

Capstone: Medical Aesthetics

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Abstract

Aesthetic Medicine is an area of medicine growing exponentially worldwide, with the Global Medical Aesthetics Market predicated to exceed more than US\$ 21.0 Billion by 2024. As the worldwide population is aging, individuals are willing to pay for aesthetic procedures to enhance appearances (Thomaidou, 2018).

This paper explores starting a subspecialty aesthetic medicine practice within a Sports medicine/Anti-aging practice. The following question is researched, “In a medical practice, is opening a subspecialty aesthetics practice both ethical and safe?” The purpose of this paper is to explore the ethics and safety of a Medical Aesthetics Practice. This paper meets the requirements for the Capstone project in the Doctor of Nursing Practice Program (DNP).

Keywords: aesthetics industry, medical aesthetics, ethics and aesthetic medicine, botulinum toxin for cosmetics, Botox, Botulinum toxin A for wrinkles, Botox, botulinum toxin A complications, aesthetic medicine; dermal fillers, dermal fillers and complications, aesthetic guidelines.

Capstone: Medical Aesthetics

Aesthetic Medicine is an area of medicine growing exponentially worldwide. As of 2015, the American society for plastic surgery reported over \$13.5 billion in patient spending, with non-surgical procedures accounting for 42%. According to a USA comprehensive analysis in 2016, the American medical aesthetics market is expected to increase by 5.5 percent over the next five years. As the worldwide population is aging, individuals are willing to pay for aesthetic procedures to enhance appearances (Thomaidou, 2018).

The subspecialty of aesthetic medicine has expanded beyond plastic surgeons and dermatologists and is currently being offered by a variety of practitioners across all areas of medicine, to meet patient demand for services. During the last decade, there is a drastic increase in cosmetic treatments worldwide, and the absence of regulations in this area is concerning. As medical aesthetics is driven by patient preference, rather than provider diagnosis, aesthetic practitioners must focus on high ethical standards, guided by patients' best interest and safety, while being cautious not to practice as a "businessperson with a medical degree" (Thomaidou, 2018).

As I am currently working in the field of anti-aging medicine, within a sports medicine practice, my colleagues and I took note of the predicted growth in this field of medicine. In the current medical practice, patients are physically improving from minor and major musculoskeletal injuries; along with improvements in physical health, patients refocus their goals to improve their physical appearance. Many patients are seeking services in cosmetic medicine outside of our practice, since it is not currently offered within our practice. On discussing the subspecialty of aesthetic medicine within the existing practice, we had many questions. This paper explores the following question, "In a medical practice, is opening a subspecialty

aesthetics practice both ethical and safe?” For the purpose of this paper aesthetics practice will be limited to the areas of injectable neuromodulators (Botox, Dysport or Xeomin - referred to as Botox for the purpose of this paper and dermal fillers (containing hyaluronic acid).

Syntheses of Evidence from Review of Literature/Systematic Review

A review of the literature was conducted using multiple data bases: Academic Search Elite, CINAHL with full text, Ebsco host, MEDLINE with full text, Up To Date, Google Scholar, and PubMed. Data bases were searched with the following search terms from 2015-2019: aesthetics industry, medical aesthetics, ethics and aesthetic medicine, botulinum toxin for cosmetics, Botox, Botulinum toxin A for wrinkles, Botox complications, aesthetic medicine; dermal fillers, dermal fillers and complications, aesthetic guidelines. Inclusion criteria were articles and abstracts pertaining to Botox and other neuromodulators used for facial cosmetic purposes, and facial cosmetic dermal fillers derived from hyaluronic acid. Exclusion criteria were articles regarding surgical aesthetics, botulinum toxin (Botox) for migraine, overactive bladder, or other non-cosmetic purposes, and articles studying combination therapy (for example, Botox and laser therapy, dermal fillers injection in conjunction with surgery). Fifty-two articles were retrieved, forty-two were further eliminated for combination therapy or expert opinion funded by Allergan.

