purpose of this paper is to support the theoretical treatment by providing evidence from treatment modalities in other conditions or settings, such that their real-world implementation and combination seems most suitable.

Possible vascular dermal filler complications

These procedures are mostly safe, although cosmetic facial filler injections could lead to devastating complications such as blindness[11]. Injecting filler directly into arteries can lead to serious complications, including:

Vascular Occlusion is one of the most significant risks of arterial filler injections, where the filler material obstructs blood flow in the artery. Soares[24] suggested

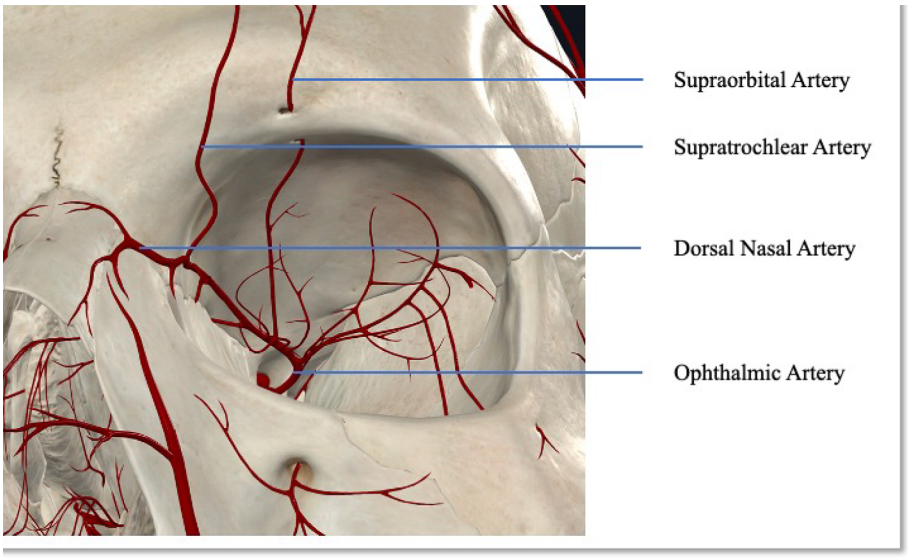

Figure 1. Important vessels related to blindness. Image courtesy of complete anatomy.

that filler-induced vascular occlusion represents an impending tissue infarction caused by the unintentional administration of dermal filler into an artery which causes distal embolization, thrombosis, and potential spasms of the affected artery. Filler material injected into the arteries can embolize to distant sites. Ocular and cerebral embolism can occur when the filler travels from the distal injection site to proximal retinal and ophthalmic arteries, leading to sudden pain, blindness, a possible stroke, and tissue necrosis (Refer to Figure 1 for the arterial blood supply to the eye).

According to Paolini and Kenmuir[22], central retinal artery occlusion is a cause of acute vision loss, that can lead to permanent blindness. It has been stated by Hayreh et. al[9] that timing is important when it comes to treatment, as it has been measured that in some cases there is no permanent vision loss recorded for the first 97 minutes of occlusion. Nonetheless, if the occlusion period lasts between 105-240 minutes, patients may be left with partial vision loss. Irreversible vision loss has been recorded after an occlusion period of 240 minutes. Occlusion of the ophthalmic artery and its branches have been classified into six types, based on the origin of fluorescein angiographic findings, and found that the more diffused occlusion type was linked with poorer visual consequences.

The supratrochlear and supraorbital arteries are believed to be the potential route for retrograde embolism in the glabellar region and the anastomosis of the dorsal nasal artery and angular artery appears to be the possible inlet of nasally injected embolic material. But the precise mechanism of retrograde embolism is still vague, and emboli is difficult to localize when it is only diagnosed by fundus fluorescein angiography, especially when the presumed occlusion site is proximal to the central retinal arteries.

In earlier studies, the two most generally injected materials, autologous fat (fat) and HA showed different clinical features. Fat injection was remarkably more often associated with diffuse occlusion, whereas skin necrosis associated with facial filler injections was more common in HA injected cases. The size difference between fat and HA seems to be related in part to the differences in the clinical features of retinal artery occlusions linked with cosmetic facial injections of these materials. Cerebral angiography offers more detailed information on the circulation of the ophthalmic artery as well as surrounding orbital area which cannot be covered by the fundus fluorescein angiography[11].

