

**Improving Compliance and Prevention in Vascular Occlusion Management: Development
and Implementation of Protocols and Toolkits for Dermal Filler Providers**

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Abstract

The implementation of this project aimed to improve adherence to protocols on the compliance and prevention of vascular occlusion (VO) management among dermal fillers injectors at a medical spa. VOs are serious complications of hyaluronic acid dermal filler injections that may lead to severe patient outcomes if not promptly and properly managed. Data was collected through chart reviews and checklists before and after implementation of the protocol, the project assessed changes in VO occurrences and adherence rates. A new protocol and toolkit were introduced, while also incorporating a training program that enhances injector education and skills in preventing and managing VO complications. The data analysis revealed a complete elimination of reported VO incidents (reduction from 0.63% to 0%) and a 100% increase in adherence to the protocol. However, there were several limitations that influenced the results such as potential biases in data reporting, short time frame of the project, and limited sample size. These circumstances can affect the generalizability and long-term sustainability of the results.

The implementation of a standardized protocol on compliance of VO prevention and management significantly enhanced injectors' education in preventing and managing VOs. This project demonstrates the value of standardized protocols and well-structured training to prevent and improve safety outcomes in medical aesthetics. This protocol offers a model for other practices to use to improve quality and safety in VO prevention and management compliance. This project highlights the importance of future research in aesthetic practices and inspires future research to refine protocols and understand their long-term impact in medical aesthetics.

Improving Compliance and Prevention in Vascular Occlusion Management: Development and Implementation of Protocols and Toolkits for Dermal Filler Providers

Vascular occlusion (VO) caused by hyaluronic acid (HA) filler injections poses a significant risk in aesthetic medicine due to potential necrosis, tissue damage, and blindness (Wang et al., 2023). Despite efforts to mitigate risks of VO with proper technique, there remains a lack of comprehensive guidelines, standardized protocols, and developed VO kits in most medical aesthetic settings. Creating an emergency protocol and kit can identify beneficial steps to prevent and manage hyaluronic acid-induced vascular occlusion. Practices that struggle to accurately assess VO's; create challenges in treating adverse reactions, thereby increasing the risk of necrosis and other life-altering issues for their patients.

Medical spas that are not properly trained in vascular occlusion (VO) prevention and management continue to endanger their patients' health. Many of these spas lack essential resources such as hyaluronidase vials, basic protocols, ultrasound equipment, appropriate medications for treatment, and advanced knowledge on how to assess a VO accurately. Understanding the depth, distribution, and common variations of major vessels is critical for safe injection practices (Murray, 2021). This issue becomes more pressing as injectables become more and more popular. A SWOT analysis highlights the strengths, weaknesses, opportunities, and threats in the absence of proper protocols and management of VO, highlighting the need to develop VO kits, protocols, and educational resources for effective management.

The Doctor of Nursing Practice (DNP) project advocates for developing and implementing an evidence-based treatment protocol, and kit to manage hyaluronic acid-induced vascular occlusions. A visual diagram was utilized to illustrate the scope of this problem through a SWOT analysis (Appendix A).

Project Question

For providers involved in administering dermal fillers, does the implementation of a standardized vascular occlusion (VO) management and prevention protocol and toolkit improve compliance with management practices and reduce the incidence of vascular occlusions over a 5-week period compared to baseline rates?

Search Methods

A literature search focused on vascular complications associated with HA fillers, treatment options, and prevention interventions. Databases such as Science Direct, Embase, Cochrane Library, EBSCO, Google Scholar, PubMed, and CINAHL were searched for articles within the last five years. The search terms that were used included “treatment kit,” “hyaluronic acid filler,” “vascular occlusions,” “complications,” and “protocol.” The target population comprised of individuals who receive dermal filler injectables, including injectors and providers experienced in VO management. Exclusion criteria was low level evidence, outdated research, and research presented outside of the English language.

Review of Study Methods

The literature included multi-centered cross-sectional studies, evidence-based, peer-reviewed guidelines, systematic reviews of peer-reviewed research studies, and a clinical practice guideline. These methods are aligned with the aims of the reviewed studies and were selected for their relevance and quality, contributing significantly to this DNP project. These study trials are relevant to this DNP project because they are reliable and valid since they provide proper injection guidelines and preventative measures to avoid possible VO adverse outcomes.

Review Synthesis

According to Colon et al. (2023) HA is one of the most popular dermal filler options available that is widely used in medical and cosmetic aesthetics to promote healing and hydrating tissue. However, its injection can sometimes lead to vascular occlusions, which in mild cases shows itself as erythema, bruising, swelling and pain while extreme cases can lead to blindness and necrosis. These research studies were conducted through an assessment from clinics that use hyaluronic acid dermal fillers. The literature provided proper preventative measures like implementing ultrasound machines that will effectively observe the precise location of a hyaluronic acid embolus. Establishing a well-rounded staff with proper knowledge of vascular anatomy is essential for all filler injectors. The literature suggests implementing a research-based guideline to manage hyaluronic acid induced vascular occlusion to reduce complications. Creating a protocol with proper steps on how to diagnose a VO is essential for the treatment process. Implementing standardized procedures and protocols will educate providers, thereby decreasing the risk of a VO progressing to necrosis.

Based on the literature discussed by Wang et al. (2022) HA fillers compared to traditional plastic surgery procedures are seen as the top cosmetic choice for young women. Even though HA injections are considerably safe, the rate of hyaluronic acid-induced vascular occlusions is still between 0.001% and 0.005%, which comes from a very widespread use of HA injectables. There were three different patients who experienced occlusion, this incurred a comprehensive treatment plan to develop. The treatment plan developed involved the use of oral aspirin, intravenous amoxicillin, tobramycin dexamethasone eye drops, vasodilators, as well as hyperbaric oxygen therapy and massage for certain occluded areas. This literature influences the DNP project by implementing a comprehensive treatment plan to accommodate each patients' outcomes that creates a prepared approach.

According to Middleton (2022) there was a growth of HA fillers of more than 300% between 2000 to 2017 which now increases the incidence of complications by more than 130% from 2015 to 2019. With the risk, comes a high potential to cause blepharoptosis, ophthalmoplegia, and partial or total blindness. Although, there is no proven preventative treatment for blindness from HA injections, it is beneficial to implement a research-based up to date emergency protocol to reduce the risks. Previous protocols follow low dose and hyper diluted treatment plans which should not be administered as a first step against VO events. Overall, while HA injections are considered safe, vascular occlusions are still prominent and remain a potential for serious complication. Prompt intervention and proper technique are essential components to minimize the risk and manage complications.

Hyaluronic acid-induced VO occurs when the injected substance obstructs blood vessels which leads to potential necrosis and tissue ischemia. Common complications of HA induced VO's come from improper placements and inexperienced physicians (Aviv et al., 2022). As HA injections increase in popularity, the rate of complication also proposes a risk for higher outcome of adverse events. This presents a new challenge for providers presenting minor procedures that can later result in disability and facial deformities if not addressed within the preferred time frame. Implementing the proper prevention strategies such as proper patient selection, meticulous injection technique, using cannulas instead of needles, and awareness of vascular anatomy creates awareness for providers.

It is crucial to understand that all areas of the face should be given the same special attention and anatomical knowledge when injecting. According to King et al. (2020) there are two main areas on the face that have a higher chance of a vascular occlusion occurring: the nasolabial fold, alar triangle, nasal tip, and the glabellar region. Since there are high risk areas,

practitioners should have a comprehensive knowledge of facial anatomy no matter the area that is being treated. Using caution and practicing safe injection techniques creates a less likely chance of a VO event from occurring. Implementing follow up visits is required when an onset of vascular occlusion has been suspected. As DNP-prepared nurses gain more autonomy and open independent practices, it is important to curate a prepared staff and implement evidence-based protocols especially in the worst case scenarios of a VO adverse event.

Alam et al. (2020) discussed that there is a growing perception among experts that HA VO events reduce when using microcannulas rather than needles. Also, there are other variables involving safe injecting which have to do with the provider's number of years injecting fillers, number of years in practice, and number of VO events per device type. There are many aspects that go into choosing the right approach depending on patient factors such as anatomic site and type of defect being treated. This is why as a DNP prepared nurse it is sufficient to implement a strategic analysis prior to injection to understand the patient factors that will dictate the safest option when injecting.

Within this article, it discussed the benefits of HA filler and the reason why patients receive injectables. Lipko-Godlewska et al. (2021) discussed the change of HA fillers on how they are used today which has evolved compared to last two decades. Curating a treatment plan for every patient that is based off anatomy, sex, and individual adjacent features is specifically important that begins with the first visit. As a DNP prepared nurse, from a leadership standpoint, it is important to implement guidelines that assist staff to give proper patient care. This will improve overall patient outcomes and educate staff on new trends that can be discussed within coordinated monthly meetings.

Impact of the Problem

The incidence of VO from Dermal fillers complications has increased to more than 190 cases associated with retinal vascular occlusion in four years, where 95% experienced complete loss of vision and in worse cases, death (Middleton, 2022). Dermal fillers can result in VO through direct injection into an artery or blockage of the blood vessel from product which typically presents itself through blanching and pain (King et al., 2020). The concern with VO from dermal filler injections in an aesthetic medical practice is the health risks to the patients, and potential lawsuits to a practice. Having ill-prepared staff members preventing and managing VO's can lead to unhappy patients, further health issues with the patient, and puts a practice at risk for lawsuits. The contributing problem with the risk of VO incidents is due to lack of education on how to prevent, treat VO, injection anatomy, technique, assessment, and improper post patient care. There are efforts to reduce the risks through proper education to injectors, injection techniques, assessment, and product selection. The incidence of VO persists, which creates an inclusion for effective management strategies and research-based protocols.

