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Guidleine Implementation for Dermal Filler Administration Via Blunt-tip Cannula to Decrease Post-Procedure Hematoma Formation

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Background

Totalling more than 2.1 million treatments in 2015, dermal filler treatments of hyaluronic acids (HAs) are the second most common in-office cosmetic procedure performed in the United States (van Loghem, Humzah, & Kerscher, 2016). In an attempt to minimize dermal filler complications, blunt-tipped cannulas have emerged as an alternative technique to the use of 27-gauge needle administration. Because blunt-tipped cannulas navigate through the dermis without the sharp tip of a needle, cannulas are believed to cause less pain and bruising in addition to less risk of arterial embolization (AE) (Ozturk et al., 2013).

Intra-procedural pain and extended post procedure recovery due to bruising are dermal filler complications that negatively impact patient overall experience (Brandt, Bank, Cross, & Weiss, 2010). Therefore, techniques to limit these complications are important in a competitive consumer based medical model such as that seen in a med-spa. The ability to offer potential clients a less painful technique, with less bruising and less risk of arterial embolization is a significant competitive advantage. A Southern California medical practice with three facilities and five aesthetic providers was selected as the site for an evidence based project to evaluate a best practice technique.

Introduction to the Evidence

A review of the literature was conducted via electronic searches through an institution library. Databases searched included PubMed, Cochrane and CINAHL. Articles were synthesized and evaluated based on relevancy, applicability to practice setting, level of evidence and publication date. When utilizing similar aesthetic technique, both cannula and needle have been shown to provide equal aesthetic

improvement with less pain and bruising as compared to needle administration (Fulton, Caperton, Weinkle & Dewandre, 2012). A study of cadaver heads evaluating placement of HAs by both cannula and needle demonstrated a more precise placement with cannula use and intra-arterial injection with needle (van Loghem, Humzah, & Kerscher 2016). Although no specific clinical trials or studies have demonstrated cannula use completely prevents AE, cannula use is recommended to decrease AE events (Yeh, Fabi, & Welsh, 2017). Additional techniques shown to decrease pain, bruising and AE include aspiration before injection, retrograde injection, slow speed of injection, and reduced ejection force (Glogau & Kane, 2008). However, it is important to note that Yeh, Fabi and Welsh (2017), reported two cases of AE occurred while using a blunt-tipped cannula.

In a 2012 article by Lazzeri et al., serious complications arising from AE were explored. Of the 32 cases reviewed, 29 documented cases of blindness followed dermal filler administration were attributed to AE. Complication rates of AE from dermal fillers are unclear, but a 2011 estimate reported a 0.0001% risk of AE with the glabella, nose and nasal labial folds as the areas most frequently affected (Ozturk et al., 2013).

Although dermal filler administration is a relatively low risk procedure, research highlights that provider technique and knowledge of anatomy are important factors in decreasing the risk of AE (van Loghem, Humzah & Kerscher, 2016).

Methods

Comparing intra-procedural pain and post-procedural bruising in patients receiving dermal filler administration for mid and lower face volumization was established as the project purpose. A six-week time period was identified and 24 female patients presenting for volumization of the mid and lower face were enrolled in the

project. Patient demographics to include age, number of previous dermal filler treatments and history of aspirin product within 48 hours of the treatment was collected (see Table 1).

Table 1. Sample Demographics

Table: 1	Age Range (years)	Total (n)
	21-35	3
	36-50	11
	51-65	10
Average Age (years)	47	
Aspirin taken within 48 hours (n)	0	
Average number of previous HA treatments	1.29	

The face was divided into four treatment quadrants with all treatments being initiated in the right upper quadrant. Subsequent treatments followed a clockwise pattern until the right lower quadrant was reached (see figure 1).

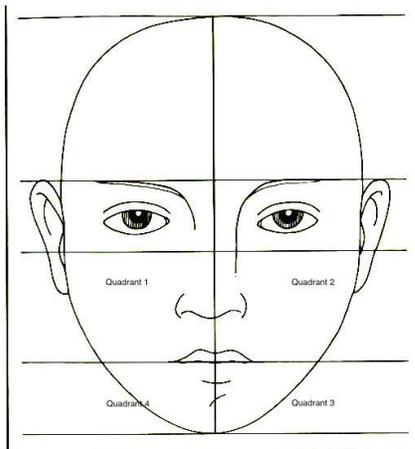


Figure 1. Four Facial Quadrants

Patients were administered a total of two milliliters (ml) of hyaluronic acid, one ml per side for treatment of the mid and lower face. Each patient had one side of their face randomized and treated with a 27-gauge, 1-inch blunt-tip cannula and the other side treated via the pre-packaged 27-gauge 1-inch needle. 1 milliliter of hyaluronic acid was administered to each side and the same injector performed all treatments after pretreating the area with a topical anesthetic.

