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REVIEW ARTICLE

A structured approach with Swiss cheese model to reduce vascular adverse events of filler injections

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Abstract

Background: Filler injection is among the most popular nonsurgical aesthetic procedures worldwide. Though relatively noninvasive, filler injection can lead to severe vascular adverse events. Even though the incidence is rare, it may cause devastating and irreversible outcomes. A Swiss cheese model has been widely applied for risk analysis and management approach in medical field.

Aims: In this review article, we adopt the Swiss cheese model and create a structured approach to prevent severe vascular complications caused by filler injections.

Methods: We reviewed the current literature regarding the knowledge and techniques of preventing vascular adverse events in the filler injection.

Results: We propose four structured strategies in this model to reduce the risk of severe vascular adverse events of filler injections, including clinical facial anatomy, safe filler injection principles, real time imaging and auxiliary instruments, and implication of checklist.

Conclusion: This review provides clinicians a structured approach before and during the filler injection procedure to reduce the risk of vascular adverse events and improve its safety and outcome.

KEYWORDS
COVID-19, filler injection, hyaluronic acid, Swiss cheese model, vascular adverse events

1 | INTRODUCTION

Filler injection is among the most popular nonsurgical aesthetic procedures worldwide. Severe adverse events, such as blindness,[1] skin necrosis (Figure 1), stroke, and infection, are the worst-case scenario of filler injections. Even though the incidence of severe vascular adverse events in filler injection procedures is <0.015%, these may cause devastating sequelae.[2] Patients, physicians, and products are the three pivotal factors in the context of filler injection. Problems with any of these factors may lead to an increased risk of complications, such as flawed products or products without antidote combined with poor patient communication by inexperienced

practitioners. A "blind injection," including physical blindness without imaging tools and intellectual blindness without the knowledge about facial anatomy and safe injection principles, might cause an injection-induced blindness. A Swiss cheese model, a risk analysis and management approach, was put forward by Professor James Reason in 1990.[3] In this article we adopted this concept to rethink and recapitulate the process of daily tasks of filler injections and to create a structured approach to prevent severe vascular complications caused by filler injections.

2 | RISK

The worst-case scenario of filler injections strikes us unexpectedly. There are complications of "unknown unknowns," a phrase from the United States Secretary of Defense Donald Rumsfeld. These are called "black swans,"[4] which are adverse events that are improbable and unpredictable. Some other adverse events are "known unknowns," "unknown knowns," and "known knowns," and these are called "the gray rhino,"[8] suggesting that dangers are probable and predictable but were ignored, such as using a sharp needle for nose augmentation without performing safety measures of aspiration or not keeping the needle moving and at the wrong plane (Table 1). The risks of filler injections should be recognized to optimize the therapeutic outcomes and prevent complications.

FIGURE 1 Severe adverse vascular event of skin necrosis due to fill injection.

3 | SWISS CHEESE MODEL

The Swiss cheese model of accident causation is a model used in risk analysis and management, such as in aviation safety, engineering, healthcare,[5] and safe hospital preparedness during the COVID-19 pandemic.[6] The model has gained widespread acceptance and it is sometimes called the "cumulative act effect." The Swiss cheese model of the severe vascular adverse events of filler injections illustrates that although many layers of defense lie between hazards and accidents, there are flaws in each layer that, if aligned, can allow an accident to occur. In the Swiss cheese model we proposed, the four slices stacked side by side are clinical facial anatomy, safe filler injection principles, real time imaging and auxiliary instruments, and implementation of checklist (Figure 2). A structured approach with this Swiss cheese model and strengthening of the aforementioned four layers of defense by closing the holes can help avoid these severe vascular adverse events.

