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Table of Contents

Abstract

This project set out with the goal(s) of developing screening guidelines to assist aesthetic providers in the prompt recognition of dermal filler caused vascular occlusions, educating providers on the associated warning signs, and increase the overall screening for these complications post dermal filler injection. There are two types of vascular occlusions that can occur and they are arterial (during injection) and venous (delayed injection). Previous research on the topic of vascular occlusions discusses the prevalence of their occurrence as quite rare, but through the findings of this project it appears their occurrence is around 1.25%. As the worldwide popularity of aesthetic procedures continues to grow it is imperative individuals injecting these products have the tools necessary to recognize problems as they occur. Timely recognition equals prompt mitigation and quick action can lead to minimizing the risk of tissue degradation, skin necrosis, and even blindness. Utilizing in clinical practice the Vascular Occlusion Recognition Tool (VORT) protocol as discussed in this paper will guide providers to make the most informed decision when determining whether their patient is cleared to be discharged post dermal filler procedure.

Keywords: HA filler, Hyaluronidase, Vascular Occlusion, Vascular Complications, Filler complications, VO Protocol, Dermal Filler Complication Recognition, Dermal Filler Complication Manegment, Early Vascular Occlusion Recognition, Vascular Compromise, Dermal Filler Risk, Hylenex, Retinal Artery Occlusion, Retrobulbar Injection

Recognizing Dermal Filler Complications: Implementation of Dermal Filler Complication Recognition Guidelines

As the popularity, accessibility, and acceptability of the use of nonsurgical cosmetic procedures continues to rise, a greater number of individuals are utilizing aesthetic medicine to chase the proverbial fountain of youth. Over the last twenty years, nonsurgical cosmetic procedures have seen a 144% increase in their use and with the increased popularity and usage, complications will inevitably arise (Ballin, Brandt, & Cazzaniga, 2015). One such complication is a vascular occlusion which can occur when hyaluronic acid (HA) is injected either intravascularly or near an artery, causing a compression blockage. HA dermal fillers are utilized in aesthetics as a way to treat loss of volume and laxity. Facial volume loss occurs through descent of fat pads, reabsorption of facial bones, and the breakdown of subcutaneous tissue (Small & Hoang, 2012).

Currently, the estimates for vascular occlusions occur in roughly 7 out of 10,000 injections with the highest areas of risk in the nasolabial fold, glabellae, nasal area, and temple (Hwang, 2016). In 2018, a worldwide study of 52 experienced aesthetic injectors was conducted and 62% of respondents admitted to having one or more vascular occlusions in their career (Urdiales-Gálvez et al., 2018). Due to the potentially irreversible effects of a vascular occlusion, it is imperative aesthetic providers learn the signs and symptoms associated with a vascular occlusion. The practice problem identified for this quality improvement (QI) project is the lack of guidelines to screen for vascular occlusions in a medical spa. The purpose of this QI project is to integrate guidelines into practice for the early recognition of vascular occlusions.

Background

A vascular occlusion has the potential to occur if dermal filler is injected near a blood vessel causing restriction or cessation of blood flow or if dermal filler is directly injected into a

blood vessel (De Boulle & Heydenrych, 2015). The two main types of vascular occlusions are arterial (during injection) and venous (delayed onset). A vascular occlusion can lead to necrosis, tissue degradation, and even blindness (De Boulle & Heydenrych, 2015). Early recognition on the part of the provider can provide the patient with the best possible outcome and with aggressive treatment the effects can be mitigated. If vascular occlusions are not treated expeditiously and effectively the patient could suffer skin necrosis and possibly even blindness (Salval, Ciancio, Margara, & Bonomi, 2017). In addition to vascular occlusions, there are other adverse events that can occur up to four weeks post dermal filler injections. The following complications, although considered minor, should also be documented in the patient chart and include the following: ecchymosis, edema, pain, blanching, and redness (Urdiales-Gálvez et al., 2017). Although many medical spas have a treatment plan in place for vascular occlusions, they lack the signs for recognizing vascular occlusions swiftly in their treatment protocols. The protocols need to address the timely recognition of vascular occlusion that presents as white blanching or violaceous reticular pattern of the skin with an onset typically no later than six hours after treatment (Small & Hoang, 2012). White blanching of the skin presents itself as whiter patches of skin near the injection site and a violaceous reticular pattern skin appear as a violet colored spider web near the injection site.

Problem Statement

Vascular occlusions occur in roughly 7 out of 10,000 dermal filler injections (Ciancio, Tarico, Giuseppe, & Perrotta, 2019). These numbers might make the prevalence of vascular occlusions seem rare, but these numbers are only inclusive of vascular occlusions that are reported to the drug manufactures and true numbers are estimated to be much higher (Ciancio, Tarico, Giuseppe, & Perrotta, 2019). This QI project will be implemented at a Southern California medical spa that does not currently include vascular occlusion recognition guidelines in their post

dermal filler injections standardized procedures. Unless there are signs of a vascular occlusion, patients are immediately discharged following the dermal filler injection with a follow-up scheduled for approximately two to four weeks later to check for symmetry, satisfaction, complications, and healing progression. When performing dermal filler injection procedures, clear guidelines are needed to assist providers in recognizing vascular occlusions early to prevent adverse outcomes.

Purpose Statement

The purpose of this QI project is to develop and implement evidence-based screening guidelines to assist with the early recognition of vascular occlusions caused by HA injections received in a medical spa setting.

Project Question

The Problem Intervention Comparison Outcome Time (PICOT) format was utilized to develop the project question:

P- There are currently no screening guidelines for providers to recognize vascular occlusions post HA dermal filler injections.
I- Develop evidence-based screening guidelines for providers to assist in recognizing vascular occlusions post dermal fillers.
C- The comparison will be drawn through chart audits of procedures completed both prior and after implementation of the new post-procedure dermal filler guidelines.
O- Increase in screenings and early recognition of vascular occlusions post dermal fillers
T- Four weeks
Will the implementation of guidelines increase screening and early recognition of vascular occlusions post dermal filler injections?

Project Objectives

1. Develop screening guidelines based on current evidence for the early recognition of vascular occlusions caused by HA fillers. A manual data sheet will be utilized to determine adherence to the new protocol and the use of additional screening guidelines.
2. Educate registered nurses, nurse practitioners, and physician assistants on screening guidelines and revised protocol and pre-and post-knowledge test to evaluate the effectiveness of the education provided. Pre and posttests shall be administered in addition to educational sessions including handouts, discussions, and PowerPoint presentations.
3. Increase the number of screenings for vascular occlusions and document accordingly in the patient's chart. The number of screenings shall be confirmed through documentation in the patient chart as well as a manual data collection sheet kept in a locked drawer to ensure all HIPPA regulations and privacy guidelines are strictly adhered to.

This QI project will improve screening practices for vascular occlusion and increase early identification of adverse reactions allowing for immediate intervention. The measures of accomplishment will be attained by comparing HA filler injection pre-implementation and post-implementation to see if there was an increase in screening and a reduction in adverse outcomes associated with dermal fillers through early recognition of vascular occlusions.

Significance

Through the end of 2018, revenue from dermal filler procedures accounted for an almost three hundred and fifty-billion-dollar business annually and by 2026, these numbers are expected to almost double (NASDAQ OMX's News Release Distribution Channel, 2019). As the popularity of these procedures continues to increase, so does the likelihood that a vascular occlusion will occur. It is important providers are given information to identify a vascular occlusion early so they

can act quickly and attempt to mitigate the potential tissue necrosis or visual impairment. At the medical spa where this QI project will be implemented, there is no internal policy that explicitly states the signs and symptoms of a vascular occlusion or how to appropriately chart them if a complication were to arise. There are no national or clinical guidelines/recommendations for early recognition of vascular occlusions at this time, so reference for recommendations will be made through peer-reviewed journals.

Search Terms

The guidance for this literature review was channeled by the question: will the implementation of guidelines increase screening and early recognition of vascular occlusions post dermal filler injections? The online databases that were used to locate information for the literature review were Proquest and CINAHL with filters for articles published from 2014 to 2020 that were retrieved from a scholarly journal. Search terms used were: dermal filler complications, vascular occlusion, skin necrosis, injectable filler complications, soft filler complications, hyaluronidase, hyaluronic acid, vascular compromise, assessment, prevention, and treatment.

Review Coverage and Justification

Inclusion data were comprised of articles that referenced dermal filler patients and the complications that had occurred. Exclusion data involved articles that referenced semi-permanent or permanent dermal fillers as well as articles mentioning injections into areas other than the head, neck, or hands. Filters were utilized to exclude articles that were not full-text/peer-reviewed or from a scholarly journal. After accounting for both inclusion and exclusion criteria, as well as utilizing both Proquest and CINAHL, there were approximately four hundred articles returned and fifteen were utilized for this project.

Review of Literature

The literature was utilized to establish guidelines for early recognition of a vascular occlusion. There are many factors that are important for providers to consider prior, intra, and post dermal filler procedure. A thorough understanding of a patient's medical history, anatomy, and proper injection techniques are paramount to avoiding complications associated with dermal fillers (Vedamurthy, 2018). This QI project has utilized the most recent and relevant data available with the purpose to assist providers in recognizing the early signs of a vascular occlusion and with an expeditious treatment plan.

Impact of the problem

The popularity of dermal fillers is increasing worldwide due largely in part to their use being relatively safe, delivering immediate results, and being inexpensive. According to the American Society for Dermatologic Surgery, dermal fillers are the second most sought after non-surgical cosmetic treatment (only behind botulinum toxin injections) seeing a 16% increase from 2015-2016 (Vedamurthy, 2018). Aesthetic injectors must have proper injection techniques and superior knowledge of soft tissue, bone, and vascular anatomy to reduce the risk of a vascular occlusion (Hwang, 2016). Prevention is an important step and can be achieved through the acquisition of theoretical knowledge, hands-on workshops, and shadowing experienced injectors (Vedamurthy & Vedamurthy, 2010). Theoretical knowledge is gained from textbooks, journal articles, and didactic education while hands-on and shadowing are considered a more practical approach to learning. Knowing the warning signs of early vascular occlusion recognition is important to treat the effects of either tissue necrosis or visual impairment. Vascular occlusion treatment is currently based on the recommendations of a variety of practitioners but the consensus

favors introducing large amounts of hyaluronidase into the affected area in an attempt to reinvigorate blood flow to the region affected (Hwang, 2016).

Vascular Occlusion Prevention

The recognition of a vascular occlusion intra and post-procedure is significant, but ultimately the goal is to avoid an occurrence altogether. Heydenrych et al. (2017) discusses a ten point plan for avoiding dermal filler complications that includes the following: History/patient selection, assessment, consent, reversibility, product characteristics determining product placement, product layering, photographs, proper procedure planning, anatomical knowledge and technical knowledge. The ten-point plan discusses the importance of a patient's medical history including skin conditions and systemic disease, assessing the patients wants versus needs, the provider having superior knowledge of facial anatomy, and the importance of their knowledge of injection depth, placement and speed (Heydenrych et al., 2017). Recognizing patients who are appropriate candidates for a procedure is an important factor and not to be overlooked.

