8-2024

A bundle of care for prevention, early recognition, and treatment of hyaluronic acid dermal filler associated vascular occlusion

Genny Sanders
University of Louisvi, gennypsanders@gmail.com

A Bundle of Care for Prevention, Early Recognition, and Treatment of Hyaluronic Acid Dermal Filler Associated Vascular Occlusion

by

Genny Sanders

Paper submitted in partial fulfillment of the
requirements for the degree of

Doctor of Nursing Practice

School of Nursing, University of Louisville

August 1, 2024

Lynn P. Roser

Dr. Lynn P. Roser
DNP Project Chair

August 8, 2024
Date

Nancy Kern

Dr. Nancy Kern
DNP Project Committee Member

August 8, 2024
Date

Dr. Sara Robertson
Associate Dean DNP and APRN Programs

August 8, 2024
Date

Acknowledgements

I would like to thank my father for always encouraging me to pursue my doctorate degree. I am so proud to be your daughter and to fulfill this dream that you have always had for me. My entire family has supported me as well, and they are my inspiration and reason for success. My project chair, Dr. Lynn Roser, has shown patience and encouragement throughout the process. Thank you for being a guiding light and mentor that I will always cherish as part of this milestone in my life.

Abstract

Background: Hyaluronic acid (HA) dermal fillers, an injectable used for cosmetic use, are gaining popularity, and are expected to continue to do so in the projected future. With the rise in the number of patients seeking these procedures there is a correlated rise is adverse events, including the complication of vascular occlusion. Vascular occlusion has the potential for detrimental outcomes, and clinicians performing these procedures are responsible for educating patients about these risks. As whole, the healthcare community must be prepared.

Purpose: A quality improvement (QI) project was created to help clinicians prepare, prevent, recognize, and treat hyaluronic acid dermal filler induced vascular occlusion by improving clinician knowledge and confidence on this topic.

Methodology: The QI project was created with the foundation of a review of literature focused on dermal filler associated vascular occlusion and related topics. The Institute for Healthcare Improvement (IHI)'s Plan-Do-Study-Act (PDSA) model was used as the structure for the project. Being the first cycle of the PDSA, the QI project data results give insight for future cycles to improve processes and identify further needs.

Intervention: The intervention included a pre-recorded educational video, 45-minutes in length, discussing the five elements of a bundle of care for vascular occlusion events. There was a pre- and post-test (immediate and 1-month) on knowledge and confidence surrounding the video

Results: Improvement in participant knowledge and confidence was seen. Knowledge improved from a mean of 69% to 92% immediate post-test and 95% one-month post-test, and this was a 33% and 37% percentage of change, respectively. Confidence also improved at both post-test intervals, and none of the questions had a decline in confidence. For nine out of the ten pre-test questions on confidence, the highest percentage of responses were "agree." In the two post-test

intervals this improved with the highest percentage of responses being “strongly agree” for nine out of the ten questions.

Keywords: Dermal Filler, Vascular Occlusion, Bundle of Care

Contents

A Bundle of Care for Prevention, Early Recognition, and Treatment of Hyaluronic Acid Dermal Filler Associated Vascular Occlusion

Introduction

The American Society of Plastic Surgeons (ASPS, 2021), which serves at the national clearinghouse of plastic surgery procedural statistics in the United States (US), reported that over 15.6 million cosmetic procedures (both surgical and minimally invasive) were performed in 2020. A large portion, or 85% of those procedures, were considered minimally invasive in nature. Approximately 22%, or 3.4 million, of all cosmetic procedures, are attributed to soft tissue dermal fillers (ASPS, 2021). As a minimally invasive procedure, dermal fillers are injected with a needle or blunt tip cannula into the soft tissue to restore volume and smooth lines, and they are the second most performed non-surgical cosmetic procedure after botulinum toxins (ASPS, 2021; Murray et al., 2021; Zeltzer, et al., 2020).

Hyaluronic acid (HA) fillers first gained US Food and Drug Administration (FDA) approval in the US in 2003, and since that time multiple others have entered the market (Gold, 2010; Soares, 2022; US Food and Drug Administration, 2021). Hyaluronic acid fillers now comprise 80% of the dermal fillers injected in the US (ASPS, 2021). Popularity of dermal fillers can be attributed to their natural appearing results, acceptance across all age and gender groups, easy accessibility, affordable cost, short recovery time, and ability to dissolve with a special solution in the case of an adverse event or patient dissatisfation (Abduljabbar & Basendwh, 2016; Dominguez et al., 2017; Liu, 2020; Ors, 2020; Snozzi & van Loghem, 2018; Soares, 2022; Urdiales-Galvez, et al., 2018). The International Society of Aesthetic Plastic Surgery (ISAPS) conducted a survey that identified HA dermal fillers as the second most popular non-surgical procedure in 2020, with an over 20% increase since 2016.

From an economic perspective, the dermal filler market is projected to grow from a US dollar value of 5.31 billion in 2022 to 8.74 billion by 2029, equivalent to a compound annual growth rate of 7.4% for that forecast period (Fortune Business Insights, 2021). The economic advantages and the growth of popularity of dermal fillers supports an anticipated increase in the number of healthcare clinicians performing these procedures, patients receiving them, and complications arising from them (Murray et al., 2021; Ors, 2020; Soares, 2022; Urdiales-Galvez, et al., 2018; Zeltzer, et al., 2020). With the increased use of dermal filler products, there has been a concurrent increase in the medical device reports (MDR) of adverse events related to these procedures (FDA, 2021; Soares, 2022).

Unintended injection into blood vessels resulting in poor perfusion distal to the injection site is the most concerning risk or complication that can occur with the use of all types of dermal fillers (Abduljabbar & Basendwh, 2016; FDA, 2021; Jones et al., 2021; King et al., 2020; Murray et al., 2021; Soares, 2022; Vargas-Laguna et al., 2021). This complication can lead to tissue necrosis, vision abnormalities (including blindness), stroke, and even death if not treated appropriately (FDA, 2021; Jones et al., 2021; Kapoor et al., 2020; Murray et al., 2021; Soares, 2022). Statistical data regarding adverse events are incomplete as reporting patient complications related to dermal fillers is voluntary, making the extent of the problem difficult to assess (Soares, 2022; Urdiales-Galvez et al., 2018). The FDA designates dermal fillers as a device, and incident reports can be submitted to the US Federal Manufacturer and User Facility Device Experience (MAUDE) database. Due to the voluntary nature of reporting, it is expected that this database is deficient in data surrounding this issue (Beleznay et al., 2019; Soares, 2022).

Significance of the Problem

Considering that underreporting is likely, cases of severe visual impairment due to unintentional intravascular injection are rising (Beleznay et al., 2019; FDA, 2021; Jones et al., 2021). The MAUDE database had 470 vascular events reported between 2015-2020, of which 20% had vision-related sequelae (Beleznay et al., 2019; FDA, 2021; Soares, 2022). A review of literature by Beleznay et al. (2019) reported 48 cases of partial or complete vision loss documented over three years from 2015-2018, and this was a drastic increase relative to the time in comparison to their 2015 publication that identified 98 published cases from years 1906-2015 (Beleznay et al., 2015). Kapoor et al. (2019) looked specifically at reports of vision loss associated with HA dermal fillers and identified 44 relevant cases in the literature from 2004 to 2019. In conjunction with the rise of reported cases of visual impairment, stroke and ischemic skin injuries have also dramatically increased (Beleznay et al., 2019; Soares, 2022; Wang, et al., 2022). A literature review by Wang et al. (2022) demonstrated a 300% spike in dermal filler-associated stroke between 2000-2020, and Soares et al. (2022) identified a 30-fold increase in filler-induced ischemic skin injuries in that same period.

With continued acknowledgment of underreporting recognized, incidence rates of dermal filler-associated vascular occlusion have been estimated (Jones et al., 2021). Alam et al. (2021) found that the risk of occlusion with any filler type was 1 per 5000 syringes injected amongst 370 dermatologists included in their retrospective study, and 28% of them reported at least one case of vascular occlusion. Schelke et al. (2020) calculated an incidence of 1 in 6558 (0.015%) for vascular adverse events in their specialized clinic for filler complications over 25 months.

The FDA has historically enforced efforts to increase awareness amongst providers and patients regarding dermal filler risk for vascular occlusion; however, with the rise in reported

incidents and growing popularity of these procedures, there is an urgency for improvement in education, practice, and standardization of training (FDA, 2021; Heydenrych et al., 2021; Jones et al., 2021). Additionally, there are continued anecdotal reports of patients not being adequately informed of the risk of dermal filler-related vascular occlusion, which is unacceptable given the potential for life-altering consequences relative to the cosmetic gain offered (FDA, 2021).

Gap Analysis

A regional training company in Kentucky offers basic and advanced training on the injection of dermal fillers to healthcare providers. The owner of the training company, a registered nurse, provides the trainings to many types of healthcare professionals including physicians, registered nurses (RNs), advanced practice nurses (APNs), and physician assistants (PAs). The courses offered are composed of online training modules, didactic lectures, and hands-on instruction with live patient models. Prior to training and injection of patient models, a signed contract from the trainee is required. The contract includes a list of required supplies, one of which is on-site hyaluronidase (reversal agent) in case of a vascular occlusion. The contents of the course for dermal fillers includes a brief overview of complications including vascular occlusions.

Through offering training to multiple clinicians and facilities, the owner of the company identified the need for more intense training focused on the treatment of vascular occlusion. The owner reported an observed lack of preparation for vascular occlusion events amongst facilities and clinicians. Although clinicians are aware of vascular occlusion complications and the need for preparation, facilities appeared to lack written policies and procedures outlining step-by-step protocols to manage an event. In one specific case, the owner of the training company was called to a facility where a previous training had taken place because the trained clinician was able to

identify a vascular occlusion and had hyaluronidase available but was unsure how to manage carry out the appropriate treatment. In this specific case, at the time of the event, the medical director of that facility was not able to be reached for consultation.

With the anticipated growth of the aesthetic industry, there will be an increase in the number of healthcare clinicians performing dermal filler procedures, patients receiving them, and complications arising from them. In alignment with the FDA and the best interest and safety of patients and trained clinicians, the development of a bundle of care related to this topic was developed.

Setting

The setting of the QI project was an on-site training offered by a regional training company in Kentucky. The company offers basic and advanced training on the injection of dermal fillers to clinicians within their own facilities located in Kentucky, Indiana, Ohio, and West Virginia.

Target Population

The target population of the QI project was healthcare providers who had been trained to perform dermal filler procedures, were familiar with facial anatomy, had at least basic knowledge of vascular occlusions, and were legally able to offer these procedures to patients.

Stakeholders

Dermal filler injections are performed by many types of healthcare professionals. Laws dictating the required licensing varies by state. A stakeholder assessment was performed and identified key stakeholders who would benefit from the QI intervention. Healthcare professionals who inject dermal filler products play a significant role in safety and outcomes, and the project was structured to focus on them due to their vital impact. Other identified stakeholders included

patients, patient families, healthcare facilities, supporting staff, training companies and their employees, and dermal filler manufacturers.

Barriers to Change

Anticipated barriers to success of the QI project included the time commitment required by professionals to watch the training video and completing the questionnaires, acceptance of the bundle components as a priority in practice, ability to retain the information, and implementation of the bundle components into practice.

Purpose

This quality improvement (QI) project aimed to improve healthcare provider preparedness to educate patients and to provide informational support for the treatment of HA dermal filler-induced vascular occlusions in outpatient clinics. The overall goal was to promote patient safety and decrease morbidity related to this adverse event. The QI project did not fall under research involving human subjects as it did not seek to develop or generate new generalizable knowledge or evaluate a hypothesis.

Project Approvals

The project gained approval from the University of Louisville Institutional Review Board (IRB). Written approval and support were obtained from the owner of the regional training company in Kentucky. The project aligned with the training company's mission to thoroughly prepare their trainees on all important aspects of performing dermal filler procedures.

Conceptual Framework

The Donabedian (1980) Theoretical Model for Evaluation of Healthcare Systems provided guidance for the project. According to Donabedian (2005), there are three factors that measure quality of healthcare including a) structure; b) process; and (c) outcomes. Each of the

components work in tandem with each other, and all of them had to be in place to successfully implement the QI project. Structure measures are the attributes of a healthcare organization that outline physical and organizational characteristics such as staffing and operating times of the service (Donabedian, 1980; Donabedian, 2005). Process measures aim to reflect the delivery of care to the patient (Donabedian, 1980; Donabedian, 2005). Outcome measures specify the goals and impact on patient populations and offer substantive measures that demonstrate whether a QI intervention has achieved the desired outcomes (Donabedian, 1980; Donabedian, 2005). Donabedian (2005) believed that structure impacts process, and process impacts outcomes. In addition to this triad of measurements, QI projects should also anticipate unintended consequences of changes which are referred to as balancing measures. Together, Donabedian (2005) suggests all components be used for evaluating quality of care. The QI project utilized Donabedian's evaluation of healthcare framework as the lens through which various measures were evaluated.

Within the Donabedian framework, the QI project also utilized the Institute for Healthcare Improvement's (IHI) Plan-Do-Study-Act (PDSA). The four steps (plan, do, study, and act) are intended for use as the approach to implement necessary change as it accounts for a rapid cycle of improvement and evaluation of activities (IHI, 2022).

Implementation of the QI project consisted of the first cycle of the PDSA framework. Starting with the initial 'plan' phase, a bundle of care was developed with the intent to increase knowledge and confidence in treating dermal filler associated vascular occlusion amongst healthcare professionals. The 'do' phase was implementation of the educational intervention amongst willing participants. The 'study' phase was the evaluation of the data collected from the pre- and post-tests. The 'act' phase will be future adjustments to implementations conducted in

the ‘do’ phase based on the results of the ‘study’ phase. Future cycles of the PDSA will be influenced by the gaps and results of the previous cycles and will promote ongoing improvement of the intervention.

Review of Literature

A total of six elements were identified for best practices related to the preparation of injection of HA dermal fillers and the evaluation of HA dermal filler-associated vascular occlusion and incorporated into the proposed bundle of care. The identified elements include (a) provider or organizational preparation; (b) pre-procedural patient assessment and consent; (c) safe injection; (d) early recognition; (e) early intervention; (f) follow-up and appropriate referrals when necessary. Key elements of the review and the strength of evidence using the Johns Hopkins Nursing Evidence-Based Practice Levels (Table 1) are summarized in Table 2.