4 | KNOWLEDGE OF FACIAL ANATOMY

The knowledge of facial anatomy is very important for preventing severe vascular adverse events from filler injections, especially over the vascular danger zones including the glabella, nose, forehead, tear trough, and nasolabial folds (Table 2; Figure 3).[7] The familiarity with the facial anatomy is crucial to aim at the target plane for augmentation and avoid vulnerable vessels. Vascular injuries after a filler injection cause ecchymosis, hematoma, venipuncture, intraarterial

TABLE 1 The risk matrix of severe vascular adverse events in filler injection.

Risk matrix	Known	Unknown
Known	Known knowns (The gray rhino)	Unknown knowns (The gray rhino)
	Filler injection can cause vascular adverse events is well known, and to the best of our known knowledge to avoid them	We do not know whether the patient in front of me will suffer from known adverse vascular events or not
Unknown	Known unknowns (The gray rhino)	Unknown unknowns (The black swan)
	According to previous case report, we know filler injection to chin can cause blindness, but we do not know the mechanism and might be due to unknown vascular variants	Bolus injection to bone with a previous negative aspiration test causes a complication of skin necrosis

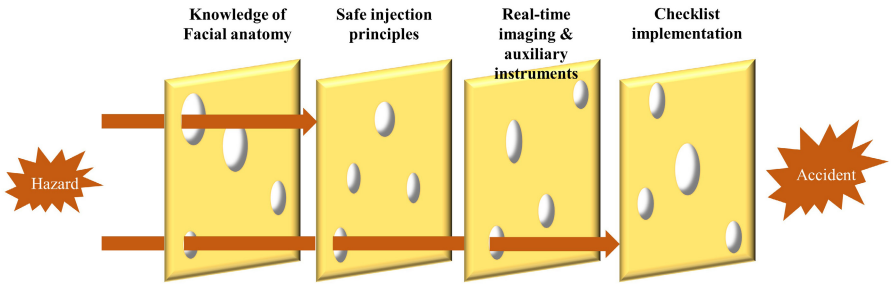

FIGURE 2 We proposed a Swiss cheese model comprising four strategies to reduce the risk of severe vascular adverse events of filler injections, including knowledge of facial anatomy, safe filler injection principles, real time imaging and auxiliary instruments, and implementation of checklist.

embolization of skin necrosis, blindness, stroke, and intravenous embolization of cavernous sinus syndrome.

On the central part of the forehead and glabella, central vessels, such as central arteries, paracentral arteries, and supratrochlear arteries, are prone to injuries due to the thin overlying skin and their location. According to one previous three- dimensional computed tomography and dissection study, the glabellar arteries are mainly located in the subcutaneous tissue, with a depth of 1.1 to 3.9 mm. Therefore, the authors suggested performing filler injections in the supraperiosteal layer.[8] The supraorbital artery and the frontal branch of the superficial temporal artery of the lateral forehead and upper temple are located one finger breadth above the lateral eyebrow.[9] One previous Doppler ultrasound study revealed supratrochlear arteries and supraorbital arteries locate within 1.0–2.0 cm and within 2.0–4.0 cm from the midline at the horizontal level of orbital foramen, respectively. In addition, the supratrochlear arteries and supraorbital arteries were superficial and deep to the frontalis muscle at the superior brow margin, respectively.[10] The anterior and posterior branches of the deep temporal artery and middle temporal vein should be treated with caution during vertical bolus injection or horizontal fanning injection to the temple. Previous computed tomographic studies of temporal vessels demonstrated the anatomical level of the deep temporal arteries are located between the temporal muscle and the periosteal layer. The distance between the temporal fusion line and the anterior branch of deep temporal artery was approximately 9.30 mm, and the authors recommended performing the injection at least 1 cm outward at the starting point of the temporal fusion line to prevent vascular adverse events.[11] In another study of computed tomographic angiography, Wang et al. suggested two safe injection areas in temple region. The first area is located between superficial temporal artery and middle temporal vein, anterior to jugale, and 22–32 mm above bony lateral canthus. The second area is located between middle temporal vein and zygomatic arch, anterior to zygion, and within 20 mm height above the zygomatic arch.[12]