In the study done by Kim[11], researchers aimed to evaluate cerebral angiographic features of cosmetic filler-related ophthalmic and retinal artery occlusion

patients who had undergone intra-arterial thrombolysis (IAT). The study retrospectively reviewed medical records of patients who experienced ophthalmic artery or retinal artery occlusion after receiving cosmetic facial filler injections of fat or HA and subsequently underwent IAT along with cerebral angiography. IAT was performed for patients presenting within 24 hours of symptom onset and the absence of systemic conditions that contraindicated thrombolysis. Thrombolytic agents, urokinase or rt-PA, were injected to dissolve emboli, with dosages varying based on the embolic material. Most patients were young women who had filler injections for non-surgical rhinoplasty. Despite their prompt arrival and treatment, only partial recanalization was achieved in two patients. This supports the importance of *hyaluronidase* in the proposed IVCM.

According to Soares[25], Vascular occlusion injuries caused by fillers are quite uncommon at 0.01% to 0.05% per treatment. It should also be expected that as more non-medical injectors perform these treatments, the risks are likely to increase.

Oh[19] suggested that blindness is caused by ischemic retinal damage that results from occlusion of the central retinal artery and ophthalmic artery by filler embolism. In these cases, aesthetic surgeons introduce hyaluronidase to dissolve the peptide bonds of the long-chain proteins in the HA. In this study, a 33-year-old female presented with sudden total vision loss of her right eye, as 0.7ml of filler had been injected into the glabella and nasal ala.

An examination of her eye showed a dilated, non-reactive pupil, upper eyelid ptosis and skin discoloration around the eye. In order to break down the HA, the patient was injected with 700u of hyaluronidase and 20 000u of urokinase into the ophthalmic artery and 800u of hyaluronidase into the branches of the External Carotid Artery (ECA). After the hyaluronidase infusion, the angiography showed partial recanalization of the ophthalmic artery and ECA, particularly in the anterior deep temporal artery. However, subsequent angiography revealed no significant improvement in blood flow around the orbit. The following day, the patient had no light perception in their eye, though skin discoloration decreased. After a month, vision in the eye hadn't improved. It was concluded that Intra-arterial hyaluronidase, previously utilized in peripheral arterial occlusive diseases without major complications, was ineffective in recanalizing the central retinal artery and enhancing vision. However, partial recanalization of the ophthalmic artery and its branches was achieved safely. Once again there is evidence for the proposed IVCM.

In a study conducted by Spindel[26] rats had been injected with HA fillers into the femoral artery. These rats were randomly selected to receive one of the following perivascular treatments: saline, hyaluronidase, alteplase, or hyaluronidase and alteplase. Reperfusion, distal bleeding and other findings were only measured four hours after intervention. 60% of the hyaluronidase group re-perfused, of which 10% re-perfused completely and the rest only partially. In the alteplase group, 50% had a partial reperfusion, and in the group where a combination of hyaluronidase and alteplase were used, a 50% partial and a 50% complete reperfusion rate was observed. Therefore, Spindel[26] concluded that using both hyaluronidase and a thrombolytic agent together would achieve better reperfusion rates.

In a study done by Alvares[3] to determine an effective dose of subcutaneous hyaluronidase to dissolve a hyaluronic acid embolism and the effect that it has on the surrounding tissue, fifteen rabbits were divided into six groups of low, medium, and high hyaluronidase. On each, an inguinal incision was performed on the femoral artery in order to create an embolism with hyaluronic acid. The hyaluronidase was then administered subcutaneously. It was found that regardless of the persistence of intravascular HA, differences have been visible between the embolism control group and the embolism hyaluronidase high-dose group. It was confirmed that a 500 IU hyaluronidase dose partially prevents damage caused by the embolism without harming surrounding tissue, and that using a combination of a thrombolytic therapy and a higher dose of hyaluronidase subcutaneously was preferred.