Upon the completion of treatment for each quadrant, participants were asked to rate their pain on a Likert-type scale that ranges from 0 to 10. Participants were instructed that a rating of 10 equals intense pain and a rating of 0 equals no pain. All patients received discharge instructions not to massage the area and to return in 2 days. Upon return to the clinic, patients were interviewed regarding their adherence to the discharge instructions given to them at the previous visit. If bruising was assessed, bruising for each quadrant was recorded in millimeters.

Results

The average diameter for bruising with cannula administration was 0.43 mm in comparison to 1.68 mm with needle administration and was statistically significant ($p < 0.01$) (see figure 2). When bruising present, bruising with cannula use was less in all four quadrants in comparison to needle.

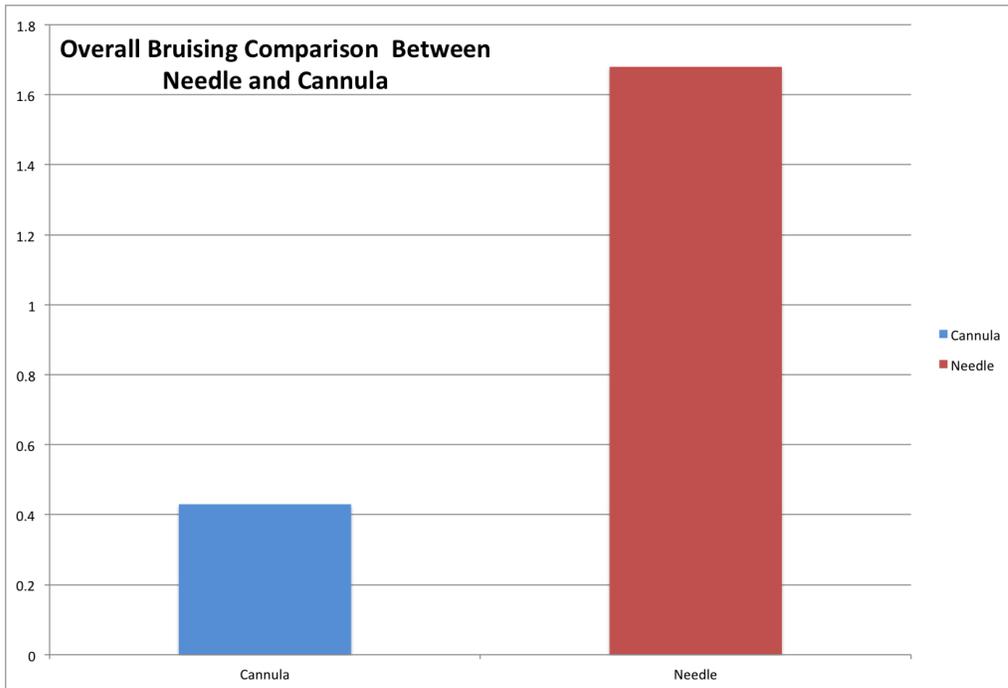


Figure 2. Overall Bruising Comparison between Needle and Cannula

Pain was also less in cannula administration with overall pain rated as 1.93 as compared to 3.18 with needle administration ($p < 0.01$) (see figure 3). In support of the evidence, cannula use also resulted in less pain in all four quadrants in comparison to pain.