For an augmentation to the infraorbital hollow, a close attention should be paid to the infraorbital artery, angular artery, and vein. In one previous cadaveric study, Hufschmidt et al. suggested performing injections at least 2 mm from the periosteum to prevent injury the nasal branches of infraorbital artery in the medial cheek area. On the other hand, they advised to do injections on the periosteum on the lateral cheek to minimize risks of the vascular adverse events in the zygomaticomalar branches of infraorbital artery.[13] The nasolabial fold is one of the most popular locations that people want to address for rejuvenation, and variations in the course of the facial artery is complicated. In one ultrasonographic study, Shen et al. found facial arteries most frequently run inferiorly to the nasolabial folds in the layer of dermis and subcutis and suggested deep injection into the periosteum is safer than superficial layers.[14] Inadvertently, intravascular filler injection into the facial artery will lead to skin necrosis and even blindness.

Filler-associated blindness is caused by three pathways. First, a filler embolus flows reversely through the branches of the ophthalmic artery, such as the supratrochlear artery, supraorbital artery, and dorsal nasal artery. Second, the true anastomoses between the branches of the ophthalmic artery and external carotid arterial system come from the frontal branch of the superficial temporal artery, angular artery, and lateral nasal artery. Third, the arteriovenous shunting between the ophthalmic artery and vein is located in the orbit and inner canthus.[15] Therefore, one should have a good anatomical knowledge before injecting to the danger zones (Table 2; Figure 3).

5 | SAFE INJECTION PRINCIPLES

Several studies have proposed safe injection principles to avoid vascular adverse events. Huang et al. organized these principles to create a novel "mind map" for practitioners.[16] The mind map of "CARES" is composed of five acronymic letters: "C" stands for customer, cannula, consensus, and checklist; "A" for aspiration test, antidote of hyaluronidase, anatomical danger zone, and aids of real time imaging or other instruments; "R" for retrograde injection techniques; "E" for a low extrusion force; and "S" for keep the needle sliding and moving, slowly inject, giving small aliquots, and nondominant smart fingers to help pinch, protect, stretch, or press. It is a simple and easy tool for an injector to memorize the safe injection principles, recapitulate the whole process, be reminded of the key steps, recheck crucial details, and prevent negligence before starting filler injection.

History taking is crucial before filler injection. For example, previous surgical interventions and filler injections in the face can change the location and pattern of vessels, and fibrosis or scar tissue after previous procedures may confine the vasculatures and harden the soft tissues, making the skin vulnerable to vascular adverse events. Preparing an antidote, such as hyaluronidase, for hyaluronic acid injection is very important. Moreover, a blunt

TABLE 2 Vascular danger zones of face based on clinical facial anatomy.

25 Landmarking vessels	Upper face			Middle face			Lower face				
Target	Forehead	Glabella	Temple	Upper eyelid	Tear troughs & infraorbital hollowness	Nasolabial fold	Cheek	Nose	Marionette lines	Lips	Chin & mandible
Key artery	STrA SOA	CA PCA STrA	FbSTA DTA ZOA	EMP/OA	IOA AA	FA	TFA	DNA LNA	ILA	SLA ILA	FA SMA
Key vein	SV		SV MTV		IPV AV	FV		ICV			FV SMV

Abbreviations: AA, angular artery; AV, angular vein, CA, central artery; DNA, dorsal nasal artery; DTA, deep temporal artery; EMP/OA, emerging point of ophthalmic artery; FA, facial artery; FbSTA, frontal branch of superficial temporal artery; FV, facial vein;ICV, intercanthal vein; ILA, inferior labial artery; IOA, infraorbital artery; IPV, inferior palpebral vei;. LNA, lateral nasal artery; MTV, middle temporal vein; PCA, paracentral artery; SLA, superior labial artery; SMA, submental artery; SMV, submental vein; SOA, supraorbital artery; STrA, supratrochlear artery; SV, sentinel vein; TFA, transverse facial artery; ZFA, zygomaticofacial artery; ZOA, zygomatico-orbital artery.