Multiple studies, including Aldrich et al[1], have shown an improvement in visual acuity, using local intra-arterial fibrinolysis to treat the occlusion of the central retinal artery.

Farahani[8] mentioned that Crossed linked HA is a polysaccharide and is a frequently used reversible filler. HA is a hydrophilic molecule that creates a gel-based substance when it attracts water. Farahani[8]

also suggested that a high molecular weight HA has anti-inflammatory benefits, however HA with a low molecular weight is pro-inflammatory.

Middleton[16] found that adverse events apparently stem from a limited understanding of complex facial anatomy, coupled with challenges in pinpointing blood vessel locations accurately.

Materials and Methods

Numerous studies have been reviewed to identify relevant and useful methods to prevent and treat vascular compromise resulting from a filler injection. The selected methods were summarized and included in the "background and literature review", "prevention" and "in the room" sections, and a treatment protocol is suggested based on the evidence available for each of the elements that make up the IVCM protocol. Basic principles of physics and physiology are also considered.

Results

Prevention

Injection techniques

Based on the available literature, some authors have suggested that the injection technique, site, and substance can have significant influence on the level of risk for an adverse vascular event[24]. To reduce these risks, practitioners performing filler injections must be trained in vascular anatomy, injection techniques and the management of complications. They should also carefully assess patients for risk factors such as prior surgeries, vascular disorders, or allergies, before proceeding with the procedure. Additionally, adherence to strict injection protocols and the use of appropriate filler materials can help minimize the likelihood of adverse events. Murray[17] stated that establishing open communication with each patient is crucial. Pain perception varies, so any discomfort beyond the expected level should be promptly communicated. While some discomfort is typical, experiencing severe pain or alterations distal to the injection site is abnormal and should be reported immediately.

Injection techniques to reduce the risk of intra-arterial injection include

- Serial Injection Technique: Multiple small injection droplets are preferred to large boluses. This would reduce the volume that may be introduced into any vessel.
- Site Selection: Murray[17] gave a breakdown and description of certain facial areas with their risk levels. Starting with the highest risk level areas; the glabella, nose and forehead were included. Under generally high risk, we found the temples, nasolabial folds, tear troughs, peri-orbital area, and the medial cheek. Under moderate risk, there were lips, the perioral area and the anterior cheeks. Lastly, researchers placed the jawline, marionette lines, the lateral cheek area and the chin under low-risk areas. It is important to note that there are no "no risk" areas.
- Level in the skin: Lee[12] conducted a study investigating the distribution patterns of the superior labial artery. Where arteries are expected to be running superficially, injections should be placed deep and vice-versa.
- Limit Volume per session: Dividing the total injectable dose into the area over multiple sessions reduces the total volume injected during each session. External compression of vessels is deemed unlikely[5], however other studies show external compression confirmed by ultrasounds[13]. It is therefore worth reducing the total amount injected per session to limit the possibility of such an occurrence. However, should this occur, a localized hyaluronidase injection and an anti-inflammatory treatment should be sufficient to manage this along with a massage and heating, as supported in other places in this document.
- Apply digital pressure: Attempt to compress arteries that are expected to supply the injected area, especially in cases where the area being injected is known to have collateral communications with the Internal Carotid Artery and its branches. Doing so should logically limit the

ability of fillers to travel against the stream of blood flow.

- Low pressure: Loh[14] suggested that injections should be administered slowly, applying minimal pressure on the plunger, while carefully monitoring for any signs of pain and observing the skin for blanching or mottling, particularly in areas supplied by the vessel.

