DATE: February 23, 2025

FROM: Valerie Tokarz, Rhode Island Physician

TO: RHODE ISLAND HEALTH AND HUMAN SERVICE COMMITTEE

SUBJECT: BILL H5351 – OPPOSITION STATEMENT

Dear Representatives on the HHS Committee,

I'm writing in opposition to Bill H5351 (Medical Aesthetics Practice Safety Act).

As recently as July 2024, our Department of Health published guidelines pertaining to the safety of medical spas and IV infusion centers (Rhode Island Department of Health Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses). This occurred after many years where they sought the expert opinions of physicians in Rhode Island, including my specialty as a dermatologist. The guidelines are based not only from patient injuries in our state but on multiple case reports and studies published in peer reviewed journals. I'm attaching several of those in support of this.

The bill leaves much open to interpretation, including what is considered the practice of surgery by the American Medical Association and should only be performed by physicians (whose scope of practice includes such training). This would include several lasers such as resurfacing or ablative lasers. Therapy with such devices are known to have an extremely high risk for scarring, wound infection, and nerve damage. Fillers are semi-permanent gel implants – in fact, as a physician who uses them frequently, it says so right on the package. However, the word itself sounds very simplified. Fillers can cause significant problems such as severe wounds, clots and even blindness. Knowledge of facial anatomy (years, not 20 hours) is needed to appreciate this. Many of us who practice with fillers agree these are complex, cosmetic surgical procedures and not simple.

H5351 leaves much open to interpretation. For example, "supervision" by a physician, PA, or APRN of a non-medical person is vague as is "training" for 20 hours (equal to one half of a work week). I could interpret this to my advantage: I could hire an employee with no medical knowledge or even a high school diploma, and could "train" them in my office for half of a week. This law would then allow me to "supervise" that employee in the practice of medicine, which includes cosmetic medical procedures such as lasers (risks above), Botox injections (risk for infection, nerve and vessel damage), fillers (which are semi-permanent medical implants with serious risks for infection, nerve damage, blindness and stroke) and any new cosmetic medical technologies that come after this bill. From a financial standpoint, this would make for an extremely lucrative business model. I could hire non-medical personnel (even without a high school diploma) at a much lower rate then I pay qualified medical personnel to do exactly what took me 4 years of college, 4 years of medical school and 4 years of residency to learn. Right now, it costs over half a million dollars to train a physician.

In my own experience, I've had numerous patients tell me stories about being treated improperly at medical spas. Many have come to me to help them after erroneous treatments. I've asked over and over for them to report to the department of health, and time and again, the patients often don't. They tell me it's time consuming, they tell me they're embarrassed, and they often know friends of the owners or someone in the community and feel bad "telling on" someone they're connected to.
As an example: One of my long time patients had a treatment at a medical spa using an ablative inside her vagina (the medical spa does not have a physician, and already that's against the DOH guidelines). She told me she was scheduled to go back for "G-spot injections" as part of the offer that she paid for – describing that a needle would go into her clitoris and they would inject a concentration of her platelets (called PRP). She told me that they told her the procedure had "no risks" because it was using her own blood. This is totally incorrect, as any needle into that sensitive area runs a risk for infection and injury and that PRP carries a risk for clot formation and tissue necrosis (as many studies in medical literature have pointed out). She was not told about any of these risks. She knows the medical spa owners and told me she is too embarrassed about the sensitivity of the procedure to report it.

Please refer to a recent Rhode Island court case where a patient was severely injured when a "trained" laser tech was allowed to perform laser hair removal while the "supervising APRN" was not onsite. The case was won by the Plaintiff :Wanda Contrearas vs. Regen Medical Spa. The medical spa was found negligent on all 5 counts. H5351 if passed into law would make it much easier for these kinds of negligent errors to happen and more people will get injured.

As part of a continuing effort, the Rhode Island Dermatology Society supports our department of health with regulation for the safe practice of these procedures. We know this is an area that is constantly evolving as new technologies hit the market and as more and more studies are published. Please understand that I am not opposed to non-physicians practicing these procedures, but the best models are when medical spas have physicians as the medical directors and those performing these procedures are doing so within the scope of their practice and have hundreds of hours of physician supervised training.

Thank you for your time and your commitment to the health and safety of our state's population.

Best Regards,

Valerie Tokarz

Experiences With Medical Spas and Associated Complications: A Survey of Aesthetic Practitioners

Jordan V. Wang, MD, MBE, MBA,* Christian A. Albornoz, MD,* Hayley Goldbach, MD,† Natasha Mesinkovska, MD, PhD,† Thomas Rohrer, MD,‡ Christopher B. Zachary, MBBS, FRCP,† and Nazanin Saedi, MD*

BACKGROUND Medical spas have experienced a recent rise in popularity. However, rules and regulations vary nationwide. Given the number of complications attributable to medical spas, questions remain about currently regulatory practices and whether they are sufficient to protect patients from harm.

OBJECTIVE Our study investigated the current state of medical spas and their associated patient complications in the aesthetic field as well as the experiences and attitudes of practitioners.

MATERIALS AND METHODS A survey was distributed to current members of the American Society for Dermatologic Surgery.

RESULTS Of all cosmetic complications encountered in the past 2 years, the majority reported that the percentage of complications seen in their practice attributable to medical spas ranged from 61% to 100%. The most commonly cited complications from medical spas were burn, discoloration, and misplacement of product, whereas the most commonly cited treatments resulting in complications were fillers, intense pulsed light, and laser hair removal. For safety and outcomes, medical spas were rated as inferior to physician-based practices.

CONCLUSION Patient complications associated with medical spas are not uncommon. Overall, practitioners believe medical spas are endangering to patient safety, think that stricter rules and regulations are necessary, and request more support from the specialty medical societies.

The authors have indicated no significant interest with commercial supporters.

In a society which places a growing value on aesthetic beauty, the prevalence of noninvasive and minimally invasive cosmetic procedures has continued to rise. A recent member survey of the American Society for Dermatologic Surgery (ASDS) demonstrated that in 2018, over 3.7 million injectable procedures were performed.[1] Injection of filler products experienced a 78% increase from 2012. Laser, light, and energy-based treatments grew by 74%, and body sculpting procedures increased over 400% during this time period. The increasing popularity of aesthetic treatments has undoubtedly contributed to the trend of medical spas opening across the country.

These aesthetically focused facilities offer treatments similar to those historically performed in physician-based practices—often at discounted prices—but with varying standards of oversight and credentialing. Ironically, the efforts of states to improve access to primary health care by loosening the regulations for nonphysician providers have fostered an appetite for more lucrative aesthetic services in a spa environment. These state legislations have created an influx of nonphysician providers practicing aesthetic services with either no or partial supervision, despite vocal opposition from various specialty societies, such as the ASDS and American Academy of Dermatology.[2,3] Owing to a gross lack of uniform regulations between

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states, the roles and responsibilities of providers have become increasingly blurred, and the divide between aesthetic dermatology and cosmetology has narrowed. The detrimental consequences of this shift are clear and have already resulted in various adverse events for patients and consumers.

Tracking adverse events attributable to nonphysicians or nondermatology providers is difficult. Previous studies have examined complication rates, but this does not paint a complete picture. Although the literature has consistently demonstrated low complication rates with most procedures, these studies have traditionally focused on board-certified dermatologists or plastic surgeons as opposed to other providers who may possess more limited training or skillset.[4] These reports may therefore underrepresent the true rate of adverse events related to cosmetic procedures in all settings and falsely minimize the true potential for harm to patients.

Despite the recent attention focused on the rise of medical spas in aesthetic medicine, no formal studies have thoroughly examined their presence in the field in connection with their associated complications through a national survey of aesthetic practitioners. Our study aims to fill this gap in the literature by surveying members of the ASDS. Our results offer information and insights into how we can better educate practitioners and patients about the potential risks and dangers.

Materials and Methods

Online surveys were distributed via the Internet to current members of the ASDS as of 2019. Each individual was asked for demographic data, as well as their experiences interacting with and attitudes toward medical spas and associated complications.

Results

A total of 306 respondents completed the survey. There was a mean 13.9 years of experience working in aesthetic medicine. The majority worked in an urban setting (56.9%) compared with suburban (40.5%) and rural (2.6%) locations. For the vast majority (80.7%), the closest medical spa was <5 minutes away using typical transportation for the area.

In the past 2 years, the majority (70.3%) of respondents have had 1 to 20 patients experience cosmetic complications from medical spas. Of all cosmetic complications encountered in the past 2 years, the majority (63.1%) reported that the percentage of complications seen in their practice attributable to medical spas ranged from 61% to 100% (Figure 1).

The top 5 most cited cosmetic complications from medical spas were burn (89.7%), discoloration (80.1%), misplacement of product (74.6%), scar (69.4%), and bruise (52.9%) (Figure 2). The top 5

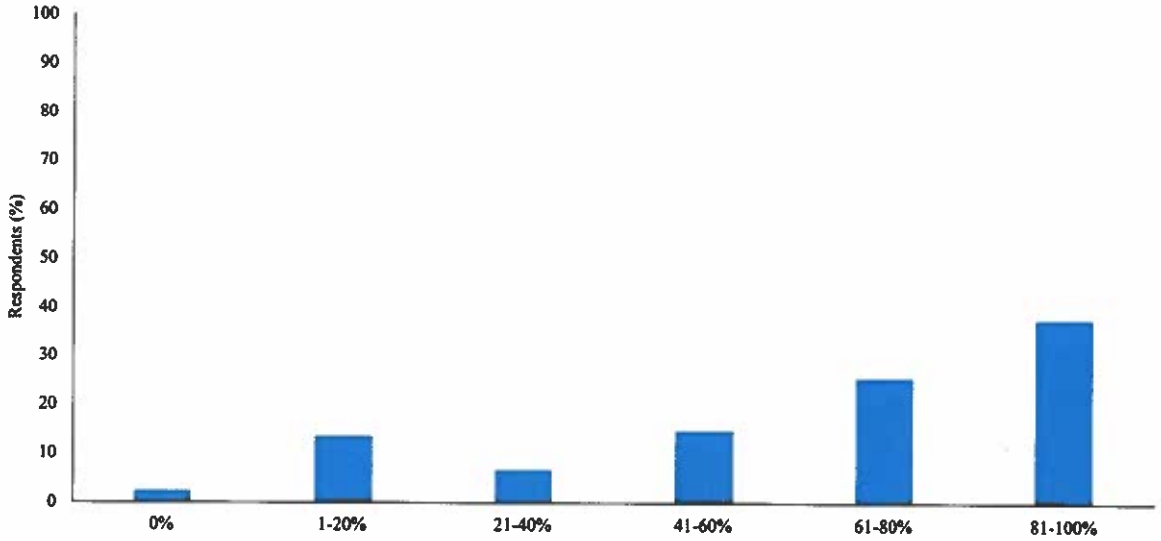

Figure 1. Percentage of all cosmetic complications in the past 2 years which were associated with medical spas.

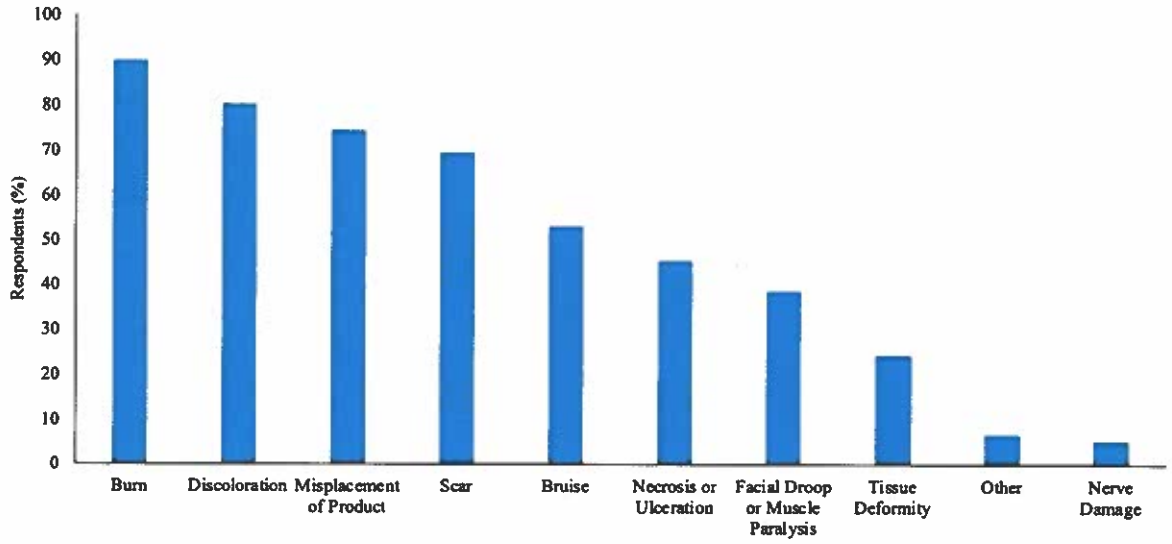

Figure 2. Types of cosmetic complications associated with medical spas.

most cited treatments resulting in complications were fillers (80.4%), intense pulsed light (74.9%), laser hair removal (73.4%), neurotoxins (54.0%), and lasers for discoloration (50.5%) (Figure 3). The top 3 most cited reasons for why these complications may have occurred were improper training or education (90.0%), improper technique (88.3%), and improper device setting (77.3%).

When the training background of the medical director for the medical spa was known, the top 3 most cited specialties were family medicine (40.9%), obstetrics/gynecology (25.1%), and emergency medicine (23.7%). Interestingly, dermatology was the least cited (2.4%) (Figure 4).

Regarding safety, medical spas were rated by respondents to be worse than the average physician practice for fillers (97.6%), intense pulsed light (95.2%), skin tightening and resurfacing (94.3%), laser hair removal (91.3%), laser tattoo removal (89.6%), neurotoxins (80.9%), and body contouring (67.6%).

Regarding outcomes, medical spas were rated by respondents to be worse than the average physician

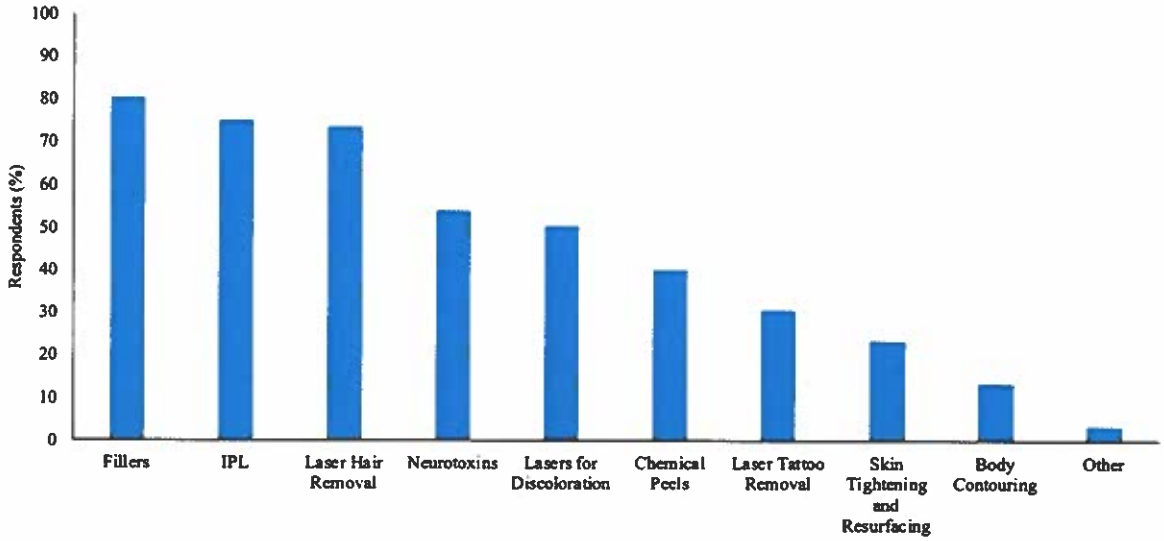

Figure 3. Sources of cosmetic complications associated with medical spas.