cannula is important for fanning and linear threading techniques in filler injection. However, it does not ensure the total avoidance of vascular complications, and may create a false sense of security.[10] Vascular complications may occur even with the use of a blunt cannula. In addition, a cannula with a diameter <25 gauge might be regarded as a sharp needle, and may cause vascular damage during filler injection (Table 3).[17]

Many techniques have been proposed to prevent complications during filler injection, including aspiration before filler injection, retrograde injection technique, slowly proceeding with small aliquots, and using the fingers of the nondominant hand to compress the vessels or pinch the skin in danger zones. Aspiration is one of the most popular tests for a safe filler injection, and Tseng et al. demonstrated that it can be beneficial if a right product/needle combination is used. However, the estimated incidence for having positive aspiration procedures was 0.04%–0.9%.[18] Whether aspiration prior to filler injection is beneficial in preventing inadvertent vascular adverse events remains unclear. Goodman et al. explained that aspiration cannot be relied on because its movement and false negative results can lead to a "false sense of security" in preventing intravascular injection and its serious consequences, with the primary concern being a false negative result in the aspiration test.[17] Based on basic biomedical statistics and Bayes' theorem, Huang et al. reported that the aspiration test has a low sensitivity and a high specificity and positive predictive value, and repeating this can increase its sensitivity.[19] This test is simple, inexpensive, quick, and can easily be combined with other safety measures. It is believed that the aspiration test prior to filler injection is still valuable. We consider that a true or false negative result in the aspiration test is a superposition state like Schrödinger's cat; the needle tip might be in or off the vascular lumen, and the concept of "aspiration matrix" was proposed to react properly on true or false positive or negative results.[20]

The extrusion force given by practitioners follow the Poiseuille's law of rheology ($Q = \Delta P \pi r^4 / 8 \mu L$, Q: fluid velocity, ΔP: differential pressure, r: needle radius, L: needle length, μ: viscosity of fluid), which reveals a longer and thinner needle with a thicker (high G' and viscosity μ) product will cause a bigger extrusion force under the same flow rate.[15] By contrast, aspirating a filler product with a higher viscosity in a longer and thinner needle is more difficult. Thus, according to Poiseuille's law and satisfying the assumptions of continuum mechanics and rheology, a rapid and high-pressure injection will make filler particles under a high energy and speed, increasing the risk of breaking into flawed vessels and spreading intravascular emboli distantly. Therefore, injection with a low extrusion force is strongly suggested, and the viewpoint is consistent with the aforementioned consensus of a slow injection.

During injection, treating one side of the face at a time can help us closely watch if skin pallor and reticulate purpura appear, which indicate a severe vascular event.[16] Monitoring sharp pain or visual loss immediately after injection for 30 min–1 h and contacting a patient for follow up one day after the treatment are important in identifying acute or delayed severe vascular events.[10]