  Ophthalmic artery occlusion has been said to cause severe pain short after injection, whereas central retinal and branch artery occlusions may cause blindness without ocular pain. Madala, 2024, also support the low pressure, low volume method of injection.
- Small-bore needles: Loh[14] also suggested that using small-bore needles and cannulas is the preferred method for administering filler materials due to their potential to cause less trauma. The flow rate is directly related to the diameter of the needle to the power of four, meaning that an increase in diameter by two, will increase the flow rate sixteen times.
- Aspiration: Loh[14], again, confirmed that aspirating to check for the presence of blood backflow can be helpful in identifying accidental intravascular placement of the cannula or needle tip. However, Murray[17], argues that medical professionals should not rely on this method, as it is only reliable in 53% of all cases.
- Vascular Mapping: An understanding of facial vascular anatomy and the areas that pose higher risks is vital. High-resolution imaging techniques such as ultrasound or Doppler ultrasound may be used to visualize the arteries and their branches, helping to guide the injection process and minimize the risk of inadvertent vascular injury.

These methods are unlikely to be available to the injector in an average aesthetic setting.

Blindness has been caused by administering fillers through blunt cannulas and needles. According to Loh[14] it is always less expected to puncture a vessel with a blunt cannula. A sharp needle that pierces the skin perpendicular can easily penetrate both walls of an artery. However, a cannula introduced along the path of the artery, will remain in the lumen if it does pierce through the artery. Murray[17] confirmed that there are unfortunately possible complications with either a needle or cannula.

Post procedure observation

According to Murray[17] a detailed observation is crucial post-injection. It is important to assess capillary refill time (CRT) immediately along the artery's distribution. If the high-risk area has still been injected, even after this advice to avoid or to not ever inject those areas, then after injecting those high-risk areas like the nose, glabella, or forehead, it's advisable to observe the patient for 30-45 minutes. CRT, the time for blood to return after compression, should be checked bilaterally and is normal if it takes less than two seconds.

Skin color serves as a significant indicator of ischemic changes. These changes can be categorized into stages 1-5 to predict the likelihood of tissue breakdown and the need for wound management. Following blood supply interruption or restriction, tissue may initially appear pale or dusky. This pallor or blanching may be temporary but can transition to a reticulated purple pattern as deoxygenated blood and filler travel into more distant vasculature branches[17].

Detailed images are provided in the article by Murray for reference. Ischemic skin changes such as pallor and reticulation don't guarantee tissue necrosis, and different tissues tolerate ischemia for varying durations. The extent of tissue damage depends on both the severity and duration of ischemia. Refer to Figure 2 for more details on the initial treatment protocols.

In room steps

These steps may be used on their own, where neuro-vascular management is unobtainable or whilst awaiting neurovascular care, however these steps should not cause the delay of neurovascular care when deemed necessary.

Hyaluronidases are a group of six mucolytic enzymes that break down HA, a key component of many dermal fillers. According to Farahani et al[8] Hyaluronidase is an enzyme that can be found in bacteria, and in bee or snake venom. In the context of arterial fillers,

