

Research Article

Transparency of Medical Spas in North Carolina

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Received: July 04, 2018; Accepted: August 14, 2018;

Published: August 21, 2018

Abstract

Background: Medical spas are rapidly growing entities marketing injectable products and laser procedures, which have been associated with devastating complications, including skin necrosis, vision loss, disfigurement, scarring, infection, and death.

Methods: We performed an internet search to determine North Carolina state laws and regulations for ownership, procedure delegation, and medical oversight of businesses registered within the state. The website for each medical spa was reviewed for medical director's name, specialty, procedures performed, performing clinician's qualifications, and physician supervision.

Results: A Google™ search yielded 62 medical spas in North Carolina that met inclusion criteria. Of these businesses, 77.4% (48) listed a medical director by name on their website. The State Department corporations registry revealed 53.3% (32) of businesses were registered under the medical director (or spouse) or another physician, while 8.1% (5) were registered under a nurse, cosmetologist, or aesthetician and 19.4% (12) under a non-medical individual or entity. Plastic surgery was the most commonly represented specialty with 17.7% (11), followed by Internal Medicine with 12.9% (8). Regarding supervision, 44.2% (23) reported physician-conducted or supervised procedures, whereas 13.5% (7) indicated licensed aestheticians or nurses alone perform consultations and procedures.

Limitations: Our study is limited by publically-available information ascertainable from an internet search, which might be otherwise available through membership-only organizational websites.

Conclusion: The devastating adverse events associated with minimally-invasive cosmetic procedures fall within the scope of medicine and surgery. It is the professional and ethical responsibility of physicians to more actively address the rapidly expanding market of medical spas.

Keywords: Medical spa; Cosmetic procedures; Injectables; Laser surgery

Abbreviations

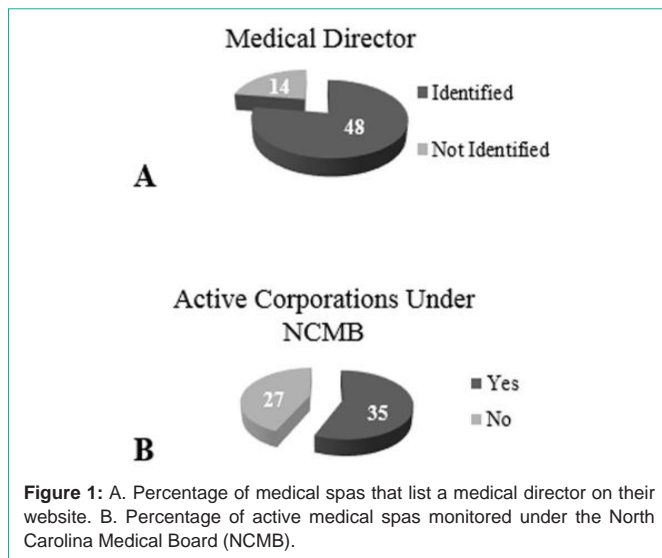
NCMB: North Carolina Medical Board; RN: Registered Nurse; LPN: Licensed Practical Nurse

Introduction

Data from the American Society of Plastic Surgeons indicates that minimally invasive cosmetic procedures are on the rise. From 2000 to 2015, botulinum for cosmetic use increased 759%, soft tissue facial filler increased 274%, laser hair removal increased 52%, and chemical peels increased 14% [1,2]. While touted to be minimally invasive, devastating complications have been reported from these procedures, including skin necrosis, loss of vision, and disfigurement from scarring, infection, stroke, and even death [3]. A literature review by Beleznay, et al revealed 98 world-wide reported cases of blindness after filler injection and found that the highest risk anatomical locations were the glabella and nasal region [4]. In another study, Park, et al reported 44 cases of permanent vision loss occurring from obstruction at varying branches of the ophthalmic artery and found that this complication was more frequent in patients receiving autologous fat injections followed by hyaluronic acid [5]. In 2004, a North Carolina college student died of neurotoxicity after improper

use of a 10% lidocaine 10% bupivacaine topical anesthetic for laser hair removal [6]. Safe and effective performance of these procedures is contingent upon proper training, knowledge of the relevant anatomy and tissue physiology, appropriate patient selection, and the ability to promptly identify and manage impending complications [4].