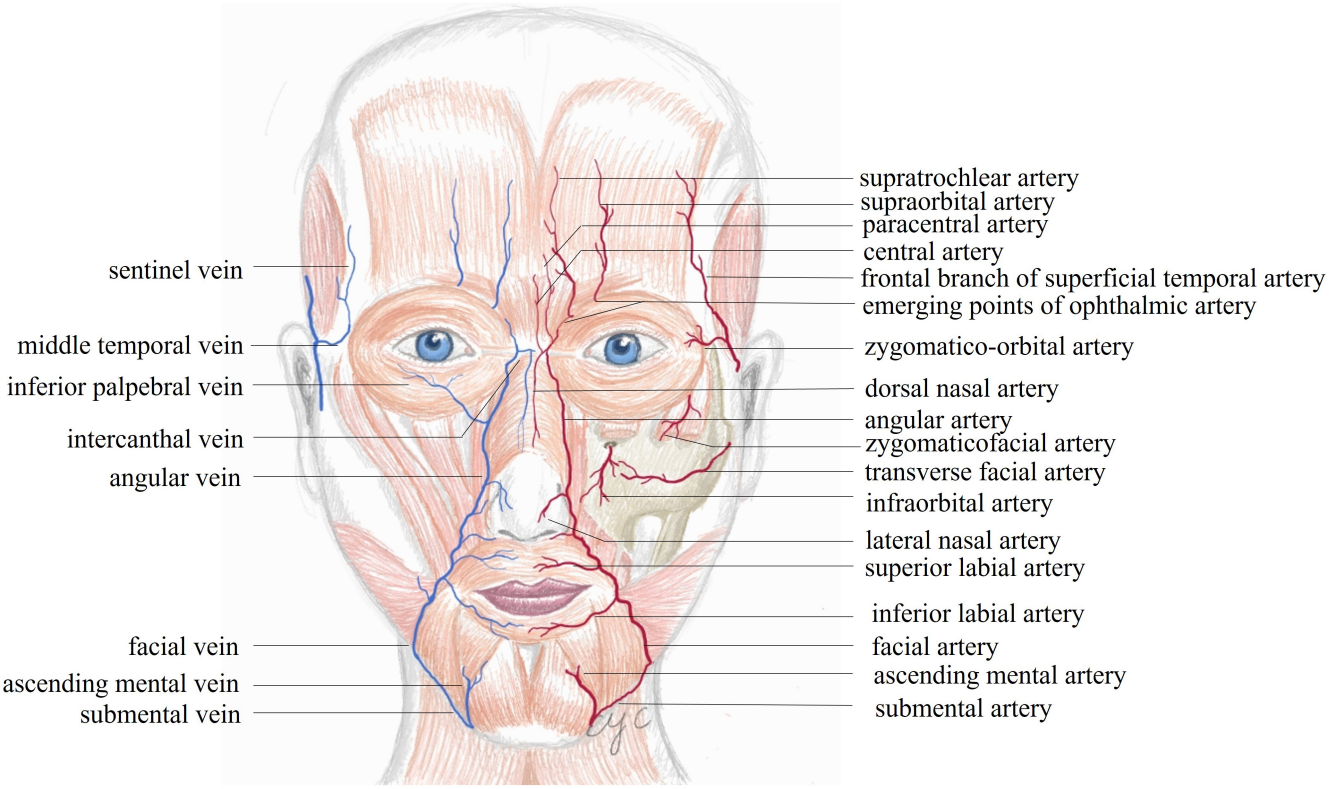

FIGURE 3 The anatomy of facial vascular danger zones.

6 | REAL TIME IMAGING AND AUXILIARY INSTRUMENTS

Although the knowledge about facial anatomy may minimize the risk, the anatomical distribution of vessels can vary among individuals. We never know the actual anatomical variations in a patient just in front of us. We think that the real time imaging of a vein detector, ultrasound, and Doppler can bridge the chasm of surface facial anatomy and surgical or cadaveric anatomy. Real time imaging can be applied in many aesthetic procedures, such as filler injection for the face and dorsal hands,[21] axillary hyperhidrosis therapy,[22] injection lipolysis for submental fullness,[23] and thread lifting.[24]