According to De Boulle & Heydenrych (2015), there are dermal filler contraindications that, if avoided, could potentially prevent issues from arising. Patients should be made aware of the limitations of dermal filler and be provided realistic expectations to avoid dissatisfaction post-procedure. Providers should be consistent with photographing patients prior to and post aesthetic procedure to assess the effectiveness of the filler as well as documenting adverse effects. A thorough review of a patient's medical history is of utmost importance to the feasibility of performing an aesthetic procedure on the patient. Patients with thin skin (either corticosteroid or rheumatoid arthritis induced) or a history of anaphylaxis or severe allergies should not be medically cleared for dermal filler treatment. The facial dermis (skin thickness) on the face ranges from 0.4 mm to 1.2 mm and different HA products should be injected at different depths. For

example, if a patient's cheeks were at 0.6 mm instead of 1.2 mm (standard depth), the product would not be in the correct plane and a vascular occlusion would be more likely to occur. Instructions provided from the manufacturer should also be closely followed as there are product-specific contraindications detailed extensively. Prior to the injection of dermal filler, the provider should prophylactically aspirate the injection area. Aspiration occurs when the provider inserts a new needle into the patient's skin and if blood enters the needle the injection point needs to be altered as the needle is in a blood vessel. After a bloodless aspiration has been completed, the provider should inject the dermal filler slowly with special attention to pain or changes in skin color during the treatment (De Boulle & Heydenrych, 2015).

Vascular Occlusion Recognition

Both intra and post-procedure patient monitoring are important and according to Vedamurthy (2018), the two most common types of vascular occlusions that can occur during or after a dermal filler treatment are tissue necrosis and visual impairment. Cutaneous necrosis occurs either by a vascular compression that minimizes blood perfusion resulting in a scar or if the dermal filler is administered via an intra-arterial injection and there is damage to the endothelial cells causing ischemic changes of the skin. If cutaneous necrosis is suspected, the patient will display painless blanching intra-procedure with severe pain post-procedure followed by a color change resulting in a dusky discoloration. Visual loss occurs when there is a filler embolism affecting ophthalmic vasculature causing immediate pain and vision loss in the affected eye (Vedamurthy, 2018).

Understanding and recognizing dermal filler induced vascular occlusions is important for the aesthetic injector. Funt & Pavicic (2013), state there are over fifty companies producing over one hundred and sixty dermal filler products and providers must be competent in their use and

aware of the complications that might arise. Knowledge of facial anatomy is crucial as there are nine arteries in the face that aesthetic injectors must avoid as they directly coincide with dermal filler injection sites. These arteries are located in the temple, nasal area, glabellae, and nasolabial fold. When an injector has an "intra-arterial injection into one of the distal branches of the ophthalmic artery" blood supply is being blocked to the retina with the potential for visual impairment or blindness (Funt & Pavicic, 2013, p. 307). Tissue necrosis also occurs when dermal fillers are injected into vessels and carried through the vasculature of the area. The initial signs of potential necrosis are excessive pain and blanching that turns a dusky purple color, which calls for immediate action (Funt & Pavici, 2013).

Vascular Occlusion Treatment

If a vascular occlusion is suspected, the provider should stop the injection and attempt to regain blood flow to the area immediately. This can potentially be achieved through applying a warm compress, massaging or tapping the area, and applying 2% nitroglycerin paste to promote vasodilation (De Boulle & Heydenrych, 2015, p. 210). The provider should then immediately attempt to dissolve the product that was injected utilizing hyaluronidase. Hyaluronidase is a product that can be utilized to treat all forms of vascular compromise as it helps to reduce vessel-occluding pressure and minimize edema. De Boulle & Heydenrych (2015) discuss that there are no guidelines pertaining to the amount of hyaluronidase to be injected, but the suggestions are no less than twenty units per dermal filler injection site. As long as there are lingering signs of a necrosis, patients should be injected again with hyaluronidase twenty-four hours after the initial injection. Patients should also start taking an anticoagulant, antibiotics, and be capable of keeping the area clean and changing their bandages regularly. The patient should also be seen on a regular

basis for scar evaluation and management with a possible surgical consult for any possible reconstruction (De Boulle & Heydenrych, 2015).

The most serious complications associated with dermal fillers are vascular occlusions. A vascular occlusion can cause visual impairment, vision loss, and even tissue necrosis (Goodman, Roberts & Callan, 2016). Given the severity of vascular occlusions, many researchers have spent countless hours compiling data in hopes of developing the most effective treatment methodology. Hwang (2016) discusses a treatment protocol that includes hyaluronidase, warm compresses, nitroglycerine paste, and hyperbaric oxygen but argues that flushing a high-dose of hyaluronidase (750 IU) within four hours of the initial dermal filler treatment is ultimately the best option (Hwang, 2016).

Benefits of Current Recommendations

Benefits of currently available recommendations are that many experienced aesthetic providers around the world have experienced a vascular occlusion and are willing to share their experiences about what led up to the event, what was observed during/after the procedure, and how the provider treated the patient. Utilizing the experience of injectors along with scholarly research to support early recognition of a vascular occlusion, new protocols will be created and enacted to mitigate adverse events more expeditiously. Research has shown "prompt effective management leads to favorable outcomes and will prevent catastrophic consequences such as skin necrosis" it is imperative providers are provided with the tools necessary to recognize vascular occlusions quickly (Goodman, Roberts, & Callan, 2016, p. 549). Recognition of a vascular occlusion becomes increasingly difficult due in part to lack of guidelines for their identification but also because new products are constantly being introduced with little research regarding potential adverse events that could occur (Durdu, Bozca, & Kocer, 2017).

Issues still under investigation

As the aesthetic industry continues to grow, new HA based dermal products (160 different products and counting) are constantly being introduced into the market (Funt & Pavicic, 2013). The consistent influx of products makes it imperative providers are aware of the warning signs of a vascular occlusion as the placement, viscosity, and elasticity of a product can increase or decrease the risks associated with HA based dermal fillers (Imhof & Kuhne, 2012). Due to informed consent obtained from patients prior to a procedure, patients are aware of the complications that may arise but it is the duty of the provider to be able to recognize and treat these emergencies in an expeditious and efficient manner.

Issues not yet addressed

Issues not yet addressed in this project are semi-permanent or permanent fillers. Semi-permanent and permanent fillers treat facial volume loss in the same way as HA based dermal fillers, but with greater longevity. Another issue not discussed in literature is a template or plan for recognizing vascular occlusions more expeditiously. There is much research discussing the signs and symptoms of a vascular occlusion, but there is yet to be a defined recognition and treatment plan (Funt & Pavicic, 2013).

Controversies

Controversies exist surrounding how the information pertaining to vascular occlusions is collected and disseminated. Dermal filler procedures are an elective procedure performed by a provider of one's own choosing and there is difficulty in obtaining randomized control trials (RCT's) relevant to the early recognition of vascular occlusions. A lack of RCT's in conjunction with the information being collected mostly from providers could bias results to lower incidences of reported vascular occlusions because some providers are utilizing superior injection techniques

(De Boulle & Heydenrych, 2015). Injection technique is important and although many providers tout the importance of aspiration, there is little consensus as to the efficacy of performing aspiration prior to the injection of dermal fillers. According to Vedamurthy (2018), aspiration must be done prior to each injection and dermal filler should be injected slowly with multiple passes if necessary. In comparison, Petrou (2011) admits that although aspiration could help to prevent a vascular occlusion, it is not fail-proof and needle insertion/placement are far more important.

Review of Study Methods

After extensive review of the relevance of methods and techniques to the early recognition of a vascular occlusion have presented themselves and are clearly described. These themes include the importance of patient selection, vascular occlusion recognition, and vascular occlusion treatment (De Boulle & Heydenrych, 2015). The literature outlines a meta-analysis of both qualitative and quantitative experiences of aesthetic providers from around the world (Goodman, Roberts, & Callan, 2016). The methods explored are relevant to the QI project as they present various approaches with the ultimate goal of recognizing a vascular occlusion sooner.

Seven studies have discussed the prevention, recognition, and treatment of vascular occlusions utilizing qualitative and quantitative data, which includes articles written by the following authors (Vedamurthy, 2018; Hwang, 2016; Vedamurthy & Vedamurthy, 2010; Heydenrych et al., 2017; De Boulle & Heydenrych, 2015; Funt & Pavicic 2013; Goodman, Roberts, & Callan, 2016). One study discussed a ten-point plan to minimize the risk of vascular occlusions (Heydenrych et al., 2017), two studies discussed the treatment of vascular occlusions (De Boulle & Heydenrych, 2015; Goodman, Roberts, & Callan, 2016), three studies discussed

vascular occlusion prevention best practices (Vedamurthy, 2018; Hwang, 2016; Vedamurthy & Vedamurthy, 2010) and lastly vascular occlusion recognition was explored (Funt & Pavicic, 2013).

Significance of Evidence to the Profession

The scholarly and practical significance of early recognition of a vascular occlusion post dermal filler injection is imperative as over 2.6 million procedures are performed annually in the United States (PR Newswire, 2019). Using data on reported cases of vascular occlusions caused by dermal fillers (a rate of around 7 out of 10,000 in conjunction with the over 2.6 million dermal filler procedures performed annually), there is a reported occurrence of almost two thousand vascular occlusions occurring annually in the United States (Ciancio, Tarico, Giuseppe, & Perrotta, 2019). As licensed vocational nurses, registered nurses, and nurse practitioners are performing many dermal filler injection procedures at a higher rate than in the past, the importance of vascular occlusion early recognition is paramount to the nursing profession (Small, Kelly, & Spinelli, 2014). The numbers of nurse injectors are growing so rapidly that the International Society of Aesthetic Plastic Surgery (ISAPS) wrote a journal article in 2014 "*Are Nurse Injectors the New Norm?" (*Small, Kelly, & Spinelli, 2014).

This purpose of this QI project is to utilize relevant scholarly literature to create and put into practice evidence-based screening guidelines to support the provider in prompt identification of vascular occlusions caused by dermal filler injections in any setting that provides dermal filler injections. The QI project will utilize scholarly inquiry to assist the aesthetic provider as to the most appropriate and relevant recognition of vascular occlusions that can occur both during and post dermal filler injection. The lack of a comprehensive screening tool for dermal filler caused vascular occlusions has immense scholarly significance. Currently, aesthetic providers obtain information through a variety of sources in an attempt to recognize the signs of a vascular

occlusion early, but there is little scholarly-reviewed consensus on the topic (Vedamurthy, 2018). Incorporating best evidence of vascular occlusion early recognition requires extensive journal review and is imperative to a patient's well-being and the aesthetic profession as a whole.

Theoretical Framework

Avedis Donabedian MD, MPH was born on January 7th, 1919 in Beirut Lebanon (Frenk, 2000). Donabedian received his medical degree from the American University of Beirut and subsequently immigrated to the United States where he became a professor at the University of Michigan (Frenk, 2000). According to Ayanian and Markel (2016), Donabedian published an article in July 1966 titled "Evaluating the Quality of Medical Care" that would become one of the most frequently cited articles related to public health over the next fifty years. Donabedian's model was based on a "triad of structure, process, and outcome to evaluate the quality of health care" and will be utilized as the theoretical framework for this QI project (Ayanian & Markel, 2016, p. 2016).

Utilizing the triad of structure, process, and outcome, the Donabedian Model is useful within the nursing profession as it well equipped to determine the quality of nursing care (Voyce, Gouveia, Medinas, Santos, & Ferrerira, 2015). The Donabedian Model (see Appendix A) ties into healthcare as a means of determining quality measurements within a specific healthcare system. Donabedian was one of the first scholars to measure the effect of healthcare on the status of patients and populations (Donabedian, 2005, p. 169).