Medical spas combine the concept of a day spa with a medical clinic to offer a myriad of medical and surgical aesthetic procedures. As the popularity of minimally invasive cosmetic procedures has increased, so has the abundance of medical spas in the United States, which grew in number from 471 in 2003 to 1,750 in 2011 [7]. While by definition a medical spa requires a physician medical director, specific laws and regulations vary by state with many states lacking clear rules on patient safety issues including the delegation and supervision of procedures, adverse event reporting, and transparent marketing. A 2011 study by Choudhry, et al contacted 50 United States state medical boards and found that of the 31 state boards that responded, 63% allowed the medical director to delegate procedures to non-physician providers, only 42% required physician on-site supervision, and 13% expressly allowed off-site supervision [8]. Even within states with stronger regulations, medical spa transparency and adherence to these laws remains unclear.



In order to better understand these issues and how they affect patient safety in North Carolina, our study evaluated the transparency of medical spas in the state of North Carolina by reviewing each medical spa's website for medical director's name, specialty, name and credentials of the staff members performing procedures, and physician supervision requirements for non-physician providers. Further, we reviewed the websites of the governing bodies to determine the extent of oversight in place to monitor these businesses.

Materials and Methods

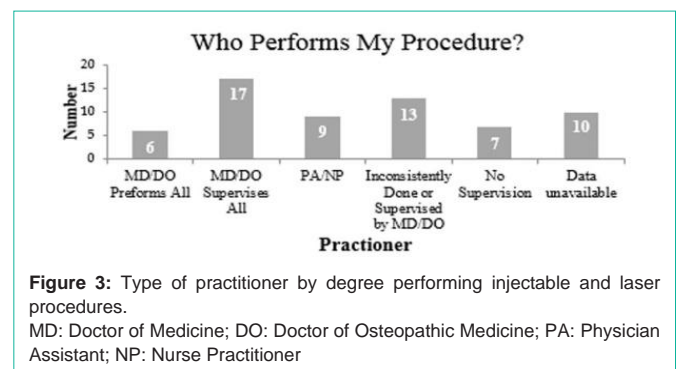
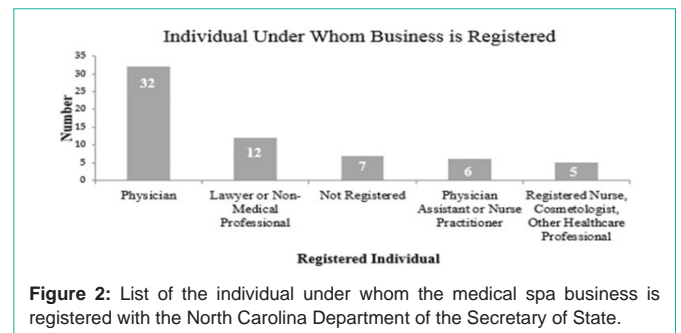
An internet search was performed to determine the North Carolina state laws and regulations for the ownership, procedure delegation, and medical oversight of medical spas registered within the state. Public letters of concern issued by the North Carolina Medical Board to owners or medical directors of medical spas were reviewed to elucidate the disciplinary actions taken by the state of North Carolina.

A database search of the corporations registered with the North Carolina Secretary of State was performed to determine medical spa ownership. The website for each medical spa was reviewed, and the availability of the following information was noted: 1) medical director name; 2) medical director specialty; 3) on-site procedures performed; 4) performing clinician name and qualifications; 5) discussion of physician procedure supervision. Websites that did not contain this information were called, and these items were queried. All internet research was performed between August 14th, 2015, and August 18th, 2015.

Results

The North Carolina Medical Board (NCMB) and the North Carolina Board of Nursing have limited publically-available laws and regulations directing the practice of cosmetic medical procedures at medical spas [9,10].