Addressing Hyaluronic Acid Induced Vascular Occlusions

There is a need in the medical spa industry using HA filler for new updated VO kits and protocols. Murray et al. (2021) emphasized the lack of safe injection planes, comprehensive guidelines, and protocols that specifically address VO management, prevention, and recognition. The gap within the current practice is supplying injectors with existing protocols and necessary tools that are not effective nor significant for adverse events from a VO.

Clinical practices need to be reliant on national guidelines and regulatory statements as they play a critical role in enhancing the current practice. Clinicians should work to adopt a safer injection technique and emphasize the importance of three-dimensional facial anatomy.

According to Sito (2019) there are protocols that are outdated and suggest a low dose and hyper

diluted treatment against HA-induced VO. Implementing new research-based protocols within the facility and providing trainings to the providers; can generate increased competency and successful management of adverse outcomes in an emergency management response for VO incidents. This gap will create more efficient guidelines rather than leaving providers to rely solely on their experience and expertise which would lead to inconsistencies in the practice. Middleton (2022) stated that although there are millions of procedures performed each year it is still necessary to mandate emergency protocols based on the existing research to reduce the risks.

Compliance for Vascular Occlusions

Collaborating with other injectors, plastic surgeons, and healthcare professionals to assess that protocols align with best practice in the industry and are feasible for the clinic is important when developing a VO kit and protocol. A VO kit will be created and implemented within a 5-week timeframe and should include at least 30 vials (30 ml) of hyaluronidase, medication needed (aspirin, clopidogrel), and an evidence-based protocol for preventions, early detection and management (King et al. 2020). After creating and implementing a treatment kit and protocol there will continue to be further review, development, and training.

Evidence Gaps and Controversies.

The current level of healthcare for HA-induced VO is not having sufficient vials of hyaluronidase and an educated staff to perform dissolving agent in case of a VO. The optimal level of healthcare at the site will be equipped with fully stocked basic and advanced kits. This will be filled with 30 vials of hyaluronidase per kit as well as a protocol used to guide the injector (Murray et al. 2021).

Project Aims

The optimal outcome would be improved compliance with VO prevention, and management protocols, resulting in a decrease in adverse reactions from dermal fillers.

Incorporating an evidence-based protocol and kit on how to treat a VO will create preparedness in the medical spa. Designing a treatment kit that includes essential tools such as (hyaluronidase, warm compresses, a treatment protocol, and nitroglycerin paste) for the management of vascular occlusions in a medical aesthetic setting. The aim of this project through these interventions is to improve compliance with VO management, and to prevent and decrease the number of adverse reactions to dermal fillers.

Project Objectives

1. **Assess the baseline compliance:** with existing vascular occlusion management protocols among dermal filler providers before the implementation of a new protocol and toolkit.
2. **Develop a standardized vascular occlusion (VO) management toolkit:** created for dermal filler providers, incorporating evidence-based guidelines and best practices.
3. **Develop a standardized vascular occlusion management protocol:** for dermal filler providers, incorporating evidence-based guidelines and best practices.
4. **Design and implement a comprehensive toolkit:** that supports the compliance to the newly developed vascular occlusion management protocol among dermal filler providers.
5. **Evaluate the impact of the protocol and toolkit:** by compliance rates among dermal filler providers, and impact of patients with VO by comparing pre- and post-implementation data.
6. **Identify barriers and facilitators:** influencing the adoption of the vascular occlusion management protocol and toolkit among dermal filler providers.

7. **Provide recommendations:** for long term compliance and continuous quality improvement in vascular occlusion management practices among dermal filler providers.

Implementation Framework

The implementation framework utilized for this project is through a PDSA (Plan-Do-Study-Act). The model has been applied to this project through the visual diagram located in Appendix B.

Population of Interest

The population of interest will include two Family Nurse Practitioners (FNP's) and three registered nurses who are all given the same training on injection anatomy and techniques. The indirect population is considered through the number of patients seen by the project site consistently for hyaluronic acid dermal fillers.

The inclusion criteria for this project include individuals aged 18 years or older, those in good health, those desiring facial enhancement procedures, individuals without current skin infections or allergies, those who are not pregnant or breastfeeding, those who have provided informed consent, and patients with vascular occlusions resulting from dermal fillers. While the exclusion criteria include minors, anyone with an allergy or hypersensitivity to lidocaine or hyaluronic acid, anybody with an active infection or cold sore, anyone who is pregnant or breastfeeding, anyone with an autoimmune disease or blood clotting disorder, anyone with dysmorphic disorder, a compromised immune system or history of keloid formation, or anyone with past adverse reactions to filler or are on blood thinners.

Setting

The DNP project will be implemented at a medical spa which is in an affluent area in Las Vegas, Nevada with five injectors and 12-15 employees staffed at one time. On average

there are 5 dermal filler injections performed per day which allows for the opportunity of a VO incident. This practice specializes in fillers, lasers, neurotoxins, body contouring, weight loss (through Semaglutide), facials, laser hair removal, Sculptra (restoration of volume loss), and chemical peels. This practice site makes it easy to access medical records and document patient progress notes, demographics and photo's through EMR. This is a private practice owned and operated by an APRN-FNP-C.

Stakeholders

The key stakeholders involved in this project include one owner, two FNPs, three registered nurses, the medical spa manager, and five patient coordinators. The FNP's and registered nurses' role are to consult with patients, prevent and assess possible VO incidents, comply with the vascular occlusion protocol, initiate treatment, and decide on next steps for following treatment and follow up care (although registered nurses are not able to prescribe medications for patients and need to consult with medical director). The patient coordinators are responsible for booking consultations and follow-ups, while the medical spa manager oversees medication orders, addresses patient dissatisfaction, and coordinates referrals for collaborative interventions, such as the need for hyperbaric chamber treatment. For the project site there is no affiliation agreement necessary between the university and the project site.

Interventions

The implementation of this quality improvement project is crucial for ensuring staff adherence to the new emergency protocol for managing vascular occlusions induced by hyaluronic acid dermal fillers. The intervention project team consists of project lead, and nurse manager/medical director. A medical record review will be conducted to establish baseline

compliance for any current treatment of VO. The education component will include group training that encompasses an assessment of competency, the distribution of updated training materials, a PowerPoint presentation, the protocol, and ongoing quarterly training sessions and evaluations. There will be detailed instructions on preventing and recognizing vascular occlusions, how to properly use necessary tools, and visual aids to effectively support the staff in understanding the new protocol effectively. The education will be delivered by the nurse manager (NP), and project lead to other NP, RN's, and managers during scheduled paid staff meetings.

A compliance audit will determine if the staff are adhering to the new guidelines and protocol, policies, and procedures. This intervention includes monitoring staff actions through auditing charts, quarterly evaluations, observing treatments performed, and conducting one-on-one meetings to assess their comprehension of the new process as well as gathering feedback. The implementation project will be reviewed and analyzed over a 5-week period in which participants will be audited and assessed to measure the level of compliance, and to make necessary adjustments (Appendix D).

Tools

Emergency Protocol Tool

The vascular occlusion emergency protocol will be established with help from reliable sources within the Complications in Medical Aesthetics Collaborative (CMAC) to help introduce reputable best practice protocols (Murray et al., 2021). Appendix E includes the management guideline that will be used to present proper protocol for treatment of vascular occlusions from hyaluronic acid dermal filler. This management guideline will be achieved by collaborating with stakeholders, communicating with other leaders in the industry, and evaluating current evidence-

based guidelines and researched based guidelines to help in the development process. The CMAC management guideline has been used in treating hundreds of vascular occlusions over the past eight years and is now used to provide support and education to medical aesthetic clinicians (Murray et al., 2021). The protocol and toolkit will be approved by the nurse manager/medical director.

Handouts for Staff

The project lead will administer handouts for staff (Appendix F and Appendix G) that is evaluated and approved by the nurse manager/medical director to be used as a quick reference to prevent, detect, and treat signs and symptoms of VO. There are refresher handouts on human skin microcirculation which contain visual aids on microcirculation and factors affecting vascular responses (Lamprea et al., 2022). The project lead also provided a handout that reviews the evaluation methods of perfusion. The assessment used takes therapeutic measures that can be done using either metabolic or clinical parameters or those that are minimally invasive (Lamprea et al., 2022). The assessments and visual aids were validated through the International Sepsis Guidelines to emphasize significance of early detection.

Educational Resources and Training Materials

To aid in the implementation of proper protocol guidelines, the project leads developed training materials and educational resources that will enhance participants' understanding of the material. A PowerPoint presentation is used as an educational tool to help the staff fully understand the extent of the project (Appendix G). Implementing visual aids, step-by-step procedures, and instructional guides will determine the validity of effectiveness and accuracy. A visual aid is attached in (Appendix H) to demonstrate to staff members the anatomical risk levels depending on facial areas. The project leader combined their own knowledge with visual aid

diagrams established and validated by CMAC which were useful to enhance the training with visualization of the anatomical risk zones (Murray et al., 2021). The project team will evaluate and provided feedback on the implementation material during the development process before approving it.

Create a Comprehensive Toolkit

This comprehensive toolkit is needed to ensure there is appropriate tools and medications issued to treat a vascular occlusion. The project lead determined the tools required which are validated through the Journal of the American Society of Plastic Surgeons and the Journal of Cosmetic Surgery, as well as collaborating with other leaders in the industry. This comprehensive kit will encompass key elements such as medications, procedural protocols, and medical devices. What is required is hyaluronidase (750 units), aspirin (or clopidogrel if client is allergic to aspirin), hot pack(s), Medrol dose pack, nitroglycerin paste, and a 25-gauge two-inch microcannula (Appendix I) (Farber et al., 2020).

In more extensive cases to visualize location, injection size, and depth of soft tissue fillers as well as hyaluronic acid fillers, an ultrasound machine is a valuable tool to guide, treat, monitor, and diagnose outcomes. Ultrasound helps guide hyaluronidase to the exact depth, and location of the embolism to better ensure adjustments in technique if needed to reach the filler effectively (Schelke et al., 2023). It is crucial to incorporate both the protocol with the tools necessary to create a proper management emergency kit. The nurse manager/medical director will evaluate and approve the developed Protocol.