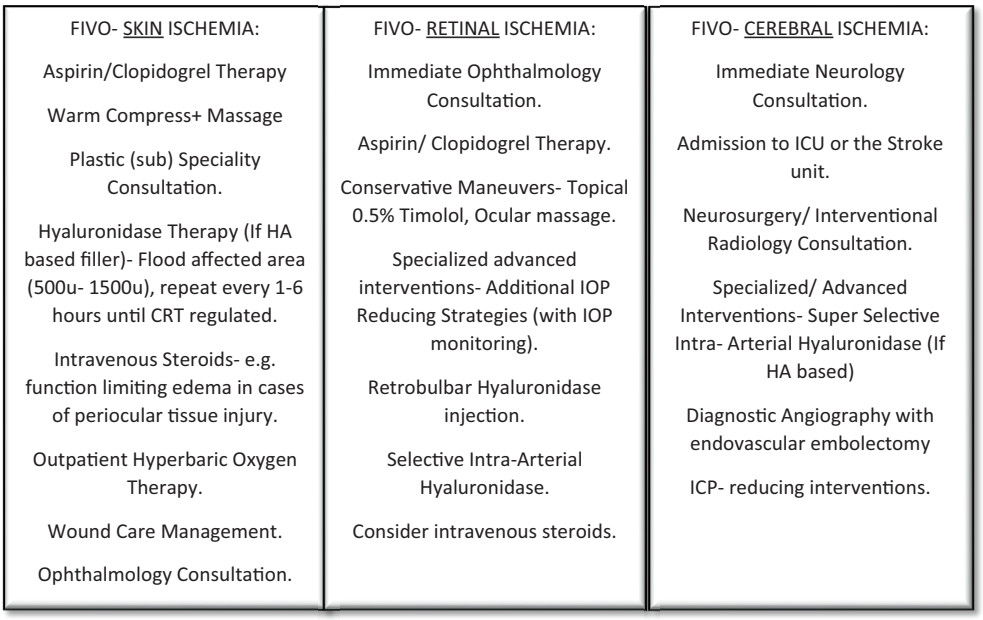

Figure 2. Taken from Soares et al (2023[25]).

Hyaluronidase may be used as a reversal agent or as part of the management of complications related to filler injections. Whilst Hyaluronidase can be highly effective in reversing filler-induced vascular occlusion or embolization, its improper, or even proper, administration or dosage can lead to adverse effects such as allergic reactions, tissue damage, or ineffective treatment outcomes. Close monitoring of patients following the administration of Hyaluronidase is essential to assess treatment response and to mitigate potential complications. Hyaluronidase cannot be for patients with allergies of bee or wasp stings. Medications like aspirin, corticosteroids, estrogens, furosemide, benzodiazepines, and antihistamines will cause the tissue to be less sensitive to hyaluronidase and therefore more units will be needed for people on these medications[8].

Adjunctive Therapy: Hyaluronidase may also be used as adjunctive therapy in combination with other interventions, such as topical *nitroglycerine* or *hyperbaric oxygen* therapy[17], to enhance tissue perfusion and promote healing in cases of vascular compromise or tissue necrosis. The precise management approach will depend on the specific clinical scenario and the severity of the complications encountered.

Chuchvara[7] stated that the main treatment in this case is the administration of Hyaluronidase followed by a massage to decrease pressure in the anatomic compartment by dissolving endogenous HA and administered HA. According to Chuchvara[7] oral *aspirin* will prevent clot circulation in the setting of compromised vasculature and the use of vasodilating agents such as Tadalafil may speed up the resolution.

The Intra-Venous treatment includes Heparin at 12000 units, infused until a PTT of 60-80 is reached, tPA (tissue plasminogen activator) 50mg[22], IV Methylprednisolone to manage the inflammatory response[15].

Apply heat and gently massage the area to facilitate the mechanical breakdown of the hyaluronic acid. Lowering intraocular pressure can dislodge the embolus into more peripheral retinal vessels, leading to an amplified perfusion, and it will avoid more damage to still-viable central retinal tissue. To decrease intraocular pressure, a topical application of timolol, or oral acetazolamide and an ocular massage can be performed.

Re-assess and re-evaluate CRT and compare with the pre-hyaluronidase assessment. If CRT remains delayed (>3 seconds), repeat the process.

Discussion and Conclusions

IVCM: Arterial occlusion of the face and brain may be treated with a neurovascular intervention. These procedures are performed in an endovascular suite (AKA catheter lab). A catheter is guided into the internal or external carotid artery and their branches, confirming their placement through a contrasting injection into the vessel. This should also reveal the location of occlusion. Once determined, the thrombus is either lysed with fibrinolytic agents or is physically (mechanically) removed. The bolus of HA is then removed as well, (similarly by dissolving the HA filler with Hyaluronidase or by physically removing it), and finally any remaining thrombus on the other side of the HA bolus is removed. Reperfusion is visualised and confirmed by once again using a contrasting injection and through the external observation of the involved body region, where possible. Time is of the essence when an ophthalmic artery or other intracranial vessel occlusion is suspected. The patient must be attended to urgently and should be treated as a true emergency, on par with the treatment of a stroke. In room treatment with attempted hyaluronidase injections should be avoided if a neurovascular intervention is confirmed to accept the patient.

When other soft tissue injury is suspected due to arterial occlusion to the face, the situation is still urgent but may be more forgiving, and in-room treatments may be attempted. In case of failure the patient should be referred and transferred immediately to the neurovascular surgeon. As soon as the vascular occlusion is suspected, the neurovascular surgeon should be notified so that a preparation may be made for an angiography and a possible intervention.