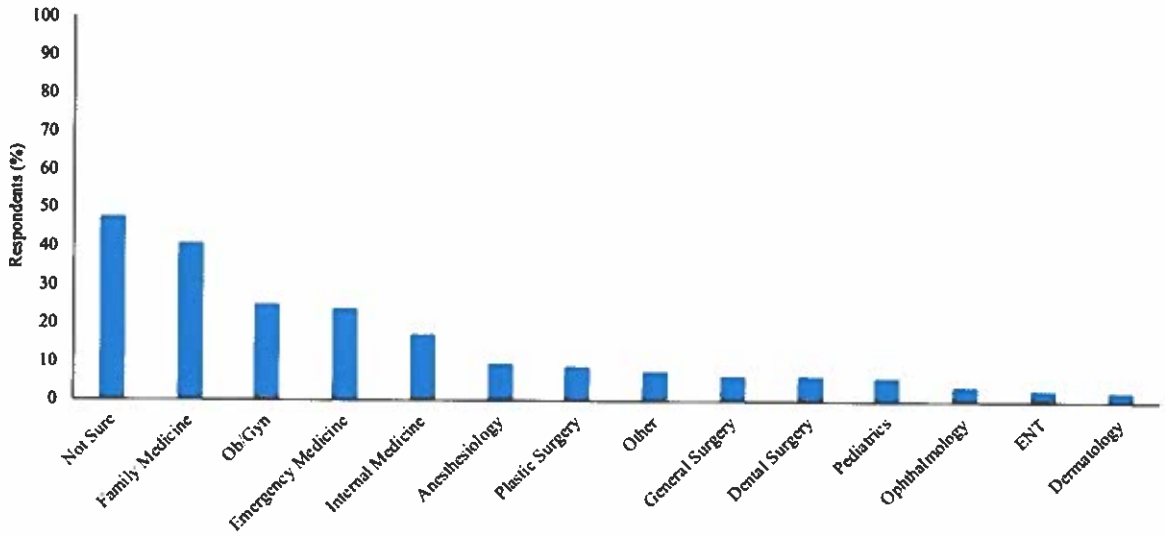

Figure 4. Training background of medical director for medical spa when complications were encountered.

practice for fillers (96.6%), skin tightening and resurfacing (92.0%), intense pulsed light (91.2%), neurotoxins (89.0%), laser tattoo removal (86.0%), laser hair removal (80.2%), and body contouring (69.6%).

The majority (58.8%) believed medical spas are either very or extremely endangering to patient safety. The majority (67.0%) was either not familiar with or only somewhat familiar with the rules and regulations, whereas 95.8% believed these should be stricter. Most respondents (84.3%) would like more information and support from medical societies.

Discussion

Demand for noninvasive and minimally invasive aesthetic procedures continues to grow at a remarkable pace. Medical spas have capitalized on this opportunity with over 5,400 facilities across the country in 2018, representing a total value approaching nearly $10 billion.[5] Many of these facilities are located in states that do not require direct physician oversight and are often managed by nurse practitioners, nurses, and naturopaths. A recent study demonstrated that the majority of medical directors possessed training backgrounds that were neither dermatology nor plastic surgery.[6] Interestingly, nearly 30% of the interviewed medical spas had a medical director who did not perform any procedures themselves, and nearly half were off-site for the majority of the time. Inconsistent supervision and disparate state-by-state regulations coupled with the rapid expansion of medical spas have created a perfect storm for patient endangerment.

The majority of respondents had a medical spa within 5 minutes of their workplace, which is consistent with the recent expansion. An alarming majority also treated several patients who suffered a cosmetic complication from a medical spa. Furthermore, cosmetic complications from medical spas comprise a significant portion of complications treated by responding practitioners. Although this study certainly has recall bias due to the inherent nature of the survey, no other studies have yet to thoroughly examine these trends, and this study begins to shed light on this topic.

The survey attempted to address the systemic faults associated with medical spas that may be responsible for these adverse outcomes. Respondents suspected that the most common reasons for these complications may be improper training, technique, and device settings. However, the causes of complications were likely assumed in many cases. Further investigation into the background of the medical directors also revealed an interesting trend. The top 3 most cited specialties were family medicine, obstetrics/gynecology, and emergency

medicine, whereas dermatology was by far the least cited at 2.4%. Interestingly, plastic surgery was cited at only 8.9%. Furthermore, the field continues to expand, and physicians from other specialties, such as general surgery and pediatrics, have ventured into the procedural aesthetic field.[7]

Expertise certainly plays an integral role in patient safety and outcomes. Very few specialties outside of dermatology and plastic surgery dedicate comparable clinical training to mastering skin pathology, anatomy, and medical and aesthetic treatments. A retrospective biopsy study found that dermatologists were more clinically accurate at diagnosing neoplastic and cystic lesions than nondermatologists, including family physicians, various surgeons, internists, and pediatricians.[8] Compounding these issues, physicians—dermatologists included—are increasingly delegating aesthetic procedures to physician extenders whose qualifications and training lack a universal standard.[9] To further highlight the associated dangers, numerous reports have begun to surface documenting the cosmetic referral of pigmented lesions that are ultimately diagnosed as melanomas.[10]

Regarding the safety and outcomes of common cosmetic procedures, respondents consistently rated medical spas as inferior to the average physician-based practice, especially for laser devices. However, these numbers may be somewhat skewed because practicing dermatologists may have an inherent bias. A recent study demonstrated that laser hair removal was the most commonly litigated procedure, with nonphysicians operating these devices 40% of the time.[11] From 2008 to 2011, the percentage of medical professional liability claims stemming from cutaneous laser surgery performed by nonphysicians increased by nearly 115%, from 36.3% to 77.8%.[12] During the same time period, procedures performed by nonphysicians in medical spas represented almost 80% of lawsuits. Adequate training and proper treatment are vital to patient safety, and sufficient oversight can provide an additional layer of protection.

Nearly two-thirds of respondents reported that they were not familiar with or only somewhat familiar with current guidelines governing medical spas. Unfortunately, rules and regulations are not universal. There are nationwide variations in state medical board bylaws regulating the number of nonphysicians a single physician may supervise, the requirement of physicians to be on-site, and the extent to which delegation of procedural tasks may occur.[13] For these reasons, it is clear why most respondents desired more information and support from our field's medical societies. Additional advocacy on behalf of patients, consumers, and physicians is needed to regulate acceptable standards of care at medical spas across the country.

Conclusion

Patients who have experienced complications from medical spas are not uncommon in aesthetic dermatology. Overall, practitioners believe medical spas are endangering patient safety, think that stricter rules and regulations are necessary, and request more support from the specialty medical societies.

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Medical Oversight and Scope of Practice of Medical Spas (Med-Spas)

Juliet F. Gibson, MD, Divya Srivastava, MD, and Rajiv I. Nijhawan, MD*

BACKGROUND The regulation of medical spas (med-spas) in the United States varies considerably from state to state with important ramifications for patient safety.

OBJECTIVE To describe the current state of med-spas in the United States and degree of medical oversight in these facilities.

MATERIALS AND METHODS Descriptive study based on web search and standardized phone interviews of med-spas in the most heavily populated cities in each state of the United States. Information obtained included the following: whether medical directors were listed; if so, whether they were advertised as being on site; medical directors' training and board certification; and services offered.

RESULTS Of 247 medical spas reviewed, 72% advertised a medical director on their website, and 6.5% claimed that the director was on site. Of listed medical directors, 41% were trained in dermatology and/or plastic surgery. In phone interviews, 79% of med-spas endorsed the medical director to be board certified, and 52% stated that the medical director was on site less than 50% of the time.

CONCLUSION There is significant variation in medical directorship and oversight among medical spas in the United States. Appropriate regulation of medical directors' training and the degree of oversight provided are warranted to optimize patient safety.

J.F. Gibson was awarded an American Society for Dermatologic Surgery (ASDS) Cutting Edge Research Grant for this study. The authors have indicated no significant interest with commercial supporters.

Medical spas (med-spas or medispas for short) are cosmetic facilities with varying degrees of oversight that offer minimally invasive cosmetic procedures (MICPs) in a spa-type setting for the purpose of well-being and/or appearance. Minimally invasive cosmetic procedures include cutaneous laser, fractional nonablative and ablative laser resurfacing, other laser/light based procedures, radiofrequency, ultrasound, injectable soft-tissue augmentation, neuromodulator toxin, and superficial to medium-depth chemical peels. The market for medical aesthetic procedures is several billion dollars annually and growing.[1] In fact, according the American Society for Dermatologic Surgery (ASDS), almost 2 million neuromodulator injections were performed in 2016 by ASDS members, a 50% increase in the last 5 years, and 1.35 million procedures involving soft-tissue fillers were performed during this year, a 48% increase in the same time frame.[2] Although most states require medical supervision, the definition of supervision is vague: some medical spas operate with physicians off site, and nonphysicians can perform most, if not all, services. Media reports of adverse events occurring in medical spas continue, identifying a potential need of greater regulation to ensure patient safety.

Regulation of medical spas occurs chiefly through state legislatures and medical boards. State laws vary: some states allow for naturopaths to serve as medical directors (Arizona), whereas others such as California have made significant changes in state law to define cosmetic

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procedures as medical procedures requiring the same degree of oversight as any other procedure (Assembly Bill No. 1548, 2012).[2] Among such variability, a representative of the American Med Spa Association estimated that half of the medical spas operating across the country are not in compliance with the law in 2015.[3] A recent study led by Catherine DiGiorgio examined laws and regulations of laser operators in the United States and showed that several states allow for laser procedures to be delegated to nonphysicians. The study also showed considerable variability in laws and regulations pertaining to the need for on-site physician supervision.[4]

Medical boards similarly offer variable regulations regarding physician oversight of medical spas. A 2012 survey study by Choudhry and colleagues showed wide variation across state medical boards regarding the rules for delegation and supervision of MICPs. These variations include on-site versus off-site supervision; the types and numbers of nonphysician providers who can be supervised; and the requirements for reporting adverse events.[5]

Cosmetic procedures have low complication rates,[6] but the risk is not negligible. A recent article by Vanaman and colleagues demonstrated complications in cosmetic dermatology ranging from temporary eyelid ptosis to glabellar necrosis and permanent blindness, both occurring in the setting of soft-tissue augmentation. In the setting of laser and energy therapies, risks range from temporary erythema to dyspigmentation, burns, and eye injury.[7–9] Of note, rates of complications are those reported by physicians, and the rates of complications by nonphysician operators are not known. Physicians receive significantly more hours of training than other medical professionals and are better equipped to manage complications from MICPs. Furthermore, plastic surgery and dermatology are 2 of the very few subspecialties in medicine in which there is an expectation for appropriate training in neurotoxin and soft-tissue augmentation. Most other specialties, by contrast, have no formal requirement for training in these procedures, although most med-spa directors are trained in these specialties. Not unexpectedly, Jalian and colleagues showed an increased frequency of litigation from MICPs over the past decade and later demonstrated that although nonphysician operators performed only one-third of hair removal cases, 75% of lawsuits were brought against nonphysician operators.[10,11]

With increasing concern regarding medical oversight and patient safety of med-spas voiced by the American Academy of Dermatology (AAD) and the ASDS[12,13] and shared by the general public, the authors sought to define the current state of physician overnight of medical spas. In this study, the authors aim to describe current variation in oversight and scope of practice in medical spas with the hope that this information may highlight areas of variation that may motivate changes in law and regulations governing medical spas.

Methods

This study is descriptive based on (1) World Wide Web search of popular medical spas in the United States and (2) phone interviews of the same cohort of med-spas. The authors elected to study the most heavily populated city in all 50 states of the United States to describe practices, which impact the largest population of US citizens within each state.

World Wide Web Search

Using Google search engine, the top 5 results using search terms "State City Med-spa" were obtained for each city from all 50 states being studied. These websites were reviewed for the following information: if there are physicians listed as medical directors; if so, if they are advertised as being on site; the specialty in which they are trained; and if they are advertised as being board certified and services offered including neuromodulators, fillers, chemical peels, microdermabrasion, cool sculpting, liposuction, ablative laser, nonablative laser, and laser hair removal.

Telephone Interviews

Telephone interviews of receptionists were completed using the list of medical spas created from the web search with the goal of corroborating website data and gaining additional information that may not have been listed on websites. Phone interviews were conducted over a period of 4 weeks. When med-spas were unable to be reached, 5 attempts were made on different days during this 4-week period.

- Hi, my name is_____, and I'm really interested to find out a little more about your med-spa. Do you mind if I I ask a few questions?
  - Is there a medical director or associated physician?
  - In what specialty is this physician trained?
  - Is this physician board certified?
  - Is the medical director on site?
  - If a physician needed to perform injectables (Botox, filler)?
  - Does the medical director perform no services?

Figure 1. Standardized script for telephone interview.

Telephone interviews were structured using a standardized script, and all med-spas were asked the same set of questions (Figure 1). Interviewees were asked if there is a medical director associated with the medical spa. For those with a medical director, further questions included if that person is board certified and the specialty in which the director is trained, whether the director is on site (>50% of time), if only physicians can perform injectables (neuromodulators and fillers), and if most (>50%) services are performed by a physician.

Statistical Methods

Information listed above was analyzed using statistics including absolute numbers and percentages.

Results

Two hundred forty-seven medical spas were identified from the web search, 5 from every state except Hawaii, which had only 2 medical spas accessible through web search for Honolulu, HI. Of these 247 medical spas, 50 (17%) listed multiple locations, and 47 (20.2%) were associated with a dermatology or plastic surgery practice.

Website review revealed that 71.7% (177/247) advertised a medical director and 55.1% (136/247) advertised the medical director as being board certified (See **Supplemental Digital Content 1**, Table, http://links.lww.com/DSS/A125). Only 16/247 (6.5%) med-spas specified that the medical director was on site

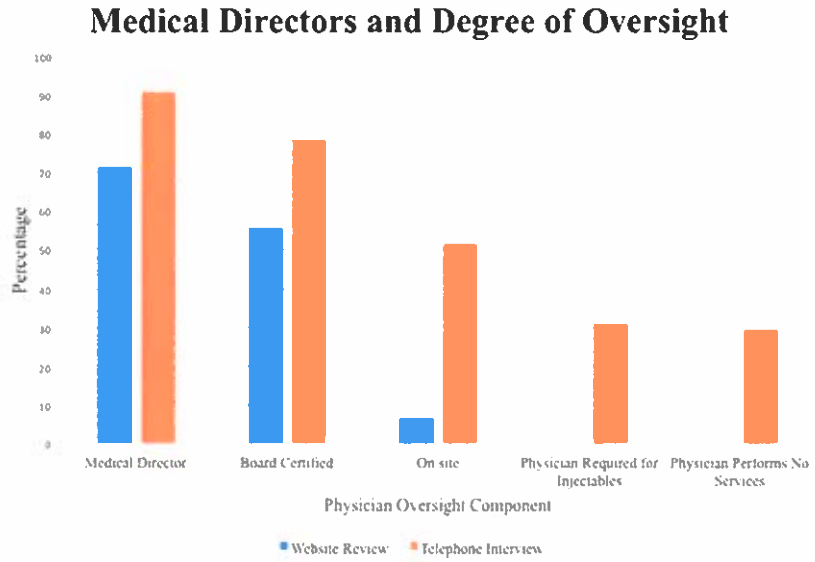

Figure 2. Physician oversight advertised on websites and as described through telephone interviews. MD, medical doctor.