Ethics/Human Subjects Protection

The project leader will implement measures appropriately to relieve ethical concerns for this project. TUN does not require IRB or QI committee to oversee protocols, guidelines,

objectives, risks, methods, benefits, and consent procedures. Confidentiality is maintained on the compliance assessment tool and the purpose of the project is clearly described. All participant information is de-identified and assigned letters only known by the project lead. This information is reviewed only to determine if the intervention is effectively adhered to by the staff.

Project Participants

The respondents will be given an option to participate and will be invited through internal communications such as direct emails. The benefits for the participants are to enhance their skills, build confidence in preventing VO, treating VO, and increase their knowledge on best practice strategies when introduced to vascular occlusions by hyaluronic acid filler. Participants are devoting training time to understand the procedures and protocols, which could lead to potential risks of emotional, physical, mental, and professional impacts. These risks will be mitigated by having and encouraging open communication, and one-on-one trainings offered as well as quarterly evaluations and conversations. The recruited participants that will join this project include two Nurse Practitioners (NPs), three registered nurses, and the manager from the project site. All participation in this quality improvement project is voluntary. All providers that will not be present must reschedule a time for one-on-one training to continue to see patients within a 30-day timeline. Compensation for participation includes paid clock in time, as well as some approved healthy snacks at the beginning of the meeting.

Data Collection

The aim of data collection is to obtain relevant information that will help achieve the project objectives. Data will be collected before, during, and after implementation to evaluate the success of the interventions. The data will be collected using observational methods, including standardized checklists and systemic chart reviews, to help record whether these interventions

were successful. A systematic chart review will evaluate baseline compliance with any existing VO management protocols, how a provider is responding to VO, and how many VO incidents have occurred within the medical spa. A post-implementation review is done to evaluate the compliance and impact of the new protocol and toolkit and identify any barriers. By creating a standardized checklist, we can establish a comprehensive evaluation for preventing and recognizing VO while also assessing the overall impact of the interventions.

Chart Audit

A chart audit will be conducted weekly on patients receiving hyaluronic acid dermal fillers, focusing on preventative care and symptoms of possible vascular occlusion incidents. The chart audit will be collected from every provider for patients 12 weeks pre-intervention (3-month period, 180 charts pulled), and 5 weeks post-intervention on every patient treated with fillers. The chart review is managed by the project lead using the EMR (Vagaro) from the medical spa facility. The information that will be collected includes patient history, all charting on each patient, any incident reports, and training records.

The data retrieved from analysis during and after is recorded using the chart audit form (Appendix J and Appendix K). The purpose of the chart audit is to gather data on VO prevention, vascular occlusion events that occurred, and interventions used. This information can help promote protocol adjustments, ongoing training and education, ensure injectors are following training and protocol, and assess improvement rates (Appendix K and Appendix L).

Checklist

A customized checklist will be provided for each patient chart to determine whether the participant was assessed based on specific criteria for vascular occlusion management and prevention (Appendix M). This includes pre-treatment assessment of patient history and whether

the risks of VO from filler were discussed. It will also include intervention procedures by asking if proper technique was used, and if a VO was identified. The checklist will include a response to adverse reactions on whether hyaluronidase was administered, if an ice pack for swelling was used, and if a patient was monitored for changes. Lastly, it includes a follow up section asking if findings were documented in the patient's chart and if follow up appointments were made. This tool will ease the process of ensuring that all crucial elements of the protocol can be assessed post implementation.

The checklist is printed and ready for each participant to use if any signs or symptoms of VO occur. Responses consist of yes and no questions to simplify data collection. Any "no" responses indicate the protocol was not followed, while all "yes" responses ensure the protocol was followed. The checklist will be filled out for each patient showing any signs or symptoms of VO by providers for 5 weeks post-protocol implementation. The provider will notify the project lead and nurse manager about any filled-out checklist within 24 hours of the incident.

Participant Confidentiality and Data Protection

Maintaining participant confidentiality is crucial to protect their privacy and ensure the security of the intervention data. Identifiable information collected through chart reviews and checklists will be replaced with unique identifiers to maintain anonymity. The Health Insurance Portability and Accountability Act (HIPAA) safeguards patient medical information and any identifiers that could be linked to individuals (Butler & Middleman, 2018). Participants will receive consent documents outlining the interventions procedures, study purpose, and confidentiality measures (Appendix N). The participant will have the option to withdraw from the study at any time.

Plan for Data Analysis

The data analysis approach that will be used is descriptive statistics using the Statistical Package for Social Science (SPSS) to assess the baseline compliance with existing VO management protocols before the implementation of the new protocol and toolkit. To evaluate the impact of the protocol and toolkit, the data will be analyzed using descriptive statistics to determine specific measures in the tool and chi-square test. This will help understand compliance rates from the participants. The plan for data analysis is outlined in Table 1, with additional details located in Appendix O.

Table 1
Plan for Data Analysis

Project Objectives: (paste project objectives from DNP Project I here)	Planned data collection approach to achieve objective (if applicable)	Planned data analysis approach (if applicable). Choose option a, b, c, or d (listed below)	Data analysis software: SPSS, Excel, statistician (please list)
Objective 1: Assess the baseline compliance: with existing vascular occlusion management protocols among dermal filler providers before the implementation of a new protocol and toolkit.	Pre observation and chart audit	Descriptive Statistics	SPSS
Objective 2: Develop a standardized vascular occlusion (VO) management toolkit: created for dermal filler providers, incorporating evidence-based guidelines and best practices.	Research and collaborative relationships	N/A	N/A

Objectives 3: Develop a standardized vascular occlusion management protocol: for dermal filler providers, incorporating evidence-based guidelines and best practices.	Research and collaborative relationships	N/A	N/A
Objective 4: Design and implement a comprehensive toolkit: that supports the compliance to the newly developed vascular occlusion management protocol among dermal filler providers.	Research and feedback	N/A	N/A
Objective 5: Evaluate the impact of the protocol and toolkit: by compliance rates among dermal filler providers, and impact of patients with VO by comparing pre- and post-implementation data.	Checklist and chart audit	Descriptive Statistics and CHI square test	SPSS
Objective 6: Identify barriers and facilitators: influencing the adoption of the vascular occlusion management protocol and toolkit among dermal filler providers.	Staff & observation	N/A	N/A
Objectives 7: Provide recommendations: for long term compliance and continuous quality improvement in vascular occlusion	Post audits & team meeting	N/A	N/A

management practices among dermal filler providers.			
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Analysis of Results

The results were reviewed using descriptive statistics in SPSS to assess baseline compliance through pre-observation checklists and chart audits. There are a series of questions based on the objectives, checklist, and chart audits that the injectors were assessed on. Due to insufficient data a chi square test was not performed at this time but will be conducted once more data is available.

Informed Consent Compliance

Based on the consent forms provided to the five participants (injectors), all participants provided their informed consent for the entirety of this project, achieving a frequency of 100% participation on both pre- and post-assessment. This indicates that the informed consent data remained the same before and after the intervention (Table 2).

Table 2. Descriptive Statistics: Informed Consent Documentation

Pre-Assessment:

Informed_Consent	Frequency	Percent	Valid Percent	Cumulative Percent
yes	5	100.0	100.0	100.0

Post-Assessment:

Informed_Consent

	Frequency	Percent	Valid Percent	Cumulative Percent
yes	5	100.0	100.0	100.0

Medical History Documentation

After reviewing the pre and post chart audits in Appendix J and K for past patient medical history, the pre-assessment data reported that 153 patients (95.62%) had their medical history filled out, while 7 patients (4.38%) did not. Following the implementation of the protocol, all 56 patients (100%) had their past medical history documented and reviewed. This indicates that the protocol was successful in ensuring that the patient medical history was properly filled out and reviewed after implementation (Table 3).

Table 3. History Assessment: Documentation of Relevant Medical History

Pre-Assessment:

History_Assessment				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	7	4.38	4.38	4.38
Yes	153	95.62	95.62	95.62

Post-Assessment:

History_Assessment				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	0	0	0	0
Yes	56	100	100	100

Vascular Occlusion (VO) Assessment and Prevention

The pre-implementation collection tool showed data that revealed 1 “Yes” (0.63%) for possible adverse reaction and 159 “No’s” (99.37%). The assessed possible VO was determined by an adverse reaction of slow capillary refill time with minor bruising and swelling. After

implementation of the protocol there were 100% No's for adverse reactions for all 56 patients which indicates the goal of improving VO reduction was achieved (Table 4).

Table 4. V.O Assessment: Assessment of vascular occlusion

Pre-Assessment:

VO_Assessment				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	159	99.37	99.37	99.37
Yes	1	0.63	.63	100.00

Post-Assessment:

VO_Assessment				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	56	100	100.0	100.0

VO Preventative Measures

After gathering data from the chart audit data collection tool (Appendix J) prior to protocol implementation, the data returned that 1 patient (.63%) out of 160 patients were treated for possible VO with preventative measures after hyaluronic acid injection.

When reviewing the patient charts post- protocol implementation (Appendix K), the data shows that all 56 patients were treated with preventive measures after hyaluronic acid injection.

Although not all interventions were done, charting showed massages were performed after every patient to increase and assess blood flow. This indicates that there was a significant increase of 100% in compliance with preventative measures used (Table 5) by improving provider adherence to preventative care.

Table 5. Were VO preventative measures used? (I.g. techniques)

Pre-assessment:

VO_preventative_measures				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	159	99.38	99.38	99.38
Yes	1	0.63	0.63	0.63

Post-assessment:

VO_Preventative_measures				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	0	0	0	0
Yes	56	100.0	100.0	100.0

Follow-Up Completion

Follow-up completion rates both pre- and post-implementation were 100% for all patients after hyaluronic acid filler appointments. Both the pre- and post-assessment results indicate that follow-up procedures remained unchanged and effective (Table 6).