A Google™ search using the search phrase "medical spas in North Carolina" yielded 112 results and the search phrase "list of medical spas in North Carolina" yielded five additional results for a total of 117 medical spas in North Carolina. Duplicate results (20),



medical spas located outside of North Carolina (12), non-medical spas (i.e., weight loss centers, day spas, salons, physician offices, or facilities labeled as medical spas but not offering injectables or laser procedures) (19), facilities of unclear distinction (2), and permanently closed businesses (2) were excluded from the analysis for a total of 62 facilities identified as medical spas providing either injectable or laser services.

Of the 62 medical spas included in this analysis, 77.4% (48) listed a medical director by name on their website (Figure 1). The NCMB lists 56.5% (35) of the included medical spas as active corporations monitored by the board (Figure 1). State Department corporation registrations revealed that 53.3% (32) of the medical spas were registered under the medical director (or spouse of that individual) or another physician, 9.7% (6) were registered under a physician assistant, nurse practitioner/advanced registered nurse practitioner, or an advanced practice registered nurse, 8.1% (5) were registered under a Registered Nurse (RN), cosmetologist, or aesthetician, 19.4% (12) under a lawyer, corporation, or other non-medical individual or entity, and 11.3% (7) were not identified in the database at the time of our search (Figure 2).

Of the 62 websites evaluated, 66.1% (41) of medical spas identified the medical staff and their job descriptions. Medical specialties of the medical directors or physician assistants identified either on the website or by internet search of the practitioner's name, were available for 82.3% (51) of medical spas. Plastic surgery was most commonly represented with 17.7% (11), followed by Internal Medicine and subspecialties with 12.9% (8), Obstetrics and Gynecology 11.3% (7), Emergency Medicine 9.7% (6), Dermatology and General Surgery each with 6.5% (4), Family Medicine with 4.8% (3), Otolaryngology and Ophthalmology each with 3.2% (2), and Pediatrics, Orthopedic Surgery, Neurosurgery, and Anesthesia each represented in one practice (Table 1).

Table 1: Distribution of sub specialties represented by medical directors or physician assistants owning or operating the medical spas.

Medical Specialty	Number of Practices
	(N=62)
Plastic Surgery	11 (17.7%)
Internal Medicine & Sub-specialties	8 (12.9%)
Obstetrics & Gynecology	7 (11.3%)
Emergency Department	6 (9.7%)
Dermatology	4 (6.5%)
General Surgery	4 (6.5%)
Family Medicine	3 (4.8%)
Otolaryngology	2 (3.2%)
Ophthalmology	2 (3.2%)
Pediatrics	1 (1.6%)
Orthopedic Surgery	1 (1.6%)
Neurosurgery	1 (1.6%)
Anesthesia	1 (1.6%)
Data unavailable	11 (11.7%)

Of the medical spas included in this study, 8.1% (5) perform only laser procedures, 6.5% (4) perform only injectables, and 85.5% (53) perform both laser procedures and injectables. Data on supervision was available for 52 spas and revealed procedures are conducted or supervised by a physician at 44.2% (23) of facilities, while physician assistants and nurse practitioners perform the procedures at 17.3% (9) of facilities. The physician inconsistently performs or supervises at 25.0% (13), while there is no physician supervision at 13.5% (7) (Figure 3).

Discussion

Although North Carolina has taken one of the more proactive state approaches to regulating medical spas, the laws and regulations both nationally and statewide were difficult to ascertain through an internet search. The American Med Spa Association and the International Aesthetics and Laser Association contained links to state regulations but required membership for access.

While most of the medical spas included in this evaluation are corporations registered with the North Carolina Department of the Secretary of State, a large portion of these registered corporations are not listed as active corporations monitored under the North Carolina Medical Board. This discrepancy brings to light an important regulatory concern, specifically why some medical spas registered in the state of North Carolina are entities monitored by the medical board and thereby subject to the laws of the medical board, whereas other companies operating under the title of a medical spa are not identified as active corporations under the medical board.