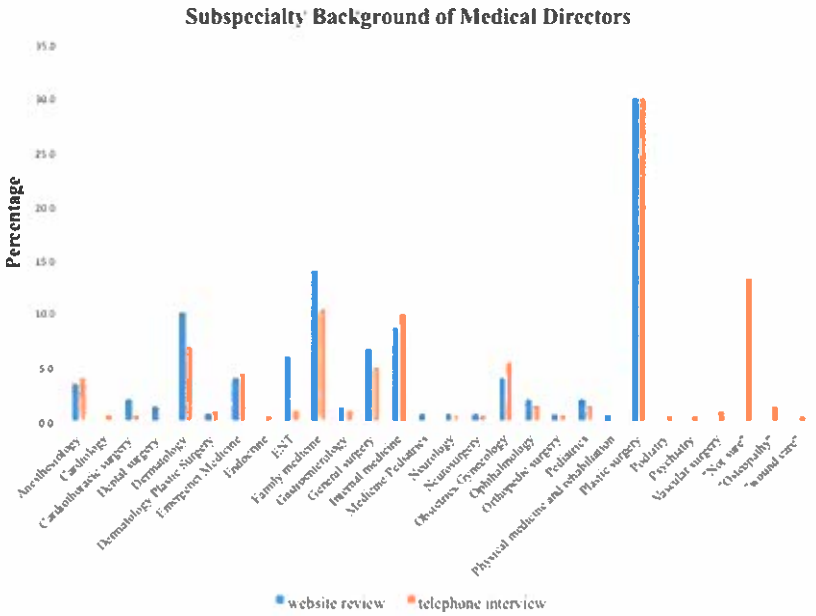

Figure 3. Medical subspecialties of medical directors as advertised on websites. Subspecialties found by website review (blue) include the following: plastic surgery (45), family medicine (21), dermatology (15), internal medicine (13), general surgery (10), otolaryngology (9), emergency medicine (6), obstetrics and gynecology (6), anesthesiology (5), cardiothoracic surgery (3), ophthalmology (3), pediatrics (3), dental surgery (2), gastroenterology (2), dual-trained dermatology and plastic surgery (1), medicine and pediatrics (1), neurology (1), neurosurgery (1), orthopedic surgery (1), and physical medicine and rehabilitation (1). Different information was found from phone interview where specialties listed include anesthesiology (8), cardiothoracic surgery (1), dermatology (14), dual-trained dermatology and plastic surgery (2), emergency medicine (9), otolaryngology (2), family medicine (21), gastroenterology (2), general surgery (10), internal medicine (20), neurology (1), neurosurgery (1), obstetrics and gynecology (11), ophthalmology (3), orthopedic surgery (1), pediatrics (3), and plastic surgery (61). Additional subspecialties listed that were not seen by website review included wound care (1), cardiology (1), endocrinology (1), podiatry (1), psychiatry (1), vascular surgery (2), and osteopathy (3).

(Figure 2). Of this 6.5%, 43% were plastic surgery or dermatology trained. Plastic surgery and dermatology accounted for only 40.9% by website review (Figure 3) of the 149 med-spas that reported subspecialties (See **Supplemental Digital Content 1**, Table, http://links.lww.com/DSS/A125). The most common services offered were neurotoxin, filler, chemical peels, nonablative laser, and laser hair removal (Figure 4).

Phone interviews were also attempted for all 247 med-spas. Although 229 medical spas were reached and amenable to questions, 2 refused to interview, and 207/229 (90.3%) reported a medical director. Of these, 180 med-spas reported subspecialties, and 27 med-spas were "unsure" of the specialty (See **Supplemental Digital Content 1**, Table, http://links.lww.com/DSS/A125). Some discrepancies occurred between subspecialties of medical directors obtained using phone interviews as compared to website review. Other types of medical directors listed included the following: nurse practitioner,[6] naturopathic provider,[4] and registered nurse.[1] Of those who participated in the authors' interview, 180/229 (78.6%) med-spas endorsed the medical director to be board certified. Of the medical spas with a medical director, only 52.1% (108/208) stated that the medical director was on site greater than 50% of the time. When specifically asked if only a physician can perform injectables (e.g., neuromodulators and filler), 72/229 (31.4%) responded "yes." On the other hand, 67/229 (29.3%) answered that most or all procedures were not performed by a physician.

States that had such nonphysician providers are shown in Figure 5 and **Supplemental Digital Content 2**, Table (http://links.lww.com/DSS/A126), and include Arizona (1 naturopath by website review and 3 naturopaths of 5 surveyed by phone), California (1 nurse practitioner (NP) by phone interview and website review), Idaho (1 NP by

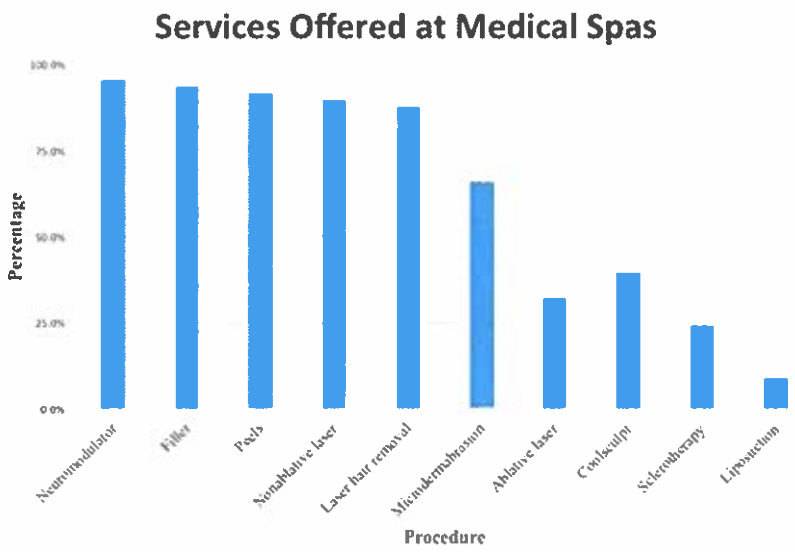

Figure 4. Procedures offered by medical spas surveyed (website). Neurotoxins (235/247; 95.1%), fillers (231/247; 93.5%), chemical peels (226/247; 91.5%), nonablative laser (221/247; 89.5%), laser hair removal (217/247; 87.9%), microdermabrasion (162/247; 65.6%), Coolsculpt (97/247; 39.3%), ablative laser (79/247; 32.0%), sclerotherapy (60/247; 24.3%), and liposuction (22/247; 8.9%).

website review and phone interview), Iowa (1 NP by phone interview), Kentucky (1 NP by website review), Montana (1 registered nurse (RN) by website review), New Hampshire (2 NP by phone interview), New Mexico (1 NP by website review and by phone interview), North Dakota (1 NP by phone interview), Oregon (1 naturopath by website review and phone interview), Rhode Island (1 RN by website review), and Washington (1 NP by website review). In Missouri, 2 medical spas listed the same medical director and when called, both said that the medical director performs no procedures. Figure 5 illustrates states that the authors found with the least amount of oversight as defined by only one medical spa sampled having a medical director or having an advertised medical director who is off site.

Discussion

The demand for cosmetic procedures has increased dramatically over the past decade, leading to a concurrent growth in the number of medical spas in the United States. With an increase in the number of MICPs come complications, which are best handled by trained physicians. States vary in regards to the regulation of cosmetic procedures, which is reflected in the authors' findings.

In this study, the authors demonstrate significant variation in medical directorship and oversight among medical spas in the United States. Most medical spas reported a physician as the medical director, but in a number of cases, information provided online was inconsistent with information obtained from telephone interview. This variability is seen in the distribution of medical directors across the various subspecialties. In 2 cases where a nonphysician was listed online, phone interview confirmed a medical director, 1 in vascular surgery and 1 where the receptionist was "not sure" of the specialty. Two medical spas provided a medical director of a naturopath when

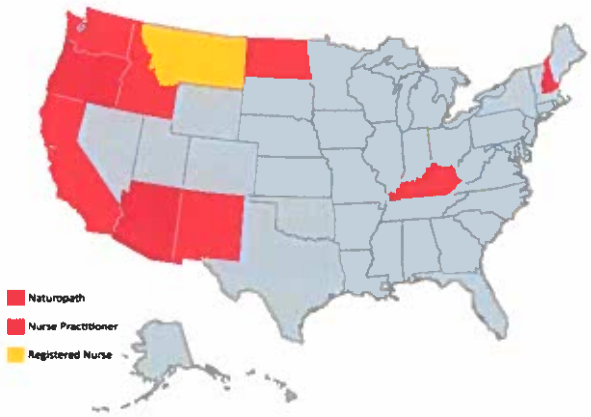

Figure 5. States with nonphysician medical directors by website review or phone interview.

the websites advertised a physician medical director. This inconsistency is concerning.

Medical directorship occurred across many medical specialties, including those with little to no training in MICPs. The authors provide examples of medical spas that have no physician oversight and are instead managed by nurse practitioners, nurses, and naturopaths. In this study, the authors found nonphysician medical directors in 8 medical spas by website review and 11 from phone interview. This finding has implications for patient safety. Although a doctorate of nursing on average requires 500 to 900 clinical hours, physicians complete 10,000 clinical hours in residency on average.[14] This training is not unimportant, given the potential for adverse outcomes in MICPs. Medical boards are limited in their ability to regulate nonmedical professionals such as aestheticians and technicians, whom the authors show to perform a large number of MICPs: nearly 30% of medical spas admitted on phone interview that the medical director performs no MICPs. In addition, not only are there medical board regulations, but also nursing board regulations. An article by Gillum and Dellavalle[15] in 2013 outlined cases of contradictory regulations created by medical and nursing boards in regards to laser treatments in Kentucky and Louisiana. The study also alluded to facilities in each state that operate without the oversight of a physician, a finding the authors corroborate in this study given that most medical spas operate with a physician off site and another 29% offer services, all of which are not provided by a physician. The authors highlight states that may most benefit from legislative change in Figure 5.

From this study, the authors offer 3 recommendations. First, the authors recommend standardization of state law to define cosmetic procedures as medical treatments that require the same regulation as any other medical procedure. In 2012, California enacted laws defining cosmetic procedures as medical treatments and thus subject to the same laws as medical procedures, along with a requirement that medical businesses be owned at least 51 percent by a physician and the remainder by a licensed practitioner, such as a nurse, and that a physician or advanced practitioner examine patients before any treatments are administered. The authors support making this type of legislation uniform among all states.

Second, the authors recommend that medical directors should be board-certified physicians with appropriate training in MICPs and with appropriate oversight by the state medical board. Finally, the authors recommend that the relevant specialty societies such as ASDS, AAD, American Society of Plastic Surgeons (ASPS), and American Society for Laser, Medicine, and Surgery (ASLMS) offer resources for their member medical directors to pursue additional training in MICPs.

Limitations to this study include its descriptive nature and design. The authors sampled medical spas across the United States based on a Google World Wide Web search. These data may not capture smaller medical spas that do not have an active internet presence but may be popular in a given area. Furthermore, they may reflect medical spas that are more tightly regulated given the ease of scrutiny through website review. The nature of the authors' telephone interview is also biased in that they chose to interview receptionists rather than physicians. The authors felt receptionists were the first line of advertising to a given patient over the phone, but it is possible that data accumulated from physicians, nurses, or aestheticians could be different. The authors' study reports a lack of oversight by many medical directors who are not on site and do not perform procedures. Future studies should examine how many medical spas are not in compliance with state laws and how often disciplinary actions are taken against medical spas/directors.

In conclusion, there is significant variation in medical directorship and oversight among medical spas in the United States. Proper oversight of procedures that are deemed to be medical and surgical interventions at medical spas is imperative given the risks associated with each of these procedures. The authors support standardized regulation regarding medical directors' training and experience as well as the degree of oversight they exercise to optimize patient safety.

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The Differences in the Practice of Cosmetic Dermatologic Procedures Between Physicians and Nonphysicians

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BACKGROUND With a rise in demand for cosmetic dermatologic procedures comes an increase in nonphysician providers performing such procedures. However, little is known about the practice of cosmetic procedures performed by nonphysicians.

OBJECTIVE To assess the differences in the practice of cosmetic procedures provided by physicians and nonphysicians.

MATERIALS AND METHODS A cross-sectional analysis was performed using participant ($n = 4,062$) responses to an 18-point, web-based survey about previous cosmetic procedures.

RESULTS In total, 1,328 participants reported having previous cosmetic procedures done by a physician ($n = 828$), a nonphysician ($n = 413$), or an unknown provider ($n = 87$). Respondents of all age ranges and male respondents ($p < .001$) tended to choose physicians over nonphysician providers when choosing a practice. Moderate adverse events were more frequently seen when nonphysician providers completed cosmetic procedures ($p < .001$). Despite a higher frequency (73.3% vs 51.8%) of more moderate complications seen in procedures done by nonphysician providers, over 70% of respondents believe that nonphysician providers are qualified enough to continue performing cosmetic procedures.

CONCLUSION People should be encouraged to make an informed decision when choosing a provider because cosmetic procedures are still considered medical procedures.

Cosmetic dermatologic procedures, such as neurotoxins, fillers, laser hair removal, or chemical peels, have become increasingly popular in the United States during recent years. According to the American Society for Dermatologic Surgery (ASDS), there was an increase in the number of cosmetic procedures completed in the United States, rising from 12.5 million procedures in 2018 to 14 million procedures in 2019.[1,2] With an increasing demand for cosmetic dermatologic procedures, there is an accompanying rise of nonphysician providers performing cosmetic procedures in nonmedical settings. As delegated by 48% of state boards, unlicensed nonphysician providers are permitted to perform cosmetic procedures under the assumption that there has been adequate training.[3] However, in a 2014 survey conducted by Rossi and colleagues,[4] there was a higher number of skin discoloration and burns when cosmetic procedures were performed by nonphysicians in a spa setting, with improper technique by nonphysician providers being the most common cause.

A different study done in millennials, defined as those born between 1981 and 1996, found that 70% of surveyed patients thought that physician practices were"more trustworthy" in comparison with medical spas.[3] In total, 72% of the surveyed patients reported interest in returning for future procedures done at a physician practice, but only 56% of patients indicated that they were interested in returning to a medical spa, with credentials, safety, and reputation cited as the most highly valued parameters for selecting or reselecting a practice.[3] Although research has established that patients tend to prefer physician practices to medical spas likely because of implied greater safety, there is little literature that explores patient-reported complications of procedures done by physicians compared with nonphysicians.

Although increasingly common to have cosmetic procedures done by nonphysician providers, patient safety in such situations continue to be a concern. The purpose of this study was to compare patient-reported differences in the practice of cosmetic procedures performed by physicians and nonphysicians.

Methods

An 18-point, web-based targeted survey pertaining to previous cosmetic procedures was delivered through

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electronic mail to respondents 18 years of age and above, in all regions of the United States using Survey Monkey (http://www.SurveyMonkey.com). Respondents answered by completing and returning the survey electronically via the web.

The survey contained multiple-choice questions regarding the type of provider, the location where the procedure was performed in, adverse events, influential factors in choosing a provider, and perceptions regarding type of provider.

A cross-sectional analysis was performed using participant (n = 4,062) responses to the web-based survey. Written informed consent was obtained for each participant. Responses were analyzed using Chi-square test for categorical variables and the t-test for continuous variables, with $p < .05$ considered statistically significant.

Results

Of the 4,026 survey participants, 1,328 participants (33%) reported that they had previous cosmetic procedures done by a physician (n = 828, 62%), a nonphysician (n = 413, 31%), or an unknown provider (n = 87, 7%). Physician providers were most commonly dermatologists, plastic surgeons, and facial plastic surgeons, whereas nonphysician providers were most commonly estheticians/cosmetologists, physician assistants, nurses, medical assistants, and medical spa employees. Of the providers performing procedures, dermatologists comprised 48% of physicians and estheticians/cosmetologists comprised 42% of nonphysicians.

Respondents Demographics

Respondents within ages 25 to 34 years were more likely to have cosmetic procedures (p = .002). The most common respondents to the survey were respondents residing in Southern US regions and reporting an annual household income of $50,000–74,999. Respondents in all groups tended to select physician providers more often than nonphysician providers for procedures (Table 1). Male respondents were significantly more likely to have their cosmetic procedures done by physicians, whereas female respondents were more likely to have procedures done by nonphysician providers ($p < .001$).