Preparation

With patient safety set as a priority, clinicians and their practices should prepare themselves for adverse events. There is limited research surrounding clinician preparedness for dermal filler-induced vascular occlusions. However, some studies demonstrate that in general healthcare clinicians are under-prepared for handling urgent situations in outpatient settings. The identified studies noted insufficiencies in preparation on how to manage urgent situations, lack of written protocols within practices for clinicians to follow, and unfamiliarity with published policy (Abulebda et al. 2021; Alsayed, 2020; de Bedout et al., 2018; Pendleton & Stevenson, 2015). A clinical audit of a single organization that reviewed cases of vascular occlusion within six office branches found that each case was variable from one physician to another, and the events were not correctly documented (Alsayed, 2020). The following studies are summarized

and highlight the importance of clinician and organizational preparedness for vascular occlusions.

An exploratory study by de Bedout et al. (2018) assessed the knowledge and preparedness of dental professionals affiliated with the Indiana University School of Dentistry (IUSD) to manage common medical emergencies. The dentists were divided into four groups – general practice faculty members, specialist faculty members, residents, and periodontists in practice. A total of 95 dentists participated, and participants were asked to evaluate, diagnose, and select the appropriate intervention for ten clinical medical emergency case scenarios. Of the four groups, there was no statistically significant difference in correct diagnosis and intervention of the scenarios. Participants appropriately diagnosed a mean of eight of the ten scenarios and selected the appropriate intervention a mean of 6-7 times out of ten. Interestingly, participants who had recently graduated (as early as 2012) and those still in school treated cases more appropriately than the other participants. Additionally, the American Dental Association (ADA) recommends that staff training for medical emergencies is provided, and that "mock" drills occur annually (American Dental Association, n.d.). Data collected from the study found that 69% felt comfortable managing medical emergencies, but 83% reported that they did not practice handling emergencies regularly or did so seldom. Although the researchers found that the participants did well overall, they concluded that there is room for improvement in preparing dentists for medical emergencies and suggested periodic mock drills and participation in continuing education courses to help dentists better manage medical emergencies.

Two studies in pediatric outpatient settings also found similar results related to lack of preparation. Pendleton & Stevenson (2015) conducted a cross-sectional survey of outpatient pediatric faculty and gratis faculty of the Division of General Pediatrics at the University of

Louisville. The purpose of the study was to determine pediatricians' self-reported experience and preparedness for outpatient clinic emergencies, and it also surveyed their familiarity with a policy statement on outpatient emergencies published by the American Academy of Pediatrics (AAP) in 2007. A total of 57 responses were obtained, and 39% of the participants reported treating at least one or more emergencies per month in their practice. Despite frequent emergencies, the study found that pediatricians may not be adequately prepared to manage them. Results implicated that pediatricians may not have the necessary supplies, comfort in using these supplies, or current maintenance of certifications such as Basic Life Support (BLS) or Pediatric Advanced Life Support (PALS) to manage emergencies in the pediatric population. Additionally, only half of the respondents were aware of the AAP policy statement on outpatient emergency preparedness, and only a third reported that their office had a written emergency protocol.

Abulebda et al. (2021) conducted an observational study evaluating the ability of pediatric offices to manage emergencies in outpatient clinics. The study was national and included 42 offices in nine states. Emergency preparedness was calculated according to adherence to two checklists based on the AAP guidelines for essential equipment and supplies and policies and protocols. Emergency care quality was measured by simulation. The mean emergency preparedness was 74.7%, the mean essential equipment and supplies score was 82%, and the mean policies and protocols score was 57%. The simulation scenarios to evaluate emergency care quality were related to asthma and seizure cases. The median asthma case performance was 63.6%, and the median seizure case score was 69.2%. The investigators concluded that overall emergency preparedness was suboptimal among the study participants, noting variability amongst the degree of preparedness and quality of simulated emergency care.

Most offices did not have essential life-saving equipment or an emergency policy and procedure (Abuledba et al., 2021).

Alsayed et al. (2020) performed a clinical audit within their single organization of six office branches. They looked at the incidence of vascular occlusions within their organization over three years and identified four cases. The audit concluded that the management of the four cases was individually variable from one physician to another, and the events were not adequately documented. As a result of the audit, the organization developed a protocol and performed a re-audit after implementation. Two new incidences of vascular occlusion occurred during the re-audit, and both patients were treated and fully recovered. The efficiency of the treatment performed was attributed to the newly developed protocol.

Policy and Procedure

The presented studies indicate healthcare providers in outpatient settings are underprepared to handle emergency situations, many clinics do not have written policies and procedures to follow for handling emergencies, they do not frequently prepare for these events or exercise mock drills, some clinics do not have the proper essential equipment, and providers are inconsistent in completing continuing education related to the management of medical emergencies (Abulebda et al. 2021; Alsayed, 2020; de Bedout et al., 2018; Pendleton & Stevenson, 2015). According to the World Health Organization (WHO), clear policies must be implemented to successfully implement patient safety within healthcare practice (World Health Organization, 2019). Without clear policies, management of adverse events is at risk of inconsistencies in treatment and poor documentation (Alsayed, 2020). Expert consensus recommendations by Urdiales-Galvez et al. (2018) include establishing emergency protocols to reduce the severity of adverse outcomes from HA filler complications in cosmetic settings.

Policy and procedure development for treating vascular occlusions is an initial step that should be completed before offering dermal filler injections and ensures consistency in the standard of care that is expected within a facility.

Emergency Kit

As part of preparation, an emergency kit for treatment of vascular occlusion should be prepared. The kit should be stored in a designated area for quick access and facilitation of early intervention to reduce patient morbidity (DeLorenzi, 2014; Loyal et al., 2022; Urdiales-Galvez et al., 2018; Vargas-Laguna et al., 2021). Contents of the filler crash cart should be prepared using the most up-to-date literature and guidelines. A review of current guidelines and literature suggests the use of the following:

Hyaluronidase (HYAL), an enzyme that breaks down hyaluronic acid, provides reversibility making it the most important of the contents of the emergency kit (DeLorenzi, 2017; Heydenrych et al., 2021; Jones et al., 2021; King et al., 2020; Loyal et al., 2022; Murray et al., 2021; Philipp-Dormston et al., 2017; Salinas-Alvarez et al., 2021; Soares, 2022; Witmanowski & Blochowiak, 2020; Wollina & Goldman, 2020; Zeltzer et al., 2020). An adequate amount of HYAL should be available as high doses may need to be repeated multiple times to treat a vascular occlusion appropriately; guidelines recommend as much as 7500 iu should be kept on site (DeLorenzi C., 2017; Heydenrych et al., 2021; Zein et al., 2020). Additional contents should include warm compresses, aspirin or Plavix, injection materials, reference guides, documentation templates, contact information for potential referrals, sildenafil, and lidocaine for local anesthesia (Goodmanet al., 2020; Heydenrych et al., 2021; King et al., 2020; Loyal et al., 2022; Philipp-Dormston, et al., 2017; Snozzi & van Loghem, 2018; Vargas-Laguna et al., 2021; Wollina & Goldman, 2020). Although extremely rare, the complication of vision loss related to a dermal

filler-induced vascular occlusion makes it pertinent to include a flashlight and Snellen chart for vision assessment, a paper bag for re-breathing, and timolol or apraclonidine eye drops (Heydenrych et al., 2021; Humzahet al., 2019; Loh, et al., 2016; Urdiales-Galvez, et al., 2018; Walker et al., 2021;). If financially feasible, the availability of ultrasound (US) technology helps identify the location of a vascular occlusion and allows more precise injection of HYAL into the filler deposit (Rocha et al., 2021; Schelke et al., 2018). It is recognized that anaphylaxis is a rare but potential reaction to the injection of HYAL, and preparation for this type of event is also recommended (Jones et al., 2021).

Mock Drills

Mock drills are an essential part of preparation for both clinicians and their supporting staff. Contents included in drills should help define roles of each person involved, provide guidance on how to handle post-procedure patient reported concerns, provide time to review the clinic policy and procedure, and designate the location and contents of the emergency kit (Loyal et al., 2022). Performance of mock drills should be done annually at the very least (American Dental Association, n.d.).

Auditing and Competency

Lastly, facilities should conduct routine scheduled audits to assess their competancy in handling vascular occlusion events. The Center for Disease Control and Prevention's (CDC) ICAR (Infection Control Assessment and Response) tools can be used a model to develop a standardized tool for assessing and auditing preparedness to handle vascular occlusion events within a facility. The ICAR tools are used to systematically assess a healthcare facility's practices and guides quality improvement activities by addressing identified gaps (CDC, 2023). These ICAR tools are divided into three sections including a review of demographic information

and clinical infrastructure, assessment modules that are used for discussion of policies and practices within the facility, and observation forms that are used for observing the practices of the facility in handling a specific situation (CDC, 2023). An annual internal or external audit using the ICAR model is an additional layer of assessing a facilities ability to appropriately and efficiently treat vascular occlusion.

Patient Assessment and Pre-Procedural Consent

Before consideration of dermal filler treatments, patient assessment and evaluation should be comprehensive for any complication or contraindication. However, for this quality improvement project, only the essential aspects of assessment related to vascular occlusions will be discussed. As mentioned, the target audience for this project is clinicians who have the training to perform dermal filler procedures, an intimate understanding of anatomy, and have basic knowledge of vascular occlusions. This foundation is essential before considering the contents of this bundle of care.

Patient Exam and Medical History

Zeltzer et al. (2020) published a universal guideline for handling filler complications. The approach includes three steps or "ART" (avoid, recognize, and treat), and part of the "avoid" recommendations is awareness through assessment of possible anatomical variations in a patient's anatomy, which are identified by visual examination or are due to previous surgical procedures. Therefore, surgical history should be explored as scar tissue from surgery or other conditions can surround vessels and keep them more rigid and less likely to roll away from a needle or cannula (Zeltzer, et al., 2020). Allergies should be reviewed as patients with a wasp or bee sting allergy are at higher risk for an anaphylactic reaction to hyaluronidase, the reversal agent that may be needed to treat a vascular occlusion (Murray et al., 2021). A pre-procedural

vision assessment is helpful for comparison in the event of occlusion with ocular symptoms, and pre-procedural capillary refill assessment familiarizes the injector with the patient's normal findings and strengthens the ability to recognize a change (Heydenrych et al., 2021; Murray et al., 2021). Discussing upcoming travel plans is essential, as vascular occlusions can occur up to 72 hours after treatment. Travel plans may need to be altered, or the procedure may need rescheduled (Goodman et al., 2020). Lastly, the provider should be aware of previous dermal filler treatments to the area intended for injection and should screen for a history of dermal filler-induced vascular occlusions or complications (Goodman et al., 2020).

Informed Consent

Successful patient safety strategies include patient involvement in their care (World Health Organization, 2019). An essential aspect of patient involvement is informed consent, an accepted legal and ethical principle obtained before performing a procedure (Jones et al., 2021; Kinnersley et al., 2013). Informed consent involves a discussion between the clinician and the patient in which the clinician explains the procedure, discloses the risks and benefits, and provides alternative options (Kinnersley et al., 2013). A signed consent serves as evidence that informed consent has occurred; however, clinicians are responsible for ensuring that patients understand the information provided and can communicate their decision (Kinnersley et al., 2013). A systematic review by Kinnersley et al. (2013) found that giving patients materials or resources, such as written pamphlets, videos, and websites, improves patient knowledge and understanding and enhances the process of informed consent.

Although vascular occlusion is considered a rare complication related to dermal filler injections, it is imperative that clinicians explicitly discuss this risk with patients as there is potential for tissue necrosis, permanent vision abnormalities including blindness, stroke, and

even death (Heydenrych et al., 2021; US Food and Drug Administration, 2021). Patients should be counseled on the specific type of visual disturbances that can occur with vascular occlusions (Goodman et al., 2020). Also, to prevent delay in treatment, and in the case of an emergency, pre-treatment consent should include permission for the management of complications as well as the use of photography and video (Goodman et al., 2019; Heydenrych et al., 2021). Photographs and video documentation are essential for comparing pre-treatment and post-treatment analysis, but they are also invaluable tools for documenting the progression of treatment of complications (Heydenrych et al., 2021).

Safe Injection

Literature supporting safe injection techniques is comprised of expert consensus recommendations and minimal evidence-based studies. Knowledge of facial and neck anatomy is imperative, and if an injector is untrained, the risk of injury increases (Jones et al., 2021; Wang, et al., 2022). The specific aspects of anatomy that are pertinent for safe injection are depth perception, injection into the correct plane, identification of the usual location of blood vessels and common variations, and awareness of surgical alterations and scarring (Beleznay et al., 2019; DeLorenzi, 2017; Goodman et al., 2020; Goodman et al., 2019; Heydenrych et al., 2021; Humzah et al., 2019; King et al., 2020; Loh, et al., 2016; Murray et al., 2021; Zeltzer, et al., 2020). Facial vascular anatomy is complex, and with the many anastomoses between different arteries, any injection location is at risk for severe complications (Beleznay et al., 2015; Jones et al., 2021).

Aspiration

Pre-injection aspiration occurs when an injector places a needle in the area of the intended injection, keeps the needle and syringe stationary, and pulls back on the plunger of the

syringe in an attempt to draw blood into the needle hub as a way to check for unintended intravascular placement (Kapoor, et al., 2021). Per a study by Casabona et al. (2015), the reliability of aspiration is only about 53%. Another study by Van Loghem et al. (2018) found similar results and estimated that aspiration reliability is only about 33-63%. The sensitivity of aspiration is impacted by many variables such as product rheology, needle size (lumen, length), needle brand, syringe dimensions, aspiration time, the negative pressure created during aspiration, and the patient's blood pressure (Van Loghem et al., 2018). It is recommended that this technique be used but with caution, as negative aspiration should not create a false sense of safety (Murray et al., 2021; Van Loghem et al., 2018; Vargas-Laguna et al., 2021).

Needle vs. Cannula

Using a sharp needle or a blunt-tip cannula to deliver dermal filler product is usually a clinician preference. However, the location of treatment is essential when choosing a needle or cannula, and in places like the nose, a needle is the safer method (Goodman, et al., 2019). A literature review by Beleznay et al. (2019) studied reported cases of blindness from dermal fillers. Only 33% of the reported cases included information on if a sharp needle or a cannula was used. Of that 33%, 10 cases used needles, and six used cannulas. Larger cannula sizes, 25 gauge or greater, are recommended as it is believed that they are less likely to pierce a blood vessel, but there have been reported cases of vascular compromise with various cannula sizes (Beleznay et al. 2019; Humzah et al., 2019; Jones et al., 2021). A retrospective study by Alam, et al. (2021) found that the risk for vascular occlusion with a needle was 1 per 6410 per 1-mL syringe injections, and the risk with a cannula was 1 per 40,882 per one mililiter (mL) syringe injections. Zhou et al. (2020) reported that over three years, 28 cases of severe HA-related intravascular events were referred to their department, and 89% were injected with cannulas.