National Practice Guideline Review

Although the medical aesthetic industry is growing, guidelines are lacking (Thomaidou, 2018), therefore, practitioners in all areas need to explore alternative reliable resources for guidance. The Principles of Biomedical Ethics: beneficence, non-maleficence, respect for autonomy and, justice (Gillon, 2015), state guidelines (American Med Spa, 2019), and FDA approved products manufacturer’s recommendations (Carruthers & Carruthers, 2019) are all

readily available resources. In the Principles of Biomedical Ethics, the principle of beneficence can be applied to the aesthetics business, it is the core principle of patient advocacy. Beneficence is the desire to do good and to take positive action to help others (Gillon, 2015). As the practice of aesthetics varies by state, the individual state practice laws must be reviewed and upheld, both for the individual licensed practitioners as well as for marketing of services. “New York considers the injection of any substance, such as Botox, to be the practice of medicine. As such physicians, physician assistants (PAs) under the supervision of a physician whose scope of practice includes the administration of Botox, and nurse practitioners (NPs) working pursuant to written protocol or in collaboration with a physician whose scope of practice includes the administration of Botox, may all administer Botox. New York law does not prohibit a medical spa from paying a person or entity to market the spa's services...all physician advertising must never be in any way false, fraudulent, deceptive, misleading, sensational, or flamboyant” (AM SPA, 2019).

Systematic Review/Level of Evidence

A systematic review of the evidence is presented in Table 1, organized according to the level of evidence hierarchy. The research findings from all sources support the safety and effectiveness of Botox and dermal fillers for cosmetic purposes. Studies of Botox as a single therapy were more abundant than dermal fillers, as studies regarding dermal fillers are often conducted as a combination therapy, and, therefore did not meet the inclusion criteria. All 10 studies included in this review described a clear and systematic data collection method and provided well-supported conclusions; all studies were determined to be both valid, as the scores measured the intended variables, and reliable, due to consistency of measure. Eight of the studies investigated Botox and/or dermal fillers, one study evaluated the entity of the aesthetics medical

community, and one study investigated patient decision-making factors for choosing to receive aesthetics services.

Carruthers & Carruthers (2019) conducted a large (n=1425) systematic review and meta-analysis of randomized trials indicating no evidence of serious adverse effects in patients treated with onabotulinumtoxin A for medical for cosmetic purposes. Because the effect of botulinum toxin is temporary, patients require additional treatment to for maintenance. Carruthers & Carruthers (2015) reported maintenance therapy is proven safe, with minimal side effects, after three consecutive treatments in a retrospective study of over 4,000 treatments in 945 patients. Additionally, the researchers state serious adverse effects reported to the FDA are low in number; with only 36 serious adverse effects associated with cosmetic reported from 1989-2003, 12 of which had pre-existing conditions. While the risk of serious adverse effects is low with cosmetic use, side effects such as aspiration, dysphagia, pneumonia, anaphylaxis, botulism, and death, have been reported in association with the use of botulinum toxin. Subsequently the United States Food and Drug Administration (US FDA) instituted a requirement for boxed warnings on product labels and a Risk Evaluation and Mitigation Strategy (a consumer guide outlining the risks associated with treatment) for all botulinum toxin products (Carruthers & Carruthers, 2019).

These studies support the earlier work of Rivers et al. (2015), who studied the effectiveness and patient satisfaction of treating facial wrinkles with onabotulinum toxin A. In a randomized-double blind prospective study, the researchers concluded Botox is safe and effective for treating facial wrinkles for glabellar lines and crow's feet lines, with patient satisfaction significantly greater than placebo. Similarly, the work of Molina et al. (2015) concluded, in a large-scale observational study, treatment of glabellar lines with

onabotulinumtoxinA yielded a high level of patient satisfaction, and corresponded with a positive self-perception, four months after treatment. This study is significant because it is one of the first clinical trials on patient-reported outcomes, and patient satisfaction associated with the treatment of facial wrinkles utilizing onabotulinumtoxinA. Dayan et al. (2015) reported similar findings in patient reported outcomes in a double-blind placebo-controlled trial for the treatment of crow's feet lines with onabotulinumtoxinA. Most subgroups receiving onabotulinumtoxinA demonstrated significant improvements in psychological impact versus placebo on day 30 and onabotulinumtoxinA-treated subjects consistently rated themselves as looking younger versus placebo in all subgroups on day 30. Overall, subjects were satisfied with their appearance.