Cosmetic Procedure Providers

In all surveyed procedure types, physicians were more often the performing provider, with laser hair removal treatments as the least frequent procedures done by physicians (55% of all providers), but the most frequent procedures done by nonphysician providers (37% of all providers). Moreover, hair transplantation was done by mostly physicians (79% of all providers). Laser and light treatments, chemical peels, laser hair removal treatments, and microdermabrasions were outsourced to nonphysician providers approximately one-third of the time (Figure 1).

There was a significant difference in severity of adverse events when cosmetic procedures were performed by physicians compared with nonphysician providers ($p < .001$). Respondents reported having more moderate adverse events when having cosmetic procedures done by a nonphysician provider (n = 55, 73.3%), whereas respondents reported having more mild than moderate or severe adverse events when procedures were done by a physician provider (n = 125, 41.8%). There was no statistically significant difference in adverse events between different physician specialties.

Influential Factors in Choosing a Provider

The most influential factor for choosing any provider (physician and nonphysician) was a referral from a physician. Most respondents who ultimately chose a nonphysician over a physician cited price as the reason (Table 2).

Perceptions Regarding the Type of Provider

In total, 70.3% of the respondents (n = 394) believed that nonphysicians were qualified to perform cosmetic procedures. The most commonly cited reason for belief that nonphysician providers were not qualified being "inadequate level of training" (n = 295, 74.9%). Patient suggestions to limit frequency of adverse events included having a physician in the room or on-site during procedures, more thorough training or certification processes, and restricting the scope of practice for nonphysician providers to only performing less invasive cosmetic procedures.

Discussion

Although approximately one-third of cosmetic procedures done are performed by nonphysician providers, the survey results demonstrate that adverse events after procedures completed by nonphysician providers are more likely to be greater in severity than complications after procedures completed by physician providers. Furthermore, many cosmetic procedures are being performed by estheticians/cosmetologists. Men were more likely to choose physicians over nonphysicians for their cosmetic treatments. There were no significant differences in the practice of cosmetic procedures performed by the different specialties of physicians.

A potential explanation could be the robust surgical training and anatomy education through exposure to cadavers in medical schools that build the foundation of cosmetic procedures. Further, longer educational and training requirements mandated of physicians in comparison with nonphysician providers. After obtaining a baccalaureate/bachelor's degree from an accredited university, physicians are required to undergo a minimum 7 years of medical training, pass an end-of-residency examination to become officially board certified for independent practice, and fulfill Maintenance of Certification requirements by passing a recertification examination every 10 years.[5] In contrast, in Pennsylvania, estheticians are

TABLE 1. Demographics of Respondents Who had Cosmetic Procedures

% of Provider Type	Physicians	Nonphysicians	Unknown	*p*
Age (yr)				.002
25–34 (*n* = 342)	65.79	25.15	9.06	
35–44 (*n* = 419)	66.35	27.45	6.21	
45–54 (*n* = 349)	59.03	35.53	5.44	
>55 (*n* = 217)	54.38	40.55	5.07	
Gender				<.001
Male (*n* = 540)	73.33	19.81	6.85	
Female (*n* = 774)	54.91	38.76	6.33	
Region of residence in the United States				.114
Northeast (*n* = 290)	66.90	26.90	6.21	
Midwest (*n* = 215)	56.28	37.21	6.51	
South (*n* = 439)	62.41	31.21	6.38	
West (*n* = 371)	63.34	29.65	7.01	
Household income ($)				.162
50,000–74,999 (*n* = 444)	63.51	28.15	8.33	
75,000–99,999 (*n* = 318)	60.38	32.70	6.92	
100,000–124,999 (*n* = 230)	58.26	36.09	5.65	
125,000–149,999 (*n* = 154)	68.18	28.57	3.25	
150,000–174,999 (*n* = 117)	59.83	35.04	5.13	
175,000–199,999 (*n* = 54)	64.81	29.63	5.56	

Respondents who more frequently elected to have cosmetic procedures done were those aged 25 to 34 years ($p = .002$), residing in the Southern region of the United States ($p = .114$), and had an annual household income of $50,000–74,999 ($p = .162$). Overall, physicians were more commonly selected by patients to conduct cosmetic procedures than nonphysician providers.

required to obtain a 10th grade equivalence of education, complete 300 hours of skin care education at an accredited cosmetology school, and pass an end-of-training examination issued by the State Board of Cosmetology with no continuing education requirements. Requirements for estheticians may fluctuate per state, but do so only minimally.[6] Physician assistants are required to obtain a baccalaureate/bachelor's degree, graduate from an accredited 2 to 2½ years of PA program, pass the Physician Assistants National Certifying Examination to become certified for practice, and fulfill continuing education requirements by completing 100 hours of education credits per 2 years and passing a recertification examination every 10 years.[7]

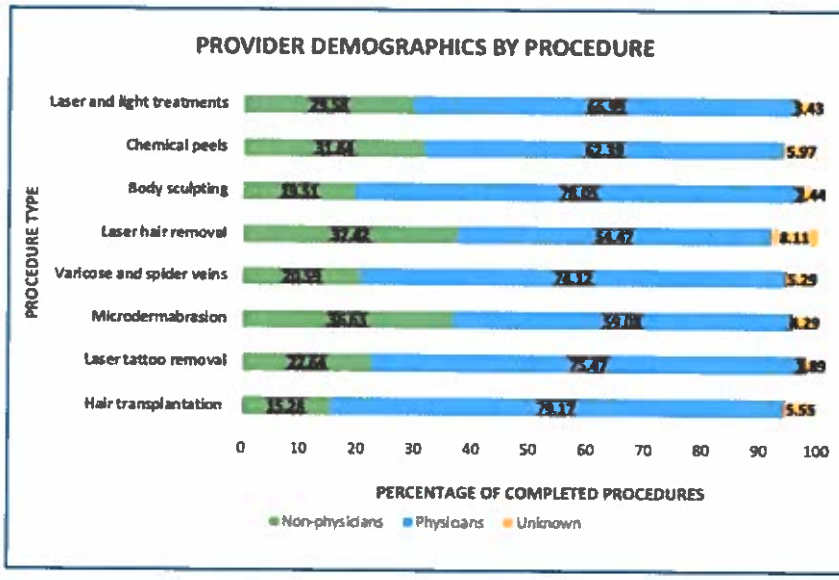

Figure 1. Provider licensing demographics with respect to procedure. Although all procedures were more frequently performed by physicians, approximately one-third of laser and light treatments, chemical peels, laser hair removal treatments, and microdermabrasions were completed by nonphysician providers.

TABLE 2. Patient-Reported Reasons for Choosing Physician or Nonphysician Providers for Cosmetic Procedures

	Physician, %	Nonphysician, %	Unsure, %
Referral from a physician	66.81	25.73	7.46
Referral from a friend	55.70	36.69	7.60
Being affiliated with a professional organization	65.72	28.09	6.19
The specialty in which the physician is board-certified	67.81	26.52	5.67
The level of licensure of the practitioner (i.e. physician, nurse, physician assistant, and cosmetologist)	59.77	34.10	6.13
The location of the practitioner	59.14	35.80	5.06
Physician or practice website	73.14	24.00	2.86
Being a pioneer in the field	75.00	24.22	0.78
Before-and-after photographs	59.83	32.05	8.12
Number of procedures performed by the practitioner	56.46	40.82	2.72
Price	42.50	47.50	10.00

The most frequently cited reasons that patients selected a physician were the physician's reputation as a "pioneer" in the field, the physician's or practice website, and the physician's specialty. Patients most commonly reported selecting nonphysician providers because of price, number of procedures performed by the provider, and referrals from friends.

Although overlap of educational content may occur between different types of providers, greater quantity and quality of research demonstrates improved patient outcomes and avoided medical emergencies. Furthermore, in a study investigating who pioneered the field of cosmetic procedures, dermatologists were found to be the top contributors to most cosmetic procedures.[8] Furthermore, one study examined the impact of an additional seminar in caring for asthmatic patients. Pediatricians who completed the seminar more frequently appropriately prescribed corticosteroid treatments and provided adequate patient education than physicians who did not attend the seminar, resulting in significantly fewer symptoms, necessary follow-up visits, crises requiring emergency medical attention, and hospitalizations.[9] Given the significant improvement that even a single seminar of further medical education provided to better patient outcomes, longer and consequently more thorough educational requirements for cosmetologists, as similarly mandated of physicians, could be key to ensuring patient safety and satisfaction with cosmetic procedures.

Although the study data demonstrates that physicians continue to more frequently perform all surveyed procedures, approximately one-third of laser and light treatments, chemical peels, laser hair removal treatments, and microdermabrasions are, concerningly, outsourced to nonphysician providers. In a survey completed by the ASDS, physicians reported that 61% to 100% of their complication treatments stemmed from procedures completed at medical spas, which are more likely to employ nonphysician providers such as estheticians or cosmetologists.[10] Furthermore, quantitative evidence supported that the most common treatments leading to complications were laser hair removal treatments, fillers, and intense pulsed light.[10] Although one-third of laser hair removal is performed by nonphysicians, Jalian and colleagues[11] reported that 75.5% of hair removal lawsuits from 2004 to 2012 were performed by nonphysicians. Allowing for nonphysician providers to perform treatments evidenced to more frequently lead to complications requiring physician treatment (i.e. laser treatments) at such a high frequency and without guideline change is likely to worsen patient safety prospects moving forward. The ASDS study concluded that 58.8% of the physicians categorized procedures completed at medical spas to be "very" or "extremely" endangering towards patient safety, with 95.8% of the physicians desiring stricter regulations on procedures available at medical spas.[10] In addition to more thorough education requirements, stricter regulations can doubly serve as a line of defense against complications arising from cosmetic procedures.

Although moderate adverse complications were more likely to occur when procedures were performed by a nonphysician in comparison with a physician provider, approximately 70% of respondents believe that nonphysicians are qualified to complete cosmetic procedures. These results may reflect either an unawareness of complication frequency in relation to licensing status of providers or the growing sentiment that nonphysician providers can provide care that is a satisfactory substitute for physician care. In a 2016 study investigating patient perceptions about nurse practitioners in comparison to physicians, patients reported

feeling that nurse practitioners were more holistic in their care.[12] Furthermore, patients reasoned that picking a provider with more experience was more important during selection than provider type, thus influencing patients to pick nurse practitioners who fit these conditions.[12] As such, the current cosmetic landscape has begun to shift toward patients more commonly selecting nonphysician providers for completion of cosmetic procedures.

Factors that may influence whether respondents choose physicians or non-physician providers included sex and procedure costs. As found in the study results, men were more likely to see physicians than nonphysician providers for cosmetic procedures, possibly because of who is more likely to provide referrals. An interview study found that men often underuse health care services because of the societal pressure for men to appear invulnerable, immune, and without need for help.[13] The findings implicate that men may choose to confide directly in physicians for referrals of cosmetic procedures to avoid demonstrating help-seeking behavior in their personal social circles. As physicians are more likely to refer to other physicians or nonphysician providers within their own practice, men may be choosing to see physicians more often than nonphysician providers for cosmetic procedures simply because of who they have asked for advice. However, no confirmatory data are currently available. Price also plays a large role in the choosing of a provider. As shown by the normality of medical tourism, a phenomenon in which patients will seek to complete cosmetic or health procedures outside of one's own home country in favor of cheaper costs despite the many risks (i.e. infection), patients may choose nonphysician providers for lower prices.[14]

Limitations of the study included self-reporting bias and recall of events, as well as patient subjective judgment of severity of adverse outcomes of cosmetic procedures (i.e. mild, moderate, or severe).

Findings of this study support that patient safety is more compromised when nonphysician providers, rather than physicians, complete cosmetic procedures. As respondents indicated in this survey, more rigorous training for nonphysician providers performing cosmetic procedures, ensuring a physician is readily available to reverse complications, or limiting the scope of practice for nonphysician providers may be essential for preventing adverse events. On a consumer level, having more accessible information explaining the differences of training, experience, and qualifications between physicians and nonphysician providers may allow consumers to more accurately perform cost–benefit analyses when deciding on a practice.

Conclusion

The surge in popularity of cosmetic procedures is currently being met by an increase of nonphysician providers completing cosmetic procedures in addition to physicians. However, adverse effects that occur under the care of a nonphysician provider tend to be more severe than adverse outcomes that occur under physicians. Although people may ultimately choose to have procedures done by nonphysicians because of referrals or reduced costs, patient safety and satisfaction should always remain the utmost priority, which may necessitate encouraging people to make an informed decision when choosing a provider.

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Nonphysician Practice of Cosmetic Dermatology: A Patient and Physician Perspective of Outcomes and Adverse Events

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BACKGROUND Nonphysicians are expanding practice into specialty medicine. There are limited studies on patient and physician perspectives as well as safety outcomes regarding the nonphysician practice of cosmetic procedures.

OBJECTIVE To identify the patient (consumer) and physician perspective on preferences, adverse events, and outcomes following cosmetic dermatology procedures performed by physicians and nonphysicians.

MATERIALS AND METHODS Internet-based surveys were administered to consumers of cosmetic procedures and physician members of the American Society for Dermatologic Surgery. Descriptive statistics and graphical methods were used to assess responses. Comparisons between groups were based on contingency chi-square analyses and Fisher exact tests.

RESULTS Two thousand one hundred sixteen commenced the patient survey with 401 having had a cosmetic procedure performed. Fifty adverse events were reported. A higher number of burns and discoloration occurred in the nonphysician–treated group and took place more often in a spa setting. Individuals seeing nonphysicians cited motivating factors such as level of licensure (type) of nonphysician, a referral from a friend, price, and the location of the practitioner. Improper technique by the nonphysician was cited most as a reason for the adverse event. Both groups agree that more regulation should be placed on who can perform cosmetic procedures. Recall bias associated with survey data.

CONCLUSION Patients treated by nonphysicians experienced more burns and discoloration compared with physicians, and they are encountering these nonphysicians outside a traditional medical office, which are important from a patient safety and regulatory standpoint. Motivating factors for patients seeking cosmetic procedures may also factor into the choice of provider.

KEY POINTS Both patients and physicians think more regulation should be in place on who can perform cosmetic procedures. More adverse events such as burns and discolorations occurred with patients seeing nonphysicians compared with those seeing physicians. In addition, for those seeing nonphysicians, a majority of these encounters took place in spa settings. Patient safety is of utmost concern when it comes to elective cosmetic medical procedures. More adverse events and encounters occurring outside traditional medical settings when nonphysicians performed these procedures call into question the required training and oversight needed for such procedures.

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There is an ongoing increase in the demand for medical, surgical, and cosmetic procedures.[1] According to the 2016 American Society for Dermatologic Surgery (ASDS) Survey on Dermatologic Procedures, members saw a significant increase in minimally invasive cosmetic treatments over the prior year. In 2016, there were over 3.3 million injectable neuromodulators and soft-tissue

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filler procedures performed, and nearly 2.8 million were laser/light/energy-based procedures. In the past 5 years, there has been a 48% increase seen in soft-tissue filler procedures and 2.5 times increase in body contouring procedures performed.[2] Furthermore, the 2017 ASDS Consumer Survey on Cosmetic Dermatologic Procedures found that of the 7,322 people surveyed, nearly 7 in 10 are considering a cosmetic procedure. The top 4 of 11 factors influencing the selection of a practitioner included: price (49%), specialty in which the physician is board certified (41%), referral from a physician (37%), and level of licensure of the practitioner (32%).[3] This increased demand for cosmetic services has resulted in a substantial influx of nonphysicians offering cosmetic procedures and patients turning to nonphysicians for aesthetic medical treatments.[4] Nonphysicians are also starting to practice medicine independently in some states. Although originally intended for the shortage of primary care physicians, nonphysician providers (aestheticians, nurses, physician assistants, and nurse practitioners) are entering into specialty medical fields, even though formal medical training in these areas may be lacking. This is concerning from a patient safety standpoint.