The authors warned that cannulas should not create a false sense of safety (Zhou et al., 2020). It is recommended that clinicians use caution with both needle and cannula when injecting dermal filler, that location of the injection is taken into consideration when choosing which one to use, and if using a cannula a 25 gauge or larger is used.

Minimal Pressure

The use of minimal pressure and avoidance of high pressure when injecting dermal fillers is recommended to reduce the risk of retrograde flow against arterial blood flow (Goodman et al., 2020; King et al., 2020; Van Loghem et al., 2018; Vargas-Laguna et al., 2021; Zein et al., 2020; Zeltzer, et al., 2020). However, Lee et al. (2021) found that despite low pressure with injection, the ejection forces measured in their study were still significantly higher than systolic blood pressure. It is important to note that intravascular occlusion from the retrograde flow is still possible even with a slow push.

Minimal Use of Product

A systematic review by Kapoor et al. (2020) found that blindness was reported in a case where only 0.2ml of a dermal filler product was injected. A cadaver study by Khan et al. (2017) showed that as little as 0.04ml of filler injected into the supratrochlear artery could reach retinal circulation and cause ocular complications. Clinical recommendations often mention that low-volume injections are safest, although the exact amount varies, many suggest 0.1ml or less per aliquot (DeLorenzi, 2017; Humzah et al., 2019; Signorini, et al., 2016; Zeltzer, et al., 2020). Van Loghem et al. (2018) specify that periosteal bolus injections with a needle should consist of small aliquots of 0.05ml or less, and injections in the periorbital area (close to the supratrochlear artery) should be even smaller at less than (<)0.04ml or less due to increased risk of blindness in this region. Further, many experts believe that it is better to space out treatments into multiple

sessions when a high amount of volume is required, as overfilling increases the risk of complications (King et al., 2020; Wang, et al., 2022; Zeltzer, et al., 2020). The amount of product pushed per injection should be measured to prevent or minimize the severity of vascular occlusions, and avoidance of large-volume boluses is recommended to avoid occlusions of large areas (Van Loghem et al., 2018).

Anesthetic Considerations

The use of epinephrine-containing anesthetic during dermal filler injections has a few considerations. Those in favor of use note that vasoconstriction from epinephrine decreases vessel size, and in theory, could decreases the risk of entering a vessel (Beleznay, 2019; Zeltzer, et al., 2020). The opposing school of thought believes that blanching of the skin caused by epinephrine can inhibit a clinician's ability to identify signs of vascular occlusion (Goodman et al., 2020; King et al., 2020; Murray et al., 2021). It is recommended that clinicians recognize the potential benefits and risks when choosing to use an epinephrine-containing anesthetic.

Use of Digital Pressure

The use of digital pressure over the area of a nearby vessel can serve as a landmark or danger zone for injection, and the occluding pressure is theorized to prevent the retrograde flow of product (Murray et al. 2021; Scheuer, et al., 2017; Vargas-Laguna et al., 2021; Zein et al., 2020). A cadaver study by Tansatit et al. (2015) demonstrated that digital pressure to the superior nasal corners decreased the risk of filler products traveling to the orbit.

Position, Angle, and Direction of Injection

Position or angle recommendations during injection are often mentioned in published guidelines. If using a needle, with respect to a vessel, it should be introduced perpendicular or parallel, and with the use of a cannula, it should be placed parallel (Goodman, et al., 2019; Loh,

et al., 2016; Zein et al., 2020). The direction of injection should be away from the eye when close to that area (Goodman et al., 2020). Any resistance felt with injection should prompt repositioning (Signorini, et al., 2016). Lastly, keeping the needle or cannula in constant motion decreases the risk of an intravascular bolus (Beleznay et al., 2019; Goodman, et al., 2019; Scheuer, et al., 2017; Signorini, et al., 2016; Zein et al., 2020).

Ongoing Assessment and Communication

Ongoing assessment and communication with the patient are both crucial. The injector should frequently assess for pain, capillary refill, skin color changes, and ocular or neurological symptoms (Heydenrych et al., 2021; King et al., 2020; Lee et al., 2021; Loh, et al., 2016; Murray et al. 2021; Philipp-Dormston, et al., 2017; Signorini, et al., 2016). If there is any concern for a vascular occlusion, the procedure should be stopped immediately (Humzah et al., 2019; King et al., 2020; Loyal et al., 2022).

Use of Ultrasound

If available, US technology is an invaluable tool for vascular mapping before injection and can help mitigate the risk of vascular occlusion (Rocha et al., 2021; Schelke et al., 2018). Although trained injectors should know what is considered normal or the most common patterns of vascular anatomy, variations of anatomy occur and may be more frequent than expected (Rocha et al., 2021). Further, it is believed that use or US-guided technology will become the norm and ultimately will ensure patient safety and legal protection for professionals performing these procedures (Rocha et al., 2021).

Early Recognition

Early recognition of a dermal filler-induced vascular event dramatically impacts the outcome of the injury. Depending on which organ or organs are affected, there is variation in the

period for which reversal is possible (Soares, 2022). With dermal filler procedures in the face, organs that can potentially be affected are the skin, eyes, and brain (US Food and Drug Administration, 2021). Approximately 80% of cases involve the skin (Soares et al., 2022; US Food and Drug Administration, 2021). The skin has the best tolerance to ischemia and has a more significant time for reversibility (about 12-24 hours), whereas the eyes or retina (about 90 minutes or less) and brain (about 1.5-4.5 hours) are much less tolerant and are medical emergencies that should be handled in a hospital setting (US Food and Drug Administration, 2021). The clinician's ability to recognize these events is an invaluable skill that will determine the patient's outcome and potential for reversal.

Patient Education and Device Card

Symptoms of vascular occlusion may occur up to 72 hours after injection, so it is essential for the patient to be educated about these symptoms and to report them immediately (Soares, 2022). Still, most of the symptoms will occur during the injection requiring the injector to be vigilant (Goodman et al., 2020). The patient should always be provided with a 24-hour accessible phone number to report any concerning symptoms. The use of a portable patient device card (Figure 1) is a valuable tool to promote patient safety, especially if there is a transition of care to another provider or in an emergency (King et al., 2020; US Food and Drug Administration, 2021).

Skin Involvement

Dermal filler-induced vascular occlusions involving the skin, if left unaddressed, will lead to necrosis, tissue loss, and scarring, but a wound can be averted if caught early (Farmer, et al., 2021; Jones et al., 2021; Soares, 2022). Although occlusions localized to the skin should be addressed immediately, there is some time for collaborative management when necessary

(Murray et al., 2021). The initial symptom of vascular occlusion affecting the skin is a color change, with blanching or pallor and delayed capillary refill being the first changes, followed by a blue-gray phase known as livedo reticularis usually within a few hours, and the patient typically (but not always) will complain of pain which can be mild to severe (Farmer, et al., 2021; Jones et al., 2021; Snozzi & Loghem, 2018; Soares, 2022; Urdiales-Galvez, et al., 2018). If necrosis ultimately occurs, the beginning of this phase usually starts with pustules or blister lesions in the affected area around 72 hours post-injury, which will require wound care or even surgical intervention if severe (Farmer, et al., 2021).

Ocular and Neurological Involvement

A systematic review by Soares et al. (2022) found that of 250 published cases of dermal filler-associated vascular occlusions involving facial skin injuries, 20% of them had concomitant visual deficits. Of those, another 20% had an ischemic stroke. Clinicians performing dermal filler injection procedures should be ready to perform a complete neuro-ophthalmologic exam and recognize the symptoms of these injuries. It should also be remembered that all areas of the face have the potential for cerebroretinal injury due to the numerous anastomotic connections (Soares et al., 2022). Retinal occlusion symptoms reported include blindness, blurry vision, diplopia, ptosis, ophthalmoplegia, and headache (Snozzi & Loghem, 2018; Soares et al., 2022; Urdiales-Galvez, et al., 2018). Cerebroretinal occlusion is the most damaging type of occlusion possible; it can be severely disabling and has even been reported to result in death (Soares, 2022). In these cases, the patient may have stroke symptoms, such as altered consciousness, hemiplegia, headache, aphasia, or facial palsy (Soares, 2022).

Early Intervention

As discussed, interventional treatments for HA dermal filler-induced vascular occlusions vary based on the clinical symptoms of the patient and the suspected type. Those with skin involvement can be managed in an office setting, while those with ocular and neurological involvement require immediate attention at a hospital. Staff members (when available) should perform duties assigned in previous mock drills such as documenting the event and interventions performed with time stamps, bringing the emergency treatment kit to the bedside, obtaining photographs and video, notifying persons as requested by the patient, and assisting in any other way as requested by the provider (Loyal et al., 2022; Murray et al., 2021).

Stop, Inform, & Seek Assistance

Injection should be immediately stopped if any type of vascular occlusion is suspected and the patient should be informed of the complication and the clinician's plan for treatment (Jones et al., 2021; King et al., 2020; Loyal et al., 2022). The clinician should then seek assistance from supporting staff, a medical director when appropriate, and call 911 in the case of ocular or neurological symptoms (Jones et al., 2021; King et al., 2020).

Treatment of Skin Involvement

Massage and Warm Compress. Firm massage and application of a warm compress over the suspected area of occlusion are two simple interventions that should be implemented immediately and can be repeated throughout the treatment process as needed (King et al., 2020; Loyal et al., 2022). If these interventions do not resolve the issue on their own, injection of hyaluronidase should be performed (DeLorenzi, 2017; Jones et al., 2021; King et al., 2020; Loyal et al., 2022).

Hyaluronidase. Hyaluronidase (HYAL) is a soluble protein that has been used in the medical industry since 1949 for various purposes, but its use in aesthetic medicine is for dissolving hyaluronic acid by a hydrolysis reaction (DeLorenzi, 2017; Murray et al., 2021). Hyaluronidase is the mainstay of early intervention and should be instituted as soon as possible and repeated until the vascular occlusion is resolved (DeLorenzi, 2017; Murray et al., 2021). Some patients may need to return to the clinic for several days for ongoing treatment, and the cut-off time for the use of HYAL is accepted to be up to four days (Heydenrych et al., 2021). The use of ultrasound should be used when available as a guide for a more precise injection of HYAL directly into the affected area of occlusion, it can also assist the clinician in determining resolution the problem (Loyal et al., 2022; Rocha et al., 2021; Schelke et al., 2018).

Clinicians must understand the safety profile of HYAL, including the risks and directions for use (Murray et al., 2021). The risk for anaphylaxis with HYAL is infrequent and typically cited as 0.1% or less, with the majority of the reported reactions are localized (Murray et al., 2021). Patients with a wasp or bee sting allergy are at higher risk for anaphylaxis and should be screened appropriately before injection (Murray et al., 2021). Current data suggest that intradermal skin testing performed by medical aesthetic professionals is not valid or reliably sensitive. If a patient has a possible history of anaphylaxis to HYAL or wasp/bee stings, injection should not be performed, and a referral to a specialist should be considered (Murray et al., 2021). In the United States, using HYAL for aesthetic purposes is considered off-label, which should be disclosed to the patient (Murray et al., 2021). With several brands of HYAL available on the market, the proper storage temperature, compatibility with other medications such as lidocaine, and reconstitution instructions should be followed according to the package insert (Murray et al.,

2021). If compatable, mixing HYAL with 1-2% lidocaine is recommended to assist with patient comfort as well as vasodilation (Loyal et al., 2022).

DeLorenzi (2017) published a high-dose pulsed hyaluronidase (HDPH) protocol which is accepted as the current industry gold standard for vascular occlusion events. Many professional guidelines published in the last few years have referenced this recommendation. DeLorenzi is respected and recognized as a vascular occlusion expert due to his clinical experience as a consulting physician using the HDPH with dozens of cases as of 2016. Before that, he was involved with more than 50 cases that used previous protocols. The HDPH protocol was developed with the recognition that the human body actively metabolizes HYAL as soon as it's injected, therefore, at least hourly or more frequent administration of HYAL should be repeated until resolution of the occlusion is determined (DeLorenzi, 2017; Heydenrych et al., 2021; Jones et al., 2021; King et al., 2020; Loyal et al., 2022; Murray et al., 2021). The dose of HYAL required is determined by the number of areas affected; there are three possible areas to include in the calculation (lips, nose, and forehead), 500 iu per affected area is recommended, and up to 1500 iu per dose is required if all three areas are ischemic (DeLorenzi, 2017). The use of the HDPH protocol in dozens of cases over approximately two years yielded excellent results, and it was noted to provide complete resolution to normal with no scabbing or other long-lasting secondary changes (DeLorenzi, 2017). After administration of HYAL, use of vigorous skin massage in the area helps with dispersement of the product (Loyal et al., 2022).

An animal study on the femoral artery in rabbits studied the effective concentration of subcutaneous HYAL to dissolve HA and the effects on the surrounding tissue (Salinas-Alvarez, et al., 2021). The study found that 500iu of HYAL partially prevented the damage caused by an embolism of HA, it did not affect the surrounding tissue, and there was an observed presence of

thrombosis (Salinas-Alvarez, et al., 2021). The authors concluded that higher doses of HYAL should be administered (Salinas-Alvarez, et al., 2021).

An ex-vivo study by Rauso et al. (2020) used a harvested anterior jugular vein and facial artery to analyze HYAL and its effect on HA. The specimens were injected with cross-linked HA filler and then soaked in 150iu of HYAL in a test tube for four hours. The amount of HA filler in the vein specimen was reduced by 60% and the artery specimen by 90%. The authors concluded that a single dose administration of HYAL may not be adequate for resolving vascular occlusion.

One retrospective study of a single clinic between 2010-2019 explored the dosing, timing, and efficacy of HYAL use in skin necrosis of patients with vascular occlusion or compression-induced ischemia from hyaluronic acid dermal filler procedures (Ors, 2020). The cases before 2015 received palliative treatment only, and those after 2015 received 4-6 doses of 300iu HYAL in addition to palliative treatment. The authors concluded that HYAL injection shortened the recovery period of limited skin necrosis, and immediate HYAL injection allowed minor damage to heal quickly. In cases of large necrosis, HYAL did not eliminate the damage, but it did limit necrosis (Ors, 2020).

Anti-platelet Therapy. The use of aspirin or plavix, if not contraindicated, is recommended to reduce platelet activity that occurs with vascular occlusion (DeLorenzi, 2017; King et al., 2020; Salinas-Alvarez, et al., 2021). A single dose of one of these anti-platelet medications should be administered immediately and continued daily until the occlusion is resolved (King et al., 2020; Loyal et al., 2022).