Table 6. Follow-Up Completion: Participants Completed Follow-ups

Pre-Assessment:

Follow_Up_Completion				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	160	100	100.0	100.0

Post-Assessment:

Follow_Up_Completion				
	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	56	100	100.0	100.0

Protocol Adherence

A review of the pre-assessment chart audit (Appendix J) confirmed that no VO protocol was used, giving 100% “No” for all 160 patients. The post-assessment data confirmed that the protocol was followed for all 56 patients, demonstrating a significant improvement from 100% “No” in the pre-assessment to 100% “Yes” in the post-assessment results (Table 7). This shift indicates that the VO prevention and management protocol was integrated successfully into practice.

Table 7. Protocol Adherence: Was a VO protocol Used?

Pre-Assessment:

Protocol Adherence				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	160	100	100.0	100.0
Yes	0	0	0	0

Post-Assessment:

Protocol Adherence				
	Frequency	Percent	Valid Percent	Cumulative Percent
No	0	0	0	0
Yes	56	100	100.0	100.0

The progress of the implementation is shown in visualizations, including the timeline attached in **Appendix P and Q**, and the data that was collected from the chart audits are interpreted in **Tables 2-7**. The quantitative results showed a major improvement in compliance from providers, which led to better patient outcomes. As for the qualitative results, providers indicated they are developing more confidence in their practices when using prevention and management strategies of the protocol. Providers discussed the importance of using a protocol,

and proper preventative measures, such as using correct techniques to effectively prevent occlusion before it occurs.

Summary

The implementation of a standardized vascular occlusion (VO) management and prevention protocol and toolkit resulted in significant improvement in patient safety outcomes over a 5-week period. Pre- and post-assessment data showed an increase from 95.62% to 100% for history assessment reviewed, and .63% to 100% for preventative measures used. No reported VO's post-implementation that suggests the protocol was effective in preventative care. Additionally, follow-up completion rates remained the same. Overall, the data shows that the protocol was successful in enhancing provider care, and patients' outcomes. Providers gave positive overall feedback on the new protocol.

Interpretation

Patient safety and satisfaction is the goal in aesthetic intervention, which allows injectors to improve their injection skills, achieve superior cosmetic outcomes, and avoid complications (McDonald & Heydenrych, 2022). The literature suggests that injectors who are consistently improving their skills provide better patient outcomes and can avoid complications. This aligns with the project results shown after implementation. All providers adhered to the VO prevention and management protocol by achieving 100% compliance. This implementation impacted both providers confidence in handling VO prevention and management and patients on safety and satisfaction. Providing a checklist and visual aids created great tools for the injectors to use as a reference alongside the protocol, which was a major implication for professional development. The protocols impact on patient safety and satisfaction was achieved by lowering the rate of VO

incidents while also enhancing the quality of care, which creates a more consistent, and safe treatment.

Based on the data, the results demonstrate a positive impact, since prior to the protocol's implementation, there was 1 reported possible VO case (slow capillary refill), and post-implementation chart review followed with no reported cases of VO incidents. These outcomes show an improvement in the providers' ability to prevent and manage VO incidents. The observed outcomes are closely aligned with expectations, that significantly improve protocol compliance and provide confidence. Although more data is needed to assess the protocols' long-term effectiveness due to a short implementation period, the data did suggest the overall intervention was successful with protocol compliance, and reducing VO incidents from pre-implementation period to post-implementation.

Although the intervention was successful, there are costs and strategic trade-offs to consider. The costs include the time spent on training as well as developing the toolkit and protocol. Given the small sample of participants, the cost of training is manageable. To help injectors in the transition, some possible opportunity costs include hiring additional employees to avoid overwhelming current employees by condensing their schedules. Since the chart reviews and checklists can be time-consuming, it is important that the process does not oversaturate injectors' time while providing consistent care. The focus on resources for implementing the protocol and training providers, could consist of trade-offs with other potential investments, which can include marketing or expanding services. Creating long-term benefits that improve patient safety and provider confidence could avoid financial risks, compliance risks with regulatory standards, and poor patient safety (McDonald & Heydenrych, 2022).

Limitations

There are several factors that influenced the results of the project based on the data analysis. Although there were several limitations encountered during this project and the efforts to minimize them, the overall implications identified were bias, design, data collection, and data analysis.

Bias

To address potential bias, the project ensured that all participants received a similar level of training and were provided with identical protocols for improving compliance and prevention in VO management. This approach created a standardized training experience for all participants to reduce any possible differences in the outcomes.

Design

There was a significant limitation that came from the small sample size that consisted of two nurse practitioners, three registered nurses, and a manager all working in a single medical spa. This limited participant size does not reflect the broader population of healthcare providers involved in aesthetic procedures, which limits the results of the study.

The time frame of the implementation was limited to only 5 weeks, which created a challenge in assessing the long-term effectiveness of the protocol. A longer implementation period could have allowed for more data to be evaluated to determine the long-term effects of the protocol on vascular occlusions. Even though there was a short implementation period, data was still collected before and after implementation, which compares the changes in both protocol adherence and VO management.

Data Collection

The project relied on observational methods such as checklists and chart audits, which may introduce inconsistencies if not properly recorded or interpreted. Incomplete data from

injectors failing to fill out documentation could lead to underreporting and overreporting of compliance. To minimize data collection risks, the project team conducted regular check-ins with participants to reinforce protocol adherence and clarify any uncertainties.

Data Analysis

The small sample size restricted the use of advanced statistical tests, such as the chi-square test, to assess changes in outcomes. Instead, only descriptive statistics were used, which may not have fully captured the complex relationships influencing protocol adherence and VO occurrences. More time would allow for more robust statistical analysis. Despite the limitations, the project successfully measured protocol adherence, ensuring the effectiveness of the intervention.

Conclusion

This project successfully enhanced providers knowledge of VO prevention and management in dermal filler injectables. The comprehensive protocol and toolkit increased awareness, improved standardized practice approaches, and reduced VO incidents. A notable shift in data was observed from one reported possible VO case pre-implementation period to zero post-implementation period. The impact on compliance and preventative measures promoted both patient safety results and provider confidence, which reached a 100% increase in using preventative measures on patients and reduced VO incidents. While the timeframe of data collected was limited, these findings underscore the positive impact on provider response to VO's, and patient safety. To be able to see continuous improvements and sustainability, the project should implement monthly audits by designated staff, track outcomes, and provide ongoing feedback to providers. Resources and training tools should be updated regularly to reflect the latest evidence-based practices. This includes further investigation to be done to

determine if the response is sufficient and if the training is sufficient to improve patient outcomes.

It is important for this project to extend into a longitudinal study with a larger and more diverse sample size that would allow for comprehensive statistical analysis and validation of long-term results. This project promotes the importance of protocol adherence, recurring training, and systematic data collection in improving patient outcomes. It also shows the critical role of nurses in aesthetic medicine and the need for comprehensive education in this growing field. These standardized procedures could influence policies and be adopted by other medical spas, fostering industry-wide compliance in VO prevention and management. The next steps should focus on evaluating the long-term effects of the protocol, particularly reducing VO's over time. To address these limitations, future research should focus on extended timelines and larger sample sizes to determine the protocols efficacy from various providers and aesthetic facilities. This will create a better understanding of the future long-term benefits of the intervention and can help improve the protocol on a larger scale.

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Appendix A

Gap Analysis

Best Practices	Best Practice Strategies	How do project site practices differ from best practices?	Barriers to best practice implementation
Research based guideline to educate team on adverse events	Set up a team meeting to deliver new implementation information to staff. Guide staff on what guidelines entail.	Project site does not have a step-by-step protocol on how to treat and assess hyaluronic acid induced vascular occlusion. Best practice will have protocols and kits available and taught to all members at the project site.	Poor staff adherence to the protocol
Assembling a treatment kit including hyaluronidase, saline solution, and warm compresses.	Equipped with enough supplies through access from referrals.	Project site is limited to only a couple vials of hyaluronidase. Best practice will be fully equipped with at least 30 vials of hyaluronidase per basic treatment kit.	Not having inventory control to carry proper number of supplies to treat the occlusion
Schedule follow up appointments	Providing patients with post injection instructions and contact information just in case there are delayed complications.	Project site does not follow up and contact patient prior to appointment to assure there are no severities. Best practice will schedule follow-up	Injectors do not follow post procedural instructions and risk a patient having a possible delayed adverse event.

		visits with patients to assure there are no new signs of possible vascular occlusion siting's.	
Referrals for proper machinery to accelerate healing time	Access to hyperbaric chamber, red light therapy	Project site does not carry or have referrals to access proper machines in case of a vascular occlusion. Best practice will offer next steps advanced cases if basic protocol is not sufficient for patients' vascular occlusion.	Not being able to make connections for referrals, or purchase advanced machines to accelerate healing time for our VO patients
Visually localizing depth and location of filler using advanced machines.	Equipped with an ultrasound machine or access through referral	Project site relies on visually localizing occlusion based on color. Best practice is supplied with ultrasound machine, or access through referral to understand depth, size, and location of embolus.	Not having enough funds, or connections to be able to purchase or have access to an ultrasound machine.

SWOT Analysis

Strengths	Weaknesses
What does the organization do well? What organizational resources exist to support the project?	What can the organization improve upon? What organizational resources are lacking that would be necessary to support the project?
1. <ul style="list-style-type: none"> • Being able to understand the need for prevention and proper protocols. • • Proper education on facial anatomy 	<ul style="list-style-type: none"> • Not having an established referral and transfer process
2. <ul style="list-style-type: none"> • Research based existing protocol. • Feedback from injectors and staff. 	2. <ul style="list-style-type: none"> • Not having a proper care coordination method
Opportunities	Threats
What opportunities are available for the project? How can strengths be turned into opportunities?	What threats could harm the project? What threats do the weaknesses expose?
1. <ul style="list-style-type: none"> • To have a protocol for staff to refer to. • To be able to have access to proper medication to treat a patient's vascular occlusion. 	1. <ul style="list-style-type: none"> • Not having proper medication on site • Providers having lack of knowledge on VO assessment.
2. <ul style="list-style-type: none"> • A prepared team that knows how to access a vascular occlusion kit, how to treat, and how to assess the situation if needed. 	2. <ul style="list-style-type: none"> • Not having prepared staff with a researched protocol on how to handle a VO event that could cause necrosis to the tissue.