Historical Development of the Theory

Donabedian considered himself an outsider as he obtained medical training outside of the United States but attended the Harvard School of Public Health for his graduate degree in Health Services Administration (Ayanian & Markel, 2016). Donabedian credits the creation of his

framework to his interest in how medical care is delivered ranging from large health care systems to small clinics (Ayanian & Markel, 2016). The healthcare profession underwent significant evolution after the release of Donabedian's framework in 1966. Donabedian "eloquently explicated how the social response to health problems is not a collection of unrelated events, but rather a complex process that follows general principles (Frenk, 2000, p. 1475). The complex process Donabedian mentioned is applicable to the nursing profession as structure, process, and outcome are imperative to the nursing profession as the framework strives for quality assurance in nursing.

Donabedian was one of the first to address quality issues in healthcare and was the first to put great emphasis in the patient satisfaction perspective of healthcare (Naidu, 2009). The Donabedian Model paved the way for the formation of healthcare groups with the primary focus of ensuring providers were adhering to medical standards of care. In the 1970's, Professional Standards Review Organizations (PSROs) were created and over time they have been replaced with the incorporation of Quality Improvement Organizations (QIOs) (Warrier and McGillen, 2011). QIOs partner with providers to improve the quality of care delivered utilizing best evidence of care obtained from the local level (Warrier and McGillen, 2011).

Applicability of Theory to Current Practice

Donabedian's Quality of Care framework is applicable to current practice as aesthetic providers are constantly trying to improve the structure, process, and outcomes of the patients they encounter while performing procedures. Donabedian's framework is especially important as nurses "have a social responsibility to evaluate the effect of nursing practice on patient outcomes in the areas of health promotion, injury and illness prevention" (Jones, 2016, p. 2). Utilizing the framework provided by Donabedian, researchers have the ability to measure outcomes of care.

Outcomes of care are regarded as the most important aspect of quality assessment as they focus primarily on the patients themselves (Jones, 2016). One should never undervalue the measures of outcome derived from patient care but understand these metrics to allow for increased advancement of the practitioner's skill level and the entire medical profession as a whole.

The Donabedian Model posed many questions that are applicable to current practice and also how they relate to this DNP project. Donabedian pursued the answer to the question "What goes on here?" when searching for evidence and data to determine the effectiveness of current practice (Ayanian & Markel, 2016, p. 206). Reframing the inquiry from a fairly vague direction of how can things could be better and utilizing Donabedian Model to search deeper and understand the pre, intra, and post-procedure process for dermal filler injections allows the provider to ensure understand a wider range of aspects during the treatment and provide an overall higher level of care to the patient.

Major Tenets

According to Warrier and McGillen (2011), the major tenets of the Donabedian Framework are structure, process, and outcome. Donabedian utilized his tenets of structure, process, and outcome in conjunction with metrics obtained from various social systems and cultures and the results have the ability to either detract or enhance overall patient care (Ayanian & Markel, 2016). Utilizing the Donabedian Model for this DNP project will allow for an overall understanding of the aesthetic procedure from consultation to results. All tenets of the Donabedian Model apply to this DNP project on multiple levels. Structure relates to provider qualifications, process utilizes evidence-based guidelines (which this project is working to develop and incorporate), and outcome reflects patient results and the delivery of high-quality care.

Structure. Structure addresses the qualifications of the providers, settings, and the administrative systems that assist to facilitate care (Warrier & McGille, 2011). Structure is important to this DNP project as providers, medical spa facility, and support/administrative systems are qualified to perform, document, and appropriately monitor dermal filler procedures pre, intra, and post procedure. Structure is vital to the nursing profession as board certification and the accreditation of hospitals are measures that have been put in place monitor clinical performance. Over time, structure has evolved to include organizations such as the Occupational Safety and Health Administration (OSHA) as well as The Joint Commission. Various organizations work cohesively to ensure quality in clinics/hospitals, safe conditions and practices are followed, and providers are competent in their duties (Ayanian and Markel, 2016).

Process. Process is important as it directly relates to how care is delivered to patients (Warrier & McGille, 2011). Understanding how to recognize vascular occlusions quickly is paramount to this DNP project. During his research, Donabedian drew similarities between process and the troubleshooting of electronics as it shares many of the characteristics of medical diagnosis and treatment (Donabedian, 1966).

Research on patient care must be evaluated to ensure it is evidence-based, safe, and aligns with national guidelines (Warrier & McGillen, 2011). Donabedian believed that pieces of the process must be dissected so they may be understood more clearly before they could be attributed to certain goals (Donabedian, 1966).

Outcome. The outcome of the Donabedian framework is the restoration of functional recovery to survival but more importantly, patient attitudes (Warrier and McGillen, 2011). In order to have a successful outcome, Donabedian suggested, assurance of performance requires measurement of performance (Jones, 2016, p.2). The measurement of outcome as it relates to this

DNP project is an important measure of phenomena (i.e. the occurrence of a vascular occlusion post dermal-filler injection), which will in turn generate selective attention leading to selective improvement (Kurtzman & Jennings, 2008). Additionally, Donabedian encouraged actively leading as well as molding of high-quality care within organizations to provide optimal outcomes for patients of varying socio and ethnic backgrounds (Ayanian & Markel, 2016).

Theory Application to the DNP Project

The Donabedian Framework and this DNP project are interconnected on a variety of levels. The main goal of the project is the early recognition of a vascular occlusion. Currently, there is little consensus as to the warning signs of a vascular occlusion in the field of aesthetic medicine (Vedamurthy, 2018). The lack of uniform guidance for early vascular occlusion recognition has pushed for the creation and ultimate implementation of this DNP project. Through the use of Donabedian's framework of structure, process, and outcome, an early recognition vascular occlusion guideline will be created and implemented into a medical spa setting.

The DNP project has the goal of utilizing structure through continued training and certification of the registered nurses, nurse practitioners, and physician assistants that are currently performing aesthetic procedures. The project tenet will also include charting software capable of documenting the outcomes of the dermal filler treatments in a way that is easily accessible for the DNP project and future follow-up care.

The process of the DNP will be continuing education to increase the awareness of vascular occlusion recognition with the overall goal of helping registered nurses, nurse practitioners, and physician assistants in early recognition.

The DNP project aims to expand the standard of care post-dermal filler injection to include signs indicative that a vascular occlusion is occurring. Expanding the standard of care will utilize

evidence-based research to guide providers in their delivery of care to dermal filler patients post procedure. Post procedure guidelines will be introduced that include questions surrounding the injection technique, whether aspiration was performed, patient complaining of pain during or post procedure, any blanching noticed during the procedure, and if there was capillary refill in the area of less than two seconds.

The outcome of the DNP project will be measured through the early recognition of a vascular occlusion and prompt treatment to mitigate any further risks. The information gained from this DNP project is vital to the ever-growing aesthetic industry as patient safety surrounding dermal procedure injections is paramount. This DNP project has the primary objective of incorporating the most recent, relevant, and evidence-based process of care to dermal filler injection procedures.

Project Design

The overall purpose of this evidence-based DNP quality improvement (QI) project is to create and implement best practice guidelines for the recognition of vascular occlusions in a more expeditious manner allowing the provider an immediate intervention. The measures of accomplishment will be gained by comparing HA filler injections both pre-and post-implementation to determine if an increase in screenings increased the likelihood of early recognition of adverse outcomes. This DNP project will occur in a naturalistic setting and the goal will be to develop a deeper understanding of the phenomenon of interest as it relates to aesthetic community as a whole (Polit & Beck, 2017). The population of interest will be aesthetic providers working in an outpatient clinical setting performing derma filler injections. The data analysis methods that will be utilized are pre and post-tests administered after a presentation discussing vascular occlusion recognition (see Appendix B). The pre and post-test will be numbered to

protect the anonymity of the participant while also providing a way to monitor the progress of the participants both pre and post-test. The information gained from the presentation and post-test will ensure providers are performing and incorporating the information learned from the educational material disseminated at the beginning of the project implementation. The protocol will include the recognition and documentation of provider screenings and whether a vascular occlusion had occurred. Data collection on both protocol adherence and results of the screenings will occur weekly through a chart audit of the various providers within the clinic who are performing HA dermal filler procedures. Providers will complete no less than ten screenings over the course of four weeks during protocol implementation. Data collection review will ensure adherence of not only the protocol but if the provider actually followed the appropriate documentation of procedures as instructed.

The independent variable for this QI project would be the vascular occlusion recognition protocol and the dependent variable would be the healthcare providers' adherence to the protocol and the protocols impact on both vascular occlusion recognition and screening. The project design is an important step as it works to connect the information obtained in the literature review and guide it towards a successful DNP project implementation. Donabedian believed that everything is capable of being improved upon and with this knowledge the idea for this DNP project was created and is centered on Donabedian's Framework of structure, process, and outcome (Ayanian & Markel, 2016). Structure, as it applies to this project, is the training and pre/post-test that will be administered to the aesthetic providers; the process is the continuing education to these providers (accounting for needle placement, depth, and injection technique based on procedure), and the outcome will be the early recognition of a vascular occlusion to allow for an immediate treatment response.

Population of Interest

The population of interest for this DNP project is aesthetic providers performing elective dermal filler treatments on both male and female patients over the age of twenty-one. The healthcare providers that will be included in this project are medical doctors, nurse practitioners, physician assistants, and registered nurses. The project will include no more than five aesthetic providers who perform no less than ten dermal filler injection procedures each over a four-week span. Providers working in a medical spa setting performing dermal filler injections will be included in this project. Medical providers who work in an aesthetic setting but do not perform HA based dermal filler injections will not be included in the project.

Setting

The DNP project will take place in an outpatient clinic setting that is most often referred to as a medical spa. The medical spa is located in Southern California and performs approximately two hundred dermal filler injection procedures monthly. Permission was received from the facility to develop an evidence-based protocol to decrease adverse reactions and implement this DNP project within the clinic (see Appendix C). Training will be provided to the aforementioned aesthetic providers about the early recognition of vascular occlusions and chart audits will be utilized to determine provider adherence to the redesigned protocol.

Stakeholders

The stakeholders for this DNP project are vast and varied and they include aesthetic injectors, clinic managers, drug manufacturers, and most importantly patients receiving these elective treatments. Aesthetic injectors are vested in this DNP project as they would prefer avoidance of a vascular occlusion but due to the prevalence (approximately 7 out of 10,000 injections) in the profession, this is unlikely (Hwang, 2016). Clinic managers are vested in this

project as they want to ensure their providers are recognizing vascular occlusions early to avoid increased complications that accompany a delayed response. Drug manufacturers would be interested in the success of this project as they are impacted by complications that arise from the use of their products. HA based dermal fillers are FDA approved and as such complications and issues that arise from their use are thoroughly documented. Although patients are aware of the risks as they sign an informed consent outlining vascular occlusions prior to a procedure being performed, they want to be confident their provider has the training and experience to recognize and handle a complication if it were to arise both intra or post-procedure.

Even though a relationship exists between the project lead and providers at the implementation site, it is imperative that engagement and established rapport is continued through the culmination of this project. The project lead will ensure that all stakeholders have early involvement in the QI process and that a rapport is maintained with the facility to ensure the educational needs of aesthetic providers is accomplished.

Recruitment Methods

The DNP project is a QI initiative and both the personal and health protected information of the patient(s) will remain confidential throughout the duration of the project. Privacy and confidentiality of provider's data will be maintained by the project lead. There will be zero incentives offered to providers partaking and advertising will be achieved by asking individual providers to partake in the QI project. Aesthetic providers will be asked to participate in the study and chart audits will be conducted until forty charts have been reviewed and whether they had adhered to the new recommendations will be documented.