Optional Interventions. For large areas of ischemia, use of a phosphodiesterase inhibitor (ex: sildenafil) can be used to assist with vasodilation (Loyal et al., 2022). Antibiotics

such as doxycycline and steroids may be beneficial for their anti-inflammatory properties if clinically indicated (Loyal et al., 2022).

Treatment of Ocular and Neurological Involvement

Due to the lack of evidence for the treatment of HA-induced vascular occlusions causing visual compromise, multidisciplinary collaboration within the setting of an emergency department (ED) gives the patient the best prognosis (Heydenrych et al., 2021; Walker et al., 2021). Ophthalmic incidents can cause irreversible damage within 60-90 minutes or less, so the patient should be transferred by ambulance accompanied by the clinician when possible, and staff should alert the ED of the patient's impending arrival and history (Heydenrych et al., 2021). While awaiting immediate transfer to the ED, the primary focus of treatment for the patient should be efforts to reduce intraocular pressure and increase retinal perfusion (Walker et al., 2021). The patient's visual symptoms should be documented and timed, vision tests should be conducted (light perception, hand movement, finger count, Snellen chart, reading, and pupillary reflex), and medical interventions can be initiated if time permits (Heydenrych et al., 2021; Walker et al., 2021). Recommended medications that may be beneficial for treatment goals are apraclonidine drops, timolol 0.5% drops, acetazolamide 500mg orally, and aspirin or Plavix (Heydenrych et al., 2021; Walker et al., 2021). Ocular massage is recommended and should be performed with the patient supine, eyes closed, firm pressure, 5-15 seconds at a time, and repeated for a total of five times (Heydenrych et al., 2021; Walker et al., 2021). Having the patient breathe into a brown paper bag promotes vasodilation and should be performed for 10 minutes in 30-minute cycles (Heydenrych et al., 2021; Walker et al., 2021). HYAL in high doses can be used to treat visible skin ischemia, but it should not delay transfer to the hospital (Heydenrych et al., 2021; Walker et al., 2021). Walker et al. (2021) provide additional

recommendations for interventions for ophthalmology-trained clinicians; however, these will not be discussed in detail for this project.

Considerations for Patients Receiving Hospital Treatment. A study by Zhang et al. (2020) included 24 patients with decreased visual acuity and other complications from HA facial injections. The patients were given emergent intra-arterial thrombolysis therapy by injection of HYAL alone or HYAL with urokinase. In both scenarios, they also received general symptomatic treatment and nutritional therapy. HYAL ranged from 500-1500 iu, and urokinase dosing ranged from 100,000 to 250,000 iu. The results found that 42% had improvements in visual acuity even when the treatment had passed the recommended window for optimal results, patients' facial skin necrosis was restored to nearly normal appearance in all cases, and HYAL combined with urokinase was more effective than HYAL alone (Zhang, et al., 2020).

For nonthrombolytic dermal filler-associated vascular occlusions that lead to cerebral embolism, antiplatelet/anticoagulant therapies are ineffective and can increase the risk of cerebral hemorrhage (Wang, et al., 2022). In these cases, treatment should be focused on symptomatic and nutritional therapies such as hyperbaric oxygen, neuropharmaceuticals, mannitol, and steroids (Wang, et al., 2022). Based on the study by Zhang et al. (2020), intra-arterial thrombolysis therapy may be considered (Wang, et al., 2022).

Follow-Up

This quality improvement project will not discuss the recommended follow-up treatment for patients who require emergent transfer to the hospital (retinal/cerebral occlusions). For cases involving the skin, the goal is an early treatment plan leading to reperfusion of an ischemic area and averting wound development (Farmer, et al., 2021). However, if the ischemic area is not successfully treated and necrosis occurs, wound development typically starts about three days

after the injury, and frank necrosis is most evident after six days (Farmer, et al., 2021; Loyal et al., 2022). Therefore, patients treated for HA filler-induced vascular occlusion of the skin should be continuously monitored for possible skin breakdown for several days (Loyal et al., 2022).

If skin necrosis occurs, stringent wound support is required (Murray et al., 2021). The use of antibiotics, wound dressings, pain management, and oxygen therapy are generally accepted options for care (Farmer, et al., 2021; King et al., 2020). Treatment for large areas of necrosis should be escalated and referred to a plastic surgeon (Farmer, et al., 2021). Lastly, proactive conversations with a medical defense organization may be beneficial as vascular events are distressing and may lead to legal claims (King et al., 2020).

Feasibility and Sustainability

This project was feasible with support and participation through the regional training company in Kentucky. Vascular occlusion is a known significant risk of HA fillers and as the injectable industry continues to grow there will be an ongoing need for provider and patient education surrounding this topic. Central themes of this project, including preparation for treating the complication, patient assessment and consent prior to performing the procedure, safe injection techniques, early recognition of a complication, early intervention of the complication, and appropriate follow-up, are vital for the treatment of vascular occlusion, but are also relevant to many potential complications that are encountered in healthcare practices. The concepts of this bundle of care can be further adapted by healthcare professionals to apply to several scenarios.

Budget

The QI project used free versions of software for development of the training video and pre/post test questions. The regional training company assisted in identifying voluntary

participants, and neither party required compensation. The project was budget neutral with no funding required.

Intervention

A bundle of care is an evidenced based set of processes, a structure of steps that when performed together improve patient outcomes (IHI, n.d.; Resar, et al., 2005). A bundle of care related to hyaluronic acid dermal filler associated vascular occlusions was presented to former trainees of a regional training company in Kentucky via a pre-recorded training video. Appendix B outlines the contents of the video based on the six elements of the bundle: (a) provider or organizational preparation; (b) pre-procedural patient assessment and consent; (c) safe injection; (d) early recognition; (e) early intervention; (f) follow-up and appropriate referrals The bundle of care provided a tool for participants to use in their practice of injecting dermal fillers to improve their preparation and confidence in the treatment of vascular occlusions.

Pre-Recorded Training Video

Description of the training video:

- The training video was pre-recorded using Prezi® and uploaded to YouTube®.
- Approximately 15 minutes of preparatory work in the form of pre-test questions was administered via Google Forms® and was required prior to viewing the training video.
- A link to the training video was shared via an email to the participants and required approximately 45 minutes to complete.
- Approximately 15 minutes was required for post-test questions administered via Google Forms® and done immediately after the training video and one-month later.

Learning Objectives

Learning objectives were constructed as goals that were specific, measurable, achievable, relevant, and time-bound) SMART:

- Provide an evidenced based process and structure of steps to prepare clinicians performing dermal fillers to treat a vascular occlusion.
- The clinicians' knowledge on the topic of vascular occlusion by 20% within the two-month period as evidenced by measuring baseline pre-test, post-test, and one-month post-test.
- The clinician' confidence on the topic of vascular occlusion would improve whereby at least 50% of the clinicians would "strongly agree" with questionnaire statements as evidenced by measuring baseline pre-test, post-test, and one-month post-test.

Methods

Participation was voluntary, and the training was offered to former trainees of the regional training company in Kentucky. The training company provided a list of potential participants, each was contacted via telephone or email, and those who elected to participate were sent an email with links to access all components of the training. Participants used their own computer, tablet, or smart phone device to access and complete the training.

Outcomes Assessment

A pre-test and post-test of identical questions using a Likert scale, and a true/false quiz was administered via Google Forms® (Appendix C & Appendix D). Pre and post-tests were coded with a unique participant ID number and did not contain identifying information. The project leader was not privy to the ID numbers of the participants. The short-term goals of this

project were to increase both knowledge and confidence in preventing VO when using HA as a dermal filler.

Measures

Self-Confidence and Knowledge

A pre and post-test measured participant's confidence and knowledge before and after completion of the training video. A 10-item Likert-type questionnaire and 10-item knowledge based true/false quiz was accessible to participants via Google Forms®.

Data Collection

Data collection occurred at three separate points using Google Forms® online. Former trainees who agreed to participate completed a pre-intervention questionnaire prior to the watching the educational video, and the same questions were asked immediate post-intervention and at one-month post-intervention. Demographic data for the participants was collected including age, gender, years of experience, and medical credentials.

Pre- and post-Knowledge

Pre-intervention quiz total scores were compared to the post-intervention quiz scores to calculate an increase in knowledge score.

Pre- and post-Confidence

Pre-intervention confidence levels were compared to post-intervention confidence levels, and the majority level of confidence percentages were highlighted.

Evaluation

Analysis of data collected on participant knowledge and confidence were evaluated using measures of central tendency, percentage, percentage of change, and rates. The results of the data analysis will be utilized for further cycles of the QI as structured by the PDSA.

Human Subjects Protection

All data collected was stored on a password-protected laptop computer that was only accessible by the DNP project leader. The data did not include participant identifiers, and all participants used a five-digit number associated with their phone number to track submissions. No patient information was relevant to the project, and none was collected or used for results.

Implementation Timeline

The project timeline, illustrated in Table 3, was conducted over the course of years 2023 and 2024. During this time meetings were held routinely with the project chair at the University of Louisville, supporting faculty members, and the training company owner. To begin, permission was obtained from the University of Louisville IRB and the training company. In Spring of 2024, the project QI project was implemented. The data collection and analysis took place in the Summer of 2024.

Results

All willing participants were sent an email that contained hyperlinks to the pre- and post-tests as well as the training video. Instructions in the email requested a two-week completion time for the initial data collection. This was extended to four weeks to improve participation and according to requests from participants to allow more time. Reminder emails were sent out during the initial data collection interval and again one-month post-intervention for the final data collection. Participants were given two weeks to complete the one-month post-test.

Pre and Post-test Knowledge

Results of the knowledge assessment are listed in Table 5. A total of 15 participants took the pre-test and 13 participants completed the immediate-post and one-month post-test. The goal of this project was to demonstrate a 20% overall increase in knowledge of injectors. Of the ten

questions, nine of them saw a positive percentage of change at both the immediate and one-month post-test intervals. The highest percentage of change was seen on question 3, which was related to the FDA recommendation for use of a Patient Portable Device Card (PPDC). For this question only 20% of participants answered correctly on the pre-test, and post-test percentage of change was 360% immediately after the intervention and 285% at one-month. Another significant improvement was seen with question 7, which was related to informed consent. This question had improvement from 40% correct pre-test to 130% percentage of change at both the immediate-post and one-month post-test intervals. Both significant improvements (questions #3 and #7) also had the poorest pre-test scores. None of the questions had a negative percentage of change, and only one had 0% percentage of change (Question #8). The overall mean of correct answers for the pre-test quiz was 69%, this improved to 92% immediately post-test and 95% one-month post-test. The percentage of change in scores for all questions was 33% immediate post-test and 37% one-month post-test.

Pre- and Post-Test Confidence

Confidence was measured using a 10-item Likert-type questionnaire constructed by the DNP leader with input from the sponsoring agency. Response options ranged from *1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree.* The results of this questionnaire are summarized in Table 6. Confidence levels improved for all questions in the immediate and one-month post-test intervals, and none of the questions had a decline in confidence at post-test intervals. For nine out of the ten pre-test questions, the highest percentage of responses were “agree.” In the two post-test intervals this improved with the highest percentage of responses being “strongly agree” for nine out of the ten questions. There is

note of a slight decline in confidence levels from the immediate-post to the one-month post-test interval, but all ten questions still had majority of responses in the "strongly agree" category.

Demographics

A summary of participant demographics is illustrated in Table 4. Female participants were the majority at 80%. Ages ranged from 29-60 years old, and the highest number of participants (40%) were between 31-40 years old. Medical credentials of participants included Advanced Practice Nurses (20%), Registered Nurses (66.6%), and Physicians (13.3%). Lastly, years of experience ranged from 1-19 years. Majority of the participants, or 66.6%, fell within the 0-5 years of experience range.

Discussion

Considering this was the first cycle of the PDSA, the QI project was highly successful in improving both knowledge and confidence in healthcare professionals who participated in the educational intervention. Knowledge about use of the Patient Portable Device Card and how to appropriately obtain informed consent had the highest percentages of change from pre- to post-test, which is an interesting trend that can continue to be emphasized in future cycles. In general, participant knowledge base pre-test was not poor (69%), but it did improve to a mean of greater than 90% at both post-test intervals. These results support the need for a bundle of care and reference video for prevention of vascular occlusions of HA for aesthetic purposes along with pre- and post-test knowledge checks. Similarly, while the majority of participants agreed with feeling confident on the topics discussed, they demonstrated increased levels of confidence at both post-intervention data collection intervals.

Limitations/Challenges

The QI project was able to gain participation from 15 individuals. The list of former trainees provided by the regional training company had 23 total emails for potential participants, so approximately 65% of them showed interest. There was a slight decrease in participation at the post-test intervals (N=13). The original data collection timeline had to be extended to improve participation numbers, and reminder emails proved to be a necessary for retention. A sample with a similar number of male participants would have been optimal. Participants were mostly Registered Nurses, and a better variety of healthcare credentials wound have been preferred.

Recommendations

There are several points of consideration for future cycles of the PDSA. Gaining participation proved to be challenging, and providing incentive in the future may be considered. Other considerations include breaking up the educational video into smaller increments and offering the education as part of the initial training provided by the training company rather than targeting former trainees.

Knowledge of participants improved, but reinforcing the elements of the bundle of care should be incorporated into practice. Reminders to use the PPDC and the appropriate way to obtain informed consent could be included in a note template for every patient getting a dermal filler treatment in a practice. Providing a digital template of the PPDC and a reference card for the recommended contents of the filler crash kit are tangible items that participants may also appreciate and find useful in the future.

Implications

This project sought to improve healthcare professionals' knowledge and confidence on the topic of vascular occlusion by presenting a bundle of care in an educational video. The bundle of care on this topic was intended for use of both practices and individual providers to improve safety and outcomes of their patients. Participants were encouraged to take responsibility for the important aspects of patient safety. Improvement in the overall preparation for adverse events and the systematic way of planning for these events are takeaways that could be useful amongst many healthcare practitioners and facilities.

Feasibility and Sustainability

This project was feasible with support and participation through the regional training company in Kentucky. Vascular occlusion is a known significant risk of HA fillers and as the injectable industry continues to grow there will be an ongoing need for provider and patient education surrounding this topic. Central themes of this project, including preparation for treating the complication, patient assessment and consent prior to performing the procedure, safe injection techniques, early recognition of a complication, early intervention of the complication, and appropriate follow-up, are vital for the treatment of vascular occlusion, but are also relevant to many potential complications that are encountered in healthcare practices. The concepts of this bundle of care can be further adapted by healthcare professionals to apply to several scenarios.