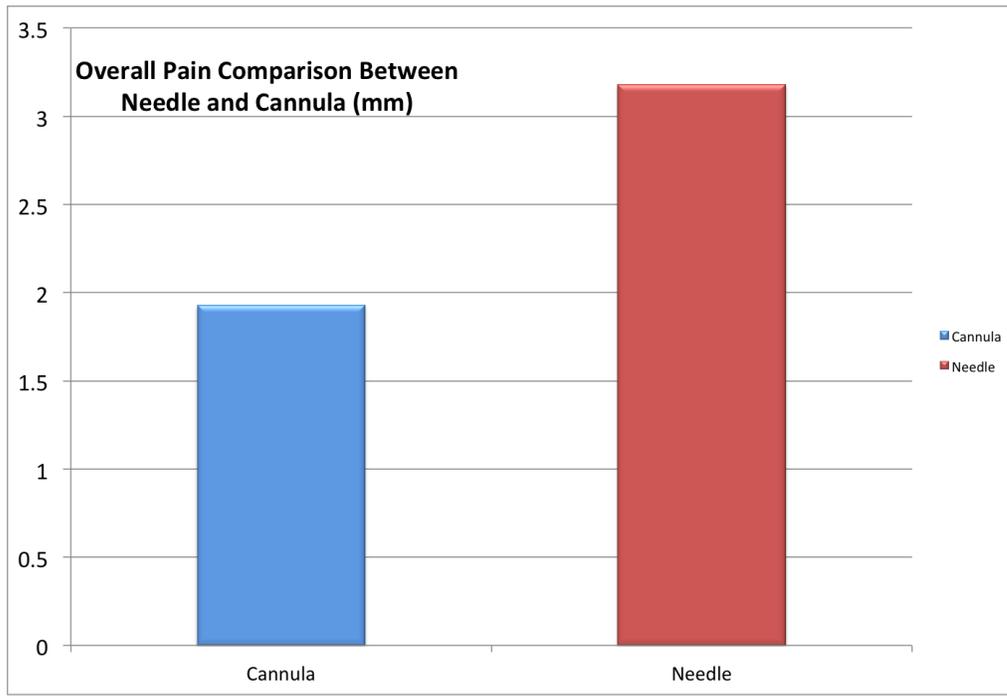


Figure 3. Overall Pain on Likert Scale from 0 to 10

Cannula use not only resulted in overall less pain and bruising, when bruising was present, bruising from needles averaged 3.12 mm as compared to only 2.5 mm with cannula. Additionally, bruising was not present in 83% of areas treated with cannula in comparison to only 45% for areas treated with a needle.

Costs Savings

The total additional cost associated with the EBP implementation was \$150.00. EBP costs consisted of \$6.00 per cannula and one 30-minute training session for five non-medical staff. Other than the additional material cost of purchasing one \$6.00 cannula per patient, inclusion of cannulas does not have cause the practice to incur any additional fixed costs. However, in order to provide more information on the advantages of cannula technique to the clinics market base, additional marketing tools to include website modification, magazines, email campaigns, and in-clinic advertising flyers will need to be considered.

In contrast to the relatively low product cost, cannula use has significant potential for business growth. EBP findings support decreased pain and hematoma formation when using cannula. As a result, patients receiving dermal fillers via cannula technique would be more likely to have an improved overall experience from those who received dermal fillers via needle. Considering that aesthetic medicine is a consumer-based practice model, the blunt-tipped cannula technique would help increase practice revenue due to improved patient experience

Implications for Practice

An important secondary gain of blunt-tipped use would be the potential decrease in arterial embolization (Hexsel et al., 2012). Van Loghem, Humzah, and Kerscher (2016) suggest that the smooth tip of the cannula may protect patients against inadvertent injection of hyaluronic acid within the artery. Because the smooth tip of the cannula cannot puncture the vessel wall, the cannula navigates through the dermis, pushing soft tissue structures such as blood vessels out of the way. Although the authors admit that the risk of embolization still occurs, it is suggested that the risk is significantly less with cannula use. Additional research in arterial embolization from cosmetic procedures is needed to fully understand the risk that patients take with dermal fillers.

Sustainability

Sustainability of the project will be challenged by tendencies for providers to resort back to familiar injection techniques utilizing a needle. Additional challenges are expected due to the material costs of purchasing cannulas. However, after considering the decreased risk of AE and increased business growth, sustainability should be a priority for both the clinician and the organization as a whole.

A decrease risk in hematoma formation and potential embolization of facial arteries provide a safer environment for the aesthetic provider to practice and this idea will need to be reinforced by the lead DNP for the practice. It is expected that patient's preference for treatments that result in decreased pain and bruising will also help sustainability. Ultimately, the facility will be responsible for practice guidelines updates and enforcement.

Limitations

Sample size for the EBP was relatively small. It is recommended that a longer time frame, or period of time with higher volume be considered for future projects. Additional limitations to the project included a lack of male patients, and few patients with no history of previous dermal fillers. Research into cool packs and their affect on bruising was not established as well as a bruising tool with established reliability and validity was not utilized. However, a literature review failed to locate a standardized bruising tool for the assessment of bruising post cosmetic facial procedure.

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Institutional Review Board Project Action Summary

Action Date: June 24, 2016

Note: Approval expires one year after this date.

Type: New Full Review New Expedited Review Continuation Review Exempt Review
 Modification

Action: Approved Approved Pending Modification Not Approved

Project Number: 2016-06 -247

Researcher(s): Tony Rosales DNP student SON
Dr. Sue Hoyt Fac SON

Project Title: Conversion from needles to blunt-tipped cannulas for administration of dermal fillers in patients requesting mid-face augmentation

Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.

Modifications Required or Reasons for Non-Approval

None

The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited review at any time.

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