Tools/Instrumentation

The tools/instruments that will be utilized for the project are a redesigned protocol, Electronic Medical Record (EMR) system, educational material for the provider, pre and post-tests, a more detailed post-care instruction sheet for patients to take home including a section on how to recognize a vascular occlusion on their own at home, and whether there was an increase in screenings and if an uptick in recognition of vascular occlusions had occurred.

Vascular Occlusion Recognition Tool (VORT)

A new post-procedure evidence-based protocol titled the *Vascular Occlusion Recognition Tool (VORT)* will be implemented to include ways to recognize a vascular occlusion and how to test the skin's response to stimuli in an attempt to rule out the occurrence of a vascular compromise. The protocol will include how to appropriately document the occurrence of a vascular occurrence within the EMR (Appendix D).

EMR System

The EMR system utilized for this QI Project will be Aesthetic Record. Aesthetic Record has the ability to add, delete, modify, and search within a patient's chart with ease allowing for a thorough data review process.

Educational Material for Provider

The education material given to the aesthetic provider will be a PowerPoint presentation describing what the provider should look for during and post dermal filler injection and how to document the findings (see Appendix E).

Pre and Post Test

A pre and post-test will be administered to the aesthetic providers participating in this QI project to measure their knowledge both prior and after the review of the PowerPoint presentation.

The pre-test will consist of ten questions to gauge the overall knowledge, skill, and experience of a provider prior to the PowerPoint presentation. The post-test will consist of ten questions (same questions as pretest just in a different order) that can be answered with the information learned in the PowerPoint presentation. A Content Validity Index (CVI) for the pre and post-test questions was completed (see Appendix F). The CVI score was rated at 3.8 out of 4.0 which indicates a very high CVI level. A CVI score of 3.8 is indicative the test questions created for this QI project were highly relevant and clearly written. The CVI was derived as a mean of the score of three different doctoral prepared nurses including one who has been injecting HA based fillers for over twenty years and is considered an expert in the field of aesthetic injectables.

Detailed Post-Care Instruction Sheet

A detailed post-care instruction sheet will be sent home with the patient that outlines signs and symptoms of a vascular occlusion and what they should be aware of with regards to complications that have the potential to present themselves (see Appendix G).

Manual Data Collection Sheet

A Manual Data Collection Sheet (MDCS) will be completed and maintained by the project lead to ensure there is confidentiality maintained throughout the project (see Appendix H). Data collection for this QI project will include a manual review of providers notes and patients charts to document protocol adherence and occlusion recognition.

Data Collection Procedures

Data collection procedure will begin with the aesthetic providers completing a pre and posttest. Seven days after the posttests are completed, the first charts will be reviewed and they will be assigned a random number (001-040). The data will then be compiled into the Manual Data Collection Sheet (MDCS), secured in a HIPPA compliant locking cabinet, and made available

to the project lead only to determine whether there was an increase in screenings and subsequent recognition of vascular occlusions occurring. The project lead will utilize the MDCS to show protocol adherence, number of screenings, referrals, and documentation into an excel spreadsheet to determine if after implementation of the protocol there was an increase in screenings and whether the recognition of a vascular occlusion had increased.

Data collection will be comprised of chart audits utilizing the Aesthetic Record EMR software to search for HA based filler treatments performed in the facial area on a weekly basis over a four-week period at a predetermined Southern California clinic location. There will be a minimum of 30 HA based filler EMR chart audits with a maximum of 40 being performed. The chart audits will be conducted to determine provider adherence to protocol screening guidelines, what the results were, and if referrals were made.

Intervention

The intervention will be introducing a protocol that requires the provider to incorporate a post HA dermal filler vascular occlusion screening protocol.

Project Timeline

The project timeline for the vascular occlusion post-dermal filler injection QI project is four weeks. The timeframe will include the implementation of the VORT intervention, collection of data submitted via the providers, and analysis/interpretation compiled by the project lead. The week of June 24th through June 30th, 2020 will be the pre-implementation phase. The pre-implementation phase includes a final review of the material to be presented (including dissemination of materials to clinic manager), advise the clinic staff and management that the following week the QI project is going to begin, and have a final sit-down meeting with the project mentor to review all goals the project is attempting to accomplish over the next four weeks.

Week #1: July 1st through July 7th, 2020

- Present the PowerPoint at the scheduled meeting on July 1st, 2020, to providers who agree to participate in this QI project. During the same meeting, the project lead will administer the pre and posttest to the providers.
- By July 7th, 2020, the project lead will review pre and post-test and document the findings.

Week #2: July 8th through July 14th, 2020

- July 8th, 2020 there will be a meeting with the participants of this QI project. The meeting will address any questions or concerns with the goal of maintaining an open line of communication and rapport with the participants.
- The project lead will utilize the EMR system to perform once weekly chart audits reviewing for protocol adherence and vascular occlusion recognition.
- The project lead will compile the results from the chart audit into the MDCS.

Week #3: July 15th through July 21st, 2020

- July 15th, 2020 will be the third meeting with participants of this QI project. If any concerns from the participants have arisen over the last two weeks they will be discussed and handled appropriately.
- The project lead will utilize the EMR system to perform once weekly chart audits reviewing for protocol adherence and vascular occlusion recognition.
- The project lead will compile the results from the chart audit into the MDCS.

Week #4: July 22nd 2020 through July 28th, 2020

- July 22nd, 2020 will be the fourth meeting with the participants of this QI project.
- The project lead will utilize the EMR system to perform once weekly chart audits

reviewing for protocol adherence and vascular occlusion recognition.

- All information obtained during chart audits will be compiled and inputted into the MDCS.
- By July 28th, 2020 all chart audits will be completed (with the anticipation of roughly forty audits per provider for a total of eighty chart reviews) and entered into the MDCS.
- July 29th, 2020 will mark the fifth and final meeting with the QI project participants. Any lingering questions will be addressed and they will be thanked for their participation.

Ethics/Human Subjects Protection

Anonymity and confidentiality of human subjects will be protected throughout the entirety of this evidence-based QI project. Patient treatment plans will remain as they had requested and they will not receive inferior care or any unrequested treatments, as providers will not modify their customary practice. The population of interest will be a nurse practitioner and physician assistant. Per Touro University Nevada IRB policy, the QI project will submit a project team determination form, although it is not anticipated that the project will require a full IRB review (see Appendix I). The benefits to participants of the QI project would be early recognition of vascular occlusions allowing for quicker intervention, typically resulting in a reduced adverse event (Hwang, 2016). There will be neither risks for participation nor awarded compensation for individuals participating. Privacy and confidentiality of patients will be protected as only the project lead will collect the data and the MDCS will be stored in a locked cabinet complying with Health Insurance Portability and Accountability Act (HIPAA). The MDCS and all additional information obtained will be transferred from the locked cabinet and shredded no later than December 31st, 2020.

Plan for Analysis/Evaluation

Pre and Post-Test

A pre-test will be administered to the aesthetic providers to measure their knowledge of HA based fillers, vascular occlusion prevention and recognition. A PowerPoint presentation will be reviewed by the project lead with the providers and a post-test will be administered. The Wilcoxon Signed Rank Test will be utilized to analyze the results of the pre and post-test. The assumptions are that the provider will score high on both the pre and post-test as they are experienced aesthetic injectors and should be knowledgeable in the topics covered in the pre and post-test.

Chart Audits

Chart audits utilizing the clinic's EMR will occur between July 8th and July 28th, 2020 and will be utilized as a way to measure provider adherence to the newly created protocol. In addition to protocol adherence, this QI project will also document if a vascular occlusion was discovered post HA dermal filler injection. Data will be transferred from the chart audit to the MDSC and analyzed in order to determine adherence and whether a vascular occlusion had occurred. This QI project has the aim of reaching a wide range of aesthetic providers and should provide a way to ensure vascular occlusions are recognized in the most expeditious manner. The number of vascular occlusions and percentage of time protocol was adhered to will be the points of data that are derived from this QI project.

Project Assumptions

The assumptions of this QI project are if providers are given additional training and the tools necessary to recognize a vascular occlusion, they will ultimately identify vascular emergencies sooner increasing response time to a vascular emergency.

Implications for Nursing

The significance of this QI project to nursing is that nurses are the largest pool of providers to administer HA fillers worldwide (Small, Kelly, & Spinelli, 2014). As the aesthetic industry continues to evolve, so does the nursing profession. With over 2.6 million dermal filler procedures performed yearly in the U.S., it is imperative that the nursing profession is up to challenge of timely vascular occlusion recognition (PR Newswire, 2019). The prevention of vascular occlusions is an important first step when injecting HA based fillers and avoiding this complication should be the ultimate goal of any aesthetic procedure. Providers must be conscious of assessment, consent, history/patient selection, reversibility, product placement, layering, pre and post-procedure photographs, procedure planning, technical/anatomical knowledge, and the filler product characteristics (Heydenrych et al., 2017). If providers are able to incorporate the aforementioned techniques during filler injections, many of the risks to patients can be mitigated.

Vascular recognition is paramount for the aesthetic injector and with numerous filler products with various compounds and ingredients it is imperative providers are not only proficient in their use but also cognizant of the complications that could arise (Funt & Pavicic, 2013). Superior understanding of facial anatomy and the nine arteries that run directly in line with dermal filler injection sites is imperative for any injector and filler placement in these arteries must be avoided (Funt & Pavicic, 2013). Unfortunately, for inexperienced injectors, these arteries are located in the nasolabial fold, glabellae, nasal area, and temple, which are incredibly popular areas to receive dermal filler injections. If providers follow the VORT protocol as set forth in this QI project, they are armed with the tools for early recognition of a vascular occlusion post HA filler injections.

Once a vascular occlusion is believed to have occurred, the injector must immediately stop injecting and work to send as much blood flow to the area as possible. There are three ways to accomplish this, which are massaging the area, applying a warm compress, and the application of 2% nitroglycerin paste (De Boulle & Heydenrych, 2015). After these first initial steps are taken, the provider should immediately start injecting the vascular compromise with HA in an attempt to reduce any vessel-occluding pressure. Early recognition leads to potentially mitigated adverse events leading to better outcomes for providers and patients everywhere.

Although the prevalence of vascular occlusions after a dermal filler procedure might seem low (7 out of 10,000 injections), with so many procedures being performed annually in the US it is imperative aesthetic injectors are aware of and able to recognize complications as they occur (Ciancio, Tarico, Giuseppe, & Perrotta, 2019). Vascular occlusion recognition is an afterthought in most literature available as the primary focus is on prevention and treatment. This QI project seeks to unify vascular occlusion recognition signs and symptoms from a variety of sources and provide aesthetic injectors performing HA injections a clear set of guidelines to recognize vascular occlusions promptly to mitigate the risks associated with a delayed response. This QI project utilizes the most recent and relevant evidence-based practice found in literature to develop the guidelines that were incorporated into the VORT protocol.

Analysis of Results

The goal(s) of this QI project was to utilize the best available research to aid in the early recognition of vascular occlusions caused by HA fillers, educate providers through a PowerPoint presentation and pre and post-knowledge test, and increase the amount of screenings administered prior to a patient leaving the clinic. Data was collected and inputted into the MDSC over the four-

week implementation timeframe and subsequently transferred into the IBM SPSS Statistics Data Editor software program.

Pre and Post-Test

The pre-test was administered to the two program participants on July 1st, 2020. The pre-test results for both participants was a score of 9/10. Both providers missed question number six (see Appendix B) about when consent should be received to administer Hyaluronidase to patient. After the PowerPoint was administered (see Appendix E), both participants answered all ten questions correctly. The increase in score between the pre and post-test demonstrated a knowledge increase as evident by both providers answering all questions correctly on the second attempt. After inputting the pre and post-test results into SPSS, the Asymp. Sig. (2-tailed) displayed a result of .317 which indicates the difference between the two scores is not statistically significant (see Table 1).