Budget

The QI project used free versions of software for development of the training video and pre/post test questions. The regional training company assisted in identifying voluntary

participants, and neither party required compensation. The project was budget neutral with no funding required.

Dissemination

The data collected and final report of this project was shared with the regional training company. The training company plans to utilize the data to help with the development of future education on vascular occlusion for trainees. Additionally, the DNP project lead will be publicly sharing the project contents and education with professionals in the industry.

References

Abduljabbar, M. H., & Basendwh, M. A. (2016). Complications of hyaluronic acid fillers and their managements. *Journal of Dermatology & Dermatologic Surgery*, *20*(2), 100–106. https://doi.org/10.1016/j.jdds.2016.01.001

Abulebda, K., Yuknis, M. L., Whitfill, T., Montgomery, E. E., Pearson, K. J., Rousseau, R., Diaz, M. C., Brown, L. L., Wing, R., Tay, K.-Y., Good, G. L., Malik, R. N., Garrow, A. L., Zaveri, P. P., Thomas, E., Makharashvili, A., Burns, R. A., Lavoie, M., & Auerbach, M. A. (2021). Preparedness for pediatric office emergencies: A multicenter, simulation-based study. *Pediatrics*, *148*(3), 65–74. https://doi.org/10.1542/peds.2020-038463

Alam, M., Kakar, R., Dover, J. S., Harikumar, V., Kang, B. Y., Wan, H. T., Poon, E., & Jones, D. H. (2021). Rates of vascular occlusion associated with using needles vs cannulas for filler injection. *JAMA Dermatology*, *157*(2), 174–180. https://doi.org/10.1001/jamadermatol.2020.5102

Alsayed, A. A. (2020). Activating a protocol for prevention, management and follow up of dermal filler injection related vascular occlusion (a clinical audit). *Modern Plastic Surgery*, *10*(04), 120–126. https://doi.org/10.4236/mps.2020.104014

American Dental Association. (n.d.). *Medical emergencies in the dental office.* American Dental Association. Retrieved August 31, 2023, from https://www.ada.org/en/resources/research/science-and-research-institute/oral-health-topics/medical-emergencies-in-the-dental-office

American Society of Plastic Surgeons. (2021). *2020 Plastic surgery statistics report*. Retrieved May 21, 2022, from

https://www.plasticsurgery.org/documents/news/statistics/2020/plastic-surgery-statistics-full-report-2020.pdf

Beleznay, K., Carruthers, J. D., Humphrey, S., & Jones, D. (2015). Avoiding and treating blindness from fillers: A review of the world literature. *Dermatologic Surgery*, *41*(10), 1097–1117. https://doi.org/10.1097/dss.0000000000000486

Beleznay, K., Carruthers, J. D., Humphrey, S., Carruthers, A., & Jones, D. (2019). Update on avoiding and treating blindness from fillers: A recent review of the World Literature. *Aesthetic Surgery Journal*, *39*(6), 662–674. https://doi.org/10.1093/asj/sjz053

Casabona, G. (2015). Blood aspiration test for cosmetic fillers to prevent accidental intravascular injection in the face. *Dermatologic Surgery*, *41*(7), 841–847. https://doi.org/10.1097/dss.0000000000000395

de Bedout, T., Kramer, K., Blanchard, S., Hamada, Y., Eckert, G. J., Maupome, G., & John, V. (2018). Assessing the medical emergency preparedness of dental faculty, residents, and practicing periodontists: An exploratory study. *Journal of Dental Education*, *82*(5), 492–500. https://doi.org/10.21815/jde.018.058

DeLorenzi, C. (2013). Complications of injectable fillers, part I. *Aesthetic Surgery Journal*, *33*(4), 561–575. https://doi.org/10.1177/1090820x13484492

DeLorenzi, C. (2014). Complications of injectable fillers, part 2: Vascular complications. *Aesthetic Surgery Journal*, *34*(4), 584–600. https://doi.org/10.1177/1090820x14525035

DeLorenzi, C. (2017). New high dose pulsed hyaluronidase protocol for hyaluronic acid filler vascular adverse events. *Aesthetic Surgery Journal*, *37*(7), 814–825. https://doi.org/10.1093/asj/sjw251

Dominguez, S., Moshrefi, S., & Dobke, M. (2017). Treatment protocol for acute arterial occlusion secondary to facial revolumization procedures. *Emergency Medicine, 49*(5), 221–229. https://doi.org/10.12788/emed.2017.0030

Donabedian, A. (1980). *Explorations in quality assessment and monitoring: The definition of quality and approaches to its assessment.* Health Administration Press.

Donabedian, A. (2005). Evaluating the quality of medical care. *The Milbank Quarterly, 83*(4), 691-729. https://doi.org/10.1111/j.1468-0009.2005.00397.x

Farmer, A., Murray, G., Croasdell, B., Davies, E., & Walker, L. (2021). Facial vascular events and tissue ischemia: A guide to understanding and optimizing wound care. *The Journal of Clinical and Aesthetic Dermatology, 14*(12 Suppl 1), S39–S48. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8903221/

Fortune Business Insights. (2022). *Dermal Fillers Market Size, Share & COVID-19 Impact Analysis, By Material (Hyaluronic Acid, Calcium Hydroxylapatite, Poly-L-lactic Acid, PMMA (Poly (Methyl Methacrylate)), Fat Fillers, and Others), By Product (Biodegradable and Non-Biodegradable), By Application (Scar Treatment, Wrinkle Correction Treatment, Lip Enhancement, Restoration of Volume/Fullness, and Others), By End-user (Specialty & Dermatology Clinics, Hospitals & Clinics, and Others), and Regional Forecast, 2022-2029*. https://www.fortunebusinessinsights.com/industry-reports/dermal-fillers-market-100939

Gold, M. (2010). What's new in fillers in 2010? *The Journal of Clinical and Aesthetic Dermatology, 3*(8), 36–45. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2945864/

Goodman, G. J., Liew, S., Callan, P., & Hart, S. (2020). Facial Aesthetic Injections in clinical practice: Pretreatment and posttreatment consensus recommendations to minimize adverse outcomes. *Australasian Journal of Dermatology*, *61*(3), 217–225. https://doi.org/10.1111/ajd.13273

Goodman, G. J., Magnusson, M. R., Callan, P., Roberts, S., Hart, S., McDonald, C. B., Clague, M., Rudd, A., Bekhor, P. S., Liew, S., Molton, M., Wallace, K., Corduff, N., Arendse, S., Manoharan, S., Shamban, A., Heydenrych, I., Bhatia, A. C., Peng, P., … Kosenko, D. E. (2019). A consensus on minimizing the risk of hyaluronic acid embolic visual loss and suggestions for immediate bedside management. *Aesthetic Surgery Journal*, *40*(9), 1009–1021. https://doi.org/10.1093/asj/sjz312

Heydenrych, I., De Boulle, K., Kapoor, K. M., & Bertossi, D. (2021). The 10-point plan 2021: Updated concepts for improved procedural safety during facial filler treatments. *Clinical, Cosmetic and Investigational Dermatology*, *Volume 14*, 779–814. https://doi.org/10.2147/ccid.s315711

Humzah, M. D., Ataullah, S., Chiang, C. A., Malhotra, R., & Goldberg, R. (2018). The treatment of hyaluronic acid aesthetic interventional induced visual loss (AIIVL): A consensus on practical guidance. *Journal of Cosmetic Dermatology*, *18*(1), 71–76. https://doi.org/10.1111/jocd.12672

Institute for Healthcare Improvement. (2022). *Science of improvement: Testing changes*. https://www.ihi.org/resources/how-to-improve

International Society of Aesthetic Plastic Surgery. (2021). *ISAPS International Survey on Aesthetic/Cosmetic Procedures Performed in 2020*. https://www.isaps.org/media/evbbfapi/isaps-global-survey_2020.pdf

Jung, H. (2020). Hyaluronidase: An overview of its properties, applications, and side effects. *Archives of Plastic Surgery*, *47*(04), 297–300. https://doi.org/10.5999/aps.2020.00752

Jones, D. H., Fitzgerald, R., Cox, S. E., Butterwick, K., Murad, M. H., Humphrey, S., Carruthers, J., Dayan, S. H., Donofrio, L., Solish, N., Yee, G. J., & Alam, M. (2021). Preventing and treating adverse events of injectable fillers: Evidence-based recommendations from the American Society for Dermatologic Surgery Multidisciplinary Task Force. *Dermatologic Surgery*, *47*(2), 214–226. https://doi.org/10.1097/dss.0000000000002921

Kapoor, K. M., Kapoor, P., Heydenrych, I., & Bertossi, D. (2019). Vision loss associated with hyaluronic acid fillers: A systematic review of literature. *Aesthetic Plastic Surgery*, *44*(3), 929–944. https://doi.org/10.1007/s00266-019-01562-8

Kapoor, K. M., Murthy, R., Hart, S. L., Cattin, T. A., Nola, P. F., Rossiter, A. P., Singh, R., & Singh, S. (2020). Factors influencing pre-injection aspiration for hyaluronic acid fillers: A systematic literature review and meta-analysis. *Dermatologic Therapy*, *34*(1). https://doi.org/10.1111/dth.14360

Khan, T. T., Colon-Acevedo, B., Mettu, P., DeLorenzi, C., & Woodward, J. A. (2016). An anatomical analysis of the supratrochlear artery: Considerations in facial filler injections and preventing vision loss. *Aesthetic Surgery Journal*, *37*(2), 203–208. https://doi.org/10.1093/asj/sjw132

King, M., Walker, L., Convery, C., & Davies, E. (2020). Management of a vascular occlusion associated with cosmetic injections. *The Journal of Clinical and Aesthetic Dermatology*, *13*(1), E53–E58. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7028373/

Kinnersley, P., Phillips, K., Savage, K., Kelly, M. J., Farrell, E., Morgan, B., Whistance, R., Lewis, V., Mann, M. K., Stephens, B. L., Blazeby, J., Elwyn, G., & Edwards, A. G. K.

(2013). Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.cd009445.pub2

Lee, K. E., Kim, G. J., & Sa, H. S. (2021). The clinical spectrum of periorbital vascular complications after facial injection. *Journal of Cosmetic Dermatology*, *20*(5), 1532–1540. https://doi.org/10.1111/jocd.14019

Lee, Y., Oh, S. M., Lee, W., & Yang, E. J. (2021). Comparison of hyaluronic acid filler ejection pressure with injection force for safe filler injection. *Journal of Cosmetic Dermatology*, *20*(5), 1551–1556. https://doi.org/10.1111/jocd.14064

Liu, K. (2020, January 7). *Dermal fillers: The good, the bad and the dangerous*. Harvard Health. https://www.health.harvard.edu/blog/dermal-fillers-the-good-the-bad-and-the-dangerous-201907152561

Loh, K. T., Chua, J. J., Lee, H. M., Lim, J. T., Chuah, G., Yim, B., & Puah, B. K. (2016). Prevention and management of vision loss relating to facial filler injections. *Singapore Medical Journal*, *57*(8), 438–443. https://doi.org/10.11622/smedj.2016134

Loyal, J., Hartman, N., Fabi, S. G., Butterwick, K. J., & Goldman, M. P. (2022). Cutaneous vascular compromise and resolution of skin barrier breakdown after dermal filler occlusion—implementation of evidence-based recommendations into real-world clinical practice. *Dermatologic Surgery*, *48*(6), 659–663. https://doi.org/10.1097/dss.0000000000003452

Murray, G., Convery, C., & Walker, L. (2021). Guideline for the management of hyaluronic acid filler-induced vascular occlusion. *The Journal of Clinical and Aesthetic Dermatology*, *14*(5), E61–E69. https://www.ncbi.nlm.nih.gov/pubmed/34188752

Murray, G., Convery, C., Walker, L., & Davies, E. (2021). Guideline for the safe use of hyaluronidase in aesthetic medicine, including modified high-dose protocol. *The Journal of Clinical and Aesthetic Dermatology*, *14*(8), E69–E75. https://www.ncbi.nlm.nih.gov/pubmed/34840662

Ors, S. (2020). The effect of hyaluronidase on depth of necrosis in hyaluronic acid filling-related skin complications. *Aesthetic Plastic Surgery*, *44*(5), 1778–1785. https://doi.org/10.1007/s00266-020-01759-2

Ouyang, H. W., Li, G. F., Zhu, Y., Lei, Y., Gold, M. H., & Tan, J. (2019). Treatment of skin soft tissue embolism after hyaluronic acid injection for injection rhinoplasty in Asian patients. *Journal of Cosmetic Dermatology*, *18*(3), 747–754. https://doi.org/10.1111/jocd.12968

Pendleton, A. L., & Stevenson, M. D. (2015). Outpatient emergency preparedness a survey of pediatricians. *Pediatric Emergency Care*, *31*(7), 493–495. https://doi.org/10.1097/pec.0000000000000310

Philipp-Dormston, W. G., Bergfeld, D., Sommer, B. M., Sattler, G., Cotofana, S., Snozzi, P., Wollina, U., Hoffmann, K. P. J., Salavastru, C., & Fritz, K. (2017). Consensus statement on prevention and management of adverse effects following rejuvenation procedures with hyaluronic acid-based fillers. *Journal of the European Academy of Dermatology and Venereology*, *31*(7), 1088–1095. https://doi.org/10.1111/jdv.14295

Rauso, R., Zerbinati, N., Fragola, R., Nicoletti, G. F., & Tartaro, G. (2020). Transvascular hydrolysis of hyaluronic acid filler with hyaluronidase. *Dermatologic Surgery*, *Publish Ahead of Print*. https://doi.org/10.1097/dss.0000000000002773

Resar, R., Pronovost, P., Haraden, C., Simmonds, T., Rainey, T., & Nolan, T. (2005). Using a bundle approach to improve ventilator care processes and reduce ventilator-associated

pneumonia. *The Joint Commission Journal on Quality and Patient Safety*, *31*(5), 243–248. https://doi.org/10.1016/s1553-7250(05)31031-2

Rocha, P. S., Guerra, T. A., & Teixeira, D. A. (2021). Description of a safe Doppler ultrasound-guided technique for hyaluronic acid filler in the face—a method to avoid adverse vascular events. *Journal of Cosmetic Dermatology*, *21*(7), 2783–2787. https://doi.org/10.1111/jocd.14492