Since the accidental death of a college student in North Carolina in 2004, the state has actively tried to increase its regulation of medical spas. The medical board has issued several public letters of concern to medical directors citing issues, such as the unlicensed corporate practice of medicine, the failure to complete pre-procedural health examinations by a licensed medical professional, and unethical fee-

splitting. However, oversight of medical spas continues to lag behind the rapid growth and expansion of these corporations, as evidenced by the inconsistencies in information available on websites and the lack of medical spa affiliations listed for medical directors under licensee searches within the North Carolina Medical Board database.

Furthermore, due to the lack of a formal reporting system, it is believed that adverse events after cosmetic procedures are significantly under reported. High volume cosmetic dermatologists and plastic surgeons are familiar with treating these under reported adverse events from improperly trained providers, including laser injury (burns, scarring, ocular injury, hyper pigmentation and hypo pigmentation), filler complications (tissue ischemia, granulomas, infection, blindness), chemical peel complications (scarring, infection, pigmentary complications), and neuromodulator adverse events (ptosis, vocal cord compromise) [11-14]. However, our research shows the majority of medical spas are under the direction of a physician who did not complete a formal residency or fellowship training in either of these core aesthetic medical specialties.

Confusion among medical providers interested in finding a career in medical spas exists due to variations in the laws and regulations of the licensing committees of medical professionals employed by these businesses, including physicians, physician assistants, nurses, aestheticians, cosmetologists, massage therapists, and laser technicians. The North Carolina Medical Board and North Carolina Board of Nursing have agreed to laws regarding the ownership of medical spas and whether the performance of cosmetic procedures, such as injectables and laser procedures, is within the scope of an RN or Licensed Practical Nurse (LPN) practice. Specifically, the boards have determined that medical spas by definition provide medical services and must, therefore, be owned by a licensed physician, nurse practitioner, physician assistant, or some combination thereof. However, the board allows allied nursing staff to perform a range of cosmetic procedures provided they are appropriately trained in the safety and execution of the services and the patient has a medical examination by a licensed physician or other licensed practitioner acting within the scope of his/her practice. The definition of appropriate training in these services is not described on either website for the Board of Nursing or Medicine [9,10]. Furthermore, because a professional nursing corporation can act only within the scope of the field of nursing, ownership of a medical spa by an RN or LPN is prohibited by North Carolina law.

This study has several limitations. First, it is an internet search conducted to determine publically-available data on medical spas; thereby, it is limited in the information that can be ascertained, which might be otherwise available through the membership-only websites of the American Med Spa Association and the International Aesthetics and Laser Association. Second, published data on complications after cosmetic injectables and laser treatments is limited in the United States, as many of these cases are currently tied up in litigation. Lastly, data was obtained from the Internet by a single researcher without contact with the individual medical spas included in this study.

Conclusion

The goal of this research is not to apportion blame to any individual or governing body; rather, it is to elucidate the lack of

transparency in medical spas as it pertains to patient safety. As members of the medical profession, our ethical priority is to do no harm. The devastating adverse events that have been reportedly associated with minimally-invasive cosmetic procedures fall within the scope of medicine and surgery; thus, it is the professional duty of physicians to more actively address the rapidly expanding market of medical spas.

Acknowledgement

The authors have the following disclosures: JAW serves as a physician consultant for Allergan, Galderma, Merz, EltaMD, SkinCeuticals, and Lutronic and as a speaker for Galderma and Merz. SGC and NL do not have any financial disclosures. This research is supported by the following aesthetic physicians: Sue Ellen Cox, MD, Charlie Finn, MD, Timothy Flynn, MD, Rosalyn George, MD, Duncan Hughes, MD, Brooke Jackson, MD, Ilya Leyngold, MD, Jason Liss, MD, Jeff Marcus, MD, Gilly Munavalli, MD, Elizabeth Rostan, MD, and Charles Woodward, MD.

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