Table 1

Wilcoxon Signed Ranked Test of Pre and Post-Test Results

Test Statistics

	Pre and Post-Test
Z	*-1.000b*
Asymp. Sig. (2-tailed)	*.317*

a. *Wilcoxon Signed Ranks Test*
b. *Based on Positive ranks.*

Procedures Performed

Of the eighty chart audits performed of procedures involving HA filler injections to the face the following are ranked in order of procedures performed: Lip augmentation (30%), chin (16.3%),

tear trough augmentation (11.3%), perioral augmentation (10%), temple augmentation (8.8%), jawline contouring (8.8%), nasolabial folds (7.5%), and cheek augmentation (7.5%).

Table 2

Breakdown of Procedures Performed

Procedure

	Frequency	Percent	Valid Percent	Cumulative Percent
Lip	24	30	30	30
Nasolabial	6	7.5	7.5	37.5
Cheek	6	7.5	7.5	45
Chin	13	16.3	16.3	61.3
Temple	7	8.8	8.8	70
Jawline	7	8.8	8.8	78.8
Perioral	8	10	10	88.8
Tear Troughs	9	11.3	11.3	100
Total	80	100	100	

Adherence to the Protocol

There were eighty chart audits performed for this QI Project and both of the providers on all eighty patients adhered to the protocol at a rate of 100% (see appendix D). Their adherence to the VORT protocol is documented on the MDSC.

Recognized Complications

Current estimates of vascular occlusion rates being reported worldwide are roughly 7 out of 10,000 injections (Hwang, 2016). Utilizing this figure and comparing it to the outcome of this QI Project (one suspected vascular occlusion occurred out of eighty patients) demonstrates vascular occlusions are occurring at a rate much greater than previously estimated. 1 out of 80 patients

leads the actual rate of a vascular occlusion to 1.25% as opposed to current literature of their occurrence at .0007%.

The complications documented during this QI Project included; 5% of patients displaying a mottled appearance, 1.3% of patients displaying a dusky appearance, 1.3% of patients experienced blanching, and lastly 1.3% of patients stated they had unilateral pain. Fortunately, none of the eighty program participants experienced vision change and all areas injected with HA experienced capillary refill to the injected area prior to leaving the clinic. The one suspected vascular occlusion did not require Hyaluronidase as after a vigorous massage of the treatment area, blood flow had returned (see Appendix J).

Discussion

The results of this QI project are important as they will give the aesthetic community a more in-depth understanding as to the heightened occurrence of vascular occlusions in practice. Upon agreeing to participate in this QI project, two providers were given a pre-test measuring their ability to recognize a vascular occlusion post HA filler injection. Both participants incorrectly answered one question on the pre-test and were shortly thereafter provided a PowerPoint presentation discussing vascular occlusions and warning signs. After the two participants completed reviewing the PowerPoint, both answered all ten questions correctly. An increase in correct answers between the pre and post-test provided an important measurement prior to the implementation of this project as it displayed an increase in participant knowledge base.

This project allowed the providers involved to achieve a better understanding of the occurrence of a vascular occlusion post VORT incorporation into the standardized protocol of a medical spa. Providers followed the protocol on all eighty chart audits that were reviewed and 5% of patients displayed a mottled appearance, 1.3% a dusky appearance, 1.3% stated they had

unilateral pain, and 1.3% experienced blanching. Although only 1.25% of patients experienced a suspected vascular occlusion throughout the duration of this QI project, and this number seems quite low, it is actually about 1700 times more likely to have occurred than current literature suggests (Hwang, 2016).

This project was developed with the goal of the earliest possible recognition of a vascular occlusion post HA filler. Early recognition of a vascular occlusion leads to a quicker diagnosis and subsequently allows for treatment with Hyaluronidase with the goal of mitigating the vascular emergency entirely. Second, this project focused on creating uniform guidance to accomplish this task and did so through the creation and incorporation of the evidence-based VORT protocol. Throughout an exhaustive search of ProQuest and other scholarly databases there was no identifiable protocol similar to the one designed for this QI project. Incorporating the VORT protocol is a step-by-step process that utilizes best practices to recognize vascular occlusions in an efficient and expeditious manner. Incorporating the protocol as outlined in this QI project accomplished the main goals of this endeavor as there were no patients that had left the clinic with complications that were discovered at a later time. The complications that were referenced in the recognized complication section (most notably a mottled appearance as it affected 5% of patients) had all been resolved prior to a patient being discharged from the clinic.

With little documented consensus as to the warning signs of a suspected vascular occlusion, this QI project worked to incorporate current literature with updated guidelines to recognize these medical emergencies in the most expeditious manner possible (Vedamurthy, 2018). It is important to understand as the popularity of procedures continue to rise (up over 144% over the past two decades), providers are constantly learning new techniques and incorporating new protocols that can assist with early recognition of a vascular occlusion (Ballin, Brandt, & Cazzaniga, 2015).

Patient monitoring both intra and post-procedure are two of the most important factors of early recognition of a vascular occlusion (Vedamurthy, 2018). Throughout this project providers were given the opportunity to take additional time both during and after the procedure to recognize signs indicative of a vascular occlusion. Based on allowing providers additional time to discover these vascular comprises and document succinctly as to their presence or absence led to a greater recognition of their occurrence.

Significance

The significance of this project casts a more accurate picture as to the prevalence of a vascular occlusion and as such should create a productive dialogue within the aesthetic community. This QI project will complement the available recommendations of aesthetic injectors worldwide in recognizing HA filler vascular complications and provide individuals with the necessary tools (i.e. all of the documented signs of a vascular occlusion) and ensure injectors can recognize these symptoms in the quickest manner possible. As an ever-increasing number of nurses enter the field of aesthetics and the relatively low accepted rate of vascular occlusions, it is imperative nurses are provided the framework to accurately recognize these medical emergencies as expeditiously as possible. This significance of this project to nurses working in aesthetic medicine cannot be understated and through the incorporation of the VORT protocol into HA filler injection protocol, an increase in recognition of vascular occlusions can lead to better patient outcomes.

This QI project has great implications in the world of aesthetic medicine as there is an abundance of nurses entering the field at ever increasing rates (Goodman, Roberts, & Callan, 2016). As various physician led plastic surgeon organizations have noted, nurse injectors are becoming the new norm and understanding vasculature of the face is very important for the future of the aesthetic nursing profession (Small, Kelly, & Spinelli, 2014). At least in California, nurse

practitioners, registered nurses, and even licensed vocational nurses (while being supervised by a physician) are qualified to inject HA Fillers so recognizing vascular complications that may arise is crucial to maintain the integrity of the professionals performing the procedures. The overarching goal of this project is the early recognition of vascular occlusions and this objective has been met through the utilization of best practices as well as educating providers as to the signs and symptoms associated with a vascular occlusion.

Limitations

This QI project worked to mitigate the potential limitations that could arise but even so there were limitations. One of the limitations that could have potentially caused problems for project implementation would have been SARS-CoV-2 also known as COVID-19. COVID-19 is a respiratory illness that forced the closure of many industries throughout Southern California from the middle of March to the beginning of June (OC Health Care Agency, 2020). Fortunately, this project implementation did not occur until July so COVID-19 did not any effect on this project as the medical facility where this project was implemented had reopened. If anything, patients going almost three months without procedures created a pent-up demand allowing for a quicker attainment of the project aim of performing eighty chart audits. The data recruitment for this project were the two providers that were enrolled in the study and both adhered to the newly developed protocol on all eighty chart audits. Due to the time constraints of this project (only having four-weeks for implementation), additional providers were not included and chart audits were limited to only forty per provider. With regards to project design, if more facilities and additional providers had the ability to participate in the project there would be additional procedures performed by a wider group of providers potentially changing the outcome of this project. As regulations vary by State, additional providers with varying levels of training,

education, and experience could potentially have been included in this project creating a potential for a different outcome.

Dissemination

In order to reach the target population for this QI Project, dissemination efforts will be guided towards the faculty of Touro University, Nevada (TUN), the students of TUN, the International Society of Plastic and Aesthetic Nursing annual conference, the Journal of Aesthetic Nursing, and lastly the Doctoral Project Repository found at doctorofnursingpractice.org. Presenting this project in the form of a PowerPoint to the faculty of Touro University will be a great opportunity to prepare for future dissemination of this QI project. The Journal of Aesthetic Nursing is the only peer-reviewed journal for aesthetic nurses and is published ten times yearly with a worldwide audience of nurse injectors. Achieving publication in the Journal of Aesthetic Nursing would allow for the greatest number of nursing aesthetic providers worldwide to review the findings and incorporate into practice. The project will also be uploaded into an online project repository for review for both scholars and fellow injectors as well as way to showcase the culmination of this DNP endeavor. A presentation of the findings of this project will be created and disseminated at the clinic where this project was implemented to ensure the largest number of individuals are informed and the advantage of utilizing the VORT protocol.

Project Sustainability

Project sustainability will be accomplished through the incorporation of the VORT protocol into the clinic's Hyaluronic Acid Standardized Procedure. The monthly ongoing monitoring of this protocol will be continued with the anticipation of additional data useful to the field of aesthetics will continue to be discovered. There has been discussion about expanding the protocol to additional clinics, unfortunately at this point, no additional clinics have been willing to incorporate

the protocol. Use of the post-procedure protocol has been incorporated into the EMR system and prior to discharging a patient, providers must document if they are experiencing any unilateral pain, vision change, blanching, mottled or dusky appearance, or suspected vascular occlusion had occurred. Over time, as additional research emerges and new advancements are made within the field of aesthetic medicine, this protocol will be updated to incorporate the latest findings to ensure providers are armed with the necessary tools to provide high quality patient care.

Conclusion

This QI Project sought to address a shortfall that currently exists in academic or professional literature as it relates to the recognition of vascular occlusions caused by HA filler injections. Best available research was compiled to assist in the prompt recognition and rapid treatment of a vascular occlusion and educating current and future aesthetic injectors. The research was then utilized to develop the VORT protocol and incorporated into practice with the aim of increasing the number of screenings for patients and documenting said findings into the patient's chart. Eighty patients were included in this project and the two providers utilized the VORT protocol with a 100% adherence rate on all patients receiving HA fillers. Through the implementation of the VORT protocol into a Southern California based aesthetic practice, a potential vascular occlusion complication rate of 1.25% or about 1700 times more likely than the leading peer reviewed literature suggest was discovered (Hwang, 2016). With the completion and dissemination of this project additional providers and patients will have a greater understanding of the recognition of a vascular occlusion and be armed with the best resources to act promptly when a complication arises.