Appendix B

PDSA Framework: Quality Improvement Project
Framework developed by Edward Deming and Walter Shewhart in 1939, identified in their book, "Statistical Method from the viewpoint of Quality Control"



Appendix C

Project Implementation Timeline

Introduction	
Project Site	Medical Spa
Project Mentor	Elizabeth Solomon
Project Purpose	The purpose of this project is to improve compliance with VO prevention, and management protocols, resulting in a decrease in adverse reactions from dermal fillers.
Project Question	For providers involved in administering dermal fillers, does the development and implementation of a vascular occlusion (VO) management protocol and toolkit increase compliance with VO management protocols over a 5-week period compared to the compliance rates during the pre-implementation period?
Project Timeline	
The project will be executed over five weeks, with a focus on education, implementation, data collection, and analysis. The timeline is as follows:	
Week 1	<ul style="list-style-type: none"> • Conduct pre assessment by observing and chart audits. • Provide training session on protocol and kit. • Provide information during paid scheduled staff meetings to adhere to the procedures. • Official “go live” with protocol. Implement protocol into practice.
Week 2	<ul style="list-style-type: none"> • Start collecting data on any occurrences of VO’s and treatment responses based on updated protocol. • Administer compliance assessments to participants to gather feedback. • Handout visual aid to participants to analyze and review. • Conduct chart review
Week 3	<ul style="list-style-type: none"> • Analyze data to identify any consistent trends or issues. • Consistently document treatments, participant feedback, and incidents. • Conduct chart review
Week 4	<ul style="list-style-type: none"> • Continue conducting analysis of collected data • Initiate staff interviews to conduct feedback. • Conduct chart review
Week 5	<ul style="list-style-type: none"> • Create a summary of the findings and feedback • Adjust the protocol and kit based off final findings and recommendations

	<ul style="list-style-type: none">• Conduct chart review
--	------------------------------------------------------------------------

Appendix D

Group Training Outline

- 1. Training Introduction – 5 min**
- 2. Objectives – 2 min**
- 3. PowerPoint Presentation – 15 min**
 - o Improving Compliance with Vascular Occlusion Protocol and Toolkit
 - o Understanding the Risk of Vascular Occlusion
 - o Understanding Vascular Occlusion
 - What is a Vascular Occlusion
 - o How do we treat VO
 - o Measuring Compliance
 - o What Does This Mean for Injectors
 - o What's Next
 - o References
- 4. Pass Out and Go over Vascular Occlusion Protocol and Kit – 15 min**
- 5. Role Play with Scenarios of Patients with VO – 20 min**
- 6. Ask Questions – 5 min**

Appendix E: Protocol

Prevention and Management Guideline for Treatment of Vascular Occlusions Induced by Hyaluronic Acid Dermal Filler

Expectations: Injectors should be well educated and prepared with the provided visual aids (Appendix F), powerpoints (Appendix G), and detailed information of the three-dimensional anatomy of the area that will be treated (Appendix H). During every procedure, injectors must be aware of signs of a potential occlusion and how to prevent, assess, manage, and monitor changes to the affected area. Refer to Protocol visual as a quick reference (Appendix I).

Treatment Kit Includes:

30 vials (30 ml) of Hyaluronidase
Aspirin (Clopidogrol)
1mL and 3mL Syringes
25-30 guage Needles
Sterile Gauze, Bandages, alcohol swabs, gloves
Topical nitroglycerin paste
Heating pad

Pre-Treatment Assessment:

- Review patient medical history (Contraindications: allergy or previous reaction to filler, pregnancy or breast feeding, and active herpes in area of injection)
- Ensure patient is aware of the risks that can cause a vascular occlusion.
- Provide patient with post treatment instructions
- Ensure patient is aware of any minor complications that may occur such as edema, pain, erythema, itching, and more serious complications that result in blindness and skin necrosis (Colon et al., 2023).

VO Prevention:

1. Anatomical risk zones to help prevent an occlusion from occurring (Appendix H):
 - **Lower Risk Areas:** Chin, Cheek, Jawline

- **Moderate Risk Areas:** Lips, Midface, around the mouth
 - **High Risk Areas:** Periorbital (around eyes), Nasolabial folds, Glabellar Region (in between the eyebrow), temples, nose, forehead
2. Ensure proper injection technique is followed with aspirating needle upon injection, and massaging injection site after injection.
 3. Check for blood supply by assessing capillary refill after injection
 4. Avoid injecting into areas with previous scarring (King et al., 2020).

Injection Technique:

- Aspirate before injecting to ensure the injection is not intravascular (King et al., 2020).
- Using a cannula of 25 gauge or larger is recommended (Murray et al., 2021).
- Use small volumes of filler in increments to avoid overfilling the area (King et al., 2020).
- Inject slowly (Use a slow injection technique at low pressure) (King et al., 2020).
- During injection observe for skin discoloration and slow capillary refill

****Immediately stop injection if signs have been detected and continue to Vascular Occlusion Assessment.****

Vascular Occlusion Assessment

1. During and after injection, observe the patient for possible signs of occlusion such as blue/gray appearance, blanching, and livedo pattern within the treatment area (King et al., 2020).
2. Assess patient's capillary refill time (CRT) which is considered the distal body region that can regain color after being compressed. CRT is two to three seconds for men and women under 65 years of age, and four seconds for elderly patients (King et al., 2020).
3. If there is discoloration or slow capillary refill then firmly tap and massage the area for several minutes to increase blood flow (King et al., 2020).
4. Apply heat to the area using a heating pad.

If symptoms have not resolved and CRT is not less than 3 seconds, then continue on with the next step.

5. Inject hyaluronidase as it will break down hyaluronic acid by injecting into or around the

treatment area to dissolve the dermal filler (Murray et al, 2021).

- a. Large volume of hyaluronidase of 450-1500 units (5-15 vials) should be distributed over the entire area in intervals every 30 minutes until occlusion has broken down (King et al., 2020).
6. Provide aspirin or clopidogrel to limit platelet aggregation.

After assessing the treatment area if worsening continues that is when an advanced protocol is necessary which is when the injector will follow steps 7 and 8.

7. Use high-frequency ultrasound machine that allows the injector to gain visualization on the depth, size, and location of the embolus (Murray et al., 2021).
8. Refer patient to hyperbaric chamber clinic. In extensive cases hyperbaric oxygen therapy can help prevent necrosis after vascular occlusions and can improve tissue regeneration through inhaling oxygen in a pressurized chamber (Rodriguez & Nieto, 2023).

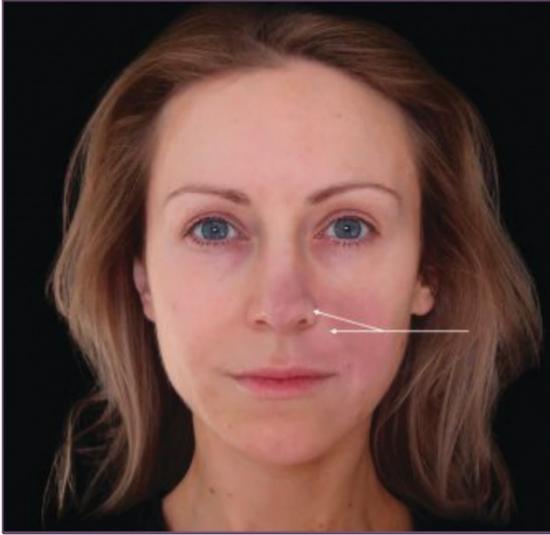
Follow up care

9. Initiates follow up post procedure appointments every 24 hours for 5 days for recurring updates on patient status.
10. Provide patient written instructions on the signs and symptoms of complications and what to watch for. Instruct them on how to get ahold of provider if any further issues occur.

Appendix F: Handouts

Assessing a Possible Vascular Occlusion

(Murray et al., 2022)