Salinas-Alvarez, Y., Welsh, E. C., Soto-Dominguez, A., Quiroga-Garza, A., Hernandez-Garate, Y. A., De-La-Garza-Castro, O., Elizondo-Omaña, R. E., & Guzman-Lopez, S. (2021). Hyaluronic acid embolism treated with subcutaneous high and low hyaluronidase doses: Efficacy and surrounding tissue effect. *Plastic & Reconstructive Surgery*, *148*(6), 1281–1288. https://doi.org/10.1097/prs.0000000000008523

Schelke, L. W., Decates, T. S., & Velthuis, P. J. (2018). Ultrasound to improve the safety of hyaluronic acid filler treatments. *Journal of Cosmetic Dermatology*, *17*(6), 1019–1024. https://doi.org/10.1111/jocd.12726

Scheuer, J. F., Sieber, D. A., Pezeshk, R. A., Gassman, A. A., Campbell, C. F., & Rohrich, R. J. (2017). Facial danger zones: Techniques to maximize safety with during soft-tissue filler injections. *Plastic and Reconstructive Surgery*, *139*(5), 1103–1108. https://doi.org/10.1097/prs.0000000000003309

Signorini, M., Liew, S., Sundaram, H., De Boulle, K. L., Goodman, G. J., Monheit, G., Wu, Y., Trindade de Almeida, A. R., & Swift, A. (2016). Global aesthetics consensus: Avoidance and management of complications from hyaluronic acid fillers Fillers—evidence- and opinion-based review and consensus recommendations. *Plastic and Reconstructive Surgery*, *137*(6), 961e–971e. https://doi.org/10.1097/prs.0000000000002184

Snozzi, P., & van Loghem, J. A. (2018). Complication management following rejuvenation procedures with hyaluronic acid fillers—an algorithm-based approach. *Plastic and Reconstructive Surgery - Global Open*, *6*(12). https://doi.org/10.1097/gox.0000000000002061

Soares, D. J. (2022). Bridging a century-old problem: The pathophysiology and molecular mechanisms of HA filler-induced vascular occlusion (fivo)—implications for therapeutic interventions. *Molecules*, *27*(17), 5398. https://doi.org/10.3390/molecules27175398

Soares, D. J., Bowhay, A., Blevins, L. W., Patel, S. M., & Zuliani, G. F. (2022). Patterns of filler-induced facial skin ischemia: A systematic review of 243 cases and introduction of the foem scoring system and grading scale. *Plastic & Reconstructive Surgery*, *151*(4). https://doi.org/10.1097/prs.0000000000009991

Tansatit, T., Moon, H. J., Apinuntrum, P., & Phetudom, T. (2014). Verification of embolic channel causing blindness following filler injection. *Aesthetic Plastic Surgery*, *39*(1), 154–161. https://doi.org/10.1007/s00266-014-0426-z

Urdiales-Gálvez, F., Delgado, N. E., Figueiredo, V., Lajo-Plaza, J. V., Mira, M., Moreno, A., Ortíz-Martí, F., del Rio-Reyes, R., Romero-Álvarez, N., del Cueto, S. R., Segurado, M. A., & Rebenaque, C. V. (2018). Treatment of soft tissue filler complications: Expert consensus recommendations. *Aesthetic Plastic Surgery*, *42*(2), 498–510. https://doi.org/10.1007/s00266-017-1063-0

US Food and Drug Administration. (2021, March). *FDA executive summary general issues panel meeting on dermal fillers*. https://www.fda.gov/media/146870/download

US Food and Drug Administration. (2021, October). Dermal fillers (soft tissue fillers). https://www.fda.gov/medical-devices/aesthetic-cosmetic-devices/dermal-fillers-soft-tissue-fillers

Van Loghem, J. A. J., Fouché, J. J., & Thuis, J. (2017). Sensitivity of aspiration as a safety test before injection of soft tissue fillers. *Journal of Cosmetic Dermatology*, *17*(1), 39–46. https://doi.org/10.1111/jocd.12437

Vargas-Laguna, E., García-Gavín, J., & Bárcena-Ruiz, E. (2021). Safety in dermatologic procedures: Vascular occlusion by filling materials. *Actas Dermo-Sifiliográficas (English Edition)*, *112*(9), 794–797. https://doi.org/10.1016/j.adengl.2021.07.026

Walker, L., Convery, C., Davies, E., Murray, G., & Croasdell, B. (2021). Consensus opinion for the management of soft tissue filler induced vision loss. *The Journal of Clinical and Aesthetic Dermatology*, *14*(12), E84–E94. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8794490/

Wang, H. C., Yu, N., Wang, X., Dong, R., Long, X., Feng, X., Li, J., & Wu, W. T. (2021). Cerebral embolism as a result of facial filler injections: A literature review. *Aesthetic Surgery Journal*, *42*(3). https://doi.org/10.1093/asj/sjab193

Witmanowski, H., & Błochowiak, K. (2020). Another face of dermal fillers. *Advances in Dermatology and Allergology*, *37*(5), 651–659. https://doi.org/10.5114/ada.2019.82859

Wollina, U., & Goldman, A. (2020). Facial Vascular Danger Zones for filler injections. *Dermatologic Therapy*, *33*(6). https://doi.org/10.1111/dth.14285

World Health Organization. (2019). *Patient safety*. World Health Organization. Retrieved October 22, 2022, from https://www.who.int/news-room/fact-sheets/detail/patient-safety

Zein, M., Tie-Shue, R., Pirakitikulr, N., & Lee, W. W. (2020). Complications after cosmetic periocular filler: Prevention and management. *Plastic and Aesthetic Research, 2020*. https://doi.org/10.20517/2347-9264.2020.133

Zeltzer, A., Geeroms, M., Antoniazzi, E., Giunta, G., De Baerdemaeker, R., Hendrickx, B., & Hamdi, M. (2020). The "art" of facial filler injections: Avoid, recognize, and treat hyaluronic acid-induced complications. *Journal of Cosmetic Dermatology*, *19*(9), 2229–2236. https://doi.org/10.1111/jocd.13611

Zhang, L.-xia, Lai, L.-ying, Zhou, G.-wen, Liang, L.-ming, Zhou, Y.-chao, Bai, X.-yue, Dai, Q., Yu, Y.-tao, Tang, W.-qiang, & Chen, M.-liang. (2020). Evaluation of intraarterial thrombolysis in treatment of cosmetic facial filler-related ophthalmic artery occlusion. *Plastic and Reconstructive Surgery*, *145*(1). https://doi.org/10.1097/prs.0000000000006313

Zhou, S.-B., Chiang, C.-A., & Liu, K. (2020). False sense of safety: Blunt cannulas cause the majority of severe vascular complications in hyaluronic acid injection. *Plastic & Reconstructive Surgery*, *146*(2). https://doi.org/10.1097/prs.0000000000007022

Table 1

Johns Hopkins Nursing Evidence-Based Practice Levels

Level	Criteria
I	Experimental study, randomized controlled trial (RCT), a systematic review of RCTs with or without meta-analysis
II	The quasi-experimental study, systematic review of 1) a combination of RCTs and quasi-experimental or 2) quasi-experimental studies only with or without meta-analysis
III	Non-experimental study, systemic review of 1) a combination of RCTs, quasi-experimental, and non-experimental studies or 2) non-experimental studies only with or without meta-analysis
IV	Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence
V	Based on experiential and non-research evidence including literature reviews, quality improvement program/evaluation, case reports, opinions of nationally recognized experts based on experiential evidence

Table 2

Key Elements of Literature Review

Key Elements	Strength of Evidence	Supporting Evidence
Provider or Organization Preparation		
• Policy & Procedure – a written guideline to standardize care & treatment of vascular occlusion	III, IV	Abulebda et al. 2021; Alsayed, 2020; de Bedout et al., 2018; Pendleton & Stevenson, 2015; Urdiales-Galvez et al., 2018; World Health Organization, 2019
• Emergency Kit – printed copy of protocol for reference, medications, supplies, contact information for referrals, & charting materials	IV	DeLorenzi, 2014; Loyal et al., 2022; Urdiales-Galvez et al., 2018; Vargas-Laguna et al., 2021
• Mock Drills – annual staff training to identify roles, review policy & procedure, review the emergency kit contents, & provide guidance on how to handle post-procedure patient concerns	IV	American Dental Association, n.d.; Loyal et al., 2022
• Auditing & Competency – routine scheduled audits to assess preparedness of a facility to handle vascular occlusion events	IV	CDC, 2023
Patient Assessment and Consent		
• Exam & Medical history – review contraindications, visual assessment, surgical hx, allergies, basic vision	IV	Goodman et al., 2020; Heydenrych et al., 2021; Murray et al., 2021; Zeltzer et al., 2020

exam, capillary refill assessment, discuss if any travel plans, & screen for hx of previous vascular occlusion		
• Informed Consent (verbal and written) – explain procedure & product being used, risks vs. benefits, discuss alternative options, provide materials for review, explicitly discuss vascular occlusion and how to recognize symptoms, permission for photos/video, & include permission to treat complications	I, IV, V	Goodman et al., 2020; Heydenrych et al., 2021; Jones et al., 2021; Kinnersley et al., 2013; US Food and Drug Administration, 2021; World Health Organization, 2019
Safe Injection • Training and knowledge of facial and neck anatomy • Pre-injection aspiration • Needle vs. cannula • Minimal pressure • Minimal use of product • Anesthetic considerations • Use of digital pressure • Position, angle, and direction of injection • Ongoing assessment and communication • Use of ultrasound	III, IV, V	Alam et al., 2021; Beleznay et al., 2019; Casabona et al., 2015; DeLorenzi, 2017; Goodman et al., 2020; Goodman et al., 2019; Heydenrych et al., 2021; Humzah et al., 2019; Jones et al., 2021; Kapoor, et al., 2020; Khan et al., 2017; King et al., 2020; Lee et al., 2021; Loh, et al., 2016; Loyal et al., 2022; Murray et al., 2021; Philipp-Dormston, et al., 2017; Rocha et al., 2021; Schelke et al., 2018; Scheuer, et al., 2017; Signorini, et al., 2016; Tansatit et al., 2015; Van Loghem et al., 2018; Vargas-Laguna et al., 2021; Wang, et al., 2022; Zein et al., 2020; Zeltzer, et al., 2020; Zhou et al., 2020

Early Recognition • Most cases occur during injection but can happen up to 72 hours post injection • Patient should be provided 24-hour accessible phone number • Use of a portable device card provided to patient at departure	III, IV	Goodman et al., 2020; King et al., 2020; Soares, 2022; US Food and Drug Administration, 2021

• Skin Ischemia (most common type)
  ○ Can lead to necrosis, tissue loss, scarring, and wound if not addressed as soon as possible
  ○ Signs/Symptoms - skin color change with pallor or blanching, livedo reticularis, pain, and pustules or blister lesions (later if left untreated)
	III, IV	Farmer et al., 2021; Jones et al., 2021; Murray et al., 2021; Snozzi & Loghem, 2018; Soares, 2022; Urdiales-Galvez et al., 2018

• Retinal Occlusion (medical emergency) ○ Signs/Symptoms – blindness, blurry vision, diplopia, ptosis, ophthalmoplegia, and headache	III, IV	Snozzi & Loghem, 2018; Soares et al., 2022; Urdiales-Galvez et al., 2018
• Stroke (medical emergency) ○ Signs/Symptoms- altered consciousness, hemiplegia, headache, aphasia, and facial palsy		

Early Intervention • If VO suspected during treatment, immediately STOP the procedure • Inform the patient of a complication • Visual changes or stroke symptoms require 911 call for emergency treatment in a hospital, injector should accompany patient and bring HYAL. ED should be called enroute and appropriate specialist notified • Gather supportive staff and document all interventions with time stamp and video before and after each intervention	IV, V	Jones et al., 2021; King et al., 2020; Loyal et al., 2022; Murray et al., 2021

<u>Skin Ischemia</u>
• Firmly massage area
• Apply warm compress
• Identify area of occlusion with ultrasound when available
• Use Hyaluronidase (HYAL) when conservative measures fail
  ○ Safety
  ▪ Screen for potential allergy prior to injection
  ▪ Intradermal skin testing should be performed by a specialist prior to injection of dermal filler if potential allergy
  ▪ Disclose off-label use (as noted in consent)
	III, IV, V	DeLorenzi, 2017; Heydenrych et al., 2021; Jones et al., 2021; King et al., 2020; Loyal et al., 2022; Murray et al., 2021; Ors. 2020; Rauso et al. 2020; Rocha et al., 2021; Salinas-Alvarez, et al., 2021; Schelke et al., 2018

        - Read package insert for compatibility with lidocaine and storage directions
    - Cut off time for use – 4 days post occlusion
    - Mix HYAL with lidocaine (if compatible) for patient comfort and vasodilation benefits
    - High-dose pulsed protocol
        - Dose determined by number of areas included (1 area = 500iu/dose, 2 areas = 1000iu/dose, 3 areas = 1500iu/dose)
        - Dosing repeated hourly or more frequently until occlusion is resolved and capillary refill returns to <3 sec
    - Anti-platelet therapy (ASA, Plavix) if no contraindications
    - Other interventions at provider discretion and per clinical judgement
        - Phosphodiesterase inhibitor (ex: sildenafil) for large areas of ischemia

▪ Doxycycline & steroids (anti-inflammatory benefits) **Suspected Retinal Occlusion** • While awaiting transfer to ED by ambulance o Perform vision assessment (light perception, hand movement, finger count, Snellen chart, reading, pupillary reflex) o Reduce intraocular pressure and increase retinal perfusion ▪ Ocular massage ▪ Breathe into brown paper bag (10 min) o Inject HYAL for treatment of any skin ischemia (see above) • Discuss use of medications with retinal specialist – timolol, apraclonidine, acetazolamide, anti-platelet therapy, intra-arterial thrombolysis with injection of HYAL alone of HYAL with urokinase **Suspected Stroke** • Discuss use of medications and treatment with neurologist • Consider intra-arterial thrombolysis • Anti-platelet and anti-coagulation therapies not beneficial and can **increase** risk of cerebral hemorrhage	III, IV, V	Heydenrych et al., 2021; Walker et al., 2021; Wang et al., 2022; Zhang et al., 2020

• Focus on symptomatic and nutritional therapies ▪ Hyperbaric oxygen ▪ Neuropharmaceuticals ▪ Mannitol ▪ Steroids		
Follow-Up (Skin Ischemia) • Bring patient to the office daily for 4-6 days after treatment of VO to monitor skin for wound development • If ischemia is not successfully treated it will lead to necrosis and wound formation around 3 days after injury and is most evident around 6 days • Stringent wound support will be required for necrosis, consider referral to plastic surgeon • Proactive conversation with a medical defense organization may be beneficial in cases where legal claims may be involved	IV, V	Farmer et al., 2021; King et al., 2020; Loyal et al., 2022; Murray et al., 2021

Note. John Hopkins Nursing Evidence-Based Practice Levels: Level of Evidence: Level I – Experimental study, RCT, systematic review of RCTs with or without meta-analysis; Level II – Quasi-experimental study, systematic review of 1) a combination of RCTs and quasi-experimental or 2) quasi-experimental studies only with or without meta-analysis; Level III – Non-experimental study, systematic review of 1) a combination of RCTs, quasi-experimental, and non-experimental studies or 2) non-experimental studies only with or without metal-analysis; Level IV – Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence; Level V - Based on experiential and non-research evidence including literature review quality improvement program/evaluation, case reports, opinion of nationally recognized experts based on experiential evidence.