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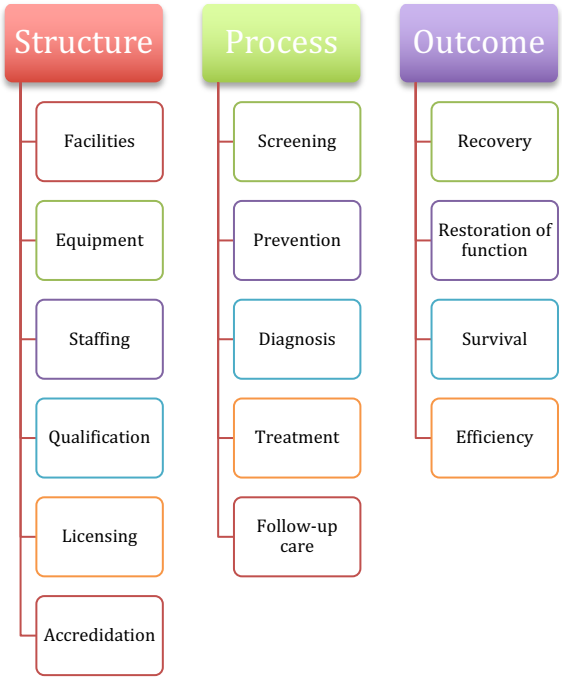
Appendices

Appendix A

Donabedian Framework



Appendix B

Vascular Occlusion Pre-Test

1) What causes a vascular occlusion?

a) HA filler injected intravenously

b) HA filler injected subcutaneously

c) HA filler injected near an artery causing a compression blockage

d) A and C

2) What are the top prevention factors for vascular occlusion?

a) Knowledge of injection depth

b) Knowledge of facial anatomy

c) Knowledge of injection placement

d) All of the above

3) What are signs of vascular occlusion?

a) White blanching of the skin

b) Violaceous reticular pattern

c) Pain and redness

d) All of the above

4) What is an effective test for determining if a vascular occlusion has occurred post HA injection?

a) Testing for capillary refill

b) Completing a titer test

c) Completing a test for Waddell Sign's

d) Performing a comprehensive metabolic panel

5) What is the main purpose of Hyaluronidase?

a) Allows for smoother injection of dermal filler
b) Non HA based dermal filler
c) A product used to treat all forms of vascular compromise
d) Injection technique involving the pulling of a plunger to test

6) When should consent for Hyaluronidase (filler dissolving agent) be signed?

a) Before any dermal filler procedure has begun
b) Once a vascular occlusion is recognized
c) After the procedure has been completed and you are looking for a vascular compromise
d) Should be sent home with the patient in their post-care packet to review at home and determine if they even need to sign the paperwork at all

7) Which patient would cause the most concern for receiving dermal fillers?

a) A single mother in her thirties looking for a little extra plump in her pout
b) A male in his forties looking to enhance his jawline
c) A women in her fifties looking to replace fat loss in her cheeks
d) A women in her thirties refusing to look in the mirror during her consultation

8) If you suspect a patient is suffering from a vascular occlusion, what type of compress should immediately be placed on the area?

a) Cold
b) Warm
c) Room Temperature
d) None

9) What are the highest risk areas for a vascular occlusion?

a) Nasolabial Fold

b) Glabellae

c) Nasal Area

d) Temple

e) All of the above

10) Why are people injecting HA based fillers into their face?

a) To hide unsightly moles

b) To treat facial volume loss and laxity

c) To help minimize the effects of migraines

d) To prevent acne breakouts

Vascular Occlusion Post-Test

1) What is an effective test for determining if a vascular occlusion has occurred post HA injection?

a) Testing for capillary refill

b) Completing a titer test

c) Completing a test for Waddell Signs

d) Performing a comprehensive metabolic panel

2) Which patient would cause the most concern for receiving dermal fillers?

a) A single mother in her thirties looking for a little extra plump in her pout

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c) Knowledge of injection placement

d) All of the above

10) What are signs of vascular occlusion?

a) White blanching of the skin

b) Violaceous reticular pattern

c) Pain and redness

d) All of the above

Appendix C

Clinical Agreement

Sloane Bowsher <sbowsher@student.touro.edu>

Clinical Agreement

1 message

Morgan Shipley <morgan@wildrosenewport.com> Tue, Mar 10, 2020 at 10:14 PM
To: sbowsher@student.touro.edu

Hi Sloane,

Thank you so much for reaching out and there is no need for a clinical agreement. If your school needs anything further please feel free to contact me at the clinic at 949-490-4741.

Morgan Shipley
Clinic Manager

Appendix D

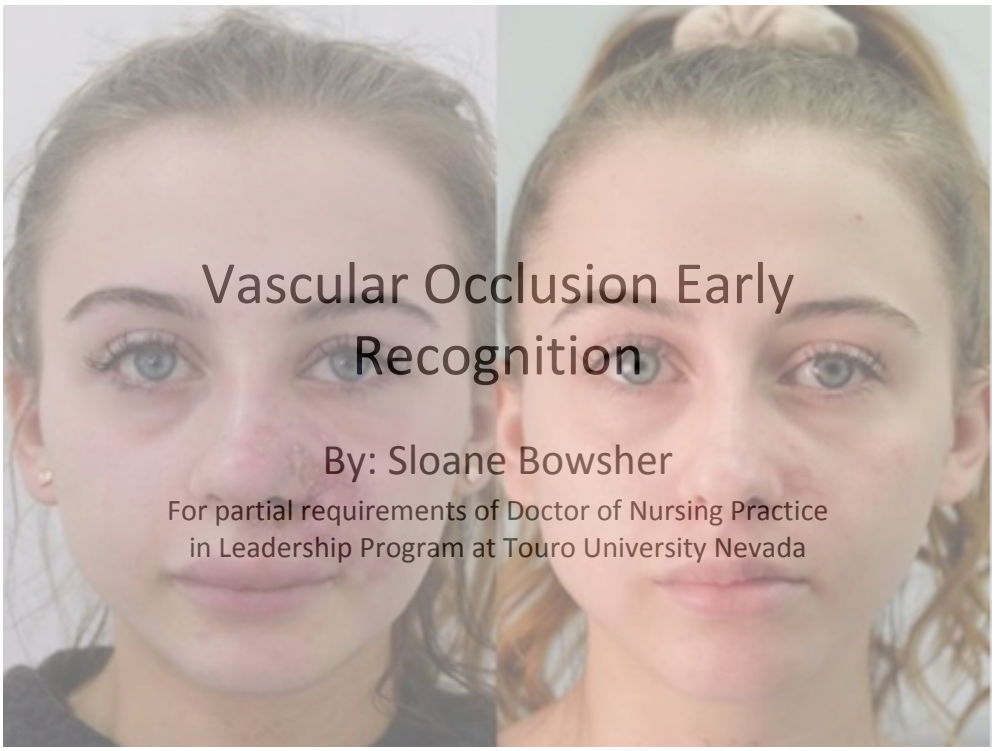
Vascular Occlusion Recognition Tool (VORT)

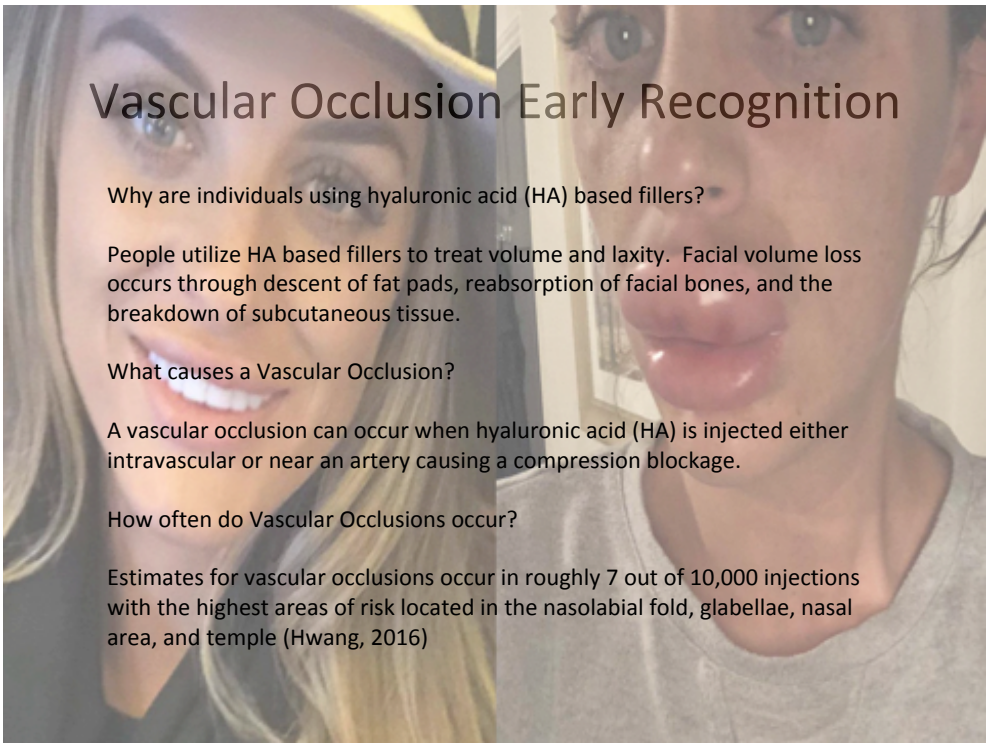
Post HA Dermal Filler Treatment Protocol to Assess for Vascular Occlusions

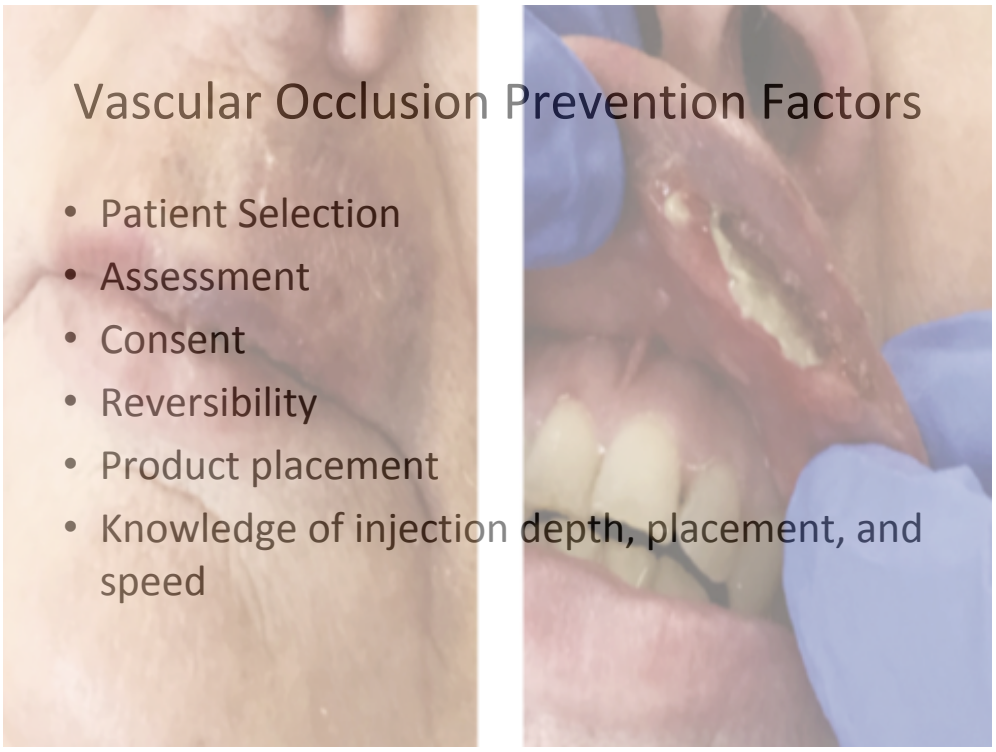
- Assess the patient for a mottled appearance consisting of redness and possibly areas that are blue and/or white
    - Could potentially appear to be a bruise in its infancy or change to a darker, duskier appearance within a couple of hours
        - If goes untreated appeared will become darker, taking the appearance of a port wine stain
- Assess the patients capillary refill in any injection site and surrounding areas for blood flow or lake thereof
- Be on the lookout for swelling, erythema, pain, itching, prolonged redness, tenderness, and acne type lesions
- Monitor for hematomas, nodules, discoloration including Tyndall effect, necrosis, abscess formation, granuloma, hypersensitivity and infection
- If patient claims vision loss, immediately call 911 and advise you have a clinical emergency and a presumed central retinal artery occlusion from a presumed intravascular hyaluronic acid filler injection
- Note in the patients chart a thorough post-filler examination had been completed and document thoroughly any adverse events associated