Increasingly, nonphysicians are offering cosmetic procedures in a multitude of medical and nonmedical arenas. The boundaries between cosmetic surgery and cosmetology are obscured, with procedures being performed on otherwise healthy individuals by nonphysicians.[5] Although often promoted as a "quick fix," real risks and complications associated with these procedures may be marginalized.

Studies have also shown that dermatologists and nondermatologist physicians delegate cosmetic procedures to nonphysician providers to keep up with growth in demand.[4] This study seeks to determine the outcomes of cosmetic procedures performed by physicians and nonphysicians as well as the patient and physician perspectives of such. The authors describe the incidence and scope of adverse events as reported by both consumers and physicians. A better understanding of these outcomes will help guide physician oversight of these procedures and the training and regulations required of those who perform these procedures to ensure patient safety.

Methods

With IRB approval, Internet-based surveys (Survey Monkey: http://www.SurveyMonkey.com) were administered to consumers of cosmetic dermatology procedures and physician members of the ASDS. The consumer survey was web-based and opened by 2,116 consumers nationally via SurveyMonkey, which allows surveys to be distributed to a random prescreened population. The English language survey was distributed via email. The survey contained 24 multiple-choice questions related to provider type, setting where services were provided, and adverse events. Based on the question, participants were allowed to choose single or multiple responses, and responders were able to skip questions or stop the survey at any time (see **Supplemental Digital Content 1**, Appendix, http://links.lww.com/DSS/A131).

A separate physician survey was sent to members of the ASDS via email. This survey assessed members' opinions and experiences with cosmetic procedures performed by nonphysicians (see **Supplemental Digital Content 1**, Appendix, http://links.lww.com/DSS/A131).

After acquiring completed surveys, each was assessed individually by the investigators. Participants were allowed to stop the survey at any point and were allowed to skip questions. Statistical analysis and comparisons between groups were based on contingency chi-square analyses and Fisher exact tests.

Results

Consumer Survey (N = 2,116)

Demographics

Of the 2,116 surveys commenced by consumers, over half (55.9%) indicated that they either had a cosmetic procedure (19.1%, 401/2,098) or were considering having a cosmetic procedure (36.8%, 773/2,098)

TABLE 1. Demographics of Consumers

Descriptor	*Percent*
Gender	
Female	95.4
Male	4.6
Age	
Under 30	0.1
30–40	21.1
41–50	24.4
51–60	37.7
Over 60	16.6
Employment status	
Full time	69.0
Part time	10.9
Unemployed	1.9
Homemaker/retired/other	18.1

(Table 1). Of the patients who received cosmetic procedures, 145 went to a physician, 144 saw nonphysicians, and 97 have had procedures done by both physicians and nonphysicians. The remaining responders did not know the level of training of the individual who performed the procedure.

Scope of Procedures and Providers

The most common procedures consumers received were laser hair removal, injectable wrinkle-relaxing treatments, microdermabrasion, chemical peels, and injectable filler treatments (Table 2). Table 2 includes the breakdown of procedures reported to be done by nonphysicians as well as the percent of adverse events per procedure. Of the respondents who had a cosmetic procedure done by only a nonphysician, the top procedures performed included: laser hair removal, 49% (71); microdermabrasion, 35.9% (52); chemical peels, 23.4% (34); laser and light devices for facial problems, 13.8% (20); and injectable wrinkle-relaxing treatments, 13.1% (19). Most procedures performed by physicians were done by either a plastic surgeon (33.1%) or a dermatologist (32.3%). Other types of physicians included family practitioners, otolaryngologists, and vascular specialists (responders were able to choose more than one if applicable). Of the procedures performed by nonphysicians, the majority was performed by an aesthetician (43.5%) followed by a nurse (21.9%) (Table 3). Other nonphysician providers included nurse practitioners and laser technician.

Location of Cosmetic Procedures

The vast majority of consumer respondents who had their procedure performed by a physician identified the location as the physician's office (87.6%) ($p < .0001$). This was followed by a spa location (4.1%) or an aesthetician's office. By contrast, for patients who had their procedures performed by nonphysicians, this most often took place in a spa (36.8%, $p < .001$), followed by an aesthetician's office (25.7%, $p < .001$) and a physician's office (22.2%) (Table 4 and Figure 1).

Adverse Events

Fifty of the 404 respondents who had cosmetic procedures reported an adverse event (Table 5 and Figures 2 and 3). A total of 54% ($n = 27$) occurred in patients who saw physicians and 46% ($n = 23$) in patients who saw nonphysicians. The most common adverse events occurring in procedures performed by physicians were: "bruising" (40.7%, $n = 11$), "discoloration" (14.8%, $n = 4$), "scarring" (14.8%, $n = 4$), and "nerve damage" (14.8%, $n = 4$). In procedures performed by nonphysicians, the most common adverse events were "discoloration" (43.4%, $n = 10$), "burn" (34.7%, $n = 8$), and "bruising" (26.1%, $n = 6$)

TABLE 2. Consumer Survey: Scope of Cosmetic Procedures and Adverse Events

Procedure	*Total Number, N = 401, (%)*	*Nonphysician Procedures, N Answered = 144, (%)*	*Physician Procedures, N Answered = 149, (%)*	*n = Total No. of Participants Who Experienced a Complication*	*Percentage of Total Complications*
Laser hair removal	132 (33.0)	71 (49)	21 (14.1)	20	12.58
Injectable wrinkle-relaxing treatments	121 (30.3)	19 (13.1)	49 (32.9)	26	16.35
Microdermabrasion	120 (30.0)	52 (35.9)	120 (30.0)	21	13.21
Chemical peels	98 (24.5)	34 (23.4)	98 (24.5)	12	7.55
Laser and light treatment to reduce redness, improve skin tone, or improve scars	85 (21.3)	20 (13.8)	85 (21.3)	19	11.95
Injectable filler treatments	75 (18.8)	11 (7.6)	75 (18.8)	22	13.84
Varicose or spider vein treatments	72 (18.0)	8 (5.5)	72 (18.0)	15	9.43
Body sculpting (e.g., cryolipolysis, laser lipolysis, tumescent liposuction, and ultrasound fat reduction)	60 (15.0)	3 (2.1)	60 (15.0)	9	5.66
Ultrasound, laser, light, and radiofrequency treatments for skin tightening and wrinkle smoothing	50 (12.5)	10 (15.3)	50 (12.5)	11	6.92
Laser tattoo removal	6 (1.5)	2 (1.4)	6 (1.5)	3	1.89
Hair transplantation	3 (0.8)	1 (0.7)	3 (0.8)	1	0.63

Respondent can select multiple responses.

(Table 5). The difference in rates of discoloration and burns was significantly higher in procedures performed by nonphysicians compared with physicians ($p < .03$) (Figure 2). The occurrence of nerve damage after procedures performed was cited in 4 cases by the responders. All 4 physicians performing these were cited as nondermatologist physicians and the procedures performed included

TABLE 3. Consumer Survey: Provider Performing the Cosmetic Procedure (Responders Were Able to Choose More Than One)

Provider	*Number (%), N (%)*
Physician	
Plastic surgeon	82 (33.1)
Dermatologist	80 (32.3)
Facial plastic surgeon	21 (8.5)
Oculoplastic surgeon	2 (0.8)
I do not know	27 (10.9)
Other type of physician	36 (14.5)
Nonphysician	
Aesthetician	117 (43.5)
Nurse	59 (21.9)
Spa staff (other than aesthetician)	32 (11.9)
Physician assistant	17 (6.3)
I do not know	27 (10.0)
Other type of nonphysician	10 (3.7)

TABLE 4. Consumer Survey: Location of the Cosmetic Procedure by Provider (Responders Were Able to Choose More Than One)

Location	*Physician Provider*	*Nonphysician Provider*	*Fisher Exact p**
Physician's office	127	32	<.0001*
Dental office	1	1	.749
Nurse's office	0	9	.002*
Aesthetician's office	6	37	<.001*
Physician assistance's office	1	2	.497
Spa	6	53	<.001*
I do not know	4	10	.082

*Statistically significant between the 2 groups compared.

neurotoxin (1), body sculpting (2), and varicose vein treatment (1). When adverse events are further sorted between dermatologists, plastic surgeons, other physicians, and nonphysicians, the rates of discolorations and burns are still higher for nonphysicians (Figure 3).

Consumer Viewpoint of Provider Qualifications

Consumers were asked which nonphysician providers were qualified to perform cosmetic procedures. A majority of respondents felt physician assistants (68.0%) and nurses (57.3%) were qualified to perform cosmetic medical procedures. Conversely, a majority felt that medical assistants (70.7%), aestheticians (57.9%), and spa staff other than aestheticians (90.8%) were not qualified (multiple responses were accepted).

If consumers selected "no," indicating that a particular group was not qualified to perform cosmetic medical procedures, 34.1% said it was because the individual was not a physician. Greater percentages of respondents said it was due to a lack of training (47.5%) or an inadequate level of training (75.4%). Responses under "other" included a "lack of accountability," "lack of experience handling difficult cases," and "no certifying or supervisory agency."

Consumer Motivation to Choose Provider

Consumers were asked what factors were important when choosing a provider for their cosmetic procedure (Figure 4). Of individuals who responded to this question and saw a physician ($n = 140$), the most important factors were board certification of physician (66.4%, $n = 93$, $p < .0001$), referral from a physician (59.3%, $n = 83$), number of procedures performed (37.1%, $n = 52$), and level of licensure of physician (36.4%, $n = 51$). For those who responded to this question and saw nonphysicians ($n = 137$), the most important factors were level of

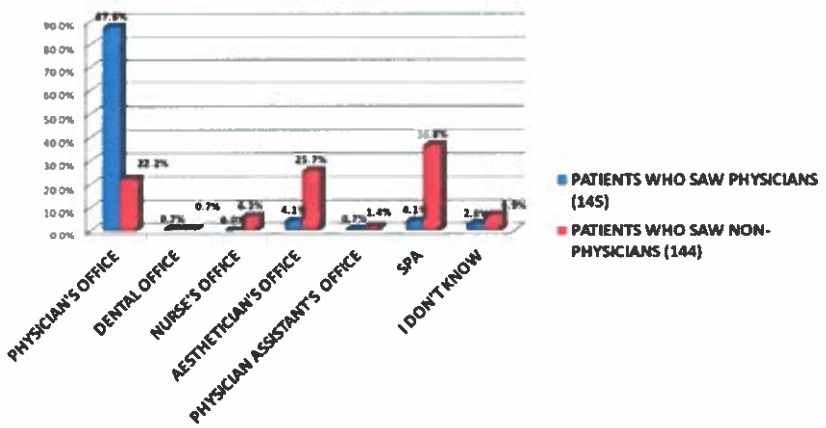

Figure 1. Graph of location of the cosmetic procedure by a provider (responders were able to choose more than one).

TABLE 5. Consumer Survey: Statistically Significant Adverse Events by a Provider (Responders Were Able to Choose More Than One)

Adverse Event	*Physician Provider (N = 27 Responded), N (%)*	*Nonphysician Provider (N = 23 Responded), N (%)*	*Fisher Exact p*
Discoloration	4 (14.8)	10 (43.5)	.031*
Burn	2 (7.4)	8 (34.8)	.03*

*Statistically significant between groups.

licensure (59.1%, $n = 81$, $p < .0001$), referral from a physician (48.2%, $n = 66$), and referral from a friend (41.6%, $n = 57$, $p < .05$). Price ($p = .053$) and the location of the practitioner ($p < .005$) were also important for those seeing nonphysicians. Consumers who responded with the "other" option cited patient reviews, web sites, and the complexity of the procedure as motivating factors for choosing a practitioner.

Physician Survey (N = 118 Responses)

Dermatologic Surgeon Treatment of Cosmetic Complications

This survey assessed the types of complications that physicians have encountered with cosmetic procedures performed by nonphysicians. Of the 118 ASDS members who responded to the survey, 65 (55%) stated that they treated a complication from a cosmetic procedure performed by a nonphysician. Most respondents (43.1%) reported treating 1 to 3 complications, whereas 24.6% treated 4 to 6 complications, and 7.7% treated complications 7 to 9 times. Nearly a quarter of respondents (24.6%) reported treating 10 or more cases of complications resulting from cosmetic procedures performed by nonphysicians (Figure 5).

American Society for Dermatologic Surgery members were then asked to select which types of complications they observed following cosmetic procedures performed by nonphysicians. The most common adverse event was a burn (67.2%) followed by misplacement of a filler product (53.1%). Other common complications included facial drooping (34.4%), tissue deformity (29.7%), and bruising (28.1%). "Other" responses included hypopigmentation or hyperpigmentation, leg ulcers, and scarring (Figure 5).

Physicians were then asked to evaluate the most likely contributing factors for the adverse events that were encountered. The most common response was improper technique (43.8%) followed by improper settings (12.5%). Less than 10% of complications were considered an expected adverse event (Figure 6).

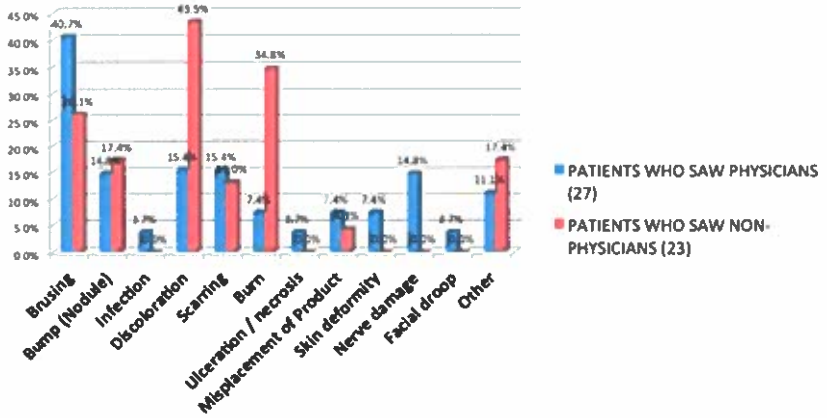

Figure 2. Graph of consumer survey: adverse events by a provider (responders were able to choose more than one).

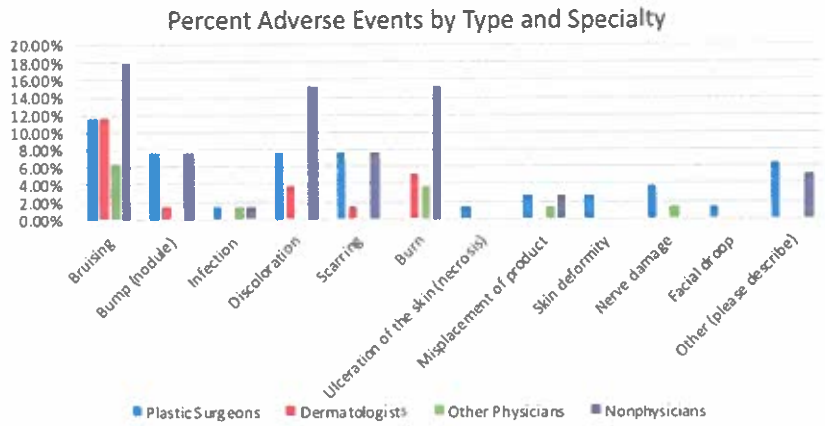

Figure 3. Graph of consumer survey: percent of adverse events stratified by dermatologists, plastic surgeons, and nonphysicians (responders were able to choose more than one).

Regulation of Cosmetic Procedures

Both physician and consumers were polled as to whether there should be stricter regulations on who can perform cosmetic procedures. The majority of ASDS members (86.3%) said there should be stricter regulation. Of the consumers surveyed, a majority (85.8%) also said there should be stricter regulations. There was no difference between the physician group and consumers group ($p = .88$).