Cohen & Scuderi (2017) conducted a systematic review of the published literature (from January 2000 to January 2016) to determine the safety of, and patient satisfaction with, the aesthetic use of abobotulinumtoxin A (ABO or BoNT-A). In addition to the licensed indications, other special populations were considered for discussion. The potential impact of neutralizing antibodies and systemic toxicity were also addressed. A total of 364 papers were screened and 86 were found to be relevant to the population, interventions, and outcomes stipulated in the protocol. The adverse event profile for BoNT-A proved comparable to placebo and other formulations of BoNT-A for multiple indications is associated with significantly high levels of patient satisfaction, which correlates with the efficacy of treatment. In aesthetic use, neither the incidence of neutralizing antibodies, nor systemic toxicity, was demonstrated in clinical studies of BoNT-A for aesthetic use

A similar literature review by Satriyasa (2019) supports the safety and effectiveness of both Botox and dermal fillers for reducing the appearance of facial wrinkles. The investigators noted complications are rare for Botox injection, with the most common complications noted as

ecchymosis and purpura; these complications are minimized with the application of ice pre and post Botox injection. Similar complications are noted for dermal fillers, i.e., bruising and hematoma, with additional side effects attributed to practitioner expertise: undercorrection, overcorrection, and lumping. These findings are consistent with the earlier work of Sumisita et al. (2016); in a small (n=10) prospective clinical trial, the researchers determined treatment with Botox is simple, safe, effective, and cost-effective procedure for reduction of forehead wrinkles. The effects of dermal filler were previously studied by Monheit et al. (2018), utilizing Juvéderm Vollure XC (VYC-17.5 L) in a randomized double-blind study of 123 adults, with moderate to severe nasolabial folds. The researchers concluded VYC-17.5 L is safe and effective for treating moderate to severe nasolabial folds, with effects lasting up to six months in 93 % of subjects.

Wu et al (2018) utilized self-evaluations to study the impact of emotional support, informational support, and norms of reciprocity on trust for the medical aesthetics community. Their research indicated there are advantages to medical aesthetic communities actively participating in online discussions. Social sharing fosters a community of trust, which leads to increased patient scheduling of aesthetic medical services. Through the QUEST Observatory, Ehlinger-Martin et al. (2016) studied women's attitudes on beauty, aging, and the use of cosmetic procedures. This study shows most women become aware of skin aging in their mid-thirties, when fine lines appear, and their chief complaint is "looking tired". While almost 50% of women consider the possibility of having a cosmetic procedure, less than 10 % follow through; fear of side effects or "unnatural" results are noted as the rationale. Knowledge about the procedure, confidence in the practitioner, and good post procedure follow-up are noted as important decision-making criteria.

Action Plan/Method

Based on the review of the current literature, we decided to begin a medical aesthetics practice, as a subspecialty of the sports medicine/anti-aging practice. The business guidelines recommended by Sachdev and Britto (2014) are the framework for this new aesthetic practice; the framework is presented below, followed by a customized framework tailored specifically for the new medical aesthetics practice.

1. Place: The location of the business is important, and knowledge of surrounding hospitals, dermatology clinics, and other aesthetic centers is important.

2. Purpose: Maintaining an office of excellence is accomplished by keeping up to with the knowledge and skills in the field of aesthetics. In medical aesthetics, a patients' health and safety is as much a priority as appearance and convenience. Maintaining professionalism and competence for each individual is important.

3. Practice and Personnel: Viewing your practice from a patient's perspective in all aspects can guide you through necessary changes, for example, wait time, streamlining practices, and friendliness of office personnel. Training staff for proper scheduling time frames is necessary.

4. Procedures: Informed consent should be obtained at every appointment, with and explanation of benefits, risks, and alternatives

5. Photography: Photographs help in monitoring patient progress.

6. Professional skills: Fellowships are available in clinical dermatology.

7. Equipment: Identifying preferred vendors for equipment based on multiple factors: cost of the equipment, trainings provided by the vendor, credibility of the company, after sales services and annual maintenance, system performance, warranty and extended warranties.

8. Patient records: Maintaining an accurate database of patient records is essential, an electronic medical records (EMR) is recommended.

9. Publicity and Promotion: Internet marketing and mobile advertising can cut marketing expenses, but it must be ethical, accurate, and follow guidelines defined by medical boards. Keep the patient population informed via Webinars, email, patient newsletters, social media or personal blogs etc.