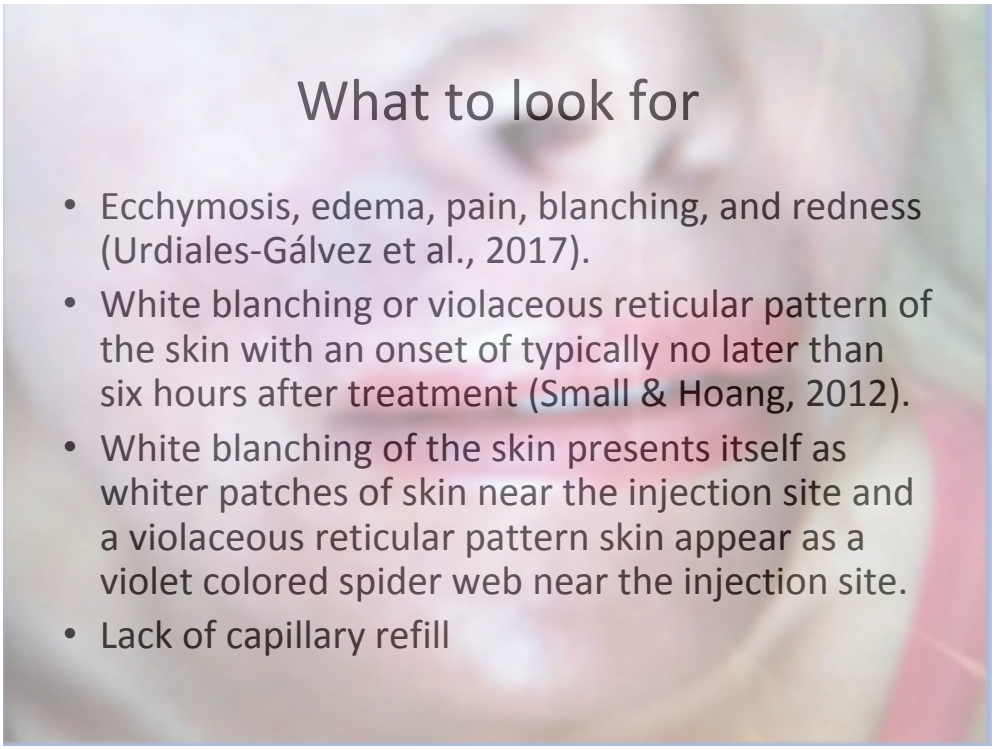
Appendix E

PowerPoint Instruction






Vascular Occlusion Prevention Factors
• Patient Selection
• Assessment
• Consent
• Reversibility
• Product placement
• Knowledge of injection depth, placement, and speed

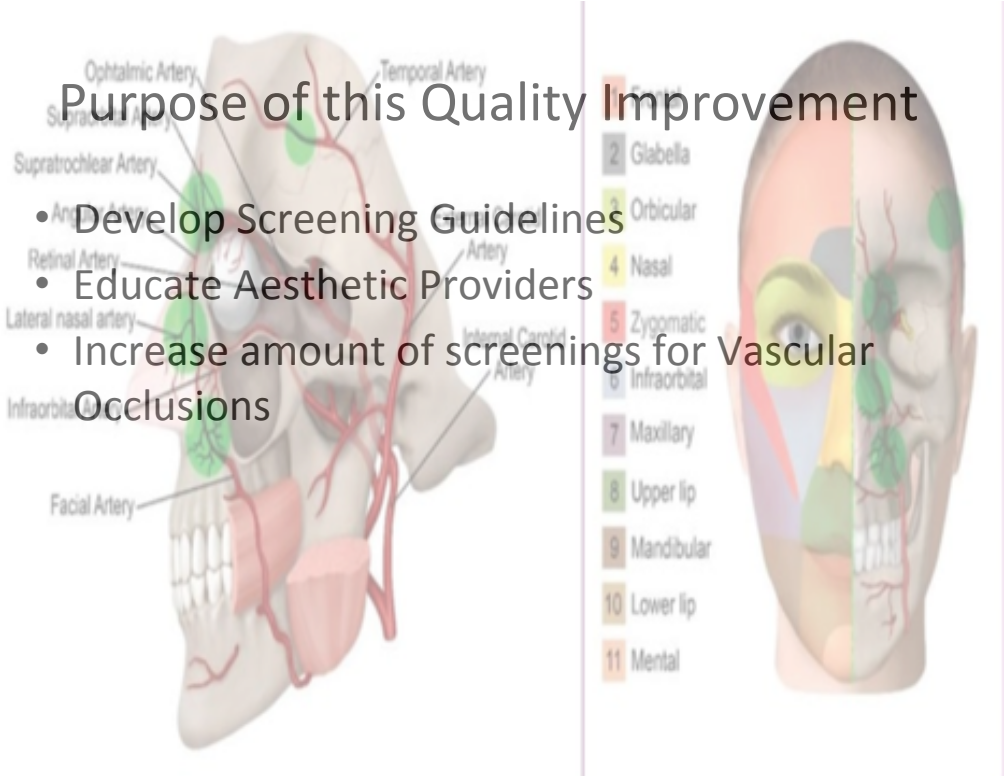

What to look for
• Ecchymosis, edema, pain, blanching, and redness (Urdiales-Gálvez et al., 2017).
• White blanching or violaceous reticular pattern of the skin with an onset of typically no later than six hours after treatment (Small & Hoang, 2012).
• White blanching of the skin presents itself as whiter patches of skin near the injection site and a violaceous reticular pattern skin appear as a violet colored spider web near the injection site.
• Lack of capillary refill

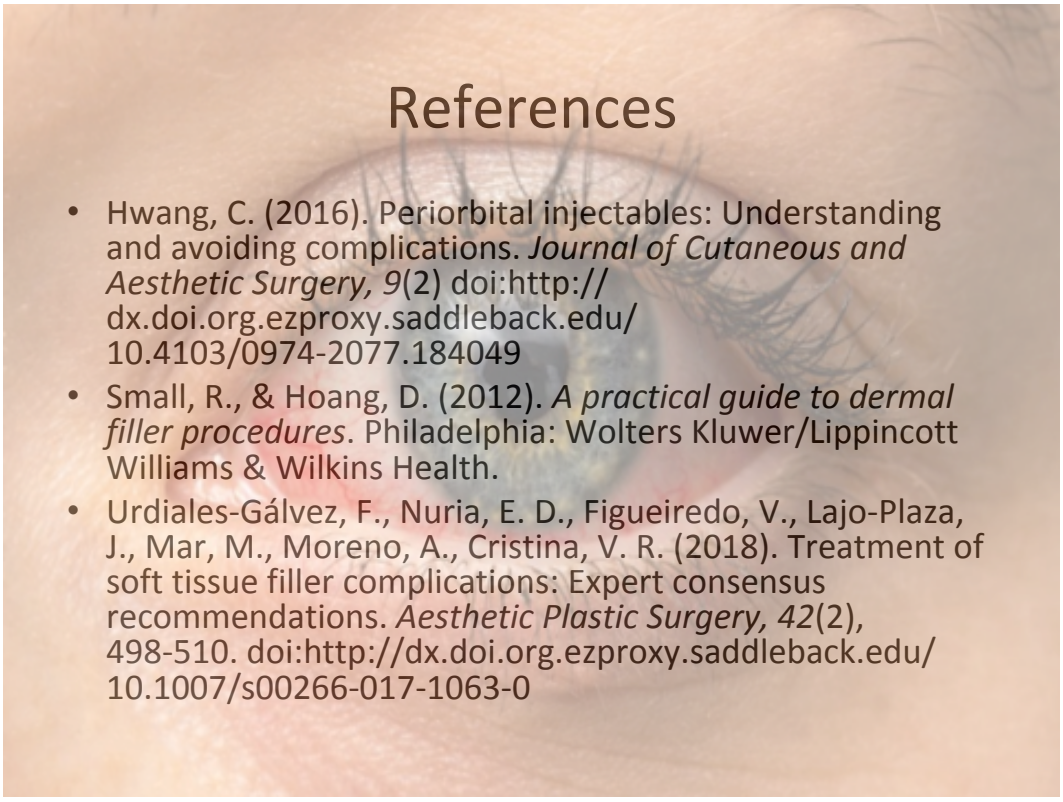
Treatment Options

- Vascular occlusion treatment is currently based on the recommendations of a variety of practitioners but the consensus favors introducing large amounts of hyaluronidase into the affected area in an attempt to reinvigorate blood flow to the region affected (Hwang, 2016).

Purpose of this Quality Improvement

- Develop Screening Guidelines
- Educate Aesthetic Providers
- Increase amount of screenings for Vascular Occlusions





Appendix F

CVI

Content Validity Index Table

Pre-Test Item	Expert 1	Expert 2	Expert 3	Mean
1	4	4	4	4
2	4	4	4	4
3	4	4	4	4
4	4	4	3	3.66
5	4	4	4	4
6	4	4	3	3.66
7	3	3	4	3.33
8	4	4	4	4
9	4	4	4	4
10	4	3	4	3.66

Appendix G

DERMAL FILLERS PRE & POST CARE PATIENT INSTRUCTIONS

Pre-Treatment Instructions:

- For optimal results, and to minimize the chance of bleeding or bruising at the injection site, please avoid all blood-thinning medications and supplements for one week prior to your appointment. This includes over-the-counter medication such as aspirin, Motrin, ibuprofen, and Aleve. Also avoid herbal supplements such as garlic, vitamin E, gingko biloba, St. John's Wort and omega-3 capsules. If you have a cardiovascular history, please check with your doctor prior to stopping use of aspirin.
- Inform your provider if you have a history of Perioral Herpes to receive advice on antiviral therapy prior to treatment. (Valtrex 500 mg BID, 5 days, start 2 days prior to treatment)
- Avoid topical products such as Tretinoin (Retin-A) retinols, retinoids, glycolic acid, alpha hydroxy acid, or any "anti-aging" products for two days before and after treatment.
- Do not drink alcoholic beverages 24 hours before or after your treatment to avoid extra bruising.

- Do not use dermal fillers if you are pregnant or breastfeeding, are allergic to any of its ingredients or suffer from any neurological disorders.

Post-Treatment Instructions:

- Avoid significant movement or massage of the treated area unless instructed by provider.
- Avoid strenuous exercise for 24 hours.
- Avoid extensive sun or heat for 72 hours.
- Avoid consuming excess amounts of alcohol or salts to avoid excessive swelling.
- If you have swelling, you may apply a cool compress for 15 minutes each hour.
- Use Tylenol (acetaminophen) for discomfort.
- Try to sleep face up and slightly elevated if you experience swelling.
- Take Arnica (typically found in health food stores) to help the bruising and swelling. Begin taking at least two days prior to injections.
- Wait a minimum of four weeks before skin care or laser treatments
- If you experience any unilateral pain (i.e. pain that is incrementally more painful than other areas on your face, notice a bruise in a non-injection site, or if your skin takes on a pale or dusky appearance please reach out to the clinic right away.

*Dermal fillers last, on average, 6-12 months. It is recommended at the time of your treatment to schedule your next appointment for optimal anti-aging benefits. The most typical side effects (bruising, swelling, redness) are temporary and will resolve.