A Doppler ultrasound can reveal the vessels, especially arteries, and planes of a facial structure. In addition, vein detection devices through transillumination can prevent accidental venipuncture and reduce injection-related bruising.[16] It is a device that uses near-infrared light to illuminate the subject's skin.[25] Near-infrared light penetrates the skin and subcutis with a low absorption. In contrast, it is absorbed by blood and forms a dark shadow. Therefore, it could reveal superficial vasculatures and assist us in choosing an entry point to prevent venipuncture and bruises. Furthermore, landmarking a vein can indicate accompanying facial homonymous arteries; for example, the supraorbital vein and facial vein can be illuminated and indicate its homonymous artery. Consequently, a vein detector can help determining good entry points and safe zones for filler injection and define the boundaries of venosomes/angiosomes, while filler-related embolization occurs in the facial skin. A two-step method using a vein viewer (Christie Medical Holdings, Inc., Memphis, TN) and ultrasonography (Acuson X150™, Siemens Medical Solution USA, Mountain View, CA) has been devised to assist in filler injections.[14] In the first step, a vein viewer is used to detect the superficial vein distribution over the treated area and to choose an entry point without venipuncture. In the second step, ultrasonography with a color Doppler is performed to detect sequential deep anatomic structures and guide the pathway of filler injection to prevent intravascular infusion.

In addition, the filler version of microautologous fat transplantation injector (MAFT GUN™), which was initially developed by Lin et al for the accurate delivery of small fat aliquots, was adopted for danger zones of the upper eyelid, nose, and forehead to prevent intravascular injection.[21] The key features of the MAFT GUN™ are: transforming from manually pushing the plunger to mechanical triggering, producing precise microaliquots (about 1/240 mL) that cannot be made manually, giving a low extrusion force and accumulated pressure, adopting a large-gauged blunt cannula (21G for filler and 18G and 16G for fat), and being suitable for both fat grafting and filler injection.[26]

In summary, dual real time imaging is useful for filler injection. The timing for its use is before, during, and after procedures for checking, guiding, and solving malpractice. A pre-injection examination with dual real time imaging is suggested for a danger zone or frequently filled face. It is advantageous because it can identify good

TABLE 3 Qualitative analysis: the sharp needle and blunt cannula matrix.

Qualitative analysis	Pros	Cons	Thick	Thin	Remark in injection technique
Sharp needle	1. Approaching most superficially to dermis and deeply to bone 2. Easily giving a deep vertical bolus to bone 3. Save on usage	1. Frequently piercing skin 2. Easily penetrate vessels 3. Easily bruising	The most dangerous Large-gauged sharp needle has a higher chance to cut vessels	Moderate risky Sharp needle smaller than 21G (about 0.8mm in outer diameter) in size could penetrate facial vessels	1. To bone with bolus or vertical depot techniques 2. To dermis with small depots or linear threading technique 3. To any one of facial 5 layers with caution
Blunt cannula	1. Fewer skin punctures 2. Safer with less bruising and vascular events 3. Aspiration test is unnecessary	1. Uneasily approaching superficially to dermis and deeply to bone 2. Less usage saves 3. False sense of security	The safest Large-gauged cannula could produce more blunt dissection during fanning	Relative safe but be cautious It would be better to regard a blunt cannula smaller than 25G in size as a sharp needle	1. To subcutaneous fat (superficial fat compartments) or deep fat compartments with fanning or linear threading techniques 2. To bone with obliquely vigorous approaching and non-dominant hand pinching

entry points and relatively safe zones and anatomical planes, but it is time-consuming and has interference. The limitation of its utility is a false negative imaging due to device-dependent, user-dependent, patient-dependent, and anatomy-dependent issues; for example, too small vessels cannot be detected.