Discussion

The demand for cosmetic medical procedures continues to rise and patients are seeking treatment in a variety of settings by both physicians and nonphysicians. This undersupply of board-certified dermatologists has had a significant impact on patient access to care and has resulted in long wait times with patients seeking alternative providers for their care.[1,6] The performance of cosmetic procedures warrants close inspection and a survey of the current landscape of procedures being performed, as it is important to understand who is performing these procedures, the adverse event profiles, and outcomes. A major finding of this study was that the majority of cosmetic procedures being performed by nonphysicians took place outside of a traditional medical office setting. Procedures occurring in other settings may raise concerns regarding oversight, standards, and regulations that are in place to protect patients and ensure safety. In addition, burns and discolorations were cited as the most common adverse events encountered by patients treated by nonphysicians.

Adverse Events

Overall, numbers of adverse events were quite low in this study, with only 50 adverse events reported by

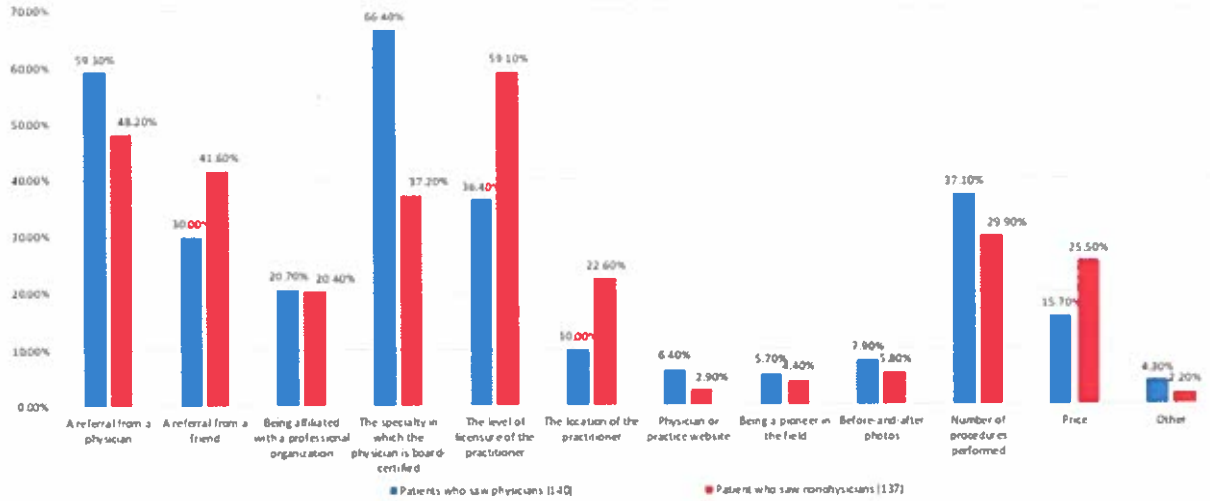

Figure 4. Consumer motivating factors for choosing a physician versus nonphysician.

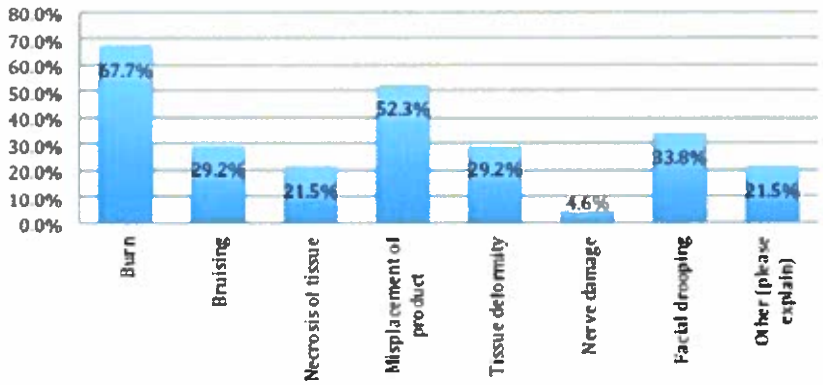

Figure 5. Physician survey: types of complications following procedures performed by a nonphysician.

consumers, the nature of which is in line with reports regarding the safety of dermatologic cosmetic procedures.[7] Although this study looks at both physicians and nonphysicians, this number may underestimate the actual prevalence, as reporting of adverse events is not mandatory, especially for procedures that take place outside of a physician's office. Of the specific adverse events, there was a statistically significant greater difference in the rates of discoloration and burns in the nonphysician group compared with the physician group. This echoes previous published reports by Jalian and colleagues[8] of a higher rate of litigation for laser burns when performed by nonphysicians. The burns and discoloration experienced by patients after procedures performed by nonphysicians may result from inadequate training in how the skin responds to cosmetic procedures (such as lasers) or from insufficient training in selecting the ideal patient and appropriate laser parameters. The majority of adverse events reported by consumers who saw physicians was bruising, and bruising can be an expected part of certain procedures. Of note, the prevalence of nerve damage was reported by consumers, which approached significance in the physician-treated group. None of the nerve damage was cited as permanent, and the procedures performed included neurotoxin (1), body sculpting (2), and varicose vein treatment (1). It was not gauged as to what type of, sensory or motor, impairment occurred in these 4 cases.

Consumer Viewpoint of Qualified Providers

Consumer motivation is a major factor in aesthetic medicine. A further understanding of the motivating factors that drive patients to certain practitioners is important for comprehending the role of nonphysicians. Regarding provider qualification, consumers favored nurses and physician assistants to perform cosmetic medical procedures over other nonphysicians. However, this is interesting because a majority of patients in this survey treated

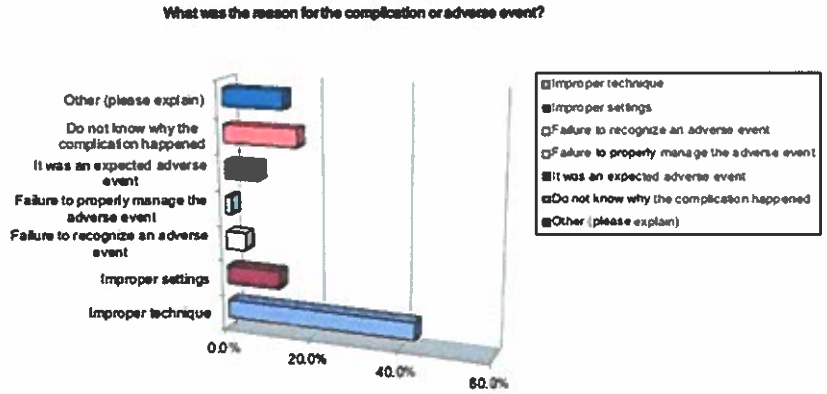

Figure 6. Physician survey: suspected reason for the adverse event when performed by a nonphysician.

by nonphysicians were treated by an aesthetician. This suggests that there are competing factors, such as location, affordability, and persuasive marketing strategies, in place that effectively entice patients into having cosmetic procedures in nonmedical settings by those that they perceive as less qualified. This could also echo previous American Medical Association surveys showing that patients may not understand the different levels of licensure or types of nonphysician providers.[9]

American Society for Dermatologic Surgery Members' Responses

Almost a quarter of ASDS members reported treating 10 or more complications from procedures performed by nonphysicians. This number is higher than consumer-reported complications and could underscore the notion that most complications go unreported by patients or providers. From the complications that ASDS members reported treating, a laser burn was the most common adverse event, which reinforces recent literature and the authors' own results from this study. Interestingly, misplacement of a filler product was the second most common event, and "improper technique" was cited as the most common reason. Anatomy knowledge, injection technique, and selecting appropriate patient cases to perform are all factors that could contribute to this. Other physician surveys have shown that although the majority of physicians feel nurses are capable of administering vaccines, they are not as capable as physicians at administering injectable cosmetic procedures.[10,11] This could be because of the nature of the procedures, a physician's in-depth knowledge and hands on training in anatomy, and the complexity involved. In this study, over 85% of dermatologic surgeons and consumers alike said there should be stricter regulation over who can perform cosmetic procedures. Clarification on training requirements and scope of practice guidelines might help ensure standards are upheld and patient safety is preserved.

Limitations

This study has limitations due to the nature of survey-based research and inherent response bias. This was an email-based survey that may also not fully capture the complete demographic of consumers, and patients were not asked how many times they had a procedure performed. Also, as previous American Medical Association surveys have shown, patients may not know the exact degree or title of the treating practitioner, which may have influenced their ability to accurately respond to questions. Physician members of the ASDS were not asked specifically about adverse events that resulted from cosmetic procedures performed by other physicians. Other studies have shown that cosmetic procedures are performed by various specialties outside of dermatology, including: general surgery, otolaryngology ophthalmology, facial plastic surgery, family medicine, pediatrics, and internal medicine.[12] Future studies are warranted to better characterize adverse events following physician-performed cosmetic procedures, as this may call into question scope of practice of various providers.

Conclusion

Adverse events reported by consumers following cosmetic procedures are infrequent, but still occur. The most common types of adverse events reported with cosmetic procedures performed by nonphysicians are burns and discoloration. This contrasts adverse events from procedures performed by physicians in this study, which consisted mainly of bruising, which does not imply a complication per se. A majority of patients seeing nonphysicians are encountering them outside the traditional medical office, including spas. This could reflect the growing number of "medispas" that are being operated by nonphysicians and could represent a potential concern for safety and regulation. Attention should be given to this alarming trend, as these untraditional settings may not be held to medical practice standards and have inadequate oversight from qualified physicians. Moving forward, the authors need improved data collection on adverse events and outcomes, which may help guide regulations and oversight necessary for providing quality care and ensuring patient safety.

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Causes of Injury and Litigation in Cutaneous Laser Surgery: An Update From 2012 to 2020

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OBJECTIVE To identify common causes of injury and liability claims related to cutaneous laser surgery from 2012 to 2020.

MATERIALS AND METHODS Search of online national legal database of public legal documents regarding cutaneous laser surgery litigation.

RESULTS From 2012 to 2020, 69 cases of liability claims due to a cutaneous laser surgery device were identified. Of these, 49 (71%) involved a nonphysician operator (NPO); 12 incidents (17%) involved non–core physician operators performing the procedure; 6 cases (9%) involved a plastic surgeon operator; and 2 cases (3%) involved a dermatologist operator. Laser hair removal was most litigated (44 cases, 64%), followed by laser skin rejuvenation (20 cases, 30%). Thirty-six of 69 cases had a discernible outcome, 53% ($n = 19$) rendered judgements in favor of the plaintiff, with a mean indemnity payment of $320,975 (range, $1,665–$1.5 million).

CONCLUSION Previous work evaluating trends in laser surgery litigation from 1985 to 2012 identified increasing injury and legal action when performed by NPOs. Data from this study are consistent with these previous findings. Both studies demonstrate that NPOs account for most cases of legal action with an increasing proportion of cases being performed by NPOs. In this study, unsupervised NPOs comprise nearly three-quarters of laser surgery lawsuits, but the data may underestimate the frequency of injury and litigation caused by unsupervised NPOs.

The number of laser, light, and energy-based cutaneous surgeries continue to rise in the United States, and these treatments continue to be among the most utilized elective cosmetic procedures. Among dermatologists alone, it is estimated that approximately 3.2 million laser, light, and energy-based treatments were rendered in 2017, which comprises a 17% increase from the previous year and a 2-fold increase from 2011.[1] Countless more of these procedures were performed by physicians specializing outside of dermatology, as well as nonphysician operators (NPO) of these devices. Plastic surgeons accounted for an additional 2.5 million cutaneous laser surgeries in 2017.[2] The increased utilization of these energy-based modalities has demonstrated a concomitant proliferation in the incidence of patient injury and adverse outcome–related litigation.

Previous work from the author group evaluating trends in malpractice litigation pertaining to cutaneous laser surgery from 1985 to 2012 identified increasing patient injury and legal action when the procedure was performed by nonphysicians, and particularly when performed outside of traditional medical settings, such as medical spas. Nonmedical facilities providing cosmetic and aesthetic procedures and services, termed medical spas or "med spas," continue to increase in number and post record revenues, and are more likely to have NPOs with varying degrees of training and certification performing these procedures.[3] In the context of medical spas, unsupervised NPOs frequently deliver these treatments without any physician oversight or involvement.[4,5] Meanwhile, physicians in traditional medical practices also often delegate these procedures to NPOs in an effort to increase revenue. The increased utilization of NPOs to deliver these treatments has led to a steady increase in the number of legal claims naming both the supervising physician and NPO as defendants since 2008.[6]

There are currently no federal regulations that address who may operate a laser or whether physician supervision is required. Different state regulatory bodies have various requirements dictating specific instances where physician supervision is lawfully required; however, in many states, a physician is not even required to be available on site at the time treatment is rendered by the NPO.[7,8] Despite the fact that physicians may act as supervisors and delegate the laser procedure, they are still legally liable for any services

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provided by any physician extender, including laser surgery, within the scope of their employment.

The objective of this study was to update previously published data exploring laser procedures that resulted in legal action and to further examine the incidence of litigation when laser- and light-based cutaneous surgeries are delegated to NPOs or performed outside of traditional medical settings versus when performed by physicians.

Materials and Methods

The online legal research resource Thomson Reuters Westlaw (http://www.westlaw.com), which is a national database used as a primary source in law to collate legal documents in the public record, was queried. Various keywords were used as previously reported to maintain continuity between studies.[4] The study was exempt from review, as determined by the Institutional Review Board at the Massachusetts General Hospital.

Using the search terms, 1,147 documents consisting of cases, trial court orders, and jury verdicts and settlements were identified. Each of these documents were thoroughly reviewed for relevance. Pertinent information included year and cause of action, provider education or certification, type of procedure, alleged injuries, verdict, and indemnity payments. Of these 1,147 documents, 69 cases involving cutaneous laser surgery injury were identified. Of these 69 cases, only 36 had discernible outcomes. A nonphysician operator (NPO) is defined as a non-MD or non-DO provider/operator. A variety of allied health professionals were noted to comprise this category, including medical assistants, registered nurses, nurse practitioners, physician assistants, aestheticians, and laser technicians.

Results

From January 2012 to January 2020, 69 cases of injury and liability claims resulting from operation of a cutaneous laser surgery device were identified. Of these, the greatest number of cases arose from New York (21), California (12), Texas (7), Nevada (7), and Massachusetts (4), followed by several states with 1 or 2 reported cases (See **Supplemental Digital Content 1**, Figure S1, http://links.lww.com/DSS/A994). Consistent with previously published data, the most common procedure involved laser hair removal, in 44 of the 69 cases (64%). This was followed by laser skin rejuvenation related suits in 20 of the 69 cases (30%). For the purpose of this study, laser rejuvenation encompassed several procedures, including intense pulsed light (IPL), pulsed dye laser (PDL), fractionated and nonfractionated ablative resurfacing, and fractional nonablative resurfacing. Two additional cases involved ablative laser resurfacing, in combination with surgical face lifts. There were several single isolated cases involving laser tattoo removal, laser treatment for cutaneous warts, and IPL treatment to "melt away" improperly placed dermal fillers.

Similar to previous studies, injuries sustained in legal cases from January 2012 to January 2020 were led by burns (77%), scarring (39%), pigmentary disturbances (23%), and blistering (12%), with infection/cellulitis (4%), pain and suffering (3%), ocular injury (3%), and dyspareunia (1%) being other reported injuries (Table 1). The most frequently documented legal cause of action was negligence (89%) and lack of informed consent (22%), followed by a variety of others, including fraud and battery (Figure 1). Note that the sum exceeds 100% as multiple injuries were sustained and multiple causes of action were reported in some cases.

Of the 36 cases with a discernible outcome, 53% of them had judgments in favor of the plaintiff with damage or indemnity payments ranging from $1,665 to $1.5 million. The mean and median was $320,975 and $132,108, respectively (See **Supplemental Digital Content 2**, Figure S2, http://links.lww.com/DSS/A995). However, cases that were brought in more recent years have not yet reached a final outcome because these cases are either pending or ongoing.