10. Problems: Have a conservative approach and ensure patients have realistic expectations. It is better to under treat the patient, and if a complication occurs, corrective treatment can be offered gratis.

11. Protection: Professional liability insurance protects the doctor against financial consequences of an error or omission during the service or professional act such as aesthetic treatments and services.

We developed a business plan based on these guidelines.

1. Place: The medical aesthetics practice is to open in the existing office space within the practice; this location is preferable as it is central to main highways, has a large patient population, and is lacking other aesthetics practices in close proximity.

2. Purpose: To provide excellent medical aesthetics utilizing extensive knowledge and skills in the area of facial rejuvenation.

3. Practice and Personnel: The aesthetics team consists of the Medical Director-Medical Doctor; Nurse Practitioner: Clinician assisting with providing services, marketer/manager, and two assistants, one with a clinical background in ultrasound technology and one with scheduling experience. The timeline is to roll out the Aesthetics Program over eighteen months. Clearly defining the “practice within the practice” is identified by the

Aesthetics team as one of the greatest challenges, as well as streamlining processes. Viewing the process from a patient perspective will aide in this process and several “test patients” will be scheduled prior to opening the practice.

4. Procedures: Thorough history taking and realistic goal setting with the patients are mandatory for successful outcomes.

A clearly defined protocol will include informed consent, pre-procedure instructions, post-procedure instructions, and a follow up phone call by the NP two weeks post-treatment.

5.. Photography: Photographs will be taken once informed consent is signed, prior to any treatment, utilizing the office iPad with consistency in location and lighting.

6. Professional skills: Additional trainings for the MD and NP will be scheduled as necessary through Aesthetic Medical Education Training to maintain knowledge and skills.

7. Equipment: Vendors will be explored by the MD and marketer/manager. Botox Cosmetic, Xeomin, Juvaderm and Radiesse are the products chosen to begin with, based on safety, effectiveness, cost and ease of use.

8. Patient records: A new electronic database will be selected, separate from the current EMR for the sports medicine practice and training will be provided.

9. Publicity and Promotion: Marketing will begin prior to scheduling patients, with monthly specials announced and posted in the sports medicine office. On-line advertising will include email blast to current patients. The aesthetics team will participate in events in the community, such as Town Day.

10. Problems: Patients will be properly assessed, realistic goals will be set, and each patient will be aware of risks prior to beginning any treatments. Should a complication occur, the patient and will be examined and treated promptly, free of charge.

11. Protection: Professional liability insurance is update prior to commencing the aesthetics practice.

12. Review: The Aesthetic Committee will have monthly meetings to review services, finances, and feedback from patients and staff. In addition, the program will be reviewed in order to maintain sustainability: bi-annual review of the program will take place for the first year, and annually thereafter. The review will consist of three components: complication rate, financial viability, and patient satisfaction. Complication rate will be determined via EMR data retrieval, and patient satisfaction will be determined via Press-Ganey questionnaire. Financial review will be conducted by the Chief financial officer. Startup cost will be minimal as the aesthetic medical office is a subspecialty within an established office. The office space, equipment, and supplies are already purchased, and the medical director has budgeted for an assistant to serve as Marketing/Manager. The only cost will be training fees to clinical staff and purchase of Botox and dermal filler, which w. Minimal ordered at start-up, on demand for services.

13. Change Theory- Kurt Lewin's change theory is the model to be followed for the process of starting a subspecialty. Lewin's theory involves three stages: the unfreezing stage, the moving stage, and the refreezing stage force (Schriner, Deckelman, Kubat, Lenkay, Nims & Sullivan, 2010). The unfreezing stage is usually the most difficult part of the process and this is where we will spend the most time on the project. Presenting the staff with the facts and explaining how and why this will benefit the practice, as well as the individual staff members, will aide in the process. The moving stage is where individuals begin to resolve their uncertainty and begin to demonstrate actions and behaviors that support the change. Since administration is supportive, but middle management is not supportive of the change, there are many barriers to overcome; communication with all the stakeholders must be on-going in order for successful

outcomes. The refreezing stage begins when changes are taking shape and staff members have embraced the new subspecialty. On-going identification of supporting factors and barriers need to be identified and success should be celebrated.