7 | CHECKLIST IMPLEMENTATION

We think that the last line of defense for preventing adverse events of filler injections is implementation of a checklist.[19] Developing and implementing a checklist have been fully applied in many highly specialized fields, such as in aviation industry, architecture, finance, and surgery. It is a quick and simple way to integrate teams, remind problems, avoid dangers, reduce errors, and improve performance. According to the principles of a safe injection, the aforementioned concise mind map with the acronym "CARES" was created to easily memorize them, recapitulate the key points, and quickly be reminded of the critical steps.[16] Furthermore, Gawande et al proposed a surgical safety checklist to reduce the morbidity and mortality worldwide.[27] Thus, the World Health Organization's 2009 edition of surgical safety checklist was modified, and a novel version of a safe filler injection checklist with 19 items was developed.[28] Time-out indicates a pause before starting surgery or filler injection. Consequently, the checklist only takes 1 min. An ideal checklist should be concise, convenient, and easy to perform. Under careless circumstances, everyone might commit errors and mistakes. We think that the checklist is not a game-changing breakthrough, but it is indispensable and should be followed. With the assistance of the checklist, filler injection can be performed carefully step by step, the risk of negligence can be minimized, and the safety of the procedure can be increased.

The summary of recommendations of Swiss cheese model to reduce vascular adverse events of filler injections was demonstrated in Table 4. In addition, we also proposed a multiple risk analysis model describing the strategies of Swiss cheese model in managing the risks of injection therapy (Figure 4).

8 | LIMITATIONS

8.1 | Simplistic representation

The Swiss cheese model, as a risk analysis and management approach, is a simplified representation of complex systems. While it offers a visual framework to understand how accidents can occur when multiple layers of defense have flaws that align, it might oversimplify the intricate nature of filler injections and the various factors contributing to adverse events. In reality, filler injections involve multifaceted interactions between patient characteristics, injection techniques, product properties, and anatomical variability, which may not be fully captured by the model.

TABLE 4 Summary of recommendations Swiss cheese model to reduce vascular adverse events of filler injections.

Swiss cheese model	Recommendations
Knowledge of Facial anatomy	1. Glabella area: It is recommended performing filler injections in the supraperiosteal layer between supratrochlear arteries and supramuscular layer in the territory of supraocular arteries. Besides, it is suggested avoid injection in the area within 1.0*2.0 cm from the midline 2. Temple area: It is recommended performing the injection at least 1 cm outward at the starting point of the temporal fusion line. Besides, it is also suggested two safe injection points: The first area is located between superficial temporal artery and middle temporal vein, anterior to jugale, and 22 to 32 mm above bony lateral canthus. The second area is located between middle temporal vein and zygomatic arch, anterior to zygion, and within 20 mm height above the zygomatic arch 3. Infraorbital area: It is recommended performing injections at least 2 mm from the periosteum in the medial cheek area and on the periosteum on the lateral cheek 4. Nasolabial folds: It is recommended performing deep injection into the periosteum
Safe injection principles	1. It is recommended to complete injection-related medical and surgical history taking before the treatment 2. Preparation of an antidote, such as hyaluronidase, for hyaluronic acid injection is suggested 3. The aspiration test is still recommended prior to filler injection. Besides, injection with a low extrusion force is also important 4. Monitoring symptoms and signs of sharp pain or visual loss immediately after injection for 30 min to 1 h and contacting a patient for follow up one day after the treatment are important in identifying acute or delayed severe vascular events
Real time imaging and auxiliary instruments	1. A pre-injection examination with dual real time imaging of Doppler ultrasound and vein viewer is suggested for a danger zone of the face 2. The filler version of microautologous fat transplantation injector can produce precise microaliquots and a low extrusion force, which is beneficial for the injection procedure
Checklist implementation	A safe filler injection checklist can remind practitioners about the precautions of injection procedure and minimize the risk of negligence

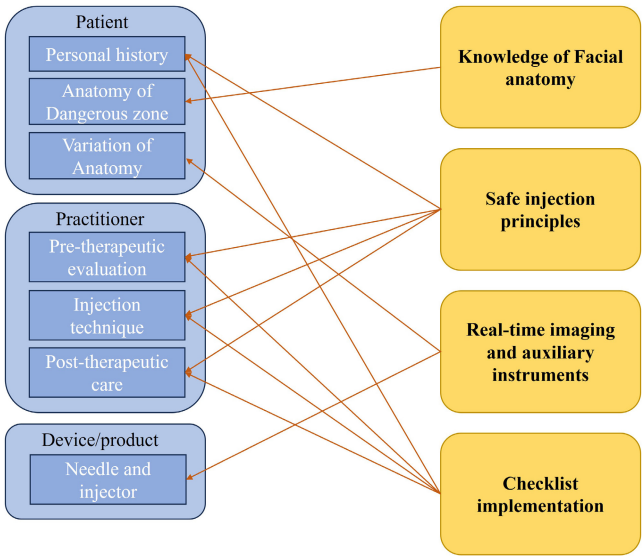

FIGURE 4 Multiple risk analysis model.