Laser surgical cases performed by nonphysicians comprised the largest number of legal actions, regardless of supervising physician subspecialty, with 71% ($n = 49$) of legal claims occurring when NPOs performed the procedure. When laser treatments were administered directly by a physician, plastic surgeons were alleged to have caused patient injury with 6 identified claims (9%), followed by dermatologists with 2 identified claims (3%). The lower incidence among dermatologists, who perform more laser surgeries than any other specialty, may be attributable to the greater emphasis on laser education in dermatology residency programs with a higher minimum laser case requirement in dermatology training programs as highlighted by the Accreditation Council for Graduate Medical Education.[9] Most other medical specialties do not have any specific laser training curriculum or minimum case number prior to graduation. Physician operators outside of dermatology and plastic surgery specialties, when taken as a group, were alleged to directly cause patient injury leading to legal action in 12 cases (17%) (Figure 2). These specialties included family medicine, general surgery, obstetrics/gynecology, ophthalmology, emergency medicine, pediatrics, and radiation oncology.

The data were further stratified by categorizing the physician subspecialty supervising the NPO laser operator implicated in the legal suit. Nine cases were initiated against internal medicine/family practice, followed by 5 cases against dermatology, 4 cases against obstetrics/gynecology, 3 cases against plastic surgery, 2 cases against pulmonology, and 1 case each against emergency medicine, gastroenterology, general surgery, and neurology (See **Supplemental Digital Content 3**, Figure S3, http://links.lww.com/DSS/A996).

Discussion

The current work evaluating legal data from January 2012 to January 2020 further demonstrates that NPOs account for the majority of cases of legal action pertaining to the use of cutaneous laser surgical devices. In fact, there is an increasing national trend in the past decade for a higher proportion of cases being performed by NPOs. As physician

TABLE 1. Cutaneous Injuries Sustained in Legal Cases From January 2012 to January 2020	
Injury	**Number (%)**
Burn	53 (77%)
Scarring	27 (39%)
Pigmentary disturbance	16 (23%)
Blistering	8 (12%)
Cellulitis/infection	3 (4%)
Pain & suffering	2 (3%)
Ocular injury	2 (3%)
Dyspareunia	1 (1%)

delegation of laser procedures increase, health care providers must remain vigilant to the fact that the supervising physician may be legally liable for any patient injury, misconduct, or negligence that occurs when the laser is used by anyone under the physicians' purview, despite their lack of physical involvement in the case. This scenario falls under the legal doctrine of respondeat superior, as this principle is frequently invoked within legal proceedings to hold an employer responsible for the conduct of the employee when he or she is operating within the scope of employment.

Notably, most lasers used in cutaneous surgery have been developed by dermatologists, and it is the medical specialty performing the largest number of laser cases each year in the United States.[1,2,10] Yet, the current data demonstrate that physicians from other specialties who perform laser surgery, when evaluated as a group, make up a far larger proportion of the legal cases seen from 2012 to 2020. Among the legal claims pursued pertaining to a physician-operated laser malpractice case, 18 cases (90%) were brought against nondermatologist physicians, while 2 of the 20 cases (10%) were initiated against dermatologists. This may reflect the level of training received while in residency and fellowships, and merits further study.

The current data show that litigated injuries occurred more commonly when the laser procedure was performed by an NPO in either medical spa or traditional medical setting, despite a deterrent for attorneys to pursue cases against practitioners who are not covered by medical malpractice insurance. In exploring the legal structure of a medical spa, it is notable that many of these establishments, which are owned and operated by nonphysicians, do not have medical liability insurance to satisfy a potential malpractice claim. To satisfy a claim against a medical spa, an attorney must address an alternative set of legal elements to those necessary to satisfy a claim against a defendant with medical malpractice insurance in a medical malpractice case. The set of elements that must be proved against a defendant who is not a health care professional are likely more opaque. The imprecision of the set of claims that would sufficiently satisfy a case against a non–health care professional could act as a deterrent for an attorney to bring a case against a medical spa. Alternatively, the legal elements necessary to satisfy a claim against a medical practitioner are less impervious to frivolous claims because professional liability insurance inherently addresses the financials of frivolous lawsuits more efficiently and fully.[11]

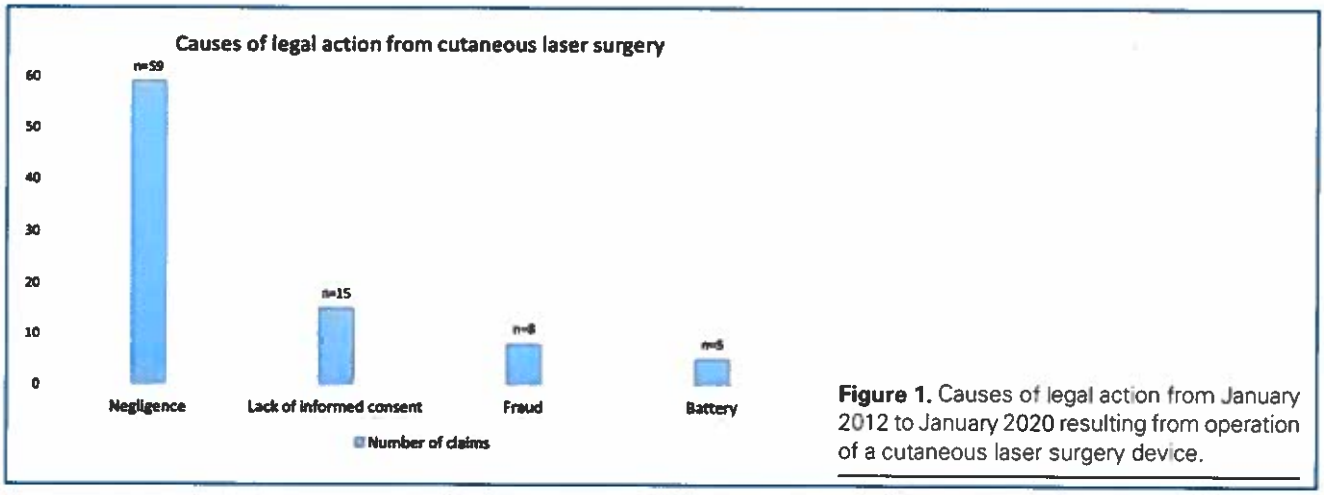

Figure 1. Causes of legal action from January 2012 to January 2020 resulting from operation of a cutaneous laser surgery device.

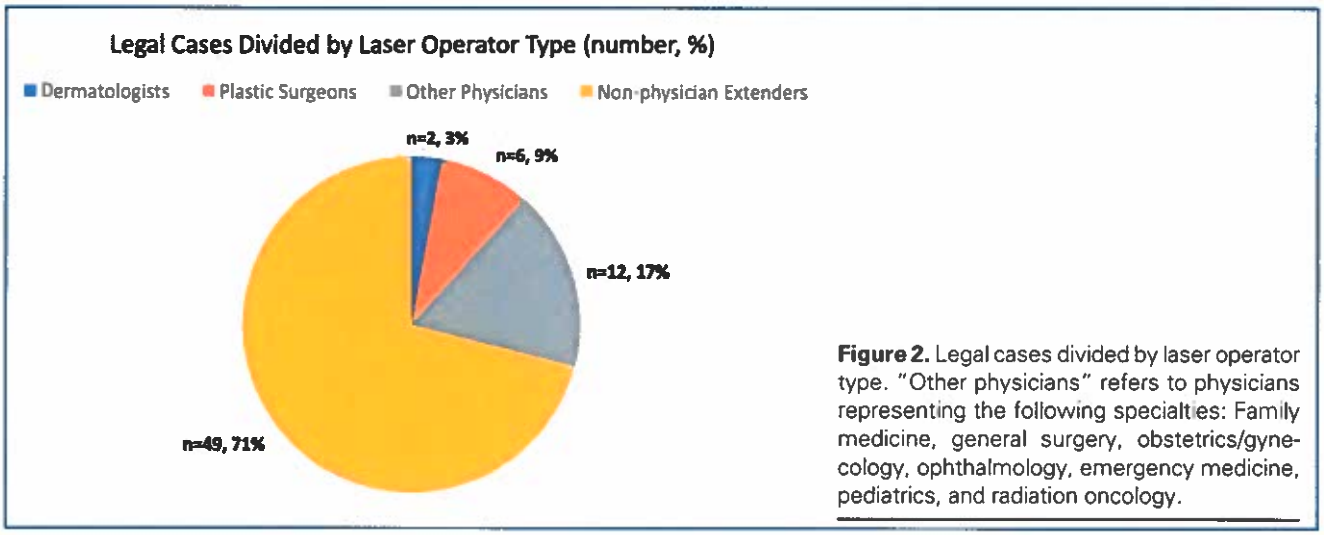

Figure 2. Legal cases divided by laser operator type. "Other physicians" refers to physicians representing the following specialties: Family medicine, general surgery, obstetrics/gynecology, ophthalmology, emergency medicine, pediatrics, and radiation oncology.

Thus, because most medical spas are more likely to employ nonphysicians to carry out a procedure, it may be logically concluded that the number of cases that could be brought against medical spas are likely underreported. Conversely, attorneys would be more likely to bring a lawsuit against health care professionals covered by medical malpractice insurance. However, despite this deterrent, it was found that NPOs still had the highest rate of alleged patient injury and legal cause of action. In reality, this rate is likely underrepresented based on the lack of malpractice insurance and corresponding lack of indemnity to be pursued in a legal claim.

When the current data are taken together with prior work by the authors, dating back to 1985, a clear trend emerges in the current legal framework and jurisprudence surrounding laser-related litigation. Specifically, the trend shows that even in the absence of state regulations that mandate physician supervision, physicians are more likely to be held legally liable for patient injuries that occur under their purview, regardless of whether they operated the laser- or light-based device. Furthermore, identifying common causes of legal action can highlight areas that should be addressed to improve patient safety and decrease professional liability. Patient injuries and negative outcomes will continue to occur because these are risks inherent to any surgical procedure. However, physicians who wish to perform laser surgery may mitigate these associated risks by ensuring that the laser operator has a deep fund of knowledge regarding laser physics, skin optics, and both therapeutic and warning endpoints.

A coalition called the Patients/Physicians United for Laser Safety and Efficacy (PULSE), started by the American Society of Dermatologic Surgery Association, calls upon state regulatory boards to have more stringent regulation of NPOs in terms of training and supervision.[12] As shown in Jalian and colleagues,[4,5] and echoed in the current work, current trends in legal precedent show that physician and nonphysician laser operators are held to the same standard of care under the legal doctrine of respondeat superior. Thus, in light of this doctrine, it is in the best interest of physicians who delegate laser operations to nonphysician employees to be aware that claims for negligence, battery, or medical fraud arising out of improper technique or a failure to obtain informed consent may still be legally aimed toward the physician; this is regardless of personal involvement in the delivery of the procedure. Furthermore, current data lend support for increased regulations of NPO laser treatments.[13] It is critical that physicians mitigate risk to patients by ensuring robust training for their extenders, by directly supervising procedures or by being immediately available and physically on-site, as is recommended by the official position on this matter by the American Society for Laser Medicine and Surgery, A multispecialty laser- and energy-based devices society.[14]

Notably, core aesthetic physician practitioners understand that patient complications associated with nonphysician operators are not uncommon, especially when performed outside of traditional medical settings, such as medical spas. A survey of members of the American Society for Dermatologic Surgery found that in the preceding 2 years from that study, 61% to 100% of complications seen in their practices were performed in medical spas, with LHR and IPL being among the top 3 most common procedures with complications.[15] Indeed, the rising demand for cosmetic services has seen a significant increase in the number of medical spas performing such procedures by NPOs, particularly with medical directors from non–core physician practioners.[16] As noted in the present study and supported by prior work, such nontraditional contexts are where the preponderance of patient complications occur. Despite this, most cities in the United States have more medical spas than core aesthetic physician practices, and most aesthetic physicians have a medical spa within 5 minutes of their office.[17]

There are limitations to this study. The search included only one legal database, and it does not include cases handled outside of the court/judicial system. Thus, many frivolous claims brought outside of the judicial system may be immediately dropped. Additionally, claims may be settled through third-party arbitration. The study is also limited by the search terms entered into the database—the authors may have not captured cases that did not include the terms that were used. Finally, only incomplete information was available for some cases even when supplemented through other resources and additional research.

Conclusion

The data suggest that most cases of legal action and claims of injury in the setting of cutaneous laser surgery involve nonphysician operators, supporting the past published literature. The data published by the author group suggest that patient safety increases, and legal claims of negligence and injury decreases, when laser surgery is performed by physician operators, in particular those with a medical subspecialization in dermatology. If the physician does delegate laser surgical procedures to an NPO, the physician is ultimately responsible in the court of law for the NPO's performance and actions. It is thus essential that physicians and their agents receive appropriate and robust training in the execution of cutaneous laser surgery in attempt to minimize adverse outcomes for patients and subsequent legal risk.

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Midlevel Injectable Practice Patterns in Dermatology and Plastic Surgery Offices

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BACKGROUND There is limited knowledge on the extent physicians delegate cosmetic procedures to midlevel providers.

OBJECTIVE To assess dermatology and plastic surgery practice patterns for the injections of neurotoxins and dermal fillers.

MATERIALS AND METHODS Four hundred ninety-two dermatology and plastic surgery practices were identified from 10 major US metropolitan areas. These practices were contacted, and staff were asked a series of questions to best characterize the practice patterns in regard to who performs the injectables in the office.

RESULTS Although most dermatology and plastic surgery practices had physicians as the only provider who gives injectables, 18.35% of dermatology and 25.4% of plastic surgery practices had nurse practioners and physician assistants giving injectables both with and without oversight of the supervising physician onsite.

CONCLUSION In a large majority of both plastic surgery and dermatology practices, physicians exclusively perform injections of neurotoxins and fillers. For practices that allow midlevel providers to perform injectables, the level of physician supervision is variable. In a small percentage of plastic surgery practices, surveyed midlevel providers exclusively performed injectables.

In recent decades, the use of cosmetic soft tissue injectables and neurotoxins has risen dramatically, with more than 15 million minimally invasive procedures performed in 2018.[1] The increased popularity of injectables is due to excellent and reproducible aesthetic results with limited-to-no recovery time. Although these procedures have an excellent safety profile, they are not risk free. The use of soft tissue modulators has a small but significant risk of cutaneous necrosis and permanent blindness, whereas neuromodulators placed incorrectly can result in ptosis, asymmetry, and functional defects of the eyelid lasting for months.[2] It is imperative that injectors understand the different characteristics of each type of filler, risks of complications, injection techniques, and management of patients who experience adverse events.[3] Urgent interventions by knowledgeable providers can restore blood flow after vascular compromise due to filler injection. Relief of ischemia due to retinal artery occlusion may require advanced techniques, such as retrobulbar injection of hyaluronidase by physicians.[2]

Previous studies have shown that midlevel providers are being increasingly used in the delivery of dermatologic care. The term "midlevel practitioners" is defined by the US Drug Enforcement Administration as an "individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of midlevel practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice."[4] Although nurse practitioner (NP) and physician's assistant (PA) roles evolved at first to meet the rising needs in primary care, they later expanded to specialties in medicine, including dermatology.[5] The number of individuals becoming NPs and PAs is rising each year; the US Bureau of Labor Statistics predicts a 37% increase in employment for PAs and a 31% increase in employment for NPs from 2016 to 2026.[6,7] They provide a cost-efficient supply of hands-on care previously provided by physicians.[4] Although PAs, NPs, and board-certified physicians all perform cosmetic procedures, there is a discrepancy between the length of education training and hours of training. Board-certified dermatologists have a minimum of 8 years of graduate medical education and between 12,000 to 16,000 hours of patient care. Physician's assistants have 2 to 3 years of graduate education with 2000 required hours of patient care. Finally, NPs have 2 to 4 years of graduate education, depending on if they get a masters or doctoral degree with 500 to 720 hours requirements.[8] Because of the discrepancy in the length of training and rigor of didactics, medical practices traditionally have physician-led, team-based care. Physicians maintain authority for patient care in this team-based approach to guarantee patient safety and quality of care.