Table 3

Project Timeline

2023-2024	Nov	Dec	Jan	Feb	Mar	Apr	May	June	Jul	Aug
Draft proposal										
Defend proposal										
Submit to IRB										
Implementation										
Collect data										
Analyze data										
Interpret results										
Complete project report										
Disseminate findings										

Table 4

Demographics of those who participated in watching the vascular occlusion training video. Participants from April 15, 2024-June 23, 2024 (N=15)

Variables	n	%
Gender		
Male	3	20
Female	12	80
Age		
21-30 years	1	6.6
31-40 years	6	40
41-50 years	4	26.6
51-60 years	4	26.6
Medical Credentials		
Advanced Practice Nurse	3	20
Registered Nurse	10	66.6
Physician	2	13.3
Years of Experience Performing Dermal Filler Injections		
0-5	10	66.6
6-10	1	6.6
11-15	2	13.3
16-20	2	13.3

Table 5

Rate of Change in Pre and Post-Test Percentage of Correct Responses of Knowledge (N=15)

Item No.	Variable: Question Based on Bundle Elements	Pre-Test Mean Scores (n=15)	Immediate Post-Test Mean Scores (n=13)	1-Month Post-Test Mean Scores (n=13)	Percentage of Change in Scores (Pre and Immediate Post)	Percentage of Change in Scores (Pre and 1 Month Post)
1	It is currently mandatory to report dermal filler associated vascular occlusions to the FDA.	53	85	92	+60%	+74%
2	Retinal occlusions can be handled in the office with proper training.	87	100	100	+15%	+15%
3	The FDA recommends the use of a Patient Portable Device Card for patients receiving dermal filler products.	20	92	77	+360%	+285%
4	Wound development from a vascular occlusion can be avoided if treated successfully.	93	100	100	+8%	+8%
5	The only preparation needed for vascular occlusion events is having hyaluronidase on site.	93	100	100	+8%	+8%
6	Dermal filler associated vascular occlusions are extremely rare and the number of cases in the last 20 years has been decreasing.	60	77	92	+28%	+53%

7	Informed consent for patients getting dermal fillers can be written only and verbal consent is optional.	40	92	92	+130%	+130%
8	The following should be considered for safe injection of dermal fillers: knowledge of facial and neck anatomy, use of aspiration, choosing needle vs. cannula, use of minimal pressure with injection, use of an ultrasound, position/angle/direction of injection.	100	100	100	0.00%	0.00%
9	Dermal filler associated vascular occlusions leading to stroke are only possible in areas of the face that are high-risk.	67	85	100	+27%	+49%
10	In general, healthcare practices do very well in preparing for urgent medical situations with patients.	73	85	92	+16%	+26%
11	Overall Scores	69	92	95	+33%	+37%

Note. Pre- and post-scores based on one point for each element and calculated by percentage correct.

Table 6

Pre and Post-Test Confidence Scores

Item No.	Variable: Question Based on Bundle Elements	Pre-education (n=15)	Immediate Post-Education (n=13)	1-Month Post-Education (n=13)
1	I feel fully prepared to treat a vascular occlusion caused by a hyaluronic acid dermal filler.	13% - Strongly Agree 73% - Agree 7% - Neutral 7% - Disagree 0% - Strongly Disagree	62% - Strongly Agree 38% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	46% - Strongly Agree 46% - Agree 8% - Neutral 0% - Disagree 0% - Strongly Disagree
2	I am confident in my ability to recognize the signs and symptoms of dermal filler induced vascular occlusion.	33% - Strongly Agree 67% - Agree 0% - Neutral 0% - Disagree 0% - Strongly Disagree	85% - Strongly Agree 15% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree
3	I feel confident in my knowledge about facial/neck anatomy and safe injection techniques to reduce the risk of vascular occlusion when performing dermal filler injections.	13% - Strongly Agree 73% - Agree 7% - Neutral 7% - Disagree 0% - Strongly Disagree	46% - Strongly Agree 54% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	54% - Strongly Agree 38% - Agree 8% - Neutral 0% - Disagree 0% - Strongly Disagree
4	I feel confident in performing pre-procedural informed consent with patients regarding the risks associated with dermal filler injections - including discussion of risk for skin ischemia, vision loss, and stroke risk.	33% - Strongly Agree 47% - Agree 13% - Neutral 7% - Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	54% - Strongly Agree 46% - Agree 0% - Neutral 0% - Disagree 0% - Strongly Disagree

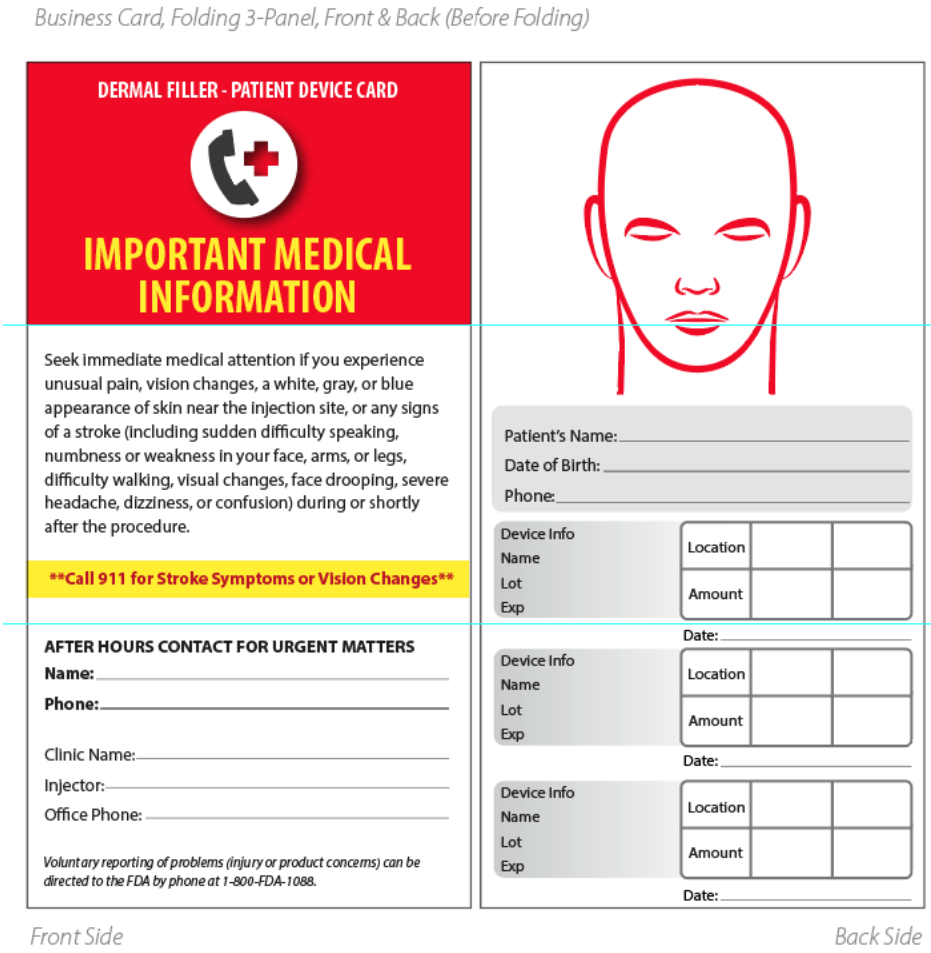
Item No.	Variable: Question Based on Bundle Elements	Pre-education (n=15)	Immediate Post-Education (n=13)	1-Month Post-Education (n=13)
5	I feel confident in my knowledge of what items should be included in a dermal filler emergency kit or "filler crash cart."	20% - Strongly Agree 53% - Agree 7% - Neutral 20% - Disagree 0% - Strongly Disagree	77% - Strongly Agree 23% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree
6	I feel confident in my ability to provide follow-up care and necessary referrals for a patient with dermal filler induced vascular occlusion.	20% - Strongly Agree 53% - Agree 20% - Neutral 7% - Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	54% - Strongly Agree 46% - Agree 0% - Neutral 0% - Disagree 0% - Strongly Disagree
7	I feel confident in my knowledge about the steps I should take to prepare myself or my facility for treating a vascular occlusion.	20% - Strongly Agree 53% - Agree 13% - Neutral 13% - Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	62% - Strongly Agree 23% - Agree 15% - Neutral 0% - Disagree 0% - Strongly Disagree
8	I feel confident in my knowledge of the important aspects of a pre-procedural patient assessment or exam (Good Faith Exam) when performing dermal filler injections.	33% - Strongly Agree 53% - Agree 13% - Neutral 0% - Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	62% - Strongly Agree 38% - Agree 0% - Neutral 0% - Disagree 0% - Strongly Disagree

Item No.	Variable: Question Based on Bundle Elements	Pre-education (n=15)	Immediate Post-Education (n=13)	1-Month Post-Education (n=13)
9	I am confident in my knowledge about the importance of performing mock drills for vascular occlusion in my facility.	20% - Strongly Agree 33% - Agree 33% - Neutral 13% - Disagree 0% - Strongly Disagree	69% - Strongly Agree 23% - Agree 8%- Neutral 0%- Disagree 0% - Strongly Disagree	54% - Strongly Agree 38% - Agree 8% - Neutral 0% - Disagree 0% - Strongly Disagree
10	I feel confident in my knowledge about hyaluronidase, including how much my facility should keep on hand, proper dosing, and contraindications for use.	13% - Strongly Agree 60% - Agree 13% - Neutral 13% - Disagree 0% - Strongly Disagree	69% - Strongly Agree 30% - Agree 0%- Neutral 0%- Disagree 0% - Strongly Disagree	54% - Strongly Agree 46% - Agree 0% - Neutral 0% - Disagree 0% - Strongly Disagree

Note. Pre- and post-scores based on a Likert scale.

Figure 1

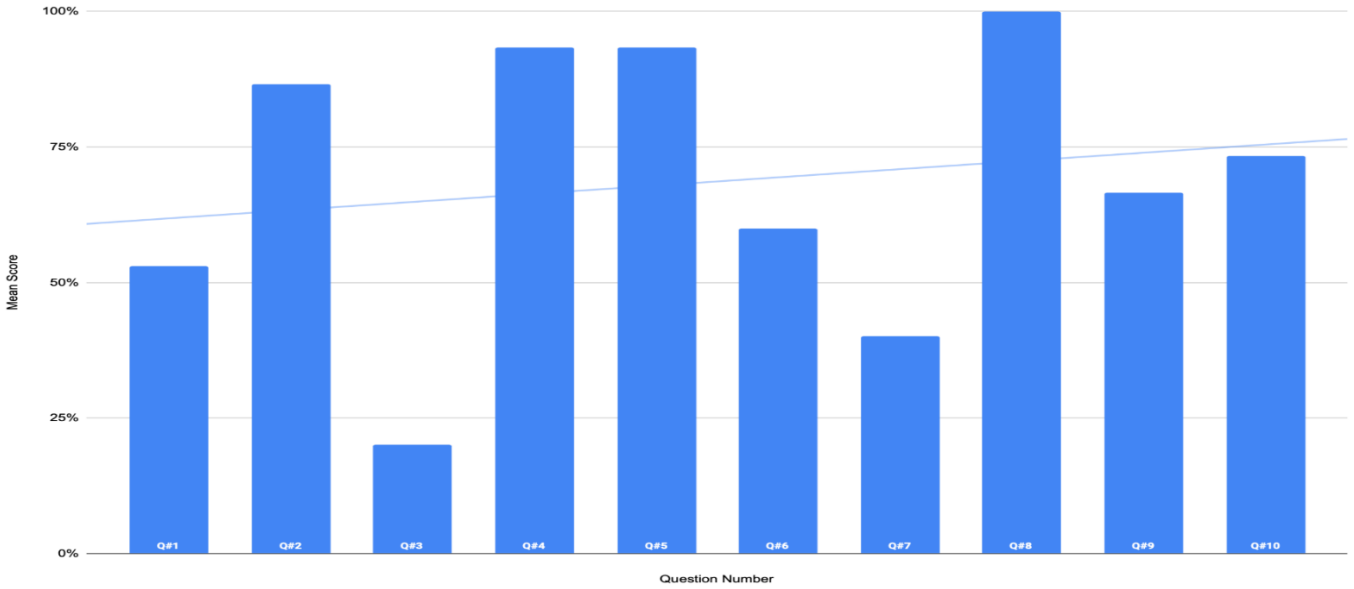
Dermal Filler - Patient Portable Device Card



Note. The Patient Portable Device Card can be a physical or digital card and should be provided to a patient at the time of a dermal filler procedure. The card information should be completed by the facility providing the procedure, it should be carried by the patient for safety and reference should complications occur.