8.2 | Lack of quantitative approach

The Swiss cheese model does not provide a quantitative assessment of risk probability or severity. It depicts the existence of potential vulnerabilities in different layers of defense, but it does not quantify the likelihood of these vulnerabilities aligning to cause an adverse event. Without a quantitative assessment, it becomes challenging to prioritize prevention strategies based on their impact and efficacy.

8.3 | Limited predictive capability

The Swiss cheese model is retrospective in nature, explaining how accidents have occurred in the past. While it aids in understanding the factors contributing to past adverse events, it may not be as effective in predicting future events or preventing them proactively. Filler injections are continually evolving, and new products, techniques, and patient populations might present novel risks not fully captured by the model.

8.4 | Lack of specific recommendations

The Swiss cheese model provides a conceptual framework but does not offer specific, actionable recommendations to mitigate risks in filler injections. It identifies potential weaknesses in different layers, such as clinical facial anatomy, safe injection principles, real time imaging, and checklist implementation. However, the model does not prescribe concrete steps or guidelines for practitioners to follow, limiting its practical application.

8.5 | Limited evidence-based validation

While the Swiss cheese model has gained acceptance in various industries, its application to the field of filler injections lacks substantial evidence-based validation. The model's effectiveness in reducing vascular adverse events requires empirical validation through

rigorous clinical studies and data analysis. The current paper adopts the model conceptually but does not provide evidence of its real-world effectiveness in clinical practice.

8.6 | Single model approach

The Swiss cheese model, as proposed in the paper, comprises only one conceptual approach to risk analysis and prevention. However, risk management in medical procedures, such as filler injections, may benefit from a combination of multiple risk analysis models to comprehensively address various aspects of safety.

9 | CONCLUSIONS

In the era of "faceconomics," people upload their pictures or videos to social media, including Facebook, Instagram, Twitter, Line, or YouTube, to earn fame and money every day. Practitioners use needles to help their patients stay beautiful. However, there is volatility, uncertainty, complexity, and ambiguity everywhere, not only during the COVID-19 pandemic but also in aesthetic medicine and filler injection. The worse-case scenario of filler injections can strike unexpectedly. According to the aforementioned four layers of defense for preventing severe vascular adverse events, this feasible structured approach is implemented, and it is much easier to stay out of trouble now than to get out of it later. Nevertheless, practitioners should also be alerted to the false sense of security. Li et al. had proposed "hot cheese model" which indicated features interactions between the defense systems.[29] For example, anatomy varies from case to case and false negative aspiration and imaging examination may result in risky injection. Besides, excessive reliance on checklist may make it formalistic. Further research is needed to confirm the benefits and how many harms can be mitigated by adopting this Swiss cheese model.

AUTHOR CONTRIBUTIONS

Conceptualization: Yau-Li Huang. Methodology: Yau-Li Huang. Data curation: Yau-Li Huang, Shyue-Luen Chang, Sindy Hu, Mei-Ching Lee, Chun-Wei Lu, Wen-Hung Chung, Tsai-Ming Lin, Chun-Yu Cheng. Writing: Yau-Li Huang, Chun-Yu Cheng. Visualization: Chun-Yu Cheng. Validation: Ching-Chi Chi, Chun-Yu Cheng.

CONFLICT OF INTEREST STATEMENT

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Not available.

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