A Systematic Review and Meta-Analysis found intra-arterial thrombolytics for acute central retinal artery occlusion to be a promising treatment with results significantly favouring the treatment[21].

A stroke like protocol has been suggested and the potential use of thrombolytics discussed by Madala[15], which also reports on a study that found that hyaluronidase on its own had a 60% recovery of vision, versus 100% in patients treated with hyaluronidase and tPA combined. Refer to Figure 3 for a cad simulation of the resulting filler-clot obstruction that would need to be targeted.

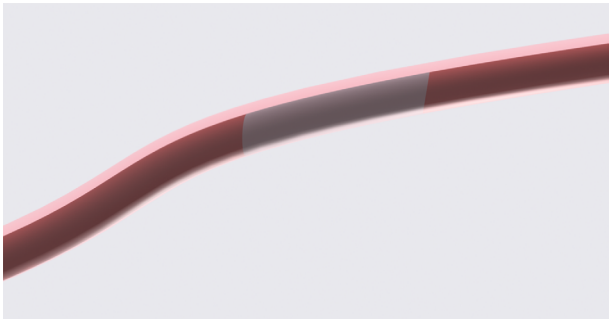

Figure 3. A CAD model of HA surrounded by thrombus.

A case report supports the use of this combination protocol using 1500 IU of Hyaluronidase and 8mg or Alteplase, which was used to treat a secondary occlusion following a successful treatment using hyaluronidase alone to treat a filler induced occlusion of the right ophthalmic artery[18]. It may be reasonable to consider that the secondary occlusion may have been less likely to have occurred if the combination of hyaluronidase and alteplase had been used in the original treatment.

42% of patients in a study by Zhang et.al.[30] showed improvements in visual acuity when treated with a combination of Urokinase and Hyaluronidase, versus a 36% increase in patients treated with hyaluronidase alone. Importantly all of these patients were treated beyond the ninety-minute period of irreversible damage, between 2 and 168 hours after injection. The recommendation proposed in this paper is to treat these conditions urgently as an emergency.

Venous occlusion, which has less severe consequences, may also be treated with neurovascular intervention and should be considered a suspected large vein occlusion, or when patients complain of significant pain, oedema or bruising following injection.

Thrombolytics may cause side effects such as a haemorrhagic stroke. Although there is a low risk of this happening[2], the risk still stands and could potentially be avoided if a physical extraction is performed. These treatments may be used for non-HA filler emboli as well, such as fat or non-hyaluronic acid fillers, representing an added advantage. A systematic review of forty studies found that compared with intra-arterial thrombolytics, mechanical thrombectomy had a better

technical success rate and patency, or at least that the dose of thrombolytics used reduced, accompanied by a reduced hospital stay[20], however this was for lower limb arterial obstructions.

Intra-cranial combination tPA with mechanical thrombectomy showed improvement in all eight patients included in a study by Tsai[27], although this treatment was administered for a venous sinus pathology. It has been shown though, that mechanical thrombectomy significantly improved functional independence compared to intra venous thrombolysis alone[10]. Within the options of mechanical thrombectomy, the combination of *contact aspiration* with *stent retriever* is preferable to stent retriever on its own[29]. Xu also suggests that mechanical thrombectomies are actually preferred to medical thrombolysis in larger vessel occlusions. Aspiration alone in cerebral infarction achieved revascularization in 78% of cases, and when combined with stent retrievers, this rate improved to 95%[28].

The use of alteplase *after* mechanical thrombectomy has been shown to increase the likelihood of excellent neurological outcomes at ninety days[6]. Furthermore, mechanical thrombectomy *after* Alteplase improved functional independence versus alteplase alone, without increasing mortality[4].

Given the evidence for the lack of certainty provided by all previous methods of treatment, practitioners should perhaps not attempt to inject patients with facial fillers if they are not prepared for the possible unfortunate adverse events and are not ready and able to transport the patient to the appropriate specialist care. To do so would subject the patient to an unnecessary risk, especially seeing as these are elective, non-essential treatments.

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