Figure 2

Pre-Education Knowledge – True/False Questionnaire Results

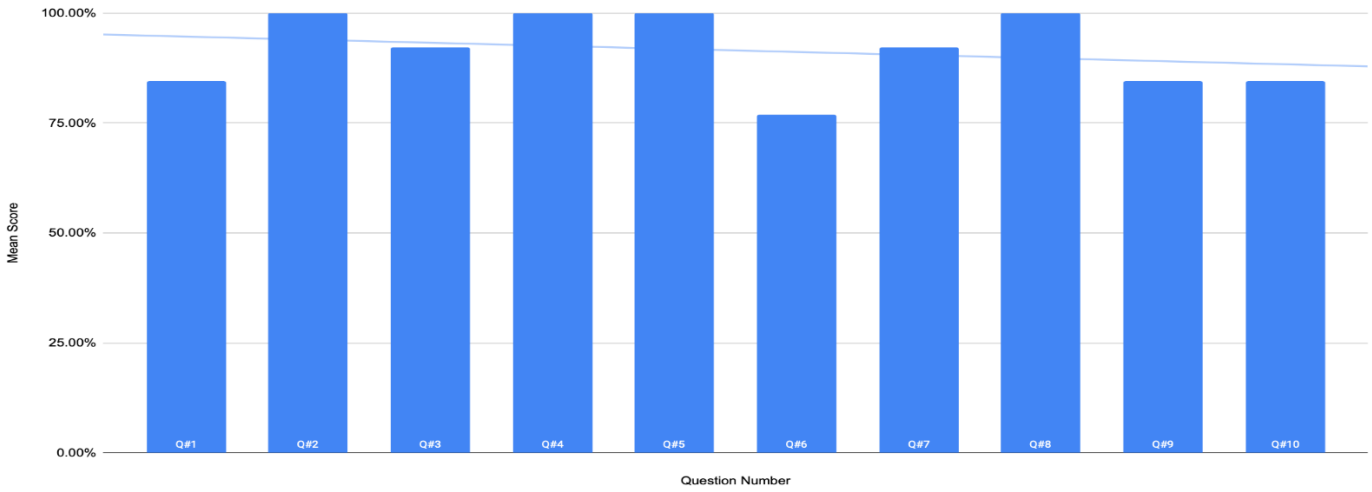


Legend: Q#1=It is currently mandatory to report dermal filler associated vascular occlusions to the FDA; Q#2=Retinal occlusions can be handled in the office with proper training; Q#3=The FDA recommends the use of a Patient Portable Device Card for patients receiving dermal filler products; Q#4=Wound development from a vascular occlusion can be avoided if treated successfully; Q#5= The only preparation needed for vascular occlusion events is having hyaluronidase on site; Q#6=Dermal filler associated vascular occlusions are extremely rare and the number of cases in the last 20 years has been decreasing; Q#7= Informed consent for patients getting dermal fillers can be written only and verbal consent is optional; Q#8=The following should be considered for safe injection of dermal fillers: knowledge of facial and neck anatomy, use of aspiration, choosing needle vs. cannula, use of minimal pressure with injection, use of an ultrasound, position/angle/direction of injection; Q#9=Dermal filler associated vascular occlusions leading to stroke are only possible in areas of the face that are high-risk; Q#10=In general, healthcare practices do very well in preparing for urgent medical situations with patients.

Note: Scores based on one point for each element and calculated by percentage correct, n=15.

Figure 3

Immediate Post-Education Knowledge – True/False Questionnaire Results

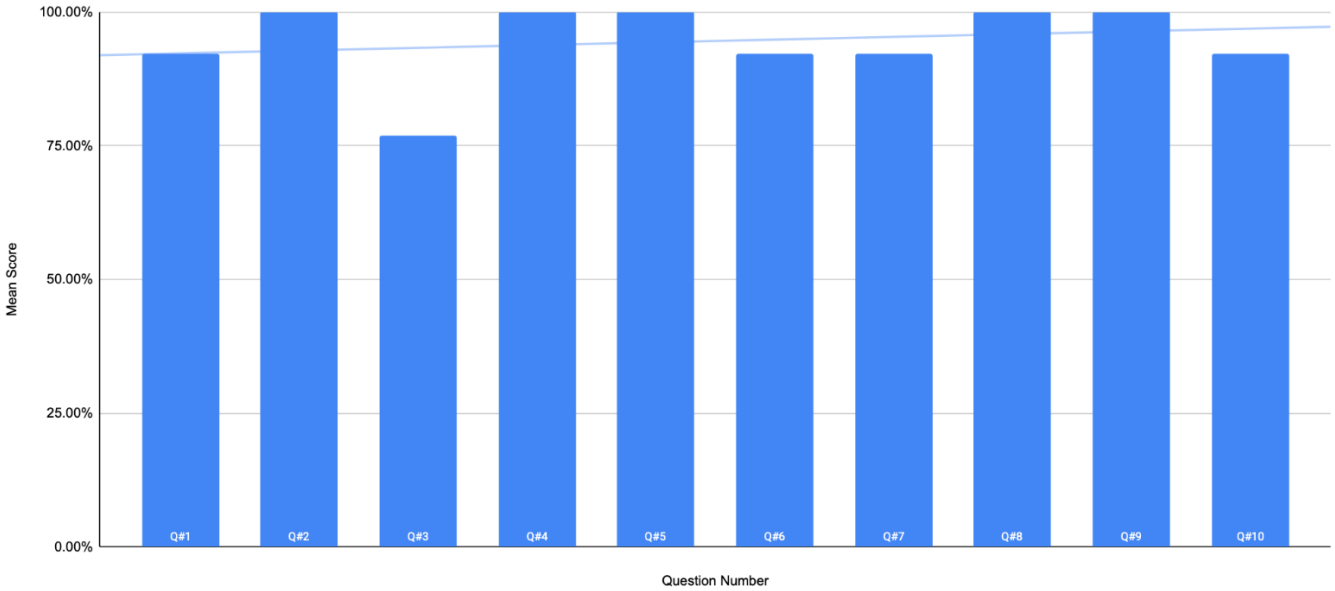


Legend: Q#1=It is currently mandatory to report dermal filler associated vascular occlusions to the FDA; Q#2=Retinal occlusions can be handled in the office with proper training; Q#3=The FDA recommends the use of a Patient Portable Device Card for patients receiving dermal filler products; Q#4=Wound development from a vascular occlusion can be avoided if treated successfully; Q#5= The only preparation needed for vascular occlusion events is having hyaluronidase on site; Q#6=Dermal filler associated vascular occlusions are extremely rare and the number of cases in the last 20 years has been decreasing; Q#7=Informed consent for patients getting dermal fillers can be written only and verbal consent is optional; Q#8=The following should be considered for safe injection of dermal fillers: knowledge of facial and neck anatomy, use of aspiration, choosing needle vs. cannula, use of minimal pressure with injection, use of an ultrasound, position/angle/direction of injection; Q#9=Dermal filler associated vascular occlusions leading to stroke are only possible in areas of the face that are high-risk; Q#10=In general, healthcare practices do very well in preparing for urgent medical situations with patients

Note: Scores based on one point for each element and calculated by percentage correct, n=13.

Figure 4

1 Month Post-Education Knowledge – True/False Questionnaire Results



Legend: Q#1 It is currently mandatory to report dermal filler associated vascular occlusions to the FDA; Q#2=Retinal occlusions can be handled in the office with proper training; Q#3=The FDA recommends the use of a Patient Portable Device Card for patients receiving dermal filler products; Q#4=Wound development from a vascular occlusion can be avoided if treated successfully; Q#5= The only preparation needed for vascular occlusion events is having hyaluronidase on site; Q#6=Dermal filler associated vascular occlusions are extremely rare and the number of cases in the last 20 years has been decreasing; Q#7=Informed consent for patients getting dermal fillers can be written only and verbal consent is optional; Q#8=The following should be considered for safe injection of dermal fillers: knowledge of facial and neck anatomy, use of aspiration, choosing needle vs. cannula, use of minimal pressure with injection, use of an ultrasound, position/angle/direction of injection; Q#9=Dermal filler associated vascular occlusions leading to stroke are only possible in areas of the face that are high-risk; Q#10=In general, healthcare practices do very well in preparing for urgent medical situations with patients.
Note: Scores based on one point for each element and calculated by percentage correct, n=13.

Appendix A

Letter of Support from Agency Practice Site

INJECTOR4U LLC

INJECTOR4U LLC

To Whom It May Concern,

My name is Amanda Rube, founder and master trainer for Injector4U LLC. Injector4U LLC is a private training company for new and advanced injectors. It is top priority to utilize safe injection technique in the field of aesthetics.

I am very excited and willing to allow Genny Sanders, APRN access to train and teach nurses on vascular occlusion complications. Utilizing Genny's tool kit for injectors in such an event will assist new and seasoned injectors with a systematic approach if the situation was to occur.

If you have any other questions or inquiries on how Genny and I can work together to benefit the field of aesthetics please feel free to reach me via email or phone.

Best Regards,

Amanda Rube BSN, RN
INJECTOR4U@gmail.com
www.INJECTOR4U.com
(502) 681-4746

INJECTOR4U LLC

Appendix B

Topics Reviewed on Vascular Occlusion of Filler Educational Video

1. Background – Why is this important?
2. Preparation
    a. Policy & Procedure
    b. Mock Drills
    c. Annual Audit of Policies and Staff Preparedness
    d. Preparing a Filler Crash Cart
3. Patient Assessment & Pre-procedural Consent
    a. Obtain medical history
        i. Medical conditions
        ii. Screen for contraindications
        iii. Allergies
        iv. Surgical history
        v. Medications
        vi. Social history
        vii. Travel Plans
    b. Perform assessment
        i. Capillary refill
        ii. Vision Exam
        iii. Skin assessment
    c. Obtain Informed Consent
        i. Explain procedure
        ii. Risks & Benefits
        iii. Alternative Options
        iv. Patient signed consent
            1. Include consent for photos/video & treatment of complications
        v. Provide resources to enhance the learning process such as pamphlets, video, website, etc.
4. Safe Injection
    a. Understanding of facial anatomy
        i. Depth perception
        ii. Injection into the correct plane
        iii. Usual location of blood vessels
        iv. Common anatomical variations
        v. Awareness of surgical alterations or scarring
    b. Pre-Injection Aspiration
    c. Cannula size - 25 Gauge or larger
    d. Minimal pressure with injection – Avoid high pressure injections
    e. Avoid large boluses, low volume injections are safest, overfilling increases risk of VO
    f. Use of epinephrine containing anesthetic
        i. Blanching may mask ability to identify occlusion

        ii. Vasoconstriction decreases vessel size, could reduce risk of entering vessel
    g. Digital pressure over area of nearby vessel while injecting
    h. Positioning of need in respect to vessel
    i. Continuous assessment of capillary refill, skin color, pain, neurological and vision
    j. Stop injection immediately for any concerns
5. Use of ultrasound technology when available
6. Early Recognition of VO
    a. Patient education about signs and symptoms of VO
        i. Skin changes
        ii. Pain
        iii. Vision loss or symptoms
        iv. Stroke symptoms – sudden difficulty speaking, numbness or weakness in the face, arms, or legs, difficulty walking, visual changes, facial drooping, severe headache, dizziness, or confusion
    b. Use of a portable patient device card and how to complete
        i. Importance in VO after visit and case of transition of care
    c. Initial symptom – change in skin color
        i. Blanching
        ii. Delayed capillary refill less than four seconds
        iii. Livedo reticularis (blue-gray color of skin)
        iv. Pain – mild – severe
    d. Late symptom – necrosis (about 72 hours later if not treated successfully)
        i. Blistering of the skin
        ii. Wound development
7. Early Intervention
    a. Warm compress
    b. Massage
    c. Hyaluronidase
        i. Safety
            1. Contraindications
            2. Risks
            3. See package insert – storage, compatibility with lidocaine and others, and reconstitution
        ii. Dosing & frequency of injection
    d. Aspirin or Plavix
    e. Use of ultrasound
    f. Contact colleagues for support
    g. Optional interventions
        i. Sildenafil
        ii. Doxycycline/Steroids
    h. Real – time documentation
        i. Photographs and video
        ii. Written notes
    i. Vision loss or stroke symptoms
        i. Call 911

ii. Contact Retinal Specialist for vision loss
Perform if time:
1. Vision assessment
2. Ocular massage
3. Hyaluronidase if evidence of skin involvement
4. Apraclonidine or timolol drops
5. Have patient breathe into paper bag

iii. Accompany patient and bring hyaluronidase
iv. Contact family

8. Follow up care
    a. Bring patient to office/clinic daily for several days to monitor for wound development
    b. Wound care
        i. Antibiotics
        ii. Wound dressings
        iii. Pain management
        iv. Oxygen therapy
        v. Refer to plastics for complicated or large areas

Appendix C

Pre- and Post-Questionnaire for Confidence Bundle of Care for Hyaluronic Acid Dermal Filler Associated Vascular Occlusion Confidence Assessment

Please circle one number for each question: 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree. Your information is anonymous.

1	2	3	4	5	1. I feel fully prepared to treat a vascular occlusion caused by a hyaluronic acid dermal filler.
1	2	3	4	5	2. I am confident in my ability to recognize the signs and symptoms of dermal filler induced vascular occlusion.
1	2	3	4	5	3. I feel confident in my knowledge about facial/neck anatomy and safe injection techniques to reduce the risk of vascular occlusion when performing dermal filler injections.
1	2	3	4	5	4. I feel confident in performing pre-procedural informed consent with patients regarding the risks associated with dermal filler injections – including discussion of risk for skin ischemia, vision loss, and stroke risk.
1	2	3	4	5	5. I feel confident in my knowledge of what items should be included in a dermal filler emergency kit or "filler crash cart."
1	2	3	4	5	6. I feel confident in my ability to provide follow-up care and necessary referrals for a patient with dermal filler induced vascular occlusion.
1	2	3	4	5	7. I feel confident in my knowledge about the steps I should take to prepare myself or my facility for treating a vascular occlusion.
1	2	3	4	5	8. I feel confident in my knowledge of the important aspects of a pre-procedural patient assessment or exam (Good Faith Exam) when performing dermal filler injections.
1	2	3	4	5	9. I am confident in my knowledge about the importance of performing mock drills for vascular occlusion in my facility.
1	2	3	4	5	10. I feel confident in my knowledge about hyaluronidase, including how much my facility should keep on hand, proper dosing, and contraindications for use.

Appendix D

Pre- and Post-Questionnaire for Knowledge of Bundle of Care for Hyaluronic Acid Dermal Filler Associated Vascular Occlusion Knowledge Assessment

Please circle True (T) or False (F) for the following items. Your information is anonymous.

True or False…

T	**F**	1. It is currently mandatory to report dermal filler associated vascular occlusions to the FDA.
T	**F**	2. Retinal occlusions can be handled in the office with proper training.
T	F	3. The FDA recommends the use of a Patient Portable Device Card for patients receiving dermal filler products.
T	F	4. Wound development from a vascular occlusion can be avoided if treated successfully.
T	**F**	5. The only preparation needed for vascular occlusion events is having hyaluronidase on site.
T	**F**	6. Dermal filler associated vascular occlusions are extremely rare and the number of cases in the last 20 years has been decreasing.
T	**F**	7. Informed consent for patients getting dermal fillers can be written only and verbal consent is optional.
T	F	8. The following should be considered for safe injection of dermal fillers: knowledge of facial and neck anatomy, use of aspiration, choosing needle vs. cannula, use of minimal pressure with injection, use of an ultrasound, position/angle/direction of injection.
T	**F**	9. Dermal filler associated vascular occlusions leading to stroke are only possible in areas of the face that are high-risk.
T	**F**	10. In general, healthcare practices do very well in preparing for urgent medical situations with patients.

_____ Total Knowledge Score (0-10)