However, please call the office to notify us if you experience any additional side effects.

Appendix H

Manual Data Sheet

Manual Data Collection Sheet

#	Provider/Credentials	Date of Procedure	Procedure	Patient Age	Mottled Appearance	Dusky Appearance	Blanching	Unilateral Pain	Vision Change	Capillary Refill	Vascular Occlusion	Was the Vascular Occlusion Recognized prior to patient leaving clinic
0	SB/NP	4/15/20	Lip Augmentation	24	N	N	N	N	N	Y	N	N

Appendix I

Touro Nevada IRB Exemption Form

APPENDIX E

DNP PROJECT TEAM DETERMINATION: QUALITY IMPROVEMENT PROJECT OR RESEARCH

This form is to be filled out by the student at the time the IRB application is filled out. All students will fill out the IRB application as this experience will provide insight into the IRB process. This decision form will then be used to guide the student and the project team as to whether the IRB application should be submitted to IRB. Although all IRB applications should be submitted to the course drop-box, IRB applications are only submitted to the IRB for review when they are determined to be research (not quality improvement) and involve human subjects.

All DNP Projects regardless of methodology must uphold the highest standards of ethical practice including confidentiality and privacy as described in the ANA Code of Ethics. Accordingly, basic principles of ethics, confidentiality and privacy must be addressed and maintained in each phase of the DNP Project implementation. Methods for maintaining such should be described in full detail within body of the DNP Project Paper.

If the determination is made that the DNP Project is a "Quality Improvement Project", then the project should be referred to as such in all future communications both in writing and verbally. "Quality Improvement Projects" should not be referred to as research or research projects. In addition, these projects are not subject to any form of IRB review. Additionally, the student should not make any claim in writing or verbally of IRB exemption status, acceptance, or review in such projects.

Section A should be completed and submitted by the student. Section B should be completed by the faculty.

SECTION A:

Student Name: Sloane Bowsher

DNP Project Title: Recognizing Dermal Filler Complications

DNP Project Instructor: Dr. Heidi Johnston

Academic Mentor: Dr. Samantha Peckham

Quality Improvement or Research Worksheet

Rachel Nosowsky, Esq.

ITEM	Issue and Guidance	Rating
1	Are participants randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? Randomization done to achieve equitable allocation of a scarce resource need not be considered and would not result in a "yes" here.	____ YES X ____ NO
2	Does the project seek to test issues that are beyond current science and experience, such as new treatments (i.e., is there much controversy about whether the intervention will be beneficial to actual patients – or is it designed simply to move existing evidence into practice?). If the project is performed to implement existing knowledge to improve care – rather than	____ YES X ____ NO

	to develop new knowledge – answer "no".	
3	Are there any potential conflicts of interest (financial or otherwise) among any researchers involved in the project? If so, please attach a description of such in an attachment to this form.	____ YES X ____ NO
4	Is the protocol fixed with a fixed goal, methodology, population, and time period? If frequent adjustments are made in the intervention, the measurement, and even the goal over time as experience accumulates, the answer is more likely "no."	X ____ YES ____ NO
5	Will data collection occur in stages with an effort to remove potential bias? If so is there any potential for data skewing from this process?	X ____ YES ____ NO
6	Is the project funded by an outside organization with a commercial interest in the use of the results? If the answer to this question is "Yes" please also answer question 6a and 6b. If the project is funded by third-party payors through clinical reimbursement incentives, or through internal clinical/operations funds vs. research funds, the answer to this question is more likely to be "no."	____ YES X ____ NO
6a	Is the sponsor a manufacturer with an interest in the outcome of the project relevant to its products?	____ YES ____ NO
6b	Is it a non-profit foundation that typically funds research, or internal research accounts?	____ YES ____ NO

Adapted from Hastings Center, "The Ethics of Using Quality Improvement Methods to Improve Health Care Quality and Safety" (June 2006) If the weight of the answers tends toward "yes" overall, the project should be considered "research" and approved by an IRB prior to implementation. If the weight of the answers tends toward "no," the project is not "research" and is not subject to IRB oversight unless local institutional policies differ. Answering "yes" to sequence #1 or #2 – even if all other answers are "no" – typically will result in a finding that the project constitutes research. It is important to consult with your local IRB if you are unsure how they would handle a particular case, as the analysis of the above issues cannot always be entirely objective and IRB policies and approaches vary significantly.

Obtained from:
https://irb.research.chop.edu/sites/default/files/documents/quality_improvement_or_research_worksheet.pdf

Additional resources:

http://humansubjects.stanford.edu/research/documents/qa_qi_faqs_AID03H16.pdf

https://irb.research.chop.edu/quality-improvement-vs-research

SECTION B:

Project Classification Decision:

The project team consisting of a minimum of two faculty members will select one of the three classifications listed below.

___x__ This DNP Project is a quality improvement project. Do not submit to IRB for review.

_____ This DNP Project contains research methodology and an IRB application should be submitted to the TUN IRB committee for exemption determination and/or full IRB review.

_____ This DNP Project is not clearly delineated as quality improvement or research of discovery. Additional consultation will be obtained from the IRB committee by the project team. The advice of the IRB committee regarding the need for review will be noted in writing and the student will be informed of such (Please attach any pertinent documentation from IRB review as an Appendix to this document.)

By signing below, each member of the project team indicates that they agree with the above selection.

Printed Name of Project Team Member 1: ___Dr. Heidi Johnston

Signature of Project Team Member 1: Heidi Johnston

Printed Name of Project Team Member 2: Samantha Peckham

Signature of Project Team Member 2: Samantha Peckham

Appendix J

Procedure Frequency of Complications

PROCEDURE1 * SUSPECTEDVASCOCCLUSION1 Crosstabulation

			SUSPECTEDVASCOCCLUSION1		
			N	Y	Total
PROCEDURE1	LIP	Count	23	1	24
		% within PROCEDURE1	95.8%	4.2%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	29.1%	100.0%	30.0%
		% of Total	28.7%	1.3%	30.0%
	NASOLABIAL	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHEEK	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHIN	Count	13	0	13
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	16.5%	0.0%	16.3%
		% of Total	16.3%	0.0%	16.3%
	TEMPLE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%
	JAWLINE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%
	PERIORAL	Count	8	0	8
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	10.1%	0.0%	10.0%
		% of Total	10.0%	0.0%	10.0%
	TEARTROUGHS	Count	9	0	9
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	11.4%	0.0%	11.3%
		% of Total	11.3%	0.0%	11.3%
Total		Count	79	1	80
		% within PROCEDURE1	98.8%	1.3%	100.0%
		% within SUSPECTEDVASCOCCLUSION1	100.0%	100.0%	100.0%
		% of Total	98.8%	1.3%	100.0%

			MOTTLED1		
			N	Y	Total
PROCEDURE1	LIP	Count	21	3	24
		% within PROCEDURE1	87.5%	12.5%	100.0%
		% within MOTTLED1	27.6%	75.0%	30.0%
		% of Total	26.3%	3.8%	30.0%
	NASOLABIAL	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within MOTTLED1	7.9%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHEEK	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within MOTTLED1	7.9%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHIN	Count	13	0	13
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within MOTTLED1	17.1%	0.0%	16.3%
		% of Total	16.3%	0.0%	16.3%
	TEMPLE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within MOTTLED1	9.2%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%
	JAWLINE	Count	6	1	7
		% within PROCEDURE1	85.7%	14.3%	100.0%
		% within MOTTLED1	7.9%	25.0%	8.8%
		% of Total	7.5%	1.3%	8.8%
	PERIORAL	Count	8	0	8
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within MOTTLED1	10.5%	0.0%	10.0%
		% of Total	10.0%	0.0%	10.0%
	TEARTROUGHS	Count	9	0	9
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within MOTTLED1	11.8%	0.0%	11.3%
		% of Total	11.3%	0.0%	11.3%
Total		Count	76	4	80
		% within PROCEDURE1	95.0%	5.0%	100.0%
		% within MOTTLED1	100.0%	100.0%	100.0%
		% of Total	95.0%	5.0%	100.0%

			DUSKY1		
			N	Y	Total
PROCEDURE1	LIP	Count	23	1	24
		% within PROCEDURE1	95.8%	4.2%	100.0%
		% within DUSKY1	29.1%	100.0%	30.0%
		% of Total	28.7%	1.3%	30.0%
	NASOLABIAL	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHEEK	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHIN	Count	13	0	13
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	16.5%	0.0%	16.3%
		% of Total	16.3%	0.0%	16.3%
	TEMPLE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%
	JAWLINE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%

	PERIORAL	Count	8	0	8
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	10.1%	0.0%	10.0%
		% of Total	10.0%	0.0%	10.0%
	TEARTROUGHS	Count	9	0	9
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within DUSKY1	11.4%	0.0%	11.3%
		% of Total	11.3%	0.0%	11.3%
Total		Count	79	1	80
		% within PROCEDURE1	98.8%	1.3%	100.0%
		% within DUSKY1	100.0%	100.0%	100.0%
		% of Total	98.8%	1.3%	100.0%

			BLANCHING1		
			N	Y	Total
PROCEDURE1	LIP	Count	23	1	24
		% within PROCEDURE1	95.8%	4.2%	100.0%
		% within BLANCHING1	29.1%	100.0%	30.0%
		% of Total	28.7%	1.3%	30.0%
	NASOLABIAL	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHEEK	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHIN	Count	13	0	13
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	16.5%	0.0%	16.3%
		% of Total	16.3%	0.0%	16.3%
	TEMPLE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%
	JAWLINE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%

	PERIORAL	Count	8	0	8
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	10.1%	0.0%	10.0%
		% of Total	10.0%	0.0%	10.0%
	TEARTROUGHS	Count	9	0	9
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within BLANCHING1	11.4%	0.0%	11.3%
		% of Total	11.3%	0.0%	11.3%
Total		Count	79	1	80
		% within PROCEDURE1	98.8%	1.3%	100.0%
		% within BLANCHING1	100.0%	100.0%	100.0%
		% of Total	98.8%	1.3%	100.0%

			UNILATERALPAIN1		
			N	Y	Total
PROCEDURE1	LIP	Count	23	1	24
		% within PROCEDURE1	95.8%	4.2%	100.0%
		% within UNILATERALPAIN1	29.1%	100.0%	30.0%
		% of Total	28.7%	1.3%	30.0%
	NASOLABIAL	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within UNILATERALPAIN1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHEEK	Count	6	0	6
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within UNILATERALPAIN1	7.6%	0.0%	7.5%
		% of Total	7.5%	0.0%	7.5%
	CHIN	Count	13	0	13
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within UNILATERALPAIN1	16.5%	0.0%	16.3%
		% of Total	16.3%	0.0%	16.3%
	TEMPLE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within UNILATERALPAIN1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%
	JAWLINE	Count	7	0	7
		% within PROCEDURE1	100.0%	0.0%	100.0%
		% within UNILATERALPAIN1	8.9%	0.0%	8.8%
		% of Total	8.8%	0.0%	8.8%

	PERIORAL	Count	8	8
		% within PROCEDURE1	100.0%	100.0%
		% within VISIONCHANGE1	10.0%	10.0%
		% of Total	10.0%	10.0%
	TEARTROUGHS	Count	9	9
		% within PROCEDURE1	100.0%	100.0%
		% within VISIONCHANGE1	11.3%	11.3%
		% of Total	11.3%	11.3%
Total		Count	80	80
		% within PROCEDURE1	100.0%	100.0%
		% within VISIONCHANGE1	100.0%	100.0%
		% of Total	100.0%	100.0%