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Although advanced practice nurses (APNs) and PAs are certified nationally, state laws actually determine the specific level of care allowed by midlevel providers.[9] Specifically, they determine the level of education needed, the amount of prescriptive authority allowed, and the amount of physician involvement required. Although some states have detailed legislation, many states have open-ended and ambiguous legislation.[10] The state scope-of-practice laws place limits on the clinical boundaries advanced practioners must abide by.[10] The American Medical Association (AMA) strongly supports these scope-of-practice laws as necessary to ensure patient safety and best practice.[10] Legally, NPs and PAs are allowed to give injectables, with physician oversight. The interpretation of what "physician oversight" entails and whether physicians need to be physically on the premises is not detailed in federal laws. As a result, the level of care allowed by midlevel providers is open to the interpretation of each supervising physician.

Although it is known that some physicians delegate cosmetic procedures to midlevel providers, no studies exist to determine current practice patterns. In this study, we sought to identify the individual practice patterns for the injections of neurotoxins and fillers for dermatologist and plastic surgeons. Specifically, we wanted to identify which provider within these practices is performing these treatments (midlevel providers vs dermatologists/plastic surgeons). We hypothesize that although most dermatologists and plastic surgeons perform injections themselves, there is still a minority delegating these procedures to midlevel providers. This will allow for an improved understanding of how cosmetic procedures are delegated and help providers determine practice standards when deciding who in their office should perform cosmetic procedures.

Materials and Methods

Study Design

Our study design centered on telephone calls to offices of dermatologists and plastic surgeons in the largest US metropolitan areas. Calls involved a series of questions to determine if cosmetic injectable procedures were offered for patients and if offered, who performed the procedure (MD, NP, PA, or others).

Each practice was assigned a number, and the answers to the above questions were recorded. Neither the names of the practices nor the practicing physicians were recorded. The answers to the questions and the type of practice were recorded.

A different researcher then analyzed the data, with all practices and physician's deidentified, to determine the percentage of offices that offer injectable procedures and have injectable procedures performed by physicians versus nonphysician providers.

Number of Subjects

In this study, we identified dermatology and plastic surgery practices located within 11 major US metropolitan areas using the American Academy of Dermatology and American Society of Plastic Surgeons Web sites. The cities included were New York, Chicago, Boston, Philadelphia, Washington D.C., Atlanta, Dallas, Houston, Los Angeles, San Francisco, and Miami. In total, 492 dermatology and plastic surgeon practices were queried. Practices located outside of major city limits were excluded. In addition, several practices were excluded because of incorrectly listed phone numbers and front desk staff who were unable to answer questions.

Procedure

A trained member of our staff called the offices using contact information provided on the professional organization Web sites (American Academy of Dermatology and American Society of Plastic Surgeons) and asked a series of questions: (1) Does their practice offer injectables? (2) Are the injections performed by an MD, PA, NP, or other providers? (3) If a nonphysician typically performs the injections, is an MD available to inject on request? (4) If an MD performs the initial injection, will they also perform the injections at follow-up visits? and (5) If a nonphysician performs injections, is a physician on-site? The answers were then recorded on a data recording sheet with no identifiable information to prevent any association of answers with the practices that gave them. The list of practices (identified through professional organizations) was also kept separate from the data recording sheet (See **Supplemental Digital Content 1**, Table S1, http://links.lww.com/DSS/A658).

Statistical Analysis

The data were analyzed by a physician investigator who did not perform the initial data collection to determine the percent of practices in which MDs or other providers perform injectables in these scenarios. Data analysis was performed using Microsoft Excel (Microsoft Corporation, Redmond, WA).

Results

Of the 250 dermatology and 582 plastic surgery practices identified, 117 dermatology and 373 plastic surgery practices met inclusion criteria. Of those, an additional 8 dermatology practices were excluded, and 23 plastic surgery practices were excluded because these practices did not offer injections of neurotoxins or dermal fillers. Of the dermatology practices identified, 81.7% reported that the physician was the only individual to perform the injections, whereas 74.6% of plastic surgery offices reported that the physician was the only individual to perform the injections (Table 1). Consequently, 18.4% of dermatology practices offering injectables answered to having midlevels performing injectables and 20.3% of plastic surgery offices have midlevels performing injectables. Of the practices surveyed, 0% dermatology practices and 5.1% of plastic surgeons had no MD oversight, with only midlevels performing injections.

TABLE 1. Survey Results		
Dermatology Practices	**Response Number**	**Percent**
Doctor only	89	81.65
Multiple providers	20	18.35
No injections offered	8	
Plastic Surgery Practices	**Response Number**	**Percent**
Doctor only	261	73.6
Multiple providers	71	20.3
No injections offered	23	
No physician at practice	18	5.1

Of the 20 dermatology practices with midlevel injectors, 2 practices confirmed that a physician was onsite at all times, whereas of the 71 total plastic surgery offices with midlevel injectors, 26 confirmed that a physician was onsite at all times. The other midlevel injectable practices had varying responses that included: never, not always, or did not know the office policy on midlevel injectable physician supervision. Many offices also responded that the supervising physicians were in a separate building or separate floor.

Discussion

The role of midlevel practitioners in dermatology and plastic surgery practices is controversial and highly debated. However, studies have shown that midlevel providers are being increasingly used in the delivery of dermatological care. Little knowledge exists on what the breakdown is for types of health care professionals delivering cosmetic procedures in the United States. There are no current studies identifying practice patterns.

This study identified practice patterns and norms, which is informative to both patients seeking cosmetic treatments as well as physicians delegating procedures within their offices. A large majority of both dermatology practices (81.7%) and plastic surgery practices (74.6%) use only physicians in the delivery of cosmetic injectables. Although most of both dermatologists and plastic surgeons are still the main provider of injectables in their respective practices, approximately 20% of both dermatology and plastic surgery practices also used midlevel providers for injectable neurotoxins and fillers. 5.1% of surveyed plastic surgery practices used midlevel providers exclusively for injectables. This evidence suggests that there is an expanded role of midlevel providers on a national level.

As NPs and PAs define their role in this shifting environment, concerns about their effectiveness and use are often brought up. A 2015 study by Nault and colleagues showed that the number of biopsies required to find a malignancy was twice as high for advanced practice professionals (APPs) as compared to dermatologists. Consequently, this study concluded that the use of APPs increased morbidity and cost of care compared with a board-certified dermatologist.[11] By contrast, a study in JAMA from 2000 found no significant difference in primary care outcomes primary care physicians and NPs.[12] Evidence from other studies confirm primary care services such as the management of uncomplicated illness and chronic disease can be provided by NPs at least as effectively as physicians.[13]

The utility of midlevels in a primary care capacity has been widely accepted; however, the capacity in which they practice is widely variable. The scope-of-practice laws are state-specific restrictions that determine what tasks midlevel practioners may undertake while treating patients. Each state has different regulations for the scope-of-practice of NPs and PAs.[14] There is variation in prescribing privileges, oversight and chart reviews, and the maximum "collaboration ratios" for NPs working with physicians.[13] Sixteen states and the District of Columbia had standardized their scope-of-practice regulations and allow NPs to practice and prescribe independently.[13]

With the growing use of nonsurgical aesthetic procedures across the country, practices have adapted to meet this growing demand from consumers.[1] Physicians continue to delegate these procedures to nonphysician providers with supervision, depending on their individual state's scope-of-practice.[15] Presently, there are no specialty boards that regulate the practice of these providers.[15] One of the key concerns is the lack of a common method taught to these midlevel providers guiding midlevel practioners on the use of dermal fillers and injectables. A study in Plastic Surgery Nursing surveyed 103 nursing providers and found that there were common core deficits in respondents' knowledge of contradictions for the use of injectables and management of postprocedure complications.[15] Most respondents of this survey performing a minimum of 10 procedures under physician supervision before practicing independently, whereas 12.5% of the respondents reported more than 20. It is essential that competencies are developed to assess and evaluate the quality of current practice to ensure safe treatments.

We were surprised to see that a significant number of practices that use midlevel injectors could not verify on-site supervision at all times. As described above, there are risks of temporary and permanent side effects from improper techniques. Different injectables have a wide range of properties and associated adverse events. The injector needs to be sufficiently experienced with the products being used, maintain a detailed understanding of facial anatomy, and be prepared to provide appropriate treatment in the case of adverse events. The ultimate responsibility for each patient's outcome rests on solely on the supervising physician. For

optimal results, physician oversight is essential to providing high-quality injectables.

This study had several limitations. First, individual practice information was restricted to the knowledge of the office staff who provided the responses that would limit the accuracy of responses. Responses may also be biased with staff more likely to overstate the degree to which physicians perform injections and deemphasize the amount of injections delegated to nonphysicians. In addition, the sequence of questions asked may lead to skewed responses for respondents. Many physicians have multiple offices with various ways that injections are performed which may not be accurately assessed by our survey, although it was requested for respondents to include answers for their offices. Another limitation is that this study only examined practices within the 10 major cities. The generalizability of our results is limited to practices that fall within metropolitan areas. It is possible that there is a difference between practice patterns between suburban and rural groups. Future studies may examine if there is a difference between these environments.

One of the national concerns has been the change in practice model created by the introduction of private equity backed conglomerate practices. These business investments made by private equity groups have a profit-centered focus. Financial analysts and businessmen are dictating how doctors practice to make the highest profit. The use of midlevels rather than board-certified physicians saves costs leading to higher profits. Private equity groups made up 30% of the dermatology practices using midlevel providers (n = 6), whereas nationally, only 16% of dermatology practices belong to private equity groups.[16] Because of the low sample size, these data were not included in our initial analysis. Future studies might further examine the private equity group use of midlevel injectors on a national level compared with academic institutions.

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Trends in Medical Spa Statistics and Patient Safety

In 2023, the medical spa industry in the United States is projected to garner as much as $20 billion in revenue, doubled from just 4 years prior.[1] This net growth occurred even as 84% of medical spa locations temporarily closed their doors because of the global COVID-19 pandemic.[1] By 2025, the annual revenue is expected to increase by another 25%.[1] Anyone can open a clinic by collaborating with a licensed member of the medical community, which may account for 70% of the medical spas lacking any affiliation with a medical practice.[1]

The average annual revenue expected for an individual medical spa is more than $1.5 million as of 2021, with an annual expected growth of >10%.[1] Consequently, this is an immensely profitable industry that has exploded in popularity in the past decade. Since 2010, the number of medical spas nationwide have increased nearly six-fold and currently employ more than 70 thousand people.[1] These clinics offer various services including botulinum toxin, injectable fillers, and laser procedures. However, questions abound regarding the safety of these procedures to the consumer in an industry growing faster than it can be regulated.

As of 2022, 66% of medical spas were owned by a private, single individual; however, only 37% were owned by physicians. Of the physician-owned spas, dermatologists accounted for only 4%, despite being one of the few specialties with postgraduate residency training requirements in cosmetics. 23% of single-owner medical spas were owned by nurse practitioners, doubling from 11% in 2019 (Figure 1).[1]

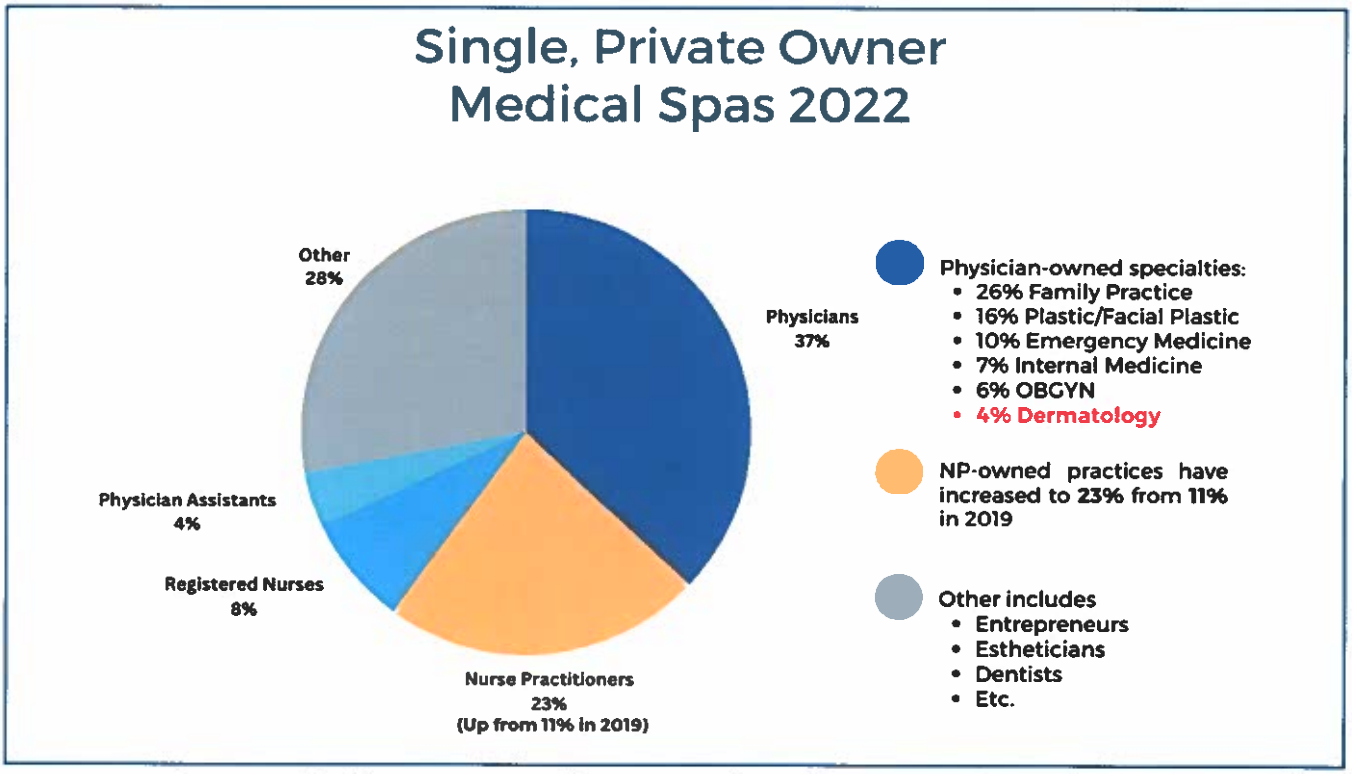

Figure 1. According to the AmSpa State of the Industry Report, 37% of single, private owner medical spas were owned by physicians in 2022. Merely 4% of physician-owned medical spas were owned by dermatologists. Medical spas owned by NPs (nurse practitioners) have more than doubled from 11% to 23% since 2019.

A 2020 survey demonstrated that 70% of surveyed dermatologists in the United States reported seeing at least 1 patient, and as many as 20, with cosmetic complications in the past 2 years. Most of these were attributable to treatments received from medical spas.[2] The most common complications included burn, discoloration, misplacement of product, bruising, and scar. From 2008 to 2011, the number of litigated cases involving a nonphysician performing laser surgery more than doubled. Similarly, from 2008 to 2012, nonphysicians performing laser hair removal represented approximately 85.7% of lawsuits despite performing only one-third of laser hair removal procedures in 2012.[3] These authors concluded that there is inherent risk in acquiring cosmetic services through nonphysicians.[3] By contrast, dermatologists accounted for laser complication rates of 0.24%.[4]

Most surveyed dermatologists believe that medical spas jeopardize patient safety and warrant increased regulation by governing bodies.[2] However, federal and state governments have not tightly regulated the medical spa industry. Given the variable geographic distribution of medical spas in the United States, meaningful legislation may have to occur at the state level.[5] Ideally, regulations would acknowledge that most cosmetic dermatologic procedures are safe when performed by board-certified dermatologists.[4] This calls for dermatologists to educate patients and lawmakers on the potential complications of seeking cosmetic procedures by inadequately trained or inadequately supervised practitioners at medical spas.

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