Stage 1: Blanching



Stage 2: Livedo Reticularis

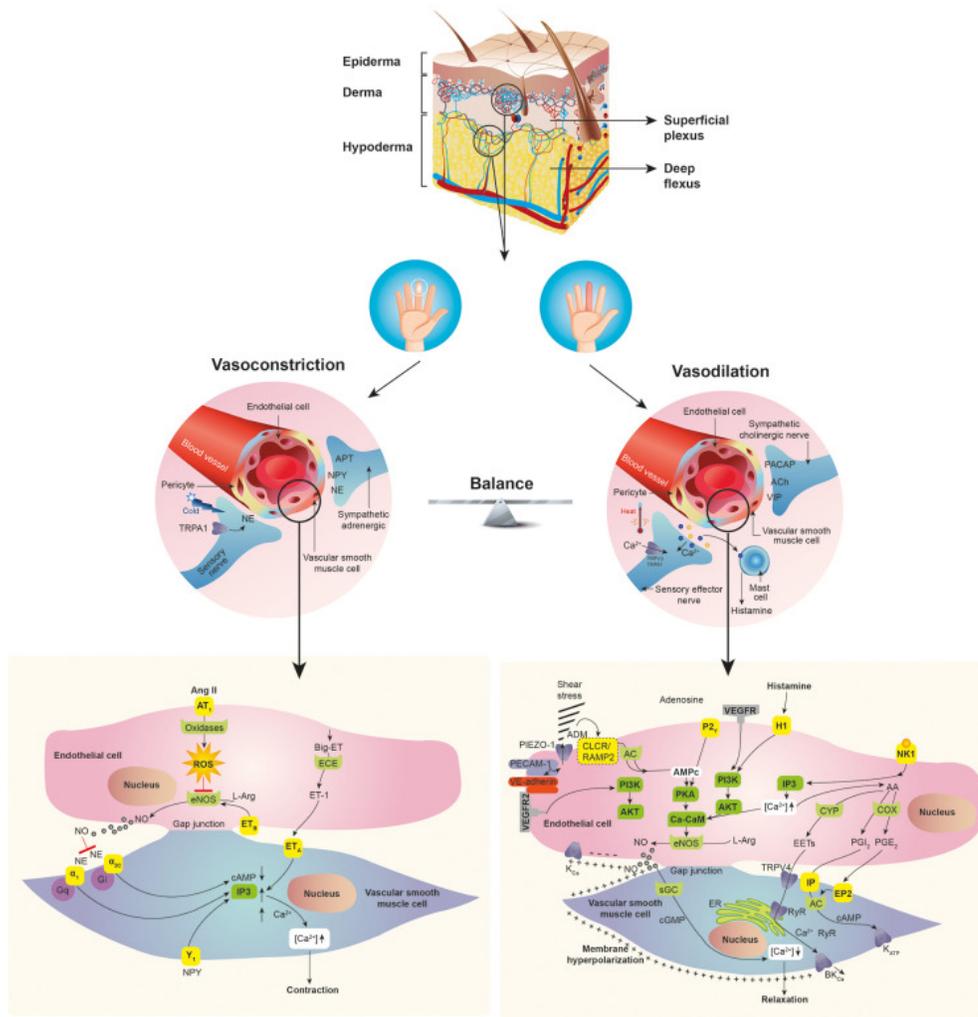


Stage 3: Bacterial Bioburden



Stage 4: Coagulation

Human skin microcirculation



(Lamprea et al., 2022)

Normal CRT ranges. (Capillary Refill Time)

Age group	Normal capillary refill time	Comments	Reference
Newborns (<7 days)	Up to 5–7 s	Newborn skin immaturity 55% sensitivity and 81% specificity for detecting low blood flow	(6 , 22)
Infants and children	<2 s (measured in the index finger)	Five seconds of pressure on the index finger and at a temperature between 20°–25°C	(5 , 11 , 26)
	<4 s (foot or chest)	Same conditions as above	(16)
Adolescents and adults	<3.5 s		(21)
Older adults	<4.5 s	Related to vascular changes	(21)

(Lamprea et al., 2022)

Description of perfusion evaluation methods.

Evaluation	Method	Cut-off point	Advantage	Disadvantage	Reference
Clinical evaluation	Body temperature		Low cost and easy implementation Allows assessment of “cold” or “warm” shock	Requires an assessment tool; is dependent on room temperature	(4 , 5)
	Temperature difference	Skin temperature difference assessed	Low cost and easy implementation	Observer-dependent	(4 , 5)

Evaluation	Method	Cut-off point	Advantage	Disadvantage	Reference
		using the back of the hand			
	Skin findings	Pallor, cyanosis, skin mottling	Low cost and easy implementation Microcirculatory evaluation Interobserver agreement	Difficult to evaluate in people with dark skin	(4 , 5 , 8)
	Capillary refill time	<2 s	Low cost and easy implementation Quantification of capillary perfusion Microcirculatory approach	Depends on room temperature, skin color, age	(5)
Metabolic evaluation	Lactate	<2 mmol	Low cost and easy implementation Flow-sensitive parameter	Increased lactate with beta-adrenergic stimulation	(4 , 9)
	SvmO2— ScvO2	70%	Continuous and/or intermittent measurement Interchangeable for clinical purposes Flow-sensitive parameter	SvmO2 requires blood drawn from a pulmonary artery catheter, while ScVO2 can be easily obtained from a central venous catheter	(4 , 9)

Evaluation	Method	Cut-off point	Advantage	Disadvantage	Reference
	Venous-arterial CO2 difference	6 mmHg	Flow-sensitive parameter	Intermittent measurements, need for arterial and venous samples	(4 , 9)
Evaluation with imaging	Doppler		Flow assessment using Doppler	Requires equipment and trained staff	(4)
Other evaluation methods	NIRS		Non-invasive	Requires equipment Evaluate limitations: edema, jaundice	(4)
	Video-microscopy	Depends on the approach	Direct visualization of the microcirculation	Result variability Requires equipment	(4 , 10)

(Lamprea et al., 2022)

Appendix G

Training Materials: PowerPoint Presentation

COMPLIANCE WITH VASCULAR OCCLUSION PROTOCOL AND TOOLKIT

KAMILLE BOSTON CROCKETT

IMPORTANCE OF IMPROVING COMPLIANCE WITH A PROTOCOL AND KIT

- **PROBLEM STATEMENT:** PATIENT SAFETY IS AT RISK WITH VASCULAR OCCLUSION (VO) FROM DERMAL FILLERS. THE PRACTICE IS ALSO AT RISK WITHOUT A PROTOCOL AND KIT IN PLACE FOR PROVIDERS TO BE ABLE TO PROPERLY TREAT VO'S

- **RATIONALE:** THIS IS A CRITICAL ISSUE THAT AFFECTS PATIENT SAFETY AND LIABILITY OF MEDICAL SPA. THE OVERALL SAFETY OF THE PRACTICE AND PATIENT NEEDS TO IMPROVE WITH PROPER VO MANAGEMENT.

- **INJECTORS ROLE:** ALL INJECTORS INJECTING HYALURONIC ACID FILLER SHOULD BE ABLE TO CONFIDENTLY TREAT A VASCULAR OCCLUSION WITH ALL ITEMS NEEDED AVAILABLE TO THEM.

- **OBJECTIVE:** TO IMPROVE PROVIDER COMPLIANCE WITH VO MANAGEMENT PROTOCOLS

UNDERSTANDING THE RISK OF VASCULAR OCCLUSION

1. **PATIENT SAFETY:** VO CAN CAUSE NECROSIS AND BLINDNESS TO THE PATIENT (MURRAY ET AL., 2021).

• 2. **LIVELIHOOD:** OUR JOB/LICENSE AS MEDICAL PROVIDERS IS AT RISK.

• 3. **LIABILITY:** THE PRACTICE IS LIABLE.

UNDERSTANDING VASCULAR OCCLUSION

WHAT IS VASCULAR OCCLUSION?

- VASCULAR OCCLUSION OCCURS WHEN HYALURONIC ACID (HA) COMPRESSES OR OBSTRUCT A BLOOD VESSEL WHICH LEADS TO TISSUE NECROSIS (MIDDLETON, 2022).

- SIGNS AND SYMPTOMS: MOTTLING, PAIN, SLOW CAPILLARY REFILL (KING ET AL., 2020).

- RISKS: BLINDNESS, NECROSIS, SEVERE PAIN, AND OTHER COMPLICATIONS (MURRAY ET AL., 2021).

- PREVENTION IS KEY. SAFE INJECTION TECHNIQUE AND ASSESMENT.

PowerPoint Presentation (Continued)

HOW DO WE TREAT IT?

- NOTIFY APRN/MEDICAL DIRECTOR
- FOLLOW DEVELOPED PROTOCOL AND USE ITEMS IN KIT ACCORDING TO PROTOCOL.
- WATCH AND WAIT, FOLLOW UP WITH PATIENT THE NEXT DAY AND USE ADVANCED PROTOCOL IF NEEDED.
- SET UP FOLLOW UPS WITH PATIENT EVERY DAY FOR 1 WEEK
- GOOD ASSESSMENT, COMMUNICATION WITH PATIENT, AND CHARTING IS IMPORTANT.

MEASURING COMPLIANCE

- **BASELINE DATA:**
 - - CHART AUDITS ON PAST VO'S AND MANAGEMENT
 - - PRE TRAINING QUESTIONNAIRE
- **POST TRAINING DATA:**
 - - COMPARE PATIENT OUTCOMES
 - - COMPARE COMPLIANCE WITH QUARTERLY QUESTIONNAIRE AND STAFF DEMONSTRATION

WHAT DOES THIS MEAN FOR US?

- SAFER AND HAPPIER PATIENTS
- ADVANCING OUR SKILL LEVEL
- MORE CONFIDENCE IF SOMETHING GOES WRONG

WHAT'S NEXT?

- -EDUCATIONAL MATERIALS AVAILABLE
- -CONTINUED QUARTERLY EDUCATION ON VO'S
- - QUARTERLY STAFF EVALS
- -OPEN COMMUNICATION AND FEEDBACK FROM STAFF

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Appendix H: Training Materials