Lewin's theory depends on the presence of driving and resistant forces; the driving forces are the change agents who push employees in the direction of change (the Aesthetics' Team & the administrators), the resistant forces are employees who do not want the proposed change (middle management). Success is achieved when the driving force dominates the resistant force (Schriner, Deckelman, Kubat, Lenkay, Nims & Sullivan, 2010).

The results of this literature review prove the safety and effectiveness of neuromodulators and dermal fillers when used for cosmetic purposes. As guidelines as lacking in this field of medicine, practitioners must utilize the resources available, always keeping congruent with The Principles of Biomedical Ethics. In the rapidly growing field of aesthetic medicine, consumers driven by personal goals, with individual perceptions of beauty, paying cash, may easily influence the unethical practitioner. Practitioners must devise and reinforce, national as well as local guidelines; while continuing to be knowledgeable of the current trends and research in aesthetic medicine, in order to ensure best practices are followed for optimal patient outcomes.

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Table 1

| Author | Title | Findings | Level of Evidence |
|--------------------------------|---|--|-------------------|
| Carruthers & Carruthers (2019) | Overview of botulinum toxin for cosmetic indications | Examination of the available data on botulinum toxin reveals an impressive safety record for cosmetic purposes. | 1 |
| Rivers et al. (2015) | Subject satisfaction with onabotulinumtoxinA treatment of glabellar and lateral canthal lines using a new patient-reported outcome measure. | High satisfaction rates are achieved and sustained in subjects treated with onabotulinumtoxinA for glabellar and lateral canthal lines combined | 1 |
| Monheit et al. (2018) | Safety and Effectiveness of the Hyaluronic Acid Dermal Filler VYC-17.5L for Nasolabial folds: Results of a Randomized, Controlled Study | Dermal filler VYC-17.5L (hyaluronic acid with lidocaine) is safe and effective for correcting moderate to severe nasolabial folds, with results lasting through six months in 93% of patients. | 1 |
| Dayan et al. (2015) | Effects of onabotulinumtoxinA treatment for crow's feet lines on patient-reported outcomes. | Most subgroups receiving onabotulinumtoxinA demonstrated significant improvements in psychological impact. | 1 |
| Molina et al. (2015) | Patient satisfaction after the treatment of glabellar lines with Botulinum toxin type A (Speywood Unit): a multi-centre European observational study. | Treatment of the glabellar lines with BoNT-A led to a high level of patient satisfaction and a more positive self-perception up to 4 months after the treatment, regardless of whether the patients were naive or not to BoNT-A treatment. | 2 |
| Cohen & Scuderi (2017) | Safety and Patient Satisfaction of AbobotulinumtoxinA for Aesthetic Use: A Systematic Review | The adverse event profile for ABO has been shown to be comparable to placebo. ABO treatment for aesthetic indications is associated with consistently and significantly | 2 |

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| | | high levels of patient satisfaction, which correlates with the efficacy of treatment. | |
| Satriyasa (2019) | Botulinum toxin (Botox) A for reducing the appearance of facial wrinkles: a literature review of clinical use and pharmacological aspect. | Intramuscular injection is more effective than nanomicroneedle in treating dynamic wrinkles | 3 |
| Sumisita et al. (2016) | An Evaluation of Use of Botulinum Toxin Type A in the Management of Dynamic Forehead Wrinkles - A Clinical Study | Treatment with Botox is simple, safe, effective and cost-effective procedure for reduction of forehead wrinkles. | 2 |
| Wu, Khan, Chien, & Lee (2019) | Impact of Emotional Support, Informational Support, and Norms of Reciprocity on Trust Towards the Medical Aesthetic Community: The Moderating Effect of Core Self-Evaluations | Medical aesthetic communities actively participating in online discussions creates a community of, trust, leading to increased social sharing and buying intentions. | 2 |
| Ehlinger-Martin., Cohen-Letessier, Ta€ieb., Azoulay, MA, E., & du Crest (2016) | Women's attitudes to beauty, aging, and the place of cosmetic procedures: insights from the QUEST Observatory. | Approximately 50% of women contemplate cosmetic procedures, while under 10% follow through. Confidence in the practitioner and good post procedure follow-up are as influential as efficacy, safety, and cost in decisions about cosmetic procedures. | 3 |