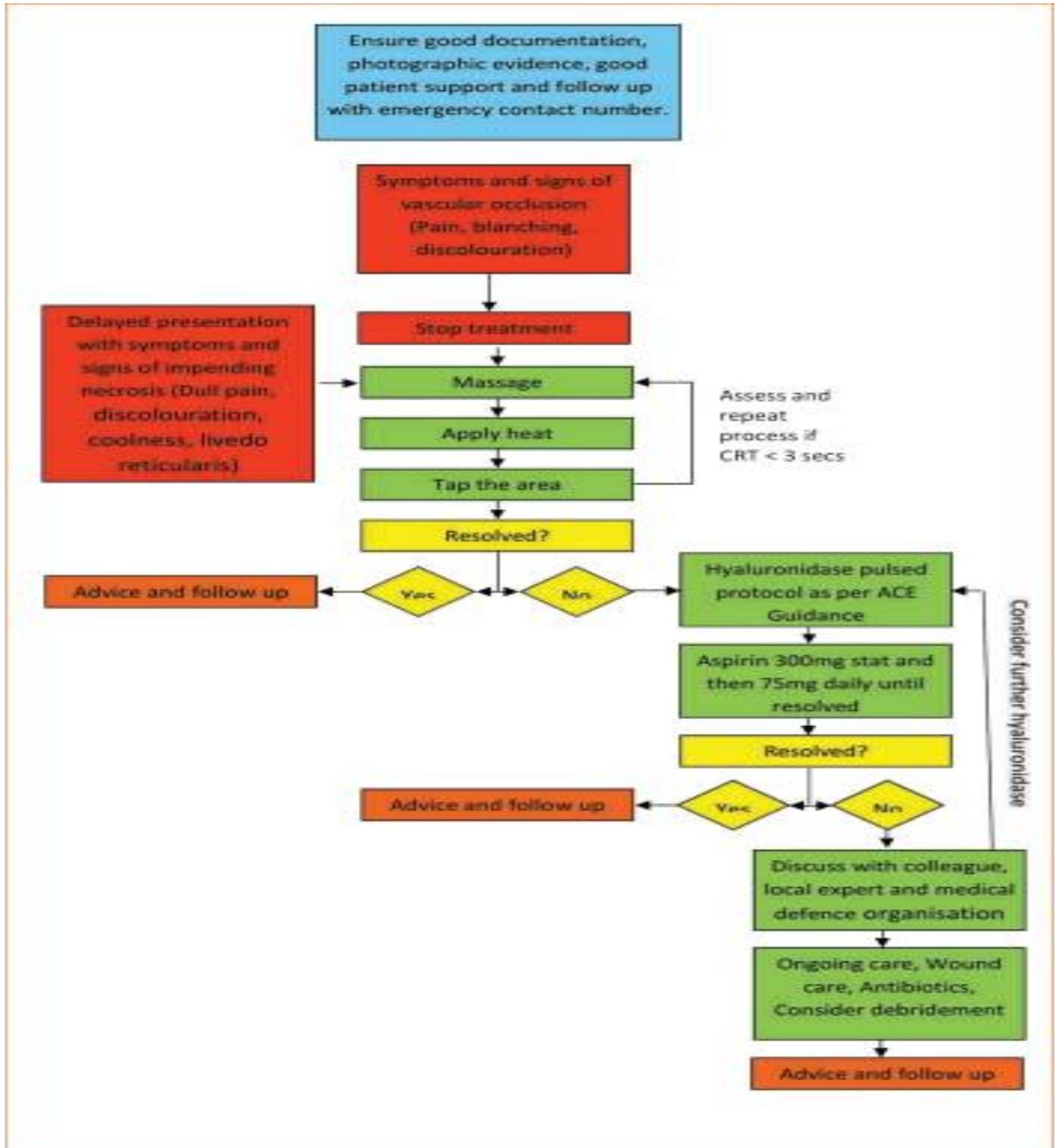
Visual Aid: Anatomical Risk Zones of Injection

Risk Evaluation	Facial Areas of Injection
Lower Risk Areas	Chin, jawline, Cheek
Moderate Risk Areas	Midface, around the mouth, lips
High Risk Areas	Periorbital (around eyes), Nasolabial folds, Glabellar Region (in between the eyebrow), temples, nose, forehead



Appendix I

Emergency Toolkit



Appendix J: Data Collection Tool
Chart Audit: 12 weeks Pre-Implementation

Key:

Juvederm – Hyaluronic A

Restylane – Hyaluronic B

Versa - Hyaluronic C

Patient ID	Type of Filler Used	Type of Reaction	Was past patient medical history reviewed?	Adverse Reaction (Yes/No)	Were VO preventative measures used? (I.g. techniques)	Were follow ups completed?	Was a VO protocol used?
001	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
002	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
003	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
004	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
005	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
006	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
007	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
008	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
009	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
010	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
011	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
012	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
013	Hyaluronic C	Normal reaction	No	No	No	Yes	No
014	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
015	Hyaluronic C	Normal reaction	No	No	No	Yes	No
016	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

017	Hyaluronic B	Normal reaction	Yes	No	No	Yes	No
018	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
019	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
020	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
021	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
022	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
023	Hyaluronic C	Normal reaction	No	No	No	Yes	No
024	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
025	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
026	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
027	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
028	Hyaluronic C	Slow sluggish capillary refill	Yes	Yes	message	Yes	No
028	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
029	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
030	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
031	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
032	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
033	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
034	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
035	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
036	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

037	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
038	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
039	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
040	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
041	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
042	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
043	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
044	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
045	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
046	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
047	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
048	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
049	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
050	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
051	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
052	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
053	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
054	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
055	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
056	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
057	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
058	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

059	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
060	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
061	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
062	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
063	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
064	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
065	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
066	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
067	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
068	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
069	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
070	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
071	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
072	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
073	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
074	Hyaluronic B	Normal reaction	Yes	No	No	Yes	No
075	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
076	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
077	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
078	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
079	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
080	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

081	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
082	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
083	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
084	Hyaluronic B	Normal reaction	Yes	No	No	Yes	No
085	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
086	Hyaluronic C	Normal reaction	No	No	No	Yes	No
087	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
088	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
089	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
090	Hyaluronic C	Normal reaction	No	No	No	Yes	No
091	Hyaluronic B	Normal reaction	Yes	No	No	Yes	No
092	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
093	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
094	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
095	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
096	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
097	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
098	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
099	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
100	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
101	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
102	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

103	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
104	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
105	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
106	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
107	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
108	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
109	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
110	Hyaluronic C	Normal reaction	No	No	No	Yes	No
111	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
112	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
113	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
114	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
115	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
116	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
117	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
118	Hyaluronic C	Normal reaction	No	No	No	Yes	No
119	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
120	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
121	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
122	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
123	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
124	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

125	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
126	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
127	Hyaluronic B	Normal reaction	Yes	No	No	Yes	No
128	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
128	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
129	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
130	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
131	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
132	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
133	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
134	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
135	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
136	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
137	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
138	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
139	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
140	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
141	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
142	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
143	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
144	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
145	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

146	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
147	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
148	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
149	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
150	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
151	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
152	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
153	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
154	Hyaluronic A	Normal reaction	Yes	No	No	Yes	No
155	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
156	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
157	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
158	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
159	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No
160	Hyaluronic C	Normal reaction	Yes	No	No	Yes	No

Appendix K: Data Collection Tool
Post Chart: 5 weeks post Implementation

Key:

Juvederm – Hyaluronic A

Restylane – Hyaluronic B

Versa - Hyaluronic C

Patient ID	Type of Filler Used	Type of Reaction	Was past patient medical history reviewed?	Adverse Reaction (Yes/No)	Were VO preventative measures used? (I.g. techniques)	Were follow ups completed?	Was a VO protocol used?
001	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
002	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
003	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
004	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
005	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
006	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
007	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
008	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
009	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
010	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
011	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
012	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
013	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
014	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
015	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes

016	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
017	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
018	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
019	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
020	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
021	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
022	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
023	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
024	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
025	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
026	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
027	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
028	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
028	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
029	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
030	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
031	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
032	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
033	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
034	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
035	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
036	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes

037	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
038	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
039	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
040	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
041	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
042	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
043	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
044	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
045	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
046	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
047	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
048	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
049	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
050	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
051	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
052	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
053	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
054	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
055	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes
056	Hyaluronic C	Normal reaction	Yes	No	Yes	Yes	Yes

Appendix L: Post- Intervention Chart Review Tool

Are Injectors following vascular occlusion protocol

Participant	1= Yes 2=No
1	
2	
3	
4	
5	

Appendix M: Checklist Data Collection Tool

Checklist Item	Yes	No
Pre-Treatment Assessment		
Was the patient's history reviewed? (allergies, skin conditions, and previous reactions to fillers)		
Were risks of vascular occlusion caused by filler discussed with the patient?		
Intervention Procedures		
Was proper injection technique used?		
Was there a Vascular occlusion identified? If yes answer		
Response to Adverse Reactions		
Was hyaluronidase administered?		
Was an ice pack used to reduce swelling?		
Was patient monitored for any changes?		
Follow Up		
Were all findings documented in the patient's chart?		
Were follow up appointments scheduled to monitor the area?		

Appendix N

CONSENT FORM FOR PARTICIPATION FOR DURATION on Improving Compliance and Prevention in Vascular Occlusion Management: Development and Implementation of Protocols and Toolkits for Dermal Filler Providers

Participant Name:

Contact Information: [Phone Number] | [Email Address]

Purpose of the Study:

This training is made to educate injectors on the comprehensive protocol and treatment kit developed to prevent and treat vascular occlusions that occur from hyaluronic acid dermal fillers. This training aims to prevent and improve the safety and efficacy of aesthetic procedures.

Procedures:

If you provide consent in this training, you will:

1. Attend a training meeting that will include a PowerPoint presentation that enhance participants knowledge on the material.
2. Receive visual aids such as instructional guides and anatomical risk level of the facial anatomy.
3. Engage in hands-on practice to apply comprehensive techniques during vascular occlusion incidents in the medical spa.
4. Complete checklist to determine if the protocol is being followed and adhered to.
5. Complete all charting needed and allow access to charts
6. Follow protocol

Confidentiality:

Your participation in this study will be kept confidential. data. Identifiable information collected through chart reviews and checklists will be replaced with unique identifiers to maintain anonymity. The participant will have the option to withdraw from the study at any time.

Risks:

While the training is designed to minimize risks, potential risks include:

- If participant handles a challenging situation during hands on training.
- Discussing complications with patients may cause psychological stress.

Benefits:

Participants can benefit from improving compliance with vascular occlusion maintenance and decrease the number of adverse reaction to dermal fillers.

Consent Statement:

Participants has read and agreed to the information provided above based on the purpose, procedures, risks, and benefits of the participation in this training. I voluntarily agree to participate and understand that I can withdraw at any time without penalty.

Participant Name (Printed): _____

Participant Signature: _____

Date: _____

Once completed, copy and paste Table 1 into your paper; the entire Data Analysis Plan worksheet should be added as an Appendix.

During this module, you will design the data collection and analysis approach. Please evaluate which option most aligns with the outcomes desired for your DNP project. You should utilize no more than two and no less than one statistical analysis tool(s). Use Table 1 to map out your statistical test(s) and the software you will use to analyze data*

Table 1
Plan for Data Analysis

Project Objectives: (paste project objectives from DNP Project I here)	Planned data collection approach to achieve objective (if applicable)	Planned data analysis approach (if applicable). Choose option a, b, c, or d (listed below)	Data analysis software: SPSS, Excel, statistician (please list)
Objective 1: Assess the baseline compliance: with existing vascular occlusion management protocols among dermal filler providers before the implementation of a new protocol and toolkit.	Pre observation and chart audit	Descriptive Statistics	SPSS
Objective 2: Develop a standardized vascular occlusion (VO) management toolkit: created for dermal filler providers, incorporating evidence-based guidelines and best practices.	Research and collaborative relationships	N/A	N/A
Objectives 3: Develop a standardized vascular occlusion management protocol: for dermal filler providers, incorporating evidence-based	Research and collaborative relationships	N/A	N/A

guidelines and best practices.			
Objective 4: Design and implement a comprehensive toolkit: that supports the compliance to the newly developed vascular occlusion management protocol among dermal filler providers.	Research and feedback	N/A	N/A
Objective 5: Evaluate the impact of the protocol and toolkit: by compliance rates among dermal filler providers, and impact of patients with VO by comparing pre- and post-implementation data.	Checklist and chart audit	Descriptive Statistics (determine what happened with specific measures in the tool) and CHI square test (Report compliance rates of staff)	SPSS
Objective 6: Identify barriers and facilitators: influencing the adoption of the vascular occlusion management protocol and toolkit among dermal filler providers.	Staff & observation	N/A	N/A
Objectives 7: Provide recommendations: for long term compliance and continuous quality improvement in vascular occlusion management practices among dermal filler providers.	Post audits & team meeting	N/A	N/A

*Note: some objectives don't require data collection to determine if the objective was met. For example, educating staff would not require data collection. Determining compliance or rates of infection would require data collection. If no data collection is required, write "n/a" in the column for data collection/analysis.

Option	Outcome	Considerations
Option A: paired t-test OR Wilcoxon signed rank test	Type of data: Numerical scores or rates that can be assigned to participant/provider/ location and that are measured before and after the intervention Looking at paired data. Examples: <ol style="list-style-type: none"> 1. Pre/post observations on the same person for each data set (examples: cultural competence survey, intent to stay survey, etc.) 2. Compliance rates per provider, reviewing the same number of charts before and after per provider 	Evaluate the assumptions of each test to determine which test to use. <ul style="list-style-type: none"> • Paired t-test: use to compare means, assumption of approximately normal distribution for the differences (post-pre). • Wilcoxon signed rank test: use when assumption of normality is not met. Compare ordering of the data.
Option B: Chi Square Test OR Fisher’s exact test	Type of data: Counts of participants/providers/charts that can be assigned to a particular category, such as compliant/not compliant, or injured/not injured. Examining the difference between expected outcomes and observed outcomes. Examples: <ol style="list-style-type: none"> 1. Compare provider compliance rates on a protocol before and after training (provider not identified individually, and compliance is yes/no) 2. Compare rates of hospital acquired infections after intervention if the intervention was not present before. Compare rates pre-intervention to rates post intervention. 	Evaluate the assumptions of each test to determine which test to use. <ul style="list-style-type: none"> • Chi Square Test: used to compare observed vs expected values. At least 5 expected values for each combination of the two variables should be present. If this is not met, then use Fisher’s exact test.
Option C: Descriptive Statistics with Confidence Intervals	Descriptive statistics are used to describe phenomenon from a sample of a population. Confidence intervals reflect uncertainty about how the estimate applies to the population as a whole. Examples:	Descriptive statistics example: Often displayed in table and graph to show rates. <ul style="list-style-type: none"> • Mean and standard deviation/95% CI for each group (approximately normal

	<p>1. Out of 30 telemedicine patients who screen positive for depression, how many of them received appropriate referral for psychiatry? $x/30 = xx\%$</p>	<p>continuous (ordinal or ratio) data)</p> <ul style="list-style-type: none"> • Percent with 95% confidence interval, making sure to include the sample size. • Frequency table, preferably including counts and percentages in some format.
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<p>Option D: Independent t-test OR Mann-Whitney <i>U</i> Test</p>	<p>Type of data: One categorical, independent variable (This test tells you if there is a statistically significant difference between two different groups of people or conditions)</p> <p>Examples: 1. Whether males and females differ significantly in terms of their self-esteem</p>	<p>Evaluate the assumptions of each test to determine which test to use.</p> <ul style="list-style-type: none"> • Independent t-test: use to compare means of two different groups or conditions, normal distribution. • Mann-Whitney <i>U</i> Test: use when assumption of normality is not met.
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Design Considerations:

- Use survey to measure outcomes that could not otherwise be assessed through objective means such as chart review. For example, don't use a pre-posttest to determine staff knowledge if the primary outcome can be measured through more objective means (e.g., compliance with the protocol through chart review).
- Compliance is usually measured based on a checklist, which means that you must define what compliant/not compliant means. Alternatively, the checklist could be used to derive a % compliance, which would be measured using a t-test (unpaired).

Option A

Paired t test: Utilized to compare means between two similar samples. (Generally, you would pair the same group of people's test results before and after an intervention such as pre-posttest)

Assumptions of Paired t test:

1. Independence: two separate observations are being compared. Example: pre-test and post-test
2. Normality: Normal distribution between pairs
3. No extreme outliers

If any assumption is violated, then this would be an invalid test.

If a different group of people is examined from before and after, then see option B.

Wilcoxon Signed Rank Test: Utilized to compare two separate observations between two similar samples when the assumption of normality is not present. Wilcoxon signed rank test should be used over a t test if there will be outliers in the data. Where the t test examines the means between two data sets, the Wilcoxon Signed Rank Test examines the ordering of the data instead of the means of the data. An example where this may be more helpful is if there will be various disciplines of medicine with widely varied educational background taking the same survey.

Assumptions of Wilcoxon Signed-Rank Test:

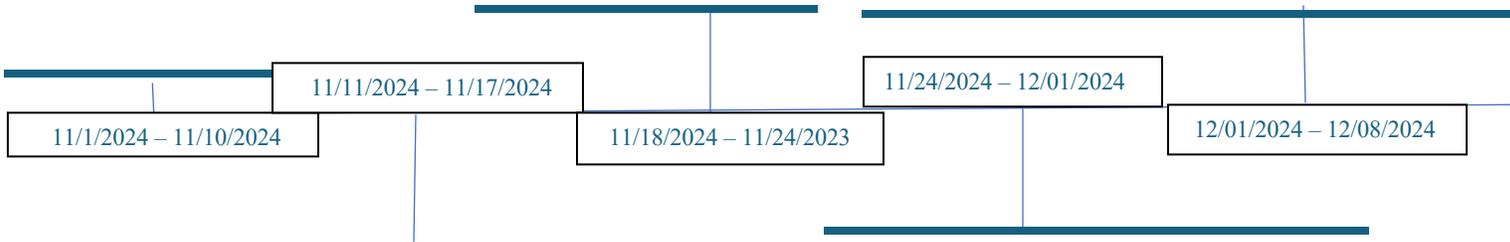
1. The dependent variable is ordinal and continuous. (example: Likert scale)
2. Independent variable being compared is matched or related, or the same subjects are examined before and after.
3. Distribution of differences is symmetrical between groups.

Appendix P: Illustration of Timeline

Week 1: Conducted pre-implementation chart review (180 charts from the past 12 weeks)
 Provided training to the 6 participants involved (2 FNP's, 3 registered nurses, and the manager) on the new protocol and toolkit
 Official protocol "go live" on 11/11/2024

Week 3: Continued helping staff with questions on how to fill out data analysis forms. Consistently noted participant feedback and treatment outcomes.

Week 5: Conducted a final chart review, no VO's have been reported.
 Participants are continuing to have trouble filling out forms. Follow ups and reminders continue to ensure participants are remaining compliant.
 Refresher training was initiated and participant felt confident with the outcome.
 Reviewed protocol tools and added gloves for immediate care. Continuous observations will be done after the implementation.



Week 2: Participants were supported through completing chart reviews from 11/11/2024 to 11/18/2024. There were no reported VO cases thus far. I reviewed chart reviews and gathered good feedback from participants on the visual aids and how helpful they were while reviewing the protocol.

Week 4: Continued data analysis, there were no VO's that have occurred. There has been challenges with 1 participant who was having trouble filling out the forms in a timely manner. Follow ups were initiated to ensure participants are properly documenting data.
 Staff interviews were initiated, gathered feedback from participants on a request for refresher training to properly fill out forms.

Appendix Q: Sample mixed methods table

Quantitative results	Qualitative results	Example quote
<p>Pre-protocol implementation: High risk of vascular occlusion incidents and non-compliant prevention practices.</p>	<p>Providers were unfamiliar with proper prevention and management techniques.</p>	<p>Participant 3 (registered nurse): “Prior to the protocol, I was not aware of proper prevention procedures. There has been no protocol in place to know what to look for after injecting.”</p>
<p>Post-protocol implementation: Improvement in compliance from 0% (prior to implementation) to 100% (post implementation) on prevention and management protocol.</p>	<p>Providers were compliant with the new protocol.</p>	<p>Participant 2 (FNP): “Now having a prevention and management protocol in place I can prevent issues before they occur and have easy to follow management steps.”</p>
<p>Incidence of VO cases: There was a reduction of incident cases by .625% from baseline data that included 1 possible VO incident (slow capillary refill time that resolved after massage) to 0% incidence rate from proper prevention and management strategies (use of protocol for correct injection technique, avoiding high risk areas, and use of hyaluronidase).</p>	<p>Providers noticed fewer possible VO occurrences and discussed the positive impact the protocol has on preventative measures.</p>	<p>Participant 1 (FNP): “I am able to use preventative measures to ensure my patients are safe”.</p>